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DRUID

Driving under the Influence of Drugs, Alcohol and Medicines

Integrated Project
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Evaluation of oral fluid Screening devices by TISPOL to Harmonise European police Requirements (ESTHER)

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Cor Kuijten
Leader ESTHER task DRUID project

Every year approx. 40.000 persons are killed and hundred thousands are severely injured at traffic accidents on European roads.

The road toll is enormous.

Not all traffic accidents can be avoided or prevented.

Causation studies have made clear that the use of alcohol and other psychoactive substances contribute significantly to the annual road toll.

Driving a motor vehicle after the consumption of alcohol or after the use of other psychoactive substances is dangerous and is a contributing factor to a substantial number of accidents with fatalities and severely injured road users.

These kind of accidents can be avoided or prevented.

"Don't drive after the consumption of alcohol"
"Don't drive after the use of psychoactive substances"

Or as a positive one-liner

"Drive sober and clean"

To support this one-liner it is necessary that national governments have specific articles in their traffic act forbidding drivers of vehicles to drive while impaired or driving after the use of psychoactive drugs. The purpose of drug testing in traffic enforcement is to detect drivers under the influence of psychoactive drugs.

In this report recommendations are provided related to tools for the police to support the one-liner.

The recommendations are based on the operational experiences of police officers during normal traffic law enforcement activities. These operational activities are transformed into different operational advices to improve the possibilities of the police to enforce this specific area of road traffic and to describe the required tools to improve road safety related to drugs and driving.

The recommendations cover three areas
1. The increase of the police power to check motorists on drink-driving and on drugged-driving.
2. Requirements for oral fluid screening devices to check motorist on the use of specific drugs.
3. An outline of the legal requirements for specific legislation to reduce drugged driving.

Index of Abbreviations

AD	Alcohol and Drugs (working group)
ADHD	Attention Deficit Hyperactivity Disorder
AMP	Amphetamine
BZO	Benzodiazepine
CE-mark	Conformité Européenne mark
COC	Cocaine
DPO	Dedicated Police Officer
DRE	Drug Recognition Expert
DRUID	Driving under the Influence of Drugs, Alcohol and Medicines
ESTHER	Evaluation of oral fluid Screening devices by TISPOL to Harmonise European police Requirements
FDA	Food and Drug Administration
GC/MS	Gas chromatography-mass spectrometry
IACP	International Association of Chiefs of Police
KLPD	Netherlands National Police Agency
MBDB	Methylbenzodioxolylbutanamine
MDEA	3,4-Methylenedioxy-N-ethylamphetamine
MDMA	3,4-Methylenedioxy-N-methylamphetamine
MET	Methadone
NICC	National Institute for Criminalistic and Criminology (Brussels).
OPI	Opiates
PCP	Phencyclidine
PURS	Police User Requirements and Specifications
ROSITA	Roadside Testing Assessment
TCA	Tricyclic Antidepressants
THC	Tetrahydrocannabinol
THCCOOH	11-nor-9-Carboxy- Tetrahydrocannabinol
TISPOL	European Traffic Police Network

Table of content

Summary

ESTHER teams, devices and phases

In the period October 2006 till August 2008 thirteen different oral fluid screening devices for drugs of abuse have been evaluated in operational police practice.
This study was a part of work package 3 of the EU funded integrated project DRUID.
DRUID is a 6th framework program focussed on improvement of road safety related to the problem of alcohol drugs and medicines used or abused by drivers of vehicles in the road transport system.
The operational tests have been performed by eleven so called ESTHER teams derived from police forces in six EU member states. Teams were located in Germany (3x) Belgium (2x) Ireland, Finland, Spain and the Netherlands (3x). Each team had four so called Dedicated Police Officers (DPO's) and has been led by a senior police officer.
The thirteen screening devices that have been evaluated in police practice has been selected from the ROSITA II project added with new or improved devices from existing or new manufacturers. Devices have been tested for operational aspects. Evaluation of sensitivity and specificity of devices has not been an aspect of task 3.1 ESTHER. Task 3.2 will study these aspects.
TISPOL has invited manufacturers of oral fluid screening devices to contribute to the practical evaluation of oral fluid screening devices. Many manufacturers expressed their willingness to participate in the practical evaluation. A number of manufacturers was unable to present a screening device in an operational stage of development and had to withdraw from the evaluation.
Evaluation of the oral fluid screening devices has been performed as a part of the normal enforcement procedure in the participating ESTHER teams. The legal system in the six member states differs. Therefore a procedure has been developed that is suitable and practical for each of the ESTHER teams. This procedure has respected the legal requirements of all the teams.
The thirteen oral fluid screening devices have been evaluated by the teams in two phases.

Phase 1

In the first phase – performed in the period October 2006 till February 2008 – ten oral fluid screening devices have been evaluated in operational practice. This first phase was divided in two parts.
During the first part ten devices have been tested and based on the interim evaluation in June 2007 some manufacturers have improved their device by modifying the device according to the first practical recommendations from the teams. These ten devices were

Mavand RapidSTAT	*Avitar Drugometer*	*Branan Oratect III*
EnviteC SmartClip	*Innovacon OrALert*	*Securetec Drugwipe 5+*
Sun OraLine s.a.t.	*Surescreen oral drug test*	*Ultimed Salivascreen VI*
Varian OraLab 6.		

Four improved devices have been tested in the second part of phase 1. This second part started in January 2008 and lasted till February 2008.
At the end of phase 1 it was concluded that some devices could be qualified as promising from a practical police perspective to be used during daily traffic law enforcement activities.
These devices were

Mavand RapidSTAT (improved)	*Branan Oratect XP (improved III)*	*Innovacon OrALert*
Securetec Drugwipe 5+	*Varian OraLab 6*	

These five devices have been recommended to be examined for reliability in task 3.2.

Phase 2

In the second phase – performed in the period March 2008 till August 2008 – three oral fluid screening devices have been evaluated in operational practice.
The three devices were

Cozart DDS	*Dräger Drug Test 5000*	*Biosensor BIOSENS*

At the end of phase 2 it was concluded that two devices could be qualified as promising from a practical police perspective to be used during daily traffic law enforcement activities.
These devices were

Cozart DDS	*Dräger Drug Test 5000*

Also the *Biosensor BIOSENS* was qualified as promising from a police perspective to be used during very specific control activities where a great number of persons should be tested in a limited period of time. This device could be used at mega dance and music parties.

Practical evaluation of each of the thirteen screening devices

In October 2008 during the second ESTHER evaluation meeting each manufacturer of devices that has been evaluated by the teams has been informed about the operational experiences with their specific device. During this meeting each manufacturer of the tested devices has been informed by the task leader about the operational results of their device. The provided evaluation information has been related to the device itself, the training of the DPO's in the eleven teams and the operational aspects of the device. Recommendations about modifications from a practical police perspective are provided as well as a summary of the strong and weak aspects of the device.

Police user requirements and specifications

Based on the operational experiences with the thirteen screening devices a set of Police User Requirements and Specifications (PURS) has been developed. These PURS are based on the experiences of the eleven teams with the thirteen devices. These experiences have been retrieved from over 2950 tests in the period from October 2006 till August 2008. Performing oral fluid screening test in operational police practice can not be compared with tests performed by volunteers in a controlled environment like a laboratory or a research institute where tests are performed under the supervision of a medical doctor or a researcher. Differences will occur when a tested person has to cooperate at the roadside or at the (mobile) police station as the result of this cooperation could lead to the status of a suspected driver of a vehicle. From a police perspective an oral fluid screening device is a piece of equipment to enhance traffic law enforcement. This kind of screening devices will never be that accurate that they can be used as evidence for an offence. Therefore these kind of devices are allowed to make mistakes. This is comparable to the policy for alcohol screening devices. In the PURS qualifications for the operability as well as for the sensitivity, the specificity, the accuracy and the positive and negative predictive values are provided.

Outline of legislation

An outline of effective legislation for drugs and driving has been formulated.
This outline is based on different aspects:

1. The operational experiences of the ESTHER teams with oral fluid screening devices within the framework of the existing national legislation on drugs and driving.
2. The existing legislation for drugs and driving in the six EU members states and the experiences of the police with their national legislation.
3. Benchmarking of operational procedures in the six EU member states and in other relevant member states.
4. Experiences in the states of Australia with the zero tolerance approach for illicit drugs in road traffic.
5. Experiences with the Drug Recognition Evaluation system as used in different states in the United States of America.
6. New developments in relevant EU member states e.g. Belgium, Germany, Italy and France.

This deliverable is based on the operational police activities and conclusions provided by the members of the ESTHER teams in the six EU member states. Conclusions can be based on objective data obtained during testing e.g. time needed to collect an oral fluid sample. Conclusions can also be based on subjective data like opinions of police officers or tested persons.

This report represents a part of the evaluation of oral fluid screening devices.
The findings in this task have a relevant relation with the results of the study in task 3.2.
In this study the scientific evaluation of a number of oral fluid screening devices is performed.

Evaluation of oral fluid Screening devices by TISPOL to Harmonise European police Requirements

1. General

In this report the results of the practical evaluation of thirteen different oral fluid screening devices are presented. This evaluation is the deliverable of one of the tasks of the EC funded road safety project DRUID (**DR**iving **U**nder the **I**nfluence of **D**rugs, Alcohol and medicines). The project is divided into different work packages. Work package 3 deals with enforcement issues. This report deals with the first task mentioned in work package 3 "Enforcement" of the DRUID project plan:

The practical **E**valuation of oral fluid **S**creening devices by **T**ISPOL to **H**armonise **E**uropean police **R**equirements **ESTHER**.

In the period from October 2006 till August 2008 thirteen different oral fluid screening devices have been tested in eleven police teams in six EU member states.

In *Chapter 2* a description of the goal of the DRUID project, work package 3 Enforcement and the ESTHER task is provided together with the outline of the testing procedure. Devices have been tested for operational aspects. Evaluation of sensitivity and specificity of devices has not been an aspect of task 3.1 ESTHER. Task 3.2 will study these aspects.

In *Chapter 3* of this report a description of the TISPOL organisation and the involved eleven ESTHER teams of police forces in Belgium, Finland, Germany, Ireland, Spain and the Netherlands is given.

Chapter 4 gives a summary of the legislative situation in the six EU member states where the ESTHER teams are located.

Chapter 5 provides information on the thirteen devices evaluated by the DPO's in the eleven ESTHER teams during the ESTHER task. Also methods used in this task to perform the testing and reporting about the findings are mentioned in this chapter. The time schedule for testing the devices is presented as well. Tests with the thirteen oral fluid devices took place in two phases.
Each phase has been divided into two parts. The testing has been performed in the period October 2006 – August 2008.

In *Chapter 6* an evaluation of the training of the DPO's in the eleven teams is presented. Based on these evaluations recommendations for training of police officers in EU member states are given.

Chapter 7 summarizes the evaluation of tests with ten oral fluid screening devices as performed during the first part of the first phase and the three devices during the second phase..

Chapter 8 summarizes the evaluation of tests with four improved oral fluid screening devices during the second part of the first phase.

Chapter 9 provides user specifications and functional requirements for screening devices, to be used by police agencies.

Chapter 10 presents the promising oral fluid screening devices based on the evaluation of the thirteen screening devices.

Chapter 11 describes the legal requirements for new legislation on drugs and driving from a police perspective.

Chapter 12 is devoted to developments on the thirteen oral fluid screening devices tested during the ESTHER task and developments at other manufacturers of these kind of devices.

In *Chapter 13* some references are given.

Annex 1 describes the procedure that has been followed by the ESTHER teams while testing the oral fluid screening devices.

Annex 2 provides the oral fluid test form used by DPO's to register the collected data during phase 1.

Annex 3 provides the oral fluid test form used by DPO's to register the collected data during phase 2.

Annex 4 provides the impairment test form used by DPO's to register signs and symptoms that could be related to the drug use of tested persons.

Annex 5 gives the format of the standardised evaluation report to be delivered by the team leader at the end of each testing period.

In Annex 6 a list with the tables and graphs used in this report is provided.

Annex 7 gives information about the oral fluid screening devices tested during the ESTHER task. This information has been provided by the manufacturers.

2. The DRUID project

2.1 General

In October 2006 the EC Funded Integrated Project DRUID has been started.
The objective of DRUID was to give scientific support to the EU transport policy to reach the 2010th road safety target by establishing guidelines and measures to combat impaired driving.
The project lasts 4 years – from October 2006 till October 2010 - and is devoted to seven different working areas (WP's) related to drugs, both illicit and drugs of prescription.

DRUID aimed at obtaining specific results in order to create a comprehensive basis of knowledge for future measures.

2.2 Work package 3 Enforcement

In work package 3 of the DRUID project enforcement of the traffic law related to drugged driving has been the central issue.
In WP 3 the intention was to improve possibilities to detect drug driving in Europe by means of oral fluid screening and the preceding pre-selection based on signs of impairment. This was realised by four different activities:

1. Large-scale practical evaluation of onsite oral fluid screening devices for the detection of psychoactive drugs in drivers. (Task 3.1)
2. Large-scale scientific evaluation of onsite oral fluid screening devices for the detection of psychoactive drugs in drivers. (Task 3.2)
3. Scientific evaluation of some road side checklists of signs of impairment. (Task 3.2)
4. A cost-benefit analysis of drug driving enforcement by the police. (Task 3.3)

The objective of WP3 in DRUID has been to combat impaired driving and to detect the best practices of controls by the police forces and to have an evaluation of the best tracking devices in terms of psychoactive substances.
Task 3.1 and 3.2 have been focussed on illegal drugs and medicines. Medicinal drugs included in the oral fluid screening devices can be benzodiazepines. The restriction to this two medicinal drugs derives from the fact that saliva testing has been decided to be the focus of this task and that at this moment oral fluid screeners for other medicines – if they exist – will probably not be reliable enough to be included in the study at this moment.
The Cost-Benefit-Analyses as mentioned in task 3.3 included alcohol and other psychoactive substances.

2.3 Evaluation of oral fluid Screening devices By TISPOL to Harmonise European police Requirements and specifications (ESTHER)

2.3.1 General

In the past different scientific studies on the reliability of oral fluid screening devices have been performed in e.g. the ROSITA studies.
Manufacturers of screening devices for psychoactive substances are constantly developing the technology and the reliability of their oral fluid screening devices. As with most new technologies these developments will go on till a situation will be achieved where no further improvements are reasonably possible. With breath alcohol screening devices for alcohol such a development could be observed in the past 30 years. The technology of oral fluid screening for drugs is similar to the screening for drugs in a urine sample. The main difference between the two screening procedures is that oral fluid is a new medium and that the required antibodies to detect traces of illicit drugs can differ from the antibodies needed for urine screening. A second relevant difference is that the amount of urine will generally be much greater than the amount of oral fluid especially when the tested person has recently used illicit drugs. The amount of collected oral fluid might be small due to a dry mouth. In exceptional cases this could lead to an insufficient amount of oral fluid to perform a screening test. The concentration of drugs is often much lower in oral fluid compared to urine.

Selective police enforcement on drugged driving has been performed in a limited number of EU member states and mostly urine based screening devices have been used by the police in these countries. The experiences of the police have given evidence that performing this procedure is very complicated at the road side. Sanitary facilities are mostly not available at the control location. On the other hand the police officer mostly does not have the possibility to prevent the tested person to add other substances to the urine sample or prevent the tested person to fraud the collection procedure by providing an old (clean) urine sample. These are just two reasons why TISPOL is very keen in possibilities to detect drugged drivers by other screening devices than by urine-based devices. Experiences in different states of Australia (e.g. Victoria, New South Wales and Queensland) have convinced TISPOL that oral fluid screening devices could be appointed in Europe as well to be used as a piece of equipment for the police to detect drugged drivers in road traffic. Therefore it is relevant that the police formulate Police User Requirements and Specifications (PURS). This was one of the reasons why TISPOL expressed their willingness to participate in the DRUID project through the representation of the Program EU of the Netherlands National Police Agency (KLPD). TISPOL also wanted to advise on the needed legal requirements in the Traffic Act to realise an efficient and effective enforcement procedure to detect drugged drivers on Europe's roads and to stop them endangering other road users. It is estimated that based on the Australian experiences at least approx. 10% of the persons killed in road traffic will be caused by drug related accidents.

2.3.2 Outline of the ESTHER task

2.3.2.1 Testing under legal and operational conditions

The limitations of the police operations during the ESTHER activities have been given by the legal framework provided by the various national Road Traffic Acts. To make sure that the findings of scientific research would have value under operational police enforcement conditions, practical and formal limitations had to be respected. As the evaluation during the ESTHER activities did take place under real life conditions, the legal procedure and the police investigation to detect offenders were leading.
Suspects' rights must be respected during the criminal investigation and this also has been the case when specifically trained police officers (DPO's) checked motorists. That is one of the responsibilities of the investigating police officer. Therefore the investigation always has taken place in a "suspect-police setting" where no other persons have been allowed to be present. That is why the ESTHER task could only be executed by the police officers involved.
Each brand of oral fluid screening device has been tested according to a fixed protocol by the DPO's in eleven ESTHER teams under operational field conditions. Testing of the devices has been a part of their regular drink driving enforcement activities. Screening tests have been performed as a part of the normal police procedure in those teams where specific legislation on drugs and driving exists. (Belgium, Germany, Spain, Finland). In Ireland and in the Netherlands the screening tests have been performed as a check on impaired driving as described in the National Traffic Act because no specific legislation on drugs and driving did exist during the operational testing of the devices in these two member states.
Each ESTHER team has been led by a team leader and consisted of four team members. These team members had specific experiences and knowledge about drugs symptoms and have been trained in the use of the different oral fluid screening devices. These team members are named DPO's. (Dedicated Police Officers DPO's). Some teams did have reserve DPO's in their team depending on the normal daily workload of the ESTHER team members. The activities performed by the ESTHER teams for the DRUID project were very practical and based on daily police activities. This deliverable is a practical report providing operational recommendations based on traffic law enforcement activities of the police.

2.3.2.2 Testing in two phases divided in two parts each

In the ESTHER task thirteen different oral fluid screening devices have been tested under operational police conditions in eleven different testing teams in police forces in six EU member states during two testing phases. These devices have been tested according to a fixed protocol This protocol is described in operational terms in the Annexes 1, 2 and 3. Phase 1 has been divided in two parts.

- *Phase 1 part 1*

The first part of phase 1 started in October 2006 and lasted till December 2007. In this testing period ten oral fluid screening devices have been tested. All of the devices were disposables. The operational testing has been carried out during ten test periods of four weeks each. In a testing period each ESTHER team has performed the required number of tests with one of the ten different screening devices. Each manufacturer of screening devices has been invited to participate in this evaluation by providing information and devices to be tested. After each test period one week has been dedicated to the collection of the information of the performed tests in the past test period and the preparation for the next test period. After five test periods a meeting with all ESTHER police teams and representatives of the manufacturers has been organised in order to discuss the interim results and experiences till then. Therefore an interim evaluation meeting has been held in June 2007 in Stein (Netherlands). All ESTHER teams and the representatives of the participating manufacturers have been invited to attend this meeting. After all test periods were passed the findings have been studied and documented.

- *Phase 1 part 2*

Based on the findings during the ten testing periods manufacturers have been given the opportunity to modify their devices based on the operational findings of the ESTHER teams. After modification the manufacturer have been given the opportunity to let the teams evaluate the improved devices during a second part of the testing activities (Phase 1 part 2). Four of the ten manufacturers did request for participation in the second part of phase 1. They have modified their device based on at least some of the recommendations as provided by the ESTHER teams during the interim evaluation. The manufacturers have provided improved test devices to be evaluated in the second part of Phase 1. This second part started in January 2008 and lasted till March 2008. As the devices had mainly to be tested on the modified issues the tests have been performed by tested persons during normal police control activities or by the Dedicated Police Officers (DPO's) themselves.
After ending the second phase data of the tests have been collected and analysed.

- *Phase 2*

During the first phase of testing new manufacturers have provided the ESTHER task leader group with information on new oral fluid screening devices and expressed their interest to participate in the operational testing program. At the interim evaluation meeting in Stein (June 2007) manufacturers of five new oral fluid screening devices have been invited to present their product and to explain and motivate why their device would be worth to be tested by the ESTHER teams. Two other manufacturers declared that they were developing oral fluid screening devices too but that the stage of development would make it impossible to have their device operational and ready for evaluation by January 2008. Based on the obtained information, presentation and demonstration of the five devices it has been decided that these devices could be included in the second phase. The only condition was to have their device available for testing in the ESTHER teams by January 2008.
By the end of 2007 two manufacturers had to state that they - unfortunately - did not have an oral fluid screening device available to be tested in the second phase of the ESTHER task. Three manufacturers were able to meet this condition and have been accepted to be evaluated in the second phase. The three devices tested in this phase have been qualified as instrumental devices. An electronic reader included in the processor unit was an integrated part of the device. The devices tested in this phase would perform best in a police truck or at a police station.
The kick off meeting of this second phase has been held on 11 – 12 March 2008 in the Netherlands (Driebergen meeting March 2008). The first part started on 17 March 2008 and lasted till August 2008. This phase had two testing periods for two devices. The format was similar to the tests held in the first part of phase 1. The third device differed significantly from the other two devices and was therefore evaluated during special events in the period April – August 2008. After finishing the operational testing of these three devices data have been collected and the devices have been evaluated by each team. After the end of the test periods the findings have been studied and documented.
Results of the two phases of operational testing have been presented at the plenary ESTHER meeting in October 2008 in Landgraaf (Netherlands).
All ESTHER teams and representatives of the manufacturers of tested oral fluid screening devices have been invited to attend this meeting.

2.3.2.3 Design of the operational ESTHER activities

It has been considered as a police requirement that all tests with screening devices would be realised in a similar setting and under conditions that could enable the comparison of the findings and conclusions of the eleven teams and even the approx. sixty DPO's involved.
Each performed test with an oral fluid device has been documented and validated from an operational police perspective. By testing all the different devices in each participating police force the most realistic view on user requirements, specifications and operational validation of the devices has been obtained. These results have been used as an input for developing successful legislative activities in the EU and other European countries.
All tests with oral fluid screening devices have been performed under operational police conditions and within the framework of the Road Traffic Act in the specific country. The use of oral fluid as a matrix to screen for drugs of abuse is currently not a prescribed part of the national legal procedure in some of the participating test teams and in the majority of the EU member states. Therefore these tests have to be executed in such a way that it can be considered as operational testing under real life situations, both from an operational and legal police perspective. Persons to be screened for drug use are often suspected of having committed a (serious) traffic offence. This is the reason why the developed procedure of testing the devices has been derived from the legal procedures in the different participating countries and states. In the *Annex 1* this procedure is described. All ESTHER teams have followed the operational procedure as described in this document. By using this mode of police operation all the testing could be done as a part of the normal legal procedure.
All tests are registered and documented in a similar way. Therefore an oral fluid test form and an impairment test form have been developed and provided in the six different languages of the participating ESTHER teams. (English, German, Finnish, French, Spanish and Dutch). For the evaluation of each test period and each device a format for an evaluation report has been developed. These forms are attached as *Annex 2, 3, 4 and 5*. There are only minor differences in the forms used during the different parts and phases of the ESTHER task. In each testing period all ESTHER team have performed a number of tests with one of the thirteen different screening devices. Each manufacturer of screening devices has been invited to participate in this evaluation by providing information and devices to be tested. After each test period one week has been dedicated to the collection of the information of the executed tests and methods in the past test period and the preparation for the next test period.
At the end of the thirteen testing periods in the first part phase 1 and at phase 2 up to approx. 200 tests with each device have been performed and evaluated. The practical evaluation, under realistic enforcement conditions, has been directed to functional and user (drivers, police, and judicial system) requirements, comprising the willingness of drivers to co-operate, time consumption, user friendliness and material cost.

2.3.2.4 Expected outcome of the ESTHER task

By performing tests with the different oral fluid screening devices for drugs it was expected that police requirements and specifications for the use of screening devices to detect drugged drivers of motor vehicles could be formulated. It was expected that a large number of motorists with illicit drugs in their system would not show clear signs of impairment even though their capability to drive a motor vehicle in a safe way would have been decreased. By observing the behaviour of motorists only a small proportion of drugged drivers will be detected by police officers. Therefore a screening device to detect the presence of specific drugs in the system of a motorist is required to be able to get these dangerous drivers of the road. Apart from this activity it would be beneficial if police could formulate the main elements of the legal regulations forbidding persons to drive a (motor)vehicle when their capacity to drive in a safe way has been decreased through the use of specific drugs that have a detrimental impact on reaction and on driving behaviour. The required legal regulation could in some way be compared with existing regulation for alcohol and driving. This regulation exists already since the 50's of the last century. It must however been kept in mind that no legal limits – other than the zero-limit – can be based on the results of scientific studies up till now.

Based on these expectations two different products as outcome of the ESTHER task have been formulated. These two products are:

1. A set of user specifications and functional requirements for screening devices, to be used by police agencies.
2. A set of legal requirements from a police point of view related to new legislation as a countermeasure against driving a vehicle while one or more psychoactive substances are active in the system of the driver.

Realisation of product 1:
This product has been realised by testing all the different devices in each participating ESTHER team under operational police circumstances. This has led to the most realistic view on user requirements, specifications and operational validation of the devices from a police perspective.

Realisation of product 2:
Oral fluid tests has been performed within the framework of the national legislation on drugs and driving. Experiences in the different teams will be compared. Result of this activity has been that a police proposal for a legal system for drugs and driving has been formulated. The result can be an input for successful legislative activities in the EU and in individual EU member states.

Additionally to these two ESTHER products the teams provided a set of requirements and recommendations, useful for the manufacturers of oral fluid immunoassay devices in the process of enhancing the operability of these systems. The confidential evaluation of each of the different devices has been based on the obtained experiences with the device and has led to required and desired modifications of the devices from an operational police perspective. These evaluations have been discussed with the representatives of each of the manufacturers and are not published to ensure confidentiality.

2.3.2.5 General aspects to be evaluated

Before starting the practical evaluation of oral fluid screening devices to detect the presence of specific drugs in the collected sample a list of issues of interest has been formulated.
The practical evaluation of the screening devices has been focussed on specific issues mentioned in the registration forms in the annexes 2 and 3. Some of these aspects are:

- The successfulness of the performed tests.
- The time required to collect a sufficient oral fluid sample
- The time required to analyse an oral fluid sample.
- The hygienic aspects of oral fluid sampling and testing.
- DPO's impression of the reliability of the obtained indication.
- DPO's qualification of the simplicity of the test

Oral fluid screening devices should be able to present the result of the test rather quickly after the sample has been provided. It will be useless to compare the required time to perform an oral fluid screening test with the time required to perform a breath tests on an alcohol screening device. Based on the ROSITA studies it would be realistic to accept a period of up till 15 minutes to perform a test including explanation to the person to be tested, the process of collecting and analysing the sample.
The collecting time of an oral fluid sample should be short (up to a few minutes), the process of analysing should be less than ten minutes. The handling of the device should be simple and hygienic. Indication lines should be clearly visible. Just a few EU member states (e.g. Finland, Spain) have (limited) experiences with oral fluid screening devices.

2.3.2.6 Relation with task 3.2 of the DRUID project

This report represents a part of the evaluation of oral fluid screening devices. The findings in this task have a relevant relation with the results of the study in task 3.2 where the scientific evaluation of a number of oral fluid screening devices is performed. Findings of the operational testing are used as an input for task 3.2. Task 3.2 is recommended to perform a scientific evaluation of oral screening devices that have been qualified as promising devices from an operational police perspective.

2.3.2.7 Summary of planning and performing activities in the ESTHER task

Planning and performing of the activities is provided in chapter 6. A summary is given.

Operational testing of the devices has been performed in two phases.

1. Performing Phase 1 part 1, Testing 10 oral fluid screening devices after training on the device.
2. Plenary Evaluation interim experiences Phase 1 part 1, the first discussion session on police user requirements and specifications (PURS) and the first draft of an outline of legislation for drugs and driving from a police perspective,
3. Complete testing phase 1 part 1.
4. Performing Phase 1 part 2, Testing 4 improved devices from phase 1 part 1 on modified aspects.
5. Performing Phase 2, Testing 3 oral fluid screening devices after training on the device.
6. Plenary evaluation experiences Phase 1 and Phase 2. Evaluation, second discussion session on police user requirements and specifications (PURS) and final outline of legislation for drugs and driving from a police perspective,

3. TISPOL and the eleven ESTHER teams

3.1 TISPOL

The TISPOL Organisation has been established by the traffic police forces of Europe in an effort to improve enforcement of the road traffic laws and attempt to reduce the casualty rate.
Working together and exchanging best practices can result in a better more co-ordinated approach. Additionally with enforcement based on research and information this can be targeted and increased so as to be more effective.
TISPOL and the traffic police forces of Europe are working together to reduce the human cost of 43.000 killed and over 1.7 million injured on EU roads annually. Their aim at both national and European level is to focus on better traffic enforcement.
TISPOL has the following objectives:
To bring together the Roads and Traffic Police Forces in Europe and to promote the development of road safety and law enforcement in connection with roads policing within Europe by:

- The continuous exchange of ideas and the collection of information on road safety methodologies, policies and techniques applied in member nations;
- Initiating and supporting research on road safety;
- Providing an informed police opinion on road safety issues;
- Serving as a transfer point for best practices throughout Europe;
- Organising and co-ordinating multinational operative campaigns;
- Exchanging information to assist investigative processes.

TISPOL aims are not only to enable a better and more co-ordinated approach to be taken on enforcement, but also to enable the partners to exchange best practices and pool ideas. This should result in cost saving and the dissemination of expertise.
For more information on TISPOL visit www.tispol.org.

TISPOL has invited the Program EU (PEU) of the Netherlands National Police Agency (KLPD) to lead and coordinate the police activities in the DRUID project. TISPOL council members expressed their willingness to support the activities if required by KLPD. The TISPOL working group on alcohol and drugs (AD) expressed their willingness to act as a consulting group for the ESTHER task leader.

3.2 TISPOL Partners/ ESTHER teams

Testing oral fluid screening devices can best be executed under operational police conditions. In certain countries the use of screening devices is permitted by the criminal law and the traffic act. Police in other countries do not have this authority. This is a consequence of having legislation on a national level. It is clear that if these screening devices have to be tested under operational police conditions the testing protocol has to respect the national legal restrictions. Oral fluid screening devices to detect recent use of psychoactive substances are considered as police equipment to be used during normal and specific police control activities in road traffic. This means that the devices must be able to work during all kind of European weather conditions. During sunny days as well as in winter when the temperatures are below zero. 24 hours a day, 365 days a year. To obtain a good general view on the operational possibilities of this kind of screening devices members of the international traffic police network TISPOL have been invited to participate at this testing program. Six TISPOL members expressed their willingness to participate and provided TISPOL with one or more testing teams. Each team had four Dedicated Police Officers (DPO's) executing operational activities and have been led by a team leader.

3.2.1 Belgium

The national contact point for Belgium has been the TISPOL council member for Belgium who also has been the chairman of the TISPOL AD working group (Alcohol and Drugs) in the period 2006-2008. Belgium participated with two ESTHER teams located at different parts of the country and representing both the federal police and the local police.

- The first Belgium team has been located in Gent. Due to other police priorities this team had to stop their participation in the ESTHER task immediately after the start of phase 1 part 1.
- The second Belgium ESTHER team has been located at Péruwelz. This Wallonia team was a part of the Federal Highway Police Section Hainaut (Belgium 2). The leader of this team was a senior representative of the police management in Hainaut.
- The third Belgium ESTHER team has been located at Arendonk and Turnhout. Initially this was a combined team of the Federal Highway Police and the Police Zone Kempen Noord-Oost.(Belgium 3). The leader of this team was the head of an operational police group of the local police. During the ESTHER activities for efficiency reasons the DPO's of the Federal Highway Police have been replaced by DPO's from the Police Zone Kempen Noord-Oost.

The Belgium teams have tested the oral fluid screening devices in a setting where it is forbidden to drive a motor vehicle when certain psychoactive substances are detectable in the plasma of the driver. Belgium police also make use of observation of signs and symptoms of drug use by performing a specific test protocol (standardised test battery). This test battery is also derived from the DRE program as prescribed by the IACP DRE section. Evidence of the offence is given by the presence of specific illicit drugs in the analysed blood sample of the suspected driver. Analysis of the blood sample has been realised by a GC/MS analysis performed by the forensic laboratory of the National Institute for Criminalistic and Criminology (NICC) in Brussels.

3.2.2 Irish Republic

The national contact point for this team has been the TISPOL council member. The Irish Republic participates with one team of the An Garda Siochana. The DPO's of this team have been located at different police stations of the Garda in the Irish Republic. The leader of this team was a senior representative of the management of the Garda who was also a member of the TISPOL working group AD. This team was named Ireland.

The Irish team has tested the oral fluid screening devices in a setting where it is forbidden to drive a motor vehicle when a motorist is impaired by the use of psychoactive substances. The findings of the test itself therefore did not have legal consequences for the tested subject.

3.2.3 Finland

The national contact point for this team has been the TISPOL council member for Finland who is also a member of the executive committee of TISPOL and chairman of the AD working group (Alcohol and drugs) since 2008. Finland participated with one team of the National Traffic Police. This team has been located at Helsinki. The leader of this team was a senior representative of the Finnish National Traffic Police. This team was named Finland.

The Finnish team has tested the oral fluid screening devices in a setting where it is forbidden to drive a motor vehicle when certain psychoactive substances are detectable in the blood of the driver. Finnish police also use observation of signs and symptoms of drug use by performing a specific test protocol.

3.2.4 Spain

The contact point for this team has been the head of the traffic police of the Mossos d'Esquadra. Spain participated with one team of this police force in Catalonia. The leader of this team was the head of the traffic police. This team was located at Barcelona (Catalonia). This team was named Spain.

The Spanish team has tested the oral fluid screening devices in a setting where it is forbidden to drive a motor vehicle when certain psychoactive substances are detectable in the blood, the urine or the saliva of the driver. Mossos d'Esquadra also uses results of observation of signs and symptoms of drug use by performing specific tests. Mossos d'Esquadra is the only ESTHER participant with an own police laboratory doing GC/MS analysis of samples of suspects for alcohol and other psychoactive substances.

3.2.5 Germany

The federal contact point for the German teams has been the TISPOL council member for Germany who is also a member of the executive committee of TISPOL and president of TISPOL since 2008. Germany participated with three ESTHER teams.

- The first German ESTHER team has been located in North Rhine Westphalia. (Germany 1). The leader of this team was a senior representative of the police management in Cologne.
- A second German ESTHER team has been located in Baden Württemberg. (Germany 2). The leader of this team was a senior representative of the police management in Heidelberg.
- The third German ESTHER team has been located in Saarbrücken in Saarland (Germany 3). The leader of this team has been a senior representative of the police management in Saarbrücken.

The German ESTHER teams have tested the oral fluid screening devices in a setting where it is forbidden to drive a motor vehicle when certain psychoactive substances are detectable in the urine or blood of the driver. German police also use observation of signs and symptoms of drug use by performing a specific test protocol derived from the drug recognition evaluation (DRE) program as prescribed by the International Association of Chiefs of police (IACP) DRE section. Evidence of the offence is given by the presence of specific illicit drugs in the analysed blood sample of the suspected driver. Analysis of the blood sample is realised by GC/MS analysis by an appointed forensic laboratory. (Gerichtsmedizinisches Labor)

3.2.6 Netherlands

The national contact point for the Netherlands have been the TISPOL council member for the Netherlands who is also a member of the executive committee and the director of TISPOL. The director of TISPOL has acted as a liaison between the ESTHER task and the TISPOL organisation.
The Netherlands participated with three ESTHER teams. In these teams both the National Police Agency and two regional police forces have been represented.

- The first Netherlands ESTHER team was located at Breda. This team has been derived from the unit Breda of the Traffic Police of the National Police Agency. (Netherlands 1). The leader of this team was a senior representative of the National Police Agency in Breda.
- The second Netherlands ESTHER team was a combined team of the Regional police force Limburg-Zuid located in Maastricht and the unit Maasbracht of the Traffic Police of the National Police Agency located at Maasbracht. (Netherlands 2). The leader of this team was a senior representative of the police management of the police force Limburg-Zuid.
- The third Netherlands ESTHER team was also a combined team. This team has been derived from police officers of the Regional police force Gelderland-Zuid in Nijmegen and the unit Wolfheze of the Traffic Police of the National Police Agency located in Wolfheze. (Netherlands 3). The leader of this team was a senior representative of the police management of the police force Gelderland-Zuid.

The Netherlands teams have tested the oral fluid screening devices in a setting where it is forbidden to drive a motor vehicle when the motorists is impaired by the use of psychoactive substances. Netherlands police have to give evidence of impairment to prosecute the offender. This evidence is based on observing the behaviour of the motorist and the noticed signs and symptoms of impairment. In case of a suspected driver a blood sample will be taken and analysed by the forensic laboratory. A report of the forensic laboratory is an essential part of the report that will be sent to the public prosecutor. Testing of oral fluid screening devices has been performed on a voluntary base by stopped motorists and suspected drivers. The findings of the test did not have independent legal consequences for the tested subject.

4 Legislative situation in the member states of the ESTHER teams

Police officers in the six participating EU member states enforce the traffic law according to the existing legislation. There are substantial differences in the six national legal systems. In this chapter the existing national legal systems related to drugs and driving are presented.
For task 3.1 ESTHER a method to test the different devices under real life conditions based on the legal system of each of the participating member states has been developed. Therefore the legal system of the six member states have been used as a starting point. In annex 1 the police procedure to perform tests with the screening devices during the ESTHER task is presented.

4.1 Irish Republic

4.1.1 Legislation related to drugs and driving

The main law in this area is the Road Traffic Act 1961 – 2002, and specifically section 10 Road Traffic Act (RTA) 1994, which forbids driving in a public place while a subject "is under the influence of an intoxicant to such an extent as to be incapable of having proper control of the vehicle". Intoxicant is defined to include alcohol, drugs, or any such combination. There is thus a limit of impairment, and the law does not distinguish between specific drugs. Tests can only take place following suspicion.
All offences are heard in the criminal court. They would result in licence suspension and the driver is liable to a fine not exceeding € 1.270,- or up to six months' imprisonment or both. Licence suspension would be not less than 2 years in the case of a first offence and not less than 4 years in the case of a second or any subsequent offence under the same section.
The law belongs to the criminal law and covers all illegal substances. Legal limits for other substances than alcohol are not specified. Driving or attempting to drive a mechanical propelled vehicle and animal-drawn vehicles and pedal cycles while intoxicated – drunk or drugged – is prohibited.

4.1.2 Drug testing in the Irish Republic

In the Irish Republic the application of roadside drug test devices is actually not prohibited by any valid regulation, but no devices are routinely used because of the absence of validated test systems. Compared to the alcohol test numbers, the numbers of subjects tested for the abuse of drugs is very low. Drug testing is so far solely based on the analysis of a blood or urine specimen in the laboratory, thus requiring the presence of the police, and toxicologist as well as the medical doctor in court.
Blood and urine samples can be obtained in cases, when clear indications for drug use are obvious and the responsible police officer can request the examination of the obtained specimen for illegal drugs.
During general traffic control actions the behaviour of a driver is evaluated for signs of impairment. In this context the police officer decides on the driving capability of the suspect and may take further legal measures. He may arrest the suspect if she/he has the opinion that a driver is incapable of having proper control over a vehicle due to the consumption of drugs.

4.2 Germany

4.2.1 Legislation related to drugs and driving

Three provisions in the German Criminal Code (*Strafgesetzbuch,* StGB) address drugs and driving:

1. § 315 c StGB, "Endangering road traffic", which prohibits driving while not in a condition to do so safely due to consumption of intoxicants, thereby endangering life, limb or property of significant value.
2. § 316 StGB, "Drunkenness in traffic", which prohibits driving while not in a condition to do so safely due to consumption of intoxicants, but without the risk of endangerment in s.315c
3. § 323 a StGB, "Total intoxication" may also be used on certain occasions; it provides for an offence when a person knowingly or negligently gets intoxicated and commits an offence in such condition, and lacks mental capacity to be judged guilty for that offence.

The provisions in the Criminal Code refer to “alcoholic drinks or any other intoxicating substances”, which includes all controlled drugs. These offences give rise to a fine or up to five years imprisonment, and for breach of s. 316 a fine or up to one year in prison. Under s. 44 of the criminal code, they may also receive a driving ban from 1-3 months. They operate on an impairment level – there is no specified limit as there is no scientific proof of them yet, but this area is currently under research.
There is a separate provision in the Road Traffic Code, § 24 a StVG (*Straßenverkehrsgesetz*) , "Ordnungswidrigkeiten wegen Genusses von Alkohol oder berauschenden Mitteln". Since August 1998 (with the amendment of §24a StVG) Germany pursues an analytical approach with a zero-tolerance limit for illicit drugs. Germany was the first European country introducing this kind of zero-tolerance legislation for drugs. The law prohibits driving under the influence of the drugs cannabis, cocaine, heroin, morphine, amphetamine and the designer drugs MDMA (ecstasy) and MDE, if any of these specially listed drugs is detectable in the blood of a driver. For heroin and cocaine their degradation products morphine and benzoylecgonine have to be measured to provide the necessary evidence. Any infringement of this new law is dealt with an administrative offence and is punished with a fine of up to € 1.500,-. In cases of repetition an additional driving ban of up to three months may be decided. §24a contains explicit exceptions for substances which are taken due to a prescription for a specific illness. For the moment, this is only the case for morphine.

In addition to the administrative level of offence, there are regulations covering the offence of driving under the influence of drugs in the penal code. This provision covers alcohol and the substances specified in the annex, namely cannabis (THC), heroin, morphine, cocaine (benzoylecgonin), amphetamine, and two designer amphetamines (MDE and MDMA).
For detection, originally only a trace was needed to start the administrative procedure (a zero tolerance approach). However, there are specified limits for the named substances, over which the driver will clearly be impaired. On the basis of scientific advice, the government has proposed to set 50% of these limits as a new level, below which no procedure would be started, in order to reduce the number of cases. This must still be approved by the 16 Länder. Breach of this provision is an administrative offence, enforced by municipal authorities. From 1 April 2001, this could be punished with an administrative fine of € 250,- and a 1 month driving ban, and a repeat offence by a € 750,- fine and a 3 month ban. A doctor’s advice may also be submitted regarding possible dependence or drug abuse.

Finally, there is a provision § 14 VeF, „Klärung von Eignungszweifeln im Hinblick auf Betäubungsmittel und Arzneimittel“, contained in „Verordnung über die Zulassung von Personen zum Straßenverkehr (VeF) vom 18. August 1998 (BGBl. I S. 2214), in Kraft ab 01.01.1999”. The VeF lists three categories; “illicit” drugs, psychoactive medicines, and other psychoactive substances.

4.2.2 Drug testing in Germany

In Germany, roadside drug tests have been introduced on a routine basis in most of the Länder.
Generally, drug test devices help the police officer to decide on the necessity of a blood analysis. Detectable blood concentrations of drugs are the only objective criterion for driving under the influence of drugs accepted by court. In addition to the police report, the suspect statement, results of a clinical evaluation and a statement of an expert witness are used by the courts to decide on the offence driving under the influence of drugs.
If in a traffic control situation (or in a specific drug control action) indications of the use of drugs are obvious, the police officer interviews the suspect and offers a roadside drug test to confirm or deny his initial suspicion. In the case of refusal the provision of a blood sample can be enforced. In case of a positive test result the officer can order a blood sample to be taken to give evidence to support the statement of the police officers.
If a test was performed because of a suspicion regarding §24a and the result is negative, there is no more basis for further action. If the test result is negative, but indications according to §316 exist for a criminal offence, the blood sample has to be taken to gain the necessary evidence in court (the toxicological analysis is extended to all of the ”intoxicating” substances).
In cases when a negative roadside test result is obtained or in cases when co-operation is refused and clear signs of impairment are obvious, further legal actions are acceptable to prove alcohol or drug use.
If a driver seems to be too influenced so that he is not able to co-operate, he can directly be forced to give a blood specimen. In addition an evaluation by an expert witness can be requested.
The different types of roadside test devices can be applied everywhere where the dignity of man is protected. Saliva and sweat samples can be collected and tested directly at the roadside, whereas urine samples should only be collected and tested at police stations or at public lavatories.
Reasons for testing drivers for the abuse of alcohol or drugs are general traffic controls, specific roadblocks, special checkpoints, accidents and if general driving faults are observed. Police does not have the authority to check motorist at random for drug(ab)use. (Suspicion is needed).
Policemen perform an evaluation based on an evaluation scale comparable to the US DRE system with training programmes for police officers. Since 1988 in case of reasonable suspicion of driving under the influence of illicit drugs or medicines a mandatory blood sample is collected.
The screening tests in Germany are performed on specific devices. These devices require a sample of urine or sweat. The used urine screener (Mahsan) can detect cannabis, cocaine, opiates and amphetamines. With a sweat screener (Drugwipe II) similar substances can be detected.

4.3 Belgium

4.3.1 Legislation related to drugs and driving

On March 30th 1999, a new version of the traffic law was adopted by the Belgian parliament. This new law punishes driving under the influence of cannabis, cocaine, opiates and amphetamines and includes not only specific substances, but mentions also analytical legal limits for these substances in plasma. Drivers identified with a plasma concentration higher than 2 ng/ml THC, 20 ng/ml morphine or 50 ng/ml of amphetamine, MDMA, MDEA, MBDB, cocaine or benzoylecgonine, are infringing the new 'per se' regulation and can be condemned to a fine and/or a prison sentence. This new specific regulation is a zero tolerance-type law but blood sampling and analysis is only allowed if signs of impairment are obvious, and if a roadside urine test is positive for amphetamines, cannabis, cocaine or opiates. For the conviction, the observed signs of impairment are usually not taken into consideration; Article 35 of the Belgian Traffic Law stipulates that driving while being impaired is forbidden, but that statement is very broad, and until now very few subjects have been convicted in Belgium by Article 35.
If any of these substances are detected at all, the driver is guilty of an offence. The first penalty is prohibition of driving for 12 hours, renewable every 6 hours until signs of influence disappear – this is a safety measure. Following this, there can be a suspension of the driving licence by order of the judicial criminal authorities. If there is a criminal prosecution, the offender may be sentenced to imprisonment for 15 days to 6 months and/or a fine of € 1.000,- to € 10.000,- or imprisonment for 1 month to 2 years and/or a fine of € 2.000,- to € 25.000,- in case of recidivism within three years.
Both the driver of a vehicle, and the supervisor of a learner driver, may be checked and penalised if drugs are found. Those who may be subject to the test include any person who is driving or about to drive in a public place, or who is accompanying a driving student. It is also possible to test the person presumed responsible for a car accident, or anyone who could have contributed to its cause, even if it is the victim.
In June 2009 a proposal to modify the Traffic Act related to driving with psychoactive substances in the system has been brought to parliament. In this proposal random oral fluid drug testing and analysis of an oral fluid sample for evidence (comparable to the Australian situation) is described. This law has now been passed.

4.3.2 Drug testing in Belgium

The identification of "drugged" drivers at the roadside is currently strictly oriented at the determination of signs of impairment by the police. If signs of impairment are observable during traffic controls, roadside testing for impairment by drugs is justified. Roadside testing consists of a three step procedure.
To detect and clarify signs of impairment police forces apply a modified field sobriety test, which was derived from the US drug recognition program.
Positive suspects are subjected to an immunological urine screening test. Urine drug tests can be performed by police forces at any place where the privacy of the subject is guaranteed and sampling can be performed under hygienic conditions. Drug testing is only allowed after an initial suspicion. The police are allowed to control all persons who are involved in traffic accidents for the consumption of drugs. If a suspicion for impairment exists, the application of a drug screening device has to be accepted by the suspect.
A positive urine test leads to a blood analysis and the presence of illegal drugs in blood is the basis for the conviction. If the test result is negative, but there are signs of impairment, further legal action can be undertaken under the direction of a prosecutor. If the driver refuses or is unable to give a urine sample, he can be forced to give a blood sample for a laboratory analysis. In this case the driver is infringing a valid regulation and this will be equated to a positive result (prohibition to drive during 12 hours + conviction, similar to alcohol > 0.8 mg/ml blood). A negative screening result and the absence of any indication for impairment exonerate the suspect.

4.4 Spain

4.4.1 Legislation related to drugs and driving

The Spanish Penal Code contains within the Section "Crimes against Public Safety" a subsection related to crimes against road safety. In this subsection driving under the influence of drugs, narcotics, hallucinogenic substances or alcoholic drinks is regulated.
The Law on Traffic and Road Safety stipulates in article 12.1:
"If the driver of a vehicle exceeds the legal limits pertaining to alcoholic drinks, narcotics, hallucinogenic substances, stimulants or other analogous substances, he may not drive upon any public road".
Only alcohol limits are mentioned. The current Spanish approach to deal with driving under the influence of drugs is impairment-oriented.
This is in contrast to the alcohol control field, where Spain relies on both: exact analytical limits for the allowed alcohol concentrations in blood or breath as well as examined signs of impairment.
The Organic Law 10/1995, of 23 November, modified Article 379 of the Penal Code:
"A driver under the influence of poisonous, narcotic or psychotropic substances or alcohol, will be punished by the penalty of 8-12 weekend arrests for 3-8 months, and in any case, suspension of the driving licence for one to four years."
The law on traffic and road safety (Real Decreto Legislativo 339/1990, of 2 March, amended by the Law 19/2001 of 19 December), lays down in article 65.5 the serious offence, when it can not already be considered a crime, of driving under the effects of any narcotic or psychotropic substances or any substance with analogous effects. Article 67.1 of the traffic law foresees a fine (€ 302,- to € 602,-) and the suspension of the driving licence (up to three months) and a six points penalty for the drivers licence. The offences can therefore be either a criminal offence or an administrative infraction. Drivers may be tested at any time, for instance during traffic checks. Both levels of tolerance are addressed. Although both phrases refer to driving under the influence or under the effects, it is reported that when it is proven that the driver has taken drugs because the analysis is positive, it will be an administrative infraction. If the drugs taken have some effect on the road traffic, and other drivers are put at risk, it will be a criminal offence.

4.4.2 Drug testing in Spain

Under legislative aspects there is no difference between the abuse of alcohol or drugs in road traffic; this is due to the formulation of the Spanish Traffic Act referring to alcohol, toxic drugs, and other substances influencing driving ability. But from the technical point of view, there is no drug test device available which can be used in the same way as a screening device for alcohol. For testing the influence of intoxicating substances other than alcohol, Spanish regulations stipulate that a procedure should be applied which will consist of a medical examination and a clinical analysis which the forensic scientists and medical expert may deem appropriate.
With regard to the other substances than alcohol mentioned in the Spanish Traffic Law the possibility is already foreseen, that roadside test devices to detect the presence of other substances than alcohol (Article 12.3) will be developed and introduced.
In Catalonia the police has the possibility to require an oral fluid test when the driver of the vehicle shows signs and symptoms related to the use of illicit drugs. The police can ask the suspected driver to perform a test on an oral fluid screening device and if the police officer suspects the motorist to have illicit drugs in his system he can order the suspected driver to provide an oral fluid sample and a blood sample to be analysed by the laboratory of the police.

4.5 Finland

4.5.1 Legislation related to drugs and driving

A person who operates a motor-driven vehicle after having consumed alcohol so that his/her blood alcohol level is at least 0,5 per mill or his/her exhalation contains at least 0,25 milligrams of alcohol per one litre of air during or after driving is considered to be driving while intoxicated.
To combat driving under the influence of drugs the Finnish government pursues a combination of an analytical and an impairment approach. Since 1977 § 23 of the penal code has regulated driving under the influence of drugs. For punishment of a driver it has to be demonstrated that the driving capability is impaired and significant amounts of drugs are present in the bloodstream of the respective driver. Included are all substances that can cause impairment of performance.
Under the Penal Code, Chapter 23, section 3, an offence of “driving while intoxicated” is committed by a person who, after having used other narcotic substances than alcohol, so that there is a narcotic drug or its metabolite in his or her blood during or after driving. The punishment for driving while intoxicated is a fine or imprisonment for at most six months. According to s.12, for the purposes of this chapter, *narcotic substance* means also performance-reducing pharmaceuticals. However, medical products, which the driver has had the right to use, are excluded from the zero-tolerance approach of section 3.
Under section 4, an offence of “driving while seriously intoxicated” is committed due to impairment: if his/her ability to perform as required in the operation is significantly reduced, and the conditions are such that the offence is conducive to causing a hazard to others. The punishment for this is at least 60 day-fines or imprisonment for at most two years. This does not have the same exclusion for medical products, suggesting that trace amounts are acceptable but impairing driving ability is not.
Section 8 defines a separate offence of relinquishing a vehicle to a person “who is apparently in such a state that he/she is guilty of an offence mentioned in sections 3 – 7”, which is punishable by a fine or imprisonment for at most one year.
A driver found guilty of driving while intoxicated, having been under the influence of a drug specified in the Narcotics Act (1289/93) may also be found guilty of a drug-user offence (Criminal Code 50:2a).
The offences are the type "zero-tolerance", with any detection of drug or metabolite. They have been changed from “impairment”, where no precise figures for blood/drug levels were given, only the verbal descriptions (reduced and seriously reduced ability, respectively). In the preparatory materials of the previous legislation it was explained that the levels of reduction should be comparable to those caused by the given levels of alcohol, in order to be punishable. According to the Ministry of Interior directions to the police (3/011/1999) the intoxication shall be detected by an analysis of a blood sample and a clinical medical examination, which includes filling an observation form on the suspect's performance.
Under Chapter 6 of the Coercive Measures Act (450/1987), drivers can be tested any time in traffic in order to detect use of alcohol or other intoxicants. Practices also include stop checks where everyone is tested (quick tests for drugs are performed, but a positive result must be confirmed by a laboratory test), and tests after stopping an individual driver on grounds of suspicion. An alcohol test is taken as a rule after an accident, and the practice of drug testing in similar conditions is spreading, limited presently by availability of suitable test kits.
The driving licence must be suspended if a person has been found guilty of driving while intoxicated or seriously intoxicated. Suspension of driving licence is for maximum five years. Besides this, there are administrative sanctions on not issuing or returning the driving licence to persons with intoxicant addiction. The Road Traffic Act (267/1981) lays down provisions on licence suspension in section 75,76 (546/1999), 77,78 and 79 (676/1990). The practices are guided by directions laid down by the Ministry of Social Affairs and Health for physicians (1998:6), and by the Ministry of Interior for the police (Dno 3/011/99).

4.5.2 Drug testing in Finland

If signs of impairment or drug utensils indicate the abuse of illegal drugs, the subject is taken to a hospital for obtaining a blood (and on a voluntary basis also urine) sample; usually breath testing for alcohol is the introductory step during a traffic control situation, but this is not obligatory. Under certain circumstances drivers under suspicion can be brought directly for a medical examination and blood sampling. In case of “Reasonable Suspicion” of impaired driving, the field policemen requires a medical doctor, to proceed to a clinical evaluation and to a blood and urine sampling for a laboratory screening and confirmation. Oral fluid tests can be performed every time a police officer stops a

motorist. As these screening tests are more expensive and performing such a test is more time consuming than a screening test for alcohol these oral fluid tests will mostly be performed after a test on an alcohol screening device resulting in an indication that is not in line with the observations of the controlling police officer. Prohibited drugs in road traffic are those illicit drugs listed in the UN conventions on narcotics. If a motorist is positive for drugs on a screening device the police officer will fill in a documentation form on detected sign and symptoms of drug use and the medical doctor who will take the blood sample will do a medical examination by performing clinical tests related to mental status and behaviour of the suspected person.

4.6 The Netherlands

4.6.1 Legislation related to drugs and driving

In The Netherlands both an analytical approach and an impairment oriented approach are pursued. Since 1974 (last change 1987), article 8 of the Traffic Act (section 1) makes driving under the influence of any substances that influence driving behaviour (illicit drugs and certain drugs of prescription) punishable. Impairment of driving performance as well as the presence of significant concentrations of drugs in a driver's blood has to be demonstrated. Included are all substances that might influence driving behaviour.
According to the Road Traffic Act 1994 in article 8, section 1, there are three offences of criminal status:

- Causing a fatal traffic accident under influence of drugs may be punished with a maximum imprisonment of nine years or a maximum fine of € 45.000,- .
- Causing an accident under influence of drugs, which inflicted bodily harm, may be punished with a maximum imprisonment of three years or a maximum fine of € 11.250,-.
- If a person has driven a motor vehicle under influence of drugs which affect one's ability to drive or has his motor vehicle driven by someone who is under influence of such drugs, his driving licence may be suspended for a maximum period of five years. There is no distinction between drugs, and the tolerance is to a level of impairment. Testing can take place if there is a presumption of driving under influence of drugs.

4.6.2 Drug testing in The Netherlands

No roadside devices for the detection of the abuse of illegal drugs in road traffic are in use in the Netherlands. The Dutch Traffic Act does not contain any regulation concerning drug screening devices or their application. If the result of an alcohol screening test is less than 350 µg/l breath, but there are indications for impairment, the policy of the public prosecutor is that the police officer can try to prove the abuse of psychoactive substances. Distinct indications of intoxication are required to suspect a driver of driving under the influence of drugs and to request blood/urine sampling. To gain suspicion roadside observations provide the necessary indications, but no impairment specific test program is in regular use. Any observation is documented in a protocol. In addition the medical doctor will take a blood sample and performs an examination for the abuse of illicit substances. Evidence of drug-impaired driving is given by the police report including a description of observations, the medical examination and the analysis of the blood sample by the forensic laboratory.
Refusal to cooperate at the blood test or the evidential breath analysis is a major offence. (Punishment similar to impaired driving).

5 Material and methods

5.1 Material

During the ROSITA 2 study a number of oral fluid screening devices have been tested by research institutes in a number of EU member states and by some institutes in the US.
After finishing this study manufacturers have improved their devices based on information from the market of potential users of these kind of devices and the recommendations of the ROSITA study.
Manufacturers of oral fluid screening devices who participated in the ROSITA studies have been contacted by TISPOL. These manufacturers have been informed about task 3.1 ESTHER and have been asked about their willingness to participate in this field trial.
In 2004 during the preparation of the practical evaluation of oral fluid screening devices as mentioned in task 3.1 TISPOL has decided to place information on this activity on their website. In this publication TISPOL has invited all known manufacturers of oral fluid screening devices for drugs to contribute to the ESTHER task by providing screening devices to be tested by specific teams of dedicated police officers in a number of European member states under operational police conditions.
Apart from that investigation has been performed to identify manufacturers of screening devices by exploring the internet and collecting data of manufacturers participating in different research projects related to drugs and driving. Experiences of police forces outside Europe (especially Nord America and Australia) have been collected and used as input for the selection of manufacturers. Initially sixteen manufacturers have shown their interest to contribute to the practical evaluation of their device(s). Contacts, discussions and information provided by the manufacturers as well as by the ESTHER task leader have resulted after two years in ten manufacturers signing a letter of intent to contribute to the ESTHER task. The remaining six manufacturers provided reasons not to participate or to withdraw from the task.
One manufacturer Cozart (RapiScan) declared not to participate in the first phase of the ESTHER task.
The other five manufacturer showed their interest and signed a letter of intent but were forced to withdraw for a variety of reasons.

1. Dräger Security (Drug test UPT link) had to withdraw from the task as the development and production of the device was stopped for commercial and strategic reasons.
2. Life Point (Impact device) had to withdraw from the task as the company went bankrupt.
3. Bamburgh Marrsh (VerOFy) had to withdraw from the task as the new device – a test worthy concept – would not be available at the start of the DRUID project.
4. Instant Technologies (*i*Screen) had to withdraw from the task based on commercial and strategic arguments.
5. Biosensor AB (BIOSENS) had to withdraw from the task as this company did not have enough resources and representatives in the participating countries to support the task in a qualitative way.

Each manufacturer has been informed in a detailed way on the development of the preparation of the DRUID contract and the reasons why the start of the activities was delayed. They have been asked to provide information on their device and prepare training materials for the eleven ESTHER teams in the participating police forces. During the first phase of testing three manufacturers – Biosensor, Cozart and Dräger – requested to be included in the second phase of testing as they had new developed devices available. In annex 7 the thirteen manufacturers are presented by providing information from their websites completed with additional information from the manufacturers.

The practical evaluation of the screening devices has been focussed on specific issues mentioned in the registration forms in the annexes 2 and 3. Some of these aspects are:.

- The successfulness of the performed tests.
- The time required to collect a sufficient oral fluid sample
- The time required to analyse an oral fluid sample.
- The hygienic aspects of oral fluid sampling and testing.
- DPO's impression of the reliability of the obtained indication.
- DPO's qualification of the simplicity of the test

Apart from these aspects tested persons have been asked for their opinion on the tests they performed and the relevance of specific legislation for drugged driving.
In the next subparagraphs (5.1.1 – 5.1.13) participating manufacturers present their company profile.

5.1.1 Mavand solution GmbH

MAVAND Solutions GmbH is a biotechnology company that develops manufactures and markets accurate, cost-effective immunoassay diagnostic test kits, including some of the world's most effective point of collection saliva and urine tests for drugs of abuse. The Company and its distribution network throughout Europe target the police, customs, workplace, government, corrections, clinical and educational markets.
MAVAND Solutions GmbH is European Master Distributor of ABMC. This company is offering one of the largest portfolio of oral fluid and urine drug of abuse tests as well as evaluation instruments, f.e. the Mobile Reader for roadside measurements, the Desk Reader and Desk Reader Professional. With its database management MAVAND Solutions provides a unique solution for evaluation, documentation and archiving of drug of abuse tests.

5.1.2 Avitar Inc.

Avitar Inc. is a leading company in oral-based instant diagnostics. Their proprietary disposable drugs-of-abuse test will change the way that drug testing is done worldwide. Avitar is investigating oral-fluid based diagnostic strategies for disease and clinical testing, such as tests for influenza, diabetes and pregnancy.

5.1.3 Branan medical Corporation

Branan Medical Corporation is an ISO 13485 certified and FDA licensed California based company that develops, manufactures and markets unique products for drugs-of-abuse testing. The company offers a complete line of rapid, on-site drug and adulteration tests in urine and oral fluids as well as quality control products. All its products have received CE marks. Developed with lateral flow immunoassay technology, Branan Medical's products are accurate, precise and sensitive. Branan Medical Corporation is dedicated to provide innovative products, excellent quality and friendly customer service.

5.1.4 EnviteC Wismar GmbH

EnviteC was founded in 1992 and employs approx. 100 people, a large proportion of them in research and development. In order to ensure the company's middle and long-term growth, EnviteC invests a large part of its profits in the research and development of new products and technology. Right from the start the emphasis has been on the development and production of sensors and high-quality monitoring devices. Today the spectrum includes sensors and instruments used in medical, industrial and environmental technology, such as breathalysers for police traffic controls and medical applications.

5.1.5 Innovacon Inc.

Innovacon, Inc. is a subsidiary of Inverness Medical Innovations. Innovacon, Inc. markets lateral flow rapid diagnostic healthcare products based on a philosophy of high quality, low price, and superior flexibility. Prior to April 1, 2006, when Innovacon was acquired by Inverness Medical Innovations, Innovacon was known as ACON Laboratories. ACON has brought its customers high quality, low price rapid diagnostics for over eight years. Innovacon carries on the tradition established by ACON. Key product segments of Innovacon are Drugs of Abuse, Fertility, Infectious Disease, Cardiac Markers, and Tumour Markers. Most of these products are available for sale in the U.S. Innovacon’s primary focus is support for our OEM partners and distributors. Innovacon draws upon the extensive OEM experience that we gained while we were ACON Laboratories. The rapid test products are available in generic OEM packaging or custom formats, including customized devices, custom packaging, and custom labelling

5.1.6 Securetec Detektions-Systeme AG

Securetec Detektions-Systeme AG was founded in 1995 and has established itself as a successful solution provider who develops, manufactures and sells field applicable detection systems for a wide range of threats and targets. Both development and production meet the highest international standards.
In close cooperation with clients, Securetec Detektions-Systeme AG develops high quality detection solutions for drugs, explosives and dangerous substances which are both innovative and user-friendly. As experts in the development and application of detection systems, Securetec also offers consulting, training and after sales services.

5.1.7 Sun OraLine

Sun Biomedical Laboratories, Inc. researches, manufactures, develops and distributes innovative biomedical diagnostic products, including rapid "on-site" drug tests for drugs of abuse and alcohol. On the cutting edge of science and technology, we apply the newest biotech research in the development of diagnostic products, therapeutic reagents and devices for drug testing kits. Sun Biomedical Laboratories Inc. specializes in developing on-site drug testing kits for diagnostic applications. Goal is to provide customers with the most effective drug test kits while offering them service with courtesy, confidentiality, reliability and professionalism.

5.1.8 Surescreen Diagnostics Ltd.

Surescreen evolved in 1991 when a group of British forensic scientists realised that their analytical skills were as valid in medicine as they were at a murder scene.
It's their lateral thinking which puts Surescreen ahead of the competition, by bringing together sophisticated technologies to create our unique range of cutting edge diagnostic products.
Surescreen Diagnostics Ltd. has become leaders in in-vitro diagnostics test kits and devices for drugs, pregnancy, disease and lifestyle tests and in detection and management of medical conditions via screening and clinical chemistry. Surescreen provides complete screening and programmes and training.

5.1.9 Ultimed Products GmbH

"The Ultimate Pharma Products GmbH" was founded by managing director, Matthias W. Engel, in 1994 in Lübeck, and was renamed later into Ultimed Products (Deutschland) GmbH. From the beginning Ultimed is specialized in manufacturing, im- and exporting as well as distribution of in-vitro diagnostic medical devices. Ultimed develops special IVD and methods of analysis like saliva drug tests - patents are pending.
In cooperation with famous institutes in Europe and the USA, Ultimed uses a wide range of modern research and development laboratories.
As one of the first manufacturers of IVD, Ultimed was certified in the year 2000 according ISO standards after the installation of an extensively quality assurance system for all sections of the company. From manufacturing to the registration of the products, and the distribution as well as the despatch of every shipment, Ultimed is associated with high quality.

5.1.10 Varian Inc.

Varian, Inc. has emerged as the acknowledged expert in all phases of toxicology and onsite drug testing. Training and education have long been hallmarks of our dedication to customers' satisfaction. Varian, Inc.'s SMARTesting™ solutions offers SMARTknowledge, SMARTdata, and SMARTresults through our commitment to education, 24/7 support, expert consultants, intelligent data management, and laboratory services.

5.1.11 Cozart, a wholly owned subsidiary of Concateno plc

Concateno is Europe's leading drug and alcohol testing provider and a manufacturer of clinical diagnostic products. Concateno is committed to working with government, employers, health and law professionals to help reduce the impact of this problem. Our testing expertise is unmatched and our staff are passionate about working with customers to find the best possible solution for them.

5.1.12 Dräger AG & Co. KGaA

Drägerwerk AG & Co. KGaA is a leading international corporation in medical and safety technology: Dräger products protect, support and save lives. Founded in 1889, the technology corporation achieved a global turnover of € 1.819,5 million in 2007 and an EBIT of € 151,9 million. Today the corporation headquartered in Lübeck employs approx. 10.000 people in over 70 sales and service companies world-wide and is represented in 190 countries. The subsidiary Dräger Safety offers products, services and system solutions for a comprehensive risk management, especially for personal and plant protection.

5.1.13 Biosensor Applications Sweden AB

Biosensor Applications is a Swedish company located in Solna, outside of Stockholm, and in Bonn, Germany. The company develops, manufactures and sells biotechnology based detection systems for drugs and explosives.
The detection equipment combines proven immunoassay technology with Quartz Crystal Micro balance (QCM) resulting in systems with both high selectivity and sensitivity for the target substances and very short detection time.

5.2 Methods

5.2.1 Selecting and training police officers

TISPOL council members have selected a number of police officers to participate in the ESTHER task. For each team a team leader and four officers have been selected. These police officers were already well informed about drugs and driving and were involved in the enforcement of the specific regulation on drugs and driving in their own country. To develop user requirements and specifications of oral fluid screening devices these special selected police officers have been informed again about specific signs and symptoms of motorists driving a vehicle after the consumption of illicit drugs.
After this information has been provided by the manufacturers about their oral fluid screening devices. Before starting with the operational use of the device during normal traffic control activities each police officer has been trained in the use of the device. In annex 7 specific information/documentation provided by the manufacturer is given. This information has been used for training. In most situations the training has been provided by an instructor of the company.

5.2.2 Standardised procedure to test motorist during police control activities

A procedure and guidelines for Task 3.1 ESTHER has been developed. These guidelines have been developed to be used by Dedicated Police Officers (DPO's) in a number of European countries.
Only by following these guidelines the results of the tests, findings and opinions of motorists that have been tested and the opinions of DPO's on the different devices can be compared.
In Annex 1 the procedure and guidelines are presented. Motorists will be stopped by a police officer to be checked for the use and/or abuse of alcohol. After performing an alcohol screening test an indication of the alcohol consumption will be presented.

- If the motorist is suspected of driving with an alcohol concentration above the prescribed limit, the motorist will be considered a suspect and the judicial procedure for that country will be followed. After the completion of the legal procedure the motorist will be requested to co-operate, on a voluntary basis, at an oral fluid based screening for the presence of illegal and prescription drugs. This test will be led by the DPO. The oral screening devices to be used in this trial have not yet been type approved by the various governments and cannot yet be used in subsequent legal proceedings.
- If, after the alcohol screening test, the motorist is found not to be above the prescribed limit for alcohol he will be asked to participate in the oral fluid screening test. This can only be done on a voluntary basis and without any legal consequences. The test will be led by the DPO.

These tests will always respect the differences between the legal procedure and the testing activities.

5.2.3 Time schedule for testing

Thirteen oral fluid screening devices have been tested in the eleven ESTHER teams. The operational testing started in October 2006 and lasted till August 2008. Each ESTHER team has tested all the devices. The scheduling of testing has been made in such a way that each team could test the device without knowledge of the experiences of other teams with the same device.
Ten different oral fluid screening devices have been tested in the first phase. All devices were one-way devices. Disposables that could be used once. Some devices did have the possibility to use an electronic reader but all devices could work without such a reader.
Three devices have been tested during the second phase. Two of these devices were devices where the reader was an integrated part of the testing system. Next to the reader a collecting device and a test cassette was needed for each test. In the ESTHER task these devices have been categorised as instrumental screening devices with a test cassette
One device was an instrumental device with a specific tissue to collect the fluid sample from the tongue of the tested person. This tissue had to be placed in the analysis system to search for the presence of specific drugs. In the analysis system a BioCell, a kind of cartridge, for the selected relevant substances must be placed. The BioCell can be used for five days independent of the number of positive tests. In the ESTHER task this device has been categorised as a Automated Drugs-Detecting System. The tested devices are 01 Mavand RapidSTAT, 02 Avitar Drugometer, 03 Branan Oratect III, 04 EnviteC SmartClip, 05 Innovacon OrALert, 06 Securetec Drugwipe 5+, 07 Sun OraLine 08 Surescreen Drug Test, 09 Ultimed Salivascreen VI, 10 Varian OraLab 6, 11 Cozart DDS 12 Dräger Drug test 5000 and 13 Biosensor BIOSENS

Testing the devices has been performed in two phases.
A testing period in the two phases lasted five weeks with an overlap of one week. The first week has been devoted to the training of the team. Four weeks of testing and the sixth week has been used for evaluation of the past period and training for the next period.
In each period each team tried to realise twenty tests with the device under operational police conditions at traffic enforcement activities.
Each manufacturer participating during the first phase have been given the opportunity to improve their device from an operational perspective and to be tested in a second part of the testing phase by DPO's on these improvements.
A testing period in the second part of a phase lasted just one week. Training and evaluation of the improved device took place in the same week.
A detailed time schedule for the two phases has been developed and used as a roadmap for the teams and the manufacturers. (See tables 5.2.3.1 – 5.2.3.7)
It was not efficient and effective to test the thirteenth device, the Automated Drug Detection System, in a similar way as the other devices. This device was not suitable to be used every now and then in patrol cars. Operational use of this device is specifically interesting during mega-festivals and mega dance parties with lots of participants where the police want to check motorists on drug use in a similar way as motorists are tested on alcohol during at random alcohol control actions.

Phase 1 part 1 (10 devices)	
Period 1:	13-11-2006 till 22-12-2006
Period 2:	18-12-2006 till 26-01-2007
Period 3:	22-01-2006 till 02-03-2007
Period 4:	26-02-2007 till 06-04-2007
Period 5:	02-04-2007 till 11-05-2007
Period 6:	07-05-2007 till 15-06-2007
Period 7:	11-06-2007 till 20-07-2007
Period 8:	16-07-2007 till 24-08-2007
Period 9:	20-08-2007 till 28-09-2007
Period 10:	24-09-2007 till 02-11-2007
Period 11:	29-10-2007 till 07-12-2007 (reserve)

Table 5.2.3.1: ESTHER time schedule phase 1 part 1

Testing schedule Phase 1 part 1												
Team/Period	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12
NL 1	01	02	03	04	05	06	07	08	09	10		
NL 2	01	02	03	04	05	06	07	08	09	10		
NL 3	01	02	03	04	05	06	07	08	09	10	R	R
Belgium 2	03	04	05	06	07	08	09	10	01	02	E	E
Belgium 3	04	05	06	07	08	09	10	01	02	03	S	S
Ireland	05	06	07	08	09	10	01	02	03	04	E	E
Finland	06	07	08	09	10	01	02	03	04	05	R	R
Spain	07	08	09	10	01	02	03	04	05	06	V	V
Germany 1	08	09	10	01	02	03	04	05	06	07	E	E
Germany 2	09	10	01	02	03	04	05	06	07	08		
Germany 3	10	01	02	03	04	05	06	07	08	09		

Table5.2.3.2: ESTHER testing schedule phase 1 part 1

Phase 1 part 2 (4 improved devices)	
Period 1:	13-01-2008 till 19-01-2008
Period 2:	20-01-2008 till 26-01-2008
Period 3:	27-01-2008 till 02-02-2008
Period 4:	03-02-2008 till 09-02-2008
Period 5:	10-02-2008 till 16-02-2008 (reserve)

Table 5.2.3..3: ESTHER time schedule phase 1 part 2

Testing schedule Phase 1 part 2				
Team/Period	P1	P2	P3	P4
NL 1	01	03	06	08
NL 2	01	03	06	08
NL 3	01	03	06	08
Belgium 2	03	06	08	01
Belgium 3	03	06	08	01
Ireland	06	06	01	03
Finland	06	08	01	03
Spain	06	08	01	03
Germany 1	06	01	01	03
Germany 2	08	01	03	06
Germany 3	08	01	03	06

Table 5.2.3.4: ESTHER testing schedule phase 1 part 2

Phase 2 (2 instrumental devices + 1 automated system)	
Period 1:	17-03-2008 till 25-04-2008
Period 2:	21-04-2008 till 30-05-2008
Period 3:	26-05-2008 till 04-07-2008 (reserve)

Table5.2.3.5: ESTHER time schedule phase 2

Testing schedule Phase 2			
Team/Period	1	2	3
NL 1	11	12	
NL 2	11	12	
NL 3	11	12	R
Belgium 2	11	12	E
Belgium 3	11	12	S
Ireland	12	11	E
Finland	12	11	R
Spain	11	12	V
Germany 1	12	11	E
Germany 2	12	11	
Germany 3	12	11	

Table 5.2.3.6: ESTHER testing schedule phase 2

The second phase has not been divided into parts as a second part of this phase has not been considered as relevant. (unable to modify devices in a couple of weeks). Testing of The BIOSENS had to take place during control activities of the police at mega dance and music parties. These parties and activities have been organised in the working areas of the teams in the period April – August 2008. Teams could cooperate during these parties if required or relevant. One team tested this device during a major traffic control activity of the police in that particular part of the country. The other teams selected mega dance and music parties. (Table 5.2.3.7)

Testing schedule Biosensor BIOSENS		
Team	Date	Name of mega party
NL 1 NL 2 NL 3	31 May 2008 + 01 June 2008	Emporium + Pinkpop
Belgium 2	8 June 08	DIDRO 4
Belgium 3	27 – 29 June 2008	Graspop
Ireland	10 – 14 July 2008	Oxygen Concert
Finland	14 June 2008	Myotatuuli Rock
Spain	23 – 24 June 2008	San Juan
Germany 1	4 – 6 July 2008	Time Wrap
Germany 2	-	-
Germany 3	3 August 2008	Nature One

Table 5.2.3.7: ESTHER testing schedule for BIOSENS

5.2.4 Registration form, impairment form and evaluation reports

Registration form

Relevant findings of a performed test have been registered in a uniform way. A specific registration has been developed and used during the two phases. Forms were available in Finnish, German, Spanish, English and Dutch. In Annex 2 the English version of the registration form for phase 1 is provided. In Annex 3 the registration form for phase 2.

Impairment form

To help DPO's to detect signs and symptoms of drug use an impairment form has been developed to be used during observations of stopped motorists. The form could be used to register observed signs and symptoms and to register findings of specific tests. provided Each test

Standardised evaluation report

At the end of each testing period each team evaluated the devices they tested. For this evaluation report an outline of such an evaluation report is provided as a help for teams but also to harmonise the evaluations.

5.2.5 Evaluation meetings

Approx. 30 one-day meetings of the task leader and each ESTHER team have been organised. During these meetings control activities have been performed and discussions about the required specifications and other issues related to the use of oral fluid screening devices have been held. The results of these discussions are used as an input for the two plenary evaluation meetings.

The two 3-days plenary meetings have been held in Stein (NL) 5 – 7 June 2007 and in Landgraaf (NL) 14 – 16 October 2008.
During these two evaluation meetings the conclusions of the one day meetings with each of the teams have been discussed and resulted in a list of user requirements and specifications and an outline of the desired legislation from a police perspective.

6. Training of DPO's on oral fluid screening devices

6.1 Phase 1

At the beginning of each testing period DPO's in ESTHER teams have been trained in the use of the specific screening device they would evaluate in that particular period. These training sessions took place in police premises in the participating members states on the day and time mentioned in the detailed ESTHER roadmap. Manufacturers have been invited to train the DPO's in each ESTHER team by sending an instructor on behalf of the manufacturer or providing specific training material for self-training. Approx. 75% of the training sessions have been realised by personal instructions of a representative of the manufacturer (M). 25% of the training sessions were led by the specific ESTHER team leader (T). (See table 6.1.1) In general it was concluded that manufacturers with representatives in Europe tend to perform personal training on the spot. In June 2006 some manufacturers of oral fluid screening devices used the interim evaluation meeting of the ESTHER task to perform personal training to some ESTHER teams. It has been concluded that a personal training of the ESTHER teams is more effective than training by using (interactive) CD ROMs.

Training given by manufacturer (M) or Team leader (T) Phase 1 part 1										
	01	02	03	04	05	06	07	08	09	10
NL 1	M	T	M	M	M	M	M	M	M	M
NL 2	M	T	M	M	M	M	M	M	M	M
NL 3	M	T	M	M	M	M	M	M	M	M
B 2	T	T	M	M	T	M	T	M	M	T
B 3	M	T	M	M	-	M	T	M	M	M
D 1	M	T	T	M	T	M	T	M	M	M
D 2	M	T	T	M	T	M	T	T	M	M
D 3	M	T	T	M	-	M	T	-	M*	M
Ireland	M	M	M	M	M	M	M	M	M	M
Finland	M	T	T	M	T	M	M	M	M	M
Spain	M	T	M	M	M	M	M	M	M	M

Table 6.1.1: Training of ESTHER teams by representatives of manufacturers of devices or by team leaders Phase 1 part 1.

01 Mavand RapidSTAT
02 Avitar Drugometer
03 Branan Oratect III
04 EnviteC SmartClip
05 Innovacon OrALert
06 Securetec Drugwipe 5+
07 Sun OraLine
08 Surescreen Drug Test
09 Ultimed Salivascreen VI
10 Varian OraLab 6

Training of DPO's in ESTHER teams has been realised in the first week of each ESTHER period. The training has been given in a police station and was attended by the leader of the specific ESTHER team and the DPO's. The time spend to the training has been depended from the information provided by the manufacturer. In general sessions where a representative of the manufacturer provided the instruction the training lasted longer than in other sessions. Oral fluid screening devices are rather easy to use. Three planned training sessions have not been realised. Belgium 3 and Germany 3 did not receive material from Innovacon for training and testing. Germany 3 also did not get training material and devices from Surescreen. Germany 3 has received training and testing material from Ultimed but the provided device differed from the device tested in the other ESTHER teams. After consultation of the team leader of Germany 3 with the ESTHER task leader it was decided not to evaluate this device.

Time spent during training sessions Phase 1 part 1										
	01	02	03	04	05	06	07	08	9	10
NL 1	1,5	2	1,5	1	1	2	1	1	1	1
NL 2	1,5	2	1,5	1	1	2	1	1	1	1
NL 3	1,5	2	1,5	1	1	2	1	1	1	1
B 2	1,5	1,5	2	2	1	2	1	1,5	1	1
B 3	1,5	1	2	2	-	1	1	1	2	2
D 1	1,5	2	1,5	1	0,2	1	1	3	3	2
D 2	1,5	2	0,3	1	0,2	1	1	1	2	1
D 3	2,5	3	2	3	-	2	3	-	-*	2
Ireland	1	1	1	1	0,5	1	1	1	1	1
Finland	1	0,3	1	1	-	2	2	2	1	3
Spain	3	1,5	0,5	2	1	2	2	2	2	2

Table 6.1.2: Time spent by ESTHER teams to training sessions Phase 1 part 1
* Another device was provided by the manufacturer. Training data and test data are excluded from this study.

In general a training session with practical instruction and use of the device lasted approx. 1 – 1,5 hour. Training sessions where no oral information and instruction has been given by the manufacturer normally lasted less long. 0,5 – 1 hour. See table 6.1.2

Examination Phase 1 part 1										
	01	02	03	04	05	06	07	08	09	10
NL 1	N	Y	N	N	N	N	N	N	N	N
NL 2	N	Y	N	N	N	N	N	N	N	N
NL 3	N	Y	N	N	N	N	N	N	N	N
B 2	N	N	N	N	N	N	N	N	N	N
B 3	N	N	N	N	-	N	N	N	N	N
D 1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
D 2	N	N	N	Y	N	N	N	N	N	N
D 3	N	N	N	N	-	N	N	-	-*	N
Ireland	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Finland	N	N	N	N	N	N	N	N	N	N
Spain	N	Y	Y	N	N	N	N	N	N	N

Table 6.1.3: Training finished by examination Phase 1 part 1
* Another device was provided by the manufacturer. Training data and test data are excluded from this study.

01 Mavand RapidSTAT
02 Avitar Drugometer
03 Branan Oratect III
04 EnviteC SmartClip
05 Innovacon OrALert
06 Securetec Drugwipe 5+
07 Sun OraLine
08 Surescreen Drug Test
09 Ultimed Salivascreen VI
10 Varian OraLab 6

Most teams did not finish the training with an examination of the DPO's as can be seen in table 6.1.3.
The Irish team and Germany 2 team did finish all the training sessions with an examination.
If a training on a new device was given to a police officer the standard procedure had to be checked whether the police officer was capable to work with the device in a successful way. This could be realised by an examination. Best way to perform such an examination is to have an interactive examination on the intranet of the police force. Each police officer can realise his own examination and the results can be stored on the computer network of the police force.

Improvement of the training

ESTHER teams have been asked to provide suggestions to improve the training on the oral fluid screening devices. During the training sessions ESTHER teams have made suggestions for training improvement.
The most important recommendation of the teams has been that training should be realised by a well informed representative of the manufacturer. This will make it possible to get answers on specific questions from police officers.

Other suggestions to improve the training of police officers have been mentioned during several evaluation meetings of the ESTHER teams.

- It would be good to have the user manual available in different languages. E.g. English, French, Spanish, German, Finnish and Dutch.
- The instruction material should be available through the intranet of the police forces.
- A CD ROM with test simulation and real training is preferable.
- During training sessions police officers should be advised how to work in a hygienic way while using oral fluid screening devices. The use of protective gloves should be an integrated part of the training and could eventually be included in the package of each device.
- Instruction manuals explaining the do's and don'ts with the device are preferred. This can really improve the training and the operational use of the device.
- A computerised examination on the intranet of the police network, together with the instruction material can improve the quality of the police officer when using the device under operational circumstances. However it must be kept in mind that most police networks do not allow their users to work with "exe files". The IT organisation of the police forces will have to formulate the format of electronic training materials.

During the second part of the first phase four modified/improved oral fluid screening devices have been tested and evaluated. The procedure to work with these devices was almost the same as with the devices tested in the first part of this phase. Manufacturers have provided the teams with new instruction material especially focussed on the improved aspects of the device. Improved aspects were related to the device itself – improved collecting device, improved analysing process – or to the additional reader. The modifications on the device did not make it necessary to organise a complete training session with instruction from the manufacturer. Both manufacturers and teams agreed on that. It has been decided that the training would be done by the leaders of the ESTHER teams themselves. This has not been a problem for the team leaders. One team has been trained by a representative of the four manufacturers.
Teams have been provided with CD ROMs, instruction cards, handouts and user manuals and it was expected that this would be sufficient for the training. In most cases it was. Teams reported that in general the instruction material was clear and sufficient to be used during training and would give trust in the successfulness of the operational activities. There was however one specific problem that occurred during training.
Three of the four improved devices (01 Mavand, 06 Securetec, 08 Surescreen) had an additional electronic reader. During the training and also during the testing these readers needed specific attention and instruction to operate in the required and satisfying way. The software for the reader was rather complicated due to the large amount of unnecessary submenu's for operational police officers. A PDA with a lot of extra possibilities will only invite people to "play" with the device. The police officer might "get lost" in the software or change the settings. A "one-button-reader" would already be enough for operational activities. The requirements can be compared with those of a mobile telephone. Making and receiving phone calls is the only real requirement. All the rest are extra's. "Nice to have but no need to have". With electronic readers for screening devices the requirements are similar. The reader should read results. All the rest are extra's. It has been clear for teams that at least one reader has been a new development that did not have the robustness one would like to have. The user friendliness could be improved but overall this has been considered as sufficient. Comments of the DPO's could be solved easily by the manufacturer as it was either a software problem or a hardware design problem and had nothing to do with the operational aspects of the device itself.
The fourth device (03 Branan) was not provided with a reader.
The instructions for this device have been classified as good. The reader was not available at the start of the second part of phase 1**.**
The developed reader for the Branan device was available in April/May 2008 and for practical reasons this reader has just been tested by one of the Netherlands ESTHER teams.
This team was satisfied with the "one-button" reader.

6.2 Phase 2

Each testing period in phase 2 started with a training session for DPO's in the ESTHER teams. DPO's have been trained in the use of the specific screening device they would evaluate in the next period. These training sessions took place in police premises in the participating members states on the day and time mentioned in the detailed ESTHER roadmap. Manufacturers have been invited to train the DPO's in each ESTHER team. All training sessions have been realised by personal instructions of a representative of the manufacturer together with accompanying CD ROMs and other instruction materials. Training of DPO's in ESTHER teams has been realised in the first week of each ESTHER period. The training sessions were attended by the leader of the specific ESTHER team and the DPO's in this team. The time spend to the training has been depended from the information provided by the manufacturer. In general a training session with practical instruction and use of the device lasted approx. 1 – 2 hours. All training sessions have been realised by an instructor of the manufacturer. Most of the instructions have been considered as both practical and professional. The Spanish ESTHER team did not get specific training on the Cozart DDS device as this team has been using the DDS device already for a longer period as a part of the normal traffic law enforcement activities. See table 6.2.1

Time spent during training sessions Phase 2			
	11 Cozart DDS	**12 Dräger Drug Test 5000**	**13 Biosensor BIOSENS**
NL 1	1	2	1,5
NL 2	1	2	1,5
NL 3	1	2	1,5
B 2	1	1,5	-
B 3	1	2	1,5
D 1	2	1,5	1
D 2	1,5	1,5	-
D 3	2	2	2
Ireland	1	1	1
Finland	1	2	2
Spain	-	2	1

Table 6.2.1 Time spent by ESTHER teams to training sessions Phase 2

Most teams did not finish the training session with an examination of the DPO's. The Irish team, the Spanish team and the Germany 2 team did finish all the training sessions with an examination. If a training on a new device has to be given to a police officer the standard procedure has to be checked to be sure the police officer will be capable to work successfully with the device. This could be realised by an internal examination. The best way to perform such an examination is to have an interactive examination on the intranet of the police force. Each officer then can do his own examination and the results can be stored on the computer network of the police force. See table 6.2.2.

Examination Phase 2			
	11 Cozart DDS	**12 Dräger Drug Test 5000**	**13 Biosensor BIOSENS**
NL 1	No	No	No
NL 2	No	No	No
NL 3	No	No	No
B 2	No	No	-
B 3	No	No	No
D 1	Yes	Yes	Yes
D 2	No	No	-
D 3	No	No	No
Ireland	Yes	Yes	Yes
Finland	No	No	No
Spain	Yes	Yes	Yes

Table 6.2.2 Training finished by examination Phase 2

7 Evaluation of oral fluid screening devices Phase 1 part 1 and Phase 2

7.1 Number of tests performed with the devices

7.1.1 Phase 1 part 1

During phase 1 part 1 of the ESTHER task the eleven teams performed tests with the ten different oral fluid screening devices. ESTHER teams were required to perform 20 tests with each device under operational conditions. It was expected that 2200 tests would be performed during the first part of phase 1. Due to other priorities 1995 tests (95%) were realised. (see table 7.1.1)

Number of tests performed with oral fluid screening devices Phase 1 part 1											
	01	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**	**Total**
NL 1	17	20	21	22	20	20	25	21	21	20	207
NL 2	19	18	20	20	18	15	9	17	17	20	173
NL 3	18	20	16	21	18	18	12	9	18	16	166
Belgium 2	20	20	18	20	20	20	20	20	20	20	198
Belgium 3	21	22	20	21	12	18	20	10	17	20	181
Germany 1	20	20	20	20	20	20	8	20	20	20	188
Germany 2	13	19	17	18	20	17	14	12	20	21	171
Germany 3	20	16	5	10	0	23	12	0	0	20	106
Ireland	20	32	32	19	26	31	11	0	13	20	203
Finland	23	22	25	25	20	20	21	21	20	20	217
Spain	20	20	20	20	10	20	20	20	15	20	185
Total	**211**	**229**	**213**	**216**	**184**	**222**	**172**	**150**	**181**	**217**	**1995**

Table 7.1.1: Number of tests performed with oral fluid screening devices Phase 1 part 1

The ten devices as mentioned in the table above (01 -10) are
01: Mavand RapidSTAT
02: Avitar Drugometer
03: Branan Oratect III
04: EnviteC SmartClip
05 Innovacon OrALert
06 Securetec Drugwipe 5+
07 Sun OraLine
08 Surescreen Drug Test
09 Ultimed Salivascreen
10 Varian OraLab 6

The number of tests performed with the Surescreen Drug Test is rather low compared to the tests with the other devices. Two teams did not get the required amount of devices in the period when they had to perform the tests. With the Innovacon device something similar occurred. The Innovacon OrALert and the Surescreen Drug Test are similar devices. The only difference is that the Surescreen device operates with an electronic reader. Based on this specific situation it can be concluded that 78 – 104% of the required tests per device have been realised during the first part of the first phase.

One manufacturer and his device needs to be mentioned here.
Ultimed provided the team leader of Germany 3 during the first part of phase 1 with another device than agreed. This happened without the agreement of the task leader. This has been discovered after a couple of days and led to a disqualification of the tests. This device has not been tested and Ultimed has been blamed for not respecting the content of the signed letter of intent. Ultimed has been excluded from further testing in the second part of phase 1. The findings of the Salivascreen VI as tested in the other teams have been collected and have been used for this report nevertheless.

Less tests have been performed with the Innovacon OrALert, the Sun OraLine, the Surescreen Drug Test and the Ultimed Salivascreen VI device compared to the other devices. Several reasons for these differences have been mentioned by the ESTHER teams.
The Innovacon OrALert device has not been provided to the German 3 team so these 20 expected tests are failing.
The Sun OraLine device was not very hygienic to work with. Two teams performed a small number of tests and refused to go on as the process was very unhygienic.
The Surescreen Oral Drug Test device has not been provided to two teams for evaluation. This meant that up to 40 tests were not done.
Tests with the Ultimed Salivascreen VI device have not been performed by the Germany 3 team as they were provided with another type of devices than agreed on.
Overall it can be concluded that ESTHER teams have got a good impression of the practical possibilities and limitations of the ten oral fluid screening devices. The number of tests with each device has been sufficient to do some analysis. These analysis are presented in the next paragraphs.
The tests have been performed on motorists stopped by the police to be tested for alcohol and other psychoactive substances.
The majority of checked motorists have not been suspected of committing the offence of driving with too much alcohol in their system or being impaired by other psychoactive substances than alcohol. In this report this group of motorists has been qualified as non-suspected motorists.
Belgium and German teams could arrest motorists with a certain amount of specific psychoactive substances in their system based on their national traffic act. In the report this subgroup of tested motorists has been qualified as suspected motorists.

7.1.2 Phase 2

During phase 2 of the ESTHER task the teams have performed tests with three different oral fluid screening devices. One device (BIOSENS) had a totally different concept compared to the two other devices tested in this phase and the ten devices tested in the first phase. For this device it has been agreed that in stead of twenty tests up to fifty tests per team would be required and that these tests would preferably be performed during control activities on motorists before or after visiting mega dance and music parties. As the BIOSENS is a device to be used during more specific events teams have been required to perform up to thirty extra tests with this device to test the possibilities to use this device more intensively during a short time period. Mega dance and music parties seem to be excellent situations to test and use this device on motorists after they left these parties. It has been expected that eleven teams would perform approx. 220 test with the Cozart and with the Dräger device. During eight specific events it was expected to perform approx up to 400 tests with the Biosensor device on motorists. These events were Pink pop 01-06-08 (NL), Emporium 31-05-08 (NL), Myotatuuli Rock 14-06-08 (Finland), San Juan 24-06-08 (Spain), Gras pop 28-06-08 (Belgium), Summer Jam 405-06-08(Germany), Oxygen Concert 14-07-08 (Ireland) and a control action in Germany. In table 7.1.2 the actual number of tests with these three devices are presented.

Number of tests performed with oral fluid screening devices Phase 2			
	11 Cozart DDS	**12 Dräger Drug Test 5000**	**13 Biosensor BIOSENS**
NL 1	21	21	34
NL 2	20	20	9
NL 3	17	15	21
Belgium 2	20	20	-
Belgium 3	20	24	39
Germany 1	20	20	50
Germany 2	9	18	-
Germany 3	11	20	25
Ireland	22	20	50
Finland	22	20	29
Spain	25	20	45
Total	**207**	**218**	**302**

Table 7.1.2: Number of tests performed with oral fluid screening devices Phase 2

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7.2 Gender of tested persons

7.2.1 Phase 1 part 1

The 1995 tests during the first part of phase 1 have been performed under operational police conditions. 1599 (80,2%) tests were performed on males. 392 tests (19,6%) on females. It is known that the majority of motorists who have used illicit drugs before or during driving a vehicle are male. The number of tests are rather well divided over the 10 different devices. At each device the percentage of male tested persons was between 77% and 82%.
Four tests (0,2%) have been performed without reporting the gender of the tested person. See table 7.2.1. It is not likely that the findings of the different devices have been influenced by the gender of the tested persons.

Gender of persons tested with oral fluid screening devices Phase 1 part 1				
	Male	**Female**	**Unknown**	**Total**
01 Mavand RapidSTAT	165	44	2	211
02 Avitar Drugometer	176	53	0	229
03 Branan Oratect III	169	44	0	213
04 EnviteC SmartClip	177	39	0	216
05 Innovacon OrALert	143	41	0	184
06 Securetec Drugwipe 5+	182	40	0	222
07 Sun OraLine	139	33	0	172
08 Surescreen Drug Test	126	24	0	150
09 Ultimed Salivascreen VI	145	36	0	181
10 Varian OraLab 6	177	38	2	217
Total	**1599**	**392**	**4**	**1995**

Table 7.2.1: Gender of tested persons Phase 1 part 1

7.2.2 Phase 2

727 tests have been performed during phase 2. In table 7.2.2 a total of 584 (80,3%) tests have been performed on males. 143 tests (19,7%) on females. This was similar to tests performed during phase 1. At the Cozart and Dräger devices the percentage of male tested persons was 83 – 84%. For the Biosensor device this percentage was 75%.
It is presumed that during mega dance and music festivals more females could be tested than during normal traffic control activities.

Gender of persons tested with oral fluid screening devices Phase 2			
	Male	**Female**	**Total**
11 Cozart DDS	175	32	207
12 Dräger Drug Test 5000	182	36	218
13 Biosensor BIOSENS	227	75	302
Total	**584**	**143**	**727**

Table 7.2.2: Gender of persons tested during Phase 2

7.3 Age of the tested persons

7.3.1 Phase 1 part 1

The age of the persons who performed tests on the devices varied from 18 years till 65 years and over. The majority of the tested persons (74%) were younger than 35 years. There were differences if the age curves of tested persons at different devices are observed. 68% – 81% of the tested persons were younger than 35 years on the different devices. See table 7.3.1. The majority of persons using illicit drugs are considered to be in these two age groups.

Age of persons tested with oral fluid screening devices Phase 1 part 1							
	18 – 25	**26 – 35**	**36 – 45**	**46 – 55**	**56 – 65**	**> 65**	**Total**
01 Mavand RapidSTAT	90	59	40	19	3	0	211
02 Avitar Drugometer	95	71	44	14	3	2	229
03 Branan Oratect III	86	63	39	15	9	1	213
04 EnviteC SmartClip	77	84	31	22	2	0	216
05 Innovacon OrALert	69	56	35	17	5	2	184
06 Securetec Drugwipe 5+	93	86	22	15	5	1	222
07 Sun OraLine	74	63	23	11	1	0	172
08 Surescreen Drug Test	54	58	20	15	2	1	150
09 Ultimed Salivascreen VI	70	53	33	22	3	0	181
10 Varian OraLab 6	79	98	32	6	2	0	217
Total	**787**	**691**	**319**	**156**	**35**	**7**	**1995**

Table 7.3.1: Age of persons tested with oral fluid screening devices Phase 1 part 1

7.3.2 Phase 2

80% of the tested persons in this phase were younger than 35 years. (See table 7.3.2). More persons in the age group 18 – 24 years have been tested on the Biosensor device than on the other two devices. This is probably due to the time and location were the tests have been performed. Test with the Biosensor device have mainly been performed at mega dance and music festivals where the majority of motorised visitors have been younger than the group of motorist that would normally be checked during normal police control activities at the road side.

Age of persons tested with oral fluid screening devices Phase 2						
	18 – 25	**26 – 35**	**36 – 45**	**46 – 55**	**56 – 65**	**Total**
11 Cozart DDS	76	66	38	21	6	207
12 Dräger Drug Test 5000	101	67	31	17	2	218
13 Biosensor BIOSENS	192	79	15	14	2	302
Total	**369**	**212**	**84**	**52**	**10**	**727**

Table 7.3.2 Age of persons tested during Phase 2

7.4 Non-suspected and suspected motorists

Persons who performed a test on one of the oral fluid screening devices could have been suspected of driving with too much alcohol in their system and/or driving while impaired by alcohol or drugs. Some tested persons could be or even were suspected of another (traffic) offence. Some tested persons were just motorists stopped for a routine control by the police. All tested persons could be divided in these two groups.

7.4.1 Phase 1 part 1

12% of the all the persons tested on one of the devices were motorists who were suspected of driving with psychoactive substances in their system. (See table 7.4.1). There were differences in the percentage of suspected persons depending on the device they were tested on. This was caused by the selection of motorists during the control activities of the police. The percentage of suspected motorists varied from 9% to 20%. The percentage of suspected motorists varied also depending on the police force (member state) where the test has been performed. In the road traffic act of Belgium, Germany, Finland and Spain persons with psychoactive substances in their blood commit a traffic offence and can and will be considered as suspected drivers.
In Ireland and in the Netherlands these persons will only be prosecuted if police can prove that they are impaired by these substances and these substances are detected by the forensic laboratory at an analysis of the blood sample.

Non-suspected and suspected motorists tested with oral fluid screening devices Phase 1 part 1			
	Non-suspected motorists	**Suspected motorists**	**Total**
01 Mavand RapidSTAT	190	21	211
02 Avitar Drugometer	201	28	229
03 Branan Oratect III	182	31	213
04 EnviteC SmartClip	195	21	216
05 Innovacon OrALert	151	33	184
06 Securetec Drugwipe 5+	203	19	222
07 Sun OraLine	157	15	172
08 Surescreen Drug Test	129	21	150
09 Ultimed Salivascreen VI	144	37	181
10 Varian OraLab 6	194	23	217
Total	**1746**	**249**	**1995**

Table 7.4.1: Non-suspected and suspected motorists Phase 1 part 1

7.4.2 Phase 2

13% of the persons tested on one of the three devices were motorists who have been suspected of driving with psychoactive substances in their system. (See table 7.4.2). There are minor differences in the percentage of suspected motorists depending on the device they have been tested on. The percentage of suspected drivers varied from 10% to 15%. The percentage of suspected motorists varied also depending on the police force (member state) where the test has been performed.

Motorists/suspected persons tested with oral fluid screening devices Phase 2			
	Non-suspected motorist	**Suspected motorists**	**Total**
11 Cozart DDS	187	20	207
12 Dräger Drug Test 5000	186	32	218
13 Biosensor BIOSENS	258	44	302
Total	**631**	**96**	**727**

Table 7.4.2 Motorists and suspected persons tested during Phase 2

7.5 DPO's opinion on the operational success of tests

DPO's have been asked to validate the tests performed by motorists and suspected persons. After the test was ended the DPO was asked whether he/she considered the test as successful from an police perspective. The opinion of DPO's about the successful use of oral fluid screening devices varied between 20% and 89%. This is a subjective indication. It reflects the willingness of DPO's to work with a specific device.

7.5.1 Phase 1 part 1

1993 tests have been validated. Two test have not been validated. The results are presented in table 7.5.1.1. Goal of this evaluation was to find out if the device could be suitable in police practice. It is relevant to keep in mind that the tests have been performed as a kind of routine check of motorists during normal traffic control activities. This meant that tests have been performed at the roadside in the open air, in a patrol car, in a police truck or at the police station. If a device worked well at the police station – where the testing conditions were optimal – this did not mean that the tests would also be successful at the road side or in a patrol car. In the next table an indication of the success rates at different test conditions is provided. It can be noticed that the success rates of the devices differ. Some devices were good, other were less successful. Also between teams differences have been noticed. The latter might be caused by different operational situations such as weather conditions and locations where the test has been performed. DPO's qualified 59% of all the performed tests as successful. Next to the time needed to perform a test other operational aspects might be relevant for the DPO to conclude whether a test has been qualified as successful.
Great differences can be observed when the table is analysed. The vast majority of test with the EnviteC SmartClip and the Securetec Drugwipe 5+ device have been qualified as successful. The majority of the test with the Sun OraLine and the Ultimed Salivascreen have been qualified as not successful. This has been caused by the problems to collect a sufficient amount of the oral fluid and/or the problems to analyse the collected sample within a time range of 15 minutes.

Performed tests qualified as successful by DPO's Phase 1 part 1							
	Successful			**Not Successful**			**Total**
	Car and Road side	Truck and Station	Total	Car and Road side	Truck and Station	Total	
01 Mavand RapidSTAT	62	70	132	50	29	79	211
02 Avitar Drugometer	74	44	118	60	51	111	229
03 Branan Oratect III	66	44	110	58	44	102	212
04 EnviteC SmartClip	117	72	189	9	18	27	216
05 Innovacon OrALert	47	54	101	39	44	83	184
06 Securetec Drugwipe 5+	110	83	193	14	14	28	221
07 Sun OraLine	31	32	63	52	57	109	172
08 Surescreen Drug Test	53	48	101	28	21	49	150
09 Ultimed Salivascreen VI	22	8	30	87	64	151	181
10 Varian OraLab 6	53	89	142	56	19	75	217
Total	**635**	**544**	**1179**	**453**	**361**	**814**	**1993**

Table 7.5.1.1: Performed tests qualified as successful by DPO's Phase 1 part 1

55% of all the tests have been performed at the road side or in a patrol car. 58% of all the tests at the road side have been considered as successful. (See table 7.5.1.2).
There are however great differences if the individual devices are studied. EnviteC and Securetec had high success rates when tests were performed at the roadside or in a patrol car. (93% and 89%).
Ultimed scored rather bad at the roadside. 60% of the tests with the Ultimed device have been performed at the road side or in a patrol car. Only 20% of these tests were successful .
The Innovacon device and the Surescreen device are identical. The only difference is the reader that is used with the Surescreen device. Reason for these differences might be that the Surescreen device operates with an electronic reader. Therefore it seems very relevant to check whether the add-ons on the device really improve the operability of the device.

Percentage of successful tests at the road side or in a patrol car Phase 1 part 1	
	Successful
01 Mavand RapidSTAT	55%
02 Avitar Drugometer	55%
03 Branan Oratect III	53%
04 EnviteC SmartClip	93%
05 Innovacon OrALert	55%
06 Securetec Drugwipe 5+	89%
07 Sun OraLine	37%
08 Surescreen Drug Test	65%
09 Ultimed Salivascreen VI	20%
10 Varian OraLab 6	49%
Total	**58%**

Table 7.5.1.2 Percentage of successful tests at road side or in a patrol car Phase 1 part 1

7.5.2 Phase 2

727 tests have been validated during this phase..
In table 7.5.2.1 an indication of the success rates at different test conditions is provided. It can be noticed that the success rates of the devices differ. It must be kept in mind that the devices tested in Phase 2 are devices that can best be used in a police station or in a police truck. It is of course also possible to install the device in a patrol car but a lot of space is needed to install the device and to perform the test. DPO's qualified between 80% and 90% of all the performed test with the devices as successful from an operational perspective.

Performed tests qualified as successful by DPO's Phase 2							
	Successful			**Not successful**			**Total**
	Car and Road side	Truck and Station	Total	Car and Road side	Truck And Station	Total	
11 Cozart DDS	75	108	183	19	5	24	207
12 Dräger Drug Test 5000	67	108	175	30	13	43	218
13 Biosensor BIOSENS	85	187	272	14	16	30	302
Total	**227**	**403**	**630**	**63**	**34**	**97**	**727**

Table 7.5.2.1 Performed tests qualified as successful by DPO's during Phase 2

40% of all the tests have been performed at the road side or in a patrol car. 78% of all the tests at the road side have been considered as successful. There are differences if the individual devices are studied as can be seen in table 7.5.2.2. Cozart and Biosensor had higher success rates when tests were performed at the roadside or in a patrol car than when tests were performed with the Dräger device. This might be caused by the rather long analysing time of the Dräger Drug Test 5000.

Percentage of successful tests at the road side or in a patrol car Phase 2	
	Successful
11 Cozart DDS	(80%)
12 Dräger Drug Test 5000	(69%)
13 Biosensor BIOSENS	(86%)
Total	**(78%)**

Table 7.5.2.2 Percentage of successful tests at road side or in a patrol car Phase 2

7.6 Time needed to get a sufficient oral fluid sample

The time needed to collect an oral fluid sample of a motorist is a relevant issue. If a rather long time is needed to collect an oral fluid sample just a limited number of motorists can be checked in a certain time period. Persons with drugs in their system very often have a dry mouth. This makes the collection procedure more time consuming. A dry mouth can be considered as an exceptional case where often other signs and symptoms of the use of drugs can be observed by the police officer. It is necessary to collect a sufficient amount of oral fluid to realise an analysis of the sample in the device. Unfortunately most of the tested oral fluid screening devices did not have an indicator for having collected a sufficient sample of oral fluid. It has been up to the DPO to decide when the amount of collected oral fluid was sufficient. This was not considered to be a very solid approach. If an insufficient amount of oral fluid has been collected this would result in a failed analysis of the sample later.

7.6.1 Phase 1 part 1

During this phase all test data have been registered including collecting time. In table 7.6.1.1 it is shown how many oral fluid samples could be collected and have been considered as sufficient by the DPO. This however did not mean that the device has been able to analyse the sample. It was possible that the test did not run despite the collected oral fluid sample. The table shows that the Branan Oratect III, the Ultimed Salivascreen and the Varian OraLab 6 had quite a number of failed collections of oral fluid.

Time needed to get a sufficient oral fluid sample Phase 1 part 1				
	Successful collections	**Average time (min, seconds)**	**Failures**	**Total**
01 Mavand RapidSTAT	206	2'30"	5	211
02 Avitar Drugometer	225	3'	4	229
03 Branan Oratect III	175	4'30"	38	213
04 EnviteC SmartClip	214	1'45"	2	216
05 Innovacon OrALert	181	3'	3	184
06 Securetec Drugwipe 5+	222	1'	0	222
07 Sun OraLine	163	2'30"	9	172
08 Surescreen Drug Test	140	2'30"	10	150
09 Ultimed Salivascreen VI	151	5'	30	181
10 Varian OraLab 6	195	3'50"	22	217
Total	**1872**	**2'55"**	**123**	**1995**

Table 7.6.1.1: Time needed to get a sufficient oral fluid sample Phase 1 part 1

The average collecting time of all the tests was just less than 3 minutes. Most devices have been able to collect an oral fluid sample in up to an average of 3 minutes. Two devices that had a much longer average collecting time. Branan Oratect III (4'30") and Ultimed Salivascreen VI (5').

Collecting time (minutes) Phase 1 part 1																	
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**>15**	**Total**
01 Mavand	99	39	24	14	14	9	3	4	0	3	0	1	0	0	0	1	211
02 Avitar	17	74	55	16	28	7	1	0	0	3	2	1	1	0	0	20	229*
03 Branan	16	37	21	25	27	10	9	7	0	16	2	2	0	0	3	38	213
04 EnviteC	125	48	24	10	6	1	0	0	0	0	0	0	0	0	0	2	216
05 Innovacon	9	52	83	20	12	2	1	0	0	2	0	0	0	0	0	3	184
06 Securetec	207	9	4	1	1	0	0	0	0	0	0	0	0	0	0	0	222
07 Sun	109	15	8	6	6	1	5	5	0	5	1	0	0	0	2	9	172
08 Surescreen	32	51	29	15	9	3	0	0	0	1	0	0	0	0	0	10	150
09 Ultimed	8	26	23	25	19	10	11	9	3	9	1	3	0	2	2	30	181
10 Varian	27	48	48	20	24	4	1	6	2	8	1	1	0	0	5	22	217
Total	**649**	**399**	**319**	**152**	**146**	**47**	**31**	**31**	**5**	**47**	**7**	**8**	**1**	**2**	**12**	**135**	**1995**

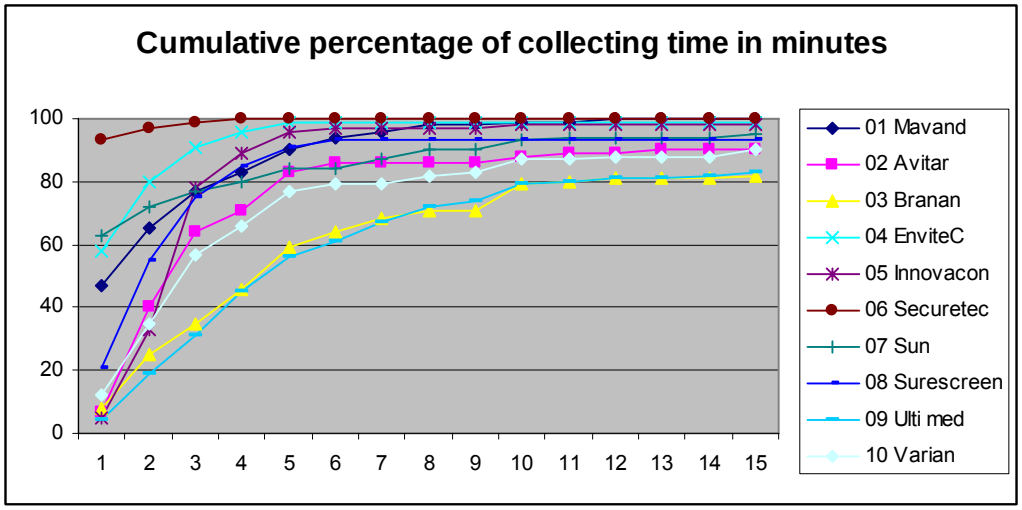
Table 7.6.1.2: Oral fluid collecting time in minutes per device Phase 1 part 1

* Four tests with the Avitar DRUGOMETER are performed without registration of the collecting time.

Differences between the collecting time of an oral fluid sample have been reported. With some devices an oral fluid sample could be retrieved rather quickly from the tested person. With other devices more time has been required. (See table 7.6.1.2).
In Graph 8.6.1.1 the cumulative percentages of successful tests are presented. Some devices need a very short time period to collect a fluid sample. If the collecting time would be limited to 3 minutes:

- 2 devices completed 91 – 99% of the test (04 EnviteC, 06 Securetec);
- 4 devices completed 75 – 78% of the tests (01 Mavand, 05 Innovacon, 07 Sun, 08 Surescreen);
- 1 device completed 64% of the tests (02 Avitar);
- 1 device completed 57% of the tests (10 Varian);
- 2 devices completed 31 – 35% of the test (03 Branan and 09 Ultimed).

Mavand and Branan improved their collecting system based on the interim evaluation of the devices in June 2007. These improved devices have been tested during the second part of phase 1. Tests performed during this second part of phase 1 showed an improvement in collecting time. For the Mavand the collecting time has decreased to 30 seconds thanks to the improved collector. Branan improved the whole device. Compared to the initial device (Oratect III) the improved device (Oratect XP) required only half the amount of oral fluid to run the test and provide an indication of drug use.



Graph 7.6.1.1: Cumulative percentage of collecting time in minutes Phase 1 part 1

DPO's have been asked about the time required to collect an oral fluid sample. Under operational conditions collecting time can be qualified as acceptable based on a number of circumstances. The time is the most relevant issue but the status of the persons providing a sample could have influence on the opinion of the DPO at a particular test. The same goes for the weather conditions and the use of specific drugs by the tested person. Acceptability is a subjective issue and therefore these kind of indications have just a limited value. Nevertheless it is interesting to study this aspect in order to get a better view on relevant operational aspects of oral fluid screening devices. See table 7.6.1.3.

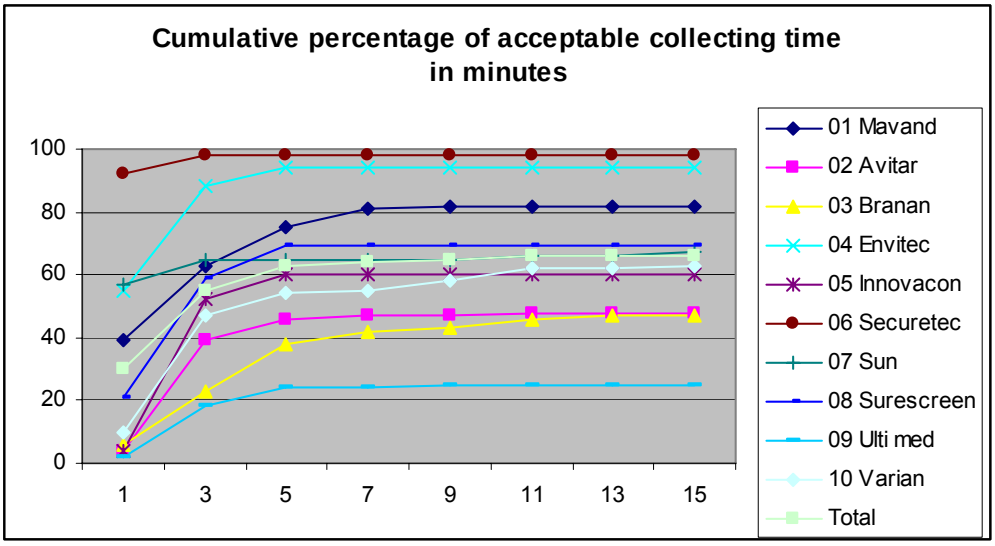
	Collecting time marked as 'acceptable' by DPO's (minutes) Phase 1 part 1																
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**>15**	**Total**
01 Mavand	82	33	18	14	11	9	3	3	0	1	0	0	0	0	0	0	174
02 Avitar	10	39	41	5	11	1	1	0	0	2	0	0	0	0	0	2	116*
03 Branan	13	20	17	15	15	5	4	3	0	7	0	1	0	0	0	4	104
04 EnviteC	119	46	24	8	5	1	0	0	0	0	0	0	0	0	0	0	203
05 Innovacon	8	44	43	10	5	1	0	0	0	0	0	0	0	0	0	0	111
06 Securetec	205	9	3	0	0	0	0	0	0	0	0	0	0	0	0	0	217
07 Sun	98	10	3	0	1	0	0	0	0	2	0	0	0	0	1	5	120
08 Surescreen	31	39	18	10	5	0	0	0	0	0	0	0	0	0	0	6	109
09 Ultimed	4	19	9	8	3	0	0	2	0	0	1	0	0	0	0	0	46
10 Varian	22	40	40	6	10	2	0	4	2	8	1	0	0	0	2	3	140
Total	**592**	**299**	**216**	**76**	**66**	**19**	**8**	**12**	**2**	**20**	**2**	**1**	**0**	**0**	**3**	**20**	**1340**

Table 7.6.1.3: Acceptable oral fluid collecting time in minutes per device Phase 1 part 1
* Four tests with the Avitar DRUGOMETER are performed without registration of the collecting time.

In table 7.6.1.4 the cumulative percentages of tests that were validated by DPO's as successful have been presented for each of the devices. Graph 7.6.1.2 shows that there are great differences between the devices. It must be kept in mind that the reliability of the devices is unknown so successful just means that the DPO has been satisfied with the collecting process and procedure. If the collecting time would be limited to 3 minutes the qualification "successful" has been given by DPO's to the different devices. The Ultimed (18%) and the Branan (23%) had a very poor score.
The Avitar (39%) and the Varian (47%) had a low score.
The Innovacon/Surescreen (52 – 59%), the Mavand (63%) and the Sun (65%) had a moderate score.
The EnviteC (88%) and the Securetec (98%) had a high score.
The average score of tests with an acceptable collection time is 67%.
Mavand and Branan improved their collecting system based on the interim evaluation of the devices in June 2007. The acceptability rate for Mavand and Branan has been improved in their modified screening devices.

Cumulative percentage of "acceptable" (DPO) collecting time (minutes) Phase 1 part 1																
Minutes Device	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**>15**
01 Mavand	39	55	63	70	75	79	81	82	82	82	82	82	82	82	82	82
02 Avitar	4	21	39	41	46	47	47	47	47	48	48	48	48	48	48	49
03 Branan	6	15	23	31	38	40	42	43	43	46	46	47	47	47	47	49
04 EnviteC	55	76	88	91	94	94	94	94	94	94	94	94	94	94	94	94
05 Innovacon	4	28	52	57	60	60	60	60	60	60	60	60	60	60	60	60
06 Securetec	92	96	98	98	98	98	98	98%	98	98	98	98	98	98	98	98
07 Sun	57	63	65	65	65	65	65	65	65	66	66	66	66	66	67	70
08 Surescreen	21	47	59	65	69	69	69	69	69	69	69	69	69	69	69	73
09 Ultimed	2	13	18	22	24	24	24	25	25	25	25	25	25%	25	25	25
10 Varian	10	29	47	50	54	55	55	57	58	62	62	62	62	62	63	65
Total	30	45	55	59	63	64	64	65	65	66	66	66	66	66	66	67

Table 7.6.1.4: Acceptable oral fluid collecting time in minutes per device Phase 1 part 1
* Four tests with the Avitar DRUGOMETER are performed without registration of the collecting time.



Graph 7.6.1.2: Cumulative percentage of acceptable collecting time in minutes (validated by DPO's) Phase 1 part 1

7.6.2 Phase 2

The Cozart and the Dräger device have an indicator on the collector that will turn blue once enough oral fluid has been collected. For the Biosensor the collecting procedure prescribes to wipe the collector four to five times over the tongue. By doing this enough oral fluid will have been collected for the test on the Biosensor device.
During phase 2 all test data have been registered including collecting time.
In table 7.6.2.1 it is shown that all but three collecting activities have been successful.
The different average collecting time for each device is shown in the next table.
The average collecting time of all the tests has been just over one and a half minute.

Time needed to get a sufficient oral fluid sample Phase 2				
	Successful collections	**Average time (min, seconds)**	**Failures**	**Total**
11 Cozart	207	1'54"	0	207
12 Dräger	215	2'15"	3	218
13 Biosensor	302	50'	0	302
Total	**724**	**1"34"**	**3**	**727**

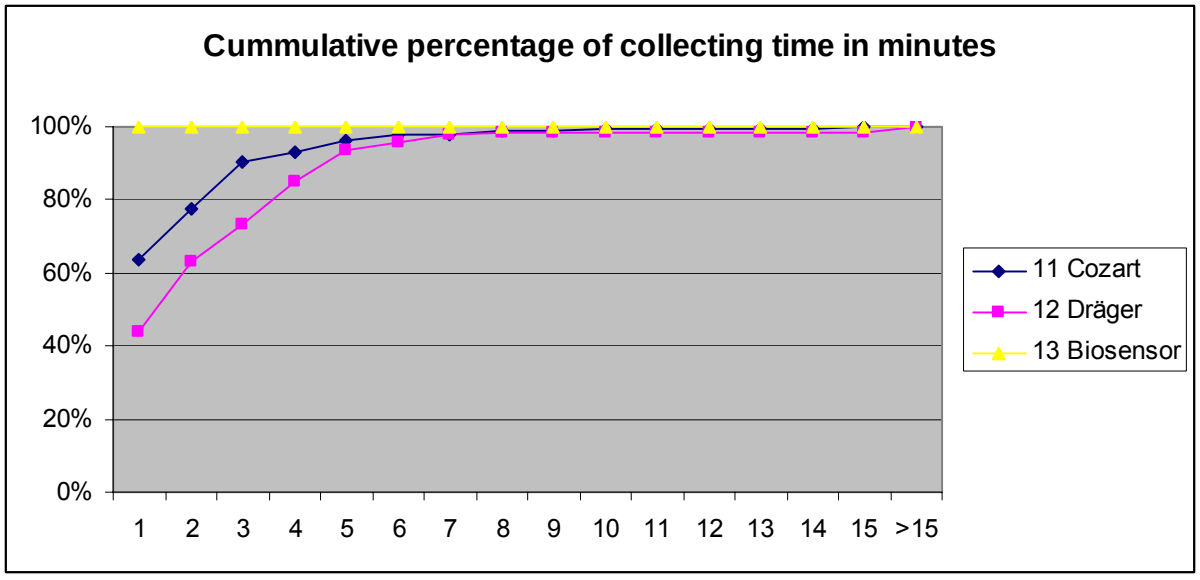
Table 7.6.2.1 Time needed to get a sufficient oral fluid sample during Phase 2

Differences between the collecting time of an oral fluid sample have been reported. (See table 7.6.2.2). With Biosensor all samples could be collected within 1 minute. With the Cozart and the Dräger device 64% and 47% of all samples could be collected within 1 minute. 90% of the collecting activities with the Cozart would be realised within 3 minutes. For Dräger this would be 77%.

Collecting time (minutes) Phase 2																
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**>15**	**Total**
11 Cozart	132	29	26	6	6	4	0	2	0	1	0	0	0	0	1	0	207
12 Dräger	96	42	22	25	19	5	4	1	0	0	0	0	0	0	1	3	218
13 Biosensor	302	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	302
Total	**537**	**71**	**48**	**31**	**25**	**9**	**4**	**3**	**0**	**1**	**0**	**0**	**0**	**0**	**2**	**6**	**737**

Table 7.6.2.2: Oral fluid collecting time in minutes per device Phase 2

Graph 7.6.2.1 with the cumulative percentage of collecting time shows that these three devices have acceptable collecting times.



Graph 7.6.2.1: Cumulative percentage of collecting time in minutes Phase 2

7.7 Time needed to analyse the oral fluid sample

After the collection of an oral fluid sample the sample has to be analysed in the screening device. Therefore the oral fluid has to run through the device to be able to show the indication lines at the indication window of the device. Some devices were equipped with an electronic reader to facilitate the interpretation of the results of the screening by the DPO.
The detection of cannabis (Δ9-THC) in an oral fluid screening device is more difficult and more time consuming then the detection of other substances.

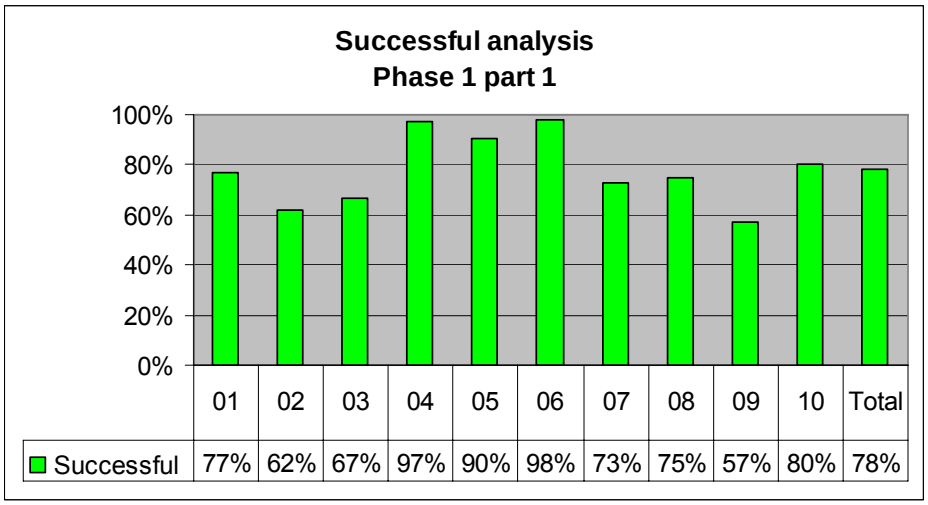
7.7.1 Phase 1 part 1

The EnviteC SmartClip device did not detect Δ9-THC. This device therefore could analyse a sample in a shorter time than the other devices. As cannabis is the drug of first choice this has been qualified by the DPO's as a very relevant disadvantage of this device. DPO's qualified 1872 (94%) collections of oral fluid as successful. The table gives evidence that when the DPO qualified the sample as sufficient this would not mean that the device has been able to analyse the sample. See table 7.7.1.1. Of all the collected oral fluid samples just in 78% of these cases an analysis could be performed. Of all the collected oral fluid samples qualified as sufficient by the DPO 83% of these samples could be analysed.

Average time needed to analyse an oral fluid sample Phase 1 part 1				
	Successful analysis	**Average time (min, seconds)**	**Failures**	**Total**
01 Mavand RapidSTAT	162	11'	49	211
02 Avitar Drugometer	142	3'	87	229
03 Branan Oratect III	142	5'30"	71	213
04 EnviteC SmartClip	210	3'15"	6	216
05 Innovacon OrALert	166	7'	18	184
06 Securetec Drugwipe 5+	217	5'10"	5	222
07 Sun OraLine	125	8'30"	47	172
08 Surescreen Drug Test	112	7'30"	38	150
09 Ultimed Salivascreen VI	104	8'	77	181
10 Varian OraLab 6	174	7'20"	43	217
Total	**1554**	**6'40"**	**441**	**1995**

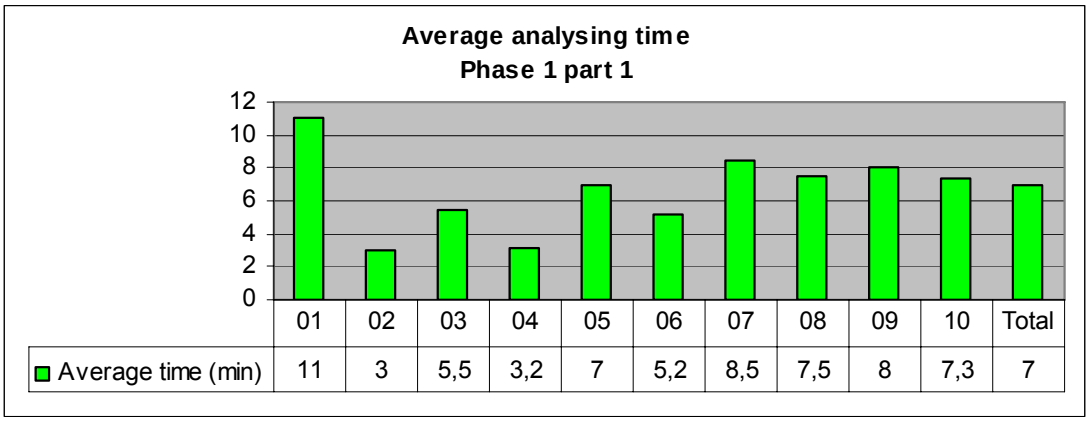
Table 7.7.1.1: Average time needed to analyse an oral fluid sample Phase 1 part 1

The percentage of successful analysis is presented in graph 7.7.1.1.



Graph 7.7.1.1: Percentage of successful analysis of oral fluid sample Phase 1 part 1

The average analysing time of all the successful analysis was approx. 7 minutes.(Exclusive the analysis performed with the EnviteC SmartClip device). There were some devices with a longer average analysing time (Mavand RapidSTAT, Sun OraLine, and Surescreen Oral Drug Test, Ultimed Salivascreen and Varian OraLab 6). See graph 7.7.1.2



Graph 7.7.1.2: Average analysing time in minutes Phase 1 part 1

Analysing time (in minutes)																	
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**>15**	**Total**
01 Mavand	0	2	2	9	2	17	16	25	20	34	4	4	5	6	19	46	211
02 Avitar	3	4	15	16	29	10	16	9	8	25	0	1	0	0	2	87	229*
03 Branan	15	10	19	18	29	7	5	8	7	13	5	2	0	1	3	71	213
04 EnviteC	40	50	41	34	22	10	7	2	3	1	0	0	0	0	0	6	216
05 Innovacon	2	9	7	13	29	10	17	7	16	33	3	4	10	0	6	18	184
06 Securetec	3	21	61	33	26	10	15	10	15	21	0	0	1	0	1	5	222
07 Sun	0	1	3	5	18	6	9	12	5	43	11	2	0	0	10	47	172
08 Surescreen	0	3	5	7	18	8	11	15	9	24	0	1	2	2	7	38	150
09 Ultimed	3	4	2	7	13	5	4	9	10	23	4	5	4	6	5	77	181
10 Varian	2	1	15	32	18	7	12	16	6	46	5	4	3	3	4	43	217
Total	68	105	170	174	204	90	112	113	99	263	32	23	25	18	57	438	1995

Table 7.7.1.2: Time needed to analyse an oral fluid sample Phase 1 part 1
* Analysing time of two tests with the Avitar has not been registered.

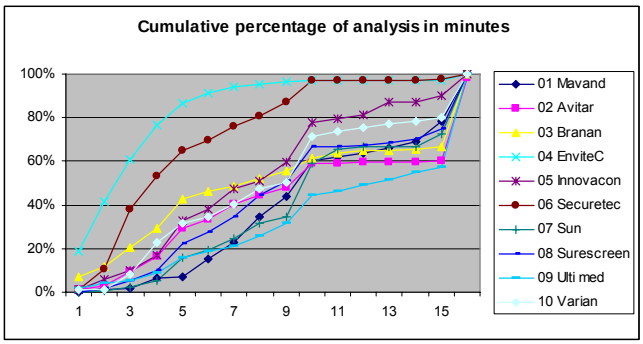
Differences between the analysing time of an oral fluid sample are reported. See table 7.7.1.2. With some devices an oral fluid sample from the tested person could be analysed rather quickly. With other devices more time was required.
04 EnviteC was unable to detect cannabis so the analysis of the oral fluid sample using this device lasted very short.
In the next table (7.7.1.3) the different percentages of successful analysis of the oral fluid sample by the different devices are presented.
In the ESTHER teams these scores are considered as an indication of the operational reliability. Operational reliability is defined as the chance that a screening test will present a result within a period of 15 minutes. For the score it is irrelevant whether the indication is correct compared to the observations of the DPO or the result of another screening tests or the result of the analysis of a blood or oral fluid sample. It can be concluded that for each device approx. 10 minutes are needed to analyse an acceptable percentage of oral fluid samples (> 60%). From this perspective – apart from 04 EnviteC and 06 Securetec with a good all over score – acceptable percentages have been scored by 05 Innovacon (78%), 10 Varian (71%), 08 Surescreen (67%), 03 Branan (62%), 01 Mavand (60%), 02 Avitar and 07 Sun (59%). 09 Ultimed scored a very low percentage successful analysis.

Cumulative percentage of analysing time (minutes)																
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	>15
01 Mavand	0	1	2	6	7	15	23	35	44	60	62	64	66	69	78	100
02 Avitar	1	3	10	17	29	34	41	45	48	59	59	59	59	59	60	98
03 Branan	7	12	21	29	43	46	48	52	55	62	64	65	65	65	67	100
04 EnviteC	19	42	61	76	87	91	94	95	97	97	97	97	97	97	97	100
05 Innovacon	1	6	10	17	33	38	47	51	60	78	79	82	87	87	90	100
06 Securetec	1	11	38	53	65	69	76	81	87	97	97	97	97	97	98	100
07 Sun	0	1	2	5	16	19	24	31	34	59	66	67	67	67	73	100
08 Surescreen	0	2	5	10	22	27	35	45	51	67	67	67	69	70	75	100
09 Ultimed	2	4	5	9	16	19	21	26	31	44	46	49	51	55	57	100
10 Varian	1	1	8	23	31	35	40	47	50	71	74	76	77	78	80	100
Total	3	9	17	26	36	41	46	52	57	70	72	73	74	75	78	100

Table 7.7.1.3: Cumulative percentage of time needed to analyse an oral fluid sample Phase 1 part 1

Observing the group of tests with an analyse time of more than 15 minutes it can be concluded that, depending of the device, the percentage of tests with this score varied from 2 – 43%. As these tests are considered as failures it can be concluded that the operational reliability of the devices varies strongly. The operational reliability has been the best for 06 Securetec, 04 EnviteC and 05 Innovacon. These three devices are followed by 10 Varian, 01 Mavand, 08 Surescreen, 07 Sun, 03 Branan, 02 Avitar and 09 Ultimed. The average operational reliability of the tested devices is 78%. This is an indication of the operational reliability of oral fluid screening devices for operational police officers when using such a device during traffic law enforcement activities. The higher this percentage the more likely the police officer will be willing to use that device during traffic control activities (in future). It is known that a lot of problems with the operational reliability has to do with the amount of collected oral fluid. (Some manufacturers are or have been improving their device to increase the operational reliability).

In the graph below (graph 7.7.1.3) the cumulative percentages of successful analysis are presented.



Graph 7.7.1.3: Cumulative percentage of analysis of oral fluid screening devices in minutes Phase 1 part 1

In the graph the cumulative percentage of successful analysis with the oral fluid screening devices is presented. The graph shows that some devices need a short time period to analyse an oral fluid sample. If the indication time would be limited to 5 minutes only two devices would have a sufficient percentage of acceptable analysis from a time consuming perspective. (04 EnviteC, 06 Securetec). It must be kept in mind that the EnviteC device has no test for THC. As the detection of THC (both ∆9-THC and THCCOOH) costs extra time for the analysis the “acceptability-rate” for this device is not a realistic one. For the Securetec Drugwipe 5+ it is unknown if the device is able to detect THC in an acceptable percentage of tests.
For the other devices the time to analyse a sample has been much longer;
An analysing time of ten minutes would result in
2 devices able to complete 71 – 78% of the tests (05 Innovacon, 10 Varian)
3 devices able to complete 60 – 67% of the tests (01 Mavand, 03 Branan, 08 Surescreen)
2 devices able to complete 59% of the tests (02 Avitar, 07 Sun)
2 devices able to complete 44% of the tests (09 Ultimed)

Cumulative percentage of "acceptable" analysing time (minutes) Phase 1 part 1																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	>15	Total
01 Mavand	0	1	1	3	4	11	18	27	34	46	47	48	49	50	55	59	59
02 Avitar	1	3	8	12	21	23	28	31	32	38	38	38	38	38	38	47	48
03 Branan	7	11	20	26	38	41	43	46	48	51	52	52	52	53	53	60	60
04 EnviteC	18	40	58	73	82	87	90	91	91	92	92	92	92	92	92	93	93
05 Innovacon	0	4	8	15	23	26	33	35	39	43	43	45	46	46	47	48	48
06 Securetec	1	11	38	52	64	67	74	78	84	92	92	92	92	92	93	94	94
07 Sun	0	0	1	2	8	9	13	14	15	22	24	25	25	25	25	31	31
08 Surescreen	0	1	3	8	19	25	30	35	37	44	44	44	45	45	47	55	55
09 Ultimed	1	3	3	4	8	8	8	9	12	17	17	17	17	18	18	20	20
10 Varian	1	1	7	19	26	29	33	37	39	55	56	58	69	59	61	66	66
Total	3	8	16	23	31	34	38	42	52	52	52	53	53	53	54	59	59

Table 7.7.1.4: Cumulative percentage of acceptable analysing time in minutes by DPO's Phase 1 part 1

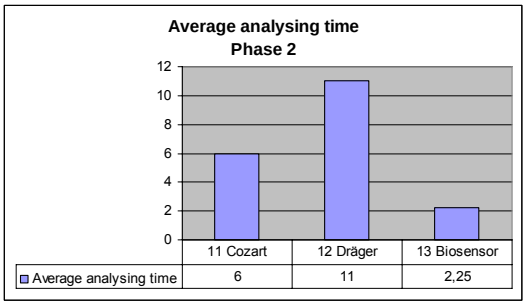
7.7.2 Phase 2

727 oral fluid samples have been taken. 719 (99%) of these tests have been successfully analysed. Eight tests did not show an indication result. See table 7.7.2.1.

Average time needed to analyse an oral fluid sample Phase 2				
	Successful analysis	Average time (min, seconds)	Failures	Total
11 Cozart DDS	205	6'	2	207
12 Dräger Drug Test 5000	212	11'	6	218
13 Biosensor BIOSENS	302	2"15"	0	302
Total	**719**	**6'**	**8**	**727**

Table 7.7.2.1 Average time needed to analyse an oral fluid sample Phase 2

The average analysing time of all the successful analysis has been approx. six minutes.
The Biosensor device presented the results in average within just over two minutes.
The Dräger device had the longest analysing time. (See graph 7.7.2.1).



Graph 7.7.2.1 Average analysing time in minutes Phase 2

Analysing time (in minutes) Phase 2																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	>15	Total
11 Cozart	25	5	6	5	7	19	12	36	8	12	1	1	0	0	0	2	207
12 Dräger	0	0	0	0	2	0	1	1	3	104	51	38	11	1	0	6	218
13 Biosensor	2	254	38	6	2	0	0	0	0	0	0	0	0	0	0	0	302
Total	27	259	44	11	79	19	13	37	11	116	52	39	11	1	0	8	727

Table 7.7.2.2: Time needed to analyse an oral fluid sample Phase 2

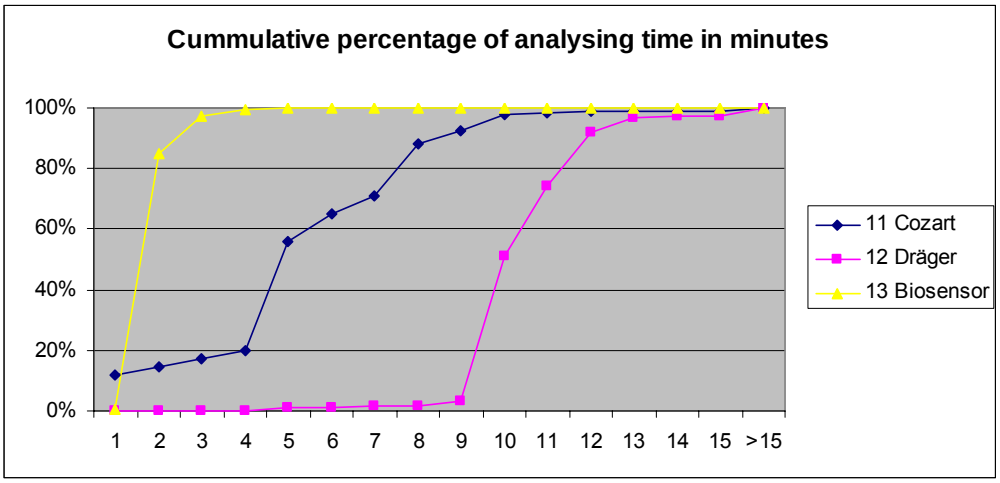
Differences between the analysing time of an oral fluid sample are reported. See table 7.7.2.2.

With the 12 Dräger device the rime to analyse a sample was 10-12 minutes due to the procedure of the test. 11 Cozart analysed the majority of the samples within 8 minutes.
The 13 Biosensor BIOSENS device analysed the sample within 3 minutes.
Almost all tests have been qualified as successful. the cumulative percentage of successful analyses will show a similar table as the table with the cumulative percentage of analysing time. See table 7.7.2.3.

Cumulative percentage of analysing time (in minutes) Phase 2																
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	>15
11 Cozart	12	14	17	20	56	65	71	88	92	98	99	99	99	99	99	100
12 Dräger	0	0	0	0	1	1	1	2	3	51	74	92	97	97	97	100
13 Biosensor	1	85	97	99	100	100	100	100	100	100	100	100	100	100	100	100

Table 7.7.2.3: Cumulative percentage of time needed to analyse an oral fluid sample Phase 2

In graph 7.7.2.2 these data are presented as curves.



Graph 7.7.2.2: Cumulative percentage of analysis or oral fluid screening devices in minutes Phase 2

7.8 Testing in a hygienic way

When using an oral fluid screening test the DPO should avoid to have contact with the oral fluid of the tested person. Contact with oral fluid is not only very unhygienic but oral fluid is often a source of infections and diseases. Therefore DPO's have been advised to use protective gloves when an oral fluid screening test of a person had to be performed. DPO's have been asked if an oral fluid test could be done in a hygienic way. It is also important that from the perspective of the tested person hygienic aspects are respected. Motorists are not used to a procedure where another person than a medical doctor of nurse collect a sample from their mouth.

7.8.1 Phase 1 part 1

In the table 7.8.1 the opinion of the DPO's is presented. In general at 1550 tests (78%) performed by tested persons DPO's had the opinion that the test with the devices could be done in a safe and hygienic way. There are however great differences between the devices. These differences can also be caused by the location were the test have been performed. It is clear that DPO's who performed tests in a police truck or at the police station had more positive feelings about doing the test in a hygienic way than when DPO's were doing the test at the road side.

Hygienic testing Phase 1 part 1				
	Yes	**No**	**No answer**	**Total**
01 Mavand RapidSTAT	147	62	2	211
02 Avitar Drugometer	165	61	3	229
03 Branan Oratect III	188	22	3	213
04 EnviteC SmartClip	212	4	0	216
05 Innovacon OrALert	132	52	0	184
06 Securetec Drugwipe 5+	214	7	1	222
07 Sun OraLine	49	123	0	172
08 Surescreen Drug Test	146	4	0	150
09 Ultimed Salivascreen VI	109	72	0	181
10 Varian OraLab 6	188	29	0	217
Total	**1550**	**436**	**9**	**1995**

Table 7.8.1: Opinion of DPO's on hygienic aspects Phase 1 part 1

Just one device (07 Sun OraLine) had a very negative score when it comes to the hygienic aspects during testing. Only 49 tests (28%) with this device have been qualified as hygienic. This has been caused by the method to collect the oral fluid sample. The other devices have been considered sufficient hygienic to be used by DPO's. Three devices scored even very good in respect of hygiene.

7.8.2 Phase 2

Hygienic testing Phase 2			
	Yes	**No**	**Total**
11 Cozart DDS	175	32	207
12 Dräger Drug Test 5000	218	0	218
13 Biosensor BIOSENS	288	14	302
Total	**681**	**46**	**727**

Table 7.8.2 Opinion of DPO's on hygienic aspects Phase 2

In general at 681 tests (94%) performed by tested persons during phase 2 the DPO's had the opinion that the test with the devices could be done in a safe and hygienic way.
There are some differences between the devices as can be seen in table 7.8.2.
Dräger Drug Test 5000 scored 100%, the BIOSENS 95% and the Cozart had the lowest score 85% but was still considered as very acceptable from a hygienic perspective.

7.9 Rely on the indication

Almost half the teams could not compare the indications of drug use retrieved from the oral fluid screening devices with the indications from other screening devices or the result of an analysis of a sample (blood, saliva, urine) by a forensic laboratory. DPO's have been asked if they would rely on the obtained indication of drug use. The ESTHER teams from Germany and Belgium had the possibility to check the indication of some of the oral fluid screening tests with the result of the legally prescribed urine test and sometimes with the results of the blood analysis. The opinion of the DPO's in all teams has been based on the observation of the tested person and not on the result of an evidential analysis. Thanks to the specific legislation in Belgium and Germany the Belgian and German teams could also base their opinion on the result of a screening test on the urine device if such a test had been performed. Indication lines are mostly clearly visible (with or without an electronic reader..

7.9.1 Phase 1 part 1

Overall the DPO's did rely ratherly good on the indication of drug use obtained by a test with the 01 Mavand RapidSTAT, the 04 EnviteC SmartClip, 05 Innovacon OrALert, 06 The Securetec Drugwipe 5+ and the 10 Varian OraLab 6. These five devices were considered as sufficiently reliable (76 – 83%) even though no comparison with the results of the analysis of a blood sample was available. It must be kept in mind that the 04 EnviteC SmartClip Multidrug was not able to do a screening tests for cannabis (THC). The Ultimed Salivascreen was considered as insufficiently reliable by the DPO's.
Data are presented in table 7.9.1

Rely on obtained indication Phase 1 part 1				
	Yes	**No**	**Unknown**	**Total**
01 Mavand RapidSTAT	175	34	2	211
02 Avitar Drugometer	142	82	5	229
03 Branan Oratect III	141	67	5	213
04 EnviteC SmartClip	177	37	2	216
05 Innovacon OrALert	143	41	0	184
06 Securetec Drugwipe 5+	182	39	1	222
07 Sun OraLine	122	50	0	172
08 Surescreen Drug Test	109	41	0	150
09 Ultimed Salivascreen VI	84	97	0	181
10 Varian OraLab 6	165	50	2	217
Total	**1440**	**538**	**17**	**1995**

Table 7.9.1: DPO's opinion on reliability of the obtained indications Phase 1 part 1

7.9.2 Phase 2

DPO's relied on the indication of drug use obtained by a screening test on each of the three tested devices during phase 2. (See table 7.9.2).
In general in 83% of the tests the DPO trusted the indication given by the device.
The Dräger device had the highest score 194 out of 218 (89%). Biosensor scored 81% and Cozart 79%. These results are very promising even though no results of forensic analysis of a specimen of the tested person were available at most teams.

Rely on obtained indication Phase 2			
	Yes	**No**	**Total**
11 Cozart DDS	163	44	207
12 Dräger Drug Test 5000	194	24	218
13 Biosensor BIOSENS	244	58	302
Total	**601**	**126**	**727**

Table 7.9.2 DPO's opinion on reliability of the obtained indications Phase 2

7.10 Simple test

Screening tests for motorists to detect the use of a psychoactive substance in their system should be simple, fast to perform and almost impossible to be manipulated by the tested person..
Alcohol screening devices are a good example of these requirements. For screening of other substances than alcohol more time will be needed as drugs can not be detected in the expired breath.

7.10.1 Phase 1 part 1

1597 (80%) performed tests with the different devices have been considered as simple to perform. There were differences between the devices due to the procedure that had to be followed. Some devices have been developed in such a way that the test could be performed almost without any instruction at all. It is important that the test is simple to perform but this should not decrease the accuracy, specificity and sensitivity of the screening device.

Test simple to perform Phase 1 part 1				
	Yes	**No**	**Unknown**	**Total**
01 Mavand RapidSTAT	139	71	1	211
02 Avitar Drugometer	200	25	4	229
03 Branan Oratect III	173	38	2	213
04 EnviteC SmartClip	209	7	0	216
05 Innovacon OrALert	122	62	0	184
06 Securetec Drugwipe 5+	217	4	1	222
07 Sun OraLine	96	76	0	172
08 Surescreen Drug Test	126	24	0	150
09 Ultimed Salivascreen VI	130	51	0	181
10 Varian OraLab 6	185	32	0	217
Total	**1597**	**390**	**8**	**1995**

Table 7.10.1: DPO's opinion on simplicity to perform a screening test Phase 1 part 1

In table 7.10.1 the differences in opinions of DPO's on the simplicity of the ten devices is easy to see. 06 Securetec Drugwipe 5+ and 04 EnviteC SmartClip Multidrug are considered as absolutely simple to use. 02 Avitar Drugometer, 03 Branan Oratect III, 08 Surescreen Oral Drug Test and 10 Varian OraLab 6 are very simple to use. 09 Ultimed Salivascreen VI is considered as simple to use in 72%.
01 Mavand RapidSTAT device and 05 Innovacon OrALert device are considered as simple to use in 2 out of 3 tests (66%).07 SUN OraLine has an insufficient score in this respect (56%).

7.10.2 Phase 2

Test simple to perform Phase 2			
	Yes	**No**	**Total**
11 Cozart DDS	180	27	207
12 Dräger Drug Test 5000	180	38	218
13 Biosensor BIOSENS	227	75	302
Total	**587**	**140**	**727**

Table 7.10.2 DPO's opinion on simplicity to perform a screening test Phase 2

587 (81%) performed tests with the different devices have been considered as simple to perform. (table 7.10.2). There were differences between the devices due to the procedure that had to be followed. It is important that the test is simple to perform but this should not decrease the accuracy and sensitivity of the screening device. The Cozart device has been considered as absolutely simple to use. 87% of the tests with this device were classified as simple to perform. Dräger scored 83% and Biosensor 75%. All scores are acceptable from a police perspective. It should be stated that the tests with the BIOSENS have mostly been performed by a representative of the manufacturer. DPO's might have concluded based on this situation that it was not simple to perform a test. It has been reported that a limited number of errors and failures occurred with the BIOSENS that could not have been solved by the DPO due to lack of specific knowledge to solve problems with the device.

7.11 Transferred to surface

Performing an oral fluid tests with one of the tested screening devices could require that the oral fluid sample had to be transferred manually from the collection swab to the device itself. Some devices required such a procedure. This is a very precise activity as oral fluid might be spoiled.

7.11.1 Phase 1 part 1

Almost three out of four performed tests did not cause any problem in this respect. Seven devices did not have a separate collection part. These devices had the collection section integrated in the device. These one-part-devices could not have problems with the transport of the sample from the swab to the device itself. Four devices had a separate oral fluid collection part. (Mavand, Innovacon, Surescreen and Varian). Eight devices had a score of over 70%. (02 Avitar Drugometer had 5% non response).
Two devices 07 Sun OraLine (28%) and 09 Ultimed Salivascreen VI (57%) had an insufficient score related to the ease to bring the oral fluid to the test surface. With the 07 Sun device this has been caused by the collecting procedure (the cup to collect an oral fluid sample). With the 09 Ultimed device this was caused by the problems to collect an oral fluid sample. (See table 7.11.1)
Collected oral fluid was often leaking along the device.

Transferred to surface Phase 1 part 1				
	Yes	**No**	**Unknown**	**Total**
01 Mavand RapidSTAT	154	56	1	211
02 Avitar Drugometer	157	60	12	229
03 Branan Oratect III	191	20	2	213
04 EnviteC SmartClip	215	1	0	216
05 Innovacon OrALert	137	47	0	184
06 Securetec Drugwipe 5+	211	10	1	222
07 Sun OraLine	48	124	0	172
08 Surescreen Drug Test	142	8	0	150
09 Ultimed Salivascreen VI	103	78	0	181
10 Varian OraLab 6	168	49	0	217
Total	**1526**	**453**	**16**	**1995**

Table 7.11.1: DPO's opinion on ease to transfer the sample to the test strip Phase 1 part 1

7.11.2 Phase 2

Just 41 of the performed tests have not been considered as successful from this respect. See data in table 7.11.2.
686 tests (94%) did not cause any problem in bringing the collected sample into the analyser.
All three devices had a separate collecting unit. All three devices scored over 90% which is very acceptable. Dräger scored 99%. This means that the procedure to prepare the analysis of a collect oral fluid sample is perfect. The procedure with Biosensor (93%) and Cozart (92%) to prepare the analysis of the collected oral fluid sample is almost perfect.

Transferred to surface Phase 2			
	Yes	**No**	**Total**
11 Cozart DDS	191	16	207
12 Dräger Drug Test 5000	215	3	218
13 Biosensor BIOSENS	280	22	302
Total	**686**	**41**	**727**

Table 7.11.2 DPO's opinion on ease to transfer the sample to the test strip Phase 2

7.12 Easily at road side

From an operational perspective it must be possible to perform a screening tests for drugs at the road side under all light and weather conditions. Screening devices will not work with the reliability as claimed by the manufacturer when temperature conditions are less than required. This is a similar situation as with alcohol screening devices. Practical solutions for this problem can and will be found in operational police practice. For alcohol devices similar problems have been solved in a practical way.

7.12.1 Phase 1 part 1

During this phase 1484 (74%) of all the tests have been qualified by the DPO's as easy to be performed at the road side as can be seen in table 7.12.1. Six devices had a positive score over the average of all the devices (74%). The score of three devices has been lower than the average score.
For Mavand (53 %) this has been caused by the rather complicated procedure to perform the test. Three different components were needed to do the test. (collection swab, buffer, device itself). For Sun (44%) the very low score was explained by the DPO's due to the complicated way to collect the oral fluid sample and to bring this to the device. Also the condition that the device should be placed horizontal to let the oral fluid run has been considered as a difficult requirement at the road side.
The 09 Ultimed Salivascreen scored low (69%) due to the difficulties DPO's encountered at collecting a sufficient amount of oral fluid from the tested persons.

Easily at road side Phase 1 part 1				
	Yes	**No**	**Unknown**	**Total**
01 Mavand RapidSTAT	112	93	6	211
02 Avitar Drugometer	185	38	6	229
03 Branan Oratect III	170	40	3	213
04 EnviteC SmartClip	194	19	3	216
05 Innovacon OrALert	123	61	0	184
06 Securetec Drugwipe 5+	211	9	2	222
07 Sun OraLine	76	94	2	172
08 Surescreen Drug Test	114	36	0	150
09 Ultimed Salivascreen VI	122	59	0	181
10 Varian OraLab 6	177	36	4	217
Total	**1484**	**485**	**26**	**1995**

Table 7.12.1: DPO's opinion on ease to use the device at the road side Phase 1 part 1

7.12.2 Phase 2

The three devices tested during phase 2 are instrumental devices where the analyser is connected to an integrated reading device. Interpreting of the screening result by the DPO is not needed/possible. This makes the interpretation of the indication objective. 432 out of 727 tests have been qualified as easy to use at the roadside. See table 7.12.2

Easily at road side Phase 2			
	Yes	**No**	**Total**
11 Cozart DDS	155	52	207
12 Dräger Drug Test 5000	130	88	218
13 Biosensor BIOSENS	147	155	302
Total	**432**	**295**	**727**

Table 7.12.2 DPO's opinion on ease to use the device at the road side Phase 2

The BIOSENS is very big, heavy and needs a 220V power supply. This limits possibilities to use the device at the roadside unless specific conditions are fulfilled. In almost 50% of the cases the device could easily be used at the roadside. Probably by using a truck as a screening test centre.
The Dräger device scored 60%, it has its own battery and can theoretically be used at the roadside.
The Cozart DDS device has the smallest size of the three devices and can rather easily be used at the road side. DPO's considered 75% of the performed tests as easy to be used at the roadside.

7.13 Opinions of tested persons

Tested persons have been asked about their opinion on the test they just performed. Some persons did not want to answer these questions. The majority of them did answer the questions. The answers on these questions have been registered and analysed. It should be kept in mind that there was no control at all about the way the tested persons answered the raised questions. Answers provided by tested persons have only an indicative value. The non-response rate at these questions has been rather high. Answers received from the tested persons have been based on the experience they had with the screening test. It is relevant to realise that the tested persons who answered the question had a recent experience with the oral fluid test and most likely not with a urine test or a sweat test.

7.13.1 Opinion on collecting time of the oral fluid devices

Motorists and suspected persons who provided an oral fluid sample have been asked about their opinion on the collecting time. Keeping a collecting device for oral fluid in the mouth for a longer period can cause unpleasant feelings and sometimes even vomiting reactions might be shown. If the collecting device has a bad taste even a short collecting time can be experienced as unpleasant.

7.13.1.1 Phase 1 part 1

1851 persons answered this question (93%). 44% of the tested persons considered the collecting time as short. 26% considered the collecting time as long. 22% as moderate. Differences can be seen in table 7.13.1.1. Tested persons preferred a short collecting time. It is very hard to define a short collecting time. Relevant variables are weather conditions, the location, a dry mouth, the mental state of the tested person and other issues. Five out of ten devices scored better than average. (01 Mavand, 04 EnviteC, 06 Securetec, 07 SUN and 08 Surescreen).

Opinions on collecting time Phase 1 part 1					
	Long	**Moderate**	**Short**	**No answer**	**Total**
01 Mavand*	24	72	100	15	211
02 Avitar	57	90	67	15	229
03 Branan*	97	59	44	13	213
04 EnviteC	17	38	143	18	216
05 Innovacon	44	63	67	10	184
06 Securetec	3	20	173	26	222
07 Sun	30	22	106	14	172
08 Surescreen	20	51	72	7	150
09 Ultimed	96	41	36	8	181
10 Varian	60	66	73	18	217
Total	**448**	**522**	**881**	**144**	**1995**

Table 7.13.1.1 Opinion of tested persons on collecting time Phase 1 part 1

* These manufacturers did modify their devices based on the recommendations of the DPO's as provided during the interim evaluation of the testing phase 1 part 1. These modified devices are tested during the second part of phase 1.(see chapter 9) Modification of 01 Mavand and 03 Branan had specifically to do with collecting and analysing time.

7.13.1.2 Phase 2

Table 7.13.1.2 shows that 576 persons answered this question (91%). 56% of the tested persons considered the collecting time as short. 13% as long. 22% as moderate. Tested persons prefer a short collecting time. It is very hard to define a short collecting time.

Opinion on collecting time Phase 2					
	Long	**Moderate**	**Short**	**No answer**	**Total**
11 Cozart DDS	25	51	104	27	207
12 Dräger Drug Test 5000	41	63	83	31	218
13 Biosensor BIOSENS	15	25	169	0	209
Total	**81**	**139**	**356**	**58**	**634**

Table 7.13.1.2 Opinion of tested persons on collecting time during phase 2

7.13.2 Acceptable collecting time

Tested persons have been asked for their opinion on acceptable collecting time. Their answers were based on the experience they just had with the test on a specific device.

7.13.2.1 Phase 1 part 1

A collecting time of up to three minutes was considered as acceptable by at least 57% of the tested persons. If the answers for each device are studied it can be concluded that the answers have been influenced by the experience during the just performed test. The Securetec device is the devices with the shortest collecting time. Mostly less than 15 seconds. Tested persons had the opinion that the collecting time was short. See table 7.13.2.1.1

Acceptable collecting time in minutes Phase 1 part 1								
	1	**2**	**3**	**5**	**5-10**	**>10**	**Unknown**	**total**
01 Mavand	68	15	79	31	3	1	14	211
02 Avitar	60	23	98	34	0	0	14	229
03 Branan	52	28	86	30	1	0	16	213
04 EnviteC	67	18	86	24	2	0	19	216
05 Innovacon	51	12	87	25	1	0	8	184
06 Securetec	139	18	20	16	2	0	27	222
07 Sun	54	9	66	25	3	1	14	172
08 Surescreen	31	14	67	29	2	0	7	150
09 Ultimed	50	11	66	45	0	1	8	181
10 Varian	47	29	94	28	1	0	18	217
Total	**619**	**177**	**749**	**287**	**15**	**3**	**145**	**1995**

Table 7.13.2.1.1: Opinion of tested persons on acceptable collecting time Phase 1 part 1

For each device the average collecting time based on all performed test where an oral fluid sample could be collected is known. See table 7.13.2.1.2. If the actual average collecting time is compared with the acceptable collecting time as indicated by the tested person on that particular device it can be concluded that over 50% of all tested persons had the opinion that the collecting time of the device has been acceptable. There are however two clear exceptions. Branan and Ultimed. Branan improved the device especially to decrease the collecting time. Ultimed showed rather a lot of problems to obtain successful tests. The collection of oral fluid was problematic. But even if the oral fluid sample has been collected in an acceptable collecting time this was not a guarantee that the device would be able to analyse the collected sample. It can be concluded that tested persons already were reasonably happy with the majority of the screening devices if it comes to the time needed to collect an oral fluid sample.
83 – 100% of all the tests had a successful collection of oral fluid.
This did not mean however that a sufficient amount of oral fluid has been collected to analyse the sample.

	Average collecting time in minutes	**Acceptable collecting time tested persons (%)**
01 Mavand	2,5	55 %
02 Avitar	3	58 %
03 Branan	4,5	14-40 %
04 EnviteC	2	59 %
05 Innovacon	3	61 %
06 Securetec	1	63 %
07 Sun	2,5	55 %
08 Surescreen	2,5	68 %
09 Ultimed	5	25 %
10 Varian	4	13-56 %

Table 7.13.2.1.2:Opinion of tested persons on average collecting time and acceptable collecting time Phase 1 part 1

7.13.2.2 Phase 2

A collecting time of up to 3 minutes has been considered as acceptable by at least 55% of the tested persons who answered this question. See table 7.13.2.2.1. The Biosensor device is the device with the shortest collecting time. Mostly less than fifteen seconds. Persons who just performed a test on this device had the opinion that the acceptable collecting time was very short (1 minute: 44%).

Acceptable collecting time Phase 2								
	1	**2**	**3**	**5**	**5 – 10**	**>10**	**Unknown**	**Total**
11 Cozart	66	12	73	28	1	0	27	207
12 Dräger	57	17	87	25	0	1	31	218
13 Biosensor	91	15	72	25	4	1	1	209
Total	**214**	**44**	**232**	**78**	**5**	**2**	**59**	**634**

Table 7.13.2.2.1 Opinion of tested persons on acceptable collecting time Phase 2

If the actual average collecting time is compared with the acceptable collecting time as indicated by the tested person on that particular device it can be concluded that over 50% of all tested persons had the opinion that the collecting time of the device was acceptable. There are however differences for each device. See table 7.13.2.2.2.

	Average collecting time in minutes	**Acceptable collecting time tested persons (%)**
11 Cozart	2	55 – 69%
12 Dräger	2	59 – 74%
13 Biosensor	1	57 – 66%

Table 7.13.2.2.2: Opinion of tested persons on average collecting time and acceptable collecting time Phase 2

7.13.3 Acceptable analysing time

Tested persons have been asked for their opinion on acceptable analysing time. Their answer could have been related to the time they needed to provide an oral fluid sample on the screening device they just had used. They also had the possibility to observe the analysing process. Their opinion on analysing time therefore was influenced by these two variables and also by the successfulness of the analysis. Some devices showed a rather high percentage of failed analysis. Tested persons did not have any idea what a reasonable time for the analysis from a technical perspective would be. They therefore could only give a subjective opinion probably also based on the opinion about the collecting time. Therefore it is not surprising that the acceptable analysing time of an oral fluid sample is very short. The analysis of the collected oral fluid sample costs a certain amount of time. The speed of this process can not be increased by the DPO. The tested person and the DPO will have to wait till the analysis is completed and an indication will be provided.

7.13.3.1 Phase 1 part 1

An analysing time of five minutes (or more) has been considered as acceptable by 37 – 44% of the tested persons. See table 7.13.3.1.1.

Acceptable analysing time in minutes Phase 1 part 1								
	1	**2**	**3**	**5**	**5-10**	**>10**	**Unknown**	**total**
01 Mavand	12	9	59	92	20	5	14	211
02 Avitar	19	14	88	83	8	2	15	229
03 Branan	21	9	89	68	10	1	15	213
04 EnviteC	16	20	99	55	7	0	19	216
05 Innovacon	14	14	80	62	5	1	8	184
06 Securetec	13	8	89	73	7	6	26	222
07 Sun	14	7	82	42	11	2	14	172
08 Surescreen	11	5	48	69	8	2	7	150
09 Ultimed	13	13	70	63	10	4	8	181
10 Varian	11	8	89	82	6	3	18	217
Total	**144**	**107**	**793**	**689**	**92**	**26**	**144**	**1995**

Table 7.13.3.1.1: Opinion of tested persons on acceptable analysing time Phase 1 part 1

For each device the average analysing time based on all performed test where an oral fluid sample could be collected is approx. six minutes. If the actual average analysing time is compared with the acceptable analysing time as indicated by the tested person on that particular device it can be concluded that approx. 35% of all tested persons had the opinion that the analysing time of the device was acceptable.
There are however some clear exceptions.
01 Mavand, 08 Surescreen and 10 Varian.
At these devices a higher percentage of acceptable analysing time has been measured. There is no direct and clear explanation for this. It is a fact that these devices are not one-piece-devices.
01 Mavand has a collection part, a buffer, a cassette and a reader.
08 Surescreen has a collection part a cassette and a reader.
10 Varian has a collection part a cassette and a card.
For these 3 devices specific actions of the DPO are needed. This costs extra time. The tested person was waiting for the result of the analysis and during the time of preparation and analysis of the sample the tested person could observe what the DPO was doing. There was “a lot” to see.

For the other devices the fluid did run almost immediately after the tested person has been told he could take the collection device out of his mouth. During the time needed to let the fluid run and to do the analysis there was nothing “to do” for the DPO and nothing “to see” for the tested person. 5 minutes waiting than could easily be qualified as “long”.
The other devices are one-piece devices with only one exception. The 05 Innovacon OrALert.
This device is similar to the 08 Surescreen device. The only difference is that the 05 Innovacon is not equipped with an electronic reader. This is the only difference that could explain the differences between the acceptability of longer analysing time for these two devices.

The percentage of acceptable analysing time from the perspective of the tested person related to the percentage of successful analysis (acceptable analysis x successful analysis) gives an indication of the acceptability from both a tested persons perspective and an enforcement perspective. See table 7.13.3.1.2. In the last column this indicator is shown.
01 Mavand, 04 EnviteC, 06 Securetec, 08 Surescreen and 10 Varian do have a higher index than the other devices. This means that these devices were better accepted by tested persons if it came to the analyse time and DPO's did consider these devices as relatively successful taking into account the feeling of the tested persons.

	Average analysing time in minutes	% Acceptable analysing time	% Successful analysis	% Acceptable + successful analysis
01 Mavand	11	59 %	77 %	45 %
02 Avitar	6,5	43 %	60 %	26 %
03 Branan	5,5	40 %	67 %	27 %
04 EnviteC	3,25	52 %	97 %	51 %
05 Innovacon	7	39 %	90 %	35 %
06 Securetec	5,2	43 %	98 %	42 %
07 Sun	8,5	35 %	73 %	26 %
08 Surescreen	7,5	55 %	75 %	41 %
09 Ultimed	8	45 %	56 %	25 %
10 Varian	7,4	46 %	80 %	37 %

Table 7.13.3.1.2: Opinion of tested persons on average analysing time and acceptable analysing time Phase 1 part 1

7.13.3.2 Phase 2

An analysing time of five minutes (or more) was considered as acceptable by 40 – 49% of the tested persons. See table 7.13.3.2.1.

Acceptable analysing time Phase 2								
	1	2	3	5	5 – 10	>10	Unknown	Total
11 Cozart	23	7	61	78	10	1	27	207
12 Dräger	9	4	76	74	21	3	31	218
13 Biosensor	31	33	76	56	9	3	1	209
Total	**63**	**44**	**213**	**208**	**40**	**7**	**59**	**634**

Table 7.13.3.2.1 Opinion of tested persons on acceptable analysing time during Phase 2

For each device the average analysing time based on all performed test where an oral fluid sample could be collected is approx. six minutes. If the actual average analysing time is compared with the acceptable analysing time as indicated by the tested person on that particular device it can be concluded that approx. 7 – 16% of all tested persons had the opinion that the analysing time of the device was acceptable. There are however some clear exceptions. These exceptions are most likely caused by the analysing time of the test they just performed.
There are clear indications that the short analysing time of the Biosensor device is highly appreciated by the tested persons. On the other hand it is clear that the long analysing time of the Dräger has not been appreciated by the tested persons. See table 7.13.3.2.2

	Average analysing time in minutes	% Acceptable analysing time	% Successful analysis	% Acceptable + successful analysis
11 Cozart	6'	43 – 56%	87 – 88%	37 – 42%
12 Dräger	11'	1 – 15%	77 – 80%	8 – 9%
13 Biosensor	2'15"	68 – 72%	88%	85%

Table 7.13.3.2.2: Opinion of tested persons on average analysing time and acceptable analysing time Phase 2

7.13.4 Used illicit drugs

A number of tested persons had recently used drugs before they have been tested on a screening device by a DPO.

7.13.4.1 Phase 1 part 1

After the oral fluid test was ended 484 out of 1995 tested persons admitted to have used illicit drugs. DPO's asked them what kind of drugs they had used. The vast majority of these persons (425) stated that they had used cannabis. In a number of ESTHER teams these persons had committed a specific traffic offence as in these countries driving with cannabis in the system of the driver is forbidden by law.
In general almost one out of four tested persons had admitted to have used one or more illicit drugs during the last 24 hours. Almost 88% of the persons who had used illicit drugs during the last 24 hours admitted that they had used cannabis. See table 7.13.4.1.

Admitted drug use Phase 1 part 1			
	Drugs	**Cannabis**	**Total**
01 Mavand	50	44	211
02 Avitar	54	47	229
03 Branan	47	41	213
04 EnviteC	45	39	216
05 Innovacon	29	29	184
06 Securetec	58	47	222
07 Sun	53	48	172
08 Surescreen	49	44	150
09 Ultimed	39	38	181
10 Varian	60	48	217
Total	**484**	**425**	**1995**

Table 7.13.4.1: Admitted use of drugs by tested persons Phase 1 part 1

7.13.4.2 Phase 2

After the oral fluid test was ended 152 out of 634 tested persons admitted to have used illicit drugs.
The vast majority of these persons (113) stated that they had used cannabis. In a number of ESTHER teams these persons had committed a specific traffic offence while in these countries driving with cannabis in the system of the driver is forbidden by law. See table 7.13.4.2.
In general almost one out of four tested persons admitted to have used one or more illicit drugs during the last 24 hours. Almost 75% of the persons who used illicit drugs during the last 24 hours admitted that they had used cannabis.

Admitted drug use Phase 2			
	Drugs	**Cannabis**	**Total**
11 Cozart DDS	45	35	207
12 Dräger Drug Test 5000	59	46	218
13 Biosensor BIOSENS	48	32	209
Total	**152**	**113**	**634**

Table 7.13.4.2: Admitted use of drugs by tested persons during Phase 2

7.14 Specific article on drugs in the traffic act.

7.14.1 Illicit drugs

Tested persons have been asked if they would like to have a specific article in the Road Traffic Act forbidding to drive a vehicle with an illicit drug in their system.

7.14.1.1 Phase 1 part 1

Table 7.14.1.1 shows that 1239 (62%) tested persons stated they would be in favour of implementing such a specific article in the traffic act forbidding to drive with illicit drugs in the system of the motorist. 293 motorists did not think it was necessary to have such an article in the traffic act. 328 motorists did not answer this question. 221 of them had admitted earlier that they had used cannabis during the last 24 hours. Apart from that 135 motorists did not want to answer questions at all. More than 50% of this group were persons suspected of driving with illicit substances in their system. These persons were – based on the legal system in the specific country – ordered to provide a blood sample to be analysed in a forensic laboratory. It must be kept in mind that in a number of ESTHER teams a group of tested persons were suspected drivers. They were informed not to be obliged to answer questions. It can be concluded that of all the tested persons at least 62% would appreciate a specific article in law forbidding motorists to drive with an illicit drug active in their system. It must be kept in mind that the answers have been provided when interviewed by the police officer. These answers could of course be "socially desired" answers. Therefore the answers and indications could have a limited value.

Opinion on specific law for illicit drugs Phase 1 part 1						
	Yes	No	No answer		Empty	Total
			Total	Cannabis		
01 Mavand	134	22	40	28	15	211
02 Avitar	150	33	34	25	12	229
03 Branan	135	35	32	28	11	213
04 EnviteC	129	31	37	24	19	216
05 Innovacon	118	28	30	14	8	184
06 Securetec	128	40	30	25	24	222
07 Sun	88	36	35	22	13	172
08 Surescreen	99	24	17	14	10	150
09 Ultimed	123	18	34	18	6	181
10 Varian	135	26	39	23	17	217
Total	**1239**	**293**	**328**	**221**	**135**	**1995**

Table 7.14.1.1: Opinion of tested persons on specific traffic law for illicit drugs Phase 1 part 1

7.14.1.2 Phase 2

Table 7.14.1.2 shows that 421 (62%) persons stated that they would be in favour of implementing a specific article in the traffic act forbidding to drive with illicit drugs in the system of the motorist. 69 motorists did not think it was necessary to have such an article in the traffic act. 86 motorists did not answer this question. 55 of them had admitted before that they had used cannabis during the last 24 hours. Apart from that 58 motorists did not want to answer questions at all. It can be concluded that of all the tested persons 62 – 75% would appreciate a specific article in the traffic law forbidding motorists to drive while an illicit drug is active in their system and is influencing the driving capability.

Opinion on specific law for illicit drugs Phase 2						
	Yes	No	No answer		Empty	Total
			Total	Can		
11 Cozart DDS	130	24	26	15	27	207
12 Dräger Drug Test 5000	122	25	40	29	31	218
13 Biosensor BIOSENS	169	20	20	11	0	209
Total	**421**	**69**	**86**	**55**	**58**	**634**

Table 7.14.1.2: Opinion of tested persons on specific traffic law for illicit drugs during Phase 2

7.14.2 Drugs of prescription

Tested persons have been asked if they would like to have a specific article in the Road Traffic Act forbidding to drive a vehicle with an illicit drug in their system.

7.14.2.1 Phase 1 part 1

1218 (61%) tested persons were in favour of introduction a specific article in the traffic act forbidden motorists to drive with drugs of prescription in their system. See table 7.14.2.1. 279 tested persons did not have the opinion such an article in the traffic act was needed. 358 tested persons did not answer this question. 214 of these 358 tested persons had used cannabis. Apart from that 140 motorists did not want to answer questions at all. 69 of them were suspected of driving with illicit substances in their system. These persons were – based on the legal system in the specific country – ordered to provide a blood sample to be analysed in a forensic laboratory. It must be kept in mind that in a number of ESTHER teams a group of tested persons were suspected drivers. They were informed not to be obliged to answer questions. It can be concluded that at least 61% of tested persons would appreciate a specific article in the traffic law forbidding motorists to drive while a specific drug of prescription is active in their system and is influencing the driving capability. It can be concluded that there is hardly a difference between the opinion of tested persons when driving capability is decrease due to illicit drugs or due to drugs of prescription.

Opinion on specific law for drugs of prescription Phase 1 part 1						
	Yes	No	No answer		Empty	Total
			Total	Cannabis		
01 Mavand	128	24	45	28	14	211
02 Avitar	143	37	36	23	13	229
03 Branan	133	31	36	21	13	213
04 EnviteC	133	27	37	25	19	216
05 Innovacon	117	27	32	13	8	184
06 Securetec	128	36	34	25	24	222
07 Sun	89	31	39	21	13	172
08 Surescreen	103	20	17	14	10	150
09 Ultimed	119	19	37	18	6	181
10 Varian	125	27	45	26	20	217
Total	**1218**	**279**	**358**	**214**	**140**	**1995**

Table 7.14.2.1: Opinion of tested persons on specific traffic law for drugs of prescription Phase 1 part 1

7.14.2.2 Phase 2

404 (64%) tested persons were in favour of introduction a specific article in the traffic act forbidding motorists to drive with drugs of prescription in their system impairing the driving behaviour. See table 7.14.2.2. 75 tested persons did not have the opinion that such an article in the traffic act was needed. 97 tested persons did not answer this specific question. 51 of these 97 tested persons had used cannabis. Apart from that 58 motorists did not want to answer questions at all. It can be concluded that 64 – 73% of the tested persons would appreciate a specific article in the traffic law forbidding motorists to drive while a specific drug of prescription is active in their system and is influencing the driving capability. There is hardly any difference between the opinion of tested persons when driving capability is decrease due to illicit drugs or due to drugs of prescription.

Opinion on specific law for drugs of prescription Phase 2						
	Yes	No	No answer		Empty	Total
			Total	Can		
11 Cozart DDS	129	23	28	16	27	207
12 Dräger Drug Test 5000	118	22	47	24	31	218
13 Biosensor BIOSENS	157	30	22	11	0	209
Total	**404**	**75**	**97**	**51**	**58**	**634**

Table 7.14.2.2: Opinion of tested persons on specific traffic law for drugs of prescription during Phase 2

8 Evaluation of improved screening devices during Phase 1 part 2

After finishing the first part of phase 1 of the ESTHER task participating manufacturers have been given the possibility to modify and improve their device from an operational perspective based on the recommendations of DPO's as formulated during the interim evaluation in June 2007. In January 2008 the ESTHER teams could start with the evaluation tests of four improved devices.

- *Improved Mavand RapidSTAT*

Four operation-based modifications have been realised.
1. New collecting device. The new collector is made from a micro fibre which absorbs the drug contamination inside the mouth easily and quickly. The new collector has to collect saliva for just 30 seconds.
2. Improved Visibility/Readability of the lines. The new test strip has been modified in such a way that the negative lines form stronger and faster so that the visual reading of the test is easier. When desired Mavand can provide an evaluation instrument the Mobile READER.
3. Integration of the different parts of the device (all-in-one). To facilitate the handling for the operator Mavand combined the 3 components, collector, buffer bottle and test in a clip system within the new version.
4. Improved hygienic aspect. The new incubation device has been redesigned. The operator does not have contact with the sample.

- *Branan Oratect XP*

Five operation-based modifications have been realised.
1. 4 panel test. The improved Oratect XP (Oratect 4 panel) is a four drug testing device (THC, Cocaine, Opiates, Methamphetamine/MDMA).
2. Single strip. The Oratect 4-panel has a single test strip.
3. A smaller amount of oral fluid is needed. The test pad for the Oratect 4-panel is much smaller and requires approximately half as much oral fluid as the Oratect III (0,27 ml vs. 0,55 ml).
4. Decreased indication time. The time needed to obtain the result has also been reduced by approximately 50%.
5. Oravue Reader. An optional reader (Oravue Reader) – a hand held device that provides an LCD Readout of the Oratect 4-panel results – has been introduced.

- *Securetec Drugwipe 5+*

An improved electronic reader has been added to the screening device.

- *Surescreen Oral Drug Test*

An improved electronic reader (PDA) has been added to the screening device.

Phase 2 part 2

During the planning of the second phase of the ESTHER activities it was thought that a second part of phase 2 could be required based on the findings during the first part of this second phase. Based on the experiences of the ESTHER teams it has been decided to skip a second part of this second phase of testing. This decision has been based on three arguments.
1. Just three devices were tested in part 1 of the second phase.
2. The first phase of testing period lasted just four months and during this short period no interim proposals for modification of the devices could be provided by the ESTHER teams.
3. Manufacturers stated that the concept of the devices tested in the second phase was based on the most actual stage of development.

8.1 Number of tests performed with the devices

During phase 1 part 2 of the ESTHER task the eleven teams performed tests with the four improved oral fluid screening devices. (See table 8.1). ESTHER teams have been required to perform five tests with each improved device under operational conditions. It has been expected that 220 tests would be performed during the second part of phase 1. All together 238 tests have been performed. This is 8% over the expected amount of tests. The number of tests performed with the Mavand RapidSTAT is rather high compared to the test with the other devices. This is due to the possibilities the Germany 3 team had to perform more tests with the improved device.

Number of tests with improved devices Improved oral fluid screening devices Phase 1 part 2					
	01	**03**	**06**	**08**	**Total**
NL 1	5	5	5	5	20
NL 2	5	5	5	5	20
NL 3	5	5	5	5	20
Belgium 2	5	5	5	5	20
Belgium 3	7	6	5	5	23
Germany 1	5	5	5	5	20
Germany 2	5	5	5	5	20
Germany 3	20	5	5	6	36
Ireland	3	4	4	4	15
Finland	5	8	5	6	24
Spain	5	5	5	5	20
Total	**70**	**58**	**54**	**56**	**238**

Table 8.1: Number of tests performed with the improved devices Phase 1 part 2

The four devices as mentioned in the table above are
01: Mavand RapidSTAT
03: Branan Oratect XP
06: Securetec Drugwipe 5+
08: Surescreen Drug Test

8.2 Gender of tested persons

The 238 tests during the second part of phase 1 have been performed under operational police conditions as well as in the police station. As only the improved aspects had to be evaluated it was not felt as a necessity to do the tests only on motorists or suspected drivers. Tests could also be performed by DPO's themselves as they were well aware of the ins and outs of the device that has been tested in the first part of this phase. Some teams preferred to do the tests on motorists nevertheless. 208 (88,1%) tests have been performed on men, 28 on females. (Table 8.2)
Two tests have been performed without reporting the gender of the tested person.
It is not likely that the findings of the different improved devices have been influenced by the gender of the tested persons.

Gender of persons tested Improved oral fluid screening devices Phase 1 part 2				
	Male	**Female**	**Unknown**	**Total**
01 Mavand RapidSTAT	62	6	2	70
03 Branan Oratect XP	51	7	0	58
06 Securetec Drugwipe 5+	51	3	0	54
08 Surescreen Drug Test	44	12	0	56
Total	**208**	**28**	**2**	**238**

Table 8.2 Gender of tested persons Phase 1 part 2

8.3 Age of the tested persons

The age of the persons who performed tests on the devices varied from 18 years till 65 years as can be seen in table 8.3. In general 58% of the tested persons were younger than 35 years. There were differences if the age curves of tested persons at different devices are observed. These differences are minor taking in account the limited number of tests with each device. The majority of persons using illicit drugs are considered to be in these two age groups. There has been three tests where no information on the age of the tested person was available.

Age of persons Improved oral fluid screening devices Phase 1 part 2							
	18 – 25	**26 – 35**	**36 – 45**	**46 – 55**	**56 – 65**	**Unknown**	**Total**
01 Mavand RapidSTAT	22	22	19	7	0	0	70
03 Branan Oratect XP	6	31	15	5	1	0	58
06 Securetec Drugwipe 5+	8	19	17	9	1	0	54
08 Surescreen Drug Test	6	23	14	9	1	3	56
Total	**42**	**95**	**65**	**30**	**3**	**3**	**238**

Table 8.3: Age of persons tested with oral fluid screening devices Phase 1 part 2

8.4 Non-suspected and suspected motorists

All tested persons can be divided in two groups. 25% of all the persons tested on one of the devices were motorists who were suspected of driving with psychoactive substances in their system. The rest of the tested persons were motorists stopped and checked by the police or DPO's who performed the tests themselves. See table 8.4. There have been differences in the percentage of suspected persons depending on the device they have been tested on. This probably has been caused by the limited number of tests but also the tests where DPO's acted as tested persons. For some of the improvements there would not be a difference between tests performed by tested persons or by DPO's.

Non-suspected and suspected motorists Improved oral fluid screening devices Phase 1 part 2			
	Non-suspected motorist*	**Suspected motorists**	**Total**
01 Mavand RapidSTAT	53	17	70
03 Branan Oratect XP	43	15	58
06 Securetec Drugwipe 5+	35	19	54
08 Surescreen Drug Test	47	9	56
Total	**178**	**60**	**238**

Table 8.4: Non-suspected and suspected motorists Phase 1 part 2
* Tests performed on non-suspected motorists include tests performed on DPO's

8.5 Successful tests

DPO's have been asked to validate the tests performed by DPO's, motorists and suspected persons. After the test was ended the DPO was asked whether he/she considered the test as successful from an police perspective. In table 8.5 the 238 tests were validated. Goal of this evaluation has been to find out if the improved device was more suitable in police practice compared to the tests with the device tested in the first part of phase 1. It is relevant to keep in mind that the tests have been performed as a kind of routine check of motorists during normal traffic control activities as well as by DPO's themselves.
It was expected that the improvements of the devices would increase the number of successful tests. This qualification is a subjective one and is influenced by the complexity of the testing procedure, the time needed to complete the analysis and other issues. Data in the table above are compared with similar obtained during the first part of this phase.

8.5.1 Mavand RapidSTAT

The improved *Mavand OralSTAT* device did not show noticeable changes in results compared with the test performed during the first part.

8.5.2 Branan Oratect XP

The *Branan Oratect XP* device did show changes in results compared with the tests performed during the first part. The number of successful tests at the road side, in a patrol car or a police truck has been increased. Most likely thanks to the modifications on the Oratect III device.

8.5.3 Securetec Drugwipe 5+

The *Securetec Drugwipe* with the improved reader did not result in an increased number of successful tests. DPO's did not consider the new reader as a relevant issue to improve the success rate of tests.

8.5.4 Surescreen Drug Test

The *Surescreen Drug Test* device with the new reader did not result in an improved successfulness of the performed tests according to the opinion of the DPO's. DPO's did not think the software and the reader were in a sufficient stage of development. A decrease in the number of successful tests can be observed. As the new reader is the only improvement of the tested device compared to the device and reader tested in the first part it can only be concluded that the decrease in success is caused by the reader.

Performed tests qualified as successful by DPO's Improved oral fluid screening devices Phase 1 part 2							
	Successful			**Not successful**			**Total**
	Car and Road side	Truck and Station	Total	Car and Road side	Truck and Station	Total	
01 Mavand RapidSTAT	7	38	45	8	17	25	70
03 Branan Oratect XP	14	23	37	4	17	21	58
06 Securetec Drugwipe 5+	18	27	45	3	6	9	54
08 Surescreen Drug Test	2	22	24	6	26	32	56
Total	**41**	**110**	**151**	**21**	**66**	**87**	**238**

Table 8.5: Performed tests qualified as successful by DPO's Phase 1 part 2

8.6 Time needed to get a sufficient oral fluid sample

DPO's have tested the four devices in part 2 of phase 1 and registered the collecting time. Results are presented in table 8.6. As the four devices have been modified according the recommendations as provided to the manufacturers at the interim evaluation of phase 1 it was expected that the number of successful collections of oral fluid would have been increased as well as the time needed to collect an oral fluid sample.

Time needed to get a sufficient oral fluid sample Improved oral fluid screening devices Phase 1 part 2				
	Successful	**Average time**	**Failures**	**Total**
01 Mavand RapidSTAT	69	2'	0	69
01 Branan Oratect XP	54	3'	4	58
06 Securetec Drugwipe 5+	54	1'30"	0	54
08 Surescreen Drug Test	54	1'30"	0	54
Total	**231**	**2'**	**4**	**235**

Table 8.6: Time needed to get a sufficient oral fluid sample Phase 1 part 2

If these data are compared with the data retrieved from these devices in the first part of this phase improvements can be observed.

8.6.1 Mavand RapidSTAT (improved)

Successful tests:
In the second part all collecting tests were successful.
Average collecting time:
The average collecting time has been improved from 2,5 minutes to 2 minutes. According to the information from the manufacturer 30 seconds would be sufficient.

8.6.2 Branan Oratect XP

Successful tests: In the first part 18% of the collecting tests failed. In the second part this figure was decreased to 6%.
Average collecting time: The average collecting time has been improved from four minutes to three minutes.

8.6.3 Securetec Drugwipe 5+ and improved reader

Successful tests: In both parts all the collecting tests were successful.
Average collecting time: The average collecting time has been improved from 1 minute to 1,5 minutes.

8.6.4 Surescreen Drug Test and improved reader

Successful tests: In the second part all collecting tests were successful.
Average collecting time: The average collecting time has been improved from 2,5 minutes to 1,5 minutes.

8.7 Time needed to analyse the oral fluid sample

Time needed to analyse an oral fluid sample Improved oral fluid screening devices Phase 1 part 2				
	Successful	**Average time**	**Failures**	**Total**
01 Mavand RapidSTAT	60	7’	4	64
03 Branan Oratect XP	51	6’	5	56
06 Securetec Drugwipe 5+	52	4’30”	2	54
08 Surescreen Drug Test	52	4’30”	2	54
Total	**215**	**2’**	**13**	**228**

Table 8.7: Time needed to analyse an oral fluid sample Phase 1 part 2

Table 8.7 provides data about the analysing time of the four devices during this second part. If the data about the time needed to analyse the oral sample during this part are compared with the data retrieved from these devices in the first part phase improvements and changes can be observed.

8.7.1 Mavand RapidSTAT (Improved)

Successful tests In the second part 7% of the analysis failed. (23,2% during the first part).
Average analysing time: The analysing time has been improved from 11 minutes to 7 minutes.

8.7.2 Branan Oratect XP

Successful tests: In the second part the failure rate was 11%. (33,3% during first part)
Average analysing time: The analysing time has been improved from 5,5 minutes to 6 minutes.

8.7.3 Securetec Drugwipe 5+ and improved reader

Successful tests: In the first part and the second part the failure rate was 2%.
Average analysing time: The analysing time has been improved from 5 minutes to 4,5 minutes.

8.7.4 Surescreen Drug Test and improved reader

Successful tests: In the second part 4% of the analysis failed. (25,2% during the first part)
Average analysing time: The analysing time has been improved from 7,5 minutes to 4,5 minutes.

8.8 Testing in a hygienic way

Hygienic testing Improved oral fluid screening devices Phase 1 part 2				
	Yes	**No**	**No answer**	**Total**
01 Mavand RapidSTAT	42	26	2	70
03 Branan Oratect XP	49	9	0	58
06 Securetec Drugwipe 5+	54	0	0	54
08 Surescreen Drug Test	48	8	0	56
Total	**193**	**43**	**2**	**238**

Table 8.8: Opinion of DPO's on hygienic aspects Phase 1 part 2

When using an oral fluid screening test the DPO should avoid to have contact with the oral fluid of the tested person. The improved devices did not change the opinion of the DPO's about the hygienic aspects. However there are differences between the devices.(See table 8.8)

8.9 Rely on the indication

Rely on obtained indication Improved oral fluid screening devices Phase 1 part 2				
	Yes	**No**	**Unknown**	**Total**
01 Mavand RapidSTAT	51	17	2	70
03 Branan Oratect XP	47	11	0	58
06 Securetec Drugwipe 5+	43	11	0	54
08 Surescreen Drug Test	33	23	0	56
Total	**174**	**62**	**2**	**238**

Table 8.9: DPO's opinion on reliability of the obtained indications Phase 1 part 2

Almost half the teams could not compare the indications of drug use retrieved from the improved oral fluid screening devices with the indications from other screening devices or the result of an analysis of a sample (blood, saliva, urine) by a forensic laboratory. DPO's have been asked if they would rely on the obtained indication of drug use. The ESTHER teams from Germany and Belgium had the possibility to check a number of the indications of the oral fluid screening tests with the result of the legally prescribed urine test and sometimes with the results of the blood analysis. DPO's of other teams could only compare the indication of the device with their own observations of the status of the tested persons. Overall the DPO's relied rather good on the indication of drug use obtained by a test with the improved devices.(See table 8.9)

8.9.1 Mavand RapidSTAT

The reliability of the Mavand RapidSTAT, as experienced by DPO's, has decreased a bit compared to the device tested in part 1. No explanation for this decrease could be found.

8.9.2 Branan Oratect XP

The reliability of the Branan Oratect XP increased in a substantial way.

8.9.3 Securetec Drugwipe 5+

The reliability of the Securetec Drugwipe was already good and could hardly be improved.

8.9.4 Surescreen Drug Test

The reliability of the Surescreen during the second part was clearly less than during the first part.
As the only modification has been the modified reader it is likely that this accessory has been responsible for the reduced reliability of this device.

8.10 Simple test

Test simple to perform Improved oral fluid screening devices Phase 1 part 2				
	Yes	**No**	**Unknown**	**Total**
01 Mavand RapidSTAT	30	39	1	70
03 Branan Oratect XP	53	5	0	58
06 Securetec Drugwipe 5+	54	0	0	54
08 Surescreen Drug Test	33	23	0	56
Total	**170**	**67**	**1**	**238**

Table 8.10: DPO's opinion on simplicity to perform a screening test Phase 1 part 2

In this second part two devices were one-part-devices. Branan Oratect XP, Securetec Drugwipe 5+. These devices have been qualified as more simple to operate than the other two devices.(See table 8.10)

8.10.1 Mavand RapidSTAT

The reader of the Mavand RapidSTAT has been qualified as a good accessory but indication lines were also well to read without the additional reader. The complexity to perform a test with this device – three different parts and the procedure to prepare the indication process and to let the test run – have led to the conclusion that the device is less simple to use.

8.10.2 Branan Oratect XP

The Branan Oratect XP had an improved collecting system to perform the test in a shorter period. DPO's did not notice differences in the simplicity of the test.

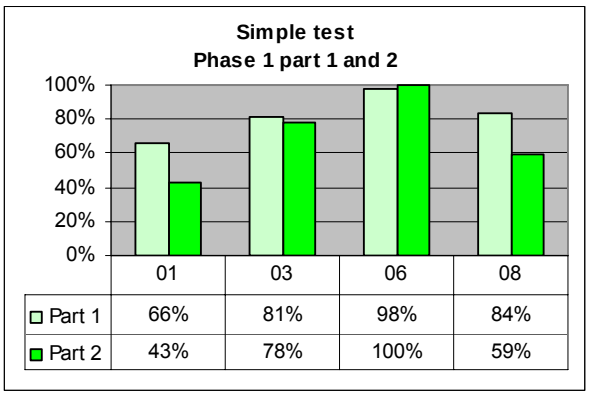
8.10.3 Securetec Drugwipe 5+

The Securetec did have an additional reader but some teams stated that they did not need the help of that reader as the indication lines were clear to see without an additional reader.

8.10.4 Surescreen Drug Test

The improved Surescreen device has not been considered as more simple to operate compared to the device tested in the first part of phase 1. This was most likely caused by the reading device making the testing procedure more complicated. Also the software accompanying the reader (PDA) caused some problems for a good performing of the screening test.

The comparison of the simplicity to perform a test during part 1 and part 2 can be seen in graph 8.10.



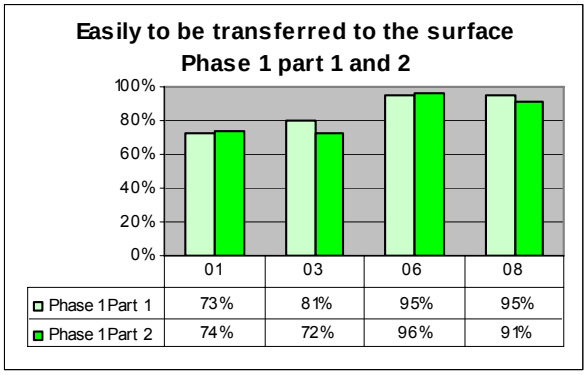
Graph 8.10. Percentage of DPO's opinion on simplicity to perform a screening tests Phase 1 part 1 and 2

8.11 Transferred to surface

Transferred to surface Improved oral fluid screening devices Phase 1 part 2				
	Yes	**No**	**Unknown**	**Total**
01 Mavand RapidSTAT	52	17	1	70
03 Branan Oratect XP	42	16	0	58
06 Securetec Drugwipe 5+	52	2	0	54
08 Surescreen Drug Test	51	5	0	56
Total	**197**	**40**	**1**	**238**

Table 8.11: DPO's opinion on ease to bring to sample to the test strip Phase 1 part 2

Comparing the retrieved answers from the first part with the second part makes clear that only at the Branan device differences in answering this question have been measured. See table 8.11 and graph 8.11. It is unclear what might have caused these differences.



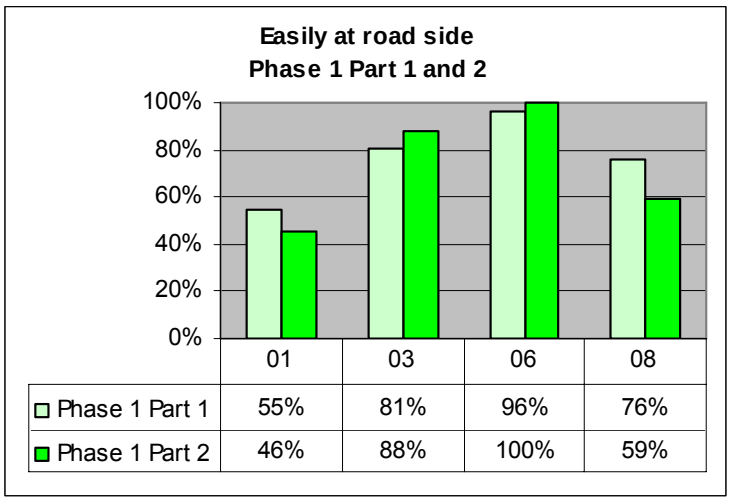
Graph 8.11 Percentage of DPO's opinion on ease to transfer sample to the test surface Phase 1 part 1 and 2

8.12 Easily at road side

Easily at road side Improved oral fluid screening devices Phase 1 part 2				
	Yes	**No**	**Unknown**	**Total**
01 Mavand RapidSTAT	32	35	3	70
03 Branan Oratect XP	51	7	0	58
06 Securetec Drugwipe 5+	54	0	0	54
08 Surescreen Drug Test	33	23	0	56
Total	**170**	**65**	**3**	**238**

Table 8.12: DPO's opinion on ease to use the device at the road side Phase 1 part 2

DPO's have qualified the ease to use the improved devices at the road side. The number of test during the second part have been limited so the differences in qualifications could easily be caused by this small number of tests. (See table 8.12) The simplicity to use the device at the roadside has decreased for the Mavand and the Surescreen device. In the second part of phase 1 these two devices have been tested together with the electronic readers. Using readers at the roadside is a more complicating situation compared to tests with just the device. This can be an explanation for the decreased percentage of positive answers in this respect for the two devices. See graph 8.12.



Graph 8.12 Percentage of DPO's opinion on ease to use the device at the road side Phase 1 part 1 and 2

01: Mavand RapidSTAT
03: Branan Oratect XP
06: Securetec Drugwipe 5+
08: Surescreen Drug Test

9 Police User Requirements and Specifications (PURS)

Based on the experiences collected during the 137 training sessions on the thirteen oral fluid screening devices and the 2960 tests that have been performed with these devices a number of realistic Police User Requirements and Specifications (PURS) has been formulated during two plenary evaluation meetings of all ESTHER teams..
These requirements and specifications can be divided in three main categories.

- Requirements for training of police officers on the use of oral fluid screening devices.
- Requirements for operational use of these devices.
- Requirements for documentation.

The requirements and specifications as mentioned in this chapter of the report are realistic taking into account the possibilities of the police to be trained in an efficient and effective way on screening devices, embedding of the devices into effective and efficient police operations during traffic law enforcement activities and providing easy to use documentation of the device. The two Belgian and the three German teams had already been trained in the use of the urine screening devices within their national legal system. These experiences have also been used to formulate the PURS.
All together approx. 30 one-day meetings of the task leader and each ESTHER team have been organised. During these meetings control activities have been performed and discussions about the required specifications and other issues related to the use of oral fluid screening devices have been held. The results of these discussions are used as an input for the two plenary evaluation meetings. These 3-days plenary meetings have been held in Stein (NL) 5 – 7 June 2007 and in Landgraaf (NL) 14 – 16 October 2008.
During these two evaluation meetings the conclusions of the one day meetings with each of the teams have been discussed and resulted in the content of this chapter.
In this chapter the requirements and specifications of oral fluid screening devices from a police perspective are presented. The chapter is divided into three paragraphs. The most important requirements and specifications in these three paragraphs are summarised in table 9.1.

Summary of Main Police User Requirements and Specifications	
Training	1. Police officers trained by police instructors (0,5 – 1 hour) 2. Police instructors trained by manufacturer (1 – 2 hours) 3. Learning by demonstrating 4. Learning by doing 5. Information about do's and don'ts 6. Clear hygienic and safety measures 7. Instruction card for each officer during training 8. Material available through police intranet 9. All materials in native language
Operational testing	1. 75% of tests qualified as simple to operate 2. Hygienic use of device 3. Sufficient amount of collected oral fluid 4. Detectable substances at least Cannabis, Cocaine, Opiates, Amphetamines(analogues) 5. At least 75% of the tests should be correct for at least one of the substances. 6. Indication lines should remain visible for at least 3 minutes
Documentation	1. Device user manual in native language 2. Device instruction card for each trained officer 3. CD ROM or DVD available for each force/unit 4. (User manual for electronic reader)

Table 9.1 Summary of Main Police User Requirements and Specifications

9.1 Training

Before police officers will be able to use an oral fluid screening device during operational traffic law enforcement activities in practice an adequate training is required. Police officers should be trained in the correct use of the device under all kind of operational circumstances. Their knowledge and experience related to drugs screening in general and the operational use of a specific oral fluid screening device should be sufficient to lead an oral fluid screening test in operational practice.
In this paragraph specific attention will be given to duration, content, examination, training material, hygienic aspects and other relevant issues.

9.1.1 Duration of the training

- Training of a police officer to operate an oral fluid screening device should not last longer than 0,5 – 1 hour. During the ESTHER task it has been proved that a training session of up to 1 hour has been sufficient to train the police officer to operate the screening device. It must be kept in mind that after implementing a new specific article in the national Traffic Act of a member state an initial training is required for all operational police officers involved with traffic law enforcement.
- The training should be given by a police instructor. These police instructors should preferably be operational police officers working in that specific police force. At the introduction of an oral fluid screening device all police officers must be trained. This training should preferably be given in the officers police stations to avoid extra travel time. Once the device is in operational use new aspirant-police-officers should be trained on the screening device as well. This training should be part of the general training and education of new police officers at police schools and police academies.
- Training of the police instructor should not last longer than two hours. It is preferred to train police instructors at an institute where all relevant equipment is available. It is recommended to train police instructors in a specific police training centre. The presence of a police computer network might be relevant to realise computer supported training at the police intranet that can be available for the training of police officers as well.
- The training of the police instructor should be given by a representative of the manufacturer who is familiar with the device and who will be able to answer questions on the technology and operational aspects of the device. This training can probably best be realised by a representative with sufficient scientific background. (e.g. R&D department of the manufacturer. Trained police officers could be rechecked and updated by the police instructor for their capability and experience to operate oral fluid tests. This will be dependent on the operational performance of the officer. Experiences with the use of other police equipment have led to the conclusion that if specific police equipment is used on a regular base the need to retrain the officer will be limited. Oral fluid screening devices are devices that have to be used by any police officer involved with traffic law enforcement.
- After introducing oral fluid screening devices and specific legislation related to drugs and driving in the national legal system not every police officer will use an oral fluid screening device on a daily, weekly or even monthly base during the first year(s). To enhance the operational use of the device and the enforcement activities there should be a possibility to recheck the capability of the police officer to use the oral fluid screening device in a correct and successful way. New information about the use or the modification of the device could also be used to update the knowledge and experience of the police officer.
- Rechecking and updating police officers by a police instructor should not last longer than fifteen minutes. It is advisable to realise this recheck and update activity in such a way that the normal enforcement activities of the police officer will not be disturbed. For example rechecking and updating activities could be part of one of the daily briefing activities. Updates could be available at the police intranet.
- Annually police instructors could be updated by the manufacturer about the improvements and modifications related to the operational use of the oral fluid tests. Updating will depend on the improvements and modifications and should not last longer than one hour.

9.1.2 Content

- Oral fluid screening devices will be used by police officers during daily traffic enforcement activities. Motorists will be tested on the device to get an indication of the use of specific psychoactive substances and/or the decreased capability of that motorist to drive a motor vehicle in a safe way. There is no need to enhance the knowledge of the operational police officer to a level where he is familiar with the technology of the oral fluid screening device. The content of the training should be very practical and police-use oriented.
- "Learning by demonstrating" has proven to be a successful approach to inform police officers on new technologies. During the training this approach can be one of the issues of the training program. The police instructor should clearly demonstrate the proper use of the device.
- "Learning by doing" is a practical approach to train police officers. This is an important aspect of the general training of police officers. During the training session police officers in the class should perform a screening test with the device under the supervision of the police instructor. By acting in this way the police instructor can easily detect errors or mistakes when the police officer is performing a screening test. By explaining what went wrong during the test specific guidelines to perform a test in a good way can be provided by the police instructor. This approach makes training successful and effective.
- The training session should go on until each officer – according to the opinion of the instructor – has performed at least one successful test. This could be the approach during the normal training and education of new police officers at a police training school. If the training is given to police officers who are already fully operational a similar training can be given. The police instructor can decide that officers who performed a successful test are free to leave the training class to start or continue their operational police activities.
- Oral fluid screening devices look simple to use but it must be kept in mind that these kind of devices are very sensitive. Police officers should try to create the most ideal circumstances for the device to run a test. On the other hand some actions should absolutely be avoided to prevent failures. Police instructors will be able to provide the police officers with a small document with "Do's and Don'ts" of the operation of the screening test. The instructor should pay specific attention to these aspects.
- Instruction material explaining the use of the device should be available in the native language of the police officers. Examples of materials are a manual, a CD ROM etc. In these materials the use of the device should be presented. The police instructor should use these documents to discuss the ins and outs of the device and its proper use in practice.
- The computer systems of a police force normally do not allow access to the internet and will protect the system against attacks by blocking external websites and executable files. Mostly this policy will make it impossible for police officers to visit the websites of the manufacturers of oral fluid screening devices. Most computer working stations in police forces do not have a USB port or a CD Rom drive. If a working station is equipped with a CD ROM drive the system will mostly block a self starting CD ROM. It is recommended however that all the information is available through the intranet of the police force in their native language. Therefore the IT service or the webmaster of a police force has to embed the information in the intranet system in such a way that the security policy of the police force will be respected.

9.1.3 Examination

- Each training session could be finished by an examination of the trained police officer to be sure that the officer has been trained in a good way and will be able to perform the tests without problems. However it is the policy of the police force to decide whether an examination of the trained police officers is required.
- In situations where an examination is required – e.g. at the training of new police officers at police schools – it is recommended that the (new) police officer performs one or more practical tests with the screening device under the supervision of the police instructor.
- In situations where a trained police officer is examined or checked on his/her capability to perform a screening test the police instructor could register the police officers who passed the examination if required according to the policy of the police force.
- The examination could be done in a classroom or by performing an examination on the police intranet. This is up to the policy of the force or the instructor.
- If an officer is examined the police instructor can conclude that the officer has passed the examination or has to follow additional training.
- Police officers capable to do screening tests and officers who passed the examination are considered to have enough knowledge and experience to perform an oral fluid test in a successful and effective way.
- It must be kept in mind that if an examination is required to be allowed to use these screening devices the actual list with appointed operators of the device will be legally required.

9.1.4 Material

- Training material should be present on the police intranet to be available for all police officers. Training material should also be available as a hardcopy. It is up to the police force to decide how many hardcopies will be required.
- Training material should be available in the native language of the police officer or the languages of the member state.
- A CD ROM with instructions and demonstrations is required for training of the police officers as well as for personal training by the police instructor. A self-starting CD ROM can be provided to a police force to be used outside the computer system of the police.
- A PowerPoint presentation with additional information about the device as well as concerning the technology of immunoassays can be part of the training material.
- For security reasons it is not possible to have a self-starting CD ROM or DVD. The IT departments of the police forces will have to modify these materials and place them on the intranet according to the existing police IT protocols.
- It is recommended that the manufacturer provides the police with devices specifically for testing and training. The normal devices are rather expensive and it would be considered as a waste of equipment to use these operational devices for training. Test devices are to be considered as “blanks” as the antibodies for the substances are not required in the test devices. During training the screening tests will be performed by police officers.

9.1.5 User manual

- The oral fluid screening device should have a user manual in the native language of the police officer or the languages of the member state.
- In this manual “do’s and don’ts” should be presented in a clear way.
- Based on the experiences of the police instructors and the police officers the manual should be updated regularly.
- Police forces using the oral fluid screening devices should be on the mailing list of the manufacturer for updates of the user manual.
- Police instructors should always have access to the latest version of the user manual.
- Police instructors can inform trained police officers about modifications in the device and updates since the training (and eventually the examination) of the police officers.
- The user manual should be available as a hardcopy. The electronic version of the manual can be placed on the police intranet.

9.1.6 CD ROM

- A demonstration CD ROM/DVD of the screening device should be available through the police intranet.
- The manufacturer should provide the IT department of the police forces in the member state(s) with one or more (interactive) CD ROM/ DVD.
- The IT department will – if required for IT-security reasons – modify the CD ROM/DVD before placing this on the intranet.
- On stand-alone computers the interactive self-starting CD ROM/DVD can be used without modification.

9.1.7 Hygiene

- Hygienic aspects need extra attention during training.
- Oral fluid can contain all kind of substances that can cause a health problem if there is a direct contact between the police officer and the oral fluid sample of the tested person. (Hepatitis, AIDS etc.)
- Tested persons should (be able to) perform a screening test in a hygienic and safe way
- Protective gloves could be provided by the manufacturer but for other purposes police forces do have and use protective gloves in their daily work.
- Guidelines informing the police officers about "What to do with the remaining waste after an oral fluid test is completed" should be part of the information on hygienic aspects.
- Information about the used materials in the device should be provided by the manufacturer to avoid health and environmental problems.

9.1.8 Additional information

- Information about the cut off values for the different substances should be provided by the manufacturer.
- Information about the reliability of the device based on research done by independent scientific research institute should be added to the documentation. Detailed information about the publication of the results of the research should be included.
- Information about the reliability of the device based on tests performed on behalf of the manufacturer could be added to the documentation when the sources are clearly provided.
- Information about the operational use of the device by the police in other countries and/or states can be provided in a document as well.
- Information about cross reactivity of the device should be provided by the manufacturer.
  This is very important, e.g. information on positive opiate tests due to the use of codeine or other cough medication.

9.1.9 Other aspects

During the training of police officers it is necessary to clarify that oral fluid screening devices will only be able to detect the presence of a limited number of substances. Therefore it is possible that an officer will detect signs and symptoms of the use of psychoactive drugs by a driver of a vehicle while an oral fluid screening test will not give an indication for the use of one or more of the specific drugs. The oral fluid screening devices are just sensitive for a very limited number of (illicit) drugs. It will be possible in daily practice that motorists show signs of use of psychoactive drugs but the oral fluid screening test does not detect the presence of a drug. In these situations psychoactive drugs of prescription or specific illicit drugs might be active in the system of the tested person. Persons using these specific psychoactive other substances (drugs of prescription as well as specific illicit drugs) can also be impaired and unable to drive a vehicle in a safe way. Examples of these prescribed substances are different benzodiazepines (rather often used by motorists). Examples of other illicit drugs are LSD, GHB, Ketamine, PCP, magic mushrooms etc.
Some psychoactive drugs of prescription are known to be abused by drug users. Examples are methylphenidate – to treat children with Attention Deficit Hyperactivity Disorder (ADHD) – and Flunitrazepam (Rohypnol) a benzodiazepine known as an abused substance in the drug scene.

9.2 Operational testing

Oral fluid screening devices to detect drugs in the system of drivers of vehicles will be used by police officers during daily traffic law enforcement activities. But also at investigations of traffic accidents and controlling the involved drivers of vehicles a screening test for drugs can be used. This policy can be similar to the policy related to alcohol consumption and driving a vehicle. Based on this approach police will tend to formulate a policy for operational testing of motorists for the use of drugs. However it must be kept in mind that the state of the art of screening devices for drugs can not be compared to the use of alcohol screening devices since the last ten years. A screening tests for alcohol can be performed in less than one minute, can be done at the roadside, using a small instrumental device with a disposable mouthpiece. The disposable mouthpieces are inexpensive. This enables the police to test motorists at random. A screening test for drugs will last up till ten minutes or more. Screening tests for drugs are mostly disposable devices. Up till now these devices are (rather) expensive. The devices are sensitive for a limited number of psychoactive substances. At this moment the legal system in most EU member states does not allow the police to use oral fluid screening devices or other devices at random. Manufacturers of oral fluid screening devices are constantly improving their devices. Actual requirements for operational use of screening devices for drugs will be complicated.

9.2.1 Preparing activities

- Most oral fluid screening devices for drugs are disposables. This means that the devices and the added parts will be sealed separately for hygienic reasons. The police officer must be able to unpack the sealed (collector of the) device within a couple of seconds without the use of a knife or a pair of scissors. Direct contact between the hands or fingers of the officer and the collection part of the oral fluid should be avoided.
- Some oral fluid screening devices consist of an instrumental device and a disposable collector. It should not take longer than three minutes to warm up the instrumental device to be ready to do a screening test with an oral fluid sample of the person to be tested.

9.2.2 Hygienic aspects

- When performing an screening test contact between the DPO and the collected oral fluid should be avoided or should be impossible.
- Police forces will normally already use protective gloves during specific police activities. Protective gloves can be enclosed in the package of the collecting device if required by the police force.
- Protective gloves should be used by the police officer when a screening test has to be performed. This is a requirement from a hygienic perspective. The safety of the working conditions of police officers during traffic law enforcement activities requires specific countermeasures. To protect the officer against infections or diseases during contacts with road users that might have used psychoactive drugs and to avoid contact with the oral fluid the use of protective gloves is required. Also persons performing an oral fluid tests should be protected against infections and diseases.

9.2.3 Ease of operation

- A device to detect psychoactive substance in an oral fluid sample should be simple to operate.
- Based on the operational testing of the devices at least 75% of the tests (three out of four tests) should be qualified as simple by police officers who tested and used the device. The device should work fast. Tests should not last longer than fifteen minutes. During the ESTHER task this period has been considered as acceptable from a practical perspective if the device was qualified as “promising”. This qualification has been the result of the (subjective) validation of all relevant operational aspects of the device provided by the DPO’s.
- In theory it must be possible to perform a screening test for drugs at the road side under all light and weather conditions, similar to the alcohol screening test.
- The simplicity of the devices and the time to analyse the sample should not decrease the reliability of the indication of drug use provided by the device at the end of the test.
- It is acceptable if the reliability of the device and the readability of the indication lines decreases a bit due to extreme low temperatures or rather poor light conditions.

9.2.4 Collecting oral fluid

- Collecting oral fluid can be done by the tested person himself. Such an approach will have hygienic advantages. It is also possible that the police officer will help to collect an oral fluid sample of the tested person.
- In general the collecting process should not last longer than approx. four minutes. It must be kept in mind that persons who have used drugs often have a decreased production of oral fluid. This will most likely increase the time needed to collect sufficient oral fluid. This has to be accepted. It is a consequence of the use of specific drugs.
- The device can be equipped with a buffer solution to be added to the oral fluid sample.
- The oral fluid sample should be taken from the tongue and/or the mucous membranes in the mouth of the tested person.

9.2.5 Sufficient amount of oral fluid

- The device should preferably have an indicator that a sufficient amount of oral fluid has been collected. It is also acceptable to have a fixed period (e.g. one minute) to collect a sufficient amount of oral fluid with the collector.
- The amount of collected oral fluid should be sufficient to do the screening test.
- It is a benefit for the device if a sufficient amount of oral fluid can be stored in a reservoir in the device to be sent to a (forensic) laboratory for analysis.
- The sample for forensic analysis can be stored in the reservoir of the used screening device or a second sample should be collected and stored in a separate collection reservoir. Therefore it is required that a sufficient amount of oral fluid can be collected and stored. If it will be impossible to collect a sufficient amount of oral fluid for the forensic analysis of the sample another medium has to be used (blood, urine) depending on the policy in the member state.

9.2.6 Analysing oral fluid

- The analysing process of the collected oral fluid sample by the screening device should start as soon as the collecting process has been completed.
- The device should analyse the sample for the presence of at least cannabis, amphetamine, amphetamine analogues, cocaine and opiates.
- Analysing the sample for other substances (e.g. benzodiazepines) can be required depending on the prevalence of the abuse of these category of psychoactive substances by drivers of vehicles in specific member states.

9.2.7 Indications

- The device should provide a clear indication about the presence of one or more of the specific illicit substances. This indication can be given by the absence or presence of specific indication lines.
- An indication of the presence of a substance or substance group should be shown as the presence or absence of a specific indication line or as a text on a display.
- The device should give an indication that the test is completed by showing a control line on the device.
- The device should be sensitive for at least C-S-O: **C**annabis (THC), **S**timulants (Cocaine, Amphetamine, Methamphetamine and analogues) and **O**piates. (heroine, morphine)
- To read the indication in the most objective way it is preferred to use an electronic reading device. But apart from that it should also be possible that the police officer can read the indications on the device itself without an electronic reader.
- Electronic readers should be calibrated to ensure the proper reading of the indication lines. Periodically calibration rechecks of the reader must be performed.
- Indication lines or the absence of one or more indication lines should remain visible during at least three minutes after the control line is visible.

9.2.8 Operability

- It is preferred of course to use the device in situations where the light and weather conditions are good. Traffic law enforcement will be performed 24 hours a day on all days of the year. It is required that the device is capable to work under different operational conditions.
- The device should be able to work in a police truck or at a police station without other additional requirements than power supply. If the device is a one-way device (disposable) it should be possible to use the device at the roadside or in a patrol car.
- The sensitivity of an oral fluid screening device indicates the number of correct positive indications as a percentage of the total number of positive samples. This comparison is presented as a percentage. The higher the sensitivity the less persons *with a specific drug* in their system will remain undetected. Based on operational experiences in real life situations the sensitivity of an oral fluid screening device for the different substances should be 70% or more. This means that at least 2 out of 3 tests performed with persons having one or more specific psychoactive substances in their system should be detected by the device. The suspicion that a motorist has psychoactive substances in his/her system will primarily be based on the specific police observation of sign and symptoms of drug use of the stopped motorist. It is the opinion of the DPO's that a false negative indication of the screening device will be detected by the police officer if signs and symptoms of specific drug use are available. If the motorist has used other psychoactive substances that can not be detected by the device suspicion of the use of these other drugs that have a detrimental impact on driving behaviour will be based on the observations of the police officer.
- The specificity of an oral fluid screening device indicates the number of correct negative indications as a percentage of the total number of negative samples. This comparison is presented as a percentage. The higher the specificity the less persons *without a specific drug* in their system will be considered as suspected to have that specific drug or these specific drugs in their system. Based on operational experiences in real life situations the specificity of an oral fluid screening device for the different substances should be 70% or more. This means that at least 2 out of 3 tests performed with persons having no specific psychoactive substances in their system should be qualified as negative by the device. The suspicion that a motorist has psychoactive substances in his/her system will primarily be based on the specific police observation of sign and symptoms of drug use of the stopped motorist. It is the opinion of the DPO's that a false positive indication of the screening device can be detected by the police officer if no signs and symptoms of specific drug use are present. If the motorist has used other psychoactive substances that can not be detected by the device suspicion of the use of these other drugs will be based on the observations of the police officer.
- The accuracy of an oral fluid screening device indicates the number of *correct positive and negative indications* as a percentage of the total number of performed tests. This comparison is presented as a percentage. The higher the accuracy the less "mistakes" will be made by the police officer in validating the status of the tested person based on the indications on the screening device. Based on operational experiences in real life situations the accuracy of an oral fluid screening device for the different substances should be 75% or more. This means that at least 3 out of 4 tests performed with persons should provide a correct indication about the use of the specific drug. The conclusion whether a motorist has one or more psychoactive substances in his/her system or not will primarily be based on the specific police observation of signs and symptoms of drug use of the stopped motorist. The indication provided by the device can support the initial conclusion of the police officer. If the conclusion of the police officer and the indication provided by the device are not in line with each other the police officer will try to get a reliable indication by further observing the motorist for signs and symptoms of drug use and by raising questions to be answered by the motorist. Based on these extra information the police officer will obtain a more reliable indication about the status of the motorist related to drug use.
- It must be kept in mind that after implementing oral fluid screening in the Traffic Act of an EU member state police will have to use the devices in a prudent way. Testing motorists on an oral fluid screening device will most likely be restricted to times and locations where the likelihood of drugged driving is rather high. Apart from that police do already have specific knowledge and information about drug users. This means that the prevalence of tested drivers of vehicles with psychoactive substances in their system will be rather high. If police check motorists on a screening device after observing signs and symptoms of drug use the number of false positive results will be limited.

9.3 Documentation

Equipment to be used by police officers during daily enforcement activities should be accompanied by adequate documentation. This documentation can be a user manual, an instruction card, a CD Rom or a DVD demonstrating the proper use, storing and maintenance of the device. Most oral fluid screening devices are disposables and are able to detect very low concentrations of specific substances.
To enable this process it is absolutely necessary to follow the prescribed procedure in the proper way. As the device will be used under operational circumstances and as well at the roadside as in a police office there is a great risk of failures if the required procedure will not be respected.

9.3.1 User manual

- The manufacturer of an oral fluid screening device should develop a user manual describing the required procedure. Illustrations how to use the device should be part of the manual as well as a description of all parts of the device.
- The reliability of the screening device for the different substances based on documented studies should be presented in the user manual.
- The cut off levels for the different substances should be provided in the user manual as well as information about cross reactivity.
- Information about storing issues of the devices at the office should be included in the user manual. E.g. temperature, storing period etc.
- A list with do's and don'ts for operational use should be part of the manual.
- The manual should be written in the native language of the user or the languages of the member state.

9.3.2 Instruction card

- The manufacturer should provide an instruction card illustrating how to perform a test with the oral fluid screening device.
- Each step of the testing procedure should be described and shown together with the estimated time to perform each of the steps.
- The instruction card should be plasticised and have a size to be stored in the pocket of the uniform of the police officer if required or in the front locker of the police car. The text on the instruction card should be printed in the native language of the user or the languages of the member states.

9.3.3 CD ROM or DVD

- A CD ROM or DVD with a demonstration how to perform a test should be added.
- The text on the CD ROM or DVD should be (subtitled) in the native language of the user or being available in the languages of the member state.
- The CD ROM or DVD should not last longer than fifteen minutes.

9.3.4 Specific requirements for instrumental devices and readers

- Instrumental devices using electronic systems should be provided with a specific user manual. In this manual specific information about the use of the software has to be given together with information how to modify the settings of the device and how to dump data stored in the device to another computer system or to a USB data stick.
- An electronic reading device can be integrated in an instrumental device or can be added to a disposable screening device. Electronic readers should be described in the manual of the device or in a separate user manual that has to be a part of the electronic reader. In this manual specific information about the use of the reader and the software has to be provided together with information how to calibrate or check the calibration of the reader.
- Instrumental devices should be able to work on 12 V power as well as on 220V. Instrumental devices may be equipped with an own battery enabling at least fifty tests when completely loaded.

9.4 Summary

The most important police user requirements and specifications for oral fluid screening devices described in this chapter can be summarised in six main issues.

1. Easy to use

The device should be easy to use in police practice. This means that the training of officers to use the device should be simple and short with do's and don'ts.

2. Maximum acceptable time for testing process

The process of performing a test on a screening device should not take too much time. It is not realistic to compare the process time of an oral fluid test for drugs with a screening test on an alcohol device. In the requirements and specifications it is mentioned that the whole process of oral fluid sampling and analysis should not last longer than 15 minutes. A shorter period of course is appreciated. It must be kept in mind that the process time for the first alcohol screening tests also took up to 10 minutes to detect a certain amount of alcohol in a breath sample. With the actual oral fluid screening devices four or more different categories of psychoactive substances can be detected.

3. Hygienic aspects and waste

Oral fluid can be a source of infection and diseases. Safety at the workplace requires that police officers should be able to perform their task without risks of infection due to contact with all kind of substances including specimen of body fluid from motorists. Oral fluid can be a relevant source of infection. Therefore police officers should be able to work in a hygienic way with oral fluid screening devices. Also persons to be tested on the device should be able to do this in a hygienic and safe way. Best solution from a police perspective would be a test where the tested person can collect the sample himself/herself. The test will then be performed without interference from the controlling police officer. If the police officer has to work with the collected oral fluid sample and the analysing part of the device the use of protective gloves is required.

4. Privacy, discreet testing

The person to be tested on a screening device should be able to do this in a discreet way respecting his/her privacy.

5. Reading and detecting results

Reading results of performed tests on an oral fluid screening device can be done visually by the police officer. Indication lines should be clearly visual. Results can also be presented on a screen of an electronic reader.

6. Reliability

Results of an oral fluid screening test should have a certain accuracy indicating the number of correct positive and negative indications. A high accuracy indicates the reliability of the device for the specific substances. Based on operational experiences in real life at least 3 out of 4 tests performed with persons should provide a correct indication about the use of the specific drugs.
The conclusion of the police officer whether a motorist has psychoactive substances in his/her system or not will primarily be based on the specific police observation of signs and symptoms of drug use of the stopped motorist. The indication provided by the device can support the initial conclusion of the police officer. False negative and false positive indication will be unavoidable. Police can live with false negative results. No visible signs and symptoms and a false negative indication can be considered as a failure in the category "benefit of the doubt". False positive indications will/could lead to an arrest of the motorist for driving while influenced by specific psychoactive substances. In these situations the result of the forensic analysis of the sample will lead to the conclusion that the driver did not commit that specific offence.

10 Promising oral fluid screening devices to detect drugs of abuse

Relevant operational findings of tested devices				
	Average collecting time minutes, seconds	**Average analysing time minutes, seconds**	**% Successful analysis**	**Promising device**
01 Mavand RapidSTAT	2.30 / 2.00 (0.30)	11.00 / 7.00	77% / 93%	YES
02 Avitar Drugometer	3.00	3.00	62%	NO
03 Branan Oratect III	4.30 /3.00	5.30 / 6.00	67% / 89%	YES
04 EnviteC SmartClip	1.45	3.15	97%	NO
05 Innovacon OrALert	3.00	7.00	90%	YES*
06 Securetec Drugwipe 5+	1.00 / 1.30	5.10 / 4.30	98% / 98%	YES
07 Sun OraLine	2.30	8.30	73%	NO
08 Surescreen Drug Test	2.30 / 1.30	7.30 / 4.30	75% / 96%	YES*
09 Ultimed Salivascreen VI	5.00	8.00	57%	NO
10 Varian OraLab 6	3.50	7.20	80%	YES
11 Cozart DDS	2.00	6.00	99%	YES
12 Dräger Drug Test 5000	3.00	11.00	97%	YES
13 Biosensor BIOSENS	0.50	2.15	100%	YES

Table 10.1: Relevant operational findings of tested devices
* Innovacon OrALert and Surescreen Drug Test are similar devices.

During the practical evaluation of the thirteen oral fluid screening devices DPO's have been asked to give their opinion on the tests they performed. Each team has been asked to provide the task leader with an evaluation report for each brand of device that has been tested by the team. In November 2007 the first impression on the operability of the tested devices could be given based on the evaluations during the first six months as discussed and concluded during the first plenary evaluation meeting in Stein (NL) . Some of the tested devices were qualified as "promising". It has been advised to include these devices in the scientific evaluation of the oral fluid screening devices (DRUID task 3.2). This recommendation could not be the final conclusion as the practical evaluation of the first ten devices was still in operation. The practical evaluation of three new oral fluid screening devices would not start earlier than the beginning of 2008. During the second plenary DRUID evaluation meeting in October 2008 more final information about the operability of the devices tested in both phases of the ESTHER task has been given. Five devices tested during phase 1 have been recommended for scientific research for reliability. The three devices tested during the second phase have been recommended for this kind of research as well.
From an operational perspective the promising devices can be divided in three categories.

10.1 Screening devices to be used everywhere without specific requirements

These kind of devices can be used at the road side by every police officer independent of kind of vehicle the police officer is using. In practice these are devices that can be used 24 hours a day 7 days a week on all kind of locations during all kind of law enforcement activities. On this category five screening devices are nominated by the DPO's. The five devices in this category are Branan Oratect XP, Innovacon OrALert, Securetec Drugwipe 5+, Varian OraLab 6 and Cozart DDS.

10.1.1 Branan Oratect XP

This device has been improved after the evaluation at the end of the first part of phase 1.
In the second part of phase 1 the improved device has been tested on the modifications.
Five operation-based modifications have been realised.

1. 4 panel test. (THC, Cocaine, Opiates, Methamphetamine/MDMA)
2. Single strip. The Oratect 4-panel has a single test strip.
3. A smaller amount of oral fluid is needed. (0,27 ml vs. 0,55 ml).
4. Decreased indication time. (Reduction by approximately 50%).
5. Oravue Reader. An optional reader (Oravue Reader)

10.1.2 Innovacon OrALert

This device has been tested during the first phase and has not been modified afterwards.

10.1.3 Securetec Drugwipe 5+

This device has been improved after the evaluation at the end of the first part of phase 1 by providing the device with a reader device.

10.1.4 Varian OraLab 6

The device has been improved after the end of phases 1 and 2 and an improved device has been presented at the second plenary ESTHER evaluation meeting on October 15, 2008.

10.1.5 Cozart DDS

This device has been tested during the second phase.

10.2 Screening device to be used in specific police vehicles

In this category two devices are mentioned requiring more specific conditions. These devices can be defined as instrumental devices. They require specific conditions to realise a successful test. Tests on these devices require a fixed location sometimes power supply and rather good light conditions to perform a test and an analysis. It is possible to perform the test under less good conditions but the result could be a decreased percentage of successful tests. Performing the test outside of a (specific) police vehicle could be more complicated.
The two devices in this category are Mavand RapidSTAT and Dräger Drug Test 500.

10.2.1 Mavand RapidSTAT

This device has been improved after the evaluation at the end of the first part of phase 1.
Four operation-based modifications have been realised.

1. New collecting device. (micro fibre). Improved collecting time (30 seconds)
2. Improved Visibility/Readability of the lines. Negative lines form stronger and faster.
3. Integration of the different parts of the device (all-in-one).
4. Improved hygienic aspect. Redesigned incubation device.

10.2.2 Dräger Drug Test 5000

This device has been tested during phase 2 and has not been modified afterwards.

10.3 Screening devices to be used during mass events with high testing capacity per hour to be used at police stations or mobile police offices.

In this category just one device has been tested and qualified as promising. With this device it is possible to test up to approx. 17 persons per hour. This can be an advantage if motorists leaving a parking area after visiting a mega dance party or a music festival should be checked for drugged driving. It must be kept in mind that public order and safety as well as mobility at the end of these kind of parties and festivals will limit the possibilities to check a substantial number of motorists. Therefore a selection of potential drugged drivers should be made to avoid queues.

10.3.1 Biosensor BIOSENS

This device has been tested during phase 2 and has not been modified afterwards.

11 Outline of legislation for drugs and driving from a police perspective

In chapter 4 of this report the legal situation related to drugs and driving in the EU member states where ESTHER teams have been active in testing oral fluid screening devices has been described.
The legal situation in these member states can be divided in two main systems.

- Member states with an impairment approach for drugs and driving.
- Member states with next to the impairment approach also have a kind of zero tolerance approach for specific drugs.

A third possibility would be a system with a zero tolerance for all psychoactive drugs (illicit drugs, medical drugs) next to an impairment approach for all other psychoactive substances (e.g. glue). The guarantee for a fair trial in case of a drugged driving offences should be similar to the already existing guarantee for drink driving offences. In this chapter an outline of the legislation from a police perspective is given. This outline is not based on the operational tests with the screening devices. The content of this chapter is based on the legal systems in the 6 EU member states and on the legal system in different states in Australia. The information on the Australian system has been presented during the ICADTS conferences in 2007 in Seattle.
During the operational testing of the oral fluid screening devices ESTHER teams have worked within the framework of their own national legislation. Two plenary evaluation meeting with all team leaders and team members has been held in the Netherlands (Stein, June 5 – 7, 2007 and Landgraaf, October 14 – 16 October 2008). During these two plenary meetings of the ESTHER teams team leaders and DPO's have discussed about the desired legislation related to drugs and driving from an operational police perspective. Conclusion of this discussion was that the national Road Traffic Act in the six EU member states needs to be modified. The existing legal system in Australian states – especially the state Victoria – is used as an example of how to improve the national Traffic Act in the six EU member states. Australian states have specific legislation on drugs and driving. Information from police forces in Victoria, New South Wales and Queensland has been collected. A draft of a proposal for a legal system has been developed based on the legal systems in Victoria, New South Wales and Queensland Australia. The draft has been used as starting point for the discussions during the two plenary evaluation meetings. The discussion has been focussed on legislation from a police perspective with possibilities to advice on a legal system from an European TISPOL perspective. Conclusions of discussions during these two meeting have been presented in several meetings of the TISPOL alcohol an drugs working group as well as during the plenary TISPOL council meeting in Berlin May13, 2009. Agreement has been achieved on the proposed recommendations for a legal system for drugs and driving. These recommendations are provided from a police perspective.
Governments developing new policy on drugged driving will be informed by several governmental and non-governmental organisations. The advice for new legislation from an police perspective is strongly operation-oriented. The legal system that will be acceptable for a member state should be in line with the legal history of that state and the acceptability of the proposal by the national parliaments, judges and other legal authorities. Public support for a legal proposal is essential too. It is recommended by the ESTHER teams and by TISPOL to include these police recommendations in the preparation of a legal system to reduce driving a (motor) vehicle while influenced by the recent use of psychoactive substances. Mid 2009 Belgium accepted an improved legal system to prevent drugged driving. A lot of issues mentioned in this chapter have been implemented in the new Belgian legal system.
The discussion during the plenary evaluation meetings and the police recommendations based on the discussions are divided into six main categories

1. *Illicit substances*
   The use of illicit drugs in society is increasing. Cannabis is the most popular illicit drug in most EU member states. Often cannabis users are drivers of vehicles. Often cannabis is detected in the system of motorists stopped and checked by the police or motorists involved in traffic accidents. Apart from cannabis other illicit drugs are used by drivers of vehicles as well. It is well known that the use of illicit drugs decreases to possibilities to drive a vehicle in a safe and prudent way. There is no need from a medical perspective to use illicit drugs to have a better, more safe performance in road traffic. That is why, from a police perspective, driving a vehicle with psychoactive substances retrieved from illicit drugs in the system of the driver should be forbidden. Next to illicit drugs certain other substances can have a similar impact on driving behaviour. (Glue, poppers).
2. *Medical drugs*
   Some medical drugs have a detrimental impact on road safety.

These drugs are prescribed by doctors as treatment for a specific illness or disease. Next to the drugs prescribed by a doctor some substances can be bought over the counter in a drugstore. These substances can have a similar effect on driving behaviour and performance as specific drugs of prescription. Using these kind of drugs in the prescribed way normally will only have a temporary or minor effect on performance and driving capability. These substances however will have a severe impact when misused or used in combination with specific other substances.

3. *Police power*
   In most EU countries police can check drivers of vehicles on the use of drugs if there is a suspicion. For alcohol most EU member states have given the police the power to check drivers of vehicles at random without any suspicion. From a road safety perspective alcohol and drugs have a similar negative effect on road safety. From this perspective the police should have the possibility to check any driver of a vehicle on the use of drugs at random. Due to the high costs and the time required to do an oral fluid screening test this power will be used by police forces in a prudent way, comparable to the introduction of the first (expensive) alcohol screening tubes.
4. *Screening*
   For screening purposes an operational acceptable oral fluid screening device is preferred.
5. *Evidence*
   For evidence the analysis of an oral fluid sample by an appointed forensic laboratory is preferred.
6. *Drivers licence*
   A drivers licence is considered as a privilege and a permission for drivers of motor vehicles. The government has the authority to withdraw the drivers licence if the owner of the licence does not respect specific rules prescribed by the government.

11.1 Illicit substances and zero tolerance

Every now and then producers of illicit drugs are developing new psychoactive drugs. Amphetamine analogues are good examples. But also other products like certain mushrooms or volatile substances like glue, cleaning products and other substances can be abused and will have a detrimental impact on reaction and driving behaviour. It will be very difficult to bring all these substances under the regime of a specific article in the national traffic act. From a police perspective the approach for the legislation should have two main lines. The first approach should deal with known illicit substances. In this approach a zero tolerance should be prescribed in the national traffic act. The second approach should deal with those psychoactive substances not – or not yet – mentioned in the (inter)national conventions or laws but from which it is known that these substances are sniffed, smoked, inhaled, injected a.s.o. For these substances, mostly not mentioned in the Traffic Act, an impairment approach is required. Several issues on illicit substances and zero tolerance are relevant.

- All Illicit drugs are psychoactive substances and do have an influence on the capability to drive a vehicle or operate machines in a safe way.
- The use of illicit drugs increases the risk to cause or get involved in a traffic accident.
- From a medical perspective there is no need to use illicit drugs.
- In the national traffic act of a member state it should be stated that it is forbidden to drive a vehicle when “any detectable amount” of an illicit drug is active in the system of the driver of a vehicle.
- Therefore a zero tolerance for illicit drugs must be the approach in road traffic and road safety and consequently in the (national) Road Traffic Act.
- Illicit drugs are those substances mentioned in the annex of the 1961 Single Convention on Narcotic Drugs (New York) as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs of 1961, The 1971 Convention on Psychotropic Substances and the 1988 UN Convention Against Illicit Trafficking of Narcotic Drugs and Psychotropic Substances and substances mentioned in the national legislation on illicit drugs.
- Some drugs mentioned in the annex of the conventions and legislation above might be prescribed by medical specialists for treatment of patients. Some patients might have the practical possibility to drive a vehicle. In these rare situations the substance is not considered as illicit from a road traffic perspective. The prescribed use of the drug should however be on a therapeutic level.
- Driving a vehicle with other substances that can have a detrimental impact on reaction time, coordination, divided attention and driving behaviour is forbidden if the driver is not capable to drive the vehicle in a safe way. This suspicion can be based on observed driving behaviour or a kind of drug recognition evaluation by a police officer. (impairment approach)
- A driving instructor as well as the student-driver are considered as equal parties for the regulation on alcohol and drugs in the traffic act.

11.2 Medical drugs and concentrations

A number of psychoactive substances are prescribed by medical doctors as a treatment for patients with a specific illness or disease. These so-called drugs of prescription can have a detrimental impact on driving capability of the patient. These prescribed medication always have to be provided to the patient together with the specific label with information about the influence of the medication on driving performance. The advice on the label should be respected. Not all drugs of prescription do have such psychoactive effects. In DRUID WP 4 a classification of drugs of prescription will be developed.

- Some drugs of prescription (registered medicines) are or contain psychoactive substances.
- Using these medicines by drivers of a vehicle can increase the risk to cause or get involved in a road traffic accident.
- For certain patients under treatment of a medical doctor there is a medical need to use one or more of these registered medicines.
- The single use of these medicines at a therapeutic level will not automatically endanger road safety when used by the driver of a vehicle.
- Driving with these registered medicines can normally be allowed. It is required that the driver can give evidence (recipe) that the medicines are prescribed by the medical doctor who treats his/her illness, that the driver is using this medication according to the prescribed recipe and that the driver does not show signs or symptoms of impairment caused by the use of these registered medicines or other substances.
- Drivers of vehicles with registered psychoactive medicines in their system, unable to present a medical recipe for this medicine, should automatically be considered as users of illicit drugs.
- A driving instructor as well as the student-driver are considered as equal parties for the regulation on alcohol and drugs in the traffic act.

11.3 Police power to check motorists

Police have the authority and task to enforce rules provided in the national traffic act. Therefore the police have been given specific authority and tools to check road users on the proper use of the infrastructure and vehicles and on their driving behaviour. Police have the authority to stop a vehicle to check the driver and the vehicle. The driving licence, the car registration documents and the technical status of the vehicle can be checked without any suspicion. In most EU member states the police have been given the authority to stop a driver of a vehicle and to check the driver on his alcohol consumption. For illicit substances this power is given in a limited form. Most member states allow police to check a driver of a vehicle on the use of drugs if signs and symptoms of drug use or impairment are present or if they have such a suspicion. Only in very specific situations – e.g. a traffic accident – some member states have given the police the authority to check the drivers involved for the use of psychoactive drugs. This power is considered as a “post-crash” power of the police. For road safety purposes it is required that the police will have similar power in the “pre-crash” phase.

- Police have been given or should have the power to check any driver of a vehicle for his capability to drive a vehicle in a safe way.
- Police have been given the authority to check any driver of a vehicle for the consumption of alcohol. Therefore an appointed alcohol screening device will be used.
- Police have to be given the authority to order any driver of a vehicle to perform a test on a screening device to check if there is a suspicion that illicit drugs are present in his/her system.
- Refusal to perform the screening test for alcohol is an offence.
- Refusal to perform the screening test for psychoactive substances should also be an offence.
- A screening test for alcohol will be performed by taking a breath sample of the driver.
- A screening test for other psychoactive substances than alcohol can be performed by checking a sample of body fluid from the driver. The sample of body fluid can be an oral fluid sample, an urine sample, a sweat sample or a bloodspot sample. From a practical and police perspective an oral fluid screening test for other substances than alcohol is preferred. Oral fluid testing is the less invasive form of testing.
- In situations where the driver is unable to actively cooperate at the screening test the police should be authorised to collect an oral fluid sample or a sweat sample for screening purposes. As soon as the driver is able to express his/her will permission to use the collected sample this permission will be asked. Refusal to give this permission should be an offence.

11.4 Suspicion based on the result of a screening test

In some member states the result of a screening test can be used by the police. This is one of the elements to be used as a base for the suspicion that a driver of a vehicle has psychoactive substances in his/her system. In most situations a number of reaction, coordination and divided attention tests will/must be performed. The results of these tests together with the result of a screening test can lead to a situation where the police officer can conclude that he suspects the driver to have psychoactive substances in his/her system. This procedure is very time consuming. The screening test will normally last less than 10 – 15 minutes. The reaction, coordination and divided attention tests can last 30 – 60 minutes depending on the status of the driver. Performing these behavioural tests required well trained police officers. In a number of members states some relevant tests can only be performed by medical doctors e.g. measuring body temperature, pulse frequency and blood pressure. The medical doctor who would perform these tests could refuse to provide these data to the police. He could consider these data as medical data and therefore for medical use only. This kind of data however can give relevant clues upon which the suspicion of the police officer can be based. This behaviour of a medical doctor could reduce the possibilities of enforcement. This enforcement procedure is comparable to the policy followed at the drug recognition evaluation in many of the United States of America. Doing a screening test and a drug recognition evaluation to get suspicion of drugged driving has two important disadvantages.

1. Police officers must be trained to perform a drug recognition evaluation. In the US these drug recognition experts are trained during 10 days (2 days PRE DRE school, 7 days DRE school and 1 day for evaluation). A DRE has to be re-certificated every year after performing a required number of successful evaluations. In the US approx. 5000 DREs are operational.
2. The time needed to conclude that a driver of a vehicle is a suspected person will be 40 – 75 minutes if the persons is capable to perform the tests. For foreign drivers it will be very difficult to understand the instructions given by the police officer to perform other tests than an oral fluid screening test. Communication between a police officer and the driver of a vehicle can be very difficult if both persons do not speak a common language. This is a less known problem in the US. They (can) communicate in their native language in most of the cases. Sometimes speaking Spanish is required .

Based on these facts and the experiences during tests with oral fluid screening devices by the ESTHER teams in the six EU member states the impairment tests does not have a added value in situations where drugs are used that can be detected by a(n oral fluid) screening device. Not all drug users will always show signs of impairment. The observations of the police officer will always be the first indications of drug use and will be compared with the indications of the screening tests. If these two indicative results are not in line with each other the police officer will try to get a proper indication about drug use by interviewing and further observing the controlled driver of the vehicle. Only in situations where other illicit and other substances are used the suspicion will have to be based on performance and reactions of the driver. In practice this will most likely be a minority of the controlling activities of the police related to drugs and driving.

- From a police perspective suspicion of driving a vehicle with illicit substances in the system should be based on the result of the screening test performed by the driver. Therefore one or more screening device have to be appointed in the national traffic act. Screening devices to detect psychoactive drugs in the system of a driver can be based on oral fluid, urine, sweat or blood.
- Suspicion can also be based on the refusal to cooperate at the screening test for drugs if just one sign or symptom of possible impairment is present and observed by the police officer.
- For the suspicion of having psychoactive substances in the system of a person there should not be a difference between a person who is driving a vehicle or a person who is getting ready to drive a vehicle.
- Suspicion of driving a vehicle with psychoactive substances in his/her system that can not be detected by a prescribed screening device can also be based on signs and symptoms of impairment or indications of drug use..
- Signs and symptoms of impairment and indications of drug use can be observed by the police officer.
- Suspicion of abuse of drugs of prescription (= use of illicit drugs) should be based on the absence of a medical prescription for use.

11.5 Additional suspicion

Apart from checking stopped motorists for routine checks police can observe inefficient driving behaviour during normal and specific surveillance. Therefore specific techniques and police vehicles can be used. On the other hand police do have specific knowledge of the attitude of persons living in the specific area or region where the police officer is working. Police officers are familiar with specific locations, times and problems in their working area/region. They know where to pay attention to specific kind of behaviour or offences committed by specific persons or groups at a specific time. Based on this kind of intelligence police surveillances can and will be focussed. This Intelligence Led Policing can also be focussed on drugged driving. For the police two conditions must be fulfilled.

1. Drugged driving is recognised as a serious road safety problem.
2. Enforcing the specific article in the national traffic act can be done in an efficient way.

- Police officers can get suspicion that a person is driving a vehicle with psychoactive substances in his system based on observed driving behaviour or on video observation by the police for traffic and other purposes.
- Suspicion of driving with psychoactive substances can be indicated by specific knowledge of the police about the drivers' addiction to drugs.
- Suspicion of having used illicit drugs can also be based on the location and the time where the persons was stopped by the police. (Near "coffee shops", "drugs houses" or other areas of drug use, "hang outs", locations where people come together for "after parties" etc.)

11.6 Evidence of drugged driving

Evidence of drugged driving is given by the analysis of a blood sample by an appointed laboratory. The analysis of the blood sample is done according to the methods of analysis as prescribed in the national legislation on drugs and driving. The results of the analysis will be a statement of the laboratory providing information about the presence of relevant substances and/or metabolites in the examined blood sample and their concentrations. The results of the analysis of the sample is sufficient to be used as evidence. Complicating issue in this procedure is to collect a blood sample. Taking a blood sample is an activity to be performed by a medical doctor. Normally no medical doctors are at the location where the suspected driver is stopped and checked. Therefore a medical doctor must be invited to come to a certain location to take a blood sample and to perform a short medical diagnosis. This procedure is very expensive and time consuming. A period of up to one hour can be required from finding/calling a medical doctor till the moment the blood sample has been taken. It would be very efficient to replace the blood sample by an oral fluid sample to be analysed for drugs. This would mean that the presence of a medical doctor is no longer required. This is comparable to the breath analysis procedure for alcohol. This would mean an enormous time benefit from at least 30 minutes up to more than one hour. Saving costs as no blood samples have to be collected would mean saving of materials up to € 25,- for each evidential sample and up to € 325,- costs for the medical doctor for each blood sample. Costs for the sampling and storing of an oral fluid sample will be just a few Euros (less than € 5,-). Therefore from a police perspective evidence of drugged driving should preferably be realised by the analysis of an oral fluid sample. This procedure is already daily practice in different states of Australia. A similar legal proposal is now (mid 2009) adopted by the Belgian government.

- The evidence of driving a vehicle with psychoactive substances is preferably given by the analysis of an oral fluid sample from the driver.
- An appointed laboratory will analyse the oral fluid sample according to the prescribed method.
- The result of the analysis is the presence of a psychoactive substance in the examined oral fluid sample.
- For a selected number of substances the result of the analysis is the measured concentration of a specific psychoactive substance or substances in the examined oral fluid sample.
- The result of the analysis can be accompanied by a statement of the toxicologist about the presumed status of the donor at the moment of sampling the oral fluid. This can be required in situations where a specific substance is detected and measured or when a special combination of different psychoactive substances are measured.
- The costs of the analysis of the oral fluid sample and the costs of the blood sampling and analysis of that sample should preferably be costs for the suspected driver if the result is that psychoactive substances are found in the sample (oral fluid or blood) of the driver.

11.7 Alternative evidence

Specific situations or the status of the suspected driver may lead to the conclusion that for medical reason taking an oral fluid sample from this person is unwanted or impossible. This might be the case in situations where the suspected driver is unconscious, severely injured, in a life threatening situation etc. Some diseases cause a dry mouth. In these situation taking an oral fluid sample for analysis can be replaced by taking a blood sample as an alternative medium. The analysis of the blood sample will only be performed after the suspected driver is formally asked or ordered to give his permission to take a blood sample. Refusal to cooperate at the sampling of the blood sample is a major offence.

- If for medical reasons collecting an oral fluid sample of the suspected driver for forensic analysis is not possible the driver should be asked to give a blood specimen to be analysed.
- If the suspected driver does not cooperate he will be ordered to provide a blood sample.
- If the suspected driver is unable to express his will due to his medical situation a blood sample should be taken and he/she should be asked, or if needed ordered, to give his permission for the (already realised) blood sampling. If the suspected driver refuses to give his permission the sample will be destroyed.
- Refusal to provide a blood sample to be analysed for drugs should be a major offence.
- The blood sample should be taken by a doctor or a registered nurse if the suspected driver has stated that he/she will cooperate.
- The blood sample of the suspected driver will be sent to the (forensic) laboratory to be analysed for the presence of drugs. (illicit drugs as well as drugs of prescription).
- If for medical reasons a blood sample can not be taken from the suspected driver a urine sample will be taken and will be sent to the laboratory for analysis.
- Evidence of driving while impaired can also be based on the observations of the police officer without the analysis of a specimen of body fluid. In those situations it will be the task of the police officer to describe in a detailed way what observations are made by him and what other facts and circumstances have led to the conclusion of the arresting officer that the suspected person has psychoactive substances in his system and that he/she is unfit to drive due to these substances.

11.8 Contra expertise

It is the right of a suspect to ask for a contra expertise if an oral fluid, a blood sample or a urine sample has been taken to be analysed for substances. This is comparable to the possibilities for contra expertise in case of the analysis of a blood sample for the presence and concentration of alcohol. The sample for contra expertise should be provided immediately after the collection of the first sample. The suspected driver will have to give the order that a contra expertise of the sample should be performed at his/her costs. The government will have to select laboratories that are appointed to do these contra expertise according to the prescribed method(s) of analysis. The results of the analysis will be sent to the address provided by the suspected driver.

- The suspected driver has the right to let an appointed laboratory analyse the fluid specimen (oral fluid, blood, urine) as a contra expertise.
- The police will ask the suspected driver if he wants to have an specimen of the collected sample (oral fluid, blood, urine) to be used for analysis as a contra expertise. If so the suspected driver can be asked to provide another specimen of the collected body fluid in case the collected first sample seems to be too small to be divided into two samples.
- The police will provide the driver with a list of appointed laboratories for contra expertise.
- The order to analyse the sample as a contra expertise must be given by the suspected driver to the forensic laboratory and the laboratory chosen to perform the contra expertise.
- The costs for such a contra expertise have to be paid by the suspected driver. Therefore costs must be paid in advance or a guarantee must be given to that laboratory.
- The oral fluid sample and if relevant the extra sample for contra expertise will be sealed and packed by the police and will be sent to the appointed laboratory where the sample will be analysed according to the legal procedure. The suspected driver can order the laboratory chosen by him to contact the laboratory where his sample(s) are sent to by the police. Requests from the chosen laboratory will be realised if the suspected driver has sent a request for that to the first laboratory.

11.9 Temporarily disqualification

After all the legally required activities have been completed the suspected driver is mostly free to continue the trip. As the suspected driver was considered as being unable to drive the vehicle in a safe way he will get a temporarily disqualification for the time that this status will remain if no other substances are consumed. For drivers of vehicles with alcohol in their system a similar policy is followed. There is insufficient knowledge about the time needed to recover from the use of a specific drug and to be able again to drive a vehicle in a safe way. The amount of drugs used by the driver, the setting of the consumption and the experiences of the driver with the consumption of drugs are relevant – but unknown – factors. A great deal of suspected drivers might be multi-users. This makes it even more complicated to give an estimation of the time needed to recover after being stopped by the police. Therefore the time period for the temporarily disqualification will be dependent from the observations of the police officer. Similar to alcohol the maximum period for the temporarily disqualification should be 24 hours. Depending on the actual situation observations and detected psychoactive substance(s) at the oral fluid screening test the police officer can conclude that a shorter period for the temporarily disqualification will be sufficient. It is the policy of – at least – one member state to retest a person who has been given a temporarily disqualification at the end of this temporarily disqualification. From a safety perspective this is a good countermeasure but implementing this policy has a lot of operational consequences for the police force. Therefore this specific policy aspect should not be recommended on a EU level but could be an issue for the national policy.

- Persons suspected of driving with drugs in their system should get a temporarily disqualification to drive for the time that the status of being influenced by the used drug will continue to exist.
- The time period of the temporarily disqualification can last up to 24 hours, depending on the specific drug(s) used by the suspected driver.
- Ignoring a temporarily disqualification should be qualified as a major traffic offence.
- After the end of the disqualification time the person could be retested on a screening device to be sure that psychoactive drugs are no longer active in the system of the person.

11.10 Driving licence

Making a protocol against persons driving a motor vehicle with psychoactive substances in their system is a part of the criminal law procedure. These persons will be sent to a criminal court and will be punished according to the criminal law by a judge. Punishment for this kind of criminal offences can be a fine, a disqualification for a certain period or a sentence.
Next to this criminal law approach an administrative law approach will be followed in qualified cases of driving a vehicle with psychoactive substances in the system of the driver. The Minister of Transport, responsible for the driving licence policy has the power to order a driver of a motor vehicle suspected of driving with these substances in his system to be retrained to get more familiar with the do's and don'ts in road traffic. This policy is not only followed for persons with alcohol and drugs in their system while driving but also for risky and un-responsible driving behaviour in general.
For alcohol and drugs a more severe countermeasure is possible. Persons suspected to be addicted in any way to alcohol or drugs can be tested for their suitability or capability to drive a motor vehicle or can be retested or retrained. Their drivers licence could be withdrawn based on a medical, psychological or other examination.

- Police will report persons who are suspected of driving with illicit drugs in their system to the national Minister of Transport to start a procedure for administrative withdrawal of the driving licence.
- For administrative withdrawal of driving licences member states already have a national policy. Harmonisation of this procedure and policy on an EU level is required and advised from a police perspective.

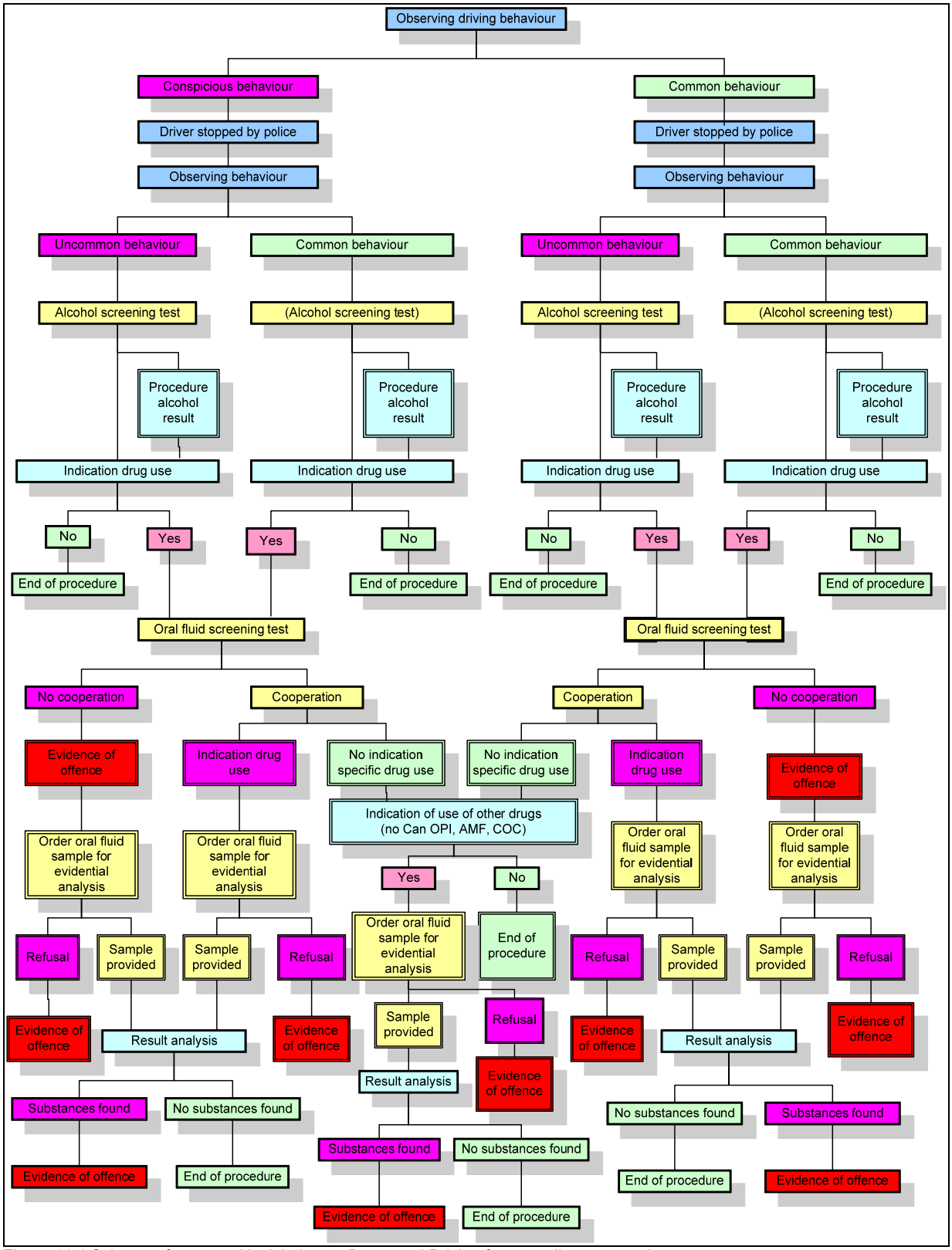


Figure 11.1 Scheme of proposed legislation on Drugs and Driving from a police perspective

In figure 11.1 the operational main police procedure linked to the proposed outline of legislation on drugs and driving as described in this chapter is presented in the scheme. Based on the experiences during the operational testing of oral fluid screening devices from a police point of view this outline of legislation will be most efficient and effective to reduce driving under the influence of alcohol and other psychoactive substances.

12 Developments on oral fluid screening

Since January 2008 manufacturers of oral fluid screening devices have developed their devices according to evaluations in their own R&D department as well as in practical experiments performed in police forces in Europe and abroad.

The group of manufacturers can be divided into three main groups.
1. Participating manufacturers in phase 1 or 2 of the ESTHER task.
2. Manufacturers that had to withdraw from activities in the ESTHER task.
3. Other/New manufacturers of oral fluid screening devices for drugs

12.1 Manufacturers participating in the phase 1 or 2 of the ESTHER task

Manufacturers of the devices tested during phase 1 and 2 of the ESTHER task have more or less made benefit of the experiences and further developed their devices or decided to quit their activities.

12.1.1 Mavand

Mavand Solutions GmbH modified the RapidSTAT device after the end of Phase 1 part 1. The improved device has successfully been tested in the second part of Phase 1. In November 2008 Mavand Solutions GmbH stated that further improvements of the device might be expected in 2009.

12.1.2 Avitar

Avitar Inc. ended their activities in 2008. Parts of Avitar are embedded in the Innovacon company. It is not expected that the DRUGOMETER will be developed any further by Innovacon Inc.

12.1.3 Branan

Branan Medical Corporation modified the Oratect III device after the end of Phase 1 part 1. The improved device – Oratect XP - has successfully been tested in the second part of Phase 1. The company developed also an electronic reader. This reader has not been part of the evaluation activities during the second part of phase 1. Up till November 2008 no further improvements have been reported by Branan Medical Corporation.

12.1.4 EnviteC

EnviteC-Wismar GmbH participated in Phase 1 part 1. They did not modify their device in the proper time to be able to participate during the second part of Phase 1. In December 2007 EnviteC stated that including THC in their device would be part of a study and the results of this study would not be available before summer 2008. Mid 2008 EnviteC decided to stop the development of the SmartClip.

12.1.5 Innovacon

Innovacon Inc. participated in the first part of Phase 1 of the ESTHER activities. The company did not modify or improve their OrALert device afterwards. In November 2008 no new developments on the OrALert device could be reported.

12.1.6 Securetec

Securetec Detektions-Systeme AG participated in the first part of Phase 1 and provided a new reading device for testing in the second part of Phase 1. In 2008 Securetec presented an improved device. Securetec stated that with this device the sensitivity for cannabis would be 3 times higher. The device is already available for testing. No tests with the new device have been performed in the ESTHER task. The device was presented at the exhibition of the 4th European Expert meeting "Drogenerkennung beim polizeilichen Einschreiten – quo vadis?" on November 4th 2008 in Saarbrücken (Germany).

12.1.7 Sun

Sun Biomedical Laboratories Inc. participated in the first part of phase 1. During the interim evaluation of this device during the first ESTHER evaluation meeting in Stein (NL) modifications of the device were suggested. Sun started to modify the device according to the recommendations provided during that meeting. In November 2008 during the second ESTHER evaluation meeting in Landgraaf Sun presented the OraLine 8. In this device a great deal of recommendations provided by the ESTHER teams were realised. The OraLine 8 could not be tested during the ESTHER activities. The OraLine 8 was also presented at the Medica exhibition in November 2008 in Düsseldorf (Germany).

12.1.8 Surescreen

Surescreen Diagnostics Ltd. did not modify their Oral Drug Test since the end of phase 1 of the ESTHER activities. They improved their electronic reader. This reader could be tested during the second part of phase 1. Mid November 2008 during the Medica exhibition in Düsseldorf Surescreen provided information that they are improving the electronic reading device.

12.1.9 Ultimed

Ultimed Products GmbH did not modify the Salivascreen VI since the end of phase 1 of the ESTHER activities. It is known that Ultimed is developing their drugs screening products further. Also based on the experiences of the ESTHER teams. In February 2009 Ultimed Products GmbH showed a prototype of a new device: The Saliva Direct Cup Oral Fluid Drug test. This new device has not been tested by the ESTHER teams.

12.1.10 Varian

Varian Inc. presented an improved OraLab+ device during the second ESTHER evaluation meeting in Landgraaf in November 2008. This device has some clear practical advantages compared to the OraLab 6 device. The OraLab+ device has not been tested during the ESTHER activities. There is a close cooperation between Varian and Dräger. Varian represents Dräger and their oral fluid screening device in the USA. Dräger represents Varian and their oral fluid screening device in Europe.

12.1.11 Cozart

Concateno plc consists of a number of companies. One of these companies is Cozart. Cozart did not improve their DDS device since the testing activities in phase 2 of the ESTHER activities in 2008.

12.1.12 Dräger

Dräger Safety AG &Co KGaA did not improve their Drug Test 5000 device since the testing in Phase 2 of the ESTHER activities in 2008. In November 2008 at the Medica exhibition in Düsseldorf Dräger stated that they will further develop the Drug Test 5000 to make the device smaller and also shortening the process of analysis of the oral fluid sample.

12.1.13 Biosensor

Biosensor Application Sweden AB did improve their BIOSENS device since the testing in Phase 2 of the ESTHER activities in 2008. The device to collect an oral fluid sample has been improved as recommended during the evaluation in phase 2 of the ESTHER activities. The improved collecting system and the BIOSENS device has been presented at the exhibition of the 4th European Expert meeting “Drogenerkennung beim polizeilichen Einschreiten – quo vadis?” on November 4th 2008 in Saarbrücken (Germany).

12.2 Manufacturers who had to withdraw from activities in the ESTHER task

Three manufacturers of oral fluid screening devices showed their interest to participate in the practical evaluation of oral fluid screening devices for drugs. For various reasons these manufacturers have not been able to present a device in such a state of development that including their device(s) in the first or second phase of the ESTHER task. In this paragraph these three manufacturers and their devices are mentioned.

12.2.1 Lion

Lion Laboratories has been one of the manufacturers with the intention to be included in the testing activities during the second phase of the ESTHER activities. Unfortunately Lion had to withdraw from this activity as their device was not ready for testing at a proper time.
In December 2008 the situation was unchanged. Lion is still working on developments but it is unknown when their screening device will be available for evaluation in police practice or in scientific studies.

12.2.2 Oxtox

Oxtox Limited is a British company, a platform technology company devoted to the sensing of drugs.
Oxtox' core technology was invented by Oxford University's Department of Chemistry. Oxtox is developing the Drugsensor. At the start of phase 2 of the ESTHER task Oxtox had to withdraw from the evaluation as the device was not in a stage of development that would make testing successful. Unlike most of the other devices Drugsensor would not use immunoassay technology. The Drugsensor uses electrochemistry. It is unknown if a prototype of this device will be available for evaluation during the lifetime of the DRUID project.

12.2.3 Heriot Watt

The Technology & Research Services of the Heriot Watt University in Edinburgh has been developing an oral fluid screening device in 2007. Unfortunately they have not been able to provide a device to be evaluated during the second phase of testing in the ESTHER task.
In December 2008 the device was still in a stage of development. It is unknown if a prototype of this device will be available for evaluation during the lifetime of the DRUID project.

12.3 Other/New manufacturers of oral fluid screening devices for drugs

The requirement to develop reliable oral fluid screening devices is clearly visible. In European countries as well in America and Asia.
Manufacturers all over the world started to develop these kind of screening devices. Since 2007 a number of new manufacturers have presented themselves. Some of these manufacturers were able to express their willingness to contribute to the activities in the ESTHER task. At the end of the operational ESTHER activities devices of 13 manufacturers have been evaluated. Their results are presented in this report. After the end of the second phase of the ESTHER task an inventory has been made of those new manufacturers who did not participate in the ESTHER evaluations or had to withdraw from these activities. Making an inventory like that requires an survey on the internet and information from relevant exhibitions. In November 2008 the Medica exhibition was held in Düsseldorf. At this exhibition new and up till then unknown companies presented their products for a medical market. Some of the companies present at this exhibition (also) presented oral fluid screening devices for drugs. In this paragraph these companies and the headlines of their products are presented.

12.3.1 Alfa Scientific Designs Inc.

Alfa Scientific Designs, Inc. is a manufacturer of in-vitro diagnostic devices. Alfa specializes in rapid immunoassays for the detection of drugs of abuse. At the Medica exhibition they presented a five panel oral fluid screening device (Amphetamine, Benzodiazepine, Cannabis, Cocaine and Opiates) and a three panel test (Cannabis, Cocaine and Opiates).

12.3.2 BioSino Bio-technology and Science Inc.

BioSino Bio-Technology and Science is a clinical diagnostic company in Beijing China. The company develops and manufactures clinical chemistry reagents. Their products include one-step rapid test kits and immunology reagents kits. They produce an Oral Rapid Cassette test for morphine/heroine.

12.3.3 InTec Products Inc.

InTec Products Inc. is committed to providing a wide range of products and services to the diagnostics and biotechnology world. The company is located in Xiamen China. They provide screening devices for drugs of abuse both in urine and in oral fluid. For oral fluid there is a 7 drugs test profile (Amphetamine, Methamphetamine, Ecstasy, Benzodiazepines, Cannabis, Cocaine and Opiates)

12.3.4 Philips/Cozart

Philips is developing a new oral fluid screening device in close cooperation with Cozart.
At the Medica exhibition in Düsseldorf information has been given about this development. The device has not been available mid 2009.

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Annex 1 Procedure

POLICE PROCEDURE FOR THE TASK 3.1 ESTHER IP DRUID

- **General**

ESTHER is an integral part of the Integrated Project DRUID.
In this document the procedure and guidelines for Task 3.1 ESTHER will be explained.
These guidelines are written for the use of Dedicated Police Officers (DPO's) in a number of European countries.
Only by following these guidelines the results of the tests, findings and opinions of motorists that have been tested and the opinions of DPO's on the different devices can be compared.
Motorists will be stopped by a police officer to be checked for the use and/or abuse of alcohol.
The exact limit as mentioned in this annex will differ depending from the specific member state. Limits can vary from 0,0‰ till 0,8‰. In the six member states where the ESTHEr task has been performed the limits varied from 0,2‰ till 0,8‰.

- If the motorist is suspected of driving with an alcohol concentration above the prescribed limit, the motorist will be considered a suspect and the judicial procedure for that country will be followed. After the completion of the legal procedure the motorist will be requested to co-operate, on a voluntary basis, for an oral fluid based screening for the presence of illegal and prescription drugs. This test will be led by the DPO. The oral screening devices to be used in this trial have not yet been type approved by the various governments and cannot yet be used in subsequent legal proceedings.

- If, after the alcohol screening test, the motorist is found not to be above the prescribed limit for alcohol he will be asked to participate in the oral fluid screening test. This can only be done on a voluntary basis and without any legal consequences. The test will be led by the DPO.

These tests will always respect the differences between the legal procedure and the testing activities.

- **The first selection at the roadside**

ESTHER will be executed at the roadside as an integral part of a planned alcohol control action or other police activity. The DPO's will be part of the group of the police officers involved in the activity.
It is also possible that the motorist will be stopped by a police officer during normal daily police surveillance.
In section 1 and 2 the preventive alcohol control action is described related to the execution of the ESTHER task.
In section 3 the normal control activities during the daily police surveillance are described related to the ESTHER task.

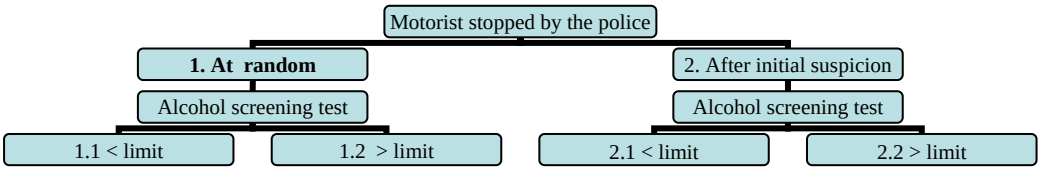
Stopping the motorist and check for alcohol

1. Stopping a motorist at random

The first step in the procedure will be to stop a motorist. In some countries this can be done at random but in other countries the legislation does not permit this. In those countries the proper legal procedure must be adhered to. The paragraph below is devoted to random checks.

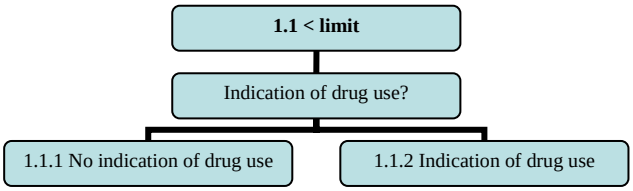
Cooperate at a screening test for alcohol

At the start of the operational procedure the motorist is required to provide a specimen of breath for analysis, on an approved hand held breath test device for that country. The screening device will provide an indication of alcohol consumption either by LED's or by digital readout. Based on the result of the screening device the officer can then decide if the result is above or below the prescribed limit applicable to that country and apply the legal procedure as appropriate to that country.



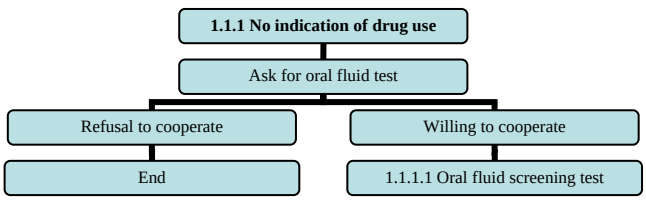
1.1 Stopped at random no alcohol indication Check for impairment other substances

In situations where a motorist is stopped at random and the police do not suspect that the driver is impaired by alcohol, or has an alcohol concentration above the prescribed limit, the officer will check for drug use by observing such signs and symptoms that may be evident of drug use. Such signs and symptoms are the size of the drivers pupils, reaction of the pupils to light, red eyes, divided attention test, balance test, speed of speech. All these symptoms can be observed by a police officer without performing complicated tests.



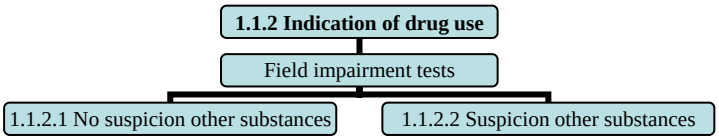
1.1.1 Stopped at random no alcohol indication on screening device No indication of drug use → oral fluid screening test

If no indication of driving whilst impaired exists the officer will request the driver to participate, on a voluntary basis, for certain psychoactive substances using a oral fluid screening test. If the driver agrees, a DPO will perform a test. The findings of this test will be registered anonymously and the driver informed of the opinion the DPO has of the result. The fact that the motorist is not willing to participate in the voluntary test should also be registered.



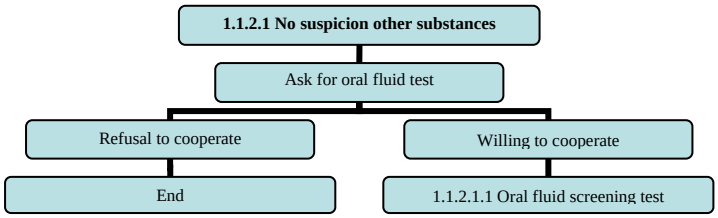
1.1.2 Stopped at random no alcohol indication Indication of drug use → field impairment test

If the result of the screening test for alcohol is negative the police officer may conclude that further investigation is necessary to check for the presence of psychoactive substances in the body of the motorist. The police officer can then require the motorist to perform the various prescribed field impairment tests as permitted by the legislation of each country.



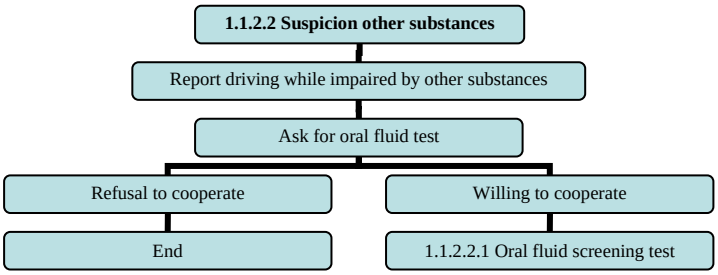
1.1.2.1 No suspicion of impairment caused by other substances than alcohol → Oral fluid screening test

If, as a result of the field impairment tests, there is no suspicion that the driver is impaired, he will be asked to take part in a voluntary test of an oral screening device. This test will be under the supervision of a DPO and will be documented. The subject of the test will be interviewed after the test for his opinion, which will be also be recorded. This test is purely voluntary and the motorist can refuse to take part.



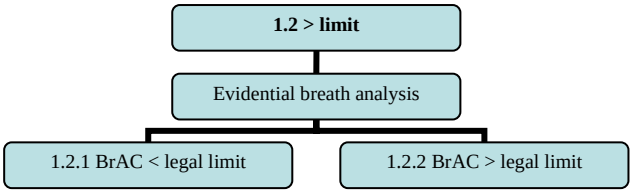
1.1.2.2 Suspicion of impairment caused by other substances than alcohol → Report driving while impaired oral fluid screening test

If the result of the field impairment tests gives cause to suspect that the driver may be impaired by psychoactive substances he should, where possible, be arrested under the relevant legislation for that country. After the legal process has been completed the driver will be requested to take part in the voluntary use of the oral fluid screening testing device. This test will be under the supervision of a DPO and will be documented. The subject of the test will be interviewed after the test for his opinion, which will also be recorded.



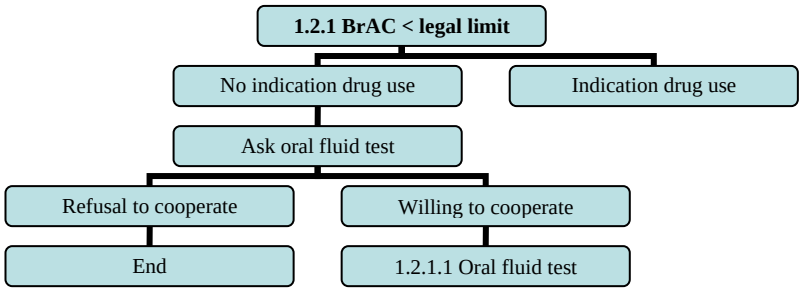
1.2 Stopped at random, positive alcohol indication screening device → Arrest for alcohol offence

If the initial screening test for alcohol is positive the motorist will be arrested on suspicion of driving with an alcohol concentration above the prescribed limit under the relevant legislation for that country. The legal process for that country will then take place resulting in a prosecution.



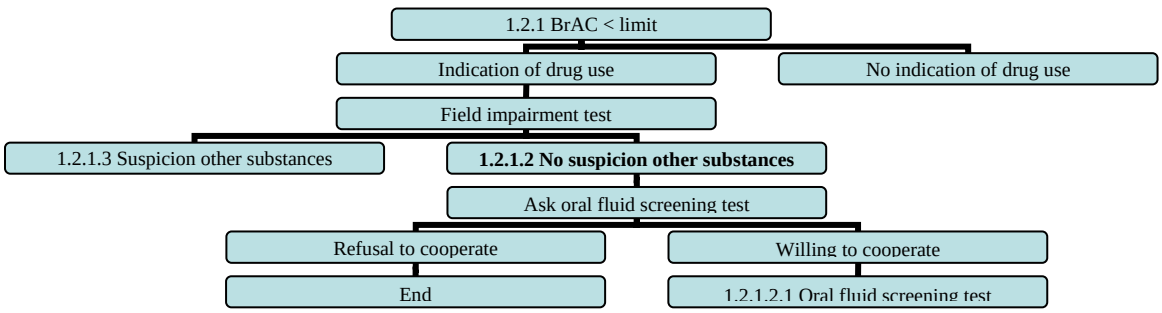
1.2.1.1 Negative alcohol evidential test, no indication of drug use → Oral fluid screening test

If there is no suspicion of driving whilst impaired and the evidential breath test is below the prescribed limit then the police officer will request the subject to participate in a voluntary test with a screening device sensitive for certain psychoactive substances. This will be an oral fluid screening test. If the motorist is willing to co-operate, a DPO will perform the test. The findings of the test will be recorded anonymously. After the test the motorist will be interviewed by the DPO for his opinion of the device and registered on the interview form, a refusal to take part should be noted.



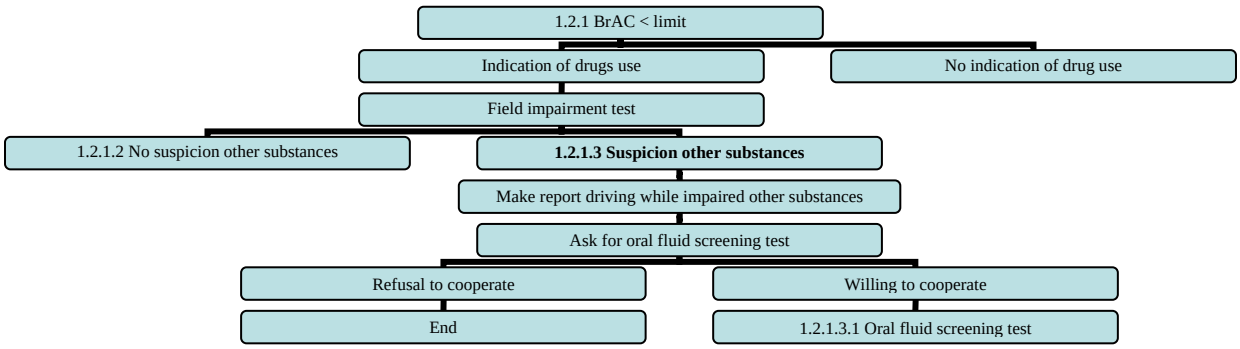
1.2.1.2 Negative alcohol evidential test, indication of drug use → Field impairment test → No suspicion and oral fluid screening test

If the police officer does have an indication that the motorist might be impaired by the use of other psychoactive substances than alcohol then the driver will be either requested or required, depending on the relevant country's legislation, to take a field impairment test. If the police do not get a confirmation that there is impairment, then the test is terminated. The motorist will then be asked for a voluntary screening test using an oral fluid screening test. The test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form



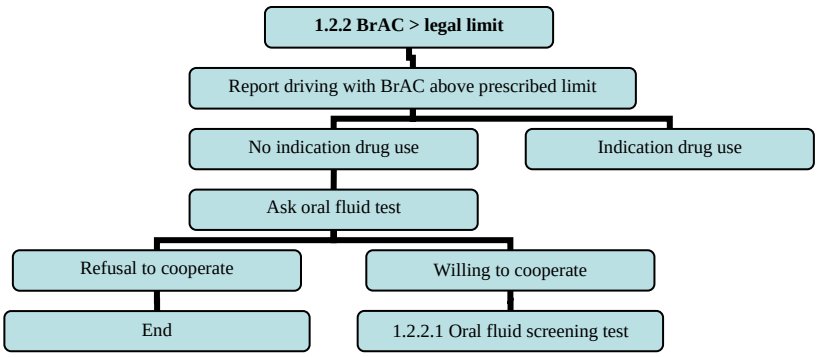
1.2.1.3 Negative alcohol evidential test, indication of drug use → Field impairment test →Suspicion and oral fluid screening test

If the police officer does have an indication that the motorist might be impaired by the use of other psychoactive substances than alcohol then the driver will be either requested or required, depending on the relevant country's legislation, to take a field impairment test. If the police get a confirmation that there is impairment, then the legal procedure for that offence and for that country will start, i.e. blood sample taken and sent for forensic analysis. After completion of the administrative process for that offence under the country's legislation, the motorist will be requested to take part in a voluntary test using an oral fluid screening test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



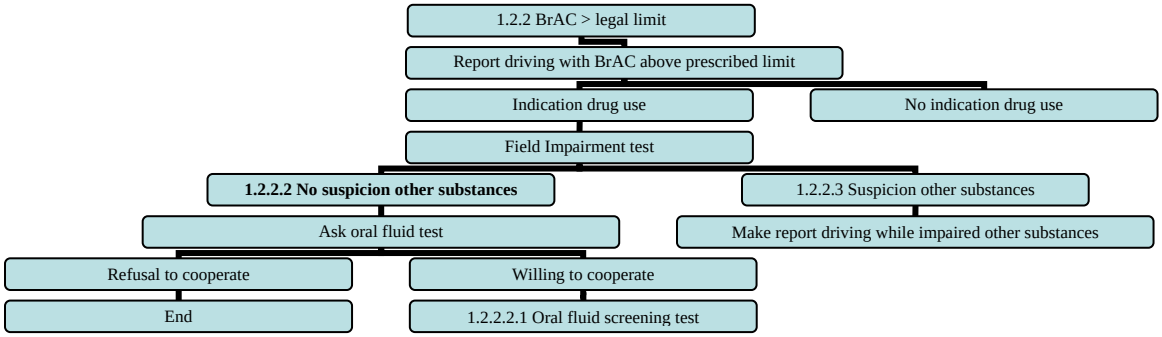
1.2.2.1 Positive alcohol evidential test, no indication of drugs use → Oral fluid screening test

If the police officer has no indication that the motorist might also be impaired by psychoactive substances other than alcohol, he will request the motorist to take part in a voluntary oral fluid test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



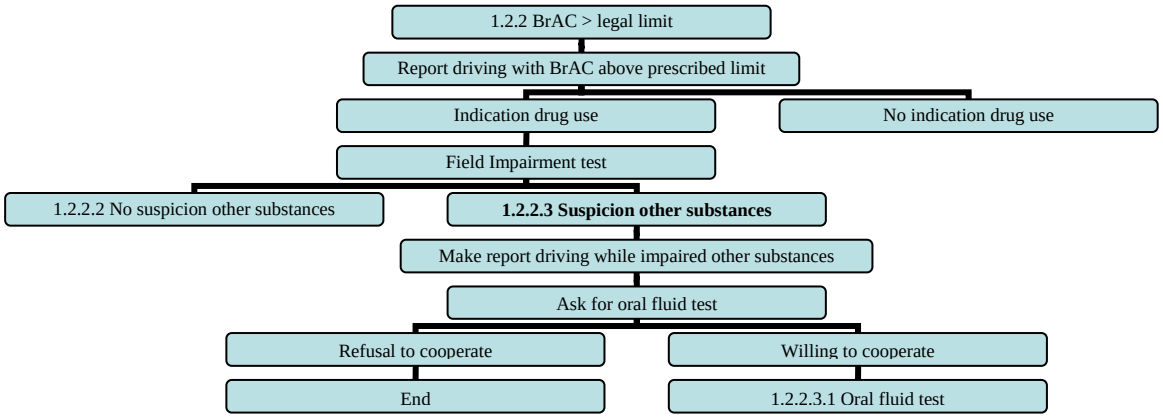
1.2.2.2 Positive alcohol evidential test, indication of drug use → Field impairment test → No suspicion and oral fluid screening test

If the police officer has an indication that the motorist might be impaired by psychoactive substances, other than alcohol, the officer may require the motorist to co-operate with a field impairment test, according to that country's legislation. If the field impairment test proves negative the officer will ask the motorist to voluntarily take part in an oral fluid screening test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



1.2.2.3 Positive alcohol evidential test, indication of drug use → Field impairment test → Suspicion of impairment caused by other substances than alcohol

If the police officer suspects that he motorist is impaired by other substances than alcohol then the legal procedure for that offence and for that country will start, i.e. blood sample taken and sent for forensic analysis. After completion of the administrative process for that offence under the country's legislation, the motorist will be requested to take part in a voluntary test using an oral fluid screening test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.

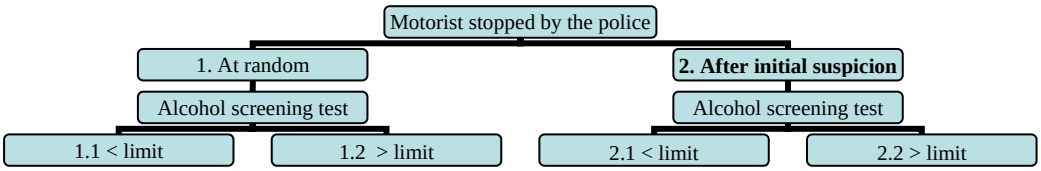


2. Stopping a motorist after suspicion of an offence

This paragraph is devoted to checking a motorist after a suspicion of an offence or road traffic collision. In some countries random checks are permitted. In those countries that do not permit random checks the police must have an reason to stop a motorist, these reasons could be the commission of a minor traffic offence by the motorist such as excessive speed, vehicle defect, or even the belief that because of the manner of driving the motorist is under the influence of drugs or alcohol.

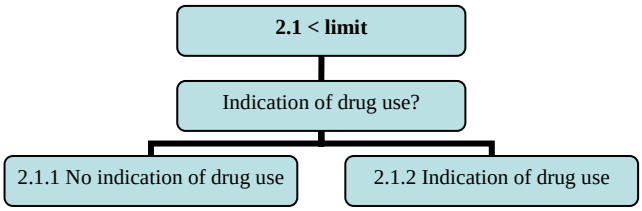
Cooperate at a screening test for alcohol

Depending on the legislation for that country the driver will be required to take an alcohol screening test using a type approved device for that country. The screening device will, depending on the country, give a digital readout or LED indication of alcohol consumption. The result from the alcohol screening device will either give the police officer powers of arrest for a positive sample or in the case of a negative sample allow the driver to proceed.



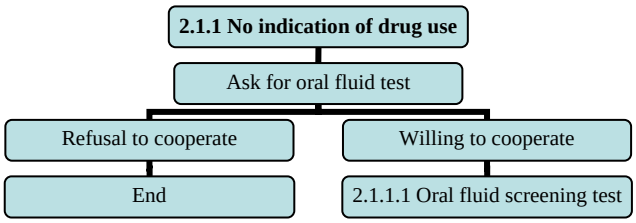
2.1 Stopped after suspicion of an offence no alcohol indication Check for impairment other substances

In situations where a motorist is stopped and the police do not have any suspicion that the driver has an alcohol concentration above the prescribed limit, after a test using a type approved screening device, the motorist should be checked for signs of drug use. The officer will check by observing signs and symptoms that may be evident of drug use. Such signs and symptoms are the size of the drivers pupils, reaction of the pupils to light, red eyes, divided attention test, balance test, speed of speech. All these symptoms can be observed by a police officer without performing complicated tests.



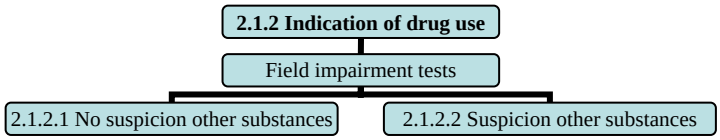
2.1.1 Stopped after suspicion of an offence, no alcohol indication on screening device, no indication of drug use →Oral fluid screening test

If there is so suspicion that the motorist was driving whilst impaired, the police officer will request the driver to voluntarily take part in a test using an oral fluid screening device. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



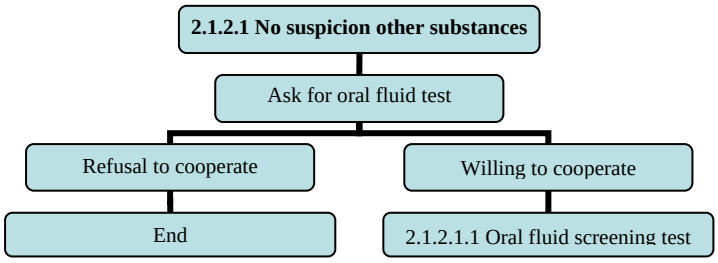
2.1.2 Stopped after suspicion of an offence, no alcohol indication Indication of drug use → Field impairment test

If the result of the screening test for alcohol is negative the police officers might conclude that further investigation is required to check for the presence of psychoactive substances in the system of the motorist. The police officer will then ask the motorist to perform the field impairment tests approved by that country under the relevant legislation.



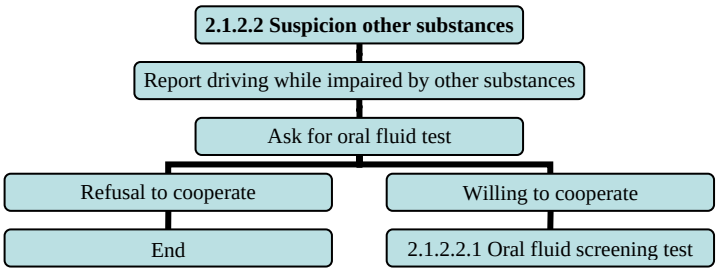
2.1.2.1 No suspicion of impairment caused by other substances than alcohol → Oral fluid screening test

If the result of the impairment tests does not give any suspicion that the driver is impaired, he will be requested to voluntarily take part in an oral fluid screening test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



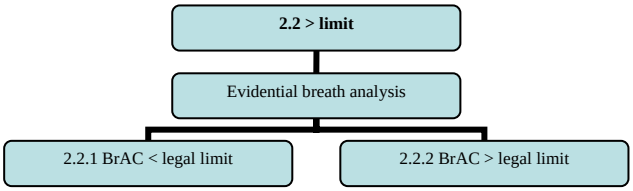
2.1.2.2 Suspicion of impairment caused by other substances than alcohol → Report driving while impaired oral fluid screening test

If the result of the impairment tests gives suspicion that the driver may be impaired by psychoactive substances, then the driver should be arrested under the relevant legislation for that country. The National legal procedures for that country will then be followed, i.e. blood sample taken and submitted for forensic analysis. The driver will be requested to voluntarily take part in an oral fluid screening test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



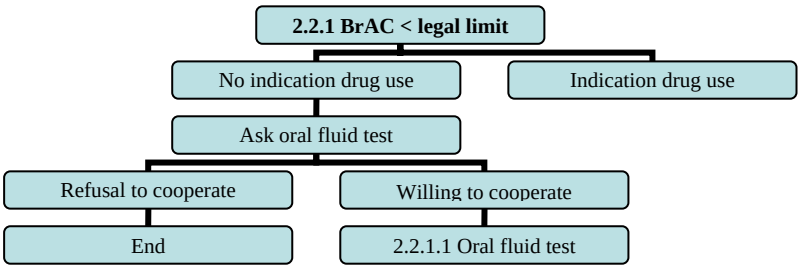
2.2 Stopped after suspicion of an offence positive alcohol indication screening device→ Arrest for alcohol offence

If the initial screening test for alcohol is positive the motorist will be arrested under the relevant legislation for that country. An evidential breath analysis procedure will then take place under the legal process for that country, and the driver prosecuted under that country's guidelines.



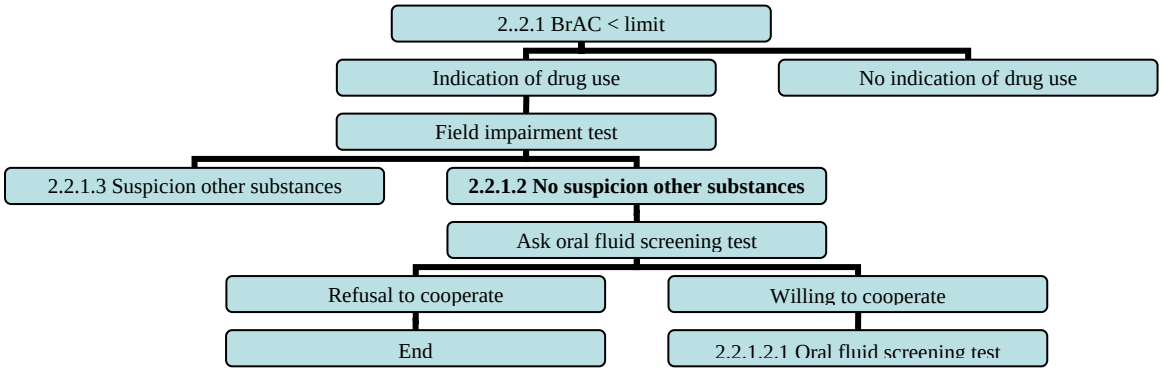
2.2.1.1 Negative alcohol evidential test, no indication of drug use → Oral fluid screening test

If no suspicion of driving while impaired exists and the evidential breath analysis results in an alcohol concentration below the legal limit the police officer will request the motorist to take a voluntary oral fluid screening test to detect psychoactive substances. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



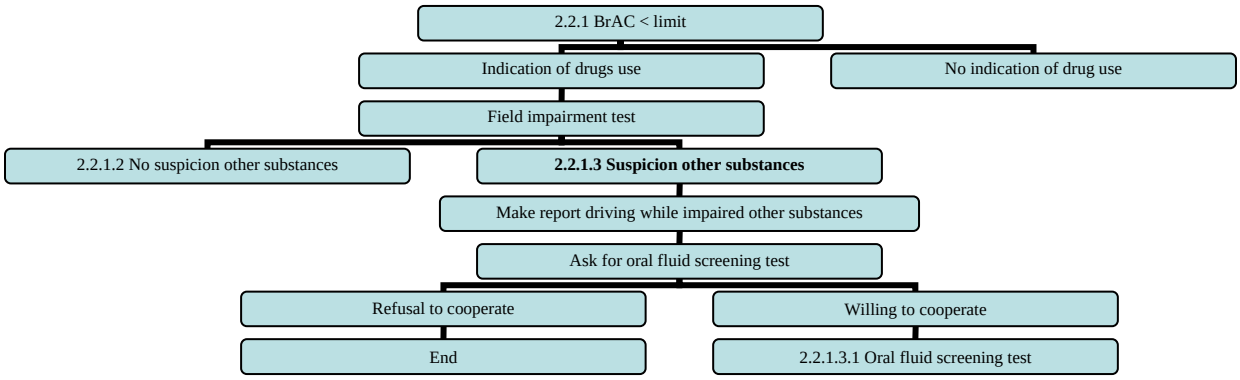
2.2.1.2 Negative alcohol evidential test, indication of drug use → Field impairment test → No suspicion and oral fluid screening test

If the police officer does have an indication that the motorist might be impaired by the use of psychoactive substances other than alcohol then the driver will be required to take part in field impairment tests in accord with the legislation of that country. If there is no confirmation of impairment then the driver will be requested to voluntarily take part in an oral fluid screening test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



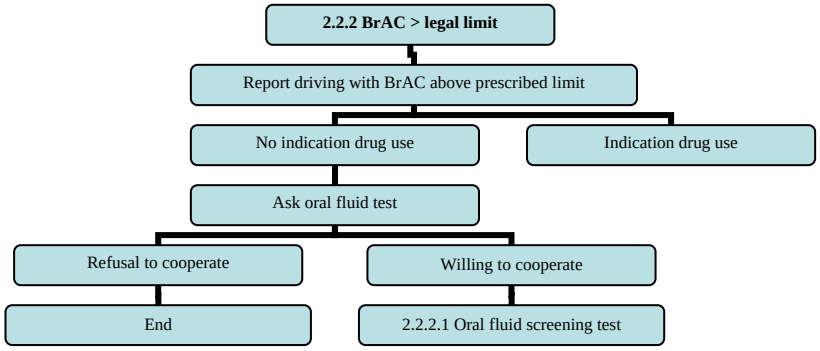
2.2.1.3 Negative alcohol evidential test, indication of drug use → Field impairment test → Suspicion and oral fluid screening test

If the police officer has an indication that the motorist may be impaired by the use of psychoactive substances other than alcohol the driver will be required to take part in field impairment tests, if the legislation of that country supports such testing. In countries whose legislation does not support field impairment tests, the legal procedure for this type of offence will start. In both cases it is expected that a blood sample will be taken and sent for forensic testing. The driver will then be requested to voluntarily take part in an oral fluid screening test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



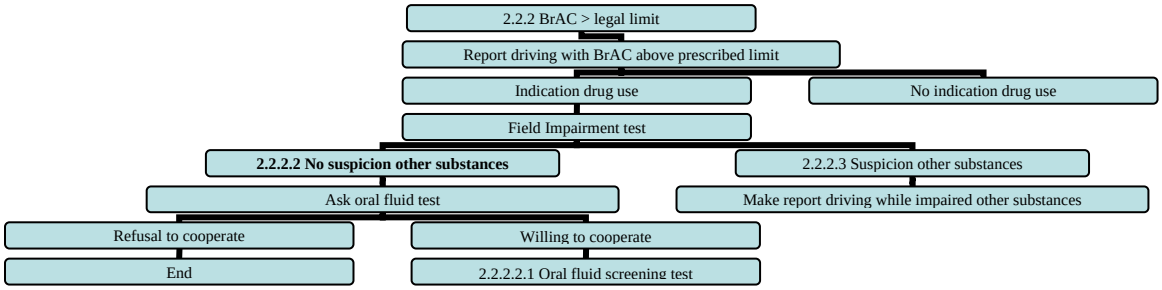
2.2.2.1 Positive alcohol evidential test, no indication of drugs use → Oral fluid screening test

If the police officer has no indication of the use of psychoactive substances other than alcohol then the motorist will be asked to voluntarily co-operate in the test of an oral fluid screening device. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



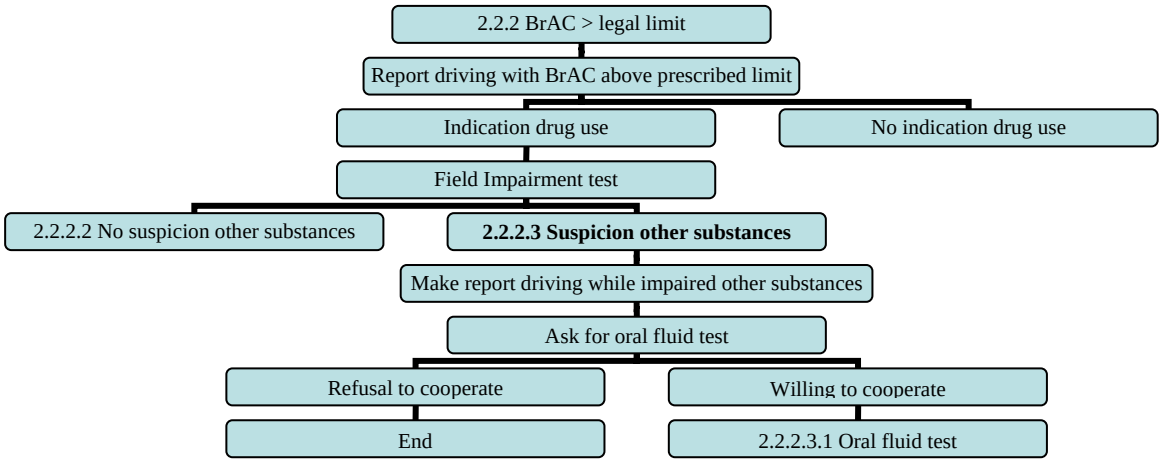
2.2.2.2 Positive alcohol evidential test, indication of drug use → Field impairment test → No suspicion and oral fluid screening test

If the police officer has an indication that he motorist might be impaired by the use of psychoactive substances other than alcohol the motorist will be required to take field impairment tests in accord with the legislation of that country. If the police officer has no indication of the use of psychoactive substances other than alcohol then the motorist will be asked to voluntarily co-operate in the test of an oral fluid screening device. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



2.2.2.3 Positive alcohol evidential test, indication of drug use → Field impairment test→ Suspicion of impairment by other substances than alcohol

If the police officer suspects the motorist to be impaired by other substances than alcohol the driver should be arrested under the relevant legislation for that country and the legal procedure started, i.e. take blood sample for forensic analysis. After the legal procedure has finished the driver should be asked I he wishes to voluntarily take part in an oral fluid test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.

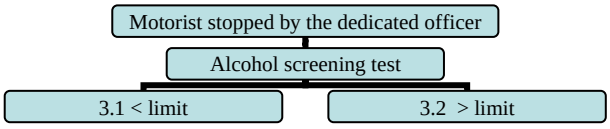


3. Stopping a motorist after suspicion of an offence or at random during daily surveillance

This paragraph is devoted to checking a motorist after a suspicion of an offence or road traffic collision. In some countries random checks are permitted. In those countries that do not permit random checks the police must have an reason to stop a motorist, these reasons could be the commission of a minor traffic offence by the motorist such as excessive speed, vehicle defect, or even the belief that because of the manner of driving the motorist is under the influence of drugs or alcohol. For the procedure during the normal surveillance this does not make any difference. Normally the start of the procedure will be to check the vehicle registration and the drivers licence of the motorist. If the driver is stopped for any offence or specific behaviour the police officer can ask him/her to cooperate at a screening test for alcohol. That is the starting situation for this procedure. In this section the police officer will be the dedicated police officer.

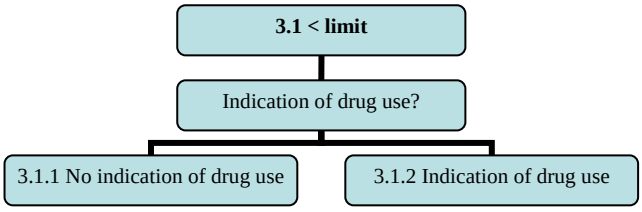
Cooperate at a screening test for alcohol

Depending on the legislation for that country the driver will be required to take an alcohol screening test using a type approved device for that country. The screening device will, depending on the country, give a digital readout or LED indication of alcohol consumption. The result from the alcohol screening device will either give the police officer powers of arrest for a positive sample or in the case of a negative sample allow the driver to proceed.



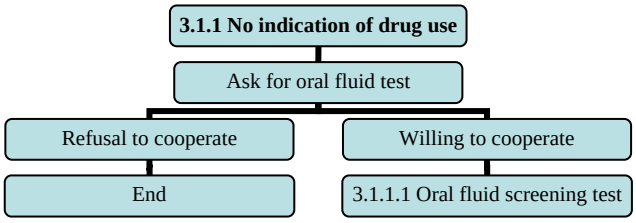
3.1 Stopped after suspicion of an offence or at random no alcohol indication → Check for impairment other substances

In situations where a motorist is stopped and the police do not have any suspicion that the driver has an alcohol concentration above the prescribed limit, after a test using a type approved screening device, the motorist should be checked for signs of drug use. The officer will check by observing signs and symptoms that may be evident of drug use. Such signs and symptoms are the size of the drivers pupils, reaction of the pupils to light, red eyes, divided attention test, balance test, speed of speech. All these symptoms can be observed by a police officer without performing complicated tests.



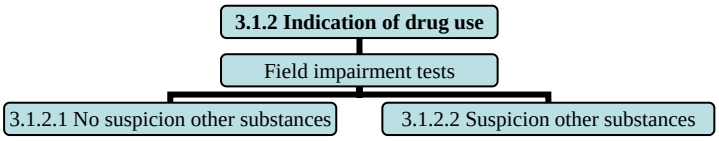
3.1.1 Stopped after suspicion of an offence no alcohol indication on screening device No indication of drug use →Oral fluid screening test

If there is so suspicion that the motorist was driving whilst impaired, the police officer will request the driver to voluntarily take part in a test using an oral fluid screening device. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



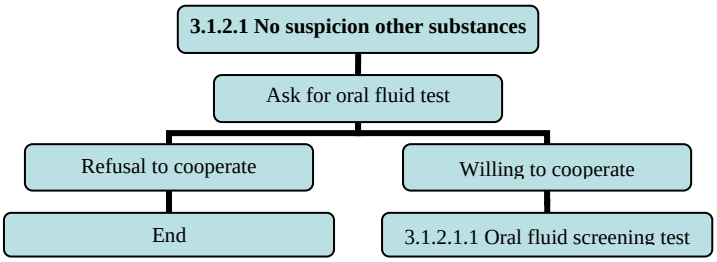
3.1.2 Stopped after suspicion of an offence, no alcohol indication Indication of drug use → Field impairment test

If the result of the screening test for alcohol is negative the police officers might conclude that further investigation is required to check for the presence of psychoactive substances in the system of the motorist. The police officer will then ask the motorist to perform the field impairment tests approved by that country under the relevant legislation.



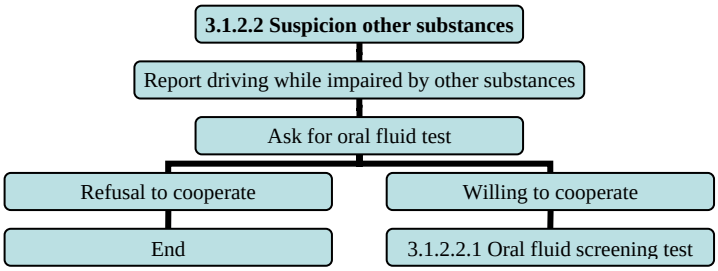
3.1.2.1 No suspicion of impairment caused by other substances than alcohol → Oral fluid screening test

If the result of the impairment tests does not give any suspicion that the driver is impaired, he will be requested to voluntarily take part in an oral fluid screening test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



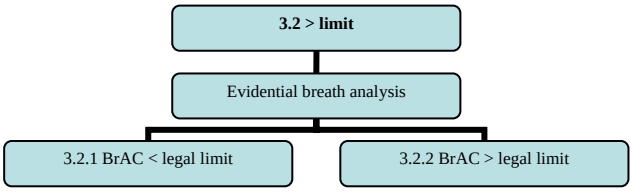
3.1.2.2 Suspicion of impairment caused by other substances than alcohol → Report driving while impaired oral fluid screening test

If the result of the impairment tests gives suspicion that the driver may be impaired by psychoactive substances, then the driver should be arrested under the relevant legislation for that country. The National legal procedures for that country will then be followed, i.e. blood sample taken and submitted for forensic analysis. The driver will be then requested to voluntarily take part in an oral fluid screening test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



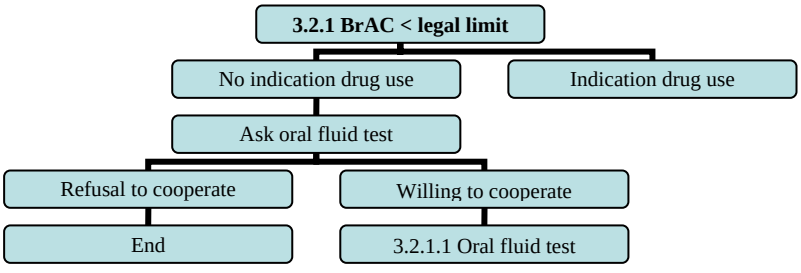
3.2 Stopped after suspicion of an offence positive alcohol indication screening device→ Arrest for alcohol offence

If the initial screening test for alcohol is positive the motorist will be arrested under the relevant legislation for that country. An evidential breath analysis procedure will then take place under the legal process for that country, and the driver prosecuted under that country's guidelines.



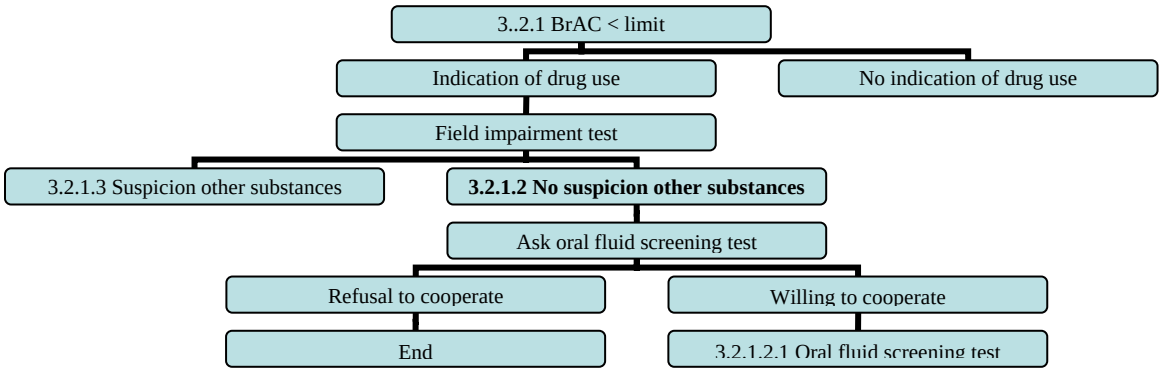
3.2.1.1 Negative alcohol evidential test, no indication of drug use →Oral fluid screening test

If no suspicion of driving while impaired exists and the evidential breath analysis results in an alcohol concentration below the legal limit the police officer will request the motorist to take a voluntary oral fluid screening test to detect psychoactive substances. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



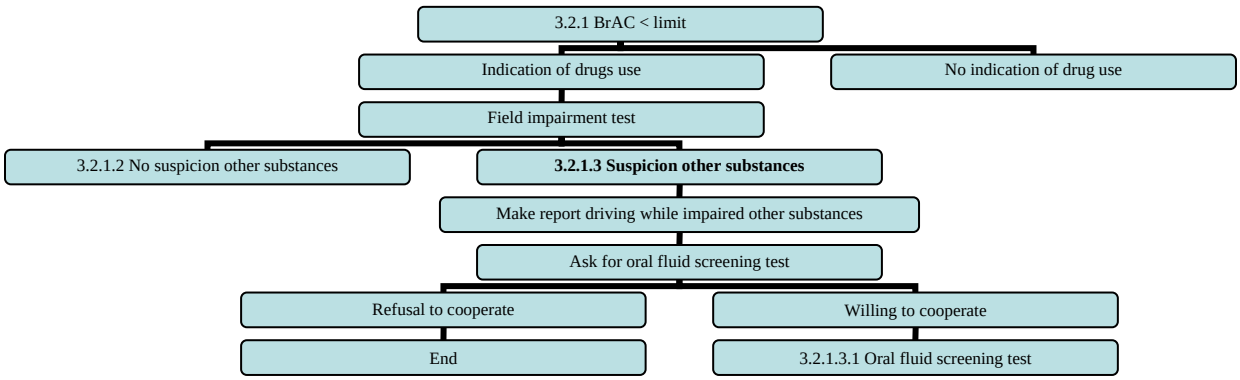
3.2.1.2 Negative alcohol evidential test, indication of drug use → Field impairment test → No suspicion and oral fluid screening test

If the police officer does have an indication that the motorist might be impaired by the use of psychoactive substances other than alcohol then the driver will be required to take part in field impairment tests in accord with the legislation of that country. If there is no confirmation of impairment then the driver will be requested to voluntarily take part in an oral fluid screening test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



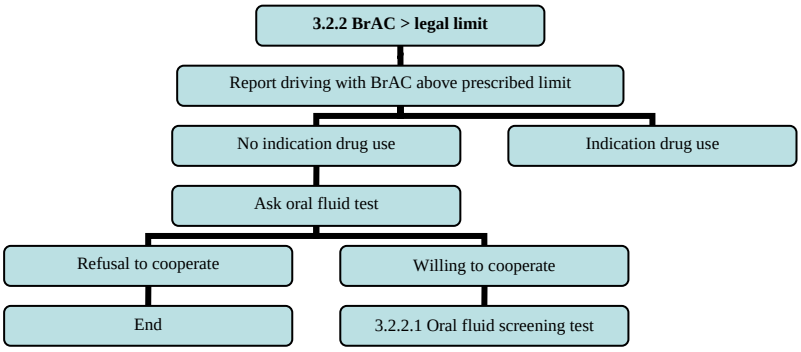
3.2.1.3 Negative alcohol evidential test, indication of drug use → Field impairment test → Suspicion and oral fluid screening test

If the police officer has an indication that the motorist may be impaired by the use of psychoactive substances other than alcohol the driver will be required to take part in field impairment tests, if the legislation of that country supports such testing. In countries whose legislation does not support field impairment tests, the legal procedure for this type of offence will start. In both cases it is expected that a blood sample will be taken and sent for forensic testing. The driver will then be requested to voluntarily take part in an oral fluid screening test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



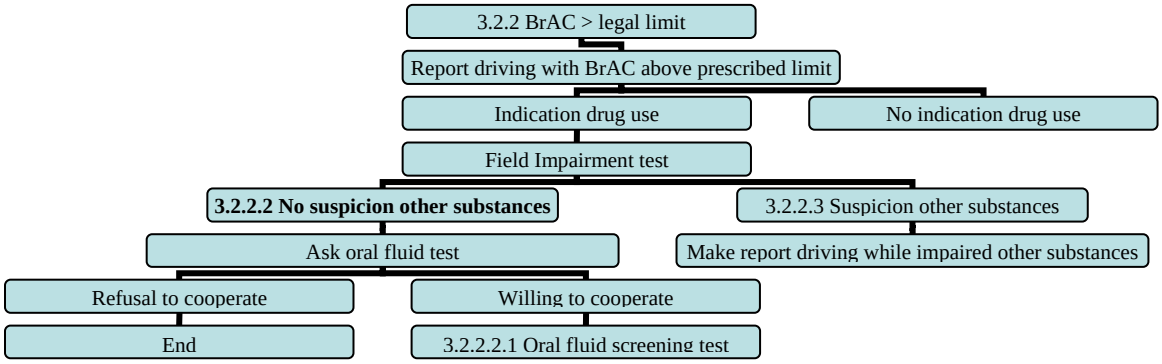
3.2.2.1 Positive Alcohol Evidential test, no indication of drugs use →Oral fluid screening test

If the police officer has no indication of the use of psychoactive substances other than alcohol then the motorist will be asked to voluntarily co-operate in the test of an oral fluid screening device. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



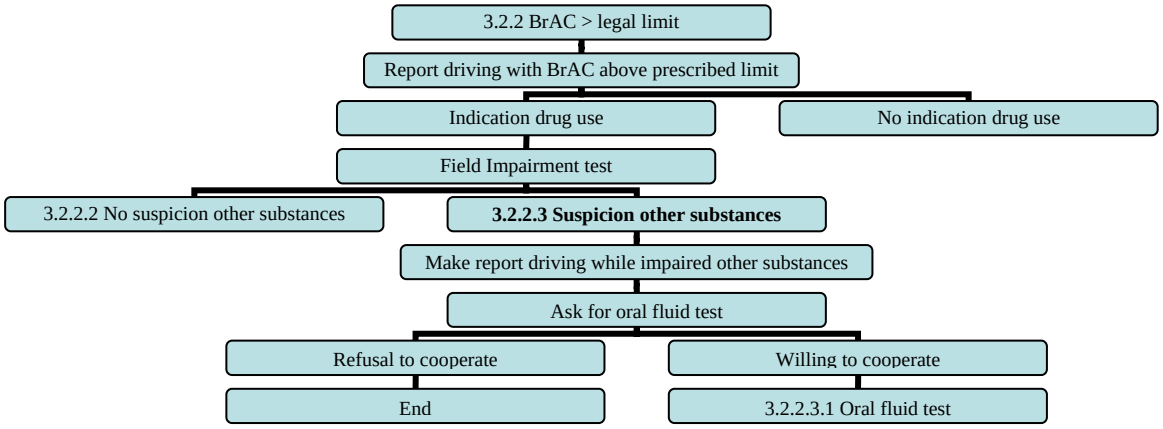
3.2.2.2 Positive alcohol evidential test, indication of drug use → Field impairment test → No suspicion and oral fluid screening test

If the police officer has an indication that he motorist might be impaired by the use of psychoactive substances other than alcohol the motorist will be required to take field impairment tests in accord with the legislation of that country. If the police officer has no indication of the use of psychoactive substances other than alcohol then the motorist will be asked to voluntarily co-operate in the test of an oral fluid screening device. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



3.2.2.3 Positive alcohol evidential test, indication of drug use →Field impairment test → Suspicion of impairment caused by other substances than alcohol

If the police officer suspects the motorist to be impaired by other substances than alcohol the driver should be arrested under the relevant legislation for that country and the legal procedure started, i.e. take blood sample for forensic analysis. After the legal procedure has finished the driver should be asked I he wishes to voluntarily take part in an oral fluid test. This test will be performed by the DPO. After the test the motorist will be interviewed by the DPO for his opinion of the device and those comments noted on the interview form.



Annex 2 Oral fluid test form Phase 1

ORAL FLUID TEST FORM (Task 3.1 ESTHER Project DRUID)

POLICE FORCE		
☐ Police Netherlands 1 KLPD DVP Breda	☐ Police Netherlands 2 Limburg Zuid KLPD DVP Maasbracht	☐ Police Netherlands 3 Gelderland Zuid KLPD DVP Wolfheze
☐ Federal Police Belgium 1 Highway Police O. Vlaanderen	☐ Federal Police Belgium 2 Highway Police Hainaut	☐ Local Police Belgium 3 Kempen Noord
☐ Police Germany 1 North Rhine-Westphalia	☐ Police Germany 2 Baden-Württemberg	☐ Police Germany 3 Saarland
☐ Police Finland National Traffic Police	☐ Police Spain Mossos 'd Esquadra	☐ Police Ireland An Garda Siochana
CODE OF THE DEDICATED POLICE OFFICER LEADING THE SCREENING TEST: ……		

DATA RELATED TO TESTED PERSON				Sequence Number:
Type of test	☐ Suspected person	☐ Motorist	☐	
Gender	☐ Male	☐ Female		
Age :	☐ 18- 25 years	☐ 26 - 35 years	☐ 36 - 45 years	
	☐ 46- 55 years	☐ 56 - 65 years	☐ > 65 years	

ORAL FLUID SCREENING TEST				
Date of oral fluid test (dd:mm:yy):		…..-……- ……..		
Time of oral fluid test (xx.xx hrs):		…… hours		
Location of oral fluid test:	☐ Road side	☐ Patrol car	☐ Police truck	☐ Police station
Weather conditions	☐ Sunshine	☐ Rain	☐ Cloudy	☐ Snow
Light conditions	☐ Daylight	☐ Darkness	☐ White street light	☐ Orange street light
Brand of oral fluid screening device	☐ MAVAND RapidSTAT	☐ Avitar Inc. Oralscreen	☐ Branan Medical Oratect	☐ EnviteC SmartClip
	☐ Innovacon DSF 765	☐ Securetec Drugwipe	☐ Sun Biomedical OraLine	☐ Surescreen Oral Drug Test
	☐ Ultimed Salivascreen	☐ Varian OraLab	☐	☐
Time (in minutes) needed to collect a sufficient oral fluid sample:				
Time (in minutes) needed to analyse the oral fluid sample after collecting:				
Oral fluid sample stored in intercept collecting device for forensic analysis			**Device number:**	

Results Oral fluid screening test	positive	negative	Short description of situation
THC (Cannabis)	☐	☐	
MDMA (Ecstasy)	☐	☐	
Amphetamine	☐	☐	
Methamphetamine	☐	☐	
Cocaine	☐	☐	
Morphine (opioids)	☐	☐	
Benzodiazepines	☐	☐	
Barbiturates	☐	☐	
	☐	☐	

Additional remarks dedicated police officer:
……
……

☐ The suspected person ☐ The motorist
has been informed that the test with the oral fluid screening device is voluntary.
The result of the oral fluid screening test will not be used in any legal procedure.

Questionnaire for the motorist who performed this test:			
1. Screening tests for drugs can be realised by screening a urine, an oral fluid or a sweat sample. What kind of screening test would you like most?	☐ Urine test	☐ Saliva test	☐ Sweat test
2. Why would you prefer this kind of test?	☐ Easy	☐ Privacy	☐ Fast screening
3. What is your opinion about the time needed to collect the oral fluid sample?	☐ Short	☐ Moderate	☐ Long
4. What do you consider to be an acceptable time to collect an oral fluid sample?	☐ 3 minutes	☐ 5 minutes	☐ ..... minutes
5. What do you consider to be an acceptable time to get a result from the screening device?	☐ 3 minutes	☐ 5 minutes	☐ ..... minutes
6. Did you use any illicit drugs the last 24 hours? (Your answer will be considered as confidential and will not be used in a legal procedure)	☐ Yes	☐ No	☐ No answer
7. If you used illicit drugs during the last 24 hours. What kind of drugs did you use?	☐ Cannabis	☐ Ecstasy	☐ Amphetamines
	☐ Methamphetamine	☐ Cocaine	☐ Heroine
	☐ Morphine	☐ Methadone	☐ PCP
	☐	☐	☐ .....
8. Did you use any drug of prescription the last 24 hours? Your answer will be considered as confidential and will not be used in a legal procedure.	☐ Yes	☐ No	☐ No answer
9. If you used a prescription drug during the last 24 hours, what kind of drugs did you use?	☐ Benzodiazepine	☐Antidepressant	☐ .....
	☐	☐	☐ .....
10. Do you think more specific legislation related to illicit drugs and driving is needed in our country?	☐ Yes	☐ No	☐ No answer
11. Do you think more specific legislation related to certain drugs of prescription and driving is needed in our country?	☐ Yes	☐ No	☐ No answer

Questionnaire for the DPO who led this screening test:

1. Do you consider this test as successful from an operational perspective?	☐ Yes	☐ No
2. Is the indication given by the device in accordance with your observations related to use of substances of the tested person?	☐ Yes	☐ No
3. Do you consider the time to collect a saliva sample of this person as acceptable from an operational perspective?	☐ Yes	☐ No
4. Do you consider the time to get an indication from the device as acceptable from an operational perspective?	☐ Yes	☐ No
5. Were you able to work in a hygienic and safe way during this test with this oral fluid screening device?	☐ Yes	☐ No
6. Do you consider the tested person as cooperative and a good example for testing the device?	☐ Yes	☐ No
7. Would you rely on the indications received in this test?	☐ Yes	☐ No
8. Are the required activities to prepare a screening test simple enough to be done at the road side?	☐ Yes	☐ No
9. Can the collected saliva sample of the tested person be brought to the testing surface in a hygienic and simple way?	☐ Yes	☐ No
10. Could this test easily be performed at the roadside?	☐ Yes	☐ No
11. Could this test only be used at a patrol car, a truck or a police station?	☐ Yes	☐ No

12. If you answered "No" to one or more questions 1 – 10 please specify your answer:
……
……
……

13. Any specific remarks related to this test:
……
……

DATA RELATED TO SCREENING TEST ALCOHOL, BREATH ANALYSIS etc.

☐ ***Alcohol screening test***

Date of alcohol screening test (dd:mm:yy)		….-……- ……..		
Time of alcohol screening test (xx.xx hrs)		…… hours		
Location of screening test:	☐ Road side	☐ Patrol car	☐ Police truck	☐ Police station
Brand of screening device:	……	Alcohol indication:	……	

☐ ***Breath analysis***

Date of breath analysis (dd:mm:yy):		….-……- ……..		
Time of breath analysis (xx.xx hrs):		…… hours		
Location of breath analysis	☐ Road side	☐ Patrol car	☐ Police truck	☐ Police station
Brand of Breath analysis instrument:		……		
Alcohol concentration at breath analysis:		BrAC ……. Micrograms/ litre breath BAC ……. Milligrams/millilitre of blood (‰)		

☐ ***Blood sample***

Taken from suspected motorist for analysis	☐ No	☐ Yes, **Sample number**: ……..

Result of blood analysis: (report found psychoactive substances, concentrations, report number laboratory etc):
……
……
……

01-11-2006

Annex 3 Oral fluid test form Phase 2

ORAL FLUID TEST FORM (Task 3.1 ESTHER Project DRUID)

POLICE FORCE		
☐ Police Netherlands 1 KLPD DVP Breda	☐ Police Netherlands 2 Limburg Zuid KLPD DVP Maasbracht	☐ Police Netherlands 3 Gelderland Zuid KLPD DVP Wolfheze
☐ Federal Police Belgium 1 Highway Police O. Vlaanderen	☐ Federal Police Belgium 2 Highway Police Hainaut	☐ Local Police Belgium 3 Kempen Noord
☐ Police Germany 1 North Rhine-Westphalia	☐ Police Germany 2 Baden-Württemberg	☐ Police Germany 3 Saarland
☐ Police Finland National Traffic Police	☐ Police Spain Mossos 'd Esquadra	☐ Police Ireland An Garda Siochana
CODE OF THE DEDICATED POLICE OFFICER LEADING THE SCREENING TEST: ……		

DATA RELATED TO TESTED PERSON				Sequence Number:
Type of test	☐ Suspected person	☐ Motorist	☐	
Gender	☐ Male	☐ Female		
Age :	☐ 18- 25 years	☐ 26 - 35 years	☐ 36 - 45 years	
	☐ 46- 55 years	☐ 56 - 65 years	☐ > 65 years	

ORAL FLUID SCREENING TEST				
Date of oral fluid test (dd:mm:yy):		…..-……- ……..		
Time of oral fluid test (xx.xx hrs):		…… hours		
Location of oral fluid test:	☐ Road side	☐ Patrol car	☐ Police truck	☐ Police station
Weather conditions	☐ Sunshine	☐ Rain	☐ Cloudy	☐ Snow
Light conditions	☐ Daylight	☐ Darkness	☐ White street light	☐ Orange street light
Brand of oral fluid screening device	☐ Cozart DDS	☐ Dräger Drug Test 5000	☐ Biosensor BIOSENS	
Time (in minutes) needed to collect a sufficient oral fluid sample:				
Time (in minutes) needed to analyse the oral fluid sample after collecting:				
Oral fluid sample stored in intercept collecting device for forensic analysis		**Device number**:		

Results Oral fluid screening test	positive	negative	Short description of situation
THC (Cannabis)	☐	☐	
MDMA (Ecstasy)	☐	☐	
Amphetamine	☐	☐	
Methamphetamine	☐	☐	
Cocaine	☐	☐	
Morphine (opioids)	☐	☐	
Benzodiazepines	☐	☐	
Barbiturates	☐	☐	
	☐	☐	

Additional remarks dedicated police officer:
……
……

☐ The suspected person ☐ The motorist
has been informed that the test with the oral fluid screening device is voluntary.
The result of the oral fluid screening test will not be used in any legal procedure.

Questionnaire for the motorist who performed this test:			
1. Screening tests for drugs can be realised by screening a urine, an oral fluid or a sweat sample. What kind of screening test would you like most?	☐ Urine test	☐ Saliva test	☐ Sweat test
2. Why would you prefer this kind of test?	☐ Easy	☐ Privacy	☐ Fast screening
3. What is your opinion about the time needed to collect the oral fluid sample?	☐ Short	☐ Moderate	☐ Long
4. What do you consider to be an acceptable time to collect an oral fluid sample?	☐ 3 minutes	☐ 5 minutes	☐ ..... minutes
5. What do you consider to be an acceptable time to get a result from the screening device?	☐ 3 minutes	☐ 5 minutes	☐ ..... minutes
6. Did you use any illicit drugs the last 24 hours? (Your answer will be considered as confidential and will not be used in a legal procedure)	☐ Yes	☐ No	☐ No answer
7. If you used illicit drugs during the last 24 hours. What kind of drugs did you use?	☐ Cannabis	☐ Ecstasy	☐ Amphetamines
	☐ Methamphetamine	☐ Cocaine	☐ Heroine
	☐ Morphine	☐ Methadone	☐ PCP
	☐	☐	☐ .....
8. Did you use any drug of prescription the last 24 hours? Your answer will be considered as confidential and will not be used in a legal procedure.	☐ Yes	☐ No	☐ No answer
9. If you used a prescription drug during the last 24 hours, what kind of drugs did you use?	☐ Benzodiazepine	☐Antidepressant	☐ .....
	☐	☐	☐ .....
10. Do you think more specific legislation related to illicit drugs and driving is needed in our country?	☐ Yes	☐ No	☐ No answer
11. Do you think more specific legislation related to certain drugs of prescription and driving is needed in our country?	☐ Yes	☐ No	☐ No answer

Questionnaire for the DPO who led this screening test:

1. Do you consider this test as successful from an operational perspective?	☐ Yes	☐ No
2. Is the indication given by the device in accordance with your observations related to use of substances of the tested person?	☐ Yes	☐ No
3. Do you consider the time to collect a saliva sample of this person as acceptable from an operational perspective?	☐ Yes	☐ No
4. Do you consider the time to get an indication from the device as acceptable from an operational perspective?	☐ Yes	☐ No
5. Were you able to work in a hygienic and safe way during this test with this oral fluid screening device?	☐ Yes	☐ No
6. Do you consider the tested person as cooperative and a good example for testing the device?	☐ Yes	☐ No
7. Would you rely on the indications received in this test?	☐ Yes	☐ No
8. Are the required activities to prepare a screening test simple enough to be done at the road side?	☐ Yes	☐ No
9. Can the collected saliva sample of the tested person be brought to the testing surface in a hygienic and simple way?	☐ Yes	☐ No
10. Could this test easily be performed at the roadside?	☐ Yes	☐ No
11. Could this test only be used at a patrol car, a truck or a police station?	☐ Yes	☐ No

12. If you answered "No" to one or more questions 1 – 10 please specify your answer:
……
……
……

13. Any specific remarks related to this test:
……
……

DATA RELATED TO SCREENING TEST ALCOHOL, BREATH ANALYSIS etc.

☐ ***Alcohol screening test***

Date of alcohol screening test (dd:mm:yy)		….-……- ……..		
Time of alcohol screening test (xx.xx hrs)		…… hours		
Location of screening test:	☐ Road side	☐ Patrol car	☐ Police truck	☐ Police station
Brand of screening device:	……	Alcohol indication:	……	

☐ ***Breath analysis***

Date of breath analysis (dd:mm:yy):		….-……- ……..		
Time of breath analysis (xx.xx hrs):		…… hours		
Location of breath analysis	☐ Road side	☐ Patrol car	☐ Police truck	☐ Police station
Brand of Breath analysis instrument:		……		
Alcohol concentration at breath analysis:		BrAC ……. Micrograms/ litre breath BAC ……. Milligrams/millilitre of blood (‰)		

☐ ***Blood sample***

Taken from suspected motorist for analysis	☐ No	☐ Yes, **Sample number**: ……..

Result of blood analysis: (report found psychoactive substances, concentrations, report number laboratory etc):
……
……
……

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Annex 4 Impairment test form

POLICE FORCE		
☐ Police Netherlands 1 DVP KLPD Breda	☐ Police Netherlands 2 Limburg Zuid Maasbracht	☐ Police Netherlands 3 Gelderland Zuid Wolfheze
☐ Federal Police Belgium 1 Vlaanderen Oost	☐ Federal Police Belgium 2 Hainaut	☐ Local Police Belgium 3 Kempen Oost
☐ Police Germany 1 North Rhine Westphalia	☐ Police Germany 2 Baden Württemberg	☐ Police Germany 3 Saarland
☐ Traffic Police Finland	☐ Police Spain Mossos 'd Esquadra	☐ Police Ireland Garda Siochana
CODE OF THE DEDICATED POLICE OFFICER LEADING THE IMPAIRMENT TEST:……		

DATA RELATED TO TESTED PERSON				SEQUENCE Number:
Type of test	☐ Suspected person	☐ Motorist	☐	
Date of oral fluid test (dd:mm:yy):		…..-……- ……..		
Gender	☐ Male	☐ Female		
Age :	☐ 18- 25 years	☐ 26 - 35 years	☐ 36 - 45 years	
	☐ 46- 55 years	☐ 56 - 65 years	☐ > 65 years	

ORAL FLUID TEST number: …….		
☐ Blood sample taken from suspected motorist for analysis:	☐ No	☐ Yes, sample number: …….
☐ Report analysis Forensic Laboratory number	☐ No	☐ Yes, report number: ……
Result of blood analysis: (report found psychoactive substances and concentrations etc):		

OBSERVATION BY THE POLICE OFFICER:					
ATTITUDE:	☐ Cooperative	☐ Restless	☐ Polite	☐ Laughing	☐ Confused
	☐ Loss of memory	☐ Hallucinating	☐ Drowsy	☐ Disoriented	☐ Agitated
	☐ Fumbling	☐ Stupurous	☐ Anxious	☐ Disinterested	☐ Combatative
	☐ Argumentative	☐ Agitated	☐ Excited	☐ Insulting	☐ Other, ……
	☐ Changing moods	☐ Abnormal fear	☐ Panic	☐ Apathic	☐ Inhibited
	☐ Lethargic, Inert	☐ Nervous	☐ Aggressive	☐ Unsteady	☐ Reckless
	☐ Inconspicuous	☐ Depressed	☐ Excited	☐ Restlessness	☐ Euphoria
	☐ Self-complacency	☐ Other,			
COORDI-NATION:	☐ Cannot stand still	☐ Normal	☐ Disturbed balance	☐ Decreased	☐ Unsteady
GESTURE/ SIGNS	☐ Uncoordinated	☐ Facial itching	☐ Dry mouth	☐ Exaggerated	☐ Licking at lips
	☐ Grinding of teeth	☐ Other,			
SPEECH:	☐ Non communicative	☐ Incoherent	☐ Slow	☐ Thick/slurred	☐ Talkative
	☐ Repetitive	☐ Unintelligible	☐ Rapid	☐ Other	
BREATH ODOR	☐ Chemicals	☐ Cannabis	☐ Alcohol	☐ Other,	
FACE:	☐ Normal	☐ Flushed	☐ Pale	☐ Other,	
PUPILS:	☐ Dilated	☐ Constricted	☐ Pulsing	☐ Normal	☐ Other,
EYES:	☐ Heavy eyelids	☐ Bloodshot	☐ Watery	☐ Pink, red	☐ Normal
	☐ Other,				
DRIVING BEHAVIOUR:	☐ Reaction too late at stop sign	☐ Try to avoid to be controlled	☐ Wavering	☐ Ignoring red traffic light	☐ No reaction on stop sign
	☐ Traffic accident	☐ Sudden stop	☐ Other,		
CONTACT:	☐ Does not react	☐ Talkative	☐ Normal	☐ Affectionate	☐ Dilated
	☐ Hardly any reaction at external stimuli		☐ Other		
BODY REACTION:	☐ Goose flesh	☐ Trembling	☐ Vomiting	☐ Nausea	☐ Perspiring
	☐ Increased breathing	☐ Normal	☐ Other		
MENTAL STATUS:	☐ Disorientated	☐ Delusions	☐ Confused	☐ Forgetfulness	☐ Absurd talking
	☐ Lack of concentration	☐ Depressed	☐ Disturbed sense of distances		
	☐ Can only concentrate on only one issue at the time			☐ Illogic thoughts	
	☐ Given instructions must be repeated			☐ Disturbed sense of time	
	☐ Can not understand the content of long sentences			☐ Other.	
OTHER ISSUES:	☐ Cannot be woken up	☐ Coma	☐ Sleepy	☐ Deep sleep	☐ Other
	☐ Known drug user	☐ Smell of cannabis		☐ Recent injection marks	
	☐ Drug paraphernalia in possession	☐ Drugs found on passengers		☐ Drugs in possession driver	

INTERVIEW OF THE MOTORIST/SUSPECT BY THE POLICE OFFICER:		
Do you take insulin?	☐ No	☐ Yes, ...
Are you sick or injured?	☐ No	☐ Yes, ...
Are you taking medicines or drugs?	☐ No	☐ Yes, ...
Are you diabetic or epileptic?	☐ No	☐ Yes, ...
Are you under the care of a doctor or dentist?	☐ No	☐ Yes, ...
Do you have corrective lenses?	☐ No	☐ Yes, glasses, contact lenses

EYE EXAMINATION			
Reaction of the pupils to light	☐ Normal	☐ Slow	☐ No reaction
Estimated pupil size:	LEFT EYE	RIGHT EYE	
Room light:	mm	mm	
indirect light :	mm	mm	
Near total darkness	mm	mm	

HORIZONTAL GAZE NYSTAGMUS		
Does the eyeball pursue, or track smoothly?	☐ Yes	☐ No
Does the eyeball jerk distinctly at maximum deviation?	☐ Yes	☐ No
What is the angle of onset of the jerking?		
VERTICAL GAZE NYSTAGMUS		
Present?	☐ Yes	☐ No
EYE CONVERGENCE EXAMINATION		
Lack of convergence right eye?	☐ Yes	☐ No
Lack of convergence left eye?	☐ Yes	☐ No

ROMBERG BALANCE TEST			
Able to stand still or steadily with the feet together?		☐ Yes	☐ No
Any statement during test?		☐ Yes	☐ No
Any unusual sound during test?		☐ Yes	☐ No
Test carried out safely and correctly?		☐ Yes	☐ No
Test performed in ☐ .....seconds in stead of 30 seconds			
Other noteworthy observations:			
TREMORS:	Body tremors?	☐ Yes	☐ No
	Eyelid tremors?	☐ Yes	☐ No
MUSCLE TONE:	More rigid?	☐ Yes	☐ No
	More flaccid?	☐ Yes	☐ No
	Normal	☐ Yes	☐ No

WALK AND TURN		
Cannot keep balance?	☐ Yes	☐ No
Starts too soon?	☐ Yes	☐ No
Stops walking?	☐ Yes	☐ No
Misses heel-to-toe?	☐ Yes, ... Times	☐ No
Raises the arms while walking?	☐ Yes	☐ No
Steps off the line?	☐ Yes, ... Times	☐ No
Turns improperly	☐ Yes	☐ No
Wrong number of steps?	☐ Yes, ... steps	☐ No
Test carried out safely and correctly?	☐ Yes	☐ No

ONE LEG STAND		
Sways while balancing?	☐ Yes	☐ No
Uses arms to balance?	☐ Yes	☐ No
Hopping?	☐ Yes	☐ No
Puts foot down?	☐ Yes	☐ No
Test carried out safely and correctly?	☐ Yes	☐ No

FINGER TO NOSE TEST		
Missed nose with left finger?	☐ Yes, ... times	☐ No
Missed nose with right finger?	☐ Yes, ... times	☐ No
Test carried out safely and correctly?	☐ Yes	☐ No

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Annex 5 Format ESTHER Evaluation report

Team:	**NL 1 NL 2 NL3** **Belgium 1 Belgium 2 Belgium 3** **Germany 1 Germany 2 Germany 3** **Finland Spain Ireland**
Period:	**1 2 3 4 5 6** **7 8 9 10 11 12**
Device:	**MAVAND RapidSTAT Avitar DRUGOMETER** **Branan Oratect III EnviteC SmartClip** **Innovacon OrALert Securetec Drugwipe 5+** **Sun OraLine Surescreen OralTest** **Ultimed Salivascreen Varian OraLab 6**
Date:	
Team leader:	

1. Training/Instruction

(Provide text where attention is given to the issues mentioned below)

1.1 How was the training/instruction realised?
(CD ROM, instructor from manufacturer, instruction card, handouts etc.)

1.2 What was the date of the training? How many hours.
(Was the time sufficient for 6raining? What would be an acceptable minimum time for training on this device?)

1.3 Did all DPO's attend the training session.
(If not, how were absent DPO's trained?)

1.4 Was the training ended by an "examination" of the DPO.
(What were the most relevant issues for the "examination")

1.5 What training material and checklists were available for the DPO's

1.6 Was the training practical?
(Could DPO's get a good impression of situations they might be confronted with in practical testing? Information provided on Do's en Don'ts?)

1.7 Could all DPO's train with the devices?

1.8 What specific questions were raised by DPO's during the training and instruction?
(Questions where the answers could not be found in the instruction manual)

1.9 Was the trainer/instructor able to answer questions in an operational way?

1.10 What suggestions are raised by the DPO's to improve the training/instruction?

1.11 What suggestions are raised by the DPO's to improve the instruction material?

2. Testing

2.1 General

(DPO's have tested the device under operational conditions, Each test is evaluated by the DPO. Therefore a registration form is completed. At each registration form on page 3 questions are raised to be answered by the DPO. The answers related to the 20 tests executed during the period should be take in consideration in this section of the evaluation report)

2.1.1 Operability
Do you consider this test as successful from an operational perspective?
(question 1 page 3 oral fluid test form)

2.1.2 Indication
Is the indication given by the device in accordance with your observations related to use of substances of the tested person?
(question 2 page 3 oral fluid test form)

2.1.3 Collecting time
Do you consider the time to collect a saliva sample of this person as acceptable from an operational perspective?
(question 3 page 3 oral fluid test form)

2.1.4 Analysing time
Do you consider the time to get an indication from the device as acceptable from an operational perspective?
(question 4 page 3 oral fluid test form)

2.1.5 Hygienic aspects
Were you able to work in a hygienic and safe way during this test with this oral fluid screening device? (use of gloves etc.)
(question 5 page 3 oral fluid test form)

2.1.6 Cooperation of tested persons
Do you consider the tested person as cooperative and a good example for testing the device?
(question 6 page 3 oral fluid test form)

2.1.7 Operational trust in screening result
Would you rely on the indications received in this test?
(question 7 page 3 oral fluid test form)

2.1.8 Preparing activities at the road side
Are the required activities to prepare a screening test simple enough to be done at the road side?
(question 8 page 3 oral fluid test form)

2.1.9 Bringing saliva to the test strip
Can the collected saliva sample of the tested person be brought to the testing surface in a hygienic and simple way?
(question 9 page 3 oral fluid test form)

2.1.10 Ease of operation
Could this test easily be performed at the roadside?
(question 10 page 3 oral fluid test form)

2.1.11 Useable in different police vehicles
Could this test only be used at a patrol car, a truck or a police station?
(question 11 page 3 oral fluid test form)

2.2 User requirements based on testing of the device
Provide the opinion of the team related to the user requirement formulated based on performing screening tests using this device.

E.g. - possibilities to read the indications
- possibilities to avoid contact with saliva
- activities to prepare a test
- indication of collection of a sufficient amount of oral fluid

2.3 Required modifications of the device to improve operability
Provide suggestions of the team related to the improvement of the operability of the device based on performing screening tests using this device.

2.4 Recommendations for operational use of the device
Suppose this oral fluid screening device is appointed to be used by the police for screening purposes. What advice related to the use of the device could the team give to colleagues. (do's and Don'ts)

3. Conclusion

Summarise the strong and the weak aspects of this device from an operational perspective.

01-11-2006

Annex 6 Tables, Graphs and Figures

Tables

Graphs

Figures

Annex 7 Information on screening devices

The information provided in this annex are the claims of the manufacturers.

The information about the screening devices is provided by the manufacturer after a request of the task leader.

The information has not been checked by the task leader or by TISPOL and therefore does not reflect the opinion of TISPOL.

1. MAVAND Solutions GmbH

1.1 Company profile

- *General*

MAVAND Solutions GmbH is a biotechnology company that develops manufactures and markets accurate, cost-effective immunoassay diagnostic test kits, including some of the world's most effective point of collection saliva and urine tests for drugs of abuse. The Company and its distribution network throughout Europe target the police, customs, workplace, government, corrections, clinical and educational markets. MAVAND Solutions GmbH is European Master Distributor of ABMC. This company is offering one of the largest portfolio of oral fluid and urine drug of abuse tests as well as evaluation instruments, f.e. the Mobile Reader for roadside measurements, the Desk Reader and Desk Reader Professional. With its database management MAVAND Solutions provides a unique solution for evaluation, documentation and archiving of drug of abuse tests.

- *Products*

Highlight of the product range of MAVAND Solutions is the RapidSTAT® - a revolutionary point-of-collection test for saliva drug testing and surface wipe testing. It combines the easy handling of a saliva test with the sensitivity, accuracy and precision of a laboratory test which results are available in about 6-8 hours and is the first saliva drug test able to detect the limit of detection of 1 ng/ml THC in blood. RapidTOX®, RapidONE®, Rapid Drug Screen®, and InCup™ are high quality tests for the determination of presence/absence of drugs in urine.
The Mobile Reader is a Touch Screen Tablet PC with measurement unit that includes an integrated high resolution CCDE camera. It is small and handy and can be used perfectly for all roadside applications. The software evaluates automatically the positive or negative results and sends a signal as soon as the measurement is completed.
The Desk Reader™ is a compact device that can be connected to any computer or laptop via USB port. The Desk Reader Professional is a stand-alone touch screen with integrated PC. All instruments include the same software benefits, they interpret the results of a MAVAND drug test, data are archived, reports can be generated, results can be sent to a data management system, enabling the test administrator to easily manage their drug testing program.

- *Address*

MAVAND Solutions GmbH
Ulrichstr. 23
72116 Mössingen
Germany
Telephone +49 7473 958028
Fax +49 7473 958029

1.2 MAVAND RapidSTAT

- *General*

The components of the RapidSTAT are combined in a one-hand-clip system. RapidSTAT consists of:
- Incubation device and test cassette.
- Collection stick with aroma field.
- Buffer bottle (Figure 1..1).

The buffer bottle is needed to mix the oral fluid with the buffer fluid (Figure 1.2).
The result of the test can be read on the test device (Figure 1.3).

MAVAND RapidSTAT

Figure 1.1

Figure 1.2

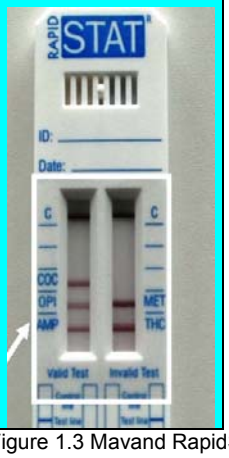


Figure 1.3 Mavand RapidSTAT

- *Cut off values*

MAVAND RapidSTAT cut off values	
Amphetamines	25 ng/ml
Benzodiazepines	10 ng/ml
Cocaine	12 ng/ml
Methadone	25 ng/ml
Methamphetamines	25 ng/ml
MDMA (ecstasy)	50 ng/ml
Opiates	20 ng/ml
Phencyclidine	2,5 ng/ml
Cannabis (Δ9-THC)	15 ng/ml

Table 1.1: Cut off values Mavand RapidSTAT

The RapidSTAT is developed for the detection of the following drugs in oral fluid:
- Amphetamines
- Benzodiazepines
- Cocaine
- Methadone
- Methamphetamines (including MDMA/Ecstasy)
- Opiates
- PCP
- THC – parent drug (Δ9-THC) /not the metabolite (THCCOOH)

The device is available in different variations.
One 5-panel test (COC / OPI / AMP / MET / THC)
Three 6-panel tests (COC / OPI / AMP / BZO / MET / THC)
(COC / OPI / AMP / PCP / MET / THC)
The procedure to perform an oral fluid screening test is as follows:

- *Collection and preparation of the sample*

1. In order to increase salivation of the donor, rub for four seconds over the aroma field on the collection stick in order to activate the scent.
2. Donor has to collect saliva by rotary movements in the mouth on both sides between cheek and gum (30 seconds). During this process remove foil from buffer bottle.
3. Put the collection stick into the buffer bottle. Agitate and twist the collector quickly back and forth for ten seconds.
4. Put the collection stick back in its tube and press the dropper lid onto the bottle.

- *Test procedure*

1. Pipet 7 drops into each well of the test device.
2. Close the lid until position 1 and shake it for 10 seconds.
3. Wait 4 minutes.
4. Test has to lay flat now: bend stopper and press down the lid completely.

- *Test results*

1. When all lines (drug- and control lines) have formed the test results can be read.
2. As soon as all lines have formed the test is negative.
3. If one or more lines are not visible, read the test in the 8th minute. Do not read the results after 8 minutes.

If all drug results are negative or when no further confirmation test is needed, dispose of the test components. For confirmation purposes the buffer bottle can be closed with a lid and sent to the lab.

- *Extreme temperatures and other weather conditions*

According to the test results available it is to detect that the RapidSTAT test does not work properly at a temperature of -4° C. Either the saliva-buffer-conjugate mixture moves very slowly on the strips or does not run at all. Therefore the device of the RapidSTAT test was designed the way that it can be kept on a warm place (car, pocket, etc.) in order not to be exposed to a temperature below 10° C. Having started the test by pressing down the lid completely the test can again be brought to a warmer and safe place (10° C).
The test window of the cassette is protected by a transparent cover implemented in the clip system in order to safeguard that no water or snow can come on the test strips.

- *MAVAND Mobile Reader (Reader 600)*

MAVAND Mobile Reader

Figure .1.4 Mavand Mobile Reader 600

Next to the RapidSTAT device MAVAND offers a Mobile Reader to interpret the reading of the device, to store the data and to send these data to a central data collection station or generate reports (Figure 1.4).
A special software for roadside measurements was designed in order to facilitate the data entry and reading of the results of the test.

- *Procedure: measurement with the Mobile Reader*

1. Switch on the Tablet PC. The Mobile Reader program boots up automatically and states the comment " READER System is started" (multi language).
2. Click on "New Measurement".
3. Enter data: the actual date appears automatically, select test type, select vehicle, enter identification number e.g. job list no., select gender. If no data is required, immediately click "OK".
4. Insert the test that has started running.
5. Start camera sequence by clicking on "continue".
6. The Mobile Reader software now starts automatically and will check whether the test valid lines have built. Then it starts to interpret the test.
7. As soon as the test results are ready the Mobile Reader will give a signal and the results can be used.

- *Test results Mobile Reader*

1. The test results can be sent or transmitted either via e-mail or via export function.
2. In addition to that the test results can be printed out on location by a blue-tooth printer.
3. All additional application modes are described in detail in the Mobile Reader manual included at each device.

- *Mavand Desk Reader Professional (Reader 710)*

Figure 1.5: Mavand Desk Reader professional 710

The Desk Reader Professional (Reader 710) is a desk top device with integrated PC and Touch Screen function. (Figure 1.5) It includes 4 USB ports. The Desk Reader professional enables the user to integrate drug testing in their daily working routine. The Reader interprets the test results and creates all relevant reports. The reader is an office/laboratory solution. A fully functional Windows PC is integrated with WLAN, Bluetooth and digital imaging system. The Reader is easy to handle by using pen or touch screen, has 4 USB ports, is completely factory installed with simplistic software enabling quick and fully automatic measurements preventing contamination with oral fluid samples. Software features and handling see Mobile Reader.

- *MAVAND Desk Reader (Reader 210)*

Figure 1.6: Mavand desk reader 210

The Desk Reader is a comfortable solution for all places where a PC or Laptop is available (Figure 1.6). The Desk Reader can be installed easily and quickly to every PC only by using an USB port and without needing an external power supply. The software (see software features and handling of Mobile Reader) allows an easy and rapid performance of examinations.

2. Avitar Inc.

2.1 Company profile

- *General*

Avitar Inc. is a leading company in oral-based instant diagnostics. Their proprietary disposable drugs-of-abuse test will change the way that drug testing is done worldwide. Avitar is investigating oral-fluid based diagnostic strategies for disease and clinical testing, such as tests for influenza, diabetes and pregnancy.

- *Products*

Avitar developed and launched ORALscreen™ , the world's first disposable oral fluid point-of-collection test (POCT) for drugs-of-abuse (DOA). In 2000, the company began marketing their four-panel test device for detection of marijuana, cocaine, opiates, and methamphetamines, including MDMA or Ecstasy, which can identify 96% of all positive drug screens. ORALscreen™ enables customers, specifically corporate, schools and criminal justice systems, to rapidly determine, with less down time, the status of those being tested, thereby lowering costs.
Oralscreen 4 removes the barriers to drug testing: Avitar's ORALscreen™ product enables on-site drug testing without the need for medical personnel, bathroom facilities or the embarrassment of supervised urine collection. ORALscreen™ can be used by virtually anyone, any time, in any place.
The Oralscreen device can be used in combination with a reader device. Test results will be available in approx. 15 minutes. The DRUGOMETER is the next generation of oral fluid screening devices based on the concept of the ORALscreen™ .

- *Address*

Avitar Inc.
65 Dan Road
Canton MA 02021
United States
Telephone : + 1 781 821 2440
Fax: + 1 760 942 8027

2.2 Avitar DRUGOMETER

- *General*

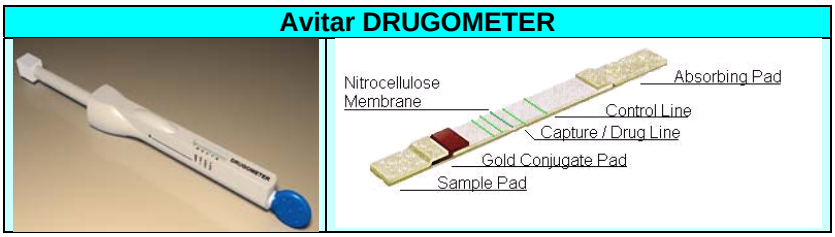


Figure 2.1 Avitar DRUGOMETER

The Oralscreen DRUGOMETER is the second generation product from Avitar. The device tests for the presence of drugs of abuse. It is an integrated sample collection and test device that is as easy to use as a thermometer. No special collecting facilities are required so a test can be performed almost everywhere and at any time. No handling of oral fluid is required. (Figure 2.1)

- *Cut off values*

Avitar Oralscreen DRUGOMETER cut off values	
Amphetamine/Methamphetamine including MDMA	50 ng/ml
Cocaine	20 ng/ml
Cocaine – BE	10 ng/ml
Opiates – Oxymorphone	100 ng/ml
Opiates - Morphine, Codeine, DiHydrocodeine, Hydrocodone, Hydromorphone	4 ng/ml
Opiates – Oxycodone	70 ng/ml
Hydrocodone (Lortab)	10 ng/ml
THC cannabis	50 ng/ml

Table 2.1: Cut off values Avitar DRUGOMETER

The DRUGOMETER is sensitive for the following drugs in oral fluid:

- Cocaine (including BE)
- Amphetamines - Methamphetamines (including MDMA/Ecstasy)
- Opiates (6-am, heroin, morphine, codeine, dihydrocodine, oxycodone, oxymorphone, hydrocodone, hydromorphon)
- THC – parent drug (∆9-THC) /not the metabolite (THCCOOH)

The device is available as a 4-panel test (COC/AMP/OPI/THC)

The procedure to perform an oral fluid screening test is as follows:

- *Collection and preparation of the sample*

1. Remove the DRUGOMETER from its individual package. Complete the specimen ID Section on the test device. Note the presence of five green indicator lines before the test is used. Push the DRUGOMETER handle to the forward position exposing the foam collector.
   Note: Please dispose of the small packet of desiccant which is in the package with the device.
2. Have the subject pucker their mouth and accumulate oral fluid before inserting the foam end of the DRUGOMETER into their mouth and gently move the DRUGOMETER around in their mouth for at least 3 minutes.
   Pressing gently with one's tongue may help the oral fluid to enter the foam. The donor should keep their mouth closed during the collection and not chew or suck on the foam.

   After 3 minutes, request that the subject remove the device from their mouth and hand it back.
   Note: The foam collector should swell in size after the sample collection.
   It may also appear floppy or weighted due to the oral fluid inside the foam. If you suspect an insufficient amount of sample was collected prior to locking the DRUGOMETER, simply reinsert the collector into the subject's mouth for additional time. Once the DRUGOMETER is locked in the downward position additional sample collection cannot occur.

3. Now the DRUGOMETER is ready to process the sample. Hold the DRUGOMETER at eye level, in an upright position with the test window facing you. The foam end of the DRUGOMETER should be slightly tilted towards you.

   Still holding the DRUGOMETER in the upright position count to 3 while slowly pulling the handle of the DRUGOMETER downward. You will begin to feel resistance as the foam collector enters the body of the device, however, continue to slowly pull the handle until the red indicator arrow is fully visible. The red stop line located directly above the tip of the red arrow, should also be visible and the handle will lock.

4. Immediately after step 3 gently place the DRUGOMETER on a table or flat horizontal surface, while keeping the test window facing upward. Soon after the device is placed on the table, a red wash will begin to flow across the test window, this is an indication that the device is running properly.
   Note: In order for the device to function properly: it must be placed on a flat horizontal surface immediately after step 3.

- *Test results*

The test results are determined by the presence or absence of red lines. It is possible that line intensity may vary for each drug line. Do not compare line intensities when interpreting results. The DRUGOMETER is a qualitative test. Variations in line intensity do not reflect drug concentration.
A drug negative interpretation may be made once a red line is clearly visible at the C (control) position and also indicated for the drug.
A non-negative interpretation must be made at 15 minutes after the DRUGOMETER is locked into the final position and placed on the table.

Note: Do not read results beyond 15 minutes after the DRUGOMETER is locked into the final position and placed on the table.

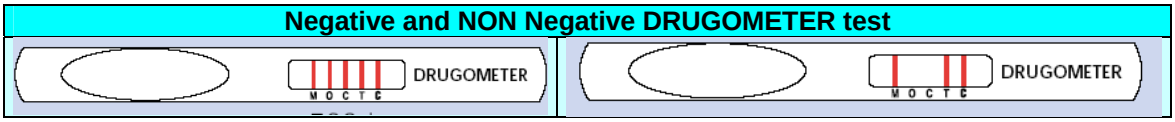


Figure 2.2 Negative DRUGOMETER test Figure 2.3 Non-negative DRUGOMETER test

A negative test result for all four drugs is indicated by the presence of five red lines. (Figure 2.2)
A non-negative test result is indicated by the absence of a red line at the position indicated for the drug. More than one drug line may be absent indicating a multiple non-negative.(Figure 2.3)

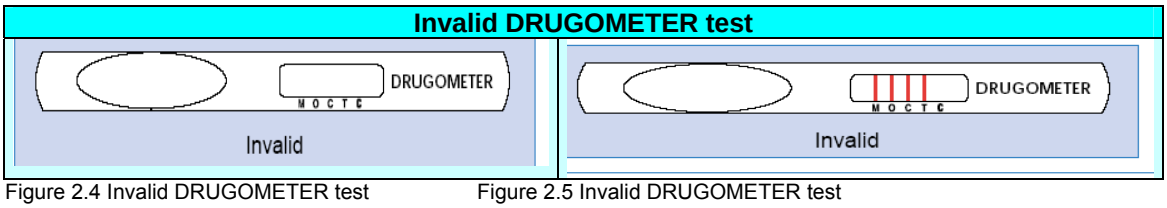


Figure 2.4 Invalid DRUGOMETER test Figure 2.5 Invalid DRUGOMETER test

An invalid test result is indicated by the absence of the red line at the C (control) position. (Figures 2.4 and 2.5)
In order to be valid, all test results must have a red control line present. If there is no red Control line, the test is invalid and the device and collector should be discarded. Open another package and repeat the process.

- *Extreme temperatures and other weather conditions*

The DRUGOMETER test does not work properly at a temperature of -4° C. The device should be stored on a warm place (car, pocket, a.s.o.) in order not to be exposed to a temperature below 10° C. Having started the screening of the oral fluid sample the device has again to be brought to a warmer and safe place (10° C).

3 Branan Medical Corporation

3.1 Company profile

- *General*

Branan Medical Corporation is an ISO 13485 certified and FDA licensed California based company that develops, manufactures and markets unique products for drugs-of-abuse testing. The company offers a complete line of rapid, on-site drug and adulteration tests in urine and oral fluids as well as quality control products. All its products have received CE marks. Developed with lateral flow immunoassay technology, Branan Medical's products are accurate, precise and sensitive. Branan Medical Corporation is dedicated to provide innovative products, excellent quality and friendly customer service.

- *Products*

The Oratect III product tests for the presence or absence of drugs of abuse in oral fluid. The test is intended to be administered by a trained professional. It should be used without supervision. The product is intended for forensic use only and not for diagnostic procedures.

- *Address*

Branan Medical Corporation
10015 Muirlands Dr, Ste. C
Irvine,
California CA 92618
USA
Telephone: + 1 949-598-7166 Ext. 115
Fax: + 1 949-598-7167
BMC has appointed representatives of the company in a number of European countries participating in the ESTHER task.

3.2 BMC Oratect III

- *General*

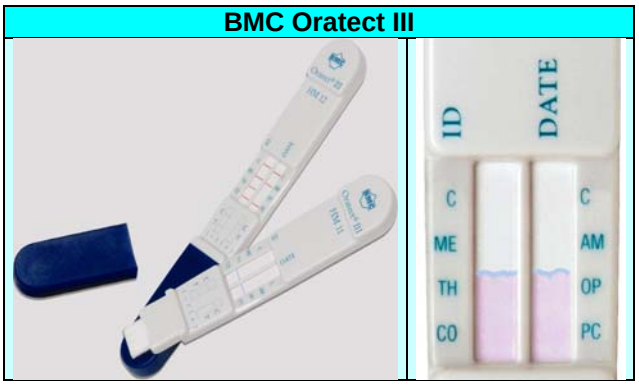


Figure 3.1 Branan Oratect III

The Oratect® III Oral Fluid Drug Screen Device is a one-step chromatographic immunoassay device for the qualitative simultaneous detection of amphetamines, benzodiazepines, opiates, phencyclidine PCP, cannabis THC, methamphetamine (including MDMA (Ecstasy)) and cocaine in oral fluid. (Figure 3.1). The Oratect® III has a simple, rapid, non-invasive, on-site, one step procedure. The total collection and testing time is less than 7 minutes. It will test simultaneous for 6 drugs, eliminates uncomfortable gender observation requirements, provides simple visual results and can be stored at room temperature.

- *Cut off values*

BMC Oratect III cut off values	
Amphetamines	25 ng/ml
Cocaine	20 ng/ml
Methamphetamines	25 ng/ml
MDMA (ecstasy)	25 ng/ml
Opiates	10 ng/ml
Benzodiazepines	5 ng/ml
Pencyclidine PCP	4 ng/ml
∆9-THC cannabis	40 ng/ml


Table 3.1 Cut off values Branan Oratect III

The BMC Oratect III device is sensitive for the following drugs in oral fluid:

- d-Amphetamine.
- Cocaine.
- d-Methamphetamine/MDMA (Ecstasy).
- Morphine.
- Benzodiazepines.
- Phencyclidine (PCP).
- ∆9-Tetrahydrocannabinol (not the metabolite THC-COOH).

The device is available as two 6-panel test

- Amphetamine, Methamphetamine (MDMA), Cocaine, THC, Opiates, PCP.
- Amphetamine, Methamphetamine (MDMA), Cocaine, THC, Opiates, Benzodiazepines.

The procedure to perform an oral fluid screening test is as follows:

- *Collection and preparation of the sample*

1. Remove the blue cap by holding the sides and pulling gently. This will expose the collection pad. Note: Do not touch the test window area.
2. Let the test subject open its mouth and let him rub the collection pad for 15 – 20 times inside its mouth against the cheek in a circular motion. Make sure to let the subject keep its head levelled.
3. Rub the collection pad 15 – 20 times against the opposite cheek in a circular motion.
4. Rub the collection pad 15 – 20 times on top of the tongue. Do not chew, suck, bite or bend the collection pad.
5. Rub the collection pad 15 – 20 times underneath the tongue.
6. Place the collection pad underneath the tongue for approx. 30 seconds to collect saliva. Instruct the subject to hold the device in place with its hand. If no flow of the blue lines appears in the test window after 30 seconds repeat step 2 – 6.
7. Remove the device from the mouth as soon as the flow of the blue line patterns appear at both the test windows. Replace the blue cap on the device.
   Note: the total time needed to collect an oral fluid sample under normal conditions is approx 3 minutes.
8. Lay the device on a flat surface and read the results in 5 minutes after removing the device from the mouth.
   Note: Do not read results after 30 minutes.

- *Test results*

The test results are determined by the presence or absence of red lines. It is possible that line intensity may vary for each drug line. Do not compare line intensities when interpreting results. The Oratect III is a qualitative test. Variations in line intensity do not reflect drug concentration.
For each of the test windows coloured bands should be observed: One band at the control region (C) and one band at the specific drug abbreviation (AM, OP,CO,PC,TH,ME,BD) in the test region.

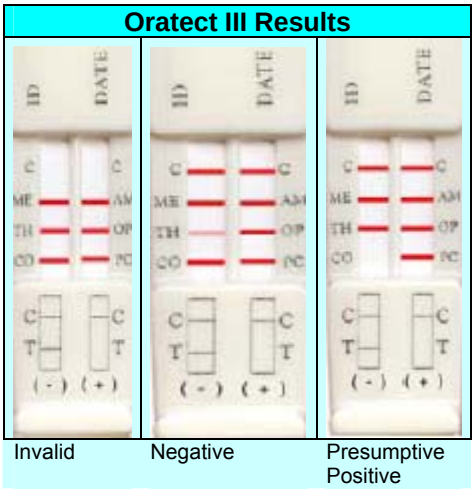


Figure.3.2 Branan Oratect test results

- *Invalid Results*

When no band appears in the control region (C), the test is invalid regardless of the results of the test region. If the test is invalid, check the testing procedures, and samples. (Figure 3.2)

- *Negative results*

Any band that can be seen visually, no matter how faint, is a negative result. Read each test independently. (Figure 3.2)

- *Presumptive positive results*

When the control band is visible in the control region (C) and no band appears at the specific test region , the result is presumptive positive for that particular drug. (Figure 3.2)

- *Extreme temperatures and other weather conditions*

The Oratect III device should be stored at room temperature.

3.3 Oratect XP and Oravue Reader

BMC Oratect XP and Oravue Reader

Figure 3.3 Branan Oratect XP and Oravue

The Oratect® XP Oral Fluid Drug Screen Device is a one-step chromatographic immunoassay device for the qualitative simultaneous detection of opiates, cannabis THC, methamphetamine (including MDMA (Ecstasy)) and cocaine in oral fluid. (Figure 3.3). The Oratect® XP has a simple, rapid, non-invasive, on-site, one step procedure. The total collection and testing time in less than 7 minutes. It will test simultaneous for 4 drugs, eliminates uncomfortable gender observation requirements, provides simple visual results and can be stored at room temperature.
The Oravue Reader enables the interpretation of the result of an oral fluid test on the Oratect XP device (Figure 3.3).

4 EnviteC Wismar GmbH

4.1 Company profile

- *General*

EnviteC was founded in 1992 and employs approx. 100 people, a large proportion of them in research and development. In order to ensure the company's middle and long-term growth, EnviteC invests a large part of its profits in the research and development of new products and technology. Right from the start the emphasis has been on the development and production of sensors and high-quality monitoring devices. Today the spectrum includes sensors and instruments used in medical, industrial and environmental technology, such as breathalysers for police traffic controls and medical applications.

- *Products*

The SmartClip® combines the sample collection unit and the analysis unit in one device. The use of saliva or sweat enables uncomplicated, painless, non-invasive sample collection.
Due to a special protecting system the contact with the potentially contaminated sample material has been minimized for the operating staff.
The hygienic packaging and the sterilised sampling sponge assure the high safety standard also for the tested subject.
All materials in contact were tested regarding their biocompatibility according to ISO 10993-5.

- The SmartClip® Multidrug detects simultaneously Amphetamines, Methamphetamines, Ecstasy, Cocaine, Crack and Opiates by using oral fluid or sweat.
- SmartClip® THC/AM detects simultaneously Cannabinoids and Amphetamines by using sweat.

The SmartClip® provides reliable results in a matter of 1-10 min after starting the test.
The internal control line secures the validity of the result.
It's easy to use and no additional equipment is required.

- *Address*

EnviteC-Wismar GmbH
Alter Holzhafen 18
23966 Wismar
Telephone: + 49 3841 360 304
Fax: + 49 3841 360 222

4.2 EnviteC SmartClip Multidrug

- *General*

Figure 4.1.: EnviteC SmartClip Multidrug

The SmartClip Multidrug can be used to detect 4 drug groups simultaneously (Amphetamine, MDA, BDB; cocaine (also as Crack); Morphine, Heroin, Codeine; Ecstasy, Methamphetamine, MBDB) in the saliva or sweat of a test subject. (Figure 4.1). The product is designed as a screening test for single use by a trained user. Results will be available within 10 minutes.
The device must be closed to analyse the collected sample for drugs.

- *Cut off values*

EnviteC SmartClip Multidrug cut off values	
Amphetamines	50 ng/ml
Cocaine	20 ng/ml
Methamphetamines	100 ng/ml
MDMA (ecstasy)	100 ng/ml
Opiates	40 ng/ml


Table 4.1 Cut off values EnviteC SmartClip Multidrug

The procedure to perform an oral fluid screening test is as follows:

- *Collection and preparation of the sample*

1. Remove the SmartClip from the package.
2. Remove protective cap from the sponge.
3. Test subject soaks collection sponge with saliva under the tongue with the mouth closed.
4. The subject conducting the test checks whether the sponge has swollen to approx 3 times its original size.
   Note: If this is not the case the test subject must again soaks the collection sponge with saliva under the tongue with the mouth closed.
5. Apply 10 – 12 buffer solution drops onto the sponge.
6. If enough saliva is collected remove the clamp from the holder of the SmartClip.
7. Close the SmartClip so that viewing window faces upwards and test is in horizontal position.
8. Press SmartClip together firmly for 5 seconds. Do not re-open SmartClip.
9. After 1 – 10 minutes in horizontal position the test can be evaluated.

- *Test results*

The test with the SmartClip can be evaluated as soon as all 6 test-lines are visible in the viewing window. This can often occur within just 1 – 3 minutes. If individual lines are missing: Inspect 10 minutes after folding. (Analysis is possible up to a maximum of 30 minutes after the test is folded).
If both control lines “C” can be seen, the test was successfully completed and can be analysed.
Note that for the analysis of the drug lines, a visible line indicates that the respective drug group was not detected.
If the respective line is not visible, however, this indicates that the respective drug group was detected by he test. As long as a line as such is visible it counts as being present.

5 Innovacon Inc.

5.1 Company profile:

- *General*

Innovacon, Inc. is a subsidiary of Inverness Medical Innovations. Innovacon, Inc. markets lateral flow rapid diagnostic healthcare products based on a philosophy of high quality, low price, and superior flexibility. Prior to April 1, 2006, when Innovacon was acquired by Inverness Medical Innovations, Innovacon was known as ACON Laboratories. ACON has brought its customers high quality, low price rapid diagnostics for over eight years. Innovacon carries on the tradition established by ACON. Key product segments of Innovacon are Drugs of Abuse, Fertility, Infectious Disease, Cardiac Markers, and Tumour Markers. Most of these products are available for sale in the U.S. Innovacon's primary focus is support for our OEM partners and distributors. Innovacon draws upon the extensive OEM experience that we gained while we were ACON Laboratories. The rapid test products are available in generic OEM packaging or custom formats, including customized devices, custom packaging, and custom labelling

- *Products*

The OrALert Saliva device consist of a sample collector and multi-drug device. The use of saliva or sweat enables uncomplicated, painless, non-invasive sample collection.
The device has a separate collector and specimen chamber. As the donor collects his or her own specimen and expresses the specimen into the chamber the test administrator has minimal chance of getting in contact with the specimen. No additional equipment is required. The OrALert design allows for visual interpretation. The test administrator is not required to wear gloves.

- *Address*

Innovacon Inc.
4106 Sorrento Valley Boulevard
San Diego,
California
CA 92121
United States
Tel: +1 858 535 2030
Fax: +1 858 535 2035

5.2 Innovacon OrALert

- *General*

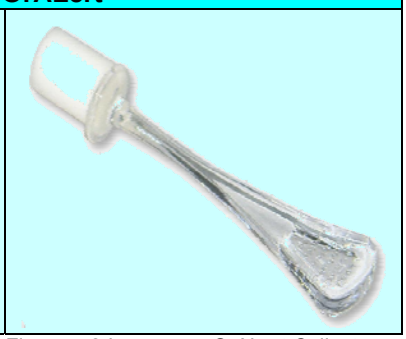
Innovacon OrALert	
	

Figure 5.1 Innovacon OrALert device Figure 5.2 Innovacon OrALert Collector

The OrALert Saliva device can be used to detect 6 drugs simultaneously (Cannabis, Amphetamine, Methamphetamine (including MDMA) Cocaine, Opiates, Methadone, PCP and Benzodiazepines. (Figure 5.1). The product is designed as a screening test for single use. The oral fluid collector (Figure 5.2) has a coating with sucrose and citric acid encourages the saliva production.
The test can be performed by the tested subject without help of the test administrator. The collecting time is approx. 3 minutes. The total test time is approx. 10 minutes.

- *Cut off values*

Innovacon OrALert cut off values	
Amphetamines	50 ng/ml
Cocaine	20 ng/ml
Methamphetamines	50 ng/ml
MDMA (ecstasy)	50 ng/ml
Opiates	40 ng/ml
Δ9-THC (Cannabis)	100 ng/ml
PCP	10 ng/ml

Table 5.1 Cut off values Innovacon OrALert

The procedure to perform an oral fluid screening test is as follows:

- *Collection and preparation of the sample*

1 Instruct the donor to insert the sponge end of the collector into the mouth and actively swab the inside of the mouth and top of the tongue.
2 As soon as the sponge softens slightly, instruct donor to gently press the sponge between the tongue and teeth to ensure complete saturation.
3 Collect sample for a total of three (3) minutes before removing the sponge.
4 Instruct donor to insert the collector into the test device by pushing it into the chamber and rotating the collector clockwise until engaged, an audible “click” will be heard.
5 Wait 60 seconds after the audible “click”.
6 After 60 seconds, instruct donor to rotate the collection chamber counterclockwise.
7 Set timer for 9 minutes.
8 Interpret results at 9 minutes.
9 Read results at 9 minutes.
10 If positive results are observed, instruct the donor to remove the collector by turning it counter-clockwise and pulling. Instruct donor to secure the cap over the collection chamber and seal the reservoir with tamper evident tape. The device can then be forwarded to a laboratory for confirmation testing. The laboratory can access the sample reservoir through the stopper.

- *Test results*

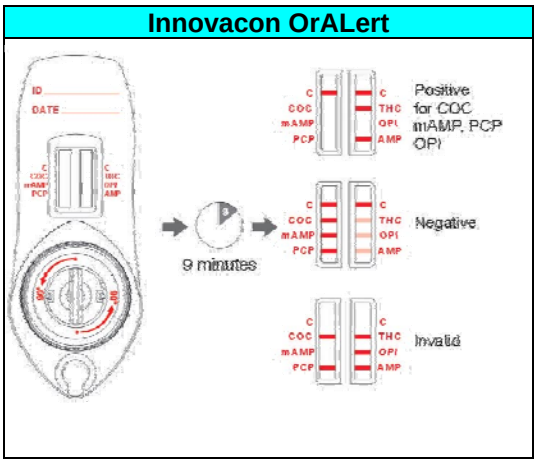


Figure 5.3 Test results Innovacon OrALert

The test with the OrALert device can be evaluated after the nine minutes have past. (Figure 5.3)
If both control lines “C” can be seen, the test was successfully completed and can be analysed.
Note that for the analysis of the drug lines, a visible line indicates that the respective drug group was not detected.
If the respective line is not visible, however, this indicates that the respective drug group was detected by the test.
As long as a line as such is visible the test should be considered negative.

6 Securetec Detektions-Systeme AG

6.1 Company profile

- *General*

Securetec Detektions-Systeme AG was founded in 1995 and has established itself as a successful solution provider who develops, manufactures and sells field applicable detection systems for a wide range of threats and targets. Both development and production meet the highest international standards.
In close cooperation with clients, Securetec Detektions-Systeme AG develops high quality detection solutions for drugs, explosives and dangerous substances which are both innovative and user-friendly. As experts in the development and application of detection systems, Securetec also offers consulting, training and after sales services.
Securetec primarily provides solutions for road safety, customs and drug enforcement authorities, as well as consultancy services to corporations, educational institutions and prevention/rehabilitation organisations. Securetec works with a number of international organisations to ensure the timely identification of, and reaction to, global trends in drug-abuse.

- *Products*

Drugwipe® rapid tests from Securetec AG, are helping officers to quickly and reliably gain suspicion of drug-abuse both at the roadside and in the police station. Thanks to leading-edge antibody detection technology, Drugwipe tests can be applied non-invasively, using either saliva or sweat. Both specimen demonstrate significant advantages over urine and are much easier to handle for both the tester and the subject being tested.
Traditional laboratory testing takes time and is costly, even more so if it subsequently proves to be incorrect. Drugwipe results are available within 3 – 10 minutes and up to 5 substances can be reliably detected in a single specimen. The Drugwipe device is available in different configurations (single, twin and 5 panel tests) and can be complemented with an electronic reader.

- *Address*

Securetec Detektions-Systeme AG
(StartPoint Technologie Park)
Eugen-Sänger-Ring 1
D-85649 Brunnthal / Munich
Germany
Tel.: +49 89 203080-1651
Fax: +49 89 203080-1652
Email: info@securetec.net
www.securetec.net

6.2 Securetec Drugwipe

- *General*

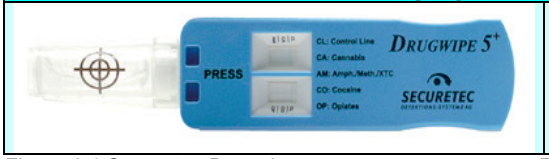
Securetec Drugwipe 5+	
	

Figure 6.1 Securetec Drugwipe 5+ Figure 6.2 DrugRead

- *Cut off values*

Securetec Drugwipe 5+ cut off values			
d-Amphetamine	100 ng/ml		
Cocaine	50 ng/ml		
d-Methamphetamine	50 ng/ml		
MDMA (ecstasy)	100 ng/ml		
Opiates	20 ng/ml		
Cannabis Δ9-THC	30 ng/ml		

Table 6.1: Cut off values Drugwipe 5+

Additional single tests cut off values	
Benzodiazepines	10 ng/ml
Methadone	30 ng/ml

Table 6.2: Cut off values additional single test

The procedure to perform an oral fluid screening test is as follows:

- *Collection and preparation of the sample*

1. Check the „expiration“ date of the device and be sure there is NO damage to the packet.
2. Tear open the foil packet at the cut, remove the device.
3. Advice the tested person to move the tongue around the cheek for 3 times.
4. Lift off the blue cover of the device and separate it from the white body.
5. Wipe down the tongue 3 times with moderate pressure. Alternatively advice the tested person to collect the sample. Only 10 µl of sample is required.
6. Replace the blue cover onto the white body gently and close firmly with a double click.
7. Bring the test into a vertical position. Press strongly with your thumb on the mark shown on the ampoule until you hear a click indicating the breaking of the ampoule.
8. Hold the device vertical for 15 seconds to allow the running buffer moving up the test strips.
9. Hold the device horizontal for 3 – 10 minutes (reaction time). Reaction time depends on the type and quantity of drugs that are available in the saliva sample.
10. The display will show the red control line (CL) and other lines if drugs have been consumed. When using Drugwipe in bad weather conditions protect the result window from ingress of rain water.

- *Test results*

The test with the Drugwipe device can be evaluated after 3 – 10 minutes.
The result of the Drugwipe 5+ is shown as red lines: the Test Lines and the Control Lines. The position of the Test and the Control lines are indicated in the original (unused) Drugwipe 5+ with a blue dye. These blue lines will disappear during the test cycle and will be replaced by the red Test Lines and a red Control Line.
The Test Line is also to be interpreted as positive if it is incomplete over the whole of the width of the strip. An uneven or incomplete Test Line is due to an uneven sample distribution on the test path of the wiping element. In case the Control Line does not appear the test has to be interpreted as invalid and has to be repeated.

7 Sun Biomedical Laboratories Inc.

7.1 Company profile

- *General*

Sun Biomedical Laboratories, Inc. researches, manufactures, develops and distributes innovative biomedical diagnostic products, including rapid "on-site" drug tests for drugs of abuse and alcohol. On the cutting edge of science and technology, we apply the newest biotech research in the development of diagnostic products, therapeutic reagents and devices for drug testing kits. Sun Biomedical Laboratories Inc. specializes in developing on-site drug testing kits for diagnostic applications. Goal is to provide customers with the most effective drug test kits while offering them service with courtesy, confidentiality, reliability and professionalism.
Sun Biomedical Laboratories Inc. provides cost-effective solutions for the growing drug problem that the public needs now more than ever. With patented, clinically studied, and FDA approved drug and alcohol tests, as well as other drug test components, the company is providing ammunition to help fight the war against drug abuse.
Sun Biomedical Laboratories has formed many alliances, both private and public.

- *Products*

OraLine's® unique design makes on-site testing a snap by eliminating the need to handle potentially messy bodily fluids, embarrassing collection observation, and the possibility of sample adulteration. The OraLine® test is fast, accurate and affordable. Results are available in just 10 – 12 minutes. OraLine provides on-site rapid-results for THC, COC, OPI & MET. The device is easy to administer anywhere and anytime. The patented collection process is safe and clean. There is no need for special training or expensive equipment to administer the test.

- *Address*

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7.2 Sun OraLine

- General

Figure 7.1 Sun OraLine

- *Cut off values*

Sun Biomedical Labs Inc. OraLine cut off values	
Amphetamines	50 ng/ml
Cocaine	25 ng/ml
Methamphetamines	50 ng/ml
MDMA (ecstasy)	50 ng/ml
Opiates	40 ng/ml
Cannabis THC COOH	4 ng/ml

Table 7.1: Cut off values Sun OraLine

The procedure to perform an oral fluid screening test is as follows:

- *Collection and preparation of the sample*

1. If the test device was stored refrigerated, allow the test device to come to room temperature prior to opening the pouch.
2. Make sure that the subject being tested has had nothing in his/her mouth for at least five (5) minutes before the oral fluid sample is collected (including food and chewing gum).
3. The subject being tested must be able to produce and deliver a sufficient volume of oral fluid sample (about 0.4 ml) with minimum amount of bubbles in order for the test to function properly. In case of collection difficulty, the administrator may choose to collect the oral fluid in a disposable cup first. The oral fluid could be delivered into the spoon by pouring or using a pipette.
4. Remove the test device from the pouch. Verify that five (5) green lines are present in the test window (thin arrow). If the green lines are not present, a new device with 5 visible green lines should be used. Mark the device with the subject's name or ID number (wide arrow) and remove the cap.
5. Prepare for the OraLine test by explaining the test procedures to the test subject while allowing the subject to accumulate enough saliva in the mouth for about a minute.
6. Place the spoon end of the device into the subject's mouth and collect a spoonful of oral fluid. Make sure *the spoon is in a horizontal position with the handle upward*. If pouring the sample from a cup, also ensure that the spoon is held horizontally with the handle in an upward position.
7. Once the spoon is filled, do not replace the cap until the sample shows up in the view window. Place the device on a protected flat surface, and allow running for 10 minutes.

- *Test results*

1. The test results are read between 10 – 12 minutes in the viewing window. Make sure the control line (C) is clearly visible before reading and recording the results.
2. For normal negatives, the red lines will replace all green lines as the test runs. Absence of any test line is presumptive positive for the tested drug. The OraLine® test has shown effective in detecting recent drug usage. (Please refer to the product insert for detailed description).
3. If the test is read before ten (10) minutes or after twelve (12) minutes, the results may be different. Thus, it is most important to record the results within 10 – 12 minutes.

8 Surescreen Diagnostics Ltd.

8.1 Company profile

- *General*

Surescreen evolved in 1991 when a group of British forensic scientists realised that their analytical skills were as valid in medicine as they were at a murder scene.
It's their lateral thinking which puts Surescreen ahead of the competition, by bringing together sophisticated technologies to create our unique range of cutting edge diagnostic products.
Surescreen Diagnostics Ltd. has become leaders in in-vitro diagnostics test kits and devices for drugs, pregnancy, disease and lifestyle tests and in detection and management of medical conditions via screening and clinical chemistry. Surescreen provides complete screening and programmes and training.

- *Products*

Oral fluid is an ideal drug test medium because saliva drug levels relate to blood levels and hence indicate impairment. This easy to use test detects the six main drug types, is very accurate and easy to read. The test takes about 6 minutes..

- *Address*

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www.surescreen.com

8.2 Surescreen Oral twist cassette

- *General*

Surescreen Oral Twist cassette	
	

Figure 8.1 Surescreen Oral twist cassette Figure 8.2 Reader

- *Cut off values*

Surescreen Oral twist cassette cut off values		
Amphetamines	50 ng/ml	
Benzodiazepines	3 ng/ml	
Cannabis ∆9-THC	100 ng/ml	
Cannabis (metabolite)	12 ng/ml	
Cocaine	20 ng/ml	
Methamphetamine	50 ng/ml	
Methadone	15 ng/ml	
Opiates	50 ng/ml	
Phencyclidine	10 ng/ml	

Table 8.1: Cut off values Surescreen Oral Twist cassette

The procedure to perform an oral fluid screening test is as follows:

- *Collection and preparation of the sample*

1. Place the spoon into the subject's mouth and start collecting oral fluid.
2. The Surescreen collector softens and starts to droop when there is enough saliva collected. Thanks to the stimulant, this can take less than a minute, and rarely more than two minutes.
3. Tell the donor to chew on the sponge and only remove it when all the hard bits have disappeared.
4. Take the test cassette out of the pouch and put it on a flat surface.
5. The sponge collector is inserted into the chamber then pushed down and rotated clockwise until it latches into the spigot. This keeps the collector in place. The test will run automatically.
6. If the test has not started to run after a minute or so, ask the donor to put the sponge back in their mouth to collect more fluid, and repeat the exercise.

- *Test results*

1 Results are shown in the results window, and should be read at five to ten minutes. The presence of a line against the drug type is a negative, and the absence of a line at the drug type is a positive indication. The presence of any line, however faint it is, is classed as a negative result. As soon as a line forms, you can be sure the test is negative, even when this is before the five minutes has elapsed.
2 Wait the full 10 minutes before you record the absence of a line
3 Confirmation of a positive result is easy with this test, because there is a chamber in the test which stores the excess oral fluid. Simply rotate the knurled ring clockwise until it reaches its stops, and send the whole cassette to the laboratory.

9 Ultimed Products GmbH

9.1 Company profile

- *General*

"The Ultimate Pharma Products GmbH" was founded by managing director, Matthias W. Engel, in 1994 in Lübeck, and was renamed later into Ultimed Products (Deutschland) GmbH. From the beginning Ultimed is specialized in manufacturing, im- and exporting as well as distribution of in-vitro diagnostic medical devices. Ultimed develops special IVD and methods of analysis like saliva drug tests - patents are pending.
In cooperation with famous institutes in Europe and the USA, Ultimed uses a wide range of modern research and development laboratories.
As one of the first manufacturers of IVD, Ultimed was certified in the year 2000 according ISO standards after the installation of an extensively quality assurance system for all sections of the company. From manufacturing to the registration of the products, and the distribution as well as the despatch of every shipment, Ultimed is associated with high quality.

- *Products*

The Salivascreen VI can detect the presence of 6 main groups of drugs. The device can be completed by a reader. Results of a screening test will be available within 10 minutes.

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www.ultimed.de

9.2 Salivascreen VI

- *General*

Ultimed Salivascreen VI


Figure 9.1 Ultimed Salivascreen VI

- *Cut off values*

Ultimed Salivascreen VI cut off values	
Amphetamines	50 ng/ml
Cocaine	20 ng/ml
Methamphetamines	50 ng/ml
MDMA (ecstasy)	50 ng/ml
Opiates	40 ng/ml
Cannabis THC COOH	12 ng/ml
Methadone	40 ng/ml

Table 9.1 Cut off values Ultimed Salivascreen VI

The procedure to perform an oral fluid screening test is as follows:

- *Collection and preparation of the sample*

1. Allow the test device, specimen, and or controls to reach room temperature (15 - 30º C) prior to testing.
2. Remove the Salivascreen VI from the pouch and use it as soon as possible.
3. Insert the absorbent pad end of the cassette into the mouth of the test subject and instruct him to move the absorbent pad from top to bottom of the tongue and back again filling the absorbent pad with saliva.
4. Instruct the test subject not to pull on or chew the absorbent pad.
5. While collecting saliva hold the result window end of the cassette down.
6. When liquid is flowing onto the test strip remove the cassette from the tested subjects mouth.
7. Total time to saturate the absorbent pad will vary between 1,5 – 4 minutes depending on the saliva production of the tested subject.
8. Place the cap on the cassette and wait 10 minutes before reading the test results.
9. Test results can also be read by a hand held reader.

- *Test results*

1. After 10 minutes the results of the test can be read at the test line region if the test is valid.
2. A coloured line in the control line region indicates that the test is valid.
3. A coloured line in the test line region indicates a negative result for the specific drug. This indicates that the drug is not present or the drug concentration in the oral fluid specimen is below the designated cut-off level for that specific drug.
4. Absence of the coloured line in the test line region together with the presence of the coloured line in the control line region indicates a positive result for a specific drug. This indicates that the drug concentration in the oral fluid specimen exceeds the designated cut-off level for that specific drug.
5. If the control line fails to appear at the end of the test this indicates that an insufficient volume of oral fluid is provided or incorrect procedural techniques caused the failure of the device.
6. The test result can also be provided by a handheld reader. The test can be stored in the memory of the reader, transferred to a PC or printed by a mobile printer.

- *The reader and printer*

Figure 9.2 Salivascreen VI and Reader

There is an option to use a handheld reader to let the system read the indications on the device. This reader can be beneficial during bad weather and at night. It is possible to produce a printed copy of the results and the test files can be downloaded to a computer.

- *The Reader*

The Reader is a battery powered, hand held or table mounted device which incorporates advance electronics, software and features all of which remove subjectivity from the reading of Ultimed test cassettes and provide a definitive test result document (Figure 5.9.2). The Reader can generate a printed report containing filled out test forms, test results and a photograph of the actual test cassette. The total system including compact carrying case weighs less than 3,2 kilograms. The procedure to use the reader is rather simple.

1. Inserting the cassette after providing enough oral fluid by the test subject. Remove the plastic cap from test cassette opening of the reader and insert the Test Cassette, plastic end first into the Reader. The test window faces towards the small end of the Reader. The green light on the label will illuminate when the Test Cassette is inserted.
2. Test. Touch *Test* on the lower centre of the display. Note that a Test in Process bar shows progress of the cassette reading, and the green light on the label blinks. Within 10 seconds, the cassette tests and results appear on the screen with a photograph of the actual test cassette.
3. Signature Pad. A signature pad can be provided under the test results (optional). This may be signed with the stylus provided. A signature can be erased by selecting the menu item *File, Erase Signature.*
4. Information Form. To fill out User/Subject information forms, select *File* from the menu on the lower left of the screen. Then touch *Information Form* from the menu. Fill in the information form using the keyboard accessed by touching the *keyboard icon* at the lower right on the screen. To remove keyboard from screen, press *keyboard icon*.
5. Save data. Press the *Save button* to save the form data. To exit the form without saving the information, press *Cancel*.
6. Exit Test. To exit the test press the *Exit* menu item in the lower right hand corner of the screen. The user will be prompted to complete the information form if it was not done. If the user uses the *OK* button on the top right of the screen to exit the Test Results screen, this prompt will not occur.
7. Remove Cassette. Remove the test cassette and insert the cap on the Reader cassette opening.

- *Mobile printer*

1. Turn on the printer. To print, first turn on the Brother printer by pressing the top on/off switch. An amber light appears upper left of the printer. Then turn on Bluetooth interface by moving the slide switch on the left side towards the top. A blue light appears upper left of the printer indicating that Bluetooth is on. The printer is now ready to receive wireless communication.
2. Print Test Results. On the Reader touch File and then Print in the lower left corner of the screen A “Bluetooth Browser” screen with appear on the Reader display. Touch the icon on the screen and wait while it prepares then send the test result to the Brother Printer. The printed page will emerge from the top of the printer. Note: If this is the first time that a reader and printer are being used together, the reader will search for a Bluetooth device. When it finds the Brother printer, it will ask for a passkey. Enter the last 4 numbers of the printer’s serial number (displayed along with the printer icon or also found on the back of the printer).
3. To *Review Print*, press that item on the menu. To print, see instructions that follow. Upon leaving the present test, it will be saved in the memory of the reader.

10 Varian Inc.

10.1 Company profile

- *General*

Varian Inc. takes the guesswork out of safeguarding your world. Trust On-Site® and OnTrak™, Varian, Inc.'s convenient, cost-conscious drug screens, to deliver rapid, reliable results when and where you need them most - pre-employment screening, reasonable cause or incident-driven assessment, routine workplace testing, or court-mandated compliance. The patented design and careful manufacturing free you from strict test timing and false positives. Choose the test most in keeping with your needs - urine or saliva - in many multiple screen combinations.
Varian, Inc. has emerged as the acknowledged expert in all phases of toxicology and onsite drug testing. Training and education have long been hallmarks of our dedication to customers' satisfaction. Varian, Inc.'s SMARTesting™ solutions offers SMARTknowledge, SMARTdata, and SMARTresults through our commitment to education, 24/7 support, expert consultants, intelligent data management, and laboratory services.

- *Products*

On•Site OraLab is a simple, qualitative assay that detects recent drug use in oral fluids. Its uniquely designed container splits the specimen, using half for immediate drug-of-abuse testing and storing the remaining sample in a tamper-evident container for confirmation testing, if required. OraLab is specially designed to collect, test, and store oral fluids in one container without the test administrator handling the sample. Results will be available in less than 15 minutes. OraLab identifies cocaine, morphine (Opiates), amphetamines, methamphetamines, PCP and cannabis THC.
Dräger Safety AG & Co is providing the OraLab6 device under the Brand Dräger DrugScheck for the European market.

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10.2 Varian OraLab6

- *General*

Varian Oralab6


Figure 10.1 Varian OraLab 6

- *Cut off values*

Varian OraLab 6 cut off values		
d-Amphetamine	50 ng/ml	
Cocaine	20 ng/ml	
d-Methamphetamine	50 ng/ml	
MDMA (ecstasy)	50 ng/ml	
Opiates	40 ng/ml	
Cannabis ∆9-THC	50 ng/ml	
Phencyclidine	10 ng/ml	

Table 10.1 Cut off values Varian OraLab 6

The procedure to perform an oral fluid screening test is as follows:

- *Collection and preparation of the sample*

Prior to collection, instruct the subject to drink four (4) ounces of water, and to place nothing else in the mouth such as food, drink, gum, or tobacco products for 10 minutes. Then instruct the subject to draw a pool of oral fluid into the mouth with a “puckering” action for a few moments before collection.
Collect fresh oral fluid specimens as follows; no preservative, special handling, or pre-treatment is required, and no diluents, dilution, or buffer is necessary.

1. Instruct the subject to remove the collector from the plastic wrap, and place the collector foam inside the mouth for up to three (3) minutes, completely saturating the collector foam with oral fluid.
   Specifically, instruct that the donor:
   - Bathe the collector foam in the pool of oral fluid.
   - Alternatively, stimulate salivation by continuously moving the collection foam along the sides and lower margin of the tongue.
   - Not chew, compress, or suck on the collector foam.
2. Observe the collection.
3. Have the subject remove the collector from the mouth and hand it to the administrator. The collector foam should be very wet, and must not be compressed when removed. (It is very important that the collector remain in the donor’s mouth for a sufficient time period. The goal is to collect a minimum of one (1) millilitre of sample (use the markings on the tube as a guide). If insufficient sample is collected, repeat the collection with a new collector/expresser, adding the additional sample to the same tube.
   - Guide the collector foam down into the oral fluid expresser at the opening of the tube, and slowly push the collector downward until it comes to a firm stop. (There will be some resistance and a popping sound about 2/3 the way down the expresser, make sure the collector is pushed past that point, all the way to the bottom of the expresser. To express the maximum amount of sample, lift up slightly and push downward a second time.)
   - Oral fluid flows directly into the collection tube.
   - Pull straight up on the collector and lift out of the tube; the expresser will be attached to it. Throw both of these pieces away.
4. Open the foil pouch and remove profile card. Record subjects ID if desired in the writable area and drop card down into the tube, “arrow” first. Allow testing card to drop to the bottom of the tube. (Do not place profile card in mouth).
5. Wait 10 minutes and interpret results. Do not read results after 15 minutes.
6. If result confirmation is necessary, remove the testing card and firmly seal the tube. Place evidence tape up and over the cap, and place tube into a chain-of-custody bag. Always ship in accordance with applicable local, state, or federal regulations.

- *Test results*

Test validity and results must be interpreted between 10 and 15 minutes after initiating the test.

1. Interpret test validity: A valid test is indicated by a band in the area of the card next to the “TV”. TV = Test Valid, A = Amphetamine, P = Phencyclidine, O = Opiate, M = Methamphetamine, C = Cocaine, T = THC. Since a valid test may give a faint or incomplete band, any Test Valid band confirms that the test is valid. Due to the high viscosity and variability of some saliva samples, test results may require up to 15 minutes to form. An invalid test is indicated by the absence of a distinct band in the Test Valid area or by a reddish reagent background on the strip which obscures the presence of bands 15 minutes after the test is initiated. If an invalid result is obtained, see Step 3 .
2. Immediately interpret test results as either negative or preliminary positive.
    - A negative result for a given drug (i.e., drug absent or below the cut-off) is the presence of a band in the area adjacent to the drug label. (The intensity of the bands in the results area may vary. A negative sample may give a faint or incomplete band; any band in the result area indicates a negative result.
    - A preliminary positive result for a given drug (i.e., drug present above the cut-off, suggesting current or recent drug use) is the absence of a band in the test result area adjacent to the drug label. The adjacent area appears off-white.
    - If all drug results are negative, or if no further confirmation tests are required, properly discard the test card and tube.
    - When confirmation of a preliminary positive screen result is required, follow established Chain-of-Custody procedures for shipment to a laboratory.
3. If test did not run, or if invalid test results are obtained, use a second OraLab 6 device, after discarding the first.
    - Instruct the donor to drink 4 ounces of water. Assure that this water is swallowed and that nothing else is placed in the mouth for three to five minutes.
    - During the minute or two prior to collection, instruct the donor to draw a pool of saliva into the mouth with a “puckering” action.
    - Provide a second packaged collector to the donor, and repeat collection instructions with emphasis on:
        - Bathing the collection foam in saliva, and/or
        - Continuous gentle movement of the collector over the tongue throughout the collection
    - Observe a 4-minute collection and perform the test according to the instructions in “Collect Saliva & Start Test” section.

11 Cozart (Concateno plc)

11.1 Company profile

- *General*

Concateno is Europe's leading drug and alcohol testing provider and a manufacturer of clinical diagnostic products. Concateno is committed to working with government, employers, health and law professionals to help reduce the impact of this problem. Our testing expertise is unmatched and our staff are passionate about working with customers to find the best possible solution for them.

- Largest group of toxicology and drug testing scientists in Europe.
- Recognised worldwide experts in the field.
- Award winning research & innovation.
- Resources and capabilities to meet every customer requirement.
- Unmatched international accreditation.

The Concateno group, which consists of Medscreen, Marconova, CPL, Trichotech, Euromed, Altrix and Cozart, has the most comprehensive drug and alcohol programme available to meet each customers' specific needs - from point-of-care instant tests through to independently audited and accredited laboratory analysis for urine, oral fluids, hair, blood or sweat.

- *Point of Care Products*

Concateno can provide point of care products suitable for testing using oral fluid, urine and sweat. We can also provide on-site systems for the detection of drugs of abuse in powders, tablets, resins and liquids, as well as on surfaces. The Cozart® DDS is the latest on site oral fluid system from Cozart, which was launched in 2006 and is already used by a number of police forces across the world. The Cozart® DDS is a simple and accurate system, providing rapid detection of six drug classes, within five minutes and detection of two drug classes in 90 seconds.

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11.2 DDS

- *General*

A point of care, oral fluid test with reader and optional printer; collects and tests a sample for up to six drugs of abuse in minutes. The system was designed specifically with the roadside market in mind, where speed and reliability are essential. The system comprises of:

- Cozart® Oral swab for collection of the oral fluid sample

Sample collection indicator - Guarantees accurate defined sample volume - Optimised for drug detection - Designed to have minimal loss of drugs, which means that more drug is available for testing

- A disposable test cartridge
  - Evaluates the oral fluid sample for the presence of drugs
  - A range of cartridge configurations are available depending on requirements

- A handheld instrument
  - Interprets and digitally displays the results and stores them for future reference
- Optional Printer
  - Provides a permanent record of the test results with date and time

All of these elements have been optimised to ensure that the user gets a rapid and reliable result with minimal user steps.

- *Cut off values*

Cozart DDS cut off values	
Cannabis (∆9-THC)	* 31ng/ml
Cocaine (Benzoylecgonine)	30 ng/ml
Opiates (Morphine)	30 ng/ml
d-Methamphetamine	50 ng/ml
Amphetamine	50 ng/ml
Benzodiazepines (Temazepam)	20 ng/ml
Methadone	20 ng/ml

Table 11.1 Cut off values Cozart DDS

* Fortifying samples with Δ^9THC is difficult due to losses of material to surfaces and degradation. Validation using real samples was employed to illustrate the levels of Δ^9THC found in DDS positive samples. Fifty-five poly-drug positive samples were obtained at a drug clinic. Twenty six samples gave a DDS positive response for cannabis and were further tested by GCMS for the presence of Δ^9THC in oral fluid. All DDS screen positives were found to contain Δ^9THC. Six of the twenty six samples had Δ^9THC concentrations between 31 and 150 ng/ml. The remaining twenty samples had concentrations of Δ^9THC ranging from 174 to 3006 ng/ml. This illustrates that the DDS system is able to detect at least 31 ng/ml of Δ^9THC.

- *Test Procedure*

1. To collect an oral fluid sample actively swab the Cozart® Oral Swab around gums, tongue and inside cheek until the sample presence indicator turns completely blue.
2. Remove cap from the sample buffer bottle and place the Cozart® Oral Swab into the bottle bud-end first.
3. Snap the stem of the Cozart® Oral Swab by gently bending it at the scored break-point. Place the flip top lid on the sample buffer bottle,
4. Mix the contents of the bottle by gently moving it from side to side for 30 seconds, while holding the bottle upright and on a flat surface.
5. Ensure the DDS is now ready to begin a new test. Open the flip-top lid of the sample buffer bottle. Hold the bottle vertically and apply 4 drops of the fluid across the sample well of the test cartridge.
6. As soon as the fluid appears on each of the 4 white cartridge membrane strips (this will take between 2 and 30 seconds) insert the cartridge into the DDS instrument with the arrow facing upwards.
7. Initiate a new test. Once completed the results will be displayed on the screen of the DDS instrument.

- *Test results*

Test results are shown on the display of the reader device. Results are presented as positive of negative for a specific named substance on the display.

There is an optional small printer that can be connected to the reader, providing a hard copy of the results of the test with date and time.

12 Dräger

12.1 Company profile:

- *General*

Drägerwerk AG & Co. KGaA is a leading international corporation in medical and safety technology: Dräger products protect, support and save lives. Founded in 1889, the technology corporation achieved a global turnover of € 1.819,5 million in 2007 and an EBIT of € 151,9 million. Today the corporation headquartered in Lübeck employs approx. 10.000 people in over 70 sales and service companies world-wide and is represented in 190 countries. The subsidiary Dräger Safety offers products, services and system solutions for a comprehensive risk management, especially for personal and plant protection.

- *Products*

The products of Dräger Safety detect and protect against hazardous substances, as part of a total solutions concept for hazardous substance management. The range of products and services designed for the identification and early detection of gaseous hazardous substances, including: toxic gases and vapours explosive gases and vapours oxygen and alcohol and drugs.
The Focus Group Diagnostics product portfolio comprises a wide variety of breath alcohol detection systems, drug testing devices and services as exemplified on the picture.

- *Address*

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12.2 Drug test 5000

- *General*

Figure 12.1 Dräger Drug Test 5000

The Dräger Drug Test®5000 system comprising two main components: the Drug Test 5000 Test Kits and the Drug Test 5000 Analyzer. It is an immunochemical in-vitro diagnostics system for the fast, accurate performance of testing qualitatively oral fluid samples for drugs of abuse, such as amphetamines, designer amphetamines, opiates, cocaine and metabolites, benzodiazepines and cannabinoids. The Drug Test 5000 Analyzer as complete “work station for the field”. With a simple three-key operation the analyzer can be linked to a wide variety of data recording devices. Data management, built-in self-test capability controls temperature, optics and general operations. The analyzer is suitable as a complete “Substance abuse monitoring” setting for on-the-spot measurement.

The test kits are ready for immediate use. The design of the collection device properties guaranties hygienic use.

- *Cut off concentrations*

Dräger Drug Test 5000 cut off values				
Substance class	Calibrator			
Δ9-THC	Δ9-THC	25 ng/ml		
Cocaine	Cocaine	20 ng/ml		
Opiates	Morphine	20 ng/ml		
Amphetamine	D-Amphetamine	50 ng/ml		
Methamphetamine	D-Methamphetamine	25 ng/ml		
Benzodiazepine	Diazepam	15 ng/ml		

Table 12.1 Cut off values Dräger DrugTest5000 system

Dräger DrugTest5000 Test Kits consists of one major part, a test cassette complete with oral fluid collector and a buffer cartridge.

The procedure to perform an oral fluid screening test is as follows:

- *Collection and preparation of the sample*

1. Check that the analyzer is switched on.
2. Remove the protective cap from the oral fluid collector of the test cassette and hand the test cassette to the tested person.
3. Instruct the tested person to place the oral fluid collector inside the cheeks and move it carefully from one side of the mouth to another.
4. Do not chew or suck on the oral fluid collector.
5. Once the sample adequacy indicator turns blue, normally after approx. one minute, an adequate sample amount has been collected. NOTE: in very rare cases (<1%) the blue discoloration will not appear (viscosity of the samples etc.). Stop the collection process at least after 4 minutes and proceed as normal.
6. Take the test cassette from the tested person, open the door of the analyzer and insert the test cassette into the lower compartment until it engages audibly; the user display on the display will show a “quit” of the action.
7. Insert the cartridge into the upper compartment of the analyzer until it engages audibly; the user display on the display will show a “quit” of the action.
8. Close the door of the Analyzer and follow the instructions shown on the screen.
9. After closing the door the analyser autonomously carries out the further processing:
   - The cartridge is lowered onto the collector of the cassette and thus washes the specimen out of the mouthpiece and into the specimen dish of the cassette,
   - Thereafter the specimen-buffer solutions is homogenized by several mixing steps,
   - The analyser controls and sets the desired temperature to ensure constant conditions, enhancing precision,
   - A programme is now executed according to the bar coded identifier of the test cassette to develop the test strip.
   - The analyser displays an intermediate result of the already completed analyses after 5 minutes.
10. After completion of the test the Analyzer displays results for each drug on the screen. These results can be “positive” or “negative”, optional protocol onside is possible immediately; measurement data are stored in the analyzer memory.
11. Remove the cassette with the cartridge attached from the Analyzer after completed analysis and dispose of the test kit.

13 Biosensor Applications Sweden AB

13.1 Company profile:

- *General*

Biosensor Applications is a Swedish company located in Solna, outside of Stockholm, and in Bonn, Germany. The company develops, manufactures and sells biotechnology based detection systems for drugs and explosives.
The detection equipment combines proven immunoassay technology with Quartz Crystal Micro balance (QCM) resulting in systems with both high selectivity and sensitivity for the target substances and very short detection time. The technology creates detection capabilities within nanogram levels for both explosives and narcotics with a combined sampling and analysis time of less than 3 minutes.
Biosensor's customers are found among police and correctional authorities, border control, security companies, military, rehabilitation clinics and workplace control on a world-wide basis. Biosensor Applications uses advanced biotechnology to create state of the art products for security and narcotic abuse testing applications. High selectivity and sensitivity in exposed environments are keywords for such applications and are the base of our entire product portfolio.

- *Products*

The BIOSENS® system is comprised of the Collection System and the Analysis System. It is very versatile and suitable for a number of different applications.
The BIOSENS® system provides a unique method for detecting the presence of narcotics in humans through sweat analysis or analysis of oral samples. This approach can greatly reduce the need for invasive urine based screening.
The BIOSENS® system also provides a versatile tool for trace detection in security applications, where reliability and robustness combined with high sensitivity and very low false alarm rate are the key criteria.

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13.2 Biosens

- *General*

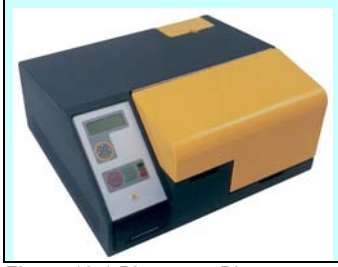
Biosensor Biosens		
		

Figure 13.1 Biosensor Biosens, cartridges and collection probe

The BIOSENS® Dynamic S is a quick, non invasive drug screening system for on-site testing. It is based on proven immunoassay technology for a high specificity combined with Quartz Crystal Microbalance (QCM) for a high sensitivity
Samples are collected by wiping the tongue. The mucosal material from the surface of the tongue is collected by using a special developed collection device (Patent pending).
The sample is then automatically processed in the BIOSENS® oral screening system. A full analysis takes approximately two-three minutes including sample acquisition.
The screening result is printed as a receipt and can be stored in the BIOSENS® and recalled at a later stage for report purposes.

- *Cut off values*

Drugs accumulate to the surface of the tongue due to interactions with the mucosal surface layer on the tongue. The concentration of drugs in the mucosal layer of the mouth is between 10 - 100 times higher than found in the surrounding saliva. This means that a sample collected from the tongue contains a higher amount of drugs even if the drug content in saliva is low.
In the table the amount of drugs on the tongue-sample is converted to an equivalent saliva concentration using a low accumulation factor of 20 (used as an average).

Biosensor Biosens cut off values		
Cannabis ∆9-THC	12 ng/ml	
Cocaine	8 ng/ml	
Opiates	10 ng/ml	
MDMA (Ecstasy)	12 ng/ml	
Methamphetamine	12 ng/ml	

Table 13.1 Cut off values Biosensor Biosens

- *BIOSENS Start up & Verification*

Before analyzing samples the BIOSENS has to be verified. Verification should be conducted at start up or once every day. Daily maintenance should also be performed to ensure that no contamination is left in the BIOSENS.

1. Select "*Maintenance* " and then select "*Clean probes*" from the menu.
2. Wipe the probes, sample tray and the dome with a moistened alcohol swab. Confirm the display message with the "*GO*" button when ready.
3. When finished, Press the "*GO*" button to run a blank sample to ensure that there are no contamination left in the BIOSENS.
4. Select "*Verification*" by scrolling down with the arrow keys. Press "*GO*" to continue.
5. Now press the "*GO*" button to start verifying.
6. Insert the verification sample on the sample tray.
7. This message is displayed when the verification is successful.
8. The receipt shows the successful result including substance names, time and date.
9. The BIOSENS is now ready for analyzing samples .

- *Collection and preparation of the sample*

1. Remove the protective bag. Take out the collection probe, grip the end of it. The "*THIS SIDE UP*" marking must face upwards.
2. Hold the collection probe parallel with the tongue. Rub the designated collection area firmly 4 – 5 times back and forth on the surface of the tongue.
3. Visually inspect that the sample is within the designated collection area.
4. When the sample is obtained, snap the perforated part in the middle of the collection probe and fold it until it snaps in place.
5. Place the oral collection probe on the BIOSENS sample tray. The "*THIS SIDE UP*" marking must face upwards.
6. Press the "*GO*" button on the BIOSENS to start analyzing the sample.
7. The result will be presented on the display within 2 minutes.

- *Test results*

The test result will be shown on the display. The result can be
"*NEGATIVE*" or "*POSITIVE".*

NEGATIVE result: Confirm the result by pressing the "*GO*" button. The BIOSENS is ready for the next sample .
POSITIVE result: Confirm the result by pressing the "*GO*" button. An automatic cleaning will start. When finished the BIOSENS is ready for the next sample.