

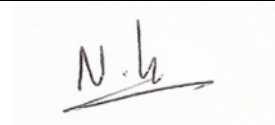
Drug Screening Devices

A Guide to Type-Approval Procedures
for Drug Screening Devices Used for
Transport Law Enforcement in Great Britain

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Summary

Drug screening tests for a wide range of transport operatives were introduced into Great Britain in July 2003 as part of the Railway and Transport Safety Act 2003. The primary legislation dealing with drug driving offences is the Road Traffic Act 1988. The Railways and Transport Safety Act 2003 creates similar offences for operators of marine and air transport. All of this legislation requires that Drug Screening Devices be of a type-approved by the Secretary of State for the Home Department. In this context the definition of a drug is very wide and includes any substance other than alcohol that may affect a person's ability to operate transport safely.

This Guide contains a description of the technical requirements to be met for consideration of type-approval for new Drug Screening Devices for police use in Great Britain. It is intended to be a reference for manufacturers wishing to develop new devices. The document contains details concerning the construction of Drug Screening Devices, their operation and the methods for testing prior to submission to the Secretary of State for the Home Department for consideration for type-approval. This is a functional requirement for products that may be manufactured by any process.

Any requirements for goods or materials to comply with this Guide shall be satisfied by compliance with either a British Standard or other named international standard. National standards or technical regulations, or traditional procedures of manufacture of any Member State of the European Community, where these are the subject of a written technical description sufficiently detailed to permit assessment of the goods or materials for the use specified, shall be acceptable provided that the standard, code of practice, or technical specification provides, in use, equivalent levels of safety, suitability and fitness for purpose (see paragraph 1.4).

Legal and technological changes may render parts of this Guide obsolete and the Home Office reserves the right to revise it accordingly. In that case a revised Guide will be published but the change may be introduced prior to such publication.

Electromagnetic Compatibility (EMC)

A note has been added at Annex B, page 21, to inform manufacturers, that where appropriate, devices supplied for evaluation and subsequent use in Great Britain must comply with the mandatory requirements for Electromagnetic Compatibility (EMC) as given in the European Directive 2004-108-EC dated 15 December 2004.

In addition, all devices supplied for evaluation and subsequent use by police in Great Britain must also comply with the EMC Immunity Test Procedures for Breath Alcohol Measuring Devices FSS-BAU-3/02.

The Forensic Science Service produced this document on behalf of the Home Office and enquiries relating to it should be addressed to:

Type Approval Manager
Forensic Science Service
109 Lambeth Road
London SE1 7LP

A Guide to Type-Approval Procedures for Drug Screening Devices

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1 Introduction

1.1 The type-approval procedure consists of a number of technical performance tests that are carried out on devices supplied by the manufacturers or their appointed agents. The performance tests are detailed in Annexes A, B and C.

1.2 The purpose of this document is to define requirements for the construction of Drug Screening Devices, their operation and the means and methods employed in testing them. This document is intended to be a guide to manufacturers and their agents but the procedures will be updated from time to time to take account of legal and technical changes, and amended versions of this Guide will be issued when appropriate; such changes may be introduced prior to such publication.

1.3 The following national and international standards and specifications are referred to in this document:

- ISO 9001-2000 - Quality management systems. Requirements.
- BS EN ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories.
- BS EN 61000-6-3 - Electromagnetic compatibility. Generic emission standard.
- BS EN 61000-6-1 - Electromagnetic compatibility. Generic immunity standard.
- BS EN 55022:1994 + A1:1995 + A2:1997 - Information technology equipment. Radio disturbance characteristics. Limits and methods of measurement
- BS EN 60068-1:1995 - Environmental testing. General and guidance.
- BS EN 60068-2-30:1999, Environmental testing. Test Db - Damp Heat, Cyclic
- BS EN 60068-2-27:1993, Environmental Testing. Test Ea - Shock
- BS EN 60068-2-7:1993, Environmental Testing. Test Fc - Vibration (Sinusoidal)
- BS EN 60068-2-68 dated 1996, Environmental Testing Test 2L - Dust & Sand
- BS EN 60068-2-68 dated 2001, Environmental Testing Test 2R - Water
- 2004-108-EC dated 15 December 2004 European Council (EC) Directive on Electromagnetic Compatibility (EMC)
- OIML Doc 11, General Requirements for Electronic Measuring Devices (Draft Document - 2003)
- IEC 61000-4-1 (2000-04), Electromagnetic compatibility - Testing and measurement techniques - Overview of IEC 61000-4 series
- FSS-BAU-3/02 EMC Immunity Test Procedures for Breath Alcohol Measuring Devices

1.4 Any requirement for goods or materials to comply with a specified standard shall be satisfied by compliance with:

- i. a relevant standard or code of practice of a national standards body or equivalent body of any Member State of the European Community, or
- ii. any relevant international standard recognised for use in any Member State in the European Community, or
- iii. a relevant technical specification acknowledged for use as a standard by a public authority of any Member State of the European Community, or
- iv. traditional procedures of manufacture of a Member State of the European Community where these are the subject of written technical description sufficiently detailed to permit assessment of the goods or materials for the use specified, or
- v. a specification sufficiently detailed to permit assessment for goods or materials of an innovative nature (or subject to innovative processes of manufacture such that

they cannot comply with a recognised standard specification) and which fulfil the purpose provided by the specified standard

if the proposed standard, code of practice, technical specification or procedure of manufacture provides, in use, equivalent levels of safety, suitability and fitness for purpose.

2 Type Approval Procedures

2.1 Manufacturers should, in the first instance, make a request in writing to:

Road Crime Section SC1 (Public Order and Police Co-operation)
Home Office
Fry Building
2 Marsham Street
SW1P 4DF

2.2 Before submission for formal type approval, a new Drug Screening Device will undergo user trials by two or more police forces. ACPO Road Policing will arrange these trials at the request of Road Crime Section. User trials will only be arranged if the device is thought to have potential for police use where type-approved equipment is required. Devices accepted for user trials must have the potential to:

- i. Be practical to use in a police operational environment.
- ii. Comply with the requirements of this guide.

User trials will be designed to assess the suitability of the device for use under operational conditions. User trials may not be required prior to re-testing of already approved devices that have been modified or updated.

2.3 Following satisfactory completion of the practical assessment by ACPO Road Policing, the device shall be submitted for laboratory evaluation to the Home Office nominated laboratory. The Home Office nominated laboratory shall be accredited by the United Kingdom Accreditation Service (UKAS).

2.4 Laboratory testing shall consist of three categories. These are Response to Drugs (Annex A), Response to Physical Interference (Annex B) and Software Validation (Annex C). The manufacturer is expected to bear the full costs of the test laboratory's evaluation work.

2.5 The results of checks and tests carried out by the bodies and laboratories of other Member States, including in particular those in conformity with BS EN ISO/IEC 17025:2000, may be taken into consideration for the tests at Annex B, provided that such results provide a level of accuracy, fitness and suitability for purpose equivalent to the results of tests carried out in the United Kingdom. Such bodies and laboratories must offer suitable and satisfactory guarantees of technical and professional competence and independence.

2.6 When the assessments at Annex B have been satisfactorily completed, the manufacturers shall supply a device (or devices, where the device is a single-use disposable device) on loan to the Home Office nominated laboratory. Sufficient proprietary reagents, single-use test cartridges or other consumables required to complete the assessment shall be supplied to the Home Office nominated laboratory free of charge. The devices must be accompanied by all the relevant reports issued by the approved test houses and the documentation required by Annex C.

2.7 The Home Office nominated laboratory shall carry out the tests detailed in Annex A, functional tests required to check the requirements of Annex C, and such additional user acceptance testing as it deems necessary, to be assured that the device meets the requirements specified in this Guide.

2.8 The manufacturers shall provide (where appropriate) the following at the time of testing:

- A handbook or a set of written instructions for the use of the device operator
- A handbook or a set of written instructions for the use of the device supervisor
- A written technical description of the device's operation
- A full circuit diagram with all the circuit components clearly indicated
- Details of the internal analytical unit including details of the measurement technique(s) used and the algorithm employed to interpret the results
- A full specification for any embedded software in the device plus copies of the source and object code for that software.
- Details of the quality assurance and validation protocols used by the software developers. This system shall be certified to the ISO9001-2000 standard.

NOTE

- The design and operation of the device will determine which materials and documents must be provided, and this should be agreed in advance with the Home Office nominated laboratory.
- Documents referred to in paragraphs (iv) to (vi) above will be returned to the manufacturer at the completion of evaluation of the devices, unless the device is recommended for type-approval.

2.9 The Home Office or its agents shall accept no liability for breakage or damage.

2.10 On completion of the type-approval testing the manufacturers shall supply, free of charge, to the Home Office nominated laboratory an identical device (see notes 2 and 3 below) to the final type-approved device. This device will be held by the Home Office nominated laboratory as an exemplar device. It may be used to test any modifications to the type-approved device, before recommending the proposed change for type-approval or any other testing the Home Office nominated laboratory or Home Office deems necessary.

2.11 When a device has satisfactorily completed all testing, the Road Crime Section of the Home Office shall consider obtaining the agreement of the Secretary of State for the Home Department for formal type-approval for police use in Great Britain. The Road Crime Section shall prepare a supporting agreement for signature by the supplier and Home Office officials on behalf of the Secretary of State for the Home Department. For the purposes of type-approval, the agreement shall, unless specifically advised by the Home Office, require the manufacturers (see paragraph 4.5):

- Not to change the approved device in any way without the written agreement of the Secretary of State or his agent.
- To ensure that the type and serial number of each device is clearly identified by an indelible marking.
- To ensure that the serial number is unique to each device.
- To ensure that any repair and calibration facility relating to the device is accredited to the ISO/IEC 17025 and open to inspection by the Home Office, any UK Police Force, the Home Office nominated laboratory, or UKAS.
- To ensure that any update of the operating instructions shall be sent to all users including the Home Office nominated laboratory on behalf of the Home Office.
- To label with a version number any software or firmware.
- To deposit documentation detailing the program with the Home Office free of charge. This documentation to include:
 - Source and object code for the software.
 - The relevant check sums for the software.
- To supply free of charge to the Home Office a full circuit diagram of the device with all the circuit components clearly indicated.
- To supply free of charge to the Home Office nominated laboratory, on behalf of the Home Office, an exemplar device (see notes 2 and 3 below) identical to the

type-approved device, which may be one of the devices provided for type-approval testing.

NOTE

1. In paragraph (i) above a change means physical modifications to the analytical system, the electronic boards or the program instructions of the computer program but excludes:
 - Use of electronic components that meet the same technical specification
 - Changes to agreed data parameters used by the computer program (see Annex C)
2. The exemplar device (paragraph ix above) may be used to test any modifications to the type-approved device, before recommending the proposed change for type-approval or any other testing the Home Office nominated laboratory or Home Office deems necessary.
3. If the type-approved device is a single-use disposable cartridge, or any part of the approved device uses single-use disposable items, the manufacturer must provide six examples of each new batch of the disposable cartridge (or item(s)) as exemplar devices to the Home Office nominated laboratory. Each new batch may be used to check that there is no difference between batches supplied to the police service.
4. With the agreement of the Home Office the requirement to deposit documents in paragraphs (vii) & (viii) may be satisfied by an agreement to hold them in escrow.

2.12 The Home Office and the Home Office nominated laboratory undertake to keep all information provided confidential in so far as that undertaking does not conflict with any duty of disclosure in a criminal prosecution.

3 General Requirements

3.1 The device and all associated components should be designed to ensure the safety of both the operator and the user of the device. Particular attention should be made to the design and use of electrical connections, electrical supply wires and the materials chosen for construction of swabs, mouthpieces or any other item with which the user will have intimate contact.

3.2 Manufacturers shall ensure that all servicing and adjustment of approved devices will be carried out by an organisation accredited to the ISO/IEC 17025 standard by the United Kingdom Accreditation Service (UKAS).

3.3 Manufacturers shall ensure that when devices are supplied for police use in Great Britain, either when new or after factory servicing, they meet the standards detailed in this document.

3.4 The manufacturer shall check the calibration of re-usable devices every six months. A calibration certificate shall be issued and held by the police. A calibration label from a UKAS-accredited supplier showing the number of the current calibration certificate and the calibration due date shall be fixed to the device. Manufacturers of single-use disposable test cartridges shall test a representative sample of each production batch of the test cartridge to ensure that they meet the standards detailed in this document.

3.5 Calibration of approved devices in operational use shall be carried out by a trained and competent person.

3.6 All equipment used for calibrations having a significant effect on the accuracy or validity of the result of calibration shall be calibrated before use. Such calibrations shall be traceable to recognised national or international standards. Traceability shall be evidenced by calibration certificates bearing the UKAS Accreditation Mark or equivalent.

3.7 Any repair and subsequent recalibration shall be carried out by the manufacturers or their appointed agents, who shall keep accurate records, which shall be open to inspection by the Home Office and/or UKAS.

3.8 The manufacturers shall make provision for expert witnesses for court cases with regard to the operation and performance of the device.

3.9 Assistance with police training in respect of the device operation shall be made available by the manufacturers.

4 Definitions

4.1 Adjustment or Verification to a Standard

Adjusting or verifying the device, using a standard mixture of drugs in buffered aqueous solution. When this adjustment or verification is being carried out the drug mixture must pass through the entire analytical train.

4.2 Carry-over

Carry-over is an elevated response to a drug in subsequent samples following the analysis of a sample containing a high concentration of that drug.

4.3 Cut-off

The cut-off is the lowest concentration of a target drug that shall be used to indicate the presence of that drug.

Note - The cut-off levels listed in Annex A are analytical cut-off values only. They should not be taken to represent an "impairment threshold".

4.4 Drug Screening Device

A device designed to detect the presence of a specified drug or drugs or groups of drugs in saliva and to provide an indication of the presence of one or more of these in the specimen by means of a colorimetric change, lights or an alphanumeric display.

The results may also be presented in the form of a printed report.

The Drug Screening Device shall consist of two modules:

- 1) Sample Collection (see paragraph 4.10)
- 2) Test Reader (see paragraph 4.13)

The Sample Collection Module may be capable of operating independently, connected to the Test Reader Module at the appropriate point in the measurement cycle, or both modules may be permanently connected in a single unit.

4.4.1 Fixed Drug Screening Device

A Drug Screening Device intended for permanent installation and use within a building and powered from the mains electrical supply.

4.4.2 Powered Portable Drug Screening Device

A powered Drug Screening Device designed or capable of being used either from the mains electricity supply, a locally generated electrical supply, internal batteries or external batteries.

4.4.3 Un-powered Portable Drug Screening Device

A Drug Screening Device with no electrical power requirements i.e. one that does not incorporate an electronic Test Reader Module.

NOTE - Drug Screening Devices should not be used when the influence factors do not correspond to the rated operating conditions (see Annex B).

4.5 Manufacturer

The company that controls the design, specification and quality of devices submitted for type-approval. It must be able to fulfil all the duties regarding type-approval and have authority to deal with any issues raised by the type-approval Authority.

4.6 Measuring Position

The state in which the device can make measurements at the rate normally expected in service. It shall be clearly apparent when the device is in this state. In this position the device shall meet the metrological requirements of this Guide.

4.7 Normal Operation

The normal mode of use that corresponds to the programme of operations specified for devices in service (see paragraph 5.7).

4.8 Police Station

A police station is a permanent building, or a semi-permanent portable structure.

4.9 Saliva

Saliva is any fluid collected from the oral cavity by use of either absorbents, or expectoration or direct collection of glandular secretions from the salivary glands.

4.10 Sample Collection Module

The sample collection module is one or more components designed to collect a specimen of saliva from a subject. It may be entirely independent and indicate sufficient volume has been collected, e.g. by a colorimetric change. Alternatively it may be incorporated within a Test Reader Module.

4.11 Stand-by Position

The state of the device in which only certain circuits are energised. The purpose is to conserve power and to be able to attain the measuring state more rapidly than would be possible if starting from the un-powered state.

4.12 Test Mode

An optional mode whereby the device may perform tests either in accordance with the normal test cycle (see paragraph 5.7 below) or be capable of performing multiple tests (at least 20) after the initial calibration verification step. At the end of a multiple test sequence the results should be capable of being printed out. The ability to run multiple tests must not be available to a normal operator.

4.13 Test Reader Module

The Test Reader Module analyses the sample and reports the results. It may be permanently combined with the Sample Collection Module or there may be two distinct units that are only connected at an appropriate point in the analytical cycle.

5 General Technical Specification

5.1 Target Drugs

Devices shall be capable of detecting the presence of one or more substances in the following broad categories (See Annex A for more details):

Cannabinoids
Benzodiazepines

Cocaine
Amphetamine
Methylamphetamine
Methadone
Opiates

5.2 Cut-offs

Specific analytical cut-offs for each drug are set out in Annex A.

5.3 Display

The presence of one or more of the target drugs shall be clearly indicated. For devices with electronic Test Reader Modules, the result of the test shall be displayed by means of lights or an alphanumeric display.

Devices that do not use electronic Test Reader Modules should present the result of the test using colours of high visual contrast.

The display shall be easily readable in all levels of ambient illumination, including direct sunlight.

5.4 Printer

Devices may be equipped with a printing device that prints the result of the analysis.

- The printout copy shall be durable and black on white.
- Pre-printed paper may be used; that is paper which is specially prepared for the printing device.
- The result printed shall not differ from that recorded and displayed by the device at the time of the test.

5.5 Start-Up Time

The device shall be ready for use 1 minute after switching from the “stand-by position” to the “measuring position”, provided the device can be retained in the “stand-by position” for at least 12 hours.

If a device will not normally be kept in the “stand-by position” it shall be ready for first use within 10 minutes of being switched on.

5.6 Measuring Conditions

The general environmental conditions under which a Drug Testing Device shall be capable of use are as follows:

- i. ambient temperature 15°C to 35°C
- ii. ambient relative humidity (RH) 30% to 90%
- iii. atmospheric pressure (AP) 860hPa to 1060hPa

The device shall be clearly labelled with the operating temperature range for which it has been Approved.

In normal operation, the device shall only indicate a result when the measuring cycle has been successfully completed. Messages, other visual indications and other check values are permitted to indicate to the operator the current stage of the cycle. When a negative test result is produced it shall be incapable of being confused with the indication prior to measurement. This requirement is satisfied when the device indicates the various phases of the measuring cycle.

Where an electronic Test Reader Module is used, the device shall display a message to indicate that it is ready to accept a specimen. Analysis of a specimen shall not be possible before the device is ready.

5.7 Subject Test Procedure

The sequence of actions required to run a subject test shall be specified in the Operator's Manual. As a minimum the test procedure shall include:

1. The subject test.
2. A check to ensure that the subject test has run correctly.

In addition if a device incorporates a Test Reader Module the test procedure shall also include:

3. An automatic "self-check" of all electrical parts of the system using simulated inputs for each analysis.
4. A check to ensure that Quality Assurance Checks and the Calibration Certificate are current.

Failure of any of these checks should terminate the test and an error message should be shown on the screen and printout (if applicable).

5.8 Quality Assurance

For devices which incorporate a Test Reader Module manufacturers shall supply, to the police, quality control samples with the following composition:

- i. No drug or metabolite.
- ii. All of the drugs and metabolites listed in Annex A at 60% of the cut-off.
- iii. All of the drugs and metabolites listed in Annex A at 140% of the cut-off.

A certificate from a UKAS accredited laboratory (or equivalent) shall accompany each batch of standard samples setting out the concentration of each component of the mixture.

Where a device relies on a colorimetric change on a single-use cartridge it shall be acceptable with the agreement of the Home Office and UKAS to substitute these test solutions with standard cartridges, which give an equivalent response. A certificate from an accredited laboratory shall accompany each standard cartridge setting out the equivalent concentration of each component of the mixture.

The Drug Screening Device shall record the results of these quality control samples. If these samples do not give the expected results ("No drug detected" for (i) & (ii) and "Lab Test required" for (iii)) the device shall accept no further subject specimens until it has been serviced. The Drug Screening Device shall display the date of the last Quality Assurance test. If such a test has not been carried out for more than one month the device shall shut down until the Quality Assurance tests have been run (see paragraph 6.6.1).

5.9 Results Display

If the test indicates the presence of one or more of the target drugs the display shall indicate which drug class or classes has been detected. Devices which utilise an electronic Test Reader Module shall display the result unambiguously as either:

- "No drug detected"
- or
- "Lab test required".

Note

- 1) Results shall not be reported as "Negative" or "Positive".

- 2) "No drug detected" indicates that no drug was detected above the analytical cut-off level.
- 3) "Lab test required" indicates that a drug has been detected at a concentration above the analytical cut-off level.

5.10 Printout of Results

Where a device is fitted with a printer, the readings obtained during a measuring cycle shall be printed on completion.

Any printout produced by the device shall contain, or have provision for the following information:

1. Identification of device
2. Software version number
3. Location of device (Police Force and Station/Unit)
4. Date & time of test
5. Name of subject
6. Gender of subject
7. Date of birth of subject
8. Space for signature of subject
9. Result of the device self test
10. Detailed results from test as set out in paragraph 5.9
11. Name of operator
12. Space for signature of operator

Items 1, 2, 3, 9 and 10 shall be produced by the device. All other items may have space provided for the operator to write in the details.

For use in Wales, the printout shall be produced by the device as shown, or the entire printout details may be in the Welsh language or both in English and Welsh. The operator shall be able to choose which of these options to use in any particular case. An approved Welsh translation of the printout and statement can be obtained from the Home Office nominated laboratory.

For use in Scotland, the printout shall be modified to provide space for the corroborating officer's signature.

5.11 Length of Time to Indicate a Result

The test and subsequent method for measuring the test result (excluding sample collection) should be capable of producing results within a maximum time span of 8 minutes at normal room temperature. The entire process of collection, analysis and recording of results should be capable of completion within 15 minutes.

NOTE - This is a minimum requirement, a more rapid response is desirable

While the device is in operation the results of a test shall be retained in readable or printable form until the next time a test is initiated.

The result of a test on a non-powered single-use disposable device shall be readable for at least 15 minutes from the time the result is first indicated.

The results of tests may be stored in the device memory. If such a memory facility exists, the contents shall be capable of being printed or downloaded only on authorised demand.

5.12 Sample Collection Module

5.12.1 Sample Volume

The sample collection system shall provide for a sufficient volume of saliva to be collected from each subject. The system shall incorporate a mechanism (e.g. a colour reaction or minimum sampling time) to ensure sufficient sample has been collected.

5.12.2 Identification

Single use sample collection devices and single-use Test Cartridges and single-use Drug Screening Devices, which incorporate the sample collection module, shall carry an identifying code that indicates the panel of drugs that the Drug Screening Device is Approved for use with, and the manufacturing batch. This information shall be in both human and machine-readable form.

5.12.3 Collection Time

The time taken to collect the required volume of saliva should not exceed 5 minutes.

5.12.4 Safety

If the collection system involves a requirement for an absorbent material or other component to be placed in the mouth, there shall be no part that may become detached in the mouth that could provide a choking hazard to the donor of the sample.

Collection devices shall not incorporate any sharp points or edges that could cause damage to the inside of the mouth or that could be used as a weapon to harm the device operator. Collection devices shall not contain anything which will artificially increase the production of saliva (such as salts or citric acid).

The sample fluid collection kit shall be supplied complete with Health and Safety instructions and advice for the disposal of the waste.

The system shall be designed to ensure that device operators are not exposed to potential hazards.

5.13 Test Reader Module

5.13.1 Basic Requirements

When provided, the Test Reader Module shall interface with the Sample Collection Module to analyse the sample and display the results. It shall incorporate a mechanism to enable the operator to enter a unique identifier to link a test result with the donor of the test specimen. When a single-use sample collection device is used the Test Reader Module shall be capable of reading and recording the identifying code (see paragraph 5.12.2 above) on the collection device.

5.13.2 Data Storage

Where a device has a memory, it should have the capability to retain at least 200 records of test results linked to donor identifiers. The device shall give a warning to the operator that the device is approaching capacity, and it shall give this warning when there are less than 20 memory storage positions available.

The data storage shall meet the following requirements:

- The result stored by the device shall not differ from that recorded by the device at the time of the test.
- Protection from accidental or deliberate alteration.
- Detect and report corrupted data.
- Password protected limiting access to a supervisor.
- Provide a facility to allow an operator to print the results of the most recent test (if applicable).

5.13.3 External Links

Electronic devices shall have the capability to be linked to an external computer via a standard interface to enable all data to be down loaded and stored within an appropriate data base / records storage system. Transferred data shall include a “check-sum” or other form of redundancy check to ensure that any corruption during transfer is detected. After data has been downloaded the memory shall be cleared and be re-usable. Access to download data and to clear the memory shall be password controlled and should not be available to a normal operator.

This data link can permit any information from the Drug Screening Device to be transferred to the external data system, but the data link shall only permit the transfer of communications protocol information from the external data system to the Drug Screening Device.

5.14 Safety and Security

5.14.1 Hygiene

The device shall be capable of use under satisfactorily hygienic conditions. It shall be possible to change the mouthpiece, or any other item with which the user will have intimate contact, for each measurement when required. These components shall be supplied new and individually wrapped. The design of this packaging shall be such as to minimise the chance that the mouthpiece or sample collection tube may become blocked by a piece of the packaging.

5.14.2 Safety in Use

Devices shall conform to relevant regulations and standards (including electrical safety) currently in force.

Any item with which the test subject will have intimate contact shall not contain substances which may cause common allergic reactions.

The outer casing of electronic devices shall be splash / spill resistant such that the device should be capable of operation if subjected to a minor spillage of aqueous liquid.

The device shall be designed with the health and safety of the operator and the user in mind. Particular attention shall be paid to the design and use of electrical connections, electrical supply wires and any sample collection design as well as the materials chosen for the construction of sample collection devices. Any external connections should be of minimal practicable length and should ideally be located at the rear of the device.

5.14.3 Means of Adjustment

The means by which the device is adjusted (particularly the means for adjusting the sensitivity) shall not be accessible to the routine operator or user.

5.14.4 Mode of Operation Changes

The means used to change from the normal mode of operation to another mode of operation shall be inaccessible to the routine user of the device. It shall be made accessible only by the disabling of a security system.

6 Metrological Characteristics

6.1 Cut-offs

Drug Screening Devices must achieve the cut-offs set out in Annex A within $\pm 20\%$.

- Correct results shall be given in 90% or more of the tests undertaken.
- The percentage of false positive test results shall not exceed 5%.

6.2 Repeatability

90% of samples that contain a drug concentration 40% greater than the cut-off must indicate a positive result for that particular drug or group of drugs. These tests shall be carried out using all of the drug groups listed in 5.1 either alone or as a mixture of two or more drug groups as specified in Annexes A.4.1 and A.4.3.

6.3 Interfering Substances

The manufacturer shall provide details of all the interfering substance testing that they have carried out. Minimum requirements are specified in Annex A.4.2.

6.4 Carry-Over

There shall be no detectable response when a control sample containing no drug follows a sample containing a concentration of drug that is four times the cut-off.

6.5 Markings

A Drug Screening Device and its associated single-use test cartridges conforming to this specification shall be marked legibly with the following:

- The name of the manufacturer and/or supplier
- The name of the device and model type
- The device serial number
- The cut-off value for each individual drug test that the device is Approved for
- The ambient temperature range in which the device may be used
- The storage temperature range for the device
- Where appropriate the UKAS accreditation label showing the number and date of issue of the current calibration certificate and the calibration due date

6.6 Requirements for Operational Use

6.6.1 Periodic Quality Assurance Checks

When a device incorporates an electronic Test Reader Module, a properly trained and competent operator shall carry out Quality Assurance checks at least once per month. Each of the test solutions or standard cartridges listed in paragraph 5.8 above shall be applied to the device in turn. If the expected results are not obtained the device shall be placed out of use until the manufacturer has serviced it.

6.6.2 Periodic Service Interval

The normal interval for service and recalibration should be 6 calendar months. The extent and nature of the work required shall be agreed between the manufacturer, Home Office and UKAS.

6.6.3 Single-Use Cartridges

If the device depends on single-use cartridges for detection and measurement of the target drugs these shall be supplied in numbered batches. Each batch delivered to a police customer shall be accompanied by a quality control report issued by an accredited laboratory (or a laboratory which meets the requirements of paragraph 1.4 above) confirming that the cartridges in the batch meet the requirements of this guide.

Annex A

Test Scheme for Device Response to Drugs

A1 Introduction

This Appendix lists the drugs that a Drug Screening Device must be able to detect one or more of. They are grouped into classes of drugs based on chemical similarity and their antigen / antibody reactions. The compounds that must be detected are listed under each group along with the analytical cut-off for each substance. The groups of target drugs are based on the outcome of screening tests based on immunoassay technology. However alternative technology capable of achieving the same results may be utilised. Detection of one or more of the drugs listed in this Annex is a minimum requirement. Devices with a demonstrated ability to detect other psychotropic drugs may be approved.

NOTE

- A device which can detect multiple drug targets, at the required analytical cut-off, from a single saliva sample is most desirable.
- Devices will be tested according to the operating instructions provided by the manufacturer. If these instructions specify the addition of a buffer solution, then the test solutions will be diluted with the buffer as per the instructions.
- Other drugs will only be added to the panel if the ability to detect them is of potential value in the enforcement of anti-drug driving and related legislation.
- Manufacturers wishing to have additional drugs added to the approved panel should contact the Road Crime Section to establish the sensitivity and selectivity requirements.
- Once established these requirements will be published.

A2 Test Solution Matrix

Unless otherwise stated, all test solutions will be made up in an artificial oral fluid matrix using distilled water as the solvent. The composition of the synthetic oral fluid shall be:

Table 1 Composition of Synthetic Oral Fluid Test Matrix

Component	Concentration (mg/l)
Potassium chloride	40
Sodium chloride	40
Potassium thiocyanate	20
Sodium carboxymethylcellulose	100
Mucin	100
Amylase	100
Urea	100

A3 Target Drugs

A Drug Screening Device must be able to detect one or more of the drugs listed in the second column of Table 2. The requirement is for the compounds listed in column 2 to be detected at the analytical cut-offs listed in column 3.

Table 2 Target Drugs and Cut-offs

Drug class	Compounds to be detected	Cut-off (nanogram/ml)
Cannabinoids	Delta-9-tetrahydrocannabinol	10
Benzodiazepines	Nordiazepam	10
	Oxazepam	10
	Temazepam	10
	Diazepam	10
Cocaine	Cocaine	30
	Benzoyllecognine	(as a composite)
Amphetamine	D-amphetamine equivalents	40
Methylamphetamine	Methylamphetamine	40
	MDA	40
	MDMA	40
Methadone	Methadone	50
Opiates	Morphine	40

NOTE

1. These cut-offs are not to be construed as a legal threshold or as an “impairment threshold”.
2. The opiate test must have at least 10% cross-reactivity or equivalent response to 6-monoacetyl morphine. If 6-monoacetyl morphine can be analysed individually, the analytical cut-off has been set at **10ng/ml**.
3. A test for buprenorphine would also be desirable.

A4 Test Procedure

A.4.1 Target Drugs

Each drug for which type approval is sought will be tested separately. Synthetic oral fluid test solutions containing:

1. The target group of drugs at 25% of the cut-off
2. The target group of drugs at 60% of the cut-off
3. The target group of drugs at 140% of the cut-off
4. The target group of drugs at 175% of the cut-off

will be used. Twenty individual aliquots of each of these test solutions shall be presented to the Drug Testing Device. The response of the device shall be:

- | | |
|------------|--|
| Solution 1 | All results reported as “No drug detected” |
| Solution 2 | At least 90% of result’s reported as “No drug detected” |
| Solution 3 | At least 90% of result’s reported as “Lab Test required” |
| Solution 4 | All results reported as “Lab Test required”. |

A.4.2 Interfering Substances

Manufacturers shall provide details of all testing carried out to determine the effect, if any, of interfering substances and adulterants on the Drug Screening Device. As a minimum the

substances listed in Table 3 shall be tested but manufacturers shall provide assurance that the Drug Screening Device is not susceptible to interference from any other commonly encountered substance

Table 3 - Interfering Substances

Number	Interfering Substance	Concentration (ng/ml)
1	Cigarette Smoke	**
2	Sodium Bicarbonate	50
3	Glycerol Trinitrate	50
4	Caffeine	50
5	Menthol	50
6	Vitamin C	50
7	Phenylalanine	50

** The test solution for cigarette smoke shall be prepared as follows:
The smoke from two menthol cigarettes shall be bubbled through 50ml of synthetic saliva solution with each cigarette being “smoked” in a timeframe of 3 to 4 minutes. This is most easily achieved by using a dreschel bottle, or similar “bubbler” glassware. The solution shall be used without further dilution for the test to check for false positive results; and the correct concentration of target drugs shall be added to the undiluted solution for the test to check for false negative results.

NOTE In the light of experience, the Home Office may add other interfering substances to this list.

Two tests shall be run for each substance as follows:

- 1) a test with the target interfering substance at the stated concentration to test for false positive results; and
- 2) a test with the target interfering substance at the stated concentration and spiked with drugs as per solution 6 in Table 3, to test for false positive results

The results from all of the tests in 1) above shall be “no drug detected”, and the results for all of the tests in 2) above shall show the presence of each drug in the mixture.

A.4.3 Multiple Drugs

The response of Drug Screening Devices to a mixture of drugs will be tested. Table 4 gives the composition of test solutions that will be used. Concentrations are expressed as a percentage of the cut-off for the drug. The device shall only be tested using those mixtures which contain a drug for which type approval is sought.

Table 4 - Multiple Drug Test Solutions

Number	Drug class	Concentration	Response
1	Amfetamine	140%	Lab test required
	Delta 9 THC	60%	No drug detected
2	Cocaine	60%	No drug detected
	Methadone	140%	Lab test required
	Morphine	60%	No drug detected
3	Benzodiazepine	140%	Lab test required
	Methadone	60%	No drug detected
	Methylamfetamine	140%	Lab test required
4	Amfetamine	60%	No drug detected
	Cocaine	140%	Lab test required
	Benzodiazepine	60%	No drug detected
5	Delta 9 THC	140%	Lab test required
	MDMA	60%	No drug detected
	Morphine	140%	Lab test required
6	Amfetamine	140%	Lab test required
	Benzodiazepine	140%	Lab test required
	Delta 9 THC	140%	Lab test required
	Cocaine	140%	Lab test required
	Methadone	140%	Lab test required
	Methylamfetamine	140%	Lab test required
	Morphine	140%	Lab test required

NOTE A device which does not have an electronic test reader module, shall display the correct result of the test in its standard format.

Each solution shall be run 20 times. The outcome for each drug group must be as indicated above in 90% of cases.

A.4.4 Carry Over

A test solution containing the following drugs at a concentration that is four times the cut-off listed in Table 2 shall be prepared. The device shall only be tested using those mixtures which contain a drug for which type approval is sought.

1. Delta 9 THC
2. Benzylecogonine
3. Morphine
4. Diazepam
5. MDMA
6. Methadone

This solution shall be passed through the device followed by a control solution containing no drugs. The device shall give no detectable response to the control solution. This test shall be repeated 5 times.

If the device uses a single-use cartridge, the design of which makes it impossible for there to be carry over from one sample to the next, this test may be waived.

A5 General Device Functions

In addition to the drug analysis requirements (paragraphs A2 to A4), checks shall be made on device functions to ensure that the device performs in accordance with the manufacturer's information. The Home Office nominated laboratory shall carry out these checks.

Annex B

Test Scheme for Device Response to Physical Interference

B1 Introduction

This scheme sets out the laboratory procedure for the assessment of the effects of changes in physical conditions on the performance of:

- Fixed Drug Screening Devices powered from the mains electricity supply,
- Portable Drug Screening Devices powered from:
 - the mains electrical supply
 - a locally generated electrical supply
 - internal batteries
 - external batteries
- Un-Powered Drug Screening Devices

It also includes tests to assess the performance of a Drug Screening Device in accordance with European Community (EC) Directive 2004-108-EC on Electromagnetic Compatibility (EMC).

NOTE

1. All devices for use in Great Britain must comply with European Directive 2004-108-EC dated 15 December 2004. The tests can be found in the following test procedures: BS EN 61000-6-3 and BS EN 61000-6-1. Where the EMC tests in Annex B are similar to those stated in 2004-108-EC, the test conditions have been harmonised to meet the requirements of the EC Directive. The additional EMC tests required under 2004-108-EC are stated under B6. All other EMC tests listed in Annex B shall be carried out as stated.
2. Where appropriate, guidance notes on the interpretation of test requirements are given in italics.
3. For all tests in B3.2, B3.3, B4.4, B4.5, B5.1, B5.2 and B5.3, the device shall undergo a normal test procedure using a new test cartridge and standard drug solutions. For all other tests in Annex B, the device shall be tested using either a new test cartridge and standard drug solutions, or a pre-prepared cartridge as defined in Section 5.8.
4. Un-powered Drug Screening Devices, i.e. those that do not incorporate an electronic Test Reader Module, shall not be required to pass the tests in Sections B3.1, B5.2, B5.3, B5.6, B5.7 and B6.

B2 Test Method

A functional test referred to in this scheme will comprise of full drug tests using standard drug solutions (ii) and (iii) as specified in paragraph 5.8 above. A complete functional test shall comprise two tests with each solution. The result of any drug test performed as part of this scheme shall be:

- i. "No drug detected" for each drug in solution (ii).
- ii. "Lab test required" for each drug in solution (iii).

B3 Physical Influence Factors

The effect of each factor shall be determined in turn with all other factors at their reference level. The effects shall not be combined. In performing the tests in this scheme a functional test as defined in paragraph B2 above shall be carried out for each influence factor. Tests shall be run at the reference points and the extreme points of each condition listed.

B.3.1 Power Supply

Testing under this section shall be carried out in accordance with OIML Document 11 - General Requirements for Electronic Measuring Devices (2004).

B.3.1.1 AC Supply

B.3.1.1.1 Voltage

Reference condition: Nominal voltage (240 Volts)
Extreme values: -15% of nominal voltage
+10% of nominal voltage

Each voltage variation shall be applied to the device for one complete functional test (as defined in paragraph B2 above) – and for not less than 15 minutes in total.

B.3.1.1.2 Frequency

Reference condition: Nominal frequency (50Hz)
Extreme values: $\pm 2\%$ of nominal frequency

Each frequency extreme shall be applied to the device for one complete functional test (as defined in paragraph B2 above).

B.3.1.2 Internal Battery

Reference condition: Nominal battery voltage.
Extreme values: Voltage at which DUT detects low-level battery condition

If an alternative power source is used for these tests it shall have the same internal impedance as the specified battery. Tests shall be conducted at the nominal voltage, the extreme value and sufficient steps in between to demonstrate that the DUT functions correctly until the low-level battery condition is reached. Each voltage variation shall be applied to the device for one complete functional test (as defined in paragraph B2 above).

NOTE

A Drug Screening Device will only be required to satisfy those tests that are relevant to the power supply or supplies that it uses.

B4 Temperature and Humidity

B.4.1 Ambient temperature

Reference condition: 20°C
Extreme values: 15°C and 35°C

The device under test (DUT) shall be placed in the test chamber. The DUT shall consist of all normal components of the device necessary to carry out a subject test contained within the normal protective case intended for supply to the police service. The temperature shall be reduced to the minimum temperature specified and the DUT allowed to stabilise for at least 3 hours. During this period, steps should be taken to prevent condensation on the DUT. A Functional Test shall then be carried out as described in paragraph B2. The temperature shall then be raised to the maximum temperature specified in not less than 1 hour to minimise the risk of condensation occurring and the DUT allowed to stabilise for at least 3 hours. A functional test (as defined in paragraph B2 above) shall be carried out.

B.4.2 Storage Temperature

B.4.2.1 Storage – Ambient Conditions

This test is to be performed with the device power OFF. The chamber conditions shall be such as to inhibit condensation at all times.

Cold	Temperature	0°C	Duration	2 hours
Hot	Temperature	+40°C	Duration	6 hours

After the test, the device shall be allowed to stabilise at 20°C for 10 minutes after which a functional test (as defined in paragraph B2 above) shall be carried out.

The device under test (DUT) shall be placed in the test chamber. The DUT shall consist of all normal components of the device necessary to carry out a subject test contained within the normal protective case intended for supply to the police service. The temperature shall be reduced to the minimum temperature specified and the DUT allowed to stabilise for at least 2 hours. During this period, steps should be taken to prevent condensation on the DUT. A Functional Test shall then be carried out as described in paragraph B2. The temperature shall then be raised to the maximum temperature specified in not less than 1 hour to minimise the risk of condensation occurring and the DUT allowed to stabilise for at least 6 hours. A functional test (as defined in paragraph B2 above) shall be carried out.

B.4.3 Ambient Relative Humidity (RH)

Reference condition	Ambient RH in testing laboratory
Extreme values	30% RH at 15°C
	90% RH at 35°C

The device under test (DUT) shall be placed in the test chamber. The DUT shall consist of all normal components of the device necessary to carry out a subject test contained within the normal protective case intended for supply to the police service. The temperature shall be set to the reference level and the humidity adjusted to the minimum RH specified (30%). A normal Measuring Cycle shall then be carried out as described in paragraph B2. The humidity shall then be raised to the maximum RH specified (90%). The temperature shall then be increased to the maximum temperature (35°C) in not less than 1 hour while maintaining the RH at maximum. A functional test (as defined in paragraph B2 above) shall be carried out as described in paragraph B2.

B5 Physical Disturbance Factors

B.5.1 Test Methods

Testing under this section shall be carried out to conform with IEC 61000-4 and in accordance with OIML Document 11 - General Requirements for Electronic Measuring Devices (Draft Document – 2003).

B.5.2 Short Time Reduction in Electricity Supply.

During a functional test (as defined in paragraph B2 above) the following disturbances shall be applied:

- i. Reduce supply voltage by 100% for 10 milliseconds
- ii. Reduce supply voltage by 50% for 20 milliseconds

The time interval between successive disturbances shall be at least 10 seconds.

It is permissible for no result to be displayed after this test.

The reduction shall be referenced to the zero cross-over of the mains supply, and at least three reductions, separated by 10 second intervals, shall be applied for each condition during a functional test.

B.5.3 Parasitic Voltages on Electricity Supply

Disturbances shall be applied during the measuring cycle.

Randomly phased transient over-voltages of each polarity are to be applied to the supply generated in common mode.

- ii. The repetition rate shall be set to 5kHz for signal/control lines and to 2.5kHz for power lines.

- iii. The amplitude of the interference shall be 1kV for signal/control lines and 2kV for power lines.
- iv. The duration of the burst of over-voltage transients is to be 15 milliseconds, repeated every 300 milliseconds.
- v. The rise time of the impulse is to be 5 nanoseconds; the impulse duration (50% value) is to be 50 nanoseconds.
- vi. These tests apply to all power lines but if the signal/control lines do not exceed 3 metres in length they are exempt from the test.

The test must be performed over at least 60 seconds. The amplitude of the voltages applied is to be measured open-circuit and supplied from a 50-ohm source. The induced signal for the control and data lines must be capacitively coupled.

NOTE

Tests B.4.2 & B.4.3 are only required for devices dependant on an external power supply.

B.5.4 Vibration

This test should be made with reference to BS EN 60068-2 Test Fc - Sinusoidal Vibration. The device shall be subjected to vibration on 3 perpendicular axes in turn with a swept range of frequencies from 10Hz to 150Hz at 1 octave per minute, and an RMS acceleration of 1.6m/s^2 .

If any resonant frequencies are observed than a vibrational test shall be carried out at each observed frequency for a period of 2 minutes, followed by a followed by a functional test (as defined in paragraph B2 above).

B.5.5 Mechanical Shock

The device shall be placed on a rigid surface in its normal attitude.

The test consists of raising each lower edge in turn and allowing the device to fall freely onto the surface.

The device shall be raised by 25mm subject to a maximum inclination of 30° .

Each test shall be followed by a functional test (as defined in paragraph B2 above).

B.5.6 Electrostatic Discharge

During a normal functional test the device shall be subjected to random discharges of 4kV for contact discharges and 8kV for air discharges from a 150pF capacitor through a 330ohm resistor onto surfaces accessible to the operator.

10 positive and 10 negative discharges are to be applied separated by at least 10 seconds to the user-accessible points of the DUT for both contact and air tests. The contact discharge test is applied to conductive user accessible areas, and the air discharge test is applied to non-conductive user-accessible areas of the DUT.

The device shall be grounded through the normal electrical connection or to a grounded plate that extends 0.1m around the DUT on all sides. The ground connection from the discharging capacitor shall be as short as possible.

B.5.7 Electromagnetic Field

The device shall be exposed to electromagnetic fields as detailed in EMC Immunity Test Procedures for Breath Alcohol Measuring Devices FSS-BAU-03/02

B6 Emission Tests; EC Directive 2004-108-EC

This test shall be carried out to meet the requirements of EN50081-1 and the European Community requirements on EMC as in European Directive 2004-108-EC in accordance with EN55022. Measurements of radiated emissions from the device shall be made over the frequency range 27 - 1000MHz at a distance of 10m.

B7 Other Regulatory Requirements

A Drug Screening Device shall meet any other appropriate regulatory requirements (for example laser light) that its design requires.

Annex C Software Validation & Verification

C1 Introduction

This Annex sets out the requirements for the validation and verification of the software used to control electronic Drug Screening Devices. Devices for use by the police in the United Kingdom must comply with the requirements of the relevant legislation. It is suggested that suppliers of approved equipment separate the software modules that handle the analysis of samples from those that provide the user interface. It is accepted that the analytical software may be generic but the user interface must comply with the need of the criminal justice system in the UK.

C2 Security

C.2.1 Access Levels

Access to the functions of a Drug Screening Device shall be passcode protected. The level of access that an individual will have shall depend on the role that he or she plays. Four levels of access are required and whilst the precise functions that each level will have access to will be dependant on the design of individual devices, an outline of the basic requirements is:

C.2.1.1 Operator

- Run subject tests
- Carry out quality assurance checks
- Print result of last test result

C.2.1.2 Police supervisor

- Run subject tests
- Carry out quality assurance checks
- Reset the device after over-due quality assurance test
- Grant access to new operators & supervisors
- Authorise access by Field Service Engineer
- Print result of all tests in the memory
- Download results to an external data system & clear memory

NOTE

Whilst a police supervisor must authorise access by a field service engineer s/he must not be able to open, adjust and reseal the device.

C.2.1.3 Field Service Engineer

- Run subject tests
- Carry out quality assurance checks
- Open and reseal case
- Reset the device
- Re-calibrate the device
- Print result of all tests in the memory

C.2.1.4 Manufacturer

- Access to further functions above those of “Field Service Engineer”

C.2.2 Data Protection

All personal data held in a Drug Screening Device shall be stored in a way that allows the police service to comply with the requirements of the Data Protection Act 1998.

Data stored in a Drug Screening Device may be used to demonstrate to a criminal court that the device was operating correctly. It must therefore be held securely and protected against accidental or deliberate alteration. Data shall be protected by a check sum or other redundancy check to demonstrate that it has not been altered since it was stored.

If data is transmitted to an external database there shall provision in the data transfer protocol to provide assurance that the information received by the external system is the identical to that in the Drug Screening Device.

C.2.3 Compliance

A version number shall identify the software that controls an approved Drug Screening Device. This version number shall appear on all reports generated by the device.

The software installed in Drug Screening Devices supplied to the police service in the United Kingdom shall be identical to that tested as part of the type-approval process. This will be assured by the use of a digital signature.

The software version will form part of the Type-Approval Order for a Drug Screening Device. Revision to the software will require a new version number and a new Type-Approval Order. Software in operational devices shall only be changed at the manufacturer's premises.

C3 Validation & Verification by the Manufacturer

Software for Drug Screening Devices shall be developed by, or on behalf of, the manufacturer using a quality assurance scheme that is accredited to the ISO 9001-2000 standard. The manufacturer shall provide the Home Office nominated laboratory with:

- Details of the quality assurance procedures adopted.
- The results of the validation & verification tests.
- A list the data variables classified as:
 - Jurisdiction specific constants
 - Device specific constants
 - Occasional Adjustments
 - Calibration Factors

C.3.1 Software Testing

Whilst the functional testing described in Appendix A & B will provide some assurance that the software performs correctly the Home Office nominated laboratory may carry out additional user-acceptance tests including some or all of the following additional tests:

- i. Repeat of a sub-set of the software developer's validation.
- ii. Boundary conditions, eg:
- iii. Tests carried out over midnight.
- iv. Changes between summer & winter time.
- v. Negative testing to ensure that the device does nothing that it should not do.