Mobile Preliminary Drug Testing Devices

A Guide to Type Approval Procedures
for Mobile Preliminary Drug Testing Devices
used for
Transport Law Enforcement in Great Britain

Version 1.0
August 2013

Summary

Under the Road Traffic Act 1988 it is an offence to drive or be in charge of a motor vehicle whilst unfit through a drug or drugs. Drug includes any intoxicant other than alcohol, whether or not it is a controlled substance. A further provision (section 5A) in the Act will when implemented make it also an offence to drive or be in charge of a motor vehicle with a concentration in the blood or urine of a specified controlled drug above a specified limit. To obtain an indication whether a person has a drug in his body and (when the new offence is implemented) if so whether the drug is a specified drug and the amount is likely to be above the specified limit, the Act authorises a police officer to require a preliminary drug test of the person's saliva or sweat. The test may be administered at or near any place where the requirement is made, e.g. at the roadside or in a hospital, or at a police station. A positive result allows the person to be required to give a blood specimen without medical authorisation. The preliminary test must be conducted using a device of a type approved by the Secretary of State

This Guide contains a description of the technical requirements to be met for consideration of type approval for new Mobile Preliminary Drug Testing 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 Mobile Preliminary Drug Testing Devices, their operation and the methods for testing prior to submission to the Secretary of State for consideration for type approval. The document details functional requirements which are not intended to limit the device to any specific type of technology or manufacturing method.

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 as the type approval authority 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.

The Home Office Centre for Applied Science and Technology produced this document on behalf of the Home Office Public Order Unit and enquiries relating to it should be addressed to:

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A Guide to Type Approval Procedures for Mobile Preliminary Drug Testing Devices

Contents

1 Introduction

1.1 The type approval procedure includes 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 Mobile Preliminary Drug Testing Devices intended for use either in a police station, or elsewhere than at a police station, for example at the roadside. The device when used at the roadside or elsewhere than at a police station will be primarily for obtaining by use of a specimen of saliva an indication whether the person has a drug in his body and if so whether it is a specified controlled drug and if it is, whether the proportion of it in the person's blood or urine is likely to exceed the specified limit for that drug. When the device is used at a police station its primary purpose will be to identify the presence of a drug to enable police to require specimens of blood without having to obtain a doctor's opinion that the person has a condition which might be due to some drug. Mobile Preliminary Drug Testing Devices should be single person portable and operable, may be stored and carried in police vehicles, may be used in police vehicles, and may be used in both indoor and outdoor environments, under both daytime and night-time operating conditions. The Guide also defines devices' 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: 2008 – Quality management systems – Requirements –Technical corrigendum 1 – 2009
- BS EN ISO/IEC 17025: 2005 - General requirements for the competence of testing and calibration laboratories
- BS EN 61000-6-3: 2007 + A1: 2011 – Electromagnetic compatibility (EMC) – Part 6-3: Generic standards – Emission standard for residential, commercial and light-industrial environments
- BS EN 61000-6-1: 2007 – Electromagnetic compatibility (EMC) – Part 6-1: Generic standards – Immunity for residential, commercial and light-industrial environments.
- BS EN 55022: 2010 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: 2005 Environmental testing – Part 2: Tests – Test Db and guidance: Damp, Heat, Cyclic (12 + 12 Hour Cycle)
- BS EN 60068-2-27:2009 Environmental Testing – Part 2 -27: Tests – Test Ea and guidance: Shock
- BS EN 60068-2-6: 2008, Environmental Testing – Part 2-6: Tests – Test Fc: Vibration (Sinusoidal)
- BS EN 60068-2-68: 1996 (R2005) Environmental Testing – Part 2: Test L: Dust and Sand
- BS EN 60068-2-18: 2001(R2005) Environmental Testing – Part 2-18: Tests R and guidance: Water
- 2004-108-EC dated 15 December 2004 European Council (EC) Directive on Electromagnetic Compatibility (EMC)
- OIML Doc 11 Edition 2004 (E) General Requirements for Electronic Measuring Instruments (Draft Document – 2004)
- IEC 61000-4-1:2007 Electromagnetic compatibility (EMC) – Partial 4-1: Testing and

measurement techniques – Overview of IEC 61000-4 series
- FSS-BAU-3/02 EMC Immunity Test Procedures for Breath Alcohol Measuring Devices (Quoted in BS Draft 09/30202737DC)

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 a 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.

1.5 The use of equivalent standards does not remove the need to comply with any statutory requirements, such as relevant EU safety directives.

2 Type Approval Procedures

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

Public Order Unit
Home Office
Fry Building
2 Marsham Street
SW1P 4DF

2.2 Following the request to the Home Office a new Mobile Preliminary Drug Testing Device will undergo user trials by two or more police forces. The National Policing Lead for Roads Policing will arrange these trials at the request of the Public Order Unit. User trials will only be arranged if the device is thought to have potential for police use. Devices accepted for user trials must have the potential to:

i. Be practical to use in a police operational environment other than at a police station, for example, at the roadside (see paragraph 1.2)
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.

Manufacturers are expected to provide, at their own risk, sufficient equipment and consumable items for these trials to be run concurrently in at least 6 separate areas. The equipment and consumables shall be provided at no cost to the police service.

2.3 Following completion of the user trials manufacturers will have an opportunity to take into account feedback from these trials, before submitting the device for laboratory testing.

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. It is the responsibility of the manufacturer to organise Annex B testing at suitably accredited testing facilities. These tests are carried out prior to Annex A and Annex C testing, which will be carried out by the Home Office nominated laboratory. The Home Office nominated laboratory shall be accredited by the United Kingdom Accreditation Service (UKAS).

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 17025:2005, 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 to the Home Office nominated laboratory of technical and professional competence and independence.

2.6 When the assessments at Annex B have been satisfactorily completed, the manufacturers shall supply on loan to the Home Office nominated laboratory for the purposes of Annex A and C testing three devices (or, where the device is a single-use disposable device, sufficient devices to undertake Annex A and Annex C testing). 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 reports relevant to that device 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:

i. A handbook or a set of written instructions for the use of the device operator.
ii. A handbook or a set of written instructions for the use of the device supervisor.
iii. A written technical description of the device's operation.
iv. Details of the detection technology employed by the device (including specific details of any antibodies, buffers, reagents, or other components critical to the analysis of a sample).
v. A full circuit diagram with all the circuit components clearly indicated.
vi. Details of the internal analytical unit including details of the measurement technique(s) used and the algorithm employed to interpret the results.
vii. A full specification for any embedded software in the device plus copies of the source and object code for that software.
viii. Details of the quality assurance and validation protocols used by the software developers. This system shall be certified to the ISO 9001:2008 standard.
ix. A complete set of reports issued by suitably accredited testing facilities which demonstrate that the tests at Annex B have been satisfactorily completed. The

manufacturer shall present this evidence in a structured way that clearly demonstrates compliance with the Annex B requirements.

NOTE

1. 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.
2. Documents referred to in paragraphs (v) to (vii) 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 successful 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 On successful completion of the type approval testing, the Public Order Unit of the Home Office shall consider obtaining the agreement of the Secretary of State for the Home Department for type approval for police use in Great Britain. The Public Order Unit 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):

i. Not to change the approved device in any way without the written agreement of the Secretary of State or her agent.
ii Not to advertise the approved device as being type approved for any use other than that for which it has been type approved.
iii. To ensure that the type and serial number of each device is clearly identified by an indelible marking.
iv. To ensure that the serial number is unique to each device.
v. To ensure that any manufacturing and repair facility relating to the device is suitably accredited or certified, and that any calibration facility relating to the device is accredited to the ISO/IEC 17025: 2005 standard and open to inspection by the Home Office, any UK Police Force, the Home Office nominated laboratory, or UKAS.
vi. To ensure that any update of the operating instructions is sent to all device operators including the Home Office nominated laboratory on behalf of the Home Office.
vii. To label with a version number any software or firmware.
viii. 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.
ix. To supply free of charge to the Home Office a full circuit diagram of the device with all the circuit components clearly indicated.
x. 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 (as detailed in paragraph 2.10).

NOTE

1. In paragraph (i) above a change means any modifications to the approved device (including software), 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 x 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 twenty 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 (viii) & (ix) 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 of the device and the test subject. 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 test subject 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: 2005 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 ensure that the calibration of re-usable devices is stable for a period of at least six months. The manufacturer shall check the calibration of re-usable devices every six months. A calibration certificate shall be issued and copies held by manufacturers and the police. A calibration label from a suitably accredited or certified 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, or a standard cartridge which is used to check the response of a device. When this adjustment or verification is being carried out any drug mixture must pass through the entire analysis train starting with the sample collection module.

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.

4.4 Mobile Preliminary Drug Testing Device

A single person portable and operable device, when used in operational settings such as described in paragraph 1.2, designed to give by means of a colorimetric change, lights or an alphanumeric display an indication whether there is in a specimen of oral fluid one or more specified controlled drugs and if so whether the level of any such drug is above the cut off levels specified in Table 2 Annex A.

NOTE

1. The results may additionally be presented in the form of a printed report.
2. Other methods of indication may be acceptable by prior agreement with the Home Office.

The Mobile Preliminary Drug Testing 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, may be 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 Powered Mobile Preliminary Drug Testing Device

A Mobile Preliminary Drug Testing Device designed or capable of being used from the mains electricity supply, a locally generated electrical supply, internal batteries and/or external batteries. Devices that are designed to be used solely from the mains electricity supply are not considered as mobile.

4.4.2 Un-powered Mobile Preliminary Drug Testing Device

A Mobile Preliminary Drug Testing Device with no electrical power requirements

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

For the purposes of this Guide, a police station is a permanent building, or a semi-permanent structure dedicated to police use.

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 stand-by position is 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 position 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 a multiple test sequence (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 a multiple test sequence must not be available to a normal operator (see Annex C).

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 must be able to detect both delta-9-tetrahydrocannabinol and cocaine. Devices may also be submitted for consideration for type approval for benzoylecgonine. (See Annex A for more details):

5.2 Cut-offs

Specific analytical cut-offs for each drug are set out in Annex A (table 2).

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 ranging from the illumination provided, for example, by the interior lights of a police vehicle at night through to 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 first use within 10 minutes of being switched on.

Any device with a “stand-by position” should be ready for use 1 minute after switching from the “stand-by position” to the “measuring position”.

5.6 Measuring Conditions

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

i. ambient temperature 0 °C to 40 °C

ii. ambient relative humidity (RH) 30% to 90%

iii. atmospheric pressure (AP) 860 hPa to 1060 hPa….

Note: The device must be capable of operation between 5 °C and 40 °C and tests will be carried out to ensure that the device meets the metrological requirements of this Guide at these two extremes of temperature. If a device cannot be used at all temperatures within the range 0 °C to 40 °C, it shall incorporate a mechanism which clearly indicates to the operator when the environmental conditions exceed the operating conditions of the device, and shall clearly indicate to the operator that the device cannot be used.

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.

NOTE

Mobile Preliminary Drug Testing Devices should not be used when the influence factors do not correspond to the rated operating conditions (see Annex B).

5.7 Subject Test Procedure

The sequence of actions required to run a subject test shall be specified in the Operator 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 an electronic Test Reader Module manufacturers shall supply, to the police, quality control samples with the following composition:

i. No drug or metabolite.
ii. A solution containing a drug from each of the drug groups that the device is capable of analyzing at 60% of the cut-off.
iii. A solution containing a drug from each of the drug groups that the device is capable of analyzing at 140% of the cut-off.

NOTE

These solutions are to be provided in an appropriate matrix

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 or on a single-use cartridge it shall be acceptable with the agreement of the Home Office to substitute these test solutions with standard cartridges, which give a comparable device response.

The Mobile Preliminary Drug Testing Device shall record the results of these quality control samples. If these samples do not give the expected results ("No specified drug detected" for (i) & (ii) and "Specified drug detected" for (iii)) the device shall accept no further subject specimens until it has been serviced. The Mobile Preliminary Drug Testing 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 group or groups has been detected. Devices which utilise an electronic Test Reader Module shall display the result unambiguously as either:

- "No specified drug detected"

or

- "Specified drug detected".

NOTE

1. If the analysis of a sample does not complete as expected, the device shall indicate this by the use of an error message. It shall not be possible to confuse this error message with either of the results given for a valid analysis.
2. Results shall not be reported as "Negative" or "Positive".
3. "No specified drug detected" indicates that no drug was detected above the analytical cut-off level.
4. "Specified drug detected" 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 space for, the following information:

1. Identification of device
2. Software version number
3. Location of device (Police Force)
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, 4, 9 and 10 shall be produced by the device on completion of every test. All other items may be printed by the device or may have space provided for the operator to write in the details.

Items 3, 5, 6, 7, 8, 11 and 12 shall be produced by the device on completion of every test, but this function must also have the capability to be switched off or be capable of being skipped.

For use in Wales the device should:

- Allow the operator to choose to print either in Welsh or English; or
- Print out in Welsh and English.

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 shall be capable of completion within 15 minutes under the environmental conditions specified in paragraph 5.6.

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 sample collection mechanism shall reproducibly collect a known (unspecified but declared by manufacturers to the Home Office Nominated Laboratory with supporting evidence) volume of saliva ± 10%. 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 Mobile Preliminary Drug Testing Devices, which incorporate the sample collection module, shall carry an identifying code that indicates the panel of drugs that the Mobile Preliminary Drug Testing 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

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 an electronic 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 downloaded 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 Mobile Preliminary Drug Testing 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 Mobile Preliminary Drug Testing Device.

5.14 Safety and Security

5.14.1 Hygiene

The device shall be capable of use under hygienic conditions. It shall be possible to change any item with which the test subject 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 sample collection module 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 test subject 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 operator or test subject.

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 operator of the device. It shall be made accessible only by the disabling of a security system.

6 Metrological Characteristics

6.1 Cut-offs

Mobile Preliminary Drug Testing Devices must achieve the cut-offs set out in Annex A, Table 2 within ±20%. Tests in Annex A will be conducted using solutions containing drugs at specific concentrations, defined in terms of percentage of the cut-off values stated in Annex A, Table 2.

For the tests detailed in A.4.1 and A.4.3:

- 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 (as stated in Annex A Table 2) must indicate a positive result for that particular drug or group of drugs.

90% of samples that contain a drug concentration 40% less than the cut-off (as stated in Annex A Table 2) must indicate a negative result for that particular drug or group of drugs.

The device will be tested for each of the drugs listed in paragraph 5.1 for which approval is sought.

The device will be tested for response to each drug individually (as specified in A.4.1), and as a mixture (as specified in A.4.2 and A.4.3).

6.3 Interfering Substances

The manufacturer shall provide details of all the interfering substance testing (including cross-reactivity) that they have carried out.

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 Mobile Preliminary Drug Testing Device and/or 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 drugs that the device is Approved to test for
The expiry date (where applicable)
The manufacturing lot number (where applicable)
The device serial number
The ambient temperature range in which the device may be used
The environment in which the device may be used
The storage temperature range for the device
Where appropriate the UKAS calibration 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 a suitably accredited or certified laboratory (or a laboratory which meets the requirements of paragraph 1.4) 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 Annex lists the drugs that a Mobile Preliminary Drug Testing Device must be able to detect, and additional drugs that a device can be submitted for in consideration of type approval. They are grouped into classes of drugs based on structural similarity. The compounds are listed under each group along with the analytical cut-off for each substance. Any technology capable of meeting the following requirements may be utilised. **Detection of both THC and cocaine is a minimum requirement.** Devices with a demonstrated ability to detect additional psychoactive drugs may be approved.

NOTE

1. 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.
2. 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.
3. Manufacturers wishing to have additional drugs considered for addition to the approved panel should contact the Public Order Unit to establish the sensitivity and selectivity requirements.
4. 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. A small amount (< 0.1%) of surfactant may be added to the solutions used in type approval testing to improve solution stability. The composition of the synthetic oral fluid shall be:

Table 1 Composition of Synthetic Oral Fluid Test Matrix

Component	Concentration (mg/l)
Potassium chloride	1360
Bovine Mucin (from sub-maxilliary glands)	1300
Potassium hydrogen phosphate	950
Sodium chloride	860
Sodium azide	500
Sodium hydrogen carbonate	440
Potassium thiocyanate	250
Calcium chloride	210

Urea	180
Magnesium chloride	60

A3 Target Drugs

A Mobile Preliminary Drug Testing Device must be able to detect both delta-9-tetrahydrocannabinol and cocaine. A Mobile Preliminary Drug Testing Device may also be submitted for consideration for type approval for benzoylecgonine. The requirement is for the compounds listed in Table 2, column 2 to be detected (as a minimum, both THC and cocaine) at the analytical cut-offs listed in Table 2, column 3.

Table 2 Target Drugs and Cut-offs

Drug group	Drugs to be detected	Cut-off (nanogram/ml)
Cannabinoids	Delta-9-THC	10
Cocaine	Cocaine	30
	Benzoylecgonine	30

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

will be used. The term 'cut-off' refers to the cut-off values for each drug given in Table 2 above. Twenty individual aliquots of each of these test solutions shall be presented to the Mobile Preliminary Drug Testing Device. The response of the device shall be:

Solution 1 All results reported as "no specified drug detected"
Solution 2 At least 90% of results reported as "no specified drug detected"
Solution 3 At least 90% of results reported as "specified drug detected"
Solution 4 All results reported as "specified drug detected"".

NOTE

Devices which analyse more than one drug in a certain drug group (e.g. cocaine and benzoylecgonine) shall be tested for their response to each of those drugs individually. The device shall only be considered for Approval for each drug if it passes the required tests for each drug. The device shall not be considered for Approval for a general drug group unless it can demonstrate suitable accuracy and precision for every drug listed in column two of Table 2 for that drug group.

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 Mobile Preliminary Drug Testing Device. As a minimum the substances listed in Table 3 shall be tested but manufacturers shall provide assurance that the Mobile Preliminary Drug Testing Device is not susceptible to interference from other commonly encountered substances.

Table 3 - Interfering Substances

Number	Interfering Substance	Concentration (ng/ml)
1	Cigarette Smoke	**
2	Caffeine	3000
3	Menthol	3000
4	Vitamin C	3000
5	Phenylalanine	3000
6	Glucose	3000
7	Taurine	3000
8	Thiamine	3000

** The test solution for cigarette smoke shall be prepared as follows:
The smoke from two menthol cigarettes shall be bubbled through 50 ml 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

The Home Office may add other interfering substances to this list.

Forty tests shall be run for each substance as follows:

1) Twenty tests with the target interfering substance at the stated concentration to test for false positive results; and

2) Twenty tests with the target interfering substance at the stated concentration and spiked with drugs as per solution 3 in Table 4, to test for false negative results

The results from all of the tests in 1) above shall be "no specified drug detected", and the results for at least 90% of the tests in 2) shall be reported as "specified drug detected"'.

A.4.3 Multiple Response Solutions

The response of Mobile Preliminary Drug Testing 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 term 'cut-off' refers to the cut-off values for each drug given in Table 2.

Table 4 - Multiple Response Test Solutions

Solution Number	Drug Group	Drug	Concentration	Response
1	Blank oral fluid; no drug present	None present	No drug present	No drug detected
2	Cannabinoids Cocaine	Delta-9-THC Cocaine	60% 60%	No drug detected No drug detected
3	Cannabinoids Cocaine	Delta-9-THC Cocaine	140% 140%	Lab test required Lab test required
4	Cannabinoids Cocaine	Delta-9-THC Cocaine	1000 ng/ml 1000 ng/ml	Lab test required 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. For solutions 1 and 4, the outcome for each drug group must be as indicated above in 100% of cases. For solutions 2 and 3, the outcome for each drug group must be as indicated above in 90% of cases.

A.4.4 Carry Over

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

This solution shall be passed through the device followed by a control solution of solution 1 in Table 4. The response of the device to solution 1 shall be “no specified drug detected”.

This test shall be carried out 20 times, with the expected response of ‘no drug detected’ being displayed in 100% of cases.

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:

- Mobile Preliminary Drug Testing Devices powered from:
  - the mains electrical supply
  - a locally generated electrical supply
  - internal batteries
  - external batteries
- Un-Powered Mobile Preliminary Drug Testing Devices

It also includes tests to assess the performance of a Mobile Preliminary Drug Testing 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 (2007) and BS EN 61000-6-1 (2007). 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 B.4, B.5.4, B.5.5 and B.8.2, B.8.3 and B.8.4, where a device uses single-use cartridges, the device shall undergo a normal test procedure using a new test cartridge and drug solutions as defined in Section 5.8. For all other tests in Annex B, the device shall be tested using either a new test cartridge and standard drug solutions, or a standard cartridge as defined in Section 5.8.
4. Un-powered Preliminary Drug Testing Devices shall not be required to pass the tests in Sections B.3, B5.2, B5.3, B5.6, B5.7, B6 and B8.1.

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 Section 5.8. Where a device relies on an electronic reader module which uses a colorimetric change or a single-use cartridge it shall be acceptable to substitute these test solutions with standard cartridges which give equivalent responses.

All of the tests detailed in B.4, B.5.4, B.5.5 and B.8 must be carried out using drug solutions (ii) and (iii) as specified in Section 5.8 (i.e. not standard cartridges which give equivalent responses) on the Mobile Preliminary Drug Testing Device as intended for operational use.

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:

1 “No specified drug detected” for each drug in solution (ii).

2. “Specified drug detected” 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 shall be carried out for each influence factor. Tests shall be run at the reference points and the extreme points of each condition listed.

NOTE

Mobile Preliminary Drug Testing Devices shall only be required to pass the tests relevant to the type of power supply they are designed to use.

B.3.1 Power Supply

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

B.3.1.1 AC Supply Voltage

Reference condition: Nominal voltage (230 Volts)
Extreme values: -30% of nominal voltage
+20% of nominal voltage

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

B.3.1.2 AC Supply Frequency

Reference condition Nominal frequency (50 Hz) Extreme values: ±5% of nominal frequency

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

B.3.1.3 DC Supply Voltage

Reference condition: Nominal voltage required by the instrument
Extreme values: -8% of nominal voltage
+24% of nominal voltage

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

B.3.1.4. Ripple on DC (frequency range 40Hz to 400Hz)

Reference condition: 0V
Extreme values: 0.2V peak to peak

The test should be carried out with ripple frequencies in 50 Hz steps whilst a functional test (as defined in paragraph B2) is run at each step.

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).

B4 Temperature and Humidity

B.4.1 Ambient temperature

Reference condition: 20°C

Extreme values: 0°C and 40°C

The test chamber temperature shall be set to one of the extreme values, and the chamber allowed to stabilize for one hour. The Device Under Test (DUT) shall consist of all normal components of the device necessary to carry out a subject test contained within the normal packaging intended for supply to the police service. The DUT shall be placed into the test chamber and allowed to stabilize for one hour. The DUT shall be removed from the test chamber and a Functional Test shall then be started. The DUT shall immediately be placed back into the test chamber for the duration of the remainder of the Functional Test, as described in paragraph B2. The result of the test shall be read according to the manufacturer's instructions immediately on removal of the DUT from the test chamber at the conclusion of the Functional Test.

This test shall be repeated with the test chamber temperature set to the remaining extreme value.

As stated in paragraph 5.6, all devices must be capable of operation between 5 °C and 40 °C. If a device cannot be used at 0°C, the device will be tested as detailed above using the extreme values detailed above to ensure that the device correctly indicates it cannot be used at this temperature. In addition, it will also be tested as detailed above using 5°C (rather than 0°C) as the lower extreme reference value. If a device cannot be used within the 0°C to 40°C temperature range, it shall incorporate a mechanism which clearly indicates to the operator when the environmental conditions exceed the operating conditions of the device, and shall clearly indicate to the operator that the device cannot be used.

B.4.2 Ambient Relative Humidity (RH)

Reference condition	Ambient RH and temperature 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 Functional Test 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) shall than be carried out.

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 Instruments (2004).

NOTE

Mobile Preliminary Drug Testing Devices shall only be required to pass the tests relevant to the type of power supply they are designed to use.

B.5.2 Short Time Reduction in Electricity Supply

During a functional test (as defined in paragraph B2) 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 a Functional test (as defined in paragraph B2).

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

i. The repetition rate shall be set to 5 kHz for signal/control lines and to 2.5 kHz for power lines.
ii. The amplitude of the interference shall be 1kV for signal/control lines and 2 kV for power lines.
iii. The duration of the burst of over-voltage transients is to be 15 milliseconds, repeated every 300 milliseconds.
iv The rise time of the impulse is to be 5 nanoseconds; the impulse duration (50% value) is to be 50 nanoseconds.
v. 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.5.2 & B.5.3 are only required for devices which use an external power supply.

B.5.4 Vibration

This test shall be carried out on a device without its carrying case

This test should be made with reference to BS EN 60068-2-6 (2008) Test Fc - Sinusoidal Vibration. The device shall be subjected to vibration on 3 perpendicular axes in turn with a swept range of frequencies from 10 Hz to 150 Hz at 1 octave per minute, and an RMS acceleration of 9.8 m/s^2.

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

If no resonant frequencies are observed, then a vibrational test shall be made at a frequency of 50 Hz for a period of 2 minutes, followed by a functional test (as defined in paragraph).

B.5.5 Mechanical Shock

This test shall be carried out on a device without its carrying case

This test shall be carried out with reference to BS EN 60068-2-27:2009 – Environmental Testing – Part 2-27: Tests – test Ea and guidance: Shock and is intended to test the device's reaction to general rough handling

The device shall be subjected to mechanical shock consisting of 1000 shocks in each of 3 perpendicular directions at a frequency of 2 Hz. The device shall be rigidly mounted on a suitable surface. Each shock shall comprise a 10G severity, 6 milliseconds duration, half sine pulse. At the end of the test a Functional Test (as defined in paragraph B2) shall be carried out.

B.5.6 Electrostatic Discharge

During a functional test (paragraph B2) the device shall be subjected to random discharges of 4kV for contact discharges and 8kV for air discharges from a 150 pF capacitor through a 330 ohm 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 0.1 m around the DUT on all sides. The ground connection from the discharging capacitor shall be as short as possible.

B.5.7 Electromagnetic Field

In addition to the standard tests for immunity to electromagnetic interference, the device shall be exposed to the specific electromagnetic fields designed to check for immunity against TETRA waveforms 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 BS EN 61000-6-3:2007 + A1 (2011) 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 27–1000 MHz at a distance of 10 m.

B7 Other Regulatory Requirements

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

B8 Environmental Tests

B8.1 Damp Heat (Cyclic) This test is set out in BS EN 60068-2-30:2005 - Environmental Testing – Part 2-30: Tests – Test Db: Damp heat, cyclic (12h + 12h cycle) and exposes the instrument to temperatures of 25°C and 55°C with high humidity. The test is intended to induce condensation on the DUT. The test shall be performed with the instrument power OFF and in its normal packaging intended for supply to the police service.

i. Place the DUT in the test chamber and set to 25°C and 95% RH
ii. Raise the temperature from 25°C to 55°C over a period of 3 hours whilst maintaining 95% RH.
iii. Maintain at 55°C and 95% RH for 9 hours
iv. Reduce temperature from 55°C to 25°C over a period of 3 hours while maintaining 95% RH.
v. Maintain at 25°C and 95% humidity for 9 hours

The Damp Heat test cycle shall be performed twice, after which the instrument shall be allowed to stabilise at 20°C and ambient RH for 10 minutes. A Functional Test (paragraph B2) shall then be carried out.

B8.2 Storage – Ambient conditions

Cold Temperature –25°C Duration 2 hours
Hot Temperature +70°C Duration 6 hours

This test is to be performed with the instrument power OFF. The chamber conditions shall be such as to inhibit condensation at all times. After the test, the instrument shall be allowed to stabilise at 20°C after which a Functional Test (paragraph B2) shall be carried out.

If a device or any of the associated consumables necessary to perform a test cannot be exposed to this temperature range, the affected module shall incorporate a mechanism which clearly indicates to the operator when the device has been exposed to temperatures which exceed the minimum or maximum storage temperatures for the device. This mechanism shall clearly and permanently indicate to the operator that the device has been exposed to temperatures which are outside of the minimum or maximum temperature storage range, and shall indicate that the device cannot now be used. The device will be tested as detailed above using the extreme values detailed above to ensure that it cannot be used once it has been exposed to temperatures outside of the declared storage conditions. The device will also be tested as detailed above, but using the extreme temperature storage conditions declared by a manufacturer. All other test conditions shall remain the same. A device must pass a Functional Test as detailed in paragraph B2 after exposure of a device and all associated consumables necessary to perform a test to the extreme temperature storage conditions declared by a manufacturer.

B8.3 Shaking

This test is designed to simulate the effects on an instrument of transportation in a vehicle.
Wave shape: Sinusoidal
Acceleration: 10g (g = 9.81m/s^2)
Duration: 6ms
Frequency: 2Hz
Number of axes: 3 perpendicular
Number of shakes: 100 per axis

The device shall be placed in its reference position on the test table.
At the end of the test, a Functional Test (paragraph B2) shall be performed.

B8.4 Blown Dust

This test is designed to simulate the effect of dust in the atmosphere on the operation of the instrument. It is based on Method Lc2 - Free Blowing Dust in BS EN 60068-2-68:1996, IEC60068-2-68:1994 - Environmental testing – Part 2: Tests - Test L: Dust and sand. The following test conditions will apply (the numbers in brackets refer to the section in the standard where the condition is defined):
Test Dust Variant 1 - Fine Dust (6.1.4.1)
Severity
- dust concentration $1g/m^3 \pm 0.3\ g/m^3$ (6.1.4.2)
- air velocity 3m/s ± 0.3 m/s (6.1.4.4)
- duration 2 hours (6.1.4.7)

The DUT shall be allowed to stabilise for one hour at ambient laboratory temperature. A Functional Test shall then be started, and the DUT immediately placed into the test chamber for the duration of the remainder of the Functional Test, as described in paragraph B2. The result of the test shall be read according to the manufacturer's instructions immediately on removal from the test chamber.

B8.5 Water Resistance

This test is designed to simulate exposure to rain or spray during operational use. It is based on Method Ra1 - Artificial Rain in BS EN 60068-2-18:2001 - Environmental testing. Test methods. Tests R and guidance. Water. The following test conditions, as defined in section 5.2.2 of the standard will apply:
Intensity 10 mm/h ±5mm/h
Drop Size Distribution D_{50} = 1.9 mm ±0.2mm
Duration 10 minutes
Tilt Angle normal orientation for use

The DUT shall be allowed to stabilise for one hour at ambient laboratory temperature. A Functional Test shall then be started, and the DUT immediately placed into the test chamber for the duration of the remainder of the Functional Test, as described in paragraph B2. The result of the test shall be read according to the manufacturer's instructions immediately on removal of the DUT from the test chamber.

NOTE
Tests B8.4 and B8.5 will not be required if the instrument is designed solely for transport & use in a weather-resistant enclosure such as a police vehicle.

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 Mobile Preliminary Drug Testing 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 needs of the criminal justice system in the UK.

C2 Security

C.2.1 Access Levels

Access to the functions of a Mobile Preliminary Drug Testing 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 dependent 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
- Run multiple test sequence (if available).

C.2.1.4 Manufacturer

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

C3 Data Protection

Personal data held in a Mobile Preliminary Drug Testing 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 Mobile Preliminary Drug Testing 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 be provision in the data transfer protocol to provide assurance that the information received by the external system is identical to that in the Mobile Preliminary Drug Testing Device.

C4 Compliance

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

The software installed in Mobile Preliminary Drug Testing 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 Mobile Preliminary Drug Testing Device. Revision to the software will require a new version number and a new type approval order. Software in operational devices shall only by changed at the manufacturer’s premises.

C5 Validation & Verification by the Manufacturer

Software for Mobile Preliminary Drug Testing Devices shall be developed by, or on behalf of, the manufacturer using a quality assurance scheme that is accredited to the ISO 9001:2008 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 of the data variables classified as:
    - Jurisdiction specific constants
    - Device specific constants
    - Occasional Adjustments
    - Calibration Factors

C6 Software Testing

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

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