

Evidential Breath Alcohol Analysis Instruments

A Guide to Type Approval Procedures
for Evidential Breath Alcohol Analysis Instruments used
for Law Enforcement in Great Britain

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Summary

Evidential breath alcohol testing was introduced into Great Britain on 6 May 1983 as part of the Transport Act 1981. The primary legislation dealing with drinking and driving offences is the Road Traffic Act 1988. The Transport and Works Act 1992 and the Railways and Transport Safety Act 2003 create similar offences for operators of rail, marine and air transport. All this legislation requires that evidential breath alcohol analysis instruments are of a type approved by the Secretary of State.

Evidential Breath Alcohol Analysis Instruments detect and measure ethanol in expired alveolar air. As well as the Evidential Breath Alcohol Analysis Instrument itself, the system will also include a Gas Delivery System. This allows a certified ethanol gas mixture to be introduced into the Evidential Breath Alcohol Analysis Instrument in order to check it is properly calibrated. This check may be done within each operational test sequence, or it may be done at least once every 28 days where the Evidential Breath Alcohol Analysis Instrument has a means to simulate this check within each operational test sequence.

This document contains a description of the technical requirements to be met for consideration of type-approval for new Evidential Breath Alcohol Analysis Instruments for police use in Great Britain, and is intended to be a reference for manufacturers wishing to develop new instruments. The document contains details concerning the construction of Evidential Breath Alcohol Analysis Instruments, 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 which may be manufactured by any process.

Any requirements for goods or materials to comply with this Guide may 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 are acceptable. These standards, regulations or procedures must be the subject of a written technical description sufficiently detailed to permit assessment of the goods or materials for the use specified. Any alternative standard, code of practice, or technical specification must provide equivalent levels of safety, suitability and fitness for purpose in use (see paragraph 1.7 below).

Legal and technological changes may render parts of this Guide obsolete and the Home Office reserves the right to revise it accordingly. Additional tests may also be carried out (for example to check the response of the instrument at different legal limits). 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 B6, page 24, to remind manufacturers that instruments 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.

In addition, all instruments supplied for evaluation and subsequent use by police in Great Britain must also operate correctly when subject to the relevant frequencies, waveforms and peak field strength levels detailed in the EMC Immunity Test Procedures for Breath Alcohol Measuring Devices FSS-BAU-3/02.

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 Evidential Breath Alcohol Analysis Instruments

Contents

1. Introduction.....	1
2. Type Approval Procedures.....	2
3. General Requirements	4
4. Definitions.....	5
5. General Technical Specification.....	8
6. Metrological Characteristics	13
Annex A - Test Scheme for Instrument Response to Chemical Interference.....	16
Annex B - Test Scheme for Instrument Response to Physical Interference	18
Annex C - Test Scheme for Instrument Response to Alcohol Vapour Samples	25
Annex D - Software Validation & Verification	30

Introduction

1.1 The primary legislation dealing with drinking and driving offences in Great Britain is the Road Traffic Act 1988 and this permits the use of evidential breath alcohol analysis. The Transport and Works Act 1992 and the Railways and Transport Safety Act 2003 create similar offences for operators of rail, marine and air transport. All this legislation requires that evidential breath alcohol analysis instruments are of a type approved by the Secretary of State. There are currently two statutory limits in Great Britain - $9\mu\text{g}/100\text{ml}$ and $35\mu\text{g}/100\text{ml}$.

Note: These limits may change and may also differ between England and Wales and Scotland. Limits may also differ in Northern Ireland.

1.2 The Organisation Internationale de Métrologie Légale (OIML) has issued an international recommendation (R126) applying to Evidential Breath Testing Apparatus, and this Guide is based on those recommendations. The OIML recommendation applies to Evidential Breath Alcohol Analysis Instruments that measure accurately the concentration of ethanol in exhaled breath. Such instruments are used in Great Britain to obtain evidence that a transport operator is under the influence of alcohol. The information given here gives specific examples for Evidential Breath Analysis Instruments that exploit the phenomenon of infra-red absorption, but does not preclude the use of any technique of similar proven performance.

1.3 This document does not apply to instruments used for preliminary breath tests for detecting alcohol in exhaled breath. These are used by the police in Great Britain for the initial detection of alcohol in exhaled breath samples. The requirements for this type of instrument are set out in a separate Guide.

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

1.5 The purpose of this document is to define requirements for the performance of Evidential Breath Alcohol Analysis Instruments, 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 developments, and amended versions of this Guide will be issued when appropriate.

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

- i. ISO 9001-2008- Quality management systems. Requirements
- ii. BS EN ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories.
- iii. BS EN 61000-6-2 - Electromagnetic Compatibility (EMC) - Part 6-2: Generic Standards - Immunity For Industrial Environments
- iv. BS EN 61000-6-1:2007 - Electromagnetic Compatibility (EMC): Generic Standards. Immunity for Residential, Commercial and Light Industrial Environments
- v. BS EN 61000-6-3:2007+A1:2011 - Electromagnetic Compatibility (EMC): Generic Standards. Emission Standard for Residential, Commercial and Light Industrial Environments
- vi. BS EN 60068-1:1995 - Environmental testing. General and guidance.
- vii. BS EN 60068-2-30:2005 - Environmental testing. Tests. Test Db and guidance: Damp Heat, Cyclic (12h + 12h cycle)
- viii. BS EN 60068-2-27:2009 - Environmental Testing. Tests. Test Ea and guidance. Shock

- ix. BS EN 60068-2-6:2008 - Environmental Testing. Tests. Test Fc - Vibration (sinusoidal)
- x. BS EN 60068-2-68:1996, IEC60068-2-68:1994 - Environmental testing. Test methods. Test L - Dust and sand
- xi. BS EN 60068-2-18:2001, IEC 60068-2-18:2000 - Environmental testing. Test methods. Tests R and guidance. Water
- xii. 2004-108-EC - DIRECTIVE 2004-108-EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC
- xiii. FSS-BAU-3/02 EMC Immunity Test Procedures for Breath Alcohol Measuring Devices (2002)
- xiv. BS EN 61000-4-1:2007 - Electromagnetic compatibility (EMC). Testing and measurement techniques. Overview of IEC 61000-4 series
- xv. OIML Doc 11 Edition 2004 (E), General requirements for electronic measuring instruments
- xvi. OIML R126 Edition 2012 (E), Evidential breath analysers

1.7 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,

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

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

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
LONDON SW1P 4DF

2.2 Following the request to the Home Office a new instrument 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 Home Office Public Order Unit (HO POU). User trials will only be

arranged if the instrument 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.
- ii. Comply with the requirements of this guide

User trials will be designed to assess the suitability of the instrument in operational conditions. User trials may not be required for re-testing of already approved instruments that have been modified or updated.

The manufacturers are expected to provide 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 four categories. These are:

- Response to Chemical Interference (Annex A)
- Response to Physical Interference (Annex B)
- Response to Ethanol Vapour Samples (Annex C)
- Software Validation & Verification (Annex D)

The manufacturers are expected to bear the full costs of the test laboratory's evaluation work. It is the responsibility of the manufacturer to organise Annex A and Annex B testing at suitably accredited testing facilities. These tests are carried out prior to Annex C and Annex D testing, which will be carried out by the Home Office nominated laboratory.

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 A and 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, including those in the United Kingdom, must be accredited to BS EN ISO/IEC 17025:2005 by UKAS or equivalent accreditation bodies and 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 A and Annex B have been satisfactorily completed, the manufacturers shall supply three instruments on loan to the Home Office nominated laboratory for the purposes of Annex C and D testing. Sufficient consumables required to complete the assessment shall be supplied to the Home Office nominated laboratory free of charge. The instruments must be accompanied by all the relevant reports issued by the approved test houses and the documentation required by Annex D. The supplied test reports shall be clearly marked to show that the instrument has satisfactorily passed each required test.

2.7 The Home Office nominated laboratory will carry out all the tests involving response to Alcohol Vapour Samples (Annex C) and Software Validation & Verification (Annex D).

2.8 The manufacturers shall provide the following at the time of testing:

- i. A handbook or a set of written instructions for the use of the instrument operator.
- ii. A handbook or a set of written instructions for the use of the instrument supervisor.
- iii. A service manual or standard operating procedures for use by the service engineers.
- iv. A written technical description of the instrument's operation.
- v. A full circuit diagram with all the circuit components clearly indicated.

- vi. Details of the internal analytical unit including the transmission spectra of any IR filters used and the algorithm employed for their combined use. Equivalent information shall be supplied if an alternative analytical technique is employed.
- 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 in compliance with Annex D.

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

2.10 When a device has satisfactorily completed the laboratory testing, the Home Office Public Order Unit will consider obtaining the agreement of the Secretary of State for the Home Department for formal type approval for police use in Great Britain. The Home Office 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 require the manufacturers:

- i. Not to change the approved instrument in any way without the agreement of the Secretary of State or her agent.
- ii. Not to advertise the approved instrument for any use other than the approved use
- iii. To ensure that each instrument supplied matches the approved specification and to declare where and by whom the instruments will be manufactured. Any manufacturing facility must be accredited to the ISO 9001-2008 standard and open to inspection by the Home Office and the accrediting body.
- iv. To ensure that the type and serial number of each instrument is clearly identified by an indelible marking.
- v. To ensure that the serial number is unique to each instrument.
- vi. To ensure that any repair, servicing or calibration facility relating to the instrument:
 - operates in compliance with the Quality Framework for Evidential Breath Alcohol Analysis Instruments
 - is accredited to the ISO/IEC 17025:2005 Standard
 - is open to inspection by the Home Office, any UK Police Force, and UKAS.
- vii. 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 Public Order Unit.
- viii. To label with a version number any software or firmware and deposit documentation detailing the program with the Home Office free of charge.
- ix. To supply free of charge to the Home Office a full circuit diagram of the instrument with all the circuit components clearly indicated.
- x. To supply free of charge to the Home Office full documentation, including source & object code, and any relevant checksums for the embedded software used in the instrument.
- xi. To supply free of charge to the Home Office the results of the validation of the software including details of the procedures used
- xii. To supply free of charge to the Home Office nominated laboratory, on behalf of the Home Office ,an exemplar instrument, identical to the type approved instrument.

Note

- 1. In paragraph (i) above a change means any modifications to the approved device (including software) but excludes:
 - Use of electronic components of equivalent specification
 - Changes to agreed data parameters used by the computer program (see Annex D)

2. The exemplar instrument (paragraph xii above) may be used to test any modifications to the type approved instrument, before recommending the proposed change for type approval, or any other testing that the Home Office nominated laboratory deems necessary.
3. 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.

2.11 The Home Office undertakes to keep all information provided confidential in so far as that undertaking does not conflict with any duty of disclosure in a criminal prosecution or other legal obligation. However this agreement must be signed by the manufacturer or any person in a position to fulfil the duties regarding type approval prior to the Secretary of State signing the formal type approval document.

General Requirements

3.1 The instrument should be designed as far as possible to ensure the safety of both the operator of the instrument and the test subject. Particular attention should be made to the design and use of electrical connections, electrical supply wires and breath tube design as well as the materials chosen for mouthpiece construction.

3.2 Manufacturers shall ensure that all servicing and adjustment of approved instruments is carried out in compliance with the Quality Framework for Evidential Breath Alcohol Analysis Instruments (2013). Servicing and adjustment of approved devices in operational use shall only be carried out by a trained and competent person

3.3 Manufacturers and agents authorised by them shall ensure that when instruments are supplied for police use in Great Britain, following initial calibration of new instruments or recalibration of factory serviced instruments, they meet the standards detailed in this document.

3.4 The instruments shall be serviced every six months and the calibration checked by the manufacturers. If a service and calibration check is more than 28 days overdue the instrument shall not be capable of operation.

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

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

3.7 The manufacturer shall be responsible for the supply, installation and maintenance of the simulator (Section 4.6 or 4.8 below). For the Gas Simulator, this shall be the Gas Simulator Unit comprising the pressure-reduction valve, change-over valve (where fitted) and the associated pipework.

3.8 Any instrument that meets all of the requirements detailed in this document, and is capable of use at more than one prescribed limit shall only be capable of operating at one of those limits (e.g. 9µg/100ml or 35µg/100ml) for any particular test.

Any instrument that is capable of use at more than one limit, as described above shall indicate to the operator at the start of each test which limit it is operating at.

Any instrument which only meets the requirements, and which only passes tests allowing it to be used at one specific limit shall prominently display that limit on the instrument in question.

Definitions

4.1 Atmospheric Temperature and Pressure

The atmospheric temperature and pressure may have an influence on the ethanol concentration of any gas used for checking the calibration of the instrument.

When a Liquid Simulator is used the temperature of the solution and ethanol vapour supplied to the instrument shall be as stated in paragraph 4.8 below.

4.2 Adjustment

Adjusting the instrument to ensure the correct response to ethanol, using a certified standard mixture of gases having a relative humidity of at least 90% and a temperature of $34^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$. When this adjustment or verification is being carried out the ethanol/air mixture must pass through the entire gas analysis train, starting with the mouthpiece. Calibration must be carried out using a liquid simulator (paragraph 4.8 below).

4.3 Drift

The change in the analytical result obtained which occurs during a stated period of time at a given concentration.

4.4 Evidential Breath Alcohol Analysis Instrument

An instrument that measures accurately the concentration of alcohol in “end-expiratory” air to provide a result that can be used as evidence in drinking and driving offences.

4.4.1 Fixed Evidential Breath Alcohol Analysis Instrument

An Evidential Breath Alcohol Analysis Instrument intended for permanent installation and use within a building and powered from the mains electrical supply.

4.4.2 Mobile Evidential Breath Alcohol Analysis Instrument

An Evidential Breath Alcohol Analysis Instrument designed or capable of being used inside or outside a building, powered either from the mains electricity supply, a locally generated electrical supply, internal batteries or external batteries.

Note - Evidential Breath Alcohol Analysis Instruments should not be used when the influence factors do not correspond to the rated operating conditions (see Annex B below).

4.5 End-expiratory Air

A breath specimen that contains air from the end of a forced expiration from the lungs. End expiratory air is generally considered to contain an ethanol concentration representative of the ethanol concentration plateau.

4.6 Gas Simulator

A device for producing a standard mixture of dry gas. This device may comprise a gas cylinder filled with air containing a known concentration of ethanol under pressure to be maintained at ambient temperature. The temperature of the gas when introduced into the measuring system must be at least 34°C . This will require a suitable heated inlet as part of the instrument. The simulator gas should be stable for at least two years and the gas cylinder shall be clearly marked with the date that its contents are no longer warranted to meet this requirement.

4.6.1 Gas Simulator Unit.

The Gas Simulator Unit shall comprise a pressure reduction valve, one or more gas cylinders and the associated pipe work and valves to supply the standard mixture of dry gas to the instrument at an inlet pressure of the order of 20kPa (3psi). If two cylinders are connected to the gas simulator unit then a changeover valve shall be installed that allows an operator to

change cylinders when one becomes empty. If only one cylinder is connected to the gas simulator unit, either the unused connection on the changeover valve shall be blanked off or the changeover valve may be removed or omitted and a single cylinder attached directly to the pressure reduction valve.

4.7 Hysteresis and Memory Effect

Hysteresis is the property of a measuring instrument by which the response to a given input signal depends on the sequence of earlier input signals.

Where in a gas analyser an influx of gas of high concentration is interposed between two influxes of gas of lower concentration, the difference between the indications obtained with the gas of lower concentration is normally called the memory effect.

4.8 Liquid Simulator

A device for producing a standard mixture of gases having a relative humidity of at least 90% and a temperature of $34.0^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$. This device may comprise a suitably constructed vessel containing an aqueous ethanol solution of known concentration at a constant temperature of $34.0^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$. Air is passed through the solution so as to generate the ethanol/air mixture required for instrument testing. Liquid simulators shall be capable of delivering the required concentration of ethanol vapour during use.

4.9 Manufacturer

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

4.10 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 instrument is in this state. In this position the instrument must meet the metrological requirements of this Guide.

4.11 Metrological Test Mode

In Metrological Test Mode the instrument is not subject to the constraints regarding two breath samples within the acceptance limits set out in paragraph 5.7.1 below. In this mode the instrument performs tests either in accordance with the normal measuring cycle (paragraph 5.7) or be capable of performing multiple tests (at least 20) after the initial calibration verification step. The results must be displayed to $0.1\mu\text{g}/100\text{ml}$. At the end of a multiple test sequence the results should be capable of being printed out.

4.12 Normal Mode

In normal mode the instrument must perform tests in accordance with the measuring cycle (paragraph 5.7 below) and within the constraints of the acceptance limits set out in paragraph 5.7.1 below. Results must be displayed and printed rounded down to integer values.

4.13 Normal Operation

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

4.14 Stand-by Position

The state of the instrument 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.

4.15 Units of Measurement

For instruments manufactured for use in Great Britain the concentration of alcohol in the breath sample and ethanol in air for test gases must be expressed in $\mu\text{g}/100\text{ml}$.

This unit of concentration is used throughout this document. ($1\mu\text{g}/100\text{ml}$ is equivalent to $0.01\text{mg}/\text{litre}$)

4.16 Verification of Calibration

Checking that the instrument is correctly adjusted either:

4.16.1 To a Standard

That is verifying that the instrument is properly adjusted, using:

- (a) a certified standard mixture of gases having a relative humidity of at least 90% and a temperature of $34^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$
or

- (b) a certified dry ethanol/air (or ethanol/nitrogen) mixture

providing it can be demonstrated on the instrument under test that results from both (a) & (b) are equivalent.

4.16.2 By Simulation

That is verifying that the instrument is properly adjusted by a procedure other than that specified in paragraph 4.16.1 above, notably by the simulation of the effects of the passage of a standard mixture of gases as described in paragraph 4.16.1.

For analyses based on the principle of infra-red absorption a satisfactory method consists, of interposing in the optical path of the infra-red beam a filter which absorbs a known fraction of the beam. Measurements made by other analytical techniques may be adopted providing the methodology is validated to demonstrate specificity, accuracy and precision.

Note

1. Verification by a gas other than that described in paragraph 4.16.1 above is verification by simulation.
2. Verification by simulation (paragraph 4.16.2 above) requires that a satisfactory number of the internal elements of the instrument are in operation. The exact requirements for this will vary depending on the design of the particular instrument, but as a minimum requirement it is expected that the analytical assembly (including the detector) will be checked during each verification operation.

General Technical Specification

Evidential Breath Alcohol Analysis in Great Britain requires the analysis of two separate exhalations of breath. The lower breath alcohol concentration is used for prosecution. Instruments for use in Great Britain shall express their results in units of $\mu\text{g}/100\text{ml}$.

5.1 Measuring Range

Instruments shall be capable of measuring accurately all concentrations in the range 0 to $200\mu\text{g}/100\text{ml}$, but the maximum range may extend to $300\mu\text{g}/100\text{ml}$. However, in normal operation the instrument may indicate $0\mu\text{g}/100\text{ml}$ for all concentrations less than $3\mu\text{g}/100\text{ml}$.

Where the level is above the maximum of the instrument this shall be indicated along with a suitable message.

5.2 Scale Interval

5.2.1 Normal Mode

The scale interval shall be 1µg/100ml in normal operation rounded down to the nearest whole figure.

5.2.2 Metrological Test Mode

During metrological testing or calibration it shall be possible to discriminate to 0.1µg/100ml.

5.3 Display

The result of a measurement shall be displayed digitally by means of aligned figures. When the instrument is in normal operation it shall measure to 0.1µg/100ml, but only display the rounded down integer value.

The height of the figures shall be equal to at least:

- 5mm for fluorescent registering devices or devices having a luminosity that is recognised as equivalent.
- 10mm for all other cases

The name of the unit of measurement or its symbol shall appear in close proximity to the figures indicating the result, and the characters which are used shall have a height of at least 3mm.

The display, especially on mobile Evidential Breath Alcohol Analysis Instruments shall be easily readable in all levels of illumination. In the case of mobile instruments this shall include direct sunlight.

5.4 Printer

Instruments shall be equipped with a printer which prints the result of the measurement, and the symbol of the unit in which the result is expressed.

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

5.5 Start-up Time

At all temperatures for which the instrument is approved (15°C to 35°C for fixed instruments, or 0°C to 40°C for mobile instruments), the instrument shall be capable of attaining the “measuring position”:

- 60 minutes after switching on for fixed and 20 minutes for mobile Evidential Breath Alcohol Analysis Instruments, and/or
- 5 minutes after switching from the “stand-by position”.

5.6 Measuring Conditions

5.6.1 The general environmental conditions under which a fixed Evidential Breath Alcohol Analysis Instrument shall be capable of meeting the requirements in this document are as follows:

- i. ambient temperature 15°C to 35°C

- ii. ambient relative humidity (RH) 30% to 90%
- iii. atmospheric pressure (AP) 86.0 kPa to 106.0 kPa

In addition, a mobile Evidential Breath Alcohol Analysis Instrument shall be capable of meeting the requirements in this document over the extended temperature range 0°C to 40°C.

When a Gas Simulator is used, the temperature control of the gas entering the instrument shall be as given in paragraph 4.6 above and, in addition, compensation for variation in atmospheric pressure at the time of use shall be made. Fluctuations in atmospheric pressure in Great Britain, from data obtained from the Meteorological Office, can occur between the highest (105.0 kPa) and lowest (94.0 kPa) values producing a difference of 12%. This will give rise to a variation of similar percentage in the ethanol concentration of the calibration gas when expressed in µg/100ml. This variation is outside the error limits allowed for instrument operation as given in paragraph 6.1 below. The atmospheric pressure at each calibration check shall be measured by the instrument using a built-in pressure sensor with an accuracy of better than ± 0.5 kPa. The result of this measurement shall be used to correct automatically the ethanol concentration of the simulator gas in accordance with standard atmospheric pressure of 101.3 kPa.

5.6.2 In normal operation, the instrument shall only indicate the ethanol concentration in each breath specimen when the measuring cycle has been successfully completed. Calibration check results (see 5.7 below) shall be displayed at the time of analysis. Messages and other check values are permitted to indicate to the operator the current stage of the cycle. When the result of a measurement is zero, such a result shall be incapable of being confused with the zero indicated prior to measurement. This requirement is satisfied when the instrument indicates the various phases of the measuring cycle.

5.6.3 The instrument shall monitor the continuity of exhalation and the ethanol concentration in the breath specimen in order to identify an acceptable ethanol concentration plateau and make a measurement. A device shall give an indication if the flow of exhaled air ceases (momentarily or altogether) between the beginning of the exhalation and the establishment of the acceptable ethanol concentration plateau.

5.6.4 The exhalation pressure necessary to obtain a specimen of exhaled air with the mouthpiece fitted should not be excessive, and it shall not exceed 2.5 kPa at a flow rate of 10 litres/min.

5.6.5 The instrument shall display a message to indicate that it is ready to accept a breath specimen. Measurement of the alcohol content of a breath specimen shall not be possible when the instrument is not ready to take a measurement.

5.6.6 When the instrument is ready to accept a breath specimen, a period of 3 minutes shall be allowed during which the subject shall be required to provide a satisfactory breath specimen. Any breath specimen commenced within the 3-minute period that satisfies the breath sampling requirements shall be deemed valid and allowed to proceed to completion. If no satisfactory breath specimen is provided (or started) within the 3-minute allowance the instrument shall print a report indicating that no specimen has been supplied. The instrument shall then abort the cycle and re-set.

5.7 Measuring Cycle

The instruments intended for use in Great Britain shall perform the following measuring cycle:

1. Purge and check zero
2. Verify calibration by simulation/to a standard
(at a concentration equal to the limit at which the instrument is operating)
3. Purge and check zero
4. Take and analyse sample 1
5. Purge and check zero

6. Take and analyse sample 2
7. Purge and check zero
8. Verify calibration by simulation/to a standard
(at a concentration equal to the limit at which the instrument is operating)
9. Print out readings

5.7.1 Acceptance Limits

The readings obtained for the various parts of this measuring cycle shall be subject to acceptance limits as follows:

- | | |
|---------------------|--|
| Verify calibration: | 32.0 to 37.9µg/100ml where the limit is 35µg/100ml
7.0 to 10.9µg/100ml where the limit is 9µg/100ml |
| Specimens: | Readings from the two required breath specimens shall only be accepted if separated by no more than 15% of the lower reading up to a maximum of 200µg/100ml, or where the difference is greater : <ul style="list-style-type: none">• 5µg/100ml where the limit is 35µg/100ml• 2µg/100ml where the limit is 9µg/100ml |

Note: Other limits may be introduced due to changes in legislation. If new limits are introduced, the relevant acceptance limits will be supplied on request by the Home Office nominated laboratory.

5.7.2 Printout of Results

The readings obtained during a measuring cycle shall only be printed on completion. The time at each stage in the measuring cycle shall be given on the printout. If it is not possible to perform the second breath measurement it shall be possible to obtain the result from the first breath measurement. In this case the instrument shall indicate that the measuring cycle has not been completed.

5.7.3 Printout Details

The printout produced by the instrument shall contain, or have provision for the following information:

1. Identification of instrument and software version number.
2. Location of instrument
 - Police Force and Station for fixed instruments
 - Police Force and Unit for mobile instruments
3. Date of test
4. Name of subject
5. Date of birth of subject
6. Space for signature of subject
7. Detailed results from the tests according to the measuring cycle (paragraph 5.7)
8. Name of operator
9. The statement:

I CERTIFY THAT IN THIS STATEMENT, READING ONE RELATES TO THE FIRST SPECIMEN OF BREATH PROVIDED BY THE SUBJECT NAMED ABOVE AND READING TWO TO THE SECOND, AT THE DATE AND TIME SHOWN HEREIN.

10. Space for signature of operator

Items 1, 2, 3 and 7 shall be produced by the instrument. The statement (item 9) should only be printed when it is required by Section 16.1 Road Traffic Offenders Act 1988.

For use in England, the statement (item 9) shall be produced by the instrument as shown.

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 this printout and statement (item 9) shall be modified to replace “statement” with “report” and to provide space for the corroborating officer’s signature.

All other items may have space provided for the operator to write in the details.

5.8 Return to Zero

The instrument shall automatically check the zero position at the beginning of each measuring cycle by purging the sampling system with ambient (alcohol free) air and the result shall be similarly checked at the indicated points in the cycle as described in 5.7 above..

5.9 Verification of Correct Operation

Verification of correct operation of the instrument comprises, in particular, checking that:

The separate internal, analytical elements of the instrument operate correctly.

The measuring cycle is correctly performed.

The instrument is properly adjusted in conformity with paragraphs 4.16 and 5.7.1 above.

The instrument returns to zero as required by paragraph 5.8 above

Instruments shall verify correct operation automatically during the measuring cycle. The result of the measurement shall not be indicated or recorded until correct operation has been verified.

When an error signal is detected, particularly when correct operation is being checked, the instrument shall not give a result that may be considered valid and an error message shall be displayed and printed.

5.10 Adjustment for Calibration or Verification of Correct Adjustment

For purposes of maintenance and of legal metrological control it shall be possible to adjust, or verify correct calibration of the instrument using the standard mixture of gases under the conditions specified in 4.16 above. Instruments shall be verified to be correctly adjusted at a scale value between:

33.0 and 36.9µg/100ml where the limit is 35µg/100ml

8.0 and 9.9µg/100ml where the limit is 9µg/100ml

5.11 Verification of Correct Adjustment During Operation

Verification of the correct instrument calibration shall be carried out during the measuring cycle before and after the supply of breath alcohol samples for analysis. This shall be performed in conformity with paragraphs 4.16 and 5.7.1 above.

When the automatic verification of correct adjustment no longer gives a confirmatory result, the instrument shall not be capable of making a measurement.

If verification of the correct instrument calibration is carried out by simulation in accordance with paragraph 4.16.2 above it shall be possible for an operator to verify calibration by a standard in accordance with paragraph 4.16.1 above. If such a calibration check has not been carried out for 28 days prior to a measuring cycle the instrument shall prevent a measurement being made. The operator shall be given warning that verification to a standard is due within the next 48 hours.

5.12 Length of Time to Indicate a Result

While the instrument is in operation the results of the most recently completed test shall be retained in readable and printable form until the next time a test is initiated.

5.13 Instrument Memory

The results of tests shall be stored in the instrument memory and shall only be accessed on authorised demand.

5.13.1 Data Storage

The memory facility shall have the capability to retain at least 500 records of test results. When the memory is full the oldest result shall be deleted and replaced by the most recent one, provided that the result to be deleted is more than 8 months old. If as a result of this requirement the memory remains full no further tests shall be permitted. The operator shall be warned at the commencement of each test when the memory has space to store the results of ten tests or fewer.

The data storage shall meet the following requirements:

- Protection from accidental or deliberate alteration
- Detect and report corrupted data
- Passcode protected limiting access to a supervisor
- Provide a facility to allow an operator to print the results of the last test.

The following information shall be recorded:

- Date and time of each test sequence
- The results obtained for standards, blanks and samples
- The name of the subject (if entered into the instrument)
- The name of the operator (if entered into the instrument)

The contents shall only be capable of being exported or printed on authorised demand (See Section D.2.1).

5.13.2 External Links

The instrument memory shall have the capability to be linked to an external computer via a standard interface to enable data to be downloaded and stored within an appropriate database / 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 and verified, the memory shall be cleared and be re-usable. Access to download data and to clear the memory shall be passcode controlled and shall not be available to a normal operator.

This data link may permit any information from the Evidential Breath Alcohol Analysis Instrument 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 Evidential Breath Alcohol Analysis Instrument.

5.14 Safety and Security

5.14.1 Hygiene

The instrument shall be capable of use under satisfactorily hygienic conditions. It shall be possible to change the mouthpiece for each measurement when required and the mouthpieces shall be supplied new and individually wrapped. The design of this packaging shall be such as to minimise the chance that the mouthpiece may become blocked by a piece of the packaging.

5.14.2 Safety in Use

Instruments shall conform to relevant regulations and standards for electrical safety and use of compressed gases currently in force.

The instrument 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 breath tube design as well as the materials chosen for mouthpiece construction. This is of particular importance to Mobile Evidential Breath Alcohol Analysis Instruments.

5.14.3 Security in Use

Fixed instruments shall have the facility to be permanently secured within a security enclosure and shall be capable of operation within that enclosure.

Access to the software of the instrument (whether mobile or fixed) shall only be possible subject to the requirements detailed in Annex D.2.1.

5.14.4 Means of Adjustment

The means by which the instrument is adjusted (particularly devices for adjusting the sensitivity and zero position) shall only be accessible to the manufacturer or field service engineer (see Section D.2.1).

5.14.5 Mode of Operation Changes

The means used to change from the normal mode of operation to another mode of operation shall be inaccessible to a normal operator of the instrument.

Changing the mode of operation shall be restricted to a Field Service Engineer or Factory Access as defined in section D.2.1 below.

5.15 Breath Sampling Tube

The breath sampling tube shall be heated to at least 35°C in order to prevent condensation from the subject's breath entering the instrument.

5.16 Mouthpiece

Mouthpieces shall be constructed so as to prevent any moisture droplets in the subject's breath from entering the instrument. The mouthpiece and/or the breath sampling tube shall be so constructed as to prevent the user from inhaling any vapours that are already in the instrument.

The pressure drop caused by the mouthpiece shall not be greater than 1.0 kPa at a flow rate of 10 litres/minute.

5.17 Analytical Chamber Temperature

The temperature of the analytical chamber and other temperature sensitive components of the instrument shall be maintained in the range 38°C – 50°C. This is to ensure that no condensation can occur from vapour samples supplied for analysis and that external temperature fluctuations have no influence on the calibration of the instrument. The manufacturer shall state the actual temperature of the analytical chamber within this range, and

a tolerance of $\pm 3^{\circ}\text{C}$ shall be allowed on that stated value. A means for measuring the analytical chamber temperature shall be provided.

5.18 Gas Simulator Unit

The gas simulator unit designed to deliver standard gas to the Evidential Breath Alcohol Analysis Instrument for calibration checking purposes shall be tested in accordance with National Physical Laboratory Report NPL DQM (D) S71 (September 1993) [Annex D]. Whilst the Gas Simulator Unit may be tested independently, the supplier must specify the combination of Gas Simulator Unit and Evidential Breath Alcohol Analysis Instrument for which approval is sought.

Metrological Characteristics

6.1 Error Limits

6.1.1 Instruments at Initial Verification Testing

Maximum permissible error on each indication shall be:

$\leq 50\mu\text{g}/100\text{ml}$	$\pm 2.0\mu\text{g}/100\text{ml}$
> 50 but $\leq 200\mu\text{g}/100\text{ml}$	$\pm 5\%$
$> 200\mu\text{g}/100\text{ml}$	$\pm 10\%$

Initial verification testing shall be performed with the instrument in Metrological Test Mode, and the results displayed to $0.1\mu\text{g}/100\text{ml}$.

6.1.2 Instruments at Service Testing and Normal Operation

Maximum permissible error on each indication shall be

$\leq 50\mu\text{g}/100\text{ml}$	$-3\mu\text{g}/100\text{ml}$ to $+2\mu\text{g}/100\text{ml}$
> 50 but $\leq 200\mu\text{g}/100\text{ml}$	$\pm 7\%$
$> 200\mu\text{g}/100\text{ml}$	$\pm 15\%$

Service testing shall be performed in accordance with the Measuring Cycle (paragraph 5.7) with the instrument in Metrological Test Mode.

6.1.3 Rounding

When the instrument is in normal operation mode the readings shall be rounded **down** to the nearest integer value. During metrological testing or calibration (Metrological test mode) it shall be possible to discriminate to $0.1\mu\text{g}/100\text{ml}$ (see paragraphs 5.2 & 5.3 above)

6.2 Repeatability

6.2.1. Calculation of Standard Deviation

The standard deviation of a set of readings shall be calculated using the formula for estimating population standard deviation.

6.2.2 Requirements

The standard deviation for readings shall not exceed $\frac{1}{3}$ of the maximum permissible error specified in paragraph 6.1.1

6.2.3 Probability of compliance

The statistical probability that the instrument satisfies the requirements of 6.2.2 above shall not be less than 95% for each concentration.

6.3 Drift

The measured drift of indication shall be:

Short term drift

Zero	< 1.5µg/100ml in 4 hours
At 50µg/100ml	< 1.5µg/100ml in 4 hours
Long term drift	
At 50µg/100ml	< 2µg/100ml in 2 months

6.4 Hysteresis and Memory Effect.

6.4.1 Memory Effect for Large Changes in Concentration

For tests at 35µg/100ml this test shall use ethanol concentrations of 35µg/100ml (Test Gas 4) and 200µg/100ml (Test Gas 9).

For tests at 9µg/100ml this test shall use ethanol concentrations of 9µg/100ml (Test Gas 2) and 105µg/100ml (Test Gas 7).

6.4.2 Hysteresis Effect for Small Changes in Concentration

For tests at 35µg/100ml this test shall use ethanol concentrations of 35µg/100ml (Test Gas 4) and 50µg/100ml (Test Gas 5).

For tests at 9µg/100ml this test shall use ethanol concentrations of 9µg/100ml (Test Gas 2) and 35µg/100ml (Test Gas 4).

6.5 Markings

An Evidential Breath Alcohol Analysis Instrument conforming to this specification shall be marked legibly with the following: -

- The name of the manufacturer and/or supplier
- The name of the instrument and model type
- The instrument serial number
- The measurement range
- The Breath Alcohol Limit(s) at which it operates
- The ambient temperature range in which the instrument may be used
- The UKAS accreditation label showing the number of the current calibration certificates and the dates of issue

6.6 Requirements for Operational Use

6.6.1 Servicing and Calibration

Instruments in service must be maintained in compliance with the Quality Framework for Evidential Breath Alcohol Analysis Instruments

6.6.2 Service Interval

The normal interval for calibration verification should be 6 calendar months. If a service and calibration check is more than 28 days overdue the instrument shall not be capable of operation.

Annex A

Test Scheme for Instrument Response to Chemical Interference

A1 Introduction

This scheme sets out the chemical compounds required to assess the performance of an Evidential Breath Alcohol Analysis Instrument. It outlines the laboratory procedure for the assessment of the analytical performance of the instrument in relation to the measurement of vapour samples containing ethanol and specified amounts of possible interfering substances that may be encountered in the course of breath analysis. This laboratory procedure is based on the recommendations of the Organisation Internationale de Métrologie Légale (OIML).

NOTE - Where appropriate, guidance notes on the interpretation of test requirements are given in *italics*.

A2 Assessment of the Analytical Unit

The operation of the analytical unit – comprising the sample chamber and detection system – shall be evaluated from the detailed information supplied in order to assess its sensitivity to ethanol and each of the interfering substances detailed in Table 1. With infra-red analytical instruments this shall include detailed information of the transmission spectra of the IR filters used and any algorithm employed for their combined use. Equivalent information will be required for instruments that use alternative analytical systems.

A3 Assessment of the Evidential Breath Alcohol Analysis Instrument

A series of test gases comprising the vapour sample, as detailed in paragraph A5, and each of the interfering substances (Table 1) shall be introduced into the instrument under test. The results obtained shall be in agreement with the assessment made of the detailed information supplied by the manufacturer (paragraph 2.8iv & 2.8vi above) and shall not exceed the additional maximum response detailed in Table 1.

NOTE - It is permissible for no result and the message “Interfering Substance” to be given following a test for a substance listed in Table 1.

A4 Possible Interfering Substances

Table 1 is a list of substances that may occur on the breath of a person required to supply a sample of breath for alcohol analysis, in addition to ethanol. It gives the test vapour concentration and a maximum permitted response for each compound in the absence of an “Interfering Substance” message.

A5 Test Method

For these tests the instrument shall be used in Metrological Test Mode to read in 0.1µg intervals. For the purposes of these tests a vapour sample should be presented to the instrument at a rate of 3 litres in 5 seconds.

The test gas shall comprise air with ethanol at a nominal concentration at the limit(s) for which it has been submitted, and the selected interfering substance at the concentration indicated in Table 1.

Note: If an Evidential Breath Alcohol Analysis Instrument is submitted for testing at more than one limit, the instrument shall be separately tested as described above with alcohol vapour samples of 9 µg/100ml and 35 µg/100ml. If an Evidential Breath Alcohol Analysis Instrument is submitted for testing at only one limit, the instrument shall only be tested with alcohol vapour samples at that limit.

At least 5 tests shall be performed with each substance so as to properly assess the interference. The indicated concentration of each substance is in addition to the nominal concentration of ethanol. There are three possible outcomes for these tests:

- The response is less than the maximum permitted response - the instrument has passed the test for the interfering substance concerned.
- The response is greater than the maximum permitted response - the instrument has failed the test for the interfering substance concerned.
- The response is an “Interfering Substance” message - an additional test shall be run.

If the instrument gives an “Interfering Substance” indication the test shall be repeated using a test gas containing 20% of the concentration of the interfering substance given in Table 1 plus ethanol at the relevant concentration. The maximum elevated response for this test shall not exceed 1µg/100ml.

Table 1 - Interfering Substances

Substance	Vapour Concentration (µg/100ml)(±5%)	Maximum Allowable Response (µg/100ml)
Acetone	75	10
Isopropanol	20	10
Acetaldehyde	20	10
Methanol	20	10
Carbon Monoxide	25	10
Toluene	25	10
Xylene (1:1 meta:para)	25	10
Benzene	25	10
Perchloroethylene	25	10
Methyl Ethyl Ketone	30	12.5
Methyl iso-butyl Ketone	30	12.5
Ethyl Acetate	30	12.5
Methane	50	12.5
n-Pentane	50	12.5
n-Hexane	50	12.5
n-Heptane	50	12.5
n-Octane	50	12.5
Diethyl Ether	50	12.5

Annex B

Test Scheme for Instrument Response to Physical Interference

B1 Introduction

This scheme sets out the tests to assess the performance of an Evidential Breath Alcohol Analysis Instrument in accordance with:

- Recommendation R126 of the Organisation Internationale de Métrologie Légale (OIML)
- European Community (EC) Directive 2004-108-EC on Electromagnetic Compatibility .

It gives the laboratory procedure for the assessment of the effects of changes in physical conditions on the performance of:

- Fixed Evidential Breath Alcohol Analysis Instrument powered from the mains electricity supply,
- Mobile Evidential Breath Alcohol Analysis Instrument powered from:
 - the mains electrical supply
 - a locally generated electrical supply
 - internal batteries
 - external batteries

NOTE

1. Where a section has two parts (a) and (b), all Evidential Breath Alcohol Analysis Instruments shall be required to pass the tests set out in Section (a). Only Evidential Breath Alcohol Analysis Instruments designed for, or capable of being used as, mobile devices shall be required to pass the tests in Section (b).
2. All instruments for use in Great Britain must comply with European Community (EC) Directive 2004-108-EC. The tests can be found in the following test procedures: BS EN 61000-6-4:2007+A1:2011 and BS EN 61000-6-3:2007+A1:2007. 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 below. All other EMC tests listed in Annex B shall be carried out as stated.
3. Where appropriate, guidance notes on the interpretation of test requirements are given in *italics*.

B2 Functional Test Requirements

A Functional Test shall comprise two complete measuring cycles. For these tests the instrument shall be used in Metrological Test Mode to read in 0.1µg intervals. For these tests a vapour sample should be presented to the instrument at a rate of 3 litres in 5 seconds.

The test gas shall comprise air with ethanol at a nominal concentration at the limit(s) for which it has been submitted.

Note: If an Evidential Breath Alcohol Analysis Instrument is submitted for testing at more than one limit, the instrument shall be subject to a complete Functional Test as described above with alcohol vapour samples of 9 µg/100ml and a complete Functional Test as described above with alcohol vapour samples of 35 µg/100ml (i.e. four complete measuring cycles per environmental condition).

If an Evidential Breath Alcohol Analysis Instrument is submitted for testing at only one limit, the instrument shall only be subject to a Functional Test with alcohol vapour samples at that limit (i.e. two complete measuring cycles per environmental condition).

B3 Permissible Error

The result of any breath test performed in this scheme shall exhibit an error of no more than ±2.0µg/100ml from the expected value. Where applicable it is permissible for no result to be

displayed after these tests, but a message shall be given in all cases to indicate that no result is permissible.

B4 Physical Influence Factors

B4.1 Functional Test

A Functional Test shall be carried out for each influence factor. The effect of each factor shall be determined in turn with all other factors at their reference level. The effects shall not be combined. Tests shall be run at the reference points and the extreme points of each condition listed.

NOTE

Mobile Evidential Breath Alcohol Analysis Instruments shall only be required to pass the tests relevant to the type of power supply they are designed to use.

B4.2 AC Supply Voltage

- (a) Reference condition: Nominal voltage (230 Volts)
Extreme values: -15% of nominal voltage
+10% of nominal voltage
- (b) Reference condition: Nominal voltage (230 Volts)
Extreme values: -30% of nominal voltage
+20% of nominal voltage

Each voltage variation should be applied whilst a Functional Test (paragraph B2 above) is run – and not less than 15 minutes in total.

B4.3 AC Supply Frequency

- (a) Reference condition: Nominal frequency (50Hz)
Extreme values: $\pm 2\%$ of nominal frequency
- (b) Reference condition: Nominal frequency (50Hz)
Extreme values: $\pm 5\%$ of nominal frequency

The tests should be carried out at each frequency extreme whilst a Functional Test (paragraph B2 above) is run.

B4.4 DC Supply Voltage

- (a) Not required
- (b) Reference condition: Nominal voltage required by the instrument
Extreme values: -8% of nominal voltage
+24% of nominal voltage

Each voltage variation should be applied whilst a Functional Test (paragraph B2 above) is run – and not less than 15 minutes in total.

B4.5 Ripple on DC Supply (Frequency Range 40Hz to 400Hz)

- (a) Not required
- (b) Reference condition: 0V
Extreme value.: 0.2V peak to peak

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

NOTE

Mobile Evidential Breath Alcohol Analysis Instruments shall only be required to pass the tests relevant to the type of power supply they are designed to use).

B4.6 Ambient Temperature

- (a) Reference condition: 20°C
Extreme values: 15°C and 35°C
- (b) Reference condition: 20°C
Extreme values: 0°C and 40°C

The instrument under test (IUT) shall be placed in the test chamber. The temperature shall be reduced to the minimum temperature specified and the IUT allowed to stabilise for at least 3 hours. During this period, steps should be taken to prevent condensation on the IUT. A Functional Test (paragraph B2 above) shall then be carried out. 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 IUT allowed to stabilise for at least 3 hours. A Functional Test (paragraph B2 above) shall then be carried out.

B4.7 Ambient Relative Humidity (RH)

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

The instrument under test (IUT) shall be placed in the test chamber. The temperature shall be set to the reference level and the humidity adjusted to the minimum RH specified (30%). A Functional Test (paragraph B2 above) shall then be carried out. 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 (paragraph B2 above) shall then be carried out.

B4.8 Atmospheric Pressure

- Reference condition: 101.3kPa
- Extreme values: 86kPa and 106kPa (IEC 68-1/2)

The instrument under test (IUT) shall be placed in the test chamber. During this test the correct readout of the pressure-compensating device fitted to the IUT shall be verified, and the pressure correction verified by running a series of Functional Tests (paragraph B2 above) at different pressures.

B4.9 Total Hydrocarbon Content of Atmosphere (as Methane)

- Reference condition: 2ppm
- Extreme value: 5ppm

Special atmosphere gas samples are required for this test. For the reference test the IUT shall be connected to the sample vapour bottle and gas container bag containing the reference atmosphere (2ppm methane) using a change-over valve. A Functional Test (paragraph B2 above) shall be carried out ensuring the IUT carries out each purge/blank check using the special atmosphere gas .

The gas container bag shall then be purged and filled with the extreme level gas (5ppm methane) and a repeat Functional Test shall be carried out as described in paragraph B2 above. The result shall be compared with the reference atmosphere test.

B5 Physical Disturbance Factors

B5.1 Test Methods

Testing under this section shall be carried out to conform with IEC 61000-4 and in accordance with OIML Doc 11 Edition 2004 (E), General requirements for electronic measuring instruments.

NOTE

Mobile Evidential Breath Alcohol Analysis Instruments shall only be required to pass the tests relevant to the type of power supply they are designed to use).

B5.2 Short Time Reduction in Electricity Supply.

During the Measuring Cycle 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 (paragraph B3 above).

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 (paragraph B2 above).

B5.3 Parasitic Voltages on Electricity Supply

Disturbances shall be applied during Functional Test (paragraph B2 above).

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

- i. The repetition rate shall be set to 5kHz for signal/control lines and to 2.5kHz for power lines.
- ii. The amplitude of the interference shall be 1kV for signal/control lines and 2kV 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.

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.

B5.4 Vibration

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

- (a) This test should be made with reference to BS EN 60068-2-6:2008 - Environmental Testing. Tests. Test Fc - Vibration (sinusoidal) recommendations. The instrument 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 then a vibrational test shall be carried out at each observed frequency for a period of 2 minutes, followed by a Functional Test (paragraph B2 above).

- (b) The test shall be carried out in the same way as B5.4(a), but with an RMS acceleration of 9.8m/s^2 .

B5.5 Mechanical Shock

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

- (a) The instrument shall be placed on a rigid surface in its normal attitude.

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

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

Each test shall be followed by a Functional Test (paragraph B2 above).

- (b) This test shall be carried out with reference to BS EN 60068-2-27:2009 - Environmental Testing. 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 2Hz. 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 (paragraph B2 above) shall be carried out.

B5.6 Electrostatic Discharge

During a Functional Test (paragraph B2 above) the instrument 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 IUT 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 IUT.

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

B5.7 Electromagnetic Field

The instrument shall be exposed to Electromagnetic fields as detailed in EMC Immunity Test Procedures for Breath Alcohol Measuring Devices FSS-BAU-3/02

B5.8 Magnetic Field

The instrument shall be placed in a magnetic field of 50Hz and an intensity of 60A/m such as may be produced by a square coil of 50 turns, side 1m, carrying a current of 1 Amp. The use of a Helmholtz coil is recommended for this test.

The field shall be applied during two Functional Tests as described in B2 above.

The square coil should be placed at a distance of not greater than 25mm from the IUT.

B6 Emission Tests (DIRECTIVE 2004-108-EC)

Tests and test limits required by the generic standards given in BS EN61000-6-3:2007+A1:2011

Table 2 - Emission Tests

Port	Frequency Range	Limits
Enclosure	30 - 230MHz 230-1000MHz	37dB μ V/m at 10m 37dB μ V/m at 10m
Mains	0.15-0.5MHz	66-56dB μ V quasi-peak 56-46dB μ V average (Decreasing linearly with log frequency)
	0.5-5MHz	56dB μ V/m quasi-peak 46dB μ V/m average
	5-30MHz	60dB μ V/m quasi-peak 50dB μ V/m average
	0.15-30MHz	Discontinuous Interference

B7 Ageing Test

- (a) The instrument shall be placed in a controlled environment chamber for 8 hours in the “stand by” condition. The chamber shall be controlled at 40°C and 90% RH.

At the end of the period, the power shall be turned off and the temperature raised to 60°C and 30% RH over a period of not less than 1 hour. This set of conditions shall be maintained for a period of 1 hour.

The temperature shall then be returned to ambient and allowed to stabilise, after which the instrument shall be subjected to a further vibration test.

The conditions for this vibration test shall be:

Frequency range:	10Hz – 150Hz sinusoidal
Rate of sweep:	1 octave per minute
RMS acceleration:	1.6m/s ²
Sweep Axis:	3 perpendicular axes separately
Number of sweep cycles:	5 up and down on each axis

The instrument shall then be returned to the chamber in the “stand by” condition and subjected to rapid temperature cycling. Temperature cycling shall be 0°C to 40°C for a period of 16 hours, changing from one temperature to the other every hour, the change to take place in about 30 minutes in each direction. During this temperature cycling, condensation on the instrument is to be avoided.

At the end of this ageing test the instrument shall be returned to room temperature and humidity, and 5 Functional Tests (paragraph B2 above) shall be run. The results of the breath tests shall exhibit an error of no more than $\pm 3\mu\text{g}/100\text{ml}$ for an applied vapour concentration of $35\mu\text{g}/100\text{ml}$ and/or an error of no more than $\pm 2\mu\text{g}/100\text{ml}$ for an applied vapour concentration of $9\mu\text{g}/100\text{ml}$.

- (b) This test is the same as B7.1 (a), with the following exceptions:

- The RMS for the vibration test shall be 9.8m/s²

- The rapid temperature cycling should take place for a period of 36 hours
- The temperature cycling shall take place over 10 minutes in each direction

B8 Environmental Tests (Mobile Instruments only)

B8.1 Damp Heat (Cyclic) This test is set out in BS EN 60068-2-30:2005 - Environmental testing. Tests. Test Db and guidance: 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 IUT. The test shall be performed with the instrument power OFF.*

- Place the IUT in the test chamber and set to 25°C and 95% RH
- Raise the temperature from 25°C to 55°C over a period of 3 hours whilst maintaining 95% RH.
- Maintain at 55°C and 95% RH for 9 hours
- Reduce temperature from 55°C to 25°C over a period of 3 hours while maintaining 95% RH.
- 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 above) shall then be carried out

B8.2 Storage – Ambient conditions

B9.2.1 Cold Temperature –25°C Duration 2 hours

B9.2.2 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 above) shall be carried out.

B8.3 Shaking

This test is designed to simulate the effects on an instrument of transportation in a vehicle.

Wave shape:	Sinusoidal
Acceleration:	10g ($g = 9.81\text{m/s}^2$)
Duration:	6ms
Frequency:	2Hz
Number of axes:	3 perpendicular
Number of shakes:	100 per axis

The instrument shall be placed in its reference position on the test table.

At the end of the test, a Functional Test (paragraph B2 above) 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. Test methods. 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 0.5 g/m ³	(6.1.4.2)
- air velocity	3m/s 0.3 g/m	(6.1.4.4)

- duration 2 hours (6.1.4.7)

The instrument shall be placed in its reference position in the test chamber. It shall be allowed to stabilise for 1 hour before the conditioning commences. At the end of the conditioning period a Functional Test (paragraph B2 above) shall be performed. The instrument shall not be cleaned prior to this test apart from that necessary to fit a mouthpiece and observe the display.

B8.5 Water Resistance

This test is designed to simulate exposure to rain or spray during transport. It is based on Method Ra1 - Artificial Rain in BS EN 60068-2-18:2001, IEC 60068-2-18:2000 - 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 $\pm$ 5mm/h
Drop Size Distribution	$D_{50} = 1.9 \text{ mm} \pm 0.2\text{mm}$
Duration	10 minutes
Tilt Angle	0°, 30° & 90°

The instrument shall be supplied in a waterproof case. The instrument shall be placed in this waterproof case in the test chamber at the first Tilt Angle. It shall be allowed to stabilise for 1 hour before conditioning commences. At the end of the conditioning period the instrument shall be removed from its case and a Full Functional Test as described in paragraph B4.1 above shall be performed. This cycle of stabilisation, condition and test shall be repeated for each of the Tilt Angles specified.

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

Test Scheme for Instrument Response to Alcohol Vapour Samples

C1 Introduction

This scheme sets out the tests to assess the performance of an Evidential Breath Alcohol Analysis Instrument in accordance with the recommendations of the Organisation Internationale de Métrologie Légale (OIML). It outlines the laboratory tests for analysis of vapour samples containing specified amounts of ethanol, and the error limits associated with each test.

C2 Calibration

The IUT shall be calibrated at the concentration for which type approval is sought. If approval is sought for use at both limits then, unless otherwise stated, the tests set out below shall be carried out with the instrument calibrated at both limits.

C3 Test Method

For these tests the instrument shall be used in Metrological Test Mode to read $0.1\mu\text{g}$ intervals. The standard vapour sample shall be presented to the instrument at a rate of 3 litres in 5 seconds, with an ethanol concentration plateau of 3 seconds, at a temperature of $34.0^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$. Unless otherwise stated, the strength of the ethanol vapour sample shall be the same as the statutory limit for which type approval is being sought. If approval is sought at more than one limit, the instrument shall be tested at both levels below. For the time being the two concentrations that apply in Great Britain are:

- $9\mu\text{g}/100\text{ml}$ (Test Gas 2)
- $35\mu\text{g}/100\text{ml}$ (Test Gas 4)

Both test gases shall contain a carbon dioxide concentration of $5\% \pm 1\%$.

C4 Test Rig

A test rig used to generate vapour samples for laboratory testing of instruments should deliver vapours having ethanol concentrations similar to those that evolve during exhalation of a breath sample. This evolution is characterised by having a plateau on the curve (of ethanol concentration against time) during the last part of the sample, the duration of which is fixed for the test.

C5 Accuracy/Repeatability

C5.1 Test Gases

The accuracy and repeatability shall be verified at the values shown in Table 3. The values for the test gases have been chosen to fit in with the current legislation in Great Britain.

C5.2 Calibration Adjustment

The calibration of the IUT shall be adjusted before the test by one of the following methods:

- 1) The gas used to adjust the calibration of the IUT shall reflect the limit at which approval is being sought. If approval is sought at more than one limit, the IUT shall first be calibrated at $35\mu\text{g}/100\text{ml}$ and the full range of tests carried out. The IUT shall then be calibrated at $9\mu\text{g}/100\text{ml}$ and the tests repeated using Test Gases 1, 2, 3 and 4.

or

- 2) If the design and operation of the instrument allows the calibration adjustment to be carried out at one level, and the instrument demonstrates a linear response across the full measuring range within the applicable error limits in paragraph 6.1 above, it is allowable for the IUT to be calibrated according to the manufacturer's instructions, and one set of tests using the full range of test gases in Table 3 below shall be carried out.

C5.3 Number of Tests

The instrument shall be tested with 20 samples of each of the listed test gases, and the individual results shall be within the error limits indicated for each test gas (paragraph C5.1 above).

Table 3 - Test Gases

Test Gas No	Concentration of ethanol ($\mu\text{g}/100\text{ml}$)($\pm 2\%$)	Max Permissible Error ($\pm\mu\text{g}/100\text{ml}$)
1	0	2.0
2	9	2.0
3	20	2.0
4	35	2.0
5	50	2.0
6	70	3.5
7	105	5.2
8	140	7.0
9	200	10.0

Note: The Maximum Permissible Error (MPE) shall be determined by reference to the actual applied ethanol vapour concentration at the plateau.

C6 Drift

Tests to be carried out to verify compliance with paragraph 6.3.

10 measurements shall be made with the following sample pair:

- (1) No alcohol (Test Gas 1)
- (2) 50 $\mu\text{g}/100\text{ml}$ (Test Gas 5)

The complete schedule shall be repeated after 4 hours (short term drift). The average value of the repeat tests shall not differ by more than 1.5 $\mu\text{g}/100\text{ml}$ from the average value of the original tests.

The tests at 50 $\mu\text{g}/100\text{ml}$ (Test Gas 5) shall be repeated after 2 months (long term drift). The average value of the repeat tests shall not differ by more than 2.0 $\mu\text{g}/100\text{ml}$ from the average value of the original tests.

If approval at more than one limit is sought, this series of tests need only be carried out with the instrument calibrated at 35 $\mu\text{g}/100\text{ml}$.

C7 Hysteresis Test

C7.1 Memory Effect With Large Change in Concentration

The purpose of this test is to check the memory effect of following a high value sample with a lower value sample.

C7.1.1 Tests at 35µg/100ml

For tests at 35µg/100ml this test shall consist of 10 measurements made with a sample of 35µg/100ml (Test Gas 4) followed by 10 pairs of measurements made with 200µg/100ml (Test Gas 9) followed by 35µg/100ml.

The average value of the readings obtained at the lower concentration (35µg/100ml) when testing the pairs shall not differ by more than 2.0µg/100ml from the average value of the readings obtained from the initial analyses of the lower concentration (35µg/100ml).

C7.1.2 Tests at 9µg/100ml

For tests at 9µg/100ml this test shall consist of 10 measurements made with a sample of 9µg/100ml (Test Gas 2) followed by 10 pairs of measurements made with 105µg/100ml (Test Gas 7) followed by 9µg/100ml.

The average value of the readings obtained at the lower value (9µg/100ml) when testing the pairs shall not differ by more than 2.0µg/100ml from the average value of the readings obtained from the initial analyses of the lower value (9µg/100ml).

C7.2 Small Change in Concentration

The purpose of this test is to check that the average of the result obtained from the analysis of the lower of two samples of close concentration has an error of no more than the error for the same sample analysed alone.

C7.2.1 Tests at 35µg/100ml

For tests at 35µg/100ml this test shall consist of 10 samples of 50µg/100ml (Test Gas 5) followed by 5 samples of 35µg/100ml (Test Gas 4).

The error in the average value of the lower sample of 35µg/100ml shall be no more than given in Table 3.

C7.2.2 Tests at 9µg/100ml

For tests at 9µg/100ml this test shall consist of 10 samples of 35µg/100ml (Test Gas 4) followed by 5 samples of 9µg/100ml (Test Gas 2).

The error in the average value of the lower sample of 9µg/100ml shall be no more than given in Table 3.

C8 Effect of Delivered Volume

The test schedule to assess the effect of volume change is as follows:

Sample 1 - 1.5 litres (in 5 seconds, with a 3 second plateau)
followed by

Sample 2 - 4.5 litres (in 15 seconds, with a 6-second plateau).

This schedule shall be repeated 10 times and the individual results shall be within the error limits indicated in Table 3 above.

C9 Effect of Duration of Sample

C9.1 Slow Delivery of Sample With Long Ethanol Concentration Plateau

A sample of 3 litres should be presented to the instrument in 15 seconds with the last 6 seconds being a plateau of the ethanol concentration present in the sample gas.

The test shall be repeated 10 times and the individual results shall be within the error limits indicated in Table 3 above.

C9.2 Standard Delivery of Sample With Short Ethanol Concentration Plateau

A sample of 3 litres should be presented to the instrument in 5 seconds as in paragraph C3 above, but with a plateau of only 1.5 seconds.

The test shall be repeated 10 times and the individual results shall be within the error limits indicated in paragraph Table 3 above.

C10 Effect of Variation in Breath Composition

C10.1 Concentration of Carbon Dioxide

Reference condition: 5% $\pm$ 1%
Extreme values: 3% $\pm$ 1%
10% $\pm$ 1%

A standard test as detailed in paragraph C3 above but with a carbon dioxide concentration at each of the extreme conditions shall be performed. The test shall be repeated 10 times at each concentration of carbon dioxide and the individual results shall be within the error limits indicated in Table 3 above.

C10.2 Concentration of Water Vapour

Reference condition: 4 % $\pm$ 1%
Extreme values: (2% $\pm$ 1 %
6% $\pm$ 1%

A standard test as detailed in paragraph C3 above but with a water vapour concentration at the reference level and each of the extreme conditions shall be performed. The test shall be repeated 10 times at each concentration of water vapour and the individual results shall be within the error limits indicated in Table 3 above.

C11 Effect of Interrupting Sample Flow

C11.1 A sample of the standard test gas of 3 litres in 5 seconds shall be interrupted after 1 second.

C11.2 A sample of slow delivery test gas of 3 litres in 15 seconds shall be interrupted after 6 seconds.

In tests C11.1 & C11.2 the test shall be repeated 10 times. No result shall be recorded and the instrument shall give a suitable message.

C12 Effect of the Presence of Ethanol in the Upper Respiratory Tract

C12.1 Introduction

Alcohol in the mouth or dead space of the upper respiratory tract will contaminate a breath sample resulting in an elevated breath alcohol concentration. A breath sample contaminated in this way is likely to exhibit an initial rapid rise in ethanol concentration, followed by a negative rate of change of ethanol concentration with time.

C12.2 Test Rig

A test shall be carried out which is designed to simulate the effect on the instrument of mouth alcohol or alcohol vapour in a repeatable way. A sample of 3 litres of test gas should be presented to the instrument in 15 seconds. The concentration of ethanol in this test gas shall rise to a maximum of 40µg/100ml in 5 seconds. Thereafter the concentration of the test gas shall drop to 20µg/100ml at a rate of 10µg/100ml per second. No result shall be recorded and the instrument shall give a "Mouth Alcohol" message. This test shall be carried out 10 times.

C12.3 In-Vivo Test

An in-vivo test for Mouth Alcohol shall be carried out to test the ability of an instrument to detect different Mouth Alcohol profiles. This test shall be arranged by the manufacturer or supplier and supervised by the Home Office nominated laboratory.

Six volunteers will be selected, none of whom will have been involved in the type approval of Evidential Breath Alcohol Analysis Instruments, to carry out the test as detailed below.

Prior to the commencement of the tests the volunteers will be given sufficient alcohol to ensure that their breath alcohol concentration is approximately equal to the limit for which approval is sought. If approval is sought at more than one limit, then three volunteers will be given sufficient alcohol to ensure their breath alcohol concentration approximates to 40µg/100ml and a further three volunteers will be given sufficient alcohol to ensure that their breath alcohol level approximates to 15µg/100ml.

All tests are to be carried out using a normal Measuring Cycle as described in paragraph 5.7 above with the instrument in Normal mode (paragraph 4.15 above).

- i. Two background checks of the level of alcohol on the subject's breath will be carried out with an interval of 10 minutes between them. The result of the second check should not exceed that from the first by more than 15%. Background checks shall be repeated at 10 minute intervals until this criterion is met.
- ii. The subject will swill their mouth with either a 2% or a 4% solution of alcohol. The alcohol solution will be spat out, not swallowed. (A total of 5 tests using each solution will be carried out, in a random order as decided by staff from the Home Office nominated laboratory).
- iii. After a three-minute wait, the subject will start another breath test cycle.

If the results from step (ii) are higher than the background alcohol level from step (i) by more than the acceptance criteria (paragraph 5.7.1 above) then a "Mouth Alcohol" message shall be given.

Step (iii) will be repeated until the subject is able to supply 2 specimens of breath into the instrument without registering a "Mouth Alcohol" message. At this point the results of the 2 specimens of breath must not differ by more than the acceptance criteria (paragraph 5.7.1 above) and should be compatible with the background breath alcohol level from step (i).

This sequence of background check, dose and test shall be repeated for each volunteer using the second alcohol solution.

No more than one test sequence at each level shall fail to report a "mouth alcohol" when such a report should be given.

C13 General Instrument Functions.

In addition to the breath analysis requirements (paragraphs C5 to C12 above), checks shall be made on instrument functions to ensure that the instrument performs in accordance with the manufacturer's information.

Annex D

Software Validation & Verification

D1 Introduction

This Appendix sets out the requirements for the validation and verification of the software used to control Evidential Breath Alcohol Analysis Instruments. Instruments 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.

D2 Security

D.2.1 Access Levels

Access to the functions of a Evidential Breath Alcohol Analysis Instrument 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 instruments, an outline of the basic requirements is:

D.2.1.1 Operator

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

D.2.1.2 Police supervisor

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

D.2.1.3 Field Service Engineer

- Run subject tests
- Carry out quality assurance checks
- Print result of last test
- Reset the instrument after over-due quality assurance test
- Print result of all tests in the memory
- Download results to an external data system & clear memory
- Gain access to Metrological Test Mode
- Reset the instrument after over-due service interval
- Open and reseal case
- Reset the instrument
- Re-calibrate the instrument

D.2.1.4 Factory Access

- Unrestricted access

NOTE - After servicing or repair the Instrument must be returned to Normal Mode before it is returned to operational use. It is strongly recommended that this should occur automatically.

D.2.2 Data Protection

All personal data held in an Evidential Breath Alcohol Analysis Instrument 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 an Evidential Breath Alcohol Analysis Instrument may be used to demonstrate to a criminal court that the instrument 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 Evidential Breath Alcohol Analysis Instrument.

D.2.3 Compliance

The software that controls an approved Evidential Breath Alcohol Analysis Instrument shall be identified by a version number. This version number shall appear on all reports generated by the instrument.

The software installed in Evidential Breath Alcohol Analysis Instruments supplied to the police service in the United Kingdom shall be identical to that tested as part of the Type Approval process. This shall be assured by the use of a digital signature.

The software version will form part of the Type Approval Order for a Evidential Breath Alcohol Analysis Instrument. Revision to the software will require a new version number and a new Type Approval Order. The preferred system for changing the software in operational instruments is by replacement of the memory modules containing the program. Manufacturers shall obtain approval from the Home Office nominated laboratory for any alternative procedures.

D3 Validation & Verification by the Manufacturer

Software for Evidential Breath Alcohol Analysis Instruments shall be developed by, or on behalf of, the manufacturer using a quality assurance scheme that is accredited to the ISO 9001 standard. The manufacturer shall provide the Home Office nominated laboratory with:

- Details of the quality assurance procedures that were adopted.
- The results of the validation & verification tests
- A list of the data variables classified as:
 - Jurisdiction specific constants
 - Instrument specific constants
 - Occasional Adjustments
 - Calibration Factors
- The circumstances when the data variables may be changed

The Home Office nominated laboratory will review the information received, and may ask for clarification on specific issues. The Home Office nominated laboratory may use the assessment of the information provided as supporting evidence for its decision on whether to recommend an instrument for type approval.

D4 Software Testing

In addition to the functional testing described in Annex A, B & C the Home Office nominated laboratory may carry out some or all of the following additional tests:

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