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Breath Alcohol Screening Devices

A guide to type-approval procedures for
breath alcohol screening devices used for
law enforcement in Great Britain

THE FORENSIC SCIENCE SERVICE®

Home Office and
Forensic Science Service

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Summary

Breath alcohol testing was introduced into Great Britain in October 1967 with the Road Safety Act 1967. This has been replaced by the Road Traffic Act 1988. Similar provisions covering other modes of transport are included in the Transport and Works Act 1992 and the Railways and Transport Safety Act 2003. All three Acts require Breath Alcohol Screening Devices to be of a type approved by the Secretary of State.

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

This document is written as a Guide for the type-approval procedure to be followed for new Breath Alcohol Screening Devices. Any appropriate technology capable of providing the functionality required in this guide may be used.

Any requirements for goods or materials to comply with this Guide shall be satisfied by compliance with either a British Standard or other named international standard. Alternative approaches that provide an equivalent level of assurance will be accepted (see paragraph 1.6 below).

Electromagnetic Compatibility (EMC)

Devices supplied for evaluation and subsequent use in Great Britain must comply with the mandatory requirements for Electromagnetic Compatibility (EMC) as given in the European Directive 89/336/EEC dated 1989.

In addition, all devices supplied for evaluation and subsequent use by police in Great Britain must comply with FSS Report BAU 03-02.

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

Breath Alcohol Unit
Forensic Science Service
109 Lambeth Road
London SE1 7LP

Guide to Type Approval Procedures for Breath Alcohol Screening Devices

Contents

1 Introduction

1.1 The Organisation Internationale de Métrologie Légale (OIML) has issued International Recommendation R126 that applies to Evidential Breath Testing Instruments and a separate Guide to Type Approval Procedures for Evidential Breath Analysis Instruments[1] based on that recommendation has been published.

1.2 This document applies to devices used as Breath Alcohol Screening Devices that are used in Great Britain for the initial detection of alcohol in breath samples in order to assist the police.

1.3 The type approval procedure consists of a number of technical performance tests that are carried out on devices supplied by the manufacturers or their appointed agents. The performance tests are detailed in Annex A and Annex B below.

1.4 The purpose of this document is to define requirements for the construction of Breath Alcohol Screening Devices, their operation and the means and methods employed in testing them. This document is a guide to manufacturers and their appointed agents but will be updated from time to time to take account of developments and amended versions of this guide will be issued when appropriate.

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

i. ISO 9001-2000 - Quality management systems. Requirements
ii. BS EN ISO/IEC 17025:2000 – General requirements for the competence of testing and calibration laboratories.
iii. BS EN 50081-1:97 - Electromagnetic compatibility. Generic emission standard.
iv. BS EN 50082-1:97 - Electromagnetic compatibility. Generic immunity standard.
v. BS EN 55022:1998, CISPR 22:1997 - Information technology equipment. Radio disturbance characteristics. Limits and methods of measurement
vi. BS EN 60068-1:1995 - Environmental testing. General and guidance.
vii. BS EN 60068-2-30:1999, Environmental testing. Test Db - Damp Heat, Cyclic
viii. BS EN 60068-2-27:1993, Environmental Testing. Test Ea - Shock
ix. BS EN 60068-2-7:1993, Environmental Testing. Test Fc - Vibration (Sinusoidal)
x. EC 89/336/EEC dated 1989, European Council (EC) Directive on Electromagnetic Compatibility (EMC)
xi. EC 95/54/EEC Dated 1995, European Council (EC) Vehicle Directive
xii. FSS-BAU-3/02, EMC Immunity Test Procedures for Breath Alcohol Measuring Devices
xiii. OIML International Document D11, General Requirements for Electronic Measuring Devices (Draft Document - 2003)
xiv. IEC 61000-4-1 (2000-04), Electromagnetic compatibility - Testing and measurement techniques - Overview of IEC 61000-4 series

1.6 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 of the European Community, - or
iii. a relevant technical specification acknowledged for use as a standard by a public authority of any Member State of the European Community, - or
iv. traditional procedures of manufacture of a Member State of the European Community where these are the subject of a written technical description sufficiently detailed to permit assessment of the goods or materials for the use specified, - or

1. A Guide to Type Approval Procedures for Evidential Breath Testing Instruments.

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 or specification) and which fulfil the purpose provided by the specified standard,

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

2 Type Approval Procedure

2.1 A manufacturer, or any person in a position to fulfil the duties regarding type approval (simply referred to as a manufacturer in the rest of the document), should in the first instance make a request in writing to:

Road Crime Section (RCS)
Home Office
50 Queen Anne's Gate
LONDON SW1H 9AT

2.2 Before submission for formal type approval a device will under go user trials by one or more police forces. The Association of Chief Police Officers (ACPO) Road Policing will arrange these trials at the request of Road Crime Section (RCS). User trials will only be arranged if the device is thought to have potential for police use and will be designed to assess the suitability of the device in operational conditions. This assessment may not be required for re-testing of already approved devices that have been modified or updated.

2.3 For devices which satisfy the assessment by police forces, manufacturers shall supply free of charge to the Forensic Science Service (FSS) - the Home Office designated testing laboratory - Breath Alcohol Testing Devices of the type intended for sale, for testing purposes. These devices shall be returned to the manufacturers on completion of the evaluation. The FSS is accredited by the United Kingdom Accreditation Service (UKAS).

2.4 On completion of the type approval testing the manufacturers shall supply free of charge to the Forensic Science Service two devices identical to the final type approved device. These devices will be held by the FSS as exemplar devices, and may be used to test any modifications to the type-approved device, before recommending the proposed change for type approval.

2.5 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 device operator.
ii. A handbook or a set of written instructions for the use of the device supervisor.
iii. A written technical description of the device's operation.
iv. A full circuit diagram with all the circuit components clearly indicated.
v. Details of the internal analytical unit used by the device.
vi. Source and object code for the embedded software.
vii. Details of the test and validation programme that the software has undergone. This system shall be certified to the ISO9001-2000 standard

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

2.7 Laboratory testing of electronic breath screening devices shall comprise two categories. These are Response to Physical Testing (Annex A) and Response to Alcohol Vapour Samples (Annex B). The manufacturers are expected to bear the full costs of the test laboratories evaluation work.

Note - The results of checks and tests carried out by the bodies and laboratories of other countries, including in particular those in conformity with EN ISO/IEC 17025 shall be taken into and suitability for purpose equivalent to the results of tests carried out in the United Kingdom,

and where bodies offer suitable and satisfactory guarantees of technical and professional competence and independence.

2.8 When the assessments at Annex A have been satisfactorily completed and the full report has been issued, the manufacturers shall supply sufficient devices, as specified in paragraph B.2 below, to the Breath Alcohol Unit of the Forensic Science Service.

The assessment made there shall be for the tests involving response to Alcohol Vapour Samples (Annex B below).

2.9 Reports on devices that successfully complete the testing procedure in the two categories set out in paragraph 2.7 above, and the police assessment (where necessary), shall be submitted by the FSS to RCS, Home Office. RCS shall consider obtaining the agreement of the Secretary of State to formal type approval for police use in Great Britain.

2.10 RCS, Home Office 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 device in any way without the agreement of the Secretary of State.
ii. To ensure that the type and serial number of each device is clearly identified by an indelible marking.
iii. To ensure that the serial number is unique to each device.
iv. To ensure that any repair and calibration facility relating to the device is certified to the ISO9001-2000 and open to inspection by the Home Office, any UK Police Force, the FSS or UKAS.
v. To ensure that any update of the operating instructions shall be sent to all users including the Home Office.
vi. To label with a version number of any software or firmware
vii. Deposit documentation detailing the program with the Home Office free of charge. This documentation to include:
    - Source and object code for the software
    - The relevant check sums for the software.
viii. Any changes to the software shall be given a new version number.
ix. To supply free of charge to the Home Office a full circuit diagram of the device with all the circuit components clearly indicated.
x. To supply free of charge to the Forensic Science Service, on behalf of the Home Office two exemplar devices, identical to the type approved device.

This agreement must be signed by the manufacturer prior to the Secretary of State signing the formal type approval document. The Home Office and the Forensic Science Service undertake to keep all information provided confidential in so far as that undertaking does not conflict with any duty of disclosure in a criminal prosecution.

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

2.12 Assistance with police training in respect of the device's operation shall be made available by the manufacturer or his agent.

3 General Requirements

3.1 The device should be designed as far as possible to ensure the safety of both the operator and the user of the device. Particular attention should be made to the design and use of electrical connections as well as the materials chosen for mouthpiece construction.

3.2 The manufacturer shall ensure that when devices are supplied for police use in Great Britain, following initial calibration of new devices or recalibration of factory repaired devices, they meet the requirements of this document.

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

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

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

4 Definitions

4.1 Screening Device

A hand held device designed to detect the presence and measure the concentration of alcohol in 'end expiratory air' (e.g. as determined by measurement of the volume given) and to provide an indication of the level of alcohol in the specimen by means of lights or an alphanumeric display.

4.2 End Expiratory Air

A breath sample containing air from the end of a forced expiration from the lungs.

4.3. Operating Position

The state of the device in which it is able to take and analyse a specimen of breath at the frequency normally expected in service. It shall be clearly apparent when the device is in this state. In this position the device shall meet the metrological requirements of this guide.

4.4. Adjustment or Verification to a Standard

Adjusting or verifying the device using:

(a) a certified standard ethanol/air mixture having a relative humidity of at least 90% and a temperature of 34 ± 0.5°C

or

(b) a certified dry ethanol/air mixture;

providing it can be demonstrated on the device that the results from both (a) and (b) are equivalent.

4.5 Liquid Simulator

A device for producing a standard mixture of gases having a relative humidity of at least 90% and a temperature of 34 ± 0.5°C. This device may comprise a suitably constructed vessel containing an aqueous ethanol solution of known, suitable, concentration maintained at a constant temperature of 34 ± 0.2°C. Air is passed through the solution so as to generate the ethanol/air mixture required for device testing or calibration.

4.6 Gas Simulator

A device for providing a standard mixture of dry gas. This device may comprise a gas cylinder filled with air or an inert gas such as nitrogen containing a known, suitable, concentration of ethanol under pressure to be maintained at ambient temperature, fitted with a suitable dispensing regulator. The simulator gas shall 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.

4.7 Units of Measurement

For devices manufactured for use in Great Britain the concentration of ethanol in the sample shall be expressed in µg/100ml when the device is in test mode. In normal mode the results of measurements may be presented in a form that indicates whether they are above or below the legal limit.

4.8. Normal Mode

In normal mode the device shall be capable of automatically taking a sample of the breath presented to it. The result of measurement of the ethanol content of the sample may be presented in two ways:

- Indicating format where the ethanol content of the sample is presented in the format ZERO, PASS, AIR-FAIL (customer option), WARN, or FAIL either by a system of lights, or characters on an alpha-numeric display.
- Digital format where the ethanol concentration is expressed numerically in µg/100ml.

It shall be permissible for a device to operate in Indicating and Digital mode simultaneously. For devices manufactured for police use in Great Britain it shall not be possible for the display to be converted from indicating format to digital format in normal mode. In normal mode there shall be no provision for manual sampling of the breath specimen.

4.9 Test Mode

In test mode the device shall display the result of a measurement in numerical format and in units of µg/100ml rounded down to integer values. The device shall have provision for manual sampling of the vapour presented to it when conducting calibration adjustment or verification operations as well as metrological tests.

5 General Technical Specification

Breath Alcohol Testing is carried out in Great Britain for the purpose of determining whether or not a subject has a breath alcohol concentration above the legal limit at present in force. Results of these tests are not presented evidentially, but are used to justify further action by the police.

5.1 Measuring Range

Devices shall be capable of measuring Alcohol Concentrations in the range 0 to 200µg/100ml. In normal mode - indicating format devices shall indicate the result in bands corresponding to the states of ZERO, PASS, AIR-FAIL, WARN, or FAIL. The point of change shall be:

- WARN to FAIL - one scale interval above the legal limit for Breath Alcohol Concentration as specified in the Road Traffic Act 1988 (ie 36µg/100ml).
- AIR-FAIL to WARN - around 30µg/100ml.
- PASS to AIR-FAIL - one scale interval above the legal limit for Breath Alcohol Concentration as specified in Part 5 of the Railways and Transport Safety Act 2003 (ie 10µg/100ml).
- ZERO to PASS - around 3µg/100ml

For a temperature range of 0 - 40°C

5.2. Scale Interval

The scale interval for calibration, verification, or metrological testing shall be 1µg/100ml.

5.3 Display

The result of a measurement shall be displayed in digital format with a scale interval of 1µg/100ml and/or in indicating format as ZERO, PASS, AIR FAIL, WARN, or FAIL either by a system of coloured lights or characters on an alpha-numeric display. The alpha-numeric

display may show either the entire word or the appropriate initial letter, the choice being made by the manufacturer.

5.4. Measuring Conditions

5.4.1 The general environmental conditions under which the device shall be capable of use are as follows:

i. ambient temperature 0°C to 40°C
ii. ambient relative humidity (RH) 30% to 90%
iii. atmospheric pressure (AP) 86-106kPa (BS EN60068)

If the manufacturer specifies operating conditions different to those stated the device shall be tested to those conditions.

5.4.2 In normal operation the device shall indicate the breath test result as soon as it has been determined, by the means set out in 5.3 above.

5.4.3 The device shall monitor the continuity of exhalation and the volume passed in order to identify an acceptable specimen for analysis. The device shall give a signal if the acceptable volume is not achieved and shall terminate the sampling at that point, after which the device may reset automatically and indicate readiness to accept a further attempt. Manufacturers may at their discretion set a limit for the number of attempts to provide a specimen for analysis from any one subject.

5.4.4 The device shall indicate when it is ready to accept a breath specimen. Measurement of the alcohol content of a breath specimen shall not be possible when the device is not ready to make a measurement.

5.4.5 When the device is ready to accept a breath specimen a period of not less than 3 minutes or greater than 10 minutes shall be allowed for a satisfactory specimen to be provided after which time the device may automatically switch off.

5.5. Acceptance Limits

The acceptance limits for verification testing (calibration checking) using a calibration standard containing 35µg/100ml alcohol in air (see 5.7) shall be 32.0 - 37.9µg/100ml rounded down to integer values for devices in police use. When a device has been newly calibrated the acceptance limits shall be 34.0 - 36.9µg/100ml rounded down to integer values.

5.6. Return to Zero

The device shall verify that the detector is free of alcohol before indicating that it is ready to accept a specimen of breath. The device shall also verify that all alcohol has been cleared from the detector after a specimen has been analysed before indicating that it is ready to accept a further specimen.

5.7. Adjustment to a Standard (Calibration)

The device shall be calibrated using certified standards with an ethanol concentration of 35 ± 0.5 µg/100ml, from either:

(a) a liquid simulator producing a vapour with a relative humidity of at least 90% at a temperature of 34 ± 0.5°

or

(b) a dry gas mixture

provided that it can be shown on the device that the results from both (a) and (b) are equivalent. This adjustment shall normally be carried out within the temperature range 15 - 35°C, or any other wider range specified by the manufacturer.

5.8. Verification of Adjustment (Calibration Check)

It shall be possible to verify for maintenance and legal metrological control that the device is correctly adjusted. The sample source shall be the same as for adjustment (see 5.7) and the results shall lie between 32.0 and 37.9µg/100ml rounded down to integer values in normal use. If the verification test gives readings outside this range then the device shall be re-calibrated to 35µg/100ml. When the device is newly adjusted the verification results shall lie between 34.0 and 36.9µg/100ml rounded down to integer values.

5.9. Safety and Security

5.9.1 General comments

The device should be designed as far as possible to ensure the safety of both the operator and the user of the device. Particular attention should be made to the design and use of electrical connections as well as the materials chosen for mouthpiece construction.

5.9.2 Hygiene

The device shall be capable of use under satisfactorily hygienic conditions. It shall be possible to change the mouthpiece for each test and the mouthpieces shall be supplied new and individually wrapped.

5.9.3 Electrical Safety

The device shall be capable of operating within the requirements of Electrical Safety legislation

5.9.4 Means of Adjustment

The means by which the device is adjusted shall not be accessible to the routine user of the device.

5.9.5 Mode of Operation Change

The means used to change from the normal mode of operation to another mode of operation shall not be accessible to the routine user of the device.

5.9.6 Memory

Where a long term memory facility is provided the minimum data that must be stored for each test or attempted test shall be:

i. Date & time
ii. Type of test (moving traffic, suspected alcohol, collision)
ii. Result of the test in µg/100ml or an indication that the test was not completed
iii. Any indication given by the device (ie PASS, WARN, FAIL etc)
iv. Was the test an RTA screening test or for some other purpose

Additional information may be stored if requested by users. All memory functions must work properly. If the memory is full the device shall prevent any more tests being carried out until the data has been recovered and the memory cleared. The operator shall be given a warning that the memory is approaching capacity. The contents of the memory shall not be accessible to the routine user of the device.

6 Metrological Characteristics.

6.1 Error Limits

The result of each test made within the normal operating temperature range (paragraph 5.4.1) shall not differ from the expected result by more than ±10%. If the manufacturer specifies a temperature range greater than the normal 0 - 40°C range specified in this guide

the device shall be tested to that range and any readings taken at temperatures outside the normal limits shall not differ from the expected result by more than ±20%.

6.2 Rounding

The device shall determine the result of each test to the nearest 0.1µg/100ml and shall report the result of each test rounded down to the nearest integer when in test mode or normal mode - digital format and the appropriate band when in normal mode - indicating format.

6.3. Repeatability

The results from a repeatability test using a vapour sample having an ethanol concentration 5µg/100ml higher than the legal limit shall be within the required ±10% of the expected value, and shall also indicate FAIL for each sample.

6.4. Periodic Verification / Recalibration

The calibration of the device shall be verified at the intervals accepted by police forces - normally 1 month and no longer than 6 weeks - and shall be recalibrated by a device supervisor if the result of this verification lies outside the limits laid down in paragraph 5.8. If a calibration check is overdue the device shall prevent any more tests being carried out until a calibration check is done. The operator shall be given a warning that the date for a calibration check is approaching. Manufacturers shall recalibrate any device that has been serviced by them before the device is returned to the police.

6.5. Markings

A screening device that conforms to this specification shall be marked legibly with the following: -

- The name of the manufacturer or supplier
- The name of the device and model type
- The serial number of the device
- The version number of the software installed
- The specified legal limits that devices are approved for.

Annex A

Test Scheme for Device Response to Physical Interference

A1 Introduction

This scheme sets out the tests required to assess the performance of a screening device in accordance with the recommendations of the Organisation Internationale de Métrologie Légal (OIML, Draft Document D11) and the requirements of the European Community (EC) directive on Electromagnetic Compatibility 89/336/EEC. It gives laboratory tests for assessing the effects of changes in physical conditions on the performance of screening devices that are self-powered.

> **NOTE -** All electronic equipment for use in Great Britain must comply with the requirements of European Community (EC) EMC Directive 89/336/EEC dated 1989. The tests can be found in the standards BS/EN 50081-1 and BS/EN 50082-1.

A2 Display

For these tests the device shall provide a digital readout of test results rounded down to integer values. The vapour sample to be used for these tests shall be 35μg/100ml ethanol in air and 9μg/100ml ethanol in air. Breath test conditions shall be in accordance with the manufacturer's instructions.

A3 Maximum Error

The result of any breath test performed as part of this scheme shall exhibit an error of no more than ±10% relative to the applied vapour sample, or ±2μg/100ml for an applied 9μg/100ml vapour sample.

A4 Physical Influence Factors

A4.1 Procedure

The effect of each factor shall be determined in turn with all other factors being at their reference level. The effects shall not be combined. In performing the tests in this scheme a full breath test using the standard vapours shall be carried out. Wherever possible, this breath test shall be a normal test that allows all aspects of the normal operation of the device to be verified. Each vapour shall be applied to the device twice for each influence factor. Tests shall be run at the reference point and the extreme points of each condition listed.

A4.2 Ambient Temperature

Reference Condition:	20°C
Extreme Values	0°C and 40°C

The device under test (IUT) shall be placed in the test chamber at the reference temperature and a breath test shall be carried out as described in paragraph A4.1 above. The temperature shall then be reduced to the minimum specified and the IUT allowed to stabilise for at least 3 hours. Steps shall be taken to avoid condensation at the lower temperature. A breath test shall be carried out as specified in paragraph A4.1 above. The temperature shall then be raised to the maximum level 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 breath test shall then be carried out as described in paragraph A4.1 above.

A4.3 Ambient Relative Humidity

Reference condition	Ambient RH in the testing laboratory
Extreme conditions	(a) 30% relative humidity at 5°C
	(b) 90% relative humidity at 40°C

The IUT shall be placed in the test chamber at the reference condition and a breath test shall be carried out as described in paragraph A4.1 above. The humidity and temperature shall

be reduced to the minimum specified. A breath test as described in paragraph A4.1 shall be carried out. The humidity shall then be increased to the maximum specified. The temperature shall be increased to the maximum specified in not less than 1 hour while maintaining the humidity level at maximum. A breath test as described in paragraph A4.1 shall then be carried out.

A4.4 Atmospheric Pressure

Reference condition	101.3kPa
Extreme conditions	86 and 106kPa

The IUT shall be placed in the test chamber and breath tests as described in paragraph A4.1 shall be carried out at the reference and extreme conditions in turn

A4.5 Total Hydrocarbon Content of Atmosphere (as Methane)

Reference condition	2ppm
Extreme condition	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 breath test as described in paragraph A4.1 shall be carried out.

The gas container bag shall then be purged and filled with the extreme level gas (5ppm methane) and a repeat breath test shall be carried out as described in paragraph A4.1. The result shall be compared with the reference atmosphere test.

A5 Physical Disturbance Factors

A5.1 Procedure

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

A5.2 Vibration

This test should be made with reference to BS EN 60068-2 Test Fc - Sinusoidal Vibration.

The device shall be subjected to vibration as follows:

Frequency	10Hz to 150Hz
Sweep rate	1 octave/minute
RMS Acceleration	$9.8 m/s^2$
Axes	3 perpendicular

If any resonant frequencies are observed then a vibrational test shall be carried out at each observed frequency for a period of 30 minutes followed by inspection for obvious damage and a breath test as described in A4.1.

If no resonant frequencies are observed then a vibrational test shall be made consisting of 20 sweeps at the test conditions above, after which the device shall be inspected for obvious damage and a breath test as described in A4.1 shall be carried out.

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

A5.3 Mechanical Shock

This test shall be carried with reference to BS EN 60068-2 Test Ea - 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 the device shall be inspected for obvious damage and a breath test as described in A4.1 shall be carried out.

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

A5.4 Impact

This test shall be carried out with reference to BS EN 60068-2 Test Ea - Shock and is intended to simulate the effect of an impact on a device carried loose in a motor vehicle.

The device shall be subjected to 3 mechanical shocks of 50G severity, 11 milliseconds duration, half sine pulse in each of the 6 directions to give a total of 18 shocks. At the end of the test the device shall be inspected for obvious damage and a breath test as described in A4.1 shall be carried out.

This test shall be carried out with the device in its carrying case.

A5.5 Electrostatic Discharge

This test shall comprise 8kV air discharges both positive and negative from a 150pF capacitor through a 330ohm resistor onto the casing of the device. A total of 10 positive and 10 negative discharges shall be applied separated by at least 10 seconds onto areas of the casing where discharge occurs.

After the test the device shall be inspected for obvious damage and a breath test as described in A4.1 shall be carried out.

A5.6 Immunity to Radiated Electric Fields

This test shall be carried out to meet the requirements of FSS BAU 3-02.

The device shall operate normally throughout the test.

A5.7 Test of Radiated Electric Field Emissions

This test shall be carried our to meet the requirements of EN50081-1 and the European Community requirements on EMC as in European Directive 89/336/EEC in accordance with EN55022. Measurements of radiated emissions from the device shall be made over the frequency range 27 - 1000MHz at a distance of 10m.

A5.8 Storage Ambient Conditions

1)	**Cold**	Temperature	0°C
		Duration	2 Hours
2)	**Hot**	Temperature	+70°C
		Duration	6 Hours

The two conditions shall be tested separately with the device power OFF. The chamber conditions should be such as to inhibit condensation at all times.

After each separate test the device shall be allowed to stabilise at 20°C for 1 hour after which a breath test as described in A4.1 shall be carried out.

A5.9 Damp Heat (Cyclic)

This test is set out in BS EN 60068-2 Test Db - Damp Heat and exposes the device to temperatures of 25°C and 55°C with high humidity. The test is intended to induce condensation on the Device Under Test. The test shall be performed with power OFF and the device out of its carrying case.

i. Place device in test chamber and set to 25°C and 95% RH
ii. Raise temperature from 25°C to 55°C over a period of 3 hours while maintaining 95% RH
iii. Maintain at 55°C and 93% Relative Humidity for 9 hours

iv. Reduce temperature from 55°C to 25°C over a period of 3 hours while maintaining 95% RH
v. Maintain at 25°C and 95% Relative Humidity for 9 hours

The test cycle shall be performed twice after which the device shall be allowed to stabilise at 20°C and ambient RH for 1 hour. A breath test as described in paragraph A4.1 above shall then be carried out.

Annex B

Test Scheme for Device Response to Alcohol Vapour Samples

B1 Introduction

This testing schedule details the laboratory evaluation of a screening device prior to submission to the Home Office for consideration for type approval. The evaluation shall consist of a check to verify that the device conforms to the manufacturer's published specification and a series of tests designed to determine its reaction to rapid and intermittent testing, the operating temperature range, calibration stability, and user acceptability. Materials supplied for use in calibrating the device are also tested for their accuracy and reliability.

B2 Number of Devices

The number of devices required for evaluation is as follows:

(i.) 6 indicating and 10 digital readout devices

or

(ii.) 12 devices which have both indicating and digital readout systems for display of the result

NOTE - Devices approved for police use in Great Britain shall NOT be supplied in a form that allows them to be easily converted from Indicating to Digital format.

B3 Re-evaluation

Devices submitted for re-evaluation following modification shall undergo a reduced programme of tests related to the nature of the modification. If considered appropriate a modified device shall undergo a full assessment.

B4 Test Schedule

B4.1 Rapid Testing

B4.1.1 Higher Limit

The aim of rapid testing of a screening device is to assess the accuracy and repeatability of each individual reading at two different alcohol vapour concentrations; the memory effect arising from tests involving two different, widely separated, concentrations; the hysteresis effect of two different but close concentrations; and the fatigue effect on the detector of a large number of tests separated by a short period of time.

The device shall be tested with the following pairs of alcohol vapours.

i. High Pair
   Sample 1 90µg/100ml BrAC followed by
   Sample 2 35µg/100ml BrAC check sample

ii. Low Pair
   Sample 1 25µg/100ml BrAC followed by
   Sample 2 35µg/100ml BrAC check sample

The test shall consist of 25 pairs of samples at approximately 5 minute intervals to give a total of 50 samples per sequence. Each pair shall be tested twice on separate days to give a grand total of 200 tests over 4 testing days. At the indicated frequency of testing, a check on the calibration of the device is made at approximately 10-minute intervals.

For this test 3 devices shall be used, either 2 indicating and one digital display or 3 combined indicating and digital display together.

NOTE - The check level of 35µg/100ml breath alcohol concentration (BrAC) is the current legal limit for drink drive offences in Great Britain. If this level changes at some time in the future, the vapour concentrations used for this test will change to reflect the new limit.

B4.1.2 Rapid Testing (Lower limit)

The device shall be tested with the following pair of alcohol vapours.

Sample 1 35µg/100ml BrAC followed by
Sample 2 9µg/100ml BrAC check sample

The test shall consist of 25 pairs of samples at approximately 5 minute intervals to give a total of 50 samples per sequence. The pair shall be tested twice on separate days to give a grand total of 100 tests over 2 testing days. At the indicated frequency of testing, a check on the accuracy of the device at the lower level is made at approximately 10-minute intervals.

For this test 3 devices shall be used, either 2 indicating and one digital display or 3 combined indicating and digital display together.

NOTE - The check level of 9µg/100ml breath alcohol concentration (BrAC) is the current legal limit for certain air transport staff in Great Britain. If this level changes at some time in the future, the vapour concentrations used for this test will change to reflect the new limit.

B4.2 Intermittent Testing

Intermittent testing is performed 4 times over a 6 hour period at approximately 2 hour intervals using 3 different devices as detailed in 'Rapid Testing' (see paragraph B.4.1 above), and using the same vapour samples namely a low combination pair and a high combination pair on different days.

A total of 32 tests are performed over 4 testing days for each device. The tests assess the performance of the device under conditions of infrequent use.

B4.3 Repeatability Testing

B4.3.1 Higher Limit

This test consists of a series of 50 tests using an alcohol vapour concentration of 40µg/100ml, and the same devices as used for rapid testing. This is designed to show that an indicating device will record FAIL for all tests and a digital device will record values above the legal limit in the Road Traffic Act 1988 and related legislation for all tests.

B4.3.2 Lower limit

This test consists of a series of 50 tests using an alcohol vapour concentration of 12µg/100ml, and the same devices as used for rapid testing. This is designed to show that an indicating device will record AIR-FAIL for all tests and a digital device will record values above the legal limit in part 5 of the Railways & Transport Safety Act 2003 for all tests.

B4.4 Operating Temperature Testing

B4.4.1 Procedure

This test shall be carried out at a series of temperatures each of which is stable throughout the test. The test samples shall be 35µg/100ml ethanol in air and 9µg/100ml ethanol in air generated from liquid simulators maintained at a temperature of 34 ± 0.2°C.

Five of the digital devices available for testing shall be used and 3 measurements of each vapour strength shall be made with each device for each temperature condition. This gives a total of six results for each temperature condition. The temperature condition is a combination of Calibration Temperature and Operating Temperature.

The test is designed to show that the device will operate correctly within the stated limits for the various calibration and operating temperature conditions.

B4.4.2 Calibration Temperature

The device shall normally be capable of being calibrated between temperatures of +15°C and +35°C. The manufacturer may define a different temperature range for calibration purposes.

For operating temperature testing the device shall be calibrated at the extremes of its range as well as at room temperature (19 - 22°C)

B4.4.3 Operating Temperature

The device shall be capable of operating over the temperature range 0°C to +40°C with an accuracy of ±10% for a 35μg/100ml vapour sample, or ±2μg/100ml for an applied 9μg/100ml vapour sample. The manufacturer may state an extended operating range for the device that shall operate to an accuracy of at least ±20% for a 35μg/100ml vapour sample, or ±2μg/100ml for an applied 9μg/100ml vapour sample over this extended temperature range.

B5 In Vivo Test

An in-vivo test shall be carried out which is designed to test the ability of a device to work with real subjects. The tests shall be arranged by or on behalf of the manufacturer and supervised by the Forensic Science Service.

Three volunteers will be selected, none of whom who will have been involved in the type-approval of Breath Alcohol Screening Devices, to carry out the test as described below.

Prior to the commencement of the test the volunteers will be given sufficient alcohol to ensure that their breath alcohol concentration approximates to 40μg/100ml. Each subject shall be tested on the device under test and then on an approved evidential breath analysis instrument. The results of the two tests shall not differ by more than ±10%. This sequence of tests shall be repeated every 15 minutes until the result on the device under test is less than 20 μg/100ml.

B6 Simulator Supplies

The manufacturer's means of calibration shall be tested.

Any solution for use in a liquid simulator shall be analysed to accurately establish the value of the ethanol in air vapour produced by a liquid simulator maintained at 34±0.2°C.

Any dry gas cylinder shall be checked against a liquid simulator containing a new standard simulator solution.

The device, set to display a digital reading of the result of the test, shall be calibrated using the means provided by the manufacturer and the calibration shall be checked by presenting samples from a liquid simulator containing a new standard solution.

B7 Calibration Stability

Two devices set to record digital results are calibrated using the means of calibration provided by the manufacturer and a 35μg/100ml ethanol in air vapour from a liquid simulator is used to check the calibration. The devices' response to a 35μg/100ml ethanol in moist air vapour are then checked at approximately 2 week intervals for at least 3 months from the date of calibration so as to check the manufacturer's claims regarding calibration stability. On each occasion a total of 5 tests are performed on each device using a new standard solution in the liquid simulator.

B8 General Device Functions

In addition to the breath analysis requirements, checks shall be made on general device functions to ensure that the device performs in accordance with the manufacturer's information.