BRITISH STANDARD

BS EN
12470-5:2003

# Clinical thermometers —

## Part 5: Performance of infra-red ear thermometers (with maximum device)

The European Standard EN 12470-5:2003 has the status of a British Standard

ICS 17.200.20



BSI
British Standards

# National foreword

This British Standard is the official English language version of EN 12470-5:2003.

The UK participation in its preparation was entrusted by Technical Committee LBI/36, Laboratory glassware and related apparatus, to Subcommittee Thermometers, LBI/36/3 which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

**Cross-references**

The British Standards which implement international or European publications referred to in this document may be found in the BSI Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Search" facility of the *BSI Electronic Catalogue* or of British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

**Compliance with a British Standard does not of itself confer immunity from legal obligations.**

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 25 April 2003

**Summary of pages**

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 28, an inside back cover and a back cover.

The BSI copyright date displayed in this document indicates when the document was last issued.

**Amendments issued since publication**

| Amd. No. | Date | Comments |
|---|---|---|
| | | |
| | | |
| | | |
| | | |



ISBN 0 580 41677 1

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN 12470-5

April 2003

ICS 17.200.20

English version

# Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device)

Thermomètres médicaux - Partie 5: Performance des thermomètres tympaniques à infrarouges (avec dispositif à maximum)

Medizinische Thermometer - Teil 5: Anforderungen an Infrarot- Ohrthermometer (mit Maximumvorrichtung)

This European Standard was approved by CEN on 27 December 2002.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Management Centre: rue de Stassart, 36 B-1050 Brussels**



Ref. No. EN 12470-5:2003 E

# Contents

page

Foreword ..... 3

1 Scope ..... 4

2 Normative References ..... 4

3 Terms and definitions ..... 4

4 Unit ..... 5

5 Type of thermometers ..... 5

6 Requirements ..... 6
6.1 General ..... 6
6.2 Range of displayed temperature ..... 6
6.3 Maximum permissible error ..... 6
6.4 Environmental requirements ..... 6
6.5 Indicating unit ..... 7
6.6 Construction ..... 8

7 Test Methods ..... 9
7.1 General ..... 9
7.2 Sampling ..... 9
7.3 Testing for compliance of the range of displayed temperature ..... 9
7.4 Testing for compliance of the maximum permissible error within ambient operating range ..... 10
7.5 Testing for compliance of maximum permissible error under extended operating conditions ..... 11
7.6 Testing for compliance of maximum permissible error under changing environmental conditions ..... 12
7.7 Testing for compliance with maximum permissible clinical repeatability - Procedure ..... 13
7.8 Testing for compliance with the effect of storage and long term stability ..... 14
7.9 Method of test for mechanical shock ..... 14
7.10 Testing for compliance with the variation of the supply voltage ..... 14
7.11 Testing for compliance with cleaning and disinfection ..... 15

8 Information supplied by the manufacturer ..... 16
8.1 General ..... 16
8.2 Marking ..... 16
8.3 Instructions for use ..... 16

Annex A (informative) Clinical trial to determine clinical accuracy ..... 18
A.1 Introduction ..... 18
A.2 Clinical accuracy ..... 18
A.3 Clinical trial procedure ..... 18
A.4 Clinical bias and its standard deviation ..... 19
A.5 Clinical repeatability ..... 19

Annex B (informative) Suggested types of testing for the requirements of this standard ..... 21

Annex C (informative) Example for a suitable design of a black body radiator ..... 23

Annex D (informative) Alternative approaches to prove compliance with 6.3 ..... 26
D.1 General ..... 26
D.2 Separation of the maximum permissible error for the instrument and for the probe covers ..... 26
D.3 Calculation of the error using error propagation analysis ..... 26

Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives ..... 27

Bibliography ..... 28

# Foreword

This document (EN 12470-5:2003) has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2003, and conflicting national standards shall be withdrawn at the latest by October 2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

This European Standard applies to clinical thermometers which are used for measuring the body temperature of humans.

EN 12470 consists of the following Parts under the general title “Clinical thermometers”:

Part 1: Metallic liquid-in-glass thermometers with maximum device

Part 2: Phase change-type (dot matrix) thermometers

Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device

Part 4: Performance of electrical thermometers for continuous measurement

Part 5: Performance of infra-red ear thermometers (with maximum device)

Annexes A, B, C, and D are informative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

# 1 Scope

This Part of EN 12470 specifies the metrological and technical requirements for clinical infra-red (IR) ear thermometers with maximum device for intermittent determination of human body temperature.

This European Standard applies to devices that when taking temperatures are powered by a power supply either internal or by mains and that provide an indication of the subject's body temperature through measurement of thermal radiation from all or part of the ear canal.

NOTE Devices designed to measure tympanic membrane temperature only are also covered by this standard.

# 2 Normative References

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 980, *Graphical symbols for use in the labeling of medical devices.*

EN 1041, *Information supplied by the manufacturer with medical devices.*

EN 60601-1, *Medical electrical equipment - Part 1: General requirements for safety (IEC: 60601-1:1988).*

EN 60601-1-2, *Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard - Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2001).*

ISO 2859-2:1985, *Sampling procedures for inspection by attributes - Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection.*

# 3 Terms and definitions

For the purposes of this European Standard the following terms and definitions apply.

**3.1**
**ambient operating range**
ambient temperature and humidity which allows correct operation of an IR ear thermometer

**3.2**
**black body**
reference source of infra-red radiation made in the shape of a cavity and characterized by precisely known temperature of the cavity walls and having effective emissivity at the cavity opening sufficiently near to one

**3.3**
**body temperature**
temperature measured at a human body site, e.g. pulmonary artery, distal œsophagus, urinary bladder, ear canal, oral, rectal or axillary

**3.4**
**clinical accuracy**
ability of an IR ear thermometer to give a reading close to the temperature of the site that it purports to represent as measured by the reference thermometer

**3.5**
**clinical bias**
clinical bias and its standard deviation specifies an average difference between temperatures estimated by the device under test and temperatures of subjects as measured by the reference thermometer

**3.6**
**clinical repeatability**
experimental standard deviation of changes in multiple ear canal temperature readings as taken from the same subject from the same ear with the same IR ear thermometer by the same operator

**3.7**
**contact thermometer**
instrument which is adapted for measuring temperature by means of thermal contact when negligible thermal energy flows between the thermometer and the object of measurement

**3.8**
**infra-red ear thermometer (IR ear thermometer)**
opto-electronic instrument that is capable of non-contact infra-red temperature measurement when applied to the ear canal of a subject

**3.9**
**maximum device**
part or function of the thermometer which stores and indicates the numerical value of the maximum temperature measured

**3.10**
**modes**

**3.10.1**
**ear mode**
mode in which the IR ear thermometer displays the temperature measured from a subject's ear canal. This mode allows for corrections to compensate for variations such as ambient conditions and emissivity

**3.10.2**
**calibration mode**
mode in which an IR ear thermometer displays the temperature measured from a reference black body

**3.10.3**
**estimated mode**
mode in which an IR ear thermometer displays an estimated temperature for a body site other than the ear canal

**3.11**
**probe**
part of an IR ear thermometer that channels net infra-red radiation between the subject and the sensor

**3.12**
**site offset**
numerical value of the difference between a temperature reading in ear mode and in an estimated mode

## 4 Unit

The unit of temperature shall be the degree Celsius, symbol $^{o}$C.

## 5 Type of thermometers

IR ear thermometers determine body temperature of a subject via thermal radiation of the ear canal and/or tympanic membrane.

# 6 Requirements

## 6.1 General

If the IR ear thermometer is designed for use with protective probe covers, the thermometer together with the probe cover (complete thermometer) shall meet the requirements specified in this standard.

## 6.2 Range of displayed temperature

The IR ear thermometer shall cover in all modes the range of displayed temperature from 35,5 °C to 42,0 °C.

NOTE The range of displayed temperature can differ from the measuring range by an instrumental offset.

Testing shall be performed in accordance with 7.3.

## 6.3 Maximum permissible error

### 6.3.1 Maximum permissible error within ambient operating range

The maximum permissible error within ambient operating range as in 6.4.1 and the range of the displayed temperature as in 6.2 shall be ± 0,2 °C.

Testing shall be performed in accordance with 7.4.

### 6.3.2 Maximum permissible error under extended operating conditions

If the IR ear thermometer gives a temperature reading outside the conditions in 6.2 and 6.4.1, the maximum permissible error under those conditions shall be ± 0,3 °C.

Testing shall be performed in accordance with 7.5.

### 6.3.3 Maximum permissible error under changing environmental conditions

The maximum permissible error shall comply with 6.3.1 under changing ambient conditions. If the thermometer is not capable of meeting the accuracy requirements, it shall not provide a temperature reading.

Testing shall be performed in accordance with 7.6.

### 6.3.4 Maximum permissible clinical repeatability

Clinical repeatability shall be determined separately for each device model, every patient age group (new-born, children, and adults) for which the IR ear thermometer is intended to be used including febrile subjects.

Clinical repeatability shall not exceed ± 0,3 °C.

Testing shall be performed in accordance with 7.7.

## 6.4 Environmental requirements

### 6.4.1 Ambient operating conditions

The minimum ambient temperature operating range of the IR ear thermometer shall be from +16 °C to +35 °C and the relative humidity range shall be up to at least 85 % (non-condensing).

Testing shall be performed in accordance with 7.4.

#### 6.4.2 Effects of storage and long term stability

The IR ear thermometer shall meet the requirements specified in 6.3 after having been stored in an environment of -25 °C to +55 °C and a relative humidity up to 85 % (non-condensing) for a period of 28 days.

Testing shall be performed in accordance with 7.8.

#### 6.4.3 Electromagnetic compatibility

The IR ear thermometer shall comply with EN 60601-1-2.

#### 6.4.4 Mechanical shock

IR ear thermometers with a housing of plastic or metal shall comply with 6.3 after testing according to 7.9.

If the IR ear thermometer does not meet the requirement after being subjected to mechanical shock, it shall not provide a temperature reading.

### 6.5 Indicating unit

#### 6.5.1 Digital increment

The digital increment of the indicating unit shall be 0,1 °C or smaller.

Testing shall be performed by visual inspection.

#### 6.5.2 Display

Numerical values on the display shall be at least 4 mm high or optically magnified to appear that height.

Testing shall be performed by visual inspection.

#### 6.5.3 Warning signals

The IR ear thermometer shall provide a visual warning or it shall not provide a temperature reading when one or more of the following are outside the limits specified by the manufacturer:

a) power supply voltage;

b) measuring range;

c) ambient temperature operating range.

Testing shall be performed by visual inspection.

#### 6.5.4 Variations of the voltage supply

For power supply by mains, the indicated temperature shall not show a change for variations from nominal values of ± 10 % for voltage or ± 2 % for frequency.

For power supply by battery or an auxiliary power source, the IR ear thermometer shall provide a recognizable indication or warning signal, or shall not display a temperature reading, when the voltage is outside the limits specified by the manufacturer. If the supply voltage is within these specified limits, the thermometer shall meet the requirements specified in 6.3.

Testing shall be performed in accordance with 7.10.

#### 6.5.5 Modes

An IR ear thermometer shall have an ear mode.

For calibration purposes a calibration mode shall be accessible by either setting the instrument into that mode directly or by a conversion technique from the ear mode.

NOTE 1 This can be identical to the ear mode.

If estimated modes are available, e.g. core, rectal, oral, the displayed values shall be clearly identified as estimates. In addition, the manufacturer shall provide information on clinical accuracy and derivation of these estimates. The information shall include site offsets, clinical bias and its standard deviation.

NOTE 2 See annex A for further information.

Testing shall be performed by visual inspection.

### 6.6 Construction

#### 6.6.1 Material

All materials that can come in contact with the operator or subject shall be free from biological hazards.

NOTE See EN ISO 10993-1 as guidance for the selection of appropriate test methods.

#### 6.6.2 General requirements for safety

The complete IR ear thermometer shall comply with EN 60601-1.

#### 6.6.3 Mechanical

The temperature probe or probe tip, alone or in combination with probe covers, shall be smoothly rounded in order to prevent tissue damage and injury to a subject of any age during use.

Testing shall be performed by visual and tactile inspection.

#### 6.6.4 Cleaning, disinfection and/or sterilization

##### 6.6.4.1 Thermometer

If the manufacturer indicates that the IR ear thermometer can be cleaned, disinfected and/or sterilized, instructions for these processes shall be given.

After cleaning, disinfection and/or sterilization in accordance with the manufacturer’s specification, the IR ear thermometer shall comply with the requirements specified in 6.3 and the marking of the housing shall not be affected.

Testing shall be performed in accordance with 7.11.1.

##### 6.6.4.2 Multiple use probe covers

When the manufacturer indicates that the probe cover is for multiple use, the complete IR ear thermometer shall meet the requirements specified in 6.3 after it has been subjected to the cleaning, disinfection and/or sterilization procedure as specified by the manufacturer.

Testing shall be performed in accordance with 7.11.2.

#### 6.6.5 Probe covers

If a probe cover is required by the manufacturer, it shall maintain its physical integrity while being placed on the probe or probe tip, and during temperature measurement to ensure a sanitary barrier between a subject and the probe or probe tip.

If a probe cover is required by the manufacturer, the IR ear thermometer shall either not display a temperature reading when it is used without a probe cover or shall contain appropriate information on the display that a new probe cover shall be used prior to the next measurement.

The probe cover and the thermometer shall comply with the requirements specified in 6.3 when tested in accordance with 7.4.

#### 6.6.6 Functional safety test

The IR ear thermometer shall have an automatic self-test sequence. The correct operation shall be indicated by an appropriate display.

The manufacturer shall provide information as to how the self-test sequence operates.

Testing shall be performed by visual inspection.

## 7 Test Methods

### 7.1 General

Laboratory accuracy of a particular type or model of an IR ear thermometer (with the specified probe covers if applicable) shall be tested in ear mode or, if available, in calibration mode on samples selected in accordance with 7.2 to verify compliance with the requirements specified in 6.3.

### 7.2 Sampling

Each individual lot of IR ear thermometers and probe covers shall be subjected to testing, either individual or statistical. For statistical testing the lot shall be homogenous and the mixing of the thermometers or probe covers from various sources is not allowed.

The sampling plan shall correspond to ISO 2859-2:1985, level II with a limiting quality level LQ=5 %.

NOTE 1 Other sampling plans can be used if they are statistically equivalent.

NOTE 2 For suggested types of testing see annex B.

### 7.3 Testing for compliance of the range of displayed temperature

#### 7.3.1 Apparatus

##### 7.3.1.1 Black body radiator

Under laboratory conditions, the IR ear thermometer under test shall be tested against a black body radiator whose radiance temperature is calibrated with an uncertainty not greater than 0,07 °C (coverage factor k=2). The calibration shall be performed by either a national metrological institute or by a calibration laboratory competent for radiation thermometric calibrations and shall be traceable to a national measurement standard.

The operating radiance temperature range of the black body radiator shall be sufficient to cover the full radiance temperature range required for laboratory testing in accordance with this standard.

NOTE See annex C for information.

#### 7.3.1.2 Climatic chamber

Climatic chamber, capable of producing the ranges of temperature and humidity given in 7.3, 7.4, 7.5, 7.6 and 7.8.

### 7.3.2 Reference laboratory conditions

The reference laboratory conditions shall be an ambient temperature of (23 ± 5) °C and a relative humidity of (50 ± 20) %.

### 7.3.3 Procedure

Take a reading of the temperature of the black body with the IR ear thermometer under test in accordance with a procedure recommended by the manufacturer for the particular IR ear thermometer under reference laboratory conditions.

Repeat the tests at two black body temperatures, $t_{BB}$ set within ± 0,2 °C of the following temperatures:

a) minimum displayed temperature minus offset as specified by the manufacturer +0,5 °C.

b) maximum displayed temperature minus offset as specified by the manufacturer –0,5 °C.

The temperature reading shall be displayed and the result recorded.

Report the temperature reading and assess the compliance with requirement 6.2.

## 7.4 Testing for compliance of the maximum permissible error within ambient operating range

### 7.4.1 Apparatus

The apparatus described in 7.3.1 shall be used.

### 7.4.2 Procedure

Take a reading of the temperature of the black body with the IR ear thermometer under test in accordance with the procedure recommended by the manufacturer for the particular IR ear thermometer.

Repeat the tests for three black body temperatures approximately equally spaced throughout the range of displayed temperature.

At each black body temperature, repeat the tests under the ambient conditions stated in Table 1.

**Table 1 — Conditions of ambient temperature and humidity for testing an IR ear thermometer with a black body for each of three black body settings**

| Operating Temperature (°C) | Relative Humidity (%) |
|---|---|
| 16 to 18 | less than 50 |
| 16 to 18 | 80 to 85 |
| 24 to 26 | 40 to 60 |
| 33 to 35 | less than 25 |
| 33 to 35 | 80 to 85 |

Prior to the measurements, stabilize the IR ear thermometer at given conditions of ambient temperature and humidity for a minimum of 30 min, or longer if so specified by the manufacturer.

At each combination of operating temperature and humidity in Table 1, take at least 3 readings for each black body temperature, $t_{BB}$. The number of readings shall be the same for all combinations. Use a new disposable probe cover (if applicable) for each test reading.

NOTE If measurements are performed without changing probe covers, the manufacturer should provide measurements on the error of the thermometer and the probe covers separately that confirm that the error of the whole system including randomly selected probe covers complies with 6.3. For information see annex D.

Carry out this procedure in the calibration mode or, if not available, in the ear mode.

If no calibration mode is available, use the correction method to derive unadjusted temperatures from readings in ear mode in accordance with the manufacturer's recommendation, which shall be available from the manufacturer upon request.

The error in an individual reading is:

$$e = \left| t_j - t_{BB} \right| \quad (1)$$

where

$t_j$ is the individual reading of the IR ear thermometer when measuring the black body; and

$t_{BB}$ is the corresponding temperature of the black body.

Assess the compliance of the obtained results for the measurement errors $e$ with requirement 6.3.1.

## 7.5 Testing for compliance of maximum permissible error under extended operating conditions

### 7.5.1 Apparatus

The apparatus described in 7.3.1 shall be used.

### 7.5.2 Procedure

Take a reading of the temperature of the black body with the IR ear thermometer under test in accordance with a procedure recommended by the manufacturer for the particular IR ear thermometer under reference conditions.

Repeat the tests at three black body temperatures, $t_{BB}$ set within ± 0,5 °C at three temperatures approximately equally spaced throughout the indicating range.

At each black body temperature, repeat the tests under the ambient conditions stated in Table 2.

**Table 2 — Conditions of ambient temperature for testing an IR ear thermometer under extended operating conditions**

| Operating temperature[a] (°C) | Relative humidity (%rh) |
|---|---|
| ($t_{max}$ - 1) ± 1 | Less than 30 |
| ($t_{min}$ + 1) ± 1 | Less than 50 |
| ($t_{min}$ + 1) ± 1 | 80 to 85 |
| ($t_{max}$ - 1) ± 1 | 80 to 85 |

[a] $t_{min}$ and $t_{max}$ are the minimum and maximum ambient operating temperatures as specified by the manufacturer.

Prior to the measurements, stabilize the IR ear thermometer at given conditions of ambient temperature and humidity for a minimum of 30 min, or longer if so specified by the manufacturer.

At each combination of operating temperature and humidity in Table 2, take at least 3 measurements for each black body temperature, $t_{BB}$. The number of readings shall be the same for all combinations. Use a new disposable probe cover (if applicable) for each test reading.

Carry out this procedure in the calibration mode or, if not available, in the ear mode.

If no calibration mode is available, use the correction method to derive unadjusted temperatures from readings in ear mode in accordance with the manufacturer's recommendation, which shall be available from the manufacturer upon request.

The individual error is defined as in 7.4.2.

## 7.6 Testing for compliance of maximum permissible error under changing environmental conditions

### 7.6.1 Apparatus

The apparatus described in 7.3.1 shall be used.

### 7.6.2 Procedure

Carry out the tests at one black body temperature, $t_{BB,}$ set to (37 ± 0,5) °C.

After thermal stabilization, take three initial readings in the black body and use the average calculated as the reference value.

Store the IR ear thermometer in a climatic chamber at a temperature (10 ± 0,5) °C above the actual laboratory ambient temperature with a relative humidity within the range of 30 % to 70 %.

After stabilization of the thermometer, remove the thermometer from the climatic chamber and take readings of the black body directly after removal and then 1 min, 2 min, 3 min, 4 min, 5 min, 10 min, 20 min and 30 min after removal. Between the readings store the thermometer on a table at actual ambient conditions.

Carry out this procedure in the calibration mode or, if not available, in the ear mode.

If no calibration mode is available, use the correction method to derive unadjusted temperatures from readings in ear mode in accordance with the manufacturer's recommendation, which shall be available from the manufacturer upon request.

Repeat the above procedure for a climatic chamber temperature of (10 ± 0,5) °C below the actual laboratory ambient temperature.

The requirements of 6.3.3 state that no individual error (see 7.4.2) exceeds the specified limits for the maximum permissible error.

## 7.7 Testing for compliance with maximum permissible clinical repeatability - Procedure

Perform the clinical trial at an ambient temperature of (21 ± 3) °C and a relative humidity of (50 ± 20) %.

Take three consecutive readings of the temperature with the device under test at the same subject at the same ear by the same operator. The time between each reading shall be not less than 1 min and no more than 3 min.

The method of taking temperatures with the device under test shall be in full compliance with the recommendations of their respective manufacturers.

Perform the clinical trial separately on all age groups with which the thermometer is intended for use. The number of subjects of each age group shall be sufficiently large to minimise the effect of random components of measurement error i.e at least 50. The total number of subjects shall be not less than 100. In each age group at least 30 % of the subjects shall be febrile (temperature above 38 °C).

Define age group as follows:

1) new-born up to 1 year;

2) between one year and five years;

3) older than five years.

Calculate the clinical repeatability according to equation 2 below.

The clinical repeatability $\hat{s}_R$ is defined as the average over all subjects of the range of three consecutive measurements on each subject. It can be estimated for each age group separately by:

$$\hat{s}_R = \frac{1}{n}\sum_{i=1}^{n}\hat{s}_{Ri} \tag{2}$$

with

$$\hat{s}_{Ri} = R_{Ri}/q \tag{3}$$

with

$$R_{Ri} = \max(t_{ij}) - \min(t_{ij}) \tag{4}$$

for $j = 1 \ldots I$

where

$\hat{s}_{Ri}$ is the estimated standard deviation of the readings from subject i ;

$n$ is the total number of subjects in the corresponding age group;

$R_{Ri}$ is the span between the maximum read temperature and the minimum read temperature of all taken readings of subject i ;

$I$ is the total number of readings per subject (I = 3);

$q$ is the proportional factor q (I = 3) = 1,65;

$t_{ij}$ is the reading j of subject i.

Assess the compliance of the obtained results for clinical repeatability with the requirement.

## 7.8 Testing for compliance with the effect of storage and long term stability

### 7.8.1 Apparatus

The apparatus described in 7.3.1 shall be used.

### 7.8.2 Procedure

Carry out the test according to EN 600 68-2-14 using the change rate of (1 ± 0,2) °C/min.

Place the thermometers in a climatic chamber and let them undergo the following test cycle:

Lower the temperature to (-25 ± 3) °C. Keep this temperature for 16 h then raise the temperature to (55 ± 2) °C and a relative humidity of 85 % (non-condensing). Maintain this climate for 720 h. Lower the temperature to (-25 ± 3) °C and maintain it for 16 h. Raise the temperature to (25 ± 3) °C. Remove the thermometers from the chamber and keep them at room temperature for at least 24 h.

Testing shall be performed in accordance with 7.4.

## 7.9 Method of test for mechanical shock

### 7.9.1 Apparatus

**7.9.1.1 Apparatus** as described in 7.3.1 shall be used.

**7.9.1.2 Block of hardwood** of density greater than 700 kg/m$^3$ and of suitable size lying flat on a rigid base shall be used.

### 7.9.2 Procedure

Drop the thermometer freely through a vertical distance of 1 m onto a hard surface (7.9.1). Perform this drop once for each of three different orientations of the complete thermometer. One of these directions shall be a drop onto the probe tip of the thermometer.

After performing the drops the thermometer shall be tested in accordance with 7.4.

## 7.10 Testing for compliance with the variation of the supply voltage

### 7.10.1 Power supplied by mains

#### 7.10.1.1 Apparatus

Power supply with a voltage range of at least ± 15 % of the specified supply voltage of the IR ear thermometer and a frequency range of at least ± 3 % of the specified supply frequency of the thermometer.

#### 7.10.1.2 Procedure

When tested in accordance with 7.4 with a supply voltage range of ± 10 % of the specified supply voltage, the thermometer shall comply with 6.3.1. Perform the test at the lower and upper ends of the range of displayed temperature at ambient conditions (see 6.4.1).

When tested in accordance with 7.4 with a supply voltage frequency of ± 2 % of the specified frequency, the thermometer shall comply with 6.3.1. Perform the test at the lower and upper ends of the temperature measuring range at ambient conditions (see 6.4.1).

#### 7.10.2 Voltage supplied by battery or auxiliary power supply

##### 7.10.2.1 Apparatus

Direct current voltage supply.

##### 7.10.2.2 Procedure

Replace the internal power supply by a variable dc voltage supply (7.10.2.1).

Reduce the voltage of the supply until a low battery indication or warning signal is activated or the display is extinguished.

If a power supply other than battery is intended to be used, increase the voltage of the supply until a high battery indication or warning signal is activated or the display is extinguished.

Testing shall be performed in accordance with 7.4 only at ambient temperature and at one black body temperature.

### 7.11 Testing for compliance with cleaning and disinfection

#### 7.11.1 Thermometer

##### 7.11.1.1 Apparatus

Use the apparatus as described in 7.3.1.

##### 7.11.1.2 Cleaning and/or disinfecting fluids

Cleaning and/or disinfecting fluids and tools as specified by the manufacturer

##### 7.11.1.3 Procedure

Carry out the cleaning, disinfection and/or sterilization procedure as specified by the manufacturer at least twenty times.

Test the influence on the marking of the housing by visual inspection.

Test the accuracy of the units in accordance with 7.4 only at ambient temperature and at one black body temperature.

#### 7.11.2 Multiple use probe covers

##### 7.11.2.1 Apparatus

The apparatus described in 7.11.1.1 shall be used.

##### 7.11.2.2 Procedure

Carry out the cleaning, disinfection and/or sterilization procedure as specified by the manufacturer at least the number of reuses specified by the manufacturer but not more than twenty times.

Testing shall be performed in accordance with 7.4.

# 8 Information supplied by the manufacturer

## 8.1 General

Information supplied by the manufacturer shall comply with EN 1041. If symbols are used, they shall be in accordance with EN 980.

## 8.2 Marking

In addition to the marking required by 8.1, the IR ear thermometer shall be marked with at least the following information:

a) whether protective probe covers are required;

b) the symbol "°C" adjacent to the numerical value, if not indicated at the display;

c) body site, i.e., ear;

d) the estimated mode(s) if applicable, e.g. estimated core, estimated rectal, estimated oral, adjacent to the numerical value, if not indicated at the display;

e) year and month of manufacture, and of first calibration if different.

## 8.3 Instructions for use

### 8.3.1 Instructions

The IR ear thermometer shall be accompanied by instructions for use containing at least the following information:

a) reference to this European Standard , including the complete title;

b) installation, operation procedures, and mains voltage, and frequency, if applicable;

c) description of the self testing sequence and other warnings;

d) body site, i.e., ear;

e) use of estimated mode(s), e.g. estimated core, estimated rectal, estimated oral, to adjust displayed temperature to a body site, if applicable;

f) subject categories for each mode, if applicable, e.g. for new-born, for children and for adults. If any subject group is excluded, a clear warning shall be given;

g) precautions with respect to the safety of operators and patients;

h) probe cover usage and specification whether the probe cover is intended for single or multiple use, if applicable. If multiple use is intended, cleaning, disinfection and/or sterilization instructions and criteria for determining when a probe cover should be discarded shall be given;

i) troubleshooting guide;

j) recommended maintenance and frequency of calibration and information on how to obtain these services;

k) instructions and precautions for proper cleaning, disinfection and sterilization, if applicable;

l) disposal of the thermometer;

m) detailed instructions for training in the operation, application and care of the thermometer;

n) list of all offsets and associated algorithm(s) used to calculate the estimated modes and, if possible, the method of switching to calibration mode;

o) variables affecting the clinical accuracy of the device, e.g. mechanical shock.

### 8.3.2 Warnings

The instructions for use shall also include warnings if the performance of the thermometer can be adversely affected should one or more of the following occur:

a) storage outside of the specified temperature and humidity ranges;

b) manufacturer-defined soiled or damaged infra-red optical components;

c) absent, defective, or soiled probe cover, if applicable;

d) use of unspecified probe covers, if applicable;

e) operation outside of the specified ambient operating conditions;

f) operation outside of the specified subject temperature range;

g) mechanical shock. Following mechanical shock, the thermometer should not be used before recalibration.

### 8.3.3 Operating Characteristics

The instructions for use shall also include a section containing operating characteristics with at least the following information:

a) a description of the possible error sources associated with disposable or reusable probe covers, if applicable;

b) a description of possible errors associated with operators' technique, anatomical variations, earwax build-up, subject cooperation, etc.

### 8.3.4 Specifications

The instructions for use shall include a section containing specifications with at least the following information:

a) displayed measuring range;

b) measuring range and ambient operating range;

c) maximum permissible error within specified operating range;

d) storage conditions;

e) values of site offsets used to adjust displayed temperature to a specific body site, if applicable;

f) information on the clinical repeatability

# Annex A
(informative)

# Clinical trial to determine clinical accuracy

## A.1 Introduction

This annex is intended to give information about the procedure to obtain data on the clinical accuracy of the device under test and how to calculate the accuracy information provided in the instruction for use.

## A.2 Clinical accuracy

The clinical accuracy is specified by two characteristics: clinical bias with its standard deviation and the clinical repeatability. Both characteristics can be evaluated from the same data set.

Clinical accuracy should be calculated using statistical methods.

## A.3 Clinical trial procedure

Clinical accuracy should be determined separately for each device model, each adjusted mode, every age group including febrile subjects in all age groups for which the IR ear thermometer is intended for use.

The clinical trial should be performed at an ambient temperature of (21 ± 3) °C and a relative humidity of (50 ± 20) %.

Two types of thermometers should be used in the tests: the IR ear thermometer under test and a non-predictive contact thermometer (the reference thermometer), adapted for measuring temperature from the specified reference body site of the subjects.

For the purpose of determining clinical bias, its standard deviation and clinical repeatability, three consecutive readings of the temperature with the device under test at the same ear and one reading of each subject with the reference thermometer should be taken by the same operator. The time between each reading should be not less than 1 min.

The method of taking temperatures with both the device under test and the reference thermometer should be in full compliance with the recommendations of their respective manufacturers.

Before and after testing, laboratory accuracy of the reference thermometer should be verified in a water bath. The water bath described in C.4 is recommended.

The clinical trial should be performed separately on all age groups with which the thermometer is intended for use. The number of subjects of each age group should be sufficiently large to minimise the effect of random components of measurement error i.e at least 50.The total number of subjects should be not less than 100. In each age group at least 30 % of the subjects should be febrile (temperature above 38 °C).

It is recommended that the age group are defined as follows:

1) new-born up to 1 year;

2) between one year and five years;

3) older than five years.

## A.4 Clinical bias and its standard deviation

The clinical bias $\Delta t_b$ and its standard deviation $s_b$ specify an average difference between temperatures measured by the device under test and temperatures of subjects as measured by the reference thermometer. The clinical bias is a measure for the validity of the site offset built into the device under test as specified in the instruction for use.

The clinical bias $\Delta t_b$ can be calculated for all age groups separately by:

$$\Delta t_b \equiv \frac{1}{n}\sum_{i=1}^{n}\Delta t_{bi}\,, \tag{A1}$$

with

$$\Delta t_{bi} \equiv \frac{1}{3}\sum_{j=1}^{3}\left(t_{ij} - t_{Ri}\right) \tag{A2}$$

where

$\Delta t_{bi}$ is the bias of subject i

$t_{ij}$ is the reading j of subject i

$t_{Ri}$ is the reference reading of subject i

$n$ is the total number of subjects in the corresponding age group

The standard deviation of the clinical bias $s_b$ can be calculated by:

$$s_b = \sqrt{\frac{\sum_{i=1}^{n}\left(\Delta t_{bi}\right)^2 - n\left(\Delta t_b\right)^2}{n-1}} \tag{A3}$$

## A.5 Clinical repeatability

The clinical repeatability $\hat{s}_R$ shows how consistently the device under test measures temperatures from the same subject at the same ear by the same operator. The repeatability test requires taking three consecutive readings from the same patient at the same ear under the same conditions and comparing these readings with each other.

The clinical repeatability is defined as the average over all subjects of the range of three consecutive measurements on each subject. It can be estimated for each age group separately by:

$$\hat{s}_R = \frac{1}{n}\sum_{i=1}^{n}\hat{s}_{Ri} \tag{A4}$$

with

$$\hat{s}_{Ri} = R_{Ri}/q \tag{A5}$$

with

$$R_{Ri} = \max\left(t_{ij}\right) - \min\left(t_{ij}\right) \tag{A6}$$

for $j = 1 \ldots l$

where

$\hat{s}_{Ri}$ is the estimated standard deviation of the readings from subject i

$R_R$ is the span between the maximum read temperature and the minimum read temperature of all taken readings of subject i

$l$ is the total number of readings per subject ($l = 3$)

$q$ proportional factor $q(l = 3) = 1,65$

# Annex B
(informative)

## Suggested types of testing for the requirements of this standard

In order to comply with the requirements of the EU declaration of conformity, thermometers comply with the requirements of either;

a) Annex II or

b) Annex VII coupled with annex IV or annex V or annex VI

of the EU Directive for Medical Devices 93/42/EEC of 14 June 1993.

Annex A informs and recommends on the volume of testing suggested to comply with the requirements of the Medical Device Directive.

The tests described in this standard should be performed as follows:

1) Type A: Tests that should be performed like type examination tests. After initial verification of the corresponding requirements these tests are to be repeated as frequently as required to guarantee a uniform production or product. The tests are to be repeated whenever a relevant design or component change is performed.

   These tests are appropriate where compliance with the requirements of the standard can be demonstrated by investigating a small number (typically 10) of samples of the product.

2) Type B: Tests that show each lot of product complies with the requirements of the standard.

Tests according to Table B.1 should be performed on each sample or according to a statistical sampling plan that complies with the requirements of chapter 6 of Annex IV of the EU Directive for Medical Devices 93/42/EEC.

**Table B.1 — Suggested tests**

| Clauses on the requirements and test methods | Lot by lot testing, Type B[a] |
|---|---|
| 6.2/7.3 | |
| 6.3.1/7.4 | X |
| 6.3.2/7.5 | X |
| 6.3.3/7.6 | X |
| 6.4.1/7.4 | |
| 6.4.2/7.7 | |
| 6.4.3/7.9 | |
| 6.4.4/EN 60601-1-2 | |
| 6.4.5/7.10 | |
| 6.5.1/Visual inspection | |
| 6.5.2/Visual inspection | |
| 6.5.3/Visual inspection | X |
| 6.5.4/7.11 | |
| 6.5.5/Visual inspection | |
| 6.6.1/EN ISO 10993-1 | |
| 6.6.2/EN60601-1 | |
| 6.6.3/Visual inspection | |
| 6.6.4.1/7.12.1 | |
| 6.6.4.2/7.12.2 | |
| 6.6.5/7.4 | |
| 6.6.6/Visual inspection | X |
| 8.2/Visual inspection | X |
| 8.3/Visual inspection | X |
| [a] Type A testing is compulsory for all clauses | |

# Annex C
(informative)

# Example for a suitable design of a black body radiator

**C.1** A suitable design of a black body radiator for the testing according to 7.3, 7.4, and 7.5 is given in this annex. This black body radiator, which is in accordance with the specifications set up in 7.3.1.1 of this standard, is shown in Figure C.1[1)]. The main technical data are depicted in Table C.1. For the purpose of this standard the radiance temperature of the black body radiator is directly given by the reading of a contact thermometer.

**C.2** The cylindrical black body cavity with an inclined but flat bottom and the aperture are made of oxygen-free copper. Their inner surfaces are coated with a diffusely reflecting black paint of spectral emissivity greater than 0,95 in the wavelength range from 8 µm to 15 µm with thickness after drying of around 100 µm. The copper parts are connected to a surface box made of a material having low thermal conductivity, such as polymethyl methacrylate. The black body radiator is immersed into a stirred water bath in such a way that the bottom of the surface box is well below the surface of the water. The box is firmly fixed to the housing of the water bath to prevent the black body radiator from free floating on the surface of the water.

**C.3** The aperture opening of the black body radiator for the insertion of the probe end of the thermometer has a diameter sufficiently small for the snug fitting of the probe end with a probe cover attached (if applicable). For most thermometers a diameter of the opening of 10 mm is suitable. The opening should assure that the probe is properly positioned in the black body radiator when manually inserted.

**C.4** The water bath should have a minimum volume of 3 l, a temperature stability within ±0,02 °C over a period of 1 h and spatial temperature uniformity within ±0,01 °C. The temperature of the water is measured with an uncertainty not greater than 0,03 °C (coverage factor $k$=2) by an immersed contact thermometer (preferably Pt100 type). The contact thermometer calibration is traceable to a national standard of temperature. The contact thermometer should be positioned into the water in close proximity to the black body cavity.

**C.5** For traceability of the radiance temperature of the black body radiator to the temperature standard it is sufficient to calibrate the contact thermometer alone, if the black body radiator is properly built according to this annex. However, to verify its specifications set up in 7.3.1.1 it is recommended to calibrate at least one item of a production batch by a national metrology institute or a certified testing authority.

**C.6** If the black body radiator is operated at such temperatures that humidity from the ambient could precipitate onto its painted inner surface, precautions should be taken to avoid such precipitation. For this purpose it can be sufficient to close the opening of the black body radiator between the measurements.

---

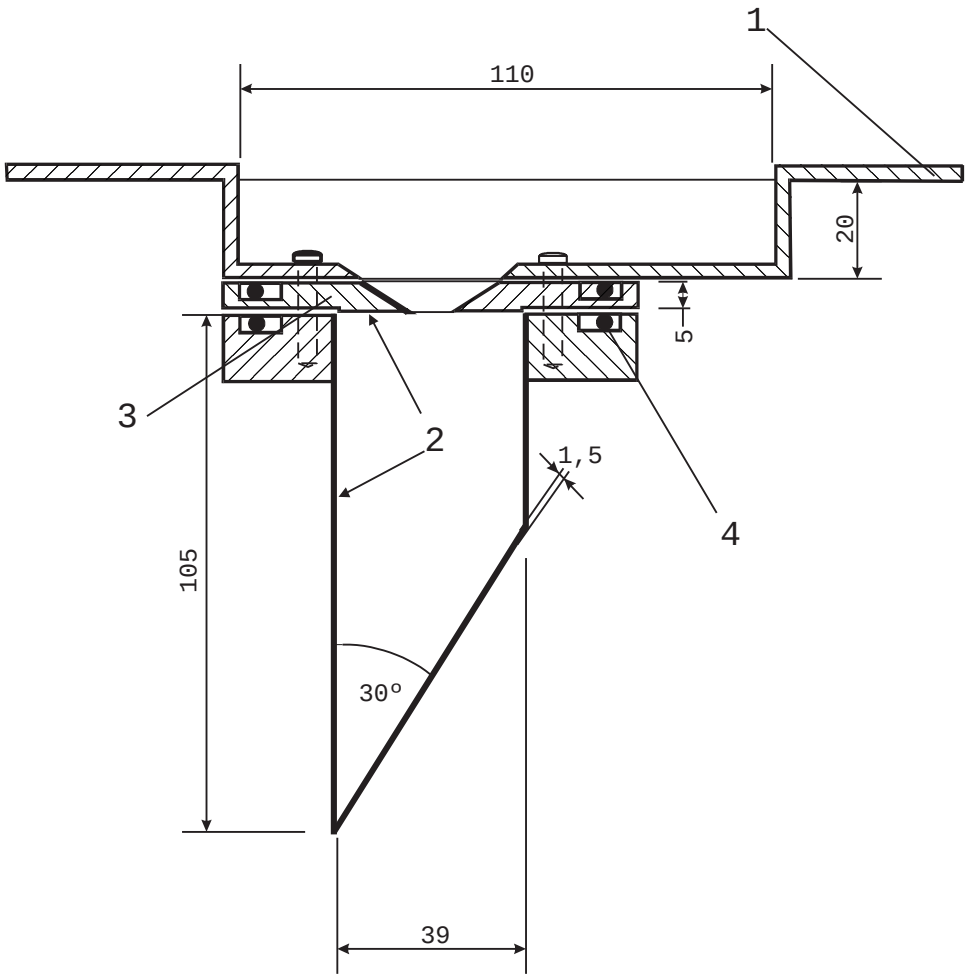
1) Design is based on the development of the Physikalisch-Technische Bundesanstalt (PTB).

**Table C.1 — Main technical data of the black body radiator**

| Property | Dimension/material |
|---|---|
| temperature range | 15 °C to45 °C |
| temperature stability | 0,02 °C |
| length of cavity | 105 mm |
| diameter of cavity | 39 mm |
| bottom shape | flat, 30 ° inclined |
| coating | black paint[a] |
| emissivity of coating | > 0,95 for 8 µm < λ < 15 µm |
| fluid medium | water |

[a] An example of a suitable paint is Nextel velvet-coating 811-21. This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named.

Dimensions in millimetres




**Key**

1 Surface box
2 Black paint
3 Aperture
4 O ring

**Figure C.1 — Example of a black body radiator**

# Annex D
(informative)

# Alternative approaches to prove compliance with 6.3

## D.1 General

The procedure in 7.4.2 describes how compliance with 6.3 can be proved. This procedure requires changing probe covers after each black body reading if applicable. Methods which avoid this disadvantage are conceivable and allowed.

For example the following methods are outlined:

## D.2 Separation of the maximum permissible error for the instrument and for the probe covers

### D.2.1 General

In 6.3 the maximum permissible error of the complete IR ear thermometer, including the probe covers, if applicable, has been established. To prove compliance with this standard, the maximum permissible error can be separated into one component related to the instrument and another component related to the covers. The sum of both components should give the maximum permissible error of 6.3. The distribution of the maximum permissible error to the components for the instrument and for the covers should be determined by the manufacturer.

By proceeding this way, the compliance of the instrument and of the covers should be proved separately. Both parts of this procedure should be fulfilled to prove the compliance of the complete thermometer.

### D.2.2 Compliance of the instrument:

Perform the measurements as stated in 7.4.2 without changing probe covers. The instrument passes the testing if it fulfils the requirements using the relevant component of the maximum permissible error as determined by the manufacturer.

### D.2.3 Compliance of the probe covers:

The method to prove compliance of the covers can be defined by the manufacturer. An applicable procedure is to perform measurements in a black body with a temperature of about 37 °C at reference laboratory conditions 23 °C ± 5 °C using a specially verified instrument. The number of probe covers under test should be determined according to a sampling plan (ISO 2859-2:1985, level II). The probe covers pass the testing if they fulfil the requirements using the relevant component of the maximum permissible error as determined by the manufacturer.

## D.3 Calculation of the error using error propagation analysis

This procedure also permits proving compliance by separating the measurements on the instrument and on the probe covers. This procedure is similar to that described in D.2 and consists of three steps.

**D.3.1** Perform the measurements on the instrument as outlined in D.2.2. Then calculate the error distribution for the instrument on a statistical basis.

**D.3.2** Perform the measurements on the probe covers as outlined in D.2.3. Then calculate the error distribution for the probe covers also on a statistical basis.

**D.3.3** Calculate the convolution integral (cross-correlation) of both error distributions. Determine the width and the centre of the resulting distribution. By comparing these results with the maximum permissible error using the appropriate quality level (ISO 2859-2), compliance with this standard can be shown.

# Annex ZA
(informative)

## Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive for Medical Devices 93/42/EEC.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC:

Compliance with this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

**Table ZA.1 — Correspondence between this European Standard and EU Directives**

| Clause/sub-clause of this European Standard | Corresponding Essential Requirement of Directive 93/42/EEC | Comments |
|---|---|---|
| 4 | 10.3 | |
| 5 | 1; 2; 3 | |
| 6 | 1; 2; 3; 4; 5 | |
| 6.1, 6.2, 6.3 | 10.1 | |
| 6.4 | 5; 9.2 | |
| 6.5.1 | 10.1 | |
| 6.5.2 | 10.2 | |
| 6.5.3, 6.5.4 | 9.2 | |
| 6.5.5 | 10.1 | |
| 6.6.1 | 7.1 | |
| 6.6.2, 6.6.3, 6.6.6 | 9.2 | |
| 6.6.4 | 8.1 | |
| 6.6.5 | 8.1; 10.1; 13.3j | |
| 7 | 1; 2; 3; 4; 5 | |
| 7.2; 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9 | 10.1 | |
| 7.10 | 9.2 | |
| 7.11 | 8.1 | |
| 8 | 10.1; 13 | |

# Bibliography

EN 60068-2-14, *Environmental testing - Part 2: Tests - Test N: Change of temperature (IEC 60068-2-14:1984).*

EN 60601-1-2, *Medical electrical aquipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility; Requirements and tests (IEC 60601-1-2:2001).*

EN ISO 10993-1, *Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997).*

GUM 1993, *Guide to the expression of uncertainty in measurements.*

*blank*

# BSI — British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

**Revisions**

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Tel: +44 (0)20 8996 9000. Fax: +44 (0)20 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

**Buying standards**

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: +44 (0)20 8996 9001. Fax: +44 (0)20 8996 7001. Email: orders@bsi-global.com. Standards are also available from the BSI website at http://www.bsi-global.com.

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

**Information on standards**

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact the Information Centre. Tel: +44 (0)20 8996 7111. Fax: +44 (0)20 8996 7048. Email: info@bsi-global.com.

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration. Tel: +44 (0)20 8996 7002. Fax: +44 (0)20 8996 7001. Email: membership@bsi-global.com.

Information regarding online access to British Standards via British Standards Online can be found at http://www.bsi-global.com/bsonline.

Further information about BSI is available on the BSI website at http://www.bsi-global.com.

**Copyright**



BSI
389 Chiswick High Road
London
W4 4AL