INTERNATIONAL STANDARD

IEC 60601-2-23

Second edition
1999-12

Medical electrical equipment –

Part 2-23:
Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment

Appareils électromédicaux –

Partie 2-23:
Règles particulières de sécurité et performances essentielles des appareils de surveillance de la pression partielle transcutanée

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Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

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International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
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6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-23 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 60601-2-23 cancels and replaces the first edition published in 1993, and constitutes a technical revision. This second edition also covers the scope of IEC 60601-3-1 published in 1996.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/335/FDIS	62D/345/RVD

Full information on the voting for the approval of this Particular Standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

A bilingual version of this standard may be issued at a later date.

Appendix L forms an integral part of this Standard.

Annex AA is for information only.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;

– notes, explanations, advice, instructions, general statements, exceptions and references: in smaller roman type;

– *test specifications: in italic type*;

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 60601-1 OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that this publication remains valid until 2005. At this date, in accordance with the committee's decision, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment

SECTION ONE – GENERAL

The clauses and subclauses of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety, including essential performance, of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT, as defined in 2.101 and hereinafter referred to as EQUIPMENT, whether this EQUIPMENT is stand alone or part of a system.

It applies to transcutaneous monitors used with adults, children and neonates, and it includes the use of these devices in foetal monitoring during birth.

It does not apply to haemoglobin saturation oximeters or to devices applied to surfaces of the body other than the skin (for example conjunctiva, mucosa).

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety, including essential performance, of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 2.101.

1.3 Particular standards

Addition:

This Particular Standard amends and supplements a set of IEC publications consisting of:

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, amendment 1, amendment 2,

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests* and

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems.*

For brevity, IEC 60601-1 is referred to, in this Particular Standard, either as the "General Standard" or as the "General Requirement(s)".

The term "this Standard" covers the Particular Standard used together with the General Standard and any Collateral Standards.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and any additional items *aa), bb),* etc.

Clauses and subclauses for which there is a rationale are marked with an asterisk*. These rationales can be found in an informative annex AA. Annex AA should be used in determining the relevance of the requirements addressed, but should never be used to establish additional test requirements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or Collateral Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or Collateral Standard takes precedence over the corresponding General Requirement(s).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5
APPLIED PART

Replacement:

TRANSDUCER and its connecting lead.

Additional definitions:

2.101
TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT (EQUIPMENT)
device and associated TRANSDUCERS for the monitoring of partial pressures of oxygen and/or carbon dioxide at the skin surface

2.102
TRANSDUCER
device for converting the partial pressure of a gas into a signal for monitoring or recording

2.103
TEMPERATURE LIMITER
means of limiting the temperature of the APPLIED PART INTERFACE

2.104
SET TEMPERATURE
desired applied part interface temperature

2.105
WARNING SIGNAL
means of signalling a predetermined state of a physiological parameter or EQUIPMENT

2.106
APPLIED PART INTERFACE
that portion of the APPLIED PART intended to come into contact with the PATIENT's skin

2.2.102
MULTIFUNCTION PATIENT MONITORING EQUIPMENT
stationary or mobile EQUIPMENT powered by an electrical power source and including one or more physiological monitoring units designed to collect information from a PATIENT, process it and generate ALARMS

2.12.101
ALARM
signal which indicates abnormal events occurring to the PATIENT or EQUIPMENT

2.12.102
PHYSIOLOGICAL ALARM
signal which either indicates that a monitored physiological parameter is out of the specified limits or indicates an abnormal PATIENT condition

2.12.103
TECHNICAL ALARM
signal which indicates that an EQUIPMENT is not capable of accurately monitoring or no longer monitors the PATIENT's condition

2.12.104
SILENCING
stopping an auditory ALARM manifestation by manual action

2.12.105
SILENCING/RESET
stopping a visual and/or auditory ALARM manifestation and re-enabling the equipment response to an abnormal PATIENT condition

2.12.106
INHIBITION
disabling, or SILENCING and disabling, an ALARM until intentionally revoked

2.12.107
SUSPENSION
disabling, or SILENCING and disabling, an ALARM temporarily

2.12.108
LATCHED ALARM
an ALARM, the visual and auditory manifestation of which does not stop when the parameter returns to a value which no longer exceeds the ALARM limit or when the abnormal PATIENT condition does not exist any longer

2.12.109
NON-LATCHED ALARM
an ALARM, the visual and auditory manifestation of which stops when the parameter returns to a value which no longer exceeds the ALARM limit or when the abnormal PATIENT condition does not exist any longer

3 General requirements

This clause of the General Standard applies except as follows:

3.6 SINGLE FAULT CONDITION

Additional item:

aa) Any single failure in the EQUIPMENT resulting in a transfer of energy to the APPLIED PART which is greater than that necessary to maintain the SET TEMPERATURE value.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.11 Sequence

Amendment:

The tests called for in item h) of clause 17 shall be performed prior to the LEAKAGE CURRENT and dielectric strength tests of clauses C.24 and C.25 of the General Standard.

5 Classification

This clause of the General Standard applies except as follows:

***5.2** According to the degree of protection against electric shock:

Amendment:

Delete TYPE B APPLIED PART.

5.6 According to the mode of operation:

Amendment:

Delete all but CONTINUOUS OPERATION.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.8.2 Instructions for use

Additional item:

aa) Supplementary instructions for use

Advice shall be given on the following:

1) Procedures affecting the safety of operation, in particular the temperature selection and duration of monitoring time, on that particular site at that temperature, based upon clinical evaluation of the PATIENT, for example age, weight and physiological condition.

2) Choice of TRANSDUCERS and ACCESSORIES, where the use of other TRANSDUCERS and ACCESSORIES could degrade the safety of the EQUIPMENT.

*3) Use of the EQUIPMENT with high frequency surgical EQUIPMENT, to avoid burns to the PATIENT and damage to the TRANSDUCER, including, if applicable, a statement that the TRANSDUCER shall be removed from the PATIENT during the high frequency surgical procedures.

4) The ACCOMPANYING DOCUMENTS shall contain information on protection against the effects of defibrillation.

5) Those parts of the EQUIPMENT which are protected against the effects of a discharge of a cardiac defibrillator.

6) Any precautions to be taken when a defibrillator is used on a PATIENT and information on any effects of a discharge of a cardiac defibrillator on the EQUIPMENT and the TRANSDUCER.

7) The ACCOMPANYING DOCUMENTS shall contain a statement to the effect: "This EQUIPMENT is not a blood gas device".

*8) For TRANSDUCERS and cables, particularly disposable TRANSDUCERS, the manufacturer shall state the recommended usable safe life.

*9) Proper handling of TRANSDUCERS and their ACCESSORIES to avoid damage to these delicate components, thereby extending their useful life. In addition, these instructions shall refer, in particular, to the TRANSDUCER to cable connection and provide information on the measures that the USER should adopt to prevent damage to this connection.

10) If the EQUIPMENT can be connected to other medical or non-medical EQUIPMENT, this combination shall comply with IEC 60601-1-1.

11) Information on the warm-up time for the TRANSDUCER and EQUIPMENT.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

14 Requirements related to classification

This clause of the General Standard applies except as follows:

*14.6 TYPES B, BF and CF APPLIED PARTS

Replacement:

The APPLIED PART shall be TYPE BF or TYPE CF.

17 Separation

This clause of the General Standard applies except as follows:

Item h)

Addition:

For EQUIPMENT specified as being protected against the effects of a cardiac defibrillator discharge, item h) of the General Standard applies (as does the specified test voltage of 5 kV) with the following addition:

After the test, and following a recovery period of 1 min, the EQUIPMENT shall be capable of meeting all the requirements of this Particular Standard.

20 Dielectric strength

This clause of the General Standard applies except as follows:

*20.2 Requirements for EQUIPMENT with an APPLIED PART

Amendment:

B-b does not apply.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

21 Mechanical strength

This clause of the General Standard applies except as follows:

*21.1 TRANSDUCERS and cables

Re-usable TRANSDUCERS and cables shall be provided with a strain relief at the cable/TRANSDUCER junction, capable of withstanding the tensile forces occurring during NORMAL USE.

After the test, neither the insulation of the cable nor the strain relief shall show any degradation and the TRANSDUCER shall function normally.

Compliance is checked by the following test.

The cable shall be subjected to a suddenly applied load of 5 N in any direction within the conic sectional space having an apex angle of 90°, with the said apex coinciding with the point of exit of the cable from the TRANSDUCER, and limited by a flat plane coinciding with the intended plane of application of the TRANSDUCER to the PATIENT.

The test shall be repeated five times at different angles of the cable from the TRANSDUCER, these angles being chosen at random within the conic section described (see figure 101).

***21.5 Mechanical strength – Free fall**

Addition:

TRANSDUCERS shall not present a SAFETY HAZARD as a result of a free fall from a height of 1 m on to a hard surface.

After the test, and after remembraning and calibration according to the ACCOMPANYING DOCUMENTS, all the thermal and electrical requirements of this Particular Standard shall be satisfied.

Compliance is checked by the following test.

The unpowered sample to be tested is allowed to fall freely once from each of three different starting positions, from a height of 1 m on to a 50 mm thick hardwood board (for example hardwood with a density greater than or equal to 600 kg/m^3), which lies flat on a rigid base (for example a concrete floor).

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard apply except as follows:

***36 Electromagnetic compatibility**

The EQUIPMENT is not a LIFE-SUPPORTING EQUIPMENT as defined in 2.201 of IEC 60601-1-2.

The Collateral Standard IEC 60601-1-2 applies except as follows:

36.201 Emissions

36.201.1.1

Replacement:

The EQUIPMENT shall comply with the requirements of CISPR 11, Group 1, Class A or B depending on intended use.

36.201.1.7

Replacement:

The EQUIPMENT shall be tested with the TRANSDUCER specified by the manufacturer.

The SIGNAL INPUT and SIGNAL OUTPUT cables (if applicable) shall be attached to the EQUIPMENT during the test (see 36.202.2.2a) and figure 104 of this Particular Standard).

36.202 Immunity

Addition to paragraph 4:

The EQUIPMENT shall not change its operating state, shall not lose or change any stored data and, for pO_2 in the range 40 to 100 mm Hg and for pCO_2 in the range 30 to 60 mm Hg, the change in the accuracy of the partial pressure reading shall not exceed ±6 mm Hg.

Compliance is checked by the following test.

– *Set up the EQUIPMENT and TRANSDUCER as outlined in figure 104.*
– *Calibrate the TRANSDUCER according to the ACCOMPANYING DOCUMENTS.*
– *Expose the EQUIPMENT to the specified disturbances (radio frequency, transients, magnetic) at any NOMINAL sensitivity.*

36.202.1 Electrostatic discharge

Replacement of the second sentence:

A level of 6 kV shall apply for contact discharge to conductive ACCESSIBLE PARTS and coupling planes.

Addition:

The EQUIPMENT shall return to its previous operating mode within 1 min, without loss of any stored data.

36.202.2 Radiated radio-frequency electromagnetic fields

36.202.2.1.a)

Replacement:

The EQUIPMENT shall comply with IEC 61000-4-3

36.202.2.1 d)

Replacement:

The IMMUNITY level for this EQUIPMENT shall be 3 V/m.

The EQUIPMENT shall not change its operating state, shall not lose or change any stored data and, for pO_2 in the range 40 to 100 mm Hg and for pCO_2 in the range 30 to 60 mm Hg, the change in the accuracy of the partial pressure reading shall not exceed ±6 mm Hg.

36.202.2.2 a)

Replacement:

The EQUIPMENT shall be exposed to an a.m. r.f. field with 80 % modulation at a frequency of 0,1 Hz.

The TRANSDUCER cable, if longer than 1 m, shall be shortened to 1 m as shown in figure 104. The signal input, signal output cables (if applicable) and the POWER SUPPLY CORD shall be arranged horizontally and vertically from the EQUIPMENT (figure 104).

36.202.3 Transients

Addition:

Immediately following each of the tests of 36.202.3.1 and 36.202.3.2, the EQUIPMENT shall return to its previous operating mode within 30 s, without loss of any stored data.

36.202.5 Conducted disturbances induced by radio frequency fields above 9 kHz

When exposed to conducted electromagnetic fields via the POWER SUPPLY CORD, the EQUIPMENT shall operate within normal specifications.

The test methods and instruments shall be as described in IEC 61000-4-6.

The noise voltage that is injected into the MAINS power input shall be 3 V r.m.s. over the frequency range of 150 kHz to 80 MHz. It shall be modulated at 80 % index at any frequency within the passband of the EQUIPMENT.

36.202.6 Magnetic fields

Additions:

No degradation of performance or loss of functionality shall occur when the EQUIPMENT is exposed to the following magnetic field:

Magnetic field intensity:	3 A/m
Frequency:	SUPPLY MAINS

Compliance is tested by exposing the EQUIPMENT to the specified field on all its faces. The TRANSDUCER and PATIENT lead shall be connected to the EQUIPMENT. During exposure, the EQUIPMENT shall function within the normal limits of this Particular Standard.

NOTE As the EQUIPMENT is unlikely to function without the TRANSDUCER being connected (unless a simulator is used), the TRANSDUCER and distal part of the PATIENT lead may be arranged to extend outside the magnetic field for this test.

***36.202.7 Electrosurgery interference**

No requirement.

SECTION SIX – PROTECTION AGAINST THE HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

42 Excessive temperatures

This clause of the General Standard applies except as follows:

42.3 Temperature of APPLIED PARTS

Additional subclauses:

42.3.101 EQUIPMENT having a heater in the APPLIED PART shall be provided with means for controlling the temperature of the APPLIED PART.

42.3.102 Means shall also be provided for indicating numerically the SET TEMPERATURE (during temperature setting and on request of the OPERATOR).

***42.3.103** The SET TEMPERATURE shall not exceed 45 °C.

Compliance is checked by inspection.

42.3.104 The temperature of the APPLIED PART INTERFACE shall not exceed the SET TEMPERATURE by more than 0,6 °C for more than a total of 20 s, in any period of 30 minutes after the settling period recommended by the manufacturer (see also 42.3.107).

Compliance is checked by measurement of the APPLIED PART INTERFACE temperature.

Procedure:

Plug in the TRANSDUCER; place the TRANSDUCER over the thermocouple in test fixture of figure 102; apply force to compress foam to half thickness; take readings from the thermocouple.

With the TRANSDUCER mounted as in figure 102, the temperature of the APPLIED PART INTERFACE is measured continuously in any 30 minutes in the four hours after energising the EQUIPMENT, taking into account the settling period.

Operation shall be as in the instructions for use, with any recommended contact medium.

42.3.105 EQUIPMENT having a heater in the APPLIED PART shall be provided with a TEMPERATURE LIMITER for the APPLIED PART INTERFACE which cannot be adjusted by the OPERATOR and which functions independently of the normal temperature control means, which, in the SINGLE FAULT CONDITION of 3.6, prevents the temperature of the APPLIED PART INTERFACE from exceeding 45 °C for more than a total of 20 s, with a maximum of 46 °C.

Compliance is checked by inspection for the presence of a TEMPERATURE LIMITER and by introducing a SINGLE FAULT CONDITION as described in 3.6, then by measuring the temperature of the APPLIED PART when mounted as in figure 102. After a stabilization period of 20 min, the SINGLE FAULT CONDITION is introduced and the temperature of the APPLIED PART INTERFACE is measured continuously for a period of 30 min.

For EQUIPMENT having an INTERNAL ELECTRICAL POWER SOURCE, the requirements in subclauses 42.3.101 to 42.3.105 shall be met for any state of discharge of the INTERNAL ELECTRICAL POWER SOURCE.

42.3.106 The OPERATOR shall be made aware of the operation of a TEMPERATURE LIMITER by a visual indication.

Compliance is checked by inspection.

***42.3.107** There shall be a visual indication showing when the temperature of the APPLIED PART INTERFACE exceeds the SET TEMPERATURE by more than 0,6 °C.

Compliance is checked by inspection.

42.5 Guards

Amendment:

Not applicable to any heated stylus or printing element of the EQUIPMENT.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

This clause of the General Standard applies except as follows:

44.3 Spillage

Addition, after the compliance test:

If the EQUIPMENT forms part of a MULTIFUNCTION PATIENT MONITORING EQUIPMENT, it shall not be subjected to the foregoing test, unless the EQUIPMENT or part of the EQUIPMENT is separable whilst remaining functional, in which case the said EQUIPMENT or part of the EQUIPMENT shall be subjected to the above test.

*44.6 Ingress of liquids

Addition:

TRANSDUCERS shall be protected against the ingress of liquids. After the following test, the EQUIPMENT shall function as described in the ACCOMPANYING DOCUMENTS.

Compliance is checked by immersing the TRANSDUCER during normal function for 1 h, with at least 10 cm of its lead wire immersed in water 5 cm deep and having the same temperature as the set temperature ±0,6 °C.

49 Interruption of the power supply

This clause of the General Standard applies except as follows:

49.3 *Replacement*:

a) When the SUPPLY MAINS to the EQUIPMENT in which there is no INTERNAL ELECTRICAL POWER SOURCE is interrupted for less than 30 s and the TRANSDUCER is energised, either

1) the mode of operation and all OPERATOR settings shall not be changed, or

2) the TRANSDUCER shall be de-energised and any indication of partial pressure shall be cancelled.

Compliance is checked by observing the EQUIPMENT operating mode and interrupting the SUPPLY MAINS for a period of 10 to 30 s, any ON-OFF switch on the EQUIPMENT being left in the "ON" position.

b) When the SUPPLY MAINS to the EQUIPMENT in which there is no INTERNAL ELECTRICAL POWER SOURCE is interrupted for more than 30 s and the TRANSDUCER is energised, the TRANSDUCER shall be de-energised and any indication of partial pressure shall be cancelled.

Compliance is checked by test and measurement.

c) When the EQUIPMENT contains an INTERNAL ELECTRICAL POWER SOURCE and the SUPPLY MAINS is interrupted, 49.3 a) and 49.3 b) do not apply. In this case, the EQUIPMENT shall continue operating, and the mode of operation and all OPERATOR settings shall not be changed.

Compliance is checked by test and inspection.

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

The clauses and subclauses of this section of the General Standard apply except as follows:

51 Protection against hazardous output

This clause of the General Standard applies except as follows:

Addition:

*51.5 Non-linearity and hysteresis

For pO_2 in the range 40 to 100 mm Hg, the combined effects of non-linearity and hysteresis for the calibrated EQUIPMENT shall be within ±6 mm Hg or the equivalent in kilopascals.

For pCO_2 in the range 30 to 60 mm Hg, the combined effects of non-linearity and hysteresis for the calibrated EQUIPMENT shall be within ±6 mm Hg or the equivalent in kilopascals.

Table 101 – Required readings and tolerances

Measurements	O_2 concentration	pO_2 reading	CO_2 concentration	pCO_2 reading
1 (test gas 1)	12 ± 0,1 %	x	5 ± 0,1 %	y
2 (test gas 2)	6 ± 0,1 %	$x \cdot \frac{6\,\%}{12\,\%} \pm 6$ mm Hg	10 ± 0,1 %	$y \cdot \frac{10\,\%}{5\,\%} \pm 6$ mm Hg
3 (test gas 1)	12 ± 0,1 %	$x \pm 6$ mm Hg	5 ± 0,1 %	$y \pm 6$ mm Hg
NOTE In the above table, x and y are the actual values of the partial pressure displayed and are in mm Hg.				

The combined effects of non-linearity and hysteresis for the calibrated EQUIPMENT outside the ranges given in the table shall be stated by the manufacturer in the ACCOMPANYING DOCUMENTS.

Compliance is checked in the most common range, at two points, with a mean set temperature of 43 °C.

NOTE For the linearity test, both values should be equally spaced using the zero point of the scale as a reference.

Example of calibration test set:

– calibration test gases;
– gas mix chamber (see figure 103) with means for connecting the test gas bottles and the TRANSDUCER (pO_2, pCO_2 or combinations of both);
– tubing.

Table 102 – Calibration test gases

Test Gases	O_2	CO_2	Remainder
Gas bottle 1	12 ± 0,1 %	5 ± 0,1 %	N_2
Gas bottle 2	6 ± 0,1 %	10 ± 0,1 %	N_2
NOTE The accuracy of the test gases shall be ±0,1 % absolute.			

Procedure:

Calibrate the EQUIPMENT according to the ACCOMPANYING DOCUMENTS.

Set the gas flow in the range 10 to 20 ml/min.

Take one reading each with test gas 1, test gas 2 and test gas 1, allowing a 10 min stabilising period for each test gas.

At each stage, the readings shall be within the figures given in table 101.

The test may be repeated if the readings are unstable and, therefore, inconclusive.

Repeat the same procedure with the pCO_2 sensor.

NOTE In the short period of half an hour, the drift is insignificant and can be neglected.

51.5.1 Drift

The manufacturer shall state the drift per hour for O_2 and CO_2, either from laboratory tests using humidified test gases or as a result of statistically valid data gathered from *in vivo* measurements.

51.5.4 Interfering gases and vapours

The manufacturer shall state any interfering gases or vapours which, when the ACCOMPANYING DOCUMENTS are being prepared, are known to cause deviation outside the range specified.

51.5.5 Response time

The manufacturer shall state, in the accompanying documents, the maximum time required for the EQUIPMENT to display a 10 % to 90 % response to a step change between test gases 1 and 2 in either direction. The test shall be repeated three times.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

*51.8 ALARMS

51.8.1 PHYSIOLOGICAL ALARM device

The monitoring EQUIPMENT shall be provided with at least one auditory and one visual PHYSIOLOGICAL ALARM device.

51.8.2 TECHNICAL ALARM device

The monitoring EQUIPMENT shall be provided with at least one auditory and one visual TECHNICAL ALARM device.

*51.8.3 SUSPENSION or INHIBITION of all PHYSIOLOGICAL ALARMS and TECHNICAL ALARMS

The monitoring EQUIPMENT may be provided with means to SUSPEND or INHIBIT all PHYSIOLOGICAL ALARMS and TECHNICAL ALARMS. The OPERATOR shall be allowed to activate these means in NORMAL USE. The selection (configuration) of the SUSPENSION or INHIBITION functions shall be protected. The ACCOMPANYING DOCUMENTS shall describe the selection procedure.

If the monitoring EQUIPMENT is provided with means to SUSPEND or INHIBIT the PHYSIOLOGICAL ALARMS and the TECHNICAL ALARMS, only one of the SUSPENSION or INHIBITION functions shall be selectable.

The duration of the SUSPENSION may be adjustable but the OPERATOR shall not be able to make the adjustment in NORMAL USE. The duration and/or the adjustment range of the duration shall be specified in the OPERATOR'S MANUAL.

If the SUSPENSION or INHIBITION of ALARMS is activated by the OPERATOR in NORMAL USE, this shall be indicated visually.

Except in the case where isolation of the PATIENT is required, the ALARMS shall only be INHIBITED and SUSPENDED near the PATIENT.

51.8.4 SILENCE/RESET of ALARMS

The monitoring EQUIPMENT shall be equipped with means to SILENCE/RESET ALARMS.

51.8.5 NON-LATCHED ALARMS

The monitoring EQUIPMENT may be equipped with NON-LATCHED ALARMS. In this case, the ALARM is SILENCED and RESET automatically (without any interaction by the OPERATOR) as soon as the monitored parameter comes back within the adjusted limits, or if the abnormal PATIENT condition does not exist any longer.

51.8.6 LATCHED ALARMS

The monitoring EQUIPMENT may be equipped with LATCHED ALARMS. In this case, the ALARM shall be SILENCED and RESET manually by the OPERATOR.

51.8.7 Monitoring EQUIPMENT ALARM delay time

The delay time necessary to transfer the ALARM from the alarming EQUIPMENT to the remote EQUIPMENT shall not exceed 5 s.

The monitoring EQUIPMENT ALARM delay time of remote ALARMS is checked by provoking an ALARM by the local EQUIPMENT and measuring the time delay at the remote EQUIPMENT.

51.8.8 Remote control of INHIBITION and SUSPENSION of ALARMS

If the isolation of the PATIENT is required, at the request of the OPERATOR and on his responsibility, the ALARMS may be SUSPENDED or INHIBITED remotely. The selection (configuration) of remote SUSPENSION or INHIBITION shall be protected. The ACCOMPANYING DOCUMENTS shall describe the selection procedure.

51.8.9 Remote control of SILENCE/RESET

SILENCE/RESET may be remote-controlled.

Additional subclauses:

51.8.101 PHYSIOLOGICAL ALARM

The PHYSIOLOGICAL ALARM limits shall cover the whole measuring range provided by the EQUIPMENT. Software-controlled EQUIPMENT shall have a default function for all PHYSIOLOGICAL ALARMS.

A short power failure, less than 5 s (mains breakdown), shall not change the set alarm limits.

51.8.102 INHIBITION or SUSPENSION of PHYSIOLOGICAL ALARMS

The monitoring EQUIPMENT may be equipped with means to INHIBIT or SUSPEND all PHYSIOLOGICAL ALARMS.

51.8.103 INHIBITION of individual PHYSIOLOGICAL ALARMS

The monitoring EQUIPMENT that monitors more than one physiological parameters may be equipped with means to INHIBIT its individual PHYSIOLOGICAL ALARMS. Such means INHIBIT the auditory and visual manifestations of individual PHYSIOLOGICAL ALARMS. Each INHIBITION status shall be indicated visually and shall identify each INHIBITED physiological parameter.

***51.8.104 SILENCE/RESET of PHYSIOLOGICAL ALARMS**

After SILENCE/RESET, the ALARM device shall RESET automatically if the monitored parameter is within the adjusted limits or if the abnormal PATIENT condition does not exist any longer.

51.8.105 Delay time of PHYSIOLOGICAL ALARMS (triggering delay)

The triggering delay of the PHYSIOLOGICAL ALARM after the parameter value has exceeded an ALARM limit shall not exceed 30 s.

The triggering delay shall be specified in the OPERATOR'S MANUAL.

The delay time shall be checked by simulating an ALARM and measuring the time until the auditory, visual and remote ALARM manifestations are indicated.

51.8.106 Auditory manifestation of PHYSIOLOGICAL ALARMS

The auditory manifestation shall be discontinuous.

After SILENCE/RESET, the auditory manifestation shall disappear.

SILENCE/RESET shall only apply for the PHYSIOLOGICAL ALARM(S) that has(have) been SILENCED/RESET by the OPERATOR (because a more severe PHYSIOLOGICAL ALARM may follow).

The auditory manifestations of PHYSIOLOGICAL ALARMS may be INHIBITED and SUSPENDED.

51.8.107 Visual manifestation of PHYSIOLOGICAL ALARMS

The visual manifestation shall be either continuous or discontinuous.

51.8.108 Visual indication of PHYSIOLOGICAL ALARMS

If the EQUIPMENT is part of a MULTIFUNCTION MONITORING EQUIPMENT and if more than one physiological parameter is monitored, the parameter generating the PHYSIOLOGICAL ALARM shall be indicated visually.

If the EQUIPMENT is provided with means to SUSPEND the visual manifestation of PHYSIOLOGICAL ALARMS, the duration shall be the same as for the auditory ALARM manifestation.

51.8.109 SILENCE/RESET of PHYSIOLOGICAL ALARMS

SILENCE/RESET shall not stop the visual ALARM manifestation as long as the parameter is not within the adjusted limits or if the abnormal PATIENT condition continues.

LATCHED ALARMS:

After SILENCE/RESET, the ALARM device shall reset automatically if the monitored parameter is within the adjusted limits or if the abnormal PATIENT condition does not exist any longer.

NON-LATCHED ALARMS:

The auditory and visual ALARM device shall reset automatically with or without SILENCE/RESET if the monitored parameter is within the adjusted limits or if the abnormal PATIENT condition does not exist any longer.

***51.8.110 INHIBITION and SUSPENSION of PHYSIOLOGICAL ALARMS**

The visual manifestation of PHYSIOLOGICAL ALARMS may be INHIBITED or SUSPENDED.

If the EQUIPMENT is provided with means to INHIBIT or SUSPEND ALARMS, these means shall also INHIBIT or SUSPEND the auditory PHYSIOLOGICAL ALARMS.

***51.8.111 TECHNICAL ALARM**

TECHNICAL ALARMS shall be NON-LATCHED ALARMS.

In the case of a TECHNICAL ALARM, the measured value of the parameter shall be displayed in such a way that the significance of the measured value can be identified by the OPERATOR.

During the TECHNICAL ALARM status, the physiological parameter may not be capable of initiating a PHYSIOLOGICAL ALARM.

51.8.112 Auditory manifestation of TECHNICAL ALARMS

The auditory manifestation shall be either continuous or discontinuous.

The auditory manifestation of a TECHNICAL ALARM shall be indicated as soon as the EQUIPMENT detects the TECHNICAL ALARM condition.

INHIBITION and SUSPENSION shall disable, or SILENCE and disable, the auditory manifestation of TECHNICAL ALARMS.

After SILENCE/RESET the auditory manifestation shall disappear.

SILENCE/RESET shall apply only for the TECHNICAL ALARMS that have been SILENCED/RESET by the OPERATOR.

51.8.113 Visual manifestation of TECHNICAL ALARMS

The visual manifestation shall be either continuous or discontiuous.

The INHIBITION or SUSPENSION of ALARMS shall not disable, or stop and disable, the visual manifestation of TECHNICAL ALARMS.

If an EQUIPMENT can derive more than one TECHNICAL ALARM, the reason for the TECHNICAL ALARM shall be indicated visually.

SILENCE/RESET shall not stop the visual ALARM manifestation as long as the reason for the TECHNICAL ALARM continues.

51.8.114 Connections to remote EQUIPMENT

If the monitoring EQUIPMENT is equipped with interfaces to remote equipment to duplicate ALARMS, the EQUIPMENT shall be so designed that a failure in the remote equipment or network will not affect the correct ALARM function of the ALARM generating EQUIPMENT.

***51.8.115** The EQUIPMENT shall have means to monitor the elapsed time that the TRANSDUCER is applied on the PATIENT's skin (site timer) and to activate an ALARM at the end of the preset time. This protects the PATIENT against burns resulting from exceeding the allowed application time. This ALARM shall be both audible and visible, and shall be a LATCHED ALARM.

51.8.116 The EQUIPMENT shall ALARM if the TRANSDUCER is disconnected from the EQUIPMENT.

The EQUIPMENT should ALARM if the TRANSDUCER loses contact to the PATIENT. These ALARMS shall be at least audible.

Compliance is checked by inspection and testing.

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply except as follows:

52 Abnormal operation and fault conditions

This clause of the General Standard applies except as follows:

52.1 SINGLE FAULT CONDITION

Addition:

IEC 60601-1-4 applies.

Compliance is checked by inspection of the risk management record.

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

The clauses and subclauses of this section of the General Standard apply except as follows:

56 Components and general assembly

This clause of the General Standard applies except as follows:

56.6 Temperature and overload control devices

Addition:

See also 42.3 of this Particular Standard.

56.7 INTERNAL ELECTRICAL POWER SOURCE

EQUIPMENT provided with and driven by an INTERNAL ELECTRICAL POWER SOURCE shall provide an indication, when appropriate, to remind the USER that only a limited monitoring time is available.

Compliance is checked by inspection and testing.

57 MAINS PARTS, components and layout

This clause of the General Standard applies except as follows:

57.3 POWER SUPPLY CORDS

c) *Cross-sectional area of conductors*

Addition:

Note to Table XV: For CLASS II EQUIPMENT with nominal rated currents up to and including 3 A, the cross-sectional area of the conductors of the POWER SUPPLY CORDS shall not be less than 0,5 mm^2.

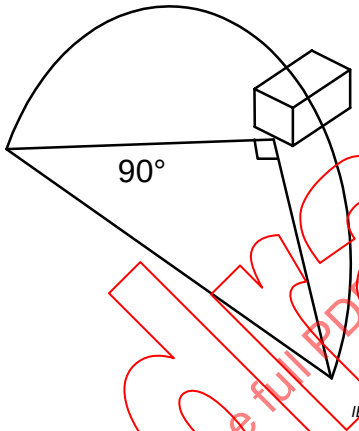


Figure 101 – TRANSDUCER cable strain relief test (see 21.1)

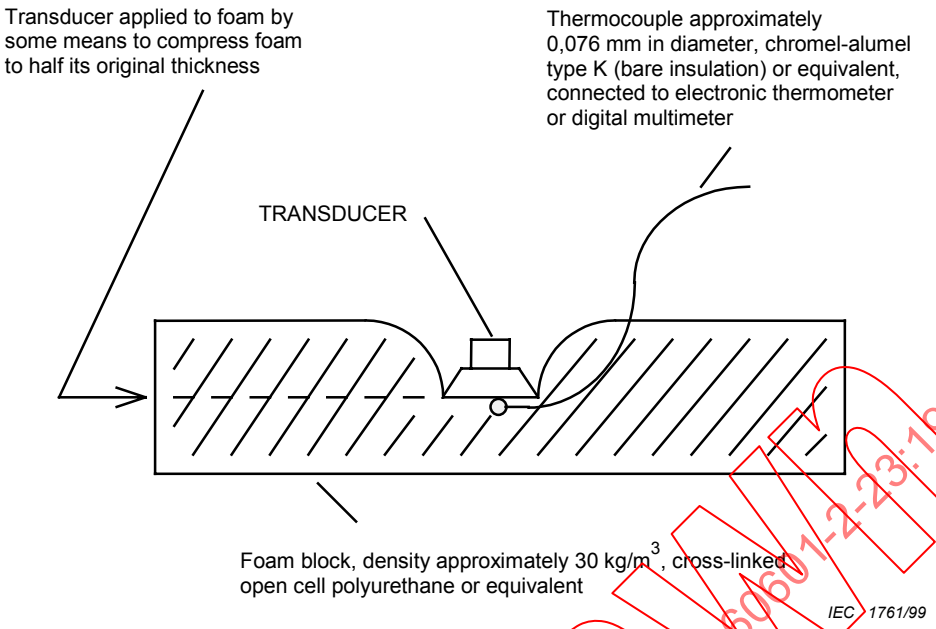
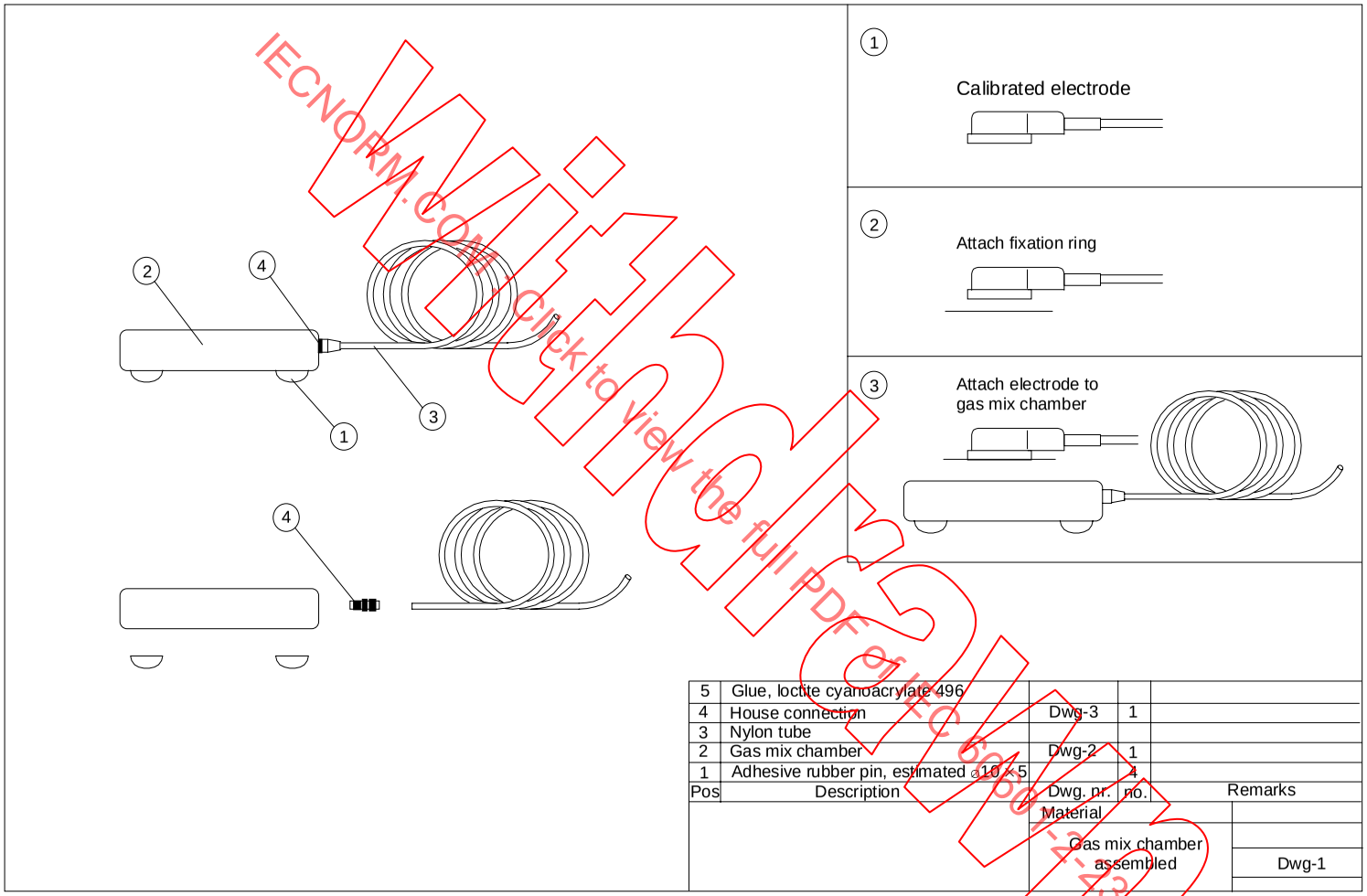


Figure 102 – Foam block test (see 42.3.104 and 42.3.105)

This is a representative test, equivalent methods may be used.

Materials required for the test:

1) Digital thermometer.
2) Chromel-alumel type K thermocouple, reproducible to 0,1 °C. (Measurement uncertainty shall be established and quoted for each EQUIPMENT certification.)
3) Means to apply force to the TRANSDUCER.
4) Foam insulation material.



Pos	Description	Dwg. nr.	no.	Remarks
5	Glue, loctite cyanoacrylate 496			
4	House connection	Dwg-3	1	
3	Nylon tube			
2	Gas mix chamber	Dwg-2	1	
1	Adhesive rubber pin, estimated ⌀10 × 5		4	

Material

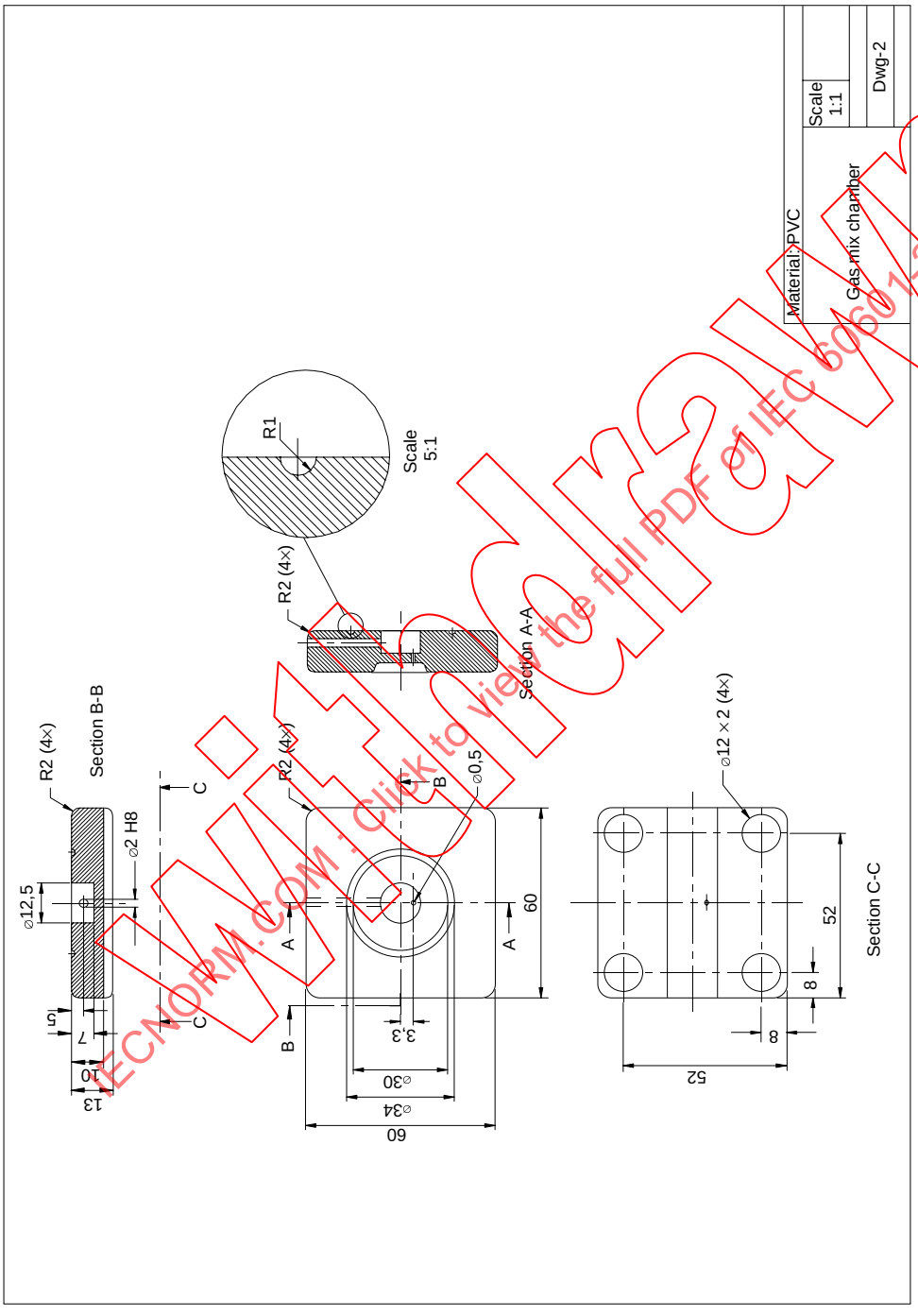
Gas mix chamber assembled

Dwg-1

IEC 1763/99

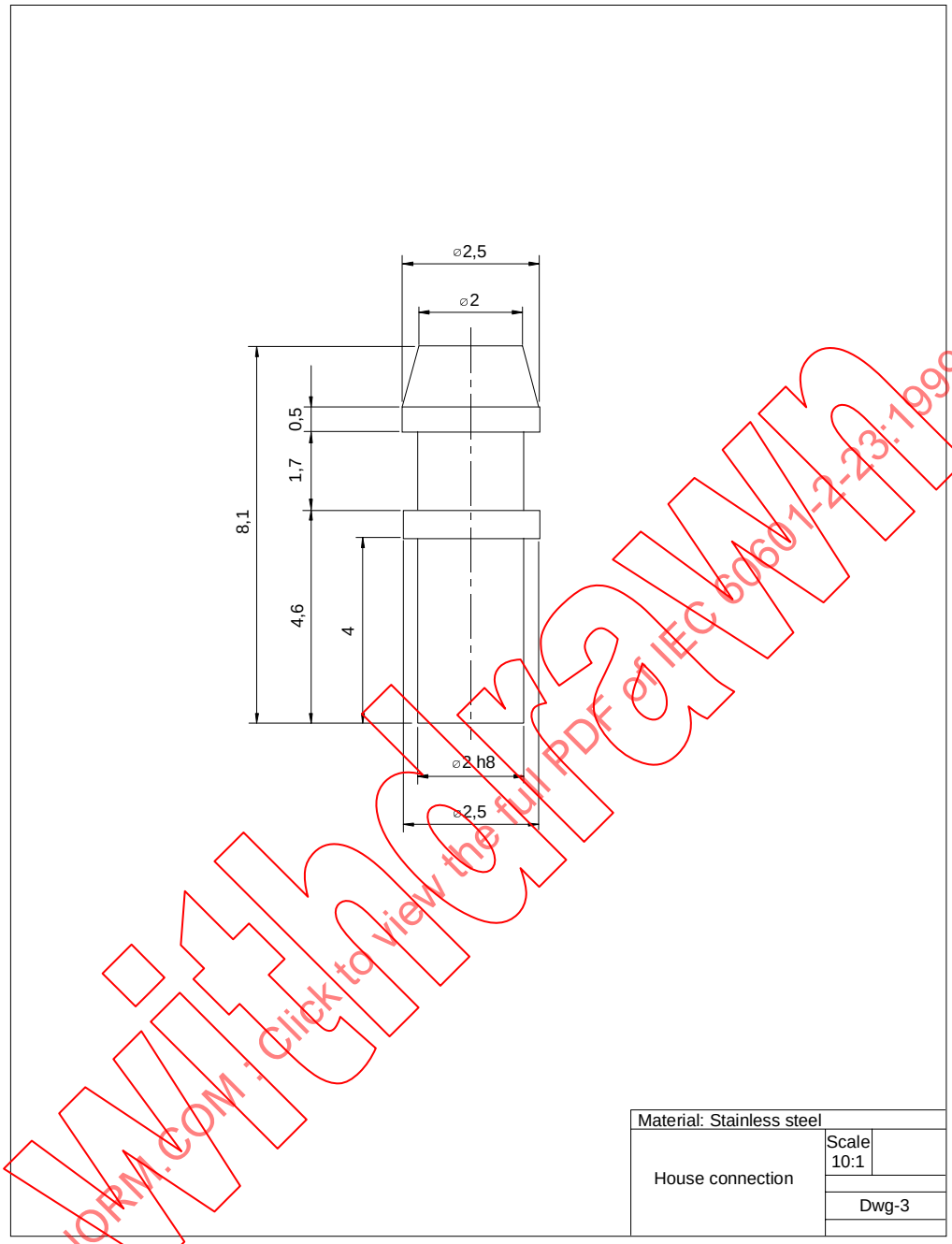
Dimensions in millimetres

Figure 103a – Linearity and hysteresis test set-up – Gas mix chamber, assembled



Dimensions in millimetres

Figure 103b – Linearity and hysteresis test set-up – Gas mix chamber, manufacturing dimensions



Dimensions in millimetres

Figure 103c – Linearity and hysteresis test set-up – Gas mix chamber, dimensions of hose connector