

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-23: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de surveillance de la pression partielle transcutanée



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2011 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de la CEI ou du Comité national de la CEI du pays du demandeur.

Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI de votre pays de résidence.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

- Catalogue of IEC publications: www.iec.ch/searchpub

The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, withdrawn and replaced publications.

- IEC Just Published: www.iec.ch/online_news/justpub

Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

- Electropedia: www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.

- Customer Service Centre: www.iec.ch/webstore/custserv

If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:

Email: csc@iec.ch

Tel.: +41 22 919 02 11

Fax: +41 22 919 03 00

A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

- Catalogue des publications de la CEI: www.iec.ch/searchpub/cur_fut-f.htm

Le Catalogue en-ligne de la CEI vous permet d'effectuer des recherches en utilisant différents critères (numéro de référence, texte, comité d'études,...). Il donne aussi des informations sur les projets et les publications retirées ou remplacées.

- Just Published CEI: www.iec.ch/online_news/justpub

Restez informé sur les nouvelles publications de la CEI. Just Published détaille deux fois par mois les nouvelles publications parues. Disponible en-ligne et aussi par email.

- Electropedia: www.electropedia.org

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International en ligne.

- Service Clients: www.iec.ch/webstore/custserv/custserv_entry-f.htm

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions, visitez le FAQ du Service clients ou contactez-nous:

Email: csc@iec.ch

Tél.: +41 22 919 02 11

Fax: +41 22 919 03 00



IEC 60601-2-23

Edition 3.0 2011-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

**Part 2-23: Particular requirements for the basic safety and essential performance
of transcutaneous partial pressure monitoring equipment**

Appareils électromédicaux –

**Partie 2-23: Exigences particulières pour la sécurité de base et les performances
essentiels des appareils de surveillance de la pression partielle transcutanée**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX



ICS 11.040.55

ISBN 978-2-88912-370-4

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
201.1 Scope, object and related standards	8
201.2 Normative references.....	10
201.3 Terms and definitions.....	10
201.4 General requirements	11
201.5 General requirements for testing of ME EQUIPMENT	11
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	12
201.7 ME EQUIPMENT identification, marking and documents	12
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	13
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	14
201.10 Protection against unwanted and excessive radiation HAZARDS	14
201.11 Protection against excessive temperatures and other HAZARDS	14
201.12 Accuracy of controls and instruments and protection against hazardous outputs	18
201.13 HAZARDOUS SITUATIONS and fault conditions	23
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	23
201.15 Construction of ME EQUIPMENT.....	23
201.16 ME SYSTEMS	23
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	24
202 Electromagnetic compatibility – Requirements and tests	24
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	28
Annexes	34
Annex AA (informative) Particular guidance and rationale.....	35
Annex BB (informative) Alarm diagrams of Clause 208/IEC 60601-1-8:2006	43
Index of defined terms used in this particular standard.....	46
Figure 201.101 – TRANSDUCER cable strain relief test.....	14
Figure 201.102 – Foam block test (see 201.11.1.2.2.104 and 201.11.1.2.2.105)	15
Figure 201.103 – Linearity and hysteresis test set-up – Gas mix chamber, assembled.....	20
Figure 201.104 – Linearity and hysteresis test set-up – Gas mix chamber, manufacturing dimensions	21
Figure 201.105 – Linearity and hysteresis test set-up – Gas mix chamber, dimensions of hose connector	22
Figure 202.101 – Set-up for radiated and conducted EMISSIONS testing according to 202.6.1.1.2 a)	25
Figure 202.102 – Set-up for radiated immunity test according to 202.6.2.3.2	27
Figure BB.1 – NON-LATCHING ALARM SIGNALS without ALARM RESET.....	43
Figure BB.2 – NON-LATCHING ALARM SIGNALS with ALARM RESET	43
Figure BB.3 – LATCHING ALARM SIGNALS with ALARM RESET	44
Figure BB.4 – Two ALARM CONDITIONS with ALARM RESET.....	44

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements	11
Table 201.102 – Required readings and tolerances	19
Table 201.103 – Calibration test gases	19
Table 208.101 – ALARM CONDITION priorities	29
Table 208.102 – Characteristics of the burst of auditory ALARM SIGNALS	30

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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

This third edition cancels and replaces the second edition published in 1999 and constitutes a technical revision. This edition of IEC 60601-2-23 was revised to align structurally with the 2005 edition of IEC 60601-1.

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

FDIS	Report on voting
62D/885/FDIS	62D/907/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 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT. It amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The requirements of this particular standard take priority over those of the general standard.

A “General guidance and rationale” for the more important requirements of this particular standard is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this Standard.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 201.3.63 and hereinafter referred to as ME EQUIPMENT, whether this ME EQUIPMENT is stand alone or part of a system.

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

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

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the General Standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 201.3.63.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

¹ The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2007 and IEC 60601-1-8:2006 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, *except as follows*:

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Addition:

IEC 60601-2-49:2011, *Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, *except as follows*:

201.3.8

APPLIED PART

Addition:

TRANSDUCER and its connecting lead

Replacement:

201.3.63

TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT ME EQUIPMENT

device and associated TRANSDUCERS for the monitoring of partial pressures of oxygen and/or carbon dioxide at the skin surface

Additional definitions:

201.3.201

APPLIED PART INTERFACE

that portion of the APPLIED PART intended to come into contact with the PATIENT'S skin

201.3.202

PATIENT CABLE

insulated wire(s) between the TRANSDUCER and the ME EQUIPMENT

201.3.203

SET TEMPERATURE

desired APPLIED PART INTERFACE temperature

201.3.204

TEMPERATURE LIMITER

means of limiting the temperature of the APPLIED PART INTERFACE

201.3.205**TRANSDUCER**

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

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

SINGLE FAULT CONDITION includes any single failure in the ME EQUIPMENT resulting in a transfer of energy to the APPLIED PART which is greater than that necessary to maintain the SET TEMPERATURE value.

Additional subclause:

201.4.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Non-linearity and hysteresis	201.12.1.101.1
Time to alarm for pO ₂ and pCO ₂ ALARM CONDITIONS	208.6.6.1.103

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.4 Other conditions

Addition:

Unless otherwise stated, tests shall be carried out with the ACCESSORIES and the recording materials specified by the MANUFACTURER.

For ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE, if the test result is affected by the INTERNAL ELECTRICAL POWER SOURCE voltage, then the test shall be performed using the least favourable INTERNAL ELECTRICAL POWER SOURCE voltage specified by the MANUFACTURER. If necessary for the purpose of conducting the test, an external battery or d.c. power supply may be used to provide the necessary test voltage.

The values used in test circuits, unless otherwise specified, shall have at least an accuracy as given below:

- resistors: $\pm 1\%$;
- capacitors: $\pm 10\%$;
- inductors: $\pm 10\%$;
- test voltages: $\pm 1\%$

201.5.8 * Sequence of tests

Amendment:

If applicable, the tests specified in 8.5.5 of the general standard shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests described in subclauses 8.7 and 8.8 of the general standard.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 * Protection against electric shock

Replacement of the last paragraph:

APPLIED PARTS shall be classified as TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS (see 7.2.10 and 8.3 b) of the general standard).

201.6.6 Mode of operation

Replacement:

ME EQUIPMENT shall be classified for CONTINUOUS OPERATION (see.7.2.11).

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 Additional instructions for use

The operating instructions shall include the following:

- a) the INTENDED USE including the environment of use;
- b) 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;
- c) instructions for connecting a POTENTIAL EQUALIZATION CONDUCTOR, if applicable;
- d) the choice and application of the specified TRANSDUCERS and ACCESSORIES;
- e) * use of the ME EQUIPMENT with high frequency surgical ME EQUIPMENT, to avoid burns to the PATIENT and damage to the TRANSDUCER; a statement, if applicable, that the TRANSDUCER is to be removed from the PATIENT during the high frequency surgical procedures;
- f) precautions to take when using a defibrillator on a PATIENT; a description how the discharge of a defibrillator affects the ME EQUIPMENT and the TRANSDUCER; a warning that defibrillator protection requires use of MANUFACTURER specified ACCESSORIES including TRANSDUCERS and PATIENT CABLES, if applicable. The specification (or type-number) of such ACCESSORIES is to be disclosed;
- g) a statement to the effect: "This equipment is not a blood gas device";
- h) * for TRANSDUCERS and cables, particularly disposable TRANSDUCERS, its MANUFACTURER shall state the recommended usable safe life;

- i) * 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 clinical OPERATOR should adopt to prevent damage to this connection;
- j) information on the warm-up time for the TRANSDUCER and ME EQUIPMENT;
- k) the drift per hour for O₂ and CO₂ and recommendations for recalibration;
- l) any interfering gases or vapours that are known to cause deviation outside the range specified;
- m) the maximum time required for the ME EQUIPMENT to display a 10 % to 90 % response to a step change between test gases 1 and 2 in either direction;
- n) advice regarding testing of the ME EQUIPMENT and ACCESSORIES on a daily basis (by the clinical OPERATOR) and on a scheduled basis (as a service activity). Emphasis should be placed on how the clinician may test visual and auditory ALARM SIGNALS;
- o) simple fault finding methods for troubleshooting problems by which the clinical OPERATOR can locate problems if the ME EQUIPMENT appears to be functioning incorrectly;
NOTE This relates to simple operator difficulties, not to technical malfunctions;
- p) the subsequent operation of the ME EQUIPMENT after interruption of SUPPLY MAINS exceeding 30 s (see 201.11.8);
- q) * description of how to disable ALARM SIGNALS for TECHNICAL ALARM CONDITIONS if the TRANSDUCER or module is intentionally disconnected by the clinical OPERATOR;
- r) the configuration procedure that allows the ALARM SIGNAL inactivation states (ALARM PAUSED, AUDIO PAUSED, ALARM OFF or AUDIO OFF) or the function ALARM RESET to be controlled remotely (see 208.6.11.101), if provided;
- s) advice on the preferred ALARM SETTINGS and configurations of the ALARM SYSTEM when its INTENDED USE includes the monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR;

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

Additional subclause:

201.8.101 * TRANSDUCERS and cables

Re-usable TRANSDUCERS and cables shall be provided with 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:

Suddenly apply a load of 5 N to the cable in any direction within the conic sectional space having an apex angle of 90°, with 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.

Repeat this test five times at different angles of the cable from the TRANSDUCER; choose these angles being at random within the conic section (see Figure 201.101).

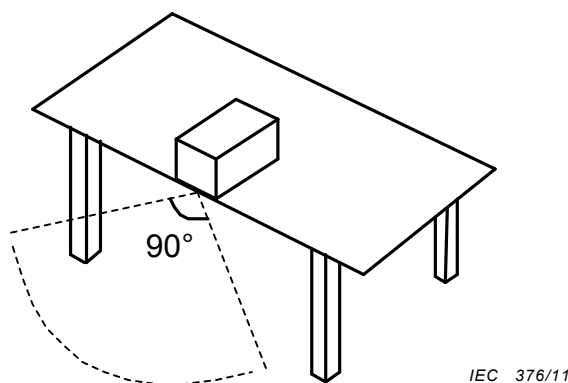


Figure 201.101 – TRANSducer cable strain relief test

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1.2 Temperature of APPLIED PARTS

201.11.1.2.2 * APPLIED PARTS not intended to supply heat to a PATIENT

Replacement for the first sentence:

In NORMAL CONDITION the maximum temperature of the APPLIED PART of the TRANSducer shall not exceed 45 °C. The maximum temperature shall not exceed 45,6 °C for 20 s in any period of 30 min.

NOTE 45,6 °C is the maximum temperature of the APPLIED PART (45°C) plus an allowed overshoot of 0,6 °C.

Addition:

201.11.1.2.2.101 Heater in the APPLIED PART

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

Compliance is checked by inspection.

201.11.1.2.2.102 Indication of SET TEMPERATURE

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

Compliance is checked by inspection.

201.11.1.2.2.103 SET TEMPERATURE

The SET TEMPERATURE shall not exceed 45 °C.

Compliance is checked by inspection.

201.11.1.2.2.104 Temperature overshoot

In NORMAL CONDITION 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 min after the settling period recommended by the manufacturer (see also 201.11.1.2.2).

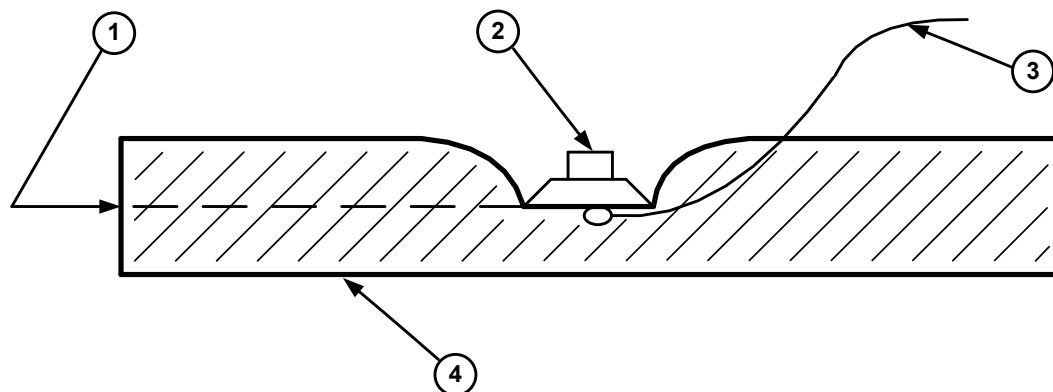
Compliance is checked by measurement of the APPLIED PART INTERFACE temperature.

Procedure:

Plug in the TRANSDUCER; place the TRANSDUCER over the thermocouple in test fixture of Figure 201.102; apply force to compress foam to half thickness; take readings from the thermocouple.

With the TRANSDUCER mounted as in Figure 201.102, measure the temperature of the APPLIED PART INTERFACE continuously for any 30 min in the 4 h after the ME EQUIPMENT is energised, taking into account the settling period.

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



IEC 377/11

Key

- 1 Transducer applied to foam by some means to compress foam to half its original thickness
- 2 TRANSDUCER
- 3 Thermocouple approximately 0,076 mm in diameter, chromel-alumel type K (bare insulation) or equivalent, connected to electronic thermometer or digital multimeter
- 4 Foam block, density approximately 30 kg/m³, cross-linked open cell polyurethane or equivalent

Figure 201.102 – Foam block test (see 201.11.1.2.2.104 and 201.11.1.2.2.105)

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

Materials required for the test:

- a) digital thermometer;

- b) chromel-alumel type K thermocouple, reproducible to 0,1°C (measurement uncertainty shall be established and quoted for each ME EQUIPMENT certification);
- c) means to apply force to the TRANSDUCER;
- d) foam insulation material.

201.11.1.2.2.105 Temperature limiter

ME 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 clinical OPERATOR and which functions independently of the normal temperature control means.

In SINGLE FAULT CONDITION (as specified in subclause 4.7), this TEMPERATURE LIMITER shall prevent the temperature of the APPLIED PART INTERFACE from exceeding 45,6 °C for more than a total of 20 s in a 30 min period but never exceeding 46°C.

Compliance is checked by inspection for the presence of a TEMPERATURE LIMITER and by introducing a SINGLE FAULT CONDITION as described in 201.4.7, then by measuring the temperature of the APPLIED PART when mounted as in Figure 201.102. 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 ME EQUIPMENT having an INTERNAL ELECTRICAL POWER SOURCE, the requirements in subclauses 201.11.1.2.2 to 201.11.1.2.2.105 shall be met for any state of discharge of the INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by inspection.

201.11.1.2.2.106 * Indication of temperature deviation in SINGLE FAULT CONDITION

When the temperature of the APPLIED PART INTERFACE exceeds the SET TEMPERATURE by more than 0,6 °C in NORMAL CONDITION a TECHNICAL ALARM CONDITION shall be indicated.

Compliance is checked by causing the temperature of the APPLIED PART INTERFACE to exceed the SET TEMPERATURE by more than 0,6 °C and verifying that a TECHNICAL ALARM CONDITION occurs.

201.11.1.2.2.107 Timer indicating an elapsed time

ME EQUIPMENT shall be provided with a clinical OPERATOR adjustable timer that initiates a TECHNICAL ALARM CONDITION when the adjusted time has been elapsed. This timer may also de-energise the TRANSDUCER. The elapsed time shall be visually indicated.

Compliance is checked by inspection and functional test.

NOTE The purpose of this timer is to inform the clinical OPERATOR that the TRANSDUCER has to be re-positioned or that the heating of the TRANSDUCER has been switched off to prevent burns.

201.11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

PORTABLE/TRANSPORTABLE ME EQUIPMENT or parts of the ME EQUIPMENT separable while remaining functioning shall be constructed so that, in the event of spillage of liquids (accidental wetting) no HAZARDOUS SITUATION results from the ingress of liquids.

The ME EQUIPMENT shall meet the dielectric strength requirements specified in 8.8.3 of the general standard and shall comply with the requirements of this particular standard.

Compliance is checked by the following test:

Place the PORTABLE/TRANSPORTABLE ME EQUIPMENT or parts of the ME EQUIPMENT in the least favourable position of NORMAL USE. Subject the ME EQUIPMENT for 30 s to an artificial rainfall of 3 mm/min falling vertically from a height of 0,5 m above the top of the ME EQUIPMENT.

A test apparatus is shown in Figure 3 of IEC 60529.

An intercepting device may be used to determine the duration of the test.

Immediately after 30 s exposure, remove any visible moisture on the ENCLOSURE.

Immediately after the above test, verify (by inspection) that any water that entered the ME EQUIPMENT cannot adversely affect the BASIC SAFETY of the ME EQUIPMENT. Verify that the ME EQUIPMENT meets the relevant dielectric strength test (8.8.3 of the general standard) and does not result in a HAZARDOUS SITUATION.

After this test, verify that the ME EQUIPMENT complies with the requirements of this particular standard.

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

Compliance is checked by immersing the TRANSDUCER during normal operation for 1 h. At least 10 cm of its lead wire is immersed 5 cm deep in water that is at the SET TEMPERATURE $\pm 0,6$ °C.

201.11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

If the SUPPLY MAINS to the ME EQUIPMENT in which there is no INTERNAL ELECTRICAL POWER SOURCE is interrupted for 30 s or less and the TRANSDUCER is energised, either

- a) the mode of operation and all OPERATOR settings shall not be changed, or
- b) the TRANSDUCER shall be de-energised and any indication of partial pressure shall be cancelled. This de-energised state shall be indicated by a TECHNICAL ALARM CONDITION. This TECHNICAL ALARM CONDITION shall be indicated by LATCHING ALARM SIGNALS.

NOTE The ME EQUIPMENT does not have to be operating during the interruption of the SUPPLY MAINS.

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

If the SUPPLY MAINS to the ME 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.

If the SUPPLY MAINS is interrupted for more than 30 s, the subsequent operation shall be one of the following:

- reversion to the MANUFACTURER'S default settings,
- reversion to the previous RESPONSIBLE ORGANIZATION'S default settings or
- reversion to the last settings used.

NOTE There may be provision for the clinical OPERATOR to select one or more than one of the above options.

Compliance is checked by functional test.

If the ME EQUIPMENT contains an INTERNAL ELECTRICAL POWER SOURCE and the SUPPLY MAINS is interrupted, 201.11.8 b) does not apply. In this case, the ME EQUIPMENT shall continue normal operation by switching automatically to operating from its INTERNAL ELECTRICAL POWER SOURCE, and the mode of operation, all OPERATOR settings and stored data shall not be changed.

ME EQUIPMENT shall visually indicate when it is operating from its INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by interrupting the SUPPLY MAINS and observing that OPERATOR settings and stored data are not changed, that normal operation continues, and that a visual indication is displayed that the ME EQUIPMENT is operating from its INTERNAL ELECTRICAL POWER SOURCE. The 'on-off' switch needs to remain in the 'on' position.

201.11.8.101 * Protection against depletion of battery

ME EQUIPMENT powered from an INTERNAL ELECTRICAL POWER SOURCE shall not cause a HAZARDOUS SITUATION to the PATIENT when the state of discharge can no longer maintain the NORMAL USE of the ME EQUIPMENT (see 201.15.4.4.101). The ME EQUIPMENT shall provide a TECHNICAL ALARM CONDITION to inform the clinical OPERATOR about the state of discharge and shall power down in a controlled manner as follows:

- a) The ME EQUIPMENT shall provide a TECHNICAL ALARM CONDITION at least 5 min prior to the time that the ME EQUIPMENT can no longer function in accordance with the MANUFACTURER'S specification when powered from the INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by functional test.

- *b) When the state of discharge of any INTERNAL ELECTRICAL POWER SOURCE is such that the ME EQUIPMENT can no longer function in accordance with the MANUFACTURER'S specification the ME EQUIPMENT shall power down in a manner which causes no HAZARDOUS SITUATION to the PATIENT.

Compliance is checked by operating the ME EQUIPMENT from the INTERNAL ELECTRICAL POWER SOURCE and by functional test.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 ESSENTIAL PERFORMANCE OF ME EQUIPMENT

201.12.1.101.1 * Non-linearity and hysteresis

For pO₂ in the range 40 mmHg to 100 mmHg (5,3 kPa to 13,3 kPa), the combined effects of non-linearity and hysteresis for calibrated ME EQUIPMENT shall be within ± 6 mmHg (± 0,8 kPa).

For pCO₂ in the range 30 mmHg to 60 mmHg (4 kPa to 8 kPa), the combined effects of non-linearity and hysteresis for calibrated ME EQUIPMENT shall be within ± 6 mmHg (± 0,8 kPa).

Table 201.102 – 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 %	$x \cdot \frac{6\%}{12\%} \pm 6 \text{ mmHg}$	10 ± 0,1 %	$y \cdot \frac{10\%}{5\%} \pm 6 \text{ m Hg}$
3 (test gas 1)	12 ± 0,1 %	x ± 6 mmHg	5 ± 0,1 %	y ± 6 mmHg
NOTE In the above table, x and y are the actual values of the partial pressure displayed and are in mmHg.				

The combined effects of non-linearity and hysteresis for the calibrated ME EQUIPMENT outside the ranges given in Table 201.102 shall be disclosed in the ACCOMPANYING DOCUMENTS.

Compliance is checked at two points in the most common range, 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 (see Table 201.103);
- gas mix chamber (see Figure 201.104) contains all dimensions needed for manufacturing of the gas mix chamber such as lengths, drill holes (i) and radii (R1/R2);
- gas mix chamber (see Figure 201.103) with means for connecting the test gas bottles and the TRANSDUCER (pO₂, pCO₂ or combinations of both); the pictures A, B and C of Figure 201.103 illustrate how the calibrated electrode is attached to the gas mix chamber;
- dimensions of hose connector (see Figure 201.105) contains all dimensions needed for manufacturing of the hose connector; (lengths and diameters);
- tubing.

Table 201.103 – 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 needs to be ±0,1 % absolute.			

Procedure:

Calibrate the ME EQUIPMENT according to the ACCOMPANYING DOCUMENTS.

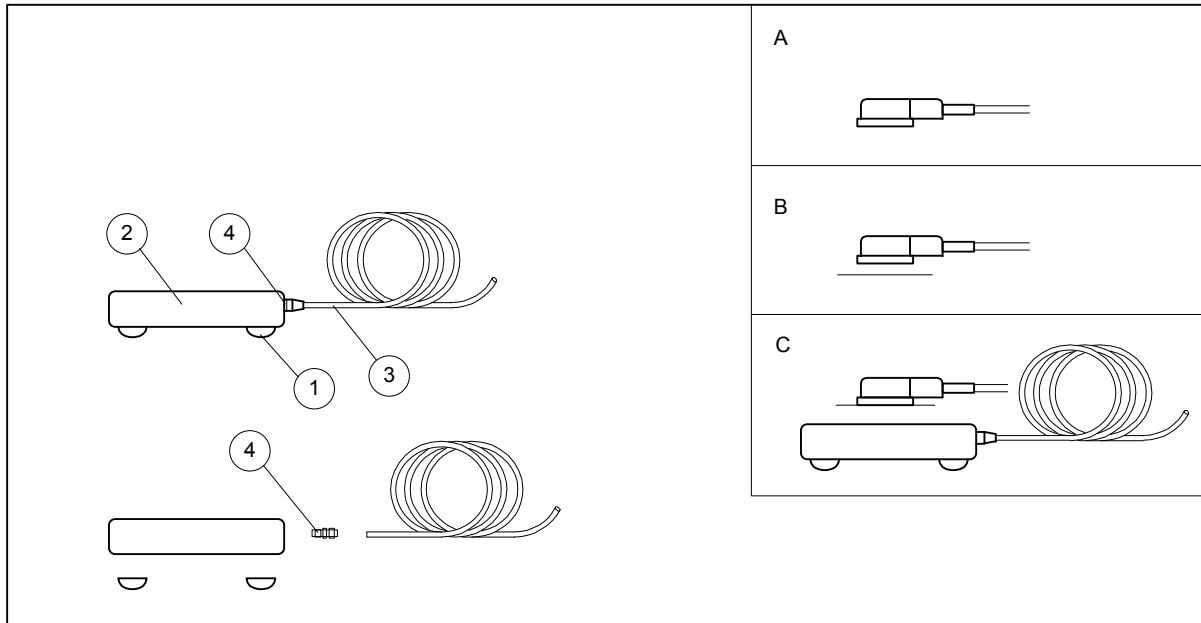
Set the gas flow in the range 10 ml/min to 20 ml/min.

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 values given in Table 201.102.

Repeat the same procedure with the pCO₂ sensor.

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



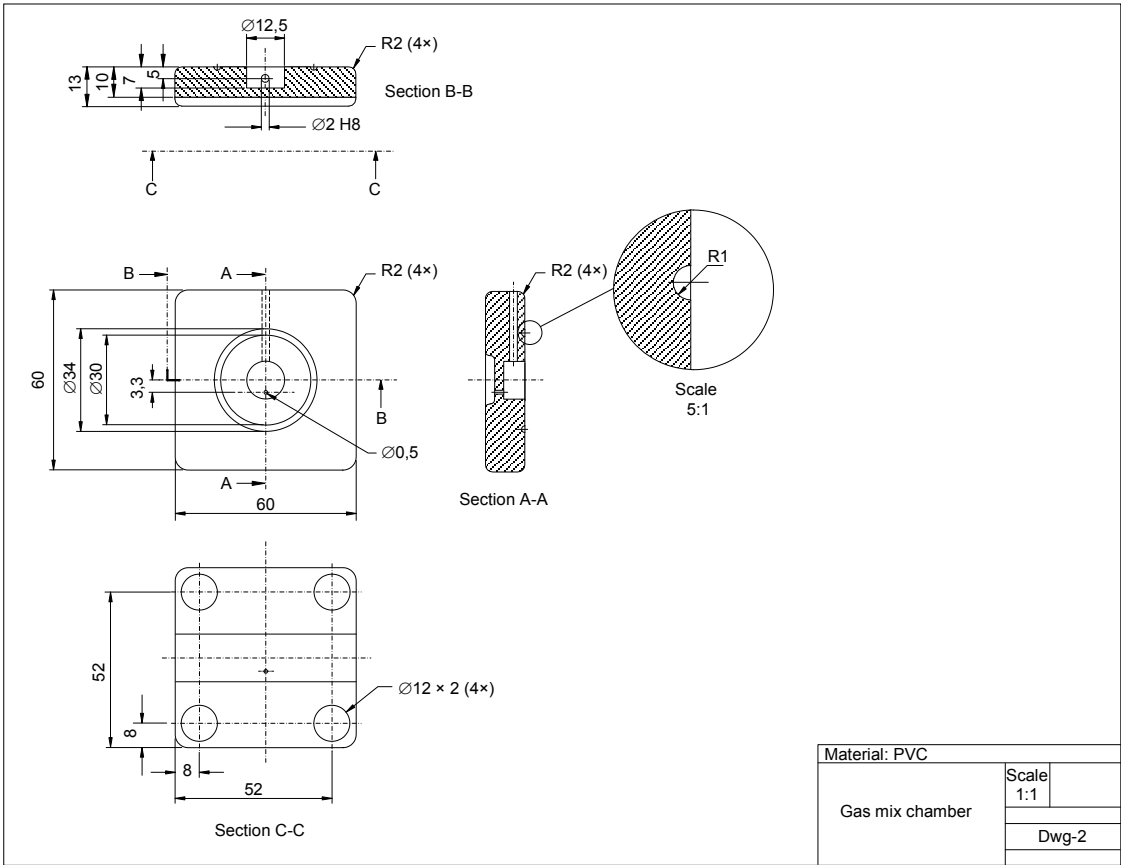
IEC 378/11

Key

- ① Adhesive rubber pin, estimated size 10 mm × 5 mm
- ② Gas mix chamber
- ③ Nylon tube
- ④ House connection (glue, loctite cyanoacrylate 496)
- A Calibrated electrode
- B Attach fixation ring
- C Attach electrode to gas mix chamber

**Figure 201.103 – Linearity and hysteresis test set-up –
Gas mix chamber, assembled**

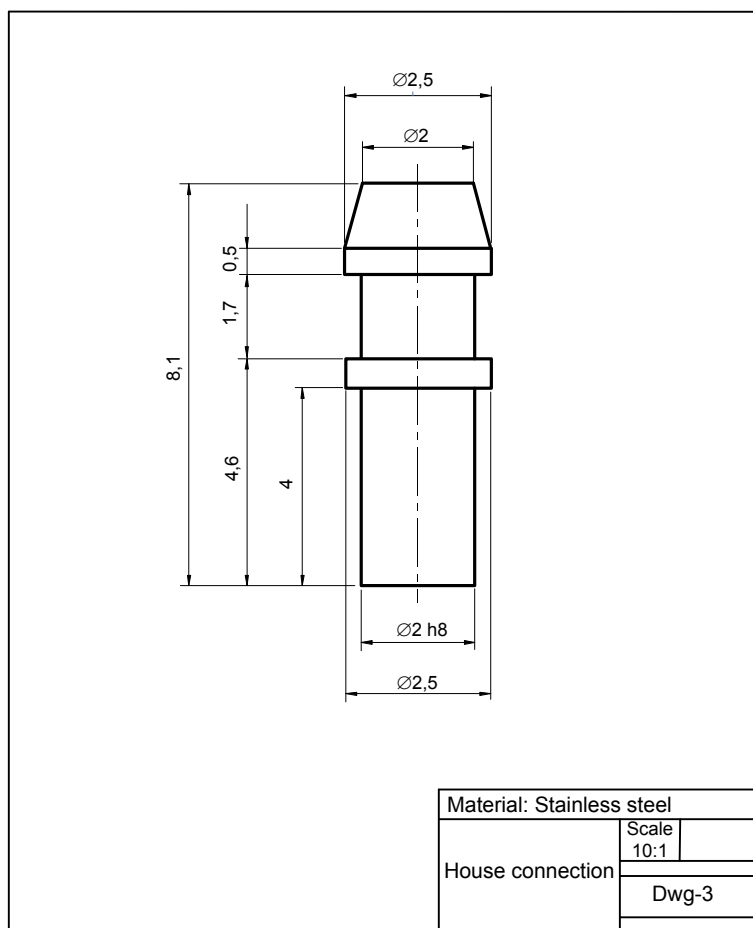
Dimensions in millimetres



IEC 379/11

Figure 201.104 – Linearity and hysteresis test set-up – Gas mix chamber, manufacturing dimensions

Dimensions in millimetres



IEC 380/11

Figure 201.105 – Linearity and hysteresis test set-up – Gas mix chamber, dimensions of hose connector

201.12.1.101.2 * Drift

The MANUFACTURER shall state the drift per hour for O₂ and CO₂, either from laboratory tests using humidified test gases or as a result of statistically valid data gathered from in vivo measurements.

Compliance is checked by inspection of the laboratory or in vivo test report of the MANUFACTURER.

201.12.1.101.3 Response time

The MANUFACTURER shall state, in the ACCOMPANYING DOCUMENTS, the maximum time required for the ME EQUIPMENT to display a 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 laboratory test report of the MANUFACTURER.

201.12.3 Alarm systems

Addition:

ME EQUIPMENT shall be equipped with an ALARM SYSTEM as specified in Clause 208 of this particular standard.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.3.4 Drop test

201.15.3.4.1 * HAND-HELD ME EQUIPMENT

Replacement:

TRANSDUCERS shall not present a HAZARDOUS SITUATION for the PATIENT as a result of a free fall from a height of 1 m on to a hard surface.

After the test, all BASIC SAFETY requirements of this standard shall be satisfied.

Compliance is checked by the following test.

Allow an unpowered test sample 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/m³), which lies flat on a rigid base (for example a concrete floor).

201.15.4.2 Temperature and overload control devices

See also 201.11.1.2.2 of this particular standard.

201.15.4.4 Indicators

Addition:

201.15.4.4.101 Indicator of battery operation and battery status

ME EQUIPMENT shall visually indicate when it is operating from its INTERNAL ELECTRICAL POWER SOURCE, unless it is only INTERNALLY POWERED.

INTERNALLY POWERED ME EQUIPMENT shall visually indicate its remaining battery capacity when operating from its INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by inspection and measurement.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies, except as follows:

Addition:

Clause 202 of this particular standard applies.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies, except as follows:

202.5.2.2.2 Requirements applicable to ME EQUIPMENT and ME SYSTEMS other than those specified for use only in a shielded location

Addition:

ME EQUIPMENT and its ACCESSORIES shall not be considered LIFE-SUPPORTING ME EQUIPMENT.

202.6 ELECTROMAGNETIC COMPATIBILITY

202.6.1 EMISSIONS

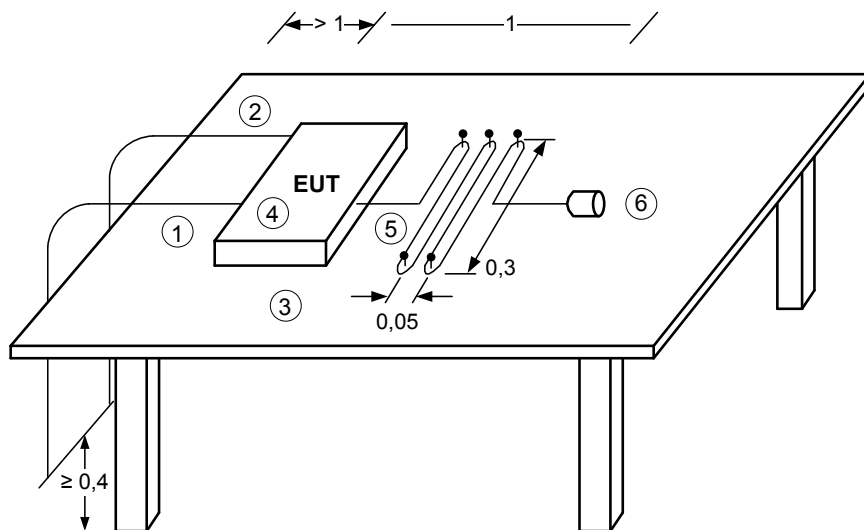
202.6.1.1.2 Tests

a) **PATIENT cables*

Replacement:

ME EQUIPMENT shall be tested with the TRANSDUCER with cable as specified by the MANUFACTURER with all SIP/SOP cables connected to ME EQUIPMENT (see Figure 202.101). The distances of SIP/SOP cables between the open end and floor (ground plane) shall be ≥ 40 cm.

Dimensions in m



IEC 381/11

Components

- ① Mains cable
- ② Signal cable
- ③ Table made of insulating material
- ④ ME EQUIPMENT under test
- ⑤ TRANSDUCER cable
- ⑥ TRANSDUCER

Figure 202.101 – Set-up for radiated and conducted EMISSIONS testing according to 202.6.1.1.2 a)

202.6.2 * IMMUNITY

202.6.2.1.10 Compliance criteria

Addition:

The ME EQUIPMENT shall not change its operating state, shall not lose or change any stored data and, for pO_2 in the range 40 mmHg (5,3 kPa) to 100 mmHg (13,3 kPa) and for pCO_2 in the range 30 mmHg (4,0 kPa) to 60 mmHg (8,0 kPa), the change in the accuracy (ESSENTIAL PERFORMANCE) of the partial pressure reading shall not exceed ± 6 mmHg (0,8 kPa).

Compliance is checked by the following test.

- Set up the ME EQUIPMENT and TRANSDUCER as outlined in Figure 202.101.
- Calibrate the TRANSDUCER according to the ACCOMPANYING DOCUMENTS.
- Expose the ME EQUIPMENT to the specified disturbances (radio frequency, transients, magnetic) at any NOMINAL sensitivity.

202.6.2.2 ELECTROSTATIC DISCHARGE (ESD)

202.6.2.2.1 Requirements

Addition:

ME EQUIPMENT may show temporary DEGRADATION during discharges. Within 60 s the ME EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function and maintain ESSENTIAL PERFORMANCE (see 202.6.2.1.10).

202.6.2.3 Radiated RF electromagnetic fields

202.6.2.3.1 Requirements

Addition to item a):

IMMUNITY TEST LEVEL of 3 V/m applies.

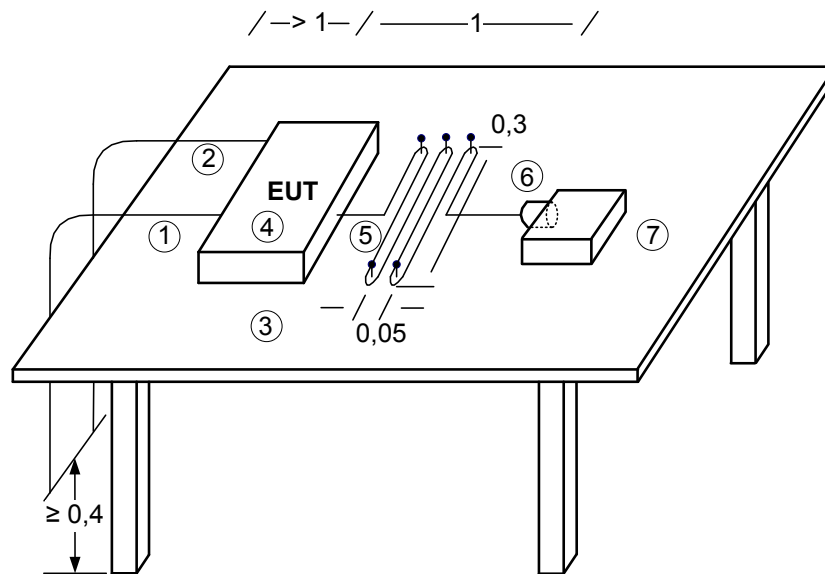
202.6.2.3.2 Tests

Addition:

Test setup for radiated RF electromagnetic fields:

- aa) *Any SIGNAL INPUT PART/SIGNAL OUTPUT PART cable and POWER SUPPLY CORD arranged generally as in Figure 202.102. Maintain distances of ≥ 40 cm between SIP/SOP and the floor (ground plane).*

Dimensions in m



IEC 382/11

Components

- ① Mains cable
- ② SIP/SOP cable
- ③ Table made of insulating material
- ④ ME EQUIPMENT under test
- ⑤ TRANSDUCER cable
- ⑥ TRANSDUCER
- ⑦ Gas mix chamber

**Figure 202.102 – Set-up for radiated immunity test
according to 202.6.2.3.2**

202.6.2.4 Electrical fast transients and bursts**202.6.2.4.1 Requirements**

Addition:

When exposed to electrical fast transients and bursts, via the POWER SUPPLY CORD, the ME EQUIPMENT shall continue to perform its intended function and maintain ESSENTIAL PERFORMANCE (see 202.6.2.1.10).

Testing of TRANSDUCER cables and interconnecting cables specified to be more than 3 m in length may show temporary DEGRADATION during exposure of fast transients and bursts. Within 60 s the ME EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.

202.6.2.4.2 Tests

Addition:

- aa) ME EQUIPMENT shall be located $0,8\text{ m} \pm 0,08\text{ m}$ above the reference ground plane.
- bb) The power cord provided with the ME EQUIPMENT shall be used to connect ME EQUIPMENT to the output of the EFT/B generator.

202.6.2.6 Conducted disturbances, induced by RF fields

202.6.2.6.1 Requirements

Addition:

- aa) When exposed to a conducted radio frequency voltage, via the POWER SUPPLY CORD, the ME EQUIPMENT shall continue to perform its intended function and maintain ESSENTIAL PERFORMANCE (see 202.6.2.1.10).
- bb) * TRANSDUCER cables are exempt from this requirement.

202.6.2.6.2 Tests

Addition:

- aa) Subclause 6.2.6.2, items c) and e) of IEC 60601-1-2:2007 do not apply.

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006 applies except as follows (see also alarm diagrams in Annex BB):

208.6 ALARM SYSTEMS

208.6.1 ALARM CONDITION

208.6.1.2 * ALARM CONDITION priority

Addition:

ME EQUIPMENT that includes in its INTENDED USE/INTENDED PURPOSE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR in NORMAL USE shall treat ALARM CONDITIONS that may result in minor injury and delayed onset of potential HARM as LOW PRIORITY ALARM CONDITIONS (see Table 208.101).

The ACCOMPANYING DOCUMENTS shall describe how the RESPONSIBLE ORGANIZATION may enable or disable auditory ALARM SIGNALS for LOW PRIORITY ALARM CONDITIONS. The requirements of 6.7 of IEC 60601-1-8:2006 apply.

NOTE This adaptation of Table 1 of IEC 60601-1-8:2006 necessitated an additional configuration capability for this ME EQUIPMENT. This capability is necessary when the RESPONSIBLE ORGANIZATION needs auditory ALARM SIGNALS for LOW PRIORITY ALARM CONDITIONS such as for intensive care units when central monitoring is not being used.

Table 208.101 modifies Table 1 – ALARM CONDITION priorities, for ME EQUIPMENT that includes in its INTENDED USE/INTENDED PURPOSE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR in NORMAL USE: