

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

Appareils électromédicaux –

Partie 2-34: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de surveillance de la pression sanguine prélevée directement



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 It also gives information on projects, withdrawn and replaced publications.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

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

Appareils électromédicaux –

Partie 2-34: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de surveillance de la pression sanguine prélevée directement

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX

XB

ICS 11.040.55

ISBN 978-2-88912-495-4

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references	8
201.3 Terms and definitions.....	9
201.4 General requirements.....	10
201.5 General requirements for testing of ME EQUIPMENT.....	10
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	11
201.7 ME EQUIPMENT identification, marking and documents.....	11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	13
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	20
201.10 Protection against unwanted and excessive radiation HAZARDS.....	21
201.11 Protection against excessive temperatures and other HAZARDS.....	21
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	23
201.13 HAZARDOUS SITUATIONS and fault conditions.....	29
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	29
201.15 Construction of ME EQUIPMENT	29
201.16 ME SYSTEMS	30
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	30
202 Electromagnetic compatibility – Requirements and tests	30
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	36
Annexes	45
Annex AA (informative) Particular guidance and rationale	46
Annex BB (informative) Alarm diagrams 208/IEC 60601-1-8:2006.....	59
Bibliography.....	61
Index of defined terms used in this particular standard.....	62
Figure 201.101 – Dynamic test for limitation of energy from different parts – Recovery test	15
Figure 201.102 – Diaphragm leak test.....	16
Figure 201.103 – Measuring circuit for PATIENT LEAKAGE CURRENT via the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(S)	17
Figure 201.104 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of CLASS I ME EQUIPMENT caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED.....	18
Figure 201.105 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of INTERNALLY POWERED ME EQUIPMENT caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED.....	19
Figure 201.106– Clarification of leakage current tests.....	20
Figure 201.107 – Over-pressure test.....	21
Figure 201.108 – Test for accuracy of pressure measurements	25

Figure 201.109 – Test sequence for sensitivity, repeatability, non-linearity, drift and hysteresis	26
Figure 201.110 – Pressure measurement system for accuracy of systolic and diastolic pressure	27
Figure 201.111 – Frequency response of ME EQUIPMENT and TRANSDUCER	28
Figure 202.101 – Test layout for conducted and radiated emission and radiated immunity test	31
Figure 202.102 – Test circuit for high-frequency surgery interference measurement, when the isolation of the APPLIED PART is in the monitor	34
Figure 202.103 – Test circuit for high-frequency surgery protection, when the isolation of the APPLIED PART is in the TRANSDUCER	35
Figure 202.104 – Test set-up for high-frequency surgery protection	36
Figure 208.101 – Test for delay times of ALARM SIGNALS indicating PHYSIOLOGICAL ALARM CONDITIONS	41
Figure 208.102 – Test for delay times of ALARM SIGNALS indicating PHYSIOLOGICAL ALARM CONDITIONS	42
Figure AA.1 – Pressure TRANSDUCER error band	53
Figure BB.101 – NON-LATCHING ALARM SIGNALS without ALARM RESET	59
Figure BB.102 – NON-LATCHING ALARM SIGNALS with ALARM RESET	59
Figure BB.103 – LATCHING ALARM SIGNALS with ALARM RESET	60
Figure BB.104 – Two ALARM CONDITIONS with ALARM RESET	60
Table 201.101 – ESSENTIAL PERFORMANCE requirements	10
Table 208.101 – ALARM CONDITION priorities	37
Table 208.102 – Characteristics of the BURST of auditory ALARM SIGNALS	38

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood 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 60601-2-34 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 of IEC 60601-2-34 published in 2001 and constitutes a technical revision. This edition 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/906/FDIS	62D/923/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 INVASIVE BLOOD 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 2-34: Particular requirements for the basic safety and essential performance of invasive blood 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 particular standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT as defined in 201.3.63, hereinafter referred to as ME EQUIPMENT.

This particular standard does not apply to catheter tubing, catheter needles, Luer locks, taps and tap tables that connect to the DOME.

This particular standard does not apply to NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INVASIVE BLOOD 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.

IEC 60601-1-2:2007 and IEC 60601-1-8:2006 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3 does 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.

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

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 60601-2-2:2009, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60601-2-27, *Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*²

IEC 60601-2-49, *Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*³

ISO 15223-1:2007 *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

NOTE Informative references are listed in the bibliography beginning on page 61.

201.3 Terms and definitions

NOTE An index of defined terms is found beginning on page 61.

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

Replacement:

201.3.63

MEDICAL ELECTRICAL EQUIPMENT ME EQUIPMENT

Addition:

INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT (ME EQUIPMENT)

device including associated TRANSDUCERS, that is used for internal measurement or monitoring of circulatory system pressures

Replacement:

201.3.8

APPLIED PART

TRANSDUCER, including its associated catheter and any fluid-filled system

Additional definitions:

201.3.201

CATHETER TIP TRANSDUCER

TRANSDUCER mounted at, or close to, the tip of a catheter and intended for insertion into the cardiovascular system

201.3.202

DOMES

means for hydraulically coupling the PATIENT'S blood pressure to a TRANSDUCER external to the PATIENT

² Third edition, to be published.

³ Second edition, to be published.

201.3.203

NOMINAL SENSITIVITY

ratio of the change in TRANSDUCER output to a change of the value of the pressure at any selected pressure range

201.3.204

TRANSDUCER

device for converting pressure into an electrical signal

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements for INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT are found in subclauses listed in Table 201.101.

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Defibrillator protection	201.8.5.5.1
Accuracy of pressure measurements	201.12.1.101
Electrosurgery interference	202.6.2.101
Delays to or from a DISTRIBUTED ALARM SYSTEM	208.6.4.2
PHYSIOLOGICAL ALARM CONDITIONS, ALARM LIMITS and delay time of physiological ALARM SIGNALS	208.6.6.2.101
Detection of TRANSDUCER and TRANSDUCER cable fault	208.6.6.2.102
Detection of disconnected catheter	208.6.6.2.103

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 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:

Tests called for in 201.8.5.5.1 of this particular standard and 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 and prior to the tests specified in subclause 201.12.1.101.

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 CF APPLIED PARTS (see 7.2.10 and 8.3 of the general standard). APPLIED PARTS shall be classified as DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5 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:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.10 APPLIED PARTS

Addition:

If fulfilment of TYPE CF APPLIED PART isolation depends on the TRANSDUCER, then symbol 27, Table D.1 of the general standard, shall be marked on the TRANSDUCER.

201.7.2.17 * Protective packaging

Addition:

The packaging of TRANSDUCER and DOMES supplied in sterile condition shall be marked with symbol 5.20 of ISO 15223-1:2007 and the time limit for safe use, expressed as the year and month by which these ACCESSORIES should be used (symbol 5.12, and 5.20 to 5.24).

The packaging of TRANSDUCER and DOMES that are for single use shall be marked with symbol 28 in Table D.1 of the general standard.

201.7.9.2.9 Operating instructions

Addition:

201.7.9.2.9.101 Additional instructions for use

The operating instructions shall include the following:

- a) the INTENDED USE including the environment of use;
- b) for ME EQUIPMENT a list of the specified ACCESSORIES such as TRANSDUCER(S) and DOME(S);
- c) for TRANSDUCERS, a list of ME EQUIPMENT that complies with the requirements of this standard when used with these TRANSDUCERS;
- d) descriptions of how to connect the TRANSDUCERS and ACCESSORIES, how to calibrate the TRANSDUCERS and suggested means for removing entrapped air from the hydraulic system;
- e) advice to the clinical OPERATOR regarding whether the TRANSDUCERS or ME EQUIPMENT incorporates means to protect the PATIENT against burns when used with HIGH-FREQUENCY (HF) SURGICAL EQUIPMENT. Advice shall be given regarding the location of electrodes, TRANSDUCERS, etc. to reduce the hazards of burns in the event of a defect in the neutral electrode connection of the HF SURGICAL EQUIPMENT;

NOTE 'Neutral electrode' here refers to a term defined in IEC 60601-2-2.

- f) precautions to take when using a defibrillator on a PATIENT; a description of how the discharge of a defibrillator affects the ME EQUIPMENT; a warning that defibrillator protection requires use of MANUFACTURER specified ACCESSORIES including TRANSDUCERS and adapter cables. The specification (or type-number) of such ACCESSORIES shall be disclosed;
- g) a warning that single-use ACCESSORIES are not to be reused;
- h) if the TRANSDUCER and/or DOMES are reusable, information on the appropriate processes for cleaning, disinfection, packaging and, where appropriate, the method of sterilization, and any restriction on the number of reuses;
- i) if the ME EQUIPMENT has to be connected to other equipment in order to achieve its INTENDED USE, sufficient details of its characteristics to correctly identify the equipment necessary for safe operation;
- j) precautions to be taken in the event of changes in performance of the tubing, TRANSDUCER, or cable as a result of ageing and environmental conditions;
- k) the warm-up time for the ME EQUIPMENT and TRANSDUCER(S) if greater than 15 s;
- l) * 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;
- m) instructions for connecting a POTENTIAL EQUALIZATION CONDUCTOR, if applicable;
- n) the default settings (e.g. ALARM SETTINGS, modes, and filter);
- o) performance specification (e.g. accuracy, bandwidth, measurement range) of ME EQUIPMENT including specified TRANSDUCERS and adjustment ranges of all physiological ALARM SETTINGS (see 208.6.6.2.101);
- p) explanation of TECHNICAL ALARM CONDITIONS (see 208.6.6.2.102 and 208.6.6.2.103);
- q) 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;
- r) 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 difficulties, not to technical malfunctions.

- s) the subsequent operation of the ME EQUIPMENT after interruption of the SUPPLY MAINS exceeding 30 s (see 201.11.8);
- t) * description of how to disable ALARM SIGNALS for TECHNICAL ALARM CONDITIONS if TRANSDUCERS or modules are intentionally disconnected by the clinical OPERATOR (see 208.6.8.101);
- u) advice on the preferred ALARM SETTINGS and configurations of the ALARM SYSTEM when the INTENDED USE includes 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:

201.8.3 Classification of APPLIED PARTS

Replacement:

The APPLIED PART shall be a TYPE CF APPLIED PART.

201.8.5.5.1 * Defibrillation protection

Addition:

ME EQUIPMENT shall have DEFIBRILLATOR-PROOF APPLIED PARTS.

Addition to item b):

The recovery time after defibrillation shall not exceed 10 s.

Addition to common-mode test to verify a):

Compliance is checked by testing in accordance with Figure 201.101. The requirement is met when after operation of S_1 , the peak voltage between the points Y1 and Y2 does not exceed 1 V.

In the case of a CATHETER TIP TRANSDUCER, the CATHETER with its TRANSDUCER is immersed in the saline solution for a length of 75 cm or 90 % of the actual length of the CATHETER excluding its connector, whichever is the shorter.

- *Remove the diaphragm of the DOME, destructively if necessary.*
- *Disposable TRANSDUCERS and CATHETER TIP TRANSDUCERS must be tested intact and complete.*

Repeat the test with the 5 kV supply (V1) reversed.

After this test the ME EQUIPMENT must meet all requirements and tests of this particular standard and continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

Following this test, replace the DOME with one that has an intact diaphragm and repeat this test. Verify that the diaphragm was not punctured during the test.

Compliance is checked (test described in Figure 201.102) by applying air pressure gradually over about 0,5 s, holding that pressure for about 10 s, and noting the absence of bubbles.

Addition to common-mode test to verify b):

Compliance is checked by applying a test pressure to the TRANSDUCER sufficient to produce 30 % to 70 % of full-scale deflection (output) at any NOMINAL SENSITIVITY.

While the pressure is maintained, the ME EQUIPMENT is subjected to a test discharge. Figure 201.101 is used as the test arrangement under the following conditions:

CLASS I ME EQUIPMENT

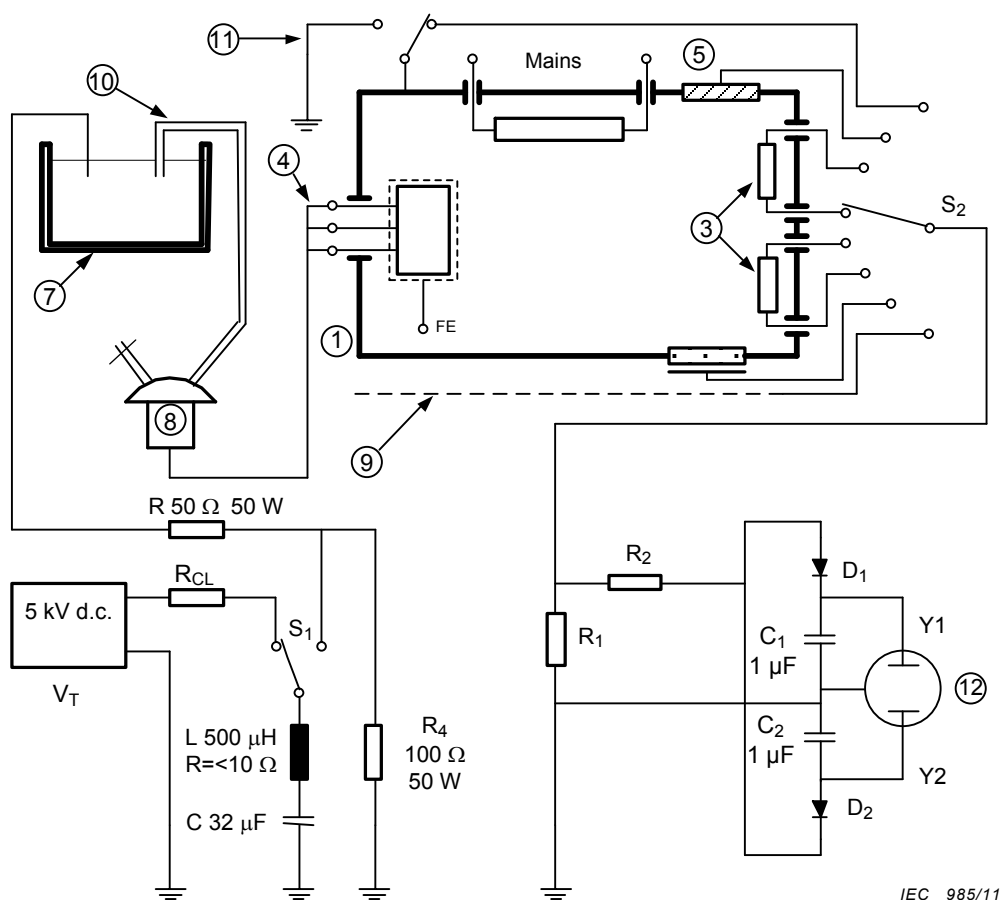
- *Connect the PROTECTIVE EARTH TERMINAL and any FUNCTIONAL EARTH TERMINAL to the PROTECTIVE EARTH TERMINAL of the test circuit.*

CLASS II ME EQUIPMENT and INTERNALLY POWERED ME EQUIPMENT

- *Connect foil and any conductive ACCESSIBLE PART not connected to FUNCTIONAL EARTH TERMINAL and any FUNCTIONAL EARTH TERMINAL to the PROTECTIVE EARTH TERMINAL of the test circuit.*

Verify that the deflection (output) returns to within 20 % of the original value (output) within 10 s after the discharge and remains within these limits for at least a further 30 s.

Compliance is checked (test as described in Figure 201.102) by applying air pressure gradually over about 0,5 s, holding that pressure for about 10 s, and noting the absence of bubbles.



Key

- 1 ME EQUIPMENT ENCLOSURE
- 3 SIGNAL INPUT/OUTPUT PART short circuited or loaded
- 4 TRANSDUCER connections
- 5 Unearthed ACCESSIBLE PARTS
- 7 Insulating protective container filled with physiological saline
- 8 TRANSDUCER with DOME; stopcock closed
- 9 Foil at base of ME EQUIPMENT
- 10 Plastic tube 50 cm
- 11 PROTECTIVE EARTH CONNECTION of CLASS I ME EQUIPMENT
- 12 Display device $Z_{in} > 1 \text{ M}\Omega$

$C_{1,2}$ 1 μF , 5 %

$D_{1,2}$ Small signal silicon diodes

R_1 1 $\text{k}\Omega$, 2 %, not less than 2 kV

R_2 100 $\text{k}\Omega$, 2 % not less than 2 kV

R_{CL} Current limiting resistor

S_1 Switch for applying the test voltage

S_2 Switch for measuring output voltages

V_T Test voltage

For the remaining legends of symbols refer to Table 5 of the general standard and Figure 9

NOTE 1 Reusable and/or disposable DOME as furnished by the MANUFACTURER of the ME EQUIPMENT.

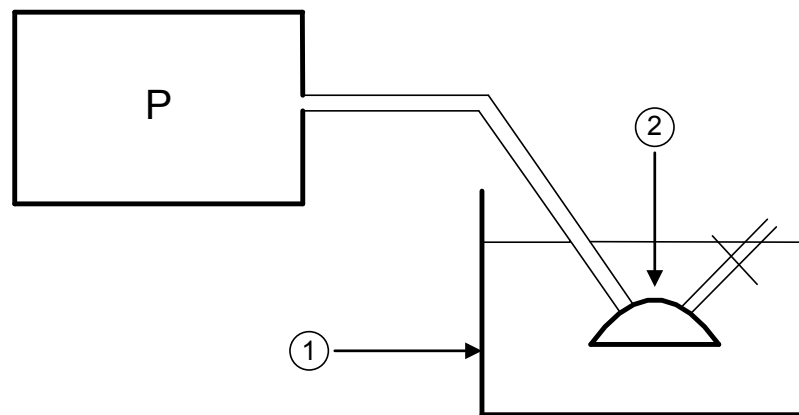
NOTE 2 50 Ω simulates the resistance of a low impedance CATHETER filled with physiological saline or a CATHETER TIP TRANSDUCERS.

NOTE 3 Value of resistor R_{CL} is determined by need to limit initial charging current peak.

NOTE 4 Oscilloscope of 5 % accuracy. Input impedance of approximately 1 $\text{M}\Omega$.

Figure 201.101 – Dynamic test for limitation of energy from different parts – Recovery test

(see 8.5.5.1 of the general standard and 201.8.5.5.1 of this particular standard)



IEC 986/11

Key

- 1 Container filled with water
- 2 DOME; stopcock closed
- P Pressure source; +50 kPa (+400 mmHg); The pressure system has to be air-filled and the air pressure is applied gradually over about 0,5 s and held for about 10 s.

Figure 201.102 – Diaphragm leak test
(see 201.8.5.5.1)

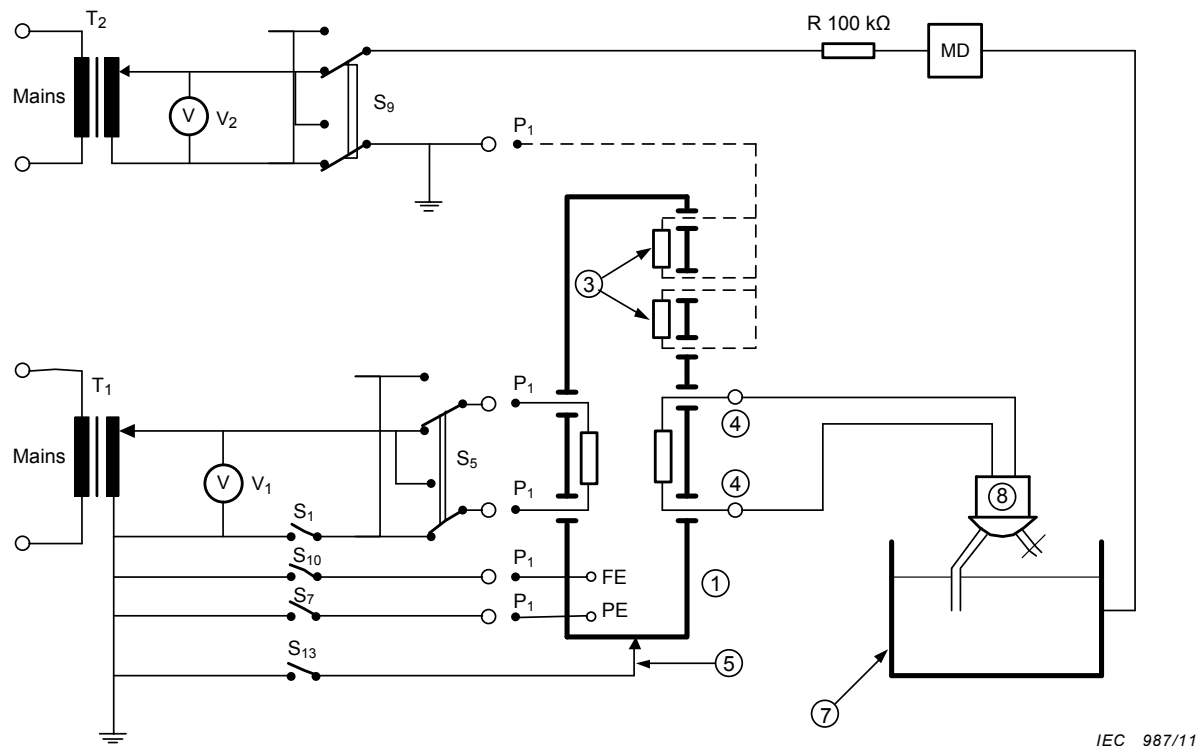
201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Addition:

Compliance is checked by measurement according to Figures 201.104 and 201.105.

Perform testing with any reusable and/or disposable DOME removed. Disposable TRANSDUCERS and CATHETER TIP TRANSDUCERS are tested intact and complete. Conductive ACCESSIBLE PARTS in the hydraulic circuit beyond the DOME and parts within the cardiovascular system in NORMAL USE are excluded from testing.

For the MAXIMUM MAINS VOLTAGE on the APPLIED PART test, see Figure 201.103. A more pictorial representation providing additional clarification is shown in Figure 201.106.



IEC 987/11

Key

- 1 ME EQUIPMENT ENCLOSURE
- 3 SIGNAL INPUT/OUTPUT PART short circuited or loaded
- 4 TRANSDUCER connections
- 5 Metal ACCESSIBLE PART not being an APPLIED PART and not PROTECTIVELY EARTHED
- 7 Conductive container filled with physiological saline
- 8 TRANSDUCER with DOME; stopcock closed
- P₁ Sockets, plugs, or terminals for supply connections

For the remaining legends of symbols refer to Table 5 of the general standard

When using a CATHETER TIP TRANSDUCER, immerse the TRANSDUCER.

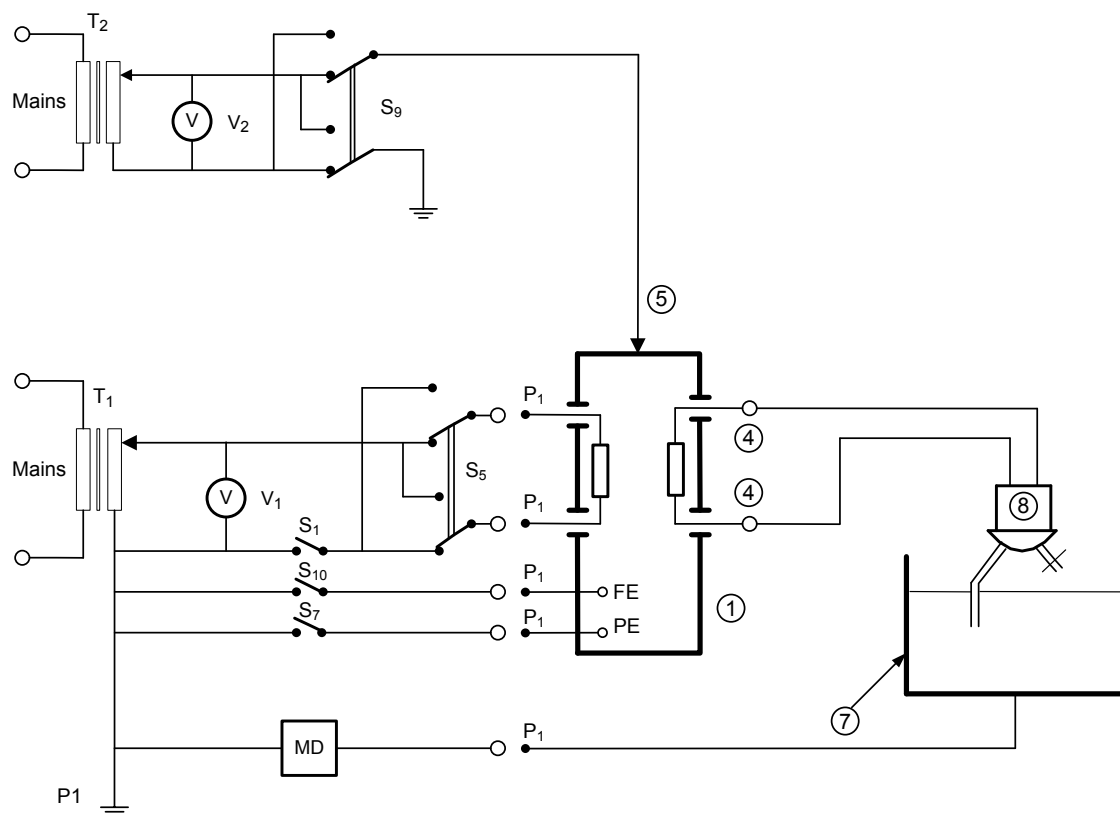
Measure (with S₇ closed, if CLASS I ME EQUIPMENT) the PATIENT LEAKAGE CURRENT with S₁ closed under all possible combinations of positions of S₅, S₉, S₁₀ and of S₁₃ (external voltage on the PATIENT CONNECTION).

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S₇ are not used.

Conductive ACCESSIBLE PARTS, if any, are connected to earth by means of connection 5 and S₁₃.

Example with the measuring supply circuit of Figure F.1

Figure 201.103 – Measuring circuit for PATIENT LEAKAGE CURRENT via the PATIENT CONNECTION(s) of an F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(s)



IEC 988/11

Key

- | | |
|----------------|---|
| 1 | ME EQUIPMENT ENCLOSURE |
| 4 | TRANSDUCER connections |
| 5 | Metal ACCESSIBLE PART not being PROTECTIVELY EARTHED |
| 7 | Conductive container filled with physiological saline |
| 8 | TRANSDUCER with DOME; stopcock closed |
| P ₁ | Sockets, plugs, or terminals for supply connections |

For the remaining legends of symbols refer to Table 5 of the general standard

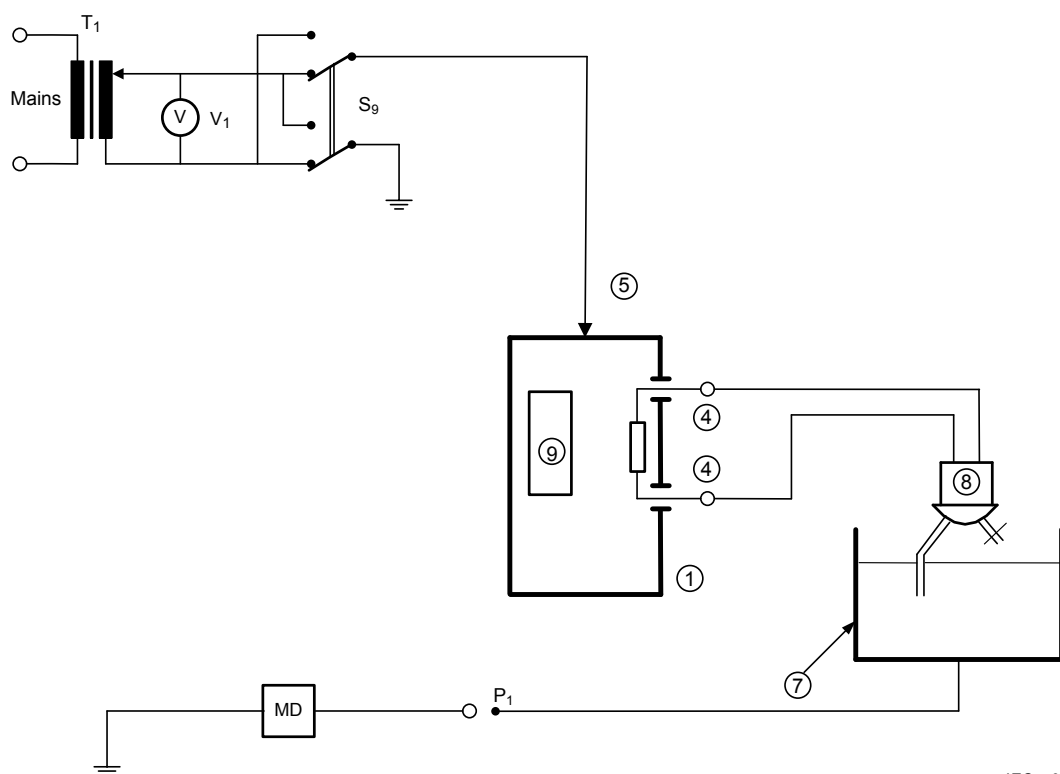
NOTE 1 Measure (with S₇ closed, if CLASS I) with S₁ closed under all possible combinations of positions of S₅, S₉ and S₁₀ (SINGLE FAULT CONDITION).

NOTE 2 For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION(S) and S_7 are not used.

NOTE 3 Example with the measuring circuit of Figure 16 of the general standard (see 8.7.4.7 b)).

Example with the measuring supply circuit of Figure F.1

Figure 201.104 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of CLASS I ME EQUIPMENT caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED.



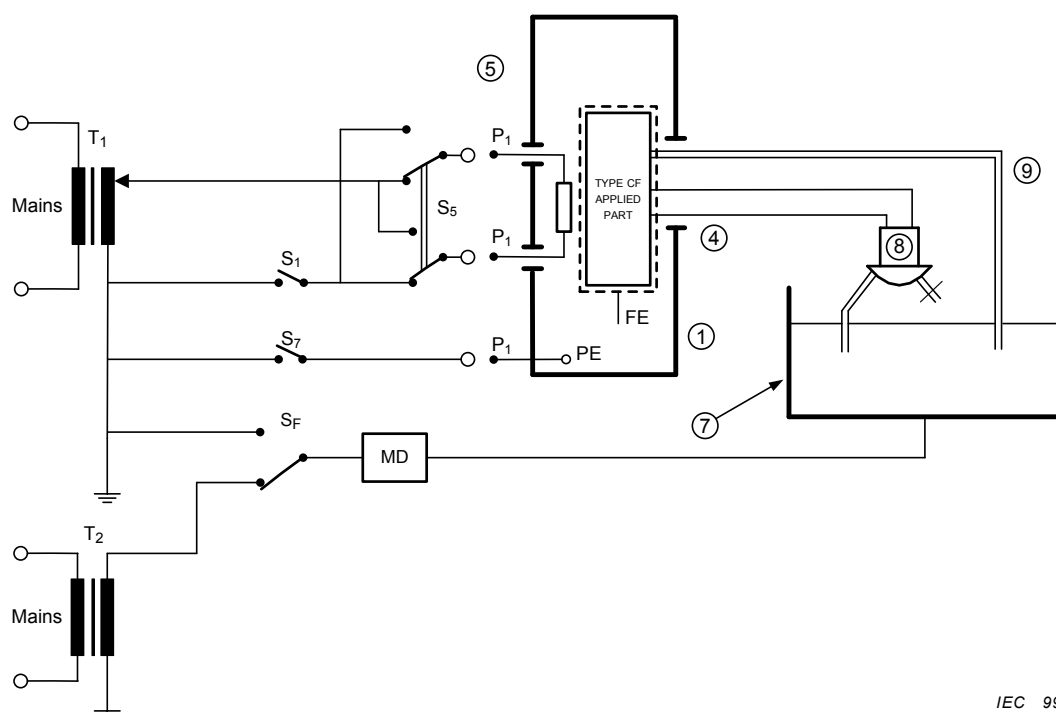
IEC 989/11

Key

- 1 ME EQUIPMENT ENCLOSURE
- 4 TRANSDUCER connections
- 5 Metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED
- 7 Conductive container filled with physiological saline
- 8 TRANSDUCER with DOME; stopcock closed
- 9 INTERNAL ELECTRICAL POWER SOURCE
- P₁ Sockets, plugs, or terminals for supply connections

For the remaining legends of symbols refer to Table 5 of the general standard

Figure 201.105 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of INTERNALLY POWERED ME EQUIPMENT caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED



IEC 990/11

Key

- | | |
|----------------|---|
| 1 | ME EQUIPMENT ENCLOSURE |
| 4 | PATIENT CONNECTIONS |
| 5 | Metal ACCESSIBLE PART not being an APPLIED PART and not PROTECTIVELY EARTHED |
| 7 | Conductive container filled with physiological saline |
| 8 | TRANSDUCER with DOME; stopcock closed |
| 9 | CATHETER TIP TRANSDUCER* |
| P ₁ | Sockets, plugs, or terminals for supply connections |
| S ₇ | SINGLE FAULT CONDITION CLASS I or NORMAL CONDITION, CLASS II |
| S _F | Switch; switches between NORMAL CONDITION, CLASS I, and MAXIMUM MAINS VOLTAGE on the APPLIED PART |
| S _M | Switch; applies MAINS VOLTAGE to the APPLIED PART |

For the remaining legends of symbols refer to Table 5 of the general standard

* Only one TRANSDUCER at a time immersed in the saline solution, with any disposable membrane removed

Example with the measuring supply circuit of Figure F.1

Figure 201.106– Clarification of leakage current tests
(see 8.7.4.7 of the general standard)

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure

201.9.7.5 * Pressure vessels

Replacement:

The following requirement and test do not apply to CATHETER TIP TRANSDUCERS

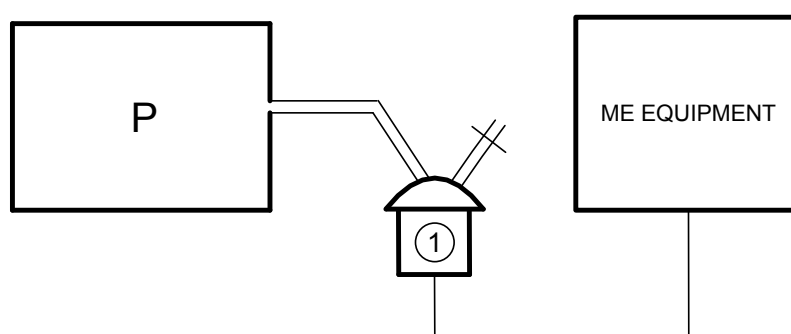
Pressure above and below atmospheric

TRANSDUCERS with reusable or disposable DOME shall withstand a pressure of 500 kPa (4 000 mmHg) above standard atmospheric pressure (SAP) and a pressure of 50 kPa (400 mmHg) below standard atmospheric pressure.

The requirements of this particular standard shall be satisfied after the following test (see 201.5.8):

Figure 201.107 illustrates the test configuration.

Gradually apply over approximately 0,5 s the pressure of 500 kPa above standard atmospheric pressure and hold that pressure for approximately 1 s. Repeat this once within 10 s. Repeat the test for the pressure of 50 kPa below standard atmospheric pressure.



IEC 991/11

Key

- 1 TRANSDUCER with DOME; stopcock closed
- P Pressure source; +500 kPa (+4 000 mmHg); –50 kPa (–400 mmHg); liquid-filled pressure system.

Figure 201.107 – Over-pressure test
(see 201.9.7.5)

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:

201.11.6.5 * 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:

A test pressure is applied to the TRANSDUCER sufficient to produce 50 % of full-scale deflection at any NOMINAL SENSITIVITY. The pressure and the resultant deflection (output) are noted and the ME EQUIPMENT switched off.

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 the 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 tests (8.8.3 of the general standard) and does not result in a HAZARDOUS SITUATION.

The same test pressure as before is applied again to the TRANSDUCER. Compare the newly measured deflection to the deflection noted at the beginning of this test. Verify that the deflection is unchanged within the tolerance allowed by the specification disclosed in the ACCOMPANYING DOCUMENTS.

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

TRANSDUCERS and ME EQUIPMENT parts containing insulation, the failure of which could result in a HAZARDOUS SITUATION or changes in ESSENTIAL PERFORMANCE according to this particular standard, and which in NORMAL USE are subject to immersion in liquids, shall be watertight according to IPX7 of IEC 60529. After the test no water shall have entered. The test need not be performed if examination of the construction and circuit arrangement shows that no HAZARDOUS SITUATIONS are possible.

Compliance is checked after application of the tests of IEC 60529. After this test the relevant parts are opened and inspected of ingress of water.

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

Addition:

If the SUPPLY MAINS to the ME EQUIPMENT is interrupted for 30 s or less, no change of clinical OPERATOR settings shall occur, including the mode of operation, and all stored PATIENT data shall remain available.

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, OPERATOR settings, and stored data and interrupting the SUPPLY MAINS for a period of between 25 s and 30 s by disconnecting the POWER SUPPLY CORD.

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 Means may be provided for the 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, 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. Power-saving measures may be taken provided the ME EQUIPMENT continues to conform to this particular standard.

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 ME EQUIPMENT is operating from its INTERNAL ELECTRICAL POWER SOURCE. The 'on-off' switch needs to remain in the 'on' position.

Addition:

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. 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 * Accuracy of pressure measurements

201.12.1.101.1 * Measurement range, sensitivity, repeatability, non-linearity, drift and hysteresis

The pressure measurement range shall be at least –30 mmHg to 250 mmHg. The combined effects of sensitivity, repeatability, non-linearity, drift and hysteresis shall be within $\pm 4\%$ of reading or $\pm 0,5$ kPa (± 4 mmHg), whichever is greater. Corrections of the results for changes in barometric pressure during testing are applied to the tests.

Compliance is checked as follows (see Figure 201.108 for the test configuration and Figure 201.109 for the test sequence):

Repeat this test for each TRANSDUCER the MANUFACTURER specifies.

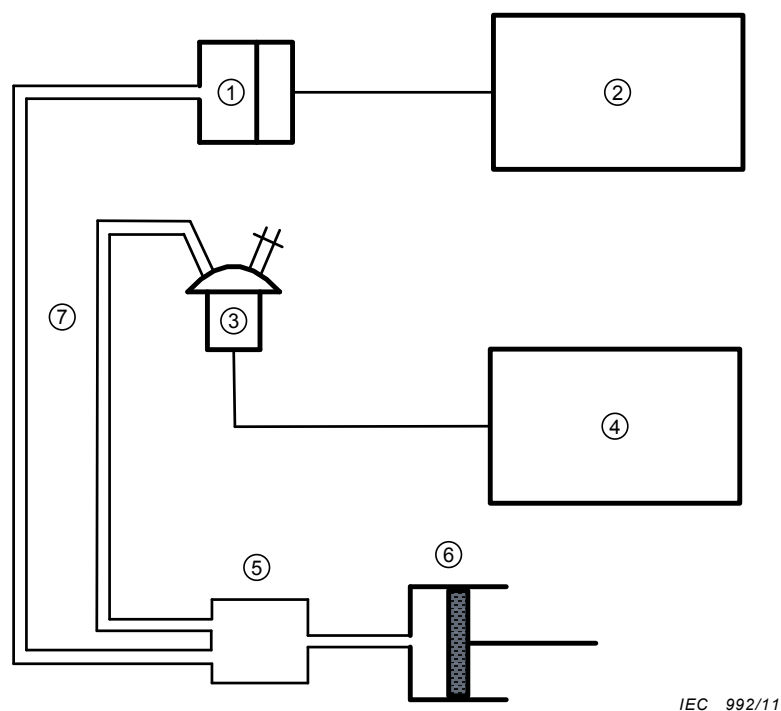
For all but CATHETER TIP TRANSDUCERS:

Energize the ME EQUIPMENT.

- a) Fill the TRANSDUCER and its hydraulic parts with water.*
- b) Equilibrate the TRANSDUCER and ME EQUIPMENT at $25\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ for 2 h.*
- c) Balance the TRANSDUCER to obtain zero pressure output with zero pressure input. Note the barometric pressure.*
- d) Using a pressure source referenced to atmospheric pressure with a combined non-linearity and hysteresis error of $\pm 0,1\%$ of full scale, apply pressures as a percentage of the largest full-scale pressure range of 0, 10, 20, 50, 80, 100, 80, 50, 20, 10, 0, -10 , and 0 %. The output pressure shall be within $\pm 4\%$ of reading or $\pm 0,5\text{ kPa}$ ($\pm 4\text{ mmHg}$), whichever is greater, compared to the reference measurement.*
- e) Equilibrate the TRANSDUCER and ME EQUIPMENT for 2 h at $15\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$. Apply pressure as in d). Note the barometric pressure and apply correction prior to determining compliance.*
- f) Equilibrate the TRANSDUCER and ME EQUIPMENT for 2 h at $25\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$. Apply pressure as in d). Note the barometric pressure and apply correction prior to determining compliance.*
- g) Equilibrate the TRANSDUCER and ME EQUIPMENT for 2 h at $35\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$. Apply pressure as in d). Note the barometric pressure and apply correction prior to determining compliance.*
- h) Equilibrate the TRANSDUCER and ME EQUIPMENT for 2 h at $25\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$. Apply pressure as in d). Note the barometric pressure and apply correction prior to determining compliance.*

For CATHETER TIP TRANSDUCERS (see Figure 201.109 for test sequence)

- i) Follow b).*
- j) Follow c).*
- k) Follow d).*
- l) Follow g).*
- m) Remain at $35\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ for 4 h. Apply pressure as in d). Note the barometric pressure and apply correction prior to determining compliance.*
- n) Follow f). Apply pressure as in 4). Note the barometric pressure and apply correction prior to determining compliance.*



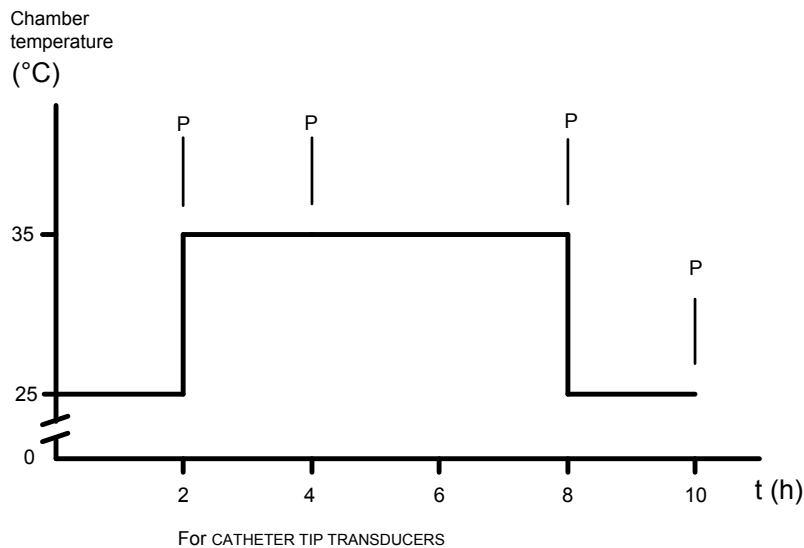
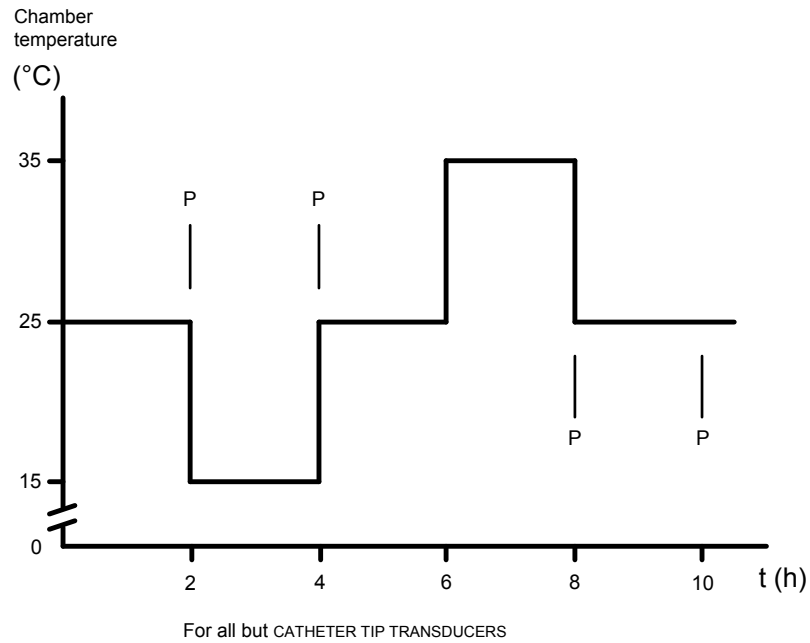
IEC 992/11

Key

- 1, 2 Reference pressure measuring system consisting of transducer (1) and monitor (2); reference pressure accurate to $\pm 0,4$ mmHg
- 3 TRANSDUCER with DOME under test; stopcock closed
- 4 ME EQUIPMENT under test
- 5 Hydraulic system filled with water
- 6 Static pressure source
- 7 Tubing

Figure 201.108 – Test for accuracy of pressure measurements

(see 201.12.1.101.1)



IEC 993/11

Key

P Apply pressure

NOTE Temperature change should be completed within 10 min.

Figure 201.109 – Test sequence for sensitivity, repeatability, non-linearity, drift and hysteresis
(see 201.12.1.101.1)

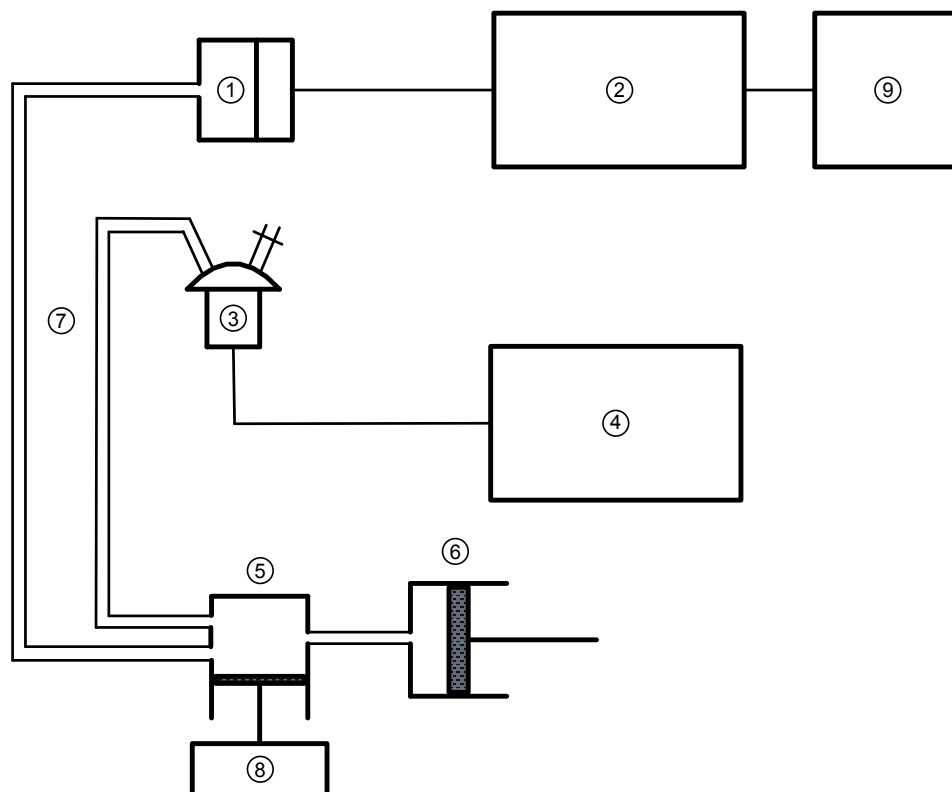
201.12.1.101.2 * Accuracy of systolic and diastolic pressure

The accuracy of systolic and diastolic pressures shall be within 0,5 kPa (± 4 mmHg) at a frequency of 1 Hz.

Refer to Figure 201.110. Although actual pressure sources are shown, electrically simulated pressures may be used.

Compliance is to be checked as follows:

- a) Using static pressure, calibrate the reference pressure measuring system (RPMS) using an output display device with at least 1 % accuracy and that can display a 1 Hz waveform.
- b) Apply a static pressure until the RPMS output display device reads 90 mmHg peak.
- c) With the static pressure applied, apply a 1 Hz sine-wave pressure until the output display device reads 120 mmHg for the upper peak pressure and 60 mmHg for the lower peak pressure (peak-to-peak pressure is 60 mmHg).
The RPMS then has a systolic pressure of 120 mmHg and a diastolic pressure of 60 mmHg.
- d) Verify that the readings of the ME EQUIPMENT under test are within 120 mmHg $\pm$ 4 mmHg for systolic pressure and 60 mmHg $\pm$ 4 mmHg for diastolic pressure.



IEC 994/11

Key

- 1, 2 Reference pressure measuring system consisting of transducer (1) and monitor (2); reference pressure accurate to $\pm 0,4$ mmHg
- 3 TRANSDUCER with DOME under test; stopcock closed
- 4 ME EQUIPMENT under test
- 5 Hydraulic system filled with water
- 6 Static pressure source with accuracy of $\pm 0,5$ mmHg
- 7 Tubing
- 8 Sine-wave generator 1 Hz
- 9 1 Hz sine-wave display

Figure 201.110 – Pressure measurement system for accuracy of systolic and diastolic pressure
(see 201.12.1.101.2)

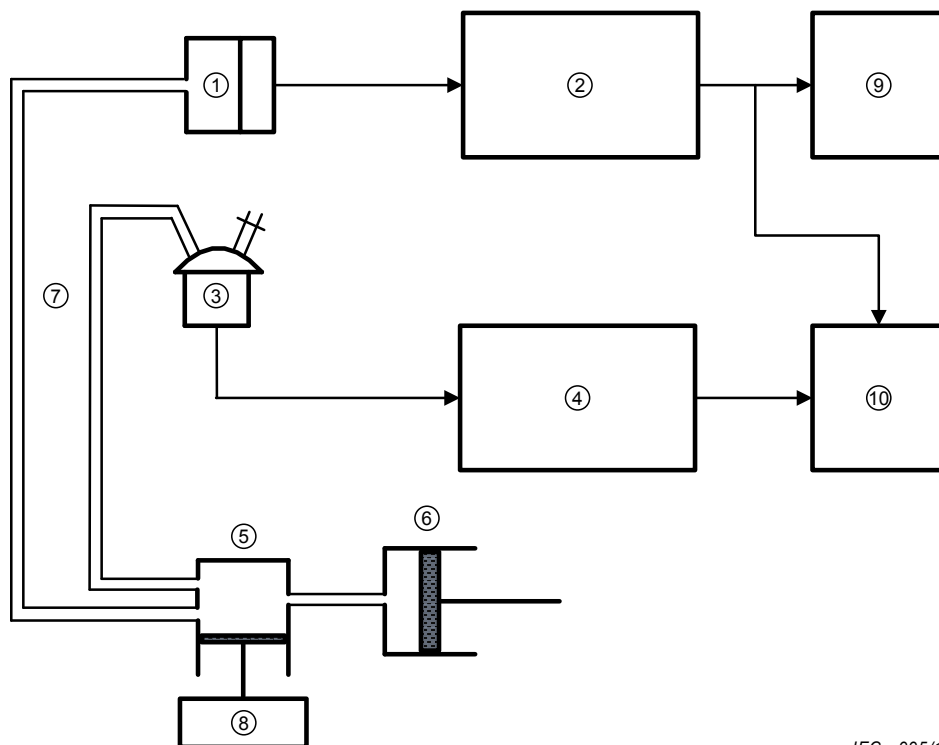
201.12.1.101.3 * Frequency response

The frequency response of the ME EQUIPMENT and TRANSDUCER shall be at least from d.c. to 10 Hz.

Compliance is checked by connection of a hydraulic sinusoidal pressure source to the ME EQUIPMENT as shown in Figure 201.111:

- Adjust the sine-wave generator to 1 Hz.
- Adjust the sine-wave generator, static pressure and controls to produce nominal 100 mmHg peak-peak deflections on displays.
- Vary sine-wave generator frequency to 10 Hz, keeping peak-peak amplitude on reference pressure measuring system equal to that at 1 Hz.
- Note amplitude of ME EQUIPMENT under test.

Verify that the sinusoidal output pressure at 10 Hz is within 3 dB of the pressure reading at 1 Hz.



IEC 995/11

Key

- 1, 2 Reference pressure measuring system consisting of transducer (1) and amplifier/monitor (2); transducer bandwidth together with display shall be 50 Hz or greater.
- 3 TRANSDUCER with DOME under test; stopcock closed
- 4 ME EQUIPMENT under test
- 5 Hydraulic system filled with water; water to be air free
- 6 Cylinder for applying static pressure**
- 7 Rigid tubing; as short as possible; same length for both tubes, bubble-free
- 8 Sine-wave generator
- 9 Reference waveform display
- 10 Two channel display (alternative)

** Adjust static pressure to make a 100 mmHg pp deflection visible on displays.

Figure 201.111 – Frequency response of ME EQUIPMENT and TRANSDUCER
(see 201.12.1.101.3)

201.12.3 Alarm systems

Addition:

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

Catheterization laboratory ME EQUIPMENT is excluded from this requirement.

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:

Addition:

201.15.3.4 Drop test

Addition:

201.15.3.4.101 * TRANSDUCER drop test

The TRANSDUCER, if separable from the ME EQUIPMENT by the clinical OPERATOR, without its DOME if removable, shall not present a HAZARDOUS SITUATION after a free fall from a height of 1 m onto a hard surface.

Compliance is checked by the following test:

Allow the TRANSDUCER sample to fall freely from a height of 1 m onto a 50 mm thick hardwood board (for example, hardwood > 600 kg/m³) lying flat on a rigid base (concrete block). Do this once each for three different attitudes.

After this test, no parts shall become accessible that exceed the values of the LEAKAGE CURRENTS when touched with the test finger. Cracks not visible to the naked eye and surface cracks in fibre-reinforced mouldings and the like shall be ignored. After this test all requirements of this particular standard shall be satisfied and the ME EQUIPMENT shall function normally.

201.15.4 ME EQUIPMENT components and general assembly

201.15.4.1 * Construction of connectors

Addition:

Unless the isolation of the APPLIED PART necessary to comply with this particular standard is incorporated in the TRANSDUCER, the TRANSDUCER cable to ME EQUIPMENT connector and any detachable connectors within the APPLIED PART shall, when separated from the ME EQUIPMENT, comply with subclause 8.5.2.3 of the general standard.

Compliance is checked by inspection and measurement.

Additional subclause:

201.15.4.101 * DOME

The DOME shall be transparent.

Compliance is checked by ensuring that small air bubbles in water or saline solution are visible through the DOME.

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 continuously visually indicate its remaining battery capacity when operating from its INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by inspection.

201.15.4.7.2 * Accidental operation of ME EQUIPMENT

Addition:

Means shall be provided to reduce the likelihood of unintended operation of the zeroing control.

NOTE See also the USABILITY ENGINEERING FILE.

Compliance is checked by inspection.

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:

See Clause 202.

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:

INVASIVE BLOOD PRESSURE MONITORING 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

Addition:

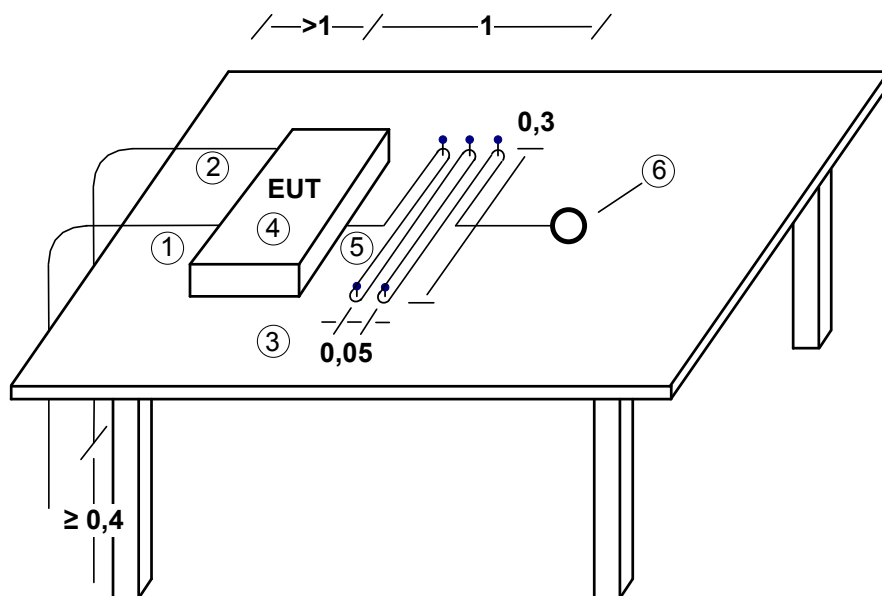
* aa) TRANSDUCERS

TRANSDUCERS are tested using all invasive blood pressure monitors specified in the instructions for use of the TRANSDUCER except where the electrical invasive blood pressure monitor design is identical.

Invasive blood pressure monitors are tested using all TRANSDUCER(S) specified in the instructions for use of the invasive blood pressure monitor except where the electrical TRANSDUCER design is identical.

Testing is performed 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.

NOTE This may be established either by testing or constructional equivalence.



Key

- 1 Mains cable (if applicable)
- 2 Signal output cable as applicable
- 3 Table made of insulating material
- 4 ME EQUIPMENT under test
- 5 Signal input cable as applicable connecting the TRANSDUCER with EUT
- 6 TRANSDUCER

IEC 996/11

Figure 202.101 – Test layout for conducted and radiated emission and radiated immunity test
(see 202.6.1)

202.6.2 * IMMUNITY

202.6.2.1.3 Operating mode and configuration

Addition:

TRANSDUCER shall be tested using all invasive blood pressure monitors specified in the instructions for use of the TRANSDUCER except where the electrical invasive blood pressure monitor design is identical.

Invasive blood pressure monitor shall be tested using all TRANSDUCER(S) specified in the instructions for use of the invasive blood pressure monitor except where the electrical TRANSDUCER design is identical.

202.6.2.1.10 Compliance criteria

Addition:

ME EQUIPMENT shall not change the operating state, lose or change any stored data, generate errors in control software that cause an unintended change in output, or cause errors in blood pressure readings that are outside of the MANUFACTURER'S specifications. The ME EQUIPMENT shall comply with the requirements of 6.2.1.10 of IEC 60601-1-2:2007 and the accuracy requirements of 201.12.1.101.2 except for subclauses 202.6.2.2.1 and 202.6.2.101 in this particular standard. These criteria do not apply during ESD testing.

Compliance is checked by the following test:

- *Setup the ME EQUIPMENT and TRANSDUCER as outlined in Figure 202.101.*
- *Balance the TRANSDUCER to obtain zero pressure at zero pressure input.*
- *Expose the ME EQUIPMENT and TRANSDUCER sequentially to the specified disturbances (radiofrequency, transients, magnetic) at any NOMINAL SENSITIVITY.*

202.6.2.2 ELECTROSTATIC DISCHARGE (ESD)

202.6.2.2.1 Requirements

Addition:

The ME EQUIPMENT may show temporary DEGRADATION during discharges. Within 10 s the ME EQUIPMENT shall resume normal operation in the previous operating mode, without loss of OPERATOR settings or stored data, and shall continue to perform its intended function and comply with the requirement as specified in 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:

- aa) Any SIGNAL INPUT PART/SIGNAL OUTPUT PART cable and POWER SUPPLY CORD are arranged generally as in Figure 202.101. Maintain distances of ≥ 40 cm between SIP/SOP cables and the floor (ground plane).*

202.6.2.4 Electrical fast transients and burst

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 as specified in 202.6.2.1.10.

Testing of TRANSDUCER, signal and interconnecting cables specified to be more than 3 m in length may show temporary DEGRADATION during exposure of fast transients and bursts. Within 10 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 comply with the requirement as specified in 202.6.2.1.10.

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 as specified in 202.6.2.1.10.
- bb) * TRANSDUCER cables are exempt from this requirement.

202.6.2.6.2 Tests

Addition:

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

Addition:

202.6.2.101 * Electrosurgery interference

Means shall be provided to protect against malfunction caused by electrosurgery. Perform the test below, using any TRANSDUCER, TRANSDUCER cables and settings recommended by the MANUFACTURER.

When the ME EQUIPMENT has been used together with HF SURGICAL EQUIPMENT it shall return to the previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL EQUIPMENT without loss of any stored data.

Compliance is tested (a) according to Figures 202.102 and 202.104. If the isolation of the TYPE OF APPLIED PARTS is in the TRANSDUCER, the compliance test is (b) according to Figures 202.103 and 202.104.

Use HF SURGICAL EQUIPMENT which complies with IEC 60601-2-2 and has a minimum power cut mode capability of 300 W, a minimum power coagulation mode capability of 100 W, and a working frequency of $400\text{ kHz} \pm 10\%$.

a) Test in cut mode

Set the blood pressure monitor to a range of 120 mmHg to 150 mmHg and the output power of the HF SURGICAL EQUIPMENT to the 300 W setting. Calibrate the monitor with the zero line visible. Set any filter to a wideband position. For test (a) adjust the resistor R_t to generate a simulated pressure signal of 100 mmHg. For test (b) apply an external static pressure of 100 mmHg.

Touch the metal plate in the test set-up (see Figures 202.102 and 202.103) with the ACTIVE ELECTRODE and remove the electrode slowly to get an arc.

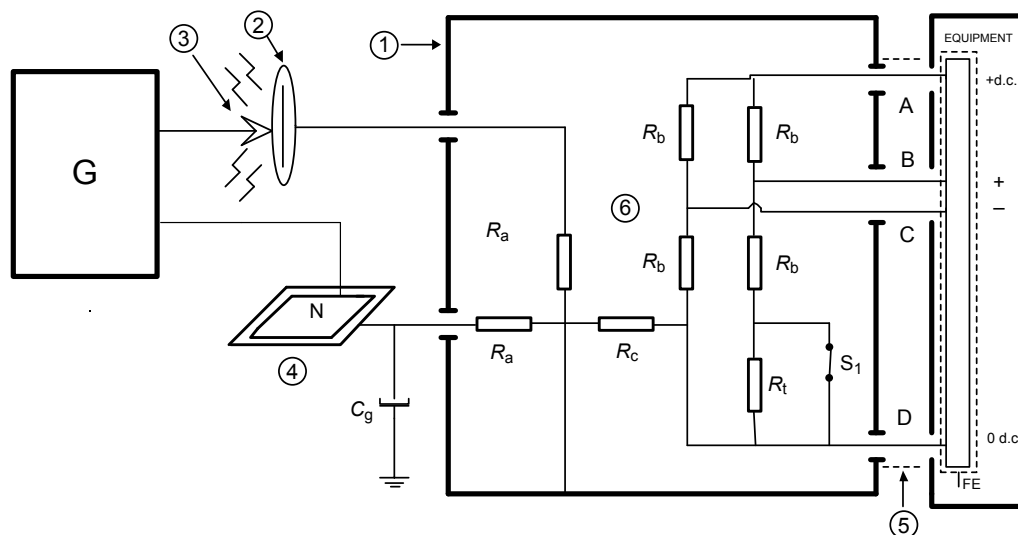
Immediately after the operation open S_1 in Figure 202.103 (test (a) only). Verify whether the applied pressure is recorded/displayed within 10 s and the ME EQUIPMENT returns to the previous operating mode without loss of any stored data.

Repeat the procedure five times.

b) Test in the coagulation mode

Repeat the test in item a) except with an output power of 100 W.

Test of the spray coagulation mode is excluded.



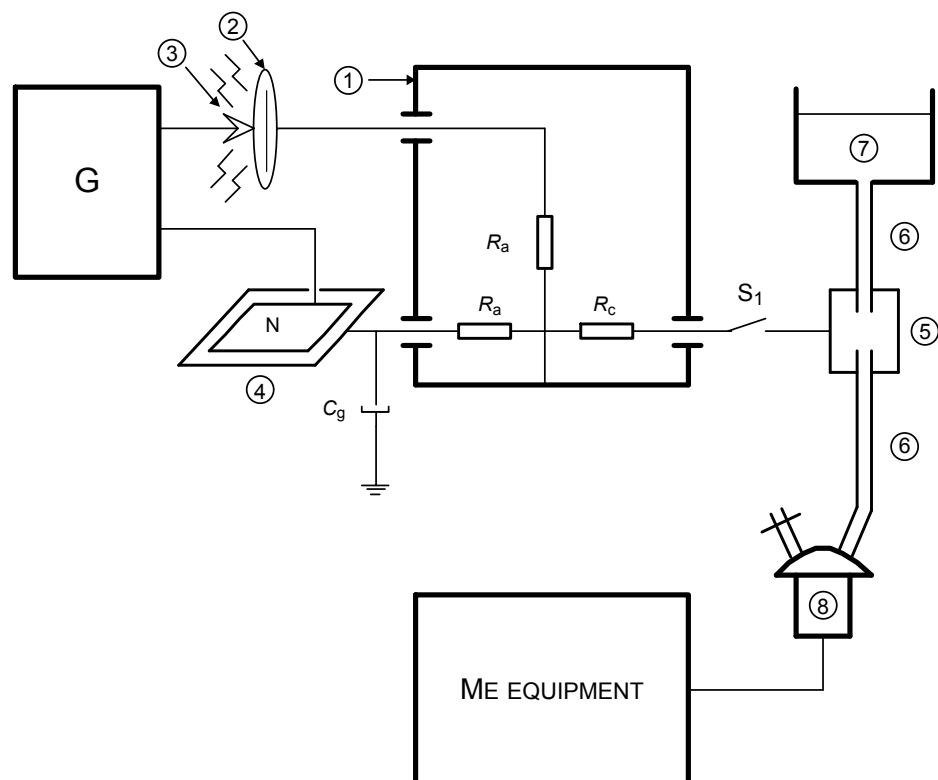
Key

- 1 Metal box
- 2 Metal plate
- 3 ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
- 4 Metal plate/NEUTRAL ELECTRODE (N) of HF SURGICAL EQUIPMENT
- 5 Connecting cable; 2 m cable length between ME EQUIPMENT and metal box; screen around connecting cable
- 6 Coupling network
- G HF SURGICAL EQUIPMENT
- R_a 220 Ω , 200 W (low-inductive, simulates PATIENT impedance)
- R_b 500 Ω (simulates TRANSDUCER bridge)
- R_c 50 k Ω (simulates CATHETER impedance)
- R_t selected for 100 mmHg
- C_g 47 nF (to minimise the influence of different types of HF SURGERY EQUIPMENT designs)
- S_1 Switch

IEC 997/11

NOTE The test report should identify the HF SURGICAL EQUIPMENT that was used.

Figure 202.102 – Test circuit for high-frequency surgery interference measurement, when the isolation of the APPLIED PART is in the monitor
(see 202.6.2.101)



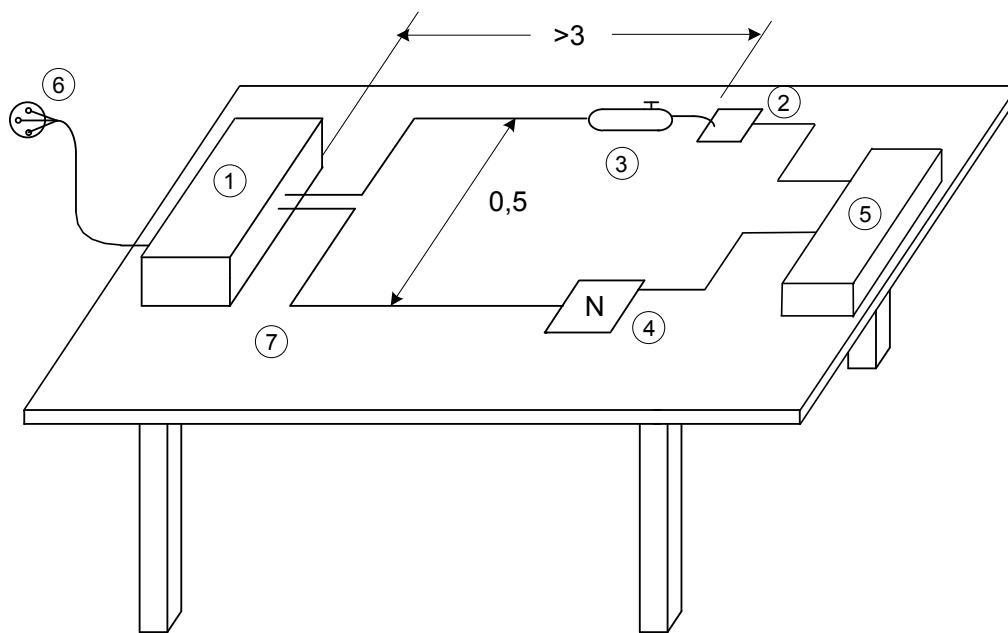
IEC 998/11

Key

- 1 Metal box
- 2 Metal plate
- 3 ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
- 4 Metal plate/neutral electrode (N) of HF SURGICAL EQUIPMENT
- 5 Metal container
- 6 Non-conductive tubing
- 7 Physiological saline solution in non-conductive container; pressure of 12,5 kPa (100 mmHg; 1,26 water)
- 8 TRANSDUCER with DOME; stopcock closed
- G HF SURGICAL EQUIPMENT
- R_a 220 Ω , 200 W (low-inductive, simulates PATIENT impedance)
- R_c 50 k Ω (simulates CATHETER impedance)
- C_g 47 nF (to minimise the influence of different types of HF SURGICAL EQUIPMENT designs)
- S_1 Switch; closed when applying power

NOTE The test report should identify the HF SURGICAL EQUIPMENT that was used.

**Figure 202.103 – Test circuit for high-frequency surgery protection,
when the isolation of the APPLIED PART is in the TRANSDUCER
(see 202.6.2.101)**



IEC 999/11

Key

- 1 HF SURGICAL EQUIPMENT
- 2 Metal plate from Figures 202.102 and 202.103
- 3 ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
- 4 Neutral electrode of the HF SURGICAL EQUIPMENT from figures 202.102 and 202.103
- 5 Test set-up according to Figures 202.102 and 202.103
- 6 SUPPLY MAINS
- 7 Table made of insulating material

Figure 202.104 – Test set-up for high-frequency surgery protection
(see 202.6.2.101)

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 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 subclause 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 monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR in NORMAL USE:

Table 208.101 – ALARM CONDITION priorities for ME EQUIPMENT intended to monitor PATIENTS who are not continuously attended by a clinical OPERATOR

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM ^a		
	Immediate ^b	Prompt ^c	Delayed ^d
Death or irreversible injury	HIGH PRIORITY ^e	HIGH PRIORITY	MEDIUM PRIORITY
Reversible injury	HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Minor injury or discomfort	MEDIUM PRIORITY	LOW PRIORITY	LOW PRIORITY
^a Onset of potential HARM refers to when an injury occurs and not to when it is manifested. ^b Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action. ^c Having the potential for the event to develop within a period of time usually sufficient for manual corrective action. ^d Having the potential for the event to develop within an unspecified time greater than that given under “prompt”. ^e Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.			

208.6.3.3 Auditory ALARM SIGNALS

208.6.3.3.1 * Characteristics of auditory ALARM SIGNALS

Addition:

For ME EQUIPMENT that includes in its INTENDED USE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR in NORMAL USE:

- auditory ALARM SIGNALS shall annunciate for LOW PRIORITY ALARM CONDITIONS (delete footnote “d” from Table 3 of IEC 60601-1-8:2006);
- replace “> 15 s or no repeat” with “2,5 s to 30,0 s” in the “LOW PRIORITY ALARM SIGNAL” column of Table 3 of IEC 60601-1-8:2006;
- auditory ALARM SIGNALS shall annunciate for TECHNICAL ALARM CONDITIONS.

Table 208.102 modifies Table 3 – Characteristics of the burst of auditory ALARM SIGNALS, for ME EQUIPMENT that includes in its INTENDED USE monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR in NORMAL USE:

Table 208.102 – Characteristics of the BURST of auditory ALARM SIGNALS for ME EQUIPMENT intended to monitor PATIENTS who are not continuously attended by a clinical OPERATOR

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL
Number of PULSES in BURST ^{a, e}	10	3	1 or 2
PULSE spacing (t_s) (see Table 208.101)			
between 1 st and 2 nd PULSE	x	y	y
between 2 nd and 3 rd PULSE	x	y	Not applicable
between 3 rd and 4 th PULSE	$2x + t_d$	Not applicable	Not applicable
between 4 th and 5 th PULSE	x	Not applicable	Not applicable
between 5 th and 6 th PULSE	0,35 s to 1,30 s	Not applicable	Not applicable
between 6 th and 7 th PULSE	x	Not applicable	Not applicable
between 7 th and 8 th PULSE	x	Not applicable	Not applicable
between 8 th and 9 th PULSE	$2x + t_d$	Not applicable	Not applicable
between 9 th and 10 th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL ^{b, c} (t_b)	2,5 s to 15,0 s	2,5 s to 30,0 s	>2,5 s to 30 s
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB
Where x shall be a value between 50 ms and 125 ms. Where y shall be a value between 125 ms and 250 ms. The variation of x and y within a BURST shall be $\pm 5\%$. MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$.			
^a See also Table 4 of IEC 60601-1-8:2006 for characteristics of the PULSE. ^b Unless otherwise specified in a particular standard for a particular ME EQUIPMENT. ^c MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the source of the ALARM CONDITION. ^e Unless inactivated by the clinical OPERATOR, MEDIUM PRIORITY and LOW PRIORITY auditory ALARM SIGNALS shall complete at least one BURST, and HIGH PRIORITY auditory ALARM SIGNALS shall complete at least half of one BURST.			

The ACCOMPANYING DOCUMENTS shall describe how the RESPONSIBLE ORGANIZATION may enable or disable auditory ALARM SIGNALS for LOW PRIORITY ALARM CONDITIONS and may restrict access to control over the INTERBURST INTERVAL for all auditory ALARM SIGNALS. The requirements of 6.7 of IEC 60601-1-8:2006 apply.

NOTE This adaptation of Table 3 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 to repeat for LOW PRIORITY ALARM CONDITIONS such as for intensive care units when central monitoring is not being used.

RISK MANAGEMENT shall be applied to determine the maximum INTERBURST INTERVAL for auditory ALARM SIGNALS associated with HIGH, MEDIUM, and LOW PRIORITY ALARM CONDITIONS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

208.6.3.3.2 Volume of auditory ALARM SIGNALS and INFORMATION SIGNALS

Addition:

208.6.3.3.2.101 * Volume of auditory ALARM SIGNALS reducible to zero

If the clinical OPERATOR reduces the volume of auditory ALARM SIGNALS to zero (no sound pressure), the ALARM SIGNAL inactivation state AUDIO OFF shall be initiated, unless ME EQUIPMENT is part of a DISTRIBUTED ALARM SYSTEM where the ALARM SIGNALS are repeated at remote components of a DISTRIBUTED ALARM SYSTEM.

Compliance is checked by functional test.

208.6.4.2 * Delays to or from a DISTRIBUTED ALARM SYSTEM

Addition:

The ALARM SIGNAL GENERATION DELAY of PHYSIOLOGICAL ALARM CONDITIONS and TECHNICAL ALARM CONDITIONS at remote equipment shall be limited so that PATIENT treatment is not unacceptably delayed. RISK MANAGEMENT shall be applied to determine the maximum ALARM SIGNAL delay time that is acceptable before presentation of ALARM SIGNALS at remote components of a DISTRIBUTED ALARM SYSTEM.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

208.6.6 ALARM LIMIT**208.6.6.2 Adjustable ALARM LIMIT**

Addition:

208.6.6.2.101 * Physiological ALARM CONDITIONS, ALARM LIMITS and delay time of physiological ALARM SIGNALS

- a) ME EQUIPMENT shall provide at least one of the following physiological parameters for alarm selection:
 - Systolic pressure
 - Diastolic pressure
 - Mean pressure
- b) The ALARM LIMITS of PHYSIOLOGICAL ALARM CONDITIONS shall be adjustable. The range of adjustment shall cover the specified measurement range for the physiological pressures provided by the ME EQUIPMENT.

Compliance is checked by inspection and testing.

- c) Time to alarm

The sum of ALARM CONDITION DELAY and ALARM SIGNAL GENERATION DELAY shall not exceed 20 s for a value of pressure that exceeds the high ALARM LIMIT or falls below the low ALARM LIMIT.

Figure 208.101 describes the test configuration for compliance. Although actual pressure sources are shown, any equivalent means (i.e. electrical pressure simulators) of generating sinusoidal or physiological pressures may be used. Sinusoidal or simulated pressure signals are to be 1 Hz.

Compliance is determined as follows:

Pressures are set to within $\pm 5\%$ of their indicated values to allow pressure steps of less than 2 s.

Upper systolic ALARM LIMIT:

Disable the diastolic, mean and lower systolic pressure ALARM LIMITS.

Set the upper systolic ALARM LIMIT to 50 % of the arterial measurement range (AMR). Using static and sine-wave pressure sources, generate an output reading of systolic pressure of (25 ± 5) % of the AMR (see Figure 208.102 a).

Within less than 2 s, vary the static and sine-wave pressures until a systolic pressure of (75 ± 5) % of the AMR is reached. Record the time to generate an ALARM SIGNAL.

Lower systolic ALARM LIMIT:

Disable the diastolic, mean and upper systolic pressure ALARM LIMITS.

Set the lower systolic ALARM LIMIT to 45 % of the AMR. Using the static and sine-wave pressure sources to generate an output reading of systolic pressure of 75 % of the AMR (see Figure 208.102 b).

By using a step of less than 2 s, vary the static and sine-wave pressures until a systolic pressure of 25 % of the AMR is reached. The time to generate ALARM SIGNALS must not exceed 20 s.

Upper diastolic ALARM LIMIT:

Disable the systolic, mean and lower diastolic ALARM LIMITS.

Set the upper diastolic ALARM LIMIT to 50 % of the AMR. Using static and sine-wave pressure sources to generate an output reading of diastolic pressure of 25 % of the AMR (see Figure 208.102 c).

By using a step of less than 2 s, vary the static and sine-wave pressures until a diastolic pressure of 75 % of the AMR is reached. The time to generate ALARM SIGNALS must not exceed 20 s.

Lower diastolic ALARM LIMIT:

Disable the systolic, mean and upper diastolic ALARM LIMITS.

Set the lower diastolic ALARM LIMIT to 45 % of the AMR. Using static and sine-wave pressure sources to generate an output reading of diastolic pressure of 75 % of the AMR (see Figure 208.102 d).

By using a step of less than 2 s, vary the static and sine-wave pressures until a diastolic pressure of 25 % of the AMR is reached. The time to generate ALARM SIGNALS must not exceed 20 s.

Upper mean ALARM LIMIT:

Disable the systolic, diastolic and lower mean ALARM LIMITS.

Set the upper mean ALARM LIMIT to 50 % of the AMR. Using static and sine-wave pressure sources to generate an output reading of mean pressure of 25 % of the AMR (see Figure 208.102 e).

By using steps of less than 2 s, vary the static and sine-wave pressures until a mean pressure of 75 % of the AMR is reached. The time to generate ALARM SIGNALS must not exceed 20 s.

Lower mean ALARM LIMIT: