



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN 60601-2-34:2014. It is identical to IEC 60601-2-34:2011. It supersedes BS EN 60601-2-34:2001, which will be withdrawn on 27 June 2017.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/4, Electromedical equipment.

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

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

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EN 60601-2-34

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Supersedes EN 60601-2-34:2000

English Version

Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment (IEC 60601-2-34:2011)

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
(CEI 60601-2-34:2011)

Medizinische elektrische Geräte - Teil 2-34: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von invasiven Blutdruck-
Überwachungsgeräten
(IEC 60601-2-34:2011)

This European Standard was approved by CENELEC on 2011-05-16. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of document 62D/906/FDIS, future edition 3 of IEC 60601-2-34, prepared by SC 62D, "Electromedical equipment", of IEC TC 62, "Electrical equipment in medical practice", was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-34:2014.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2014-12-27
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2017-06-27

This document supersedes EN 60601-2-34:2000.

EN 60601-2-34:2014 was revised to align structurally with EN 60601-1:2006.

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.

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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60601-2-34:2011 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 80601-2-30 NOTE Harmonized as EN 80601-2-30.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of the general standard applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replacement:</i>				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
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	EN 60601-1-8 + corr. March	2007 2010
<i>Addition:</i>				
IEC 60601-2-2	2009	Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2 + A11	2009 2011
IEC 60601-2-27	-	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	EN 60601-2-27 ¹⁾	-
IEC 60601-2-49	-	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment	EN 60601-2-49 ¹⁾	-
ISO 15223-1	2007	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	EN ISO 15223-1	2012

¹⁾ At draft stage.

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except as follows:

- Essential Requirement 6a
- Essential Requirement 7.4
- Essential Requirement 7.5 paragraph 2 & 3
- Essential Requirement 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

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

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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

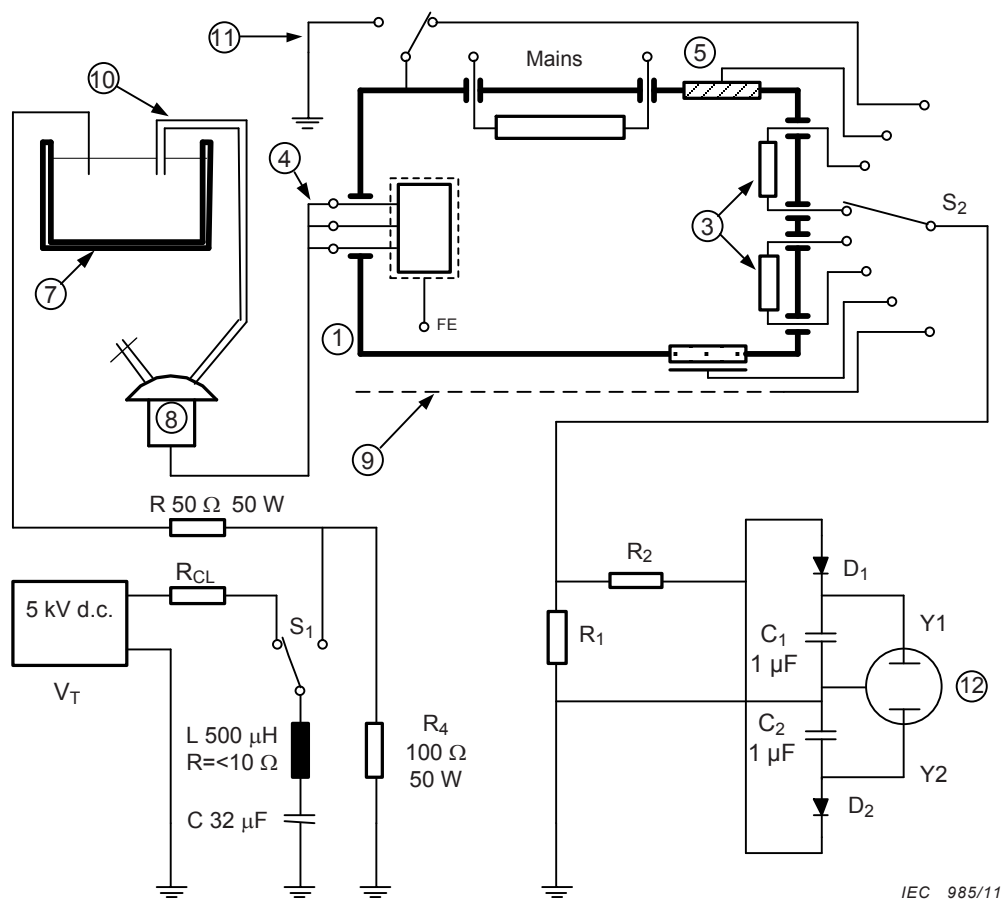
- *Connect the PROTECTIVE EARTH TERMINAL and any FUNCTIONAL EARTH TERMINAL to the PROTECTIVE EARTH TERMINAL of the test circuit.*

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.



IEC 985/11

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.

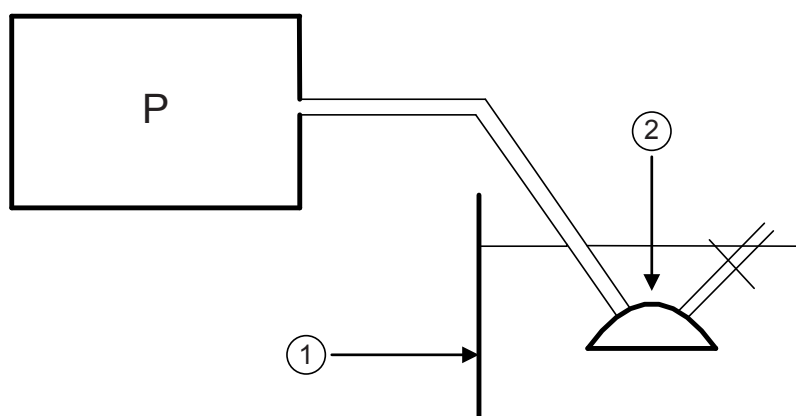
NOTE 2 50 Ω simulates the resistance of a low impedance CATHETER filled with physiological saline or a CATHETER TIP TRANSDUCERS.

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)



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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)

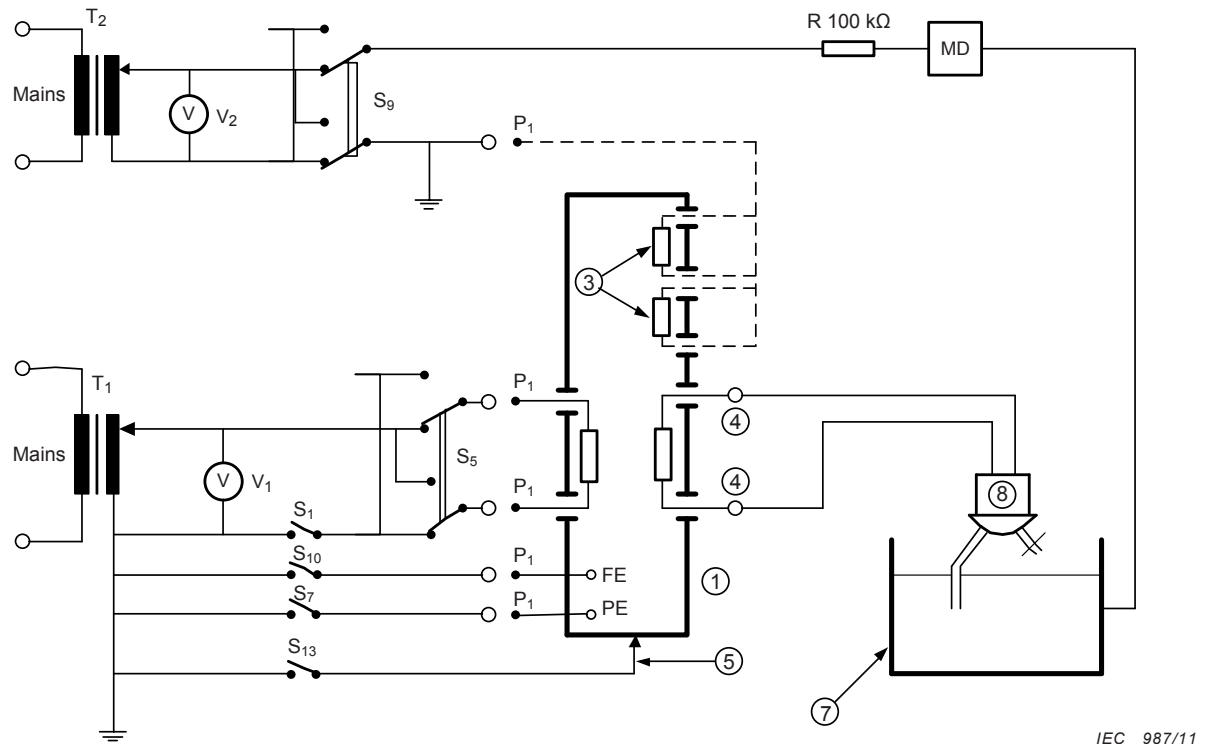
201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

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.



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 |
| P ₁ | 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 S_7 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)