IEC 62353

Edition 2.0 2014-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment

Appareils électromédicaux – Essai récurrent et essai après réparation d'un appareil électromédical

IEC 62353:2014-09(en-fr)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
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.

IEC Catalogue - webstore.iec.ch/catalogue
The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in 14 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
More than 55 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

A propos de l'IEC
La Commission Electrotechnique Internationale (IEC) 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 IEC
Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Catalogue IEC - webstore.iec.ch/catalogue
Application autonome pour consulter tous les renseignements bibliographiques sur les Normes internationales, Spécifications techniques, Rapports techniques et autres documents de l'IEC. Disponible pour PC, Mac OS, tablettes Android et iPad.

Recherche de publications IEC - www.iec.ch/searchpub
La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études,…). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et aussi une fois par mois par email.

Electropedia - www.electropedia.org
Le premier dictionnaire en ligne de termes électroniques et électriques. Il contient plus de 30 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans 14 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary
Plus de 55 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

Service Clients - webstore.iec.ch/csc
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: csc@iec.ch.

IEC 62353

Edition 2.0 2014-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment

Appareils électromédicaux – Essai récurrent et essai après réparation d'un appareil électromédical

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX XB

ICS 11.040

ISBN 978-2-8322-1847-1

Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – RECURRENT TEST AND TEST AFTER REPAIR OF MEDICAL ELECTRICAL 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 62353 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 62353 published in 2007.

This edition constitutes a technical revision. The principle revisions are:

a) clarification in 5.3.4.1 that measurements of leakage currents based on test configurations derived from IEC 60601-1 are an allowable alternative method and the inclusion of informative explanation in Annex A;
b) revision of the PROTECTIVE EARTH RESISTANCE requirements for MEDICAL ELECTRICAL SYSTEMS using multiple socket outlets to take account of IEC 60601-1:2005/AMD1:2012 on the safe allowed values of protective earth resistance of plugged-in equipment;
c) the inclusion of expected minimum insulation resistance values in Table 2; and
d) a reordering of the sequence of testing in Annex B.

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

FDIS	Report on voting
62A/942/FDIS	62A/953/RVD

Full information on the voting for the approval of this 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;

– 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 USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3: IN SMALL CAPITALS.

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 A.

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.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

MEDICAL ELECTRICAL EQUIPMENT – RECURRENT TEST AND TEST AFTER REPAIR OF MEDICAL ELECTRICAL EQUIPMENT

1 Scope

This International Standard applies to testing of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS, or parts of such equipment or systems, which comply with IEC 60601-1:1988 (second edition) and its amendments and IEC 60601-1: 2005 (third edition) and its amendments, before PUTTING INTO SERVICE, during MAINTENANCE, INSPECTION, SERVICING and after REPAIR or on occasion of RECURRENT TESTS to assess the safety of such ME EQUIPMENT or ME SYSTEMS or parts thereof. For equipment not built to IEC 60601-1 these requirements may be used taking into account the safety standards for the design and information in the instructions for use of that equipment.

This standard contains tables with allowable values relating to different editions of IEC 60601-1. For the purpose of this standard, the application of measuring methods is independent of the edition according to which the ME EQUIPMENT or ME SYSTEM is designed.

This standard contains:

– "general requirements", which contain clauses of general concern, and
– "particular requirements", further clauses handling special types of ME EQUIPMENT or ME SYSTEMS and applying in connection with the "General requirements".

NOTE At this stage, there are no particular requirements.

This standard is not suitable to assess whether ME EQUIPMENT or ME SYSTEMS or any other equipment comply with the relevant standards for their design.

This standard is not applicable to the assembly of ME SYSTEMS. For assembling ME SYSTEMS see Clause 16 of IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012[1].

This standard does not define requirements for REPAIR, exchange of components and MODIFICATION of ME EQUIPMENT or ME SYSTEMS.

All MAINTENANCE, INSPECTION, SERVICING, and REPAIR done in accordance with MANUFACTURER's instructions maintain the conformity to the standard used for the design of the equipment. Otherwise conformity to applicable requirements should be assessed and verified, before the tests of this standard are performed.

This standard is also applicable to tests after REPAIR.

IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012 requires that, as part of the RISK MANAGEMENT PROCESS, the MANUFACTURER considers how the safety of ME EQUIPMENT or an ME SYSTEM can be ensured during product lifetime. As part of the risk management process the MANUFACTURER may have identified MAINTENANCE procedures. This includes defining the respective tests for ME EQUIPMENT or for ME SYSTEM.

---

[1] This citation refers to IEC 60601-1:2005 as amended by Amendment 1 published in 2012.

The MANUFACTURER may have defined necessary measurement settings and methods including performance assurance tests in the instructions for use or other ACCOMPANYING DOCUMENTS. This standard provides consistent test procedures.

This standard is not intended to define time intervals for RECURRENT TESTS. If such intervals are not defined by the MANUFACTURER, Annex F can be used to help establish such intervals.

Testing of the electrical installation, including the SUPPLY MAINS and associated wiring, in medical locations is excluded from this standard. Such tests are covered by IEC 60364-7-710 or national equivalents,

2 Normative references

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

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
IEC 60601-1:1988/AMD1:1991
IEC 60601-1:1988/AMD 2:1995

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* [2]
IEC 60601-1:2005/AMD1:2012

IEC 60417, *Graphical symbols for use on equipment.* Available from: <http://www.graphical-symbols.info/equipment>

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements*

IEC 61010-031, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 031: Safety requirements for hand-held probe assemblies for electrical measurement and test*

IEC 61140, *Protection against electric shock – Common aspects for installation and equipment*

IEC 61557-1, *Electrical safety in low voltage distribution systems up to 1 000 V a.c. and 1 500 V d.c. – Equipment for testing, measuring or monitoring of protective measures – Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE Some of the definitions are necessarily different from those in IEC 60601-1, as different measuring methods are used.

---

2 There exists a consolidated edition 3.1 including IEC 60601-1:2005 and its Amendment 1 (2012).

3.1
ACCESSIBLE CONDUCTIVE PART
an electrically conductive part of the ME EQUIPMENT other than an APPLIED PART, which is accessible to the patient or to the operator in contact with the patient or can come in contact with the patient

3.2
ACCESSORY
additional part for use with equipment in order to:

– achieve the intended use,
– adapt it to some special use,
– facilitate its use,
– enhance its performance, or
– enable its functions to be integrated with those of other equipmentt

[SOURCE: IEC 60601-1:2005, 3.3]

3.3
ACCOMPANYING DOCUMENT
document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or operator, particularly regarding basic safety and essential performance

[SOURCE: IEC 60601-1:2005, 3.4]

3.4
APPLIED PART

part of ME EQUIPMENT that in normal use necessarily comes into physical contact with the patient for ME EQUIPMENT or an ME SYSTEM to perform its function

[SOURCE: IEC 60601-1:2005, 3.8, modified – The notes in the original definition have been deleted because they were only internally relevant to the source document.]

3.5
APPLIED PART LEAKAGE CURRENT
current flowing between an F-TYPE APPLIED PART and all of the following as applicable:

– MAIN PARTS and
– ACCESSIBLE CONDUCTIVE PARTS of the enclosure;

caused by an external voltage on the F-TYPE APPLIED PART.

3.6
CLASS I
term referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for accessible parts of metal or internal parts of metal to be protectively earthed

[SOURCE: IEC 60601-1:2005, 3.13]

3.7
CLASS II
term referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions

Note 1 to entry: CLASS II ME EQUIPMENT can be provided with a functional earth terminal or a functional earth conductor.

[SOURCE: IEC 60601-1:2005, 3.14]

3.8
CONFIGURATION
term that refers to software settings or hardware settings of ME EQUIPMENT, or the arrangement and interconnection of ME EQUIPMENT and any other equipment that form an ME SYSTEM, that are appropriate for an intended clinical application

3.9
DETACHABLE POWER SUPPLY CORD
flexible cord intended to be connected to electrical equipment by means of a suitable appliance coupler for mains supply purposes

[SOURCE: IEC 60601-1:2005, 3.21]

3.10
EARTH LEAKAGE CURRENT
current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.25, modified – Reference to the functional earth connection removed.]

3.11
ELECTRICAL SAFETY
status of protective measures within an equipment/system designed and produced in accordance with IEC 60601-1 which limit the effects of electrical current on a patient, user or other individuals in accordance with this standard

Note 1 to entry: Safety is defined as freedom from unacceptable risk (refer to ISO 14971:2007, definition 2.24).

3.12
EQUIPMENT LEAKAGE CURRENT
total current flowing from MAINS PARTS to earth via

a) the PROTECTIVE EARTH CONDUCTOR and ACCESSIBLE CONDUCTIVE PARTS of the enclosure and APPLIED PARTS (differential and alternative method), or

b) the ACCESSIBLE CONDUCTIVE PARTS of the enclosure and APPLIED PARTS (direct method)

3.13
F-TYPE ISOLATED (FLOATING) APPLIED PART (herein F-TYPE APPLIED PART)
APPLIED PART in which the patient connections are isolated from other parts of the ME EQUIPMENT to such a degree that no current higher than the allowable PATIENT LEAKAGE CURRENT flows if an unintended voltage originating from an external source is connected to the patient, and thereby applied between the patient connection and earth

Note 1 to entry: F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

[SOURCE: IEC 60601-1:2005, 3.29]

3.14
FUNCTIONAL CONNECTION
connection, electrical or otherwise, including those intended to transfer signals, data, power or substances

Note 1 to entry: Connection to a fixed SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

[SOURCE: IEC 60601-1:2005, 3.33]

3.15
INSPECTION
combination of all means for verification and assessment of a status quo

3.16
INTERNAL ELECTRICAL POWER SOURCE
electrical power source for operating equipment that is a part of the equipment and which produces electrical current from some other form of energy

EXAMPLE Chemical, mechanical, solar, or nuclear

Note 1 to entry: An INTERNAL ELECTRICAL POWER SOURCE can be inside the principal part of equipment, attached to the outside, or contained in a separate enclosure.

[SOURCE: IEC 60601-1:2005, 3.45]

3.17
LINE-TO-EARTH VOLTAGE
voltage between a line conductor and earth/ground.

[SOURCE: IEC 60050-195:1998, 195-05-03, modified – Replaced "reference earth at a given point of an electrical circuit" with "earth/ground".]

3.18
MAINS PART
part of electrical equipment forming a circuit that is intended to be connected to the SUPPLY MAINS

Note 1 to entry: The MAINS PART includes all conductive parts that are not separated from the SUPPLY MAINS by at least one means of protection.

Note 2 to entry: For the purpose of this definition, the PROTECTIVE EARTH CONDUCTOR is not regarded as a part of the MAINS PART.

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.49]

3.19
MAINS PLUG
part, integral with or intended to be attached to a POWER SUPPLY CORD of electrical equipment, to be inserted into a mains socket-outlet

[SOURCE: IEC 60601-1:2005, 3.50, modified – A note referring to IEC 60083 and IEC 60309-1 has been deleted.]

3.20
MAINS VOLTAGE
voltage of a SUPPLY MAINS between two line conductors of a polyphase system or voltage between the line conductor and the neutral conductor of a single-phase system

[SOURCE: IEC 60601-1:2005, 3.54]

3.21
MAINTENANCE
combination of all technical and administrative means, including supervisory ones, to keep ME EQUIPMENT or an ME SYSTEM in a normal working condition or restored to normal working condition

3.22
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

Note 1 to entry: ISO 13485 [9][3] defines "labelling" as written, printed or graphic matter

- affixed to a medical device or any of its containers or wrappers, or
- accompanying a medical device,

related to identification, technical description and use of the medical device, but excluding shipping documents. In this standard, that material is described as markings and ACCOMPANYING DOCUMENTS.

Note 2 to entry: "Adapting" includes making substantial MODIFICATIONS to ME EQUIPMENT or an ME SYSTEM already in use.

Note 3 to entry: In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

Note 4 to entry: Adapted from ISO 14971:2007 [10], definition 2.8.

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.55]

3.23

MEDICAL ELECTRICAL EQUIPMENT
ME EQUIPMENT
electrical equipment having an APPLIED PART or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS, and
b) intended by its MANUFACTURER to be used:
   – in the diagnosis, treatment, or monitoring of a patient, or
   – for compensation or alleviation of disease, injury or disability

Note 1 to entry: ME EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the normal use of the ME EQUIPMENT.

Note 2 to entry: Not all electrical equipment used in medical practice falls within this definition (e.g. some *in vitro* diagnostic equipment).

Note 3 to entry: The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of IEC 60601-1.

[SOURCE: IEC 60601-1:2005, 3.63, modified – Two notes in the original definition have been deleted because they were only internally relevant to the source document.]

3.24
MEDICAL ELECTRICAL SYSTEM (ME SYSTEM)
combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET

[3] Numbers in square brackets refer to the Bibliography.

Note 1 to entry: Equipment, when mentioned in this standard, should be taken to include ME EQUIPMENT.

Note 2 to entry: ME SYSTEM includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the normal use of the ME SYSTEM.

[SOURCE: IEC 60601-1:2005, 3.64, modified – A second note to entry has been added.]

3.25
MODIFICATION
changing constructional or functional features of ME EQUIPMENT or an ME SYSTEM in a way not described in its ACCOMPANYING DOCUMENTS

Note 1 to entry: This definition should not be confused with "change of ACCESSORIES" because the latter means changing of ME EQUIPMENT or ME SYSTEMs in a way described in its ACCOMPANYING DOCUMENTS.

3.26
MULTIPLE SOCKET-OUTLET
MSO
one or more socket-outlets intended to be connected to, or integral with, flexible cables, cords or ME EQUIPMENT providing SUPPLY MAINS or equivalent voltage

Note 1 to entry: A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.67]

3.27
NON-DETACHABLE POWER SUPPLY CORD
POWER SUPPLY CORD fixed to equipment

3.28
NORMAL CONDITION
condition in which all means provided for protection against hazards are intact

[SOURCE: IEC 60601-1:2005, 3.70]

3.29
PATIENT ENVIRONMENT
any volume in which intentional or unintentional contact can occur between a patient and parts of the ME EQUIPMENT or ME SYSTEM or between a patient and other persons touching parts of the ME EQUIPMENT or ME SYSTEM

Note 1 to entry: It is difficult to define dimensions for the volume in which diagnosis, monitoring or treatment occurs. The dimensions for the PATIENT ENVIRONMENT given in Figure D.1 have been justified in practice.

[SOURCE: IEC 60601-1:2005, 3.79, modified – A note to entry has been added.]

3.30
PATIENT LEAKAGE CURRENT
current:

– flowing from the PATIENT CONNECTIONS via the PATIENT to earth, or
– originating from the unintended appearance of a voltage from an external source on the PATIENT and flowing from the PATIENT via the PATIENT CONNECTIONS of an F-TYPE APPLIED PART to earth

[SOURCE: IEC 60601-1:2005, 3.80]

3.31
PERMANENTLY INSTALLED
term meaning electrically connected to the SUPPLY MAINS by means of a permanent connection that can only be detached by the use of a tool