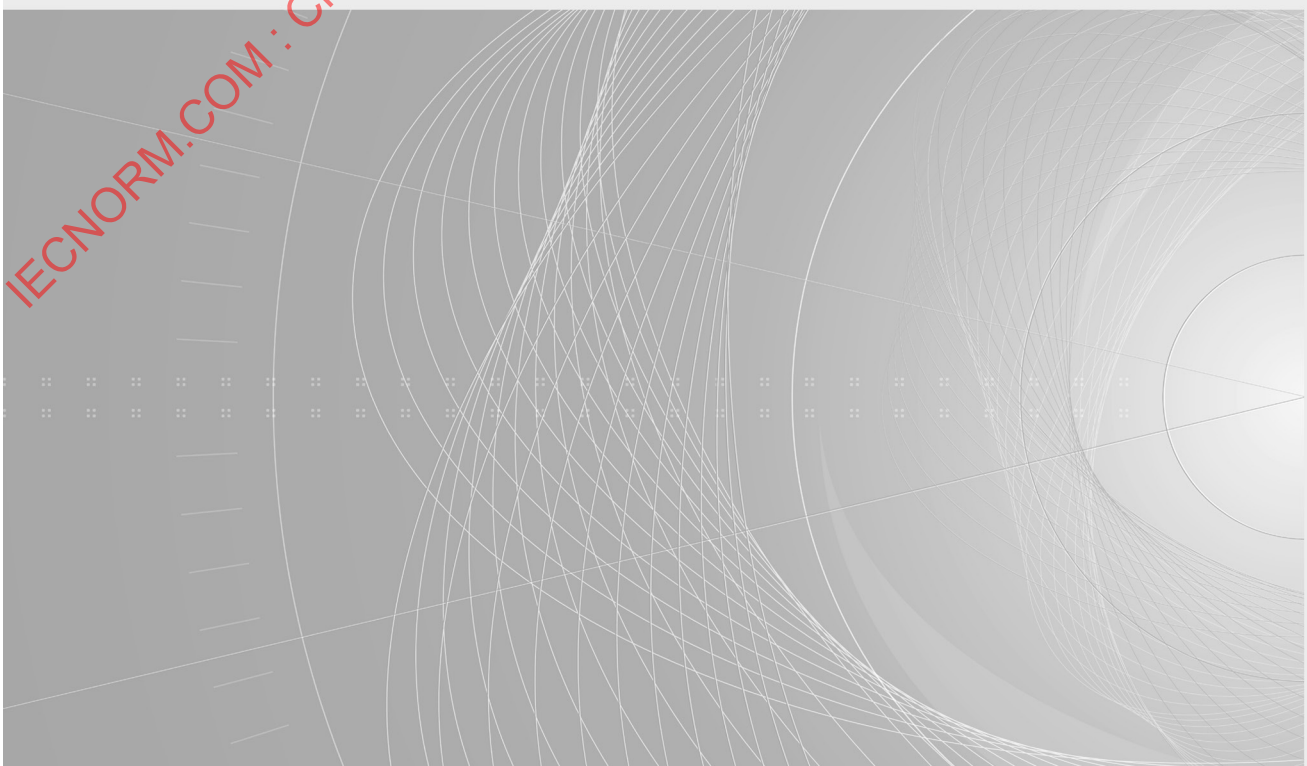
IEC 80601-2-49

Edition 1.1 2024-09
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment –
Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors



IEC 80601-2-49:2018-03+AMD1:2024-09 CSV(en)

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

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors

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.
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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 document may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 80601-2-49 edition 1.1 contains the first edition (2018-03) [documents 62D/1547/FDIS and 62D/1559/RVD] and its amendment 1 (2024-09) [documents 62D/2146/FDIS and 62D/2164/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International standard IEC 80601-2-49 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and of ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This first edition cancels and replaces the second edition of IEC 60601-2-49, published in 2011. This edition constitutes a technical revision to align with the current edition and Amendment to IEC 60601-1, new versions of collateral standards and amendments thereto. Major changes are in Clause 208 because many of the former requirements are now addressed by IEC 60601-1-8.

It is published as a double logo standard.

Full information on the voting for the approval of this document can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by XXX P members out of YYY having cast a vote.

In this document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "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 80601 International Standard, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document and its amendment will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

NOTE The attention of users of this document 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 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 committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this document 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.

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of MULTIFUNCTION PATIENT MONITORS. It amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this edition is to bring this particular standard up to date with reference to the edition 3.1 of the general standard and new versions of collateral standards and amendments thereto through technical changes.

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

A "Particular guidance and rationale" for the 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, this Annex AA does not form part of the requirements of this document.

INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised may be found within the IEC document 62D/1792/DC. The results and comments on the DC may be found within 62D/1808/INF. The review report for this amendment is 62D/1835A/RR.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This part of the 80601 International Standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE requirements of MULTIFUNCTION PATIENT MONITORS as defined in 201.3.201, hereafter referred to as ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS. This particular standard applies to MULTIFUNCTION PATIENT MONITORS intended for use in professional healthcare facilities as well as in the EMERGENCY MEDICAL SERVICE ENVIRONMENT or the HOME HEALTHCARE ENVIRONMENT.

The scope of this document is restricted to ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS intended for connection to a single PATIENT that has two or more PHYSIOLOGICAL MONITORING UNITS.

NOTE For purposes of this document, a pregnant mother and her fetus(es) are considered a single PATIENT.

This document does not specify requirements for individual PHYSIOLOGICAL MONITORING UNITS such as ECG, invasive pressure and pulse oximetry. The particular standards related to these PHYSIOLOGICAL MONITORING UNITS specify requirements from the perspective of stand-alone ME EQUIPMENT. This particular standard addresses the additional requirements related to MULTIFUNCTION PATIENT MONITORS. MULTIFUNCTION PATIENT MONITORS can be integrated into other ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS. When this is the case, other relevant standards also apply.

EXAMPLE 1 MULTIFUNCTION PATIENT MONITOR incorporated into a critical care ventilator where ISO 80601-2-12 also applies.

EXAMPLE 2 MULTIFUNCTION PATIENT MONITOR incorporated into a homecare ventilator for dependent PATIENT where ISO 80601-2-72 also applies.

EXAMPLE 3 MULTIFUNCTION PATIENT MONITOR incorporated into anesthetic workstation where ISO 80601-2-13 also applies.

EXAMPLE 4 MULTIFUNCTION PATIENT MONITOR incorporated into haemodialysis equipment, IEC 60601-2-16 also applies.

This document does not apply to implantable parts of MULTIFUNCTION PATIENT MONITORS.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MULTIFUNCTION PATIENT MONITORS as defined in 201.3.201.

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1 The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020, as well as IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply as modified in Clauses 202, 206 and 208 respectively. IEC 60601-1-3 and IEC 60601-1-9 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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

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

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are 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 document 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 IEC 60601-1-2 collateral standard, 208.6 in this particular standard addresses the content of Clause 6 of the IEC 60601-1-8 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.~~147~~154, additional definitions in this document 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, 208 for IEC 60601-1-8, etc.

The term "this document" 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

NOTE Informative references are listed in the bibliography beginning on page 38.

Clause 2 of the general standard applies, except as follows.

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020

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*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/AMD1:2020

IEC 60601-2-2:2017, *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 60601-2-27:2011, *Medical electrical equipment – Part 2-27, Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11, IEC 60601-1-12, IEC 60601-2-2, IEC 60601-2-27, IEC 60601-2-34 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 39.

Addition:

201.3.201
*** MULTIFUNCTION PATIENT MONITOR**
modular or pre-configured ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS whose primary intended function is monitoring of a single PATIENT, has more than one PHYSIOLOGICAL MONITORING UNIT, either displays those information or distributes the information for remote display, and either includes an ALARM SYSTEM or is a component of a DISTRIBUTED ALARM SYSTEM

201.3.202
PHYSIOLOGICAL MONITORING UNIT
part of the MULTIFUNCTION PATIENT MONITOR whose purpose is to collect physiological signal(s) from a single sensor type and to process it for monitoring

EXAMPLE 1 The pulse oximetry signal can provide information about oxygen saturation, pulse rate, perfusion, etc.

EXAMPLE 2 The signals from ECG ELECTRODES can provide information about ECG and thoracic respiration rate.

Note 1 to entry: Examples of physiological signals include (a) electrocardiography, (b) non-invasive blood pressure, (c) invasive blood pressure, (d) pulse oximetry, (e) temperature, (f) electroencephalography, (g) transcutaneous gas analysis, and (h) respiratory gas analysis. Each of these is a single physiological signal within the meaning of this definition.

Note 2 to entry: It is recognized that more than one variable or parameter may be derived from a single physiological signal.

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements for MULTIFUNCTION PATIENT MONITORS are found in subclauses listed in Table 201.101.

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Displaying data according PRIMARY OPERATING FUNCTIONS	206.101 c)
Determination of ALARM CONDITIONS and assignment of priority	208.6.1.2
Indication of validity of measured values	208.6.3.2.101
or generating a TECHNICAL ALARM CONDITION	208.6.1.2
~~or failure that is readily identifiable by the OPERATOR[a]~~	
~~[a] Examples of failures readily identifiable by the OPERATOR are a completely non-functional MULTIFUNCTION PATIENT MONITOR, a completely non-functional PHYSIOLOGICAL MONITORING UNIT, etc.~~	

201.4.5 * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

Addition before the first paragraph:

When several particular standards simultaneously apply to a MULTIFUNCTION PATIENT MONITOR, all relevant requirements from those standards shall be applied as applicable to BASIC SAFETY and ESSENTIAL PERFORMANCE. If requirements from particular standards are in conflict, the RISK MANAGEMENT PROCESS shall be used to identify which standard's requirement applies. While performing this PROCESS, MANUFACTURERS are strongly recommended to give the requirements of this particular standard additional weight whenever possible.

201.5 General requirements for testing ME EQUIPMENT

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

201.5.4 Other conditions

Addition:

If necessary for the purpose of conducting the test, the INTERNAL ELECTRICAL POWER SOURCE may be replaced by an external battery or a DC power supply to provide the necessary test voltage, for tests according to 201.11.8.101.

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

– resistors: ±1 %;
– capacitors: ±10 %;
– inductors: ±10 %;
– test voltages: ±1 %.

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 associated with MULTIFUNCTION PATIENT MONITOR shall be classified as TYPE BF or 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), unless other applicable particular standards permit non-DEFIBRILLATION-PROOF APPLIED PARTS for the respective PHYSIOLOGICAL MONITORING UNIT or technical limitations prevent the design of DEFIBRILLATION-PROOF APPLIED PARTS.

201.6.6 Mode of operation

Replacement:

MULTIFUNCTION PATIENT MONITORS 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

Additional subclause:

201.7.2.101 Connectors for APPLIED PARTS

Connectors on a MULTIFUNCTION PATIENT MONITOR intended to connect APPLIED PARTS shall be marked to identify the APPLIED PARTS that can be connected.

NOTE Examples of markings are MODEL OR TYPE REFERENCE of the APPLIED PART, function of the APPLIED PART (e.g. ECG, ECG/respiration, SpO_2, temperature, etc.) or color coding.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall include a warning that defibrillator protection requires use of MANUFACTURER specified APPLIED PARTS, PATIENT CABLES, LEAD WIRES, TRANSDUCERS and ACCESSORIES.

201.7.9.2.9 Operating instructions

Additional subclause:

201.7.9.2.9.101 Additional instructions for use

The instructions for use shall include the following:

a) that the use of the MULTIFUNCTION PATIENT MONITOR is restricted to one PATIENT at a time;

b) precautions to take when using a defibrillator on a PATIENT, if APPLIED PARTS not being protected against the effects of defibrillation are being used; a description of how the discharge of a defibrillator affects the MULTIFUNCTION PATIENT MONITOR;

c) information indicating whether the MULTIFUNCTION PATIENT MONITOR incorporates means to protect the PATIENT against burns when used with HIGH-FREQUENCY (HF) SURGICAL EQUIPMENT and advice 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;

d) advice and PROCEDURES regarding testing of the MULTIFUNCTION PATIENT MONITOR and ACCESSORIES on a daily basis (by the clinical OPERATOR).

e) identification of PHYSIOLOGICAL MONITORING UNIT(S) with which the MULTIFUNCTION PATIENT MONITOR is intended to be used;

f) simple fault-finding methods for troubleshooting problems by which the clinical OPERATOR can locate problems if the MULTIFUNCTION PATIENT MONITOR appears to be functioning incorrectly;

g) the subsequent operation of the MULTIFUNCTION PATIENT MONITOR after interruption of the SUPPLY MAINS exceeding 30 s (see 201.11.8);

h) advice on the preferred ALARM SETTINGS and configurations of the ALARM SYSTEM when INTENDED USE includes the monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR;

i) * description of how to invoke an ALARM SIGNAL inactivation state for TECHNICAL ALARM CONDITIONS if sensors, probes, or modules are intentionally disconnected by the clinical OPERATOR;

j) the adjustment ranges of the ALARM LIMITS and the resolution of ALARM LIMIT settings;

k) advice on preferred ALARM SETTINGS and ALARM PRESETS of the ALARM SYSTEM by PATIENT population as needed.

Compliance is checked by inspection of the instructions for use.

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

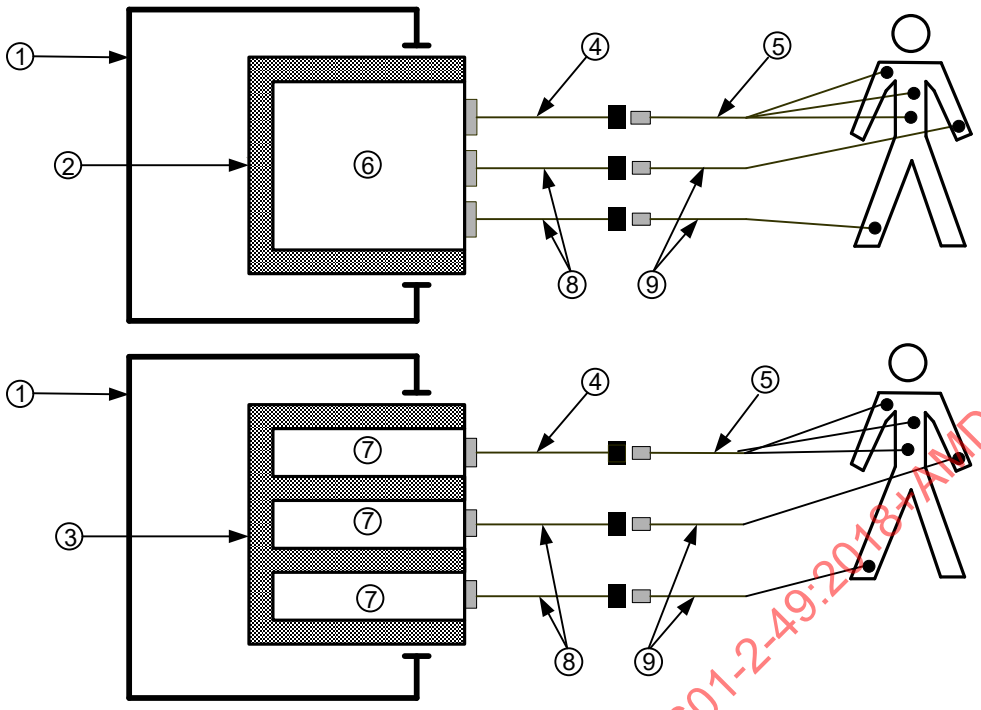
Replacement of item c):

c) An APPLIED PART not covered by a) or b) shall be a TYPE BF APPLIED PART or TYPE CF APPLIED PART.

201.8.5.2.3 * PATIENT leads or PATIENT cables

Addition after the note:

Any connector for electrical connections on a PATIENT lead or PATIENT cable that is at the end of the lead or cable remote from the MULTIFUNCTION PATIENT MONITOR shall be so constructed that conductive parts of said connector cannot be connected to earth or possible hazardous voltage while PATIENT CONNECTIONS of any APPLIED PART, not separated by at least one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE, contact the PATIENT (see Figure 201.101).



IEC

Key

① MULTIFUNCTION PATIENT MONITOR

② Insulation barrier (MOPP) of the PATIENT circuit with multiple (3) PHYSIOLOGICAL MONITORING UNITS

③ Insulation barriers (MOPP) of multiple PATIENT circuits (3) each with a single PHYSIOLOGICAL MONITORING UNIT

④ PATIENT CABLE

⑤ LEAD WIRES

⑥ Single PATIENT circuit with multiple (3) PHYSIOLOGICAL MONITORING UNITS

⑦ Multiple PATIENT circuits (3) each with a single PHYSIOLOGICAL MONITORING UNIT separated from each other by at least one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE

⑧ Extension cable

⑨ PATIENT or sensor cable

□ Connectors at the end of the extension cables, sensor cables, PATIENT CABLES and PATIENT leads remote from the PATIENT

■ Connectors at the end of the extension cables, sensor cables, PATIENT CABLES and PATIENT leads remote from the MULTIFUNCTION PATIENT MONITOR

● PATIENT CONNECTIONS

Figure 201.101 – MULTIFUNCTION PATIENT MONITOR with single PATIENT circuit (6) with multiple PHYSIOLOGICAL MONITORING UNITS and multiple PATIENT circuits (7) each with a single PHYSIOLOGICAL MONITORING UNIT

201.8.5.5.1 * Defibrillation protection

Replacement of last dash in a):

– any unused or disconnected connector at the MULTIFUNCTION PATIENT MONITOR for the connection of APPLIED PART(S). MULTIFUNCTION PATIENT MONITORS that is completely BODY-WORN (e.g. a Holter monitor) is exempt from this requirement.

Addition at the end of b):

Additionally, the MULTIFUNCTION PATIENT MONITOR shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

NOTE 101 The recovery time can be defined in other particular standards

Addition:

aa) MULTIFUNCTION PATIENT MONITORS shall be energized for the common-mode test and differential mode test.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

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

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

Addition:

TRANSPORTABLE MULTIFUNCTION PATIENT MONITORS or TRANSPORTABLE parts of the MULTIFUNCTION PATIENT MONITORS separable while remaining functioning shall have an ingress protection of at least IPX1 so that, in the event of accidental wetting, no loss of BASIC SAFETY or ESSENTIAL PERFORMANCE results from the ingress of liquids

Compliance is checked by the following test:

Expose the TRANSPORTABLE MULTIFUNCTION PATIENT MONITOR *to wetting according of IEC 60529:1989, IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013.*

Immediately after exposure, remove any visible moisture on the ENCLOSURE and confirm that BASIC SAFETY and ESSENTIAL PERFORMANCE of this document are maintained.

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

Replacement:

If the SUPPLY MAINS to the MULTIFUNCTION PATIENT MONITOR 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 MULTIFUNCTION PATIENT MONITOR does not have to be operating during the interruption of the SUPPLY MAINS.

Compliance is checked by observing the MULTIFUNCTION PATIENT MONITOR 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.

Means may be provided to the OPERATOR to select one or more than one of the above options.

Compliance is be checked by functional test.

If the MULTIFUNCTION PATIENT MONITOR contains an INTERNAL ELECTRICAL POWER SOURCE and the SUPPLY MAINS is interrupted, the MULTIFUNCTION PATIENT MONITOR 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 MULTIFUNCTION PATIENT MONITOR continues to conform to this particular standard.

Compliance is checked by interrupting the SUPPLY MAINS and observing that OPERATOR settings and stored data are not changed and that normal operation continues. The 'on-off' switch needs to remain in the 'on' position.

Additional subclause:

201.11.8.101 Protection against depletion of the INTERNAL ELECTRICAL POWER SOURCE

A MULTIFUNCTION PATIENT MONITOR 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 MULTIFUNCTION PATIENT MONITOR (see 201.15.4.4.101).

a) A MULTIFUNCTION PATIENT MONITOR shall provide a TECHNICAL ALARM CONDITION at least 5 min prior to the time that the MULTIFUNCTION PATIENT MONITOR can no longer function in accordance with the MANUFACTURER's specification when powered from the INTERNAL ELECTRICAL POWER SOURCE.

b) When the state of discharge of any INTERNAL ELECTRICAL POWER SOURCE is such that the MULTIFUNCTION PATIENT MONITOR can no longer function in accordance with the MANUFACTURER's specification, the MULTIFUNCTION PATIENT MONITOR shall power down in a manner which causes no HAZARDOUS SITUATION to the PATIENT other than loss of function.

Compliance is checked by functional testing while operating the MULTIFUNCTION PATIENT MONITOR from the INTERNAL ELECTRICAL POWER SOURCE.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

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

201.12.3 ALARM SYSTEMS

Replacement:

A MULTIFUNCTION PATIENT MONITOR that includes an ALARM SYSTEM or is component of a DISTRIBUTED ALARM SYSTEM shall comply with Clause 208 of this particular standard.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

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

201.15.1 Arrangements of controls and indicators of ME EQUIPMENT

Additional subclauses:

201.15.101 Display of PATIENT data

Displayed data (PATIENT data, visual ALARM SIGNALS and visual INFORMATION SIGNALS) shall be CLEARLY LEGIBLE from the intended position of the OPERATOR.

NOTE PATIENT data include real-time waves, numeric values, trends and their time intervals, diagrams and signal quality indicators.

If abbreviations are used, they shall be explained in the instructions for use.

Compliance is checked by inspection of the instructions for use and the tests of the general standard, 7.1.2.

201.15.102 Units of measurement

Units of measurement of PATIENT data should be indicated either continuously or on demand by the OPERATOR.

201.15.4.4 Indicators

Additional subclause:

201.15.4.4.101 Indicator of operation from the INTERNAL ELECTRICAL POWER SOURCE and the status of the INTERNAL ELECTRICAL POWER SOURCE

MULTIFUNCTION PATIENT MONITORS shall visually indicate when they are operating from their INTERNAL ELECTRICAL POWER SOURCE, unless they are only INTERNALLY POWERED.

INTERNALLY POWERED MULTIFUNCTION PATIENT MONITORS shall visually indicate their remaining battery capacity when operating from their INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by inspection and measurement.

201.16 ME SYSTEMS

Clause 16 of the general standard does apply.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standarddoes apply as modified in 202.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

202.7 ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS

202.7.1 Protection of radio services and other EQUIPMENT

Additional subclause:

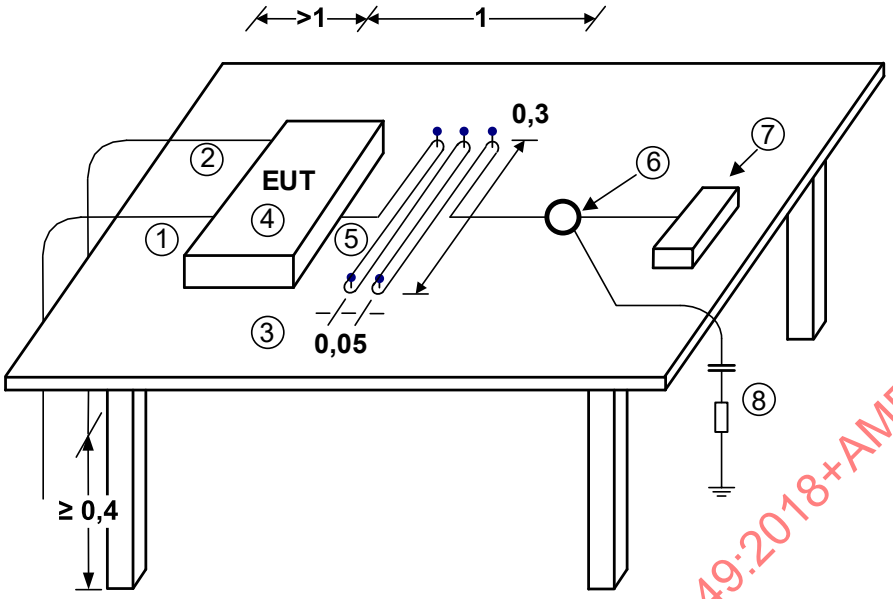
202.7.1.101 * EMISSIONS test setup

MULTIFUNCTION PATIENT MONITORS shall be tested configured with the maximum number of PHYSIOLOGICAL MONITORING UNITS. All specified PHYSIOLOGICAL MONITORING UNITS shall be tested. Representative samples from each family of PATIENT CABLES, LEAD WIRES, sensors, probes and/or TRANSDUCERS with similar construction listed in the ACCOMPANYING DOCUMENTS shall be tested with the corresponding PHYSIOLOGICAL MONITORING UNITS specified by the MANUFACTURER.

MULTIFUNCTION PATIENT MONITORS shall be tested with all PATIENT CABLES, LEAD WIRES, sensors, probes and TRANSDUCERS and with all SIP/SOP cables connected to the MULTIFUNCTION PATIENT MONITOR (see Figure 202.101). The distances of SIP/SOP cables between the open end and floor (ground plane) shall be ≥ 40 cm.

The artificial hand of Figure 202.101 shall be connected only if required by IEC 60601-1-2.

Dimensions in m



IEC

Key

①	Mains cable (if applicable)
②	SIGNAL INPUT / OUTPUT PART cable(s) as applicable
③	Table made of insulating material
④	MULTIFUNCTION PATIENT MONITOR under test (EUT)
⑤	Cable(s) connecting TRANSDUCERS, sensors, ELECTRODES or probes, etc. with equipment under test (EUT)
⑥	TRANSDUCER, sensor, ELECTRODES or probe, etc.
⑦	PATIENT signal simulator, if applicable (shielded and, if necessary, low pass filtered, if susceptible to radio frequency interference)
⑧	Artificial hand according to 4.3.2 of IEC 60601-1-2:2014

Figure 202.101 – Test layout for conducted and radiated EMISSIONS and IMMUNITY test
(see 202.7.1.101 and 202.8.101)

A PATIENT signal simulator is required only if needed for normal operation of the MULTIFUNCTION PATIENT MONITOR or to confirm that the MULTIFUNCTION PATIENT MONITOR provides ESSENTIAL PERFORMANCE during IMMUNITY tests (see also 7.1.9 and 8.2 of IEC 60601-1-2:2014).

202.8.1 General

Replacement of paragraph below NOTE 5:

During and after non-transient phenomena (i.e. radiated radiofrequency electromagnetic fields, proximity fields from radiofrequency wireless communications equipment, RATED power frequency magnetic fields, conducted disturbances induced by radiofrequency fields, and voltage dips):

– the MULTIFUNCTION PATIENT MONITOR shall meet the IMMUNITY pass/fail criteria for BASIC SAFETY and ESSENTIAL PERFORMANCE as determined by MANUFACTURER, and shall not change operating modes, OPERATOR settings and any stored data, or

– the MULTIFUNCTION PATIENT MONITOR shall generate a TECHNICAL ALARM CONDITION, or

– interference shall be readily identifiable by the OPERATOR.

NOTE Examples of readily identifiable interferences are large noise on the ECG waveform, heavily and rapidly fluctuating numeric values, etc.

During transient phenomena (i.e. electrostatic discharge, electrical fast transients/bursts, surges, electrical transient conduction along supply lines and ~~voltage interruptions~~ proximity magnetic fields), MULTIFUNCTION PATIENT MONITORS shall meet the IMMUNITY pass/fail criteria for BASIC SAFETY. Within 30 s after the transient electromagnetic phenomena are discontinued, MULTIFUNCTION PATIENT MONITORS shall resume normal operation without OPERATOR intervention, without loss of any OPERATOR settings or stored data and shall provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

For requirements for voltage interruptions, see 201.11.8.

Additional subclauses:

202.8.101 * IMMUNITY test setup

MULTIFUNCTION PATIENT MONITORS shall be tested configured with the maximum number of PHYSIOLOGICAL MONITORING UNITS. All specified PHYSIOLOGICAL MONITORING UNITS shall be tested. Representative samples from each family of PATIENT CABLES, LEAD WIRES, sensors, probes and/or TRANSDUCERS with similar construction listed in the ACCOMPANYING DOCUMENTS shall be tested with the corresponding PHYSIOLOGICAL MONITORING UNIT specified by the MANUFACTURER.

See Figure 202.101.

202.8.102 * Disturbances from HF SURGICAL EQUIPMENT

If the intended environments of use as specified by the MANUFACTURER in the instructions for use include environments where HF SURGICAL EQUIPMENT is used, then the MULTIFUNCTION PATIENT MONITOR shall return to its previous operating mode within 10 s after exposure to disturbances produced by HF SURGICAL EQUIPMENT, without any change in operating mode and OPERATOR settings and without loss of any stored data.

NOTE For example, a MULTIFUNCTION PATIENT MONITOR intended solely for use in the HOME HEALTHCARE ENVIRONMENT is not intended to be used together with HF SURGICAL EQUIPMENT.

Compliance is checked according to Figures 202.102 and 202.103. Figures 202.102 and 202.103 represent test setups to be used for APPLIED PARTS with PATIENT CONNECTIONS. For other types of APPLIED PARTS, the test set-up shall follow that which is defined in the particular standard for the PHYSIOLOGICAL MONITORING UNIT *that is associated with the APPLIED PART. For APPLIED PARTS that are not defined in any particular standard for a* PHYSIOLOGICAL MONITORING UNIT*, the test set-up described in Figure 202.104 is to be used.*

Use PATIENT CABLES, LEAD WIRES, sensors, probes, TRANSDUCERS, ACCESSORIES and settings recommended by the MANUFACTURER and HF SURGICAL EQUIPMENT which complies with IEC 60601-2-2 and has a minmum power cut mode capability of 300 W, a minimum coagulation mode capability of 100 W and a working frequency ~~of~~ between 300 kHz ~~to~~ and 600 kHz.

a) Test in pure cut mode

Set the output power of the HF SURGICAL EQUIPMENT to the 300 W position.

Touch the metal plate in the test setup (see Figures 202.102, 202.103 and 202.104) with the ACTIVE ELECTRODE and remove it slowly to get an arc.

Confirm that the MULTIFUNCTION PATIENT MONITOR returns within 10 s to the previous operating mode without change of any OPERATOR settings and without loss of any stored data.

Repeat the PROCEDURE *five times.*

b) Test in coagulation mode:

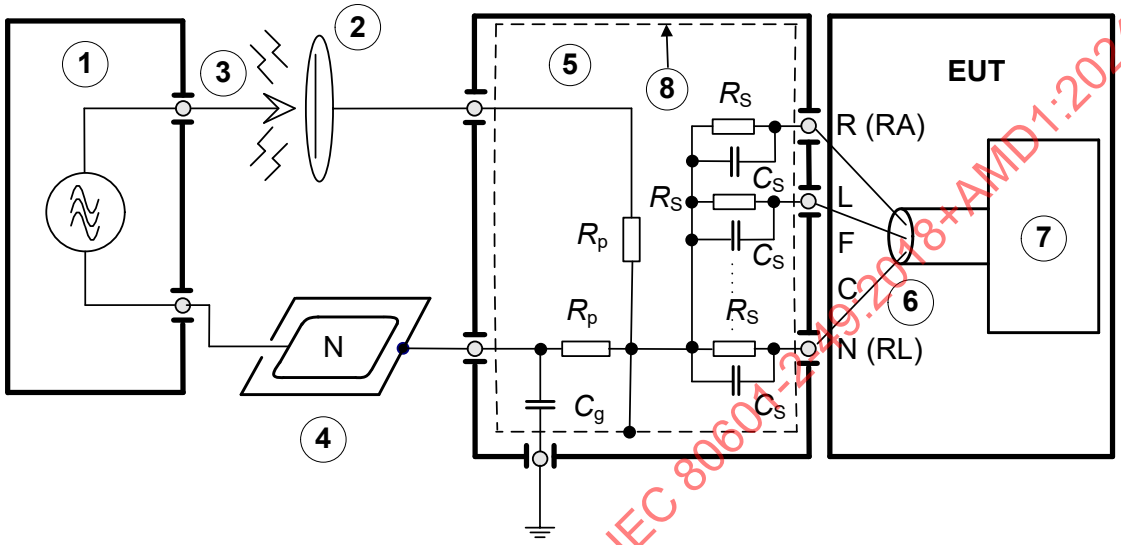
Set the output power of the HF SURGICAL EQUIPMENT to the 100 W position.

Touch the metal plate in the test setup (see Figures 202.102, 202.103 and 202.104) with the ACTIVE ELECTRODE *and remove it slowly to get an arc.*

Confirm that the MULTIFUNCTION PATIENT MONITOR *returns within 10 s to the previous operating mode without change of any* OPERATOR *settings and without loss of any stored data.*

Repeat the PROCEDURE *five times.*

Testing of the spray coagulation mode is not required.



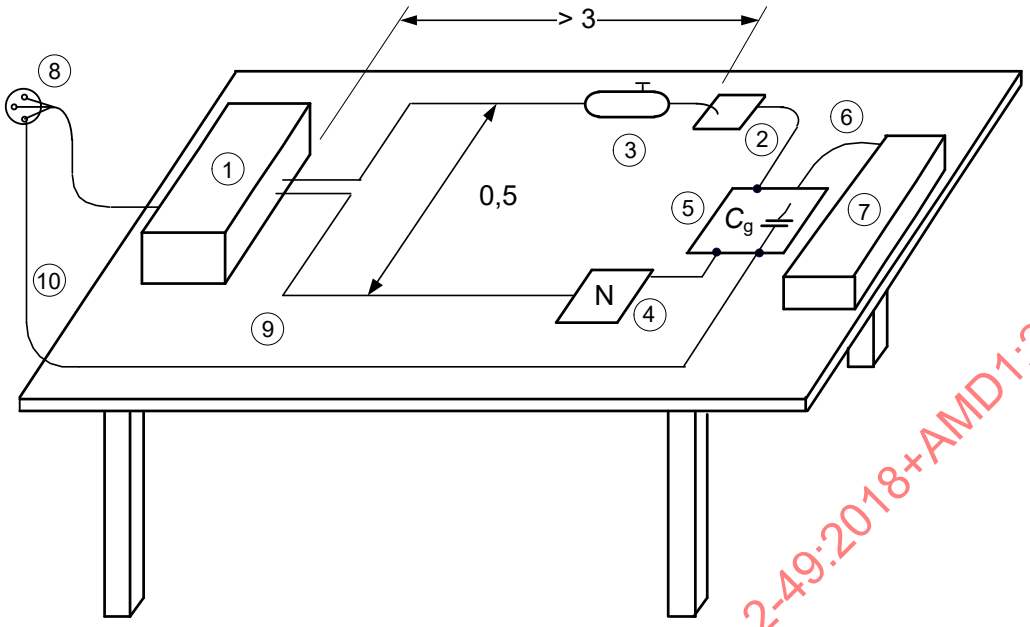
Components

① HF SURGICAL EQUIPMENT
② Metal plate
③ ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
④ Metal plate/NEUTRAL ELECTRODE (N) of HF SURGICAL EQUIPMENT
⑤ Coupling network
⑥ PATIENT CONNECTIONS, PATIENTcables
⑦ MULTIFUNCTION PATIENT MONITOR
⑧ Shielding
R_p 500 Ω ± 10 %, 200 W (low-inductive, < 5 µH, simulates PATIENT impedance)
C_g 47 nF (to minimize the effect of different types of HF SURGICAL EQUIPMENT designs)
R_s 51 kΩ (R_s//C_s simulate the skin impedance)
C_s 47 nF
R, L, F, C, N PATIENT CONNECTIONS

Figure 202.102 – Test circuit for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102 with PATIENT CONNECTIONS

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

Dimensions in m

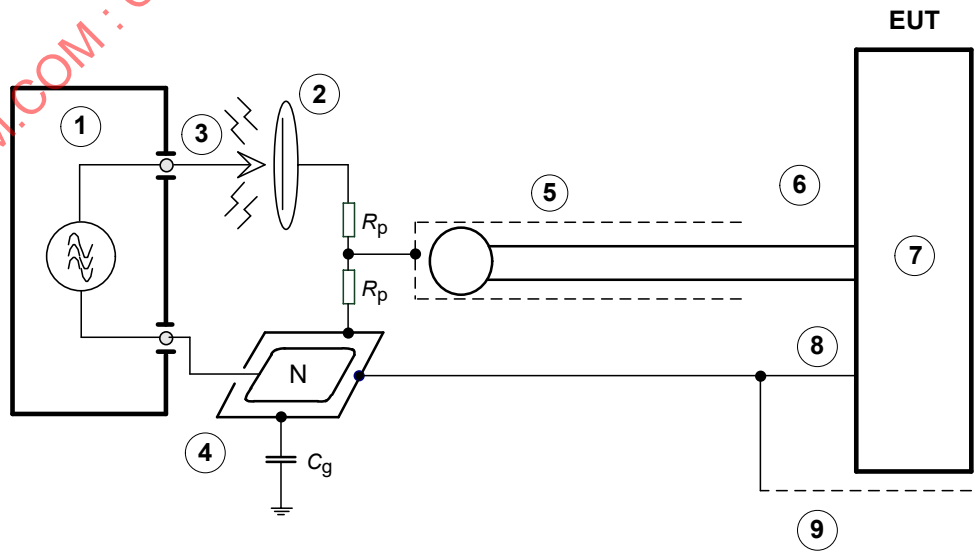


IEC

Components

① HF SURGICAL EQUIPMENT
② Metal plate
③ ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
④ NEUTRAL ELECTRODE of the HF SURGICAL EQUIPMENT
⑤ Coupling network – test set-up according to item 5 in Figure 202.102
⑥ PATIENT CABLE (ECG) and other cables connected to PATIENT
⑦ MULTIFUNCTION PATIENT MONITOR under test
⑧ SUPPLY MAINS
⑨ Table made of insulating material
⑩ Connection to PROTECTIVE EARTH CONDUCTOR for grounding

Figure 202.103 – Test setup for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102



IEC

Components

① HF SURGICAL EQUIPMENT

② Metal plate

③ ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT

④ Metal plate/NEUTRAL ELECTRODE (N) of HF SURGICAL EQUIPMENT

⑤ Copper foil connected to PATIENT impedance (Rp)

⑥ Non-conductive APPLIED PART: Sensor or TRANSDUCER with connection cable

⑦ MULTIFUNCTION PATIENT MONITOR

⑧ For CLASS I EQUIPMENT: Metal plate/NEUTRAL ELECTRODE (N) of HF SURGICAL EQUIPMENT connected with the ENCLOSURE of the MULTIFUNCTION PATIENT MONITOR

⑨ For CLASS II EQUIPMENT: Metal plate/NEUTRAL ELECTRODE (N) of HF SURGICAL EQUIPMENT connected with a copper foil surrounding the ENCLOSURE of the MULTIFUNCTION PATIENT MONITOR

R_p 500 Ω ± 10 %, 200 W (low-inductive, < 5 μH, simulated PATIENT impedance)

C_g 47 nF (to minimize the effect of different types of HF SURGICAL EQUIPMENT designs)

Figure 202.104 – Test circuit for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102 with non-conductive APPLIED PART

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

206 USABILITY

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply, except as follows:

Additional subclause:

206.101 PRIMARY OPERATING FUNCTIONS

For MULTIFUNCTION PATIENT MONITORS, the following shall be considered PRIMARY OPERATING FUNCTIONS:

a) switching on/off,

b) connecting/disconnecting PATIENT cables, sensor, probes and TRANSDUCERS,

c) observing monitored physiological parameters, waveforms and visual ALARM SIGNALS from the display,

d) setting the OPERATOR-adjustable controls relevant for PATIENT safety,

e) setting ALARM LIMITS,

f) inactivating ALARM SIGNALS,

g) adding or removing PHYSIOLOGICAL MONITORING UNITS, where applicable.

Compliance is checked by inspection of the MULTIFUNCTION PATIENT MONITOR and the instructions for use.

208 General requirements, tests and guidance for ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply, except as follows:

208.6.1.2 * Determination of ALARM CONDITIONS and assignment of priority

Addition:

A MANUFACTURER-configured ALARM PRESET shall assign at least LOW PRIORITY to TECHNICAL ALARM CONDITIONS that prevent the generation of PHYSIOLOGICAL ALARM CONDITIONS, unless an INTELLIGENT ALARM SYSTEM determines that an INFORMATION SIGNAL or no ALARM CONDITION is appropriate.

The ALARM SYSTEM shall include the ALARM CONDITIONS that are specified in the particular standard of the respective PHYSIOLOGICAL MONITORING UNIT and other ALARM CONDITIONS specified by the MANUFACTURER in the instructions for use.

Compliance is checked by inspection.

208.6.3.2 Visual ALARM SIGNALS

Additional subIcause:

208.6.3.2.101 * Indication of validity of measured values

During a TECHNICAL ALARM CONDITION, if the MULTIFUNCTION PATIENT MONITOR displays a measured value of a related PHYSIOLOGICAL MONITORING UNIT, then the MULTIFUNCTION PATIENT MONITOR shall provide information to permit the OPERATOR to assess the validity of the displayed value.

NOTE During a TECHNICAL ALARM CONDITION, the PHYSIOLOGICAL MONITORING UNIT might not be capable of accurately detecting PHYSIOLOGICAL ALARM CONDITIONS.

Compliance is checked by functional test and inspection of the ACCOMPANYING DOCUMENTS.

208.6.5 ALARM PRESETS

Addition:

If INTENDED USE includes unattended monitoring, at least one MANUFACTURER-configured ALARM PRESET suitable for unattended monitoring shall be included in the ALARM SYSTEM.

Compliance is checked by inspection.

208.6.8 ALARM SIGNAL inactivation states

208.6.8.1 * General

Addition:

MULTIFUNCTION PATIENT MONITORS may provide a single control to initiate:

– ALARMS OFF or ALARMS PAUSED for the group of PHYSIOLOGICAL ALARM CONDITIONS, and
– AUDIO OFF or AUDIO PAUSED for the group of TECHNICAL ALARM CONDITIONS.

Symbols IEC 60417-5319:2002-11 or IEC 60417-5319:2002-11 (symbol 3 and 4 in Table C.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012) or alternative marking 2 and 4 in Table C.2 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, as appropriate,

may be used to identify the combined control and shall be used to indicate the resulting ALARM SIGNAL inactivation state. The function of this combined control shall be disclosed in the instructions for use.

The combined control may also remove all visual and auditory indicators of the technical alarms if it is related to intentional ending of measurements by the clinical OPERATOR.

Compliance is checked by inspection.

208.6.10 * NON-LATCHING and LATCHING ALARM SIGNALS

~~*Addition to the first paragraph:*~~

~~For MULTIFUNCTION PATIENT MONITORS that support mixtures of LATCHING ALARM SIGNALS and NON-LATCHING ALARM SIGNALS means shall be provided for the RESPONSIBLE ORGANIZATION to configure and restrict access of MULTIFUNCTION PATIENT MONITORS to have all LATCHING ALARM SIGNALS or for which latching is only needed for special purposes and no subsequent clinical activity is needed or a particular standard requires latching ALARM SIGNALS for PHYSIOLOGICAL ALARM CONDITIONS.~~

~~NOTE 1 This requirement adds an additional configuration capability for use in intensive care units where the RESPONSIBLE ORGANIZATION desires LATCHING ALARM SIGNALS for all ALARM CONDITIONS.~~

~~NOTE 2 LATCHING ALARM SIGNALS have been documented to contribute to alarm fatigue. Thus ALARM SYSTEM logging, as presented in 208.6.12, can be a preferred alternative to review no longer active ALARM CONDITIONS in MULTIFUNCTION PATIENT MONITORS.~~

~~*Compliance is checked by functional test.*~~

Additional subclause:

208.6.10.101 * NON-LATCHING ALARM SIGNALS for TECHNICAL ALARM CONDITIONS

TECHNICAL ALARM CONDITIONS shall trigger NON-LATCHING ALARM SIGNALS, unless otherwise specified by a particular standard.

Compliance is checked by inspection.

208.6.11.1 Existence of ~~DISTRIBUTED ALARM SYSTEM~~ a DIS or DAS

Addition:

The ALARM SYSTEM of a modular MULTIFUNCTION PATIENT MONITOR is not considered a DISTRIBUTED ALARM SYSTEM (see Figure AA.2).

208.6.12 ALARM SYSTEM logging

~~*Replacement of first sentence and a):*~~

~~MULTIFUNCTION PATIENT MONITORS should be equipped with an ALARM SYSTEM log:~~

~~a) the ALARM SYSTEM shall log the occurrence and identity of HIGH PRIORITY ALARM CONDITIONS and MEDIUM PRIORITY ALARM CONDITIONS and~~

~~– the date and time, or~~

~~– the elapsed time since the occurrence of the ALARM CONDITION, or~~

~~– the elapsed time from the start of use of the MULTIFUNCTION PATIENT MONITOR;~~

~~*Addition before the compliance statement:*~~

~~The ALARM SYSTEM log shall:~~

~~– store initial ALARM SETTINGS, any changes to the ALARM SETTINGS (including ALARM SIGNAL inactivation states), occurrence, identity, and priority of all ALARM CONDITIONS and REMINDER SIGNALS with a capacity of at least 1 000 events;~~

~~– not lose the contents of the ALARM SYSTEM log for a loss of power for less than 7 days unless deleted by RESPONSIBLE ORGANIZATION action;~~

~~– not permit the clinical OPERATOR to erase the contents of the ALARM SYSTEM log.~~

~~The ALARM SYSTEM log may be provided by means of a FUNCTIONAL CONNECTION to an ME SYSTEM. MULTIFUNCTION PATIENT MONITORS should be equipped with a FUNCTIONAL CONNECTION to export the contents of the ALARM SYSTEM log as well as the identification of the PATIENT, equipment or equipment location.~~

~~EXAMPLES PATIENT name or medical record number, room and bed number or equipment serial number.~~

~~*Compliance is checked by inspection and functional testing.*~~

208.6.12.1 General

Replacement of the first paragraph:

The ALARM SYSTEM of a MULTIFUNCTION PATIENT MONITOR shall be equipped with an OPERATOR ALARM SYSTEM log and a RESPONSIBLE ORGANIZATION ALARM SYSTEM log.

208.6.12.2 OPERATOR ALARM SYSTEM logging

Addition before the compliance statement:

aa) the ALARM SYSTEM log shall have a capacity of at least 1 000 events.

208.6.12.3 RESPONSIBLE ORGANIZATION ALARM SYSTEM logging

Addition before the compliance statement:

aa) MULTIFUNCTION PATIENT MONITORS should be equipped with a FUNCTIONAL CONNECTION to export the contents of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log as well as the identification of the PATIENT, MULTIFUNCTION PATIENT MONITOR or location.

Annexes

The annexes of the general standard apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 Rationale and background

This annex provides a concise rationale for the important requirements of this particular standard. It is intended for those who are familiar with the subject of the particular standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of this particular standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any future revision of this particular standard necessitated by these developments.

AA.2 Rationale for particular clauses and subclauses

Subclause 201.1.1 – Scope

This particular standard specifies BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MULTIFUNCTION PATIENT MONITORS as defined in 201.3.201. The key criteria for determining when to apply this particular standard are whether more than one PHYSIOLOGICAL MONITORING UNIT exists and whether a need exists to detect ALARM CONDITIONS and to generate ALARM SIGNALS (e.g., to perform alarm monitoring). While other ME EQUIPMENT, such as catheter laboratory systems or stress test systems, provide more than one PHYSIOLOGICAL MONITORING UNIT, these systems not always perform alarm monitoring and therefore, can fall outside the definition of MULTIFUNCTION PATIENT MONITOR.

Subclause 201.3.201 – MULTIFUNCTION PATIENT MONITOR

Figures AA.1 to AA.4 show examples of MULTIFUNCTION PATIENT MONITORS.

Figure AA.1 shows an example of a pre-configured MULTIFUNCTION PATIENT MONITOR with invasive pressure monitoring and ECG in one device.

Figure AA.2 shows an example of a modular MULTIFUNCTION PATIENT MONITOR with invasive pressure monitoring and ECG. Both functions are monitored in separate devices and the data is displayed on a separate display. The modular MULTIFUNCTION PATIENT MONITOR is created by (wired or wireless) FUNCTIONAL CONNECTIONS.

Figure AA.3 shows an example of a MULTIFUNCTION PATIENT MONITOR with invasive pressure monitoring and ECG connected to a central station by means of a FUNCTIONAL CONNECTION. The central station is not in the scope of this document provided the MULTIFUNCTION PATIENT MONITOR complies with the requirements of this document without the FUNCTIONAL CONNECTION to a central station (e.g. the ALARM SYSTEM is part of the MULTIFUNCTION PATIENT MONITOR).

Figure AA.4 shows an example of a MULTIFUNCTION PATIENT MONITOR with invasive pressure monitoring and ECG monitoring. Both functions are integrated in a ventilator. While this module is considered to be a MULTIFUNCTION PATIENT MONITOR, the ventilator itself is not within the scope of this document, even though physiological conditions (e.g. gas flow) are measured from the hosting medical device.

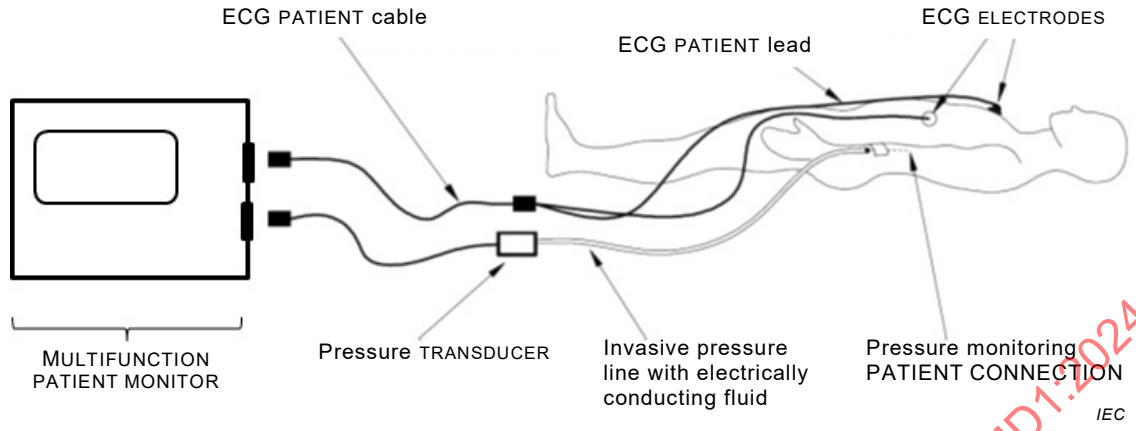


Figure AA.1 – Example of a pre-configured MULTIFUNCTION PATIENT MONITOR

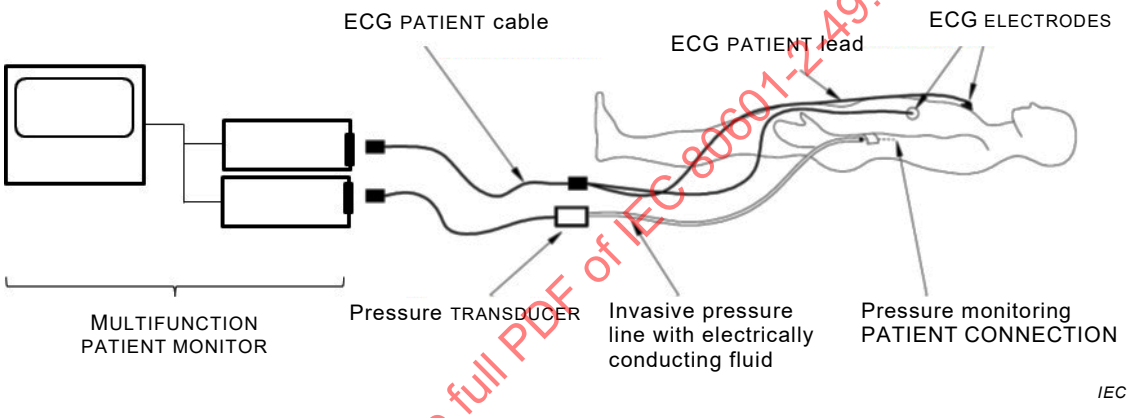


Figure AA.2 – Example of a modular MULTIFUNCTION PATIENT MONITOR

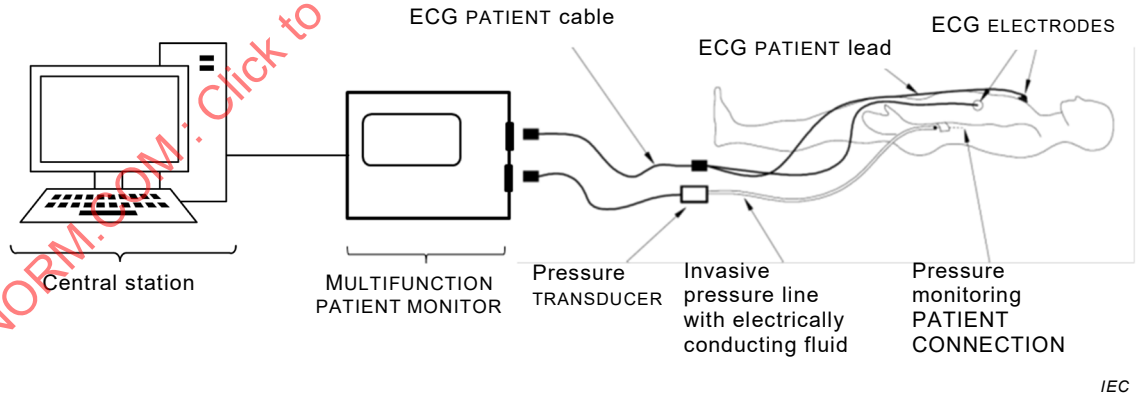


Figure AA.3 – Example of a MULTIFUNCTION PATIENT MONITOR connected to a central station

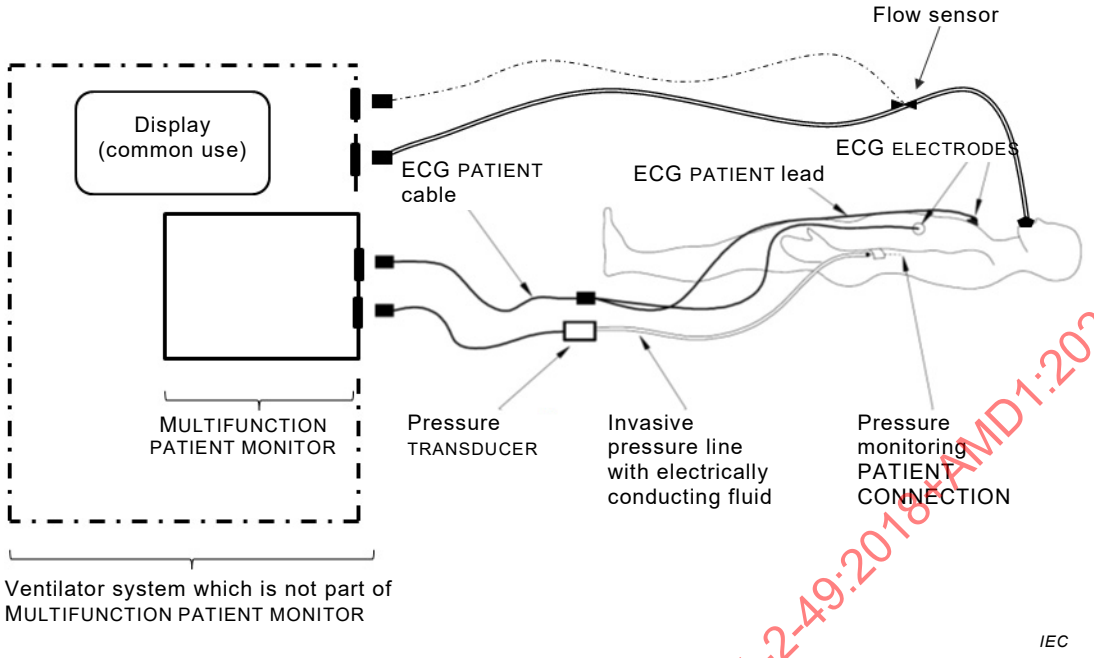


Figure AA.4 – Example of a MULTIFUNCTION PATIENT MONITOR integrated into a ventilator

Subclause 201.4.5 – Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

Particular standards for PHYSIOLOGICAL MONITORING UNITS like ECG, invasive pressure and pulse oximetry define requirements from the perspective of stand-alone ME EQUIPMENT. MULTIFUNCTION PATIENT MONITORS, whether configured or modular, are physically larger and necessarily have broader INTENDED USES than this stand-alone equipment. Therefore, these differences have to be considered accordingly.

The MULTIFUNCTION PATIENT MONITOR used to monitor PATIENTS integrates various PHYSIOLOGICAL MONITORING UNITS (e.g., ECG, invasive and non-invasive blood pressure, SpO_2, temperature, etc.) into a single ME EQUIPMENT. Ensuring that this integrated ME EQUIPMENT can be safely used (USABILITY according to IEC 60601-1-6 and IEC 62366 (all parts)) requires that specific characteristics of this system (e.g., interruption of the power supply, protection against depletion of the battery or the ALARM SYSTEM) be consistently implemented for all available physiological measurements. PATIENT safety and overall USABILITY will likely be compromised if the requirements in particular standards for individual PHYSIOLOGICAL MONITORING UNITS are applied rather than this document's well considered requirements for the integrated MULTIFUNCTION PATIENT MONITOR.

Ensuring consistent operation is critically important to maintaining PATIENT safety in an integrated system. Imagine the chaos if different power supply interruption requirements from, for example, IEC 60601-2-27 (ECG), IEC 60601-2-34 (invasive pressure) and ISO 80601-2-56 (temperature), were all applied simultaneously. The same can be said for having three different ALARM PAUSE durations from these three standards. Under best case conditions, implementing different concepts from the standards for individual PHYSIOLOGICAL MONITORING UNITS will confuse clinical OPERATORS and result in HAZARDOUS SITUATIONS for PATIENTS.

Subclause 201.6.2 – Protection against electric shock

A MULTIFUNCTION PATIENT MONITOR is frequently used in environments in which other medical equipment is connected to the same PATIENT. The reference to TYPE B APPLIED PARTS is therefore deleted, as it is important for the safety of the PATIENT that all these devices have TYPE BF or TYPE CF APPLIED PARTS to avoid unwanted current paths to earth. The construction of MULTIFUNCTION PATIENT MONITORS with TYPE BF or TYPE CF APPLIED PARTS presents no technical difficulties.

In addition, this document was adapted to A.3.5 of IEC TR 60513:1994: "For non-intracardiac applications, the significant difference between F-TYPE APPLIED PART and TYPE B APPLIED PARTS is that, if the PATIENT accidentally contacts MAINS VOLTAGE, a F TYPE APPLIED PART restricts the current flowing through it to a reasonably safe level, while the current flowing in a TYPE B APPLIED PART can only be limited by the impedance of the PATIENT and can present a serious electrocution HAZARD."

Not all ACCESSORIES specified by the MANUFACTURER (i.e. certain TRANSDUCERS or sensors) are protected or can be protected against the effects of defibrillation. This limitation is normally given by technological restrictions. This means that such ACCESSORIES can be destroyed during defibrillation. The use of such ACCESSORIES requires that the clinical OPERATOR removes non-defibrillation-proof ACCESSORIES from the PATIENT before defibrillation. Marking the concerned ACCESSORIES draws attention to the clinical OPERATOR to take the necessary precautions.

Subclause 201.7.9.2.9.101 i) – Additional instructions for use

ALARM SIGNALS of TECHNICAL ALARM CONDITIONS are also indicated when TRANSDUCERS, sensors, probes, or modules are intentionally disconnected by the clinical OPERATOR because the MULTIFUNCTION PATIENT MONITOR can not distinguish between intentional and unintentional disconnection. In cases where a TRANSDUCER, sensor, a probe, or a module is intentionally disconnected by the clinical OPERATOR, a means to permantenly disable the ALARM SIGNALS of those TECHNICAL ALARM CONDITIONS is required. A possible situation is, for instance, that an invasive blood pressure measurement is intentionally discontinued because a non-invasive pressure measurement is adequate and associated with a lower risk for the PATIENT.

Subclause 201.8.5.2.3 – PATIENT leads or PATIENT cables

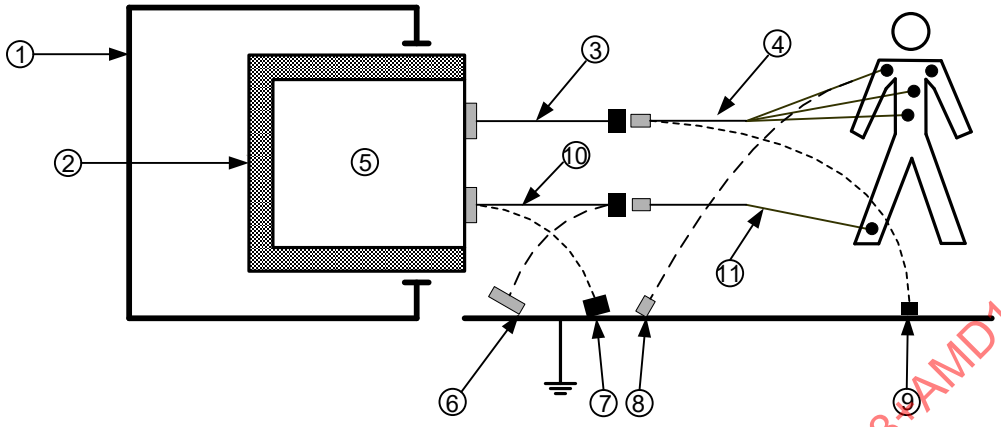
There are two cases to guard against.

– Firstly, accidental connection of the PATIENT to earth or hazardous voltages directly via disconnected connectors for electrical connections at the end of PATIENT leads or LEAD WIRES and PATIENT CABLES (ECG) and other cables connected to the PATIENT remote from the PATIENT.
– Secondly, accidental connection of the PATIENT to earth or hazardous voltages via disconnected connectors for electrical connections at the end of PATIENT LEAD or LEAD WIRES and PATIENT CABLE (ECG) and other cables connected to the PATIENT remote from the MULTIFUNCTION PATIENT MONITOR.

Subclause 8.5.2.3 of the general standard protects PATIENTS from HAZARDS arising from accidental connection of the PATIENT to earth or hazardous voltages directly via disconnected connectors for electrical connections at the end of PATIENT leadsLEAD WIRES and PATIENT CABLE (ECG) and other cables connected to the PATIENT remote from the PATIENT.

The addition in 201.8.5.2.3 of this particular standard provides protection for HAZARDS arising from accidental connection of the PATIENT to earth or hazardous voltages indirectly via disconnected connectors for electrical connections at the end of PATIENT leads and PATIENT cables remote from the MULTIFUNCTION PATIENT MONITOR, if PHYSIOLOGICAL MONITORING UNITS are not separated by at least one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE.

Figure AA.5 illustrates the requirements and rationale of 8.5.2.3 of the general standard and 201.8.5.2.3.



Key

① MULTIFUNCTION PATIENT MONITOR
② Insulation barrier (MOPP) of a single PATIENT circuit with 2 PHYSIOLOGICAL MONITORING UNITS
③ PATIENT CABLE
④ LEAD WIRES
⑤ Single PATIENT circuit with multiple (2) PHYSIOLOGICAL MONITORING UNITS
⑥ Potential PATIENT to earth connection via a connector at the end of the cable remote from the PATIENT (8.5.2.3 of the general standard)
⑦ Potential PATIENT to earth connection via a connector at the end of the cable remote from the ME EQUIPMENT (201.8.5.2.3 of this particular standard)
⑧ Potential PATIENT to earth connection via a connector at the end of the LEAD WIRE remote from the PATIENT (8.5.2.3 of the general standard)
⑨ Potential PATIENT to earth connection via a connector at the end of the LEAD WIRE remote from the MULTIFUNCTION PATIENT MONITOR (201.8.5.2.3 of this particular standard)
⑩ Extension cable
⑪ PATIENT cable or sensor cable
□ Connectors at the end of the PATIENT cables and PATIENT leads remote from the PATIENT
■ Connectors at the end of the PATIENT cables and PATIENT leads remote from the MULTIFUNCTION PATIENT MONITOR
● PATIENT CONNECTIONS

Figure AA.5 – Single PATIENT circuit with multiple PHYSIOLOGICAL MONITORING UNITS and PATIENT cables

Subclause 201.8.5.5.1 – Defibrillation protection

If the MULTIFUNCTION PATIENT MONITOR has more than one connector to connect APPLIED PARTS, it is possible that at least one APPLIED PART is connected to the PATIENT while at least one other connector is unused, i.e. can be touched by the an OPERATOR or bystander. This is considered to be as likely as touching a part of the ENCLOSURE or SIGNAL INPUT/OUTPUT PARTS.

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

In the hospital environment, PATIENTS may be transported between different building of a hospital. Thus some level of ingress protection is required. After being wetted in NORMAL USE, the MULTIFUNCTION PATIENT MONITOR needs to continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE to continue monitoring the PATIENT.

IPx1 was selected to have a standardized test class. IPx1 is close to the former requirement.

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

Interruptions of the SUPPLY MAINS for less than 30 s are mainly caused by switching to an emergency power supply. Such power interruptions are considered NORMAL USE and consequently should not result in a HAZARDOUS SITUATION to the PATIENT. When power returns, the MULTIFUNCTION PATIENT MONITOR needs to resume the same mode of operation and restore all OPERATOR settings and PATIENT data that were in use before the SUPPLY MAINS was interrupted. Examples of typical stored data that can impact PATIENT safety are operating mode, ALARM SETTINGS (volume of auditory ALARM SIGNAL, ALARM LIMITS, ALARM OFF, etc.), trend data, and pacemaker pulse rejection, if OPERATOR-selectable. In contrast to these, neither the instantaneous heart rate nor the displayed ECG waveform is stored.

Subclause 202.7.1.101 – EMISSIONS test setup and Subclause 202.8.101 – IMMUNITY test setup

Modular and preconfigured MULTIFUNCTION PATIENT MONITORS that are used today in intensive care units or operating theatres allows many different combinations of PHYSIOLOGICAL MONITORING UNITS. The requirement of this subclause is based on the assumption that a MULTIFUNCTION PATIENT MONITOR configured with the maximum number of PHYSIOLOGICAL MONITORING UNITS represents the worst-case configuration for testing. Testing of all possible combinations of PHYSIOLOGICAL MONITORING UNITS with all specified ACCESSORIES is not economically feasible.

Subclause 202.8.102 – Disturbances from HF SURGICAL EQUIPMENT

There is no ideal test method to generate disturbances from HF SURGICAL EQUIPMENT in a test laboratory but the ones given in Figures 202.102, 202.103 and 202.104 have been shown by experience to reproducibly give results similar to those seen in surgical practice. The test needs to be reproducible and should be done in the normal working range of the HF SURGICAL EQUIPMENT (load of approximately 500 Ω).

Disturbances caused by HF SURGICAL EQUIPMENT are considered NORMAL USE and consequently should not result in HAZARDS to the PATIENT. Therefore, after an appropriate recovery time, the MULTIFUNCTION PATIENT MONITOR should resume normal operation without loss of stored data. Examples of typical stored data that can impact PATIENT safety are operating mode, ALARM SETTINGS (volume of auditory ALARM SIGNAL, ALARM LIMITS, ALARM OFF, etc.). In contrast to these settings, the instantaneous values such as heart rate or the displayed ECG waveform do not fall under stored data.

The most critical test is the application of a common-mode HF voltage as shown in Figure 202.103. Capacitive coupling of HF SURGICAL EQUIPMENT to functional earth can cause the MULTIFUNCTION PATIENT MONITOR to fail to recover within the specified time if at all. For this reason it is not necessary to perform this test with a differential-mode HF voltage.

Subclause 208.6.1.2 – Determination of ALARM CONDITIONS and assignment of priority

The intersection of the "Delayed" column and the "Discomfort or reversible minor injury" row in Table 1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 contains "LOW PRIORITY ALARM CONDITION, no ALARM CONDITION or INFORMATION SIGNAL". Selection of "no ALARM SIGNAL" can be appropriate for these ALARM CONDITIONS in environments of use where a clinical OPERATOR continuously attends the PATIENT during NORMAL USE or the MULTIFUNCTION PATIENT MONITOR is connected to a central station.

Such a selection can be inappropriate for a MULTIFUNCTION PATIENT MONITOR that is not continuously attended during NORMAL USE and not connected to a central station. Not providing an ALARM SIGNAL can cause that the ALARM CONDITION goes undetected for an extended period of time. Thus a MANUFACTURER-configured ALARM PRESET shall assign at least a LOW PRIORITY ALARM CONDITION to TECHNICAL ALARM CONDITIONS that prevent the generation of PHYSIOLOGICAL ALARM CONDITIONS unless an INTELLIGENT ALARM SYSTEM determines that an INFORMATION SIGNAL or no ALARM CONDITION is appropriate.

Subclause 208.6.3.2.101 – Indication of validity of measured values

A TECHNICAL ALARM CONDITION can influence the validity of a measured value. For instance, the TECHNICAL ALARM CONDITION "ECG leads-off" prevents the heart rate from being calculated and displayed. Continuing to display the previously calculated heart rate can lead to misinterpretations by the clinical OPERATOR because this value is invalid during the TECHNICAL ALARM CONDITION. Appropriate means to indicate that the heart rate is invalid might be to display a blank heart rate value or a symbol where the heart rate is displayed.

In other cases, the tolerance of the measured values might be influenced or the measurement might be unreliable. In those cases, the clinical OPERATOR should be informed that the currently displayed value might be questionable. The displayed value should be marked accordingly.

208.6.8.1 – General

For MULTIFUNCTION PATIENT MONITORS it can be desirable that visual ALARM SIGNALS of TECHNICAL ALARMS CONDITIONS are displayed even in the ALARM OFF and ALARM PAUSED states to inform the OPERATOR that and why the MULTIFUNCTION PATIENT MONITOR (or a part of the MULTIFUNCTION PATIENT MONITOR) is not operating. Using a TECHNICAL ALARM SIGNAL when ALARMS are activated and an INFORMATION SIGNAL when ALARMS are inactivated might confuse OPERATORS because the same technical problem is indicated differently depending on the ALARM SYSTEM activation state. IEC 60601-1-8 allows that inactivation of ALARM SIGNALS applies only to a group of ALARM CONDITIONS. In this case, the ALARM SIGNALS are grouped into PHYSIOLOGICAL ALARM CONDITIONS and TECHNICAL ALARM CONDITIONS. However, IEC 60601-1-8 does not explicitly mention if one combined control can be used to initiate different inactivation states for different groups of ALARM SIGNALS and, if such control is provided, how it should be identified. Thus, such allowance and requirements for identification of the control have been added in this document.

Subclause 208.6.10 – NON-LATCHING and LATCHING ALARM SIGNALS

Different use models exist for MULTIFUNCTION PATIENT MONITORS that 1) is continually attended by a clinical OPERATOR (such as in operating theatres/rooms) and 2) is not continually attended by a clinical OPERATOR (such as in an ICU). In environments of use such as an ICU or emergency department, where PATIENTS are not continuously attended, a clinical OPERATOR normally cares for several PATIENTS.

Clinical OPERATORS who are caring for several PATIENTS cannot observe all of their PATIENTS at the same time. Clinical OPERATORS cannot easily identify short ALARM CONDITIONS that occur on a MULTIFUNCTION PATIENT MONITOR that provides NON-LATCHING ALARM SIGNALS or for mixes of NON-LATCHING and LATCHING ALARM SIGNALS. This inability to identify and quickly respond to important short ALARM CONDITIONS (e.g., short tachycardias) puts PATIENTS in HAZARDOUS SITUATIONS.

Configuring MULTIFUNCTION PATIENT MONITORS to only provide LATCHING ALARM SIGNALS ensures that clinical OPERATORS can respond to every ALARM CONDITION. While this is conceptually a good idea, frequent false ALARM CONDITIONS due to artefact or improperly set ALARM LIMITS can place a substantial administrative burden on the clinical OPERATOR.

LATCHING ALARM SIGNALS can be desirable within DISTRIBUTED ALARM SYSTEMS where remote equipment of an ME SYSTEM is not continuously attended by a clinical OPERATOR. NON-LATCHING ALARM SIGNALS can be desirable in an environment of use where the MULTIFUNCTION PATIENT MONITOR is continuously attended by a clinical OPERATOR.

Subclause 208.6.10.101 – NON-LATCHING ALARM SIGNALS for TECHNICAL ALARM CONDITIONS

A TECHNICAL ALARM CONDITION indicates a physiological measurement is not ready or has been interrupted for technical reasons. Such technical interruptions of a measurement can be caused by an unintentional disconnection of a TRANSDUCER, or a LEAD WIRE. For instance, the TECHNICAL ALARM CONDITION indicating that a sensor is disconnected implies that the relevant physiological parameter is not being measured and displayed. This implies that the physiological parameter is not being monitored and, as a consequence, potential ALARM CONDITIONS can not be indicated. Requiring NON-LATCHING ALARM SIGNALS for TECHNICAL ALARM CONDITIONS means those ALARM SIGNALS are being displayed as long as the ALARM CONDITION exists and cease without clinical OPERATOR interaction when the TECHNICAL ALARM CONDITION is corrected or a TRANSDUCER is reconnected.

Subclause 208.6.12 – ALARM SYSTEM logging

~~As described in Annex A of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, ALARM SYSTEM logging is important for both real-time clinical and retrospective adverse event investigation purposes. The general ALARM SYSTEM logging requirements of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 are intended for a wide variety of devices, some of which cannot typically be expected to include adequate resources to even support an alarm log. In recognition of this reality, in the collateral standard an ALARM SYSTEM log is optional and only limited functionality is required if a log is implemented. Instead, a variety of important design considerations for an ALARM SYSTEM log are identified in Annex A of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012.~~

~~Because MULTIFUNCTION PATIENT MONITORS are used for vigilance monitoring, the functions of the ALARM SYSTEM log are particularly related to PATIENT safety considerations. While not necessarily life-supporting or life-sustaining, these MULTIFUNCTION PATIENT MONITORS are often relied upon to provide timely responses to critical ALARM CONDITIONS. The typically unattended (or inattentively attended) use of such MULTIFUNCTION PATIENT MONITORS makes the ALARM SYSTEM log a critical element of ensuring their safe use. The associated ALARM SYSTEM complexity can often make root cause analysis of adverse events occurring during monitoring difficult or impossible without detailed retrospective information.~~

~~Experience has shown that potentially critical signals notifying of impending loss of monitoring, such as ECG leads off and low battery alarms are frequently set by users as LOW PRIORITY alarms. In some cases this results in adverse events, some involving PATIENT deaths, for which the root cause analysis cannot be determined if only HIGH PRIORITY alarms are logged (as is required by 6.12 IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012). Logging of all ALARM CONDITIONS and REMINDER SIGNALS provides important contextual information that allows the user to confirm the proper functioning of the MULTIFUNCTION PATIENT MONITOR.~~

~~Because ALARM SETTINGS such as threshold limits can be changed at any time, in order to retrospectively confirm the proper operation of the ALARM SYSTEM, the initial ALARM SETTINGS and any changes thereto and the value(s) of any variable(s) resulting in the ALARM CONDITIONS should be logged.~~

~~Because some circumstances do not permit analysis of the log for several days, it is important that the log be secure, of adequate capacity, and available for an adequate period to allow for such cases. Clinical input considered a period of 7 days adequate time to allow the RESPONSIBLE ORGANIZATION to determine the need for the alarm log data to be extracted, even in the most extended emergency situations. However, the expected alarm load will vary depending on the INTENDED USE population and environment. Therefore, the capacity of the alarm log is left to the MANUFACTURER to determine and justify for their device based on published literature or other evidence and disclose such evidence in the instructions for use.~~

Because MULTIFUNCTION PATIENT MONITORS are used for vigilance monitoring, the ALARM SYSTEM logs are particularly related to PATIENT safety. While not necessarily life-supporting or life-sustaining, MULTIFUNCTION PATIENT MONITORS are often relied upon to provide timely responses to critical ALARM CONDITIONS. The typical use of MULTIFUNCTION PATIENT MONITORS makes the ALARM SYSTEM logs critical elements of ensuring their safe use. The associated ALARM SYSTEM complexity can often make analysis of the causal factors for adverse events occurring during or after monitoring difficult or impossible without detailed retrospective information.

To enable a meaningful analysis of adverse events it is important that the log has adequate capacity.

Bibliography

[1] IEC 62366 (all parts), *Medical devices*

[2] IEC 60601-2-16, *Medical electrical equipment – Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment*

[3] ISO 80601-2-12, *Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

[4] ISO 80601-2-13, *Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

[5] ISO 80601-2-56, *Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

[6] ISO 80601-2-72, *Medical electrical equipment – Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

[7] IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*

Index of defined terms used in this particular standard

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors

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.
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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 document may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 80601-2-49 edition 1.1 contains the first edition (2018-03) [documents 62D/1547/FDIS and 62D/1559/RVD] and its amendment 1 (2024-09) [documents 62D/2146/FDIS and 62D/2164/RVD].

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

International standard IEC 80601-2-49 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and of ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This first edition cancels and replaces the second edition of IEC 60601-2-49, published in 2011. This edition constitutes a technical revision to align with the current edition and Amendment to IEC 60601-1, new versions of collateral standards and amendments thereto. Major changes are in Clause 208 because many of the former requirements are now addressed by IEC 60601-1-8.

It is published as a double logo standard.

Full information on the voting for the approval of this document can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by XXX P members out of YYY having cast a vote.

In this document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "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 80601 International Standard, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document and its amendment will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

NOTE The attention of users of this document 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 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 committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this document 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.

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of MULTIFUNCTION PATIENT MONITORS. It amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this edition is to bring this particular standard up to date with reference to the edition 3.1 of the general standard and new versions of collateral standards and amendments thereto through technical changes.

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

A "Particular guidance and rationale" for the 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, this Annex AA does not form part of the requirements of this document.

INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised may be found within the IEC document 62D/1792/DC. The results and comments on the DC may be found within 62D/1808/INF. The review report for this amendment is 62D/1835A/RR.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This part of the 80601 International Standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE requirements of MULTIFUNCTION PATIENT MONITORS as defined in 201.3.201, hereafter referred to as ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS. This particular standard applies to MULTIFUNCTION PATIENT MONITORS intended for use in professional healthcare facilities as well as in the EMERGENCY MEDICAL SERVICE ENVIRONMENT or the HOME HEALTHCARE ENVIRONMENT.

The scope of this document is restricted to ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS intended for connection to a single PATIENT that has two or more PHYSIOLOGICAL MONITORING UNITS.

NOTE For purposes of this document, a pregnant mother and her fetus(es) are considered a single PATIENT.

This document does not specify requirements for individual PHYSIOLOGICAL MONITORING UNITS such as ECG, invasive pressure and pulse oximetry. The particular standards related to these PHYSIOLOGICAL MONITORING UNITS specify requirements from the perspective of stand-alone ME EQUIPMENT. This particular standard addresses the additional requirements related to MULTIFUNCTION PATIENT MONITORS. MULTIFUNCTION PATIENT MONITORS can be integrated into other ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS. When this is the case, other relevant standards also apply.

EXAMPLE 1 MULTIFUNCTION PATIENT MONITOR incorporated into a critical care ventilator where ISO 80601-2-12 also applies.

EXAMPLE 2 MULTIFUNCTION PATIENT MONITOR incorporated into a homecare ventilator for dependent PATIENT where ISO 80601-2-72 also applies.

EXAMPLE 3 MULTIFUNCTION PATIENT MONITOR incorporated into anesthetic workstation where ISO 80601-2-13 also applies.

EXAMPLE 4 MULTIFUNCTION PATIENT MONITOR incorporated into haemodialysis equipment, IEC 60601-2-16 also applies.

This document does not apply to implantable parts of MULTIFUNCTION PATIENT MONITORS.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MULTIFUNCTION PATIENT MONITORS as defined in 201.3.201.

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1 The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020, as well as IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply as modified in Clauses 202, 206 and 208 respectively. IEC 60601-1-3 and IEC 60601-1-9 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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

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

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are 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 document 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 IEC 60601-1-2 collateral standard, 208.6 in this particular standard addresses the content of Clause 6 of the IEC 60601-1-8 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 3.154, additional definitions in this document 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, 208 for IEC 60601-1-8, etc.

The term "this document" 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

NOTE Informative references are listed in the bibliography beginning on page 36.

Clause 2 of the general standard applies, except as follows.

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020

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*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/AMD1:2020

IEC 60601-2-2:2017, *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 60601-2-27:2011, *Medical electrical equipment – Part 2-27, Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11, IEC 60601-1-12, IEC 60601-2-2, IEC 60601-2-27, IEC 60601-2-34 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 37.

Addition:

201.3.201
*** MULTIFUNCTION PATIENT MONITOR**
modular or pre-configured ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS whose primary intended function is monitoring of a single PATIENT, has more than one PHYSIOLOGICAL MONITORING UNIT, either displays those information or distributes the information for remote display, and either includes an ALARM SYSTEM or is a component of a DISTRIBUTED ALARM SYSTEM

201.3.202
PHYSIOLOGICAL MONITORING UNIT
part of the MULTIFUNCTION PATIENT MONITOR whose purpose is to collect physiological signal(s) from a single sensor type and to process it for monitoring

EXAMPLE 1 The pulse oximetry signal can provide information about oxygen saturation, pulse rate, perfusion, etc.

EXAMPLE 2 The signals from ECG ELECTRODES can provide information about ECG and thoracic respiration rate.

Note 1 to entry: Examples of physiological signals include (a) electrocardiography, (b) non-invasive blood pressure, (c) invasive blood pressure, (d) pulse oximetry, (e) temperature, (f) electroencephalography, (g) transcutaneous gas analysis, and (h) respiratory gas analysis. Each of these is a single physiological signal within the meaning of this definition.

Note 2 to entry: It is recognized that more than one variable or parameter may be derived from a single physiological signal.

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements for MULTIFUNCTION PATIENT MONITORS are found in subclauses listed in Table 201.101.

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Displaying data according PRIMARY OPERATING FUNCTIONS	206.101 c)
Determination of ALARM CONDITIONS and assignment of priority	208.6.1.2
Indication of validity of measured values	208.6.3.2.101
or generating a TECHNICAL ALARM CONDITION	208.6.1.2

201.4.5 * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

Addition before the first paragraph:

When several particular standards simultaneously apply to a MULTIFUNCTION PATIENT MONITOR, all relevant requirements from those standards shall be applied as applicable to BASIC SAFETY and ESSENTIAL PERFORMANCE. If requirements from particular standards are in conflict, the RISK MANAGEMENT PROCESS shall be used to identify which standard's requirement applies. While performing this PROCESS, MANUFACTURERS are strongly recommended to give the requirements of this particular standard additional weight whenever possible.

201.5 General requirements for testing ME EQUIPMENT

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

201.5.4 Other conditions

Addition:

If necessary for the purpose of conducting the test, the INTERNAL ELECTRICAL POWER SOURCE may be replaced by an external battery or a DC power supply to provide the necessary test voltage, for tests according to 201.11.8.101.

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

– resistors: ±1 %;
– capacitors: ±10 %;
– inductors: ±10 %;
– test voltages: ±1 %.

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 associated with MULTIFUNCTION PATIENT MONITOR shall be classified as TYPE BF or 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), unless other applicable particular standards permit non-DEFIBRILLATION-PROOF APPLIED PARTS for the respective PHYSIOLOGICAL MONITORING UNIT or technical limitations prevent the design of DEFIBRILLATION-PROOF APPLIED PARTS.

201.6.6 Mode of operation

Replacement:

MULTIFUNCTION PATIENT MONITORS 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

Additional subclause:

201.7.2.101 Connectors for APPLIED PARTS

Connectors on a MULTIFUNCTION PATIENT MONITOR intended to connect APPLIED PARTS shall be marked to identify the APPLIED PARTS that can be connected.

NOTE Examples of markings are MODEL OR TYPE REFERENCE of the APPLIED PART, function of the APPLIED PART (e.g. ECG, ECG/respiration, SpO_2, temperature, etc.) or color coding.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall include a warning that defibrillator protection requires use of MANUFACTURER specified APPLIED PARTS, PATIENT CABLES, LEAD WIRES, TRANSDUCERS and ACCESSORIES.

201.7.9.2.9 Operating instructions

Additional subclause:

201.7.9.2.9.101 Additional instructions for use

The instructions for use shall include the following:

a) that the use of the MULTIFUNCTION PATIENT MONITOR is restricted to one PATIENT at a time;

b) precautions to take when using a defibrillator on a PATIENT, if APPLIED PARTS not being protected against the effects of defibrillation are being used; a description of how the discharge of a defibrillator affects the MULTIFUNCTION PATIENT MONITOR;

c) information indicating whether the MULTIFUNCTION PATIENT MONITOR incorporates means to protect the PATIENT against burns when used with HIGH-FREQUENCY (HF) SURGICAL EQUIPMENT and advice 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;

d) advice and PROCEDURES regarding testing of the MULTIFUNCTION PATIENT MONITOR and ACCESSORIES on a daily basis (by the clinical OPERATOR).

e) identification of PHYSIOLOGICAL MONITORING UNIT(S) with which the MULTIFUNCTION PATIENT MONITOR is intended to be used;

f) simple fault-finding methods for troubleshooting problems by which the clinical OPERATOR can locate problems if the MULTIFUNCTION PATIENT MONITOR appears to be functioning incorrectly;

g) the subsequent operation of the MULTIFUNCTION PATIENT MONITOR after interruption of the SUPPLY MAINS exceeding 30 s (see 201.11.8);

h) advice on the preferred ALARM SETTINGS and configurations of the ALARM SYSTEM when INTENDED USE includes the monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR;

i) * description of how to invoke an ALARM SIGNAL inactivation state for TECHNICAL ALARM CONDITIONS if sensors, probes, or modules are intentionally disconnected by the clinical OPERATOR;

j) the adjustment ranges of the ALARM LIMITS and the resolution of ALARM LIMIT settings;

k) advice on preferred ALARM SETTINGS and ALARM PRESETS of the ALARM SYSTEM by PATIENT population as needed.

Compliance is checked by inspection of the instructions for use.

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

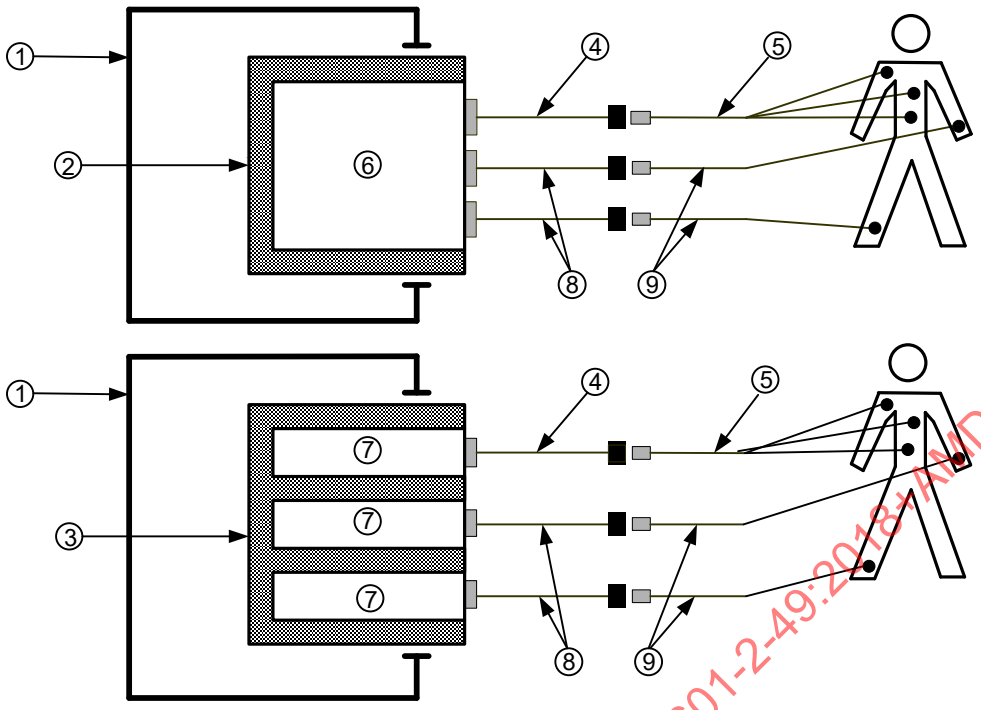
Replacement of item c):

c) An APPLIED PART not covered by a) or b) shall be a TYPE BF APPLIED PART or TYPE CF APPLIED PART.

201.8.5.2.3 * PATIENT leads or PATIENT cables

Addition after the note:

Any connector for electrical connections on a PATIENT lead or PATIENT cable that is at the end of the lead or cable remote from the MULTIFUNCTION PATIENT MONITOR shall be so constructed that conductive parts of said connector cannot be connected to earth or possible hazardous voltage while PATIENT CONNECTIONS of any APPLIED PART, not separated by at least one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE, contact the PATIENT (see Figure 201.101).



IEC

Key

① MULTIFUNCTION PATIENT MONITOR

② Insulation barrier (MOPP) of the PATIENT circuit with multiple (3) PHYSIOLOGICAL MONITORING UNITS

③ Insulation barriers (MOPP) of multiple PATIENT circuits (3) each with a single PHYSIOLOGICAL MONITORING UNIT

④ PATIENT CABLE

⑤ LEAD WIRES

⑥ Single PATIENT circuit with multiple (3) PHYSIOLOGICAL MONITORING UNITS

⑦ Multiple PATIENT circuits (3) each with a single PHYSIOLOGICAL MONITORING UNIT separated from each other by at least one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE

⑧ Extension cable

⑨ PATIENT or sensor cable

□ Connectors at the end of the extension cables, sensor cables, PATIENT CABLES and PATIENT leads remote from the PATIENT

■ Connectors at the end of the extension cables, sensor cables, PATIENT CABLES and PATIENT leads remote from the MULTIFUNCTION PATIENT MONITOR

● PATIENT CONNECTIONS

Figure 201.101 – MULTIFUNCTION PATIENT MONITOR with single PATIENT circuit (6) with multiple PHYSIOLOGICAL MONITORING UNITS and multiple PATIENT circuits (7) each with a single PHYSIOLOGICAL MONITORING UNIT

201.8.5.5.1 * Defibrillation protection

Replacement of last dash in a):

– any unused or disconnected connector at the MULTIFUNCTION PATIENT MONITOR for the connection of APPLIED PART(S). MULTIFUNCTION PATIENT MONITORS that is completely BODY-WORN (e.g. a Holter monitor) is exempt from this requirement.

Addition at the end of b):

Additionally, the MULTIFUNCTION PATIENT MONITOR shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

NOTE 101 The recovery time can be defined in other particular standards

Addition:

aa) MULTIFUNCTION PATIENT MONITORS shall be energized for the common-mode test and differential mode test.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

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

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

Addition:

TRANSPORTABLE MULTIFUNCTION PATIENT MONITORS or TRANSPORTABLE parts of the MULTIFUNCTION PATIENT MONITORS separable while remaining functioning shall have an ingress protection of at least IPX1 so that, in the event of accidental wetting, no loss of BASIC SAFETY or ESSENTIAL PERFORMANCE results from the ingress of liquids

Compliance is checked by the following test:

Expose the TRANSPORTABLE MULTIFUNCTION PATIENT MONITOR *to wetting according of IEC 60529:1989, IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013.*

Immediately after exposure, remove any visible moisture on the ENCLOSURE and confirm that BASIC SAFETY and ESSENTIAL PERFORMANCE of this document are maintained.

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

Replacement:

If the SUPPLY MAINS to the MULTIFUNCTION PATIENT MONITOR 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 MULTIFUNCTION PATIENT MONITOR does not have to be operating during the interruption of the SUPPLY MAINS.

Compliance is checked by observing the MULTIFUNCTION PATIENT MONITOR 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.

Means may be provided to the OPERATOR to select one or more than one of the above options.

Compliance is be checked by functional test.

If the MULTIFUNCTION PATIENT MONITOR contains an INTERNAL ELECTRICAL POWER SOURCE and the SUPPLY MAINS is interrupted, the MULTIFUNCTION PATIENT MONITOR 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 MULTIFUNCTION PATIENT MONITOR continues to conform to this particular standard.

Compliance is checked by interrupting the SUPPLY MAINS and observing that OPERATOR settings and stored data are not changed and that normal operation continues. The 'on-off' switch needs to remain in the 'on' position.

Additional subclause:

201.11.8.101 Protection against depletion of the INTERNAL ELECTRICAL POWER SOURCE

A MULTIFUNCTION PATIENT MONITOR 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 MULTIFUNCTION PATIENT MONITOR (see 201.15.4.4.101).

a) A MULTIFUNCTION PATIENT MONITOR shall provide a TECHNICAL ALARM CONDITION at least 5 min prior to the time that the MULTIFUNCTION PATIENT MONITOR can no longer function in accordance with the MANUFACTURER's specification when powered from the INTERNAL ELECTRICAL POWER SOURCE.

b) When the state of discharge of any INTERNAL ELECTRICAL POWER SOURCE is such that the MULTIFUNCTION PATIENT MONITOR can no longer function in accordance with the MANUFACTURER's specification, the MULTIFUNCTION PATIENT MONITOR shall power down in a manner which causes no HAZARDOUS SITUATION to the PATIENT other than loss of function.

Compliance is checked by functional testing while operating the MULTIFUNCTION PATIENT MONITOR from the INTERNAL ELECTRICAL POWER SOURCE.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

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

201.12.3 ALARM SYSTEMS

Replacement:

A MULTIFUNCTION PATIENT MONITOR that includes an ALARM SYSTEM or is component of a DISTRIBUTED ALARM SYSTEM shall comply with Clause 208 of this particular standard.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

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

201.15.1 Arrangements of controls and indicators of ME EQUIPMENT

Additional subclauses:

201.15.101 Display of PATIENT data

Displayed data (PATIENT data, visual ALARM SIGNALS and visual INFORMATION SIGNALS) shall be CLEARLY LEGIBLE from the intended position of the OPERATOR.

NOTE PATIENT data include real-time waves, numeric values, trends and their time intervals, diagrams and signal quality indicators.

If abbreviations are used, they shall be explained in the instructions for use.

Compliance is checked by inspection of the instructions for use and the tests of the general standard, 7.1.2.

201.15.102 Units of measurement

Units of measurement of PATIENT data should be indicated either continuously or on demand by the OPERATOR.

201.15.4.4 Indicators

Additional subclause:

201.15.4.4.101 Indicator of operation from the INTERNAL ELECTRICAL POWER SOURCE and the status of the INTERNAL ELECTRICAL POWER SOURCE

MULTIFUNCTION PATIENT MONITORS shall visually indicate when they are operating from their INTERNAL ELECTRICAL POWER SOURCE, unless they are only INTERNALLY POWERED.

INTERNALLY POWERED MULTIFUNCTION PATIENT MONITORS shall visually indicate their remaining battery capacity when operating from their INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by inspection and measurement.

201.16 ME SYSTEMS

Clause 16 of the general standard does apply.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standarddoes apply as modified in 202.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

202.7 ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS

202.7.1 Protection of radio services and other EQUIPMENT

Additional subclause:

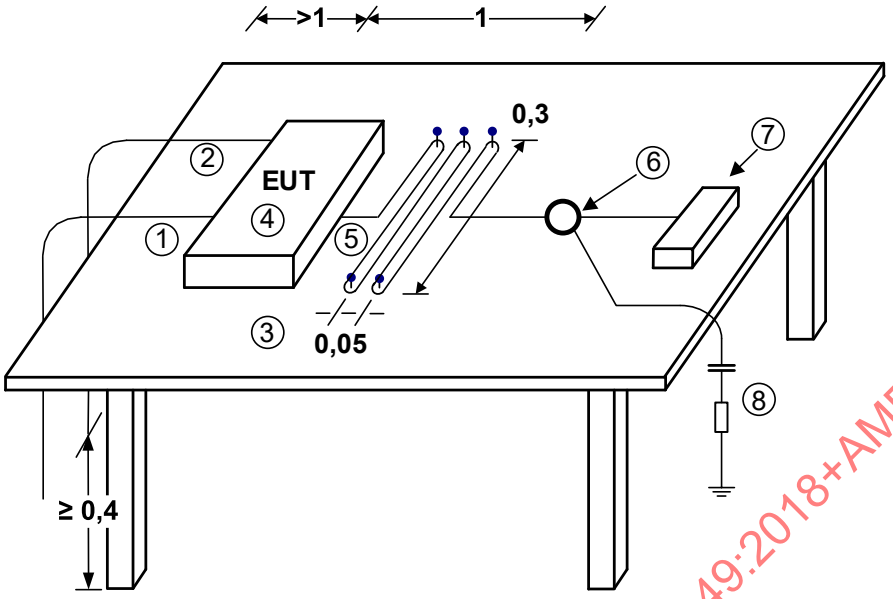
202.7.1.101 * EMISSIONS test setup

MULTIFUNCTION PATIENT MONITORS shall be tested configured with the maximum number of PHYSIOLOGICAL MONITORING UNITS. All specified PHYSIOLOGICAL MONITORING UNITS shall be tested. Representative samples from each family of PATIENT CABLES, LEAD WIRES, sensors, probes and/or TRANSDUCERS with similar construction listed in the ACCOMPANYING DOCUMENTS shall be tested with the corresponding PHYSIOLOGICAL MONITORING UNITS specified by the MANUFACTURER.

MULTIFUNCTION PATIENT MONITORS shall be tested with all PATIENT CABLES, LEAD WIRES, sensors, probes and TRANSDUCERS and with all SIP/SOP cables connected to the MULTIFUNCTION PATIENT MONITOR (see Figure 202.101). The distances of SIP/SOP cables between the open end and floor (ground plane) shall be ≥ 40 cm.

The artificial hand of Figure 202.101 shall be connected only if required by IEC 60601-1-2.

Dimensions in m



IEC

Key

①	Mains cable (if applicable)
②	SIGNAL INPUT / OUTPUT PART cable(s) as applicable
③	Table made of insulating material
④	MULTIFUNCTION PATIENT MONITOR under test (EUT)
⑤	Cable(s) connecting TRANSDUCERS, sensors, ELECTRODES or probes, etc. with equipment under test (EUT)
⑥	TRANSDUCER, sensor, ELECTRODES or probe, etc.
⑦	PATIENT signal simulator, if applicable (shielded and, if necessary, low pass filtered, if susceptible to radio frequency interference)
⑧	Artificial hand according to 4.3.2 of IEC 60601-1-2:2014

Figure 202.101 – Test layout for conducted and radiated EMISSIONS and IMMUNITY test
(see 202.7.1.101 and 202.8.101)

A PATIENT signal simulator is required only if needed for normal operation of the MULTIFUNCTION PATIENT MONITOR or to confirm that the MULTIFUNCTION PATIENT MONITOR provides ESSENTIAL PERFORMANCE during IMMUNITY tests (see also 7.1.9 and 8.2 of IEC 60601-1-2:2014).

202.8.1 General

Replacement of paragraph below NOTE 5:

During and after non-transient phenomena (i.e. radiated radiofrequency electromagnetic fields, proximity fields from radiofrequency wireless communications equipment, RATED power frequency magnetic fields, conducted disturbances induced by radiofrequency fields, and voltage dips):

– the MULTIFUNCTION PATIENT MONITOR shall meet the IMMUNITY pass/fail criteria for BASIC SAFETY and ESSENTIAL PERFORMANCE as determined by MANUFACTURER, and shall not change operating modes, OPERATOR settings and any stored data, or

– the MULTIFUNCTION PATIENT MONITOR shall generate a TECHNICAL ALARM CONDITION, or

– interference shall be readily identifiable by the OPERATOR.

NOTE Examples of readily identifiable interferences are large noise on the ECG waveform, heavily and rapidly fluctuating numeric values, etc.

During transient phenomena (i.e. electrostatic discharge, electrical fast transients/bursts, surges, electrical transient conduction along supply lines and proximity magnetic fields), MULTIFUNCTION PATIENT MONITORS shall meet the IMMUNITY pass/fail criteria for BASIC SAFETY. Within 30 s after the transient electromagnetic phenomena are discontinued, MULTIFUNCTION PATIENT MONITORS shall resume normal operation without OPERATOR intervention, without loss of any OPERATOR settings or stored data and shall provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

For requirements for voltage interruptions, see 201.11.8.

Additional subclauses:

202.8.101 * IMMUNITY test setup

MULTIFUNCTION PATIENT MONITORS shall be tested configured with the maximum number of PHYSIOLOGICAL MONITORING UNITS. All specified PHYSIOLOGICAL MONITORING UNITS shall be tested. Representative samples from each family of PATIENT CABLES, LEAD WIRES, sensors, probes and/or TRANSDUCERS with similar construction listed in the ACCOMPANYING DOCUMENTS shall be tested with the corresponding PHYSIOLOGICAL MONITORING UNIT specified by the MANUFACTURER.

See Figure 202.101.

202.8.102 * Disturbances from HF SURGICAL EQUIPMENT

If the intended environments of use as specified by the MANUFACTURER in the instructions for use include environments where HF SURGICAL EQUIPMENT is used, then the MULTIFUNCTION PATIENT MONITOR shall return to its previous operating mode within 10 s after exposure to disturbances produced by HF SURGICAL EQUIPMENT, without any change in operating mode and OPERATOR settings and without loss of any stored data.

NOTE For example, a MULTIFUNCTION PATIENT MONITOR intended solely for use in the HOME HEALTHCARE ENVIRONMENT is not intended to be used together with HF SURGICAL EQUIPMENT.

Compliance is checked according to Figures 202.102 and 202.103. Figures 202.102 and 202.103 represent test setups to be used for APPLIED PARTS with PATIENT CONNECTIONS. For other types of APPLIED PARTS, the test set-up shall follow that which is defined in the particular standard for the PHYSIOLOGICAL MONITORING UNIT *that is associated with the APPLIED PART. For APPLIED PARTS that are not defined in any particular standard for a* PHYSIOLOGICAL MONITORING UNIT*, the test set-up described in Figure 202.104 is to be used.*

Use PATIENT CABLES, LEAD WIRES, sensors, probes, TRANSDUCERS, ACCESSORIES and settings recommended by the MANUFACTURER and HF SURGICAL EQUIPMENT which complies with IEC 60601-2-2 and has a minmum power cut mode capability of 300 W, a minimum coagulation mode capability of 100 W and a working frequency between 300 kHz and 600 kHz.

a) Test in pure cut mode

Set the output power of the HF SURGICAL EQUIPMENT to the 300 W position.

Touch the metal plate in the test setup (see Figures 202.102, 202.103 and 202.104) with the ACTIVE ELECTRODE and remove it slowly to get an arc.

Confirm that the MULTIFUNCTION PATIENT MONITOR returns within 10 s to the previous operating mode without change of any OPERATOR settings and without loss of any stored data.

Repeat the PROCEDURE *five times.*

b) Test in coagulation mode:

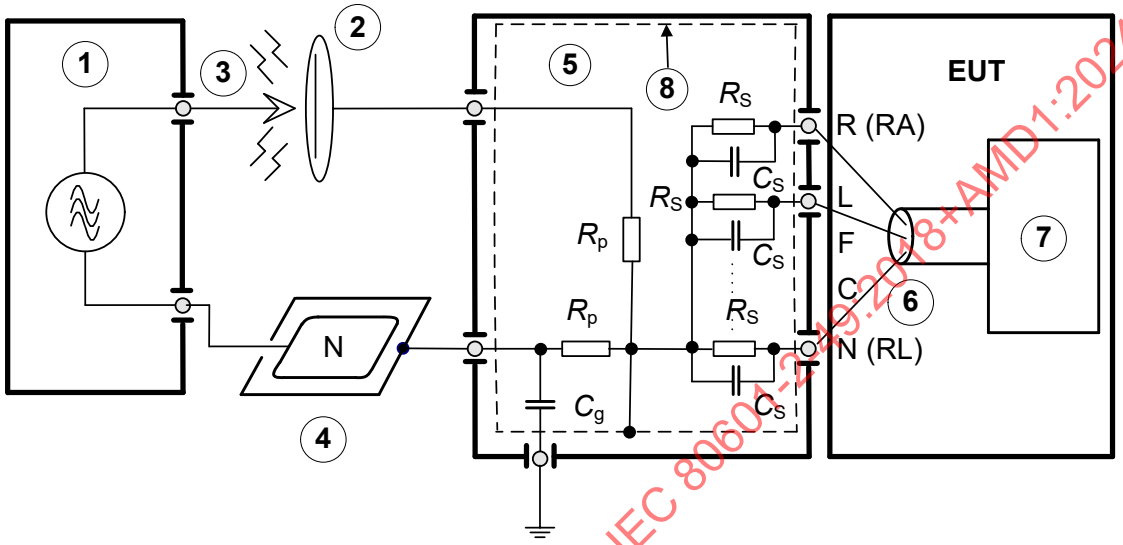
Set the output power of the HF SURGICAL EQUIPMENT to the 100 W position.

Touch the metal plate in the test setup (see Figures 202.102, 202.103 and 202.104) with the ACTIVE ELECTRODE *and remove it slowly to get an arc.*

Confirm that the MULTIFUNCTION PATIENT MONITOR *returns within 10 s to the previous operating mode without change of any* OPERATOR *settings and without loss of any stored data.*

Repeat the PROCEDURE *five times.*

Testing of the spray coagulation mode is not required.



IEC

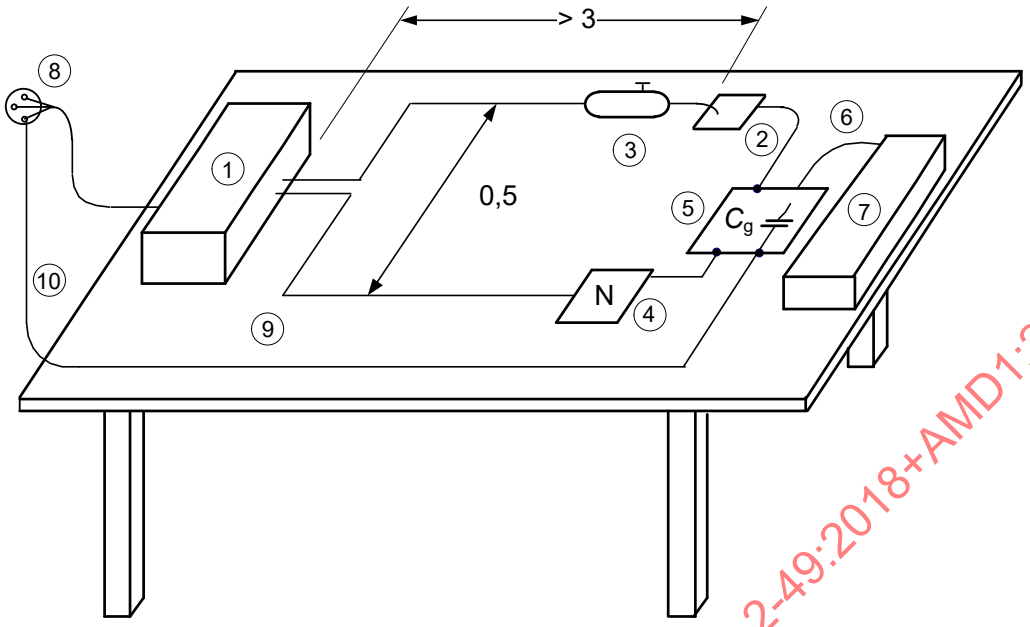
Components

① HF SURGICAL EQUIPMENT
② Metal plate
③ ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
④ Metal plate/NEUTRAL ELECTRODE (N) of HF SURGICAL EQUIPMENT
⑤ Coupling network
⑥ PATIENT CONNECTIONS, PATIENTcables
⑦ MULTIFUNCTION PATIENT MONITOR
⑧ Shielding
R_p 500 Ω ± 10 %, 200 W (low-inductive, < 5 µH, simulates PATIENT impedance)
C_g 47 nF (to minimize the effect of different types of HF SURGICAL EQUIPMENT designs)
R_s 51 kΩ (R_s//C_s simulate the skin impedance)
C_s 47 nF
R, L, F, C, N PATIENT CONNECTIONS

Figure 202.102 – Test circuit for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102 with PATIENT CONNECTIONS

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

Dimensions in m

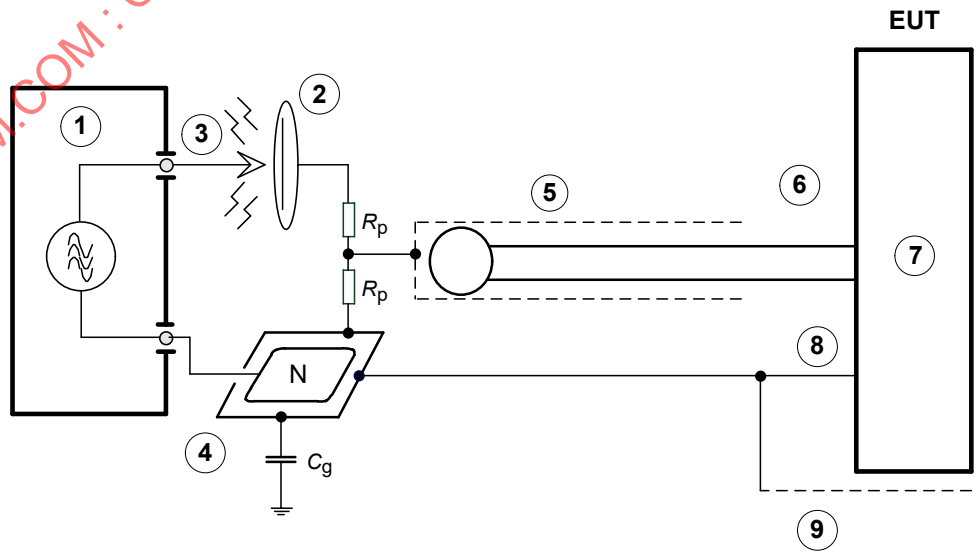


IEC

Components

① HF SURGICAL EQUIPMENT
② Metal plate
③ ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
④ NEUTRAL ELECTRODE of the HF SURGICAL EQUIPMENT
⑤ Coupling network – test set-up according to item 5 in Figure 202.102
⑥ PATIENT CABLE (ECG) and other cables connected to PATIENT
⑦ MULTIFUNCTION PATIENT MONITOR under test
⑧ SUPPLY MAINS
⑨ Table made of insulating material
⑩ Connection to PROTECTIVE EARTH CONDUCTOR for grounding

Figure 202.103 – Test setup for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102



IEC

Components

① HF SURGICAL EQUIPMENT

② Metal plate

③ ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT

④ Metal plate/NEUTRAL ELECTRODE (N) of HF SURGICAL EQUIPMENT

⑤ Copper foil connected to PATIENT impedance (Rp)

⑥ Non-conductive APPLIED PART: Sensor or TRANSDUCER with connection cable

⑦ MULTIFUNCTION PATIENT MONITOR

⑧ For CLASS I EQUIPMENT: Metal plate/NEUTRAL ELECTRODE (N) of HF SURGICAL EQUIPMENT connected with the ENCLOSURE of the MULTIFUNCTION PATIENT MONITOR

⑨ For CLASS II EQUIPMENT: Metal plate/NEUTRAL ELECTRODE (N) of HF SURGICAL EQUIPMENT connected with a copper foil surrounding the ENCLOSURE of the MULTIFUNCTION PATIENT MONITOR

R_p 500 Ω ± 10 %, 200 W (low-inductive, < 5 μH, simulated PATIENT impedance)

C_g 47 nF (to minimize the effect of different types of HF SURGICAL EQUIPMENT designs)

Figure 202.104 – Test circuit for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102 with non-conductive APPLIED PART

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

206 USABILITY

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply, except as follows:

Additional subclause:

206.101 PRIMARY OPERATING FUNCTIONS

For MULTIFUNCTION PATIENT MONITORS, the following shall be considered PRIMARY OPERATING FUNCTIONS:

a) switching on/off,

b) connecting/disconnecting PATIENT cables, sensor, probes and TRANSDUCERS,

c) observing monitored physiological parameters, waveforms and visual ALARM SIGNALS from the display,

d) setting the OPERATOR-adjustable controls relevant for PATIENT safety,

e) setting ALARM LIMITS,

f) inactivating ALARM SIGNALS,

g) adding or removing PHYSIOLOGICAL MONITORING UNITS, where applicable.

Compliance is checked by inspection of the MULTIFUNCTION PATIENT MONITOR and the instructions for use.

208 General requirements, tests and guidance for ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply, except as follows:

208.6.1.2 * Determination of ALARM CONDITIONS and assignment of priority

Addition:

A MANUFACTURER-configured ALARM PRESET shall assign at least LOW PRIORITY to TECHNICAL ALARM CONDITIONS that prevent the generation of PHYSIOLOGICAL ALARM CONDITIONS, unless an INTELLIGENT ALARM SYSTEM determines that an INFORMATION SIGNAL or no ALARM CONDITION is appropriate.

The ALARM SYSTEM shall include the ALARM CONDITIONS that are specified in the particular standard of the respective PHYSIOLOGICAL MONITORING UNIT and other ALARM CONDITIONS specified by the MANUFACTURER in the instructions for use.

Compliance is checked by inspection.

208.6.3.2 Visual ALARM SIGNALS

Additional subIcause:

208.6.3.2.101 * Indication of validity of measured values

During a TECHNICAL ALARM CONDITION, if the MULTIFUNCTION PATIENT MONITOR displays a measured value of a related PHYSIOLOGICAL MONITORING UNIT, then the MULTIFUNCTION PATIENT MONITOR shall provide information to permit the OPERATOR to assess the validity of the displayed value.

NOTE During a TECHNICAL ALARM CONDITION, the PHYSIOLOGICAL MONITORING UNIT might not be capable of accurately detecting PHYSIOLOGICAL ALARM CONDITIONS.

Compliance is checked by functional test and inspection of the ACCOMPANYING DOCUMENTS.

208.6.5 ALARM PRESETS

Addition:

If INTENDED USE includes unattended monitoring, at least one MANUFACTURER-configured ALARM PRESET suitable for unattended monitoring shall be included in the ALARM SYSTEM.

Compliance is checked by inspection.

208.6.8 ALARM SIGNAL inactivation states

208.6.8.1 * General

Addition:

MULTIFUNCTION PATIENT MONITORS may provide a single control to initiate:

– ALARMS OFF or ALARMS PAUSED for the group of PHYSIOLOGICAL ALARM CONDITIONS, and
– AUDIO OFF or AUDIO PAUSED for the group of TECHNICAL ALARM CONDITIONS.

Symbols IEC 60417-5319:2002-11 or IEC 60417-5319:2002-11 (symbol 3 and 4 in Table C.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012) or alternative marking 2 and 4 in Table C.2 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, as appropriate,