

Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

Amendment No. 1

International adoption identical

Publishing and Approval Dates

Council of Standards Australia Approval: 26 May 2022

New Zealand Standards Approval Board Approval: 1 June 2022

Published: 17 June 2022

Summary

This Amendment applies to the following elements:

- Front cover
- Preface
- Amendment 2

Amendment Details

AS/NZS IEC 60601.1:2015 is amended as follows. The amendments should be inserted in the locations as instructed.

Element	Instruction / New text
Front cover	Top right-hand corner, after IEC 60601-1 Ed.3.1 (2012) <i>add</i> the following: IEC 60601-1:2005/AMD2:2020 (Incorporating Amendment No. 1)
Preface	After the first paragraph, <i>add</i> the following: Amendment No. 1 to this Standard was prepared by the Standards Australia Committee HE-003, Medical Electrical Equipment. <i>Delete</i> third paragraph and <i>replace</i> with the following: This Standard is identical with, and has been reproduced from, IEC 60601-1:2012 (ED. 3.1), <i>Medical electrical equipment, Part 1: General requirements for basic safety and essential performance</i> , which incorporates its Corrigendum 1 (2006), Corrigendum 2 (2007) and Amendment 1 (2012), and its Amendment 2 (2020), which has been added at the end of the source text.
Amd 2 (new)	After Index of defined terms used in this collateral standard, <i>add</i> the following Amendment No. 2 (2020):

FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62A/1389/FDIS	62A/1404/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

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

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- withdrawn,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

NOTE The attention of the 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 or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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

INTRODUCTION TO AMENDMENT 2

The third edition of IEC 60601-1 was published in 2005 and amended in 2012. Since the publication of IEC 60601-1:2005/AMD1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees and questions submitted to IEC/SC 62A/Working Group (WG) 14. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in Amendment 2 and should not wait until the fourth edition of IEC 60601-1, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 109 items were presented to the National Committees present. A total of 78 items received the required 2/3 majority of the National Committees present and voting and were included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the fourth edition of IEC 60601-1.

The "short list" of issues was documented in the design specification for Amendment 2. The responsible expert groups were directed to consider each issue assigned to it in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to the 2005 edition of IEC 60601-1, the style in force at the time of publication of IEC 60601-1 has been applied to this amendment. The style specified in ISO/IEC Directives, Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

INTRODUCTION

Add, after the existing last paragraph, the following paragraph:

Throughout this document, there are many references to, and requirements incorporated from IEC 60950-1. Some of these requirements are derived from IEC 60950-1. For example, the requirements for spaces filled by insulating compound in 8.9.3. In other cases, the requirements are incorporated by a normative reference to IEC 60950-1:2005. For example, the requirements for solid insulation forming a MEANS OF OPERATOR PROTECTION in 8.5.1.3. The requirements incorporated by reference are primarily found in Clause 8 of this document, including many of the tables used to determine the requirements for MEANS OF PROTECTION, primarily MEANS OF OPERATOR PROTECTION and INSULATION CO-ORDINATION. The requirements incorporated by reference are addressed in Amendment 2. The derived requirements will be addressed during the development of the fourth edition of this document.

1.3 * Collateral standards

Replace the existing second paragraph with:

Applicable collateral standards shall apply together with this standard.

Delete the existing third paragraph.

1.4 * Particular standards

Replace the existing first paragraph with:

In the IEC 60601 series, particular standards specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the particular ME EQUIPMENT and ME SYSTEMS. Particular standards may modify, replace or delete requirements contained in this standard and applicable collateral standards as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration.

Replace the existing second paragraph with:

A requirement of a particular standard takes priority over this standard and applicable collateral standards.

2 * Normative references

Replace the existing second paragraph with:

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, shall apply together with this standard when applicable. They shall be considered as being included among the normative references below. See 1.3.

Replace the following existing references to IEC 60601-1-2, IEC 60601-1-3 modified by Amendment 1, IEC 60601-1-6 and IEC 60601-1-8 by the following new references:

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*
Amendment 1:2020

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
Amendment 1:2013

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
Amendment 1:2013
Amendment 2:2020

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*
Amendment 1:2012
Amendment 2:2020

Add the following new reference to the list:

IEC 60747-5-5:2007, *Semiconductor devices – Discrete devices – Part 5-5: Optoelectronic devices – Photocouplers*

Replace, in the existing reference to IEC 60825-1, "2007" with "2014".

Replace the existing references to IEC 60950-1 and IEC 62304 by the following new references:

IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*
Amendment 1:2009
Amendment 2:2013

IEC 62304:2006, *Medical device software – Software life cycle processes*
Amendment 1:2015

Add the following normative references to the existing list:

IEC 62133-2, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems*

IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

Replace the existing references to ISO 7000-DB:2004 by the following new reference:
ISO 7000, *Graphical symbols for use on equipment*

Replace, in the existing reference to ISO 7010, "2011" with "2019".

Replace, in the existing reference to ISO 14971, "2007" with "2019".

Replace, in the existing reference to ISO 15223-1, "2012" with "2016".

3 * Terminology and definitions

3.38

*** HARM**

Replace the existing term and definition, modified by Amendment 1, with:

3.38

*** HARM**

injury or damage to the health of people or animals, or damage to property or the environment

[ISO 14971:2019, definition 3.3, modified – "Or animals" added to the definition]

3.39
HAZARD

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.4]

3.40
*** HAZARDOUS SITUATION**

Replace the existing term and definition, modified by Amendment 1, with:

3.40
*** HAZARDOUS SITUATION**

circumstance in which people, property, or the environment is/are exposed to one or more HAZARDS

[ISO 14971:2019, definition 3.5, modified – Note 1 to entry deleted.]

3.44
INTENDED USE
INTENDED PURPOSE

Replace the existing term and definition, modified by Amendment 1, with:

3.44
INTENDED USE
INTENDED PURPOSE

use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

NOTE 1 The intended medical indication, PATIENT population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the INTENDED USE.

NOTE 2 INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

[ISO 14971:2019, definition 3.6, modified – Note 2 added.]

3.55
MANUFACTURER

Replace the existing term and definition, modified by Amendment 1, with:

3.55
MANUFACTURER

natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person himself or on his behalf by another person(s)

NOTE 1 ISO 13485 [30] defines "labelling" as "label, instructions for use, and any other information that is related to identification, technical description, INTENDED PURPOSE and proper use of the ME EQUIPMENT or ME SYSTEM, but excluding shipping documents".

NOTE 2 "Adapting" includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

NOTE 3 In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

NOTE 4 Adapted from ISO 14971:2019, definition 3.9.

3.72

OBJECTIVE EVIDENCE

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.11]

3.88

PROCEDURE

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.13, modified – Note 1 to entry deleted.]

3.89

PROCESS

Replace the existing term and definition, modified by Amendment 1, with:

3.89

PROCESS

set of interrelated or interacting activities that use inputs to deliver an intended result

NOTE 1 Whether the “intended result” of a PROCESS is called output, product or service depends on the context of the reference.

NOTE 2 Inputs to a PROCESS are generally the outputs of other PROCESSES and outputs of a PROCESS are generally the inputs to other PROCESSES.

NOTE 3 Two or more interrelated and interacting PROCESSES in series can also be referred to as a PROCESS.

[ISO 14971:2019, definition 3.14]

3.98

RECORD

Add the following NOTES and replace the existing source statement for definition, modified by Amendment 1, with:

NOTE 1 RECORDS can be used, for example, to formalize traceability and to provide evidence of VERIFICATION, preventive action and corrective action.

NOTE 2 Generally RECORDS need not be under revision control.

[ISO 14971:2019, definition 3.16]

3.100

RESIDUAL RISK

Replace the existing term and definition, modified by Amendment 1, with:

3.100

RESIDUAL RISK

RISK remaining after RISK CONTROL measures have been implemented

[ISO 14971:2019, definition 3.17]

3.102

RISK

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.18]

3.103

RISK ANALYSIS

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.19]

3.104

RISK ASSESSMENT

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.20]

3.105

RISK CONTROL

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.21]

3.106

RISK EVALUATION

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.23]

3.107

RISK MANAGEMENT

Replace the existing term and definition, modified by Amendment 1, with:

3.107

RISK MANAGEMENT

systematic application of management policies, PROCEDURES and practices to the tasks of analysing, evaluating, controlling and monitoring RISK

NOTE For the purposes of this standard, RISK MANAGEMENT does not include planning for or monitoring of production and post-production information; whereas this is required for compliance with ISO 14971 (see 4.2.2).

[ISO 14971:2019, definition 3.24, modified – NOTE added.]

3.108

RISK MANAGEMENT FILE

Replace the existing NOTE and source statement for definition, modified by Amendment 1, with:

NOTE All safety related information including MANUFACTURER'S calculations, test results, etc. is considered to be part of the RISK MANAGEMENT FILE. See also 4.2.

[ISO 14971:2019, definition 3.25, modified – NOTE added.]

3.114

SEVERITY

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.27]

3.136

USABILITY

Replace the existing term and definition, modified by Amendment 1, with:

3.136

USABILITY

characteristic of the OPERATOR interface that facilitates use and thereby establishes effectiveness, efficiency, and OPERATOR satisfaction in the intended use environment

[IEC 62366-1:2015, definition 3.16, modified – Replace "user" with "OPERATOR" in two places and delete Note 1 to entry.]

3.137

USABILITY ENGINEERING

Replace the existing term and definition, modified by Amendment 1, with:

3.137

USABILITY ENGINEERING

HUMAN FACTORS ENGINEERING

application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of ME EQUIPMENT (including software), systems and tasks to achieve adequate USABILITY

[IEC 62366-1:2015, definition 3.17, modified – Replace "medical devices" with "ME EQUIPMENT" and delete Note 1 to entry.]

3.138

VERIFICATION

Replace the existing NOTES and source statement or definition, modified by Amendment 1, with:

NOTE 1 The OBJECTIVE EVIDENCE needed for a VERIFICATION can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

NOTE 2 The activities carried out for VERIFICATION are sometimes called a qualification PROCESS.

NOTE 3 The word "verified" is used to designate the corresponding status.

[ISO 14971:2019, definition 3.31]

3.146

PRIMARY OPERATING FUNCTION

Replace the existing term and definition, added by Amendment 1, with:

3.146

PRIMARY OPERATING FUNCTION

function that involves OPERATOR interaction that is related to the safety of the ME EQUIPMENT

[IEC 62366-1:2015, definition 3.11, modified – Replace "user" with "OPERATOR" and "medical device" with "ME EQUIPMENT", and delete Note 1 to entry and Note 2 to entry.]

3.147

USABILITY ENGINEERING FILE

For the existing definition, added by Amendment 1, replace "[IEC 62366:2007, definition 3.19]" with "[IEC 62366-1:2015, definition 3.18]".

Add, after the existing definition 3.147, added by Amendment 1, the following new terms and definitions:

3.148

ELECTROMAGNETIC DISTURBANCE

EM DISTURBANCE

any electromagnetic phenomenon that could degrade the performance of a device, equipment or system

NOTE An ELECTROMAGNETIC DISTURBANCE can be electromagnetic noise, an unwanted signal or a change in the propagation medium itself.

[IEC 60601-1-2:2014, definition 3.3]

3.149

HIGH PRIORITY

indicating that immediate OPERATOR response is required

NOTE 1 The priority is assigned through RISK ANALYSIS.

NOTE 2 Immediate implies the interruption of current workflow is expected.

[IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, definition 3.22, modified – Internal reference to IEC 60601-1-8, 6.1.2 in NOTE 1 deleted and bibliographic citations removed from NOTE 2.]

3.150

*** INFORMATION SIGNAL**

any signal that is not an ALARM SIGNAL or a reminder signal

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO2 tone

EXAMPLE 3 Fluoroscopy beam-on indication

NOTE An advisory is a type of INFORMATION SIGNAL.

[SOURCE: IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, definition 3.23]

3.151

LOW PRIORITY

indicating that OPERATOR awareness is required and future action might be needed

NOTE 1 The priority is assigned through RISK ANALYSIS.

NOTE 2 Awareness implies the planning of future workflow is expected.

[IEC 60601-1-8:2006/AMD2:2020, definition 3.27, modified – Internal reference to IEC 60601-1-8, 6.1.2 in NOTE 1 deleted and bibliographic citations removed from NOTE 2.]

3.152

*** MAXIMUM EQUIPMENT PRESSURE**

the maximum gauge pressure to which a part of ME EQUIPMENT can be subjected in NORMAL CONDITION and SINGLE FAULT CONDITION

3.153

MEDIUM PRIORITY

indicating that prompt OPERATOR response is required

NOTE 1 The priority is assigned through RISK ANALYSIS.

NOTE 2 Prompt implies the re-planning of current workflow is expected.

[IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, definition 3.28, modified – Internal reference to IEC 60601-1-8, 6.1.2 in NOTE 1 deleted and bibliographic citations removed from NOTE 2.]

3.154

SAFETY SIGN

sign giving a general safety message, obtained by a combination of a colour and geometric shape and which, by the addition of a graphical symbol, gives a general or particular safety message

[ISO 7010:2019, definition 3.3, modified – Replace "gives a particular safety message" with "gives a general or particular safety message".]

4.2.1 Introduction to RISK MANAGEMENT

Replace, in the existing second paragraph, added by Amendment 1, "ISO 14971" with "ISO 14971:2019" (3 places).

4.2.2 General requirement for RISK MANAGEMENT

Replace, in the introductory paragraph before the dashes, added by Amendment 1, "ISO 14971:2007" with "ISO 14971:2019".

Replace the existing first and second dashes, added by Amendment 1, with:

- the planning for and execution of production and post-production monitoring (subclause 4.1, fourth dash, subclause 4.4, item g), and Clause 10 of ISO 14971:2019), and
- periodic reviews of the suitability of the RISK MANAGEMENT PROCESS (third paragraph of ISO 14971:2019, subclause 4.2).

Figure 6 – Standard test finger (see 5.9.2.1)

Replace, in the existing NOTE 3 of this figure, the reference to "IEC 60950-1" with "IEC 60950-1:2005".

6.3 * Protection against harmful ingress of water or particulate matter

Delete, in the existing title, the asterisk ().*

7.1.2 * Legibility of markings

Replace, in the existing first dash, "safety signs" with "SAFETY SIGNS".

7.2.3 * Consult ACCOMPANYING DOCUMENTS

Replace the existing subclause, modified by Amendment 1, with:

When the MANUFACTURER uses consulting the ACCOMPANYING DOCUMENTS as a primary RISK CONTROL measure for a specific RISK (e.g. the instructions for use contain information for safety) and the USABILITY ENGINEERING PROCESS determines that marking the ME EQUIPMENT is required for the effectiveness of the RISK CONTROL, the ME EQUIPMENT shall be marked with the refer to instruction manual/booklet mandatory action SAFETY SIGN ISO 7010-M002 (see Table D.2, SAFETY SIGN 10).

Otherwise, symbol ISO 7000-1641 (2004-01) (see Table D.1, symbol 11) may be used to advise the OPERATOR of the location of the instructions for use or to consult the ACCOMPANYING DOCUMENTS.

7.2.5 ME EQUIPMENT intended to receive power from other equipment

Replace, in the existing second dash modified by Amendment 1, "safety sign" with "SAFETY SIGN" in two places.

7.2.9 IP classification

Replace the existing second paragraph with:

If the IP classification of the ENCLOSURE of the ME EQUIPMENT or its parts is not specified (i.e. IPXX) or is specified as IP00, IPX0 or IP0X, then the ME EQUIPMENT or its parts need not be marked as such.

7.2.10 * APPLIED PARTS

Replace, in the final paragraph, "safety sign" with "SAFETY SIGN" in two places.

7.2.13 Physiological effects (safety signs and warning statements)

Replace, in the existing title, "safety signs" with "SAFETY SIGNS", and in the existing first paragraph, "safety sign" with "SAFETY SIGN" in two places.

7.2.17 Protective packaging

Replace, in the existing third paragraph, "safety sign" with "SAFETY SIGN".

7.3.2 * HIGH VOLTAGE parts

Replace, in the existing paragraph, modified by Amendment 1, "safety sign" with "SAFETY SIGN".

7.3.3 Batteries

Replace the existing third paragraph with:

Where lithium batteries or fuel cells are incorporated and where incorrect replacement (e.g. reversed polarity) would result in a HAZARDOUS SITUATION (such as excessive temperatures, fire or explosion), a warning indicating that replacement by inadequately trained personnel could result in such a HAZARDOUS SITUATION shall be given in addition to the identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS.

7.3.7 Supply terminals

Delete, in the existing first paragraph, modified by Amendment 1, "unless it can be demonstrated that no unacceptable RISK can result if connections are interchanged".

7.4.1 * Power switches

Delete, in the existing first paragraph modified by Amendment 1, "or its parts,".

Add, after the third dash of the existing third paragraph modified by Amendment 1, the following paragraphs:

Switches used to control power to parts of ME EQUIPMENT shall have their "on" and "off" positions:

- marked with symbols as specified above; or
- with IEC 60417-5264 (2002-10) and IEC 60417-5265 (2002-10) (see Table D.1, symbols 16 and 17); or

- indicated by an adjacent indicator light; or
- indicated by other unambiguous means.

A switch that brings the ME EQUIPMENT into the "stand-by" condition may be indicated by use of symbol IEC 60417-5009 (2015-03) (see Table D.1, Symbol 29).

7.4.2 * Control devices

Delete, in the existing first paragraph, modified by Amendment 1, ", e.g. by use of symbols IEC 60417-5264 (2002-10) and IEC 60417-5265 (2002-10) (see Table D.1, symbols 16 and 17)"

Delete the existing final paragraph, modified by Amendment 1.

7.5 Safety signs

Replace, in the existing title, "Safety signs" with "SAFETY SIGNS", in the existing first paragraph, modified by Amendment 1, "safety sign" with "SAFETY SIGN" in three places, and in the existing second paragraph, "safety sign" with "SAFETY SIGN".

Replace, in existing list item a), "safety sign" with "SAFETY SIGN" and "safety signs" with "SAFETY SIGNS".

Replace, in existing list items b), c) and d), "safety sign" with "SAFETY SIGN".

Replace, in the existing third paragraph, "safety sign" with "SAFETY SIGN", and in NOTE 2, replace "safety signs" with "SAFETY SIGNS".

Replace, in the existing fourth and fifth paragraphs, "safety signs" with "SAFETY SIGNS".

7.8.1 Colours of indicator lights

Add an asterisk () at the beginning of the subclause title.*

Table 2 – Colours of indicator lights and their meaning for ME EQUIPMENT

Replace the existing table and its title with the following new table:

**Table 2 – Colours and meanings of indicator lights
and alarm indicator lights for ME EQUIPMENT**

Name	On when	Indicator light ^a	Alarm indicator light	Accompanied by sound	Operator requirement
Warning ^b	HAZARDOUS SITUATION is to be avoided	Red, not flashing	–	– ^c	Avoidance of a HAZARDOUS SITUATION which could cause death or serious injury
Caution ^b	HAZARDOUS SITUATION is to be avoided	Yellow, not flashing	–	–	Avoidance of a HAZARDOUS SITUATION which could cause minor or moderate injury or equipment damage
Ready for use	ME EQUIPMENT is ready for use	Green	–	–	–
HIGH PRIORITY ALARM CONDITION	Interruption of current workflow is needed	–	Red, flashing ^d	Typically ^d	Immediate action to prevent injury
MEDIUM PRIORITY ALARM CONDITION	Re-planning of current workflow is needed	–	Yellow, flashing ^d	Typically ^d	Prompt action to prevent injury
LOW PRIORITY ALARM CONDITION	Planning of future workflow is needed	–	Yellow or cyan, not flashing ^d	Optional ^d	Awareness for future action
Other	Situations other than that of red, yellow or green	Any colour other than red, yellow, cyan or green	–	–	–
^a These indicator lights are INFORMATION SIGNALS and IEC 60601-1-8 requires that they be perceived as different than visual ALARM SIGNALS. ^b Such warnings and cautions are frequently accompanied by a SAFETY SIGN. ^c Sound may be utilized, but IEC 60601-1-8 requires that it be perceived as different than auditory ALARM SIGNALS. ^d As specified in IEC 60601-1-8.					

7.9.2.1 * General

Replace, in the existing fourth paragraph, "safety signs" with "SAFETY SIGNS".

7.9.3.1 * General

Replace, in the second dash of the existing second paragraph, modified by Amendment 1, "safety signs" with "SAFETY SIGNS".

8.4.2 ACCESSIBLE PARTS and APPLIED PARTS

Renumber the existing NOTE as NOTE 1.

Add, after the final paragraph of existing list item c) modified by Amendment 1, the following text:

If the ME EQUIPMENT has SIP/SOP connectors or separate power supply output connectors, measure the voltage of all conductive ACCESSIBLE PARTS of the SIP/SOP connectors or power output connectors to earth:

- *Connect a resistor of $10\text{ k}\Omega \pm 500\text{ }\Omega$ (8 W for measurements up to 280 V r.m.s.) between the SIP/SOP-pin (or other output connector) to earth.*
- *Connect in parallel to the $10\text{ k}\Omega$ resistor a peak voltmeter or an oscilloscope to measure the voltage.*

If the voltage measured above is less than or equal to 60 V d.c. or 42,4 V peak a.c., a subsequent LEAKAGE CURRENT test is not necessary.

NOTE 2 A similar approach exists in IEC 60950-1:2005, 1.4.9.

NOTE 3 $10\text{ k}\Omega$ has been selected, because it is a value higher than the body impedance of the OPERATOR ($\approx 1\text{ k}\Omega$) and lower than the expected impedance of the insulation barrier (approximately $1\text{ M}\Omega$). Furthermore, IEC 60950-1:2005, 1.4.9 used a $5\text{ k}\Omega$ resistor and therefore using a $10\text{ k}\Omega$ resistor provides greater safety.

If the voltage measurement above exceeds the specified levels, then the TOUCH CURRENT from SIP/SOP connectors to earth and from any separate power supply output connectors to earth shall be measured.

Measure the TOUCH CURRENT derived from the SUPPLY MAINS by applying the limits in 8.7.3 c) from the connectors described above in:

- *NORMAL CONDITION including open FUNCTIONAL EARTH CONDUCTOR (if applicable); and*
- *SINGLE FAULT CONDITION (respectively open neutral conductor; open PROTECTIVE EARTH CONDUCTOR (if applicable)).*

NOTE 4 If the SIP/SOP circuit is completely isolated from the floating (non-earth referenced) SECONDARY CIRCUIT by an own insulation barrier of at least 1 MOOP based on MAINS VOLTAGE, i.e. a SEPARATION DEVICE according to 16.5, the measurement of the SIP/SOP connector to earth TOUCH CURRENT does not need to be conducted. In such cases it is sufficient to evaluate the effectiveness of the SEPARATION DEVICE by measurement according to 8.7.4.7 c).

NOTE 5 For CLASS I ME EQUIPMENT with earth referenced SECONDARY CIRCUITS in NORMAL CONDITION, the LEAKAGE CURRENT derived from the SUPPLY MAINS will be superimposed by the secondary voltage generated current. However, the SUPPLY MAINS derived LEAKAGE CURRENT will usually be equal to the TOUCH CURRENT measured on parts connected to the PROTECTIVE EARTH TERMINAL both in NORMAL CONDITION and in SINGLE FAULT CONDITION (open neutral conductor; open PROTECTIVE EARTH CONDUCTOR). If in doubt, the measurement can usually be done by setting the voltage meter to AC-measurement only or by using an oscilloscope or any other equivalent method to assure that the secondary voltage will not influence the measurement result.

8.5.1.1 General

Replace the existing second paragraph with:

Each MEANS OF PROTECTION shall be categorized in relation to the ME EQUIPMENT part(s) which it protects from exceeding permitted limits. It is a MEANS OF PATIENT PROTECTION if it protects APPLIED PARTS or parts that are identified according to 4.6 as needing to be subject to the same requirements as APPLIED PARTS. Otherwise the requirements for either MOPP or MOOP shall be used as shown in Figure 40.

Replace the existing NOTE, modified by Amendment 1, with:

NOTE Coatings and other insulation that are intended as a MEANS OF PROTECTION and that comply with IEC 60950-1:2005 or IEC 62368-1:2018 can be used as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF PATIENT PROTECTION. For MEANS OF PATIENT PROTECTION, considerations can arise as a result of the RISK MANAGEMENT PROCESS.

Add, after the existing sixth paragraph, added by Amendment 1, the following new figure:

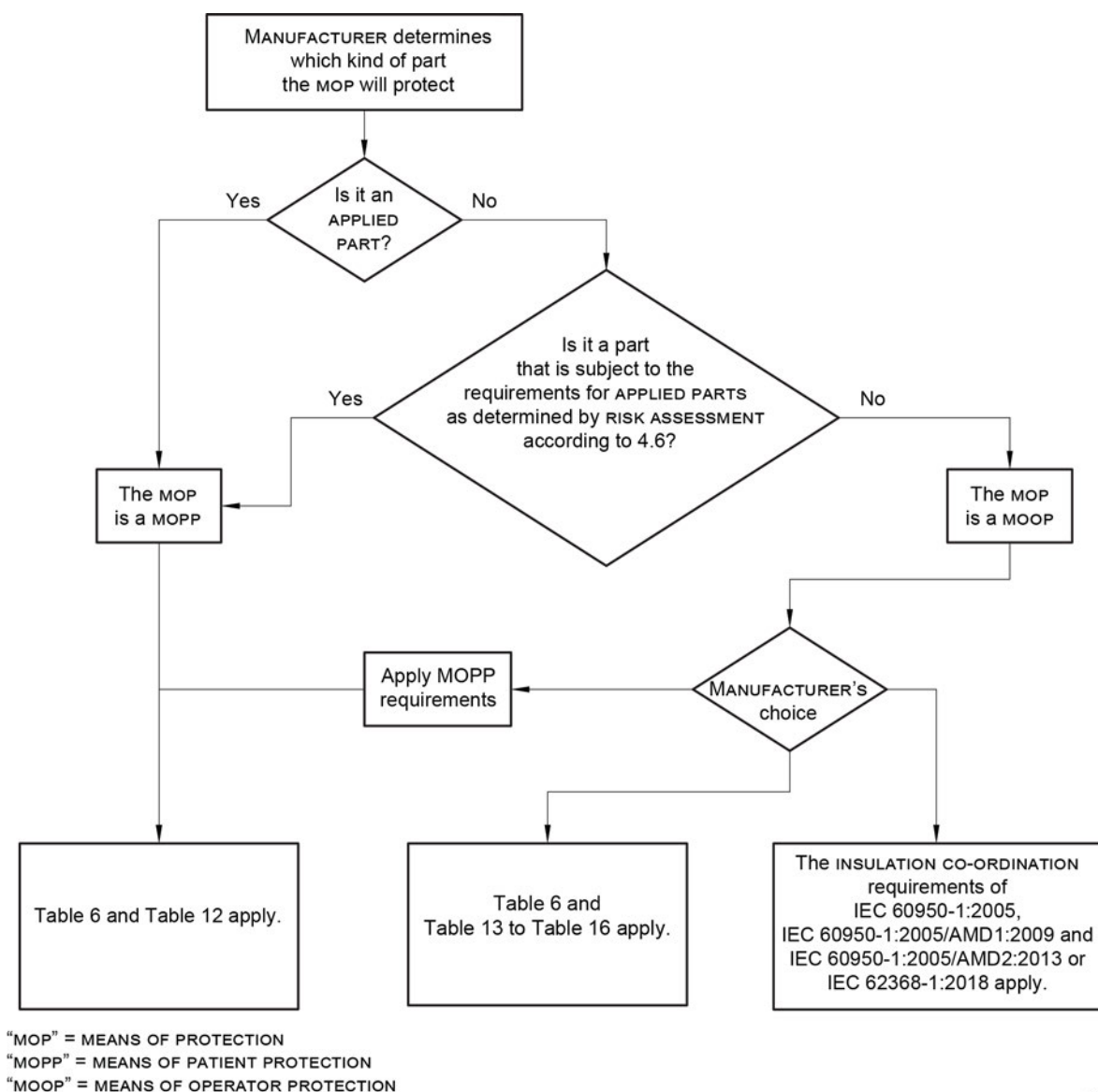


Figure 40 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION

8.5.1.2 * MEANS OF PATIENT PROTECTION (MOPP)

Add, after the existing second paragraph, the following NOTES:

NOTE 1 Barriers providing 2 MOOP with AIR CLEARANCE values according to Table 13 to Table 15 (inclusive) or according to IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 meet the requirements for 1 MOPP according to Table 12 for WORKING VOLTAGES up to 707 V d.c. / 500 V r.m.s. At higher WORKING VOLTAGES, 2 MOOP does not necessarily provide 1 MOPP.

Barriers providing REINFORCED INSULATION (2 MOOP) with AIR CLEARANCE values according to IEC 62368-1:2018 for WORKING VOLTAGES up to and including 354 V d.c. / 250 V r.m.s. meets the requirements for 1 MOPP according to Table 12. At higher WORKING VOLTAGES, REINFORCED INSULATION (2 MOOP) does not necessarily provide 1 MOPP.

See also 8.5.1.3.

NOTE 2 Barriers providing REINFORCED INSULATION (2 MOOP) with CREEPAGE DISTANCES according to IEC 62368-1:2018, Table 17 and Table 18 or IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009, IEC 60950-1:2005/AMD2:2013, Table 2N meet the requirements for 1 MOPP according to Table 12.

Add after the existing fifth paragraph, added by Amendment 1, the following text: