

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance**

**Appareils électromédicaux –
Partie 1: Exigences générales pour la sécurité de base et les performances
essentielles**

STANDARD PREVIEW
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**MEDICAL ELECTRICAL EQUIPMENT –
Part 1: General requirements for basic safety
and essential performance**

INTERPRETATION SHEET 1

This interpretation sheet has been prepared by SC 62A: Common aspects of electrical equipment used in medical practice

The text of this interpretation sheet is based on the following documents:

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Subclause 1.1

This subclause is clarified by the following:

IEC 60601-1 does not apply to medical gas pipeline systems covered by ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum.*

NOTE Subclause 6.3 of ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and alarm signals.

This clarification will remain valid until a new version of IEC 60601-1 is published.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 2

This interpretation sheet 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 interpretation sheet is based on the following documents:

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62A/634/ISH	62A/640/RVD

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Subclause 11.3

This subclause is clarified by the following: [https://standards.iteh.ai/catalog/standards/sist/1f7471e5-217f-493a-b9fa-8cd58aa8a268/iec-](https://standards.iteh.ai/catalog/standards/sist/1f7471e5-217f-493a-b9fa-8cd58aa8a268/iec-60601-1-2005)

As stated in the rationale for this subclause, fire ENCLOSURES are intended to be used only where there is a significant likelihood of fire due to the presence of a source of ignition (as described in the subclause) *and* a *significant* source of fuel. Most materials used in the construction of ME EQUIPMENT are not considered to be such a source of fuel unless they are in the presence of an OXYGEN RICH ENVIRONMENT. MANUFACTURERS should determine, through analyses documented in the RISK MANAGEMENT FILE, whether the ME EQUIPMENT contains combustible materials (fuel) in sufficient quantities to support combustion in conjunction with ignition sources (capable of releasing greater than 900 J).

Subclause 13.1.2

This subclause is clarified by the following:

As stated in subclause 4.7, it is the MANUFACTURER'S RISK ANALYSIS that determines which components are subject to failure testing based on the associated RISK. Where the associated RISK of fire exceeds the MANUFACTURER'S criteria for RISK acceptability, the MANUFACTURER'S simulation analysis (such as FMEAs) should be accepted in lieu of physical testing. As also stated in 4.7, component reliability and ratings are to be considered in such failure simulation analyses. Common electronic components that have a history of use without causing equipment fires should not be considered a likely source of ignition.

Where the subclause identifies "emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;" as a hazardous situation, this refers to emissions from *the ENCLOSURE* not from components themselves. Where it identifies "exceeding the allowable values for 'other components and materials' identified in Table 22 times 1,5 minus 12,5 °C", this applies only where doing so would result in an unacceptable RISK (as identified in the MANUFACTURER'S RISK ANALYSIS according to 4.7). Typically, this would be cases where

ESSENTIAL PERFORMANCE would not be maintained or where greater than 900 J of energy would be released in the presence of flammable materials that could sustain combustion.

The first exemption to fault analysis or testing identified in subclause 13.1.2 (“The construction or the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J.”) is intended to apply where the component design itself (“The construction”) or fusing (or other current limiting devices) in the supply circuit (“or the supply circuit”) assure the energy released during failures will not exceed the limits. For most common signal level components rated for operation below 5 Watts, the energy released by short-circuiting of outputs will not exceed the 900 J limit.

This clarification will remain valid until a new version of IEC 60601-1 is published.

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**MEDICAL ELECTRICAL EQUIPMENT –
Part 1: General requirements for basic safety and essential performance**

INTERPRETATION SHEET 3

This interpretation sheet 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 interpretation sheet is based on the following documents:

ISH	Report on voting
62A/858/ISH	62A/875/RVD

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

Subclause 13.1.2 fourth dash (Emissions, deformation of ENCLOSURE or exceeding maximum temperature)


This subclause states the following:

The following HAZARDOUS SITUATIONS shall not occur:

- IEC 60601-1:2005
- <https://standards.iteh.ai/catalog/standards/sist/1f7471e5-217f-493a-b9fa-8cd58aa8a268/iec-60601-1-2005>
 - temperatures of ME EQUIPMENT parts that are not APPLIED PARTS but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3;

This is clarified by the following:

The above requirement is regarded as fulfilled in accordance with Subclause 4.5 for temperatures at the surfaces of the enclosure, if the following conditions are fulfilled:

- The maximum allowed temperature on OPERATOR accessible surfaces in SINGLE FAULT CONDITION is 105 °C; and
- the instructions for use contain a warning that, under some SINGLE FAULT CONDITIONS, the temperature of: (*indicate the surface of concern*) could get hot and there is a possible RISK of a burn if touched, and
- if the RISK ANALYSIS demonstrates a need for a warning symbol on the ENCLOSURE, safety sign ISO 7010-W018 () shall be used on or adjacent to the hot spot on the ENCLOSURE; and
- the RISK ASSESSMENT demonstrates that the temperature attained in the SINGLE FAULT CONDITION is acceptable, and
- the RISK ASSESSMENT demonstrates that applying the alternative RISK CONTROL measures in this Interpretation Sheet results in a RESIDUAL RISK that is comparable to the RESIDUAL RISK resulting from applying the requirement of the standard.

NOTE 1 This Interpretation Sheet is intended to be used with both Edition 3.0 and Edition 3.1 of IEC 60601-1.

NOTE 2 An example of an analysis that demonstrates an adequately low probability of occurrence of HARM is shown below.

Example RISK ASSESSMENT:

The sum failure rate for parts that could increase the surface temperature of parts of the enclosure of XYZ device touchable only by the OPERATOR to values above those of Table 23 calculates to be 60 FIT (1 FIT = 1E-9/h) according to the standard MIL-HDBK-217F where FIT stands for "failure in time". In case of such failures, the device would emit an odour and would no longer function properly. It is estimated, that only in one of 3 cases the device would not be switched off immediately and the hot surface would be resulting in a burn.

The resulting overall probability of such HARM where adequate warning is provided in the instructions for use in combination with warning sign ISO 7010 W018 would be: probability = $1/3 * 60 \text{ FIT} = 2 \text{ E-8/h} \approx 0,0002$ per year.

In this example, the WXW Company's RISK acceptance criteria require that a HARM of that severity must have a probability of less than 0,0003 per year for the associated RISK to be considered acceptable. Based on that RISK acceptance criterion, the RISK associated with overtemperature of the ENCLOSURE caused by single faults in the circuitry is acceptable.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 1

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The text of this interpretation sheet is based on the following documents:

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62A/1403/DISH	62A/1414/RVDISH

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

Interpretation of Subclauses 4.3 of IEC 60601-1:2005/AMD1:2012 and 4.7 of IEC 60601-1:2005

This interpretation sheet is intended to clarify the requirements which are needed to maintain ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION.

Subclause 4.3 * ESSENTIAL PERFORMANCE

The requirements in this subclause of IEC 60601-1:2005/AMD1:2012 are clarified by the following.

- aa) IEC 60601-1:2005/AMD1:2012 requires that both the NORMAL CONDITION and the SINGLE FAULT CONDITIONS are to be considered in the identification of ESSENTIAL PERFORMANCE, because:

- 1) ESSENTIAL PERFORMANCE is defined in terms of the performance of a clinical function (see 3.27);

NOTE 1 ESSENTIAL PERFORMANCE can have multiple aspects.

- 2) in particular, SINGLE FAULT CONDITIONS can cause or contribute to the loss or degradation of such a clinical function that results in unacceptable RISK; and
- 3) according to IEC 60601-1:2005, 4.7, ME EQUIPMENT is required to remain SINGLE FAULT SAFE or the RISK remains acceptable and this also applies to ESSENTIAL PERFORMANCE.

bb) The subclause requires the MANUFACTURER to:

NOTE 2 Many particular standards specify performance limits, RISK CONTROL measures and VERIFICATION methods for some aspects of ESSENTIAL PERFORMANCE.

- 1) identify performance of clinical functions, other than that related to BASIC SAFETY, that is necessary to achieve the INTENDED USE or that could affect safety;
- 2) specify performance limits between fully functional and total loss of the identified performance in both
 - i) NORMAL CONDITION, and
 - ii) SINGLE FAULT CONDITION;

NOTE 3 The specified performance limits can be different in NORMAL CONDITION and SINGLE FAULT CONDITION.

- 3) evaluate the RISK from loss or degradation of the identified performance beyond the specified limits;
 - i) Where the resulting RISK is unacceptable, the identified performance is ESSENTIAL PERFORMANCE.
- 4) implement RISK CONTROL measures to reduce these RISKS to an acceptable level for both
 - i) NORMAL CONDITION, and [IEC 60601-1:2005](https://standards.iteh.ai/standards/sist/1f7471e5-217f-493a-b9fa-8cd58aa8a268/iec-60601-1-2005)
 - ii) SINGLE FAULT CONDITION;
- 5) assess and determine which RISK CONTROL measures need VERIFICATION of effectiveness; and
- 6) specify methods for the VERIFICATION of the effectiveness of the RISK CONTROL measures.

cc) The requirements of IEC 60601-1:2005/AMD1:2012 4.3 as clarified in items 4.3 bb) 1) to 4.3 bb) 6) above include documentation of the relevant results in the RISK MANAGEMENT FILE. The documentation is intended to serve as OBJECTIVE EVIDENCE that the required activities have been performed.

dd) The compliance statement refers to “inspection of the RISK MANAGEMENT FILE”. Inspection means the careful examination or scrutiny of the contents of the RISK MANAGEMENT FILE. Only confirming the existence of a RISK MANAGEMENT FILE is insufficient. Inspection can include functional tests as clarified in IEC 60601-1:2005/AMD1:2012/ISH1 items 4.3 bb) 5) and 4.3 bb) 6). This is similar to the other uses of “inspection” throughout this standard.

Subclause 4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

The requirements in this subclause of IEC 60601-1:2005 are clarified by the following.

- aa) IEC 60601-1:2005 requires that ME EQUIPMENT remains SINGLE FAULT SAFE or the RISK remains acceptable according to 4.2 during the EXPECTED SERVICE LIFE and this also applies to ESSENTIAL PERFORMANCE.
- bb) SINGLE FAULT CONDITION (as defined in 3.116) describes the condition where “a single means for reducing a RISK is defective or a single abnormal condition is present”. Either condition anticipates the failure or fault of one component [other than those indicated in 4.7 a), e.g. a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS].

Component failure or fault can relate to:

- 1) a single part (e.g. resistor, capacitor, wire, mechanical part),
- 2) a subassembly (e.g. battery block, power supply unit, line filter, PESS), or
- 3) a device with a specified function (e.g. protective unit, control unit, monitoring unit).

Any SINGLE FAULT CONDITION that could result in a HAZARDOUS SITUATION, including those mentioned in 13.1, needs to be simulated, physically or theoretically. Care needs to be taken to adequately determine the worst case situation when analysing failure or fault of subassemblies and functional units.

- cc) It can be necessary to investigate the consequences of a second independent fault or failure. This is relevant when the initial fault or failure remains undetected during NORMAL USE for the EXPECTED SERVICE LIFE or when the fault or failure is so likely that it is considered to be a NORMAL CONDITION. See 4.7 b) and 5.1 and their rationales in Annex A.
- dd) The RISK ASSESSMENT is used to determine which SINGLE FAULT CONDITIONS are to be tested in agreement with 4.3, 4.7 and 5.1. This includes consideration of a second independent fault or failure following an initial SINGLE FAULT CONDITION that remains undetected during NORMAL USE for the EXPECTED SERVICE LIFE. This also applies to the VERIFICATION of the effectiveness of the RISK CONTROL measures needed to maintain ESSENTIAL PERFORMANCE [see IEC 60601-1/AMD1:2012/ISH1 4.3 bb) 5) and 4.3 bb) 6)].
- ee) The requirements of 4.7 include documentation of the relevant tests in the RISK MANAGEMENT FILE. The documentation is intended to serve as OBJECTIVE EVIDENCE that the required activities have been performed.

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CONTENTS

FOREWORD.....	11
INTRODUCTION.....	14
INTRODUCTION TO AMENDMENT 1	16
INTRODUCTION TO AMENDMENT 2	16
1 Scope, object and related standards.....	18
1.1 * Scope	18
1.2 Object	18
1.3 * Collateral standards.....	18
1.4 * Particular standards.....	19
2 * Normative references.....	19
3 * Terminology and definitions	24
4 General requirements.....	45
4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS.....	45
4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS	45
4.3 * ESSENTIAL PERFORMANCE	48
4.4 * EXPECTED SERVICE LIFE	49
4.5 * Equivalent safety for ME EQUIPMENT or ME SYSTEMS * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	50
4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	50
4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT.....	50
4.8 * Components of ME EQUIPMENT	51
4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT.....	52
4.10 * Power supply	53
4.11 Power input.....	53
5 * General requirements for testing ME EQUIPMENT	54
5.1 * TYPE TESTS.....	54
5.2 * Number of samples.....	54
5.3 Ambient temperature, humidity, atmospheric pressure.....	54
5.4 Other conditions	54
5.5 Supply voltages, type of current, nature of supply, frequency	55
5.6 Repairs and modifications	55
5.7 * Humidity preconditioning treatment.....	55
5.8 Sequence of tests	56
5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS	56
6 * Classification of ME EQUIPMENT and ME SYSTEMS.....	59
6.1 General.....	59
6.2 * Protection against electric shock.....	59
6.3 Protection against harmful ingress of water or particulate matter	59
6.4 Method(s) of sterilization	59
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT	59
6.6 * Mode of operation.....	59
7 ME EQUIPMENT identification, marking and documents.....	60
7.1 General.....	60

7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)	61
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)	66
7.4	Marking of controls and instruments (see also Table C.3).....	67
7.5	Safety signs SAFETY SIGNS	69
7.6	Symbols	70
7.7	Colours of the insulation of conductors	70
7.8	* Indicator lights and controls	71
7.9	ACCOMPANYING DOCUMENTS	72
8	* Protection against electrical HAZARDS from ME EQUIPMENT	79
8.1	Fundamental rule of protection against electric shock.....	79
8.2	Requirements related to power sources	80
8.3	Classification of APPLIED PARTS	80
8.4	Limitation of voltage, current or energy.....	81
8.5	Separation of parts	84
8.6	* Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	97
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	100
8.8	Insulation	122
8.9	* CREEPAGE DISTANCES and AIR CLEARANCES	129
8.10	Components and wiring	147
8.11	MAINS PARTS, components and layout	149
9	* Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	155
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	155
9.2	* MECHANICAL HAZARDS associated with moving parts.....	155
9.3	* MECHANICAL HAZARD associated with surfaces, corners and edges.....	161
9.4	* Instability HAZARDS	161
9.5	* Expelled parts HAZARD	166
9.6	Acoustic energy (including infra- and ultrasound) and vibration	167
9.7	* Pressure vessels and parts subject to pneumatic and hydraulic pressure.....	168
9.8	* MECHANICAL HAZARDS associated with support systems	171
10	* Protection against unwanted and excessive radiation HAZARDS	177
10.1	X-Radiation	177
10.2	Alpha, beta, gamma, neutron and other particle radiation	178
10.3	Microwave radiation	178
10.4	* Lasers and light emitting diodes (LEDs)	179
10.5	* Other visible electromagnetic radiation	179
10.6	* Infrared radiation	179
10.7	* Ultraviolet radiation	179
11	Protection against excessive temperatures and other HAZARDS	179
11.1	* Excessive temperatures in ME EQUIPMENT.....	179
11.2	* Fire prevention.....	184
11.3	* Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	188
11.4	* ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	191
11.5	* ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	191