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Edition 3.1 2012-08
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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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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

IEC 60601-1:2005-07+AMD1:2012-08 CSV(en-fr)

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colour inside

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IEC 60601-1:2005-07+AMD1:2012-08 CSV(en-fr)

Publication IEC 60601-1 (Third edition – 2005) I-SH 01

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:

ISH	Report on voting
62A/599/ISH	62A/613/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 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.

April 2008

Publication IEC 60601-1 (Third edition – 2005) I-SH 02

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 2

This interpretation sheet has been prepared by subcomittee 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/634/ISH	62A/640/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 11.3

This subclause is clarified by the following:

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.

SC 62A/Publication IEC 60601-1:2005, including Amendment 1:2012, Third edition/I-SH 03

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:

– ....

– 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 FIT = 2 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.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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IEC 60601-1
Edition 3.0 2005-12
Amendement 1 2012-07

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 1

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:

DISH	Report on voting
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.

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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:

IEC 60601-1:2005-12/AMD1:2012-07/ISH1:2021-03(en)

ICS 11.040.01

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

   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.

CONTENTS