INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

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.

_____

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.