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TECHNICAL REPORT

Guidelines for administrative, medical, and nursing staff concerned with the safe use of medical electrical equipment and medical electrical systems

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

GUIDELINES FOR ADMINISTRATIVE, MEDICAL, AND NURSING STAFF CONCERNED WITH THE SAFE USE OF MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEMS

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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IEC 60930, which is a technical report, 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.

This second edition cancels and replaces the first edition published in 1988. This edition constitutes a technical revision. This edition has been aligned with IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-8:2006 and IEC 62353:2007. This edition includes medical electrical systems within its scope.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/614/DTR	62A/626/RVC

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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.

A bilingual version of this publication may be issued at a later date.

INTRODUCTION

The amount of electrical equipment and the number of medical procedures employing MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS continue to grow. In order to prevent accidents or near accidents such as burns, excessive radiation, electrical shock or even cardiac arrest, procedures should be available to handle the selection, installation, application and MAINTENANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS by qualified personnel.

In order to establish a satisfactory level of BASIC SAFETY and performance for MEDICAL ELECTRICAL EQUIPMENT, MEDICAL ELECTRICAL SYSTEMS and electrical installations in medical locations, requirements for design and construction are specified in standards prepared by the IEC. These standards are intended to cover the design and construction of new equipment and installations (see the Bibliography). The requirements of these standards should also be met if the equipment or installation is REPAIRED or modified. IEC 60513 explains the basic aspects of safety philosophy.

The following guidelines are suggested:

– The MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM has to be safe, that is, built to the relevant IEC standards.

– The electrical installation in medical locations has to be safe, that is, in accordance with the relevant IEC standards or corresponding national regulations.

– The instructions for use have to be available at the site of use. The instructions for use, warning statements and markings on MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM have to be written in a language acceptable to the OPERATOR.

– Besides their knowledge of the medical procedure, the OPERATORS need to know the BASIC SAFETY characteristics and performance of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM. This can be achieved by instruction and training under the supervision of the RESPONSIBLE ORGANIZATION, e.g. by the MANUFACTURER or the CLINICAL ENGINEERING DEPARTMENT of the health care facility.

NOTE 1 In IEC 60601-1:2005, the RESPONSIBLE ORGANIZATION is defined as the entity accountable for the use and maintenance of the ME EQUIPMENT or the ME SYSTEM. The accountable entity can be, for example, a hospital, an individual clinician or a lay person. In home use applications, the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION can be one and the same person. In earlier editions of IEC 60601-1, the RESPONSIBLE ORGANIZATION was referred to as the "user."

– The RESPONSIBLE ORGANIZATION and CLINICAL ENGINEERING DEPARTMENT have to ensure that BASIC SAFETY and performance, including the ESSENTIAL PERFORMANCE, of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM are maintained by an effective MAINTENANCE scheme. This can be achieved by an adequate MAINTENANCE programme and regular SERVICING performed by an appropriately staffed and organized CLINICAL ENGINEERING DEPARTMENT.

NOTE 2 This report contains a simplified explanation which is partly related to IEC 60513:1994, *Fundamental aspects of safety standards for medical electrical equipment*, and partly to IEC 60601-1:2005: *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*, IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests* and 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*. Due to the nature of this report it is recommended that it be translated into the language spoken in each country. At the same time, National Committees are asked to go through the report thoroughly in order to amend the text to contain the special national requirements (e.g. depending on the electrical installations).

This technical report applies to MEDICAL ELECTRICAL EQUIPMENT, MEDICAL ELECTRICAL SYSTEMS and electrical installations in medical locations. The term "equipment" should be understood to mean MEDICAL ELECTRICAL EQUIPMENT or other electrical or non-electrical equipment in the context of a MEDICAL ELECTRICAL SYSTEM. That equipment will usually be electrically powered (i.e. connected to a SUPPLY MAINS or INTERNALLY POWERED). It can be assumed, however, that the approach to the subject in this report will generally be equally valid for medical equipment powered by other energy sources, such as compressed gases.

GUIDELINES FOR ADMINISTRATIVE, MEDICAL, AND NURSING STAFF CONCERNED WITH THE SAFE USE OF MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEMS

1 Scope

This technical report is intended to lessen the RISK to PATIENTS, OPERATORS, and their surroundings by providing a code of safe application. This reduction of RISK is in addition to that brought about by the RISK CONTROL measures incorporated in the MEDICAL ELECTRICAL EQUIPMENT, the MEDICAL ELECTRICAL SYSTEM, and the electrical installation in medical locations, hereafter referred to as ME EQUIPMENT, ME SYSTEM and installation respectively.

Not all existing ME EQUIPMENT, ME SYSTEMS or installations meet the requirements of the relevant IEC standards. From time to time, OPERATORS and RESPONSIBLE ORGANIZATIONS will encounter ME EQUIPMENT and ME SYSTEMS complying with older safety standards. However, the guidelines for safe application given in this technical report should nevertheless be followed in so far as this is possible.

The guidelines in this technical report can be used with ME EQUIPMENT or ME SYSTEMS for the home healthcare environment provided the MANUFACTURER has included home use in the INTENDED USE or the CLINICAL ENGINEERING DEPARTMENT has checked that the electrical installation and the physical environment will not result in any unacceptable RISKS. These guidelines can also be applied to equipment used for compensation or alleviation of disease, injury or disability.

If the ME EQUIPMENT, an ME SYSTEM or the installation does not comply with the relevant IEC standards, the RESPONSIBLE ORGANIZATION should consult with the CLINICAL ENGINEERING DEPARTMENT or the MANUFACTURER for instructions on how to achieve an adequate level of safety.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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 62353:2007, *Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions in IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-8:2006 and IEC 62353:2007 and the following term and definition apply.

NOTE 1 The term "electrical equipment" is used to mean ME EQUIPMENT or other electrical equipment. This technical report also uses the term "equipment" to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM.

NOTE 2 An index of defined terms used in this technical report is found beginning on page 27.

3.1
CLINICAL ENGINEERING DEPARTMENT
entity accountable on behalf of the RESPONSIBLE ORGANIZATION for the safe and effective management of technology and the application of medical and biomedical engineering within the clinical environment.

NOTE Clinical engineering services can be provided by the health care facility or they can be obtained from outside.

4 Nature of HAZARDS

ME EQUIPMENT or ME SYSTEMS can introduce a number of HAZARDS for PATIENTS, OPERATORS or the surroundings (e.g. poisonous gases, overpressure, explosion, electrical shock). These can be caused by misapplication, faults in the equipment that might not be obvious, improper functioning, installation or environmental conditions.

PATIENTS can be exceptionally sensitive to HAZARDS because they are either unaware of them, unable to react normally (for example, if they are unconscious), or because the nature of their treatment makes them more susceptible.

Proper construction of the ME EQUIPMENT, ME SYSTEM or the installation alone do not always achieve the desired safety; the mode of use (application), environment, MAINTENANCE and training also need to be considered.

5 BASIC SAFETY provisions of and symbols on ME EQUIPMENT

5.1 General

This clause contains a description of those BASIC SAFETY provisions of ME EQUIPMENT that need to be available to the OPERATOR in order to operate the ME EQUIPMENT properly. The OPERATOR should also know the meaning of all symbols marked on the ME EQUIPMENT. For the BASIC SAFETY provisions for ME SYSTEMS, see Clause 9.

5.2 ACCOMPANYING DOCUMENTS

ME EQUIPMENT is provided with ACCOMPANYING DOCUMENTS, which are considered to be an essential part of the ME EQUIPMENT.

The ACCOMPANYING DOCUMENTS consist partly of instructions for use intended for the OPERATOR and partly of a technical description for the CLINICAL ENGINEERING DEPARTMENT. The two parts can be provided in separate volumes.

The instructions for use contain all the information necessary to operate the ME EQUIPMENT and ensure its correct functioning. The instructions for use should be easily accessible to the OPERATOR. Whenever possible, the instructions for use should remain with the ME EQUIPMENT.

Short instructions for use (in the form of a label or a sheet) should be fixed to the ME EQUIPMENT if its use is not obvious or if it represents special HAZARDS to the PATIENT. A copy of such short instructions should be incorporated in the instructions for use.

NOTE Prior to the publication of IEC 60601-1:2005, the symbol  was used in the IEC 60601 series of standards to mean "Attention, consult accompanying documents". In IEC 60601-1:2005, that symbol is used to indicate caution, which aligns with its common usage outside the ME EQUIPMENT sector. IEC 60601-1:2005 added a symbol  to indicate, "follow operating instructions". Additionally, a new safety sign  has been added to mark ME EQUIPMENT where failure to follow operating instructions could place the PATIENT or OPERATOR at RISK.

5.3 Colours of indicator lights

A description of the colours used for indicator lights is given in Table 1.

Table 1 – Colours of indicator lights and their meaning for ME EQUIPMENT

Colour	Meaning
Red	Warning – immediate response by the OPERATOR is required
Yellow	Caution – prompt response by the OPERATOR is required
Green	Ready for use
Any other colour	Meaning other than that of red, yellow or green

Dot-matrix and other alphanumeric displays are not considered to be indicator lights unless they are used to simulate alarm indicator lights. See Table 3 for a description of the colours used for alarm indicator lights.

5.4 Markings on ME EQUIPMENT

Warnings, marking of controls, and other symbols are explained in the instructions for use. Additional markings provide help to identify each piece of ME EQUIPMENT for REPAIR and MAINTENANCE purposes (see also note in 5.2).

When markings are used to convey a warning, prohibition or mandatory action that mitigates a RISK that is not obvious to the OPERATOR, the MANUFACTURER should use a safety sign selected from ISO 7010. When a safety sign is not available, the MANUFACTURER can use:

– the general warning sign  along with an affirmative statement describing the principal RISK(S) foreseen (e.g. "May cause burns", "Risk of explosion");

– the general prohibition sign  along with a statement describing what is prohibited (e.g. "Do not open", 'Do not drop"); or

– the general mandatory action sign  along with text describing the required action (e.g. "Wear protective gloves", "Scrub before entering").

5.5 Protection against electric shock

5.5.1 Method of protection for ME EQUIPMENT

In order to protect the PATIENT, the OPERATOR and other persons against the danger of electric shock, ME EQUIPMENT is constructed according to the following classes:

a) CLASS I ME EQUIPMENT (PROTECTIVELY EARTHED)

The BASIC SAFETY of CLASS I ME EQUIPMENT is ensured by BASIC INSULATION and by being PROTECTIVELY EARTHED.

b) CLASS II ME EQUIPMENT (with DOUBLE INSULATION)

The BASIC SAFETY of CLASS II ME EQUIPMENT is ensured by DOUBLE or REINFORCED INSULATION. CLASS II ME EQUIPMENT can be identified by the symbol  .

c) INTERNALLY POWERED ME EQUIPMENT

INTERNALLY POWERED ME EQUIPMENT gets the power necessary for its operation from an INTERNAL ELECTRICAL POWER SOURCE, such as a battery.

INTERNALLY POWERED ME EQUIPMENT usually has no connection to a SUPPLY MAINS. However, INTERNALLY POWERED ME EQUIPMENT that has a means of connection to a SUPPLY MAINS is required to be CLASS I or CLASS II while connected to the SUPPLY MAINS (e.g. to recharge batteries).

NOTE Electrical equipment not belonging to these classes should not be used for medical purposes.

5.5.2 Degree of protection of APPLIED PARTS

The APPLIED PARTS of the ME EQUIPMENT are further classified according to the degree of protection they provide against electrical shock. The different types are: TYPE B, TYPE BF, and TYPE CF APPLIED PARTS. The degree of protection is indicated by the symbols in Figure 1 marked adjacent to or on the connector for the APPLIED PART.

a) TYPE B APPLIED PART b) TYPE BF APPLIED PART c) TYPE CF APPLIED PART

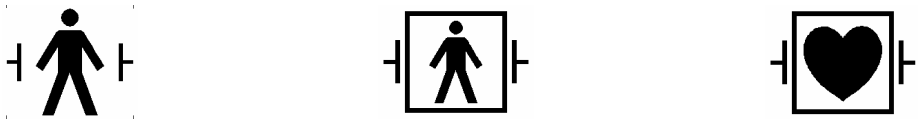
Figure 1 – Symbols indicating the degree of protection provided by an APPLIED PART

If there is no connector, then the symbol should appear on the APPLIED PART.

Only TYPE CF APPLIED PARTS are suitable to be used in DIRECT CARDIAC APPLICATIONS.

EXAMPLE A catheter that comes into direct contact with the heart muscle during an ablation procedure.

APPLIED PARTS can be protected against the effects of a discharge of a cardiac defibrillator. These APPLIED PARTS can be recognized by the symbols in Figure 2.



a) TYPE B APPLIED PART with protection against the effects of a discharge of a cardiac defibrillator

b) TYPE BF APPLIED PART with protection against the effects of a discharge of a cardiac defibrillator

c) TYPE CF APPLIED PART with protection against the effects of a discharge of a cardiac defibrillator

Figure 2 – Symbols indicating the degree of protection against the effects of a discharge of a cardiac defibrillator