



MALAYSIAN STANDARD

MS IEC 60601-2-49:2007

**MEDICAL ELECTRICAL EQUIPMENT -
PART 2-49: PARTICULAR REQUIREMENTS
FOR THE SAFETY OF MULTIFUNCTION
PATIENT MONITORING EQUIPMENT
(IEC 60601-2-49:2006, IDT)**

ICS: 11.040.55

Descriptors: medical electrical equipment, particular requirements, safety, multifunction, patient monitoring

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Committee representation

The Medical Devices Industry Standards Committee (ISC R) under whose authority this Malaysian Standard was adopted, comprises representatives from the following organisations:

Association of Malaysian Medical Industries
Biomedical Engineering Association Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institute for Medical Research
Institut Penyelidikan Teknologi Nuklear Malaysia
Lembaga Perlesenan Tenaga Atom
Malaysian Medical Association
Malaysian Medical Devices Association
Malaysian Organization of Pharmaceutical Industry
Ministry of Health Malaysia
Persatuan Pengguna-pengguna Standard Malaysia
Pharmaceutical Association of Malaysia
Radiation Physics, Biophysics and Medical Physics Sub-Group of Institute of Physics Malaysia
SIRIM QAS International Sdn Bhd (Product Certification Section)
Universiti Kebangsaan Malaysia (Faculty of Allied Health Sciences)
Universiti Teknologi Malaysia (Faculty of Science)

The Technical Committee on Anaesthetic/Respiratory and Electromechanical Devices which recommends adoption of the IEC Standard consists of representatives from the following organisations:

Academy of Medicine of Malaysia (College of Anaesthesiologists)
Biomedical Engineers Association of Malaysia
Malaysian Medical Association
Malaysian Medical Devices Association
Ministry of Health Malaysia (Biomedical Engineering Section)
Ministry of Health Malaysia (Mechanical Engineering Section)
SIRIM Berhad (Secretariat)
Universiti Malaya (Biomedical Engineering Department)
Universiti Teknologi Malaysia (Faculty of Science)
Universiti Teknologi MARA (Electrical Engineering Faculty)

NATIONAL FOREWORD

The adoption of the IEC Standard as a Malaysian Standard was recommended by the Technical Committee on Anaesthetic/Respiratory and Electromechanical Devices under the authority of the Medical Devices Industry Standards Committee.

This Malaysian Standard is identical with IEC 60601-2-49:2006, *Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment*, published by the International Electrotechnical Commission (IEC). However, for the purposes of this Malaysian Standard, the following apply:

- a) in the source text, "this International Standard" should read "this Malaysian Standard";
- b) the comma which is used as a decimal sign (if any), to read as a point;
- c) references to International Standards should be replaced by equivalent Malaysian Standards as follows:

Referenced International Standards

IEC 60601-1, *Medical electrical equipment - Part 1: General requirements for safety*

IEC 60529, *Degree of protection provided by enclosures (IP code)*

Corresponding Malaysian Standards

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

MS IEC 60529, *Degree of protection provided by enclosures (IP code)*

- d) the basis IEC 60601-2-49 is printed in English and French languages. However, only the English version is retained for this Malaysian Standard.

Compliance with a Malaysian Standard does not of itself confer immunity from legal obligations.

NOTE. IDT on the front cover indicates an identical standard i.e. a standard where the technical content, structure, and wording (or is an identical translation) of a Malaysian Standard is exactly the same as in an International Standard or is identical in technical content and structure although it may contain the minimal editorial changes specified in clause 4.2 of ISO/IEC Guide 21-1.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-49: Particular requirements for the safety
of multifunction patient monitoring equipment

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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International Standard IEC 60601-2-49 has been prepared by subcommittee 62D: Electro-medical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This bilingual version (2006-01) replaces the English version.

The text of this standard is based upon the following documents:

FDIS	Report on voting
62D/409/FDIS	62D/412/RVD

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

The French version of this standard has not been voted upon.

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

In this Particular Standard the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
- *test specifications, headings of subclauses and headings of items: in italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

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.

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