



IEC/TC or SC TC 62	Secretariat Germany	Date 2011-09-23
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Title of TC

TC 62: Electrical equipment in medical practice

Sub Committees:

- SC 62A Common aspects of electrical equipment used in medical practice
- SC 62B Diagnostic imaging equipment
- SC 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry
- SC 62D Electromedical equipment

A Background

TC 62 was established in 1968.

TC 62 prepares international standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment.

NOTE: This scope includes items that are also within the scopes of other committees and will be addressed through cooperation. Attention will focus on safety and performance (e.g. radiation protection, data security, data integrity, data privacy and environmental aspects) and will contribute to regulatory frameworks. Healthcare includes medical practice as well as emergency medical services, homecare, and support of persons with disabilities in their daily lives (i.e. Ambient Assisted Living).”

Prepared by TC 62, the main publication of the IEC 60601 family is, together with its collateral standards, the essential foundation for standards for medical electrical equipment and systems. Within the IEC 60601 series, the specific issues related to categories of medical devices are addressed in detail in the 60601 collateral standards.

In recent years, IEC TC 62 has increasingly worked in the field of software, IT and networks and developed new International Standards and other publications in that area.

IEC standards published by TC 62 and its subcommittees cover safety and performance for specific products, such as diagnostic imaging, radiotherapy, nuclear medicine, radiation dosimetry, electromedicine, anaesthesia, critical care, surgery, artificial respiration and paediatrics.

Where appropriate and if related to safety and performance, other aspects such as data security, integrity and privacy and radiation protection of patients, operators and environment are covered.

If related to healthcare, aspects of “ambient assisted living” are covered. Ambient assisted living addresses items and features supporting elderly persons and/or persons with disabilities in their daily life.

The world’s leading experts, working within TC 62, hardware and software engineers, as well as physicists and physicians, come from industry, hospitals, test houses, consulting firms, academia and governmental bodies. They have the specialized knowledge needed to

understand how these products should be designed, produced, operated and maintained. Regulators from Europe, North America and Asia participate in this work.

When appropriate, TC 62 and its Subcommittees cooperate with other Committees of IEC, ISO or other organisations, based on the expertise each organization embodies. To ensure that International Standards in the healthcare sector fit together seamlessly, joint projects and standards combine expertise from other organizations. The ISO 14971 and the IEC 60601 series enable medical electrical equipment manufacturers to produce safe and effective products, including complex systems and assemblies.

It is the policy of TC 62 to issue all publications in its subcommittees.

B Business Environment

B.1 General

External environment:

Healthcare services and the application of medical electrical equipment, healthcare software and IT networks are growing rapidly driven by the facts that

- the life-expectancy of the population is increasing,
- the population is significantly growing,
- there is an increasing impact of information technology,
- new technologies such as bioengineering are contributing,
- cost saving goals are gaining importance in medical practice and
- developing countries are generating new equipment markets.

Internal environment:

Regulation affecting medical devices is increasing with a growing emphasis on quality systems and standards. Examples are within the European Community where certification to standards plays a key role in demonstrating compliance with medical device regulations and within the US Food and Drug Administration, which is enlarging its use of international standards in the device approval process. In China there is an increasing importance of international standards for the approval of products.

B.2 Market demand

Customers of standards:

Standards for healthcare equipment should meet the demands of users and manufacturers, legislative organisations and confirmatory and regulatory bodies. Attention has to be paid that ethically sound and cost effective solutions for the patient diagnosis and treatment are kept in focus.

Representation of customers in TC 62:

The Committee has achieved a considerable active representation of its standards users. However, further participation from the medical and academic community is desirable. The high rate of innovations in healthcare sets the pace for the standardisation.

International use of the standards of TC 62:

Medical electrical equipment within the scope of TC 62 is complex and affordable development costs along with high performance can be achieved to the benefit of the patient on global markets only. Therefore there is an increasing need for global harmonisation of legislation and regulation and as a consequence for international rather than for local standards.

Maintenance versus development work in TC 62:

The field of medical electrical equipment does generate new work items. Nevertheless is maintenance work is important.

Applicability of horizontal standards in TC 62:

The business environment of TC 62 requires a broad approach for risk management. ISO 14971 and IEC60601 Ed 3 cover all healthcare needs. The Committee therefore has provided adequate risk management for compliance with legal and regulatory requirements specific in the healthcare area. Therefore general aspects of IEC 61508 are excluded.

B.3 Trends in technology

Software and the integration of medical electrical equipment and systems with IT-networks will be an integral element affecting almost all aspects of the work of TC 62. This is one area where the changing technology is creating a demand for standards and other documents that is outstripping the ability of the traditional project model to deliver the needed documents in a timely manner. The TC will adapt its traditional ways of working to meet the demands both for international standards and for other document types (e.g. technical reports, technical specifications, publicly available specifications and industry technical agreements) that address the needs of a rapidly changing technological landscape. However, the full consensus process will continue to be applied for standards written to support regulation.

Medical electrical equipment is of increasing importance in areas that were traditionally covered by non-electrical medical equipment. Also in order to keep track of the innovations in the healthcare field there will be an increasing need for cooperation with other organisations.

Highest reliability and cost effectiveness are essential.

B.4 Market trends

The trade for medical electrical equipment is global whereas the regulatory environment is local to each specific jurisdiction. This lends emphasis and importance to an international approach to standardisation.

The Global Harmonization Task Force (GHTF) working at the international convergence of regulations is an important liaison of IEC and TC 62 in achieving that goal.

Some countries tend to regulate the safety aspects of healthcare software the same way as of medical equipment.

In European Countries requirements known from machinery equipment have been introduced into the medical device regulations.

The growth rate in Asia is expected to remain significantly above average.

Healthcare Software and IT networks are increasingly subject to governmental regulation and often are classified as medical devices.

B.5 Ecological environment

Compatibility of the equipment to natural environment is of growing significance to users and manufacturers.

Environmental protection is increasingly addressed in the standards.

Under safety related aspects the standardisation on human interfaces in medical electrical equipment will be enforced.

C System approach aspects

System Committees (TC 62 as a supplier)

Medical electrical equipment and software are part of the hospital and homecare environment. Furthermore the standards of TC 62 are used to demonstrate compliance to the regulations in the Member Countries. TC 62 therefore encourages the participation of clinicians, health academics and medical device regulators.

Furthermore TC 62 maintains liaisons to stakeholder organisations representing its customers:

GHTF Global Harmonization Task Force

CENELEC TC 62

IEEE EMS

Within the IEC the following Committees refer to and use the standards of TC 62:

- TC 29: Electroacoustics
- TC 64: Electrical installations and protection against electric shock
- TC 76: Optical radiation safety and laser equipment
- TC 87: Ultrasonics

This list is not complete as ISO Committees (e.g. ISO TC 121) refer to and use the standards of IEC TC 62 as well.

Component committees (TC 62 as a customer)

The standards of TC 62 and its Subcommittees reference the standards of the following Committees of IEC:

TC 8 Systems aspects for electrical energy supply

TC 16: Basic and safety principles for man-machine interface, marking and identification

TC 20: Electric cables

SC 23B: Plugs, socket-outlets and switches

SC 23G: Appliance couplers

TC 29: Electroacoustics

TC 31: Equipment for explosive atmospheres

SC 32C: Miniature fuses

TC 33: Power capacitors

TC 35: Primary cells and batteries

TC 39: Electronic tubes

TC 40: Capacitors and resistors for electronic equipment

TC 55: Winding wires

TC 61: Capacitors and resistors for electronic equipment

TC 64: Electrical installations and protection against electric shock

TC 70: Degrees of protection provided by enclosures

TC 72: Automatic controls for household use

TC 76: Optical radiation safety and laser equipment

TC 87: Ultrasonics

TC 89: Fire hazard testing

TC 96: Transformers, reactors, power supply units and similar products for low voltage up to 1100 V

TC 104: Environmental conditions, classification and methods of test

TC 108: Safety of electronic equipment within the field of audio/video, information technology and communication technology

TC 109: Insulation co-ordination for low-voltage equipment

TC 112: Evaluation and qualification of electrical insulating materials and systems

D Objectives and strategies (3 to 5 years)

The continuous introduction of new methods in healthcare and progress in technology require for the work of TC 62

- a close co-operation with committees in ISO, IEC and other organisations, orientated to information and further new technologies applicable in the healthcare field,
- a programme for particular standards according to the technical and healthcare innovations,
- a maintenance programme for standards in the area of mature technologies.

The amendment 1 of IEC 60601-1:2005 of SC 62A will be a pace setter for further modifications in the domain of other subcommittees of TC 62 and its liaison organisations, which will have to adapt the collateral and particular standards.

Healthcare Software will gain importance in TC 62. Close cooperation with other committees and organisations in the software and IT network sector such as ISO TC 215 and DICOM will be maintained.

The cooperation with regulatory and user organisations will be continued.

The standards of TC 62 must be adapted to follow the regulatory evolution in the important markets.

E Action plan

Particular standards are intended to be aligned with IEC 60601-1:2005 by 2011.

Amendment 1 to IEC 60601-1:2005 is intended to be completed by 2012.

Particular standards are intended to be aligned with Amendment 1 of IEC 60601-1:2005 by 2015.

F Useful links to IEC web site

[IEC/TC 62 dashboard](#) giving access to Membership, TC officers, Scope, Liaison, WG/MT/PT structure, Publications issued along with their Stability Dates, Work Programme and similar information for SCs.

Name or signature of the secretary

Norbert Bischof