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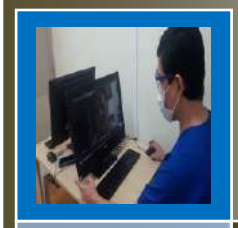

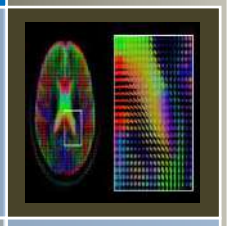

ISO 80601-2-72:2015 Medical electrical equipment

What is ISO 80601-2-72:2015 Medical electrical equipment?

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.
For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment,* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.
This first edition of ISO 80601-2-72 cancels and replaces the second edition of ISO 10651-2:2004. This edition of ISO 80601-2-72 constitutes a major technical revision of ISO 10651-2:2004 and includes an alignment with the third edition of IEC 60601-1 and the second edition of IEC 60601-1-11.
The most significant changes are the following modifications:

- — extending the scope to include the VENTILATOR and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the VENTILATOR, and thus, not only the VENTILATOR itself;
- — identification of ESSENTIAL PERFORMANCE for a VENTILATOR and its ACCESSORIES;
- — modification of the obstruction of the expiratory limb (continuing AIRWAY PRESSURE) ALARM CONDITION requirement;

and the following additions:

- — tests for ventilation performance;
- — tests for mechanical strength (via IEC 60601-1-11);
- — new symbols;
- — requirements for a VENTILATOR as a component of an ME SYSTEM;
- — tests for ENCLOSURE integrity (water ingress via IEC 60601-1-11);
- — tests for cleaning and disinfection PROCEDURES (via IEC 60601-1-11);
- — consideration of contamination of the breathing gas delivered to the PATIENT from the gas pathways.

This is a list of publishedInternational Organization for Standardization (ISO) standards and other deliverables. For a complete and up-to-date list of all the ISO standards, see the ISO catalogue.

The standards are protected by copyright and most of them must be purchased. However, about 300 of the standards produced by ISO and IEC's Joint Technical Committee 1 (JTC 1) have been made freely and publicly available.

ISO Brand

This is a dynamic list and may never be able to satisfy particular standards for completeness. You can help by adding missing items with reliable sources.

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Conformance testing

(Redirected from Conformity assessment)
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Conformance testing — an element of conformity assessment, and also known as compliance testing, or type testing — is testing or other activities that determine whether a process, product, or service complies with the requirements of a specification, technical standard, contract, or regulation. Testing is often either logical testing or physical testing. The test procedures may involve other criteria from mathematical testing or chemical testing. Beyond simple conformance, other requirements for efficiency, interoperability or compliance may apply. Conformance testing may be undertaken by the producer of the product or service being assessed, by a user, or by an accredited independent organization, which can sometimes be the author of the standard being used. When testing is accompanied by certification, the products or services may then be advertised as being certified in compliance with the referred technical standard. Manufacturers and suppliers of products and services rely on such certification including listing on the certification body's website, to assure quality to the end user and that competing suppliers are on the same level.

Aside from the various types of testing, related conformance testing activities include:

- Surveillance
- Inspection
- Auditing
- Certification
- Accreditation.

Forms of conformance testing

The UK government identifies three forms of testing or assessment:

- 1st party assessment (self-assessment)
- 2nd party assessment (assessment by a purchaser or user of a product or service)
- 3rd party assessment (undertaken by an independent organisation)

Typical areas of application

Conformance testing is applied in various industries where a product or service must meet specific quality and/or regulatory standards. This includes areas such as:

- biocompatibility proofing
- data and communications protocol engineering
- document engineering
- electronic and electrical engineering
- medical procedure proofing
- pharmaceutical packaging
- software engineering
- building construction (fire)

Electronic and electrical engineering

In electronic engineering and electrical engineering, some countries and business environments (such as telecommunication companies) require that an electronic product meet certain requirements before they can be sold. Standards for telecommunication products written by standards organizations such as ANSI, the FCC, and IEC have certain criteria that a product must meet before compliance is recognized. Incountries such as Japan, China, Korea, and some parts of Europe, products cannot be sold unless they are known to meet those requirements specified in the standards. Usually, manufacturers set their own requirements to ensure product quality, sometimes with levels much higher than what the governing bodies require. Compliance is realized after a product passes a series of tests without occurring some specified mode of failure.

Compliance testing for electronic devices include emissions tests, immunity tests, and safety tests. Emissions tests ensure that a product will not emit harmful electromagnetic interference in communication and power lines. Immunity tests ensure that a product is immune to common electrical signals and electromagneticinterference (EMI) that will be found in its operating environment, such as electromagneticradiation from a local radio station or interference from nearby products. Safety tests ensure that a product will not create a safety risk from situations such as a failed or shorted power supply, blocked cooling vent, and powerline voltagespikes and dips.

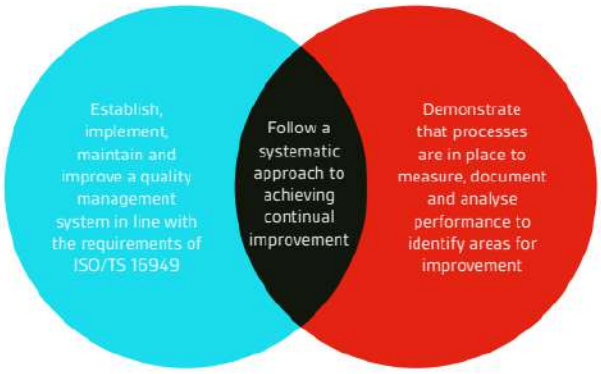
For example, Ericsson's telecommunications research and development subsidiary TelcordiaTechnologies publishes conformance standards for telecommunication equipment to pass the following tests:

Standardization and agreements

Several international standards relating to conformance testing are published by the International Organization for Standardization (ISO) and covered in the divisions of ICS 03.120.20 for management and ICS 23.040.01 for technical. Other standalone ISO standards include:

- ISO/TR 13881:2000 Petroleum and natural gas industries—Classification and conformity assessment of products, processes and services
- ISO 18436-4:2008 Condition monitoring and diagnostics of machines—Requirements for qualification and assessment of personnel—Part 4: Field lubricant analysis
- ISO/IEC 18009:1999 Information technology—Programming languages—Ada: Conformity assessment of a language processor

The principal requirements of the standard are illustrated below:



The next few pages of the guide takes you through the Plan-Do-Check-Act (PDCA) methodology, common in all ISO management systems and how DCS can help and support you on your ISO/TS 16949 journey.

Understanding the principles of continual improvement