

Classification per IEC60601-1

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Classification of the electrical medical product under test is the first step in determining the test program for compliance to IEC 60601-1/EN60601-1 based standards. There are numerous requirements within IEC60601-1 and its Particular and Collateral standards, not all of which may apply to the medical device under test. Therefore classifying the medical device prior to testing, in conjunction with a gap analysis or construction review, will help yield a test program required for compliance to IEC60601-1/EN60601-1 based standards.

Not only will classification of an electrical medical device help determine the test program the product needs to be tested and/or certified to, it also will help determine certain marking, labeling and physical construction requirements.

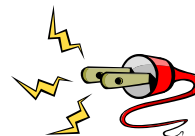
Classification Categories

When classifying your product to electro-medical device based standards IEC60601-1, EN60601-1, UL2601-1, CSA C22.2 No. 601.1, etc. complete consideration should be given to the following concerns:

- ◆ Protection against electrical shock
- ◆ Installation & Use of Product
- ◆ Ingress of Liquids
- ◆ Equipment Mode of Operation
- ◆ Use with Flammable Anesthetics
- ◆ Degree of Protection Against Electric Shock (Applied Parts)
- ◆ Sterilization or Disinfection Methods

Protection Against Electrical Shock

If the medical device to be tested (MD) is powered from an external source, the product may be classified as a Class I or Class II product. For an internally powered product such as with a battery there is no additional classification.



Class I product: A product that is provided with a reliable protective earth (PE) such that all accessible metal parts cannot become live in the event of a failure of basic insulation and therefore will provide protection against electric shock in the case of failure of basic insulation.

Class II product: A product without a protective earth (PE) and where double or reinforced insulation is relied upon to provide the protection against electric shock. The Class II symbol is a double walled square, ◻ indicating the product's double insulation.

More Classification Categories

Installation and Use of Product (Equipment)

There are seven classifications of how equipment may be used. These terms are fixed, hand-held, mobile, permanently installed, portable, stationary and transportable equipment. Although some of these words seem identical in terminology they have distinct definitions when applied to electrical medical equipment.

Ingress of Liquids

If the standards require or the manufacturer decides that the medical device (MD) should be tested for water ingress, then the product must be marked with the appropriate symbol. The symbols are based on IEC 529, Degree of protection provided by enclosures (IP code).



Example: In the case of a footswitch used in operating rooms the requirements state that the footswitch meet IPX8 per clause 56.11d of the standard. There are a variety of IPX codes from IPX0 to IPX8 (where the part or product is submersed in water). If the medical device (MD) is classified IPX0 it does not need to be marked. All other enclosure IP codes (IPX1 – IPX8) must be marked on the applicable product, part or accessory.

Equipment Mode of Operation

There are five separate modes of operation defined in the IEC60601-1 based standards: continuous, short-time, intermittent, continuous operation with short-time loading and continuous operation with intermittent loading. The most common classification of operation is continuous and if the product is used as such, it does not have to be identified (marked) 'continuous'. The four other modes of operation limit the range in which the product is utilized and tend to be a disadvantage unless the product was specifically designed for an application requiring less than continuous use.

Use with Flammable Anesthetics



There are two classifications for products that have the potential of coming in contact with flammable anesthetics. Almost all electrical medical products today are not for use in the presence of flammable anesthetics. This is because anesthetic currently in use are not flammable. It is rare to come across medical electrical equipment marked with either classification AP or APG.

More Classification Categories

Degree of Protection Against Electric Shock

This product classification deals with the definition of Applied Parts, those parts or circuits that are connected to the patient. There are three types of Applied Part Classifications: B, BF and CF. This definition has changed from the system type designation to the specific applied part in question. If the medical product being tested has multiple applied parts then there may be different classifications for the different applied parts. Defibrillation-proof applied parts are an additional consideration if the medical product under test may be utilized in a situation when the product is connected to the patient while defibrillation is applied.



Sterilization and Disinfection Methods

Many medical products have parts that touch or are introduced into the patient. These parts need to be disinfected or sterilized for single or multiple uses depending on many variables. The manufacturer needs to determine this before IEC 60601-1 testing and may have to provide samples that have to go through multiple cycles of the appropriate method.

Acronyms & Definitions

Acronyms:

AP: Flammable anesthetic proof mixtures with air.

APG: Flammable anesthetic proof mixtures with oxygen or nitrous oxide

B: Non-cardiac grounded, Applied Part

BF: Non-cardiac floating, Applied Part

CF: Cardiac floating, Applied Part

IPXY: Ingress Protection per IEC 529

X = Protection of ingress against solid object.

Y = Protection against ingress of water.

MD: Medical device (product or equipment) under test.

Acronyms & Definitions

Definitions:

Accessible Part:	any part of the product under test that can be touched by the patient or operator without the use of a tool.
Applied Part:	any part of the product under test that intentionally comes in contact with the patient.
Basic Insulation:	any insulation, the failure of which could cause a risk of electric shock.
Double Insulation:	insulation comprising both basic insulation and supplementary insulation.
Enclosure:	is the outer case of the product under test.
Functional Earth (FE):	the conductor on the product under test not intended for chassis ground.
Ordinary:	Not tested for ingress of water per IEC 529. This means the units would be rated IPX0. No marking on product is required for an IPX0 (ordinary rating).
Protective Earth (PE):	the ground conductor in the power cord or ground wire used to protectively (Earth) ground the product under test. Also known as Chassis Ground.
Patient Lead:	any deliberate electrical connection that can carry current between an appliance and a patient. This is an example of an Applied Part.
Reinforced Insulation:	single insulation system that provides protection against electric shock not less than that provided by double insulation.
Supplementary Insulation:	independent insulation applied in addition to basic insulation in order to provide protection against electric shock in the event of a failure of basic insulation.

Next IEC60601-1 Installment

Classifying a product in the initial design phase can save the manufacturer time and money in the final product test phase. This and the previous three IEC60601-1 application notes have discussed the standard and the rationale for testing a medical product. Installment #5 turns the focus of the discussion to the Electrical Safety Tests (EST) to be performed on the medical product. EST terminology shall be defined and the basic tests: AC/DC Hipot, Ground Bond, Ground Continuity and Line Leakage shall be explained. Tune in next time for a shocking explanation.



To find out more about IEC60601-1 and classification please contact Eisner Safety Consultants at (805)-884-9680 visit us on the web at <http://www.eisnersafety.com/> or e-mail us at Leo@EisnerSafety.com. Eisner Safety Consultants specializes in assisting clients with obtaining the European CE Mark and meeting US and Canadian regulatory safety standards. Specialties include product evaluation to safety standards, Agency coordination, CE Mark, Quality Systems and training.

For complete product specifications on the 6100 Production Safety Analyzer for Electronic Medical Devices or any of QuadTech's products, visit us at <http://www.quadtech.com/products>.

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