Quick learn about Medical Power Standards: IEC60601-1

What is IEC60601 and its history?

IEC 60601 is a series of technical standards for the safety and effectiveness of medical electrical equipment.

In 1977,the firstIEC 60601-1 was published.
In 1988,the 2nd edition was published, focused on safety within the vicinity of a patient.
In 2005, the 3rd edition in 2005, which reflected a further change of perspective, looking at "means of protection"both for patients (MOPP)and equipment operators(MOOP).
In 2012,the amendment, known as Edition 3.1, was introduced.
In 2014,a new version of collateral standard IEC 60601-1-2 that is EMC 4th Edition was published. (if you are interested in4th Edition EMC standard, please read our another article "IEC60601-1-2 4th Edition vs old editions")

Why medical power supply need to meet IEC60601-1?

The IEC 60601-1 standard has a significant impact on the medical device development process. This is because product complexity
While power supplies by themselves are not medical devices and, are therefore, not directly covered by the IEC 60606-1 directives. However, the power supplies are integrated in the medical devices and most electrical items (IEC60601-1) are applied to the AC to DC power supplies.
So if the power supplies are certified to IEC60601-1, the device designers' work will be simplified.

Highlights of 2nd edition

There are three different types of applied parts. An applied part is a part that in normal use will come into contact with the patient or needs to be touched by the patient. These are classified as B, BF or CF.

Leakage Current	Type B		Type BF		Type CF	
	NC	SFC	NC	SFC	NC	SFC
Earth Leakage Current*	500µA	1mA	500µA	1mA	500µA	1mA
Enclosure Leakage Current	100µA	500µA	100µA	500µA	100µA	500µA
Patient Leakage Current	100µA	500µA	100µA	500µA	10µA	50µA

NC = Normal Conditions **SFC** = Single Fault Conditions
*US earth leakage current 300µA Figures quoted are for portable equipment

Classification	Isolation	Creepage	Insulation
Type B	1500 Vac	2.5 mm	Basic
Type BF	3000 Vac	5 mm	Double
Type CF	4000 Vac	8 mm	Double

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Highlights of 3rd edition

The 3rd edition of IEC 60601-1 extends the patient focus to require an overall means of protection (MOP) that combines one or more “means of operator protection” (MOOP) and “means of patient protection” (MOPP).

Classification	Isolation	Creepage	Insulation
One MOOP	1500 Vac	2.5 mm	Basic
Two MOOP	3000 Vac	5 mm	Double
One MOPP	1500 Vac	4 mm	Basic
Two MOPP	4000 Vac	8 mm	Double

Please note that the changes from 2nd to 3rd edition are more a matter of definition than performance. The 3rd edition was produced by a new group who referred to 2nd edition and IEC60950 regulations to complete the 3rd edition IEC60601.
Risk management was introduced.

About of 3.1 edition

60601-1 Edition 3.1 was to address many issues identified as unclear or ambiguous in the original 3.0 standard.
Almost 500 changes including essential performance, risk management, mechanical testing, temperature testing, and humidity testing. The amended standard also defines several new specifications for mechanical and electrical hazards

4th Edition EMC

See our “ IEC60601-1-2 4th Edition vs old editions”.