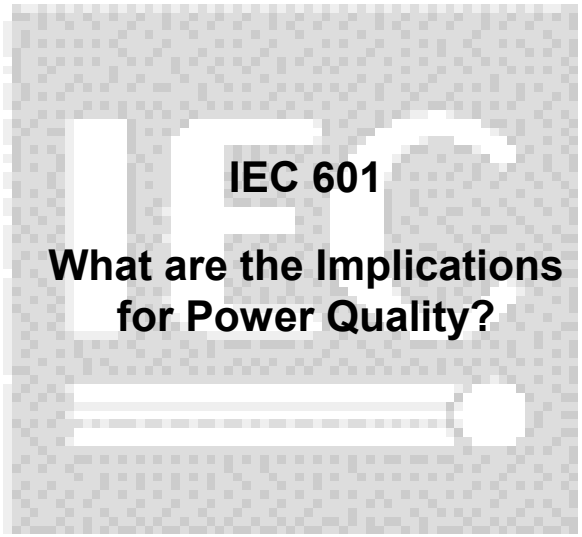
White Paper # 211



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The Essence of Safety

Regulatory bodies the world around are concerned about the safety of products sold by manufacturers to the consuming public. For many years, however, a common approach to safety has not been in place. As might be expected, this has led to a diverse array of safety standards throughout the globe, each administered by a national safety agency with its own rules, regulations and standards. Some countries are concerned only that if a product should fail, it should fail in a safe manner. Other countries have been additionally concerned that products be safe for their intended use or safe to operate in the intended way.

The recent movement toward globalization is only the culmination of a long period of international trade. The import and export of a wide variety of products across international borders has educated countries about the necessity of harmonizing many of the standards that relate to product safety.

Nowhere has this need been more acute than in the area of safety as it pertains to the care of medical patients. In addition to the United States and the European Community, by the end of 2001, over forty different countries from Cuba to Viet Nam had standards regulating the sale of medical devices and instruments for patient care. Clearly such circumstances validate the activities of the International Electrotechnical Commission in its formulation of a standard defining the safety of electrical devices used for the care and treatment of patients. The applicable standard is labeled IEC 60601. It is the basis for derivative standards in other parts of the world including EN60601 for the European Community, UL2601-1 in the United States, and CSA C22.2 No. 606.1 in Canada

The IEC 60601 Standard

Often referred to as simply IEC 601, this conformity standard is actually a combination of four basic or collateral standards designated IEC 60601-1-X (where the X represents standards 1 through 4). The collateral standards themselves support forty-five additional specific standards designated IEC 60601-2-X (where the X represents specific standards numbered 1 through 50). Each of the specific standards amends or clarifies the basic standards as they relate to various types of electrical equipment used in the treatment of patients.

Tables 1 and 2, in the Appendix of this white paper illustrate the basic and specific standards. IEC 60601 addresses four basic areas as they relate to the safety of the patient. These include:

Mechanical Requirements – Is the equipment enclosure strong enough to endure the wear and tear of normal use? Are moving parts properly protected to ensure a safety hazard is not created? Is the unit stable and lacking sharp corners, edges, etc.?

Markings – IEC 60601 defines a list of data that must be present on the product's nameplate including information on its electrical requirements, model number, manufacturer, etc. In addition, IEC60601 defines test protocol for the durability of markings to ensure that they are not erased or worn off through normal use.

Earthing – Earthing defines how the device is attached to the earth or safety ground connection of an electrical power supply to provide safety in the event of an electrical fault. IEC 60601 uses the term "applied part" to define how the electrical device may come into contact with the patient. Under IEC 60601, there are three types of Applied Parts designated "B", "BF", and "CF". Type CF Applied Parts are intended for direct contact with the human heart. Type BF Applied Parts have conductive contact with the patient in an external fashion such as an electrode used for ECG or EEG applications. Type B Applied Parts are those easily or readily released from the patient or not in conductive contact with the patient. IEC 60601 specifies that Type BF and CF Applied Parts must be "floating" or not connected to earth whereas Type B Applied Parts may be (and often are) connected to earth.

Electrical – Finally, IEC 60601 addresses the actual issue of electrical safety as it relates to the use of the medical electrical equipment in the process of caring for the patient. The compliance standard requires that the medical system operate safely not only under normal conditions but also in the event of what the IEC calls a "single fault" condition. Single faults are such occurrences as the failure of a component or the shorting or failure of basic insulation. IEC 60601 requires that in the event of a single fault, no safety hazard (electrocution, fire, etc.) will occur. These requirements do not pertain to multiple independent faults known as a "double fault" condition. There are other electrical considerations as well.

Stringent Precautions

The electrical guidelines for the safety of medical electrical equipment are more demanding than for other electrical products – and for some very good reasons. In an intensive care ward, for example, a patient might be connected to several electrical devices at the same time. Some of these devices might be intended to make conductive contact with the patient. An ECG lead might be a good example. Finally, it's entirely conceivable that connection to the patient might be by way of an invasive device either through an opening in the skin or via a natural body orifice.

In any case, electrical safety is tantamount. In 1976, O.Z. Roy, J.R. Scott, and G.C. Park published findings in *IEEE Transactions in Biomedical Engineering*[1] showing that currents as low as 100 mA (one hundred-thousandths of an amp) could paralyze the respiratory system and cause the heart muscle to fibrillate. Clearly, the safety of electrical devices used in healthcare is of great importance. It is the purpose of this white paper to examine the general guidelines for electrical safety under IEC 60601. Additionally, this white paper will explore how a manufacturer of electrical medical and dental equipment can efficiently and economically ensure that a system meets the requirements of IEC 60601, through the application and use of appropriately selected power conditioning and uninterruptible power supply devices.

1. O.Z. Roy, J.R. Scott, G.C. Park, "Ventricular Fibrillation and Pump Failure Thresholds Versus Electrode Area", IEEE Transactions in Biomedical Engineering, 1976, pp. 23, 45-48.

Electrical Compliance Requirements

IEC 60601 addresses electrical safety in several ways. The standard describes both mechanical and electrical issues, which may affect electrical safety. It also addresses the subject of insulation and the previously mentioned topic of earthing.

Recalling the 1976 pioneering work of Roy, Scott, and Park, it's important to note that IEC 60601 (as do other medical safety standards) assumes that, from an electrical standpoint, patient safety hinges not on voltage but on current. As Roy, Scott, and Park discovered, it takes only a small amount of current to cause respiratory arrest, ventricular fibrillation, and possibly death. IEC 60601 assumes that this current will come from stray sources and be of no functional use in the operation of the electrical equipment. For this reason, it is referred to as *leakage current.* IEC 60601 defines leakage current from three different sources.

Earth Leakage Current: Current originating in the mains or electrical system and flowing through or across system insulation into the protective earth conductor (safety ground conductor or green wire in North American electrical systems).

Enclosure Leakage Current: Current originating from the enclosure (or part of the enclosure) of the electrical device and flowing through another external connection other than the protective earth conductor and then back to another part of the enclosure.

Patient Leakage Current: Current flowing from the Applied Part via the patient to earth or flowing from the patient via an Applied Part to earth, which originates from an unintended voltage appearing on an external source.

Some Differences in Standards

As previously mentioned, IEC 60601 has been adapted for use in other countries around the world. This has resulted in some differences in the way the standard is interpreted, which has in turn resulted in some differences in the requirements that are applied.

UL2601-1 in the United States is a good example. UL2601-1 defines leakage current in a simpler fashion by saying that it is *"any current, including capacitively coupled currents, which may be conveyed from accessible parts of an appliance to ground or other accessible parts of the appliance and which is not intended to be applied to the patient."*

IEC 60601 and UL2601-1 specify different maximum allowable leakage currents, too. Largely determined by the specific way in which the electrical device is used, the maximum allowable leakage current specification can be quite stringent. More on that later. For now, it's interesting to know how IEC 60601 approaches limiting leakage current in the construction of electrical medical equipment.

Limiting Leakage Current By Design

IEC 60601 provides design guidelines that for the manufacture of electrical system components, which will meet or exceed leakage current requirements. These guidelines address the design of the power supplies and printed circuit boards used to assemble the electrical medical system.

One way to decrease leakage currents is to observe some mechanical guidelines for the physical separation of electrical circuits. Some types of circuits (even though they share the same circuit board) must be physically separated from each other to achieve compliance with leakage current requirements. Another way is to observe IEC guidelines with regard to conductor insulation and earthing or grounding.

IEC 60601 provides a lot of detail on the subjects of air clearances and creepage distances on printed circuit boards as well as the basic, double, reinforced, and supplementary insulation techniques aimed at preventing excessive leakage currents from forming. For the medical system designer, meeting the electrical safety requirements of IEC 60601 means making sure that every power supply and every circuit board used in the system meets the design and construction guidelines. And that task may be made more difficult and expensive given the differences that exist between different countries with respect to maximum allowable leakage currents.

UL2601-1 vs. IEC 60601

As mentioned, some differences do exist in the way that IEC 60601 standards are interpreted and applied by different agencies. A good example is Underwriters Laboratories and the standards that have been established by them for leakage current limitations under UL2601-1. Both IEC 60601 and UL2601-1 address leakage current for two different applications. These applications are defined as *patient connected* and *patient vicinity*.

All connections to the patient such as pads, contacts, probes, sensors, cuffs plus any associated leads, cables, components and wiring (both internal and external to the device or appliance enclosure) are designated as patient connected. Patient connected circuits extend from the patient into the equipment until they reach a point where a protective impedance or isolation is provided by the system design.

Patient vicinity is defined as any space with surfaces likely to be contacted by the patient or any medical personnel who may touch the patient. Patient vicinity space encompasses an area within 6 feet (or 1.83 meters) beyond the perimeter of the bed, examination table, dental chair, etc. and extending vertically for 7.5 feet (or 2.29 meters) above the floor of the patient room.

For patient vicinity, both IEC 60601 and UL2601-1 limit maximum leakage current to 300 micro-amps (300 millionths of an amp). For patient connected circuits or devices, however, UL2601-1 is much more stringent. UL2601-1 limits patient connected leakage currents to 50 micro-amps where IEC 60601 is less strict with a limit of 100 micro-amps.

Even though patient safety standards have been harmonized, there are still clear differences in how the standards are interpreted and applied. This represents one

more challenge to the manufacturer attempting to design a medical system that will be universally approved for use in the global marketplace.

Enter the Personal Computer

As is the case in many applications, the personal computer has all the processing power needed to be the "platform of choice" for the medical system designer. The GUI interface offered by Microsoft's Windows® operating system is frequently a desirable one for the manufacturer to offer the medical system operator whose computer literacy lends well to a faster learning curve and easier use.

It's little wonder then that most system engineers would prefer to design their new medical system around low cost "off the shelf" personal computer components. Doing so creates a challenge, however, since personal computer hardware is built using power supplies which do not meet the requirements of IEC 60601. Frequently, the collective leakage currents of all the supplies used in the system's components are many times the allowable maximums. When confronted with this dilemma the designer frequently has limited solutions. The first is to replace the non-compliant power supplies with ones that have been designed to meet IEC 60601.

Given that the medical system may incorporate a CPU, color graphics display, printer, and frequently other peripherals as well, the system designer may well have to replace not one but several power supplies. This may prove to be a very expensive alternative adding hundreds of dollars to the system cost and thousands of dollars to the system sale price. Does the system manufacturer have any alternatives, which are both effective and cost efficient?

Welcome Back an Old Friend

A second solution to this design problem is to power the entire medical system with an isolation transformer. This device acts as an interface between the electrical system and the medical system, and, if properly designed, has the ability to reduce leakage currents to the limits specified by IEC 60601 and even UL2601-1.

Isolation transformers are easily designed to satisfy the mechanical requirements of spacing as well as the electrical requirements regarding insulation. A single isolation transformer will reduce the collective leakage current of multiple switch mode power supplies. System design is simplified. The multiple peripherals found in most medical systems benefit from having a single point source of power and grounding. It's easy to meet the earthing requirements of the guidelines, too.

Isolation transformers are a proven technology. They've been used effectively as a power quality tool for many years. Their strength in preventing power quality related problems is due to the fact that the secondary neutral conductor is bonded to ground (earth). This neutral to ground bond eliminates common mode noise voltage, which is usually the chief cause of unreliable operation, lockups, and "No Problem Found" service calls.

Frequently isolation transformers are combined with other elements to improve their handling of a variety of power quality problems. Noise filter-surge diverter-isolation transformer combinations are common and an efficient way of meeting minimum power

quality and IEC 60601 requirements in a single cost efficient power conditioning package. In a few instances, manufacturers have combined IEC 60601 compliant isolation transformers with uninterruptible power supply circuitry that is itself IEC 60601 compliant. The result is an IEC 60601 compliant uninterruptible power supply that can be used to meet IEC 60601 requirements while at the same time providing backup power during periods of commercial power outage.

Conclusion

Ensuring that every component of a medical system uses an IEC 60601 compliant power supply is advantageous only from the design standpoint of size and weight. The high cost of such a decision is disadvantageous from the point of total system cost and market competitiveness. It also limits the system manufacturer's ability to easily multi-source power supplies or to quickly substitute vendors in the event that competitive market conditions create cost changes that would be advantageous to the manufacturer

Designing medical systems around an IEC 60601 compliant power conditioner or UPS with an IEC 60601 compliant isolation transformer at the heart of its design is an obvious choice in the interest of patient safety, design efficiency, and cost performance. There are added benefits, too. Systems designed in this fashion more easily integrate into the wide variety of electrical and regulatory environments found throughout the globe. In addition, experience has shown that isolation transformers combined with properly selected power conditioning and UPS components are instrumental in reducing system failures, improving system reliability, maximizing system uptime, reducing system maintenance and warranty costs, and increasing customer satisfaction.

Appendix

Table 1 – IEC 60601 Collateral Standards

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IEC 60601-1-1	MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY 1: COLLATERAL STANDARD: SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS
IEC 60601-1-2	MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY 2. COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY – REQUIREMENTS AND TESTS
IEC 60601-1-3	MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY – COLLATERAL STANDARD: GENERAL REQUIREMENTS FOR RADIATION PROTECTION IN DIAGNOSTIC X-RAY EQUIPMENT
IEC 60601-1-4	MEDICAL ELECTRICAL EQUIPMENT: PART 1-4: GENERAL REQUIREMENTS FOR COLLATERAL STANDARD: PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS

Table 2 – IEC 60601 Specific Standards

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IEC 60601-2-1	MEDICAL ELECTRICAL EQUIPMENT - PART 2-1: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTRON ACCELERATORS IN THE RANGE 1 MeV TO 50 MeV
IEC 60601-2-2	MEDICAL ELECTRICAL EQUIPMENT - PART 2-2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF HIGH FREQUENCY SURGICAL EQUIPMENT
IEC 60601-2-3	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF SHORT-WAVE THERAPY EQUIPMENT
IEC 60601-2-4	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF CARDIAC DEFIBRILLATORS AND CARDIAC DEFIBRILLATORS - MONITORS
IEC 60601-2-5	MEDICAL ELECTRICAL EQUIPMENT - PART 2-5: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ULTRASONIC PHYSIOTHERAPY EQUIPMENT
IEC 60601-2-6	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF MICROWAVE THERAPY EQUIPMENT
IEC 60601-2-7	MEDICAL ELECTRICAL EQUIPMENT - PART 2-7: PARTICULAR REQUIREMENTS FOR THE SAFETY OF HIGH-VOLTAGE GENERATORS OF DIAGNOSTIC X-RAY GENERATORS
IEC 60601-2-8	MEDICAL ELECTRICAL EQUIPMENT - PART 2-8: PARTICULAR REQUIREMENTS FOR THE SAFETY OF THERAPEUTIC X-RAY EQUIPMENT OPERATING IN THE RANGE 10 kV TO 1 MV
IEC 60601-2-9	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF PATIENT CONTACT DOSEMETERS USED IN RADIOTHERAPY WITHELECTRICALLY CONNECTED RADIATION DETECTORS

IEC 60601-2-10	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF NERVE AND MUSCLE STIMULATORS
IEC 60601-2-11	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF GAMMA BEAM THERAPHY EQUIPMENT
IEC 60601-2-12	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF LUNG VENTILATORS FOR MEDICAL USE
IEC 60601-2-13	MEDICAL ELECTRICAL EQUIPMENT - PART 2-13: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ANAESTHETIC WORKSTATIONS
IEC 60601-2-14	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF ELECTROCONVULSIVE THERAPY EQUIPMENT
IEC 60601-2-15	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF CAPACITOR DISCHARGE X-RAY GENERATORS
IEC 60601-2-16	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF HAEMODIALYSIS EQUIPMENT
IEC 60601-2-17	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF REMOTE-CONTROLLED AUTOMATICALLY DRIVEN GAMMA-RAY AFTER-LOADING EQUIPMENT
IEC 60601-2-18	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ENDOSCOPIC EQUIPMENT
IEC 60601-2-19	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS OF SAFETY OF BABY INCUBATORS
IEC 60601-2-20	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF TRANSPORT INCUBATORS
IEC 60601-2-21	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF INFANT RADIANT WARMERS
IEC 60601-2-22	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF DIAGNOSTIC AND THERAPEUTIC LASER EQUIPMENT
IEC 60601-2-23	MEDICAL ELECTRICAL EQUIPMENT - PART 2-23: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF TRANSCUTANEOUSPARTIAL PRESSURE MONITORING EQUIPMENT
IEC 60601-2-24	MEDICAL ELECTRICAL EQUIPMENT - PART 2-24: PARITCULAR REQUIREMENTS FOR THE SAFETY OF INFUSION PUMPS AND CONTROLLERS
IEC 60601-2-25	MEDICAL ELECTRICAL EQUIPMENT - PART 2-25: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROCARDIOGRAPHS
IEC 60601-2-26	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROENCEPHALOGRAPHS
IEC 60601-2-27	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT
IEC 60601-2-28	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY SOURCE ASSEMBLIES AND X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS

IEC 60601-2-29	MEDICAL ELECTRICAL EQUIPMENT - PART 2-29: PARTICULAR REQUIREMENTS FOR THE SAFETY OF RADIOTHERAPHY SIMULATORS
IEC 60601-2-30	MEDICAL ELECTRICAL EQUIPMENT - PART 2-30: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT
IEC 60601-2-31	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF EXTERNAL CARDIAC PACEMAKERS WITH INTERNAL POWER SOURCE
IEC 60601-2-32	MEDICAL ELECTRICAL EQUIPMENT PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ASSOCIATED EQUIPMENT OF X-RAY EQUIPMENT
IEC 60601-2-33	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF MAGNETIC RESONANCE EQUIPMENT FOR MEDICAL DIAGNOSIS
IEC 60601-2-34	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY, INCLUDING ESSENTIAL PERFORMANCE, OF INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT
IEC 60601-2-35	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF BLANKETS, PADS AND MATTRESSES, INTENDED FOR HEATING IN MEDICAL USE
IEC 60601-2-36	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF EQUIPMENT FOR EXTRACORPOREALLY INDUCED LITHOTRIPSY
IEC 60601-2-38	MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FORTHE SAFETY OF ELECTRICALLY OPERATED HOSPITAL BEDS
IEC 60601-2-39	MEDICAL ELECTRICAL EQUIPMENT - PART 2-39: PARTICULAR REQUIREMENTS FOR THE SAFETY OF PERITONEAL DIALYSIS EQUIPMENT
IEC 60601-2-40	MEDICAL ELECTRICAL EQUIPMENT - PART 2-40: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELETROMYOGRAPHS AND EVOKED RESPONSE EQUIPMENT
IEC 60601-2-41	MEDICAL ELECTRICAL EQUIPMENT - PART 2-41: PARTICULAR REQUIREMENTS FOR THE SAFETY OF SURGICAL LUMINAIRES AND LUMINAIRES FOR DIAGNOSIS
IEC 60601-2-43	MEDICAL ELECTRICAL EQUIPMENT - PART 2-43: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY EQUIPMENT FOR INTERVENTIONAL PROCEDURES
IEC 60601-2-44	MEDICAL ELECTRICAL EQUIPMENT - PART 2-44: PARTICULAR REQUIREMENTS FOR THE SAFETY OF X-RAY EQUIPMENT FOR COMPUTED TOMOGRAPHY
IEC 60601-2-45	MEDICAL ELECTRICAL EQUIPMENT - PART 2-45: PARTICULAR REQUIREMENTS FOR THE SAFETY OF MAMMOGRAPHIC X-RAY EQUIPMENT AND MAMMOGRAPHIC STEREOTACTIC DEVICES
IEC 60601-2-46	MEDICAL ELECTRICAL EQUIPMENT - PART 2-46: PARTICULAR REQUIREMENTS FOR THE SAFETY OF OPERATING TABLES
IEC 60601-2-50	MEDICAL ELECTRICAL EQUIPMENT - PART 2-5O: PARTICULAR REQUIREMENTS FOR THE SAFETY OF INFANT PHOTOTHERAPY EQUIPMENT