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AN INTRODUCTION TO CERTIFICATION AND REGULATORY REQUIREMENTS

The following information is provided to help you with your design and safety evaluation decisions

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Designing Medical Electrical Equipment to Meet Safety Certification and Regulatory Requirements

Note - On April 25, 2003, UL issued "UL 60601-1" to replace "UL 2601-1". There are no requirement differences between UL 60601-1 and UL 2601-1 (format changes only).

Medical equipment is highly regulated and held to a higher level of safety than nearly all other types of equipment on the market. The main reasons for this are that medical equipment may be used on patients

who are not able to respond to hazardous conditions or pain, an actual electrical connection between the equipment and patient may exist, and certain types of medical equipment function as life support, the failure of which could result in the death of the patient.

While Engineers spend years in school and the workplace learning about how to design equipment, they usually do not learn about the certification and regulatory requirements that the equipment must meet to comply with the US and international codes and laws. Understanding these requirements before the design phase of the equipment will result in a reduction of product development cost, faster certification turnaround, and increased product safety.

This information is intended to increase awareness of product safety certification requirements by exploring the requirements for medical equipment both in the US and internationally. We will look at the applicable safety standards and review their philosophy of safety, then show the process of evaluation and documentation. We will then discuss the most common noncompliances seen when evaluating medical equipment to safety standards.

MEDICAL EQUIPMENT FOR THE US AND CANADA (FDA, UL)

In the United States, the Food and Drug Administration (FDA) sorts devices into three categories (Class I, II, or III), depending upon the degree of regulation necessary to provide a reasonable assurance of their safety and effectiveness. Class I devices are subject to premarket notification, registration and listing, prohibitions against adulteration and misbranding, and rules for good manufacturing practices. Class II devices also need performance standards, and Class III devices need premarket approval from the FDA. A 510(k) is a collection of documents and forms used to show substantial equivalence to a device that was either in commercial distribution before May 28, 1976 or has been reclassified into Class I or II.1 The FDA or accredited Third Party Reviewer examines the documentation and determines whether the device is substantially equivalent to the specified predicate device or not. If the device is found to be substantially equivalent, it can be marketed and sold in the US. If the device is not found to be substantially equivalent (due to new technology or differences in intended use), then the submitter must present information, such as clinical trial data, statistical data, and safety testing results to the FDA to show that the device is safe and effective. If the FDA finds the information and data adequate, they will grant premarket approval for the device.

The FDA Federal Food, Drug, and Cosmetic Act requires that all medical devices be "safe and effective," and recognizes safety standards as a means to support a declaration of conformity. Many "Authorities Having Jurisdiction" (AHJ) and purchasers of medical electrical equipment in the US and Canada require a safety certification mark on the equipment. Therefore, a product that carries a safety certification mark will usually reach its full market potential.

Underwriters Laboratories Inc. (UL) is the major product safety certification organization in North America. Manufacturers of medical equipment submit product samples and information to UL for evaluation to applicable safety standard(s) and products that meet these requirements are authorized to apply the appropriate UL Mark for the US and/or Canada.

MEDICAL EQUIPMENT FOR THE EUROPEAN UNION (CE Marking)

All but low-risk, non-measuring, non-sterile medical devices used in Europe must bear the CE mark, reviewed by a Notified Body (CE mark with the Notified Body's identification number). A Notified Body is a third party designated by European authorities to assess compliance with the Medical Device Directive

(93/42/EEC). The Medical Device Directive is essentially the European "law" for medical devices. This assessment by a Notified Body evaluates compliance with the Medical Device Directive requirements for safety, performance, suitability for intended use, and risk analysis. Manufacturers can choose from several conformity assessment routes, most involving a quality assurance assessment of the manufacturer's facilities.

MEDICAL ELECTRICAL SAFETY STANDARDS

Product Safety certification agencies use safety standards to evaluate many different types of products. These safety standards are consensus documents, which define the minimum construction and performance requirements. Table 1 provides an example of UL Standards that cover medical and related product categories. A complete list of UL standards, covering more than 5,000 product categories, can be found at http://ulstandardsinfonet.ul.com.

UL 187	*X-Ray Equipment (withdrawn end of 2010, product freeze at end of 2004)*
UL 198	*Fuses*
UL 498	*Appliance Inlets*
UL 544	*Medical and Dental Equipment (withdrawn end of 2010, product freeze at end of 2004)*
UL 1577	*Optical Isolators*
UL 60950-1	*Information Technology Equipment - Computers, etc.*
UL 2111	*Motors*
UL 2601-1	*(Changed to "UL 60601-1")*
UL 60601-1	*Medical Electrical Equipment*
UL 61010-1	*Electrical Equipment for Laboratory Use*

Table 1. Example of UL Standards

Since 1972, electrically operated medical equipment used in the US has been evaluated to the UL544 Standard for Medical and Dental Equipment. This standard will be withdrawn at the end of 2004, requiring both new and current UL544 equipment to be evaluated to the UL 2601-1 Standard to continue to apply the UL Mark. Underwriters Laboratories published UL2601-1 in 1994. UL2601-1 was written as an IEC601-1 (renamed IEC60601-1) harmonized standard. Prior to this harmonization initiative, manufacturers were required to comply with different standards for different countries. This often required that multiple product models had to be designed and manufactured to meet different national standards if they were to be used in more than one country. Using an internationally harmonized safety standard meant that a product could be designed and evaluated for compliance with a single standard, such as UL2601-1, and also be eligible for use in many different countries. Other countries that use an IEC60601-1 harmonized standard include the European Union, Canada, Brazil, Japan, Korea, and Australia. In addition to being the base of so many harmonized standards, IEC60601-1 is an FDA recognized consensus standard, used to support a manufacturer's declaration of conformity. Visit the FDA website to see all the FDA-CDRH recognized standards at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

The UL2601-1 safety standard contains the full text of IEC60601-1 and adds US deviations, as shown in Figure 1. The US deviations contain national requirements, such as those for the mains circuit (National

Electric Code, UL), component requirements (ANSI, UL), lower leakage current limits (AAMI, UL), enclosure flame ratings (UL), and production line testing (OSHA, UL). Since these deviations do not conflict with the base standard, the equipment is still in compliance with IEC60601-1.

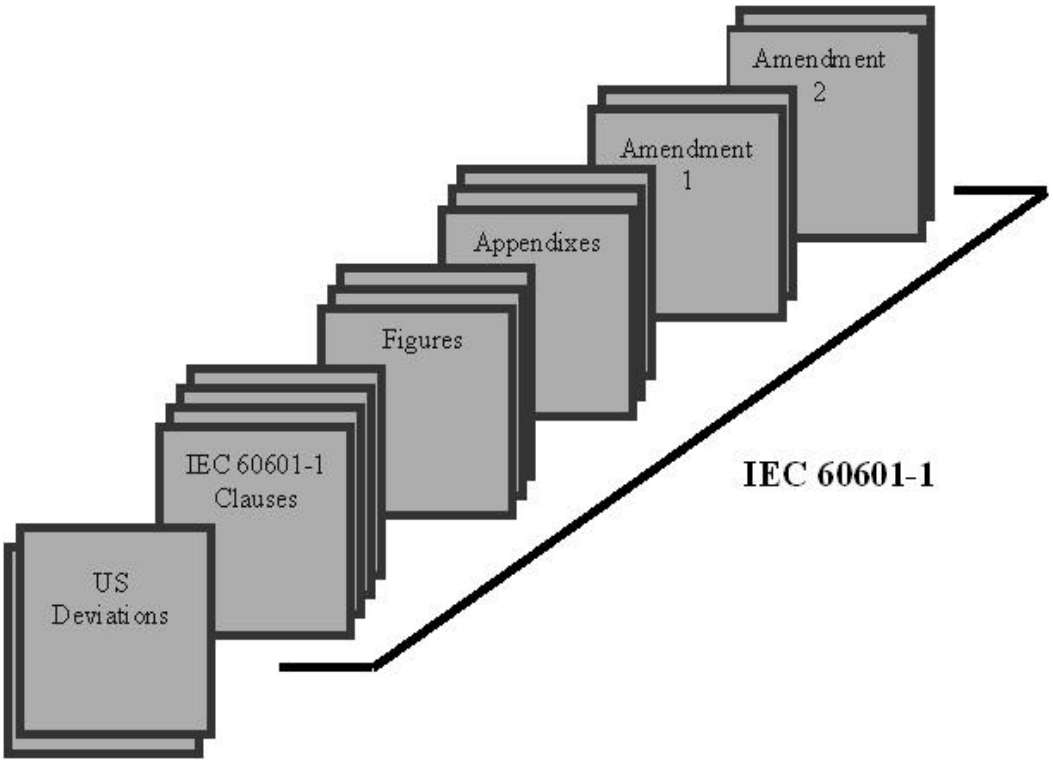
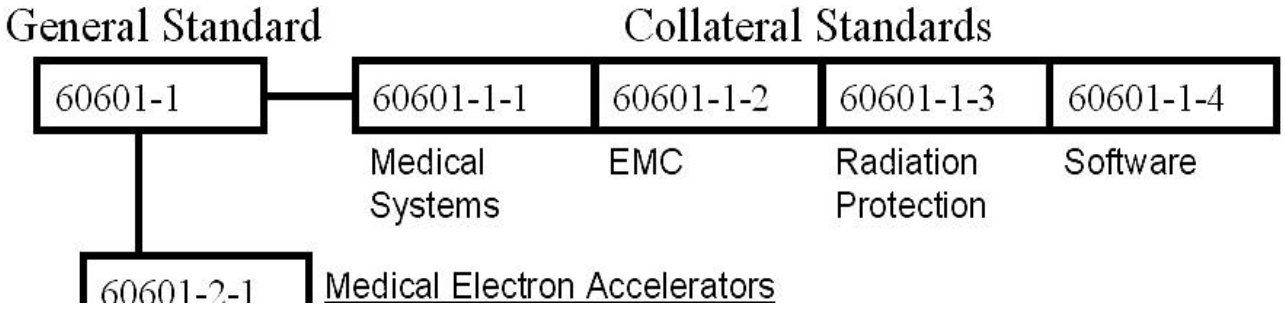


Figure 1. Structure of UL2601-1

The second edition of IEC60601-1 currently has two amendments that were published in 1991 and 1995. These amendments are additions and corrections to the base standard. The standard also has collateral (horizontal) standards, numbered IEC60601-1-x, and particular (vertical) standards, numbered IEC60601-2-xx. The collateral standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical systems (-1-1), EMC (-1-2), radiation protection in diagnostic X-ray equipment (-1-3), and software (-1-4). The particular standards apply to specific equipment types, such as Medical Electron Accelerators (-2-1), High Frequency Surgical Equipment (-2-2), and hospital beds (-2-38). Figure 2 illustrates the organization of the collateral and particular IEC60601 standards. The US deviations, amendments, collateral, and particular standards are used together to evaluate the medical electrical equipment. They all use the same clause numbering system, which allows cross-referencing of the requirements, and each may have amendments.



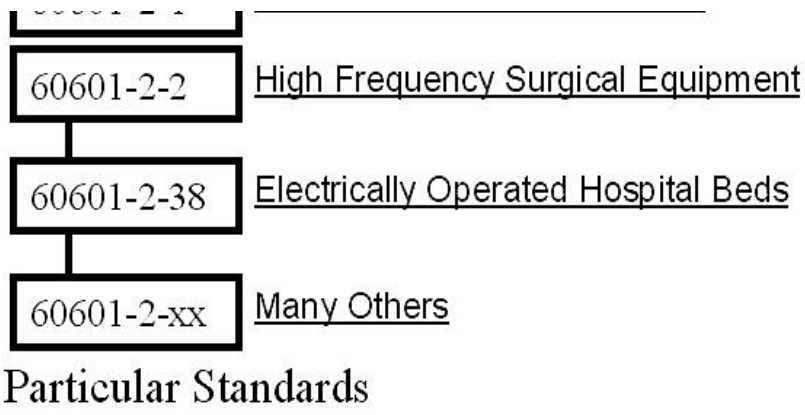


Figure 2. Organization of the IEC60601-1 Standard

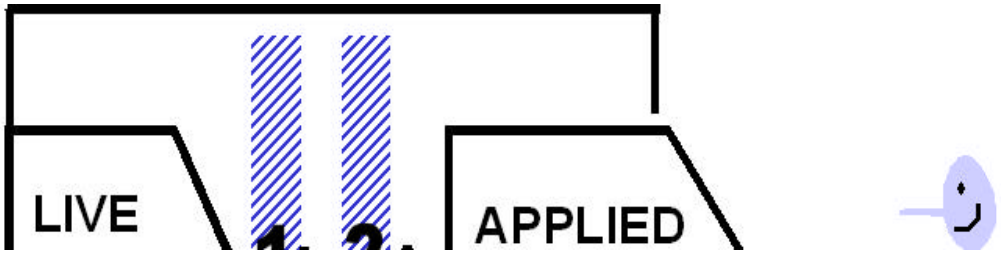
IEC60601-1 REQUIREMENTS

Philosophy

The underlying philosophy of the IEC60601-1 harmonized standards is that equipment must be safe in normal condition (NC) and single fault condition (SFC). To understand the electrical safety requirements, we need to first define a few terms:

- An Applied Part is any pieces of the equipment that can intentionally or unintentionally be brought in contact with the patient.
- Creepage is spacing along a surface (as an ant crawls).
- Clearance is spacing through the air (as a bug flies).
- LOP is a level of protection (2 required by standard).
- Basic Insulation (BI) is a spacing or a physical insulation barrier providing 1 LOP.
- Supplemental Insulation (SI) is also a spacing or a physical insulation barrier providing 1 LOP.
- Double Insulation (DI) is BI + SI and provides 2 LOP.
- Reinforced Insulation (RI) is a single spacing or physical insulation barrier that provides 2 LOP.
- Protective Impedance is a component (such as a resistor) that provides 1 LOP.
- Protective Earth (PE) is a well-grounded part that provides 1 LOP.
- Class I Equipment is defined as using PE as 1 LOP.
- Class II Equipment (also known as Double Insulated) is defined as not using PE as 1 LOP.

For electrical safety, the standard requires 2 LOP against excessive unintentional current, defined as leakage current, passing through the patient or operator. Figure 3 graphically depicts the 2 LOP between the live part (mains) and the patient (1A and 2A), and between the live part and the enclosure (1B and 2B). In the case of 1A and 2A, the levels of protection are BI and SI. For 1B and 2B, they are BI and PE.



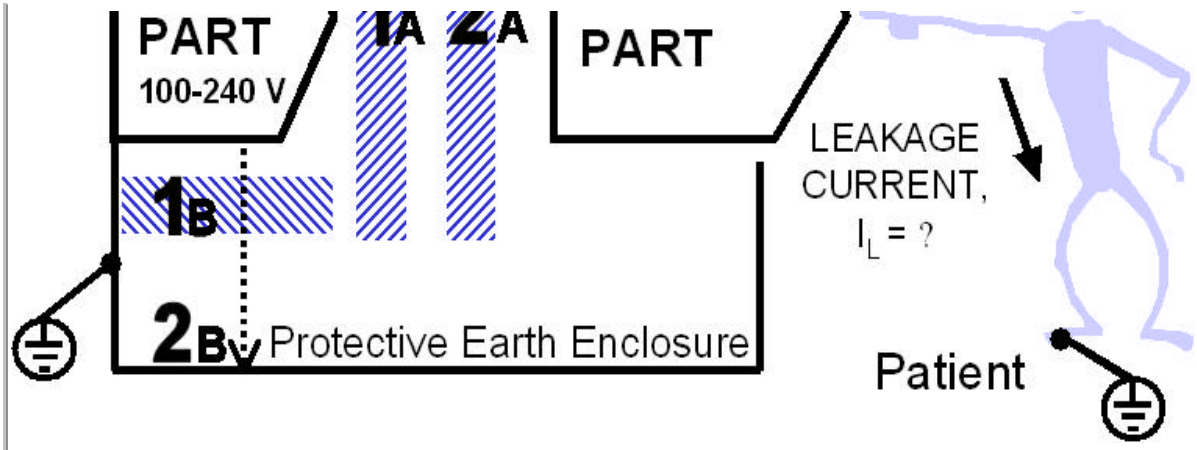


Figure 3. Two Levels of Protection (2 LOP)

Table 2 provides an example of the minimum spacing requirements and dielectric (hipot) requirements for these barriers. If the insulation does not meet both the dielectric and the spacing requirements, it cannot be considered as a level of protection and can be shorted as a normal condition. Note that BI and SI spacing requirements are the same, however the SI dielectric values are greater than the BI values. To be considered protectively earthed, the grounding path of the equipment must pass 15 Amps or 1.5* rated current for 5 seconds from the protectively earthed part to the earth connection, with 0.1 Ohms resistance for equipment with a detachable power supply cord or 0.2 Ohms for equipment with a non-detachable power supply cord. The Canadian requirement changes the current to 30 Amps or 2* rated current and changes the time to 2 minutes. Since this is the only major difference between the US and Canadian standards, the test is typically done at 30 A for 2 minutes as the "worst case" for testing protective earthed parts.

CREEPAGE & CLEARANCE REQUIREMENTS (in millimeters)						
Voltage	DC	≤15	≤36	≤75	≤150	≤300
Voltage	AC	≤12	≤30	≤60	≤125	≤250
BOP	Creepage	0.8	1.0	1.3	2.0	3.0
	Clearance	0.4	0.5	0.7	1.0	1.6
BI / SI	Creepage	1.7	2.0	2.3	3.0	4.0
	Clearance	0.8	1.0	1.2	1.6	2.5
DI / RI	Creepage	3.4	4.0	4.6	6.0	8.0
	Clearance	1.6	2.0	2.4	3.2	5.0

DIELECTRIC WITHSTAND TEST VOLTAGES (in Volts)			
Reference Voltage	0 < V ≤ 50	50 < V ≤ 150	150 < V ≤ 250
BI	500	1K	1.5K
SI	500	2K	2.5K
DI / RI	500	3K	4K

Table 2. Insulation Spacing and Dielectric Requirements (excerpt from full tables)

To demonstrate that medical equipment is safe in normal and single fault condition, the following conditions must be addressed when evaluating the equipment. These conditions are specified in the Standard and need to be addressed when designing medical equipment and/or selecting components.

Likely to Occur (Normal Condition)

· Reverse polarity of supply mains
· Failure of insulation less than basic

Could Occur (Single Fault Condition)

· Interruption of protective earth
· Interruption of one supply conductor
· Mains voltage on floating (F-type) applied part(s)
· Mains voltage on communication ports
· Failure of electrical components, one at a time
· Failure of mechanical parts, one at a time
· Failure of temperature limiting devices, one at a time
· Shorting of basic or supplemental insulation
· Overload of mains supply transformers
· Interruption and short circuit of motor capacitors
· Locking of moving parts
· Impairment of cooling (fans, vents)

Unlikely to Occur (Not evaluated)

· Total breakdown of double or reinforced insulation
· Loss of protective earth on permanently installed equipment
· More than one Single Fault Condition at a time
· Failure of a UL Recognized optocoupler barrier
· Failure of a UL Recognized Y1 capacitor, acting as a barrier

EVALUATION OF MEDICAL EQUIPMENT

The process of evaluating medical equipment for compliance with the requirements in UL2601-1 includes not only the equipment itself, but the user's manual, markings, software (if it mitigates a hazard), biocompatibility of applied parts and electromagnetic compatibility (EMC). Before submitting equipment for evaluation, the following information should be developed:

· Does equipment fit the scope of UL2601-1?
· Does equipment fit the scope of IEC60601 Collateral or Particular standards?
· List all equipment functions and accessories that can be used with the basic product.
· Is the medical equipment connected to other equipment, such as a computer or printer?
- Any other equipment must have IEC certification (evaluated to IEC standard) or be part of the medical equipment evaluation.
- Does equipment have electrical Signal Input/Output Parts (SIP/SOPs)?
- What could be connected to the SIP/SOPs?
- Computers and other IT equipment are considered to have 50 V in Normal Condition, Mains in Single Fault Condition on their data ports.
· Create insulation diagram (graphic illustration of the LOPs)
· Determine classifications from the standard

· Document components that cross all barriers per insulation diagram
· Verify creepage and clearance spacing requirements, per the insulation diagram (printed wiring boards, transformers, relays, etc.)
· Examine enclosure openings
  - IEC test finger (access to live parts)
  - IEC test pin (top openings to live parts)
  - Need for a tool to access any live parts
· Determine potential mechanical hazards, pinch points, sharp edges
· Determine potential hazards under abnormal use
· Document components that must meet a nationally recognized standard, such as ANSI in the US:
  - Primary circuit components (including wiring), up to mains transformer(s)
  - Lithium batteries (also requires reverse charge protection circuitry)
  - CRTs > 5 inches
  - Printed wiring boards with > 15 W available
  - Wiring/tubing with > 15 W available
  - Optical isolators with > 15 W available and/or acting as barrier per insulation diagram
  - Conductive coating process
· Verify that component ratings meet the equipment's ratings
· List enclosure materials
  - UL 94 flame rating requirements for polymeric enclosures if there is > 15 W available power in the enclosure
  - V-2 min. for mobile, portable equipment
  - V-0 min. for fixed or stationary equipment
· Verify mains fuse requirements (equipment or wall plug-in power supply):
  - Class I: Line and neutral
  - Class II with functional earth: Line and Neutral
  - Class II: Line only
  - Permanently installed equipment: Line only
· Verify protective earth conductors are green with yellow stripe
· Verify wires secured from hazardous movements
· Verify equipment marking requirements (labels)
· Verify accompanying document requirements
· Provide illustrations of equipment, complete with all accessories, showing critical components (digital *.JPG files)

Once this information is developed, the safety evaluation of the equipment can be initiated. One or more samples are required, depending on the equipment type and time requirements. Multiple samples of components may be needed to perform destructive tests (transformers, relays, plastic enclosures, motors etc.). For medical equipment, it may be advantageous to conduct a preliminary evaluation at the manufacturer's facilities. This allows for more expedient changes to the equipment if there are construction or test-related noncompliances.

<u>The following are the steps for a typical evaluation of medical electrical equipment:</u>

· Review the information previously identified

· Evaluate construction of equipment
· Perform required testing
  - Electrical, Mechanical, Temperature, Abnormal Condition Testing, etc.
· Software evaluation (IEC60601-1-4) + (ISO/IEC12207) + (ANSI/UL1998, 2nd Edition)
  - Required if mitigating fire, shock, mechanical hazards, or requirements of particular standard(s)
· Electromagnetic Compatibility (EMC) testing (optional for UL Classification)
  - Per collateral standard (IEC60601-1-2)
· Review of biocompatibility documentation on patient contact parts (optional for UL Classification)
  - Per ISO 10993-1 standard
· Develop critical component list
  - If it affects test results or requirements in the standard, it's a critical component
  - May be design specifications (spacings, colors, etc.)
· Prepare the technical report and optionally, the Informative Test Report
  - Preferred document for CE Marking technical files

THE PROCESS OF DOCUMENTATION

The documentation developed as a result of a safety evaluation depends on the manufacturer's requirements. The three common types of documentation are a UL report, an Informative Test Report, and a Certified Body (CB) report. A UL report (consisting of a product description and test report) authorizes the manufacturer to apply the UL/C-UL (US/Canada) Mark to products covered in the report. It describes the equipment evaluated and its critical components. UL conducts quarterly audits using this report to verify that the equipment bearing the UL/C-UL Mark is the same as the equipment that was tested. An Informative Test Report is a complete documentation of all the requirements in a standard (N/A, Pass, or Fail), a test record, insulation diagram, illustrations, equipment markings, and other applicable information. It is the preferred document for MDD technical files (required for CE marking) and required by some international hospitals and clinics for equipment purchases. A CB report, or National Certification Body report, is similar to an Informative Test Report, but also contains a certificate from the issuer, who is required to be a member of the IECEE CB Scheme. A CB report is used to obtain certification marks in different countries without repeating the full evaluation of the equipment. The Informative Test Report or CB Report are very important to have for the equipment's technical files, and act as an international "passports" for a device.

COMMON NONCOMPLIANCES

There are many common noncompliances that could have been easily avoided had the designers been aware of the safety standard requirements early in the design phase. The most common noncompliance item relates to the accompanying documents. All the '601 standards have very specific requirements for inclusions in the accompanying documents. Since most companies have separate departments that create these documents, they are often not aware of the requirements. The next most common (and likely the most costly) noncompliance is the power supply selection. The best advice is to use a UL 2601-1 Recognized power supply (evaluated to UL2601-1 by UL). By doing this, compliance with spacing, leakage current, and mains component requirements is assured. Also, the cost to evaluate the power supply and the required UL quarterly inspections at the power supply manufacturer is avoided. Many designers begin with a non-UL recognized power supply, only to change to a UL recognized one when they discover the

associated costs of using a non-recognized power supply, or when they realize that it does not comply with the requirements. When designing medical equipment, it is also important to be aware that there are minimum spacing requirements for electrical barriers. Inadequate spacings on circuit boards are another typical mistake. An example of this is DC-C converters. Nearly all DC-DC converters, including UL recognized models, do not provide the spacing or insulation barrier required by these standards. Make sure you get the specifications on the spacings or barriers from input to output. For equipment with plastic enclosures, there will also be flammability requirements for the plastic material. Make sure the plastic chosen for the enclosure has at least a UL Recognized V-0 flame rating for fixed equipment, and a UL Recognized V-2 flame rating for all other types of equipment. The last typical mistake relates to indicator lights. Red indicator lights can only be used for a warning, yellow for caution. Keep this in mind when selecting LEDs for any indicator lights. These common noncompliances can be easily avoided with knowledge of the applicable standards and they are the major reasons that preliminary investigations of medical equipment are routinely done in the early design phase.

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THE BASICS OF INSULATION DIAGRAMS

An Insulation Diagram (sometimes called an Isolation Diagram) is a graphic illustration of the insulation barriers required by UL 2601-1 / UL 60601-1 / IEC 60601-1 for electrical safety. The key to a successful Insulation Diagram is to keep it simple. It is not a schematic and should not show greater detail than is required to illustrate the required barriers.

The following are examples of the items that need to be graphically illustrated in the Insulation Diagram: spacings, components, physical insulation, protectively earthed parts (parts with a good connection to earth ground), and protective impedances (resistors, etc).
Some of the barriers that are required include:
- Between mains circuit and accessible parts, secondary circuits, patient circuits, the patient, etc.
- Between secondary circuits and accessible parts, patient circuits, the patient, etc.
- Between data ports (SIP/SOPs) and secondary circuits, accessible parts, patient circuits, the patient, etc.

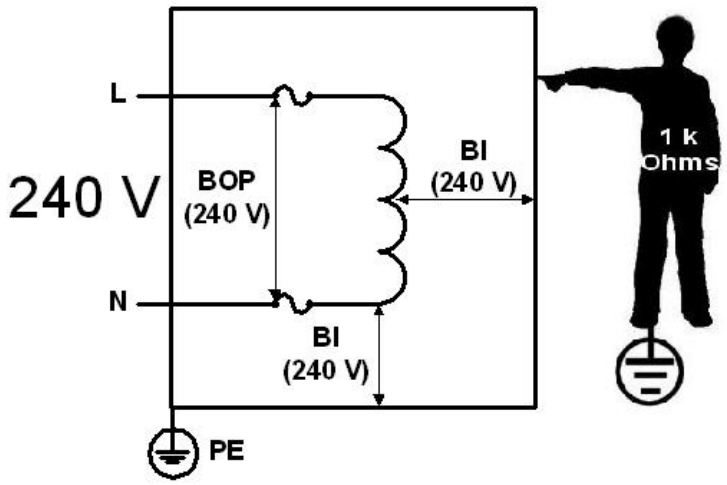
The underlying philosophy of the IEC60601-1 harmonized standards is that equipment must be safe in normal condition (NC) and single fault condition (SFC). To understand the electrical safety requirements that are used to create the insulation diagram, we need to first define a few terms:

- An **Applied Part** is any pieces of the equipment that can intentionally or unintentionally be brought in contact with the patient.
- **Creepage** is spacing along a surface (as an ant crawls).
- **Clearance** is spacing through the air (as a bug flies).
- **LOP** is a level of protection (not defined by the standard).
- **Basic Insulation (BI)** is a spacing or a physical insulation barrier providing 1 LOP.
- **Supplemental Insulation (SI)** is also a spacing or a physical insulation barrier providing 1 LOP.
- **Double Insulation (DI)** is BI + SI and provides 2 LOP. Note that BI + BI does not result in DI
- **Reinforced Insulation (RI)** is a single spacing or physical insulation barrier that provides 2 LOP.
- **Protective Impedance** is a component (such as a resistor) that provides 1 LOP.
- **Protective Earth (PE)** is a well-grounded part that provides 1 LOP.
- **Class I Equipment** uses PE as 1 LOP.
- **Class II Equipment (also known as Double Insulated)** does not use PE as an LOP.

For electrical safety, the standard requires 2 LOP against excessive unintentional current, defined as leakage current, passing through the patient or operator.

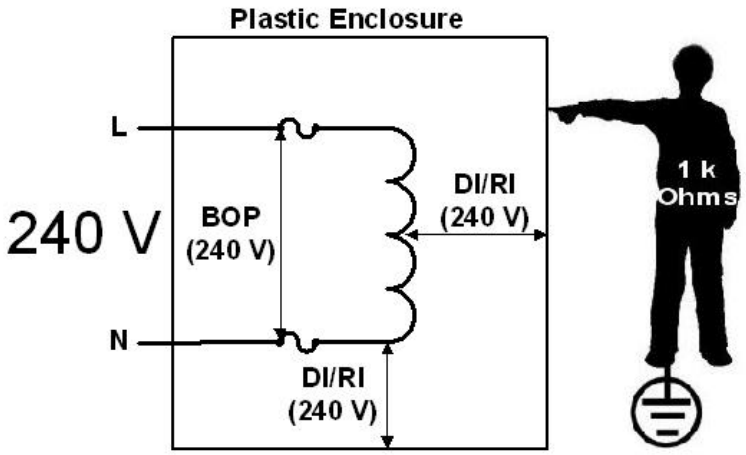
The following illustrate the above terms and the requirement for 2 LOP

- **Insulation Diagram**
  Class I Equipment: BI + PE = 2 LOP



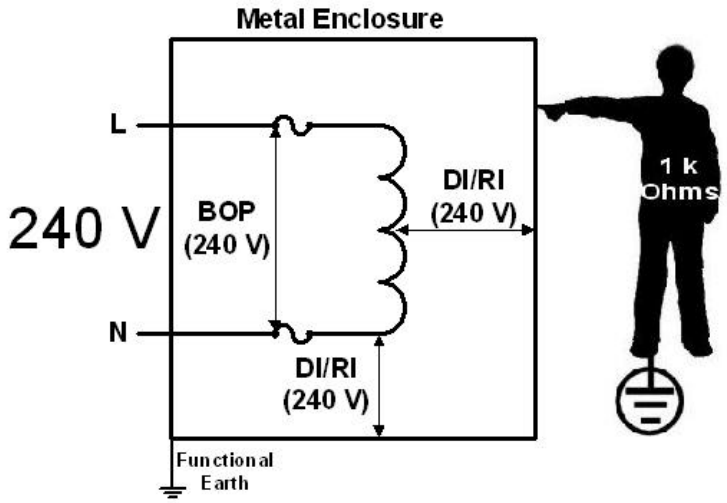
- **Insulation Diagrams (Continued)**

  Class II Equipment: DI or RI = 2 LOP



Insulation Diagrams (Continued)

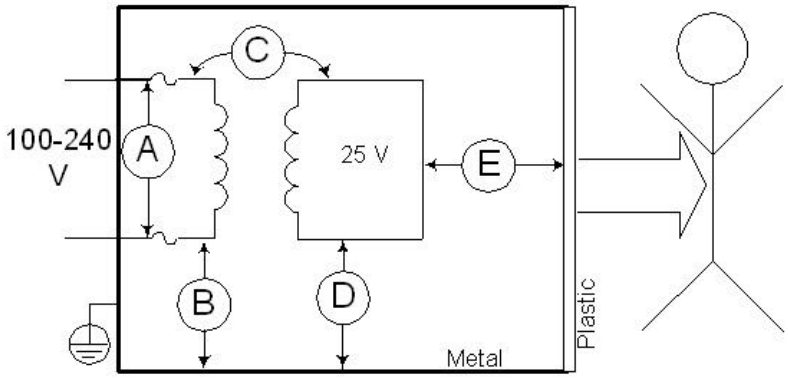
Class I or II Equipment: DI or RI = 2 LOP ***(Note - Enclosure is Not PE)***



For the following examples, the specifications in red on the right are the options for the equipment - Each option is a valid Insulation Diagram

Insulation Diagrams (Continued)

- **Class I Equipment, Metal & Plastic Enclosure**



A = BOP (240 V)
B = BI (240 V)
C = DI/RI (240 V)
D = OP
E = DI/RI (25 V)

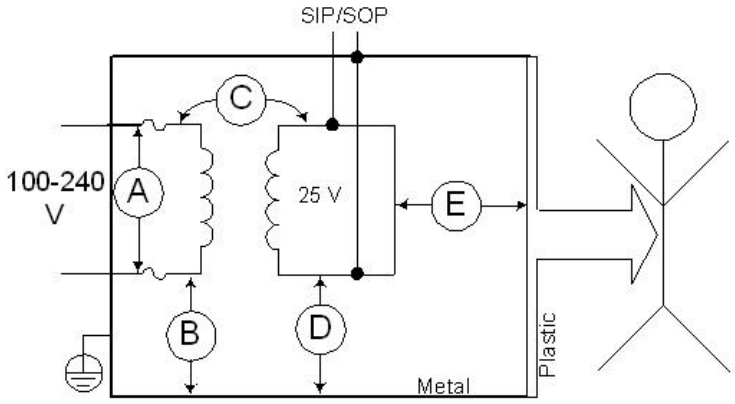
A = BOP (240 V)
B = BI (240 V)
C = DI/RI (240 V)
D = BI (25 V)
E = SI (25 V)

A = BOP (240 V)
B = BI (240 V)
C = BI (240 V)
D = OP
E = SI (240 V), DI/RI (25 V)

Insulation Diagrams (Continued)

- **Class I Equipment, Metal & Plastic Enclosure, SIP/SOPs**

IT Equipment: 50 V NC, Mains V SFC. SIP/SOP accessible by operator only

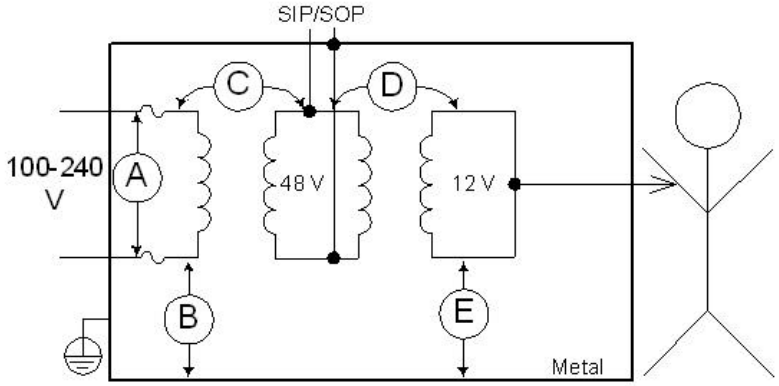


A = BOP (240 V)
B = BI (240 V)
C = DI/RI (240 V)
D = OP
E = DI/RI (50 V), BI (240 V)

A = BOP (240 V)
B = BI (240 V)
C = BI (240 V) **NOT ALLOWED**
D = OP
E = DI/RI (50 V), BI (240 V)

Insulation Diagrams (Continued)

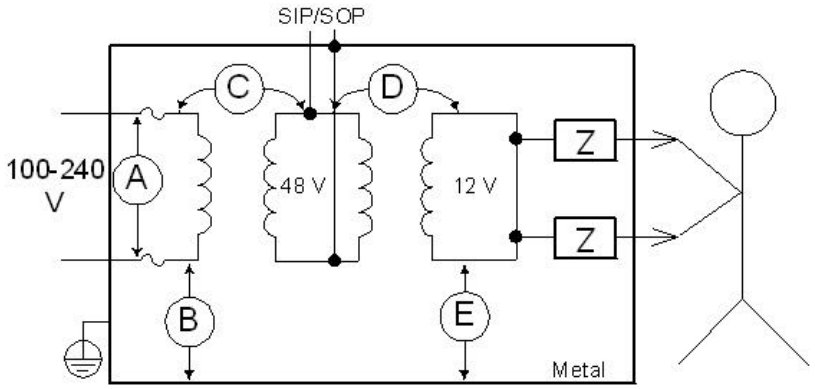
- **Class I Equipment, Metal Enclosure, SIP/SOPs**



A = BOP (240 V)
B = BI (240 V)
C = DI/RI (288 V)
D = DI/RI (50 V), BI (240 V)
E = DI/RI (12 V)

Insulation Diagrams (Continued)

- **Class I Equipment, Metal Enclosure, SIP/SOPs**

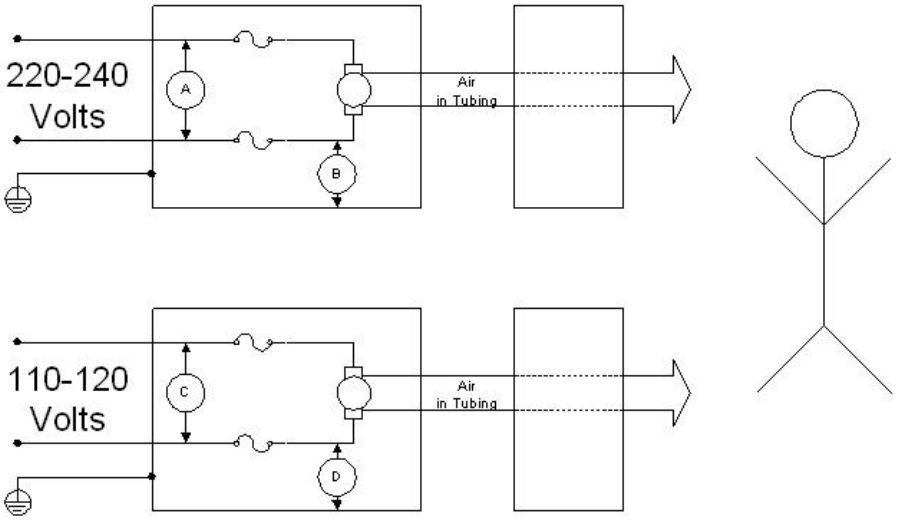


A = BOP (240 V)
B = BI (240 V)
C = DI/RI (288 V)
D = DI/RI (50 V), BI (240 V)
E = DI/RI (12 V)

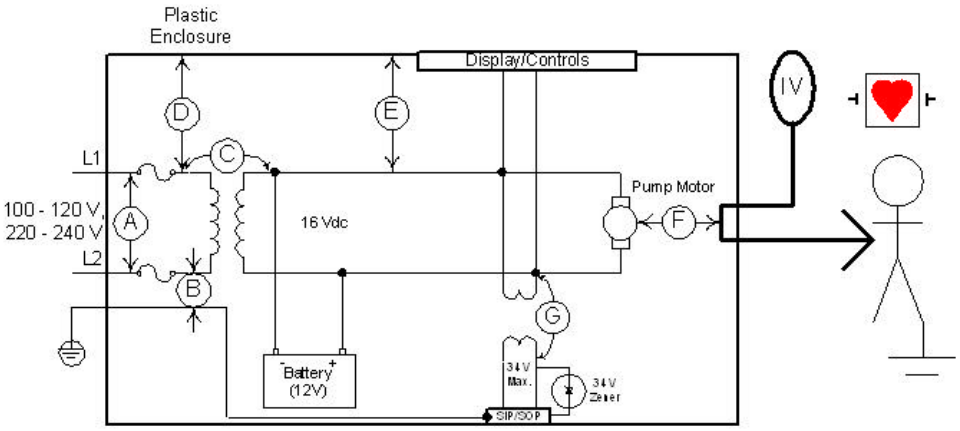
Z = Protective Impedance to limit auxiliary leakage current in Normal & Single Fault Cond.

The following are actual Insulation Diagrams created for products
- As you can see, they illustrate the required barriers for each device, as in the examples

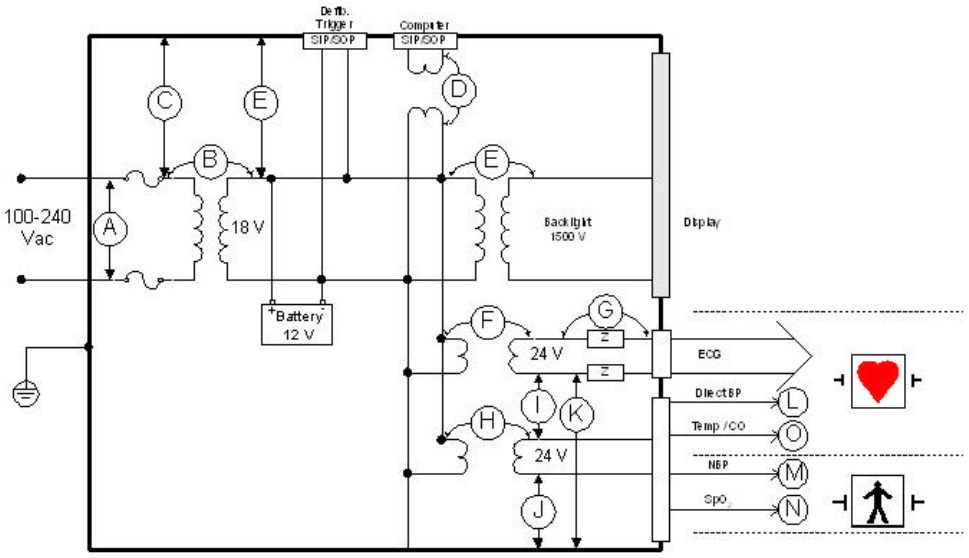
You will also notice that the format, tables, and information provided vary between them. This is simply because there is no formal format and every engineer has a little different way that he or she creates them. It simply needs to illustrate the required barriers and other electrical protection in the simplest way. The rest depends on the artistic capability of the engineer and the time they have to create it.



	Insulation Type	20.1/20.2 Designation	Max Voltage	Required Creepage mm	Required Clearance mm	Measured Creepage mm	Measured Clearance mm	Dielectric Strength
(A)	BOP	A-f	240 Vac	3.0 mm	1.6 mm	3.5 mm	3.5 mm	N/A
(B)	BI	A-a1	240 Vac	4.0 mm	2.5 mm	5 mm	4.5 mm	1.5 kV
(C)	BOP	A-f	120 Vac	2.0 mm	1.0 mm	3.5 mm	3.5 mm	N/A
(D)	BI	A-a1	120 Vac	3.0 mm	1.6 mm	5 mm	4.5 mm	1.0 kV



	Insulation Type	Max Voltage	Required Creepage mm	Required Clearance mm	Measured Creepage mm	Measured Clearance mm	Dielectric Strength
A	BOP	240	3.0	1.6	> 3.0	> 1.6	N/A
B	BI	240	4.0	2.5	> 4.0	> 2.5	1.5 kV
C	DI	240	8.0	5.0	> 8.0	> 5.0	4.0 kV
D	DI	240	8.0	5.0	> 8.0	> 5.0	4.0 kV
E	OP	16	N/A	N/A	-	-	N/A
F	DI / BI	16 / 240	4.0	2.5	> 4.0	> 2.5	1.5 kV
G	DI / BI	34 / 240	4.0	2.5	4.0	2.5	1.5 kV



	Insulation Type	Max Voltage	Required Creepage mm	Required Clearance mm	Measured Creepage mm	Measured Clearance mm	Dielectric Strength
A	BOP	240 Vac	3.0 mm	1.6 mm	4.0 mm	4.0 mm	N/A
B	DI	240 Vac	8.0 mm	5.0 mm	8.0 mm	8.0 mm	4.0 kV
C	BI	240 Vac	4.0 mm	2.5 mm	4.0 mm	4.0 mm	1.5 kV
D	BI	240 Vac	4.0 mm	2.5 mm	> 4.0 mm	> 4.0 mm	1.5 kV
E	OP	N/A	N/A	N/A	N/A	N/A	N/A
F	DI/BI/SI	24/240/60	4.0 mm	2.5 mm	8.0 mm	8.0 mm	2.0 kV
G	BI	24 Vdc	2.0 mm	1.0 mm	>10 mm	>10 mm	Protective Impedance
H	DI/BI/SI	24/240/60	4.0 mm	2.5 mm	8.0 mm	8.0 mm	2.0 kV
I	DI/BI	24/240	4.0 mm	2.5 mm	4.0 mm	4.0 mm	1.5 kV
J	DI/BI	24/240	4.0 mm	2.5 mm	9.0 mm	9.0 mm	1.5 kV
K	DI/BI	24/240	4.0 mm	2.5 mm	>10 mm	>10 mm	1.5 kV
L	BI	24 Vdc	2.0 mm	1.0 mm	Through Insulation		500 V
M	BI	24 Vdc	2.0 mm	1.0 mm	No Electronics in Patient Vacinity		N/A
N	BI	24 Vdc	2.0 mm	1.0 mm	Through Insulation		500 V
O	BI	24 Vdc	2.0 mm	1.0 mm	Through Insulation		500 V

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TABLE VALUES AND TEST LIMITS FOR IEC 60601-1, UL 2601-1, EN 60601-1, & CSA C22.2 No. 601.1

All Amendment changes and US Deviations have been integrated in these tables.

TABLE IV

LEAKAGE AND PATIENT AUXILIARY CURRENT LIMITS (in mA)

Type of Leakage / Auxiliary Current	Type B		Type BF		Type CF	
	N.C.	S.F.C.	N.C.	S.F.C.	N.C.	S.F.C.
EARTH* - Class I Equipment	0.5, 0.3*	1.0	0.5, 0.3*	1.0	0.5, 0.3*	1.0
EARTH* - All likely accessible surfaces non-conductive	0.5*	1.0	0.5*	1.0	0.5*	1.0
EARTH* - Class II Equipment (functional earth)	0.15*	1.0	0.15*	1.0	0.15*	1.0
EARTH* - All likely accessible surfaces non-conductive	0.25*	1.0	0.25*	1.0	0.25*	1.0
EARTH (Permanently Installed Equip.)	5.0	10.0	5.0	10.0	5.0	10.0
EARTH (No PE accessible, Mobile X-ray equipment)	2.5	5.0	2.5	5.0	2.5	5.0
ENCLOSURE*	0.1	0.5, 0.3*	0.1	0.5, 0.3*	0.1	0.5, 0.3*
PATIENT (ac)	0.1	0.5	0.1	0.5	0.01	0.05
PATIENT (dc)	0.01	0.05	0.01	0.05	0.01	0.05
PATIENT (Mains on SIP/SOP)	---	5.0	---	---	---	---
PATIENT (Mains on Applied Part, SIP/SOPs grounded)	---	---	---	5.0	---	0.05
PATIENT AUXILIARY CURRENT (ac)	0.1	0.5	0.1	0.5	0.1	0.5
PATIENT AUXILIARY CURRENT (dc)	0.01	0.05	0.01	0.05	0.01	0.05

*US Deviation N.C. limits: the highest voltage ratings (120 & 240 V) may be used instead of the 90 – 110% of voltage rating

TABLE V

DIELECTRIC WITHSTAND TEST VOLTAGES (in Volts)

Reference Voltage	0 < V ≤ 50	50 < V ≤ 150	150 < V ≤ 250	250 < V ≤ 1K	1K < V ≤ 10K
BI	500	1K	1.5K	2V + 1K	V + 2K
SI	500	2K	2.5K	2V + 2K	V + 3K
DI / RI	500	3K	4K	2(2V + 1.5K)	2(V + 2.5K)

TABLE XVI

CREEPAGE & CLEARANCE REQUIREMENTS (in millimeters)

Voltage	DC	≤15	≤30	≤75	≤150	≤300	≤450	≤600	≤800	≤900	≤1200
Voltage	AC	≤12	≤30	≤60	≤125	≤250	≤400	≤500	≤660	≤750	≤1000
BOP	Creepage	0.8	1.0	1.3	2.0	3.0	4.0	5.5	7.0	8.0	11.0
	Clearance	0.4	0.5	0.7	1.0	1.6	2.4	3.0	4.2	4.5	6.0
BI / SI	Creepage	1.7	2.0	2.3	3.0	4.0	6.0	8.0	10.5	12.0	16.0
	Clearance	0.8	1.0	1.2	1.6	2.5	3.5	4.5	6.0	5.9	9.0
DI / RI	Creepage	3.4	4.0	4.6	6.0	8.0	12.0	16.0	21.0	24.0	32.0
	Clearance	1.6	2.0	2.4	3.2	5.0	7.0	9.0	12.0	13.0	18.0

TABLE Xa

MAXIMUM ALLOWABLE TEMPERATURES (From 10°C to 40°C Ambient)

Parts	°C	Parts	°C
Windings – Class A	105	Operator accessible, continuously held surfaces (metal)	55
Windings – Class B	130	Operator accessible, continuously held surfaces (porcelain/vitreous)	65
Windings – Class E	120	Operator accessible, continuously held surfaces (rubber/wood)	75
Windings – Class F	155	Operator accessible, surfaces held for short time (metal)	60
Windings – Class H	180	Operator accessible, surfaces held for short time (porcelain/vitreous)	70
Adjacent to Switches & Thermostats with T marking	T	Operator accessible, surfaces held for short time (rubber/wood)	85
Rubber/PVC insulation of wiring/cords with T marking	T	Other op. accessible parts (except lamps, heaters/guards, handles)	85
Motor Caps with maximum operating temperature marked (2tc)	Tc-	Parts that may have brief contact with the Patient in normal use	50
Parts in contact with oil having flash-point (fp)	fp-25	**Applied parts not intended to supply heat to a Patient	41

** From Subclause 42.3

TABLE Xb

MAXIMUM ALLOWABLE TEMPERATURES (At 25°C Ambient)

Parts	°C	Parts	°C
Appliance Inlets (hot conditions)	155	Moldings of urea- formaldehyde	90
Appliance Inlets (other conditions)	65	Polyester with glass-fiber reinforcement	135
All terminals for external conductors	85	Polytetrafluorethylene	290
Adjacent to Switches & Thermostats without T marking	55	Pure mica and tightly sintered ceramics used as RI or SI	425
Flexible cords (if flexing is likely to occur)	60	Used as thermal insulation and in contact with hot metal	-
Flexible cords (if flexing is unlikely to occur)	75	-Laminates bonded with Melamine/phenol formaldehyde resins	200
Natural rubber, used for safety (when used as RI or SI)	60	-Laminates bonded with phenol furfural resins	200
Natural rubber, used for safety (in other cases)	75	-Laminates bonded with urea formaldehyde resins	175
Cord sheaths used as SI	60	-Moldings of phenol formaldehyde with cellulose fillers	200
Impregnated or varnished textile/paper/press board, no wires	95	-Moldings of phenol formaldehyde with mineral fillers	225
Laminated bonded with melamine/phenol formaldehyde resins	110	-Moldings of melamine- formaldehyde	175
Laminated bonded with phenol furfural resins	110	-Moldings of urea- formaldehyde	175
Laminated bonded with urea- formaldehyde resins	90	Wood in general	90
Moldings of phenol formaldehyde with cellulose fillers	110	Electrolytic Capacitors, without tc marking	65
Moldings of phenol formaldehyde with mineral fillers	125	Other Capacitors, without tc marking	90
Moldings of melamine- formaldehyde	100	Supports, Walls, Ceiling, Floor of test corner	90

TABLE XIX

Transformers Under Short Circuit and Overload at 25°C

Winding Class	Max. Temp. °C
A	150
E	165
B	175

TABLE XX

Test Current/Time for Transformer Overload

Rating of Protector (A)	Mult. Factor	Test Duration
IEC 127/241 ≤ 4 A	2.1	IEC 127: 30 min. / IEC 241: 60 min.
IEC 127/241 > 4 – 10 A	1.9	IEC 127: 30 min. / IEC 241: 60 min.
IEC 127/241 > 10 – 25 A	1.75	IEC 127: 30 min. / IEC 241: 60 min.

F	190		IEC 127/241 > 25A	1.6	IEC 127: 30 min./IEC 241: 60 min.
H	210		UL Listed Fuse	1.35	60 min.
			All Others	Max from Fuse Curve	30 min.

MOTOR TEMP TABLE

Motors Under Locked Rotor Test at 25°C					
Winding Class	Max. Temp. °C				
	Attended, timer, 5 min max use	Impedance Protected	Protection acts < 1 hr.	Protection acts > 1 hr.	Ave. after 1st hr.
A	200	150	200	175	150
E	215	165	215	190	165
B	225	175	225	200	175
F	240	190	240	215	190
H	260	210	260	235	210

MINIMUM GAPS TO AVOID CRUSH/PINCH POINTS

Requirements for Medical Electrical Equipment (Covered by IEC 60601-1)
From EN 394: Safety of machinery - Minimum gaps to avoid crushing of parts of the human body (1993)

Crushing Zone
Zone in which the human body or parts of the human body are exposed to a crushing/pinching hazard.
This hazard will be generated if:
- two movable parts are moving towards one another;
- one movable part is moving towards a fixed Part

Methodology
a) Identify the crushing hazards.
b) Assess the risks from these hazards
c) From table, select the appropriate minimum gap relating to the body part at risk
d) If adequate safety cannot be achieved by the minimum gaps selected from the table, other or additional measures and/or means shall be used

Note: A crushing zone is considered only for powered movements or where weight or momentum may generate sufficient force to generate a crushing/pinching hazard.

The possibility of access to a crushing zone for a particular part of the body is dependent on the following:
- The gap between the parts;
- The depth of the crushing zone;
- The dimensions c of the opening in the protective structure and its distance d from the crushing zone.

Dimensions in millimetres

Part of body	Minimum gap a	Illustration
Body	500	
Head (least favourable position)	300	
Leg	180	
Foot	120	
Toes	50	
Arm	120	

		
Hand Wrist Fist	100	
Finger	25	

HELPFUL CONVERSIONS

1 cm = 0.394 in. (1 m = 39.4 in)
1 in. = 2.54 cm (1 ft. = 30.48 cm)

10 degree tilt: (Distance One Side Lifted) = (Width of Base)(0.173648)

F = (C x 1.8) + 32
C = (F / 1.8) - 32

1 N = 0.225 lbf
1 kg = 2.2 lb (1 g = 0.0022 lb)

1 m/sec = 2.237 mph

1 Nm = 141.6 in.oz = 0.7376 ft.lbs = 8.851 in.lbs

1 l = 33.8 oz (200 ml = 6.76 oz)
1 l = 61 in2

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