



Medical Devices Isolation-“How safe is safe enough”

WHITE PAPER

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Abstract

The design of medical electronic equipment and the integration of power supplies into medical equipment have long posed unique challenges to engineers and system designers. Medical equipments used to diagnose, treat, or monitor is designed to come into direct contact with the patient hence the medical Devices Isolation plays a vital role in this industry.

The IEC 60601-1 - General Requirements for Safety is the regulatory standard addressing many of the risks associated with electrical medical equipment. Ensuring that a device complies with IEC 60601 can be a complex task and the design methodologies to achieve the required isolation make the equipment safe. The goal of two of the most widely recognized standards for medical electronic devices, Underwriters Laboratories (UL) and International Electro technical Commission (IEC) is to ensure that all medical electronic products provide a high level of safety for the operator and the patient.

The standard has both mechanical and electrical requirements intended to reduce the electrical hazards both under normal and single fault conditions. Unlike other standards, electrical safety is not considered to be dependent on voltage, but on leakage currents. This is because even a very low voltage, when applied to internal tissue/organs, can cause leakage currents through the body which may be fatal. IEC 60601-1 gives the requirements for leakage currents.

An overall consideration in designing for safety is the principle of single fault conditions. A medical electrical product must be designed so that it operates safely not only in normal conditions, but also in abnormal and single fault conditions.

There are many ways to achieve the basic insulation or isolation in medical devices and every isolation scheme 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.

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1. INTRODUCTION

The use of electricity for medical diagnostic, measurement, and therapy equipment potentially exposes patients and even care givers to the risk of electrical shock, burns, internal-organ damage, and cardiac arrhythmias directly due to leakage current resulting from improper grounding and electrical isolation. The electrical conductivity of body fluids and the presence of various conductive solutions and gels in the patient care system make this environment even more vulnerable.

Several techniques commonly provide isolation when designing electronic equipment. Careful component placement and printed-circuit-board layout can provide adequate room for creepage and clearance of components in close proximity of high voltages. The clearance distance is the shortest path through the air between two conductors that must be isolated. The creepage distance is the shortest distance between two conductors, measured along the insulation surface. Meeting these two specifications can be a tedious, time-consuming task, and each component subject to them must meet the requirements called out in the applicable standards.

2. Medical Equipment Class.

The primary and obvious difference between Information Technology Equipment (ITE) and medical equipment is that medical equipment is intended to diagnose, treat, or monitor a patient. Therefore, medical equipment normally comes in intentional contact with the patient; equipment surfaces within the patient vicinity can be contacted by the patient, or contacted by an operator who is also contacting the patient. As patients can be unconscious, connected to multiple equipments, or have incisions on skin regions, the risk of electric shock can be great. Again, power supplies play an important role in protecting against an electric shock hazard in such settings.

3. Medical Equipment Regulation

Most major world markets regulate medical equipment. In the United States, the Federal Food, Drug, and Cosmetic Act (and succeeding acts) requires that all medical devices be "safe and effective," and FDA recognizes consensus standards as a means to support a declaration of conformity (new 510(k) paradigm, "abbreviated 510(k)"). FDA lists IEC 60601 + national deviations (UL 2601-1) as a recognized consensus standard.

In Europe, the Medical Devices Directive (93/42/EEC, Article 3) requires medical devices to meet the "essential requirements." Compliance is presumed by conformity to the harmonized standards in the *Official Journal of the EC* (93/42/EEC, Article 5). IEC 60601 + regional deviations (EN 60601) is a harmonized standard. Similarly, IEC 60601 forms the basis for national medical equipment safety standards in many countries, including Japan, Canada, Brazil, Australia, and South Korea.

IEC 60601 is a series of standards. The basic standard containing the core safety requirements for all electrical medical equipment is *Medical Electrical Equipment—Part 1 General Requirements for Safety*, IEC 60601-1, 2nd edition, (1988-12) + Amendment 1 (1991-11) + Amendment 2 (1995-03). There are collateral (horizontal) standards, which supplement the core requirements by providing technology-related safety requirements. The naming convention for collateral standards is IEC 60601-1-xx. Technologies addressed by collateral standards include medical systems, EMC, x-ray radiation, and programmable systems. There are also particular (vertical) standards, which supplement the core requirements by providing device-specific safety and performance requirements. The naming convention for particular safety standards is IEC 60601-2-xx. Specific devices addressed by particular standards include RF surgical devices, ECG monitors, infusion pumps, and hospital beds. There are approximately 40 Part 2 standards.

IEC (International Electro technical Commission) 60601-1 defines medical-equipment electrical-safety conditions necessary to protect patients, operators, and the surroundings.

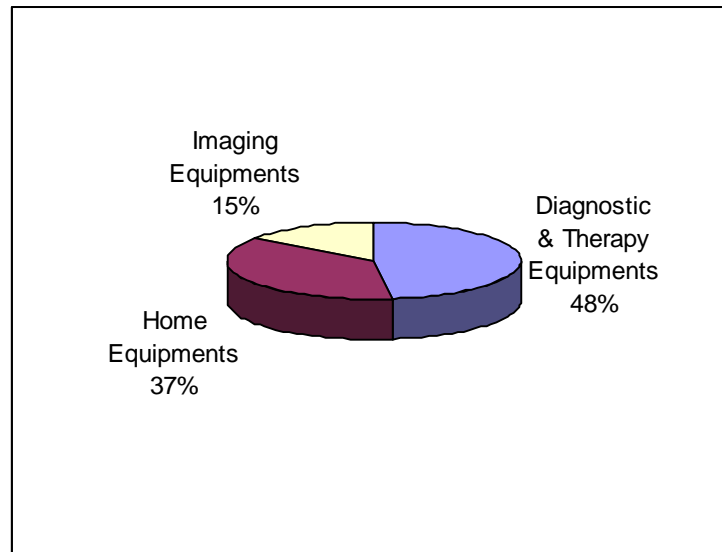
Safety regulations for medical devices mandate isolated power supplies and I/O lines. The goal of these regulations is simple, do not

electrocute the patient. You can use a variety of techniques including transformers, opto isolators and advanced isolation ICs.

4. Common Safety Philosophy

When designing a product to provide reasonable protection against injury and property damage, how safe is safe enough? This is the question that safety standards address. IEC standards are consensus documents, which define the minimum design requirements. As technology advances, device usage evolves, and other factors change, a standard can become out of date and its requirements no longer appropriate. Thus, the use of standards does not preclude the need to conduct a risk analysis on products.

The medical industry divides the medical electronics into three major categories viz diagnostics and therapy equipments, home equipments (Medical, such as a nebulizer or a Blood Pressure Monitor), and imaging equipment. Roughly the diagnostics-and-therapy segment contributes 48% of revenue, with the home segment contributing 37% and imaging contributing 15%.



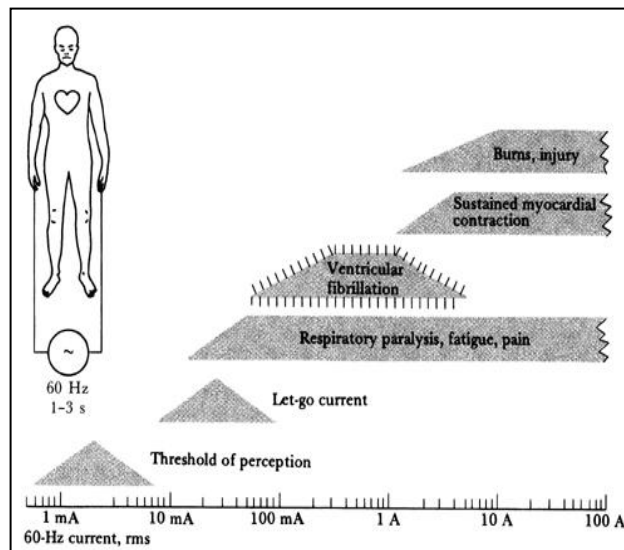
Medical Equipment Category (Approximated)

4.1 What type of Applied Parts does the end equipment have?

1. Type B - No electrical contact with the Patient and may be earthed.
2. Type BF - Electrically connected to the Patient but not directly to the heart.
3. Type CF - Electrically connected to the heart of the Patient.
4. Type F = Floating with respect to earth i.e. basic insulation to earth at mains voltage.

4.2 Physiological Effects of Electricity

The below picture illustrates the physiological effects of electricity on human beings. Here the current is applied via copper wires grasped by the hands, so there is a large benefit of skin resistance. The average adult exhibits a resistance between 100,000 ohms (Ω) and 1,000,000 Ω , measured hand to hand. The resistance depends on the body mass and moisture content. The effects are many times more when the electrical signal passes through the body fluids/ heart etc.



Threshold or estimated mean values are given for each effect in a 70 kg human for a 1 to 3 s exposure to 60 Hz current applied via copper wires grasped by the hands. Courtesy: J. G. Webster (ed.), Medical instrumentation: application and design. 3rd Ed. New York: John Wiley & Sons, 1998.

The threshold of perception for an average adult is approximately 1 mill ampere (mA). This amount of current will produce a slight tingling feeling through the fingertips. Between 10 and 20 mA, the person experiences muscle contractions and finds it more difficult to release his or her hand from an electrode. An externally applied current of 50 mA causes pain, possibly fainting, and exhaustion. An increase to 100 mA will cause ventricular fibrillation.

Electrical Current can have following effects on the human body

- **Electrolysis**

The movement of ions of opposite polarities in opposite directions through a medium is called electrolysis and can be made to occur by passing DC currents through body tissues or fluids. If a DC current is passed through body tissues for a period of minutes, *ulceration* begins to occur. Such ulcers, while not normally fatal, can be painful and take long periods to heal.

- **Burns**

When an electric current passes through any substance having electrical resistance, heat is produced. The amount of heat depends on the power-dissipated (I^2R). Whether or not the heat produces a burn depends on the current density. Human tissue is capable of carrying electric currents quite successfully. Skin normally has a fairly high electrical resistance while the moist tissue underneath the skin has a much lower resistance. Electrical burns often produce their most marked effects near to the skin, although it is fairly easy for internal electrical burns to be produced which if not fatal can cause long lasting injury.

- **Muscle cramps**

When an electrical stimulus is applied to a motor nerve or muscle, the muscle does exactly what it is designed to do in the presence of such a stimulus i.e. it contracts. The prolonged involuntary contraction of muscles (tetanus) caused by external electrical stimulus is responsible for the phenomenon where a person who is holding an electrically live object can be unable to let go.

- **Respiratory arrest**

The intercostal muscles* need to repeatedly contract and relax in order to facilitate breathing. Prolonged tetanus of these muscles can therefore prevent breathing.

- **Cardiac arrest**

The heart is a muscular organ which needs to be able to contract and relax repetitively in order to perform its function as a pump for the blood. Tetanus of the heart musculature will prevent the pumping process.

- **Ventricular fibrillation**

The ventricles of the heart are the chambers responsible for pumping blood out of the heart. When the heart is in ventricular fibrillation, the musculature of the ventricles undergoes irregular, uncoordinated twitching resulting in no net blood flow. The condition proves fatal if not corrected in a very short space of time. Ventricular fibrillation can be triggered by very

small electrical stimuli. A current as low as 70mA flowing from hand to hand across the chest or 20microamps directly through the heart may be enough. It is for this reason that most deaths from electric shock are attributable to the occurrence of ventricular fibrillation.

***Intercostal muscles** are groups of muscles that run between the ribs, and help form and move the chest wall.

5. Classification of electro medical equipment

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 product:** A product that is provided with a reliable protective earth such that all accessible metal parts can't become live in the event of a failure of Basic Insulation and therefore will provide protection against electric shock in the case of the failure of Basic Insulation.

Class 1 equipment has a protective earth. The basic means of protection is the insulation between live parts and exposed conductive parts such as the metal enclosure. In the event of a fault which would otherwise cause an exposed conductive part to become live, the supplementary protection (i.e. protective earth) comes into effect. A large fault current flows from the mains part to earth via the protective earth conductor which causes a protective device (usually a fuse) in the mains circuit to disconnect the equipment from the supply. The effective resistance of the ground conductor should be less than 0.1 ohm.

Confusion can arise due to the use of plastic laminates for finishing equipment. A case that appears to be plastic does not necessarily indicate that the equipment is not class I.

- **Class II product:** A product without a protective earth and where Double or Reinforced Insulation (typically a plastic enclosure) is relied upon to provide the protection against electric shock.

Products that have a two-prong power cord are Class II products. Class II products rely not only on basic insulation but also supplemental insulation or reinforced insulation. These products are often referred to as double insulated products as protection against shock relies on two layers of insulation.

The method of protection against electric shock in the case of class II equipment is either double insulation or reinforced insulation. In double insulated equipment the basic protection is afforded by the first layer of insulation. If basic protection fails then supplementary protection is afforded

by a second layer of insulation preventing contact with live parts. Class II medical electrical equipment should be fused at the equipment end of the supply lead in either mains conductor or in both conductors if the equipment has a functional earth.

- **Class III product:** A product with internally powered source, such as a battery.

Class III equipment is defined as that in which protection against electric shock relies on the fact that no voltages higher than safety extra low voltage (SELV) are present. SELV is defined in turn in the relevant standard as a voltage not exceeding 25V ac or 60V dc.

- In practice such equipment is either battery operated or supplied by a SELV transformer.
- If battery operated equipment is capable of being operated when connected to the mains (for example, for battery charging) then it must be safety tested as either class I or class II equipment. Similarly, equipment powered from a SELV transformer should be tested in conjunction with the transformer as class I or class II equipment as appropriate.
- The standard relating to medical electrical equipment does not recognize class III equipment since limitation of voltage is not sufficient to ensure safety of the patient, but use: Internally Powered Equipment

6. What Is Isolation?

Isolation physically and electrically separates two parts of a circuit, the two parts can interact. The isolation is achieved by using electromagnetic field coupling between the two circuits. The three most commonly used methods are optocouplers (light), transformers (magnetic flux), and capacitive couplers (electric field). Isolation provides several advantages

- It breaks ground loops.
- It improves common-mode voltage rejection.
- It permits the two parts of the circuit to be at different voltage levels, which means one can be safe while the other sides at hazardous voltage levels. For isolation to be safe, it needs to have two things -- high-integrity isolation components (optocouplers, transformers, capacitive couplers) and a safe insulator barrier. For example, this insulator can be a piece of plastic, a keep-out space in a PWB, or an air gap.

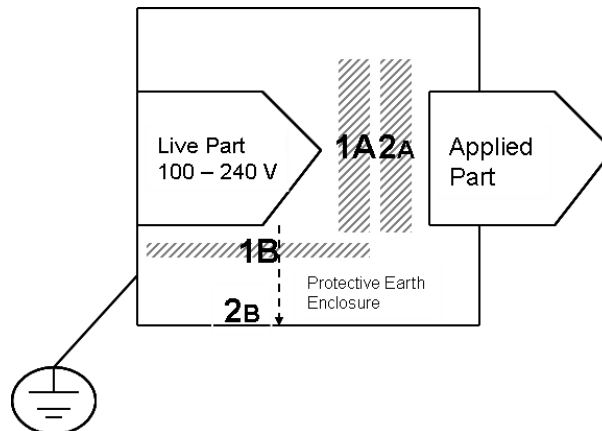
6.1 IEC60601-1

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:

- 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.

- f. **Supplemental Insulation (SI)** - is also spacing or a physical insulation barrier providing 1 LOP.
- g. **Double Insulation (DI)** - is BI + SI and provides 2 LOP. Note that BI + BI does not result in DI
- h. **Reinforced Insulation (RI)** - is a single spacing or physical insulation barrier that provides 2 LOP.
- i. **Protective Impedance** - is a component (such as a resistor) that provides 1 LOP.
- j. **Protective Earth (PE)** - is a well-grounded part that provides 1 LOP.
- k. **Class I Equipment** - uses PE as 1 LOP.
- l. **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. Figure below 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.



Two Levels of Protection 2 LOP

6.2 Insulation Spacing and Dielectric Requirements

Table below 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 mm						
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 Voltages - in Volt						
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
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Insulation Spacing and Dielectric Requirements

6.3 Fault Conditions

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.

6.3.1 Likely to Occur (Normal Condition)

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

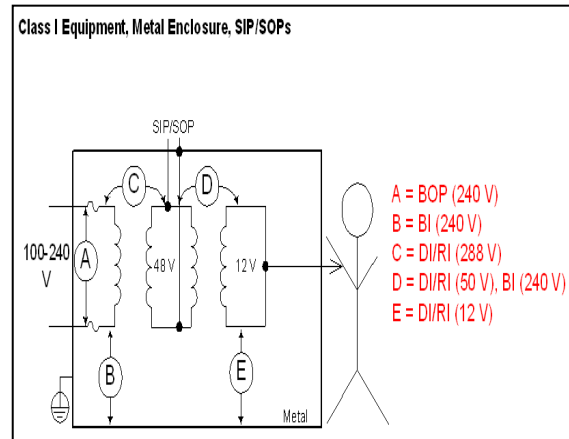
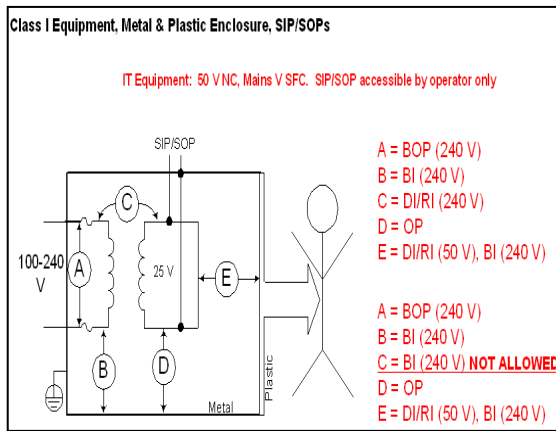
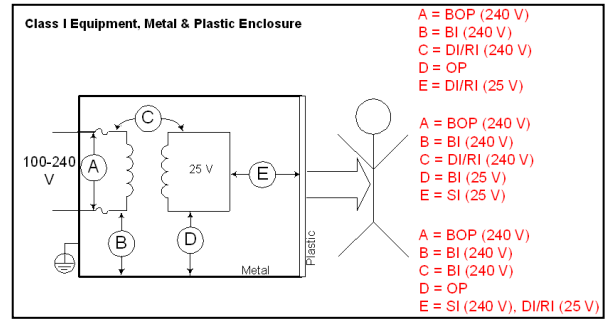
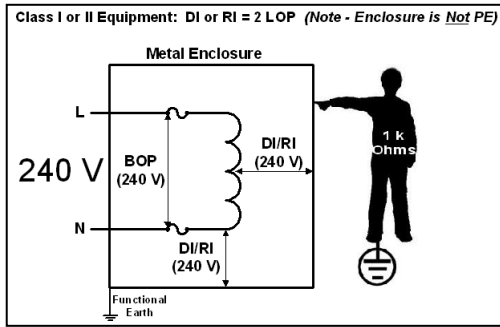
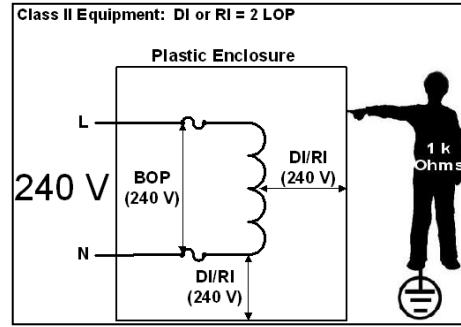
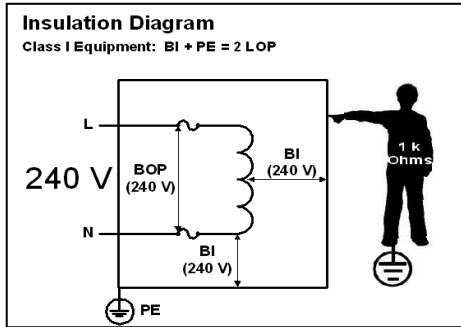
6.3.2 Could Occur (Single Fault Condition)

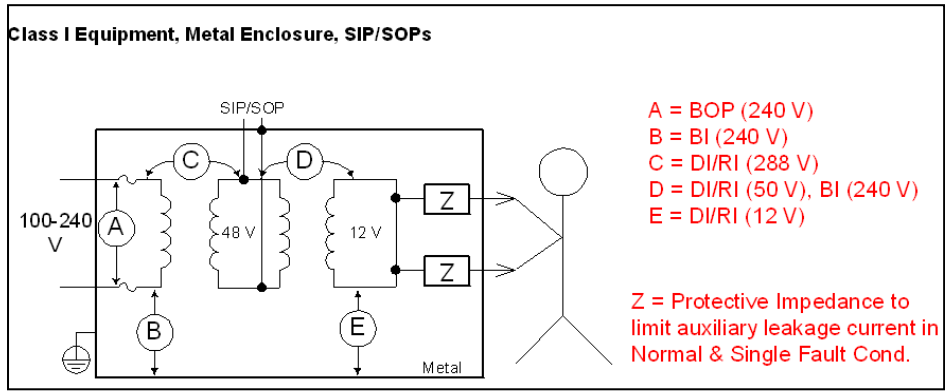
- Interruption of protective earth
- Interruption of one supply conductor
- Mains voltage on floating (F-type) applied part(s)
- Mains voltage on communication ports
- Failure of electrical components, one at a time
- Failure of mechanical parts, one at a time
- Failure of temperature limiting devices, 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)

6.3.3 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

6.4 Two Levels of Protection (2 LOP) Illustration





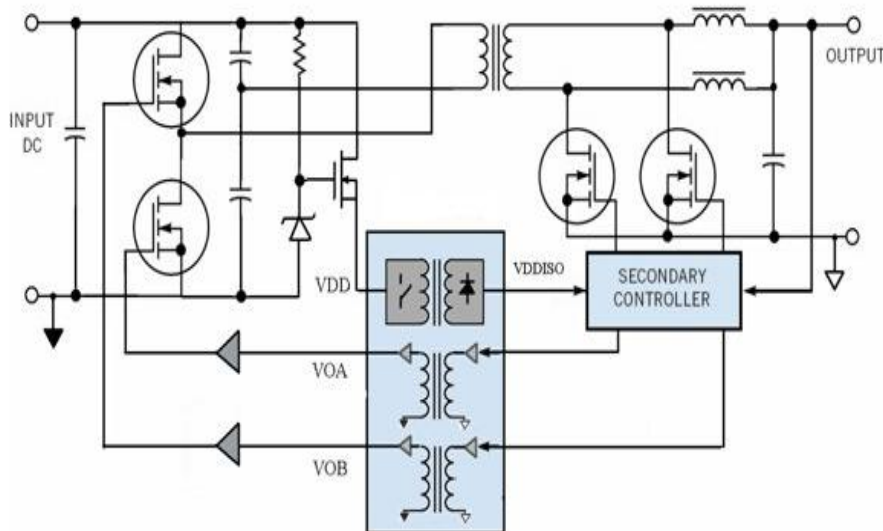
(Courtesy: Medical Equipment Compliance Associates, USA)

It is obvious from the above schematics that the isolation schemes 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.

	Insulation Type	Max Voltage	Required Creepage- mm	Required Clearance mm	Dielectric Strength
A	BOP	240 Vac	3.0 mm	1.6 mm	N/A
B	DI	240 Vac	8.0 mm	5.0 mm	4.0 KV
C	BI	240 Vac	4.0 mm	2.5 mm	1.5 KV
D	BI	240 Vac	4.0 mm	2.5 mm	1.5 KV
E	OP	NA	N/A	N/A	N/A
F	DI/BI/SI	24/240/60	4.0 mm	2.5 mm	2.0 KV
G	BI	24 Vdc	2.0 mm	1.0 mm	Protective Impedance
H	DI/BI/SI	24/240/60	4.0 mm	2.5 mm	2.0 KV
I	DI/BI	24/240	4.0 mm	2.5 mm	1.5 KV
J	DI/BI	24/240	4.0 mm	2.5 mm	1.5 KV
K	DI/BI	24/240	4.0 mm	2.5 mm	1.5 KV
L	BI	24 Vdc	2.0 mm	1.0 mm	500V
M	BI	24 Vdc	2.0 mm	1.0 mm	N/A
N	BI	24 Vdc	2.0 mm	1.0 mm	500 V
O	BI	24 Vdc	2.0 mm	1.0 mm	500 V

7.2 Isolation devices - Examples

7.2.1 DC – DC Power Isolation (Courtesy Analog Devices)

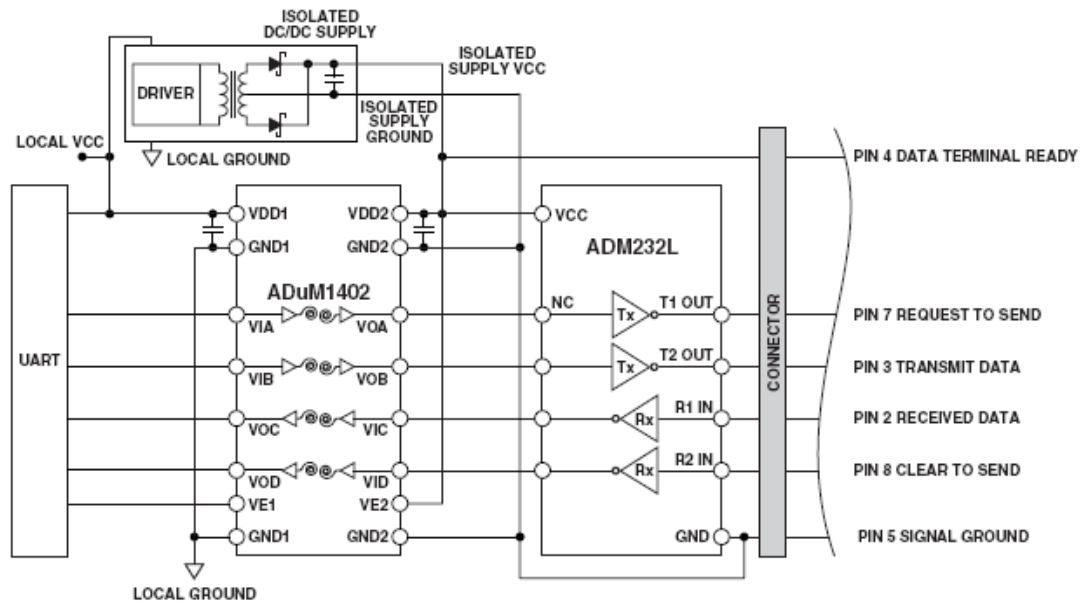


The above Device (ADuM5242) is an integrated isolated dc-to-dc converter used for low power applications. The isolation levels provided by

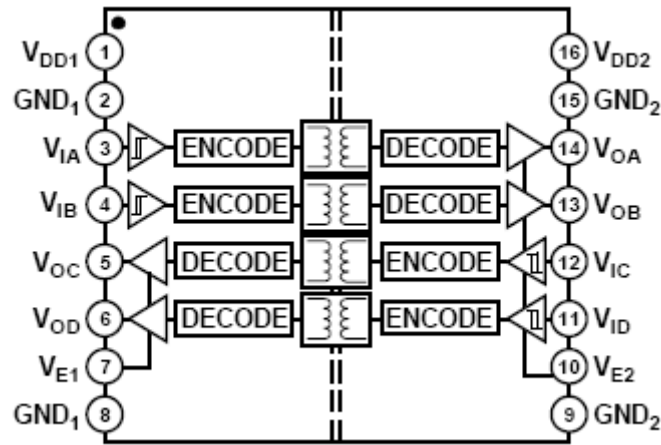
this device is 2500 Vrms. The dc-to-dc converter section of the ADuM5242 works on principles that are common to most modern power supply designs. Input power is supplied to an oscillating circuit that switches current into a chip-scale air core transformer. Power is transferred to the secondary side where it is rectified to a high dc voltage. The power is then linearly regulated down to about 5.2 V and supplied to the secondary side data external use.

The micro-transformers used in *ADuM5242* are built on top of a CMOS substrate. The transformer series resistance is minimized through the use of 6µm thick plated Au for both the primary and the secondary spirals. The 20µm thick polyimide in between the primary and the secondary provides HV isolation up to 5KV.

7.2.2 RS – 232 Isolation Example (Analog Devices)



RS - 232 Isolation Scheme



ADuM 1402

The ADuM1402 are digital isolators combining high speed CMOS and monolithic air core transformer technology, these isolation components provide outstanding performance levels of 2500 Vrms insulation. By avoiding the use of LEDs and photodiodes, these devices remove the design difficulties commonly associated with opto-couplers. The typical optocoupler concerns regarding uncertain current transfer ratios, nonlinear transfer functions, and temperature and lifetime effects are eliminated with these digital isolators.

Here simple digital isolators do not support the RS-232 signal standard; it is not possible to insert a digital isolator between the RS-232 transceivers and the RS-232 cable. Theoretically, transformers could be used to supply isolation at that location. However, the very slow speeds of the bus would require large transformers, making this solution impractical. RS-232 signal path isolation is accomplished by designing isolators into the digital signal path between the RS-232 transceiver and the local system. The system side RS-232 transceivers utilize digital logic level signals of 0 V to 5 V or 0 V to 3 V, and typically connect to a universal asynchronous receiver/transmitter (UART) or processor. Placing a ADuM1402 coupler in this location electrically isolates the RS-232 cable bus signals from each system connected to it. To complete the isolation of the RS-232 circuits from the local system, a dc to dc isolated power converter is required. The isolated power supply is used to supply power to the local RS-232 transceiver and RS-232 side of the isolator. The isolated power supply is typically supplied from the local system.

8. Conclusion

An attempt is been made to explain the Isolation requirements of medical equipments in this document. User discretion is highly recommended while referring this document since the standards are updated regularly and also there are deviations for different countries.

More and more medical complex equipment is being used in the hospital and in more critical applications. Designing of safe medical equipment is critical to provide a safe environment for the patient, reliable and accurate results for diagnostic tests and to meet regulatory requirements.

References

1. IEC 60601-1, “General Requirements for Basic Safety and Essential Performance,”
International Electro technical Commission, www.iec.ch.
2. IEC 60601-1-2, “International Standard for Medical Equipment,”
International Electro technical Commission, www.iec.ch.
3. Analog Devices Design Examples, www.analog.com

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