Methods of Protection , MOOPs and MOPS

Abstract: There are many documents which summarize and detail the differences between EN60601-1:1990 and EN60601-1:2005. This document will focus on only one aspect of these, and that is namely means of protection (MOPs) which are outlined in the scope of IEC 60601-1:2005.

Background:

In the past "A" stood for live parts and "B" the applied parts. Isolation diagram had labels like A-a1, A-e and B-d. This corresponded to a series of specific dielectric strength values and spacing distances between parts of the product.

With the introduction of the EN60601-1:2005, the terminology now moved this to a means of protection (MOP). This protection includes insulation, clearance, creepage distances, impedances and protective earth connections.

The two classifications are

1. MOOP (means of operator protection), and reduces the risk of electric shock to persons other than the patient.
2. MOPP (means of patient protection). MOPP reduces the risk of electric shock to the patient.

The standard now calls for the design team to focus on the on the question "who is being protected?" and structures the requirements for this protection accordingly. We now must distinguish between parts, which can come in contact with the Operator, and parts that can come into contact with the Patient, as well as Applied Parts. Applied parts are those parts that come in contact with the patient in order for the medical equipment to perform their intended function. There are 3 types of applied parts.

1. Type B has a reference to ground,
2. Type BF is floating and
3. Type CF is for direct connection to the patient's heart (and is, of course, floating!).

Type CF provides the highest degree of protection against electric shock (i.e., lowest allowed leakage).

Safety Requirements:

The requirements for MOOP are derived from the standard IEC 60950-1. As such, the requirements for dielectric strength, clearance, creepage distances and protective earth connections of MOOPs are aligned with IEC 60950-1. MOPPs hold true to the medical specifications previously found in IEC 60601-1.

- A Power Supply which is approved in accordance to IEC60950-1 fulfills all insulation requirements for IEC60601-1 operator contact (MOOP is required).
- If patient contact is required the requirements of EN60601 for MOPP is requested.

The scope of IEC 60601-1:2005 3rd edition applies to basic safety and essential performance of medical electrical (ME) equipment and medical electrical systems. ME equipment has one connection to the mains supply and is used for the diagnosis, treatment and monitoring of the patient. This equipment has an applied part, which is in physical contact with the patient, or transfers or detects energy transfer to or from the patient. ME systems are those comprised of at least one piece of ME equipment.

Worked Example:

We can illustrate this by comparing hipot and creepage distance values for protection from a mains part.

At a working voltage of 240 VAC, one MOOP (basic / 1 layer of insulation) has a test voltage requirement of 1500 VAC and a creepage distance of 2.5 mm.

Two MOOP (double/2 layers of insulation) has a test voltage of 3000 VAC and 5.0 mm of creepage. For one MOPP, the voltage is the same but the distance is raised to 4.0 mm. For two MOPP, the voltage is increased to 4000

VAC and the creepage is even higher at 8.0 mm. Refer to table 1 for the measured distances on the Xgen series.

The standard allows for three defensive approaches that may be used in various combinations— safety insulation, protective earth, and protection impedance. It's therefore essential to determine several key factors from the outset of the equipment design process, including its insulation class and whether it will rely upon a protective earth connection. These considerations extend to the "applied part", if present, that is deliberately attached to the patient. Such applied parts are separately classified as to the level of electric shock protection that they provide.

Significantly for power supplies, the 3rd edition distinguishes between protecting the equipment's operator and the patient within its Means of Operator Protection (MOOP) and Means of Patient Protection (MOPP) categories. This distinction can result in quite different safety insulation and isolation requirements for circuits that operators and patients may come into contact with. Specifically, anything that falls within the remit of operator protection only has to meet the clearance and creepage requirements that IEC/EN 60950 specifies for general-purpose information and technology equipment. By contrast, circuitry that falls within the realm of patient protection must meet the far more exacting requirements that the 2nd edition of IEC 60601-1 introduced. As to who determines whether it is MOOP or MOPP is up to the manufacturer and they will need to record this in the risk management file.

Medical requirements with respect to MOOPs and MOPs.

The power supply should provide a robust and steadfast platform for any of your supply requirements in the medical field. We now focus on the creepage and clearance levels that have been achieved in this high power density design.

	Type	Required Creepage	Actual	Required Clearance	Actual
A	Basic	3 mm	3.5 mm	1.6 mm	2 mm
B	Basic	4 mm	4.1 mm	2.5 mm	3mm
C	Reinforced	12 mm	12	7 mm	7.4
D	Reinforced	8 mm	8.5 mm	5 mm	5.6 mm

Table 1: Creepage and Clearance distances on the Xgen series

• The Xgen compliance to EN 60601 3rd edition is based on EN60950 testing. This is shown in detail in table 1 above. In this respect, the Xgen in it existing format, provides a Method of Operator Protection.
• If a method of Patient Protection is required then this will need to be considered by the end user.

Summary & Conclusions:

MOOPs and MOPs will now be the common phrases used when describing creepage and clearance levels going forward. Since June 1st 2012, the 2nd edition 60601 has been withdrawn in Europe, and will be withdrawn in the US in June 20th 2013 (UL60601-1:2003 1st ed). It is important that system designers make themselves aware of these phrases and what they will mean to their safety requirements.