Methods of Protection, MOOPs and MOPPs

Abstract: There are a number of substantial changes in the 3rd Edition of IEC 60601-1 and this paper focuses on one of these changes, the introduction of the concept of MOOPs and MOPPs. In order to ease the design in of a suitable power supply, Advanced Energy offers Xgen and UltiMod products with 2 x MOPPs as standard. This paper will focus on one of the high visibility changes between the second and third edition of the IEC 60601-1, the introduction of MOOPs and MOPPs.

Introduction:

In the 2nd Edition of IEC 60601-1 there is no distinction between the safety requirements of the operator of the medical equipment and the patient. Why the difference ? The potential risks to the operator are very different to that of the patient. As an example the operator is less sensitive to shocks (being is generally good health) and is also trained in the correct use of the equipment. As a result, the level of protection provided to the patient must be considerably higher than that of the operator.

In order to address this issue, the 3rd Edition of 60601-1 has defined different requirements for protection of the operator - MOOP (Means of Operator Protection) which are less strict than the requirements for the protection of the patient - MOPP (Means of Patient Protection).

MOPP/MOOP requirements are therefore more general in their nature than the 2nd Edition and this can lead to some confusion. For example, the MOOP requirements for operator safety suggest that the use of cost-saving off-the-shelf components such as an IEC 60950 compliant power supply will be sufficient. While this may be possible, it must be very carefully analyzed to assure that there can never be any possible contact with the patient and may actually require expensive precautions to ensure that this contact never occurs. It can often be simpler and more economic to choose a power supply that meets the MOPP requirements patient safety.

Xgen and UltiMod now being offered with 2 MOPPs as standard:

From this point of view , most system designers are adopting a fail safe strategy to select a power supply that not only meets the MOP rating required by the application but actually exceeds it. Power supplies designed to support two MOPPs provide greater design flexibility with the assurance that they can minimize the risk of shock hazard and can demonstrate that fact as part of the risk-management process. For this reason the Xgen and UltiMod are now being offered with 2 MOPPs as standard.

MOOP and MOPP Safety Requirements:

In the 3rd Edition of IEC 60601-1 there are detailed and complex tables for determining test voltages and creepage and clearance distances. (These replace A-a l/k and B-a/e which are no longer used). These requirements are divided into MOPP (based on old requirements) and the more liberal MOOP (based on IEC 60950-1). While the new tables are far more complex than the old ones, they allow for a much fairer application of test voltages and spacings.

Means of Protection (MOP):

ME Equipment (medical electrical equipment) refers to electrical equipment that has a part (known as an applied part) that in normal use necessarily comes into physical contact with the patient in order to perform its function.

ME equipment should have two means of protection (MOP) in order to prevent applied parts or other operator / patient accessible parts from exceeding voltage, current or energy limits defined in part 8.4 of IEC 60601-1. This ensures that if one MOP fails, there is always another MOP to protect the patient or operator.

Each MOP is defined as a means of patient protection (MOPP) or a means of operator protection (MOOP). Any insulation, creepage distance, air clearances, components or earth connection not complying with Part 8.5.1.2. (MOPP requirements) or Part 8.5.1.3. (MOOP requirements) of IEC 60601-1 shall not be

considered a MOP. Failure of these non-MOP parts is considered during normal operation testing.

MOOPs MOPPs and the Xgen

Figure 1 below is the insulation diagram of the Xgen power supply, and depicts the means of protection utilised for the Xgen.

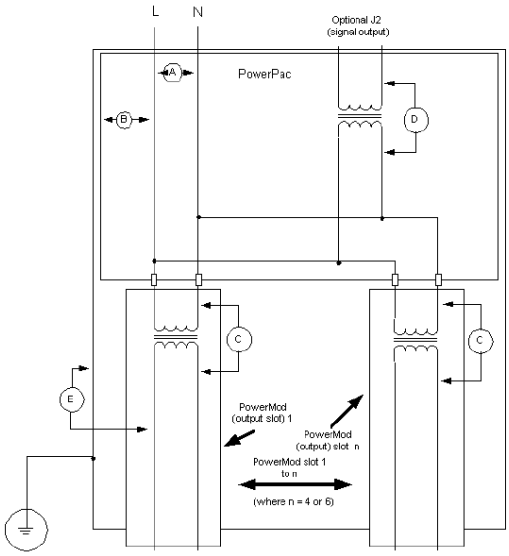

Figure 1 Xgen Insulation Diagram

The table in Appendix 1 below shows the insulation level of each MOP used by the Xgen and the creepage, clearance and test voltage required to attain that insulation level.

Paths to patient or operator contact:

There are three possible paths to patient or operator contact, either via the output, via the chassis, or via the signal connector J2. For the Xgen to be considered a two MOPP device there must be two MOPPs on each path.

1. Mains to Output - C

The MOP labelled C is known as reinforced insulation and is the equivalent of two MOPPs.

2. Mains to serial connector J2 – D

The MOP labelled D is known as reinforced insulation and is the equivalent of two MOPPs.

3. Mains to Chassis – B and E

The MOP labelled B is the equivalent of one MOPP. The earth connection is the equivalent of one MOPP. Together they are two MOPPs.

Summary and Conclusions

MOOPs and MOPPs 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 has been 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.

The Xgen and UltiMod platform is designed to have two methods of patient protection in order to maximise flexibility for the medical devise designer.

Appendix 1:

Designator	Description	Insulation Level	Working Voltage (Vrms)	Working Voltage (Peak)	Required Creepage	Measured Creepage	Required Clearance	Measured Clearance	Test Voltage
A	Live to Neutral	1 MOOP	240	340	3 mm	3.5 mm	1.6 mm	2 mm	1500 Vac
B	Live to Chassis	1 MOPP	240	340	4 mm	4.2 mm	2.5 mm	3.93 mm	1500 Vac
C	Primary to Secondary	2 MOPP	240	400	12 mm	12 mm	7 mm	7.7 mm	4131 Vac
D	Primary to Secondary (J2)	2 MOPP	240	368	8.26 mm	8.4 mm	5.13 mm	5.6 mm	4040 Vac
E	Output to Chassis	Not Measured	-	-	-	-	-	-	-