MOOPs and MOPPs - separating isolation requirements for operator and patient

The introduction of EN 60601-1:2006 (edition 3) was a major change for the medical electrical equipment and medical electrical systems industry. The transition to a hazard, risk based format meant that a power supply certified for medical applications would no longer ensure that the end product would conform to the medical standard. In this paper, which is intended for electronics engineers and designers working with power systems in medical equipment, Chris Maidment, Marketing Director, outlines the two classifications of means of protection – MOOPs and MOPPs.

References

www.emea.lambda.tdk.com/medical
www.emea.lambda.tdk.com/mu4

MOOPs and MOPPs - separating isolation requirements for operator and patient

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The introduction of EN 60601-1:2006 (edition 3), replacing the previous EN 60601-1 :1990 standard, was a major change for the medical electrical equipment and medical electrical systems industry. The transition to a hazard, risk based format meant that a power supply certified for medical applications would no longer ensure that the end product would conform to the medical standard. This is because medical equipment is now split into two categories; in vitro diagnostic medical devices (IVD) and medical devices.

In vitro is Latin for “within the glass”, and these types of medical devices cover biological sample testing, to determine a person’s health for example. Most of these devices would not come into contact with a patient’s body and include blood or fluid analysers.

Medical devices though, may have direct connection to the patient, which raises the risk that the device could present a hazard. Examples of these types of electrical equipment are patient monitors, surgical tables, scanners and blanket warmers. They also include dental and healthcare equipment. Manufacturers of medical devices will conduct risk management in accordance with ISO 14971 and record that information in their files.

Means of Protection (MOP)

A MOP prevents not only the patient from receiving a hazardous electrical shock from a medical device, but also the operator. Two examples of a means of protection would be suitable insulation or a protective earth (PE) ground connection. The safety standard IEC/EN 60601-1 defines the minimum creepage and or clearance of the insulation depending upon the voltage. The creepage distance is measured across the surface of an insulator and the clearance measured through the air between the primary and secondary sides of a power supply for example (Figure 1).

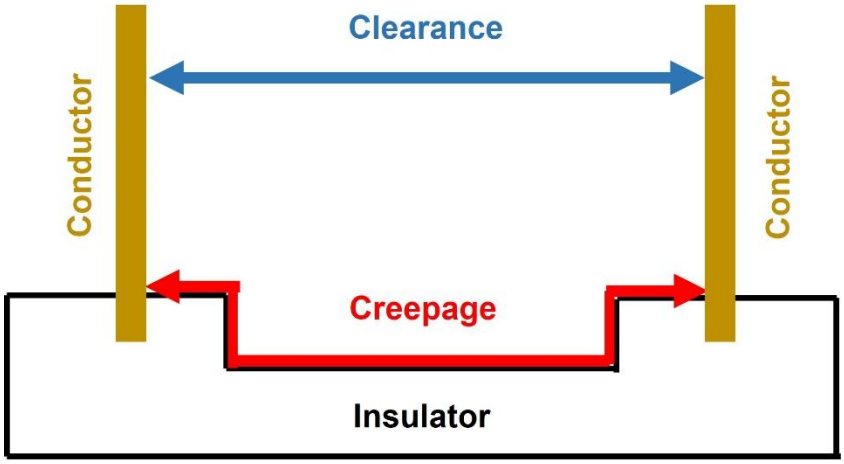

Figure 1: Creepage and clearance

There are two classifications of means of protection. Means of operator protection (MOOP) and means of patient protection (MOPP). As a patient is much more likely to be in a weakened condition than an operator, like a nurse, doctor or technician, the MOPP limits are more stringent. MOOP limitations are more in line with IEC/EN 62368-1, used for audio/video, information and communication technology equipment.

There are 2 sub-classifications within MOP:

Means of Operator Protection (MOOP)

1 x MOOP is equivalent to basic insulation for an operator under IEC 62368-1

2 x MOOPs is equivalent to reinforced insulation, the same as in IEC 62368-1

Means of Patient Protection (MOPP)

1 x MOPP is equivalent to basic insulation for a patient under IEC 60601-1

2 x MOPPs is equivalent to reinforced insulation under IEC 60601-1

Table 1 shows the difference in withstand voltage, creepage and the insulation between the MOP classifications. A withstand voltage test is used to ensure that an isolation barrier has sufficient insulation to prevent a potentially harmful voltage and the resulting current from making human contact.

Classification	Withstand Voltage	Creepage	Insulation
1 MOOP	1,500VAC	2.5 mm	Basic
2 MOOP	3,000VAC	5.0 mm	Double/Reinforced
1 MOPP	1,500VAC	4.0 mm	Basic
2 MOPP	4,000VAC	8.0 mm	Double/Reinforced

Table 1: Withstand voltage, creepage and insulation type for MOP

Patient connected medical devices

A medical power supply may provide output power to a medical device which physically touches the patient during normal operation via an 'Applied Part' (AP) (Figure 2).

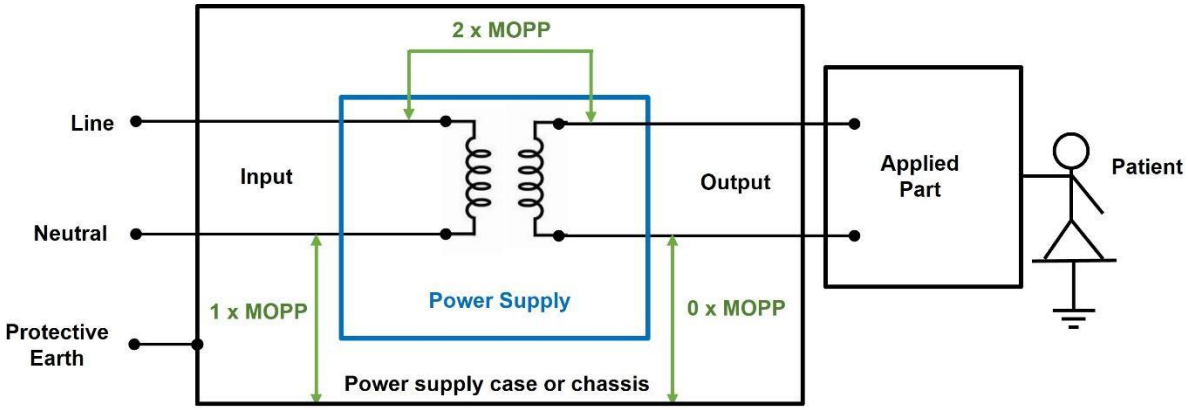

Figure 2: The applied part between the power supply and patient

There are three classifications in IEC 60601-1 according to the nature of the medical device and the type of contact. Each classification has a different protection level against electrical shock.

Type B ("Body") is for applied parts and is the least stringent classification. It is used for applied parts that are normally not conductive and can be immediately released from the patient. Examples of that would be LED operating lighting, medical lasers, MRI body scanners, hospital beds and phototherapy equipment.

Type BF ("Body Floating") is more stringent than Type B, and is generally used for applied parts that have conductive contact with the patient, or having medium or long term contact with the patient. Examples of this type of equipment are blood pressure monitors, incubators and ultrasound equipment. Type CF ("Cardiac Floating") is the most stringent classification, and is used for applied parts that may come in direct contact with the heart, such as dialysis machines.

As most medical power supplies have functional isolation (500VDC or 500VAC) between output and earth, the applied part must provide the isolation.

The power supply can be designed so that it assists the system requirements, in some cases without further isolation (Figure 3). To qualify, the power supply would need to meet the following MOPs:

1 x MOPP (1,500VAC) between primary and protective earth
2 x MOPP (4,000VAC) between primary and secondary
1 x MOPP (1,500VAC) between secondary and protective earth

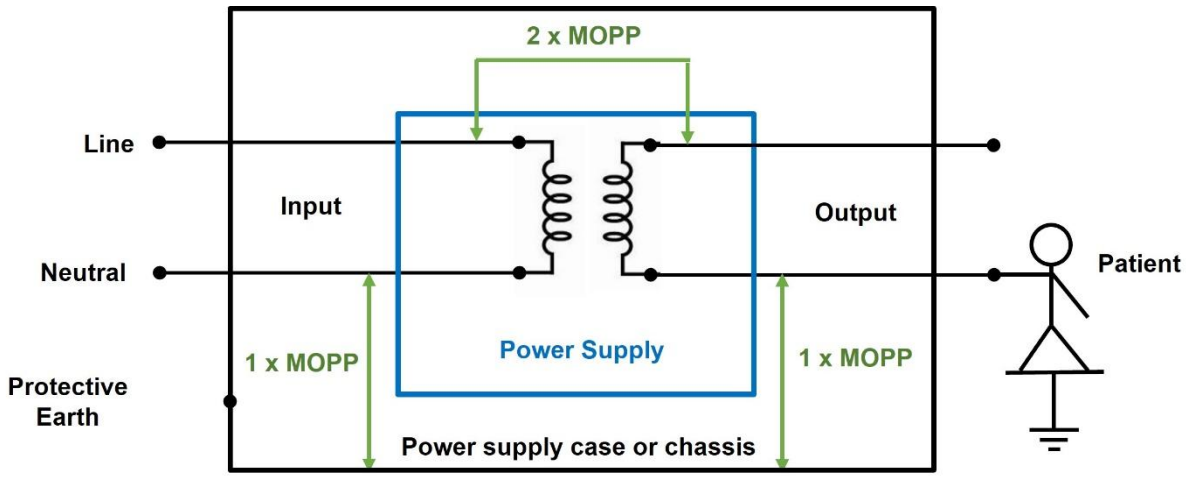

Figure 3: Power supply diagram with 1 x MOPP between output and earth

Recently companies like TDK-Lambda have launched configurable (modular) power supplies with full MOPP isolation. The MU series of 1U high low audible noise and QM series products offer 1 x MOPP from output to earth (Figure 4).

Figure 4: TDK-Lambda MU4 800W power supply

Another alternative if the AC/DC power supply can only provide 1 x MOPP, is including an isolated DC/DC converter meeting 1 x MOPP. This can help gain two means of patient protection (2 x MOPP). However, most system designers in the medical industry prefer to ensure that all power components reach the necessary standards instead of 'doubling up' to increase safety.

Summary

There are large numbers of companies offering medical power supplies. It is recommended to select one that has extensive experience in assisting customers. Every medical development has an overall system leakage current "budget". Knowledgeable Field Application support can interface between Engineering teams, offering advice and even providing a minor product change that can save the customer both time and money.

For more information about power supplies from TDK-Lambda, please visit:

www.emea.lambda.tdk.com/medical
www.emea.lambda.tdk.com/mu4

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