

# Understanding leakage currents in medical applications

IEC 60601-1 is a series of international standards for basic safety and essential performance of medical electrical equipment. It is widely used in many countries and is now deemed a requirement for most commercially available products. One key aspect of the standard is avoiding an electric shock, which could cause injury or even death, particularly due to excessive leakage currents. In this paper, which is intended for electronics engineers and designers working with power systems, David Buck, Product Manager, outlines the various types of medical leakage currents.

## References

[www.emea.lambda.tdk.com/medical](http://www.emea.lambda.tdk.com/medical)  
[www.emea.lambda.tdk.com/cus250m](http://www.emea.lambda.tdk.com/cus250m)  
[www.emea.lambda.tdk.com/cus30\\_60m](http://www.emea.lambda.tdk.com/cus30_60m)

# Understanding leakage currents in medical applications

*David Buck, Product Manager, TDK-Lambda*

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## Leakage Current

Leakage current is the current measured flowing through the protective conductor to ground. If there is no ground connection, it is the current that could flow to ground if a conductive path is present, which includes the human body.

In modern residential and office applications, if that current exceeds dangerous limits, the Residual Current Device (RCD) would trip, isolating the equipment or device from the AC source. Many people will have experienced this if they have cut the AC cable while using a garden hedge trimmer.

For healthcare applications, the maximum limit for leakage currents is set much lower, depending on the type of medical device being used. Medical leakage currents are not intended to be applied to a patient.

## How does an AC-DC power supply generate leakage currents?

A certified medical power supply must comply with many other restrictions besides the leakage current limitations. These include EMC (Electro Magnetic Compatibility) for conducted and radiated emissions, along with immunity against voltage dips, electrostatic discharges (ESD), input transients, RF (radio frequency) and even magnetic fields. Meeting these EMC standards is a legal obligation in many countries. It ensures that electrical and electronic equipment functions correctly in its environment and does not generate unacceptable disturbances that could affect other equipment.

Power supplies use high frequency, high voltage switching circuits, typically operating between 40kHz to over 500kHz. These circuits generate high frequency electrical noise. To pass the conducted and radiated emissions standards, filtering circuitry is required. Ceramic filter capacitors are used to reduce electrical noise (Figure 1).

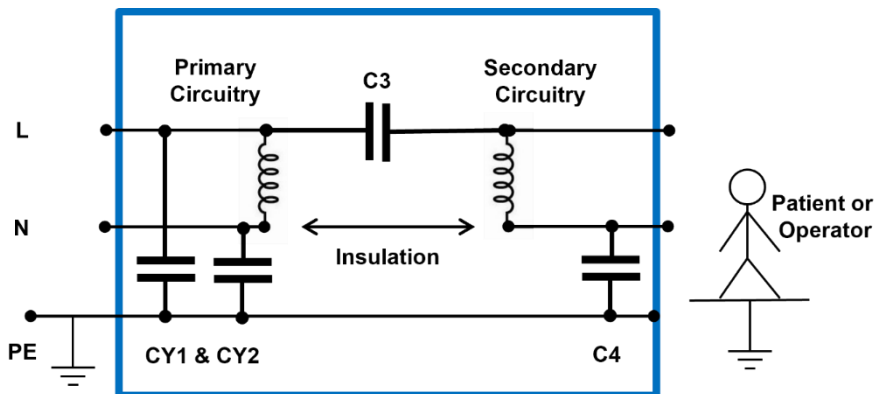


Figure 1: The location of the noise reducing ceramic capacitors in an AC-DC power supply

Capacitors CY1 and CY2 are used in conjunction with filter inductors (not shown). High frequency noise is diverted away from the AC source, through the capacitors into the earth ground (Protective Earth) connection. This technique avoids interference with other equipment also using the AC feed.

Capacitor C3, connected between the primary and secondary sides of the transformer, reduces high frequency noise and also represents the interwinding capacitance of the transformer.

C4 reduces output noise and has little effect on the leakage current, the dominant components being CY1 and CY2 between line and earth and neutral and earth.

Lower capacitance values of CY1 and CY2 will result in a lower leakage current. But it may then cause the power supply to fail the conducted and radiated EMI standard requirements.

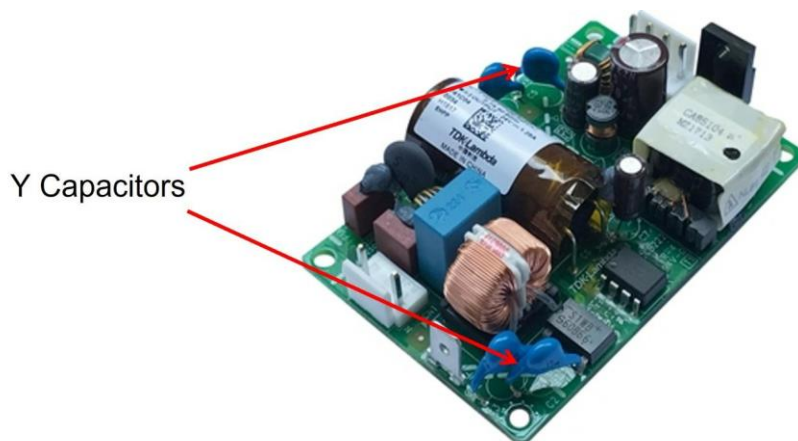


Figure 2: Y capacitors on the TDK-Lambda CUS30M

### Types of medical leakage currents

IEC 60601-1 refers to the following three main types of medical leakage current. They are measured under two conditions - Normal Conditions (NC) and Single Fault Conditions (SFC). Under a Single Fault Condition, for example, where the earth connection on a pluggable device is disconnected, a higher leakage current limit is allowed according to IEC 60601-1.

**Earth leakage current** flows from the primary circuitry through or across insulation into the Protective Earth (PE) conductor. No current flows from the enclosure via the Patient or Operator when touching the medical device (Figure 3).

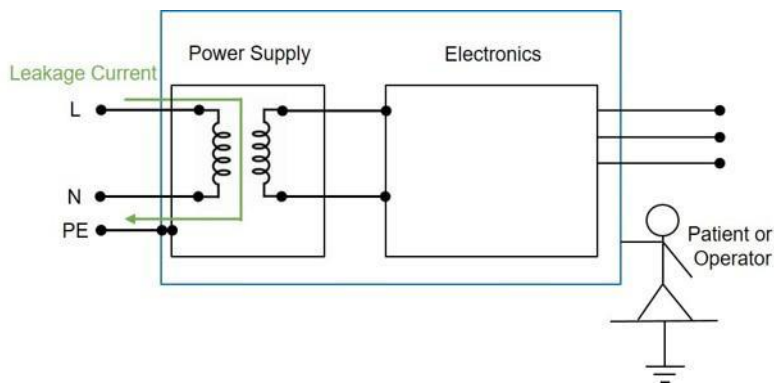


Figure 3: Earth leakage path

|                                 | Normal condition (NC) | Single fault condition (SFC) |
|---------------------------------|-----------------------|------------------------------|
| Equipment enclosure leakage     | 100µA                 | 500µA                        |
| Permanently Installed Equipment | 5mA                   | 10mA                         |

Table 1: Maximum earth leakage current

**Touch current** flows from the medical device's enclosure or parts thereof, excluding patient connections, and is accessible to patients or operators in normal use through an external path (not PE) to the earth (Figure 4).

The touch current is also measured on the output terminals, which may be accessible to the patient depending upon the final system.

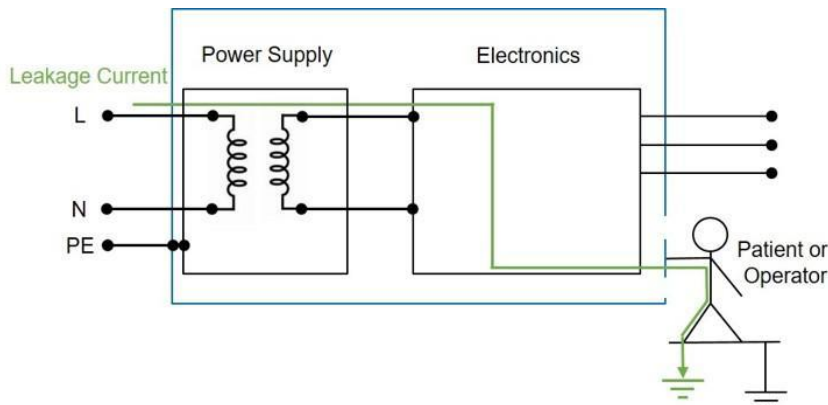


Figure 4: Touch current path

|                                   | Normal condition (NC) | Single fault condition (SFC) |
|-----------------------------------|-----------------------|------------------------------|
| Equipment enclosure touch current | 100µA                 | 500µA                        |

Table 2: Maximum touch current

**Patient leakage current** flows from patient connections of the electrical medical equipment (Applied Part) via the patient to earth, this is considered a Normal Condition (NC). An Applied Part is a part of the equipment that under normal operating conditions contacts the patient. There are three main categories:

B rated (Body):

May be connected to earth

Normally not conductive and can be immediately released from the patient

Examples: Medical lasers, MRI body scanners, phototherapy equipment, beds and cables

BF rated (Body Floating):

Has conductive contact with the patient

Examples: Blood pressure monitors, incubators, ultrasound equipment

CF rated (Cardiac Floating):

May come in direct contact with the heart

Example: Dialysis machines

Patient leakage current flows from patient connections of the electrical medical equipment – the Applied Part - via the patient to earth (Figure 5).

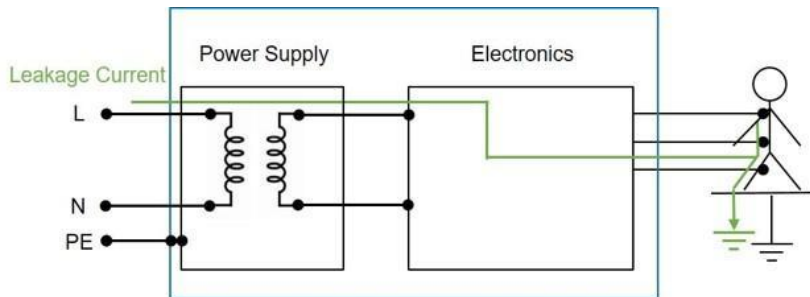


Figure 5: Patient leakage path

|                 | Normal condition (NC) | Single fault condition (SFC) |
|-----------------|-----------------------|------------------------------|
| Patient Leakage | 100µA                 | 500µA                        |

Table 3: Maximum patient leakage current

### Power supply design

Ensuring that the internal electrical noise generated by the switching converter is minimised allows the value of the capacitors to be reduced. This, in turn, reduces the power supply's leakage current and still retains compliance to the EMI standards.

The design specification for TDK-Lambda's 250W rated CUS250M power supply had aggressive targets for leakage currents and EMI performance. The engineering team knew that this could not be an afterthought. A patent pending output terminal / inductor combination was developed to reduce common mode noise, a custom ferrite core was designed for the power factor correction (PFC) circuit to reduce EMI and, importantly, the engineering team took significant care in the layout of the printed circuit board (PCB).



Figure 6: CUS250M series of medical power supplies

The result was a leakage current of less than 150 $\mu$ A (at 264Vac 63Hz - the worst case voltage and frequency), a touch current of <10  $\mu$ A (Class I) and <70 $\mu$ A (Class II, no ground connection). Despite low leakage currents, the EMI performance for both Class B conducted and radiated emissions had significant margins.

### 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](http://www.emea.lambda.tdk.com/medical)

[www.emea.lambda.tdk.com/cus250m](http://www.emea.lambda.tdk.com/cus250m)

[www.emea.lambda.tdk.com/cus30\\_60m](http://www.emea.lambda.tdk.com/cus30_60m)

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