Leakage Current Considerations for Medical Power Supplies

IEC 60601-1 Edition 3.2 is the internationally recognized safety standard for medical electrical/electronic equipment. It covers the basic safety and essential performance requirements in order to protect both operators and patients. It includes strict guidance for critical parameters such as isolation voltages, creepage and clearance distances and leakage currents. Compliance with the standard is vital to prevent risk of electric shocks which could cause serious injury or even prove fatal.

Effect of Electric Shock on the Human Body

An electric shock is the pathophysiological effect of an electric current passing through the human body. The severity of an electric shock is determined by a number of factors including the level of current flowing, the voltage present, the duration of the shock, the frequency (for ac), the condition of the human body and the location on the body to which the shock is applied.

Dry skin has a relatively high resistance which, however, can vary considerably from person to person but it usually in the range 20-30kΩ/cm². Wet skin and broken or punctured skin resistance is up to 100 times lower thus significantly increasing the current flow for a given applied voltage. Internal body resistance is at a similarly low level.

IEC 60479-1 details the effects of current on the human body which are characterized into 4 zones of current magnitude and duration of flow.

- **Zone 1:** Imperceptible
- **Zone 2:** Perceptible
- **Zone 3:** Reversible effects: e.g. muscular contraction
- **Zone 4:** Possibility of irreversible effects e.g. ventricular fibrillation

A current of 50mA applied via a hand and passing through to earth by the foot is enough to cause ventricular fibrillation if applied for 2 seconds or more – a weakened patient undergoing healthcare may be more susceptible. Therefore IEC 60601-1 imposes limits for the different types of leakage current described below. At this point it is important to note that a medical power supply is not considered to be a “Medical Device” within the meaning of the standard, but selection of a compliant product greatly simplifies the overall medical system design for the customer.

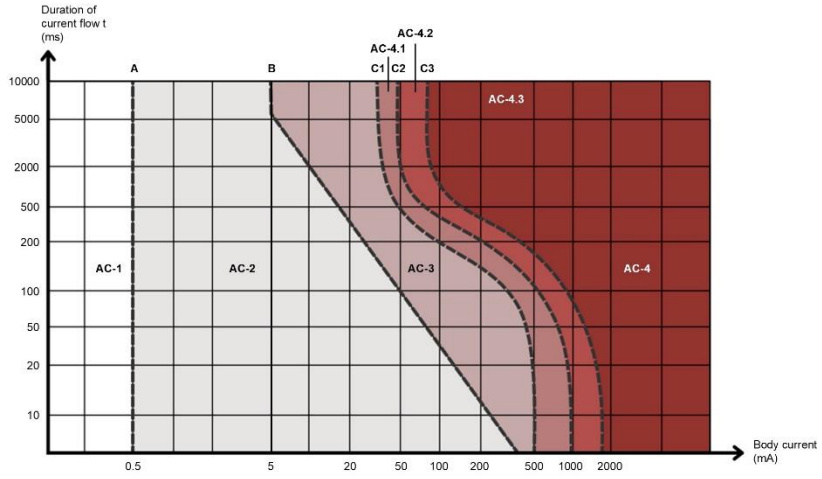

Figure 1: Zones time/current of effects of AC current on human body. (Source: IEC60479-1 Standard)

Leakage Currents

Leakage current is any current which has no functional purpose. It will flow from an intended circuit either to earth or a chassis for example. It can be generated due to a number of reasons such as parasitic capacitance in a transformer, non-perfect insulators and capacitive coupling from EMC filter circuits. It not intended to be applied to a patient body and is therefore restricted to non-hazardous levels by IEC 60601-1. Two types are relevant for medical power supplies: Earth Leakage Current and Touch Current (previously referred to as Enclosure Leakage Current in Edition 2).

A third category, described below, is Patient Leakage Current which is relevant for the end system.

1 Earth Leakage Current

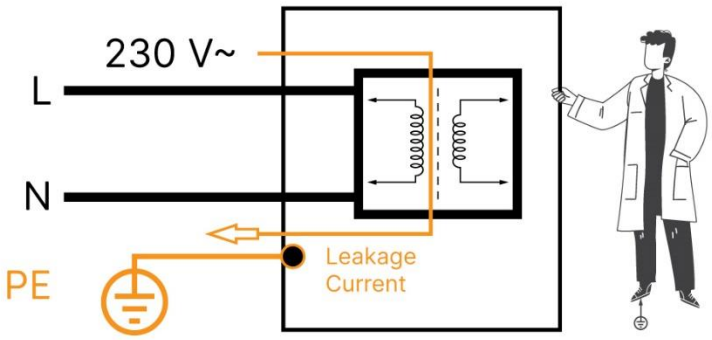

Figure 2: Illustration of Earth Leakage Current

It flows from mains to Protective Earth (through or across the insulation).

It does not flow through patient or operator touching.

Maximum values: NC (Normal Condition) 500μA and SFC (Single Fault Condition) 1000μA

2 Touch Current

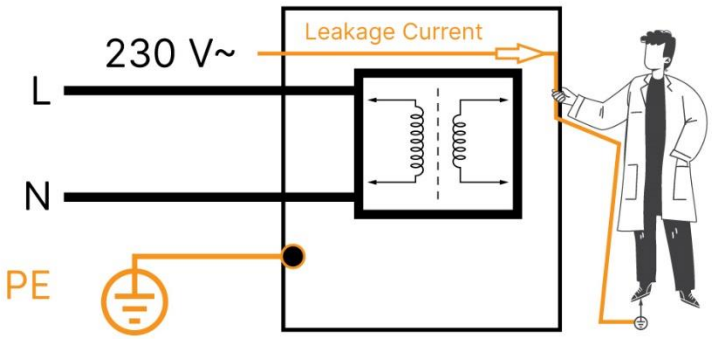

Figure 3: Illustration of Touch Current

It flows in normal use from a conductive part of the enclosure to earth through a conductor which is not the PE conductor e.g. Through operators and/or patients (excluding patient connections).

Maximum values: NC (Normal Condition) 100μA and SFC (Single Fault Condition) 500μA.

3 Patient Leakage Current

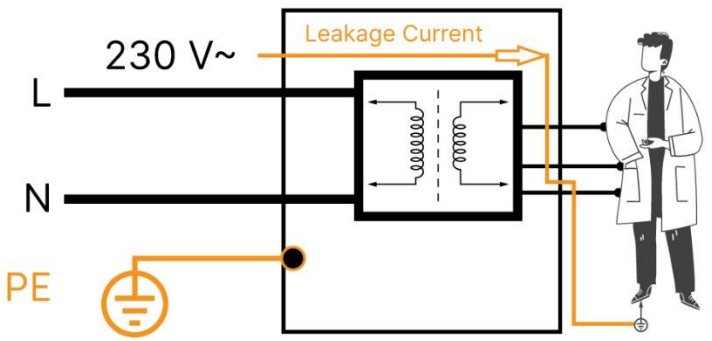

Figure 4: Illustration of Patient Leakage Current (NC)

It flows from patient connections of the medical device (Applied Part) via the patient to earth or another part of the system enclosure, under NC (normal condition). But in the case of a SFC (single fault condition), the flow will be from the patient who may be connected to other sources of voltage) back to earth. Maximum values differ according to the type of Applied Part required (see definition below).

Maximum values for B and BF type Applied parts
NC: 100μA SFC: 500μA

Maximum values for CF type Applied parts
NC: 10μA SFC: 50μA

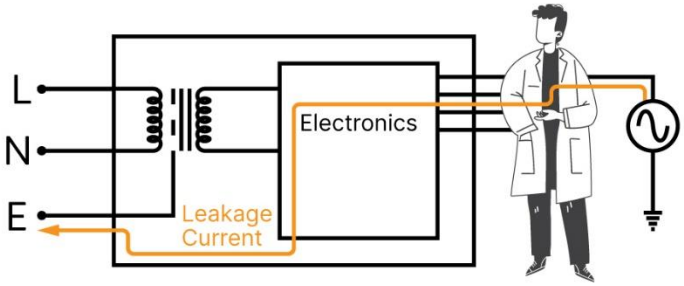

Figure 5: Illustration of Patient Leakage Current (SFC)

What Are Applied Parts?

An Applied Part is defined as one that can be applied to, or be in direct contact with, the patient. There are three types of Applied Parts: Body (B), Body Floating (BF) and Cardiac Floating (CF). The medical device manufacturer will define the appropriate Applied Part category according to the intended application.

Type B: Not intended to provide a current for diagnostic, treatment or therapeutic purposes. May be connected to PE. Equipment types include MRI/CT scanners, LED lighting and medical lasers. (REF NO 5840)

Type BF: Intended for contact with the patient for diagnostic, treatment and therapeutic purposes but must not be connected to the heart directly or through the bloodstream. The patient is not directly connected to earth. Equipment types include Ultrasound machines, incubators, dental equipment, ventilators and blood pressure monitors. (REF NO 5333)

Type CF: May be in contact with the heart either directly or indirectly via the bloodstream for example. Equipment types include Cardio electro surgery equipment and dialysis machines. (REF NO 5335)

Limits of Leakage Current - Summary

The limits of all three types of leakage currents are shown in Table-1 below, as defined by IEC 60601-1 Edition 3.

Leakage Current	Type B		Type BF		Type CF	
	NC	SFC	NC	SFC	NC	SFC
Earth Leakage Current *	500µA	1mA	500µA	1mA	500µA	1mA
Touch Current	100µA	500µA	100µA	500µA	100µA	500µA
Patient Leakage Current	100µA	500µA	100µA	500µA	10µA	50µA

* For Permanently Installed Equipment the limits increase to 5mA NC and 10mA SFC

Table 1: Leakage Current Limits

In summary, achieving compliant leakage current limits within a medical electrical system is challenging. Medical power supplies that meet lower than maximum levels of leakage current can significantly ease the task.

Delta’s Medical Power Supplies Feature Low Leakage Current

Known for lower leakage currents, superior EMI performance and exceptional reliability, Delta’s medical power supply solutions set the industry standard. Features such as low acoustic noise, high power density, reinforced isolation with two means of patient protection (2 x MOPP), and low leakage highlight Delta’s commitment to adaptable and patient-safe technology. The portfolio includes power supplies with capacities exceeding 2,000 W and lower capacities for small and portable devices, engineered to ensure medical equipment operates with efficiency and safety.

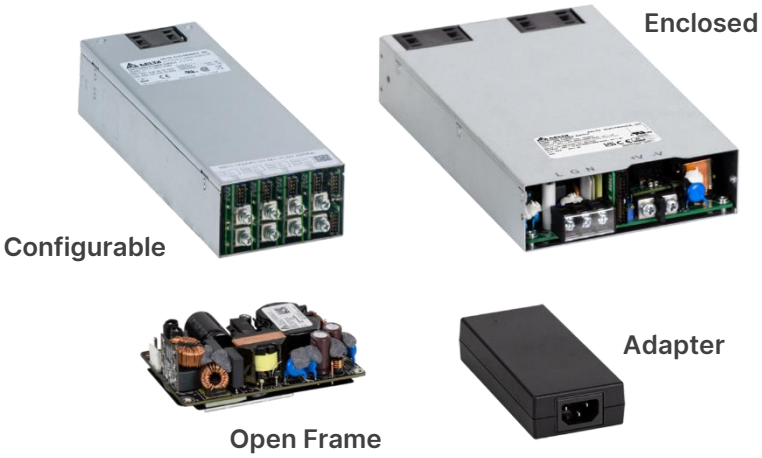

Figure 6: Delta’s enclosed, open frame, configurable medical power supplies and medical adapters all feature low leakage current.

For local purchase and service of industrial and medical power supplies, please contact our authorized distributors at https://deltapsu.com/en/contact/find-a-distributor.