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# Medical leakage currents

Earth leakage, Patient leakage and Touch Current



Medical



Home Medical

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United Kingdom  
October 21, 2019

## What is a Medical leakage current?

A medical leakage current is an electric current in an unwanted conductive path of an electrical medical device that is operating in a normal, faultless state, known as **Normal Condition** (NC).

An electrical medical device operating in a **Single Fault Condition** (SFC) may experience higher leakage currents.

Medical leakage currents are not intended to be applied to a patient.

The levels of permissible leakage currents are specified in IEC60601-1 standards.

The limits are based on real life experience / probability of what is potentially harmful to a patient / operator. These limits vary according to the application and/or fault condition.

IEC60601-1 refers to the following 3 main types of medical leakage current:

- Earth leakage current
- Patient leakage current
- Touch current

## Earth leakage current -1

Earth leakage flows from Mains Part through or across insulation Into the **Protective Earth** (PE) conductor (Figure 1.)

No current flows from the enclosure via the Patient or Operator when touching the medical device

**Touch current: IEC 60601-1 3rd Ed maximum values table 1.**

	Normal condition (NC)	Single fault condition (SFC)
Equipment enclosure leakage	100 $\mu$ A	500 $\mu$ A
Permanently Installed Equipment	5mA	10mA

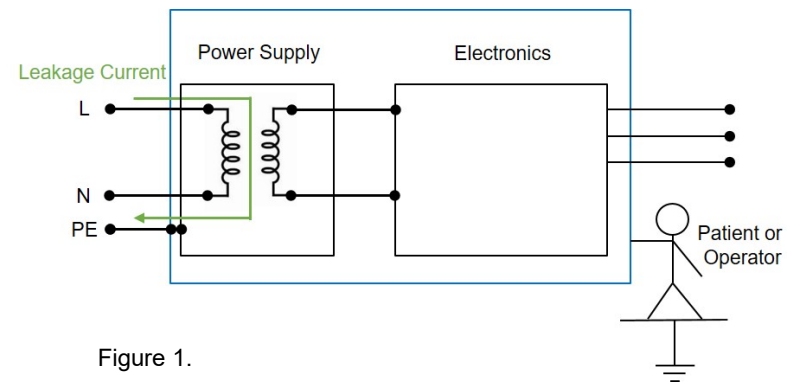
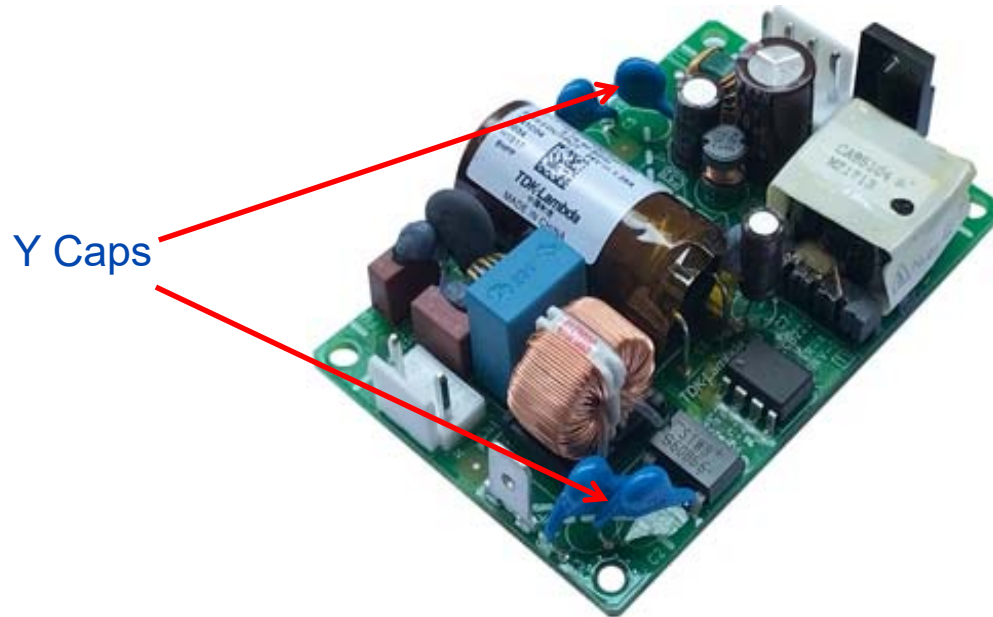


Figure 1.

## Earth leakage current -2

The earth leakage is dominated by the line to earth “Y” capacitors.  
“Y capacitors help to reduce the EMI from the power supply



## Touch current

Touch current flows from Enclosure or parts thereof, excluding patient connections, Accessible to Patients / Operators in normal use through an external path (not PE) to Earth

The touch current is also measured on the output terminals as this may be accessible to the patient depending upon the final system

Touch current: IEC 60601-1 3rd Ed maximum values table 2.

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

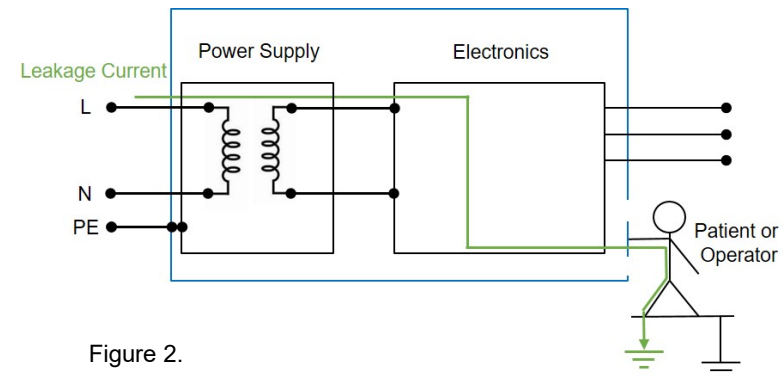


Figure 2.

## Patient leakage current - The Applied Part (AP)

To aid the definition of patient leakage it is necessary to understand the terminology of Electrical medical equipment applied parts (AP).

There are 3 main categories

### B rated (Body):

Maybe connected to earth

Normally not conductive and can be immediately released from the patient

Examples: Medical lasers, MRI body scanners, phototherapy equipment, Beds 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: A dialysis machine

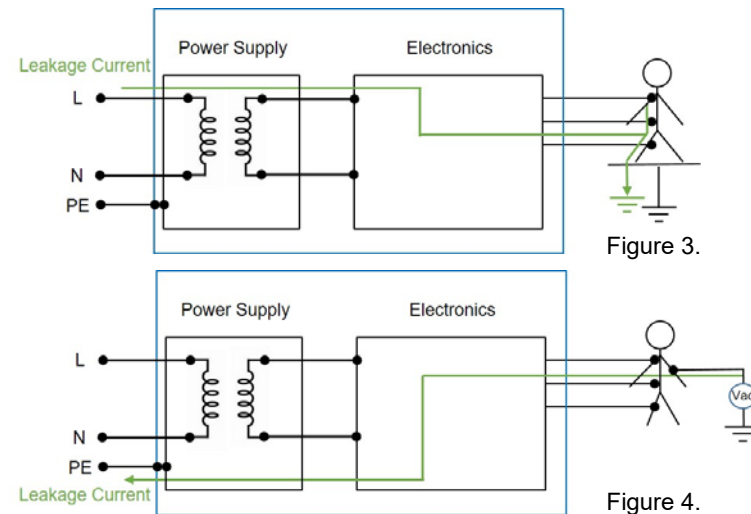
## Patient leakage current

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) Figure 3.

If the patient becomes connected to another voltage source this is considered a Single Fault Condition (SFC) and patient leakage current flows from the voltage source through the patient, through the electrical medical equipment back to earth Figure 4.

Touch current: IEC 60601-1 3rd Ed maximum values table 3.

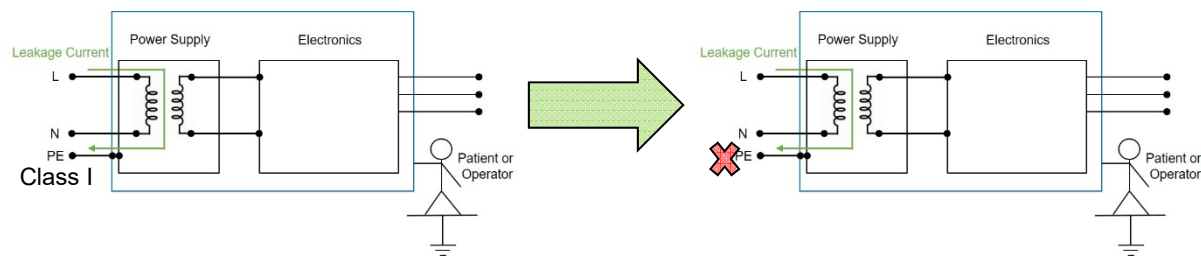
	Normal condition (NC)	Single fault condition (SFC)
Patient Leakage	100µA	500µA



## Earth leakage current - revisited

The **Earth leakage** can become the **Touch current** during a SFC

- During the earth connection removal test in a Class I product  
The maximum earth leakage becomes  $500\mu\text{A}$  - if the enclosure is touched
- In this case, the output's  $100\mu\text{A}$  touch current limit must also be considered  
The earth leakage and touch current are additive, so the maximum earth leakage is  $400\mu\text{A}$



- \* Note - If two power supplies are in the end equipment, their limits are halved  
Leakage current is additive, so each must be  $\leq 50\%$  of the medical standard's limit



## Class I and Class II products

Class I – EARTHED (Has L,N and E)

- One level protection provided by Earth connection
- One level by basic insulation

Class II – No EARTH (L,N)

- Must have 2 layers of insulation : double or re-inforced

\* Certain applications like Home Healthcare (IEC60601-1-11),  
**MUST** use Class II equipment  
Because safety earth cannot be guaranteed in the home  
environment



Suitable for Class I Installations



Suitable for Class II Installations

# Trust

## TDK-Lambda

### For all your Healthcare Power needs

#### TDK-Lambda Expertise:

Over 30 years' experience in medical power applications

An independently recognized market leader

Approved supplier to many top global manufacturers

Global Multi-site design, manufacture and local technical department

#### Approved to latest medical safety standards

- ISO13485 designed and manufactured products
- IEC, UL, CSA, ANSI/AAMI 60601-1 (Ed. 3) Safety compliance
- EN60601-1-2: 2015 (Ed. 4) EMC compliance
- B & BF capability, Class I & Class II applications

