RIGEL MEDICAL
GMC-INSTRUMENTS GROUP

Why perform electrical safety tests?

Electrical safety testing ensures medical equipment (ME) is electrically safe for use in a healthcare environment by testing for breakdown or damage. Medical device safety testing is more stringent when compared with generic electrical devices. Patients are significantly exposed to electrical hazards as they are connected directly to electrical devices. During medical procedures intra-cardiac electrical connections are also present, whereby low leakage currents could cause ventricular fibrillation.

When looking at electrical leakages of medical devices, there are two types of potential electrical shocks to be considered; macroshock and microshock. Macroshock is an electrical current applied externally (between an electrical source and the skin) and is dispersed over a larger surface area than microshock. Ventricular fibrillation (VF) of the heart occurs around 100mA. Microshock occurs when current flows directly through the myocardium via intra-cardiac connections e.g., pacemakers or saline catheters. Current density is much larger and close to myocardial tissue so VF can occur between 20 and 100 □A (Over 100 times less than macroshock!).

To ensure patient safety, leakage limits reflect these potential hazards. Furthermore, applied parts are classified into different classifications:

• Type B (Body) – Non-invasive. Earth Reference e.g., hospital bed
• Type BF – Non-invasive, patient circuit floating type e.g., defibrillator paddle
• Type CF – Invasive, cardiac. Patient circuit floating type e.g., pacemaker, ECG module

In the 3rd edition of IEC 60601-1 leakage limits under normal fault conditions vary significantly (Earth leakage - 5000□A, patient leakage (DC) - 10 □A, patient leakage (AC) - 100 □A). There are additional fault conditions

provided in medical safety testing to adhere to the stringent parameters. For instance, on F-type tests (BF and CF) a fault condition with mains on applied part is produced.

If you require more help, please contact us at https://www.seaward.com/gb/enquiry/.