RIGEL MEDICAL
GMC-INSTRUMENTS GROUP

What is electrical safety testing?

Safety testing ensures the safety of clinicians, visitors or patients who may come in contact with any electrical devices. It is always part of preventative maintenance procedures and is developed to prevent danger to anyone from electric shock. The international standard, IEC 60601-1, states the safety requirements for manufacturers of medical devices but this standard has also been adapted for routine testing of medical devices. However, in-service, recurrent and post repair standards have been developed specifically for a unified approach to routine testing, such as IEC 62353.

Electrical equipment powered by mains are classified into two different types of protection; either Class 1 (earthed) or Class 2 (double insulated). Medical devices are required to have supplementary protection to ensure adequate electrical isolation from any applied parts. Patient protection is classified as B (Body), BF (body floating) or CF (cardiac floating) and all medical devices are required to be labelled with a classification.
Electrical safety of medical devices according to international standards falls into four primary tests:

• Earth bond/continuity – Protective earth is the primary form of protection for class 1 devices. It provides a low resistance path incase of leakage or fault currents. Safety testing ensures a low resistance earth path exists.
• Leakage tests (Enclosure/Earth) – Ensures current leakage from equipment falls within a specified limit.
• Patient leakage tests – Ensures current leakage from any applied parts falls within a specified limit (A higher degree of isolation is required for patient connections within medical devices and the specified current limits are much lower than other leakage tests)

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