



PAT Testing Medical Equipment

Are you PAT testing medical equipment correctly?

Many medical devices in the UK are incorrectly tested using PAT testing equipment. This means that the standards for testing of medical equipment are not being adhered to making this equipment potentially unsafe for use. Here we will provide information for those responsible for or carrying out testing on medical equipment to ensure they are meeting the correct standards.

What is a medical device?

Facilities including care homes, doctors surgery's, hospices, veterinary surgeries, home care, dentists, gyms, even shopping centres & workplaces use a variety of electrical equipment that must be tested to a medical standard. The equipment ranges from specialist medical, laboratory and IT equipment to ordinary domestic appliances. Any electrical equipment used during or in the vicinity of the treatment, monitoring or diagnosis of a patient is classed as a medical electronic device. For example: beds, operating tables, infusion pumps, hoists, CPAPs, suction pumps, dentist chairs, heart rate monitor's and also scales.

How do I identify a medical device?

Medical devices are classified in 2 ways. Firstly on the power supply side as class 1 (earthed) or class 2 (double insulated). Secondly on the patient protection side as B (body), BF (body floating) or CF (cardiac floating). The

below symbols are used to represent these connection types.



Type B



Type BF



Type CF

All medical devices are required to be labelled with the appropriate symbol(s) to identify their classification.

What are the test requirements for medical devices in the UK?

The medical standards adhered to in the UK are IEC 60601, IEC 62353 & IEC 61010. IEC 60601 is a manufacturer's test type and has been adapted for routine testing of medical equipment. These are the tests required:

- Visual Check
- Earth Continuity
- Earth Leakage
- Enclosure/Touch Leakage
- Patient Leakage
- Patient Auxiliary leakage
- Patient Type F Leakage

IEC 62353 defines the requirements for electrical safety testing of medical electrical (ME) equipment and systems during routine intervals. This includes:

- Visual Check
- Earth Continuity
- Equipment Leakage
- Applied Part Leakage

IEC 61010 is the standard for testing lab equipment. This includes:

- Visual Check

- Earth Continuity
- Touch Voltage
- Enclosure Leakage (if required)

Why doesn't a PAT tester meet medical standards?

Standard PAT testers are not suitable for testing medical or laboratory equipment due to the following reasons:

- Body model - To ensure a standardised method of simulating the impedance of the human body, measurement circuits have been designed to simulate the average, typical electrical characteristics of the human body. These measurement circuits are referred to as a Body Model or Measuring Device. PAT testers do not use the body model specified in IEC 60601.
- Fault conditions – Both IEC 60601 & IEC 62353 require leakage tests to be performed in fault conditions such as earth open, neutral open and reverse supply. Standard PAT testers do not have this functionality.
- Leakage limits – Humans begin to feel current around 1mA but as little as 50µA can affect the organs. PAT testers are not capable of measuring such low currents.

Why should I use the SafeTest 60 to test medical devices?



As well as the above reasons there are many benefits of using the SafeTest

60:

- Easy to use – Simple manual control of tests and large colour display.
- Cost effective – Competitively priced for PAT price range rather than medical safety
- Efficient testing – Fast boot up and easy to navigate user interface.
- Flexible – Capable of testing to IEC 60601, IEC 62353, IEC 61010*.
- Versatile - Suitable for testing medical equipment such as beds, operating tables, infusion pumps, hoists, CPAPs, suction pumps, blood pressure monitors, dentist chairs, scales, gym equipment, nebulisers, homecare equipment and more.

* items without applied parts only

See the SafeTest 60 in action

If you require more help, please contact us at

<https://www.seaward.com/cms/enquiry/>.