MHRA Advice on Electrical Aspects for Clinical Investigations

Scope. This document aims to provide basic supporting explanatory advice for devices that are electrically powered **but it is not prescriptive because devices vary in complexity.**

MHRA recommends that a Clinical Investigation application includes a separate document is submitted for electrical safety and electromagnetic disturbances (EMD), which is the generic IEC term for both Electromagnetic Compatibility (EMC) and Electromagnetic Interference (EMI).

The document should include the following sections -

1. **Device Description**

   A clear description of function and electrical terms must be used for our assessors. Block diagrams are welcomed to save lengthy paragraphs.

   This should include electrical voltage and protection class (I, II, SELV, or Battery) information.

   Applied Part details along with any patient isolation design methods.

   Details of protective or functional earth conductors. Circuit diagrams are always welcomed and should show how the functional earth connects to the protective earth.

   Any relevant mechanical build specifications should also be included.

2. **Device Specification**

   Electrical Rating Details.

   List all standards complied with, especially those used for presumption of conformity (e.g., EN 60601-1 – General requirements for basic safety and essential performance, EN 60601-1-2 – Electromagnetic Disturbances). This would also apply for any mains PSU that has been bought “off the shelf”, which should include “Means of Patient and Operator Protection” compliant with EN 60601-1 (IEC 60601-1).

3. **Foreseeable Risks and the mitigation methods.**

   a. One example is liquid ingress and how the device is sealed.
   b. Electromagnetic Interference, even on battery powered devices.
   c. Devices that use electrical energy as part of the actual treatment or have a connection to the patient that enters the vascular system, are deemed higher risk, so a detailed application is required.
   d. Any battery powered device may have the inherent safety compromised with a connection to other equipment, such as a data cable to a laptop, so should also be considered.

4. **Verification and Testing Methods and details of the test facility.**

   a. The tests should include any SELV power supply.
   b. Provide details of all relevant tests, including leakage current measurements.

c. The test plan for Electromagnetic Disturbances and Electromagnetic compatibility should include the environment the device will be used in.
d. If a battery powered device includes a changer the safety and use of this must be explained in the Instructions for Use and appropriate tests completed.
e. Ensure the UK mains lead and 13A plug (BS 1363-1) is compliant. This is often overlooked with devices already submitted for trials in Europe or the USA.

5. **UK Mains Supply – Specific Requirements for Medical Devices**

The instructions for use (IFU) must indicate how a loss of mains supply can affect safety and the mitigations required to achieve this (e.g., EN 60601-1 or IEC 60601-1 – clause 7.9.2.4). In any case interruption or restoration of the power supply should not result in loss of basic safety or essential performance (e.g., EN 60601-1 or IEC 60601-1 – clause 11.8 and 16.8).

6. **List of standards referenced for electrical build quality.**

a. Provide a list of standards referenced for the electrical build quality. Ideally, the application should include a checklist of applicable clauses for any standard used along with an associated compliance justification column.
b. The current list of designated Medical Device standards can be found here: https://www.gov.uk/government/publications/designated-standards-medical-devices