

EMC Rationale

Technical Rationale

The Product is a “Direct” copy of the existing product.

All probes are tested with the OEM instruments and extension cables where applicable.

Details of significant design aspects

a. Specific Features adopted:

The original manufacturers specification, construction techniques and wiring have been adopted. Particular attention has been given to match the original screening.

b. Component Specifications:

Components have been chosen to match the OEM.

c. Procedures used to control variants in Design & explanation of procedures used to assess if the product should be re-tested:

Original manufacturers probes are continually monitored via the repair service to ensure all changes and improvements are monitored. Any major changes are recorded.

d. Details of any theoretical modelling:

Most probes are derivatives of the configurations of a small number of major manufacturers, and use genetically compatible components and wiring. As the probe does not in itself emit any radiation, the instrument contains any additional components required to comply with the EMC regulations. It is therefore possible to test only the major supplier and assume the others comply. For completeness, as many as possible, of probes and cables, are tested using the original manufacturers “Pulse Oximeter”. It is deemed not necessary to test all probes. In order to clarify the situation, the following can be tested either directly or via a conversion cable into the following manufacturers monitors e.g.:

Nellcor
Criticare
Datex

Cables are “Class I” and all are simply “Connector to Connector”, via a short cable length. The original manufacturers cables have been reproduced.