
EMC REPORT

An Independent report has been produced with regard to Pulse Oximetry – Probes. As follows:

EMV – Report No 498ENV11

20th January 1998 - EnviteC – Wismar – Germany.

Measurements for Device Safety – Report No 498ENV12

20th January 1998 - EnviteC – Wismar – Germany.

Both tests showed no relevant function impairment

The test results for both of the above can be found in Section “Z – Sub-section 20”

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 and extension cables 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 simply “Connector to Connector”, via a short cable length. The original manufacturers cables have been reproduced.

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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.

T:\Kevin Rush\CE Files\CE files current\SpO2_Probes\SpO2 Probes_CE File_2004\D.

Classification\EMC Classification\D. EMC Rationale_SpO2 Probes.doc

12/07/2004

Page 1

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EMC Rationale

Product: Pulse Oximeter probes

Technical Rationale:

Direct copy of existing product.

Probes 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 techniques.

b) component specifications Components have been chosen to match the OEM's

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

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P857RA	Nelcor	
P859RA	"	"
P860RA	"	"
P886RA	"	"
P862RA	Criticare	
P869RA	"	
P865RA	Sensormedics	not available
P877RA	"	"
P871RA	Datex	

Cables are Class I and all are simply connector to connector via a short cable length. The Original manufacturers cables have been reproduced.