PRE-PURCHASE QUESTIONNAIRE **EXTENDED FORM PPQ – June 2003**

Produced by NHS Purchasing and Supply Agency, Scottish Healthcare Supplies, Northern Ireland CSA Regional Supplies Service and Welsh Health Supplies in conjunction with the Association of British Healthcare Industries

This form is intended to supply prospective purchasers with information about equipment being considered for purchase. It is intended principally for pre-purchase information on electrical medical, dental, ophthalmic and laboratory equipment. The form may also be used for other products, including non-electrical items, and to give information prior to equipment being supplied on loan, in which case not all the questions will be relevant. Please ensure all relevant questions are answered.

For issue and completion by purchaser: **PPQ Master Reference:**	
A unique reference (preferably ten characters maximum) must be given by the supplier: **Supplier's Reference:**	002436/06-06

Generic Device Type:	Handheld Pulse Oximeter	Equipment Model:	N65-1
Country of Origin:	United States	Manufacturer:	Nellcor Puritan Bennett
Supplier:	Viamed Ltd	Telephone No:	01535634542
Fax No:	01535635582	E-mail:	info@viamed.co.uk

CE MARKING

1. a) Does the product carry the CE marking? YES [X] NO [ ]

   b) If YES, to which EC Directive(s):

   i) Active Implantable Medical Devices Directive (90/385/EEC) YES [ ]

   ii) Medical Devices Directive (93/42/EEC) YES [X]

   If YES, state classification of device (93/42/EEC Annex IX) [IIb]

   iii) *In Vitro* Diagnostic Medical Devices Directive (98/79/EC) YES [N/A]

   If YES, is the device: For self-testing? YES [ ] Covered by Annex II: List A? YES [ ] List B? YES [N/A] NO [ ]

   For ii) and iii) above, Identification No. of Notified Body, if applicable [0123 TUV]

   iv) EMC Directive (89/336/EEC or superseding directive)) YES [X]

   v) Low Voltage Directive (73/23/EEC) YES [X]

   vi) Other Directive(s) (please specify) [N/A]

2. a) Is the product a 'custom-made device' (93/42/EEC)? YES [ ] NO [X]

   b) Is the product intended for 'clinical investigation' (93/42/EEC) or 'performance evaluation' (98/79/EC)? YES [ ] NO [X]

   If YES to a) or b) above, does the device comply with the UK Medical Devices Regulations? YES [ ] NO [ ]

MANAGEMENT SYSTEM STANDARDS

3. a) Is the manufacturer currently registered to any management system standards (eg ISO 9001, ISO 14001, ISO 13485)? YES [X] NO [ ]

   If YES, please state the standard(s) and certification body: [ISO 913485-2003]

   b) Is the supplier's service and repair organisation currently registered to any management system standards? YES [X] NO [ ]

   If YES, please state the standard(s) and certification body: [ISO 13485]

SAFETY STANDARDS

4. For products not CE marked to 1 b) i), ii) or iii) above, with which safety standard(s) does the product comply?

Standard	*Test House*	*Certificate Number*	*Date*
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A

SERVICE / SPARES / INSTALLATION

5. Is service/repair information available? YES [X] NO [ ] If NOT f.o.c. please state current price [32.44] Indicate contents below:

(Please state YES, NO or N/A)

Full circuit diagrams	YES	Fault finding procedure	YES	Preventative maintenance	YES
Repair information	YES	Spare parts listing	YES	List of special tools/test equipment/etc	YES

If YES, please state whether also available on: Disk [X] Website [X] If Web, please state address [www.nellcor.com]

6. a) In addition to the service/repair information/manual, will training be required before competent technical personnel can provide:

(Please state YES, NO or N/A)

First-line maintenance	N/A	Calibration	N/A
Planned preventative maintenance	N/A	Repair	N/A

   b) Is the supplier able to provide this training for the purchaser's or a third party's technical personnel? YES [X] NO [ ]

   If YES, will this be free of charge? [ ] Or chargeable? [X]

   If NO, please indicate if details of an organisation that is able to provide this training are available on request? YES [ ] NO [ ]

Supplier's Reference:	N65-1

c) Is the provision of service repair information conditional upon completion of training? YES [ ] NO [X]

d) In order to undertake maintenance repair calibration, is any special software test equipment tooling required? YES [X] NO [ ]

If YES, please indicate that details of special software test equipment tooling are provided on a separate sheet: YES [X]

7. a) Is the supplier able to provide an 'as required' repair maintenance service in the UK? YES [X] NO [ ]

b) Is the supplier able to provide a contract repair maintenance service? YES [X] NO [ ]

If YES, please confirm that details of repair maintenance contracts are provided on a separate sheet. YES [X]

c) i) If repairs are normally performed by the supplier on the purchaser's site, please state typical response time: N/A

ii) If repairs are performed off-site, where will these be carried out?

Company: Tyco Healthcare (UK) Ltd. Location: Bicester Typical turnround time: 10 Days

iii) Is free of charge loan equipment normally available? YES [X] NO [ ]

8. Please state if repair parts will be available to the purchaser's or a third party's suitably trained and equipped personnel: YES [X] NO [ ]

If YES, is the supply of repair parts conditional upon acquisition of repair information? YES [X] Or training? YES [ ] NO [X]

9. Please indicate when this model was first placed on the market: March 2006

10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed? 7 Years

b) Is the product still in current production? YES [X] NO [ ] If NO, indicate year of last manufacture:

11. Is installation necessary? YES [ ] NO [X]

If YES, please confirm that details of all services required are provided on a separate sheet: YES [ ]

12. Will software upgrades be notified? N/A [ ] YES [X] NO [ ]

IONISING RADIATION

13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation? YES [ ] NO [X]

DECONTAMINATION / REPROCESSING

14. a) i) Is the item intended to be processed reprocessed? YES [X] NO [ ] If NO, go to Question 15.

ii) If YES, is the item intended to be: Non-sterile for single use [ ] Sterilized [X] Disinfected [ ] Other And Cleaned

iii) Is there a recommended maximum number of uses? YES [ ] NO [X] If YES, please state:

iv) Are decontamination reprocessing instructions supplied? YES [X] NO [ ]

v) Are instructions available for safe disposal? YES [X] NO [ ]

b) i) Is manual cleaning the only cleaning method specified before further reprocessing? YES [X] NO [ ]

ii) What is the maximum temperature that can be used for thermal disinfection? Temp: N/A

iii) Are there any restrictions on detergent disinfectant types? YES [X] NO [ ] If YES, please state: Mild Detergent Only

iv) Can the item withstand autoclaving at 137 °C for 3 mins? YES [ ] NO [X]

v) Is the item compatible with other sterilization methods? YES [ ] NO [X] If YES, please state:

vi) Does reprocessing require the use of specified equipment? YES [N/A] NO [ ]

If YES, please state equipment type (eg containers, processors, etc) and, where appropriate, parameters of operation (eg temp, pressure, etc):

c) i) Are tools required to aid dismantling reassembly, or are lubricants required? YES [N/A] NO [ ]

ii) If YES, are they supplied with the device or available optionally? Supplied [ ] Optional [ ] Neither [ ]

d) Is decontamination reprocessing training available? YES [N/A] NO [ ] If YES will this be: Free of charge? [ ] Chargeable? [ ]

e) Are reprocessing instructions available on the Web? YES [N/A] NO [ ] If YES, please state address:

WARRANTY

15. Please confirm that a copy of the warranty is provided on a separate sheet: YES [X]

DECLARATION

When reference is made to this form and its attachments within the process of obtaining the item, we agree that the purchaser will be entitled to rely upon the contents and subsequent non-compliance with the statements contained herein will entitle the purchaser to seek redress.

Name: Derek Lamb Signed: D Lamb Position: Director

Company Address: 15, Station Road

Viamed Ltd. Crosshills Keighley

West Yorkshire, BD20 7DT Date:

tyco Healthcare

Oximetry Monitor Warranty

All monitors are guaranteed against manufacturing faults and defects for a period of one year. They are not covered against misuse, accidental or wilful damage.

If your monitor should develop a fault within this period please contact our Technical Services Department on 01869 328000 to arrange a repair under our warranty scheme.

The provision of a loan monitor whilst a monitor is being repaired may be provided on request subject to availability.

Repairs under our warranty scheme are carried out free of charge.

Karl Brown
Marketing Manager
Monitoring
UK Medical Marketing Department