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:**	**860325**		
Generic Device Type:	**TraceMaster Vue**	Equipment Model:	860325
Country of Origin:	**USA**	Manufacturer:	**Philips Healthcare**
Supplier:	**Philips Healthcare**	Telephone No:	01483 792249
Fax No:	01483 298842	e-mail:	Healthcare@philips.com

CE MARKING

1. a) Does the product carry the CE marking? YES [√] 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 [√]

   If YES, state classification of device (93/42/EEC Annex IX) Class 1 Rule 1 Annex IX: 11b

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

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

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

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

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

   vi) Other Directive(s) (please specify)

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

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

   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 [√] NO [ ]

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

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

   If YES, please state the standard(s) and certification body: **ISO9001**

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*

SERVICE / SPARES / INSTALLATION

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

(Please state YES, NO or N/A)

Full circuit diagrams	**No**	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 [ ] Website [√] If Web, please state address: Incenter.medical.philips.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	**Yes**	Calibration	**Yes**
Planned preventative maintenance	**Yes**	Repair	**Yes**

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

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

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

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

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

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

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

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

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

c) i) If repairs are normally performed by the supplier on the purchaser's site, please state typical response time: **Next Working day**

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

Company: [ ] Location: [ ] Typical turnround time: [ ]

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

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

9. Please indicate when this model was first placed on the market: 2009

10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed? **5 years**

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

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

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

12. Will software upgrades be notified? **Details in service manual** N/A [ ] YES [√] NO [ ]

IONISING RADIATION

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

DECONTAMINATION / REPROCESSING

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

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

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

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

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

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

ii) What is the maximum temperature that can be used for thermal disinfection? Temp: [ ]

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

iv) Can the item withstand autoclaving at 137 ºC for 3 mins? YES [ ] NO [√]

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

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

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

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

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

WARRANTY

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

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: **Bob Childe** Position: **HI Sales Manager**

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Date: **3rd Dec 2010**