

## 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:		213.10278
A unique reference (preferably ten characters maximum) must be given by the supplier: Supplier's Reference:		
Supplier's Reference: 3410080		
Generic Device Type: Blanket for Patient Warming		Equipment Model: Barkey thermcare plus XPT
Country of Origin: Germany		Manufacturer: Barkey GmbH & Co. KG
Supplier:	Viamed Ltd	Telephone No: 01535 634542
Fax No:	01535 635582	E-mail: info@viamed.co.uk

### CE MARKING

1. a)	Does the product carry the CE marking?	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
b)	If YES, to which EC Directive(s):		
i)	Active Implantable Medical Devices Directive (90/385/EEC)	YES <input type="checkbox"/>	
ii)	Medical Devices Directive (93/42/EEC)	YES <input checked="" type="checkbox"/>	
If YES, state classification of device (93/42/EEC Annex IX)			
iii)	In Vitro Diagnostic Medical Devices Directive (98/79/EC)	YES <input type="checkbox"/>	
If YES, is the device: For self-testing? YES <input type="checkbox"/> Covered by Annex II: List A? YES <input type="checkbox"/>			
For ii) and iii) above, Identification No. of Notified Body, if applicable			
iv)	EMC Directive (89/336/EEC or superseding directive))	YES <input checked="" type="checkbox"/>	
v)	Low Voltage Directive (73/23/EEC)	YES <input type="checkbox"/>	
vi)	Other Directive(s) (please specify)		
2. a)	Is the product a 'custom-made device' (93/42/EEC)?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
b)	Is the product intended for 'clinical investigation' (93/42/EEC) or 'performance evaluation' (98/79/EC)?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
If YES to a) or b) above, does the device comply with the UK Medical Devices Regulations?			

### MANAGEMENT SYSTEM STANDARDS

3. a)	Is the manufacturer currently registered to any management system standards (eg ISO 9001, ISO 14001, ISO 13485)?	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
If YES, please state the standard(s) and certification body: ISO 9001 and ISO 13485			
b)	Is the supplier's service and repair organisation currently registered to any management system standards?	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
If YES, please state the standard(s) and certification body: ISO 9001 and 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

### 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	No	Preventative maintenance	Yes
	Repair information	Yes	Spare parts listing	Yes	List of special tools/test equipment/etc	No

If YES, please state whether also available on: Disk  Website  If Web, please state address

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	No	Calibration	No
	Planned preventative maintenance	No	Repair	No

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

c) Is the provision of service/repair information conditional upon completion of training?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
d) In order to undertake maintenance/repair/calibration, is any special software/test equipment/tooling required?	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
If YES, please indicate that details of special software/test equipment/tooling are provided on a separate sheet:		
7. a) Is the supplier able to provide an 'as required' repair/maintenance service in the UK?	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
b) Is the supplier able to provide a contract repair/maintenance service?	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
If YES, please confirm that details of repair/maintenance contracts are provided on a separate sheet.		
c) i) If repairs are normally performed by the supplier on the purchaser's site, please state typical response time:	YES <input checked="" type="checkbox"/>	
ii) If repairs are performed off-site, where will these be carried out?	7 Days	
Company: <b>Viamed</b>	Location: <b>West Yorkshire</b>	Typical turnaround time: <b>10 days</b>
iii) Is free of charge loan equipment normally available?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
8. Please state if repair parts will be available to the purchaser's or a third party's suitably trained and equipped personnel:	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
If YES, is the supply of repair parts conditional upon acquisition of repair information? YES <input type="checkbox"/> Or training? YES <input type="checkbox"/>		
9. Please indicate when this model was first placed on the market:	2007	
10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed?	7	
b) Is the product still in current production? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> If NO, indicate year of last manufacture:		
11. Is installation necessary?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
If YES, please confirm that details of all services required are provided on a separate sheet:		
12. Will software upgrades be notified?	N/A <input type="checkbox"/>	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
<b>IONISING RADIATION</b>		
13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
<b>DECONTAMINATION / REPROCESSING</b>		
14. a) i) Will the item be reprocessed (cleaned, disinfected, sterilised)? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> If NO, go to Question 15.		
ii) If YES, is the item intended to be: Non-sterile for single use <input type="checkbox"/> Sterilized <input type="checkbox"/> Disinfected <input checked="" type="checkbox"/> Other <input type="checkbox"/>		
iii) Is there a recommended maximum number of uses? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> If YES, please state: <input type="text"/>		
iv) Are decontamination/reprocessing instructions supplied?	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
v) Are instructions available for safe disposal?	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
b) i) Is manual cleaning the only cleaning method specified before further reprocessing?		
ii) What is the maximum temperature that can be used for thermal disinfection?	Temp: <b>N/A</b>	
iii) Are there any restrictions on detergent/disinfectant types? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> If YES, please state: <b>None oxygen releasing</b>		
iv) Can the item withstand autoclaving at 137 °C for 3 mins?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
v) Is the item compatible with other sterilization methods? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> If YES, please state: <input type="text"/>		
vi) Does reprocessing require the use of specified equipment?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
If YES, please state equipment type (eg containers, processors, etc) and, where appropriate, parameters of operation (eg temp, pressure, etc): <input type="text"/>		
c) i) Are tools required to aid dismantling/reassembly, or are lubricants required?	YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
ii) If YES, are they supplied with the device or available optionally?	Supplied <input type="checkbox"/>	Optional <input type="checkbox"/>
iii) If YES, are they supplied with the device or available optionally?	Neither <input type="checkbox"/>	
d) Is decontamination/reprocessing training available? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> If YES will this be: Free of charge? <input type="checkbox"/> Chargeable? <input type="checkbox"/>		
e) Are reprocessing instructions available on the Web? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> If YES, please state address: <input type="text"/>		

#### 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: Derek Lamb	Signed: 	Position: Director
Company/Address: 15, Station Road		Date:
Viamed Ltd, Crosshills Keighley		
West Yorkshire, BD20 7DT		