

Puritan Bennett 840 Ventilator

PRE-PURCHASE QUESTIONNAIRE

PROPOSED 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.

<i>For issue and completion by purchaser:</i> PPQ Master			
Reference: A unique reference (preferably ten characters maximum) must be given by the supplier:		Supplier's	003574/12-06
Reference:			
Generic Device Type:	NPB840 VENTILATOR	Equipment Model:	840
Country of Origin:	USA	Manufacturer:	NELLCOR PURITAN-BENNETT CORPORATION
Supplier:	Tyco Healthcare UK Commercial Ltd	Telephone No:	01329 224280
Fax No:	01329 224284	e-mail:	

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)

 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

 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:

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:

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:

<i>(Please state YES, NO or N/A)</i>	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

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

<i>(Please state YES, NO or N/A)</i>	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	<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:	YES	<input checked="" type="checkbox"/>		
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.	YES	<input checked="" type="checkbox"/>		
c) i)	If repairs are normally performed by the supplier on the purchaser's site, please state typical response time:	1 WORKING DAY			
ii)	If repairs are performed off-site, where will these be carried out?				
	Company: <input type="text" value="Tyco Healthcare"/> Location: <input type="text" value="Bicester, Oxon."/>	Typical turnaround time:		<input type="text" value="10 DAYS"/>	
iii)	Is free of charge loan equipment normally available? (SUBJECT TO AVAILABILITY)	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"/>			NO	<input checked="" type="checkbox"/>
9.	Please indicate when this model was first placed on the market:	<input type="text" value="1998"/>			
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 <input checked="" type="checkbox"/> NO <input type="checkbox"/> If NO, indicate year of last manufacture:				
11.	Is installation necessary?	YES	<input checked="" type="checkbox"/>	NO	<input type="checkbox"/>
	If YES, please confirm that details of all services required are provided on a separate sheet:	YES	<input checked="" type="checkbox"/>		
12.	Will software upgrades be notified?	N/A	<input type="checkbox"/>	YES	<input type="checkbox"/>
				NO	<input checked="" type="checkbox"/>
IONISING RADIATION					
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"/>
DECONTAMINATION / REPROCESSING					
14. a) i)	Is the item intended to be processed/reprocessed?	YES	<input checked="" type="checkbox"/>	NO	<input type="checkbox"/>
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="text"/>				
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 type="checkbox"/>	NO	<input type="checkbox"/>
b) i)	Is manual cleaning the only cleaning method specified before further reprocessing?	YES	<input checked="" type="checkbox"/>	NO	<input type="checkbox"/>
ii)	What is the maximum temperature that can be used for thermal disinfection?	Temp: <input type="text"/>			
iii)	Are there any restrictions on detergent/disinfectant types? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> If YES, please state: <input type="text" value="See instruction manual for"/>				
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 checked="" type="checkbox"/> NO <input type="checkbox"/> If YES, please state: <input type="text" value="Please see manual"/>				
vi)	Does reprocessing require the use of specified equipment?	YES	<input type="checkbox"/>	NO	<input 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 checked="" type="checkbox"/>	NO	<input type="checkbox"/>
ii)	If YES, are they supplied with the device or available optionally? Supplied <input type="checkbox"/> Optional <input type="checkbox"/> Neither <input checked="" 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	<input type="checkbox"/>		
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:	<input type="text" value="Teresa Keen"/>			Position: <input type="text" value="Contracts Assistant"/>	
Company/Address:	<input type="text" value="Tyco Healthcare (UK) Commercial Limited"/>				
	<input type="text" value="154 Fareham Road"/>				
	<input type="text" value="Gosport,"/>				
	<input type="text" value="Hampshire, PO13 0AS"/>			Date: <input type="text" value="19<sup>th</sup> December 2006"/>	



TECHNICAL SERVICES AND SUPPORT

For service you can count on

Test Equipment And Software Required for Service of 840 Ventilator

- PTS2000 Pneumatic Tester
- 840 VTS Ventilator Performance Test Software package
- 840 ventilator software downloader program
- Software Download Breakout box
- Laptop Computer including PCMCIA Serial and Ethernet cards
- 'Gold Circuit' Test Tubing
- Various Cabling and pneumatic connections.



TECHNICAL SERVICES AND SUPPORT

For service you can count on

Procedures Required During Installation

- Ventilator Cart Assembly
- Ventilator Modules Assembly into Cart
- Ventilator Warm Up Period
- Various Calibrations (Flow sensors, oxygen cell etc.)
- Extended Self Test
- Short Self Test (Includes patient circuit).