

PRE-PURCHASE QUESTIONNAIRE

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

PROPOSED EXTENDED FORM PPQ – June 2003

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.

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|---|-----------------------------|------------------|-----------------------------------|
| 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: | | | IHC010306 |
| Generic Device Type: | Air / Oxygen Blender | Equipment Model: | IHC 2003 & IHC 2004 |
| Country of Origin: | USA | Manufacturer: | Bio Med Devices Inc. |
| Supplier: | Inspiration Healthcare Ltd. | Telephone No: | + 44 (0) 116 235 1010 |
| Fax No: | + 44 (0) 116 235 0150 | e-mail: | info@inspiration-healthcare.co.uk |

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)
- ii) Medical Devices Directive (93/42/EEC)

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

- iii) In Vitro Diagnostic Medical Devices Directive (98/79/EC)

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)
- v) Low Voltage Directive (73/23/EEC)
- vi) Other Directive(s) (please specify)

YES YES

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 9001-1984 ISO 13485-2003 : BSI

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: ISO 13485: 2003 BSI

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 |
|----------|------------|--------------------|------|
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SERVICE / SPARES / INSTALLATION

5. Is service/repair information available? YES If NOT f.o.c. please state current price Indicate contents below:

| | | | | | | |
|-------------------------------|-----------------------|-----|-------------------------|-----|--|-----|
| (Please state YES, NO or N/A) | Full circuit diagrams | NA | 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:

| | | | | |
|-------------------------------|----------------------------------|-----|-------------|-----|
| (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

| | | | |
|-----------------------|--|--|--|
| Supplier's Reference: | | | |
|-----------------------|--|--|--|

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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: | | |
| 7. a) Is the supplier able to provide an 'as required' repair/maintenance service in the UK? | YES <input type="checkbox"/> | NO <input checked="" 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: | NA | |
| ii) If repairs are performed off-site, where will these be carried out? | | |
| Company: Inspiration Healthcare Ltd. | Location: Leicester | Typical turnaround time: 1-2 DAYS |
| 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"/> | NO <input checked="" type="checkbox"/> | |
| 9. Please indicate when this model was first placed on the market: | 1993 | |
| 10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed? | 10 | |
| 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 checked="" type="checkbox"/> | YES <input type="checkbox"/> NO <input type="checkbox"/> |

IONISING RADIATION

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| 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"/> |
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DECONTAMINATION / REPROCESSING

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|---|---|--|---|
| 14. a) i) Is the item intended to be processed/reprocessed? | 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 checked="" type="checkbox"/> | Disinfected <input checked="" type="checkbox"/> |
| iii) Is there a recommended maximum number of uses? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> | If YES, please state: | | |
| 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? | YES <input checked="" type="checkbox"/> | NO <input type="checkbox"/> | |
| ii) What is the maximum temperature that can be used for thermal disinfection? | Temp: NA | | |
| iii) Are there any restrictions on detergent/disinfectant types? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> If YES, please state: | | | |
| iv) Can the item withstand autoclaving at 137 °C for 3 mins? | YES <input type="checkbox"/> | NO <input type="checkbox"/> | <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: | | | |
| vi) Does reprocessing require the use of specified equipment? | YES <input type="checkbox"/> | NO <input checked="" type="checkbox"/> | |
| If YES, please state equipment type (e.g. containers, processors, etc) and, where appropriate, parameters of operation (e.g. temp, pressure, etc): | | | |
| 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 checked="" type="checkbox"/> | 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: | | | |

WARRANTY

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| 15. Please confirm that a copy of the warranty is provided on a separate sheet: | YES <input checked="" type="checkbox"/> (In Manual) |
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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.

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| Name: SIMON MOTLEY | Position: DIRECTOR |
| Company/Address: UNIT 14 BARSHAW PARK, LEYCROFT ROAD, BEAUMONT LEYS LEICESTER LE4 1ET, UK | Date: 1st MARCH 2008 |