

**PRE-PURCHASE QUESTIONNAIRE**

**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 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: <b>PPQ Master Reference:</b>			
A unique reference (preferably ten characters maximum) must be given by the supplier: <b>Supplier's Reference:</b>		3102000	
Generic Device Type:	RESPIRATORY THERAPUTIC	Equipment Model:	FLUTTER
Country of Origin:	USA	Manufacturer:	SCANDIPHARM Inc.
Supplier:	Clement Clarke Int. Ltd	Telephone No:	01279 414969
Fax No:	01279 635232	e-mail:	<a href="mailto:info@clement-clarke.com">mailto:info@clement-clarke.com</a> Web: <a href="http://www.clement-clarke.com">www.clement-clarke.com</a>

**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 I**

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: **ISO 9001**

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 9001, ISO 13485 - SGS (UK) Ltd**

**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		Fault finding procedure		Preventative maintenance	
Repair information		Spare parts listing		List of special tools/test equipment/etc	

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	N/a
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

Supplier's Reference:

- 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:   
ii) If repairs are performed off-site, where will these be carried out?  
Company:  Location:  Typical turnaround 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:
10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed?   
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? 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 °C 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:	P Hallybone	Position:	Quality Manager
Company/Address:	Clement Clarke Int. Ltd, Edinburgh Way, Harlow, Essex CM20 2TT		
Date:	14/10/03		

## **Additional Information**

### **Warrantee**

This product is supplied with one-year parts and labour guarantee against faulty workmanship or defects.