PRE-PURCHASE QUESTIONNAIRE **FORM PPQ – January 2002**

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:	Itouch Sure		
Equipment Description / Model:	Single Channel EMS Unit		
Country of Origin:	China	Manufacturer:	Tenscare Ltd
Supplier:	Tenscare Ltd		
Telephone No:	01372 723434	Fax No:	01372 745434

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): IIA

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

   If YES, is the device: (a) For self-testing? YES ☐

   (b) Covered by Annex II List A? YES ☐

   (c) Covered by Annex II List B? YES ☐

   (d) None of the above? YES ☐

   For ii) and iii) above, Identification No. of Notified Body, if applicable: 0473

   iv) EMC Directive (89/336/EEC) 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, EN 46001)? YES ☒ NO ☐

   If YES, please state the standard(s): ISO 9001 EN46001

   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):

SAFETY STANDARDS

4. For devices 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*

For Supplier's Reference:
Itouch Sure

SERVICE / SPARES / INSTALLATION

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

(please answer YES, NO or N/A)

Full circuit diagrams	YES	Fault finding procedure	N/A	Preventative maintenance	N/A
Repair information	N/A	Spare parts listing	YES	List of special tools/test equipment/etc	N/A

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 answer 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 which is able to provide this training are available on request? YES ☐ NO ☐

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: [5 days]

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

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 ☐

9. Please indicate when this model was first placed on the market: 2001

10. For how many years from the date of last manufacture is the supply of spare parts guaranteed? [7 Years]

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? NOT APPLICABLE YES ☐ NO ☐

RADIOACTIVE EMISSIONS

13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation? YES ☐ NO ☒

DECONTAMINATION

14. Does decontamination/sterilization require the use of specific equipment? YES ☐ NO ☒

If YES, please state equipment type and parameters of operation (eg temperature, pressure, etc):

[ ]

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:	Andrew Brown
Position:	Sales Manager
Company:	Tenscare Ltd
Address:	9 Blenheim Road Epsom, Surrey KT19 9BE

[Date] 17th January 2010