

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: 2572	
A unique reference (preferably ten characters maximum) must be given by the supplier: Supplier's Reference: 04000-600	
Generic Device Type: Tympanic Ear Thermometer	Equipment Model: Braun 04000-600
Country of Origin: Germany	Manufacturer: Braun
Supplier: Welch Allyn	Telephone No: 0207 365 6780
Fax No: 0207 365 9694	e-mail: ukorders@welchallyn.com

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) **IIB**

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 **0297**

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 13485, 2003 DQS**

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 DQS**

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	YES	Preventative maintenance	YES
	Repair information	YES	Spare parts listing	NO	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	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 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) Will the item be reprocessed (cleaned, disinfected, sterilised)? YES NO If NO, go to Question 15.
 ii) If YES, is the item intended to be: Non-sterile for single use Sterilised 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:	<i>D. H. W.</i>	Position:	<i>CS</i>	
Company/Address:	Welch Allyn UK Cublington Road, Aston Abbots, Bucks, HP22 4ND		Date:	<i>28/6/2010</i>

Additional comments on PPQ

WARRANTY

Welch Allyn warrants Braun 4000 Unit when new, to be free of defects in material and work-manship and to perform in accordance with manufacturer's specifications for a period of 2 years from the date of purchase from Welch Allyn or its authorized distributors or agents. Welch Allyn will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the customer. It shall be the purchaser's responsibility to return Braun 4000 Unit to Welch Allyn or an authorized distributor, agent or service representative. This warranty does not include breakage or failure due to tampering, mis-use, neglect, accidents, modification or shipping. This warranty is also void if the instrument is not used in accordance with manufacturer's recommendations or if repaired by other than Welch Allyn or an authorized agent. Purchase date determines warranty requirements. No other express warranty is given.

6d) Special Tools

The accuracy of infrared thermometers can only be tested with a blackbody device (BB-3200 Series, no longer available for purchase) or the 9600 PLUS Calibration Tester.

The Model 9600 PLUS Calibration Tester can be ordered through Welch Allyn Customer Service (see page 8) for Welch Allyn contact information.

<u>Model</u>	<u>Welch Allyn P/N</u>	<u>Braun P/N</u>
9600 PLUS Calibration Tester	01802-110	N/A

The blackbody has to be calibrated every 18 months by the manufacturer. Contact Welch Allyn Customer Service to get a Return Material Authorization number to have your unit calibrated. Refer to Customer Service Listing (see page 8) for Welch Allyn contact information.

10a)

Welch Allyn guarantees Product Supportability for a standard period of minimum 5 years from the date of last manufacture. During this period Welch Allyn cannot guarantee the availability of each individual repair part, but in case will ensure that appropriate alternative parts, components and/or solutions are made available. Beyond this standard period, Welch Allyn will continue to provide repair parts and support services on a best effort basis.

Care and cleaning

Braun ThermoScan probe covers are intended for single use only!

To ensure accurate measurements, always use Braun ThermoScan disposable probe covers with the Pro 4000 thermometer. Damaged, perforated, or soiled probe covers can lead to inaccurate temperature measurements. Additionally, the accuracy of your temperature measurement can be affected by damage to the probe window, or the presence of dirt or cerumen on the probe window.

Probe Window

To assure a high level of accuracy, it is very important to keep this window clean, dry and undamaged. Fingerprints, cerumen, dust and other soiling compounds reduce transparency of the window and result in lower temperature measurements. If the thermometer is accidentally placed in the ear without a probe cover installed, the window must be cleaned immediately. Additionally, the window and/or probe tip area should never be modified, changed, or adjusted. These changes will affect calibration and accuracy of the thermometer.

To clean the window, gently wipe its surface with a cotton swab slightly moistened with alcohol and immediately wipe dry with a clean cotton swab. After cleaning, allow at least 5 minutes drying time before taking temperatures. Make sure probe window is clean and dry. Avoid touching the window except when cleaning is required. If the window is damaged, the thermometer must be returned to Welch Allyn for service.

Note: Do not use any chemical other than alcohol to clean the probe window.

Thermometer

Use a soft cloth slightly moistened with alcohol to clean the thermometer display and exterior. Do not use abrasive cleaners. Never submerge the thermometer in water or any other liquid. Store thermometer and probe covers in a dry location (the thermometer is not protected against ingress of water), free from dust and contamination and away from direct sunlight. The ambient temperature at the storage location should remain fairly constant and within the range of 50 °F to 104 °F (10 °C to 40 °C).

Appliances with readings outside the permissible range where the probe tip is contaminated can be cleaned carefully with a cloth soaked with alcohol. After cleaning wait at least 5 minutes before retest.