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:**	2087632
A unique reference (preferably ten characters maximum) must be given by the supplier: **Supplier's Reference:**	PPQ-CAS 740

Generic Device Type:	Vital signs Patient Monitor	Equipment Model:	CAS 740 NIBP-NIBP/SpO2-NIBP/SpO2/Temp Monitor
Country of Origin:	USA	Manufacturer:	CAS
Supplier:	Artemis Medical Ltd	Telephone No:	01322 628877
Fax No:	01322 628878	e-mail:	info@artemismedical.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) 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 0086

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: EN46001:1996, ISO 13485:1996, ISO 9001:1994

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 9001:2000

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 £50.00 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	YES	List of special tools/test equipment/etc	YES

If YES, please state whether also available on: Disk YES Website NO 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	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:	PPQ-CAS 740

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: N/A – return to base

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

Company: Artemis Medical Ltd Location: Dartford Typical turnround time: 7-10 days

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: 2003

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 [ ] 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 [ ] Sterilized [ ] Disinfected [✓] Other See Append 1

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: NA

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: NA

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):

NA

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: David Stow Position: Managing Director

Company/Address: Artemis Medical Ltd
Butterly Avenue, Questor Business Park, Dartford, Kent. DA1 1JG Date: 14 December 2005

Append 1
CLEANING/ DECONTAMINATION
CLEANING OVERVIEW
CAUTION:
Do not open the monitor to clean or repair it. Contact CAS Medical System for service needs.
WARNING:
Do not, under any circumstances, perform any testing or maintenance on the monitor while the monitor is being used to monitor a patient.
CAUTION:
Unplug the monitor from the AC power source and remove all the accessories from the monitor before cleaning. The monitor must be turned off and not running on the internal battery. Never clean the monitor when it is being operated.
THE MONITOR
On a daily basis, examine the monitor's case for any damages and check the AC power cord for bent or broken prongs, cracks or fraying. Neither the monitor nor the power cord should be used if damaged. If any damage is noted, contact the appropriate service personnel.
CAUTION:
Do not spray any water or cleaning solution directly onto the monitor.
Every three (3) months, or as needed, clean the monitor using a soft cloth dampened with a mild dishwashing detergent solution and gently rub the soiled area until clean. Use a clean soft cloth to dry the monitor. DO NOT use abrasive cleaners on the monitor. DO NOT use either isopropyl alcohol or solvent to clean the monitor. Use of these cleaners can cause damage to the monitors' surface. DO NOT immerse the monitor or power cord in the cleaning solution.
When necessary, the monitor surfaces may be disinfected using a soft cloth saturated with a 10% (1:10) solution of chlorine bleach in tap water. When all of the surfaces have been disinfected, wipe the entire surface of the monitor using a soft cloth dampened with fresh water to remove any trace amounts of residue and/or fumes.
NOTE:
Thoroughly wipe off any excess cleaning solutions. Care should be taken to prevent water or cleaning solution to run into connector openings or crevices.
CAS 740 Monitors
THE DISPLAY
CAUTION:
Use care when cleaning the display. Scratches may occur.
Occasionally, as needed, clean the display window using a soft, lint-free cloth sprayed with an alcohol free glass cleaner. DO NOT use either isopropyl alcohol or solvent to clean the display. Use of these cleaners can cause damage to the display. The use of paper towels is not recommended as it may scratch the surface.
CUFFS AND SENSORS
Prior to each patient use, inspect the blood pressure cuffs, SpO_2 finger sensor and cables for damage. The blood pressure cuffs and finger sensors should periodically be cleaned following the manufacturers' instructions for the particular item in use.
CAUTION:
Do not sterilize the sensors by steam or any other method or solution. Do not immerse the sensors in water or cleaning solution.
NOTE:
Refer to the documentation enclosed with each accessory for any additional sterilization or disinfection instructions.
PNEUMATIC TUBING
Prior to each patient use, inspect the NIBP Inflation Hose for proper connection, cracks and kinks. As necessary, clean the pneumatic tubing using a soft cloth dampened with a germicidal solution.
PRINTER
When the printer becomes dirty, wipe with a soft dry cloth. For extreme dirt buildup, soak a cloth with mild detergent, wring well and wipe. Dry by wiping with a soft dry cloth.
CAUTION:
Before cleaning the printer, disconnect the AC adapter from the printer.
Do not use volatile chemicals such as thinner, benzine, etc.
Never wet the inside of the printer mechanism.
Refer to the printer User's Manual for more information.

WARRANTY POLICY
MONITORS (CAS 740)

Warranty excludes accidental and malicious damage. Warranty void if main unit has been opened without prior written authorisation by Artemis Medical. Authorisation will generally only be granted when suitably qualified Trust bio-med personnel have received technical training by Artemis Medical or CAS. Minimum qualification for technical training is HNC/ONC (or equivalent) in Medical Electronics or similar.

CAS Medical Systems, Inc. warrants the monitor, when new, to be free from defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of two (2) years from the date of original purchase from CAS or its authorized distributors or agents except as noted below. The same warranty conditions are made for a period of one (1) year with respect to printers and battery and ninety (90) days on non-disposable accessories and certain components consisting of reusable SpO_2 sensors, reusable temperature probes and other accessories provided by CAS as part of the original purchase. CAS warrants blood pressure cuffs and disposable or single-patient-use products for out-of-box failure only. Where the accessory is not a CAS manufactured product, the manufacturers own warranty conditions apply.
CAS reserves the right to perform warranty service operations in its own factory, at an authorized repair facility, or at the customers' site.
Our obligation under this warranty is limited to repairing or, at our option, replacing any defective parts or our equipment, without charge, if such defects occur in normal service and with prompt notification.
Damage to any part through misuse, neglect, or accident, or by affixing any accessories or attachments other than CAS, Masimo®, Nellcor®, Nonin®, and Welch Allyn® manufactured accessories or attachments, is not covered by this warranty.

ACCESSORIES, BATTERIES, CUFFS, AND CERTAIN COMPONENTS

In all cases, policy applies from date of purchase from CAS or its authorized distributors or agents.
Accessories: Ninety (90) Days - Masimo, Nellcor and Nonin Sensors, Welch Allyn Temperature Probes.
Batteries: One (1) Year
Cuffs (all): Out-of-box failure only.
External Printer: One (1) Year
Other Accessories: Out-of-box failure only.
THERE ARE NO WARRANTIES, WHICH EXTEND BEYOND THOSE EXPRESSLY DESCRIBED IN THIS AGREEMENT AND THE COMPANY MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Service Tools

A Calibration Kit, is included with the monitor. The kit contains a T-connector with a male and a female luer fitting (for a Calibration Check) and a male luer plug (to be used for the Pneumatic Check).
Obtain a mercury/electronic manometer whose accuracy meets the AAMI/ANSI Standard for Non-Automated Sphygmomanometers, 1994.

Temperature Calibration Key
SpO_2 Simulator (Masimo Tester Pn: 1593)
Fixed volume 500 ml Pressure Cylinder (CAS p/n 01-02-0248).

Service Contract Prices – January 2005

CAS 740 Patient Monitor
Minimum 2 year contract term

	1 annual visit	2 annual visit	Call out insurance (Single payment covers 2 years)	Spare parts Insurance (Single payment covers 2 years)
CAS 740-1 (NIBP)	£42.00	£42	£32.00	£34.00
CAS 740-2 (NIBP/SpO_2)	£42.00	£42	£32.00	£45.25
CAS 740-3 (NIBP/SpO_2/Temp)	£42.00	£42	£32.00	£62.90
On-Site Attendance Fee (per site visit only, not per unit)	£147.00			

Notes:
1. All accessories supplied during annual service visits will be charged for in addition: e.g. Cuffs and hoses etc
2. Internal battery to be changed on 2nd annual visit at an additional charge.

Non-contract charges:
Call out: £180 (includes fault assessment and addressing any "finger" problems e.g. monitor not plugged in, faulty sensor etc)
Hourly charge: £100 per hour first hour, £110 per hour thereafter, charged in 30 minute increments
All prices exclude VAT