Appendix 6 – Medical Devices & Equipment Replacement Application Form

Complete this form to request consideration for purchase of medical equipment replacement needs only. This form does not apply to requests for purchase of equipment required for expansion of existing services or the provision of new clinical services.

Existing Equipment Description:	**Asset Number(s):**
Directorate/Department:	
Name of Head of Department	**Contact No:** **Email Address:**
Outline the reason for request:	
Is the device a replacement?	□YES □NO

If yes give medical devices product name and details below What is the estimated purchase price including VAT? Will there be an additional installation required and what cost? **If yes give details below** If replacing an existing piece of equipment, will the old equipment be decommissioned? **If not, give the reason:**	□YES □NO YES □NO
a) Clinical Requirements:	
• What impact does this device have on existing clinical practices? • List the general profession of key users (e.g. nurses, doctors, physiotherapists, etc.)	

Will there be any change to the number of clinical procedures carried out (e.g. increased patient through-put) if this piece of equipment is not replaced? **Give details of any significant changes below**	□YES □NO
b) Installation:	
Does the device require additional services (e.g. water, power, ventilation etc..)?	□YES □NO
Does the device require any IT interface to the IT network?	□YES □NO

Does the device require storage space on the IT network/server?	□YES □NO
Are further safety measures required?	□YES □NO
If you have answered yes, to any of the questions in **b)** above please provide details.	
c) Consumables:	
Does the device require consumables of a type not currently purchased by Procurement?	□YES □NO
Are generic consumables available or must consumables be purchased from the equipment supplier?	□YES □NO
What is the total expected annual consumable Cost (incl. of VAT)?	**£**
d) Maintenance/Licensing:	
Are there any additional operating costs (e.g. Preventative Maintenance Checks/Calibration as per manufacturers' recommendations)?	□YES □NO
Will this equipment require a service contract?	□YES □NO
Is there an annual validation requirement?	□YES □NO
Is there a recurring software license fee?	□YES □NO
If you have answered yes, to any of the questions in d**)** above please provide details.	

e) Cleaning and Decontamination:	
Who will be responsible for cleaning the equipment?	
Will any equipment components require decontamination – if so state decontamination requirements?	
Is there sufficient capacity and skill within current services to carry out the decontamination? If not, please provide details of your proposal to decontaminate the equipment.	
Has funding been sought/received from other sources? **If yes, give details:**	□YES □NO

Cost Assessment	**Amount (£)**
Cost of equipment incl. VAT	
Warranty period	___Years
Estimated cost of annual maintenance contract	

Estimated change in consumable costs from current	
Estimated change in cost of annual validation, if applicable?	
If additional facilities required (test equipment, water, power, ventilation etc.) – state estimated cost	
Total Estimated Cost	**(£)**

For Clinical Services, this form must be signed by the Head of Department and Clinical Services Manager.

Name:

Signed:_____Date: _____

Name:

Signed:_____Date: _____

Reviewed by Medical Devices Group
□ Yes □ No □ Not Applicable

Chair Name:
Signed:_____Date: _____

Approval No. (if applicable): _____ Date: _

Comments:
Signature:

Note: Approval is valid for 12 months.

PRE-PURCHASE QUESTIONNAIRE (PPQ Form)

The purpose of this questionnaire is to support the pre-acquisition assessment and approval of proposals to procure Devices and accessories under purchase, exchange, rental, lease, loan, donation or other agreements. Please ensure that all relevant sections have been completed and that all supplementary information requested has been provided.

(Note: The term 'Devices', as used here, includes equipment and systems; in the case of systems the requirements below apply both to the individual constituent Devices and to the configured system as a whole.)

Product Description:			
Type:	Make:		
	Model:		
Manufacturer:			
Supplier:		PRODUCT DETAILS: (*Manufacturer, Supplier, or other)	

1 a) When was this Model first placed upon the market?

b) Is this Model still in production? YES ☐ If not, when did production cease? ☐ NO☐

c) Any outstanding Field Safety Corrective Actions / Field Safety Notices? YES ☐ If YES, details attached? ☐ NO☐

d) Has a product brochure and specification been attached to this return?

e) Does this return cover a range of Model variants and / or Accessories? YES ☐ If YES, all item details attached? ☐ NO☐

Appendix 7 – Disposal of Medical Devices Standard Operating Procedure

Purpose

This SOP has been produced for all those who are responsible for the management of single-use and reusable medical devices when the devices are no longer required This is to ensure all medical devices are replaced as/when required and used devices are disposed of in line with waste regulations. Disposal must comply with relevant Health and Safety legislation, local directives and WEEE legislation. Medical devices must always be decontaminated before reuse, relocation, sale, donation or disposal.

Who does the procedure apply to?

- Authorised Staff of diagnostic and therapeutic equipment
- Ward/Department Managers

When should the procedure be applied?

- When a medical device requires replacing: it has passed its life expectancy or spare parts are unavailable
- When a medical device is condemned
- When a medical device needs to be disposed of

How to carry out this procedure:

Notification

When a medical device has passed its life expectancy or unavailability of spare parts but is still usable, the contracted engineer will issue the user with a Notification Form.

This is to inform the user that the device will need replacement and if the contracted company is able to replace this device they shall replace it, where the contracted company is not able to replace the devices, this shall be raised with the Medical Device Lead.

This device can still be used until the stated date.

Condemnation

When a medical device is permanently removed from use, servicing engineer will issue the user with a Condemnation Certificate and the user shall forward the certificate to the Medical Device Lead who will arrange for removal. The Condemnation Certificate will be signed by the condemning engineer and countersigned by service manager or Clinical Lead for that service when the device has been physically removed from service. A Condemnation Certificate will be issued for one of the following criteria:

- worn out beyond economic repair
- damaged beyond economic repair
- unreliable through service history
- clinically or technically obsolete
- spare parts no longer available when a repair is required
- unable to be cleaned effectively prior to disinfection and/or sterilisation
- a device identified in accordance with MPCE local procedure

Once a Condemnation Certificate has been issued under no circumstances must the device be brought back into service?

Disposal

Disposal of medical devices can be arranged through Hilditch Group in line with the guidance of MHRA Managing Medical Devices 2014. The service shall email the medical device lead and inform them about devices to be disposed. They should include the condemnation certificate. Medical device lead shall arrange for the disposal of the condemned devices. For medical devices with patient identifiable information managers should ensure that all patient identifiable data is securely and correctly removed/deleted from the equipment prior to disposal. The Trust has a duty to maintain the security and confidentiality of patient information.

Devices will be either transferred to a Trust approved auctioneer or waste disposal agent in compliance with all national and legal requirements (WEEE regulations) for safe environmental disposal of the device(s).

Condemned devices should be disinfected and packed per infection control protocol

Staff should remove all Trust identifiable labels attached to the medical devices before they are removed from Trust premises for disposal or sale through an approved auctioneer.

What do these terms mean?

WEEE – Waste Electrical and Electronic Equipment regulations apply to the disposal of medical devices to ensure:

- Waste arising from these products is minimised and their re-use is promoted
- The waste products are treated and meet recovery and recycling targets for the waste materials

Medical device management includes a wide range of activities:

- Advice and assistance with equipment evaluation prior to purchase
- Help with Deciding on the model that most fits the user department needs
- Preparation ready for implementation of the device which includes commissioning the equipment and training the staff how to use it
- Technical and clinical support of the equipment and staff during its lifetime
- Planned end of life replacement correct disposal of the old equipment

MHRA – Medicines and Healthcare products Regulatory Agency is a government body, which was set up in 2003 to bring together the functions of Medicines Control Agency (MCA) and Medical Devices Agency (MDA). These include the regulation of medicines and medical devices and equipment used in healthcare and the investigation of harmful incidents.