Policy for the Management of Medical Devices (V5)

Medical Device Procedures

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META DATA

TITLE	Policy for the Management of Medical Devices Medical Device Procedures
Date:	November 2011
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Created by:	Medical Devices Manager
Source:	Medical Devices Committee
Stored Centrally:	Trust Intranet
Linked Trust Policies and Documents:	Medical Devices Policy Standing Financial Instructions Procurement Strategy Decontamination Policy Point of Care Testing (POCT) Policy and Procedures Incident Reporting Policy and Procedure CAS Procedure Medical Engineering Quality Management System

1 INTRODUCTION

The procedures described in this document apply to :

- All medical staff, nursing staff and allied health professionals
- All staff who are involved in the purchase, use and maintenance of any medical device.

2 PROCUREMENT OF NEW MEDICAL DEVICES (Appendix 1)

The process to be followed in the procurement of a new medical device is illustrated at **Appendix 1.**

Prior to completion of the web-based procurement form and the relevant business case proposal forms (**Appendix 1**) the following must be considered:

Funding – Capital and revenue resources must be sufficient with adequate provision for installation, user training, maintenance, consumables and final disposal.

Specification – Functional requirements should be defined in detail. They shall refer to applicable legislation, standards and guidelines. Service manuals should be purchased with re-usable medical devices.

Standardisation & Maintainability – In general all medical devices must be standardised, and chosen from a list of devices approved by the Trust. This ensures inter-changeability, ease of staff training, availability of spare parts, and more cost effective contracts. When a non-standard medical device is required, the reason and choice must be justified and account taken of all relevant issues (function, compatibility, cost and compliance with directives). The decision on whether a non-standard medical device is acquired rests with the Medical Devices Committee, **NOT** with the end-user of that device. Compatibility with existing medical devices and facilities should be achieved wherever possible (use must be made of standard devices), after discussing the legal issues with the Specialist Buyer within Procurement.

To reduce risks arising from inadequate user training, medical devices intended for common applications must be standardised. Other common medical equipment types should also be standardised to reduce costs. The Trust's Medical Devices Group will select and maintain a list of standard medical equipment, specifying up to 3 models for each common area of application within the Trust. The selection process will involve representation from Medical Engineering, appropriate clinical users and directorate procurement managers. Requisitioners of medical equipment should contact Medical Engineering for information on current standard models. All requisitions for electrically operated medical equipment will be forwarded to Medical Engineering to ensure compliance with this policy.

Requests for alternative models to those on the standard medical equipment list will be considered by the Medical Devices Committee, taking into account clinical requirements and risks, technical specification and purchase and consumable costs. The Procurement Department will only proceed with the purchase of alternative models with the agreement of the Medical Devices Committee.

Selection – Final selection of a medical device should be made in close consultation with those responsible for its use, taking into account relevant technical and financial information. This will include lifetime costs (e.g. training, maintenance and consumables) warranty provision and the availability of technical support and service manuals. Budget Managers must confirm with their Finance link that any maintenance costs are affordable and within budget. The purchaser may set other specific performance criteria with the supplier against which the medical device will be judged before it is accepted, for example, reusable devices must be capable of being decontaminated using available facilities.

CE Mark – Only CE marked devices should be purchased. The CE (European Community) mark is a declaration by the manufacturer that the device meets the essential requirements of all relevant European Directives.

Safety and performance - Before an order is placed, prospective suppliers of medical equipment to the Trust will be required to demonstrate that their equipment is safe and suitable for its intended purpose and that it can be cleaned and decontaminated adequately between patient episodes. Information on compliance with relevant technical standards, EC directives and decontamination methods will be requested by the Procurement Dept. through use of the Pre-purchase Questionnaire (PPQ) for scrutiny by Medical Engineering. This process will also ensure that the supplier is able to provide continued technical support following purchase. Medical equipment supplied to the Trust must meet the essential requirements of the Medical Devices Directive (93/42/EEC). The PPQ procedure is not normally required where the Procurement Department already holds an approved PPQ from a previous purchase of an identical model e.g. for standardised equipment.

All new medical devices are legally required to comply with EU directives and the relevant UK legislation for performance and safety. Medical Engineering **MUST APPROVE ALL EQUIPMENT**.

Acceptance and commissioning – Acceptance checks must be carried out however devices are acquired. Acceptance checks will be carried out by Medical Engineers on all reusable medical devices that are new to the Trust and device details will be entered in the equipment database (asset register). It is the responsibility of the first time user to ensure that acceptance checks have been carried out. Users should consult Medical Engineering in the first instance for guidance where electrically active devices are involved. Delivery must be made to Medical Engineering, with the only exception being large pieces of equipment.

Any equipment that is delivered direct to a clinical area must be quarantined until acceptance testing has been carried out by Medical Engineers, and not used until certification of acceptance is issued by them.

IT and building services requirements - Some types of medical equipment include standard computing devices (e.g. a PC) or have a requirement for network connections or data storage. Proposals to buy such equipment should be referred to the IT Department to ensure that these requirements can be met and that the equipment is compatible with existing Trust IT equipment.

Additional services - Equipment which may consume significant electrical power or require connection to other mains services such as water or medical gases, or require environmental control (e.g. air conditioning) should be referred to the Estates Directorate.

Ionising radiations - For equipment which generates ionising radiation, it is the duty of the installer to carry out a critical examination of the radiation safety features of the equipment in accordance with the Ionising Radiations Regulations 1999 (IRR99). Medical Engineers will carry out acceptance tests on behalf of the Trust. For further advice on radiation safety, users should contact the Radiation Protection Adviser.

3 MANAGEMENT OF MEDICAL DEVICES

The process for the management of medical devices is illustrated at **Appendix 2**.

3.1 Incident reporting

If an incident occurs which involves a medical device it is the responsibility of the staff to report the event in line with the Trust Incident Reporting Policy. The medical device should be removed from the patient immediately / at the earliest opportunity. Details must be recorded in the clinical notes. The person reporting the incident should record details of the equipment involved and isolate the equipment in a secure environment until further notice. The equipment must be clearly labelled with all consumables in place and settings unchanged. If the device cannot be moved a notice should be placed on it warning against using it. Those incidents where a medical device contributed to the incident will be reported to the MHRA. Where device malfunction is suspected, the equipment and accessories should be referred to Medical Engineering for investigation, accompanied by a job request and a copy of the incident report form.

This process should also be followed where a drug error has occurred and when a medical device was involved with the administration of the drug (e.g. IV via syringe driver). Equipment should be quarantined until it has been checked by Medical Engineering and its release authorised.

All equipment should be decontaminated according to Trust guidelines prior to removal from the clinical area.

3.2 CAS reporting

The Central Alert Safety reporting System (CAS) is an electronic system developed by the Department of Health, with the MHRA, NHS Estates and the National Patient Safety Agency (NPSA). Specific types of safety alerts are emailed to Trusts for processing at a local level. The Health and Safety Department undertakes this activity for the Trust which involves dissemination, central recording of responses, monitoring of responses and updating the CAS website of Trust compliance. It is absolutely essential that Groups respond in a timely fashion to the Health and Safety Department about CAS alerts. See CAS Policy

3.3 Decontamination of medical devices

The Decontamination Policy provides an appropriate, rational and cost effective basis for the control of microbial contamination of medical devices and the environment within Trust premises, additionally highlighting responsibilities for maintaining a safe environment. It is the user's responsibility to ensure that equipment is cleaned according to protocol after use and before being sent to maintenance departments for repair. Please refer to the Trust's Decontamination Policy for further details and guidance.

3.4 Modification of medical devices

No medical device is to be customised without formal agreement from the Medical Devices Committee and the knowledge and agreement of Medical Engineering.
Modifying or using medical devices for purposes not intended by the manufacturer "off label use" has serious safety implications and liability may be partly or wholly transferred to the person or organisation making the modifications if the device is implicated in an incident.

3.5 Construction of New and Novel Medical Devices

Medical Devices constructed in or custom made for the Trust must receive approval before clinical use. Approval is obtained through the Medical Devices Committee. Transfer of ownership to a separate legal entity of any working medical device designed, constructed, modified or manufactured by the Trust is equivalent to putting the medical device on the market. Such transfers shall not be made unless the Medical Devices Committee approves the transfer and the transferee accepts the arising liabilities.

3.6 Re-use of Medical Devices

Current general guidance from the Medicines and Healthcare products Regulatory Agency is contained in DB2006 (04). In the key points summary, it states *'a device designated for 'single use' must not be reused under any circumstances'*. This is consistent with the Department of Health Service Circular 1999/179, action point (iv) *'never re-use medical devices designated for single use'*.

Devices labelled as "single use" must be used within the marked "use by" date and this must be checked prior to use. Packaging must be checked to ensure sterility and damaged packs or devices must not be used.

3.7 Diagnostic Medical Devices

Medical devices used for quantitative measurements, including those used for point of care testing, need to be CE marked for this purpose. Diagnostic medical devices may not be suitable for use with all patients and medical conditions. Instructions should be consulted and specific training and advice obtained before use. Further specific information on point of care testing devices is within the Trust's Point of Care Testing Policy.

3.8 Maintenance & Repair

Maintenance and repair of medical equipment is the responsibility of the Trust's Medical Engineers and is performed in accordance with their Quality Management System. Procedures described in the Quality System include scheduled preventative maintenance, repair of faulty equipment and retention of maintenance records. Planned maintenance schedules and details of all maintenance, repairs and calibrations performed by Medical Engineers are recorded in the relevant equipment database.

Where directorates have external contracts for maintenance the contract should represent good value for money and managers should ensure that contracted work is carried out satisfactorily. Advice on maintenance contracts is available from Medical Engineering and the Trust's Procurement Department.

When malfunction of an item of medical equipment is identified or suspected, the item should be removed from service immediately and labelled clearly to prevent further use. The user department should ensure that the item is referred to its normal maintenance agency for testing or repair. All items for repair must be accompanied by a completed Decontamination Status Certificate. Copies of the Decontamination Status Certificate are available from the Medical Devices website on the intranet.

3.9 Replacement

The Trust makes provision for capital replacements including medical and scientific equipment as part of the annual block allocation, approved by the Capital Prioritisation Group. Replacement of equipment not possible due to funding issues should be placed on the relevant risk register. (Please see Risk Management Policy for further details)

3.10 Disposal

Disposal of medical devices will have financial and environmental implications. Medical devices may also create safety hazards when disposed of incorrectly. Disposal must comply with relevant Health & Safety legislation, European Union Directives and WEEE legislation. The relevant asset register holder must be informed of any disposal.

Medical equipment which is worn out, broken or damaged beyond safe or economical repair must be removed from the Trust and scrapped. Equipment which is clinically or technically obsolete or surplus to requirements may still have some residual value. Such equipment should be disposed of in a way which maximises the financial return to the Trust as required by financial regulations. This may involve trading in for new equipment or selling through tender or auction. In some circumstances, it may be useful to retain technically obsolete equipment as a back up to new equipment where it is safe to do so. For information and advice contact Finance and/or Medical Engineering.

When equipment is disposed of through an internal maintenance department it will be recorded as disposed. When equipment is disposed of directly by the user (e.g. traded in or scrapped), the relevant maintenance department should be informed. When capital items of equipment are disposed of, the finance department must be informed.

3.11 Records

The Trust will keep records of medical devices which will provide evidence that any medical device has been maintained in good condition and that staff are competent to use it correctly.

4 LOANING OUT OF MEDICAL DEVICES

There may be occasions when medical equipment, surgical instruments or other medical devices are supplied on loan to other NHS Trusts. The process & checklist for the loaning out of medical devices is illustrated at **Appendix 3, Attachments 1 & 2**.

Surgical instruments or medical equipment that has been used for neurosurgical procedures **MUST NOT** be loaned out under any circumstances.

Surgical instruments, medical equipment or flexible endoscopes that have been used for a procedure on a patient known or suspected to have Creutzfeldt-Jakob Disease (CJD) **MUST NOT** be loaned out under any circumstances**.**

5 LOANING IN AND TRIALS OF MEDICAL DEVICES

The process and checklist for the loaning in and trials of medical devices is illustrated at **Appendix 4, Attachment 1 & 2**. This procedure is intended to manage and minimise the liability of the trust when borrowing in equipment from another Trust, equipment supplier or other provider. The procedure is also intended to reduce the risk of harm by ensuring the quality of the borrowed in equipment and the competency of the persons using it.

Equipment/goods can be introduced into the Trust for trial and evaluation purposes such as:

- Equipment on loan/trial
- Free issues with purchase of consumables
- Demonstrations on patients or staff
- Temporary replacement for equipment undergoing repair

In all these instances, equipment must comply with the policy statements on standardisation and performance, and the Trust must be covered by the Suppliers Indemnity (NHS Indemnity) form shown in **Appendix 4, Attachment 3**.

Procurement **MUST** be notified prior to any department seeing Representatives regarding the loaning into the Trust of medical devices.

All equipment must be tested for electrical safety by Medical Engineers, and a suitable delivery note completed before the equipment is used.

All loaned equipment must meet the Trust's requirements for safety, cleaning and disinfection.

All medical device suppliers and company representatives must conform to the Trust Protocol attached in **Appendix 4, Attachment 4**

6 LOANING OF MEDICAL DEVICES TO PATIENTS (PRESCRIBING)

This section refers to medical devices or equipment on loan or prescribed to patients for use at home. The process is illustrated at **Appendix 5**.

Prescribers of medical devices must have appropriate professional qualifications and relevant experience of the devices being prescribed.

When issuing medical devices to patients for use at home the issuing department must ensure that:

- training is given to the patient or carer on the safe use of the device
- written approved/manufacturers' instructions are provided where appropriate, and are suitable for the individual concerned
- contact details are given to the patient or carer, in the event that any technical support becomes necessary
- when on loan for an extended period, arrangements are in place for the device to receive regular maintenance
- arrangements have been made to recover the device when no longer in use by the patient
- details of the device on loan (type, model, serial no.) have been entered in the patient's notes.

7 MEDICAL DEVICES TRAINING

The process for the recording of training in medical devices is illustrated at **Appendix 6, Attachment 1**

Self assessment and medical device training requirements of the Trust are delivered at Corporate induction for all clinical staff, Clinical Bank staff receive the same information during their registration process.
This should be followed up at local induction to include medical devices used in specific clinical areas.

Each department should ensure that Medical Device Management is included in their local induction programme and include, where relevant, procedures for acquisition, training, decontamination, maintenance and disposal. An annual review and audit of staff training competencies should be undertaken.

Updates for the Trust Medical Equipment Training Database will be requested regularly from department managers. Time spans for this will be dependent on the type of medical equipment in use, audit status and compliance of each department.

7.1 Self Assessment

All clinical staff are required to self assess their competence relating to the use of medical devices. The self assessment questions document **(Appendix 6, Attachment 2)** should be used to facilitate this exercise.

Staff endeavoring to self assess who have uncertainty relating to their own competence **MUST** inform their Ward/Department Manager who will arrange relevant training; Medical Staff must inform their line manager or Clinical Director.
All clinical staff must complete the Staff Record of Medical Equipment Training **(Appendix 6, Attachment 5)** at induction, along with a Medical Equipment Self Assessment of Competency document. An example is attached at **(Appendix 6, Attachment 3).** These documents should be reviewed and updated annually.

Competency levels are defined as follows:

Beginner: Has received Basic safety training and has demonstrated and understood the principles for safe use and practice of the device and has the necessary learning tools to work towards competency. Requires further training and education in the use of equipment.

Competent: Device Specific demonstration and discussion by user. Using Trust competency statement documentation and/or other learning tools learning is verified by a Competent or Proficient user. User understands, demonstrates specific device safely and can relate problem solving to device and patient care. Can demonstrate use of the device to others.

Proficient: Has a deeper understanding and is able to analyse problems with specific devices and relate knowledge to patient physiological parameters.
Has more in depth knowledge base and can demonstrate device for competency sign off.

All self assessment is subject to random verification by a Faculty Educator, Professional Clinical Educator or Competent/ Proficient practitioner in order to monitor the process.

7.2 Types of training available

Training will be delivered by a Faculty Educator Medical Devices (FEMD), Professional Clinical Educator, Core Trainer or Competent/ Proficient practitioner.

Trust Policy on the training & use of medical equipment is delivered at Corporate Induction for all clinical staff, and during the registration process for Clinical Bank staff.

The following training provision options may also be offered when training needs analysis and risk assessment indicate their feasibility:

- Equipment workshops
- Specialist study days.
- Ward based training
- One to one training and assessment.
- I skills – Providing a clinical library of podcasts, vodcasts and video lectures
- E Learning Packages
- Device specific information and company literature is available to staff on the Medical Devices Training page of the Trust Intranet for self directed learning.

Introduction of new equipment will be risk assessed and training delivered in line with the risk assessment and training needs analysis. New high risk equipment will not be authorised for use until a minimum of 50% of staff in each clinical area, planning to use it, are trained & competent to do so.

For advice and assistance on the provision of training, users should email FEMD on:

medicalequipmenttrainingcoordinators@heartofengland.nhs.uk

7.3 Manuals/instruction sheets

All areas must have, for all clinical staff, a readily accessible resource folder containing manuals and/or instruction sheets for **ALL** high risk medical devices used in that department. The Trust Medical Equipment Categories Risk Analysis identifies which equipment is assessed to be high risk and which staff groups are permitted to use specific categories of equipment. (**Appendix 6, Attachment 6**)

7.4 Equipment Inventory Register

An equipment inventory register should be compiled by ward/department managers identifying all medical equipment in use in their area and all potential users of each device. The register must be updated with any additional equipment identified or purchased. A separate Equipment Inventory Register document is not required if the Training Competency Management Matrix Tool (see section 7.5 below) is in place as this records the required information.

7.5 Training Competency Management Matrix Tool (Appendix 6, Attachment 4)

The competency management matrix tool records the names of individual staff members and their current level of competency to use the medical devices identified from the equipment inventory register. This information is obtained from the self assessment competency documents completed by staff and the equipment inventory register.

The matrix should be updated when new equipment is implemented and at least on an annual basis using self assessment documentation. This document provides a training needs analysis for each local area.

Appendix 1

Attachment 1 – Process for the procurement of a new medical device

Attachment 2 – Mini business case proforma

Attachment 3 – Capital proposal form

Attachment 4 – Risk Scoring Matrix

Procurement of a New Medical Device

TO ASSIST IN THIS PROCESS THE FOLLOWING POLICIES AND PROCEDURES MUST BE CONSULTED

- Decontamination Policy
- Infection Control Policy
- Point of Care Testing Policy
- CAS Protocol
- Incident Reporting Policy

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THE DEVICE MUST

- Have CE mark
- Comply with EU Directives and relevant UK legislation for performance and safety

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Access Procurement Capital Portal on the Trust Intranet

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Complete the web form in accordance with the guidance provided and note capital portfolio reference number

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COMPLETE EITHER

- Detailed Capital Proposal Form for the procurement of devices >£5000
- Mini Business Case Proforma for the procurement of devices <£5000

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Obtain approval for expenditure

↓

Raise Requisition

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Submit Completed Business Case Form to Procurement in accordance with approval process detailed on form

(Appendix 1, Attachment 2)

Mini Business Case Proforma
(for the procurement of a device <£5000)

NB: To be completed only when a full Business Case is not required for a small change in practice/procedure that is either self funding or requires approval/agreement from internal sources **only**

Directorate: _____ **Clinical Director:** _____

Directorate Manager: _____

Commercial Finance Manager: _____ **Date:** _____

Capital Portal Reference Number _____

Benefits/Reasons for change: *(Details of existing equipment vs. new equipment)*

Cost Implications:

Capital Purchase:

Disposables:

Quantity:

Potential Risks If Purchase Not Approved: *(Please give further details on any identified risks to the change, whether they will occur if change does not take place, or whether they could result from the change: they could include costs, increased LOS, patient uptake, no NICE guidance etc.)*

Other Considerations:

Decontamination costs:

Replacement scheme:

Ongoing maintenance/capital costs:

Training costs:

Infection control implications

Does device comply with EU/UK legislation:

Does device have the CE Mark of approval:

Timeframe for Change: *(Please identify any time constraints or needs to delivering this change)*

Signatures

Directorate Manager: _____ Date: _____

Commercial Finance Manager/Deputy: _____ Date: _____

EBME Manager: _____ Date: _____

CAPITAL PROPOSAL FORM
(for the procurement of a device >£5000)

Title:			**Ref No:** *[Finance Use]*
Directorate:		**Commercial Finance Manager:**	
Directorate Manager:		**Operations / Estates Director:**	

1. Summary of Business Case

*[Please write a **brief** summary on the purpose of the business case, detailing the current arrangements for the service and how this bid will improve patient care. You should also state how it fits with the Trust and Business Unit Strategy and include details on the Risk to the Trust of not undertaking the project and complete the scores below]*

2. Benefits

[What are the benefits to the Trust and our customers? Consider tangible and intangible benefits such as the impact on the HEFT brand; cost avoidance, new income etc. State the timescales for the delivery of these benefits (min/max range of dates)]

3. Scoring Summary	**Score (0-5)**	**Weighting**	**Weighted Score**
Risk Avoidance		25	
Patient Care Improvement		25	
Fit with Strategy / Mission		25	
Impact on Market Share		10	
Financial Viability		15	
TOTAL	**N/a**	**100**	

3.1 Risk Avoidance [Include the rationale and evidence for the score above]

3.2 Patient Care [Set out evidence to support the scoring in relation to the direct improvements to patient care]

3.3 Fit with Mission & Service Strategy [Set out the evidence & rationale for how this proposal contributes to the delivery of the Trust's Service Development Strategy and its mission]

3.4 Impact on Market Share [Set out the evidence and rationale to support the score above]
3.5 Financial Viability [Please demonstrate how the financial viability score has been arrived at]

4. Is the equipment or area detailed above included on the Departmental Risk Register?	
YES / NO [Delete as appropriate]	If Yes, please complete Risk Register reference:

5. Capital Funding Source	**£000's**
Annual Block Allocation *[Specify Block]* :	
TOTAL	

6. Financial Information		
	£'000	**Supporting Narrative**
Capital Costs • Building • Equipment • Other		
Additional Revenue Costs / (Savings)		
Additional Income		
Opportunity Savings / Costs		
Other		

7. Revenue Funding Sources *[Where there are additional revenue costs please provide details of how the business unit proposes to fund these].*

8. Expenditure Profile *[Estimate the cash expenditure profile for the project]*					
	Year 1				**Year 2 +**
	Quarter 1	**Quarter 2**	**Quarter 3**	**Quarter 4**	
Estimated expenditure					

9. PROPOSAL APPROVAL

	NAME	SIGNATURE	DATE
Prepared by			
Reviewed by			
Capital Team Review			
Committee Approval	*[Enter name of committee, e.g. MMC, IM&T Exec, Facilities Exec Board etc.]*		
Comments and Feedback:			

SCORE	RISK AVOIDANCE (i.e. NOT DOING) (25%)	IMPROVEMENT TO PATIENT CARE (25%)	FIT WITH MISSION/STRATEGY (25%)	IMPACT ON MARKET SHARE (10%)	FINANCIAL VIABILITY (15%)
5	**Very high** risk score (≥ 20) as per Trust's Risk Assessment Matrix	Clear evidence that the case **delivers a specific & tangible** improvement to patient care	Clear evidence that the case **delivers a specific & tangible** element of the Trust's Strategy	Growth in Market share is **real**, **sustainable, increases** income & is agreed with the Trust's key stakeholders	**Revenue surplus > £500k** &/or Pay back period < 3 years AND NPV +ve
4	**High** risk score (15 to 19) as per Trust's Risk Assessment Matrix	Clear evidence that the case **directly drives** a **specific & tangible** improvement in patient care	Clear evidence that the case **directly drives** a **specific & tangible** element of the Trust's Strategy	Case identifies real **potential for future** sustainable increases in income & Market share	**Revenue surplus £251k to £500k** &/or Pay Back period < 4 years AND NPV +ve
3	**Medium** risk score (9 to 14) as per Trust's Risk Assessment Matrix	Clear evidence that the case **directly drives** the Strategy on improving patient care	Clear evidence that the case **directly drives** the delivery of the Trust's Strategy & Mission	Case directly **influences** other opportunities for future growth in income & Market share	**Revenue surplus £101k to £250k** &/or Pay Back period < 5 years AND NPV +ve
2	**Moderate** risk score (4 to 8) as per Trust's Risk Assessment Matrix	Evidence that the case **influences** a **specific** part of the Strategy on improving patient care	Evidence that the case **influences** a **specific** part of supports the wider delivery of the Trust's Strategy & Mission	Case is needed to **maintain** our current market share & income	**Revenue surplus £0 to £100k** &/or Pay back period < 5 years AND NPV +ve
1	**Low** risk score (1 to 3) as per Trust's Risk Assessment Matrix	Evidence that the case **influences** improvements in patient care	Evidence that the case **influences** the delivery of the Trust's Strategy & Mission	**No impact** on market share & income	No revenue implications – **cost neutral** AND NPV +ve
0	**No risk**, score 0	**No impact** on patient care improvements	**No impact** on delivering the Trust's Strategy & Mission	**Reduces** market share & income	Net revenue **loss** and/or NPV –ve
SCORE	*Eg. 4*	*Eg. 3*	*Eg. 3*	*Eg. 1*	*Eg.2*
WEIGHTING	*4 x 25 = 100*	*3 x 25 = 75*	*3 x 25 = 75*	*1 x 10 = 10*	*2 x 15 = 30*
WEIGHTED SCORE	*290*				

(Appendix 1, Attachment 4)

RISK ASSESSMENT MATRIX

Table 1 Measurement of likelihood

Level	Descriptor	Description
0	**Never**	The event cannot happen under any circumstances.
1	**Rare**	The incident may occur only in exceptional circumstances
2	**Unlikely**	The incident is not expected to happen but may occur in some circumstances
3	**Possible**	The incident may happen occasionally
4	**Likely**	The incident is likely to occur, but is not a persistent issue
5	**Almost Certain**	The incident will probably occur on many occasions and is a persistent issue

Table 2 Measurement of consequence

Level	Descriptor	Description
0	**None**	No injury or adverse outcome. Low financial loss
1	**Insignificant**	No injury or adverse outcome; First aid treatment; Low financial loss
2	**Minor**	Short term injury/damage (e.g. resolves in a month); a number of people are involved
3	**Moderate**	Semi permanent injury (e.g. takes up to year to resolve)
4	**Major**	Permanent injury; major defects in plant, equipment, drugs or devices; the incident or individual involved may have a high media profile
5	**Catastrophic**	Death

Table 3 **ASSESSMENT MATRIX** The risk factor = likelihood. x consequence

	CONSEQUENCE					
LIKELIHOOD	**None 0**	**Insignificant 1**	**Minor 2**	**Moderate 3**	**Major 4**	**Catastrophic 5**
0 Never	0	0	0	0	0	0
1 Rare	0	1	2	3	4	5
2 Unlikely	0	2	4	6	8	10
3 Possible	0	3	6	9	12	15
4 Likely	0	4	8	12	16	20
5 Almost Certain	0	5	10	15	20	25

By using the matrix above the risk score can be calculated to determine risk category. This ranges ranging from 1 (low severity and unlikely to happen) to 25 (just waiting to happen with disastrous and widespread consequences). The risk score can now form a basis upon which to determine the urgency of any actions.

CATEGORISATION OF RISK

Key		
0	No Risk	White category
1-3	Low Risk	Green Category
4 - 8	Moderate Risk	Yellow Category
9 – 14	Significant Risk	Orange Category
15 - 25	High Risk	Red Category`*

*Risks which have a priority score of 9 or more should be reviewed by the Directorate Management Team immediately. Risks with a score of 15 or more must be notified to the Risk Register Office

Appendix 2

Attachment 1 – Process for the management of medical devices

(Appendix 2, Attachment 1)

Management of Medical Devices

RECORDS

RECORDS KEPT SHOULD INCLUDE THE FOLLOWING:

- Procurement details
- Maintenance history, including commissioning and acceptance
- Quality assurance (for POCT devices)
- Adverse incidents
- Transfers and disposals

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THE FOLLOWING POLICIES WILL APPLY DURING THE LIFETIME OF THE MEDICAL DEVICE

- Incident Reporting Policy
- CAS Protocol
- Decontamination Policy
- Infection Control Policy
- Point of Care Testing Policy

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MODIFICATION OF MEDICAL DEVICES

- **ONLY EXCEPTION** – Allowed within the instructions issued by manufacturer
- Devices that do not meet service requirements – modification may only be authorised by the manufacturer or by the Medical Devices Committee acting in conjunction with the medical device manufacturer

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RE-USE OF MEDICAL DEVICES

- Devices designed for single use **MUST NOT** under any circumstances be re-used
- Sterile Single Use devices must be used within their specified "use by" date

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DIAGNOSTIC MEDICAL DEVICES

- Must be CE marked for purpose
- Instructions consulted and specific training and advice obtained before use
- Consult Point of Care Testing Policy

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REPLACEMENT

Follow procedure detailed in **Appendix 1**

DISPOSAL

- Electrically active devices: by or in conjunction with Medical Engineers
- Must comply with Health and Safety Legislation and EU directives
- Must meet requirements of Trust's Standing Financial Instructions and other relevant policies and procedures
- Arrangements must be made to transfer the appropriate liability when working or non working devices are transferred to a third party
- The asset register holder must be informed

Appendix 3

Attachment 1 – Process for the loaning out of medical devices

Attachment 2 – Checklist for the loaning out of medical devices

LOANING OUT OF MEDICAL DEVICES

- Loan of surgical instruments, medical equipment and/or flexible endoscopes only undertaken in exceptional circumstances
- Supplied in same condition as would be supplied to a user within Trust
- Surgical instruments, medical equipment and/or flexible endoscopes that have been used for neurological surgery **MUST NOT** be loaned out
- Surgical equipment, medical equipment and/or flexible endoscopes **MUST NOT** be loaned out for a procedure on a patient known or suspected to have Creutzfeldt Jakob Disease (CJD)

LENDER
Nominated person 'responsible' (person in charge of ward/department for loan must ensure:-

Maintenance & Training
- Planned maintenance is up to date
- Arrangements in place for additional planned maintenance needed
- User operating instructions provided
- Up to date maintenance records for devices maintained/repaired directly by manufacturer

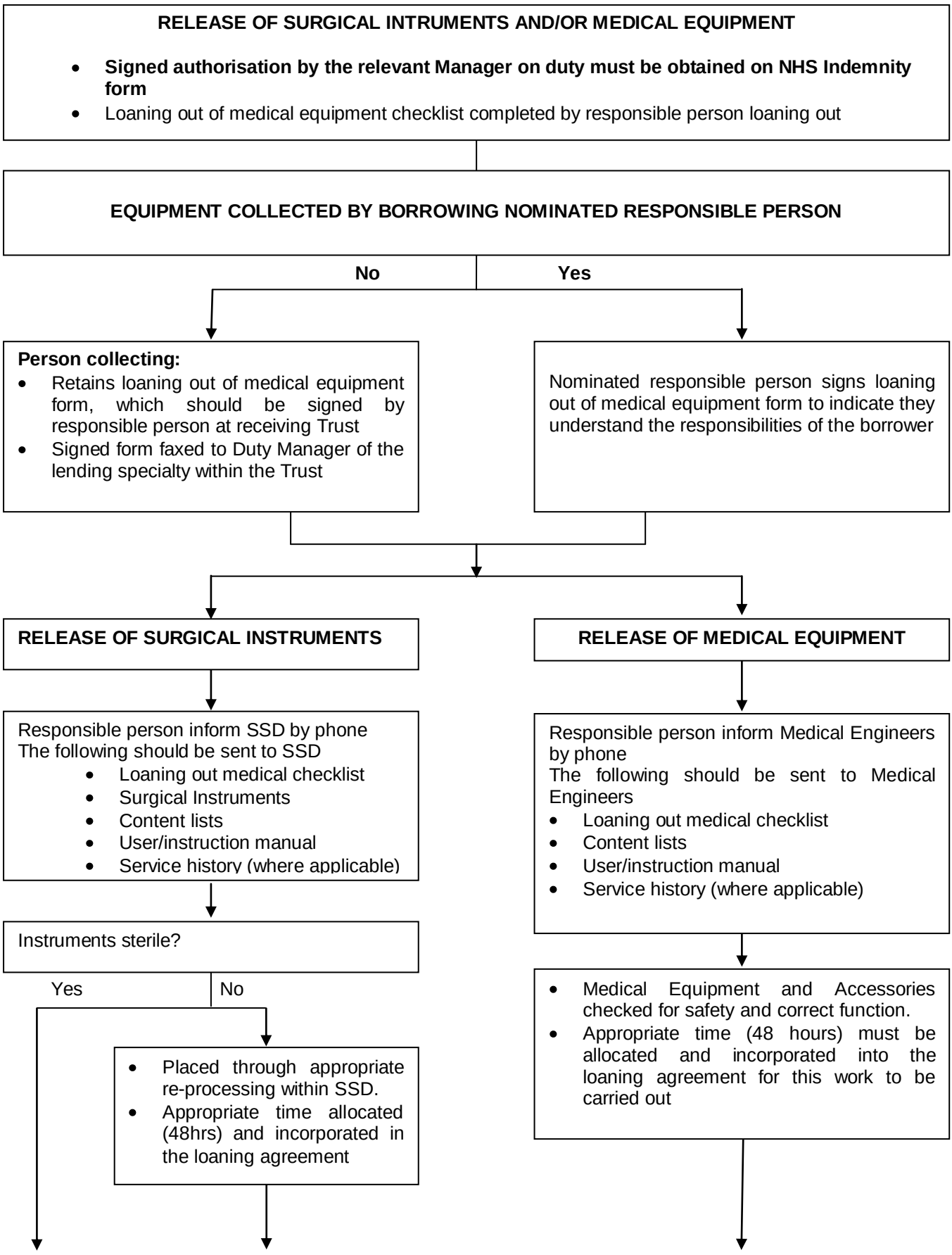
Tracking
- Arrangements in place to ensure equipment returned
- Checklist for loaning out medical devices completed by borrower and lender prior to device leaving premises **(Attachment 2)**

Competence
- Signature obtained from borrower, accepting responsibility for ensuring equipment will only be used by competent users

Competence must cover:
- Correct operation
- Use of compatible consumables
- User maintenance
- Decontamination of the equipment
- Procedure to follow should device develop a fault
- Financial implications of any loss or damage

BORROWER
Nominated person 'responsible' for equipment must ensure:-

- Re-imbursement of the cost or repair or replacement should equipment be lost or damaged
- Equipment only used:-
  - In accordance with instructions supplied
  - By persons competent to use
- Faults reported in writing to responsible person loaning out


RELEASE OF SURGICAL INTRUMENTS AND/OR MEDICAL EQUIPMENT
Signed authorisation by the relevant Manager on duty must be obtained on NHS Indemnity form
Loaning out of medical equipment checklist completed by responsible person loaning out
EQUIPMENT COLLECTED BY BORROWING NOMINATED RESPONSIBLE PERSON
No
Yes
Person collecting:
Retains loaning out of medical equipment form, which should be signed by responsible person at receiving Trust
Signed form faxed to Duty Manager of the lending specialty within the Trust
Nominated responsible person signs loaning out of medical equipment form to indicate they understand the responsibilities of the borrower
RELEASE OF SURGICAL INSTRUMENTS
RELEASE OF MEDICAL EQUIPMENT
Responsible person inform SSD by phone
The following should be sent to SSD
Loaning out medical checklist
Surgical Instruments
Content lists
User/instruction manual
Service history (where applicable)
Responsible person inform Medical Engineers by phone
The following should be sent to Medical Engineers
Loaning out medical checklist
Content lists
User/instruction manual
Service history (where applicable)
Instruments sterile?
Yes
No
Placed through appropriate re-processing within SSD.
Appropriate time allocated (48hrs) and incorporated in the loaning agreement
Medical Equipment and Accessories checked for safety and correct function.
Appropriate time (48 hours) must be allocated and incorporated into the loaning agreement for this work to be carried out

DISPATCH OF INSTRUMENTS

NHS indemnity form signed and dispatched from SSD by the authorised Operations/Deputy Manager on duty

Following packaged in appropriate containers:

- Sterile surgical instruments
- Documentation and forms
- A copy of the following should be retained by SSD
- Loaning out of medical equipment checklist
- Content list
- NHS indemnity form

DISPATCH OF EQUIPMENT

Equipment must be dispatched by Medical Engineers with all relevant documentation completed

RETURN OF EQUIPMENT

- As soon as practical after use
- With a signed decontamination statement
- Any loss of accessories or damage made good
- Faults reported
- Must not be put back into use until all documentation has been received back and checked

SURGICAL INSTRUMENTS

Borrower returns to Trust SSD/Operations/Deputy Manager the following:

- Surgical instrument
- Documentation
- Completed NHS indemnity form

MEDICAL EQUIPMENT

Borrower returns to appropriate Medical Engineering Manager the following:

- Equipment
- Documentation
- Completed NHS indemnity form (not required if loaned to patient)

SSD Operations/Deputy Manager

- Checks the decontamination status
- Re-process to Trust standard
- Sign relevant forms
- Retain relevant forms and send copy to Finance Manager

Returns the following to the originating clinical area:

- Surgical instruments
- Content list
- User/instruction manual
- Service history
- NHS Indemnity form

Medical Engineering Manager

- Checks the decontamination status
- Verify correct function/safety checks
- Sign relevant forms
- Retain relevant forms and send copies to SSD

Operational Manager and Finance Manager

Returns the following to the originating clinical area:

- Medical equipment
- Content list
- User/instruction manual

Originating clinical area

Notify Medical Engineering of any returned instrument that is found to be defective

(Appendix 3, Attachment 2)

CHECK-LIST FOR LOANING OUT MEDICAL EQUIPMENT

Equipment Name	
Model	
Manufacturer	
Equipment Control No.	

Loaning-Out Dept		Borrowing Trust & Dept	
Location of Dept.		Location of Dept.	
Responsible Person loaning out		Responsible Person borrowing in	
Designation		Designation	
Contact Details		Contact Details	

Duration of Loan	

Statement by Responsible Person loaning out	• I certify that the equipment meets the standards described in the policy. • I certify that I have supplied written operator's instructions with the equipment	Signature: Date:
Statement by Responsible Person borrowing in	• I certify that the equipment will only be used by competent persons. • I accept financial responsibility for any loss or damage to the equipment, as a result of negligence, whilst it is in my possession. • I undertake to ensure that all the conditions of the loan are adhered to.	Signature: Date:

End of Loan	State of Device		**Yes**	**No**
	Decontamination status:	Known to be contaminated? (give details if "yes")		
	Repair required?	Give details if ("yes")		

Details of person receiving equipment back to HOEFT					
Signature		Print name		Date	

NHS INDEMNITY FORM YES ☐ NO ☐ (Please tick appropriate box)

Appendix 4

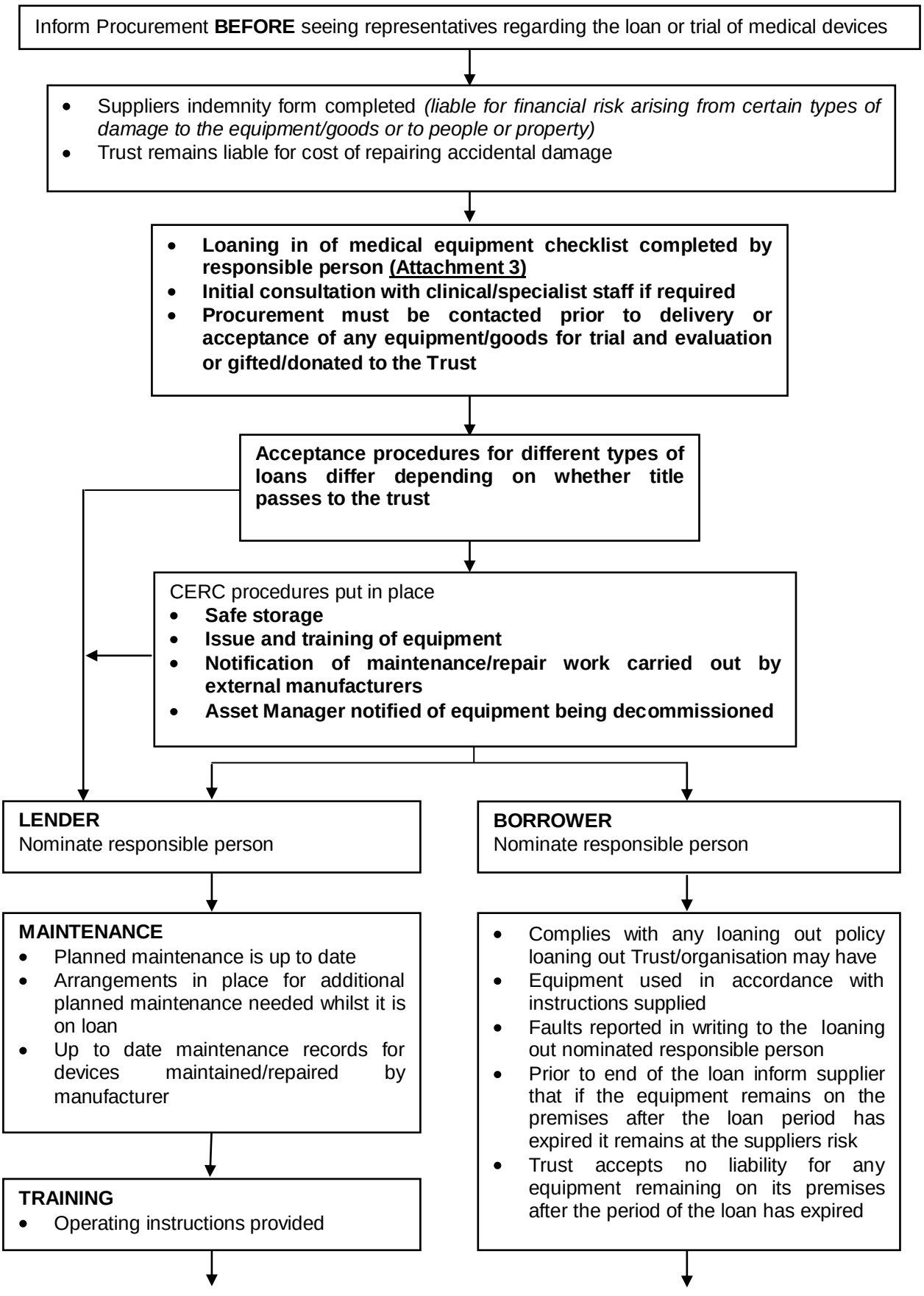
Attachment 1 – Process for the loaning in and trials of medical devices

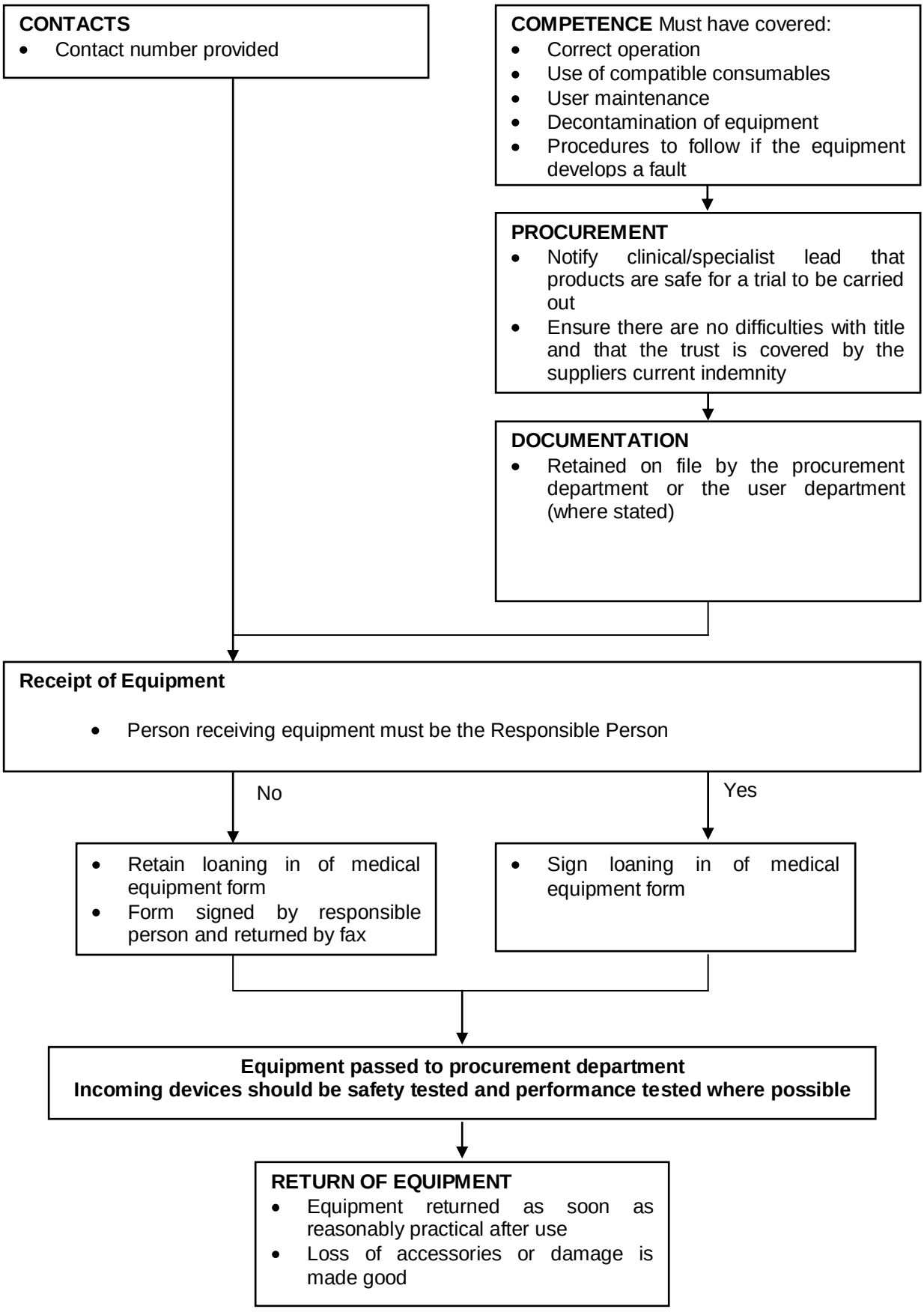
Attachment 2 – Checklist for the loaning in of medical equipment

Attachment 3 –Suppliers Indemnity (NHS Indemnity form)

Attachment 4 – Trust protocol for medical device suppliers and company representatives

LOANING IN OF MEDICAL DEVICES




CONTACTS
Contact number provided
COMPETENCE Must have covered:
Correct operation
Use of compatible consumables
User maintenance
Decontamination of equipment
Procedures to follow if the equipment develops a fault
PROCUREMENT
Notify clinical/specialist lead that products are safe for a trial to be carried out
Ensure there are no difficulties with title and that the trust is covered by the suppliers current indemnity
DOCUMENTATION
Retained on file by the procurement department or the user department (where stated)
Receipt of Equipment
Person receiving equipment must be the Responsible Person
No
Yes
Retain loaning in of medical equipment form
Form signed by responsible person and returned by fax
Sign loaning in of medical equipment form
Equipment passed to procurement department
Incoming devices should be safety tested and performance tested where possible
RETURN OF EQUIPMENT
Equipment returned as soon as reasonably practical after use
Loss of accessories or damage is made good

(Appendix 4, Attachment 2)

CHECK-LIST FOR LOANING-IN MEDICAL DEVICES

Incoming devices should be safety tested and performance tested – where possible

Equipment Name	
Model	
Manufacturer	
Equipment Control No.	

Loaning-Out Organisation		Borrowing Trust & Department	Heart of England NHS Foundation Trust
Location of Dept.		Location of Dept.	
Responsible Person loaning out		Responsible Person borrowing in	
Designation		Designation	
Contact Details		Contact Details	

Duration of Loan	

Statement by Responsible Person Loaning out	• I certify that the equipment meets the standards described in the policy. • I certify that I have supplied written operator's instructions with the equipment	Signature: Date:
Statement by Responsible Person Borrowing in	• I certify that the equipment will only be used by competent persons. • I undertake to ensure that all the conditions of the loan are adhered to.	Signature: Date:

End of Loan	State of Device		**Yes**	**No**
	Decontamination status:	Known to be contaminated? (give details if "yes")		
	Repair required?	Give details if ("yes")		

Details of person receiving equipment back to the loaning Trust or organisation					
Signature		Print name		Date	

(Appendix 4, Attachment 3)

NHS Form of Indemnity – A Reference Number [ ]

Equipment on loan

A DEED made the ..... day of ..... 200_ **BETWEEN:**

EITHER*

NHS Trust/NHS Foundation Trust/Health Authority*

…… ("the Authority");

OR

NHS Purchasing and Supply Agency ("PASA");

AND

Supplier …… ("the Supplier").

WHEREAS

The Supplier is the owner of equipment (the "Equipment") and wishes to make the Equipment available directly to the Authority or through PASA to NHS Trusts, NHS Foundation Trusts, Health Authorities and other users ("Users") agreed by the parties for a specified period in accordance with the terms of this Deed. The Equipment and the period for which the Equipment will be on loan to the Authority or the relevant User(s) shall be specified in either an NHS delivery note or, where this Deed acts as a master indemnity agreement for all loans made by the Supplier, a Supplier standard delivery note, in each case completed by the Supplier and the Authority or the relevant User(s) at the outset of the loan (a "Delivery Note"). For the avoidance of doubt, there shall be no limit on the number of Delivery Notes which may be completed pursuant to this Deed. "Equipment" shall be deemed to include any part or parts of the Equipment and all replacements and additions supplied by the Supplier during the continuance of this Deed.

IT IS HEREBY AGREED that the Supplier shall make the Equipment available to the Authority or the relevant User(s) by way of loan free of charge for the period agreed between the Authority or the relevant User(s) and the Supplier, at the premises ("the Premises") specified in the relevant Delivery Note on the terms set out in this Deed:-

1. - For the avoidance of doubt, this Deed is not a contract for hire pursuant to the Supply of Goods and Services Act 1982.

*** Delete as appropriate**

Form of Indemnity – B Reference Number [ ]

Free issues

A DEED made the ..... day of ..... 200_ **BETWEEN:**

EITHER*

NHS Trust/NHS Foundation Trust/Health Authority*

…… ("the Authority");

OR

NHS Purchasing and Supply Agency ("PASA");

AND

Supplier …….. ("the Supplier").

WHEREAS

The Supplier is the owner of goods (the "Goods") and wishes to transfer the legal and equitable title in the Goods to the Authority or to NHS Trusts, NHS Foundation Trusts, Health Authorities and other users agreed with PASA ('Users) in accordance with the terms of this Deed. The Goods shall be specified in a NHS Delivery Note completed by the parties at the time of the transfer. For the avoidance of doubt, there shall be no limit on the number of NHS Delivery Notes which may be completed by the parties pursuant to this Deed.

IT IS HEREBY AGREED that the Supplier shall transfer the legal and equitable title in the Goods to the Authority or the relevant User(s) free of charge on the terms set out below:

1. Sections 12 to 15 of the Sale of Goods Act 1979 (as amended) are to be implied into this Deed.

2. Clause 16 (Limitation of liability) and Clause 17 (Insurance) of the *NHS Conditions of Contract for the Purchase of Goods* (March 2004 edition) shall be incorporated into this Deed.

*** Delete as appropriate**

EXECUTED AND DELIVERED AS A DEED BY AND ON BEHALF OF: -

Name of NHS Trust/ NHS Foundation Trust / Health Authority:-

[ ]

OR NHS Purchasing and Supply Agency *

acting by:

Name:

Position:

Signature:

EXECUTED AND DELIVERED AS A DEED BY, FOR AND ON BEHALF OF: -

Supplier Name:

acting by:

1st Signatory

Name:

Position: Director/Company Secretary**

Signature:

2nd Signatory

Name:

Position: Director/Company Secretary**

Signature:

***Delete as appropriate (the form should be executed by the Authority OR by NHS PASA – see Guidance Notes)*

*** Delete as appropriate*

HEFT Protocol for Medical Device Suppliers and Company Representatives

Introduction

- This protocol covers all suppliers of goods and services of Medical Devices within Heart of England NHS Foundation Trust (HEFT).
- In order to establish and maintain good working relationships with the Trust's suppliers compliance with this protocol is mandatory and the following points must be adhered to:

Visits

- Company Representatives may only approach clinical/other staff in the Trust to facilitate product/service discussions by making an **appointment in advance** of their visit.
- Representatives must not enter wards and clinical areas without prior appointment.
- All Supplier/Sales Representatives must register their name and company with the department manager/lead on arrival.
- Staff have the right to refuse to meet Supplier/Sales Representatives who do not have an appointment. Staff should exercise a degree of caution/confidentiality when dealing with companies. Any concerns should be reported to Medical Devices Management. If staff are unsure of what information to disclose they are to refer the company to Procurement.
- Representatives must wear an official company identification badge at all times whilst on site.
- While on Trust property, Representatives will conduct themselves in a professional and businesslike manner at all times, and be aware of the Health and Safety at Work Act. and the Data Protection Act
- Representatives will need to take instruction from Trust staff for specialist areas.
- Representatives must at no time approach patients or visitors to discuss products/services.
- Patient's dignity & confidentiality must be maintained at all times and Company Representatives must follow direction from HEFT staff in this regard.
- Infection Control instructions must be adhered to at all times.
- Representatives visiting Trust sites may be stopped and asked to confirm their identity and purpose, as part of a regular audit of this protocol. Those not complying will be asked to leave.

Service/Maintenance Engineers

Service Engineers are required to report to the Estates department and register to work onsite. They must obtain an authorised "Contractor" badge and be informed of relevant Health & Safety information. Copies of all service reports must be left with the Medical Engineering Dept. on completion of work, listing any test equipment used and detailing remedial problems encountered & remedial work carried out.

Purchase Orders

Commitment to purchase goods and services is only entered into by the raising of an official trust Purchase Order. Representatives must not accept any instruction to deliver/provide unless a purchase order number is issued. The Trust will not be liable for goods and services delivered where no purchase order has been placed. Nor will a quotation be legally binding if it is signed by a non authorised signatory and is not accompanied with an official order number.

Agreements

No commercial agreement may be entered into unless it has been approved by the Procurement Department and/or Medical Devices Manager. Agreements and contracts must be submitted to a Procurement Category Manager for consideration and for approval by the relevant Directors before they will be considered valid.

Samples and/or consignment stock

All devices brought into the Trust for clinical use must hold a CE mark and be within "use by date" marked on packaging. Samples of consumables and clinical products must not be left with wards/departments. Unauthorised distribution and use of samples could contravene scheduled treatment and prove harmful to patient care.
All product evaluations must be agreed with Procurement, and Medical Devices Management. Samples may only be delivered directly to departments if Procurement or Medical Devices Management have authorised this.

Medical Equipment Evaluation

All equipment evaluation requires authorisation by Procurement, Medical Devices Management and Medical Engineering. Pre Purchase Questionnaire and Indemnity documentation must be completed and approved prior to equipment being brought on site. If appropriate, Medical Engineering must complete electrical safety checks and training provision must be documented and agreed with the evaluating department.

To gain Trust authorisation for evaluations Representatives must contact Procurement in the first instance.

Liability

The trust will not be liable for any Supplier property left on its premises, without formal Trust agreement.

Infection Control

Representatives must be aware that all personnel who visit clinical areas have the potential to introduce and transmit micro- organisms. With all equipment, there is a risk that if adequate cleaning and decontamination is not carried out, organisms can be transmitted not only from one patient to another, but from one hospital to another. The infectious status of patients is not always realised, therefore all patients should be treated as possible infection risks. Frequent hand washing and decontamination of demonstration equipment must be a priority.

All equipment brought on site must have decontamination certification.

Sponsorship of Education Centre meetings and events

Companies wishing to sponsor meetings or events at any of the Education Centres or Partnership Learning Centre must book their places in advance via 'sponsorship' at www.qualityvenues.co.uk and sign up to the sponsorship terms and conditions.

If the Sponsoring Company wishes to arrange catering for the meeting / event, they must do so via the approved caterers listed on the above website.

Hospitality, Sponsorship, Gifts and Promotional Material

All Company Representatives **MUST** comply with the Bribery Act 2010 and all Department of Health Guidelines. Links for information are below.

Bribery Act 2010
http://www.justice.gov.uk/guidance/making-and-reviewing-the-law/bribery.htm

Department of Health guidelines http://www.dh.gov.uk/assetRoot/04/07/60/78/04076078.pdf

Contacts

For further information and copies of this Protocol contact medicaldevicesmanagement@heartofengland.nhs.uk

Procurement Dept. – James Harkin, Senior Procurement Officer, james.harkin@heartofengland.nhs.uk

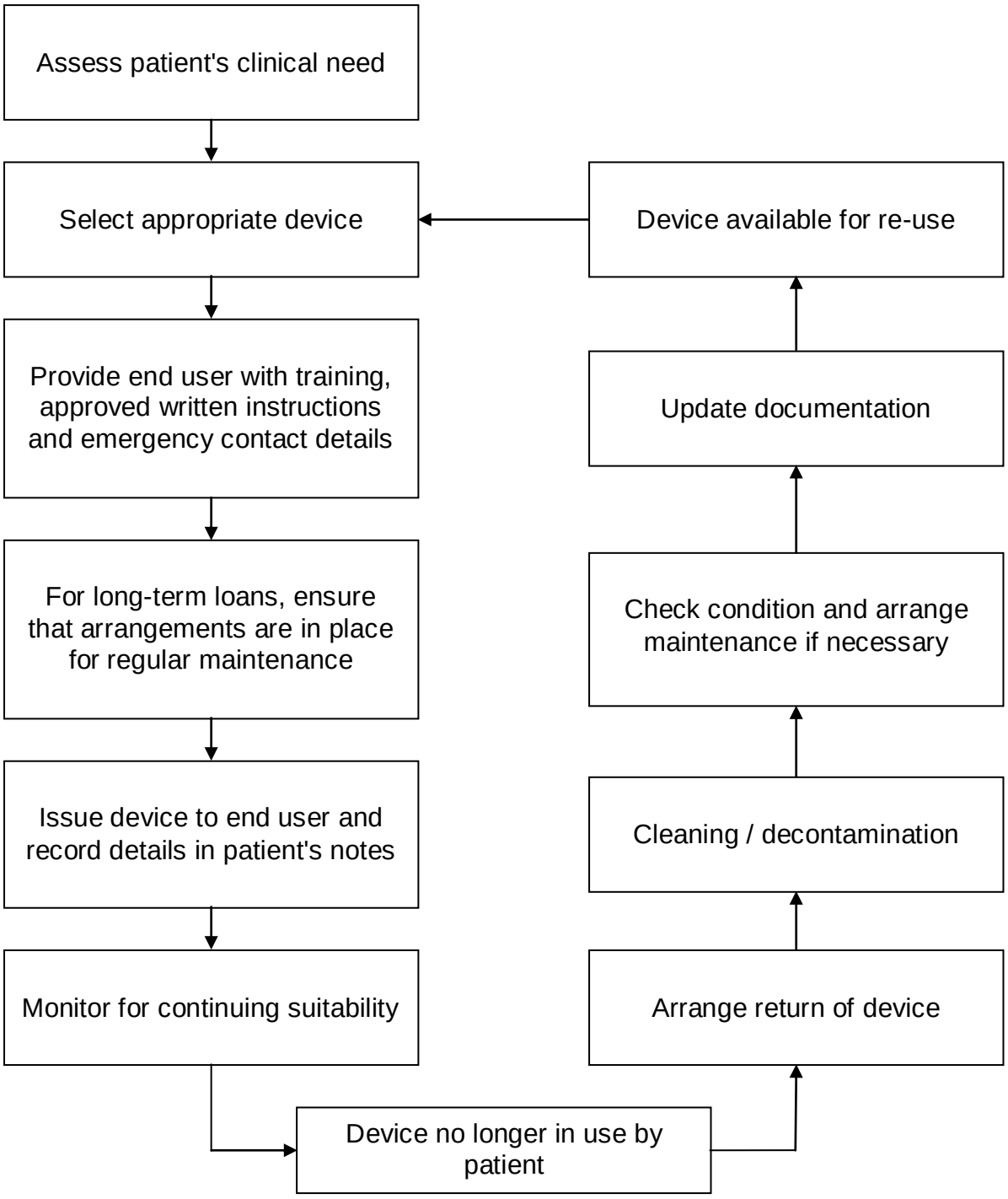
Medical Devices Management – Nicola Phillips, Medical Devices & Decontamination Coordinator, nicola.phillips@heartofengland.nhs.uk

Education Centres – David Twist, Learning Resources & Access Manager, Heartlands Education Centre david.twist@heartofengland.nhs.uk

Appendix 5

Attachment 1 - Process for the loan of medical equipment to patients

Loaning of Medical Devices to Patients (Prescribing)



Appendix 6

Attachment 1 – Training Process Flowchart for medical equipment

Attachment 2 – Medical equipment competency self assessment questions

Attachment 3 – Medical equipment self assessment of competency matrix

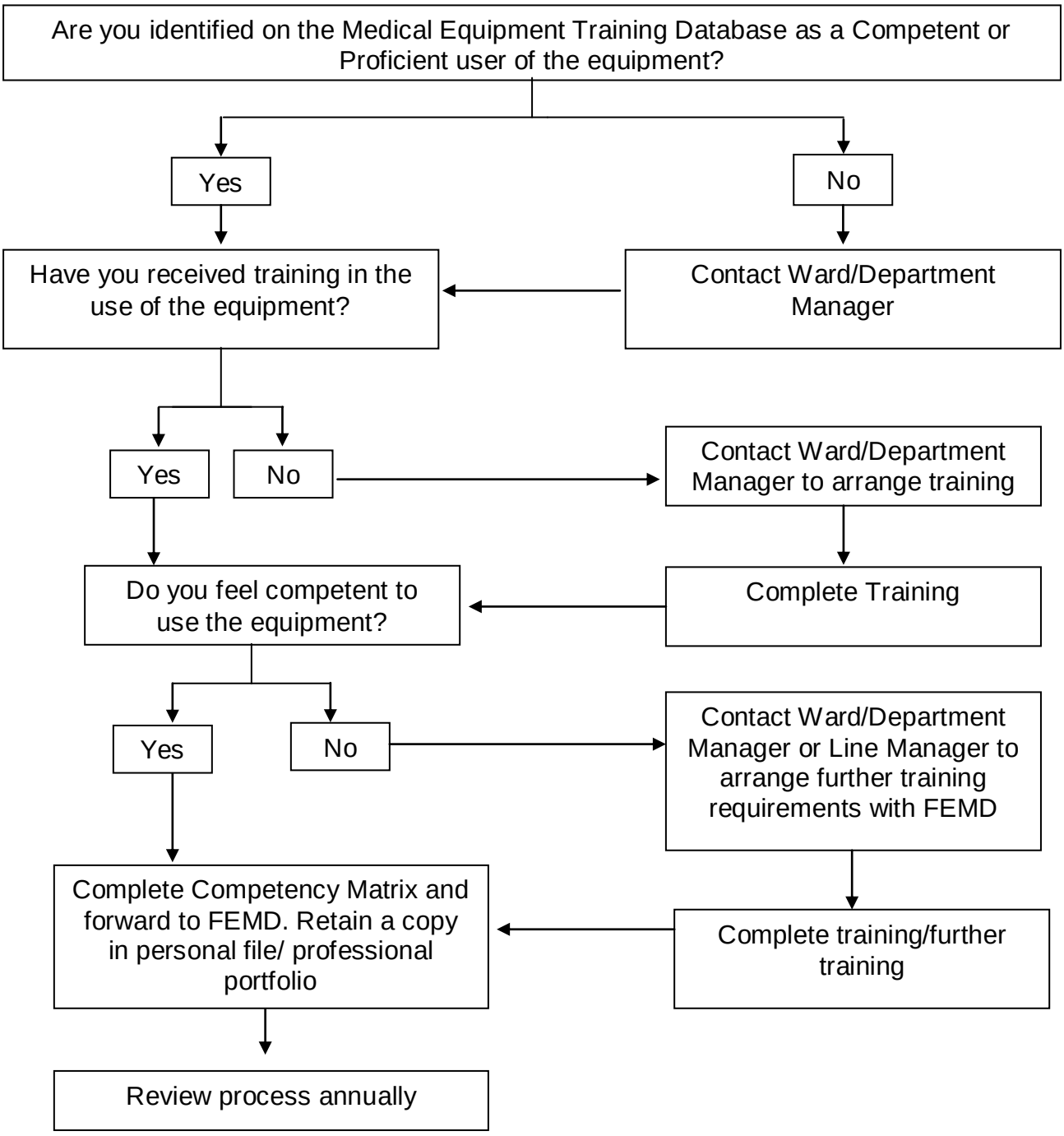
Attachment 4 - Training Competency management matrix tool

Attachment 5 – Staff record of medical equipment training

Attachment 6 – Medical Equipment Categories Risk Analysis

(Appendix 6, Attachment 1)

TRAINING PROCESS FLOWCHART



MEDICAL EQUIPMENT COMPETENCY SELF ASSESSMENT QUESTIONS

EACH MEMBER OF STAFF SHOULD ASK THEMSELVES THE FOLLOWING QUESTIONS IN ORDER TO MAKE A DECISION REGARDING COMPETENCY TO USE EACH PIECE OF EQUIPMENT IDENTIFIED ON THE COMPETENCY MATRIX

1. Do I have the prerequisite accredited training required to use the equipment?
2. Am I required to complete any local training programmes before I am able to use the equipment?
3. Have I received training to use the equipment?
4. Am I an experienced user?
5. Can I calibrate the equipment (if appropriate to my role)?
6. Am I aware of the indications and limitations of this piece of equipment?
7. Do I know how to set up the equipment for use?
8. Do I know which items are compatible with this equipment?
9. Can I recognise if the equipment is operating normally?
10. Would I recognise a fault?
11. Do I know what I should do if something goes wrong with the equipment?
12. Am I aware of the procedures to safely clean and decontaminate the equipment?
13. Do I feel confident in my ability to use this piece of equipment safely and effectively?

		Indicate on competency matrix
Proficient	Capable of training other members of staff in the use of equipment	**P**
Competent	Competent to use equipment and demonstrate use to others	**C**
Beginner	Have received demonstration or theory based training and require further practice in the use of equipment	**B**

Modifying the Benner (1984) scale to accommodate 3 as oppose to 5 levels of competence has created these competency levels.

EXAMPLE - Medical Equipment Self Assessment Matrix

Many devices will be the same but each department will have a self assessment matrix which documents the specific devices in use locally.

WARD TEMPLATE

Please state competency level or non user for equipment listed below:-	
Beginner	Has received basic safety training and has demonstrated and understood the principles for safe use and practice of the device and has the necessary learning tools to work towards competency.
Competent	Device specific demonstration and discussion by the user. Using Trust competency statements, documentation and/or other learning tools. Learning is verified by a competent or proficient user. User understands and demonstrates device safely and can relate problem solving to device and patient care. Can demonstrate device to others.
Proficient	Has a deeper understanding and is able to analyse problems with specific devices and relate knowledge to physiological paramaters. Has more in depth knowledge base and can demonstrate device for competency sign off.

MEDICAL DEVICE RISK : SELF ASSESSMENT OF COMPETENCY

NAME:		**DATE of COMPLETION:**	

COMPETENCE: Non user / Beginner / Competent / Proficient

INFUSION DEVICES								**Signature: Verifier**	**Print Name: Verifier**	**Date:**
	McKinley T34 Ambulatory pump	**N**	**B**	**C**	**P**					
	Smiths Omnifuse PCA syringe driver	**N**	**B**	**C**	**P**					
	Codan Argus 708	**N**	**B**	**C**	**P**					
	Smiths MS26 Driver	**N**	**B**	**C**	**P**					
	Alaris SE1	**N**	**B**	**C**	**P**					
	Nutricia Infinity Feed Pump	**N**	**B**	**C**	**P**					
RESUSCITATION										
	Phillips Heartstream XL defibrillator	**N**	**B**	**C**	**P**					
	Philips Heartstart MRX M3535A	**N**	**B**	**C**	**P**					
	Ambu bag and O2 flow meter	**N**	**B**	**C**	**P**					
POINT OF CARE MONITORING										
	Abbott Optium Xceed glucose monitor	**N**	**B**	**C**	**P**					
RESPIRATORY										
	Oxygen regulator Wall	**N**	**B**	**C**	**P**					
	Portable O2 cylinder and flow meter	**N**	**B**	**C**	**P**					
	Suction - Wall - Regulator inc Medivaccontainer	**N**	**B**	**C**	**P**					
	Portable Suction Unit Laerdal LSU	**N**	**B**	**C**	**P**					
MONITORING EQUIPMENT										
	Critikon Dinamap Pro 300	**N**	**B**	**C**	**P**					
	Welch Allyn -Vital signs Monitor	**N**	**B**	**C**	**P**					
	GE Mac 1200 lead ECG machine	**N**	**B**	**C**	**P**					
OTHER										
	Mallinckrodt Medical Warm touch (Bair hugger)	**N**	**B**	**C**	**P**					
	Braun Pro 4000 Tympanic Thermometer	**N**	**B**	**C**	**P**					
	Arjo Bath Hoist	**N**	**B**	**C**	**P**					
	Arjo Standing Hoist	**N**	**B**	**C**	**P**					
	Hill Rom Total Care bed	**N**	**B**	**C**	**P**					

Form can be accessed from Medical Devices Training Intranet site from or from http://sharepoint/medicaldevices/default.aspx

Example of Training Competency Management Matrix Tool **WARD/DEPARTMENT** **DELETE DEVICE/S YOU DO NOT USE or ADD NEW DEVICES** **Enter Date of Training and Competency letter for each individual**				Nutricia Infinity	McKinley T34 Ambulatory Pump	Wall Suction - Medivac (ALL)	Hewlett Packard - ECG Recorder
NAME	**Band**	**Staff Group**	**CxL= Risk**				
ANN OTHER	**6**	**ODP**		**14/03/11 C**			
BILL BROWN	**2**	**HCA**		**N/A**			
FRED BLOGGS	**5**	**RGN**		**14/03/11 B**			
RON BAILEY	**5**	**RGN**		**14/03/11 P**			

Form can be accessed from Medical Devices Training Intranet site or from
http://sharepoint/medicaldevices/default.aspx

Staff Record of Medical Equipment Training
Safety & Operation of Medical Equipment

Name:..... (Please print clearly)
Designation:.....
Department:..... Site: BHH/GHH/Sol/Other (Delete as appropriate)

I have reviewed the Medical Equipment Self Assessment of Competency document attached. I have indicated my level of competence against each device and included any additional high risk equipment used.

Competency Statement:

I am able to understand and operate the specified equipment and I am able to adopt a safe working practise in this regard.
(List of equipment attached*)

Competency Criteria Achieved

1. I am aware of, and am able to avoid, potential hazards associated with the use of the equipment listed*

2. I am confident to effectively and safely operate the equipment as listed *

3. I will not operate any high risk medical equipment unless I have received training and I am competent to do so.

Self Assessment

All Self assessments will be subject to random verification
Competency self assessed as per attached list*

I hereby declare that I have / I will read and will adhere to the Trust's Medical Devices Policy and Procedure documents

Signature: .....
Date: / /

Please retain this record, together with completed Medical Equipment Self Assessment of Competency document and review annually.

Where you are unable to operate any piece of equipment safely and require additional training, please contact The Faculty Educators, Medical Devices Team
Faculty Educators, Medical Devices Team, Undergraduate Office, Heartlands Hospital, Heart of England NHS Foundation Trust.
Medicalequipmenttrainingcoordinators@heartofengland.nhs.uk

Form can be accessed from Medical Devices Training Intranet site and from http://sharepoint/medicaldevices/default.aspx

(Appendix6, Attachment 6)

MEDICAL EQUIPMENT CATEGORIES RISK ANALYSIS

EQUIPMENT CATEGORY	Clinical Areas	Authorised Users if Trained & Competent	Likelihood	Consequence	SCORE (LXC)	Training Type	Update Requirements
DEFIBRILLATORS/RESUSCITATION EQUIPMENT	Theatre, Midwifery and Obstetrics, Wards, Critical care	ODP, RGN, Jnr Doc, Reg, Cons, CNS, Midwife	4	5	20	Taught Course - Resus Team	Annual
PUMPS (INFUSION)	Theatre, Midwifery and Obstetrics, Wards, Critical care	ODP, RGN, Midwife, Reg, Cons	4	5	20	Taught Course - FEMD & Manufacturers, Local Induction, Self Assess (Verifi	As identified at annual review
DIATHERMY AND LITHOTRIPTOR EQUIPMENT	Theatre	Jnr Doc, Reg, Cons	4	4	16	Local Induction / Taught Course University /Manufacturers	As identified at annual review
DRILLS	Theatre, Orthodontics	Reg, Cons, Dentist, Orthodontist	4	4	16	Local Induction	As identified at annual review
PACEMAKER EQUIPMENT	Cardiology, X-ray, Critical Care	Radiographer, Cardiologist, RGN	3	5	15	Formal Education & Local Induction	As identified at annual review
VENTILATORS	Theatres, ITU, SCBU, A&E, X-Ray, Harvey	ODO,ODP, RGN, SHO, Reg,Cons	3	5	15	Medics - Local Induction / ODP, RGN - Taught Course University	As identified at annual review
ANALYSING ING EQUIPMENT AND POINT OF CARE	Microbiology. Biochemistry, Pathology, Haematology, Critical Care , All Clinical areas	ODP, RGN, Jnr Doc, Reg, Cons, CNS, Midwife	3	5	15	Local Induction / Specialist Training	As identified at annual review
DIALYSIS EQUIPMENT	Renal Units, Critical care	Jnr Doc, Reg, Cons, CNS	3	5	15	Local Induction / Specialist Training	As identified at annual review
ANAESTHETIC EQUIPMENT & RESP MONITORS	Theatre, Midwifery, Obstetrics	ODP,RGN,RM,Jnr Doc,Reg,Cons,	3	4	12	Medics - Local Induction / ODP, RGN - Taught Course University	As identified at annual review
LASER EQUIPMENT	Theatres, Physiotherapy, Ophthalmology	Physiotherapist, Ophthalmologist	3	4	12	Local Induction / Taught Course University /Manufacturers	As identified at annual review
SCOPES - ENDOSCOPES, BRONCHOSCOPES ETC	Endoscopy, Theatre	ODP,RGN,Jnr Doc,Reg,Cons	3	4	12	Taught Course - Manufacturer / Local Induction	As identified at annual review
TOURNIQUETS	Theatre	ODP, RGN, Jnr Doc, Reg,Cons	3	4	12	Local Induction	As identified at annual review
TRACTION EQUIPMENT	Theatre, Critical care,	ODP, RGN, RSCN, Jnr Doc, Reg,Cons	3	4	12	Local Induction	As identified at annual review
X-RAY/RADIOTHERAPY	X-ray, Radiology, Theatre,	Radiologist, Radiographer, RGN, ODP	3	4	12	Formal Education & Local Induction	As identified at annual review
MONITORING EQUIPMENT - INVASIVE	Theatre, Midwifery and obstetrics, Wards, Critical care	ODP, NVQ, HCA, RGN, Reg, Cons	3	4	12	Local Induction / Specialist Training	As identified at annual review
SUCTION EQUIPMENT	Theatre, Midwifery and Obstetrics, Critical care, Wards	ODP, RN, RM, Jnr Doc, Reg, Cons, RSCN,	3	3	9	Demonstration & Self Assessment	As identified at annual review
CAUTERIZATION EQUIPMENT	Theatre	Jnr Doc, Reg, Cons	3	3	9	Practitioner Led Training	As identified at annual review
HEATING EQUIPMENT (Patient Warming)	Theatre, Midwifery and Obstetrics, Critical care, Wards	ODP,RGN,Jnr Doc,Reg,Cons	3	3	9	Demonstration & Self Assessment, Local Induction	As identified at annual review
OXYGEN/AIR/ENTONOX THERAPY EQUIPMENT	Theatre, Midwifery and Obstetrics, Critical care, Wards	ODO,ODP,RGN,Midwife,Jnr Doc, Reg,Cons	3	3	9	Demonstration & Self Assessment, Local Induction	As identified at annual review
WATER AND WAX BATH EQUIPMENT	Physiotherapy	Physio	3	3	9	Demonstration & Self Assessment, Local Induction	As identified at annual review
BED TABLE TROLLEY EQUIPMENT	Theatre, Midwifery and Obstetrics, Wards, Critical care	ODO, Porter, NVQ, HCA, RGN, ODP	2	4	8	Demonstration & Self Assessment, Local Induction	As identified at annual review
INSUFLATION EQUIPMENT	Theatre	ODP,RGN,Jnr Doc,Reg,Cons	2	3	6	Practitioner Led Training	As identified at annual review
BLOOD WARMING EQUIPMENT	Theatre Critical care, Midwifery and Obstetrics	ODP, NVQ, HCA, RGN, Midwife	3	2	6	Demonstration & Self Assessment, Local Induction	As identified at annual review
SHORTWAVE THERAPY EQUIPMENT	Physiotherapy	Physiotherapist	3	2	6	Demonstration & Self Assessment, Local Induction	As identified at annual review
THERAPEUTIC LAMPS - UV	Physiotherapy	Physiotherapist	2	3	6	Demonstration & Self Assessment, Local Induction	As identified at annual review
HOISTS	All clinical area	All clinical staff	3	2	6	Corporate Induction Taught Course , Competency Assessed, Manual handlin	As identified at annual review
MONITORING EQUIPMENT NON INVASIVE	Theatre, Midwifery and Obstetrics, Wards, Critical care, X-ray, Endoscopy	All Departments	2	2	4	Demonstration & Self Assessment	As identified at annual review
RESPIRATORY THERAPY, NEBULISER, VITALOGRAPH, LUNG FUNCTION	Resp Phys, Theatres, Wards, OPD	Technician, RGN, HCA	2	2	4	RGN, HCA - Practitioner Led / Tech - Formal Education	As identified at annual review
SEQUENTIAL COMPRESSORS	Theatres, Endoscopy	ODP, RGN, Reg, Cons, CNS	2	2	4	Practitioner Led Training	As identified at annual review
EXERCISE EQUIPMENT	Physiotherapy, Cardiology, Resp	Physio, CCSO, Resp Tech	2	2	4	Demonstration & Self Assessment, Local Induction	As identified at annual review
BLOOD PRESSURE EQUIPMENT	Wards, Critical Care, Theatre	Cadet, NVQ, HCA, ODP, RGN, HO, Jnr Doc, Reg, Cons, CNS, Midwife,	2	2	4	Demonstration & Self Assessment, Local Induction	As identified at annual review
TEMPERATURE EQUIPMENT	Theatre, Midwifery and Obstetrics, Wards, Critical care, X-ray, Endoscopy	HCA, ODP, RGN, Jnr Doc, Reg, Cons, CNS, Midwife, Nursery Nurse,	1	3	3	Demonstration & Self Assessment, Local Induction	As identified at annual review
AUDIOMETRY/EAR EQUIPMENT	OPD	Audiometrist	1	2	2	Demonstration & Self Assessment, Local Induction	As identified at annual review
ECG RECORDERS	Cardiology, Wards, Critical Care	RGN, CNS,	1	1	1	Demonstration & Self Assessment, Local Induction	As identified at annual review
PLASTER/RING SAW EQUIPMENT	Plaster room, Theatre, Critical care	Plaster Technician, Jnr Doc, Reg, Cons, CNS	1	1	1	Practitioner Led Training	As identified at annual review
STIMULATORS	Theatres, Physiotherapy	Physiotherapist, Jnr Doc, Reg, Cons	1	1	1	Demonstration & Self Assessment, Local Induction	As identified at annual review