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## META DATA

| TITLE                          | Policy for the Management of Medical Devices  
|                               | Medical Device Procedures                   |
| Date:                         | November 2011                               |
| Review Date:                  | November 2013                               |
| Created by:                   | Medical Devices Manager                     |
| Source:                       | Medical Devices Committee                   |
| Stored Centrally:             | Trust Intranet                              |
| Linked Trust Policies and     | Medical Devices Policy                      |
| Documents:                    | 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 interchangeability, 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.
- 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](mailto: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.
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

THE DEVICE MUST

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

Access Procurement Capital Portal on the Trust Intranet

COMPLETE EITHER

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

Obtain approval for expenditure

Raise Requisition

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

<table>
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<tr>
<th>Directorate: __________________________</th>
<th>Clinical Director: __________________________</th>
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<tr>
<td>Directorate Manager: __________________</td>
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<td>Commercial Finance Manager: __________</td>
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<td>Capital Portal Reference Number: ______</td>
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**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)*

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<th>Directorate Manager:</th>
<th>Operations / Estates Director:</th>
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### 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

<table>
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<th>Risk Avoidance</th>
<th>Patient Care Improvement</th>
<th>Fit with Strategy / Mission</th>
<th>Impact on Market Share</th>
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### 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

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TOTAL

6. Financial Information

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<th>£’000</th>
<th>Supporting Narrative</th>
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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]

<table>
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<tr>
<th>Estimated expenditure</th>
<th>Year 1</th>
<th>Year 2 +</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quarter 1</td>
<td>Quarter 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 9. PROPOSAL APPROVAL

<table>
<thead>
<tr>
<th></th>
<th>NAME</th>
<th>SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepared by</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reviewed by</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capital Team Review</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Committee Approval**  
[Enter name of committee, e.g. MMC, IM&T Exec, Facilities Exec Board etc.]

**Comments and Feedback:**  

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

<table>
<thead>
<tr>
<th>SCORE</th>
<th>WEIGHTING</th>
<th>WEIGHTED SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>4 x 25 = 100</td>
<td>290</td>
</tr>
<tr>
<td>4</td>
<td>3 x 25 = 75</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1 x 25 = 75</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 x 10 = 10</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2 x 15 = 30</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
RISK ASSESSMENT MATRIX

Table 1 Measurement of likelihood

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

Table 2 Measurement of consequence

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

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

<table>
<thead>
<tr>
<th>LIKELIHOOD</th>
<th>CONSEQUENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Insignificant</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Key</th>
<th>Description</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No Risk</td>
<td>White category</td>
</tr>
<tr>
<td>1-3</td>
<td>Low Risk</td>
<td>Green Category</td>
</tr>
<tr>
<td>4 - 8</td>
<td>Moderate Risk</td>
<td>Yellow Category</td>
</tr>
<tr>
<td>9 – 14</td>
<td>Significant Risk</td>
<td>Orange Category</td>
</tr>
<tr>
<td>15 - 25</td>
<td>High Risk</td>
<td>Red Category*</td>
</tr>
</tbody>
</table>

*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
Attachment 1 – Process for the management of medical devices
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

**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

**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

**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

**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

**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
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 INSTRUMENTS 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

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
</table>
| 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

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)

Instruments sterile?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
| - Placed through appropriate re-processing within SSD.  
  - Appropriate time allocated (48hrs) and incorporated in the loaning agreement | |

RELEASE OF MEDICAL EQUIPMENT

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)

- 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
# CHECK-LIST FOR LOANING OUT MEDICAL EQUIPMENT

<table>
<thead>
<tr>
<th>Equipment Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Equipment Control No.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Loaning-Out Dept</th>
<th>Borrowing Trust &amp; Dept</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Location of Dept.</td>
<td>Location of Dept.</td>
<td></td>
</tr>
<tr>
<td>Responsible Person loaning out</td>
<td>Responsible Person borrowing in</td>
<td></td>
</tr>
<tr>
<td>Designation</td>
<td>Designation</td>
<td></td>
</tr>
<tr>
<td>Contact Details</td>
<td>Contact Details</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of Loan</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Statement by Responsible Person loaning out</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I certify that the equipment meets the standards described in the policy.</td>
<td></td>
</tr>
<tr>
<td>I certify that I have supplied written operator's instructions with the equipment</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statement by Responsible Person borrowing in</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I certify that the equipment will only be used by competent persons.</td>
<td></td>
</tr>
<tr>
<td>I accept financial responsibility for any loss or damage to the equipment, as a result of negligence, whilst it is in my possession.</td>
<td></td>
</tr>
<tr>
<td>I undertake to ensure that all the conditions of the loan are adhered to.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>End of Loan</th>
<th>State of Device</th>
<th>Yes</th>
<th>No</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Decontamination status:</td>
<td>Known to be contaminated? (give details if &quot;yes&quot;)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repair required?</td>
<td>Give details if &quot;yes&quot;</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Details of person receiving equipment back to HOEFT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature</td>
<td>Print name</td>
</tr>
</tbody>
</table>

**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

Inform Procurement BEFORE seeing representatives regarding the loan or trial of medical devices

- Suppliers indemnity form completed (liable for financial risk arising from certain types of damage to the equipment/goods or to people or property)
- Trust remains liable for cost of repairing accidental damage

- Loaning in of medical equipment checklist completed by responsible person (Attachment 3)
- Initial consultation with clinical/specialist staff if required
- Procurement must be contacted prior to delivery or acceptance of any equipment/goods for trial and evaluation or gifted/donated to the Trust

Acceptance procedures for different types of loans differ depending on whether title passes to the trust

CERC procedures put in place
- Safe storage
- Issue and training of equipment
- Notification of maintenance/repair work carried out by external manufacturers
- Asset Manager notified of equipment being decommissioned

LENDER
Nominate responsible person

MAINTENANCE
- Planned maintenance is up to date
- Arrangements in place for additional planned maintenance needed whilst it is on loan
- Up to date maintenance records for devices maintained/repaired by manufacturer

BORROWER
Nominate responsible person

- Complies with any loaning out policy loaning out Trust/organisation may have
- Equipment used in accordance with instructions supplied
- Faults reported in writing to the loaning out nominated responsible person
- Prior to end of the loan inform supplier that if the equipment remains on the premises after the loan period has expired it remains at the suppliers risk
- Trust accepts no liability for any equipment remaining on its premises after the period of the loan has expired

TRAINING
- Operating instructions provided
Receipt of Equipment
- Person receiving equipment must be the Responsible Person

No
- Retain loaning in of medical equipment form
- Form signed by responsible person and returned by fax

Yes
- 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

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)
# CHECK-LIST FOR LOANING-IN MEDICAL DEVICES

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

<table>
<thead>
<tr>
<th>Equipment Name</th>
<th>Model</th>
<th>Manufacturer</th>
<th>Equipment Control No.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Loaning-Out Organisation</th>
<th>Borrowing Trust &amp; Department</th>
<th>Heart of England NHS Foundation Trust</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location of Dept.</td>
<td>Location of Dept.</td>
<td></td>
</tr>
<tr>
<td>Responsible Person loaning out</td>
<td>Responsible Person borrowing in</td>
<td></td>
</tr>
<tr>
<td>Designation</td>
<td>Designation</td>
<td></td>
</tr>
<tr>
<td>Contact Details</td>
<td>Contact Details</td>
<td></td>
</tr>
</tbody>
</table>

### 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**

<table>
<thead>
<tr>
<th>State of Device</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decontamination status: Known to be contaminated? (give details if “yes”)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repair required? Give details if “yes”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Details of person receiving equipment back to the loaning Trust or organisation**

<table>
<thead>
<tr>
<th>Signature</th>
<th>Print name</th>
<th>Date</th>
</tr>
</thead>
</table>
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.
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](http://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

Department of Health guidelines [http://www.dh.gov.uk/assetRoot/04/07/60/78/04076078.pdf](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](mailto:medicaldevicesmanagement@heartofengland.nhs.uk)

**Procurement Dept.** – James Harkin, Senior Procurement Officer, [james.harkin@heartofengland.nhs.uk](mailto:james.harkin@heartofengland.nhs.uk)

**Medical Devices Management** – Nicola Phillips, Medical Devices & Decontamination Coordinator, [nicola.phillips@heartofengland.nhs.uk](mailto:nicola.phillips@heartofengland.nhs.uk)

**Education Centres** – David Twist, Learning Resources & Access Manager, Heartlands Education Centre [david.twist@heartofengland.nhs.uk](mailto:david.twist@heartofengland.nhs.uk)
Attachment 1 - Process for the loan of medical equipment to patients
Loaning of Medical Devices to Patients (Prescribing)

1. Assess patient's clinical need
2. Select appropriate device
3. Provide end user with training, approved written instructions and emergency contact details
4. For long-term loans, ensure that arrangements are in place for regular maintenance
5. Issue device to end user and record details in patient's notes
6. Monitor for continuing suitability
7. Device available for re-use
8. Update documentation
9. Check condition and arrange maintenance if necessary
10. Cleaning / decontamination
11. Arrive return of device
12. Device no longer in use by patient
13. For long-term loans, ensure that arrangements are in place for regular maintenance
14. Issue device to end user and record details in patient's notes
15. Monitor for continuing suitability
16. Device available for re-use
17. Update documentation
18. Check condition and arrange maintenance if necessary
19. Cleaning / decontamination
20. Arrange return of device
21. Device no longer in use by patient
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
TRAINING PROCESS FLOWCHART

Are you identified on the Medical Equipment Training Database as a Competent or Proficient user of the equipment?

Yes

Have you received training in the use of the equipment?

Yes

Do you feel competent to use the equipment?

Yes

Complete Competency Matrix and forward to FEMD. Retain a copy in personal file/professional portfolio

Review process annually

No

No

Complete training/further training

Contact Ward/Department Manager to arrange further training requirements with FEMD

Complete Training

Contact Ward/Department Manager to arrange training

Contact Ward/Department Manager
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?

<table>
<thead>
<tr>
<th>Competency Level</th>
<th>Description</th>
<th>Indicate on competency matrix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proficient</td>
<td>Capable of training other members of staff in the use of equipment</td>
<td>P</td>
</tr>
<tr>
<td>Competent</td>
<td>Competent to use equipment and demonstrate use to others</td>
<td>C</td>
</tr>
<tr>
<td>Beginner</td>
<td>Have received demonstration or theory based training and require further practice in the use of equipment</td>
<td>B</td>
</tr>
</tbody>
</table>

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:-

<table>
<thead>
<tr>
<th>BEGINNER</th>
<th>COMPETENT</th>
<th>PROFICIENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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.</td>
<td>Has a deeper understanding and is able to analyse problems with specific devices and relate knowledge to physiological parameters. Has more in depth knowledge base and can demonstrate device for competency sign off.</td>
</tr>
</tbody>
</table>

### MEDICAL DEVICE RISK : SELF ASSESSMENT OF COMPETENCY

<table>
<thead>
<tr>
<th>NAME:</th>
<th>DATE of COMPLETION:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature:</td>
<td>Verifier</td>
</tr>
<tr>
<td>Verifier</td>
<td>Verifier</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INFUSION DEVICES</th>
</tr>
</thead>
<tbody>
<tr>
<td>McKinley T34 Ambulatory pump</td>
</tr>
<tr>
<td>Smiths Omnifuse PCA syringe driver</td>
</tr>
<tr>
<td>Codan Argus 708</td>
</tr>
<tr>
<td>Smiths MS26 Driver</td>
</tr>
<tr>
<td>Alaris SE1</td>
</tr>
<tr>
<td>Nutricia Infinity Feed Pump</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RESUSCITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phillips Heartstream XL defibrillator</td>
</tr>
<tr>
<td>Phillips Heartstart MRX M3535A</td>
</tr>
<tr>
<td>Ambu bag and O2 flow meter</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>POINT OF CARE MONITORING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Optium Xceed glucose monitor</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RESPIRATORY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen regulator Wall</td>
</tr>
<tr>
<td>Portable O2 cylinder and flow meter</td>
</tr>
<tr>
<td>Suction - Wall - Regulator inc Medivaccontainer</td>
</tr>
<tr>
<td>Portable Suction Unit Laerdal LSU</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MONITORING EQUIPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critikon Dinamap Pro 300</td>
</tr>
<tr>
<td>Welch Allyn -Vital signs Monitor</td>
</tr>
<tr>
<td>GE Mac 1200 lead ECG machine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mallinkrodt Medical Warm touch (Bair hugger)</td>
</tr>
<tr>
<td>Braun Pro 4000 Tympanic Thermometer</td>
</tr>
<tr>
<td>Arjo Bath Hoist</td>
</tr>
<tr>
<td>Arjo Standing Hoist</td>
</tr>
<tr>
<td>Hill Rom Total Care bed</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>NAME</th>
<th>Band</th>
<th>Staff Group</th>
<th>CxL= Risk</th>
<th>Date of Training</th>
<th>Competency Letter</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANN OTHER</td>
<td>6</td>
<td>ODP</td>
<td></td>
<td>14/03/11 C</td>
<td></td>
</tr>
<tr>
<td>BILL BROWN</td>
<td>2</td>
<td>HCA</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FRED BLOGGS</td>
<td>5</td>
<td>RGN</td>
<td></td>
<td>14/03/11 B</td>
<td></td>
</tr>
<tr>
<td>RON BAILEY</td>
<td>5</td>
<td>RGN</td>
<td></td>
<td>14/03/11 P</td>
<td></td>
</tr>
</tbody>
</table>

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
(Appendix 6, Attachment 6)
### MEDICAL EQUIPMENT CATEGORIES RISK ANALYSIS

<table>
<thead>
<tr>
<th>EQUIPMENT CATEGORY</th>
<th>Clinical Areas</th>
<th>Authorised Users if Trained &amp; Competent</th>
<th>Likelihood</th>
<th>Consequence</th>
<th>SCORE (LXC)</th>
<th>Training Type</th>
<th>Update Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defibrillators/Resuscitation Equipment</td>
<td>Theatre, Midwifery and Obstetrics, Wards, Critical care</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>5</td>
<td>5</td>
<td>20</td>
<td>Taught Course - Resus Team</td>
<td>Annual</td>
</tr>
<tr>
<td>Pumps (Infusion)</td>
<td>Theatre, Midwifery and Obstetrics, Wards, Critical care</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>5</td>
<td>5</td>
<td>20</td>
<td>Taught Course - FEMD &amp; Manufacturers, Local Induction, Self Assess (Verify)</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Diathermy and Lithotripter Equipment</td>
<td>Theatre</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>Local Induction / Taught Course University, Manufacturers</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Drills</td>
<td>Theatre, Orthodontics</td>
<td>Reg, Cons, Dentist, Orthodontist</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Pacemaker Equipment</td>
<td>Cardiology, X-ray, Critical Care</td>
<td>Radiographer, Cardiologist, RGN</td>
<td>3</td>
<td>5</td>
<td>15</td>
<td>Formal Education &amp; Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Ventilators</td>
<td>Theatres, ITU, SCBU, A&amp;E, X-Ray, Harvey</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>5</td>
<td>15</td>
<td>Medics - Local Induction / ODP, RGN - Taught Course University</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Analysing NG Equipment and Point of Care</td>
<td>Microbiology, Biochemistry, Pathology, Haematology, Critical Care</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>5</td>
<td>15</td>
<td>Local Induction / Specialist Training</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Dialysis Equipment</td>
<td>Renal Units, Critical care</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>5</td>
<td>15</td>
<td>Local Induction / Specialist Training</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Anaesthetic Equipment &amp; Resp Monitors</td>
<td>Theatre, Midwifery, Obstetrics</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>Medics - Local Induction / ODP, RGN - Taught Course University</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Laser Equipment</td>
<td>Theatres, Physiotherapy, Ophthalmology</td>
<td>Physiotherapist, Ophthalmologist</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>Local Induction / Taught Course University, Manufacturers</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Scope - Endoscopes, Bronchoscopes Etc.</td>
<td>Endoscopy, Theatre</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>Taught Course - Manufacturer / Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Tourniquets</td>
<td>Theatre, Critical Care, Endoscopy, X-ray, Critical Care</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>X-ray/Radiography</td>
<td>X-ray, Radiology, Theatre</td>
<td>Radiologist, Radiographer, RGN, ODP</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>Formal Education &amp; Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Monitoring Equipment - Invasive</td>
<td>Theatre, Midwifery and Obstetrics, Wards, Critical care</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>Local Induction / Specialist Training</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>SUCTION Equipment</td>
<td>Theatre, Midwifery and Obstetrics, Critical care, Wards</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>Demonstration &amp; Self Assessment</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>CAUTERIZATION Equipment</td>
<td>Theatre</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>3</td>
<td>9</td>
<td>Practitioner Led Training</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>HEATING Equipment (Patient Warming)</td>
<td>Theatre, Midwifery and Obstetrics, Critical care, Wards</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>3</td>
<td>9</td>
<td>Demonstration &amp; Self Assessment, Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Oxygen/Air/O2 Therapy Equipment</td>
<td>Theatre, Midwifery and Obstetrics, Critical care, Wards</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>3</td>
<td>9</td>
<td>Demonstration &amp; Self Assessment, Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Water &amp; Wax Bath Equipment</td>
<td>Physiotherapy</td>
<td>Physio</td>
<td>3</td>
<td>3</td>
<td>9</td>
<td>Demonstration &amp; Self Assessment, Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Bed Table Trolley Equipment</td>
<td>Theatre, Midwifery and Obstetrics, Wards, Critical care</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>4</td>
<td>12</td>
<td>Demonstration &amp; Self Assessment</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Insulation Equipment</td>
<td>Theatre</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>Practitioner Led Training</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Blood Warning Equipment</td>
<td>Theatre, Critical care, Midwifery and Obstetrics</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>Demonstration &amp; Self Assessment, Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Shortwave Therapy Equipment</td>
<td>Physiotherapy</td>
<td>Physiotherapist</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>Demonstration &amp; Self Assessment, Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Therapeutic Lamps - UV</td>
<td>Physiotherapy</td>
<td>Physiotherapist</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>Demonstration &amp; Self Assessment, Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Hoists</td>
<td>All clinical areas</td>
<td>All clinical staff</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>Corporate Induction, Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Monitoring Equipment Non Invasive</td>
<td>Theatre, Midwifery and Obstetrics, Wards, Critical care, X-ray, Endoscopy</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>Demonstration &amp; Self Assessment</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Respiratory Therapy, Nebuliser, Vitalography, Lung Function</td>
<td>Respir Phys, Theatres, Wards, ODP</td>
<td>Technician, RGN, HCA</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>RGN, HCA - Practitioner Led / Tech - Formal Education</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Sequential Compressors</td>
<td>Theatres, Endoscopy</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>Practitioner Led Training</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Exercise Equipment</td>
<td>Physiotherapy, Cardiology, Respiratory Physiotherapy, CSSD, Resp Tech</td>
<td>Physio, CSSD, Resp Tech</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>Demonstration &amp; Self Assessment, Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Blood Pressure Equipment</td>
<td>Wards, Critical Care, Theatre</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>Demonstration &amp; Self Assessment, Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Audiology/Ear Equipment</td>
<td>Audiology, Wards, Critical Care</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>Demonstration &amp; Self Assessment, Local Induction</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>EEG Recorders</td>
<td>Cardiology, Wards, Critical Care</td>
<td>Jnr Doc, Reg, Cons.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Practitioner Led Training</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Plastering Saw Equipment</td>
<td>Plaster Room, Theatre, Critical Care</td>
<td>Plaster Technician, Jnr Doc, Reg, Cons.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Practitioner Led Training</td>
<td>As identified at annual review</td>
</tr>
<tr>
<td>Stimulation</td>
<td>Theatres, Physiotherapy</td>
<td>Physiotherapist, Jnr Doc, Reg, Cons.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Demonstration &amp; Self Assessment, Local Induction</td>
<td>As identified at annual review</td>
</tr>
</tbody>
</table>