LINCOLNSHIRE PARTNERSHIP NHS FOUNDATION TRUST

MEDICAL DEVICES MANAGEMENT POLICY

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Author:	**Head of Physical Healthcare, IPC and Lead for Medical Devices**
Approving Body:	**Legislative Committee**
Approval Date:	**July 2018**
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Ratified Date:	**August 2018**
Committee, Group or Individual Monitoring the Document	**Medical Devices Group**
Review Date:	**July 2021**

Contents

1. Introduction

1.1 This policy was originally compiled by a multi-disciplinary county-wide group, comprising members from ULHT Clinical Engineering, ULHT Procurement, LPFT Clinical, Estates and Facilities Services.

1.2 The current version (07/18) has been reviewed by the LPFT Medical Devices Group (MDG)

2. Purpose

2.1 Medical devices and equipment are used every day by most health care professionals to support the care and treatment of patients. The objective of this policy is to provide a framework for the management of medical devices and minimise hazards related to the use of medical devices. To ensure that staff are properly trained and competent in the use of medical devices and that devices are maintained in a safe and reliable condition and recorded on a central database/inventory.

2.2 Risk assessments should be undertaken to identify any hazards associated with medical devices and steps taken to eliminate these risks. Where they cannot be eliminated they must be reduced to a minimum and appropriate control measures identified.

2.3 The policy will promote the requirement for procedures which will instil a safer, more efficient, and high quality management of all medical devices.
Good management will involve assessment of medical devices from the justification of the need, through service life, training and use, until the ultimate disposal of the device.

2.4 This policy should be read in conjunction with:

Safety, Health, Environment & Fire Policy
Reporting and Management of Risk Policy
Infection Control Policies

Read in conjunction with: Standards for Better Health, NHSLA (National Health Service Litigation Authority) Standards, Medicines and Healthcare Products Regulatory Agency (MHRA) guidance, including DB2006(05). The MHRA is responsible for: ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy.3.

Definitions

The term “medical device” covers a wide range of products used every day in primary care settings. Devices include items such as needles, syringes, infusion pumps, endoscopes, examination gloves, dressings, walking sticks, and blood glucose meters. In other words, any instrument, apparatus, appliance, material or health care product, excluding drugs, used for, or by, a patient or service user for:

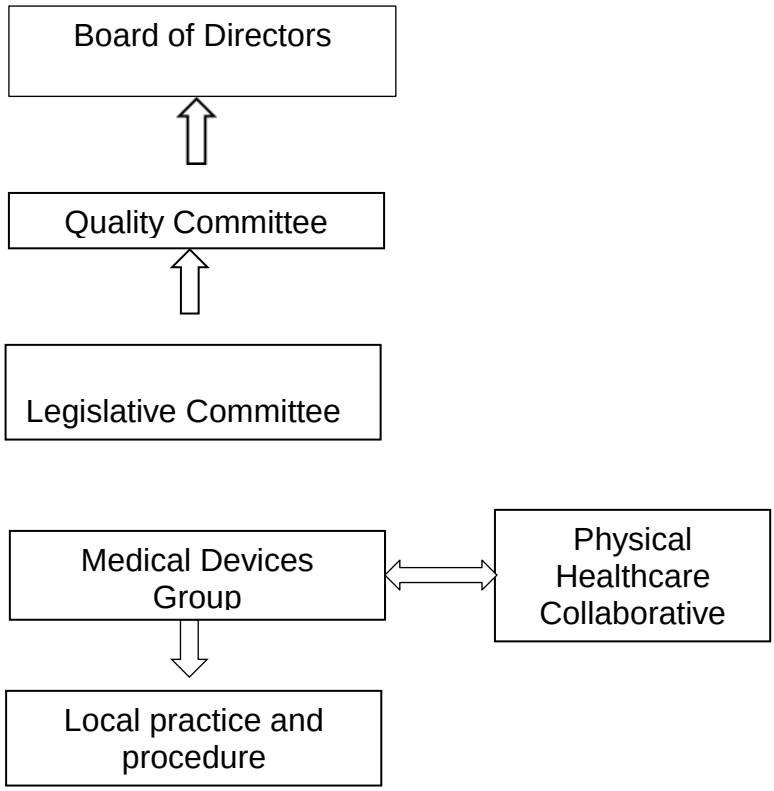
- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or impairment.
- Investigation, replacement, or modification of the anatomy or of a physiological process.
- Control of conception.

A further list of some of the products covered by the definition of medical device and prepared by the Medical Devices Agency is attached at **Appendix A**.

4. Duties

The following reporting structure shows lines of accountability throughout the organisation.

Reporting Structure:



4.1 **Director of Nursing, AHPs and Quality**

The Director of Nursing is the Board-level director with the lead for Quality Committee and has overall responsibility for the management of medical devices within LPFT**.**

4.2 **Medical Devices Group**

For constitution and Terms of Reference see Appendix B.

The Medical Devices Group will advise the Legislative Committee on policy and procedures relating to the management of medical devices. Any residual risks will be escalated to the Quality Committee.

4.3 **Quality Committee**

The Quality Committee oversees risks within the organisation and will incorporate any issues relating to medical devices management in its report to the Board, as required.

4.4 **Equipment Controllers - Ward Managers/Team Coordinators**

Ward Managers and Team Coordinators will be responsible for the local management of medical devices. This will include identifying all equipment, authorised users and training needs within their area. They are responsible for:

- Ensuring that a local list of equipment and records of training are maintained for their clinical area

Ensuring purchasing of new equipment is in line with the guidelines within this

Policy (see section 5).

Ensure receipt and commissioning of all new equipment

Ensure all new equipment is entered onto the LPFT asset register

Ensure appropriate servicing and maintenance of medical devices and maintain accurate records are available for inspection upon request

Recommend replacement of medical devices as appropriate in line with this policy

Ensure appropriate disposal and decontamination of equipment

Notify any problem with a medical device to the ward manager/team coordinator and complete a Datix form.

Ensure the device is taken out of use and that all staff in the clinical area concerned are aware that the equipment must not be used. (See section 13).

4.5 **All staff**

All staff have responsibility with regard to adverse incident reporting and should follow the Reporting and Management of Risks Policy in respect of medical devices.

Staff must take reasonable care for their own health and safety and also of other people who may be affected by their acts or omissions. They should report any problems relating to use, maintenance, servicing or decontamination as contained in this policy. Any incident involving equipment related to medical devices should be reported via Datix.

5. Procurement

5.1 For all queries and actions in relation to procurement of medical devices we have an overarching procurement policy in conjunction with ULHT. This covers all aspects of procurement including:

- The Decision Making Process
- Identification of Need
- Prescription of Devices
- To refurbish or replace?
- Evaluation and Selection of Equipment
- The case for standardisation and variety reduction
- Acquisition methods
- Purchasing (guidance available via the following link)
- http://sharon/physical-healthcare/Documents/Forms/AllItems.aspx?RootFolder=%2fphysical%2dhealthcare%2fDocuments%2fMedical%20Devices&FolderCTID=&View=%7bF48C17F1%2dAEBC%2d4B05%2d9AB2%2dE367DD4756C9%7d
-
- Leasing
- Devices on Loan to the Trust
- Indemnity Forms
- Donations to the NHS
- Pre-Purchase Questionnaires (PPQs)
- Suppliers responses
- Approval of PPQs
- Contract documentation
- Retention
- Summary
- Acceptance of Medical Devices
- Acceptance testing
- Checking and/or modifying instructions

Please use the following link for all enquiries regarding procurement of medical devices: purchaseorders2@ulh.nhs.uk

6. Storage

6.1 All medical devices must be stored in accordance with manufacturing guidance and/or in line with Appendix J.

6.2 Equipment powered by re-chargeable batteries must be stored plugged in to electrical outlet socket to ensure it is available for immediate use.

6.3 Where devices may be stored for some time their shelf life must be monitored with a stock rotation system in place.

6.4 The physical condition of the storage area also requires consideration i.e. wet, inappropriate temperatures will impact on device performance.

6.5 It is important that equipment requiring decontamination or awaiting repair are stored separately and clearly labelled.

7. Training

7.1 It is the responsibility of each individual member of staff to ensure that they are conversant with the content of this policy and are appropriately trained and competent to use the medical devices which they are required to use as part of their duties.

7.2 It is the responsibility of line managers to ensure their supervisees are conversant with the policy content and are appropriately trained and competent to use medical devices which they are required to use as part of their duties. This will be implemented at local induction and subsequently monitored at management supervision as required.

7.3 Managers should ensure that all personnel assigned responsibilities and tasks within the management system are competent to use any equipment necessary.

7.4 All staff need training in the safe use of equipment, in the case of equipment for lifting and handling, the organisation has a duty of care and this training is organized by the Moving and Handling Lead.

7.5 Mandatory training for resuscitation will be monitored by the Training Department. Training for other devices will be monitored by the individual ward/team managers.

7.6 An outline of staff authorized to use medical devices and the training required is included in **Appendix K** (Medical Devices Training Needs Guidance).

7.7 Managers are responsible for maintaining local training records for medical devices. The Centre for Research, Learning and Development will maintain records of staff trained in Moving and Handling and Life Support

7.8 **Training for Professional Staff**

The Manager is responsible for ensuring that staff training is received by the appropriate staff, and documented, including any student on placement. Refresher training must also be provided where appropriate.

7.9 Training for Technical Staff (see 10.2)

All technical staff should be, where appropriate, trained on a variety of general Medical Devices in order to know:

- How the equipment is clinically used.
- What safety precautions, both clinically and technically, need to be adhered to.
- How to approach the equipment in a professional manner, in order to instil confidence in the users.

7.11 Training for Service Users

Professional staff should be aware that a failure to pass on to the service user the manufacturer's original instructions on how to use a device may not only comprise the service user's ability to us the device safely, but instructions on the use of a device should be suitable for both service users and their carers. Where necessary these may need to be explained or adapted. Service users with particular disabilities or medical conditions will need special instructions and training from their prescriber.

7.12 New Devices

When new models of Medical Devices are delivered into the Trust, all technicians, where appropriate, should have the opportunity to familiarise themselves with the fundamental operation of the device.

7.13 User Manuals and Training

The original user manuals should be supplied along with the device, in order to ensure clear and safe use. Recommendations on any other necessary training should be given. The original manufacturer should be able to provide this information, along with any updates which may have been issued since manufacture. Full details on how to maintain or service the device should also be supplied.

Ward/Unit/Team/Department training records will be held by the Band 7 manager or their nominated deputy.

NB: If manuals and training information are not available, the medical device may have been rendered unsuitable for passing onto a new user.

8. Decontamination

8.1 Reference should be made to the Decontamination Policy via the following hyperlink:

http://www.lpft.nhs.uk/assets/files/Accessing%20our%20information/Policies%20and%20Procedures/policy-7g-decontamination-v2-approved-at-qc-20.10.17.pdf

8.2 It is the responsibility of the Trust to ensure that all medical devices do not carry a biological or chemical hazard. The Trust has a duty to ensure that decontamination of any device is applied before re-use, submission to maintenance, or repair and before being transported to another location.

8.3 All equipment should be decontaminated as per the suppliers/manufacturer's instructions. Items subject to inspection, service or repair must be decontaminated appropriately prior to these activities. Any loaned items being returned to a manufacturer/supplier must also be decontaminated.

8.4 For decontamination go to Appendix M and follow the link to the LPFT Decontamination Policy

8.5 Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled and placed in quarantine. MDA and the manufacturer/supplier should be contacted for advice prior to any further action being taken.

9. Cleaning

9.1 All medical devices will fall into specific categories on how to clean and disinfect the particular device. The cleaning agent will be dependent upon the category to which the device belongs.

10. Medical Device/Equipment Maintenance

10.1 User Checks

Professional users and service users are responsible for pre-use checks, regular cleaning and preparation for use.

10.2 Service and Repair

Where medical devices are required to be repaired or serviced various options are available dependent on the device. The Trust has contracts or Service Level Agreements (SLA's) with the:

I. Manufacturer/distributor/external provider

II. Clinical Engineering (ULHT) – via Service Level Agreement

Keeping medical devices safe and effective needs both routine maintenance procedures supervised by professional users, and planned maintenance and repair carried out by suitability trained technicians.

Planned maintenance should follow manufacturer's guidance on procedures and staff training. Devices which need maintenance work must be cleaned, and where relevant, decontaminated before release.

It is currently the responsibility of the individual ward/dept. to arrange for servicing of medical equipment. The equipment will have a sticker on with the date of the last service if it has already been serviced. If new the service will have to be arranged by the ward/dept. A central record will be kept electronically of which equipment needs servicing, how often and when it was last serviced and next due. This is the Asset Register which is currently held by Estates.

Moving & Handling equipment is processed by the Moving & Handling Lead and a separate servicing agreement made.

Copies of the Medical Equipment Maintenance Request Form and Category List are available on request by email to clinical.engineering@ulh.nhs.uk

Copies of the Medical Equipment Service Request form are available on the internet and should be used when submitting equipment to Clinical Engineering at ULHT, for service.

10.3 **Register/Database**

Capital assets are recorded on the Trust's asset register. This includes medical devices. Best practice is to record all medical devices with the following details Make, Model, Date of Installation, order number, cost centre, asset number etc., so that the asset register is accurate.

11. Disposal

11.1 Medical devices can be disposed of by one of three methods:

I. Transfer of ownership

II. Decommissioning

III. Disposal

11.2 Risk Management is an essential tool to aid with the decision making process for disposing of a used device in the most appropriate and safe method. Staff should consult Clinical Engineering ULHT for queries in relation to disposal of medical devices where unclear using the flowing link: clinical.engineering@ulh.nhs.uk

The manufacturer should provide information on safe methods of disposal.

11.3 Transfer of ownership is subject to national legislation to ensure the equipment is safe for use. There should be documented evidence of legal liability, and legal advice may be required.

11.4 Decommissioning aims to make equipment safe and unusable, while minimizing damage to the environment. It should include decontamination.

11.5 . The disposal of electrical/electronic equipment is subject to specific regulations (WEEE Regulations – Waste of Electrical Electronic Equipment), which means that there is a separate process for disposal of such equipment. Refer to the Medical Devices disposal form via the following linkhttp://sharon/physical-healthcare/Documents/Forms/AllItems.aspx?RootFolder=%2fphysical%2dhealthcare%2fDocuments%2fMedical%20Devices&FolderCTID=&View=%7bF48C17F1%2dAEBC%2d4B05%2d9AB2%2dE367DD4756C9%7d

12. Re-Use/Re-Issue

12.1 Devices designated for single use must not be re-used under any circumstances.

13. Adverse Incidents

13.1 An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of the patients, users or other persons. Reference should be made to the Reporting and Management of Incidents, Complaints & Claims Policy

13.2 There is a Safety Alert system in place to ensure that every ward department is notified of any hazard notices. This includes any notices in relation to the safety of medical devices.

13.3 Defective items

Defective items should be removed from use and reported for repair or disposal.

An investigation should be carried out as per the Reporting and Management of Incidents, Complaints & Claims Policy

13.4 Evidence

All material evidence should be labelled and kept secure. This includes the products themselves and, where appropriate, packaging material or other means of batch identification. The evidence should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports.

If a patient dies unexpectedly, any medical device implicated in the death must not be interfered with in any way, unless necessary for safety reasons or to prevent loss of samples. The procedure for reporting serious adverse incidents is then followed.

The manufacturer should be informed but not allowed to inspect the equipment or remove any part of it without the express consent of the coroner.

The Department of Health has agreed with the Coroners' Society that, with the consent of the coroner, an officer from the MHRA can examine suspect products so as not to delay remedial action designed to protect others.

14. Medical Devices on loan to Patients

14.1 Units issuing patients with devices for use both within the Trust and outside should ensure that:

- Training is given to the patient on the safe use of the medical device.
- Written and approved manufacturer's instructions are provided where appropriate.
- Contact details are given to the patient in the event of any necessary support being required.
- When on loan for an extended period all medical devices requiring regular maintenance (M.D.A. directive) should be on a programme for planned preventative maintenance.
- Arrangements must be made to recover the device when no longer in use by the patient.

15. Development of Policies and Procedures

15.1 This policy was originally compiled by a multi-disciplinary county-wide group, comprising members from ULHT Clinical Engineering, ULHT Procurement, LPFT Clinical, Estates and Facilities Services and adapted for use by LPT.

16. Consultation, Approval and Ratification Process

16.1 This policy has been consulted upon in line with Corporate Documents and Policies Procedure

16.2 Feedback from the consultation was maintained by the policy author in line with Corporate Documents and Policies Procedure and any necessary amendments made before submission for approval.

17. Review and Revision Arrangements including Version Control

17.1 The policy will be reviewed by the Medical Devices Group on a tri-Annual basis.

17.2 Corporate and Legal Services will maintain a version control sheet, as per Corporate Documents and Policies Procedure

18. Dissemination and Implementation of a Policy

18.1 The policy will be disseminated as per Corporate Documents and Policies Procedure

18.2 Training will ensure trust-wide implementation, as detailed in **section 7** above

19. Policy Control including Archiving Arrangements

19.1 Corporate and Legal Services will retain a copy of each policy for a minimum of 10 years in line with the recommendations contained within 'Records Management NHS Code of Practice for Health and Social Care (2016)

20. Monitoring Compliance with and Effectiveness of Policies and Procedures

Systems	**Monitoring and/or Audit**				
Criteria	Measurables	Lead Officer/group	Frequency	Reporting to	Action Plan/Monitoring
Systems in place to maintain the approved product list.	Asset register corresponds with the approved product list.	Medical Devices Group (MDG)	Annual review.	Legislative Committee	Asset register monitored by LPFT electronic method
Systems in place to monitor the number of adverse incidents/near misses involving medical devices	Number of reported incidents	Medical Devices Group	Quarterly	Legislative Committee Patient Safety and Experience Committee	MDG to review the number and type of reported incidents.
Systems in place to monitor the impact of Medical Alerts	Responsible Managers disseminate information to teams	Quality and Safety Department	Quarterly	Patient Safety and Experience Committee	Monthly compliance report

20.2 Standards/Key Performance Indicators

TARGET/STANDARDS	KEY PERFORMANCE INDICATOR
Department of Health – Standards for Better Health C4 Health care organisations keep patients, staff and visitors safe by having systems to ensure that: **- all risks associated with the acquisition and use of medical devices are minimised.**	Availability of an approved product list. The number of patient safety incidents involving medical devices.
Department of Health – Standards for Better Health C4 Health care organisations keep patients, staff and visitors safe by having systems to ensure that: **- all reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are well managed.**	The number of patient safety incidents involving medical devices.

21. References and related Policies

The former NHS Litigation Authority (2008) NHSLA Risk Management Standards for MH and LD Trusts www.nhsla.com

22. Associated Documentation

Appendix A - Common categories of medical devices

Appendix B - Medical Devices Group Terms of Reference

Appendix C - Refurbish or Replace

Appendix D - Total Costs checklist

Appendix E - Purchasing

Appendix F - Servicing and Callibration

Appendix G - NHS Form Indemnity A&B

Appendix H - Acceptance Checklist

Appendix I - New Device Checklist

Appendix J - Storage

Appendix K - Training Needs Guidance

Appendix L - Training Record Form

Appendix M - Decontamination

Appendix A

COMMON CATEGORIES OF MEDICAL DEVICE

This list is not exhaustive. It provides examples of medical devices. Equipment used in the diagnosis or treatment of disease, or monitoring of patients, such as:

- Chiropody and podiatry equipment
- Dental instruments, equipment and materials.
- Dressings
- Endoscopes
- ECT
- Examination gloves
- Gastrostomy tubes
- Intravenous (IV) administration sets and pumps
- Nebulisers
- Ophthalmic equipment
- Peak flow meters
- Surgical instruments
- Suction equipment
- Syringes and needles
- Sphygmomanometers
- Thermometers
- Ultrasound Doppler
- Urinary catheters

Equipment used in life support such as:

- Defibrillators
- Domiciliary oxygen therapy systems
- Insulin injectors
- Pulse oximeters
- Ventilators used in the home

In vitro diagnostic medical devices and their accessories, such as:

- Blood glucose measuring devices
- Cholesterol test kits
- Pregnancy test kits

- Specimen collection tubes
- Urine test strips

Equipment used in care, such as:

- Adjustable beds
- Lifting poles
- Patient hoists
- Pressure relief equipment
- Stoma care equipment

Equipment used by people with disabilities, such as:

- Bathing equipment
- Commodes
- External prostheses and orthoses
- Hearing aids
- Prescribable footwear
- Standing frames
- Urine drainage systems
- Walking aids
- Wheelchairs and special support seating

Other examples include:

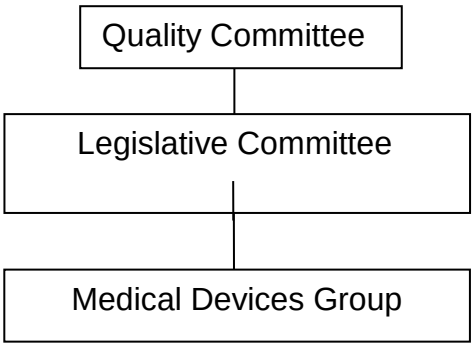
- Condoms
- Contact lenses and care products
- Intra-uterine devices (IUDs)
- Drug and Alcohol screening equipment

Appendix B

MEDICAL DEVICES GROUP

Terms of Reference

Structures and Relationships



Reporting Arrangements

- The Medical Devices Group reports to the Legislative Committee, which will escalate issues as required to Quality Committee.
- The Medical Devices Group works closely with other Trust Committees and Groups, reporting issues, concerns, feedback and information as required.

Specific Objectives for the Medical Devices Group

1. Ensure the Trust has appropriate and effective governance systems and processes in place to monitor and manage medical devices across the Trust.
2. Ensure the planning, monitoring and implementation of continuous improvement in the management of medical devices, including the procurement and maintenance of medical devices. Ensure this is achieved through Point 1 (above) and through implementation of relevant national and local policy and guidance.
3. Provide both clinical and non-clinical leadership and expertise to support medical devices developments across the Trust, identified through Points 1 and 2 above. This includes identifying the support required for staff to achieve and maintain high levels of medical devices management as appropriate to their job roles and responsibilities.
4. Receive feedback from staff and partners, to inform development requirements, to problem-solve, and to identify lessons for learning.
5. Coordinate clear communication in respect of medical devices across the Trust and with key related partners, to support consistently high standards of related practice.
6. Receive Central Alerting System (CAS) Alert updates, including any related system or process issues.

7. Receive procurement reports, including updates on any concerns related to maintaining an up-to-date data base of the approved medical devices product lists.
8. Receive Clinical Engineering reports, including updates on any concerns related to the maintenance of the Trust's medical devices.
9. Receive medical devices related contracting updates and concerns as required.
10. Provide updates bi-annually to the Legislative Committee, escalating between times as required in line with the Trust's Board Assurance and Escalation Framework.
11. Monitor the successful management of the Trust's medical devices assets, including holding to account the clinical Divisions in respect of their assurance of the maintenance of robust and up-to-date medical devices asset registers across the Trust.
12. Ensure prompt escalation and resolution of medical devices related concerns to ensure patient and staff safety is not compromised.
13. Ensure learning from adverse incidents involving medical devices.
14. Ensure the Trust's Medical Devices Policy is up-to-date and reviewed at the required frequency.
15. Provide feedback, and where required instruction, to Trust staff in respect of medical devices, to ensure compliance with local and statutory requirements.
16. Monitor and review any medical devices serious incidents and medical devices related Datix incidents that arise.
17. Ensure medical devices risk issues identified are escalated as required in line with the Trust's Board Assurance and Escalation Framework.

Members are required to attend all meetings or to send deputies where absence is unavoidable.

Head of Physical Healthcare, IPC and Lead for Medical Devices (Chair)

Matron Older Adult Services (Deputy Chair)

Matron Adult Inpatient Services Associate Director of Facilities and Estates

Head of Clinical Engineering (ULHT)

Deputy Operational Purchasing Manager/Capital Buyer (ULHT)

Patient Safety Lead

Specialist Services Division Representative

General Adult Services Representative

Infection Prevention and Control Specialist Nurse

Other staff will be required to attend to support specific case or subject discussion including the following:

Head of Workforce and Development

Head of Contracting (or delegated deputy)

Medical Representative

Clinical Systems Team Coordinator

Chief Pharmacist

Physical Healthcare Practitioners

Trust AHP Lead

Head of Informatics

Frequency of Meetings

Quarterly

Quorum: A quorum must include at least five of the required membership.

Approval Date: March 2015

Review Date: July 2018. Review annually

Appendix C

Refurbish or Replace

Factor	**Notes**
Life cycle/replacement	For many items, especially disability equipment, the price is linked to solidity of construction and quality of materials; hence to the useful life of the device.
Fitness for intended application	The device chosen must meet the user organisation's performance specification, but unnecessary features may be a disadvantage – complicated devices tend to break down more frequently and are harder to use.
Guarantee/warranty	Comparison of terms needs to be undertaken as part of the process.
Safety	Check compliance with safety and performance standards. Which have been used? Do MDA publications reveal persistent problems? Can professionals identify safety problems?
Reliability	Take into consideration whether other users have experience problems and failures.
Service support	Check that spares are readily available and that service support is guaranteed. Also if a response

	time is guaranteed.
Maintenance requirements	Check the intervals between service, frequency and complexity of checks and calibrations needed during operation.
Technical advice	Is there free access to technical advice from the manufacturer for professional users and technical staff? Is there a 24-hour helpline?
Diversity	Assess whether choosing another device will increase the number of types in use. Will this introduce risks in terms of staff requiring training using unfamiliar equipment?

Appendix D

Total costs checklist

Cost	**Notes**
Price	In some cases, manufacturers will seek to offset low purchase prices with expensive contracts for consumables or servicing
Tendering	The resources needed to manage and participate in the tendering process.
Risk assessment	Is the device CE-marked? Any previous concerns raised? Any MHRA publications related to this device?
Installation	Any special services required that may not currently be available (e.g. power, water, gas, electricity) plus any minor building works. Costs in terms of environmental and safety.
Professional user costs	Local production of procedure manuals, if needed. Cost of training sessions for all relevant staff. Updating any 'local' catalogues. NB: Complex devices may also require additional staff.

Consumables/accessories	Are third party and upgrade consumables or accessories cheaper than those produced by the device manufacturer? Are they fully compatible? Are they acceptable to use (e.g. invalidation of any guarantees/warranties from the device manufacturer?) Are hardware or software upgrades planned? Would there be any additional costs in 'retro-fitting' later?
Overheads	Any additional personal protective equipment needed, e.g. masks, goggles? Are there any additional costs in terms of environmental or health monitoring.
Utilities	Operational costs to be considered, including electricity, water, laundering and cleaning.
Maintenance	Maintenance contracts and costs of spares
Repair	Call-out charges and the need for back-up devices in case of failure
Disposal	Indemnity insurance may be required Some types of device are required to be disposed of in such a manner that attracts additional costs (e.g. radioactive isotopes)

Appendix E

<u>Purchasing</u>

Topic	**Notes**
Device details	Type number, software version, power supply details, professional user chosen options, standards complied with – as agreed and where relevant.
Manuals	Professional user manuals, end-user manuals, other technical literature (parts list, circuit diagrams, cleaning instructions)
Warranty	Specify agreed terms

Ancillaries	Leads and connectors probes and sensors, calibration equipment
Consumables	
Installation/Commissioning	Any work which the manufacturer or supplier is to do
Training	For users of servicing personnel, including initial training on delivery, and on-going training needs during operation Details of your acceptance procedure (see paragraph 5.4)
Quantity, price, terms, discount	
Maintenance agreement	Intervals and response times – level of service required and agreed cost
Any other conditions of supply	For example a ceiling on future prices for consumables and spare parts
Delivery Date	
Delivery point	All deliveries should be addressed to a single named department, so devices do not get put into service without acceptance checks (see paragraph 5).

Appendix F

Servicing and Callibration

It is the responsibility of the ward/unit/department/team to maintain accurate servining records on the LPFT Medical Devices register which is contained within the Trust's Asset Register. Information about servicing and calibration is available from the manufacturers of your devices.

Appendix G

NHS Form Indemnity A & B

NHS form of Indemnity A ("Form A") is to be used for equipment on loan from a supplier to a trust. Only one form A needs to be executed by a supplier.

NHS form of Indemnity B ("Form B") is to be used for goods in which the legal rights of ownership are to be transferred by the supplier to the Trust (namely, when the Trust is the beneficiary of a gift from a supplier). Only one Form B needs to be executed by a supplier.

Before executing Form A or B, it is advisable that proof of the Suppliers indemnity insurance is seen. On expiry of the insurance, proof of renewal should be obtained from the supplier.

Some suppliers and manufacturers have signed a Master Indemnity Agreement with the NHS Purchasing and Supply agency. A list of these can be found on the Agency's website at http://nww.pasa.nhs.uk/purchasing/shared/mia/ (NHS net users only). If a supplier's indemnity form(s) is shown as having expired in the list provided, a check should be made with the agency as to whether a new indemnity form is in the process of being processed **BEFORE** continuing with a trial or loan.

NB. The use of an Indemnity Form does not remove the need for manufacturer's quality control inspection, or for acceptance tests conducted by the borrower.

Appendix H

Acceptance Checklist

Timescale	**Possible Checklist**
Immediately on delivery	□□Check packaging for damage □□Check goods against order – leads accessories, manuals, consumables □□Check any identification labels against invoice – model numbers, mains voltage □□Check device for obvious defect or damage □□Check usage and maintenance instructions are included and any other documents required □□Record who does the acceptance checking
During functional and safety tests	□□Follow manufacturer's instructions for setting up and testing device □□Check the device performs within original specification* □□Unless manufacturer's instructions specifically advise against perform relevant safety tests*# □□Update training records for relevant staff □□Update maintenance requirements through Asset Register before first use □□Perform the same checks used when a device is returned to use after maintenance* □□Recheck suitability of device for intended application*

*** checks needing technical or clinical training**

 # For example, hoist load tests needed for insurance purposes, and electrical safety tests

Appendix I

New Device Checklist

Topic	**Action**
Physical conditions	Add new item to the Asset Register on Sharon. Attach label with inventory number.
Storage	□□Organise appropriate training for users □□For new models of a familiar device: professional users need to know how the operators manual is organised, how any controls and adjustments work, and to be aware of potential errors arising from misleading similarities to existing devices □□For complex or novel devices, formal training sessions, possibly run by the manufacturer are needed; □□Any necessary training for technical and maintenance staff □□Update training records
Planned and preventative maintenance	□□Inform users about day to day checks and operations □□Note which servicing organisation is to be used □□Work out date for firs service, enter in record keeping system

	□□File maintenance manuals
Labels and documentation	Attach appropriate labels, possibly: □□Warning professional users that this is a new device, and they should monitor treatment carefully □□Warning end users to wait until they have been trained □□Giving date when preventative maintenance will be needed □□Giving basic instructions Make sure copies of manuals are supplied to users with devices (e.g. place on ward/department reference shelves). For large items, open a log book (to remain with the device) – enter acceptance test results, who to contact in case of problems.

Appendix J

Storage

Topic	**Problems**
Physical conditions	□□Dirty or wet conditions □□Inappropriate temperature or humidity (labels on packaging should indicate appropriate storage conditions)
Storage system	□□Stacks too high □□Fragile equipment stored too far off the ground, likely to be damaged by falling from shelves.
Separation of equipment needing decontamination and repair from equipment ready to issue.	□□Inadequate space for demarcated areas for quarantine, etc. □□Inadequate labelling of zones □□Inadequate packaging and refurbished equipment.
Shelf life and stock rotation	□□No stock handling procedures, so earliest

	deliveries are not issued first. □□Inventory system does not identify out –of date stock. □□Excessive storage times cause rubber components to set in position (ventilators), lubricants to migrate (motor-driven devices) and wood to dry out and shrink (crutches) □□Shelf life of batteries and sterile produces is exceeded. □□Rechargeable batteries may be damaged if not subjected to regular charge/discharge cycles.

Appendix K

Training Needs Analysis

NB: If non nursing/medical staff member (e.g. Occupational Therapist, Social Worker) is required to use any medical device they will follow the requirements identified for registered or non-registered nursing staff depending on what the device is and whether registered.

Technical staff and Student Nurses will have their training needs assessed on an individual ward/unit/team/department basis. This will be the responsibility of the assigned Medical Devices Lead for each ward/unit/team/department.

Medical Devices Guidance

RN – registered nurse

SuW – Support Worker

AHP – Allied Healthcare Professional

Dr – Doctor

Not all equipment will be required in every ward/unit/department.

MEDICAL DEVICES GUIDANCE			
Devices	**Frequency of Training**	**Discipline**	**Method**
BP Monitor (Manual)	one off	RN, SuW, AHP, Dr	Formal Training (Pre-registration)
BP Monitor (Electronic)	one off	RN, SuW, AHP, Dr	Formal Training (Pre registration)
Blood Glucose Monitor	yearly	RN, SuW, AHP, Dr	PHILiP course (Physical Healthcare Improvement and Learning in Practice) or ward/unit/team led update
Alcometer	yearly	RN, SuW, AHP, Dr	Supplier/instruction info
Thermometer	one off	RN, SuW, AHP, Dr	Formal Training (Pre registration)
Nebuliser	one off	RN, AHP, Dr	Supplier/instruction info
Peak Flow Meter	one off	RN, SuW, AHP, Dr	Formal Training (Pre registration)
Resus Equipment	yearly	RN, SuW, AHP, Dr	Life Support Training and local practice
Suction Equipment	yearly	RN, SuW, AHP, Dr	Life Support Training and local practice
Syringe/ Needles	one off	RN, AHP, Dr	Formal Training (Pre registration)
Urinary Catheters (registered nurses)	one off	RN	Formal Training with the Physical Healthcare Team
Urinary Catheters (doctors)	one off	Dr	Formal Training (Pre-registration)
Oxygen	one off	RN, SuW, AHP, Dr	Formal Training (Pre-registration)
Insulin Syringes	one off	RN, Dr	Formal Training (Pre-registration)
Urine Test Strips	one off	RN, SuW, AHP, Dr	Formal Training (Pre-registration)
Moving & Handling Equipment	In line with guidance from LPFT Health & Safety Manual LEAFLET 07 MANUAL HANDLING		
Drug Screening Equipment	one off	RN, SuW, AHP, Dr	Supplier/instruction info
Epilepsy Seizure Alarms	one off	RN, SuW, AHP, Dr	Supplier/instruction info
ECT equipment	one off	Dr	

Any other Medical Devices – please liaise with Medical Devices Group

Appendix L

LINCOLNSHIRE PARTNERSHIP NHS FOUNDATION TRUST

MEDICAL DEVICES GROUP

Medical Devices Staff Training Record – Yearly Review

I certify that the staff member

Name:

Role:

Ward/Unit/Team/Department

has demonstrated the required safe level of competency in the use, maintenance (cleaning and decontamination), storage and reporting (servicing and calibration alerts) of the following medical devices.

Medical Device	**In use (Y/N/NA)**	**Medical Device**	**In use (Y/N/NA)**
BP Monitor (Manual)		Resus Equipment	
BP Monitor (Electronic)		Suction Equipment	
Blood Glucose Monitor		Syringe/ Needles	
Thermometer		Urinary Catheters (registered nurses)	
Nebuliser		Urinary Catheters (doctors)	
Peak Flow Meter		Moving & Handling Equipment	
Drug Screening Equipment		ECT equipment	
Epilepsy Seizure Alarms			

Signed:

Print name:

Role:

Date:

NB: It is the employee's responsibility to alert their supervisor/manager/physical healthcare practitioner that they are due for their yearly medical devices competency review.

Appendix M

For Decontamination advice and guidance, Please refer to Infection Prevention and Control Policy 7g

http://www.lpft.nhs.uk/assets/files/Accessing%20our%20information/Policies%20and%20Procedures/policy-7g-decontamination-v2-approved-at-qc-20.10.17.pdf