Leicestershire Partnership NHS Trust

Medical Devices Policy

This policy describes the process for the management of medical devices.

Key Words:	Medical Devices, Medical Equipment	
Version:	6	
Adopted by:	Quality Assurance Committee	
Date adopted:	12 December 2017	
Name of originator/author:	Medical Devices Asset Manager	
Name of responsible committee:	Health and Safety Committee with consultation from the Patient Safety Group	
Date issued for publication:	December 2017	
Review date:	June 2023	
Expiry date:	30 September 2024	
Target audience:	All staff	
Type of Policy	Clinical √	Non Clinical √
Which Relevant CQC Fundamental Standards?		

Leicestershire Partnership NHS Trust

CONTRIBUTION LIST

Circulated to the following individuals for comments and circulated further by them

Name	Designation
Members of the Medical Devices Group as per Terms of Reference	As per Terms of Reference
Bernadette Keavney	Head of Health Safety & Compliance
Members of the Health & Safety Committee as per the Terms of Reference & onward dissemination to Divisional Health & Safety Groups	As per Terms of Reference
Members of the Patient Safety Group as per the Terms of Reference	As per Terms of Reference

Contents

Version Control and Summary of Changes

Version number	Date	Comments (description change and amendments)
2	02.04.2012	Added key words Pg6, 8 – removed LCCHS and added LPT Defined 'single patient use' Pg7- custom made devices added Pg. 9 Role of Infection Prevention and Control team/nurse amended NRS changed to ICES Pg. 6 - added medical devices are only prescribed by those who are qualified and competent to do so Pg. 6 – added prescription Pg. 19 – Health and Safety Committee added
3	March 2013	NHSLA Monitoring Section update
4	November 2013	Document update to reflect the new MDAM role in the organisation, current situation and new processes & procedural changes. Also new guidance issued by the MHRA
5	January 2015	Re-write of the policy to reflect role of Medical Devices Asset Manager
6	November 2017	Re-write of the policy to reflect the changes to systems and processes implemented since the last review and commencement of the servicing and maintenance contracts procured since April 2016

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For further information contact:

Contact Details of Policy Author/Owner

Medical Devices Asset Manager
Leicestershire Partnership NHS Trust
Tel: 07827 807 819

Definitions and acronyms that apply to this Policy

ICES	Integrated Community Equipment Service
NHS	National Health Service
DH	Department of Health
CQC	Care Quality Commission
MHRA	Medicines and Healthcare Products Regulatory Agency
SFI	Standing Financial Instructions
SFO	Standing Financial Orders
PUWER	Provision and use of Work Equipment Regulations
PPM	Planned Preventative Maintenance
SI	Significant Incident
LOLER	Lifting Operations and Lifting Equipment Regulations
MDAMT	Medical Devices Asset Management Team
MDG	Medical Devices Group
LPT	Leicestershire Partnership NHS Trust
PDR	Personal Development Review
DoC	Declaration of Conformity. "*A certificate to demonstrate that products meet all relevant requirements of all applicable product safety directives. It is a sign that a product has been designed and constructed for compliance with relevant essential requirements. It is not a safety certificate. Purchasers and users must check associated CE marking and the product to check for obvious or known defects".*
CE Mark	Mark required for all new products which are subject to one or more of the European Product Safety Directives. It is a visible sign that the manufacturer of the product if declaring conformity.

Equality Statement

Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

It takes into account the provisions of the Equality Act 2010 and promotes equal opportunities for all.

This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity.

In carrying out its functions, LPT must have due regard to the different needs of different protected equality groups in their area.

This applies to all the activities for which LPT is responsible, including policy development and review.

Due Regard

LPT must have **due regard** to the aims of eliminating discrimination and promoting equality when policies are being developed. Information about due regard can be found on the Equality page on e-source and/or by contacting the LPT Equalities Team.

The Due regard assessment template is Appendix 21 of this document

1.0 Introduction

Medical devices are increasingly used by health care professionals within LPT to support the care and treatment of patients. The aim of this policy is to ensure that benefits to patients from the use of medical devices are maximised and risks minimised. To achieve this it is essential that

- New devices meet relevant safety and quality standards, can be effectively cleaned and disinfected where appropriate, are suitable for their intended purpose and represent good value for money
- LPT owned devices in use are effectively managed and maintained in safe working condition, disposed of in accordance with current regulations and replaced when beyond economical repair or become obsolete
- Medical devices are only prescribed by those who are qualified and competent to do so
- Medical devices are used only by those who have received equipment demonstrations or training (as appropriate) and are competent to use medical devices safely
- Cross infection risks are minimised through effective cleaning and decontamination between patient use
- Medical devices are purchased by services to ensure there are sufficient quantities of devices to provide safe and effective patient care
- Compliance with the requirements of this policy is audited annually

2.0 Purpose

The organisation recognises the risk to patients, staff and others created by the use of medical devices. It intends to ensure there is a suitable and robust operational system in place to manage the procurement, prescription, use, maintenance and disposal of medical equipment to meet the requirements of legislation. It will also promote the safe use of equipment through equipment demonstration, training, information, instruction and supervision.

2.1 This policy has been developed to ensure the following

- The risks associated with the acquisition and use of medical devices, both for patients and health care professionals are minimised
- An organisation wide system is in place for the management of medical devices, and identification of users' and prescribers' roles and their responsibilities
- A centrally held register of medical devices is established and maintained for the organisation, including service and calibration due dates
- A system to demonstrate that devices are maintained, tested and calibrated (where applicable) in accordance with manufacturer's instructions
- A system for identifying risks associated with the procurement, use and disposal of medical devices is maintained.
- A system to ensure the organisation complies with all external legislative requirements and standards is established
- Appropriate training stakes place for staff whether at induction, mandatory training or at the local place of work to ensure staff are competent to safely use the medical equipment in their work place and a system is in place to record and maintain training received
- Planned preventative maintenance regimes to be in place to ensure that regular maintenance takes place
    - Whenever a medical device is used it is;
    - Suitable for its intended purpose
    - Used in line with the manufacturer's instructions
    - Traceable, where possible
    - Maintained in a safe and reliable condition, with associated records kept
    - disposed of appropriately at the end of its useful life
- A system is in place to support services in the procurement of medical devices
- processes are in place to ensure medical devices can be added/removed from the central asset register by clinical services via notification to the Medical Devices Asset Management Team (MDAMT)

3.0 Scope of the Policy

3.1 The policy applies to all staff within LPT, whether directly employed or not, who are involved in the management and use of medical devices. This includes those staff on honorary contracts and students.

3.2 This policy applies to all medical equipment used by staff within the Organisation or loaned in or out of the organisation regardless of whether it is purchased, leased, rented, on loan, on trial, donated, has been in use in another organisation or brought into the organisation by a patient, carer, employee or contractor.

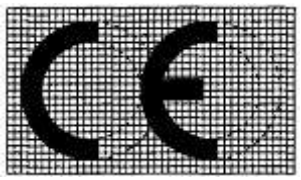
4.0 Definition of a Medical Device

4.1 The Medicines and Healthcare Products Regulatory Agency (MHRA) defines a medical device in the Medical Devices Regulations 2002 (SI 2002 No.618 as amended), 'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes, or both, and necessary for its proper application' for the purpose of:

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

Medical devices owned and purchased by LPT must be supplied with a Declaration of Conformity and carry the relevant CE mark(s).

Figure 1 – Prescribed form of a CE Mark, letters must be at least 5mm tall (unless this is not possible for very small products).



A list of examples of medical devices is included in Appendix 1.

There are occasions when a device is 'custom made' i.e. hand and foot splints. These devices are defined as:

- manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner or a professional user which gives, under his/her responsibility specific characteristics as to its design; and
- That it is intended for the sole use of a particular patient.

More information can be found on custom made devices on the MHRA website *"Guidance notes for manufacturers of custom made devices, 2009."*

4.2 A medical devices register

The centrally held medical devices register is different to the Trust's asset register. The Trust's asset register is the responsibility of the finance department and they will send this register out annually to service managers for verification.

The medical devices central asset register will contain all medical equipment regardless of cost or budget for which it is paid. A centrally held register will be maintained by the Medical Devices Asset management team (MDAMT) in conjunction with the Directorates and this will include:

- Unique identifying number (asset tag number)
- Equipment type
- Date acquired (where possible)
- End of life date, if specified
- Purchase price of the equipment (where possible)
- Manufacturer details
- Location of equipment
- Maintenance arrangements, PPM and reactive
- Maintenance supplier information
- Make, model and serial number
- Last test date and due date of next test
- Last calibration date and due date of the next test

The Directorates will be responsible for notifying the MDAMT of any changes to the register by completing the Medical Devices Form at Appendix 7 and ensuring the item has been asset tagged. This includes new equipment purchases, equipment donated by charitable organisations, the transfer of equipment from service to service and condemned equipment/equipment disposal.

4.3 Definition of a single use device

Devices that are labelled **"**single use", "use once only" or "do not reuse" by the manufacturer must not be re-used. (*MDA DB 2000(04)*)

This will be clearly displayed on the packaging by the International Organisation for Standardisation symbol, which is the figure 2 with a diagonal line drawn through it.

4.4 Definition of single patient use

This is a device that can be re-used on the same patient as long as the device has been cleaned in accordance manufacturer's recommendations and the organisations cleaning and decontamination policy. This device should not be reused on any other patient other than the intended to ensure it meets the definition.

Please note that 4.3 and 4.4 above do not currently form part of the central asset register of medical devices.

5.0 Roles and Responsibilities

5.1 Chief Executive

The Trust's Chief Executive has overall responsibility for Risk Management and therefore has overall responsibility for ensuring that there is an effective management system for medical devices within the Trust.

5.2 Divisional Director – Chief Nurse

- Is the lead for the organisation and 'nominated individual' responsible for ensuring all personnel comply with the obligations in meeting the standards set by the, MHRA and associated guidance.
- Ensure compliance with the requirements of the CQC Fundamental Standards 12, 15 & 17 in relation to safety, availability and suitability of equipment.

5.3 Heads of Service/Locality Service Managers/Line Managers

It is the responsibility of all managers to:

- Ensure staff working within their area of responsibility are aware of and adhere to this policy
- Ensure representation from their service at the Medical Devices Group and associated groups, where appropriate
- Be responsible for the local management of medical devices; this will include identifying all equipment on local registers and authorised users
- Ensuring the devices are maintained in a safe and reliable condition
- Notifying the MDAMT of any new equipment purchases, transfers of equipment between services and disposals of equipment to allow updating of the medical devices central asset register with current information. This can be communicated to the MDAMT by completing the Medical Devices Form at Appendix 7
- Ensure all equipment is suitably decontaminated following the manufacturer's specific guidelines and the Trusts' Infection Prevention and Control Policy document. Whomever is awarded the contract for Integrated Community Equipment Service (ICES) will have responsibility for their equipment that is used (currently Nottingham Rehabilitation Service, known as NRS)
- Action any MHRA device alerts and bulletins as directed by the Risk Assurance Department
- Ensure that all new, temporary and permanent employees attend appropriate induction training and receive sufficient information, instruction and training to ensure they are competent in the safe use and operation of all medical devices within the service
- Personal development reviews should be used to identify any further training needs
- Ensure that Personal Protective Equipment is available and suitable for use as required
- Ensure that any equipment is managed and used in the correct manner in line with the manufacturer's instructions
- Ensure that any unsafe equipment is managed appropriately, immediately taken out of use and securely stored to prevent use in error;
- Inform their senior manager of any risks related to the management of medical devices within their service, ensure risks are assessed and entered onto the risk register
- Identify where there are equipment shortages to enable adequate purchasing to take place therefore ensuring there are sufficient quantities of equipment available to deliver the service or activity required
- Ensure staff receive the appropriate training at local level and subsequent refresher training on specific medical devices

- Maintain accurate records of medical device training for staff, recording competencies and training needs on individuals personal development reviews (PDR)
- Any new medical device purchased has a competency statement written, training needs identified and actioned for relevant staff, risk assessments undertaken and competencies evidenced for inclusion in the PDR process
- Participate in reviewing and updating all profession specific competency statements as required
- Ensuring that the lifecycle of new equipment is taken into consideration at the point of purchase including selection of equipment, acquisition, acceptance checking of the device, maintenance required for the life of the item, repair, monitoring, traceability, appropriate disposal and associated costs, replacement of disposed equipment. See Appendix 9

5.4 Medical Devices Asset Manager

It is the responsibility of the MDAM to:

- Ensure there is a robust data management system in place for the recording and tracking, where possible, of medical devices owned by LPT
- Maintaining a centrally held medical devices asset register
- Continue establishing maintenance scheduling for planned preventative maintenance
- Lifecycle planning including forecast costs for replacing redundant equipment
- Management of revenue and capital budgets for the management of medical devices
- Create change management systems including the development and implementation of local policies and procedures
- Develop and implement standardisation for the acquisition of medical devices to address safety, quality, performance, lifetime costs and range rationalisation
- Ensure an effective, co-ordinated programme for servicing and maintenance of the organisations owned medical devices in accordance with legislation, and manufacturer's instructions
- Ensure arrangements are in place to make sure that all equipment is decommissioned and disposed of and the end of its useful life in accordance with Trust policies and current legislation
- Lead a Medical Devices Group that includes representation from Directorates including clinical, , infection control, risk management, training, procurement and finance staff
- Lead a group to identify, develop and communicate requirements to ensure the Trust's training strategies incorporate generic medical device awareness, at new staff induction Develop an e-Learning package to support the safe use of a medical device
- To seek assurances from Heads of Service/Locality Service Managers/Line Managers that staff are completing the Safe Use of Medical Devices checklist and guidance at Appendix 4
- Identify, develop and implement arrangements to ensure that annual audits are undertaken of specific medical devices held on the central asset register
- Provide reports including quarterly reports and an annual report to give assurance to relevant Trust groups that LPT owned equipment meets current legislative requirements, and manufacturer's instructions

- Support the organisation to meet the required CQC Fundamental Standards for the safe use of medical devices
- Ensure the MDG monitors medical device related incidents and alerts and supports investigations where necessary
- Review and monitor medical device service and maintenance contracts and contractors performance

5.5 Infection Prevention and Control Team/Nurses

It is the responsibility of the Infection Control Team/Nurse to:

- Provide specialist advice on the purchasing and acquisition of medical devices
- Attend or send appropriate representation to the Medical Devices Group and associated groups
- Advise on all elements of infection prevention and control in relation to medical devices including the decontamination of devices
- Ensure appropriate guidelines and policies that are developed in the remit of infection prevention and control reflect the requirements for the management of medical devices
- Develop and support the audit process around medical devices
- Ensure that training packages for infection prevention and control purposes reflect the requirements of medical devices
- Report any exceptions to the Infection Prevention and Control Committee and Divisional infection prevention and control groups

5.6 Risk Assurance Department

It is the responsibility of the Risk Assurance Department to:

- Assess, issue and seek assurance for medical device related alerts
- Onward report medical device related adverse incidents to the MHRA in accordance with the Yellow Card system. An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons. Causes may include
    - The design or manufacture problems
    - Poor use instructions or training
    - Inappropriate modifications
    - Inadequate maintenance
    - Unsuitable storage and use conditions
- Provide bi-monthly reports to the MDG relating to medical device incidents and alerts

5.7 All staff

All employees of the Trust have a responsibility to be risk aware at all times and to recognise their personal responsibility.

It is the responsibility of each individual member of staff to ensure they are appropriately trained and competent to use any medical devices which they are required to use as part of their duties. Any member of staff not feeling competent in

the use of a medical device must not use the device and seek further training/advice from their manager.

They should carry out visual safety checks on the prior to use to ensure the device is fit for purpose and safe for use, see the Safe Use of a Medical Device and supporting guidance at Appendix 4. Visual checks must also include checking the device has an in-date last serviced and next service due date. Any devices that do not have a valid service sticker or any problems relating repair, servicing, maintenance, calibration or failure of the device must be taken out of use and reported to the appropriate servicing and maintenance contractor for a service to be completed as there is no guarantee of the accuracy of the data. See the servicing and maintenance flowcharts at Appendix 12, 14, 15 and 16. All staff should ensure that devices considered to be unsafe for use must be clearly marked ‘do not use’, removed from service and securely stored to prevent further use. If removal of the device from use has an adverse impact on service provisions please contact the MDAMT for assistance. Surplus or loan devices may be available for use until such time that the original device can be serviced and put back into use.

Staff should escalate issues relating to insufficient quantities of medical equipment to their line manager to enable future purchasing arrangements to be made that are reflective of the additional equipment need, and to safely deliver the activity required meeting the needs of the Service, patient and/or service user. Where the unavailability of equipment causes harm or presents a risk of harm to patients, this should be reported on the Trusts incident reporting system ‘Safeguard’ and in line with the Incident Reporting Policy.

This policy and all Trust policies can be found on the intranet website e-Source under the Policies and Documents tab.

5.8 Medical Device Group

The Medical Device Group reports to the Health and Safety Committee and the Patient Safety Group. Governance arrangements and the Terms of Reference for the Group are at Appendix 8.

6.0 Procurement of Medical Devices

Procurement of medical devices is currently carried out by the Leicestershire and Rutland NHS Procurement Partnership. The Procurement Partnership’s main responsibilities are;

- To purchase medical device goods or services on behalf of LPT, ensuring they meet the required quality standards and indemnities
- To comply with the Trusts Standing Financial Instructions (SFI) and Standing Orders (SO) and relevant EU and UK legislation
- Ensure appropriate representation at the Medical Devices Group and associated groups
- Provide value for money
- Add value to non-stock requisitions
- Make savings
- Negotiate contracts for medical device goods and services

- In relation to purchases, ensure the Trust is compliant with fire regulations and quality assurance regulations
- Provide advice and support in obtaining competitive quotations
- Provide expert advice and support on the public tender process and contract award, including specifications and tender evaluation
- Take up customer service issues and complaints with suppliers, including medical device failures whilst under warranty period
- Provide a comprehensive product catalogue library
- Source products and suppliers and progress orders
- Provide guidance and assistance to staff in the organisation wanting to purchase products and services, onward refer to the MDAM should further advice be required
- Support the standardisation of preferred medical devices including the acquisition of the most appropriate device following evaluation
- Establish and maintain a database of medical devices loaned into the Trust from external sources
- Maintain appropriate records pertaining to the Pre-Purchase Questionnaire (PPQ) / Pre-Acquisition Questionnaire for medical devices to ensure complaint with current legislation

The Chief Executive will ensure that appropriate Contract/Service level agreements are in place with the Leicestershire and Rutland Procurement Partnership, which will provide formal acceptance and testing services. The organisation must be externally accredited for the provision of these services.

6.1 Acceptance Checking / Testing

The recommendations below need to be followed when in receipt of a new medical device. It is the responsibility of the requisitioner to complete the acceptance check and maintain a record of this, see Appendix 2.

- Check the device matched the acquisition specification, is undamaged, is accompanied by all the necessary information and documentation and that it is;
    - Appropriately configured
    - Supplied with appropriate accessories
    - Supplied with appropriate consumables
    - Supplied with appropriate instructions for use
    - Declaration of conformity certificate
- Make sure that the appropriate acceptance checks and tests (see Appendix 2) have been carried out in accordance with the risk assessment and legal requirements
- Where required, medical devices have been appropriately installed
- Details of the device i.e. make, model, serial number, date of purchase. The manufacturer's instructions must been retained for local use / referral and provided to the MDAM for retention on the medical device central asset register
- Training needs have been identified and acted on
- For reusable devices, the MDAM has been notified of the new purchase by completing the Medical Devices Form (Appendix 7), asset tagging arrangements have been made and maintenance has been scheduled

6.2 Standardisation of equipment across LPT

For the purpose of consistency, where possible all sites must use and/or purchase the same equipment. This assures the organisation that its employees using the equipment are more likely to be familiar with its use. It also reduces the requirement for additional/different training when employees work across sites.

As part of a process of standardisation the Trust will have in place a list of 'preferred' devices that will be produced through the Medical Devices Group and in conjunction with clinical colleagues to address safety, quality, performance, lifetime costs and range rationalisation. This list will be subject to review taking into account technological and manufacturer changes.

When adding to existing stock or replacing worn out devices the Medical Devices Group should make reference to the purchasing and standardisation considerations in 6.3 below prior to contacting Leicestershire and Rutland Procurement Partnership for purchase or tender.

The Procurement Department is able to help with this process.

6.3 Purchasing Equipment

The Chief Executive has delegated responsibility for ensuring that all medical devices purchased by the organisation are purchased appropriately taking into account the criteria laid out below

Considerations must be made by the Medical Device Group when advising on equipment purchases and standardising equipment that do not prejudice nor conflict with Standard Financial Instructions within the Trust or current EEC procurement regulations:

The advantages of purchasing the make and model currently in use are

- Servicing and maintenance arrangements will be in place
- No additional training needs are required
- Maintenance is simplified and optimised
- Risks of 'error user' minimised as familiarity with device and functional capability
- Compliance with existing legislation

The disadvantages of purchasing the make and model currently in use

- Reliance on a single model can become problematic if there was a manufacturers recall or system failure
- Manufacturer becomes bankrupt or withdraws a product line
- Monopoly of manufacturer re : weakens the purchasers negotiating position with the supplier

Medical devices should only be purchased via the NHS Supply Chain or through the Leicestershire and Rutland Procurement Partnership iProc and E-Catalogue system. There are wide ranges of manufacturer products available through NHS Supply

Chain, the Procurement Department and MDAMT can provide advice and support on purchases where required.

Petty cash, purchasing cards and credit cards must not be used for purchasing medical devices.

6.4 Manufacturer's Instructions

Professional users, end-users, maintenance staff and maintenance providers must have access to manufacturer's user instructions. It is the responsibility of the requisitioning Ward/area to keep these instructions accessible at all times and located with the device where possible.

Requisitions must contain a request that manufacturers issue any revised instructions/guidance to the person requisitioning the device.

7.0 Medical Equipment Loans

7.1 Equipment loaned temporarily from LPT services to other LPT services or departments

When loaning equipment to each other Clinical Services must maintain records of these loans to ensure the location of the equipment is easily traceable. This record must include the make, model and serial number of the equipment. The manager of the department receiving loaned equipment must ensure that staffs are competent to operate the equipment safely and that the equipment is suitable and sufficient for use. The Medical Devices form at Appendix 7 can be utilised for this purpose. The completed form should be forwarded to the MDAMT for processing.

The equipment must be appropriately cleaned and decontaminated before being loaned and when it is taken back from loan.

7.2 Free issues of medical equipment from suppliers

Some suppliers offer free issues of medical equipment to organisations in return for a commitment to purchase consumables for use with the equipment.

Where equipment is offered to departments and locations within LPT by representatives or organisations to loan or evaluate, the offer must not be accepted until the loan or evaluation has been approved by the Medical Devices Group (MDG) and checked / registered by the Procurement Department. Please see the loaning-in guidance and forms for completion at Appendix 17.

The Procurement Department will check whether the supplier is covered by the Department of Health's Master Indemnity Agreement (MIA) scheme, under which the supplier indemnifies the Trust against any incidents or claims arising out of the trialling or use of the equipment whilst it still belongs to the supplier.

If the supplier is not on the MIA Scheme, the Procurement Department will obtain indemnity assurance for that specific piece of equipment. It will also allow the MDG and MDAMT and Risk Assurance to support staff should a field safety notice or medical device alert be received from the MHRA.

Trust staff must not accept equipment without checking with the Procurement Department first, as this may pose a risk to the Trust, and to patient safety. Staff managing the trial or loan must ensure they only retain the equipment for the agreed period of the loan or trial, and that it is returned as agreed with the supplier. Unapproved extension of the period of loan or trail could constitute an agreement to purchase the equipment. Such offers must be referred to Procurement Department before any agreement is signed.

7.3 Equipment loaned for use to patients/carers.

All LPT owned equipment loaned to patients / carers must be recorded by the line manager/service or team lead and ensure the following;

- All equipment must be appropriately cleaned and d3ecomstaminated prior to being loaned, and again when it is brought back under the care of LPT
- Before a medical device is issued to a patient or carer they must receive a demonstration or training in how to use the device, they should sign a statement confirming that they have received and understood the written / verbal instructions provided.
- Accurate records of demonstration training must be retained by the service completing the task.

This training must be supported by written guidance. The manufacturer's instructions must provide some information but this must be tailored to the needs of the individual patient or carer. Written guidance must cover the following:

- The name of the device
- The operation and control of the device
- Checking the device whilst in use
- Recognition of a device failure or fault
- Action to be taken in the event of a device failure or fault
- Ensure is suitable and sufficient for use
- Ensure training is given on appropriate cleaning and decontamination
- Ensure it has been serviced and/or calibrated in accordance with the manufacturer's instructions
- Individuals to be contacted in an emergency

A copy of the manufacturer's instructions must accompany any piece of equipment on loan which should include information on how to clean the equipment.

If it is identified that the service user or carer do not use English as their first language, or other formats of communication are required such as sign language or Braille then staff can access the Ujala Resource Centre Guidelines or Pearl Linguistics via the staff intranet as this supports all communication / language needs.

7.4 Equipment that belongs to the Integrated Community Equipment Loan Service (ICELS) that is loaned in Patient's Homes through the preferred contract provider

Nottingham Rehabilitation Supplies (NRS) is the current provider of community equipment management services under a Partnership Agreement and Contract.

Under the terms of the contract the NRS is responsible for equipment purchase, stock and storage management, equipment labelling, delivery and installation, the collection of equipment from patients and the decontamination of the equipment and ensuring the equipment is serviced, maintained and or calibrated in accordance with the manufacturer's instructions.

The provision of community equipment such as NRS is managed and commissioned by the ICES Commissioning Manager on behalf of the Leicester City Council and health and social care agencies across Leicester, Leicestershire and Rutland.

If the service user requires training to use the equipment, the equipment prescriber has a legal duty of care to ensure that an appropriate demonstration and/or training has taken place, please refer to section 7.3

7.5 Transportation of Medical Equipment that is not issued through ICES

Transportation of medical equipment must be completed in line with manufacturer's instructions. Prior to the transportation of any medical equipment a risk assessment needs to be completed to identify any hazards that may require addressing. The risk assessment will identify if control measures are required and if so, then a safe system of work must be introduced and adhered to. Equipment that has been subjected to abnormal stresses during transport must be tested prior to use.

In addition equipment on loan to the Trust must not be transferred from the site to where it was originally loaned without first ensuring it is within agreement of the supplier to do so. Clean and dirty equipment must not be transported in the same vehicle. The Procurement Department must be notified of any site to site transfers.

8.0 Storage

Inappropriate storage of medical devices affects their subsequent safe use. The manufacturers' information and instructions both on storage conditions and shelf life must be followed.

9.0 Training

9.1 A trained and competent person who uses a medical device(s) on, on behalf of a person during the provision of healthcare must understand how the manufacturer intends the device/equipment to be used, and how it works normally, to be able to use it effectively and safely.

Where relevant they should:

- be aware of differences between models, compatibility with other products and any contraindications or limitations on use
- be able to fit accessories and to be aware of how they may increase or limit the use of the device
- be able to use any controls appropriately
- understand any displays, indicators, alarms, etc.
- be aware of requirements for maintenance and decontamination including cleaning, in accordance with the manufacturer's and relevant local procedures
- be able to show service users how to use the device

- be aware of known pitfalls, including those identified in safety advice from the MHRA, manufacturers and other relevant bodies
- be able to recognise device defects or when a device is not working properly and know what to do
- understand the importance of reporting device-related adverse incidents in line with the Incident Reporting Policy for the Risk Department lead to onward report to the MHRA
  (*Managing Medical Devices DB 2006(05))*

Specific training on particular medical devices must be based on the manufacturer's instructions.

To ensure all new staff have attended the relevant training a new starter form will be sent to the LPT Learning and Development Team indicating the training requirements for the new starter. The Learning and Development Team will book all staff that requires medical device training as part of their induction onto the first available course. The Training and Development Team will annotate the record of all staff for who medical device training is indicated, according to the Training Needs Frequencies & Method of Training form and with a requirement to have training records medical devices incorporated into the central U-Learn system. Reminders to book on the relevant training sessions will be sent by the Learning and Development Team to those staff identified as needing medical device training until they have booked on a course. Those who fail to attend will be identified by the Training and Development Team via u-Learn and followed up with a booking for the next available course, with a copy to their Line Manager.

Refresher training for specific medical devices will be completed as indicated in Appendix 3.

It is the line manager's responsibility to ensure that the training needs of staff in the safe use of medical devices has been identified and acted on, the Safe Use of Medical Devices checklist and supporting guidance at Appendix 4 has been created to support this. Training and competency records must be completed and stored for every member of staff required to use a medical device and for each type of equipment used as part of the daily activities. The records should be held as part of the PDR process and uploaded onto the ULearn System by the staff member. Staff must only use equipment where suitable instructions and demonstration or training have been provided.

Staff carrying out maintenance, repair, and/or decontamination will require additional technical information or training.

9.2 Training of Bank, Agency or Locum Staff

If bank, agency and / or locum staff are required and authorised to use a medical device, then demonstration or training will be provided as part of their local induction by the Line Manager or Service employing the individual for the role. Each service employing temporary staff must ensure that they are competent to use relevant equipment. In the case of short term or short notice employment it may be necessary to limit the use of certain devices if competence cannot be determined. The service manager / team leader must inform the individual of equipment that they are authorised to use and any exceptions and retain records pertaining to authorised use/exceptions.

9.3 Device Demonstration or Training Record keeping

Accurate and accessible records are a key factor in effective device management.

The MHRA stipulates that ‘before a medical device is issued staff must receive appropriate training and be assessed as competent.’

A Safe use of Medical Device checklist template and associated guidance on use and frequency of training (Appendices 4, 5 & 6) has been developed for the purpose of:

- Identification of all medical devices within for which local induction and/or specialist training is required
- Identifying the individual staff and the devices they are authorised and required to use
- Ascertaining current levels of competency in the use of medical devices
- Completion of regular training needs analysis to facilitate future planning of equipment training
- Records must be kept up to date by line managers / team leaders and held as evidence as part of the PDR process to ensure that only staff trained to use the equipment do so (Appendices 5 & 6)
- Access to manufacturers guidance will be available for use by Services at local level to support the safe use of equipment

Clinical competencies pertaining to the clinical activity being undertaken or interpretation of clinical data is not covered by the Safe use of a Medical Device template. Clinical Services must ensure that competencies are held and that staff feel competent in the use of the devices in their daily activities. These should be recorded as part of the PDR process.

10. Maintenance and Servicing

All medical devices are subject to the Provision and Use of Work Equipment Regulations (PUWER), 1998. The regulations cover all work equipment in use. It is important to note that there is a current requirement for all equipment to be inspected where the safe use of equipment depends on the condition of installation and where it is exposed to conditions causing deterioration which could result in danger (Regulation 6, PUWER, 1998).

The Provision and User of Equipment Regulations and the Management of Health and Safety at Work Regulations require that equipment provided for staff should be suitably risk assessed and fit for purpose, furthermore the regulations also require the employer to:

- Ensure that work equipment is suitable for the purpose for which it is used
- Ensure that the selection of work equipment has regard to working conditions and any additional risks posed by the use or work equipment
- Ensure that employees only use the equipment for operations for which it is suitable

Ensure that users and supervisors of equipment must be given adequate health and safety information, and where appropriate, specified written instructions relating to the use of work equipment

Keeping medical devices safe and effective needs both planned preventative maintenance and ad hoc maintenance when devices are in need of repair, both must be carried out by suitably trained and qualified technicians.

Medical device servicing and maintenance contracts are in place to support staff in reporting both planned and ad-hoc maintenance requirements. The contracts are funded centrally by the Trust via the medical devices budgets.

Process flowcharts for reporting planned preventative and ad-hoc maintenance to the contracted service provider/s can be found at Appendix 12, 14, 15 and 16.

All medical device users at local level are responsible for routine maintenance; including the regular cleaning, preparation for use, and visual inspection of devices prior to each use

Medical devices for servicing/repair must be in a condition that is safe to be handled by all personnel who may come into contact with them during transit and subsequent handling. The device must not only be mechanically and electrically safe, but also must be properly decontaminated and carry no risk of causing infection. Please refer to the decontamination process in the Infection Prevention and Control Cleaning and Decontamination of equipment, medical devices and the environment (including the management of blood and bodily fluids) policy. The Declaration of contamination status form can be found at Appendix 13.

10.1 Planned Preventative Maintenance

Maintainable devices must be subject to a planned preventative maintenance (PPM) regime in line with manufacturer guidance. Users must be aware which devices are subject to PPM. The original manufacturer, third party maintainer or an appropriate NHS Electrical and Biomedical Engineering Department can undertake PPM. Records must be kept by the Services at local level and also evidenced on the centrally held medical devices register. In instances where equipment has PPM undertaken by a third party maintainer, the maintainer must hold servicing records detailing the date of last maintenance and date of any future PPM in addition to this information being held on the central asset register of medical devices.

Medical device users must ensure that if the service ‘next due date’ on the device has expired, or if no date is visible the device must be removed from use and reported to the contracted servicing and maintenance provider, details of this can be found at Appendix 11. If removing the device from use has an adverse effect on service provision please contact the MDAMT for assistance. Surplus medical devices or loan devices may be available for use until the servicing has been completed.

10.2 Repairs & Breakdowns

Occasionally medical devices breakdown and require repair, All staff need to be aware of what action to take following a device breakdown, Procedures are in place for each item of equipment to ensure the breakdown is rectified as soon as possible. Breakdowns can be dealt with either by routine or urgent repair if the device is deemed to be service critical.

Service critical devices are detailed in the Avensys UK Ltd equipment fault reporting procedure at Appendix 12. These devices will be either repaired or replaced with an appropriate loan device within a 24 hour period. All other devices reported as a routine call out will be repaired within 5 working days, pending receipt of parts.

Appendix 12, 14, 15 and 16 show the processes to follow for the differing types of medical device.

If the equipment is supplied through the ICES NRS contract they will need to be contacted.

A device requiring maintenance / repair must be taken out of use and clearly marked as “Awaiting Repair – Do Not Use” to remove the risk of it being used by another member of staff.

When a device is used for the first time after repair / maintenance where appropriate the user must make sure it is set / calibrated correctly before being used and document it has been calibrated.

10.3 Defects, Faults and Replacement Equipment

Where a defect is found that could affect the safe operation of the equipment, or has the potential to cause harm to a staff member, patient, visitor or contractor an incident must also be reported following the Trusts Incident Reporting Policy. The stage may be reached at which replacement must be considered. If any of the following criteria apply, the device is no longer serviceable:

- Worn out beyond economic repair
- Damaged beyond economic repair
- Unreliable (check service history with MDMAT)
- Clinically or technically obsolete/no longer supported by the manufacturer
- Spare parts no longer available
- More cost effective or clinically effective devices have become available

All decisions to purchase new/replacement devices must take into account all points identified in section 6.0 and the lifecycle process in Appendix 12 and must be in consultation with Procurement and the MDAM.

If equipment purchased is over £5k and funded from a capital budget an asset addition form will need to be completed which can be obtained from the Finance Department. In addition, any new purchases should be brought to the attention of the MDAMT by completing the Medical Devices Form (Appendix 7) so that the items can be asset tagged and added to the centrally held medical devices register for planned maintenance purposes.

10.4 Disposal of Medical Devices

All medical devices which are worn out, broken, or damaged beyond safe or economical repair must be removed from use and disposed of in line with the Trust’s Disposals Policy, Waste Policy and current legislation. The Finance Department and the MDAMT should be contacted and advised of the disposal to ensure the relevant asset register is updated; the Medical Devices Form can be emailed to you for completion, accessed at Appendix 7 or via the Trusts intranet site e-Source under the Support Services tab.

10.5 Patient Lifting equipment e.g. sling, hoist.

Patient lifting equipment is subject to the Lifting Operations and Lifting Equipment Regulations 1998, (LOLER), which detail the conditions that must be in place to ensure safety in the use of all lifting equipment (Appendix 6).

Annual maintenance of all lifting equipment is paramount to the safety of both patients and staff. It is the staffs' responsibility to ensure that the lifting equipment has an in-date service sticker visible on the device prior to each use. Staff must also ensure that the device has a current LOLER inspection tag – see Appendix 6 for the current LOLER inspection tag colour. Equipment without a current tag must be taken out of service and reported to the MDAMT for an inspection to be carried out.

If equipment is loaned via the ICES then they will be responsible for ensuring they meet the LOLER requirements.

Further information on moving and handling including LOLER requirements can be found in the Trusts Manual Handling Policy

11.0 Cleaning and Decontamination

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

All equipment should be decontaminated as per the suppliers/manufacturer's instructions and the Trusts Infection Prevention and Control Policy *Cleaning and Decontamination of equipment, medical devices and the environment (including the management of blood and bodily fluids) policy.* 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. The Declaration of Decontamination Certificate must be completed prior to maintenance, repair, collection and disposal. This can be found in the Infection Prevention and Control Policy and at Appendix 13

11.1 Cleaning

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 and the manufacturers instruction on cleaning the medical device.

Information on both cleaning and decontamination requirements of the device will have been obtained prior to purchase using the Pre-Purchase Questionnaire/Pre-Acquisition Questionnaire on infection control issues. Further advice should be sought from the Infection Prevention and Control Team / Nurse.

11.2 Pre-Use Visual Inspections and Calibration

Professional users and service users are responsible for pre-use visual checks to ensure the medical device is safe for use, has been cleaned and/or decontaminated between patient uses and in fit for purpose. Medical device users must also ensure that the device has an in-date last serviced sticker visible on the device as referenced in 10.1 Planned Preventative Maintenance.

Records must be maintained for frequency and completion of calibration (referenced in the medical devices register section 5.3). It is essential that calibration (where required) is completed as stated by the manufacturer to optimise the accuracy and efficiency of the equipment so as to prevent an incident, in particular one that may place patients or staff at risk of injury or harm.

12.0 Incident Reporting and Near Misses

Any incidents or 'near misses' involving the use of medical devices must be reported in line with Trusts Incident Reporting Policy.

If there is an incident where a medical device may be considered to have played a part in the circumstances surrounding an error, this equipment must be quarantined until it is confirmed safe to use by the manufacturers or third party maintainer or an appropriate NHS Electrical and Biomedical Engineering Department.

If the incident falls within the Medicines and Healthcare Products Regulatory Agency and Adverse Incident Centre (MHRA) definition it must be reported electronically as instructed by the MHRA on the MHRA website by the Risk Assurance Department.

Manufacturer recall of a device will take precedence over all other considerations and will happen in the event of a defect as detailed in 10.1

13.0 Monitoring and Audit

The Medical Devices Group will report to the Patient Safety Group and the Health and Safety Committee as defined in the Terms of Reference

The Medical Devices Group will monitor the implementation of this policy and medical device management by:

- Providing reports to the Health and Safety Committee, Patient Safety Group and other governance groups as required (bi-monthly, quarterly or annually)
- Progressing action plans arising from audits undertaken either internally or through a 3rd party audit body
- Reviewing the medical devices incidents that will be reported to the Medical Devices Group on a bi-monthly basis

The policy will also be audited by means of an annual review of the centrally held medical devices register and the Safe Use of a Medical Device checklist template and guidance is evidenced as part of the PDR process. In addition

- All clinical areas will keep an up to date register/inventory of medical devices in use
- The training required for staff authorised to use the equipment will be recorded in accordance utilising the Training Needs Frequencies & Method of Training (Appendix 3) and Safe Use of Medical Devices checklist template (Appendix 4)

Audit reports and results will be submitted to the governance groups for review and monitoring completion of action plans developed as a result of the audits to provide assurance.

13.1 Review

The implementation and content of this policy will be reviewed in three years unless an earlier review is prompted.

14. Legislation

This section gives examples of legislation that may apply to LPT; it is not an exhaustive list.

- Consumer Protection Act 1987 (Consumer Safety and Product Liability)
- Health and Safety at Work etc. Act (HASAWA) 1974
- In Vitro Diagnostic Medical Devices Regulations
- Ionising Radiation (Medical Exposures) Regulations 2000
- Ionising Radiations Regulations 1999
- Management of Health and Safety at Work Regulations 1999
- Medical Devices Regulations 2002 (SI2002 NO 618 as amended)
- Sale and Supply of Goods Act 1994 (Chapter 35)
- The Common Law of Negligence: Law Reform (Contributory Negligence) Act
- 1945
- The Control of Substances Hazardous to Health Regulations 2002
- The Electrical Equipment (Safety) Regulations 1994
- The Electricity at Work Regulations 1989
- The Employers' Liability (Compulsory Insurance) Regulations 1998
- The General Product Safety Regulations 2005
- The Health and Social Care Act 2008 (Regulated Activities) Regulations
- 2010. Regulation 16 Safety, availability and suitability of equipment
- The Lifting Operations and Lifting Equipment Regulations 1998
- The Pressure Systems Safety Regulations 2000
- The Provision and Use of Work Equipment Regulations 1998
- The Waste Electrical and Electronic Equipment Regulations 2006 and The
- Waste Electrical and Electronic Equipment (Amendment) Regulations 2007
- Trade Descriptions Act 1968
- Unfair Contract Terms Act 1977

15. References

- Care Quality Commission. Essential standards of quality and safety. 2010
- Medical Devices Directive (MDD) 93/42/EEC as amended 2007/47/EC
- NHS England and MHRA. Improving medical device incident reporting and learning. March 2014
- Department of Health. Records Management: NHS Code of Practice. 2006
- MHRA. Devices in Practice
- BS EN 62366:2008 Medical devices. Application of usability engineering to medical devices
- MHRA. Medical devices in general and non-medical products MDA/2010/001
- BS EN 60601-1-8:2007, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. 2007
- BS EN 62353:2008 Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment
- Department of Health. NHS Master Indemnity Agreement July 2010

- BS 7671:2008 Requirements for electrical installations. IET Wiring Regulations. Seventeenth edition. 2011
- The Electricity at Work Regulations 1989
- Health and Safety at Work etc. Act 1974
- Consumer Protection Act 1987 (Consumer Safety and Product Liability) (Chapter 43). Part I: Product Liability, Part II: Consumer Safety
- The General Product Safety Regulations 2005
- The Common Law of Negligence: Law Reform (Contributory Negligence) Act 1945
- Ionising Radiations Regulations 1999
- BS EN ISO 13485:2012 Medical devices. Quality Management Systems. Requirements for regulatory purposes
- BS EN ISO 9001:2008 Quality management systems. Requirements
- Department of Health. Management and decontamination of surgical instruments used in acute care. 2013
- MDA/2011/096
- BS ISO/IEC 15408-1:2009 Information technology. Security techniques.
- Evaluation criteria for IT security Introduction and general model
- HMG Information Assurance Standard No. 5 - Secure Sanitisation. Part of a larger family of IT security standards published by CESG.
- Carriage of Dangerous Goods by Road Regulations 1996
- Chemicals (Hazard Information and Packaging for supply) Regulations 2009
- Royal Mail. Prohibited goods – business customers
- Trade Descriptions Act 1968
- The Electrical Equipment (Safety) Regulations 1994
- Unfair Contract Terms Act 1977
- The Personal Protective Equipment at Work Regulations

16. Trust Policies

Trust Induction Policy
Mandatory Training Policy
Manual Handling
Health and Safety Policy
Records Management Policy
Risk Management Strategy
Policy for the Safe Use of Bedrails
Disposals Policy
Infection Prevention & Control Policy
Waste Policy
Using Hoists to Move Patients Policy
Incident Reporting Policy
Delegation of Task Process Policy
Alerts Policy
Portable Appliance Testing Guidance

17. Useful Websites and Other References

- Department of Health www.dh.gov.uk
- MHRA www.mhra.gov.uk
- ICELS – The Management of Community Equipment (medical devices) and Codes of Practice – **this can be obtained from the ICELS Commissioning Manager**
- Ujala Good Practice Guide- Interpreting and Translating Services, March 2008.

Appendix 1

COMMON CATEGORIES OF MEDICAL DEVICES

The list below is not comprehensive but gives a sense of the wide range of products that are considered to be medical devices. (MDA 2000)

Equipment used in the diagnosis / treatment of disease, or monitoring of patients, such as:

Syringes and needles
Dressings
Catheters (urinary, cardiac)
Surgical instruments
Endoscopes
IV administration sets and pumps
Patient monitoring equipment,
e.g. cardiac monitors
Anaesthetic equipment
Surgical implants,
e.g. orthopaedic prostheses, bone cements,
heart valves
Powered implants,
e.g. pacemakers, implantable defibrillators
Ultrasound imagers and CT/MR scanners
Radiotherapy equipment
Dental equipment and materials
Ophthalmic equipment
Chiropody/podiatry equipment
Sphygmomanometers
Thermometers
Physiotherapy equipment
Beds, mattresses and covers
Examination gloves
Plastic aprons

Equipment used in life support, such as:

Ventilators
Defibrillators
In vitro diagnostic medical devices and their accessories, such as:
Blood gas analysers
Blood glucose measuring devices
Hepatitis and HIV test kits
Urine test strips
Pregnancy test kits
Specimen collection tubes

Equipment used in the care of disabled people, such as:

External prostheses and orthoses
Wheelchairs and special support seating
Patient hoists
Walking aids
Pressure relief equipment
Aids to daily living, such as:
Commodes
Hearing aids
Urine drainage systems
Domiciliary oxygen therapy systems
Incontinence pads
Prescribable footwear

Equipment used by ambulance services, but not the vehicles themselves, such as:

Stretchers and trolleys
Resuscitators

Other examples of medical devices include:

Condoms
Contact lenses and care products
Intra-uterine devices (IUDs)

We are also interested in products which, whilst not themselves medical devices, are used in close conjunction with these devices, e.g.:

Centrifuges
Blood tissue storage systems
Fluid warming cabinets
Disinfecting and sterilising equipment,

Appendix 2

Acceptance Checklist

The following is an 'acceptance checklist': (Reference Provision and Use of Work Equipment Regulations 1998 (except part IV) as amended in 2002)

Timescale	Checks	Date Completed
Immediately on delivery	Check packaging for damage	
	Check goods against order, including leads, accessories, manuals, consumables and certificate of conformity	
	Check any identification labels against invoice including model numbers and mains voltage requirements	
	Check device for obvious defect or damage	
During functional and safety tests	Follow manufacturer's instructions for setting up and testing the device	
	Check that the device performs within the original specification *	
	Unless manufacturer's instructions specifically advise otherwise, perform relevant safety checks **	
Before first use	Perform same checks used when a device is returned to use after maintenance	
	Check suitability of device for intended application*	

* checks needing technical or clinical training
** for example, hoist load tests needed for LOLER compliance and electrical safety tests (if portable, refer to the Trust's Portable Appliance Testing Guidelines)

Please retain a copy of your acceptance checklist at local level as part of your evidence base for medical equipment

Appendix 3

Training Needs Frequencies & Method of Training

If non nursing/medical staff (e.g. Therapy Service) 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

Registered Nursing Staff		
Devices	**Frequency of Training**	**Method**
Blood Pressure Monitor	One off	Formal training pre-registration
Blood Glucose Meter	Yearly	Formal training pre-registration or manufacturers/supplier instruction or information
Alcometer	Yearly	Manufacturers/supplier instruction or information
Thermometer	One off	Formal training pre-registration
Nebuliser	One off	Manufacturers/supplier instruction or information
Peak Flow Meter	One off	Formal training pre-registration
Resus Equipment (defibs)	Yearly	ILS and BLS Training
Suction Equipment	One off	Formal training pre-registration
Syringe/needles	One off	Formal training pre-registration
Urinary catheters	One off	Formal training pre-registration
Oxygen	One off	Formal training pre-registration
Insulin Injectors	One off	Formal training pre-registration
Urine Test Strips	One off	Formal training pre-registration
Moving & Handling Equipment	Two Yearly	Moving and Handling Level 2 Training
IV Equipment	One off	Manufacturers/supplier instruction or information
Syringe Drivers	Yearly	In-house training at local level
Profiling beds	One off	Moving and Handling Level 2 Training
Air mattresses	One off	In-house training at local level

Un-Registered Nursing Staff		
Devices	**Frequency of Training**	**Method**
BP Monitor	One off	In-house training at local level
Thermometer	One off	In-house training at local level
Urine Test Strips	One off	In-house training at local level
Moving & Handling Equipment	Two Yearly	Moving and Handling Level 2 Training
Profiling beds	Two Yearly	Moving and Handling Level 2 Training
Air mattresses	One off	In-house training at local level

Medical Staff		
Devices	**Frequency of Training**	**Method**
Blood Pressure Monitor	One off	Basic training
Blood Glucose Monitor	Yearly	Basic training
Alcometer	Yearly	Manufacturers/supplier instruction or information
Peak Flow Meter	One off	Basic training
Resus Equipment (defibs)	Yearly	ILS and BLS Training
Suction Equipment	Yearly	Basic training
Syringe/needles	One off	Basic training
Insulin Injectors	One off	Basic training

Appendix 4

Safe Use of Medical Devices Equipment Checklist

Name of Individual:	
Name of Device:	
Make & Model Number:	

The Purpose of this checklist is to ensure that you understand the intended use of the device in order for it to be used effectively and safely. It is important to highlight that any medical device should be used and maintained in line with the manufacturer's instructions.

Prior to using the medical device that has been identified you are required to undertake the checklist below.

This checklist does not include a declaration that that the individual has achieved a level of competency to undertake a clinical procedure with the piece of equipment. If a level of competency is required, this checklist should accompany the assessment process.

CHECKLIST CRITERIA

I can access the manufacturer's instructions for the piece of equipment	Yes / No / Not applicable
I can state the intended use of the pieces of equipment	Yes / No / Not applicable
I am aware of the limitations for its use	Yes / No / Not applicable
I am aware of how to fit accessories and how they may increase/limit the piece of equipment	Yes / No / Not applicable
I can demonstrate the use of controls appropriately	Yes / No / Not applicable
I am aware of any displays, indicators, alarms etc. and how to respond to them	Yes / No / Not applicable
I am aware of the requirements to maintain the device and cleaning procedures	Yes / No / Not applicable
I can recognise when the device may not be working properly, know how to take it out of use and how to report it.	Yes / No / Not applicable
I have been informed of any pitfalls with using the piece of equipment which include any relevant Trust safety alerts	Yes / No / Not applicable
I know how to perform a visual safety check before each use	Yes / No / Not applicable
Have any addition training requirements been identified, if so please state	Yes / No / Not applicable

Comments:

Individual statement: Having answered "Yes" or "n/a" to all the questions above me understands the intended use of the piece of equipment for it to be used effectively and safely.

Name:		Area of Work:	
Signature:		Date:	

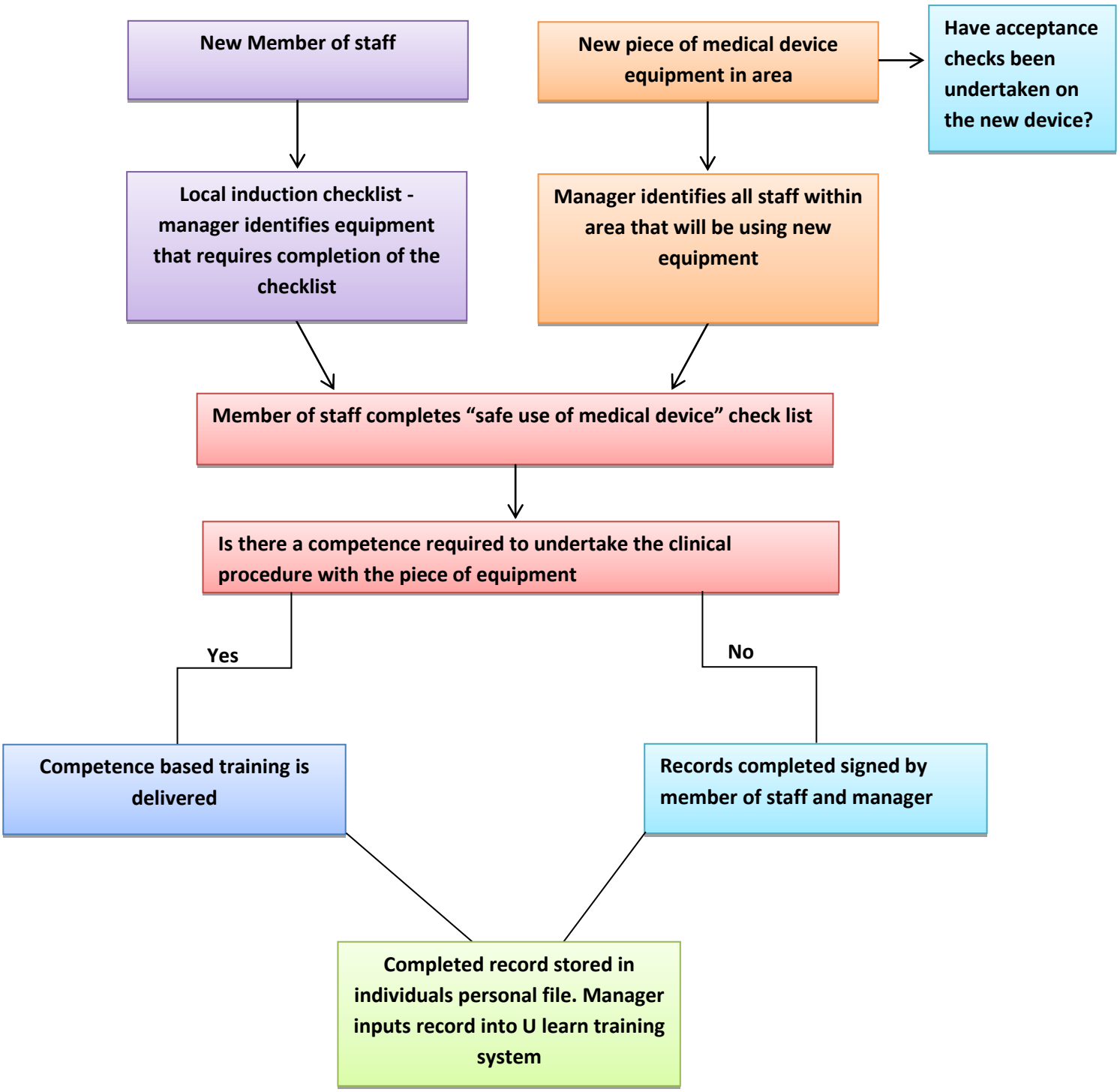
Manager statement: As a manager or nominated person I am satisfied that the individual understands the intended use of the piece of equipment for it to be used effectively and safely.

Name:		Area of Work:	
Signature:		Date:	

To be stored in individuals personnel file. Manager to input into u-Learn training system

Appendix 4

Process for Assuring the Safe Use Of a Medical Device



Appendix 4

PROCESS FOR ASSURING THE SAFE USE OF MEDICAL DEVICES
GUIDANCE NOTES

Terminology/ Question	Guidance
Manager identifies Medical Devices in their area	The Trust has a 'central asset register' which details medical devices within each area. If required a manager can request that a copy of the asset register relevant to their area identifying equipment
Medical Devices checklist	This checklist identifies the key components a member of staff needs to be aware of for the safe use of the medical device. This is taken from the MHRA Managing Medical Devices April 2014 guidance. The checklist needs to be completed by the individual discussing and identifying the correct responses with a manager or nominated person. A nominated person is a person who can demonstrate the safe use of a medical device. The checklist needs to be completed in the local areas as it relates to the specific make and model of a device within that area. It is envisaged that the checklist will be sufficient to demonstrate safe use of many medical devices.
Manufacturer instructions	A key emphasis here is on ensuring staff are aware of and can access the manufacturer instructions. Areas are encouraged to either attach the manufacturer's instructions to the medical device or allocate an area where manufacturer's instructions can be accessed. A central site for manufacturer instructions is currently being developed within the centralised system however in the interim Kerry Palmer, Medical Devices Asset Manager can provide some manufacturer's instructions on request
What training requirements might be needed from the checklist	An example would be accessing patient handling training which would focus on the principles of using the piece of equipment and reinforce knowledge or maybe some specific training which is provided by the company you have purchased the equipment from
When would procedural competence training be required	This would be required for a piece of equipment where a clinical procedure is undertaken and the area has identified the need for individuals to demonstrate a procedural competence. Here the user would be required to demonstrate a knowledge / understanding and meet performance criteria. A recommended tool would be LCAT however there is a licencing and training implication relating to the use of LCAT that would need to be funded by the Service. An example of LCAT use or procedural competence training would be in children's services where procedural competence training is required for all staff who undertakes mechanical ventilation and oxygen saturation monitoring.

Appendix 5

Leicestershire Partnership NHS Trust

LOCAL INDUCTION CHECKLIST

Welcome to your new role within the Trust. This induction checklist has been designed to help you to become acquainted with your new role.

It may also be useful to refer to our staff handbook for new employees, to help familiarise yourself and items on the checklist.

Start completing this form on your first day and should be completed within two working weeks of your commencement with the Trust. The completed and signed document must be kept in your personal file. Managers are required to inform Learning and Development once completed (see overleaf)

1. Welcome to your new work area	yes/no not applicable
Received tour of work area	
Introduced to colleagues	
Shown staff facilities	
Informed of car parking arrangements	
Informed of dress /uniform code	
Informed of security/ access to building	
Informed of team/division structure*	
Informed of key emergency telephone numbers relevant to area	
2 . Pay/Terms and conditions	
Received HR pack (includes contract of employment, request for identity badge, HMRC starter checklist & pennies from heaven form)	
Informed of Trade Union membership options*	
Informed of staff benefit schemes*	
Aware of pay arrangements* and informed of rules regarding salary overpayment	
Informed of sickness reporting procedure* and rules regarding work whilst sick	
Agreed hours to be work/ working pattern/On call arrangements	
Aware of Trust Code of Business Conduct and informed of gifts and hospitality rules	
Informed of responsibility for maintaining/updating professional registration requirements*	
Application to use a private motor vehicle on official business (register through e pay or P4 form for non users & medical staff)	
Manager activated epay for travel claims	
3. Patient & staff safety	
Informed of channels to express concerns about patient safety*	
Discussed reasonable adjustments to be considered for relevant protected characteristics	
Informed of incident reporting procedure (eIRF)*	
Informed of local fire safety procedure*	
Informed of lone working/personal safety procedure*	
Informed of first aid & COSSH procedure*	
Display screen equipment assessment undertaken	
Informed of key health and safety risks relevant to role	
Informed of infection control procedures & personal protective equipment*	
Informed of data protection and confidentiality procedures*	
Informed of Counter Fraud Policy and reporting procedures	
Informed of no smoking arrangements*	
Informed of waste disposal and sharps procedure*	
Informed of medical devices management arrangements including asset tagging, reporting faults, undertaking visual checks prior to use, how to use the device safely & record keeping.	

4. Learning and Development	
Check that all mandatory training requirements have been booked	
New employee to confirm has read mandatory key messages in handbook (equality & diversity/safeguarding/ infection control/ health and safety/fire safety/back injury prevention/conflict resolution/medical devices/ counter fraud/information governance*	
Has agreed initial appraisal date (to be undertaken within 3 months of commencing)	
Informed of learning and development course directory/ HIS IT training courses*	
Discussed supervision/ preceptorship arrangements	
Has agreed information governance training date (to be undertaken within 6 weeks of commencing) Informed of e-learning helpline	
5. Communications and IT systems	
Manager has activated email account (access to network form completed) *	
Informed of how to access Trust intranet site*	
Informed Staff attitude survey*	
Informed of Trust newsletter/people matters magazine/team brief*/Counter Fraud newsletter	
Informed of divisional brief, team meeting etc.*	
Check Smart Card was received on induction and PIN number has been changed from the default (if card not received contact the RA Team on x3500 Option 6)	
Manager to complete RA02 form to enable access to relevant clinical systems	
Informed of policy regarding use of Trust mobile devices (phones; wireless dongles; etc.)	
6. Health & Wellbeing	
New employee has completed and returned occupational health screening form	
Occupational Health post employment health screen interview arranged	
Informed of staff physiotherapy service*	
Informed of amica telephone counselling service*	
Informed of emotional resilience support training*	
Informed how to contact staff ombudsman*	
Informed of staff support groups*	
Informed of anti bullying support services*	
Informed of staff benefits*	
7. Other local area specific introduction checklist arrangement (manager to identify)	
Orientation programme arranged	

*An easy reference link will be provided in the staff handbook. This has been provided to assist managers in accessing the correct information.
Nb This checklist also applies to volunteers; some areas of the checklist will not be applicable

Employee's Name and Assignment Number _____

Employee's Signature _____ Date _____

Manager's Signature _____ Date _____

To managers – To notify Learning & Development that this checklist has been completed please log on to eSource, go to: Knowledge and Development > Learning & Development > Record Your Learning > Local Induction Checklists and complete the online form. This will be recorded against the employee's learning record. The checklist should be completed within two weeks of the employee's start date.

Appendix 6

Inspection of Patient Moving & Handling Equipment

Above is an example of the marking system used to denote when a piece of Moving & Handling Equipment has been inspected. There will be a coloured cable tie attached to the hoist or sling. The coloured cable tie donates the equipment has passed its L.O.L.E.R. examination and the colour indicated when this inspection took place, below is a table indicating periods of inspection and the corresponding colours. If the equipment does not have the appropriate colour for the date then it should be withdrawn from service until an inspection is carried out. Any none compliances with this guidance must be reported through the Trust's incident reporting system.

Period of Inspection	**Colour of Cable Tie**
October 2017 – April 2018	Red
April 2018 – October 2019	Yellow
October 2019 – April 2020	Blue
April 2020 – October 2021	Green

PLEASE BE AWARE ALL HOISTS & SLINGS SHOULD BE INSPECTED BY THE USER PRIOR TO USE

**NOTE: LOLER Inspections do not apply to the use of Disposable Slings currently in located in LPT Inpatient Sites, as these are disposed of 6 monthly*

Appendix 7

Leicestershire Partnership NHS Trust

MEDICAL DEVICES FORM

This form should be completed for new medical device purchases, medical device relocations for services that are moving and for the disposal of medical devices.

About the person completing this form

Name:_____

Service:
_____

Division:_____ Date:_____

Device location: _____

Or, device relocating from (location):

_____ to
_____

Medical Device details (tick as appropriate below)

New Device ☐ Device Relocation ☐ Disposal ☐

Device type (i.e. Digital BP monitor, Sphyg, ECG Machine,)

_____

_____

Asset tag no (if applicable): _____

LPT Green ☐ Interserve Green ☐ Interserve Silver ☐

Other unique identifying numbers: _____

_____

Make & Model: _____

Serial Number No:_____

Year of manufacture/date of purchase: _____

Cost of item: _____

Length of manufacturer warranty (found in manual): _____

_____
____

For completion by Medical Devices Team:

Maintenance required: YES ☐ NO ☐

Service Level: _____

Contract Location: _____

Equipment Category: _____

Comments: _____

_____

_____

_____

ONCE FULLY COMPLETED PLEASE FORWARD YOUR FORM VIA EMAIL or INTERNAL POST TO:

kerry.palmer@leicspart.nhs.uk Tel: 07827 807819
matthew.buxton@leicspart.nhs.uk Tel: 07880 081494

Medical Devices
Estates & Facilities Team
Beaumont Leys Health Centre
1 Littlewood Close, Leicester LE4 2AR

YOUR DEVICE WILL BE ADDED TO THE CENTRAL REGISTER OF MEDICAL DEVICES FOR ON-GOING SERVICING, MAINTENANCE, TESTING AND CALIBRATION

THANK YOU

Appendix 8

Medical Devices Group
Terms of Reference

References to 'the Group' shall mean the Medical Devices Group

1.0 Purpose of the Group

1.1 This Group is established to ensure that the requirements of Regulation 16 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 are being met "to ensure the safety, availability and suitability of equipment to protect service users and others who may be at risk from the use of unsafe equipment by ensuring that equipment is provided for the purposes of carrying on of a regulated activity" (1).

1.2 To provide the organisation with an overarching view of medical devices where we have a legal responsibility to ensure equipment is

- Properly maintained and suitable for its purpose
- Used correctly
- Available in sufficient quantities in order to ensure the safety of service users and meet their assessed needs
- Where equipment is provided by LPT or other external stakeholders to support service users in their day to day living, such equipment promotes the independence and comfort of service users, as far as reasonable practicable

1.3 The Medical Devices Group is accountable to the Health and Safety Committee and provide quarterly reports to demonstrate and assure the committee that medical devices are effectively managed on behalf of the organisation.

1.4 The Medical Devices Group provide bi-monthly assurance reports to the Patient Safety Group to enable engagement with clinicians, an understanding of how medical devices management is undertaken within the organisation therefore allowing appropriate challenge in systems and processes followed (where necessary).

1.5 The definition of a medical device is contained within the LPT Medical Devices policy.

2.0 Clinical Focus and Engagement

2.1 The Patient Safety Group considers clinical engagement and involvement to be an essential element of its governance arrangements and as such the Trust's integrated governance approach aims to mainstream clinical governance into all planning, decision-making.

2.2 The Health & Safety Committee provides the organisation with an overarching view of health and safety and provides assurance that non-clinical risks are effectively managed on behalf of the organisation.

2.3 The monitoring of this sub-groups activity will be undertaken by the Health & Safety Committee.

3.0 Authority

3.1 The Group is authorized by the Health & Safety Committee to conduct its activities within its Terms of Reference and the Trust's Standing Orders and Standing Financial Instructions.

3.2 The Group is authorized by the Health & Safety Committee to seek any information it requires from any employee of the Trust in order to perform its duties.

4.0 Membership

4.1 The Medical Devices Group will be chaired by the Medical Devices Asset Manager.

4.2 In the absence of the Medical Devices Asset Manager the Deputy Chair will be decided by the Group as appropriate prior to commencement of the next meeting.

4.3 The membership of the Group will comprise of the necessary persons to ensure that operational practices across the Trust comply with Regulation 16 of the Health and Social Care Act 2008, the Medical Devices Regulations 2002 and any other pertinent NHS best practice standards i.e. CQC Fundamental Standards 12, 15 and 17. Only members of the Group or their nominated representative have the right to attend meetings; however other individuals and officers of the Trust may be invited to attend for all or part of any meeting as deemed appropriate.

4.4 Membership of the Group will be reviewed and agreed annually the Health & Safety Committee.

4.5 The group will be made up of members who must attend regularly and meet the 75% attendance criteria and attendees who will need to attend when they have papers to present when required to do so for specific agenda items. Members will be

Medical Devices Asset Manager
Health & Safety Advisor
Learning and Development Representative
Finance Representative
Procurement Representative
Service Representation for each Directorate / Service within
Moving and Handling Representative
Infection Prevention and Control Representative
Risk Assurance and/or Patient Safety Representative
Tissue Viability Representative

5.0 Secretary

5.1 Secretarial support will be provided by the Health and Safety Compliance Department.

6.0 Quorum

6.1 The quorum necessary for the transaction of business shall be six members of which three must be from the Divisions and three from enabling services. Should

members be unable to attend appropriate representation must provide in their absence. A duly convened meeting of the Group at which a quorum is present shall be competent to exercise all or any of the authorities, powers and discretions vested in or exercisable by the Group.

7.0 Frequency of Meetings

7.1 The Group shall meet on a bi-monthly basis unless the Chair or members of the group decide otherwise at the exigency of the business.

7.2 Members will be expected to attend at least three-quarters (75%) of all meetings.

8.0 Agenda and Notice of Meetings

8.1 Notice of each meeting confirming the venue, time and date together with an agenda of items to be discussed shall be forwarded to each member of the Group and any other person required to attend

8.2 Papers must be received ten days in advance for the meeting and will be issued to group members five working days prior to the meeting

8.3 Papers will not be tabled without the express permission of the Chair. Any tabled paper will be accompanied by the Trust front page template

8.4 Any other business must be notified to the Chair in advance of the meeting and cannot be tabled on the day unless considered urgent by the Chair

9.0 Minutes of Meetings

9.1 The proceedings and resolutions of all Group meetings will be minuted including the names of those present and in attendance

9.2 Minutes of the meetings shall be circulated to all members and shall be issued within five working days of the forthcoming meeting. The minutes will be open to scrutiny by the Trust's auditors

9.3 A summary of key risks, issues and actions (with deadlines) will be brought to the attention of and presented to, the Health & Safety Committee and the Patient Safety Group

9.4 The minutes will be disseminated through the Health & Safety Committee

10.0 Duties

10.1 Ensure a centrally held register of equipment is created and maintained in keeping with legal requirements and in accordance with organisational policies and procedures.

10.2 To set up and monitor task and finish groups to manage key pieces of work relating to the safe management of medical devices throughout the Trust, ensuring outcomes are measured and issues escalated through the appropriate governance routes.

10.3 Monitor, audit and review the effectiveness of the sub- group's activity and outcomes relating to the safe management of medical device processes and procedures.

10.4 Receive, review and monitor minutes and action plans from the task and finish groups, provide support to these groups where necessary and seek assurance of compliance from them.

10.5 Oversee, influence, develop, review and approve organisational Medical Device policies, procedures, guidelines and codes of practice.

10.6 Give strategic direction, management and support of medical device activities across the organisation.

10.7 Provide and maintain a positive link with the organisational committees and groups to ensure Directors are kept fully informed of the issues.

10.8 Review incident statistics and trends throughout the organisation to ensure that correct action, prioritisation of high-risk issues are brought to the attention of the appropriate groups and act as an early warning mechanism to alert the Trust to emerging risks.

10.9 Ensure there is a structure and/or framework for the integration and organisational management of medical devices and ensure objectives are embedded within the organisation.

10.10 To ensure good procurement practice relating to the purchase or pertaining to contracts, services or medical device equipment in accordance with best practice guidance and the Trust's standing financial orders and standing financial instructions.

10.11 Risks arising from the task and finish groups activities and the subsequent activities of the Medical Devices Group are entered onto the organisation's risk register, are monitored and reviewed in line with the Risk Management Strategy.

10.12 Establish clear communication
Routes for dissemination of information to staff and other stake holders relating to the implementation of new or reiteration of existing processes and procedures for the management of medical devices.

10.13 Disseminate information and provide feedback to appropriate groups, committees, staff and other stake holders on environmental and risk issues.

10.14 Develop, monitor and review medical device compliance across the whole of the Trust's business undertakings.

10.15 Specific responsibility for monitoring the delivery and evidence to support the requirements of the Care Quality Commission standards as a centralised function and in addition to evidence held within the Services.

10.16 Consider new and revised legislation and best practice guidance and how it may impact the Trust providing recommendations and guidance to the Trust and measures required to comply.

10.17 Devise, implement, agree and approve policy within the remit of the Group prior to presenting it at the Health and Safety Committee for approval/ratification.

10.18 To promote and support the standardisation of medical devices where possible.

11.0 Reporting Responsibilities

11.1 The Group shall make recommendations to the Health & Safety Committee via Quarterly reports. A copy of the minutes will be submitted to the Health and Safety Committee for information only.

11.2 Produce quarterly reports of the Medical Device Group on the work it has undertaken during the course of the year, including attendance of members in time for the relevant governance groups meeting in May.

11.3 Send a front sheet summary of the group's activities on a bi-monthly basis to the Patient Safety Group.

11.4 Determine any issues that need escalation to the relevant governance groups.

12.0 Annual Review

12.1 The Group shall, at least once a year review its own performance, constitution and terms of reference, including membership to ensure it is operating at maximum effectiveness and recommends any changes it considers necessary to t the Health & Safety Committee.

13.0 Risk Responsibility

13.1 The Group has special responsibility for all aspects of medical device managements across the full scope for the Trust's business undertakings.

13.2 The Group is accountable for providing assurance for the Care Quality Commission Fundamental Standards 12, 15 and 17 (Regulation 16 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010)

13.3 The Group is also responsible for ensuring compliance with the following legislative documentation

EU Directives
90/269/EEC Directive concerning Manual Handling of Loads
92/59/EEC Directive concerning General Product Safety
93/42/EEC Directive concerning Medical Devices

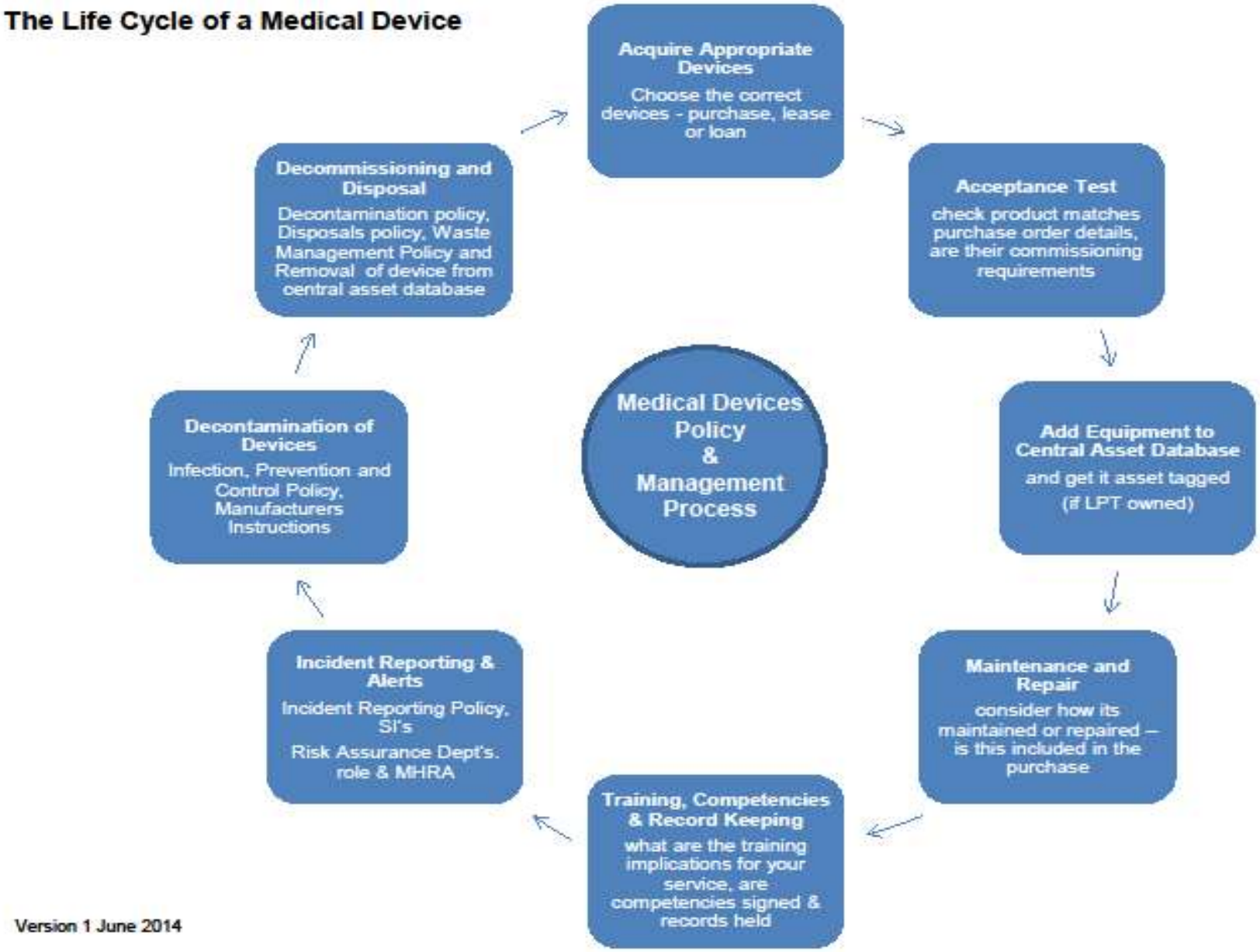
Acts of Parliament
Employers Liability (Defective Equipment) Act 1969
Health & Safety at Work etc. Act 1974
Consumer Protection Act 1987 {Part
1) Sale of Goods Act 1979

Statutory Instruments

Control of Substances Hazardous to Health (COSHH) Regulations 1994
Electrical Equipment (Safety) Regulations 1994
Electricity at Work Regulations 1989
The General Product Safety Regulations 1994
The Medical Devices Regulations 2002 No. 618
The Medical Device (amendment) Regulations 2012
Display Screen Regulations 1992
Management of Health & Safety at Work Regulations 1999
Provision & Use of Work Equipment Regulations 1998
Lifting Operations and Lifting Equipment Regulations 1998
Personal Protective Equipment Regulations 1992
Workplace (Health, Safety & Welfare) Regulations 1992
Medical Devices Policy (C/YEL/gen/02) Page 8 of 43 Regulations 1998
Nursing Home (Lasers) Regulations 1984
Manual Handling Operations Regulations 1992
Supply of Machinery (Safety) Regulations 1992
Pressure Systems & Transportable Gas Containers Regulations 1989
Pressure Equipment Regulations 1999
Pressure Systems Safety Regulations 2000
Reporting of Injuries, Diseases & Dangerous Occurrences (RIDDOR) Regulations 2013

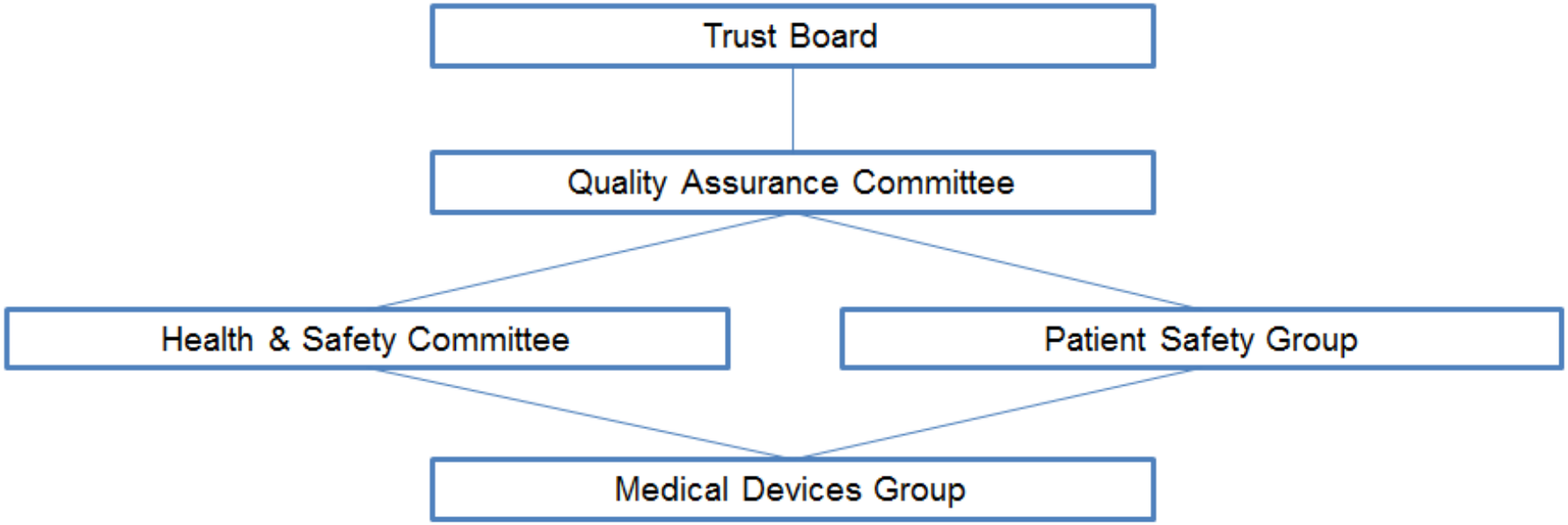
(1) Reference to Statutory Instrument 2010 No. 781 the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 Regulation 16. Safety, availability and suitability of equipment.

Appendix 9


The Life Cycle of a Medical Device
Acquire Appropriate Devices
Choose the correct devices - purchase, lease or loan
Acceptance Test
check product matches purchase order details, are their commissioning requirements
Add Equipment to Central Asset Database
and get it asset tagged (if LPT owned)
Maintenance and Repair
consider how its maintained or repaired – is this included in the purchase
Training, Competencies & Record Keeping
what are the training implications for your service, are competencies signed & records held
Incident Reporting & Alerts
Incident Reporting Policy, SI's
Risk Assurance Dept's. role & MHRA
Decontamination of Devices
Infection, Prevention and Control Policy, Manufacturers Instructions
Decommissioning and Disposal
Decontamination policy, Disposals policy, Waste Management Policy and Removal of device from central asset database
Medical Devices Policy & Management Process
Version 1 June 2014

Appendix 10

Medical Devices Groups Governance Structure



Appendix 11

Maintenance of Medical Devices

Current Arrangements & Existing Maintenance Provider

Existing Maintenance Provider	Equipment Maintained & Calibrated
1) Avensys Medical UK Ltd 01562 745858	Reactive & Planned Maintenance for all General Medical Equipment / Devices, (e.g., BP monitors, Nebulisers, ECG Machines, Sphygmomanometers, Thermometers, Pulse Oximeters, Syringe Drivers, Vital Signs Monitors, Infusion Pumps, Suction Units, Defibrillators, Ear Syringes), Wheelchairs, Washer Disinfectors, Sterilisers, Patient Lifting Equipment, Patient Weighing Equipment, Drug Fridges
2) Medstrom Healthcare Ltd 0843 506 0531	Beds Mattresses Plinths / Couches
3) Verathon Medical	Bladder Scanners
4) UHL Medical Physics Department 0300 303 5624	Diana Children's Therapy Service – Equipment ECT Suite – Equipment Audiology Oxygen Gas Regulators

Appendix 12

Equipment Fault Reporting Procedure – Avensys UK Ltd

EQUIPMENT FAULT REPORTING PROCEDURE
FOR MEDICAL DEVICES ONLY

Clinical Staff identify faulty equipment, fill in Faulty Equipment Report card with ALL requested information and attach card to equipment. Equipment cleaned and decontamination certificate attached to the device.

↓

Ring Avensys on 01562 745858 and report fault, Avensys will give you a job reference number to be written on the fault report card.

↓

Staff should request either urgent or routine call out

Urgent call out will be repaired within 24 hours
Routine call out will be repaired within 5 days
URGENT call-out will only apply to 'service critical medical devices' that are listed below

URGENT is defined as 'no alternative equipment available for use on site or a solution that can be implemented'

↓

Staff to attach fault report card and isolate faulty equipment.
Large equipment to be left in situ.

↓

Equipment repaired and returned to user

If an urgent call is reported and the repair has not been completed within 24 hours for 'service critical medical devices' a loan device will be provided by Avensys for use in the interim

User is to complete 'Ready for Use' section of card and store card in Avensys Maintenance folder.

PLEASE NOTE

- Equipment that has not been cleaned and decontamination certificate attached will be returned to clinical staff
- Equipment that has not had fault report card completely filled in will be returned to clinical staff
- Equipment that does not have an Avensys job number on the back of the card will be returned to clinical staff

SERVICE CRITICAL DEVICES LIST

- Hoists – passive and active
- Defibrillator
- Patient weighing scale
- Syringe driver
- ECG machine
- Washer disinfector
- Steriliser
- Vital signs monitor/SATS machine
- Vaccine/Drugs fridge
- Infusion pump

Equipment Fault Report Card – Avensys UK Ltd

Avensys

Call Avensys on
01562 745858

EQUIPMENT REPAIRED READY FOR USE

The following item of equipment has been inspected / repaired / electronically tested and can be returned to service.

Equipment ID No. / Asset Number: _____

Avensys Job Card No: _____

Comments: _____

Engineer Name: _____

Signature: _____ Date: _____

Company Name: _____

Equipment Use Checks

Users are reminded to carry out function test prior to putting this equipment into service.

Check Equipment Settings prior to use.

Once the above has been completed this label can be removed

Avensys

Call Avensys on
01562 745858

FAULTY EQUIPMENT
DO NOT USE

Reported by: _____

Department: _____

Date Reported: _____

Avensys Job Card No: _____

Equipment Description: _____

Model: _____ Serial No: _____

Equipment ID / Asset Number: _____

Purchase Order No: _____

Decontamination certificate completed and attached Y / N ?

Fault Description: _____

Internal Post Process for Medical Device Maintenance, Calibration or Repair

INTERNAL POST PROCESS FOR MEDICAL DEVICE MAINTENANCE, CALIBRATION OR REPAIR

From **November 2016** medical devices that require servicing, calibration, maintenance or repair can be sent to Avensys at their workshop located at:

Loughborough Hospital - VIA THE INTERNAL POST SYSTEM

➔ Before sending via internal post **please contact Avensys** on 01562 745858 to:

- Log a call and receive a reference number for the service or repair
- Complete the Avensys faulty equipment report card
- Clean / Decontaminate the device
- Complete the 'Declaration of Decontamination Status' form (IPC Policy)
- Package the device securely including any batteries or chargers and the completed faulty equipment report card
- Do not send just the faulty part of the device if it can be detached from the equipment i.e. hose to a blood pressure monitor - send the **whole** device
- Fix the 'Declaration of Decontamination Status' form to the **outside of the packaging**
- Put into the internal post system

Only devices with a Declaration of Decontamination Status will be assessed

SEND TO: AVENSYS ENGINEERS WORKSHOP, POST ROOM, LOUGHBOROUGH HOSPITAL

Avensys will endeavour to return your repaired device within 7 days of receipt (subject to availability of parts or a need to return the device to the manufacturer)

Devices appropriate for the Internal Post system are:

- Sphygmomanometer
- Digital Blood Pressure Monitor
- Blood Glucose Monitor
- Ear Syringe
- Pulse Oximeter
- Auroscope / Otoscope
- CO Meters
- Ultrasound / Doppler
- Thermometer
- Syringe Driver

The MAXIMUM size recommended for the internal post system would be a syringe driver. Please only send devices if they can be safely packaged to prevent damage.

Any queries should be directed to Kerry Palmer, Medical Devices Asset Manager, or Matthew Buxton, Medical Devices Compliance & Audit Officer via email or phone
kerry.palmer@leicspart.nhs.uk 07827 807819
matthew.buxton@leicspart.nhs.uk 07880 081494
or the Infection Prevention Control Team 0116 2951668

Do not send via internal post if the repair is urgent or you do not have any other devices available for use within your location. Contact Avensys on 01562 745858 and request an engineer's visit - (£65.00 minimum charge incurred).

PLEASE PRINT ME AND THE ACCOMPANING DOCUMENTS TO ASSIST YOU WITH THE PROCESS

Appendix 13

DECLARATION OF DECONTAMINATION STATUS – LPT MEDICAL EQUIPMENT

- Please complete all appropriate sections of the below form prior to the return & inspection of any Trust owned medical equipment.
- Equipment will **not** be accepted for service / repair without completion of this form.

Department: **Address:**	
Asset Number or Serial No:	**Equipment Type / Model:**
Nature of request: Routine Maintenance ☐ Fault ☐ Acceptance ☐ Other (Please State) ☐	**Give any details related to request:** …… …… …… …… ……
NB: Dispose of contents as per procedure. Please return equipment with all leads and accessories (e.g. batteries).	

CONTAMINATION STATUS

- ***Please tick box A if applicable. Otherwise, please tick & complete all parts of B on page 2, providing further information as requested or appropriate***

A ☐

This equipment/item has not been used in any invasive procedure or been in contact with blood, other body fluids, respired gases, or pathological samples. It has been cleaned in preparation for inspection, servicing, repair, or transportation.

B ☐

Has this equipment/item been exposed internally or externally to hazardous materials as indicated below:	***YES***	***NO***
Blood, body fluids, respired gases, pathological samples		
Other biohazards		
Chemicals or substances hazardous to health		
Other hazards		
Has this equipment/item been cleaned and decontaminated?	***YES***	***NO***
Indicate the methods and materials used:		
If the equipment/item could not be decontaminated indicate why:		
*** Such equipment must not be returned/presented without the prior agreement of the recipient whose reference or contact name must be given above.*		
Has the equipment/item been suitably prepared to ensure safe handling/transportation?	***YES***	***NO***

DECLARATION:

I, the undersigned, declare that I have taken all reasonable steps to ensure the accuracy of the above information in accordance with HSG (93) 26.

SIGNED:

PRINT NAME:

POSITION:

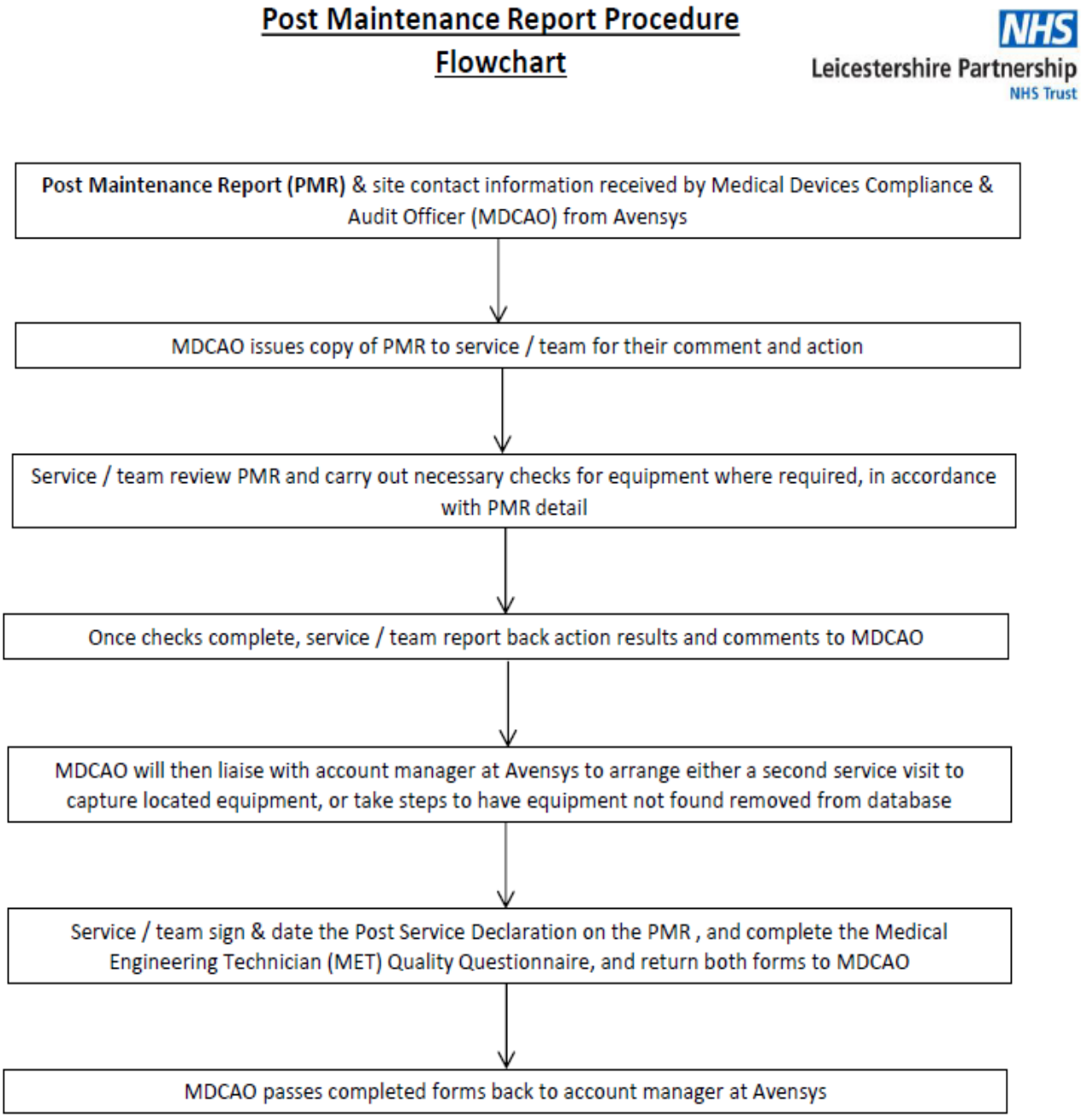
DEPARTMENT:

DATE:

TEL NO:

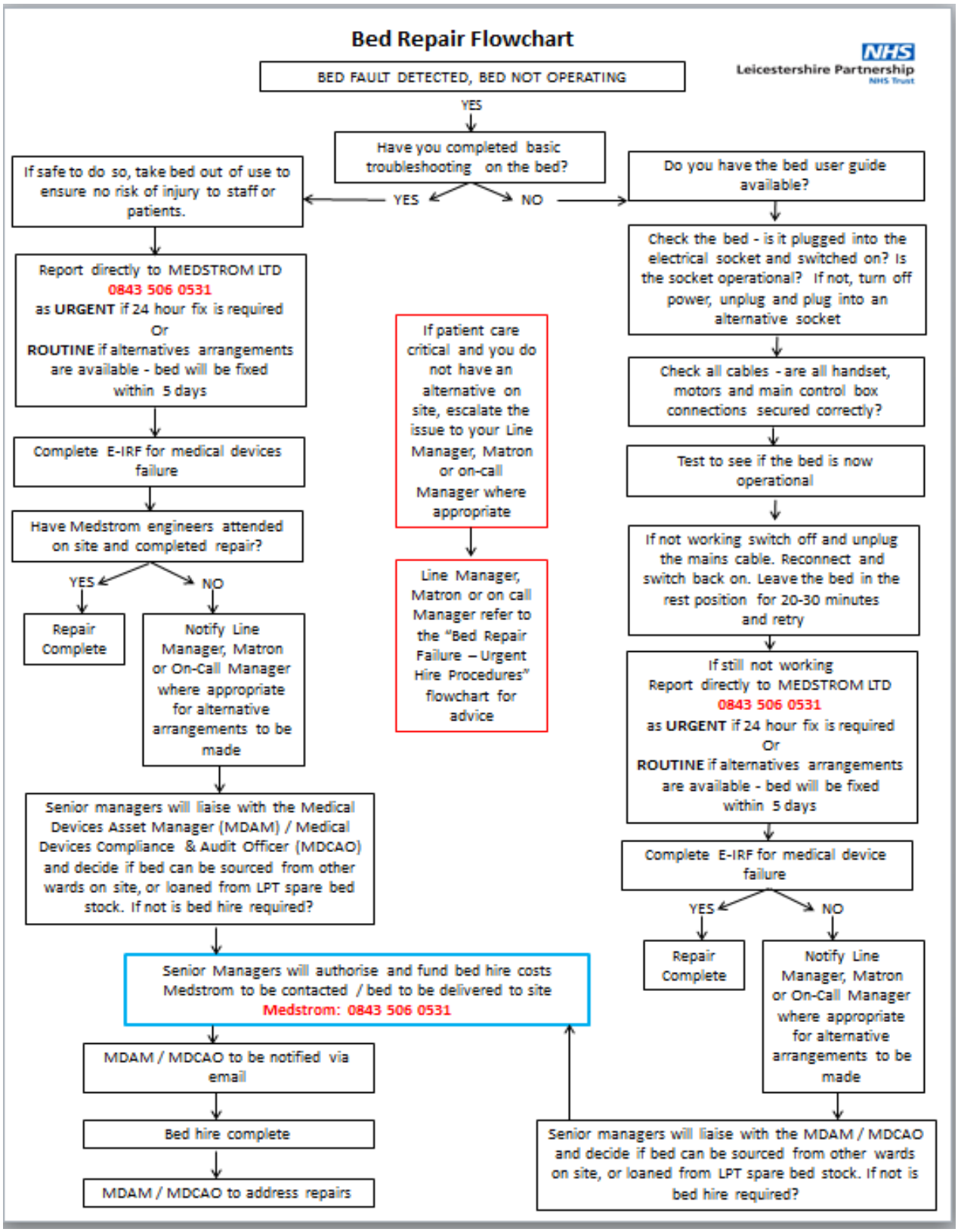
Appendix 14

Post Maintenance Reports Procedure – Avensys UK Ltd

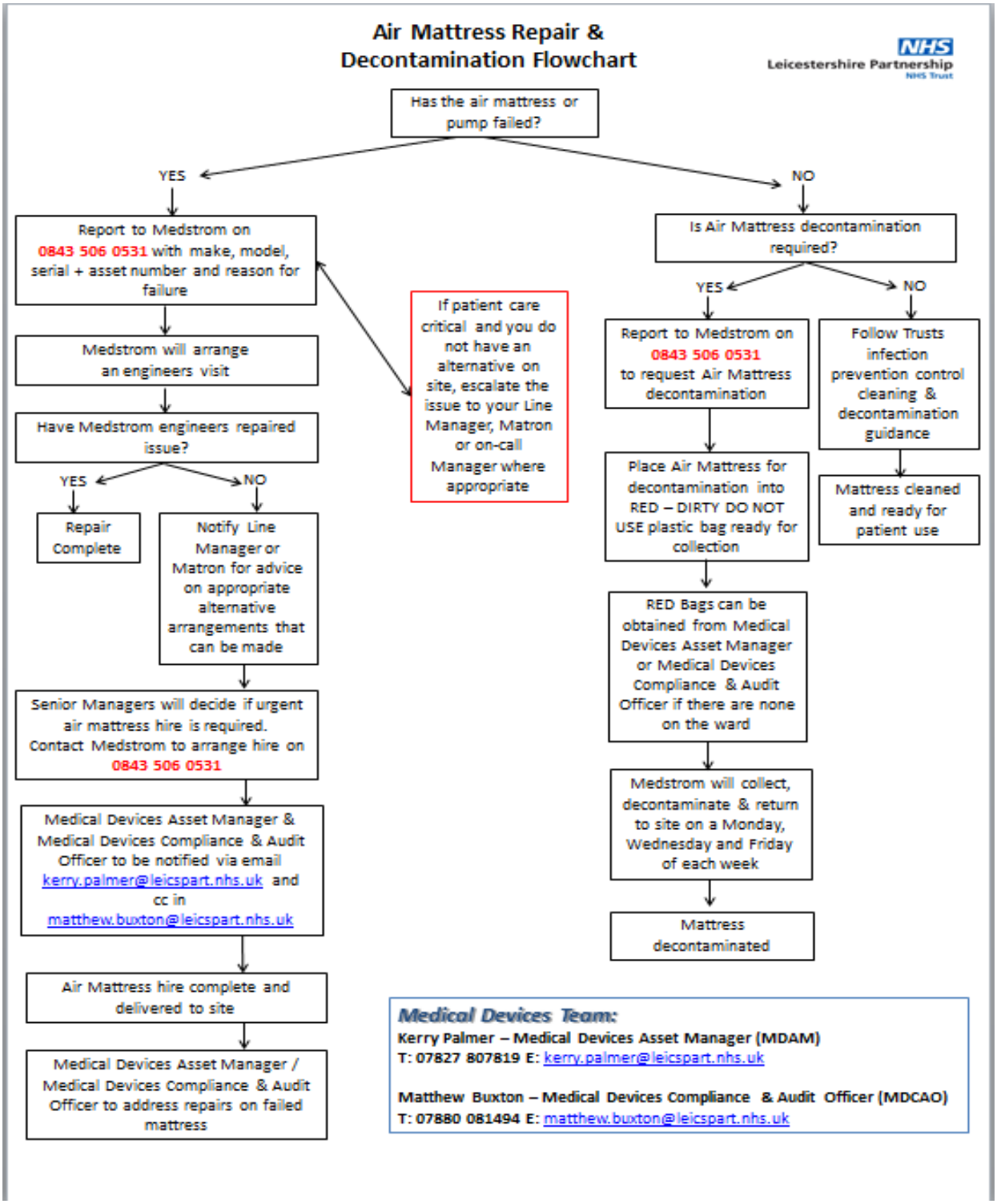


Appendix 15

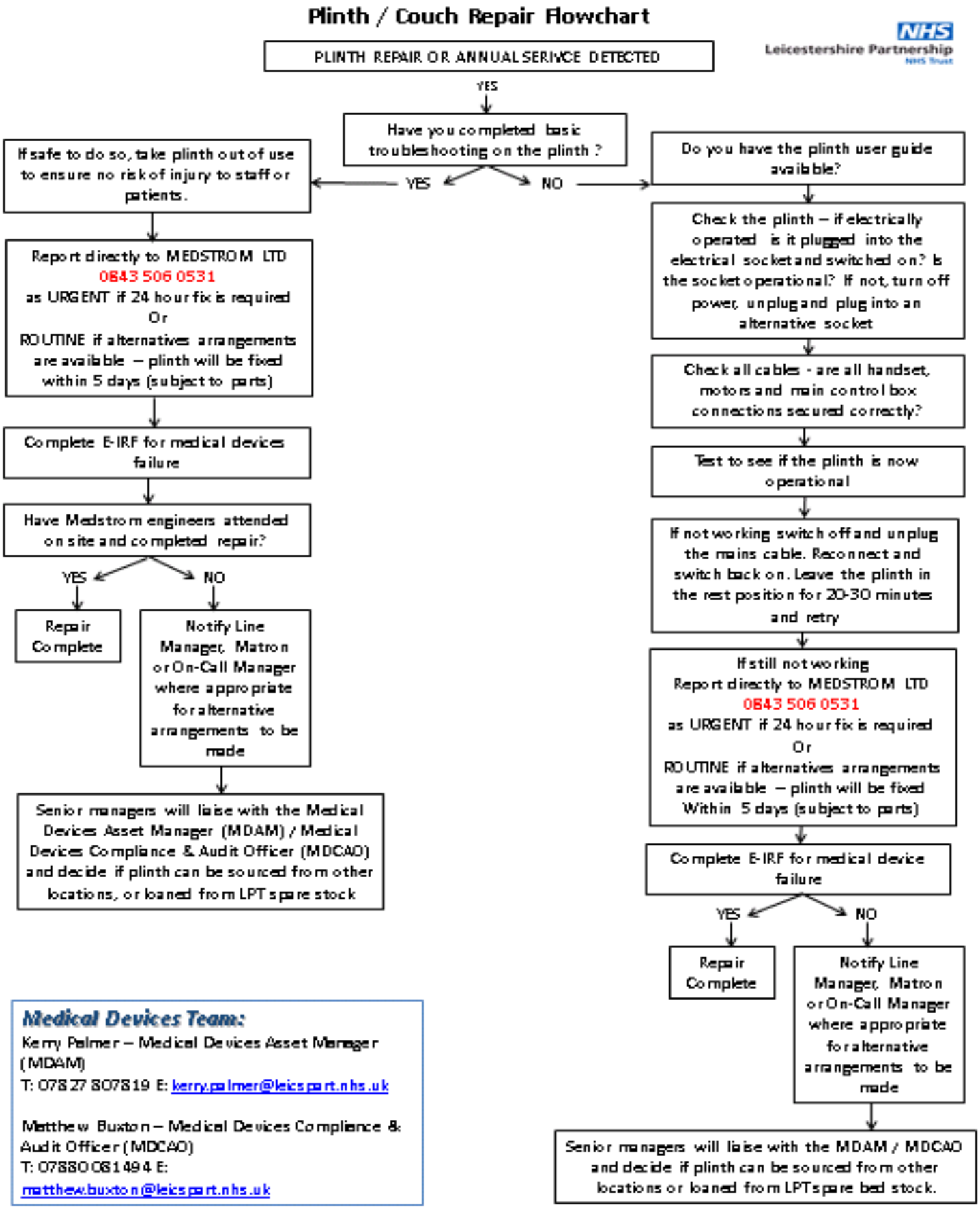
Bed Repair Flowchart – Medstrom Healthcare Ltd



Air Mattress Repair & Decontamination Flowchart – Medstrom Healthcare Ltd



Plinth / Couch Repair Flowchart



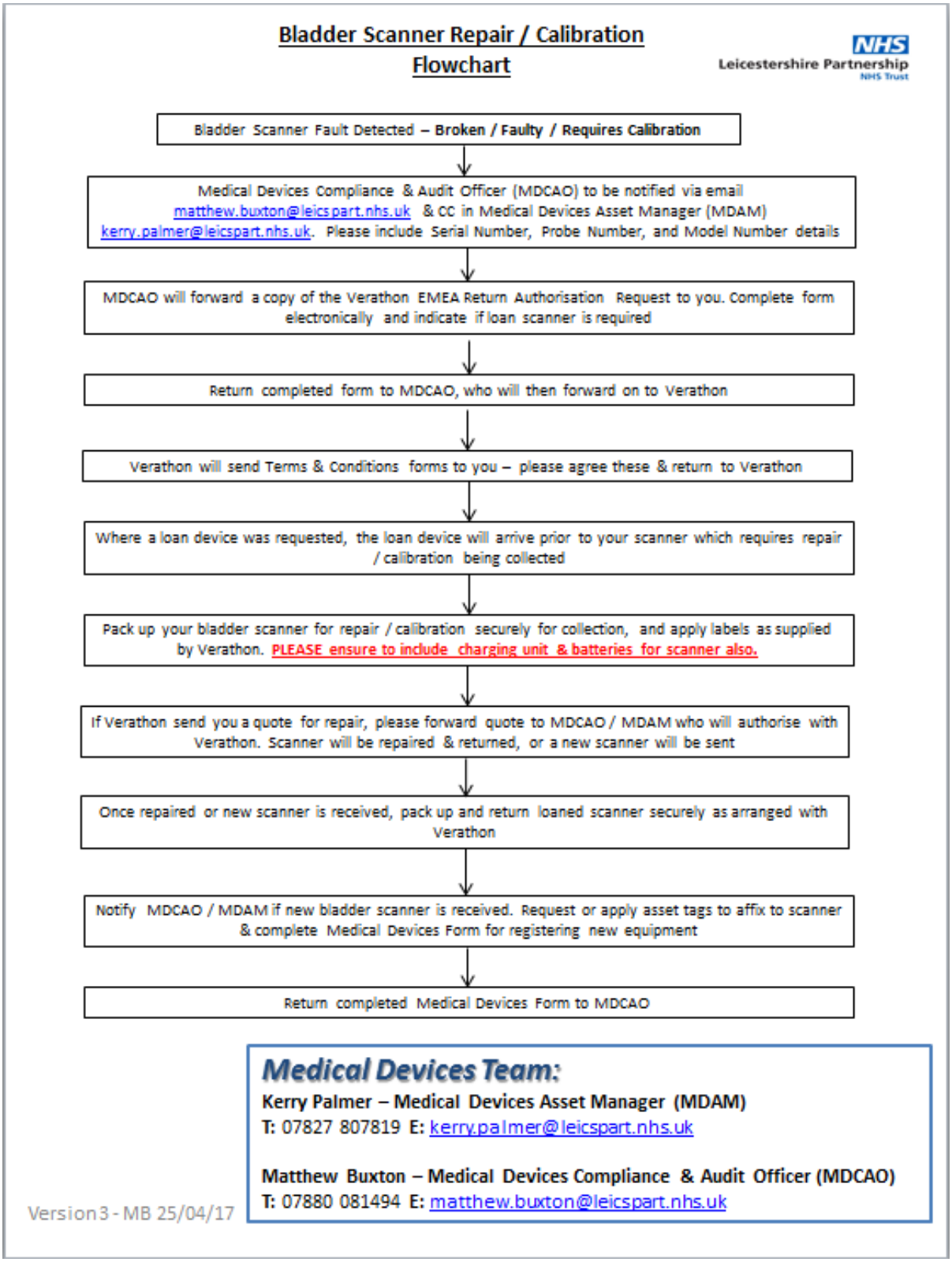
Medical Devices Team:

Kerry Palmer – Medical Devices Asset Manager (MDAM)
T: 07827 807819 E: kerry.palmer@leicspart.nhs.uk

Matthew Buxton – Medical Devices Compliance & Audit Officer (MDCAO)
T: 07880 061494 E:
matthew.buxton@leicspart.nhs.uk

Appendix 16

Bladder Scanner Repair / Calibration Flowchart – Verathon Medical Ltd



Appendix 16

Bladder Scanner Returns Form – Verathon Medical Ltd

Verathon (EMEA) Return Authorization Request

Please complete and return this form to request a product return authorization number.

Company Name: | Telephone:
Contact Name: | Email:
Position: | Date Incident Occured:

Shipping Adress | ***Billing Adress***

Street: | Street:
City: | City:
Postal Code: | Postal Code:
Province: | Province:
Country: | Country:

Affected Product (please mention all units that will be returned)

Product System	Assembly Type	Serial Number	Description	Warranty or Service Contract?	Loaner needed?
				Yes ◯ No ◯	Yes ◯ No ◯
				Yes ◯ No ◯	Yes ◯ No ◯
				Yes ◯ No ◯	Yes ◯ No ◯

If you need a loaner and your device is not under warranty or service contract, do you accept the £300 loaner fee? Yes ◯ No ◯
(please refer to our Terms and Conditions for further details)

Please describe the issue in all details:

Is the problem reproducible? Yes ◯ No ◯ | Is the problem intermittent Yes ◯ No ◯

When was the malfunction detected? Patient Procedure ◯ Installation ◯ Cleaning ◯
Inspection ◯ Other ◯

Is the reported event associated with any of the following?

Patient or User death? ---------- Yes ◯ No ◯
Patient or User injury? ---------- Yes ◯ No ◯
A device fire, battery explosion, electric shock? ---------- Yes ◯ No ◯
Medical intervention due to the reported event? ---------- Yes ◯ No ◯
Compromised product sterility (sterile product only)? ---------- Yes ◯ No ◯
Malfunction that occured during an emergency care procedure and resulted in delayed treatment? ---------- Yes ◯ No ◯

Please note that Terms and Conditions apply to any Service Request or any Loaner Request

EUCC-0094-ENUK-00-92

clear form

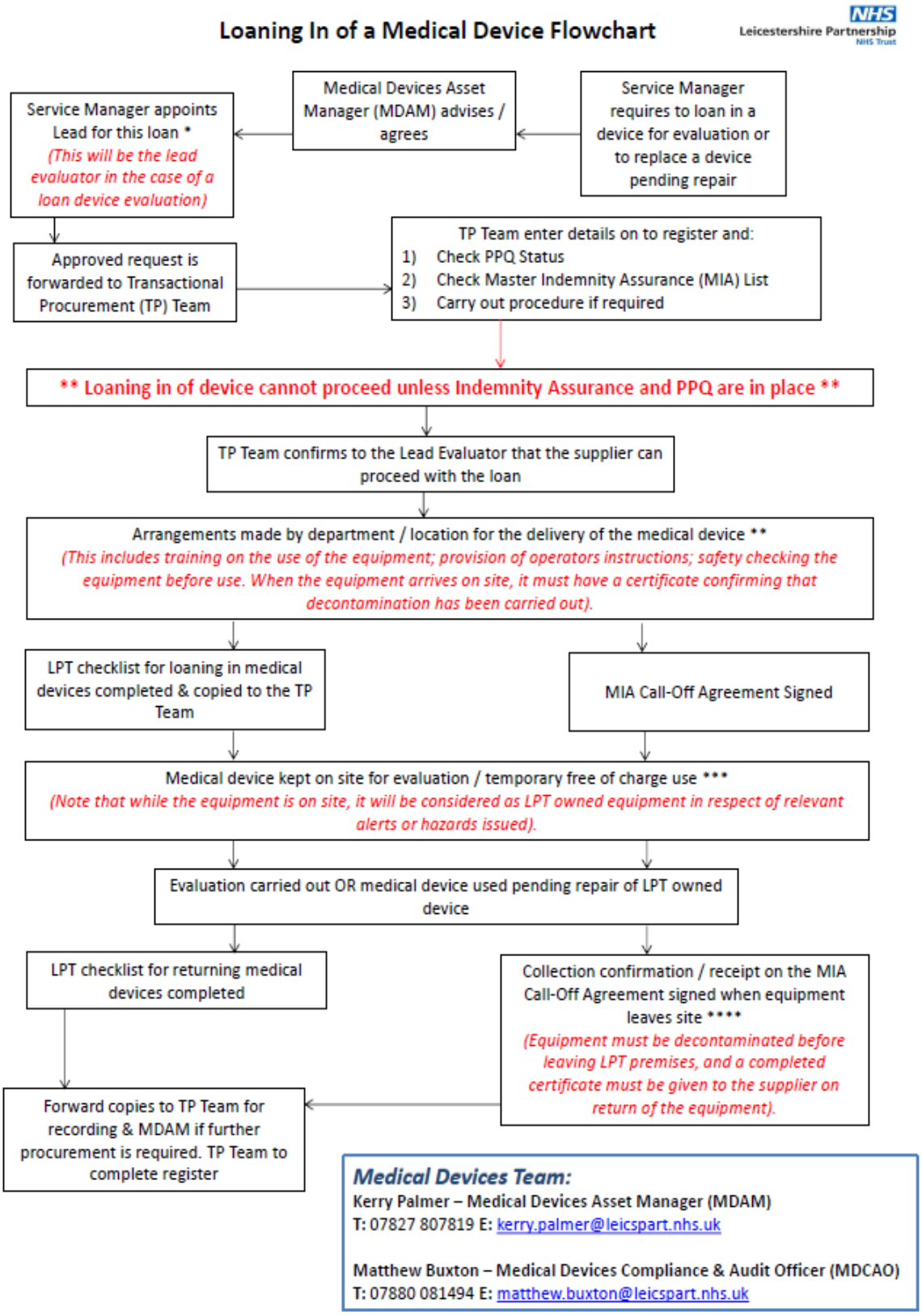
Verathon Medical B.V.
Linnaeusweg 11
3401 MS, IJsselstein
Nederland

Verathon Medical UK Ltd.
Unit C2, De Havilland Court, Penn Street,
Amersham, Buckinghamshire, HP7 0PX
United Kingdom

Pag. 1 / 1

Appendix 17

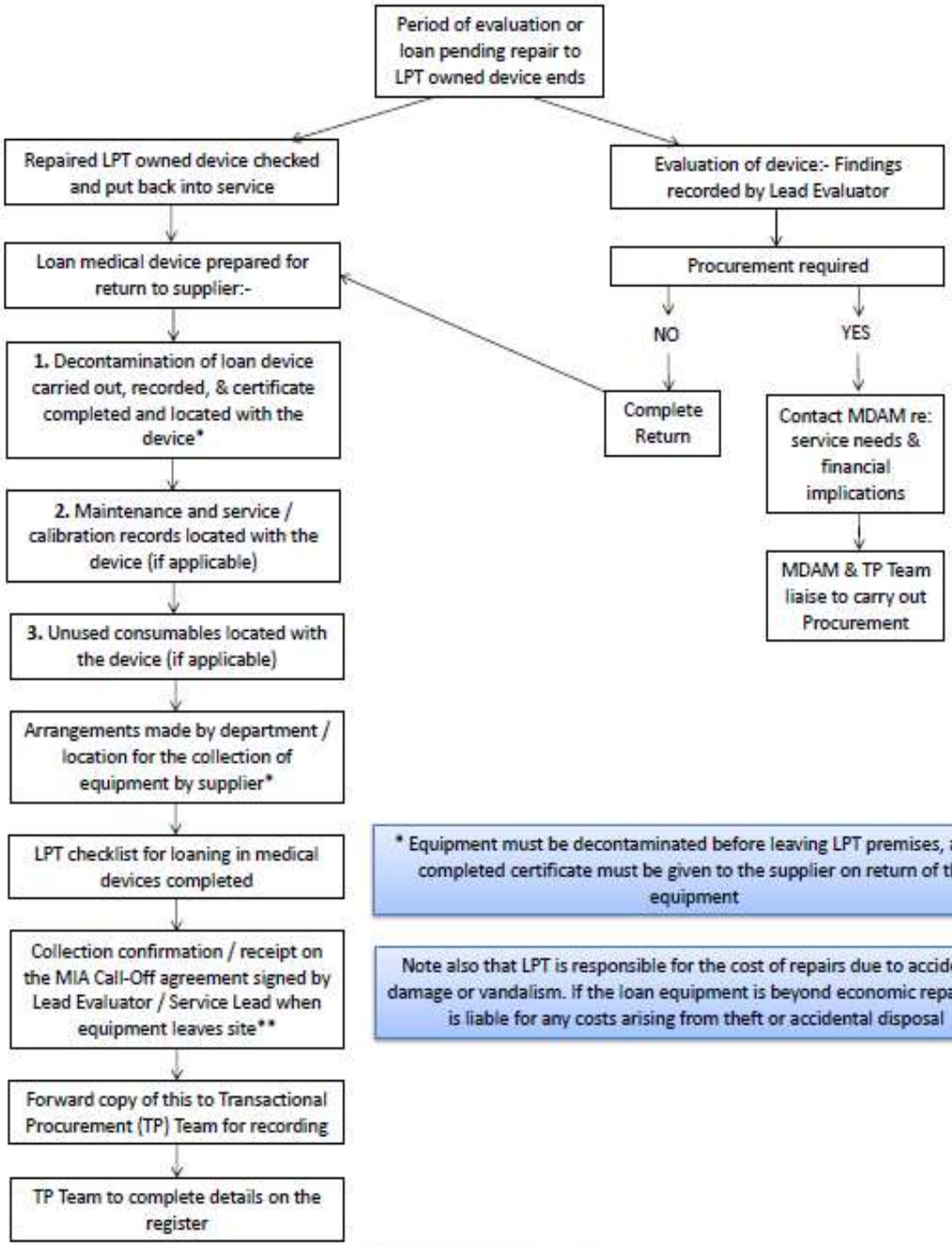
Loaning in of a Medical Device Process



Return of a Medical Device Flowchart

(for evaluation or pending repair to LPT owned medical device)

Leicestershire Partnership NHS Trust



* Equipment must be decontaminated before leaving LPT premises, and a completed certificate must be given to the supplier on return of the equipment

Note also that LPT is responsible for the cost of repairs due to accidental damage or vandalism. If the loan equipment is beyond economic repair, LPT is liable for any costs arising from theft or accidental disposal

Medical Devices Team:

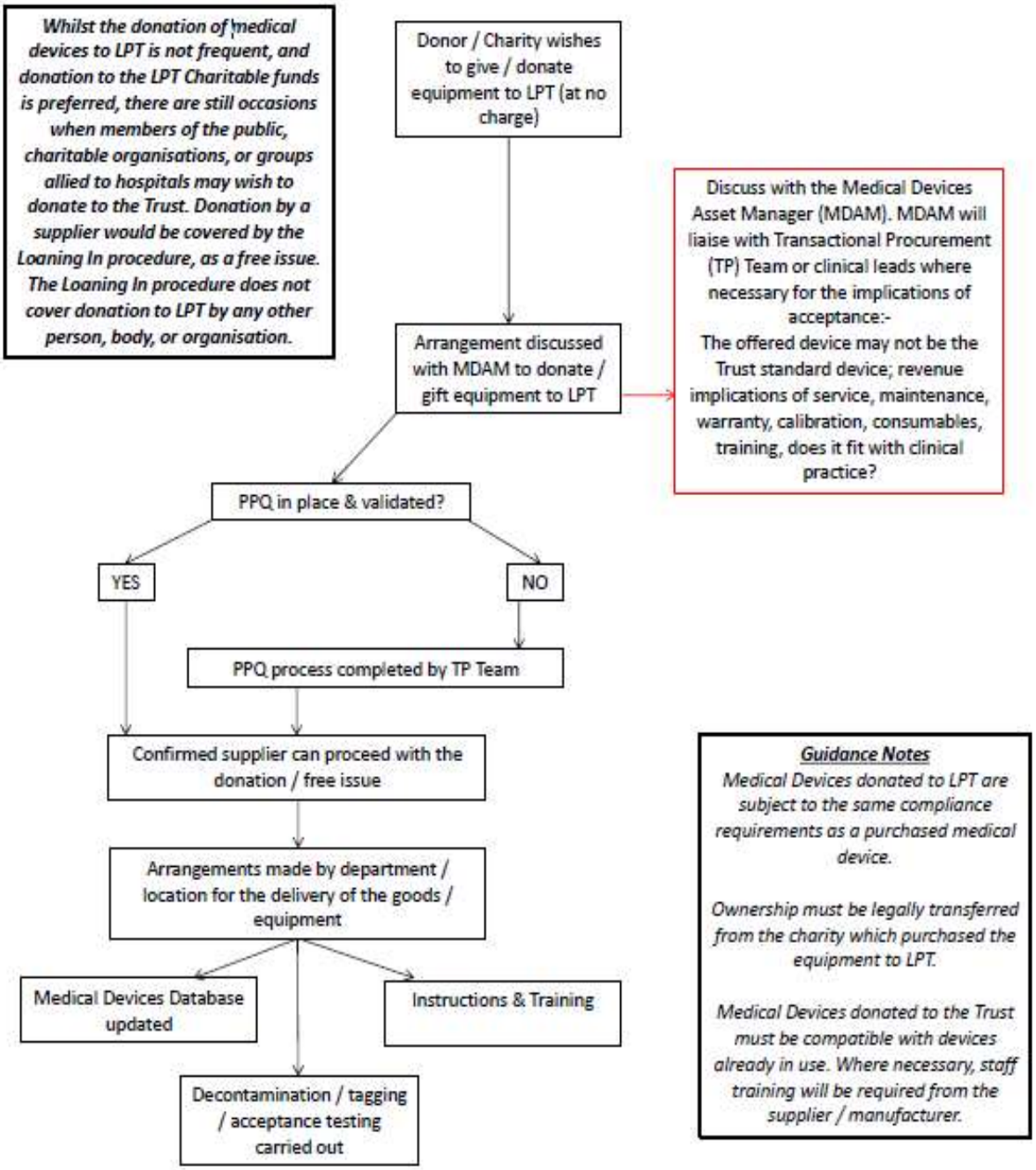
Kerry Palmer – Medical Devices Asset Manager (MDAM)
T: 07827 807819 **E:** kerry.palmer@leicspart.nhs.uk

Matthew Buxton – Medical Devices Compliance & Audit Officer (MDCAO)
T: 07880 081494 **E:** matthew.buxton@leicspart.nhs.uk

Donation / Free Issue of Medical Devices to LPT's Ownership by a Charitable Body Flowchart

Leicestershire Partnership NHS Trust

Whilst the donation of medical devices to LPT is not frequent, and donation to the LPT Charitable funds is preferred, there are still occasions when members of the public, charitable organisations, or groups allied to hospitals may wish to donate to the Trust. Donation by a supplier would be covered by the Loaning In procedure, as a free issue. The Loaning In procedure does not cover donation to LPT by any other person, body, or organisation.



Guidance Notes

Medical Devices donated to LPT are subject to the same compliance requirements as a purchased medical device.

Ownership must be legally transferred from the charity which purchased the equipment to LPT.

Medical Devices donated to the Trust must be compatible with devices already in use. Where necessary, staff training will be required from the supplier / manufacturer.

Medical Devices Team:

Kerry Palmer – Medical Devices Asset Manager (MDAM)
T: 07827 807819 **E:** kerry.palmer@leicspart.nhs.uk

Matthew Buxton – Medical Devices Compliance & Audit Officer (MDCAO)
T: 07880 081494 **E:** matthew.buxton@leicspart.nhs.uk

Appendix 18

Monitoring Compliance and Effectiveness

Reference	Minimum Requirements to be monitored	Evidence for self assessment	Process for Monitoring	Responsible Individual / Group	Frequency of monitoring
5.4 (b); 5.5 (b)	how the organisation includes all items of diagnostic and therapeutic equipment on an inventory	Section 4.2 and Appendix 1 & 7	Central asset register of equipment Annual verification of assets on register Perpetual updating of asset register	Medical Devices Asset Manager	Annual
5.4 (c)	how reusable diagnostic and therapeutic equipment is maintained	Section 10 and Appendix 11, 12, 13, 14, 15, 16	Routine maintenance procedures and planned preventative maintenance carried out by suitably trained and qualified technicians	Medical device users and Medical Devices Asset Manager	In accordance with manufacturer's recommendations
5.4 (d)	how reusable diagnostic and therapeutic equipment is repaired	Section 10 and Appendix 11, 12, 13, 14, 15, 16	Carried out by suitably trained and qualified technicians as required	Medical device users and Medical Devices Asset Manager	In accordance with manufacturer's recommendations
5. 5 (c)	how the organisation identifies which permanent staff are authorised to use the equipment listed on the inventory	Section 9 and Appendix 3, 4, 5	The safe use of a medical device checklist to be utilised at local level with each permanent staff member along with the training frequencies table and local induction checklist	Service Managers, Line Managers & others with delegated responsibility Learning & Development	Annual

Appendix 19

Policy Training Requirements

The purpose of this template is to provide assurance that any training implications have been considered

Training topic:	Medical Devices Management
Type of training:	√ Mandatory (must be on mandatory training register) √ Role specific ☐ Personal development
Division(s) to which the training is applicable:	√ Adult Learning Disability Services √ Adult Mental Health Services √ Community Health Services √ Enabling Services √ Families Young People Children √ Hosted Services
Staff groups who require the training:	All staff groups responsible for or using medical equipment in their day to day activities
Update requirement:	As stated in Appendix 3 for specific medical devices in addition to three yearly mandatory training
Who is responsible for delivery of this training?	Mandatory training – The Academy Local induction training – Line Managers or delegated responsibility PDR Process – Line Managers
Have resources been identified?	YES
Has a training plan been agreed?	YES
Where will completion of this training be recorded?	√ Trust u-Learn Training System √ Other (please specify) PDR Process
How is this training going to be monitored?	Via the PDR Process

Appendix 20

The NHS Constitution

NHS Core Principles – Checklist

Please tick below those principles that apply to this policy

The NHS will provide a universal service for all based on clinical need, not ability to pay. The NHS will provide a comprehensive range of services

Shape its services around the needs and preferences of individual patients, their families and their carers	☐
Respond to different needs of different sectors of the population	√
Work continuously to improve quality services and to minimise errors	√
Support and value its staff	√
Work together with others to ensure a seamless service for patients	√
Help keep people healthy and work to reduce health inequalities	√
Respect the confidentiality of individual patients and provide open access to information about services, treatment and performance	☐

Appendix 21

Due Regard Screening Template

Section 1	
Name of activity/proposal	Medical Devices Management
Date Screening commenced	November 2014
Directorate / Service carrying out the assessment	Health and Safety Compliance Team
Name and role of person undertaking this Due Regard (Equality Analysis)	Kerry Palmer, Medical Devices Asset Manager
Give an overview of the aims, objectives and purpose of the proposal:	
AIMS: The aim of this policy is to provide a framework for the management of medical devices throughout the organisation including process and procedures to follow to ensure equipment is safe for use.	
OBJECTIVES: To provide clear processes and procedures for the management of medical devices.	
PURPOSE: To ensure there is a consistent approach to the management of medical devices across all Divisions.	

Section 2		
Protected Characteristic	**Could the proposal have a positive impact Yes or No (give details)**	**Could the proposal have a negative impact Yes or No (give details)**
Age	No	No
Disability	No	No
Gender reassignment	No	No
Marriage & Civil Partnership	No	No
Pregnancy & Maternity	No	No
Race	No	No
Religion and Belief	No	No
Sex	No	No
Sexual Orientation	No	No
Other equality groups?	No	No

Section 3			
Does this activity propose major changes in terms of scale or significance for LPT? For example, is there a clear indication that, although the proposal is minor it is likely to have a major affect for people from an equality group/s? Please tick appropriate box below.			
~~Yes~~		No	
High risk: Complete a full EIA starting click here to proceed to Part B		Low risk: Go to Section 4.	

Section 4			
It this proposal is low risk please give evidence or justification for how you reached this decision:			
Signed by reviewer/assessor	Kerry Palmer	**Date**	
Sign off that this proposal is low risk and does not require a full Equality Analysis			
Head of Service Signed		**Date**	02/11/17