Medical Devices Policy

This policy describes the process for the management of maintenance and repair of medical devices.

Key words: Medical Devices, Medical Equipment, Repair, Maintenance

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Contents

Policy On A Page

SUMMARY & AIM

This policy describes the process for the management of maintenance and repair of medical devices within Leicestershire Partnership NHS Trust, with the aim of ensuring all staff working within our clinical services are aware of the procedures concerning ongoing management & maintenance of all medical devices.

KEY REQUIREMENTS

Staff should be aware of all processes & procedures in place to ensure the effective ongoing management of maintenance for all medical devices, inclusive of contacting the relevant maintenance contractor to escalate any faults/damage.

Staff must also ensure completion of the infection control certificate (ICC) to ensure devices are clean and safe for engineers to access.

All medical equipment purchases must be discussed with the Medical Devices team to ensure on standardisation and that the correct Procurement processes are being adhered to.

All trials or loans of medical equipment must be discussed with the Medical Devices team to ensure the relevant documentation supporting any such trial have been completed and are in place.

All medical equipment disposals must be discussed with the Medical Devices team to ensure the safe & appropriate disposal of any equipment no longer fit for use or required.

TARGET AUDIENCE:

All users of Medical Devices within Leicestershire Partnership NHS Trust.

TRAINING

There is no training required for this policy.

1.0 Quick look summary

This policy describes the process for the management of maintenance and repair of medical devices.

1.1 Version control and summary of changes

Version number	Date	Comments (description change and amendments)
2	02/04/2012	Added key words. Pg 6, 8 – removed LCCHS and added LPT Defined 'single patient use.' Pg 7 – custom made devices added. Pg 9 – Role of Infection Prevention and Control team/nurse amended. NRS changed to ICELS. 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
7	April 2024	Re-write of the policy to reflect the changes to systems & processes implemented since the last review.

For Further Information Contact: Medical Devices Team
lpt.medicaldeviceteam@nhs.net.

1.2 Key individuals involved in developing and consulting on the document

Name	Designation
Mark Jones	Medical Devices Service Manager
Matthew Buxton	Deputy Medical Devices Asset Manager
Wider Consultation	Members of the Medical Devices Group Members of the Patient Safety Improvement Group Members of the Estates & Medical Equipment Group Trust Policy Experts

1.3 Governance

Level 2 or 3 approving delivery group	Level 1 Committee to ratify policy
Patient Safety Improvement Group	Quality Assurance Committee

1.4 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.

If you would like a copy of this document in any other format, please contact lpt.corporateaffairs@nhs.net.

1.5 Due Regard

LPT will ensure that due regard for equality is taken and as such will undertake an analysis of equality (assessment of impact) on existing and new policies in line with the Equality Act 2010. This process will help to ensure that:

- Strategies, policies and procedures and services are free from discrimination.
- LPT complies with current equality legislation.
- Due regard is given to equality in decision making and subsequent processes.
- Opportunities for promoting equality are identified.

Please refer to due regard assessment (Appendix 3) of this policy.

1.6 Definitions that apply to this policy.

CE Mark	Conformity marking used for products being placed on the market in the European Economic Area (EEA).
CQC	Care Quality Commission
CSO	Clinical Safety Officer
DGSA	Dangerous Goods Safety Adviser
DoH	Department of Health
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".*
EMEG	Estates & Medical Equipment Group
ICELS	Integrated Community Equipment Loan Service
IPC	Infection Prevention & Control
LOLER	Lifting Operations and Lifting Equipment Regulations 1998
LPT	Leicestershire Partnership NHS Trust
MD Team	Medical Devices Team
MDG	Medical Devices Group
MDSM	Medical Devices Service Manager
MDSO	Medical Devices Safety Officer
MHRA	Medicines and Healthcare Products Regulatory Agency
NHS	National Health Service
PAQ	Pre-Acquisition Questionnaire
PPM	Planned Preventative Maintenance

PSIG	Patient Safety Improvement Group
PUWER	Provision and Use of Work Equipment Regulations 1998
SFI	Standing Financial Instructions
SI	Significant Incident
UKCA	Conformity marking used for products being placed on the market in Great Britain (England, Scotland, and Wales).

2.0 Purpose and 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 clinical competency 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 the Medical Devices Team (MD Team), the Procurement Team, and LPT's Clinical Services to ensure there are sufficient quantities of devices to provide safe and effective patient care.

3.0 Policy Requirements

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, clinical competency training, information, instruction, and supervision.

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 minimized.
- 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 repair information and planned maintenance schedules.
- 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 legislative requirements and standards is maintained.
- Device demonstration or clinical competency training appropriate for staff whether at induction, mandatory training, clinical education training or at the local place of work to ensure staff are competent to safely use the medical equipment in their workplace and systems are 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 database by clinical services via notification to the MD Team.

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 bank staff, those on honorary contracts, students, and agency.

This policy applies to all medical equipment used by staff within 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 Duties within the Organisation

4.1 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.

4.2 Executive Director of Nursing / Chief Nurse

The Trust's Executive Director of Nursing / Chief Nurse will:

- Be the lead for the organisation and 'nominated individual' responsible for ensuring all personnel comply with their obligations in meeting the standards set within Medical Device legislation and MHRA guidance.
- Ensure compliance with the requirements of the CQC Fundamental Standards 12, 15 & 17 in relation to safe care and treatment, premises and equipment and good governance.
- Ensure compliance in relation to HTM 01-01 Decontamination of surgical instruments, HTM 2010 Part 3 Sterilisation and the Pressure Equipment (Safety) Regulations 2016.

4.3 Heads of Service/Directors of Nursing/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 appropriate representation from their service at the Medical Devices Group (MDG).
- Be responsible for the local management of medical devices; this will include ensuring all identified medical devices are captured on local registers and authorised users are able to operate the devices safely.
- Ensure the devices are maintained in a safe and reliable condition.
- Make sure that new service developments, service changes, or increases in medical device asset numbers are communicated to the Medical Device Group and MD Team.
- Identify funding for servicing, maintenance, ad-hoc repair costs and device disposal at the point of purchase. This is to ensure that the equipment is fully funded for the lifetime of the product. The MD Team can support services by identifying costs related to maintenance.

- Ensure all equipment is suitably decontaminated following the manufacturer's specific guidelines and the Trust's Infection Prevention and Control Policy document *"Cleaning and Decontamination of Equipment, Medical Devices, and the Environment, (Including the management of blood and bodily fluid spillages)"*. Whomever is awarded the contract for the Integrated Community Equipment Loan Service (ICELS) will have responsibility for their equipment that is used (currently Mediquip).
- Act on any MHRA device alerts and bulletins as directed by the Patient Safety Team and the Weekly Alerts Review meeting.
- Ensure that all new, temporary, and permanent employees attend appropriate mandatory training and clinical educational training to receive sufficient information and instruction to identify they are competent in the safe use and operation of all medical devices within the area of work.
- Identify any further training needs via use of clinical supervision sessions and/or staff appraisals.
- Ensure that all 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, ensuring that any 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 a local level and subsequent refresher training on specific medical devices and that it is recorded locally.
- Ensure all medical devices in use within their service have an asset tag and in date service sticker affixed to each device.
- Notify the MD Team of any medical device without an asset tag or service sticker; or with an 'out of date' service sticker so that the device can be serviced and compliant for use.

4.4 Medical Devices Service Manager (MDSM) (including MDSO role)

It is the responsibility of the MDSM to:

- Ensure there is a robust data management system in place for the recording and tracking, where possible, of medical devices owned by LPT.
- Oversee lifecycle planning, including forecast costs, for replacing any equipment at the end of their product life, or if deemed beyond economical repair.

- Manage revenue and capital budgets relating to the management of medical devices.
- Oversee change management systems, including the development and implementation of local policies and procedures.
- Ensure implementation of standardisation for the acquisition of medical devices to address safety, quality, performance, lifetime costs and range rationalisation.
- Contact a Trust Clinical Safety Officer (CSO) to support a hazard review of medical devices, where applicable.
- To request the relevant documentation from the manufacturer of any medical device requiring a CSO hazard review.
- Ensure arrangements are in place to make sure that all medical devices are decommissioned and disposed of at the end of its useful life in accordance with Trust policies and current legislation.
- Lead a Medical Devices Group (MDG) that includes representation from Directorates including clinical, infection control, health & safety, moving & handling, risk management, training, procurement, patient safety, and finance staff.
- Identify, develop, and implement arrangements to ensure that annual audits are undertaken of specific medical devices held on the central asset database.
- Provide reports as specified in the MDG Terms of Reference to give assurance to relevant Trust groups that LPT owned equipment meets current legislative requirements, and manufacturer's instructions.
- Provide verification of evidence which underpins the organisation's compliance to meet the required CQC Fundamental Standards (standards 12, 15, and 17) for the safe use of medical devices.
- Review and monitor medical device service and maintenance contracts and contractors' performance through regular contract review meetings.

4.5 Medical Devices Safety Officer (MDSO) (incorporated into the MDSM role)

It is the responsibility of the MDSM to also undertake the role of the Medical Devices Safety Officer (MDSO). The MDSO is a mandated post by NHS England and is responsible for reporting adverse incidents involving medical devices to the MHRA and other official agencies.

It is the responsibility of the MDSO to:

- Manage medical device incident reporting within LPT and improve the reporting and learning from these. This includes promoting reporting on Ulysses throughout LPT so that all incidents are recorded correctly.
- Inform the CSO of any medical device incident if the device falls into the scope of the Trust CSO for a hazard review.

- Monitor the dedicated MDSO mailbox to ensure all relevant medical device alerts and field safety notices are captured and addressed.
- Provide insight and feedback to the MHRA and NHS England that may contribute to national medical device related alerts.
- Implement national medical device patient safety actions and field safety notices within LPT and ensure the correct actions are carried out.
- Report any trend data relating to medical device incidents to the MDG and Patient Safety Improvement Group (PSIG) where action plans can be agreed and implemented.
- Ensure medical devices are safe, suitable for use, and properly maintained as per CQC standards.

4.6 Infection Prevention & Control Team/Nurses

It is the responsibility of the Infection Prevention & Control (IPC) Team/Nurse to:

- Attend or send appropriate representation to the MDG 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.
- Ensure that training packages for infection prevention and control purposes reflect the requirements of medical devices.
- Support compliance in relation to HTM 01-01 Decontamination of Surgical Instruments, HTM 2010 Part 3 Sterilisation and the Pressure Equipment (Safety) Regulations 2016.

4.7 Patient Safety Team

It is the responsibility of the Patient Safety Team to:

- Assess, issue, and seek assurance from Directorates that compliance has been met for medical device related alerts.
- Onward report adverse medical device 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 monthly reports to the MDSO mailbox / MD Team relating to medical device alerts and incidents to allow the review, monitor and recommend any actions necessary to support Trust wide learning.
- Support Directorates and MD Team in identifying, documenting, and quantifying the level of risk to the trust in relation to medical device compliance.

4.8 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. Identification of training needs and record keeping is the responsibility of the staff members' line manager.

All users of medical devices must carry out the relevant pre-use/visual safety checks on the equipment prior to use to ensure the device is safe for use, and only used for its intended purpose. Visual checks must also include:

- That the device has an in-date service label, indicating its next service date.
- The device has a valid LPT asset label.
- There are no exposed wires or visual defects.
- The device has been cleaned and/or decontaminated between patient uses.

Any devices that do not have a valid in date service sticker on the device, or encounter any problems relating to repair, servicing, maintenance, calibration, or failure, must be taken out of use, and reported to the appropriate servicing and maintenance contractor. Please see the servicing & maintenance flowcharts at Appendix 8-10, and 12-18.

All staff must ensure that devices considered to be unsafe for use are clearly marked as **'do not use'**, removed from service, and safely quarantined to prevent further use. If removal of the device from use has an adverse impact on service delivery, staff should contact the MD Team to understand if surplus or loan devices are available.

Staff must escalate issues relating to insufficient quantities of medical devices to their line manager. This will enable planning for future purchasing arrangements which are reflective of the need. Where the unavailability of equipment causes harm or presents a risk of harm to patients, this should be reported on the Trust's incident reporting system *'Ulysses'*, and in line with the Trust's *"Incident Reporting and Management Policy".*

5.0 Policy Detail

5.1 Definition of a Medical Device

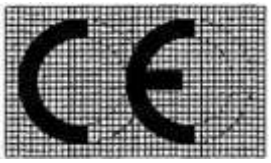
The Medicines and Healthcare Products Regulatory Agency (MHRA) defines a medical device in the Medical Devices Regulations 2002 (SI 2002 No.618 as amended), 'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, 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.

For the purposes of this policy, a Medical Device will relate to those which require ongoing maintenance or any other regulatory statutory testing or monitoring necessary for their intended use for their full lifespan.

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).



5.1.1 UKCA marking

The UKCA (UK Conformity Assessed) marking is a UK product marking used for certain goods, including medical devices, being placed on the Great Britain market (England, Wales, and Scotland). Manufacturers of medical devices can use either the UKCA marking or the CE marking on devices they place on the Great Britain market. CE marking is planned to be phased out with regards to medical devices in line with the following:

- General medical devices compliant with the EU medical devices directive (EU MDD) or EU active implantable medical devices directive (AIMDD) with a valid declaration and CE marking can be placed on the Great Britain market up until the sooner of expiry of certificate or 30 June 2028

- In vitro diagnostic medical devices (IVDs) compliant with the EU in vitro diagnostic medical devices directive (IVDD) can be placed on the Great Britain market up until the sooner of expiry of certificate or 30 June 2030, and
- General medical devices including custom-made devices, compliant with the EU medical devices regulation (EU MDR) and IVDs compliant with the EU in vitro diagnostic medical devices regulation (EU IVDR) can be placed on the Great Britain market up until 30 June 2030.

Existing medical devices purchased before the above timelines above and displaying the CE mark will remain compliant; there is no requirement to retrospectively change an existing CE Mark to the new UKCA Mark.

An image of the new UKCA mark is displayed below.

5.1.2 Custom Made Devices

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 medical practitioner, or other person authorised to write such a prescription by virtue of their professional qualification which gives under their specific characteristics as to its design.
- Intended for the sole use of a particular patient but does not include a mass-produced product which comprises a medical device and medicinal product forming a single integral product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user.

More information can be found on custom made devices on the GOV.UK website, *“Guidance on custom-made devices in Great Britain”.*

5.2 Medical Devices database

The medical devices asset databases are 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 asset databases will contain all medical equipment regardless of cost or budget for which it is paid. The databases will be maintained through the MD Team, 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.
- Planned maintenance arrangements and schedules.
- Reactive repair work details.
- Maintenance supplier information.
- Make, model and serial number.
- Last service date and due date of next service.
- Last calibration date and due date of the next calibration.

The Directorates will be responsible for notifying the MD Team of any changes to the relevant database by contacting the team via email through the central inbox (lpt.medicaldeviceteam@nhs.net). This includes new equipment purchases, equipment donated by charitable organisations, and the transfer of equipment from service.

Directorates must notify the MD Team of any medical device disposal and return this equipment to the MD Team. The assets will then be removed from the relevant database and disposed of via the correct waste stream to ensure compliance with waste & disposal legislation.

5.3 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.

5.4 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 with manufacturer’s recommendations and LPT’s

"Cleaning and Decontamination of Equipment, Medical Devices, and the Environment, (Including the management of blood and bodily fluid spillages) Policy". This device should not be reused on any other patient other than the intended to ensure it meets the definition.

Please note that 5.3 and 5.4 above do not currently form part of any database held and maintained by the MD Team.

5.5 Procurement of Medical Devices

The MD Team and LPT's Procurement Department work together to procure medical devices, goods, and services in conjunction with LPT's Directorates. The Procurement Department's main responsibilities are:

- To purchase medical device goods or services on behalf of LPT, ensuring they meet the required quality, regulations, standards, and indemnities.
- To comply with the Trust's Standing Financial Instructions (SFI) and Standing Orders (SO) and relevant EU and UK legislation.
- Ensure appropriate representation at the MDG and associated groups.
- Negotiate contracts for medical device goods and services ensuring value for money.
- 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.
- Manage a contract review process with equipment and service suppliers.
- Source products and suppliers and progress orders.
- Provide guidance and assistance to staff in the organisation wanting to purchase products and services, and onward refer to the MDSM should further advice be required.
- Support the standardisation of preferred medical devices including the acquisition of the most appropriate device following evaluation.

5.5.1 New Equipment

When receiving any new equipment or devices, it is imperative that the MD Team are advised of this to ensure and enable that the appropriate commissioning and asset labelling is completed.

The actions below need to be followed when in receipt of a new medical device. It is the responsibility of the person receiving the equipment to complete the delivery acceptance check.

- Check the equipment matches the requisition, is undamaged, is accompanied by all the necessary documentation and that it is:
  - Supplied with appropriate accessories/consumables.
  - Supplied with appropriate instructions for use.

- Declaration of Conformity (DoC) certificate.

5.5.2 Acceptance Testing / Commissioning

All reusable medical devices and equipment entering the Trust must undergo acceptance tests by the relevant contractor, as required by MHRA guidance *'Managing Medical Devices'*, before being put into use.

- Any electrical/mechanical medical devices delivered to the Trust by suppliers must be forwarded by the Directorates/Clinical Services to the MD Team, who will facilitate the acceptance testing with the relevant contractor in line with manufacturer's instructions and LPT's policies and procedures. The medical device must be appropriately configured in line with its clinical use.
- Devices and equipment may be tested prior to use by the supplier or associated representative. Where this happens, the work will be overseen by the MD Team and / or relevant contractor.
- Asset and service labels shall be attached to all items which have been through this process to indicate the date serviced and next service due, if applicable.
- All asset labelled medical equipment will be entered onto the relevant database with all information as outlined in Section 5.2 above.
- The manufacturer's instructions must be retained with the product, and accessible for instruction and training purposes.
- Any staff training needs must be identified and then acted on or escalated to the appropriate line manager.
- Staff must notify the MD Team of any new equipment purchases by contacting the central inbox (lpt.medicaldeviceteam@nhs.net). Asset labelling arrangements will be made, and the equipment added to the relevant database for planned maintenance requirements.
- Inappropriate storage of medical devices affects their subsequent safe use. The manufacturer's information and instructions both on storage conditions and shelf life must be followed.

5.5.3 Standardisation of Equipment across LPT

For the purpose of consistency, all clinical services must use and/or purchase the same standardised equipment unless there is a specific clinical requirement for an alternative.

As part of a process of standardisation LPT have in place a standard equipment list agreed via the MDG. This list will be subject to review taking into account technological and manufacturer changes.

5.5.4 Purchasing Equipment

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

When purchasing items, the following aspects will be inclusive of the process:

- Provision of ongoing servicing and maintenance arrangements.
- User manuals / technical services guides.
- Provision of user training.

Medical devices should only be purchased in collaboration with the LPT Procurement Team and MD Team.

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

5.6 Medical Equipment Loans

The following sub-sections describe the processes & procedures which underpin the trial or loan of medical equipment within LPT.

5.6.1 Medical Equipment Loans between LPT Services (Internal)

If equipment is moved from its designated location, staff must notify the MD Team via the central inbox (lpt.medicaldeviceteam@nhs.net) so its location can be updated on the relevant database.

The equipment must be appropriately cleaned and decontaminated before being loaned and when it is taken back from loan. For further guidance, please refer to the Infection, Prevention and Control document, *"Cleaning and Decontamination of Equipment, Medical Devices, and the Environment, (Including the management of blood and bodily fluid spillages) Policy".*

5.6.2 Free issues of medical equipment from suppliers

Suppliers can 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 under a consumables agreement, the offer must not be accepted until it has been approved by the MDG and checked / registered by the Procurement Department.

5.6.3 Medical Equipment Trials & Loans

Please refer to the loaning-in guidance at Appendix 21 and 22.

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, MD Team, and Patient Safety Team 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 of a medical device 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. An unapproved extension of the period of the loan or trial could constitute an agreement to purchase the equipment. Such offers must be referred to the Procurement Department before any agreement is signed.

5.6.4 Medical Equipment loaned for use to patients/carers

All LPT owned equipment that is loaned to patients / carers must be recorded by the line manager or service/team lead. They must then contact the MD Team via the MD Team inbox, so the relevant database is updated to reflect the new location of the equipment.

Before the equipment is loaned to the patient, the clinical staff should ensure:

- The device is in service date for the planned period of the loan.
- All equipment is appropriately cleaned and decontaminated prior to being loaned, and again when it is brought back under the care of LPT.
- The patient or carer has received a demonstration or training in how to use the device before it is issued. They should also sign a statement confirming that they have received and understood the written / verbal training or instructions provided.
- Accurate records of demonstration training must be retained by the service completing the loan.

Any 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 be in a format understood by the user, and cover the following:

- The name of the device.

- The operation and control of the device.
- How to check the device whilst in use and ensure it is suitable/sufficient for use.
- How to recognise a device failure or fault.
- Action to be taken in the event of a device failure or fault.
- Individuals to be contacted in an emergency/device failure situation.
- How to appropriately clean and decontaminate the device.
- How to ensure the device is serviced and/or calibrated in accordance with the manufacturer's instructions.

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

5.6.5 Community Care Pathway, Equipment Loans – Integrated Community Equipment Loan Service (ICELS)

Medequip are the current provider of community equipment. Under the terms of this contract, Medequip are responsible for equipment purchase, stock and storage management, equipment labelling, delivery and installation, the collection of equipment from patients, the decontamination of the equipment, whilst also ensuring the equipment is serviced, maintained and or calibrated in accordance with the manufacturer's instructions.

If the patient 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 5.6.2.

5.6.6 Transportation of Medical Equipment

Transportation of medical equipment must be completed in line with manufacturer's instructions, Dangerous Goods Safety Adviser (DGSA) recommendations, and Infection Prevention & Control (IPC) procedures. Any equipment that has been subjected to abnormal stresses during transport must be tested prior to use.

5.7 Medical Equipment Donations – LPT to External Body/Charity

As per guidance in the Trust document *"Disposal of Trust Equipment and Consumables Policy"*, surplus medical devices that cannot be re-used / re-cycled within LPT, or devices that can no longer be utilised in a UK healthcare environment or disposed of by re-sale, can be donated to a charitable organisation. It is the staff member's responsibility to ensure that any donation made is to a legitimate charitable organisation that is registered with the Charity Commission Service. If the charitable organisation that you choose is not registered with the Charity Commission Service, you must not donate any medical devices. Further information on the Charity Commission Service can be found via this link: www.gov.uk/find-charity-information.

A full disclaimer for any future liability in the use of the medical device/s donated must be obtained prior to donation. Please see a copy of the disclaimer form for completion at Appendix 20.

The MD Team must be notified of any donations to enable removal of the assets from the relevant database and servicing and maintenance contract. Staff can action this by contacting the MD Team via the central inbox (lpt.medicaldeviceteam@nhs.net).

5.7.1 Medical Equipment Donations – External Body/Charity to LPT

The Trust may receive requests from patients or their families/relatives/carers regarding possible donation of equipment into our wards/services.

In the event of this scenario, staff should contact the MD Team so they can ensure a thorough assessment of the equipment can take place, including aspects such as the equipment's age & condition, its suitability of use in a clinical environment, any provision for ongoing maintenance needs and how these can be managed etc.

If it is deemed that the equipment would be appropriate for use in the organisation, donation can be accepted and the same processes for Acceptance Testing / Commissioning (as detailed in Section 5.5.2 above) would apply. Please see a copy of the disclaimer form for completion at Appendix 20.

5.8 Training

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

The Line Manager should identify the equipment the staff member (e.g., substantive, bank, or locum etc.) is using and therefore any relevant training needs. It is the line manager's responsibility to ensure that their staff have undertaken the appropriate training and have recorded this in accordance with their local training log.

5.9 Maintenance & Servicing (Planned Preventative / Reactive)

All medical devices are subject to regulations for maintenance and servicing.

- Provision and Use of Work Equipment Regulations (PUWER), 1998.
- Lifting Operations and Lifting Equipment Regulations (LOLER), 1998.
- The Pressure Equipment (Safety) Regulations (PE(S)R), 2016.

Medical device servicing and maintenance contracts are in place and are actively managed by the MD Team. This includes both planned preventative and reactive maintenance, with all work undertaken by qualified service contractors. It is essential that maintenance activity, including calibration, is completed as per the equipment manufacturer's guidance. This will optimise the accuracy and efficiency of the equipment so as to prevent any adverse incidents, in particular ones that may place

patients or staff at risk of injury or harm. Asset records of all equipment, inclusive of current and next servicing dates, will be evidenced on the relevant database.

Process flowcharts for reporting reactive maintenance to the contracted service provider/s can be found at Appendix 8-10, and 12-18.

Referring to LOLER testing, staff must ensure that the device has a current LOLER inspection tag – see Appendix 11 for the current LOLER inspection tag colour. Equipment without a correct colour tag must be taken out of service and reported to the MD Team for an inspection to be carried out.

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

Medical device users are responsible for ensuring devices are in service date by checking there is an in-date service label affixed to the device. There must also be an asset label affixed to the device. If this is not visible on the device or if the service label is out of date, the medical device **must be** isolated, labelled as DO NOT USE to prevent incorrect use, and reported to the contracted servicing and maintenance provider. Example images of labelling used can be found in Appendix 24.

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 be mechanically and electrically safe, and properly decontaminated and carry no risk of causing infection. For further guidance, please refer to the Trust's Infection, Prevention and Control document, *"Cleaning and Decontamination of Equipment, Medical Devices, and the Environment, (Including the management of blood and bodily fluid spillages) Policy".*

The Declaration of Contamination Status form can be found at Appendix 7 and must be completed by the device user/s prior to any servicing or maintenance completed on the device.

5.9.1 Replacement Equipment

A repair may not always be possible and therefore replacement of the equipment may need to be considered. If any of the following criteria apply, the device is no longer serviceable:

- End of life cycle / damaged beyond economic repair.
- Unreliable (check service history with MD Team).
- Clinically or technically obsolete/no longer supported by the manufacturer.
- Spare parts are no longer available.
- More cost effective or clinically effective devices have become available.
- Technological advancement / change to LPT clinical practice.

All decisions to purchase new or replacement devices must take into account all points identified in Section 5.5 along with the lifecycle process in general of a medical device and must be in consultation with the Procurement Team and the MDSM.

If the equipment purchased is over £5,000 and funded from a capital budget, an asset addition form will need to be completed by the person raising the order. In addition, staff should ensure that the MD team are notified of any new purchases by contacting the team through the central inbox (lpt.medicaldeviceteam@nhs.net). This will ensure that the items can be asset labelled and added to the relevant database for ongoing planned maintenance purposes.

5.9.2 Disposal of Medical Devices

The medical devices used as part of our clinical activities are subject to the disposal routes below. The MD Team will be able to provide you with advice and support should it be required.

Prior to disposal staff must consider if the device can be:

- Re-used / Recycled.
- Appropriate for re-sale.
- Donated to a legitimate charitable organisation.
- Condemned items disposed of via an appropriate waste stream.

All medical device disposals must be processed and disposed of by the MD Team. If staff have a device that is broken, end of life cycle, or damaged beyond repair, this equipment must be removed from use and returned to the MD Team for decommissioning and disposal. This will ensure that the device is removed from the relevant database and servicing and maintenance contract. Further guidance can be found in Appendix 19, Disposal of Medical Devices.

All returned equipment must be cleaned and accompanied by a decontamination certificate (Appendix 7). If the devices are too large to be returned via internal post, please inform the MD Team and appropriate arrangements will be made for collection.

**** Services must not dispose of any medical device themselves. ****

5.10 Cleaning & 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 between patients, before 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 Trust's Infection, Prevention and Control document, *"Cleaning and Decontamination of Equipment, Medical Devices, and the Environment, (Including the management of blood and bodily fluid spillages) 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. A copy of this can be found in the above-mentioned IPC policy, and at Appendix 7.

5.10.1 Cleaning Procedures

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 manufacturer's instructions on cleaning the medical device. Information on both the cleaning and decontamination requirements of the device will have been obtained prior to purchase using the Pre-Acquisition Questionnaire (PAQ) on infection control issues. Cleaning procedures can also be found in the user guide for each medical device.

Further advice should be sought if required from the IPC Team / Nurse, or the MD Team.

5.11 Incident Reporting & Near Misses

Any incidents or 'near misses' involving the use of medical devices must be e-IRF reported in line with Trust's Incident Reporting Policy, *"Incident Reporting and Management Policy"*. This would encompass all adverse incidents pertaining to medical devices, including the theft or loss of a medical device.

If there is an incident where a medical device may be considered to have played a part in the circumstances surrounding the incident, this equipment must be quarantined until it is confirmed safe to use by the MD Team, or the appropriate external contractor employed to maintain LPT's equipment.

If the incident falls within the Medicines and Healthcare Products Regulatory Agency and Adverse Incident Centre (MHRA) definition it must be reported via the Yellow Card scheme on the MHRA website by the Patient Safety Team. Manufacturer recall of a device will take precedence over all other considerations and will happen in the event of a defect, as detailed LPT's *"Alert Management Policy"*.

5.12 Monitoring & Audit

The MDG will report to the Estates and Medical Equipment Group (EMEG) and the Patient Safety Improvement Group (PSIG) as defined in the Terms of Reference for the group.

The MDG will monitor the implementation of this policy and medical device management by:

- Providing reports to the EMEG, PSIG and other governance groups as required (monthly, 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 MDG on a bi-monthly basis.
- Monitor the levels of medical device compliance in relation to planned maintenance.

The policy will also be audited by means of an annual review of the centrally held medical devices database. In addition to this:

- All clinical services will keep an up-to-date register/inventory of medical devices in use, with staff names detailed where applicable.
- All clinical areas will ensure that training required for staff authorised to use the equipment will be recorded locally.

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

5.12.1 Review

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

5.13 Legislation

This section gives examples of legislation that may apply to LPT and Medical Devices; it is not an exhaustive list:

- Health and Safety at Work etc. Act (HASAWA) 1974
- In Vitro Diagnostic Medical Devices Regulations (IVDR)
- Ionising Radiation (Medical Exposures) Regulations 2018 (IR(ME)R)
- Ionising Radiations Regulations 2017 (IRR17)
- Management of Health and Safety at Work Regulations 1999
- Medical Devices Regulations 2002 (SI 2002 No 618, as amended)
- Sale and Supply of Goods Act 1994 (Chapter 35)
- The Electrical Equipment (Safety) Regulations 2016 (as amended)
- The General Product Safety Regulations 2005
- The Health and Social Care Act 2008 (Regulated Activities) Regulations
- 2014. Regulation 15, Premises and Equipment
- The Lifting Operations and Lifting Equipment Regulations 1998 (LOLER)

- The Pressure Equipment (Safety) Regulations 2016 (PE(S)R)
- The Provision and Use of Work Equipment Regulations 1998 (PUWER)
- The Waste Electrical and Electronic Equipment Regulations 2013 (as amended)

5.14 Useful Websites

- Department of Health - www.dh.gov.uk
- MHRA - www.mhra.gov.uk
- CQC - www.cqc.org.uk

6.0 Monitoring Compliance and Effectiveness

Page/Section	Minimum Requirements to monitor	Method for Monitoring	Responsible Individual /Group	Frequency of monitoring
Page 16, Section 5.2	How the organisation includes all items of diagnostic and therapeutic equipment on an inventory	Central asset register of equipment. Annual verification of assets on register. Perpetual updating of asset register.	Medical Devices Group	Annual
Page 22-25, Section 5.9	How reusable diagnostic and therapeutic equipment is maintained.	Routine maintenance procedures and planned preventative maintenance carried out by suitably trained and qualified technicians.	Medical Devices Group	Annual
	How reusable diagnostic and therapeutic equipment is repaired.	Carried out by suitably trained and qualified technicians as required.	Medical Devices Group	Annual

7.0 Fraud, Bribery and Corruption consideration

The Trust has a zero-tolerance approach to fraud, bribery, and corruption in all areas of our work and it is important that this is reflected through all policies and procedures to mitigate these risks.

Fraud relates to a dishonest representation, failure to disclose information or abuse of position in order to make a gain or cause a loss. Bribery involves the giving or receiving of gifts or money in return for improper performance. Corruption relates to dishonest or fraudulent conduct by those in power.

Any procedure incurring costs or fees or involving the procurement or provision of goods or service, may be susceptible to fraud, bribery, or corruption so provision should be made within the policy to safeguard against these.

If there is a potential that the policy being written, amended or updated controls a procedure for which there is a potential of fraud, bribery, or corruption to occur you should contact the Trusts Local Counter Fraud Specialist (LCFS) for assistance.

Appendix 1 Training Needs Analysis

Training topic:	Medical Devices Management	
Type of training: (see study leave policy)	Not Required	
Directorate to which the training is applicable:	N/A	
Staff groups who require the training:	N/A	
Regularity of Update requirement:	N/A	
Who is responsible for delivery of this training?	N/A	
Have resources been identified?	N/A	
Has a training plan been agreed?	N/A	
Where will completion of this training be recorded?	N/A	
How is this training going to be monitored?	N/A	
Signed by Learning and Development Approval name and date		Date:

Appendix 2 The NHS Constitution

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

Appendix 3 Due Regard Screening Template

Section 1	
Name of activity/proposal	Medical Devices Management
Date Screening commenced	June 2024
Directorate / Service carrying out the assessment	Enabling, Estates & Facilities, Medical Devices Team
Name and role of person undertaking this Due Regard (Equality Analysis)	Mark Jones, Medical Devices Service Manager
Give an overview of the aims, objectives, and purpose of the proposal:	
AIMS: The aim of this policy is to describe the process for the management of maintenance and repair of medical devices.	
OBJECTIVES: To provide clear processes and procedures for the management of medical devices across the Trust.	

Section 2	
Protected Characteristic	If the proposal/s have a positive or negative impact please give brief details
Age	Policy covers all age groups for who the Trust provides services for
Disability	No negative impact
Gender reassignment	No negative impact
Marriage & Civil Partnership	No negative impact
Pregnancy & Maternity	No negative impact
Race	No negative impact
Religion and Belief	No negative impact
Sex	No negative impact
Sexual Orientation	No negative impact
Other equality groups?	No negative impact

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 X**
High risk: Complete a full EIA starting click here to proceed to Part B	Low risk: Go to Section 4.

Section 4			
If this proposal is low risk please give evidence or justification for how you reached this decision:			
This policy covers all services where medical devices are used within the delivery of patient care.			
Signed by reviewer/assessor	Mark Jones	Date	01/10/2024
Sign off that this proposal is low risk and does not require a full Equality Analysis			
Head of Service Signed		Date	

Appendix 4 Data Privacy Impact Assessment Screening

Data Privacy impact assessment (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet Individual's expectations of privacy. The following screening questions will help the Trust determine if there are any privacy issues associated with the implementation of the Policy. Answering 'yes' to any of these questions is an indication that a DPIA may be a useful exercise. An explanation for the answers will assist with the determination as to whether a full DPIA is required which will require senior management support, at this stage the Head of Data Privacy must be involved.		
Name of Document:	**Medical Devices Policy**	
Completed by:	**Mark Jones**	
Job title	**Medical Devices Services Manager**	**Date: 01/10/2024**
Screening Questions	**Yes / No**	**Explanatory Note**
1. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document.	No	
2. Will the process described in the document compel individuals to provide information about them? This is information in excess of what is required to carry out the process described within the document.	No	
3. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document?	No	
4. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?	No	
5. Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics.	No	
6. Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them?	No	

7. As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private.	No	
8. Will the process require you to contact individuals in ways which they may find intrusive?	No	
If the answer to any of these questions is 'Yes' please contact the Data Privacy Team via Lpt-dataprivacy@leicspart.secure.nhs.uk In this case, ratification of a procedural document will not take place until review by the Head of Data Privacy.		
Data Privacy approval name:	**N/A**	
Date of approval	**N/A**	

Acknowledgement: This is based on the work of Princess Alexandra Hospital NHS Trust

Appendix 5 Common Categories of Medical Devices

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, e.g., 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, e.g., 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
Medical grade extension lead

Appendix 6 Medical Device Maintenance – Current Maintenance Providers by Equipment Type

Existing Maintenance Provider	Equipment Maintained & Calibrated
Avensys Medical UK Ltd **T: 01562 745858**	Reactive & Planned Maintenance for all General Medical Equipment / Devices, (e.g., BP Monitors, Sphygmomanometers, Thermometers, Pulse Oximeters, Nebulisers, Oxygen Concentrators, ECG Machines, Syringe Drivers, Vital Signs Monitors, Infusion Pumps, Defibrillators, Suction Units, Wheelchairs, Rotundas, Commodes, Washer Disinfectors, Sterilisers, Patient Lifting Equipment, Patient Weighing Equipment, Drug Fridges).
Medstrom Healthcare Ltd **T: 0843 506 0531** **E: ops@medstrom.co.uk**	Profiling Beds Mattresses / Mattress Pumps Examination Tables / Clinic Couches / Plinths
Verathon Medical **E: customercareuk@verathon.com**	Bladder Scanners (BVI9400 / Prime Plus)
UHL Medical Physics Department **T: 0116 2584657**	Diana Children's Therapy Service – Equipment ECT Suite – Equipment Audiology Service – Equipment CHS Wards – Oxygen Gas Regulators
Medi UK Ltd **T: 01432 373 500** **E: abpi@mediuk.co.uk**	Mesi ABPI Doppler
A. Menarini Diagnostics Ltd **T: 0800 243667** **E: myglucomen@menarinidiag.co.uk**	Blood Glucose Meters
Roche Diagnostics **T: 0808 100 1920 (option 2, option2)** **E: burgesshill.tsgpm@roche.com**	INR Machines (CoaguChek Pro II)
Vivid.Care **T: 01423 799960** **E: aftersales@vivid.care**	Raizer II Chairs

Appendix 7 Declaration of Decontamination Status – Form

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:

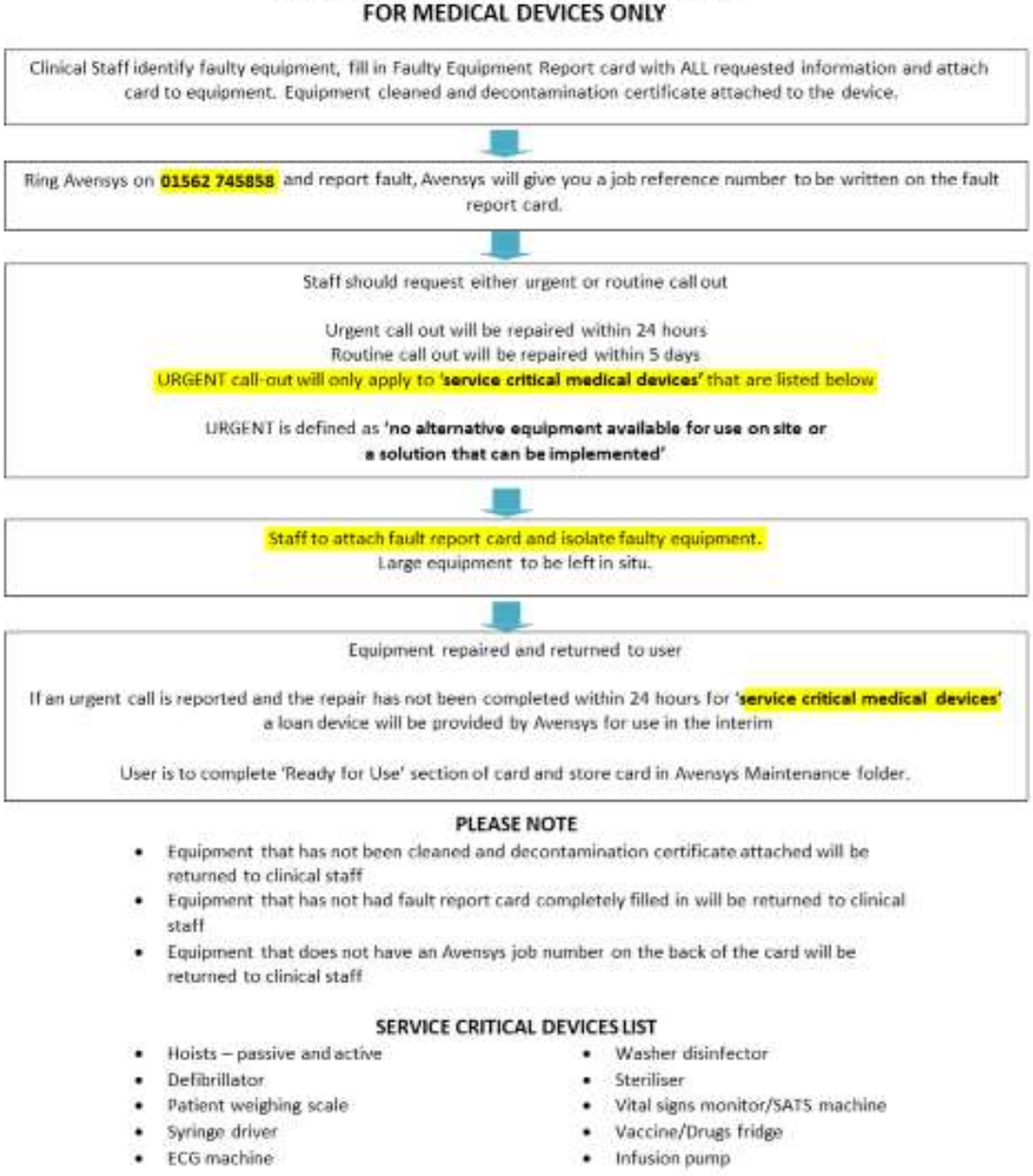
I, the undersigned, declare that I have taken all reasonable steps to ensure the accuracy of the above information in accordance with HSG (93) 26.

SIGNED: ***PRINT NAME:***

POSITION: ***DEPARTMENT:***

DATE: ***TEL NO:***

Appendix 8 Avensys UK Ltd – Equipment Fault Reporting Procedure



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.

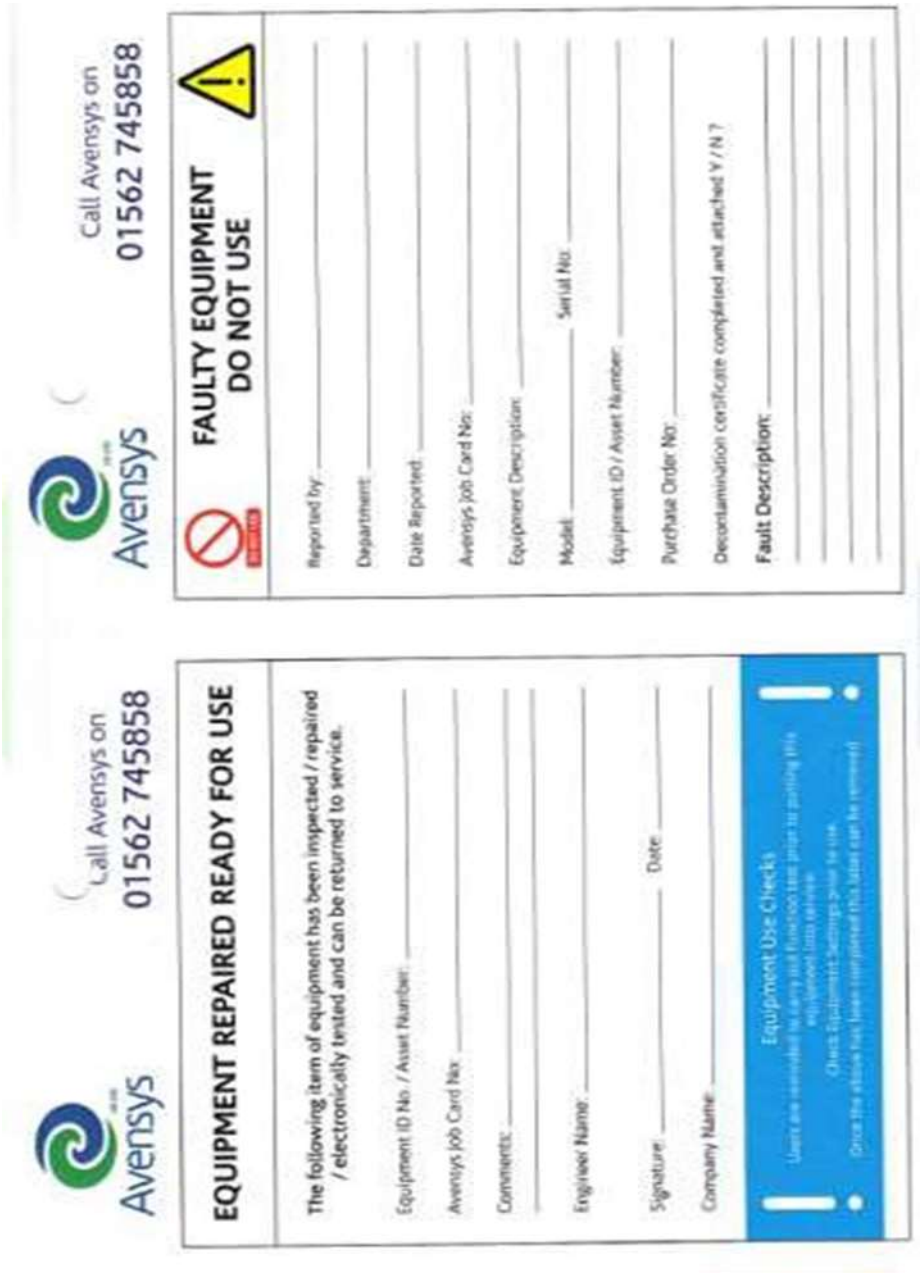
PLEASE NOTE

- 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

Appendix 9 Avensys UK Ltd – Equipment Fault Report Card



Appendix 10 Avensys UK Ltd – Internal Post Process, Medical Device Maintenance

INTERNAL POST PROCESS FOR MEDICAL DEVICE MAINTENANCE, CALIBRATION, OR REPAIR

From **January 2023** medical devices that require servicing, calibration, maintenance, or repair can be sent to Avensys at their workshop located at:

Unit 2, Meridian South, Meridian Business Park - 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, LPT MEDICAL DEVICES TEAM, UNIT 2, MERIDIAN SOUTH, MERIDIAN BUSINESS PARK

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
- 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 LPT's Medical Devices Team:
E: lpt.medicaldeviceteam@nhs.net

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 - (£71.50 minimum charge incurred).

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

Appendix 11 LOLER (1998) Testing, Requirements

Leicestershire Partnership NHS Trust

KNOW YOUR LOLER COLOUR

LOLER EXAMINATION REQUIREMENTS FOR LPT OWNED PATIENT LIFTING EQUIPMENT

As an organisation we are required to undertake a thorough examination of equipment and accessories used for lifting people. This is to comply with the Lifting Operations and Lifting Equipment Regulations 1998 (LOLER).

The requirement is to undertake an examination every 6 months.

This includes LPT owned equipment, such as mobile and fixed ceiling track hoists (including accessory spreader bars) stand aids, hoisting shower chairs and any accessories such as fabric non-disposable slings. This is undertaken by an external supplier on our behalf.

This does not include the inpatient Oxford Disposable slings, or In-Situ slings as these are disposed of within 6 months

The system in place for identifying that a piece of equipment has passed its LOLER examination is a coloured cable tie. See pictures below as examples of the coloured cable ties used

The coloured cable tie denotes that the equipment has passed its LOLER examination and when the inspection has taken place. Below is a table that indicates the period of inspections and the corresponding coloured cable tie.

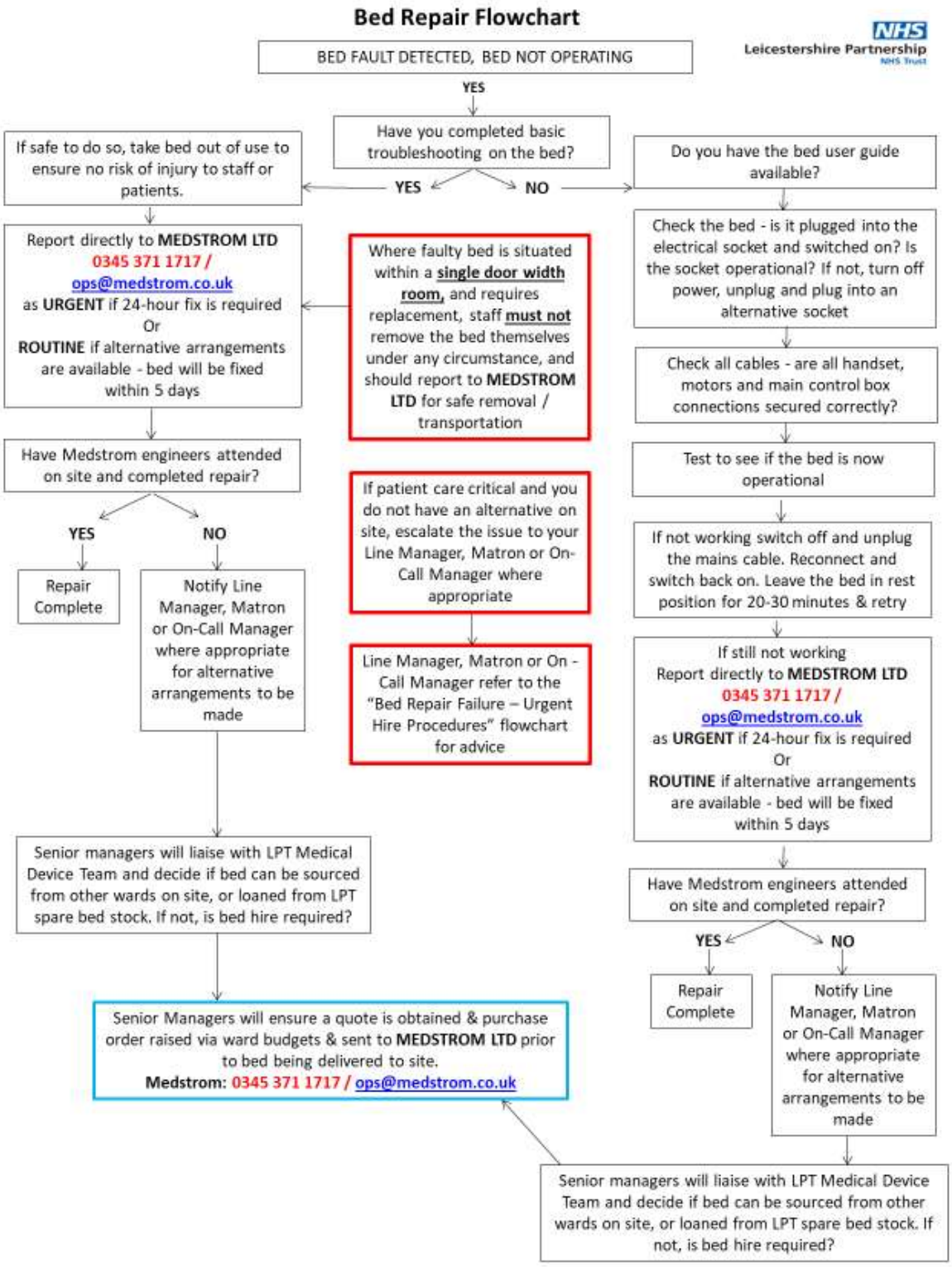
Period of examination	Colour of Cable Tie
April 2024 – October 2024	YELLOW
October 2024 – April 2025	GREEN
April 2025 – October 2025	BLUE
October 2025 – April 2026	RED
April 2026 – October 2026	YELLOW

If the equipment does not have the appropriate colour for the examination period, it should be withdrawn from the service until the examination is undertaken. Any non-compliance with this guidance must be reported through the Trusts incident reporting system.

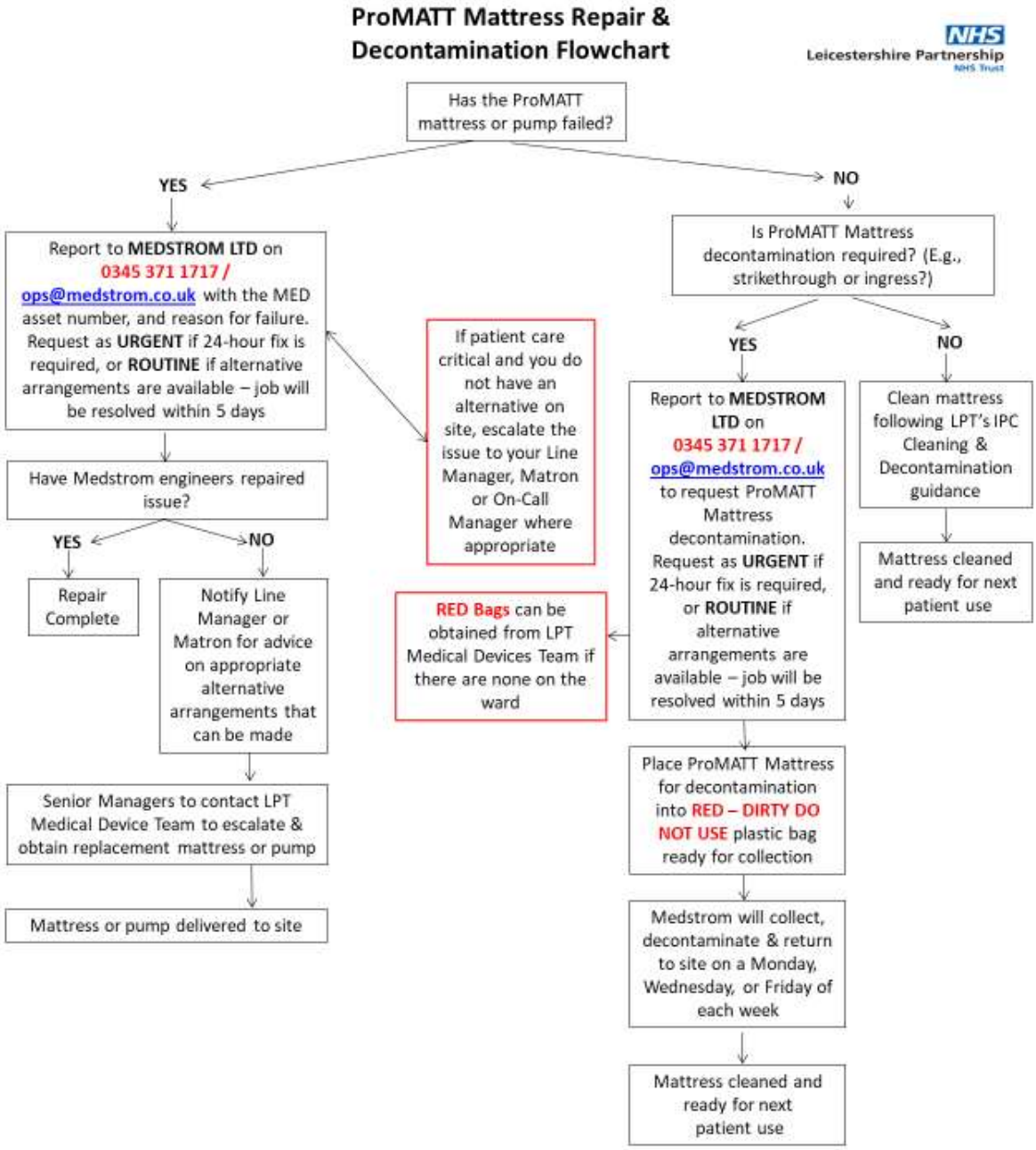
Any queries regarding examination are to be directed to:
Medical Devices Team email lpt.medicaldeviceteam@nhs.net
Moving and Handling Advisor ☎ 07767 006343 mark.dearden@nhs.net

PLEASE NOTE THAT THIS DOES NOT REPLACE OUR INDIVIDUAL RESPONSIBILITY OF INSPECTING A PIECE OF EQUIPMENT PRIOR TO ITS USE.

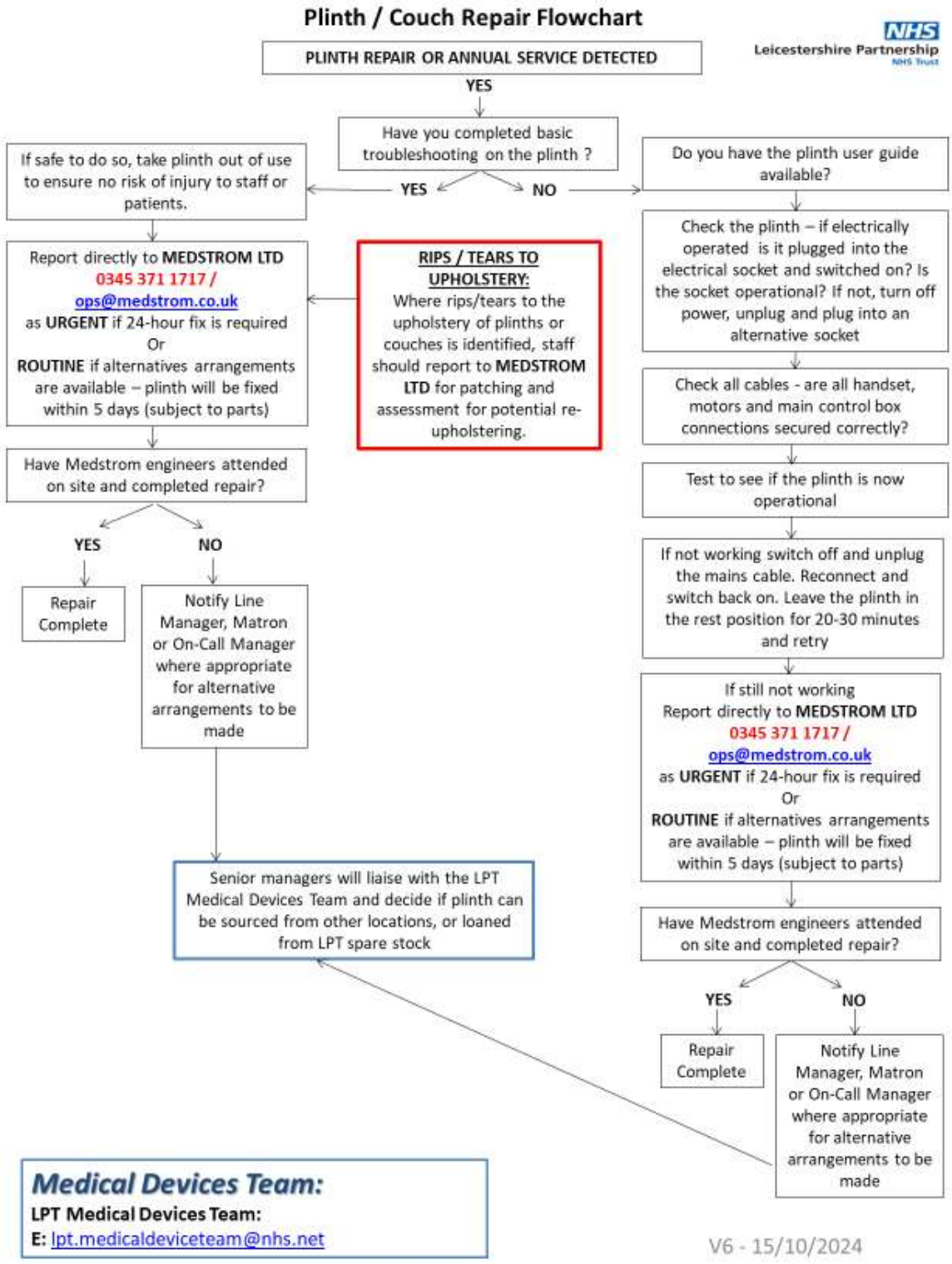
Appendix 12 Medstrom Healthcare Ltd – Profiling Bed Repair / Reporting Process



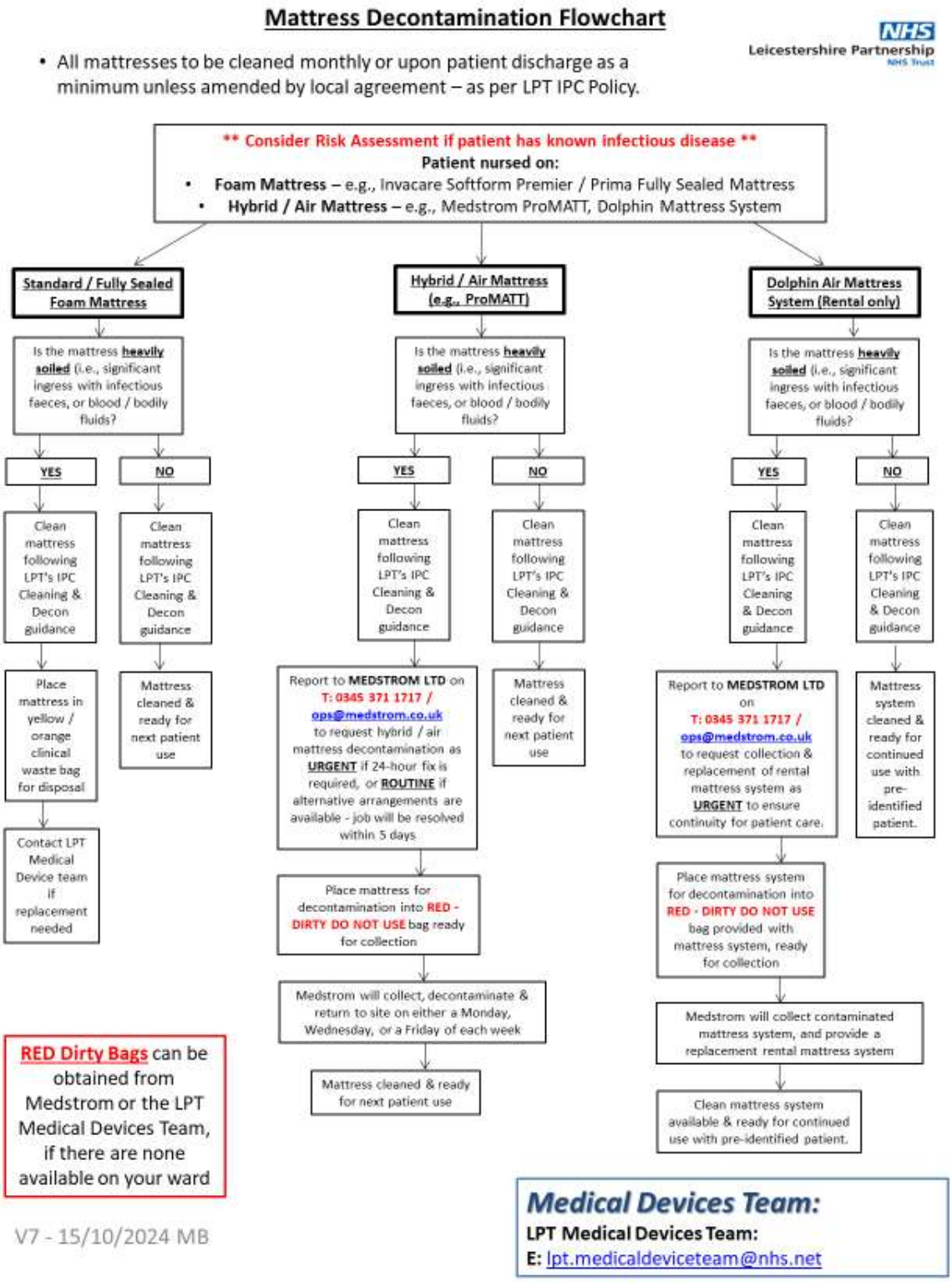
Appendix 13 Medstrom Healthcare Ltd – ProMatt Mattress Repair & Decontamination Flowchart



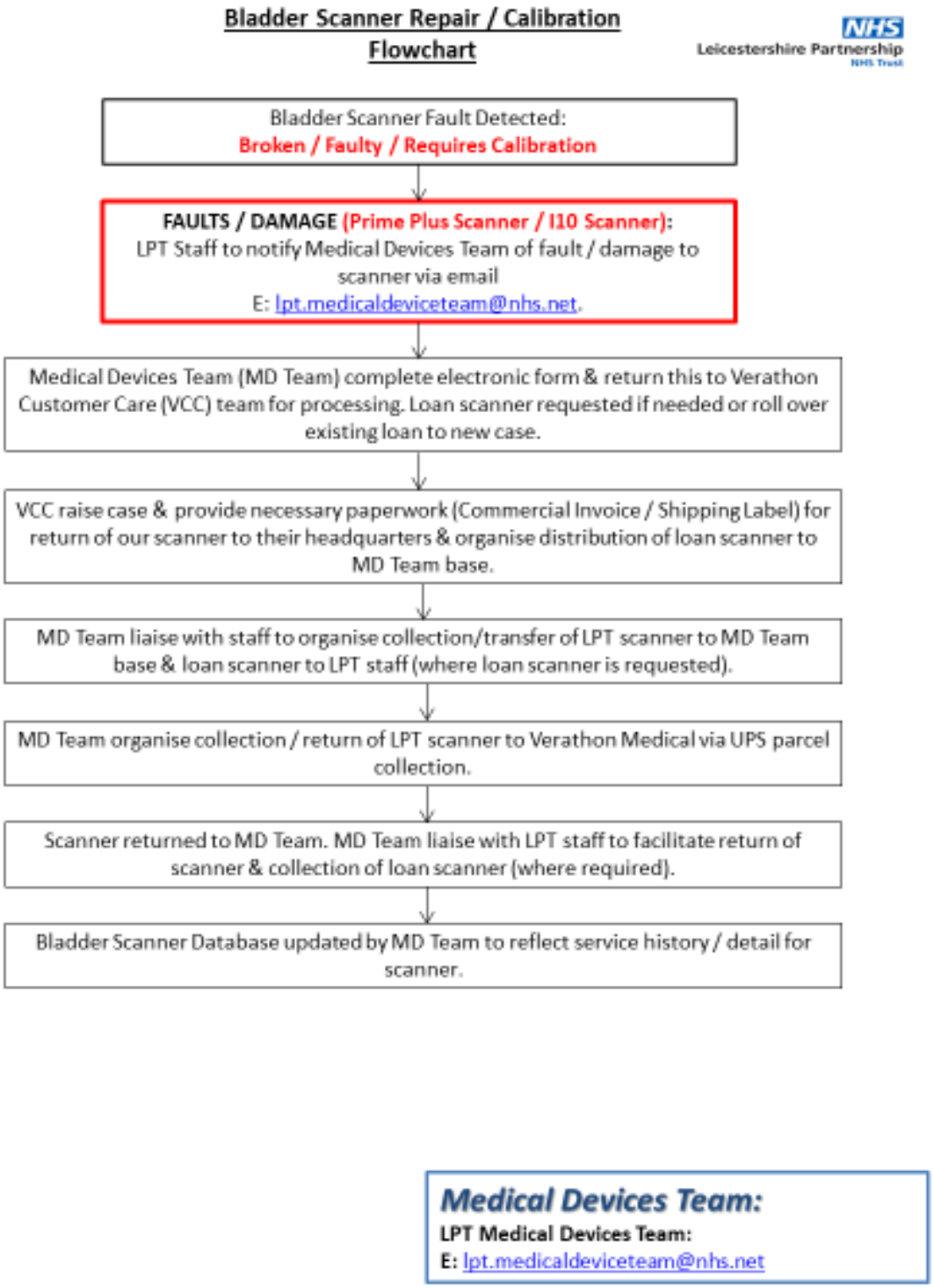
Appendix 14 Medstrom Healthcare Ltd – Examination Plinth & Couch Repair Flowchart



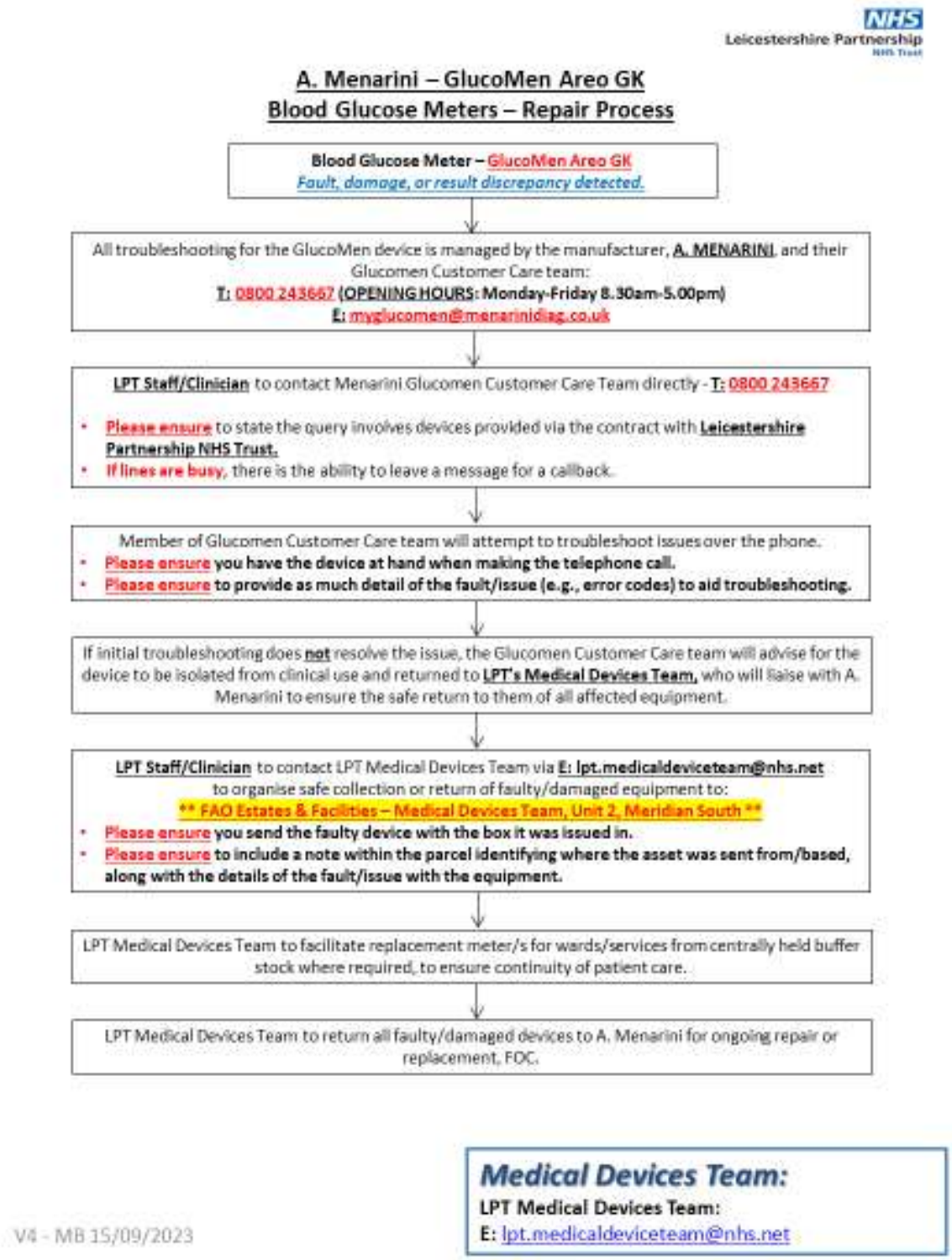
Appendix 15 Medstrom Healthcare Ltd – Mattress Decontamination Flowchart



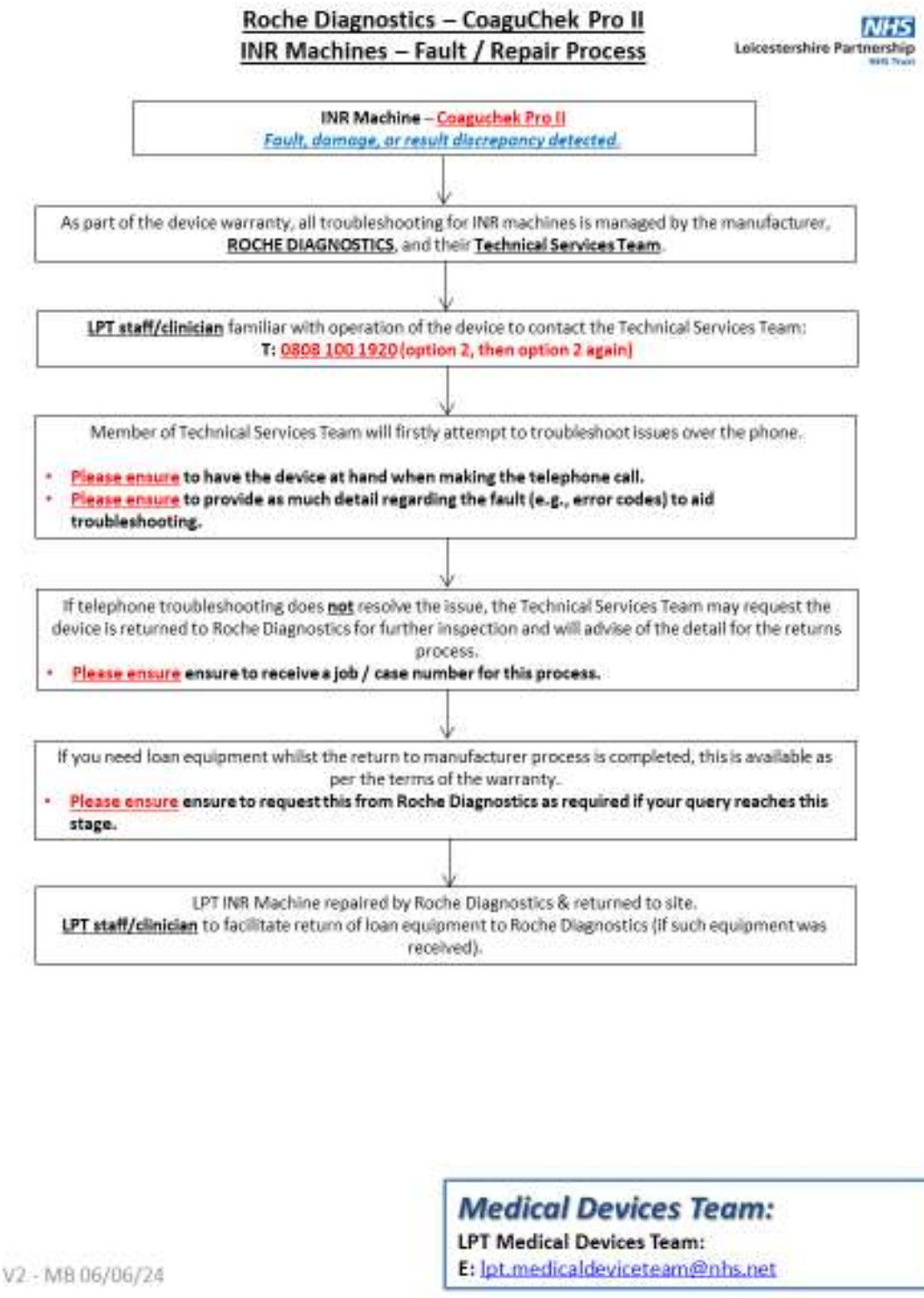
Appendix 16 Verathon Medical Ltd - Bladder Scanners, Repair / Calibration Process



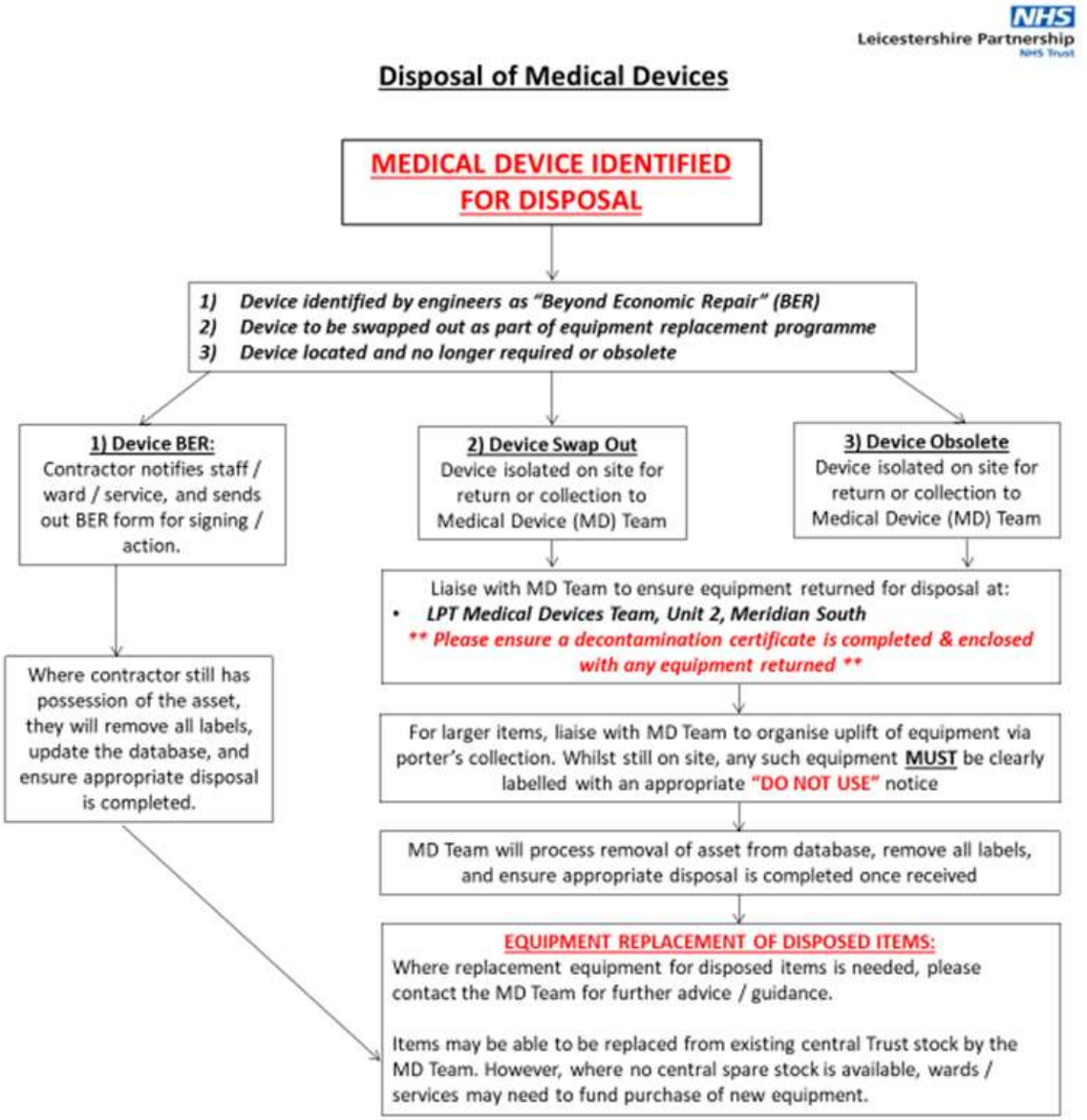
Appendix 17 A. Menarini – Blood Glucose Meters, Repair Process



Appendix 18 Roche Diagnostics – INR Machines, Repair Process



Appendix 19 Disposal of Medical Devices Flowchart



Medical Devices Team:
LPT Medical Devices Team:
E: lpt.medicaldeviceteam@nhs.net

Appendix 20 Medical Devices - Disclaimer / Donation Form

Leicestershire Partnership NHS Trust

DONATION OF SURPLUS MEDICAL / NON-MEDICAL EQUIPMENT, FURNITURE, OR CONSUMABLES

From: ***XXX***

To: ***XXX***

DISCLAIMER:

XXX is donating the goods as listed below to XXX. We therefore discharge all legal responsibility and accountability for the future use of the equipment, its maintenance and upkeep, and any training for its correct use.

List of Equipment / Goods

-

I, XXX, accept and am fully aware of the condition of said item and as such, will absolve XXX of any responsibility whatsoever concerning the item as detailed above:

SIGNED:

PRINT:

DATE:

SIGNED:

PRINT:

ON BEHALF OF:

DATE:

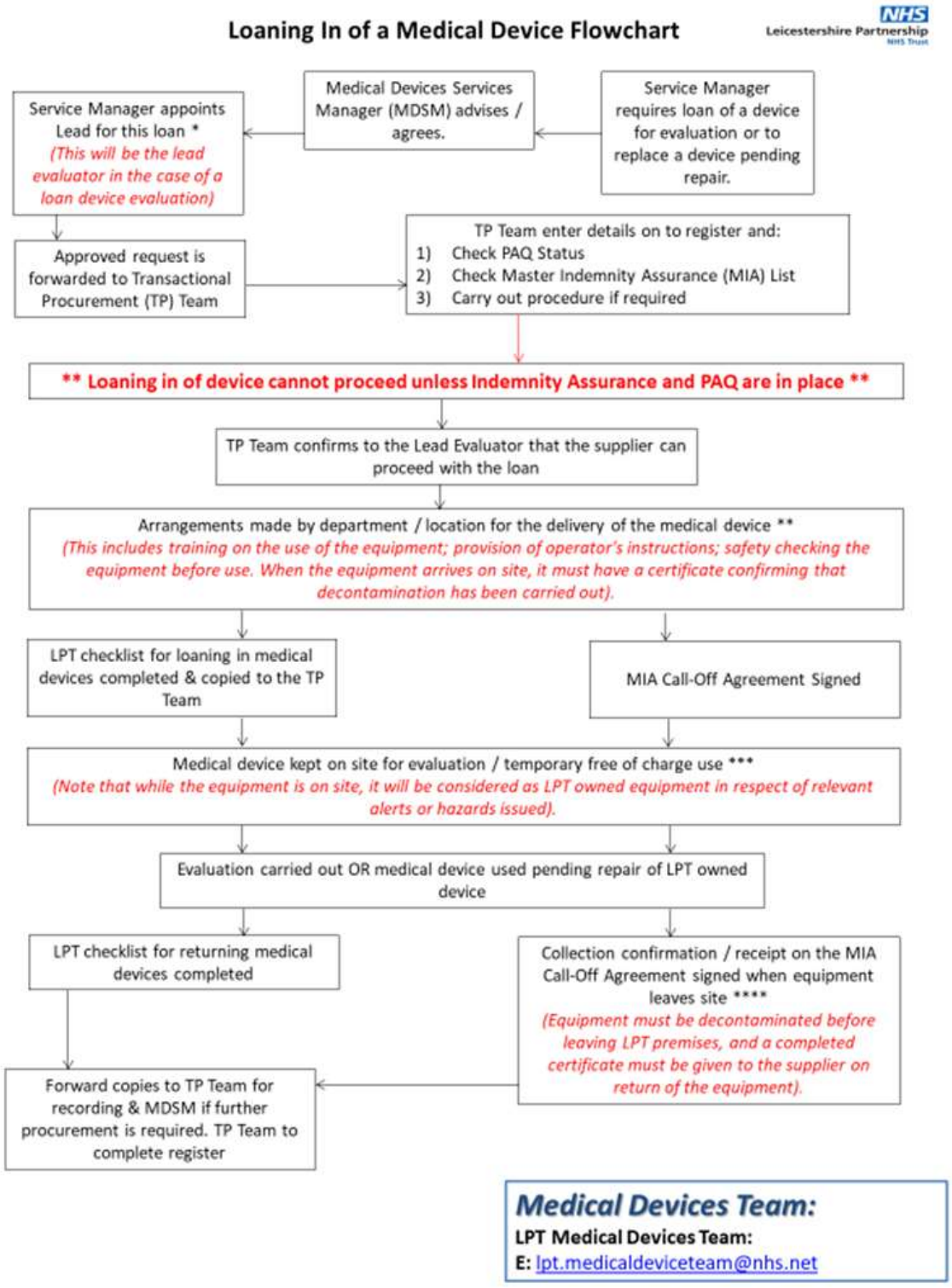
Please return all forms to:

Mark Jones, Medical Devices Team, Leicestershire Partnership NHS Trust, Unit 2, Meridian South, Leicester, LE19 1WY.

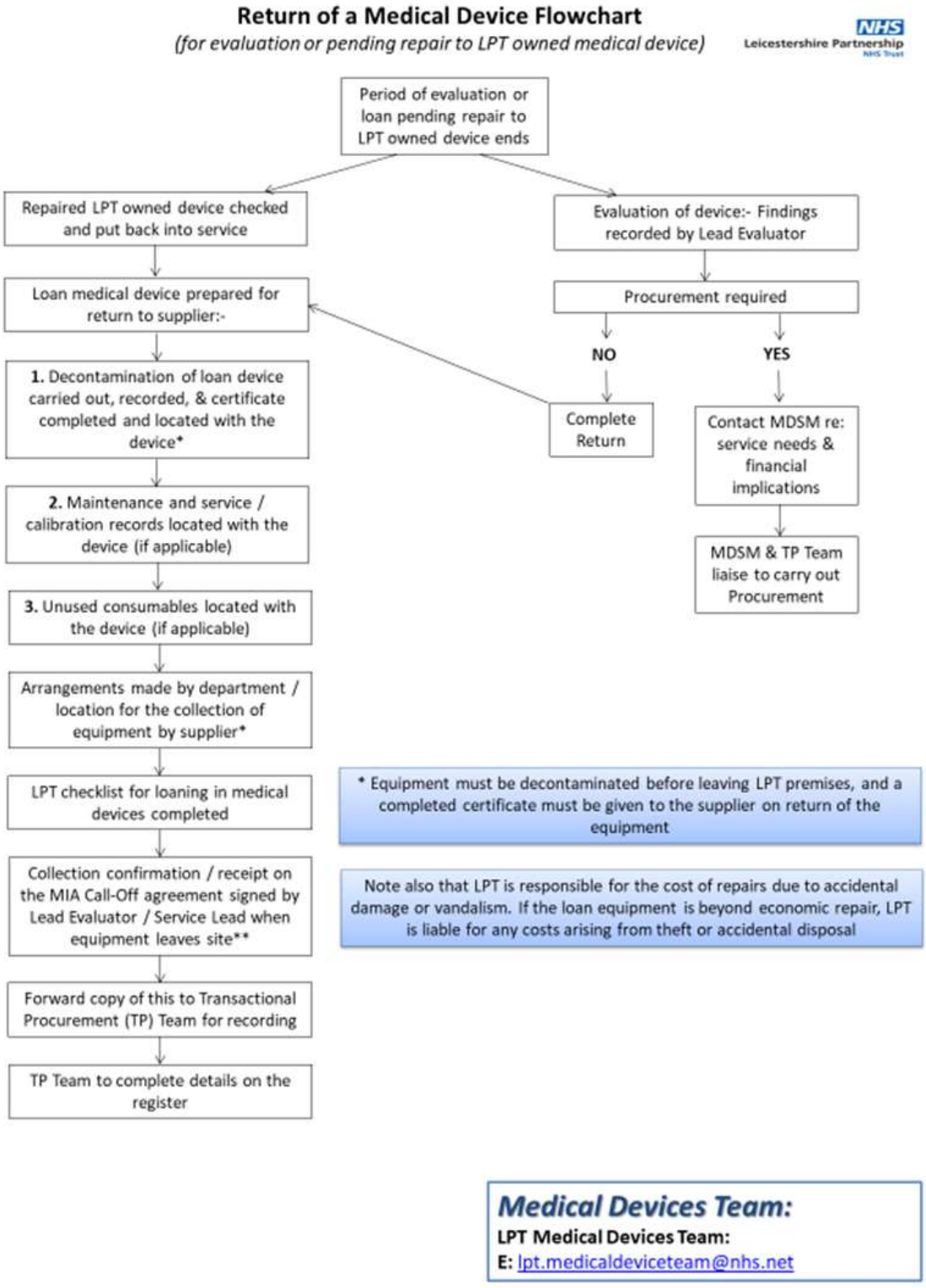
T: 07917 393341

mark.jones112@nhs.net

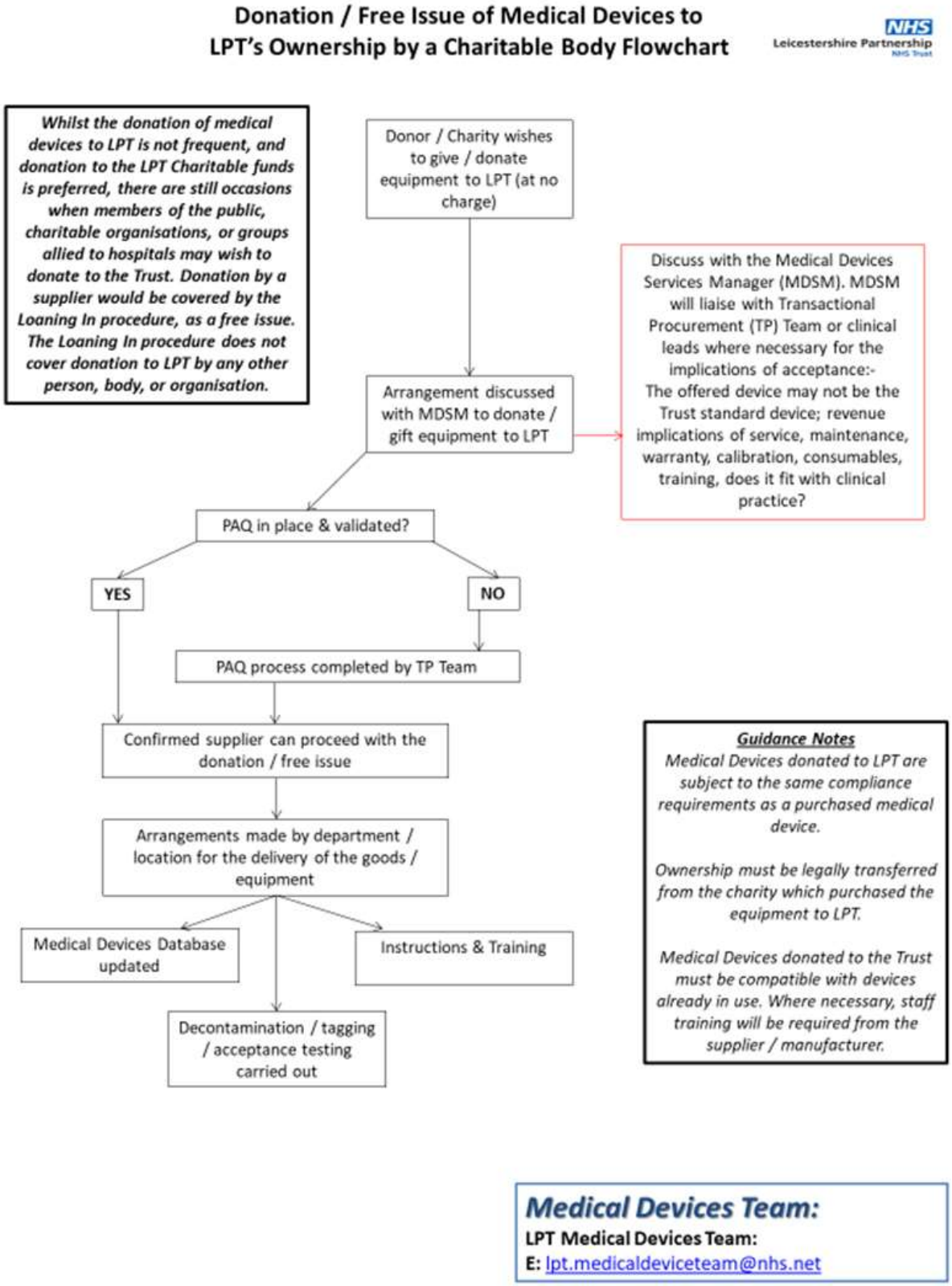
Appendix 21 Medical Devices – Loaning In



Appendix 22 Medical Devices – Return of a Loaned Medical Device



Appendix 23 Medical Devices – Donation & Gifting



Medical Devices Team:
LPT Medical Devices Team:
E: lpt.medicaldeviceteam@nhs.net

Appendix 24 Medical Devices - Asset / Service Labelling Images

LPT Asset Label:

UHL Medical Physics Asset Label:

UHL Medical Physics Service Label:

Avensys Service Label:

Mesi Doppler Service Label:

Arjo Service Label (e.g., Patient Lifting equipment)

Medstrom Asset Label:

Medstrom Service Label:

Raizer II Chairs Service Label: