County Durham and Darlington NHS Foundation Trust

POLICY DOCUMENT CONTROL SHEET

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Final Approval

Executive Sponsor's Signature:	
Name & Job title of Executive Sponsor	Jeremy Cundall, Executive Medical Director
Master copy held at:	Corporate Records Office, Trust Headquarters, Darlington Memorial Hospital

Previously known as POL/NG/0009

VERSION CONTROL TABLE

Date of Issue	Version Number	Status
July 2003	1.0	Superseded
May 2005	2.0	Superseded
November 2007	3.0	Draft
November 2007	3.1	Superseded
November 2009	3.2	Superseded
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June 2012	3.6	Superseded
May 2013	3.7	Superseded
Feb 2016	4.0	Superseded
June 2017	4.1	Superseded
Jan 2019	4.2	Approved

TABLE OF REVISIONS

Date	Section	Revision	Author
May 2005		General revision to update new terminology, and add in introduction of medical devices Policy/Guidelines & Resource Files, and reference to a separate Training & Competencies Policy for Medical Devices	Sandra Ross
Nov 2007		General revision to meet requirements of new MHRA Device Bulletin DB2006 (05) Guidance for healthcare and social service organisations (which replaces DB98 (01). To also include a section on 'Monitoring'.	Sandra Ross/Steve Morley
Nov 2007	18	Section added in on IT	Sandra Ross
Nov 2009		General revision to update titles and terminology.	Mike Roberts
Jan 2011		General revision to update titles together with relevant changes to integrate Community Health Services requirements	Mike Roberts
Sep 2011		General update	Mike Roberts/ Rhona Beecham
Jan 2012		General update against procedure for policies	Mike Roberts/ Rhona Beecham
Jun 2012		General update	Mike Roberts /Rhona Beecham
May 2013		Addition of flow charts and update to monitoring table/terms of reference of Medical Devices Group	Mike Roberts/ Rhona Beecham
Feb 2016		Overall policy revision and update based on new MHRA guidance HS/PSA/D/2014/006, Managing Medical Devices (2015)	Rhona Beecham
Jun 2017		Minor Review to reflect the change from CDDFT in-house services to CDD Services, update re single-use devices, trial procedure. Transfer to new policy ref: POL/EF/CLIN.E/0002 from POL/NG/0009.	Rhona Beecham

Jan 2019		Minor update with clarification around device lifecycle, maintenance as recommended following external audit.	Rhona Beecham

This Policy/Procedure/Guideline has been reviewed and updated to comply with the General Data Protection Regulations (May 2018)

CONTENTS

1 INTRODUCTION

The Medicines and Health Care Products Regulatory Agency (MHRA) is an executive agency of the Department of Health. It has responsibility for ensuring the safety and quality of all medical devices used in the United Kingdom.

Medical devices and equipment are used every day to support the care and treatment of patients or clients. To ensure the risks associated with the use of medical devices are minimised or eliminated, it is important that the Trust has a policy and implements systems which address:

- responsibilities in relation to medical device management
- decontamination
- the equipment life cycle (including; selection, acquisition, acceptance, maintenance, repair, monitoring, traceability and disposal/replacement) of all medical devices
- risk management include adverse incident reporting and actions required on MHRA's medical device alerts and manufacturers' field safety notices
- training and access to manufacturer's instructions
- records, including device inventory
- equipment deployment, tracking and utilisation
- equipment financing

This policy should be regularly reviewed and all Trust staff that use medical devices must ensure that whenever a medical device is used it is:

- suitable for its intended purpose
- used in line with manufacturer's instructions
- maintained in a safe and reliable condition, with maintenance up-to-date
- is traceable, where possible
- disposed of appropriately at the end of its useful life

See some examples of Medical Devices in the Table below: *(MHRA 2015)*

Function	Examples
Diagnosis or treatment of disease	Diagnostic laboratory device, X-ray machines, magnetic resonance imaging scanners, vascular catheters, dressings, surgical instruments, syringes, hip replacement implants, standalone software for diagnosis
Monitoring of patients	ECG, pulse oximeter
Critical Care	Infant incubators, blood-gas analysers, defibrillators, ventilators, vascular stents
Improving function and independence of people with physical impairments	Hoists, orthotic and prosthetic appliances, pressure care devices, walking aids, wheelchairs
Community-based healthcare	Dressings, domiciliary oxygen therapy systems, urine drainage systems

Emergency Services (ambulances)	Stretchers, trolleys, defibrillators

2 PURPOSE

2.1 Policy Objectives

This policy has the following objectives:

- To identify clear lines of accountability within the Trust for medical device and equipment management.
- To provide and communicate a framework for the safe acquisition and use of medical devices and equipment which reflects national guidance from: MHRA, NHS England, Care Quality Commission Standards.
- To put in place a process for introducing new and/or trial medical devices

3 SCOPE

This Policy applies to all Trust staff that comes into contact with medical devices and clinical equipment. It also applies to external service providers, such as CDD Services, QE Facilities and PFI providers involved in medical device management/maintenance and procurement. Training in relation to medical devices is fully covered in:

- POL/EF/CLIN.E/0003 Medical Devices Training & Competency Policy

4 DUTIES

The Trust will identify and communicate clear lines of accountability within the organisation for medical device management. Responsibilities are defined from Board level to clinical service level and include external service providers. (Appendix 2)

4.1 Trust Board

A Board level director has overall responsibility for medical device management.

4.2 Integrated Quality and Assurance Committee

Responsible for providing assurance on progress and performance relating to the quality strategy, CQC outcomes and registration, effective clinical governance, audit and implementation of national recommendations.

4.3 Safety Committee

The Safety Committee is a sub-committee of the Integrated Quality and Assurance Committee and has primary responsibility for ensuring that processes are in place for safe delivery of care for patients, staff and visitors. The Safety Committee will ensure that lessons are learned from incidents, complaints and legal cases to improve the standards of health care provision delivered to patients within the Trust.

4.4 Clinical Standards and Therapeutics Committee

The Clinical Standards and Therapeutics Committee is a sub-committee of the Integrated Quality and Assurance Committee and has a responsibility for reviewing and approving clinical guidelines and procedures, which may include the use of medical devices.

4.5 Medical and Surgical Equipment Capital Replacement Group

This is a sub-group of the Investment Planning and Assurance Group and manages the replacement programme for capital medical devices across CDDFT NHS Foundation Trust.

4.6 Medical Devices Group

This is a broad-based group containing wide-ranging representation that promotes the safe and effective management and use of medical devices in order to ensure greater user awareness and consequently contribute to safer patient care.

4.7 Specialist Sub-Groups

Specialist sub-groups/small task and finish groups can be convened as appropriate to consider specific issues or to co-ordinate practice and responsibilities regarding certain groups of medical devices. For example; Point of Care Testing.

4.8 Clinical Engineering Department (CED) provided by CDD Services

This department is registered to BS EN ISO 9001:2015 and operates to provide equipment maintenance, repair and management of medical devices throughout the Trust. The department provides professional, technical advice and training to professional users, end users, and clinical specialists in areas of device application, safety and adherence to National/European standards. The department is responsible for providing a service to the Trust to help ensure all reusable medical devices are maintained, repaired and managed through the Trust asset management system.

4.9 Estates Department Services provided by QE Facilities

This department operates to provide equipment maintenance, repair and management of medical furniture e.g. dental chairs, patient trolleys, theatre tables etc, to the Trust and in conjunction with PFI partners, in line with MHRA guidance.

4.10 Sterile Services Department provided by CDD Services

This department is registered to BS EN ISO 13485:2016 and provides a decontamination service for medical devices and their accessories for the Trust, adhering to the European Medical Devices Directive 93/42/EEC. It provides information and advice on decontamination requirements.

4.11 Procurement Department provided by CDD Services

This department implements and manages contracts with suppliers, regarding medical devices and their consumables. All purchases of medical devices are made in conjunction with CED/Estates and / or the relevant Clinical Team. All staff are responsible for ensuring the correct processes are followed for trialing or procuring new devices in line with Trust Standing Financial Instructions and the Public Contracts Regulations (2015). Procurement are responsible for ensuring the correct processes are in place to trial new devices in conjunction with the Clinical Engineering Department.

4.12 The Patient Safety Team

The Patient Safety Team's function is to ensure robust systems and processes are in place to enable the monitoring and management of untoward incidents, ensuring lessons learned from incidents are identified and shared across the organisation to prevent recurrence and improve the care provided to patients. The team is also responsible for the identification of clinical risk and ensuring that sufficient controls or contingencies are in place to reduce risks to acceptable levels.

4.13 Clinical Care Groups and Leads

Clinical Care Groups and Leads are responsible for managing equipment requirements and equipment continuity for service provision. This may include establishing business cases for the equipping needs of their areas of responsibility.

4.14 Medical Devices Safety Officer (MDSO) provided by CDD Services

The Medical Devices Safety Officer is responsible for improving medical device incident reporting and learning, promoting safe use and providing expert advice and serving as an essential link for the identification and implementation of local/national safety initiatives and as a member of the National Medical Devices Safety Network. They will also act as the main contact for NHS England/MHRA and medical device manufacturers. The MDSO will report adverse incidents to the MHRA.

4.15 Head of Clinical Engineering provided by CDD Services

The Head of Clinical Engineering is responsible for providing a service via CDD Services for medical equipment management including acceptance, maintenance, repair, servicing and overall management of medical devices throughout the Trust. The service provides professional and technical guidance/advice and training to professional users, end users, and clinical specialists in areas of device application.

4.16 Medical Devices Nurse (MDN) provided by CDD Services

The Medical Devices Nurse chairs the Medical Devices Group on behalf of the Trust, which reviews monthly medical device incident reports. The MDN will also co-ordinate/deliver general infusion device training programmes to reduce risk. The Medical Devices Nurse will ensure this policy is reviewed and ratified at the appropriate committees.

4.17 Equipment Controllers

Each clinical area will have an identified Equipment Controller with specific responsibilities for co-ordinating medical device issues at ward/department level (see Appendix 3). The Medical Devices Nurse will maintain a central list of Equipment Controllers Trust wide that will be updated annually. Wards/Departments must ensure that they provide updated staffing information in order to ensure effective communication. An electronic distribution list exists for communication with Equipment Controllers.

4.18 Equipment Loan Library Operators provided by CDD Services

Central Equipment Loan Library (CELL) operators provide a service to the Trust via CDD Services and are responsible for the delivery, collection and cleaning/decontamination of specific CELL equipment. All CELL equipment will be carefully inspected on collection and during the decontamination process - any equipment damage identified will be reported to the relevant department via the Incident reporting system and also to CED, so repairs can be carried out quickly and recharged accordingly to the service. These staff will also maintain an equipment tracking base which records the devices allocated to patients.

4.19 Infection Control & Prevention Team

The Infection, Prevention & Control Team are responsible for providing advice on the cleaning, disinfection and decontamination of medical devices and participate in audit and monitoring relating to decontamination, cleaning and disinfection issues

4.20 Key Trainers For Medical Devices

Key Trainers are responsible for delivering and recording medical device training within their local department and cascading registers to coursebookings.

4.21 Ward/Department Managers

Ward/Department Managers are responsible for nominating a named member of staff to act as Equipment Controller for their areas and also ensuring that all staff receive instruction and guidance on the use of any new equipment. This must be completed as part of the local induction process for new starters, followed by annual reviews of competencies thereafter.

Managers are also responsible for ensuring the release of staff for training and ensuring staff are made aware of any medical device policies affecting their area or their role. Managers will ensure staff update as outlined in the Medical Devices Training & Competency Policy. These managers are also responsible for ensuring that equipment accessed from the Loan Libraries are accurately tracked to each patient by providing the relevant patient details to the Equipment Library Operators or Out of Hours CELL providers.

Ward/Department Managers that loan equipment from the Central Equipment Loan Library which becomes damaged will ensure Cardea repair requests sent from Clinical Engineering are authorised promptly. This will allow repairs to be initiated and equipment returned to use in the Central Equipment Loan Library without delay.

Ward Managers will ensure Medical Device Alerts, Field Safety Notices and Patient Safety Alerts are actioned and communicated fully to their respective teams.

Ward/Service Managers will ensure an inventory of the department's reusable medical devices is maintained and updated annually.

Ward/Service Managers will ensure that all relevant reusable medical devices have been maintained in accordance with the service intervals listed in appendix 5 or other manufacturer's instruction. In addition they will also ensure any 'Equipment Not found forms' are actioned and equipment presented to CED for appropriate servicing.

Ward/Service Managers will ensure that the correct process is followed for introducing new medical devices into the Trust.

4.22 All staff

Staff are responsible for ensuring they only use equipment for which they have received training and must update as outlined in the Medical Devices Training & Competency Policy. All staff must report problems experienced with medical devices to their Line manager for onward reporting to the Clinical Engineering or Procurement departments and via the Trust incident reporting system.

All staff must follow the guidance within the policy and in particular the user responsibilities listed.

5 DEFINITIONS/GLOSSARY OF TERMS USED

Acceptance testing – this term is used in this policy to refer to the procedures conducted by CED or Estates, to ensure new equipment is logged on the Trust asset management system, assigned an asset number, any servicing schedule is applied and devices are correctly assembled, configured and tested.

Adverse incident – is an event that causes or has the potential to cause, unexpected effects involving the safety of patients, users, or other persons.

Asset - An item of economic value owned by the Trust, In CDDFT an asset is defined as a piece of equipment owned by the Trust with a value >£150 or where failure could result in a compromise to service delivery. A capital asset has an individual item value >£5000 and incurs capital charges or a group of assets which form a single collective asset with a value > £5000.

BST – British Summer Time

CAS - Central Alerting System

CCG – Clinical Commissioning Group

CDD Services – County Durham & Darlington Services which is a wholly owned operated healthcare facility of CDDFT NHS Foundation Trust. CDD Services include Clinical Engineering, CELL, SSD, Procurement, Facilities

CED - Clinical Engineering Department

CELL - Central Equipment Loan Library

CQC – Care Quality Commission

CE mark – stands for "Conformité Européene" (‘European Conformity’), It is a visible sign that the manufacturer of the product is declaring conformity with all of the directives relating to that product.

Electrical safety testing – describes tests carried out to ensure mains powered medical devices are electrically safe.

GMT – Greenwich Mean Time

IT – Information Technology

ITU – Intensive Therapy Unit

KPI – Key Performance Indicators

Medical Device - the term ‘medical device’ covers a broad range of products and the definition in European and UK law is: ‘any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

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

and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

MDSO - Medical Devices Safety Officer

MHRA – Medicines and Health Care Products Regulatory Agency, an agency that promotes public health and patient safety, by regulating medical devices in the U.K

OOH – Out of hours services

PFI – Private Finance Initiative

PPM – Planned Preventative Maintenance

PAQ – Pre-Aquisition Questionnaire, previously referred to as Pre-Purchase Questionnaire (PPQ)

SSD – Sterile Services Department

QEF (QE Facilities) – Queen Elizabeth Facilities is the service provider that provides the Estates service at DMH. QE Facilities is a wholly owned subsidiary company of Gateshead Health NHS FoundationTrust.

6 PROCUREMENT

6.1 Acquisition and Replacement of Medical Devices

The procurement of medical devices is managed by the Procurement Department and by the Clinical Engineering Department via CDD Services in conjunction with clinical users.

The Procurement Team will identify and advise on the processes and controls to be adopted when purchasing/loaning/trialling/disposing of medical devices to ensure that safety, quality, performance and standardisation are addressed. Procurement will ensure compliance with Trust standing financial instructions, legal obligations and European legislation in respect of tendering and contract procedures. The Trust will seek to procure 'standardised' equipment as this forms an important risk reduction measure.

The Medical and Surgical Equipment Capital Replacement Group is a sub-group of the Investment Planning and Assurance Group and manages the capital medical device replacement programme across the Trust. As part of a planned programme, the Trust will seek to replace devices, where issues of obsolescence, decontamination, standardisation, safety, technology advancement and cost benefit are proven to be significant factors.
Any requests for new capital equipment, either replacement or additional, is required to go through this group initially and onward to the Investment Planning and Assurance Group, a business case must be submitted with full financial support.
Non Capital items (i.e. less than £5000 in value) are the responsibility of individual Care groups for replacement.

It is essential that the project lead for any new service development takes into account the need for new or additional equipment and consults with Clinical Engineering and Procurement to procure accordingly.

Purchase via charitable funds should satisfy the same product selection criteria as those purchased directly by the Trust and should be approved via the relevant service lead.

The Trust Procurement Manual is available and includes information and resources that staff can utilise to gain further information on procurement. See link below:
http://intranet/Directorates/CorporateDirectorates/FinanceChiefOpOfficer/Procurement/Lists/Announcements/DispForm.aspx?ID=122

Please also refer to the Trust Supplier Representative Policy

6.2 Important Factors to Consider Before Acquisition:

- Enquire to see if there is already a standardised model that is available for purchase, contact Procurement in the first instance.
- Agree the requirements for the intended medical procedure and/or needs of the end user.
- Suitability for intended purpose/application by reviewing manufacturer's guidance.
- Safety issues and any limitations to use – Check the device is CE marked.

- Software compatibility.
- Any electronic medical devices which process data needs to be validated and secure. Please refer to the Information Governance Policy for guidance.
- Ease of use. *(consider user experience feedback and evaluation NB refer to Appendix 7 Trust Evaluation Form – this must be used in conjunction with procurement)*
- Evaluate and assess readability of manufacturer's instructions.
- Availability, type and scope of training. *(Is training for users, maintainers or both? Does training include decontamination training?)* Advice and help – what advice services does the supplier offer?
- Ensuring the operating/environmental conditions of the place where the device will be used are compatible with those of the device.
- Decontamination and disposal procedures, ensuring the Trust will be able to reprocess in line with the Manufacturer's instructions *(Consult with the Infection Prevention Team)*
- Pre-use set-up, testing requirements, installation requirements and commissioning procedures.
- The projected service life and warranty details.
- Whole life costs; acquisition and operational, maintenance, spare parts, consumables, training, risk, renewal and disposal costs.
- Planned preventative maintenance/Ad-hoc maintenance for any faults that occur/supplier response time to attend for breakdown maintenance. *(It is important to plan and include any specialist testing equipment and technical training that may be required if the Trust Clinical Engineering/Estates Department will be required to maintain any new devices)*
- Ability/capacity or funding availability of Clinical Engineering to carry out the servicing work.
- Rationalising the range of models versus diversity.
- Reliability and previous performance.

A Pre-Acquisition form (PAQ) must be completed for all new type devices, this will provide many of the details listed above and ensure all areas are considered prior to purchase. This is available from the Procurement department.

6.3 Equipment for Evaluation/Trial

The Medicines and Health Regulatory Authority (MHRA) are required to have given a '**Notice of no objection**' to all trials of medical devices conducted within the UK; except where devices are to be used within their intended purpose, or the device has been manufactured for 'in house' use (i.e. the device has been manufactured by an healthcare establishment and will only be used on their own patients). Any staff interested in using a piece of equipment for anything other than what the manufacture states, or if it is not CE marked must liaise with Research and Innovation.

For devices that are CE marked and are to be used for their intended purpose - Any staff trialing new equipment (with a view to replacement) MUST also seek approval when there is a significant change to the previously agreed procedure and the designated lead requesting the trial must ensure all stakeholders have been appropriately consulted.

The Research and Innovation team will provide the appropriate guidance and support, approval will need to be sought and individuals will be directed to the relevant ethics committee.

6.4 Procurement process for new and/or trial medical devices

The procurement department must be contacted prior to the trial or purchase of new medical devices.

Managers/Line Managers are responsible for ensuring staff follow the procedures outlined below:

To bring new and / or trial medical devices into the Trust, staff must:

- Upon identifying that a new medical device is required, staff must contact the procurement department in the first instance.
- Procurement will carry out the necessary checks to ascertain whether there are contracts in place that already meet the Trust's needs (and therefore no new medical device is required) and whether the Trust has a standardisation programme in place that may influence what new medical device can be procured or trialled and inform the staff member.
- If the medical device requires a trial to take place a **New Product Trial Request Form** must be completed and returned to the procurement department (please request this form from Procurement).
- The procurement department will seek approval to trial the new medical device and will advise the staff member of the outcome.
- In all instances a **Master Indemnity Call Off Agreement (MIA)** (https://www.gov.uk/government/publications/master-indemnity-agreement-mia) must be completed and approved by Clinical Engineering prior to any new medical devices entering Trust sites for trial or loan.

Please see section 7.5 for further information on managing loan equipment.

6.5 New or existing equipment connected to the Trust's IT Network

All Equipment must conform to the Trust's standards for IT and network security as detailed in the Trust's IT Security Policy. These include appropriate and regularly updated anti-virus protection, robust access control and the management of third party access to the system. All mobiles devices (tablet devices) must be encrypted. In order to comply with the Trusts Standing Orders (SO's) and Standing Financial Instructions (SFI's) staff should seek approval, prior to purchase of medical equipment from the Trust's IT department.

All purchases must conform to the standards for IT security set out in the Trust's IT Security Policy. This includes all systems connecting to a PC or Trust device. Where applicable, purchases of devices new to the Trust must have the ICT specification document completed before acquisition. This is available from the I.T department.

7 PROCESS FOR ENSURING THAT ALL MEDICAL DEVICES AND EQUIPMENT ARE RECORDED, MAINTAINED AND REPAIRED

7.1 Systematic inventory of re-usable medical devices & equipment

A systematic inventory of all re-usable medical devices and equipment used in the Trust is compiled via the Trust asset management system. Each clinical area will also maintain a local medical device inventory to include equipment and medical devices in each individual service and agreed service intervals (this does not include single-use items/consumables).

It is the responsibility of the Ward/Service Manager in conjunction with the Equipment Controller to ensure that this is updated annually, a prompt to review and update inventories will be sent out annually by the Medical Devices Nurse via the Equipment Controller network.

7.2 Acceptance testing and maintenance scheduling

The Trust utilises an asset management system which manages the medical device from acceptance to disposal, it includes an equipment plant history for acceptance, planned preventative maintenance (PPM) where applicable, unscheduled repairs and reactive work.

When equipment or a medical device is received, the relevant service department, such as Clinical Engineering will perform an acceptance test, at this time the equipment is appropriately assembled, inspected and all relevant conformity/safety checks and commissioning procedures will be carried out prior to use. A unique asset ID is allocated and an asset label applied to the device. This information is entered onto the asset management system, along with information regarding the type of device, model, manufacturer, serial number, cost and deployment area. The recommended PPM schedule is applied where applicable and alerts the relevant service department when a maintenance visit is required. Refer to: Flowchart of process for ensuring medical devices are maintained (Appendix 4).

CED adopts a risk based approach to medical device maintenance. This is based upon manufacturer's guidance, equipment knowledge, equipment history, available resource and peer group discussion.

Following acceptance testing, the device will be released to the department. Managers of departments where new equipment is deployed should ensure all staff have documented training prior to commencing initial use of a new device.

The Manager/Equipment Controller must also ensure any new devices are added to the local medical device inventory and also to their local Medical Devices Training Assessment.

7.3 Specialist maintenance device contracts

Although many medical devices in use are maintained by Clinical Engineering or Estates there will also be a number of specialist devices that are maintained by manufacturers' or agreed specialist third parties. Original Equipment

Manufacturers (OEM's) are the default option for specialised medical device service support. Moving away from this source should not be undertaken lightly and needs to be an auditable process to define liabilities, responsibility and associated risks. These decisions and associated responsibilities need clearly documenting to the individuals concerned. Please refer to additional documentation around Third Party Maintenance, where this is considered, it must follow a fully risk assessed process signed off by Care Group Leads. All further information and templates can be sourced via Procurement in CDD Services.

External contractors for medical devices will be required to follow the recognised route for entry within Trust premises and show evidence of identity. Please refer to the Health & Safety policy and the Supplier Representative Policy or follow guidance within the Quality Management procedures within Estates/Clinical Engineering.

Medical device contracts along with records of maintenance carried out will be held in Clinical Engineering/Estates or by the designated specialist department. It is the Care Group users responsibility to ensure continuity of service arrangements for equipment remaining in use.

7.4 Configuration of medical devices

It is essential that all devices requiring configuration are correctly set-up for their required application. For any of these devices, an agreed configuration sheet will need to be completed to detail the mode of operation intended for use in the Trust. This will be signed by the relevant Clinical Lead. It is good practice for service leads to review these configurations regularly and inform CED if changes are required.

7.5 Management of Loan Equipment in the Trust

It is the responsibility of the Departmental manager or designated deputy, who arranged the equipment loan to monitor and manage the equipment throughout the loan period. This includes:

- Arrange for the manufacturer to liaise with Clinical Procurement to ensure completion of the necessary procurement documentation in relation to loans of new product/device trials.(refer to section 6.4)
- Arranging with the relevant service department such as CED or Estates for the loan acceptance procedure to be implemented for reusable equipment, this will include:
  - **Labeling the device clearly as 'loan equipment'**
  - **Completion of a Master Indemnity Agreement Call Off Agreement** - all devices on loan from a manufacturer should be subject to a written agreement which defines the device management requirements, responsibilities and liabilities; this includes completion of indemnity documentation which will be returned to procurement for central recording.
  - **An electrical safety test where applicable as minimum to be carried out -** this MUST be completed BEFORE the equipment can be put into general use and before being used on a patient.
  - **Addition to the Trust Asset management system for the agreed period and location(s) of use.**
- Advising the relevant service department of any specialist maintenance, calibration required and how this will be arranged with the manufacturer.

- Advising the relevant service department when the period of loan has ended and the device has been returned to the manufacturer, so the asset management system can be updated.
- Advise the relevant service department if the period of loan is to be extended or if the equipment is to move to another site.

7.6 Repairs

Breakdowns or faults with equipment subject to a satisfactory scheduled maintenance system should be relatively infrequent. However random faults and failures can occur from time to time. In such cases arrangements for the equipment to be returned to the relevant service department for repair should be made as soon as practically possible, along with accurate details of the specified fault/query. Refer to: Flowchart of process for ensuring medical devices are repaired (Appendix 4). The device must be decontaminated by the clinical ward/department prior to transfer to Clinical Engineering.

Clinical Engineering will carry out any repairs to medical devices where possible, recharging wards as applicable. The Clinical Engineering department can be contacted directly, Monday to Friday 08:30 - 16:30. For urgent issues outside of these hours please contact switchboard for the on call Clinical Engineer.

7.7 Time settings on medical devices

From March 2015, the Trust has adopted the standardised use of Greenwich Mean Time (GMT) settings when acceptance testing new small portable medical devices within CDDFT, recognising the fact that it is impractical to change these settings twice a year to accommodate the switch to British Summer Time (BST). However, larger equipment that is more readily adjustable can be changed to reflect the prevailing “real” time throughout the year. Where the equipment time cannot be set by the user, requests can also be made to reset clocks on Anaesthetic machines, ITU monitors, ECG machines where having the current time displayed on the equipment is a necessary factor in its use.

Staff must therefore be aware when reviewing event logs from devices as part of any incident investigations, that devices may still be set to GMT in BST and may have an hours discrepency to take into account. They must also be aware of any discrepency in the actual time set on devices.

7.8 Agreed service schedule for medical devices

An agreed service schedule for medical devices is detailed fully in appendix 5; this highlights the frequency of service intervals and departments responsible for service/maintenance. Please note the list is not exhaustive and there are some non-medical devices included in the table for additional guidance.

The CED planned preventative maintenance regime for acute sites is equipment based; Technicians will actively look for individual medical devices in accordance with the intervals shown in appendix 5. The planned preventative maintenance regime for community premises and items identified for EST+ differs slightly as it is location based. Each location receives a scheduled visit and all medical devices provided at the time of the visit will be checked. Any devices expected to be found but not made available will receive an ‘*Equipment not Made Available*’ form, a visit to check the devices not previously found should then be arranged – this is the responsibility of the equipment users.

Previously when devices had been inspected/serviced by the CED - a 'tested sticker' was applied, this highlighted the date of the last service/test and the details of the Engineer completing this check. From April 2017 onwards, when devices have been inspected/serviced by the CED – a "Next Test Due" sticker will now be applied, this clearly highlights to users the date that the next test/service is due.

7.9 Quality Management System

Service Department procedures will cover the provision of maintenance and repair of all medical devices in accordance with specified standards. Clinical Engineering (CDD Services) is accredited with the BS EN ISO 9001:2015 Quality Management System. To ensure the department is working to the agreed standards, the equipment management and maintenance services are audited externally once a year, internal audits are also implemented as part of this system.

PPM and Reactive Work (Including repairs) is monitored on a monthly basis utilising a Trust Performance Scorecard System. This highlights the amount of PPM carried out as a percentage, with set targets to reach each month, Performance Scorecard data is compiled and reported at Team Leaders meetings and onward via quarterly Governance Reports.

7.10 Disposal

Where equipment is beyond economic repair and considered no longer usable, the equipment should be appropriately disposed of in a safe and appropriate manner. When equipment is to be permanently removed from service, the point of contact is Clinical Engineering or Estates who can ensure the equipment is appropriately decommissioned and this is recorded on the asset register. Regulations for Waste shall be adhered to.
In exceptional circumstances medical devices and equipment may be kept for training purposes *(for e.g: as part of a clinical skills lab).* These devices must be clearly labeled **'not for clinical use'** and this must be noted on the asset register. These devices would still require an Electrical Safety Test but would not receive full manufacturers recommended maintenance.

7.11 Medical Device Replacement

The Trust have decided upon a nominal lifespan of 10years for medical devices in general and 5years for ultrasound equipment. The replacement of capital (value >£5000) items is managed through the Medical & Surgical Equipment (M&SE) replacement programme. Revenue items are the responsibility of the owning Care Group to manage replacement.

8 KEY USER RESPONSIBILITIES

All professional and 'end-users' should have access to relevant manufacturer's instructions. Each clinical area should seek to build up its own library of equipment user manuals available for the medical devices used within their clinical areas. Any shortcomings in the instructions should be reported to the MHRA as an adverse incident. Electronic copies of manuals for many general devices can also be accessed from the Trust intranet, via the Clinical Engineering site.

All professional and 'end-users' should have access to relevant manufacturer's instructions. Each clinical area should seek to build up its own library of equipment user manuals available for the medical devices used within their clinical areas. Any shortcomings in the instructions should be reported to the MHRA as an adverse incident. Electronic copies of manuals for many general devices can also be accessed from the Trust intranet, via the Clinical Engineering site.

Clinical users must ensure routine maintenance entails regular inspection and care, as recommended in the manufacturer's user information. This should show the routine tasks required. Examples of routine tasks by users include:

- All users must visually check each medical device prior to use and any devices receiving or showing evidence of damage or faults or defects must be removed from use immediately and reported to the local Clinical Engineering Department (or other relevant department) for inspection.
- Any medical devices used in invasive/surgical procedures must be checked pre and post use to ensure they are fully intact and no parts of the device have been retained.
- Checking the maintenance status of the device prior to use (to ensure it is within its next service date)
- Ensure all items with an expiry date are within date prior to use.
- All battery / mains operated equipment must be charged when not in use as per the user manual.
- Equipment must be cleaned and stored according to manufacturer's instructions. Staff must also follow any additional infection control guidance outlined in the policy for the decontamination of medical devices.
- Where equipment is contaminated Infection Control Policies must be followed and relevant departments/people that may come into contact with the device, made aware.
- All accessories e.g. mains leads, oxygen saturation sensors, blood pressure cuffs must be compatible with the device and kept in good order.
- Contacting the relevant servicing department if any problems are found.
- Ensuring any loaned equipment is fully recorded and monitored for return (section 7.5).

8.1 Loaning equipment to and from other clinical areas in the Trust

When loaning equipment to other clinical areas, Ward/Department staff should ensure a record is maintained of the equipment's location and who is responsible for the safe use of the equipment.

When borrowing equipment from another clinical area it is essential that staff are familiar with its use and that reference is made to the user manual before clinically using the device.

Please note; some devices may appear identical but may be configured differently – always check before loaning. For e.g; a GH infusion pump used in ITU is configured and used differently to a GH infusion pump in general use (CELL). The loaning of equipment should be limited to urgent situations only.

Before release to other areas and when returned to the originating area, the device should be inspected, cleaned and tested, prior to use OR return to the equipment storage area.

8.2 Mobile phones and radios

Electronically powered medical devices may fail to function properly when exposed to strong electromagnetic fields. A specific policy exists which identifies responsibilities and appropriate procedures to follow. Mobile phones/radios should be used in line with the Trust Mobile Communications Policy.

8.3 Modifying and changing use

Modifying existing devices or using them for purposes not intended by the manufacturer (off label use) has safety implications. Liability may be partially or wholly transferred to the organisation or person making the modifications, if the device is implicated in an adverse incident.

No Modifications to medical devices shall be allowed unless they are authorised by the person responsible for technical servicing, in conjunction with manufacturers to ensure that the safety of medical devices is not compromised. This also applies to service contract support and associated maintenance/repair work regarding third party suppliers.

8.4 Special Considerations

The MHRA advises that some products should be risk assessed before first use, as highlighted below:

- Devices manufactured outside the scope of the Medical Devices regulations e.g. In-House manufacture
- Devices within the scope of the medical devices Regulations, but not CE marked e.g. custom made for a named patient or under clinical investigation.

This may form a generic risk assessment covering groups of devices.

9 CENTRAL EQUIPMENT LOAN LIBRARY (CELL)

The CELL service provided by CDD Services is available on the Darlington Memorial Hospital and University Hospital of North Durham sites to centralise electronic infusion devices and pressure relieving equipment within general use. It has responsibilities for the decontamination of these devices and implementation of the service; this provides a more efficient service making the equipment available for repeated use.

Satellite services also run to other Trust hospital sites to supply pressure relieving systems. The Trust will actively consider further development of the above service as a means of managing resources more effectively and in the reduction of risk factors concerning use of medical devices / clinical equipment.

The Libraries are staffed with Equipment Library Operators between 8am to 5pm Monday to Friday and will collect any used equipment from wards twice daily.

Equipment requests can be made to the library, with the following details:

- ward location
- patient name
- hospital number
- type of device required

This information along with the asset number of the device supplied will be added to a tracking database to provide a full audit trail. If the equipment is then transferred to another ward please advise the CELL department, so the location can be adjusted on the tracking database. The receiving ward of any patient transfer with this equipment must check for any damage before accepting it into continued use.

All equipment will be inspected for damage on collection, any equipment damage will be reported via the safeguard system and repairs recharged to wards to ensure adequate stock levels of functional equipment are maintained and available in CELL.

Outside normal staffing hours, equipment can be accessed via the 'Out of hour's OOH service' (*this includes periods from 5pm-8am weekdays and covers the whole weekend period)* Equipment request forms will need to be submitted and OOH staff made aware of any equipment requests.

When staff have completed use of the equipment, they must surface clean the device and place in a designated collection point. Please refer to the full Trust policy for the decontamination of medical devices.

For instances where there is a lack or unavailability of infusion devices from CELL, staff should seek to locate a pump from a nearby ward, decontaminate and re-use, please submit as an incident on safeguard to highlight shortages. (Always ensure to source a CELL pump only and not a type that is configured differently, such as those used in specialist areas, ITU, SCBU, etc)

Where PRS are unavailable, these can be externally rented, but only between the hours of 8am-5pm.

Ambulatory syringe pumps (T34 pumps) may be discharged with patients into a continuing care setting; however this must be fully documented within the discharge plan along with details of the planned treatment by the device. Arrangements must also be made for the rapid return of the device and the CELL department must also be informed of any equipment movement made out of the Trust. If these Infusion pumps are not returned to CELL within a 3 month period, the wards transferring the device out of the Trust and/or the service the device was loaned to will be recharged for a replacement, this will ensure adequate stocks remain in CELL for continued use by other patients. External Home Equipment Loan Service

10 EXTERNAL HOME EQUIPMENT LOAN SERVICES

An external 'Home Equipment Loan service co-ordinates the requisition, supply and maintenance of equipment to patients in the community. This type of service may be provided to patient or carer upon discharge or as part of patients ongoing care needs. This service is provided via a Commissioning Support Unit on behalf of our Local Clinical Commissioning Groups (CCGs).

The MHRA highlights that where devices are issued on a long term loan basis, some device management will transfer either to the individual end user or a healthcare worker or carer, it is important that staff involved in this service understand their responsibilities for each aspect of management including:

- decontamination procedures

- maintenance and associated record keeping
- availability of up-to-date instructions and other information, and passing to end users, where appropriate
- period and type of use
- device identification and traceability
- contact details (users and healthcare establishment)

The supplying organisation remains accountable for collecting these items when no longer needed. The Requisitioner of equipment is responsible for ensuring any training in the use of equipment is provided.

11 DECONTAMINATION

Staff must ensure decontamination requirements take account of the degree of infection risk associated with use of the device. All items subject to inspection, service, repair or disposal must be decontaminated beforehand by clinical staff. Contaminated items must not be sent through the post.

Staff must take into account relevant Trust Infection Control Guidelines for Decontamination of Medical Devices and also manufacturer's instructions. Decontamination policy, procedures and processes are heavily regulated by the relevant national agencies. The internal governance structure to ensure compliance for the Trust is contained within the Decontamination Policy.

11.1 Single-use/single-patient use & limited use medical devices

Single use devices: Current recommendations state that 'devices designated for Single-use must not be re-used

Single-use devices are intended to be used on an individual patient during a single procedure and then discarded, and not intended to be re-processed to be used on another patient. The expression 'single use' on the packaging of medical devices means that the manufacturer intends the device to be

- Used once only then discarded
- Considers the device not suitable for use on more than one occasion
- Has evidence to confirm that re-use would be unsafe.

The symbol below is used on medical device packaging indicating 'Do Not Re-Use' and may replace any wording:

Where single-use medical devices are used, always inspect prior to use to ensure the device is intact and fully and correctly assembled, where defects are present – do not use and arrange reporting to Procurement if minor or to the MHRA if there is potential for an adverse incident to occur. After use, especially if used during invasive/ surgical procedures; ensure the device is re-inspected to confirm it remains fully intact prior to disposal and no parts have been retained.

Single patient use devices can be re-used, if re-processed using an appropriate method and the device is used on the same patient only. The

duration of use is dependent upon undertaking a risk assessment of individual risk factors, and/or in line with manufacturer's instructions.

Limited use devices are intended only for a specified number of uses. The device may be re-processed using an appropriate method. The number of times each individual item can be, and is, reprocessed must be documented and an appropriate record of re-use maintained.

Controls and monitoring arrangements must be in place to ensure that the agreed number of reprocessing episodes is not exceeded.

Legal implications: Anyone who re-processes requests the reprocessing or re-uses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness.

Anyone who re-processes a 'single-use' device and passes it to a separate legal entity (i.e. another organisation/individual) for use has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.

If 'single-use' devices are not processed in accordance with the manufacturer's guidelines, warranties for the devices are likely to become void. This means that the manufacturer can avoid their legal obligations and liabilities associated with damage or injury resulting from the use of such medical devices. This effectively transfers manufacturer's liability and responsibility to anyone taking the decision to re-process or re-use designated 'single-use' devices.

Where single use items or single patient use items fail, these must be reported as an incident following the Trust Incident Reporting Policy as with all other equipment failures.

12 MANAGING RISK & INCIDENT REPORTING

12.1 Adverse incident reporting

Any adverse incident which may be considered as having the potential to produce unexpected or unwanted effects involving the safety of patients, users or other persons must be reported via the Trust incident reporting system. Any known problems associated with product design, documentation and common use related issues should also be reported, for follow up. It is important to also report user problems with a device, software failures, or problems with the instructions for use.

In the event of an adverse incident involving: equipment failure / malfunction/ damage/ suspected defects or design faults, please follow the steps outlined below, the priority is to see to the patients or staff (user) clinical needs and offer any stabilising or corrective treatment:

- The device must be quarantined and removed immediately from use
- A label must be attached to the equipment, which must be dated and include a description of perceived fault/potential hazard.
- The necessary precautions to avoid infection hazards must be adhered to and the contaminations status should be highlighted. If decontamination will not

interfere with the investigation and can safely be completed, the device should be cleaned according to recommended guidelines.
- The device settings should not be altered.
- Packaging, batch and model numbers must be retained along with any disposable or consumable items.
- As soon as possible after the event, an incident report must be completed which includes details of equipment involved such as: type of device, model, asset number and/or serial number, batch or LOT number.
- Contact the relevant service dept such as Clinical Engineering/Estates to arrange the return of any affected devices that they maintain.
- The patient and family should be informed of what has happened and an apology made, this is not an admission of liability (see being open policy)
- The MDSO must be advised immediately in the case of suspected failures or defects/design faults and a MHRA adverse incident report completed.
- The MDSO will co-ordinate all reporting directly to the MHRA, this will ensure there is a central contact for the Trust and reporting is monitored centrally.
- The Trust's MDSO may arrange for the equipment and documentation to be collected and forwarded to the company for investigation, where there is no police or coroner involvement.
- Responses received from the MHRA will be forwarded to the initial reporter

Adverse incident reporting is essential to ensure lessons are learnt and adverse incidents are not repeated, National reporting allows any trends to be spotted and appropriate action taken across the country, for example through medical device alerts and other safety warnings.

For general equipment faults/breakdown -The device should be quarantined, labeled and the appropriate service department contacted as soon as possible to arrange checking/repair of the equipment so that it can be returned to use in a timely manner.

The Central Alert System will communicate relevant alerts (e.g. medical devices alerts, field safety notices) to the appropriate Heads of Department/Service or Central Alert Leads who will then ensure they are communicated to all their teams. Those people who have been identified to take action must do so in a manner according to the level of risk identified in the alert. (Refer to Trust Central Alert policy).

Risk Assessments will be carried out annually in each area on the equipment used. Consideration must also be given by care groups to long-term planning for ensuring issues of obsolescence, decontamination, standardisation, safety, technology advancement and cost benefit are taken into account. Issues identified by each service are required to be recorded against the Corporate, Care Group or Department Risk Register.

13 MEDICAL DEVICES POLICIES/ GUIDELINES & RESOURCES

Policies are all available on the Trust Intranet to communicate all relevant guidance to staff and users of medical devices.

Each department should maintain a Medical Device Resource Folder which is kept updated.

There is a dedicated 'Clinical Engineering page' which also contains relevant documentation and resources associated with medical devices management, such as medical devices forms, and a Medical Devices Resource folder, etc. see link below:

http://intranet/Directorates/CorporateDirectorates/EandF/ClinEng/Pages/default.aspx

14 COMPLIANCE & EFFECTIVENESS MONITORING FOR THIS POLICY

14.1 Key Performance Indicators

Detail how performance will be measured:

- Numbers and types of medical devices maintained
- Numbers and types of medical devices repaired
- Quality Management System audits of CED
- Review of medical device incidents
- User responsibilities outlined in this policy are completed

14.2 Compliance and Effectiveness Monitoring Table

Compliance with this policy will be monitored as outlined in the table below.

Monitoring Criterion	Response
Who will perform the monitoring?	Head of Clinical Engineering, Clinical Engineering Team Leaders & Medical Devices Nurse (CDD Services)
What are you monitoring	• Process for ensuring that all medical devices and equipment are maintained and repaired. *(this includes Planned Performance Maintenance and Reactive Work)* • Medical devices related incidents • User Responsibilities in relation to Medical Devices are being met
When will the monitoring be performed?	At various intervals throughout the year: monthly, quarterly and annually
How are you going to monitor?	• Performance Scorecards, which captures performance in relation to Planned Preventative Maintenance (PPM). • Asset Management System that manages diagnostic & therapeutic equipment from acceptance to disposal including a plant history of PPM, unscheduled repairs, manufacturers upgrades, etc. • Quality Management System subject to an annual external audit and subsequent internal audits. • Medical devices related incidents - at Clinical Engineering Team Leader's meetings and at Medical Devices Group, onwards to Safety Committee • Annual Medical Devices Policy Audit

	• Annual review of Medical Devices Training Assessments/Equipment Controller networks
What will happen if any shortfalls are identified?	• Any deficiencies will be addressed at Clinical Engineering Team Leader's Meetings with corrective & preventative actions implemented. • Reports on performance detailing all 'equipment not made available' will be fed back directly to Care Groups to action. • Audit actions will be developed in an audit action plan and monitored through until completion.
Where will the results of the monitoring be reported?	• External audit of the quality management system and results of monthly PPM against performance targets will be logged onto a monthly Performance Scorecard. These results are discussed at Team Leaders Meetings and presented via CDD Services KPI'S. The results are also in the annual Medical Devices report with onward annual reporting to Integrated Quality & Assurance Committee. • Audit results will be included in the annual Medical Devices report that goes to Safety Committee.
How will the resulting action plan be progressed and monitored?	• Progressed and monitored as above, any deficiencies that cannot be immediately rectified will be entered onto a risk register, and monitored via CDD Services.
How will learning take place?	Implementation of corrective & preventative actions as discussed at Team Leaders Meetings with feedback to respective teams. Change of practice as dictated by external and internal audits. Lessons learned from Trust incidents. Recommendations or actions requested from Directorate or Committee Meetings

15 ASSOCIATED DOCUMENTATION

This Policy refers to the following guidance, including national and international standards:

- The Medical Device Regulations 2002
- Care Quality Commission, Essential Standards of Quality & Safety
- MHRA 2006. Reporting Adverse Incidents and Disseminating Medical Device Alerts. http://www.mhra.gov.uk
- Health & Safety at Work Act 1974
- MHRA (2015) Managing Medical Devices - Guidance for healthcare and social service organisations. April 2015, v1.1 http://www.mhra.gov.uk
- European Medical Devices Directive 93/42/EEC 2007/47/EC
- ISO13485: 2016 Medical Devices
- MHRA Patient Safety Alert Stage 3; Directive improving medical device incident reporting and learning. 20 March 2014. NHS/PSA/2014/006
- Department of Health (2009) Using mobile phones in NHS hospitals. Gateway ref 9768
- BS EN ISO 9001: 2015 Quality Management System Requirements

Please also refer to the following CDDFT Trust policies and procedures:

- Being Open Policy
- Central Alert Policy
- Clinical Audit & Effectiveness Policy
- Electronic Infusion Devices Policy
- Incident Management Policy
- IT Security Policy
- Medical Devices Training & Competency Policy
- Mobile Communications Policy
- Policy for the Decontamination of Medical Devices
- Staff Induction Policy & Procedures
- Waste Policy
- Health and Safety Policy
- Supplier Representative Policy

16 APPENDICES

Appendix 1: Equality Impact Assessment

Appendix 2: Accountability structure for medical device management

Appendix 3: Roles and Responsibilities of Equipment Controllers

Appendix 4: Flow charts: How Medical Devices are maintained and repaired

Appendix 5: A Guide to agreed service intervals for Medical Devices & other equipment

Appendix 6: Dissemination Plan

Appendix 7: Product Evaluation Form

16.1 Appendix 1: - Equality Analysis/Impact Assessment (v4/2018)

Division/Department:	Clinical Engineering Dept CDD Services
Title of policy, procedure, decision, project, function or service:	Medical Devices Policy
Lead person responsible:	Medical Devices Nurse
People involved with completing this:	Medical Devices Group/Clinical Engineering & Estates Team, Procurement.

Type of policy, procedure, decision, project, function or service:

Existing	☒
New/proposed	☐
Changed	☐

Date Completed:	08/08/18

Step 1 – Scoping your analysis

What is the aim of your policy, procedure, project, decision, function or service and how does it relate to equality?

To provide and communicate a framework for the safe use and management of medical devices in the Trust

Who is the policy, procedure, project, decision, function or service going to benefit and how?

All staff who manage or use medical device equipment, The patients as recipients.

What barriers are there to achieving these outcomes?

Staff unaware of policy

How will you put your policy, procedure, project, decision, function or service into practice?

This policy applies to all staff that come into contact with medical devices; The policy is available on the staff intranet.

Does this policy link, align or conflict with any other policy, procedure, project, decision, function or service?

The Medical Devices Training and Competencies Policy and Electronic Infusion Devices Policy links with the medical devices policy.

Step 2 – Collecting your information

What existing information / data do you have?

Current equality data is available on the workforce

Who have you consulted with?

Medical Devices Group

What are the gaps and how do you plan to collect what is missing?

None

Step 3 – What is the impact?

Using the information from Step 2 explain if there is an impact or potential for impact on staff or people in the community with characteristics protected under the Equality Act 2010?

Ethnicity or Race

No

Sex/Gender

No

Age

No

Disability

No

Religion or Belief

No

Sexual Orientation

No

Marriage and Civil Partnership (applies to workforce issues only)

No

Pregnancy and Maternity

No

Gender Reassignment

No

Other socially excluded groups or communities e.g. rural community, socially excluded, carers, areas of deprivation, low literacy skills etc.

No

Step 4 – What are the differences?

Are any groups affected in a different way to others as a result of the policy, procedure, project, decision, function or service?

No

Does your policy, procedure, project, decision, function or service discriminate against anyone with characteristics protected under the Equality Act 2010?

Yes ☐ **No** ☒

If yes, explain the justification for this. If it cannot be justified, how are you going to change it to remove or mitigate the affect?

Step 5 – Make a decision based on steps 2 - 4

If you are in a position to introduce the policy, procedure, project, decision, function or service? Clearly show how this has been decided.

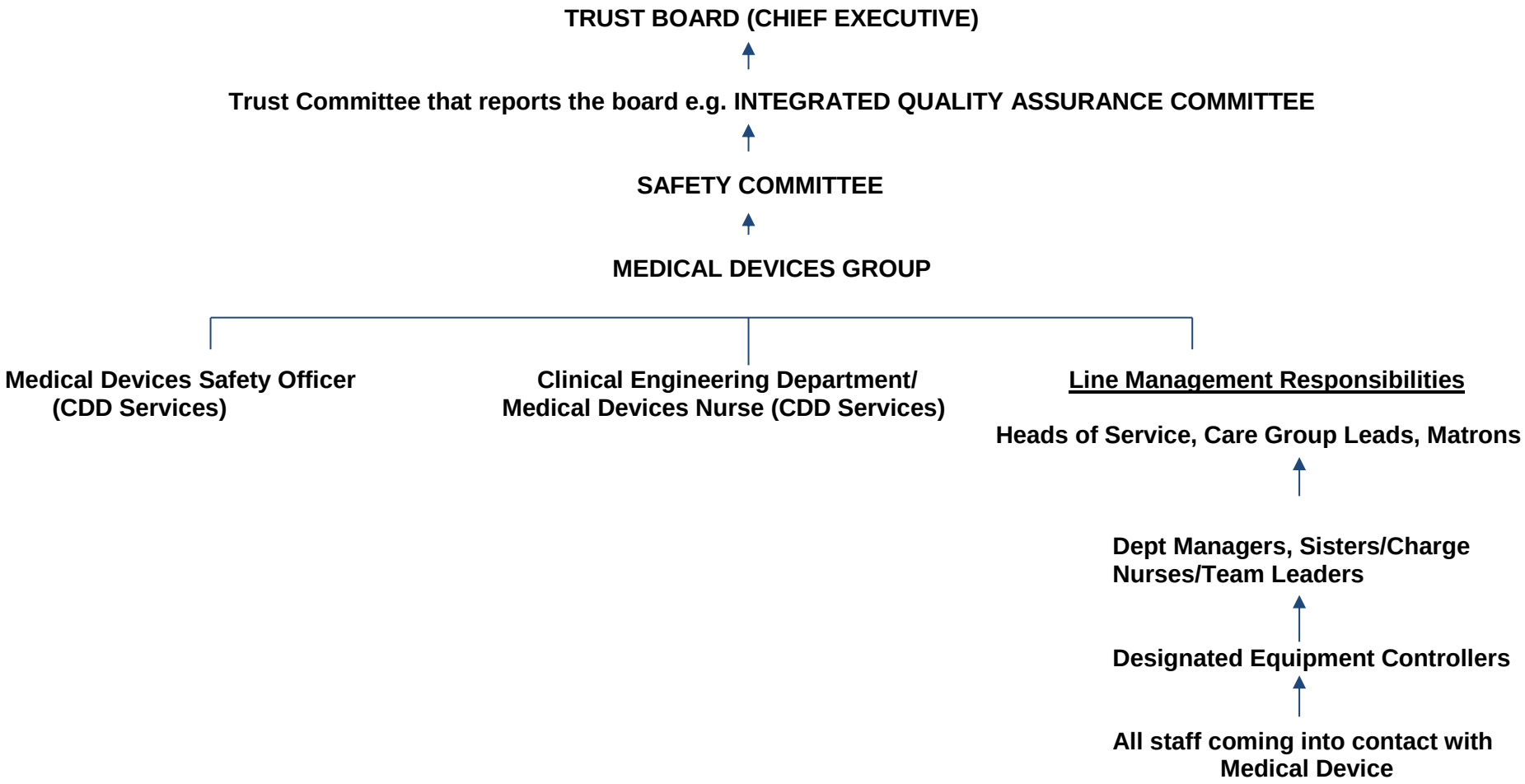
This is an existing Policy for CDDFT staff, awareness of this updated policy will be raised to services at Medical Devices Equipment Controller training and communicated via the Equipment Controller network and via the Medical Devices Newsletter

If you are in a position to introduce the policy, procedure, project, decision, function or service, but still have information to collect, changes to make or actions to complete to ensure all people affected have been covered please list:

How are you going to monitor this policy, procedure, project or service, how often and who will be responsible?

This policy will be monitored as outlined in the monitoring section/table within the policy

16.2 Appendix 2 – Accountability Structure for Medical Device Management



16.3 Appendix 3 - Roles and Responsibilities of Ward/Department Equipment Controllers

1. Assist managers to ensure formal arrangements are in place at Ward/ Department/Service level for the handover of equipment for repair/servicing and for receiving it back when work is completed.

2. Act as a medical device safety champion, taking an active role in improving the safe use of medical devices, taking action to improve reporting and learning locally.

3. Assist managers to set up a system where equipment records are kept at ward/ dept level to ensure repairs and servicing are carried out regularly and promptly.

4. Work with their managers to help ensure safety alert bulletins are communicated to staff and appropriate action taken at Ward/Department/Service level.

5. Maintain Medical Devices Resource Folders at Ward/Department/Service levels and making sure that they are updated and accessible to all staff.

6. Work with colleagues to promote awareness regarding equipment decontamination in accordance with requirements before handing over for servicing.

7. Raise awareness of any risk issues for medical device related issues at Ward / Department/Service level; ensure any incidents with medical devices are reported.

8. Help to ensure staff have access to manufacturer's instructions and evaluate instructions for adequacy.

9. Promote good practice with colleagues regarding ensuring all equipment is correctly stored at Ward / Department / Service level.

10. Raise awareness amongst colleagues of various policies/resources in place in the Trust concerning medical devices issues

11. Liaise with Clinical Engineering or Estates to help set up an inventory of all medical devices at Ward/Department/Service level. This should include service guidance regarding agreed intervals and will be need to be reviewed and updated by the ward/service annually.

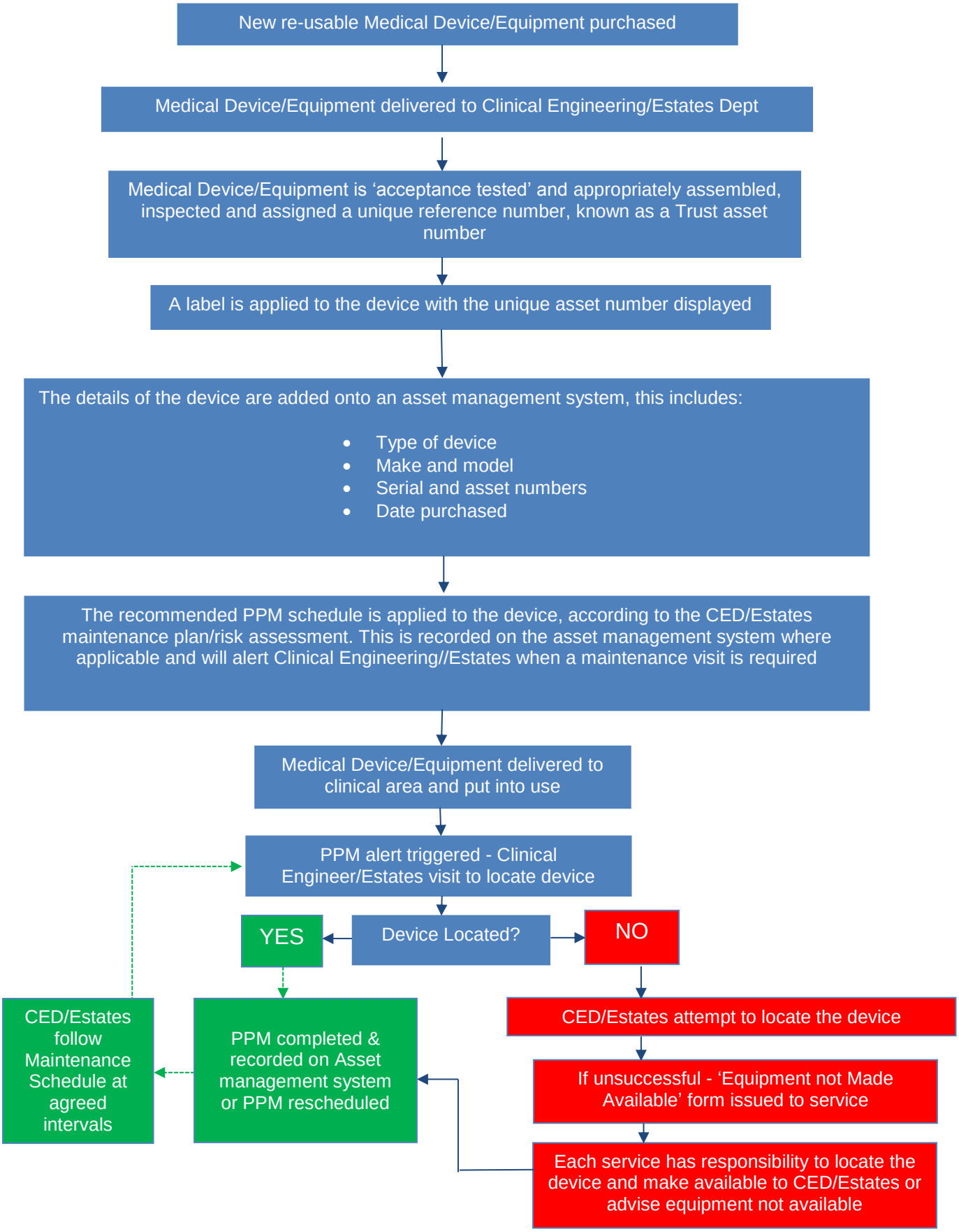
12. Work with colleagues at ward/dept. level to identify and address training needs for medical devices

13. Act as a point of communication between central departments in the Trust e.g. Patient Safety, Clinical Engineering, the Medical Devices Group, Medical Devices Safety Officer and with staff at Ward / Department/Service level.

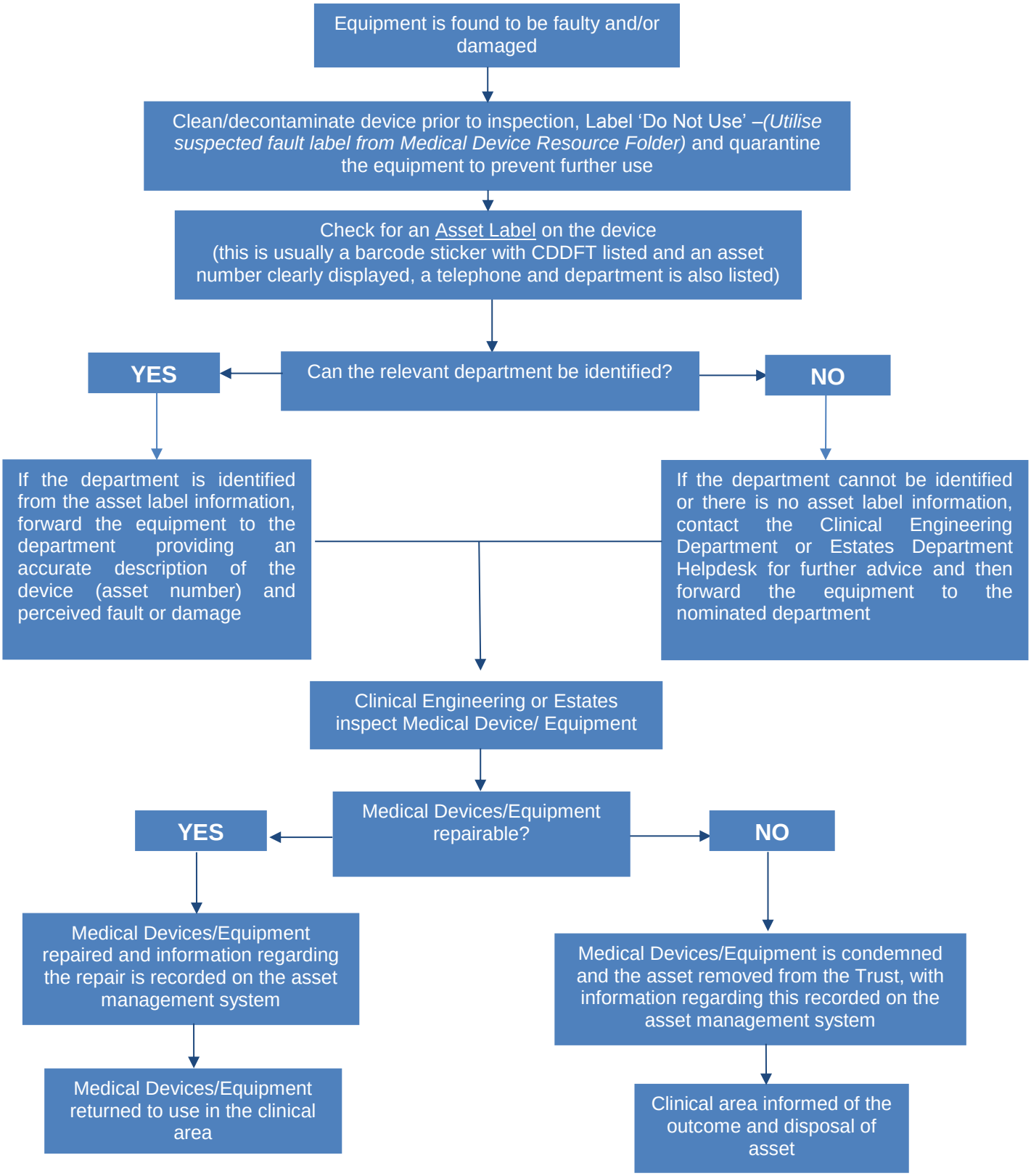
14. Attend specific meetings and training around medical device related issues and feedback to colleagues.

15. Assist Managers in the annual review of departmental Medical Devices Training Assessments and audits

16.4 Appendix 4 - Flow Chart – Process for ensuring medical devices are maintained



Flow Chart – Process for ensuring medical devices are repaired



16.5 Appendix 5 - A Guide to agreed service intervals for Medical Devices & other equipment

Type of Medical Device	Interval	Maintenance carried out by:
Hoists (Ceiling Track/Mobile)	6 Monthly	Approved agent via CED
Ventilator	Annual	Clinical Engineering
Incubator	Annual	Clinical Engineering
Defibrillator	Annual	Clinical Engineering
T34 Infusion /T60/TPCA	Annual	Clinical Engineering
SE/Signature Infusion Pumps	Annual	Clinical Engineering
Anaesthetic Machines/Vaporisers	Annual	Clinical Engineering
Bladder Scanners	Annual	Clinical Engineering
Epidural pumps/PCA/Regional Block Pump	Annual	Clinical Engineering
X-ray equipment	Annual	Manufacturer/Approved agent via CED
Biliblanket/Phototherapy Equipment	Annual	Clinical Engineering
Weighing scales (platform, chair, baby)	Annual	Clinical Engineering/Approved agent
Image intensifier	Annual	Manufacturer/Approved agent via CED
Camera Stacks	Annual	Clinical Engineering
RA machine (dentistry)	Annual	Clinical Engineering
Ultrasound imager/scanner	Annual	Clinical Engineering
Oxygen Concentrators	Annual	Clinical Engineering
Laser equipment	Annual	Manufacturer/Approved agent via CED
Spirometer	Annual	Clinical Engineering
Endoscopes (Rigid/Flexible)	Annual	Manufacturer/Approved agent via CED
Telemetry (ECG)	Annual	Clinical Engineering
Critical Care Monitoring	Annual	Clinical Engineering
ECG Stress Analysis Systems	Annual	Clinical Engineering
Radiotherapy Equipment	Annual	Clinical Engineering
Wheelchairs	Annual	Approved agent via Portering Lead
Bone densitometer	Annual	Manufacturer/Approved agent via CED
Elk/Camel/HoverMatt *(lifting/transfer devices)*	Annual	Approved agent via CED
Diathermy	Annual	Clinical Engineering
Operating Tables	Annual	Estates
Enteral feeding Pumps (Nutricia)	2 Yearly	Loan via Clinical Engineering
Hospital Bed Frames	2 Yearly	Clinical Engineering
GP, GH, CC Infusion pumps	3 Yearly	Clinical Engineering
Nebulisers	4 Yearly	Clinical Engineering
CPAP/BIPAP	4 Yearly	Clinical Engineering
Electrical Suction equipment	4 Yearly	Clinical Engineering
Gas cylinder regulators	4 Yearly	Clinical Engineering
Sequential Compressors	4 Yearly	Clinical Engineering
Snellen eye test charts	4 Yearly	Clinical Engineering
Bair huggers (patient warming device)	4 Yearly	Loan via Clinical Engineering
Blood warming equipment	4 Yearly	Clinical Engineering
12 Lead ECG	4 Yearly	Clinical Engineering
Foetal monitoring/CTG	4 Yearly	Clinical Engineering

Type of Medical Device	Interval	Maintenance carried out by:
Surgical Tourniquet	4 Yearly	Clinical Engineering
Headlamps	4 Yearly	Clinical Engineering
Slit Lamp	4 Yearly	Clinical Engineering
Microscope	4 Yearly	Clinical Engineering
Pressure Relieving Systems (mattress/cushions)	4 Yearly	Clinical Engineering
Examination Lights	4 Yearly	Clinical Engineering
Foetal Monitor	4 Yearly	Clinical Engineering
Apnoea mattress	4 Yearly	Clinical Engineering
Hearing testing Equipment	4 Yearly	Clinical Engineering
Neurothesiometer	4 Yearly	Clinical Engineering
Voice output communication aid	4 Yearly	Clinical Engineering
Coag-u-chek	4 Yearly	Clinical Engineering
Urinalysis Analyser	4 Yearly	Clinical Engineering
Hyfrecator *(Electrosurgery device)*	4 Yearly	Clinical Engineering
General Path Lab equipment	4 Yearly	Clinical Engineering
Smoke Evacuator	4 Yearly	Clinical Engineering
Ear Syringing/Irrigation equipment	4 Yearly	Clinical Engineering
Breast Pumps	4 Yearly	Clinical Engineering
Humidifiers	4 Yearly	Clinical Engineering
Opthalmascope/Aurascopes	At user request	Clinical Engineering
Ambit PCA Pump	At user request	Loan via Clinical Engineering
Suction Controller	At user request	Clinical Engineering
TENS machine	At user request	Clinical Engineering
Oxygen analyser	At user request	Clinical Engineering
Cots	At user request	Clinical Engineering
Doppler ultrasound device	At user request	Clinical Engineering
Flowmeters	At user request	Clinical Engineering
Thermometers	At user request	Clinical Engineering
Manual Sphygmomanometers	At user request	Clinical Engineering
Enuresis alarm	At user request	Clinical Engineering
Accu-Chek Performa - blood glucose meter	At user request	Manufacturer via POCT lead
HemaCue *(point of care testing meter)*	At user request	Manufacturer via POCT lead
Inform Meter - Connected Blood glucose meter	At user request	Manufacturer via POCT lead
Blood Gas Analyser	At user request	Manufacturer via POCT lead
Commodes	At user request	Estates
Patient Transfer Trolley/Examination Plinths	At user request	Estates
Vacuum Assisted Wound Technology	At user request	External Rental agreement via TVNs
Dental chair	Estates perform weekly tests	Estates

Please be aware this is a general guide; some devices may differ in requirements.

CED (CDD Services), Estates (QE Facilities) or PFI department may inspect initially and refer to an external contractor where required. Services may need to provide cost codes for any applicable charges for repairs and maintenance costs.

Where devices are covered by maintenance contracts, are community based devices or are part of the EST+ regime, then the next maintenance visit is not identified by the Bactraq schedule. It is by the maintenance provider or by the provided locational visit. Items identified as 4yearly are part of the EST+ regime. Items identified as 'at user request' would also be assessed at the EST+ visit if made available.

Please contact Clinical Engineering, Estates, PFI dept or other applicable lead for further advice.

16.6 Appendix 6 - Dissemination Plan

All clinical staff that use medical devices need to be aware of this updated policy document. Following ratification, awareness of this policy will be:

- highlighted via the Trust weekly bulletin.
- circulated to the Medical Device Group members
- circulated via the Equipment Controller Network
- highlighted via the Medical Devices Newsletter.
- highlighted on Equipment Controller Training.

16.7 Appendix 7 - Product Evaluation Form

Evaluation of Product [xxxxxxxxxxxxxxx]

Hospital Site: [xxxxxxxxxxxxx]	**Evaluation Start Date: [xxxxxxxxxxxxx]**
Ward / Department: [xxxxxxxxxxxxx]	**Evaluation End Date: [xxxxxxxxxxxxx]**
Supplier: [xxxxxxxxxxxxx]	**Supplier Representative: [xxxxxxxxxxxxx]**
Product Code / Batch No: [xxxxxxxxxxxxx]	**Care Group / Department Lead: [xxxxxxxxxxxxx]**

How do you rate the product in the following areas?

Evaluation Criteria	Excellent [x 5 x] / For Info	Good [x 4 x] / For Info	Acceptable [x 3 x] / For Info	Poor [x 2 x] / For Info	Very Poor [x 1 x] / For Info
[xx Packaging xx]					
[xx Instructions for Use xx]					
[xx Visual Appearance xx]					
[xx Performance xx]					
[xx Ease of Use xx]					
[xx Product and Company Support xx]					

Items highlighted in yellow must be amended as required, please delete this from your final version.

[xx How does this product compare to your usual product? Xx]

Better	Same	Worse

General Comments

Completed by (print name): **Date:**

Thank you for completing evaluation form, your input is much appreciated.

The forms will be collected by [xx insert procurement officer name xx]

For any queries please contact [xx insert procurement officer name and contact details xx]