Managing Medical Devices Safely

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Introduction

The primary aim of this policy is to ensure that the right devices (through robust legal procurement and planning processes) are available at the right time (through ensuring maximum uptime of equipment) to ensure the effective use of Medical Devices to deliver patient care (through effective clinical training and competence).

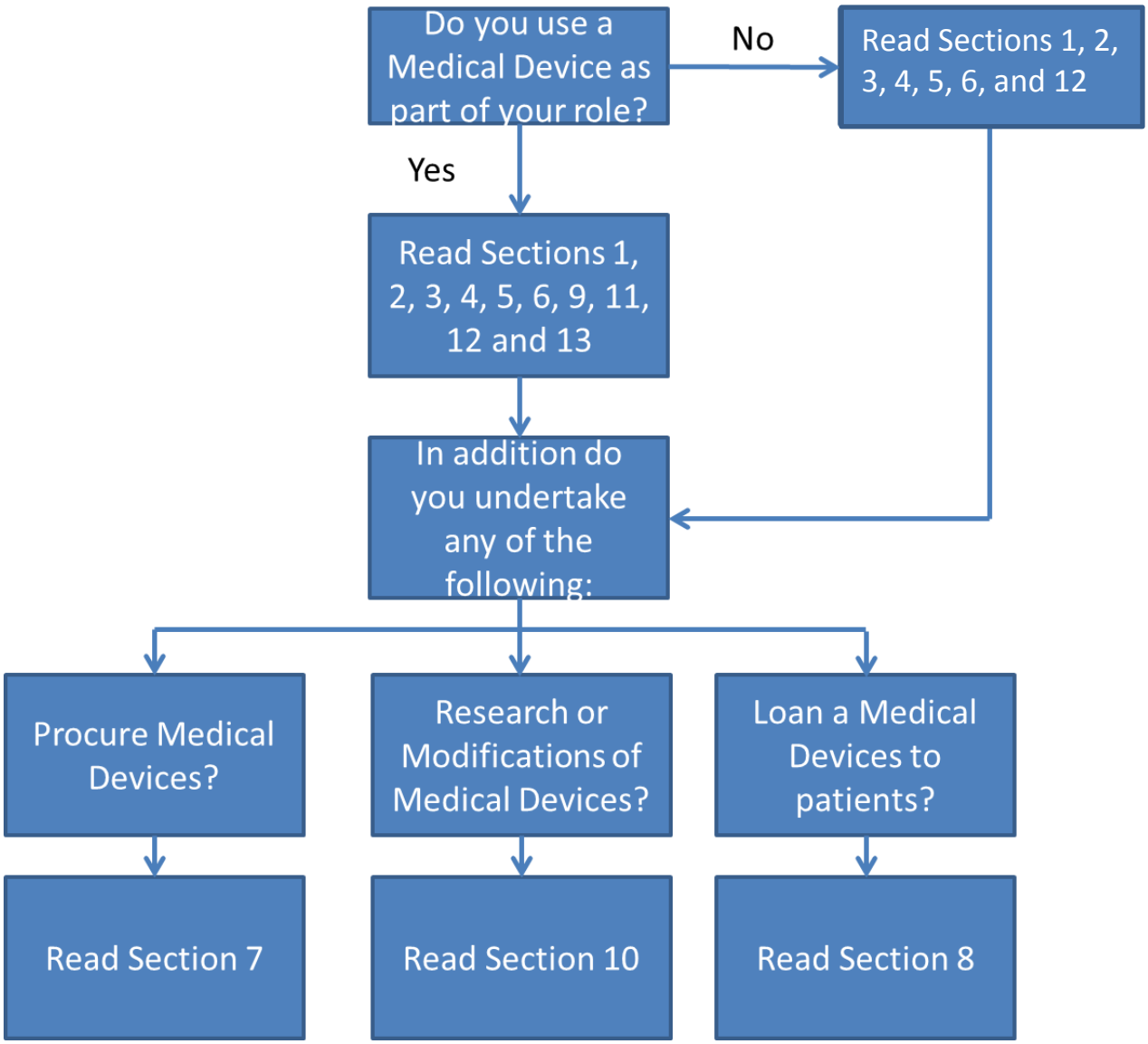
This document governs Trust Clinical Policy for the management of reusable Medical Devices in the Trust. It is founded on the requirements of the Care Quality Commission Regulations, recommendations from government regulatory agencies e.g. Medicines and Healthcare Products Regulating Agency (MHRA) e.g. "Managing Medical Devices, April 2015".

These national documents alongside this Managing Medical Devices Safely Policy aim to produce a systematic approach to the management of the lifecycle of a Medical Device from procurement and planning, maintenance and repairs, reporting of incidents to the safe and appropriate disposal of Medical Devices, minimising the risk to patients and ensuring compliance with the necessary standards expected of a modern health service within University Hospitals Bristol NHS Foundation Trust.

[1] Divide number of words (1226) by 240 for average reading time and add 25% for specialist content.

Document Change Control				
Date of Version	**Version Number**	**Lead for Revisions**	**Type of Revision**	**Description of Revision**
	1	Head of Clinical Engineering	Major	Change from Controls Assurance model
26/09/06	2	Head of Clinical Engineering	Major	Comply with NHSLA L2
01/09/2009	3	Head of Clinical Engineering	Minor	Improved clarity
31/08/12	4	Head of Clinical Engineering	Major	To meet CQC Regulation 12 & NHSLA 1, 2 & 3. Introduction of precautions against malware.
31/07/13	5	Head of Clinical Engineering	Major	Approved
03/08/2017	6	Head of Clinical Engineering	Major	Updated and increased clarity of information and new processes in place, sections added for malware and Cyber security, updated flow charts, revised definitions, addition of re-manufactured devices section and rewording of other all other sections within the policy.

Flowchart highlighting appropriate sections in policy to read for each group of staff:



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1. Introduction

The primary aim of this policy is to ensure that the right devices (through robust legal procurement and planning processes) are available at the right time (through ensuring maximum uptime of equipment) to ensure the effective use of Medical Devices to deliver patient care (through effective clinical training and competence).

This policy governs the requirements for effective management of reusable Medical Devices in the Trust. It is founded on the requirements outlined by the Care Quality Commission Regulations, recommendations from government regulatory agencies e.g. Medicines and Healthcare Products Regulating Agency (MHRA) and guidelines such as Managing Medical Devices, April 2015.

These documents aim to produce a systematic approach to the management of the lifecycle of a Medical Device from pre-procurement decision and procurement process and planning, maintenance and repairs, reporting of incidents to the safe and appropriate disposal of Medical Devices, minimising the risk to patients and ensuring compliance with the necessary standards expected of a modern health service.

The Trust recognises that risks are created by the use of Medical Devices to patients, staff and others and as such it requires safe working practice to be maintained. The Trust aims to ensure that all staff that utilise a Medical Device for diagnostics or therapies can do so in a safe and effective manner. This is undertaken through:

- Ensuring the device purchased is suitable for use
- Ensuring the device is maintained to an appropriate standard with mechanisms in place to report this
- Ensuring incident reporting is available to develop and continuously improve the system through effective learning and action.
- Ensuring effective disposal and capital planning processes are in place to have the right equipment in the right place at the right time
- Ensuring appropriate training is in place prior to technical staff maintaining devices and clinical staff utilising a device on a patient.
- Ensuring device procurement follows correct process to ensure suitability of use and most economically advantageous through the life cycle of the equipment

The Medical Device Management Group (MDMG) is responsible for overseeing and reviewing this policy and for seeking assurance from Divisions that it is being implemented. MDMG reports to the Trust's Clinical Quality Group. The Medical Director and Chief Nurse have joint overall responsibility for safe and effective management of Medical Devices within the Trust; operationally this is supported a number of specialist teams within the organisation.

2. Purpose and Scope

The purpose of this document is to outline a systematic approach to the management of all aspects in the lifecycle of reusable Medical Devices. It aims to ensure that the risks associated with all aspects of procurement, utilisation, record integrity, decontamination, disposal and ongoing maintenance of Medical Devices is managed in line with best practice to minimise these risks.

This policy is intended for University Hospitals Bristol NHS Foundation Trust staff and staff working on behalf of the Trust, who are responsible for the management and use of Medical Devices.

3. Definitions

(a) Acceptance

The process by which reusable Medical Devices are brought into the Trust and placed on an appropriate inventory/tracking system. There may be some element of commissioning of the new equipment.

(b) Acquisition

The way in which a device has been procured e.g. specification, technical, clinical and financial evaluation, route to market (eg tender, quote, loan, gift, lease, transfer, research)

(c) Clinical

Directly involved in the diagnosis, investigation, monitoring, treatment and care of patients.

(d) Clinical Engineering (MEMO)

Service who manage and deliver a significant proportion of the maintenance, repair and development of medical equipment on behalf of the Trust

(e) Clinical Quality Group (CQG)

Medical Device Management Group reports in to CQG as part of the Medical Device Governance arrangements.

(f) Competent person

A competent person is one who is appropriately trained and up-to-date with the knowledge required to undertake the task outlined

(g) CQC

Care Quality Commission

(h) Critical Equipment

Any item of equipment or technology which is used during the delivery of patient care which, if suddenly unavailable, would constitute the risk of harm to the patient. The equipment may have associated IT or service connections that contribute to its functionality, which must be maintained.

(i) DoH

Department of Health

(j) Divisional Medical Device Lead / Equipment Co-Ordinator

A person (s) appointed by the division to co-ordinate all aspects of equipment governance, replacement and training etc.

(k) EBME

Electro Biomedical Engineering

(l) End User

A patient, client, relative or carer who uses a reusable Medical Device, unsupervised at home.

(m) Malware

Malicious software used to either infect equipment with a software virus, take over control of the device or steal information.

(n) Medical Device

Covers all healthcare products including related software used in healthcare for the diagnosis, prevention, monitoring or treatment of illness. It excludes medicines and those products containing medicines e.g. preloaded syringes.

(o) Medical Equipment

Any electrical Medical Device used in the diagnosis, investigation, monitoring, treatment and care of patients.

(p) MDMG

Medical Device Management Group

(q) MHRA

Medicines and Healthcare products Regulating Agency.

(r) Patients Equipment

Medical Devices or equipment that a patient has with them when they come into hospital.

(s) PPM

Planned Preventative Maintenance - Servicing operations carried out at fixed intervals by technical staff

(t) Prescriber

A person who decides which is an appropriate device for a given patient or client. It will encompass any Medical Device used in direct contact with a patient. It could be to directly treat (e.g. Defibrillator), facilitate therapy (e.g. intravenous infusion pump) or diagnose (e.g. ECG machine)

(u) Professional User

A healthcare professional using Medical Devices

(v) Procurement Team

Professional services provided to ensure robust legal process and value for money obtained for the equipment lifecycle.

(w) Re-Manufactured Device

A single use device which has been remanufactured to the same standard as the OEM product and is recertified through the CE Marking process.

(x) Service connections

May include (but not limited to) water, steam, compressed air, suction, medical gases, operating lights.

(y) Single use device:

The use of a device for one occasion and one patient use only

(z) Supplier

The manufacturer or their agents.

(aa) User Department

Clinical department/ward which owns and/or uses medical and/or loans them to end - users (i.e. a patient or carer).

(bb) User Maintenance

Inspection, calibration and device-care operations carried out by end users and professional users.

4. Duties, Roles and Responsibilities

4.1 Trust Board of Directors (Medical Director)

(a) The Trust Board has overall responsibility for the safe management of Medical Devices. The Trust's Medical Director has overall responsibility for the Trust's Management of Medical Devices and Compliance with the relevant External Assurance Standards

4.2 Trust Board of Directors (Chief Nurse)

(a) The Chief Nurse has a shared responsibility for the Trust's management of Medical Devices and compliance with the relevant external assurance standards.

4.3 Bristol and Weston NHS Purchasing Consortium

(a) To ensure robust legal and commercial process is followed to safeguard the Trust and its employees from legal challenge

(b) To provide commercial and business support to Departments, directorates and individuals wishing to purchase Medical Devices to ensure that this is undertaken to meet the requirements of NHS directives, Standing Financial Instructions and EU Procurement law.

(c) Support clinical evaluation process as an enabler

(d) To support the Trust in the implementation of the policies and procedures outlined within this document.

4.4 Head of Clinical Engineering (MEMO)

(a) To ensure that scientific and technical staff are competent and appropriately trained to work upon the Medical Devices within the Trust in line with this policy

(b) To support divisions and managers on the effective procurement and project planning related to Medical Devices and their effective utilisation and deployment

(c) To remain up to date with the latest guidelines and requirements relating to the effective management of Medical Devices and put plans in place to ensure that the requirements are implemented.

(d) To support the appropriate delivery of SOPs and policies for the safe and effective use of Medical Devices within the Trust.

(e) To review and update the Managing Medical Devices Safely Policy in line with the timeframes highlighted in the document.

4.5 Departmental and ward managers

(a) To have systems in place to ensure that staff using Medical Devices are adequately trained and competent in their use

(b) Ensuring that the Medical Devices Training Coordinator has the relevant documentation for staff training competencies.

(c) Informing the Clinical Engineering team and other inventory holders of any disposals, additions to support the accurate maintenance of the asset registers for the Trust.

(d) Ensuring that equipment is stored in a safe and secure location when not in use

(e) Completing appropriate risk assessments for devices which pose a risk to patients or staff and undertaking the necessary actions to mitigate these risks as far as reasonably practical

(f) To make available equipment for routine servicing and repairs when required by the appropriate maintenance team.

(g) To ensure that staff are aware of their responsibilities regarding the safe use of Medical Devices.

(h) To inform/ consult Procurement at the outset of consultation regarding new/ replacement equipment decision process

(i) To adhere to Trust policy for Supplier Representatives

(j) To adhere to Trust SFIs, Procurement Policy's and Legal Procurement Regulations including OJEU

4.6 Medical Devices Management Group

(a) To provide a multidisciplinary approach to monitor compliance with the Medical Devices Policy.

(b) To ensure the development of the appropriate strategy, policies and procedures for the safe, optimal and best-practice employment of Medical Devices, and to ensure organisational compliance with regulatory requirements and essential standards relating to their management and use relating to the use of Medical Devices within UH Bristol.

(c) To monitor and review the risks associated with Medical Devices within the Trust.

(d) To ratify and develop an approved Medical Device List to support the standardisation of equipment unless there is a specific clinical requirement approved by the group.

(e) To provide assurance to the Board of Directors in line by escalating appropriate information through the Clinical Quality Group and Senior Leader Team (SLT) groups.

4.7 Medical Device Safety Officer (MDSO) (MDSO@UHBristol.nhs.uk)

(a) The MDSO reviews all UH Bristol incidents reported on DATIX involving Medical Devices for identification of trends, requirement of reporting to MHRA, and to further investigate (or assist with) where required.

(b) A regular summary of these incidents will be provided for review by the Medical Devices Management Group. Any reports made to the MHRA will be kept on a central record by the MDSO.

4.8 Medical Devices Training Coordinator

(a) To provide assistance to Divisions in identifying and co-ordinating the medical equipment training needs of professional users.

(b) To develop standards of training for professional users relating to Medical Equipment in Trust wide use.

(c) To plan and co-ordinate the development and coverage of Trust-wide training programmes.

(d) To assist clinical areas to develop learning plans/packages and ensure good practice is shared.

(e) To audit compliance with the Medical Device Training Policy, e.g. spot checks on training matrices and documentation.

4.9 Divisional Patient Safety Leads

(a) To ensure the appropriate co-ordination, completion and appropriate reporting back to the MDSO of any Field Safety Notice, CAS alert or any other alerts the Trust receives.

4.10 All Staff

(a) To have read through and understood the information contained within this policy

(b) To always visual inspect the equipment for signs of damage prior to use and to ensure that the device is not overdue for service

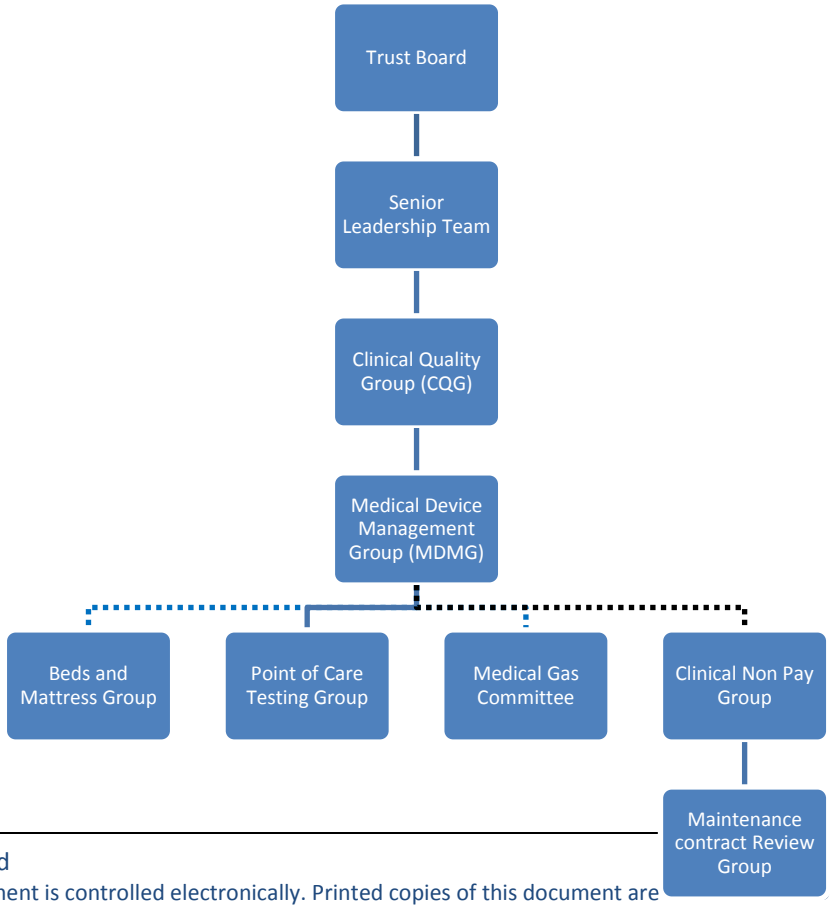
(c) That all devices are appropriately decontaminated between each patient use

(d) To escalate, isolate and report any equipment which is faulty or requires a service to the appropriate team for rectification and ensure that it available for maintenance tasks.

(e) To know where the user manuals / instructions are kept for their devices and attend the appropriate training for the Medical Devices which are utilised and only utilise devices which they are trained to do so.

(f) To be aware of the Trust Procedures for reporting an incident or near miss event.

5. Reporting Structure and links to other Committees for Medical Devices



6. Policy Statement and Provisions

6.1 Life Cycle of a Medical Device

This policy outlines the approach which University Hospitals Bristol NHSFT takes to manage the life cycle of Medical Devices. The effective management of this process will ensure that they are fit for purpose, appropriately maintained, disposed and purchased to ensure that they provide safe and effective treatment for the patients who utilise the services provided by University Hospitals Bristol NHSFT. This is effectively underpinned by continuous monitoring and assessments to ensure that the system remains fit for purpose in the dynamic healthcare environment. The Life cycle of a Medical Device can be summarised by Figure 1.

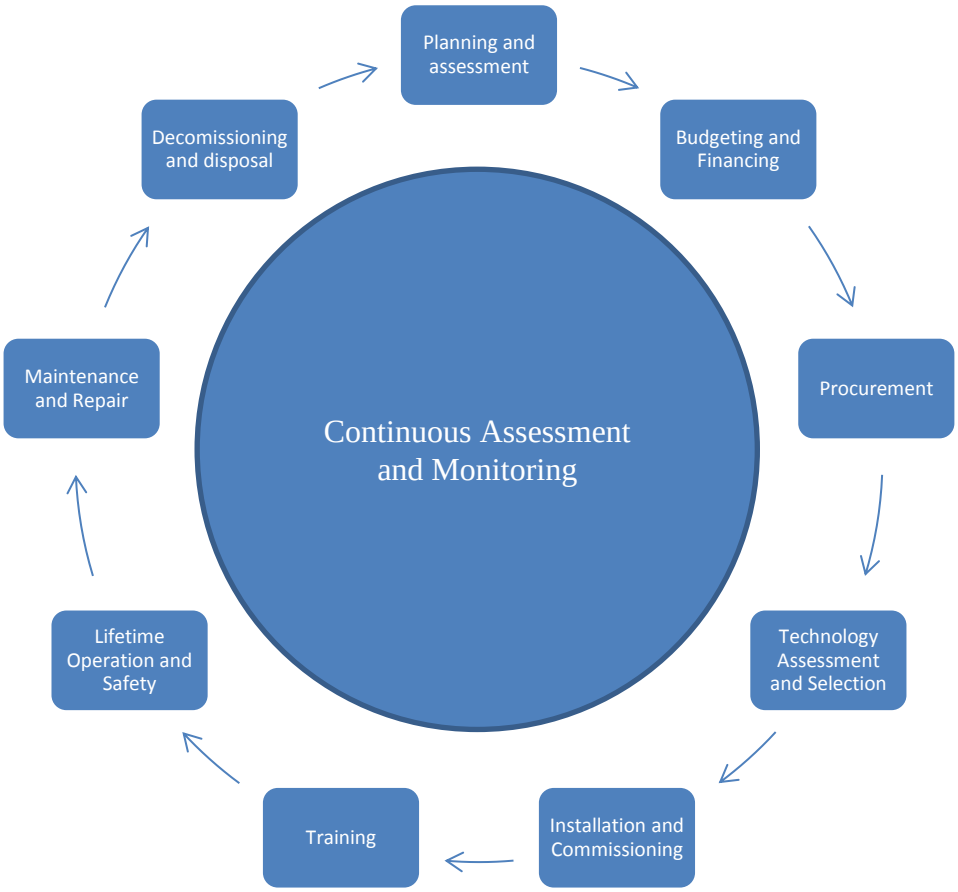


Figure 1: Medical Device Life Cycle

The approach that the Trust takes to ensure that each stage is managed effectively is highlighted within the various sections below; these sections take into account the requirements to meet the standards set out by the CQC as well as the MHRA's guidelines discussed in "Managing Medical Devices, April 2015.

6.2 Single Use Devices

Single use devices will be identifiable by the symbol highlighted below:

Figure 2: Single use device symbol

Within University Hospitals Bristol NHSFT single use devices will not be re-used or reprocessed as the re-use of single use devices can affect their safety, performance and effectiveness, as well as leading to potential infection risks for patients and staff.

Due to the practicalities of placing all single use devices on an asset register this is not undertaken. Therefore it is the responsibility of all users and managers of single use devices to ensure that they are appropriately operated by users and are not reused.

Under no circumstances will repair or maintenance tasks be undertaken on a single use device within University Hospitals Bristol NHSFT, if these devices are not functioning correctly then the issues will be escalated directly to the manufacturer of the device or the MHRA depending upon which is the most suitable course of action.

Further details of Single Use Devices can be found within the Trust's Decontamination Policy.

Disposal of Single use devices will take place in line with the Management of Waste Policy and SOPs.

6.3 Re-manufactured single use items

The remanufacture of single-use Medical Devices (SUDs) involves the inspection, cleaning, changing of components (if applicable), testing, sterilising, and repackaging of previously used SUDs. Crucially, a remanufacturer must obtain a CE-mark from a 'Notified Body' (such as the UK Medicines and Healthcare Products Regulatory Agency [MHRA]) to ensure that remanufactured SUDs meet the same safety and functionality requirements as a new, original equipment manufacturer (OEM) device. The remanufactured device would be placed onto the market or put into service as a single-use device.

It is estimated that remanufacturing of SUDs presents an opportunity to deliver direct savings of £4.4m-£18.2m p/a for the NHS.

The 'single-use' label is not imposed by a regulator, but independently designated by an OEM to signify that they cannot, or will not, accept liability for the product beyond a single use. However, many or all components of the device may actually remain serviceable beyond a single use. It is therefore possible for a remanufacturer to develop their own technical specifications in order to disassemble, clean, change components (if applicable), reassemble, test, sterilise and repackage devices as part of a regulated remanufacturing process.

Remanufacture is referred to in many countries as 'reprocessing'. The UK, however, defines 'reprocessing' as merely the cleaning and sterilisation of devices, with no regulated process for placing the product on the market under a new CE mark. A single-use device should never be reused (i.e. the SUD reprocessed or used again on a patient), but either disposed of or returned to the remanufacturer if appropriate. Reuse of single-use devices that have merely been 'reprocessed' is prohibited.

Remanufacturing is regulated and assured through the CE marking system overseen by the UK Medicines and Healthcare Products Regulatory Agency (MHRA). The remanufacturer takes on liability/obligations for the device, to the same extent as an OEM. Patient consent is not required to use remanufactured SUDs, as they are equivalent to OEM versions.

Cardiovascular • Blood Pressure/Tourniquet Cuffs* • Cardiac Stabilization & Positioning Devices • DVT Compression Sleeves* • Electrophysiology (EP) Cables • Diagnostic EP Catheters • Pulse Oximetry Sensors* Orthopaedic/ Arthroscopic • External Fixation Devices*	Laparoscopic • Endoscopic Trocars & Components • Harmonic Scalpels Gastroenterology • Biopsy Forceps General Surgery • Balloon Inflation Devices • Infusion Pressure Bags*
* Class I SUDs not currently permitted for remanufacture by the MHRA. Compression sleeves may be Class IIa if they use a powered pump.	

Table 1: Areas where Re Manufactured devices are most commonly used

University Hospital's Bristol will accept the use of Re-Manufactured devices if they are assured through the CE Marking system and liability and obligations for the device are the same as the OEMs. The product should deliver the same functionality as the original device. Where such a device is used a risk assessment from the using department will be undertaken to ensure that the Risks are acceptable to the Trust and have no adverse effects upon patients.

For areas wishing to explore the use of these devices advice should initially be sought from Bristol and Weston NHS Purchasing Consortium and/or Clinical Engineering if the item is used in association with a Reusable Medical Device.

Under no conditions will single use devices will be remanufactured in-house.

6.4 Point of Care Testing Devices

Point-of-Care Testing (POCT) refers to any analytical test or procedure performed for a patient by a healthcare professional outside a conventional, accredited laboratory environment. POCT is also variously known as near-patient testing (NPT), bedside testing and extra-laboratory testing.

OR

'Near-patient testing is testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient' [ISO 22870:2006]

OR

'POCT is defined as any analytical test undertaken by a member of the healthcare team or by a non-medical individual in a setting distinct from a normal hospital laboratory' [Royal College of Pathologists, 2004]

All Medical Devices which fall into this category will be managed through the Trust's Point of Care Testing policy:

6.5 Inventory and Identification of Reusable Medical Devices

To ensure that there are appropriate records of the Reusable Medical Devices the Trust utilises a series of asset registers containing details of all of the reusable Medical Devices within the Trust, these outline as a minimum requirement:

- Unique Identifier, e.g. a Clinical Engineering (MEMO) number
- The purchase price of the device
- All the identifiable information to allow the device to be located e.g. Serial number, Model, Category of equipment, manufacturer
- Details of repairs, routine servicing or actions resulting from a safety notice
- Anticipated end of life date.

The various asset registers are held within:

- Clinical Engineering (MEMO)
- Estates (for infrastructure and plant equipment)
- Pathology (for Point of Care Testing)
- Pharmacy
- CSSD (for items which require reprocessing)

7. Procurement of new Devices

All Re-usable Medical Devices which are purchased by University Hospitals Bristol NHS Foundation Trust must adhere to the Trusts Standing Financial Instructions (SFIs) and EU/Government Directives to ensure fair and open competition to ensure the best value for money.

All equipment utilised within the Trust should be appropriately CE marked, covered under the Medical Devices Directive: 2017/745 and 2017/746 and be deemed fit for purpose. The only exception to this rule is devices which are being utilised for research or clinical evaluation which are covered within the research section of this policy.

Table 2 highlights the various financial controls and processes which must be undertaken to ensure compliance with SFIs and all EU/Government Directives relating to public sector spending.

Value of Purchase	Process	Authorisation
<£5,000	Best value sought but requisitions can be placed to order goods	Heads of Service/delegated budget holders
>£5,000 < £24,999	3 written quotes for product received.	Divisional Director and Director of Purchasing and Supply
£25,000 – £100,000	Three Competitive Tenders received against a specification for goods or services	As above plus Director of Finance
>£100,000	OJEU Tender received against a specification for goods or services.	As above plus Chief Executive/Trust Board

Table 2: Purchase Value, Process and authorisers for purchase of goods and services

A simplified version of the procurement flow chart is shown in Figure 3, whilst not going into the detail of each step it demonstrates the necessary steps required to ensure the equipment purchased is fit for purpose.

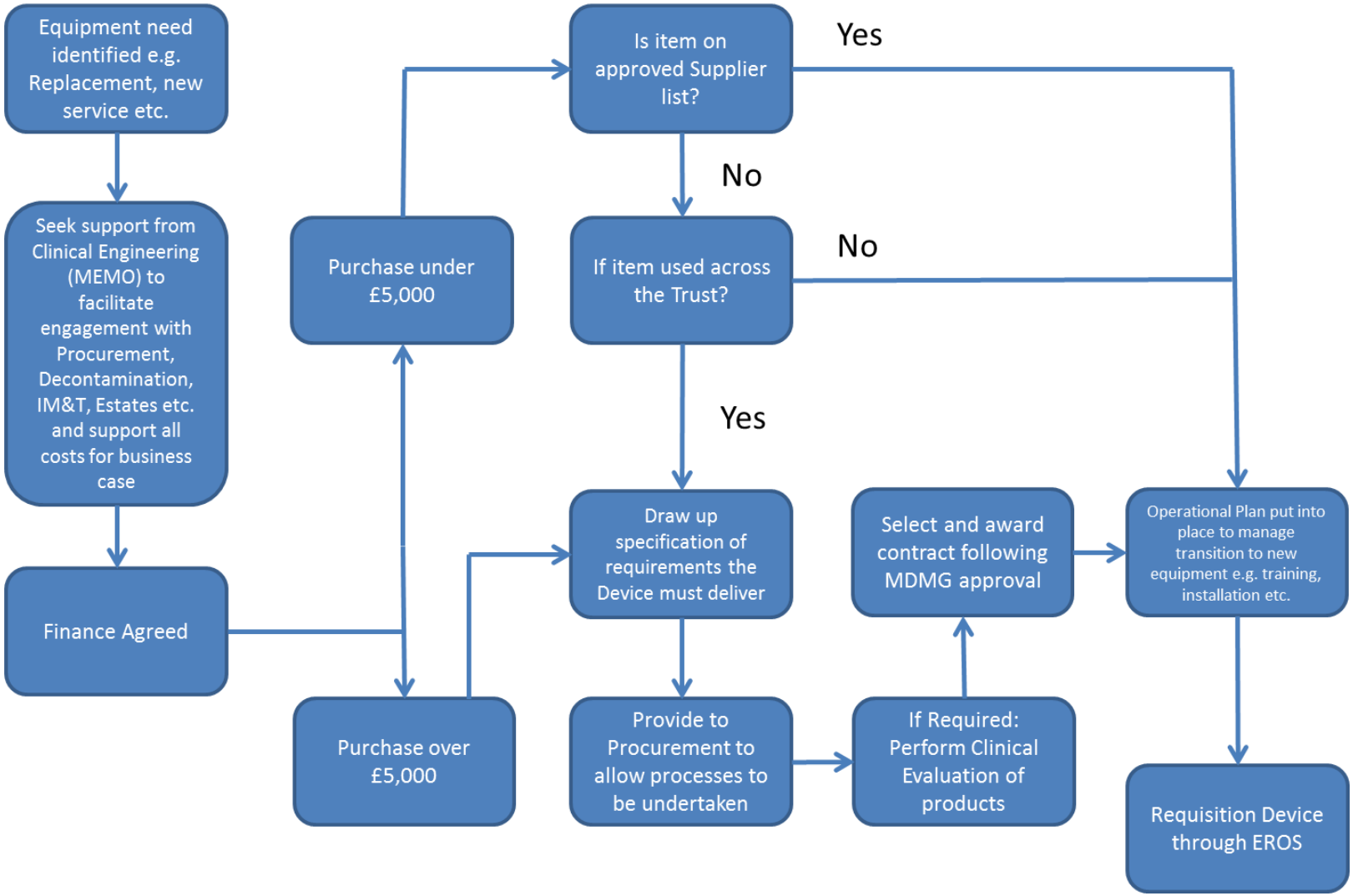


Figure 3: Purchasing of Reusable Medical Devices Flow Char

7.1 Consumable Deals

There are various circumstances which arise where suppliers offer Medical Devices as part of a consumable agreement. An example of this type of agreement would be:

E.g. where the Trust purchases 'x' number of warming blankets they get 'y' number of blanket warming devices

These deals are essential to ensure the safe and effective operation of many procedures within the Trust and have capital financial advantages as they allow revenue purchases which will happen anyway to support the capital requirements to deliver a treatment.

To set up a consumable deal, Procurement and Clinical Engineering (MEMO) should be involved at the OUTSET to ensure regulatory compliance and that these devices are appropriately inserted into the asset register, maintenance is agreed and managed and that the agreement is procured utilising appropriate methodology to ensure the best value for the Trust.

7.2 Replacement of Assets

All Medical Devices supporting service delivery are expected to be reliable and safe to use. Risks arise in many shapes and forms through the use of a Medical Device in practice. Replacement should be planned when the risks of using the device outweigh the benefits e.g. it becomes unsafe to use, no longer producing clinically acceptable results or the technology within it becomes obsolete and can no longer be supported. All Medical Devices within the Trust will be allocated a realistic lifespan of between 5 – 10 years when purchased where the device is expected to fulfil its requirements and should in an ideal world be replaced.

Clinical Engineering will support the divisions to help them identify devices where they are technologically beyond their working life or become obsolete from technical support. Divisional ward and departmental managers will work with professional users to determine the clinical position. This multidisciplinary approach will ensure that technical and clinical considerations are taken into account as part of the replacement programs undertaken by the Trust.

All replacement of devices should take place in line with the latest technological advances and in line with the Trust's strategic direction to ensure that University Hospitals Bristol NHSFT can deliver cutting edge treatment to users of the Trust with the right equipment available.

7.3 Equipment Trial and Evaluation

All marketing and product evaluation trials must be conducted in partnership with Bristol and Western NHS Purchasing Consortium and other relevant departments e.g. Clinical Engineering (MEMO), Manual Handling etc. to ensure that the equipment being utilised has been tested and is safe to use and that they are conducted appropriately to ensure the information can be utilised as part of the procurement of the device if necessary.

Clinical Engineering will ensure that the supplier is party to the NHS Master Indemnity Agreement, or arrange for an individual indemnity to be provided and that the guidelines are adhered to.

Approval must also be sought from the Infection Prevention and Control Team, and advice taken from other relevant Trust advisers as appropriate e.g. IM&T, Estates, Clinical specialists, Medical Physics for any device involving radiation exposure (including Lasers) prior to the trial taking place.

Any device requiring decontamination through CSSD or an automated endoscopic reprocessor should have all reprocessing information sent through to the Trust Decontamination Manager to approve the process

prior to the device being purchased by the Trust to ensure that reprocessing can take place and that the device can be appropriately decontaminated.

N.B. Any connections to the Trust's IT network required as part of any trial IM&T should be notified in advance of the trial taking place as part of the agreement to trial.

For all devices, all trials and evaluations must be conducted as part of the tendering process.
An evaluation report and recommendations must be available for scrutiny and signed off by the project lead/s.

Clinical managers or project leads must ensure that all reusable Medical Devices are functional tested (including Electrical safety testing) by Clinical Engineering (MEMO) prior to commencement of the trial.

7.4 Indemnity process

To ensure that the Trust is protected upon receipt of equipment or goods from a supplier an appropriate indemnification process is undertaken. This is in line with the Department of Health Guidelines:

As part of this guideline there is a form to be completed. This form is available via the link above and is called the "MIA call off agreement" form. This form should be filled in and signed irrespective of whether the device in question is being loaned to the Trust for evaluation, or given to the Trust as a gift.

The supplier concerned should have signed up to the MIA overarching agreement scheme. The form for suppliers to sign up this scheme is also available via the link above. A list of suppliers who have signed up is also available via the link above and the list contains the expiry date of their current insurance certificate.

If a supplier has not signed up to the Overarching Agreement they may still provide equipment to the Trust as long as they can prove they have the relevant insurance cover. A signed copy of the certificate must be provided to the Trust for evidence. A copy should be provided to the MDSO for review and recording on the Asset Register.

There are also guidance notes available via the link which explains how the system works.

Any loan of Medical Devices through this process must be accompanied by appropriate clinical training and also an appropriate methodology of dealing with the routine servicing (if required) and the appropriate actions to take should the device become faulty during the trial period.

All items which come into the Trust through this process will be managed by the appropriate area conducting the trial, for Clinical Engineering teams the loans will be communicated to the MDSO team for record keeping. All loans should be recorded on the Clinical Engineering Asset Management System. Work Orders should be raised outlining details of the device and the purpose for the loan

7.5 Standardisation of Devices

Standardisation of Medical Devices has a number of advantages for the Trust. These are:

- Reduction in risk as staff will only need to be trained in one product type rather than many reducing the risk of patient harm

- Reduction in purchase cost and maintenance costs, bulk deals with suppliers often lead to greater economy of scale. Maintenance costs will be lower as Clinical Engineering (MEMO) will need to

hold fewer varieties of spares again increasing economies of scale on spare part purchasing, reducing down time of equipment.

Strategic purchasing will take place with the aim to standardise models which are commonly used across the Trust with the aim of achieving the above advantages. Candidates for this type of purchasing will include but not exclusive to:

- BP/SPO2 Monitors
- ECG Recorders
- Infusion Devices
- Thermometers
- ITU Equipment
- Beds, etc.

To ensure compliance with the necessary procurement directives purchases will be made through an appropriate supply contract with the supplier following a tender/evaluation process covering a period of between 2 – 5 years subject to the anticipated technological/medical developments.

7.6 Critical Equipment

Critical Equipment will be monitored through the MDMG to ensure that appropriate controls and measures are in place to ensure that the risk of patient harm is minimised. When purchasing new equipment all pieces of equipment will be assessed to determine if they are critical and measures required to maintain continuity of service will be considered as part of the whole life cost of the equipment purchase.

Each Division is responsible for maintaining their list of critical equipment ensuring it is accurate and up to date. There will be a relevant SOP linked closely with the business continuity plan for each division outlining how they manage the various approaches relating to their critical equipment to ensure business continuity of the various services which operate.

The Critical Equipment lists for each division can be found by following the link.

8. Loan of Devices

8.1 To another healthcare provider or another organisation

It is essential to ensure that the legal liabilities that may expose the Trust to litigation are managed and controlled with regard to instruments and other Medical Devices which are loaned to third party or other healthcare providers.

Departments and wards that loan equipment to other healthcare providers must keep accurate records to include device make, model, serial number, contact information and that any consumables or accessories supplied with it are appropriately documented to ensure safe return of equipment.

Clinical Engineering must always be informed that the device is out on loan through reporting to the MDSO, Clinical Engineering Team Leaders or appropriate Asset Register Holder. This will ensure the accuracy of the various asset registers are maintained and will prevent time being wasted looking for a device which is not

on site for service or if a MHRA Safety Alerts requires actions on a loaned device. It will also provide contact details of the person who issued the device on loan and for how long to support this process.

Equipment must not be loaned to other non-NHS Organisations without the appropriate approval of the Division Director and notification to the Asset Register Holder.

If a device is on loan prior to a procurement process being undertaken Procurement must be informed to prevent influencing the outcome of any forthcoming supplier engagement

8.2 To a Patient

Circumstances arise where it is necessary for Trust equipment to be loaned to a patient to ensure effective ongoing treatment to them outside of a Hospital setting into the community e.g. Nebuliser, CPAP Devices etc.

Local protocols must be in place to ensure any healthcare professional with a responsibility for prescribing equipment has the appropriate qualifications, experience and training to do so.

The issuing department must ensure that the end user receives appropriate training and that training is supported by written manufacturer's instructions in a format which enables the end user to understand both the safe operation and user maintenance required for the issued equipment. Contact numbers for operational and technical support must also be provided. The Trust expects that the MHRA Checklist for Patients discharged with a Medical Device is followed.

The department should also check that maintenance contracts are in place and funding for this is arranged with the local commissioners.

The end user should sign a written statement, confirming that they have received and understood the instruction and information given and retained by the department. The form of training provided should be documented in the patient's notes e.g. verbal, written, practical demonstration.

The issuing department is responsible for ensuring that appropriate documentation is available documenting which patients have which pieces of equipment should the need arise to recall the devices in response to a Field Safety Notice or Central Alert from the MHRA, as well as being in a position to recall devices for service as they reach their maintenance due date.

8.3 From a supplier

Any loans of Medical Devices from a Supplier will follow the indemnification process outlined within this policy. For any advice relating to the loan of Devices to a patient for standard clinical practice, contact Clinical Engineering or Bristol and Weston NHS Purchasing Consortium.

For any item which is being loaned as part of a clinical trial please follow the approach undertaken in section 10 of this policy and discuss with the Research and Development department.

9. Training

9.1 Training of Clinical Staff/instructions for use

This policy should be read in conjunction with the Medical Device Training Policy which contains the full details of how training of clinical staff is undertaken within UH Bristol

All Medical Devices have been prioritised into appropriate user training risk categories to ensure that staff utilising the devices do so are appropriately trained and this training is monitored. The risk categories are defined in Table 3:

Clinical User Risk Category	Definition
High Risk	Medical Devices where use error, misuse, misinterpretation, or equipment failure could have immediate and potentially severe consequences to either patient or staff e.g. ventilators, anaesthetic machines, invasive monitoring, and resuscitation equipment.
Medium Risk	Medical Devices where misuse or, failure or unavailability would have a significant impact on patient care but is unlikely to cause serious harm, or, where clinical decisions would only be likely to be made alongside other diagnostic indicators e.g. non-invasive vital signs monitoring equipment and electric beds.
Low Risk	Medical Devices whose misuse or failure is unlikely to result in serious consequences for patients or staff. E.g. Examination Lamps

Table 3: Risk Category definitions for Medical Device Training

Clinical training records for sessions undertaken by the Medical Devices Training Co-ordinator will be collated and monitored within this area, however each ward manager should have a record of all clinical staff upon their wards and their levels of competence with the Medical Devices they will come into contact with.

Any agency / temporary / bank staff should have evidence that they have received appropriate training to allow them to safely operate any Medical Devices they may be asked to use in the area in which they are working. Records of such competencies, temporary / bank staff to be kept by the temporary staffing bureau and /or the department involved. Agencies are required to provide confirmation that staff provided, have received appropriate training for Medical Device in use in the area in which they are working.

A clinical training needs analysis will be undertaken by the procuring manager as part of any new equipment purchase that the Trust undertakes. It is anticipated that any new device not previously utilised within the Trust will have clinical staff competency training, as well as technical training included as part of the procurement of the device. Existing equipment should also have a training need established to ensure that staff receive refresher courses on the safe use of a device and to ensure that there have been no changes to the protocols or best practice in utilising the device.

9.2 Technical Training approach

A technical training program will be managed by the Head of Clinical Engineering (MEMO) to ensure any repairs or technical work undertaken on a Medical Device by UH Bristol employees are completed by competently trained individuals and they are appropriately signed off as competent.

An appropriate risk assessment utilising standard methodology will be undertaken to assign a risk category of devices within the Trust. Staff will be required to comply with the below principles of technical training prior to undertaking maintenance tasks upon a Medical Device.

Clinical Engineering Risk Category	Definition
High Risk	Manufacturer training must be demonstrated prior to work being undertaken upon this type of device.
Medium Risk	Where possible technical training from manufacturers will be undertaken to demonstrate an appropriate level of competence for these devices. However where this is not possible formal in-house training appropriately signed off by a member of the Clinical Engineering team and authorised by a service lead or Head of Clinical Engineering (MEMO) is acceptable. The internal competency forms will be assessed as part of the staff member's appraisal.
Low Risk	Working alongside departmental protocols and procedures combined with the qualifications of staff working within the department is deemed an acceptable level of competence for these devices as they are unlikely to cause harm to patients or service users. However where possible in-house training competencies signed off by an appropriate trainer will be utilised to demonstrate the appropriate level of competence.

Table 4: Medical Device Training Priorities

A prioritised technical training plan will be generated by Clinical Engineering (MEMO) on an annual basis. This will ensure in-house staff who undertake technical work on UHB sites are competent to do so.

A central record of all training undertaken by Clinical Engineering (MEMO) staff will be held centrally outlining their appropriate level of competency to undertake the roles required of them. This will be regularly reviewed at least annually as part of the appraisal process. Any updates required to maintain competency will be delivered in line with the prioritised training plan outlined in the point above.

10. Research/Medical Device Developments, Modifications and Trials

Medical Devices should not be used for any purpose other than what it was designed for unless it is part of an approved research scheme. “In-house” manufacture or modification of a Medical Device must comply with the Medical Device Regulations at the design, manufacture and clinical evaluation stages.

All clinical trials must be registered with and approved by the Research and Development department to ensure that compliance to ethics and governance issues are completed prior to the trial starting. Further information on the requirements to undertake this can be found on the Research and Development connect page.

11. Maintenance

11.1 In House Maintenance

To ensure the protection of patients and staff against failure or malfunction of reusable Medical Devices appropriate maintenance programs should be in place to ensure items are appropriately functioning. All devices maintained within the Trust should be undertaken in such a way to ensure that appropriate measures are in place to ensure the safety and integrity of the device is maintained.

In house servicing by Clinical Engineering will be undertaken in line with the principles which are demonstrated within the risk categorisation in Table 5. A regular review of the maintenance frequencies will assess the latest evidence and supporting information to ensure that the intervals agreed still meet the requirements necessary to ensure patient safety and clinical governance.

Maintenance Risk Category	Definition
High Risk	Equipment is maintained in strict accordance with the manufacturer's service procedures. Where in-house maintenance is not possible, an external service contract with an accredited service agent will be required.
Medium Risk	Equipment is maintained in-house or by an accredited service agent or a third-party service-provider. Work is generally carried out in accordance with manufacturers' recommendations, but may be varied where experience identifies the need or justifies the change. The decision-making process for varying manufacturers' instructions must be documented.
Low Risk	Equipment receives the minimum maintenance necessary to comply with statutory requirements

Table 5: Risk Priorities and impact on Maintenance

All Devices which are used within the Trust will have an appropriate record of their next service due date. For devices which are maintained by Clinical Engineering the next service due date is identified with a yellow sticker upon the Device as well as being centrally recorded in the Trust's asset register. A program of items requiring servicing each month will be available through the Clinical Engineering Team for those devices which are maintained by Clinical Engineering.

All professional users must ensure that the device is within this service period prior to its use and where it falls outside this date the planned maintenance should be arranged before it is put into use again. Whilst Clinical Engineering aim to ensure that routine maintenance is undertaken on the devices within their asset register, responsibility for ensuring that a device is serviced remains with the professional users. Use of a Medical Device outside of its service date is only permissible if the impact on patient safety exceeds that of not using the device. If this is the case then the situation must be raised as a DATIX incident.

All devices are appropriately risk assessed to evidence the category which they have been placed within. This tool is available within Clinical Engineering and has been developed based upon best practices adopted in other Trusts, IPEM information as well as Clinical Engineering National Performance Advisory Group (NPAG) templates.

Where Divisions elect not to have an item on a maintenance agreement with Clinical Engineering an equivalent level of cover with the Manufacturer or 3rd Party supplier is required to ensure compliance with the necessary information within this policy and appropriate assurances kept.

All professional users should ensure that settings are checked prior to use as settings may have been changed/altered as part of the service undertaken to ensure that the appropriate range of tests are completed. Every effort will be made to ensure that they are returned either in a mode which minimises the risks to patients or in the setting which they were configured to when arriving for service.

11.2 Repair Service (Corrective Maintenance)

Medical Devices can and do fail as part of their routine usage. The process which is followed to ensure that if they can be repaired the appropriate documentation and competency of the repair undertaken is assessed.

All equipment which requires repair should be appropriately decontaminated to ensure the device is appropriately clean prior to technical staff undertaking work upon it. There are various decontamination certificates to highlight this, E.g. Clinical Engineering's DC1 form for any item being returned to Clinical Engineering, Suppliers decontamination forms prior to returning items to a supplier for repair

All Medical Equipment which requires repair should be reported as soon as possible to the appropriate responsible party, where this is unknown then contact Clinical Engineering's Central Response on ext. 23333 as a starting point. While awaiting repair or collection of the device it must be appropriately labelled as requiring repair with the full description of the fault and who first identified it as faulty so any follow up discussions e.g. further discussion of the fault can be undertaken. It should be stored in a designated place away from the fully functioning stock to prevent accidental deployment back into use.

Under no conditions should a device that has been identified as faulty be used by a professional user.

Professional Users are expected to check that all controls and specifications for use are within the parameters expected prior to the device being redeployed and utilised on a patient, extra vigilance should be undertaken during the first use of the device following it being returned from repair or service.

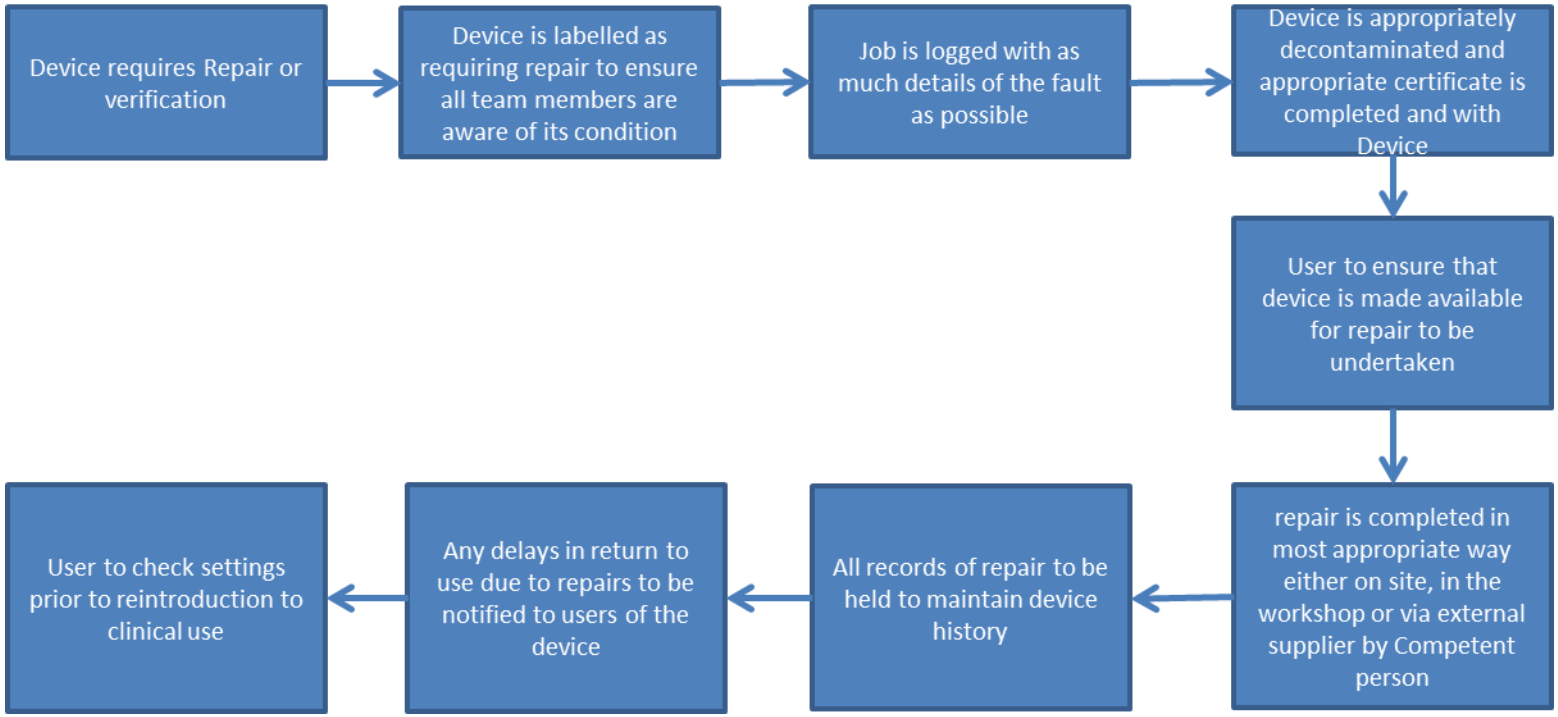


Figure 4: Repair/Verification simplified process

11.3 External Maintenance Contracts

Due to the complex nature of the Medical Devices which are used throughout the healthcare environment it may not always be possible for in-house Clinical Engineering staff to perform the repair or routine servicing on a range of Medical Devices. This may be due to a number of reasons (some of which are highlighted below):

- Technical competency within the Clinical Engineering team is unavailable and not possible to obtain from the supplier or manufacturer.
- It is more cost effective to utilise an external maintenance agreement with a supplier
- To ensure compliance with all the necessary guidelines
- Added benefits, e.g. availability of loans, speed to rectification which is unable to be duplicated in-house.

Maintenance contracts will be agreed with either original equipment manufacturers (OEMs) or they will be agreed with a 3rd party supplier of maintenance, who are not the original equipment manufacturer for the device but are able to offer the level of cover required to maintain effective performance of the device. Each of these approaches has advantages and disadvantages which are shown within the table below:

Agreement type	Advantages	Disadvantages
OEM Agreement	The equipment will be returned to manufacturers specifications in line with their latest test procedures Availability of spare parts will be of OEM standard No problems with warranty of the device following maintenance by OEM. Availability of latest loan devices for breakdowns is increased	Have to deal with many suppliers for the full range of device maintenance agreements each with different contacting/reporting processes for faults and breakdowns. Often these agreements are higher cost than 3rd Party. These contracts may have finite life cycles which can impact capital planning processes due to obsolesce of support.
3rd Party Supplier agreement	It is possible for a wide range of devices to be managed by one supplier rather than many, making renewal negotiations easier. Financially often the cost for a 3rd party agreement is lower than that of an OEM Agreement. It is possible to have a single point of contact for maintenance on various devices Can elongate an Asset lifetime as 3rd parties may be able to supply stock or support for longer than OEMs	Spare parts utilised upon devices may not be of original standard. There may be devices which cannot be added to an agreement due to complexity etc. Time for the device to be returned to service may be longer Tests undertaken may not be in line with manufacturers information Training and competency of staff may not have come from original manufacturer of the devices May lead to “pre contract inspection” costs to return to OEM spec if returning to OEM.

Table 6: Advantages and Disadvantages of 3rd Party Contracts and OEM Contracts

University Hospital’s Bristol utilises a combination of these various contracts to ensure that it provides a cost effective service whilst ensuring that the quality of the tasks undertaken ensure a safe service delivery to patients and users of the Trust. Each type will be considered as part of the Trust’s maintenance strategy and which meets the needs for the Local Manager.

Most service providers regardless of if they are 3rd Party or OEMs tend to offer varying levels of cover. These often fall into one of 3 categories however the terms and conditions of these may vary between suppliers or may not be available from all suppliers:

- Routine service only – this will be an agreed number of services undertaken through a year and the necessary spare parts required for these planned visits. Any repairs required including labour and spare parts will be an additional cost to these contracts. These are often the lowest price for the contract but additional costs may be high.

- Routine service plus any labour associated with repairs, so any callouts for breakdowns will be covered as part of this contract but spare parts will be charged extra for these agreements, there may be a discount on spares or priority response times as part of these agreements.

- Fully Comprehensive – the majority of these will cover the complete costs of all services and repairs relating to the Medical Device. There may be some exceptions as to what is covered but this is the highest level of cover and as such the costs reflect the risk undertaken by the supplier.

All maintenance contracts set up within the Trust should adopt a multidisciplinary approach coordinated between the highlighted teams within Figure 5 to ensure value for money and clinical governance. Each team has a specific role to undertake as part of this process to ensure the appropriate level of cover and the appropriate supplier are agreed between all parties:

- Clinical Engineering (MEMO) – will lead on all external maintenance (within the scope of this policy) on Medical Devices within the Trust. These should be agreed by Clinical Engineering to ensure that the contracts deliver the necessary maintenance requirements to ensure compliance with the appropriate Legislation.

- Procurement – will ensure that all the NHS Procurement protocols are adhered to and appropriate process has been adhered to, to ensure a competitive process has been undertaken.

- Finance will monitor and ensure that best value for money has been obtained and agreed and that finances are in place to set up the contract.

- Local Management teams – will ensure that the appropriate level of cover is selected to suit their needs, to provide the criteria of what is required. To review the options provided by Clinical Engineering and select the best option to meet clinical and operational requirements.

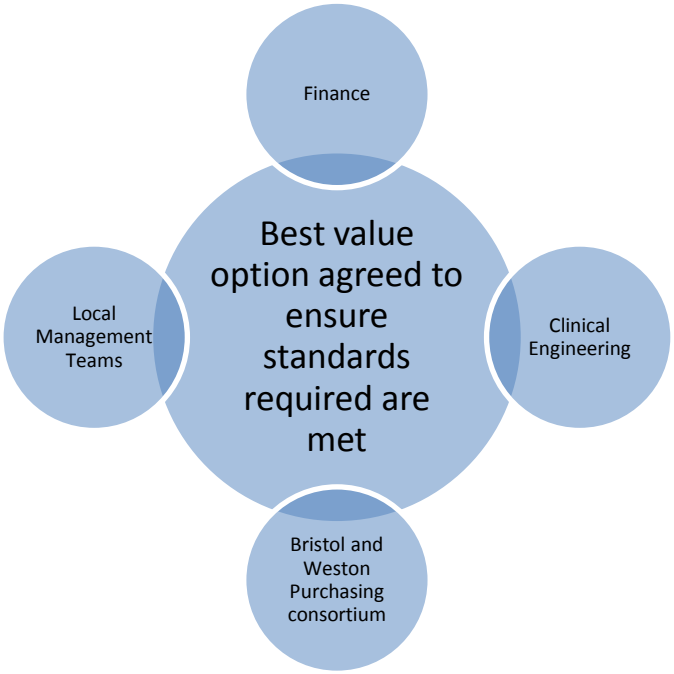


Figure 5: Stakeholders to ensure most cost effective use of support contracts

11.4 Acceptance Testing

Appropriate acceptance testing ensures that the device delivered to the Trust meets the requirements of the organisation and is in line with the specification utilised to procure the device. Simple checks upon delivery can prevent longer term costs and future disputes with the supplier regarding the device. Through appropriate acceptance checks it is possible to avoid unnecessary delays to clinical care as it is possible to identify any issues with a device prior to patients being booked in for procedures requiring use of the new device

All acceptance tests within University Hospitals Bristol will consist of the following principles for new devices which enter the Trust:

Acceptance Test Process	Details
Documentation	The creation of all documentation relating to the lifecycle of the device is maintained and stored appropriately, some examples would be: • ensuring procedural documentation for maintenance are created • it is added to an appropriate routine service schedule • the asset is added to the Trust's asset register etc. • appropriate training documentation is in place • risk assessments for the safe use of the device are put into place
Configuration	To ensure that health and safety issues relating to the device are put

	into place, some examples would be: • for laser equipment or X-ray equipment ensure the room requirements are appropriate to meet the safety standards expected • ensure protocols are appropriately set up on the device for drugs libraries etc. • ensure that the IT/Estates infrastructure and installation work is undertaken etc. • ensure appropriate links are set up to patient systems which are needed to document results where required.
Acceptance Test process	Technical tests required to ensure that the device is safe and fit to be utilised in clinical practice, some examples would be: • functional tests, • electrical safety tests • performance verification tests

The acceptance testing process and responsibilities are outlined in Figure 6, outlining the process for local Clinical Engineering managers to add items to the in-house service schedule with Clinical Engineering and ensure that devices enter the organisation are efficiently and safely brought into clinical use.

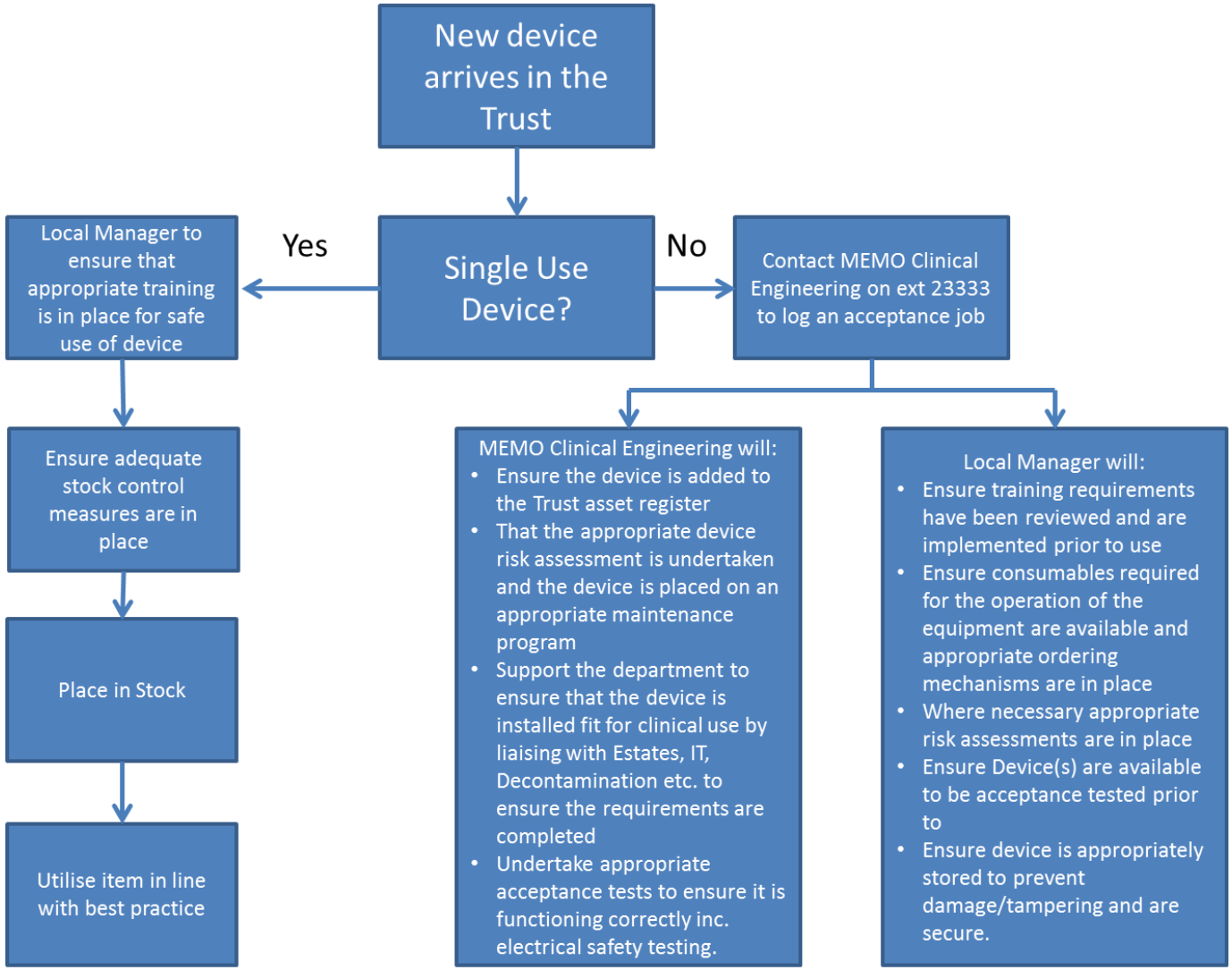


Figure 6: Acceptance Testing procedure and responsibilities

11.5 Prescription and use

The Trust requires that all prescribing decisions are made by staff with appropriate healthcare professional qualifications, training and level of experience. These decisions will be supported by appropriate administrative, clinical and technical support to ensure the actions are carried out.

If a device is prescribed for end users to use outside Trust premises; records identifying the make, model, serial number or Clinical Engineering (MEMO) number of the Medical Device, must be maintained alongside end user contact details by the department issuing the device to ensure that maintenance can be carried out upon the device where necessary or it can be recalled to comply with any safety notifications.

All divisions are required to provide assurance that clinical departments maintain adequate records (often contained within patients notes) for all implantable devices and disposable point of care testing kits used on patients e.g. pacemakers, orthopaedic implants, intraocular lenses, pregnancy testing kits. As a minimum these records should contain:

- patient's contact details
- make /model
- serial number (where applicable)
- expiry date of the device (Where applicable)

(a) End user training:

Local protocols must be in place to ensure any healthcare professional with a responsibility for prescribing equipment has the appropriate qualifications, experience and training to do so.

The issuing department must ensure that the end user receives appropriate training and that training is supported by written manufacturer's instructions in a format which enables the end user to understand the safe operation and user maintenance required for the issued equipment. Contact numbers for operational and technical support must also be provided. The Trust expects that the MHRA Checklist for Patients discharged with a Medical Device is followed.

The department should also check that support contracts are in place and funding for this is arranged with the local commissioners

The end user should sign a written statement, confirming that they have received and understood the instruction and information given and retained by the department.

(b) Refusal of patients or carers to have/use a prescribed device:

If a patient or carer refuses equipment used for their prescribed treatment and a mental capacity assessment indicates that the patient is capable of taking that decision the following action should be taken to ensure;

- That the patient/carer understands why this device has been prescribed and the importance of the device in the treatment they require.
- That we understand why they are refusing to use the device.
- That the patient/carer understands the implications of not using the device.
- That the patient/carer is aware of any alternative options and is making an informed choice
- That any associated discussions and Regulations are dated and documented in the

patients notes.
- Relevant members of the multidisciplinary team are apprised of the situation.
- A clinical incident form is completed so that possible trends can be identified.

Where a patient is not capable of taking the decision following a mental capacity assessment the Mental Capacity Act Policy should be followed.

11.6 Use of Spare parts/Consumables

Types and quantities of equipment spare parts and consumables held in stock will be optimised to minimise on-site stock holdings (thereby reducing expenditure, wastage and storage requirements), whilst holding sufficient stock to achieve minimal equipment servicing downtimes (i.e. avoiding equipment servicing delays resulting from unavailability of necessary parts/consumables). Decisions upon types and quantities of stock held should be based upon considerations of criticality, demand and delivery times from suppliers of spare parts.

Inventory management should ensure traceability of spare parts and their usage in equipment servicing. Parts and components used during servicing activities should be identifiable in the equipment's servicing history; any critical parts used need to be delivery-referenced and individually traceable to the original supplier in equipment servicing records.

Whilst manufacturer approved spare parts and consumables are the preferred spare parts to be used in the servicing of Medical Equipment. However use of non-approved goods may be used as an alternative where the use of them does not affect the performance of the device or have a detrimental effect on the safety of staff or patients. Where these are used a competent person will assess the compatibility with specifications and ensure that any associated risks are understood and managed.

Pre-used parts may be used for equipment servicing in exceptional circumstances, however the use of these must be justified by a full documented risk assessment, supported by knowledge of the particular part's history and this should be documented upon the service history of the device.

Approval of risk assessments is the responsibility of the Head of Clinical Engineering and authorised deputies.

11.7 Batteries

Batteries will naturally discharge over time. If they are not tested and regularly replaced or recharged, they may not operate correctly when required clinically and may even become damaged, due to extensive discharge.

For example, some patient monitors and infusion pumps have battery capacity indicators. If the batteries have not been charged in line with the manufacturer's instructions, the indicator itself may not give an accurate reading. This can result in the device shutting down unexpectedly. Therefore the indicators should be used for guidance only.

The management of batteries within a Medical Device will be monitored and replaced within UH Bristol as part of the routine servicing of the device undertaken by Clinical Engineering (for items requiring dismantling) or it will be undertaken as part of functional checks undertaken by users. The frequencies of battery replacement will be in line with manufacturer's recommendations, local knowledge of the use of the device including risk category/criticality of device and known failures of the batteries within these items.

11.8 Incidents involving Medical Devices

No device involved in a clinical incident should be put back into use until it has been appropriately investigated and found to be working correctly.

The Clinical Engineering (MEMO) Inventory Number and/or Serial number must be recorded on the clinical incident form so it is possible to track the item as required.

In addition to the Trusts own local procedures for reporting clinical and non- clinical incidents, ***any event involving a Medical Device, consumable or point of care testing device that gives rise to, or has the potential to produce unexpected, or unwanted effects, involving the safety of patients, users or other persons, should be reported to the MHRA via the MDSO team (MDSO@UHBristol.nhs.uk)***.

If it is decided it poses an extremely high level of risk then these may be reported directly online via the MHRA in which case the MDSO should be copied in to ensure appropriate records and details are appropriately stored.

Where medical equipment is involved MEMO CE will submit a report to the MHRA as appropriate.

11.9 Central Alerting System and Field Safety Notices

It is a national requirement that the Trust has a system in place to ensure that notices from the Central Alerting System (CAS) are distributed appropriately and to monitor that recommendations and actions are implemented. Clinical Engineering (MEMO) undertakes this work for the Trust and distributes all MHRA notices relating to Medical Device Alerts to nominated personnel at divisional level.

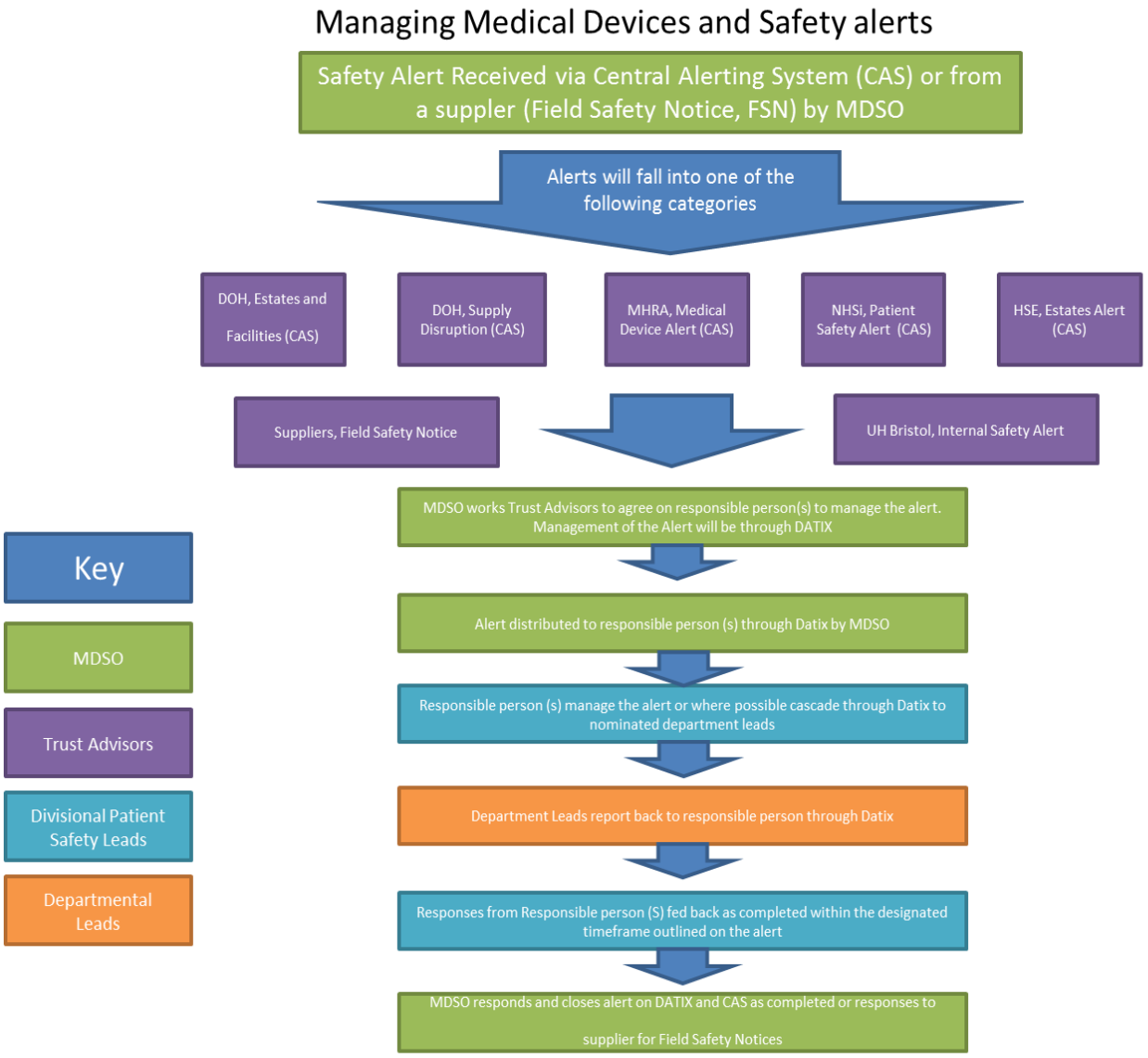
It is the responsibility of nominated Divisional Leads to disseminate the notices to all appropriate health care professionals, ensure that recommendations are implemented where appropriate, and a response is first obtained from the relevant personnel/departments and submitted to the Trust MDSO Team within the stated target period.

It is the responsibility of the nominated Trust MDSO Team to ensure that a response is entered onto CAS on behalf of the Trust.

If a department or service user receive any Field Safety notices or any other type of notification which required adjustments to Medical Devices, these should also be sent through to the MDSO to ensure that they are appropriately dealt with and responded to on behalf of the Trust.

Clinical Engineering will actively search relevant sources to locate Field Safety notices to ensure that the Trust has undertaken all recommendations relating to them appropriately minimising the risks to patients to known alerts published.

The process for dealing with all alerts is shown within Figure 7.



Note: Trust Advisors will be different for each type of alert
For Estates Alerts it will be the Estates Quality Manager and/or the Senior Electrical Engineer or the Trust Health and Safety Lead.
For NHS Improvement Patient Safety alerts, it will be either the Head of Quality (Patient Safety) or the chair of the patient safety group. Where an executive lead is required it will be the Medical Director or chief Nurse
For Medical Device Alerts, Field Safety Notices and Internal Safety Alerts it will be the MDSO and in some cases Patient Safety Leads.
For Supply Disruption Alerts it will be the MDSO working with BWPC.
Where appropriate the following leads will also be consulted: Infection control, Health and Safety, BWPC, Medicines Safety Officer

Figure 7: Safety Alerts process

11.10 Personal Information stored within Devices

It is essential for University Hospitals Bristol NHSFT to utilise patient information in a secure way to prevent loss or access to this data by those who shouldn't have access. Any device which has a memory function which stores this type of information should be password controlled to ensure only those who require access can obtain it.

Any images or information capture should be updated to relevant patient records as soon as possible after the procedure and then removed from the local storage space on the device. If the information is required for future procedures then this should be adequately secured to prevent the loss of this data.

Any incidents which occur where there may have been a loss of data should be reported through the Trust's Incident reporting system so investigations can be put into place and learning outcomes can be put into practice.

11.11 Cyber Security of Medical Devices

Increasingly Medical Devices are connecting to networks and information technology infrastructures to provide connectivity to patient record systems or data management systems.

The increase in connectivity has led to greater exposure of these systems to cyber-attacks in the forms of ransomware, viruses, malware etc. which can infect and cause disruptions to these clinical systems.

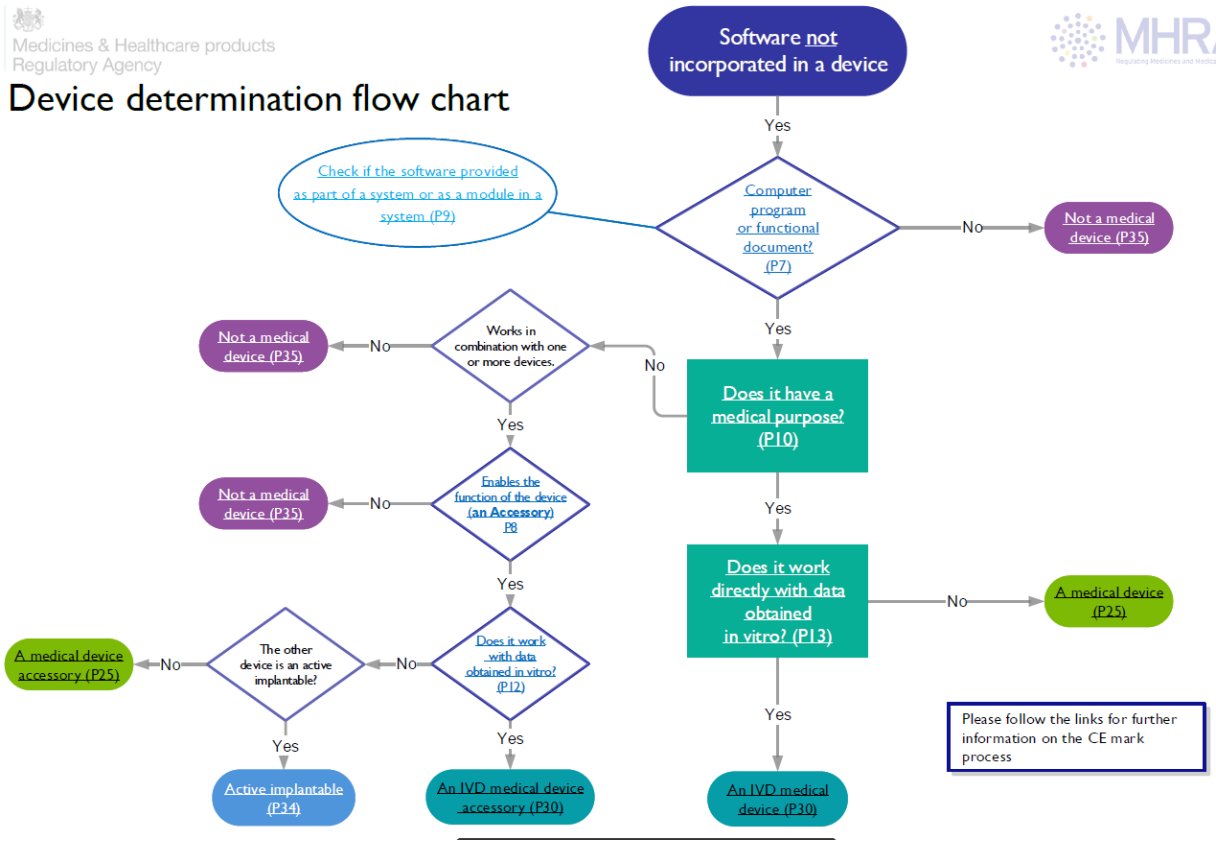
Any device which connects into an IT system should contain appropriate levels of cyber security to minimise the risk of any malicious disruptions to the system. E.g. Firewalls, virus scanning software, appropriate levels of patching and software updates.

For systems of this nature IM&T and/or Clinical Engineering should be involved in the procurement of the system to ensure that appropriate levels of security are in place to minimise the risk of clinical disruption of a clinical system.

Further information can be obtained within the IM&T document: Information Security – Principles, Guidelines & Procedures.

11.12 Applications and Standalone software

Software is becoming an increasingly essential part of diagnostics and healthcare. Under recent MHRA guidelines there may be a requirement for standalone software and applications to be developed and documented as a Medical Device and be CE marked. The below flow chart is an overview of how to determine if the application being developed is applicable as a Medical Device. This is taken from the Medical Device, Stand-alone software including applications Guidelines available on the link:



Therefore any software which is developed and deemed to be a Medical Device should be appropriately CE Marked. For support on determining if a development is a Medical Device contact the Scientific computing team within Medical Physics and Bioengineering who will be able to support the developments and requirements of this type of software.

11.13 Storage, accessibility and Security of Equipment

All devices must be stored in accordance with manufacturer's guidance or in line with the following principles:

Equipment which is electrically powered by re-chargeable batteries must be stored plugged in (e.g. Beds, Infusion Devices) to ensure that it is available for immediate use if required.

Where devices may be stored for some period of time their shelf life must be monitored and have appropriate stock control principles in place.

Where devices are not available in suitable quantities or are unavailable for clinical use, the incident should be raised on the Trust's incident system to escalate the concern and allow these factors to be investigated and resolved through appropriate operational planning or procurement processes.

Physical condition of the storage area should:

- Maintain appropriate temperature, humidity, and cleanliness in line with Trust standards
- Storage racking and systems are appropriately stable and items store at appropriate heights to prevent risk of falling or being damaged through being dropped.

- Contaminated equipment is stored away from equipment which is ready for use to prevent inadvertent use of contaminated equipment on a patient.
- Any consumable items with shelf lives or expiration dates are appropriately stock rotated to prevent loss of stock
- Storage areas are secure to prevent tampering or loss of equipment

12. Decontamination

Decontamination is a combination of processes (cleaning, disinfection and/or sterilisation) which removes or destroys contamination so that infectious agents cannot reach a susceptible site in sufficient quantities to cause harm to a patient or device user.

Differing levels of decontamination are used depending on the device and the procedure involved

Decontamination regarding Medical Devices within the Trust is governed through the Trust's Decontamination policy.

Users of Medical Devices are responsible for ensuring that the device is appropriately decontaminated in line with the manufacturer's instructions and the requirements outlined by the Trust's Decontamination Manager and Infection Prevention and Control Team.

13. Disposal

Prior to disposal taking place the disposing department should ensure that no other areas within the Trust can utilise the device or that the device can be used as part of a contingency plan in another area.

In all episodes of disposal or transfer of a reusable Medical Device the inventory holder of the device should be notified to ensure accuracy of the Trust's Asset Register is maintained e.g. Clinical Engineering, MDSO etc.

The disposal of Medical Devices will be undertaken based upon a range of criteria, these include but are not restricted to:

- Uneconomical repair
- Obsolete from technical support or from clinical practice
- No longer required due to changing service needs
- Inability to obtain spare parts or consumables required for safe operation of the device.

Disposal of Medical Devices must be undertaken to ensure that it complies with Trust waste management policies. There are a number of different ways in which a Medical Device can be disposed of these include:

- Auction
- Donation
- Scrapping

- Recycling

Waste Electrical and Electronic Equipment (WEEE) regulations relating to the disposal of electrical equipment will be followed. Where replacement purchases of equipment is undertaken the costs of this process should be taken into account as part of the planning cycle.

Any advice required in regards to disposal or transfer of assets should be discussed with Clinical Engineering to ensure that appropriate processes are undertaken.

14. Standards and Key Performance Indicators

14.1 Applicable Standards

(a) CQC Regulation 12 and 15

(b) Managing Medical Devices (April 2015)

(c) European Medical Devices Directive 2017/745 and 2017/746

14.2 Measurement and Key Performance Indicators

The implementation and adherence to this policy is monitored through the reports arriving into the Medical Devices Management Group (MDMG) which are escalated through the reporting structure outlined in section 5.

External inspections are undertaken by CQC on a regular basis to ensure ongoing compliance with Regulations 12 and 15 which directly relate to Medical Devices as well as any other regulations where Medical Devices are indirectly attributable to the outcomes of the key standards.

KPI's around performance of the following maintenance tasks are reported through D&T and act as part of the review process undertaken by Senior Managers within the Trust. These are currently:

1. Acceptance of Equipment
2. Completion of planned maintenance
3. Corrective maintenance turnaround time.

Clinical Engineering's Processes are externally audited by BSI on a 6 monthly basis to ensure that the tasks are delivered as documented.

15. References

- MHRA Managing Medical Devices Safely (April 2015)
- CQC Regulation 12 and 15
- Health and Safety at work act 1974

16. Associated Documentation

Certificate of Decontamination DC1 form

Clinical Engineering Quality Management Documents

Clinical Engineering Medical Device risk assessment document

Critical Equipment Workspace

Decontamination Policy

Medical Device Training Policy

Point of Care Testing Policy

Trust Competency Framework

Trust Standing Financial Instructions

Waste management Policy

17. Appendix A – Monitoring Table for this Policy

Description	Section checked	Evidence Provided	Evidence Reviewed by:	Evidence Prepared by:
The organisation has approved documentation which describes the process for managing risks associated with the maintenance of reusable medical devices and equipment.	Managing Medical Devices Safely – Trust Policy items 4.9, 4.10 and 4.11	Trust Policy	Medical Device Management Group	Head of MEMO CE Procurement Representative. Medical Devices Training Co-ordinator. (every 6 months)
Requirement to have a systematic inventory of all reusable medical devices and equipment used in the organisation	4.5 Acceptance	Acceptance Report. Procurement Report	Medical Device Management Group /Minimum of 6 times per year.	Head of MEMO CE Procurement representative Minimum of 6 times per year.
Process for ensuring that all reusable medical devices and equipment are properly maintained and repaired	Maintenance – Duties 4.6 page 11	Ward Repair summary MEMO CE Records	MEMO CE	Quality Assurance Manager/MEMO CE Project Manager (every 6 months)
Process for checking that calibration of all reusable devices are completed within specific time frames.	MEMO CE internal process	MEMO CE records, Asset Plus data and quality assurance system	MEMO CE (monthly) BSI inspection (annually)	MEMO CE Team Leaders and quality assurance manager and Key performance indicators (monthly)

18. Appendix B – Dissemination, Implementation and Training Plan

18.1 The following table sets out the dissemination, implementation and training provisions associated with this Policy.

Plan Elements	Plan Details
The Dissemination Lead is:	Head of Clinical Engineering
This document replaces existing documentation:	Yes
Existing documentation will be replace by:	Rescinding of superseding document
This document is to be disseminated to:	All Trust staff who use Medical Devices as part of their role
Method of dissemination:	Through email circulation through the members of the Medical Devices Group, via the DMS system and also through newsbeat.
Training is required:	Yes
The Training Lead is:	Medical Devices Training Coordinator

Additional Comments
Not Applicable

19. Appendix C – Document Checklist

19.1 The checklist set out in the following table confirms the status of 'diligence actions' required of the 'Document Owner' to meet the standards required of University Hospitals Bristol NHS Foundation Trust Procedural Documents. The 'Approval Authority' will refer to this checklist, and the Equality Impact Assessment, when considering the draft Procedural Document for approval. All criteria must be met.

Checklist Subject	Checklist Requirement	Document Owner's Confirmation
Title	The title is clear and unambiguous:	Yes
	The document type is correct (i.e. Strategy, Policy, Protocol, Procedure, etc.):	Yes
Content	The document uses the approved template:	Yes
	The document contains data protected by any legislation (e.g. 'Personal Data' as defined in the Data Protection Act 2000):	Yes
	All terms used are explained in the 'Definitions' section:	Yes
	Acronyms are kept to the minimum possible:	Yes
	The 'target group' is clear and unambiguous:	Yes
	The 'purpose and scope' of the document is clear:	Yes
Document Owner	The 'Document Owner' is identified:	Yes
Consultation	Consultation with stakeholders (including Staff-side) can be evidenced where appropriate:	Yes
	The following were consulted:	MDMG Group members, Clinical Quality Group Members, Clinical Engineering Staff
	Suitable 'expert advice' has been sought where necessary:	Yes
Evidence Base	References are cited:	Yes
Trust Objectives	The document relates to the following Strategic or Corporate Objectives:	Patient safety
Equality	The appropriate 'Equality Impact Assessment' or 'Equality Impact Screen' has been conducted for this document:	Yes
Monitoring	Monitoring provisions are defined:	Yes

Checklist Subject	Checklist Requirement	Document Owner's Confirmation
	There is an audit plan to assess compliance with the provisions set out in this procedural document:	Yes
	The frequency of reviews, and the next review date are appropriate for this procedural document:	Yes
Approval	The correct 'Approval Authority' has been selected for this procedural document:	Yes

Additional Comments
[DCL - Additional Comments]

20. Appendix D – Equality Impact Assessment

Query	Response	
What is the aim of the document?	To provide a comprehensive overview of how medical devices will be managed within University Hospital Bristol NHS FT.	
Who is the target audience of the document (which staff groups)?	Staff who utilise Medical Devices as part of their role Staff who have to send items away or coordinate maintenance from a contractor Staff who procure medical devices Staff who undertake research, trials or modification to Medical Devices Staff who loan equipment to other parties. Add ☑ or ☒	
Who is it likely to impact on **and how**?	**Staff**	Yes – as it determines the appropriate approach required to utilise and obtain access to Medical Devices
	Patients	No
	Visitors	No
	Carers	No
	Other	N/A
Does the **document** affect one	**Age** (younger and older people)	No

Query	Response	
What is the aim of the document?	To provide a comprehensive overview of how medical devices will be managed within University Hospital Bristol NHS FT.	
	Disability (includes physical and sensory impairments, learning disabilities, mental health)	No
	Gender (men or women)	No
	Pregnancy and maternity	No
	Race (includes ethnicity as well as gypsy travelers)	No
	Religion and belief (includes non-belief)	No
	Sexual Orientation (lesbian, gay and bisexual people)	No
	Transgender people	No
	Groups at risk of stigma or social exclusion (e.g. offenders, homeless people)	No
	Human Rights (particularly rights to privacy, dignity, liberty and non degrading treatment)	No

End of Policy