CLINICAL POLICY
Medical Devices

Policy Number	CLP040
Version:	V6.1
Purpose:	This policy sets out the standards required by providers in relation to medical devices, ensuring they are fit for purpose, properly decontaminated and that colleagues have been trained and are competent to use them.
Consultation:	Clinical Policy Group; Buildings, Environment and Medical Equipment Group (BEME), Medical Devices Group, IPC
Approved by:	Clinical Policy Group
Date approved:	10/03/2023
Author:	Alison Hartless – Medical Equipment Manager
Date issued:	20/03/2023
Review date:	01/03/2026
Audience:	All staff within GHC
Dissemination:	The policy will be communicated with colleagues via line managers following the approved process. The policy will be made available on the Trust's Intranet.
Impact Assessments:	This Policy has been subjected to an Equality Impact Assessment. This concluded that this policy will not create any adverse effect or discrimination on any individual or particular group and will not negatively impact upon the quality of services provided by the Trust

Version History

Version	Date Issued	Reason for Change
	Sept 2018	Building and Environment Group Membership comments
V4	November 2018	Put into latest format, minor amendments and reviewed until January 2020
V4.1	April 2019	Appendix 6 added
V4.2	01/10/2019	Transferred to new Trust Template and updated Trust Name and details following merger of trusts, GHT amended to GMS, links updated
V4.3	26/03/2020	Extension to review date as advised by Director of Nursing, Therapies and Quality during Trust Prioritisation of Services for Covid19
V4.4	15/07/2020	Extension to review date whilst the process of merging the physical and mental health policy information takes place
V4.5	01/07/2021	Policy reuploaded after mistakenly being deleted by Comms on 11.6.21, 'under review' added to review date field
V5	15/07/2021	Full Review for merged Trust

V6	20/03/2023	Minor amendments and updates to account for changes for legislation / Amendments and additions to processes / Addition of governance and assurance routes / Purpose of committee / Scope and purpose revision, roles respecified / Use of equipment in patients' home and patient/carer training added / Disposal process updated.
V6.1	20/06/2023	New section on DSPT added, updated references and associated policies

SUMMARY
This policy aims to ensure that recommended safety standards and legislation is adhered to in the use of medical devices and that it is the Trust's intention to adopt best practice standards in the management of medical devices.

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ABBREVIATIONS

Abbreviation	*Full Description*
GHC	Gloucestershire Health and Care NHS Foundation Trust
MHRA	Medicines and Healthcare Products Regulatory Agency
MDG	Medical Devices Group
GMS	Gloucestershire Managed Services
LOF	League of Friends
NICE	National Institute for Health and Care Excellence
KPI	Key Performance Indicator
MDSO	Medical Devices Safety Officer
PUWER	Provision and Use of Work Equipment Regulations 1998 (PUWER)
MEMS	Medical Equipment Management System - OPTIM
MEM	Medical Equipment Manager
FSN	Field Safety Notice
LOLER	Lifting Operations and Lifting Equipment Regulations 1998
DHSC	Department of Health and Social Care
MIA	Master Indemnity Agreement
CSO	Central Alerts Systems Safety Officer
CAS	Central Alerts System
PPM	Planned Preventative Maintenance
MDT	Multi-Disciplinary Team
PSS	Procurement Shared Services
BEME	Buildings, Environment and Medical Equipment Group
CMG	Capital Management Group
IPC	Infection Prevention and Control
DPST	A system where the Trust demonstrates and affirm compliance with NHS Digital mandatory standards for Security and protection of information, assets, networks and systems. The tool is also used for the Trust to report data breaches and cyber security incidents.
DTAC	The Digital Technology Assessment Criteria for health and social care (DTAC) gives staff, patients and citizens confidence that the digital health tools they use meet our clinical safety, data protection, technical security, interoperability and usability and accessibility standards.

1. INTRODUCTION

1.1 Gloucestershire Heath and Care NHS Foundation Trust is committed to providing services that are excellent, of high quality and safe for patient care and colleagues. The Trust provides a wide range of health-related services to the people in and around Gloucestershire. The Trust recognises its duties and legal responsibilities to ensure, as far as reasonably practicable, the health, safety and welfare of its patients and employees. This also incorporates the procurement and maintenance of medical

equipment and the training of the staff to use the equipment in a safe and appropriate way.

1.2 The following organisational documents may be used in conjunction with this policy:

- Health Records and Clinical Record Keeping Policy (CLP005)
- A-Z of Equipment Decontamination Policy (CLP077)
- Central Alerting System (CAS) Policy (CLP014)
- Equipment Maintenance Policy
- Health and Safety Policy
- Incidents Policy including Serious Incidents (CGP001)
- Bed Rail Assessment and Safe Use Policy (CLP127)
- Moving and Handling Policy
- Lifting Operations and Lifting Equipment Regulations (LOLER) Management Policy
- Provision and Use of Work Equipment Regulations (PUWER) Management Policy.
- IGP002 GHC System Management Policy
- Information Governance Management System
- Cyber Security Policy
- IT Information Security.

2. PURPOSE

2.1 The Trust owns and relies upon a large stock of clinical and diagnostic medical devices in order to carry out its function of patient care.

2.2 The purpose of the policy is to provide a clear understanding of the Trust's principles regarding the management and decontamination of medical devices and sets out the standards and guidance to ensure systems are in place to provide assurance for safe acquisition, use, storage, decommissioning and disposal of all medical devices.

2.3 The term medical device or medical equipment covers all products, except medicines, used in health care for diagnosis, prevention, monitoring or treatment of illness or disability. According to the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), a medical device is described as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is 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, alleviation of or compensation for an injury or handicap investigation, replacement or modification of the anatomy or of a physiological process, or control of conception. A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these.

2.4 This policy sets out the arrangements for the management of these devices throughout the Trust based upon the requirements of legislation and good practice as defined in the following documents.

- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 15 (Premises and Equipment)

- Bulletins issued by the Medicines and Healthcare products Regulatory Agency (MHRA) Device Bulletin DB 2006
- Medical Devices Regulations 2002 (No 618)
- Managing Medical Devices January 2021
- Care Quality Commission (CQC)
- National Patient Safety Agency (NPSA)
- Health and Social Care Act 2008
- Regulation 12 Provision and Use of Work Equipment Regulations 1998 (PUWER)
- Lifting Operations and Lifting Equipment Regulations 1998 (LOLER)
- Department of Health (DOH) and other relevant national and international standards.

3. SCOPE

3.1 This policy should be followed by all staff in Gloucestershire Health and Care NHS Foundation Trust and applies to all medical devices used in the Trust irrespective of whether the equipment has been purchased, loaned or received as a gift.

3.2 The management of medical devices is to ensure that the correct equipment is available when required, in a safe and serviceable condition and at a reasonable cost.

4. DUTIES

4.1 **The Chief Executive and Directors have overall responsibility for medical devices** throughout the Trust and ensuring that safe standards and procedures are maintained as far as reasonably practicable.

4.2 **Associate Director of Estates, Facilities and Medical Equipment** is responsible for service and maintenance contracts for medical devices; Accountable for effective monitoring and liaison with Gloucester Managed Services Medical Engineers and their contracted responsibilities for this policy.

4.3 **Medical Equipment Manager is responsible** for providing effective management of medical devices and equipment procedures from acquisition to disposal.

4.4 **Heads of Service, Managers and Team Leaders' Responsibilities** are responsible for informing and educating all existing employees, volunteers, contractors, and patients or carers where applicable about the requirements of the Medical Devices Management Policy and Guidelines and dealing with any immediate concerns.

They are also responsible for ensuring that only Trust approved medical devices are procured, unless permission to vary is obtained from the Medical Devices Committee.

4.5 **Managers** are responsible for ensuring that:

- All staff undertake the required medical devices training.
- Any specific training needs are identified through the annual Individual Performance Review and Personal Development Plan Process, and these requirements are met.
- All staff are familiar with and can use the make and model of equipment used within their ward/department.
- All medical devices are in good repair and order, and all faults or incidents are

reported.

And are responsible for maintaining an accurate inventory of medical devices within their location to ensure actions are followed in the event of MHRA alerts and manufacturers modification recalls; the rolling replacement of medical devices, safe use and training.

4.6 **Infection Prevention and Control Team** are responsible for auditing and advising services using **reusable** and single use medical devices. In addition, advising and supporting acquisitions, training needs and decontamination processes through the effective monitoring of compliance.

4.7 **All staff** are responsible for ensuring their own health and safety, and also that of others who may be affected by their actions or inactions in the safe use of medical equipment.

4.8 **Medical Devices Safety Officer (MDSO)**
One of the MDSO key roles, as set out in the alert, is to promote the safe use of medical devices across their organisation and be the main point of reference for medical device safety. The MDSO is expected to:

1. Manage medical device incident reporting within the Trust and improve the reporting and learning from these.
2. Provide insight and feedback to the MHRA and NHS England and Improvement that may contribute to national medical device related alerts.
3. Be an 'expert' in understanding how national medical device patient safety actions and field safety notices have and should be acted upon within the Trust.
4. Know how to escalate issues from the Medical Device Safety Committee to the Executive Board.

The MDSO is responsible for implementing national learning shared through the MDSO network and the forum to improve local medical device safety; This will occur via the generic MDSO inbox (MedicalDevices@ghc.nhs.uk) and by direct link with MHRA CAS team.

4.9 **Buildings, Environment and Medical Equipment Group (BEME)** has responsibility for the development and implementation of the Medical Devices Policy, associated procedures and guidelines; ensuring compliance with relevant legislation when reviewing and monitoring medical devices related reports. BEME presents exception reports to the Audit and Assurance Committee, quarterly.

4.10 **The Medical Devices Committee (MDC)**
Purpose and Remit
The aim of the group is to oversee the Trust's compliance with all aspects of safety and legislation in relation to the prescription, procurement maintenance and calibration of all medical devices within the Trust. This includes external contracts related to medical devices and equipment. Specifically:

- The Group is accountable for monitoring the procurement, use and maintenance of medical devices in the Trust.
- The Group ensures that the devices are procured with due attention to

standardisation policies.

- The Group oversees the Trust's replacement strategy for medical devices.
- The Group ensures that an accurate and up to date medical devices inventory is maintained.
- The Group ensures that systems are in place to assure the Trust that staff are competent to use all equipment and medical devices by ensuring suitable training is provided and monitoring training records.
- The Group reviews incidents and near misses with equipment to ascertain themes or issues requiring further investigation and action.
- The Group ensures that an approved equipment list is developed and maintained.
- The group ensures that there is a clear Trust process for decontamination and disposal of medical devices
- The group ensures the process for procuring single use equipment.

Membership

The sub-committee shall be chaired by an appointed senior manager in the Estates and Facilities team. The membership of the group will include representatives from the following:

- Head of Estates, Facilities and Professional Services (Chair)
- Associate Director of Estates, Facilities and Medical Equipment (Deputy Chair)
- Head of Patient Safety and Learning (MDSO and CSO)
- Deputy Director of Nursing and Quality (Deputy Chair)
- Medical Equipment Manager
- Business Manager for Ambulatory Care
- Community Manager
- Decontamination Lead or Infection Control Representation
- Procurement and Contracts Manager
- Health and Safety Compliance Manager
- Resuscitation and Training Team Lead
- Dental Services Representation
- Head of IT Operations
- Estates and Facilities Administrator
- A representative from the Trust's Learning and Development Team invited as required
- Other Clinical Services and Corporate Team representatives as required and on invitation from the committee
- A representative from the Clinical Engineering contractor as required and on invitation from the committee
- Each Clinical Service across the Trust's directorates where it is reasonably assumed that medical devices will be used during day-to-day clinical care. In the absence of an appointed representative's ability to attend they shall send a deputy, which could be the Physical Health Nurse in a Mental Health setting.

Quorum and Frequency of Meetings

Meetings will be every month, and the Chair can request additional meetings as required for the activity of the group.

The quorum for the committee is the chair, and at least one representative from each

clinical directorate as stated above - this can include deputy.

The group may invite additional internal and external people to the meeting as required.

Reporting and Accountability
Minutes of the committee meetings will be formally recorded with an action tracker and circulated to committee members within ten working days of the meeting.

The updates/progress report will be sent on to Quality Assurance Group twice per year.

The committee will produce an annual report.

5. POLICY DETAIL

5.1 Use of Medical Equipment

The use of medical equipment for non–designated purpose; any modification or use of equipment other than its intended use is a clear breach of the terms of the manufacturer's warranty.

5.2 Incidents which occur that involve medical devices can have the potential to produce unexpected or unwanted outcomes that may affect the safety of patients, service users, staff and visitors:

a) Injuries as a result medical device failure or misuse
b) Treatment is interrupted or compromised
c) Risk of infection from contaminated device if not handled, collected and transported in a manner that avoids risk and decontaminated in accordance to best practice
d) Decontaminated equipment is subject to validation, calibration and monitoring by qualified personnel.
e) The procedure for monitoring and reporting incidents/events should be followed and all near misses or incidents must be escalated using the DATIX system.

5.3 Loan Equipment

Loaned medical equipment trials should be reviewed and feedback brought to the MDG. Agreements must demonstrate all indemnity, legal and liability checks are completed, and ensure that manufacturers quality control inspections have been completed prior to use within the Trust using the MIA supported by the DHSC.

The Master Indemnity Agreement (MIA) register provides a list of all approved suppliers to NHS organisations: Master Indemnity Agreement (MIA) Register of Approved Suppliers (supplychain.nhs.uk).

The check list for Infection Control Approval must also be completed (see appendix 2).

5.4 Trialling Medical Devices

Suggestions for medical device trials need to be presented at the Medical Devices group meeting. Trials can be procurement led or direct with the supplier.

All financial implications, IPC, competence and confidence training, service support and maintenance and MIA should be in place before the trial commences, with agreement by the MEM and/or MDC. Master Indemnity Agreement (MIA) Register of

Approved Suppliers (supplychain.nhs.uk).

The check list for Infection Control Approval must also be completed prior to the trial (see appendix 2).

6. PROCESS FOR THE PROCUREMENT OF MEDICAL DEVICES

6.1 All potential purchases of medical equipment, new or replacement must be agreed by the clinical lead or team manager with consideration given to service and maintenance, standardisation and training, regardless of the value or quantity. It must follow the process with consideration given to income, risk and the profitability of the service where possible; as outlined in the flow chart: Appendix 1.

6.2 Purchases under £5k can be single supplier or quotation via procurement. Intended purchases of £5k and over should be reported into the MDC for discussion. If agreed, a business case must be prepared for presentation to the Capital Management Group (CMG). The director with responsibility for Infection Prevention and Control is to be notified and have IPC sign off on ALL business cases prior to approval at CMG.

6.3 All capital investment purchases of medical equipment will be processed through the Estates and Facilities Admin team to ensure consistency and control.

6.4 Medical devices should be purchased through the Procurement (Medical Equipment Specialist) Team to ensure that the equipment is a nationally recognised and approved framework agreement; the details of the equipment required is submitted using a procurement Statement of Requirement (SOR) form obtained from Procurement. All new equipment is subject to completion of a pre-requisition form to ensure that any service and maintenance contracts are established and all new medical equipment is recorded on OPTIM, the medical equipment management system (MEMS).

6.5 All new medical devices or enabling works for new medical devices is subject to completion of:

- Infection Control Approval form (Appendix 2).

6.6 It is necessary to ensure that active measures are in place to ensure the safety and security of digitally enabled medical devices to minimise the risk of patient harm. The Trust's IT services must be included in all intended purchases of medical devices which require network-based access.

6.7 All purchases of digitally enabled medical devices that have the facility to store patient information (even if temporary) must be added to the Trust Medical Devices Register held by the MEM. This register presents a current record of all medical devices connected to the internet along with site, location and asset number. On decommissioning of digitally enabled devices reference to 13.2.

6.8 In the case of large-scale medical equipment purchases (e.g. Trust wide replacement of patient beds or Trust wide upgrade of X-ray equipment) and ALL purchases of decontamination equipment/devices a pre-procurement MDT must be identified and arranged. For decontamination equipment the MDT membership must always include the following key stakeholders:

- Authorising Engineer
- Estates Senior Manager
- Medical Equipment Manager
- IPC Lead
- PSS Procurement Capital Specialist for medical equipment
- GHC Procurement Manager
- Information Governance representative
- IT representative.

The title of the meeting to be formatted as {*service*} {*equipment*} Pre-procurement MDT.

6.9 All requests to purchase medical equipment will be monitored by the Medical Equipment Manager via a technical sign-off facility through the financial purchasing system to ensure standardisation wherever applicable.

7. LEAGUE OF FRIENDS PURCHASES (LOF)

7.1 The League of Friends is a voluntary organisation that supports the work of the hospitals in the Trust and helps provide funding for medical equipment. To ensure a standardised approach for purchases supported by the LOF, the Standard Operational Procedure must be followed. (See appendix 3).

8. NEW MEDICAL DEVICES

8.1 On receipt, new medical devices must be acceptance tested on arrival and should be complete with user manuals. Maintenance instructions should be followed in accordance with the manufacturer's detailed information; medical devices should be selected and acquired in accordance with the MHRA "Managing Medical Devices" January 2021 document and all other relevant recommendations with regard to the following:

a) Technical specifications regulatory compliance
b) Maintenance, disposal and replacement costs
c) Standardisation to single models where possible
d) Monitoring and manufacturing advice for training and support where needed
e) Record of pre-requisition questions
f) Compliance with MHRA guidelines and supplier indemnity agreement documents.
g) Asset registered, recorded, labelled and checked by Medical Engineers before use
h) Subject to calibration if required
i) Decontaminated before patient use
j) Recorded on local inventory.

9. OPTIM, PLANNED PREVENTATIVE MAINTENANCE AND REPAIRS

9.1 The OPTIM database is used to record all medical devices within the Trust; the database is owned and managed by Gloucester Managed Services (GMS) who are responsible for updating and maintaining accurate records and providing reports for medical devices, service, maintenance, contractual arrangements, obsolescence, risk and manufacturers alerts.

9.2 The Trust also has direct contractual agreements in place with some suppliers for

devices such as X-ray and Endoscopy equipment and other devices. These are arranged via our procurement and contracts leads for the Trust.

9.2 Procedures should be in place for regular routine, performance or maintenance checks conducted by Medical Engineering (GMS) as indicated in the manufacturer's instruction manual and recorded to provide monthly reports for assurance to the BEME Group. PPM and KPI reports should be presented at the Medical Devices Group meeting to provide assurance to the BEME Group.

9.3 All staff are responsible for following safe working practices and reporting any problems associated with medical devices. Clinical staff are responsible for ensuring medical devices are available for scheduled planned preventative maintenance (PPM) and reactive repairs.

9.4 Any medical device that is found to be faulty must be removed from service, suitably decontaminated and labelled to await repair. Once returned, the medical device must be decontaminated before use. Repairs can be arranged by contacting GMS Medical Engineering team via the following link:
http://ghtmejr.glos.nhs.uk/MedEng/en/Customer/index.asp

10. ADVERSE INCIDENT REPORTING

10.1 The Trust MDSO will ensure that arrangements are in place to receive and disseminate safety warnings and bulletins issued by the MHRA. (Refer to the Central Alerts System (CAS) Policy) and other expert and professional bodies i.e. NICE.

10.2 Managers will be responsible for ensuring that all device users are aware of local procedures for reporting incidents.

Any adverse incident involving a medical device will be reported to the MHRA as soon as possible after the event and the Health and Safety Compliance Officer via the Trust intranet using the Incident Reporting to GHC Datix.

The MHRA runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products, like a side effect with a medicine or an adverse medical device incident. The scheme relies on voluntary reporting of problems to a healthcare product by the public (including patients, parents and carer givers) as well as from healthcare professionals. The scheme also collects suspected safety concerns involving defective (not of an acceptable quality), falsified or fake healthcare products.

11. DECONTAMINATION OF MEDICAL DEVICES

11.1 All reusable medical devices must follow a decontamination process to ensure the equipment is safe to use and it is essential that adequate information demonstrates and evidences a complete record of the decontamination process. This must be held locally in order to provide assurance that the equipment has been decontaminated in accordance with legislation and guidance.

11.2 Manufacturers of medical devices are required to provide advice on how the equipment is required to be decontaminated and this should always be followed. The CE mark on

reusable devices provides the appropriate process to follow for decontamination and is the declaration the device meets the requirement of the medical device's directive.

11.3 It is illegal to transport contaminated medical devices. Do not send contaminated equipment elsewhere as it must not be transported without a declaration stating the method of decontamination used; if it is impossible to decontaminate before transportation the equipment should be wrapped and labelled declaring the status.

Refer to the Trusts Infection Control Policy and Guidelines for further details: A-Z of Equipment Decontamination Policy (CLP077).

12. SINGLE USE ITEMS

12.1 Single use items can be defined as "a device that is intended to be used on an individual service user/patient during a single procedure and then discarded." Therefore, the practice of reusing medical devices labelled by the manufacturer 'for single use only' will not be permitted.

Single use items are identified by the symbol: 

12.2 The Consumer Protection Act 1978 will hold a person liable if a single use item is re-used against the manufacturers recommendations and the Trust would be liable in the event of an adverse outcome. The Medical Devices Agency 2000 (04) states the hazards and risks associated with using single use items.

12.3 Equipment Used in the Patient's Home

Where the ownership and management of the devices remain with the supplier, such as enteral feeding pumps, the manufacturer's pre-dispatch tests, combined with simple pre-use checks by those responsible for the care of the end user in the community, (e.g. community nurse), should provide adequate safety assurance. In this situation, record-keeping is the supplier's responsibility with input from the end user, as appropriate.

For devices owned by healthcare services (Community Medical Equipment Supplier) and loaned to end users in the community for use at home, the responsibility for ensuring that the device is delivered and is safe to use the responsibility of the healthcare service. However, this may include an agreement for the end user to carry out basic assembly or safety checks before use.

13. DECOMMISSIONING AND DISPOSAL

13.1 Any reusable medical device which is no longer serviceable should be decommissioned. Decommissioning or disposal of a medical device must include decontamination, making safe and unusable (unless to be sold, donated or auctioned).

13.2 All patient data should be extracted before the device is removed from its location by the clinician responsible.

13.3 Decommissioned medical equipment should be disposed of following the correct procedure for disposal or condemnation of medical equipment.

In the first instance, email the Medical Equipment Manager the following:

a) ME number
b) serial number
c) site and location of device
d) confirmation of decontamination status
e) reason for disposal
f) replacement consideration.

Following this request and complete a Medical Equipment Condemnation and Disposal Form, obtained by emailing GMS. These are individually serial numbered and therefore they need to be obtained directly by emailing Medical Engineering. ghn-tr.medeng@nhs.net

13.4 Notification of decommissioning and disposal must follow this process to ensure records are updated and equipment is removed from the asset database Optim.

13.5 The Transfer of Ownership must adhere to the correct legislation with proof of decontamination before removal from site following no the decision when sold, donated, or auctioned.

At all costs DO NOT dispose of any medical device in a skip or other waste streams without consultation with the MEM.

Adhere to the European Waste Directive, Control of Substances Hazardous to Health Regulation 2002, HTM 07-01 Safe Management of Healthcare Waste and Waste from Electrical and Electronic Equipment (WEEE) 2013.

14. CANNIBALISATION AND MODIFICATIONS

14.1 Cannibalising is the process of replacing parts which have failed in service with ones taken from other broken devices. This practice must NOT be undertaken within the Trust due to the risk of claims of negligence.

15. DATA SECURITY PROCESS FOR MEDICAL DEVICES CONNECTED TO THE NETWORK (DSPT)

The Data Security and Protection Toolkit (DSPT) online mandatory annual self-assessment tool allows organisations that process health and care data to measure their performance against the National Data Guardian's 10 Data Security Standards. As part of the DSPT there is a requirement for the Trust to explain how we assure data security during the full life cycle of all medical devices that are connected to the network. This section provides that explanation.

15.1 Digital Diagnostic and Medical devices often require connectivity to the Internet, NHS Networks, whether wired or wireless, and feed identifiable patient information into Trust systems. This carries the risk that devices can be hijacked to attack systems on the network on which they sit. Patient safety could be compromised if settings or data are altered by malicious actors remotely.

15.2 Medical devices are highly regulated and controlled due to the risks involved in patient safety. Modifications, including software and hardware, are not permitted, unless authorised by the medical device manufacturer, who will have conducted extensive validation and verification procedures in line with the appropriate regulations. Using medical devices on clinical networks therefore presents some challenges:

- It may be impossible to upgrade the operating systems due to hardware dependencies or software driver issues. In addition, medical devices may be more vulnerable due to greater software complexity, potentially employing multiple means of connectivity, a greater pressure to keep the device available vs devices in other areas, long device lifetimes (over 10 years), and greater restrictions on device updates placed on hospital ICT departments.
- as a medical device, security updates, patches and potentially virus signatures must be properly assessed by the medical device manufacturer and confirmed as safe before they can be implemented on the medical device. This can take 3 months (or longer) from the time that a security update is released. Some patches will only be implemented as an upgrade to the overall software and not as individual patches, further delaying the remediation process.
- when security updates are released, they are retro-analysed by attackers, increasing the likelihood that exploitable vulnerabilities will become known.
- the latest security mitigations not being present, increases the impact of vulnerabilities, making exploitation more likely to succeed, and making detection of any exploitation more difficult.
- the medical device may no longer be supported by the manufacturer (end of support) but still being used.

In combination, these issues mean that high-impact security incidents become more likely to occur. Security incidents affecting connected medical devices can cause significant disruption to the delivery of healthcare services.

15.3 GHC will ensure that the NHS Digital clinical risk management assessments (DCB 0129 Manufacture of Health IT Systems and DCB 0160 Deployment and Use of Health IT Systems) are completed along with the completion of the Digital Technology Assessment Criteria (DTAC).

15.4 GHC will take the following steps that will apply to any network connected medical device to safeguard the confidentiality, integrity and availability of information:

STEP 1	Identify all connected medical devices and produce a register that is reviewed on an annual basis
STEP 2	Reduce the likelihood of cyber security compromise by preventing the devices from accessing untrusted content and preventing access to sensitive data. Many medical devices are manufactured with the ability to access networks but don't have this facility enabled. This should be the default position unless connectivity is essential.
STEP 3	Eliminate the ability for medical devices to be used for end – user activity (such as email, web browsing etc.)
STEP 4	Prevent or reduce access to removable media.
STEP 5	Remove all unnecessary functionalities which are not required to support the business need.

STEP 6 Give consideration to obtaining service contracts as medical devices linked to maintenance contracts are more likely to receive security patches following a vulnerability.

STEP 7 Ensure that in all cases, any third-party organisations use multi-factor authentication and that any remote access/connections should only be initiated for specific tasks rather than allowing an 'always enabled' access facility.

STEP 8 Periodically review STEP 1

STEP 9 All medical devices that are end of life will have an identified replacement programme. All staff to follow the Trust Condemnation and Disposal Policy and ensure that all devices that store patient identifiable information have all data forensically erased, so it is unrecoverable. Any data stored on a connected medical device should be sanitised prior to disposal and before the device leaves the organisation to ensure that it cannot be read by unauthorised parties after it has left the organisation's control.

16. PROCESS FOR MONITORING COMPLIANCE

Are the systems or processes in this document monitored in line with national, regional, trust or local requirements?	YES

Monitoring Requirements and Methodology	Frequency	Further Actions
The Trust will undertake annual audits that involve medical devices as and when appropriate	Annually	The audits are presented at MDG and BEME
The Trust will also undertake "observational" spot checks of medical devices and equipment	Ad-Hoc	The audits are presented at MDG and BEME
Incident Reporting	On-going	The MDG reviews incidents and near misses with equipment to ascertain themes or issues requiring further investigation and action.

17. TRAINING AND SUPPORT

17.1 Staff Training

All users must be trained in the use, cleaning and decontamination of new equipment when introduced, and refresher training must also be provided where appropriate. Staff who have not been trained to use a medical device must not use it.

The trust has developed a risk assessment matrix which describes the nature and level of training required for each device.

Employees will be made aware of the policy and procedure at induction and followed up through ongoing training relevant to their roles and responsibilities by Team Managers. All staff who attend training for a given medical device (regardless of who is providing the training) will be signed off using the current trust process. Any additional documentation provided will be based upon the original supplier's documentation.

17.2 Patient / Client Training

It is of equal importance that patients and carers using a medical device should receive training on how to use it and clean it. Arranging or providing the training is the responsibility of the clinician supplying or recommending the equipment. Any training must be supported by written guidance and the training recorded in the clinical record. The manufacturer's instructions or contact point for assistance should provide some information – this should be tailored to the needs of individual patients/carers.

18. ASSESSING RISK

18.1 Risk is identified by several means including the review of adverse incident, review of CAS, Datix Incidents and near misses, medical device inspections, testing and PPMs.

18.2 The MDSO will be informed of any risk relating to medical devices.

19. REFERENCES

Medical Devices Agency (2000) Single use medical devices: implications and consequences of re-use MDA DB 2000(04) Medical Devices Agency, London.

Medical Devices Agency (1998) Medical Devices and Equipment Management for Hospitals and Community-based Organisations MDA DB 9801 Medical Devices Agency, London.
www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON202 5142

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17/10/2018

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 15 (Premises and Equipment)

Health Act 2008, Code of Practice for health & social care on the prevention and control of infections and related guidance

Health & Safety at Work Act 1974

Medical Devices Agency 2000(04) Single Use Medical Devices: Implications & Consequences of Reuse

HTM01-05 Decontamination in PC Dental Practices 2013

HTM01-01Part A-D Management & Decontamination of Surgical Instruments, Medical Devices in Acute Care 2016

DH 2006 Sterilisation, Disinfection & Cleaning of Medical Equipment: Microbiology Advisory Committee.

Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)

Data Protection Act 2018

UK General Data Protection Regulations

National data Guardian's 10 Data Security Standards

Guidance on protecting connected medical devices – NHS Digital

Health Industry Cyber Security Practices - Managing Threats & Protecting Patients

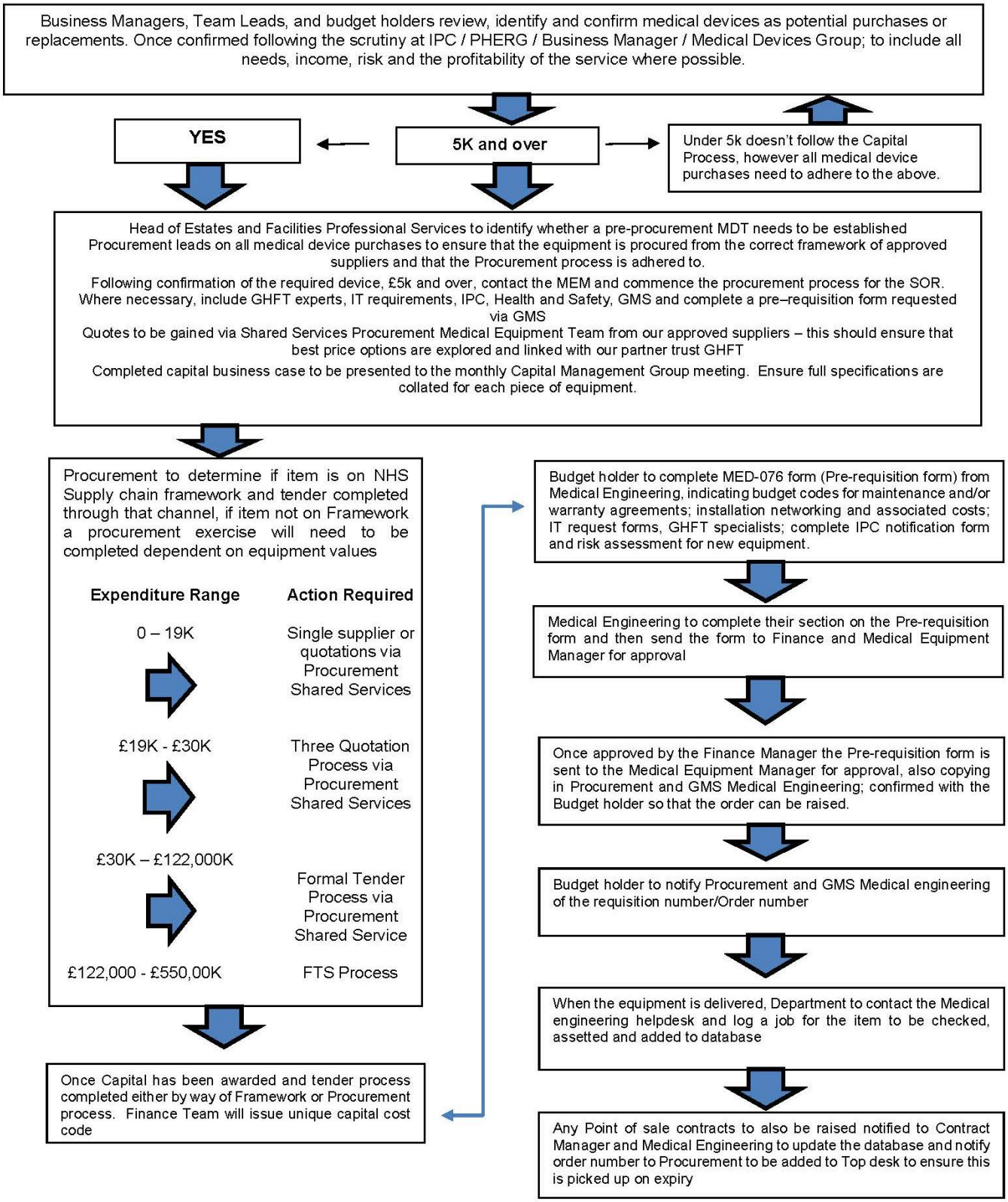
White Paper – Cyber Vulnerabilities in Digital Diagnostic and Medical Equipment used in the NHS

Digital Technology Assessment Criteria (DTAC)
Digital Technology Assessment Criteria (DTAC) - Key tools and information - NHS Transformation Directorate (england.nhs.uk)

DCB 0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems
DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems - NHS Digital

DCB 0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems
DCB0160: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems - NHS Digital

Appendix 1 - Pre-Requisition Process for Purchasing Medical Devices



Appendix 2 - Check List for Infection Control Approval for the Purchase of New Items
For a version of this form which can be typed/edited on a PC or Laptop or printed for completion, please click **here**

with you, for you

NHS
Gloucestershire Health and Care
NHS Foundation Trust

Check List for Infection Control Approval for the Purchase of New Items

(To be completed before sending to the Infection Prevention and Control team)

Date of request:	
Department name & location:	
Name of requester & contact details if any queries:	
Requested Item:	
What is it used for:	

	Question	Answer	Evidence (e.g. Link to manufacturer specs)
1.	Is the item licensed for multiple use/ patients? If not is this item for a named patient?		
2.	Is the item made if a waterproof & wipeable material?		
3.	Is the item easy to clean? • Moving parts • electronic • Easy to access areas (nooks & crannies) • Can it be dismantled & easily assembled		
4.	Can the item be cleaned with a universal Clinell wipe or detergent & water after each use?		
5.	In the event of a body fluid spillage or infectious agent, can the item withstand the use of a hydrochloric solution? Specifically, Actichlor plus at a concentration of 10,000 parts per million		
6.	Any other considerations		

Infection Control approval:	YES / NO
ICN name:	
Date:	

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Appendix 3 - Please click on the link below to access the:
Standard Operating Procedure: League of Friends (LOF) Purchases