HOLY CROSS HOSPITAL

Policy Title	Medical Device Management
Policy Group	Clinical
Policy Owner	Director of Nursing Services
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Cross References:	• Infection prevention and control policy and manual • Health & Safety policy • Risk management policy • Business continuity policy • Safe manual handing policy • Accident and incident reporting procedures • Clinical governance manual • Monitoring the quality and suitability of equipment • Audit folder • Staff competency checklist folder
References:	• Managing medical devices, Guidance for healthcare and social services organisations (MHRA)
How implementation will be monitored:	Reports to Management Team and Medical Advisory Committee, Annual audits
Policy Accepted by HSC/MT	17th February 2022
Sign off by CEO	

1. PURPOSE OF THIS POLICY

The purpose of this document is to outline a systematic approach to the management of all aspects in the lifecycle of medical devices that all risks associated with the acquisition, deployment, use, monitoring, record integrity, reprocessing, maintenance, record generation and storage, decommissioning and disposal of medical devices are minimised or eliminated.

2. POLICY STATEMENT

2.1. Definition of Medical Device (WHO)

''Medical device'' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*
- *investigation, replacement, modification, or support of the anatomy or of a physiological process,*
- *supporting or sustaining life,*
- *control of conception,*
- *disinfection of medical devices*
- *providing information by means of in vitro examination of specimens derived from the human body;*

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

2.2. For practical purposes at Holy Cross Hospital, a distinction is drawn between single use disposable items (see list in Annex 2) and other equipment which is regarded as a medical device for the purpose of this policy.

3. RESPONSIBILITIES

3.1. Chief Executive

Has overall responsibility for the safe management of medical devices and compliance with the relevant external assurance standards.

3.2. Director of Nursing Services (DNS)

Director of Nursing Services is appointed as the Medical Device Safety Officer (MDSO).

Part of the MDSO role is to report adverse incidents to the MHRA and other official agencies.

- Provides advice to the Management Team on the procurement, management and deployment of medical devices
- Helps formulate related policy/procedures in line with recommended best practice
- Overviews the list of updated medical devices, responding to changing needs of the service
- Reviews all incidents/accidents or near misses reported involving medical devices for identification of trends, requirement of reporting to MHRA, and to further investigate (or assist with) where required.
- Keeps record of a regular summary of these incidents and any reports made to the MHRA on the Hospital electronic central accidents/incidents log system

3.3. General Manager (GM)

- Provides advice to the MDSO on the management of medical devices
- Co-ordinates with MDSO in regards to the training of staff in all relevant aspects of this policy
- Keeps updated a list of medical devices, advises MDSO on changing needs of the service
- Co-ordinates with the suppliers in relation to the regular service and electrical safety test of medical devices

3.4. Department Lead

Department lead in this policy covers ward sisters, leaders for individual therapy teams.

Are responsible for the safe use of medical devices within their locations by:

- Ensures, especially at induction, that staff are aware of their responsibilities regarding the safe use of medical devices
- Has systems in place to ensure that staff using medical devices are adequately trained on relevant equipment
- Keeps appropriately documented evidence of staff training
- Ensures that any accidents or incidents involving equipment are promptly and fully investigated and reported.
- Establishes local procedures for the management of devices to comply with the requirements of this Policy
- Completes risk assessments on devices which may pose a significant risk to patients or staff
- Keeps medical device in an appropriate state of repair and is cleaned according the Hospital Infection Prevention and Control policy
- Co-ordinates locally the audit of medical devices

3.5. Medical Supplies Officer

- Maintains an equipment inventory, and disposes of medical devices in the required manner
- Ensures medical devices are stored in a safe and secure location when not in use
- Co-ordinates with ward and department lead to ensure medical devices are decontaminated and packed prior to being sent for repair or replacement
- Reports to the MDSO on issues or potential risks raised in regards to the supply, usage, maintenance and disposal of devices

3.6. Staff

It is the responsibility of employees involved in the use of medical devices to ensure:

- They are trained and competent in the use of the medical devices
- Training records are maintained and updated
- They only use medical devices if authorised to do so
- All medical devices are suitably decontaminated after each patient use
- All medical devices are safely stored and maintained when not in use
- They follow procedures regarding the management and use of medical devices
- They report any defects or faults with devices immediately
- They clearly label defective devices and ensure they are taken out of action
- They make defective devices available for maintenance
- They report all incidents/accidents or near misses to their line manager immediately

3.7. Independent Contractors

The Hospital requires that Contractors comply with all relevant policies and that managers of the area where contractors are working ensure that they are aware of any relevant Hospital policies.

Where Manufacturers or their agents carry out maintenance on medical devices on site a record of the visit must be kept centrally by the General Manager. This would normally be a copy of the company service report.

4 STANDARDS AND PRACTICE/PROCEDURE (Annex 1)

5 EQUALITY AND DIVERSITY

This policy has been checked for overt or implied discrimination within the scope of the Hospital's policies on equality and diversity and none was found.

Annex 1: Standards and Practice/Procedure

1.1. Procurement

1.1.1. Prior to ordering any new medical devices the following factors should be considered.

- Clinical requirement
- Suitability
- Patients' needs safety
- Training requirements
- Decontamination
- Maintenance implications
- Compatibility with other devices
- Whole life cost
- Standardisation/ preferred devices

1.1.3. Those proposing the purchase of a new medical device must ensure that a risk assessment has been performed on the use of the device in their area before purchase

1.1.4. Purchasing of new medical devices should be established in consultation with the professionals who will be prescribing, supplying or using them

1.1.5. An approval must be obtained from the Hospital Management Team prior to placing an order for a new medical device

1.2. Acceptance Procedures for New Equipment

1.2.1. New medical devices are to be entered onto the Hospital Medical Device Inventory (saved in O drive – Equipment – Clinical Equipment – Medical Device Inventory) before use

1.2.2. Department lead must ensure they are in receipt of the medical device user manual when accepting the device. They should ensure that all users of the devices receive appropriate training on device before it is put into use, and that this training is recorded. The user manual must be retained for the duration of the equipment's life and be available for consultation by users.

1.3. Medical Device Inventory

1.3.1. Accurate electronic records are required to be made available for future inspection, review and copying e.g. for CQC, internal audits, traceability, investigations

1.3.2. Medical device inventory database holds a minimum following information:

- Generic name
- Manufacturer
- Mode/Type
- Asset number
- Department/location
- Maintenance history/repair
- The end of life date
- Purchase price
- Installation

1.3.3. Medical device inventory must be kept up to date, informing MDSO of any changes.

1.4. Receiving a New Device

1.4.1. Check that the device matches the acquisition specification, is undamaged, is accompanied by all the necessary information and documentation, and that it is:

a) Appropriately configured
b) Supplied with appropriate accessories
c) Supplied with appropriate consumables
d) Supplied with appropriate instructions for use

1.4.2. Make sure that the appropriate acceptance checks and tests have been carried out in accordance with risk assessment and legal requirements

1.4.3. Where relevant, ensure medical devices have been appropriately installed

1.4.4. Details of the device and the manufacturer's instructions have been entered into the appropriate device monitoring and tracking systems

1.4.5. Training needs have been identified and acted on

1.4.6. For reusable devices, maintenance has been scheduled

1.4.7. All department lead must have access to manufacturers or local produced instructions both for reference purposes and to ensure that the device is operated properly and safely at all times.

1.5. Care of Devices by Users

1.5.1. Users must follow the manufacturer's guidelines on the care and user maintenance of equipment and devices. Regular basic checks by users prior to use checking for, as a minimum, any obvious signs of damage, cleanliness and faults affecting performance or safety

1.5.2. Department lead must arrange for suitable storage of medical devices when not in use. The storage facilities should take into account any special requirements for infection control, temperature, humidity, etc. and that any device that has rechargeable batteries is kept on charge

1.6. Maintenance

1.6.1 The Hospital is responsible for ensuring all medical devices are maintained appropriately, including reconditioning and refurbishment

1.6.2. Department lead must ensure that medical devices are made available for planned maintenance at the appropriate time in accordance with the manufacturers' instructions

1.6.3. Where a manufacturer or their agents carry out maintenance on medical device on site a record of the visit must be kept. This would normally be a copy of the company service report

1.7. Decontamination

1.7.1. The Hospital has an infection control manual, which outlines the process required regarding decontamination of medical device to provide safe clean device to control the spread of micro-organisms

1.7.2. When a medical device is to be returned for maintenance or repair (or to any other location, e.g. Manufacturer, after loan period) the user must ensure that it has been properly cleaned and decontaminated prior to return, and labelled as such. It is an offence to send contaminated devices through the external mail or transport system

1.8. Devices on loan/loaned out by the Hospital

1.8.1. It is essential to ensure that the legal liabilities that may expose the Hospital to litigation are managed and controlled with regard to medical devices that are loaned to third party Healthcare providers

1.8.2. Department lead are responsible for ensuring that devices borrowed from the area of their responsibility is fit for use, staff are suitably trained

1.8.3. Departments that loan devices to other healthcare providers must keep accurate records to include device make, model, serial number, contact information and any accessories or consumables

1.8.4. Devices must not be loaned to other organisations without the permission of MDSO

1.9. Replacement of Medical Devices

1.9.1. Medical devices must be replaced when it becomes unsafe to use, no longer producing clinically acceptable results or it is no longer supported by the Manufacturer. Disposal of old devices must be carried out in a safe manner and follow the Hospital Waste Management Policy

1.9.2. MDSO must be informed when a medical device is disposed of to enable the medical device inventory list to be updated

1.10. Incident Reporting

1.10.1. All incidents and near misses must be reported via the Hospital Incident Reporting System. Staff reporting incidents involving medical devices are advised to isolate and label the device and any associated consumables

1.10.2. Reporting is essential to ensure that lessons are learnt and adverse events are not repeated. National reporting is essential to ensure that trends are spotted and appropriate action is taken across the country to help ensure the safe and effective use of medical devices, for example through safety warnings and MHRA

1.11. Medical Device Developments and Modifications

1.11.1. Medical devices must not be used for any purpose other than that for which it was designed

1.11.2. ‘’In house’’ manufacture or substantial modification of medical devices must comply with the Medical Device Regulations at the design, manufacture and clinical evaluation stages. The relevance of this statement to such as wheelchairs and customised splints is under investigation.

1.12. Training

1.12.1. The Hospital requires that staff should use devices that they are confident and competent to use. Staff should not use devices for which they have not received training

1.12.2. Staff have a professional duty to ensure their own skills and training remain up to date regarding the safe use of medical devices

1.12.3. Staff need to be trained in adverse incident reporting requirements for medical devices

1.12.4. Individuals providing repair and maintenance services need to be adequately trained and appropriately qualified. This applies to directly employed staff, contracted services or others

1.13. Safety Action Bulletins

1.13.1. The Electricity at Work Regulations (EWR) and the Health and Safety at Work etc. Act (HASAWA) form the basis of programmes used by Hospital maintenance staff for the regular electrical testing or inspection of portable electrical equipment.

1.13.2. From time to time the MHRA issues Safety Action Bulletins (SAB) relevant to medical devices. There are mechanisms in place to distribute manufacturer's Field Safety Notices, MHRA Medical Device Alerts, and other MHRA safety guidance to the appropriate people in the organisation and to report incidents

- MDSO receives all MHRA Medical Device Alerts and forwards the relevant Alerts to department lead
- Department lead act on the individual Alerts accordingly (e.g. removing from the department, reporting to manufacturers or their sale agents, replacing a new device, etc.)
- Staff need to sign the Alerts to acknowledge the notification and agree on action plans
- Department lead report back to MDSO on action plans and current status
- MDSO updates the medical device inventory list

1.14. Monitoring and audit

1.14.1. Monitoring the Hospital's performance on medical device management is important to minimise or eliminate risks to patients and staff

1.14.2. Regular and random audits are carried out to examine the Hospital's policies and procedures for the safe acquisition, use, maintenance and repair, decontamination and disposal of medical devices against the checklists set out in this guidance.

1.14.3 Audit tools (see Annex 3)

Annex 2: Single use disposable items

Sterile/non-sterile gloves
Inco-pads
Incontinent pads
Feed giving sets
Syringes
Needles
Tracheostomy tube (not Silver tube)
Sterile/non-sterile gauzes
Sterile gallipots
Metalline tracheal dressing
Tracheostomy tube bands
Tracheal inner cannulas
Suction catheters
Urine leg bags
Urine night bags
Feed bottles
Dressing Packs
PEG extension sets
Fisher Paykel 3 way circuit sets
Nebulizer tubes, pots
Nebuliser/ventilator T-tubes
Catheter mounts
HME (Heat Moisture Exchange)
Swedish noses
Pennine tubes
Ambu bags
Indwelling catheters
Bibs
Plastic Aprons
Clear tubing for ventilator
Oxygen tubing
Oxygen tubing adaptor
Yankeauer Suckers
Catheterisation packs
Various dressings

Annex 3: Audit tools

- Decontamination of equipment
- Equipment cleanliness
- Stores Audit
- Use and maintenance of Vehicles, plant and equipment and PUWER
- Clinical Competency for Medical Devices

INFECTION CONTROL AUDIT TOOL
DECONTAMINATION OF EQUIPMENT

Standard: Equipment is decontaminated making it safe for use and minimising the risk of cross infection.

Date: …… **Auditors: ……..**

	Complies	Non-compliant	Comments
There are comprehensive procedures and guidelines on the decontamination of re-usable equipment *Check both wards and team room*			
Staff are aware of the guidelines and where to find them *Ask 5 day staff from each ward, 3 night staff from each ward and 3 therapy staff*			
Staff receive training in decontamination of equipment as part of infection control training *Ask 5 day staff from each ward, 3 night staff from each ward and 3 therapy staff*			
Staff are aware when and how to fill the decontamination form *Ask 5 day staff from each ward, 3 night staff from each ward and 3 therapy staff*			
Single use items are discarded after use on a single occasion *Ask 5 day staff from each ward, 3 night staff from each ward and 3 therapy staff (ask for examples)*			
Staff can recognise the symbol for single use equipment *Ask 5 day staff from each ward, 3 night staff from each ward and 3 therapy staff*			
Single patient use devices are used on more than one occasion on the same patient then discarded *Ask 5 day staff from each ward, 3 night staff from each ward and 3 therapy staff (ask for examples)*			
Pre-packed single use or single patient use devices are stored in a clean area off the floor			

Visible check			
Stock is rotated *Visible check*			
Stock is in date *Visible check*			

Other comments:

TOTALS
OVERALL SCORING
POTENTIAL TOTAL
PERCENTAGE %
STATUS
DATE OF NEXT AUDIT

INFECTION CONTROL AUDIT TOOL
EQUIPMENT CLEANLINESS

Standard: Equipment will be maintained in a condition to minimise cross infection. Equipment is visible clean, free from body fluids or other contaminant, debris and dust.

Date: …… **Auditors: ……**

	Yes	No	Comments
Patient rooms			
Beds (*check 10)*			
Bed rails (*check 10)*			
Clinical trolleys (*check 10)*			
Mattresses (*check 10)*			
Commodes *(check 3)*			
Bed pans *(check 3 in each ward)*			
Urinals *(check 10)*			
Portable hoists (Molift) *(check 3)*			
Overhead hoists(*check 10)*			
Slings and slide sheets(*check 10)*			
PAT slide			
Splints(*check 10)*			
Walking frames (2)			
Nebulisers(*check 10)*			
Suction machines(*check 10)*			
BP monitors (2)			
ECG machine (1)			
Oxygen flow meters			
Oxygen trolleys and cylinders (10)			
Ventilators			
Enteral feeding pumps(*check 10)*			
Humidifiers (10)			
Drip stands(*check 10)*			
Ampu lamp (2)			
Scales (2)			
Positioning rolls(*check 10)*			
Banana boards			
Rubber mats (5)			
Theravital exerciser (1)			
Standing frame and straps (1)			
Plinths (2)			
Tilt table and straps (2)			

Ultrasound (1)			
Stethoscopes (2)			
Ophthalmoscope			
Auroscope			
Wash bowls(*check 10)*			
Resuscitation trolleys SAF and hydro			

Other comments:

TOTALS
OVERALL SCORING
POTENTIAL TOTAL
PERCENTAGE %
STATUS
DATE OF NEXT AUDIT

Stores Audit

Date: ……. Auditors:

		Complies	Does not comply	Comments
1	All orders are placed using a purchase order			
2	Storage areas are secure and unauthorised access is prevented			
3	Stock holding levels are kept at a minimum, ideally no more than two weeks stock held			
4	Deliveries are received by Support Services Team Leader Housekeeper or designated person in their absence			
5	Delivery notes are checked and signed to confirm receipt			
6	The good are dispatched to their end location without delay.			
7	The quality of good is checked on receipt and quantities are checked against delivery note. Variations are reported to supplier without delay			
8	Deliveries are checked against the purchase order to ensure that correct good have been delivered			
9	Good received into clinical stores are checked to ensure the manufacturers use by dates are of suitable length			
10	Storage areas are kept Tidy			
11	Goods are rotated to ensure older stock is used first			
12	Good are stored in such a way to ensure they are easily accessible and do not present a manual handling risk			
13	No items are stored in corridor outside stores			

HEALTH AND SAFETY AUDIT

Use and maintenance of Vehicles, plant and equipment and PUWER

Standard: All general equipment and medical devices will be safe to use

Date: ……. Ward: …… Auditor: ……..……

	Complies	Does not comply	Comments
Vehicles owned by the organisation are: Taxed, MOT'd, all those who drive them are insured, serviced, kept in a secure area, with tight key security *Ask maintenance*			
Within vehicles where patients are taken, there are secure fixings, which are correctly used. *Check when there's an outing*			
There is a comprehensive policy for the procurement, commissioning, maintenance, repair and disposal of equipment *Check general policy book*			
Service contracts are set up for all safety critical equipment, including medical devices *Check with General Manager*			
Maintenance requisition forms are used when items need to be repaired. Equipment being labelled and taken out of use till mended *Ask 10 members of staff*			
Any medical device which malfunctions is reported to the MHRA, and the item and any packaging with batch numbers etc, quarantined until permission is given by the MHRA to release it. Batch numbers of any invasive medical device is kept in the patient's notes *Ask General Manager*			
Medical advice alerts are processed and actioned as appropriate *Ask General Manager*			
All obsolete equipment is disposed of according to the WEEE regulations by segregating for our waste contractor *Ask General Manager*			
Equipment risk assessments are written for all items which have safety implications, including medical devices *Ask General Manager*			

Equipment manuals are available for all equipment – user and maintenance manuals *Check 5 nurse servers from each ward, check all departments*			
Competency based assessments are completed for staff who use equipment which has safety implications, including medical devices *Check competency checklists on both wards and departments*			
Statutory equipment inspections have been carried out according to legal requirements eg hoists *Ask General Manager*			
Gas safety policy is written, along with risk assessment. Competent person is contracted to carry out statutory testing *Ask General Manager*			
Noise risk assessment has been carried out for the generator room and controls are always used *Ask General Manager*			
Electrical safety policy is written and staff have signed to say they have read it. *Ask General Manager*			
Electrical risk assessments are written for tasks on electrical equipment *Ask General Manager*			
All portable appliances have a label showing that they are in date *Check 10 items around hospital*			
Residual Current Devices (RCD's) are used if there is a significant risk of electrocution ie where water and electrical equipment are present *Check housekeeping equipment*			
Staff who bring in items from home, including in staff accommodation, have this visually inspected *Ask maintenance*			
The database of all electrical appliances is kept up to date, by staff identifying when new equipment is purchased			

Ask maintenance			

Other comments:

TOTALS
OVERALL SCORING
POTENTIAL TOTAL
PERCENTAGE %
STATUS
DATE OF NEXT AUDIT

Clinical Competency for Medical Devices

Name:	Role:
Base:	Date Initial Training Completed:
Medical Device Competency Reports To:	

Performance Criteria	Assessment Method (verbal, questioning, demonstration)	Date	Assessor/Self-assessed
The participant will be able to:			
Understand what the device is to be used for			
Has read and/or viewed any manufacturers materials related to the medical device			
Demonstrates an understanding of the specifications of the device			
Shows understanding and competency in setting up the device correctly			
Understands any safety features on the device and the rationale for them being there			
How to set the controls on the device appropriately			
Recognise any malfunction or error from the device and take appropriate action			
An understanding of the safety features available on the device and the level of reliance that should be placed on them			
Demonstrates safe practice by ensuring they double check both the patient and the device			
Able to monitor and check safe functioning of the device, as per manufacturers guidance			
Able to recognise when the device has failed			
Is able to decontaminate/clean the device as appropriate			
Understands when or how to obtain assistance of advice			

I confirm that I am competent to use this named piece of equipment

Name Signature Date

I confirm that I have assessed the above named person and can verify that he/she demonstrate competency in using the named medical device

Verifier/Manager Signature Date