Medical Devices Management Policy

Post Holder Responsible for Policy:	Head of Medical Device Management Services
Divisional Responsible for Policy:	Family and Support Services (FASS)
Contact Details:	Head of Medical Device Management Services
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Version Information

Version No.	Updated By	Updated On	Description of Changes
1.0	Nicki House	August 2004	New Policy
2.0	Nicki House	October 2007	Minor amendments agreed at the MDC meeting on 12 November 2007.
2.1	Linda Riddell	December 2007	Further minor amendments agreed at the MDC meeting on 3 December 2007.
2.2	Penny Daffurn Gerard Sword	May 2008	Minor amendments.
3.0	Nicki House	October 2010	Formation of new policy for maintenance causing this policy to need amending.
3.1	Kate Stovin-Bradford	July 2013	Review and minor amendments.
4.0	Nicki House	November 2015	Review and amendments to references, new MDSO role, definition of medical devices added and minor amendments.
5.0	Mandy Cripps	April 2019	Review and amendments. New policy names and references. Include more information re TWG's
6.0	Mandy Cripps	June 2022	Minor amendments. Introduction of Microguide. Removal of section related to modification of medical devices as this is not undertaken.
7.0	Alex Sims	October 2025	Minor updates to alerting, IT and Decontamination pathways. Reference updates.

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1 Introduction

1.1 The Trust owns and relies upon a large stock of medical devices in order to carry out its function of patient care and treatment. This policy was based upon the requirements of the Care Quality Commission 'Regulation 12: Safe Care and Treatment', and 'Regulation 15: Premises and Equipment'. It is further informed by the Medicines and Healthcare products Regulatory Agency (MHRA) guidance publications 'Managing Medical Devices' 2021, and Checklists for using medical devices' 2014.

1.2 The ownership and use of medical devices has a statutory basis within the Provision and Use of Work Equipment Regulations 1998 (PUWER). This policy is the basis by which the Trust complies with PUWER regulations in the use of medical devices.

1.3 The Trust operates and manages this policy through the Medical Devices Committee (MDC). The MDC provides the functions defined in paragraph 2.2 of 'Managing Medical Devices, January 2021' for a medical devices management group. The Terms of Reference of the MDC are available on request from the Head of Service, MDMS.

2 Policy Statement

2.1 This policy applies to all grades and disciplines of staff working at SFT.

2.2 The policy applies to all medical devices which are brought into the Trust, whether purchased through Trust Capital funding, revenue funding, charitable funding, research funding, loaned or donated.

2.3 This policy covers the ownership and use of medical devices in the Trust and includes references to corporate and risk management structures, evaluation and selection of new devices, information and documentation, training, decontamination, maintenance and quality systems.

2.4 The Trust will promote the safe and appropriate use of all medical devices available in the Trust by ensuring that the healthcare professionals who use such devices are aware of the associated risks and have access to training and support to develop and maintain their knowledge, skills and competence.

The Trust requires that a formal record be kept of training received.

3 Definition of a Medical Device

A medical device is any product used in the:

- diagnosis, prevention, monitoring and treatment of disease or disability
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy, or of a physiological process
- control of conception.

A list of examples of medical devices are shown in the MHRA publication *"Checklists for using medical devices, April 2014".*

4 Responsibilities

4.1 There is a Trust Board Director who has executive responsibility for all issues relating to medical devices. This is the Chief Operating Officer.

4.2 The Trust owns and accepts responsibility for all purchased or donated medical devices that have been appropriately brought into the Trust (excluding leased or contracted arrangements).

4.4 It is the responsibility of clinical staff acquiring devices which have been borrowed, loaned or are on demonstration to ensure they are used in accordance with the Policy for the Introduction of New Procedures, Techniques or Major Changes in Clinical Practice ~~s~~ within Salisbury NHS Foundation Trust, which is available on Eolas

4.5 Managerial responsibility of a medical device, including devices borrowed from the MDMS Equipment Loan Library, lies with the relevant ward or department manager. This includes ensuring that the item is maintained and used in a safe manner, and that all staff are competent and confident in its use.

4.6 Each ward or department is also responsible for highlighting the need for replacement of medical devices as they approach the end of their anticipated life. Disposal should be discussed with MDMS, who need to be informed so that the device can be removed from the asset register and can support with identifying or obtaining a replacement device. MDMS will also condemn faulty items beyond economical repair.

4.7 The person responsible for co-ordinating the Trust's medical device management is the Head of Medical Device Management Services (MDMS) within the Family and Support Services Division. The MDMS supports the Trust requirement to collate the service information provided by equipment manufacturers after completion of service procedures for the life of the device.

5 Evaluation, Selection and Purchase of Medical Devices

5.1 All bids must be approved by the relevant Divisional Management Team (DMT) along with a robust business case and risk assessment. The DMT will prioritise their Division's bids and forward to MDMS.

5.2 The Director of Finance will allocate a capital budget for the use of the MDC each year. This will cover single or multiple devices valued at over £5,000 inclusive of VAT.

5.3 As part of the Capital Bid process MDMS will ensure that all requests, for the purchase of medical devices are approved and prioritised by the relevant Technology Working Group (TWG) regardless of source of funding. Each TWG is made up of specialists who review bids under the following groupings;

- Critical Devices
- Imaging
- Assistive Technology
- Pathology and Laboratory
- Operating Theatres and Endoscopy

5.4 The bids are then further reviewed by the Medical Device Committee (MDC) regardless of the source of funding. The MDC will be responsible for prioritising the bids to ensure the capital spend is not exceeded.

5.5 The Trust's Standing Financial Instructions and Standing Orders will be always adhered to.

5.6 MDMS has established a medical equipment loan library for commonly used items of equipment. This allows for economies of scale and ensures that maximum utilisation is obtained from each device. Wards and departments can access items in the library as and when they are needed

6 Acceptance of Devices into Use

6.1 All medical devices must go through an appropriate acceptance test before being put into patient use. Electronic portable items must be sent to MDMS for these tests to be carried out; large or fixed items of equipment can be tested in their location of use; specialist items e.g. x-ray machines or pathology analysers, should be installed and commissioned in the appropriate manner by qualified personnel. Items owned by the Trust will be recorded on the Trust Asset Register and the MDMS database as will equipment on long term loan.

6.2 The Acceptance Procedure is attached as an Appendix A to the Medical Devices Maintenance Policy, which can be found on Eolas. This includes an important section of cybersecurity.

6.3 All equipment or software which connects to the Trust Network must conform to the current standards for Connectivity & Cyber Security as approved by the Trust Informatics Department.

6.4 MDMS should be advised by clinical teams or departments of all new devices for purchase or trial to ensure indemnity and entry onto the Equipment asset register. Please refer also to the Trust's "Suppliers and their Representatives – Code of Conduct".

6.5 When an item is delivered to a ward or department after having been formally accepted by MDMS, the manager must ensure that any local acceptance tests that should be undertaken are performed.

6.6 Reusable non-electronic medical devices delivered direct to the ward or department will not have been 'acceptance tested' by MDMS and the manager should ensure that they are asset registered and in good condition and working order before use. There must also be clear decontamination instructions from manufacturers for staff to follow to ensure safe use for multiple patients and staff are advised to seek assurance of compliance by contacting the Trust Decontamination Lead. The manager must advise MDMS of the arrival of all new reusable medical devices.

6.7 When a new medical device is received into a ward or department, the manager must ensure that all staff receive training on its use and have access to user instructions. Instruction manuals for commonly used medical devices will be uploaded onto the Trust's Intranet.

6.8 Managers must arrange for suitable storage of medical devices when they are not in patient use. The storage facilities must consider any special requirements for infection control, temperature, humidity, exposure to light or other requirements specified by the manufacturer. Any device that has rechargeable batteries must be kept fully charged and in optimum condition by adherence to manufacturer's recommendations.

7 Maintenance, Repair and Decontamination of Medical Devices

7.1 Managers should ensure that appropriate arrangements for maintenance and repair are in place for when the equipment warranty expires. Although MDMS undertake much of the medical device maintenance, there are items which are outside their expertise e.g. Radiological equipment. It is then the manager's responsibility to ensure that a suitable maintenance contract is negotiated via the Procurement Department.

7.2 Maintenance & repairs should only be undertaken by suitably qualified technical staff. More information can be found in the "Medical Devices Maintenance Policy" which is located on Eolas**.**

7.3 The MDMS team do not manufacture medical devices in-house.

7.4 It is the ward or department manager's responsibility to ensure that medical devices are properly decontaminated between patient use. The Trust Decontamination Policy, which includes the requirements for decontamination of medical devices is located on Eolas. Guidance on specific situations or diseases associated with increased risk of transmission of infection are also available within the Infection Prevention and Control policies also located on Eolas.

7.5 Loan library equipment must be properly decontaminated, and should have a decontamination certificate attached, before it is returned to the MDMS.

7.6 When equipment is to be repaired by MDMS, a blue label stating the fault and decontamination status must be attached. Where devices are to be returned to a manufacturer or third-party maintenance provider, the ward or department manager must ensure that is has been properly decontaminated with a decontamination certificate attached. It is illegal to send contaminated devices through the post. For advice on how to arrange collections or send equipment off-site for repair, please contact MDMS.

7.7 If a device is contaminated internally and therefore cannot be adequately cleaned before dispatch for maintenance or repair, this fact must be communicated to the technical team undertaking the work, either MDMS or external engineers, to ensure the equipment is transported in a safe and agreed manner. A decontamination certificate, stating the degree of residual contamination should always be attached. The Decontamination Lead can be contacted for advice via MDMS.

8 Training

8.1 All healthcare professionals must be trained in the correct use of each medical device relevant to their role and it is their responsibility to ensure they are competent and remain up to date. MDMS will arrange training opportunities, and it is the ward and departmental manager's responsibility to ensure that medical equipment training is accessible to all staff.

9 Safety and Incidents

9.1 The safety of patients and staff is paramount at all times. It is the responsibility of all users to ensure that medical devices are used in such a manner that the patient or staff safety is not put at risk.

9.2 Staff must ensure that a medical device is working correctly before using the device; it should be clean, within service date, have appropriate power supply and must not be showing any obvious signs of damage. It should also have a secure location for use e.g. fixed level surface or attached to a drip stand or rail designed for the purpose. It should not be used or issued if any of these requirements are not met.

9.3 Before a new medical device is put into service, the manager responsible for the equipment may undertake a risk assessment to ensure that any possible hazards arising from the use of the device are identified and appropriate precautions taken. Please refer to the Risk Management Policy and Procedure which is available on Eolas.

9.4 In the event of an adverse event occurring involving a medical device, the Datix Incident Reporting Policy must be followed, which is available on Eolas. It is vital that the asset number, serial number or batch/lot number of the device in question is recorded on the incident form to enable the device to be tracked and appropriate action taken. It is important that the affected device, and any associated consumables, are retained by the Trust as it may be required as evidence. Staff involved should remove the affected device and consumables from the clinical area and keep them secure in a ward or department office (or similar) until they can be handed over to MDMS. Photographs of damaged or failed devices can be attached to the incident report submitted via Datix and are helpful to illustrate the issue.

9.5 If there is a safety concern regarding a medical device, it should be reported externally to the MHRA. At SFT, this is routinely carried out by the Medical Devices Safety Officer (MDSO) as part of the internal investigation and ensures learning from the event or device concern is coordinated. Any individual (healthcare professional or member of the public) can report to the MHRA via the Yellow Card scheme however, so where SFT teams support equipment in use in the community, e.g. outpatient use, our patients should be encouraged to report device concerns to their healthcare professional and the MHRA.

9.6 The Head of MDMS and Trust MDSO are responsible for receiving notification of device related incidents and will monitor themes and trends, supporting teams to mitigate recurrence and promote learning.

9.7 All Medical Device Field Safety Notices (FSN) and Field Safety Corrective Actions (FSCA) sent via the national Central Alerting System (CAS) will be received into the Trusts Safety Alerts Broadcast (SABs) inbox. From here they will be co-ordinated centrally by MDMS and disseminated to all relevant healthcare professionals. Any FSNs or FSCAs sent by manufacturers or device distributors and received directly by SFT employers, should be forwarded to SABs or MDMS to ensure actions are coordinated and responses captured. Please refer to the Trust's CAS Alerts Management Policy via Eolas for further information about national alerts.

9.6 MDMS will receive manufacturer's safety or modification instructions and ensure that they are implemented with appropriate urgency for any medical devices for which they are responsible.

9.7 No modification to any medical device will be permitted unless it has been approved by the manufacturer however some devices require modification to provide bespoke treatment or

support for individual patients. In these situations, professionals with appropriate accreditation compliant with the MDR 2002 can undertake modifications and other staff should seek advice of MDMS or Medical Engineering team.

10 Prescription of Medical Devices

10.1 Any healthcare professional who prescribes medical devices for use by a patient must be qualified to do so.

10.2 Managers of wards and departments must ensure that their procedures include the prescription of medical devices and that these are enforced appropriately.

10.3 Where clinical teams issue medical devices to patients or carers, they must ensure the appropriate instructions accompany the device and training has taken place. Arrangements for technical support, maintenance and repair must also have been clarified.

11 Policy Monitoring and Audit

The implementation of this policy is monitored by the following means:

11.1 Regular Heads of Service meeting with the Family and Support Services Divisional Manager for financial, operational (including responsibilities) and resource issues.

11.2 The Head of MDMS and Trust MDSO are responsible for receiving notification of device related incidents and will monitor themes and trends, ensuring compliance with the policy and medical device regulations, supporting teams to mitigate recurrence and promote learning.

11.3 Regular meetings of the TWGs agree the purchase of new devices, and MDMS and Procurement monitor the purchase of items new to the Trust. The TWGs report directly to the MDC.

11.4 Regular meetings of the MDC monitor resource, inventory, maintenance and policy issues. (Appendix A) This group is a subgroup of, and accountable to, the Trust Management Committee (TMC). MDC minutes are recorded and emailed to the TMC.

12 Associated Policies

Medical Devices Maintenance Policy
Medical Device Training Policy
Datix Incident Reporting Policy
Policy for the Introduction of New Procedures, Techniques or Major Changes in Clinical Practice
Infection Control Policies
Decontamination Policy
Risk Management Policy and Procedure
CAS Alerts Management Policy
Suppliers and their Representatives - Code of Conduct

13 External References

Care Quality Commission: *"Regulation 12: Safe care and treatment" (2014)*
Care Quality Commission: *"Regulation 15: Premises and equipment" (2014)*
Medicines and Healthcare Products Regulatory Agency: *"Managing Medical Devices, January 2021"* *Safeguarding public health*
Medicines and Healthcare Products Regulatory Agency: *"Checklists for using medical devices, April 2014"* *Checklists for using medical devices - GOV.UK*
Medicines and Healthcare Products Regulatory Agency*: "Regulating medical devices in the UK, December 2020"*
Government Legislation: "Medical Devices Regulations 2002 (UK MDR 2002)" *The Medical Devices Regulations 2002*