Medical Devices Management Policy

Contents

1 Statement of Aims and Objectives

1.1. This Policy establishes the organisational framework and responsibilities to ensure that:

1.1.1. The risks associated with the acquisition and use of medical devices are minimised, for both patients and health care professionals.

1.1.2. The Policy provides the framework for medical equipment within the Trust from acquisition through to disposal and outlines the expected life of medical equipment used in Trust.

1.1.3. The Trust complies with all relevant Medicines and Healthcare Regulatory Agency (MHRA) guidance and regulation.

1.1.4. Systems are in place to allow health care professionals to understand their role in the safe use, purchase, and management of medical devices.

1.1.5. The policy aims to ensure the Trust medical devices:

- Comply with Care Quality Commission (CQC) standards regulation 15 on prevention of incidents by unsafe or unsuitable devices.
- Are appropriately acquired, disposed of, and replaced.
- Are used by appropriately trained end users.
- Are appropriately maintained by suitably trained Medical Equipment Specialists (MES)
- Have appropriate records and supporting documentation available to end users.
- Have a full life cycle management process.
- Have an appropriate level of governance and oversight with clear line of accountability.

1.1.6. Systems are in place to ensure regular maintenance or servicing of medical devices takes place. The Logistics Services Manager maintains responsibility to ensure these take place and are logged.

1.1.7. This policy is applicable to all staff working within the clinical operational environment and supporting services.

1.1.8. This policy applies to medical equipment purchased by the Trust **AND** medical equipment leased by the Trust as part of fleet replacement programmes and equipment and vehicles provided as part of National Resilience programs.

2 Principles

2.1. Assurance Standard

2.1.1. This policy aligns with the CQC Standards for Better Health and NHSLA standards (Maintenance of medical devices and equipment) which require

healthcare organisations to ensure that a system is in place to manage risks associated with the acquisition, use, and disposal of medical devices.

2.1.2. Medical Devices are divided into 2 categories. **Serviced** and **Non-serviced** medical devices.

2.1.3. Within the context of this Policy serviced devices relates to, devices listed in Appendix 2.

2.2. All distribution, storage, maintenance and routine servicing of medical devices and equipment used to deliver patient care will be overseen by the Logistics Team. This includes equipment provided to specialist clinicians and voluntary responders.

2.2.1. All Trust medical devices will meet the relevant national/international standards prior to procurement. Procurement will be best achieved by purchasing against National NHS Purchasing and Supplies (PASA) or Office of Government Commerce (OGC) Contracts, 'Frameworks' or as specified within National NHS guidance as informed by operational productivity and performance in National NHS Ambulance Trusts: Where this is not appropriate or not possible, the procurement department will ensure adequate controls are in place, in line with the Trust's Standing Financial Instructions (SFIs) and Standing Orders (SOs), to ensure procurement activities are adherent to organisational and relevant national/international rules/laws.

3 Roles and Responsibilities

3.1. The Trust's **Chief Executive Officer** has overall responsibility for all aspects of health and safety and for policy implementation.

3.2. Executive responsibility is devolved to the **Director of Strategy, Planning and Transformation** who is responsible for ensuring that the policy is enacted throughout the Trust.

3.3. Day to day responsibility for the delivery of specific components of the policy is devolved to specific groups and individuals within the Trust. The **Strategy, Planning and Transformation Directorate** is responsible for the routine handling of matters related to medical devices. It is the responsibility of **Logistics Services Manager, through the Associate Director for Operational Support,** to ensure the implementation of a robust infrastructure to support this aim. It is the responsibility of the **Make Ready Centre Managers (MRCM)** to ensure that Medical Equipment is in serviceable condition and to highlight any issues relating directly to it.

3.4. The **Head of Patient Safety** has responsibility for managing the process relating to the receipt, dissemination and monitoring of actions for MHRA issued Safety Alerts.

3.5. **Individual Directors** are responsible for ensuring compliance with this policy in their scope of service delivery.

3.6. The **Central Health & Safety Working Group** is responsible for ensuring that the Medical Devices Management Policy is monitored for executive board reporting. This will be achieved by reports, received from the Clinical Equipment & Consumable Working Group and when required by exception.

3.7. The **Clinical Equipment and Consumables Working Group (CECWG)** will ensure that there is a consistent and coordinated approach to medical devices management across the Trust. The CECWG is the organisational focus for advice and best practice regarding the acquisition, use and management of medical devices. The objective of the group is to ensure that all activities undertaken within the organisation concerning the acquisition, appropriate use, maintenance, monitoring, and disposal of medical devices meets the requirements of the relevant standards, Standing Finance Instructions and any other statutory standards that may apply. This will be reported to the Senior Management Group.

3.8. The **Logistics Services Manager** will take responsibility for MHRA and NPSA related matters.

3.9. The **Medical Equipment Specialists** will ensure the effective and efficient management of all issues relating to the statutory and operational requirements for medical and surgical equipment within the Trust. This includes the planning, co-ordination and implementation of statutory and incidental servicing and repair in line with Annex A. Medical Equipment Specialists will also support in the reporting of adverse incidents involving medical devices to the Medical Health Care Regulatory Authority (MHRA).

3.10. The **Community Resilience, Specialist Operations, and Resilience Teams** will ensure that all assets are recorded on the Trust and national asset registers, that equipment locations are known, and servicing of equipment is in line with manufactures requirements. Further, the Resilience Team will ensure alignment of Trust processes with National EPRR and Interoperability standards where applicable.

3.11. **All staff and contractors** are reminded of their obligations under the Health and Safety at Work Act 1974, in terms of medical devices management in practice, this means that staff and contractors:

- Only use a medical device if they have been properly trained in its use or are sufficiently supervised by a suitably qualified person.
- Understand how to report adverse incidents and to implement any proceeding action.
- Users can seek advice and guidance if required relating to medical devices.
- Always check that equipment is serviceable and within labelled service date prior to use.

- Equipment is used as per manufacturers guidance.
- Equipment is appropriately cleaned/decontaminated prior to movement to another area. Items should be clearly labelled as decontaminated.

3.12. **Each Directorate** will assist the Strategy, Planning and Transformation Directorate (Logistics) in the procurement, management and monitoring of all contracts and arrangements for the maintenance of medical devices.

4 Introducing New Equipment

4.1. The Trust's Procurement Strategy and associated policies and procedures include the approach to the procurement of all medical devices including any equipment used for training and education.

4.2. No new medical devices may be introduced to the Trust **or** trialled by any party without the formal approval of the CECWG.

4.3. The Executive Director of Strategy & Transformation holds ultimate accountability for the introduction of any new equipment into the Trust. The Logistics Service Manager is responsible for coordinating and managing associated implementation processes. This manager will collaborate with Trust stakeholders to ensure:

- The device is suitable for its intended purpose in conjunction with specialist clinicians, Consultant Paramedics as well as all grades of clinicians in Trust.
- The device life cycle is clear.
- Funding for the initial requisition, ongoing revenue costs and replacement are in place.
- There is a fully ratified servicing programme in place before the item enters service.
- The device is utilised in line with the manufacturer's instructions.
- The device can be decontaminated as required by the Decontamination Policy and Procedure, which at times, may be by a chlorine-based solution.
- The device is traceable on the Trust's asset register (Jaama Key 2 platform and Resilience Direct (for National Resilience assets)) for the purposes of servicing and fiscal responsibility.
- A full risk assessment is undertaken in the use of the medical device with support from colleagues in the Trusts Health and Safety team before entry to service.
- That the device can be safely maintained in a reliable condition. This means the device is practical for end users, make ready contractors and MES. If the device will be maintained by the MES team the resource implications of this additional workload should be considered.
- The device has an anticipated life with a costed and funded replacement programme.

- The device should be disposed of appropriately at the end of its life. If the product is still operational at the point of retirement, auctioning should be considered in line with guidance from the Trust finance team through an approved disposal agent.
- There is a system of record keeping for the device. This includes a unique identifier, value (including depreciation over life) and introduction of servicing onto the servicing catalogue.
- That a training need analysis has taken place and the requirement for staff training is considered as part of any procurement exercise.
- Any user guides, manuals or supporting information is provided to Clinical Education for publication on the Trust intranet. The MES team should also be provided with any specialist servicing documentation.
- There is a system for record keeping for the training of users. This includes competent and safe usage of the device, the ability to carry out routine check and maintenance and requirements for refresher training.
- Further guidance for the nominated accountable officer can be found in Appendix 1.

4.4. Trialling of new equipment should be completed during simulated environments wherever practicable. This provides a fair and transparent methodology of comparing equipment.

4.5. New equipment trials should be reported to the membership of the CECWG for decision making.

5 Loaned and Borrowed Equipment

5.1. All equipment loaned or donated to the Trust for the purposes of trial and evaluation, or for operational use, must be subjected to the same rigorous risk assessment, educational needs analysis, acceptance procedures, maintenance and recording processes.

5.2. End-users are given instruction in the safe use of loan equipment in accordance with manufacturers' guidelines.

5.3. Loan / donated equipment is delivered and commissioned in accordance with service area procedures.

5.4. Loan equipment is collected or returned through the logistics (equipment) department when no longer required.

5.5. It is essential that an agreement is signed with the organisation making the loan as to the purpose and duration of the loan. Insurance arrangements must be agreed in writing and an indemnity agreement must be drafted and signed, unless the supplier has already signed the register held by NHS Supply Chain.

5.6. Any equipment purchased for the CFR schemes will remain the responsibility of the MES team to ensure adequate servicing of the

equipment is completed in line with manufacturers requirements. All CFR equipment purchased within SECAmb will be treated with the same process as any other devises purchased within the Trust.

6 Deployment, Monitoring and Control

6.1. Logistics will maintain the equipment database Key2 which once completed will be an inventory of all medical devices with accompanying service and repair history. This will be completed and updated by the MES operative.

6.2. Resilience and Specialist Operations will maintain the equipment database Resilience Direct (or its replacement), which once complete will be an inventory of all national assets and equipment required under national resilience programs. Once completed, this will be an inventory of all resilience assets with accompanying service history. This will be completed and updated by Resilience and Specialist Operations equipment technicians.

6.3. Equipment must not be modified or changed without the express involvement of the manufacturer.

6.4. When a new device is delivered to the Trust, and before it is added to the Medical Devices Inventory, an acceptance check is carried out to ensure that the device is complete and not faulty and that the correct device has been delivered. The following criteria must be met:

- The device is delivered complete and in good condition without visible defects.
- It is in working order and performs as expected.
- It passes standard safety inspection, e.g., Electrical safety test and/or manufacturers Commissioning Inspection.
- Controls/configuration conforms to Trust settings for intended use.

6.5. New medical devices will be brought into the Trust in the event of:

- Replacement of retired equipment
- Introduction of new equipment not previously used.
- As part of the commissioning of new vehicles
- As equipment is broken/contaminated beyond use in normal business activity

6.6. When medical equipment is introduced after being retired, part of new equipment or as replacements for damaged equipment it is the responsibility of the **MES** team to log this onto the Key2 platform.

6.7. When medical equipment is removed from service as part of retirement (outside of decommissioning process) or due to breakage it is the responsibility of the **MES** team to remove this from Key2.

6.8. When medical equipment is removed from service as part of decommissioning it will be sent to the **MES** team for review and removal and it will be the **MES** teams' responsibility to remove any equipment deemed no longer fit for purpose from Key2.

6.9. When medical equipment is introduced as part of the commissioning of new vehicles it is the responsibility of the **MES** team to register all items purchased and send to the Fleet Administration team to enter onto an Asset Management system.

6.10. The Trust does not currently have a full track and trace function. As a temporary measure the mitigation can be found in Appendix 3 while this system is developed.

6.11. When medical equipment is deemed defective, missing, damaged or contaminated beyond salvage a request for replacement must be uploaded to MARVAL this will be actioned in one of the following ways:

- Raise a DCIQ Datix via the Trust's report platform for investigation.
- If appropriate, raise a Safety Alert on the national PROCLUS platform (in the case of specialist operations equipment) via the Resilience Team.
- Arrange to remove equipment to be repaired.
- In exceptional circumstances some repairs may be carried out at local stations
- Arrange for an outside agency to affect a repair (A copy of the final inspection report will be added to the inventory)
- Condemn the item and arrange replacement.

6.12. On completion of the repair, the item will be returned to the location or held as a spare if the item has been replaced, and the incident logged on MARVEL will be closed.

7 Maintenance and Servicing of Medical Equipment

7.1. The MES team are responsible for ensuring that all maintenance and servicing is recorded on the Key2 platform for items identified as requiring service as per manufacturers recommendations. This includes any maintenance and servicing carried out by contractors.

7.2. The Trust employs MESs to carry out routine servicing and maintenance of equipment and where possible newly acquired equipment should be maintained by the MES team. Equipment or procedures considered beyond the scope of MESs will be serviced by external contractors and the MES Team will ensure that servicing records are captured on the Key 2 system.

The Logistics Services Manager is responsible for ensuring that a 5-year plan is available for the servicing of medical equipment. This should be

reviewed annually and presented to the CECWG. The 2021-25 schedule is provided as an example in Appendix 5.

7.3. Planned Preventative Maintenance (PPM) will take place as identified in Appendix 2. This PPM schedule is either as per the manufacturers printed instruction or considered acceptable following a fully documented process such as a risk assessment and specialist technical advice from an appropriately qualified source e.g., specialist technicians from the manufacturer. This may be necessary when an annual service is not possible due to the complexity of servicing and/or when the Trust usage differs from expected usage e.g., powered hoods used much less frequently than in industry.

7.4. Medical electrical equipment is not subject to the standard PAT testing procedures outlined in the IET Code of Practice and **should not be PAT tested**. Instead, medical equipment should be tested separately in accordance with IEC 62353. Portable medical equipment that requires a power source to operate **will be** subject to PAT testing of the class 2 adaptor leads.

7.5. **LifePak 15 Defects** - It is the responsibility of the MRCM to ensure that a DCIQ Datix is completed for any defect of a LifePak 15, this to include the serial number of the device. The device would need to be returned to the Medical Equipment Hub, Telford Place, Crawley for a diagnostic test to be completed by the device supplier engineer. The defected device would need to be red tagged and the Datix printed and attached to the device before collection is permitted by the Medical Equipment Specialist Operative.

7.6. **LifePak 15 Battery Condition & Replacement –** It has been agreed at the Clinical Equipment Working Governance Group that a LifePak lithium battery will have a life span of 5 years from the date on the reverse of the battery when manufactured, or if the battery will not charge past 2 bars (50%) which is displayed on the front of the battery (whichever comes first). The battery will then need to be decommissioned and a replacement will be provided by the Medical Equipment Specialist via a Maval request on the Trusts ordering platform.

7.7. **LifePak 15 Testing -** It is the responsibility of a Make Ready Operative (MRO) to ensure that a full test is completed on each LifePak 15, and a printout is left with the device. Also, that a full battery check is included as part of this regime. The MRC must then upload these checks onto Modus platform as evidence that the above compliance checks are captured.

8 Device Recall, Field Safety Notifications and Yellow card safety notifications

8.1. Other than Resilience assets under national resilience programs, the Trust does not currently have any real time or near real time asset

tracking. This means any recalls must be completed as described in Appendix 4. This process will ensure the Trust can affect a safe, proportionate, and timely response to concerns raised.

8.2. There are several routes for recall or safety notifications that come through the Logistics Services Manager, who is the Trust Medical Device Safety Officer (MDSO), and Strategic Medical Advisors should monitor. These include:

- Medical Health Care Regulatory Authority (MHRA) notification (internally through Datix).
- National Safety Alerts via PROCLUS for resilience equipment
- Direct communications from manufacturers.
- Reports from staff members.
- Reports from the Integrated Care Boards (ICBs) or wider NHS.
- Reports from the Emergency Preparedness Resilience and Response network.
- Internally led recalls following an incident or Datix trends.

8.3. The MDSO is responsible for ensuring yellow cards are submitted to the MHRA in the event of equipment faults identified within the Trust. This action may have been completed by other members of the Trust if the fault is reported outside of normal hours e.g., by Strategic Medical Advisors, however, it is the responsibility of the MDSO to check this has occurred and is documented in accordance with this Policy prior to a yellow card being raised, an internal investigation needs to be completed via a DCIQ Datix.

8.4. This Medical Devices Management Policy links to the Incident Reporting Procedure (which is within the Incident Reporting and Investigation Manual), and they should be read and implemented in conjunction with each other.

8.5. An adverse incident involving a medical device should be reported to the (MHRA) if the incident has led to or may have led to:

- Death, Life threatening injury or illness.
- Deterioration in patient or staff health.
- Necessity for medical intervention following event.
- Significant concerns raised by staff.

8.6. It is the responsibility of those identifying a fault to highlight this through the Trust's normal incident reporting Risk Register. If the fault is deemed likely to **either** have a high probability of reoccurring in the immediate future **or** have a significant impact to patients, then staff should also notify local operational management for escalation.

9 Decontamination and Cleaning of Medical Equipment

9.1. Guidance on the decontamination of medical equipment can be found in the Decontamination Policy and Procedure documents or sourced from specialist practitioners in the **Infection Prevention and Control (IPC)** team.

9.2. Any equipment sent to the **MES** team for repair, retirement or replacement must be decontaminated as per the decontamination procedure. This should be undertaken by operational crews or through the normal contracted cleaning services.

9.3. Guidance on decontamination and cleaning of medical equipment can be found in the Trust Decontamination Policy and Procedure documents. The most up to date copy of the manual can be found on the Trust intranet.

9.4. In the event of decontamination advice being required above and beyond the information provided in the Decontamination Policy and Procedure documents. The Trust decontamination lead, who is located within Infection, Prevention & Control, should be contacted for specialist guidance.

9.5. The CECWG will liaise with the Infection Prevention and Control Subgroup to ensure that the Trust remains compliant with CQC standards and that changes of practice are reflected in the Trust Decontamination Policy and Procedure documents and the IPC manual.

10 Sale, Transfer of Ownership and Disposal of Medical Devices

10.1. The Logistics Services Manager is responsible for ensuring that any items that are sold through auction no longer hold any asset value on the Trust asset register. If in doubt the departments finance business partner should be consulted.

10.2. The Logistics Services Manager with the support of the MES team must ensure that prior to auction:

- Any Trust identifiable markers are removed from the product. If it is not possible to remove Trust identifiable markers the product may not be auctioned. It may be possible to seek assurance from auctioneers that these items are removed by the auctioneers.
- Any devices that may hold patient identifiable data are thoroughly cleansed by the MES team and that records are kept that confirm this data cleansing has taken place.
- All devices are appropriately decontaminated prior to sale.
- All items that are sent to auction are decommissioned and recorded via Jaama Key 2.

10.3. The **MES** team is responsible for ensuring that if items are disposed of that:

- Any Trust identifiable markers are removed from the product. If it is not possible to remove Trust identifiable markers a contractor may be employed to shred or destroy the product if guarantees are received.
- Any electrical waste is disposed of as per the local disposal arrangements.
- Any batteries should be removed from the items and disposed of through the fleet battery disposal system.
- The product is removed from the Jaama Key2 platform as a logged decommissioned item.

11 Device Replacement

11.1. The planned replacement of medical devices should coincide with vehicle replacement where possible. This may not be practical due to operational pressures, the dynamic nature of device movement and financial constraints upon the service.

11.2. Devices should be replaced in the following circumstances:

- Damaged beyond economic repair. This will be worked on a case-by-case basis with the **MES** making recommendations to the **Logistics Services Manager.**
- The device is so contaminated that the Trust cannot be assured that decontamination has been effective.
- The equipment is deemed to be obsolete in its intended purpose. This decision may be proposed by any member of the Trust and presented to the CECWG for approval.
- Consideration should be made for replacement when the manufacturer no longer supports the product.
- Safety concerns have been raised through the MHRA process or another reputable source of information

12 Competence

12.1. The Trust supports the appropriate training of staff in all aspects of the safe procurement, use and management of medical devices. This includes contractors, agency and locum staff working on behalf of the Trust.

12.2. The Trust's Clinical Education department shall be informed by the CECWG of any devices requiring a training plan for staff to address both technical and clinical matters when using a medical device.

12.3. Training will then be planned to meet the identified need. Device users should:

12.3.1. Understand the principles underlying the use of a device.

12.3.2. Be familiar with the practical aspects of the devices they are likely to encounter.

12.3.3. Have had their competence assessed in relation to the safe use of devices.

12.3.4. Have robust, time and dated training records, signed by the tutor and the student, which provide evidence that training has been received to the appropriate standard and that the device user is competent.

12.3.5. Understand how to report adverse incidents and defects related to medical device use.

12.4. All such records must be filed as part of the individual's personal training record.

12.5. Local Induction and staff development programmes shall cover this policy and any subsequent updates according to the medical devices inventory.

12.6. Service managers are responsible for identifying training needs within their area of responsibility and organising appropriate training in line with their staffs needs in accordance with the Training, Education and Development (TED) procedure.

13 Monitoring

13.1. The Logistics Services Manager in conjunction with other Directorates will develop an action plan annually, to achieve compliance with the Medical Devices Management Policy.

13.2. Measures of compliance with the action plan will provide key performance indicators (KPIs), enabling the SMG through the Operational Support Governance Group (OSGG) to monitor and audit its progress and any outstanding areas of concern.

13.3. KPIs and compliance will be reported internally through the OSGG and escalated to SMG.

14 Audit and Review

14.1. This Policy will be reviewed through the OSGG every three years or sooner if new legislation, codes of practice or national standards are introduced. It is the responsibility of the **Logistics Services Manager** to ensure that any planned review of the policy is completed.

14.2. The Strategy, Planning and Transformation Directorate, through the OSGG, shall develop a process of medical device management to include

developing systems and audit tools, which in turn will provide a measure of compliance.

14.3. The OSGG will assist Logistics in the management of incidents relating to medical equipment. This will be supplemented by a quarterly report from the Trust's incident reporting database highlighting any trends associated with medical equipment.

14.4. Direct working arrangements with the Central Health & Safety Working Group and Infection Prevention and Control Subgroup will be established, maintained and any implementation plans will be reviewed through these forums on a quarterly basis.

15 Associated Documentation

15.1. Procurement Strategy

15.2. Risk Management Policy accompanied with the Risk Assessment Matrix

15.3. Incident Reporting Procedure

15.4. Medical Device Manifest (Databases)

15.5. Decontamination Policy

15.6. Decontamination Procedure

15.7. Infection Prevention & Control Policy

15.8. Infection Prevention and Control Manual

15.9. Scope of Practice & Clinical Standards Policy

15.10. Resuscitation Policy

15.11. Training, Education and Development Procedure

15.12. Training Needs Analysis

15.13. Terms of Reference: Clinical Equipment and Consumables Subgroup

16 References

16.1. This policy should be read in conjunction with the following key references:

16.1.1. Managing Medical Devices: Guidance for Healthcare and Social Services Organisations. MHRA November 2006

16.1.2. Reporting adverse incidents and disseminating Medical Devices Alerts – MHRA Medical Devices Alert MDA/2006/001

16.1.3. HSC 1999/178 – Variant Creutzfeldt-Jacob Disease (vCJD): Minimizing the risk of transmission.

16.1.4. HSG (93) 26 – Decontamination of equipment prior to inspection, service, or repairs

16.1.5. Standards for Better Health. (2005). CQC

16.2. The following documents were used to prepare this policy.

16.2.1. Provision and Use of Work Equipment Regulations 1998

16.2.2. Risk Management Standard for PCTs; NHS Litigation Authority, London, 2005

16.2.3. MDA 2000: Equipped to Care: The safe use of medical devices in the 21st century; MHRA; London; 01st October 2001

16.2.4. MDA DB9801: Medical Device and Equipment Management for Hospital and Community based Organisations: MHRA; 2003

16.2.5. MDA DB9801 (Supplement 1): Checks and tests for newly delivered medical devices; MHRA; London; 02nd October 2003

16.2.6. MDA DB9801 (Supplement 2): Guidance on the Sale, Transfer of Ownership and Disposal of Used Medical Devices; MHRA; London; 02nd October 2003

16.2.7. MDA DB2000(02): Medical Devices and Equipment Management: Repair and Maintenance Provision; MHRA; London; 02nd October 2003

16.2.8. MDA DB2000(04): Single-use Medical Devices: Implications and Consequences of Reuse; MHRA; London; August 2000

16.2.9. MDA DB2002(06): Benchtop Steam Sterilizers – Guidance on Purchase, Operation and Maintenance; MHRA; London; 2002

16.2.10. MDA BD2003(05): Management of medical devices prior to repair, service, or investigation; MHRA; London; August 2003

16.2.11. MDA SN2002(17): Management of loaned medical devices, equipment or accessories from manufacturers or other hospitals

16.2.12. NAO-HC475: The Management of Medical Devices in NHS Acute Trusts in England; National Audit Office, 10 June 1999

16.2.13. ISO9001: 2000 Quality Management Systems Requirements

16.2.14. BS EN 46002: Specification for application of EN ISO 9002 to the manufacture of medical devices, 15 February 1997

16.2.15. Making a Difference: Strengthening the nursing, midwifery and health visiting contribution to health and health care; Department of Health; London; 1999

16.2.16. A First-Class Service: Quality in the New NHS; Department of Health; London; 1998

16.2.17. NHS Estates Hospital Technical Memorandum (HTM) 2010: Sterilization

16.2.18. NHS Estates Hospital Technical Memorandum (HTM) 2030: Washer Disinfectors

16.2.19. NHS Estates Hospital Technical Memorandum (HTM) 2031: Clean Steam for Sterilization

16.3 MHRA Safety Alerts Broadcast System

16.4 IET – Code of practice for In-service Inspection and Testing of Electrical Equipment 4th Edition.

16.5 NHS England EPRR and Interoperability Standards

Appendix 1: Adapted from MHRA Managing Medical Devices Guidance for Healthcare Organisations

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982127/Managing_medical_devices.pdf)

• Agree the requirements for the intended medical procedure and/or needs of the end user.

• Suitability for intended purpose/application by reviewing the manufacturer's description of the intended user, usage and the instructions for use, safety, and performance information (including detailed specifications of the medical device) and comparing against the performance specifications contained within the acquisition requirement.

• Safety issues and any limitations on use.

• Software compatibility with archive systems, patient records etc.

• Electronic medical devices which process data need to be secure; the medical device is validated, as appropriate.

• Ease of use. Evaluate the ease of use and consider user experience and manufacturer's compliance with BS EN 62366-1:2015 Medical devices. Application of usability engineering to medical devices' [6] (please note this standard has not been designated to the UK MDR 2002 but represents best practice and therefore MHRA recommends it is adhered to over older versions). Has it been designed to minimise accidental misuse? How easy is it to misuse the device and what precautions are incorporated into the design to guard against misuse? Consider user experience feedback and evaluations from the expected clinical environment.

• Evaluate and assess the readability of manufacturer's instructions. Instructions for use (IFU) should be comprehensive but intelligible. Overly complex IFU may point to poor design that has not incorporated human usability as a key design goal.

• Availability, type, and scope of training. What type of training is available e.g., face-to face, electronic, e-learning, blended? Is it on-going? Is it training for users or maintainers or both? Does training include methods of decontamination?

• Advice and help. What advice services does the supplier offer and/or what user-help guides are incorporated in or with the system to assist the user with the operation of the device and of its suitability for use for specific procedures?

• Ensuring the operating/environmental conditions of the place where the device will be used are compatible with those of the device.

• Decontamination and disposal procedures, including ensuring the healthcare organisation can reprocess in line with the manufacturer's instructions (e.g., by

trained technicians). The Infection Prevention & Control team and decontamination lead should be consulted (see section 9).

• Pre-use set up, testing requirements, installation requirements and commissioning procedure (see section 5).

• The projected service life of the product and warranty details. In the long run, it could be cheaper to purchase a device which will last for 10 years but costs twice as much, MHRA Managing Medical Devices January 2021 Page 13 of 46, as a device designed to last for only 3 years if maintenance and replacement parts and consumables are available for the lifetime.

• Whole life costs: acquisition and operational, maintenance and consumable, training, risk, renewal, and disposal costs.

• Medical devices may require routine user maintenance, planned preventive maintenance (e.g., by trained technicians) and ad-hoc maintenance, if faults occur. Many require periodic performance checks which may require specialist test equipment. Evaluate the user and planned maintenance recommendations for the device (including frequency and type). Evaluate the ease of breakdown maintenance, particularly in relation to how this will be provided, and the response time provided by the supplier for breakdown maintenance. Ensure that all medical devices can be stored, maintained, and serviced in line with the manufacturer's instructions for use. Consider all the costs associated with these before buying.

• Using profiles of existing devices. Before acquiring replacement devices, healthcare organisations should consider whether, with improved equipment management e.g., establishment of equipment libraries, they have sufficient inventory of existing devices to meet requirements.

• Rationalising the range of models versus diversity (see section 3.6). • Reliability and previous performance.

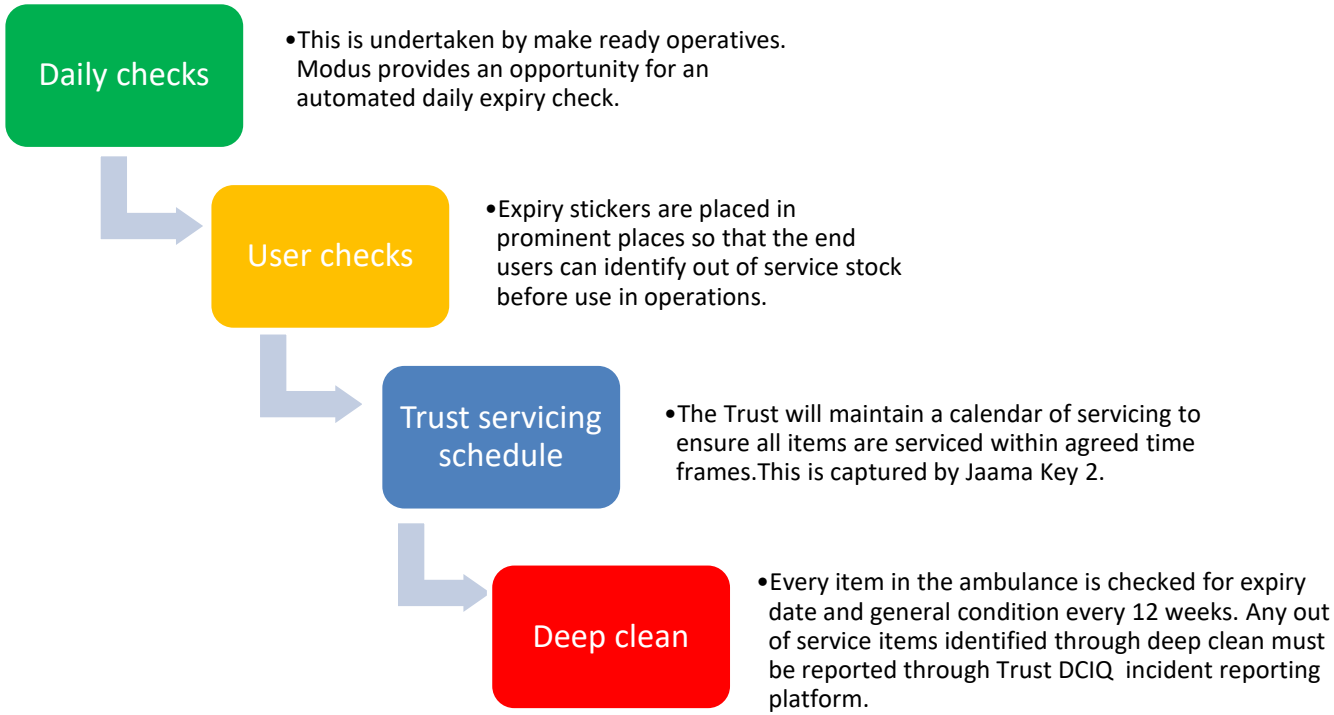
Appendix 2: Medical Device Overview & Servicing Information

Device Name	Manufacturer	Type of device	Category	Expected Service life	Manufacturer service recommendations	SECAmb Servicing Schedule	Service partner	RCM Y/N	Owner
Lifepak 15	Stryker	ECG & multi-monitoring	Medical Device	8 years	12 months however service manual recognises Trust own schedules	Annual servicing to be completed within an agreed 15-month window to allow for the three-month servicing programme and movement of devices around the Trust.	Stryker	No	Logistics
LP1000	Stryker	AED	Medical Device	8 years	None required unless self-test identifies error. Battery change every 5 years	Battery change at 4.5 years and replacement at 8.	NA	Yes	Logistics
Mangar 3	Mangar	Lifting Aids	Medical Device	8 years	Not required unless faulty	No servicing required as per manual. Advise 2 yearly check and battery change.	MES	No	Logistics
LSU	Laerdal	Suction unit	Medical Device	8 years	Every three years	Battery replacement and wear and tear parts every 3 years.	MES (training scheduled for end 2021)	No	Logistics
Ventilator	Smiths Medical	Ventilator system	Medical Device	10 years	Annually	Annual servicing to be completed within an agreed 15-month window to allow for the three-month servicing programme and movement of devices around the Trust.	Oxylitre	No	Logistics
Entonox delivery head	Oxylitre	Gas delivery system	Medical Device	6 years	Annually	Annual servicing to be completed within an agreed 15-month window to allow for the three-month servicing programme and movement of devices around the Trust..	Oxylitre	Yes	Logistics
EZIO	Telefex	Intraosseous Access	Medical Device	10 years	Not Required	N/A	N/A	No	Logistics
Kendrick	Kendrick	Immobilisation / Splinting	Medical Device	10 years	Not Required	N/A	N/A	Yes	Logistics
Pelvic Splint	SAM	Immobilisation / Splinting	Disposable Medical Device	10 years	Not Required	N/A	N/A	Yes	Logistics

Braun Tympanic	Braun	Manual physiological assessment / measurement	Medical Device	6 years	Annual accuracy check	Rolling schedule every 12 months (not possible while personally issued – responsibility to sit with individual clinician to complete/exchange)	MES	Yes	Logistics
Lucas Chest Compression System	Lucas	Chest compression system	Medical Device	6 years	Annually	Annual servicing within the 15-month period.	Stryker	No	Logistics)
Multi-flowmeter O2	Oxylitre	Gas delivery system	Medical Device	8 years	Annually	Annual servicing to be completed within an agreed 15-month window to allow for the three-month servicing programme and movement of devices around the Trust..	Oxylitre	No	Logistics
Infusion pump (CCP)	Braun	Drug Infusion pump	Medical Device			Technical safety checks every 2 years.	Manufacturer's representative	No	
Ultrasound (CCP)	CE Medical	Ultrasound	Medical Device		Not Required	No recommended periodic or preventative maintenance required.	N/A	No	
Ambulance Stretcher	Stryker	Stretcher system	Medical Device		Annually	Checked as part of vehicles planned preventative maintenance at least every 10 weeks.	Fleet	No	(Fleet)
Easy Glide Carry Chair	Ferno	Lifting Aids	Medical Device		Annually	Checked as part of vehicles planned preventative maintenance at least every 10 weeks.	Fleet	No	(Fleet)
Carry Chair	Ferno	Lifting Aids	Medical Device		Annually	Checked as part of vehicles planned preventative maintenance at least every 10 weeks.	Fleet	No	(Fleet)
Scoop Stretcher	Ferno	Lifting Aids	Medical Device		Annually	Checked as part of vehicles planned preventative maintenance at least every 10 weeks.	Fleet	No	(Fleet)
Longboard	Ferno	Lifting Aids	Medical Device		Not Required	Checked as part of vehicles planned preventative maintenance at least every 10 weeks.	Fleet	No	(Fleet)
Vacuum Mattress	Critical health	Lifting Aids	Medical Device		Not Required	N/A	N/A	No	Logistics
DuraFlo blower	Scott	PPE	Medical Device		Annually	Servicing to be completed within an agreed 24-month window. Manufacturer recommends 12 months however relatively low usage technical experts at 3M consider proposed approach proportionate.	MES	Yes	Logistics
Bariatric Graham		Lifting Aids	Medical Device			Replacement if asset becomes soiled or non-serviceable (frayed/ripped.	MES	No	Logistics

MegaMover 1500 Transfer Sheet									
Bari-Kit		Lifting Aids	Medical Device			Replacement if asset becomes soiled or non-serviceable (frayed/ripped.	MES	No	Logistics
Bariatric Butterfly Large Threshold Bridge Ramp		Lifting Aids	Medical Device			Replacement if ramp becomes non-useable.	MES	No	Logistics
Bariatric Steel Wheelchair		Moving Aids	Medical Device			As per Fleet Servicing Policy	Fleet	No	Logistics

Appendix 3: Mitigation in place



Appendix 4: Recall process