East of England Ambulance Service NHS Trust

Medical Devices Management Policy

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DOCUMENT CHANGE HISTORY		
Version	**Date**	**Comments (i.e., viewed, or reviewed, amended approved by person or committee)**
0.3	24 September 2015	Approved by the Medical Devices Safety Management Group (22/9/15)
0.3	28 January 2016	Approved by the Clinical Quality and Safety Group (13/11/15)
0.3	8 March 2016	Approved by the Executive Management Board (3/3/16). Changed to V1.0 as final document
1.1	27 January 2017	Reviewed by Daniel Liebman

Version	Date	Comments (i.e., viewed, or reviewed, amended approved by person or committee)
1.2	15 March 2017	Approved by the Medical Devices Safety Management Group (15/3/17)
1.3	31 November 2017	Approved by the Clinical Quality and Safety Group (30/8/17)
0.3	24 September 2015	Approved by the Medical Devices Safety Management Group (22/9/15)
1.3	27 December 2017	Approved by Senior Leadership Board (20/12/17)
2.0	27 December 2017	Change to version 2 following approvals
2.1	17 September 2019	Reviewed and amended by Interim Head of Medical Devices
2.2	23 September 2019	Changed to new Corporate Format
2.3	4 October 2019	Policy checklist updated
2.4	6 November 2019	Updated with new governance arrangements and comments from the Medical Devices Safety and Management Group. Change of group name to Medical Devices Group.
3.0	15 November 2019	Approved by Management Assurance Group
3.1	21 May 2021	Reviewed and amended by Head of Medical Devices. Changed to new Corporate Format.
3.2	9 June 2021	Approved by Medical Devices Group

Version	Date	Comments (i.e., viewed, or reviewed, amended approved by person or committee)
4.0	19 July 2021	Approved by Compliance and Risk Group
4.1	27 April 2023	Reviewed and amended by Head of Medical Devices
4.2	15 June 2023	Approved by Medical Devices Group
5.0	24 July 2023	Approved by Compliance and Risk Group

Document Reference	Relevant to MHRA - Managing Medical Devices – Guidance for Healthcare and Social Services Organisations January 2021 Operations Support Directorate
Recommended at Date	Medical Devices Group 15 June 2023
Approved at Date	Compliance and Risk Group 24 July 2023
Valid Until Date	24 July 2025
Equality Analysis	Completed
Linked procedural documents	Learning and Development Policy V6.0 Medical Devices SOPs
Dissemination requirements	All staff via Intranet
Part of Trust's publication scheme	Yes

The East of England Ambulance Service NHS Trust has made very effort to ensure this policy does not have the effect of unlawful discrimination on the grounds of the protected characteristics of age, disability, gender reassignment, race, religion/belief, gender, sexual orientation, marriage/civil partnership, pregnancy/maternity. The Trust will not tolerate unfair discrimination on the basis of spent criminal convictions, Trade Union membership or non-membership. In addition, the Trust will have due regard to advancing equality of opportunity between people from different groups and foster good relations between people from different groups. This policy applies to all individuals working at all levels and grades for the Trust, including senior managers, officers, directors, non-executive directors, employees (whether permanent, fixed term or temporary), consultants, governors, contractors, trainees, seconded staff, homeworkers, casual workers and agency staff, volunteers, interns, agents, sponsors or any other person associated with the Trust. All Trust policies can be provided in alternative formats.

Contents

1. Introduction

Medical devices are used extensively in the East of England Ambulance Service NHS Trust (EEAST) in the delivery of patient care.

EEAST is committed to providing safe and suitable medical devices in sufficient quantities to meet the needs of our patients and staff.

2. Purpose

The purpose of this Medical Devices Management Policy is to provide a systematic approach to the acquisition, deployment, training, maintenance, repair and disposal of medical devices.

Primary guidance from the Medicine and Healthcare Products Regulator Agency (MHRA) January 2021 – Managing Medical Devices sates:

"Medical devices play a key role in healthcare; vital for diagnosis, therapy, monitoring, rehabilitation and care. Effective management of this important resource is required to satisfy high quality patient care, clinical and financial govenance, including minimising risks of adverse incidents. Good medical device management will greatly assist in reducing their potential for harm."

3. Duties

3.1 Board

The Trust Board has a collective responsibility for managing medical devices and for ensuring effective risk management systems are in place.

3.2 Chief Executive Officer

It is the Chief Executive Officer's responsibility to ensure implementation of the Medical Devices Management Policy.

3.3 Nominated Director/Board Member

The Chief Executive Officer will nominate the Medical Director to have responsibility for the Medical Devices Management Policy.

3.4 Head of Medical Devices

The Head of Medical Devices will ensure this policy is kept up to date with relevant law, best practice and guidance. They will also provide guidance, leadership and support across the Trust in the application of this policy and will be Chair of the Medical Devices Group. They are also responsible for ensuring that any vehicle-related medical devices are managed in accordance with this policy and associated procedures.

3.5 Medical Devices Safety Officer

The Trust's nominated Medical Devices Safety Officer will provide the link to the Compliance and Risk Group, MHRA and the National Reporting and Learning Centre.

The Medical Devices Safety Officer is responsible for receiving, assessing and where appropriate, actioning, all medical device-related safety notices and alerts received by the Trust through the Central Alerting System (CAS). The Medical Devices Safety Officer will be notified of any device-related alerts by the Trust's CAS Administrator (Head of Safety and Risk).

3.6 Clinical Engineering Manager

The Clinical Engineering Manager is responsible for ensuring, where required, re-usable medical devices are maintained and repaired in accordance with this policy.

3.7 Medical Devices Business Support and Assurance Manager

The Medical Devices Business Support and Assurance Manager is responsible for all business support projects and all aspects of medical device governance and assurance.

3.8 Medical Devices Transformation Manager

The Medical Devices Transformation Manager is responsible for all transformation projects, including the medical devices age replacement programme.

3.9 Training Lead

The Trust's nominated training lead is responsible for defining and delivering suitable user training on new and existing medical devices.

3.10 Clinical Lead

The Clinical Leads are responsible for providing assurance around the delivery of the contents of this policy and its associated Standard Operating Procedures, to support Education and Development, and to monitor feedback, generating ideas to ensure processes are being cohesively delivered.

3.11 Head of Safety and Risk

The Safety and Risk Lead is responsible for monitoring, circulating and reporting all medical device related safety notices received through the CAS system.

3.12 Product and Supplies Procurement Group

The Product and Supplies Procurement Group is responsible for:

- Standardisation of products
- Reduction in whole life costs of products
- Improved quality of products
- Regulatory compliance
- Improving patient and staff user experience, through efficiency of process
- Ensuring consistent streamlining of current processes and equipment, recalling of old products
- Reducing clinical variation – tying in with the strategy of the organisation
- Reducing the amount of products used to free up money for the better products that are needed
- Sharing best practice nationally to be seen as the forerunners in procurement

3.13 Medical Devices Group

The Medical Devices Group is responsible for:

- Improving communication about medical devices within EEAST

- Ensuring involvement of clinicians, technical staff, stakeholders and users in relation to any proposed changes
- Defining persons responsible for device management tasks, training and safe device operation
- Defining and reviewing this policy
- Working closely with the Learning Group to disseminate learning from adverse incidents related to medical devices
- Reviewing incidents including governance issues relating to medical devices management
- Leading and approving risk assessments
- Defining procedures for the management of medical devices
- Defining and updating a sourcing/replacement strategy and approved product list for medical devices

3.14 Clinical Best Practice Group

The Clinical Best Practice Group is responsible for reviewing proposed medical device developments and assess whether they are in accordance with the Trust's clinical needs or aspirations.

3.15 Compliance and Risk Group

The Compliance and Risk Group is responsible for reviewing the activities of the Medical Devices Group and for assuring all aspects of medical devices are in line with the Trust clinical quality and safety policies and procedures.

3.16 Procurement Manager and Supplies Manager

The Procurement Manager and Supplies Manager will ensure only medical devices and consumables approved by this policy and related procedures, are ordered.

The Supplies Manager is responsible for collating and maintaining a list of single use medical devices, their suppliers and alternative products.

3.17 Resilience and Specialist Operations Managers

Managers within this department are responsible for ensuring that their specialist medical devices are compliant with this policy. Where it is currently not practical to manage these medical devices within the Trust's medical

devices database, local compliance records must be kept and made available.

3.18 Managers and Supervisors

Managers and Supervisors in all areas of the Trust are responsible for ensuring this policy is communicated to staff and for ensuring compliance with the policy. This policy is available to all staff on the Trust's intranet.

3.19 Staff/Volunteers

Staff and volunteers are expected to ensure that they understand and comply with their responsibilities under this policy and associated procedures.

3.20 Consultation and Communications with Stakeholders

The Trust is committed to involving personnel and key stakeholders in the development, review and monitoring of procedural documents. Consultation has been undertaken through the Medical Devices Group.

4. Definitions

4.1 Medical Device

The MHRA defines a medical device to be a device that is used to:

- Diagnose, prevent, monitor, treat or alleviate a disease
- Diagnose, prevent, monitor, treat alleviate or compensate for an injury or handicap
- Investigate, replace or modify the anatomy of a physiological process
- Control conception
- Improve function and independence of people with physical impairments

5. Development

5.1 Prioritisation of Work

The need for this policy was identified through guidance 'Managing Medical Devices', issued by the MHRA in January 2021.

5.2 Identification of Stakeholders

Stakeholder identification is coordinated by the Trust's Medical Device Group.

5.3 Responsibility for Document's Development

This policy will be reviewed as a minimum of every two years under the direction of the Medical Devices Group.

Further development will be coordinated by the Head of Medical Devices and the Medical Devices Group.

This policy will be approved by the Medical Devices Group, Compliance and Risk Group and the Executive Leadership Team. It will be disseminated by use of the Trust intranet through the Communications Department.

6. Use of Medical Devices

All users must ensure that:

- They only use medical devices approved and supplied by EEAST in the delivery of its clinical services
- Medical devices must only be used for the purpose for which they were originally designed and intended for
- Single use medical devices are not re-used
- Medical devices which have been identified for decommissioning must not be used on patients
- Medical devices are not modified without the manufacturer's and Trust's approval
- They are competent to use the medical devices safely and appropriately

7. Acquisition

7.1 Triggers

Acquisition of medical devices will be triggered by one of the following:

- Change in clinical practice

- Replacement of an existing device
- Additional existing devices required
- Change in legislation or guidance

7.2 Process/Approvals

The Product and Supplies Procurement Group will be responsible for developing and implementing local procedures on the acquisition of new medical devices which aren't already in operational use. The process should take into account:

- Safely, quality and performance
- Trust objective and the needs of patients/stakeholders
- The whole life cost of the device including consumables
- The needs of all interested parties including those involved in use, commissioning, decontamination, maintenance and decommissioning
- The balance between accessibility of medical devices and controlling their use

7.2 Procurement

All medical devices acquired must have been ordered through either the Trust's Procurement or Supplies Departments. The Medical Devices Group is responsible for the development and implementation of procedures to ensure new medical devices are appropriate and supported by safe working practices. Any acquisition must be in accordance with the Trust's Standing Financial Instructions/Standing Orders.

8. Installation/Commissioning/Configuration

Before medical devices enter service they must, where appropriate, undergo installation, commissioning and configuration. In addition, new devices must have a suitable clinical use risk assessment and Provision and Use of Work Equipment Regulations (PUWER) assessment. These assessments will be coordinated by the Medical Devices Group. Any installation, commissioning or configuration must only be undertaken by competent staff approved by the Trust.

All re-useable medical devices must have a unique identifier attached (Trust Asset Number).

All re-usable medical devices must have a Radio Frequency Identifier (RFID) tag attached.

Where appropriate, a label to clearly show the date of the next test due should be attached to the device.

If no maintenance is required in accordance with Manufacturer's guidelines, a 'No Service Required' label must be placed on the device.

Only Trust approved single-use medical devices must be used.

9. Records

All new re-usable medical devices must be registered onto the Trust's medical devices database.

All new re-usable medical devices must have an RFID tag assigned on the Trust's RFID database.

Where a medical device requires routine maintenance or checks, these will be scheduled by the medical devices database. All maintenance work carried out on a medical device will be recorded accurately on the medical devices database.

Any instances of repair, maintenance, modification or adverse incidents on re-usable medical devices will be recorded on the medical devices database.

Records on the supply of single-use medical devices will be held by the Supplies Department.

10. Decontamination

Medical devices must be decontaminated in accordance with the Trust's Decontamination Manual and associated Manufacturer's instructions.

Re-usable medical devices must be decontaminated prior to inspection, repair and disposal.

11. Training

11.1 User

User training will include training of staff and provision of instructions.

The Product and Supplies Procurement Group will identify user training requirements for new medical devices during the selection processes.

The training of staff will be in accordance with the Trust's Learning and Development Policy.

Training records must be held for individuals involved and should identify that they are appropriately trained to a level proportionate to the activities they are undertaking.

11.2 Technical

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

Training records must be held for individuals involved and should identify that they are appropriately trained to a level proportionate to the activities they are undertaking.

12. Use of Medical Devices

Medical Devices should only be used by staff/volunteers who have been appropriately trained by the Trust. Information on the use of medical devices will be held on the Trust's intranet and, where appropriate, in the Trust's clinical manual.

13. Maintenance/Repair

Maintenance and repairs to medical devices must only be undertaken by suitably competent persons. Records of any maintenance or repair must be kept in accordance with the Trust's Record Retention Policy.

Any spare parts or accessories used must be either from the original equipment

manufacturer or through the use of compatible parts as deemed in a defined process.

The Medical Devices Group will identify, approve and audit local operating procedures for the maintenance and repair of medical devices.

14. Decommission/Disposal

All reusable medical devices will be decommissioned prior to disposal. If the medical device stores patient identifiable data this must certified as securely erased before disposal. All RFID tags must be removed from medical devices and unassigned on the Trust RFID database. All medical devices will have a status of 'decommission' indicating it is no longer in service or owned by the Trust. Decommissioned devices will sit hidden in the background of the medical devices database ensuring full traceability of previously owned devices, along with any service maintenance history.

Disposal of medical devices will be in accordance with the Trust's Waste Management Policy and Standing Financial Instructions/Standing Orders.

Any medical device not deemed safe for current patient use must not be resold or donated.

15. Loan/Trial Equipment

Only loan/trial equipment approved by the Clinical Best Practice Group, Product and Supplies Procurement Group and the Medical Devices Group can be brought into the Trust. All reusable loan/trial medical devices must be registered with, and checked by, Clinical Engineering before entering service. At the end of the trial the equipment must be returned to the supplier via Clinical Engineering.

The Medical Devices Group will identify, approve and audit local operating procedures on loan/trial equipment.

Indemnity Cover needs to be provided by the supplier for any loan/trial medical device. In the first instance, the Department of Health's Master Indemnity Agreement process should be followed.

16. Replacement Planning

The Medical Devices Transformation Manager on behalf of the Head of Medical Devices will provide information to the Medical Devices Group to illustrate expected replacement dates, quantities and costs on a seven – ten year forecast.

The Clinical Engineering Manager will monitor and identify changes in medical device failure rates/reliability, availability of spare parts and maintenance repair costs to the Head of Medical Devices and inform the Medical Devices Group.

The Medical Devices Group will, in conjunction with the Compliance and Risk Group and Clinical Best Practice Group, be responsible for the development of criteria to be used to identify the planned replacement date of medical devices.

17. Adverse Incidents

Adverse Incidents relating to medical devices will be handled in accordance with the Trust's Management of Incidents Policy.

The Medical Devices Group will be responsible for developing a process of monitoring adverse incidents relating to medical devices.

18. Loss/Damage of Devices

The Medical Devices Group will be responsible for developing a process on the reporting and monitoring of loss or damage to medical devices.

19. Modifying/Change of Use

Modifying existing devices or using them for purposes not intended by the manufacturer (off-label use) has safety implications.

No modification or change of use of devices can be implemented without the prior approval of the Medical Devices Group, and the Compliance and Risk Group.

20. Patient Safety Notices/Recalls and Field Safety Notices

The Medical Devices Safety Officer is responsible for assessing and actioning any medial device related safety notices and alerts received through the CAS system.

The Medical Devices Safety Officer will also monitor the weekly Field Safety Notices (FSN) bulletins for relevance and where appropriate, undertake the required actions as recommended by the manufacturer.

21. Equality Impact Assessment

A completed Equality Impact Assessment is included in Appendix B.

22. Dissemination and Implementation

22.1 Dissemination

This policy will be disseminated via the intranet and held within the Policy Library. The Communications Team will issue a notice to all staff on the updating of this policy.

22.2 Implementation

After approval and dissemination of this policy, implementation will follow immediately. No specific training is required but where required, support can be provided by the Training and Medical Devices/Clinical Leads.

23. Process for Monitoring Compliance and Effectiveness

Compliance to this policy will be monitored through reports to the Medical Devices Group which meets in full every quarter. It receives reports on audits, reports from the Trust's Incident Reporting System and reports from key managers, staff and stakeholders. Further detail is provided in the Monitoring Table in Appendix A.

24. Standards/Key Performance Indicators

Compliance against this policy will be tracked through the Key Performance Indicators outlined in Appendix A and reviewed at both the monthly Senior

Operations Support Management meetings and Medical Device Group meetings.

25. References

- MHRA – Managing Medical Devices – Guidance for Healthcare and Social Services Organisations January 2021
- NHS England Patient Safety Alert No NHS/PSA/D/2014/006 'Improving Medical Device Incident Reporting and Learning'

26. Associated Documents

- Equality Impact Assessment
- Monitoring Table

Appendix A Monitoring Table

What	Who	How	Frequency	Evidence	Reporting Arrangements	Acting on Recommendations	Change in practice and lessons to be shared
Appropriate medical devices are being acquired	Product and Supplies Procurement Group	Reports from Head of Medical Devices	Tabled at each meeting (quarterly)	Minutes of the meeting	The Medical Devices Group is expected to read and interrogate and report to identify deficiencies in the system and act upon them	Required actions will be identified and completed in a specified timeframe	Required changes to practice will be identified and actioned within a specific timeframe. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

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What	Who	How	Frequency	Evidence	Reporting Arrangements	Acting on Recommendations	Change in practice and lessons to be shared
Medical Devices are being maintained to the required standard	The Medical Devices Group	Reports from medical devices database KPIs via Clinical Engineering Manager	Tabled at each meeting (quarterly)	Minutes of the meeting	The Medical Devices Group is expected to read and interrogate any report to identify deficiencies in the system and act upon them	Required actions will be identified and completed in a specified timeframe	Required changes to practice will be identified and actioned within a specific timeframe. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

What	Who	How	Frequency	Evidence	Reporting Arrangements	Acting on Recommendations	Change in practice and lessons to be shared
Medical Devices are being commissioned and registered	The Medical Devices Group	Reports from medical devices database KPI s	Tabled at each meeting (quarterly)	Minutes of the meeting	The Medical Devices Group is expected to read and interrogate any report to identify deficiencies in the system and act upon them	Required actions will be identified and completed in a specified timeframe	Required changes to practice will be identified and actioned within a specific timeframe. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

What	Who	How	Frequency	Evidence	Reporting Arrangements	Acting on Recommendations	Change in practice and lessons to be shared
Medical Devices are being decommissioned/disposed correctly	The Medical Devices Group	Reports from medical devices database KPI s	Tabled at each meeting (quarterly)	Minutes of the meeting	The Medical Devices Group is expected to read and interrogate any report to identify deficiencies in the system and act upon them	Required actions will be identified and completed in a specified timeframe	Required changes to practice will be identified and actioned within a specific timeframe. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

What	Who	How	Frequency	Evidence	Reporting Arrangements	Acting on Recommendations	Change in practice and lessons to be shared
Users are trained on medical devices	The Medical Devices Group	Reports from Learning and Development Unit staff training record system	Tabled at meeting	Minutes of the meeting	The Medical Devices Group is expected to read and interrogate any report to identify deficiencies in the system and act upon them	Required actions will be identified and completed in a specified timeframe	Required changes to practice will be identified and actioned within a specific timeframe. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

What	Who	How	Frequency	Evidence	Reporting Arrangements	Acting on Recommendations	Change in practice and lessons to be shared
Technical staff are suitably trained to maintain/repair devices	The Medical Devices Group	Reports from Clinical Engineering Manager	Annually	Minutes of the meeting	The Medical Devices Group is expected to read and interrogate any report to identify deficiencies in the system and act upon them	Required actions will be identified and completed in a specified timeframe	Required changes to practice will be identified and actioned within a specific timeframe. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

What	Who	How	Frequency	Evidence	Reporting Arrangements	Acting on Recommendations	Change in practice and lessons to be shared
Audits from Medical Devices Group	The Medical Devices Group will nominate lead(s) to undertake specific audits	The Medical Devices Group will identify how each required audit will be undertaken	Six-monthly	Minutes of the meeting	The Medical Devices Group is expected to read and interrogate any report to identify deficiencies in the system and act upon them	Required actions will be identified and completed in a specified timeframe	Required changes to practice will be identified and actioned within a specific timeframe. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

What	Who	How	Frequency	Evidence	Reporting Arrangements	Acting on Recommendations	Change in practice and lessons to be shared
Field Safety Notices are being checked for relevance	Medical Devices Safety Officer	Report to the Medical Devices Group	Quarterly	Minutes of the meeting	The Medical Devices Group is expected to read and interrogate any report to identify deficiencies in the system and act upon them	Required actions will be identified and completed in a specified timeframe	Required changes to practice will be identified and actioned within a specific timeframe. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

Appendix B - Equality Impact Assessment

Equality Impact Assessment

EIA Cover Sheet		
Name of process/policy	Medical Devices Management Policy	
Is the process new or existing? If existing, state policy reference number	Existing	
Person responsible for process/policy	Head of Medical Devices	
Directorate and department/section	Operational Support	
Name of assessment lead or EIA assessment team members	Head of Medical Devices	
Has consultation taken place? Was consultation internal or external? (please state below):	No, not required	
The Assessment is being made on:	Guidelines	X
	Written policy involving staff and patients	
	Strategy	
	Changes in practice	
	Department changes	
	Project plan	
	Action plan	
	Other (please state) Training programme	

Equality Analysis					
What is the aim of the policy/procedure/practice/event? To ensure all medical devices are managed effectively to reduce their potential to cause harm					
Who does the policy/procedure/practice/event impact on?					
Race	☐	**Religion/belief**	☐	**Marriage/Civil Partnership**	☐
Gender	☐	**Disability**	☐	**Sexual orientation**	☐
Age	☐	**Gender re-assignment**	☐	**Pregnancy/maternity**	☐
Who is responsible for monitoring the policy/procedure/practice/event? Head of Medical Devices					
What information is currently available on the impact of this policy/procedure/practice/event?					
Do you need more guidance before you can make an assessment about this policy/procedure/ practice/event? Yes/No **No**					
Do you have any examples that show that this policy/procedure/practice/event is having a positive impact on any of the following protected characteristics? Yes/No, If yes please provide evidence/examples: **No**					
Race	☐	**Religion/belief**	☐	**Marriage/Civil Partnership**	☐
Gender	☐	**Disability**	☐	**Sexual orientation**	☐
Age	☐	**Gender re-assignment**	☐	**Pregnancy/maternity**	☐

Please provide evidence:

Are there any concerns that this policy/procedure/practice/event could have a negative impact on any ofh the following characteristics? Yes/No. If so please provide evidence/examples: **NO** **Race** **Gender** **Age** **Religion/belief** **Disability/Gender Re-assignment** **Marriage/Civil Partnership** **Sexual Orientation** **Pregnancy/Maternity**
Action Plan/Plans – SMART **S**pecific **M**easurable **A**chievable **R**elevant **T**ime Limited

Evaluation Monitoring Plan/how will this be monitored? Who: How: By: Reported to: