

MEDICAL DEVICES AND EQUIPMENT MANAGEMENT POLICY

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CONSULTATION GROUPS:	HSSC Clinical Governance Sub Committee Medical Device Committee Resus Committee Head of Training Head of Purchasing Medicine Management
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POLICY SUMMARY

This policy and the associated documents aim to set out clear guidelines to ensure that Essex Partnership University NHS Foundation Trust (EPUT) incorporates into practice the Department of Health Fundamental Standards and CQC Key Lines of Enquiry (KLOE's). This will ensure that all risks associated with the acquisition, use and disposal of medical devices are understood and any risks minimised.

The Trust accepts the need that all medical devices used must be properly and consistently maintained in line with manufacturer's guidance.

The Trust also recognises and accepts responsibility under the Health and Safety at Work Act 1974, Management of Health and Safety at Work regulations 1992 and Provision and Use of Work Equipment Regulations 1992 as an employer providing a safe and healthy workplace for all its patients, staff and visitors.

This policy and associated guidelines apply to all staff and items which fall within the definition of a medical device.

The Trust monitors the implementation of and compliance with this policy in the following ways;

This Policy will be monitored by the Clinical Quality and Governance Sub Committee the Medical Devices Committee and Resus Committee via the Risk Management Department.

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In addition, the Clinical Quality and Governance Sub Committee and the Medical Devices Committee and the Resus Committee will use the following key indicators to demonstrate EPUT's performance against the medical devices procedure.

- Adverse events identifying actual clinical risk to patients, which may result from either medical device characteristics, training deficiencies or maintenance failures (reported quarterly to the Medical Devices Committee and the Resus Committee).
- CAS alerts to ensure that actions are completed and signed off, reported monthly to the Health Safety and Security Committee (HSSC).
- The development and maintenance of the Trust medical devices inventory, the process for maintenance and repairs, as well as device calibration will be monitored bi-monthly through KPIs in the contract with Althea (previously known as TBSGB)

Audit

The implementation of the Policy & Procedure will also be monitored by undertaking internal audits, this will examine:

- The process for identifying which permanent staff are authorised to use the equipment identified on the inventory
- The process for determining the training required to use the equipment identified on the inventory and the frequency of updates.
- The process for ensuring that the identified training needs of all permanent staff are met
- Process for maintenance and repairs, Flowchart Appendix 7.

Reports from the CAS website will also inform the HSSC of progress in meeting the alert requirements. This report will be reviewed by the Clinical Governance Committee, who will monitor any action plans identified until closure.

Where deficiencies are identified with a resulting action plan this will form part of the operational Risk Register for the relevant service.

Review

The Executive Director of Clinical Governance and Quality will ensure that this Policy and associated Procedure is reviewed every 3 years.

Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

The Director responsible for monitoring and reviewing this Policy and associated documents is the Executive Nurse.

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1.0 INTRODUCTION

- 1.1 Healthcare technology and clinical practice changes rapidly, with complex therapies and devices impacting on patient care and treatment. Staff working in the healthcare environment, need to ensure, and continually understand sometimes sophisticated medical technology to support diagnosis, treatment and care.
- 1.2 Medical devices provide a crucial role in case diagnosis and treatment of patients and patients themselves are becoming increasingly knowledgeable about health. Therefore staff need to be able to answer questions and provide professional advice surrounding the use of any device.
- 1.3 The purpose of this policy and associated guidelines need to ensure that whenever a medical device is used it should be:
- 1.3.1 suitable for its intended purpose
 - 1.3.2 properly understood by the professional user
 - 1.3.2 maintained in a safe and reliable condition
 - 1.3.3 not used unless the staff member has been trained in its use

2.0 DUTIES

- 2.1 The Trust Board has overall responsibility for ensuring the principles of this policy, associated procedure and other associated policies are implemented across the organisation. The duty of ensuring all measures needed to ensure safe working with medical devices is delegated to Directors within their areas of responsibility.
- 2.2 The Board of Directors is fully committed to a safety culture within the organisation and will ensure that the effective management of medical equipment is carried out.
- 2.3 The Director of Clinical Governance and Quality will ensure:
- Implementation of this policy and associated procedure.
 - The identification and implementation of training and educational needs arising from this clinical guideline documentation are met.
- 2.4 The Medical Director will ensure that there is effective training and information for medical staff in the use of medical equipment.
- 2.5 Directors and Senior Management will have responsibility within their own service area for:
- Monitoring the implementation of this policy and associated procedure conducted via staff supervision.
 - Monitoring staff receive training and that they are competent to work with the medical equipment that they use.
 - Monitoring training records are maintained

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- Monitor incident forms submitted via Datix involving medical equipment.
 - Complying with procurement and registration procedures.
- 2.6 The Contractor Althea (previously known as TBSGB) will:-
- Maintain a complete inventory of all medical devices and equipment within the Trust
 - Provide advice on appropriate equipment to purchase
 - Ensure maintenance and repair contracts are in place and appropriate records kept
- 2.7 The Medical Device Committee (and if required the Resuscitation Committee) will:
- Ensure that processes are in place to identify and address any risk to patients, clients, staff or visitors from the use of medical equipment in line with best practice.
 - Take decisions related to medical equipment following appropriate risk assessment and or safety alerts issued via the Central Alert System.
 - Ensure Infection Control issues are considered including decontamination and cleaning of devices and that the Trust is advised accordingly.
 - Monitor performance against the requirements of internal and external bodies within its area of responsibility via the Medical Devices Incident report and the Central Alert System bulletins relating to Medical Devices.
 - Monitor risk issues arising from medical equipment management. Addressing issues with relevant line managers.
 - Ensure that all necessary information required to manage the organisation's range of medical devices / equipment is recorded on a suitable system.
 - Ensures regular reports on medical equipment management are received and recommendations acted on.
 - Discuss and review equipment management clinical guidelines.
 - Report to the Clinical Governance Sub Committee, highlighting areas of risk via the minutes.
 - Review Datix incident reports as the Trust wide systematic approach to the identification of equipment users and their training needs.
 - Assist team leaders in ensuring any training needs regarding all medical equipment used in the Trust are completed.
 - Monitor the contract with Althea through KPI's which will provide reassurance to the Trust that medical device maintenance is in line with the Department of Health Fundamental Standards and CQC Key Lines of Enquiry (KLOE's).
 - Review capital bids and approve as appropriate for submission to the Capital Bid Committee, Appendix 8.
- 2.8 Managers and other Persons in Charge / Team Leaders / Ward Managers and Charge Nurse/ Sisters will:
- Where not acting in the role of the Health and Safety representative designate a staff member to undertake this role.
 - Have overall responsibility for ensuring that all medical equipment used by staff are fit for purpose, safe and maintained.

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- Ensure the procedures and principles detailed within the policy & associated procedures are followed and monitored, to meet with all relevant guidance.
- Ensure staff are provided with manufacturer's instructions and other relevant information such as Safe Operating Instructions, Safety Alert Bulletins, Field Safety Notices and Medical Devices Alerts.
- They must also ensure that:
 - i. Althea (prev. known as TBSGB) and the Head of Risk Management are advised of new Medical Equipment to enable it to be added asset register and include on the Trust's Medical Device inventory.
 - ii. Risk rate each piece of medical equipment using the chart – Typical Risk Levels of Medical Equipment (CG17 Appendix 4)
 - iii. Training is completed by staff, patients and/or carers in line with Trust policy;
 - iv. Up to date training and competency records are maintained and available as per medical equipment training needs register, Appendix 5 or Verification of Competency Framework Medical Devices (Safe Use) Booklet; and monitored through yearly staff appraisal and regular management supervision systems;
 - v. Any medical equipment incidents are reported using the Datix incident reporting system and investigated in line with Trust Policies.

2.9 In addition, Managers should delegate as appropriate or personally ensure management of the following responsibilities within their area:

- General management of medical equipment in the ward or area. Including all equipment on the ward is listed on the Trust inventory on the intranet and is in service.
- Ensure only suitably trained staff use medical equipment.
- Ensure all staff are aware that defective or time expired equipment is taken out of service and that it is clearly labelled as such.
- Ensure that training has been undertaken on all new equipment and that records of training are kept locally using.
- Ensure that new equipment is recorded within the appropriate register.
- Ensure that medical equipment is stored under the correct conditions.
- Attend relevant training in relation to medical equipment as required and recorded on Appendix 5/Verification Booklet.

2.10 The responsibility of all EPUT staff, whether directly employed or not is:

- To ensure that they are appropriately familiar with and competent to use medical equipment To discharge their personal responsibilities for the management of medical devices, including decontamination
- Ensure that they provide appropriate information and training about the use of medical devices to clients
- To abide by any staff group's professional standards and any locally agreed standards

Ensure that they have completed any training, including updates, required for medical Devices they use and that this has been recorded using Appendix 5/Verification Booklet.

3.0 DEFINITIONS

3.1 Medical Device

The Medicines and Healthcare Products Regulatory Agency (MHRA) define a medical device as any instrument, apparatus, appliance, material or health care product, excluding drugs, used for a patient or client for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment or alleviation of, or compensation for an injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of conception

For further details of types of device covered by this policy see Examples of Medical Devices Appendix 1 and Medical Equipment Training Needs Register within Appendix 5 or the Verification Booklet.

4.0 PRINCIPLES

4.1 This policy and associated procedural documents aim to provide staff with guidance on all aspects of Medical Devices. This covers the following areas:-

- 4.1.1 management of medical devices
- 4.1.2 justification of need/purchase of equipment
- 4.1.3 acceptance checking and testing
- 4.1.4 user training
- 4.1.5 cleaning, maintenance and servicing
- 4.1.6 loan equipment
- 4.1.7 medical device developments, trials and modifications
- 4.1.8 adverse incident reporting

5.0 MONITORING OF IMPLEMENTATION AND COMPLIANCE

- 5.1 This policy and associated procedural documents must be read and incorporated into practice by any member of Trust staff whether permanent or temporary, who is, or may become, involved in the selection or use of medical equipment.
- 5.2 Any amendments to this policy will be submitted to the Clinical Governance and Quality Sub Committee, the Medical Devices Committee and the Resus Committee for consideration prior to being ratified by the Trust Board.
- 5.3 This policy will be monitored and reviewed for its effectiveness by the Clinical Governance Department.

6.0 POLICY REFERENCES / ASSOCIATED DOCUMENTATION

6.1 Legislation applying to the use of medical devices is as follows:

- Health and Safety at Work Act 1974
- Management of Health and Safety at Work Regulations 1999
- The Medical Devices Regulations 2002 (SI No. 618)
- The Medical Devices (Amendment) Regulations 2003
- Provision and Use of Work Equipment Regulations 1998
- Lifting Operations and Lifting Equipment Regulations (L.O.L.E.R) 1998
- Ionising Radiation (Medical Exposure) Regulations 2000 (I.R.M.E.R)
- Manual Handling Operations Regulations 1992
- The Environmental Protection Act 1990
- The Special Waste Regulations 1996
- Control of Substances Hazardous to Health Regulations 2002

6.2 Guidance including;

- All relevant, current Alert Notices and Supplements received from the Medicines and Healthcare products Regulatory Agency.
- Safety Alert Bulletins
- Department of Health Fundamental Standards and CQC Key Lines of Enquiry (KLOE's).

7.0 REFERENCE TO OTHER TRUST POLICIES/PROCEDURES

- Medical Equipment Maintenance (MEMS) – Internal Purchasing Procedures
- Medical Equipment Maintenance – user guidelines
- Adverse Incident and SUI reporting Policy & Procedure (CP3)
- Reporting Incidents relating to Medical Devices
- Decontamination of Reusable Medical Devices
- Infection Control
- Financial Procedures
- Manual Handling Policy
- NPSA/2005/010- Safer Practice Notice

END