Public – To be published on the Trust external website

Medical Devices Policy

Ref: CORP-0008-v7

Status: Ratified
Document type: Policy

Contents

1 Introduction

The use of medical devices is an essential part of the daily workings of the Trust. The Care Quality Commission (CQC) and National Health Service Resolutions (NHSR) require Trusts to reduce risks associated with medical devices and equipment, to protect patients and staff from harm. Effective processes and training are integral to reducing that risk.

This policy provides a framework to ensure that all risks associated with the use of medical devices and other equipment are controlled and minimised by ensuring that all devices/equipment are:

- Suitable for their intended purpose.
- Properly understood by the user, so that they are used and managed safely and effectively.
- Maintained in a clean, safe and reliable condition.
- Used only for their intended purpose.
- Procured in such a way which affords best value for the Trust considering whole-life costs.
- Annually serviced and/or calibrated

It is essential that the Trust meet appropriate standards of safety, quality and performance, complying with all relevant directives set out by the Medicines and Healthcare Products Regulatory Agency (MHRA) and the CQC.

Work undertaken to standardise medical devices throughout the Trust supports the development of safer systems of care and quality training packages for implementation of clinical procedures.

2 Why we need this policy

2.1 Purpose

- To ensure that managers and individual members of staff are aware of responsibilities in relation to the use of medical devices.
- To identify clear lines of accountability within the Trust for the development of clinical procedures.

2.2 Objectives

Adhering to this policy will ensure that medical devices are:

- Suitable for intended purpose.
- Maintained in a safe and reliable condition.
- Used only by competent staff.

3 Scope

3.1 Who this policy applies to

This policy is relevant to all employees within TEWV NHS FT premises who use medical devices, and to those employees and departments who have responsibilities in relation to purchasing, maintenance, testing and training in the use of medical devices.

3.2 What this policy applies to

This policy covers the process for promoting the safe use of Medical Devices. This also covers the ordering, usage and monitoring of Medical Devices and in ensuring staff are aware of their responsibilities when ordering and using Medical Devices. This applies to all services wherever they are provided within Tees Esk and Wear Valleys NHS Foundation Trust.

3.3 Roles and responsibilities

Role	Responsibility
Executive Director for Nursing and Governance	• Corporate responsibility for this policy. • The provision of appropriate training and education to support implementation.
Service Directors, Associate Directors and Clinical Directors	• Implementing this policy in their areas of responsibility including the delivery of any local training programmes for the use of specific medical devices and or clinical procedures being used in their services.
Heads of service and other service managers	• Ensuring that systems and processes are in place to implement this policy. • Implementing systems to monitor that their services are meeting the requirements of this policy.
Medical Devices Committee	• Co-ordinating medical devices, clinical procedure development and equipment management within the Trust, and reporting quarterly to the Patient Safety Group.
Head of Patient Safety	• Ensuring that systems and procedures are in place to meet the requirements of the MHRA in relation to reporting adverse incidents and disseminating medical device alerts

Medical Devices Safety Officer/Deputy Medical Devices Safety Officer	• Co-ordinating the Medical Devices Group. • Consulting with the Patient Safety Team regarding medical devices related incidents and disseminating Field Safety Notices (FSNs) and Medical Device Alerts (MDA). • Promote the safe use of medical devices across the Trust. • Improve reporting and learning from medical devices incidents.
Modern Matrons/Team leaders, ward/unit managers and departmental heads	• Ensuring that systems are in place to manage medical devices safely within the clinical area. • Implementing the local level training systems regarding medical devices and clinical procedures including those required at local induction. • Identifying further training needs for staff through PDP and accurate up to date records are held to evidence staff competency. • Ensuring the central inventory of all medical devices held in the clinical area is amended to include any additions, transfers and defunct equipment. • Reporting any repairs through Cardea • Ensuring that all new staff have access to instruction and guidance on the use of equipment as part of the local induction process. • Implementation of clinical guidelines
Health Care Staff	• Only using equipment and conducting clinical procedures that they have been appropriately trained to use or have the competence to conduct in line with the written guidance provided.
IPC Champions	• Will have the delegated responsibility for ensuring the local VCB is up to date with equipment and the trust-wide medical devices register is kept up to date and reflective of devices on the ward/team/unit.
Infection Prevention and Control, Medical Devices and Physical Health Service	• Developing any other clinical guidelines and delivery of specific training programmes in conjunction with clinical specialists to reduce risk. • Consulting with the Patient Safety Team regarding medical devices related incidents. • Developing training programmes to meet the standards within clinical guidelines. • Promote the safe use of medical devices across the Trust. • Respond to requests for Non-Catalogued Items (NCI) via the Medical Devices email system.

Education and Training Department	• Coordinating specialist training programmes in conjunction with clinical specialists.
Estates and Facilities	• Commissioning new equipment. • Maintenance equipment through servicing contracts. • Disposal of old/broken and faulty equipment. • Maintenance of a Trust-wide inventory of medical devices. • Sending a monthly medical devices list to each ward and team.
Health and Safety Team	• RIDDOR reports

4 What is a Medical Device

As per the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) a medical device is defined as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or 'handicap' (please note that 'handicap is a direct quotation from the regulations and not a term we use in TEWV)
- investigation, replacement or modification of the anatomy or of a physiological process, or
- control of conception.

A *Medical Device* does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these.

A *Medical Device* includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device.

Walking aids, continence aids, contact lenses, commodes, hospital beds and wheelchairs are also medical devices. A more extensive list of products that fall within the definition of medical device can be found at www.mhra.gov.uk

4.1 Classification of Medical Devices

Medical Devices within TEWV are categorised into the following broad categories.

1) Point of care testing
2) Equipment related to the administration of treatment
3) Equipment related to the care of patients with physical care needs (see Appendix 8 Physical Health Standard Medical Equipment).
4) Moving and handling equipment
5) Resuscitation equipment
6) ECT equipment
7) Specialty specific equipment e.g., enteral feeding equipment

5 Process

5.1 Procurement and Commissioning

Procurement of medical devices is facilitated by the County Durham Procurement Consortium in accordance with the Trusts tendering procedures. Procurement of all new and replacement medical devices should be coordinated through the Medical Devices Group who will facilitate the development of trust wide approved devices list. Systems must be in place to ensure that items received into the Trust are appropriately commissioned and evaluated in accordance with directives within the Facilities Directorate.

- An approved list of medical devices has been created and approved by the Medical Devices Group. These are located on Cardea Approved Medical Device templates.
- Equipment procured through the capital works scheme will also be subject to these processes and procedures.
- Capital Purchases of Medical Devices over £5000 will need to be approved by the Medical Devices Group.
- Teams who wish to purchase medical devices not identified within the standardised approved list must follow the procedure outlined in Appendix 3.
- Any new devices must conform to the latest relevant standards for Medical Device production.

5.2 Loan and Hire Arrangements

- Equipment that is hired should be via Service Level Agreements and maintained as indicated within the contract. Any hired equipment should be returned as soon as it is no longer required.
- Staff should seek advice from all available specialist teams within the trust to ensure the equipment is appropriate.
- When loaning equipment to other clinical areas, wards/department should complete the Notification of Amendment to Asset Register Form please see Appendix 4 and forward to the Estates Department using the address on the form.
- When borrowing equipment from another clinical area it is essential that employees are familiar with its use and that reference is made to the user manual before clinically using the device.
- When loaning or borrowing equipment instructions on the safe operation of the equipment must be conducted.
- The loaning of equipment should be limited to urgent situations only.
- Before release to other areas and when returned to the originating area, the device should be inspected, cleaned and in safe working order.
- Non trust companies using their own medical devices on trust premises must have appropriate risk management systems in place and are aware of the overall policy and systems for medical device management within the trust.

Medical devices brought in by patients should not be used by clinical staff as there is limited assurance that the equipment has been adequately maintained and calibrated.

If any patient is admitted with a person specific piece of equipment which is required for their care and there is no trust purchased or loaned appropriate alternative. Please email the Medical Devices Team on tewv.medicaldevicesnursing@nhs.net for advice and support. Once approval has been authorised staff must follow the manufacturer's instructions for use and any prescribed treatment plan.

5.3 Cleaning and Decontamination of Equipment

Micro-organisms are normally present in the environment of the home and hospital.

Under normal conditions most are harmless; however, some can cause infections if transported via inadequately decontaminated environment/equipment.

It is essential that all equipment is cleaned and decontaminated in accordance with the Trust Infection Prevention and Control Guidelines for the Decontamination of Equipment are available on the trust intranet.

5.4 Single Use Medical Devices (Managing Medical Devices 2021)

5.4.1 Single Patient Use

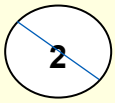
This means that devices can be used more than once on **One Patient only**. The device **may** undergo some form of decontamination after every use. A written protocol of the method of decontamination should be agreed with the Infection Prevention and Control Nurse (IPCN) and refer to the manufacturer's cleaning instructions should be available.

5.4.2 Single Use

The term 'single use' or use 'once only' on the packaging of medical devices means that the manufacturer:

- Intends the device to be used once then discarded.
- Considers the device is not suitable for use on more than one occasion.
- Has evidence to confirm that re-use would be UNSAFE (even if re-used on the same patient).

Items intended for single use are packaged and printed with the symbol.



Examples of devices not to be re-used are:

- Needles and syringes
- Medicine Pots

5.4.3 Key Issues

- Devices designated for 'single use' must not be re-used under any circumstances.
- The re-use of 'single use' devices can affect their safety, performance and effectiveness exposing patients and staff to unnecessary risk.

5.5 Operating and maintaining/calibrating equipment

The operation of the equipment on a day-to-day basis will be the responsibility of the clinical staff. This will include daily checks where necessary and if required will be documented and signed by the appropriate person.

It is the responsibility of the estates team to contract an annual programme of calibration and servicing of all relevant equipment across wards and teams.

This will include:

- Inspecting and calibrating all identified devices in the clinical area
- Electrical Safety Testing if required.
- Any necessary repairs are the responsibility of the ward/unit to escalate to the service contractors.
- Providing a test certificate and sending to the estates team to update the trust-wide inventory.

Specialist maintenance providers provide service and maintenance through Service Level Agreements across the Trust for all medical devices.

It is the responsibility of the Ward/Team Manager to ensure that the monthly medical devices list sent from the estates department reflects the equipment on the ward/team and that this is presented for servicing and calibration in line with the estates timetable.

This will be done on-site; service records will be added to the medical devices T-drive after the central database has been updated.

5.6 Accepting and Commissioning New Equipment

All new medical device equipment purchased must be reported to the Estates Department by completing a notification of amendment to medical devices inventory form, available on T drive/medical devices (see appendix 4) and emailing to Tewv.estateshelpdesk@nhs.net. They will arrange the necessary checks prior to use and set up where appropriate although for most equipment this will not be necessary. Once complete the trust medical inventory database will be updated and the equipment free to use.

5.7 Reporting Breakdowns/Repairs/Repairs of Patient Lifting Equipment

Breakdowns of both medical equipment and patient lifting devices should be reported directly to the maintenance companies for attention to the problem. Clinical areas are responsible for the costs of repairs/breakdowns. The equipment removed from service until it is repaired and safe to use. Medical devices and patient lifting devices can now be reported directly by ward and teams for repair on Cardea. These are detailed at Appendix 5.

Breakdowns of equipment subject to a satisfactory scheduled maintenance system should be infrequent. However random faults and failures can occur from time to time. In such cases the equipment should be returned immediately to the appropriate department/supplier, as soon as possible, along with accurate details of the specified fault/query.

- All battery/mains operated equipment must be charged when not in use as per the user manual.
- Equipment must be stored according to manufacturer's instructions.
- Prior to storage all equipment will be cleaned according to manufacturer's instructions and Trust Infection Control policies.
- Where equipment is contaminated refer to the Infection Prevention and Control Policy IPC-0001 v2 and Guidelines for the Decontamination of Equipment IPC-0001-005 v2.2.
- Clear records must be kept within the clinical service of the maintenance history of devices.
- The Trust will seek to replace devices, where manufacturers have discontinued the production of the device or associated parts; this will be conducted as part of a planned programme.
- Where equipment is beyond economic repair, when it is technically obsolete and spare parts are no longer available, the Medical Devices Group will advise on replacement equipment.

Hoists and slings must be checked before each use for any damage which could cause injury to the patient and/or staff. Particular attention must be paid to all the moveable parts of the hoist, the integrity of the sling material and the attachments on both pieces of equipment.

If patient lifting equipment is still required, a rental system is provided.

Estates must be notified of any patient lifting equipment which is to be transferred to another ward/unit or is for disposal.

5.8 Disposal of Obsolete/Broken Equipment

Equipment no longer in use should not be stored indefinitely within units and wards, the Estates Department should be contacted to arrange collection and suitable storage. Where equipment is no longer fit for purpose, it should be appropriately disposed of, this can also be arranged through the Estates Department. Wards/teams should complete a minor works request for this. It is the wards/team's responsibility to ensure that any equipment being disposed of is properly decontaminated beforehand.

Where equipment is to be disposed of, transferred to another site, or is a new addition, the form for notification of amendment to the medical devices inventory should be completed as outlined in section 5.6.

5.9 Network connectable devices

All Equipment must conform to the Trust's standards for IT and network security as detailed in the Trust's Information Security and Risk Policy. These include appropriate and regularly updated anti-virus protection, robust access control and the management of third-party access to the system.

All purchases must conform to the standards for IT security set out in the Trust's Information Security and Risk Policy. This includes all systems connecting to a PC or Trust device as well as standalone equipment.

Any proposal for new equipment entering the Trust that has the capability of connecting to a Trust network should at the outset be considered as part of the DTAC Procedure. This will involve the consideration of the data risks via a Data Protection Impact Assessment (DPIA), a decision on if the device influences patient care which would require a Clinical Safety Case and the technical security assessment to ensure the integrity of the estate. Once appropriate sign off has been obtained, the device can be Procured.

Upon acceptance into the Trust, the device must be logged on the Medical Device asset database specifically as a Network Connectable Medical Device.

5.10 Medical beds, trolleys, bed rails, bed grab handles and lateral turning devices

Any procurement of profiling bed frames, trolleys, bed rails (or devices containing bed rails), grab handles or lateral turning devices should appropriately reference the Trust Bed Rail Policy, be coordinated through the Medical Devices team, be cognisant of the requirements of the MHRA NPSA number 2023/010 and liaise with the appropriate Clinical teams to ensure that all of these type of devices are safe, fit for purpose, risk assessed and compliant with the latest BS EN production standards (be aware there are different standards for adults and for children & adults with atypical anatomy).

There is significant risk of entrapment in these devices if all the above conditions are not met.

Any patient using such a device should have a documented Risk Assessment in place and this should be updated should the equipment or the patients clinical condition change.

All Trust staff which use such devices should undertake appropriate regular training in their use.

5.11 Training in the use of Specialist Equipment

The Trust will identify all specialist equipment that requires specific training before use according to risk factors and legislative requirements see Appendix 7.

- Training for other categories and those responsible for training and assessing competence will be identified within Training Needs Analysis
- All clinical areas that use medical devices/clinical equipment will undertake training needs assessment. This will seek to identify which medical devices are used in each area and who the users are.
- Those employees unfamiliar with any equipment should not use the equipment unless supervised or until they are trained and competent.
- Training for employees must be based on the premise that devices are only used for their intended purpose and must not be modified in any way.

5.12 Record Keeping

A Trust wide medical devices inventory is held within the Estates Department which identifies all diagnostic and therapeutic equipment in use across the Trust regardless of professional group or location.

Ward/Team managers and AHP clinical leads are responsible for keeping the trust-wide inventory for their ward/unit/team and training records for the ward/unit team or professional group and ensuring the central inventories are accurate and contemporary. Each clinical area is responsible for keeping a current and accurate inventory of medical devices.

Accurate training records will be maintained at ward/ department level. Where a new item of equipment is introduced into service, appropriate employee training must take place and documentary evidence of this maintained at the clinical service level.

5.13 Reporting adverse incidents (includes near misses)

The Trust has an identified Central Alerting Team, this team is responsible for ensuring that systems and procedures are in place to meet the requirements of the MHRA in relation to reporting adverse incidents and disseminating medical device alerts.

a) In the event of an adverse incident where a medical device is implicated through device failures or shortcomings of design, the medical device should be immediately removed from use, packaging, batch numbers and model numbers retained, and the Patient Safety Team and Supplies Department advised immediately. **Any incident must be reported using the Trust reporting system InPhase.** The Patient Safety Team should report all incidents to the MHRA, usually within 24 hours this can be done online at www.mhra.gov.uk

b) Medical devices that have been involved in an incident should be quarantined until the MHRA have been given the opportunity to investigate. The medical device **should not** be discarded, repaired or returned to the manufacturer. The device should be left with the Patient Safety Team.

c) If a patient or member of staff is injured because of a failing piece of medical device/equipment, the incident should be reported through the Serious Incident (SI) process. As there is a potential for this incident to be RIDDOR reportable the Health and Safety Team **must** be informed.

d) Upon receipt of the report, the Trust Central Alerting Team will forward the relevant MHRA form to the ward / department /supplier and, where appropriate, arrange for the equipment and documentation to be collected. This will then be forwarded to the MHRA for investigation as per guidance in MHRA 2021.

e) Hazard/Safety warning notices provided by the MHRA will be identified to the appropriate General Manager and Associate Director who will then ensure they are communicated to all employees. Those people who have been identified to act must do so in a manner according to the level of risk identified by the MHRA in the alert.

f) Where there is information regarding the safe use of equipment, or an issue has been raised with the medical devices team an internal alert which will be approved via the Medical Devices Group will be issued using the same process outlined for Hazard/safety warning notices.

g) Records of the internal alerts or hazard/safety notices must be kept within the clinical services and be accessible to all employees.

h) The Patient Safety Team will provide reports on medical device incidents to the Medical Devices Group. The IPC, Medical Devices and Physical Health Services will respond to and follow up adverse incidents involving medical devices.

6 Definitions

Term	Definition
MDC	• Medical Devices Committee
MHRA	• Medicines and Healthcare Products Regulatory Agency
IPC	• Infection Prevention and Control
RIDDOR	• Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
NHSRA	• NHS Resolution Authority
CQC	• Care Quality Commission
FSN	• Field Safety Notice
MDA	• Medical Device Alert

7 Related documents

- Resuscitation Policy
- Manual Handling of People Procedure
- Manual Handling of Loads Procedure
- Incident Reporting and serious incident review policy
- Decontamination of Equipment
- Harm Minimisation Policy

8 How this policy will be implemented

- Awareness of the policy will be included in the mandatory training provided by the Infection Prevention and Control, Medical Devices and Physical Healthcare Team.
- Awareness of the policy will also be disseminated to all Trust employees through a line management briefing and cascaded through the operational service structures.
- It will be the responsibility of the directorate clinical governance groups to ensure implementation. Training in the use of clinical procedures and use of medical devices will be delivered using a range of approaches from formal teaching sessions where appropriate to physical healthcare practitioners working in clinical areas and local induction.
- The Trust will provide training for the use of specialist medical devices as identified.

8.1 Implementation action plan

Activity	Expected outcome	Timescale	Responsibility	Means of verification/ measurement
n/a				

8.2 Training needs analysis

Staff/Professional Group	Type of Training	Duration	Frequency of Training
All staff required to use medical devices	This will be determined by the type of equipment on each ward/unit	This will be determined by the type of equipment and/or manufacturers guidelines	This will be determined by the type of equipment and/or manufacturers guidelines

9 How the implementation of this policy will be monitored

Number	Auditable Standard/Key Performance Indicators	Frequency/Method/Person Responsible	Where results and any Associate Action Plan will be reported to, implemented and monitored; (this will usually be via the relevant Governance Group).
1	Adherence to policy requirements	Frequency = Annual Method = Spot checks Responsible = Modern Matrons/Team leaders, ward/unit managers and departmental heads	Medical Devices Policy

10 References

Care Quality Commission (2010) Essential Standards of Quality and Safety

MHRA (2021) Managing Medical Devices: Guidance for healthcare and social care organisations.
Managing medical devices - GOV.UK (www.gov.uk)

MHRA (2014) Devices in practice – Checklists for using medical devices.
Devices in practice: checklists for using medical devices - GOV.UK (www.gov.uk)

MHRA
(2021) Single-use medical devices: implications and consequences of
Reuse

Lifting Equipment and Lifting Operations Regulations 1998 (LOLER 1998)
http://www.hse.gov.uk/work-equipment-machinery/loler.htm

The Provision and Use of Work Equipment Regulations 198 (PUWER 1998)
http://www.hse.gov.uk/work-equipment-machinery/puwer.htm

Health and Safety at Work Act 1974
https://www.legislation.gov.uk/ukpga/1974/37/section/2

Management of Health & Safety at Work 1999 -
http://www.legislation.gov.uk/uksi/1999/3242/contents/made

Lifting Equipment and Lifting Operations Regulations (1998 (LOLER 1998)

The Provision and Use of Work Equipment Regulations 1998 (PUWER 1998)
Health and Safety at Work Act

11 Document control (external)

To be recorded on the policy register by Policy Coordinator

Required information type	Information
Date of approval	17 January 2024
Next review date	17 January 2027

This document replaces	CORP-0008-v6
This document was approved by	Medical Devices Committee
This document was approved	08 December 2023
This document was ratified by	Management Group
This document was ratified	17 January 2024
An equality analysis was completed on this policy on	08 December 2023
Document type	Public
FOI Clause (Private documents only)	N/A

Change record

Version	Date	Amendment details	Status
6	16 Dec 2020	• All new medical device equipment purchased must be reported to the Estates Department by completing a notification of amendment to medical devices inventory form, available on T drive/medical devices, this will ensure an accurate up-to-date inventory of medical devices trust wide. • Check central medical devices inventory once a month to ensure this reflects locally held devices, and complete Medical Device Reconciliation Confirmation • Notify any changes using 'notification of amendment to medical devices inventory' form • How to report repairs of medical devices using the online Cardea system. • A standard list of physical health equipment with photos to aid the ordering process.	withdrawn
7	December 2023	• Transfer to new policy template • External documentation update • Updated definition of a Medical Device • Addition of sections 5.9 &5.10 • Updated Incident system to InPhase • Updated devices in standard product list.	Ratified

		Note minor change to section 5.9 after approval by medical devices committee to reflect current IT procedures.	

Appendix 1 - Equality Impact Assessment Screening Form

Please note: The Equality Impact Assessment Policy and Equality Impact Assessment Guidance can be found on the policy pages of the intranet

Section 1	Scope
Name of service area/directorate/department	Medical Devices/Nursing and Governance
Title	CORP-0008-v7 Medical Devices Policy
Type	Policy
Geographical area covered	Trust wide
Aims and objectives	To set standards in practice to ensure the delivery of patient care is carried out safely and effectively by trust staff.
Start date of Equality Analysis Screening	December 2023
End date of Equality Analysis Screening	December 2023

Section 2	Impacts
Who does the Policy, Procedure, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan benefit?	Trust staff and patients
Will the Policy, Procedure, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan impact negatively on any of the protected characteristic groups? Are there any Human Rights implications?	• **Race** (including Gypsy and Traveller) **NO** • **Disability** (includes physical, learning, mental health, sensory and medical disabilities) **NO** • **Sex** (Men and women) **NO** • **Gender reassignment** (Transgender and gender identity) **NO** • **Sexual Orientation** (Lesbian, Gay, Bisexual, Heterosexual, Pansexual and Asexual etc.) **NO** • **Age** (includes, young people, older people – people of all ages) **NO** • **Religion or Belief** (includes faith groups, atheism and philosophical beliefs) **NO** • **Pregnancy and Maternity** (includes pregnancy, women / people who are breastfeeding, women / people accessing perinatal services, women / people on maternity leave) **NO** • **Marriage and Civil Partnership** (includes opposite and same sex couples who are married or civil partners) **NO** • **Armed Forces** (includes serving armed forces personnel, reservists, veterans and their families) **NO** • **Human Rights Implications NO** (Human Rights - easy read)
Describe any negative impacts / Human Rights Implications	This policy will not impact negatively on any of the protected characteristic groups.
Describe any positive impacts / Human Rights Implications	The positive impacts of this policy are that the use and maintenance of Medical Devices in the Trust will be effective and safe

Section 3	Research and involvement
What sources of information have you considered? (e.g. legislation, codes of practice, best practice, nice guidelines, CQC reports or feedback etc.)	• MHRA guidance • CQC Guidance • MMD policy • Trust strategic direction • National Guidance
Have you engaged or consulted with service users, carers, staff and other stakeholders including people from the protected groups?	Yes
If you answered Yes above, describe the engagement and involvement that has taken place	Policy circulated to the Medical Devices Committee for comment before submission
If you answered No above, describe future plans that you may have to engage and involve people from different groups	

Section 4	Training needs
As part of this equality impact assessment have any training needs/service needs been identified?	Yes
Describe any training needs for Trust staff	Training on Medical Devices as required for safe usage, in a timescale identified by individual equipment manufacturers
Describe any training needs for patients	N/A
Describe any training needs for contractors or other outside agencies	N/A

Check the information you have provided and ensure additional evidence can be provided if asked.

Appendix 2 – Approval checklist

Title of document being reviewed:	Yes / No / Not applicable	Comments
1. Title		
Is the title clear and unambiguous?	Yes	
Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2. Rationale		
Are reasons for development of the document stated?	Yes	
3. Development Process		
Are people involved in the development identified?	Yes	
Has relevant expertise has been sought/used?	Yes	
Is there evidence of consultation with stakeholders and users?	Yes	
Have any related documents or documents that are impacted by this change been identified and updated?	Yes	
4. Content		
Is the objective of the document clear?	Yes	
Is the target population clear and unambiguous?	Yes	
Are the intended outcomes described?	Yes	
Are the statements clear and unambiguous?	Yes	
5. Evidence Base		
Is the type of evidence to support the document identified explicitly?	Yes	
Are key references cited?	Yes	

Are supporting documents referenced?	Yes	
6. Training		
Have training needs been considered?	Yes	
Are training needs included in the document?	Yes	
7. Implementation and monitoring		
Does the document identify how it will be implemented and monitored?	Yes	
8. Equality analysis		
Has an equality analysis been completed for the document?	Yes	
Have Equality and Diversity reviewed and approved the equality analysis?		
9. Approval		
Does the document identify which committee/group will approve it?	Yes	
10. Publication		
Has the policy been reviewed for harm?	Yes	
Does the document identify whether it is private or public?	Yes	
If private, does the document identify which clause of the Freedom of Information Act 2000 applies?	N/A	
11. Accessibility (See intranet accessibility page for more information)		
Have you run the Microsoft Word Accessibility Checker? (Under the review tab, 'check accessibility'. You must remove all errors)	Yes	
Do all pictures and tables have meaningful alternative text?	Yes	
Do all hyperlinks have a meaningful description? (do not use something generic like 'click here')	Yes	

Appendix 3 - Form to apply for medical device approval.

CLINICAL SERVICE INFORMATION

Name	
Department/Clinical Service	
Address	
Telephone	
Date	

Proposed Medical Device information.

(You may also attach any relevant product literature with this form)

Type of Medical Device	
Model	
Manufacturer	
Supplier	
Associated Accessories	
Please list any specific maintenance, calibration or decontamination requirements	
Please specify which TEWV Trust Template you would like to add this item	

This part to be recorded via the Medical Devices Group when this process is complete:

The above medical device has **been approved*/not been approved*** for use within the Trust and added to the TEWV Trust Template System.

The member of staff listed above has been informed of the outcome by:

Name: Date:

Medical Devices Group representative

Appendix 4 - Notification of amendment to asset register

Please complete the notification of amendment to medical devices inventory form located on T drive Medical Devices

The form looks like this:

Notification of amendment to medical devices inventory	
Please select "File" > "Save As" and then save to an appropriate drive before submitting	
What would you like to do?	
If transfered, please state in this section where the item has been transferred to	
Building Name (select)	
Ward / Department (select)	
Free text if "Other" above	
Specific Location (if known)	
Description of item (select)	
Free text if "Other" above	
Manufacturer	
Model Number	
Serial Number	
Disposals	*Note - disposals should be requested via minor works form*
Disposal date	
Permanent Transfer	
Transferred from (select)	
Free text if "Other" above	
Date of transfer	
Form completed by	
Name	
Job title	
Date	
Contact number	
Click here to open an email for this form - please attach saved file to the email	
Email address (for reference)	tewv.estateshelpdesk@nhs.net

Appendix 5 - Repair Process

Step 1: Log in to Cardea.
Step 2: Click "Place Requisition"
Step 3: Click "NCI / Service" tab.
Then…
Type: Select "Standard Service"
Category (select as appropriate – see guide on next page):

- Electronic Medical Devices
  - Type in PNX and select "PNX (Electronic Equipment Repairs & Maintenance)"
- Manual Handling Type Equipment (e.g., beds, baths, hoists)
  - Type in PZA and select "PZA (Engineering Services Lift Maintenance & Automatic Door Maintenance)"

Supplier (select as appropriate):

- Calibrate UK
- Care-Ability
- Or specialist company – known locally.

Description (enter details as below – this is the key information):

- Specific location
- Contact name and number.
- Engineer to attend site to check…
  - Identify actual machine using make, model and serial number.
- Specify the actual reported error.

Price: Enter £100 (guide only)
Remove tick from "price visible to supplier."
VAT code: 37- (repairs and maintenance of equipment)

Cardea code	PNX		Cardea code	PZA
Item Description	**Contractor**		**Item Description**	**Contractor**
ECT only: Thymatron System IV	Dantec		Bath	Care-ability
Alcohol Monitor	Calibrate UK		Bed	Care-ability
Auroscope/Otoscope	Calibrate UK		Chair Hoist	Care-ability
Blood Glucose Monitor	Calibrate UK		Commode	Care-ability
Blood Pressure Monitor	Calibrate UK		Examination Couch	Care-ability

CO Monitor	Calibrate UK		Patient Handling Belt	Care-ability
Defibrillator	Calibrate UK		Patient Hoist	Care-ability
Doppler	Calibrate UK		Patient Sling	Care-ability
Ear Syringe	Calibrate UK		Patient Trolley	Care-ability
ECG Machine	Calibrate UK		Recliner Chair	Care-ability
ECG Recorder	Calibrate UK		Shower Panel	Care-ability
Fridge: Vaccines / Drugs	Calibrate UK		Shower Trolley	Care-ability
Hearing Loop	Calibrate UK		Stand Aid	Care-ability
Height Measurer	Calibrate UK		Treatment Couch/Plinth	Care-ability
Ultrasound Machine	Calibrate UK		Trolley-Manual	Care-ability
Mattress	Calibrate UK		Wheelchair	Care-ability
Medical Scales	Calibrate UK			
Nebuliser	Calibrate UK			
One Touch	Calibrate UK			
Patient Vital Signs Monitor	Calibrate UK			
Pulse Oximeter	Calibrate UK			
Sphygmomanometer	Calibrate UK			
Spirometer	Calibrate UK			
Suction Machine	Calibrate UK			
Syringe Driver	Calibrate UK			
TENS Machine	Calibrate UK			
Thermometer	Calibrate UK			

Appendix 6 - Medical Devices: Quick Reference Guide

Ordering

- Order new medical devices through cardea
- Standard templates are available in the medical devices policy

Receipt

- Check item is correct
- complete "notification of amendment to medical devices inventory" form
- Attach appropriate medical devices "flash card" (where available)
- Add to local medical devices visual control board

Training

- Ensure each applicable member of the team is appropriately trained to use the device
- Access available training through Education & Training

Reconciliation

- Check central medical devices inventory once a month to ensure this reflects locally held devices
- Complete Medical Device Reconciliation Confirmation
- Notify any changes using "notification of amendment to medical devices inventory" form

Plan for calibration

- Prepare for your planned calibration date(s). Make sure all of your devices are available to be calibrated.

Support

- Estates: tewv.estateshelpdesk@nhs.net
- Medical devices team: tewv.medicaldevicesnursing@nhs.net

Appendix 7 - Medical Devices Training

Medical Device	Risk Level	Training for device included within:
Defibrillator	High	Basic Life Support
Nutrition Feeding Pump	High	Via company initially
Alcohometer	Medium	
Auroscope/Otoscope	Medium	Medical Training
Blood Glucose Meter	Medium	Via company initially
ECG machine	Medium	Specific ECG training
Carbon Monoxide Analyser	Low	Smoking Cessation
Electric Profiling Beds	Low	Via company initially
Electronic Thermometer	Low	Physiological Observation Training
Nebuliser	Low	
Ophthalmoscope	Low	Medical Training
Pulse Oximeter	Low	Physiological Observation Training
Scales	Low	
Sphygmomanometer	Low	Physiological Observation Training

Each medical device on the above list has been assessed and given a rating according to their risk.

The above list includes devices which would be found in most ward/units.

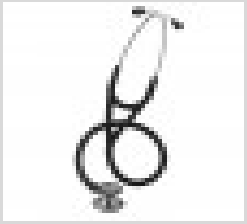
Some areas will have specialized devices which will only be in use within their given area. Local arrangements must be in place for staff to receive training.

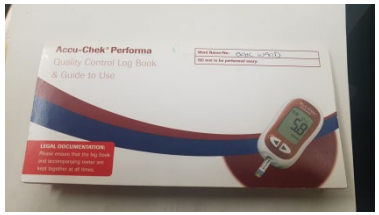
Appendix 8 - Physical Health Standard Medical Equipment

The following table illustrates equipment required to undertake physical health assessment and monitoring.

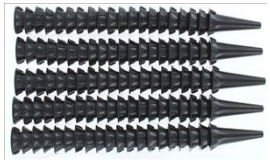
Device	Cardea medical devices template	Required accessories	Cardea template	Calibration required.	Cleaning frequency
Dinamap/ electronic sphygmomanometer 	Adult and paediatric Dinamap's Medical devices template 14	Multiple size wipeable cuffs Standard sizes: Small, Medium Large, Extra small, extra-large and thigh cuffs if required. 	14	Yearly Contact estates to recalibrate if dropped or damaged	After each use including cuff. Every 7 days if not used frequently. Before and after transfer to other departments
Community teams: Omron sphygmomanometer	Medical devices template 14	Multiple size wipeable cuffs: small, medium and large	14	Yearly	After each use including cuff. Every 7 days if not used frequently.

				Contact estates to recalibrate if dropped or damaged	Before and after transfer to other departments
Green light / manual sphygmomanometer All teams must have access to a manual BP machine. 	Medical devices template 14	Multiple size wipeable cuffs: small, medium and large	14	Yearly Contact estates to recalibrate if dropped or damaged	After each use including cuff. Every 7 days if not used frequently. Before and after transfer to other departments
Stethoscope	Medical devices template 14 & 21	-	-	N/A	After each use.

					
Pulse oximeter 	Medical devices template 14	-	-	Yearly Contact estates to recalibrate if dropped or damaged	After each use. Every 7 days if not used frequently. Before and after transfer to other departments
Thermometer 	Infrared Medical devices template 14 Tympanic	- Single use lens covers	- 14	Yearly Contact estates to recalibrate if dropped or damaged	After each use. Every 7 days if not used frequently. Before and after transfer to other departments

	Medical devices template 14				
Height / Weight Monitoring Equipment varies depending on clinical need, please see Medical Devices template 19	Medical devices template 19	-	-	Yearly Contact estates to recalibrate if dropped or damaged	After each use. Every 7 days if not used frequently. Before and after transfer to other departments
Blood glucose machine 	Medical devices template 15	Test solutions Lancets Multi-sticks Logbook 	15	Yearly plus - Local recalibration whenever new test strips are installed, if machine is dropped or if batteries are changed.	After each use. Every 7 days if not used frequently. Before and after transfer to other departments.

ECG Machine with ECG Paper & electrodes  MAC5 in patients  MAC 800 / MAC 600 community	Medical devices template 17	Electrodes  Recording Paper  	17	Yearly Contact estates to recalibrate if dropped or damaged. For new machines contact GE medical via tewv.medicaldevicesnursing@nhs.net To arrange initial set up.	After each use. Every 7 days if not used frequently. Before and after transfer to other departments
Otoscope / Ophthalmoscope	Medical devices template 21	Single use Lens covers.	21	N/A	After each use. Every 7 days if not used frequently.

					Before and after transfer to other departments
Patella hammer 	Medical Devices Template 21	-	-	N/A	After each use. Every 7 days if not used frequently.
Pen Torch – FBF2352 Timesco Healthcare 	Medical Devices Template 21				After each use. Every 7 days if not used frequently.
Tongue Depressor EVJ025 NHS Supply Chain	Medical Devices Template 21				Single use

					
Tuning Fork 	Medical Devices Template 21				After each use. Every 7 days if not used frequently.

It is advised that all in patient wards and community teams have access to all this equipment as standard, and staff know where this equipment can be borrowed from locally if required only occasionally.

Specialist equipment not included on this standard list may also require calibration, please refer to manufacturers guidelines or contact the Estates team for further advice.