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# Medical Devices Ref CORP-0008-v6

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#### 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, in order to protect patients and staff from harm. Effective processes and training is 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 taking into account 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 European Union (EU).

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

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# 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 document 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	<ul> <li>Corporate responsibility for this policy.</li> <li>The provision of appropriate training and education to support implementation.</li> </ul>	
Service Directors, Associate Directors and Clinical Directors	<ul> <li>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.</li> </ul>	
Heads of service and other service managers	<ul> <li>Ensuring that systems and processes are in place to implement this policy.</li> <li>Implementing systems to monitor that their services are meeting the requirements of this policy.</li> </ul>	
Medical Devices Group	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	<ul> <li>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.</li> </ul>	
Medical Devices Safety Officer/Deputy Medical Devices Safety Officers	<ul> <li>Co-ordinating the Medical Devices Group.</li> <li>Liaising with the Patient Safety Team regarding medical devices related incidents, and disseminating Field Safety Notices (FSNs) and Medical Device Alerts (MDA).</li> </ul>	

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	<ul> <li>Promote the safe use of medical devices across the Trust.</li> <li>Improve reporting and learning from medical devices incidents.</li> </ul>
Modern Matrons/Team leaders, ward/unit managers and departmental heads	<ul> <li>Ensuring that systems are in place to manage medical devices safely within the clinical area.</li> <li>Implementing the local level training systems regarding medical devices and clinical procedures including those required at local induction.</li> <li>Identifying further training needs for staff through PDP and accurate up to date records are held to evidence staff competency.</li> <li>Ensuring the central inventory of all medical devices held in the clinical area is amended to include any additions, transfers and defunct equipment.</li> <li>Reporting any repairs through Cardea</li> <li>Ensuring that all new staff have access to instruction and guidance on the use of equipment as part of the local induction process.</li> <li>Implementation of clinical guidelines</li> <li>Ensure staff are aware and have access to the Royal Marsden Hospital Manual of Clinical Nursing Procedures on-line.</li> </ul>
Health Care Staff  IPC Champions	<ul> <li>Only using equipment and carrying out clinical procedures that they have been appropriately trained to use or have the competence to carry out in line with the written guidance provided.</li> <li>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.</li> </ul>
Infection Prevention and Control, Medical Devices and Physical Health and Back Care Advisory Service	<ul> <li>Developing any other clinical guidelines and delivery of specific training programmes in conjunction with clinical specialists to reduce risk.</li> <li>Monitoring the contract with the Royal Marsden Hospital Manual of Clinical Nursing Procedures.</li> <li>Liaising with the Patient Safety Team regarding medical devices related incidents.</li> <li>Developing training programmes to meet the standards within clinical guidelines.</li> <li>Promote the safe use of medical devices across the Trust.</li> <li>Systematically monitor and review the Medical Device Templates in order to ensure these are up to date.</li> <li>Respond to requests for Non Catalogued Items (NCI) via the Medical Devices email system.</li> </ul>
Education and Training	Coordinating specialist training programmes in conjunction with clinical specialists.



department	
Estates and Facilities	Commissioning new equipment.
	<ul> <li>Maintenance and repair of medical device equipment through servicing contracts.</li> </ul>
	<ul> <li>Disposal of old/broken and faulty equipment.</li> </ul>
	<ul> <li>Maintenance of a Trust-wide inventory of medical devices.</li> </ul>
	<ul> <li>Sending a monthly medical devices list to each ward and team.</li> </ul>
Health and Safety Team	RIDDOR reports

# 4 What is a medical device?

A medical device can be defined as any instrument, apparatus, appliance, material or health care product, excluding drugs, used for a patient for the purpose of:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease or disability.
- Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or disability.
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state.
- The testing of alcohol and illicit drugs.

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 <a href="https://www.mhra.gov.uk">www.mhra.gov.uk</a>

#### 4.1 Classification of Medical Devices

Medical Devices within TEWV are categorised into the following broad general 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 5 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

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#### 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 tested 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 1.

# 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 2 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 carried out.
- 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 <a href="tewv.medicaldevicesnursing@nhs.net">tewv.medicaldevicesnursing@nhs.net</a> 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 IPC 0001-005 v11 available on the trust intranet. Decontamination of Equipment.

# 5.4 Single Use Medical Devices (MDA DB 2006 (04))

#### 5.4.1 Single Patient Use



This means that devices can be used more than once on <u>One Patient only</u>. 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.

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#### 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
- Safety (PAT) testing if required
- Any necessary repairs
- 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 2) and emailing to <a href="Tewv.estateshelpdesk@nhs.net">Tewv.estateshelpdesk@nhs.net</a>. 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 should be reported to the Estates Department or via the helpdesk at PFI sites, who will arrange for the appropriate maintenance provider to attend to the problem. Clinical areas are responsible for the costs of repairs/breakdowns and should provide a branch code prior to the maintenance provider attending site. Breakdowns of patient lifting equipment must be reported to the Estates Department or via the helpdesk at PFI sites immediately and if appropriate the equipment removed from service until it is repaired and safe to use. A number of medical devices can now be reported directly by ward and teams for repair on Cardea. These are detailed at Appendix 3.

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 practically 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.

In the event that patient lifting equipment is still required, a rental system is provided. A copy of this information can be accessed via the Back Care Advisory Service page on In Touch.

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

Further guidance can be gained from the Back Care Advisory Service Tel no: 0191 3333584.

# 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/teams 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 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 5.

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- 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.

# 5.10 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.

# 5.11 Reporting adverse incident s (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 (MHRA 2003).



- 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 Datix. 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 carry out an investigation. 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 as a result 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

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- 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 2003 (01).
- 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 take action 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, Physical Health and Back Care Advisory Service will respond to and follow up adverse incidents involving medical devices.

#### 6 Clinical Procedures

The Trust have agreed a three year contract to access the Royal Marsden Hospital Manual of Clinical Nursing Procedures. These nationally recognized, evidence based procedures are available to staff alongside Trust policies and procedures via inTouch by following the direct link on the policies and procedures page – Royal Marsden Clinical Guidelines.

Access is also available via the Library and Information page on InTouch by using an Athens password or the Royal Marsden website http://www.rmmonline.co.uk using the generic log in: username: Tees – password: Tees.

Having clear guidelines within Clinical Procedures will reduce risk to service users with staff having up to date evidence based processes to follow. Training will support the delivery of high quality care interventions and the standardisation of medical devices also ensures consistency with the same equipment being used in all clinical areas for the same procedures. Staff moving from one clinical area to another will be familiar with the equipment and competent in its use.

Where equipment is required to carry out a clinical procedure the equipment required will be identified and a template developed and added to the Trust standardised equipment list.

# 7 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.

# 7.1 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

# 8 How the implementation of this policy will be monitored

		able Standard/Key rmance 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	1	Adherence to policy requirements	Modern Matrons/Team leaders, ward/unit managers and departmental heads	Medical Devices group

#### 9 References

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

MHRA (2015) Managing Medical Devices: Guidance for healthcare and social service organisations.

MHRA (2008) Devices in practice – a guide for health and social care professionals

MHRA DB (2011) (01) Reporting Adverse Incidents & Disseminating Medical Device Alerts www.mhra.gov.uk

MHRA DB (2006) (04) Single Use Medical Devices: Implications and Consequences of Reuse

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MHRA DB 2006 (05) Managing Medical Devices Guidance for healthcare and social services organisations

Lifting Equipment and Lifting Operations Regulations 1998 (LOLER 1998) <a href="http://www.hse.gov.uk/work-equipment-machinery/loler.htm">http://www.hse.gov.uk/work-equipment-machinery/loler.htm</a>

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 - <a href="http://www.legislation.gov.uk/uksi/1999/3242/contents/made">http://www.legislation.gov.uk/uksi/1999/3242/contents/made</a>

<u>Lifting Equipment and Lifting Operations Regulations (1998 (LOLER 1998)</u>

<u>The Provision and Use of Work Equipment Regulations 1998 (PUWER 1998)</u>

<u>Health and Safety at Work Act</u>

#### 10 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
- Royal Marsden Hospital Manual of Clinical Nursing Procedures

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# 11 Document control (external)

To be recorded on the policy register by Policy Coordinator

Date of approval:	16 December 2020	
Next review date:	16 December 2023	
This document replaces:	CORP-0008-v5 Medical Dev	vices Policy
This document was approved	Name of committee/group	Date
by:	Medical Devices Group	01 December 2020
This document was ratified by:	Name of committee/group	Date
	Senior Leadership Group	16 December 2020
An equality analysis was completed on this document on:	July 2019	
Document type	Public	
FOI Clause (Private documents only)	N/A	

### Change record

Version	Date	Amendment details	Status
6	16 Dec 2020	The main areas for change in the policy are:	Approved pending ratification
		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.	
		<ul> <li>A standard list of physical health equipment with photos to aid the ordering process.</li> </ul>	



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# 12 Appendices

# 12.1 Appendix 1: Form to apply for medical device approval

Name		
Department/Clinical Service		
Address		
Telephone		
Date		
Proposed Medical Device inform	nation	
(You may also attach any relevant pro		
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 v	when this process is complete:
•	en approved*/not been ap	pproved* for use within the Trust and
The member of staff listed above h	•	utcome by:
Name:		.Date:
Medical Devices Group representa		
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# 12.2 Appendix 2: 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		



# 12.3 Appendix 3 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...
  - o 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)

PNX			
Item Description	Contractor		
ECT only: Thymatron System IV	Dantec		
Alcohol Monitor	Calibrate UK		
Auroscope/Otoscope	Calibrate UK		
Blood Glucose Monitor	Calibrate UK		
Blood Pressure Monitor	Calibrate UK		
CO Monitor	Calibrate UK		
Defibrillator	Calibrate UK		
Doppler	Calibrate UK		

PZA						
Item Description	Contractor					
Bath	Care-ability					
Bed	Care-ability					
Chair Hoist	Care-ability					
Commode	Care-ability					
Examination Couch	Care-ability					
Patient Handling Belt	Care-ability					
Patient Hoist	Care-ability					
Patient Sling	Care-ability					



Ear Syringe	Calibrate UK
ECG Machine	Calibrate UK
ECG Recorder	Calibrate UK
Fridge: Vaccines / Drugs	Calibrate UK
Hearing Loop	Calibrate UK
Height Measurer	Calibrate UK
Ultrasound Machine	Calibrate UK
Mattress	Calibrate UK
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

Care-ability
Care-ability

# 12.4 Appendix 4 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

# 12.5 Appendix 5 Medical Devices Training

Medical Device	Risk Level	Training for device included within:
Defribrillator	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 the majority of 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.

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# **12.6 Appendix 6 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
Dynamap/ electronic sphygmomanometer	Adult and paediatric dynmap'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  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

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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	After each use.  Every 7 days if not used



Ongs. S 8				to recalibrate if dropped or damaged	frequently.  Before and after transfer to other departments
Thermometer	Infrared 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
The state of the s	Tympanic Medical devices template 14	Single use lens covers	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	Test solutions	15	Yearly plus -	After each use.



ACCU-CASY Accuracy Casy Casy Casy Casy Casy Casy Casy Cas	devices template 15	Lancets Multisticks Log book  According Performs Contact to Book  According to Book  Acco		Local recalibration whenever new test strips are installed, if machine is dropped or if batteries are changed.	Every 7 days if not used frequently.  Before and after transfer to other departments.
ECG Machine with ECG Paper & electrodes  MAC 1200/MAC 2000 in patients	Medical devices template 17	Electrodes  ***********************************	17	Yearly  Contact estates to recalibrate if dropped or damaged.  For new machines contact GE medical via tewv.medicaldevi cesnursing@nhs.net To arrange initial set up.	After each use.  Every 7 days if not used frequently.  Before and after transfer to other departments



	1	T	1	I	1
MAC 800 / MAC 600 community					
Otoscope / Opthlamascope	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.
	Medical Devices				Single use



Tongue Depressor EVJ025 NHS Supply Chain	Template 21		
Tuning Fork	Medical Devices		After each use.
	Template 21		Every 7 days if not used frequently.

It is advised that all in patient wards and community teams have access to all of 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.

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### **Appendix 1 - Equality Analysis Screening Form**

### Please note; The Equality Analysis Policy and Equality Analysis Guidance can be found on InTouch on the policies page

Name of Service area, Directorate/Department i.e. substance misuse, corporate, finance etc.	Nursing and Governance/IPC and Physical Healthcare					
Policy (document/service) name	CORP/0008/v3 Me	dica	I Devices and Clinical Proc	edu	res Policy	
Is the area being assessed a	Policy/Strategy   √ Service/Business plan Project					
	Procedure/Guidance Code of practice				Code of practice	
	Other – Please state					
Geographical area covered	Trustwide					
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 (This is the date you are asked to write or review the document/service etc.)	July 2019	July 2019				
End date of Equality Analysis Screening (This is when you have completed the equality analysis and it is ready to go to EMT to be approved)	July 2019					

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#### You must contact the EDHR team if you identify a negative impact. Please ring the Equality and Diversity Team on 0191 3336267/3046

1. Who does the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan benefit?								
Trust staff and patients								
<ol><li>Will the Policy, Service, Function, S protected characteristic groups belo</li></ol>		ode of practice, Guidance, Project or E	Business p	an impact negatively on any of the	)			
Race (including Gypsy and Traveller)	No	Disability (includes physical, learning, mental health, sensory and medical disabilities)	No	Sex (Men, women and gender neutral etc.)	No			
Gender reassignment (Transgender and gender identity)	No	Sexual Orientation (Lesbian, Gay, Bisexual and Heterosexual etc.)	No	Age (includes, young people, older people – people of all ages)	No			
Religion or Belief (includes faith groups, atheism and philosophical	No	Pregnancy and Maternity (includes pregnancy, women who	No	Marriage and Civil Partnership	No			
belief's)		are breastfeeding and women on maternity leave)		(includes opposite and same sex couples who are married or civil partners)				
Yes – Please describe anticipated negative impact/s								
No – Please describe any positive impa								
No barriers to access or implementing	this policy							

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3. Have you considered other sources of information such as; legislation, codes of practice, best practice, nice guidelines, CQC reports or feedback etc.? If 'No', why not?				No	V					
<ul> <li>Feedback from equality bodies, Care Quality Commission, Equality and Human Rights Commission, etc.</li> <li>Investigation findings</li> <li>Trust Strategic Direction</li> <li>Data collection/analysis</li> <li>National Guidance/Reports</li> <li>Staff grievances</li> <li>Media</li> <li>Community Consultation/Consultation Groups</li> <li>Internal Consultation</li> <li>Research</li> <li>Other (Please state below)</li> </ul>										
4. Have you engaged or consulted with service users, carers, staff and other stakeholders including people from the following protected groups?: Race, Disability, Sex, Gender reassignment (Trans), Sexual Orientation (LGB), Religion or Belief, Age, Pregnancy and Maternity or Marriage and Civil Partnership										
Yes - Please describe the engagement and involvement that has taken place										
No – Please describe future plans that you may have to engage and involve people from different groups										
Not relevant to this procedure										

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Ratified date: 09 December 2020

Last amended: 09 December 2020



5. As part of this equality analysis have any training needs/service needs been identified?										
No	Please describe the identified training needs/service needs below									
A training need has been identified for;										
Trust stat	ff	No	Service users	No	Contractors or other outside agencies	No				
Make sure that you have checked the information and that you are comfortable that additional evidence can provided if you are required to do so										
If you need further advice or information on equality analysis, the EDHR team host surgeries to support you in this process, to book on and find out more please call: 0191 3336267/3046										

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