

<b>Document Title</b>	Medical Devices Policy			
<b>Reference Number</b>	CNTW(C)21			
<b>Lead Officer</b>	Anne Moore-Group Nurse Director – Infection, Prevention and Control			
<b>Author(s)</b> (name and designation)	Paul Thompson - Clinical Lead PPE/Medical Devices			
<b>Ratified by</b>	Business Delivery Group			
<b>Date ratified</b>	Feb 2021			
<b>Date issued</b>	Feb 2021			
<b>Date of full Implementation</b>	Feb 2021			
<b>Review date</b>	Feb 2024			
<b>Version Number</b>	V05			
<b>Review and Amendment Log</b>	<b>Version</b>	<b>Type of change</b>	<b>Date</b>	<b>Description of change</b>

**This policy supersedes previous Medical Devices Policy**

<b>Reference Number</b>	<b>Title</b>
CNTW(C)21 – V04.3	Medical Devices Policy

## Medical Devices Policy

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Appendix 1	Example of medical devices

### **Practice Guidance Note Index**

<b>Practice Guidance notes relating to Medical Devices Policy</b>	
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MDP-PGN-01	Roles and Responsibilities
MDP-PGN-02	Procurement
MDP-PGN-03	Equipment Acceptance
MDP-PGN-04	Equipment Information, Documentation and Manuals
MDP-PGN-05	Maintenance and Repair
MDP-PGN-06	Training
MDP-PGN-07	Weighted Equipment – Blankets/Vests/Backpacks/Belts
MDP-PGN-08	Movement, Transfer and Storage
MDP-PGN-09	Loan and Rental Equipment
MDP-PGN-10	Reporting, Incidents and Defects
MDP-PGN-11	Sale, External Transfers and External Disposal
MDP-PGN-12	Medical Devices Disposal
MDP-PGN-13	Equipment Replacement

## **1 Introduction**

- 1.1 The appropriate management and control of medical devices within Cumbria Northumberland, Tyne and Wear NHS Foundation Trust (CNTW/the Trust) is acknowledged at the highest level as being a fundamental component in ensuring the health and wellbeing of both patients and staff.
- 1.2 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 any harm. Training is integral to reducing that risk.
- 1.2 Management of medical devices encompasses the whole life cycle of the device, from pre-procurement issues to safe disposal.
- 1.3 The principles, policy and procedures relating to the management of medical devices is over seen by the Medical Devices Safety Group.
- 1.4 Report to the Quality and Performance Committee on a six-monthly basis.
- 1.5 The Trust and its staff are required to comply with any appropriate legal requirement, guidelines and recommendations and to follow best practice in all aspects of the management of medical devices.
- 1.6 This policy applies to all staff employed by the Trust.
- 1.7 Where appropriate references to other Trust policies and guidance will be made.
- 1.8 More specific information relating to the management of medical devices is provided in the Practice Guidance Notes (PGN).

## **2 Purpose**

- 2.1 Directive 93/42/EEC covers the placing on the market and putting into service of medical devices.
- 2.2 A number of additional directives amending or supplementing the original directive have been introduced.
- 2.3 This policy covers all aspects of medical device management including selection, purchase, acceptance, safety checking, decontamination, maintenance, repair, monitoring, replacement and disposal of medical devices, as well as the training of Trust employees. The document should be used in conjunction with other relevant standards, regulation, guidance, policy and procedures in order to achieve the highest acceptable and practicable standard.
- 2.4 The Trust and its staff will employ a risk management approach in the management of medical devices.

### 3 Definitions

- 3.1 Medical devices Directive 93/42/EEC) (including equipment) can be defined as all products except medicines. Used in healthcare for diagnosis, prevention, monitoring of treatment. This includes the alleviation, or compensation for an injury or handicap, the investigation, replacement or modification of the anatomy or of a physiological process and the control of conception. Under the amended European Commission Directive 2007 the term Medical Device now includes software products, and not only software required for the normal functioning of a device. (Examples of medical devices-Appendix1)
- 3.2 National Health Service Resolutions (NHSR) Has a statutory duty to manage and raise the standards of risk management throughout the NHS
- 3.3 Medicines and Healthcare Products Regulatory Agency (MHRA) is the agency charged with protecting and promoting public health and patient's safety in relation to medical devices and the use of medicines
- 3.4 Competence is a specific range of skills, knowledge or ability at a sufficient level to be able to perform effectively in an appropriate setting.

### 4 Aim

- 4.1 The aim of this policy is to help to ensure that risks associated with the use of medical devices are minimised and that the medical devices are: -
- Procured in line with the organisations procedures as outline in Trust Standing Financial instructions, Procurement Department guidelines and economic good practice.
  - Recorded on the Trusts Finance Departments asset register
  - Suitable for its intended purpose and in accordance with British Standards of Manufacturers Specifications
  - Maintained in a safe and reliable condition
  - Operated in accordance with the manufacturer's instruction by users and professionals who have obtained and maintained the correct level of knowledge and competency necessary
  - Decommissioned and disposed of appropriately at the end of its useful life.
  - Decontaminated in accordance with IPC-PGN-10, Medical Devices and Equipment – Cleaning and Decontamination.
- 4.2 The management of medical devices is a complex process this involves staff following set processes and procedures to ensure their safe use and management. The Trust will support the staff to fulfil the aims of this policy by providing the necessary resources, training, and IT systems.

## 5 Roles and Responsibilities

- 5.1 Also refer to practice guidance note **MD-PGN-01 - Roles and Responsibilities**
- 5.2 The Board of Directors has overall responsibility for ensuring that all current regulations and approved guidance and best practice are complied with.
- 5.3 In practice the responsibility for ensuring these regulations and guidance are complied with, implemented and followed will be delegated to a variety of other staff resulting in shared accountability.
- 5.4 The Trust has a Point of Contact (POC) who is the Clinical Lead for managing medical devices in accordance with government standards.
- 5.5 The Medical Device Administrator will be responsible for developing and sustaining an inventory which should include the key criteria recommended by the MHRA.
- 5.6 The Clinical Lead for Medical Devices will work to establish a replacement programme that allows budget planning. This will be managed through the Medical Devices Safety Group (MDSG).
- 5.7 Ward Managers are responsible for ensuring all aspects of the management of medical devices within their area are carried out correctly.
- 5.8 All staff have a responsibility to ensure that any equipment they use is and remains fit for purpose and that they are competent to use it.
- 5.9 The MDSG will review all Incident reports involving any Medical Devices.

## 6 Procurement

- 6.1 Also refer to practice guidance note **MD-PGN-02 - Procurement**
- 6.2 The procurement process is acknowledged as being a key factor in the ability to manage medical devices successfully.
- 6.3 The purchases of medical devices must be in line with the Trust's procurement process, which will take into account of the recommendation of the Medical and Healthcare Products Regulatory Agency and the National Audit Office (NAO) recommendations.
- 6.4 The Trust supports the identification and standardisation of medical devices wherever practicable but is fully committed to ensuring the needs of the individual are taken into account.
- 6.5 A pre-procurement process should identify as fully as possible any equipment management issues; this will include issues relating to: -
- Delivery
  - Installation

- Estate services
- Acceptance and commissioning
- Running costs
- Accessories and consumables
- Decontamination
- Training
- Maintenance and repair
- Storage and disposal including consumables

## 7 Equipment Acceptance

### 7.1 Also refer to practice guidance note MD-PGN-03 - Equipment Acceptance

7.2 The process should only be carried out by designated Trust staff or people identified and approved by the Trust. The collective process will identify the medical devices management requirement based on a risk management approach, offering assurance of clinical governance in terms of purchase of equipment.

7.3 Equipment should not be used until the acceptance process is completed satisfactorily.

7.4 Where possible, appropriate documentation will be made available to staff via the Trust's intranet/internet.

7.5 Medical Physics will complete all acceptance checks, records will be kept by the medical device department.

## 8 Maintenance and Repair

### 8.1 Also refer to practice guidance note MD-PGN-05 - Maintenance and Repair

8.2 The Trust is committed to ensuring that all medical devices are fit for purpose and remain so through appropriate maintenance, inspection and repair. A repair request form is available via the intranet, requests for repairs are sent directly to Medical Devices [MedicalDeviceADM@CNTW.nhs.uk](mailto:MedicalDeviceADM@CNTW.nhs.uk) where action will be taken to organise suitably qualified personnel, will be arranged.

8.3 Medical devices maintenance, inspection and repair will be assessed and reviewed in line with the manufacturer's recommendations as well as any legal guidance and best practice recommendations. A risk management approach will be employed.

8.4 Staff involved in maintenance, inspection and repair must be suitably trained and qualified.

8.5 Where outside contractors are used to provide these services, Service Level Agreement (SLA) should be arranged in line **Practice Guidance Note MD-PGN-02 – Procurement**, which forms part of this policy to ensure both quality and value for money.

8.6 Single use devices accessories used in equipment will where appropriate be replaced after any maintenance or repair procedures on the 'parent' equipment.

## 9 Training

- 9.1 Training is an essential element in ensuring the medical device is used, maintained and managed correctly. The Trust has a responsibility to provide, by whatever means most appropriate, any necessary training relating to the management of medical devices.
- 9.2 The Trust will ensure that staff have access to appropriate levels of training, which are identified in the training needs analysis (Appendix B) and are included in the essential training guide which forms part of CNTW(HR)09-Joint Development Review Policy, Practice Guidance Notes. Training will be co-ordinated through the Trust's Learning and Development Department following the Trust's policy and procedures.
- 9.3 The Manager is responsible to maintain, promote and develop skills that ensure the safe use of medical devices. It is important that staff work within their 'Scope of Practice'. Staff should only use, maintain or manage equipment that they can demonstrate competency in through specific training or through professional knowledge and skills.
- 9.3.1 Training on all medical devices must include appreciation of corresponding readings, values and device indicators in order to base all resulting interventions, outcomes and care'.
- 9.4 The manager must ensure the provision of supervision for all staff at appropriate levels for assessment of practical skills using medical devices.
- 9.5 Where staff are not employed by the Trust but use, maintain or manage the equipment, some confirmation of competency should be sought by Service Level Agreement (SLA).
- 9.6 Training records will be kept both locally and by the Learning Development Department and will include:
- Medical Device trained to use
  - Date training was received
  - Training delivered by
  - Updates due
- 9.7 Levels of training are identified in the training needs analysis APPENDIX B
- 9.8 Completion of specific training such as Physical Health Foundation Skill training and Intermediate Life Support training will include training on multiple Medical Devices. This will be recorded within the member of Staff's training dashboard under the training heading.
- 9.9 Some clinical areas may require staff training on specific medical devices. This will be determined at a local level and be recorded as complete on completion of the local Induction process.

## **10 Decontamination**

- 10.1 Decontamination protects service users and staff from infection following contact with medical devices and equipment. It is essential to correctly decontaminate medical devices prior and after use.  
See practice guidance note IPC-PGN-10 – Medical Devices and Equipment – Cleaning and Decontamination – part of CNTW(C)23 – Infection, Prevention and Control Policy.

## **11 Movement, Transfer and Storage of Medical Devices within the Trust**

- 11.1 Refer to practice guidance note MD-PGN-08 - Movement, Transfer and Storage

## **12 Permanent Transfer**

- 12.1 When a permanent transfer of a medical device is made The Medical Devices Administrator must be notified by email to [MedicalDeviceADM@CNTW.nhs.uk](mailto:MedicalDeviceADM@CNTW.nhs.uk) . This ensures that the central inventory can be maintained with relevant information relating to the device. This is necessary to ensure that the appropriate servicing and maintenance can be undertaken.
- 12.2 All the medical device management information and documentation relating to the operation, safety and functioning of the medical device should be transferred with the medical device.
- 12.3 The new owner takes responsibility for the medical device management from the time of transfer.
- 12.4 The medical device management requirements should be reassessed.

## **13 Temporary Transfer**

- 13.1 Any relevant medical device management information and documentation relating to the operation, safety and functioning of the device should either be transferred with the medical device or made available to the borrower.
- 13.2 A local record of the loan should be kept and if the loan period extends beyond 4 weeks the Medical Device Inventory should be updated.
- 13.3 The lender and the borrower retain shared responsibility for the device and its management.
- 13.4 The borrower should assess the medical device management requirements and ensure that it can be used safely and according to any statutory guidance and best practice recommendations.

## **14 Moving Medical Devices**

- 14.1 Using a risk management assessment, it should be determined what if any service, inspection or calibration requirements are required due to the move.

## 15 Storage of Medical Devices

- 15.1 Medical devices, reusable and single use or single patient devices and their accessories must be stored in appropriate conditions in line with the manufacturer's instructions/best practice.
- 15.2 All medical devices must be stored in a state of readiness for use unless this is contrary to the instructions/best practice.
- 15.3 All special storage considerations must be taken into account when storing the device i.e.
- Battery removal
  - Battery charging
  - Use by dates
  - Service
  - Inspection and calibration requirements
  - Data storage

## 16 Loan or Rental Equipment

- 16.1 **Refer to practice guidance note MD-PGN-09 – Loan or rental equipment**

## 17 Loan Equipment

- 17.1 Before any medical device is taken on loan, the appropriate NHS indemnity documentation must be completed and accepted by the Trust. The Trust's Supplies Department will coordinate and monitor this process.
- 17.2 Loan equipment is only acceptable from organisations approved by Medical Devices Safety Group
- 17.3 All loan medical devices must conform with all relevant standards pertaining to the type of medical device, the location and function for which it is to be used.
- 17.4 The terms of the loan must be clear and a record of which must be witnessed on behalf of both organisations.
- 17.5 Loan equipment will be subjected to acceptance testing and other medical device management procedures accordingly.
- 17.6 Employees **must not** request or be offered any incentive (whether financial or otherwise) to take any product on loan from a supplier.

## 18 Rental Equipment

- 18.1 Rental equipment should only be obtained from companies with whom the Trust has a recognised SLA to provide rental equipment.

18.2 All rental devices must conform with all relevant standards pertaining to the type of device, the location and function for which it is required.

18.3 In exceptional cases, where service user care may be compromised, rental equipment may be obtained from companies that do not have an existing SLA with the Trust; this must be arranged via the Trust's Supplies Department.

## **19 Reporting Adverse Incidents and Responding to Central Alert System (CAS)**

19.1 Refer to the Trust's policy CNTW(O)05 - Incident Reporting

19.2 Refer to Trust's policy CNTW(O)17 - Central Alerting System (CAS)

19.3 See also Trust's policy CNTW(C)23 – Infection Prevention Control **IPC-PGN-10 – Medical Devices and Equipment – Cleaning and Decontamination.**

19.4 Where necessary the reporting of any adverse incidents to external organisation will be co-ordinated by the Trust's Safer Care Group in line with Trust policy/procedure.

## **20 External Transfer of Ownership (i.e. to an external organisation) of a Used Medical Device**

- **Refer to practice guidance note –MD-PGN-11 - Sale, External Transfers and External Disposal**

20.1 Transfer of ownership by either sale or donation must be done in an approved and accountable route managed by the Trust's Supplies Department.

20.2 Statutory requirements must be followed when selling or donating used medical devices to ensure any legal liabilities aspects are addressed – failure to do so could lead to prosecution or liability for damages. The Trust may need to take expert advice in such matters.

## **21 Medical Devices Disposal**

21.1 **Refer to practice guidance note MD-PGN-12 – Medical Devices Disposal**

21.2 All medical devices must be disposed of in a safe and appropriate manner.

21.3 Disposals must follow all appropriate standards, guidance and best practice recommendations.

21.4 Disposals will be co-ordinated by the Trust's Medical Device Department through Facilities Department, and the Safer Care Group.

## **22 Equipment Replacement**

22.1 **Refer to practice guidance note MD-PGN-13 – Equipment Replacement**

22.2 Equipment will be allocated a realistic lifespan based on experience and on information provided by the manufacturer.

22.3 Equipment replacement(s) will be planned and co-ordinated and based on sound business planning to ensure that the Trust meets all its obligations in the provision of agreed healthcare services.

- 22.4 The Trust will use equipment replacement information to aid in the development of new services and the assessment and continuation of existing services.
- 22.5 The Trust will use equipment replacement information to assist in the accurate financial planning of the organisation.

### **23 Identification of Stakeholders**

23.1 This is an existing policy under review with changes reflecting revised job titles, organisational structures and updates to training and has been submitted for a 2-week Trust wide consultation.

- North Locality Care Group
- Central Locality Care Group
- South Locality Care Group
- North Cumbria Locality Care Group
- Corporate Decision Team
- Business Delivery Group
- Safer Care Group
- Communications, Finance, IM&T
- Commissioning and Quality Assurance
- Workforce and Organisational Development
- NTW Solutions
- Local Negotiating Committee
- Medical Directorate
- Staff Side
- Internal Audit
- Health, Safety, Security and Resilience

### **24 Equality and Diversity Assessment**

24.1 In conjunction with the Trust's Equality and Diversity Officer this policy has undergone an Equality and Diversity Impact Assessment which has taken into account all human rights in relation to disability, ethnicity, age and gender. The Trust undertakes to improve the working experience of staff and to ensure everyone is treated in a fair and consistent manner.

### **25 Implementation**

25.1 The continued implementation of this policy will be monitored by Medical Device Safety Group. If at any stage there is indication that there are any concerns regarding the operation or implementation of this policy the Medical Devices Safety Group will consider the development of an action plan.

### **26 Monitoring and Compliance**

26.1 The continued use of this policy will be monitored by periodic audit of the statements at Appendix 'C' – Audit/Monitoring Tool. The operation relating to Medical Devices will be monitored by the Medical Devices Safety Group.

## 27 Standard Key Performance Indicators

- 27.1 The Healthcare Commission require assurance and information relating to the management of medical devices within the Trust. Information maybe considered by the NHS litigation authority. Key performance indicators within service specifications maybe outlined relating to the use of medical devices. It is therefore required that records are maintained as specified within the medical devices policy.

## 28 Fair Blame

- 28.1 The Trust is committed to developing an open learning culture. It has endorsed the view that, wherever possible, disciplinary action will not be taken against members of staff who report near misses and adverse incidents, although there may be clearly defined occasions where disciplinary action will be taken.

## 29 Fraud, Bribery and Corruption

- 29.1 In accordance with the Trust's policy CNTW(O)23 - Fraud, Bribery and Corruption – all suspected cases of fraud and corruption should be reported immediately to the Trust's Local Counter Fraud Specialist or to the Executive Director of Finance.

## 30 Associated Documentation

- CNTW(C)23 Infection Prevention Control, practice guidance note
  - IPC-PGN-10 – Disinfection/Decontamination PGN
- CNTW(C)38 – Pharmacological Therapy Policy, PGN
  - PPT-PGN-23 – Oxygen Use in Adults
- CNTW(O)01 Development/Management of Procedural Documents
- CNTW(O)05 Incident Reporting (including SUIs)
- CNTW(O)17 Central Alerting System
- CNTW(O)23 Fraud, Bribery and Corruption Policy

## 31 References

1. DB 2006(05) Managing Medical Devices: Guidance for Healthcare and Social Service Organisations
2. MHRA: Medical Device Alert MDA/2006/001: Reporting Adverse Incidents and Disseminating Medical Device Alerts: 2006
3. MHRA: Devices in Practice: A Guide for Health and Social Care Professionals: 2001

Equality Analysis Screening Toolkit			
Names of Individuals involved in Review	Date of Initial Screening	Review Date	Service Area / Locality
Chris Rowlands Paul Thompson	Feb 2021	Feb 2024	Trust wide
<b>Policy to be analysed</b>		<b>Is this policy new or existing?</b>	
CNTW(C)21 - Medical Devices Policy– V05		Existing	
<b>What are the intended outcomes of this work?</b> Include outline of objectives and function aims			
The appropriate management and control of medical devices within Cumbria Northumberland, Tyne and Wear NHS Foundation Trust (CNTW/the Trust) is acknowledged at the highest level as being a fundamental component in ensuring the health and wellbeing of both patients and staff.			
<b>Who will be affected?</b> e.g. staff, service users, carers, wider public etc			
<b>Protected Characteristics under the Equality Act 2010.</b> The following characteristics have protection under the Act and therefore require further analysis of the potential impact that the policy may have upon them			
<b>Disability</b>	N/A		
<b>Sex</b>	N/A		
<b>Race</b>	N/A		
<b>Age</b>	N/A		
<b>Gender reassignment (including transgender)</b>	N/A		
<b>Sexual orientation.</b>	N/A		
<b>Religion or belief</b>	N/A		
<b>Marriage and Civil Partnership</b>	N/A		
<b>Pregnancy and maternity</b>	N/A		
<b>Carers</b>	N/A		
<b>Other identified groups</b>	N/A		

<b>How have you engaged stakeholders in gathering evidence or testing the evidence available?</b>	
N/A	
<b>How have you engaged stakeholders in testing the policy or programme proposals?</b>	
N/A	
<b>For each engagement activity, please state who was involved, how and when they were engaged, and the key outputs:</b>	
N/A	
<b>Summary of Analysis</b> Considering the evidence and engagement activity you listed above, please summarise the impact of your work. Consider whether the evidence shows potential for differential impact, if so state whether adverse or positive and for which groups. How you will mitigate any negative impacts. How you will include certain protected groups in services or expand their participation in public life.	
<b>No impact</b>	
<b>Now consider and detail below how the proposals impact on elimination of discrimination, harassment and victimisation, advance the equality of opportunity and promote good relations between groups. Where there is evidence, address each protected characteristic</b>	
<b>Eliminate discrimination, harassment and victimisation</b>	N/A
<b>Advance equality of opportunity</b>	N/A
<b>Promote good relations between groups</b>	N/A
<b>What is the overall impact?</b>	N/A
<b>Addressing the impact on equalities</b>	N/A
<b>From the outcome of this Screening, have negative impacts been identified for any protected characteristics as defined by the Equality Act 2010?</b>	
<b>If yes, has a Full Impact Assessment been recommended? If not, why not?</b>	
<b>Manager's signature:</b>	<b>Paul Thompson</b>
	<b>Date: 08.02.2021</b>

## Appendix B

## Communication and Training Check List

## Key Questions for the accountable committees designing, reviewing or agreeing a new Trust policy

Is this a new policy with new training requirements or a change to an existing policy?	No, staff and procedure changes only
If it is a change to an existing policy are there changes to the existing model of training delivery? If yes specify below.	Policy is to ensure that Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust staff are adequately aware of all the issues involved in the equipment management life cycle.
Are the awareness/training needs required to deliver the changes by law, national or local standards or best practice?  Please give specific evidence that identifies the training need, e.g. National Guidance, CQC, NHR etc.  Please identify the risks if training does not occur	Staff should be aware of the new legislation directives and best practice used in managing and using medical devices Levels of training are identified in the training needs analysis and are included within the Training Guide which can be accessed via CNTW Academy
Please specify which staff groups need to undertake this awareness/training. Please be specific. It may well be the case that certain groups will require different levels e.g. staff group A requires awareness and staff group B requires training.	ALL STAFF, which will have any need to use Medical Devices, this includes qualified and unqualified staff
Is there a staff group that should be prioritised for this training / awareness?	Different levels of understanding are required, depending on staff grading, and usage of equipment. Staff may be required to undertake specific training for certain types of equipment and develop new skills when new equipment is purchased.
Please outline how the training will be delivered. Include who will deliver it and by what method.  The following may be useful to consider: Team brief/e bulletin of summary	Specific to Service area and/or specific equipment.  This training may be delivered by specialist trainers, cascade training

<p>Management cascade          Newsletter/leaflets/payslip attachment          Focus groups for those concerned          Local Induction Training          Awareness sessions for those affected by the new policy          Local demonstrations of techniques/equipment with reference documentation          Staff Handbook Summary for easy reference, Taught Session , E Learning</p>	<p>This training maybe delivered as part of an induction ie physical health link worker</p> <p>Specialised training may be delivered by individuals with specialist knowledge and third parties e.g. manufacturers or suppliers.</p> <p>Knowledge available through Operator/User Manuals. Some of this information will be available through the Intranet.</p> <p>Taught sessions will be organised through Learning Development with specialist Clinical Trainers</p> <p>Suppliers of equipment will supply training as part of purchase agreements</p>
<p>Please identify a link person who will liaise with the training department to arrange details for the Trust Training Prospectus, Admin. needs etc.</p>	<p>Clinical Lead for Medical Devices Paul Thompson          Medical Devices Administrator Debra Bedir/          Tara Lamb</p>

## Appendix B – continued

## Training Needs Analysis

Staff/Professional Group	Type of training	Duration of Training	Frequency of Training
Potentially all service areas that deliver a clinical service either directly or indirectly	This will be dictated by the usage and the specific device in use		This will be dictated by the usage and the specific device in use

## Appendix C

## Monitoring Tool- Statement

The Trust is working towards effective clinical governance and governance systems. To demonstrate effective care delivery and compliance, policy authors are required to include how monitoring of this policy is linked to auditable standards/key performance indicators will be undertaken using this framework.

<b>CNTW(C)21 – Medical Devices Policy - Monitoring Framework</b>			
<b>Auditable Standard/Key Performance Indicators</b>		<b>Frequency/Method/Person Responsible</b>	<b>Where results and any associate Action Plan will be reported to, implemented and monitored;</b> (this will usually be via the relevant Governance Group).
<b>1.</b>	Local Audit Review of the Trust's Medical Devices arrangements	Annual check against local inventory by MDA	Compliance reported to Medical Devices Safety Group
<b>2.</b>	Executive Director Review of Medical Devices arrangements	Q+P report annually by Nurse Director Safer Care	Medical Devices Safety Group
<b>3.</b>	Review of incidents relating to Medical Devices breaches as appropriate	Monthly to Group Safe meetings via Medical Device Administrator Quarterly to Medical Devices Safety Group	Issues discussed at Medical Devices Safety Group, any necessary action plans developed, implemented and shared with Groups
<b>4.</b>	Compliance with CQC standards with respect to Medical Devices arrangements	The inventory will be reviewed and amended as equipment is purchased, moved or condemned	Gaps in compliance will be reported at the monthly Group Safe meeting and quarterly at the Medical Devices Safety Group

The Author(s) of each policy is required to complete this monitoring template and ensure that these results are taken to the appropriate Quality and Performance Governance Group in line with the frequency set out.

## Examples of Medical Devices

### Medical Devices used in the diagnosis/treatment of disease or monitoring of patients

- Syringes and needles
- Dressings
- Blood Glucose Meter
- Sphygmomanometers
- Thermometers
- Catheters e.g. urinary, cardiac
- Nebulisers
- Portable suction machines
- Mattresses and cushions
- All medical devices/products used in the treatment/monitoring of patients and in the diagnosis of disease
- Defibrillators
- Oxygen Cylinders
- Wheelchairs
- Aids for the disabled
- Pressure care prevention
- Patient hoists for lifting and transfer
- Commodes
- Urine drainage systems
- Oxygen therapy systems
- Mattresses and covers
- Hospital beds