Medical Device & Equipment Management Policy

29/07/2014

V2.0
Table of Contents

1. Introduction ................................................................................................................. 4
2. Purpose of this Policy ................................................................................................. 4
3. Scope ............................................................................................................................ 4
4. Definitions / Glossary ................................................................................................. 5
5. Ownership and Responsibilities ............................................................................... 6
  5.1. Role of the Trust Board ....................................................................................... 6
  5.2. Role of the Medical Devices and Clinical Products Group ..................... 6
  5.3. Role of the Medical Device Safety Officer (MDSO) ........................................... 6
  5.4. Role of Ward and Department managers ..................................................... 6
  5.5. Role of the Local Medical Device Links ........................................................... 7
  5.6. Role of Staff ......................................................................................................... 7
  5.7. Role of Independent Contractors ....................................................................... 7
6. Standards and Practice ............................................................................................. 7
  6.1. Procurement ........................................................................................................ 7
  6.2. Acceptance Procedures for New Equipment .................................................. 8
  6.3. Asset Register ..................................................................................................... 9
  6.4. Device Instructions ............................................................................................. 9
  6.5. Care of Equipment by Users .......................................................................... 9
  6.6. Maintenance ....................................................................................................... 10
  6.7. Decontamination ............................................................................................... 10
  6.8. Single Use Devices ............................................................................................. 10
  6.9. Equipment Loaned To Patients (End Users) .................................................... 11
  6.10. Equipment on Loan/Loaned Out by the Trust ............................................... 11
  6.11. Equipment Library ............................................................................................ 11
  6.12. Equipment On Trial/ Local Evaluations ....................................................... 11
  6.13. Incident Reporting ............................................................................................ 12
  6.15. Medical Device Developments, Modifications and Trials ....................... 12
  6.16. Point of Care Testing ....................................................................................... 12
  6.17. Replacement of Equipment .......................................................................... 12
  6.18. Training ............................................................................................................ 13
  6.19. Potential Hazards from Mobile Communications: ...................................... 13
  6.20. Safety Action Bulletins .................................................................................. 13
7. Dissemination and Implementation ......................................................................... 15
8. Monitoring compliance and effectiveness ............................................................... 15
9. Updating and Review.........................................................................................................................15
10. Equality and Diversity..................................................................................................................15
Appendix 1. Procedure Following an Adverse Incident With A Medical Device .........................16
Appendix 3. Governance Information.................................................................................................19
Appendix 4. Initial Equality Impact Assessment Form .......................................................................22
1. **Introduction**

1.1. This policy is based on the recommendations of the MHRA document Managing Medical Devices Guidance for healthcare and social services organisations April 2014. The guidance is to outline a systematic approach to the acquisition, deployment, maintenance (preventive maintenance and performance assurance), repair and disposal of medical devices and medical device training. to ensure that medical devices are used safely, competently and effectively for the best care of patients and to comply with all relevant legislation and guidance

1.2. This policy clarifies the method of medical device management, which includes procurement, training, maintenance, decontamination, disposal and reporting of adverse incidents, to ensure that all risks associated with using medical devices are minimised within the Trust.

1.3. The Trust recognises the risks created by the use of medical devices to patients, staff and others, and requires that a safe working practice be maintained. The Trust aims to ensure that all staff who operate diagnostic or therapeutic medical devices can do so in a safe and effective manner. A medical device should be

- Suitable for its intended use
- Properly understood by the user
- Maintained to an appropriate standard

1.4. The Trust expects all staff, including temporary staff working in the Trust or those working in the Trust from other organisations to adhere to the following principles before using any medical equipment:

- To have been trained according to the Trust Medical Device Training Policy
- Always visually inspect the equipment for signs of damage prior to use.
- Know where the user manual / instructions are located.
- Be aware of the Trust procedures for reporting an Incident or near miss event.

1.5. The policy should be read in conjunction with the Medical Devices Training policy, Procurement Policy, Contractors Policy and procedure, the Incident Reporting and Investigation policy and the Policy and Guidance for Risk Assessment and Risk Registers

1.6. Many aspects of the Trust’s generic Health and Safety Policy are applicable to Medical Devices

1.7. This version supersedes any previous version of this document

2. **Purpose of this Policy**

The purpose of this document is to outline a systematic approach to the management of all aspects in the lifecycle of medical devices, that all risks associated with the acquisition, deployment, use, monitoring, record integrity, reprocessing, maintenance, record generation and storage, decommissioning and disposal of medical devices are minimised.

3. **Scope**

This policy is intended primarily for Royal Cornwall Hospital Trust staff who are responsible for the management and use of medical devices.
4. Definitions / Glossary

**ADVERSE INCIDENT**: involving medical devices and equipment which produce, or have the potential to produce, unexpected or unwanted outcomes that affect the safety of patients, service users or other people, such as where:

- A patient, client, user, carer or professional is injured as a result of a medical device or equipment failure or its misuse.
- A patient’s or client’s treatment is interrupted or compromised by a medical device or equipment failure
- Misdiagnosis due to medical device or equipment failure leads to inappropriate treatment
- A patient’s or client’s health deteriorates due to a medical device or equipment failure.

**CARER/END USER**: An employee, carer, patient or client who uses a medical device or item of equipment in a healthcare facility or at home (e.g. infusion pump, wheelchair, chair lift etc.)

**CAS**: Department of Health ‘Central Alerting System’ – a central Department of Health led system where all medical device related incidents and/or product faults are released to the NHS

**CEMS**: ‘Clinical Equipment Management Service’ - a specialist service, based in Medical Physics, that deals with the management and maintenance of medical devices for The Trust, and external healthcare sites

**MEDICAL DEVICE**: (or medical equipment) The term ‘medical device’ encompasses medical devices as legally defined in the Medical Devices Regulations, other medical devices and assistive Technologies (examples given in Table 1). Any apparatus intended by the manufacturer to be used on human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment of, or compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or physiological process.
- Control of conception.
- A medical device does not achieve its intended action by pharmacological, immunological or metabolic means, but it may assist the human body in its function by such means.

**MHRA**: Medicines and Healthcare products Regulatory Agency – A governmental run agency that is responsible for the regulation of medicines and medical devices and equipment used in healthcare organisations and the investigation of harmful incidents.

**PPM**: ‘Planned Preventative Maintenance’ – a regular ‘scheduled service’, a maintenance programme performed by CEMS that involves the correction or prevention of faults by calibration and replacement of parts, in order to keep the medical device performing as intended by the manufacturer.

**PPQ**: Pre-Purchase Questionnaire – must be completed prior to purchase as it gives all relevant details required by The Trust on the device being considered for use.
5. Ownership and Responsibilities

5.1. Role of the Trust Board
The Trust Board has overall responsibility for the safe management of Medical Devices. The Trust Nurse Executive has overall responsibility for the Trust's management of Medical Devices and compliance with the relevant external Assurance Standards.

5.2. Role of the Medical Devices and Clinical Products Group
The forum for users to discuss Maintenance, Training, and Risk & Safety issues with regards to Medical Devices:
- Provides advice to the Trust Board via the Divisional Quality Group, or equivalent, on the procurement, management and deployment of Medical Devices.
- Helps formulate related policy/procedures.
- Ratifies a Recommended List of Medical Devices. To maintain standardisation, managers are recommended to order Medical devices from this list unless a clinical requirement approved by the medical devices Group justifies a different model.

The Trust's Executive Director of Nursing, Midwifery and AHP and The Director of Medical Physics co-chairs this group and the membership consists of key individuals listed in the terms of reference document.

5.3. Role of the Medical Device Safety Officer (MDSO)
The MDSO reviews all RCHT incidents reported on DATIX involving medical devices for identification of trends, requirement of reporting to MHRA, and to further investigate (or assist with) where required. A regular summary of these incidents will be provided for review by the Medical Devices and Clinical Products Group. Any reports made to the MHRA will be kept on a central record by the MDSO. The MDSO is supported by a Deputy MDSO, who assists in this role.

5.4. Role of Ward and Department managers
Are responsible for the safe use of Medical Devices within their location by:
- Having systems in place to ensure that staff using Medical Devices are adequately trained on relevant equipment
- Keeping appropriately documented evidence of staff training
- Establishing local procedures for the management of Devices to comply with the requirements of this Policy.
- Appointing a Local Medical Device Link to assist the area manager and the Medical Devices Training Officer with training needs analysis, training, risk assessments.
- Maintaining an equipment inventory, and disposing of medical devices in the required manner.
- Completing risk assessments on devices which may pose a significant risk to patients or staff
- Ensuring equipment is stored in a safe and secure location when not in use. Kept in an appropriate state of repair and is cleaned according to Trust policy (refer to section 8 and the decontamination policy)
- Ensure that staff are aware of their responsibilities regarding the safe use of medical devices
5.5. **Role of the Local Medical Device Links**

A Local Medical Devices Link (LMDL) will be identified for each ward or departmental area. This is a crucial role in ensuring the safe and efficient use of medical devices throughout the hospital. A LMDL will work with the Medical Device Training Officer to
- Gain advanced skills with medical devices through training programmes
- Develop valuable teaching experience.
- Support Key Trainers
- Ensure training records are accurate and update in-line with the ward manager.

5.6. **Role of Staff**

It is the responsibility of employees involved in the use of medical devices to ensure:
- They are trained and competent in the use of medical devices
- Training records are maintained and updated
- They only use medical devices if authorised to do so
- All medical devices are suitably decontaminated after each patient use
- All medical devices are adequately stored and maintained when not in use
- They follow procedures regarding the management and use of medical devices
- They report any defects of faults with equipment immediately
- They clearly label defective devices and ensure they are taken out of action
- They make items of equipment/devices available for maintenance
- They report all incidents or near misses to their line manager immediately

It is essential that training is up-to-date and documented for all the Devices that they use. See Trust Medical Device Training Policy for further information.

5.7. **Role of Independent Contractors**

The Trust requires that Contractors comply with all relevant policies and that managers of the area where contractors are working ensure that they are aware of any relevant Trust policies. Where a Manufacturer or their agents carry out maintenance on Medical Devices on site a record of the visit must be kept by the Ward or Department where it was carried out. This would normally be a copy of the company service report.

6. **Standards and Practice**

6.1. **Procurement**

6.1.1. Advice may be sought from CEMS about procurement of medical devices

6.1.2. Prior to ordering any new medical device the following factors should be considered.

- a) Clinical requirements
- b) Suitability
- c) Patients needs Safety
- d) Training requirements
- e) Decontamination
- f) Maintenance implications
- g) Compatibility with other devices
- h) Whole life cost
- i) Standardisation / preferred devices
6.1.3. Where possible, standardisation of common types of equipment is advisable in order to lessen operator confusion, to facilitate ease of training and equipment availability and to take advantage the economies which can be made from bulk purchasing.

6.1.4. Those responsible for the purchase of Devices must be aware of the technical and revenue implications of their choice of equipment, to assist in keeping maintenance and revenue costs to a minimum. The Trust’s procurement practice is to purchase standard equipment from the Trust’s recommended list (updated by Cornwall Supplies Service) or have been approved by the Medical Devices and Clinical Products group. Prior to any procurement of equipment not on the recommended list, advice should be sought from the CEMS Department, RCHT Estates and/or the Cornwall Supplies Service.

6.1.5. Purchasers of new equipment must ensure that an assessment has been performed on the use of the device in their area before purchase. This assessment must cover arrangements for the maintenance and decontamination of the device and identifying a training route for users.

6.1.6. Purchases from Charitable Funds must also be made via Supplies (see the Trust ‘Guidelines on the use and application of Charitable Funds’).

6.1.7. Loan Equipment or consumables must not be accepted by the Trust without authorisation from Cornwall Supplies Service and CEMS.

6.1.8. Where invasive reusable devices are purchased, it is the responsibility of the Manufacturer or his Agent to supply reliably validated decontamination instructions. These MUST be obtained integral with the evaluation and procurement process.

6.1.9. For more information see RCHT Procurement Policy that is accessible via the Document Library.

6.2. Acceptance Procedures for New Equipment

6.2.1. All new Medical Devices to be acceptance checked to MRHA Managing Medical Devices recommendations via the appropriate Department. This may be The Medical Physics Department, CEMS, or may be in conjunction with approved contractors or suppliers.

6.2.2. All new Devices to be entered on the Royal Cornwall Hospital Trust Asset Register before use and identified with a unique number.

6.2.3. The Departmental Manager must ensure they are in receipt of the equipment user manual when accepting the equipment. They should ensure that all users of the equipment receive appropriate training, co-ordinated by the Medical Devices Training Officer, on equipment before it is put into use, and that this training is recorded.
6.3. Asset Register

6.3.1. All non-consumable and non-implantable Medical Devices are to be entered onto a Trust Asset Register. CEMS administer a secure database holding as a minimum the following information:

- Generic name
- Manufacturer
- Model/Type
- Asset number
- Department/ location
- Purchase cost and date if known
- Maintenance history

6.3.2. Wards/departments are to maintain their own local asset register and update it on a minimum of a bi-annual basis, informing CEMS of any changes. The Local register is to include new items not entering the Trust via the normal procurement route, disposals or transfers of Devices to other Departments/locations on a permanent basis. The Local registers will be compared to the Trust Register on an annual basis.

6.3.3. It is important that the Service Manager notifies CEMS if there are plans to relocate or close a department so that the medical device Asset register can be updated.

6.4. Device Instructions

6.4.1. All professional and end users must have access to manufacturers or locally produced instructions both for reference purposes and to ensure that the device is operated properly and safely at all times. These instructions should be kept up to date with assistance from CEMS and the Medical Devices Training Officer.

6.4.2. Where instructions are produced locally for patients or their carers these must follow MDA Managing Medical Devices guidelines and be vetted by the Publications Department and Patient information group to check for clarity.

6.5. Care of Equipment by Users.

6.5.1. Users must follow the manufacturer’s guidelines on the care and user maintenance of equipment and devices. Regular basic checks by users prior to use checking for, as a minimum, any obvious signs of damage, cleanliness and faults affecting performance or safety.

6.5.2. Faults are to be reported as per the Guidelines issued by the relevant maintenance departments. Clear labelling of any fault is required to aid in a prompt turn-around of equipment.

6.5.3. Equipment must be decontaminated and labelled as such prior to being sent for repair. Approved forms are available via the Medical Physics intranet page.

6.5.4. Managers must arrange for suitable storage of medical devices when not in use. The storage facilities should take into account any special requirements for
infection control, temperature, humidity, etc. and that any equipment that has rechargeable batteries is kept on charge.

6.6. **Maintenance**

6.6.1. The RCHT has in place an agreement with various agencies for the provision of maintenance and repair of Medical Devices. They include the Clinical Equipment Management Service, Estates and Facilities Department (both in RCHT) and external contractors.

6.6.2. Maintenance may consist of Planned Preventive (PPM), reactive repair and/or Inspection/Performance checks. The frequency and level of maintenance may be adjusted at the recommendation of Medical Physics/CEMS Department or the RCHT Estates Department and will be evidence based and risks assessed.

6.6.3. Ward and Departmental Managers must ensure that medical devices are made available for Planned Maintenance at the appropriate time in accordance with the manufacturers’ instructions.

6.6.4. Where a Manufacturer or their agents carry out maintenance on Medical Devices on site a record of the visit must be kept by the Ward or Department where it was carried out. This would normally be a copy of the company service report.

6.6.5. Maintenance and repair of reusable Medical Devices must only be carried out by Competent Persons recognised as having sufficient technical knowledge and experience and operate under a recognised quality management system.

6.6.6. Pre-use functional and visual checks must be carried out by all users prior to using any medical device.

6.7. **Decontamination**

6.7.1. The RCHT has a Decontamination Policy, which outlines the process required regarding decontamination of medical equipment to provide safe clean disinfected or sterilised equipment to control the spread of micro-organisms.

6.7.2. Users of medical devices are responsible for the decontamination of the equipment in accordance with the Trust Decontamination Policy. Any equipment that has been decontaminated must be labelled as such. When a medical device is to be returned to CEMS, eg for maintenance or repair (or to any other location, eg manufacturer, after loan period) the user must ensure that it has been properly cleaned and decontaminated prior to return, and labelled as such. It is an offence to send contaminated equipment through the external mail or transport system.

6.7.3. For further information on decontamination please refer to the policy that is accessible via the Document Library.

6.8. **Single Use Devices**

Medical devices that are designated for ‘single use’ by the manufacturer and labelled as such should not be reprocessed and reused. This will include those devices that have been opened in error although not used. Single use medical devices should not be reprocessed or reused under any circumstances. See Decontamination Policy for further details.
6.9. **Equipment Loaned To Patients (End Users)**

6.9.1. It is essential that users and carers (end users) receive appropriate training in the use and maintenance of equipment loaned to them by the RCHT. They shall be given documentation and written guidance to include:

- The name of the device
- Operating instructions
- Acceptable and appropriate use of the equipment
- Action to be taken by them in the event of a failure or fault
- Emergency contact details

6.9.2. Documentation must be kept by the department loaning the item and consist of:

- Date of loan and expected length of loan
- Instructions given to patient/carer: training, maintenance and professional support available in case of equipment failure.(signed by patient to confirm)
- ID of equipment loaned to patient
- Procedure for recall of equipment at end of use or for regular maintenance of long-term loan item.

6.9.3. A record document, MD11 is available, See Appendix 2 and also available on the Medical Physics web site.

6.10. **Equipment on Loan/Loaned Out by the Trust**

6.10.1. It is essential to ensure that the legal liabilities that may expose the Trust to litigation are managed and controlled with regard to instruments and other medical devices that are loaned to third party Healthcare providers.

6.10.2. Managers of all departments within the Trust are responsible for ensuring that equipment borrowed from the area of their responsibility is fit for use, staff are suitably trained

6.10.3. Departments and Wards that loan equipment to other healthcare providers must keep accurate records to include Device make, model, serial number, contact information and any accessories or consumables.

6.10.4. Equipment must not be loaned to non-NHS organizations without the permission of the appropriate Divisional Manager.

6.11. **Equipment Library**

The RCHT has an equipment library for the short term loan of Bariatric equipment, static mattresses, tissue viability equipment and syringe drivers. For further information on the use of this service refer to the Equipment Library Guidelines for Access to the service that is accessible via the Document Library.

6.12. **Equipment On Trial/ Local Evaluations**

For further information, please refer to: A Policy for the Trial and Evaluation of Medical Devices on the Trust Documents site
6.13. **Incident Reporting**

6.13.1. All incidents and ‘near misses’ must be reported via the DATIX Incident Reporting System. Staffs’ reporting incidents involving Medical Devices are advised to isolate and label the Device and any associated consumables. The lack of Device identification on DATIX and/or evidence may slow or even stop any further investigations. Refer to the RCHT Incident Reporting & Management Policy and Procedure.

6.13.2. The MDSO will review all reported incidents involving medical devices and inform the MHRA if appropriate. The MDSO will keep a central record of reports sent to the MHRA and will provide feedback on actions to the Medical Devices and Clinical Products Group. *(Please refer to the ‘Procedure Following An Adverse Incident With A Medical Device’ in appendix 1)*

6.14. **Medical Device Risk Assessments**

Identified risks should be assessed using the Trust Risk Assessment tool on DATIX and an action plan drawn up to mitigate the risks. Where risks cannot be mitigated they should be brought to the attention of senior management using the Risk Register.

6.15. **Medical Device Developments, Modifications and Trials**

6.15.1. Medical devices should not be used for any purpose other that that which it was designed for.

6.15.2. ‘In house’ manufacture or substantial modification of Medical Devices must comply with the Medical Device Regulations at the design, manufacture and clinical evaluation stages. Proposals for manufacture/modification must first be approved by CEMS and a Risk Assessment carried out before use any such modifications take place.

6.15.3. Clinical trials must be registered with, and approved by, the Research and Development Directorate to comply with ethics and governance issues.

6.16. **Point of Care Testing**

Point of care testing is defined as any analytical measurement that takes place outside a traditional laboratory setting. The devices used for this purpose can range from simple dipstick tests to sophisticated analysers, and if used incorrectly, patients may be put at risk from inappropriate testing or incorrect results. The use of Medical Devices within POCT comes under the provisions of this Medical Devices Management Policy. The POCT Working Group of the Pathology Directorate must be contacted before any new POCT system is introduced *(see ‘Point of Care Testing Guidelines’)*

6.17. **Replacement of Equipment**

6.17.1. Equipment must be replaced when it becomes unsafe to use, no longer producing clinically acceptable results or it is no longer supported by the Manufacturer. Disposal of old equipment must be carried out in a safe manner and follow the Trust Waste Management Policy that is accessible via the Document Library.
6.17.2. CEMS must be informed when a medical device is disposed of to enable their records to be updated. (Device may be sent to CEMS for disposal) The local asset register should also be updated to show the disposal of equipment.

6.17.3. Decontamination certificates, maintenance records and instructions should be retained on any decommissioned device

6.17.4. Advice from CEMS/ Estates Department should be sought if staff are unclear of the correct disposal method

6.18. Training
6.18.1. The Trust Requires that staff should only use equipment that they are confident and competent to use. Staff should not use equipment for which they have not received training.

6.18.2. For further information please see the Trust’s ‘Medical Devices Training Policy’ that is accessible via the Document Library.

6.19. Potential Hazards from Mobile Communications:
Radio waves emitted from Mobile Communications Equipment may effect electronic medical equipment especially when in close proximity. Reference can be made to the MHRA Bulletins DB9202 [8], DB1999 (02) [9] and MHRA ref 2004/0287 [10] which refer to how interference from mobile radios, mobile telephones etc may cause malfunction of equipment with serious clinical consequences.

6.20. Safety Action Bulletins
From time to time the Medicines and Healthcare products Regulatory Agency (MHRA) issue Safety Action Bulletins (SAB) relevant to medical devices. The process for dealing with these is detailed in the Policy for the Management & Implementation of National Guidance & Alerts
Table 1: Examples of medical devices

<table>
<thead>
<tr>
<th>Function</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis or treatment of disease</td>
<td>Anaesthetic equipment, catheters, diagnostic laboratory equipment, dressings, implants, scanners, surgical instruments, surgical gloves, syringes, X-ray machines.</td>
</tr>
<tr>
<td>Monitoring of patients</td>
<td>ECG, pulse oximeter.</td>
</tr>
<tr>
<td>Critical Care</td>
<td>Baby incubators, blood-gas analysis, defibrillators, ventilators, pressure relief mattresses.</td>
</tr>
<tr>
<td>Improve function and independence of people with physical impairments</td>
<td>Communication aids, environmental controls, hoists, orthotic and prosthetic appliances, supportive seating and pressure care, walking aids, wheelchairs.</td>
</tr>
<tr>
<td>Community-based healthcare</td>
<td>Catheters, dressings, domiciliary oxygen therapy systems, glucose tests, pressure care equipment, syringes, urine drainage systems.</td>
</tr>
<tr>
<td>Emergency services:</td>
<td>Stretcher, trolleys, resuscitators.</td>
</tr>
</tbody>
</table>
7. Dissemination and Implementation

7.1. This policy will be published on the Trust Document Library following authorisation by the Executive Director. Immediately following publication the Medical Physics Department will ensure that its publication is highlighted across the Trust using various media including the Daily Bulletin. Implementation of this policy will be supported through a series of briefings, departmental visits and training as required highlighting differences from the preceding policy and resolving medical device training issues as they arise.

7.2. The training aspects relating to the implementation of this policy are contained within the main body of this document.

8. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Monitoring of medical device planned maintenance.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Assurance of compliance will be subject to audit by the Medical Devices Co-Ordinator.</td>
</tr>
<tr>
<td>Tool</td>
<td>The Trust compiles an annual return against the Department of Health Care Quality Commission and the NHSLA risk management standards. 25 devices which are subject to a planned maintenance programme will be audited for compliance. The Trusts asset management register/ system will be used to obtain the required data.</td>
</tr>
<tr>
<td>Frequency</td>
<td>Annually</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>Annual reports on the Management of Medical Devices are presented to the Divisional Quality Group and the Trust Board. A report will be produced for the Divisional Quality Group. The information will be summarized on the annual IPR report to the executive board. Reports will be reviewed by the Medical Devices and Procurement Committee.</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>Lead for actions will be held by Medical Devices Co-Ordinator. Any identified actions will completed within 6 months.</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>Medical Devices and Procurement Committee. Medical devices news letter Medical device links Senior Matrons</td>
</tr>
</tbody>
</table>

9. Updating and Review

This policy will normally be reviewed no less than every three years unless an earlier review is required.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Diversity & Human Rights Policy' or the Equality and Diversity website.

10.2. The Initial Equality Impact Assessment Screening Form is at Appendix 4.
Appendix 1. Procedure Following an Adverse Incident With A Medical Device

Incident or near miss involving a medical device

Patient harm?

YES

Respond to patient and/or carer’s needs

For Serious incidents refer to Serious Incident Management Policy

Alert all relevant clinical staff of incident

NO

Remove devices and accessories involved from use. Clearly label all items involved as involved in an incident and potentially faulty. Bag any contaminated items and label appropriately. Leave all settings in position and note any other relevant information. Note relevant serial numbers/lot numbers

Notify CEMS and arrange safe transport of items to this department

Complete a DATIX report form (online), including ID number of device

DATIX handler, Risk managers and Medical Device Safety Officer (MDSO) will assess appropriate course of action with item and incident. If necessary, the MDSO will notify the MHRA*

The MDSO will feedback to any relevant Trust staff about the incident; action taken and lessons learnt.

Do not return device to company unless asked to by the MHRA

*If staff contact the MHRA directly about a Medical Device, please ensure that a copy of the report made is sent to RCHT.MedicalDevices@cornwall.NHS.UK, for their information, by adding this email address to the report form.
Appendix 2. Record Sheet for Issuing Medical Device for use outside RCHT

Please refer to the Procedure notes for further details

1) Training Requirements
Staff member and end user should ensure all items on this list are covered.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pre-checks</td>
<td>Before use, ensure device is safe to use and perform any maintenance checks required</td>
</tr>
<tr>
<td>2. General use</td>
<td>Be aware of the capabilities of the device and it’s clinical use, and how to check it during use</td>
</tr>
<tr>
<td>3. Faults/alarms</td>
<td>Know about any common faults and errors with use and the actions to take in the event of any alarms</td>
</tr>
<tr>
<td>4. Cleaning</td>
<td>Appropriate cleaning process between use</td>
</tr>
<tr>
<td>5. Contacts</td>
<td>General contact numbers for routine enquires and emergency contact numbers in case of faults or alarms which cannot be resolved</td>
</tr>
<tr>
<td>6. Return</td>
<td>Method of returning the device after use, or for routine service</td>
</tr>
<tr>
<td>7. Consumables</td>
<td>Information of how to obtain additional accessories for the device</td>
</tr>
</tbody>
</table>

2) Confirmation of Training and Identification of Device

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Item Issued: (Manufacturer and serial/ID number)</td>
<td></td>
</tr>
<tr>
<td>Destination of item: (eg patient’s home/district/hospice)</td>
<td></td>
</tr>
<tr>
<td>Agreed date of review/return:</td>
<td></td>
</tr>
<tr>
<td>Last Service Date (please note if service is required within loan period):</td>
<td></td>
</tr>
</tbody>
</table>

We, the undersigned, agree that training and information about the medical device to be issued has been given and understood.

Staff member performing training

**PATIENT (OR PERSON TAKING RESPONSIBILITY FOR ITEM) CONFIRMATION:**

I understand that this medical device is for named patient’s use only.
I have been given clear explanation (& written instructions) of its use.
I will take reasonable care of it and report any faults to: ___________________________

**PLEASE PRINT AND SIGN YOUR NAME:** 

Name of person receiving device (please note if district nurse/hospice):

Patient NHS Number (& address):

3) Storage of Form

i) Keep original form in Patient notes as evidence of training given (copy may be given to patient)
ii) Record loan of any ward/RCHT device in separate folder & confirm it’s return
iii) Equipment Library Device? :-Fax form to Equipment Library via FAX 2909. Equipment Library will record loan and confirm return of device to RCHT

4) Return of Loan Equipment

**THIS ITEM IS ON LOAN FROM THE ROYAL CORNWALL HOSPITAL.** Please return it promptly.

On return of item, patient may ask a member of staff to confirm receipt on this form.

<table>
<thead>
<tr>
<th>Item returned to (location)</th>
<th>Received by (staff to PRINT name)</th>
<th>Date of return</th>
</tr>
</thead>
</table>
This page has been left blank for any additional notes staff may need to make.
## Appendix 3. Governance Information

<table>
<thead>
<tr>
<th><strong>Document Title</strong></th>
<th>Medical Device &amp; Equipment Management Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date Issued/Approved:</strong></td>
<td>23/9/2014</td>
</tr>
<tr>
<td><strong>Date Valid From:</strong></td>
<td>01/10/2014</td>
</tr>
<tr>
<td><strong>Date Valid To:</strong></td>
<td>01/10/2017</td>
</tr>
<tr>
<td><strong>Directorate / Department responsible (author/owner):</strong></td>
<td>Philip Conroy, Medical Physics</td>
</tr>
<tr>
<td><strong>Contact details:</strong></td>
<td>01872 252496</td>
</tr>
<tr>
<td><strong>Brief summary of contents</strong></td>
<td>Outlines all aspects of using and care of Medical Devices</td>
</tr>
<tr>
<td><strong>Suggested Keywords:</strong></td>
<td>Devices, Instruments, Machines, Maintenance, Repair</td>
</tr>
<tr>
<td><strong>Target Audience</strong></td>
<td>RCHT</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Executive Director responsible for Policy:</strong></td>
<td>Director of Nursing, Midwifery and AHP</td>
</tr>
<tr>
<td><strong>Date revised:</strong></td>
<td>May 2014</td>
</tr>
<tr>
<td><strong>This document replaces (exact title of previous version):</strong></td>
<td>Medical Device &amp; Equipment Management Policy v1.9.2</td>
</tr>
<tr>
<td><strong>Approval route (names of committees)/consultation:</strong></td>
<td>Medical Devices Clinical and Non Clinical Products Group (12/8/14) CSSC DMB (23/9/14)</td>
</tr>
<tr>
<td><strong>Divisional Manager confirming approval processes</strong></td>
<td>Not required</td>
</tr>
<tr>
<td><strong>Name and Post Title of additional signatories</strong></td>
<td>Janet Gardner, Governance Lead CSSC Division</td>
</tr>
<tr>
<td><strong>Signature of Executive Director giving approval</strong></td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td><strong>Publication Location (refer to Policy on Policies – Approvals and Ratification):</strong></td>
<td>Internet &amp; Intranet</td>
</tr>
<tr>
<td><strong>Document Library Folder/Sub Folder</strong></td>
<td>Clinical / Medical Physics</td>
</tr>
<tr>
<td><strong>Links to key external standards</strong></td>
<td>CQC Outcome 11, NHSLA Standard 5.4</td>
</tr>
</tbody>
</table>
| **Related Documents:** | • Health and Social Care Act 2008 (Regulated Activities) Regulations 2010  
• Care Quality Commission (Registration) Regulations 2009.  
• Medical Device Regulations 2002 UK |
Statutory Instrument
 Health and Social Care Act 2008 (Regulated Activities) Regulations 2010
 Care Quality Commission (Registration) Regulations 2009.
 MRHA- Devices in Practice
 MRHA Equipped to Care – The safe use of medical devices in the 21st century
 The Code of Professional Conduct UKCC
 Medicines and Healthcare products Regulatory Agency - Managing Medical Devices Guidance for healthcare and social services organisations April 2014:

Training Need Identified? No

### Version Control Table

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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</thead>
<tbody>
<tr>
<td>17 Feb 03</td>
<td>1.1</td>
<td>Original</td>
<td></td>
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<tr>
<td>15 Jun 07</td>
<td>1.4</td>
<td>Changes to training and maintenance sections</td>
<td>R Cranage</td>
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<tr>
<td>1 Jul 08</td>
<td>1.5</td>
<td>Minor corrections</td>
<td>R Cranage</td>
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<tr>
<td>23 Jan 09</td>
<td>1.6a</td>
<td>Changes to reflect S4BH C4b and NHSLA requirements</td>
<td>R Cranage/ SA Rundle</td>
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<td>2 Jun 09</td>
<td>1.6b</td>
<td>Clarification of maintenance risk process and incident reporting</td>
<td>R Cranage/ SA Rundle</td>
</tr>
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<td>22 Jul 09</td>
<td>1.6.2</td>
<td>Minor corrections and change to title of exec lead</td>
<td>R.Cranage SA Rundle</td>
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<tr>
<td>Feb 2011</td>
<td>1.7</td>
<td>Minor Revisions and corrections</td>
<td>P Conroy</td>
</tr>
<tr>
<td>9 May 11</td>
<td>1.8</td>
<td>Policy reformatted to conform to Trust template</td>
<td>Andrew Rogers Corporate Records</td>
</tr>
<tr>
<td>Date</td>
<td>Revision</td>
<td>Description</td>
<td>Author</td>
</tr>
<tr>
<td>------------</td>
<td>----------</td>
<td>------------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>10 May 11</td>
<td>1.9</td>
<td>Revision to wording to maintenance paragraph</td>
<td>P Conroy</td>
</tr>
<tr>
<td>11 Jan 12</td>
<td>1.9.1</td>
<td>Revision of wording reflecting NHSLA comments to para 6.3</td>
<td>P Conroy</td>
</tr>
<tr>
<td>20 May 12</td>
<td>1.9.2</td>
<td>Insertion of Para in 6.6 for Contractor documentation</td>
<td>P Conroy</td>
</tr>
<tr>
<td>29 May 14</td>
<td>2.0</td>
<td>Revision with up dates</td>
<td>P Conroy</td>
</tr>
</tbody>
</table>

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

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Appendix 4. Initial Equality Impact Assessment Form

| Name of service, strategy, policy or project (hereafter referred to as policy) to be assessed: Medical Device & Equipment Management Policy |
| Directorate and service area: Medical Physics |
| Is this a new or existing Procedure? Existing |
| Name of individual completing assessment: Phil Conroy |
| Telephone: 01872 252497 |

1. **Policy Aim***
   Outlines all aspects of using and care of Medical Devices

2. **Policy Objectives***
   To ensure that medical devices are used safely, competently and effectively for the best care of patients and to comply with the relevant external legislation and guidance

3. **Policy – intended Outcomes***
   Safe use of Medical Devices

4. **How will you measure the outcome?***
   Incident numbers and CQC inspection

5. **Who is intended to benefit from the Policy?***
   All staff and patients.

6a. **Is consultation required with the workforce, equality groups, local interest groups etc. around this policy?***
   No

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong> (male, female, transgender / gender reassignment)</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race / Ethnic communities /groups</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Disability</strong></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learning disability, physical disability, sensory impairment and mental health problems</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Religion / other beliefs</strong></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Marriage and civil partnership</strong></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pregnancy and maternity</strong></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</strong></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation- this excludes any policies which have been identified as not requiring consultation. or
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended.  No

9. If you are not recommending a Full Impact assessment please explain why.

No potential for differential impact identified

| Signature of policy developer / lead manager / director | Date of completion and submission |
| Names and signatures of members carrying out the Screening Assessment | 1. Phil Conroy |
| | 2. |

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed ____________________

Date _________________