Medical Device & Equipment Management Policy

V3.0

February 2019
# Table of Contents

1. **Introduction** .................................................................................................................................................................................. 3
2. **Purpose of this Policy/Procedure** .................................................................................................................................................. 4
3. **Scope** ............................................................................................................................................................................................ 4
4. **Definitions / Glossary** ................................................................................................................................................................. 4
5. **Ownership and Responsibilities** .................................................................................................................................................. 5
   5.1 Executive Responsibility ................................................................................................................................................................. 5
   5.2 Role of the Medical Devices Oversight Group ............................................................................................................................. 5
   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 ....................................................................................................................................... 6
   5.6 Role of Staff ..................................................................................................................................................................................... 7
   5.7 Role of Independent Contractors ................................................................................................................................................... 7
6. **Standards and Practice** .................................................................................................................................................................... 7
7. **Dissemination and Implementation** ............................................................................................................................................. 14
8. **Monitoring compliance and effectiveness** ....................................................................................................................................... 14
9. **Updating and Review** ....................................................................................................................................................................... 14
10. **Equality and Diversity** ................................................................................................................................................................. 14
    10.2 Equality Impact Assessment .......................................................................................................................................................... 14
Appendix 1. Governance Information .................................................................................................................................................. 15
Appendix 2. Initial Equality Impact Assessment Form .......................................................................................................................... 18
Appendix 3. Procedure Following an Adverse Incident with a Medical Device .................................................................................. 21
Appendix 4. Record Sheet for Issuing Medical Device for use outside RCHT .................................................................................. 22
Appendix 5. Medical Devices Oversight Group – Terms of Reference ................................................................................................. 24
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 (2015)”. The guidance aims to outline a systematic approach to the acquisition, deployment, maintenance (preventive maintenance and performance assurance), repair and disposal of medical devices, as well as to medical device training; this should ensure that medical devices are used safely, competently and effectively for the best care of patients, and that the Trust complies with all relevant legislation and guidance.

1.2. This policy lays down the method of medical device management to be followed, which includes procurement, training, maintenance, decontamination, disposal and reporting of adverse incidents, so as 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 safe working practices be maintained. The Trust aims to ensure that all staff that 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 device. They should:

- 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 versions of this document.

1.8 **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may
need consent; this must be explicit, informed and documented. We can’t rely on Opt out, it must be Opt in.

The DPA18 covers how the Trust obtains, hold, record, use and store all personal and special category (e.g. Health) information in a secure and confidential manner. This Act covers all data and information whether held electronically or on paper and extends to databases, videos and other automated media about living individuals including but not limited to Human Resources and payroll records, medical records, other manual files, microfilm/fiche, pathology results, images and other sensitive data.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the ‘information use framework policy’, or contact the Information Governance Team rch-tr.infogov@nhs.net

2. Purpose of this Policy/Procedure

The purpose of this document is to outline a systematic approach to the management of all aspects of the lifecycle of medical devices, to ensure that all risks associated with the acquisition, deployment, use, monitoring, record integrity, reprocessing, modification, 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: An event involving medical devices and/or equipment which produces, or has the potential to produce, unexpected or unwanted outcomes that affect the safety of patients, service users or other people. Examples may include 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.

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.)
CLINICAL TECHNOLOGY: A specialist service, based in Medical Physics & Clinical Technology, that deals with the management, maintenance and assurance of all medical devices for the Trust.

MEDICAL DEVICE: The term ‘medical device’ encompasses medical devices as legally defined in the Medical Devices Directive, other medical devices and assistive Technologies. Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer, to be used on human beings for the purpose of:

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

and which 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 Government agency that is responsible for the regulation of medicines and medical devices and equipment used in healthcare organisations and the investigation of harmful incidents.

MPCT: Directorate of Medical Physics and Clinical Technology.

PPM: ‘Planned Preventative Maintenance’ – a regular ‘scheduled service’, a maintenance programme performed by Clinical Technology 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 Executive Responsibility
The Medical Director has overall responsibility for the safe management of medical devices and compliance with relevant regulation, exercised through the Medical Devices Oversight Group.

5.2 Role of the Medical Devices Oversight Group
The body responsible for ensuring adequate governance is in place around the control of medical devices. It provides assurance to the Medical Director regarding the safe use of medical devices, and oversees issues relating to their maintenance, training, procurement and Risk & Safety. The Terms of Reference for the group is at Appendix 3.
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 investigation) where required. A regular summary of these incidents will be provided for review by the Medical Devices Oversight Group. Any reports made to the MHRA will be kept on a central record by the MDSO.

5.4 **Role of Ward and Department Managers**

Ward and Department managers are responsible for the safe use of Medical Devices within their location. They must ensure that:

- There are systems in place to ensure that staff using Medical Devices are adequately trained on relevant equipment
- Appropriately documented evidence of staff training is retained
- Local procedures are established for the management of Devices to comply with the requirements of this policy.
- A Local Medical Device Link is appointed to assist the area manager and the Medical Devices Training Officer with areas such as Training Needs Analysis, training and risk assessments.
- Medical devices no longer needed are disposed of in the required manner, liaising with MPCT to ensure removal from the asset management system.
- Risk assessments are undertaken on devices which may pose a significant risk to patients or staff.
- Equipment is stored in a safe and secure location when not in use.
- Equipment is kept in an appropriate state of repair, seeking advice from MPCT as necessary, and is cleaned according to Trust policy (refer to section 8 and the decontamination policy).
- Maintenance assurance reports from MPCE are reviewed.
- Access to devices requiring servicing is facilitated as soon as practicable and with close liaison with MPCT.
- A process is in place to ensure that devices are not routinely used if due for servicing, unless properly risk assessed against clinical urgency of need, and recorded appropriately.
- Where a Manufacturer or other contracted service provider carries out maintenance on medical devices on site, a record of the visit and work done must be kept by the Ward or Department where it was carried out, and forwarded in a timely manner to MPCT for logging on the asset management system. This would normally be a copy of the company service report.
- 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 familiar with this and the Medical Devices Training Policy
- 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
- They check the maintenance due label before using the device
- 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 or faults with equipment immediately
- They clearly label defective devices and ensure they are taken out of action
- They endeavour to make devices available for maintenance
- They report all adverse events to their line manager immediately

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.

6. **Standards and Practice**

6.1 **Procurement**

6.1.1. Advice must be sought from Cornwall Procurement and Supplies Service and MPCT about the procurement of medical devices. For more information see the RCHT Procurement Policy.

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

- Clinical requirements
- Maintenance strategy, costs and implications
- Safety
- Compatibility with other devices
- Patient needs
- Whole life cost
- Training requirements
- Standardisation / preferred devices
- Decontamination procedures

6.1.3. Where possible, standardisation of common types of equipment is desirable in order to lessen operator confusion, 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 Procurement and Supplies Service) or those that have been approved by the Medical Devices and Clinical Products group. Prior to any procurement of equipment not on the recommended list, advice must be sought from MPCT and Cornwall Procurement and 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 Cornwall Procurement and Supplies Service (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 the Cornwall Procurement and Supplies Service and MPCT; failure to do so is likely to render the Trust insurance and liability policy invalid, exposing both users and organisation to risk.

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

6.1.9. In accordance with the MHRA guidance Managing Medical Devices (2015) the Trust has established a strategic rolling replacement programme for medical equipment funded through Capital monies. Oversight is provided by the Medical Director.

### 6.2 Acceptance Procedures for New Equipment

6.2.1. All new medical devices must have acceptance checks carried out by MPCT before use.

6.2.2. Coincident with the acceptance checks being conducted, devices will be identified with a unique number and entered into the Trust’s asset management system.

6.2.3. The Departmental manager must ensure they are in receipt of the equipment user manual when accepting the equipment. They must 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 the Trust asset management system. MPCT administers the
‘eQuip’ database for all Trust devices, 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. The ‘eQuip’ system will act as the single authoritative inventory for Trust medical devices, as well as the single repository for recording all maintenance activity, be that conducted by Clinical Technology or by an external service provider.

6.3.3. It is important that Wards/Departments notify MPCT if devices are to be withdrawn from use so that the asset register can be updated and remain accurate.

6.4  **Device Instructions**

6.4.1. All 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 Clinical Technology and the Medical Devices Training Officer.

6.4.2. Where instructions are produced locally for patients or their carers, these must follow MHRA 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 must be performed by users prior to use. These should consist of, as a minimum, checking for any obvious signs of damage, cleanliness and faults affecting performance or safety. Maintenance labels must be checked to ensure servicing is not overdue.

6.5.2. Faults are to be reported as per the guidelines issued by the relevant maintenance provider. 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 MPCT 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 MPCT 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 other contracted service provider carries out maintenance on medical devices on site, a record of the visit and work done must be kept by the Ward or Department where it was carried out, and forwarded in a timely manner to MPCT for logging on the asset management system. 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.

6.6.6. Pre-use functional and visual checks must be carried out by all users prior to using any medical device, as per 6.5.1.

6.6.7. Clinical Technology will endeavour to highlight to Wards/Departments when certain categories/items of medical equipment will soon require servicing. Nonetheless, it remains the responsibility of Ward/Departmental managers to ensure that their devices remain in date for servicing and that any out-of-date devices are not used unless a risk assessment has been made as per para 5.4. Wards/Departments must facilitate any required maintenance by returning the equipment to MPCT or by identifying opportunity for timely access to the equipment by maintenance staff.

### 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 and 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 MPCT, e.g. for maintenance or repair (or to any other location, such as a manufacturer after a 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 any user receives 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 is to 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 at Appendix 2 and also on the MPCT intranet 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 loan of Bariatric equipment, tissue viability equipment and syringe drivers, as well as a range of pressure relieving mattresses and cushions. 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. Staff 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 Assessment**

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. A medical device should not be used for any purpose other than that for which it was designed.

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 MPCT 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 and Disposal of Equipment**

6.17.1. Equipment must be replaced when it becomes unsafe to use, is no longer producing clinically acceptable results or is no longer supportable. 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. MPCT must be informed when a medical device is to be disposed of to enable the Trust asset management system to be updated and to seek advice on the appropriate manner of disposal.

6.17.3. Decontamination certificates, maintenance records and instructions should be retained on any decommissioned device. Where applicable, Information Governance policies must be followed in terms of deleting patient information and data; advice on this should be sought from the Trust Information Governance team and/or CITS.

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.
7. Dissemination and Implementation

7.1. This policy will be published on the Trust Document Library following endorsement of the Medical Devices Oversight Group and authorisation by the Medical Director.

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

| Element to be monitored | 1) Monitoring of medical device planned maintenance  
|                         | 2) Medical Device training  
|                         | 3) Risk management |
| Lead                   | Chair of Medical Devices Oversight Group |
| Tool                   | 1) Review of maintenance assurance reports derived from the Trust central asset management system (‘eQuip’).  
|                         | 2) Review of assurance reports regarding medical device training across the organisation.  
|                         | 3) Review of corporate risks relating to medical devices and equipment risks escalated by divisions. |
| Frequency              | At each Medical Devices Oversight Group meeting |
| Reporting arrangements | MPCT will provide monthly assurance reports and where appropriate analyses and recommendations to both the Medical Devices Oversight Group and the Divisional Associate Directors. |
| Acting on recommendations and Lead(s) | The Medical Devices Oversight Group will lead on Device recommendations, executed through MPCT and relevant Divisional managers, in conjunction as required with Cornwall Procurement and Supplies Service.  
|                         | The Chair of the Medical Devices Oversight Group will provide exception reports to the Trust Management Group (Governance). |

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, Inclusion & Human Rights Policy’ or the Equality and Diversity website.

10.2 Equality Impact Assessment

10.3 The Initial Equality Impact Assessment Screening Form is at Appendix 2.
## Appendix 1. Governance Information

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<td>November 2017</td>
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<td>Date Valid To:</td>
<td>February 2022</td>
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<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Head of Clinical Technology</td>
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<tr>
<td>Contact details:</td>
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<tr>
<td>Brief summary of contents</td>
<td>Outlines all aspects of using and care of Medical Devices</td>
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### Links to key external standards

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<td>• Health and Social Care Act 2008 (Regulated Activities) Regulations 2010</td>
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<td>• Care Quality Commission (Registration) Regulations 2009.</td>
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### Related Documents:
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2010
- Care Quality Commission (Registration) Regulations 2009.
- Medical Device Regulations

### Training Need Identified?
No

### Version Control Table

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<td>Minor corrections and change to title of exec lead R Cranage / SA Rundle</td>
<td></td>
</tr>
<tr>
<td>Feb 11</td>
<td>1.7</td>
<td>Minor Revisions and corrections P Conroy</td>
<td></td>
</tr>
<tr>
<td>09 May 11</td>
<td>1.8</td>
<td>Policy reformatted to conform to Trust template Andrew Rogers Corporate Records</td>
<td></td>
</tr>
<tr>
<td>10 May 11</td>
<td>1.9</td>
<td>Revision to wording to maintenance paragraph P Conroy</td>
<td></td>
</tr>
<tr>
<td>11 Jan 12</td>
<td>1.9.1</td>
<td>Revision of wording reflecting NHSLA comments to para 6.3 P Conroy</td>
<td></td>
</tr>
<tr>
<td>20 May 12</td>
<td>1.9.2</td>
<td>Insertion of Para in 6.6 for Contractor documentation P Conroy</td>
<td></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
This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.
Appendix 2. Initial Equality Impact Assessment Form

This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed</th>
<th>Medical Device &amp; Equipment Management Policy V3.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directorate and service area</td>
<td>Medicine Physics</td>
</tr>
<tr>
<td>Is this a new or existing Policy?</td>
<td>Existing</td>
</tr>
<tr>
<td>Name of individual completing assessment</td>
<td>Trevelyan Foy</td>
</tr>
<tr>
<td>Telephone</td>
<td>01872 252495</td>
</tr>
</tbody>
</table>

1. *Policy Aim*  
   Who is the strategy / policy / proposal / service function aimed at?  
   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?*  
   Refer to section 8 of policy.

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

6a Who did you consult with  
   Workforce | Patients | Local groups | External organisations | Other  
   X

   b). Please identify the groups who have been consulted about this procedure.  
   Medical Devices Oversight Group.

What was the outcome of the consultation?  
   Approved.
7. The Impact
Please complete the following table. If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.

Are there concerns that the policy **could** have differential impact on:

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>No aspect of this policy has been identified as impacting upon this equality strand.</td>
</tr>
<tr>
<td><strong>Sex (male, female, trans-gender / gender reassignment)</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>No aspect of this policy has been identified as impacting upon this equality strand.</td>
</tr>
<tr>
<td><strong>Race / Ethnic communities /groups</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>No aspect of this policy has been identified as impacting upon this equality strand.</td>
</tr>
<tr>
<td><strong>Disability</strong> - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.</td>
<td>✓</td>
<td></td>
<td></td>
<td>No aspect of this policy has been identified as impacting upon this equality strand.</td>
</tr>
<tr>
<td><strong>Religion / other beliefs</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>No aspect of this policy has been identified as impacting upon this equality strand.</td>
</tr>
<tr>
<td><strong>Marriage and Civil partnership</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>No aspect of this policy has been identified as impacting upon this equality strand.</td>
</tr>
<tr>
<td><strong>Pregnancy and maternity</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>No aspect of this policy has been identified as impacting upon this equality strand.</td>
</tr>
<tr>
<td><strong>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>No aspect of this policy has been identified as impacting upon this equality strand.</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 this relates to service redesign or development

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

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

   No aspect of this policy has been identified as impacting upon the identified equality strands.
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

This EIA will not be uploaded to the Trust website without the signature of the Human Rights, Equality & Inclusion Lead.

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

Signed __ Trevelyan Foy

Date ____13/11/2017
Appendix 3. 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 4. 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.

1. Pre-checks
   Before use, ensure device is safe to use and perform any maintenance checks required

2. General use
   Be aware of the capabilities of the device and its clinical use, and how to check it during use

3. Faults/alarms
   Know about any common faults and errors with use and the actions to take in the event of any alarms

4. Cleaning
   Appropriate cleaning process between use

5. Contacts
   General contact numbers for routine enquiries and emergency contact numbers in case of faults or alarms which cannot be resolved

6. Return
   Method of returning the device after use, or for routine service

7. Consumables
   Information of how to obtain additional accessories for the device

2) Confirmation of Training and Identification of Device

<table>
<thead>
<tr>
<th>Item Issued:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Manufacturer and serial/ID number)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Destination of item:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(eg patient’s home/district/hospice)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Agreed date of review/return:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Service Date (please note if service is required within loan period):</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: ___________________________Date: ___________________________

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.

<p>| On return of item, patient may ask a member of staff to confirm receipt on this form. |</p>
<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>

Medical Device & Equipment Management Policy V3.0
Page 22 of 25
Record Sheet for Issuing Medical Device for use outside RCHT (cont)
This page has been left blank for any additional notes staff may need to make.
Appendix 5. Medical Devices Oversight Group – Terms of Reference

Accountability
The Medical Devices Oversight Group will report to the Medical Director.

Purpose
The overarching purpose of the Group will be to provide assurance to the Trust regarding the safety, suitability, availability and safe use of all medical devices in use across the Trust.

Duties and Responsibilities
To receive and review assurance reports from Medical Physics and Clinical Technology on the maintenance of all medical devices in use across the Trust, including those under contracted maintenance arrangements.

To receive reports from, and provide oversight to, the Medical Devices Safety Officer, and/or any sub-group as established by the Group, reviewing incident reports and device safety alerts as highlighted.

To endorse maintenance and servicing arrangements of new medical equipment, ensuring such arrangements are adequate, safe and resourced.

To authorise and enter device-related risks onto the Trust-wide corporate risk register, underwriting or escalating as deemed necessary, and providing ongoing oversight of such risks.

To receive reports from, and provide oversight to, the Medical Devices Training Officer, and/or any sub-group as established by the Group.

To authorise the Medical Devices Management Policy.

To review medical device decontamination and infection control issues, escalating as necessary.

To review and advise on medical devices procurement and trials issues, as well as capital investment.

To work on the establishment of an Integrated Medical Equipment Planning Group, streamlining the current process for development and oversight of the capital replacement programme as currently delivered by this, the Capability Delivery and the Medical Capital Groups.

Membership
TBC, but including:

Senior Consultant – Chair
Chairs or other representatives from Sub-Groups
Head of Clinical Technology and/or Director of Medical Physics
Head of Procurement and Supplies
Other procurement representative
Rolling Replacement Programme Manager
MDSO
Infection Prevention and Control Service Lead
Trust Decontamination Lead

Any member who cannot attend should send a suitable representative, or submit an update report.

**Chairman**
The Chairman will be appointed by the Medical Director.

**Quorum**
Five members present, with at least one clinical member shall constitute a quorum. A register of attendance will be kept by the person taking the notes/minutes.

**Frequency of Meetings**
Meetings will be held no less than quarterly, and for diary convenience may be combined with any sub-groups.

Extraordinary meetings may be called at the request of any member of the group with the approval of the Chairman.

**Reporting**
The proceedings of every meeting shall be minuted. Minutes will be taken by the Medical Physics Administrator. The person responsible for taking the minutes/notes will also produce the register of attendance.

The minutes will be in draft until agreed at the next meeting. The Committee should use an action sheet to follow up on actions and review these at each meeting for progress.

**Review**
These terms of reference must be reviewed at least on an annual basis and recorded in the minutes/notes.