



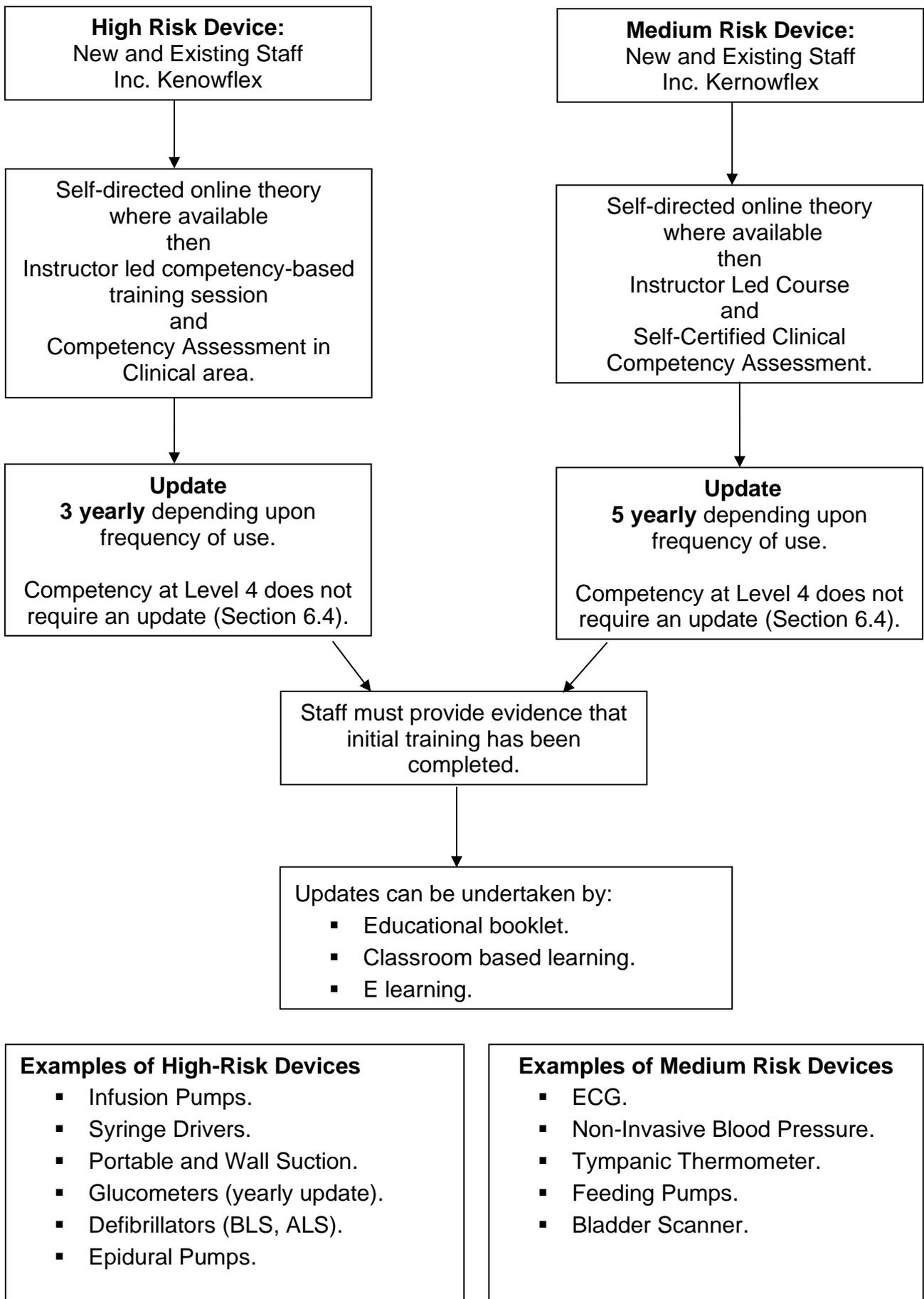
**Royal Cornwall Hospitals**  
NHS Trust

# **Medical Devices Training Policy**

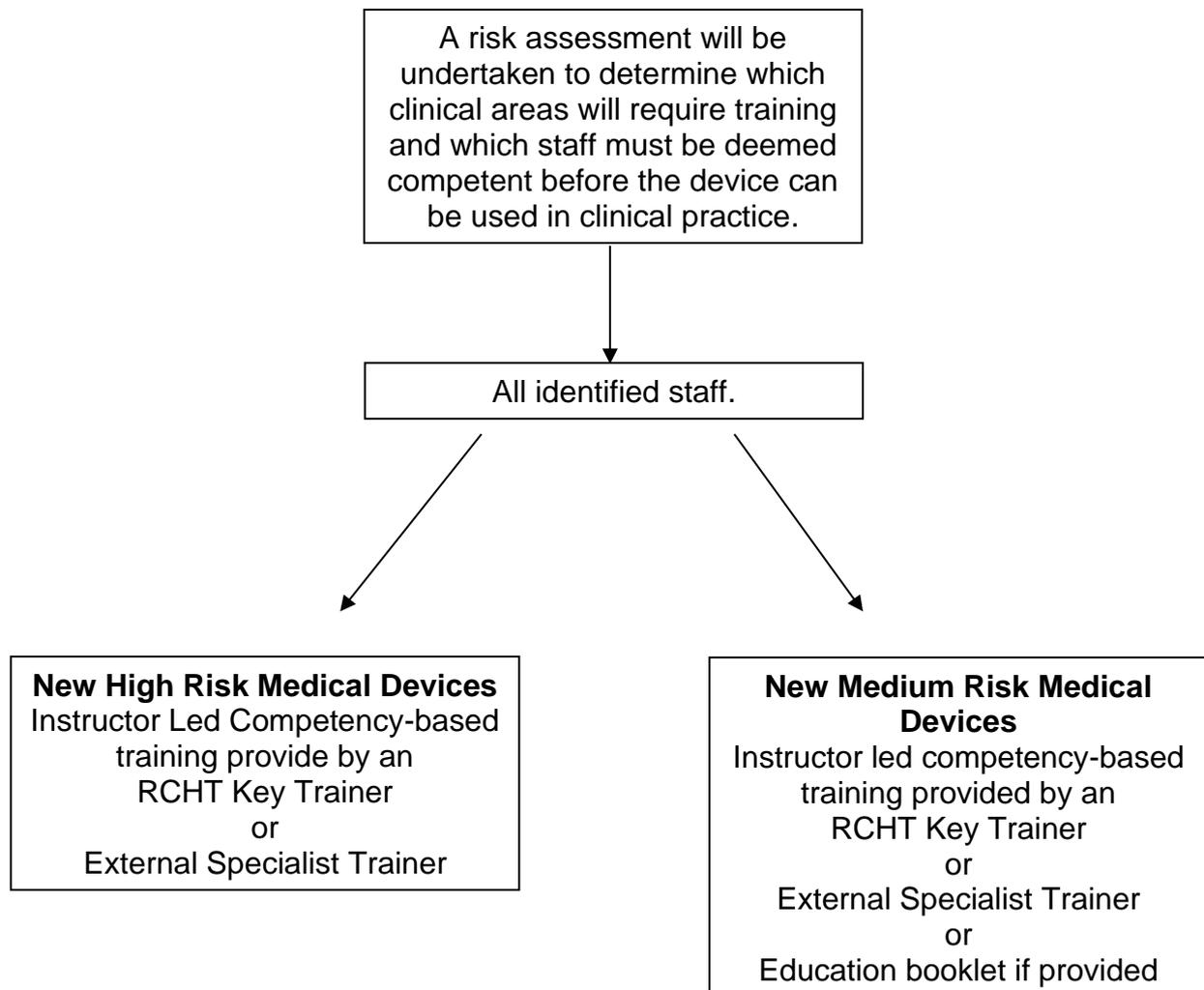
**V3.0**

**July 2023**

# Summary 1. Medical Device Training Pathway



## Summary 2. Medical Device Training Pathway for New Devices



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

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 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 cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust     [rch-tr.infogov@nhs.net](mailto:rch-tr.infogov@nhs.net)

## 1. Introduction

- 1.1. Medical devices are used every day by many healthcare professionals in the care and treatment of patients. This policy sets out the framework for the safe and effective use of medical devices within the Trust.
- 1.2. This policy has been implemented to complement other established programmes within the Trust e.g., Corporate Induction, Local Induction, Mandatory Training, Personal Development Plans and Appraisal Programmes.
- 1.3. This version supersedes any previous versions of this document.

## 2. Purpose of this Policy

The purpose of this policy is to assist the Trust in ensuring that medical devices under its control are effectively and properly used based on the requirements of the Care Quality Commission (CQC) and National Health Service Litigation Authority (NHSLA). This policy incorporates recommendations from the Medicines and Healthcare Products Regulating Agency (MHRA) and the NHS Commissioning Board.

- Provides a clear framework for training requirements and the use of medical devices.
- Ensures a consistent approach to training is in place for all appropriate disciplines within the Trust.
- Help identify and minimise hazards and reduce risk, related to the use of medical devices.
- Ensures the appropriate staff receive suitable training and are competent in the use of medical devices prior to its use in the clinical setting.

## 3. Scope

This policy applies to all RCHT staff members including Kernowflex staff who use medical devices and those responsible for managing staff members who use medical devices.

## 4. Definitions / Glossary

- 4.1. **Medical Device:** "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 for human beings for the purpose of:
  - Diagnosis, prevention, monitoring, treatment or alleviation of disease.
  - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability.
  - Investigation, replacement or modification of the anatomy or of a physiological process.

- Control of conception.

“and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”.

## 4.2. Risk Levels

### 4.2.1. Low Risk

Devices whose failure or misuse is unlikely to result in serious consequence.

### 4.2.2. Medium Risk

Devices whose failure or incorrect use would have a significant impact upon patient care or temporary adverse health consequences but would be unlikely to cause direct serious injury.

### 4.2.3. High risk

Devices that have the potential to cause a serious adverse consequence or death should they fail or be misused. Devices recently associated with serious injury.

## 4.3. Clinical Staff

Doctors, Nurses, Midwives and all Allied Health Professionals (AHPs).

# 5. Ownership and Responsibilities

## 5.1. Role of the Trust Board

- Overall responsibility for the safe use of medical devices and medical device training.
- The Chief Operating Officer has overall responsibility for the Trust's management of Medical Devices including training and compliance with the relevant external Assurance Standards.
- To provide adequate resources enabling instruction, training and supervision to take place, minimising risk and safeguarding patients and staff from the hazards associated with the use of medical devices.
- To ensure that an inventory of medical devices is maintained, kept up to date and monitored to ensure its integrity.
- To ensure that suitable policies and procedures are in place and are communicated to staff ensuring compliance with Health and Safety Regulations, NHSLA Risk Management Standards and National Standards for Safe Better Healthcare with regards to the safe use of medical devices.

## **5.2. Role of the Procurement Department**

To ensure provision of appropriate training, including initial and on-going clinical training, plus technical and decontamination processes training is included in all contract specifications relating to the purchase of medical devices.

## **5.3. Role of the Medical Devices Training Officer**

- Support Care Groups and Clinical Practice Educators (CPEs) in identifying and co-ordinating medical device training.
- Develop standards of training for professional users relating to medical device equipment used within the Trust.
- Plan and co-ordinate the development and coverage of Trust wide medical device training programmes.
- Assist clinical areas to develop learning plans, training packages and ensure good practice is shared throughout the Trust.
- Audit staff training compliance in line with the Medical Devices Training Policy.
- Review clinical incidents and Datix reports involving medical equipment.
- Organise regular meetings with Clinical Practice Educators and Local Medical Device Links to share updates on medical devices, changes to policy and training compliance.
- Provide competency reports at a local and Care Group level when requested.

## **5.4. Role of the Clinical Manager**

- Ensure training needs of staff have been identified and staff are competent with the Medical Devices in their area. Maintain well documented training records. This responsibility extends to the induction of Agency and Kernowflex staff.
- Ensure all end-users are given suitable training in the safe and effective use of medical devices.
- Ensure training records and training requirements are reviewed during Personal Development Reviews (PDRs) in accordance with the current PDR policy.
- Appoint a Local Medical Devices Link (LMDL) for each clinical area.
- Share this policy with staff and ensure that staff understand their roles and responsibilities.
- Ensure all new staff during their local induction programme review what medical device training they require and ensure they complete a device training programme accordingly.

- Maintain a concise and up to date department/ward medical device asset register.
- Maintain accurate Staff Medical Device training records in accordance with the Trust's guidelines.
- Ensure staff follow Trust procedures where a medical device training concern is identified and contact the Medical Device Training Officer (x 3515) to enable an action plan for further training.
- Ensure the MD11 'End user Documentation' is used with all loaned equipment: The MD11 form is accessible on the Medical Device page of the RCHT Intranet, Clinical Shelf.

### **5.5. Role of the Care Group Quality Managers**

- Have a system in place to ensure all staff in their Care Group using Medical Devices are adequately trained on the relevant equipment.
- Keep documented evidence of staff training in each area.
- Establish local procedures for the management of devices to comply with the requirements of this policy.
- Appoint a Local Medical Device Link (LMDL) to assist the area manager and the Medical Devices Training Officer with training needs analysis, training, risk assessments and device maintenance issues.
- Maintain an equipment inventory, to be reviewed quarterly, noting new equipment and equipment disposed of or re-located in line with the Medical Device Management Policy.
- Complete risk assessments on devices which may pose a significant risk to patients or staff.
- Ensure equipment is kept in an appropriate state of maintenance and repair and is cleaned according to RCHT's Decontamination Policy.
- Ensure staff are aware of their responsibilities regarding the safe use of medical devices.

### **5.6. Role of the Local Medical Devices Link (LMDL)**

Each clinical area will have a Local Medical Devices Link (LMDL). This is a crucial role in ensuring the safe and efficient use of medical devices throughout the Trust

They are involved in assisting in the training of their colleagues, identifying training needs in their area, and become the link between their ward and the Medical Device Training Officer for (MDTO) the improvement of staff competencies.

#### 5.6.1. LMDL Requirements:

- LMDL Must be a Band 5 qualified/registered practitioner on a permanent contract within RCHT.
- Have evidence of Key Trainer training in Medical Devices used within their area.

#### 5.6.2. LMDL Responsibilities:

- Work in association with the Medical Devices Training Officer to improve the competencies of RCHT staff within their clinical area on Medical Devices.
- In conjunction with CPE's identify the Medical Device training needs of all healthcare workers in their local area.
- Provide update training on medical devices to healthcare workers including Agency and Kernowflex staff. LMDL must be identified as a qualified trainer for the devices they teach.
- Ensure that any training provided by either the LMDL or Key Trainer is recorded on a MD07 signature sheet, and a copy sent to the Medical Device Training Officer.
- Ensure training records are accurate and up to date.
- Gain advanced skills in medical devices through Key Trainer Training programmes and develop valuable teaching experience.
- Support Clinical Practice Educators (CPEs) and other Key trainers in organising training opportunities and medical device training.
- Communicate to Ward Managers and Care Group Leads the necessity for time allocation within working hours to permit training and attend Key Trainer Training.
- Attend meetings organised by the MDTO to share experiences, identify training needs and promote good training practice within the Trust.

### **5.7. Role of the Key Trainers.**

5.7.1. Additional staff may be identified as Key Trainers of specific devices. Key Trainers will support CPE's and LMDL staff with medical device training within their clinical areas.

- Key Trainer Requirements.
- Key Trainers must be a minimum of band 5 qualified/registered practitioner and on permanent contract with the Trust.

- For intravenous devices will have undertaken extra competency-based training with the company manufacturer.
- For medium risk devices will have undertaken extra competency-based training with the Medical Device Training Officer.

#### 5.7.2. Key Trainer Responsibilities

- Commit to the Key Trainer Programme.
- Attend device specific Key Trainer Training.
- Deliver competence-based medical device update training to existing staff including Agency and Kernowflex.
- Assist the CPE and LMDL with updating their local area's training records and provide evidence of training.
- Report issues, concerns, or proposed improvements directly to the CPE.

### 5.8. Role of Individual Clinical Staff

- Staff have a legal obligation to take reasonable care for their own health and safety and that of others who may be affected by what they do or conversely fail to do whilst at work (Health and Safety at Work Act 1974).
- Staff have a legal obligation to assist the Trust to meet with any statutory duty or requirement imposed upon it in regard to health and safety and to cooperate in such a manner as to ensure that approved Trusts policy and procedure is properly applied. Additionally healthcare professionals are bound by their Code of Ethics and Scope of Professional Practice, which clearly set out the individual's responsibilities and duty of care when using medical devices and of the situation that may arise when undertaking actions that they are not trained to perform.
- All staff are required to report any suspected or known breaches of this procedure through the correct channels and cooperate in any subsequent actions as may arise.

#### 5.8.1. When considering using any medical device, it is the duty and responsibility of each individual to ensure that:

- They are deemed competent by the Trust to use the medical device. If in any doubt they should seek advice on the matter and not use the device until their competency has been confirmed.
- Any shortcoming regarding individual training, skills or competences should be reported to their CPE or Ward Manager.
- Medical devices must be used in the manner for which training has been received and in line with manufacturer's guidelines.

- Arbitrary adjustment or modification of an approved training competence is not permitted. Failure to follow correct procedure may lead to disciplinary action.
- Where it is felt that a change in practice may improve procedures this should be raised with their Line Manager in the first instance and the Medical Devices Training Officer.
- Individuals should make themselves aware of Manufacturer's user manuals/guidelines and reference this as an aide memoir.
- Refer to RCHT's Medical Device Management Policy in regard to device faults and reporting medical device concerns.
- Refer to RCHT's Decontamination Policy regarding cleaning and decontaminating medical devices.

## **5.9. Role of the Medical Equipment Procurement Group**

The Medical Devices Procurement Group (MEPG) is responsible for:

- Reviewing maintenance, training and risk and safety issues regarding Medical Devices.
- Advisors to the Trust Board via the Care Group Quality Group, or equivalent, on the procurement, management, and deployment of Medical Devices.
- Assisting formulation of common policy/procedures.
- Ratifying a Recommended List of Medical Devices.
- Reviewing trials and evaluations of new medical devices as a replacement for existing devices or devices new to the Trust.

5.10. This policy is for all Clinical Staff. It is recognised that when the use of medical devices and equipment are delegated to a Health Care Assistant or other associated support staff by a registered staff member - accountability will remain with the registered professional. They must ensure the competence of individuals and that delegation is appropriate and safe.

## **6. Standards and Practice**

### **6.1. Training Delivery**

6.1.1. Users of medical devices are responsible for ensuring their own training is appropriate and up to date; advice can be sought from the Medical Device Training Officer, Local Medical Device Links and Ward Managers. All staff that use medical devices are encouraged to use all training routes available to them.

- Clinical Skills.
- Mandatory Training booked via ESR.

- Company Representative courses.
  - Instruction manuals.
  - Clinical training provided by specialist Key Trainers.
  - E-learning packages.
- 6.1.2. **End User Training:** Any professional user delivering medical device training to patients and home carers must have the appropriate skills, knowledge and experience to train on the safe and proper use of the device They must inform the patient on how to contact the appropriate support if required. (See Appendix 3, MD11 form for details).
- 6.1.3. **Specialist Medical Device Training:** Training for specialist areas with be organised on a local level with the Medical Devices Training Officer. Records of local training will be kept at local level.
- 6.1.4. **Student Nurses and Midwives:** In accordance with the recommendations laid out in the Standards of proficiency for registered nurses Annexe B (2018) all students are expected to be introduced and have exposure to intravenous pumps, feeding pumps and patient observation devices. Student nurses and midwives in their final year of training can attend classroom based medical device training on these devices. Following successful completion of this classroom training the students will be expected to use the equipment under direct clinical supervision. Upon entering the NMC register nurses and midwives will be competency assessment for the high-risk intravenous devices within their preceptorship status prior to using the devices independently.

## 6.2. Training Competencies

- 6.2.1. Level of training required is based on the risk level of the device (See Appendix 4). The training pathway can be seen on page 2. Further information on risk level can be seen in Appendix 6: Definition of Medical Device Risk Levels.
- 6.2.2. **High Risk:** Where a device is assessed as being high risk the Trust requires training to be competency based with evaluation and Clinical Competency Assessment following training. Key Trainers who have received device specific training and can demonstrate they have the aptitude, skill, knowledge and experience to do so may train/instruct and assess others. Competency is judged against agreed assessment criteria.
- 6.2.3. Competency may need to be re-assessed:
- When there is a change in clinical practice.
  - If staff have not used the device for a period of 3 months.
  - When staff have been involved in a medical device incident pertaining to misuse or poor practice.

- 6.2.4. **Medium Risk:** Where a device is assessed as being medium risk the Trust requires any training provided to be competency based with evaluation and assessment following training. Key Trainers who have received device specific training and can demonstrate they have the aptitude, skill, knowledge and experience to do so may train and assess others. Competency is judged against agreed manufacturers assessment criteria.
- 6.2.5. **Low Risk:** Training is not required for frequent regular users who can demonstrate they have the aptitude, skill, knowledge and experience in using the devices.

### 6.3. Self-Assessment

- 6.3.1. Existing Healthcare professionals who are identified by their manager as long-term 'expert users' and use the device as part of their job role e.g., clinical staff where competency has been inferred from professional qualification; may self-certify on low, medium and most high-risk equipment.
- 6.3.2. To self-assess competency, each professional member of staff is required to read and complete a competency statement using form MD06s (See Appendix 3). The statement gives recognition to professional accountability of trained staff.
- 6.3.3. **NOTE:** Some high-risk devices require specialist training and staff are required to attend training courses, e.g., defibrillators, PCAM, Epidurals etc. Each Care Group should develop their own list of equipment relevant to their areas and staff should be made aware of these items.
- 6.3.4. This equipment may not be self-certified unless the user is deemed at level 4 (Table 1.0) competencies by a specialist user, clinical manager or the MDTO. If staff are not deemed a level 4 competency, they are required to attend specific training programmes before being authorised to use the equipment.

### 6.4. Transferral of Competency

Devices where competency has been inferred from professional qualification must be checked against the specific model of the devices in use in this Trust. This should take place at induction and any training needs identified on high-risk equipment should be addressed within 1 month of commencing work in a clinical area. It is the individual staff member's responsibility to ensure training is obtained.

## 6.5. Processes for Identifying Training Needs

### 6.5.1. New Substantive Staff

Training needs of new staff will be assessed, and training plans agreed with their relevant Line Manager during the induction period giving particular emphasis to **high-risk and medium risk medical devices**. Staff must not use these medical devices until they have been successfully trained or are deemed competent.

6.5.2. New staff will receive appropriate training, in relation to **high-risk medical devices** within 3 months. **Medium risk** medical devices training will be prioritised and timely manner.

### 6.5.3. Existing Substantive Staff

All users of medical devices, at the time of their annual appraisal, must check their competencies are up to date in accordance to their role by completing the **MD06 form**. Should training requirements be identified, a training programme must be agreed with the staff member and Line Manager to ensure that their skills, knowledge and competencies are maintained. Any agreed training should be recorded in their personal development plan as well as their MD04 form.

## 6.6. Training for new medical devices

6.6.1. Training on new medical devices will be provided by the supplier/ manufacturer. Due to resource limitations it may necessary to have “Key Trainers as the initial trainer e.g. when the amount of training in the use of the new medical devices exceeds required implementation timescales.

6.6.2. Medical Devices will not be put into operation without there being sufficient numbers of trained staff to ensure its safe and effective use (Appendix 4A). This should be at the discretion of the Medical Devices Training Officer in conjunction with clinical management. The risk level of the device and the usage, according to individual ward needs, must be taken into consideration.

## 6.7. Process for Identifying Authorised Users

6.7.1. In clinical areas, the Ward Manager will keep a list of Key Trainers for specific medical devices approved for that area.

6.7.2. All ward/department managers and other designated staff will have access to the Medical Device Shared drive to review staff training and competencies. The Medical Devices Shared drive will include all high-risk medical devices identified in that area along with the approved users of the medical devices.

## 6.8. Level of Training

Training level achieved is determined by the role in which the staff member is required to use a specific medical device. There are three levels of training achievable (See Appendix 5).

## 6.9. Training Updates

6.9.1. Refresher/Update training will be required by all users:

- When manufacturers advise that there are version changes affecting safe operation of the device.
- A new model or upgrade is purchased with additional features.
- When a Safety Alert recommendation requires it.
- When a clinical trust policy requires it.
- The Medical Device Training Pathway on page 2 will assist staff to identify the correct pathway of training according to risk of the device.

### 6.9.2. High Risk Device Refresher Update

COMPETENCY LEVEL	Required Minimum Frequency update for High Risk			
	Level 4 I am able to use the device easily and I can recognise and interpret information and troubleshoot without hesitation.	Level 3 I am able to use this device safely but some concentration is required.	Level 2 I can use this device with a lot of concentration. I cannot be distracted by conversation.	Level 1 I may have received training but do not feel competent to use this device
<b>Frequent User</b>	Update not required	3 yearly	Annual	User not authorised
<b>Occasional User</b>	Update not required	2 yearly	Annual	User not authorised

Example: If you are an occasional user but can sustain a competency level 4, an update will not be required. If you are level 3, a 2 yearly update applies.

### 6.9.3. Medium Risk Device Update

COMPETENCY LEVEL	Required Minimum Frequency update for Medium Risk			
	Level 4 I am able to use the device easily and I can recognise and interpret information and troubleshoot without hesitation.	Level 3 I am able to use this device safely but some concentration is required.	Level 2 I can use this device with a lot of concentration. I cannot be distracted by conversation.	Level 1 I may have received training but do not feel competent to use this device
Frequent User	Update not required	5 yearly	Annual	User not authorised
Occasional User	Update not required	5 yearly	Annual	User not authorised

- **Low Risk Devices:** No update is required.
- **Frequent User:** Devices are used several times per shift.
- **Occasional User:** Devices are used less than 7 times weekly.

### 6.10. Reviews of Risk Levels:

Details of risk levels are outlined in Appendix 4.

### 6.11. Training Records

#### 6.11.1. Responsibility of staff member

Each individual staff member in the Trust that is involved with medical devices must maintain a personal portfolio of training. This provides an overview of evidence of their competency level on all the devices they use. This may be used in the annual PDP review and a copy stored in their clinical area.

#### 6.11.2. Responsibility of Ward/department

An inventory of medical devices, MD01 Asset Register is a pre-requisite for all training to identify which devices are used in a specific area.

#### 6.11.3. Registers for training received

Where an approved RCHT Trainer delivers training, either on a one-to-one basis or to a group, an MD07 record of the training given must be made that will include as a minimum:

- Name of the course.

- Date of training.
- Level of training received.
- Name of staff that attended with signature.
- Trainers Name and contact details.

Company representative may use their own registers or the MD07 form. A copy of the training register should be sent to the Medical Device Training Officer, Department of Clinical Technology, Tower Block, Treliske Hospital. Truro. TR1 3LJ (X3515).

## 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 Department of Clinical Technology 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

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Trust Compliance level regarding High-Risk device training and training records
Lead	Medical Device Training Officer
Tool	Reports from Electronic Staff Records (ESR)
Frequency	The Medical Device Training officer will undertake an audit every 6 months to verify compliance and the efficacy of evidence. Training records should be reviewed quarterly by the Ward/Department Managers to ensure records remain up to date.
Reporting arrangements	All areas will be audited on a rotational basis. A report will be produced for the Care Quality Group. The information will be summarized on the annual IPR report to the executive board. Concerns will be reported and acted upon by the Medical Device Training Officer through the Learning and Development Committee and Clinical Practice Educators.

Information Category	Detail of process and methodology for monitoring compliance
<b>Acting on recommendations and Lead(s)</b>	Senior Matrons, Clinical Practice Educators, Medical Device Links and Medical Devices Training Officer will formulate an action plan and allocate actions to staff accordingly within an appropriate time scale.
<b>Change in practice and lessons to be shared</b>	Changes will be disseminated through Ward Managers, Clinical Practice Educators and the Local Medical Devices Links.  Action to be completed will be addressed through the Clinical Practice Educators Link Meetings and completed within the appointed time stated in the action plan.

## 9. Updating and Review

- 9.1. This section covers information regarding the review process. All policy documents should be reviewed no less than every three years. Where appropriate, the author may set a shorter review date.
- 9.2. 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 And Inclusion Policy](#) or the [Equality and Diversity website](#).
- 10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

## Appendix 1. Governance Information

Information Category	Detailed Information
<b>Document Title:</b>	Medical Devices Training Policy V3.0
<b>This document replaces (exact title of previous version):</b>	Medical Devices Training Policy V2.0
<b>Date Issued/Approved:</b>	04 April 2023
<b>Date Valid From:</b>	July 2023
<b>Date Valid To:</b>	July 2026
<b>Directorate / Department responsible (author/owner):</b>	Elizabeth Anderson- Medical Device Training Officer. Learning and Development Department
<b>Contact details:</b>	01872 253515.
<b>Brief summary of contents:</b>	Outline of all aspects of training staff in the safe use of Medical Devices
<b>Suggested Keywords:</b>	Medical, Devices, Baxter, Alaris, T34, McKinley, pump, training, observations
<b>Target Audience:</b>	<b>RCHT:</b> Yes <b>CFT:</b> No <b>CIOS ICB:</b> No
<b>Executive Director responsible for Policy:</b>	Chief Medical Officer
<b>Approval route for consultation and ratification:</b>	The Learning Committee Care Group Governance
<b>General Manager confirming approval processes:</b>	Richard Andrzejuk
<b>Name of Governance Lead confirming approval by specialty and care group management meetings:</b>	Kevin Wright
<b>Links to key external standards:</b>	CQC Regulation 15

Information Category	Detailed Information
<b>Related Documents:</b>	<ul style="list-style-type: none"> <li>• NHS England (2021) An operational risk management strategy for trusts.</li> <li>• Standards of proficiency for registered nurses Annex B: Nursing procedures NMC (2018).</li> <li>• Medicines and Healthcare products Regulatory Agency (MHRA) (2015) Managing Medical Devices.</li> <li>• Medicines and Healthcare products Regulatory Agency (MHRA) 2014 – Devices in practice: checklists for using medical devices .</li> <li>• Health and Social Care Act 2012 .</li> <li>• Health Information and Quality Authority (2012) – Standards for Safer Better Health.</li> <li>• Care Quality Commission (2009) Regulations.</li> </ul>
<b>Training Need Identified?</b>	Yes. Training aspects relating to the implementation of this policy are contained within the main body of this document.
<b>Publication Location (refer to Policy on Policies – Approvals and Ratification):</b>	Internet and Intranet
<b>Document Library Folder/Sub Folder:</b>	Clinical / Medical Physics

### Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
15 Dec 2004	V1.0	Initial Issue	Scott Brown
15 Dec 2006	V1.2a	Minor amendments	Scott Brown
1 June 2008	V1.3a	Minor Amendments	Richard Cranage
23 January 2009	V1.4a	Amended	Sally-Ann Rundle
7 April 2011	V1.5a	Major amendments were made to reflect current practice and new guidelines	Janine Webster
7 May 2011	V1.8	Policy reformatted to conform to Trust Template	Andrew Rogers

Date	Version Number	Summary of Changes	Changes Made by
			Corporate Records Manager
15 May 2013	V1.9	Changes to self-assessment criteria	Janine Webster
11 July 2016	V1.10	Policy reformatted to conform to Trust Template. Contact Numbers updated. Addition Training Pathway on page 2	Elizabeth Anderson Medical Device Training Lead
3 July 2019	V2.0	Changes to Divisional Governance structure to realign with new Care Groups. Additional section 6.2.4 detailing training for student nurses and student midwives.	Elizabeth Anderson Medical Device Training Lead
31 January 2023	V3.0	No major changes. Updated to reflect introduction of Clinical Practice Educators (CPE) at RCHT. Contact details updated. Review of layout and duplications removed.	Elizabeth Anderson Medical Device Training Officer and Clinical Lead for the Medical Equipment Library

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

**All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.**

**This document is only valid on the day of printing.**

**Controlled Document.**

This document has been created following the Royal Cornwall Hospitals NHS Trust [The Policy on Policies \(Development and Management of Knowledge Procedural and Web Documents Policy\)](#). It should not be altered in any way without the express permission of the author or their Line Manager.

## Appendix 2. Equality Impact Assessment

### Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team  
[rcht.inclusion@nhs.net](mailto:rcht.inclusion@nhs.net)

Information Category	Detailed Information
<b>Name of the strategy / policy / proposal / service function to be assessed:</b>	Medical Devices Training Policy V3.0
<b>Directorate and service area:</b>	Clinical Support
<b>Is this a new or existing Policy?</b>	Existing
<b>Name of individual completing EIA</b> (Should be completed by an individual with a good understanding of the Service/Policy):	Elizabeth Anderson Medical Device Training Officer and Clinical Lead for the Medical Equipment Library
<b>Contact details:</b>	01872 252275

Information Category	Detailed Information
<b>Policy Aim - Who is the Policy aimed at?</b>  (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To help staff identify the requirements of medical device training within the remit of their role.
<b>Policy Objectives</b>	To ensure staff use medical devices competently and confidently and staff are working within the guidelines of the NHSLA and Care Quality Commission.
<b>Policy Intended Outcomes</b>	Ensure all clinical staff are adequately trained in Medical Devices, improve patient safety and patient experience.
<b>How will you measure each outcome?</b>	ESR Compliance Monitoring Tool.
<b>Who is intended to benefit from the policy?</b>	All clinical staff and patients within the care of RCHT.

Information Category	Detailed Information
<b>6a. Who did you consult with?</b> (Please select Yes or No for each category)	<ul style="list-style-type: none"> <li>• Workforce: Yes</li> <li>• Patients/ visitors: No</li> <li>• Local groups/ system partners: No</li> <li>• External organisations: No</li> <li>• Other: No</li> </ul>
<b>6b. Please list the individuals/groups who have been consulted about this policy.</b>	<b>Please record specific names of individuals/ groups:</b> The Learning Committee. Care Group Governance.
<b>6c. What was the outcome of the consultation?</b>	Agreed
<b>6d. Have you used any of the following to assist your assessment?</b>	<b>National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:</b> No

**7. The Impact**

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
<b>Age</b>	No	All Clinical Staff
<b>Sex</b> (male or female)	No	All Clinical Staff
<b>Gender reassignment</b> (Transgender, non-binary, gender fluid etc.)	No	All Clinical Staff
<b>Race</b>	No	All Clinical Staff
<b>Disability</b> (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	All Clinical Staff
<b>Religion or belief</b>	No	All Clinical Staff
<b>Marriage and civil partnership</b>	No	All Clinical Staff

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	All Clinical Staff
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	All Clinical Staff

**A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.**

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Elizabeth Anderson  
Medical Device Training Officer and Clinical Lead for the Medical Equipment Library

**If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:**  
[Section 2. Full Equality Analysis](#)

## Appendix 3. A Guide to Medical Device Forms

Ward forms		Responsible staff	Location	Update
<b>MD01</b>	Local inventory list of medical devices in ward/department	Ward/departmental manager	Ward/departmental folder	On receipt/disposal of equipment
<b>MD06</b>	Medical Devices Assessment Form Equipment list for Registered and Non-Registered staff  General Ward Equipment	Ward/departmental manager to ensure completed on local Induction and yearly update at PDR	Departmental folder  Copy sent to Medical Device Training Officer	Staff are out of compliance with their medical device training
<b>MD07</b>	Attendance sheet for training sessions	Trainer	Return completed form to: <a href="mailto:tracy.surtees@nhs.net">tracy.surtees@nhs.net</a> <a href="mailto:landdadmin@nhs.net">landdadmin@nhs.net</a>	When training courses are completed
<b>MD11</b>	Record sheet to be used when Issuing Medical Devices to End-Users (patients/carers)	Staff who issue medical device	Ward/departmental folder  If item belongs to Equipment Library, copy to be sent to them for information	On issue of device, and on its return.  (Escalation process to be followed if item not returned)

All forms are located on the Medical Physics, Clinical Page, RCHT intranet site

## Appendix 4. Medical Device Risk Level

Category	Definition	Level of risk of harm to patient due to user error	Training Requirements
<b>Low risk</b>	Devices whose failure or misuse is unlikely to result in serious consequences.	None too low. <b>None</b> – little or no adverse effect on patient <b>Low</b> – discomfort, delay and inconvenience to patient	<b>Training is, ‘in-house’ or linked to professional qualifications.</b>  No formal records are required, but the user must be able to demonstrate knowledge of the specific model, equipment use, application and associated potential risks.
<b>Medium risk</b>	Devices whose failure or incorrect use would have a significant impact upon patient care or temporary adverse health consequences but would be unlikely to cause direct serious injury.	<b>Moderate</b> – semi-permanent harm to patient or increased length of stay	<b>Training records must be maintained</b>  Unless fully competent, the user must seek advice from staff competent with the device prior to using the medical device. This should be followed by formal training provided by a Key Trainer.
<b>High risk</b>	Devices that have the potential to cause serious adverse consequences or death should they fail or be misused. Devices recently associated with serious injury	<b>Severe</b> – Serious harm leading to disability or death	<b>Training and competency records must be maintained.</b>  The user must undertake competency-based training and a Clinical Competency Assessment prior to using the device.

## Appendix 5. Levels of Training

### Level 1: Basic (Awareness) Training

**WHO:** All medical equipment used by medical, nursing and professions allied to nursing.

**WHY:** This level of training is intended to provide an overview of the device including basic principles, understanding and awareness of the equipment. This level of training may be given to support staff who would not be expected to operate the equipment clinically but will need an appreciation of it for safety, to set it up for others, to clean the item or to perform routine maintenance checks.

**HOW:** Training may be provided by self-assessment, Key Trainers or manufacturer's representatives.

### Level 2: Full Training

**WHO:** All medical equipment used by medical, nursing and professions allied to nursing.

**WHY:** This level of training is intended to provide comprehensive and detailed instruction in the use of the equipment, covering all aspects of the equipment including pre use testing, setting up, operation, user problems and decontamination. This will allow the staff

to operate the equipment correctly and safely for a clinical procedure.

**HOW:** Training may be provided by self-assessment, Key Trainers or manufacturer's representatives.

### Specialist Training (Key Trainers)

**WHO:** This level of training is intended for those members of staff who use specialist equipment to a higher level than general clinical use or have been designated as Key Trainers for the equipment. Staff who have successfully completed this training can cascade train others.

**WHY:** This level of training identifies equipment requiring specific training and provides the

key trainer with information on how to train others.

**HOW:** Key trainers must have been trained by the manufacturer's representative and be Competency Assessed to teach.

Key trainers will be expected to complete the training signature form (MD07) when conducting in house training sessions and forward this to the Medical Devices Training Officer.

## Appendix 6. Person Specification to be a Key Trainer and Clinical Assessor

		Essential		Desirable
Qualifications	Q1	Appropriate Healthcare professional qualification for the device in question or equivalent level of knowledge, skills and experience	Q2	Teaching/Assessing related qualification at NVQ3 or above
Experience	E1	Ability to demonstrate sound clinical expertise and knowledge of clinical issues relating to device usage and/or	E4	Have attended a key trainer session.
	E2	Demonstrate in depth knowledge of the device.		
	E3	Proven experience of teaching and mentoring staff.		

### Skills/Abilities/Knowledge

SA1	Operating device at Competency Level 4
SA2	Ability to troubleshoot problems with the device
SA3	Awareness of professional responsibilities to self and others.
SA4	Ability to demonstrate a safe and supportive working environment for staff
SA5	Able to articulate all training aspects relating to the safe use of the device to team members including those less confident in the use of the technology
SA6	Able to judge the understanding of students and assess competency when required.
SA7	Able to identify staff requiring further support and training
SA8	Able to review and develop clinical competencies/learning packages for specialist equipment

## Attributes

<b>A1</b>	<b>Approachable</b>
<b>A2</b>	<b>Enthusiastic</b>
<b>A3</b>	<b>Manual Dexterity</b>
<b>A4</b>	<b>Demonstrate an aptitude for technology</b>