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Target audience:	Clinicians, Patients/Carers, Maintenance Staff, Loan Store Staff

1 Summary

This policy is written to provide information around the required systems to reduce the risks associated with the use of medical devices.

2 Who this document is relevant to:

Clinicians, Patients, Carers or Relatives, Maintenance staff, Loan store staff

3 Related Trust Policies

- Manual Handling Policy
- Generic Waste Management Policy
- The Health and Safety Policy
- Policy for the Prevention and Management of Latex Allergy
- Reporting of Incidents, Accidents and Near Misses Procedure
- Using Bedrails Safely and Effectively – adult inpatients
- Decontamination
- Single Use Policy

4 Related legislation and national guidance

Manual Handling Operations Regulations 1992 (MHOR 1992)
 DB 2003(05) 'Management of Medical Devices Prior to Repair, Service or Investigation'
 MDA DB2006 (05) Managing Medical Devices
 MDA/2009/001 Medical Device Alert
 Reporting Adverse Incidents and Disseminating Medical Device Alerts DB2007(01)January 2007 MHRA
 Consumer Protection Act 1987 (Consumer Safety and Product Liability).
 Control of Substances Hazardous to Health Regulations 2002

Health and Safety at Work etc. Act (HASAWA) 1974.
Lifting Operations and Lifting Equipment Regulations 1998.
Medical Devices Regulations 2002 (Amended 2003)

Clinical Equipment Maintenance Service (2003) *Clinical Equipment Users Guide OF02*. Royal Cornwall Hospitals Trust: Medical Physics Department.

Cranage, R. (2002) *Royal Cornwall Hospital Radiation Safety Policy*. Royal Cornwall Hospitals Trust:

Department of Health (1999) *Controls Assurance in Infection Control: Decontamination of Medical Devices HSC 1999/179*. London: Department of Health.

Health and Safety Executive (1989) *Electricity at Work Regulations*. London: HMSO.

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Medical Devices Agency (2001) *Guidance on the Sale, Transfer of Ownership and Disposal of Used Medical Devices MDA DB9801: Supplement 2*. London: Medical Devices Agency.

Medical Devices Agency (2002) *Management of loaned medical devices, equipment and accessories from manufacturers and other suppliers MDA SN2002(17)*. London: Medical Devices Agency.

Medical Devices Agency (2003) *Adverse Incident Reports 2002 MDA DB2003 (01)*. London: Medical Devices Agency.

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NHS Executive (2001) *Medical Devices Management Controls Assurance Standard*. London: NHS Executive.

NHS Litigation Authority (2002) *Clinical Risk Management Standards*. Bristol: Willis Limited.

NHS Litigation Authority (2002) *Risk Pooling Schemes for Trusts*. Bristol: Willis Limited.

5 Training Requirements

- 5.1 Each team will hold a asset register which identifies current diagnostic and therapeutic equipment. This outlines for each piece of equipment the frequency of training and whether the training is accredited or competency based.
- 5.2 Staff that require training will be identified through the clinical management structure. Individuals must have received training assessment of competency.
- 5.3 The education material will be agreed through the training department. Individual pieces of equipment training material must be based on the manufacturer's instructions. The protocol must be followed, where manufacturers update their information, this information must be adapted within the training material.

- 5.4 Decontamination training will agreed through the Infection Prevention and Control committee.
- 5.5 All training must be recorded, a copy kept at the team base of the list of staff who are verified to use that piece of equipment, and a copy forwarded to the workforce and learning department.
- 5.6 Manual handling equipment see manual handling policy

6 Equality Impact Assessment

The Equality Impact Assessment Form was completed on the 10th Sept 2010.

7 This document replaces:

Management of Medical Devices HS/IC/003/09

8 Process for monitoring compliance and effectiveness

There will be an annual internal audit to review the systems in place and inform the programme and priority of work.

The audit will be undertaken through the Medical Device Implementation Group, (MDIG) using the Medical Device Audit Tool found in Appendix 2. The results will be reported to the MDIG, Patient Safety Group and the Health and Safety Committee.

THE SAFE MANAGEMENT OF MEDICAL DEVICES POLICY

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Medical Device Management Policy

1.0 Introduction - Medical devices are increasingly used by health care professionals to support the care and treatment of patients. The Trust is committed to ensuring that medical devices are used safely and the risks associated with the acquisition and uses of medical devices are minimised.

The safe use of any medical device is dependent on its correct operation, appropriate decontamination and maintenance. Equally the systematic training in the use of diagnostic and therapeutic equipment is of key importance in delivering a safe service.

2.0 Aims - This Policy establishes the organisational framework and responsibilities to provide assurance that:

- The risks associated with the acquisition and use of medical devices, both for patients and health care professionals are minimised.
- The Trust complies with the Medical Devices Management Controls Assurance Standard.
- The Trust complies with DB 2007(01) Medical Devices – Reporting Adverse Incidents and Disseminating Medical Device Alerts, and MDA/2009/001 in particular that all staff are aware of their obligations and actions required to report Adverse Incidents and implement any proceeding action.
- Systems are in place to train appropriate health care professionals in the safe acquisition, use and management of medical devices.
- Systems are in place to allow appropriate health care professionals to understand their role in the safe use, purchase and management of medical devices.
- Systems are in place to ensure equipment is cleaned when required and in particular before any maintenance or servicing is performed.
- Systems are in place to ensure regular maintenance or servicing of medical devices takes place.
- Systems are in place to ensure that medical devices manufactured in-house are manufactured according to best practice as defined by The Medical Devices Regulations 2002 (UK Statutory Instrument 2002 No. 618)
- Systems are in place to ensure that medical devices are sold, transferred or disposed of in accordance with DB2006(05), in a way which minimises both the personal risk to patients and staff and the legal liability risk to the Trust.

3.0 Definition of a 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 i.e. pulse oximeter, blood glucose measuring device, dressings, Examination gloves, nebulisers, suction equipment, syringes and needles, thermometers
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, wheelchairs, walking standing frames, patient hoists, crutches, commodes, communication aids.

- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

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.

4.0 ROLES AND RESPONSIBILITIES

4.1 Chief Executive is ultimately responsible for ensuring that;

- 4.1.1 Health & Safety Regulations and approved guidance is complied with, including the implementation of all measures necessary to ensure the safe use of medical devices.
- 4.1.2 A Lead Executive Director for the Management of Medical Devices is nominated.

4.2 Executive Director/Executive Nurse is responsible for

- 4.2.1 Monitoring and reviewing annually the service level agreement between Cornwall Partnership NHS Foundation Trust (CFT) and the Royal Cornwall Hospital Trust (RCHT) Medical Physics department or any other contractor involved in the procurement, maintenance and repair of any medical device as defined in the Medical Devices Regulations 2002 (SI 2002 No. 618)
- 4.2.2 Ensuring a robust system is in place to co-ordinate the effective prescribing, procuring, checking, using, testing, maintaining, borrowing and loaning, decontaminating and disposing of medical devices and equipment within the Trust.
- 4.2.3 Systematic risk assessments relating to medical devices are carried out and completed and that action plans are produced to minimise any risk.
- 4.2.4 All shortfalls are rectified and reported to the appropriate agencies such as Medicines and Healthcare products Regulatory Agency (MHRA), National Patient Safety Agency (NPSA)
- 4.2.5 Training is provided for staff and that No staff should operate any medical device until they are fully proficient in its use. This includes new, locum and agency staff.
- 4.2.6 There is an effective maintenance system in place for all medical equipment.
- 4.2.7 Appropriate manpower and financial resources are allocated to implement this policy.

4.3 Associate Directors

- 4.3.1 The individual Associate Directors for each service are responsible for ensuring compliance with this policy within their directorates.

4.4 Central Alerting System (CAS) The Trust nominated team for CAS is the Risk Management department.

The Trust receives safety alerts via email via the DH Central Alerting System (CAS). Safety alerts are distributed electronically within the trust by the CAS nominated person. (See Central Alerting Process System)

The nominated CAS Liaison Officer is responsible for ensuring:

4.4.1 Reporting to the MHRA within 24 hours indicating adverse reactions, defective products or user errors.

4.4.2 The Process for distribution of Safety, Hazard and Product Notices.

4.5 Medical Device Alerts/Department of Health Estates and Facilities Alerts

Medical Device Alerts are issued by the MHRA formerly the Medical Devices Agency (MDA) and the Department of Health Estates and Facilities Alerts

Device alerts are received by the Trust via the Central Alerting System where the CAS Liaison Officer disseminates them accordingly. People receiving e-mail alerts should take the necessary action as specified in appendix 4 to this section.

A full audit trail will be available for all alerts.

4.6 Team managers / Professional Leads as designated by the Network Leads

Team Managers/ professional leads are responsible for ensuring that;

4.6.1 They hold, update, and manage the medical equipment inventory/asset register, equipment history database and hard-copies of manufacturer's medical equipment user-instructions.

4.6.2 Procedures / operating instructions are implemented, including making sure they are brought to the attention of all users, are readily available and kept up-to-date.

4.6.3 All medical devices are purchased and the subsequent the service, inspection and maintenance programmes as advised within this policy.

4.6.4 Ensuring that a Medical Device Risk Assessment is undertaken in accordance with Provision and Use of Work Equipment Regulations 1998 and that any staff affected is made aware of:

- The risks to their health and safety
- The precautions to be taken
- How to use control measures and how to proceed with decontamination process.

4.6.5 Audits are undertaken to evaluate compliance with this policy.

4.7.6 All medical devices are fit-for purpose, i.e. adequately maintained, serviced, and decontaminated, compatible with the patient;

4.6.7 Medical devices loaned to patients are returned when not required.

- 4.6.8 Suitable and sufficient training is available for staff, patients and carers as necessary in the safe use of medical devices. A copy of the attendance is maintained of staff who are verified as competent to use the device.
- 4.6.9 All their staff know of and understand the importance of reporting equipment failures;
- 4.6.10 Appropriate action is taken and completed when a CAS alert is received into their department. Ensure timely feedback of appropriateness and actions taken within the specified deadline to the Risk Management Coordinator. Documentation regarding action taken must be kept available for audit purposes. **NOTE where information is received from companies/field safety notices directly, the information must be forwarded immediately to the risk department for appropriate action. See procedure**
- 4.6.11 Devices that cannot be easily cleaned are identified and reported to the Risk Management Coordinator or the Infection Control Team, for discussion at the medical device implementation group for inclusion in future replacement programme
- 4.6.12 Areas where decontamination is carried out have restricted access to authorised personnel only.
- 4.6.13 Washing, disinfection and sterilisation is carried out in compliance with the Cleaning Manual and decontamination policy and the adequacy of the cleaning programme is monitored and a record kept of this.

4.7 Staff - All staff are responsible for ensuring that:

- 4.7.1 Medical equipment is safe, properly maintained and prescribed, and used correctly in accordance with the manufacturer's instructions.
- 4.7.2 Basic visual safety checks are carried out prior to using any medical device including check of expiry date and intact packaging for single use devices and items appear in working order prior to use.
- 4.7.3 They have received adequate training and that they understand the limitations of medical devices they use and how they are to be used safely.
- 4.7.4 Any concerns they have regarding medical devices are brought to the attention of their manager including concerns about the devices risk when used, appropriateness of stock level, and potentially faulty or missing items
- 4.7.5 All staff are responsible for the reporting of adverse (and near miss) incidents involving any medical device or medicinal product in line with the trusts incident accident, near miss reporting policy.
- 4.7.6 Patient details are removed following use.

4.8 Medical Physics Department. -Cornwall Partnership NHS Foundation Trust has a Service Level Agreement (SLA) with the Medical Physics Department, Royal Cornwall Hospital Trust for the maintenance of the Trust Medical Devices

4.8.1 All contractors should;

- Assess if electrical or mechanical failure of a medical device meets the criteria for MDA reporting and report accordingly.
- Inform the Risk Management Department of any relevant specialist reports received.
- Ensure any action taken relating to a MHRA Safety Notice in connection with an electrical or mechanical equipment failure is registered in the relevant record or statutory register, notifying the appropriate Head of Service and Head of Risk Management without delay (CHS).

5.0 Equipment life cycle

The device management procedure has been devised to reduce the risks associated with medical devices

5.1 Procurement

All procurement should take place via the Supplies Department. This will ensure that only devices and equipment that are on the Recommended Equipment List are purchased.

Equipment must not be donated directly to the Trust but the money involved should be used to purchase equipment through Supplies.

Purchases from Charitable Funds must also be made via the Supplies Department. This will ensure that safety; training and product liability issues are properly addressed.

The selection process should consider:

- The agreed acquisition requirement
- Fitness for intended purpose/application
 - Safety and performance information from the manufacturer (including detailed specifications of the medical device) compared against the performance specifications contained within the acquisition requirement
 - Rationalising the range of models versus diversity
 - Availability of manufacturers' instructions
 - Maintenance support services, where applicable
 - Availability of training
 - Availability of technical support and/or where applicable training for local service support
 - Decontamination and disposal procedures, including compatibility with the local decontamination processes already in use e.g. can it withstand the parameters used
 - Installation requirements and commissioning procedure
 - Support services
 - Reliability and previous performance
 - Lifetime costs
 - Warranty details
 - Other support facilities.

5.1.1 Fitness for intended purpose/application

Risk Assessment

Each ward will hold the completed risk assessments, which should be reviewed annually.

The device chosen must meet the responsible organisation's performance specification, but unnecessary features may be a disadvantage.

Points to consider are:

- Whether the device is compatible with other devices and any medicinal products that it is likely to be used with
- Whether the manufacturer intends the device to be used by those who will be using it?
- Whether the device is appropriate for the intended environment.

5.1.2 Safety and performance

- Is the device CE-marked?
- Is there any local knowledge or past history of problems with the device or type of device?
- Do MHRA safety publications, manufacturer's advisory notices or other relevant publications identify issues related to the device?

Having a variety of models for the same purpose can increase the risk of operator confusion; on the other hand, reliance on a single model can be problematic. Discuss with Medical Physics and Supplies.

5.1.3 Second hand medical devices

Purchasing - Usage and service history must always be available for prospective purchasers before sale and then supplied with the equipment at the point of sale.

As a minimum there must be a:

- Record of any reconditioning work carried out, including a record of replacement parts
- Copy of all maintenance and servicing that has been carried out including the name of maintenance/servicing organisation
- Record of usage
- Fault log
- Decontamination status.

If selling, the person disposing of the equipment needs to ensure that they have authority from the budget holder, and also that the sale/disposal is recorded on the asset register, and that the sale is via Supplies to ensure that the necessary indemnity is obtained from the purchaser at the time of sale.

5.1.4 In house manufacture

When devices are manufactured there are safety implications. This includes implications for its classification as a new device, in accordance with the Medical Device regulations.

Healthcare establishments and other related organisations should therefore review their medical device production and research activities and decide whether or not they are covered by the

Regulations. If any doubt exists, their own legal advice should be sought. If, however, any activity is identified which is subject to the provisions of the Regulations, all relevant obligations must be identified and complied with.

Even if the body decides that the activities in question are not subject to the Regulations on medical devices, it needs to be aware of its responsibilities under the general law (including consumer protection legislation) and to ensure the safety of patients, users and any relevant third party.

- Off-label use of medical devices.
- User modifications of devices other than directed by the device manufacturer.
- Use of products, other than those that are CE-marked as medical devices, for clinical purposes.

The Medical Devices Regulations (that implement the relative Directive) stipulate that the manufacturer of a device is responsible for establishing that the device is safe and that it is suitable for its intended purpose. To establish this, manufacturers implement appropriate controls on the device design and manufacture, and evaluate the safety and performance of the device in its intended application. This involves an analysis of risks that could arise during use, an assessment of relevant pre-clinical and clinical data, the preparation of appropriate instructions for use and, if necessary, specific training schemes. From such activities, manufacturers are able to verify that risks have been eliminated or minimised and are judged acceptable when weighed against the anticipated benefits to patients.

Therefore devices that are:

- used off-label (e.g. foley catheters as enteral feeding tubes)
- modified by the user (e.g. loading of an anaesthetic workstation beyond its specified capacity leading to the device overbalancing, or, reconfiguration of a Bain's breathing system, resulting in the wrong size oxygen connector being used and thus ventilation hindered)
- not intended for medical use (e.g. pillows or blankets used to position patients during MRI, leading to patient burns, or non-medical LED torches used for patient neurological observations, when the packaging warns against shining the torch into a person's eyes)

will not have undergone this level of scrutiny. The consequent lack of verification of device performance means that it cannot be assured to be safe, suitable or effective. The use of a device in these circumstances exposes users and patients to unknown and therefore unacceptable risks and may have legal and ethical implications.

Examples of potential dangers include:

- adverse reactions
- inadequate sterilisation
- insufficient mechanical strength and/or structural integrity
- insufficient durability
- misuse due to lack of adequate training for device.

As well as the risks to the patient and user, liability for the performance and safety of products that have been modified, adapted or used off-label, could be transferred to the user. Healthcare professionals should also be aware that following modification of a CE-marked medical device, the healthcare organisation and/or professional could be deemed to be the manufacturer of a new device and may therefore be subject to the requirements of the Medical Devices Regulations.

The consequences of using even simple medical devices outside their intended purpose can be serious. For example: use of tongue depressors (Class I medical devices) in a neonatal ITU as limb splints led to two deaths and one amputation because of fungal infection. The MHRA has also issued advice on the risk of entrapment and asphyxiation of people in beds used with incompatible side rails.

Action

- Ensure that you are familiar with the instructions for use including the intended purposes for all the devices you use.
- Only use devices for their intended purpose; do not modify or alter the function or structure of medical devices unless specifically sanctioned by the instructions for use.
- Do not use modified medical devices or non-medical products for clinical purposes unless there is no suitable CE-marked alternative.

5.2 Medical Devices not owned by CHS

In circumstances where CFT staff use medical devices that belong to other areas i.e. GP surgeries, residential homes and for the children's short break services when the children bring in the equipment allocated to them.

- The maintenance and servicing schedule remain with owner of the equipment. The member of staff should report any concerns regarding that piece of equipment to the owner.
- *The member of staff must also receive training to use the piece of equipment and a record of this training held within the department.*
- *Written instructions must be provided, as well as contact numbers of where help and advice can be sought, particularly in an emergency.*

5.3 Equipment on Trial/ Loan

5.3.1 Users must contact Supplies to arrange for the Supplier to obtain indemnity before any equipment or Medical Device is placed on trial in the Trust. Staff must be properly trained to use equipment on trial. Decontamination arrangements must be in place before such equipment is used. It should also be clear at the onset whose responsibility it will be should any problems arise.

5.3.2 All equipment on loan from manufacturers must be subject to a written agreement which defines the device management requirements and responsibilities and liabilities.

5.4 Maintenance, repair

The decision as to who is to maintain equipment and bear the cost of maintenance must be made before purchase. Funds must be allocated to pay for maintenance before equipment is purchased. No contract must be entered into without the approval of the supplies department.

Points to consider:

- Can the service provider maintain the device?
- How will the proposed contract or service level agreement deal with continuity of care? E.g. on site repair if needed
- Is alternative equipment available to cover periods when a device is being repaired or serviced?

- Are response times appropriate and guaranteed?
- What are the proposed intervals between service, frequency and complexity of checks and calibrations needed during operation?
- Are spares readily available and for how long?
- Is service support guaranteed, and for how long?
- What information is available e.g. circuit diagrams, preventive maintenance schedules, trouble shooting, repair procedures, parts list, special tools list?

Key points on maintenance and repair

- All medical devices and items of medical equipment are properly maintained and repaired.
- Where possible maintenance and repair providers are externally accredited for their quality management system.
- Audit and user feedback systems are in place to frequently review the processes, policies and contracts.
- All staff involved in maintenance and/or repair are appropriately trained and qualified.
- Spare parts are of the correct specification and their quality and compatibility match those supplied by the original equipment manufacturer.
- Manufacturer's maintenance instructions and timescales are adhered to.
- All medical devices returned for servicing and repairs are properly decontaminated.
- Organisations carrying out repairs and maintenance are fully insured.

5.5 Storage of medical devices

Medical Devices must be stored in accordance with manufacturer's instructions, so that deterioration is kept to a minimum, any battery re-charging or other ongoing service requirements are maintained. (Heat is often generated when devices are left on charge and adequate ventilation must be maintained). For guidance refer to DB2006 (05)

Particular care must be taken to avoid conditions where temperature and humidity may be high or where there is a danger from fluid spillage. Single use devices, such as dressings or catheters may have an expiry date and this must be borne in mind when ordering stocks. Stock rotation must be carried out to ensure devices are used before their expiry date. Check the condition of the packaging of sterile products before use.

5.6 Acceptance Procedures for new equipment

The person receiving the newly delivered device onto the ward/department must ensure that it has been formally 'accepted' by the appropriate organisation. For most Medical Devices this will be the Clinical Equipment Maintenance Service (CEMS) within the Medical Physics Department, or Cornwall Healthcare Estates and Support Services (CHESS). Under no circumstances should a Medical Device be used on a ward or department without first going through a formal acceptance. **This applies to purchased, hire and loan/trial devices.**

The users must check that;

- The device has a valid safety label affixed to it, this being a requirement under the Health and Safety Electricity at Work Regulations 1989. Safety testing within the Trust is carried out on an annual basis.

- All equipment to be acceptance checked to MDA DB2006(05) recommendations.
- All non -consumable equipment to be put on the asset register at this stage, together with future maintenance and decontamination requirements.

Simple checks need to be undertaken on consumable items as per MDA recommendations **Basic guidance on delivery checks**

	Delivery check	Skills required
Paperwork/ database	<ul style="list-style-type: none"> • Is the device compatible with specification set out in the purchase order? • Have the user, repair and maintenance information, compliance and calibration certificates, test results been included, where relevant? • Add device details and serial number on to device management records • Does the device (or any component part or accessory) need decontaminating before first use? • are the instructions for use appropriate? 	Familiarity with: <ul style="list-style-type: none"> • Ordering system • Inventory system • Names and appearances of common medical devices • Medical device documentation (instructions for use, Certificates etc.) • Serial numbers and model identification Codes.
Visual inspection	<ul style="list-style-type: none"> • Is the outer packaging intact and undamaged? • Is there any damage apparent to the device on inspection? • Are there case markings, CE marking, notified body number, electrical class, quantity in pack, storage information for Unopened pack etc.? 	<ul style="list-style-type: none"> • Knowledge of areas to check for damage. • Familiarity with: <ul style="list-style-type: none"> > the appearance of product in good condition > Common defects.

Additionally, the manufacturer's instructions may specify particular testing, calibration or adjustment before a medical device is used for the first time. It may also be desirable to generate baseline data for comparisons during subsequent maintenance

	Safety and calibration checks	Skills required
Functional check Note: this may require more extensive checks by specialist staff for complex or specialist equipment.	<ul style="list-style-type: none"> • Does the device function in line with the manufacturer's information? • Are accessories/parts included and compatible? • Do indicators and displays function correctly in line with the manufacturer's information when powered up?* • When powered up, does the device start when it should and do the dials and switches do what they say?* 	For some devices the skills required will be little more than basic training to allow the manufacturer's information to be followed. In cases where the manufacturer's instructions specify specialist assembly or manipulation, familiarity with the functions of the device and its components and accessories will be required.
Electric (basic safety)	Are the mains leads, plugs and other connectors undamaged?	Training in visual electrical safety inspection techniques.
Calibration and measurement	Where appropriate, use test device to check: <ul style="list-style-type: none"> • Accuracy of physiological measurements. • Dose delivery.* • Energy delivery.* • Accuracy of other outputs.* 	Tests should be carried out by an adequately trained and appropriately qualified person.

* only for active devices

5.7 Asset Register

In accordance with MDA DB2006 (05) each ward/department will keep a register of all their Medical Devices. This list should include an identification code, manufacturer, model and serial number and brief description.

Good record keeping is essential for the safe management of medical devices. The detail and complexity of the records will depend on the type of device and its usage during its lifetime. It must also include any specific guidance provided in the manufacturer's instructions and supporting information. The records should be maintained within one system wherever possible. For non-centralised records ensure that there are suitable cross references between the various record systems.

Records must provide evidence of:

- A unique identifier for the device, where appropriate
- A full history, including date of purchase and where appropriate when it was put into use, deployed or installed
- Any specific legal requirements and whether these have been met
- Proper installation
- Where it was deployed

- scheduled maintenance
- Maintenance and repairs
- The end-of-life date.

Your records must also show that users:

- know how to use the device safely
- can carry out routine checks and maintenance
- have been trained and had relevant refresher training.

Note: All of the aspects of medical device management covered within this guidance document will require some degree of record keeping.

Systems for managing medical devices need to take account of the different ways that the devices can be deployed, for example:

- allocated to the particular department where they are used, which is given the responsibility for managing them: examples include fixed installations, such as large X-ray machines and smaller critical care devices in some intensive therapy units
- allocated to equipment stores, pools or libraries, from which they are issued to particular users as required: examples include walking aids and commodes issued by community stores and infusion pumps and ventilators in many hospital trusts
- issued on long-term loan to an individual user for their use only

5.8 Medical Device Movements Register

When any medical device, leaves the ward/department. Whether for repair / calibration or on loan its movements should be recorded. The device should be in a decontaminated state and a label attached detailing the decontamination process.

This register should record details of the device when it moved and to where. For devices loaned to other departments it might be useful to note details of the member of staff loaning the equipment. It is the responsibility of the person taking the device on loan to ensure they are adequately trained to use it and have the necessary user/instruction manuals to refer to. The date of the device's return to the ward/department should also be recorded. For guidance refer to MDA SN2002 (17). For permanent removal the ward manager should ensure that the medical physics department is informed to enable the asset to be relocated to new department.

5.9 Care of equipment by Users.

Users must follow the manufacturer's guidelines on the care and user maintenance of equipment and devices. Faults are to be reported as per the Guidelines issued by maintenance departments. Equipment must be decontaminated prior to being sent for repair.

5.10 User/Operator Instruction Manuals

Documentation and users information on Medical Devices now comes in a variety of formats from the traditional written manual to videos and CD-ROMs

On receipt of the manual, the nominated person on the ward responsible for Medical Devices will check it's adequacy for the purpose. It is important to check, for example that the manual refers to the particular model and software revision for the device in question. It must be written in plain English

with clear diagrams and be readily understandable. Any concerns with the documentation must be taken up with the manufacturer without delay.

One copy of each manual will be kept in a central location on the ward/department as a reference. Each copy should be labelled as '**FOR REFERENCE ONLY**' and must not be removed from the known location. All members of staff must be made aware of this location as part of their local induction.

When the manufacturer updates information the new information must be sent to the training department.

5.11 Manufacturers instructions

All Trust staff users must have access to manufacturer's instructions concerning the use of any of the medical devices. (Regular updates on symbols used by manufacturers on the instructions are available from the Medicines and Healthcare product Regulatory Agency web site www.mhra.gov.uk) These must include:

- Information to use the device safely.
- The nature and frequency of use.
- The nature and frequency of maintenance and/or calibration.
- Storage and handling conditions.
- Differences between models of a given device, where these may affect safety or device function.
- Disassembly for and assembly after cleaning and the fitting of relevant accessories.
- The correct sequencing and setting of controls.
- Linking the device to patients effectively causing minimum discomfort.
- Recognising malfunctions.
- Correcting malfunctions or when to stop using the device.
- The process for removing the device from use and who to contact for advice and/or repair/decontamination.
- Be able to show the patient/client how to use the device
- Reporting of adverse incidents involving medical devices.

Staff must sign that they have read and are able to comply with the instructions for the use of the device or equipment and such a register must be held with the departmental head where the devices are used.

No new devices or equipment should be used by any staff member until the manufacturer's instructions have been read and signed as read, and the staff member has had an opportunity to undertake appropriate training in the use of the equipment where they and/or their line manager feel necessary.

Special precautions must be taken for medical devices that look superficially similar but have applications which differ and may need to be restricted for safety reasons. Such devices must be

clearly labelled indicating their class and use and posters/information clearly displayed at the point of use/issue showing which category is suitable for which application.

5.12 Instructions for Patient / Carers

All patients/carers have the right to see, read and have copies of manufacturers' instructions. In all cases, these should be given to the patient/carer. Failure to do this may not only compromise the end users ability to use the device safely, but also lay Cornwall Partnership NHS Foundation Trust open to legal liability under the Consumer Protection Act 1987 section 10, the General Product Safety Regulations 1994 and the Common Law of Negligence. Manufacturers' instructions must be given to the patient/carer with additional specific personal instructions in light of their needs and daily routine.

Personal written instructions concerning the appropriate personal use of the device/equipment must include specific instructions augmenting the manufacturers instructions:

- Specific personal information required to use the device safely;
- Specific personal information on the nature and frequency of use;
- Extra local instruction on the nature and frequency of maintenance and/or calibration;
- Specific storage and handling conditions related to the patients personal environment and area of use;
- Special features specifically explained;
- Extra risks of misuse singularly appropriate to the patient;
- Extra specific instructions for disassembly and assembly after cleaning and the fitting of relevant accessories;
- The correct sequencing and setting of controls specifically relevant to the patients needs;
- Where appropriate, linking the device to themselves/others effectively causing minimum discomfort;
- Specific instructions concerning recognising malfunctions;
- Specific instructions on correcting malfunctions or when to stop using the device;
- Specific local instructions for the process for removing the device from use and who to contact for advice and/or repair/decontamination.

5.13 Local Instructions

Local instructions should be produced with care, since "defensive" legal advice might suggest that this invites legal liability. Equally, however, Cornwall Partnership NHS Foundation Trust may be inviting liability if it knowingly passes on inadequate instructions supplied by the manufacturer. Any local instructions should therefore be:

- Clear
- Unambiguous
- Up to date (dated with last revision date)
- Have written and pictorial components where appropriate

- Be specific to the individual patient with their name, date of birth and reference number clearly on them
- Have a reference name and telephone number for queries about the use of the equipment
- Time limit for the loan period where appropriate
- Have a copy of the instructions given to the patient kept in the patients' notes or references against a central file or instructions issued

The placement of the instructions must be considered when giving a medical device to a patient to use. Options could include:

- Instructions printed on the device itself.
- Instructions on the immediate packaging of the device.
- An additional leaflet with the device.
- Print size should be considered for those with visual impairment.
- The end user may lack technical knowledge and as such the instructions must be comprehensible to them, avoiding technical jargon.
- Care should be taken to ensure that any instructions translated from or into a foreign language are accurate.

Patients should sign, as part of the issuing process that they have received and understood the instructions given to them

Where departments draft their own instructions, they must submit them to the manufacturers for approval.

NB. Manufacturer's instructions are often not returned by end users when the device is returned. Master copies are therefore essential and photocopies* may be given to the patient. (*May require permission of the manufacturer)

5.14 Replacement of Equipment

A stage will inevitably be reached when devices/equipment become unsafe. This will be determined if any of the following criteria apply to a medical device:

- Worn / Damaged beyond economic repair or lack of spare parts.
- Unreliable (check service history).
- Clinically or technically obsolete/acceptable.
- More cost-effective or clinically-effective devices have become available;
- Unable to be cleaned effectively prior to disinfection and/or sterilisation

5.15 Disposal of Medical Devices

Medical Devices must be disposed of in a safe and controlled manner. If a medical device requires disposal the Medical Physics department at the Royal Cornwall Hospital Trust will offer further guidance / or disable the device and dispose of it according to the Waste Management Policy.

They will in turn remove the item from their maintenance / testing schedule. And advise on the replacement product.

Disposal of single use devices shall be carried out in accordance with the Waste management policy.

Before the sale or donation of medical equipment for reuse the potential for future liability against the responsible organisation should be considered, advice should be obtained from medical physics, supplies and agreed by the service lead.

6. Reporting adverse incidents

6.1 Who should report incidents?

Anyone may submit an adverse incident report to the MHRA – clinicians, healthcare workers, carers, patients and members of the public. Reports *also* need to be copied governance / Risk Management Department.

6.2 What should be reported?

Any adverse incident involving a device or its instructions for use should be reported to the MHRA. Other minor safety or quality problems should also be reported as these can help demonstrate trends or highlight inadequate manufacturing or supply systems. Reports of adverse incidents that appear to be caused by human error are also helpful

6.3 When should an incident report be made?

All incidents should be reported to the MHRA as soon as possible. Serious cases should be reported by the fastest means possible. Initial incident reports should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information.

6.4 How to report an incident

Online reports may be submitted via the MHRA website on the internet or NHSNet at any time of any day. We strongly recommend that, where possible, online reporting is used.

Forms for reporting incidents may be downloaded from the MHRA website and then either completed electronically and e-mailed, or printed and sent by post or fax.

Telephone reports must always be followed up by a written (online, e-mail or fax) Confirmation.

In cases of urgency outside normal office hours, and where it is not possible to use the online reporting facility, an answering machine at the Adverse Incident Centre carries a message giving the contact telephone number for the duty officer in the MHRA's Communications team. The duty officer is able to contact senior MHRA staff.

Alternatively, telephone messages may be left on the answering machine for the next working day.

Full contact details (name, post held, telephone numbers etc.) should always be included on your forms and in your telephone messages.

Reporters should ensure that the Risk Management Department are made aware of all incidents reported to the MHRA.

6.5 Devices that have been involved in incidents.

Medical devices that have been involved in an incident **should** be **quarantined**. Until the MHRA has been given the opportunity to carry out an investigation, they **should not** be:

- discarded
- repaired
- returned to the manufacturer

All material evidence, i.e. devices/parts removed, replaced or withdrawn from use following an incident, instructions for use, records of use, repair and maintenance records, packaging material, or other means of batch identification **must** be:

- Clearly identified and labelled
- stored securely

Evidence should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports.

If you think an urgent examination of the device (and/or related items) is needed, contact the MHRA Adverse Incident Centre. An MHRA device specialist will decide whether to inspect the item urgently on site (or at other appropriate facilities), or may request that the device is sent to the MHRA.

The manufacturer or supplier should be informed promptly and, if accompanied by an appropriate person, may be allowed to inspect the items. To facilitate an investigation, it may be possible to provide the manufacturer with a sample of unused stock from a large batch. However, until advised to the contrary by the MHRA, the manufacturer must not be allowed to exchange, interfere with, or remove any part of the product implicated in the incident as this might prejudice our investigations, or those of other official bodies

In exceptional circumstances, where devices cannot be removed from use because there is no alternative available, and where patient health would otherwise suffer, the MHRA should be contacted for confirmation that the device may continue to be used or be repaired and put back into use. If it is not possible to withdraw or repair the device, users must be made aware of the need for increased vigilance and extra caution.

Once the MHRA has indicated that an item may be returned to the manufacturer, the manufacturer should be contacted to ensure that correct forms of documentation and carriage are arranged. In particular, a manufacturer's returns authorisation reference number may be required. The MHRA reference number should be quoted in all circumstances.

If responding to such a request, you must ensure that the device has been appropriately decontaminated, securely packaged, and clearly labelled (including the MHRA reference number).

Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled and placed in quarantine. The MHRA and the manufacturer/supplier should be contacted for advice prior to any further action being taken.

Important: It is illegal to send contaminated items through the post

APPENDIX 1 DIAGNOSTIC AND THERAPEUTIC EQUIPMENT COMPETENCY CHECKLIST

DIAGNOSTIC AND THERAPEUTIC EQUIPMENT COMPETENCY CHECKLIST				
Print Name:	Job Title:		Base:	Date:
YES NO N/A			NOTE	
‘Medical Devices’ identified	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Do you know who can use the equipment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Knowledge of the purpose of ‘Medical Devices’	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Single Use symbol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<u>CRITICARE/DYNAMAP/BP MACHINE</u>				
Accurate demonstration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Accurate knowledge of storage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Accurate Knowledge of cleaning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Accurate knowledge of baseline obs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
What to do with results	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<u>GENIUS FIRST TEMP THERMOMETER II</u>				
Accurate demonstration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Accurate knowledge of storage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Accurate knowledge of cleaning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Accurate knowledge of baseline obs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
What to do with the results	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

	<u>OXYGEN, PIPED/PORTABLE/BOTTLED</u>			
Accurate demonstration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Accurate knowledge of storage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Accurate knowledge of cleaning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Decontamination	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sterile environment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Maintenance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

	YES	NO	N/A	<u>NOTES</u>

DECLARATION		Signed By:-
I AGREE THAT I HAVE UNDERSTOOD THE TRAINING AND ARE COMPETENT TO USE MEDICAL DEVICES.		Trainer
I HAVE READ AND UNDERSTOOD THE INSTRUCTIONS FOR EACH DEVICE		Print Name
I HAVE COMPLETED THE EARNING "PHYSICAL HEALTHCARE MONITORING TRAINING AND HAVE A CERTIFICATE OF COMPETENCE		Trainee
		Print Name

Appendix 2 Medical Device Audit Tool

Standard: The Safe Management of Medical Devices

Date.....

Ward.....

Auditor.....

	Yes	No	N/A	Comments
All equipment has been purchased through the supplies department.				
Equipment is available in sufficient quantities to meet the needs of people who use the service				
There is programme of renewal is generated by the risk assessment process and the fitness for intended purpose				
The is evidence that the acceptance procedure for new equipment is followed.				
There is an up to date asset register, which complies with the records at medical physics.				
The risk assessment for each piece of equipment has been completed, within the required timeframe.				
The equipment is permanently installed where appropriate, in accordance with manufacturer's requirements and published guidance				
There is evidence that each piece of equipment is routinely maintained, tested in line with the manufacturer's instructions and by people who are competent to do so.				
There is no evidence that items are reused if they are manufactured as single use only				
Staff are aware of the single use policy and symbols.				
All equipment on loan has indemnity obtained by the supplies department.				
Each piece of equipment is supplied with the necessary technical information/instructions so that the risk of using them incorrectly is minimised				
Equipment is only modified in line with manufacturer's instructions, guidance and agreement.				
All equipment is stored in accordance with the manufactures instructions.				
There is a matrix for the provision of systematic training and management of Diagnostic and therapeutic equipment				
There are training records within the department that state which staff are competent to use the equipment				
Staff are aware of the procedure to follow if they are concerned that a piece of equipment is not working correctly				
Staff are aware of the arrangements for adverse events, incident, errors and near miss reporting. These should encourage local and, where applicable,				

	national reporting, learning and prompting an open and fair culture of safety				
	Staff are aware of the what will happen in the event of electricity, water or gas supply failure, or other emergencies, that affect the equipment used to meet the needs of people who use services				
	There is a system in place to receive and act alerts in regard to medical equipment.				
	Equipment required for resuscitation or other medical emergencies is available and accessible for use as quickly as possible, Where the service requires it, this equipment is tamper proof				
	There is evidence that staff actively listening to their preferences and thoughts about the equipment they need and how it is used				
	Staff support the person to understand how and why the equipment is being used				
	Staff take care in the way they use the equipment to make sure the person is comfortable and safe				
	Staff Use the equipment in a way that ensures the person's privacy and dignity				
	There is evidence of identification, assessment and review of risk. In relation to individual requirements.				
	Where risks are identified, a plan for how these are to be managed				
	Staff know what to do when a person who uses services refuses to allow use of the equipment				
	There is evidence of training for service users/carers about any equipment they are given to use themselves				
	Best interest meetings with people who know and understand the person using the services to ensure that treatment and care are taken that reflect the person's best interest				
	There is evidence of national specification scores for cleanliness, in relation to nursing equipment				
	An annual decontamination audit has been completed				

Appendix 3 - Definitions

The following terms have been defined for the purpose of this policy:

An adverse incident - is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons. Causes may include design; poor user instructions or training; inappropriate modifications; inadequate maintenance; and unsuitable storage and use conditions.

Bioburden – The population of viable infectious agents contaminating a medical device.

Contamination – The soiling or pollution of inanimate objects or living material with harmful, potentially infectious or other unwanted material. In the clinical situation, this is most likely to be organic matter and infectious agents but may also include other undesirable substances e.g. chemical residues, radioactive material, degradation products, packaging materials etc. Such contamination may have an adverse effect on the function of a medical device and may be transferred to a person during use or subsequent processing and storage.

Cleaning – A process which physically removes infectious agents and the organic matter on which they thrive but does not necessarily destroy infectious agents. The reduction of microbial contamination depends upon many factors, including the effectiveness of the cleaning process and the initial bioburden. Cleaning is an essential prerequisite to ensure effective disinfection or sterilization.

Decontamination – A process which removes or destroys contamination and thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. Three processes of decontamination are commonly used: cleaning, disinfection, sterilisation.

Disinfection – A process used to reduce the number of viable micro organisms but which may not necessarily inactivate some bacterial agents, such as certain viruses and bacterial spores.

Endotoxin – Is a toxin lipopolysaccharide, formed by the breakdown of the cell wall of Gram-negative bacteria. Bacterial endotoxins can be active even if the bacteria from which they are released are killed.

End user – A person who uses the device on or for him /herself, as distinct from a professional user.

Infectious agents – The term includes micro-organisms and other transmissible agents e.g. prions.

Intended purpose – The use for which the device is intended according to the information supplied by the manufacturer on the labelling, in the instructions and/or promotional materials.

Legal entity – An individual, institution or organisation that has its own existence for legal or tax purposes e.g. a corporation, partnership or trust.

Manufacturer – The person with responsibility for the design, manufacture, packaging and labelling of a device before placing it on the market under their own name. This can be a company or an individual.

Medical Devices - Medical device covers a wide range of products including those used everyday in most health care settings and can be defined as any instrument, apparatus, including beds, furniture, appliance, material or health care product, excluding drugs. A medical device is any instrument, apparatus, appliance, material or other article used alone or in combination, intended by the manufacturer to be used for humans for any of the following purposes:

- Control of conception
- Monitoring, diagnosis and investigation

- Treatment, alleviation or compensation for injury or incapacity
- Replacement or modification of anatomy and physiology

Prions - infectious agents smaller than virus. Unlike other pathogens, prions contain no dna or rna. Their only known component is a protein with an abnormal conformation

Prion diseases – Fatal, infectious, neurodegenerative disorders with no known immunisation or treatment.

Professional user – The trained and qualified person who operates a device for the benefit of the patient or client.

Single-use medical device – A device which is intended to be used on an individual patient during a single procedure and then discarded. It must not be used on another patient.

Sterilization – A process used to render an object free from viable infectious agents including viruses and bacterial spores.

Reprocess – To make good the device for reuse by any or a combination of the following processes:

- cleaning
- Disinfection/decontamination
- Sterilisation
- Refurbishment
- repackaging.

Note: the manufacturer of reusable devices should provide validated reprocessing instructions along with the device.

Reprocessor – A person who undertakes the reprocessing of a medical device.

Resterilisation – The repeated application of a terminal process designed to remove or destroy all viable forms of micro-organisms, to an acceptable level of sterility.

Reuse – Another episode of use, or repeated episodes of use, of a medical device, which has undergone some form of reprocessing between each episode.

Validation – Documented procedure for obtaining and interpreting the results required to establish that a process will consistently yield a product complying with predetermined specifications.

User organisation – a device owner who makes use of the device

Definition for Accredited Provider - Must hold a current certification or qualification that allows them to undertake training for said item.

Definition for Competency Based Provider - Someone who uses the equipment regularly and has developed and been assessed as having a degree of skill, safe use and knowledge that upholds best practice

Equality Impact Assessment Tool

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval. 17/12/10 – Sue Wright

		Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Comments
1.	Does the document/guidance affect one group less or more favourably than another on the basis of:			
	• Race	X		
	• Ethnic origins (including gypsies and travellers)	X		
	• Nationality	X		
	• Gender	X		
	• Culture	X		
	• Religion or belief	X		
	• Sexual orientation including lesbian, gay, transgender and bisexual people	X		
	• Age	X		
	• Disability - learning disabilities, physical disability, sensory impairment and mental health problems	X		
2.	Is there any evidence that some groups are affected differently?	X		
3.	If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?	X		
4.	Is the impact of the document/guidance likely to be negative?	X		
5.	If so, can the impact be avoided?	X		
6.	What alternative is there to achieving the document/guidance without the impact?	X		
7.	Can we reduce the impact by taking different action?	X		