

MEDICAL DEVICES POLICY

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DOCUMENT CONTROL

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Intended recipients: All staff working in areas where clinical care is given Temporary, Locum, Bank, Agency and Contracted staff.			
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1. INTRODUCTION

- 1.1 The safe use of medical devices is essential to the delivery of high quality health care on a day to day basis and it is therefore important that all staff and users are trained in the safe use and maintenance of medical devices. Somerset Partnership NHS Foundation Trust (The 'Trust') is committed to promoting patient safety and to the management of potential risks.
- 1.2 The management of medical devices encompasses the whole life cycle of the device, from decisions made pre-procurement to the transfer or safe disposal of the device.
- 1.3 The Trust and its staff are required to comply with all appropriate legal requirements including the MHRA 2006(5) Managing medical devices: Guidance for Healthcare and social care organisations, MHRA 2006, MHRA 2014 Regulatory guidance of Medical Devices guidelines and recommendations and to follow best practice in all aspects of the management of Medical Devices.
- 1.4 The principles, policy and procedures relating to the management of Medical Devices are overseen by the Medical Devices Implementation Group that reports to the Clinical Governance Group.
- 1.5 This policy must be read in conjunction with the Royal Marsden Manual of Nursing Procedures (2015) which lists all procedures undertaken, equipment needs and training requirements.
- 1.6 Medical Devices play a crucial role in diagnosis, treatment and care of patients. Due to changes in health care technology and clinical practice, increasingly complex devices are being used.
- 1.7 Healthcare professionals are personally accountable for their use of devices and therefore must ensure that they have appropriate training and assessment of competence before using any medical device. They are also personally accountable for ensuring service users and carers have received appropriate training and know how to use the device that has been provided.
- 1.8 This policy relates to all Medical Devices other than those identified for single use.
- 1.9 Medical devices should, whenever possible and practical, be single use or single patient use and under no circumstances should any item designated for single use be reused.

2. PURPOSE & SCOPE

- 2.1 The aim of this policy is:
 - to increase staff awareness of the principles and importance of equipment management;
 - to ensure that managers and individual members of staff are aware of

their responsibilities in relation to the use of medical devices;

- to ensure that all medical devices are:
 - suitable for intended purpose
 - maintained in a safe and reliable condition
 - used only by competent staff
 - decontaminated in line with Local and National guidelines.

2.2 The document applies to all Trust staff including Temporary; Locum; Bank; Agency and Contracted staff.

3. DUTIES AND RESPONSIBILITIES

3.1 **The Chief Executive** will be responsible for ensuring that all Trust personnel comply with Health and Safety regulations and approved guidance in relation to Medical Devices. In practice, tasks and responsibilities are delegated to Senior Managers, but overall responsibility will remain with the Chief Executive. Devolved responsibility for Medical Devices is the Director of Governance and Corporate Development

3.2 **The Head of Risk** is the **Medical Devices Lead** and responsible for:

- the implementation of this policy and for ensuring this policy and associated regulations and guidance is complied with;
- ensuring risk assessments relating to Medical Devices are completed by the appropriate staff, incorporated into the appropriate Risk Register and forwarded to the Head of Risk for the Trust;
- ensuring staff are competent to work with the Medical Devices they use, that staff receive training and assessment of competencies as outlined in the Royal Marsden Hospital Manual of Clinical Nursing Procedures (2015), and the training received is documented;
- ensuring adequate arrangements are implemented to ensure the safe management of Medical Devices e.g. procurement, maintenance, disposal etc;
- ensuring incidents involving Medical Devices are correctly and promptly reported by staff according to the Trust's incident reporting/Untoward Events Reporting Policy. All appropriate incidents will have an action plan that will be monitored through the Medical Devices Implementation Group;
- the development of this document and as the author will ensure this document is reviewed at least every three years or sooner if there are significant changes to local or national guidance.

3.3 **Ward/Team Managers (Mental Health Directorate) and Service Managers (Community Health Directorate)** must ensure:

- that all staff are competent before undertaking any procedure using a

medical device;

- that the device is fit for purpose;
- that equipment manuals, procedures and protocols are available in each clinical area for Medical Devices in regular use. This will include any other relevant information such as Safe Operating Instructions and Safety Action Bulletins;
- that a Medical Devices Register is maintained to ensure easy identification of individual pieces of equipment;
- that risk assessments are carried out on all relevant equipment;
- that records of local training and training updates are kept by ward/team/line managers and a copy forwarded to the Learning and Development Team to enter on the electronic staff register;
- that documentation of patient care, involving the use of Medical Devices, should be clear and unambiguously recorded on an appropriate care plan;
- that a local record is kept of Medical Devices loaned to other areas within the Trust recorded on medical devices register;
- that a local record is kept of routine decontamination of Medical Devices recorded on medical devices register;
- that, in line with the Medical Devices Agency recommendations, each ward/team should have a named person responsible for ensuring that equipment remains in good working order;
- medical devices are returned to the appropriate place when no longer required;
- any medical device related incidents are reported by completion of a web based (Datix) Untoward Event Reporting Form and investigated both internally and externally according to the grade and details of the incident.

3.4 **Individual staff members** must:

- take responsibility for maintaining their competence to use equipment in their area of work;
- not use any equipment in whose use they have not received appropriate training;
- carry visual checks and out any necessary safety checks prior to using any devices;
- bring to the immediate attention of their line manager any concerns they have regarding devices and remove device from service until concern is dealt with;
- ensure that devices are stored appropriately, equipment put on charge as appropriate and checked as advised by manufacturer;

- report equipment faults to the Medical Devices Servicing Provider and ensure the completed medical electronics' decontamination card accompanies any device sent to them for service, calibration, repair or disposal;
 - ensure that all equipment is appropriately decontaminated between uses in line with the Trust Cleaning of Equipment and Decontamination policy;
 - ensure that any equipment sent to Medical Electronics must be decontaminated in accordance with the Trust Cleaning of Equipment and Decontamination policy.
- 3.5 The **Learning and Development Team** will record all training on the electronic staff record (on receipt of the attendance sheet/training log) to assist in the monitoring of training.
- 3.6 The **Head of Patient Safety** is responsible for the management and cascade of Medical Device Alerts via CAB.
- 3.7 **Medical Devices Implementation Group** is responsible for the monitoring of adherence to policies relating to medical devices and for the Core Equipment list that staff consult prior to purchasing any new items of equipment.
- 3.7.1 The Group is responsible for the monitoring of all incidents relating to the use of Medical Devices and implementing any recommendations from Medical Device Audits undertaken.
- 3.8 **Clinical Governance Group** will monitor the work of the Medical devices Group using quarterly reports submitted to the group.

4. EXPLANATIONS OF TERMS USED

- 4.1 **Medical Device** -“all products, except medicines, used in healthcare for diagnosis, prevention, monitoring and treatment” (The Health and Social Care Act 2008).
- 4.2 **Single Use Device** – A medical device which is intended to be used on an individual patient during a single procedure and then discarded. Single use devices must not be re-processed or used on another patient. Single - use devices / products are clearly labeled on the packaging by the international organisation for standardisation symbol, which is the figure 2 with a diagonal line drawn through it.



- 4.3 **Single Patient Use** - items intended to be used a number of times on the same patient according to the manufactures guidance. If in doubt contact the Medical Devices Lead for further advice.

4.4 **New Devices** – Devices not currently used by the Trust or devices which are broadly similar to existing devices used in the Trust but have different features or performance characteristics.

4.5 **Datix** – Electronic Tool used within the Trust to record Untoward Event Reports, Risk, Medical Devices and PALS and Complaints.

5. **PROCUREMENT**

5.1 The overall aim is to ensure that:

- all medical equipment purchased by the Trust represents best value for money;
- all costs of purchase are considered, both the initial cost of the equipment and ongoing cost of associated consumables and maintenance;
- all equipment meets relevant safety standards;
- any agreed standardisation of particular brands of equipment is complied with;
- when medical equipment is purchased consideration should be given to the ease of contamination and decontamination.

5.2 The procurement process is acknowledged as being a key factor in the ability to manage Medical Devices successfully.

5.3 The Trust supports the identification and standardisation of Medical Devices wherever practicable. Standardising will ensure different types of the same device are kept to a minimum and consistent with patient safety, service demands, training requirements, and maintenance issues. The Trust is fully committed to ensuring the needs of the individual are taken into account. This may require a more expensive option be chosen requiring a single-tender action as part of the procurement process.

5.4 All Trust used medical devices must be:-

- CE marked (Medical Devices Directive 93/42/EEC);
- supplied with clear, concise and comprehensive instructions;
- supplied with details of maintenance requirements.

5.5 **New Devices** - Medical Devices which have the potential to create risk to patients may be acquired by the Trust only when the following criteria have been met:-

- the user department or person must first check the Trust's standardised Core Equipment List for preferred make and model of the device. The core equipment list can be located on Trust intranet. If the device or preferred model/make is not listed then;

- the user department or person obtaining the device must undertake a formal risk assessment of its design, function, performance, safety features, training requirements, life cycle costs and maintenance requirements. All of which must be submitted to Medical Device Implementation Group;
- the Medical Devices Implementation Group has approved its use;
- technical advice has been sought to provide an assessment, independent of clinical users, of the need for, and effectiveness of, the technology being proposed;
- there is funding available, including funding for repairs and service contracts.

5.6 **Replacement Devices** - Where the device required is a direct replacement for the same device and is the preferred make/model noted on the core equipment list, section 5.4 applies.

5.7 **Loaned Devices (Internal and External Loans)** - The Trust recognises the need to ensure that the management and use of all loaned Medical Devices minimise risk to patients, carers and staff. Occasionally it may be necessary to loan devices from other providers or suppliers.

5.8 All loaned Medical Devices will:

- be suitable for the intended use;
- be recorded on the medical devices register
- have an identified responsible member of staff;
- be included in the discharge planning process;
- will have an identified responsible patient or carer;
- be subject to any acceptance check before being put into use within the Trust;
- be properly maintained and records present to demonstrate this;
- be able to be properly decontaminated, and that where necessary suitable instruction and training is provided;
- be provided with suitable user instructions and that where necessary suitable training is provided;
- be incorporated in existing Trust procedures to manage adverse incidents.

- 5.9 A record must be kept detailing where the devices came from, service history and contact name in the event of any problems arising, and all safety acceptance checks carried out and training given before the Medical Device is put into use.
- 5.10 The borrower should ensure the commercial loaning organisation has the appropriate indemnity insurance, through the Medical Devices Servicing Providers. This is in accordance with the NHS Supplies/PASA recommendation;
http://www.dh.gov.uk/en/Publications/PublicationsPolicyAndGuidance/DH_117175
- 5.11 The borrower should assess the Medical Device management requirements and ensure that it can be used safely and according to any statutory guidance and best practice recommendations.
- 5.12 The borrower should ensure that any relevant medical advice management information and documentation relating to the operation, safety and functioning of the device should be transferred with the Medical Device.
- 5.13 The lender and the borrower retain shared responsibility for the device and its management.
- 5.14 **Charitable or Similar Organisations** - Where devices are obtained from charitable or individual donors they must comply with the Trust Standing Orders, Standing Financial Instructions, procurement policies and procedures and the Medical Devices Policy.

6. ACCEPTANCE CHECKS

- 6.1 The Ward/Team/Line/Service Manager is responsible for ensuring the safety and functionality of newly delivered medical devices.
- 6.2 This will involve:
- checking that the correct product, complete with manuals and accessories, has been supplied;
 - providing assurance that product items have been delivered in good condition and in working order;
 - ensuring that the risks associated with using a particular model for the first time have been minimized;
 - recording the device using the web based medical device database, so that appropriate planned preventative maintenance can be initiated and, in the event of an untoward incident when a new device is first used, evidence of good practice can be produced;
 - identify any training needs for staff according to the manufacturers guidance/instructions;

- ensuring that new equipment is logged onto the Medical Electronics system and is checked before use by contacting Medical Electronics .

6.3 **Registering the Medical Device** - The **Medical Devices Register** will be held on the Datix system. This will list all equipment currently used by team and by location. It will also detail:

- the asset number or serial number of each piece of equipment;
- the purpose for which the Medical Device is used;
- the staff who are trained to use the Medical Device;
- the dates of the training;
- the maintenance log of the Medical Device.

6.4 The Medical devices register will be kept 'live' by ward/team/line managers adding any new medical devices as purchased and removing old devices once disposed of.

6.5 **Evaluation, Demonstration and Trial of New Devices** - Devices may be brought into the Trust for evaluation, demonstration and trial. If as part of the evaluation, the device is to be used with, connected to or create a risk to patients the requirements a risk assessment should be completed and full evaluation of the product following the trial. Also included in the evaluation should be consideration of experience of other users' to reliability and previous performance

6.6 All necessary safety / acceptance checks by medical electronic estates and arrangements must be in place and training provided before any device is put into use. This is particularly important with high risk devices. Please see key points for consideration prior to acquisition in Appendix B.

7. **STORAGE**

7.1 Inappropriate storage of medical devices affects their subsequent safe use. Manufacturer's information and instructions both on storage conditions and shelf life should be followed.

7.2 Equipment that may be needed for urgent or emergency use should be immediately ready for use when required. For example; this means that defibrillation pads must be 'in date' and have been stored at the appropriate temperature and that all equipment with rechargeable batteries is on charge.

8. MAINTENANCE

- 8.1 Users will determine the type and frequency of the maintenance requirement of all medical devices with the Trust's specialist Medical Device advisors who are the Medical Electronics Contractors for the Trust. The service and maintenance requirement of all medical devices will be determined in liaison with the Trust's specialist Medical Device advisor under the Medical Device Management Service Contract.
- 8.2 **User Maintenance** - Users (including where appropriate patients and carers) must undertake designated safety checks prior to bringing a medical device into use or during its operation and appropriate documentation completed. They may also have responsibility for other aspects of the maintenance of the device. For example, battery changes/recharging and/or infection control issues.
- 8.3 These checks will be detailed in the manufacturer's instructions and supplemented where appropriate in the Safe Operating Instruction.
- 8.4 Users must receive adequate training in safety checks, user maintenance and recognition of faults as part of their general competency to operate the device.
- 8.5 All staff who receive a reminder for servicing from the Trust's medical electronics contractor must respond in a timely manner.
- 8.6 The user ward/team is responsible for making medical devices available for maintenance. Reference should be made to the safe operating instructions for information regarding any preparation of the device. For example, decontamination that is required prior to maintenance.
- 8.7 Each ward/team in the Trust will assist to maintain or have access to records of maintenance undertaken on medical devices used in their areas of responsibility. This will include, planned preventative maintenance (PPM), breakdown, servicing and safety checks. Records will be provided as requested under the Medical Device Management Service Contract.
- 8.8 **Cannibalisation** - Unless the circumstances are exceptional, for instance in an emergency, removal of serviceable parts from one medical device to enable a second (non-functioning) medical device to work is not permitted. This course of action can only be carried out by Medical Electronics", this would prevent unauthorized cannibalisation.
- 8.9 Where the medical device performs a Point of Care Testing service, there must be a defined process for arranging the Quality Assurance tests that are required to ensure the devices are safe and accurate. (see the Point Of Care Testing Devices (Poct) Policy for more information).

9. USE OF EQUIPMENT

9.1 This must be by the appropriately registered professional or competent person who, following an assessment of the patient to decide that devices will aid the treatment, care, diagnosis and/or rehabilitation of the patient. The appropriate staff member will be responsible for ensuring that:

- visual and physical safety checks are made of devices prior to its use or issuing to patients;
- devices are used according to manufacturer's instructions and any other supplementary information such as Safe Operating Instructions;
- devices are cleaned according to manufacturer's instructions, infection control policies and any other supplementary information;
- any device faults identified are reported;
- all device incidents are reported using the DATIX on line Untoward Events Reporting Form;
- faulty devices are taken out of use immediately a DATIX on line untoward Events Reporting Form completed and Medical electronics notified;
- acting on new guidance about device safety e.g. the Medicines and Healthcare products Agency issues medical alerts to the Central Alert System (CABs); these will be distributed within the Trust by the Head of Patient Safety;
- ensuring the patient/carer receives adequate training/information in its use etc. Any training given should be documented in the patient's healthcare record. Staff must ensure that the patient/carer understands what to do or who to contact in the event of a breakdown or emergency;
- other Trust staff are made aware of any issues affecting the safe use of the Medical Device.

9.2 **Information/Safe Operating Instructions** - Where appropriate manufacturer's instructions will be made available for staff to consult. These instructions may be supplemented by other information where the Trust has put into place configurations/uses that are not covered by the manufacturer's instructions.

9.3 These safe operating instructions may be further modified by the issue of safety action bulletins or other information.

10. INCIDENTS

- 10.1 All incidents involving Medical Devices must be reported using the web based DATIX Untoward Events Reporting form, in line with the Trust's Untoward Events Reporting Policy and Guidance.
- 10.2 Faulty medical equipment should be reported to the Trust's Head of Risk or out of hours to the Manager on call Out of Hours manager available over night from 17.00 weekdays and 24hr period over weekends and Bank holidays. The Head of Risk will ensure that all faulty equipment is reported to the Medicines and Healthcare products Regulatory Agency (MHRA).
- 10.3 Incidents to be reported include unexpected performance, suspected tampering or any other incident where patient safety was or may have been compromised.

11. Replacement of Reusable Medical Devices"

- 11.1 For all reusable medical devices, a stage is reached at which replacement must be considered. If any of the following seven criteria apply, the device is no longer considered serviceable for the following reasons, normally advised by the Medical Electronics :-

:

- worn out beyond economic repair;
- damaged beyond economic repair;
- unreliable (check service history);
- clinically or technically obsolete;
- spare parts no longer available;
- more cost-effective or clinically effective devices have become available; more technological devices are available resulting in improvements on cost/clinical devices."
- unable to be cleaned effectively prior to disinfection and/or sterilisation.

- 11.2 Replacement of medical devices should only occur after discussion with the Trust Medical Devices Lead or via the Medical Devices Implementation Group and after consulting with the Core Equipment List.

12. DISPOSAL OF CONDEMNED EQUIPMENT

- 12.1 Any item condemned should be removed from service immediately and a replacement organised.
- 12.2 Equipment which is faulty, out of date or no longer needed would normally be disposed of by Medical Electronics following completion of the necessary decontamination certification."

- 12.3 All equipment for disposal should be recorded on the Medical Device database.
- 12.4 Local users of the device need to undertake a risk assessment to decide what risk is involved in disposal based on the following and retain locally.
- 12.5 **Low Risk Devices**
- examples of low risk equipment are thermometers, sphygmomanometers etc;
 - advice should be sought from facilities around the correct disposal site to use.
 - any equipment which would not pose a risk if it were to pass into the wrong hands;
 - any equipment which is not contaminated or an infection risk.
- 12.6 **High Risk Devices**
- examples of high risk equipment include diathermy units, defibrillators, blood fridges, mercury sphygmomanometers etc;
 - any equipment which would pose a risk if it were to pass into the wrong hands;
 - any equipment which is contaminated or may be an infection risk for example, blood soaked foam mattresses;
 - all high risk equipment should be discussed with the appropriate medical devices servicing provider and if appropriate may be sent to them for disposal – they will also ensure all the necessary paperwork is completed;
 - contaminated or infected equipment must be discussed with Medical Devices Servicing Contractor and the Infection Control Advisor who will give further guidance.
13. **DECONTAMINATION** (please refer to the Trust Cleaning of Equipment and Decontamination Policy)
- 13.1 It is essential that any reusable medical equipment is cleaned and, where relevant, decontaminated prior to being dispatched for service or repair. Advice may be sought from the Infection Control Nurse, Estates Department or Medical Electronics Contractors
- 13.2 It is essential that medical equipment, not designated for single patient use, is decontaminated between clients and kept in a clean and serviceable condition when not in use. It is the responsibility of the ward/team/line manager to ensure that there is evidence available to assure that routine decontamination of medical devices is being undertaken.
- 13.3 For items such as commodes and wheelchairs that are used many times within a day for multiple patients indicator tape should be used (signed and

dated) to assure the next user of the equipment's cleanliness.

- 13.4 This should be in accordance with the manufacturer's instructions / safety operating instructions and the current Cleaning of Equipment and Decontamination Policy.
- 13.5 In situations where the condition of the item is the subject of a complaint or investigation and may be altered or influenced by a decontamination process the investigator may wish the item not to be decontaminated. In such situations the device should be quarantined and the advice of the investigating body should be sought and prior warning given to the intended recipient.

14. TRANSFER OF PATIENTS WITH MEDICAL DEVICES

- 14.1 Under normal circumstances devices must not be transferred to other areas/organisations that do not normally use that device. There is a risk that staff may not be competent in its use or it may have different configurations or performance characteristics compared to their normal device.
- 14.2 If device transfer is required adequate arrangements must be made to ensure safety. This may include:-
- seeking alternative forms of treatment. For example for intravenous therapy;
 - making a competent member of staff available to use or monitor the device;
 - briefing staff where the device is to be used on its performance characteristics.
- 14.3 These arrangements also apply to devices transferred into the Trust from all other health organisations including Musgrove Park Hospital Foundation Trust, Yeovil District Hospital Foundation Trust, Weston Super Mare Hospital and Bath Royal United Hospital.
- 14.4 Where devices are returned to the Trust or other owners, appropriate arrangements must be made for safe transportation and/or decontamination.
- 14.5 Where medical equipment is passed onto a patient or carer, Managers will ensure that this end user has all the training necessary to ensure a level of safety and operation similar to that which would be expected on the ward. In particular the manager must ensure that any instructions sent with the equipment are adequate for the knowledge level of the end user and that users have signed a receipt confirming their understanding.

14.6 Where patients are transferred home with a medical device the checklist included as Appendix D applies.

15. TRAINING REQUIREMENTS

15.1 The Trust will work towards all staff being appropriately trained in line with the organisation's Staff Mandatory Training Matrix (training needs analysis), further detail can be found in the Learning Development and Mandatory Training Policy and the Training Prospectus, accessible via the Trust Intranet.

15.2 Medical Device Training is mandatory within the Trust and further information will be located within the Learning Development and Mandatory Training Policy.

15.3 Compliance reports are issued to managers and are monitored by local managers according to the Learning Development and Mandatory Training Policy. Guidance for actions to be taken in the case of non-attendance at training is located within the Learning Development Mandatory Training Policy. Training compliance will also be monitored on a quarterly basis by the Medical Devices implementation group.

15.4 Ward/team/line managers are responsible for ensuring that manufacturers' instructions are available to staff and that their staff have the appropriate knowledge and skill to use any medical devices required, when delegating work. Ward and team managers should, as part of individual personal development appraisals, identify any training needs.

15.5 All Clinical line managers will identify all equipment used within their department for which staff need training. This range of equipment will be recorded on Medical Devices Module and must be kept up to date as new devices are purchased.

15.6 For each Medical Device the Clinical line manager will identify:-

- who needs to be trained
- the type of training required
- the frequency of training
- who will provide the training

15.7 Individual members of staff (including agency staff) are responsible for ensuring they have received written and/or oral instructions and that they are competent to use an item of medical equipment before they attempt to operate it. If there is any doubt, the individual concerned should consult their manager or shift leader and report their training needs, if necessary.

15.8 All Clinical staff must complete their mandatory 'Safe Use of a Medical Device' training DVD and competency assessment which is available on the intranet.

- 15.9 All training will be logged using the Medical Devices training log (Appendix C). Both formal and informal training should be recorded. It is the line manager's responsibility to maintain the training log for all staff within their team. A copy of all training undertaken by staff must be kept locally by ward/team/line managers with a further copy forwarded to Learning and Development
- 15.10 **Staff Joining the Organisation with Previous Experience** - The training needs for these staff will be identified and assessed by their ward/team/line manager as part of their selection or induction into the Trust. Where deficiencies in knowledge or experience are identified appropriate training and assessment must be given. It is the responsibility of both the manager and the individual to ensure that **only those who have received training are allowed to use medical equipment.**
- 15.11 **Refresher Training** - Refresher training will be assessed at ward/department level, and will be determined by the risk assessment for each device. Training records will be updated accordingly.
- 15.12 **New Staff** - New staff will be given full instruction, and demonstration of the equipment, with time to practice and demonstrate understanding and practical application before being allowed to use the device/equipment. Staff should sign that they have read the manufacturer's instructions, received training and are able to comply with the safe use of the equipment/device. Before signing, staff should be enabled to express any concerns and seek answers to any questions. It may be appropriate for staff to use the equipment under supervision until they are competent. The ward/team/line manager will determine this.
- 15.13 **Agency Staff** - Agency staff should not use equipment that they have not been trained to use. They should be asked to demonstrate that they know how to use the equipment and their competency will be assessed by the senior nurse on duty.
- 15.14 **Any staff member who has not received training or demonstrated competence in the use of a medical device should not be allowed to operate the device.**

16. EQUALITY IMPACT ASSESSMENT

- 16.1 All relevant persons are required to comply with this document and must demonstrate sensitivity and competence in relation to the nine protected characteristics as defined by the Equality Act 2010. In addition, the Trust has identified Learning Disabilities as an additional tenth protected characteristic. If you, or any other groups, believe you are disadvantaged by anything contained in this document please contact the Equality and Diversity Lead who will then actively respond to the enquiry.

17. MONITORING COMPLIANCE AND EFFECTIVENESS

- 17.1 **Monitoring arrangements for compliance and effectiveness**

- overall monitoring of compliance will be the responsibility of the Clinical Governance Group who will receive a quarterly progress report from the Medical Devices Implementation Group;
- the Medical Devices Implementation Group will monitor reported incidents each quarter reporting any areas of concern and new significant risks to the Clinical Governance Group;
- the Medical Devices Implementation Group will monitor Medical Device Alerts received via the Central Alert Systems (CAB) each quarter and report actions taken and outstanding to the Clinical Governance Group;
- the staff appraisal system will allow for all staff to have their Medical Devices Training Log reviewed annually ensuring compliance with the Medical Devices Policy;
- internal Audit will be undertaken annually by clinical areas. The Audit will be in the form of spot checking of equipment and its listing on medical Devices register.

17.2 Process for reviewing results and ensuring improvements in performance occur - Audit results will be presented to the Clinical Governance Group for consideration, identifying good practice, any shortfalls, action points and lessons learnt. This Group will be responsible for ensuring improvements, where necessary, are implemented. Lessons learnt will be forwarded to the Corporate Governance Administrator who will add to the Corporate Register of Lessons Learnt and filed on the Intranet. A brief of the audit will be provided to staff to raise awareness through the Spice newsletter with a hyperlink to the updated Corporate Register of Lessons Learnt.

18. COUNTER FRAUD

18.1 The Trust is committed to the NHS Protect Counter Fraud Policy – to reduce fraud in the NHS to a minimum, keep it at that level and put funds stolen by fraud back into patient care. Therefore, consideration has been given to the inclusion of guidance with regard to the potential for fraud and corruption to occur and what action should be taken in such circumstances during the development of this procedural document.

19. RELEVANT CARE QUALITY COMMISSION (CQC) REGISTRATION STANDARDS

19.1 Under the **Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3)**, the fundamental standards which inform this procedural document, are set out in the following regulations:

- | | |
|----------------|--|
| Regulation 12: | Safe care and treatment |
| Regulation 13: | Safeguarding service users from abuse and improper treatment |

Regulation 15:	Premises and equipment
Regulation 16:	Receiving and acting on complaints
Regulation 20:	Duty of candour
Regulation 20A:	Requirement as to display of performance assessments.

19.2 Under the **CQC (Registration) Regulations 2009 (Part 4)** the requirements which inform this procedural document are set out in the following regulations:

Regulation 18:	Notification of other incidents
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19.3 Detailed guidance on meeting the requirements can be found at <http://www.cqc.org.uk/sites/default/files/20150311%20Guidance%20for%20providers%20on%20meeting%20the%20regulations%20FINAL%20FOR%20PUBLISHING.pdf>

Relevant National Requirements

Health and Social Care Act 2008

HSC 1999/179. Controls Assurance in infection control: Decontamination of Medical Devices. Department of Health. 1999

MDA DB 9501. The Reuse of Medical Devices Supplied for Single use only. Medical Devices Agency. 1995.

HSG (93) 26. Decontamination of equipment prior to inspection, service or repair. Department of Health. 1993.

Mental Health Act Code of Practice (Chapter 15), DH 2008.

The Medical Devices Regulations 2002

The Medical Devices (Amendment) Regulations 2012

Health and safety Work act 1974

The Electricity at Work Regulations 1989

The Control of Substances Hazardous to Health Regulations

The Lifting Operations and Lifting equipment Regulations

The Waste Electrical and Electronics Equipment Regulations

Medicines Healthcare Regulatory Authority (MHRA) Managing Medical Devices - Guidance for healthcare and social services organisations, April 2014.

MDA DB2002(02) March 2002 – Management of In-Vitro Diagnostic Medical Devices.

MDA DB2010 (02) February 2010 – Management and use of IVD Point of Care Test Devices.

MHRA DB-2006 (04) – Single Use Medical Devices; Implications and consequences of Re-use.

Care Quality Commission – Regulation 15; Premises and equipment - Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

MHRA Devices in practice

BS EN 62353 – Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment.

BS EN ISO 9001:2008 – Quality management systems.

ECRI Institute device risk levels

20. REFERENCES, ACKNOWLEDGEMENTS AND ASSOCIATED DOCUMENTS

References

DH, The Health and Social Care Act 2008 – Code of Practice for health and social care on the prevention and control of infections and related guidance

MHRA (2002) SN 2002(17) – Management of loaned Medical Devices, equipment or accessories from manufacturers or other hospitals

MHRA (2004) Checklist for patients discharged from hospital with a medical device

MHRA DB 2006(4) Single use medical devices: Implications and consequences of reuse, MHRA 2006

MHRA DB 2006(5) Managing medical devices: Guidance for Healthcare and social care organisations, MHRA 2006

MHRA (2014) Regulatory Guidance of Medical Devices.

Dougherty and Lister (2015) 13th edition: The Royal Marsden Hospital Manual of Clinical Nursing Procedures

Cross reference to other procedural documents

- Cleaning of Equipment and Decontamination Policy;
- Decontamination of Flexible Endoscopic Equipment;
- Healthcare Clinical Waste Policy;
- Infection, Prevention and Control Policy;
- Sustainable Procurement Policy;
- Standing Financial Instructions and Scheme of Delegation;
- Untoward Events Reporting Policy and Guidance;
- Non Healthcare (Non Clinical) Waste Policy.
- Point of Care Testing Devices (Poct) Policy

All current policies and procedures are accessible in the policy section of the public website (on the home page, click on 'Policies and Procedures'). Trust Guidance is accessible to staff on the Trust Intranet.

21. APPENDICES

21.1 For the avoidance of any doubt the appendices in this policy are to constitute part of the body of this policy and shall be treated as such.

Appendix A	Examples of Medical Devices.
Appendix B	Factors to Consider Prior to Acquisition of a Medical Device
Appendix C	Medical Devices Training Log
Appendix D	Checklist for Patients Discharged From Hospital with a Medical Device

EXAMPLES OF MEDICAL DEVICES

Examples of common categories of medical device equipment used in the diagnosis or treatment of disease or monitoring of patients: -

Administration and giving sets	Mattresses (including foam and air wave)
Bath aids	Ophthalmic equipment
Beds (including low and adjustable)(managed by Estates Dept)	Physiotherapy equipment
Blood glucose measuring devices	Portable nebuliser
Blood pressure measuring devices	Pressure relief equipment
Chiropody and Podiatry equipment	Pulse Oximeters
Cholesterol test kits	Scales
Commodes (managed by Estates Dept)	Patient Hoists / Standing frames (patient hoists are managed by Estates Dept)
Communication aids	Stoma care equipment
Defibrillators	Surgical instruments and power tools
Dental instruments, equipment and materials	Syringe drivers / infusion pumps
Ear syringe equipment	Thermometers
ECG machine	Ultrasound Dopplers
Endoscopes and accessories	Walking aids
Feeding systems – Enteral	Wheelchairs and special support seating
Gastrostomy tubes	X-ray equipment, systems and accessories
Hearing screener	Metal Detectors
Insulin injectors	Alcohol Breathalysers

FACTORS TO CONSIDER PRIOR TO ACQUISITION OF A MEDICAL DEVICE

Selection process should consider:

- 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 (associated maintenance costs)
- warranty details
- other support facilities
- Point of care testing QA process



CHECKLIST FOR PATIENTS DISCHARGED FROM HOSPITAL WITH A MEDICAL DEVICE

General Considerations

- Is the device suitable for home use (have, for example, robustness, back-up systems, alarms been considered if appropriate, modifications needed, patient care and instructions)?
- Has the person responsible for the use of the device been identified, i.e. is it patient and/or carer?
- Is the loan equipment schedule maintenance status compatible with the loan?
- Has the device been fully tested with confirmed full functionality and fitness for purpose?

Patient/Carer Instructions

- Does the patient/carers know the name of the device?
- Does the patient/carers know how to set up the device in the home?
- Has the patient/carers been trained in the use and functions of the device?
- Has the patient/carers been provided with written instructions specifically about the device?
- Has the patient/carers been trained in how to deal with fail-safe features, e.g. alarms?
- Has the patient/carers been trained in the care of the device?
- Does the patient/carers require accessories? If so, does the patient/carers know where to obtain these and how often?
- Is maintenance required? If so, is the patient/carers aware and in possession of instructions about how this will be achieved?
- Does the patient/carers have a point of contact in the Trust for any queries?
- If relevant, does the patient/carers have a contact point in case of emergency?

Return

- Does the patient/carers know when to return the device?
- Does the patient/carers know where to return the device once treatment is complete, to whom and at what time?

<http://www.mhra.gov.uk>

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