The Newcastle upon Tyne Hospitals NHS Foundation Trust

Medical Device Management Policy

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| Ratified By: | Medical Device Steering Group |

1 Introduction

1.1 The Trust recognises that the safe and appropriate use of medical devices is critical to the delivery of high quality patient care. This policy promotes the requirement for procedures, the overall objectives of which are to ensure safe, efficient and high quality management of medical devices, thereby minimising the risks associated with the use of such medical devices.

1.2 This policy defines a clear and systematic approach to the management of medical devices to ensure compliance with Care Quality Commission (CQC) standards, Medical laboratories Requirements for quality and competence, NHS Litigation Authority (NHSLA) and Medicines and Healthcare products Regulatory Agency (MHRA) requirements for medical devices.

1.3 The purpose of this policy is to ensure best practice with regard to medical device management throughout the lifecycle of a medical device; this involves the assessment of medical devices from the justification of the need, through tender/product specification, commissioning, staff training/competency, clinical use, maintenance and disposal.

1.4 Reference should be made to the following publications:

- Care Quality Commission “Essential Standards of Quality and Safety”
- Medicines and Healthcare products Regulatory Agency (MHRA) device bulletin “Managing Medical Devices - Guidance for Healthcare and Social Services Organisations” (2014)
- Medical laboratories — Requirements for quality and competence (ISO 15189:2012)
- Point of care testing (POCT) — Requirements for quality and competence (ISO 22870:2006)

2 Policy Scope

2.1 The policy applies to medical devices used within the Trust including devices used in Community Services premises and devices supplied via the Trust for use by patients in their own homes.

2.2 All medical devices purchased through Trust capital funds, department revenue budgets, public donations, lease purchase, hire, loan, consumable agreements and gifts come under the guidance of this policy.
2.3 This policy is intended for all Trust managers, healthcare professionals, support workers and maintenance staff who are accountable for ensuring that they interact with medical devices in a safe and effective manner.

2.4 This policy does not include the Joint Loan Equipment Services, a partnership between the Trust and Newcastle City Council which provides devices and equipment for use by people within their homes, e.g. hoists, mattresses, bathing aids, etc. Equipment provided by this department is classified as a medical device and the Joint Loan Equipment Service has robust procedures in place for the procurement, purchase, issue, maintenance, repair, decommissioning and disposal of equipment. Staff who access this Service must follow local procedures.

3 Aim of the Policy

The aim of this policy is to provide guidance on medical device management issues so staff can deal effectively with and comply with relevant legislation, organisational rules and good practice; the purpose of which is to ensure that risks associated with the use of medical devices are minimised and that medical devices are fit for purpose, maintained appropriately and operated in accordance with instructions by staff with appropriate knowledge and necessary competency in order to minimise risk and maximise safety for all concerned.

4 Duties – Roles and Responsibilities *(Appendix 01)*

4.1 Chief Executive and Trust Board

The Chief Executive and Trust Board have responsibility for the safety and welfare of all Trust patients, visitors and staff. This includes overall responsibility for medical devices used within the Trust.

4.2 Medical Devices Steering Group

This group reports via the Clinical Risk Group to the Trust Board, and is responsible for developing, implementing and monitoring compliance with this policy to ensure best practice. The group is required to produce an annual report and action plan on the efficacy of the Trust’s Medical Device Management Policy. See Medical Devices Steering Group “Terms of Reference” *(Appendix 02)*.

4.3 Supplies Manager

The Supplies Manager has responsibility to ensure compliance with Trust Standing Orders, Legal Obligations and European Legislation in respect of tendering and contract procedure, to ensure compliance with guidance, codes of conduct and good practice in respect of the procurement and supply of medical devices and any associated maintenance contracts.
4.4 Clinical Governance & Risk Department (CGARD)

The CGARD Department is responsible for overseeing incident and near miss reporting involving medical devices and for disseminating CAS Alerts throughout the Trust via a nominated Medical Devices Safety Officer.

4.5 Director of Estates and Facilities

The Director of Estates and Facilities has the delegated responsibility for the maintenance and repair of medical devices within the Trust. In practice, this responsibility is delegated to the Head of EME Services and the Hospital Engineering Officer.

4.6 Sterile Services

The Directorate Manager of Perioperative & Critical Care has delegated responsibility for the decontamination of re-usable medical devices and is responsible for ensuring that the risks associated with decontamination facilities and processes are well managed in accordance with the relevant regulations.

4.7 Point Of Care Testing (POCT) Committee

The Point Of Care Testing (POCT) Committee is a sub group of the Medical Devices Steering Group chaired by the Point Of Care Testing Manager. The POCT Committee has responsibility for all performance issues relating to POCT devices within the Trust and reports to the Medical Devices Steering Group.

4.8 Medical Device Safety Officer

All Trust's must nominate a Medical Device Safety Officer to the Medical and Healthcare products Regulatory Agency (MHRA). This person is responsible for ensuring there is effective reporting and response to adverse incidents involving medical devices and acting as the Trust contact for a national collaborative. This role is undertaken by the Clinical Governance & Risk Department (CGARD).

4.9 Ward/Department Managers

Ward/Department Managers are responsible for the safe and effective use of all medical devices within their area and are responsible for ensuring that adequate physical, procedural and training controls are in place to control the risks from the use of medical devices in their areas of responsibility. They must ensure that all staff using medical devices are aware of the potential risks from the device and were necessary are trained/competent in its safe use. Managers must ensure that all staff identified as using or maintaining medical devices comply with this policy.
4.10 All Staff

All staff have a legal duty to take care of their own safety and that of others when using medical devices. It is the responsibility of individual members of staff to ensure that they are conversant with the content of this policy and are appropriately trained and competent to use the medical devices that they are required to use as part of their duties.

5 Definition of a Medical Device

For the purpose of this policy the term “Medical Device” encompasses devices as defined in *MHRA Bulletin 17 “Medical Devices and Medicinal Products”* (amended August 2009) and can be summarised as:

“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 a disease or disability
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means” *(For examples see Appendix 03).*

6 Selection Process and Standardisation Approach

6.1 The Trust, wherever practical, operates a standardisation approach with regard to the purchase of common ward based medical devices. This ensures that unless there are valid clinical or technical reasons, similar and up to date models of equipment from the same supplier are purchased in order to ensure:

- Improved quality and safety of healthcare
- Ease of user training
- Reduction in risk due to users being familiar with equipment type
- Availability of in-house expertise and ease of servicing
- Cost benefits in terms of purchase of equipment and consumables
- Cost reduction if equipment is to be placed on external contract
- Rapid issue of equipment from the Medical Equipment Loan Library in the event of a major incident.

6.2 Reference should be made to the following policies and procedures:

- Medical Devices Procurement Policy
7 Procurement Process

7.1 All medical devices must be procured via the Trust Supplies Department.

7.2 The Trust has a properly planned approach to the purchase of medical devices taking into account the needs and preferences of health care professionals and end-users. Medical Devices will be selected according to clinical based specifications. POCT devices must be selected in conjunction with the Trust Point of Care Testing Officer.

7.3 The following factors will be considered during the selection process:
   - Clinical need
   - Clinical suitability
   - Whole life costs
   - Maintenance processes
   - Decontamination processes
   - Cost and availability of consumables
   - Cost and availability of spare parts
   - Supplier product support
   - User and service training provision.

7.4 Reference should be made to the following policies and procedures:
   - Medical Devices Procurement Policy

8 Asset Management

8.1 The identification of assets is the starting point for all asset management. It is vital that the Trust has an accurate asset inventory inclusive of medical devices, this forms the basis from which medical device management is developed including ensuring appropriate maintenance is identified/implemented and enabling efficient identification of devices which are subject to a MHRA Safety Action Bulletin or manufacturer recall. It should be recognised that audit and financial management requirements are also satisfied during this process.

8.2 An inventory of all reusable medical devices and equipment is kept by the Trust. All medical devices are added to the Works Information Management System (WIMS) which is managed by the Trust Asset Management Team based within the Estates & Facilities Directorate.

8.3 To ensure that all new medical devices, whether purchased, leased, donated, hired or presented as a gift are safe and fit for purpose, all medical devices will be subject to a formal acceptance and commissioning procedure by the Electronics & Medical Engineering Department or the Estates Department in line with MHRA device bulletin Managing Medical Devices - Guidance for Healthcare and Social Services Organisations.

8.4 Where medical devices are transferred from/to other wards / departments / community premise the Trust Asset Register must be updated to reflect the change and to ensure the continuity of any necessary maintenance. In such
cases the Estates Asset Management Team should be contacted for assistance. **This does not include short-term loan in an emergency situation.**

8.5 Reference should be made to the following policies and procedures:
- Medicines and Healthcare products Regulatory Agency (MHRA) device bulletin “Managing Medical Devices - Guidance for Healthcare and Social Services Organisations”

9 **Medical Devices Commissioning**

9.1 All devices should be checked prior to first use in line with MHRA guidance Managing Medical Devices - Guidance for Healthcare and Social Services Organisations. Whenever a medical device needs to be commissioned, this may only be done by a competent agent, e.g. Trust Estates or Electronic & Medical Engineering Departments and/or the manufacturer / supplier / contractor. Checks should include:

- checking that the correct product, complete with usage and maintenance information and any relevant accessories, has been supplied

- ensuring that devices have been delivered in good condition and, where relevant, in good working order, this may include:
  - Visual inspection
  - Functional check
  - Electrical Safety test (where necessary)
  - Calibration and measurement (where necessary)

9.2 With the exception of surgical instruments all devices will be recorded on the Trust Asset Register and a label bearing a unique asset ID number will be affixed to the device, for example:

9.3 A member of the user department will be required to sign for the receipt of the device and associated user instructions, this form will be retained by EME as part of the device’s service record.

9.4 If the device is to be introduced to the user area for the first time then training and competency assessment will be required and will normally be provided by the manufacturer. Only upon satisfactory completion of this training and competency assessment can the device be put into use.

9.5 Reference should be made to the following policies and procedures:
10 Training and Competency Assessment

10.1 Healthcare professionals use medical devices themselves and may provide devices which are then used by others, e.g. patients or their carers. The need to ensure that all those using devices are competent to do so cannot be overstressed. Managers and staff have a responsibility to ensure, where necessary, competencies are set, checked and maintained. This includes regularly checking if update or refresher training is needed via supervision and appraisal/KSF review.

10.2 It is the Trust’s aim to ensure all staff using medical devices are competent in their use. To be competent is to be adequately trained, knowledgeable and capable of operating a device in a safe, effective and correct manner. Education and training is essential to ensure that users of medical devices have appropriate knowledge and skills to operate medical devices.

10.3 Staff must have completed agreed practice, be adequately trained, knowledgeable and capable of operating a device and where necessary, be deemed competent through self-assessment or by a supervisor/trainer to operate independently.

10.4 It is the responsibility of the ward/department manager to assess all new staff, regardless of experience, as part of their local induction to establish their training needs.

10.5 Staff beginning employment with the Trust must complete the Trust corporate induction programme where the following medical device related topics will be covered:
- Clinical Risk.
- Health & Safety
- Infection Control
- Reporting procedure for adverse incidents
- Safe lifting & handling

10.6 Device training should be provided by a practitioner competent in the functions and operations of the device. Competency assessment tools and further guidance is available on the Trust Intranet - EME Loan Library intranet site.

10.7 When a new medical device is introduced into an area, staff should receive training or instruction and where agreed competency assessment before using the equipment unsupervised.
10.8 Should a member of staff be unable to demonstrate competence, their ward/department manager must arrange re-training before the individual can operate the medical device in a clinical environment.

10.9 In the event of the appropriate training being unavailable from any source, the ward/department manager must raise this with their Directorate Manager. This must be identified as a risk and included on the Trust risk register. Until the issue has been resolved or rectified the device must not be used.

10.10 The ward/department manager must maintain records of staff training and dates for re-training relating to all medical devices used within that area. These records must be reviewed annually to ensure they are valid and up to date for audit/inspection purposes.

10.11 If a medical device is to be used by patients and/or carers (without direct supervision by a health professional) the following should be considered in the competency assessment (see section 11.3 below):
- Physical capabilities, e.g. manual dexterity
- Sensory capabilities, e.g. vision, hearing, language
- Ability to understand and remember
- Previous experience with the device
- The patient’s or carer’s expectations
- The environment in which the device will be used.

10.12 Reference should be made to the following policies and procedures:
- Induction Policy
- MHRA Checklist for patients discharged from hospital with a medical device (Appendix 08)
- Risk Register – Management and Use Policy.
- Training in the Safe Use of Medical Devices Policy

11 Use of Medical Devices

11.1 This policy aims to support safe practice and does not constrain clinical autonomy what so ever, clinical judgement is to be exercised at all times and as such, clinical need/emergency situations may over ride this policy. In exercising professional judgement, any alteration from this policy must be preceded by a fully documented risk assessment. This is important for legal accountability.

11.2 All medical device selection decisions must only be taken by staff who are appropriately trained and qualified. Devices must be chosen to best meet the requirements of the intended medical procedure or needs of the end user. All users must ensure that a medical device is only used for the purpose for which it was manufactured and not for any other purpose unless preceded by a fully documented risk assessment (Appendix 12).

11.3 Good clear instructions have a crucial role in the safe and effective use of a medical device. It is the responsibility of the ward/department manager to
ensure that instruction manuals are available for each medical device used within their area and that they are readily accessible to all users.

11.4 Where a patient or carer is to use a medical device, without direct supervision by a health professional, details must be held of who instructed them in the use of the particular device and, wherever practical, what guidance was given. In certain instances the device manufacturers may be involved in providing training. In addition, where manufacturer’s instructions are passed on to patients or carers, Trust staff must ensure these are explained and understood, and that records are held accordingly. It is the responsibility of the member of staff providing the medical device to provide communication support where required, to ensure the patient or carer fully understands the use of the medical device. This also applies to the provision of medical devices that require informed consent, for example in relation to contraceptive devices (Appendix 08).

11.5 Users must refer to the manufacturer’s instructions for details of how the device should be used, which consumables are suitable for use with a device, any contraindications and for whom it is suitable.

11.6 Users have a responsibility to carry out routine checks, in line with the manufacturer's instructions, to ensure that the device continues to function correctly including:
- Pre-use checks to ensure the device is working correctly
- Regular cleaning
- Specified daily/weekly checks (e.g. Quality control (QC)/Quality assurance (QA) regimes for POCT devices)
- Reporting faults or damage and discontinuing use (Appendix 11)
- Battery charging.

11.7 Users have a responsibility to routinely monitor medical devices while in use, following local guidelines as appropriate.

11.8 After use, staff must ensure that all re-usable medical devices are cleaned and stored safely ready for their next use. Single use medical devices and any consumables used in conjunction with medical devices should be disposed of in line with the Trust Waste Management Policy.

11.9 Privately owned medical devices - a patient may wish to use his or her own medical device while in hospital. Privately owned medical devices must be subject to an Electrical Safety test by the Electronics & Medical Engineering Department or Estates Department before use on Trust premises.

11.10 Reference should be made to the following policies and procedures:
- Cleaning & Disinfection Procedure
- MHRA Checklist for patients discharged from hospital with a medical device (Appendix 08)
- Oxygen Management Policy.
- Procedure to Identify Equipment for Repair (Appendix 11)
12. Medical Device Decontamination

12.1 It is the responsibility of the Trust to ensure that patients, visitors, and staff are not put at risk by unnecessary exposure to biological, chemical, or radioactive hazards. The Trust has a duty to ensure, where necessary, decontamination of any medical device is carried out before re-use, submission for maintenance/repair, or before being transported to another location.

12.2 Decontamination is the combination of processes, which may include cleaning, disinfection, and sterilisation, used to render a reusable item safe for further use on patients and handling by staff.

The Trust Decontamination Group is responsible for ensuring that decontamination facilities and processes for re-usable devices, (e.g. surgical instruments/endoscopes), are managed and validated in accordance with the relevant requirements of The Health & Social Care Act 2008 - Code of Practice for Health and Social Care on the Prevention and Control of Infections and related guidance, Health Technical Memorandum 01-01: The Decontamination of Reusable Medical Devices and Department of Health (CFPP 01-01) (2013) “Management and decontamination of surgical instruments (medical devices) used in acute care”.

12.3 Reference should be made to the following publications, policies and procedures:

- Cleaning & Disinfection Procedure
- Cleaning and Disinfection of Endoscopes Policy
- Clostridium difficile infection (CDI) Management Policy
- Control of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeldt-Jacob Disease (CJD), in the hospital and community setting
- Decontamination of Healthcare Equipment Prior to Service or Repair
- Decontamination of the Patient Environment (including Terminal & Deep Cleaning)
- Infection Prevention & Control Practice in the Operating Department
- Standard Precautions Policy

12.4 Special arrangements may need to be made for medical devices that form part of an investigation as a result of an accident or serious incident. Refer to the Policy for Management and Reporting of Accidents and Incidents and seek advice from CGARD and the Control of Infection Department if required.

13 Single Use and Single Patient Use Medical Devices

13.1 Single-use means any medical device that is intended to be used on an individual person during a single procedure and should then be disposed of appropriately. It is Trust policy that single use devices must never be reused or reprocessed.
13.2 A single-use device is **NOT** intended to be re-used or reprocessed for another procedure, even if that procedure is on the same patient, as the reuse/reprocessing of single use devices can affect their safety, performance and effectiveness, exposing patients to unnecessary risk (Appendix 09).

13.3 The symbol below indicates single-use only and is used on medical device packaging indicating ‘do not reuse’ and may replace any wording. Some single-use devices are marketed as non-sterile and require processing to make them sterile and ready for use. The manufacturer of the device will include appropriate processing instructions to make it ready for use. Every item labelled with a single-use symbol must always be disposed of after use in accordance with Trust Waste Management policy. (Symbol reproduced from BS EN 980:2003 ‘Graphical symbols for use in the labelling of medical devices’)

13.4 **Single Patient Use** means any medical device that is intended to be reused by **ONE patient** and must always be disposed of after that patient use (e.g. Oxygen Mask).

13.5 Reference should be made to the following publication:


14 Medical Device Maintenance and Repair

14.1 It is a duty of the Trust to ensure that medical devices are adequately maintained/repaired and therefore fit for purpose. The Trust recognises the benefits of providing in-house service support for medical devices via the Electronics & Medical Engineering Department and Estates Department. These departments are responsible for managing the maintenance and repair of all medical devices throughout their lifecycle, from acceptance testing of new devices to the disposal of redundant devices.

14.2 The Head of EME Services and the Senior Hospital Engineer have delegated responsibility for ensuring that arrangements are in place to provide appropriate servicing regimes for the maintenance/repair of medical devices and that action regarding MHRA Safety Action Bulletins, manufacturers’ recalls, updates and modifications are carried out when required.

14.3 Medical Devices used in the Community and some specialist hospital based equipment can prove to be more effectively maintained by manufacturers, suppliers or third party agents, in such cases depending upon the type of equipment, the Electronics & Medical Engineering Department or Estates...
Department, will approve maintenance contracts and liaise with users and the Supplies Department to provide the most appropriate cover.

14.4 Reference should be made to the following policies and procedures:

- Community Services – Medical Device Helpdesk Flowchart (Appendix 10)
- Decontamination of Healthcare Equipment following patient use and/or Prior to Service or Repair
- Decontamination of the Patient Environment (including Terminal & Deep Cleaning)
- Medical Devices Procurement Policy
- Medicines and Healthcare products Regulatory Agency (MHRA) device bulletin “Managing Medical Devices - Guidance for Healthcare and Social Services Organisations”
- Procedure to Identify Equipment for Repair (Appendix 11)

15 Condemnation and Disposal of Medical Devices

15.1 Having established that the Trust has no further use for a medical device, orderly disposal is vital from a financial, data protection and waste management objective.

15.2 Regardless of the method of disposal, medical devices can only be disposed of through the Electronics & Medical Engineering Department, Estates Department or Supplies Department; under no circumstances will users dispose of or negotiate the sale of surplus/redundant medical devices.

15.3 Once agreement regarding condemnation and disposal has been reached the Electronics & Medical Engineering Department and the Estates Department, have the authority to issue a “Replacement/Redundant Equipment Report” and remove the item from the Trust Asset Register (Appendix 05).

- Medical Devices EME Department
- Computer Hardware IT Department
- Domestic Appliances Estates Department
- Beds and Trolleys Estates Department
- Laboratory Equipment Estates or EME Department depending on who maintains the particular item.

15.4 Prior to disposal, the user must ensure the device is clean and a decontamination certificate, which can be obtained from the Estates Department or the Electronics & Medical Engineering Department, is completed to accompany the device for disposal.

15.5 Disposal of medical devices will be carried out in compliance with all applicable legislation with regard to waste management. Disposal of medical devices will be subject to the Waste Electrical and Electronic Equipment (WEEE) Directive.

15.6 Reference should be made to the following policies and procedures:
16 In House Manufacture/Modification

16.1 Any in-house modification of a medical device potentially compromises its safety and must only be carried out by authorised personnel following consultation with the manufacturer and a full risk assessment. Before a decision is made to adapt/modify a device all reasonable alternatives should be considered and the rationale for the modifications documented using the risk assessment template (Appendix 12).

16.2 In-house manufacture of medical devices is permitted under MHRA guidance. Before in-house devices are used with patients, the risk assessment template (Appendix 12) should be completed, and permission sought from the Medical Director.

16.3 Reference should be made to the following policies and procedures:
   - Risk Register – Management and Use Policy
   - MHRA: In-house manufacture

17 Medical Equipment Loan Library

17.1 A Medical Equipment Loan Library is provided on the RVI and Freeman sites and is responsible for the management of all common use medical devices. The library provides these medical devices for short-term loan, however high risk areas such as Intensive Therapy Units retain an agreed core stock level.

17.2 The Trust Intranet has a Medical Equipment Loan Library Website, which shows the range of equipment available, user instructions, staff contact details and opening times. Equipment can be requested by contacting the relevant Equipment Library (during opening hours) and through the Portering Service out of hours.

17.3 Equipment is cleaned, checked and internal batteries charged prior to issue; however, it remains the users responsibly to ensure that the device is suitable for its intended use.

17.4 Reference should be made to the following policies and procedures:
   - Medical Equipment Library – Access to Service.
18 Medical Devices On Loan to the Trust

18.1 It is common practice for medical devices to be brought into the Trust on loan, they may be:

- On trial or evaluation
- Provided for research
- To replace devices that are being repaired
- Provided as part of a disposable procurement arrangement
- From another Trust.

18.2 Medical devices loaned to the Trust are subject to the same risks concerning patient and user safety and must therefore be managed appropriately. The supplier must indemnify any device before it can be used within the Trust.

18.3 All loan devices must be reported to the Electronics & Medical Engineering Department, safety tested and included on the Trust loan equipment register before entering into service.

18.4 All loan devices must only be used by staff who have been trained in the use of the equipment. If a representative from the supplier is to demonstrate the device then it is assumed that adequate and appropriate training, and where necessary competency assessment, will be provided for the device users. If no representative is to be present then the ward/department managers must satisfy themselves that adequate user instructions are available to allow for the safe use of the device. In case of doubt, the supplier is to be contacted.

18.5 All loaned items being returned to a manufacturer/supplier must be cleaned / decontaminated prior to release.

18.6 Reference should be made to the following policies and procedures:

- Decontamination of Healthcare Equipment following patient use and/or Prior to Service or Repair
- EME-P-04 Medical Devices – On Loan (Appendix 07)
- Handling of Surgical Instruments On Loan.

19 Accident or Incident Reporting Involving A Medical Device

19.1 The Trust actively supports the promotion of a positive and non-punitive approach to incident reporting. The system for reporting accidents and incidents to patients, staff or visitors is clearly written in Trust policy “Management and Reporting of Accidents and Incidents” accessible to all staff via the Trust intranet.

19.2 Accident and incident reporting ensures that incidents involving medical devices are promptly recorded and this information along with the evidence of actions taken enables the Trust to identify areas for improvement.

19.3 Any medical device that was involved in an incident should be isolated until either the EME Services Officer – Electronics & Medical Engineering
Department or the Senior Hospital Engineer - Estates Department, has reviewed it. Where possible photographs should be taken to support analysis of the incident.

19.4 Where an incident involves a medical device:

- Do not alter any dials or settings
- Record the setting for future reference
- Retain any disposables e.g. giving sets, in a yellow bio-hazard bag within a sealed and clearly labelled clear polythene bag
- Isolate the device in an area where it cannot be accessed by staff who may inadvertently put the equipment back into service
- Do not allow the device to be returned to the manufacturer without the clear agreement of the Electronics & Medical Engineering Department, Estates Department, Health and Safety Department or CGARD.

19.5 Reference should be made to the following policies and procedures:

- Being Open Policy
- Management and Reporting of Accidents and Incidents Policy

20 Safety Alerts (Central Alert System)

20.1 The Trust has a nominated Medical Device Safety Officer, attached to the Clinical Governance and Risk Department (CGARD), who is responsible for the rapid distribution of Estates and Facilities Notices, Medical Device Alerts and Field Safety Notices including those received from the Medicines and Healthcare products Regulatory Agency (MHRA) and other bodies including the NHS Improvement.

20.2 The Medical Device Safety Officer maintains a record of all alerts, monitors and reports on the implementation of necessary action if required and records when required actions are complete.

20.3 Reference should be made to the following publications, policies and procedures:

- Central Alert System (CAS) Policy and Procedure
- MHRA DB2011(01) Reporting Adverse Incidents and Disseminating Medical Device Alerts.

21 Mobile Phones

21.1 Mobile phone use should be restricted in medical treatment areas on Trust premises as they can interfere with the operation of medical devices.

21.2 Reference should be made to the following publications, policies and procedures:

- Use of Mobile Telephones and Personal Computing Devices within Trust Premises Policy.
22 Equality and Diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This policy has been appropriately assessed.

23 Monitoring the Compliance/Effectiveness of this Policy

The Clinical Risk Group will receive the quarterly updates and an Annual report from the Medical Devices Steering Group meetings.

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24 Consultation And Review Of This Policy

This policy has been reviewed in consultation with the members of the Medical Device Steering Group.
25 Implementation of Policy (Including Raising Awareness)

This policy will be promoted electronically via the Trust New and Updated Policies Newsletter.

26 References

- Department of Health (2010) “Health Technical Memorandum 01-01: The Decontamination of Reusable Medical Devices”
- Department of Health (CFPP 01-01) (2013) “Management and decontamination of surgical instruments (medical devices) used in acute care”
- Medical Devices Agency (2002) “SN2002(17): Management of loaned medical devices, equipment or accessories from manufacturers or other hospitals”

27 Associated Documentation

- Being Open Policy
- Central Alert System (CAS) Policy
- Cleaning & Disinfection Procedure
- Cleaning and Disinfection of Endoscopes Policy
- Clostridium difficile infection (CDI) Management Policy
- Control of Transmissible Spongiform Encephalopathies (TSEs), including
Creutzfeldt-Jacob Disease (CJD), in the hospital and community setting

- Decontamination of Healthcare Equipment following patient use and/or Prior to Service or Repair
- Decontamination of the Patient Environment (including Terminal & Deep Cleaning)
- Handling of Surgical Instruments On Loan
- Induction Policy
- Infection Prevention & Control Practice in the Operating Department
- Management and Reporting of Accidents and Incidents Policy
- Medical Devices Procurement Policy
- Medical Equipment Library – Access to Service
- Oxygen Management Policy
- Risk Register – Management and Use Policy
- Standard Precautions Policy
- Training in the Safe Use of Medical Devices Policy
- Use of Mobile Telephones and Personal Computing Devices within Trust Premises Policy
- Waste Management Policy
Appendix 01

ROLES AND RESPONSIBILITIES

- Overall responsibility

- Ensure policy/framework in place to manage risks from medical devices

- Ensure risks from devices are effectively managed
  - Training is available to staff

- Ensure local protocols in place to use devices safely
  - Ensure staff are appropriately trained

- Maintain inventory of devices
  - Maintain/repair devices

- Uses devices properly
  - Ensure training is complete
  - Ensure training and information available to end users/carers
  - Report defects

- Use devices properly
  - Report defects

- Audit systems
- Formal reporting of defects
- Input to risk register

CHIEF EXECUTIVE

MEDICAL DEVICE STEERING GROUP

DIRECTORATE MANAGERS

WARD / DEPARTMENT MANAGERS

CLINICAL GOVERNANCE & RISK DEPARTMENT (CGARD)

ESTATES & FACILITIES DIRECTORATE

INDIVIDUAL STAFF MEMBERS

USER/ CARER

(may not always be end user)
Appendix 02

Medical Devices Steering Group

Terms of Reference

Purpose

The Medical Devices Steering Group will be an official subcommittee of the Clinical Risk Group. It will oversee the development and implementation of the Trusts’ Medical Devices management systems.

The Medical Devices Steering Group will be responsible for ensuring the trust meets the requirements of the Care Quality Commission’s standards and Medicines and Healthcare products Regulatory Agency (MHRA) requirements for medical devices.

Terms of Reference

The establishment of a Medical Devices Steering Group will improve communication on medical device issues within the Trust.

The Medical Devices Steering Group will identify and implement strategies as required to meet the standards on medical devices set by the MHRA and the Care Quality Commission.

The Medical Devices Steering Group will ensure that the Trust’s medical devices management arrangements conform to current legislation and guidance.

The Medical Devices Steering Group will monitor the training and education of staff in medical devices, and medical device issues.

The Medical Devices Steering Group will identify areas of best practice – both within and outside the Trust - and seek their wider implementation across the service; this will encourage improvements in working practices, thereby reducing risk to patients.

The Medical Devices Steering Group will meet bi-monthly.

A Trust Management representative will chair the Medical Devices Steering Group.

Three members of the group will constitute a quorum. Deputies may be appointed to represent members who are unable to attend.

Other Trust staff may be co-opted onto the group when necessary, or may be asked to provide expert advice and help on specific issues that may arise.

The Medical Devices Steering Group will submit reports and action plans to the Clinical Risk Group.

The terms of reference will be reviewed annually in order to monitor the performance and effectiveness of the group.
### Appendix 03

**Common Categories of Medical Device**

*(Extract from the MHRA’s guidance ‘Equipped to Care’)*

The list below is not comprehensive but gives a sense of the wide range of products that are considered medical devices.

<table>
<thead>
<tr>
<th>Equipment used for diagnosis or treatment of disease, or monitoring of patients, such as:</th>
<th>Equipment used in the care of disabled people, such as:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Syringes and needles</td>
<td>• External prostheses and orthoses</td>
</tr>
<tr>
<td>• Dressings</td>
<td>• Wheelchairs and associated postural seating</td>
</tr>
<tr>
<td>• Catheters (urinary, cardiac)</td>
<td>• Patient hoists</td>
</tr>
<tr>
<td>• Surgical instruments</td>
<td>• Walking aids</td>
</tr>
<tr>
<td>• Endoscopes</td>
<td>• Pressure relief equipment</td>
</tr>
<tr>
<td>• IV administration sets and pumps</td>
<td></td>
</tr>
<tr>
<td>• Patient monitoring equipment, e.g. Cardiac monitors</td>
<td></td>
</tr>
<tr>
<td>• Anaesthetic equipment</td>
<td></td>
</tr>
<tr>
<td>• Surgical implants, e.g. orthopaedic prostheses, bone cements, heart valves</td>
<td></td>
</tr>
<tr>
<td>• Power implants, e.g. pacemakers, implantable defibrillators</td>
<td></td>
</tr>
<tr>
<td>• Ultrasound imagers and CT / MR scanners</td>
<td></td>
</tr>
<tr>
<td>• Radiotherapy equipment</td>
<td></td>
</tr>
<tr>
<td>• Dental equipment and materials</td>
<td></td>
</tr>
<tr>
<td>• Ophthalmic equipment</td>
<td></td>
</tr>
<tr>
<td>• Chiropody equipment</td>
<td></td>
</tr>
<tr>
<td>• Sphygmanomaneters</td>
<td></td>
</tr>
<tr>
<td>• Thermometers</td>
<td></td>
</tr>
<tr>
<td>• Physiotherapy equipment</td>
<td></td>
</tr>
<tr>
<td>• Beds, mattresses and covers</td>
<td></td>
</tr>
<tr>
<td>• Examination gloves</td>
<td></td>
</tr>
<tr>
<td><strong>Equipment used in life support, such as:</strong></td>
<td></td>
</tr>
<tr>
<td>• Ventilators</td>
<td>• Stretchers and trolleys</td>
</tr>
<tr>
<td>• Defibrillators</td>
<td>• Resuscitators</td>
</tr>
<tr>
<td><strong>In vitro diagnostic medical devices and their accessories, such as:</strong></td>
<td></td>
</tr>
<tr>
<td>• Blood gas analysers</td>
<td><strong>Other examples of medical device include:</strong></td>
</tr>
<tr>
<td>• Blood glucose measuring devices</td>
<td>• Condoms</td>
</tr>
<tr>
<td>• Hepatitis and HIV test kits</td>
<td>• Contact lenses and care products</td>
</tr>
<tr>
<td>• Urine test strips</td>
<td>• Intra-uterine devices (IUDs)</td>
</tr>
<tr>
<td>• Pregnancy test kits</td>
<td><strong>The MHRA are also interested in products which, whilst not themselves medical devices, are used in close conjunction with these devices, e.g.:</strong></td>
</tr>
<tr>
<td>• Specimen collection tubes</td>
<td>• Centrifuges</td>
</tr>
<tr>
<td></td>
<td>• Blood tissue storage systems</td>
</tr>
<tr>
<td></td>
<td>• Fluid warming cabinets</td>
</tr>
<tr>
<td></td>
<td>• Disinfecting and sterilising equipment, e.g. bench top sterilisers</td>
</tr>
</tbody>
</table>
1. Introduction
The Electronics & Medical Engineering Department has a duty to ensure that new medical devices are processed in accordance with MHRA device bulletin DB2006(05) "Managing Medical Devices." Devices should be delivered to the end user fully documented, labelled and in safe working order. This procedure details the tests and documentation prior to the equipment's delivery to the user department.

2. Equipment process
New equipment is delivered to the Electronics Department from the hospital Main Store. It may be necessary to arrange to have large items taken directly to the user department where the acceptance process will take place. The equipment will be unpacked, examined for transit damage and checked against the delivery note and purchase order. The goods should be booked into the Supplies Department good receipt system and the purchase order is attached to the Field Service Report and filed "awaiting manpower". Any discrepancies or damage must be reported to the supplier immediately and goods will be placed in "quarantine" until all outstanding issues have been resolved.

3. Testing and documentation
In some circumstances, as part of the purchase agreement, a representative of the supplier can commission the equipment. Where no provision has been made for a company representative to commission the new equipment, the EME technician carrying out the acceptance tests will:

- Check that what was ordered has been received, and is complete
- Check boxes and goods for physical damage
- Check all accessories are intact and complete
- Assemble the equipment
- Ensure the mains voltage setting is correct
- Fit a mains plug if necessary
- Carry out an electrical safety check
- Carry out any relevant equipment type specific checks
- Calibrate the equipment as required
- Carry out functional checks
- Ensure the equipment is delivered to the end user with the controls set to default values for the intended application
- Enter the equipment details on the EME Equipment Management System
- Ensure the equipment details are entered on the WIMS asset database
- Fix an asset label to the equipment
- Fix new equipment label (ref: EME-L-03)
- Deliver the equipment and user manuals to the user and obtain a signature of receipt on the Field Service Report (ref: EME-F-30)
- Log any maintenance manuals or users instructions in accordance with procedure EME-P-11
- EME Services Officer should be made aware of all new equipment. It may be necessary to organise service training, service manuals, in house or manufacturer's preventative maintenance programmes.
THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST

NHS

REPLACEMENT / REDUNDANT EQUIPMENT REPORT

HOST NAME
DEPARTMENT
COMMENTS
DEL REF
DEL DATE
TO
FROM

PART A - DETAILS OF ITEM TO BE REMOVED FROM SERVICE

DESCRIPTION
MODEL
MANUFACTURER
ASSET
SERIAL NO
INTO SERVICE DATE

THE ABOVE EQUIPMENT IS TO BE REMOVED FROM SERVICE -

☐ Beyond economic repair
☐ Physically damaged beyond repair
☐ Unreliable
☐ Clinically or technically obsolete
☐ Spare parts are no longer available

SUPPORTING INFORMATION

AUTORISED

PART B - TO BE COMPLETED BY DEPARTMENT EQUIPMENT OFFICER

WILL THE ABOVE ITEM BE REPLACED? YES / NO

Authorised Signature........................................Print........................................

Designation........................................Date........................................

IF YES USE THIS FORM TO SUPPORT REQUISITION FOR REPLACEMENT EQUIPMENT. DEPARTMENT HEADS ARE REMINDED THAT A CAP3 FORM MUST BE SUBMITTED BEFORE CAPITAL EQUIPMENT CAN BE DELETED FROM THE ASSET REGISTER.

PART C - CAPITAL / REVENUE ASSET ADMINISTRATION

☐ Capital Asset
☐ Copy to user with CAP 3 form
☐ Copy to Asset Manager
☐ Revenue Asset
☐ Copy to user
☐ Deleted from Asset database

CAPITAL ASSET AUTHORISATION

PART D - METHOD OF DISPOSAL

☐ Be offered for sale or disposed of by the Supplies Department
☐ Be used by the Electronics Department for spare parts
☐ Be scrapped by the Electronics Department
☐ Remain in service whilst a replacement is purchased (maximum 6 months)
☐ Other:

THE ABOVE ITEM HAS BEEN MADE SAFE FOR RETENTION / DISPOSAL

SIGNED........................................PRINT........................................DATE........................................
1. **Introduction**
Medical devices that are considered beyond economic repair, redundant or surplus to the user requirement will be disposed of, or redistributed in an organised and safe manner. All such devices should be processed through the Electronics & Medical Engineering Department in accordance with EME-P-13 Field Service Report procedure.

2. **Equipment Beyond Economic Repair**
All equipment considered to be beyond economic repair should be assessed; taking into account age, general condition, cost of repair, cost of replacement, recommendations from suppliers and the impact of MHRA guidance. A Redundant/Replacement Equipment Report (ref: EME-F-08) should be produced via the asset register and obsolete manuals will be withdrawn from use, and the manuals register updated as appropriate.

3. **Redundant/Surplus Equipment**
Equipment that is no longer of use to the Trust may have a value to other organisations and will be offered for auction via a Trust appointed auction house. In such cases the Trust Supplies Manager should be notified in writing of the equipment for sale. EME Services Officers will be notified by the Supplies Department if/when the equipment has been sold.

4. **Administration**
A Redundant/Replacement Equipment report is required for all medical devices that are to be removed from the Trust asset register. The form will be authorised by a Deputy EME Services Officer and the ward/department manager.

For a revenue asset a copy of the form will be sent to the asset register team who will delete the asset from the Trust asset register. The disposal of a capital asset must be authorised by the EME Services Officer, who will countersign the report. A complete CAP 3 form must accompany the Redundant/Replacement Equipment Report and a copy of both forms will be sent to the asset register team. The asset team will be responsible for deleting the asset from the asset register.

The Deputy EME Services Officer will determine the most appropriate method of disposal and ensure the Redundant/Replacement Equipment Report is completed accordingly and signed by the technician responsible for ensuring the actions below.

The EME Services Officer will be responsible for keeping a signed original copy of the report.
5. **Preparing Equipment for Disposal**

The following precautions must be taken by the user before devices can be disposed of:

- remove all hazardous substances including chemical solutions, body fluids and radioactive isotopes. These should be disposed in accordance with Trust, local authority and COSHH regulations
- decontaminate the equipment and complete a decontamination form.

The following precautions must be taken by the Electronics & Medical Engineering Department before devices can be disposed of:

- remove all hazardous substances including oil, batteries and glassware. These should be disposed in accordance with Trust, local authority and COSHH regulations
- remove all asset labels
- hard disks **must** be wiped of all patient data or physically damaged beyond repair
- scrap equipment must be rendered useless to prevent unauthorised persons attempting to bring back to use
- equipment will be clearly labelled with the Redundant/Replacement Equipment Report reference number, date and any other relevant information.

The Electronics & Medical Engineering Department is responsible for disposing of equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive and all local authority and COSHH regulation.
Appendix 07

ELECTRONICS & MEDICAL ENGINEERING DEPARTMENT
PROCEDURE REF: EME-P-04
MEDICAL DEVICES - ON LOAN

1. Introduction

It is common practice for medical devices to be brought into the Trust on loan, they may be:

- On trial or evaluation
- Provided for research
- To replace devices that are being repaired
- Provided as part of a disposable procurement arrangement
- From other Trusts

Medical devices loaned to the Trust are subject to the same risks concerning patient and user safety and must therefore be managed appropriately.

2. Related documents

1. Standard Form of Indemnity (ref: EME-F-04)
2. Loan Equipment Label (ref: EME-L-01)
3. Register of Suppliers holding Master Indemnity Agreements

3. General procedure

All loan equipment should be delivered (preferably by the company representative) to the Electronics & Medical Engineering Department for checking and documentation prior to entering service. It may be necessary for some equipment that requires assembly at the point of use to be checked in the user department.

Details of the loan equipment and supplier will be entered on the Loan Equipment Register and the equipment will be allocated a reference number.

Electronics Department staff will check the equipment for electrical safety and if satisfactory a Loan Equipment Label will be attached.

The company representative will be asked to complete and sign a Standard Form of Indemnity and the Deputy EME Services Officer will sign on behalf of the Trust. This form will not be necessary if the supplier is on the Register of Suppliers holding Master Indemnity Agreements via PASA.

Every effort should be made to get indemnity cover; if this is not forthcoming, the equipment should not be allowed to enter service.

The Electronics & Medical Engineering Department must be informed when the device is returned to the supplier and the date of removal must be recorded on the
Loan Equipment Register.
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/carer know the name of the device?

- Does the patient/carer know how to set up the device in the home?

- Has the patient/carer been trained in the use and functions of the device?

- Has the patient/carer been provided with written instructions specifically about the device?

- Has the patient/carer been trained in how to deal with fail-safe features, e.g. alarms?

- Has the patient/carer been trained in the care of the device?

- Does the patient/carer require accessories? If so, does the patient/carer know where to obtain these and how often?

- Is maintenance required? If so, is the patient/carer aware and in possession of instructions about how this will be achieved?

- Does the patient/carer have a point of contact in the Trust for any queries?

- If relevant, does the patient/carer have a contact point in case of emergency?

Return

- Does the patient/carer know when to return the device?

- Does the patient/carer know where to return the device once treatment is complete, to whom and at what time?
Single-use medical devices

How do I know if a device is for single-use?

It will have this symbol on the packaging or the device:

Why shouldn’t they be reused?

The MHRA is aware of serious incidents relating to reuse of single-use devices.

Reuse can be unsafe because of risk of:
- cross-infection — inability to clean and decontaminate due to design.
- endotoxin reaction — excessive bacterial breakdown products, which cannot be adequately removed by cleaning.
- patient injury — device failure from reprocessing or reuse because of fatigue, material alteration and embrittlement.
- chemical burns or sensitisation — residues from chemical decontamination agents on materials that can absorb/adsorb chemicals.

Also, if you reuse a single-use device you may be legally liable for the safe performance of the device.

What does single-use mean?

Do not reuse. A single-use device is used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

Is single-patient use the same as single-use?

No. Single-patient use means the medical device may be used for more than one episode of use on one patient only; the device may undergo some form of reprocessing between each use.

Can I sterilize a single-use device?

A few single-use devices are marketed as non-sterile. These may require processing, in line with the manufacturer’s instructions, to make them sterile and ready for use. You must not resterilize them.
Transforming Community Services: Medical Device Helpdesk Flow Chart

Hours: 9:00am to 5:00pm Monday to Friday

- PATIENT WEIGHING SCALES
  James Grieves Ltd

- PATIENT HOISTS
  Care Ability Ltd

- PODIATRY CHAIRS/COUCHES
  RVI Estates/EME

- DENTAL EQUIPMENT
  Sunderland Dental Equipment Ltd

- ALL OTHER MEDICAL DEVICES
  TAG Medical Ltd

- Community Services Premises
  Staff Transferring to NUTH

- Campus for Ageing & Vitality (NGH) Wards & Departments
  Staff Transferring to NUTH

Requests via telephone for Medical Device faults

Daily feedback to RVI EME Manager
Procedure to Identify Equipment for Repair

Prior to inspection, service or repair (on or off site), it is essential that all medical devices and other healthcare equipment undergo an appropriate decontamination process following patient use and a “Declaration of Decontamination Status of Healthcare Equipment following Patient Use and/or prior to Service or Repair” form must be completed for each item. (See Declaration of Decontamination Status of Healthcare Equipment following Patient Use and/or prior to Service or Repair Policy/Procedure available from the Intranet).

If the equipment has been involved in an incident the DATIX reference number must also be recorded on this form.

All items for repair must be separated from use, and wherever possible, removed from the working environment. The completed “Declaration of Decontamination Status of Healthcare Equipment following Patient Use and/or prior to Service or Repair” form must be attached to the device to indicate that the device is faulty.

On completion of the repair, the equipment can be returned to use / storage location following any necessary pre-use checks.

This procedure does NOT apply to surgical instruments - for further information regarding instruments refer to the local Instrument Sharpen/ Repair Cycle procedure.
Please select from the drop-down list the Hospital Site:  
Please select from the drop-down list the relevant Hospital Area:  
Please enter the Department / Ward Name:  

Please describe the task / process to be assessed in the box below:  

Please check the relevant hazard types from the list below:  
- [ ] Workplace  
- [ ] Physical  
- [ ] Equipment  
- [ ] Substances  

For each of the Hazard Types checked above, check the specific hazard from the appropriate list below:  

<table>
<thead>
<tr>
<th>Workplace</th>
<th>Physical</th>
<th>Equipment</th>
<th>Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slips, Trips &amp; Falls</td>
<td>Violence &amp; Aggression</td>
<td>Medical Devices</td>
<td>COSHH</td>
</tr>
<tr>
<td>Temperatures</td>
<td>Noise</td>
<td>Lifting Equipment</td>
<td>Body Fluids</td>
</tr>
<tr>
<td>Lighting</td>
<td>Vibration</td>
<td>Workplace Transportation</td>
<td></td>
</tr>
<tr>
<td>Ventilation</td>
<td>Radiation</td>
<td>Machinery</td>
<td></td>
</tr>
<tr>
<td>Access / Egress</td>
<td>Manual Handling</td>
<td>Hand tools</td>
<td></td>
</tr>
<tr>
<td>Storage</td>
<td>Repetitive Work</td>
<td>Electrical Equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Needlestick Injury</td>
<td>Display Screen Equipment</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Pressure Vessels</td>
<td></td>
</tr>
</tbody>
</table>

Please explain the hazard in detail in the free text box below:  

Please select the groups potentially at risk:  
- [ ] Nursing Staff  
- [ ] Administrative / Clerical Staff  
- [ ] Patients  
- [ ] Visitors / Relatives  
- [ ] Portering / Ancillary Staff  
- [ ] Medical Staff  
- [ ] Professional allied with Medicine  
- [ ] Other  

If Other is checked, please specify:  

Please check the existing control measures in place:  
- [ ] Laboratory Coat  
- [ ] Safety Goggles  
- [ ] First Aid
Please explain current control measures in the text box below:


Please list any further control measures in the text box below:


Please calculate the risk rating

<table>
<thead>
<tr>
<th>Severity Rating</th>
<th>Frequency Rating</th>
<th>Risk Rating (Severity multiplied by Frequency)</th>
</tr>
</thead>
</table>

Please enter into the section below recommendations, who these recommendations should be actioned by and the date by which the recommendations should be implemented

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>To be actioned by:</th>
<th>Improvement Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Assessor Name:
Manager Name:
Completed Date:
Assessment Review Date:
### IMPACT ASSESSMENT – SCREENING

**Policy Title:** Medical Device Management Policy  
**Policy Author:** Jeff Stephenson, EME Services Manager

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the policy/guidance affect one group less or more favourably than another on the basis of the following: (* denotes protected characteristics under the Equality Act 2010)</td>
<td></td>
<td>This policy does not discriminate against any individual or group on the basis of race, ethnicity, nationality, gender, culture, religion, sexuality, age or disability.</td>
</tr>
<tr>
<td>• Race *</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Ethnic origins (including gypsies and travellers)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Nationality</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Gender *</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Culture</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Religion or belief *</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Sexual orientation including lesbian, gay and bisexual people *</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Age *</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Disability – learning difficulties, physical disability, sensory impairment and mental health problems *</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Gender reassignment *</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Marriage and civil partnership *</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is there any evidence that some groups are affected differently?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>If you have identified potential discrimination which can include associative discrimination i.e. direct discrimination against someone because they associate with another person who possesses a protected characteristic, are any exceptions valid, legal and/or justifiable?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Is the impact of the policy/guidance likely to be negative? (If “yes”, please answer sections 4(b) to 4(d)).</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>If so can the impact be avoided?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>What alternatives are there to achieving the policy/guidance without the impact?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Can we reduce the impact by taking different action?</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

**Comments:**

**Action Plan due (or Not Applicable):** N/A

**Name and Designation of Person responsible for completion of this form:** Jeff Stephenson, EME Services Manager  
**Date:** 09/07/2014

**Names & Designations of those involved in the impact assessment screening process:** Medical Device Steering Group

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)

---

For advice on answering the above questions please contact Frances Blackburn, Head of Nursing, Freeman/Walkergate, or, Christine Holland, Senior HR Manager. On completion this form must be forwarded electronically to Steven Stoker, Clinical Effectiveness Manager, (Ext. 24963) steven.stoker@nuth.nhs.uk together with the procedural document. If you have identified a potential discriminatory impact of this procedural document, please ensure that you arrange for a full consultation, with relevant stakeholders, to complete a Full Impact Assessment (Form B) and to develop an Action Plan to avoid/reduce this impact; both Form B and the Action Plan should also be sent electronically to Steven Stoker within six weeks of the completion of this form.

---

**IMPACT ASSESSMENT FORM A**  
October 2010