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Sussex Partnership
NHS Foundation Trust

Medical Devices Management Policy and Procedure

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Policy Author	Medical Device Safety Officer

Executive Summary

This policy and procedure details the trust arrangements for the management of medical devices throughout their lifecycles.

If you require this document in another format such as large print, audio or other community language please contact the Corporate Governance Team on: 0300 304 1195 or email: policies@sussexpartnership.nhs.uk

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Policy

2 Introduction

The trust recognises that there is a general duty under the Health and Safety at Work Act etc. 1974 to ensure the health, safety and welfare of patients and staff which includes where medical devices are being used in patient care.

These duties are prescribed further through other statutes including the Management of Health and Safety at Work Regulations, the Provision and Use of Work Equipment Regulations and the Lifting Operations Lifting Equipment Regulations.

Other recognised standards placing requirements for management of medical devices upon the trust include:

- MHRA Managing Medical Devices
- Institute of Physics and Engineering in Medicine (IPEM) Report 95 – Risk Management and its Application to Medical Device Management
- Care Quality Commission Standards
- National Institute of Clinical Excellence Guidelines

This policy applies to all medical devices that are of a type the trust has assessed and approved for use on its behalf, where devices have not been through the approvals process they shall not be used on behalf of the trust by any person.

At no point does this policy authorise any person working on behalf of the trust to use their own medical devices without explicit written approval by the Medical Device Safety Officer.

2.1 Purpose of Policy

The purpose of this policy is to establish and maintain an effective system of management for medical devices owned and used by Sussex Partnership NHS Foundation Trust employees.

The main aim of this policy is to ensure that the risks associated with medical devices are eliminated, or where this is not possible, minimised as far as is reasonably practicable.

2.2 Definitions

Medical Device

The Medical Devices Directive describes a medical device as any instrument, apparatus, appliance, software, material or other article used alone or combined for humans to:

- Diagnose, prevent, monitor, treat or alleviate disease
- Diagnose, monitor, treat, alleviate or compensate for an injury or handicap
- Investigate, replace or modify the anatomy or physiological process
- Control conception

A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these.

2.3 Scope of Policy

This policy applies to all workers of the Trust including those seconded into the Trust or working on a temporary basis i.e. agency. There will be an active lead from managers to ensure the risk management of medical devices is a fundamental part of the total approach to service delivery, risk management and health and social care governance.

The board recognises that the risk management of medical devices is an integral part of patient safety and is therefore committed to ensuring that these arrangements form an integral part of the trust risk management frameworks and that responsibility for implementation is accepted at all levels within the trust.

This policy covers all categories of medical devices and includes the entire lifecycle of medical device management from initial need identification through to its disposition on conclusion of its safe working life.

Exceptions to full implementation of this policy are only permitted where expressly indicated within this document; this allows a common sense approach to disposable medical devices where it would otherwise involve unreasonable level of administration with little benefit, for example it may not be necessary to record individual needles or contraceptives on the medical device register.

3 Duties

The following identified roles exist to support this policy and procedure, these can be supplemented by other key personnel where deemed necessary by the Medical Devices Management Group.

3.1 Chief Executive

The Chief Executive has ultimate accountability for the trust with regards to medical devices, the chief executive is supported by a director / board member who will be delegated the overall responsibility for ensuring compliance with relevant statutory and best practice requirements in respect of medical devices.

3.2 Director / Board Member

The trust has appointed a suitably authorised individual who will have overall responsibility for medical device management within the trust. Their role is to ensure that the trust has systems in place for the effective management of medical devices and reporting on the effectiveness of arrangements to the board.

The nominated Director / Board member is the Chief Nurse

3.3 Medical Device Safety Officer (MDSO)

The trust MDSO is appointed as the single point of contact for the MHRA and other official agencies with regards to medical device management.

Their role specifically requires they ensure that adverse incidents involving medical devices are reported to the MHRA. Additionally they are required to provide support and advice on implementation of this management system within services and promoting best practice for safe use of medical devices.

A handbook has been produced by the MHRA to support the nominated individual; this can be accessed through the MHRA Medical Device forums once registered as the MDSO.

The MDSO will maintain a list of Medical Device Managers and Co-Ordinators.

During periods of MDSO absence, this role will be temporarily delegated to an appropriate individual to ensure that safety matters are addressed in good time. The maximum period of time for this delegation shall not exceed 30 calendar days, should an absence be expected beyond 30 days a formal change of details will be raised with the MHRA.

The nominated MDSO is the Health and Safety Manager.

The MDSO role can be temporarily delegated to the Head of Incident Management and Safety.

3.4 Medical Devices Management Group (MDMG)

A MDMG has been setup to ensure that these procedures are defined and reviewed periodically to meet the requirements of the trust.

The core membership of this group consists of:

- Head of Incident Management and Safety (Chair)
- Physical Healthcare Lead nurse (Deputy Chair)
- Clinical Representatives (Inc. Care Home)
- Physical Health / Infection Control Representative
- Electro-medical Engineering Representative
- Finance and Procurement
- Estates and Facilitates
- Education and Training
- Medical Device Safety Officer

Where necessary the MDMG will co-opt specialists onto the group membership temporarily, to meet specific needs.

Other responsibilities of the MDMG include:

- Improving awareness of medical device management within the trust.
- Ensuring interested parties are involved in any proposed changes to medical device management.
- Defining individuals who have specific medical device management accountabilities and providing the necessary resources to fulfil their duties.
- Reviewing incidents relating to medical device management and ensuring lessons learned are acted upon and included in reviews of the medical device management framework.
- Ensuring that the Trust Medical Device Management Policy meets or exceeds the MHRA Managing Medical Devices April 2015 guidance.
- Approving medical devices for inclusion on the approved catalogue following a thorough assessment process.

The terms of reference for the Medical Devices Management Group can be found at here.

A web based working environment has been setup for the medical devices management group which can be access via the MDSO; this allows a single repository of all documents related to the group to be securely held.

3.5 Finance and Procurement

The Finance Department is responsible for maintaining a register of capital assets; this is identified through reviews of ledgers.

Procurement buyers are responsible for the purchasing of medical devices once an order is raised by teams correctly on the ordering system.

Procurement will maintain the ordering system catalogues in accordance with direction from the medical devices management group.

Where a contract is required for any medical devices, the procurement department can provide advice and assistance where necessary on procedures that need following.

3.6 Infection Control

The trust has nominated a representative from Infection Control to ensure that all procedures relating to medical devices are compliant with statutory, industry best practice and trust requirements for infection control.

The nominated representative is the Infection Control Lead Nurse

3.7 Physical Health

The trust has nominated a representative from Physical Healthcare to ensure that all procedures relating to medical devices are compliant with statutory, industry best practice and trust requirements for infection control.

The nominated representative is the Physical Healthcare Lead Nurse

3.8 Clinical

All clinical employees are encouraged to have input into the medical devices management framework and can have their input to the group by raising items for discussion here. All registered Medical Device Managers are routinely invited to the groups meetings.

3.9 Estates and Facilities (E&F)

Estates and Facilities are responsible for ensuring that Patient Handling equipment is maintained in accordance with manufacturers recommendations and that all statutory duties under LOLER and PUWER are satisfied in respect of these devices.

3.10 Education and Training (E&T)

Education and training are responsible for ensuring that the training needs identified within equipment datasheets are included in the trust training arrangements.

3.11 Electro-Medical Engineering (EME)

The trust has a Service Level Agreement (SLA) in place with Eastern Sussex Hospitals NHS Foundation Trust for the provision of EME services.

The EME Provider is responsible for the maintenance of medical devices used within the trust that are included in this framework only and where they are correctly registered with EME.

3.12 Medical Device Manager (MDM)

Each establishment will have at a medical device manager who has direct line management responsibility for one or more teams, departments or wards.

Medical Device Managers will be the primary point of contact for the MDSO to discuss matters relating to Medical Device Management in their areas of responsibility.

The MDM will be responsible for ensuring Medical Device Alerts, Patient safety notices or other safety alerts relating to medical devices are acknowledged by their managers and to act on the managers behalf when they are unavailable.

Key responsibilities of this role are ensuring this procedure is adhered to in their areas of responsibility.

3.13 Medical Device Co-ordinator (MDC)

Each ward / team will have a medical device co-ordinator and where appropriate a deputy. These MDC's are accountable for application of these procedures within their workplace.

Their primary responsibilities will be to:

- Maintain an inventory of all medical devices held in their workplace.
- Ensure EME are notified of any change in the status of a medical device (for example Location change, intent of disposal)
- Ensure instructions and equipment datasheets are held for all devices in their workplace.
- Ordering new medical devices
- Ensure medical devices have been correctly commissioned by EME before being brought into operational use.
- Ensure that appropriate representatives have inspected / serviced / maintained medical devices in their workplace as per the equipment datasheet requirements.
- Facilitate EME Service visits.
- Ensure employees in there are of management responsibility have received the correct training in the devices being used.
- Report adverse incidents involving medical devices.
- Arrange for decommissioning of equipment for disposal.
- Arrange for devices to be replaced in accordance with this procedure.

The medical device co-ordinator will be either a Ward Manager or Team Leader.

3.14 Employees

All employees are required to co-operate in full with the trust in respect of medical device management, specifically they must ensure that they are aware of the contents within this policy and how it applies to their role in the trust.

Additional responsibilities of employees include:

3.14.1 Ensuring they report any medical device concerns and incidents.

3.14.2 Ensuring they have completed the necessary training required to use specific medical devices and in general medical device management awareness.

4 Procedure

4.1 General Arrangements

4.1.1 Medical Device Prescriptions

Where a medical device subject to a prescription, it is the responsibility of the prescribing professional to ensure they are suitable qualified and experienced to write such a script out.

4.1.2 Device Rationalisation

The trust will endeavour to ensure that different medical devices used for the same purpose are minimised to reduce the risk of confusion to employees using them and allow portability of skills between environments.

The risks involved with this approach will be assessed during the approvals process to ensure that supply chain disruption or manufacturer recall impacts are minimised.

A standard catalogue of devices is to be maintained here and teams should consult this before ordering any device. Further guidance can be found here.

4.1.3 Device Central Stores

A central store for medical devices is established at Trust Headquarters, this store will hold all medical devices that are surplus to requirement, those awaiting redistribution and a very limited supply of small scale spares for use in the event a team has a device taken out of action and needs a short term loan of a suitable device during repair or replacement procedures.

4.1.4 Device Storage

All devices must be stored correctly and securely within team locations, these locations must be recorded on the central asset register on Ulysses and regular audits of equipment undertaken to ensure accuracy.

4.1.5 Medical Devices with a value over £5000

Where a medical device has an asset or replacement value of £5000 this must be reported to the Finance Department.

In the event that this criterion applies, an asset registration form must be completed and forwarded to the Procurement Manager and MDSO.

Annual audits of equipment on this list will be performed by the Finance and Procurement Department

4.1.6 Legal Liabilities and Insurance

The trust will ensure that all reasonable steps are taken to ensure that medical devices are repaired and maintained to a suitable standard.

No medical devices will be transferred to other organisations other than for final disposal following correct processes.

The trust is part of an NHS Insurance scheme which includes clinical aspects such as medical devices.

Further advice can be sought from the Legal Service Team.

4.2 Single Use Devices

A single use device is intended for use on an individual patient during a single procedure that is then discarded. Single use devices are not intended for re-processing and use on another patient.

Single Use Devices will carry labelling indicating the device is designated for single use, is disposal and not intended for reprocessing and re-use **(Figure 1)**.

Figure 1

The trust does not support the reprocessing of any device supplied by a manufacturer as single use only and the re-use of such a device has legal, technological and economic implications for the employee which may render them liable to prosecution.

Individual Single use devices can be omitted from inclusion in the medical devices Inventory, the trust will ensure that all single use devices approved for use within the trust are listed on the approved catalogue. This will ensure that in the event of CAS Alert being issued the trust can assess its relevance and disseminate for action/info accordingly.

4.3 Second hand medical devices

4.3.1 Pre-acquisition due diligence

Where second hand medical devices are to be acquired for use within the trust, usage and service history should always be reviewed by the trust prior to acquisition.

Additionally, these records must be transferred with the device when it does change owners.

It must be ensured that the records provide information that meets the requirements of this policy as a minimum:

- Records of any reconditioning work carried out, including records of replacement parts.

- Copies of all maintenance and servicing that has been carried out including the name of the maintenance/servicing organisation
- Record, type and frequency of usage of its working life
- Fault log
- Record of decontamination status
- Date of installation

Further guidance on this process can be obtained from the MDSO.

4.4 Record Keeping

Effective record keeping is an essential aspect of safe medical device management. Teams must ensure that accurate and complete records are kept and made readily available for any inspections, review and for copies to be taken where necessary, for example, CQC inspection, internal or external audit and investigations. Any records relating to medical devices will be protected to ensure their accuracy is assured and an audit trail is maintained.

Records will be stored securely to enable retrieval throughout the life of the equipment, and for the duration of the retention period following decommissioning and disposal of a device.

Each device shall have its own unique record that contains:

- Unique identifier (Serial Number)
- Asset number
- Make
- Manufacturer
- Model Number
- Device Type
- Purchase details for device (price, date, supplier)
- Details of commissioning/acceptance
- Details of all locations equipment has been used/deployed/installed
- Details of any specific legal requirements and how these have been satisfied
- Details of all maintenance and repairs
- Decontamination certificates
- Inspection and maintenance schedule/frequency details
- Anticipated end of life date (where available)
- Any information required to satisfy legislative requirements

Each record will be maintained using Ulysses Safeguard Asset module and the Trusts EME providers Equipment system. The trust system will maintain the basic metadata of the device and more detailed servicing information will be maintained by EME.

4.4.1 Training Records

Training records will be maintained for each device in accordance with the requirements detailed on the equipment datasheet (on the online catalogue); these requirements will be assessed during the approval process.

Training records will be required to demonstrate that employees for each device:

- Have been trained
- Know how to use the device safely
- Can carry out routine checks and maintenance
- Are confident/or competent to use devices in their areas of work
- Can perform correct record keeping requirements
- Have completed refreshers at prescribed intervals

4.5 Selection

Follow identification of equipment need, a trial shall take place which assesses suitability and which care groups the device can be used in. One approved by the MDMG this will be placed on the standard catalogue.

4.6 Risk Assessment

All devices must have a suitable and sufficient risk assessment which determines significant hazards, risk levels and controls required for patient and staff safety. These will be documented on the Ulysses Safeguard risk module as they are completed. A template can be obtained from the MDSO.

4.7 Acquisition

Only devices from the approved catalogue or under a controlled trial approved by the Medical Devices Management Group will be acquired.

Acquisition shall use NHS Supply Chain routes in preference to contracts setup off framework. Supply Chain will account for 90% of orders for medical devices and they can be ordered by Medical Device Managers/Co-Ordinators directly from I-Procurement (Oracle).

Where an off-catalogue item is required, a Non-Catalogue request will be made by the requestor in accordance with the guidance that can be found on the medical device's pages on the intranet.

For larger equipment, the capital projects team will need consulting. This will be completed by the requester and not the finance and procurement department under any circumstances.

4.8 Acceptance

On receipt of a new or refurbished medical device, the trust will ensure that the device is subject to rigorous acceptance checks before being put into operational use.

It is the responsibility of the EME service provider to commission medical devices before their first operational use which includes checking that the specification of the newly delivered devices matches the purchase order detail or tender specification.

A record of these acceptance tests will be produced and retained in accordance with the retention schedules in this procedure.

All medical device managers are responsible for ensuring that the necessary registrations and commissioning have taken place for devices they have ordered.

4.9 Service Contracts

The trust has established and maintains a service contract for most medical devices, exceptions to this are those where servicing is required by the estates and facilities team or directly from manufacturers which have their individual contracts arranged for this. Where this is not in place, it must be arranged by the service with assistance from the MDSO.

4.10 Maintenance

4.10.1 Routine (by end users)

Medical devices may require routine maintenance by end users at specific intervals to ensure that the device continues to function as intended.

Where this maintenance is necessary by the end user the Equipment Datasheet for the medical device will detail the regular care and inspection that is recommended by the manufacturer's guidance and as specified in local procedures. The guidance will clearly show how the routine tasks should be performed.

As a minimum, each medical device equipment datasheet will include:

- Frequency of maintenance
- The routine to be followed
- Record Keeping requirements
- How to contact the relevant service organisation

Where routine maintenance is performed by end users, any training required to carry out their responsibilities safely and effectively will be provided to them by the medical Device Manager or Medical Device co-ordinator and will include the required content from the equipment datasheet.

Where a medical device fails to meet the required standards, the equipment must be clearly marked with a FAIL CARD that must be taken is to refer to the EME for repair/replacement. These cards can be obtained from EME directly.

4.10.2 Routine Maintenance (By EME)

EME maintain a register of all devices that have been notified to them, this register also contains details of routine maintenance requirements which EME will co-ordinate.

This excludes patient handling equipment which is maintained by Estates and Facilities for which they have a similar system for maintenance.

Where a device misses its routine service schedule, it must immediately be removed from service and EME contact to arrange this. This usually involves sending the device to them via post unless they agree otherwise.

4.11 Device Breakdowns

During the life of a medical device there may be instances that a breakdown occurs despite maintenance schedules being adhered to. To ensure that equipment is ready for operational use at the point of requirement a breakdown protocol has been established to restore operational function as quickly as possible.

The device should be replaced or withdrawn from service as soon as possible and repair properly before it is put into operational use again.

The device must only be repaired in these circumstances by an authorised person.

Wherever possible, temporary repairs are to be avoided. Where they are necessary the temporary repair should be undertaken, and all interested parties informed of any special precautions or limitations pending permanent resolution. This must be documented on the device inventory record.

In the event of a breakdown of equipment, the MDC responsible should ensure that the equipment breakdown has been referred for repair to the appropriate point of contact.

4.12 Decontamination

All reusable medical devices must be properly decontaminated prior to use or maintenance.

The trust has an infection control committee which is responsible for ensuring adequate systems are in place trust wide for the decontamination of environments and equipment.

The medical devices management group requires a member of the Infection control group committee to hold standing membership to assist in producing the infection control requirements for re-usable medical devices to ensure that they are decontaminated prior to use or maintenance by any person and that the decontamination facilities and processes are well managed.

These decontamination procedures will be recorded on the Equipment Datasheet as part of the acquisition process and equipment datasheet reviews.

As a minimum they will take account of:

- Manufacturer’s instructions (to ensure completeness and appropriateness)
- The classification of infection risk associated with decontamination of the device

Where it appears manufacturer's instructions are incomplete or appear inappropriate this must be reported to the MHRA via the MDSO in accordance with section 5.15 of this procedure.

All medical devices should be decontaminated and stored in accordance with legislative and best practice requirements which are to be detailed in the equipment datasheet. These decontamination procedures will be validated.

Medical devices will be classified by the infection risk associated with their decontamination:

Risk	Application of Item	Recommendations
High	In close contact with broken skins or broken mucous membrane Introduced into sterile body areas	Cleaning following sterilisation
Medium	In contact with mucous membranes Contaminated with particularly virulent or readily transmissible organisms Before use on immunocompromised patients	Cleaning followed by sterilisation or disinfection. Note: Where sterilisation will damage equipment, cleaning followed by high level disinfection may be used as an alter Native.
Low	In contact with healthy skin. Not in contact with patient	Cleaning.

4.12.1 Decontamination of a device before inspection, maintenance, repair or disposal

Medical devices subject to inspection, maintenance, repair or disposal either on site or at a third parties' premises should be decontaminated beforehand in accordance with the equipment datasheet requirements.

Any items on loan from a third party that are being returned to them should also be decontaminated.

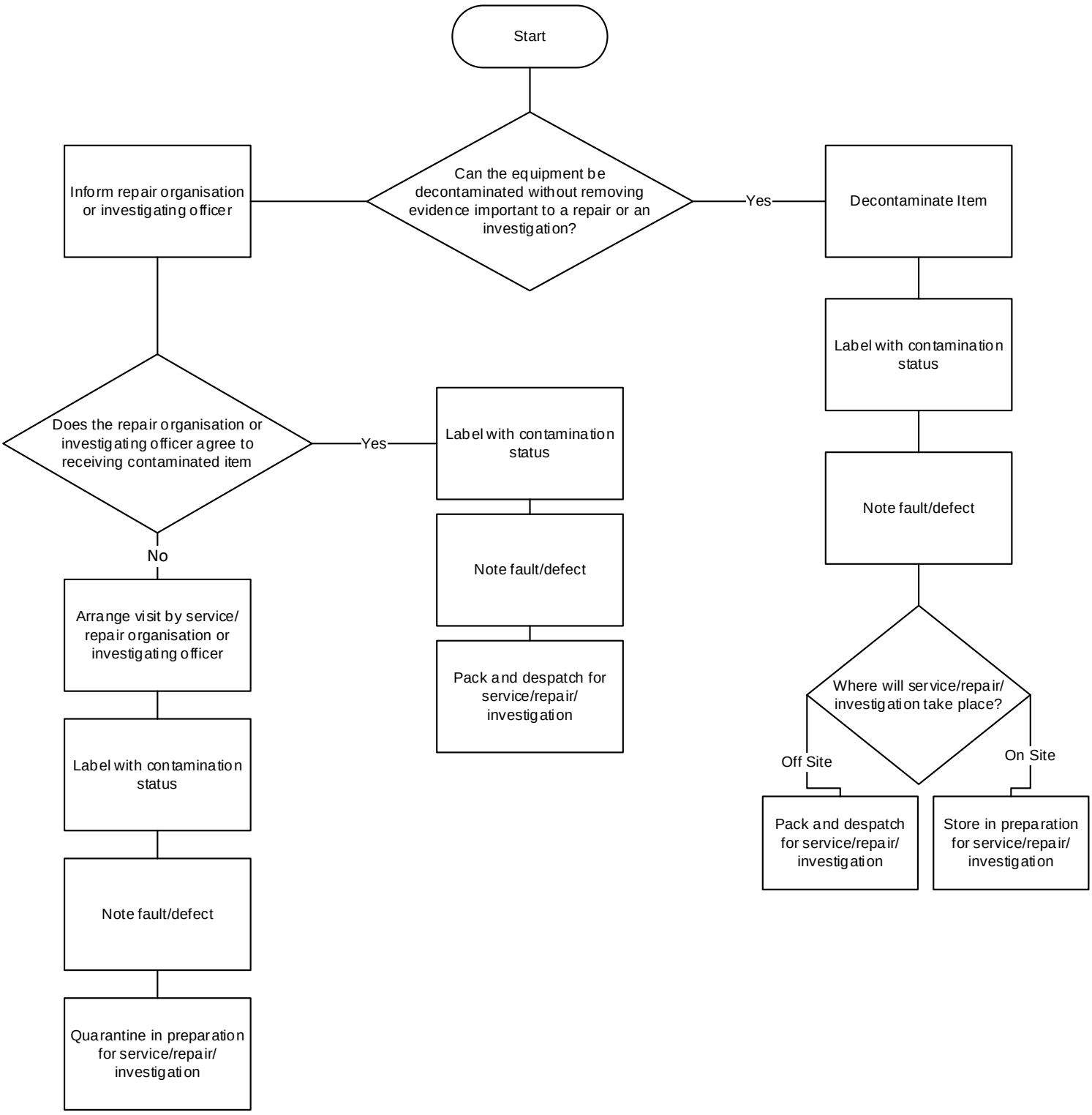
Under no circumstances must a contaminated medical device be sent via normal post, this constitutes a criminal offence.

Note: decontamination of single-use devices is not required as they are to be disposed of immediately; an exception to this rule is where the device is implicated in

an adverse incident and may be required for investigation. In this instance contact must be made with the investigating officer to determine the most appropriate method for decontamination.

Upon decontamination of a device, it should be labelled accordingly and a declaration of contamination status form / label completed. This should be readily accessible to the recipient of the device.

4.12.2 Decontamination Flowchart for devices that are being sent for investigation, repair or service



4.12.3 Declaration of contamination status

For devices being sent for investigation, repair or service. A declaration of decontamination must be affixed to the device. The EME labels can be used for this purpose as they contain an area to declare decontamination status.

4.13 Device replacement planning

It is recognised by the trust that medical devices will not last forever and at some point will require replacement; the trust will ensure that when new devices are purchased that the expected life cycle is on the inventory record and regular reviews undertaken against usage, maintenance and repair records to determine whether this date requires revision.

Where a device is subject to heavy usage or its maintenance schedule is not adhered too, this may reduce its life cycle whereas limited use may increase its life cycle.

In the event of a manufacturer issuing a recall of a device, this will take precedence over all other considerations in device replacement planning.

Medical device co-ordinators will ensure regular reviews of their medical devices takes place and where necessary arrange for replacement of their medical devices using the guidance within the procedure. In most cases MDCs can use the equipment datasheet to determine its life cycle and a suitable replacement then sourced from the approved catalogue.

The following considerations should be taken as a minimum when planning for the replacement of a medical device:

- Whether the device is damaged or worn out beyond economic repair
- Its reliability
- Clinical obsolescence
- Technical obsolescence
- Contamination status
- Local policy for device use
- Absence of manufacturers support
- Absence of supplier support
- Non-availability of correct replacement parts
- Non-availability of specialist repair knowledge
- End user opinion
- Potential benefits of newer devices (features, usability, clinical effectiveness, lower running costs)
- Life cycle of medical device
- Redeployment
- Utilisation profile (are additional units required/does it meet demands)
- Equipment downtime
- Disposal costs
- Revenue generation potential
- Changes in clinical standards

- New equipment technologies
- Changes in service provision

4.14 Decommissioning

Guidance on Decommissioning

4.15 Disposal

Guidance on Disposal

4.16 Adverse incidents

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons. Any known problems associated with product design, documentation and common use related issues should also be reported for follow up.

For example:

- A patient, user, carer or professional is injured as a result of a medical device failure or its misuse
- A patient's treatment is interrupted or compromised by a medical device failure
- A misdiagnosis due to a medical device failure leads to inappropriate treatment
- A patient's health deteriorates due to medical device failure.

Causes may include design; poor user instructions or training; inappropriate modifications; inadequate maintenance; and unsuitable storage and use conditions.

In the event of an adverse incident involving a medical device, it is imperative that all items involved be quarantined wherever possible.

Individuals must not:

- Interfere with controls (if present)
- Move the device.
- Throw the device away.
- Repair the device.
- Return the device to the manufacturer.

Employees must ensure they report all adverse events relating to a device including user problems with a device, software failures or problems with instructions for use to the Medical Device Co-ordinator for their workplace in the first instance so that immediate action can be performed to limit harm being realised.

Where an injury has occurred or urgent investigations are necessary, advice should be sought from the Clinical Governance Team on the best way to proceed to mitigate risk and allow a quicker recovery from the event.

Follow-up reporting should be undertaken through the Ulysses incident reporting system in accordance with the Incidents, Serious Incidents and Learning from Deaths Policy and Procedure.

The timely, accurate and thorough reporting of incidents will ensure that the MDSO can report incidents to the MHRA for investigation as appropriate and ensure that national lesson learning can be performed more effectively.

Medical Device Safety Officer only

The MDSO is responsible for reporting relevant incidents involving medical devices to the MHRA.

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

The Yellow Card reporting system is the preferred method of reporting to the MHRA although telephone (020 3080 7080), post and email can be used.

When making a report to the MHRA, all reports are triaged and acknowledged. The reporting individual will also be advised of the nature and outcome of the MHRA triage. It is possible that the MHRA may request that a medical device be sent to them for further analysis or ask for more information therefore until such time as an acknowledgement is received, the medical device should remain in quarantine and treated as evidence.

4.17 Medical Device Central Alerts

Where an MHRA medical device alert, field safety notice, or other MHRA safety guidance is received by the trust, the processing of the alert will be in accordance with the Central Alerting System Policy and Procedure.

5 Development, consultation and ratification

This policy and procedures were developed by the Health and Safety Manager in conjunction with members of the medical devices management group.

The policy and procedure were distributed to the Professional Policy Forum for final consultation and ratification.

This policy and procedure will be reviewed at three yearly intervals or sooner where:

- A change in legislation occurs.
- A change in national policy occurs.
- An adverse incident relating to a medical device has occurred.
- There is reason to suspect that it is no longer valid.

Employees are able to provide feedback on the medical device management system directly to the MDSO who will table this for consideration at the MDMG.

6 Equality Impact Assessment

This policy and protocol has been equality impact assessed in accordance with the Procedural documents policy, the assessment is published alongside this document.

7 Monitoring Compliance

The trust will minimise or eliminate risk to patients and staff through monitoring and audit of these arrangements and use the findings of these audits to inform continual improvement.

7.1 Internal Audit

Internal audits will be undertaken only by staff with appropriate knowledge and experience of managing medical devices.

Key performance indicators suggested in MHRA guidance to provide early warning or risk and the effectiveness of the system.

Performed by MDMG membership and report submitted to the group.

7.2 Quality and Safety Reviews

During quality and safety reviews, medical device storage, cleaning and maintenance arrangements locally shall be checked for sufficiency and compliance with this procedure.

7.3 External Audit

The Care Quality Commission as part of their regulatory functions will inspect the trust against their Essential standards of quality and safety which may take account of medical devices.

Although the trust has no ability to influence when or where these inspections take place, they can be used as a means to measure medical device management performance.

8 Dissemination and Implementation of policy

8.1 Dissemination

This policy will be published on the trust policies database in accordance with the trust Procedural documents policy. Additionally the medical devices intranet pages will contain a link to the policy.

A link to the published new version of this policy will be emailed to each member of the Medical Devices Management Group, Medical Devices Managers and Co-ordinators to ensure that they are aware of its existence for implementation as publications are made.

9 Training

The trust will ensure that any worker who has a part in the management or use of medical devices receives adequate training that is tailored and enables them to fulfil their role safely and effectively and they can understand it in the context that it is meant.

All worker within the control of the trust who are required to undertake any training identified within this policy with adequate facility time to do so.

9.1 EME

Any technician providing work under the EME service contract should have received a suitable and sufficient level of training that enables them to discharge their duties.

During agreement of the contract for EME services due diligence checks will be undertaken on training levels EME technicians have received to demonstrate they are trained to a level proportionate to the servicing they are undertaking and that they are up to date on latest maintenance techniques where necessary.

9.2 Medical Device Safety Officer

The medical device safety officer will be required to self-train based on the contents of this policy, they must ensure they are familiar with as a minimum:

- The Trust Medical Devices Policy and Procedure
- How to access the MHRA website and associated guidance
- How to report an adverse incident to the MHRA

Upon completion of this self-training, an email must be forwarded to the My Learning team to ensure it is recorded on the MDSOs individual training record.

9.3 Medical Device Co-ordinators

Managers are responsible for ensuring that all employees in their line management chain maintain their competence to use relevant medical devices and ensure that employees have their training records monitored during supervision and at annual appraisal meetings.

Managers should not expect employees to use a medical device where the employee has not received appropriate training in and been deemed competent in its use.

Where training in equipment is required, physical healthcare nurses should be consulted for this.

9.4 Employees

Employees will be trained on relevant medical devices for their role by a competent person, employees must not use any medical device until they are trained and deemed competent in their use.

Training in the use of specific medical devices must include:

- The intended use of the medical device
- Any limitations on its use
- Recognition of when a device is not working correctly
- Procedure for conducting visual inspections
- How to ensure a device is in good working order
- How to ensure a device is within its serviceability dates
- Device cleaning and decontamination procedures

Where applicable training will include:

- How to fit accessories and be aware of how they may increase or limit the use of the device
- How to use controls appropriately
- The meaning of displays, indicators, alarms, etc. and how to respond to them
- Requirements for maintenance

Additionally general training applicable to all medical devices will be provided which include:

- How to report faults with a device
- Adverse event procedures and their importance

Records of all training for medical devices will be maintained on my learning to ensure portability.

10 Document Control including Archive Arrangements

This policy and procedure will be subject to document control consistent with the requirements detailed in Procedural documents policy.

11 Reference Documents

MHRA Managing Medical Devices April 2015
MHRA Management and Use of In-vitro diagnostic point of care test devices
Blood glucose meters point of care testing

Risk Management and Strategy Policy
Procedural documents policy
Mandatory Training and Induction Policy
Central Alerting System Policy and Procedure
Incidents, Serious Incidents and Learning from Deaths Policy and Procedure

12 Bibliography

Intentionally left empty.

13 Glossary

CAS	**Central Alerting System** CAS is a system for disseminating and reacting to alerts nationally.
EME	**Electro-Medical Engineering** The EME are contracted to provide the Trust with advice, commissioning, maintenance and repair of reusable medical devices in accordance with instructions provided by manufacturers.
HSE	**Health and Safety Executive** Regulatory agency with responsibility for enforcing Health and Safety legislation.
MDA	**Medical Device Alert** Issued by the MHRA to inform Healthcare Agencies of concerns with medical devices that may affect patient safety
MDG	**Medical Devices Group** The medical devices group within the Trust are responsible for co-ordination of these arrangements at strategic level.
MHRA	**Medicines and Healthcare Products regulator agency** The MHRA are responsible for protecting and promoting public health and patient safety by regulation of medical devices within the United Kingdom.
MDM	Medical Device Manager
MDC	Medical Device Co-Ordinator
MDSO	Medical Device Safety Officer
MDMG	**Medical Devices Management Group**
NICE	**National Institute of Clinical Excellence**

14 Annexe A – Medical Devices Management Group Terms of Reference

These terms of reference are held electronically on the trust intranet pages for medical devices at this location:

http://staff.sussexpartnership.nhs.uk/medical-devices/medical-device-management-group/terms-of-reference

15 Annexe B – Medical Devices Management Group Standard Agenda

Date:
Time: 10:00 – 12:00
Subject: Medical Devices Management Group - Quarterly
Venue:
Chair:

#	**Heading**
1	Welcome, Introductions and Apologies
2	Previous meeting minutes
3	Management Systems
4	Incident Analysis
5	Membership Updates • Chair • Medical Device Safety Officer • Clinical • Electro-medical Engineering / PPM • Estates and Facilities / PPM • Finance and Procurement • Infection Control / Decontamination • Physical Health • Training and Education / Training • Occupational Health • Lindridge Care Home Management
6	Medical Devices (including obsolete equipment)
7	Monitoring and Audits
8	Communications
9	Agenda items for next meeting
10	Any other business

16 Annexe C – Medical Devices Fault Reporting Poster

Medical Devices Fault Reporting

Hoists Profiling Beds	All other Medical Devices

Estates Helpdesk	EME Helpdesk
0300 304 0040	0300 131 5151
	eme@esht.nhs.uk

When requesting assistance ensure you have the following *information at hand:*

1. *Full description of the fault*
2. *Asset number / serial number*
3. *Exact location of the equipment*
4. *Contact name*
5. *Contact telephone number*

Ensuring that:

1. *The device is clearly labelled as faulty*
2. *A decontamination certificate is attached*
3. *Where possible isolate the device.*