POLICY FOR THE MANAGEMENT OF MEDICAL DEVICES

Accountable Officer: Chris Bell, Director of Estates & Facilities
Reviewed by: Graham Biggar, Head of Estates and Facilities Infrastructure

Status: Approval date: January 2017
Ratified by: Risk Scrutiny Committee
Review date: January 2020

Patients first  •  Personal responsibility  •  Passion for excellence  •  Pride in our team
## History

<table>
<thead>
<tr>
<th>Issue</th>
<th>Date Issued</th>
<th>Brief Summary of Change</th>
<th>Author</th>
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<tr>
<td>1</td>
<td>Nov 1998</td>
<td>New policy</td>
<td>Quality &amp; Risk Management Steering Group</td>
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<tr>
<td>2</td>
<td>Feb 2007</td>
<td>Complete revision and re-naming of Management and Use of Medical Devices to include the Disposal of Medical Devices</td>
<td>Non Clinical Risk Committee</td>
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<td>3</td>
<td>Dec 2010</td>
<td>Review of policy to comply with NHSLA standards</td>
<td>Safety and Risk Committee (Chair’s action)</td>
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<td>4</td>
<td>Dec 2013</td>
<td>Review of policy to comply with NHSLA standards</td>
<td>Safety &amp; Risk Committee (Chair’s action)</td>
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<tr>
<td>6</td>
<td>Jan 2017</td>
<td>Policy reviewed in line with recommendations following formal internal audit completed by TIAA.</td>
<td>Risk Scrutiny Committee (Chair’s action)</td>
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For more information on the status of this document, please contact:

- Ollie Swan, Medical Device Safety Officer & medical Engineer Manager

**Accountable Officer**  
Chris Bell, Head of Estates & infrastructure

**Date of issue**  
January 2017

**Review due**  
January 2020

**Ratified by**  
Risk Scrutiny Committee (previously Non Clinical Risk Committee)

**Audience**  
All healthcare staff
This Policy should be read in conjunction with the following documentation:

1. Point of Care Testing Policy
2. Single Use, Single Patient Use and Limited Use Medical Devices Policy
3. Sterile Services CFPP01-01 & CFPP01-06; and HTM01-01 & HTM01 as of 06 Jan 2018
4. Medical Devices Training for Clinical Staff Policy
5. Moving and Handling Policy
6. Policy for Decontamination
7. Central Alert System (CAS) Policy
8. Cleaning and Disinfection Policy
9. Health and Safety Policy
10. Incident Reporting Policy
11. Supplier Representatives Policy
12. Trust Standing Financial Instructions

Note:
A summarised and simplified version of this Policy for everyday staff reference is included within appendix B

1. INTRODUCTION

The purpose of this policy is to outline the systems and processes to ensure Trust medical equipment is always safe to use, used correctly, and operated by competent, trained staff.

This policy applies to all devices managed by the Trust but with specific reference to:

- Medical Engineering
- Point of Care
- Sterile Services
- Moving and handling team

Within these departments, each co-ordinates their own separate systems of device management to reflect the differing nature of equipment in use. Equipment used within Imaging, Pathology and Pharmacy Departments also operate separate operational policies. This overarching policy does however require that all departments have internal governance assurance checks to ensure compliance with this policy and national standards and regulation.

This policy document is based upon the requirements of:

• Improving medical device incident reporting and learning, and the Care Quality Commission (CQC) Outcome 11 (Regulation 16 of the Health and Social Care Act 2008) Safety, availability and suitability of equipment, as well as other national and international standards.

2. POLICY PURPOSE

The aims of the policy are to:

✓ Ensure the continuing safe use of medical devices and reduce incidents involving medical devices.
✓ Ensure that management and staff are aware of their responsibilities in relation to the use of all medical devices.
✓ Increase staff awareness of the principles and importance of medical device management.

The Trust operates and manages this policy through the Medical Devices Group (MDG). The Terms of Reference of the MDG are included in Appendix A.

3. DEFINITION OF MEDICAL DEVICES

Medical devices are defined by the Medical Device Regulations, which are contained in Statutory Instruments, SI 1992, 3146; SI 1994, 3017 and SI 1995 1671.

The term “medical device” refers to any healthcare apparatus, material or article which is used for a patient in the diagnosis, treatment, prevention or alleviation of illness or injury. This policy applies primarily to electro-medical equipment. Point of Care Testing (POCT) is limited to analytical processes that would traditionally be performed by Pathology Departments.

4. RESPONSIBILITIES FOR MEDICAL DEVICES

4.1 Trust Board

The Chief Executive Officer (CEO) has overall responsibility for the management of medical devices and implementation of the medical device management policy within the Trust. The Trust Board Director with specific responsibility for Medical Devices is the Deputy CEO. The Deputy CEO discharges the day to day operational responsibility for the Estate Department through the Director of Estates and Facilities.

The Trust Board will receive an Annual Report on Medical Devices prepared by the Medical Devices Group and approved by the Trust’s Risk Scrutiny Committee.

4.2 Director Estates and Facilities

The Director’s role is to:

✓ Ensure that medical device issues are highlighted through the Deputy Chief Executive to the Trust Board, and have responsibility for proposing resources and programmes relating to medical device management including capital allocation, and the future allocation of revenue funding.
Monitor the quality of the medical engineering corporate service provided and take corrective action where appropriate and ensure policies are implemented operationally and monitored as part of assurance.

The Director discharges the duties of the management of medical devices to the Medical Devices Safety Officer.

4.3 Divisional Directors
Divisional Directors are responsible for ensuring compliance of this policy within their own Divisions and Departments. This includes:
- Ensuring management systems are in place to effect adherence to this policy.
- Appoint staff with local responsibility to co-ordinate medical devices management.

4.4 Departmental/Ward Managers
The day-to-day operational responsibility of an item of medical equipment lies with the clinical ward or department. Managers shall:

1. Authorise and be accountable for users of the equipment
2. Assist and facilitate with training needs and maintain appropriate training records.
3. Support the Medical Engineering, POCT and Sterile Services departments by notifying of changes to the medical equipment inventory – including acquisitions, returns form loan and disposals.
4. Notify Medical Engineering of service contractor visits and forward-on associated data
5. Control the loan and use of medical devices
6. Have documented risk assessments to ensure device use risks are addressed.
7. Maintain the following records and systems:
   - An up to date Competency List of the standard items of medical equipment in use.
   - Based on the Competency list there must be a training record for every staff member
   - Evidence to show that devices have been cleaned for use.
   - Each device has been checked before use to ensure that it has been maintained, serviced and calibrated as required within but not exceeding the past two years.
   - Each device in use must have an accessible user guide in electronic or hardcopy format
   - Records kept when loan devices are returned, and that the medical engineering department is notified.

Before a device is used for patient care, ensure that:
- The person(s) operating the device have records to show they are trained, competent and have authority to use it.
o The device is suitable for use, and used as intended without ad-hoc modification or repair.
o The device or its accessories or consumables is not subject to an MHRA field safety note.
o The device (and its power supplies) have no obvious defects, no signs of fluid ingress, no physical damage (e.g. powers-up and indicates no visible warning, no cracks to the casing, or has a yellow decontamination / “DO NOT USE label”).
o The device has a Trust asset tag, asset identity and record of service history.

Ward/Departmental Management Responsibilities:

1. The Trust owns and accepts responsibility for all medical equipment that has been properly brought into the Trust. Items that have been borrowed, loaned or are on demonstration must be used in accordance with the Procedure for the introduction of Medical Equipment into the Trust for Patient Treatment which is included as Appendix B

2. The Medical Engineering Department shall be informed of any servicing undertaken by 3rd party contractors in order to monitor that the policy is being adhered with.

3. Ensure that all defects and malfunctions are immediately reported to the Medical Engineering Team (through the Facilities Helpdesk on ext.2882), Sterile Services or the Point of Care Testing Team where appropriate and the equipment is withdrawn from service suitably labelled and decontaminated correctly.

4. Items of a consumable or disposable nature will be accepted into use by the ward or department manager, or their designate. Where disposable items have a use by date, the manager must ensure that stock is correctly rotated so that items never go out of date.

5. Where prosthetics or consumable items have a sticker included with the items, that identifies the serial or batch number, this must be included in the patient’s notes.

6. Managers must arrange for suitable storage of medical equipment when it is not in patient use. The storage facilities should take into account any special requirements for infection control, temperature, humidity etc. and that any equipment that has rechargeable batteries is kept on charge when not in use.

7. Items of equipment that use ionizing radiation, i.e. x-ray equipment must have a radiation protection check to ensure staff and patient safety before being put into service. The Radiation Safety Policy applies. Managers should contact the Trust’s Radiation Protection Advisor to arrange the necessary tests. Laser equipment requires similar tests to x-ray equipment although the risks are from optical rather than ionizing radiation. The Laser Safety Policy applies to this equipment. For laser equipment managers should contact the Laser Protection.
4.5 Medical Devices Safety Officer

The Medical Devices Safety Officer (MDSO) role is:

1. Manage policy compliance and medical device issues. These are reported through the Medical Devices Group.

2. Support local medical device incident reporting and learning, acts as the main contact for NHS England and the MHRA and medical device manufacturers and will take part in regional or national Medical Devices Networks to share and promote good practice.

3. Chair or support the MDG in line with MHRA alert NHS/PSA/D/2014/006.

4. Audit Trust departments for compliance with the Policy to ensure good corporate governance and assurance.

5. The MDSO is supported by the Deputy MDSO (Senior Medical Engineer) and the Health and Safety adviser.

6. Ensure that the Trust participates in a benchmarking scheme to evaluate its management of medical equipment against national standards.

7. Undertake audits to ensure clinical teams comply with medical device policy

8. Support the CAS liaison officer with the management of medical device alerts received from the MHRA and suppliers.

4.6 The Medical Devices Group

The Medical Devices Group (MDG):

The MDG is accountable to the Trust Risk Scrutiny Committee. The Terms of Reference for this group is contained within Appendix A.

The MDG:

- Oversee and coordinate the management of all medical devices

- Have membership from all Divisions and services departments implicated in the use of medical devices including: Procurement, Sterile Services, Infection Prevention and Control, Health & Safety Adviser, and Point of Care Testing (Pathology Services).

- Prepare an Annual Report on Medical Devices for approval by the Trust’s Risk Scrutiny Committee and presentation to the Trust Board.

5.0 PROCUREMENT OF MEDICAL DEVICES

New devices may only be acquired with the prior consent and involvement of the Procurement team. This also includes service and maintenance contracts for new devices.
5.1 Specification

As part of business case approval, the first stage in the procurement process is to complete a specification for the equipment, which includes…

<table>
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<th>user specific requirements</th>
<th>compatibility</th>
<th>enabling works and installation costs</th>
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<tr>
<td>safety and reliability</td>
<td>manuals and training</td>
<td>running costs (maintenance, servicing, calibration)</td>
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<tr>
<td>consumables</td>
<td>availability of spare parts</td>
<td>Cleaning/decontamination costs</td>
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<tr>
<td>Potential repair costs</td>
<td>Training costs</td>
<td>Energy and utility costs</td>
</tr>
<tr>
<td>Storage requirements</td>
<td>disposal and replacement costs</td>
<td>Operator costs</td>
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For more detail on factors to consider before acquisition refer to MHRA DB 2006(05) section 3.3. The Supplies/Procurement Department can offer advice and templates to support you in this process.

5.2 Purchase

1. Capital purchases (single items or groups of items costing £5,000 or more) have to be submitted on an Equipment Capital Bid Proforma for approval by the Medical Equipment Group.
   a. Trust Standing Financial Instructions shall apply at all times.
   b. Ongoing revenue costs such as cleaning, servicing, calibration, training, maintenance, storage and disposal costs are considered and approved prior to purchase
   c. The Manager approving the purchase is responsible for accepting any revenue consequences of ownership.
   d. Any agreed standardisation of particular brands of equipment is complied with.
   e. Ward and department managers should obtain professional advice on ownership and use of their devices. This can be from the departmental clinical lead, supplier or manufacturer. Note that the selection of any new equipment that involves drug delivery must be undertaken in conjunction with the Pharmacy Department.

2. The purchase of any Point of Care Testing device must be approved by the Point of Care Testing Committee and budget allocated before procurement

3. The Trust arrangements for purchasing from Trust monies or charitable funds should evidence strategic replacement and development procurement planning.

4. The Trust complies with guidance issued by the MHRA in the form of Safety Notices, Alerts and Bulletins.
5. That all devices are entered and tracked throughout its life on an approved Trust database. Its expected lifespan shall be recorded in the MEG business case or procurement wherever possible.

6. All new items of reusable medical equipment must be CE marked under the Medical Device Regulations.

7. The selection of any new equipment that involves drug delivery must be undertaken in conjunction with the Pharmacy Department.

8. Managers should check with Procurement, Medical Engineering or Point of Care Testing Team if appropriate, before proceeding with a purchase to see if the equipment is included in the standardisation programme.

9. For electrical and electronic equipment a PPQ (incorporating the cleaning/decontamination requirements) form is sent by the Procurement Department to the manufacturer which specifies British and International standards to which equipment must comply. The Medical Engineering/Sterile Services/Department/Point of Care Team will undertake a technical assessment of this form and their approval is required before a purchase order can be raised.

10. Ward and department managers shall obtain professional advice on ownership and use of their devices. This can be from the departmental clinical lead, supplier or manufacturer. Note that the selection of any new equipment that involves drug delivery must be undertaken in conjunction with the Pharmacy Department.

11. All medical equipment that is brought into the Trust for patient use shall follow the Procedure for the Introduction of Medical Equipment into the Trust for Patient Treatment – see next headed section below.

5.3 **Procedure for the Introduction of Medical Equipment into the Trust for Patient Treatment**

- New devices may only be acquired with the prior consent and involvement of the Supplies and Procurement team. This also includes service and maintenance contracts for new devices.
- New devices cannot enter use and circulation without inspection from Medical Engineering, POCT or Sterile Services.
- New loan devices must have a record on entry of use. They must also have an acceptance test performed before use.

All equipment properly purchased or received by the Trust, regardless of the source of funding, is the responsibility of the Trust. Employees using medical equipment do so with the full backing and authority of the Trust. The ownership of medical equipment rests with the user and the Trust.

Before employees use medical equipment the Trust requires that the devices meet regulatory and clinical standards as proscribed.

There must be adequate user training and provision for maintenance prior to the equipment being accepted into the Trust.
For the majority of electro-medical equipment this will require medical engineering to undertake an acceptance test, which will check its electrical safety and function. Function set-up and commissioning may also be provided by a 3rd party such as the supplier. In these cases the clinical lead shall satisfy themselves that the device performs as intended.

The item will be included on the relevant asset inventory. Bulky fixed items, such as pathology and radiology equipment, will be accepted by the staff responsible. The details then sent to Medical Engineering for inclusion on the inventory. If an item, which would normally be subject to Acceptance Testing by Medical Engineering, is not checked, i.e. it has been delivered direct to a ward, then the responsibility for its safety, and that of any patient on whom it is used, rests with the ward and clinician who authorised its use. Staff will be deemed to have contravened Trust Policy. The non-compliance will be raised and reported to the MDG.

From time to time manufacturers will loan equipment to the Trust for clinical trials. In these cases the manufacturer takes liability for the safety of the equipment. This must be confirmed by arranging for the manufacturer to sign a “Purchasing Indemnity Form”. These forms are held by Supplies and Procurement. If the Purchasing Indemnity Form is not completed and signed by the manufacturer, then the person who introduces the equipment onto the site and/or uses it clinically carries full legal liability for its use. Staff will be deemed to have contravened Trust Policy.

On occasions manufacturers will provide medical equipment on long-term loan. This can be as part of a trial or as part of a purchasing arrangement when the equipment is loaned, as long as the Trust purchases some disposable item. In these cases the equipment belongs to the manufacturer. The person responsible for arranging for the loaned equipment must obtain a signed Purchasing Indemnity Form from the manufacturer. If the manufacturer declines, then the relevant Trust staff member must be made aware from them in writing, that the Trust is carrying legal liability.

Device and Patient Records

The Trust is moving towards linking medical device data with patient data. Where such recording systems allow, if a medical device is used for patient care in critical care areas including A&E, ITU, Theatres, NICU, it should feature on the patient record.

This may include:

- What type of device was used
- The device asset number
- Sufficient detail of the times, date, duration and nature of the medical therapy given

For clinical teams, other than those described earlier, it may not be possible to record data as a matter of routine. However, in the event of an incident, all clinical team must take steps to retain and record all available data in a way that may support an investigation.

5.4 New Device Acceptance Checks
1. When equipment is first delivered, the Medical Engineering or the Point of Care Testing team will perform verification checks in line with MHRA guidelines before any device is released for use.

2. When an item is delivered to a ward or department after having been formally accepted by Medical Engineering, the manager shall ensure that any local acceptance tests that may be undertaken are performed. Medical Engineering will perform a safety test only, unless they have specialised test equipment for that particular model. Managers shall ensure that the equipment is safe and configured for patient use before it is first put into service.

5.5 New device training
Managers shall review the training needs of their staff when a new item of equipment is delivered. If the item is unfamiliar to any member of staff then training must be provided for that member of staff and a record kept of the training provided. Until such time as the training has been completed, the member of staff must use the equipment under supervision only. This also applies to bank, agency and locum staff.

5.6 New device maintenance and servicing arrangements
Managers shall ensure that appropriate arrangements for maintenance and repair, and calibration if necessary, are in place for when the equipment warranty expires. This can be performed by Medical Engineering or by 3rd party – depending on specialism and cost. Specialist support on this matter can be provided by Procurement in conjunction with Medical Engineering, POCT or Sterile Services departments.
New item of electro-mechanical medical equipment

Is it owned by the Trust?

Yes

Is it portable?

No

Arrange manufacturer to install

Inform Medical Engineering of installation, and provide test, calibration and service certificates

No

Arrange Purchasing Indemnity Form

Deliver to medical engineering for acceptance tests

Put into service

Return from loan, notify Medical Engineering to update asset inventory

Yes

Long term loan

Inform Trust staff member/manager

Will manufacturer sign indemnity form?

Yes

Arrange Purchasing Indemnity Form

Deliver to medical engineering for acceptance tests

Put into service

Return from loan, notify Medical Engineering to update asset inventory

No

Reject loan equipment

Is it short term loan for demo?

Yes

Short term loan

Is it portable?

No

Arrange manufacturer to install

Inform Medical Engineering of installation, and provide test, calibration and service certificates

No

Inform Trust staff member/manager

Does clinical manager agree to loan in writing?

Yes

Arrange Purchasing Indemnity Form

Deliver to medical engineering for acceptance tests

Put into service

Return from loan, notify Medical Engineering to update asset inventory

No

Reject loan equipment

Is it short term loan for demo?
6. MEDICAL EQUIPMENT LOANS WITHIN AND OUTSIDE THE TRUST

1. There are several different routes by which equipment may be loaned to, or between departments within the Trust. These include:

- Loans within departments or by the equipment library in the same hospital
- Equipment owned by another organisation but on long term loan to the Trust
- Equipment loaned temporarily from another hospital site
- Equipment owned by the Trust but loaned for use outside Trust premises.

2. Given patient movement, the urgency and nature of patient workflow and the high levels of device usage, it is impracticable for Wards and Departments loaning equipment to each other to maintain records of these loans so that the precise location of equipment is known. Nevertheless, the following apply:

- The manager of the department receiving loaned equipment should ensure that staff are competent to operate the equipment safely (see Medical Devices Training for Clinical Staff Policy).
- Where relevant the staff have received specific training on the piece of equipment from the loan company.
- The ward device Competency List shall be updated if this device has not been used before on the ward.
- Unless still connected to the patient, the device must be decontaminated.
- If the device belongs to the equipment library the device should not be transferred but returned from loan back to the library and then re-issued after cleaning and service inspection. Devices are only ever issued on a short-term basis (maximum one-month) to deal with temporary shortfalls.
- The clinical team lending the device should notify Medical Engineering, POCT or Sterile Services so that database records can be updated if necessary.
- A record of the loan issue and return shall be kept by the department that issued the loan device. Both the Sterile Services Department and the equipment library within Medical Engineering department operate internal procedures to record these loans.

3. Any equipment provided on loan or as a free issue by a supplier must be discussed with Procurement who will check to see if the supplier is registered on the Master Indemnity Agreement (MIA) http://nhsmia.bipsolutions.com. If the supplier is not included on the MIA Register then the Procurement Department will arrange for the standard indemnity forms to be completed. Indemnity forms are required for equipment loaned for any purpose, including equipment on trial or replacement for faulty equipment. This avoids liability for loss or damage. Also refer to MHRA DB 2006(05) section 4.2.2

4. New loan devices must have a record on entry of use. They must also have an acceptance test performed before use.

5. Device on loan from a supplier belong to the supplier and shall be returned, and medical engineering/ POCT advised of the return. It shall not be scrapped at the end of the contract term or device lifespan. POCT devices loaned by the supplier must only be used in exceptional circumstances and as authorised by and organised with the POCT team.

6. Devices loaned from another hospital should not enter service with the Trust, unless by exception; for example if connected to a patient arriving from another hospital. In this case as the patient is received the devices are swapped-out for equivalent Trust-operated devices.
7. Trust inpatient devices shall not routinely operate outside of Trust controls. Discharge loans of devices are made under the terms stipulated by the relevant discharge team. These again are normally exchanged for community care operated devices at the earliest opportunity.

7. DEVICE/EQUIPMENT INVENTORY

An equipment inventory is held within the Medical Engineering, Point of Care Testing, and Sterile Services departments. These databases record such information as:

- Make
- Model
- Serial Number
- Site and location
- Date of acceptance test and EST.
- Company (supplying company and manufacturer)
- Maintenance interval (schedule of maintenance)
- Lifespan (if provided within business case, supplier or from procurement, otherwise recorded as 0)
- Next service date
- Last service date
- Status
- Ownership

The compliance audit undertaken by each department will update these records as necessary for each device located. For devices that “belong” to the ward and that are not traced, the ward shall be required to state if the device has been loaned, or returned from loan, or scrapped (All without appropriate notification of Medical Engineering).

8. REPAIR AND MAINTENANCE

Repairs to Equipment

1. Clinical staff are responsible for noting when malfunction or damage has occurred. They should cease using the equipment and contact the appropriate servicing department. The clinical department must contact the Facilities Help Desk on 2882 or POCT where a work order will be raised to plan the repair. The Facilities Helpdesk will provide the requestor with a unique reference identifier to aid tracking of repair.

2. The helpdesk operator will screen the call to evaluate the priority of the work. This will be relayed to the medical engineering team. The work will then be checked by the departmental manager or engineer to confirm the prioritisation of the work. The engineer will then allocate themselves to the repair work order.

3. Equipment for repair shall be decontaminated and clearly labelled identifying the suspected fault. Medical devices shall have the Trust “Yellow tags” (available from the medical equipment library) and the device shall be removed from use.
Maintenance of Equipment

1. Ward or department managers are responsible for ensuring that appropriate maintenance arrangements are in place for every piece of medical equipment for which they are responsible. This can be performed by in-house or by external contractor.

2. Surgical instruments that require maintenance or servicing are identified by either the user or a Sterile Services Technician. Specialist instruments are returned to the manufacturer; general instruments are sent to a contracted third party repair company. Surgical instruments do not normally require calibration but if this is identified it would be the responsibility of the user to arrange this.

3. Where Medical Engineering undertake the planned procedure this will be executed as part of an annual internal audit inspection of clinical areas. The purpose of the audit in this case is to locate, inspect, test and service a device.

4. Where external contractors come to maintain medical equipment they must first register with the Medical Industry Accreditation (MIA) scheme. Contractor shall then book appointments through the scheme website. This scheme similarly applies to sales agents, actual or prospective suppliers of medical device equipment.

5. Contractors shall be instructed to contact MIA via the following contact details: help@miaweb.co.uk or call 01892 752407 to register an application to visit the Trust.

External Service contracts

With regards devices serviced by a 3rd party contractor Wards are responsible for:

1. Seeking the advice and support of Procurement to negotiate and organise the service contract arrangements.

2. Notify Medical Engineering or POCT of planned maintenance visits via the Medical Industry Accredited Scheme.

3. Ensure that contracted maintenance is carried out to all devices listed on the service schedule.

4. Ensure that the devices are serviced in accordance with the agreed contract specification

5. Ensure that additional maintenance costs are recorded, queried and cross-checked against the agreed contract specification.

6. Send copies of service records to the POCT or Medical Engineering departments

7. Where equipment is maintained by 3rd party, it is the ward or department manager’s responsibility to ensure that they make the appropriate maintenance visit and that any documentation is retained and filed.

Service Interval for routine (planned) maintenance

1. POCT, Sterile Services and Medical Engineering will determine the planned service frequency of devices. In general this shall be in accordance with supplier’s recommendations; however the repair history, risk or other local factor may also be applied to determine suitable service levels and intervals. If these are different to those recommended by the manufacturers, then a risk assessment will be undertaken and a record kept on file.

2. Records of planned maintenance and repairs shall be retained by the responsible department.
3. The ward or department manager shall ensure that if equipment was unavailable for routine maintenance at the time of a visit, then a separate maintenance check is made on this item as soon as possible when it becomes available.

9. CLEANING AND DECONTAMINATION

1. Staff must refer to the Trust Decontamination Policy. This includes the categorisation and requirements for decontamination of reusable medical equipment.

2. Point Of Care cleaning: Where staff are expected to clean devices as they go (e.g. Cliniteks or GEM4000 blood gas machines) the procedures are included in Standard Operating Procedures and training sheets which can be accessed on the Clininet Intranet pages. A Point of Care Testing icon is available on each Trust PC such that this information is readily accessible to staff.

3. Where the POC Team visit devices on a daily basis for cleaning and maintenance (e.g. the bilimeters and centrifuges on NICU), a maintenance sheet for the month is completed and left at the site of the device. The POCT have instigated a rolling programme of quality checking and ensuring the Cliniteks calibration bars are clean. The records for these are held in the POCT office in pathology.

4. It is the ward or department manager's responsibility to ensure that their medical equipment can be properly decontaminated between patient use. Advice on decontamination can be provided by the Infection Control Team. It is also a legal offence to send contaminated equipment through the postal system.

5. Technical departments that may be required to maintain contaminated equipment (including third party maintainers) must have the necessary training and facilities to undertake such work.

6. When equipment is to be returned to a manufacturer or third party maintenance provider, the ward or department manager must ensure that it has been properly decontaminated and attach a yellow service/decontamination label with the necessary decontamination section filled in.

11. EDUCATION AND TRAINING

1. Any persons(s) operating a medical device or surgical instrument must be suitably trained, competent and have suitable authority to handle and operate it.

2. Medical devices and surgical instruments are work-based equipment and are included in the Trust's mandatory training matrix. Training in the use of medical devices used within the ward or department must also be included in the local staff induction checklist.

3. Ward Managers shall maintain an up to date Competency List of the standard items of medical equipment in use. Based on this Competency list there must be a training record for every staff member. A similar record shall be kept for surgical instrument use.

4. Managers are responsible for ensuring that manufacturers' instructions are available to staff and that their staff have the appropriate knowledge and skills to use any medical devices required. They should also, as part of individual staff development appraisals, identify any training needs. The POCT team are responsible for ensuring that standard operating procedures are available and staff are trained and deemed competent before being enabled to use a POCT device.
5. Individual members of staff are responsible for ensuring that they have received written and oral instructions and that they are competent to use any item of medical equipment before they attempt to operate it. If there is any doubt the individual concerned should consult their manager and report the training needs.

6. It is the ward or department manager’s responsibility to monitor any competency lapse of their staff annually at appraisal and ensure that any member of staff who is not completely competent and confident in its use is provided with further training as defined in their personal development plan.

7. The manager will ensure that all staff in the ward or department have received training in the requirements of incident reporting as it relates to medical devices.

8. Where possible wards and departments should aim to standardise the makes of equipment used so staff are familiar and safe in using the equipment. It is the responsibility of the manager to ensure that adequate training is given to staff when new equipment is purchased or loaned.

9. Every department will hold their own training record for every staff member using medical devices.

10. Where medical equipment is passed onto a patient or carer, Managers will ensure that this end user has all the training necessary to ensure a level of safety and operation similar to that which would be expected on the ward. In particular the manager must ensure that any instructions sent with the equipment are adequate for the knowledge level of the end user and that users and/or carers have signed a receipt confirming their understanding. This record must be kept by the department manager.

12. REPORTING ADVERSE INCIDENTS RELATING TO MEDICAL DEVICES

1. An adverse incident is an event which gives rise to, or has the potential to produce, unexpected or unwanted effects involving the safety or wellbeing of patients, users or others.

2. Adverse incidents involving medical devices may arise from various causes:
   - A fault in the device itself
   - Shortcomings in the instructions for use
   - Insufficient of servicing or maintenance
   - Locally-initiated modifications or adjustments
   - Shortcomings in user practice or training
   - Environmental or other external factors such as electromagnetic interference

3. Any adverse incident relating to the use of medical devices must be reported via the Trust’s Incident Report process (Datix).

4. An adverse incident involving a device must be reported to the MHRA through the MDSO and Trust’s Health & Safety Advisor if the incident has led or could have led to:
   - A death
   - A life threatening situation
   - Deterioration in health
   - Temporary or permanent impairment of a body function or body structure
   - Necessity of medical or surgical intervention to prevent permanent impairment or damage
   - Unreliable test results leading to inappropriate diagnosis or treatment

5. The equipment should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness
reports. In serious cases this record should be witnessed and the witness should also make a personal written record.

6. The Trust MDSO will act as the Trust’s MHRA liaison officer. The liaison officer will ensure that device related adverse incidents are reported to the MHRA. In his/her absence this will fall to the Deputy MDSO and Trust Health and Safety Officer

7. It is the responsibility of every member of staff who is aware of an adverse incident involving a medical device to report the occurrence. All incidents must be reported in line with the Trust’s Incident Reporting Policy. In addition any incident involving a medical device must be reported immediately to the MDSO/CSA liaison officer.

8. Local action must be taken to ensure the safety of patients, users and others. The device must be taken out of use but otherwise left exactly as it was at the time of the incident.

9. The MDSO; CAS Liaison Officer or person authorised by the Trust will take appropriate action and will quarantine the equipment pending investigation. Quarantining of small items may be achieved by the MDSO liaison officer or authorised person removing the equipment from the ward or department but larger items will be taped off and clearly signed “DO NOT USE”.

10. Incidents will be reported to the MHRA via the online website www.mhra.gov.uk by the MDSO; CAS Liaison Officer or other nominated person of the Trust

13. MHRA MEDICAL DEVICE ALERTS (MDA) AND THE CENTRAL ALERTING SYSTEM (CAS)

1. Safety alerts from the MHRA are sent to the Trust electronically via the Central Alerting System CAS. These are then distributed internally throughout the Trust via email to relevant individuals for action. Alert timescales are set by the MHRA, within the FSN or if absent by the Trust CAS Liaison Officer. S/he is responsible for ensuring that alerts are dealt with within given timescales or deadlines and for reporting back through CAS.

2. For field safety notes that are not reported through CAS, the MDSO will co-ordinate the response to alerts, notifying the CAS Liaison Officer as each stage is completed.

3. Divisional Managers are to ensure that staff respond to CAS with an appropriate response including “not applicable” or “no action required”. No response at all is unsuitable and will prompt escalation to the Chair of the MDG and upwards through the governance structure. A response shall be provided to the MDSO/CAS Liaison Officer before the deadline given on the alert

14. DISPOSAL OF DEVICES OR RETURN FROM LOAN

1. Medical equipment may be considered for disposal as a result of its natural obsolescence, failure to meet current treatment standards, uneconomic or poor serviceability.

2. Managers shall notify POCT, Sterile Services or Medical Engineering by email to confirm the instruction to dispose or return devices.

3. The Point of Care Testing Team will take responsibility for the disposal of point of care testing equipment according to the POCT Policy.

4. Decontamination shall be carried out prior to decommissioning and disposal.

5. As part of the decommissioning process it is essential that all patient information is removed from the medical device. This includes software records, tagging details of the ward, hospital or Trust. If software details cannot be removed then the hardware (memory/hard disk) is to be removed and
disposed of in accordance. The manager shall notify the department charged with disposal (POCT, Medical Engineering or Sterile Services) of the presence or likelihood of patient data.

6. Data shall be deleted to an appropriate standard, such as BS ISO/IEC 15408 [24] and British HMG Infosec Standard 5, or IS5 [25], before disposal. Data on any device should be forensically unrecoverable, i.e. patient data must be over-written.

7. The Trust may consult the manufacturer for the best methods of waste disposal and be able to provide details of the current techniques and processes applicable to their products.

8. When equipment is disposed of for sale by auction for use by other organisations there is a process in place to remove the Trust’s liability as well as identity from the device.

15. MONITORING AND AUDITING COMPLIANCE

1. The policy will be monitored by the Medical Devices Group. This is achieved through meetings and the receipt of relevant reports.

2. Membership of the Medical Devices Group includes representatives from Divisions to enable feedback to areas when required.

3. A rolling programme of policy, procedural compliance as well as benchmarking audits will be undertaken by or on behalf of – Sterile Service, Medical Engineering, and POCT departments. Managers will be provided with a copy of the audit findings. Where areas of non-compliance are identified, the ward/department manager will be responsible for creating, following and completing an action plan to achieve compliance. Deadlines shall be set out in the action plan to close all outstanding non-compliances and observations.

4. The MDG will review the results of medical equipment audits, in order to identify themes across the Trust requiring action to address areas of identified risk.

16. EQUALITY AND DIVERSITY

This policy has been impact assessed in accordance with statutory requirements and a copy of the assessment is attached to the policy.

17. ARCHIVING

This is a Trust wide document and archiving arrangements will be made by the quality department.

18. IMPLEMENTATION AND TRAINING

This policy and procedures will be available to all staff via the Intranet. Hard copies of this document should be kept locally for easy reference.

Managers are responsible for ensuring that their staff are aware of this policy and are kept informed of any changes or additions.

The contents of this policy will be included in mandatory training and induction.

19. REFERENCES

- Managing Medical Devices, guidance for healthcare and social services organisations, DB2015 April 2015
20. APPENDICES

A: Medical devices Group - Terms of Reference
B: Equality Impact Assessment Summary
APPENDIX A

MEDICAL DEVICES GROUP
Terms of Reference

Constitution
The Safety and Risk Committee hereby resolves to establish a Group to be known as the Medical Devices Group (MDG).

Authority
The Group is authorised by the Committee to investigate any activity within its terms of reference. It is authorised to seek any information it requires from any employee and all employees are directed to cooperate with any request made by the Group.

Membership
Deputy Director of Infection Prevention and Control
Head of Estates & Facilities Infrastructure
Head of Procurement
Anaesthetics Practitioner (Theatres and ITU)
Sterile Services Manager
Senior Specialist Moving and Handling Advisor
Clinical Governance Managers
Clinical Skills Education Manager
Health Safety and Security Advisor
Pharmacy Representative
Nursing Representative
Maternity Representative
Point of Care Testing / Pathology Representative
Medical Engineering Manager

Attendance
Attendance at meetings is essential. In exceptional circumstances when a member cannot attend they must arrange for a fully briefed deputy of sufficient seniority to attend on their behalf. Members will be required to attend as a minimum, 50% of the meetings per calendar year.

Quorum
There must be at least 6 members in attendance, including representation from The Chair or the nominated deputy, procurement, Sterile Services and Clinical representation. This is necessary to conduct the meeting to exercise all or any of the authorities, powers and discretions invested in, or exercisable, by the group.

Frequency and Conduct
The group will meet quarterly.

Membership and terms of reference will only be changed with the approval of the Risk Scrutiny Committee. This will be reviewed and agreed as circumstances dictate.

Duties
• To ensure that medical devices used within the Trust are; suitable for purpose; used in accordance with the manufacturer’s instructions; maintained in a safe and reliable condition; disposed of appropriately at the end of its useful life.
• To consider any risks from medical devices to the Trust and act accordingly to mitigate those risks using the Trust risk register where appropriate.
• To ensure that the arrangements for the selection, acquisition, acceptance and disposal of medical devices follow the Trust’s Management of Medical Devices Policy.
• To ensure that there is an accurate record of re-usable medical devices including a unique identifier for the equipment, a full history including date of purchase and where it was installed.

• To ensure that there is a full maintenance history for the equipment.

• To ensure that there is a record of persons properly trained and competent to use the equipment.

• To review the divisional action plans arising from Medical Engineering Services audits and their progression to mitigate findings. To escalate those actions to Divisional Managers that remain unresolved within suitable timeframes.

**Key Responsibilities**

• To oversee compliance with outcome 11, Safety, availability and suitability of equipment, including monitoring with reference to outcomes as identified in the patient and staff surveys.

• To oversee and drive the operational management of medical equipment using all policies relating to Medical Devices making recommendations towards strategic objectives.

• To oversee compliance with NHSLA Risk Management Standards related to Medical Devices.

• To ensure effective medical equipment management via governance.

• Ensuring the appropriateness of Single Use Items.

• To review and ensure compliance with all guidance and alerts relating to medical devices.

• To monitor incidents, defects and failure information including those reported to the MHRA.

• Produce and approve equipment policies for submission to the Clinical Governance Committee or the Safety and Risk Committee for ratification.

**Reporting Lines**

The group will report to the Risk Scrutiny Committee on a quarterly basis providing a report as per Committee Group policy.

**Monitoring**

The effectiveness of the group will be monitored by the Risk Scrutiny Committee. The Chair will report to the Safety and Risk Committee at each Quarterly meeting and provide an annual report as per Committee Group policy.

**Approved by Safety and Risk Committee**

**Date:** 12 January 2017
Appendix B:

Please refer to the separate published guide called “Medical Device managers and staff guide”.
Equality Impact Assessment Summary

Background
- Description of the aims of the policy
- Context in which the policy operates
- Who was involved in the Equality Impact Assessment

This policy has been developed to comply with the requirements of the Medical and Healthcare Products Regulatory Agency (MHRA) to ensure that all staff are aware of the procedures for dealing with medical equipment.

Methodology
- A brief account of how the likely effects of the policy was assessed (to include race and ethnic origin, disability, gender, culture, religion or belief, sexual orientation, age)
- The data sources and any other information used
- The consultation that was carried out (who, why and how?)

The policy is based on guidance provided by the MHRA and is not likely to have any Equality or Diversity implications.

Key Findings
- Describe the results of the assessment
- Identify if there is adverse or a potentially adverse impacts for any equalities groups

The policy is based on current legislation and there are no potential impacts for any equality groups.

Conclusion
- Provide a summary of the overall conclusions

The policy provides fair, consistent guidance on managing medical equipment.

Recommendations
- State recommended changes to the proposed policy as a result of the impact assessment
- Where it has not been possible to amend the policy, provide the detail of any actions that have been identified
- Describe the plans for reviewing the assessment

No changes recommended.

Guidance on Equalities Groups

<table>
<thead>
<tr>
<th>Race and Ethnic origin (includes gypsies and travellers) (consider communication, access to information on services and employment, and ease of access to services and employment)</th>
<th>Religion or belief (include dress, individual care needs, family relationships, dietary requirements and spiritual needs for consideration)</th>
</tr>
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<tbody>
<tr>
<td>Disability (consider communication issues, access to employment and services, whether individual care needs are being met and whether the policy promotes the involvement of disabled people)</td>
<td>Sexual orientation including lesbian, gay and bisexual people (consider whether the policy/service promotes a culture of openness and takes account of individual needs)</td>
</tr>
</tbody>
</table>