Management of Medical Devices Policy

<table>
<thead>
<tr>
<th>CATEGORY:</th>
<th>Policy</th>
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<tr>
<td>CLASSIFICATION:</td>
<td>Governance</td>
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<tr>
<td>PURPOSE</td>
<td>To set out the principles and framework for the management of Medical Devices.</td>
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<tr>
<td>• Essential Reading for:</td>
<td>All Users of Medical Devices</td>
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<tr>
<td>• Information for:</td>
<td>All Directors, Senior Managers and Departmental Heads</td>
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## Appendices

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1. Policy Statement

1.1 University Hospitals Birmingham NHS Foundation Trust (the ‘Trust’) is committed to providing the best in patient care within a safe environment. Medical devices play a key role in patient care.

1.2 The aim of this policy is to ensure that all medical devices used within the Trust are fit for purpose, properly maintained, and used safely.

1.3 The use of all medical devices is subject to this policy and its associated procedural documents.

1.4 Only medical devices conforming to relevant specifications and standards may be used within the Trust.

2. Scope

2.1 This policy covers all aspects of the management of medical devices, including patient and staff safety, procurement, specification, training, decontamination, maintenance, contracts, disposal, infection control, tracking and tracing, documentation and certification.

2.2 This policy applies to all users of medical devices and applies to the management of all medical devices used by the Trust with the exception of Point of Care Testing Equipment which is covered by a separate policy.

3. Framework

3.1 This section describes the broad framework for the management of medical devices throughout the Trust. Detailed operational instructions for the implementation of this policy are contained in the associated Procedure for the Management of Medical Devices and the Procedure for Training in the Safe Use of Medical Devices.

3.2 The Executive Chief Nurse shall approve all procedural documents associated with this policy and any amendments to such documents, and is responsible for ensuring that such documents are compliant with this policy.

3.3 Definitions

3.3.1 For the purposes of this policy, the Medicines and Healthcare products Regulatory Agency (MHRA) definition of a Medical Device is adopted, as follows:

“any instrument, apparatus, appliance, material or health care product excluding drugs used on a patient or client for the purpose of:
Diagnosis, prevention, monitoring, treatment or alleviation of disease.

Diagnosis, monitoring, treatment or alleviation of or compensation for, an injury or handicap.

Investigation, replacement or modification of the anatomy or of a physiological process.

Control of conception.”

(MHRA publication “Devices in Practice: a guide for professionals in health care and social care”)

3.3.2 The MHRA

The MHRA is the government agency which is responsible for ensuring that medicines and medical devices work and are acceptably safe. The MHRA was set up in April 2003 from a merger of the Medicines Control Agency and the Medical Devices Agency. The MHRA is an executive agency of the Department of Health.

3.3.3 Central Alerting System (CAS)

CAS is an electronic system developed by the Department of Health and is the primary method of distributing alerts to all NHS Trusts and Primary Care Trusts (PCT’s) in England. It incorporates a feedback system to record acknowledgement and actions taken by Trusts following the receipt of the alerts.

3.3.4 Reusable Medical Device

A reusable medical device is any medical device which is intended for use on more than one patient during a single procedure.

3.3.5 Single Use

The expression “single use” means that the medical device is intended to be used on an individual patient during a single procedure and then discarded. They should not be reprocessed and used on another patient. (This excludes patient hoist slings).

3.4 Procurement of Medical Devices

It is the policy of the Trust that all medical devices purchased by or on behalf of the Trust shall be procured through the Procurement Department, which must be involved in the procurement of medical devices from the start of the process when a requirement is identified. This includes medical devices that are purchased by Trust funds,
purchased by Endowment funds, leased or donated including Charity donations.

When procuring medical devices, a pre-acquisition questionnaire (PAQ) must be completed, which shall include the following:

3.4.1 CE Marking;
3.4.2 Management System Standards;
3.4.3 Safety Standards;
3.4.4 Service/Spares/Installation;
3.4.5 Decontamination/Reprocessing; and
3.4.6 Warranty.
3.4.7 Information Governance

3.5 Use of Medical Devices

Medical Devices must be used so that patient and staff safety is ensured at all times by means of appropriate control measures which include:

3.5.1 Traceability (3.6);
3.5.2 Risk Assessment (3.7);
3.5.3 User instructions (3.8);
3.5.4 Notices affecting a medical device (3.9);
3.5.5 Training (3.10);
3.5.6 Maintenance & Cleaning (3.11) and
3.5.7 Patient Identifiable Information is stored in a safe manner

3.6 Traceability

3.6.1 The Trust shall maintain systematic inventories of all reusable medical devices used within the organisation, as follows:

a) Medical Engineering Equipment Management System – an inventory of all reusable medical devices that are not included in the two inventories below;

b) Renal Dialysis Inventory – an inventory of all renal dialysis medical devices; and
c) Engie Equipment management System – an inventory of all medical devices managed by Engie.

3.6.2 On procurement, a medical device will be assigned to one of the above inventories either by the Medical Engineering Team, Renal team or Engie.

3.6.3 Medical devices must be marked in accordance with the Procedure for the Management of Medical Devices.

3.7 Risk Assessment

All new medical devices (i.e. of a type/model that is not in current use in the Trust) shall be assessed to identify any risks associated with their use by The Medical Devices Training Group. Please refer to the Procedure for Training in the Safe use of Medical Devices for guidance on risk classification regarding training.

3.8 User Instructions

Manufacturers user instructions will be issued with all new medical devices and will be made available for all staff to view either by the Medical Engineering Team, Renal team or Engie.

3.9 Notices affecting a medical device

3.9.1 If the Trust is notified, or becomes aware of, a risk or safety alert associated with a medical device that is in use within the Trust, any staff likely to use such a device must be notified immediately of the risk by the Datix Safety Alert System which is managed by the Clinical Risk and Compliance Department.

3.9.2 All staff involved with the medical device must be made aware of the alert by their line manager. The line manager must also put in place appropriate controls to deal with the risk. Details of such safety notices must be recorded by the Safety Alert Bulletin Liaison Officer (SLO). For further information please refer to the Trust Procedure for Dissemination and Implementation of Central Alert System (including National Patient Safety Alerts).

3.10 Training

Please refer to the Procedure for Training in the Safe use of Medical Devices for further information on Training and risk classification of medical devices (low, medium and high).

3.10.1 No member of staff may use a medical device unless:

a) They have been appropriately trained or assessed as competent in the use of the particular device;
b) They are doing so under supervision as part of such training or assessment;

c) They have self-verified their competence to use the particular device; or

d) They are doing so in response to a clinical emergency.

3.10.2 All training requirements must be met in accordance with the Procedure for Training in the Safe Use of Medical Devices.

3.10.3 Accurate and up to date records of all training must be maintained in accordance with the Procedure for Training in the Safe Use of Medical Devices. All data relating to medical device training should be forwarded to the Medical Devices Training Lead. Any formal medical device training data should be forwarded to the Training Administration Team.

3.10.4 The Medical Devices Training Group (“MDTG”) shall provide a forum for the overseeing and coordinating of medical device training. It shall be chaired by the Head of Clinical Risk and Compliance.

3.11 Maintenance, Repair and Cleaning

3.11.1 The maintenance requirements for each medical device will be assessed and, where a manufacturer service agreement is not provided, a scheduled maintenance programme will be assigned. Checks will be made to ensure maintenance is carried out in accordance with manufacturer and Trust schedules.

3.11.2 If any medical device is faulty and requires repair, then it should be reported to the relevant department i.e. Medical Engineering, Engie or Renal Technicians so that the necessary action is carried out.

3.11.3 All re-usable medical devices must be cleaned/decontaminated between patients and prior to disposal in accordance with the associated Procedure for Decontamination of re-usable medical devices prior to patient use, inspection, servicing, repair or return to departments or organisations.

3.12 Advice

Liaison or advice on any of the above should be sought from the Trust’s Decontamination Advisor, Prevention and Control of Infection Team, Microbiologist, Health and Safety Advisor, Manual Handling Advisor and Medical Engineers.
4.  Duties

4.1  Executive Chief Nurse

The Executive Chief Nurse will:

4.1.1 ensure that the policy is effectively implemented throughout the Trust; and

4.1.2 ensure that any serious concerns regarding the management of medical devices are brought to the notice of the Chief Executive or the Board of Directors, as appropriate.

4.2  Divisional Directors of Operations (DDOps)

Divisional Directors of Operations (DDOps) have the responsibility for implementing and monitoring adherence to this policy and associated procedures throughout their Division. DDops will:

4.2.1 ensure that all medical devices used within their Division are procured appropriately; and

4.2.2 have overall responsibility for ensuring all contracts for the routine maintenance of medical devices are formulated and implemented in liaison with the Medical Engineering Department or Estates Department.

4.3  Director of Estates and Facilities

The Director of Estates and Facilities shall chair the Equipment Strategy Group and ensure that any significant governance and/or safety issues or serious instances of non-compliance with this policy are reported to the Executive Chief Nurse.

4.4  Group Managers, Ward Managers and Line Managers

Group Managers, Ward Managers and Line Managers have responsibility for the day to day implementation of this policy and procedure. They shall:

a) Ensure that any Medical Device is appropriate and sufficient for its intended use and that it complies with all regulatory requirements and guidance;

b) Check and identify contract maintenance needs of all medical devices and liaise with appropriate departments, notifying the needs to the Divisional Director of Operations;

c) Ensure that all Medical Device incidents are reported in accordance with the Policy for the Reporting and Management of...
Incidents including Serious Incidents Requiring Investigation and that these are immediately escalated to the appropriate personnel, (including Medical Engineering);

d) Ensure that satisfactory arrangements for all appropriate tests, checks, validation, commissioning, verification and paperwork are carried out before installation and use of medical devices. Assurance can be obtained from the relevant departments such as Medical Engineering, Engie; and

4.4.2 Be involved in identifying needs and requirements for all medical devices by developing specifications and providing these to procurement.

4.5 **Medical Engineering Manager**

The Medical Engineering manager will oversee the day to day implementation of this policy and its associated procedures throughout the Trust, which includes:

4.5.1 managing, negotiating and monitoring performance against all external service maintenance contracts for all medical devices;

4.5.2 monitoring all medical devices throughout their life cycle to ensure that they are safe and fit for their intended purposes and where applicable ensure that there are no major effects on patient care or waiting lists;

4.5.3 ensuring the provision of appropriate training for all relevant Trust staff in the safe and competent use of medical devices, and to monitor the attendance of staff at such training; and

4.5.4 maintaining an inventory of all medical devices used within the Trust regardless of monetary value, other than:

a) Single use items;

b) Renal dialysis devices;

c) Medical devices for which Engie have responsibility;

d) Therapy Services assessment and treatment items; and

e) Integrated Community Equipment Service items.
4.6 **Director of IT**

The Director of IT shall ensure that:

4.6.1 Requirements for the connection of medical devices to the Trust network have been approved and configured by the IT Services Department;

4.6.2 Medical equipment approved for connection to the Trust network meet local procedures for interoperability and security management as part of the Trust-wide implementation; and

4.6.3 Users do not permit any unauthorised party (e.g. a patient, supplier or contractor) to connect any medical device to the Trust network, without prior authorisation from the IT Services Department.

4.7 **Head of Procurement**

The Head of Procurement shall ensure that:

4.7.1 No medical device is purchased without prior approval from the Equipment Strategy Group; and

4.7.2 Requirements for all medical devices are notified to the Equipment Strategy Group, where necessary providing the specifications, manufacturer’s instructions, decontamination instructions, training needs, location and division of use, funding for maintenance and compatibility.

4.8 **Medical Devices Safety Officer (MDSO)**

The Medical Devices Safety Officer will:

4.8.1 Ensure that any reportable incidents are reported to the Medicines and Healthcare products Regulatory Agency (MHRA), following up all such reports and liaising with any relevant Trust personnel;

4.8.2 Ensure prompt onward distribution of all alerts received from the MHRA as appropriate and shall further ensure that updates and feedback on action taken are logged on the Central Alerting System website; and

4.8.3 Ensure that, whenever required, Trust Internal Hazard Notices are produced and disseminated promptly and that the implementation of such notices is monitored.
4.9 **Medical Devices Training Lead**

The Medical Devices Training Lead will oversee, audit and co-ordinate the facilitation and recording of the training of all relevant staff in the safe and competent use of medical devices, and monitor that the Trust complies with the Procedure for Training in the Safe Use of Medical Devices.

4.10 **Directorate Manager, Medical Education/ Associate Medical Director**

The Medical Education Manager shall ensure the facilitation and recording of the training of all trainee medical staff in the safe and competent use of set core medical devices during Junior Doctor induction. Training on devices specific to specialties is the responsibility of the Clinical Service Leads for those specialities. The Associate Medical Director shall do likewise for all other medical staff.

4.11 **Renal Technical Manager**

The Renal Technical Manager shall maintain an inventory of all renal dialysis medical devices (other than single use items) used within the Trust and shall ensure that this policy is implemented and monitored in respect of such items.

4.12 **Engie**

Engie shall maintain an inventory of all medical devices (other than single use items) used within the Trust and which are controlled by them and shall ensure that this policy is implemented and monitored in respect of such items.

4.13 **Therapy Services Group Manager**

The Therapy Services Group Manager shall maintain an inventory of all Therapy Services medical devices (other than single use items) used within the Trust or loaned to patients by Trust staff and shall ensure that this policy is implemented and monitored in respect of such items.

4.14 **Managers**

Managers are responsible for ensuring that the use of medical equipment as required by a role and/or department must also form part of the Local Induction process for all new starters/ transfers/ secondments/temporary staff to the Trust.

4.15 **All Staff**
It is the responsibility of all employees to make themselves aware of this policy and any associated procedural requirements. They must also:

4.15.1 ensure that they have reported to their line manager any deficiency in their training on equipment or devices used by them in their workplace. Failure to do so may render them liable for possible disciplinary action;

4.15.2 ensure that they are competent to operate any piece of medical equipment as deemed necessary for their department and for their role, as specified in the Procedure for the Training in the Safe Use of Medical Devices; and

5. **Implementation and Monitoring**

5.1 **Implementation**

This policy will be available on the Trust’s intranet site. The policy will also be disseminated through the management structure within the Trust.

5.2 **Monitoring**

Appendix A provides full details on how the policy will be monitored by the Trust.

6. **References**

Control of Substances Hazardous to Health Regulations (COSHH) 2002

Electrical Equipment (Safety) Regulations 1994

Electricity at Work Regulations 1989

Health and Safety at Work Act 1974

MHRA – Managing Medical Devices April 2015

MHRA – Managing Medical Devices – Guidance for healthcare and social services organisations 2015

Management of Health and Safety at Work Regulations 1999

Medical Devices Directive 93/42/EEC as amended 2007/47/EC

Provision and use of Work Equipment Regulations 1998

Waste Electrical and Electronic Equipment Regulations 2006 as amended 2007
7. **Associated Policy and Procedural Documentation**

Point of Care Testing Policy

Policy and Procedure for the Reporting and Management of Incidents including Serious Incidents Requiring Investigation

Procedure for Decontamination of re-usable medical devices prior to patient use, inspection, servicing, repair or return to departments or organisations

Procedure for Dissemination and Implementation of Central Alert System (including National Patient Safety Alerts)

Procedure for Loaning and Borrowing of Medical Devices

Procedure for the Management of Medical Devices

Procedure for the Trials and Evaluation of Medical Devices

Procedure for Training in the Safe Use of Medical Devices
## Appendix A

### Monitoring Matrix

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<th>MONITORING OF IMPLEMENTATION</th>
<th>MONITORING LEAD</th>
<th>REPORTED TO PERSON/GROUP</th>
<th>MONITORING PROCESS</th>
<th>MONITORING FREQUENCY</th>
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<tr>
<td>Monitor number of repair/technical advice/commissioning/decommissioning/supply/functional test/on loan/incidents/hazard/call out job requests being reported to Medical Engineering, Renal Department and Engie and ensure that they are being dealt with in the set timescales</td>
<td>Trust Medical Engineering Manager, Technical Manager – Renal and Engie Lead</td>
<td>Equipment Strategy Group</td>
<td>Provide quarterly report of Job Stats for Medical Engineering, Renal Department and Engie to the Equipment Strategy Group</td>
<td>Quarterly</td>
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<td>Where required all inventory listed medical devices will have an up to date maintenance schedule attached</td>
<td>Trust Medical Engineering Manager/Technical Manager – Renal and Engie Lead</td>
<td>Equipment Strategy Group</td>
<td>Provide quarterly Planned Preventative Maintenance stats for completed Planned Preventative Maintenance over a 12 month period, highlight any not completed and implement actions if necessary to rectify those not completed within the period.</td>
<td>Quarterly/Annual</td>
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<td>Audit of Medical Engineering’s equipment management system is provided on a quarterly and annual basis via the Quarterly/Annual Reports issued to Equipment Strategy Group</td>
<td>Quarterly/Annual</td>
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<td>Weekly/Monthly/Annual Job Stats developed for jobs in progress greater than 12 months, jobs in progress, jobs to be done, jobs to be done greater than 2 months, monthly</td>
<td>Weekly/Monthly/Annual</td>
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| Provide assurance that all medical devices are procured appropriately | Trust Medical Engineering Manager/Head of Procurement | Equipment Strategy Group | Provide bi monthly reports to the Equipment Strategy Group on the purchase of Capital Replacement Equipment. Provide bi monthly reports to the Equipment Strategy Group for the purchase of revenue medical equipment via number of revenue forms completed and number of PAQ's signed and approved within the period. |
| Monitor management of incidents and management of safety alerts | Operational Director – Decontamination/Infection Control, Trust Medical Engineering Manager and Head of Clinical Risk and Compliance | Executive Chief Nurse and Equipment Strategy Group | Annual Report to be produced to ensure compliance with the policy and associated procedures. The report will ensure: That the policy remains fit for purpose and is reviewed at least every 3 years. The report will provide assurance that:  
  - all incidents involving medical devices are reviewed and where necessary actions are implemented to reduce risk.  
  - all safety alert bulletins are disseminated appropriately and all responses are monitored and audited. |
| Monitoring of Clinical Areas to ensure Medical Device Training is being completed | Medical Devices Training Lead/ Line Managers/Clinical Service Leads | Equipment Strategy Group | Carry out audits in clinical areas to ensure that there is a nominated core trainer, a training folder in place and that training records are being updated for all permanent staff. Ensure that there is an up to date inventory of diagnostic and therapeutic equipment for each clinical area. Medical staff to be monitored through the appraisal process to ensure that any new and existing staff have received medical devices training and signed a disclaimer to confirm knowledge of the Trust policy of not using any medical devices unless competent. Provide bi monthly, quarterly and annual reports on Medical Device Training throughout the Trust, highlighting compliance for each area. | Annually |

| Monitoring of devices which store Personal Identifiable Information | Trust Medical Engineering Manager | Information Governance Group | An updated spreadsheet will be presented to the Information Governance Group as and when new Medical Devices are procured which will have the capacity to store Personal Identifiable Information. | As and when required |
| Monitoring of contracts for the procurement of Medical Devices | Trust Medical Engineering Manager | Information Governance Group | The Information Governance Group will review all contracts for the procurement of Medical Devices which will have the capacity to store Personal Identifiable Information, before the contracts are signed. | As and when required |