Wirral Community Health and Care NHS Foundation Trust

Medical Supplies & Devices Management Policy General Policy GP48 (Version 3)

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Document summary	The purpose of this policy is to ensure that staff operating diagnostic or therapeutic equipment can do so in a safe and effective manner

Document History		
Version number	Comments	Approved by
1	New 2012	Quality & Governance Committee
2	Review January 2016 Updated included: 1. Recording of medical devices competency arrangements 2. Equipment recovery	Quality and Governance Committee
3	New format and update:	Quality and Safety Committee

Policy on a page

The purpose of this policy is to ensure that:

- Staff operating diagnostic or therapeutic equipment can do so in a safe and effective manner
- Staff recognise the possible risks to service users, staff and the Trust, of the failure to meet suitable standards of safety and performance in the application and use of medical devices.
- All staff are competent in the use of medical devices that they are reasonably expected to use in their clinical area
- The trust meets the Care Quality Commission's standards on prevention of incidents by unsafe or unsuitable devices
- Wirral Community Health and Care NHS Foundation Trust to comply with Care Quality Commission Essential Standards of Quality and Safety
- New medical devices are procured in accordance with this policy
- Compliance with this policy will help staff employed by WCT to ensure equipment is safely used in accordance with guidelines, external standards and regulations
- Appropriate reporting to the Medicines and Healthcare Products Regulatory Agency (MHRA)
- WCT is following Medical Devices Guidance for Healthcare and Social Services Organisations April 2015 Health and Social Care Act 2008 (Regulated Activities) Regulations 15

SUPPORTING STATEMENTS

This document should be read in conjunction with the following statements:

SAFEGUARDING IS EVERYBODY'S BUSINESS

All Wirral Community Health and Care NHS Foundation Trust employees have a statutory duty to safeguard and promote the welfare of children and adults, including:

- being alert to the possibility of child/adult abuse and neglect through their observation of abuse, or by professional judgement made as a result of information gathered about the child/adult;
- knowing how to deal with a disclosure or allegation of child/adult abuse;
- undertaking training as appropriate for their role and keeping themselves updated;
- being aware of and following the local policies and procedures they need to follow if they have a child/adult concern';
- ensuring appropriate advice and support is accessed either from managers, *Safeguarding Ambassadors* or the trust's safeguarding team;
- participating in multi-agency working to safeguard the child or adult (if appropriate to your role; ensuring contemporaneous records are kept at all times and record keeping is in strict adherence to Wirral Community Health and Care NHS Foundation Trust policy and procedures and professional guidelines. Roles, responsibilities and accountabilities, will differ depending on the post you hold within the organisation;
- ensuring that all staff and their managers discuss and record any safeguarding issues that arise at each supervision session.

EQUALITY AND HUMAN RIGHTS

Wirral Community Health and Care NHS Foundation Trust recognise that some sections of society experience prejudice and discrimination. The Equality Act 2010 specifically recognises the protected characteristics of age, disability, gender, race, religion or belief, sexual orientation and transgender. The Equality Act also requires regard to socio-economic factors including pregnancy/maternity and marriage/civil partnership.

The trust is committed to equality of opportunity and anti-discriminatory practice both in the provision of services and in our role as a major employer. The trust believes that all people have the right to be treated with dignity and respect and is committed to the elimination of unfair and unlawful discriminatory practices.

Wirral Community Health and Care NHS Foundation Trust also is aware of its legal duties under the Human Rights Act 1998. Section 6 of the Human Rights Act requires all public authorities to uphold and promote Human Rights in everything they do. It is unlawful for a public authority to perform any act which contravenes the Human Rights Act.

Wirral Community Health & Care NHS Foundation Trust is committed to carrying out its functions and service delivery in line with a Human Rights based approach and the FREDA principles of **F**airness, **R**espect, **E**quality **D**ignity and **A**utonomy.

CONTENTS Page No.

Medical Devices Management Policy 1

General Policy GP48 1

(Version 3) 1

CONTENTS Page No. 4

1. PURPOSE AND RATIONALE 5

2. OUTCOME FOCUSED AIMS AND OBJECTIVES 5

3. SCOPE 5

4. DEFINITIONS (Glossary of Terms) 6

5. RESPONSIBILITIES, ACCOUNTABILITIES AND DUTIES 6

6 PROCESS 10

7 CONSULTATION 14

8 TRAINING AND SUPPORT 14

9 MONITORING 16

10. EQUALITY AND HUMAN RIGHTS ANALYSIS 16

11. LINKS TO OTHER POLICIES 17

12. REFERENCES 17

13. APPENDIX 1 MEDICAL DEVICES PROCUREMENT LIST 20

14. APPENDIX 2 MEDICAL DEVICE INSPECTION, SERVICING & REPAIR FORM 21

15. APPENDIX 3 EQUIPMENT TO BE SUBMITTED TO EBME 22

16. APPENDIX 4 LIFTING EQUIPMENT REGULATIONS UNDER LIFTING OPERATIONS & LIFTING EQUIPMENT REGULATIONS 1998 (LOLER) 24

17. APPENDIX 5 MEDICAL DEVICE CLASSIFICATIONS & ASSOCIATED TRAINING FOR QUIPMENT 25

18. APPENDIX 6 MONITORING COMPLIANCE WITH THE PROCESS DESCRIBED IN THE POLICY 26

19. APPENDIX 7 MIA CALL-OFF AGREEMENT 28

20. APPENDIX 8 EQUALITY & HUMAN RIGHTS ANALYSIS 32

1. PURPOSE AND RATIONALE

1.1 Introduction

Wirral Community Health and Care NHS Foundation Trust has an obligation to protect patients, carers and staff and recognises the importance of good diagnostic and therapeutic equipment management as a means of preventing risk of injury or infection to patients. Wirral Community Health and Care NHS Foundation Trust is committed to ensuring that whenever a medical device is used it should be:

- Suitable for its intended purpose
- Standardised
- Used in accordance with manufacturing instructions by staff, authorised, trained and assessed competent to do so
- Maintained in a safe and reliable condition
- Disposed of appropriately at the end of its useful life

1.2 Statement of Intent

Wirral Community Health & Care NHS Foundation Trust will subsequently be referred to as the Trust, The purpose of this policy and procedure is to ensure that:

- staff operating diagnostic or therapeutic equipment can do so in a safe and effective manner
- medical devices are maintained in a safe and reliable condition
- medical devices are only used by trained competent staff
- new medical devices are procured in accordance with this policy

Compliance with this policy will help staff employed by the Trust to ensure equipment is safely used in accordance with guidelines, external standards and regulations

- Reporting to the Medicines and Healthcare products Regulatory Agency (MHRA)
- Managing Medical Devices Guidance for healthcare and social services organisations April 2015 Health and Social Care Act 2008 (Regulated Activities) Regulations 15

2. OUTCOME FOCUSED AIMS AND OBJECTIVES

2.1 To ensure that all the Trust's medical devices are managed in a way that maximises safety, performance, efficiency, value, correct use and minimise risk

2.2 To recognise the possible risks to service users, staff and the Trust, of the failure to meet suitable standards of safety and performance in the application and use of medical devices.

2.3 To ensure all staff are competent in the use of medical devices that they are reasonably expected to use in their clinical area

2.4 Support the trust meet the Care Quality Commission's standards on prevention of incidents by unsafe or unsuitable devices

3. SCOPE

3.1 This policy & procedure applies to diagnostic and therapeutic equipment used within the trust by authorised staff whether it be owned, leased or loaned.

3.2 This policy does not apply to medical devices purchased and owned by private individuals. Where trust staff use a medical device that does not fall within the

management responsibility of the trust, the staff member should take reasonable steps to ensure that the medical device has been subject to the same management procedures as those applied by the trust. Where a member of staff cannot satisfy themselves of this or has concerns about a device they should seek to use alternative equipment that is subject to trust management procedures.

4. DEFINITIONS (Glossary of Terms)

4.1 The MHRA's definition of a medical device is:	"Any instrument, apparatus, appliance, material or health care product, excluding drugs, used for 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 contraception" For example, syringes, dressings, catheters, scanners, ECG machines, hoists, pressure relieving equipment, defibrillators, commodes etc. A more extensive list is available from the Medicines and Healthcare products Regulatory Agency (MHRA)
Medical Device Register	A list of medical devices for all services and the register is held on Datix as to the location and maintenance requirements of all equipment and updated by services
Divisional QPER	Quality, Patient Experience and Risk Group

5. RESPONSIBILITIES, ACCOUNTABILITIES AND DUTIES

5.1 The Board of Directors

The Board has responsibility for the implementation of this policy and the monitoring of compliance. The Board is made up of the Chairman, Chief Executive, Executive Directors, Medical Director and Non-Executive Directors. The Board of Directors oversee the running of the trust, making decisions that shape future direction, monitoring performance and accountability outlined in the Board Assurance Framework and Integrated Business Plan.

The Trust Board has responsibility for ensuring that it corporately meets its statutory duties in relation to Medical Devices used throughout the Trust.

This responsibility is delegated to the Standard Assurance Framework for Excellence (SAFE) Steering Group via the Medical Device and Supply Group.

The Board provides support for the Director of Medical Devices and takes a position on any recommendations and advice that are provided.

The Trust Board will receive via the SAFE Steering Group;

- Minutes of the Medical Supplies and Device Group
- Exception reports where indicated

5.2 **The Chief Executive**

As Accountable Officer, the Chief Executive must ensure that responsibility to manage the risk with regard to medical devices and the role is delegated to an appropriate executive lead.

5.3 **Board/Committee**

Trust Board

The trust Board has overall responsibility for the implementation of this policy and the monitoring of compliance.

5.4 Quality and Safety Committee

The primary function of the Quality and Safety Committee is to provide assurance to the Board of overall compliance with all statutory and regulatory obligations for the management of medical devices.

Standard Assurance Framework for Excellence

The purpose of the Standards Assurance Framework for Excellence (SAFE) Steering Group is to be responsible for the effective management and delivery of the Trust's Standard Assurance Framework providing compliance with regulatory standards.

The SAFE Steering Group will review learning from incidents, risks and complaints to ensure Trust wide dissemination to support the delivery of high quality, safe services provide assurance to the Oversight and Management Board of Trust Compliance with regulatory standards including the Care Quality Commission (CQC).

The SAFE Steering group will oversee the medical devices management strategies taking into account of cost, performance and risk across the equipment lifecycle. Ensuring there are systems of management in place to ensure reporting of medical device issues or concerns including:

- The effectiveness of the medical devices management systems
- The condition and performance of medical devices
- The execution of investment, replacement and disposal plans

The Standard Assurance Framework will provide assurance to the Quality and Safety Committee that the trust is:

- Compliant with all medical device alerts
- Where alerts are not managed within agreed timescales escalating to the Quality and Safety Committee areas of non-compliance
- Failure to meet deadlines for action is recorded on the trust risk register and escalated in line with the Procedure for Risk Identification and Management GP45

5.5 Learning and Development Group

- Develop and monitor implementation plans for external learning and development approved by the Education and Workforce Committee, escalating any risks to the committee as required.
- Plan internal learning and development activities for Community Trust staff to meet mandatory training priorities
- Set compliance rates, monitor and review attendance at Trust wide mandatory training by Division, escalating risks to the Education and Workforce Committee as required using the trusts Risk Matrix

- Develop and monitor implementation plans for new ways of learning identified by the Education and Workforce Committee, escalating any potential risks to the committee e.g. e-learning

- Recording completion of Core Mandatory Training and Job Relevant Mandatory Training on the Oracle Learning Management System Recording completion of training for devices deemed high or medium risk.

Quality and Governance Service

- Co-coordinating appropriate internal and external mandatory learning opportunities as agreed by the Learning and Development Group e.g. Essential Clinical Health and Safety Programmes and manual handling training

5.6 Divisional Quality Patient Experience and Risk Group

The divisional level Governance meetings will ensure:

- Medical device alerts are appropriately actioned and disseminated to relevant staff
- Any issues relating to availability of medical supplies/devices and /or NHS Supply Chain are identified and resolved
- Adverse reports/incidents associated with medical supplies/devices are appropriately reviewed and actioned
- Service level learning needs analysis are reviewed after the appraisal cycle concludes, and learning and development activities to support their business planning process and service redesign approved
- Monthly exception reports to provide assurance

5.7 The Director of Nursing and Quality Improvement

The Director of Nursing and Quality Improvement is the identified Lead Director for this policy and is responsible for:

- The implementation of quality, governance and risk management strategies
- will ensure there are clear lines of accountability within the trust to implement, promote and monitor the safety of patients, service users and others in respect to medical supplies and device management
- Ensure there are systems of management for medical devices
- Escalate

5.8 The Central Alerting System (CAS) Liaison Officer

The Central Alerting System (CAS) Liaison Officer is responsible for:

- The dissemination of safety alerts issued by CAS
- Confirming that appropriate action has been taken by the trust to implement each relevant alert
- Maintaining records of Medical device and NPSA alerts including action taken and reporting quarterly to the Medical Devices and Supplies Group on compliance

5.8 The Procurement Lead

The Procurement Lead is responsible for:

- Ensuring systems and processes are in place for the procurement of medical devices

- Ensuring the providers of the maintenance and repair services are competent for the work and accredited to the necessary standards

5.9 **Joint Union Staff Side (Trade Unions)**

JUSS representatives have an important part to play in providing advice, support and if required, representation to their members as well as working in partnership with managers and the HR team to ensure the Medical Supplies and Devices Management Policy is applied fairly and consistently across the Trust.

5.10 **Divisional Managers/Service Leads**

The Divisional Managers/Service Leads are responsible for ensuring:

- Medical devices that are purchased are safe, meet the needs of service users and ensure the best practicable patient experience within budgetary constraints to meet clinical need, whilst allowing for ease of decontamination and maintenance
- Medical devices are installed, used and maintained correctly with reference to the specifications, manufacturers' instructions, legislation and appropriate guidance from expert bodies
- Wherever possible and practical, the procurement of new or replacement medical devices are a trust standard make and model
- A common procedure is followed for accepting new devices into service including identifying significant risks associated with use, repair, cleaning and disposal and updating the inventory of new equipment.
- Medical devices are maintained tested and serviced under a recorded programme
- Matters relating to medical devices that cannot be solved locally within services or divisions are brought to the attention of the MDLO.
- Maintenance of an inventory of diagnostic and therapeutic devices within the service. This should be through regular updates to the central medical devices register held by the Trust
- Medical devices are disposed of appropriately and details recorded and removed from the medical devices register.
- The level of clinical risk and training required for medical devices in use within their service is identified
- Staff receive the appropriate training and have the necessary competencies for the safe use, management and disposal of medical devices.
- Instruction manuals, technical instructions etc. relating to medical devices are available to end users
- That incidents associated with medical devices are reported in line with Trust policy and to the MHRA, if appropriate
- Medical devices are appropriately decontaminated according to Infection Control Policies and manufacturer's instructions
- That patient needs are met and staff using any equipment do so in a way that has regard to their dignity, comfort and safety and promotes their independence.

5.11 **All Staff**

All clinical staff have a responsibility to ensure that they are competent to use all equipment in a safe and effective manner and have had the appropriate training and competency assessment; and are able to provide evidence of training records at annual appraisal or review.

Only staff who have attended training and or been assessed as being competent may use or operate diagnostic and therapeutic equipment without supervision. Patient safety is the highest priority and staff must seek help and advice from a more senior experienced member of staff if they have any concerns or are asked to use equipment without training.

All staff have a responsibility to:

- Report incidents and near misses associated with the performance or safety of diagnostic and/or therapeutic equipment
- Report any faults associated with the use of medical devices

6 PROCESS

6.1 Procurement

Prior to ordering any new medical device, the piece of equipment must be assessed by the budget holder using the Medical Devices Procurement Checklist see Appendix A.

While all items should be on the medical devices register, high value devices items over £5k have to be purchased from the capital budget and approved via Project Management Board (PMB).

Equipment which is new technology requires specific competencies or presents significant risk must be discussed with the Medical Device Liaison Officer.

Once assessment has been completed, the equipment should be ordered in line with the trust's Standing Financial Instructions.

After an item is received from the supplier, it is the signatory's responsibility to ensure that the device requisition is appropriate and that if required it should immediately be sent or taken to EBME (or other authorised provide) for acceptance testing and registration as well as recording on the service medical devices inventory.

Each item purchased shall have a copy of the relevant manufacturer's user instruction and information. This shall accompany the item throughout its working life. Clinical protocols should make reference to the full use of the manufacturer's operating instructions. Please note, however, this instruction may actually be part of the labelling of a device.

6.2 MedeQuip

All equipment provided from the trust falls under the classification of medical devices, the equipment provider remains responsible for servicing and maintenance of the equipment.

6.3 How the organisation includes all items of reusable diagnostic and therapeutic equipment on an Inventory

Medical devices used within each service are to be recorded on the relevant service medical devices inventory located on Datix by nominated service/divisional leads. This register will not include single-use medical devices e.g. gloves, bandages or dressings. The information included on the inventory will include the following:

- A generic name, i.e. pulse oximeter, sphygmomanometer
- Level of clinical risk
- Manufacturer/Make
- Model/type
- Department/location
- Serial No
- Maintenance contractor specific No e.g. EBME No
- Maintenance contractor
- Frequency of maintenance
- Last test date
- Next test date

- Status i.e. active or no longer in use
- Service and service specialty

This register will enable:

- A device that is subject to a recall to be traced in a timely fashion.
- The service to assist in the process for statutory maintenance, safety checks and replacement/disposal program and planned audits.

This shall not apply to items issued by the Wheelchair as an alternative system is place for recording medical devices.

6.4 Prescribing Medical Equipment

Medical equipment may be prescribed for individual service users by members of staff. Any person who prescribes medical equipment for use by a patient or carer must be qualified to do so and must ensure that:

- Service users and identified carers have received appropriate training and demonstration in the use and care of the device provided and this has been documented
- That equipment is correctly installed / fitted / set up according to manufacturers' instructions and if this is not possible this must be recorded within a risk assessment e.g. where side flaps are removed from a bath lift due to space and safety considerations.
- The equipment meets the user's clinical needs

Any inspection, maintenance, repair and examination arrangements that may be required during the issue period of the equipment must be made clear to the recipient at the time of issue and if appropriate in writing. Any written guidance must consider the ability of the user and the suitability of the device for the user, be consistent with the manufacturers' instruction and include the following:

- the name of the device
- the safe operation and control of the device
- how to check the device whilst in use
- how to recognise a device failure or fault
- what action is to be taken in the event of a failure or fault
- who to contact in the event of a change of circumstances
- individuals to be contacted in an emergency
- suitable storage arrangements

Any instructions issued with the equipment must be adequate for the knowledge level of the end user/carer recorded within the patient notes. A record of the information provided should be noted on the service user's health care plan/health records

With regard to devices issued individually on long-term loan, the trust remains accountable for the collection of these items when they are no longer needed.

6.5 How reusable diagnostic and therapeutic equipment is maintained and repaired

It is the responsibility of managers purchasing medical devices to establish the maintenance and repair requirements associated with the safe use and management of medical devices

- This should be recorded on the medical device register. Consultation with the Supplier, together with reference to technical information provided for the devices must be considered and shared with relevant persons. This may involve Departments such as the Electro Bio-Medical Equipment Service (EBME) at Wirral University Teaching Hospital NHS Foundation Trust (WUTH), other third party

maintenance providers and/or the supplier's specialist support service. The chosen provider of the maintenance and repair service must be competent for the work and accredited

- Maintenance schedules must comply with the manufacturers' technical recommendations and be clearly identified for each medical device and records must be kept of all routine and repair work undertaken. These records must be available for inspection and audit by internal and external agencies as appropriate

- In the event that a medical device fails to achieve the required standards at maintenance or repair, the servicing agent must be directed to provide managers with a written confirmation of the failure

- Any item that appears to be faulty or is awaiting repair must be taken out of service and a notice affixed stating, "Do not use" , date that the equipment is removed from service and quoting the action being taken

- Managers should ensure that there are appropriate arrangements made for the maintenance and repair of equipment when the manufacturer's warranty expires.

- All medical devices returned to the service which requires maintenance and/or repair must be accompanied by a Wirral Community NHS Trust Certificate of Decontamination and Request for Inspection, Servicing or Repair of Medical Devices form. (See Appendix B)

- Where equipment is subject to statutory examinations it is the responsibility of the Service Leads to ensure that equipment is examined by a competent body according to the relevant legislative requirements and the appropriate documentation recorded

- In the event that the maintenance provider is not able to gain access to maintain equipment for example when the equipment is located in the individual's own home it is the responsibility of the service issuing the equipment to follow up via telephone letter and/or both. In the event that access is still not available a letter will be sent to the service user informing them that we will no longer be responsible for the safe operation and condition of the equipment

6.6 Electrical Biomedical Engineering (EBME)

Medical devices are maintained by EBME shall first be registered at the EBME department. EBME will affix a label showing a unique number and the due date of its annual inspection.

6.7 Decontamination

The trust's cleaning and Disinfection Policy ICP7 outlines the procedure for the cleaning of medical devices and this should be used in conjunction with the manufacturer's guidelines.

It is the user's responsibility to ensure that medical equipment is properly cleaned / decontaminated before, during and after use.

When equipment is to be returned to a manufacturer, EBME or other maintenance contractor the sender must ensure that it has been properly decontaminated. All medical devices which require maintenance and/or repair must be accompanied by a Certificate of Decontamination and Request for Inspection, Servicing or Repair form (See Appendix C)

If an item of equipment is or could be contaminated internally and cannot be

adequately cleaned then this fact must be brought to the attention of whoever is to undertake the work. This must be done by recording on the Certificate of Decontamination and Request for Inspection, Servicing or Repair form (Appendix B).

6.8 Storage and Safekeeping of Medical Equipment

When not in use, medical equipment must be suitably stored taking into account the trust's policies and procedures and the manufacturer's instructions. The following should be considered;

- Physical – temperature, humidity, safe from damage
- Security – locked cupboard
- Power supplies – maintain charged batteries, protect and look after leads/cables applicable to the device.
- Segregation of clean/contaminated equipment
- Accessibility – easy and ready to use access

6.9 Disposal

Any item of equipment always remains a Trust asset even when it is no longer required, redundant or beyond economic repair. Equipment that is clinically or technically obsolete or surplus may have some residual value. Such equipment shall be disposed of in a way that maximises the financial return to the trust and in consultation with the Medical Device Liaison Officer

No item that is registered at WCT shall be disposed of without
1) Contacting procurement to consider the principles or re-use, recycle and/or reduce
2) Contact Finance to request "Asset Disposal, Transfer & condemnations" form (See Appendix *). The form will need to be completed by the service and then forwarded to finance to calculate any loss/profit on the asset and also to update the Fixed Asset Register. The loss/profit will be calculated once Procurement provide the market value of the asset.
3) After steps 2 and 3 have been approved, notify the maintenance contractor who will ensure it is removed from the appropriate database and that a record is made of its disposal. In addition the medical device equipment inventory will require updating to indicate that the equipment has been disposed of.

6.10 Loaning Equipment within Wirral Community NHS Trust

It is responsibility of the service to ensure that a record is kept of any equipment that is loaned to another service. This ensures both that the location of the equipment is always known and that the responsibility for it is transferred at time of loan.

Managers should review the items out on loan on a regular basis to ensure that equipment that is no longer in use is returned to the original owner.

When the equipment is returned from loan the manager should ensure that it has been decontaminated and is functioning correctly before going into service.

6.11 Devices on Loan from a Manufacturer or Other Source

Any device on loan to Wirral Community Trust from a manufacturer, supplier or another hospital should be subject to a Master Indemnity agreement that defines the device management requirements, responsibilities and liabilities.

Delivery, receipt and pre-use procedures for loaned equipment should be the same as for purchased equipment unless otherwise specified in the written agreement.

In addition equipment on loan to the trust must not be transferred from the site that received it without first ensuring it is within the agreement of the supplier to do so.

6.12 Donations of Medical Equipment

The donation of medical equipment whether from charities, patients or their relatives will not be accepted by the trust. Medical devices or equipment purchased by charities and friends of the trust and delivered by the supplier may be accepted. Devices subsequently purchased will be subject to the normal procurement and registering procedures at WCT where appropriate and the inclusion in the local services register. High value devices over £5k have to be purchased from the capital budget and approved via Programme Management Board (PMB) and will be registered on the fixed asset register.

6.13 Equipment Recovery

Relevant documentation should be completed when equipment is loaned to an individual which should include a signature of the person, or their representative, highlighting that they understand the conditions of the loan.

When it is identified that equipment has not been returned within the timescales agreed then the service loaning the equipment should attempt to make contact with the person in order to have the equipment returned. If this proves to be unsuccessful then contact should be made with the Local Security Management Specialist (LSMS) providing all relevant documentation. The LSMS will then make attempts to recover the item(s) highlighting the legal implications if individuals fail to return. If this method is unsuccessful then the LSMS will seek a legal redress.

When equipment has been returned and is damaged beyond the description of normal "wear and tear" then again contact should be made with the LSMS. The LSMS will review and consider legal address if the damage is believed to be criminal.

6.14 Transfer of Medical Devices

The trust does not support the transfer/purchase of equipment to the service user following a period of loan.

7 CONSULTATION

7.1 Medical Device Group
7.2 Quality and Safety Committee

8 TRAINING AND SUPPORT

All staff in the trust are required to comply with mandatory training as specified in the trusts Mandatory Training Matrix. Staff are also required to comply with job relevant training in their service as specified within their service training matrix and on the Learning and Development Section on the StaffZone

8.1 How the organisation decides the training and frequency of updates required

All diagnostic and therapeutic equipment used within the trust will be graded for risk purposes as follows:

- High Risk Device - Devices that have the potential to cause serious adverse consequences or death should they be misused or fail
- Medium Risk Device - Devices that would have a significant impact on patient care or cause temporary adverse health consequences should they be misused or fail
- Low Risk Device - Devices that would be unlikely to cause serious consequences or impact on patient care should they misuse or fail.

Equipment which falls within the medium and high risk categories will require specific risk assessments to be undertaken and incorporated into the relevant trust documentation. The lead identified to prepare the operating procedure/protocol for the equipment is responsible for preparing the specific risk assessment. A Trust wide generic risk assessment has been produced for equipment identified as low risk items.

Training delivery and assessment is dependent on the level of risk associated with the device and is identified in a job relevant service training matrix .Competency based training will be required for medium and high risk devices. Appendix D outlines the relationship between level of clinical risk, the training required and the frequency of updates.

Training for devices deemed as **High Risk** should be delivered by a designated trainer.

- Training for devices deemed as **Medium Risk** may be taught by a person competent in the use of the equipment. Training should be specific to the medical device and repeated at appropriate intervals

- A member of staff can learn from an experienced colleague or from the manufacturer's instruction manual for those items considered to be **Low Risk**.

8.2 How the organisation identifies which permanent staff are authorised to use the equipment listed on the inventory

The trust requires that staff should only use equipment that they are competent to use and that is within the scope of their practice. Staff should not use equipment for which they have not received appropriate training.

Divisional Managers/Service Leads are responsible for preparing a service specific training matrix which identifies which permanent staff require training in the use of equipment and the frequency of updates. This will include equipment that is listed on the medical devices inventory as well as equipment that does not belong to the service but is used within the course of work e.g. hoists, slings, stand aids etc.

8.3 How the organisation records that all staff complete training

The record of any training, update or assessment for a specific piece of equipment must be kept locally by the line manager on the individual personal file for each member of staff. Staff are also required to keep their own training up to date, undertake appropriate training and maintain a record in their personal portfolios/training logs and meet the requirements of any professional bodies. For high and medium clinical risk equipment this will also be recorded centrally by Quality & Governance Service.

New permanent staff will have their individual training needs assessed against the job relevant service specific Training matrix by their line manager at local induction and training arranged as required.

Existing members of staff will have their training records reviewed as part of the annual appraisal process to identify additional training needs and arrange future training needs.

Where a member of staff has had a prolonged absence of six months or more it is the responsibility of the line manager to determine if additional training in the use of the medical device is required for the member of staff.

The process for management of training including non-attendance and persistent non-attendance is outlined in the Learning and Development Policy GP46. In the event of persistent non-attendance at training the line manager will escalate to the Head of Service for further action in line with the trust's Standards of Conduct and Disciplinary Policy (HRP1).

9 MONITORING

9.1 Incident Reporting

Any incident involving the use of medical devices must be reported in line with the trust's Incident Reporting Policy and the current MHRA "Reporting adverse incidents and disseminating medical device alerts", via Datix.

The Medical and Healthcare Products Regulatory Agency (MHRA) investigates all adverse incidents reported concerning diagnostic and therapeutic equipment. Where the results of investigations have implications for other patients or users, the MHRA will issue a Medical Device Alert, which will advise of hazardous products or unsafe procedures.

Any adverse incident involving a medical device should be reported to the MHRA, especially those that have had led to or could lead to if they were to occur again:

- Death or serious injury
- Medical or surgical intervention (including implant revision) or hospitalisation
- Unreliable test results (and risk of misdiagnosis)

Other minor safety or quality problems should also be reported as these can help demonstrate trends or highlight inadequate manufacturing or supply systems.

Adverse incidents should be reported at the earliest opportunity, following the trust's Incident Reporting Procedure. The incident will also need reporting to the MHRA. This can be done by any individual (i.e. all grades of staff, patient, carer, public member or manufacturer). The preferred method of reporting to the MHRA is to use their on-line reporting facility at

https://yellowcard.mhra.gov.uk/

An adverse incident is an event that causes or has the potential to cause unexpected or unwanted effects involving the safety of patients, device users or other persons.

Causes of incidents involving medical devices may include

- Design or manufacture problems
- Poor user instructions and training
- Inappropriate local modifications
- Inadequate maintenance
- Unsuitable storage and use conditions

Once the incident has been reported to the MHRA, the equipment will need to be decontaminated in line with the manufacturer's instructions and quarantined. Either the MHRA or the manufacturer may wish for the equipment to be returned for further investigation. Any equipment involved in an adverse incident must not be reused prior to investigation as a repeat of the incident may occur.

Where a medical device is involved in an incident it must be suitably labelled, quarantined and stored securely by the team until investigation has been completed and the equipment declared safe to use.

10. EQUALITY AND HUMAN RIGHTS ANALYSIS

10.1 **Equality Impact Assessment (EIA)**
Refer to Appendix 8

11. LINKS TO OTHER POLICIES

11.1 The policy supports the implementation of The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance (Department of Health, 2015). DH Crown Copyright.

11.2 The policy supports the implementation of: Operational Infection Prevention Control (IPC) IPC 1 Policy

11.3 The policy supports the implementation of: IPC 6 Single Use Medical Device Policy

11.4 The policy supports the implementation of: IPC 7Cleaning and Disinfection Policy

11.5 The policy supports the implementation of: Wirral Community NHS Foundation Trust (018) Risk Strategy GP05

11.6 Health & Safety Executive – www.hse.gov.uk

12. REFERENCES

Medicines & Healthcare Products Regulatory Agency (2015) Managing Medical Devices: Guidance for healthcare and social care organisations.

Appendix 1
Medical Devices Procurement Checklist

ISSUES	
Suitability	What functions must the device perform? Consider fitness and suitability for purpose including clinical requirement.
Infection Control & decontamination	Are specific procedures required to be put in place? Are suitable decontamination facilities available?
Compatibility & Standardisation	What similar devices do we already have? Will the device be replacing older models?
CE marking	Is the device CE or equivalent standard marked
Environment	Where is the device to be used e.g. in the home or Clinic setting?
Purchase	What is the cost of the device and installation? Does there need to be a formal tendering process? Is a maintenance and servicing contract included within the price e.g. for the first 12 months? Does the contact include replacement or back up equipment in the event of a fault with the device? After 12 months will an additional service contract be required? Will the device be maintained by EBME? Is emergency breakdown cover required? What is the cost of consumables associated with the use of the equipment? Does the device require additional accessories how easy are they to obtain? What is the cost of disposal?
Maintenance	Does the device require regular maintenance via EBME? Have EBME had a specific input on the maintenance requirements? Does the equipment require regular calibration checks
Training	Does the end user/Service user require specific training in the use of the device? Will refresher training be required? Are staff trained to recognise common faults? Who will provide the training and how will this be recorded? Are manufacturer's instructions available to users? Are staff required to check equipment prior to use for signs of damage and wear and tear? If required to be recorded how will this be done?
Safety	Are there risks associated with the use of the equipment affecting staff and or service user safety? Are these acceptable or are additional measures required to be put in place? Does the equipment have any specific and storage handling requirements? Will specific arrangements be requires for the disposal of the device?

Appendix 2

Medical Device Inspection, Servicing and Repair Form

Wirral Community NHS Foundation Trust Contact Details

Please Print Name: _____ Contact Number: _____

Base: _____

Email: _____

Description of Item	Make and Model	Serial Number/ID	EBME No

Was this device involved in an incident?
Yes ☐ No ☐

If yes, complete the following:

Description of Incident:	
Incident Report Number:	**Date:**

Please ensure equipment is quarantined with the battery intact and submit to EBME

Does this equipment require **servicing/repair/calibration**? Delete as appropriate

Please provide details of fault if equipment requires repair:

Decontamination

Please confirm the item has been externally cleaned by the procedure recommended in the Infection Control Policy IPC8 in preparation for inspection/servicing/repair.

Signed _____ Date _____

For EBME Use

Received by: _____ Date: _____

Works Record No: _____

Date sent: _____ By: _____

Report Back

Servicing/Calibration

The device has been inspected/ serviced/calibrated and is confirmed as working satisfactorily. □

The next calibration inspection date is due _____

Device involved in an incident or fault identified

The device has been inspected:

No fault was identified and the equipment is confirmed as working satisfactorily	☐
A fault was identified	☐

Details of fault:

_____

_____

Action taken:

_____

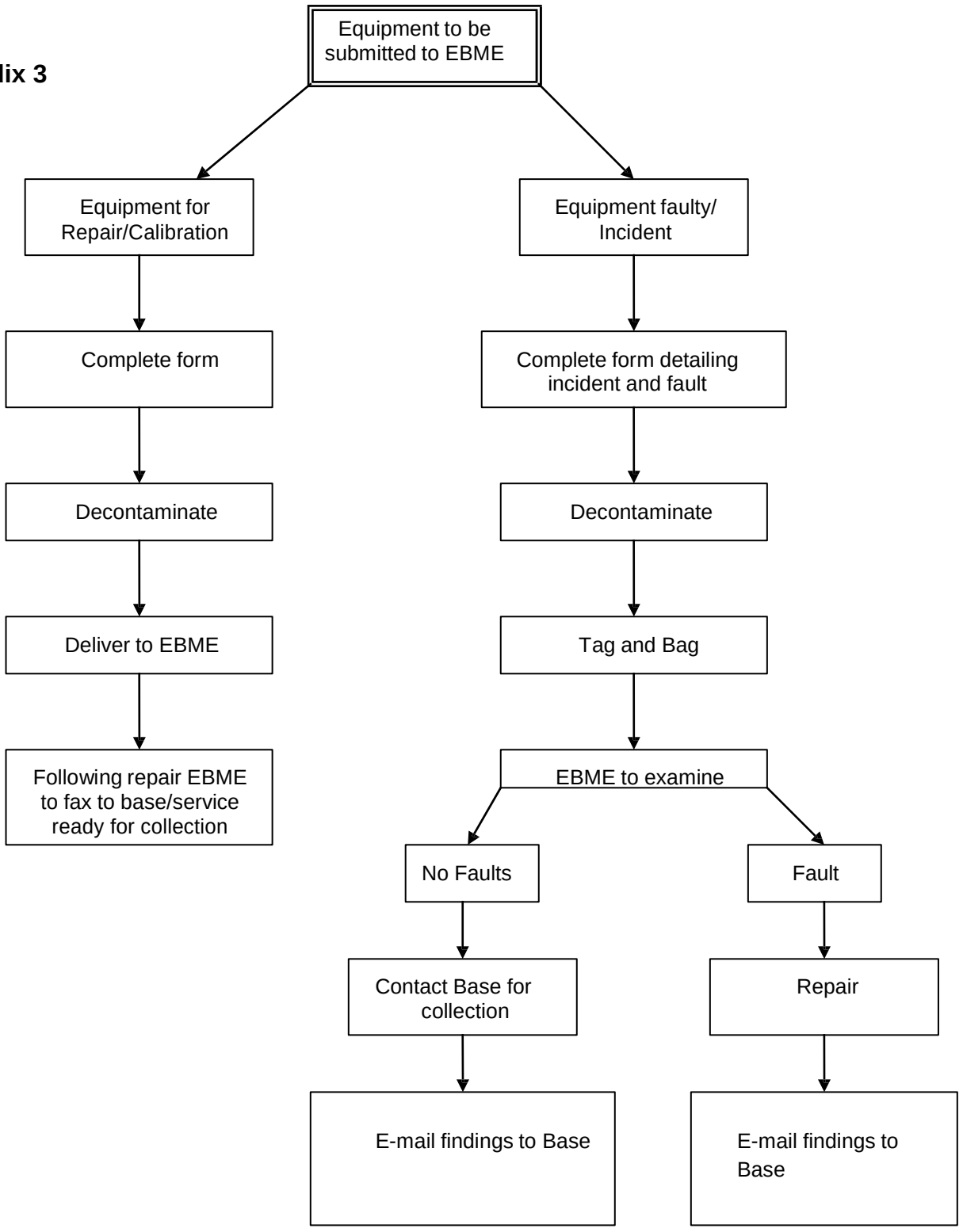
_____

The equipment is working satisfactorily and can now be collected □ The equipment is condemned □ EBME:

Name:_____ Date:_____

Email to Base

Appendix 3


Equipment to be submitted to EBME
Equipment for Repair/Calibration
Equipment faulty/ Incident
Complete form
Complete form detailing incident and fault
Decontaminate
Decontaminate
Deliver to EBME
Tag and Bag
Following repair EBME to fax to base/service ready for collection
EBME to examine
No Faults
Fault
Contact Base for collection
Repair
E-mail findings to Base
E-mail findings to Base

Appendix 4

Lifting Equipment Requirements under Lifting Operations and Lifting Equipment Regulations 1998 (LOLER)

Any equipment used at work that lifts or lowers a load is regulated by LOLER. This includes equipment used within the trust for moving and handling of patients in particular, hoists, slings and bath lifts.

Managers have specific responsibilities with regard to lifting equipment. They must ensure that all lifting equipment and accessories are

- Marked with the safe working load, this may take the form of a maximum load on hoists and sling

- Inspected regularly. Statutory inspections must be performed by a competent person and the results of these inspections recorded according to the requirements of LOLER. These inspections are in addition to annual service inspections
- Inspections should also be performed by the user prior to use (a simple visual inspection usually is sufficient)
- Only used by persons who have had suitable and sufficient information and training on its safe operation and use as well as that of any precautions or safeguards required
- Used under adequate supervision, the extent of the supervision required is dependent on the competence level of the operator

Appendix 5

Medical Device Classification and Associated Training Requirements
All medical equipment has been initially assessed to identify perceived risk
All clinical staff must carry out pre-use check and ensure that medical equipment is used in a safe and effective manner at all times

Risk category	Definition	Examples	Training and Competency Requirements
HIGH	Devices that have the potential to cause serious adverse consequences or death should they be misused or fail.	Syringe Drivers Hoist Stand Bed lever Automated External Defibrillator	Formal mandatory training required and centrally recorded Review of competence is required as part of appraisal/PDP process against Specific competency template. Frequency for attending training as defined in service training needs analysis. Typically 2 year frequency of training
MEDIUM	Devices that would have a significant impact on patient Care or cause temporary Adverse health consequences Should they be misused of fail	Central venous access devices Ear propulse machines	Formal training may be required and or demonstration of competency. Frequency for attending training as defined in service training needs analysis Typically 3 year frequency of training
LOW	Devices that would be unlikely to cause consequences should they be misused of fail	Medical weigh Scales Sphygmomanometers	No formal training Required unless an issue is raised by the employee or manager. Self-assessment of competency

Appendix 6: Monitoring Compliance with the process described in the policy

Minimum requirement to be monitored	Process for monitoring (e.g. audit)	Responsible individual / group/ committee	Frequency of monitoring	Evidence	Responsible individual for development of action plan	Responsible committee for monitoring of action plan and Implementation
Description of the duties	Annual review of the Policy	Medical Devices and Supplies Group	Annually	Minutes	Risk Manager	Quality and Safety Committee
How the organisation includes all items of diagnostic and therapeutic equipment on an inventory	Annual assurance process on medical devices	Divisional Manager	Annually		Divisional Manager	Quality and Safety Committee
How reusable diagnostic and therapeutic equipment is maintained	Annual assurance Report maintenance contractors	Medical Devices and Supplies Group	Quarterly	Report EBME	Divisional Manager	Quality and Safety Committee
How reusable diagnostic and therapeutic equipment is repaired	Assurance report from medical devices and supplies Group	Medical Devices and Supplies Group	Quarterly	Medical Device Assurance	Procurement manager Service Lead	Quality and Safety Committee

How the organisation identifies which permanent staff are authorised to use the equipment listed on the inventory	Review of job relevant service training matrix	Divisional QPER Group	Annually	Job relevant Service training matrix	Divisional Managers	Quality and Safety Committee Education & Workforce Committee

Appendix 7

MIA CALL-OFF AGREEMENT

Note: *An Authority should not enter into an MIA Call-Off Agreement unless either:*

(i) There is a current Overarching Master Indemnity Agreement with current insurance in place, as evidenced by the fact that the Supplier is on Master Indemnity Agreement Register with current insurance that can be viewed at: https://www.gov.uk/government/publications/master-indemnity-agreement-mia
; or

(ii) In exceptional circumstances for reasons of urgency where it is not possible for the Supplier to enter into an Overarching Master Indemnity Agreement prior to the delivery of the Equipment or where the insurance is not current and where the Authority itself has carried out its own checks and confirmed that the Supplier has appropriate current public liability and product liability insurance in place in respect of public liability and product liability covering the Equipment with the minimum cover per claim of five million pounds (GBP) (£5,000,000) in accordance with the requirements of the Master Indemnity Agreement Terms and Conditions (November 2018)

1)	**Company Name: ("Supplier")**		
2)	**Address:**		
		Postcode:	
3)	**Contact Name:**		
4)	**Contact E-Mail:**		
5)	**Telephone No.:**		
6)	**Company Registration Number (i.e. the registration number of the Company at Companies House or other relevant national companies registry):**		
7)	**Is there an Overarching Master Indemnity Agreement in place with current insurance? If yes, state "Yes" and insert the MIA number here. If not, state "No":**		
8)	**This box only requires completing where there is no Overarching Master Indemnity Agreement in place with current insurance. In these circumstances, the Authority should check that the insurance requirements have been met as per the note in red above and state "Insurances Checked by the Authority" here.**		

9)	**Delivery Date:**		(being the date of delivery of the Equipment to the Authority)	
10)	**Authority:**			
11)	**Authority Address:**			
			Postcode:	
12)	**Authority Contact Name:**			
13)	**Authority Contact E-Mail:**			
14)	**Authority Telephone No.:**			
	The Equipment to be supplied by the Supplier to the Authority			
15)	**Type of Equipment and its purpose:**			
16)	**Model/Make:**			
17)	**Serial Nos.:**			
18)	**Value:**			
19)	**Personal Data and Data Subjects:** **(To be completed by the Authority)**	Will the Data Protection Protocol (under Schedule 1 – Information Governance and System Security of the MIA Terms and Conditions be used) Y/N [Delete as appropriate]		
20)	**IT Systems & Security** **(To be completed by the Authority)**	The Authority's IT systems are used to provide essential services. If the Equipment is used for the purposes of any essential services **OR** together with any of the Authority's IT systems, the extent of this should be detailed here: [enter text].		

21)	**Timescales for request to audit for compliance with Data Protection and IT Systems Security** **(To be completed by the Authority)**	[Insert agreed notice period if different to 4 week notice period as set in paragraph 3.9 of the Schedule 1 of the MIA Terms and Conditions]
22)	**Loan or transfer?:** **Note. Where disposable Equipment is provided, this should be on a transfer basis.**	
23)	**Purpose of loan or transfer:**	
24)	**Loan Period (to be completed only where the Equipment is be loaned):** [days/months/years (delete as appropriate)] commencing on [ ] day of [ ] 20[ ]	
25)	**Premises and Location(s) at which the Equipment will be kept:**	
26)	In consideration of the Authority taking the Equipment on a loan or transfer basis for the purposes outlined above and the mutual exchange of obligations under the Master Indemnity Agreement Terms and Conditions (November 2018), the Authority and the Supplier confirm that the Master Indemnity Agreement Terms and Conditions (November 2018) shall apply to the provision of the above Equipment by the Supplier to the Authority (on either a loan or transfer basis as specified above) and that upon signature of this MIA Call-Off Agreement by both the Authority and the Supplier a legally binding agreement on such terms shall come into full force and effect between the parties incorporating such Master Indemnity Agreement Terms and Conditions (November 2018), which shall be effective from the delivery date of the Equipment as set out above. *For the avoidance of doubt the Master Indemnity Agreement Terms and Conditions (November 2018) and any updates are published on the* Master Indemnity Agreement *website by the Department of Health and Social Care"* By signing this MIA Call-Off Agreement, the Supplier also confirms delivery of the Equipment detailed above to the Authority. By signing this MIA Call-Off Agreement,	

	the Authority also acknowledges receipt of the Equipment detailed above on the delivery date referred to above.	
27)	**SIGNED on behalf of the Supplier:**	
28)	**Name and position:**	
29)	**Date:**	
30)	**SIGNED on behalf of the Authority:**	
31)	**Name and position:**	
32)	**Date:**	

Appendix 8

Equality & Human Rights Analysis -

Title	GP48 Medical Devices Management Policy	
Department	Quality and Governance	
What is being considered?	This policy outlines the systems and processes in place for the Management of Medical Devices.	
Who may be affected?	Patients [x] Staff [x] Public [x] Partner agencies [ ]	
Is there potential for an adverse impact against the protected groups below? Age, Disability, Gender Reassignment, Marriage and Civil Partnership, Pregnancy and Maternity, Race, Religion and Belief, Sex (gender), Sexual Orientation or the Human Rights articles?		Yes [ ] No [x] Please see comments below

To be completed at the end of the policy. Write up prior to being submitted for approval.

On what basis was this decision made? (Please complete for both 'yes' and 'no'). **For example, you may wish to consider or refer to the some of the following:** • The Medicines & Healthcare Products Regulatory Agency: Managing Medical Devices Guidance for Healthcare and Social Services (2015)
If 'No' equality relevance, sign off document below and submit this page when submitting your policy document for approval. If 'Yes' Please complete pages 2-3. With regard to the general duty of the Equality Act 2010, the above function is deemed to have no equality relevance. Equality relevance decision by Annie Baker Title:- IPS Lead & Quality Matron Date 24 April 2019