Wrightington, Wigan and Leigh Teaching Hospitals
NHS Foundation Trust

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| **STANDARD OPERATING PROCEDURE** | **MEDICAL DEVICE ACCEPTANCE PROCEDURES** |
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The WWL Way

## Version Control

| Version | Date | Amendment |
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| 4 | June 2022 | Removed inclusion and diversity and monitoring and review as not required in associated document. Also removed appendices relating to these as they are covered in the overarching policy |

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# 1 DEVICE ACCEPTANCE PROCEDURES (NEW EQUIPMENT)

1.1 All equipment will be acceptance tested in accordance with the MHRA's guidance on Managing medical devices (January 2021). For portable equipment, a variety of acceptance testing procedures may be necessary – electrical safety tests, for example. Manufacturers may recommend certain forms of acceptance testing in the device manual.

1.2 The Medical Electronics Department is responsible for carrying out device acceptance test procedures on medical equipment coming into the Trust as new, on loan or following a service or repair where a case had been removed and assembled back on.

1.3 On receipt from the supplier (new or on loan) all medical devices will be subject to the following acceptance procedures:

1.3.1 **Record Keeping**

1.3.1.1 All new medical devices will be placed on the Trust medical equipment database by an appointed responsible member of staff in the Medical Electronics Department. This includes equipment coming into the Trust for acceptance testing as new or on loan.

1.3.1.2 In line with the statutory requirements, all maintenance and testing records will be subject to a retention period of 11 years.

1.3.1.3 Records Management: The Records Management Code of Practice for Health and Social Care 2016 sets out what people working with or in NHS organisations in England need to do to manage records correctly. It's based on current legal requirements and professional best practice and was published by the Information Governance Alliance (IGA).

1.3.1.4 All NHS records are public records (apart from the relevant exemptions under the Data Protection Legislation) under the terms of the Public Records Act 1958. Each member of staff is responsible for the records they create and use.

1.3.2 **Labels and Documentation**

Attaching appropriate labels, warning professional users that this device is either a new device or has just been serviced and that user adjustment maybe required, warning end-users not to use the device until they have been trained to do so. Copies of the Instruction manuals (either printed or electronic) will also be provided to users with any new device. Some devices will have a local Logbook remaining with the device in which will be logged acceptance test results, Next Due Date in terms of the next maintenance due date and who to contact in case of problems.

1.3.3 **Planned Preventative Maintenance**

All users will be informed of appropriate maintenance procedures, including the day-to-day checks and care of the device by the technician responsible for accepting testing the device.

1.3.4 **Storage of devices**

Information will be made available to the user department on the handling and storage of equipment, the importance of ensuring all accessories are readily available and guidance on how internal batteries should be recharged. Guidance and recommendations of MHRA document Managing Medical Devices (January 2021) will be consulted and followed for more complex items of equipment which are not acceptance tested by the Medical Electronics Department.

# 2 MAINTENANCE AND REPAIR OF MEDICAL EQUIPMENT

2.1 It is Foundation Trust policy to keep medical devices safe and effective, through both routine maintenance procedures, supervised by professional users, and planned preventative maintenance by suitably trained technical staff.

2.2 All maintenance will be undertaken using the guidelines contained in the MHRA guidance document Managing Medical Devices (January 2021). Technical Maintenance of a selected group of medical equipment will be carried out by the Medical Electronics Department; however numerous other specialist or highly mechanised devices (e.g., X-Ray machines, CT, PET & MRI scanners, Anaesthetic machines and Ventilator and patient hoists etc.) would be maintained by specialist contractors or the Estates and works department.

2.3 Initial maintenance arrangements for all medical devices must be determined prior to purchase.

2.3.1 **User maintenance**

2.3.1.1 In addition to technical maintenance, equipment users also have responsibilities to ensure daily user maintenance routines are carried out. Clinical ward managers are responsible for ensuring that all medical equipment used in their areas is suitable for its purpose, available, properly maintained, used correctly and safely, promotes independence and comfortable in accordance with the manufacturers' recommendations. For Example:

- Cleaning (see cleaning and decontamination section)
- Batteries fully charged
- Pre-use checks
- "Next due date" Service stickers for technical maintenance should be checked prior to use.

2.3.1.2 They must also ensure that all storage arrangements within their area of responsibility are configured to optimum standards within available resources to secure, protect and manage equipment appropriately and ensure all staff are made aware of responsibilities and expected standards. Inadequate storage arrangements should be notified to more senior staff via risk reporting arrangements.

2.3.2 **User Manuals**

Department managers must ensure equipment user manuals and instructions are kept securely in the department and made available to equipment users upon request. User manuals in electronic format must be requested from the Supplier at the equipment purchase stage and where these are available, they should be passed on to the Medical Equipment Manager for inclusion on the Medical Equipment Manual's folder on their network drive.

2.3.3 **Repairs of Equipment Maintained by Medical Electronics Department**

All medical equipment in need of repair should be reported promptly via the Online Medical equipment fault reporting helpdesk, quoting the medical equipment number of the device and the nature of the fault. The Medical Electronics Department will carry out repairs in accordance with manufacturers' recommendations and guidance laid out in MHRA guidance on Managing Medical Devices (January 2021). All details of maintenance and repairs will be logged onto the medical equipment database and retained for a minimum of 11 years.

2.3.4 Equipment which cannot be repaired must be appropriately disposed of via WEEE regulations (where electrical components are involved) and to avoid the proliferation of clutter and to maximise available storage space.

2.3.5 **Regular Servicing (Equipment Maintained by Medical Electronics Department)**

2.3.5.1 Department Managers, with assistance from Medical Electronics Department where appropriate, are responsible for identifying medical

devices that require a maintenance regime, ensuring that new devices in their unit is registered onto the medical equipment database and are formally acceptance tested.

2.3.5.2 The Medical Electronics Department will determine the frequency of maintenance, (in accordance with manufacturers' instructions), input a pre-planned maintenance schedule (PPM) onto the medical equipment database.

2.3.5.3 Where practical the Medical Electronics Department will affix a label to the device indicating the date when the service or electrical safety test was done.

2.3.5.4 Department managers must ensure equipment is available for service at regular intervals in accordance with the planned maintenance schedule and ensure equipment which becomes overdue for service is reported onto the Online Medical equipment fault reporting helpdesk as a job request.

2.3.5.5 All maintenance and repairs undertaken will be logged by the engineer onto the medical equipment database and a history of each individual device/service event will be retained for a minimum of 11 years after the last event has been recorded.

2.3.5.6 All new items of Medical Equipment introduced into service, via Medical Electronics Department will be labelled to inform the professional users that they are the first person to use the device and that due care should be taken.

2.3.5.7 A library of technical maintenance manuals will be kept in the Medical Electronics Department and wherever possible this will be in electronic format.

2.3.5.8 Medical devices will be maintained in line with the manufacturers' guidance. If for any reason this is not practicable, proposed changes will be approved by the manufacturer, preferably prior to purchase.

2.3.5.9 Any modifications to equipment, giving sets or applications thereof will be endorsed in writing by the manufacturers/suppliers and logged and authorised by the Trust's Risk Management department, prior to being undertaken.

2.3.5.10 Medical Electronics Department 's procedures, processes, technical aspects and general quality are as specified in ISO 9001:2000.

2.3.5.11 Equipment should not also be cannibalised, i.e., used parts taken from one device and used in another unless authorised and recorded. The MHRA document 'Managing Medical Devices (April 2014)' also indicates that pre-used parts should 'only be used in exceptional circumstances after the risk has been fully analysed and documented.

## 3 MEDICAL DEVICES NOT MAINTAINED BY THE MEDICAL ELECTRONICS DEPARTMENT

3.1 A number of specialist medical devices cannot be maintained in-house, in which case managers must consider the need to purchase a maintenance contract, refer to option appraisal form for guidance. All Medical Equipment maintenance contracts will comply with the Trust's current Standing Financial Instructions Advice on equipment maintenance contracts may be sought from the Medical Equipment Manager.

3.2 Department Managers must ensure that contracts provided by external agencies are routinely monitored for quality.

3.3 In order to do this it is important that prior to the purchase of a maintenance contract, the contractor provides a full maintenance schedule, describing precisely what is included. (Medical Equipment Manager can advise if the schedule represents good value for money). A copy of the schedule should be available in the department where the device is situated.

All maintenance will be carried out in accordance with MHRA Guidance on Managing Medical Devices (April 2014) and manufacturers' instructions.

3.4 Department managers must ensure that all work described in the schedule has been carried out and monitored for quality. Again, the Medical Electronics Department can provide assistance and guidance regarding this. A second copy of the service contract/schedule should be kept in Medical Electronics Department where guidance of this type may be sought.

3.5 Maintenance contracts are offered for a fixed period of time, it is important to consider the need for renewal of each contract in advance of the end date to ascertain if the contract is still required or if the schedule needs revising. For example, a current contract may include the cost of emergency 24 callouts. This may no longer be required if our service has changed, or equipment is now running in tandem with newer equipment acquisitions.

## 4 SERVICE REPORTS

Service reports will be retained by medical electronics department and stored on the RAM database for a minimum of 11 years. (This will likely be in the form of service reports provided by the service vendor).

## 5 HUMAN RIGHTS ACT

Implications of the Human Rights Act have been taken into account in the formulation of this document and they have, where appropriate, been fully reflected in its wording.

## 6 ACCESSIBILITY STATEMENT

This document can be made available in a range of alternative formats e.g., large print, Braille and audio cd.
For more details, please contact the HR Department on 01942 77 3766 or email equalityanddiversity@wwl.nhs.uk