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Medical Devices Policy Practice Guidance Note Equipment Information, Manuals and documentation – V05		
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Author/Designation	**Paul Thompson Clinical Lead PPE/ Medical Devices**
Responsible Officer / Designation	**Anne Moore – Group Nurse Director – Infection, Prevention and Control**

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Appendices – listed separate to PGN	
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Appendix 1	Medical Device Acceptance form

1 OUTLINE

1.1 Good record keeping is essential for the safe management of medical devices. The detail and complexity of the records will depend on the type of medical device and its usage during its lifetime.

2 ELECTRONIC RECORDS

2.1 It is anticipated that in the future the Trust will operate a more comprehensive electronic database system to facilitate medical device equipment management.

3 BASIC INFORMATION TO BE RECORDED

- Inventory number*
- Medical device description*
- Model*
- Serial number*
- Medical device type and class*
- Manufacturer*
- Supplier
- Date of purchase/acceptance
- Location*
- Cost
- Warranty period
- Estimated Date for renewal

4 PROCESS FOR INFORMATION COLLECTION AND UPDATING

4.1 For new equipment, the information shall be obtained as part of the acceptance process. The individual recording and completing the acceptance test will complete the acceptance form and send it to the medical device department

4.2 It is the responsibility of the managing professional i.e. Ward, Department manager or their acting deputy to ensure that the Medical Device Department is informed of any changes relating to the medical device.

5 MANAGEMENT OF THE INFORMATION

5.1 The Medical Device Department will be responsible for coordinating medical devices data.

5.2 The data will, be stored electronically.

5.3 The Medical Device Administrator will report to The Medical Device Safety Group to ensure measures are taken to give a reasonable assurance that the data kept is up to date.

5.4 Entry and modification of the data will be restricted to the Medical Device Department.

5.5 Viewing access to basic information will not normally be restricted

5.6 The data will be used to provide basic inventory information to managers.

5.7 The data will be used to identify equipment referred to in Central Alerting System (CAS) notices but not to the exclusion of other methods.

6 EQUIPMENT MANUALS

6.1 Equipment manuals are provided in many forms with varying amounts of information. For new equipment the type of manual should be recorded as part of the acceptance check(s) and where possible marked with the equipment ID number.

6.2 For older equipment the managing professional should identify any equipment that does not have a manual and inform the Medical Device Department.

6.3 Manuals should be available to staff using the equipment to refer to.

6.4 Where appropriate, operating instructions should be attached to the equipment.

6.5 Manuals should be kept in a known location where the device is being used. i.e. the Ward or Department office

6.6 Where possible, links to electronic copies of the manuals will be made available via the Trust's Intranet. It should be noted that variations in manuals might occur due to equipment or manual revision changes. Care must be taken to access the correct manual and the correct version of manual, if there are any difficulties accessing the manuals contact MedicalDeviceADM@CNTW.nhs.uk

7 SAFETY ALERT BULLETINS

7.1 Information relating to safety and other medical device related information is circulated from the Medicines and Healthcare Products Regulatory Agency (MHRA). These are dealt with via the Trust's Safety Alert Broadcast System Lead; for details of this please refer to the Trust's policy CNTW(O)17 - SABs/CAS Policy.

8 DOCUMENTATION

8.1 All Documentation relating to medical devices will be held centrally and in an electronic format.