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1.1 The Trust owns and relies upon a large stock of medical devices in order to carry out its function of patient care and treatment. This policy was based upon the requirements of the Care Quality Commission 'Regulation 12: Safe Care and Treatment', and 'Regulation 15: Premises and Equipment'. It is further informed by the Medicines and Healthcare products Regulatory Agency (MHRA) guidance publications 'Managing Medical Devices', and 'Devices in Practice: checklists for using medical devices'.

1.2 The ownership and use of medical devices has a statutory basis within the Provision and Use of Work Equipment Regulations 1998 (PUWER). This policy is the basis by which the Trust complies with PUWER regulations in the use of medical devices.

1.3 The Trust operates and manages this policy through the Medical Devices Committee (MDC). The MDC provides the functions defined in paragraph 2.2 of 'Managing Medical Devices, April 2015' for a medical devices management group. The Terms of Reference of the MDC are included as Appendix A to this policy.

2.1 This policy applies to all grades and disciplines of staff.

2.2 The policy applies to all medical devices which are brought into the Trust, whether purchased through Trust Capital funding, charitable donation, research funding, loaned or donated.

2.3 This policy covers the ownership and use of medical devices in the Trust and includes references to corporate and risk management structures, evaluation and selection of new devices, information and documentation, training, decontamination, maintenance and quality systems.

2.4 The Trust will promote the safe and appropriate use of all medical devices available in the Trust by ensuring that the healthcare professionals who use such devices are aware of the associated risks and have access to training and support to develop and maintain their knowledge and skills

The Trust requires that a formal record be kept of training received.

A medical device is any product used in the:

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8.2 It is the ward or department manager's responsibility to ensure that their medical devices are properly decontaminated between patient use.

8.3 Loan library equipment must be properly decontaminated, and have a decontamination certificate attached, before it is returned to the MDMS.

8.4 When equipment is to be repaired by Medical Electronics or returned to a manufacturer or third party maintenance provider, the ward or department manager must ensure that is has been properly decontaminated with a decontamination certificate attached. It is illegal to send contaminated devices through the post. For advice contact MDMS.

8.5 If a device is contaminated internally, and therefore cannot be adequately cleaned before dispatch for maintenance or repair, this fact must be communicated to the technical organisation undertaking the work and the equipment transported in a safe and agreed manner. A decontamination certificate, stating the degree of residual contamination should always be attached.

9.1 All healthcare professionals must be trained in the correct use of each relevant medical device and it is their responsibility to ensure they are up to date. It is the ward and departmental manager's responsibility to ensure that training is accessib

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Medical Devices Training Policy
Medical Devices Maintenance Policy
Adverse Events Reporting Policy
Policy for the Introduction of New Health Technologies
Infection Control Policy
Decontamination Policy
Risk Management Policy and Procedure
CAS Alerts Management Policy
Suppliers and their Representatives - Code of Conduct

Care Quality Commission: *"Regulation 12: Safe care and treatment" (2014)*
Care Quality Commission: *"Regulation 15: Premises and equipment" (2014)*
Medicines and Healthcare Products Regulatory Agency: *"Managing Medical Devices, April 2015"*
Medicines and Healthcare Products Regulatory Agency: *"Devices in Practice, June 2014"*
Medicines and Healthcare Products Regulatory Agency*: "Medical Devices: the regulations and how we enforce them, February 2019"*