



Medical Equipment Training Policy

This procedural document supersedes: CORP/RISK 2 v.6 – Medical Equipment Training for Trust Staff



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Executive Sponsor(s):	Mr Sewa Singh – Medical Director
Author/reviewer: (this version)	Andrew Leverton – Medical Technical Services Manager Louise Thompson – Clinical Educator
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Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 7	19 July 2019	<ul style="list-style-type: none"> • Introduction – new definitions of medical devices and medical equipment. • Duties and Responsibilities – Chief executive and divisional clinical director added. Individual staff amended to include specifics for students, agency and NHSP. • Categories of Risk and Use – new section added, managers to retain a copy of own department risk assessment and categories of use for staff identified. • Training – matrix developed and to be retained by each department. Self-declaration for registered staff, and assessments for non-registered staff. Recording on ESR. • Recording and monitoring – includes what will be expected for departments to keep in the equipment folder. • Monitoring compliance – records to be reviewed by medical devices management group and clinical educators. Compliance to be included with education leads monthly review. • Associated trust procedural documents – volumes added. CORP/PROC6 v.4 title amended to reflect current version. • References – New Care Quality Commission reference added. • Appendix 1 – Purchase form removed. • Appendix 2 – equipment training matrix – developed and example included. • Appendix 3 – training algorithm – developed to identify training requirements • Appendix 4 – Assessment form - developed for use to assess non registered staff for competency. • Appendix 5 – Training Passport – developed to enable students, NHSP staff etc. to have evidence of training. 	Andrew Leverton/ Louise Thompson

Version 6	11 August 2017	<ul style="list-style-type: none"> • Doncaster and Bassetlaw Hospitals changed to Doncaster and Bassetlaw Teaching Hospitals throughout document. • Asset register access updated to contact MTS. • Language changed throughout the policy to reflect changes within the trust (CSU changed to Care Group and Doncaster and Bassetlaw Hospital NHS Foundation Trust changed to Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust) 	A Leverton/ Louise Thompson
Version 5	23 July 2013	<ul style="list-style-type: none"> • New style format included • Reference added to CQC and NHSLA standards • References to divisions replaced with Clinical Service Units (CSU) • Removal of responsible Nurse manager paragraph • Removal of Credentialisation paragraph • Reference to the 'Gold Standard' system. • Gold Standard templates added as Appendix 3 	A. Leverton
Version 4	June 10	<ul style="list-style-type: none"> • Reference to the asset database • Clinical Educators group replaced by Patient Safety Review group • Additional section on Delivery added • Updated recording and monitoring section • References updated 	A. Leverton
Version 3		<ul style="list-style-type: none"> • Page 6 – Additions to the list of equipment where competency based training is required. • Page 6 – Reference made to authorised users • Page 7 – Medical Equipment Training group replaced by Clinical Educators group • Page 7 – Reference to list of authorised users • Page 7 – Removal of CNST and RPST references replaced by NHSLA risk management standards • Page 7 – Reference made to the Medical Technical Services Website and accessing the asset database and training records. • Page 7 – Inclusion of a paragraph relating to update frequencies • References updated • Appendix 3 updated to indicate examples • Appendix 4 updated to include updated frequency • Appendix 5 updated to include update frequency 	A. Leverton

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1 INTRODUCTION

Medical devices and Medical Equipment play an increasingly important role in the assessment, management and quality care of patients.

The World Health Organisation (2012) provides the following definitions:

Medical Device:

“An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.”

Medical Equipment:

“Medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury, it can be used either alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single use medical devices.”

Medical equipment training is an element in the fundamental care standards produced by the Care Quality Commission (CQC) (2010 and 2017) and is also a standard produced by the NHS Litigation Authority (NHSLA) (2013). These standards help promote patient care and safety, so it is essential that the training highlighted within this policy is adhered to.

2 PURPOSE

Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust will ensure that all members of staff are provided with adequate information, training and supervision as appropriate; to enable the safe use of medical equipment relevant to their role, this is in accordance with the Health and Safety at Work Act (1974).

The Trust will keep adequate records of such training and ensure that staff are aware that medical equipment **MUST NOT** be used if they are not authorised and competent to do so.

3 GENERAL PRINCIPLES

It is expected that staff will:

- Not use equipment unless authorised and competent to do so.
- Ensure that any equipment requiring interpretation or analysis that the appropriate skills have been attained.
- Refer to own professional standards regarding accountability and competency.

- Have access to operators manual for all equipment used, be this paper or electronic format.
- Ensure that medical equipment is suitable for use.
- Be aware of any consumables related to medical equipment they use.

ALL STAFF SHOULD BE MADE AWARE AT LOCAL INDUCTION OF THEIR INDIVIDUAL RESPONSIBILITIES RELATING TO MEDICAL EQUIPMENT USAGE.

4 DUTIES AND RESPONSIBILITIES

Chief Executive

Responsible for supporting the implementation of Trust wide training to ensure that all relevant staff are aware of the policy and comply with the standards set out.

Associate Director of Nursing/Midwifery/Therapies

To ensure that divisional matrons are aware of the policy. To be informed of incidents within their division relating to medical equipment.

Clinical Directors

To ensure that all consultant teams are aware of the policy and that medical professionals complete appropriate documentation.

Matrons

To ensure that all of their ward/department managers are aware of the policy. To investigate and action any incidents relating to medical equipment and escalate these incidents to Associate Director of Nursing /Midwifery/Therapies as appropriate.

Ward/Department Managers

Responsible for ensuring that staff within the ward/department are aware of this policy. Provide support to the training co-ordinator with monitoring compliance of staff training along with sourcing training opportunities as required. Training can be arranged by contacting Medical Technical Services.

Training co-ordinator

The designated person on the ward/department who will be responsible for ensuring that the equipment folder is kept up to date.

Individual Staff

- Professional registered staff – follow training algorithm and action as indicated. Review ward/department training matrix for expected levels of use on equipment utilised within clinical area. Assess competence of non-registered staff.
- Non-registered staff – follow training algorithm and action as indicated. Review ward/department training matrix for expected levels of use on equipment utilised within clinical area.
- Students – will be responsible for accessing training/assessment by professionally registered staff and maintaining an equipment use passport (see Appendix 5).

- National Health Service Professional staff (NHSP) – responsibilities as indicated above for registered or non-registered staff as applicable. Note that are only able to use equipment they would utilise within their own clinical area. If being expected to utilise additional equipment a training passport must be commenced and produced as evidence.
- Agency staff – will not use any medical equipment within the trust until they have been assessed to do so. A training passport can be maintained and produced as evidence. For registered agency staff they may complete a self-declaration indicating they are competent to use the equipment and this can be filed in the equipment folder on the ward/department.

Patient Safety Review Group

Responsible for receiving and commenting on an annual report on the status of medical equipment training. Will provide guidance and support where applicable to improve processes.

Medical Technical Services (MTS)

Responsible for maintaining an asset register of all equipment within the Trust. To keep a record of risk assessments completed by each ward/department manager. Maintain an up to date record of manufacturers and their trainers. To disseminate Medicines and Healthcare products Regulatory Agency (MHRA) notifications relating to medical equipment. Provide support and advice on all queries/issues regarding medical equipment.

5 CATEGORIES OF RISK AND USE

5.1 Categories of Risk

The Trust recognises that it has a role to play in ensuring that staff are authorised and able to use medical equipment safely.

Each ward/department will conduct its own risk assessment of the equipment utilised by staff within their area and produce their own documentation on risk. A copy of the risk assessment will be retained in the equipment folder and a copy will be sent to MTS. The risk assessment should be reviewed annually or if there is an incident regarding a piece of medical equipment that piece of equipment should be reviewed at the time of investigation. When any amendments are made or when the annual review is completed this revised copy should be sent to MTS.

Appendix 1 has generic risk categories outlined which can be used for consideration by managers when compiling their own matrix. This matrix will provide the basis for staff in determining what actions are required from them to ensure they are safe with the use of medical equipment.

5.2 Categories of Use

The ward/department manager or training co-ordinator will complete a matrix of the medical equipment utilised within their area (Appendix 2). This will indicate to staff the level of use expected from them regarding each piece of medical equipment along with the risk category assigned to that specific piece of equipment.

The categories for use are:

Level 1 – Basic

- Collect equipment
- Report faults with equipment – broken or damaged
- Clean equipment
- Store equipment

Level 2 – Competent

- Use the equipment
- Identify alarms/warnings and take actions
- Set up the equipment and conduct necessary pre checks
- Identify consumables appropriate to use with the equipment
- Contraindications/cautions for using the equipment
- Report faults – as per level 1 along with any operational faults
- They will also meet all of the criteria outlined for Level 1

Level 3 – Specialist

- Train other members of staff on the equipment as they will have completed a train the trainers session with the manufacturer
- They will also meet all of the criteria outlined for Level 2

6 TRAINING/SUPPORT

6.1 Training

There are different options available for training relating to medical equipment, which staff can utilise should training needs be identified.

Manufacturers are able to attend and provide training on equipment, and there are also in house trainers available for certain pieces of medical equipment. There are some E-Learning packages available and additional packages added as they become available. The Trust is currently in the process of developing videos which staff will be able to access via MTS website. User manuals are also available via the MTS website. For any training needs that are identified please contact your ward/department clinical educator or Medical Technical Services who will be able to advise on the best course of action.

Staff will be expected to review the matrix compiled by their ward/department which will indicate which level of use and risk level has been identified for each piece of medical

equipment and therefore what is required from staff. Appendix 2 shows the format for use, please add additional equipment as required.

For professional registered staff, they are able to complete a self –declaration form on ESR indicating they are competent on all the equipment and to the level specified in their ward/department equipment folder. These staff are completing this form and abiding to their regulating bodies professional standards.

For non-registered staff an assessment will need completing by a competent registered professional or anyone trained to level 3 for that specific piece of equipment. This will state that they have observed the non-registered staff member use the equipment to the level specified on the ward/department matrix. All updates are outlined on the algorithm (Appendix 3), and the assessment form can be found in Appendix 4.

For registered staff the self-declaration form will automatically notify via ESR when is next due for completion. For non-registered staff once the assessment has been completed this can be loaded onto ESR again meaning notifications will be sent.

Certain pieces of medical equipment will need to be updated annually, such as the defibrillator and this is accomplished by staff attending SET days, others such as hoists will be covered when attending for Manual Handling update or via staff conducting workplace assessment for manual handling.

6.2 Recording and monitoring

There is a medical equipment folder in each ward/department and this will include the following:

- A list of medical equipment utilised in the area
- A list of manufacturers and contact information
- A list of staff employed
- Identification of the training co-ordinator(s)
- Training matrix
- Training algorithm
- Any training records e.g. copies of certificates from e-learning, registers of any training provided etc.

ESR compliance will be indicated and escalated to ward/department managers via the education leads as part of their SET and compliance updates to ward/department managers, as they are requested by managers.

For students and Agency staff if they have an equipment passport this should be photocopied and kept in the equipment folder as evidence. The staff should retain the original and keep with them at all times when at work.

7 PURCHASE OF NEW MEDICAL EQUIPMENT

An important aspect of ensuring that risks are minimised with the use of medical equipment, is to ensure that staff are familiar with the equipment available and authorised to use it. This can be achieved through training but also through standardising the equipment in the Trust. This is being actioned through finance and procurement mechanisms principally the guidance document on the procurement of Medical Equipment. Equipment should be purchased in accordance with the Provision and Use of Work Equipment 1998 as amended (PUWER)

For further information please refer to the Policy on Medical Devices Management Policy CORP/PROC 4.

8 MEDICAL EQUIPMENT ON LOAN

Many suppliers and manufacturers will provide medical equipment on loan or hire for either trial and evaluation or for a specific patient need, for example specialist surgical instrumentation or dedicated specialist beds. It is essential that all equipment on loan or hired is subject to the appropriate procedures detailed in the Medical Equipment On Loan Procedures found within Medical Devices Management Policy CORP/PROC 4. This includes the requirements to identify and ensure that user training is carried out and recorded.

9 MEDICAL EQUIPMENT AND END USERS

It may be part of a patient's clinical management that patients and their families need to be trained in the use of a particular piece of equipment. This must be done to suit the individual needs and requirements. Verbal instructions should be complemented by clearly written advice. Contact numbers of where advice and help can be sought, particularly in an emergency, must be given verbally and in writing to patients and their families. Information about where to return equipment, once it is no longer used, is very important. Home loans procedure are available from Medical Technical Services website.

10 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Training records	Medical Equipment Management Group and Clinical Educators	Annual Review of all areas	Reported to PSRG annually
Compliance with risk assessments, staff training and updates	Ward/department managers	Quarterly	EOG and divisional Governance Groups

11 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (Appendix 6)

12 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

The following procedural documents are associated with this policy and should be read in conjunction:

- **CORP/PROC 4** – Medical Devices Management Policy
- **CORP/RISK 6** - Central Alerting System Policy
- **CORP/PROC 6** – Condemnation and Disposal of Trust Assets
- **PAT/IC 24** – Cleaning and disinfection of Ward-based Equipment
- **CORP/EMP 4** - Fair Treatment for All Policy
- **CORP/EMP 27** – Equality Analysis Policy

13 REFERENCES

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<http://www.legislation.gov.uk/ukpga/1974/37/contents>

Provision and Use of Work Equipment Regulations (PUWER). (1998). Available from:
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APPENDIX 1 – MEDICAL EQUIPMENT RISK CATEGORIES

High–risk equipment

This Category includes all life-support equipment, key resuscitation equipment, and other equipment whose failure or misuse is reasonable likely to result in serious injury to patients or staff. Any equipment that has been associated with serious injury in the past (either repeatedly or by nature of its design, but not simply because of an isolated incident) should be included unless a modified equipment design has greatly reduced the risk. Many of the items in this category are therapeutic equipment capable of delivering substantial energy. Examples include electro surgical units (ESUs) and lasers, which can cause unintended burns; resuscitators, which, if not functional, could result in death; and heart-lung bypass units, which, if they fail, could result in permanent neurologic damage or death.

However, not all therapeutic equipment capable of delivering energy to the patient are classified as high risk. For example, ultrasound therapy and physical therapy neuromuscular stimulators are rated low risk because they have relatively low energy output levels, the related treatments are closely supervised, and they are not associated with a significant history of serious injuries.

Also included in the high-risk group are critical monitoring equipment. Equipment, such as oxygen monitors, ECG/heart-rate monitors, and apnoea monitors, has critical alarms; if the alarms fail, a serious condition is reasonably likely to go unnoticed and quickly result in serious patient injury or death.

Medium–risk equipment

This category includes equipment whose misuse, failure, or absence (e.g. out of service and no replacement available) would have significant impact on patient care, but would not likely cause immediate serious injury. Many diagnostic pieces of equipment, such as cardiac output units, clinical laboratory equipment, and ultrasound imaging systems, are included in this category. While a failure of this type of equipment could affect or delay therapy, major therapy changes would be made (or continued) only if the diagnostic indicator is consistent with other signs and symptoms. Patient outcome is unlikely to be significantly affected.

Low-risk equipment

This category includes equipment whose failure or misuse is unlikely to have serious consequences. Examination lights and electronic thermometers used for routine vital signs are included in this category.

The following lists have been provided by the independent Medical Equipment Management institute (E.C.R.I.) as a guide and are not meant to be comprehensive or valid in all circumstances.

Examples of High Risk Equipment

Anaesthesia Units and Vaporizers	Lasers
Anaesthesia Ventilators	Medical Gas/Vacuum Systems
Apnea Monitors (Neonatal)	
Aspirators (Emergency and Tracheal)	Oximeters (Pulse)
Autotranfusion Units	Oxygen Monitors and Analyzers
Blood Pressure Units (Invasive)	Pacemakers (External)
Capnometers	Peritoneal Dialysis Units
Defibrillators (including Defibrillator/Monitors and Defibrillator/Monitor/Pacemakers)	Phacoemulsification Units
Diagnostic Radiological Imaging Systems	Physiologic Monitors and Monitoring Systems
Electrosurgical Units	Radiant Warmers (Infant)
Foetal Monitors	Radiographic Dye Injectors
Heart-Lung Bypass Units	Regulators (for Tracheal Suction)
Haemodialysis Units	Regulators (Cardiac)
Incubators (Infant, including Transport Units)	Resuscitators (Pulmonary)
Infusion Controllers/Pumps	Suction devices
	Tourniquets (Pneumatic)
	Transcutaneous Oxygen (O ₂) and Carbon Dioxide (CO ₂) Monitors
	Ventilators

This is a broad generic list, for detailed assessments of assets please refer to the Medical Technical Services Website or contact Medical Technical Services

Examples of Medium Risk Equipment

Ambulatory ECG Recorders and Scanners	Laparoscopic Insufflators
Aspirators (Surgical, Thoracic, and Uterine)	Lithotripters
Blood Bank Refrigerators	Oxygen-Air Proportioners
Blood Gas/pH Analyzers	Phonocardiographs
Blood Pressure Units (Noninvasive Electronic (used in Critical care))	Phototherapy Units
Blood Warmers	Pneumatic Antishock Trousers
Cardiac Output Units	Pressure Transducers (All Types)
Centrifuges	Pulmonary Function Analyzers
Clinical Laboratory Equipment	Radiant Warmers (Adult)
<u>Cryosurgical Units</u>	Regulators (Air, O2, Suction (except tracheal))
Electrocardiographs	Scales for Critical Applications (e.g. Haemodialysis Units, Neonatal Care Units)
Electroconvulsive Therapy Units	Special Care Beds (e.g. Rocking, Circle, Flotation)
Electroencephalographs	Surgical Drills and Saws (Powered)
Endoscopes	Traction Units
Enteral Pumps	Treadmills
Evoked Potential Units	Ultrasound Scanners

This is a broad generic list, for detailed assessments of assets please refer to the Medical Technical Services Website or contact Medical Technical Services

Examples of Low Risk Equipment

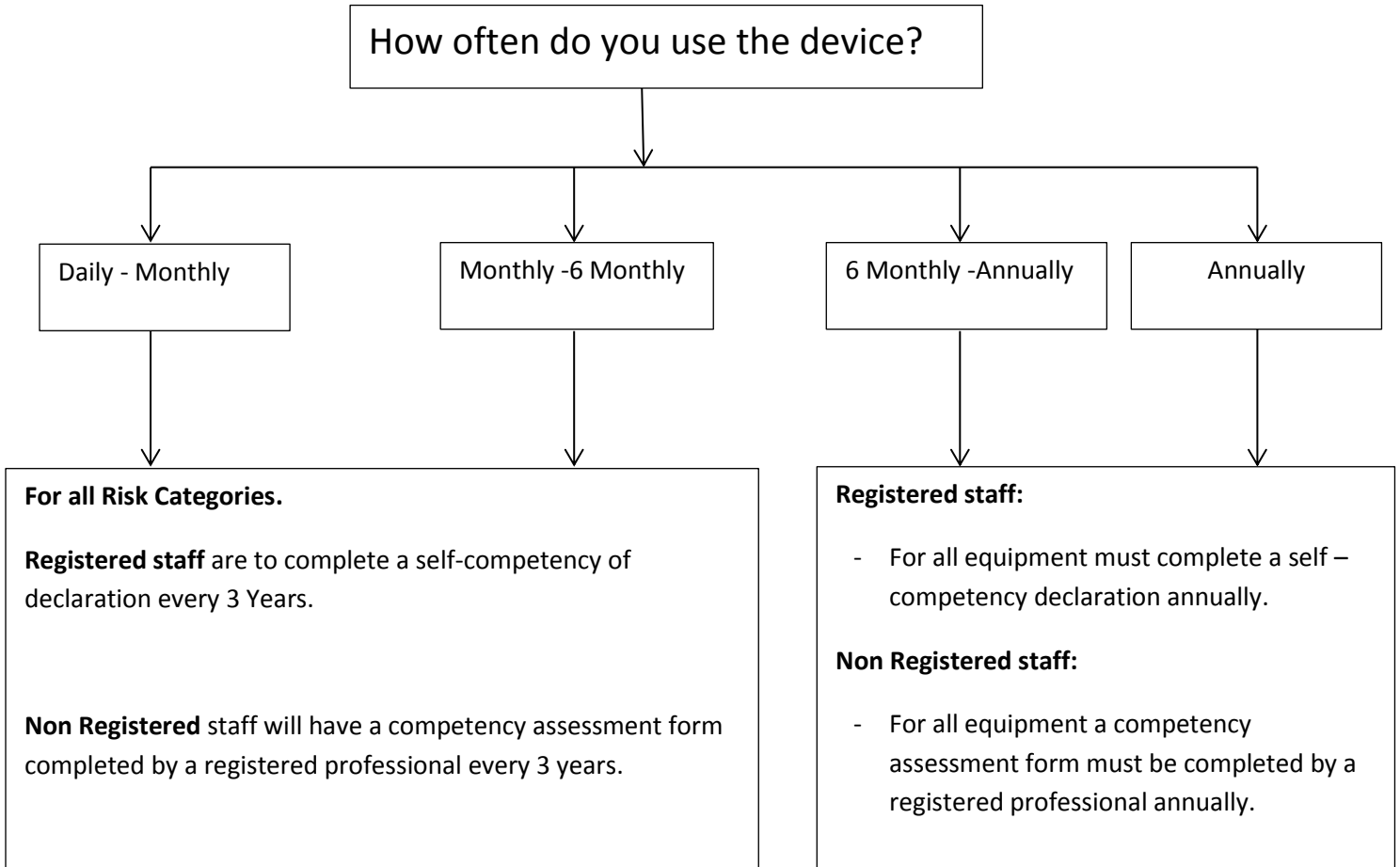
Alternating-Pressure Pads	
Aspirators (Low Volume)	Paraffin Baths
Cast Cutters	Physical Therapy Ultrasound Units
Circulating-Fluid Pumps	Pumps (Breast)
Camera Systems	
Diathermy Units (Physical Therapy)	Regulator (Low-Volume Suction)
Electric Beds	Smoke Evacuators
Electrical Receptacles	Sphygmomanometers
Electronic Scales (for General Patient Care)	Stimulators (Low-and-High-Voltage Physical Therapy Units)
Electronic Thermometers	Surgical Lights
Examination Lights	Surgical Microscope
Fiberoptic Light Sources	Surgical Tables
Isolated Power Systems	Temperature Monitors
Oto/Ophthalmoscopes	Ultrasonic Nebulisers
	Whirlpool Baths

This is a broad generic list, for detailed assessments of assets please refer to the Medical Technical Services Website or contact Medical Technical Services

APPENDIX 2 – EQUIPMENT TRAINING MATRIX

Device	Risk Category	Nurses (Band 5)	Nurses (Band 6-7)	Healthcare assistants	F1	F2	Registrar	Consultant	Allied Health Professional	AHP assistant	Housekeeper	Service worker	Assistant Practitioners
Example equipment	Low	Level 2	Level 2	Level 1	X	X	X	X	X	X	Level 1	X	X
Volumed infusion pump													
Syringe pump													
BIPAP													
Nutricia pump													
Medical gases													
Transair mattress													
Electronic Sphygmomanometer													
Genius II													
Pulse Oximeter													
T34													
Suction and Oxygen													
Electric Bed													

APPENDIX 3 – TRAINING ALGORITHM



DEFIBRILATORS – regardless of frequency of use, will be updated annually as part of SET.

NOTE: should a staff member be involved in an incident relating to medical equipment then the staff member must have a competency assessment form completed by a registered staff member who has level 3 training for that particular piece of equipment.

MEDICAL EQUIPMENT PASSPORT

Medical equipment **MUST NOT** be used unless you are deemed competent to do so.

This passport is for use by students and agency staff who will not have their competency recorded on the Trusts ESR system.

Once this is completed a copy should be taken and retained in the ward/department equipment folder and the original retained by the staff member. This should be brought to work on every shift as evidence of competence should you work on another ward/department.

If you have any queries regarding this passport please contact either medical technical services or the divisional clinical educator who will be able to provide support and assistance.

Type of Equipment _____

Training Method - Self Declaration Training Session E-Learning

Manual Read Instruction Video

Level Attained - 1 2 3

Trainer/Assessor _____ Date _____

Type of Equipment _____

Training Method - Self Declaration Training Session E-Learning

Manual Read Instruction Video

Level Attained - 1 2 3

Trainer/Assessor _____ Date _____

Type of Equipment _____

Training Method - Self Declaration Training Session E-Learning

Manual Read Instruction Video

Level Attained - 1 2 3

Trainer/Assessor _____ Date _____

Type of Equipment _____

Training Method - Self Declaration Training Session E-Learning

Manual Read Instruction Video

Level Attained - 1 2 3

Trainer/Assessor _____ Date _____

Type of Equipment _____

Training Method - Self Declaration Training Session E-Learning

Manual Read Instruction Video

Level Attained - 1 2 3

Trainer/Assessor _____ Date _____

APPENDIX 6 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Division/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Medical Equipment Training	Corporate / Estates	Louise Thompson	Existing	26 June 2018
1) Who is responsible for this policy? Name of Division: Corporate – Estates and POD – Training and Education				
2) Describe the purpose of the service / function / policy / project/ strategy? So that staff may safely use any medical equipment relevant to their role when authorised to do so				
3) Are there any associated objectives? MHRA notifications				
4) What factors contribute or detract from achieving intended outcomes? – Non-attendance or non-compliance with training				
5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? No <ul style="list-style-type: none"> • If yes, please describe current or planned activities to address the impact N/A 				
6) Is there any scope for new measures which would promote equality? N/A				
7) Are any of the following groups adversely affected by the policy?				
Protected Characteristics	Affected?	Impact		
a) Age	No			
b) Disability	No			
c) Gender	No			
d) Gender Reassignment	No			
e) Marriage/Civil Partnership	No			
f) Maternity/Pregnancy	No			
g) Race	No			
h) Religion/Belief	No			
i) Sexual Orientation	No			
8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box				
Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4	
<i>*If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a Detailed Equality Analysis form – see CORP/EMP 27.</i>				
Date for next review: August 2021				
Checked by: Andrew Leverton			Date: July 2018	