Birmingham and Solihull Mental Health NHS Foundation Trust

Diagnostic and Therapeutic Equipment and Devices

Policy number and category	**RS 19**	**Risk and Safety**
Version number and date	**4**	**April 2021**
Ratifying committee or executive director	**Trust Clinical Governance Committee**	
Date ratified	**June 2021**	
Next anticipated review	**June 2024**	
Executive director	**Executive Director of Quality and Safety**	
Policy lead	**Head of H&S and Regulatory Compliance**	
Policy author *(if different from above)*	**As Above**	
Exec Sign off Signature (electronic)		
Disclosable under Freedom of Information Act 2000	**Yes**	

POLICY CONTEXT:

The policy identifies robust procedures and processes for the procurement, maintenance, storage and safe use of diagnostic and therapeutic equipment, including the identification of authorised users, training issues and the maintenance of equipment inventories.

POLICY REQUIREMENT

The policy is required to enable compliance with Regulation 15 of the Health and Social Care Act 2008 (Regulated Activities), the Medical Devices Regulations 2002 and requirements of the Health and Safety at Work etc Act 1974. The Trust has a duty of care to service users to ensure that they are not placed at risk from the inappropriate use of medical devices and a responsibility to ensure that staff can safeguard themselves and their practice by having access to appropriate training, where indicated, in diagnostic and therapeutic equipment.

Contents

1 Introduction

1.1 Rationale

The policy is required to enable compliance with Regulation 15 of the Health and Social Care Act 2008 (Regulated Activities), the Medical Devices Regulations 2002 and requirements of the Health and Safety at Work etc Act 1974.

The Controls of Assurance Standard 2015 for Medical Devices and Equipment Management also requires that there is a system in place which ensures that all risks associated with the acquisition, use and disposal of Medical Devices and Equipment are minimised.

The policy will also enable compliance with the relevant agreed Trust Clinical Safety Standards.

All NHS organisations are subject to legal & statutory requirements relating to the duty of care that requires employers to provide competent employees, safe equipment, a safe place of work and a safe system of work (Health and Safety at Work Act (HASAWA) 1974).

Birmingham and Solihull Mental Health Foundation Trust (BSMHFT) recognises that the safe and appropriate use of equipment is critical to the delivery of high-quality care and that the use of medical devices within clinical areas plays an increasingly important role in the assessment, management and evaluation of patient care.

The Trust has a duty of care to service users to ensure that they are not placed at risk from the inappropriate use of medical devices and a responsibility to ensure that staff can safeguard themselves and their practice by having access to appropriate training where indicated in the use of diagnostic and therapeutic equipment.

1.2 Scope

This is a corporate policy that applies to all staff (permanent, contracted or agency) that undertakes activities on behalf of BSMHFT. This includes staff working in Prison Healthcare Services and any other contracted services that have accountability to the Trust.

The policy applies whenever medical devices are being procured, inspected, maintained, used or being disposed of on Trust premises or other premises where the Trust has responsibility.

1.3 Principles

The Trust believes that no service user should be harmed as a result of being exposed to medical devices or equipment that is either not fit for purpose, not adequately inspected, serviced or maintained or was not procured through approved suppliers. It will therefore ensure that there are robust procedures and systems of work in place to ensure that these can be achieved.

2 Policy

The purpose of this policy is to ensure that the Trust complies with the Medical Devices Regulations 2002, and that all staff that operate diagnostic or therapeutic equipment, as part of their role, are identified as authorised users,

receiving appropriate training to enable them to use medical devices in a safe and effective manner.

The policy lead will work with other members of the organisation to ensure that:

- Equipment is procured in accordance with the NHS Procurement Standards
- Once procured, medical devices and equipment have been tested and asset registered by the relevant Electro Bio Medical Engineering (EBME) company
- Equipment is suitable for its intended purpose.
- Procedures are in place to demonstrate that equipment receive regular, routine (pre-planned) maintenance, according to the manufacturers' instructions, to enable them to function in a safe and reliable manner (via EBME Contracts / Service Level Agreements). Records of this will be kept for the life of the equipment.
- Equipment is stored securely
- Equipment is accessible at the point of need
- Infection Control Guidance is adhered to for cleaning and disposal of equipment and devices
- Users have received appropriate training and assessment of competence in their use.

The Trust will ensure that there is a robust system in place, which will:

- Identify and record all diagnostic or therapeutic equipment in use by the Trust. This is supported by use of an external contract with an EBME company.
- Identify and record all authorised users of diagnostic or therapeutic equipment in the Trust
- Identify the training needs of authorised users of diagnostic and therapeutic equipment in use by the Trust and deliver training accordingly
- Ensure any person operating diagnostic or therapeutic equipment has sufficient understanding of its use to do so in a safe and effective manner

All staff who use diagnostic and therapeutic equipment, within the remit of their role, have a responsibility to ensure that they are competent to operate the equipment in a safe and effective manner, and seek advice and training where necessary.

It is recognised that the use of medical devices/equipment may be delegated to associated support staff, but the registered professional remains accountable at all times for the task, and for ensuring the competence of individuals, and that delegation is appropriate and safe.

The Trust will develop new procedures, or amend existing ones, as and when considered necessary, to promote the continuous improvement of the management of diagnostic and therapeutic equipment.

3 Procedure

3.1 Procurement

All diagnostic and therapeutic equipment must be fit for purpose and must be procured in accordance with the NHS Procurement Standards.

NHS Purchase Card holders must not use these to purchase medical devices/ equipment of any description, as the Trust is required to verify the safety of all medical devices/ equipment purchased for the Trust. Such checks are carried out by the Procurement team as part of the formal ordering process.

When selecting new diagnostic and therapeutic equipment, users should consider the essential and desirable requirements of the equipment to be purchased. Care should be taken to avoid over specification, as equipment can become unnecessarily complex, difficult to use and expensive.

Consideration should be given to

- Any infection control measures that may be needed for the equipment (i.e., disposable/ single use where it cannot be effectively decontaminated)
- Whether there are any safer options
- Any special clinical or technical training required for the equipment
- Guidance from the Medicines and Healthcare products Regulation Agency
- Advice from Electro Bio Medical Engineering (EBME)

Purchase specifications must require that manufacturer's instructions are supplied with new medical equipment.
The specification will also require that the manufacturers provide the Trust with any revised instructions throughout the prospective life of the device.

Once this criterion has been met, a requisition can be raised in the usual way.

3.2 CE/ UKCA Marking

The Trust must ensure that only CE or UKCA marked medical devices are purchased for use. Following the UK leaving the European Union, devices can also have the CE and UKCA mark.

The CE or UKCA mark means that a manufacturer is satisfied that his product conforms with relevant essential requirements in the Medical Devices Directives (implemented into UK legislation by the Medical Devices Regulations 2002) and it is fit for purpose.

The CE or UKCA mark is seen as a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation, including those relating to safety, and where required has been assessed in accordance with these.

3.3 Acceptance

When devices are first delivered to the Trust it is essential that the professional user carries out checks prior to use.
New equipment must be formally accepted to ensure that entry into the service is properly controlled.

The procedure will include:

- *Delivery checks*
  The person receiving the device is responsible for:

  - Checking for external damage to the package or its content.
  - Checking that the correct goods have been delivered.
  - Checking that all components and instruction manuals are present (or will be delivered.)
- *Acceptance Checks and Addition to the Asset Register*
  - Staff will then need to complete a 'Goods Received' note and send it to the Finance Department at Trust Headquarters.
  - Staff in receipt of the device must inform the Electro Bio Medical Engineering (EBME) company so that they can make arrangements for the acceptance checks prior to the device being used. Contact details are in Appendix 4.
  - Once the EBME company has been informed of the acquisition of a new item of equipment (including the make and the model and location), they will conduct the acceptance checks and notify the team of the outcome. If approved, the device will then be assigned a reference number and added to the asset register and put into the maintenance programme.

  Depending on the type of equipment, the various aspects of commissioning will be carried out by an appropriate combination of the manufacturer's technical representative, SSL Estates staff, EBME and end users. This will also include details of frequency of calibration and by whom for devices that require this.

3.4 Storage of Devices

Service Areas are to take care when storing new devices as inappropriate storage of items can affect their subsequent safe use. Manufacturer's information and instructions, both on storage conditions and shelf life, must be followed.

Service Areas should consider the following:

- Avoid storing fragile devices too far off the ground.
- Ensure storage conditions are suitable for the device and in accordance with manufacturer's instructions/guidance.
- Ensure devices and consumables are used in good rotation to avoid being stored for too long or exceeding the shelf life.

3.5 Maintenance

Diagnostic and therapeutic equipment will be subject to routine monitoring, maintenance and servicing.
During procurement, maintenance requirements must be identified in advance, and appropriate arrangements put in place.
All maintenance and servicing of the equipment will be carried out by the EBME company and records of all maintenance, servicing and repair will be held by them for the 'life' of all equipment.
Diagnostic and therapeutic equipment must, under no circumstances, be altered or modified by anyone not competent to do so. Even then, alterations and modification must only be carried out after consultation with the manufacturer or supplier.
Some types of equipment may require regular calibration checks and/or recalibration, e.g., alcometers and glucometers. This work must only be undertaken by those competent to do so i.e., supplier, manufacturer or EBME.

3.5.1 Routine Maintenance

Professional users are responsible for routine maintenance i.e. the regular cleaning, preparation for use, and checking of devices as per manufacturers' recommendations.

3.5.2 Planned Maintenance

Maintenance and checks will be carried out by EBME as part of an annual work programme and the findings recorded on a central database. Nominated staff within the Trust will have access to this database.

3.6 Electrical Safety

It is very important to observe basic rules in electrical safety when using portable and fixed appliances of any kind.
Staff should ensure that the equipment has a valid dated safety test label, which demonstrates that it has been PA tested (Portable Appliance Testing) by the relevant contractor managed by the Estates Department. This also applies to 'fixed' equipment.

Where appropriate, all staff should

1) Carry out a regular and frequent visual inspection of the plug and cable.
2) Ensure cable stowage devices are properly used
3) Arrange for the device to undergo Portable Appliance Testing (PAT) annually as a minimum

3.7 Decontamination

Decontamination is the combination of processes, including cleaning, disinfection and/or sterilisation, used to render a re-usable medical device safe for further episodes of use.

‘Medical devices and equipment which are used on more than one patient may act as vehicles for the transmission of infection between service users. All such devices must therefore be adequately decontaminated between each patient use.’ (HSC 2000/032)

- All reusable medical equipment, which is used for more than one patient, should be decontaminated between service users to ensure that there is no risk of transmitting infection by this route.
- Devices designated for 'single-use' must not be reused under any circumstances.
- The reuse of 'single-use' devices can affect their safety, performance and effectiveness, exposing service users and staff to unnecessary risk.
- Decontamination needs to take place in line with manufacturers’ guidelines and Trust decontamination procedures.

3.8 Decommissioning and Disposal

When a ward or department wishes to condemn and/or dispose of an item of equipment, staff should notify the Electro Bio Medical Engineering (EBME) contractor by following the process in Appendix 4 and sending it to them. The EBME contractor will arrange to collect the item of equipment. Where a medical device is in need of repair or modification, then only persons with overall responsibility for the technical servicing of the equipment - which is the Electro Bio Medical Engineering contractor - (and/or in conjunction with the manufacturers), can authorise this. This will ensure that the safety of the device is not compromised in any way.

Equipment that has been condemned/ decommissioned must not be offered for further use.

Devices being permanently taken out of service must be:

- Decontaminated and

- Clearly identified (i.e., labelled) as ‘removed from service’

The EBME contractor will ensure that the item of equipment is removed from any service contract or other maintenance arrangements and disposed of in compliance with the statutory waste regulations where necessary.

3.9 Replacement

The Trust makes provisions for capital replacements including medical equipment using the process approved via the Capital Review Group. Where there is a risk that equipment cannot be replaced due to lack of financial resources, this must be added to the Risk Register.

3.10 Service User Confidentiality

All service user identifiable data must be stored on medical devices in line with the requirements of GDPR and removed prior to decommissioning or disposal of the device/ equipment.

3.11 Incident Reporting

'An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including service users) or other persons.' (Medicines and Healthcare products Regulation Agency (MHRA) Jan 2006)

All incidents involving the failure, or misuse of diagnostic and therapeutic equipment, for whatever reason, must be reported to the Medical Safety Device Officer using Eclipse who will ensure that it is reported to other relevant agencies, where appropriate (e.g., Medicines and Healthcare products Regulatory Agency.)

If a near miss or untoward incident occurs involving the use of equipment, then the following action should be taken:

1. An incident report is completed using Eclipse as per the Trust Incident Management Policy
2. The equipment should be retained and clearly labelled as 'out of service' to enable its examination by the appropriate person i.e., the Electro Bio Medical Engineer (EBME) and to allow for an investigation to take place.

Examples of incidents may include:

1. Faulty equipment giving false readings
2. Injury to a patient, user, carer or health professional as a result of the failure or misuse of a piece of equipment
3. Interruption or compromise of a service user's treatment as a result of failure of equipment
4. Design or manufacture problems
5. Inappropriate local modifications
6. Selection of the incorrect device for the purpose
7. Poor user instructions or training
8. Inadequate servicing and maintenance
9. Unsuitable storage and use conditions
10. Inappropriate management procedures

Where a serious adverse incident, occurring within the Trust, has involved a piece of medical equipment, arrangements will be made to take the relevant item/s out of use (For quarantine – should an investigation be required by the MHRA).

3.12 Medicines and Healthcare products and Regulatory Agency Alerts (MHRA)

The Trust must have a nominated Medical Devices Safety Officer (MDSO). The MDSO encourages staff and users to report adverse incidents. The MDSO is responsible for all the functions of reporting, disseminating and feedback of information relating to medical devices. Some of this function can be delegated and the Health and Safety team currently assumes some of this function.

The nominated MDSO for the Trust is the Deputy Director of Nursing. The Health and Safety team is responsible for ensuring that whenever a Safety Alert notice is received via the Central Alerting System (CAS), it is disseminated to the MDSO, who in turn circulates it internally to relevant staff for action and update as necessary.

Safety information will be disseminated quickly and at all levels, including notifying users of any notified risks, until the item of equipment can be checked, repaired or modified as per the recommendations by the notice.

Actions taken as a result of the Alert, and outcomes, will be documented and shared at the Patient Safety Advisory Group on a monthly basis to ensure executive oversight.

A list of all relevant CAS alerts will also be shared at the quarterly Trust Health, Safety and Fire committee.

3.13 Classes of Medical Devices and Equipment

For the purpose of training requirements and measure of risk, medical devices are grouped into three main categories.

Class I Equipment – No additional formal training required (classed as low risk)

This applies to medical equipment that requires no formal training beyond that received by clinical staff at pre-registration level, and is low risk equipment, with clear manufacturer's instructions.

All professional staff will be competent to use this category of equipment as the knowledge and skills are integral to their professional core training.

It is acceptable for staff to be trained in the use of this equipment, in their clinical area by a safe user. This will enable staff to become familiarised with the devices that they will be using on a regular basis.

For new staff, this will be an element of their local induction to the clinical environment.

Examples - *Sphygmomanometers, Tympanic thermometers, Stethoscopes*

Class IIa and IIb Equipment – Formal training required (classed as medium risk)

This category applies to commonly used medical equipment which, if used incorrectly, or by untrained staff, could cause significant harm to staff or service users.

Individuals should only use this equipment once they have received formal training.

Examples - *Resuscitation equipment, Blood Glucometers, Pulse oximeters, ECG Machines, EEG Machine.*

Class III Equipment - Specialist Training required

This applies to equipment only found within a limited number of specialist areas in the Trust e.g., ECT Suites, Treatment Rooms, Neuropsychiatry Department etc.

Examples *Anaesthetic Gas Machine, ECT Machine, Cardio Monitors*

In addition, in terms of risk:

Class I equipment is less likely to cause a serious adverse outcome in the event of equipment failure or misuse and is therefore classed as **low risk**

Class IIa and IIb Equipment may have significant consequences for patient care or have temporary adverse health consequences and is therefore classed as **medium risk**

Class III Equipment has the potential to cause serious adverse consequence, or death, in the event of failure or misuse and is therefore classed as **high risk**

3.14 Defined Training Requirements in Relation to Risk

Each medical device should be categorised into high, medium or low risk depending on the risk to service users, which may arise due to incorrect or inappropriate use.

The following are examples only:

Sphygmomanometer	Low risk
Pulse Oximeter	Medium risk
ECT Machine	High risk

The overall risk would take into account both the consequences and likelihood of any detrimental incident occurring.

Any training should then be appropriate to the risk category of the equipment.

New employees receive a local induction from their immediate manager in their area of work, and this will include induction to medical equipment used locally in the clinical area.

Trust staff should receive training on how to use medical devices, which should be supported by written guidance. In some cases, the manufacturer or supplier of the medical device may provide the training and in some cases it may be provided in-house. Where training is provided in-house, the person providing the training must be competent both in the use of the medical device and in training delivery.

For specific training requirements see Appendix 3.

3.14.1 Training Records

Training Records related to diagnostic and therapeutic equipment training will be maintained by the individual member of staff at departmental level. (See Appendix 4) In addition a record will be kept:

- On an individual's personnel file
- Centrally on the Trust Training Database

3.15 Authorised Users

All Authorised Users must have successfully completed a Trust recognised training programme relevant to the equipment concerned and have been assessed as being clinically competent.

Staff must not use equipment brought into the Trust by a service user unless they are trained and clinically competent to do so.

The Trust considers the groups of staff listed in Appendix 2 to be the authorised users of the equipment concerned when they have successfully completed an appropriate Trust approved training programme (as stated).

4 Responsibilities

Post(s)	Responsibilities	Ref
All Clinical Staff	All clinical staff must adhere to the following criteria prior to using any item of diagnostic or therapeutic equipment: • Inspect the item of equipment for an up to date 'safety test label' and look for any visible signs of damage or wear and tear. If the equipment has an expiry or use by date, these must be complied with.	

Post(s)	Responsibilities	Ref
	• Check to ensure that the equipment is functioning correctly and set to the specifications recommended by the manufacturer. If the equipment has metres or similar monitoring gauges these should be checked to ensure they are working. • All alarms, where appropriate, must be checked as functioning and left on when equipment is in use. • All equipment should be checked to ensure that it is still appropriate in light of the changing needs of the patient, e.g., children can physically outgrow equipment • Do not use the device unless competent to do so, or under direct supervision • Know where to access the user manual or locally written instructions • Be aware of personal limitations. Declare to a senior member of staff if you are not competent to use a particular piece of equipment • Ensure any accessories and/or disposables required are recommended by the manufacturer After use, the equipment should be checked for signs of wear or visible faults. Servicing, maintenance, or repairs should be completed as required. Staff should refer to the Trust's Infection Control Policies regarding cleaning and / or decontamination of the equipment. Where necessary, the advice of the Infection Control Nurse should be sought.	
Service, Clinical and Corporate Directors	Service Directors need to ensure that: • Equipment is procured in accordance with the NHS Procurement Standards • A lead person is identified within the Service Area to develop the equipment inventory • An inventory of all diagnostic and therapeutic equipment within their Service Area is maintained and updated • All staff within the Service Area are receiving the appropriate training and support to use diagnostic and therapeutic equipment in a safe and efficient manner • All staff have access to the relevant policies pertaining to diagnostic and therapeutic equipment • Where an incident or near miss occurs involving medical equipment, it is reported as per the Reporting, Management and Learning from Incidents Policy • There is a system in place to ensure that staff are made aware of any Action/Hazard notices relating to	

Post(s)	Responsibilities	Ref
	Medical devices used within the Service Area/Trust as issued by the Health and Safety team.	
Policy Lead	The policy lead will ensure that: • The policy remains up to date and reflects current legislation, best practice and guidance • Monitor the implementation of the policy for compliance	
Executive Director of Quality and Safety	The Executive Director at Board level with responsibility for Medical Equipment is the Executive Director of Quality and Safety. He/she has the responsibility for ensuring the implementation of a process within the Trust, which will facilitates safe and effective systems and legally compliant working arrangements for medical devices.	
Ward/ Department/ Team Managers	It is the responsibility of the ward/ departmental/ team manager to ensure that a system is in place to: • Maintain an inventory of all medical devices within their ward or department • Maintain a local record of training and monitor the training records for their staff • Make available instruction and user manuals for medical equipment in their ward/department • Ensure that medical equipment is NOT modified to address local needs without consultation or advice • Ensure that the piece of medical equipment in question is suitable for the patient concerned e.g. physical restriction, compatibility • Ensure that all clinical incidents involving medical equipment are reported in line with the Trust untoward / serious untoward incident management policies • Act as a contact point for the delivery and acceptance of new equipment • Ensure that any local equipment storage is in accordance with the recommendations of the manufacturer • Act as a contact point for the dissemination of information regarding Hazard warnings, NPSA Alerts and Safety Notices received from the Risk management Department.	

5 Development and Consultation

This is a review of an existing policy.

Consultation summary	
Date policy issued for consultation	**April 2021**

Number of versions produced for consultation		1
Committees / meetings where policy formally discussed		**Date(s)**
Where received	**Summary of feedback**	**Actions / Response**
Trust H&S Committee Members	Updating section 3.3 to state who informs and how they inform the EBME company re the need for acceptance checking.	Amended accordingly
Chief Nursing Information Officer	Update Rationale re Clinical Safety Standards Add statement re software/ systems being registered as medical devices Statement re calibration added into Acceptance section Statement to be added re 'decontamination taking place in line with manufacturers' guidelines	Statement included The policy will be updated when there is a formal requirement to do so Statement included Statement included
Psychologists	Confirmation that psychologists in this Trust do not use EMG Biofeedback Unit and Enuresis Alarm	These have been removed from Appendix 2

6 Reference Documents

Health and Social Care Act 2008 (Regulated Activities)

Medicines and Healthcare products Regulatory Agency

Medical Devices Regulations 2002

7 Bibliography

None

8 Glossary

Medical Devices

The **Medicines and Healthcare products Regulatory Agency (MHRA**) have defined Medical Devices as:

'Any instrument, apparatus, appliance, material or health care product, excluding drugs, used for a patient 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'

The **UK National Audit Office** in the report, *Managing Medical Equipment Better* defined medical equipment as

*"*All medical devices connected to service users as part of their treatment and care in hospital, and medical devices used for diagnostic and laboratory purposes.'

For the purpose of this policy the term 'medical device/medical equipment' is synonymous with the term diagnostic and therapeutic equipment.

Central Alert System (CAS) - This is a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care.
Alerts available on the CAS website include National Patient Safety Alerts (from NHS England and NHS Improvement and MHRA), NHS England and NHS Improvement Estates Alerts, Chief Medical Officer (CMO) Alerts, and Department of Health & Social Care Supply Disruption alerts.

9 Audit and Assurance

Element to be monitored	Lead	Tool	Frequency	Reporting Committee
Availability of trained staff to use medical devices	Physical Health Team	Reports from OLM or other VLE platform	Annually	Physical Health Committee
Availability of appropriate devices for specific functions	Deputy Director of Nursing	• Check items on the wards against the equipment list • Incident reports	Annually	Resuscitation Committee
All medical devices are calibrated, inspected and maintained as appropriate	Deputy Director of Nursing	• EBME Database • Incident Reports	Annually	Resuscitation Committee

10 Appendices

Appendix 1

Equality Analysis Screening Form

A word version of this document can be found on the HR support pages on Connect
http://connect/corporate/humanresources/managementsupport/Pages/default.aspx

Title of Proposal	**Diagnostic and Therapeutic Equipment and Devices Policy**		
Person Completing this proposal	**Natassia James**	**Role or title**	**Head of Health and Safety and Regulatory Compliance**
Division	**Corporate**	**Service Area**	**Governance**
Date Started	**April 9, 2021**	**Date completed**	**April 9, 2021**

Main purpose and aims of the proposal and how it fits in with the wider strategic aims and objectives of the organisation.

The policy has been reviewed with the aim of continuing to protect our service users from harm by not exposing them to unsafe medical devices or to staff who do not have the skills to use the equipment.

Who will benefit from the proposal?

Service users

Impacts on different Personal Protected Characteristics – *Helpful Questions:*

Does this proposal promote equality of opportunity? *Eliminate discrimination?* *Eliminate harassment?* *Eliminate victimisation?*	*Promote good community relations?* *Promote positive attitudes towards disabled people?* *Consider more favourable treatment of disabled people?* *Promote involvement and consultation?* *Protect and promote human rights?*

Please click in the relevant impact box or leave blank if you feel there is no particular impact.

Personal Protected Characteristic	No/Minimum Impact	Negative Impact	Positive Impact	Please list details or evidence of why there might be a positive, negative or no impact on protected characteristics.
Age	**x**			
Including children and people over 65 Is it easy for someone of any age to find out about your service or access your proposal? Are you able to justify the legal or lawful reasons when your service excludes certain age groups				

Disability	**x**			
Including those with physical or sensory impairments, those with learning disabilities and those with mental health issues Do you currently monitor who has a disability so that you know how well your service is being used by people with a disability? Are you making reasonable adjustment to meet the needs of the staff, service users, carers and families?				
Gender	**x**			
This can include male and female or someone who has completed the gender reassignment process from one sex to another Do you have flexible working arrangements for either sex? Is it easier for either men or women to access your proposal?				
Marriage or Civil Partnerships	**x**			
People who are in a Civil Partnerships must be treated equally to married couples on a wide range of legal matters Are the documents and information provided for your service reflecting the appropriate terminology for marriage and civil partnerships?				
Pregnancy or Maternity	**x**			
This includes women having a baby and women just after they have had a baby Does your service accommodate the needs of expectant and postnatal mothers both as staff and service users? Can your service treat staff and service users with dignity and respect relation in to pregnancy and maternity?				
Race or Ethnicity	**x**			
Including Gypsy or Roma people, Irish people, those of mixed heritage, asylum seekers and refugees What training does staff have to respond to the cultural needs of different ethnic groups? What arrangements are in place to communicate with people who do not have English as a first language?				
Religion or Belief	**x**			
Including humanists and non-believers Is there easy access to a prayer or quiet room to your service delivery area? When organising events – Do you take necessary steps to make sure that spiritual requirements are met?				
Sexual Orientation	**x**			
Including gay men, lesbians and bisexual people Does your service use visual images that could be people from any background or are the images mainly heterosexual couples? Does staff in your workplace feel comfortable about being 'out' or would office culture make them feel this might not be a good idea?				
Transgender or Gender Reassignment	**x**			

This will include people who are in the process of or in a care pathway changing from one gender to another Have you considered the possible needs of transgender staff and service users in the development of your proposal or service?				
Human Rights	**x**			
Affecting someone's right to Life, Dignity and Respect? Caring for other people or protecting them from danger? The detention of an individual inadvertently or placing someone in a humiliating situation or position?				
If a negative or disproportionate impact has been identified in any of the key areas would this difference be illegal / unlawful? I.e. Would it be discriminatory under anti-discrimination legislation. (The Equality Act 2010, Human Rights Act 1998)				
	Yes	**No**		
What do you consider the level of negative impact to be?	**High Impact**	**Medium Impact**	**Low Impact**	**No Impact**
				x
If the impact could be discriminatory in law, please contact the **Equality and Diversity Lead** immediately to determine the next course of action. If the negative impact is high a Full Equality Analysis will be required. If you are unsure how to answer the above questions, or if you have assessed the impact as medium, please seek further guidance from the **Equality and Diversity Lead** before proceeding. If the proposal does not have a negative impact or the impact is considered low, reasonable or justifiable, then please complete the rest of the form below with any required redial actions, and forward to the **Equality and Diversity Lead.**				
Action Planning:				
How could you minimise or remove any negative impact identified even if this is of low significance?				
N/A				
How will any impact or planned actions be monitored and reviewed?				
N/A				
How will you promote equal opportunity and advance equality by sharing good practice to have a positive impact other people as a result of their personal protected characteristic.				
N/A				
Please save and keep one copy and then send a copy with a copy of the proposal to the Senior Equality and Diversity Lead at hr.support@bsmhft.nhs.uk. The results will then be published on the Trust's website. Please ensure that any resulting actions are incorporated into Divisional or Service planning and monitored on a regular basis.				

Appendix 2

Chart demonstrating category of equipment, authorised users and training required - including frequency

Equipment	Cat	Authorised User	Training	Frequency
Combined Inferential and Ultrasound	A	Chartered Physiotherapist		
Manual Sphygmomanometer	A	Registered Nurse, Trained Clinician	Manufacturer's Instructions	Initially and then on request
Stethoscope	A	Registered Nurse, Doctor		Initially and then on request
Electronic Sphygmomanometer	A	Registered Nurse, Trained Clinician	Manufacturer's Instructions	Initially and then on request
Alcometer	A	Registered Nurse, Doctor,		
Temperature Monitor	A	Registered Nurse, Trained Clinician	Manufacturer's Instructions	Initially and then on request
Ophthalmoscope	A	Doctor	Manufacturer's Instructions	Initially and then on request
Otoscope	A	Doctor	Manufacturer's Instructions	Initially and then on request
Nebuliser	A	Registered Nurse, Physiotherapist	Manufacturer's Instructions	Initially and then on request
Auroscope	A	Doctor		Initially and then on request
ECG Recorder	A	ECG Technician, Doctor, Trained Clinician	ECG Competency	Annually
EMG Monitor	A	Psychologist		
Laryngoscope	A	Doctor	ILS	Annually
Pulse Shortwave Unit	A	Chartered Physiotherapist		
O2 Regulator/Flowmeter	A	Registered nurse, Doctor	ILS	Annually
TENS Unit	A	Chartered Physiotherapist	Manufacturer's Instructions	Initially and then on request

Equipment	Cat	Authorised User	Training	Frequency
Acupuncture Needles	B	Registered Acupuncturist	British Acupuncture Accreditation Board	Yearly
		Auricular Acupuncturist	Smart (UK) Auricular Acupuncture	Yearly
Ligature Cutter	B	Registered Nurses, Doctor AHP, unqualified staff	AVERTs Training	12 – 18 Months
Cardio Monitor	B	Registered Nurses in ECT Suites, Doctors, Operating Department Assistants (ODA's)	Manufacturer	Yearly
Airways	B	Registered Nurse, Doctor	ILS	Yearly
ECG Machine	B	Doctors, Registered Nurses, ECG Technicians and Technicians in Neuropsychiatry Suites,	Manufacturer	Yearly
Paediatric Resuscitation Equipment	B	Registered Nurses, Doctors working in CAMHS/ Mother and Baby	PBLS (Paediatric)	Yearly
Suction Machine	B	Registered Nurse, Doctor,	ILS, HLS, BLS,	Yearly
EEG Machine	B	Registered Nurses & Technicians in Neuropsychiatry	Manufacturer	Yearly
Pulse Oximeter	B	Registered Nurse, Doctor and Trained Clinicians	ILS	Yearly
Vital Signs Monitor	B	Registered Nurse, Doctor,	ILS	Yearly
Bag and Mask	B	Registered Nurse, Doctor	ILS, HLS, BLS	Yearly
Laryngeal Mask Airway	B	Registered Nurse, Doctor,	ILS	Yearly
Scanner	B	Registered Nurses/Technicians in Neuropsychiatry	Manufacturer	Once and on request
Strobe Unit	B	Registered Nurses/Technicians in Neuropsychiatry	Manufacturer	Once and on request
Enteral Gravity feed Kangaroo K324	B	Medical & Nursing staff in Eating Disorders (Reed Unit)	Manufacturer	Yearly and on request
Defibrillator Biophasic (Heartstart)	B	Registered Nurses, Doctor	ILS	Yearly
Blood Sugar Monitoring Equipment (MediSense Optimum)	B	Registered Nurse, Doctor	Abbott diagnostics	Once (and on request)
Blood Sugar Monitoring Equipment (Accu Check)	B	Registered nurses, doctors at Reaside (Forensics)	Roche	Once (and on request)
ECT Machine	C	Registered Nurses & Medical Staff in ECT Suites,	Manufacturer	Yearly
Anaesthetic Gas Machine	C	Consultant Anaesthetist in ECT Suite only	Manufacturer	Yearly
Nerve stimulator	C	Consultant Anaesthetist	Anaesthetist services on SLA	Yearly
Automated External Defibrillator (AED)	C	Nurse, Doctor	ILS	Yearly
Automated External Defibrillator with ECG monitoring facility	C	Nurse, Doctor, ILS trained staff	ILS	Yearly

Appendix 3

Staff Training Record for Diagnostic and Therapeutic Equipment

Department _____ **Name** _____ **Designation** _____	

Any person operating diagnostic or therapeutic equipment must have sufficient understanding of its use to do so in a safe and effective manner.

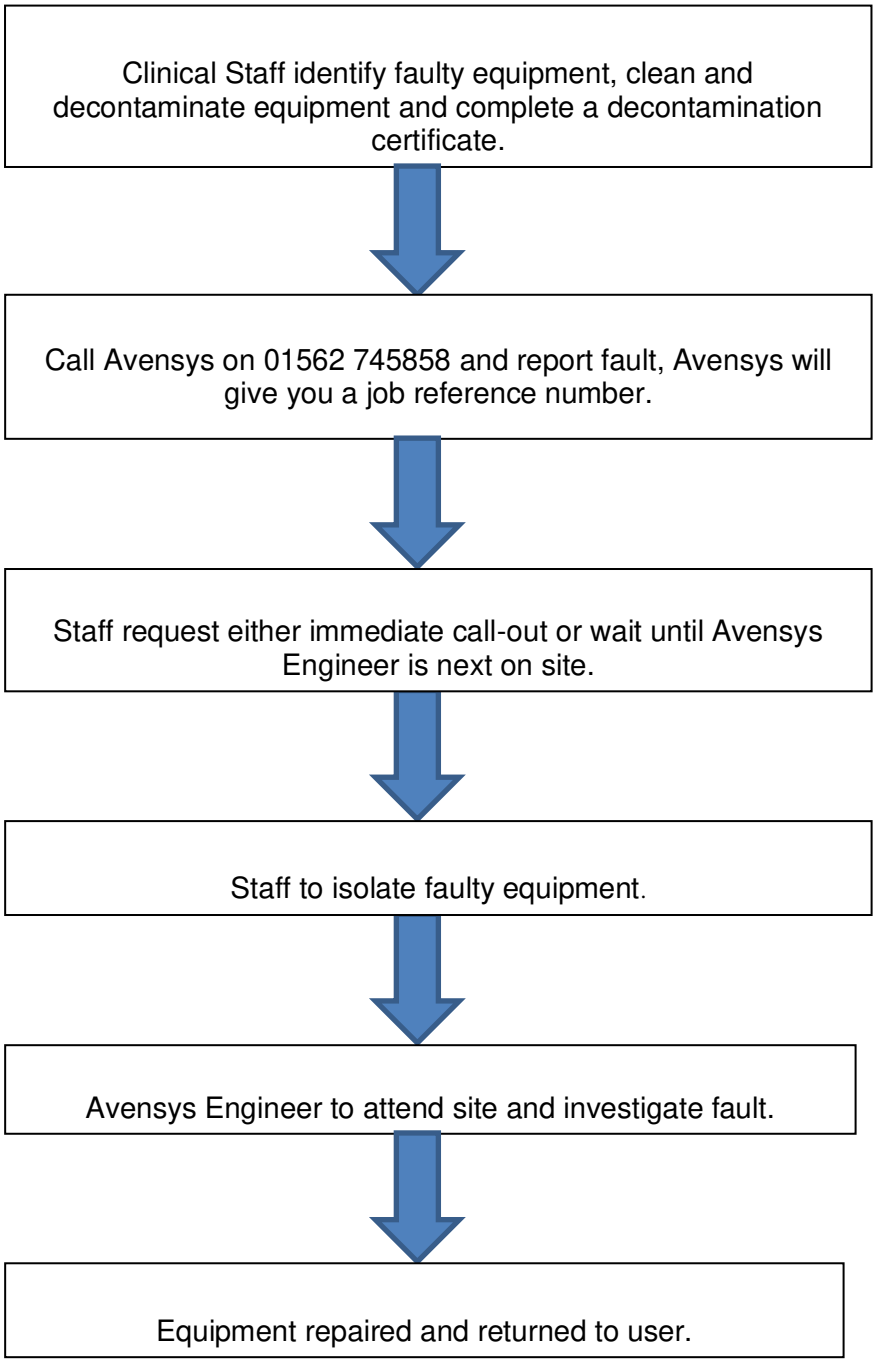
Description of Equipment	Category A, B, or C	Date of Training	Competent = Yes Not Competent = No	Equipment Trainer	Next Update Due	Signature of manager / supervisor

- Staff should complete this form as a record of training undertaken with regard to diagnostic and therapeutic equipment.
- Team managers should keep copies of this document at department level.

Appendix 4

Contact Details and Procedure for Electro Bio Medical Engineers (EBME)

Equipment Fault Reporting Procedure



Please Note: Equipment that has not been cleaned will be returned to clinical staff.