Hart First Response

Medical Devices Policy

Registered Charity 1092333

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1. Introduction

1.1. Hart First Response (HFR) recognises that the proper selection, purchasing, through life management and maintenance of medical devices is essential to the provision of high quality health care.

1.2. HFR's objectives are to provide high quality, clinically effective patient care within a safe working environment, using our resources efficiently and expediently in doing so. This document outlines a policy for the effective and systematic management of medical devices within HFR which is in line with the clinical and charitable governance objectives; MHRA standards, Health and Safety legislation; Care Quality Commission and industry best practice.

2. Scope

2.1. The Medical Devices (Amendment) Regulations 2008 No. 2936 defines medical devices as any instrument, apparatus, appliance, material or health care product or assistive technology, excluding drugs, used for, or by a patient or service user for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or impairment
- Investigation, replacement or modification of the anatomy or of a physiological process
- Critical care
- Community-based Healthcare
- Emergency Services

2.2. The scope of this policy excludes equipment only used for training purposes.

2.3. The term 'Medical device' encompasses medical devices as legally defined in the Medical Devices Regulations 2002 et seq. Examples of which are shown in Table 1 below.

Equipment uses in diagnosis or treatment of disease, or monitoring or patients	Aids to daily living: Equipment used in the care of Older Adults or those with a disability
• Syringes & needles • Dressings • IV administration sets and pumps • Sphygmomanometers • Thermometers • Beds, mattresses and covers • Cardiac monitor	• Wheelchairs and special seating • Pressure relief equipment • Slide sheets • Incontinence pads

• Examination gloves • Nebuliser • ECG Machine • Pulseoximeter	
In vitro medical devices and their accessories	Equipment used in life support
• Blood glucose measuring devices	• Oxygen • Defibrillators • Suction machine • Defibrillator drugs • Anaphylaxis pack • Vital signs monitor • First aid kit

3. Related Policies, Procedures, Guidance and Acts

3.1. The MHRA, Medicines and Healthcare products Regulatory Agency is a government agency that regulates medicines and medical equipment. They are the lead agency for issues relating to medical device, advice, safety, guidance and incident reporting. Reporting Adverse Incidents relating to medical devices – Medicines and Healthcare products Regulatory Agency, Medical Device Alert MHRA DB2010 – February 2010

3.2. The Health and Safety at Work Act 1974 requires the employer to provide safe facilities for both employees and visitors. Electrical safety, installation and safe stowage should be areas of consideration for risk assessment and management of risks to acceptable levels. Such assessments must be both suitable and sufficient.

3.3. The Electricity at Work Regulations (EWR) (under the Health and Safety at Work etc Act 1974 (HASAWA) came into force in April 1990. They form the basis of programmes used regular electrical testing of portable electrical equipment.

3.4. Provision and Use of Work Equipment Regulations 1998 and Safe use of Work Equipment ACOP 1998

3.5. The Health and Social Care Act 2008 (regulated Activities) Regulations 2010.

3.6. Managing Medical Devices Guidance for healthcare and social services organizations DB2006(05).

4. Responsibilities

4.1. The Executive Committee is responsible for the effectiveness of this policy.

4.2. The Chair has overall accountability for ensuring the health, safety and welfare of HFR volunteers, patients and members of the public with whom we come in contact during the course of our work. To achieve this, the Chair shall

- Ensure an up to date inventory is created and maintained of Medical Devices owned and used by HFR, to include all key details of each device and the current location and service status. This information will be held in such a manner as to assist HFR in taking appropriate action if manufacturer re-calls a device or issue a hazard warning.

- Ensure that all Medical Devices are maintained by an appropriately trained person / organisation, in accordance with the device manufactures guidance and the guidance set out by the MHRA. This will ensure as a minimum each device is annually checked and calibrated as necessary, and that all scheduled maintenance is undertaken in a timely manner (within a planned cycle).
- Ensure that contracts for Medical Device maintenance are appropriately procured and managed, in order to ensure each Device is appropriately maintained inline with the respective manufacturers guidance. This will include assurance that engineers appointed by HFR are appropriately qualified and trained to maintain and calibrate the respective equipment, whilst working in an unsupervised manner.
- An adequate supply of devices and spare/replacement parts will assured for the device by the manufacturer/supplier whilst in its planned service life.
- Respond to any enquires arising from or about this policy

4.3. The Officer In Charge (OIC) at events is responsible for monitoring/observing HFR volunteers to ensure best practice is adhered to.

4.4. All volunteers have a responsibility to:

- Make themselves aware of the contents of this policy and associated procedures.
- Ensure that they follow this policy at all times.
- Attend mandatory training
- Ensure they report near miss or adverse incidents (failures) relating to Medical Devices inline with the Incident Reporting policy.
- Ensure they understand how each Medical Device should be operated safety, inline with training provided and manufacturer's guidance/instructions
- Undertake pre and post-event tests and regular cleaning regimes.

5. Selection & Purchasing of Medical Devices

5.1. All procurement will be conducted on a value for money basis and will include both whole life costs and quality considerations. Accountability for the expenditure of charitable funds requires that sound economic decisions are taken in relation to procurement.

5.2. HFR will make use of the MHRA Devices in Practice guidance, and in particular the checklist 'procuring medical devices' in making purchasing decisions with respect to Medical Devices for the first time.

5.3. The selection of goods and services will be performed by the Executive Committee and in consultation with the Medical Advisor and volunteers where appropriate with aims to

- Be safety orientated
- Develop clear understanding of which goods or services are required
- Determine the most suitable devices for purchase
- Comply with all relevant legislation, e.g. CE.
- Be compatible with existing HFR equipment and where possible with that of other relevant organisations
- Improve quality of service provision
- Take note of MHRA, CAS, Patient Safety alerts.
- Deliver value for money
- Improve volunteer involvement by increased communication and engagement
- Develop strong and effective supplier management

- Ensure continuity of supply and sound business continuity arrangements

5.4. All purchases of single items with a value in excess of £300 will be reviewed by the Executive Committee prior to purchase.

5.5. Suppliers will be selected on the basis of their ability to meet HFR's requirements using an evaluation process to examine technical capability, quality, service support and total cost.

5.6. Second Hand Equipment
- Second hand equipment will be classed as new equipment when making purchasing decisions.
- All second hand equipment shall be inspected and risk assessed prior to first use by a competent person.
- Ideally second hand equipment should be provided with a full maintenance history.

5.7. Hired, Leased or Loaned Equipment
- Hired, leased or loaned equipment is treated in the same way as second hand equipment.

6. Acceptance of Medical Devices

6.1. On delivery, medical devices shall be checked to ensure:
- Delivery of the correct product, complete with usage and maintenance instructions and any relevant accessories,
- That the devices have been delivered in good condition and, where relevant, in good working order,
- Documentation supplied with the Medical Device is appropriately stored,
- As required, provide training and if required develop user 'aide-memoires' to assist with the introduction of Medical Devices,
- If appropriate, the Medical Device is added to the HFR database.

6.2. Some items, such as medical gloves, dressings, etc are delivered in bulk packs, so the following systems will be used when placing into storage:
- Check use by dates,
- Rotate stock on a first in / first out basis,
- Ensure packaging is appropriate for storage,
- Ensure instructions and safety information are available where necessary.

6.3. Medical Devices will be stored safely, to prevent damage, misuse or theft. Storage will ensure that medical devices are stored within manufacturers stated storage temperature ranges, in clean, dry locations.

7. Training in the Safe Use of Medical Devices

7.1. For all medical devices the Executive Committee in collaboration with the Medical Advisor, will identify which volunteers are authorised to use the equipment, and then prioritise the training and frequency of updates.

7.2. The trainers will then develop relevant training for volunteers to address:
- Understanding of the principles underlying the use of a device
- NICE or JRCALC guidance where relevant

- Familiarisation with the practical aspects of the devices they are likely to encounter
- Competency assessment in relation to the safe use of device
- Understanding of how to report adverse incidents and defects related to medical device use.
- Understand how to clean/decontaminate the device after use; or to be signposted to an appropriate service for cleaning/decontamination.
- Understand that the device must only be used for its intended purpose and must not be modified.
- Understand the identification and warning symbols that may be present on medical equipment.

7.3. Training records will be kept, e.g. lesson plan, handouts, list of persons trained and any competency assessments conducted.

7.4. HFR volunteers will be made aware of this policy any updates to it by members of the HFR Executive as appropriate.

7.5. All HFR volunteers are assigned mentors (members of the HFR Exec) to whom they are encouraged to approach as a first point of contact in the event of a concern.

7.6. HFR volunteers must follow the HFR Scope of Practice that determines qualification requirements, training requirements, accreditation of prior learning and experience.

8. First Use of Medical Device

8.1. Where appropriate, when a new device is first introduced, or when pre-use functional checks are complicated it should be ensured that:

- Checks are successfully carried out and documented.
- Users have all the information that they need.
- Training needs have been identified and acted on.
- Users know how the device works, and when functioning correctly.

8.2. Single use devices must not be re-used.

9. Maintenance & Inspection of Medical Devices

9.1. Maintenance and Inspection of equipment are not the same thing. Maintenance involves regular actions to prevent deterioration of equipment to a point where it becomes unsafe. Inspection involves checking equipment to ensure it is in a safe condition.

9.2. Inspection is conducted at two levels, pre-event checks and periodic inspection.

9.3. Pre-event checks comprise of simple visual inspections and functional tests of the Medical Devices as specified on check sheets. A list of relevant check sheets is provided at Appendix 2.

9.4. Completed check sheets are stored in the vehicle folder, archived into the office based vehicle folders or in long term storage in the HFR records store.

9.5. If no further detail is provided on a check list then marking a checkbox with a tick is confirmation that the device in question is:
- Available at the location specified
- Is clean and has no signs of physical damage
- Is in date and service interval, if so marked
- Simple user tests show that the device is operating correctly
- Any supporting devices or information are in place

9.6. The requirements for periodic maintenance and inspection required for medical devices have been identified from manufacturer supplied information. Details of the requirements are set out in Appendix 3.

9.7. Records of periodic maintenance and inspections are kept in the Maintenance folder.

9.8. Records of inspections, testing and filling of medical gas cylinders are kept in the HFR database.

9.9. HFR will take any corrective or preventative actions in a timely manner which follow from manufacturer's safety alerts, MHRA alerts etc, and communicate these actions as required to all volunteers.

10. Reporting of concerns and adverse incidents

10.1. An adverse incident is an event which gives rise to, or has the potential to produce, unexpected or unwanted effects involving the safety or wellbeing of patients, users or others. Adverse incidents involving medical devices may arise from various causes:
- A fault in the device itself
- Shortcomings in the instructions for use
- Lack of servicing or maintenance
- Locally initiated modifications or adjustments
- Shortcomings in user practice or training
- Environmental factors such as electromagnetic interference

Any adverse incident relating to the use of medical devices must be reported via the Incident Report form.

10.2. In the event of an incident action must be taken to ensure the safety of patients, users and others. The device must be taken out of use but otherwise left exactly as it was at the time of the incident.

10.3. HFR Executive Committee will review any reports of concerns and investigate as appropriate.

10.4. If appropriate the incident will be reported to the MHRA via the online website www.mhra.gov.uk.

10.5. If appropriate the incident will be reported to the CQC.

11. Disposal of Medical Devices

11.1. Medical devices may be considered for disposal as a result of its natural obsolescence, failure to meet current treatment standards, uneconomic or poor serviceability etc.

11.2. Decommissioning and decontamination should be carried out prior to final disposal.

11.3. The purpose of decommissioning is to make sure that the equipment is electrically and environmentally safe.

11.4. If appropriate, the date and method of disposal of the medical device shall be recorded in the HFR database.

12. Policy Consultation

12.1. This policy has been circulated to the HFR Executive and Medical Advisor for consultation.

12.2. The policy will be approved by the HFR Executive with future reviews and updates tabled for approval at Exec meetings.

13. Dissemination

Once the policy has been approved a summary of relevant changes (and a link) will be disseminated via email to the HFR volunteers, and a pdf copy of the policy placed by a member of the Exec on the member's section of the website: www.hartresponse.org.uk

14. Monitoring of Compliance and Effectiveness

Monitoring of the policy will be the responsibility of the HFR Executive. This will be through incidents reported on the HFR database, and audit. Actions and lessons learned from incident investigations will be monitored through the HFR Executive. Where any omissions or deficits have been noted results and action plans will be monitored through the HFR Executive. Lessons learned will be disseminated to the HFR volunteers through email briefings or via weekly training sessions.

15. Implementation

The HFR Executive is responsible for communicating this information to HFR volunteers and ensuring that the procedures are followed.

16. Archive Statement

The Honorary Secretary is responsible for archiving all previous versions and supporting evidence of approval for this policy.

17. References

Devices in Practice, A guide for professionals in health and social care, MHRA, 2008.

Device Bulletin: Managing Medical Devices, Guidance for healthcare and social service organisations, MHRA, November 2006, BD2006(05), http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2025142

Medical Devices Policy, West Midlands Ambulance Service, September 2008.

Policy for the management, use and disposal of medical devices, Ashford & St Peter's Hospitals NHS Trust, February 2007.

The Medical Devices Regulations 2002. Medical Devices (Amendment) Regulations 2008 No. 2936.

Health and Safety at Work Act 1974.

Management of Health and safety at work Regulations 1999.

Provision and Use of working Equipment Regulations 1998.

Medical Devices Management Policy, Sussex Partnership NHS Foundation Trust,16th December 2013, http://www.sussexpartnership.nhs.uk/gps/policies/finish/2021/274

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Appendix 1 Equality Impact Assessment

Impact	Age	Disability	Race	Gender	Religion or Belief	Sexual Orientation
Do different groups have different needs, experiences, issues and priorities in relation to the proposed policy?	N	N	N	N	N	N
Is there potential for or evidence that the proposed policy will not promote equality of opportunity for all and promote good relations between different groups?	N	N	N	N	N	N
Is there potential for or evidence that the proposed policy will affect different population groups differently (including possibly discriminating against certain groups)?	N	N	N	N	N	N
Is there public concern (including media, academic, voluntary or sector specific interest) in potential discrimination against a particular population group or groups?	N	N	N	N	N	N

Do different groups (age, disability, race, sexual orientation, gender, religion or belief) have different needs, experiences, issues and priorities in relation to the proposed policy?	We have no statistical or anecdotal evidence, at this stage, to show that this policy will affect the groups mentioned differently.
Is there potential for or evidence that the proposed policy will not promote equality of opportunity for all and promote good relations between different groups (age, disability, race, sexual orientation, gender, religion or belief)?	We have no statistical or anecdotal evidence, at this stage, to show that this policy will not promote equality of opportunity or good relations between different groups.
Is there potential for or evidence that the proposed policy will affect different population groups (age, disability, race, sexual orientation, gender, religion or belief) differently (including possibly discriminating against certain groups)?	We have no statistical or anecdotal evidence, at this stage, to show that this policy will affect the groups mentioned differently.
Is there public concern (including media, academic, voluntary or sector specific interest) in potential discrimination against a particular population group or groups (age, disability, race, sexual orientation, gender, religion or belief)?	We have no statistical or anecdotal evidence, at this stage, to show that there is public concern in potential discrimination against the protected groups identified above.

Based on the information set out above the HFR Executive has decided that a full equality impact assessment is not necessary.

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Appendix 2 List of Check Sheets

- AED Pre-use Checklist
- Ambulance Checklist
- Drugs kits checklist

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Appendix 3 Requirements for Inspection, Maintenance, Calibration & Test

The table below lists for each medical device, the requirements for inspection, maintenance and calibration, in particular identifying who can perform the action and what type of evidence is available.

Medical Device	Pre-use Inspection	Annual Inspection	Maintenance or Replacement	Calibration Test
AED & Manual Defibrillators	Ambulance Aider AED Check sheet	Contractor Report	As Required Manufacturer Report	Annual Contractor Report
Ambulance bag	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	None
Biohazard kit	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Expiry Date	n/a
Blanket	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a
BM kit	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Consumables on Expiry Date	Quarterly Ambulance Aider Control Solution
Burns Kit & Burns Dressings	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Expiry Date	n/a
Bag Valve Mask	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Replacement 5yr	n/a
Dressings	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Expiry Date	n/a
Cervical Collars	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a
Dynamed Extraction Device	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a
Disposable gloves	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a
Entonox cylinder	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Re-fill Contractor	Contractor Pressure Test 5 yr
Entonox kit	Ambulance Aider Ambulance Kit List	Contractor Report	As Required Contractor Report	Annual Contractor Report
Entonox regulator	Ambulance Aider Ambulance Kit List	Contractor Report	Annual Contractor Report	Annual Contractor Report
First aid kit & supplies	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Expiry Date	n/a
Laryngeal Mask Airway	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Expiry Date	n/a
Long board	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a
Maternity kit	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a
Nasopharyngeal Airway	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Expiry Date	n/a
Oropharyngeal Airway	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Expiry Date	n/a
Orthopaedic stretcher	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	As Required Contractor Report	n/a
Oxygen cylinder	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Re-fill Contractor	Contractor Pressure Test 5 yr
Oxygen flowmeter	Ambulance Aider Ambulance Kit List	Contractor Report	Annual Contractor Report	Annual Contractor Report
Oxygen masks	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Expiry Date	n/a
Oxygen regulator	Ambulance Aider Ambulance Kit List	Contractor Report	Annual Contractor Report	Annual Contractor Report
Paediatric Long Board	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a

Peak Flow	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a
Pulse Oximeters	Ambulance Aider Ambulance Kit List	Contractor Report	Annual Contractor Report Replacement 3 yr	Annual Contractor Report
Sphygmomanometer Auto - Wrist	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Replacement 2yr	n/a
Sphygmomanometer Manual - Arm	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a
Splints (*orange box, cardboard, SAM*)	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a
Stethoscope	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a
Stretcher Trolley	Ambulance Aider Ambulance Kit List	Contractor Report	Annual Contractor Report	Annual Contractor Report
Suction (Battery)	Ambulance Aider Ambulance Kit List	Contractor Report	Annual Contractor Report	Annual Contractor Report
Suction (manual)	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	n/a	n/a
Thermometer	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Annual Contractor Report	Annual Contractor Report
Torches	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Ambulance Aider Battery / Bulb Change	n/a
Vacuum Mattress	Ambulance Aider Ambulance Kit List	Ambulance Aider Ambulance Kit List	Ambulance Aider Repair Kit Replacement 10 years	n/a
Ventilator	Ambulance Aider Ambulance Kit List	Contractor Report	Annual Contractor Report	Annual Contractor Report