Quad Medical Ltd

Event Medical Provider
www.quadmedical.co.uk

Equipment Maintenance & Exchange Policy

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Contents

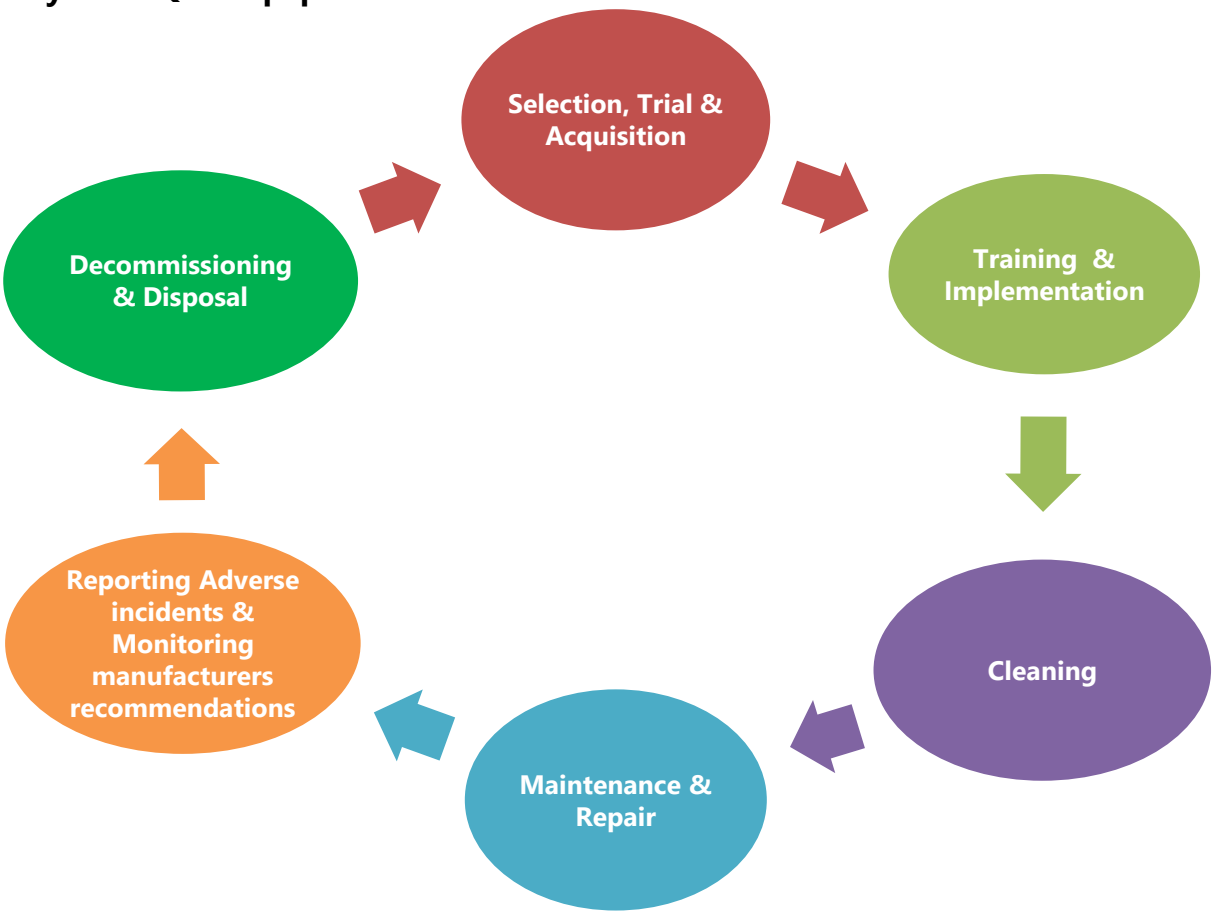
1. Introduction

1.1 This Policy has been introduced to ensure that all QML equipment is uniquely identifiable to assist in the tracking, maintenance, replacement and repair of equipment. Additionally this policy shall guide staff in the process of reporting faulty equipment and ensure such equipment is removed from operational use.

1.2 This policy covers all medical devices in use by Quad Medical Limited. Medical devices play a key role in the diagnosis, treatment, monitoring and care of patients. Efficient management of these key resources is essential in ensuring high-quality patient care and in minimising the risk of adverse incidents.

1.3 This policy shall set out the QML systematic approach to the management of medical devices as per the Medicines and Healthcare Products Authority (MHRA) document 'Managing Medical Devices Guidelines for Healthcare and Social Services Organisations (April 2015).

Life cycle of QML equipment:



2. Scope

2.1 This policy applies to the procurement, maintenance, repair, replacement and decommissioning of QML's equipment. It applies to all staff within QML who use medical devices.

3. Objectives

3.1 To comply with the Medicine and Healthcare Products Regulatory Agency (MHPRA) to assist QML in reducing and eliminating risks to patients and staff using medical equipment, through addressing each area of the equipments life cycle appropriately.

3.2 To ensure equipment is maintained in accordance with manufacturer's recommendations and servicing schedules

3.3 To ensure the isolation of faulty equipment to prevent its accidental reintroduction into service before repair, thereby protecting patients from accidental use of faulty equipment.

3.3 To ensure equipment is decontaminated and stored appropriately to prevent cross infection of patients

3.4 To ensure that all equipment sent for service or repair is disinfected in compliance with guidelines from the MHPRA.

3.5 To facilitate timely equipment exchange and maintenance as to ensure the continuity of service provision

3.6 To ensure that the management of medical devices is carried out in line with current legislation, guidance and manufacturer's recommendations

3.7 To establish the responsibilities of manager and staff in relation to the management of medical devices

4. Responsibilities

4.1 All designated duty managers are responsible for ensuring that this procedure is being adhered to at operational level at event sites and venues

4.2 It is the responsibility of all staff sending faulty equipment for repair to inform the duty manager immediately if equipment is faulty and disinfect equipment and label it appropriately before placing it in the designated faulty equipment box or returning to the duty manager

4.3 It is the responsibility of the Managing Director to ensure that all equipment is repaired for inline with the manufacturer's recommendations

4.5 It is the responsibility of the Managing Director and the Quality Assurance Manager that all equipment is sent for servicing in a timely manner. If the servicing occurs when the equipment is expected to be in use at an event or venue then the Managing Director shall have in place appropriate temporary equipment.

4.6 The Managing Director is responsible for identifying the needs of the business in terms of medical equipment and for considering requests for equipment from staff and in liaison with the clinical lead for the company.

4.7 The Managing Director is responsible for ensuring that all equipment purchased is suitable for use and fulfils the role for which it is intended

4.8 The Managing Director and the Quality Assurance Manager are responsible for ensuring that devices comply with the company's clinical, quality and safety policies and procedures including compliance with training and infection prevention and control guidelines.

4.9 The Managing Director and the Quality Assurance Manager are responsible for ensuring that appropriate information and training is provided to all staff using equipment and all equipment is used correctly and safely

4.10 The Managing director is responsible for ensuring that all medical device procurement complies with relevant procurement legislation

4.11 All staff have a professional responsibility to ensure that they are competent in the use of medical equipment and devices within their scope of practice in a safe and effective manner and that they maintain their familiarity and competency with seldom used devices.

4.12 The Managing Director will retain overall responsibility for the management of medical devices and will report adverse incidents involving equipment to the MHRA and other official agencies

5. Documentation

5.1 It is the responsibility of the managing director to ensure that all documentation relating to equipment purchase and use is updated and accessibly stored.

5.2 The managing director will ensure that for all reusable items the manufacturer's guides shall be made accessible to staff on the staff portal

5.3 The Managing Director is responsible for ensuring all equipment asset tagging all new equipment purchased is logged on to the live electronic database

5.4 All members of staff at all levels in the company are responsible for submitting an incident report and following the incident reporting procedure when a piece of equipment fails, directly resulting in patient harm or a near miss.

5.5 It is the responsibility of the person who has found a fault with equipment to label it appropriately and inform the duty manager or managing director.

5.6 Where equipment is exchanged like for like this shall be captured on the asset tracking and maintenance log (live online database)

5.7 Periodically the Quality assurance manager shall align records of vehicle equipment checks with the asset log to ensure that the procedures in this policy are being adhered to and that all assets are in the correct vehicle.

5.8 It is the responsibility of the Managing director to ensure that the 'Asset Tracking & Maintenance log is rechecked at the start of each new calendar year and information transferred on to a new log for that year. This is to identify where assets have gone missing and prompt the checking of service and calibration dates.

6. Selection, trial, acquisition of new Equipment

6.1 The procurement of new medical devices shall be undertaken in accordance with the relevant legislation, national policies and business plans.

6.2 Once the clinical need for new or replacement equipment has been identified the Managing Director shall review a selection of products and on consideration of clinical need, staff suggestion and industry recommendation, select the appropriate equipment for use by QML staff.

6.3 The Managing Director is responsible for ensuring that all equipment purchased is suitable for use and fulfils the role for which it is intended

6.4 The Managing Director is also responsible for ensuring that any new potential use purchases are not subject to investigation with the MHRA

6.5 Point for the managing director to consider when selecting a new piece of equipment:

-Is the device compatible with other devices and products used by the company
-Does the manufacturer intend the equipment to be used by those who will be using it
- Is the equipment appropriate for the intended environment?

7. Procedure for Checking Newly purchased consumables

7.1 Some equipment purchased by QML such as gloves, dressings and syringes etc arrive in bulk packs. It is inappropriate and impractical to check each individual item on delivery however the following key checks should be performed:
- Expiry dates are clearly shown on the packaging
- Appropriate marking for lots is shown (in case of product recall)
- Instructions and safety information is made available as necessary
- Packaging is intact and appropriate for storage
- Storage instructions are followed and environmental conditions for storage are clear

7.2 Staff are responsible for checking all consumable items on the equipment check list to ensure they remain in date. This should be documented on the equipment daily check sheet.

8. Training & Education

8.1 It is recognised that due to the varying levels of qualifications and experience within the QML multidisciplinary team that there are varying levels of training required. Clinical staff working for QML either as employees or contractors have a professional duty to ensure their own skills and training are up to date.

8.2 Where formal training, assessment or certification is required a record shall be kept to track the ongoing education requirements of the staff.

8.3 Training will ensure that staff are able to:
- use the equipment safely
- can carry out routine checks and maintenance
- know the indications and contraindications to use
- are confident and competent in the device use

9. Role of Ambulance Crews at the start of duty

9.1 At the start of each shift the allocated ambulance crew shall work together to ensure that the following are complete:

- Vehicle equipment checklist
- Vehicle sundries checklist
- Vehicle cleaning checklist

10. Role of Event Staff

10.1 When a device is allocated for use within a defined area such as a medical room or first aid post it will be the responsibility of the individuals working within that area for the way the device is treated and the condition in which it is left. These responsibilities also include the daily equipment checks before use and routine maintenance such as charging batteries. It is essential that all staff are aware of the equipment management systems and their responsibilities within that system to ensure all equipment is managed correctly.

10.2 Staff are encouraged to submit feedback to the managing director over their experience of using new pieces of equipment by emailing him at info@quadmedical.co.uk this will allow suitable adjustments to further acquisitions and training.

11. Equipment issued individually on long term loan

11.1 In cases where equipment has been issued for use by an individual member of staff that member of staff then becomes responsible for the following:
- Decontamination procedures
-Maintenance and informing Quality Assurance Manager of maintenance so that records can be updated centrally
- Type and use of equipment
- Safe and appropriate storage of equipment

12. Actions of staff in the event of equipment failure

12.1 Any faulty or absent equipment required for the duty identified when checking the vehicle must be reported and taken out of service. If essential equipment (as identified with * on the vehicle VDI checklist) is found to be lacking or faulty or in any other way not fit for purpose, the Managing Director should be contacted immediately so that they can arrange a replacement. In the mean time the vehicle should be taken out of service and an incident report entered.

12.2 A Fully completed equipment label must be securely attached to the equipment after it has been decontaminated

12.3 If equipment has failed whist in use on a patient the duty manager (or managing director in the absence of a duty manager) should be informed immediately and an incident report form completed and submitted as soon as possible.

12.4 Where replacement equipment is readily available this should be installed by the managing director or duty manager. Staff must not take it upon themselves to reallocate equipment and resources unless specifically told t do so by the managing director or duty manager. Any reallocation of equipment should be noted on the duty log and the quality assurance manager informed by email.

13. Asset Management, Maintenance & Repair

13.1 All reusable equipment shall be Asset tagged. Asset Numbers shall be recorded on the 'Asset Tracking & Maintenance Log (PART A) along with manufacturers recommended frequency of service and recalibration.

13.2 The equipment warranty expiration shall also be noted on 'Asset Tracking & Maintenance Log so that on yearly record checking the Managing Director can identify any equipment coming to the end of their warranty.

All items of equipment returned to the QML management team will be inspected, tested and repaired in line with the manufacturer's instructions and training. Items will then either be returned to use at the location from which they came or sent to a contracted repairer and recalibrated in accordance with manufacturers recommendations.

It is important that all returned equipment has its full complement of accessories with it to enable a full and precise test to be completed.

13.3 Where the cost of repair and recalibration exceeds the cost of a new replacement unit, the faulty equipment shall be disposed as per manufacturer's guidance and a new item purchased.

13.4 All services, calibrations and repairs should be recorded on the 'Asset tracking & Maintenance Log (Part B)'.

14. Scheduled Maintenance

14.1 Scheduled maintenance will be undertaken by approved contractors in accordance with the manufacturer's recommendations and guidelines. This will include recalibration of equipment, function tests and scheduled servicing where appropriate. Date for initial servicing, calibration and frequency of servicing and calibration are to be noted on 'Asset Tracking & Maintenance Log .

14.2 Maintenance contractors shall provide a record of all equipment serviced on their visits and this information will be used by the Managing Director to assist in identifying any times missed. These items can then be recalled for calibration and servicing within the following time frames:

Equipment	**Servicing Schedule**	**Recalibration Required**
Glass Flow Meter	Annual	Yes
Laerdal FR2 Defibrillator	Annual	Yes
Lifepak 12 Accessories	None Required	No
Laerdal Suction Unit	Annual	Yes
Oxylitre Regulator	Annual	Yes

14.3 The asset tracking system will ensure that equipment needing regular testing and maintenance is done so at a frequency that meets or exceeds that recommended by the manufacturers

14.4 Equipment that is marked as absent on the vehicle or equipment checking sheet or through annual transference of asset tracking information will be marked as missing. The Managing Director will investigate this loss using the equipment and vehicle checking lists and staff rotas to establish when the item was last used and seen

14.5 All staff has a responsibility to check any piece of equipment prior to use. For single use items this includes checking
1. The packaging is intact
2. The equipment is in date

14.6 Essential items such as Bag valve masks, suction units and defibrillators should be checked as part of the vehicle daily inspection

14.7 Manual handling equipment should be inspected for damage before use

14.8 Any item found damaged or defective must be returned to the duty manager or managing director for repair and an incident report form generated

15. Cleaning

15.1 Where possible single patient use items shall be purchased. Where this is not possible the Managing Director should account for ease of decontamination when selecting equipment.

15.2 Medical devices will be cleaned and decontaminated according to company infection prevention and control policies and manufacturers recommendations

16. Decommissioning and Disposal

16.1 The Managing Director is responsible for the final decision to remove any item of equipment from the company and dispose of it.

16.2 All reusable equipment will be formally decommissioned by the Managing Director and a record of this entered on to the 'Asset Disposal Log' . Where items are still in good working order but no longer have a use as they have been replaced by updated versions, the Managing director may store such items for future use. These items however will need to be checked as suitable for use and in good working order and correctly maintained and calibrated for use in the future. This will continue to be documented on the 'Asset Tracing & Maintenance Log .

16.4 Where items are deemed irreparable or it is not cost effective to repair them the Managing Director will confirm and follow the manufacturer's advice on disposal. Disposal will be in accordance with the QML waste disposal policy.

17. Monitoring and Audit

17.1 Monitoring the organisations performance on medical device management is important to minimise or eliminate risks to the patients and staff. Internal auditing of equipment management shall be conducted as per the companies governance arrangements.

18. Adverse Incident Reporting & Near Miss Reporting

18.1 As per the QML Incident reporting Policy the following definitions apply here:

Incident:
Any Accident, event or circumstance that led to harm, loss or damage to people, property, reputation or any other occurrence that could impact on the company's ability to provide safe healthcare.

Near-Miss:
Any incident that has not resulted in harm, loss or damage, to people, property, and reputation etc but has or had the potential to do so.

All incidents and near misses should be reported following the Incident reporting policy,

18.2 Any known problems with equipment design, documentation and common use related issues should be reported for follow up including all user problems such as software failures or problems with instructions for use

18.3 Adverse incidents involving the failure of a piece of equipment should be reported to the MHRA by the managing director through the yellow card scheme at:
https://yellowcard.mhra.gov.uk

19. References

19.1 Care quality commission. Essential standards of quality and safety. 2010

19.2 Medical devices regulations 2002

19.2 MHRA. Managing Medical Devices. 2021