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**Management of Medical Devices Policy**

**[Date of Issue]**

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# Introduction

Medical Devices are utilised across [Company Name] for treatment, therapy, monitoring, and care of our client. Effective management is required to deliver high-quality care and clinical governance and minimise risks and adverse events. This document provides guidance for acquisition, deployment, training, maintenance, repair and disposal of medical devices.

# Policy Statement

This policy describes the processes for management of medical devices and best practice based on the principles outlined in Medicines and Healthcare products Regulatory Agency (MHRA) guidance ‘Managing Medical Devices’ (2021). The purpose of this policy is to ensure that there are documented standards within [Company Name] to support safe and effective medical device management that is compliant with the guidelines stated by MHRA and meet Care Quality Commission (CQC) ‘Guidance for providers on meeting the regulations’ (2015).

# Scope

This policy applies to all [Company Name] staff involved in the use, maintenance and management of medical devices. This includes staff members, bank workers and agency workers.

# Definitions

The World Health Organisation (WHO) (2019) (Online), define the term ‘medical device’ as; any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes of:

* diagnosis, prevention, monitoring, treatment or alleviation of disease,
* diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
* investigation, replacement, modification, or support of the anatomy or of a physiological process,
* supporting or sustaining life,
* control of conception,
* disinfection of medical devices
* providing information by means of in vitro examination of specimens derived from the human body.

# Responsibilities

The Registered Manager has overall responsibility for ensuring that all current regulations and approved guidance and best practice are complied with.

In practice the responsibility for ensuring these regulations and guidance is complied with, implemented and followed will be delegated to a variety of other staff members in shared accountability.

The Registered Manager is responsible for ensuring all aspects of the management of medical devices within their area are carried out correctly.

All staff have a responsibility to ensure that any equipment they use is and remains fit for purpose and that they are competent to use it.

# Procurement

The procurement process is acknowledged as being a key factor in the ability to manage medical devices successfully.

The purchases of medical devices must consider of the recommendation of the Medical and Healthcare Products Regulatory Agency and the National Audit Office (NAO) recommendations.

Where new devices or equipment are purchased, [Company Name] can support the client and/or the person commissioning care with the identification and standardisation of medical devices wherever practicable but is fully committed to ensuring the needs of the individual are considered.

A pre-procurement process for new equipment or devices should identify as fully as possible any equipment management issues; this will include issues relating to: -

* Delivery
* Installation
* Estate services
* Acceptance and commissioning
* Running costs
* Accessories and consumables
* Decontamination
* Training
* Maintenance and repair
* Storage and disposal including consumables.

# Maintenance and Repair

Medical devices maintenance, inspection and repair will be assessed and reviewed in line with the manufacturer’s recommendations as well as any legal guidance and best practice recommendations. A risk management approach will be employed.

Staff members involved in maintenance, inspection and repair must be suitably trained and qualified. Where required a vetted, national third-party supplier will be used.

When selecting external maintenance contracts, the level of service that is most appropriate to meet the requirements should be considered against a risk, performance and cost criteria. The maintenance and repair provider must have all the necessary testing, measuring and repair equipment and ensure that this is adequately maintained and calibrated, as required.

# Training

Training is an essential element in ensuring the medical device is used, maintained and managed correctly. The company has a responsibility to provide, by whatever means most appropriate, any necessary training relating to the management of medical devices.

The Registered Manager is responsible to maintain, promote and develop skills that ensure the safe use of medical devices. It is important that staff work within their training and competencies. Members of the team should only use, maintain or manage equipment that they can demonstrate competency in through specific training or through professional knowledge and skills.

Training on all medical devices must include appreciation of corresponding readings, values and device indicators to base all resulting interventions, outcomes and care.

The Registered Manager must ensure the provision of supervision for all staff at appropriate levels for assessment of practical skills using medical devices.

# Decontamination

Decontamination protects clients and staff from infection following contact with medical devices and equipment. It is essential to correctly decontaminate medical devices prior to and after use.

All reusable medical devices will be properly decontaminated after use/prior to maintenance in accordance with the manufacturer’s instructions.

A decontamination and cleaning log will be completed after every use and for all equipment at the end of the day.

# Storage of Medical Devices

Medical devices, reusable and single use or single patient devices and their accessories must be stored in appropriate conditions in line with the manufacturer’s instructions/best practice.

All medical devices must be stored in a state of readiness for use unless this is contrary to the instructions/best practice.

All special storage considerations must be considered when storing the device i.e.

* Battery removal
* Battery charging
* Use by dates
* Service
* Inspection and calibration requirements
* Data storage.

# Safety Notices

The Registered Manager is responsible for signing up to receive email alerts from the Central Alert System (CAS). Alerts available on the CAS website include NHS England and NHS Improvement Patient Safety Alerts (PSA) and Estates Alerts, MHRA Dear Doctor letters, Medical Device Alerts (MDA) and Drug Alerts, Chief Medical Officer (CMO) Alerts and Department of Health and Social Care Supply Disruption alerts. Upon receipt of a safety alert email, the Registered Manager will determine whether the alert is relevant to the service being provided by [Company Name]. If it is determined that the alert is not relevant, no further action is required. If, however, the Registered Manager feels that the alert is relevant to the registered activities undertaken, they will be responsible for ensuring that the Leadership Team of [Company Name] are made aware of the alert for distribution throughout the entire business. Thus, ensuring that all members of the team, whose practice may be impacted by the alert, are fully up to date and informed.

Distribution of the alert is not sufficient to ensure that the alert has been read and acted upon. As such, the Registered Manager should ensure that details of the alert are included on the agenda for team meetings, supervision sessions and 1:1 meeting for discussion.

**National Patient Safety Alerts**

National Patient Safety Alerts are designated as either ‘complex’ or ‘straightforward’, each of which requires a different response:

* ‘Complex’ alerts require actions that cannot be delivered by any single division or professional group within [Company Name] and the Leadership Team will nominate a Senior Leader relevant to the alert to coordinate its delivery.
* ‘Straightforward’ alerts may be actioned on behalf of the whole organisation by agreed senior leaders (e.g., the Registered Manager). All National Patient Safety Alerts will undergo review at a Leadership Team level and governance procedures will be followed as per the Governance & Risk Policy to ensure that any changes to practice and policy are fully implemented and evidenced through follow-up audit before the National Patient Safety Alert is recorded as ‘action completed’ on the Central Alerting System (CAS). The Registered Manager will always remain responsible for ensuring that the alert has been understood and acted upon by the staff members impacted.

# Medical Device Disposal

All medical devices must be disposed of in a safe and appropriate manner.

Disposals must follow all appropriate standards, guidance and best practice recommendations.

MHRA guidance ‘Managing Medical Devices’ (2021) recommends the manufacturer is consulted for the best methods of waste disposal. They should be able to provide details of the current techniques and processes applicable to their products.

The HSE Waste Electrical and Electronic Equipment Regulations (2013) impose duties on ‘producers’, i.e., manufacturers and importers.

Some waste products need specialised disposal, for example, those that contain mercury, coolants or bodily fluids.

# Monitoring

Compliance with this policy will be monitored through routine auditing, feedback from any clients or healthcare professionals and incident reports relating to miscommunication or poor handover.

# Related Policies

* Governance and Risk Policy
* Health and Safety Policy
* Infection Prevention and Control Policy
* Safety Alert Policy

# Legislation and Guidance

**Relevant Legislation**

* Common Law of Negligence: Law Reform (Contributory Negligence) Act 1945
* Control of Substances Hazardous to Health Regulations 2002
* Electrical Equipment (Safety) Regulations 2016
* Electricity at Work Regulations 1989’
* Employers' Liability (Compulsory Insurance) Regulations 1998
* General Product Safety Regulations 2005
* Health and Safety at Work etc. Act 1974
* In Vitro Diagnostic Medical Devices Regulations 2000
* Lifting Operations and Lifting Equipment Regulations 1998
* Management of Health and Safety at Work Regulations 1999
* Medical Devices Regulations 2017
* Pressure Systems Safety Regulations 2000
* Provision and Use of Work Equipment Regulations 1998
* Sale and Supply of Goods Act 1994
* The Consumer Protection Act 1987 – Part 1 Product Liability & Part 2 Consumer Safety (in the case of a medical device)
* The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. Regulation 16 Safety, availability and suitability of equipment
* Trade Descriptions Act 1968
* Unfair Contract Terms Act 1977
* Waste Electrical and Electronic Equipment Regulations 2013

**Guidance**

* Care Quality Commission (CQC) (2015) Guidance for providers on meeting the regulations (Online). Available from:
* [Guidance for providers on meeting the regulations (cqc.org.uk)](https://www.cqc.org.uk/sites/default/files/20150324_guidance_providers_meeting_regulations_01.pdf) Accessed 11/1/21
* World Health Organisation (WHO) (2019) (Online). Available from:
* [Medical devices (who.int)](https://www.who.int/health-topics/medical-devices#tab=tab_1) Accessed: 11/1/21
* Managing Medical Devices: Guidance for Health and Social Care Organisations (Online). Available at: [Safeguarding public health (publishing.service.gov.uk)](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982127/Managing_medical_devices.pdf) Accessed 01/02/2022

# Summary of Review

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