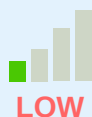




Review Sheet

Last
Reviewed
8 May 2025Last
Amended
7 May 2025This policy will be reviewed as needs require or at the following
interval:
Annual

Business Impact:

Minimal action required. Circulate information amongst
relevant parties.

Reason for this Review:

Scheduled review

Changes Made:

Yes

Summary:

This policy supports the safe and effective management of medical devices. It has been reviewed and updated with some minor word changes. The references have been checked and updated and two Further Reading links have been added.

Relevant Legislation:

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- Health and Social Care Act 2008 (Registration and Regulated Activities) (Amendment) Regulations 2015
- Health and Safety at Work etc. Act 1974
- The Medical Devices Regulations 2002
- The Medical Devices (Amendment) Regulations 2012
- Data Protection Act 2018

Underpinning Knowledge:

- Author: NHS Digital, (2023), Records Management Code of Practice (Detailed Retention Schedules) [Online] Available from: <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care/records-management-code-of-practice-for-health-and-social-care-2016> [Accessed: 08/05/2025]
- Author: MHRA, (2014), Devices in Practice - Checklists for using medical devices [Online] Available from: <https://www.gov.uk/government/publications/devices-in-practice-checklists-for-using-medical-devices> [Accessed: 08/05/2025]
- Author: GOV.UK, (2024), Medical devices regulations: compliance and enforcement [Online] Available from: <https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety> [Accessed: 08/05/2025]
- Author: MHRA, (2021), Managing Medical Devices [Online] Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/421028/Managing_medical_devices_-_Apr_2015.pdf [Accessed: 08/05/2025]



	<ul style="list-style-type: none">• Author: EU Law and Publications, (2022), Ensuring the safety and performance of medical devices [Online] Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3A4301046 [Accessed: 08/05/2025]• Author: Medicines and Healthcare Products Regulatory Agency, (2026), How we enforce medical device regulations [Online] Available from: https://www.gov.uk/government/publications/report-a-non-compliant-medical-device-enforcement-process/how-mhra-ensures-the-safety-and-quality-of-medical-devices [Accessed: 08/05/2025]• Author: Medicines & Healthcare products Regulatory Agency, (2025), Implementation of the Future Regulations [Online] Available from: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices/implementation-of-the-future-regulations [Accessed: 08/05/2025]
Suggested Action:	<ul style="list-style-type: none">• Encourage sharing the policy through the use of the QCS App
Equality Impact Assessment:	<p>QCS have undertaken an equality analysis during the review of this policy. This statement is a written record that demonstrates that we have shown due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations with respect to the characteristics protected by equality law.</p>

Quality Compliance Systems
Wellspring Recruitment and Care Services Limited
Downloaded: 21 Jan 2025
OLAJUMOKE OMOJOLA



1. Purpose

1.1 To set out how Wellspring Recruitment and Care Services Limited will ensure the safe and effective management of medical devices in use.

1.2 This policy dovetails with other relevant policies and procedures and so should be referred to for further guidance. These include:

- Personal Protective Equipment (PPE) Policy and Procedure
- Infection Control Policy and Procedure
- COSHH Policy and Procedure

1.3 To meet regulatory, legislative and best practice guidance and requirements.

1.4

Key Question

Quality Statements

RESPONSIVE	QSR1: Person-centred care
SAFE	QSS3: Safeguarding
WELL-LED	QSW5: Governance, management and sustainability

1.5 Relevant Legislation

- The Care Act 2014
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- Health and Social Care Act 2008 (Registration and Regulated Activities) (Amendment) Regulations 2015
- Health and Safety at Work etc. Act 1974
- The Medical Devices Regulations 2002
- The Medical Devices (Amendment) Regulations 2012
- Data Protection Act 2018



2. Scope

2.1 Roles Affected:

- Registered Manager
- Other management
- Care staff

2.2 People Affected:

- Service Users

2.3 Stakeholders Affected:

- Commissioners
- External health professionals
- Local Authority



- NHS



3. Objectives

3.1 Ensure a systematic approach to the management of all aspects in the lifecycle of medical devices, so that all risks associated with the acquisition, deployment, use, training, monitoring, record integrity, maintenance, storage, decontamination, decommissioning and disposal of medical devices are minimised.

3.2 Ensure there is clear evidence that Wellspring Recruitment and Care Services Limited acts upon National Patient Safety Alerts from the Medicines and Healthcare products Regulatory Agency that are relevant to its services.

3.3 For Service Users to receive timely care with the most appropriate medical devices, if required.

3.4 To ensure that medical devices are properly maintained, are clean and used only for the purpose intended by suitably trained and competent members of staff.



4. Policy

4.1 The latest guidance from the Medicines and Healthcare products Regulatory Agency on managing medical devices should be available for staff to access.

4.2 Medical Devices

A medical device is any apparatus, appliance, software, material or other article, whether used alone or in combination, intended by the manufacturer to be used by human beings for a medical purpose. (GOV.UK).

Examples of Commonly Used Medical Devices (List not exhaustive)

Diagnosis or treatment:

- Dressings
- Syringes
- Urine catheters and drainage systems
- Oxygen therapy systems
- Examination gloves
- Nebulisers
- Suction equipment

Monitoring:

- Pulse oximeter
- Sphygmomanometers
- Thermometers

Improve function and independence:

- Hoists and other transfer equipment
- Pressure care devices (pressure redistribution/relief cushions and mattresses)



- Walking and standing frames
- Wheelchairs
- Adjustable beds
- Baths with integrated hoists
- Communication aids
- External limb prostheses
- Hearing aids
- Orthopaedic footwear
- Posture management (simple cushions to complex support systems)
- Standing aids
- Walking sticks/crutches
- Mobility scooters

In vitro diagnostic:

- Urine test strips
- Blood glucose tests

Medical devices must have CE marking, UKCA marking or CE UKNI marking by law. This mark means that, provided it is used correctly, the device will work properly and is safe.

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating the UK medical devices market and medicines.

The MHRA sends out alerts, recalls and safety information for medical devices (and medicines). Olajumoke Omolola should ensure that they are signed up to receive these alerts (a link is in the Further Reading section) and that they share them with the team at Wellspring Recruitment and Care Services Limited.

4.3 Single-use Medical Devices

Single-use medical devices are not manufactured to be re-used, even on one Service User. The MHRA states:

- Single-use must not be re-used and only used on an individual Service User during a single procedure then discarded
- The re-use of a single-use device can affect their safety, performance and effectiveness exposing Service Users and staff to unnecessary risks
- Anyone who re-uses a device intended for single-use bears full responsibility for its safety and effectiveness

Single Patient Use

This means the medical device can be used more than once on one Service User only.

4.4 Responsibilities of Wellspring Recruitment and Care Services Limited

- Wellspring Recruitment and Care Services Limited will respond to, and comply fully with, alerts and recalls via the MHRA. In addition, incidents or accidents relating to medical devices will be reported to the MHRA, with due regard for and compliance with the Duty of Candour applied (where necessary)
- To ensure there is evidence that discussions and communication in relation to maintenance, risk and safety are part of the overall organisational governance
- Implementation of a regular audit process
- Responding to external monitoring, national and local guidelines



4.5 Registered Manager **Responsibilities**

- Having systems in place to ensure that staff using medical devices are adequately trained on relevant equipment
- Maintaining evidence of staff training. It is essential that training is up to date and documented for all the devices that staff use
- Maintaining an equipment inventory and disposing of medical devices in the required manner
- Completing risk assessments on devices which may pose a significant risk to Service Users
- Ensuring that equipment is stored in a safe and secure location when not in use, including storing faulty equipment separately from functioning equipment
- Keeping all equipment in a clean and appropriate state of repair
- Ensuring that staff are aware of their responsibilities regarding the safe use of medical devices
- Undertaking regular checks on all consumable items to ensure that they are not past their use by date and they are removed from use and replaced as soon as they reach their use by date
- Ensuring there is a process to make all staff aware of any alerts. There should be a record of all alerts received, detailing whether they are relevant to Wellspring Recruitment and Care Services Limited and any action taken

4.6 Staff Responsibilities

Staff using medical devices will be responsible for:

- Completing any training or competency assessments required in relation to the medical devices (and maintaining this knowledge)
- Ensuring that they do not use any equipment that they are not adequately trained to use and/or do not feel competent and confident to operate
- Only using medical devices if authorised to do so
- Using medical devices in a safe and effective manner in accordance with guidance and the manufacturer's intended use
- Ensuring that all medical devices are suitably decontaminated after each use
- Ensuring that all medical devices are adequately stored and maintained when not in use
- Following procedures regarding the management and use of medical devices
- Reporting any defects or faulty equipment immediately
- Clearly labelling defective devices and ensuring that they are taken out of action
- Ensuring that items of equipment/devices are available for maintenance
- Reporting immediately if errors are made with the use of medical devices
- Contributing to audits, risk assessments and service improvement

4.7 Where devices are provided by other healthcare professionals for the care and support of Service Users, this policy remains applicable and all responsibilities of staff remain unchanged.

4.8 The Government has made regulations (The Medical Devices (Amendment) (Great Britain) Regulations 2023) that enable CE marked medical devices to be accepted in Great Britain for defined periods beyond 30 June 2023. (GOV.UK 2023). This is to support the ongoing and safe supply of medical devices in Great Britain.



4.9 Assistive Technology

Assistive technology describes products or systems that support and assist Service Users with disabilities, restricted mobility or other impairments to perform functions that might otherwise be difficult or impossible.

Just because a product is used in a healthcare environment or by a healthcare professional does not automatically mean it is a medical device. It will only be considered a medical device if the manufacturer has stated that it has a medical purpose and if the product's primary mode of action is physical or mechanical. (GOV.UK 2024).

4.10 Assistive Technology - Medical device or not?

- Equipment intended for alleviation of, or compensation for, a disability may or may not be a medical device
- The determining factor will be whether there is a direct link between the corrective function of the equipment and the intended user
- Although two products may appear to be similar in function, one may be a medical device whilst the other is not
- This will depend entirely on the claims made by the manufacturer for each product

A manufacturer may sell two different kinds of portable wheelchairs:

- A self-propelled wheelchair intended for use by Service Users with disabilities or difficulty in walking. This wheelchair is a medical device because there is a clear link between the corrective function (compensation for injury or disability by providing a mode of transportation) and the Service Users (persons with disabilities or difficulty in walking)
- A wheelchair that is intended to be used by staff to transport Service Users around. This wheelchair is not a medical device; although the purpose is to provide transportation, it is not specifically intended to be used only by those with disabilities or difficulty walking. It is an aid for staff to transfer anyone around quickly and safely

4.11 Aids For Daily Living

These are products that help Service Users carry out day-to-day activities. Many of these products may be used by any Service User and will not have a specific medical purpose or direct link to the Service Users concerned.

These are not medical devices. Examples include:

- Bariatric chairs and stools
- Baths with easy access doors
- Chair risers
- Grab rails (for example, at doorways, stairs, beds)
- Personal alarm systems (including fall alarms)
- Portable ramps, wheelchair vehicle restraints
- Rise and recline chairs
- Shower chairs
- Stair lifts
- Toilet equipment (toilet seats, shower seats, commodes)



5. Procedure

5.1 Life Cycle Management of Medical Devices

MHRA (2021) outlines the life cycle applicable to all medical devices; this should consider:

- Management of the medical device
- Acquiring appropriate devices
- Training
- Maintenance and repair
- Reporting adverse incidents
- Decontamination
- Decommissioning and disposal

5.2 Management of Medical Devices

Wellspring Recruitment and Care Services Limited should appoint someone with responsibility for medical device management. They must also ensure that there are systems in place, including:

- Reporting of device issues
- The effectiveness of the medical devices management system
- The condition and performance of medical devices (including device failures and issues, utilisation, performance, maintenance, repair and calibration history)
- Investment, replacement and disposal plans
- Long-term approach and objectives for the management of their medical devices, including strategic replacement and development
- Equipment procurement planning

Records

Each Service User will have an individual record of their medical devices and Wellspring Recruitment and Care Services Limited will maintain a local inventory of this to aid the servicing and maintenance checks, as well as monitoring the age of the equipment.

The inventory remains the responsibility of Olajumoke Omolola and will be subject to accuracy checks and audit.

Each medical device will have a unique identifier. Wellspring Recruitment and Care Services Limited must record the unique identifier in the Care Plan to aid servicing and maintenance checks as well as monitoring the age of the equipment. The equipment record will be subject to accuracy checks and audit.

Where device maintenance is not the responsibility of Wellspring Recruitment and Care Services Limited or due to the specialist nature of the products (such as hoists), local service agreements will be in place. Staff must refer to the Purchasing Policy and Procedure, and the Moving and Handling Policy and Procedure for further details.

Audits should be carried out at Wellspring Recruitment and Care Services Limited to check:

- Safe acquisition
- Training
- Use



- Maintenance and repair
- Decontamination
- Disposal
- Records

Staff will not use any equipment that has not been serviced or calibrated in line with the manufacturer's instructions.

5.3 Acquiring Appropriate Devices

Any purchasing of new medical devices must first be discussed with Olajumoke Omolola. Where appropriate, advice and recommendations will be sought from a relevant healthcare professional (e.g. occupational therapist).

Before any new purchase, Olajumoke Omolola will consider:

- Staff training requirements
- Suitability (this may be decided in conjunction with a relevant external health professional)
- Service Users' needs
- Safety
- Ease of use
- Familiarity of staff with the type of equipment
- Advice from supplier
- Decontamination and disposal
- Maintenance and servicing requirements
- Cost benefits and quality of the products
- Standardisation/preferred devices
- Support available externally from other health and social care professionals

If medical equipment is hired, Olajumoke Omolola must ensure that they are in receipt of the equipment user manual when accepting the hire equipment.

Medical equipment will not be purchased or hired unless it is CE marked.

5.4 Loan of Medical Devices

Medical devices may be loaned from healthcare professionals or be in use by Service Users upon commencement of the care service with Wellspring Recruitment and Care Services Limited.

Staff must record these devices within the Service User's Care Plan and have access to guidance and instructions. At the point of assessment or when care needs change, Olajumoke Omolola will consider any training needs and access resources before confirming and commencing the package of care.

Staff will report any concerns or defects with the device to Olajumoke Omolola and the supplying healthcare professional.

All medical devices must be returned to the supplier when they are no longer required in a clean, decontaminated condition. Staff will keep records of this action in the Service User's file.



5.5 Service User Involvement with Medical Devices

At all times Service Users will be involved in their care planning which includes the introduction of medical devices or the use of existing ones. Competent and trained Care Workers must ensure that Service Users understand what the medical device is, how it is used and the rationale for its choice.

Service Users will be able to access information (e.g. manufacturer's guidance, leaflets) to assist with understanding the purpose of the medical device and be provided the opportunity to ask questions and make informed decisions around their care.

Where medical devices are assessed as needing to be introduced to Service Users who lack capacity to consent, staff must refer to the Mental Capacity Act (MCA) 2005 Policy and Procedure at Wellspring Recruitment and Care Services Limited.

5.6 Receiving a New Device

Wellspring Recruitment and Care Services Limited should check that the specification of newly delivered devices matches the purchase order detail.

Simple checks on delivery can save time and avoid trouble. Finding out that a device is broken or inappropriate only when someone tries to use it for the first time can delay or interrupt treatment, make it harder to establish when and where the problem arose and invalidate the warranty.

Delivery checks should include:

- Checking that the correct product, complete with usage and maintenance information and any relevant accessories, has been supplied
- Ensuring that devices have been delivered in good condition and, where relevant, in good working order
- Checking the manufacturer's instructions as they may specify particular testing, calibration or adjustment before a medical device is used for the first time
- Ensuring that any electrical testing is carried out in line with the Electrical Safety Policy and Procedure at Wellspring Recruitment and Care Services Limited
- Ensuring that checks and tests are carried out by staff with the appropriate training
- Determining whether a risk assessment needs to be completed for the medical device

5.7 Device Instructions

Clear instructions for use of a medical device are crucial to ensure safe and effective use. The manufacturer is responsible for supplying appropriate instructions. Clear responsibilities should exist for ensuring that the manufacturer's instructions are passed on to all users. The manufacturer's instructions may need to be supplemented with training.

All of the necessary information for storage, pre-use checks, use, maintenance and cleaning should be provided and shared with staff. A failure to share the manufacturer's original instructions may compromise a staff member's ability to use the device safely and may lay Wellspring Recruitment and Care Services Limited open to legal liability.

5.8 Training and Education

Medical devices must only be used by trained staff who have received training on the products and are deemed to be competent in their use.

As a minimum, device training will cover:



- Its safe use
- Its cleaning
- The reporting of incidents and accidents
- The location for the manufacturer's instructions
- The condemning of equipment

Training requirements and competency assessments will be identified by Olajumoke Omolola at induction, reviewed during supervisions and discussed as part of the yearly appraisal. Staff are expected to discuss the need for training at all other times if they feel they do not have sufficient knowledge to complete the task safely.

A training needs analysis must be completed in order to determine the need for training provision. The frequency will be determined in accordance with the manufacturer's instructions and as agreed by Wellspring Recruitment and Care Services Limited and Olajumoke Omolola.

All records of training will be available upon request for inspection.

Staff are expected to attend arranged training and achieve competency assessments as set by Wellspring Recruitment and Care Services Limited. Persistent failings to attend or achieve will result in disciplinary action or capability management by Olajumoke Omolola.

5.9 Modifying and Changing Use

Modifying existing devices or using them for purposes not intended by the manufacturer (off-label use) has safety implications. The original manufacturer's liability is limited, and liability may be partly or wholly transferred to the organisation or person making the modifications if the device is implicated in an adverse incident.

5.10 Maintenance of Medical Devices

Staff must follow the manufacturer's guidelines on the care and user maintenance of equipment and devices.

Care of Equipment when in Use:

Regular visual checks should be made prior to use, checking for (as a minimum) any obvious signs of damage, cleanliness and faults affecting performance or safety

- All single-use items must be checked to ensure that they are not past their use-by date and if they are, they are not used and disposed of
- Faults are to be reported immediately and faulty equipment must be clearly labelled and dated, removed from active use and immediately stored separately from functioning equipment
- Olajumoke Omolola must arrange for suitable storage of medical devices when they are not in use. The storage facilities should take into account any special requirements for infection control, temperature, humidity (list not exhaustive) and that any equipment that has rechargeable batteries is kept on charge
- Olajumoke Omolola must arrange for regular checks to be undertaken on all consumable items to ensure that they are not past their use-by date, and if they are, they are removed from use and replaced as soon as they reach their use-by date

Maintenance:

Where device maintenance cannot be achieved within Wellspring Recruitment and Care Services Limited due to the specialist nature of the products (such as hoists), local service agreements will be in place. Staff can refer to the Purchasing Policy and Procedure and the Moving and Handling Policy and Procedure for further details.



Staff must carry out maintenance in accordance with the manufacturer's instructions as well as following infection control principles and practices. Please refer to the Infection Control Policy and Procedure. It is the responsibility of all staff to ensure that equipment is fit for use, performs as expected and is kept clean. All equipment must be stored safely after use.

- All new medical devices must undergo a portable appliance pre-visual check, then be thoroughly tested during the next planned portable appliance test (PAT) visit
- Maintenance may consist of planned preventive maintenance (PPM), reactive repair and/or inspection/performance checks
- The frequency and level of maintenance is determined by the device's instruction manual. Olajumoke Omolola must ensure that medical devices undergo maintenance at the appropriate time in accordance with the manufacturers' instructions
- All medical device calibration and testing will be provided by an approved contractor
- Where a manufacturer or their agents carry out maintenance on medical devices on site, a record of the visit must be kept by Wellspring Recruitment and Care Services Limited where it was carried out
- When care equipment requiring servicing or repair needs to be sent away or collected, documentation should accompany the equipment stating if the item has or has not been decontaminated (It is illegal to send contaminated items through the post)
- Maintenance and repair of re-usable medical devices must only be carried out by competent persons recognised as having sufficient technical knowledge and experience, and who operate under a recognised quality management system

Record Keeping

Records will be maintained to ensure that all medical devices at Wellspring Recruitment and Care Services Limited demonstrate a servicing history, compliance with manufacturers' instructions and that an appropriate risk assessment is in place.

All maintenance records will be subject to a retention period in line with the Records Management Code of Practice (link can be found in the further reading section) and will be kept in a location that is secure. Records will be accessible for inspection upon request.

Audit

Random audits should be carried out on all elements of maintenance, repair, record generation and storage to ensure that the correct procedures are in place and being adhered to. Audits should be carried out by staff with appropriate knowledge and experience of managing medical devices.

5.11 Reporting Adverse Incidents

All incidents involving medical devices must be reported through the reporting process at Wellspring Recruitment and Care Services Limited. It is the responsibility of any member of staff who finds a problem with a medical device to report it.

It is a requirement that medical device incidents such as the following, are reported to the MHRA via the yellow card scheme, or directly via <https://www.gov.uk/report-problem-medicine-medical-device>:

- Someone is injured (or almost injured) by a medical device, either because its labelling or instructions are not clear, it is broken or has been misused
- The Service User's treatment is interrupted because of a faulty device



- Someone receives the wrong diagnosis because of a medical device
- It is thought that a medicine or medical device is fake or counterfeit

Note: Reporting of medicines is covered in medication policies and procedures.

5.12 Decontamination

All reusable equipment must be decontaminated as per the original manufacturer's instructions. It is the responsibility of the device user to ensure that the device is decontaminated and returned to storage after each use.

There are three levels of decontamination:

- Cleaning
- Cleaning, followed by disinfection
- Cleaning, followed by disinfection, followed by sterilisation

Where possible, single-use items will be used to support the Service User.

Re-usable medical devices must be decontaminated after use and before use on another Service User.

Detergent and disinfectant wipes can damage plastic surfaces of medical devices and care equipment if they are not compatible with the surface material, (such as tympanic thermometers, infusion pumps). The damage may compromise the ability to decontaminate the device adequately or affect the function of the device. Staff must check the manufacturer's instructions to ensure cleaning products are compatible with the item. (NHS 2023).

The decision about the level of decontamination required depends not only on how the device is used, but also the risk of the device transmitting infection or acting as a source of infection. Following a risk assessment, the vast majority of devices may not require much more than cleaning and occasionally disinfection; sterilisation is unlikely to be required in the community.

Medical equipment should be categorised by the level of risk:

Low:

- Equipment in contact with intact skin
- Cleaning
- Blood pressure cuffs, stethoscopes, mattresses, surfaces, hoists

Medium:

- Equipment in contact with intact mucous membranes or non-intact skin, body fluids or the Service User with a confirmed or suspected infection
- Disinfection (cleaning before)
- Commode and pan, bed pan, respiratory equipment, and immunocompromised Service User

High:

- Equipment involved with a break in the skin or mucous membrane or entering a sterile body cavity
- Sterilisation
- Needles, PEG (percutaneous endoscopic gastrostomy) tubes

Re-usable equipment that has been cleaned or disinfected should be labelled or documented, giving details of the date of cleaning and signed by the person who performed the decontamination.



Equipment not in regular use should be stored in a clean environment, e.g. cupboard, checked on a monthly basis, decontaminated as appropriate and relabelled.

5.13 Cleaning

- Staff must wear the correct personal protective equipment (PPE) and risk assess the need for facial protection
- Detergent wipes or general purpose neutral detergent, warm water and single-use disposable cloths are recommended
- Where possible, equipment cleaning should take place in a dedicated area away from Service Users
- A designated sink should be used
- Equipment should be dismantled where necessary in line with the manufacturer's instructions
- Clean from top to bottom, and clean to dirty
- The device should be fully immersed in the detergent solution, and the device scrubbed if the instructions allow for this
- Devices that cannot be immersed may be decontaminated by using wipes or a cloth soaked in detergent solution and wrung out. Wipe all the surfaces of the device:
 - The cloth should be re-immersed periodically, and the detergent solution changed frequently
- Large and flat surfaces should be cleaned using an 'S' shaped pattern, starting at the point furthest away, overlapping slightly, but taking care not to go over the same area twice. This cleaning motion reduces the amount of microorganisms, such as bacteria and viruses, that may be transferred from a dirty area to a clean area
- The detergent solution should be rinsed or wiped from the device with clean water using clean disposable cloths that have been immersed in clean water and wrung out
- If not proceeding to a disinfection stage, devices that have been cleaned must be dried prior to inspection, maintenance, repair, or storage
- Dry thoroughly after cleaning using disposable towels or paper roll (where appropriate). Items should NOT be left on surfaces to air dry
- After removing PPE, staff must wash and dry their hands

5.14 Mattress and Pressure Relieving Cushions - Decontamination

Mattresses and pressure relieving cushions with damaged or stained covers or contents can promote the growth of microorganisms, such as bacteria and viruses, which are a potential cause of transmission of infection.

Proper care, maintenance and cleaning is essential:

- When ordering mattresses and pressure relieving cushions, they should be of an appropriate thickness and covered with a waterproof cover, preferably with an integral zip fastener for easy inspection of the underside of the cover and the contents
- The covers should be able to withstand cleaning with detergent wipes or general purpose neutral detergent and warm water and disinfected with products effective against bacteria, viruses and spores as required
- Mattresses and pressure relieving cushions should be dated and numbered when put into use and replaced to a predetermined schedule according to manufacturers' instructions
- Mattress covers should be cleaned regularly and whenever visibly soiled, with detergent wipes or general purpose neutral detergent and warm water and, when



required, disinfected with appropriate products

- All covers, zip fasteners and contents should be regularly inspected for damage. Additionally, an inspection should be carried out when a room is vacated
- If a cover is stained, worn or torn, the contents should be examined and the damaged cover should be replaced immediately
- If the mattress is wet or stained, the cover and mattress should be disposed of
- Special mattresses and pressure relieving cushions, including those with hinged sections/air cells, should be maintained and cared for in accordance with manufacturers' instructions
- Used mattresses, covers and pressure relieving cushions do not normally need to be disposed of as infectious waste. They must be socially clean, i.e. cleaned with general purpose neutral detergent and warm water and have a decontamination certificate attached prior to being disposed of as household waste
- Any item that is known, thought to be infected, or heavily soiled, should be cleaned and disinfected prior to disposal as infectious waste. The items must be suitably bagged, securely sealed and labelled as biohazard. Removal must be sought via an approved contractor or the local council. Prior to removal, they should be stored in a secure area
- Prior to return to a community loan department or other supplier, special mattresses and pressure relieving cushions should be decontaminated according to manufacturers' instructions and have a decontamination certificate attached. The item should then be stored in a clean area awaiting collection
- Monthly audits to assess the standard of maintenance of mattresses, mattress covers and pressure relieving cushions must be carried out

5.15 Commode and Bed Pan - Decontamination

Commodes and bed pans require cleaning prior to disinfection. Inadequately decontaminated commodes and bed pans can promote the growth of microorganisms, such as *Clostridioides difficile* and Norovirus.

Appropriate cleaning and disinfection are essential:

- Use a bucket or sink designated for only cleaning commodes or bed pans
- Use disposable cleaning cloths and dispose of after use
- Use a general purpose neutral detergent and warm water for cleaning before disinfecting
- Use 1,000 parts per million (ppm) chlorine-based disinfectant solution, or equivalent product as per the manufacturer's instructions
- If contaminated with blood/blood stained body fluid, use 10,000 ppm, or equivalent product as per the manufacturer's instructions
- Alternatively, use a '2 in 1' product, which contains both a detergent and a disinfectant, e.g. Chlor-Clean or Actichlor™ Plus tablets, Clinell Universal Wipes
- Ensure commodes and bed pans are replaced when scratched, stained or rusted
- Monthly audits to assess the standard of cleanliness of commodes and bed pans should be carried out

5.16 Decommissioning and Disposal

Faulty equipment must be immediately removed from use and alternative equipment sourced. The item must be clearly labelled and dated to advise colleagues that the device must not be used until the servicing and maintenance is complete and it is safe to reuse the equipment, or the item has been condemned.



Items for disposal should be cleaned prior to disposal.

Items that are known, thought to be infected (e.g. been in contact with non-intact skin, mucous membranes, body fluids or the Service User with a confirmed or suspected infection) or heavily soiled, should be cleaned and disinfected prior to disposal as infectious waste. The items must be suitably bagged, securely sealed and labelled as biohazard. Removal must be sought via an approved contractor or the local council. Prior to removal, they should be stored in a secure area.

At some point, all devices will need to be replaced. The expected life cycle of a device or piece of equipment should be held in the inventory record where appropriate, and regularly reviewed against the usage, maintenance and repair record, to see if the end date needs to be adjusted.

Heavy use or irregular maintenance may reduce the life cycle of a device but limited use may extend it.

A manufacturer's recall of a device will take precedence over other considerations.

Replacement

Factors to consider:

- Whether the device is damaged or worn out beyond economic repair
- Its reliability (check service history)
- Clinical or technical obsolescence
- Disposal due to contamination
- Changes in local policies for device use
- Absence of manufacturer/supplier support
- Non-availability of correct replacement parts
- Non-availability of specialist repair knowledge
- Possible benefits of new model (features, usability, more clinically effective, lower running costs)
- Lifecycle of the medical device
- Equipment downtime
- Changes in clinical recommendations/standards
- New equipment technologies and/or technological obsolescence
- Changes in service provision

For disposal, please consult the manufacturers for the best method of disposal.

5.17 Medical Device Alerts (National Patient Safety Alerts)

The MHRA is accredited to publish National Patient Safety Alerts (NatPSA) for medical devices and medicines. These alerts are sent to the NHS in England.

NatPSA are:

- Written by the MHRA
- Targeted at senior management in healthcare organisations for system-wide action
- Sent to the healthcare sector through the [Central Alerting System](#) (a link is in the Further Reading section)
- Published on GOV.UK for action and information



NatPSAs are published only for the most serious issues that will impact on patient safety and there are strict criteria that must be met for an alert to be issued.

From time to time, the MHRA issues Safety Action Bulletins (SABs) relevant to medical devices.

These alerts are to be printed and stored in the relevant Safety Alert Folder held in each service with a record of any action taken (or not). A log is available within the Forms section of this policy for use.

Receipt of safety alerts, emergency alerts, drug alerts and medical device alerts will be responded to in a timely manner. Staff should refer to the Distribution of Safety Alerts Policy and Procedure for consistent management.

Olajumoke Omolola must ensure that there is a process to ensure all staff are aware of any alerts and there should be a record of all alerts received, whether or not they are relevant to the service, and any action taken.

5.18 Audit and Review

Olajumoke Omolola should ensure monthly audits are undertaken to assess the standard of cleanliness of re-useable medical devices.

Findings will be investigated and actions set with changes embedded in practice in a timely manner.

Records of all audits and quality assurance systems will be maintained and filed accordingly.



6. Definitions

6.1 Decommissioning

- To remove something from service

6.2 Adverse Incident

- 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 Service Users or others

6.3 Decontamination

- Decontamination is the process of removing contaminants on an object or area, including chemicals, microorganisms or radioactive substances. This may be achieved by chemical reaction, disinfection or physical removal. It refers to specific action taken to reduce the hazard posed by such contaminants, as opposed to general cleaning

6.4 Cleaning

- Process which physically removes inorganic dirt, infectious agents, and the organic matter on which they thrive, but does not necessarily remove all infectious agents

6.5 Disinfection



- Process used to reduce the number of viable microorganisms, but which may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores



7. Key Facts - Professionals

Professionals providing this service should be aware of the following:

- Medical devices play a key role in healthcare and are vital for diagnosis, therapy, monitoring, rehabilitation and care delivery
- Effective management of devices is necessary to ensure delivery of high-quality care that includes minimising the risks of adverse events
- Maintenance, servicing and day-to-day care of medical devices is everyone's responsibility
- Good record keeping is essential for the safe management of medical devices
- Equipment must be decontaminated after every use
- Olajumoke Omolola should ensure that there is a process to act on any safety alerts
- Staff should carry out a visual inspection on all equipment before use and report any concerns immediately
- Medical devices should only be used for the purpose for which they were designed



8. Key Facts - People Affected by The Service

People affected by this service should be aware of the following:

- We take your health and safety seriously and will ensure that all equipment is regularly maintained and serviced as per the manufacturer's instructions
- Staff will be fully trained and competent to support you with any medical device in use
- Staff are responsible for ensuring that your medical device remains fit for purpose, clean, serviced and well-maintained
- You are encouraged to discuss any concerns in relation to this policy with Olajumoke Omolola



Further Reading

NHS - Medical devices E-learning:

<https://www.e-lfh.org.uk/programmes/medical-equipment/>

GOV.UK - Alerts, recalls and safety information: medicines and medical devices

<https://www.gov.uk/drug-device-alerts>



Central Alerting System (CAS) - Home

<https://www.cas.mhra.gov.uk/Home.aspx>



Outstanding Practice

To be "outstanding" in this policy area you could provide evidence that:

- All incidents and near miss events in relation to medical device equipment are investigated with responsive action taken and lessons are shared
- The wide understanding of the policy is enabled by proactive use of the QCS App
- There is a clear process for managing incoming safety alerts including highlighting where they are relevant to the service and any action taken
- Staff have completed medical devices training (as per the link located in the Further Reading section of this policy)
- Olajumoke Omolola completes thematic audits and has the MHRA checklist for medical devices. Findings are discussed with staff and changes embedded in practice
- A lead role has been assigned as a medical device champion to oversee the management and best practice of device usage within Wellspring Recruitment and Care Services Limited
- Medical devices are discussed at health and safety meetings



Forms

The following forms are included as part of this policy:

Title of form	When would the form be used?	Created by
Medical Devices Safety Alerts Log - CC107	To log all medical devices safety alerts and detail any action taken if relevant.	QCS
Declaration of Contamination Status - CC107	When returning medical devices.	NHS

