# Policy:
# MD 021 Medical and Therapeutic Devices

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| **Executive Director lead** | Executive Director of Nursing and Professions |
| **Policy Owner** | Medical Devices Safety Officer |
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**Summary of the Policy.**
The aim of this document is to provide guidance to all Sheffield Health & Social Care NHS Foundation Trust (SHSC) staff on the procurement, management, maintenance, and disposal of Medical/Therapeutic equipment used across the trust. This policy will also make reference to new developments within the medical devices field and how we can respond as an organisation.

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| **Target audience** | All SHSC employees, or contracted staff from other NHS Trusts or private individuals working with SHSC service users. |

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| **Keywords** | Medical, Therapeutic, Devices, Procurement, Equipment, Suppliers, Decontamination, Maintenance, Disposal. |

**Storage**
Version 6.0 of this policy is stored and available through the SHSC intranet. This version of the policy supersedes the previous version (V5 April 2020). Any copies of the previous policy held separately should be destroyed and replaced with this version.

**Version Control and Amendment Log**

| Version No. | Type of Change | Date | Description of change(s) |
|---|---|---|---|
| 3.0 | Review / ratification / issue | Nov 2016 | Finalised and issued. |
| 4.0 | Reviewed and re-written | March – Sept 2019 | Updated to include the full acquisition of medical and therapeutic devices process – but was never up-loaded on to the intranet/internet. |
| 5.0 | Final review prior to presentation to PGG | March 2020 | References to STH Clinical Engineering SLA added. |
| 6.0 | Reviewed and re-written to make relevant and fit for purpose | December 2023 | Updated to include:<br>• Complete review of whole document. All elements of document have been reworked to include relevant and up to date information about medical and therapeutic devices. |

## Contents

## 1.Introduction

Sheffield Health & Social Care NHS Foundation Trust (SHSC) is dependent upon an extensive stock of reusable medical devices in order to deliver high quality healthcare. This Policy outlines the Trust's approach to managing medical devices throughout their entire lifecycle from initial procurement to disposal, in order to control any risks associated with this equipment. The primary objective is to ensure that where medical devices are required they are available and fit-for-purpose. This policy is based upon the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA) publication "Managing Medical Devices – Guidance for healthcare and social care organisations" (January 2021), as well as on the requirements of the Care Quality Commission. The policy will be revised in response to any changes to this guidance as necessary.

## 2. Scope

This policy applies to:

- All staff supporting service users who require any equipment for assessment/treatment/monitoring/management purposes.
- All service users across the trust who require any equipment for assessment/treatment/monitoring/management purposes.
- Any service or site within the Trust that requires the use of equipment on a more ad hoc basis.

## 3. Purpose

This Policy aims to ensure that all medical and therapeutic devices in use within SHSC:

- Are procured in accordance with Trust policies and procedures.
- Are suitable for (and only used for) their intended purpose.
- Are recorded on the Trust's Devices Asset Register (as part of the acquisition process).
- Staff are properly trained and competent in use of equipment.
- Devices are managed and maintained in a safe and reliable condition and are properly decontaminated prior to and after use following Decontamination Policy.
- Maintained and/or serviced on (at least) an annual basis, or in accordance with guidance provided by the manufacturer or supplier.
- Decommissioned and disposed of in accordance with the Trust's decommissioning, disposal and waste policies, and/or guidance provided by the manufacturer or supplier.
- Processes are followed to ensure continued safety in relation to use of all medical devices across all areas of the trust.

## 4. Definitions

| Term | Definition |
|---|---|
| **Department of Health and Social Care (DH&SC)** | A central government department, responsible for:<br>• Supporting and advising ministers to help shape and deliver policy on health and social care<br>• Setting future direction to protect and improve global and domestic health<br>• Accountability, ensuring the department and its arm's length bodies deliver on agreed plans<br>• Act as guardians of the health and care framework, ensuring the legislative, financial, administrative and policy frameworks are fit for purpose.<br>Troubleshooting: in the last resort, taking the action needed to resolve crucial and complex issues |
| **Medicines and Healthcare products Regulatory Agency (MHRA)** | An executive agency of the Department of Health and Social Care, responsible for the regulation of medicines, medical devices and blood components for transfusion. |
| **Care Quality Commission (CQC)** | The independent regulator of health and social care in England |
| **Diagnostic equipment** | Equipment that is used to aid a diagnosis, including such items as sphygmomanometers or electro-cardiograph machines. |
| **Therapeutic equipment** | Equipment that is used for the delivery of patient care and treatment. |
| **Reusable equipment** | Equipment designed to be used more than once, appropriately decontaminated between patient usage |
| **Single patient use** | All items marked by a manufacturer as "single patient use" must only be used by a single named patient. All the manufacturers' usage guidelines must be adhered to. |
| **Single use** | All single use items are clearly marked 'single use only', and by law must only be used once. |
| **Master Indemnity Agreement (MIA)** | An agreement entered into directly by a NHS organisation with a supplier when it is in receipt of equipment (including products) on either a loan or permanent transfer basis. A MIA should be completed by both parties each time a piece of equipment is provided under these arrangements.<br>The Agreement provides certain protections to both the NHS organisation and the supplier in relation to that equipment; for example, a NHS Trust will not get indemnity provisions and the supplier will not get legally binding commitments, nor will contractual limitations of liability apply. |
| **Master Indemnity Agreement Register** | A register of overarching MIAs entered into by suppliers with the Department of Health & Social Care |

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| **Decontamination** | A combination of processes, which removes or destroys contamination and thereby prevents microorganisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. This is achieved by cleaning, disinfection and/or sterilisation. |
| **Central Alerting System (CAS)** | The Medicines and Healthcare products Regulatory Agency (MHRA) operates the Central Alerting System, a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care.<br><br>Alerts available on the CAS website include 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 & Social Care Supply Disruption alerts. |
| **Field Safety Notice (FSN)** | An important communication about the safety of a medical device, sent to customers by a device manufacturer or their representative. They inform what organisations need to do to reduce the specified risks of using the medical device. The actions are referred to as 'field safety corrective actions' (FSCAs). If a Field Safety Notice is received from a manufacturer it must always be acted upon; **DO NOT** wait for a communication from the MHRA. |
| **National Patient Safety Alerts (NPSA)** | A format for the issuing of alerts developed and introduced by the National Patient Safety Alerting Committee in September 2019. NHS Improvement Patient Safety Team is the first alerting body to go through the accreditation process and is accredited to issue National Patient Safety Alerts for 3 years from July 2019. NPSAs will have the following logo on them as well as that of the issuing organisation(s): |
| **Medical Device Alert (MDA)** | The prime means of communicating safety information to healthcare organisations and the wider healthcare environment on medical devices. MDAs are prepared by the MHRA and are distributed nationally with the same reference, content and format. |

## 5. Duties/Responsibilities

### 5.1 Chief Executive and Medical Director

The Chief Executive has nominated the Medical Director to be accountable for Medical and Therapeutic Devices. The Medical Director will:

- Assume accountability for medical/therapeutic devices management within the Trust.
- Ensure compliance with the relevant CQC outcomes for medical equipment, the MHRA's Managing Medical Devices guidance, and the relevant risk management standards in relation to Medical/Therapeutic Devices.

### 5.2 Board of Directors

The Board of Directors are accountable for ensuring that suitable arrangements are in place for the safe and effective management of reusable medical devices (done via Medical Devices Safety Officer). This includes an overview of performance, significant issues, and development plans. This would be reported by Medical Devices Safety Officer to respective committees for information/escalation where required.

### 5.3 Medical Device Safety Officer

- Ensure all medical devices are appropriately procured via approved channels.
- Ensure all medical devices are logged on an inventory list (currently on ShefMed digital platform).
- Ensure that all devices are well maintained, stored appropriately, regularly serviced (including PAT testing and Loler Services), decontaminated as per decontamination policy – with oversight from Sheffield Teaching Hospital Clinical Engineering.
- Ensure where devices are not available other alternatives are sought.
- Some pieces of equipment may require additional training on safe use. Medical Devices Safety Officer to reiterate this to ward/clinical staff upon any requests and then link in with appropriate resource for example Physical Health Team to support with this.
- Ensure up to date policy is accessible to all staff.
- Action any hazard and safety notices received in relation to medical devices.
- Escalate any issues as appropriate via appropriate professional channels/groups.

### 5.4 Medical Devices Management Group

The Medical Devices Management Group (MDMG) is a corporate committee with responsibility for providing strategic direction to the management of medical devices across the Trust. The responsibilities include advising the Trust on Clinical Governance issues related to medical devices and ensuring that appropriate arrangements are in place for the maintenance of medical devices. The full details of the role and responsibilities of MDMG are outlined in the MDMG Terms of Reference.

### 5.5 Ward Manager/Deputy Ward Manager/Nurse in charge/Nursing Staff Team/AHPs/medical device users

- Ensure that systems are in place to allow compliance with and visibility of this policy.
- Ensure that staff undergo training and are competent to use the medical/therapeutic devices within their area of responsibility.
- Ensure all staff are familiar and compliant with cleaning equipment after use.
- Ensure all staff are familiar with the completion of decontamination forms.
- Deliver personalised care using medical and therapeutic devices in a way that has regard to the dignity, comfort and safety of service users and which promotes their independence and well-being.
- To ensure that the right piece of equipment is always used in every situation.
- Report incidents and near misses involving medical and therapeutic devices via electronic reporting system.
- Take appropriate action in a timely manner where problems around the safety or suitability of equipment in any care setting are identified.
- Ensure that any issues with devices ‘in use’ are reported in a timely manner to the appropriate maintenance support services (chiefly STH Clinical Engineering Department), and in accordance with any Service Level Agreement.

- Use medical and therapeutic devices safely and in the prescribed manner including ensuring that any safety checks required by manufacturers' instructions or
- procedures/guidance are carried out prior to use of medical and therapeutic devices including safe decontamination.

## 6. What is a medical and/or therapeutic device?

The term "medical device" has a specific definition under the Medial Devices Directive (93/42/EEC) which is implemented in UK Law through the Medical Devices Regulations (SI 2002 No 0618)[1] The definition is as follows:

Any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement, or modification of the anatomy or of a physiological process,
- Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means."

## 7. Classification of medical devices

### 7.1 General medical devices

When a product has been established as a general medical device, it is classified based on risk. The risk depends on factors including the intended purpose, duration of use, and whether it is invasive, implantable, active, or contains a medicinal substance. The categories are:

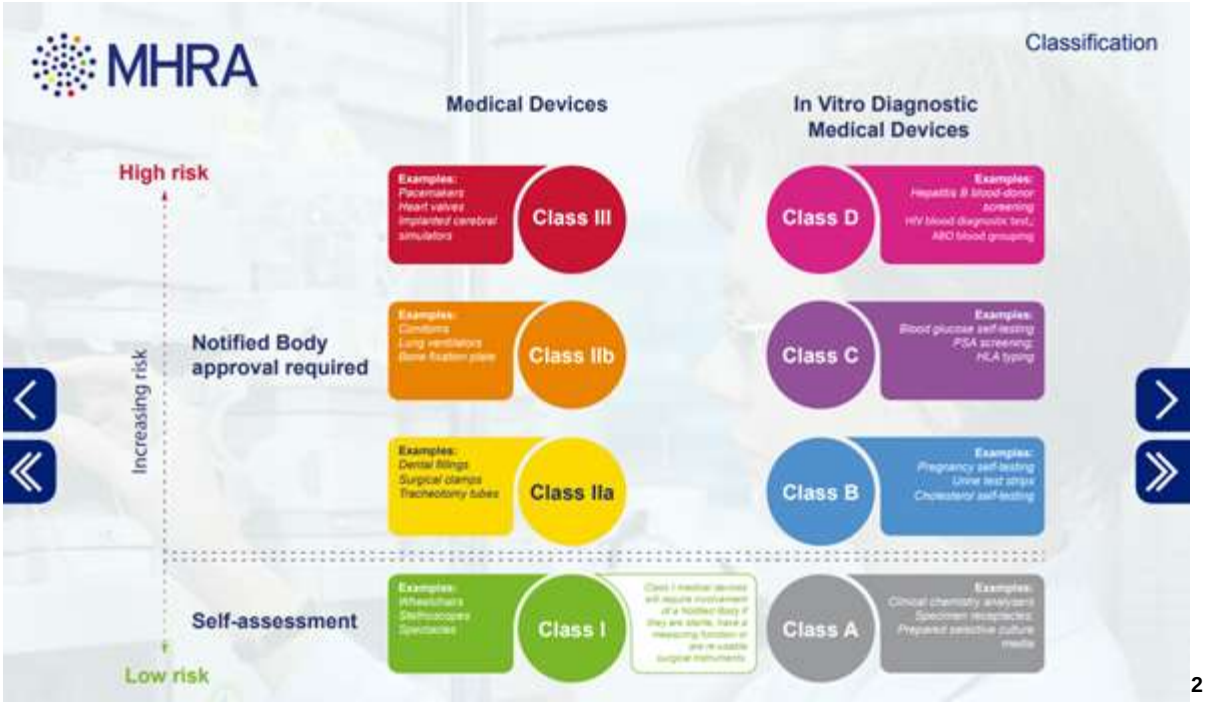
- Class I – generally regarded as low risk
- Class IIa – generally regarded as medium risk
- Class IIb – generally regarded as medium risk
- Class III – generally regarded as high risk

Accessories to medical devices are classified separately to the device. All active implantable medical devices and their accessories fall under the highest risk category (Class III).

### 7.2 In vitro diagnostic medical devices (IVDs)

In vitro diagnostic medical devices include all tests, including lab tests, point of care tests and 'self-test' devices intended to be used by a person at home (or in some inpatient settings). These are categorised differently into 4 main groups (see table below).

[1] In May 2017 the Medical Device Directive was replaced by the Medical Device Regulations, however, as there is a three year transition period for the purposes of this policy the MDD definitions are being retained.




## 8. Medical devices and digital connectivity

Over the last few years there have been a number of developments in terms or medical devices. How we use them, how we can access data, how they can be a digitally connective tool to support health care delivery.

### 8.1 Benefits

Some of the benefits of digital connectivity are:

- Patient data to be downloaded straight from a device to an electronic record
- Data can be shared across organisations for example from Primary Care (GP's) to Secondary Care settings for such as annual health checks, blood results, ECG readings etc
- Improved access to care
- Living better or living well with physical health conditions by digital monitoring

### 8.2 Digital tools that may be medical devices

Nowadays digital access can be more readily available especially with access to smart phones, tablets etc and a vast variety of downloadable apps.

Digital health tools that may be medical devices include:

- Patient facing apps that enable self-management or remote monitoring of medical conditions such as diabetes or depression for example
- Online digital tools to assist in diagnosis
- An app for example that advises on insulin dose based on a diabetic patient's blood glucose level and dietary input
- Medical calculators and algorithms

[2] NHS England » Medical devices and digital tools

As medical devices become connected via the internet, they require special consideration of the novel risks this creates regarding the need for secure internet access, software reliability, privacy, and cyber security. This would include medical devices, AR (augmented reality used in a real-world setting), VR (virtual reality) or AI (Artificial Intelligence).

### 8.3 Risks

Risks and issues associated with the use of medical devices and digital tools include:

- Lack of regulation
- Lack of integration and failure of integration – can mean if new systems do not communicate directly with existing systems inefficiencies can build up meaning valuable time is taken up manually transferring data between disparate systems. Similarly, if there has been an integration and it breaks, this can result in clinicians not having up to date information
- Reliability and cybersecurity – become more critical as medical devices become connected to the internet and perform higher risks functions, e.g. insulin pumps or artificial pancreases. This creates novel risks to privacy, physical safety, or both. This can be mitigated by ensuring that software is designed in a safe way, kept up to date and patched as new vulnerabilities are identified and by observing appropriate standards such as UKCA marking and due diligence (e.g. DTAC) (The Digital Technology Assessment Criteria is designed to be used by healthcare organisations to assess suppliers at the point of procurement to make sure digital technologies meet our minimum baseline).
- systems failure – power outages or server failures become more of a risk as care becomes more dependent on apps or electronic devices. Thought must be given to contingency or back up arrangements
- adverse incidents – are inevitable with any new technology, but they should be mitigated against by using clinical risk management.
- digital exclusion – can occur when new technology leads to unequal access to care from patients who may lack connected devices, internet connection or IT skills.
- risk of digital discrimination – where medical devices or digital tools treat a patient unfairly or inaccurately based on a certain characteristic (which could also be a protected characteristic such as race or gender). This can be mitigated if medical devices or algorithms are well designed and tested on a representative population.

Some of our service users that we see in the community or in an inpatient setting may be using self-bought medical devices bought online or downloaded as apps from app stores. These could include blood glucose meters, blood pressure monitors, self-test kits, wheelchairs etc, so we need to be mindful about this.

### 8.4 Current Position (in relation to digital health)

The current position for the trust is that we do have medical devices that have connective capacity and abilities, and further devices could definitely have the potential to develop or enhance services with access to digital technology but we don’t have the infrastructure in terms of technology to be able to support this innovative pathway at the moment. As the market around medical devices progresses, digital development plans will need to be incorporated as part of future investment plans. As new digitally capable devices become available, older machines, accessories and consumables will likely need to be replaced with more up to date models. We are unable to digitally share any data from medical devices to primary care, secondary care, third parties or third sector colleagues. Although we are unable to share digitally, we are able to share data in other formats (although may not be most effective) and currently we have to receive medical device data in an alternative format (aside from a digital download for example).

## 9. Provision of personalised care

Medical and therapeutic devices should be used in a manner which has regard to the dignity, comfort, and safety of the service user. This can be achieved by:

- Actively listening to service users' preferences and thoughts wherever possible about the equipment they need and how it is used. Religious belief will be respected regarding consent to use medical and therapeutic devices. It is appropriate that any preferences are documented within electronic records and discussing with nursing or staff team.
- Supporting the service user to understand how and why the equipment is being used (what is its purpose).
- Taking care in the way the equipment is used to make sure the service user is comfortable and safe. Individual requirements such as pregnancy, tissue viability, mobility, ongoing physical health conditions will be taken into consideration if relevant when issuing any medical or therapeutic devices.
- Using the equipment in a way that ensures the person's privacy and dignity is met (where practicably possible).
- Preference for a male or female health professional will be taken into consideration wherever possible.
- Using best interest provisions where required (refer to Capacity to Consent to Care Support and Treatment Policy).
- Include service users in ongoing discussions about their care (where possible or appropriate), so care continues to be person centred and meaningful.

## 10. Acquisition of medical devices

Any new purchase considerations of medical and therapeutic devices must be discussed with Procurement and Medical Devices Safety Officer in the first instance, to ensure that there is appropriate justification and all considerations (for a new piece of equipment) have been met. All medical devices and equipment should be selected and acquired in accordance with the Department of Health & Social Care and MHRA recommendations as well as Trust policies and procedures.

When considering the purchasing of medical devices, the following should be taken into account in the justification of need for the device:

- Clinical need
- Risk management
- Equipment replacement
- Changes in design, technology, or clinical practice
- Patient specific needs.
- Sustainability
- Cost effectiveness

10.1 There are various ways in which medical devices may be acquired, including but not limited to purchase, loan, hire and as part of a contract to purchase consumables associated with medical devices.

10.2 The procedure for making all such acquisitions must comply with the procurement procedures detailed in the Trust's Procurement Policy and all will need to be discussed with and approved by Medical Devices Safety Officer/Procurement.

10.3 However medical devices are acquired, it is essential that governance arrangements are in place to ensure that any device is fit for purpose as well as to address training, maintenance, and decontamination requirements – Medical Devices Safety Officer to oversee any purchase. Many of the Medical Devices used in the trust are either standardised or we have an approved list of both suppliers and supplies/equipment to support any purchases.

10.4 It is essential that all revenue consequences associated with the acquisition of any medical devices are fully considered and approved as appropriate. Revenue consequences include, but are not limited to, associated consumables, maintenance, commissioning, and Quality Assurance/Quality Control.

10.5 For replacement of capital medical devices (>£5k) that are required in large numbers and/or in multiple areas across the Trust, MDMG manages structured replacement programmes to ensure appropriate investment over a number of years. Any plan of this nature would be discussed in a number of appropriate forums to ensure appropriate governance and decision-making processes have been followed.

10.6 Purchase of medical devices with a value <£5k is normally the responsibility of individual directorates. If there is a requirement for a model that is not currently in use anywhere in the Trust, Clinical Engineering **must** be contacted to confirm that the requirements outlined in 10.2 are addressed, prior to purchase. Again, any purchase must be discussed with Medical Devices Safety Officer in first instance.

10.7 Purchase of medical devices with a value >£5k will need to be discussed via a business case with cost and potential usage outlined. Medical Devices Safety Officer to support for any larger purchase requirements as options and appraisals will need to be completed and potential product trials before purchase.

10.8 Medical devices may be provided on loan for a number of reasons. In all cases, because the Trust is not purchasing the device and there is no transfer of ownership, it is essential that appropriate arrangements are made for indemnity cover, in addition to the requirements outlined in 10.2. In order to ensure that appropriate arrangements are in place, anyone wishing to bring loan medical devices into the Trust **must** notify Medical Devices Safety Officer who can then liaise with Sheffield Teaching Hospital Clinical Engineering.

Clinical Engineering will normally insist that manufacturers and/or suppliers of loan medical devices are registered with the database of Master Indemnity Agreements (MIA). Any deviation from these arrangements either in terms of timeframe or registration on the MIA database can only be agreed by the Head of Clinical Engineering or the Head of Medical Device Management Services and may require written justification by Director of Nursing. For medical devices involved in clinical trials, specific arrangements for indemnity may be covered by the Clinical Trials Agreement, details of which will be required by Clinical Engineering.

10.9 Hire of medical devices should be covered by a formal agreement that includes details relating to the necessary indemnification. However, this must be reviewed and agreed by either the Head of Clinical Engineering and Medical Devices Safety Officer before devices are brought into the Trust. As for loan equipment, a minimum time window of two weeks is required between notification to Clinical Engineering and first use.

10.10 Medical devices required as part of a capital scheme will be reviewed by MDMG to ensure that all necessary considerations are taken in to account.

10.11 Medical devices purchased from charitable funds will be subject to review by MDMG in order to provide assurance to funders and the Trust that all implications of any bid receive due consideration.

10.12 Any new medical device must go through an acceptance test and be asset tagged and registered. **ALL** medical devices brought into the Trust **MUST** be acceptance tested before entering into clinical use. This will be done by Clinical Engineering.

Acceptance testing involves the following essential steps:
- Safety testing.
- Basic functional testing.
- Entry onto inventory of medical devices.
- Labelling of medical devices.
- Confirmation that arrangements are in place to satisfy the requirements outlined in 10.2 and 10.3
- Identification of schedule for planned preventive maintenance if appropriate.

Medical devices that fail any of the above criteria will not be released into clinical service until the reasons for failure have been addressed. Any exception to this approach must be agreed with the Head of Clinical Engineering and Medical Devices Safety Officer.

Any medical device that has not been acceptance tested and clearly labelled must be taken out of service immediately, or as soon as is reasonably possible without introducing unacceptable clinical risk and reported to Clinical Engineering and or Medical Devices Safety Officer.

Where a new medical device is replacing existing stock, there must be a clear plan to remove the outgoing device from service as soon as reasonably possible. To ensure continuity with 10.12 all new medical equipment must be delivered directly to SHSC Stores Department so that equipment can be logged as received and then taken to Clinical Engineering (unless previously agreed or arranged with Medical Devices Safety Officer and Clinical Engineering).

### 10.13 Donations to the NHS (in relation to medical devices or equipment)

For further advice and guidance on donations, contact SHSC Procurement and Medical Devices Safety Officer. When applying for donated monies and granting of same, managers need to be aware of the potential pitfalls in whether or not VAT exemption is applicable. Consideration would also need to be given as to whether or not the Trust can afford to operate/maintain the donated equipment (although this would usually be where complex or expensive diagnostic equipment is involved).

## 11. Medical Devices provided for Clinical Research

Where equipment is loaned or gifted specifically for use in clinical research (where that equipment is not the subject of the research), the MIA may be appropriate. Alternatively, the insurance and indemnity arrangements may be agreed through the site agreement. Under Health Research Authority (“HRA”) Approval, such agreements and associated insurance and indemnity arrangements are assessed centrally by the HRA.

## 12. Medical Devices on Loan (from outside of SHSC)

Medical devices can be loaned either from other trusts or suppliers/manufacturers. The reasons for these loans may be to avert a temporary problem, or to enable evaluation, or as an incentive to purchase. In any event, it is important to be clear about where responsibility lies for any problems that arise when a loaned device is used. Two separate SOP have been developed to advise on both loan of generic medical devices or equipment and bariatric equipment. Please see these for further detail.

### 12.1 Medical Devices on loan to clinical areas (from SHSC centralised equipment library)

SHSC has developed a vast equipment library of equipment particularly related to mobility management that is currently located in the Stores department, done to ensure all service user needs can be met in relation to access to mobility equipment to either enhance or support ongoing mobility needs, during any inpatient stay. A separate SOP has been developed to advise on loan of generic medical equipment or therapeutic equipment held centrally. Please see these for further detail.

## 13. Maintenance & Repair of Medical Devices

The primary objective of effective maintenance and repair of medical devices is to maximise the useful uptime of those devices so that they are available and fit for their intended purpose to support the delivery of high-quality healthcare.

13.1 SHSC currently has 2 Service Level Agreement (SLA) with Sheffield Teaching Hospitals (STH) for the oversight of, maintenance and repair. One is specifically for profile beds and the other is for Medical Devices. The second SLA covers almost all categories of medical equipment used within SHSC. As part of these SLA, we have a live asset register that will flag any and all routine service and maintenance dates (this is known as planned preventative maintenance (PPM). STH will independently arrange with clinical teams to go out and carry out routine maintenance. Most new devices will come with a manufacturing warranty which is also taken in to consideration if there are any faults during this warranty period time.

13.2 For any occasions where a machine or device is faulty or broken staff will either inform Medical Devices Safety Officer or direct through STH Clinical Engineering as soon as possible who will then arrange any relevant ad hoc maintenance and repairs. Equipment is often serviced on site but may need to be taken to Clinical Engineering base (where equipment is removed, we would always try and replace with like for like until repair is completed). For any equipment not covered by the SLA please speak with Medical Devices Safety Officer in the first instance for support on who to contact.

**Devices that have developed a fault or suffered accidental damage** should be removed from service immediately, or as soon as possible without introducing an unnecessary clinical risk and reported as appropriate.

13.3 Where maintenance and/or repairs to medical devices are carried out by external agents (Original Equipment Manufacturer or third parties), local records must be kept.

13.4 Any lengthy delay due to lack of availability of spare parts, for example, will be communicated to the users as well as Medical Devices Safety Officer, and assistance in accommodating any resulting downtime will be provided as far as possible, if necessary.

13.5 Before any medical device is put back into service following maintenance or repair, it will receive a safety test and basic functional test. The completion of the maintenance/repair will be recorded on the database.

13.6 Where the device is not covered by the SLA with STH - for example, where the device can only be maintained, serviced or repaired by the original device manufacturer, distributor or external provider (supplier) – contact should be made with the Procurement Department who will provide further advice. Devices not covered by STH should, generally, have a separate maintenance or service contract with the device manufacturer, distributor, or external provider (supplier).

13.7 Keeping medical devices safe and effective needs both routine maintenance procedures supervised by Trust users, and planned maintenance and repair carried out by suitably trained technicians.

13.8 Planned maintenance should follow manufacturer's guidance on procedures and staff training. Devices that require maintenance work must be cleaned and - where relevant - decontaminated before release.

## 14. Management of medical devices or equipment issued to patients

Medical devices or equipment issued to patients require special consideration as they will be used in a relatively uncontrolled environment by patients and/or carers who may not be familiar with the operation of medical devices and can be difficult to track. SHSC do not routinely provide equipment or medical devices that would not be maintained or monitored in some way by staff but on the rare occasion this may occur:

- It must be established that the patient and/or an appropriate carer is able to take responsibility for the safe use of the medical device
- Any training that is necessary in the operation of the device must be provided
- Arrangements for the provision of any consumables necessary for the continued use of the medical device must be made clear
- Any equipment loaned must be logged with a clear plan of any arrangements for return of the medical device, and any consequences of loss or damage to the device, should be made clear.

## 15. Non-standard medical devices

12.1 It is normally required that all medical equipment that is covered by the definition of a medical device in 2.2 is CE-marked to the Medical Devices Directive.

- In exceptional circumstances, it may be necessary to consider a non-standard solution to meet a specific clinical or research requirement.
- Such solutions may involve modification of an existing Medical Device; the use of a Medical Device other than for its Intended Purpose; the use of an existing device that is not CE-marked to the Medical Devices Directive; or the manufacture of a new Medical Device.
- Any such requirements must be discussed with Clinical Engineering, who will ensure compliance with all necessary guidelines and legislation, and completion of the necessary risk assessments.

## 16. Disposal of Medical Devices

Medical devices can be disposed of by one of three methods:
Transfer of ownership (very rare for SHSC)
Decommissioning
Disposal

### 16.1 Transfer of Ownership

Before sale or transfer of ownership of a device, both parties should thoroughly investigate the legal liability aspect. For example, the purchaser may inherit the liability for previous incidents or unpaid hire purchase costs if appropriate contracts are not used. A vendor may request the purchaser to sign a disclaimer to the effect that the vendor has no future responsibility for the medical device.
Alternatively, the product may be 'sold as seen' or 'buyer beware'. In these cases, liability is usually transferred to the purchaser. However, the vendor may retain contributory negligence. Support from Clinical Engineering would be required and essential for any transfer of ownership.

### 16.2 Decommissioning

The purpose of decommissioning is to make the device and environment safe prior to disposal of the device.

Any device deemed not reusable should be decommissioned. This should include decontamination, making safe, and making unusable. This is to ensure that an inappropriate person does not use the device and expose themselves to potential hazards. Medical Devices Safety Officer and Clinical Engineering will be able to support with this.

### 16.3 Medical Device Disposal

Medical devices for disposal by any route must be sent to Clinical Engineering. In the case of large fixed medical devices, Clinical Engineering must be notified of the intention to dispose of the device.

Clinical Engineering will confirm that there is no possibility of redeploying the medical device elsewhere in the organisation, or any value in retaining spare parts to support other similar devices before disposal takes place.

Clinical Engineering will ensure that where medical devices are scrapped, they are disposed of in accordance with local and national guidelines and legislation through the use of the approved STH/SHSC waste contractor.

Where there may be residual value and disposal via auction is appropriate, Clinical Engineering will pass on details to the Medical Devices Safety Officer, who can pursue further if required.

Some therapeutic equipment such as mobility aids etc will be approved for disposal by Medical Devices Safety Officer.

Whatever the disposal route, Clinical Engineering will ensure that the Inventory is updated accordingly and pass any details to Medical Devices Safety Officer.

## 17. Decontamination and Cleaning

### 17.1 Decontamination of Reusable Devices or Equipment Decontamination

Decontamination is a term used to describe the process of eliminating contaminants, which include micro-organisms and other unwanted material which would otherwise be conveyed to a susceptible site and cause infection. The effective decontamination of reusable devices is essential to reduce these infection risks. Decontamination methods will depend on the nature of the micro-organisms present, and the infection risk associated with the surface, equipment, device or procedure. All detailed procedures in relation to cleaning and decontamination can be found in the Decontamination – Environmental Cleanliness & Reusable Equipment Policy.

A written Departmental Cleaning Schedule (see above policy for detail), must be devised by each care area/department detailing equipment and medical devices used in the delivery of health & social care; specifying the persons responsible for cleaning, the frequency of cleaning, the expected outcomes and what cleaning method/product to use. Examples of equipment to include are mattresses, blood pressure monitors/cuffs, BM kits, ECG machines, couches, stethoscopes, thermometers, saturation probes, phlebotomy chairs, hoist etc.

17.2 Due regard & consideration prior to purchase of all reusable medical & therapeutic devices must be given to how an object or item is to be decontaminated appropriately between subsequent uses.

17.3 All medical devices/equipment must be decontaminated between each patient to prevent cross infection.

17.4 Use only decontamination methods advised by the manufacturer – using any other process might invalidate warranties and transfer liability from the manufacturer to the person using or authorising the process. If the manufacturer does not provide clear guidance for decontamination, please seek advice from the Medical Devices Safety Officer.

Once cleaned, staff can use decontamination stickers (ordered via NHS supplies) or decontamination certificates (found in the Trust's Decontamination Environmental Cleanliness & Reusable Equipment Policy) for tracking and auditing purposes.

## 18. Single Use Medical Devices or Equipment or consumables.

Devices or consumables designated for 'single use' must **never** be reused under any circumstances. The designated symbol for 'single use' is shown below and will be on the packaging or the device.

Some high-risk devices cannot be disinfected or sterilised and must be single use. Manufacturer's instructions must always be followed when using them. If a health or social care worker re-uses a single use device or consumable, they will transfer the legal responsibility for the safe performance & liability of the product from the manufacturer to themselves. After use these items should be disposed of as healthcare waste.

## 19. Consumables and Purchasing

Similarly to medical devices procurement, approved consumables for all equipment (related to medical devices) can be procured predominantly via two routes. These are via:

- NHS Supply Chain
- Centros (for all other suppliers)

### 19.1 NHS Supply Chain

For a person to be able to access NHS Supply Chain they must be an authorised person granted a specific budget allocation. Procurement will work with clinical areas in order to get a staff member established as a buyer on NHS Supply Chain. This must be approved by any line manager. NHS Supply Chain is on online catalogue of items that would be required in any and all health care settings. SHSC have recommended and approved consumables items that staff can access to buy for the respective clinical areas. Medical Devices Safety Officer has close links with Procurement to ensure staff are only able to buy recommended items.

### 19.2 Centros

As above Centros is an online platform for all other orders of approved health care providers. A person will need to be an approved user of Centros and any and all orders no matter of value will need to be approved by line manager and Procurement.

For any queries related to either medical devices or consumables always contact medical devices safety officer in the first instance.

## 20. Appropriate storage of medical devices and related equipment or consumables

To ensure that all clinical areas are following guidance from Infection, Prevention and Control (IPC) medical device items (equipment and consumables) should:

- Not be stored on the floor
- Not be stored in dirty or wet environments
- Not be stacked high or out of reach
- Where possible consumables should be kept in original packaging or boxes to both keep sterile and so use by dates can be easily viewed

Medical devices often come with accompanying consumables or accessories. It is essential that equipment and accessories are kept together.

Any items that have plugs or cables or power packs must be kept on charge or as indicated via manufacturing guidance. Both Clinical Engineering and Medical Devices Safety Officer can support here if there are queries.

### 20.1 Stock Rotation

To ensure consumable stock is appropriately utilised a regular stock check and stock rotation should be in place. This ensure items nearing their end of shelf life can be used first and any new stock is used later. By checking stock, it also ensures any damages or issues can be identified and rectified.

Each clinical area is responsible for the monitoring of equipment storage and stock rotation with guidance from Medical Devices Safety Officer as and when needed.

During regular preventative maintenance or ad hoc maintenance Clinical Engineering will also check dates and batteries for example.

## 21. Transportation of medical devices

It is essential that medical devices are transported appropriately to prevent damage, breakages, faults, loss etc. This is both for transportation to a clinical area and movement between local clinical areas. Please seek guidance from Medical Devices Safety Officer in first instance.

## 22. Incident reporting and related alerts

Any incident involving a medical device or medical equipment (including consumables) should be reported as detailed in the Patient Safety Incident Response Policy – done via SHSC electronic reporting system. Medical Devices Safety Officer is alerted electronically to any incident raised in relation to medical devices or equipment and will review respond accordingly. It is also good practice for staff to alert Medical Devices Safety Officer as soon as possible following incident to ensure appropriate steps can be taken at the time. All trust incidents are reviewed in the daily incident huddle and Patient Safety Team would be involved/notified.

22.1 If an incident needed rapid escalation the Trust alert response would be utilised. This is the Blue Light Alert Process (need link). Blue light alert allows for rapid cascade of information, and these are then stored on the Jarvis and can be accessed at any time.

22.2 Medical Device incidents may be reportable to MHRA for oversight.

22.3 MHRA reporting criteria is as follows:

- Someone’s injured (or almost injured) by a medical device, either because its labelling or instructions aren’t clear, it’s broken or has been misused
- A patient’s treatment is interrupted because of a faulty device
- Someone receives the wrong diagnosis because of a medical device
- A medical device is fake or counterfeit

22.4 Any medical device involved in an incident must be removed from service and quarantined immediately. The full details must be notified to STH Clinical Engineering who can support in quarantine and/or removal. Medical Devices Safety Officer must also be notified.

## 23. Alerts, Field Safety Notices, Alert Notifications (in relation to medical devices)

One of the key responsibilities of Medical Devices Safety Officer is to be able respond to and action (where required) any Alerts, Notifications, Field Safety Notices, CAS alerts etc. These alerts or notices are received by email to the Trust and then cascaded to the appropriate recipient (Medical Devices Safety Officer included). A full governance process is in place to manage and respond to all variety of received notifications via the trust electronic incident and alert platform. There is a separate process in place for management of CAS alerts (a central alerts-based system) and this process is managed by the Health & Safety Team, however actioned in the same via the electronic recording platform.

## 24. Supply Issue/Recall of product Notifications

Medical Devices Safety Officer will also receive disruption to supply/supply issue/Recall notifications. These are often sent from a company or supplier direct to Procurement or Estates (Stores Facility). They will then be sent on to Medical Devices Safety Officer for any required action.

## 25. Training and other resource implications

All staff joining the Trust will attend Core Mandatory Training as required for their role which will include some aspects of medical device training.

All staff should receive any appropriate or required training on medical devices and related accessories before clinical use.

Any new device will have an element of training that Medical Devices and Physical Health Team will oversee. Resources to support training/ongoing training will be provided.

## 26. MONITORING

Compliance with this policy is monitored through the Medical Devices Management Group, overseen by Medical Devices Safety Manager (accountable to Physical Health Management Group and then Physical Health Committee).

**Policy documents ordinarily should be reviewed every three years but it is appropriate to review Medical Devices Policy yearly due to constantly changing need due to legislative or practices change. The policy review date is 30th April 2024**

| **Monitoring Compliance Template** | | | | | |
|---|---|---|---|---|---|
| **Minimum Requirement** | **Process for Monitoring** | **Responsible Individual/ group/committee** | **Frequency of Monitoring** | **Review of Results process (e.g. who does this?)** | **Responsible Individual group committee for action plan development and monitoring** |
| Yearly Review of Policy | Review of full content of policy | Medical Devices Safety Officer | Annual | Medical Devices Safety Officer | Medical Devices Management Group<br><br>Physical Health Management Group<br><br>Physical Health Committee<br><br>Policy Governance Group |
| Stock rotation | Done on a routine basis by all clinical areas | Ward or clinical area staff team | Weekly/monthly | Ward or clinical area team | To link in with Medical Devices Safety Officer with any issues or problems |
| Incident reporting and monitoring | As and when required | Any area with an issue with a medical device or consumable | As and when required | | Medical Devices Safety Officer to review any and all incidents and support as appropriate |

## 27. Implementation Plan

| Action/Task | Responsible Person | Deadline | Progress Update |
|---|---|---|---|
| **Update current Medical and Therapeutic Devices Policy** | **Medical Devices Safety Officer** | **April 2024** | **Completed by April 2024** |
| **Send out to clinical groups for comment and approval** | **Medical Devices Management Group**<br><br>**Physical Health and Management Group**<br><br>**Physical Health Committee**<br><br>**Health & Safety Committee** | **April/May 2024** | |
| **Ratification of Medical & Therapeutic Devices Policy** | | | |
| **Make teams aware of new Medical & Therapeutic Devices Policy.** | | | |

## 28. Dissemination, storage and archiving (Control)

The policy is available on the SHSC intranet and available to all staff within 10 days of ratification. An "All SHSC" email alert will be sent to all staff. The policy will be sent to Clinical and Associate Directors for dissemination throughout the Trust. The integrated Risk/Governance Team will keep a paper & electronic version of the previous policy. Managers will be responsible for removing and replacing paper copies of the pol

## 29. Development, consultation and approval

This policy was reviewed and updated as part of an on-going policy review and revision process.

**Consultation:**
Members of the following groups were consulted for comment of the redevelopment of this policy:

- Medical Devices Management Group
- Physical Health Management Group
- Physical Health Committee
- Health & Safety Committee

**30. Verification:**
The policy was verified by the Chair of the Physical Health Commitee.

| Version No. | Type of Change | Date | Description of change(s) |
|---|---|---|---|
| 0.1 | New draft policy created/Approval and Issue | 11/2016 | Original version of Medical Devices Policy |
| 1.0 | Review | 03/2019 | Original Medial Devices Policy merged with Device Acquisition Process Document |
| 2.0 | Review/Approval | 04/2019 | Incorporates feedback from Andrea Wilson (Director of Quality) Document circulated to Medical Devices Group members for comment |
| 2.1 | Review/Approval | 04/2019 | Incorporates feedback from Helen Payne (Director of Facilities) Document circulated to Medical Devices Group members for comment |
| 2.2 | Review/Approval | 08/2019 | Incorporates feedback from Katie Grayson (Lead Nurse, Infection Control) and Charlie Turner (Deputy Physical Health Nurse) Document circulated to SUSG members for comment |
| 3.0 | Review/Approval | 09/2019 | Document amended to reflect proposed arrangements for outsourcing of maintenance, repair, & asset registration by STH Clinical Engineering, post BC approval by BPG (17.9.19) Comments incorporated/removed. References to |

| | | | |
|---|---|---|---|
| | | | documents checked and updated where necessary. Section 6.4.3 and Appendix K amended to reflect SHSC situation.<br>New Appendix E – SOP: Medical Device/Equipment Trials<br>New Appendix D – SOP: PAQs<br>New Appendix J – SOP: Receipt and Acceptance Testing of new medical/therapeutic devices<br>Other minor formatting changes. |
| 4.0 | Review/Approval | 09/2019 | Final editing based on comments received<br>Addition of Policy Authors<br>Removal of Appendix H - Medical & Therapeutic Devices Group ToR<br>Re-numbering of Appendices/update of Contents<br>Updating of Policy Checklist (Appendix F) |
| 5.0 | Review/Approval and Issue | 03/2020 | Confirmation of STH Clinical Engineering SLA references to support maintenance & repair, device acceptance and asset management. |
| 6.0 | Review and full amendments of policy | 03/2024 | Full overhaul and update of policy |

## 31. Links to other policies, standards (associated documents) and references

**Trust Associated Documents (located on the intranet site)**

- Patient Safety Incident Response Policy (October 2023)
- Safety Alerts Management Policy (May 2023)
- Procurement Policy (February 2022)
- Waste Management Policy (January 2021)
- Mandatory Training Policy (July 2022)
- Capacity and Consent to Care Support and Treatment Policy (May 2021)
- Physical Health Policy (March 2022)
- Back Care and Manual Handling Policy June 2021)
- Health and Safety Policy (June 2023)
- Infection Prevention and Control Policy (June 2023)
- Decontamination Policy October 2019 – review extension July 2024)
- Use of Bedrails on Inpatient Wards and in Nursing Homes Policy (February 2023)
- Resuscitation Policy (February 2024)
- Standard Operating Procedure Loan Maintenance of Internal Therapeutic Medical Equipment (October 2023)
- Standard Operating Procedure Loan Maintenance of Bariatric Medical Equipment (October 2023)
- Standard Operating Procedure Loan Maintenance of external Medical Equipment (October 2023)
- Department of Health (Regulating Medical Devices)

**Listed below are examples of legislation that might apply (in relation to medical devices).**

- Consumer Protection Act 1987
- Health and Safety at Work Act 2015
- The Lifting Operations and Lifting Equipment Regulations 1998
- The Medical Devices Regulations 2002
- The Health and Social Care Act 2008
- Medicines and Medical Devices Act 2021
- The General Product Safety Regulations 2005

**References**


- Care Quality Commission: Essential standards of quality and safety 2010
- Medical Devices Directive (MDD) 93/42/EEC as amended 2007/47/EC
- NHS England and MHRA. Improving medical device incident reporting and learning March 2014
- MHRA Devices in Practice
- Management of Health and Safety at Work Regulations 1999
- Health equalities and inclusion
- Artificial intelligence (AI) and machine learning
- Gov.UK. Guidance on when to notify the MRHA about medical devices
- GOV.UK, Product specific information for medications and medical devices

## 32. Contact details

| Title | Email |
|---|---|
| Medical Devices Safety Officer | Sharlene.rowan@shsc.nhs.uk |

# Appendix A

## Equality Impact Assessment Process and Record for Written Policies

**Stage 1** – **Relevance** - Is the policy potentially relevant to equality i.e., will this policy potentially impact onstaff, patients or the public? This should be considered as part of the Case of Need for new policies.

**NO** – No further action is required – please sign and date the following statement.
**I confirm that this policy does not impact on staff, patients, or the public.**

**I confirm that this policy does not impact on staff, patients, or the public.**

**Stage 2 Policy Screening and Drafting Policy** - Public authorities are legally required to have 'due regard'to eliminating discrimination, advancing equal opportunity, and fostering good relations in relation to people who share certain 'protected characteristics' and those that do not. The following table should be used to consider this and inform changes to the policy (indicate yes/no/ don't know and note reasons). Please see theSHSC Guidance and Flow Chart.

**Stage 3** – **Policy Revision** - Make amendments to the policy or identify any remedial action required and record any action planned in the policy implementation plan section.

| SCREENING RECORD | Does any aspect of this policy or potentially discriminate against this group? | Can equality of opportunity for this group be improved through this policy or changes to this policy? | Can this policy be amended so that it worksto enhance relations between people in this group and people not inthis group? |
|---|---|---|---|
| **Age** | No | No | No |
| **Disability** | No | No | No |
| **Gender Reassignment** | No | No | No |
| **Pregnancy and Maternity** | No | No | No |
| **Race** | No | No | No |
| **Religion or Belief** | No | No | No |
| **Sex** | No | No | No |
| **Sexual Orientation** | No | No | No |
| **Marriage or Civil Partnership** | **No** | | |

Impact Assessment Completed by: Medical Devices Safety Officer

Name /Date: Sharlene Rowan 15/04/2024

Please delete as appropriate: - Policy Amended / Action Identified (see Implementation Plan) / no changes made.

**Appendix B**

## Review/New Policy Checklist

This checklist to be used as part of the development or review of a policy and presented to thePolicy Governance Group (PGG) with the revised policy.

| | | Tick to confirm |
|---|---|---|
| | **Engagement** | |
| 1. | Is the Executive Lead sighted on the development/review of the policy? | Yes |
| 2. | Is the local Policy Champion member sighted on the development/review of the policy? | Yes |
| | **Development and Consultation** | |
| 3. | If the policy is a new policy, has the development of the policy been approved through the Case for Need approval process? | N/A |
| 4. | Is there evidence of consultation with all relevant services, partners and other relevant bodies? | Yes |
| 5. | Has the policy been discussed and agreed by the local governance groups? | Yes |
| 6. | Have any relevant recommendations from Internal Audit or other relevant bodies been taken into account in preparing the policy? | Yes |
| | **Template Compliance** | |
| 7. | Has the version control/storage section been updated? | Yes |
| 8. | Is the policy title clear and unambiguous? | Yes |
| 9. | Is the policy in Arial font 12? | Yes |
| 10. | Have page numbers been inserted? | Yes |
| 11. | Has the policy been quality checked for spelling errors, links, accuracy? | Yes |
| | **Policy Content** | |
| 12. | Is the purpose of the policy clear? | Yes |
| 13. | Does the policy comply with requirements of the CQC or other relevant bodies? (where appropriate) | Yes |
| 14. | Does the policy reflect changes as a result of lessons identified from incidents, complaints, near misses, etc.? | Yes |
| 15. | Where appropriate, does the policy contain a list of definitions of terms used? | Yes |
| 16. | Does the policy include any references to other associated policies and key documents? | Yes |
| 17. | Has the EIA Form been completed (Appendix 1)? | Yes |
| | **Dissemination, Implementation, Review and Audit Compliance** | |
| 18. | Does the dissemination plan identify how the policy will be implemented? | Yes |
| 19. | Does the dissemination plan include the necessary training/support to ensure compliance? | Yes |
| 20. | Is there a plan to:<br>i. review<br>ii. audit compliance with the document? | Yes |
| 21. | Is the review date identified, and is it appropriate and justifiable? | Yes |

**Appendix C**

Sheffield Health and Social Care NHS Foundation Trust

# Decontamination Certificate

Before any equipment is re-used or sent for repair or storage both within and outside Sheffield Health and Social Care premises or home it must be decontaminated (cleaned) and a certificate completed.

**The certificate must accompany the equipment: failure to comply will result in return of the equipment.**

| | | |
|---|---|---|
| Ward/Department: | | |
| Description of equipment: | | |
| Make: | Model: | Serial Number: |

Please select **ONE** box and tick accordingly:

| | |
|---|---|
| **To the best of my knowledge this equipment has NOT been in contact with potentially infected material e.g. blood, bodily fluidsand therefore has not been contaminated.** | |
| **This equipment MAY be contaminated by potentially infected material and has been decontaminated externally as per decontamination policy.** | |
| **This equipment MAY be contaminated but could not be decontaminated because, please give details** | |

The above pieces of equipment have been appropriately decontaminated following patient usage and are now ready for repair, service, storage or re-use.

Signature_____Date_____

Name_____Designation_____

## Appendix D – Flowchart of Lifecycle of Medical Devices