Policy:

MD 021 - Medical and Therapeutic Devices

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Policy Owner	Head of Procurement
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Document type	Policy
Document version number	V 5.0
Date of approval	27/04/2020
Approved by	Quality Assurance Committee (QAC)
Date of issue	10/05/2020
Date for review	30 April 2024 (extended from 20/04/2023 and 31/12/23)

Summary of policy
This policy sets out a comprehensive framework for the procurement and management and disposal of medical and therapeutic devices across the Trust. It also sets out the role of Trust services in managing their medical and therapeutic device assets and their relationship with the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Clinical Engineering Department at Sheffield Teaching Hospitals NHS Foundation Trust.

Target audience	(1) All Directorates, All SHSC staff including those on temporary or honorary contracts as well as Bank staff and students (2) Individuals working on behalf of the Trust, such as Independent Contractors, Sub-Contractors and representatives from other Partner organisations

Keywords	Medical and Therapeutic Devices, procurement, equipment, suppliers, evaluation, decontamination, maintenance, disposal, use.

Storage
Version 5.0 of this policy is stored and available through the SHSC intranet/internet. This version of the policy supersedes the previous version (V3 November 2016). 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.

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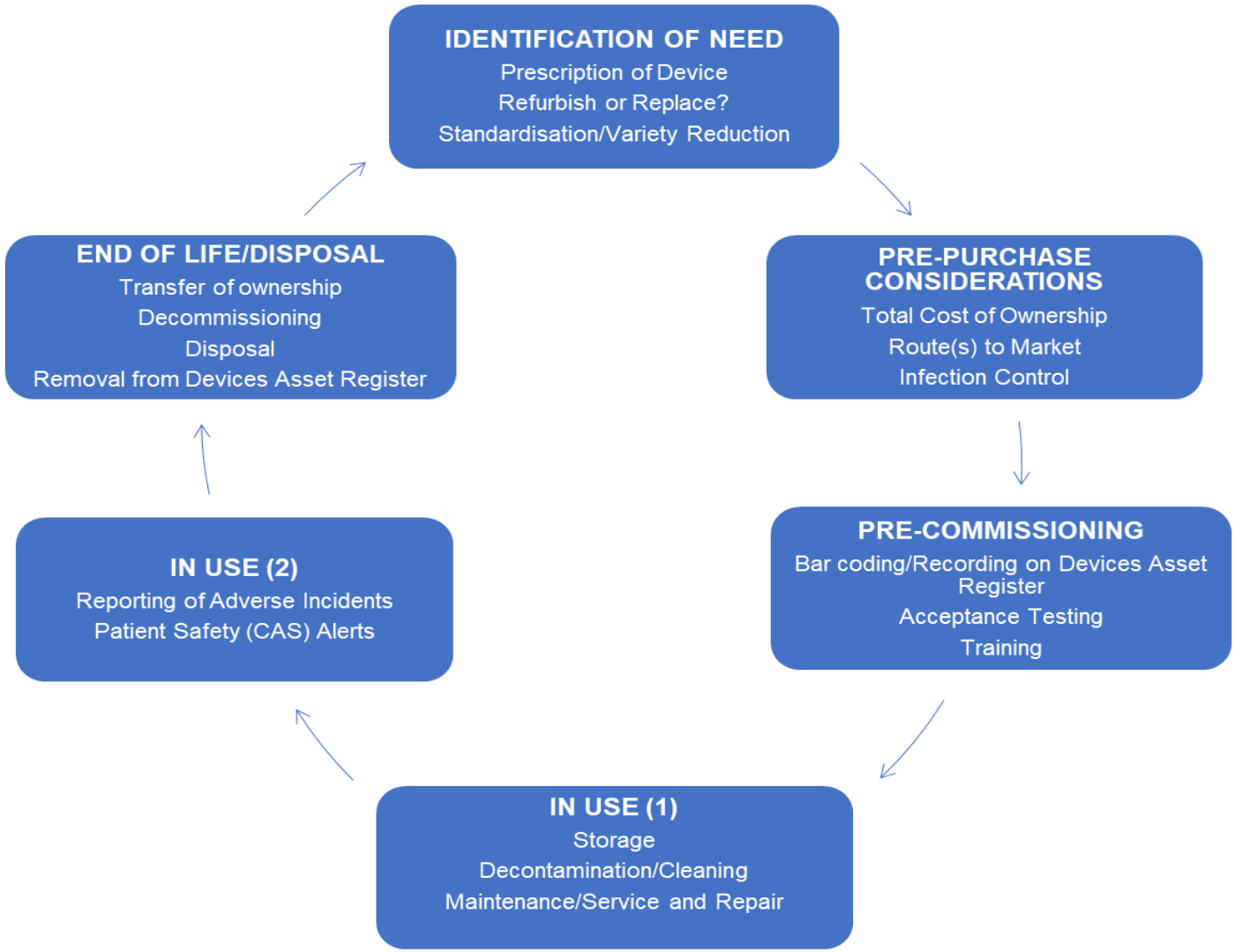
FLOWCHART – Medical and Therapeutic Devices



1 Introduction

This Policy sets out to establish a framework for the management of medical and therapeutic devices[1] utilised by staff[2] working for and on behalf of Sheffield Health and Social Care NHS Foundation Trust ('SHSC' or 'the Trust'). It also sets out, in detail, the role of SHSC's services, their relationship with the Medicines and Healthcare Products Regulatory Agency (MHRA), and the procedure to be adopted in the event of an adverse or potentially adverse incident involving a medical or therapeutic device.

Medical and therapeutic devices used by staff and patients must be:

- Suitable for (and only used for) their intended purpose and in accordance with all statutory standards;
- Operated by authorised users who have received appropriate training and are competent in the use of the device;
- Procured in accordance with the Trust's procurement procedures (as outlined in **Appendix C**) and in line with the Trust's Procurement Policy;
- Recorded on the Trust's Devices Asset Register (as part of the acquisition process);
- Maintained and/or serviced on (at least) an annual basis, or in accordance with guidance provided by the manufacturer or supplier. The device should always be kept in a safe and reliable condition;
- Decontaminated in accordance with the Trust's Decontamination – Environmental Cleanliness & Reusable Equipment Policy;
- Decommissioned and disposed of in accordance with the Trust's decommissioning, disposal and waste policies, and/or guidance provided by the manufacturer or supplier.

In order to mitigate adverse incidents involving medical and therapeutic devices and minimising any recurrence after an initial incident has been recorded, the MHRA collates information on all relevant adverse incidents, and as a result issues Medical Device Alerts (MDA) about hazardous medical devices; associated procedures of which are outlined in the Trust's Incident Management Policy and Procedure.

1.1 What are medical and therapeutic devices?

The term 'medical (or therapeutic) device' includes any instrument, apparatus, appliance, material or other article (excluding pharmaceuticals) whether used alone or in combination, together with any software necessary for its proper application, which is intended by the manufacturer to be used by a member of staff on a patient or by a patient, and/ or carer for the purposes of:

- The diagnosis, prevention, monitoring, treatment or alleviation of disease;
- The diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury or physical impairment;

[1] May be devices owned by the Trust, or on loan or on trial.

[2] Includes Permanent, Temporary or Honorary Staff, and individuals working on behalf of the Trust # (including Independent Contractors)

- Investigation, replacement, or modification of the anatomy or of a physiological process;
- Control of conception.
- Custom made appliances used in therapies, therapeutic activities and dental services.

Examples of medical and therapeutic devices used within the Trust are shown in **Appendix B**.

1.2 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 patient and promotes their independence. This will 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. If devices are advised which will result in a running cost to the service user e.g. electrical equipment, but the individual does not want to/is unable to fund the running costs, alternative equipment/care will be determined wherever possible. It will be recorded in the patient notes if consent is not given for devices to be used for any reason.
- Supporting the service user to understand how and why the equipment is being used. This includes ensuring that information about medical and therapeutic devices is provided in a format to meet the service user's/carer's individual requirements.
- Taking care in the way the equipment is used to make sure the service user is comfortable and safe. Individual requirements such as pregnancy 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. Preference for a male or female health professional will be taken into consideration wherever possible.
- Taking account of the training needs of service users with regard to any equipment they are given to use themselves.
- Using best interest provisions where required (refer to Capacity to Consent to Care Support and Treatment Policy).

2 Scope

This Policy applies to Trust staff and any staff providing services under contract or on behalf of the Trust in both hospital and community services who are involved in any aspect of medical and therapeutic devices use and management.

It applies to medical and therapeutic devices which are used in In-Patient services, in the community, and in service users' own homes.

The term 'medical' or 'therapeutic device' (see section 3) covers a wide range of products used every day in health care settings, hospital and care units, residential and nursing homes. A non-exhaustive list of the medical and therapeutic devices used within the Trust is included as **Appendix B**, which also identifies the main services involved in the use of medical and therapeutic devices.

3 Purpose

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

- are suitable for (and only used for) their intended purpose;
- staff are properly trained and competent in their use;
- devices are procured in accordance with Trust policies and procedures to minimise all risks associated with the acquisition and use of medical and therapeutic devices;
- devices are managed and maintained in a safe and reliable condition;
- all reusable medical/therapeutic devices are properly decontaminated prior to use and that associated risk with decontaminated facilities and processes are well managed;
- safety of service users and staff is enhanced by the use of processes, working practices and systemic activities that prevent or reduce the risk of harm to service users;
- the Trust fulfils the requirements of the Care Quality Commission, the Medicines and Healthcare products Regulatory Agency, and NHS Resolution (formerly NHS Litigation Authority).

The policy is set within the framework provided by MHRA's 'Managing Medical Devices; guidance for healthcare and social services organisations' (April 2015) and the relevant Care Quality Commission Fundamental Standards Regulations.

4 Definitions

Term	Definition
Central Alerting System (CAS)	The Medicines and Healthcare products Regulatory Agency (MHRA) operates the Central Alerting System[3], 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. 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.
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.
Department of Health and Social	A central government department, responsible for: • Supporting and advising ministers to help shape and

[3] https://www.cas.mhra.gov.uk/Home.aspx

Care (DH&SC)	deliver policy on health and social care; • Setting future direction to protect and improve global and domestic health; • Accountability, ensuring the department and its arm's length bodies deliver on agreed plans; • Act as guardians of the health and care framework, ensuring the legislative, financial, administrative and policy frameworks are fit for purpose; • Troubleshooting: in the last resort, taking the action needed to resolve crucial and complex issues
Diagnostic equipment	Equipment that is used to aid a diagnosis, including such items as sphygmomanometers or electro-cardiograph machines.
Field Safety Corrective Action (FSCA)	Actions listed as part of a Field Safety Notice that an organisation needs to take to reduce the specified risks of using the medical device that is the subject of the FSN.
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.
Good Manufacturing Practice (GMP)	The minimum standard that a manufacturer must meet in their production processes. Products must: • be of consistent high quality • be appropriate to their intended use • meet the requirements of the marketing authorisation (MA) or product specification
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. 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. Medical/therapeutic devices loaned or gifted specifically for use in Clinical Research (where that equipment is not the subject of the research) may be subject to different arrangements (**see Section 6.4.4**) **NOTE:** these arrangements are not suitable for clinical investigations where the equipment is the subject of the investigation. The insurance and indemnity arrangements for clinical investigations should be agreed through use of the model

	Clinical Investigation Agreement (mCIA).
Master Indemnity Agreement Register	A register of overarching MIAs entered into by suppliers with the Department of Health & Social Care. The up to date register can be viewed at https://www.gov.uk/government/publications/master-indemnity-agreement-mia
Medical device	Legally defined in the Medical Devices Regulations 2002 as an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which is intended by the manufacturer to be used for the purposes of: • Diagnosis, prevention, monitoring, treatment or alleviation of disease • Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or Physical impairment • Investigation, replacement, or modification of the anatomy or of a physiological process • Control of conception
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.
Medical Devices Safety Officer (MDSO)	A post specified within MHRA Directive NHS/PSA/D/2014/006, with the individual's contact details supplied to the CAS. The post supports local medical device incident reporting and learning and acts as the main contact for NHS E/I and the MHRA.
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.
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): 
Personal Identifiable Data (PID)	Information that, when used alone or with other relevant data, can identify an individual. This can include a hospital or NHS number for a service user.
Pre-Acquisition Questionnaire	A form developed by the Department of Health & Social Care which is issued by an NHS organisation to a supplier for

(PAQ)	completion **before** a purchase order is placed for a Medical or Therapeutic Device. The organisation will use the information provided about the Device to inform its pre-acquisition planning and approval of proposals to procure (whether by purchase, exchange, rental, lease, loan, donation or other agreement). **Note:** the term 'Device' as used here includes equipment, systems and accessories. In the case of systems the requirements apply both to the individual constituent Devices and to the configured system as a whole.
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.
Therapeutic equipment	Equipment that is used for the delivery of patient care and treatment.

5 Procurement – The Decision Making Process

5.1 Identification of Need

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.

5.2 Prescription of Devices

Trusts are responsible for ensuring that prescribing decisions are made by staff with appropriate professional qualifications and suitable experience. Procedures and policies should be introduced and managed to ensure that this is the case. Furthermore, they may wish to limit the range of devices a given professional group is allowed to prescribe.

Where joint working arrangements are in place and involve the crossing of professional boundaries in prescribing, the Trust will clarify where professional and legal responsibilities for prescription lie, particularly in relation to the monitoring of the equipment and the medical condition of the end-user.

Administrative and technical support can help prescribers to avoid hazards. Computer databases – such as the Devices Asset Register - can be used to build in certain

safeguards in relation to safety, based on the information about the equipment supplied by the manufacturer.

EXAMPLE

An example of this would be recording the manufacturer's maximum weight capacity of hoists or commodes on a computer record. When a request is input either directly by a prescribing professional or by an administrative support person for such equipment, the computer requires the inputting of the proposed user's weight. The request may then not be accepted by the system if the weight of the user exceeds the upper stated weight-bearing capacity of the equipment.

When prescribing and fitting take place in separate locations and involve different people/organisations, then a technician may sometimes need to refer patients back to the clinician if the device proves unsuitable either initially or on follow up. Consideration should be given to allow the technician to share some of the responsibility for choosing the most appropriate device.

5.3 To refurbish or replace?

For all medical devices a stage is reached at which replacement must be considered. An informed purchasing decision involves making an estimate of the likely length of life of a device (see **Table 1**).

The estimated 'life' of a device will be recorded on the Devices Asset Register. There should be a further procedure for determining when a device should be decommissioned; for example, on inspection of the device once the estimated length of 'life' has elapsed. If any of the following criteria apply, the device may be regarded as no longer serviceable:

- Worn out beyond economic repair;
- Damaged beyond economic repair;
- Unreliable (check service history);
- Clinically or technically obsolete;
- Spare parts no longer available;
- More cost-effective or clinically effective devices have become available.

If the device survives this test, a date should be set for re-testing say, in a year's time.

The simplest type of purchase involves adding to existing stock or replacing worn out devices. Within this category, the simplest decision is to buy the make and model currently in use. The case for purchase and tendering, servicing and training arrangements is covered elsewhere in this document.

Considerable savings and benefits result if a single product model is used for a given application throughout an organisation. Maintenance is simplified and safety is optimised because user errors resulting from confusion between similar devices are eliminated. However reliance on a single model can cause problems if there is a sudden failure, or a manufacturer's recall of faulty devices, or if a manufacturer goes bankrupt or withdraws a product line. It can also weaken Procurement's negotiating

position with the supplier. In any event for certain products (such as wheelchairs), different models may best suit the needs of individual end-users.

Technological change may mean that more recently designed models have significant advantages in terms of safety, performance, or value for money which outweighs any extra expenditure involved in tendering, training and maintenance. If the decision is taken to replace or add to stock with a new make or model, then the process moves on to evaluation and selection of the device.

5.4 Evaluation and Selection of New Equipment

5.4.1 Evaluation – establishing Total Acquisition Costs (Price v. Cost)

Proper evaluation of devices prior to purchase is required to ensure that purchases are justified. Before moving on to selecting a device for purchase it is important to make a realistic estimate of the total costs of acquiring a piece of equipment for its whole life. 'Total' costs include such things as maintenance, training, and running costs. It is important to ensure that the likely benefits outweigh these costs. **Table 2** shows an example of a 'total' costs checklist.

5.4.2 The case for standardisation and variety reduction

As previously described there are 'fors' and 'againsts' for standardising on medical and therapeutic devices. Consideration should always be given to the range of similar equipment already in situ in the Trust. Additionally, issues regarding staff familiarity and training and subsequent clinical risk should be taken into account.

It is good procurement practice to identify and rationalise the range of products in use within the Trust. Excess diversity can be expensive and standardisation on items of common use can make savings both in maintenance (spares) and consumables costs.

Standardisation on medical devices will be considered in order to achieve best value for money, to minimise the amount of training/re-training as staff move between areas of work and, ultimately, to reduce clinical risk. The following describes the methodology for standardisation of devices that will be adopted by the Trust.

a) The current range of devices in use across the Trust will be reviewed, and a 'Standardisation Plan' produced by the Medical & Therapeutic Devices Group. This would include prioritising the order in which devices will be considered.

b) Clinicians and other members of staff involved in using the device(s) would be invited to represent their area on the Medical & Therapeutic Devices Group. Where one area has a clear clinical 'specialism' in use of the device(s), they will be regarded as the lead on any discussions.

c) The Medical & Therapeutic Devices Group will devise generic specifications for the device(s), agree evaluation criteria, be a focal point for trialling equipment (if required), and participate in the evaluation of tenders received.

d) Once the recommendation as to the future standard of device(s) to be purchased has been made it will be detailed in a 'Best Buy Guide' that will be published on the Procurement page on the Trust's intranet site.

e) Proposals for increasing the range of devices available to the Trust, or deleting items from the available range or requesting additional items, will be agreed by the Medical & Therapeutic Devices Group and actioned by the Procurement Department.

f) The purchasing arrangements for any new or alternative product - whether contractual or in the form of a 'best buy guide' - will be adhered to.

g) In the case of "non-contract" devices being considered, advice will be sought from the Medical & Therapeutic Devices Group.

5.4.3 Product/Equipment Trials

Staff need access to adequate information in order to make an informed decision, particularly regarding new products which may be being considered. Randomised trials are the best way of assessing the effectiveness of medical devices in the practical situation. All trials must be conducted in accordance with relevant legislation and guidance, including the Trust's Standing Orders and Standing Financial Instructions, and Trust Procurement Policy.

The Standard Operating Procedure for product/equipment trials can be found at **Appendix I.**

The Product Trial Request and Evaluation form can be found at **Appendix E**.

New or alternative products to those listed on any 'best buy guide' will be considered by the Medical & Therapeutic Devices Group. They will also determine what appropriate trials and evaluations will take place prior to a decision being reached as to whether a device will be added to the 'best buy guide'. If a product has been trialled in another Trust the Medical & Therapeutic Devices Group may choose to accept the evaluation of the trial and thereby a decision be taken to change to an alternative product.

Samples of medical devices and consumable must only be left on Trust premises with the express permission of the Head of Procurement. All samples must be CE (Conformité Européene) marked. CE markings are an indication that the product has undergone some form of verification and validation process acceptable to the EU. Product indemnity must be sought in all instances (see section 7.3.2 below).

Any commercially sponsored trials/agreements must be advised through to the Procurement Department to ensure that:

- Trials are carried out in accordance with Trust guidelines for trials;
- Trials are carried out on a controlled basis;
- The product in question meets the appropriate safety standards;
- Trials are not duplicated;
- Accurate records of the trialled products and evaluation reports are kept.

Trials of equipment will only be undertaken within a clear framework for the evaluation process, identifying the key criteria that are to be assessed. This framework must be agreed in advance with the Head of Procurement and/or specific Category Manager/Buyer, and only after a source of funding has been formally agreed.

Unmonitored equipment trials may compromise existing contracts and may open the Trust to a procurement challenge with legal consequences if not notified to the Procurement Department.

Confirmation that the supplier is listed on the National Master Indemnity Agreement (MIA) should be sought prior to the trial of all medical equipment. If they are not, suppliers must register on the MIA prior to the trial to minimise the Trust's liability should the equipment malfunction and cause harm or misdiagnosis. This is in addition to the standard disclaimer form required for all trials.

The Trust requires that all medical equipment be obtained via the Procurement Department. This includes all equipment on loan (refer to the relevant section in this Policy).

Under no circumstances should medical equipment be delivered directly to a ward or department without the prior knowledge of the Procurement Department. The ward/department using the equipment should assure themselves that the process described above has been followed. The purpose of the Indemnity is to ensure the supplier is responsible for the equipment and use on patients whilst it is on Trust premises for the trial.

Where the decision has been made to procure equipment, weighted evaluation criteria will be agreed in advance with Procurement and Finance in order to enable the selection process. A clear distinction will be agreed between 'qualitative', 'quantitative' (where appropriate), 'technical' and 'financial' aspects. This will enable the whole-life costs to the Trust of owning the equipment to be assessed in conjunction with the suitability of the equipment for its intended purpose.

Contracts will only be let once relevant Budget Managers have reviewed the capital aspect and Budget Holders have confirmed their acceptance of all revenue consequences for the procurement, including those for maintenance, consumables and eventual disposal (where applicable). Any medical device to be purchased by the Trust will be subject to acceptance of the Pre-Acquisition Questionnaire (PAQ) issued to the supplier and verified/accepted by the Trust, prior to purchase.

5.4.4 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.

For further guidance on HRA Approval and other projects, please see:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/
For model agreements relating to various research scenarios please see
http://www.ukcrc.org/regulation-governance/model-agreements/

6 Duties

Roles	Responsibilities
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; • Review allocation of resources to meet identified needs in relation to medical/therapeutic devices management; • Ensure compliance with the relevant CQC outcomes for medical equipment, the MHRA's Managing Medical Devices guidance, and the relevant risk management standards for the Clinical Negligence Scheme for Trusts in relation to Medical/Therapeutic Devices.
Trust Medical and Therapeutic Devices Group	• Ensure there are safe systems in place to minimise the risks associated with the acquisition, use, maintenance, training & decontamination of medical and therapeutic devices; • To promote a structured approach to the evaluation, procurement, training, maintenance and disposal of medical equipment within the Trust; • To consider all issues relating to the management of medical and therapeutic devices including standardisation, promoting ownership and responsibility of device management at a network level, managing Medical Device Alerts and facilitating the audit process; • To work in partnership with all other stakeholders; • To provide assurance of process and risk management in relation to the evaluation, procurement, training, maintenance and disposal of medical equipment within the Trust; • To report by exception to the Trust's Service User Safety Group where escalation of a safety issue relating to a medical or therapeutic device is required. The Terms of Reference for the Medical & Therapeutic Devices Group can be found on the Trust's Intranet site.
Medical Devices Safety Officer (MDSO)	A post specified within MHRA Directive NHS/PSA/D/2014/006, with the individual's contact details supplied to the CAS. The post supports local medical device incident reporting and learning and acts as the main contact for NHS E/I and the MHRA.
Physical Health Team	Oversees links with Trust policies (e.g. Medical & Therapeutic Devices Policy) that have physical health

Roles	Responsibilities
	elements. Oversees standardisation of physical health measurement/monitoring equipment across the Trust. Ensures all staff have appropriate physical health assessment training.
Procurement Team	Will work with Trust staff to improve adherence to good procurement practices and to ensure compliance with this Policy. Responsibilities of respective Procurement managers will include: • Conducting procurement activities in accordance with the Standing Orders/Standing Financial Instructions/Scheme of Delegation framework and any other relevant governing legislation; • Working with Trust Budget Holders/Managers to ensure that total cost of ownership (e.g. initial costs, consumables, on-going support/maintenance, disposal costs) have been fully identified and costed; • Managing the evaluation and assessment of goods and services (including equipment trials), ensuring that relevant indemnities and indemnity cover has been identified and applied; • Raising requests for non-standard equipment with the Medical and Therapeutic Devices Group for advice/approval; • Ensuring that relevant pre-purchase documentation (e.g. PAQ form) is: o issued to the supplier; o returned and assessed by STH Clinical Engineering Department; o advice and recommendations based on the PAQ evaluation are shared with the Budget Holder/Manager and acted upon prior to purchase; • Liaising to ensure Medical Devices are asset tagged and registered upon installation and commissioning; • Liaising with STH Clinical Engineering Department regarding on-going maintenance and support; • Liaising with the relevant departments regarding decommissioning and eventual disposal of the

Roles	Responsibilities
	Medical Device (in accordance with the Trust's Waste Management Policy[4]); • Ensuring relevant maintenance and support contracts are cancelled on decommissioning/disposal of the Medical Device; • Managing supplier engagement with particular emphasis on contract and performance management of suppliers via regular review meetings, supporting clinical colleagues.
Trust Estates Department (including Transport Services)	• Management and staffing of the receipt point at President Park where medical and therapeutic devices may be delivered prior to commissioning; • Arranging onward delivery of devices to the Customer department that have passed delivery and commissioning checks; • Liaising with the Procurement Team regarding receipt and onward delivery of devices; • Disposal of the Medical Device (as required and in accordance with the Trust's Waste Management Policy).
Clinical Engineering Department, Sheffield Teaching Hospitals	• Provision of maintenance, repair and asset management services on the range of medical and therapeutic devices in use in SHSC; • Verification of Pre-Acquisition Questionnaires (PAQs) completed by potential suppliers of devices to SHSC at the request of SHSC prior to acquisition; • Provide technical checking and acceptance/ commissioning of new devices purchased by SHSC; • Management of an asset register of devices purchased by and in use in SHSC ('SheffMed'); • Provide support to the decommissioning and disposal process of devices (as required); • Attendance at meetings of the SHSC Medical & Therapeutic Devices Group as a formal member of the Group; • Undertake annual review meetings with SHSC representatives to evaluate progress and delivery and support the cycle of equipment renewal/ replacement and planning of capital/revenue spend;

[4] On the Trust's intranet site (EST 002 Waste Management): https://nww.xct.nhs.uk/media/Documents/Policies/Facilities/Waste%20Management%20Policy/EST%20002%20-%20Policy%20Waste%20Management.pdf

Roles	Responsibilities
	• Providing ad-hoc advice on medical and therapeutic devices where required.
Trust Infection Control Team	• Provide input into the Medical and Therapeutic Devices Group, advising accordingly in line with this Policy and other related policies and procedures; • Operationally, providing support to the acquisition process by evaluating PAQ forms (as required); • Providing advice and recommendations based on the evaluation of the PAQ form; • Providing on-going advice on infection control matters whilst the Medical Device in 'in use' including cleaning, and decontamination in the event of sending the Medical Device for repair; • Providing advice on infection control matters involved in the decommissioning of the Medical Device (as required); • Providing advice on infection control matters involved in the disposal of the Medical Device (as required and in accordance with the Trust's Waste Management Policy.
Trust Data Protection Officer	• The Trust Data Protection Officer is responsible for: • Evaluation of PAQ forms (as required); • Providing advice and recommendations based on the evaluation of the PAQ form; • Providing on-going advice on data protection matters whilst the Medical Device in 'in use' including in the event of sending the Medical Device for repair; • Providing advice on data protection matters involved in the decommissioning of the Medical Device (as required); • Providing advice on data protection matters involved in the disposal of the Medical Device (as required and in accordance with the Trust's Waste Management Policy).
Service Directors/ Senior Departmental Managers or their nominated representatives	• Ensure that staff working within their area of responsibility adhere to this policy; • Ensure that staff undergo training and are competent to use the medical/therapeutic devices within their area of responsibility; • Monitor training relating to the management of medical/therapeutic devices; • Action any hazard and safety notices (refer to CAS Policy) and comply with any guidance on

Roles	Responsibilities
	changes to the use of a device; • Ensure that all Delegated Budget Holders, Budget Managers and Authorised Signatory staff within their area of responsibility adhere to the procurement processes outlined in this policy, update them in regard to any changes, and ensure that procurement activity carried out in their area is compliant with all relevant Trust policies and procedures; • Ensure clinicians are consulted with respect to the procurement of medical/therapeutic devices; • Ensure that STH Clinical Engineering Department is notified of all changes to equipment in use by clinical services in a timely manner to support maintenance of an accurate Devices Asset Register.
All Personnel (Including Permanent, Temporary or Honorary Staff. Also includes individuals working on behalf of the Trust including Independent Contractors)	• Fully implement this policy and bring to the immediate attention of Managers any issues affecting the effective implementation of this policy; • Deliver personalised care through the use of 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; • Take account of the training needs of service users/carers with regard to any equipment the service user/carer is given to use themselves; • Report incidents and near misses involving medical and therapeutic devices via the RM electronic incident 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; • Ensure that single use medical/therapeutic devices

Roles	Responsibilities
	are never reused; • Ensure they have received sufficient training i.e. verbal and/or written instructions and are competent to use a medical or therapeutic device before attempting to operate it. If there is any doubt, the member of staff should consult their Manager and the manufacturers' instructions; • All prescribing decisions involving medical and therapeutic devices will be made by staff with appropriate professional qualifications and suitable experience; • Ensure that all Trust equipment is used and handled appropriately to ensure that unnecessary expenditure on replacement is kept to a minimum; • Adhere to standard Infection Control and Decontamination Procedures; • Every member of staff must have ownership and responsibility for minimising the impact of risk.

7 Procedure - Procurement – The Acquisition Process

There are four main methods of acquiring medical devices:

- By purchasing the device;
- By leasing the device;
- By loaning the device from a manufacturer/supplier or other NHS organisation; and
- By accepting the device as a donation or purchasing a device using donated monies.

7.1 Purchasing

The Procurement Policy (available on the Trust's Intranet site) details the procedure involved for purchasing goods and services, and should be consulted as part of the decision making process.

Table 3 provides a useful checklist when ordering equipment.

7.2 Leasing

In simple terms, leasing is a method of financing the acquisition of a piece of equipment. There are steps to be taken, and rules and regulations that need to be considered along the way, but time invested in understanding some of the basic principles **before** tendering commences will pay dividends in the long term, especially as there are financial advantages to be gained.

The types of assets that can be leased within the NHS are limitless. Small pieces of medical equipment to 'mobile' operating units, ambulance vehicles and large pieces of medical equipment, are all common items procured under lease within the NHS.

If considering leasing a piece of equipment, it is *strongly advised* that you seek the assistance of SHSC Finance and Procurement Departments.

7.3 Devices on Loan

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 (see example below)

EXAMPLE

A clinical engineering unit manager was called out to repair an electrically operated Airflow mattress after a breakdown. The mattress proved to be on loan from a manufacturer, the loan having been negotiated by ward staff without reference to either the Procurement or the Clinical Engineering department. Concerns included the lack of electrical safety checks, the non-availability of manuals, possible effects on purchasing decisions, and liability in the event of an adverse incident.

Managers should therefore ensure that device management systems and procedures include requirements for:

- Liaising with SHSC Procurement when the acquisition of loaned equipment is anticipated, including the signing of indemnity agreements and definition of the Trust's liability in the event of loss or damage to the device;
- Registration of loaned equipment, including ownership, service history, current location, service responsibility, and instructions for use;
- Initial acceptance checking of loaned equipment prior to putting into service, in accordance with manufacturers' instructions;
- Provision of instructions for use (and updates) to end users;
- Periodic checking of loaned equipment for functionality and safety and repair in accordance with manufacturers' instructions, whether by the Trust, owner/manufacturer, or a third party;
- Clear definition of responsibilities for the maintenance, repair and regular safety checks of loaned equipment (including identifying the person(s) responsible for initiating the testing of the equipment and those responsible for performing the testing);
- Adequate instructions regarding decontamination/sterilisation of re-usable equipment and availability of appropriate equipment/facilities for the Trust to carry out the process;
- Identification and withdrawal or return of unwanted or obsolete loaned equipment.

- Contact the Trust's Procurement Department for advice whenever considering purchasing contracts that include the loan of equipment and/or accessories from a third party;

- Ensure that signed indemnity agreements are obtained for rented, loaned or borrowed equipment (including equipment on trial) **BEFORE** being put into service.

7.3.1 Handling of equipment on loan from another organisation

A lack of awareness of the need to control loaned equipment can lead to delayed or cancelled patient treatment. In the past, concerns have been expressed over the decontamination status of such equipment and the lack of accompanying documentation.

The following sets out the responsibilities of the Trust in this regard.

Trust's Responsibilities

- Ensure that appropriate procedures are put in place and followed, to manage the use of loaned equipment.

- Check that indemnity forms have been completed and that responsibilities for the equipment have been identified and documented.

- Ensure that loaned equipment is included in the Trust's manual handling and/or decontamination policy.

- Ensure that systems are in place to allow equipment to be tracked through the decontamination processes and to the patient upon which it is used.

- Ensure that adequate time is allowed to carry out effective decontamination both prior to and after use.

- Decontaminate all loan equipment both before and after use in accordance with the manufacturer's instructions.

- Ensure that loaned equipment is accompanied by relevant reprocessing instructions. If these are missing or if you do not have the facilities to follow them (e.g. inappropriate sterilisation times are quoted) the equipment should not be used.

- Do not send contaminated equipment through the post.

Further information and guidance can be found in the Trust's Decontamination - Environmental Cleanliness & Reusable Equipment Policy (on the Trust Intranet).

Equipment may be loaned to the Trust so that a particular procedure can be performed. The equipment is loaned both from manufacturers and other Trusts and is returned after use. This practice increases the risks associated with the decontamination and reprocessing of such devices because the Trust may not be familiar with them. General guidance on third party handling and decontamination of devices has previously been issued by MHRA, DH&SC and others, including:

- DH&SC: Decontamination of surgical instruments (HTM 01-01);
- MHRA: Managing Medical Devices; Guidance for healthcare and social services organisations (April 2015);
- Health and Safety Executive: Methods of decontamination
- DH&SC: Health and Social Care Act 2008: code of practice on the prevention and control of infections

7.3.2 Indemnity Forms (MIA Call-Off Agreements)

Advice on the use of Indemnity Forms/MIA Call-Off Agreements can be obtained through the Procurement Department. The DH&SC have also produced a set of Master Indemnity Agreement Guidance Notes

The Indemnity Form (now more commonly referred to as the MIA Call-Off Agreement) provides protection to the Trust when the Trust is in receipt of equipment or goods from a supplier in cases where the equipment is being loaned to the Trust or where the ownership of goods is being transferred free of charge to the Trust. The basis on which the goods are supplied is set out in the MIA Call-Off Agreement. The Agreement should be completed by the Trust and supplier each time a piece of equipment is provided under these arrangements. Failure to complete an MIA Call-Off Agreement in relation to a piece of equipment will mean that the parties will not get the protections afforded by the arrangements in relation to the equipment. For example; the Trust would not get the benefits of the relevant indemnity provisions and the Supplier would not get the benefit of the legally binding commitments given by the Trust and the contractual limitations of liability as set out in the MIA Terms and Conditions.

Where a supplier has entered into an Overarching Master Indemnity Agreement with the DH&SC, this means that the DH&SC has checked the supplier's insurance arrangements so they do not need to be checked again by the Trust at the point that the supplier enters into an MIA Call-Off Agreement. Standard practice is for all suppliers to enter into an Overarching MIA with the DH&SC before entering into any specific MIA Call-Off Agreements.

The Trust should routinely check the MIA Register when a supplier completes an MIA Call-Off Agreement to confirm the supplier's Overarching MIA registration is still valid and its insurance is showing as current. If a Supplier is party to an Overarching MIA this will be noted on the MIA Register published at: https://www.gov.uk/government/publications/master-indemnity-agreement-mia If a supplier's Overarching MIA is shown as having expired in the Register, a check should be made with DH&SC as to whether a new indemnity form is in the process of being processed BEFORE continuing with a trial or loan.

NB. The use of an Indemnity Form does not remove the need for manufacturer's quality control inspection, or for acceptance tests conducted by the borrower.

These arrangements are not suitable for clinical investigations where the equipment is the subject of the investigation. The insurance and indemnity arrangements for clinical investigations should be agreed through use of the Model Clinical Investigation Agreement (mCIA) published by the UK Clinical Research Collaboration.

7.4 Donations to the NHS

For further advice and guidance on donations, contact SHSC Procurement. 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).

7.5 Pre-Acquisition Questionnaires (PAQs)

The purpose of the Pre-Acquisition Questionnaire is to provide information to the Trust about a medical device which the Trust can then use to inform its planning and approval of proposals to procure the device (whether by purchase, exchange, rental, lease, loan, donation, or other agreement). The term 'device' as used for the PAQ includes equipment, systems and accessories. In the case of systems, the requirements within the PAQ form (see **Appendix G**) apply both to the individual constituent devices and to the configured system as a whole. Accessories within the scope of the PAQ have to be identified separately within the form.

The Standard Operating Procedure for Pre-Acquisition Questionnaires can be found at **Appendix K**.

The PAQ form is issued by the Procurement Department to a supplier or manufacturer for completion as part of the decision-making process to select a device, i.e. **BEFORE issuing a purchase order**. Once the completed form has been received back into the Trust the responses given by the supplier/manufacturer have to be considered as the decision whether or not to go ahead with the acquisition will be based on their advice.

The PAQ unique reference number must be quoted on all purchase orders, together with the following statement:

> *'This order is placed on the understanding that the PAQ reference quoted is correct for the equipment described. If it has been updated, the buyer must be contacted immediately and advised of the change. Adverse changes may result in this order being cancelled.'*

This is to ensure that the supplier's/manufacturer's statements in the PAQ are incorporated into the contract for supply, and the Trust is protected if these standards change. The use of the reference number also obviates the need for repeated update requests for a PAQ which has not changed.

Returned/completed PAQ forms and any related documentation will be scanned and held on the Devices Asset Register maintained by the Trust's equipment maintenance and support supplier (STH Clinical Engineering). The information will be accessible by Procurement and ward managers. Procurement will also hold a register of PAQ forms.

7.6 Guidelines on Infection Control - Decontamination Evaluation & Risk Assessment Form

The Form (see **Appendix M**) acts as an '*aide memoire'* for Trust staff on issues to consider prior to purchase that relate to infection control and, specifically, how an item

will be decontaminated/cleaned during normal use. Staff should familiarise themselves with it particularly as a requisition will not be processed into a purchase order unless the Form has been completed by the requestor to affirm that infection control issues have been taken into consideration prior to purchase.

The completed Infection Control Forms will be retained by the Infection Control Team and form part of the device record on the Devices Asset Register.

8 Delivery, Acceptance, Storage and Training on Use of Medical and Therapeutic Devices

8.1 Delivery for Acceptance Testing

All medical and therapeutic devices will be delivered to the Trust's receipt point at President Park to enable acceptance checks to be carried out. Acceptance testing that is to be undertaken by STH Clinical Engineering Department will be carried out before the device is transported to its final destination.

In exceptional cases – for example where handling the device may cause an issue (e.g. due to weight, delicate nature of the device) - the device will be delivered directly to its final destination. However the device **MUST NOT BE USED** before full acceptance checking has been completed by the relevant department.

8.2 Acceptance Testing

Acceptance checks aim to weed out faulty products and those damaged in transit. Tests to discover whether a device is suitable for its intended application, or whether it complies with standards, are inappropriate after delivery; this information must be generated before the device is purchased.

Some checks (e.g. for visible damage, and that the order is complete) can be carried out by receipt point or administrative staff. Functional checks will be carried out by STH Clinical Engineering Department under suitable instructions. Calibrations and safety tests should only be carried out by specially trained staff. Large complex devices may require specialists to install and commission them. **In any event, an item should not be used until it has undergone the appropriate acceptance testing.**

When a new device is first put into service records need updating, staff need training and planned preventative maintenance needs putting in place. Users of the device should be aware when they are the first person to use it.

Table 4 provides basic guidance on what checks and tests should cover, and the skills required to carry them out. These checks will be dependent on device type.

Table 5 is a suggested checklist for putting new devices into use.

All devices coming into the Trust - whether they have been purchased, leased, rented, on loan, or on trial - should be treated in the same way.

8.3 Storage

Inappropriate storage of items affects their subsequent safe use. Suppliers' or manufacturers' information and instructions both on storage conditions and shelf life should be followed.

Table 6 is a suggested checklist on suitable storage conditions.

8.4 Training

Trust Management is responsible for ensuring that all relevant staff are trained in the safe use of all equipment; in the case of equipment for lifting and handling, the Trust has a duty of care.

8.4.1 Training for Trust Staff users of the device

The Service Manager is responsible for:

- Ensuring that user training is received by the appropriate staff, and documented.
- Comprehensive records of technical and mandatory training **must be kept**.

8.4.2 Training for Technical Staff (STH Clinical Engineering)

Technical training for STH Clinical Engineering's staff will be the responsibility of Sheffield Teaching Hospitals NHS Foundation Trust, as detailed in the Service Level Agreement between the trusts.

8.4.3 Training for End Users/Service Users/Carers

The Trust should be aware that a failure to pass on the manufacturer's original instructions on how to use a device to the end-user/service user/carer may not only compromise their ability to use the device safely, but instructions on the use of a device should be suitable for end-users/service users/carers. Where necessary these may need to be explained or adapted. Anyone who will use the device that has particular disabilities or medical conditions will need special instructions and training from their prescriber.

8.4.4 New Devices

When new models of medical devices are delivered into the Trust, all technicians (where appropriate) should have the opportunity to familiarise themselves with the fundamental operation of the device.

9 Decontamination and Cleaning

9.1. Decontamination

Reference should be made to the Trust's Decontamination Environmental Cleanliness & Reusable Equipment Policy.

It is the responsibility of the Trust to ensure that all medical devices do not carry a biological or chemical hazard. The Trust has a duty to ensure that decontamination of any device is applied before re-use, submission for maintenance, or repair, and before being transported to another location.

A completed Decontamination Certificate (found in the Trust's Decontamination Environmental Cleanliness & Reusable Equipment Policy).should indicate the state of decontamination.

9.2 Cleaning

All medical devices will fall into specific categories on how to clean and disinfect the particular device. The cleaning agent to be used will be dependent upon the category to which the device belongs.

Information on both decontamination and cleaning of the device will have been obtained prior to purchase using either the Pre-Acquisition Questionnaire or the Decontamination Evaluation & Risk Assessment Form (**Appendix M**).

The Service Manager is also responsible for ensuring that staff allocated to cleaning and/or decontaminating the device have received full training and guidance on cleaning/decontamination methods, in accordance with the manufacturer's or supplier's guidelines (contained in the PAQ response). Access to cleaning/decontamination information and other related information (such as COSHH data sheets) will be made available in the area where the cleaning or decontamination takes place.

10 Medical Device/Equipment Maintenance

10.1 User Checks

Trust staff are responsible for in-use pre-checks, regular cleaning, and preparation for use. This includes checking the 'last maintained date' record (which may be on a label affixed to the device), to ensure that the device is safe to use.

10.2 Maintenance, Service and Repair

Where existing medical devices are required to be maintained, serviced and repaired there may be various options available (dependent on the device).

In the first instance, contact should be made with the Clinical Engineering Department at Sheffield Teaching Hospitals NHS Foundation Trust. They will advise if the device is covered by the Service Level Agreement (SLA) between SHSC and STH. If so, they will arrange for the device to be maintained, serviced and/or repaired.

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).

In cases where the device is not covered by the SLA with STH, Trust staff should complete the appropriate maintenance request form/referral form (see **Appendix K**) which should be sent with the device and the purchase order to the device manufacturer, distributor or external provider (supplier).

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.

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.

Maintenance and repair will be fulfilled by the organisations as described above.

10.3 Asset Register/Database

Full details of all medical devices purchased, exchanged, rented, leased, loaned, donated to or otherwise acquired by the Trust will be held on the Devices Asset Register on the SheffMed system, provided and maintained by STH Clinical Engineering Department. The SheffMed system will be accessible by relevant staff within the Trust.

Details will include the following (this list is not exhaustive), and will be provided by a combination of Procurement (using purchasing data e.g. from the Pre-Acquisition Questionnaire), Device Commissioners (STH Clinical Engineering), Device Manufacturers and Suppliers, and individuals responsible for in-use Device Maintenance:

- Asset Registration (completed on commissioning of device) – Date of acquisition, Location (site/building/floor/room), Asset Code, Description, Manufacturer, Model/Type, Serial Number, Active Status (i.e. item in use or otherwise), Estimated Replacement Date;
- 'In Use' information – user manuals and training requirements, specific arrangements for cleaning and decontamination, usage record;
- Maintenance/support information – full details of maintenance and servicing requirements (by whom, frequency, planned maintenance schedule), date of last planned maintenance visit, date of next planned maintenance visit;
- Copies of maintenance reports – e.g. planned maintenance reports, unplanned maintenance/repair reports, fault log, LOLER certificates, quality assurance tests, decontamination certificates, record of reconditioning work carried out including a record of replacement parts. All maintenance and servicing records should also detail the name of the maintenance/servicing organisation;
- Safety updates (including MHRA and manufacturer's documents) that have been released since the medical device was first supplied;
- Consumables – cost of;
- Equipment replacement planning – Date of acquisition, Cost of acquisition, Expected date of replacement;
- Disposal – any special decommissioning arrangements required (e.g. environmental, recycling, structural, PID, WEEE requirements), copy of decontamination certificate, date of disposal, how disposed of, copy of disposal certificate.

11 Disposal of Medical Devices

Medical devices can be disposed of by one of three methods:

- Transfer of ownership
- Decommissioning
- Disposal

Table 7 provides a summary of the issues that need to be considered before transferring, selling or disposing of used medical devices.

Risk management is an essential tool to aid with the decision making process for disposing of a used device in the most appropriate and safe method. Staff should consult the Trust's Medical Devices Safety Officer and take into account professional and product liability and corporate governance issues.

11.1 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.

The Medical Devices Regulations 2002 do not apply to CE-marked or non-CE-marked medical devices when they are re-sold, and there is no legislation that specifically covers the resale or reuse of medical devices or equipment. Although not covered by these Regulations, they are still required to be safe under other national provisions, including (amongst others):

- Consumer Protection Act 1987 (Consumer Safety and Product Liability)
- Sale and Supply of Goods Act 1994
- Health & Safety at Work etc. Act 1974 (sections 3 and 6)
- Trade Descriptions Act 1968 (superseded by the Consumer Protection from Unfair Trading Regulations 2008)
- The Electrical Equipment (Safety) Regulations 1994
- The Control of Substances Hazardous to Health (Amendment) Regulations 2004
- Unfair Contract Terms Act 1977

Prosecution is possible under any of these references and applies to both new and used medical devices.

Under the Medical Devices Regulations, the original manufacturer is required to provide "all the information needed to verify whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times". In order to ensure good practice the vendor should apply this principle to the sale of used equipment or on transfer of ownership, to ensure device safety.

This information should be available for a prospective purchaser to view before sale and be supplied with the medical device on completion of the sale.

On selling or donating used medical devices, the following should be supplied with the device to the purchaser, by the vendor, as a minimum:

- A clear statement that the medical device is being resold/donated;
- A certificate of decontamination;
- User manuals and training requirements;
- Full details of maintenance and servicing requirements;
- Service history and manual;
- Usage history;
- Quality assurance test details;
- Safety updates (including MHRA and manufacturer's documents) that have been released since the medical device was first supplied.

11.1.1 Decontamination

Where applicable, medical devices should be decontaminated before reuse, sale or disposal (see Section 9.1).

11.1.2 User Manuals and Training

The original user manuals should be supplied along with the device in order to ensure clear and safe use. Recommendations on any other necessary training should be given. The original manufacturer should be able to provide this information together with any updates which may have been issued since manufacture. Full details on how to maintain or service the device should also be supplied from the SheffMed system.

NB: If manuals and training information are not available, the medical device may have been rendered unsuitable for passing onto a new user.

11.1.3 Device usage and service history

This should always be available for prospective purchasers before sale and then supplied with the device at point of sale. As a minimum the MHRA recommends that there should be:

- A record of the reconditioning work carried out on the device including a record of replacement parts;
- A copy of all maintenance and servicing that has been carried out on the device including the name of maintenance/servicing organisation;
- A record of usage of the device;
- A fault log.

11.2 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.

For other devices; as a minimum, general safety checks should be carried out such as power disconnection and cooling system disconnection. In addition it is advisable to consult the original PAQ submitted for the device by the manufacturer/supplier as this will contain information on decommissioning even if they are not required to carry out the decommissioning of the device. The information should include details of any environmental, disposal, recycling or structural requirements. If the manufacturer is no longer in business, the MHRA can provide sources of similar guidance.

11.3 Medical Device Disposal

For methods of waste disposal the original manufacturer can provide valuable details of the current techniques and processes applicable to their products.

Hazardous and difficult waste substances are defined in the Hazardous Waste Directive and the COSHH (Amendment) Regulations 2004. These may be toxic, harmful, corrosive, irritant or carcinogenic. Any device which may contain or be contaminated with these substances in quantities above defined thresholds, must be disposed of in accordance to the Special Waste Regulations. (For further guidance consult SHSC Estates).

Electrical and electronic medical devices are subject to the European Directive on Waste from Electrical and Electronic Equipment (WEEE). Vendors should ensure that purchasers are aware of the provisions of this Directive with regard to disposal of end of life electrical and electronic waste. It also encourages improvements in the recycling of materials, and recommends that the producers have responsibility to set up systems so that medical device owners and/or distributors can return end of life equipment (electrical or electronic). Battery disposal is also subject to specific guidance (see Trust's Waste Management Policy or for further guidance, consult SHSC Estates).

Packaging is now also regulated by The Packaging (Essential Requirements) Regulations 2015. This relates in this context to decontamination issues, previously covered.

11.3.1 Transport of Devices Prior to Disposal

When returning devices to the manufacturer at end of life, or when transporting devices on other occasions, it is essential to ensure that they are appropriately decontaminated, packaged and secured. Separate regulations apply where road or rail is used.

For further guidance on disposal issues refer to the Trust's Waste Management Policy or contact SHSC Estates.

12 Reuse or Reissue

Devices 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.

All single use items must be disposed of immediately after use in an appropriate manner. They must not be reprocessed and used again, even on the same patient.

Reuse can be unsafe because of risk of:

- cross-infection — inability to clean and decontaminate due to design.
- endotoxin reaction — excessive bacterial breakdown products, which cannot be adequately removed by cleaning.
- patient injury — device failure from reprocessing or reuse because of fatigue, material alteration and embrittlement.
- chemical burns or sensitisation — residues from chemical decontamination agents on materials that can absorb/adsorb chemicals.

Also, if you reuse a single-use device you may be legally liable for the safe performance of the device:

- Anyone who reprocesses or re-uses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness.

- Anyone who reprocesses a 'single use' device and passes it to a separate legal entity for use has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.

To re-use a 'single use' device could expose the patient and re-processor to risks which outweigh the perceived benefits of using such devices.

All equipment which has been returned as no longer being required for a particular patient **MUST** be decontaminated prior to re-issue.

Some single-use devices are marketed as non-sterile. These may require reprocessing, in line with the manufacturer's instructions, to make them sterile and ready for use. Check the manufacturer's instructions for any limit on the number of times the unused device may be reprocessed. Once used on a patient, the device must be discarded.

NOTE: *Single patient use is not the same as single-use. Single-patient use means the medical device may be used for more than one episode of use on one patient only; the device may undergo some form of reprocessing between each use.*

13 Adverse Incidents

An adverse incident is an event that causes - or has the potential to cause - unexpected or unwanted effects involving the safety of patients, users or other persons. Reference should be made to the Trust's Incident Management Policy and Procedure.

13.1 Defective or contaminated items and evidence

13.1.1 Defective items

Defective items should initially be quarantined where possible and should not be repaired (either in-house or by a third party) **OR** returned to the manufacturer/supplier **OR** discarded, before an investigation.

If devices are required for use, defective parts may be removed so that the equipment can be repaired. Any parts removed in such circumstances must be quarantined and securely stored pending investigation. If it is not possible to remove defective parts or withdraw the machine from use, staff should be made aware of the need for increased vigilance and extra caution during use (see 'Evidence' below).

13.1.2 Contaminated items

Advice on procedures to be followed if healthcare equipment is contaminated and constitutes a biohazard is contained in the Trust's Decontamination - Environmental Cleanliness & Reusable Equipment Policy (on the Trust Intranet). Device specialists can provide advice where necessary, particularly on whether arrangements should be made for the item to be examined prior to any decontamination.

Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled and placed in quarantine. MHRA and the manufacturer/supplier should be contacted for advice prior to any further action being taken.

13.1.3 Evidence

All material evidence should be labelled and kept secure. This includes the products themselves and, where appropriate, packaging material or other means of batch identification. The evidence should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports.

14 Medical Devices on Loan to Service Users

Areas within the Trust that raise demands for medical devices for use by service users from within the Trust or from outside should ensure that:

- training is given to the service user on the safe use of the medical device;
- written approved or manufacturer's instructions are provided where appropriate and suitable for the individual concerned;
- the device has been tested prior to the loan to ensure it is working as required;

- contact details are given to the service user in the event of any necessary support being required;
- when on loan for an extended period, all medical devices requiring regular maintenance should be on a programme for planned preventative maintenance;
- arrangements are made to recover the device when no longer in use by the service user.

Any equipment loaned to patients is to be recorded on their patient notes so that the location of the equipment is known. This record should include the make, model and serial number of the equipment.

It should be ensured that all equipment is returned at the end of the loan and that the normal cleaning/decontamination procedures are followed in line with manufacturer's instructions.

15 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 Medical and Therapeutic Devices Group

Verification:
The policy was verified by the Chair of the Medical and Therapeutic Devices Group.

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. New Appendix E – SOP: Medical Device/Equipment Trials New Appendix D – SOP: PAQs New Appendix J – SOP: Receipt and Acceptance Testing of new medical/therapeutic devices Other minor formatting changes.
4.0	Review/Approval	09/2019	Final editing based on comments received Addition of Policy Authors Removal of Appendix H - Medical & Therapeutic Devices Group ToR Re-numbering of Appendices/update of Contents 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.

16 Audit, monitoring and review

This section should describe how the implementation and impact of the policy will be monitored and audited. It should include timescales and frequency of audits.

If the policy is required to meet a particular standard, it must say how and when compliance with the standard will be audited.

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	Responsible Individual/group/ committee for action plan monitoring and implementation
A) Describe which aspect this is monitoring?	e.g. Review, audit	e.g. Education & Training Steering Group	e.g. Annual	e.g. Quality Assurance Committee	e.g. Education & Training Steering Group	e.g. Quality Assurance Committee

Policy documents should be reviewed every three years or earlier where legislation dictates or practices change. The policy review date is 30/04/2023.

17 Implementation plan

All policies should include an outline implementation plan (this will summarise sections 7, 8 and 9 above). It should include consideration of:

- *Dissemination, storage and archiving*
- *Training and development requirements and who will provide the training*
- *Any new job roles and responsibilities and how these will be implemented*
- *Resources needed*
- *Timescales*
- *Lead role and responsibilities for implementation*
- *Audit or monitoring of implementation planned*

The implementation plan should be presented as an action plan and include clear actions, lead roles, resources needed and timescales. The Director of Corporate Governance team can provide advice on formats for action plans however; an example layout for the plan is shown below:

Action / Task	**Responsible Person**	**Deadline**	**Progress update**
e.g. Upload new policy onto intranet and remove old version	*Chief Nurse*	*01/12/2016*	*Completed 30/11/2016*
e.g. Make team aware of new policy	*Team manager*	*17/12/2016*	*On agenda for team meeting 17/12/2016*

18 Dissemination, storage and archiving (Control)

Version	Date added to intranet	Date added to internet	Date of inclusion in Connect	Any other promotion/ dissemination (include dates)
3.0	Nov 2016		Nov 2016 via Communications Digest	
5.0	May 2020	May 2020	May 2020	

19 Training and other resource implications

All staff joining the Trust will attend Core Mandatory Training as required for their role. The Infection Control session includes a brief overview of decontamination and emphasises its importance in the delivery of care. All staff require Mandatory Training updates; please refer to the mandatory training policy or discuss with your own line manager. Training data will be collected centrally by the Education and Training Department.

Each department/team manager is responsible for ensuring that their staff receive training on this Policy and its contents, and update any locally held training records.

Staff are reminded that they should seek relevant training and be appropriately trained in clinical procedures e.g. venepuncture or catheterisation where any medical or therapeutic device is used, and maintain their competencies to ensure safe practice. This includes knowledge of the use, storage, frequency and type of necessary safety checks and requirements for rotation of stock.

Should resource implications be identified then appropriate business cases will be produced for consideration.

20 Links to other policies, standards (associated documents) and references

Trust Associated Documents (located on the intranet site)

- Trust Incident Management Policy and Procedure
- Central Alert System (CAS) Policy
- Trust Procurement Policy
- Trust Waste Management Policy
- Trust Mandatory Training Policy
- Trust Decontamination Environmental Cleanliness & Reusable Equipment Policy
- Trust Standing Orders Reservation and Delegation of Powers and Standing Financial Instructions
- Trust Delegation of Budgetary Authority
- Authorised Signatory Guidance
- Trust Capital Programme Management Policy

Legislation

Listed below are examples of legislation that might apply. It is not an exhaustive list. Note that numbers in square brackets refer to the 'References and further information' listed in the next section.

- Consumer Protection Act 1987 (Consumer Safety and Product Liability) [15]
- Health and Safety at Work etc. Act (HASAWA) 1974 [14]
- In Vitro Diagnostic Medical Devices Regulations [39]
- Ionising Radiation (Medical Exposures) Regulations 2000 [40]
- Ionising Radiations Regulations 2017 [18]
- Management of Health and Safety at Work Regulations 1999 [41]
- Medical Devices Regulations 2002 (as amended) [2]
- Sale and Supply of Goods Act 1994 (Chapter 35) [32]

- The Common Law of Negligence: Law Reform (Contributory Negligence) Act 1945 [17]
- The Control of Substances Hazardous to Health Regulations 2002 [37]
- The Electrical Equipment (Safety) Regulations 1994 [34]
- The Electricity at Work Regulations 1989 [13]
- The Employers' Liability (Compulsory Insurance) Regulations 1998 [38]
- The General Product Safety Regulations 2005 [16]
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. Regulation 16 Safety, availability and suitability of equipment [44]
- The Lifting Operations and Lifting Equipment Regulations 1998 [19]
- The Pressure Systems Safety Regulations 2000 [42]
- The Provision and Use of Work Equipment Regulations 1998 [43]
- The Waste Electrical and Electronic Equipment Regulations 2006 and The Waste Electrical and Electronic Equipment (Amendment) Regulations 2007 [26]
- Trade Descriptions Act 1968 [33]
- Unfair Contract Terms Act 1977 [35]

References

1 Care Quality Commission: Essential standards of quality and safety 2010
2 Medical Devices Regulations 2002 (as amended)
3 Medical Devices Directive (MDD) 93/42/EEC as amended 2007/47/EC
4 NHS England and MHRA. Improving medical device incident reporting and learning March 2014
5 Department of Health. Records Management: NHS Code of Practice 2006
6 MHRA Devices in Practice
7 BS EN 62366:2008 Medical devices. Application of usability engineering to medical devices
8 MHRA. Medical devices in general and non-medical products MDA/2010/001
9 BS EN 60601-1-8:2007 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. 2007
10 BS EN 62353:2008 Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment
11 Department of Health NHS Master Indemnity Agreement July 2010
12 BS 7671:2008+A3:2015 Requirements for electrical installations. IET Wiring Regulations. January 2015
13 The Electricity at Work Regulations 1989
14 Health and Safety at Work etc. Act 1974
15 Consumer Protection Act 1987 (Consumer Safety and Product Liability) (Chapter 43). Part I: Product Liability, Part II: Consumer Safety
16 The General Product Safety Regulations 2005
17 The Common Law of Negligence: Law Reform (Contributory Negligence) Act 1945
18 The Ionising Radiations Regulations 2017
19 The Lifting Operations and Lifting Equipment Regulations 1998
20 BS EN ISO 13485:2012 Medical devices. Quality Management Systems. Requirements for regulatory purposes
21 BS EN ISO 9001:2008 Quality management systems. Requirements

22 Department of Health. Management and decontamination of surgical instruments used in acute care 2013
23 MHRA. Reusable laryngoscope handles - all models and manufacturers MDA/2011/096
24 BS ISO/IEC 15408-1:2009 Information technology. Security techniques. Evaluation criteria for IT security Introduction and general model
25 HMG Information Assurance Standard No. 5 - Secure Sanitisation. Part of a larger family of IT security standards published by CESG. If you have an nhs.net email address you can register on the CESGIAP site to access their policy and guidance documents.
26 The Waste Electrical and Electronic Equipment Regulations 2006 as amended in 2007
27 Carriage of Dangerous Goods by Road Regulations 1996
28 Carriage of Dangerous Goods by Rail Regulations 1994
29 Chemicals (Hazard Information and Packaging for supply) Regulations 2009
30 The Radioactive Material (Road Transport) (Great Britain) Regulations 2002
31 Royal Mail Prohibited goods – business customers
32 Sale and Supply of Goods Act 1994 (Chapter 35)
33 Trade Descriptions Act 1968
34 The Electrical Equipment (Safety) Regulations 1994
35 Unfair Contract Terms Act 1977
36 European Association of Notified Bodies for Medical Devices. Placing on the market of fully refurbished medical devices Recommendation NB-MED/2.1/Rec5
37 The Control of Substances Hazardous to Health Regulations 2002
38 The Employers' Liability (Compulsory Insurance) Regulations 1998
39 The In Vitro Diagnostic Medical Devices Regulations 2000
40 The Ionising Radiation (Medical Exposure) Regulations 2000
41 Management of Health and Safety at Work Regulations 1999
42 The Pressure Systems Safety Regulations 2000
43 The Provision and Use of Work Equipment Regulations 1998
44 The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Further reading/information

- MHRA: Managing medical devices 2015
- The Special Waste Regulations 1996, SI1996 No. 972
- The Management of Health and Safety at Work Regulations 1999 No. 3242
- Lee P, Thompson F & Thimbleby H (2012). 'Analysis of infusion pump error logs and their significance for healthcare,' British Journal of Nursing, 21(8):S12–S22 (IV Supplement)
- BS EN 12182:2012, Assistive products for persons with disability. General requirements and test methods. 2012.
- BS EN 12184:2009, Electrically powered wheelchairs, scooters and their chargers. Requirements and test methods
- BS EN ISO 14971:2012, Medical devices. Application of risk management to medical devices
- BS EN ISO 17664:2004, Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices
- BS EN 62353:2008, Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment
- IPEM. Report 95 Risk Management and its Application to Medical Device Management 2007, IPEM: York. ISBN 978 1 903613 33 7

- IPEM. Report 97 Guide to Electrical Safety Testing of Medical Equipment: the how and why 2009, IPEM: York. ISBN 978 1 903613 36 8

27 Contact details

Title	Name	Phone	Email
Medical Devices Safety Officer	TBA	TBA	TBA
Health and Safety Risk Advisor	Charlie Stephenson	0114 2716208	charlie.stephenson@shsc.nhs.uk
Medical & Therapeutic Devices Group Chair	Andrea Wilson	0114 2264248	andrea.wilson@shsc.nhs.uk
Lead Nurse Investigations & Clinical Risk	Vin Lewin	0114 2716379	vin.lewin@shsc.nhs.uk
Head of Procurement	Vivienne Morley	0114 2711137	vivienne.morley@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 on staff, 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.*** Name/Date:	**YES,** Go to **Stage 2**

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 the SHSC 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 works to enhance relations between people in this group and people not in this group?
Age	**No**		
Disability	**No**		
Gender Reassignment	**No**		
Pregnancy and Maternity	**No**		
Race	**No**		

Religion or Belief	**No**		
Sex	**No**		
Sexual Orientation	**No**		
Marriage or Civil Partnership	**No**	[redacted]	

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

Impact Assessment Completed by:
Vivienne Morley, Head of Procurement (30/09/2019)

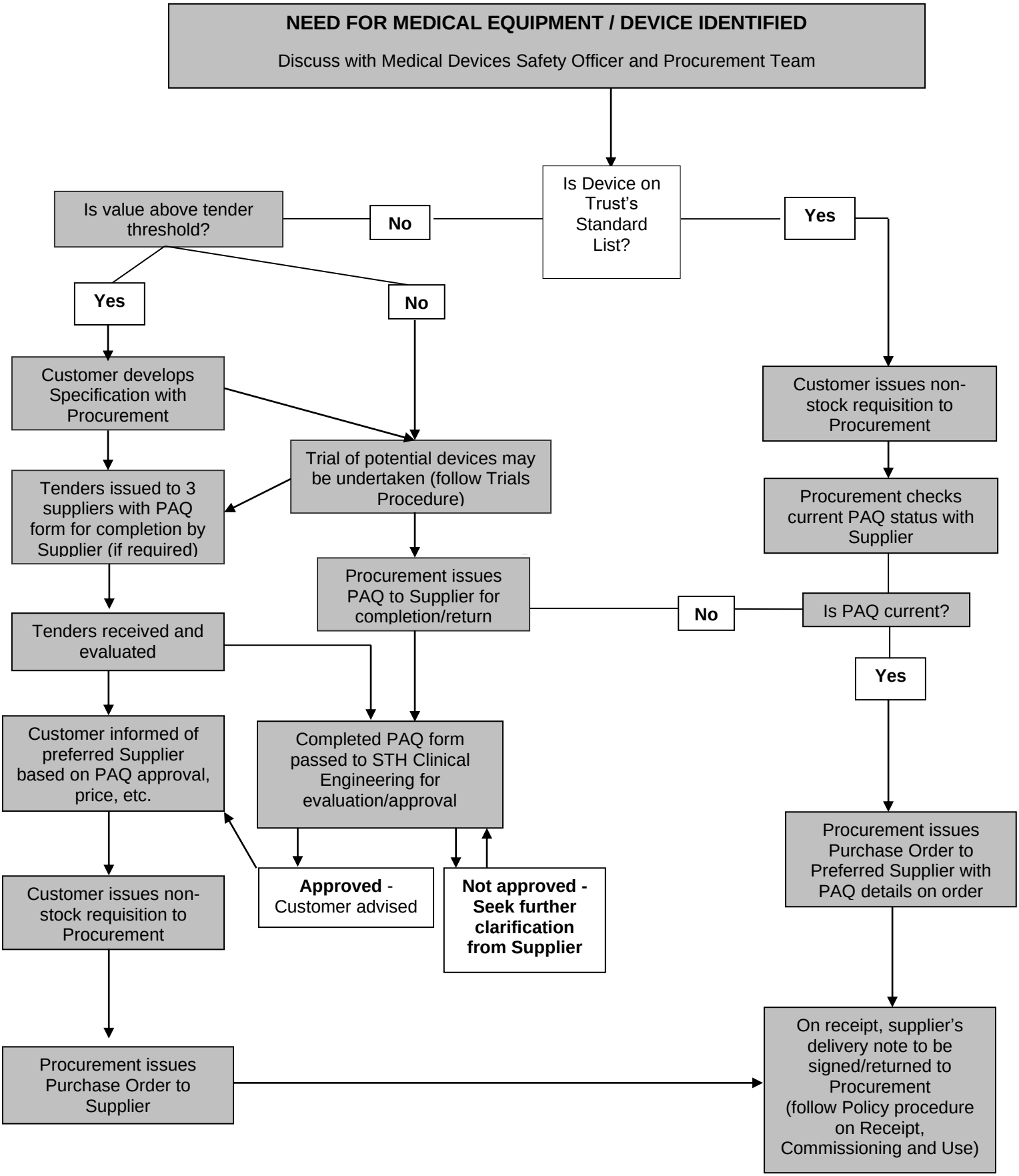
Appendix B – Common Categories of Devices

Common Categories of Medical and Therapeutic Devices produced by the Medicines and Healthcare products Regulatory Agency (MHRA). This list is not exhaustive and provides examples of medical and therapeutic devices

Equipment in the diagnosis or treatment of disease, or monitoring of patients, such as:	**In vitro diagnostic medical devices and their accessories, such as:**
• Chiropody and Podiatry Equipment	• Blood glucose measuring devices
• Dressings	• Cholesterol test kits
• Examination gloves	• Pregnancy test kits
• Intravenous (IV) admin sets & pumps	• Specimen collection tubes
• Nebulisers	• Urine test strips
• Ophthalmic equipment	**Equipment used in care, such as:**
• Peak flow meters	• Adjustable beds
• Surgical instruments	• Lifting poles
• Suction equipment	• Patient hoists
• Syringes and needles	• Pressure relief equipment
• Sphygmomanometers	• Stoma care equipment
• Thermometers	**Equipment used by people with disabilities, such as:**
• Ultrasound dopplers	
• Urinary catheters	• Bathing equipment
Equipment used in life support, such as:	• Commodes
	• External prostheses and orthoses
• Defibrillators	• Hearing aids
• Insulin Injectors	• Incontinence aids
• Domiciliary oxygen therapy systems	• Prescribable Footwear
• Ventilators used in home	• Standing frames
• Pulse oximeters	• Urine drainage systems
Other examples include:	• Walking aids
• Condoms	• Wheelchairs and special support seating
• Contact lenses and care products	
• Intra-uterine devices (IUDs)	

Source: Medical Devices Agency (2002) Devices in Practice, DOH, London

Appendix C - Procurement of Medical Equipment/Devices



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Appendix D – Standard Operating Procedure: Medical Device/ Equipment Trials

SOP Number:	**SOU 02-03**
SOP Version:	**1.0**
Effective Date:	**[Insert date month year SOP effective from]**
Review Date:	**[Insert date month year SOP to be reviewed – suggest 2 years from effective date]**
Reference:	**Medical and Therapeutic Devices Policy**
Related Documents:	**Product Trial Request and Evaluation Form (Appendix E of the Policy)**
Author:	**Vivienne Morley**
Reviewer:	**[Insert name and title of reviewer]**
Verification:	**The SOP was verified by Policy Governance Group (PGG) on [insert date verified by PGG]**
Ratification:	**The SOP was ratified by [insert name and title of Executive or Associate Director] on [Insert date ratified]**
Dissemination:	**The SOP was [state how and when the SOP was disseminated, stored and/or archived]**

Purpose and Objective:
This SOP describes the procedure for the initiation, request, conducting and evaluation feedback for medical devices and equipment, used as part of the decision-making process in the acquisition of medical and therapeutic devices. Reference to the procedure is made in the Trust's Medical and Therapeutic Devices Policy.

Scope:
This SOP applies to all medical devices and equipment trials whether the device is being acquired for the first time, or has been acquired on previous occasions.

NOTE:

1. *The terms 'acquisition' and 'acquired' refer to the purchase, exchange, rental, lease, loan, donation, or other agreement whereby the Trust is acquiring the device. Throughout this document the term 'purchase' is used as this is the most common type of acquisition process.*
2. *The term 'device' includes equipment, systems and accessories. In the case of systems, the requirements within the Trial Procedure apply both to the individual constituent devices and to the configured system as a whole. Accessories within the scope of the Trial have to be identified separately within the Product Trial Request and Evaluation Form.*

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STEP NO	RESPONSIBILITY	ACTION
1	Requestor (Customer)	When a new product is to be trialled (prior to formal evaluation and case of need taking place), the person who wishes to introduce the product must contact the Procurement Department **BEFORE** engaging with suppliers. The Customer will complete Part 1 of the Product Trial Request and Evaluation Form and submit the form to the Procurement Team.
2	Procurement Team	Procurement will submit the Product Trial Request and Evaluation Form to the Medical & Therapeutic Devices Group to make the appropriate clinical lead aware. Procurement will advise the Group whether a Pre-Acquisition Questionnaire and/or Indemnity Form is/are required (depending on the subject matter of the Product Trial). If either applies, Procurement will follow the relevant Procedure set out in the Medical & Therapeutic Devices Policy.
3	Medical & Therapeutic Devices Group	The Group will review and consider the Product Trial Request. Their feedback will be recorded in Section D of the Product Trial Request and Evaluation Form, and returned to Procurement. If the Trial is approved, they will appoint a Clinical Lead to act as 'trial manager'. They will also liaise between the participating department, Procurement, and the appropriate technical department (i.e. STH Clinical Engineering Department).
4	Procurement	Informs the Requestor of the outcome of their Product Trial Request. If approval is given, liaise with the Supplier to arrange for samples to be delivered to the Receipt Point at President Park OR (if appropriate), directly to the Requestor. Complete the relevant section on the Product Trial Request. Follow PAQ and/or Indemnity procedures as required.
5	Requestor (Customer)	Receives the samples and distributes in order to conduct the Trial Evaluation.
6	Trial Evaluators	Evaluates the product(s). Completes Part 2, Section E of the Product Trial Request and Evaluation Form for each sample trialled. Liaises with the Clinical Lead as/when required on progress with the Product Trial. Returns the completed and signed forms to Procurement.
7	Clinical Lead	Supports the Trial Evaluation. Responds to any queries raised by the Trial Evaluators. Liaises between the participating department, Procurement, and the appropriate technical department (i.e. STH Clinical

		Engineering Department) as and when required throughout the Trial Evaluation process.
8	Procurement	Submits the completed/signed Product Trial Request and Evaluation Forms to the Medical & Therapeutic Devices Group for review.
9	Medical & Therapeutic Devices Group	Reviews and considers the outcome of the Product Trial Evaluations. Approves (or otherwise) acceptance of the Product Trial and records their feedback in Section F of the Product Trial Request and Evaluation Form. Returns the form to Procurement.
10	Procurement	Informs the Requestor (Customer) of the outcome. If the product is approved, establishes the route of supply and informs relevant Trust Stakeholders accordingly. Advises Directorate Accounts of any cost pressures/savings and records accordingly. Completes the Product Trial Request and Evaluation Form and retains file record.

ADDITIONAL INFORMATION:

- All members of staff participating in the trial should be in possession of all information connected to the use of the device prior to the beginning of the evaluation.

- Where appropriate, the trial device will be provided free of charge by the supplier. Any agreements with the supplier should be obtained in writing prior to the trial taking place and forwarded to the Procurement Department for verification before commencement of the trial.

- Contact with the suppliers of the device should be kept to a minimum for the duration of the trial.

- The length of the trial should be agreed prior to commencement and will depend on the nature of the device.

- The trial manager will be responsible for information given to patients involved in the trial of the product.

- All documentation relating to the trial and subsequent evaluation will be treated with the utmost confidentiality.

- All information gathered and all results of the trial will be held in confidence by both the trial manager and Procurement. All evidence as a result of the trial will be presented to the Medical & Therapeutic Devices Group before entering into any agreement with the supplier.

- The Medical & Therapeutic Devices Group will then assist in making a strategic purchasing recommendation which would form a case of need for the product. The trial manager would demonstrate from a clinical view why the case is necessary whilst Procurement will detail the financial/commercial aspects of such a choice. The appropriate department giving technical input to the trial will give a technical assessment of the device.

- At the conclusion of the trial the supplier will be given a debriefing by the trial manager and Procurement.

- No information should be given to any company other than the supplier.

- In the interests of ensuring fair competition and a comparative evaluation, it may be required for alternative types of devices from different suppliers to be trialled before any recommendation is made by the Medical & Therapeutic Devices Group.

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Appendix E – Product Trial Request and Evaluation Form

This form is to be used to initiate and evaluate the new product introduction and/or product trial process.

All requests to introduce new products or for product trials must be reviewed and approved by the Trust's Medical and Therapeutic Devices Group.

PART 1 - REQUEST

SECTION A – Requestor Details *(to be completed by the user)*	
Trust Location (Department/Ward):	
Name:	
Job Title:	
Contact Details – Email / Phone:	
Date of Request:	

SECTION B – Request Details *(to be completed by the user)*	
This request is to: (please tick which is applicable)	
Request trial of a product	
Request introduction of a new product	
Request review of an existing product	
Extend or change the current range used	
Product Description:	
Supplier:	
Supplier Representative Details: **(include name, phone number, email)**	
Product Code, Unit of Measure and Unit Price (exc. VAT):	
Estimated Volume to be Purchased:	
Is the product replacing an existing product(s)?	*If YES, provide details of supplier, product code and unit price (exc. VAT) of item being replaced:*

What is the product to be used for?	
Why is it required?	
What are the clinical and/or operational benefits?:	
Risks of making the change:	
Risks of not making the change:	
Key Stakeholders/Users of the Product(s):	
Clinical Safety Issues (please detail): **e.g. absence of safety alerts, compatibility with existing equipment and protocols, fitness for purpose, etc.**	
Implementation Requirements (including training, additional equipment, etc.):	
Does this product change result in a cost saving/pressure? **(Detail estimated value in £):**	
If a cost pressure, does sufficient budget exist to support the request?	
If yes, where will the budget be derived from?	
Please forward to the Budget Holder and Clinical Lead (if applicable) for sign off	

SECTION C – Approval of Request *(All requests must be signed off by the Budget Holder and Clinical Lead (if applicable))*	
Budget Holder	
Name:	
Signature:	
Date:	
Clinical Lead (if applicable)	
Name:	
Signature:	
Date:	

Notes / Comments:
Please forward to Procurement. Forms must contain original signatures and can be scanned / emailed.

SECTION D – Medical & Therapeutic Devices Group Review	
Approval for Trial given:	**YES / NO**
Date of Decision:	
If 'NO', please give details of reason:	
Key Issues:	
Further information required:	
Comments:	
Feedback given to Requestor (with date):	
Completed form to be retained by Procurement. Procurement to inform Requestor of outcome.	

For Procurement use only (if approval for trial given)	
Samples requested from supplier / date:	
By:	
Samples received from supplier / date:	
Samples forwarded to evaluator/evaluation location / date:	
By:	
Acknowledgement of receipt of samples received:	

PART 2 – TRIAL EVALUATION

SECTION E – EVALUATION OUTCOMES ***(to be completed by the trial evaluator)***	
Supplier:	
Product Description:	
NPC / MPC Code:	
Framework/Contract Ref. Details (including dates)	
Unit of Measure and Unit Price (exc. VAT)	

Name of Evaluator:	
Job Title of Evaluator:	
Location of trial:	
Start date of trial:	
End date of trial:	
For the following questions please answer Yes / No and provide additional information to support your answer	
Did you find the specification of the product acceptable? **(e.g. size, weight, colour, texture)**	
Was the product easy to maintain and/or keep clean?	
Was the product durable?	
Did the product require anything additional to be able to use it correctly or safely?	
Was additional training required to use the product?	
Was the pack size suitable?	
Overall is the product acceptable and fit for purpose?	
Were there any issues with the product?	

Any additional comments?	
Evaluator's Signature:	
Date:	
Please return the completed and signed form to Procurement. Forms must contain original signatures and can be scanned / emailed.	

SECTION F – TRIAL OUTCOME *(to be completed by Medical & Therapeutic Devices Group)*	
Supplier:	
Product Description:	
NPC / MPC Code:	
Product Approved / Not Approved:	
Additional Comments; if 'NO', then reason MUST be detailed:	
Date of Decision:	
Feedback given to Requestor, Budget Holder and Clinical Lead (if applicable) (with date(s)):	
Completed form to be retained by Procurement. Procurement to inform Requestor, Budget Holder and Clinical Lead (if applicable) of outcome.	

For Procurement use only (if product approved)	
Framework/Contract Ref:	
Contracts Database updated :	
Cost Pressure / Savings identified / verified:	
Cost Pressure / Savings sheet updated:	
By:	
Date:	

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Appendix F - Standard Operating Procedure: Pre-Acquisition Questionnaires (PAQs)

SOP Number:	**SOU 02-01**
SOP Version:	**2.0**
Effective Date:	**[Insert date month year SOP effective from]**
Review Date:	**[Insert date month year SOP to be reviewed – suggest 2 years from effective date]**
Reference:	**Medical and Therapeutic Devices Policy** **Service Level Agreement with Clinical Engineering Department, Sheffield Teaching Hospitals NHS F/T**
Related Documents:	**Pre-Acquisition Questionnaire (PAQ)**
Author:	**Vivienne Morley**
Reviewer:	**[Insert name and title of reviewer]**
Verification:	**The SOP was verified by Policy Governance Group (PGG) on [insert date verified by PGG]**
Ratification:	**The SOP was ratified by [insert name and title of Executive or Associate Director] on [Insert date ratified]**
Dissemination:	**The SOP was [state how and when the SOP was disseminated, stored and/or archived]**

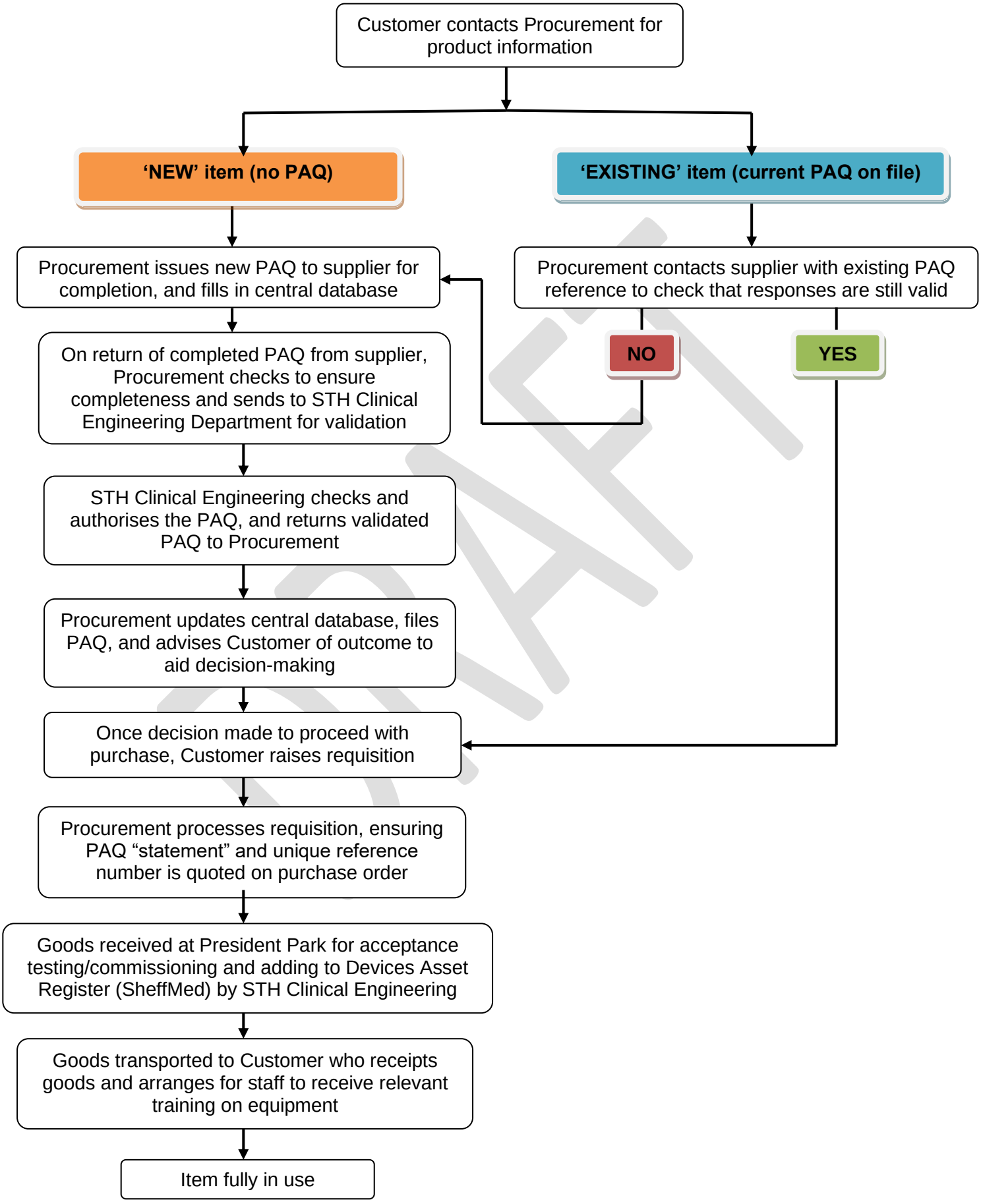
Purpose and Objective:
This SOP describes the procedure for the issuing and handling of Pre-Acquisition Questionnaires (PAQ), used as part of the decision-making process in the acquisition of medical and therapeutic devices. Reference to the PAQ is made in the Trust's Medical and Therapeutic Devices Policy.

Scope:
This SOP applies to the acquisition of all medical and therapeutic devices, whether the device is being acquired for the first time, or has been acquired on previous occasions.

NOTE:

3. *The terms 'acquisition' and 'acquired' refer to the purchase, exchange, rental, lease, loan, donation, or other agreement whereby the Trust is acquiring the device. Throughout this document the term 'purchase' is used as this is the most common type of acquisition process.*
4. *The term 'device' includes equipment, systems and accessories. In the case of systems, the requirements within the PAQ apply both to the individual constituent devices and to the configured system as a whole. Accessories within the scope of the PAQ have to be identified separately within the PAQ form.*

PAQ FLOWCHART



STEP NO	RESPONSIBILITY	ACTION
1	Customer	The Customer should contact the Procurement Department **BEFORE** engaging with suppliers.
2	Buyer	The Buyer will inform the Customer that it is a requirement under the Trust's Medical and Therapeutic Devices Policy to obtain certain information about the medical or therapeutic device **before** purchase. The Buyer will explain that the Pre-Acquisition Questionnaire (PAQ) is used to obtain information from the prospective supplier(s) on the following: • Regulatory compliance – e.g. that the device is CE marked; details of the manufacturer's certifications/quality standards; • Product commitment/support – e.g. the date to which the manufacturer's support of device is guaranteed; the recommended working lifetime of the device; the availability of user manuals; servicing information; levels of decontamination required; whether the device contains hazards that require specific safety management measures; • Implementation support – e.g. user and technical training, and resource materials available to operate/maintain the device. The Buyer will briefly explain the process involved (using the flowchart).
3	Customer and Buyer	The Customer will provide the Buyer with details of the device required. This should be either from the Trust's standards list or - if the device has not been purchased before by the Trust – by providing a specification of the device.
4	Buyer	The Buyer will consult the Device Asset Register (SheffMed) and the Trust's PAQ central database to check whether the device (or similar, if a specification only is provided) has been purchased before. If the device has been purchased before, the Buyer will note the unique PAQ reference number.
IF THE DEVICE HAS BEEN PURCHASED BEFORE, GO TO STEP 5. **IF THE DEVICE HAS NOT BEEN PURCHASED BEFORE, GO TO STEP 7.**		
5	Buyer	If the device has been purchased before, the Buyer will contact the Supplier and quote the PAQ reference number to ensure all the details submitted previously are still current.
6	Buyer	If the details are still current, go to Step 15. If any of the details have changed since the existing PAQ was issued and validated, go to Step 7.
7	Buyer	If the device has not been purchased before - or the details in the existing PAQ have changed - the Buyer must issue a PAQ to the supplier. The PAQ template can be found here. **You must always check that you are using the most up to date form on the www.gov.uk**

STEP NO	RESPONSIBILITY	ACTION
		website.
8	Buyer	Complete the PAQ Central Database (found in folder W:\Procurement\PAQs) with details of the local PAQ reference, the supplier, and date of issue. Forward the PAQ to the supplier, requesting that it be completed and returned to procurement@shsc.nhs.uk within 7 calendar days. Place a reminder in your Outlook calendar of the expected date of return so you can check if it has been returned (or to chase for a reply if not).
9	Buyer	Once the completed PAQ has been returned, check that it has been completed in full. If not, contact the supplier to ascertain why (i.e. not all sections may be applicable).
10	Buyer	Scan the completed PAQ onto the PAQ Central Database and forward an electronic copy to STH Clinical Engineering with a cover email requesting a response within 10 working days. Record the date of despatch and expected date of return on the PAQ central database. Place a reminder in your Outlook calendar of the expected date of return so you can check if it has been returned (or to chase a reply if not).
11	STH Clinical Engineering	Within 10 working days of receipt of the completed PAQ, review the Supplier's responses. If satisfactory, notify the Buyer accordingly. If unsatisfactory - or further clarification is required from the Supplier – notify the Buyer to request this.
12	Buyer	On receipt of verification confirmation from STH Clinical Engineering, update the PAQ Central Database. If accepted, notify the Customer and request that they raise a requisition. If not accepted - and further clarification is required - notify the Customer accordingly of the reason for the delay. Contact the Supplier for clarification. Update the PAQ Central Database.
13	Buyer	On receipt of clarification from the Supplier, re-submit the information to STH Clinical Engineering.
14	STH Clinical Engineering Buyer/Customer	Within 5 working days of receipt of the resubmitted information, review the Supplier's responses. If satisfactory, notify the Buyer accordingly. If Supplier's response remains unsatisfactory, discuss with the Buyer and Customer to jointly determine whether the device should be purchased under certain provisos, sourced elsewhere, or not

STEP NO	RESPONSIBILITY	ACTION
		purchased. Consider whether an alternative may be available.
15	Buyer	Once all pre-acquisition checks are satisfactorily completed, process the requisition to raise the purchase order. Ensure the PAQ "statement" and unique reference number is quoted on the purchase order. Ensure the delivery address is President Park (unless there are extenuating circumstances for delivery to be elsewhere).
16	Receipt Point	On receipt of the device, inform the Buyer.
17	Buyer	On being informed that the device has been received, arrange with STH Clinical Engineering to conduct acceptance testing/commissioning and add to Devices Asset Register (SheffMed).
18	STH Clinical Engineering	Within xx working days of notification of receipt, conduct the acceptance testing and commissioning of the device in accordance with the Supplier's/Manufacturer's recommendations outlined in the PAQ. Record the device onto the Devices Asset Register (SheffMed) and make the record live. Inform the Buyer that all checks have been satisfactorily completed. If any checks fail, inform the Buyer immediately to take up with the Supplier.
19	Buyer	Following notification of satisfactory completion of all checks, inform the Customer. If required, arrange transport of the item from the Receipt Point to the Customer. If notified by STH Clinical Engineering that any checks have failed, inform the Supplier immediately and arrange return/replacement as required.
20	Receipt Point / Transport Services	Within 3 working days of notification from the Buyer, transport the device to the Customer.
21	Customer	Arrange for all relevant staff to receive in-use training (including routine maintenance, cleaning and checking of device) **BEFORE** placing into use, in accordance with the Supplier's recommendations in the PAQ.

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Appendix G - Pre-Acquisition Questionnaire (PAQ) Form

Refer to https://www.gov.uk/government/publications/nhs-standard-terms-and-conditions-of-contract-for-the-purchase-of-goods-and-supply-of-services for the current version

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Appendix H – Decontamination Evaluation & Risk Assessment Form

DECONTAMINATION EVALUATION & RISK ASSESSMENT FORM

To be completed at the time of requisition by the requesting area/service

Item: **Requisition number:**

Briefly describe the item/equipment and its intended use:

Does <u>any</u> part of the equipment (including accessories) come into contact with the patient/client or their blood or body fluids? YES/NO – *If yes please provide details*

For parts of the equipment <u>not</u> coming into contact with the patient/client or their blood or body fluids:

a) **How is the item to be routinely cleaned e.g. from dust**

b) **Who will carry out this process, how often & where?**

c) **How will the item be decontaminated if inadvertent contact with blood or body fluids occurs?**

d) **Who will carry out this process & where?**

For parts of the equipment coming into contact with the patients/clients <u>intact skin:</u>

a) **How is the item to be cleaned between uses?**

b) **Who will carry out this process, how often & where?**

c) **How will the item be decontaminated if inadvertent contact with blood or body fluids occurs?**

d) **Who will carry out this process & where?**

For parts of the equipment coming into contact with <u>non-intact skin</u>, mucous membranes, blood or body fluids or are to be introduced into sterile body cavities: *(use single use disposable equipment wherever possible)*

a) **How is the item to be cleaned between uses prior to disinfection/sterilisation?**

b) **Who will carry out this process, how often & where?**

c) **How will the item be disinfected/sterilised?**

d) **Who will carry out this process & where?**

If the equipment is to be transferred to another area/location for processing from where it has been used:

a) **Has the department/location that will be cleaning/disinfecting/sterilising the item agreed to this & the methods to be used? YES/NO –** *please provide details*

b) **How will the equipment/item be transported to & from the processing department/location e.g. containers/bags used and by whom?**

Please provide details of the person completing this risk assessment:

Name:

Date:

Position:

Contact details: *(email & phone)*

Please provide details of the person to contact if the reviewer needs to ask further questions or to discuss the situation if the proposed process needs to be referred to the Medical & Therapeutic Devices Group/Medical Devices Liaison Officer/Infection Control Team; if different from the individual named above

Name:

Position:

Contact details: ***(email & phone)***

Please retain a copy for your records. If further advice is required please submit a copy of this to the Infection Control Team. Thank you for your time & assistance.

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Appendix I – Standard Operating Procedure: Receipt, Acceptance Testing and Commissioning of new medical/therapeutic devices

SOP Number:	**SOU 02-02**
SOP Version:	**2.0**
Effective Date:	**[Insert date month year SOP effective from]**
Review Date:	**[Insert date month year SOP to be reviewed – suggest 2 years from effective date]**
Reference:	**Medical and Therapeutic Devices Policy**
Related Documents:	**Delivery Checklist (Appendix J of the Policy)** **Service Level Agreement with Clinical Engineering Department of Sheffield Teaching Hospitals NHS Foundation Trust**
Author:	**Vivienne Morley**
Reviewer:	**[Insert name and title of reviewer]**
Verification:	**The SOP was verified by Policy Governance Group (PGG) on [insert date verified by PGG]**
Ratification:	**The SOP was ratified by [insert name and title of Executive or Associate Director] on [Insert date ratified]**
Dissemination:	**The SOP was [state how and when the SOP was disseminated, stored and/or archived]**

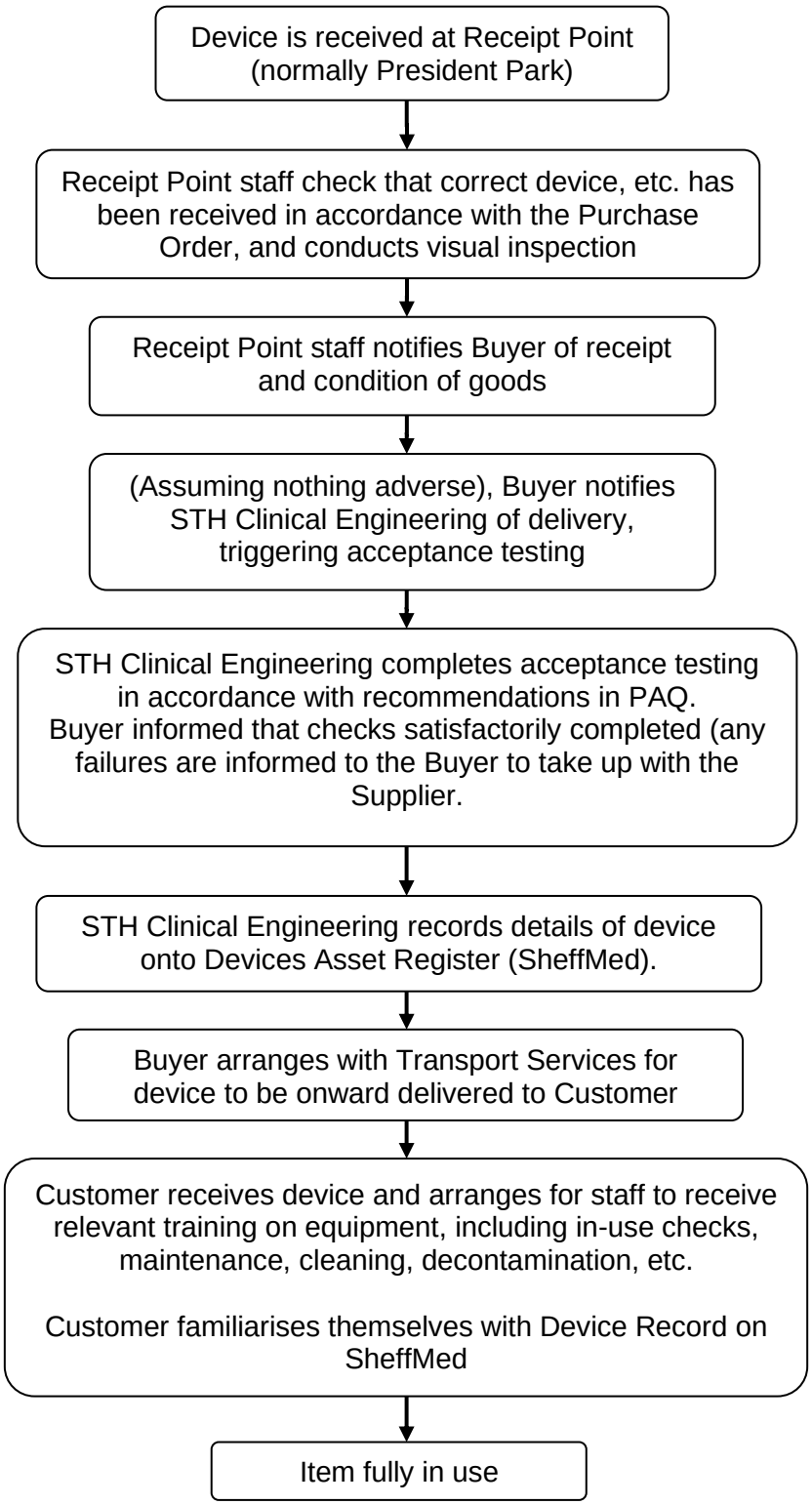
Purpose and Objective:
This SOP describes the procedure for the receipt of new medical and therapeutic devices in the Trust. Reference to the procedure and related documents is made in the Trust's Medical and Therapeutic Devices Policy.

Scope:
This SOP applies to the receipt of all medical and therapeutic devices, whether the device is being acquired for the first time, or has been acquired on previous occasions.

NOTE:

1. *The terms 'acquisition' and 'acquired' refer to the purchase, exchange, rental, lease, loan, donation, or other agreement whereby the Trust is acquiring the device. Throughout this document the term 'purchase' is used as this is the most common type of acquisition process.*
2. *The term 'device' includes equipment, systems and accessories.*

DEVICE RECEIPT FLOWCHART



STEP NO	RESPONSIBILITY	ACTION
1	Receipt Point	On receipt of the device, Receipt Point staff carry out preliminary checks to ensure that the device and associated items received match the Purchase Order details. Receipt Point staff will also carry out a visual inspection and complete Section B of the Delivery Checklist (**Appendix J**)
2	Receipt Point	Inform the Buyer that the device has been received and that the preliminary checks are satisfactory (or not).
3	Buyer	If the preliminary checks are unsatisfactory inform the Supplier immediately and progress in accordance with local Returns/Replacement Procedures. If the preliminary checks are satisfactory, inform STH Clinical Engineering to trigger the acceptance testing/commissioning process.
4	STH Clinical Engineering	Within xx working days of notification of receipt, conduct the acceptance testing and commissioning of the device in accordance with the Supplier's/Manufacturer's recommendations outlined in the PAQ. Complete Sections A, C and D of the Delivery Checklist (**Appendix J**) and retain as part of the device record on the Asset Register. Record the device onto the Devices Asset Register (SheffMed) and make the record live. Inform the Buyer that all checks have been satisfactorily completed. If any checks fail, inform the Buyer immediately to take up with the Supplier.
5	Buyer	Following notification of satisfactory acceptance testing, inform the Customer. If required, arrange with Transport Services to transport the item from the Receipt Point to the Customer. If notified by STH Clinical Engineering that any checks have failed, inform the Supplier immediately and arrange return/replacement as required, in accordance with local procedures.
6	Receipt Point / Transport Services	Within 3 working days of notification from the Buyer, transport the device to the Customer.
7	Customer	Arrange for all relevant staff to receive in-use training (including routine maintenance, cleaning and checking of device) **BEFORE** placing into use, in accordance with the Supplier's recommendations in the PAQ.
8	STH Clinical Engineering	Provide confirmation to the Customer and the Buyer that the SheffMed record is live.

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Appendix J - Delivery Checklist

A Equipment Details	
1. Decontamination certificate	Yes/No
2. Date	
3. Supplier	
4. Device type	
5. Delivery note checks with order?	Yes/No
6. Goods checks with delivery note?	Yes/No
7. Model/type identification	
8. Serial Number	
9. Mains voltage	
10. Leads supplied	Yes/No
11. Accessories supplied	Yes/No
12. User manual supplied	Yes/No
13. Instructions supplied	Yes/No
14. Maintenance manual supplied	Yes/No
15. Warranty document included	Yes/No
16. Final test certificate supplied	Yes/No
17. Local serial/inventory number	
18. Device type new to healthcare facility	Yes/No
19. If YES, instructions circulated appropriately	Yes/No
20. “New Device” sticker attached	Yes/No

B Visual Inspection	
1. Outer packaging undamaged?	Yes/No
2. Case not dented/broken	Yes/No
3. Panels etc. secure	Yes/No
4. No rattles	Yes/No

C Electrical safety	
1. Moulded IEC mains connector and mains plug	
• Connectors firmly attached	Yes/No
• No cores or bare wires visible	Yes/No
• Outer insulation intact	Yes/No
• Appropriate fuse fitted (see manual)	Yes/No
• Fuse holder secure	Yes/No
2. Mains lead permanently attached	
• Cord grips satisfactory	Yes/No
• Fuse value	
• Plugs and sockets mate	Yes/No
• Clamps and doors latch	Yes/No
• Passes PAT test	Yes/No

D Functional check	
Plug in, turn on (following instruction manual)	
1. Indicator lamps light up	Yes/No
2. Display as described in manual	Yes/No
3. Passes self-test routine	Yes/No
4. Moving parts operate properly	Yes/No
5. Knobs and switches act properly	Yes/No

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Appendix K – Medical Equipment Maintenance Request

1. Complete General Details	
Sender's Name (print)	
Contact Telephone No	
Contact Address	
Cost Centre to be charged	
Equipment No (ID)	
Equipment Make & Model	
Asset Register No	

2. State Work Required	
Acceptance Checking/Commissioning	☐
Disposal	☐
Service Only **(Equipment needs servicing but is working OK)**	☐
Repair	☐
If repair, BRIEFLY describe fault	

3. Declare Contamination Status	
Tick box to declare that '*this equipment/item has **NOT BEEN CONTAMINATED**, i.e. not used in any invasive procedures or been in contact with blood, other body fluids, respired gases, or pathological samples* **AND *you have surface cleaned it'***	☐
Tick box to declare that '*the equipment **HAS BEEN CONTAMINATED** i.e. exposed to blood, body fluids, respired gases, pathological samples OR other biohazards OR chemicals or substances hazardous to health OR other hazards* **AND *you have surface cleaned it and decontaminated it.***	☐

To declare that '*the equipment **HAS BEEN CONTAMINATED** exposed to blood, body fluids, respired gases, pathological samples OR other biohazards OR chemicals or substances hazardous to health OR other hazards **AND REMAINS CONTAMINATED** even though you have cleaned it**'**	**Call Service Provider**

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Table 1 – Factors to aid estimation of likely length of life of a medical device

FACTOR	NOTES
Life cycle/Replacement	For many items, especially disability equipment, the price is linked to solidity of construction and quality of materials; hence to the useful life of the device.
Fitness for intended application	The device chosen must meet the Trust's performance specification, but unnecessary features may be a disadvantage – complicated devices tend to break down more frequently and are harder to use.
Guarantee/Warranty	Comparison of terms needs to be undertaken as part of the process.
Safety	Check compliance with safety and performance standards. Which have been used? Do MHRA publications reveal persistent problems? Can professionals identify safety problems?
Reliability	Take into consideration whether other users have experienced problems and failures.
Service Support	Are there any equipment support problems? For example, check that spares are readily available and that service support is guaranteed. Also if a response time is guaranteed.
Technical Advice	Is there free access to technical advice from the manufacturer for professional users and technical staff? Is there a 24-hour helpline?
Diversity	Assess whether choosing another device will increase the number of types in use. Will this introduce risks in terms of staff requiring training using unfamiliar equipment?

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Table 2 – Example of a 'Total Cost' checklist

COST	NOTES
Price	In some cases, manufacturers will seek to offset low purchase prices with expensive contracts for consumables or servicing.
Tendering	The resources needed to manage and participate in the tendering process.
Risk Assessment	The costs of identifying risks and formulating mitigation strategies, particularly if performed by external suppliers/sources.
Decontamination/Infection Control	Advice should be sought from the Infection Control team at an early stage. The team will advise on the decontamination implications of the device, and what current guidance may relate to the device. An assessment of the risks associated with the device will be made. No device should be purchased if the infection control and decontamination issues have not been addressed.
Installation	Any special services required that may not currently be available (e.g. power, water, gas) plus any minor building works. Costs in terms of environmental and safety.
Professional User Costs	Local production of procedure manuals, if needed. Cost of training sessions for all relevant staff. Updating any 'local' catalogues. NB: Complex devices may also require additional staff.
Consumables/Accessories	Are third party and upgrade consumables or accessories cheaper than those produced by the device manufacturer? Are they fully compatible? Are they acceptable to use (e.g. invalidation of any guarantees/warranties from the device manufacturer)? Are hardware or software upgrades planned? Would there be any additional costs in 'retro-fitting' later?
Overheads	Any additional personal protective equipment needed, e.g. masks, goggles? Are there any additional costs in terms of environmental or health monitoring.
Utilities	Operational costs to be considered, including electricity, water, laundering and cleaning.
Maintenance	Maintenance contracts and costs of spares.
Repair	Call-out charges and the need for back-up devices in case of failure.
Storage	Consideration should be given to appropriate storage (e.g. humidity, light, temperature).

Insurance Costs	Indemnity insurance and inspection charges need to be considered.
Disposal	Some types of device are required to be disposed of in a manner that attracts additional costs.

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Table 3 – Checklist when ordering equipment

TOPIC	NOTES
Device details	Type number, software version, power supply details, professional user chosen options, standards complied with – as agreed and where relevant
Manuals	Professional user manuals, end-user manuals, servicing manuals, other technical literature (parts list, circuit diagrams, cleaning instructions)
Warranty	Specify agreed terms (e.g. period of cover, price of additional years (if required), etc.)
Ancillaries	Leads and connectors, probes and sensors, calibration equipment
Consumables	
Installation / Commissioning	Any work which the manufacturer or supplier is to carry out
Training	For users or servicing personnel, including initial training on delivery, and on-going training needs during operation
Acceptance procedure	Details of your acceptance procedure (see **Section 8**)
Quantity, price, terms, discount	E.g. early payment discount, quantity discount, rebates, etc.
Maintenance agreement	Intervals and response times – level of service required and agreed cost
Any other conditions of supply	For example; a ceiling on future prices for consumables and spare parts
Delivery date	
Delivery point	All deliveries should be addressed to a single named department, so devices do not get put into service without acceptance checks (see **Section 8**)

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Table 4 – Basic guidance on delivery checks

	Delivery check	Knowledge required
Paperwork/ Database	• Is the device compatible with specification set out in the purchase order? • Have the user, repair and maintenance information, compliance and calibration certificates, as well as test results been included, where relevant? • Ensure device details, asset number and serial number are captured on device management records. • Does the device (or any component part or accessory) need decontaminating before first use? • Are the instructions for use appropriate? • Does the device require validation? • Are the Decontamination instructions appropriate?	Familiarity with: • Ordering system • Inventory system • Names and appearances of common medical devices • Medical device documentation (Instructions for Use, certificates etc) • Serial numbers and model identification codes
Visual inspection	• Is the outer packaging intact and undamaged? • Is there any damage apparent to the device on inspection? • Is there an appropriate: expiry date, CE marking, Notified Body number, electrical class, lot number, quantity in pack, storage	• Knowledge of areas to check for damage • Familiarity with: ○ the appearance of product in good condition ○ common defects • Knowledge of medical devices and their use • Knowledge of electrical class

	Delivery check	**Knowledge required**
	information for unopened pack etc.?	symbols.
Configuration	• Configure the medical device in such a way as to ensure compatibility with all other equivalent medical devices in the healthcare organisation and with its clinical requirements. • Where this is a new medical device discuss with and get agreement from the responsible clinical manager/director as to how the device(s) should be configured, documenting the decision with reasons, where appropriate.	• Knowledge and understanding of the medical device and its clinical application • Knowledge and understanding of the impact of configuration changes on clinical care • Knowledge of how to configure this particular device.

Source: MHRA Managing Medical Devices (2015)

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Table 5 – Basic guidance on safety and calibration checks

	Safety and calibration checks	Knowledge required
Functional check **Note:** this may require more extensive checks by specialist staff for complex or specialist devices	• Does the device function in line with the manufacturer's information? • Are accessories/parts included and compatible? • Do indicators and displays function correctly in line with the manufacturer's information when powered up?* • When powered up, does the device start when it should and do the dials and switches do what they say?*	• For some devices, the skills required will be little more than basic training to allow the manufacturer's information to be followed. • In cases where the manufacturer's instructions specify specialist assembly or manipulation, familiarity with the functions of the device and its components and accessories is required.
Electric (basic safety)	• Are the mains leads, plugs and other connectors undamaged? • Are the mains plugs compatible with the sockets used in the UK (BS 1363/A)? • Mains adapters should not be used on medical devices.	• Training in visual electrical safety inspection techniques.
Calibration and measurement	Where appropriate, use test device to check: • Accuracy of physiological measurements • Dose delivery* • Energy delivery* • Accuracy of other outputs*	• Tests should be carried out by an adequately trained and appropriately qualified person.

** only for active devices*

Source: MHRA Managing Medical Devices (2015)

Table 6 – Suggested checklist on suitable storage conditions

Topic	Potential issues to consider
Physical conditions	• Dirty or wet conditions • Inappropriate temperature or humidity (labels on packaging should indicate appropriate storage conditions)
Storage system	• Stacks too high • Fragile equipment stored too far off the ground, likely to be damaged by falling from shelves.
Separation of equipment needing decontamination and repair from equipment ready to issue.	• Inadequate space for demarcated areas for quarantine, etc. • Inadequate labelling of zones • Inadequate packaging and labelling of refurbished equipment
Shelf life and stock rotation	• No stock handling procedures so earliest deliveries are not issued first, and stock is not rotated. • Inventory system does not identify out-of-date stock. • Excessive storage times may cause deterioration or corrosion of parts and components • Shelf life of batteries and sterile products is exceeded. • Rechargeable batteries may be damaged if not subjected to regular charge/discharge cycles.

Table 7 – Considerations when selling (or transferring ownership) or disposing of used medical devices