Humber Teaching
NHS Foundation Trust

Medical Devices and Non-Medical Devices and Equipment of High Cost/Volume for use in Clinical Areas – Management and Procurement (N-042)

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Policies should be accessed via the Trust intranet to ensure the current version is used

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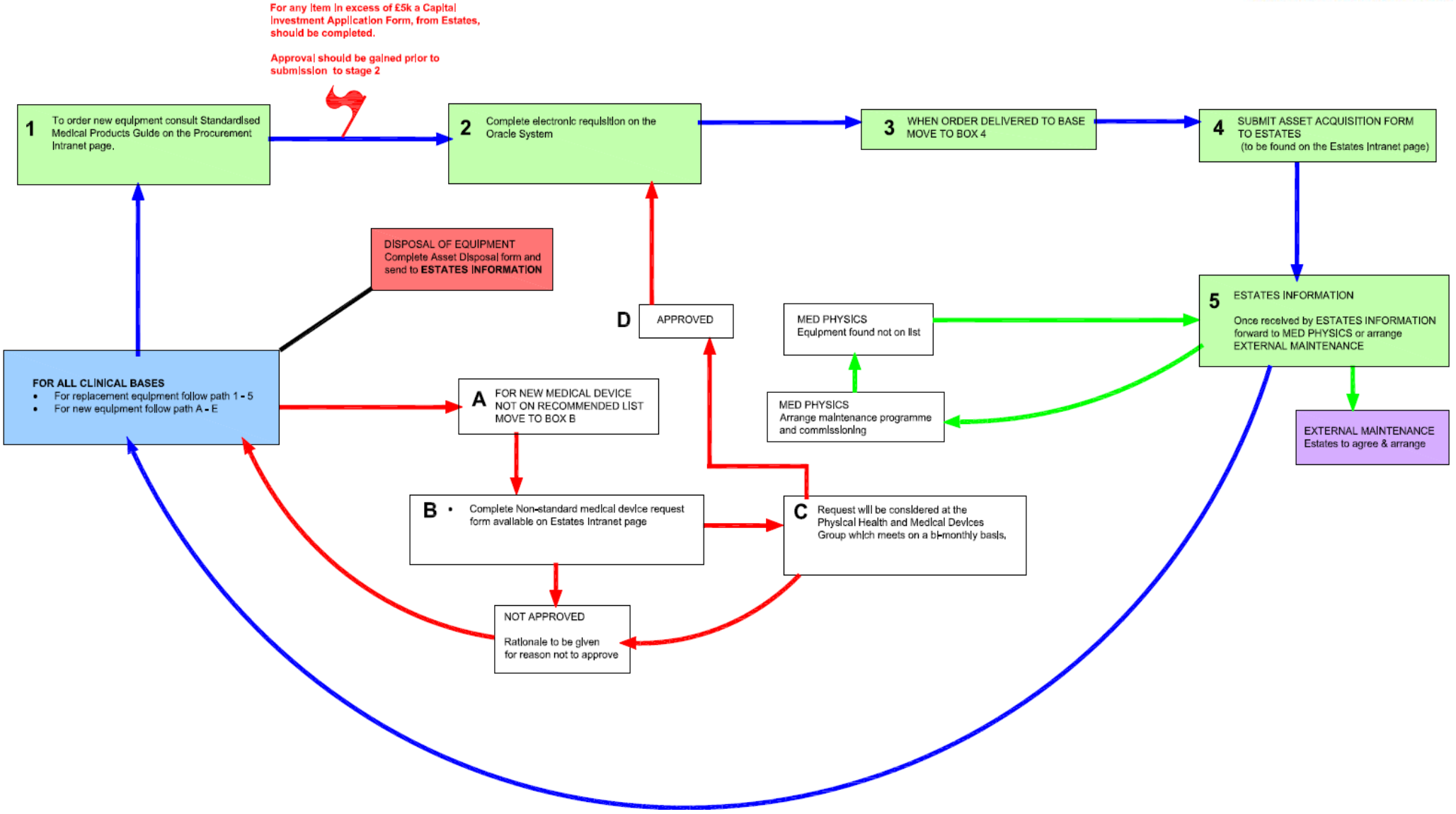
MEDICAL DEVICES FLOWCHART

Humber Teaching NHS Foundation Trust



1. INTRODUCTION

Medical/non-medical devices play a crucial role in care and treatment of patients. The purpose of this policy is to ensure that there is a consistent and uniform approach across the Trust to the procurement and management of medical/non-medical devices. The delivery of high-quality patient care depends upon access to appropriate medical/non-medical equipment that conforms to all relevant safety standards. It is essential therefore, that adequate systems are in place to ensure only equipment that meets such standards which is properly maintained, is brought into use in the Trust and that staff using the devices are adequately trained to do so.

The term “Medical Device” covers a wide range of products used every day in primary care settings, residential, nursing homes and hospitals. The term Medical Device includes any instrument, apparatus, appliance, material or health care product, excluding drugs, used for or by a patient or service user for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment or alleviation of, or compensation for an injury or impairment.
- Investigation, replacement or modification of the anatomy or of the physiological process.

Non-medical devices and equipment covers a vast range of equipment in use across several areas and departments using equipment in patient areas such as waste bins, cleaning equipment, commercial equipment, kitchen equipment, laundry equipment, Estate Services equipment, furniture, fittings, wall hangings etc.

As an overall strategy for the management of risk the Trust has an obligation to make certain that it minimises risks of using the equipment to as low a level as possible by ensuring that it keeps the most appropriate equipment for purpose, train staff how to use it competently and safely, cleans and maintains it correctly and at the end of its useful life disposes of it in an appropriate manner.

2. SCOPE

All employees of Humber Teaching NHS Foundation Trust, including agency staff and contracted services, have a duty of care to ensure the safety of patients/clients in their care. The Trust recognises the risks to patients, staff and others created by the use of certain types of equipment.

It therefore intends to ensure that there is a suitable and operational system in place to manage the procurement, usage, training, maintenance, and disposal to meet the requirements of national legislation, NHS Guidance and to make sure the equipment is fit for purpose, used safely, competently and effectively, particularly within patient areas.

This Policy applies to all staff in all departments, employed by the Trust, Bank Staff and Agency Staff who are involved with the purchase, use and maintenance of any type of medical/non- medical pieces of equipment.

The range of equipment applicable to this Policy is wide and can be defined as any instrument, apparatus, appliance, material or Healthcare product.

3. POLICY STATEMENT

The Trust recognises the risks associated with the ownership and use of medical/non-medical equipment and this can only be controlled by managing the whole life cycle of any piece of equipment. The aims of the policy include:

- Improved safety in the delivery of care to patients.
- Improved safety for the staff using the equipment.
- Improved control and utilization of valuable resources.
- Identification of the equipment needs in the area of work.
- Evaluation and proper selection of the equipment.
- Carrying out a risk assessment of the equipment prior to purchase
- Tendering and purchasing if larger amounts are involved.
- Seeking the views of manufacturers and users of the equipment.
- Training on equipment used
- Repairs and maintenance
- Safe and legal disposal.
- Compliance with legislation and standards.

By means of standardising the following:

- A standardised procedure for the procurement of medical/non-medical devices to ensure value for money and that all proposed equipment purchases satisfy local, national and EC standards.
- The installation, calibration, repairs and maintenance of equipment, together with associated record keeping is undertaken in a uniform and standardised format.
- A consistent reporting, investigation and recording of equipment related incidents.
- A consistent approach exists when dealing with the receipt of warnings from manufacturers, professional bodies and the Department of Health.
- Training, use and decontamination of equipment is compliant and consistent with MDA guidelines. (MDA.DB2000).
- Ensuring that patient safety and experience is maintained in line with the Care Quality Commission recommendations.

4. DUTIES AND RESPONSIBILITIES

Chief Executive
The chief executive carries overall responsibility for Risk Management. As such the chief executive has overall responsibility for all aspects of the management of medical/non-medical devices.

Director of Finance
Executive responsibility for the procurement of medical/non-medical devices is delegated to the director of finance, who has been designated to direct the compliance of the Trust with the external standards set for control of the procurement. The procurement and purchase of medical/non-medical devices will follow relevant national and clinical guidance and the Trust's Standing Financial Instructions.

Director of Nursing, Allied Health and Social Care Professionals
The director of nursing, allied health and social care professional is responsible for the development and implementation of this policy and for ensuring that suitable governance processes are in place relating to approval of medical devices. Responsible for ensuring training and competency assessment is available to clinical staff.

Chief Operating Officer
Responsible for their respective directorates ensuring that this Policy is applied across the Trust and for ensuring all medical/non-medical large equipment items are safe to be used and do not present a hazard to patients, employees and others when used on Trust premises.

Head of Estates and Environmental Services.
The Head of Estates and Environmental services has responsibility for the day-to-day asset management of all equipment/medical devices. This responsibility can be delegated within the team. Ensuring contracts are in place to support planned preventative and unplanned maintenance programmes for appropriate medical and non-medical devices.

Medical Device Safety Officer (MDSO)
The MDSO is responsible for receiving and processing the non-standardised medical device requests through Physical Health and Medical Devices Group.
The MDSO is responsible for distributing field safety notices and medical device safety alerts to the relevant managers within the Trust for action. This will be undertaken in consultation with the procurement team and the patient safety team.
The MDSO is responsible for reporting all relevant field safety notices and medical devices safety alerts including progress with required actions to the Physical Health and Medical Devices Group 6 weekly.
The MDSO is responsible for reviewing local incidents and near misses related to medical devices.
The MDSO will provide insight and feedback to the MHRA and NHS England & Improvement that may contribute to national medical device related alerts
The MDSO will be an active member of the National Medical Device Safety Network

Procurement Manager
It is the responsibility of the procurement manager to ensure the procurement of appropriate equipment follows the procedures outlined in this policy.

Physical Health and Medical Devices Group (for Medical Equipment) and the Clinical Environmental Risk Group. CERG (for Non-Medical Equipment)

The Groups will provide advice as required on the following:

- Equipment purchase, full running, maintenance and consumable costs. Input and advice into equipment purchase and risk management decisions. Guidelines for equipment decontamination.
- Co-ordination of equipment inventories.
- Monitoring and training and discussing equipment management procedures.
- They will oversee a wide range of purchasing issues, which will include consultation with the professionals who will be requisitioning/prescribing and using medical and non-medical devices.

Within this the following factors need to be considered:

- What equipment and accessories need to be provided and why. The range of particular devices available to cover requirements. Purchasing arrangements for new products.
- Tendering process for equipment supply, where applicable.
- What should be included in the procurement package, e.g. back-up training servicing and maintenance requirements.
- Total costs.
- Regulatory compliance information. Storage and training requirements. Product evaluation reports.

- Advice on risk assessments.
- Standardising on single models where possible, systems of record keeping including use, maintenance, and tracking, where appropriate.
- Patient information and feedback.

Senior Managers
Organisational responsibility for equipment and medical/non-medical devices lies with heads of services and service leads.

Managers (or those delegated by the manager) must:
- Assess the suitability of new equipment before it's purchased and used. Alert staff when testing, calibrating or repair of equipment is required. Have an up to date register of medical devices used by staff.
- Ensure all staff are competent to use the equipment and have the appropriate training to ensure patient safety.
- Maintain personnel records of staffs training and capability in the safe use of equipment. Ensure all equipment is suitably decontaminated following the specific manufacturers guidelines.
- Ensure all equipment is disposed of in the required manner.
- Ensure all equipment is stored adequately and maintained when in use. Ensure all incidents involving medical devices are reported.
- Ensure all safety alerts and bulletins are brought to staff attention and any actions are acted upon.

Infection Prevention and Control Team
The Infection Prevention and Control Team provides advice with regards to the cleaning requirements of equipment in accordance with manufacturer's guidance. Its advice should be sought initially to ensure reusable items can be cleaned effectively and in accordance with the manufacturer guidance.

Staff
It is the responsibility of all staff within the Trust to ensure:
- They only use medical/non-medical devices if they are competent and authorised to do so.
- They follow the principles outlined within this policy and any local procedures and protocols regarding the management and use of equipment.
- That all equipment is suitably decontaminated after each patient contact following the device manufacturers' specific guidelines.
- That all equipment is adequately stored and maintained when in use.
- They report any defects or faults with equipment immediately and clearly label defective devices and ensure they are taken out of commission.
- That staff make available items of equipment/devices for testing.
- They report any untoward incidents as soon as possible, identify the involvement of medical/non-medical devices and where appropriate record the name, and serial number(s) of the equipment.
- To participate in training appropriate to the devices in use to ensure competency and attend refresher training as appropriate.
- To ensure that they provide appropriate information and training about the use of medical/non-medical devices to clients.
- If a member of staff has not been trained in the use of an item of medical/non-medical device **or** the item of medical/non-medical device requires calibration, service or repair then this item of equipment **must not be used.**

Prescriber
A prescriber of a medical device is defined as "a trained person in the use of device, who

decides which is an appropriate medical device for a given patient" and such person carries professional responsibility for his or her own actions. Humber Teaching NHS Foundation Trust requires that staff with appropriate professional qualifications and suitable experience, backed by appropriate administrative and technical support, make all prescribing decisions.

The Estates Department is also responsible for ensuring contracts are in place to support planned preventable maintenance programmes for appropriate medical and non-medical devices.

Medical Physics
Medical Physics is provided via external contractors who keep an up-to-date record of all medical equipment that requires calibration and deliver a planned work schedule to ensure all appropriate equipment is calibrated and maintained.

5. PROCEDURES

Equipment will be required to meet the Provision and Use of Work Equipment Regulations 1998 and where equipment is hired in, the supplier will be asked to supply inspection and maintenance documentation for the equipment in line with the requirements of the Provision and Use of Work Equipment Regulations 1998.

If the equipment to be purchased needs a risk assessment carrying out prior to purchase, then if required Procurement can discuss with the supplier the need for a piece of equipment to be loaned to the Trust for trial and Risk Assessment prior to purchased.

5.1. Procurement Process for all medical equipment to include new, replacement and also when purchased with donated funds

All staff must ensure that all equipment which needs to be purchased for the Trust is done via the Procurement Department following Procurement procedures

All medical devices/equipment purchases must follow the procedure outlined within the Medical Devices Flowchart on page 4 of this document. The flowchart outlines two routes:

- Procurement of standardised medical devices/equipment already approved for use in the Trust
- New non-standardised medical devices/equipment not previously procured by the Trust

Procurement of standardised equipment already approved for use in the Trust

For replacement of standardised medical devices please refer to the standardised medical product guideline on the intranet https://intranet.humber.nhs.uk/procurement-team.htm. and complete the electronic requisition on Oracle.

New non standardised medical devices/equipment

Any new non-standardised medical devices/equipment will require approval at the Physical Health and Medical Devices Group before the item can be purchased. The person requesting the equipment must have authority to make such a request i.e. service manager, team leader. They will be required to complete the non-standard medical device request form on the Estates department intranet page https://intranet.humber.nhs.uk/estates-team.htm and submit for this to the Medical Device Safety Officer HNF-TR.mdso@nhs.net who will be responsible for bringing this to the

Physical Health Medical Device Group for review/approval. The requester is responsible for ensuring all the required fields are completed on the request form and that the subject/clinical expert has been consulted in relation to the request.

Any medical device or equipment wishing to be purchased using **donated/charitable funds** must undergo the same process as outlined above without exception. Equipment/devices will not be purchased or received via any other means.

5.2. Equipment Storage

It is the responsibility of the local manager to ensure that small, medium and large pieces of medical equipment are stored appropriately, to ensure safe use and in line with manufacturer's information and instructions.

In doing so, the following should be considered:

- Adverse environmental conditions such as, extremes of temperature, dirty or wet conditions. Storage systems that result in stacking equipment too high or fragile equipment being stored too far off the ground.
- Equipment needing decontamination and repair being stored alongside equipment that is ready for use.
- Allocating inadequate space.
- Equipment exceeding shelf life and ensure stock rotation.
- Excessive storage time, poor storage conditions also put the organisation at legal risk.

5.3. Equipment Management, Maintenance and Repair

Routine maintenance and planned preventative maintenance should ensure that equipment will work safely when used and should increase its working life.

Each piece of equipment must have an individual asset number and a identified routine maintenance plan stating the frequency of maintenance required.

This plan will be recorded in the service area maintenance record as well as on the Estates Management system and if needed by the Medical Physics Department.

The Hull University Teaching Hospitals NHS Trust Medical Physics Department will contact the service area when medical devices are due for routine maintenance to arrange to check the equipment.

The service area manager is responsible for ensuring that equipment is made available for the Medical Physics Department or service engineer as requested.

If equipment is in use at the time the maintenance was due to be carried out, it is the responsibility of the senior manager of the service area to arrange another date for the equipment to be serviced as soon as possible at the time it is recorded as due to be serviced. Should assistance or further advice be required in relation to this please contact the Trust Estates Department and the Medical Devices Safety Officer for the Trust HNF-TR.mdso@nhs.net Refer to Appendix 5 for further details.

5.4. Record Keeping

An accurate record of all equipment used within a designated service or department must be maintained and updated as appropriate by a designated person (i.e. charge nurse, ward sister, team leader). Records should also be held within the Estates Department covering the Trust as a whole.

The system used throughout this Trust must include:

- Date purchases, price and installation
- Serial number or unique identifier (if appropriate)

- Maintenance plan and any associated costs.
- Adherence to any legal requirements, e.g. PAT tests.
- Storage
- Decontamination requirements
- Training requirements
- Decommissioning/disposal
- The appropriate Asset Number

Records must show that staff know how to:

- Use the device safely
- Carry out day-to-day checks and routine decontamination, local maintenance, and have been trained in these matters including any relevant refresher training

The designated manager must ensure records are updated, staff training needs are addressed and planned preventative maintenance is put in place using a standardised pro forma.

5.5. Recording of Equipment

Recording of equipment received by a service area or sent for repair from a service area

The Estates Department must be informed of any new equipment as soon as it is delivered to a service area.

The senior staff member on duty is responsible for informing the Estates Department that there is a new piece of equipment. This can be done by completing the online asset acquisition form found on the https://intranet.humber.nhs.uk/estates-team.htm on the Estates Team intranet page. On receipt of this information the item will be added to the asset register for the location where the item is to be kept. This must be done on the day the equipment is received.

On addition to the asset register the Estates Team will identify if any on-going maintenance, inspection or servicing requirements are needed to ensure the continued safety of the device. Such maintenance regimes and practices will then be placed in action by the Estates Department to allow the use of the device. If the device is medical in nature the details of the device will be forwarded to Medical Physics for addition to their service schedules.

The Medical Physics Department will contact the service area to arrange initial checking and registering of the new piece of equipment. They will also advise the service area how frequently the equipment will need to be serviced.

The senior member of staff on duty is responsible for ensuring that the service maintenance requirements for each new piece of equipment checked by the Medical Physics Team is recorded on the service area equipment maintenance record.

If an item is to be decommissioned or transferred between sites then the Estates department must also be informed of this via the on-line asset disposal/transfer forms held on the Estates intranet page. https://intranet.humber.nhs.uk/estates-team.htm. This will enable the Estates department to amend any maintenance contracts/schedules in place.

5.6. Training Requirements and Knowledge

Training in the use and management of the medical device should be undertaken before any staff are allowed to use the device. Training requirements should be discussed and addressed at the procurement stage and should be part of the induction of equipment and training schedules. The training requirements for each device can vary according to complexity and risk to patents and staff and should be arranged and delivered according to the risk

assessment. Evidence of training records for all medical devices should be kept locally and be available for inspection as required. See Appendix 6 for more information.

5.7. Advising Service Users and Carers

Service users and carers should be fully aware of their responsibility for medical devices and should be appropriately trained in the use of the device. The service users informed choice should always be upheld.

Where appropriate they should be given written guidance from the manufacturer / supplier or they may be a Trust standard operating procedure, which supports the use of the device and covers the following:

- The name of the device
- The operation of the device
- Their responsibility for checking the device whilst in use, recognition of the device, failure and fault
- Action to be taken in the event of a device failure or fault
- Their responsibility for reporting an untoward event to the suppliers of the equipment. Telephone numbers of contact points in emergency, including out of hours
- Their responsibilities if they have bought the device themselves

5.8. Prescribing Issues

The prescription of equipment is the responsibility of the prescribing professional. There is a need to ensure that suitably qualified and experienced staff undertake the prescription of different types of equipment. Where joint working arrangements are put in place and involve the “crossing of professional boundaries” in prescribing, providers must ensure, via the Service Manager that clarity is given to a professional and legal responsibility of prescription. The service manager will need to ensure and be clear about professional responsibility for the issue of equipment, continuing responsibility and monitoring of the equipment.

Trust staff must not make statements verbally or in writing to patients and/or their carers regarding the availability or funding or procurement of equipment by commissioners, local authorities and/or the Joint Equipment Services they have contracted to do so. Any questions regarding Commissioners decisions to provide or not provide equipment must be referred to either the responsible Commissioner and/or the Equipment Provider as their agent.

5.9. Risk Management

As a part of an overall strategy for risk management the Trust has an obligation to make certain that it minimises the risks of using medical devices to as low a level as practicable by ensuring that it purchases the most appropriate equipment for the purpose required, trains its staff how to use it safely, decontaminates and maintains it correctly and disposes of it in an appropriate manner.

5.10. Loans and Transfers

All transfers of medical equipment will require documentation and the completion of a transfer form available on the on the https://intranet.humber.nhs.uk/estates-team.htm

There must be a documented undertaking from the carer/user on how they use the equipment and an agreement from the patient to return this to the Trust on completion of use.

Any loans should be discussed with the appropriate department prior to the form being completed. All appropriate indemnity forms must be signed and authorised prior to the equipment being brought onto Trust premises.

5.11. Disposal

Disposal of equipment will follow the information provided by the manufacturers.

It is important that the Estates Department is notified of all equipment to be taken out of use, which is no longer required. Managers must ensure that the appropriate procedures for updating Asset Registers and local and Trust wide Inventories are followed.

5.12. Medical Devices – Developments, Modifications or Trials

All service managers must not enter into medical device development modifications or trials with any external partner, manufacturer or university without first referring this to the Physical Health and Medical Devices Group for approval.

This is to ensure that the Group is aware of all the risks associated with these practices and have been able to take into account, in accordance with relevant legislation and guidance all issues that may affect the decision to approve or reject such an application.

5.13. Medical Devices – Designated for Single Use

All items designated for single use episodes must not be re-used under any circumstances whatsoever. For guidance on common symbols used on medical devices and packaging see Appendix 4.

Guidance on Single Use Medical Devices is given in MDA DB 2000(04) on the Hazards and Risks associated with the reprocessing and re-using of single use Equipment. The legal issues and regulatory requirements of such actions, i.e. any individual who uses or reprocesses a device intended by the manufacturer for use on a single occasion, will mean that the individual bears the full responsibility for its safety and effectiveness (Appendix 3).

Guidance on this matter can be sought from the Infection Prevention and Control Department.

5.14. Use of Medicines

Medicines must be considered as single use items unless the label and/or the supporting manufacturers guidelines clearly state that they have been prepared as multi-dose items. A risk assessment must be carried out (in conjunction with Pharmacy) for each individual product.

5.15. Cleaning and Disinfection of Medical Devices

All reusable medical devices should be cleaned and disinfected in line with the manufacturer's instructions. Further guidance is provided in Appendix 11 Guidance at a Glance Decontamination of Patient Equipment (including Medical Devices)

Managers and staff will ensure that when equipment requires maintenance and repair it is clean in accordance with the Trust Cleaning and Disinfection of Equipment and Medical Devices Policy, as per the manufacturer guidance, safe and labelled in accordance with

If a medical device cannot be cleaned or disinfected properly, this must be clearly indicated on the equipment, and the engineers must take appropriate precautions when undertaking repairs.

5.16. Repair of Equipment

When equipment requires repair the following process must be followed:

- Equipment must be decontaminated and a decontamination status form completed. Equipment must be clearly labelled that it is not for use and awaiting repair.
- The senior member of staff on duty is responsible for contacting the Estates Department to report that a piece of equipment requires repair. Information given to the Estates Department must include the type of equipment requiring repair, the asset and serial numbers of that piece of equipment.
- A record must be kept in the service area of the date and time the equipment was reported as requiring repair together with any other records of calls made to the Estates regarding each piece of equipment that has been reported to repair.

- If equipment is required to be transported to the medical physics department for repair then the Estates Department will advise how the equipment will be collected and transported or who will collect it.
- The senior member of staff on duty, or nominated locality person, is responsible for ensuring that a record is made in the service area equipment maintenance log, of the date when equipment was sent for repair, and of any further calls made to either the Estates Department or Medical Physics Department to enquire about the progress on equipment repair.
- When equipment is returned to a service area following repair or is repaired in site, the senior member of staff on duty at that time is responsible for up-dating the service area equipment maintenance log to note the date and time it was repaired and/or returned to the ward.

5.17. Medical Device Equipment Replacement

For all medical devices there is a stage that is reached at which replacement must be considered. This must be brought to the attention of the Service Manager.

6. EQUALITY AND DIVERSITY

An Equality and Diversity Impact Assessment has been carried out on this document using the Trust-approved EIA.

7. MENTAL CAPACITY

All patients/carers ability and capacity to use equipment appropriately and safely will be assessed prior to it being issued by the relevant clinician. This will be recorded in the patient's clinical records.

8. IMPLEMENTATION

This policy will be disseminated by the method described in the Document Control Policy
The implementation of this policy requires no additional financial resource.

9. MONITORING AND AUDIT

9.1. Medical Devices

Each clinical area must keep a record of all medical devices, the training record relating to them and the maintenance schedules. These will need to be available for the Physical Health and Medical Devices Group as well as for external organisations to monitor compliance.

An infection prevention and control audit will be done on an annual basis as part of the annual audit plan regarding decontamination and infection control. The Trust has cleaning schedules in all areas and these are monitored by charge nurses and modern matrons.

The Medical Devices Safety Officer will monitor compliance with this policy by the checking of 3 devices on a yearly basis to ensure the policy has been adhered to. This will focus on the procurement, maintenance, and disposal of the device
Compliance of this policy will be monitored via the following systems and processes.

Patient complaints Adverse incidents Records audit
Staff training records

9.2. Monitoring Compliance of Staff Training

Monitoring of Compliance with staff training will be carried out in the following way:

- The service area manager will keep a record of all types of equipment used in the service area.
- The service area manager will keep an up to date record of the levels and frequency of training required for all staff members in the use of all types of equipment in that area.
- The service area manager will make clear to staff at all levels in their service area what types of equipment different levels of staff can use according to their role and competence.
- The service area manager will provide an up to date report to their line manager on an annual basis of staff training records for the service area for all equipment used and relevant to each staff members role.
- Annual staff equipment training reports must include staff who are identified as not having maintained their training requirements for use of equipment relevant to their role with a plan that includes relevant action to be taken to rectify this within agreed time scales.

10. REFERENCES/EVIDENCE/GLOSSARY/DEFINITIONS

1. Medicines & Healthcare Products Regulatory Agency (MHRA). (2000). Equipped to Care: The Safe Use of Medical Devices in the 21 Century. London: MHRA.
2. Medicines & Healthcare Products Regulatory Agency (MHRA). (2001).
3. Devices in Practice – A Guide for Health and Social Care Professionals. London: MHRA.
4. Office of Public Sector Information. (2002). The Medical Devices Regulations SI 2002/618.
5. London: Office of Public Sector Information.
6. Medicines & Healthcare Products Regulatory Agency (MHRA). (2006). Bulletin No. 17 –
7. Medical Devices and Medicinal Products. London: MHRA.
8. Medicines & Healthcare Products Regulatory Agency (MHRA). (2006). Managing Medical
9. Devices – Guidance for Healthcare and Social Services Organisations. London: MHRA.
10. NHS Litigation Authority (NHSLA). (2008). NHSLA Risk Management Standards for Acute
11. Trust – Standard 2.7. London: NHSLA.

Appendix 1: Non-standard medical device request form

Humber Teaching NHS Foundation Trust

This form must be completed for all new medical device which are not available through the standardised medical products guide. All new medical devices must receive approval through the Physical Health and Medical Device Group before being purchased. Once completed this form should be sent to the Trust Medical Devices Safety Officer at HNF-TR.mdso@nhs.net

Product information	
Medical Device make and model	
Manufacturer	
Product Number/Code (if applicable)	
Details of person making request	
Name	
Job title	
Team	
Division	
Device overview	
What is the purpose of this devices?	
What is the cost of each device?	
Is the device single use?	
How many devices are required?	
Are there any on-going maintenance costs?	
How will the cost for purchase and maintenance be covered?	
Does the devices require any internal or external calibration or quality assurance checks?	
Where will the device be used for example ward, patient's own home, clinic?	
Who is the end user? i.e. registered or unregistered practitioners, patient, family/carers.	
What group of patients will benefit from this device?	
What is currently used?	
Does this device need direct access to the internet or trusts wireless network?	
Does the device store patient information?	
Risk assessment	
What risks are associated with this device?	
What are the risks of not having this piece of equipment in your clinical area/team?	
Best practice	
Is there any evidence or guidance to support the use of this device for example NICE technical appraisal?	
Who is the subject/clinical expert and have they been consulted in respect of this proposal?	
Training and competency	

What training will be required in order that staff are skilled in its safe use and how will this be delivered?			
How will competency be assessed?			
What staff will use this device? Registered or non-registered clinicians			
PHMD use only			
Has the group been reviewed the manufacturers product information/guidelines?			
Have there been any safety alerts or field safety notices published on relation to this device?			
Have any risks been identified?			
Does this device need direct access to the internet or trusts wireless network?	Y/N	Comments	
Is consultation with IG required and has a DPIA been completed?	Y/N	Date completed	
Does this device require approval at the Information Governance Group?	Y/N	Date completed	
Does this device require review by the Clinical Safety Officer?	Y/N	Date completed	
Does this device require review and approval by the Digital Delivery Group?	Y/N	Date completed	
What are the on-going costs for maintenance?	Comments:		
What are the manufacturers guidelines on cleaning and decontamination? Have IPC been consulted?	Comments:		
Has expert advice been sought in relation to this equipment request?	Comments:		
PHMD review and approval			
Date reviewed at PHMD			
Decision of review	Approved/Declined/Deferred		
Rationale for decision			

Non-standard Medical Device request form V1.0 June 2022. Form located on https://intranet.humber.nhs.uk/estates-team.htm

Appendix 2: Procurement/Financial Appraisals

Procurement/Financial Appraisal

Each senior manager, head of service or head of department, will discuss proposed equipment purchases with the relevant department, i.e. Estates, Medical Physics, Finance and Procurement. In addition, the Physical Health and Medical Devices Group for medical equipment and the Capital Programme Board for individual purchases 5k and over need to consider and review plans for major new acquisitions or replacements. Each Senior Manager/Head of Department will be responsible for identifying any planned change to the equipment inventory (purchases, other acquisitions, disposals or transfers) to the Estates Department via the forms available on the on the Estates Department intranet page. Before new medical equipment is brought into the Trust, each senior manager/head of service must ensure they follow the procedure outlined in the Medical Devices Flowchart at the beginning of this document.

The service manager will ensure that capital and revenue funds are available for the purchase and care of the equipment including ensuring again all proposed purchases with an individual item value of £5K or over are submitted firstly for approval to the Capital Programme and Estate Strategy Group Further information and required documentation for completion can be obtained from robertatkinson1@nhs.net.

They must also enlist the support of the Medical Device Safety Officer and the Senior Procurement Manager to obtain quotations/tenders in accordance with standing financial instructions to include maintenance and consumable costs of the proposed purchase. All medical equipment purchases must follow the procedure outlined within the Medical Devices Flowchart on page 4 of this document. The flowchart outlines two routes one for procurement of standardised equipment already approved for use in the Trust and one for new equipment. New non standardised equipment requires approval at the Physical Health and Medical Devices Group and requires completion of the non-standard medical request form on the Estates department intranet page https://intranet.humber.nhs.uk/estates-team.htm and submitted firstly to the Medical Devices Safety Officer HNF-TR.mdso@nhs.net

This policy applies equally to equipment that is provided on loan by the manufacturer or any other external agency which is not owned by the Trust. In such circumstances, any medical equipment to be loaned to the Trust must be covered by the supplier's indemnity. The Service Manager must ensure that such equipment is brought to the attention of the Medical Device Safety Officer and the Senior Procurement Manager which will arrange for the necessary indemnity forms and also arrange any acceptance testing if required. Any loan equipment which the supplier cannot indemnify or fails acceptance tests cannot be used in the Trust.

If the period of loan is to be extended, the service manager must notify the relevant department so that the indemnity period can also be extended. The service manager will also agree how any associated maintenance or calibration costs will be funded.

Before any new medical equipment not on the Trust standarised list is procured, a proportional Procurement appraisal should be carried out with the support of the relevant department, e.g. Finance/Procurement/Estates Department and in accordance with the Medical Devices Flowchart at the beginning of this document. This is to ensure that all relevant costs are taken into account when determining value for money, affordability and accurate cost estimates.

Points to be taken into account, and information required to produce a financial appraisal of the purchase are:

- Cost of the device, delivery charges and installation (if applicable). Maintenance and servicing requirements and associated costs.
- Can this be provided under existing service agreements or does it have to be bought from the supplier?
- Duplication of maintenance and servicing arrangements should be avoided.
- What are the maintenance intervals, what is included in the cost and does it fit the Trust's requirements?
- Other options for procurement of the device, including leasing, contract purchase, financing, loaning, and sharing (can another organisation use the device and share costs?).
- Servicing insurance cover available and cost.
- Cost of consumables and availability from other manufacturers. Value for money.
- Capital Charges.
- Storage consideration, extra security arrangements and any associated costs. Training costs – included or extra.
- Cost of recalibration, reconditioning.
- Life cycle of the device and hence replacement cost and timing/frequency.
- Level of technology involved can influence how quickly a device becomes out-dated and hence repair and replacement costs.
- Availability of technical advice or help-lines.

All these points affect the cost of the device over its life cycle and need to be taken into account at the earliest stages of procurement.

Appendix 3: Single Use Items

Single Use Items

Definition of what is a single use item is not straightforward. Manufacturers have a responsibility under British and European Law to determine where a product cannot be re-used for reasons of safety.

These may include:

- A lack of appropriate cleaning/decontamination methods.
- Inability to provide the user with information on pre-use checks.
- Inability to guarantee consistent performance during reuse.
- Concerns over Control of Infection.
- Lack of definition over the life span of the item.

Single use items often have contained limited or non-specific information about the use of the product, such as:

- “Single use” means that it can only be used once.
- “Do not re-sterilize” means it must not be cleaned/decontaminated for the purposes of re-use.
- “Single patient use” means that it might be suitable for re-use on the same patient.

If staff are in any doubt about the use of an item they must clarify it with the manufacturer before it is used/reused.

Bulletin DB2005(01) provides a list of examples of medical devices, which includes the following items that are or may be single use; catheters, dressings, examination gloves, IV administration sets, syringes and needles, vaginal specula and intra-uterine devices. Also many pieces of equipment including patient monitoring equipment and nebulisers have single use attachments.

Patients may also use items that are single-use or single patient use, these include; contact lenses, hearing aids, incontinence products and urine drainage systems.

The bulletin states that when a device is ‘single-use’ the manufacturer:

- Intends the device to be used once and then discarded.
- Considers the device is not suitable for use on more than one occasion.
- Has evidence to confirm that reuse would be unsafe.

Devices designated for ‘single-use’ must not be reused under any circumstances.

The reuse of ‘single-use’ devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.

Single-use devices are not designed to allow thorough decontamination and re-sterilisation processes.

Reprocessing single-use devices may alter the nature of the materials from which the device is made and therefore its performance to an extent that makes it unsafe to reuse.

The re-use of ‘single-use’ devices has legal implications.

Anyone who reprocesses or reuses 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.

Reprocessing may expose both staff and patients to health and safety and infection control risks and result in civil liability for any injury caused by the device.

Packaging and Labelling
This symbol, which indicates 'Do Not Reuse' appears on the packaging for single-use medical devices and may replace any wording:

Is a symbol that may appear on packaging signifying that the product is intended for single use only and must not be reused.

External Standards
The Medical Devices Agency, which is an executive agency of the Department of Health and is part of the Medicines and Healthcare Products Regulatory Agency (MHRA) re-issued a bulletin in August 2000 (originally issued in 1995) warning of the dangers of reusing single use items.

It states that:

- Devices designated for 'single-use' must not be reused under any circumstances.
- The reuse of 'single-use' devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- The reuse of 'single-use' devices has legal implications.
- Anyone who reprocesses or reuses 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.

The bulletin above is now reinforced, by the implementation of the European Council's Medical Devices Directive, into UK law.

The Department of Health (HSC 1999/179) Action of this document requires that staff 'Never reuse medical devices for single-use.' The Controls Assurance's Decontamination of Medical Devices standard, requires that a policy for single–use and single patient use devices are in place, under the Health & Safety at Work Act 1974 and Provision & Use of Work.

Appendix 4: Graphical Symbols used on Medical Devices and their Packaging

	▪ **DO NOT REUSE** Synonyms for this are: Single-use Use only once
	▪ **ATTENTION,** **SEE INSTRUCTIONS FOR USE**
	▪ **USE BY DATE** – The symbol is intended to indicate that the device should not be used after the end of the month or day shown
	▪ **DATE OF MANUFACTURE**
 **ABC 1234**	▪ **BATCH CODE** Synonyms for this are: ● Lot number ● Batch number
	▪ **STERILE**
SYMBOLS FOR 'STERILE' INCLUDING THE METHOD OF STERILIZATION	
	▪ Method of sterilization: ethylene oxide
	▪ Method of sterilization: irradiation
	▪ Method of sterilization: Steam or dry heat

Appendix 5: Equipment Management, Maintenance and Repair

Routine Maintenance

- Recommended cleaning of the device.
- Preparation of the device for use and then checking and calibration of the device.

Planned Preventative Maintenance:

- Should follow the device manufacturer's guidance.
- Is usually done by the manufacturer, supplier or agent.
- May be done by third party repairers, provided the work of the sub-contractor is of a sufficiently high standard, is audited and reviewed regularly.

Procedures for Routine Maintenance should ensure that:

- Instructions are documented and available.
- If the device has a label attached all instructions on this should be adhered to. If the label is damaged/illegible a paper copy of the instructions should be available for staff to follow.
- Staff know how to check that the device is working properly before it is used on a patient. Staff can identify whether the device is faulty and know how to get it repaired.
- Staff know how to decontaminate the device after use.
- Devices are stored safely in accordance with the manufacturer's instructions.

Procedures for Planned Preventive Maintenance should ensure that:

- Estates department manages the contract, which sets out responsibilities for repair and maintenance requirements.
- There is evidence to show that the service organisation is competent to maintain the device to the manufacturer's specification.
- Any changes to the manufacturer's maintenance recommendations have been agreed and documented.
- Following maintenance or servicing, the device is checked before it is used with a patient.
- There is a planned replacement strategy.
- Times for preventive maintenance on individual devices are brought to user's attention regularly and automatically.
- There is a system to display the date of the last and next service, if this is appropriate. Back up equipment should be available if the device is defective or requires servicing or maintenance.

Appendix 6: Training Requirements and Knowledge

Training Needs Analysis

Existing Equipment- Staff should have a clinical and technical knowledge of equipment prior to use and identify any deficits of this knowledge to their line manager. These needs should then be addressed either through supervision or by a request to the Training Department or specialists i.e. Macmillan Nurses.

Health care professionals who use medical devices within their role, and who also provide devices for use by others, e.g. a service user or carer; are accountable for the use of such equipment and must ensure:

They have the appropriate personal training to ensure the correct use of devices. Service users and carers have received appropriate training and know how to use any device that has been provided for their personal use.

Training may be accessed from a variety of sources, these may include:-

- The manufacturer or supplier.
- Internal experts or clinical leaders.
- External training packages.
- Training delivered from the Trust Training Department.

Training records for all medical devices should be kept locally and be available for inspection as required.

An individual health care professional, who advises against manufacturer's instructions, may take on liability for that advice.

In addition to formal training in the use of a medical device the following knowledge of the device is essential.

Before Use

- Is the way in which the device is to be used that intended by the manufacturer?
- What are the limitations and contra-indications for use?
- Has the device been regularly maintained?
- When the device was last serviced and when is the next service due? Has the device been checked after servicing?
- Is the device within its expiry or "use by" date? Are there any signs of wear, damage or faults? Where can a replacement device be obtained?

During Use

- What action should be taken if a device is not functioning properly? Has this been documented?
- Is there up to date documentation to record regular checking of the device?
- What are the details (name and serial number) of the device being used?
- Is the equipment still appropriate in the light of changing needs of the patient or client e.g. children can physically outgrow equipment?

After Use

- If used in the home how will the medical device be returned to the owner, disposed of, or safely stored?
- Is cleaning and/or decontamination required?

- Does the medical device show any signs of wear, damage or faults that should be reported? Is any servicing, maintenance or repair required?
- Were there any problems in using this device, which should be noted and could be rectified for the future? E.g. was any information missing from the Patient Carer Guidance which could have been useful?

Appendix 7: Risk Management

Risks will be reduced by adhering to the following principles:

- The prompt reporting of problems associated with the use of medical devices and equipment both internally via Datix and to the MHRA, which in turn will enable lessons learned to be shared and applied.
- The rapid dissemination, to all staff that need to know, of MHRA safety alerts and other equipment alerts and warnings.
- The procurement of medical devices in accordance with Trusts Procurement Procedures and Standing Financial Instructions and Procurement Policy.
- The regular inspection and maintenance and removal from use of faulty equipment and medical devices.
- Ensuring the ongoing and systematic identification of equipment that requires replacing and ensuring that equipment replacement programmes are in place.
- Ensuring that there is a robust process for ensuring that all reusable medical devices are calibrated within set and specific time frames. A programme of calibration will be communicated between all clinical areas and the medical physics department. A database for all medical devices requiring calibration will be maintained within the clinical areas.
- The standardisation of medical devices (e.g. pressure relieving equipment), wherever possible, in order to avoid confusion and reduce the potential for error.

Risk Identification

All medical device risks are systematically identified, using several approaches, including the following:

- Reviewing of incidents
- Reviewing of safety notices
- Risk assessments
- Carrying out device inspections and assessments and reviewing of appropriate audit reports.
- To support this, any medical device incidents are reported appropriately, following the Trusts Adverse Incident policy.

Risk Assessments

Risk assessments regarding all medical devices should be undertaken within all clinical areas and any serious risks reported and recorded on the Trust Risk Register. The Safer Services Committee will report and minute any medical device issues. Medical Devices issues are reported upon quarterly in the Joint Risk, Complaints and Claims Report to the Governance Committee and Trust Board and thereby allow the Board to monitor the management of medical devices within the Trust.

Incident Reporting

All incidents and near misses must be reported on Datix for any incidents regarding medical devices. Examples of unwanted or unexpected outcomes occurring as a result of incidents involving medical devices can include:

- A patient, user, carer or health professional is injured as a result of the failure or misuse of a medical device.
- A patient’s treatment is interrupted or compromised by the failure of a medical device. Misdiagnosis due to a medical device failure, leading to inappropriate treatment.
- A patient’s health deteriorates due to a medical device failure.

- Risks can also arise from the inappropriate selection or use of a medical device. Training is crucial to ensure that both staff and users use medical devices appropriately.

Distribution of Hazard Warnings and Safety Notices

The Medicines and Health Products Regulatory Agency (MHRA) and the manufacturers of Medical Equipment and devices have responsibility for issuing of field safety notices on national level to all Trusts. When these are received, they are circulated throughout the Trust and appropriate action is taken.

It is a national requirement that the Trust has a system in place to ensure that Medical Device Alerts are distributed appropriately, and any recommendations implemented.

It is the responsibility of those nominated to disseminate the notices i.e. Service managers to appropriate health care professionals and ensure the recommendations are implemented where appropriate.

The assessment of risk to patients should include:

If the medical advice is to be used by patients and carers, have the following been taken into account?

- physical capabilities e.g. manual dexterity
- sensory capabilities e.g. vision and hearing
- ability to understand and remember previous experience with a medical device the patient's or client's expectations
- environment in which the device will be used

Appendix 8: Decontamination of Reusable Equipment

All equipment must be appropriately decontaminated before inspection, service or repair and decontamination form completed and attached to the equipment. Please refer to Appendix 9 Cleaning and Disinfection of Equipment and Medical Devices.

Do not purchase new equipment without first checking that the Trust has suitable facilities for decontamination. If unsure, contact the Infection Prevention and Control Team. The purchase of new decontamination equipment, or chemical disinfectants should not be undertaken without consulting the Infection Prevention and Control Team.

It is essential that safe systems of work exist to protect **all** staff against the transmission of infection from medical devices and other equipment that may come into contact with hazardous agents. This also includes staff not employed within the Health Service.

The choice of decontamination method will depend on the risk of infection associated with the equipment. The choice of cleaning agent must best meet the overall needs of the equipment and regardless of use any equipment must as a minimum be cleaned between patients. Staff carrying out this task must ensure that they use suitable Personal Protective Equipment (PPE) as set out in the Trust's Standard Precautions Policy (P112). Where required equipment should be certified to demonstrate that appropriate decontamination has been undertaken, e.g. when sending to medical physics department for planned programmed maintenance inspection.

All reusable medical devices and equipment to be inspected, serviced, repaired, returned to the lending organisation or for disposal should undergo decontamination. This is necessary to ensure that they are in a condition that makes them safe to be handled by all personnel who may come into contact with them during transit and subsequent handling. The device and equipment should not expose the recipient to a biological, chemical or radioactive hazard.

Manufacturers have a responsibility to provide information on the compatibility of their particular medical devices or equipment with methods and agents for decontamination. It is essential this information is available and followed as inappropriate methods or agents can damage equipment.

If the manufacturer is unable to provide this information or it is inadequate the MHRA should be notified via the Trust Risk Management Department.

The choice of decontamination method should be related to the infection risk associated with the intended use of the equipment.

Prior to any equipment being issued for use or sent out to an external company, service or repairer the equipment needs to have been through the disinfection process and to ensure that the correct level of decontamination has been followed for each specific item. Where possible the equipment needs to be placed into a plastic bag as part of the packing process. A certificate should be completed and issued with the equipment to ensure that the recipient is aware that the equipment has been decontaminated appropriately**.**

A decontamination certificate will be completed and if possible placed inside the plastic bag.

All medical devices returned for servicing and repair must follow the Trust's procedure for ensuring the equipment is cleaned appropriately prior to maintenance and that the appropriate forms are attached to the piece of equipment for its onward transmission to the Estates or Medical Physics Department. Failure to follow this procedure will not only put staff at risk, but also creates a danger of legal liability being incurred if unsafe equipment is supplied to community end users. All equipment not decontaminated correctly and certified, will be returned to the department from where it came.

Decontamination Procedures

All medical devices must be decontaminated in accordance with HSC 1999/178 and HSC 1999/179. Decontamination is the combination of a process including cleaning, disinfecting and all sterilisation used to render the reusable medical device safe for further episodes of use.

Effective cleaning of medical devices prior to disinfecting or sterilisation is of utmost importance in reducing the risk of transmission of infectious agents, especially VCJD.

Upgrading and Replacement of Decontamination Equipment

Where decontamination does not meet current standards and test methods, this piece of equipment must be logged for upgrading or replacement as soon as practicable, in accordance with the planned preventive maintenance programme, to ensure that it maintains current standards of test methods.

Service Managers must ensure that an established cleaning process is available and is used before ordering. On medical devices that cannot easily be cleaned, decontamination equipment works less efficiently on the instruments that are difficult to clean and/or are in poor condition.

The Service Manager must ensure that the condition of the medical device in use is appropriate for their need and, if requiring replacement, these should be identified on a planned replacement programme and be replaced with versions which are easier to clean.

Appendix 9: Declaration of contamination status

TO: Service Department:		DATE:	
Equipment Description:			
ID:			
Fault:			
Work Order Number (if known)			
Is the item contaminated?	YES	NO	Don't Know
State type of contamination:	Blood	Body Fluids	
	Respired gases	Pathological sample Yes / No	
	Other biohazards Yes / No	Other hazards Yes / No	
	Chemicals or substances hazardous to Health. Yes / No		
Has the item been decontaminated?	YES	NO	Don't Know
What method has been used (please provide details)			
Cleaning:			
Disinfection:			
Sterilization:			
Please explain why item has NOT been decontaminated			
Declaration: I declare that I have taken all reasonable steps to ensure the accuracy of the information given in accordance with HSG (93) 26.			
Signature:			
Date			
Designation / Position:			
Telephone Number:			
Unit / Department:			

Appendix 10: Certificate Declaration of Contamination Status

CERTIFICATE DECLARATION OF CONTAMINATION STATUS

DECONTAMINATION CERTIFICATE

This is to certify that before being delivered the attached equipment has passed through the decontamination process

DECONTAMINATION CERTIFICATE	
Type of Equipment	
Serial Number	
Bar Code Number	
Method / Process Used	
Date of Decontamination	
Name of Person Undertaking Process	
Equipment Inspected	**Yes / No–(if no specify reason)**
Equipment Safe for Use	**Yes / No –(if no action taken)**
Date of Inspection	
Name of Supervisor undertaking Inspection	
Signature	

Appendix 11: Decontamination of Patient Equipment (including Medical Devices)

GUIDANCE AT A GLANCE

Decontamination of Patient Equipment (including medical devices)

These guidelines support the prevention and control of infection within Humber NHS Foundation Trust.
The principles reflect best practice and national guidelines (National Specification of Cleanliness in the NHS 2001)

All patient equipment may become contaminated with infectious agents that you may not be able to see. Maintaining good cleaning and decontamination standards will reduce the risk of cross infection.

Key Points

- All equipment must be decontaminated after use and between patient use
- Decontamination must always be carried out in accordance with manufacturers' instructions
- All products must be stored in compliance with Control of Substances Hazardous to Health (COSHH) Regulations
- Clean and dirty equipment / items must be stored separately and away from areas where cleaning is taking place to reduce risk of re-contamination
- Equipment not in regular use should be cleaned at least weekly whilst in storage. Alternatively, some smaller pieces of equipment can be contained in plastic bags or covered to reduce dust whilst in storage e.g. fans, nebulisers, portable suction machines.
- All re-usable medical devices and equipment to be inspected, serviced or repaired must be decontaminated beforehand and a declaration of contamination status form completed (see Appendix 9)

Decontamination Processes

The three stages of the decontamination process:

- **Cleaning –** Cleaning is the physical removal of dirt and organic matter. Cleaning must always be carried out in a way, so as to minimise the risk of recontamination. Staff should work from the cleanest surface to the dirtiest. The item must be cleaned thoroughly using neutral detergent and warm water, rinsed and dried. Alternatively, hard surface detergent wipes may be used – these are single use and must be discarded in between each activity/surface/item.
- **Disinfection –** Disinfection is the removal and destruction of adequate numbers of potentially harmful micro-organisms to allow the item to be handled, transported or used safely. Chemical disinfectants e. g chlorine releasing agents are commonly used.
- **Sterilisation –** Sterilisation is a process used to render the object completely free from viable microorganisms.

Risk Assessment The level of decontamination required is determined by the nature of the equipment and the risk it poses for transmission of infection. The following table summarises the classification of infection risk associated with decontamination of medical devices.

Risk	Use of Item	Minimum Decontamination Required
High	• In close contact with a break in the skin or mucous membrane • For introduction into sterile body areas	Thorough cleaning followed by **STERILISATION (autoclave)**
Medium	• In contact with intact mucous membrane, blood and body fluids • Contaminated with particularly virulent or readily transmissible organisms • Prior to use on immune compromised patients	Thorough cleaning followed **by DISINFECTION**
Low	• Items in contact with healthy skin, or not in direct contact with patient	Thorough **CLEANING**

Cleaning Schedules and Monitoring Frequency

- Each clinical area should agree the cleaning responsibilities of nursing and domestic staff and have an agreed signed list that incorporates all equipment in that area
- A written cleaning schedule should be devised for cleaning clinical equipment specifying the persons responsible for cleaning, the frequency of cleaning, the methods to be used, and the expected outcomes
- The cleanliness of the equipment will be monitored by utilisation of the MyAssurance audit tool

Appendix 12: Document Control Sheet

This document control sheet must be completed in full to provide assurance to the approving committee.

Document Type	Policy		
Document Purpose	As an overall strategy for the management of risk the Trust has an obligation to make certain that it minimises risks of using the equipment to as low a level as possible by ensuring that it keeps the most appropriate equipment for purpose, train staff how to use it competently and safely, cleans and maintains it correctly and at the end of its useful life disposes of it in an appropriate manner.		
Consultation/Peer Review:	Date:	Group/Individual	
List in right hand columns consultation groups and dates	January and April 2022	PHMD	
	June 2022	QPaS	
Approving Committee:	Quality and Patient Safety Group	Date of Approval:	17 December 2020
Ratified at:	N/A	Date of Ratification:	
Training Needs Analysis: *(please indicate training required and the timescale for providing assurance to the approving committee that this has been delivered)*		Financial Resource Impact	
Equality Impact Assessment undertaken?	Yes [✓]	No [ ]	N/A [ ] Rationale:
Publication and Dissemination	Intranet [✓]	Internet [ ]	Staff Email [✓]
Master version held by:	Author [ ]	HealthAssure [✓]	
Implementation:	*Describe implementation plans below - to be delivered by the Author:*		
	Copy this from the section in the policy		
Monitoring and Compliance:	Copy this from the section in the policy		

Document Change History: (please copy from the current version of the document and update with the changes from your latest version)

Version number/name of procedural document this supersedes	*Type of change, e.g. review/legislation*	*Date*	*Details of change and approving group or executive lead (if done outside of the formal revision process)*
1	Review	7/6/13	Merging of policies P030 (Non-medical devices) and P42 (Medical devices)
1.01	Review	18/10/13	5.8 Statement added- Humber NHS FT staff must not make statements verbally or in writing to patients and/or their carers regarding the availability or funding or procurement of equipment by Commissioners, Local Authorities and/or the Joint Equipment Services they have contracted to do so. Any questions regarding Commissioners decisions to provide or not provide equipment must be referred to either

			the responsible Commissioner and/or the Equipment Provider as their agent. Action following an SI.
1.02	Review	September 2016	Policy reviewed and updated
1.03	Review	October 2017	Addition of cleaning and disinfection guidance in appendix 9
1.04	Review	January 2018	Amendments to procedure re asset documentation and location of training records.
1.05	Review	October 2020	Amendments to procedure re asset documentation and location of training records.
1.06	Review	April 2022	Full policy review Non-standard medical devices request form added to appendix 1. Addition of references to new medical devices request form. New medical devices flow chart added. Additional section re process for standard and non-standard medical devices/equipment. Explicit process for equipment from donated funds. Clear roles and responsibilities for estates and MDSO. Amendments to committee and group names. New links to department pages on the new Intranet Removal of external documents links not required as part of this policy Removal of appendix 8 CAS alerts flow chart not required as part of this policy Updated contact details for Medical Devices Safety Officer

Appendix 13: Equality Impact Assessment (EIA)

For strategies, policies, procedures, processes, guidelines, protocols, tenders, services

1. Document or Process or Service Name:
2. EIA Reviewer (name, job title, base and contact details)
3. Is it a Policy, Strategy, Procedure, Process, Tender, Service or Other?

Main Aims of the Document, Process or Service
Please indicate in the table that follows whether the document or process has the potential to impact adversely, intentionally or unwittingly on the equality target groups contained in the pro forma

Equality Target Group	Is the document or process likely to have a potential or actual differential impact with regards to the equality target groups listed?	How have you arrived at the equality impact score?
1. Age 2. Disability 3. Sex 4. Marriage/Civil Partnership 5. Pregnancy/Maternity 6. Race 7. Religion/Belief 8. Sexual Orientation 9. Gender re-assignment	Equality Impact Score Low = Little or No evidence or concern (Green) Medium = some evidence or concern(Amber) High = significant evidence or concern (Red)	a) who have you consulted with b) what have they said c) what information or data have you used d) where are the gaps in your analysis e) how will your document/process or service promote equality and diversity good practice

Equality Target Group	Definitions	Equality Impact Score	Evidence to support Equality Impact Score
Age	Including specific ages and age groups: Older people Young people Children Early years	**Low**	**Policy review no areas of concern**
Disability	Where the impairment has a substantial and long term adverse effect on the ability of the person to carry out their day to day activities: Sensory Physical Learning Mental Health (and including cancer, HIV, multiple sclerosis)	**Low**	**Policy review no areas of concern**
Sex	Men/Male Women/Female	**Low**	**Policy review no areas of concern**
Marriage/Civil Partnership		**Low**	**Policy review no areas of concern**
Pregnancy/ Maternity		**Low**	**Policy review no areas of concern**
Race	Colour Nationality Ethnic/national origins	**Low**	**Policy review no areas of concern**
Religion or Belief	All Religions Including lack of religion or belief and where belief includes any religious or philosophical belief	**Low**	**Policy review no areas of concern**
Sexual Orientation	Lesbian Gay Men Bisexual	**Low**	**Policy review no areas of concern**

Transgender and /or Transsexual	Where people are proposing to undergo, or have undergone a process (or part of a process) for the purpose of reassigning the person's sex by changing physiological or other attribute of sex	**Low**	**Policy review no areas of concern**

Summary

Please describe the main points/actions arising from your assessment that supports your decision above Policy considered against all equality target groups and no areas of concern identified.	
EIA Reviewer – Mark Turner. Procurement Manager	
Date completed; 20th April 2022	Signature Mark Turner

Please return the completed form to: HNF-TR.policymanagement@nhs.net