A Policy for the Management of Medical Devices

For Use in:	Organisation-wide
By:	All clinical or identified staff who use medical devices and associated equipment in their role. All staff who commission, use, clean, transport, post, purchase, repair and/or dispose of medical equipment and associated equipment/consumables.
For:	The safeguarding of the health and welfare of patients in relation to medical devices across the organisation.
Division responsible for document:	Corporate
Key words:	Medical, devices, equipment, procurement, training, purchasing, disposing, hire, trial, safety.
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Supported by:	Mark Bowpitt Head of Clinical Engineering
Assessed and approved by the:	**Medical Devices Committee** **If approved by committee or Governance Lead Chair's Action; tick here ☑**
Date of approval:	20/10/2021
Ratified by or reported as approved to (if applicable)**:**	**Clinical Safety and Effectiveness Sub-Board**
To be reviewed before: This document remains current after this date but will be under review	31/10/2024
To be reviewed by:	**Richard Goodwin and Mark Bowpitt on behalf of the Medical Devices Committee**
Reference and / or Trust Docs ID No:	**11044**
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Compliance links: *(is there any NICE related to guidance)*	National Institute for Health and Care Excellence (NICE) Published guidance and advice | Guidance | NICE Medicines & Healthcare products Regulatory Agency (MHRA) Medicines and Healthcare products Regulatory Agency

	- GOV.UK (www.gov.uk)
If Yes - does the strategy/policy deviate from the recommendations of NICE? If so why?	No

Version and Document Control:

Version Number	Date of Issue	Change Description	Author
1			
2	26/09/2018	Policy supersedes the previous Medical Devices Policy and is now in line with the MHRA Managing Medical Devices Directive April 2015	Ellen Fosker
3	01/06/2021	Content reviewed and updated to match header requirements for updated policy template. Level of detail on information reviewed and revised following development of supporting procedures and standard operating procedures for medical devices. Training section updated and competency framework removed as approval process for equipment determines who needs what type of training for medical device.	Rees Millbourne and Peta Kerrigan.
3 (final)	12/10/2021	Feedback from Medical Devices Committee included	Rees Millbourne

This is a Controlled Document

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Contents

1. Introduction or Background

The term “medical device” covers a broad range of products, used every day throughout the hospital to support the diagnosis treatment and care of patients. Medical devices have a direct impact on the quality of care for our patients, which is why effective management of medical devices is essential. This will assist to reduce their risk of potential harm and ensure that National Standards and Legislation are adhered to.

2. Purpose

This policy aims to ensure that all Medical Devices in use within the Norfolk and Norwich University NHS Foundation Trust (NNUH) are suitable for their intended purpose; staff are properly trained and competent in their use; devices are maintained in safe and reliable condition and they are recorded on a central data base.

3. Scope

This policy applies to all permanent, locum, agency, bank staff, and students of NNUH who use or prescribe use of medical devices and those involved in the evaluation, selection, purchasing, commissioning, training, storage, maintenance, and disposal of all medical devices owned wholly, in part, or loaned to the Trust.

‘In the event of an infection outbreak, pandemic or major incident, the Trust recognises that it may not be possible to adhere to all aspects of this document. In such circumstances, staff should take advice from their manager and all possible action must be taken to maintain ongoing patient and staff safety’

4. Aim or Objective

The objective of this policy is to provide a framework on how medical devices will be used within the organisation and covers:

- Evaluation, Selection and Purchasing
- Loan or trial Equipment
- Training
- Deployment
- Maintenance and repair
- Disposal

5. Definitions or Explanation of Terms Used

Term	Definition
Medical Device	According to the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), a medical device is described as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used

	specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of: • diagnosis, prevention, monitoring, treatment or alleviation of disease • diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap • investigation, replacement or modification of the anatomy or of a physiological process, or • control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;
IT Enabled	Any medical device that has any connection (physical or non-physical) to the Trust's network; or includes requirements for transportable storage media it uses to be connected to the Trust's network (e.g. flash drives, SD cards, Bluetooth data transfers, USB, etc.).
In vitro Medical Device	Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: • concerning a physiological or pathological state, or • concerning a congenital abnormality, or • to determine the safety and compatibility with potential recipients, or • to monitor therapeutic measures.
Prescriber	A person who decides which is an appropriate device for a given patient.

6. Duties

Chief Executive Officer

Has overall accountability for the management of medical devices. This responsibility has been delegated by the Chief Executive to the Medical Director. The Board has a duty of care to ensure that legislation and standards are adhered to.

Medical Director

The Medical Director has been designated as the Trust lead for medical devices by the Board. The Trust lead has the responsibility to ensure the Trust meets all relevant legislation and standards.

Chief Finance Officer

Responsible for the processes and procedures around the Finance and funding, relating to Medical Devices in the Trust.

Medical Devices Committee

- To ensure that processes are in place for the procurement, management and maintenance of all medical devices operates within the most effective, safe and efficient governance framework across the Trust.

- To review and improve the Trust adherence to required safety, Infection Prevention & Control (IP&C) and governance standards for medical devices management including risk management, procurement processes and staff education.

- To be the forum for communication between technical staff, medical device users, the Procurement and Finance departments.

- To advise on the management and provision of medical devices and their associated training requirements within NNUH.

- To review and monitor adherence to the Medical Devices Policies.

Point of Care Testing (POCT) Committee and Department

- To ensure point of care testing equipment operates within the most effective, safe and efficient governance framework across the Trust.

- To review and monitor adherence to POCT Policies.

- The POCT department organise the training and repair/replacement of faulty POCT devices.

Procurement Department

- All equipment purchases have been approved by the Medical Devices Committee.
- All Pre-Acquisition Questionnaires (PAQs) are completed and signed off by the appropriate department prior to raising an order. Advice from medical engineering can be sought if required.
- Ensure training and deployment requirements have been identified by appropriate department and are factored into contractual, implementation or licensing costs.

Digital Health

To provide advice and guidance for any medical devices that are IT enabled to ensure they are managed and supported in line with appropriate digital health specific policies and procedures.

Clinical Engineering

- In liaison with Procurement, checking and ensuring that all new or replacement equipment or equipment which is part of a formal trial at departmental level is safe for use, prior to handing the equipment over to the Trust and maintain a record of all loans (trials).
- Ensure that all medical devices are to be registered on the Clinical Engineering database (E-Quip).
- Has a Planned Preventative Maintenance (PPM) schedules for medical equipment. The schedules are in line with the manufacturers recommendations and jobs are automatically generated by the E-Quip database.
- Clinical Engineering is responsible for ensuring that medical equipment is serviced either within the ward or department, the Clinical Engineering workshops or by external service providers.
- Are responsible for the formal disposal process of medical devices which includes removing the item from the asset register.

Practice Development and Education Department

The clinical skills team within PD&E will:

- Work collaboratively with clinical procurement groups, the infection prevention and control (IP&C) teams and medical devices committees, to oversee the review and trial of products and devices. Including reviewing relevant policies and procedures to improve patient outcomes and meet service delivery plans.
- Lead on product evaluations and implementations that relate to clinical skills and support wider projects within clinical teams.

Infection Prevention and Control (IP&C) Team

Have a responsibility to provide specialist advice regarding Medical Devices in line with IP&C guidance.

Health and Safety Department

Have a responsibility to provide specialist advice regarding Medical Devices in line with Health and Safety Legislation.

All Clinical Staff, including temporary staff and students

- Using medical devices safely, in accordance with their training, and within the scope of their own practice as defined in the relevant professional bodies.

- Raising any concerns they have about their own confidence in using a medical device with their Clinical Supervisor or Line Manager. Including recognising the need for updates if there has been a break in practice.

- Registered practitioners may 'prescribe' medical equipment on occasion. A prescriber decides what equipment is appropriate for a specific patient. This includes equipment such as daily living aids, moving and handling equipment, and consumables. The registered practitioner may also be required to seek the provision of equipment from third-party suppliers. (E.g. Bariatric Manual Handling Equipment).

- Attend initial training and updates for medical devices identified for their role.

- Maintain ongoing records of their training in relation to medical devices for appraisals and Continued Professional Development (CPD)
- Ensure equipment is functioning correctly when it is in use, e.g. any quality control checks have been completed and logged.
- Know how to clean/decontaminate reusable devices and dispose of single use devices.
- Seek advice when there is any doubt that equipment is not functioning correctly, or withdraw the equipment from use.
- Withdraw equipment from use when it is clear that the equipment is not functioning correctly and report fault to Clinical Engineering.

7. Processes to be followed

7.1. Evaluation, Selection and Purchasing

7.1.1. Evaluation

There are many reasons why a new piece of equipment may be required. Such as:

- clinical need
- equipment has reached the end of its lifespan
- new service provision
- to replace a piece of equipment that has been condemned/disposed of

A process has been designed for buying new or different medical devices which includes evaluating the product(s) prior to purchase.

7.1.2. Selection

Procurement will produce and maintain a list of standard items of medical devices which are commonly used by the Trust. Wards and departments must buy devices from this list unless a clinical requirement, approved through the Medical Devices Committee, the Medical Director or the Chief Executive, justifies a different model or type.

- All Medical Devices used with the Trust must be suitable for (and only used for) its intended purpose and in accordance with British Standards or

Manufacturers Specifications and be able to be decontaminated in line with NNUH IP&C guidance.

- The selection of any new device that involves drug delivery must be undertaken in conjunction with Medical Devices Committee and the Pharmacy Department

7.1.3. Purchase

To order medical equipment it is essential that Trust process is followed. The purchasing of all medical devices and consumables must go through the procurement department while following Standing Financial Instructions (SFI).

When purchasing equipment staff must consider the whole life cycle of the product; this includes costs of consumables, training requirements, cleaning process, maintenance/servicing, disposal and lifespan.

- Ward or department managers purchasing new or replacement devices must accept the on-cost revenue consequences of ownership.

For purchases over £5000 approval is required through the capital governance process. Assistance on this can be provided by the capital committee.

All Medical Devices will be recorded on the Trust's Finance Department's asset register as well as on the Clinical Engineering and Equipment Services central medical device database (E-Quip) as part of the procurement process.

7.2. Loan of Medical Devices for Evaluation (Trials)

It is recognised that manufacturers or other organisations often loan medical devices for evaluation, as part of a consumables agreement, as an incentive to purchase or as part of a clinical trial.

All requests for equipment on loan or trial should be directed via the Procurement Department. The Trust operates a rigid 'No Indemnity - No Loan' approach to the loan or trial of medical devices to ensure that trials are controlled through:

- The person initiating the trial or loan must seek approval from the Medical Devices Committee prior to using/implementing the device.

- The relevant Indemnity Form and appropriate schedule must be completed and signed to ensure that the Trust is covered in the event of any incident.

- All medical devices loaned or donated to the Trust must also receive appropriate acceptance checks, provided by the clinical engineering department prior to use.

- If any medical devices are to be used as part of a clinical research trial the Director of Research Operations or the Associate Medical Director of Research must be informed.

- Where there are funding implications (e.g. who pays for any disposable items used) the budget must be identified and agreed in advance with the relevant service Manager/ Budget Holder.

7.3. Training

Medical devices must only be used / operated by appropriately trained staff who feel confident and are competent to do so. The evaluation process of all medical devices will identify which staff require training and the method of delivery.

The Practice Development and Education Department will support and advise on training issues as appropriate.

It is the responsibility of the individual, their clinical supervisor or line manager to ensure that any clinical staff working within NNUH has completed formal training (including updates) for medical devices used within their role.
This training may be undertaken within NNUH or a previous organisation with supporting evidence. Medical Devices training should be discussed at local induction and recorded appropriately on local induction documentation

Medical device training will be delivered using a variety of formats/delivery methods, which include:

- Provided by an external provider (manufacturer)

- Internal:
    - Cascade via a NNUH trainer (face to face)

    - eLearning package

    - Direct observation of practice (within the clinical area or classroom setting)

    - Formal competency based assessment and sign off

Decontamination of specialist equipment e.g. endoscopy should only be undertaken by staff that have been deemed competent to undertake this process, who have received additional training, and where required deemed competent.

All relevant medical device training should be logged either on the individuals Electronic Staff Record (ESR), their HealthRoster profile or a departmental register and available on request for inspection.

7.4. Deployment

Deployment and Tracking. All reusable medical equipment must go through an appropriate acceptance check before being put in to patient use, as described in diagram 1 on next page. The aims of these checks are to:

- determine that the correct product, together with manuals and accessories, has been supplied
- determine that the product has been delivered in good condition, and has no visible defects.
- determine that the equipment passes a basic safety test.
- ensure that the area(s) receiving the medical device has relevantly trained staff or a training is planned to prevent the use of the device by staff without training.
- minimise the risks associated with using a product for the first time.

- that the relevant Radiation Protection Advisor must be involved in the acceptance of all equipment emitting ionising radiation.

- the medical device is added to the asset register and the clinical engineering database to be included in the maintenance schedule.

Diagram 1: Process for Deployment of a Medical Device to be followed by Ward/Department Manager.

7.5. Maintenance and repair

It is essential that all reusable medical equipment is safe for use on patients. Staff must complete and document any Quality Control processes required for medical devices. All equipment must be accurately calibrated, if this is relevant to patient treatment either through the clinical engineering department or the external equipment provider. If wards/departments are not sure if equipment has been calibrated they must contact clinical engineering for advice.

The Clinical Engineering Department will undertake routine and regular maintenance and servicing of all medical equipment that are registered with the Departments by following the Standard Operating Procedure for the Management of Medical Devices.

All staff have a duty to:

- Report any equipment that is seen to be beyond its scheduled service date to the Clinical Engineering Department.

- Make equipment available to the Clinical Engineering Department on request, when clinically possible and appropriate, to support the servicing and maintenance programme.

- Report any medical device that is suspected or confirmed to be faulty to the relevant Engineering Department and, if necessary, discontinue use until the fault has been addressed.

The diagram on the next pages shows the process for reporting faulty equipment.

Diagram 2: Reporting a Faulty Medical Device

7.6. Disposal

A medical devices replacement programme will be in place which is monitored through the Capital Committee. Medical device replacement will take into the age, condition, environment and critical nature of use. The Directorates should identify equipment that needs to be replaced as part of their Business Plans each year.

At the end of the life of the medical device, it is to be disposed of in a controlled manner which will ensure:

- A Condemning Certificate has been completed
- The device is removed from the asset register
- The device is removed from the ward/dept. register and maintenance schedule
- Appropriate specialist decontamination or decommissioning processes are completed for such items as defibrillators or where microbiological/chemical hazards exist.
- Where possible any residual value is released through appropriate routes such an auctioneer.
- A transfer process regarding liability takes place where equipment is taken on by another organisation.
- Information Governance procedures have been followed

7.7. Manufacture, Modify or Change of Use of Medical Devices

NNUH recognise that medical equipment can be manufactured in-house for use on our patients. On these occasions the device will be manufactured in line with the Medical Device Regulations and will have been approved by the Medical Devices Committee.

Should a medical device be commissioned with approval from the Medical Devices Committee for use outside of the Trust, the additional Medicines and Healthcare products Regulatory Agency (MHRA) guidance for In-house manufacture of medical devices must be followed.

Modifying existing devices or using them for purposes not intended by the manufacturer has safety implications for both our patients and staff. It may also

count as manufacture of a new device under Medical Device Regulations and change liability responsibilities between the original manufacturer and the Trust.

On rare occasions or in extreme circumstances when there is no appropriate medical device for a particular procedure and it is not possible to seek approval from the medical devices committee, a decision must be made by the lead clinician and the Exec on call, on whether to use a medical device *off-label*, to modify an existing device or to use a product for a medical purpose although it is not CE-marked as a medical device. The risks and the benefit to the patients must be balanced using the following:

- A formal risk assessment is completed and documented which includes;
- Ethical and legal implications have been considered
- All precautions to minimise any risk have been implemented
- The risk assessment is reviewed at regular intervals (if appropriate) whilst the medical device is being used and on completion of use.
- Consideration has been given and documented whether exceptional use of non-complying devices approval is sought from the MHRA.
- The patient must be fully informed during the consent procedure and a note made in their records if a device is going to be used off-label.
- A Datix incident form should be completed.

7.8. Risk Management

Incident Reporting

An adverse incident is an event which gives rise to, or has the potential to produce, unexpected or unwanted effects involving the safety or wellbeing of patients, users or others. For medical devices these may arise from various causes such as:

- A fault in the device itself.
- Shortcomings in the instructions for use.
- Lack of servicing or maintenance.
- Locally initiated modifications or adjustments.
- Shortcomings in user practice or training.
- Environmental factors such as electromagnetic interference.

Any adverse incident relating to the use of medical devices must be reported via the Trust's Datix Reporting system, with the Clinical Engineering reference or asset number must be detailed as an absolute minimum requirement.

The incident will be processed in accordance to NNUH incident management and investigation policy. However the following additional steps must be taken:

- Notify the Clinical Engineering Department to alert the Medical Device Safety Officer (MDSO) (Head of Clinical Engineering or nominated Deputy).

- To ensure the safety of patients, staff and others, the device must be taken out of use but left exactly as it was at the time of the incident with any consumables left with the device.

- The equipment 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 position of all switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports. In serious cases, this record should be witnessed and the witness should also make a personal written record. Any accessories or consumables should also be left with the device for investigation.

- The MDSO or person authorised by the MDSO will take appropriate action and will quarantine the equipment pending investigation. Quarantining of small items may be achieved by removing the equipment from the ward or department but larger items may need to be taped off and clearly signed 'Do Not Use'.

- The MDSO will ensure that device related incidents are reported to the MHRA using the Yellow Card reporting system and ensure that the outcome of the incident and any recommendations are reported to the appropriate committee and managed in line with Trust policy.

Safety Alerts
Safety alerts from the MHRA and NHSE/I are sent through to the Trust electronically via the Central Alerting System (CAS). Field Safety Notices (FSNs) will be received directly form manufactures either electronically or physically and will be managed in line with the Patient Safety and Medical Device, including Field Safety Notice (FSN) policy and procedure.

8. Development and Consultation Process

- Rees Millbourne, Senior Business Manager
- Peta Kerrigan, IV Clinical Nurse Specialist, Practice Development and Education
- Mark Bowpitt, Head of Clinical Engineering

The authors listed above drafted this document on behalf of the Medical Director who has agreed the final content.

This version has been endorsed by the Medical Devices Committee

9. Audit / Monitoring Compliance

To ensure that this document is compliant with the above standards, the following monitoring processes will be undertaken:

- The Head of Clinical Engineering will review all reported Datix incidents relating to medical equipment use, maintenance and repair, identifying any immediate action required.

- It is the responsibility of the Head of Clinical Engineering to undertake an annual audit of compliance with the maintenance and repair standards set out in both manufacturers' guidance and extant Trust policies or instructions which will be reported to the Medical Devices Committee.

- The Medical Devices Committee will review the results of all medical devices audits on a quarterly basis, as a minimum, in order to identify themes across the Trust requiring action to address areas of risk.

10. Supporting References

www.gov.uk. (n.d.). *Services and information - Medicines and Healthcare products Regulatory Agency - GOV.UK*. [online] Available at: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information.

11. Associated Documentation

- SOP 405 - Obtaining and Maintaining Medicines and Healthcare Products Regulatory Agency (MHRA) Approval for a Clinical Trial
- A Standard Operating Procedure for the Management of Medical Equipment
- New Equipment Introduction Form
- Information Governance Management Framework
- Incident Management and Investigation Policy
- Patient Safety and Medical Device, including Field Safety Notice (FSN) policy and procedure.
- Clinical Risk Management for Digital Systems

12. Equality Impact Assessment

Name of the Policy or Function/Service: Policy for the Management of Medical Devices				
Type of function or policy	Existing ☒		Proposed ☐	
Division	Corporate	**Department**	Trust Management - Medical Director	
Name of person completing form	Rees Millbourne	**Date**	1st September 2021	
Equality Area	**Potential Negative Impact**	**Impact Positive Impact**	**Which groups are affected**	**Full Impact Assessment Required YES/NO**
Race	None		N/A	No
Pregnancy & Maternity	None		N/A	No
Disability	None		N/A	No
Religion and beliefs	None		N/A	No
Sex	None		N/A	No
Gender reassignment	None		N/A	No
Sexual Orientation	None		N/A	No
Age	None		N/A	No
Marriage & Civil Partnership	None		N/A	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?				

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service**
- **The policy or function/service is assessed to be of high significance**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED
NOTES: (Please use to record and describe any decisions made or discussions had regarding the EIA)
The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.