SOP for the Management of Medical Devices

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Version	Date	Author	Reason/Change
V1.0	01/12/2014	Bob Wootton	To originate document
V2.0	26/09/2018	Ellen Fosker	Policy supersedes the previous Medical Devices Policy and is now in line with the MHRA Managing Medical Devices Directive April 2015.
V3.0	01/06/2021	Rees Millbourne & Peta Kerrigan	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 devices.
V3.1	12/10/21	Rees Millbourne	Feedback from Medical Devices Committee
V4.0	17/06/24	Mike Burton	Updated to include standard operating procedures for the oversight and management of loan, Clinical Trial and managed service medical equipment used anywhere in the organisation. Updated to include detail around the maintenance of medical equipment. Addition of new Clin Eng Equipment email address.
V4.1	28/08/2024	Mike Burton	Section 1.2 – Bullet point added. Section 3.1 – Retired policy link removed. Section 4.11 – Disposal process detailing approved disposal provider. Section 4.2 – Wording added stating responsibility.

Previous Titles for this Document:

Previous Title/Amalgamated Titles	Date Revised
None	None

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:
Radiation Protection
IP&C
POCT
H&S
Digital Health
Procurement
Finance
Clinical Engineering
PD&E
Risk/governance managers for each division

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g. changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a policy applicable to the Norfolk & Norwich University Hospital NHS Foundation Trust (NNUHFT) including Cromer Hospital, the Quadram Institute, Bob Champion building and any future NNUH estate.

Contents Page

1. Introduction

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.

1.1. Rationale

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.

1.2. Objective

The objective of the Management of Medical Devices SOP is to provide a framework on how medical devices will be used within the organisation and covers:

- All medical equipment owned by the trust.
- Trials of medical equipment
- Loan Equipment to the trust.
    - Loan equipment from manufacturer or their approved agent whilst purchased equipment off site for repair/service.
    - Loan equipment from a manufacturer or their approved agent for use in specific individual patient treatments.
    - Equipment loaned from other healthcare trusts.
- The loaning of NNUHFT Medical Equipment to patients or other healthcare trusts.
- Medical Equipment used in the trust as part of Clinical Trials and Research purposes, supplied by the individual trial sponsors.
- Medical equipment provided to the NNUHFT as part of a managed service by an external supplier and repaired and maintained by them.
- Disposal of retired medical equipment.

1.3. 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’

1.4. Glossary

The following terms and abbreviations have been used within this document:

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;
PPM	Planned Preventative Maintenance
MHRA	Medical & Healthcare Products Regulatory Agency
PAQ	Pre-acquisition questionnaire
C2	Capital Request & Approval Form
D2	Decommissioning form
T2	Transfer of Ownership form
MIA	Master Indemnity Agreement
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.

2. Responsibilities

2.1. 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.

2.2. 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.

2.3. Chief Finance Officer

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

2.4. 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.
- The POCT committee will advise on the selection and implementation of POCT devices.

- The Point of Care Testing (POCT) policy is available on trust docs, document ID: 8679.

2.5. 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.

2.6. 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.

2.7. 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.

2.8. Practice Development and Education Department

The clinical skills team within PD&E role is to:

- Work collaboratively with clinical procurement evaluation group (CPEG), 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.

2.9. Infection Prevention and Control (IP&C) Team

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

2.10. Health and Safety Department

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

2.11. 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 and relevant competencies.
- Raising any concerns they have about their own competence 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 instruct the use of 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. A 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, as directed by their line manager.
- 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. Any concerns need to be raised immediately with the line manager of the clinical area.
- Check equipment is not overdue its planned maintenance date by examining the next test date sticker or relevant documentation. Where it is identified the equipment is overdue maintenance, a clinical risk assessment must be completed before use. As soon as possible and when safe to do so, clinical engineering must be informed.
- 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. Advice should be sought from Clinical Engineering by raising a work request by calling 3601.
- Withdraw equipment from use when it is clear that the equipment is not functioning correctly and report fault to Clinical Engineering. During the hours of 8am – 5pm Monday to Friday (excluding bank holidays) please report any faulty equipment by calling Clinical Engineering on 3601. Outside of these hours an on call service is available. Users need to call the site practitioner to get permission to call a technician in to site. Equipment users should seek alternative equipment in the first instance to resolve the issue. **The on-Call**

service should only be used where no alternative equipment is available and the service to patients could become compromised.

3. Policy Principles/ Service to be delivered/Processes to be followed

3.1. 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.

3.2. 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.
- Any POCT device equipment requests must be presented to the POCT committee following filling in a POCT device request using their request form. Which can be found on trust doct:
  - Trust doc ID:12565 – Point of Care Testing, Equipment Application Form A.
  - Trust doc ID: 12566 – Point of Care Testing, Equipment Application Form B.

3.3. 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.

A PAQ must be completed for the purchases of any medical device including new or replacement devices.

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.

Any documentation associated with a purchase of equipment, including but not limited to C2 form, PAQ, MIA form, Business cases, Decision to invest, D2 form, and T2 forms must be sent to ClinEngEquipment@nnuh.nhs.uk

3.4. Loan of Medical Equipment to NNUHFT

It is recognised that there are occasions where the trust needs to obtain Medical Equipment by way of a loan. Some examples are listed below, this list is not exhaustive and will be added to without notice.

- Loan of equipment to evaluate prior to a purchase.
- Loan of medical equipment whilst another device is being repaired or serviced.
- Loan of medical equipment for a specific patient case.
- Loan of equipment as part of a consumable based deal.
- Loan of equipment as part of a Fully Managed Service (FMS).
- Loan of equipment as part of a Clinical Research Trial.

See appendix for more details.

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. Any donated equipment will be evaluated by Clinical Engineering for its suitability for use in the NNUHFT. The Clinical Engineering decision will be final on its continued use in the trust.
- 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.

4. Training & Competencies

Medical devices must only be used / operated by appropriately trained staff who are appropriately trained, competent to do so and have attended any relevant manufacturer end user training.

It is the responsibility of the individual and 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 and completed competencies as relevant.

This training may be undertaken within NNUH or a previous organisation with supporting evidence provided to the line manager of the clinical area the employee is working in. Medical Devices training should be discussed at local induction (in the context of the clinical working area) 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.

4.1. Deployment

Deployment and Tracking. All reusable medical equipment must go through an appropriate acceptance check before being put into 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.

4.2. 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.

End users have the responsibility to ensure any medical equipment they need to use in the course of their work has had any required planned preventative maintenance (PPM) carried out – before using the device. If it is identified that a piece of equipment has not had a PPM carried out when due, the equipment must have a risk assessment completed before any further use – if taking the equipment out of use is not able to be done. The equipment must be removed from use at the earliest opportunity and made available to Clinical Engineering for a PPM to be completed.

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.

4.3. Management policy for medical devices

The Clinical Engineering department at the NNUHFT is responsible for ensuring that all medical equipment in the trust are maintained appropriately. This includes:

- How each device should be maintained and repaired and by whom.
- Arrangements for maintenance and repair to be included as part of any assessment or procurement process.
- Arrangements for the most suitable persons/providers to carry out the work.
- The timescales for planned maintenance.
- The timescales for repairs to be completed.

- Maintenance databases are validated for their intended use and functionality.

Where other regulations apply, Ionising Radiations Regulations 2017 [16] and the Lifting Operations and Lifting Equipment Regulations 1998 [17] for example, the tests therin should be carried out in addition to the maintenance and testing recommended by the manufacturer in the instructions for use (IFU) supplied with the device, not instead of. The frequency and type of planned preventative maintenance should be specified, in line with the manufacturers instructions and taking account of the expected usage and the environment in which it is to be used.

4.4. Audit and review

Clinical Engineering will carry out audits on all elements of maintenance repair, record generation and storage, to ensure that the correct procedures are in place and being adhered to.

4.5. Training and experience of Clinical Engineering Technicians

Clinical Engineering will maintain a training matrix to ensure that where necessary medical devices have sufficient staff trained to maintain them where appropriate. Clinical Engineering will review to ensure that any training gaps are identified and rectified in an appropriate timescale.

All those undertaking repair and maintenance should be able to produce written evidence of appropriate and up-to-date training. They should be able to show that they are up to date on new maintenance techniques, consistent with the devices they are servicing.

All Service documentation will be regularly reviewed by Clinical Engineering to ensure that all information is relevant and up to date and latest versions of information are used in conjunction with performing any PPM. Obsolete and previous versions of service information will be removed from use.

It will be the responsibility of the purchaser to fund any initial and refresher training for the continued maintenance of medical equipment for the life of the equipment, this must be identified during the procurement process.

4.6. Spare parts and other components

There are several sources of spare parts:

- From the device manufacturer.
- From a 3rd party manufacturer
- Other healthcare organisations.
- Service providers.
- Pre-used parts.

The Clinical Engineering department will only allow authorised parts to be fitted that originate from the equipment manufacturer or their approved suppliers.

Clinical Engineering will not allow the fitting of parts obtained from any other source. Clinical Engineering will comply with all MHRA guidance relating to the use of spare parts and components.

4.7. Reusing of spare parts

Under normal circumstances, pre used parts must not be used to repair a device. They may be acceptable in exceptional circumstances after a fully documented risk assessment has been completed in line with MRHA guidance.

The stress and strains that any part has undergone in its use will vary and depend on many factors such as the age of the part and maintenance of the equipment it was originally fitted into. Due to not knowing the integrity of used parts Clinical Engineering do not allow the following second hand parts to be re used in other equipment:

- Printed Circuit boards (PCBs).
- Any cable looms or assemblies.
- Individual discreet components, e.g. transistors, diodes, individual ICs.
- Motors, safety interlock assemblies.

The above list is not exhaustive and will be added to at any time without notice as required.

4.8. Replacement batteries

Replacement batteries must provide the same power and lifecycle as those provided with the equipment when first new. The device manufacturers specifications must be followed in respect to replacement in line with MRHA guidance.

The device manufacturer may upgrade the specification of the battery or pack during the lifetime of the device to allow improved performance. The latest instructions from the manufacturer of the specific device will be followed.

4.9. Repair and maintenance methods

The Clinical Engineering department will ensure that all necessary testing, measuring and repair equipment is available and ensure that it is adequately maintained and calibrated as required.

Where necessary end users will be informed of any failure of the PPM, any items failing any accuracy or output measurements will not be returned to the end user until the error is rectified by replacement of faulty parts or replacement of the whole device.

4.10. Routine maintenance by end users

On occasions the end user is mandated by the manufacturer to be responsible for carrying out routine maintenance to ensure that the device continues to function correctly.

This will be detailed in the equipment's instructions for use (IFU) and should be read and understood before attempting to use the equipment. This will clearly show the routine tasks, how they need to be carried out and the frequency.
Any faults found during routine user maintenance should be reported to Clinical Engineering and the item taken out of use until such a time that a Clinical Engineering Technician has assessed and performed any remedial actions if needed.

Diagram 2: Reporting a faulty medical device.

4.11. Disposal

A medical devices replacement programme is 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 – if applicable.
- The device is removed from the ward/dept register and Clinical Engineering maintenance schedule.
- Appropriate specialist decontamination or decommissioning processes are completed, for example where microbiological/chemical hazards exist.
- All MHRA guidance and Information Governance procedures have been followed.
- All medical equipment will be disposed of via British Medical Auctions (BMA) only. It is prohibited for any retired medical equipment to be given away, taken, donated, or purchased directly from the NNUH by any persons whatsoever. Any person wishing to own any retired equipment is free to purchase through BMA.

4.12. 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.

4.13. Risk Management

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 with 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 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.

5. Related Documents

- 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

6. 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.

Managing Medical Devices. (n.d.). Available at: https://assets.publishing.service.gov.uk/media/6089dc938fa8f51b91f3d82f/Managing_medical_devices.pdf. (Accessed 19/04/2024).

7. Monitoring Compliance

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Ensure process is being followed	Review reported Datix incidents	Clinical Engineering Workshop Manager	Clinical Engineering Governance	Monthly.
Meeting compliance	Annual audit	Head of Clinical Engineering	Medical Devices committee (MDC).	Yearly.
Identify themes of areas of risk	Review results of Medical Devices Audits	Clinical Engineering Contracts Manager	Medical Devices committee (MDC).	Quarterly.

The audit results are to be discussed at relevant governance meetings to review the results and recommendations for further action.

8. Appendices

There are no appendices for this document.

9. Equality Impact Assessment (EIA)

Type of function or policy	Existing

Division	Estates & Facilities	**Department**	Clinical Engineering
Name of person completing form	Mike Burton	**Date**	19/04/24

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	
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

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.