Policy / Procedure Information (**Policy no CS017**)	
Subject	**Medical Devices and Medical Equipment Policy and Procedures** *(This policy is non-contractual and is subject to periodic review and will be amended according to service development needs).*
Applicable to	All staff of Nottinghamshire Hospice
Target Audience	The policy is aimed at all staff, volunteers and contractors who work for or provide care on behalf of Nottinghamshire Hospice.
Date issued	20 June 2023
Next review date	20 June 2026
Lead responsible for Policy	Director of Care
Policy Reviewed by	Palliative Care Lead
Notified to	Quality and Safety Committee 20 June 2023
Authorised by	Quality and Safety Committee 20 June 2023
CQC Standard if applicable	Safe
Links to other Policies	Infection Prevention and Control Policy CS001 Hand Hygiene Policy CS015 Personal Protective Equipment Policy for Infection Prevention and Control CS020 Waste Management Policy OP011 Manual Handling Policy (Non-patient) CS013
Links to external policies	
This policy replaces	Medical Devices and Medical Equipment Policy and Procedures April 2020
Summary	This policy and procedure provides staff with instruction on the management, procurement, deployment and control of medical devices and medical equipment within Nottinghamshire Hospice.

IMPORTANT NOTICE

Staff should refer to the Hospice website or Policies and Procedures folder on the 'N' drive for the most up to date Policy. If the review date of this document has expired it is still valid for 3 months. After that staff should seek advice from their clinical lead or manager.

VERSION CONTROL		
Status	**Date**	**Reviewed date**
Original policy written by Infection Prevention & Control Team	Feb 2016 (see below)	
Minor amendment – appendix 5 added	Mar 2019	
Temporary changes due to Covid-19.	Apr 2020	
Policy reviewed by Palliative Care Lead	May 2023	
Policy notified to Quality and Safety Sub-Group	20 Jun 2023	
Policy ratified by Quality and Safety Sub-Group	20 Jun 2023	20 Jun 2026
Updated control sheet and published on website	July 2023	

Contents

1.	**Introduction** The purpose of this policy and procedure is to provide a comprehensive, organisation-wide policy on the management of medical devices and medical equipment within Nottinghamshire Hospice. It covers all aspects of medical devices and medical equipment from procurement, deployment and control through to operation, maintenance, decontamination and training. It is important to note that medical devices and medical equipment remains the property of the organisation procuring it. List of examples and definitions see page 8. All organisations are subject to legal and statutory requirements relating to the 'duty of care' that requires employers to provide safe equipment, employees who are competent and safe in using the equipment and safe systems of work. Good medical device management will greatly assist in reducing their potential for harm. The function of this policy is to ensure that all risks associated with the acquisition and use of medical devices and other medical/clinical equipment are controlled and minimised by ensuring that all devices/equipment are: • Suitable for its intended purpose. • Properly understood by the user so that they may be managed safely and effectively. • Maintained in a safe and reliable condition and easily cleaned. • Used only for their intended purpose. • Procured in such a way which affords best (qualitative and quantitative) value for the Organisation taking into account whole-life costs.
2.	**Evidence Base** This policy and standard operating procedure has been developed from the guidance laid down in the Medicines & Healthcare products Regulatory Agency (MHRA) bulletin

	Managing Medical Devices, Guidance for Healthcare and Social Services Organisations (April 2015), which will be referred to in order to resolve any complex issues relating to medical devices use and management. NHS England and the Medicines and Healthcare products Regulatory Agency (MHRA) jointly issue patient safety alerts to help healthcare providers increase incident reporting for medical devices. The alert instructs providers to take specific steps that will improve data report quality; and will see the establishment of national networks to maximise learning and provide guidance on minimising harm relating to these incidents.
3.	**Purpose** The Medical Device and Equipment Policy and Procedures seeks to protect the health and safety of patients, carers, visitors and staff by reducing the risks from working with medical devices and medical equipment.
4.	**Scope** This policy and standard procedure applies to all staff working in Nottinghamshire Hospice, whether directly employed or not, who are involved in the management of medical devices. This includes those staff on honorary contracts such as (clinical) consultants from other organisations, and students. This policy applies to all medical devices being managed on any premises, including the Hospice and patients' place of residence where employees of Nottinghamshire Hospice provides care to patients. It applies to all medical devices loaned to clients but does not apply to private medical devices purchased by individuals, although staff working within Nottinghamshire Hospice will encourage such individuals to follow best practice. Equipment will only be suitable for use in the Hospice if it meets at least the following requirements: • Is constructed to relevant medical device standards. This provides assurance that the equipment is safe and performs as originally specified. Older equipment may not meet current safety and performance standards and its suitability needs to be assessed carefully.

	• Can be effectively cleaned and decontaminated and infection control advice should be sought. • A procedure is in place to fully inspect and service the item and ensure it passes electrical safety and manufacturer-specified performance tests. • It will provide a clinical function valuable enough to justify the time and cost spent in bringing the equipment into clinical service. Staff are trained in its safe and effective use and records are held to show this. Where a member of staff uses a medical device that does not fall within the management responsibility of Nottinghamshire Hospice, for example a hoist in a patient's home, the staff member should take reasonable steps to ensure that the medical device has been subject to the same management procedures as those applied to medical devices used by Nottinghamshire Hospice i.e. check the label that it has been serviced regularly. Where a member of staff cannot satisfy themselves of this, or has concerns about a device, they should seek to use an alternative medical device/equipment which does comply with the above and report their concerns regarding the medical device/equipment to the relevant organsiation's manager.
5.	**Definitions** **Cleaning** A process which physically removes contamination but does not necessarily destroy micro-organisms. **Contamination** This term refers to the soiling of inanimate objects or living material with harmful, potentially infectious or unwanted matter. **Decontamination** A process which removes or destroys contamination and thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to

initiate infection or any other harmful response. Three processes of decontamination are commonly used: cleaning, disinfection and sterilization.

Disinfection

A chemical agent which destroys vegetative micro-organisms but not necessarily spores.

Endotoxin

A toxin present inside a bacterial cell that is released when it disintegrates.

Medical devices

The definition of a medical device in European and UK law is

'Any instrument, apparatus, appliance, material or health care product (excluding drugs), used for a patient or client for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment or alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process.

Sanitiser

A chemical that cleans and disinfects.

Single Patient Use

These items are permitted to be used for "more than one episode of care or use of the medical device /equipment on ONE PATIENT ONLY.

Single Use: Means a device is intended to be used once on a single patient and then discarded. The symbol used to denote it is single use is:

	⊗ **Sterilisation** A process used to make an object free from all viable micro-organisms including viruses and bacterial spores
6.	**Medical Devices** The definition of a medical device in European and UK law is: 'Any instrument, apparatus, appliance, material or health care product (excluding drugs), used for a patient or client for the purpose of: • diagnosis, prevention, monitoring, treatment or alleviation of disease • diagnosis, monitoring, treatment or alleviation of or compensation for an injury or handicap • investigation, replacement or modification of the anatomy or of a physiological process. **Examples of Medical Devices** • Catheters (e.g. urinary, cardiac) • Dressings • Examination gloves • IV administration sets and pumps • Patient monitoring equipment • Physiotherapy equipment • Sphygmomanometers

- Syringes and needles
- Thermometers

Medical devices for patient transportation or moving (but **not** including ambulance vehicles):

- Carry chairs
- Lifting aids
- Stretchers and trolleys

Support aids:

- Pressure relief equipment
- Walking aids
- Wheelchairs and special support seating

For daily living:

- Incontinence products
- Prescribable footwear
- Special chairs
- Urine drainage systems

In vitro diagnostic medical devices and their accessories:

- Urine test strips

The MHRA are also interested in products which, whilst not themselves medical devices, are used closely in conjunction with these devices. For example:

- Bench top sterilizers
- Blood and tissue storage systems

	• Disinfecting and sterilizing equipment • Chemical and biological indicators used in sterilization processes Scales are ***not*** regarded as a medical device by the MHRA
7.	**Medical Applications/Data Systems** Nottinghamshire Hospice recognises that mobile medical applications (apps) and/or medical device data systems (MDDS) used on devices, such as smartphones and tablet computers, offer features that may be useful in the clinical environment. However, the Organisation is also aware of the patient safety and security risks that such devices pose. "Apps" that use person identifiable information/data (PID) **must not** be installed on Nottinghamshire Hospice devices or otherwise used without formal review: please speak to your manager to apply for review, explaining what benefit this will be to service users/Nottinghamshire Hospice. Clinical apps that do not use PID must still have clinical review to assess quality/suitability for use with patients: please use the application form listed above for submission to the Clinical Effectiveness Group for discussion.
8.	**Responsibilities** Medical devices and equipment will be monitored in accordance with the Organisation's Governance Structures. **Chief Executive Officer and Senior Leadership Team** The Chief Executive Officer and Senior Leadership Team are responsible for ensuring that there are arrangements in place within the Organisation to support the safe use of medical devices and equipment. **Registered Nurse Leads**

	• Are responsible for the safe use of medical devices and medical equipment within their location. • Keeping appropriately documented evidence of staff training. • Ensure that risk assessments are completed on patients (rather than specific items of equipment). See Manual Handling policy – slide sheets, hoists etc. • Ensure that equipment is stored in a safe and secure location when not in use and kept in an appropriate state of repair and is cleaned according to the National Standards for Healthcare Cleanliness 2021. • Ensure that staff are aware of their responsibilities regarding the safe use of medical devices and ensuring they comply with the process for ordering new equipment, and decommissioning of devices. **Facilities & Transport Manager and Care Services Administrator** • Are responsible for maintaining an up-to-date inventory of all equipment, service dates and decommissioning dates to ensure that medical devices and medical equipment are safe to use. **Role of staff** It is the responsibility of employees involved in the use of medical devices and medical equipment to ensure they: • are trained and competent in the use of medical devices and medical equipment. • only use medical devices and/or medical equipment if authorised and trained to do so. • follow procedures regarding the management and use of medical devices and medical equipment. • report any defects of faults with equipment immediately • clearly label defective devices and ensure they are taken out of action • make items of equipment/devices available for maintenance • report all incidents or near misses to their line manager immediately and complete an incident form. The correct decontamination products and processes as advised by the manufacturers are followed and used • all medical devices and medical equipment are suitably decontaminated after each patient use and are adequately stored and maintained when not in use.
9.	**Risk Management (Indications and Contra-Indications / Hazards)**

	Ensuring effective medical device and medical equipment management is an integral part of everyday practice. It facilitates the quality process and meets Care Quality Commission Regulations and guidance issued by the Medicines and Healthcare Products Regulatory Agency (MHRA). Any medical device used will only be operated in such a manner as to fall within the operating guidelines of the manufacturer. No medical device should be used in any manner other than its intended purpose. Health care professionals are individually accountable for their practice and for delegation of certain aspects of appropriate care delivery to others. Any significant or major service patient safety risks relating to medical devices will be addressed by escalating through the line manager for the service who will take appropriate action.
10.	**Reporting incidents** In the event of an incident involving a medical device or medical equipment the staff member will: • Report the event immediately to the line manager or person in charge. They in turn will ensure the Director of Care is informed to determine whether there is the need to take immediate further action (e.g. withdraw similar devices). Complete an incident form. • In the event of a serious incident out of hours the Clinical Lead on call must be contacted (full details of on-call contacts are held on the N: Drive in the 'On Call' Folder).
11.	**Purchasing** The Director of Care and Director of Finance & Resources should be contacted before any purchase of medical equipment as there could be cost savings with bulk buying of certain equipment. Lifetime costs should be accounted for before purchase and these checked for e.g. any manufacturer exclusive servicing that requires equipment to be sent abroad. Any lifetime costs or costs incurred obtaining technical information or

	training by manufacturers for staff will need to be paid for directly out of the service budget. **Standard list of equipment** Facilities Manager has the responsibility for ensuring there is an up to date list in their area of approved medical devices/equipment for Nottinghamshire Hospice. The approved list will be based on clinical preference (training/knowledge, ease of use), ease of cleaning, and value for money and service/maintenance (lifespan, internal/external maintenance, availability/price of spares) on standard equipment. Line Managers will consider any request for medical equipment to ascertain if this piece of equipment is needed, whether the need could be met with equipment already owned by the Hospice and that the equipment meets CE standards and can be cost effectively serviced and maintained to meet the requirements of this policy. **Record Keeping** All medical equipment will be delivered to Nottinghamshire Hospice by the supplier. They will be responsible for checking the equipment and that it meets the specification, is safe to use, and comes complete with a set of manufacturer's instructions. The equipment, along with a full set of manufacturers' instructions will then be sent to the service.
12.	**User Information** Information should be given verbally and in written format by the appropriate member of staff to enable the end user to understand the purpose, the safe and correct use and the proper maintenance, cleaning and care procedures of a medical device. Staff must also consider any language or disability issues and ensure an appropriate interpreter/translator or sensory impairment communicator is sought as part of the delivery of patient care. Where there are any concerns that a patient does not have the capacity to make a decision about the use of their equipment or understand the instructions given on its use then an assessment of capacity should be undertaken and recorded in the patient record. The issuer of equipment is responsible for ensuring the above.

13.	**Storage** Inappropriate storage of items may affect their subsequent safe use. Manufacturers' information and instructions both on storage conditions and shelf life must be followed. The following key topics and problem areas are to be avoided: • Physical conditions – avoid dirty or wet conditions; inappropriate temperature or humidity (labels on packaging should indicate appropriate storage conditions). • Storage system – stacks should not be too high; fragile equipment not stored too far off the ground as they are likely to be damaged falling from shelves. • Equipment needing decontamination and repair should be kept separate from equipment ready to issue. Apart from possible dangers to the end-users of the equipment, poor storage conditions also put the Organisation at legal risk. For equipment used in the home, staff must advise patients about safe storage and this must be documented in their records.
14.	**Single Use** A device designated as 'single-use' must not be reused. The medical device is intended to be used on an **individual patient** for a single procedure and then discarded. It is not to be reprocessed and used again, even on the same patient. Check the packaging or device for the single use symbol, which means do not reuse / use only once / single use. 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 under the following Acts/regulations: • Health and Safety at Work Act 1974 • Part 1 of the Consumer Protection Act 1987 • The General Product Safety Regulations 2005 • The Medical Devices Regulations 2002.

	• MHRA Single use medical devices: Implications and Consequences of Reuse 2013. Reprocessing single use devices may affect the capabilities and/or the materials from which the device is made. Many problems caused by inappropriate reuse of a single-use device fall into one or more of the following categories: inadequate cleaning and decontamination; material alteration; mechanical failure; potential for cross infection; reactions to endotoxins and retained residues from chemical decontamination agents. Single use devices are intended to be used once and disposed of in the appropriate waste stream (see Waste Management Policy).
15.	**Maintenance and Repair** All Medical Equipment (including diagnostic and therapeutic equipment) will be maintained and serviced in accordance with the manufacturer's instructions. When malfunction of a medical device is identified or suspected, the item must be removed from service immediately and labelled clearly to prevent further use. The medical device must then be sent for repair. The following instructions must be complied with so there is little risk of infection or injury to persons concerned with repair, service or inspection of equipment. • Disconnect all electrical equipment from the power supply before commencing cleaning or disinfection. • Extreme care should be taken to avoid water entering electrical equipment. • Maintain equipment according to the recommended schedule; always keep in a clean condition and, prior to transportation to organisation premises or outside agencies, thoroughly clean the equipment. • Equipment (including equipment located in patients' homes) must be cleaned and decontaminated in accordance with manufacturer's guidance on cleaning and decontamination. **User maintenance**

	In addition to technical maintenance, equipment users also have responsibilities to ensure daily user maintenance routines are carried out where appropriate.
16.	**Decontamination** Nottinghamshire Hospice will keep patients, staff and visitors safe by having systems in place: • to ensure that all reusable medical devices are properly decontaminated prior to use or repair and • that the risks associated with decontamination facilities and processes are well managed. Decontamination is a combination of processes which includes, cleaning, disinfection and sterilisation. In order to decontaminate equipment/medical devices effectively all organic debris e.g. blood, tissue and other body fluids must be removed from the item prior to disinfection and/or sterilisation. Guidance provided by the manufacturers on the decontamination process for the device should be followed. Other points to be considered before decontaminating medical equipment/instruments are: • Availability of hand hygiene facilities / equipment • Risk assessment for the appropriate use of personal protective equipment • Safe disposal and segregation of waste • The environment/area being used, is it suitable and does it require cleaning after use.
17.	**Training** It is the aim of the Organisation that all professional users and staff users of medical equipment, employed or contracted by the Organisation be safe in the appropriate use of all medical devices. This will be achieved by ensuring that health care workers who use such devices:

- Are aware of associated risks and
- Have access to training and support to develop and maintain their knowledge and skills.

Health care professionals are individually accountable for their practice and for delegation of certain aspects of care delivery to others. Therefore, they have a responsibility for ensuring that, as part of their continuing professional development, they acquire, maintain and disseminate knowledge and skills in the use of medical devices.

Providing education and training that will allow staff to grow in confidence and ensure competence in the use of medical devices will ultimately result in the delivery of high-quality care.

Records on training will be kept with Human Resources and be made available upon request.

Competence will be monitored and reviewed through personal development review and risk management processes or earlier if indicated by clinical practice. The following risk factors should be considered when determining the timescale required between competence reviews:

- Complexity and hazards of the equipment.
- Experience of the operator.
- Frequency of use by the individual.
- Errors made by the operator/s (incidents).

All staff have a responsibility to carry out dynamic competency assessments, i.e. a continual assessment and questioning of knowledge and skills prior to and during use based on the circumstances in which a device is used: Questions may include, but are not limited to:

- When did I last use the device (or observe it in use in the patient's home)?

	• Am I wholly familiar with the specific functions of the device I will use today? • What training have I received? • Have I read the instruction manual? • Am I aware of all the risk factors and control measures? • Do different circumstances/patients etc. cause changes in risk factors? • Am I up to date with latest guidance or changes in practice? **Responsibilities** All users of medical devices are responsible for ensuring that they acquire and maintain knowledge and skills in the use of medical devices. Clinical Leads of users of medical devices are responsible for ensuring that users are competent in the use of medical devices or provide access to training, as detailed in the section on training. This will include the induction of new staff and any temporary staff. Clinical Leads are responsible for determining the level of training required and ensuring that a record is kept of all equipment for that service and records of training provided in staff personal files. Any training organised through the workforce development team will be recorded and monitored by them and managers will be notified if staff do not attend specific training sessions. Managers must then follow up non-attendance with individual members of staff.
18.	**Technical** Expert technical assistance should be sought from appropriate sources as necessary for example: Contractors – External suppliers.
19.	**References**

	1. NMC, The Code; Professional standards of practice and behaviour for nurses and midwives, 2015 2. Provision and Use of Work Equipment Regulations, 1998. 3. Health and Safety at Work Act, 1974. 4. Consumer Protection Act 1987 5. Health and Social Care Act (2008) Code of Practice for Health and Adult Social Care on the Prevention and Control of Infections and Related Guidance. 6. MHRA, Managing Medical Devices – Guidance for healthcare and social services organisations. April 2015. 7. EU Directive 93/42/EEC on Medical Devices (1993) 8. The Medical Devices Regulations, 2002. 9. Improving Medical Device Incident Reporting and Learning, NHS England, 20 March 2014. 10. MHRA DB2006 (04) v2.0 Single use medical devices: Implications and Consequences of Reuse 2006.

Process for Cascading Alerts Received via CAS (Central Alert System)