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**Medical Devices Policy**

**May 2025**

**Document Profile**

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**Version Control/Changes Made**

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| **Date** | **Version** | **Summary of changes** | **Author** |
| April 2022 | 1 | It does not appear that the original policy was ever finalised and ratified therefore this is, in essence, a new policy. Transferred to current policy template. | Director of Governance, Care and Regulation and the Clinical Effectiveness Facilitator |
| May 2025 | 2 | Transferred to current templateGeneral updating to improve clarity and readability as well as to reflect current practice, (internal and external).Moves nationally to replace the CE mark with the UKCA mark have been delayedNHS England Digital Apps Library has been discontinued – Apps now recommended throughout their website rather than in one location.Some hyperlinks have been removed where these are no longer accessible/available e.g. hyperlink to a health App repository.Job Role changes reflectedAppendices 1 and 3 should be sent via email and not as a ‘hard copy’References updatedDocuments in the Appendices have been updated – the need to sign the ‘Consideration for using an app in clinical practice’ document has been removed as an email trail should exist. | Head of Quality and Safety |
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# INTRODUCTION

## Rationale

Family Nursing & Home Care (FNHC) recognises the importance of good diagnostic and therapeutic equipment management as a means of preventing risk of injury or infection to patients. FNHC is committed to ensuring that whenever a medical device is used, it should be:

* suitable for its intended purpose
* standardised
* used in accordance with manufacturing instructions by staff, authorised, trained and assessed competent to do so
* maintained in a safe and reliable condition
* disposed of appropriately at the end of its useful life

The use of medical devices is an essential part of the daily workings of the Organisation. The Jersey Care Commission (2022) require organisations to reduce risks associated with medical devices and equipment, to protect patients and staff from any harm. Training is integral to reducing that risk.

## Scope

This policy applies to all staff involved with medical devices and covers their roles and responsibilities relating to:

* the procurement process
* acceptance
* use
* decontamination
* maintenance
* training
* disposal of medical devices.

## Role and Responsibilities

The management of medical devices is a complex process that involves staff following set processes and procedures to ensure their safe use and management. The Organisation will support staff to fulfil the aims of this policy by providing the necessary resources, training, and IT systems

**The Committee**

The Committee has overall responsibility for formally reviewing the systems and processes for ensuring safe acquisition, decontamination, storage, deployment and use of medical devices, the safe management of medical devices and compliance with relevant external assurance standards e.g. Medical and Healthcare Products Regulatory Agency (MHRA)

**The Chief Executive Officer (CEO)**

The CEO is responsible for ensuring that the organisation complies with all health and safety regulations and approved guidance. In practice, the tasks and responsibilities for ensuring compliance to regulations and guidance relating to medical devices are delegated to an appropriate lead but overall responsibility will remain with the Chief Executive Officer.

**Director of Governance and Care**

The Director of Governance and Care is responsible for demonstrating compliance with regulations and guidance. They will ensure there are clear lines of accountability at management and staff levels to implement, promote and monitor the safety of patients, users and others in respect of all aspects of medical devices management.

**Director of Finance**

The Finance director is responsible for issues relating to the sourcing and procurement of medical devices including:

* the purchasing of devices from manufacturers that are approved in accordance with Medical Devices Directive (MDD) 2007/47/EC
* determining the available capital/revenue budgets for the replacement of medical equipment
* developing and implementing standardisation for the acquisition of medical devices to address safety, quality, performance, lifetime costs and range rationalisation
* ensuring that satisfactory arrangements are in place for the procurement of medical equipment
* ensuring that arrangements are in place for the maintenance and servicing of medical devices

**Facilities and Premises Manager**

The Facilities and Premises Manager will work with the Finance Director to ensure:

* there is a robust data management system in place for the recording and tracking, where possible, of medical devices owned by FNHC (Asset Register)
* an effective, co-ordinated programme for the servicing and maintenance of the organisation’s own medical devices is in place
* arrangements are in place for decommissioning and disposing of medical devices at the end of its useful life in accordance with local waste management regulations
* reports are produced where required

**Head of Quality and Safety**

The Head of Quality and Safetyis responsible for:

* managing the process for determining the suitability of medical devices
* chairing the quarterly Medical Devices Group
* facilitating investigations into serious incidents involving medical devices
* providing risk management and health and safety advice in relation to medical devices
* overseeing the organisation’s processes for medical device safety alerts

**Operational Leads/Registered Managers**

The Operational leads/Registered Managers are responsible for ensuring that:

* regardless of whether the purchase of equipment is funded centrally or by individual teams/divisions, it will be coordinated to ensure standardisation, quality, safety and best value
* staff working within their area of responsibility are aware of this policy
* systems are in place for monitoring adherence to this policy
* supporting representation from their service at the Medical Devices Group and associated groups where appropriate
* matters relating to medical devices that cannot be solved locally within services or divisions are brought to the attention of the Head of Quality and Safety
* hazard and safety notices (refer to FNHC Safety Alerts Standard Operating Procedures) are actioned and any guidance complied with
* incidents associated with medical devices are monitored and reported to the MHRA if appropriate
* the level of clinical risk and training required for medical devices in use within their service is identified

**Team Leaders**

Team Leaders are responsible for:

* identifying the need for appropriate new or different medical devices required for their service
* monitoring that medical devices are installed, used and maintained correctly within their areas
* undertaking risk assessments for medical devices in use within their service
* ensuring that staff are allocated time to receive the appropriate training in the safe use of medical devices
* monitoring that staff have the necessary competencies for the safe use, management and disposal of medical devices
* informing the Education and Development Department where training needs are identified
* updating the Education and Development Department when team level training has been undertaken
* reporting incidents associated with medical devices in line with FNHC policy (including to the MHRA if appropriate)
* monitoing that medical devices are appropriately decontaminated according to infection prevention and control best practice

**All users of Medical Devices**

All users of Medical Devices are responsible for:

* complying with this policy
* only using medical devices if they are trained to do so and competent
* maintaining records of their training and competence
* using medical devices for their intended use and in accordance with their instructions for use
* ensuring that personally held equipment is in a safe condition for use and transported and stored appropriately
* presenting their personally held equipment for checking when requested.
* ensuring that single use medical devices are not reused
* cleaning and maintaining equipment in accordance with local policy and procedures/the manufacturer’s instructions
* identifying learning needs, seeking and attending appropriate training
* inspecting medical devices before use to ensure they are in a safe condition
* reporting defective devices to their Team Leader and removing them from use in line with local policy

**Head of Education and Development**

The Head of Education and Development is responsible for:

* ensuring that training is available for all users of medical devices where a need has been identified
* maintaining records of staff training and competence to use the device safely and can carry out routine checks and maintenance
* reporting training compliance in line with organisational policy

**Medical Devices Group**

The Medical Devices Group is a sub-group of the Health and Safety Group and is responsible for:

* policy development to ensure best practice
* providing a forum to discuss all issues relating to medical devices, including incidents and safety alerts
* providing exception reports quarterly regarding Medical Devices
* monitoring equipment requirements/service needs for medical devices
* securing a supply of safe, appropriate and fully functioning equipment being available for staff
* annually approving the list of medical devices and their quantities to support availability of appropriate equipment and budgeting requirements

# POLICY

The management of medical devices encompasses the whole life cycle of the device, from pre-procurement issues to safe disposal.

Staff operating diagnostic or therapeutic equipment must so in a safe and effective manner

Medical devices must be maintained in a safe and reliable condition and only be used by trained and competent staff

Risks associated with the use of medical devices must be identified before their use is commenced and reduced as far as is reasonably practicable.

Medical devices should be:

* procured in line with organisational procedures
* suitable for its intended purpose and in accordance with relevant legislation
* recorded on the asset register
* maintained in a safe and reliable condition within the specified period as per the manufacturer’s instructions
* visually inspected prior to use including a review of any servicing labels (where appropriate)
* operated in accordance with the manufacturer’s instructions for use by users and professionals who have obtained and maintained the correct level of knowledge and competency necessary - user manuals should be easily accessible at the point of use
* decommissioned and disposed of appropriately at the end of its useful life

Medical devices/equipment should be used in such a way that has regard for patient dignity, comfort and safety and promotes their independence.

## Software Applications (‘Apps’)

‘Apps’ classified as ***medical devices*** (Royal College of Physicians 2015) include ones that:

* diagnose
* support diagnosis or clinical decision making
* make calculations to determine diagnosis or treatment

The Medicines and Healthcare Products Regulatory Authority offer guidance to help determine which apps qualify as medical devices.

<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/717865/Software_flow_chart_Ed_1-05.pdf>

Apps, classified as a medical device must not be used or downloaded onto a corporately issued mobile devices unless they have been approved.

Family Nursing & Home Care agree with the Royal College of Physicians’ (2015) recommendations for using medical apps:

* do not use medical apps (including web apps) that do not have a UKCA (United Kingdom Conformity Assured)/CE mark\* (see update below re the replacement of the CE mark)
* check that the current version of the app is also UKCA/CE marked
* if there is no UKCA/CE mark, *STOP USING THE APP -* urgently contact the app’s developers and request that they get one
* always use professional judgement before relying on information from apps
* some apps may keep data from the last time they were used, so always make sure the information is correct for the patient
* report any problems with medical apps to the Medicines and Healthcare Products Regulatory Agency (MHRA)
* always ensure the most recent version of the app is used
* some apps do not work effectively when Wi-Fi connectivity is lost as they use this in the background - test the app in ‘flight safe mode’ to see how it copes without Wi-Fi

\*Use of the CE mark continues to be recognised on the Great Britain market. The 30 June 2023 deadline for moving to the UKCA mark has been extended, and in some instances, to 2030. After this time, it is envisaged that all ‘apps’ that are classified as medical devices will have the UKCA mark.

‘Apps’ **should not be used as a sole basis for clinical decision-making**. The clinician is professionally responsible for justifying the treatment or procedure that they have undertaken. The sole use of an ‘app’ to support this is not valid justification.

# PROCEDURE

## Procurement of Medical Devices

The procurement process is acknowledged as being a key factor in the ability to manage medical devices successfully. The organisation supports the identification and standardisation of medical devices, wherever practicable, but is fully committed to ensuring the diversity of needs of individuals are taken into account.

Part A of the Suitability of Medical Devices Application form ([Appendix 1](#_10.1_Appendix_1)) should be fully completed and sent to the Coordinator/Chair of the Medical Devices Group by email. The application will be reviewed with the relevant Registered Manager and an outcome response emailed to the applicant/s using Part B of the form.

If the medical device is deemed suitable for use, the applicant should follow the organisation’s Procurement Process.

The budget holder responsible for the area requesting the equipment has the final say where the acquisition of the equipment requires a financial outlay. The ‘sign matrix’ and current procurement process should be followed.

## Acceptance

Only designated staff or those deputising for them should carry out the acceptance process.

When a piece of equipment arrives, they should be informed.

The person who ordered the equipment (whether purchased, loaned or hired), in conjunction with the Facilities and Premises Manager, will complete all acceptance checks using the ‘Medical Device Acceptance Checklist’ ([appendix 2](#_10.2_Appendix_2)). These checks will ensure that:

* the medical device is checked for damage
* the correct medical device has been delivered and is complete with all relevant manuals
* any appropriate safety tests are performed where relevant
* the medical device functions as expected and is fit for purpose
* medical device details are recorded on the Asset Register and a unique inventory number (Asset sticker) applied where relevant
* future medical device management plans are established

Documentation about the acceptance check should be attached to the corresponding record on the Asset Register. The acceptance process will apply to all medical devices entering the organisation, regardless of ownership, funding source or any other considerations. This includes all equipment:

* obtained through normal procurement procedures
* purchased/funded by another organisation
* under trial, testing or evaluation
* brought into the organisation by staff for their personal use

All equipment should go through the standard acceptance process and be recorded on the Asset Register (including loan and leased equipment). Only loaned equipment used on a sessional basis will be exempt from being registered on the Asset Register, other aspects of the acceptance checking process should be undertaken and recorded.

Certain equipment may be exempt from having to undergo certain safety checks as part of the acceptance checking process e.g. electrical safety testing. This type of testing would not be required if the manufacturer/supplier provided the equipment on a loan, rental or lease basis and the company had previously agreed to accept responsibility to supply equipment which is fit for purpose and safe. A record of this equipment would still be recorded through the other aspects of the acceptance checks.

Equipment should not be used until the acceptance process is completed satisfactorily.

## Use of Medical Devices

It is the responsibility of the staff member using the medical device/equipment to ensure that it is in good working order and safe for the intended use.

All medical devices/equipment should be visually inspected before use to identify any obvious defects.

By checking the inspection/servicing label, users should confirm that the medical device/equipment has been maintained in accordance with the manufacturer’s recommendations and statutory obligations. All lifting equipment must be inspected/serviced every six months.

Equipment that does not meet these recommendations/requirements should not be used. Report such issues immediately to the Line Manager and Facilities and Premises Manager if the equipment is maintained/serviced by Family Nursing & Home Care. The service provider may also be contacted directly.

Where it is not FNHC’s responsibility to maintain/service equipment, inform the appropriate person/organisation. Such devices/equipment should not be used, should be clearly labelled, placed in storage and not used until servicing has been performed.

## Maintenance/Servicing of Medical Devices

It is the responsibility of FNHC to ensure that an inventory of medical devices/equipment is maintained (excluding single use items) on the Asset Register.

The information on the Asset Register will include the following and will be maintained by the Facilities and Premises Manager:

* generic name e.g. pulse oximeter, sphygmomanometer
* manufacturer/make
* model/type
* person/department/location
* serial number
* maintenance contractor specific number e.g. Asset Number
* maintenance contractor
* frequency of maintenance
* last test date
* next test date
* status
* service and service specialty

This register will enable:

* a device that is subject to a recall to be traced in a timely fashion
* statutory maintenance, safety checks
* planned replacement/disposal
* audit of equipment

Where equipment is subject to statutory examinations, it is the responsibility of the Facilities and Premises Manager to ensure that equipment is examined by a competent body according to the relevant legislative requirements and the appropriate documentation recorded.

Consultation with the supplier, together with reference to technical information provided for the devices, must be considered and shared with relevant persons. This may involve Departments such as Clinical Investigation at Jersey General Hospital, other third-party maintenance providers and/or the supplier’s specialist support service. The chosen provider of the maintenance and repair service must be competent to undertake the work and, where relevant, accredited.

Maintenance schedules must comply with the manufacturer’s technical recommendations and be clearly identified for each medical device. Records must be kept of all routine and repair work undertaken. These records must be available for inspection and audit by internal and external agencies as appropriate. Where possible, maintenance records should be attached to the relevant record on the Asset Register.

If a medical device fails to achieve the required standards at maintenance, the servicing agent must be directed to provide a written confirmation of the failure.

### Un-Maintained Equipment (where FNHC is not responsible for its maintenance)

Where the person responsible for the maintenance of a piece of equipment used by FNHC staff fails to maintain the equipment despite being requested to do so, a letter will be sent by the Registered Manager. This will inform them that staff will not be able to carry out care using the equipment and this may result in the full care requirements not being completed.

##  Storage of Equipment/Medical Devices

Inappropriate storage of equipment can affect its subsequent safe use. Manufacturer’s information and instructions on storage and shelf life should be followed. The chosen location for the storage of devices and consumables should be appropriate to the device e.g. fragile or heavy equipment should not be stored at height.

Storage arrangements are to be configured within available resources to secure, protect and manage equipment appropriately.

## Repair

The repair requirements associated with the safe use and management of medical devices should be established as part of the [suitability of the medical device process](#_10.1_Appendix_1).

Any item that appears to be faulty or is awaiting repair **must** be taken out of service and decontaminated. A notice should be affixed stating, “do not use”, date that the equipment is removed from service and quoting the action being taken. A decontamination label must also be attached.

Appropriate arrangements should be made for the maintenance and repair of equipment when the manufacturer’s warranty expires. This should be recorded when the equipment is entered onto the Asset Register. The date that the warranty expires should also be recorded.

A Certificate of Decontamination and a Request for Inspection form should accompany all medical devices being sent for repair.

The Purchase Order Form completed for the repair work should state the:

* name of the piece of equipment
* name of the company completing the repairs
* nature of the repairs
* estimated cost/quote

The Facilities and Premises Manager should keep the Asset Register up to date with broken items.

Staff should:

* **never** try to undertake repair work, which should only be undertaken by a qualified technician
* **never** use broken equipment – alternatives must be sourced where required e.g. loan from another department.

## Failure of a Medical Device

In the event of there being a failure in the operation of a medical device, staff must:

* take any necessary action to protect the wellbeing of patients and staff
* seek immediate advice from their Line Manager

The Line Manager should inform the Facilities and Premises Manager and identify the maintenance/repair route. Report the equipment failure incident via the incident reporting system.

A defective/faulty device must be taken out of use as soon as it is safe to do so and labelled to ensure it is not reused. It should be decontaminated and the appropriate label applied to indicate that this has taken place.

If relevant, a record should be made of all readings, settings and positions of switches, valves dials, gauges and indicators, together with any photographic evidence.

If relevant, the incident may be reported via the ‘Yellow Card’ to the Medicines and Healthcare Products Regulatory Agency (MHRA)

## Decontamination of Equipment/Medical Devices

The Organisation will ensure that patients, staff and visitors are kept safe by having systems to ensure that all re-usable medical devices are properly decontaminated prior to use, repair or disposal.

It is the user’s responsibility to ensure that medical equipment is properly cleaned/decontaminated before, during and after use in accordance with local infection prevention and control practice. The manufacturer’s guidance should be followed to ensure safe and appropriate decontamination.

Following decontamination/cleaning, a decontamination label should be applied.

When equipment is to be returned to a manufacturer, service provider or other maintenance contractor, the sender must ensure that it has been properly decontaminated and labelled to reflect that this has taken place.

## Replacement/Disposal of Medical Devices

Equipment should be disposed of in accordance with the organisation’s Management of Waste Policy. No Family Nursing & Home Care equipment should be disposed of without first notifying the Facilities and Premises Manager who will ensure that the Asset Register is amended to reflect the disposal of the equipment.

Medical devices/equipment will need to be replaced in any of the following situations:

* worn out or damaged beyond economic repair
* unreliable
* clinically or technically obsolete
* spare parts no longer available
* more cost effective or clinically effective devices have become available
* unable to be decontaminated effectively
* manufacturer’s recall
* in response to relevant Medical Device Alerts

The relevant Senior Manager should be made aware of any equipment requiring disposal due to the above reasons. For equipment with a value of £5000 or above, the Director of Finance should also be informed/consulted.

Follow the [procurement process](#_Procurement_of_Medical) where equipment needs to be replaced.

Whilst awaiting collection for permanent removal, the equipment should be removed to an area where it cannot be used and clearly marked with a notice or stickers to prevent accidental re-use.

## Incident Reporting

Any incident involving the use of medical devices should be reported in line with the organisation’s incident reporting procedure and the current Medicines and Healthcare Products Regulatory Agency (MHRA) guidance.

The MHRA investigates all adverse incidents reported concerning diagnostic and therapeutic equipment. Where the results of investigations have implications for other patients or users, the MHRA will issue a Medical Device Alert, which will advise of hazardous products or unsafe procedures.

Any adverse (serious) incident involving a medical device should be reported to the MHRA, especially those that have led to or could lead to if they were to occur again:

* death or serious injury
* unreliable test results (and risk of misdiagnosis)

Other minor safety or quality problems should also be reported as these can help demonstrate trends or highlight inadequate manufacturing or supply systems.

Adverse incidents should be reported at the earliest opportunity, following the organisation’s incident reporting procedure.

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, device users or other persons. Causes of incidents involving medical devices may include:

* design or manufacture problems
* poor user instructions and training
* inappropriate local modifications
* inadequate maintenance
* unsuitable storage and use conditions

The relevant Operational Lead and the Head of Quality and Safety should be consulted prior to any incidents involving medical devices being reported to the MHRA. The preferred method of reporting to the MHRA is to use their on-line reporting facility [Report a problem with a medicine or medical device - GOV.UK (www.gov.uk)](https://www.gov.uk/report-problem-medicine-medical-device).

Either the MHRA or the manufacturer may wish for the equipment to be returned for further investigation. Equipment that is involved in an adverse incident must not be reused prior to investigation as a repeat of the incident may occur.

Where a medical device is involved in an incident, it must be suitably labelled, decontaminated, quarantined and stored securely until an investigation has been completed and the equipment declared safe to use.

## Software ‘Apps’ in Clinical Practice

NHS England provides access to a range of apps via links in [their website](https://www.england.nhs.uk/about/). These ‘apps’ have gone through a quality assurance process.

If a member of staff believes that there are clinical apps or other technologies that could benefit their patients/clients, this should be discussed with the Registered Manager.

Staff should check the organisation’s list of approved apps (found on the FNHC Team/General Channel/Medical Devices) to see if authorisation has already been given. If the app is not already on this list, complete the ‘Consideration for using an app for clinical purposes’ document ([Appendix 3](#_10.3_Appendix_3) Part A) and email it to the Co-Ordinator/Chair of the Medical Devices Group. This document includes criteria for evaluating such apps. Authorisation is not required if the app is not a medical device.

A written response will be emailed to applicant following consideration of the app’s use by the Medical Devices Group. (see [Appendix 3](#_10.3_Appendix_3) Part B).

# MONITORING COMPLIANCE

Implementation of the principles outlined within this policy will be monitored informally by those involved in the various aspects of the management of medical devices. Incidents involving medical devices will also be monitored as part of the monthly performance reporting process.

Exceptional reporting will also be undertaken where appropriate.

# CONSULTATION PROCESS

|  |  |  |
| --- | --- | --- |
| **Name** | **Title** | **Date** |
| Tia Hall | Registered Manager – Adult Nursing Services | 24/03/25 |
| Michelle Cumming | Registered Manager – Child and Family Services | 24/03/25 |
| Laura Baker | Facilities and Premises Manager | 24/03/25 |
| Gilly Glendewar | Tissue Viability Clinical Nurse Specialist | 24/03/25 |
| Alan Keen | Stores Support & Procurement Officer | 24/03/25 |
|  |  |  |

# EQUALITY IMPACT STATEMENT

Family Nursing & Home Care is committed to ensuring that, as far as is reasonably practicable, the way services are provided to the public and the way staff are treated reflects their individual needs and does not discriminate against individuals or groups on any grounds.

This policy document forms part of a commitment to create a positive culture of respect for all individuals including staff, patients, their families and carers as well as community partners. The intention is to identify, remove or minimise discriminatory practice in the areas of race, disability, gender, sexual orientation, age and ‘religion, belief, faith and spirituality’ as well as to promote positive practice and value the diversity of all individuals and communities.

The Family Nursing & Home Care values underpin everything done in the name of the organisation. They are manifest in the behaviours employees display. The organisation is committed to promoting a culture founded on these values.

**Always:**

* Putting patients first
* Keeping people safe
* Have courage and commitment to do the right thing
* Be accountable, take responsibility and own your actions
* Listen actively
* Check for understanding when you communicate
* Be respectful and treat people with dignity
* Work as a team

This policy should be read and implemented with the Organisational Values in mind at all times. See below for the Equality Impact Assessment for this policy.

## EQUALITY IMPACT SCREENING TOOL

|  |
| --- |
| **Stage 1 - Screening**  |
| Title of Procedural Document: Medical Devices Policy |
| Date of Assessment | 19.03.25 | Responsible Department | Quality and Safety |
| Completed by | Elspeth Snowie | Job Title | Head of Quality and Safety |
| **Does the policy/function affect one group less or more favourably than another on the basis of**: |
|  | **Yes/No** | **Comments** |
| Age | No |  |
| Disability*(Learning disability; physical disability; sensory impairment and/or mental health problems e.g. dementia)* | No |  |
| Ethnic Origin *(including hard to reach groups)* | No |  |
| Gender reassignment | No |  |
| Pregnancy or Maternity | No |  |
| Race | No |  |
| Sex | No |  |
| Religion and Belief | No |  |
| Sexual Orientation | No |  |
| **If the answer to all of the above questions is NO, the Equality Impact Assessment is complete. If YES, a full impact assessment is required: go on to stage 2.** |
| **Stage 2 – Full Impact Assessment** |
| **What is the impact** | **Level of Impact** | **Mitigating Actions****(what needs to be done to minimise / remove the impact)** | **Responsible Officer** |
|  |  |  |  |
| **Monitoring of Actions** |
| The monitoring of actions to mitigate any impact will be undertaken at the appropriate level |

# IMPLEMENTATION PLAN

|  |  |  |
| --- | --- | --- |
| **Action** | **Responsible Person** | **Planned timeline** |
| Policy to be uploaded to the Procedural Document Library | Education and Development Administrator | Within 2 weeks following ratification |
| Email to all staff  | Education and Development Administrator | Within 2 weeks following ratification |
| Upload policy (+/- assessment tool) to Virtual College and allocate to relevant staff | Education and Development Department | Within 2 weeks following ratification |
| Relevant staff to sign (via Virtual College) that they have read and understood policy. | All staff notified via Virtual College. | Within 2 months of notification |

# GLOSSARY OF TERMS

**Medical Devices** - 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. In addition, such devices are 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

A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these.

See [Appendix 5](#_10.5_Appendix_5) for examples of medical devices used by Family Nursing & Home Care.

Software Applications (‘Apps’) that are used for any medical purpose are also classified as medical devices (Royal College of Physicians 2015). These may include apps that:

* diagnose
* support diagnosis or clinical decision making
* make calculations to determine diagnosis or treatment

# REFERENCES

Medicines and Healthcare Products Regulatory Agency (2013, updated January 2025) Medical devices: how to comply with the legal requirements in Great Britain; [Medical devices: how to comply with the legal requirements in Great Britain - GOV.UK (www.gov.uk)](https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements) (last accessed 19.03.25)

Medicines and Healthcare Products Regulatory Agency (2014, updated July 2023) Medical devices: software applications (apps) [Medical devices: software applications (apps) - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/medical-devices-software-applications-apps); (last accessed 19/03/25)

Royal College of Physicians (2015) Using Apps in Clinical Practice; [Using apps in clinical practice guidance | RCP London](https://www.rcplondon.ac.uk/guidelines-policy/using-apps-clinical-practice-guidance) (last accessed 19.03.25)

# APPENDICES

## 10.1 Appendix 1 Medical Device Suitability Application

*Please complete and email to the Co-ordinator/Chair of the Medical Devices Group. Where more than one type of equipment is to be obtained, use a separate application form for each item. Do not use this form for ‘apps’ considered to be medical devices – a different form is available.*

|  |  |
| --- | --- |
| **Name of Applicant(s)** |  |
| **Service(s) Requiring the Equipment** |  |
| **Type of Medical Device Required** (e.g. sphygmomanometer, pulse oximeter) |  |
| **Brand** |  |
| **Model** |  |
| **Number Required** |  |
| **Chosen Option** (Purchase, Loan, Hire) |  |
| **If purchasing is the chosen option, has borrowing or hiring been considered?** | Yes/NoIf ‘no’, explain why: |
| **Intended Supplier** |  |
| **Purchase Cost (per unit/item)** |  |
| **Please detail the following:** |
| **Quality and Suitability** (From 30 June 2023, all medical devices should have had the UKCA (UK Conformity Assured) mark. However, this deadline has been pushed back and, in some cases, medical devices will continue to have the CE mark until 2030) | UKCA or CE mark present Yes/No*If ‘no’, do not purchase/acquire* |
| Other known regulatory requirements |
| Has the equipment been assessed as suitable for its intended purpose/application? (consider ease of use) Yes/No |
| Warranty details (check if product comes with a warranty) |
| Any safety issues or limitations on use? Yes/NoIf ‘yes’ specify |
| Any software compatibility issues? Yes/No/n/aIf ‘yes’ specify |
| Are the manufacturer’s Instructions for Use (IFU) easy to read and understand? Yes/No |
| Where will the Instructions for Use be saved (so accessible by the users of the medical device)? |
| **Supplier** | Does the supplier offer an advice service? Yes/NoIf ‘no’ will this be an issue? Yes/No |
| Are user help guides available? Yes/NoIf ‘no’ will this be an issue? Yes/No |
| **Infection Prevention and Control** | Will the equipment be easy to clean? Yes/NoIf ‘no’ specify why: |
| How is the equipment cleaned? |
| **Servicing and Repair** | How often does the equipment need to be serviced? |
| Who will service the equipment? |
| Annual cost of servicing? |
| Can repairs be carried out on Island? Yes/NoIf ‘no’ what is the process? |
| **Equipment Life Span** | How often will this equipment need to be re-placed? |
| **Training** | Detail what training will be required to safely use this equipment: |
| What plans are in place for this training? |
| How often will this training need to be repeated? |
| **Disposal** | How will the equipment be disposed of when no longer used? |
| Does this equipment require regular battery changes? If yes, how will the batteries be disposed of? |
| **Have there been any relevant safety alerts for this equipment in the past year?** (check MHRA website <https://www.gov.uk/drug-device-alerts> and provide details) |
| **Date** |  |
| **Contact Details** | Email: | Telephone |

**Part B - Outcome of Decision**

|  |  |
| --- | --- |
| **Date** |  |
| **Type of Medical Device Required** |  |
| **Name of Applicant(s)** |  Tick as appropriate |
| **Outcome** | Equipment suitability agreed |  |
| Suitability agreed with conditionsSpecify Conditions: |  |
| Equipment deemed unsuitableReason: |  |
| **Additional Comments:** |
| **Name Coordinator/Chair** |  |

*Coordinator/Chair to email Part B to the applicant.*

***N.B****. The final decision regarding the acquisition of the medical device/s rests with the* ***budget holder*** *who needs to be made aware of this document/outcome of decision.*

## 10.2 Appendix 2 Medical Device Acceptance Checklist

|  |  |
| --- | --- |
| **Name of Medical Device** |  |
| **Medical Device Requested by:** |  |
| **Date of Acceptance Check** |  |
| **Checked By:** |  |
|  |

**Date Warranty Expires: ………………………………………..……………………...................**

|  |  |  |  |
| --- | --- | --- | --- |
| Tick as appropriate (capital P) | **Yes** | **No** | **Initials** |
| Is the medical device free of damage? |  |  |  |
| Has the correct medical device been delivered?  |  |  |  |
| Are all relevant manuals present? |  |  |  |
| Have appropriate safety tests been performed where relevant?***Detail safety test/s completed:*** |  |  |  |
| Does the medical device function as expected and is fit for purpose? |  |  |  |
| Have the medical device details been recorded on the Asset Register and a unique inventory number (Asset sticker) applied where relevant? |  |  |  |
| Have future medical device management plans been established? (where relevant, include plans for when warranty ends)***Detail plans:*** |  |  |  |
| **Comments/Actions:** |

Attach document to relevant record on the Asset Register.

## 10.3 Appendix 3 Consideration for using an app for clinical purposes

**PART A**

|  |  |
| --- | --- |
| **Name of Mobile Application (app)** |  |
|  |
| **Name of Applicant/s** |  |
| **Designation** |  |
| **Contact Details** | **Phone** |  | **Email** |  |
| **Clinical area/service where the app will be used** |  |
| *If the app is already on the organisation’s list of approved apps and the proposed new use is for the same patient/client cohort (e.g. age range), then there is no need for further authorisation. Apps that are not medical devices do not require authorisation.* |
| Description of app (e.g. what is it used for? what does it do?) |  |
| Is the app suitable for both adults and children? | YES NO (please give details) |
| Does the app meet the criteria of a medical device? See [section 2.1](#_Software_Applications_(‘Apps’)) of the Medical Devices Policy or work through the [MHRA's decision-making tool](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/999908/Software_flow_chart_Ed_1-08b-IVD.pdf) | YES NO |
| If the app is a medical device, does it have a CE or UKCA mark? (if unable to find either, contact the developer to check if the most up to date version of the app has a CE or UKCA mark) | YES NO N/A |
| Evidence base for use of the app. (include in here any published scientific reviews, does it have NHS approval?) |  |
| What are the benefits of the app? |  |
| Could something else be used in place of the app? If so, what? | YES NOPlease give details |
| Strengths and weaknesses of the app (search for user ratings, app reviews for example on websites that are repositories for health apps |  |
| Evidence of usability, functionality and efficacy (e.g. from user ratings and reviews)  |  |
| If a social media query within professional or patient networks has been conducted, what was the outcome? |  |
| Outcome of pilot test of the app?  |  |
| Was there full functionality when the app was tested in the ‘flight-safe mode’?  | YESNO (if no please give details) |
| **Date of Application:** |

**Consideration for using an app for clinical purposes**

**PART B**

|  |  |
| --- | --- |
| **Name of App** |  |
| **Name of Lead Applicant** |  |
| **Date of Meeting**  |  |
| **Medical Devices Group members present who considered the suitability of the App** |  |
|  capital P to tick in box |
| **Outcome** | App approved App approved with restrictions (please give details) Approval not given  |
| **Rationale for Decision/Further Action** |  |
|  |
| **Name of Medical Devices Group Co-ordinator/Chair** |  |
|  |
| **Date Lead Applicant Informed** |  |
|  |
| **Date App added to Organisational List of Apps** |  |