Family Nursing & Home Care

Medical Devices Policy

1st June 2022

Document Profile

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Version control/changes made

Date	Version	Summary of changes made	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.	

CONTENTS

1. INTRODUCTION

1.1 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 (2019) require organisations to reduce risks associated with medical devices and equipment, in order to protect patients and staff from any harm. Training is integral to reducing that risk.

1.2 Scope

This policy applies to all staff employed by FNHC and covers the roles and responsibilities of staff in relation to procurement, acceptance, use, decontamination, maintenance, training and the disposal of medical devices.

1.3 Role and Responsibilities

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

The Board of Trustees

The Board of Trustees 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 equipment are delegated to an appropriate lead but overall responsibility will remain with the Chief Executive.

The Director of Governance Regulation and Care

The Director of Governance Regulation and Care is responsible for demonstrating compliance with regulations and guidance. The Director of Governance Regulation

and Care 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.

The 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 Administration Officer

The Facilities Administration Officer 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

The Head of Quality Governance and Care

The Head of Quality Governance and Care is responsible for facilitating investigations into serious incidents involving medical devices. They will also provide specialist risk management and health and safety advice in relation to medical devices and oversee the organisation's Central Alert System (CAS)

Operational Leads

The Operational leads 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 Governance and Care
- hazard and safety notices (refer to FNHC Central Alerting System Procedure) 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)
- monitoring that medical devices are appropriately decontaminated according to Infection Prevention and Control Policies

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
- 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

Education Lead and Practice Development Nurse

The Education Lead and Practice Development Nurse 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

Clinical Effectiveness Facilitator

The Clinical Effectiveness Facilitator is the nominated person who receives a range of safety alerts issued by the MHRA and Central Alerting System. They are responsible for complying with the organisation's Standard Operating Procedures for Safety Alerts

The Clinical Effectiveness Facilitator is also responsible for coordinating/chairing the Medical Devices Group, which is a sub-group of the Health and Safety Group. They are responsible for adhering to the requirements of this policy and the Terms of Reference set out for this group.

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
- assessing the suitability of all medical devices that areas request
- 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

2. 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 reasonable practicable.

Medical devices should be:

- procured in line with the organisation's procedures
- suitable for its intended purpose and in accordance with relevant legislation
- recorded on the organisation's 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.

2.1 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

Downloading of personal apps onto a corporately issued mobile device is not allowed. Apps for work usage must not be downloaded onto 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 CE mark* (see update below re the replacement of the CE mark)
- check that the current version of the app is also CE marked (2022 update – may now be UKCA marked)
- if there is no CE mark (2022 update – or UKCA mark), *STOP USING THE APP* - urgently contact the app's developers and request that they get one
- always use professional judgement before replying 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

Whilst the CE mark provides assurance that an 'app' meets essential criteria, works and should be safe, it does not mean that the 'app' meets best practice nor does it ensure that it has been tested for accuracy or benefits in clinical practice (Royal College of Physicians 2015). *The CE mark will continue to be recognised on the Great Britain market until 30 June 2023. After this time, all 'apps' that are classified as medical devices will have the UKCA (UK Conformity Assured) 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.

3. PROCEDURE

3.1 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 needs of individuals with different needs are taken into account.

Part A of the Suitability of Medical Devices Application form (Appendix 1) should be fully completed and sent to the Coordinator/Chair of the Medical Devices Group. The application will be reviewed and an outcome response sent 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.

3.2 Acceptance

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

When a piece of equipment arrives, the Facilities Administration Officer should be informed.

The person who ordered the equipment (whether purchased, loaned or hired), in conjunction with the Facilities Administration Officer, will complete all acceptance checks using the 'Medical Device Acceptance Checklist' (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 by another organisation
- under trial, testing or evaluation
- brought into the organisation by staff/service users 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.

3.3 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 manufacture'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 Administration Officer if the equipment is maintained/serviced by FNHC. 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.

3.4 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 Administration Officer and the Head of Quality, Governance and Care:

- generic name e.g. pulse oximeter, sphygmomanometer
- level of clinical risk
- 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 Administration Officer 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 for 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 Assure Asset Register.

In the event that 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 Family Nursing & Home Care are 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 Head of Quality, Governance and Care. 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.

3.5 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.

3.6 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.

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 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 Administration Officer should keep the Asset Register on Assure 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 other department.

3.7 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 Administration Officer and identify the maintenance/repair route. Report the equipment failure the incident via the ASSURE 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)

3.8 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 green 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.

3.9 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 Administration Officer. The Facilities Administration Officer 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 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.

3.10 Incident Reporting

Any incident involving the use of medical devices should be reported in line with the Incident Reporting Policy 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 had 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 Clinical Effectiveness Facilitator 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).

Once the incident has been reported to the MHRA, the equipment will need to be decontaminated in line with the manufacturer's instructions and quarantined. 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 by the team until an investigation has been completed and the equipment declared safe to use.

3.11 Software 'Apps' in Clinical Practice

NHS England and NHS Improvement provide access to a range of apps via links in their website. These 'apps' have gone through a quality assurance process and this means that they:

- meet the required technical and clinical safety standards
- are approved by experts in a particular area

https://www.gov.uk/government/publications/health-app-assessment-criteria/criteria-for-health-app-assessment

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 Director of Governance, Quality and Regulation in the first instance.

Staff should check the organisation's list of approved apps (found on Central Filing) 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 Part A) and submit 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 sent to applicants following consideration of the app's use by the Medical Devices Group. (see Appendix 3 Part B).

4. CONSULTATION PROCESS

Name	Title	Date
Claire White	Acting Director of Quality, Governance and Care	27/04/22
Elaine Walsh	Finance Director	27/04/22
Tia Hall	Operational Lead – Adult Nursing Services	27/04/22
Michelle Cumming	Operational Lead – Child and Family Services	27/04/22
Clare Stewart	Operational Lead – Rapid Response and Reablement	27/04/22

Teri O' Connor	Registered Manager Home Care	27/04/22
Justine Bell	Education Lead and Practice Development Nurse	27/04/22
Laura Baker	Facilities Administration Officer	27/04/22
Fiona Le Ber	Continence and Stoma Clinical Nurse Specialist	27/04/22

5. IMPLEMENTATION PLAN

Action	Responsible Person	Planned timeline
Email to all staff	Secretary/Administration Assistant (Quality and Governance Team)	Once approved by the Chief Executive Officer (CEO)
Policy to be placed on organisation's Procedural Document Library	Secretary/Administration Assistant (Quality and Governance Team)	Within 2 weeks of approval by CEO
Forms/templates to be uploaded to Central Filing	Secretary/Administration Assistant (Quality and Governance Team)	Within 2 weeks of approval by CEO
To be added to Virtual College with questions	Education Lead and Practice Development Nurse	Within one month of approval by CEO

6. MONITORING COMPLIANCE

Implementation of the principles outlined within this policy will be monitored through activities such as audit and incident monitoring.

Exceptional reporting will also be undertaken at agreed times.

7. 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 Appendix 4 for the equality impact assessment for this policy.

8. 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 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

9. REFERENCES

Medicines and Healthcare Products Regulatory Agency (2013, updated December 2020) 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) (last accessed 26/04/22)

Medicines and Healthcare Products Regulatory Agency (2014, updated July 2021) Medical devices: software applications (apps) Medical devices: software applications (apps) - GOV.UK (www.gov.uk); (last accessed 26/04/22)

Royal College of Physicians (2015) Using Apps in Clinical Practice; Using apps in clinical practice guidance | RCP London (last accessed 26/04/22)

10. APPENDIX

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/No If 'no', explain why:
Intended Supplier	
Purchase Cost (per unit/item)	

Please detail the following:	
Quality and Suitability (The CE mark will continue to be recognised on the Great Britain market until 30 June 2023, after this time all medical devices will have the UKCA (UK Conformity Assured) mark)	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/No If 'yes' specify
	Any software compatibility issues? Yes/No/n/a If '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/No If 'no' will this be an issue? Yes/No
	Are user help guides available? Yes/No If 'no' will this be an issue? Yes/No
Infection Prevention and Control	Will the equipment be easy to clean? Yes/No If '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/No If '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 conditions Specify Conditions:	
	Equipment deemed unsuitable Reason:	
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 on Assure 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 of the Medical Devices Policy or work through the MHRA's decision-making tool	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	NO Please give details		
Strengths and weaknesses of the app (search for user ratings, app reviews for example on websites that are repositories for health apps e.g. https://myhealthapps.net/				
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'?	YES NO (if no please give details)			
Signature of Lead Applicant		**Date**		

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		
Signature of Medical Devices Group Co-ordinator/Chair		
Date Lead Applicant Informed		
Date App added to Organisational List of Apps		

10.4 Appendix 4 Equality Impact Screening Tool

Stage 1 - Screening			
Title of Procedural Document: Medical Devices Management Policy			
Date of Assessment	26/04/22	Responsible Department	Quality and Governance
Name of person completing assessment	Elspeth Snowie	Job Title	Clinical Effectiveness Facilitator

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 EIA is complete. If YES, a full impact assessment is required: go on to stage 2, page 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

10.5 Appendix 5 Examples of medical devices used in the diagnosis/treatment of disease or monitoring of patients

- syringes and needles
- dressings
- blood glucose meter
- sphygmomanometers
- thermometers
- catheters e.g. urinary, cardiac
- nebulisers
- portable suctions machines
- mattresses and cushions
- all medical devices/products used in the treatment/monitoring of patients and in the diagnosis of disease
- defibrillators
- oxygen cylinders
- wheelchairs
- aids for the disabled
- pressure care prevention
- patient hoists for lifting and transfer
- commodes
- urine drainage systems
- oxygen therapy systems

The items above are examples and therefore the list is not exhaustive