Management of Medical Devices Policy

Please be aware that this printed version of the Policy may NOT be the latest version. Staff are reminded that they should always refer to the Intranet for the latest version.

Purpose of Agreement	To ensure the trust complies with the requirements of law such as the Health and Social Care Act 2008 and good practice to meet standards which are inspected and audited by such bodies as National Health Service Litigation Authority (NHSLA) and Care Quality Commission (CQC).
Document Type	Policy
Reference Number	Solent NHST/Policy/RK07
Version	5
Name of Approving Committees/Groups	Medical Devices Group, Health Safety Group, Policy Steering Group, Clinical Executive Group
Operational Date	January 2020
Document Review Date	January 2023
Document Sponsor (Job Title)	Chief Finance Officer and Deputy CEO
Document Manager (Job Title)	Health and Safety Manager
Document developed in consultation with	Medical Devices Group Infection Prevention and Control Team, H&S Manager, Learning and Development, Research and Improvements and Procurement Team
Intranet Location	Business Zone / Policies, SOPs and Clinical Guidelines
Website Location	Publication Scheme / Policies and Procedures
Keywords (for website/intranet uploading)	Medical devices, equipment, clinical engineering, Policy, RK07

Intranet and Website Upload

Intranet	Electronic Document Library Location:	Business Zone > Policies, SOPs and Clinical Guidelines
Website	Location in FOI Publication Scheme	Our Policies and Procedures
Keywords:	Medical devices, equipment, clinical engineering	

Amendments Summary:

Amend No	Issued	Page(s)	Subject	Action Date
1 – version 3	01/04/2016	various	Changed to medical devices group, additional information of procurement of medical devices inclusive of flow diagrams Minor Changes	01/04/2016
2 – version 5	July 2022	7	Connectivity and cyber security section has been added.	

Review Log
Include details of when the document was last reviewed:

Version Number	Review Date	Lead Name	Ratification Process	Notes
1	May 2013	Mike Townsend		Review of policy
2		Mike Townsend		Review of policy
3	01/04/2016	DK		Review of policy
4	01/10/2019	DK		Review of policy
5	July 2022	SB / Tracy Hammond	Chair's action approved amendment to policy – addition of section 3.9 on page 7	As outlined above

Executive Summary

This revised policy gives comprehensive guidance and identifies good practice and relevant legislation to ensure staff can deal effectively when working with medical devices. By the means of this policy, Solent NHS Trust can comply with all statutory requirements for user and patient safety.

The policy outlines the safety arrangements of the whole life cycle of medical devices around selection, standardisation, procurement, inventory, replacement and servicing/ repair of medical devices. It sets out clear roles and responsibilities and identifies a systematic approach to ensure that risks associated with medical devices are identified and managed.

1. INTRODUCTION & PURPOSE

1.1 The purpose of this policy is to outline the medical device management so staff can deal effectively with and comply with relevant legislation; the purpose of which is to ensure that risks associated with the use of medical devices are minimised and that medical devices are fit for purpose, maintained appropriately and operated in accordance with instructions by staff with appropriate knowledge and necessary competency in order to minimise risk and maximise safety for all concerned.

1.2 It also ensures safe and effective use of medical devices by all staff and that Solent NHS Trust meets all statutory requirements for user and patient safety. The policy is designed to ensure that the Trust complies with the requirements of the Health and Social Care Act 2008 and good practice to meet standards which are inspected and audited by such bodies as National Health Service Litigation Authority (NHSLA), Care Quality Commission (CQC). Medicines and Healthcare Products Regulatory Agency (MHRA) and/or any subsequent required standards associated with clinical governance requirements that identify any patient safety issues or organisational Health and Safety risks.

1.3 It is important in terms of management of medical devices to be able to identify and specify how each device has been acquired i.e. loan; operating lease, hire, donated, consumable deals, free gift or rental devices, lease purchase, purchased through public donations, funded by the Trust from capital or revenue budgets and those transferred to the organisation all come under the guidance of this policy.

2. SCOPE & DEFINITIONS

2.1 This policy applies to locum, permanent, and fixed term contract employees (including apprentices) who hold a contract of employment or engagement with the Trust, and secondees (including students), volunteers (including Associate Hospital Managers), bank staff, Non-Executive Directors and those undertaking research working within Solent NHS Trust, in line with Solent NHS Trust's Equality, Diversity and Human Rights Policy. It also applies to external contractors, agency workers, and other workers who are assigned to Solent NHS Trust.

2.2 The policy does not extend to include high volume consumable products that have a low risk for the safety of the user or the client. Certain elements of this Policy do not apply to single use devices and equipment i.e. maintenance and management. This policy does not include any community loan equipment services, for use by people within their homes, e.g. hoists, mattresses, bathing aids, etc.

SINGLE USE AND SINGLE PATIENT USE DEVICES AND OTHER HEALTH CARE PRODUCTS

2.3 Single use items are classed as consumables for the purpose of this policy. The single use consumable medical devices item is intended to be used on an individual patient during a single procedure and then discarded. The device is not intended to be reprocessed and used on another patient. Single Patient Use items are reusable items that are intended to be used more than once but on the same person/patient. Use of this device/product can occur over a period of time but on **the same patient.** Manufacturer's instructions regarding cleaning, maintenance and repeat use must be followed.

Example of single use label is shown below

2.4 HSC 1999/178 states: *'Devices designated for single episodes of use **may not** be reused under any circumstances what so ever'*, as offences may be being committed under the following Acts:

Health and Safety at Work Act 1974, Part 1 of the Consumer Protection Act 1987. The General Product Safety regulations 1994, The Medical Devices Regulations 2002 (as amended 2013).
DEFINITIONS are found in Section 13 Glossary and Definition

3. PROCESS/REQUIREMENTS

SELECTION, STANDARDISATION PROCUREMENT, INVENTORY, SERVICING/ REPAIR, REPLACEMENT of MEDICAL DEVICES

Selection

3.1 This relates to acquisitions of all descriptions – new purchases, replacements, loans, transfers of medical devices including those funded from donated monies and/or charitable donations etc. It is essential that devices and equipment of good quality with adequate performance and conforming to relevant specifications / standards are procured. **All procurement of Trust devices must to go through the Trust procurement team; anything ordered without an appropriate purchase order number cannot be paid by the Trust's Finance System.**

3.2 The procurement and Contracts team will also offer advice with regard to the contracts currently in place for the purchase of equipment. Arrangements must be made during procurement to use expert advice from relevant leads, for example health and safety department, medical device group, infection prevention and control team, estates and facilities etc.

Equipment Standardisation

3.3 Where practical, Solent NHS will standardise common types of Medical Devices Standardisation will;

- Reduce risk – clinically approved and evaluated medical devices (equipment), combined with an increased familiarity of use by staff will improve both patient/client and staff safety
- Reduce adverse incidents relating to medical devices (equipment)
- Training in the use of medical devices (equipment) becoming more manageable
- Compliance with relevant aspects NHS initiatives, Essential Standards (Care Quality Commission), Controls Assurance for Medical Devices Management, MHRA guidance, Clinical Governance, NHSLA Risk Management Standards for NHS Trusts providing Acute, Community, or Mental Health & Learning Disability Services and the Clinical Negligence Scheme for Trusts
- Financial benefits through volume purchases of medical devices (equipment) and rationalisation of consumables stocked
- An increased flexibility in the location at which medical devices can be used
- Optimum maintenance of medical devices , including staff training in routine maintenance, provision of test medical devices (equipment) and spare parts
- Optimisation of medical device asset management
- Improved business planning and resilience

Procurement Process and Medical Devices Replacement Procedure

3.4 When selecting and ordering any new medical device (equipment) , the procedures below will be followed.

- **Capital Medical Devices** "These are single devices that have a value of over £5000 or are a collection of assets valued individually at less than £5K which are functionally interdependent"

  - Capital Medical Devices Procurement flow diagram ***(Refer to Appendix 2)***

- **Revenue Medical Device** "These are devices that have a value of under £5000 inc VAT and can work independently of any system or network"

  - Revenue Medical Devices Procurement flow diagram ***(Refer to Appendix 3)***

3.4.1 Each item purchased shall have a copy of the relevant manufacturer's user instruction and information. This shall accompany the item throughout its working life.

For further guidance on receipt of new medical devices **Refer to Appendix 4 Acceptance Testing for New Delivered Medical Devices Guidance**

Medical Devices Inventory

3.5 The Trust maintains a centralised "Medical Devices" (Inventory) through the use of the external Clinical Engineering providers and will be used for the purpose of maintenance planning and the production of reports to provide evidence assurance to relevant statutory obligations and service needs. The inventory list will be retained for a minimum of six years and clinical engineering will provide inventory details to SNHST upon request.

3.5.1 All new medical devices acquired by the Trust or services , from whatever source, will be registered on the Trust's "Medical Devices " (Inventory) on approval to purchase and/or on commissioning.

3.5.2 It is the responsibility of each service line to ensure the inventory is maintained, accurate and audited.

Maintenance, Servicing and Repair

3.6 Medical devices must remain safe, serviceable and reliable throughout the working life. Maintenance of such devices will be undertaken by suitably qualified person (s) as recognised by the Trust. A formal system is in place to ensure that the devices functions safely and accurately throughout its life. Such systems do provide for:

- **Pre-use functional and visual checks** carried out by all users prior to using any medical device in accordance with the training or instructions given by the manufacturer or supplied in the user manual, in association with operating procedures.
- **Performance /preventative maintenance** by external contractors
- **Breakdown and repair maintenance** by external contractors

3.6.1 Contractual arrangements are in place with qualified medical devices engineers to ensure medical devices are serviced and maintained in accordance with manufacturer's recommendations.

Repair

3.7 Defective equipment must be taken out of circulation immediately and placed in a non-clinical area where ever possible with a secure notice stating not to be use. The reason, details of who has been notified with dates and details including contact of the person who has "decommissioned' its use.

3.7.1 Repairs are carried out as part of the contract/ Service Level Agreement by the external Clinical Engineering teams and are on a pay as you go basis. It is currently the responsibility of the

individual ward/department to arrange for repairs by contacting the external Clinical Engineering teams and fund those repairs**. Refer to Appendix 5 BCAS Biomed contact details**

Medical Devices Replacement

3.8 All medical devices reach a stage at which replacement must be considered. If any of the following seven criteria apply, the device is no longer serviceable and must be replaced:

- Worn out beyond economic repair
- Damaged beyond economic repair
- Unreliable (per the service history)
- Clinically or technically obsolete
- Spare parts no longer available
- More cost effective or clinically effective devices have become available
- Unable to be cleaned effectively prior to disinfection and or sterilisation.

3.8.1 A replacement programme for medical devices will be based on the criteria for replacement outlined above and developed by each service advice about the application of these criteria should be sought as necessary . As far as is possible, replacement of equipment should be part of an annual replacement programme, and submitted in good time for the forthcoming financial year and approved by the Medical Devices Group and/or Finance and Commercial Group. In this way, equipment planning can be more closely linked to the service and business planning

3.8.2 Custom made appliances that no longer fit the clinically intended purpose should be replaced: they cannot be redistributed to other users but should be suitably disposed of. Certain appliances fall within specific regulations that make them part of the property of the patient (e.g. dentures, prosthetic cardiac valves etc. and other long term inserts) and whilst they may be replaced, the patient must be consulted about their disposal (if the patient agrees) otherwise the patient has the right to keep these.

IT Connectivity

3.9 All new Medical Devices **that have the ability to connect to the network** (regardless if they are intended to be added to the network) will require an ICT and Cyber Security assessment to be conducted and signed off at the ICT & Cyber Security Group, prior to implementation. The Trust's Cyber Security Manager will assist and support services in the completion of this assessment.

3.9.1 All new Medical Devices that **will contain / process personally identifiable data (PID)** will require Data Protection Impact Assessment to be conducted and signed off at the ICT & Cyber Security Group, prior to implementation. This is to be completed, in line with the Trust's Privacy by Design SOP and data Protection Compliance Policy. The Trust's Information Governance Team will assist and support services in the completion of this assessment.

3.9.2 The Trust's Medical Devices Safety Officer, is to ensure that no new Medical Devices are signed off for implementation, until the above assessments have been completed, where applicable.

3.9.3 The Trust's full list of medical devices will be reviewed quarterly and an assessment of compliance with Data Protection and Cyber Security Processes, outlined above, will be undertaken. If a medical devices that either connects to the network and/or contains PID is identified to not have undertaken the appropriate assessments, a retrospective assessment is to be undertaken.

3.9.4 All new medical devices will also require a clinical safety report that needs to be approved by the CNIO/organisations Clinical Safety Officer

4. ROLES & RESPONSIBILITIES

4.1 **The Chief Executive Officer** has overall responsibility for all matters of risk management; this includes the safe use of all medical and non-medical equipment and devices within the Trust. The Chief Executive Officer will also have overall responsibility for ensuring that those sufficient resources are provided to enable the policy to be implemented and to remain effective.

4.2 Medical Devices Group (MDG) main objectives is to ensure there is a robust system for the safe use and cost effective management of medical devices, approve and standardise the use of medical devices used within the Trust and to ensure the Health and Safety Group are aware of compliance with National Standards.

4.3 Managers (Facility Managers, Support Services Managers, Premises Managers and responsible persons both clinical and non-clinical) shall be responsible for ensuring that procedures and organisational arrangements are in place for the appropriate management of medical equipment and provision of adequate numbers of appoint staff whose duties are to meet these obligations to include:

- Ensuring that all staff within their area of responsibility are made aware of the contents of this Policy.
- Maintenance of an accurate and up-to-date inventory for medical devices under his/her management and to ensure that any new medical device is registered on the centralised medical device asset list through formal notification with Clinical Engineering. **Refer to Appendix 1 Clinical Engineering BCAS Biomed Contact details**
- Ensure that all medical devices are available for service and maintained on a regular basis.
- Ensure there are provision of appropriate training for staff and others in the safe and appropriate use and decontamination of equipment, as per assessment and/or the manufacturers recommendations
- The administration of documentation recording equipment, the training given to staff for devices and their competency to use such equipment
- The reporting and subsequent investigation of any adverse incident or untoward events involving medical devices and that any resulting action plans are monitored.
- Ensuring that when alerts are received regarding the safety of medical devices which are in use these are acted upon promptly
- Disposal of devices deemed no longer serviceable must be managed by each service area in line with agreed Trust Policy for the Safe Handling and Disposal of healthcare waste.

4.4 Head of Estates and Facilities shall be responsible for supporting the Medical Devices Group in identifying the fixed medical devices e.g. ceiling mounted hoists, spa baths etc that are attached to the building fabrication which Solent are responsible for within buildings either owned , leased or where Solent employees are based

4.5 ALL Relevant Employees will co-operate and assist with the implementation of this Policy and its associated Procedures. Bring to the notice of management, any problems or failings associated with the management of medical devices and promptly **report** all incidents concerning risks and or any adverse effects arising from the management **of** medical devices and are responsible for ensuring that they:

- In association with their line manager identify and undertake any training or competency needs required for their role in regards to the use of medical devices, decontaminate reusable devices and disposal of single use devices
- Use medical devices in a safe and effective manner in accordance with guidance and/ or the manufacturers intended use
- Decline to use or operate any medical device which they have not been adequately trained to use and / or do not feel competent and confident to operate

- Bring and report any problems, faults, defects, and/ or misuse of medical devices immediately attention to their line / service manager and report the incident in accordance with the Trust's reporting of Averse Events Policy via the web-based reporting system Ulysses
- Maintain on-going records of their training in relation to medical devices for appraisals and Continued Professional Development (CPD)

4.6 **Director of Finance & Performance for** the Trust will determine the available capital / revenue budgets for the replacement of medical equipment and for :

- Arrangements to ensure compliance with the Trust's Standing Orders and Standing Financial Instructions and financial probity associated with the acquisition, use, and disposal of any item of equipment.
- Ensuring that satisfactory arrangements are in place for the procurement of medical devices.
- Ensuring the appropriate mechanism is in place for the adjudication on the purchase of specific items of medical equipment and for the receipt and assessment of individual business cases for major capital purchases.

4.7 **The Procurement and Contracts Teams are** responsible for the purchasing of all medical devices. Requisitions will only be processed which have been approved by an authorised signatory. The procurement and contracts team will also offer advice with regard to the contracts currently in place for the purchase of equipment.

5. DECONTAMINATION OR MEDICAL DEVICES AND REUSABLE DEVICES

5.1 Micro-organisms will always be present in the healthcare environment and all Solent NHS Trust staff have a responsibility to be aware of methods to prevent their transmission. The choice of decontamination method depends on a number of factors, which include the type of material to be treated, the organisms involved, the time available for decontamination and the risks to staff and patients. Decontamination of equipment and the environment is a key infection Prevention measure and this policy will outline a risk assessment strategy Trust staff must use.

5.2 The effective decontamination of re–usable devices is essential to reduce cross infection risks. Decontamination methods used will depend on the nature of the micro-organisms present and the infection risk associated with the surface, equipment, device or procedure.

5.3 Medical devices must be decontaminated between each patient. Use only the decontamination method advised by the manufacturer - using any other process might invalidate warranties and transfer liability from the manufacturer to the person using or authorising the process. If there are any doubts about the manufacturer's recommendations seek further advice from the IPCT.

5.4 For full guidance on decontamination all staff must Refer and comply with the Solent NHS Trust Decontamination Policy IPC 12.

5.5 When transferring medical devices from site to site from consignor to consignee the medical devices must be decontaminated and a Declaration of Contamination Status form must be completed, attached to the device and signed by both parties ***Refer to Appendix 9 Declaration of Decontamination Status Form***

6. DEVELOPMENTS, TRAILS, AND INNOVATIONS MANAGEMENT

6.1 No research trials of medical devices (equipment) should be commenced without the written permission of Medical Devices Group and Procurement Review Group , and the Associate Director of Research and Development.

6.2 All requests for evaluations should be made to the Medical Devices and Procurement Review Group prior to making any arrangements with external companies. The Medical Devices and

Procurement Review Group and the Trusts R&D lead will consider the request and make a decision if the evaluation should go ahead.

6.3 Evaluation of any equipment/device requires time, effort, suitable clinical environment and clients/patients. All research in the NHS must be carried out in accordance with the Research Governance Framework. Before setting up an agreement with a commercial company to trial a piece of medical device (equipment) contact should first be made with the Research Lead for guidance regarding the necessary governance checks.

6.4 'Innovation management' ensures that new ideas, innovative solutions to problems, inventions and better ways of working are given the best chance of being recognised.

6.5 The Trust intends to encourage all of its employees to make these sorts of contributions by giving them the advice and support they need to maximise the benefits.

6.6 With appropriate good management of innovation, potentially valuable intellectual property (IP) can arise. It is intended that innovations and IP from any sector of the Trusts' activities should be appropriately 'exploited' which can mean anything from dissemination throughout the Trust or the NHS, to commercial exploitation in order to access wider markets and other healthcare systems.

6.7 Commercial companies usually wish to own the intellectual property regarding a device being trialled outright, but there may be some opportunity for the Trust to benefit from their involvement in the trial of a device.

6.8 Any electrical/mechanical medical devices (equipment) purchased by the Trust must undergo a formal acceptance procedure in accordance with ***Appendix 5.*****Acceptance Testing for Newly Delivered Medical Devices (Equipment)**

7. CUSTOM MADE DEVICES

7.1 Custom made devices are provided by services, 'Custom-Made Device' means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under their responsibility, specific design characteristics and is intended for the sole use of a particular patient, whether NHS, private or independent. The above mentioned prescription may also be made out by any other person authorised by virtue of his professional qualifications to do so.

7 .2 Each service providing custom made devices is required to comply with the Medical Devices Directive. These appliances do not need to be CE marked but the manufacturer (this may also be the prescriber) must supply a certificate stating the following:

This is a custom made appliance that has been manufactured to satisfy the attributes, characteristics, properties and features specified by prescriber for the above named patient. This appliance is intended for exclusive use by this patient and conforms to the relevant essential requirements specified in Annex 1 of the Medical Devices Directive (93/42/EEC) and the Medical Devices Regulations 2002 (SI 2002 No 618). Any relevant essential requirements not met are listed (e.g. overleaf).

7 .3 Annex VIII of the Medical Devices Directive defines the requirements that must be met by the manufacturer of a custom-made device. The manufacturer of a custom-made device must draw up a statement for each device which contains the following information. A copy of the statement must accompany the device back to the prescriber:

1. Data allowing identification of the device in question (unique device identification)
2. A statement that the device is intended for exclusive use by a particular patient, together with the name of the patient
3. The name of the medical practitioner or other authorised person who made out the

prescription and, where applicable, the name of the clinic concerned

4. The particular features of the device as specified in the relevant medical prescription
5. A statement that the device in question conforms to the essential requirements set out in Annex I of the Directive and, where applicable, indicating which essential requirements have not been full met, together with the grounds
6. Each service issuing Custom Made Appliances Records is required under the regulations to keep the following records and is responsible for ensuring manufacturers comply with the Regulations for the devices it issues:
   - Unique device identification (e.g. serial number from manufacturer / issuer) Copy manufacturer's certificate and statements (see above)
   - Date of purchase / provision
   - Regular checks and servicing

   The information contained in the declarations should be kept for a period of time of at least five years.

7.4 In addition, services will keep records of manufacturers' MDD registration numbers.

7.5 These are obtained either through a trade association (e.g. Dental Laboratories Association) or through the Medicines and Healthcare Products Regulatory Agency (MHRA). There are also approved lists of materials, from the TRUST. The NHS Counter Fraud can audit records from time to time.

7.6 These records may be incorporated into clinical records or may be kept separately in a central location for a service. Examples of services providing such custom devices are Podiatry and Dental Services.

7.7 Each service user should have specific information given under the Regulations:

- Name of device
- How to use device (including cleaning and decontamination) Responsibility for checking device in use
- Recognising device failure or fault
- Action to be taken for device failure or fault
- Reporting untoward events (e.g. to manufacturer/supplier) Emergency telephone numbers.

7.8 This information will usually be in the form of written instructions, either in the form of a Trust leaflet, or service specific leaflets, which may be produced by other authorities.

8. MEDICAL DEVICES EXTERNAL LOAN to CARERS, PATIENTS and other AGENCIES

8.1 Loan medical devices come in two categories, they are:

- Medical devices loaned to clients/patients from the Equipment Store , Wheelchair Service or other services for loan to the patient
- Medical devices loaned to other clinical users either inside or outside the NHS.

8.2 There are occasions that equipment is loaned to patients for home use. The Trust must ensure safe hand over and return of Medical Equipment from the user / patient. Managers are responsible for ensuring that all staff, patients and carers required to use or operate medical device are trained in its use. It is also important to ensure that there is a full recorded audit trail of whereabouts of loaned equipment is for recall and safety testing purposes.

A Transfer of Medical Devices Form must be completed *Refer to Appendix 8*

9. ADVERSE INCDENTS

9.1 A dverse incidents are events that gives rise to, or has the potential to produce, unexpected or unwanted effects involving the safety of patients, users or other persons.
In the event of an adverse incident occurring the user must ensure that the incident is immediately reported in accordance with the Trust's Adverse Incident Reporting Policy via the online reporting system Ulysses.

9.2 Where practical the current medical device should be immediately taken out of service. Where duplicate devices of similar type exist, these may also need to be taken out of service and retained for further examination or disposal.

9.3 Medical devices involved in adverse incidents together with other material should be clearly identified and kept in quarantine. The state of the device at the time of the incident should be recorded for use in any subsequent investigation.

9.4 Local action to be taken as necessary to ensure the safety of clients/patients, users and staff at all times.

9.5 In the event of an accident, incident or defect concerning medical devices, the medical devices safety officer will review all incidents involving medical devices and inform the Medicines and Healthcare Products Regulatory Agency if applicable.

10. TRAINING & COMPETENCY

10.1 The Trust will have a process for self-assessment competency specifically for all permanent staff and other users of medical devices and may provide in-house training and/or utilise external providers. Training requirements should be identified by line manager at induction reviewed at appraisals and raised by staff. Details of medical device training & competency must be recorded, maintained by the ward/department manager and be available for review in the ward or relevant clinical area.

10.2 Managers may identify training needs and commission the Learning and Development team to acquire appropriate programmes.

"It is a Trust requirement for Medical and Dental staff to participate in Clinical and Safeguarding Supervision appropriate to their role. However it is recognised that this may not follow the model described in this policy".

10.3 The Learning and Development team will support on advising in training issues and any training organised by Learning and Development (Defib training etc.) will be recoded electronically.

10.4 Where patients/clients move between services and have been provided with equipment, the Service from which the patient was last seen should ensure that instructions for the device are formally handed over with clinical information.

11. SUCCESS CRITERIA / MONITORING EFFECTIVENESS

11.1 The policy will be monitored for effectiveness via the medical devices group meetings reviewing. Accident/ incident reports, staff complaints, management requests and review of medical devices requests and reports from the external medical devices maintenance team

12. EQUALITY IMPACT ASSESSMENT AND MENTAL CAPACITY ACT

12.1 A thorough and systematic assessment of this policy has been undertaken in accordance with the Trust's Policy on Equality and Human Rights. The assessment found that the implementation of and compliance with this policy has no impact on any Trust employee on the grounds of age, disability, gender, race, faith, or sexual orientation. **Refer to Appendix 10** Equality **impact assessment**

13. REVIEW

13.1 This document may be reviewed at any time at the request of either staff side or management, but will automatically be reviewed on a tri-annual basis unless organisational changes, legislation, guidance or non-compliance prompt an earlier review.

14. RELATED POLICIES and PROCEUDRES REFRENCES

14.1 The Trust acknowledges the following sources of advice and reference:

1. General Medical Council Ethical guidance - Good clinical care http://www.gmc-uk.org/standards
2. Medical Devices Agency (1998) Medical Device and Equipment Management for Hospital and Community-based Organisations January 1998 DB 9801
3. Medical Devices Agency (2000) Medical Devices and Equipment: Repair and Maintenance Provision June 2000 DB 2000(02)
4. Medical Devices Agency (2001) Devices in Practice ISBN 1 84182 359 7
5. Medical Devices Agency (2001) Equipped to Care The safe use of medical devices in the 21st century October 2001
6. Medical Devices Agency (2002) Management of loaned medical devices, equipment or accessories from manufacturers or other hospitals SN 2002(17)
7. Medical Devices Agency (2001)- Medical Devices - Reporting Adverse Incidents and Disseminating Safety Warnings SN 2001(01)
8. Medical Devices Agency (2006) Reporting Adverse Incidents & Disseminating Medical Device Alerts MDA/2006/001
9. MHRA (2003) Management of Medical Devices Prior to Repair Service or Investigation DB2003 (05)
10. National Audit Office (1999) Management of Medical Equipment in HNS Acute Trusts in England June 1999
11. NHS Litigation Authority (2004) NHSLA Risk Management Standards for PCT April 2004.
12. PASA Trust Operating Purchasing Procedures Manual (TOPPM) http://nww.pasa.nhs.uk/purchasing/shared/toppm//toppm.stm
12. Medical Devices Agency (2001) Guidance on the Sale, Transfer of Ownership and Disposal of Used Medical Devices MDA DB9801 Supplement 2 Oct 2001
13. EN 14971:2000 Standard: The Application of Risk Management to Medical Devices
14. Department of Health (2004) Standards for Better Health July 2004
15. HSC 2000/32 Decontamination of medical devices
16. Chief Medical Officer (2002) Getting Ahead of the Curve. Department of Health. London
17. Chief Medical Officer (2003) Winning Ways Working together to reduce Healthcare Associated Infection in England.
18. Department of Health. London
19. Department of Health (2003) Controls Assurance Standard; Decontamination of Re- usable Medical Devices. Department of Health, London
20. 20. Department of Health (2003) Controls Assurance Standard: Infection Control.
21. Department of Health, London
22. National Institute for Clinical Excellence (2003) Infection Control: Prevention of healthcare-associated infections in primary and community care.
23. Lifting Operations & Lifting Equipment regulations 1998 (1998/2307)
24. Provision & use of work equipment regulations 1998 (SI 1998/2306)
25. Medicines and Healthcare Regulatory Agency: http://www.mhra.gov.uk
26. Devices in Practice – a guide for health and social care professionals (2001)
27. Solent NHS Trust The Safe Handling and Disposal of Healthcare Waste Policy

28. Department of Health 2007 Primary care dental services: guidance on single-use instruments for endodontic procedures.
29. Health and Safety at Work Act 1974
30. Part 1 of the Consumer Protection Act 1987
31. The General Product Safety regulations 1994
32. The Medical Devices Regulations 2002 (as amended 2013)
33. Solent NHS Trust Decontamination Policy IPC 12

15. GLOSSARY and DEFINITIONS

- Department of Health **(DH)**
- Clinical Engineer **(CE)**
- Medicines and Healthcare Products Regulatory Agency**(MHRA**)
- Medical Devices Group **(MDG)**
- National Health Service **(NHS)**
- National Health Service Litigation Authority **(NHSLA)**
- National Patient Safety Agency **(NPSA)**
- Solent NHS Trust **(SNHST)**
- Purchasing and Supplies Agency **(PASA)**
- Research & Development **(R & D)**
- Central Alerting System **(CAS)**
- Planned Preventative Maintenance **(PPM)**
- Pre Purchase Questionnaire **(PPM)**

Medical Equipment Fault Reporting Process
Normal Working
Mon – Fri – 8.30 – 17.00
BCAS Biomed
Helpdesk – 01494 529527 – Option 1
OR
E-mail – callout@bcasbiomed.co.uk

Required Information
Contact Name & Number
Asset Number (if applicable)
Equipment Type
Equipment Model
Equipment Make/Manufacturer
Brief Description of Fault

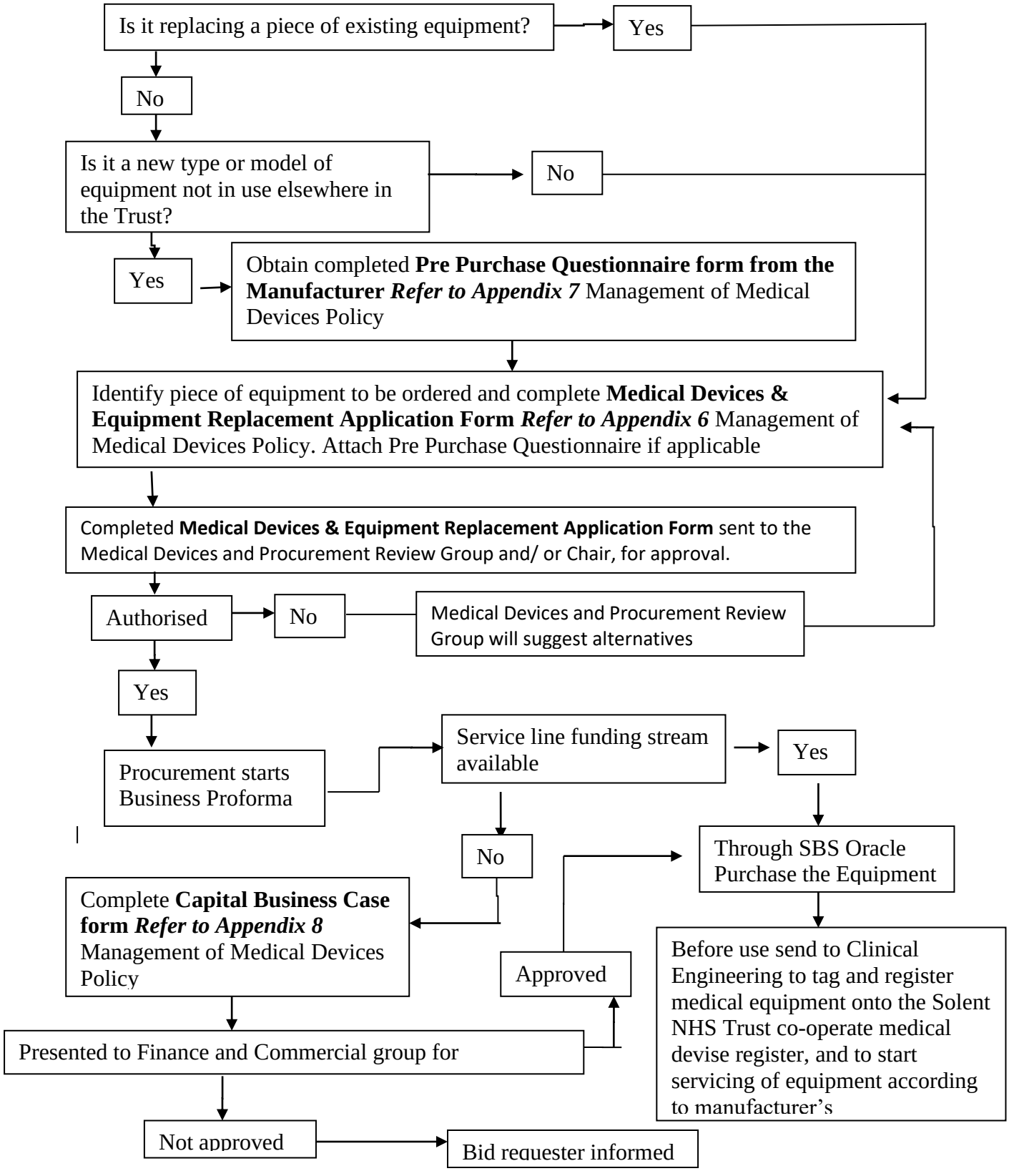
Action Taken:
- Callout request logged into Service Management Software
- BCAS Biomed to issue a Task Reference Number
- BCAS Biomed will advise on Engineer site visit
- Solent requestor will be advised of request & job

Action Taken:
BCAS Biomed Engineer attends callout request
BCAS Biomed Engineer to liaise with Service Lead Service
Report completed, Service Lead to be advised of any additional costs or re-visit
Service Lead Signature obtained
Copy of Service Report left with Service Lead

Capital Medical Devices Procurement flow diagram

All capital medical devices brought into Solent NHS Trust must follow this route regardless of the source of funding, holder, or donations etc

These are single devices that have a value of over £5000 or are a collection of assets valued individually at less than £5K which are functionally interdependent and together form a single collective asset under single managerial control

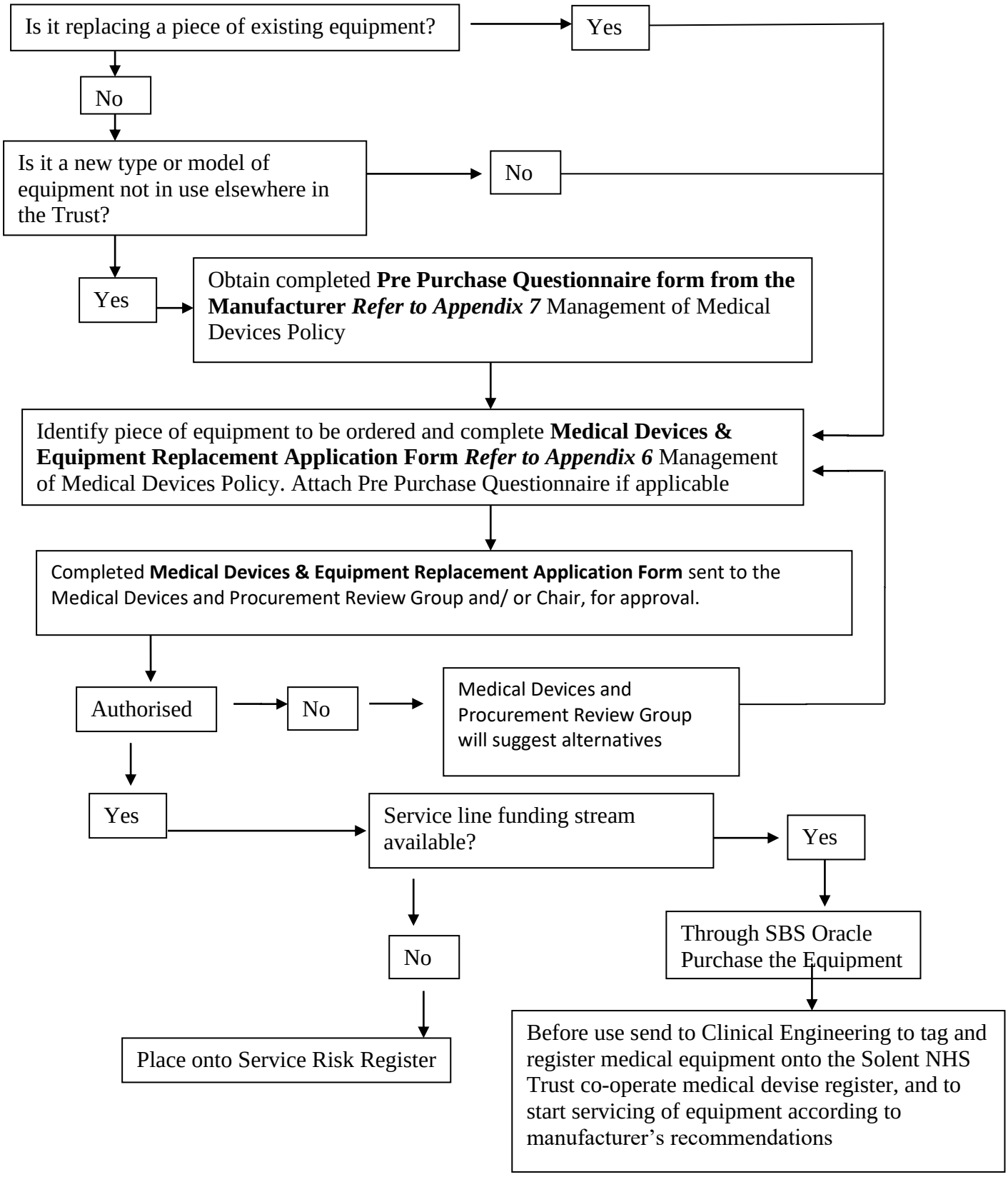


Appendix 3

Revenue Medical Devices Procurement flow diagram

All revenue medical devices brought into Solent NHS Trust must follow this route regardless of the source of funding, holder, or donations etc

These are devices that have a value of under £5000 inc VAT
and can work independently of any system or network



Appendix 4

ACCEPTANCE TESTING FOR NEWLY DELIVERED MEDICAL DEVICES

1. Safety & functionality

All clinical staff across the TRUST should check the safety and functionality of newly delivered medical devices (equipment) prior to utilisation. This should include:

Checking that the correct product, complete with manuals and accessories, has been supplied

Provide assurance that product items have been delivered in good condition and working order

Ensure that risks associated with using a product for the first time have been minimised;

Ensuring that all appropriate statutory and mandatory testing of the medical device (equipment) has taken place prior to its use, including PA testing

1. **Reusable medical devices (equipment).**

The Trust will ensure that all devices intended for repair or maintenance are safe to handle. In respect of reusable medical devices (equipment) staff should ensure:

The device is recorded on the Trust medical devices (equipment) inventory in accordance with the requirements
Ensure that appropriate maintenance support is initiated
Compliance with relevant safety legislation as appropriate
Labels and documentation are developed and attached to the device as appropriate, identifying new devices and advising monitoring of the introduction All medical devices (equipment) returned for servicing and repair are properly decontaminated

3. Other requirements

Managers should identify and organise: Training needs
Requirements for planned preventative maintenance
Technical support needs of users
Apply labels and other documentation as required

In addition records should be maintained identifying that the above procedures have been complied with.

4. Loaned medical devices (equipment).

Procedures for the delivery of medical devices (equipment) will attend to safety issues including avoidance of cross-infection, delivery of the correct item and commissioning. Clear procedures will be developed relating to different types of medical device (equipment) in order to contribute to greater safety and minimise risk.

5. Record keeping

Records of procedures followed in respect of acceptance testing for new medical devices will be maintained at a local level across the TRUST business areas.

Procedure for Replacement of Medical Devices and Equipment

Procedure

1. Service manager identifies a requirement to replace a medical device or item of Equipment.
2. Service Manager completes a Medical Device and Equipment Replacement Application Form and Cost Assessment Table. This can be done in conjunction with the advice of clinical engineering, equipment specialists and procurement.

When the Medical Device and Equipment Replacement Application Form and Cost Assessment Table has been completed it must be sent to the Medical Devices and Procurement Review Group and/ or Chair

3. Medical Devices and Procurement Review Group and/ or Chair receives and considers Medical Device and Equipment Replacement Application forms
4. Requests are sent to the Finance and Commercial Group who will consider in the context of other requests, service alignments and available resources and will either

a. Approves and purchases from Trusts revenue

b. Approves and submits to clinical Manager for funding consideration "Sufficient funds should be allocated from the relevant service budget at the outset of each financial year to take account of the planned equipment replacement programme for that year

c. Rejects application

Medical Devices & Equipment Replacement Application Form

Complete this form to request consideration for purchase of medical equipment replacement needs only. This form does not apply to requests for purchase of equipment required for expansion of existing services or the provision of new clinical services.

Existing Equipment Description:	**Asset Number(s):**
Directorate/Department:	
Name of Head of Department	**Contact No: -** **Email Address:**
Outline the reason for request:	
Is the device a replacement?	☐ YES ☐ NO

If yes give medical devices product name and details below What is the estimated purchase price including VAT? Will there be an additional installation required and what cost ? **If yes give details below** If replacing an existing piece of equipment, will the old equipment be decommissioned? **If not, give the reason:**	☐ YES ☐ NO ☐ YES ☐ NO
a) Clinical Requirements:	
• What impact does this device have on existing clinical practices? • List the general profession of key users (e.g. nurses, doctors, physiotherapists, etc.)	
Will there be any change to the number of clinical procedures carried out (e.g. increased patient through-put) if this piece of equipment is not replaced? **Give details of any significant changes below**	☐ YES ☐ NO
b) Installation:	
Does the device require additional services (e.g. water, power, ventilation etc..)?	☐ YES ☐ NO
Does the device require any IT interface to the IT network?	☐ YES ☐ NO

Does the device require storage space on the IT network/server?	☐ YES ☐ NO
Are further safety measures required?	☐ YES ☐ NO
If you have answered yes, to any of the questions in **b)** above please provide details.	
c) Consumables:	
Does the device require consumables of a type not currently purchased by Procurement?	☐ YES ☐ NO
Are generic consumables available or must consumables be purchased from the equipment supplier?	☐ YES ☐ NO
What is the total expected annual consumable cost (incl. of VAT)?	**£**
d) Maintenance/Licensing:	
Are there any additional operating costs (e.g. Preventative Maintenance Checks/Calibration as per manufacturers' recommendations)?	☐ YES ☐ NO
Will this equipment require a service contract?	☐ YES ☐ NO
Is there an annual validation requirement?	☐ YES ☐ NO
Is there a recurring software license fee?	☐ YES ☐ NO
If you have answered yes, to any of the questions in d**)** above please provide details.	
e) Cleaning and Decontamination:	
Who will be responsible for cleaning the equipment?	
Will any equipment components require decontamination – if so state decontamination requirements?	
Is there sufficient capacity and skill within current services to carry out the decontamination? If not, please provide details of your proposal to decontaminate the equipment.	
Has funding been sought/received from other sources? **If yes, give details:**	☐ YES ☐ NO

Cost Assessment	**Amount (£)**
Cost of equipment inc VAT	
Warranty period	___ Years
Estimated cost of annual maintenance contract	

Estimated change in consumable costs from current	
Estimated change in cost of annual validation, if applicable?	
If additional facilities required (test equipment, water, power, ventilation etc) – state estimated cost	
Total Estimated Cost	**(£)**

For Clinical Services, this form must be signed by the Head of Department and Clinical Services Manager.

Name :

Signed: _____ Date: _____

Name :

Signed: _____ Date: _____

Reviewed by Medical Review Panel and/or Medical Operational Group Chair

☐ Yes ☐ No ☐ Not Applicable

Chair Name:

Signed:_____Date:_____

Reviewed by Clinical Engineering Department ☐ Yes ☐ No ☐ Not Applicable

Chairperson Name:

Signed:_____Date:_____

Approval No (if applicable): _____ Date: _____

Comments:

Note Approval is valid for 12 months.

Signature:

NHS Solent NHS Trust

PRE-PURCHASE QUESTIONNAIRE (PPQ Form)

The purpose of this questionnaire is to support the pre-acquisition assessment and approval of proposals to procure Devices and accessories under purchase, exchange, rental, lease, loan, donation or other agreements. Please ensure that all relevant sections have been completed and that all supplementary information requested has been provided.

(Note: The term 'Devices', as used here, includes equipment and systems; in the case of systems the requirements below apply both to the individual constituent Devices and to the configured system as a whole.)

PRODUCT DETAILS:

(* Manufacturer, Supplier, or other)

Product Description: (GMDN Code / Group if available)		
Type:	Make:	
	Model:	
Manufacturer:		
Supplier:		
EU Authorised Representative*:		

1 a) When was this Model first placed upon the market ?

b) Is this Model still in production ? YES ☐ If not, when did production cease ?

c) Any outstanding Field Safety Corrective Actions / Field Safety Notices ? YES ☐ If YES, details attached ? YES ☐

d) Has a product brochure and specification been attached to this return? YES ☐

e) Does this return cover a range of Model variants and / or Accessories? YES ☐ If YES, all item details attached ? YES ☐

REGULATORY COMPLIANCE:

2 a) Does the Device meet the Essential Requirements of all currently applicable EC Directives? NO ☐ YES ☐

b) Which EC Directive/s apply ?

Medical Devices Directive YES ☐ Classification? ← (1, 1-m, 1-s / IIa / IIb / III)

Active Implantable Devices Directive YES ☐

In-Vitro Diagnostics Medical Device Directive YES ☐ Category? ← (general / self-test / List-A / List-B)

Other/s YES ☐

- which Directive/s?

3 a) Is the Device CE-Marked, for its intended use, to all currently applicable Directives? NO ☐ YES ☐

b) - if YES, have the EC Declaration/s of Conformity been attached to this return? YES ☐

4 If not CE-marked, (or if 'off-label' use is proposed for a CE-marked Device). then -

a) Is this a Medical Device for 'Clinical Investigation' ? NO ☐ YES ☐

- if YES, quote the MHRA 'no objection' reference number:

- if YES, has a copy of the MHRA's notice of 'no objection' been attached to this return? YES ☐

b) Is this an In-Vitro Diagnostic Medical Device for 'Performance Evaluation' ? NO ☐ YES ☐

- if YES, has a copy of notification to MHRA been attached? YES ☐

c) Is this a 'custom-made' Medical Device? NO ☐ YES ☐

- if YES, name the prescribing Medical Practitioner:

d) - if NO to 3(a), and to 4(a) (b) and (c), then provide justification of the Device's status -

5 a) Which EC conformity assessment route/s have been adopted?

☐ full QA ☐ type examination ☐ product verification ☐ production QA

☐ product QA ☐ unit verification ☐ internal control (self declaration)

b) Has this included Notified Body conformity assessment? NO ☐ YES ☐

- Notified Body identification number & name:

c) Is the manufacturer currently certified to any management system Standards? NO ☐ YES ☐

- which Standard/s? ← (eg: EN-ISO-9001, 13485, 14001, etc.)

- Certification Body:

PRODUCT SUPPORT:

6 a) Can an additional User Manual be provided (electronic format) ? YES ☐

b) Can a Technical Manual be provided (electronic format) ? NO ☐ YES ☐

c) Is free-of-charge loan equipment normally available in the event of equipment failure? NO ☐ YES ☐

Commissioning & Deployment

7 a) Has a protocol for post-delivery acceptance testing of Device function and safety been attached to this return? YES ☐

b) Does the Device have particular installation requirements and / or require ancillary services ? NO ☐ YES ☐

- if YES, then have details of all installation requirements been attached to this return? YES ☐

Technical Support

8 a) Does the manufacturer or an authorised servicing agent provide a maintenance / repair service? NO ☐ YES ☐

- if YES, then have details of all service contract options been detailed, costed and attached to this return? YES ☐

- where is the servicing facility located?

- are all servicing staff verifiably trained and competency assessed for the servicing tasks that they perform? YES ☐

b) Is the servicing organisation currently certified to any management system Standards? NO ☐ YES ☐

- which Standard/s? ← (eg: EN-ISO-9001, 13485, 17025, etc.)

- Certification Body:

c) Do the contract alternatives offered in 8(a) include an option for in-house equipment servicing by hospital staff? NO ☐ YES ☐

- have details of the availability of spare / replacement parts to support equipment servicing been attached to this return? YES ☐

- have details of information / test equipment / tooling / software required for equipment servicing been attached to this return? YES ☐

Decontamination

9 a) What level of Device decontamination / reprocessing is required ?

☐ single-use ☐ cleaning ☐ disinfection ☐ sterilisation

b) If not single-use, have validated decontamination protocol/s been attached to this return ? YES ☐

c) For sterilisable Devices, do these instructions meet the requirements of EN-ISO-17664 ? YES ☐

d) Are Devices uniquely identifiable ? NO ☐ YES ☐

e) Have all requirements for special reprocessing equipment, tools and materials been detailed in the attached information ? YES ☐

f) Have any special post-processing Device storage requirements been detailed in the attached information ? YES ☐

g) Is there a limit to the number of Device reprocessing cycles ? YES ☐ If YES, what is the limit ?

Particular Requirements

10 a) Does the product present particular hazards that require special management ? (eg: hazardous radiation, materials, etc.) NO ☐ YES ☐

- identified hazards:

- if YES, then have details of the nature of identified hazards been attached to this return ? YES ☐

b) Does the product require particular quality assurance measures ? (eg: calibration, qualification, etc.) NO ☐ YES ☐

- QA measures:

- if YES, then have details of quality assurance requirements been attached to this return ? YES ☐

c) Does the Device store or transmit patient information that will require information governance measures ? NO ☐ YES ☐

- if YES, then have details of information capture / storage / transmission / deletion been attached to this return ? YES ☐

TRAINING:

11 a) Is competency-based user training available from the manufacturer or an authorised provider? NO ☐ YES ☐

- if YES, have details of user training offered (amount / content / duration/ location / cost / etc.) been attached to this return? YES ☐

b) Is competency-based technical (equipment servicing) training available from the manufacturer or an authorised provider? NO ☐ YES ☐

- if YES, have details of technical training offered (amount / content / duration / location / cost / etc.) been attached to this return? YES ☐

c) Is competency-based decontamination / reprocessing training available from the manufacturer or an authorised provider? NO ☐ YES ☐

- if YES, have details of decontamination training offered (amount / content / duration / location /cost / etc.) been attached to this return ? YES ☐

d) Are qualification / competency records of training providers available upon request ? YES ☐

PRODUCT COMMITMENT:

12 a) To what date is product support for this Model guaranteed?

b) Does this include training; servicing, repair & availability of parts; supply of consumables / accessories ? YES ☐

c) Have warranty details been attached to this return? YES ☐ What is the warranty period?

d) Does the manufacturer / supplier have a robust system for notification of Device alerts / upgrades to a named hospital representative ? YES ☐

DECLARATION:

Please ensure that all necessary supplementary information, (as indicated by shaded boxes ☐ in the Form above) accompanies this return.

1.c)	Outstanding Field Safety Corrective Actions / Field Safety Notices	ATTACHED ☐	NOT APPLICABLE ☐
1.d)	Product brochure / specification	ATTACHED ☐	
1.e)	List of all Model variants and / or Accessories covered by this return	ATTACHED ☐	NOT APPLICABLE ☐
3.b)	EC Declaration/s of Conformity	ATTACHED ☐	
4.a)	MHRA's notice of 'no objection' for Medical Device 'Clinical Investigation'	ATTACHED ☐	NOT APPLICABLE ☐
4.b)	Notification to MHRA for In-Vitro Diagnostic Medical Device 'Performance Evaluation'	ATTACHED ☐	NOT APPLICABLE ☐
7.a)	Protocol for post-delivery Device acceptance testing	ATTACHED ☐	
7.b)	Details of installation requirements	ATTACHED ☐	NOT APPLICABLE ☐
8.a)	Service support contract options for maintenance / repair	ATTACHED ☐	
8.c)	Availability of spare / replacement parts	ATTACHED ☐	NOT APPLICABLE ☐
	Information / test equipment / tooling / software required for Device servicing	ATTACHED ☐	NOT APPLICABLE ☐
9.b)	Validated decontamination protocol/s	ATTACHED ☐	NOT APPLICABLE ☐
9.e)	Requirements for special reprocessing equipment, tools and materials	ATTACHED ☐	NOT APPLICABLE ☐
9.f)	Details of special post-processing Device storage requirements	ATTACHED ☐	NOT APPLICABLE ☐
10.a)	Details of particular hazards that require special management	ATTACHED ☐	NOT APPLICABLE ☐
10.b	Derails particular quality assurance measures required	ATTACHED ☐	NOT APPLICABLE ☐
10.c)	Details of patient information capture / storage / transmission / deletion	ATTACHED ☐	NOT APPLICABLE ☐
11.a)	Details of user training offered	ATTACHED ☐	NOT APPLICABLE ☐
11.b)	Details of technical training offered	ATTACHED ☐	NOT APPLICABLE ☐
11.c)	Details of decontamination training offered	ATTACHED ☐	NOT APPLICABLE ☐
12.c)	Warranty details	ATTACHED ☐	

When reference is made to this Form and its attachments within the process of obtaining the specified item/s, we agree that the purchaser will be entitled to rely upon the contents and subsequent non-compliance with the statements contained herein will entitle the purchaser to seek redress.

Name:			
Position:			
Company:			
Address:			
Email:		Telephone:	
Signature:		Date:	

CONTRACTUAL:

13 a) On what basis will the Device be supplied?

purchase? ☐ exchange? ☐ rental/lease? ☐ loan? ☐ donation? ☐

b) For Supply by loan or donation, does the supplier have a Master Indemnity Agreement (MIA) with the NHS? NO ☐ YES ☐

- if YES, then quote NHS MIA reference number: ← (Ref-A for loan, Ref-B for donation)
- if NO, then for supply by loan, has an NHS Form of Indemnity A been completed and attached to this return? YES ☐
- if NO, then for supply by donation, has an NHS Form of Indemnity B been completed and attached to this return? YES ☐

c) Is the particular item to be supplied a pre-used Device? YES ☐

- if YES, has usage and full service history been attached with this return? YES ☐

Name:			
Position:			
Signature:		Date:	

NHS Solent NHS Trust

Capital Funding Request Form

1. Project Lead	Name:				
2. Service Line					
3. Project Title					
4. Project cost centre (to be completed by the Finance Department)					
5. Justification for expenditure					
6. Investment (First purchase) or replacement					
7. Implications of not funding this scheme					
8. Capital Cost		**Includes VAT?**		☒	
9. Estimated useful life?					
10. Net Revenue costs p.a.	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5
Revenue savings p.a					
Revenue costs p.a					
Depreciation p.a	£0.00	£0.00	£0.00	£0.00	£0.00
Capital charges p.a	£0.00	£0.00	£0.00	£0.00	£0.00
Total Net Revenue Costs p.a	**£0.00**	**£0.00**	**£0.00**	**£0.00**	**£0.00**
11 How will the Revenue costs be funded?					
12 Revenue costs approved by Finance Business Partner					
Date					
13. What are the benefits of this investment (describe the statutory requirements or risk addressed, increased income to Trust or revenue savings that will be achieved):					
14. Operations Director Approval:					

Date	

To be completed by Capital Accountant

Capital Reserve
Opening balance
Amount requested
Closing balance
Finance Sign Off:
Position:
Date:

Approved by:
Amount:
DATE:

Appendix 8

Transfer of Medical Devices (Equipment) Form

In order to keep a good track on all medical devices (equipment), it is essential to know the location at all times. Failure to have this information can result in medical devices (equipment) not being maintained.

This is a standard transfer note which shows the information which needst o be kept for record keeping and tracking.

Please ensure every time a medical device (equipment) moves location/site the transfer note is fully completed and kept

---

Equipment:

ID/ Serial No .....

Present Site/Location:

Transferred/Loa

ned to:

Site/Location:

Left

[Date}:

Authorise

d name:

Signature

Accepted

by name;

Signature:

Returned

[Date}:

Copies to: file

Declaration of Contamination Status Form

From (consignor): …….. To

(consignee): Address: ……..

Address:

…….. ……..

……..

…….. Reference:

…….. Reference: ……..

Emergency tel: ……

Type of medical device (equipment)

…… Manufacturer:

…….. Description

of equipment: ……..... Other

identifying marks: ……..

Model No. …… Serial No

…… Fault ☐ ☐ ☐

……

Is the item contaminated? Yes No ☐ Don't know ☐

* State type of contamination: blood, body fluids, respired gases, pathological samples, chemicals (including cytotoxic drugs), radioactive material or any other hazard ……

Has the item been decontaminated? Yes No Don' know

What method of decontamination has been used? Please provide details

…… **Cleaning**

……

Disinfection

……..

Sterilisation

…… **Please**

explain why the item has not been decontamination? ……

……

This item has been prepared to ensure safe handling and transportation:

Name: …… Position: ……..

***** ***This form should accompany the item of equipment***

Equality Impact Assessment

Completed in consultation

Step 1 – Scoping; identify the policies aims	**Answer**		
1. What are the main aims and objectives of the document?	To give all staff comprehensive guidance on relevant legislation, organisational rules and good practice so staff can deal effectively when working with medical devices . This policy outlines procedures and guidelines for the systematic management of medical devices and equipment throughout the whole medical devices life cycle		
2. Who will be affected by it?	managers and staff who deal with issues relating to use of medical devices activities and maintenance of devices		
3. What are the existing performance indicators/measures for this? What are the outcomes you want to achieve?	Improved provision and maintenance of medical devices and the reduction of probability of injury with suitable support		
4. What information do you already have on the equality impact of this document?	Existing incident report data and usage data		
5. Are there demographic changes or trends locally to be considered?	No		
6. What other information do you need?	Non identified		
Step 2 - Assessing the Impact; consider the data and research	**Yes**	**No**	**Answer** (Evidence)
1. Could the document unlawfully discriminate against any group?		✓	
2. Can any group benefit or be excluded?		✓	
3. Can any group be denied fair & equal access to or treatment as a result of this document?		✓	
4. Can this actively promote good relations with and between different groups?	✓		
5. Have you carried out any consultation internally/externally with relevant individual groups?	✓		Please see routes of consultation and ratification process.
6. Have you used a variety of different methods of consultation/involvement	✓		Consultation within organisation. Please see above.

Mental Capacity Act implications			
7. Will this document require a decision to be made by or about a service user? (Refer to the Mental Capacity Act document for further information)		✓	
External considerations			
8. What external factors have been considered in the development of this policy?			This policy has taken into consideration all MHRA guidelines and appropriate Health and Safety utive legislative management
9. Are there any external implications in relation to this policy?			No
10. Which external groups may be affected positively or adversely as a consequence of this policy being implemented?			No

If there is no negative impact – end the Impact Assessment here.