**Management of Medical Devices (Equipment) 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.

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Executive Summary

This revised policy underpinned by identified good practice and relevant legislation ensures staff can deal effectively when working with medical devices (equipment). This policy outlines the management of medical devices and equipment throughout the whole medical devices life cycle and applies to all areas of the Solent NHS Trust.

By the means of this policy, Solent NHS Trust aims to meet 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.

This policy has been developed to meet that duty and ensure that risks associated with medical devices are identified and managed.
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1. INTRODUCTION & PURPOSE

1.1 The purpose of this policy is to outline the medical device (equipment) 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 This policy outlines the systematic management of medical devices and equipment throughout the whole medical devices life cycle Refer to Appendix 1.

1.3 It also ensures safe and effective use of medical devices (equipment) 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.

1.4 It is important in terms of management of medical devices (equipment) 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 The main aspects covered are medical devices and equipment throughout the whole medical devices life cycle and applies to all areas of the Solent NHS Trust, the services that it provides and all staff contracted either directly or indirectly employed to work within Solent NHS Trust’s properties in line with the organisation Trust’s Equal Opportunities Document. This policy covers:

- all clinical or identified staff using medical devices.
- all administrative managerial staff who manage distribution, collection, cleaning, disposal/scraping, recycling, repair of medical devices (equipment) whether used in an area or loaned to patients/clients/carers
- those advising/educating patients/clients/carers other staff in the safe use of medical devices (equipment)
- those using medical devices (equipment) in demonstration areas
- those involved in research, development and trials.

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.

DEFINITIONS

2.3 Equipment includes medical devices. A medical device is identified using the 2002 Medical Device Regulation and the Medical Devices (Amendment ) Regulations 2013 definition and covers any
device, instrument, apparatus, implement, material, substance or other article (used singularly or in combination) together with any accessory thereto which is intended by the manufacturer for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease; including computer software designed for this purpose
- Diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception.

2.4 A further list of some of the products covered by the definition of medical device and prepared by the Medical Devices Agency Refer to Appendix 2.

2.5 SINGLE - USE: A device that is used once, on a single patient, and then disposed of.

2.6 SINGLE PATIENT - USE: A device that can be used more than once on a single patient.

2.7 REUSABLE: A device that can be reused on multiple patients; provided it is decontaminated in accordance with manufacturer’s instructions between uses

2.8 ADVERSE INCIDENT: involving medical devices and equipment which produce, or have the potential to produce, unexpected or unwanted outcomes that affect the safety of patients, service users or other people, such as where:

- A patient, client, user, carer or professional is injured as a result of a medical device or equipment failure or its misuse.
- A patient’s or client’s treatment is interrupted or compromised by a medical device or equipment failure
- Misdiagnosis due to medical device or equipment failure leads to inappropriate treatment
- A patient’s or client’s health deteriorates due to a medical device or equipment failure.

2.9 CARER/END USER: An employee, carer, patient or client who uses a medical device or item of equipment in a healthcare facility or at home (e.g. infusion pump, wheelchair, chair lift etc.)

2.10 CAS: Department of Health ‘Central Alerting System’ – a central Department of Health led system where all medical device related incidents and/or product faults are released to the NHS

2.11 CE: ‘Clinical Engineer’- a specialist external service, that deals with the management and maintenance of medical devices for The Trust.

2.12 MHRA: Medicines and Healthcare products Regulatory Agency – A governmental run agency that is responsible for the regulation of medicines and medical devices and equipment used in healthcare organisations and the investigation of harmful incidents.

2.13 PPM: ‘Planned Preventative Maintenance’ – a regular ‘scheduled service’, a maintenance programme performed by CE that involves the correction or prevention of faults by calibration and replacement of parts, in order to keep the medical device performing as intended by the manufacturer.

2.14 PPQ: Pre-Purchase Questionnaire – is a standardised form that must be completed prior to purchase as it gives all relevant details of its requirements for its lifetime support for the buyer to establish its suitability.

3. ROLES and RESPONSIBILITIES
3.1 **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.

3.2 **The Nominated Director for Health and Safety (Chief Nurse)** will through the Trust Health & Safety Sub-committee be responsible for monitoring compliance with the management of medical devices (equipment) policy, generating status reports reporting any significant risks associated with management of medical devices (equipment) to the Quality Improvement and Risk Group. The Nominated Board level Director for health and safety has the overall responsibility of Medical Devices and will review performance against national standards and set financial priorities for a medical device (equipment) planned replacement programme including review of procurement.

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

3.4 **Health and Safety Manager** shall be responsible for co-ordinating medical device safety and management across Solent to ensure relevant statutory, mandatory, regulatory requirements are met and shall in particular:

- To be the key point of contact for all medical devices related queries for frontline staff and managers
- Reviews incidents reported on Safeguard involving medical devices for identification of trends, requirement of reporting to MHRA, and to further investigate (or assist with) where required.
- Provide a regular summary of these incidents for review by the Medical Devices Procurement Review Group
- Liase with medical devices contractual providers
- Provide adequate inspection and maintenance records for the management of Medical Devices, inclusive of Lifting Operations Lifting Equipment Regulations (LOLER) and Pressurised Systems that are used within the medical devices remit
- Produce assurance reports that management of the above have been carried out

3.5 **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 the devices under his/her
- Management and to ensure that any new device/equipment is registered on the centralised medical device asset list through formal notification with Clinical Engineering and the Medical Devices and Procurement Review Group. **Refer to Section 4 and Appendix 3 and 4**
- Identify and appoint sufficient numbers of Medical Devices Controllers/links
- The 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.

3.6 **ALL Employees (permanent/temporary/contract)**

3.6.1 All Employees (permanent/temporary/contract) 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 (equipment) and promptly report all incidents concerning risks and or any adverse affects arising from the management of medical devices (equipment).

3.6.2 All Employees (permanent/temporary/contract) are responsible for ensuring that they:

• In association with their line manager identify and undertake any training or competency needs required for their role
• 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
• Use medical devices in a safe and effective manner in accordance with guidance and/ or the manufacturers intended use
• 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)
• Know how to decontaminate reusable devices and dispose of single use devices.

3.7 **Medical Devices and Procurement Review Group (MDPRG)**

3.7.1 The Medical Devices and Procurement Review Group will support the Nominated Director for Health and Safety (Chief Nurse) the Terms of Reference for the (MDPRG) are attached at Appendix 14

3.7.2 One of the main objectives of the Medical Devices and Procurement Review Group is to approve and standardise the use of medical devices (equipment) used within the Trust and to ensure the Health and Safety Sub- Committee are aware of compliance with National Standards

3.7.3 Medical Devices and Procurement Review Group will receive completed Medical Device and Equipment Replacement Application forms and will review applications and either sanction approval for a period of 12 months or return back to author explaining why it wasn’t approved and further recommendations

3.8 **Medical Devices Controllers/ Links**

3.8.1 Medical Devices Controllers/Links will act as a representative of their area and work to support managers and the divisional or service lead in order to provide a safe, effective, efficient use and management of medical devices.

3.8.2 Medical Devices Controllers/links will be appointed by the Governance Leads/ service
They will be known to all users of medical devices (equipment) within their department(s); and to other appropriate people. A register of equipment controllers will be kept and maintained by the (MDPRG).

3.9 **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 equipment.
- 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.

3.10 **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.

4. **PROCUREMENT, SELECTION & STANDAISATION of MEDICAL DEVICES / EQUIPMENT**

4.1 This relates to acquisitions of all descriptions – new purchases, replacements, loans, transfers of medical devices (equipment) including those funded from donated monies and/or charitable donations etc.

4.2 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.**

4.3 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 risk/ health and safety department, medical device operational group, infection control etc.

**Equipment Standardisation**

4.4 Where practical, Solent NHS will standardise common types of Medical Devices (Equipment) 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 (equipment) can be used
• Optimum maintenance of medical devices (equipment), including staff training in routine maintenance, provision of test medical devices (equipment) and spare parts
• Optimisation of medical device asset management
• Improved business planning

**Procurement Process and Medical Devices Replacement Procedure**

4.5 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 3]*

• **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 4]*

4.6 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 5  Acceptance Testing for New Delivered Medical Devices (Equipment) Guidance*

5. **MEDICAL DEVICES (EQUIPMENT) REPLACEMENT**

5.1 All medical devices (equipment) 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.

5.2 A replacement programme for medical devices (equipment) should be based on the criteria for replacement outlined in 5.1 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 Review Panel and/or Medical Operational Group Chair. In this way, equipment planning can be more closely linked to the service and business planning

5.3 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...
6. **DECONTAMINATION OF MEDICAL DEVICES (EQUIPMENT) DECONTAMINATION OF REUSABLE DEVICES**

6.1 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 control measure and this policy will outline a risk assessment strategy Trust staff must use.

6.2 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.

6.3 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.

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

6.5 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 11 Declaration of Decontamination Status Form**

7. **STORING MEDICAL DEVICES (EQUIPMENT)**

7.1 Following acceptance of medical devices (equipment) they will be stored in accordance with the manufacturer’s instructions pertaining to shelf life and storage conditions.

8. **SINGLE USE AND SINGLE PATIENT USE DEVICES AND OTHER HEALTH CARE PRODUCTS**

8.1 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.

8.2 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
8.3 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:


9. DEVELOPMENTS, TRIALS, DEMONSTRATIONS AND ‘INNOVATION MANAGEMENT’

9.1 No research trials of medical devices (equipment) should be commenced without the written permission of Medical Devices and Procurement Review Group, and the Trusts R&D lead.

9.2 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.

9.3 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.

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

9.5 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.

9.6 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.

9.7 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.

9.8 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)

10. MAINTENANCE SERVICING & REPAIR

10.1 Medical devices (equipment) should remain safe, serviceable and reliable throughout the working life. Maintenance of such device (equipment) will be undertaken by suitably qualified person(s) as recognised by the Trust.

10.2 It is the service manager’s responsibility to ensure that all medical devices (equipment) are available for service and maintained on a regular basis.

10.3 A formal system is in place to ensure that the devices (equipment) 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**

10.4 Contractual arrangements will be in place with qualified personnel to ensure medical devices (equipment) are serviced and maintained in accordance with manufacturers recommendations.

**DEFECTIVE and REPAIR**

10.5 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.

10.6 Some minor front line repairs are carried out as part of the contract/ Service Level Agreement by the external Clinical Engineering teams other repairs are on a pay as you go basis. It is currently the responsibility of the individual ward/dept. to arrange for repairs and fund those repairs that are not covered by the contract/ Service level Agreement.

11. **MEDICAL DEVICES / EQUIPMENT INVENTORY**

11.1 The Trust will maintain a centralised “Medical Devices ” (Equipment 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.

11.2 Specialist medical devices contractors databases working for the Trust, will be used to provide records on behalf of the trust where contracted.

11.3 All new assets acquired by the Trust, from whatever source, will be registered on the Trust’s database on approval to purchase and/or on commissioning.

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

12 **RISK MANAGEMENT**

12.1 Risk Management of medical devices (equipment) should conform to the Trust’s Policy and Strategy for Risk Management, together with the process for Risk Assessment and Incident Reporting. The ‘owner’ of the device is therefore responsible for risk assessment and the placing of that risk on the Trust’s Register as appropriate/necessary.

13. **ADVERSE INCIDENTS**

13.1 An adverse incident is an event 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.

13.2 Where practical the current medical device (equipment) should be immediately taken out of 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.
13.3 Medical devices (equipment) involved in adverse incidents together with other material should be clearly identified and kept in quarantine, where practicable, until MHRA’s device specialists have been consulted. The state of the device at the time of the incident should be recorded for use in any subsequent investigation.

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

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

14. TRAINING & COMPETENCY

14.1 The Trust will have a process for self-assessment competency specifically for all permanent staff and other users of medical devices (equipment) 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.

14.2 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”. 

14.3 Appendix 10 provides managers with guidance on a medical device training, competency self-assessment form and a Authorised Users & Training Needs Analysis table. All users must receive training in how to use the device. This covering the following:

- The name of the device
- The operation and control of the device
- Checking of the device while in use
- Recognition of a device failure or fault
- Action to be taken in the event of a device failure or fault
- Cleaning and decontamination procedures

The manufacturer’s instructions should provide some information but this should be tailored to the needs of the individual patient or carer.

14.4 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.

14.5 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.

14.6 Employees are not permitted to use medical devices for which they or others have determined they are not competent.
15. **EQUIPMENT PRESCRIBING DECISIONS**

15.1 Staff with appropriate professional qualifications and suitable training and experience, and working within the approved list of equipment, will make prescribing decisions within the Trust. The prescription of medical device (equipment) is the responsibility of the prescribing professionals and subject to the staff member’s professional code of conduct. Each service will maintain lists of health and social care professionals who are approved prescribers and will keep records of training.

15.2 Where required equipment and device prescribers need competence to be competent in the use of the medical device in order to safely discharge their duties. In addition to this, patients (wherever applicable) must also be given written instruction relating to safe use of the devices issued to them.

16. **CUSTOM MADE DEVICES**

16.1 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.

16.2 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).*

16.3 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.*

16.4 In addition, services will keep records of manufacturers’ MDD registration numbers.

16.5 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 and Security Management Services (CFSMS - http://www.cfms.nhs.uk/) audit records from time to time.

16.6 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.

16.7 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.

16.8 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.

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

17.1 Loan medical devices (equipment) has two categories, they are:

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

17.2 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 (equipment) 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 (Equipment) Form must be completed Refer to Appendix 9

18. **SUCCESS CRITERIA/MONITORING COMPLIANCE**

18.1 The policy will be monitored for effectiveness via the medical devices procurement review group meetings with necessary reviews and audits identified below.

19. **EQUALITY & DIVERSITY AND MENTAL CAPACITY ACT**

19.1 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 12.

POLICY REVIEW

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

RELATED POLICY AND PROCEDURE REFERENCES

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
16. HSC 2000/32 Decontamination of medical devices
27. Department of Health 2007 Primary care dental services: guidance on single-use instruments for endodontic procedures.
30. The General Product Safety regulations 1994
31. The Medical Devices Regulations 2002 (as amended 2013)
32. Solent NHS Trust Decontamination Policy IPC 12
### COMMON CATEGORIES OF MEDICAL DEVICE

This list is not exhaustive. It provides examples of medical devices. Equipment used in the diagnosis or treatment of disease, or monitoring of patients, such as:

<table>
<thead>
<tr>
<th>COMMON CATEGORIES OF MEDICAL DEVICE</th>
<th>Equipment used in life support such as:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Chiropody and podiatry equipment</td>
<td>• Defibrillators</td>
</tr>
<tr>
<td>• Dental instruments, equipment and materials.</td>
<td>• Domiciliary oxygen therapy systems</td>
</tr>
<tr>
<td>• Dressings</td>
<td>• Insulin injectors</td>
</tr>
<tr>
<td>• Endoscopes</td>
<td>• Pulse oximeters</td>
</tr>
<tr>
<td>• ECT</td>
<td>• Ventilators</td>
</tr>
<tr>
<td>• Examination gloves</td>
<td></td>
</tr>
<tr>
<td>• Gastrostomy tubes</td>
<td></td>
</tr>
<tr>
<td>• Intravenous (IV) administration sets and pumps</td>
<td></td>
</tr>
<tr>
<td>• Nebulisers</td>
<td></td>
</tr>
<tr>
<td>• Ophthalmic equipment</td>
<td></td>
</tr>
<tr>
<td>• Peak flow meters</td>
<td></td>
</tr>
<tr>
<td>• Surgical instruments Suction equipment</td>
<td></td>
</tr>
<tr>
<td>• Syringes and needles</td>
<td></td>
</tr>
<tr>
<td>• Sphygmomanometers</td>
<td></td>
</tr>
<tr>
<td>• Thermometers</td>
<td></td>
</tr>
<tr>
<td>• Ultrasound Doppler</td>
<td></td>
</tr>
<tr>
<td>• Urinary catheters</td>
<td></td>
</tr>
</tbody>
</table>

**n vitro diagnostic medical devices and their accessories, such as:**

- Blood glucose measuring device
- Cholesterol test kits
- Pregnancy test kits
- Specimen collection tubes
- Urine test strips

**Equipment used by people with disabilities, such as:**

- Bathing equipment
- Commodes
- External protheses and orthoses
- Hearing aids
- Prescribable footwear
- Standing frames
- Urine drainage systems
- Walking aids
- Supporting seats
- Wheelchairs

**Equipment used in care, such as:**

- Adjustable beds
- Lifting poles
- Patient hoists
- Pressure relief equipment
- Stoma care equipment

**Other examples include:**

- Condoms
- Contact lenses and care products
- Intra-uterine devices (IUDs)
- Drug and Alcohol screening equipment
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.

Is it replacing a piece of existing equipment? Yes

No

Is it a new type or model of equipment not in use elsewhere in the Trust? Yes

No

Obtain completed Pre Purchase Questionnaire form from the Manufacturer Refer to Appendix 7 Management of Medical Devices Policy.

Identify piece of equipment to be ordered and complete Medical Devices & Equipment Replacement Application Form Refer to Appendix 6 Management of Medical Devices Policy. Attach Pre Purchase Questionnaire if applicable.

Completed Medical Devices & Equipment Replacement Application Form sent to the Medical Devices and Procurement Review Group and/ or Chair, for approval.

Authorised Yes

No

Medical Devices and Procurement Review Group will suggest alternatives.

Procurement starts Business Proforma

Service line funding stream available

Yes

No

Through SBS Oracle Purchase the Equipment

Before use send to Clinical Engineering to tag and register medical equipment onto the Solent NHS Trust co-operate medical devise register, and to start servicing of equipment according to manufacturer’s

Complete Capital Business Case form Refer to Appendix 8 Management of Medical Devices Policy

Presented to Finance and Commercial group for authorisation

Not approved

Bid requester informed

Approved
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.

Is it replacing a piece of existing equipment?  
- Yes  
- No

Is it a new type or model of equipment not in use elsewhere in the Trust?  
- Yes
  - Obtain completed Pre Purchase Questionnaire form from the Manufacturer Refer to Appendix 7 Management of Medical Devices Policy
  - Identify piece of equipment to be ordered and complete Medical Devices & Equipment Replacement Application Form Refer to Appendix 6 Management of Medical Devices Policy. Attach Pre Purchase Questionnaire if applicable

- No

Completed Medical Devices & Equipment Replacement Application Form sent to the Medical Devices and Procurement Review Group and/ or Chair, for approval.

Authorised  
- Yes
  - Service line funding stream available?  
    - Yes
      - Through SBS Oracle Purchase the Equipment
      - Before use send to Clinical Engineering to tag and register medical equipment onto the Solent NHS Trust co-operate medical devise register, and to start servicing of equipment according to manufacturer’s recommendations
    - No
      - Place onto Service Risk Register
  - No
    - Medical Devices and Procurement Review Group will suggest alternatives
- No
ACCEPTANCE TESTING FOR NEWLY DELIVERED MEDICAL DEVICES (EQUIPMENT)

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

2. 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 disinfected

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.

<table>
<thead>
<tr>
<th>Existing Equipment Description:</th>
<th>Asset Number(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Directorate/Department:</td>
<td></td>
</tr>
<tr>
<td>Name of Head of Department</td>
<td>Contact No: -</td>
</tr>
<tr>
<td></td>
<td>Email Address:</td>
</tr>
<tr>
<td>Outline the reason for request:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the device a replacement?</td>
<td>□ YES □ NO</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes give medical devices product name and details below</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
<td></td>
</tr>
</tbody>
</table>

What is the estimated purchase price including VAT?

<table>
<thead>
<tr>
<th>Will there be an additional installation required and what cost? If yes give details below</th>
</tr>
</thead>
</table>

If replacing an existing piece of equipment, will the old equipment be decommissioned?

If not, give the reason:

- □ YES □ NO

<table>
<thead>
<tr>
<th>a) Clinical Requirements:</th>
</tr>
</thead>
</table>

- What impact does this device have on existing clinical practices?

- List the general profession of key users (e.g. nurses, doctors, physiotherapists, etc.)

<table>
<thead>
<tr>
<th>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</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>b) Installation:</th>
</tr>
</thead>
</table>

- Does the device require additional services (e.g. water, power, ventilation etc..)?

- □ YES □ NO
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the device require any IT interface to the IT network?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the device require storage space on the IT network/server?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are further safety measures required?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you have answered yes, to any of the questions in b) above please provide details.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>c) Consumables:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the device require consumables of a type not currently purchased by Procurement?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are generic consumables available or must consumables be purchased from the equipment supplier?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What is the total expected annual consumable cost (incl. of VAT)?</td>
<td>£</td>
<td></td>
</tr>
<tr>
<td><strong>d) Maintenance/Licensing:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there any additional operating costs (e.g. Preventative Maintenance Checks/Calibration as per manufacturers’ recommendations)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will this equipment require a service contract?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there an annual validation requirement?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a recurring software license fee?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you have answered yes, to any of the questions in d) above please provide details.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>e) Cleaning and Decontamination:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who will be responsible for cleaning the equipment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will any equipment components require decontamination – if so state decontamination requirements?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has funding been sought/received from other sources?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, give details:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cost Assessment</th>
<th>Amount (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of equipment inc VAT</td>
<td></td>
</tr>
<tr>
<td>Warranty period</td>
<td>___ Years</td>
</tr>
<tr>
<td>-----------------</td>
<td>----------</td>
</tr>
<tr>
<td>Estimated cost of annual maintenance contract</td>
<td></td>
</tr>
<tr>
<td>Estimated change in consumable costs from current</td>
<td></td>
</tr>
<tr>
<td>Estimated change in cost of annual validation, if applicable?</td>
<td></td>
</tr>
<tr>
<td>If additional facilities required (test equipment, water, power, ventilation etc) – state estimated cost</td>
<td></td>
</tr>
<tr>
<td><strong>Total Estimated Cost</strong></td>
<td>(£)</td>
</tr>
</tbody>
</table>

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:
**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:

<table>
<thead>
<tr>
<th>(* Manufacturer, Supplier, or other)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Description:</strong></td>
</tr>
<tr>
<td><strong>Type:</strong></td>
</tr>
<tr>
<td><strong>Manufacturer:</strong></td>
</tr>
<tr>
<td><strong>Supplier:</strong></td>
</tr>
<tr>
<td><em><em>EU Authorised Representative</em>:</em>*</td>
</tr>
</tbody>
</table>

1. a) When was this Model first placed upon the market ?
   b) Is this Model still in production ? YES ☐
   c) Any outstanding Field Safety Corrective Actions / Field Safety Notices ? 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 ☐

### REGULATORY COMPLIANCE:

2. a) Does the Device meet the Essential Requirements of all currently applicable EC Directives? NO ☐
   b) Which EC Directive/s apply ?
      - Medical Devices Directive YES ☐
      - Active Implantable Devices Directive YES ☐
      - In-Vitro Diagnostics Medical Device Directive YES ☐
      - Other/s YES ☐
      - if YES, Classification? ☐
      - if YES, Category? ☐

3. a) Is the Device CE-Marked, for its intended use, to all currently applicable Directives? NO ☐
   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 ☐
      - if YES, quote the MHRA ‘no objection’ reference number: ☐
   b) Is this an In-Vitro Diagnostic Medical Device for ‘Performance Evaluation’ ? NO ☐
      - if YES, has a copy of notification to MHRA been attached? YES ☐
   c) Is this a ‘custom-made’ Medical Device? NO ☐
      - 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 ☐
      - Notified Body identification number & name: ☐
   c) Is the manufacturer currently certified to any management system Standards? NO ☐
      - which Standard/s? ☐
      - Certification Body: ☐

---

Management of Medical Devices (Equipment) Policy

Appendix 7

Page 27  Version 3
**PRODUCT SUPPORT:**

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

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

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

---

**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?
      - 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

   - 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?
   - YES

   b) Is the servicing organisation currently certified to any management system Standards?
      - which Standard/s?
      - Certification Body: (eg: EN-ISO-9001, 13485, 17025, etc.)

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

   c) Do the contract alternatives offered in 8(a) include an option for in-house equipment servicing by hospital staff?
      - if YES, then 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

   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

    - 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

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

    - QA measures:

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

    - 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

    - 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

    - 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

    - 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?  

```plaintext
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.

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

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.

---

**CONTRACTUAL:**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>13 a)</td>
<td>On what basis will the Device be supplied?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>purchase? [ ]  exchange? [ ]  rental/lease? [ ]  loan? [ ]  donation? [ ]  NO [ ]  YES [ ]</td>
</tr>
<tr>
<td>b)</td>
<td>For Supply by loan or donation, does the supplier have a Master Indemnity Agreement (MIA) with the NHS?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>if YES, then quote NHS MIA reference number:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>if NO, then for supply by loan, has an NHS Form of Indemnity A been completed and attached to this return?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>if NO, then for supply by donation, has an NHS Form of Indemnity B been completed and attached to this return?</td>
</tr>
<tr>
<td>c)</td>
<td>Is the particular item to be supplied a pre-used Device?</td>
<td>YES [ ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>if YES, has usage and full service history been attached with this return?</td>
</tr>
</tbody>
</table>

---

Name:   
Position:   
Signature:   
Date:   

---

Management of Medical Devices (Equipment) Policy  Page 29  Version 3
### Capital Funding Request Form

1. **Project Lead**
   - **Name:** [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?:** [VAT]

9. **Estimated useful life?**

10. **Net Revenue costs p.a.**
    - **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:

<table>
<thead>
<tr>
<th>Date</th>
</tr>
</thead>
</table>

**To be completed by Capital Accountant**

<table>
<thead>
<tr>
<th>Capital Reserve</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening balance</td>
<td></td>
</tr>
<tr>
<td>Amount requested</td>
<td></td>
</tr>
<tr>
<td>Closing balance</td>
<td></td>
</tr>
<tr>
<td>Finance Sign Off:</td>
<td></td>
</tr>
</tbody>
</table>

| Position: |  |
| Date: |  |

**Approved by:**

| Amount: |  |
| DATE: |  |
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 needs to 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.

<table>
<thead>
<tr>
<th>Equipment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID/ Serial No: .................................................................</td>
</tr>
<tr>
<td>Present Site/Location:</td>
</tr>
<tr>
<td>Transferred/Loa</td>
</tr>
<tr>
<td>ned to:</td>
</tr>
<tr>
<td>Site/Location:</td>
</tr>
<tr>
<td>Left</td>
</tr>
<tr>
<td>[Date]:</td>
</tr>
<tr>
<td>Authorise</td>
</tr>
<tr>
<td>d name:</td>
</tr>
<tr>
<td>Signature</td>
</tr>
</tbody>
</table>

Accepted by name; .................................................................

Signature: .................................................................

Returned [Date]: .................................................................

Copies to: file
Medical Device Training & Competency

1. Introduction

Solent has a process for self-assessment competency specifically for all permanent staff and other users of medical devices (equipment). All staff within Solent NHS Trust will be trained to an appropriate level in order to ensure the safe and effective operation of medical devices (equipment) in use within Solent NHS trust.

Safe operation of medical devices (equipment)

Professional users of medical devices (equipment) will be adequately trained to operate a device for the benefit of a patient or client. This will include understanding the normal operation of devices encompassing:

- Awareness of differences between different device models, where safety or function is potentially affected;
- Assembly and disassembly of the device where appropriate;
- Setting of controls;
- Effective linking of the device to a patient causing minimum discomfort;
- Teaching the end user how to use the device;
- Recognising malfunctions and taking appropriate action;
- Cleaning and decontamination procedures.

2. Arrangements and Responsibilities

All managers are responsible for ensuring that training needs of staff have been identified, (this responsibility will extend to include any Agency/bank staff).

Training requirements should be identified by line manager at induction reviewed at appraisals and raised by clinical 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.

A competence can be defined as “the ability to produce a result or an outcome that contributes to organisational performance”. In other words what a clinical staff needs to be able to do. It implies proficiency, ability, effectiveness, skill and capability in relation to the activities undertaken in day-to-day work.

It is recognised that support is required to enable clinical staff to achieve competency at each level. This may be achieved through personal development, clinical supervision, mentorship, management support, in-house training and/or utilise external providers.

Each service line manager will hold the competencies required for each medical device (equipment) for the clinical area.

One example appears below for Management of patients requiring the use of a suction machine.

**TOPIC: Management of patients requiring the use of a suction machine**

**Aim:** The nurse will demonstrate the safe use of a patient who requires the use of the suction machine.

<table>
<thead>
<tr>
<th>Assessment criteria</th>
<th>Personal checklist</th>
<th>Assessor’s initials (once achieved)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The nurse will understand and be able to demonstrate the assembly of the suction machine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The nurse will be able to demonstrate the correct catheter selection for the patients clinical condition

The nurse will demonstrate infection control procedures in relation to the suction machine

The nurse will be able to identify the correct clinical situations and patient groups for the procedure

The theory and rationale for the management of patients requiring the use of a suction machine has been explained to me and having completed the competency assessment criteria, I now feel competent to manage a patient requiring the use of a suction machine

Signature of Nurse: ............................................. Date: .........................

Signature of Supervisor: ............................................. Date: .........................

Comments on practice:

3. Authorised Users & Training Needs Analysis

Medical Devices
The table below details examples of people who need to know how to operate the listed equipment. It does not imply knowledge of the clinical need or application of the technology.

- Some = Some (usually in specialist areas) which will require training
- Yes = There is a need for all/large majority of this group to use this equipment & receive training
- No = There is no need for this group to use this equipment

<table>
<thead>
<tr>
<th>Staff Equipment</th>
<th>Drs. Consultants</th>
<th>Drs. Others</th>
<th>Qualified Nurses</th>
<th>Allied Health Professionals</th>
<th>Nurse Unqualified</th>
<th>Managers</th>
<th>Admin &amp; Clerical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetic equipment</td>
<td>Some</td>
<td>Some</td>
<td>No</td>
<td>Some (Podiatrist)</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Blood pressure monitoring equipment</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Defibrillating equipment</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>ECG writers</td>
<td>Yes</td>
<td>Yes</td>
<td>Some</td>
<td>Some</td>
<td>Some</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Exercising equipment</td>
<td>Some</td>
<td>Some</td>
<td>Some</td>
<td>Yes</td>
<td>Some</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Feeding pumps</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Some</td>
<td>No</td>
</tr>
<tr>
<td>Humidifying equipment</td>
<td>Yes</td>
<td>Yes</td>
<td>Some</td>
<td>Some</td>
<td>Some</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Infusion equipment</td>
<td>Yes</td>
<td>Yes</td>
<td>Some</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Oxygen Cylinders/Tubing/Masks</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Some (porters)</td>
</tr>
<tr>
<td>Nebulising equipment and compressors</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Some</td>
<td>Some</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Pressure sore relieving equipment</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Scales/weighting equipment</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Suction equipment electrical, manual, foot &amp; pipeline Laerdal Suction Unit</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Specialist</td>
<td>Some</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
4. **Adverse incident reporting**

Staff will be made aware that all medical devices adverse incidents **must** be reported via the Trust’s Adverse Incident Reporting Policy via the online reporting system Ulysses.

5. **End User Training**

Staff who issue out equipment to end users of medical devices (equipment) will be competent to provide appropriate training in the safe and effective use of medical devices (equipment); this will include performing routine maintenance task. End users will be notified of the importance of complying with manufacturer’s instructions regarding the use of medical equipment and devices. This process will assist in minimising legal liability of the TRUST in the event of adverse incidents.
Declaration of Contamination Status Form

From (consignor): .................................. To
(consignee): Address: ........................................

<table>
<thead>
<tr>
<th>Address:</th>
<th>Reference:</th>
</tr>
</thead>
<tbody>
<tr>
<td>..................................................................</td>
<td>......</td>
</tr>
<tr>
<td>..................................................................</td>
<td>......</td>
</tr>
<tr>
<td>..................................................................</td>
<td>......</td>
</tr>
<tr>
<td>..................................................................</td>
<td>......</td>
</tr>
<tr>
<td>Emergency tel: ........................................</td>
<td></td>
</tr>
</tbody>
</table>

Type of medical device (equipment)

<table>
<thead>
<tr>
<th>Manufacturer:</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>..................................................................</td>
<td>..................................................................</td>
</tr>
</tbody>
</table>

Other

identifying marks: ................................................................

Model No. ................................ Serial No

<table>
<thead>
<tr>
<th>Fault</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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’t know

What method of decontamination has been used? Please provide details

<table>
<thead>
<tr>
<th>Cleaning</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Disinfection

<table>
<thead>
<tr>
<th>Sterilisation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please explain why the item has not been decontamination?

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

Name: .............................................................. Position: ........................................

Management of Medical Devices and Equipment
### Equality Impact Assessment

Completed in consultation

#### Step 1 – Scoping; identify the policies aims

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What are the main aims and objectives of the policy?</td>
<td>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</td>
</tr>
<tr>
<td>2. Who will be affected by it?</td>
<td>All NHS Trust staff. Independent Contractors.</td>
</tr>
<tr>
<td>3. What are the existing performance indicators/measures for this?</td>
<td>Local targets. Legal requirements. Outcomes.</td>
</tr>
<tr>
<td>What are the outcomes you want to achieve?</td>
<td></td>
</tr>
<tr>
<td>4. What information do you already have on the equality impact of this policy?</td>
<td></td>
</tr>
<tr>
<td>5. Are there demographic changes or trends locally to be considered?</td>
<td>No</td>
</tr>
<tr>
<td>6. What other information do you need?</td>
<td>None identified</td>
</tr>
</tbody>
</table>

#### Step 2 - Assessing the Impact; consider the data and research

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Answer (Evidence)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Could the policy unlawfully against any group?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Can any group benefit or be excluded?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Can any group be denied fair &amp; equal access to or treatment as a result of this policy?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Can this actively promote good relations with and between different groups?</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Have you carried out any consultation internally/externally with relevant individual groups?</td>
<td>✓</td>
<td></td>
<td>Please see routes of consultation and ratification process.</td>
</tr>
<tr>
<td>6. Have you used a variety of different methods of consultation/involvement</td>
<td>✓</td>
<td></td>
<td>Consultation within organisation. Please see above.</td>
</tr>
<tr>
<td>Mental Capacity Act implications</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Will this policy require a decision to be made by or about a service user? (Refer to the Mental Capacity Act policy for further information)</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

#### Step 3 - Recommendations and Action Plans

<table>
<thead>
<tr>
<th>Management of Medical Devices and Equipment</th>
<th>Answer</th>
</tr>
</thead>
</table>
1. Is the impact low, medium or high?

2. What action/modification needs to be taken to minimise or eliminate the negative impact?

3. Are there likely to be different outcomes with any modifications? Explain these?

**Step 4 - Implementation, Monitoring and Review**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What are the implementation and monitoring arrangements, including timescales?</td>
<td></td>
</tr>
<tr>
<td>2. Who within the Department/Team will be responsible for monitoring and regular review of the policy?</td>
<td></td>
</tr>
</tbody>
</table>

**Step 5 - Publishing the Results**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>How will the results of this assessment be published and where? (It is essential that there is documented evidence of why decisions were made).</td>
<td></td>
</tr>
</tbody>
</table>
## GLOSSARY

<table>
<thead>
<tr>
<th>Term</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control of Substances Hazardous to Health</td>
<td>COSHH</td>
</tr>
<tr>
<td>Counter Fraud and Security Management Service</td>
<td>CSFMS</td>
</tr>
<tr>
<td>Department of Health</td>
<td>DH</td>
</tr>
<tr>
<td>Electronics Bio-Medical Engineering</td>
<td>EBME</td>
</tr>
<tr>
<td>Medicines and Healthcare Products Regulatory Agency</td>
<td>MHRA</td>
</tr>
<tr>
<td>Medical Devices and Procurement Review Group</td>
<td>MDPRG</td>
</tr>
<tr>
<td>National Health Service</td>
<td>NHS</td>
</tr>
<tr>
<td>National Health Service Litigation Authority</td>
<td>NHSLA</td>
</tr>
<tr>
<td>National Patient Safety Agency</td>
<td>NPSA</td>
</tr>
<tr>
<td>Occupational Therapist</td>
<td>OT</td>
</tr>
<tr>
<td>Solent NHS Trust</td>
<td>SNHST</td>
</tr>
<tr>
<td>Purchasing and Supplies Agency</td>
<td>PASA</td>
</tr>
<tr>
<td>Research &amp; Development</td>
<td>R &amp; D</td>
</tr>
<tr>
<td>Southampton University Hospitals TRUST</td>
<td>SUHT</td>
</tr>
<tr>
<td>Portsmouth Hospital Trust</td>
<td>PHT</td>
</tr>
<tr>
<td>Central Alerting System</td>
<td>CAS</td>
</tr>
<tr>
<td>Planned Preventative Maintenance</td>
<td>PPM</td>
</tr>
<tr>
<td>Pre Purchase Questionnaire</td>
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Medical Devices and Procurement Review Group (MDPRG)

Terms of Reference

1. Purpose

1.1 The purpose of the Medical Devices and Procurement Review Group (MDPRG) is to provide assurance to the Health & Safety Sub-Committee that an effective and robust system exists across Solent NHS Trust for the safe use and cost effective management of medical devices and equipment to protect staff and patients.

2. Aims

2.1 The Medical Devices and Procurement Review Group (MDPRG) will be responsible for overseeing the strategic and operational implementation of the Management of Medical Devices (Health and Safety) Policy in operational areas and seeking assurance that the activities of Solent NHS Trust are managed in a manner where staff and patient safety is of primary importance.

3. Responsibilities

To collate the information necessary to assure the health and safety sub-committee of compliance, the Medical Devices and Procurement Review Group, functions shall include, but may not be limited to:

3.1 The Medical Devices and Procurement Review Group will identify and monitor safe systems and processes at each stage of the medical devices life cycle from device consideration to disposal.

3.2 The Medical Devices and Procurement Review Group will ensure the development, implementation and audit of a Solent NHS Trust wide policy and strategy for the management of medical devices to include: procurement; training; risk assessment; maintenance, replacements and contracts.

3.3 Providing and promoting a forum for the effective consultation and communication on matters in regards to medical devices management between management and employees;

3.4 The Medical Devices and Procurement Review Group will act as an expert advisory group to inform and educate services; the group will promote and foster awareness of good medical device practice across Solent Healthcare.

3.5 Medical Devices and Procurement Review Group will approve and standardise the use of medical devices (equipment) used within the Trust.

3.6 Medical Devices and Procurement Review Group will receive and review completed Medical Device and Equipment Replacement Application forms and will either sanction approval or return to author with further recommendations.

3.7 The Medical Devices and Procurement Review Group will monitor statistics and data relating to ‘Adverse Event reports’ relating to medical devices and equipment reporting trends by service and equipment type. The Chair will alert the Health & Safety Sub-Committee immediately regarding any identified patient safety risk.

3.8 Monitoring and review of all Contracts and SLA’s relating to medical devices and equipment will be undertaken through the Medical Devices and Procurement Review Group, specifically this will include areas of procurement, clinical engineering and Estates.
3.9 The Medical Devices and Procurement Review Group will utilise finance advice to identify and plan a priority replacement programme and to identify efficiency savings through effective purchasing.

4. Membership
4.1 Members

Director responsible for Health and safety (Chair)
Director responsible for Finance
One representative from each clinical division with authority to make decisions
Head of Patient Safety
Learning and Development representative
Infection Control representative
Health and safety Manager
Head of Procurement
Clinical Engineering representative
Associated Director of Estates and Facilities

Other representatives as necessary, this membership will be monitored by Medical Devices and Procurement Review Group and amended as appropriate to take into account changes to the Trust.

4.2 Members who cannot attend a meeting shall nominate a deputy to attend in their place, who is appropriately briefed and able to attend meetings on their behalf.

5. Quorum
5.1 A quorum for the Medical Devices and Procurement Review Group will be 6 members, no business shall be transacted at the meeting unless four of the following are present;

- Director with responsibility for Health & Safety (Chair) or Designated deputy Chair
- Head of Patient Safety
- Health and Safety Manager or deputy
- Two representative from clinical divisions with authority to take decisions

6. Administration and Meetings
6.1 The Medical Devices and Procurement Review Group will meet on a Bi monthly basis.

6.2 The Health and safety manager is responsible for arranging the Secretariat to the Medical Devices and Procurement Review Group and dissemination of the minutes to members, and other groups determined by the Chair.

6.4 Where appropriate the Medical Devices and Procurement Review Group will convene if an extraordinary meeting if called by the Chair.

6.5 Members of the Medical Devices and Procurement Review Group who cannot attend a meeting shall nominate a deputy to attend in their place, who is appropriately briefed and able to attend meetings on their behalf.

7. Reporting
7.1 The Committee will provide assurance to the Health and safety sub-committee in the form of minutes and reports where required,

8. Review
8.1 These Terms of Reference shall be reviewed by the Medical Devices and Procurement Review Group Committee on a Tri annual basis, where they are believed to be no longer valid or there is a significant change in the matter to which they relate, whichever is the sooner.