Purpose of this document
This document details the Trust’s policy and procedure for the management of medical devices. This policy applies to all individuals who handle medical devices in connection with patients whose clinical care is the Trust’s responsibility, whether on or off Trust premises. The purpose of this document is to ensure appropriate management of medical devices which will cover:

- Selection, acquisition, acceptance / commissioning and disposal of all medical devices.
- Decontamination, maintenance, repair, monitoring, traceability, record keeping and replacement of all reusable medical devices.

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1. Introduction.

The Trust recognises and accepts its responsibility to ensure the safe and effective use of medical devices, compliance with the Health and Safety at Work etc. Act 1974, Electricity at Work Regulations 1989 and Care Quality Commission registration: Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 for medical device management. Guidance is based upon Medicines and Healthcare products Regulatory Agency “Managing Medical Devices April 2015” and National Audit Office HC475 “The Management of Medical Equipment in NHS Acute Trusts in England”.

The efficient and effective management of medical equipment, across the Trust, will help to minimise risks associated with the use of medical devices.

A medical device is defined as:

- An instrument.
- Apparatus.
- Appliance.
- Material or
- Other article, such as software including apps and InVitro Diagnostic Medical Devices (IVDMD).

whether used alone or in combination, together with any software necessary for its proper application, which is intended by the manufacturer to be used for the purposes of:

- Diagnosis, monitoring, treatment, alleviation or prevention of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or physical impairment.
- Investigation, replacement or modification of the anatomy or of a physiological process.
- Control of contraception.

The Trust will promote the safe management of medical devices by ensuring that whenever a medical device is used, it is:

- Suitable for its intended use.
- Installed and commissioned to ensure systems are safe.
- Used in accordance with the manufacturer’s instructions.
- Maintained in a safe and reliable condition.
- Disposed of appropriately at the end of its useful life.
- Complies with GDPR (General Data Protection Regulations), information security policy PP(060).

Training is a key element in medical device safety. Healthcare professionals working for the Trust, as employees or contractors, have a professional duty to ensure their own skills and
training are appropriate and remain up to date. Further details can be found in the Diagnostic & Therapeutic Equipment Training policy PP(206).

This document details the Trust's policy for the management of clinically associated equipment, to:

- Enable compliance with statutory obligations.
- Maximise the benefits and minimise any associated risks.

2. Roles and responsibilities.

2.1 Trust Board:

Through Health and safety responsibilities, the Trust has a duty of care to its employees to ensure that any person operating equipment has sufficient understanding of its use to do so in a safe and effective manner.

2.2 Chief Executive:

The Chief Executive has overall responsibility for the safe use of medical devices within the Trust and the Director of Operations is the executive lead for medical devices. Day to day accountability is through the Executive Directors, Associate Directors of Operations (ADO’s), Service Managers / Line Managers.

2.3 ADOs:

ADOs are responsible for ensuring that this policy is implemented in their Division. In particular they will:

- Manage any major cost or resource issue.
- Manage any concerns, which arise from line managers in relation to the implementation of this policy.
- Manage all medical device related issues.

2.4 ADO’s ↔ Senior Operations Managers (SOMs), Service Managers, Senior Matrons, Ward Managers and Departmental Managers:

- Ensuring compliance with this policy throughout their areas of responsibility.
- Ensuring that medical devices are introduced into service areas in accordance with Trust policy for selection, training and commissioning of equipment.
- Ensuring that appropriate staff is appointed within their specific management area to act as medical devices coordinators.
- Ensuring training is provided to ensure that all staff are competent to undertake the duties required as outlined in the Diagnostic & Therapeutic Equipment Training policy (PP206).
- The reporting and investigation of all accidents, dangerous incidents and near misses associated with the use of medical devices within their areas of responsibility to the Medical Device Safety Officer (MDSO) and Health and Safety and Risk Manager.
• Ensuring all staff are aware and have access to this policy.

2.5 All Employees:

All Employees have a responsibility to undertake training and be assessed as competent before using a piece of equipment without supervision and adhere to agreed policies and procedures in using equipment. To raise any concerns about personal competency and request refresher training if required.

• Only handling medical devices that they need to perform their role and for which they have received the appropriate training and are deemed competent to do so. This will be instigated, measured and monitored by ward/department managers, key appointed training officers and through manufacturers training regimes.

• Keeping up to date with their training requirements in respect of medical devices.

• Appropriate reporting of adverse incidents, using Datix (see Incident policy and procedure PP105 and 105b).

• Ensuring that the medical device is the correct device and is fit for use, and acting accordingly when issues have been identified by contacting line manager, Electro Bio-Medical Engineering (EBME), or Point of Care Testing (POCT), as appropriate. (check the equipment labels to see if it is within its test due date).

• Cleaning/decontamination of devices after use and upon return to the Medical Equipment Library, Pressure Mattress Store or EBME for repair/service, in line with the current trusts infection control policy PP204.

• Ensuring that an asset number is attached to the equipment. If one does not exist, the equipment may have not been through formal acceptance testing when brought into the Trust. So the equipment should:

  1) not be used
  2) be withdrawn from service
  3) be sent to EBME for checking and registration.

Note: It is important to have all medical devices registered onto a central database (EBME) this aids the MDSO in identifying medical devices that have safety notifications or recalls out on them.

2.6 Clinical Equipment Replacement Panel (CERP)

Responsible for ensuring risks associated with the procurement and use of medical devices are managed in accordance with this policy and local procedures. Reporting of compliance monitoring will be made to the Capital Strategy Group.

• Developing a rolling capital replacement programme and advising the Capital Strategy Group on all aspects of medical device management.

• Identifying resource requirements and costs or device replacement and development.
• Ensure medical device procurement as per policy and prioritisation of medical equipment replacement/development.

To fulfill its remit, the Clinical Equipment Replacement Panel has a broad range of membership that includes appropriate representation from among

• Clinical
• Management
• Radiology
• Purchasing
• Health, Safety and Risk Management
• Estates & Facilities
• EBME
• Community
• Nursing (Matrons)
• Finance
• IT

2.7 EBME – Department of Electro Bio-Medical Engineering

Some of the key services to support medical devices (not exhaustive):

• Maintaining an inventory (medical devices asset register) of medical devices used within the Trust, this should include all areas under the remit of the trust.

• Supporting end-users on device selection (standardising wherever possible) and aiding the acquisition through review of the Pre-Acquisition Questionnaire (PAQ) and evaluations of new devices.

• Ensuring acceptance testing of medical devices to appropriate & recognised standards;

• and supporting commissioning by the supplier to ensure equipment is fit for use.

• EBME supports devices through planned maintenance, repair and turnaround devices in a timely manner, ensuring uptime on equipment.

• Ensure that medical devices are decommissioned to ensure that the device is safe and unusable, while minimising damage to the environment.

• Establishing and maintaining a technical library of manufacturers' instructions for all medical devices used within the Trust.
• Maximising opportunities to secure technical training programmes from companies as part of the procurement process.

• Operating and maintaining the Medical Equipment Library service.

3. Procurement of Medical Equipment.

Aim.

The Trust's procurement procedure will ensure that:

   a) Equipment used on the Trust's behalf complies with the recommended standards particularly those relating to safety.
   b) Safe guards are in place to prevent unauthorised downloading, uploading or modification of data in PC controlled medical equipment/systems.
   c) Users are aware of the technical and revenue implications of their choice of equipment.
   d) A standardisation of common types of equipment is achieved in order to lessen possible confusion of operation and to facilitate ease of training and equipment availability.
   e) To keep maintenance and revenue cost to a minimum.
   f) Ensure that decontamination requirements are evaluated.
   g) All medical equipment used on Trust premises or on the Trusts behalf is registered with EBME.
   h) All equipment, whether from capital, managed service, lease, charitable funding, over/under £5K (inc VAT) will need to be identified and accounted for.

3.1 Business Case Planning

A service identification and requirement for medical device(s) must be established before proceeding through to the business plan. This needs to be sponsored by the divisional management team.

The following criteria will need to be taken into account:

   a) Do devices already exist within the unit, ward or department?
   b) Does a clinical evaluation need to take place, PP228, (section 3.2)?
   c) Has this case been justified/risk assessed?
   d) Does the device appear on the list of Trust approved devices? (held by Purchasing/EBME)
   e) Does the device meet the safety requirements for its type?
   f) If software driven, does it have a password-protected operating systems or safety lock out? For equipment that can transfer data or digital media consult with Trust Information Governance Manager and IT Quality/Cyber security Manager.
   g) has the device the capabilities of connecting to the trust’s patient information system (i.e. eCare)
   h) Has the case identified where the funding will be coming from (classed as a capital asset if the total exceeds >£5K inc VAT, smaller items can be funded out of ward or departments own budget or charitable funds).

3.2 Equipment Evaluation.

It is essential that medical equipment is evaluated from a range of suppliers before finalising a Business plan for approval.
Evaluation must be arranged in conjunction with the EBME department. Evaluation of Point of Care Testing Equipment must also involve POCT Team. Evaluation of Radiology equipment should also involve the Radiology Technician.

EBME will guide you through the process, which is to:

• Obtain suppliers Indemnity agreement number or certificate (purchasing dept. or EBME will assist)
• Equipment for trial must be logged onto the Trusts equipment register through EBME and be electrically and functionally tested prior to evaluation.
  • Training and support should be obtained by supplier at all times
  • Any facilities / environment and or IT support should be also considered with decontamination and consumables required

On acceptance the equipment will be given a unique reference number which will also be used on the Equipment Evaluation Form (Appendix B).

The number will be of the format:-

E year . sequential number - i.e. E05009
E      Equipment evaluation
05     Year 2005
09     Ninth item of equipment evaluated so far

The EBME / Estates / X-Ray department/ Pathology department can advise on models approved by the Trust.

3.3 Equipment selection.

Choosing new equipment/replacement can be difficult with the wide selections of equipment available on the market today.

A number of factors need to be taken into account before making a final decision: -

a) The user’s requirements/specification (Clinical needs)
b) Performance and patient quality benefits
c) Safety and compliance with standards and information updates
d) Electro Magnetic Compatibility and integration to IT systems
e) Equipment Standardisation
f) Point of care testing policy PP 167
g) Maintenance costs, life expectancy
h) Spare parts availability and cost
i) Training and competency assessments
j) Cleaning and decontamination
k) Consumable costs
l) Interaction with other devices (if applicable) and the IT infrastructure and their requirements
m) cost of equipment and source of funding e.g., revenue capital leasing or charitable

Note: If the equipment produces a typical pathology result e.g. blood gas analysis, blood glucose, urine analysis etc. It is essential to contact the POCT Team to ensure they can provide support. For example:

- Suitability of testing
- Result verification
- Training
- External quality assessment (EQA)
Note2: It is recommended that individuals approach the purchasing department and EBME as soon as possible to assist with this process.

3.4 Business Plan.

It will be necessary to prepare a Business Plan for consideration at Managerial level. The detail of the plan will depend upon the proposed clinical procedure, complexity of the device and its cost to procure and maintain through its life.

It will be necessary when drawing up such a plan to include the following points:

a) Clinical requirements.
   • Does the device augment existing clinical practises? If so how?
   • Does it introduce new procedures and techniques? If so are they approved, safe and are there cost implications?

b) Installation.
   • Does the device require services not already available, i.e. water, electricity, waste removal, IT systems etc.?
   • Are further safety measures required? E.g. PPE, additional signage, etc.

c) Staffing.
   • Are additional staff required to operate or carry out this service?
   • Is additional staff training required? How frequently, who will provide it and where will it be documented?

d) Consumables.
   • Does the device use consumables?
   • Are they special or are they readily available from secondary sources?
   • What is the annual consumable cost?

e) Cleaning and decontamination.
   • Can the equipment be easily cleaned and decontaminated in accordance to the Trust’s decontamination policy? Policy for Reprocessing and Sterilisation of Reusable Medical Devices: PP204.
   • Are additional decontamination facilities required?
   • Who will be responsible for cleaning and decontamination (daily, between patients and prior to maintenance or servicing)?
   • What training is required for those responsible for cleaning and decontamination?

f) Maintenance.
   • How do you intend the device to be maintained? (In-house or service contract)
   • What level of cover do you require, including response time in the event of a breakdown.
   • Are spare parts readily available? (in EBME or in the UK?)
   • If you intend to have the device maintained "In-house" have you spoken to the EBME Manager to see In-house resources are available?
   • Does the device require calibrating at regular intervals and is special equipment required for this function? Will this be done by EBME, manufacturer or the company supplying the equipment?

g) Service manual.
   • Is a full service manual available, complete with circuit diagrams and set up procedures, to allow EBME staff to repair and maintain the equipment in the event of the supplier going into liquidation?
   • Such service manuals will need to be included in the purchase.
   • Provision must also be made for manufacturers technical updates to be sent to
the EBME department this to be included in the purchase specification.

h) Training.
   • Operating and maintenance training courses need to be included in the purchase.

After completion of business plan- it must be approved by your divisional manager.

It is at this point when the detail relating to the issues of clinical requirements, revenue costs (in particular maintenance) training and the Equipment Evaluation Forms should be discussed.

Once the plan is finalised it will be passed to the Clinical Equipment Replacement Panel to be considered alongside the completed Medical Equipment Proposal for Purchase bid form, risk assessment and quotes. Paperwork can be found in appendix C.

Note: If the device is a POCT device, a POCT application must be completed and submitted to the POCT Committee for approval before a full business case is undertaken.

3.5 Request Process for new or replacement, medical equipment (<£5K).

• Follow the flow chart in Appendix D.
• Complete Medical Equipment Proposal for Purchase bid form Appendix C
• Submit a completed risk assessment and attach to the bid.
• Submit to the Clinical Equipment Replacement Panel via the EBME Manager, who will issue a unique bid number.
• If approved the originator of the purchase/bid form will be notified and the purchase will be made.
• Pre-acquisition questionnaire (Appendix A), obtained by Purchasing Department from supplier.
• Mark requisition "requires EBME checks".
• Equipment ordered, subject to receipt of acceptable Pre-Acquisition Questionnaire via the Purchasing department.

3.6 Request Process for new or replacement, of all Medical Equipment (>£5K).

As per 3.5 plus:

The Panel will consider all medical equipment bids for funding and prioritise submitted business plans based on risk to the Trust within the financial resources available. Bids that are approved and require funding >£5K will be presented to the Capital Strategy Group. Those items not approved for purchase with a risk rating of Red will be referred to the Trust Executive Group (TEG).

Note: both 3.5 and 3.6, will need to go through this process, considering all methods of funding.

3.7 EBME Manager.

The EBME Manager will call upon a number of facilities available to enable the Trust to benefit from value for money and service. Checks will be made to verify that the equipment is supportable and that break down and maintenance cover is available.

The manufacturer or supplier will be required to state in writing that the equipment complies with the relevant safety requirements. (This is normally on Pre-Acquisition Questionnaire form, Appendix A).

Full use can be made of the services offered by EBME, Estates, Purchasing and other departments to meet these requirements.
3.8 Leasing, Gifts, Donations and Hiring.

Equipment leased, donated, hired or presented as a gift must still meet the requirements of the general conditions for medical equipment. It must undergo Acceptance Testing and be logged on to the Trust’s Equipment Register, be maintained and/or calibrated to the manufacturer’s specification.

3.9 Equipment training.

Department managers must ensure they are in receipt of the equipment user manual when accepting the equipment. They should ensure that all users of the equipment receive appropriate training, preferably by the manufacturer, on equipment before it is put into use. This should include training on emergency procedures, cleaning, decontamination and any PPE provision. Provision should also be made for documentation of such courses to be recorded.

For POCT devices training and competency assessment will be organised and/or provided by the POCT Team. Users will then be given barcode access to the device, if applicable. Only users who have in date training and competency should use the device.

3.10 Service Manual updates.

The EBME department will file manufacturer’s technical update information in the appropriate service manual held in the EBME department’s service manual library, and should make every effort to make this information available electronically (usually through the trust’s intranet).

Footnote:

Some confusion arises over what is Electro-medical equipment. In this policy document it is intended to cover the following:-

Electrically operated equipment, including battery operated, for the treatment, diagnosing and the monitoring of patients. It also includes dental and podiatry equipment, i.e. drills etc., and laboratory equipment, general and specialised beds, pressure-relieving mattresses, operating tables etc.

Medical equipment includes gas regulators, flow meters, wall suction units and gas operated equipment and follows the same purchasing procedure.

4. Operation and Maintenance.

It is the departmental manager's responsibility to ensure that all equipment is maintained and tested for electrical safety on a regular basis. The EBME Manager will lend assistance in either providing this service by the “In house” team or by a service contractor.

Every practicable effort must be made to make this equipment available for service, it is the equipment owner’s responsibility to ensure all checks regarding the status of service is good before use. (checking tested labels are in date).

4.1 Acceptance checking.

On delivery new equipment is acceptance checked by the EBME department to the guidelines laid down by the MHRA’s “Managing Medical Devices April 2015”. Providing the equipment passes the specified test criteria, and the manufacturer’s performance test, the equipment is accepted and logged onto the Trust's equipment register (EBME database).
Sometimes the supplier or Original Equipment Manufacturer (OEM) will be required to commission this equipment. The I.T. Department may also be required to support the commissioning of new equipment. Similarly, the POCT Team may be required to perform additional testing e.g. result verification and device set up, before it can be put into use.

Any financial information relating to this equipment should be recorded alongside the equipment registration number, date and technician’s initials.

Note:
No equipment should be used in the Trust without following this process. It is the end user who should ensure that an asset number is attached to the equipment. If one does not exist, the equipment should not be used and should be withdrawn from service and sent to EBME.

4.2 Equipment register (EBME).

The EBME department operates a computerised equipment register for all medical devices. Each item of equipment is given a sequential unique registration number, called the Hospital Registration Number and is designated the format below,

This allows the register system to store information such as location, owner, purchasing details, maintenance schedules, breakdown records and general equipment history. Maintaining this database is the responsibility of the EBME department who continue to update the information on a regular basis.
Information contained on this database is readily available to managers and equipment inventories; etc. can be obtained by contacting the EBME manager.

4.3 Equipment maintenance.

A formal system is essential to ensure that the equipment functions safely and accurately throughout its life. Such a system will provide for :-

• Day to day maintenance by the user, including cleaning/decontamination.
• Performance / preventative maintenance.
• Breakdown maintenance.

a) Day to day maintenance.
The user will carry this out on a routine basis in accordance with the training or instructions given by the manufacturer or supplier in the user manual.

b) Performance / preventative maintenance.

This may be achieved by:-
1. Service Contractor.
2. EBME department.

1) Service contractor.
If requested by the department manager or the EBME manager does not have the resources to maintain the equipment "In house", a service contract will be raised, with the agreement of the Department manager, for the equipment to be serviced.
In consultation with the Department manager the EBME manager will agree:

- Type of contract required, i.e. comprehensive, preventative etc.
- Contractor.
- Number of visits required.

The EBME manager will agree to:-

- Raise the contract.
- Monitor the contract.
- Enter job details onto the computerised record system.
- Authorise payment.
- File copies of the service report.

The Department manager will agree to:

- Liaise with the contractor to make the equipment available for servicing.
- Supply the EBME manager with a copy of the service report to enable him to keep records.

2) EBME department.

All equipment not covered by service contract and logged onto the equipment register will be maintained by the EBME department in accordance with the manufacturer’s instructions. Electrically powered equipment will be inspected to cover the Trust under the Electricity at Work Regulations 1989. Maintenance schedules are produced by a computerised maintenance system, should managers require a copy of the schedule for their area(s) of responsibility this is available from the EBME manager.

This service is provided on the following conditions:-

- Life support and other critical equipment will be given priority.
- Equipment breakdown has over riding preference over maintenance.
- Equipment is made available for service (users responsibility).
- EBME manager has sufficient staff available.

c) Breakdown maintenance.

Breakdown maintenance will receive preference over other maintenance; priority will be given to areas of acute care and clinics with waiting patients.

4.4 Reporting Breakdowns.

Please telephone the EBME workshop

**All repairs call extension 2867**

**Medic Bleep: EBME Repairs**

[http://equip/joblogging](http://equip/joblogging) (direct job reporting into EBME database)

Out-of-hours - reporting faults & breakdowns:

Call ext. 2867 (answer phone) or use EBME Mailbox (ebme@wsh.nhs.uk).

- Make a note of any ‘Fault code’ displayed on the machine.
- Remove equipment from use and clearly label “Out of Order” (include the fault code if you have one).
- Clean in accordance with the Manufacturer instructions and Trust Policies for Reprocessing and Sterilisation of Reusable Medical Devices: PP204 and Cleaning and Disinfection Clinical Equipment and Environment (Infection Control Manual) GC10022-4 and the control of Substances Hazardous to Health (COSHH) PP39.
• Report the fault to the EBME Department on above contact list as soon as possible.

The following information will be required:

- Equipment’s Registration number (EBME Asset, example on Pg 11)
- Name of Person reporting fault
- Location – Ward/Department
- Fault description (include fault code if one displayed)

• DO NOT CONTINUE TO USE DEFECTIVE EQUIPMENT. Remove from use.
• Do not attempt to repair equipment yourself

Please ensure the equipment is clean and decontaminated and has a signed completed yellow decontamination tag.
(Please see Manufacturer instructions and Trust Policies for Reprocessing and Sterilisation of Reusable Medical Devices: PP204 and Cleaning and Disinfection Clinical Equipment and Environment (Infection Control Manual) GC10022-4 and the control of Substances Hazardous to Health (COSH) PP39; a technician may refuse to repair an item of equipment unless this criteria is met).

To ensure continuation of patient treatment, it is often easiest to substitute a similar device from the Medical Equipment Library or a loan device from the external contractor, although this is not always possible for some items. Alternative arrangements may be required to cover emergencies out of normal working hours.

4.5 Equipment returns after service or repair.

Equipment will usually be returned to the department to which it is registered, if the equipment has been loaned from another department and you wish it be returned to you, you must tell the technician.

The equipment will usually be returned with a TESTED label on. This is part of the EBME department’s quality management system, it notifies the user that the equipment has been repaired/serviced and that functional/configurational user checks will be required before use.

4.6 Cost.

The maintenance budget held by EBME is for the maintenance and repair of medical devices registered on the department’s asset database. Medical devices or accessories used with medical devices that are damaged due to undue care/attention or are discarded or missing are funded by the owning ward/department budget.

4.7 Loan equipment.

Loan equipment has two categories, they are:

a) Equipment borrowed from the Medical Equipment Library for a ward’s or department’s use (Section 5).
b) Equipment loaned to other users, including Community use (Section 6).

The EBME Department will charge the ward loaning the equipment for lost or missing items.

5. Medical Equipment Library.
5.1 Introduction.

A Medical Equipment Library is a central store where high cost medical equipment can be stored and maintained. An inventory is maintained and information is available as to whether equipment is in use and in the stated location.

Equipment available from the library:
- Infusion devices (T34 syringe drivers, Perfusor and Infusomat)
- Pulse Oximeters
- Nebulizer compressors
- NIBP monitors
- Humidifiers
- Feed pumps
- Portable suction units

To access Equipment User Manuals go to INTRANET – TRUST INFO – EBME – MEDICAL EQUIPMENT USER MANUALS.

5.2 How to access the library.

Monday to Friday 8.00 am – 7.00 pm contact the Medical Equipment Library for your equipment needs on: Extension 3222 or Medic Bleep – Medical Equipment Library

For out of hours/weekend access to equipment is via the Portering Supervisor on Ext. 3522 or Bleep 959.

When requesting equipment the following information is required:
- The type of equipment needed and that you are familiar and competent to use this device. (the act of requesting a medical device from the MEL, implies that the user is competent in the use of the bespoke device).
- ward or department
- contact name (requisition’s name)

The person issuing the equipment will ensure that all the above information is logged onto the EBME database.

5.3 Return of equipment.

All equipment must be returned via the Medical Equipment Library once it is no longer needed. It must not be passed on to another patient. A separate request must be made for equipment required for other patients. The Medical Equipment Library staff will log the return of the equipment, place it on charge where appropriate and physically check it for damage before it is re-issued. Before returning the equipment to the library it must be cleaned/decontaminated in accordance with the Trust guidelines. Decontamination labels must be completed, signed and attached to the equipment.

To return equipment to the Medical Equipment Library:

Contact Extension 3222 or Medic Bleep Medical Equipment Library

- Clean Equipment.
- Inform the Medical Equipment Library staff, who will collect equipment items from wards when no longer required.
For Out of Hours the equipment should be stored in a safe place on the ward/department to await collection on the next working day by the Medical Equipment Library staff.

5.4 Medical Equipment Cleaning Guidelines:

Clean in accordance with the Manufacturer instructions and Trust Policies for Reprocessing and Sterilisation of Reusable Medical Devices PP204 and Cleaning and Disinfection Clinical Equipment and Environment (Infection Control Manual) GC10022-4 and the control of Substances Hazardous to Health (COSHH) PP39.

5.5 If the equipment is contaminated with blood or body fluids:

a. Clean as above using a disposable paper towel to remove organic material.
b. Disinfect as per the Trust infection control manual available on the intranet and following the COSHH risk assessment (wearing appropriate PPE, ensuring adequate ventilation, etc.).
c. Repeat the above cleaning procedure to avoid residual disinfectant damaging the equipment. Do not immerse in water.
d. Dry thoroughly.
e. Dispose of gloves, aprons, and paper towels into clinical waste bag.
f. Wash hands thoroughly.
g. If you have any doubts about this procedure, contact the Infection Prevention Team.

5.6 What to do if equipment is faulty:

a. Make a note of any ‘Fault code’ displayed on the machine.
b. Remove equipment from use and clearly label “Out of Order” (include the fault code if you have one).
c. Clean in accordance with the guidelines 5.4 and 5.5 above.
d. Report the fault to the EBME Department on the contact information supplied in section 4.4 (page 12) as soon as possible.

The following information will be required:

- Equipment’s Registration number (Asset Number)
- Fault description (error code if one was displayed)
- Location
- Contact name

• DO NOT CONTINUE TO USE DEFECTIVE EQUIPMENT. Return the equipment to the library. A replacement will be issued.

Do not attempt to repair equipment yourself.

6. Equipment loaned to other users.

Managers of all wards and departments within the hospital are responsible for ensuring that all equipment allocated to the area of their responsibility is fully maintained and fit for use. They are also responsible for ensuring that all staff, patients, and carers required to use or operate this equipment are trained in its use, care and maintenance. Equipment should not be loaned unless it is fit for use, regularly maintained and that the manager concerned is confident that those using it are trained to do so.

6.1 External loans.

When a piece of equipment is loaned out (which is from the Medical Equipment Library) it
is the responsibility of the Ward Sister/Charge Nurse or the Department Head to check over the equipment with the borrower and to ensure that they have been trained, are competent to use the equipment and are aware of the maintenance/care requirements whilst in their possession. A record must be kept by the ward/department loaning the equipment and the borrower must sign this record that he/she takes the responsibility for the equipment whilst on loan.

The Ward Sister/Charge nurse or Departmental Head is responsible for ensuring that the equipment is recalled for routine maintenance/servicing whilst out on loan.

A loan form (Appendix E) must be raised in triplicate whenever equipment provided by the Medical Equipment Library is removed from the hospital to the community for Patient Support.

a. One copy to Community.
b. One copy to Medical Equipment Library
c. One copy for Ward Managers Records.

All equipment loaned from the Medical Equipment Library is loaned to a Ward. The cost of replacing items lost to the community (CCG, care homes etc) may be recovered from the Ward concerned where the correct procedures have not been followed or device is missing.

6.2 External loans carers/patients.

Equipment is loaned to patients/carers on discharge from hospital as part of their on-going care needs or as part of their outpatient treatment. Equipment is normally provided to the individual and not to the home or environment where they live.

When a patient is discharged into the care of the Community the Liaison Team will ensure that all details of outgoing treatment and associated equipment required is passed on to the Community Care Team. Arrangements will then be made with the Community Equipment Store to make this equipment available for loan to the patient.

Suffolk Health have a policy for eligibility criteria for the loan of specialist equipment which includes a matrix of responsibility and outlines the responsibilities of different Agencies and providers. This includes all equipment except for the very standard issue.

Certain specialist equipment is provided by the specialist ward/department responsible for prescribing the on-going treatment.

This currently affects mainly Ward F1, SCBU and Outpatients and involves equipment such as Enuresis Alarms, MR10 Apnoea Alarms, Nebulizer Compressors, Blood Glucose meters, Infusion Devices, Syringe Drivers and Oxygen Saturation Monitors.

6.3 Loan Procedure for Patients/Carers and outside Agencies/Hospitals.

Accurate records of any loans to outside agencies/patients/carers are essential, these must include and fall within the GDPR requirements:-

- Contactable people and telephone numbers, ensuring that staff can obtain the whereabouts of equipment

- Details of carer/agency taking responsibility for the equipment on the patient's behalf to include all necessary and permissible contact details, telephone number, emails and addresses.

- An indemnity/loan form must be signed by the patient or carer/agency taking responsibility for the equipment, following instruction from the person in charge of the ward/department. Instruction should include how to use the equipment, care and maintenance, availability of disposable supplies essential to the equipment.
The borrower must also agree to return the equipment to the ward/department for maintenance or exchange when requested. The manager concerned is responsible for ensuring that the person the equipment is loaned to is capable of taking responsibility for this equipment.

6.4 Other loans

It may be necessary for other loans in/out of the trust, on special occasions of as part of business continuity planning. These situations must be considered at a senior management level (ADO) and be treated on each individual case. Risk and patient care should also be considered and documented.

7. Condemning Equipment.

7.1 Reasons for condemning equipment.

Equipment type, operation systems and life expectancy vary widely across the whole spectrum of medical equipment. Life expectancy can be as low as 5 years for software driven systems to 15 years plus for solid made devices with simple control circuits. Each item of equipment must be taken on merit.

Reasons for condemning equipment fall into the following categories:

- Obsolete
- Clinically unsafe
- Electrically unsafe
- Mechanically unsafe
- Beyond economic repair
- Spare parts or support (including software) unavailable
- Withdraw from use instruction on a Medical Device Alert issued by the MHRA
- Unreliable operation
- Contaminated internally with body fluids or other obnoxious substances

Equipment condemned and disposed of can have an actual value of £0.00 but have a book write off value of thousands of pounds on the asset register. EBME Department will notify finance when equipment is condemned to ensure it is removed from the asset register.

7.2 Condemning procedure.

When a decision has been made that an item of equipment has reached the end of its working life, the relevant Department manager and the EBME manager will jointly complete a Condemning and Disposal Form for Medical Equipment (Appendix F). The EBME manager shall complete part 1 and the Department manager part 2.

A decision will also be made in part 1 as to the safest and most cost effective means of disposal.

On disposal of the equipment the EBME manager shall remove the equipment from the department inventory, cancel the maintenance schedule and any outstanding service contract.

If the equipment is contaminated, where safe to do so, it will be first autoclaved before disposal after seeking advice from the Microbiology department.
Waste Electrical and Electronic Equipment will be disposed of as per WEEE Directive – (2002/96/EC), see Waste Management Policy PP179.

8. Incident Reporting.

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive of the Department of Health. Their role is to take all reasonable steps to help safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union. One way in which they do this is by investigating reports of adverse incidents involving medical devices.

An adverse incident involving a device should be reported to the MHRA if the incident had lead to, or were it to occur again could lead to: -

- a death
- life/threatening illness or injury
- deterioration in health
- temporary or permanent impairment of a body function or damage to a body structure
- the necessity for medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure;
- un-reliable test results leading to inappropriate diagnosis or therapy

Report all adverse events relating to a device including: user problems with a device, software failures or problems with the instructions for use.

8.1 Procedure to be followed if a fault is found with a Medical Device.

a. If a member of staff identifies a problem with a medical device their Manager/Supervisor should be informed immediately, who will in turn inform the Governance Department, via the Datix Incident Reporting System (refer to Incident reporting and management procedure PP105 and 105b).

b. The equipment must be taken out of action and quarantined, as an independent investigation may be required, under no circumstances should the medical device be returned to the manufacturer without prior consultation with the Medical Device Safety Officer and Health, Safety and Risk Manager. Details of settings, dose rates or other volatile data must be recorded.

c. A red INCIDENT REPORT label must be completed and attached to the equipment with Datix incident report number filled in.

d. The EBME Department must be contacted and given the following details: -
   - Hospital Registration (Asset number/equipment serial number)
   - Model number/type of equipment
   - Location of the equipment
   - Datix Incident report number (if completed)
   - Name of person reporting the incident
   - Contact details of person reporting the incident

Where the results of investigations have implications for patients or users, the MHRA issues a Device Alert advising of hazardous products or unsafe procedures. The Central Alerting System (CAS) now distributes all alerts to all NHS Trusts.
CAS provides a consistent mechanism for the dissemination of alerts and reporting by the recipient of action planned and implemented. In the first instance, alerts from the following agencies will be included in the system:

- Medicines and Healthcare products Regulatory Agency (Medical Device Alerts only)
- NHS Estates
- NHS Commissioning Board Special Health Authority
- Patient safety specific guidance from the Department of Health

These alerts are sent by email to an email address within the Trust setup for this purpose (SABS Recipients). The CAS Liaison Officer receives these emails and takes action to disseminate and respond to the alert.

8.2 Distribution of Medical Device Alerts.

a. The CAS Liaison Officer receive all MDA alerts.

b. The CAS Liaison Officer will identify the lead person(s) for the MDA alert.

   For Medical Device Alerts the leads are as follows,
   
   - Medical equipment – Medical Device Safety Officer (EBME Manager)
   - Non-Medical Equipment – Estates Manager
   - Instruments – Sterile Services Manager who will liaise with theatres, endoscopy, urology and day surgery as appropriate.
   - Consumables – Purchasing Manager who will liaise with affected areas.

c. The CAS Liaison Officer will email the MDA alert to the relevant lead person(s) for action where appropriate.

d. The email will highlight the importance of the relevant alert, e.g.
   - Immediate action
   - Action
   - Update
   - Information request

e. The lead identified for the alert will assess its relevance to the Trust and based on this assessment informs the CAS Liaison Officer what (if any) action is required and report progress with action on an on-going basis.

f. The CAS Liaison Officer will monitor the deadlines stipulated by the MDA alert. Upon completion the CAS Liaison Officer will update the CAS website accordingly with an appropriate response.

g. All types of alerts will be reported to the appropriate Board Sub-Committee for monitoring purposes both in terms of receipt and appropriate action taken.

h. A CAS alert report submitted quarterly to the Corporate Risk Committee.
9. Decontamination of Medical Equipment.

9.1 Trust Responsibilities.

• The West Suffolk NHS Foundation Trust is required to comply with the Department of Health’s Guidance to ensure the development of safe systems of work for all healthcare equipment which comes into contact with patients or their bodily fluids.
• Appointment of a senior member of staff to have responsibility for managing all aspects of decontamination (See Policy for Decontamination of Reusable Medical Devices PP204 and Cleaning and Disinfection Clinical Equipment and Environment GC10022).
• All healthcare staff and users of equipment must be fully conversant with the usage and decontamination requirements of all equipment in their department.
• All healthcare staff must maintain adequate records to demonstrate how a particular device is processed.
• Managers and purchasing departments have a responsibility to select equipment, which can be suitability decontaminated.
• To follow the manufacturer instructions and COSHH guidance on cleaning, disinfection and/or sterilisation.

Equipment is divided into three categories:

A) Single use disposable - marked by manufacturers and never reprocessed (Appendix G).
B) Single patient use - for the use of a named patient.
C) Reusable - subject to the process of cleaning, disinfection or sterilisation.

9.2 Cleaning.

“The process to remove contaminants including dust, soil, large numbers of micro-organisms and organic matter.”

CLEANING IS AN ESSENTIAL PRE REQUISITE TO DISINFECTION AND STERILISATION

It is also a method of decontamination for non-invasive (low risk) items.

The use of mechanical cleaners such as washer disinfectors and ultrasonic tanks are preferred to manual cleaning of items. The cleaning method should be assessed to ensure the effectiveness of the process without damage to equipment. Mechanical cleaners require regular planned preventative maintenance and a logbook must be maintained for each machine.

9.3 Manual cleaning of medical equipment.

a. This should be carried out in a clean well-ventilated area away from others to prevent possible contamination.
b. Most medical equipment is NOT suitable to be immersed in water or cleaning solutions. Please refer to Manufacturers Cleaning instructions within the User manual and relevant COSHH assessment.

Electrical equipment must be disconnected from mains supply, and all efforts made to ensure that detergent solution does not enter electrical components. Surfaces should always be dried after cleaning.

9.4 Decontamination of equipment prior to service/repair.
a. As per COSHH assessment wear disposable gloves and plastic apron and eye protection if splashing is likely to occur.

b. Clean all external surfaces with detergent, water and dry. If the surfaces are splashed with blood, follow spillages of blood or body fluid procedure (in the infection control manual in the Pink book on the intranet).

c. When cleaning is complete attach decontamination label to equipment. Place in a plastic bag, secure the top and send to the EBME department. In particular situations where the condition of the item is the subject of complaint or investigation and may be altered or influenced by a decontamination process the investigator may wish the item not to be decontaminated. In such situations the equipment should be quarantined and the advice of the investigating body should be sought via the EBME Department.

Trust incident-reporting must be completed promptly for any incidents involving medical equipment (see sections 3.4, 4.6 and 7.0 of this policy for further guidance).

9.5 Disinfection.

Disinfection: A process to reduce the numbers of micro-organisms but not usually bacterial spores.

a. All disinfectants must be assessed under COSHH using Sypol in respect of irritancy to skin eyes and respiratory tract and approved for use by Occupational health and the Infection Prevention team.

b. Liquid chemical disinfectants may be supplied ready to use, or may require mixing with an activator. PPE must be worn if required by the COSHH assessment.

c. All irritant disinfectant residues should be removed before the item is reused and care should be taken when rinsing to ensure that items are not re-contaminated during this.

d. Some chemicals may corrode or damage equipment, particularly plastics; so all equipment must be checked regularly for corrosion, damage or deterioration.

Equipment unsuitable for purpose or damaged in any way must be withdrawn from use and reported.

Disinfectants in common use are:

• Chlorine Releasing Agents (presert /chlorclean)
  Tablet disinfectant diluted with a suitable amount of water (See manufactures guidelines). This has good microbiocidal activity but only moderate stability under 24 hours. Chlorclean comprises of a chlorine-releasing agent with a detergent and may be used to clean and disinfect simultaneously.

Endoscopic solutions specialised disinfectants are used in designated departments to decontaminate endoscopic equipment. Staff must be trained in their use and special spillage kits may be required in case of accidents.

9.6 Sterilisation

A process to render an object free from all micro-organisms including bacterial spores and viruses.

Expert advice is that effective cleaning of surgical instruments prior to sterilisation is of the utmost importance.

The Sterile Services Department (SSD) is responsible for this process and they provide a traceability service through the use of a labelling system from pack used to patients’ records. The process of steam sterilisation requires direct contact between pure, dry saturate steam and the material being sterilised at the required temperature for the required time, in the absence of air.
‘Bench top’ autoclaves are not used in the Trust, but may be used in the community. It is the users responsibility that all support (i.e. maintenance provisions, training and support) is managed.

9.7 Creutzfeldt-Jakob Disease (CJD).

Instruments and equipment used in the care of patients with confirmed CJD of any type should not be reused and should be disposed of by incineration. Instruments used on patients suspected of any CJD should be quarantined pending confirmation of a diagnosis and then incinerated or returned to the department for reprocessing. Disposable instruments must be used where indicated, as new advice becomes available from the Department of Health.

10. Monitoring.

10.1 Ward and departmental managers will monitor their clinical area’s compliance with this policy and ensure that all staff are competent to use the equipment available. The Division of Nursing & Governance will collate the competency records from all areas and ensure that these are submitted in a timely manner. Where possible, equipment training reporting will be made available from the Trust learning management system and deficits escalated to individuals, managers and Directorates.

10.2 EBME KPIs are reviewed by the Estates and Facilities Division Governance Steering Group at each meeting, on a quarterly basis. The Estates and Facilities Division Governance Steering Group review compliance rates and make recommendations for action/improvement where necessary.

10.3 The Clinical Replacement Panel will review the Medical Equipment Management process taking into account patient safety, governance, risk management and relative cost effectiveness. All proposals for the purchase of new clinical equipment will be assessed by the Group using the Trust Policies and Procedures.

10.4 Trial and evaluation of new medical devices will be documented and retained by the Department/ward managers and may be required upon for future reference. Device evaluation must be in line with policy PP228 and may be forwarded to the Trust’s Drugs and Therapies Committee for information/feedback/support, if a potential risk for change has been identified.

<table>
<thead>
<tr>
<th>Author(s):</th>
<th>EBME Manager</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other contributors:</td>
<td>Health, Safety and Risk Manager, Head of Purchasing, POCT, Finance, IM&amp;T, Fire Safety Advisor, Lead Anaesthetic Consultant</td>
</tr>
<tr>
<td>Approvals and endorsements:</td>
<td>Health and Safety Committee Facilities Management Team Trust Executive Group (TEG)</td>
</tr>
<tr>
<td>Issue no:</td>
<td>4</td>
</tr>
<tr>
<td>File name:</td>
<td>PP024 Management of Medical Equipment Policy.docx</td>
</tr>
<tr>
<td>Supersedes:</td>
<td>PP(17)024</td>
</tr>
<tr>
<td>Equality Assessed</td>
<td>Yes</td>
</tr>
<tr>
<td>Implementation</td>
<td>Equipment will not be allowed into the trust unless the processes contained in this policy are adhered to. Department managers are responsible for the implementation of this policy within their department.</td>
</tr>
<tr>
<td>Monitoring: (give brief details how this will be done)</td>
<td>The Clinical Equipment Replacement Panel will review the Medical Equipment Management process. The EBME department will monitor the maintenance of equipment. The training documentation will be monitored by the Ward/Department managers KPI’s will be monitored quarterly and reported to the Estates and Facilities Directorate Governance Steering Group. See item 10.</td>
</tr>
<tr>
<td>Additional Information:</td>
<td></td>
</tr>
</tbody>
</table>
Appendices
Note: for illustration purposes only, the purchasing department will contact the supplier to obtain this information.

Appendix A Pre Acquisition Questionnaire (PAQ)
Clinical Equipment Evaluation

Please return filled in form to the EBME Department when equipment is removed from department. Equipment must not be used in the hospital unless proof of indemnity is provided and an electrical safety check has been carried out by EBME.

Details supplied to/by EBME

Equipment No. .................................. Manufacturer ............................................. Model .............................................

Serial No. .................................. Equipment supplied by ............................................. Date equipment delivered ...............

Equip Job No. .................................. Safety tested by EBME. Y/N or N/A ...... Date equipment removed ...............

Indemnity cover confirmed Y/N ........... If NO then form of indemnity Ref Number ...............

Departmental Assessment

Marks out of ten 10 = Excellent 5 = Suitable 1 = Not Suitable

Ease of use ............ Comments

Suitability ............ Comments

Compatibility with existing equipment ............... Comments

Decontamination – Additional facilities required? Y/N ............... Comments

Assessed By: .................................. Title: ..................................

Appendix B Clinical Equipment Evaluation
Appendix C  Capital Equipment Replacement Bid Forms

The Purpose of the Group
Mainly Clinical Governance
- Patient safety - in line with the Care Quality Commission registration: Compliance with the Health and Social Care Act 2008 Regulations 2009 - standardisation where ever possible, only use equipment that meets all safety and decontamination requirements
- Protecting the Trust from litigation: Only equipment conforming to the regulations and regularly maintained, in use.
- EBME are required to maintain an up to date data base of all equipment held on Trust premises and service logs in line with MHRA Managing Medical Devices April 2014; this can only be achieved if they are aware of all new equipment.
- Recommend medical equipment for purchase from the capital budget fairly and appropriately.

Clinical Replacement Panel Information

How to get authorisation to purchase/accept equipment:
1. Complete an equipment request/bid form as fully as possible (use extra sheets if necessary to make a clear case of need) and a CIRS Risk Assessment form.
2. Get Director/General Manager to sign off and the department manager’s signature on the form.
3. Submit the bid form to the EBME Manager in Facilities (with 3 quotes from different companies if bidding for funding).

The group meets on the second Monday of every month – but if items require urgent consideration this will be facilitated.

How the group works:
1. All bids requests are discussed based on the information provided and in line with international standards and regulatory requirements.
2. Costs of consumables are considered as are the availability of the same equipment in other areas, especially if it is a low use item to see if equipment sharing is an option.
3. Consideration of case of need will be thoroughly reviewed – equipment may be perceived as being required when other departments may be able to do the same work – specifically with near patient testing.
4. Decisions are made on a majority vote if the equipment meets all regulatory requirements and the case of need is agreed.
5. If capital funding is requested and the equipment is approved for purchase the bid is taken forward to the Capital Strategy Group by the EBME Manager.
6. The bid is discussed based on the evidence provided and either approved or rejected.
7. If approved the equipment is ordered via the Purchasing Department.
8. All outcomes are communicated back to the relevant departments by the EBME Manager.

Requests or bids should be made when:
1. Existing equipment has been condemned because of breakage or no longer supportable and there is still a clinical requirement for it.
2. New equipment required to assist new developments/services.
3. To ease pressure on existing equipment due to increasing demands.
4. For spend to save initiatives.
5. The general public or company representatives are making donations or gifts of equipment.

All new equipment needs approval before being put into service.

Funding Sources:
1. Capital funds (if cost above £5,000).
2. Trust funds
3. Service directives
4. Directorate budgets
5. Operating Leases
6. Donations.
7. Gifts from the general public or company representatives.

However equipment is funded - approval must be received from the Capital Strategy Group before equipment is ordered/used in clinical areas.
# Medical Equipment Proposal for Purchase, Equipment Management Information

## General Information:

<table>
<thead>
<tr>
<th>Directorate and department:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name &amp; contact details of applicant:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Equipment item and brief description of its function:</th>
<th></th>
</tr>
</thead>
</table>

*NB: Attach up to date Quotations – 3 required as per Standing Financial Instructions or single waiver if standard/specialised equipment (Purchasing Dept. can assist).*

<table>
<thead>
<tr>
<th>Supplier/Manufacturer details, inc. contacts &amp; telephone details:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Approx. total cost (inc. vat, delivery and installation if applicable) £:</th>
<th></th>
</tr>
</thead>
</table>

## Equipment Utilisation:

<table>
<thead>
<tr>
<th>Is the purchase intended to:</th>
<th></th>
</tr>
</thead>
</table>

Replace existing equipment? If so, please quote the asset number(s) of the equipment.

If existing equipment removed and condemned attach copy/copies of condemning form(s).

If for new development has equipment been trailed/evaluated? If so, please quote the evaluation number(s) issued.

Does equipment impact or require input from other Trust department, e.g. EBME, Estates, CSSD, Pathology, Resuscitation Team, etc.
## Financial:

**Annual Revenue implications associated with this purchase:**

<table>
<thead>
<tr>
<th>Current equipment (if applicable)</th>
<th>Proposed equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post warranty repair and maintenance to include commercial service contract costs if appropriate.</td>
<td></td>
</tr>
<tr>
<td>Technical training necessary for provision of in-house technical support (if appropriate).</td>
<td></td>
</tr>
<tr>
<td>Please supply details of leasing option if available. Purchasing Dept can assist with leasing agreements available.</td>
<td></td>
</tr>
</tbody>
</table>

## Data Risk assessment ID:

**NB: Please attach copy of risk assessment**

**Description of Task / Activity / Issue:**

**Current Risk Rating (with existing controls in place):**

**EBME/Estates Technical Supporting Comments/Information (attach to Proposal)**

**EBME/Estates Manager’s signature:**

**Date:**

**Clinical/Department Manager’s signature:**

**Date:**

**Director/General Manager’s signature:**

**Date:**
Appendix D Clinical Equipment Replacement Panel Process

Completed bid form sent to EBME Manager to forward to Clinical Equipment Replacement Panel (CERP). Unique ID (CERPxxx) issued or checked by EBME Manager.

Documents required to be completed: Risk Assessment, quotations, Medical Equipment Proposal for Purchase paperwork fully completed (intranet, general forms) and POCT application (if a POCT device)

- CERP approved?
  - Y
    - Rejected bid returned with reasons to Project lead
  - N
    - Is bid total >£5k?
      - N
        - Department manager can authorise the purchase of this equipment out of own funds
      - Y
        - Identify funding source. i.e. Lease (capital), Managed Service, My Wish (charitable funding), consumer/set deal, etc.

- Bid progressed to the Bi-monthly Capital Strategy Group (CSG) for funding approval. If urgent can be expedited to director of resources

- CSG approved?
  - Y
    - Equipment ordered, subject to receipt of acceptable Pre-Acquisition Questionnaire via the Purchasing Department. Relevant stakeholders informed.
  - N
    - Rejected bid returned with reasons to Department Head, if risk rating of RED (HIGH) will be referred to the Trust Executive Group (TEG).

When there is a requirement for, or the opportunity, to receive new/replacement medical equipment a Medical Equipment Proposal for Purchase bid form must be completed and submitted to the EBME Manager for presentation at the Clinical Equipment Replacement Panel. If bid (>£5k) funding is required, 3 quotes should be supplied with the completed bid form.

A PAQ will be required prior to the order being placed, Purchasing department will request one from the supplier.
Appendix E – Loaned equipment return form

PATIENT TRANSFER TO COMMUNITY (non WSHFT) EQUIPMENT RETURN INFORMATION FORM

<table>
<thead>
<tr>
<th>PATIENT STICKY LABEL</th>
<th>ADDRESS IF DIFFERENT FROM LABEL</th>
</tr>
</thead>
</table>

WARNING: IF THIS DEVICE IS NOT RETURNED WITHIN A WEEK, IN ACCORDANCE WITH TRUST POLICY, THE WARD WILL BE LIABLE FOR REPLACEMENT COSTS OF THE DEVICE

Contact Telephone Number:............................................

District Nurse / Care Home Manager,

(Contact Name & Tel No.:............................................)

The above named patient has been transferred to you from Ward...............,, West Suffolk Hospital.

They have been transferred with the following equipment, which must be returned to the hospital as soon as possible:

  Equipment type:............................................

  Equipment Number:............................................

Please return the equipment to the Ward/EBME at your earliest convenience.

By signing this form you are in acceptance of the terms and conditions of the loan.

Signed.......................................................... Date.............................................

A copy of this form is to be sent to the Medical Equipment Library for their records
Appendix F Condemnation Form

CONDEMNING AND DISPOSAL FORM FOR ELECTROMEDICAL EQUIPMENT:

NOTE NUMBER:

SITE:
DEPARTMENT:
EQUIPMENT NAME:
MODEL:
MANUFACTURER:
HOSPITAL REGISTRATION NUMBER:
SERIAL NUMBER:
DATE LOGGED ON REFERENCE:

EBME Action

I certify the equipment listed above has been removed from use in this department for the following reason(s) Please mark with a 'X' relevant item(s)

(a) Degraded clinically unsafe [X]
(b) Electrically unsafe [ ]
(c) Mechanically unsafe [ ]
(d) Beyond economic repair [ ]
(e) Contaminated [ ]
(f) Obsolete-No parts available [ ]
(g) Other, state: [ ]

I recommend that the equipment is disposed of:

(a) Scraping (WEEE) [X]
(b) Auctioning [ ]
(c) Trade in [ ]
(d) Equipment returned to supplier [ ]
(e) Other, state: [ ]

The equipment record will be removed from the computerised record system and inventory list and all maintenance schedules and contracts cancelled.

Signature: ___________________________ Designation: EBME Manager ___________________________
Date: ______________________________

WARP Action

This equipment is no longer suitable for use in this department or is no longer required or if a replacement is required copy this completed form and attach to 'Medical Equipment Proposal for Purchase' form.

Signature: ___________________________ Designation: ___________________________
Date: ______________________________

Please photocopy on completion and return original to EBME Department manager.

Remove from Database (X) 
Autoclaved before disposal

Yes [X] No [ ]
Appendix G Single Use Medical Device

Introduction

It is based upon current publications from the Medicines and Healthcare products Regulatory Agency “Single use medical devices: implications and consequences of reuse December 2013”. This document is intended to give guidance and instruction on the use of “Single use Devices”.

To reuse a single - use device without considering the consequences identified in this document could expose patients and staff to risks which outweigh the perceived benefits of using the devices.

Definition of Single-use

The expression ‘single-use’ means that the medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

Key points:

- A device designated as ‘single - use’ must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

- The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.

- The reuse of single-use devices has legal implications:
  - anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness;
  - anyone who reprocesses a single-use device and passes it to a separate legal entity for use, has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.

- Check the packaging or device for the symbol below, which means do not reuse/use only once/single use.

- Disposal of single use devices must be in accordance with trust policy on infection prevention and waste management. If a device has batteries fitted it is essential that ALL batteries are removed prior to disposal.