

Medical Equipment Users Guide

Issue Date	Review Date	Version
March 2017	March 2022	Version 6

Purpose

These procedures communicate Trust policy on the management and use of medical devices for users of all medical devices used within Plymouth Hospitals NHS Trust

Who should read this document?

- All users of medical devices within Plymouth Hospitals NHS Trust should read and be familiar with the procedures contained in this document.
- Relevant staff in the Clinical Management Directorate, because they deliver or oversee Training in the correct use of medical devices.

Key Messages

- Knowledge of the correct procedures for the management and use of medical devices is key to delivering safe patient care
- Accessing correct and timely technical support can save time and money and significantly reduce risk
- Accurate medical devices database records require the cooperation of all equipment users and technical support staff and are essential to the safe and efficient use of the Trusts medical devices resource.

Core accountabilities

Owner	Head of Clinical Technology
Review	Medical Devices Strategy Group
Ratification	Medical Director / Director of Healthcare Science and Technology
Dissemination	Head of Clinical Technology
Compliance	Medical Devices Strategy Group

Links to other policies and procedures

Management and Use of Medical Devices Policy
 Medical Device Training Policy
 Clinical Risk Classification Scheme for Medical Devices
 Management of Contamination Incidents SOP

Version History

1	June 1991	Written A. Dawson
2	April 1996	Reviewed and amended A. Dawson
3	Nov 2008	Reviewed and amended M. Webber
4	Oct 2010	Reviewed, amended and incorporate Library Supplement J. Applebee
5	Jan 2013	Rewrite into SOP format and incorporate Single Use Items J. Applebee
6	Mar 2017	Reviewed and amended J. Applebee

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents on StaffNET. Larger text, Braille and Audio versions can be made available upon request.

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

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Standard Operating Procedure (SOP) Medical Equipment Users Guide

1 Introduction

- These procedures communicate Trust policy on the management and use of medical devices and give general guidance for users of all medical devices in Plymouth Hospitals NHS Trust (PHNT).
- The principles contained here apply to all medical devices. However, some specialist medical devices e.g. x-ray, require specialist maintenance, calibration, testing, protocols and user training which may be carried out by specialist departments or external contractors. If in doubt contact MEMS for advice.
- These procedures cover the use of reusable medical devices except where stated.
- These procedures do not cover the use of pathology / laboratory equipment Please refer to (Lab Equipment SOP)

2 Definitions

- **Medical device** - any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used in human clinical care for the purpose of:
 - diagnosis, prevention, monitoring, treatment or alleviation of disease
 - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
 - investigation, replacement or modification of the anatomy or of a physiological process
 - control of conceptionand which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
- **Medical equipment** - term used to describe the sub-group of medical devices that includes electro-mechanical **medical equipment** - The words equipment and device are often interchanged.
- **Maintenance, servicing** – performing planned routine actions which keep the device in working order, or prevent trouble from arising. For the purposes of this SOP, this excludes the everyday good practice that device operators should follow to ensure that the device remains in good working order. In this SOP, the word **maintenance** is used to include **calibration** and **repair**, unless specifically stated.
- **Calibration** – setting the correctness and magnitude of measurements made by a piece of equipment against a device, or reading with the known or assigned correctness, called the standard.
- **Repair** – performing un-planned actions to make good a device, which is no longer functioning as it should.

- **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. The symbol below is used on medical device packaging indicating ‘do not reuse’ and may replace any wording. Some single-use devices are marketed as non-sterile which require processing to make them sterile and ready for use. The manufacturer of the device will include appropriate processing instructions to make it ready for use.
- **Single Patient Use** – means that a medical device might be suitable for re-use on the same patient.



3 Regulatory Background

These procedures are intended to implement the recommendations contained in the Medicines and Healthcare products Regulatory Agency (MHRA) document Managing Medical Devices April 2015 which outlines a systematic approach to the purchasing, deployment, maintenance, repair and disposal of medical devices.

The procedures include provision for electrical safety testing of medical devices to BS EN 62353 standard.

The procedures also form part of MEMS Quality System which is externally accredited to ISO 9001:2008 by Lloyds Register.

The Medical Equipment Library was set up following the recommendations contained in the National Patient Safety Agency (NPSA) Safer Practice Notice issue 1 May 2004, ‘Improving Infusion Device Safety’.

The relevant Trust policy that these procedures support is ‘The Management and Use of Medical Devices Policy’

4 Key Duties

Medical Device Users

It is the responsibility of all medical device users in PHNT to follow these procedures. The procedures have been developed to enable the best level of device support to be delivered by MEMS and the best operational service to be obtained from the devices themselves.

Medical Equipment Management Service (MEMS)

MEMS has responsibility for medical devices management in this Trust. Medical devices can be identified by an orange label as shown.

If there is no label please contact MEMS for advice.

MEMS range of services is as follows:-

- Pre-purchase assessment of new medical devices.
- Acceptance and commissioning checks.
- Maintain medical equipment Asset Register and service records.
- Medical Equipment Library service
- Monitoring of warranty period.
- Preventative and corrective maintenance.
- Routine safety testing to BS EN 62353.



- Quality assurance testing.
- Modification of equipment.
- Development of innovative medical devices
- Advisory service to equipment users.
- Negotiation and monitoring of Service Contracts.
- Investigation of Untoward Incidents involving medical devices.
- Recycling equipment.
- Condemning equipment which is beyond economic repair.
- Selling equipment which is no longer of use to the Trust

Medical Equipment Library (MEL)

The Medical Equipment Library is responsible for providing access to a range of general purpose medical devices for the whole of Plymouth Hospitals NHS Trust. Its purpose is:-

- To improve the availability of medical equipment through one central location with 24 hour access
- To improve safety for patients and staff through access for servicing , decontamination and standardising equipment
- To maximise financial benefits through efficient usage of equipment, central purchasing and minimising rental costs.

5 Access to the Services

Contacts

MEMS Help Desk

Internal phone number

31333

Fax

53565

Head of Clinical Technology

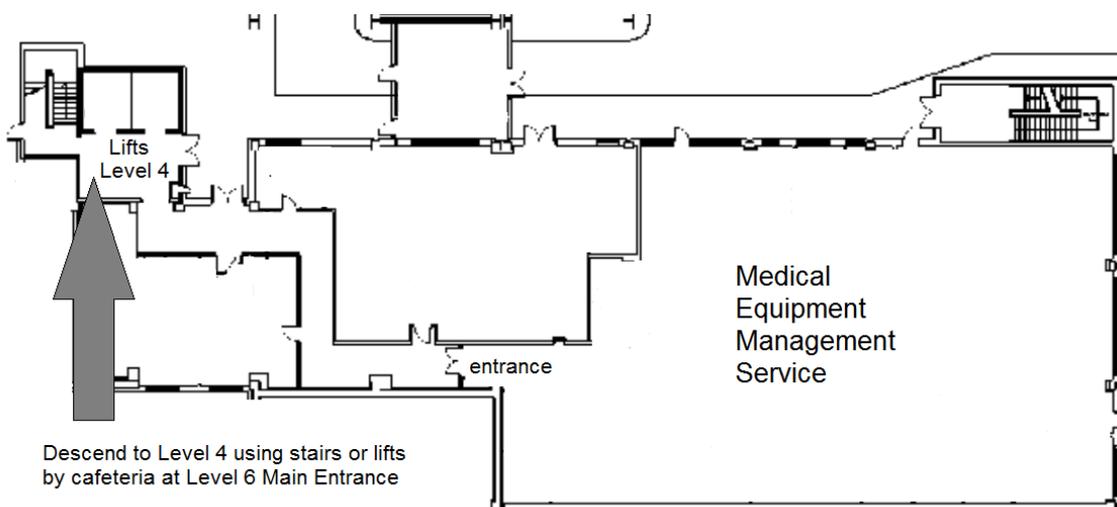
32179

Medical Equipment Library

32181

MEMS

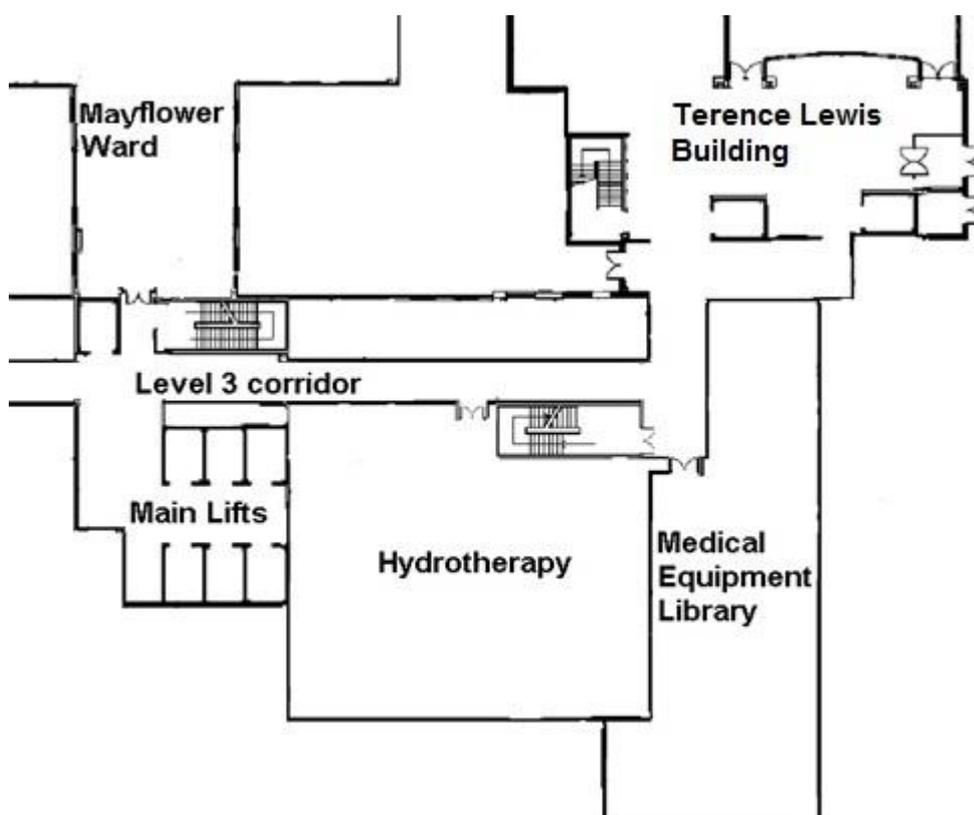
MEMS accommodation is located on Level 4 below Pharmacy at Derriford Hospital, Plymouth. We can be found by descending the staircase or pair of lifts adjacent to the cafeteria area at the main entrance, Level 6.



MEMS is open 0830-1700hrs Monday - Friday. There is no out of hours on-call service. However, in a genuine emergency, MEMS staff may be contactable via Derriford Switchboard and will attend voluntarily if appropriate. Medical device users should be aware of this limitation and formulate alternative strategies accordingly.

MEL

Using the Main bank of 6 lifts that serve the tower block or the stairs behind them continue down to Level 3. Exit the lift area and turn right along the main corridor, or exit the stair well and turn left along the main corridor. Proceed past Hydrotherapy to the 'T' junction. The Medical Equipment Library is on your right. From the Terence Lewis Building level 3 foyer pass through the doors towards the main building. The Medical Equipment Library is immediately in front of you. Hospital staff including porters can use their ID card to enter the Library at any time.



The Medical Equipment Library operates 24 hours a day 365 days a year. Between the hours of 08:30 hrs to 17:00, 7 days a week, the Medical Equipment Library is manned by Library Staff. Whilst the Library Staffs' duties include assisting staff when they visit the Library they also assist staff by visiting the Wards and Departments who have equipment on loan from the Library. If during these hours, Monday to Friday, assistance is required but the Library is temporarily unmanned, please contact staff in the main MEMS Department using the phone in the Library.

6 Pre-Purchase Assessment of Medical Equipment

This section describes the procedure to be followed by medical equipment users who are considering the purchase of new medical equipment. Inadequate assessment prior to

purchase can result in many years of excessive expenditure and inconvenience to the equipment user. Pre- purchase assessment is necessary:-

- To ensure that only Medical Equipment of an approved type is introduced, using the following assessment criteria:-
- To negotiate the best level of support from manufacturer/supplier to ensure that MEMS may provide the equipment user with a rapid and cost-effective support service with minimum equipment down-time.
- For the above negotiation to take place at a time when the supplier is likely to be most helpful in order to secure a sale.
- To grant 'type-approval' to new equipment that meets the requirements of equipment users and is favourably assessed by MEMS.
- To withdraw 'type approval' when appropriate (e.g. in-service problems not properly resolved by the manufacturer, supplier, or equipment obsolescence etc.).

Action

On identification of the need for the purchase of a medical device the clinical users, MEMS and Procurement should liaise to action the following

1. Consider all Health and Safety implications (COSHH) and decontamination requirements in particular.
2. Consider all Clinical suitability issues.
3. Consider whole of life financial implications
4. Arrange a clinical trial if appropriate.
5. If appropriate that equipment is delivered directly to MEMS for assessment.

7 Medical Equipment on Trial, Loan or for Research

This section details the procedures to be followed before use when medical equipment is obtained on trial, loan or for research. This situation usually arises when equipment is trialled for pre-purchase assessment. Failure to comply with the following procedure may cause delay and could cause legal complications in the event of an adverse incident involving the equipment.

This procedure's target is:-

- To ensure patient and user safety by testing to confirm compliance with BS EN 62353.
- To ensure that the Trust has been indemnified against all liability arising from the use of the equipment on trial.
- To ensure staff receive appropriate training before using trial or loan equipment.
- To facilitate inspection of the equipment by MEMS as part of their pre-purchase assessment of the equipment. (This normally only applies to equipment which is not already type-approved by MEMS).
- To obtain product information for pre-assessment by means of the NHS Supply Chain Pre-Acquisition Questionnaire (PAQ).
- To give further opportunity for assessment of clinical suitability and whole of life costs.

Action

1. MEMS and the Procurement department must be notified as soon as a decision is made to request or to accept medical equipment on loan.
2. MEMS will check if Master Indemnity is registered with DOH. If not Procurement will then arrange for the completion of the Standard Form of Indemnity, the PAQ and any supplementary MEMS questions.

3. As soon as possible, MEMS will start the trial process, safety check the equipment and give notice to Procurement to ensure that the manufacturer's indemnity is received before equipment is put into service on a temporary basis.
4. Do not use equipment which has not been safety checked - look for our device number label and a valid electrical safety test label for confirmation of testing.
5. Ensure you have taken appropriate action to comply with relevant health and safety regulations.
6. Contact the Clinical Education Facilitators/Clinical Educator to confirm appropriate training is received.
7. If, subsequently, it is proposed to purchase the equipment, please notify MEMS before the equipment is removed. This will enable a more detailed assessment to be made to ensure long term safety and maintainability.
8. For loan or research a device number will be allocated by MEMS and service history started and maintained.
9. Equipment must not remain on loan or trial beyond the agreed period that it is covered by the supplier's indemnity insurance. .
10. Equipment users must inform MEMS as soon as the Loan or Trial equipment is no longer required so that it can be removed from the inventory and returned to the supplier

8 Ordering New Medical Equipment

This section explains the procedure to be followed when ordering new medical equipment after pre-purchase assessment by MEMS. The procedure's target is:-

- To ensure that only CE marked equipment is ordered.
- To ensure that correct equipment is ordered.
- To ensure that best price is achieved by Procurement
- To ensure that promises made by the supplier as a result of negotiation by MEMS or others become conditions of order.
- To ensure that equipment is initially delivered to MEMS for acceptance testing.

Action

1. Equipment user liaises with MEMS for type approval.
2. User requisitions equipment via the 'Oracle' purchasing system, or if a capital item, through Procurement.
3. Procurement should confirm type approval with MEMS and any conditions of order before placing order.
4. Equipment must be delivered to MEMS for acceptance testing.
5. MEMS will check equipment on receipt, allocate a device number to the item, start the service history and forward it to the user.

9 Acceptance Testing of New Medical Equipment

The following objectives and procedure apply to all incoming medical equipment including local purchases; regional purchases; donated equipment; leased equipment, loaned equipment and trust fund purchases. Acceptance testing of new medical equipment is necessary:-

- To ensure all incoming equipment is subjected to electrical safety testing as required by Managing Medical Devices April 2015 and BS EN 62353

- To ensure new equipment is entered into the medical equipment Asset Register.
- To commence service records as required by Product Liability Legislation.
- To ensure new equipment is complete, serviceable and undamaged.
- To facilitate monitoring of the warranty period and the planning of subsequent maintenance arrangements.

Action

1. Portable or mobile equipment should be delivered direct to us for testing prior to use. Procurement should ensure that this is specified on the order.
2. Non-mobile equipment can be delivered to its required location but prior arrangements must be made with us for acceptance testing. This will enable us to make contact with the manufacturer's representative or installation engineer.
3. A copy of the user instructions for the equipment will be left with the equipment. Please retain for future reference.
4. Do not use new medical equipment unless you have received training and you are competency assessed (if required, as determined by the clinical risk category).
5. Do not use new medical equipment unless you are sure it has been checked. Look for MEMS orange device number labels for confirmation and a valid electrical safety test label.

10 Good Practice in the Use of Medical Equipment

Please remember, it is our policy to try to get you out of trouble as quickly as possible. Adherence to good practice in the use of Medical Equipment will largely prevent any untoward events and possibility of harm

Storage

1. Equipment should be stored in a designated safe storage area and a record kept of any equipment sent for repair. Consult the Medical Devices Link Practitioner, (MDLP), for your area.
2. Accessories and connecting cables should be stored with the equipment.
3. Instruction manuals and any clinical protocols should be stored nearby for easy reference. The MDLP will be able to advise on access to the user manuals for the devices in your area. Copies of most manuals are available electronically through Trustnet.
4. Adequate fresh stocks of the correct disposables and batteries should be held nearby.
5. In the event of long term storage, remove dry batteries or, in the case of rechargeable equipment, charge batteries at least monthly.

Routine testing

1. Equipment which is used in an emergency situation should be checked daily or more frequently. This will also keep the user familiar with the equipment.
2. Testing should be in accordance with the manufacturer's user instructions and should include carrying out any user maintenance specified by the manufacturer.
3. Equipment powered by mains or battery should be tested on both power sources.
4. If there are any problems, report fault immediately.

Before use

1. Always follow manufacturer's instructions.
2. Always follow relevant clinical protocols.
3. Ensure you have received adequate training.
4. Ensure equipment has been cleaned / decontaminated.

5. Ensure you comply with relevant health and safety regulations.
6. Visually check the equipment for signs of damage, especially for evidence of having been dropped, fluid ingress, or deterioration of electrical connections and cables.
7. Check for presence of a valid electrical safety test label. If label is missing or is past the stated expiry date, contact us for advice. Do not use the equipment. Also check for presence of warning label which will be attached to new / recently serviced equipment. Take heed of any advice given on label.
8. Connect accessories using minimum force and check for compatibility with equipment.
9. Check alarms and any other functions for correct operation.
10. Set all controls to safe operating settings.
11. Connect to the patient, only if satisfied with all of the above.

During use

1. Monitor operation immediately after set-up and at sufficient regular intervals thereafter to ensure that the equipment is operating correctly. A written record should be kept of checks made and time of check.
2. Adjust user controls to optimise operation.
3. If operating on battery power, monitor battery charge state. Where mains powering is possible connect to mains power as soon as possible
4. For equipment that is in use continuously for long periods, regular checks must be made sufficient to ensure correct functioning, including alarms and safety interlocks.
5. Equipment that is subject to prolonged use should be cleaned at least daily, and evidence provided that this has happened.
6. Equipment that is visibly soiled should be decontaminated as soon as it is identified.
7. Replace disposables at the intervals recommended by manufacturer.
8. If malfunction is suspected, withdraw equipment from use and report details to MEMS without delay. Clearly label equipment to prevent further use.

After use

1. Disconnect from patient, retaining all accessories.
2. Clean/decontaminate in accordance with the manufacturer's instructions. Avoid fluid ingress and do not use alcohol or other solvents. Contact SDU for advice if unsure. Evidence of decontamination should be provided
3. Recharge batteries if appropriate.
4. Check equipment is switched off.
5. Return to storage.

11 User Training

Medical equipment which is used incorrectly will, at best, cause inconvenience to the user and at worst will be directly hazardous to the patient or operator. There is also the possibility of damage to the equipment and misleading clinical measurements. All of this is entirely preventable by means of adequate user training to:-

- Ensure patient and user safety.
- Optimise use of medical equipment.
- Minimise risk of damage to equipment.
- Plan for the unexpected e.g. equipment failure or adverse incident.

Action

1. Clinical users of new equipment should consider training requirements prior to purchase of equipment when equipment suppliers may include training free of

- charge. This should be discussed with the appropriate staff in the Clinical Management Directorate
2. Clinical users of existing equipment should ensure that appropriate training and retraining in the use of that equipment has been carried out (depending on the clinical risk classification of the equipment).
 3. Special consideration should be given to hospital equipment which is sent home with patients and the Medical Device Training Policy (MDTP).
 4. MEMS will liaise with the appropriate staff in the Clinical Management Directorate and give advice regarding the technical aspects of user training where appropriate.
 5. Staff unfamiliar with equipment must not use it unless adequately supervised or considered competent as indicated in MDTP.

12 Single Use Items

Single use medical devices carry an identifying mark as shown below and their use is subject to regulatory requirements. This procedure is to ensure that the Trust:

- Does not expose patients and staff to unnecessary risk
- Uses medical devices as the manufacturers designed and intended them to be used
- Complies with the regulations relating to Single Use Medical devices and Single Patient Use Medical Devices

Action

Users of single use medical devices must ensure that:

1. The device or packaging is checked for the symbol below, which means do not reuse / use only once / single use
2. Single Use Devices are only used once
3. Single Use Devices are not cleaned / decontaminated for re-use
4. Single Patient Use Devices are only used on one patient
5. The devices are disposed of safely, after use



13 Clinical Protocols

Local clinical protocols are in addition to the manufacturers' operating instructions for medical equipment. Their purpose is:-

- To ensure that clinical protocols make suitable references to the manufacturers' published operating instructions and the appropriate sections of this Medical Equipment Users' Guide (e.g. 'good practice in the use of medical equipment', 'fault reporting', 'incidents' etc).
- To ensure that clinical protocols are amended in accordance with Medical Device Alerts and Field Safety Notices issued by the MHRA and notices issued direct from manufacturer.
- To ensure that clinical protocols are periodically reviewed to take account of in-service clinical or technical problems.

Action

1. Authors of clinical protocols should liaise with MEMS when drafting or re-drafting protocols for the use of medical equipment.

2. Authors should make reference to this guide and manufacturers' instructions as appropriate.
3. MEMS will advise authors of any Safety Information received, or in-service problems which may necessitate changes to the protocol.
4. It is also recommended that clinical protocols be periodically reviewed in association with MEMS.
5. Some Clinical Protocols will require input from other specialist support services. If in doubt contact MEMS

14 Fault Reporting

- To ensure that defective medical equipment does not remain in service.
- To provide us with sufficient information for quick diagnosis and rectification of the fault.

Action

1. Please ensure that equipment for repair is clean and free of contamination as required by the hospital decontamination procedure.
2. Attach decontamination certificate and complete the fault details.
3. Ensure that defective equipment is clearly labelled to prevent use.
4. Report defect to MEMS without delay. Telephone 31333.
5. This also applies to equipment subject to a supplementary service contract by a manufacturer or his agent.
6. Be prepared to STATE the following:-
 - a. The device number (on label).
 - b. Full details of the problem.
 - c. Your name, location and contact number.
7. Please record brief details on 'decontamination certificate'.
8. Keep a note of the device number and date reported. This will assist us in answering queries.
9. Do not send equipment to MEMS unless asked to do so.
10. Do not continue to use defective equipment.
11. Do not attempt to repair equipment yourself. We can take no responsibility for the consequences.
12. Equipment which has been dropped or immersed in liquid may be dangerous even if it still appears to function. Always report such occurrences immediately. Prompt action may save big repair bills.

15 Accidents, Incidents and Near Misses Involving Medical Equipment

This section describes the procedure to be followed in the event of an accident, incident or near miss involving medical equipment, which in this context is where the actual behaviour of the equipment was different from the intended behaviour resulting in a hazard to patient or staff. This procedure is intended to facilitate our technical investigation and is supplementary to the Trusts' overall policy on the subject. For further advice contact the Trust's Patient Safety Manager.

- To provide sufficient information to ensure that any accident, incident or near miss involving medical equipment is properly investigated.
- To prevent a recurrence of the problem.

- To ensure technical defects are reported to the MHRA when appropriate.

Action

1. Equipment subject to an incident should be removed from service (quarantined) whilst clinical safety is being assessed in order to minimise the risk of further harm.
2. Accidents, incidents and near misses must be reported electronically on the Datix system. Refer to your line manager without delay.
3. Record as much factual information as possible about the intended and actual behaviour of the equipment.
4. Report the occurrence by telephone to MEMS as soon as possible.
5. Retain (quarantine) all accessories and consumables in use at the time, (for example, giving sets or syringes).
6. Do not alter any control settings.
7. If contamination is suspected, observe the precautions in section on Decontamination of Medical Equipment.
8. If sharps are involved refer to the Staff Health and Wellbeing department and the Standard Operating Procedures on the Management and Prevention of Contamination Incidents
9. Consider discontinuing use of other equipment of the same type. Liaise with MEMS for advice. MEMS will feedback initial findings to enable an early review of the decision taken.

Medical Device users are reminded that it is their responsibility to ensure that relevant health and safety regulations are complied with for equipment in their charge. Further Health and Safety information can be obtained from the Staff Health and Wellbeing department at Derriford Hospital.

16

Medical Device Alerts and Field Safety Notices from MHRA or Equipment Manufacturer

- To ensure that appropriate and prompt action is taken to comply with the requirements of Medical Device Alerts from the MHRA (or Manufacturer) which are relevant to medical equipment.
- This may involve withdrawal and modification of the equipment or an alteration in the way in which it is used.

Action

1. Equipment users must follow any recommendations as to the way equipment is used. If in doubt contact MEMS before use.
2. MEMS will arrange a programme of equipment modification as necessary.
3. Clinical Protocols should be revised as appropriate.

Compliance with medical device alerts is essential to ensure patient safety. We can only ensure compliance if we know of the existence and current location of all medical equipment - please refer to sections on 'procurement of new medical equipment' and 'location of equipment'.

17

Location of Medical Equipment

- To ensure accuracy of the asset register.
- To enable all equipment to be located quickly for routine or urgent maintenance. This is particularly important to allow us to respond rapidly to Medical Device Alerts from the MHRA or manufacturer.

Action

1. MEMS will record the original location of equipment onto a centrally held asset register as part of the acceptance procedures for new equipment, and label accordingly.
2. Equipment users or the MDLP, should liaise with MEMS to keep the register of equipment in their charge up to date. They should also keep a record of equipment that is sent for repair which includes the Device Number.
3. Inform MEMS on 31333
4. Quote - original location, device number, new location.
5. Records must be kept of equipment and accessories loaned; department and person borrowing, date loaned, date expected back and any significant events such as repairs.
6. Always record the equipment number from our service label. See section on 'Key Duties'. This will enable us to help you if the equipment goes missing, and to prove ownership.
7. Some equipment bears an equipment location label. If the information on the label is incorrect, please let us know.



18 Supplementary Service Contracts

Although the vast majority of medical equipment is maintained 'in-house' by MEMS, there are a number of cases where MEMS will setup a supplementary maintenance contract with the equipment supplier or agent. This procedure is necessary:-

- To assess the need for a supplementary service contract, and available options, before equipment is purchased.
- To set any resulting contract to achieve a logical and cost effective blend of 'in-house' and manufacturer's expertise.
- To monitor contracts to ensure the contractor fulfils his obligations.
- To review such contracts annually.

Action

1. MEMS will assess the need for a contract prior to purchase and negotiate better support where necessary.
2. Criteria include:-
 - a. Existing and projected MEMS resources
 - b. Need for service training
 - c. Speed of response
 - d. Staffing / Test equipment implications
 - e. Value for money
3. MEMS will setup the contract in conjunction with Procurement and monitor the contractor's performance and quality of work.
4. MEMS will review the contract annually.
5. In some cases, additional funding may be required to cover cost of contract.

19 Routine Inspection and Electrical Safety Testing

This section describes procedures for the routine inspection and electrical safety testing of medical equipment.

- To ensure that medical equipment continues to meet the electrical safety requirements of BS EN 62353 and The Electricity at Work Regulations 1989.

Action

1. It is intended that all locations will be visited at least annually for the inspection and electrical safety testing of items of medical equipment. We will contact you at the appropriate time.
2. Equipment users should be aware of which items of equipment are under their control and their current location. See section on 'location of equipment'. It is the responsibility of the user to ensure that these items are made available for testing at a mutually convenient time.
3. If the safety of equipment is in doubt (e.g. equipment dropped, damaged wiring etc), equipment users should contact MEMS 31333 to request additional safety testing. Do not use equipment if unsure. See section on 'fault reporting'.
4. As an additional safeguard, an inspection / electrical safety test label showing next due date should be attached to the equipment. Do not use if test is overdue. Contact us and request a test. This should only occur when equipment has been mislaid or has missed the routine safety test.
5. The correct inspection / electrical safety test label is shown. Any other label referring to testing is not relevant to this procedure.



20 Withdrawing, Condemning and Redeployment of Medical Equipment

- To ensure the safe disposal of withdrawn and condemned medical equipment.
- To amend the asset register.
- To redeploy medical equipment within the Trust where possible.

Action

1. Contact MEMS for advice if you no longer require a piece of Medical Equipment. Quote device number from our service label on the equipment. Withdraw the equipment from use and arrange for transfer of the equipment to MEMS.
2. Medical Equipment which has been returned to MEMS as withdrawn will be checked and redeployed where possible. If this is not possible, it will be offered for sale to external medical users, or sent for medical auction. Purchasers must complete the Trust's Sales Particulars Form which indemnifies the Trust against any product liability.
3. If an item of Medical Equipment is deemed to be uneconomic to repair, or unsafe to use, but is still required for clinical use, MEMS will issue a condemned note. The user should then follow the pre-purchase assessment guide for its replacement. Refer to section on 'pre-purchase, trial and ordering of new medical equipment' for further advice.
4. Medical Equipment which has been condemned will be scrapped through the Trust's approved waste disposal agent.

21 Medical Equipment in Use in Patients' Homes

Special consideration should be given to the management of medical equipment which is owned by the Trust and used in patients' homes by patients themselves or their carers, bearing in mind the nature of the equipment and the potential liability of the Trust. The purpose of this procedure is to:-

- Ensure patient safety.
- Optimise use of equipment.
- Plan for efficient resolution of problems.

Action

1. Equipment should be checked by MEMS prior to issue to patient.
2. The Department issuing the equipment should refer to the MDTP and ensure that adequate training has been given to the patient, the patient's carer or relative, and has been understood and recorded.
3. Training should be backed up by a written protocol which includes:-
 - a. Relevant clinical instructions / protocol.
 - b. All necessary information on storage, pre-use checks, use, maintenance and cleaning, including manufacturers' published operating instructions and taking into account any disability issues.
 - c. Details of a clinical point of contact in case of problems.
 - d. An instruction to report any suspected malfunction without delay to MEMS.
 - e. An absolute ban on 'DIY' repairs.
 - f. Arrangements for supply of consumables.
 - g. Instructions for disposal of sharps and clinical waste.
4. The Department issuing the equipment should arrange for the equipment to be returned to MEMS at least annually for checking and before equipment is re-used after the patient has finished with it.
5. The department issuing the equipment should keep a record of the new location of the equipment
6. In the case of short term loans to patients the department issuing the equipment should actively encourage its return to the hospital as soon as possible.
7. It is recommended that in the event of equipment failure the problem is resolved by 'service exchange' via the clinical point of contact.

22 Decontamination of Medical Equipment

Health and Safety legislation requires that all items of health care equipment that may be contaminated with blood, faeces, other body fluid or any contaminant hazardous to health, must be decontaminated before inspection, service or repair. This applies to all items and all wards / departments. Decontamination of equipment is the responsibility of the user, i.e. the Manager of the ward or department.

Action

1. Following decontamination of equipment, complete and attach a decontamination certificate. If there is no certificate, service will be refused!
2. The requirement to decontaminate and attach certificate applies to all equipment sent to MEMS and commercial contractors and companies.
3. For items requiring complex decontamination processes e.g. surgical instruments, please contact SDU at Derriford who will arrange for their return or collection.

4. Decontamination certificates are available through the oracle ordering system, order code WZK1435.
5. It is a legal requirement that all items are accompanied by a decontamination certificate, irrespective of whether the equipment is contaminated or clean.
6. It is the responsibility of the borrowing Ward or Department to clean each item of medical equipment borrowed before returning it to the Library.
7. A decontamination certificate must be completed and attached to the equipment before returning it to the Library.
8. If the equipment could not be effectively cleaned or if ingress of liquid into the case is suspected this must be stated on the certificate and the equipment placed in a plastic bag with the certificate attached outside before returning it to the Library.
9. A disposable detergent wipe is recommended to clean the exterior of most medical equipment.
10. Do not use alcohol or alcohol impregnated wipes on any plastic surfaces or cables.
11. Do not allow liquid to enter the casing of any medical equipment.

23 Health and Safety in the Medical Equipment Library (MEL)

The Medical Equipment Library is accessible by all PHNT staff 24/7. The facility is manned during office hours only. Please familiarise yourself with these safety instructions before using this facility.

Fire Action

1. If you suspect or discover a fire
 - a. Sound the fire alarm by breaking the glass in the nearest call point
 - b. Dial 3333 and give details of fire to switchboard. There is a phone provided in the main store area of the Library.
 - c. Close doors near you.
 - d. Evacuate everyone from immediate danger, preferably behind a fire door. The nearest fire exit is through level 3 of the Terence Lewis Building
 - e. Tackle fire if safe to do so.
 - f. Do not re-enter building to look for missing staff or rescue your possessions.
2. On hearing continuous alarm
 - a. Close doors and windows.
 - b. Replace all telephone receivers.
 - c. Check the department for signs of fire.
 - d. Help evacuation if necessary. Move everyone out behind fire doors.
 - e. Tackle fire if safe to do so.
 - f. Do not re- enter building to look for missing staff or rescue your possessions.
3. On hearing intermittent alarm
 - a. You are not in an immediate risk area
 - b. Close doors and windows.
 - c. Replace all telephone receivers and await instructions from switchboard.
 - d. Send available staff to indicator panel in lift lobby or corridor to locate incident and assist if possible.

Security

1. CCTV cameras linked to the Security Office are monitoring the Library continuously for your security.

2. If you have any security concerns whilst in the Library dial 3333 on the phone provided in the main store area.

Manual Handling

1. Medical equipment available for loan from the Library may be heavy and / or bulky.
2. Whilst in the Library, staff must comply with all manual handling and safety notices. Do not climb the shelving.
3. Avoid over stretching and twisting.
4. Use manual handling aids provided e.g. kick step.
5. Use the correct lifting technique for heavier items and items from low or high shelving.
6. Staff coming to the Library to borrow or return equipment should consider bringing a suitable trolley with them from their Ward or Department to transport the equipment on and reduce the risk of manual handling injuries.

Electrical Safety

1. Many items of medical equipment available for loan in the Library will be plugged into a mains socket to keep their internal battery charged.
2. Care should be taken when lifting these items off the shelf, as the plug will need to be disconnected from the mains socket on the shelf.

Decontamination

1. Refer to section on 'Decontamination of Medical Equipment'

24 Borrowing Equipment from the MEL

Selection

When selecting equipment to borrow from the Medical Equipment Library the following issues must be considered:-

1. Clinical Suitability – Is the selected equipment correct for the intended treatment or procedure?
2. Training – Have the staff intending to use the equipment received adequate training in its correct use?
3. Consumables – Has the borrowing Ward or Department got access to the correct consumables (e.g. batteries, giving sets, disposable electrodes) for the equipment being borrowed?
4. User Manuals or Information sheets – Has the borrowing Ward or Department got access to the user manual or instructions for the correct operating of the equipment borrowed?

Booking Out

1. Select Equipment - Select the correct equipment from the Library main store area according to the above criteria.
2. Health and safety - All staff must comply with the Health and Safety requirements stated previously.
3. Library Checkout - Take the equipment and accompanying accessories or instructions to the Library Checkout. Select 'Loan' on the checkout touch screen and follow the screens through the process scanning the device label and swiping your ID card when required.
4. Safe Transport - Take equipment to the borrowing Ward or Department. Staff coming to the Library to borrow or return equipment should consider bringing a suitable trolley with them from their Ward or Department to transport the equipment on and reduce the risk of manual handling injuries.

If stocks are low

1. Ask about the MEMS Database - The Medical Equipment Library database keeps an up to date log of where each loan item is in the hospital. During hours when the Library is staffed information on where a suitable item may be available for use will be available from the staff.
2. Check Returns Shelf - Out of office hours, (and when the staff are not available), visit the Library. When items of equipment are returned to the Library they will normally be checked for cleanliness, correct functionality and safety before being made available for loan again. At evenings and weekends and if stocks of processed items become low returned items that have not been processed may be borrowed again provided they are not marked as being faulty or contaminated. Do not use faulty or contaminated returns. Check carefully before use.
3. Complete Unfulfilled Request Form - If a request to borrow an item of medical equipment cannot be fulfilled at all an Unfulfilled Request Form (available in Med. Equip. Library) should be completed. The data collected from such events will enable the Library to obtain a more accurate picture of medical equipment needs within the hospital and plan ahead to meet those needs.

25 Returning Equipment to the MEL

Before Equipment Leaves the Ward

1. Ensure that medical equipment is cleaned after use following the procedure described under Health and Safety, Decontamination, above.
2. Complete a 'decontamination' certificate and attach it to the equipment.
3. If decontamination of the equipment cannot be assured place the equipment in a plastic bag. Complete a decontamination certificate accordingly and attach it to the bag.

Faulty Equipment

1. Report faulty equipment immediately to MEMS 31333. Clean the equipment and report fault on the decontamination certificate with a brief explanation of the fault.

When Equipment Leaves the Ward

1. Accessories. Ensure all accessories borrowed with the equipment are complete.
2. Return Promptly. Return the equipment and its accessories to the Library as promptly as possible using Ward staff or a porter.

Booking in at the MEL

1. Returns Shelf. At the Library, place the returned equipment on the Returns shelf beside the Library checkout.
2. Library Checkout. Select 'Return' on the checkout touch screen and follow the screens through the process scanning the device label when required.
3. Prompt returns mean that more equipment is available for use by other wards and departments in the hospital!

26 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Medical Devices Strategy Group and ratified by the Medical Director.

Non-significant amendments to this document may be made, under delegated authority from the Medical Director, by the nominated author. These must be ratified by the Medical Director and should be reported, retrospectively, to the Medical Devices Strategy Group

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

27 Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Medical Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

28 Monitoring and Assurance

- MEMS monitors compliance with this procedure and reports the results of this monitoring, by exception and through MEMS Key Performance Indicators to the MDSG and to the Medical Director. Compliance is also subject to annual audit by Internal Audit and the results of these audits are reported to the Medical Devices Strategy Group for action.
- The inventory of Medical Devices is monitored each month by the MEMS Department. Additions and deletions are reported to the Finance Department. This process is audited by the MEMS Department through 6 monthly internal audits and annual external audits in accordance with MEMS ISO9001:2008 Quality System
- Monitoring of all aspects of device maintenance is completed by MEMS through 6 monthly internal audits and annual external audits in accordance with ISO9001:2008 Quality System. Reported through HCST Directorate Board.
- Non-compliance with the Quality System is reported through the 6 monthly ISO9001:2008 MEMS Quality System's Management Review Meetings and any serious non-conformances are escalated to the Medical Device Strategy Group.
- The Board receives reports by exception.

- Management of Health and Safety at Work Regulations 1999.
- BS EN 62353:2014 Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment
- Manual Handling Operations Regulations 1992.
- Workplace (Health, Safety and Welfare) Regulations 1992.
- Personal Protective Equipment Regulations 2002.
- Health and Safety (Display Screen Equipment) Regulations 1992 (amended 2002).
- Control of Substances Hazardous to Health Regulations 2004.
- PHNT Management and Use of Medical Devices Policy, Version 6, March 2017
- PHNT Medical Devices Training Policy, Version 5, January 2015
- Guidelines For The Evaluation Of Medical Devices and Technologies Plymouth Hospitals NHS Trust
- PHNT Medical Devices Strategy Group Terms of Reference, Nov 2010
- Single use medical devices: implications and consequences of re-use MDA DB2006(04) Medicines and Healthcare Products Regulatory Agency
- Reporting Adverse Incidents and Disseminating Medical Device Alerts DB 2011(01). Medicines and Healthcare Products Regulatory Agency
- Managing Medical Devices – April 2015. Medicines and Healthcare products Regulatory Agency
- The Ionising Radiations Regulations 1999, SI 1999/3232 Stationery Office 1999 ISBN 0 11 085614 7
- Health and Safety at Work Act HMSO 1974 ISBN 0 10 543774 3
- Safe Use of Work Equipment, Provision and Use of Work Equipment Regulations 1998. Approved Code of Practice and Guidance L22 HSE Books 1998 ISBN 0 7176 1626 6
- Electricity at Work Regulations 1989 SI 1989/635 HMSO 1989 ISBN 0 11 096635 X
- PHNT Management of Adverse Events Policy, Version 1, May 2012
- PHNT Decontamination Certificate and Fault Report, Issue 4, September 2016
- Medical Devices Directive 93/42/EEC 1993
- Single-Use Medical Devices: Implications and Consequences of Reuse MHRA DB2006(04) v2.0