Livewell Southwest

Medical Devices and Equipment Management Policy

Version No.1.3

Review: April 2019

Notice to staff using a paper copy of this guidance

The policies and procedures page of Intranet holds the most recent version of this guidance. Staff must ensure they are using the most recent guidance.

Author: **Head of Corporate Risk and Compliance**

Asset Number: **425**

Reader Information

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Associated documentation	Risk Management Strategy Infection Prevention and Control Policy Waste (Safe Handling & Disposal of) Policy and Procedure Disinfection & Cleaning Policy Incident Reporting Policy MHRA's Reporting Adverse Incidents & Disseminating Device Alerts Electrical Safety Policy
Supersedes document	Medical Devices and Equipment Management Policy v 1.2
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Document review history

Version no.	Type of change	Date	Originator of change	Description of change
0.1	New document	10/11/13	Assistant Director of Risk and Safety Management	New document.
1	Ratified	27/11/13	Policy Ratification Group	Minor amends.
1.1	Reviewed and Updated	3/2/16	Head of Corporate Risk and Compliance	Minor Amendments
1.2	Reviewed	22/4/16	Head of Corporate Risk and Compliance	Revised Capital Bid Form
1.3	Reviewed	8/4/17	Head of Corporate Risk and Compliance	Revised following redundancy of Equipment Facilitator

Medical Devices and Equipment Management Policy

1 Introduction

1.1 This policy details the roles, responsibilities and processes in place in order to minimise the risks associated with the use of medical devices and other equipment.

1.2 “Medical Devices and Equipment” include such items as beds, commodes, anaesthetic equipment, catheters, diagnostic laboratory equipment, dressings, implants, scanners, surgical instruments, surgical gloves, syringes, X-ray machines, ECG, pulse oximeter blood-gas analysis, defibrillators, ventilators, pressure relief mattresses, communication aids, environmental controls, hoists, orthotic and prosthetic appliances, supportive seating and pressure care, walking aids, wheelchairs. Catheters, dressings, domiciliary oxygen therapy systems, glucose tests, pressure care equipment, syringes, urine drainage systems, stretchers, trolleys, resuscitators etc. This list is not exhaustive.

2 Purpose

2.1 The purpose of this document is to outline a systematic approach to the management of medical devices and equipment across Livewell Southwest. This policy will cover the whole life cycle of medical devices and equipment, including, **procurement, inventory, training, use, decontamination, maintenance, storage, adverse incident reporting and disposal.**

2.2 This document is based upon the guidance contained in DB 2006(05) – Managing Medical Devices, issued by the MHRA (Medicines and Healthcare Regulatory Agency).

3 Duties

3.1 The **Chief Executive** has overall responsibility for all aspects of health and safety, and for policy implementation.

3.2 The **Director of Patient Experience, Safety & Quality** has Board level responsibility for demonstrating compliance with all legislative and other standards which contain requirements relating to medical devices and equipment management.

3.3 The **Head of Corporate Risk and Compliance** is the Livewell Southwest’s MHRA’s Liaison Officer and the Safety Alert Broadcast System (SABS) Liaison Officer. These roles entail taking responsibility for the effective reporting of adverse incidents involving medical devices to the MHRA, and the dissemination of key safety alerts (including Hazard Notices, Device Alerts and Safety Notices) issued by CAS; (Central Alerting System) as well as confirming that appropriate action has been taken by Livewell Southwest to implement each relevant alert. The post holder is also required to review and update this policy.

3.4 The **Head of Estates** is the Livewell Southwest liaison contact with MEMS (Medical Equipment Management Service) and is responsible for developing a

process which ensures that all medical equipment and devices is routinely inspected and maintained according to the Provision and Use of Work Equipment Regulations 1998 and the Lifting Operations and Lifting Equipment Regulations 1998 and ensuring that inspection and maintenance records are retained.

3.5 **Locality Managers, Deputy Locality Manager, Service Managers** are responsible for ensuring that all staff have access to relevant medical device and equipment procedures and guidelines and for ensuring compliance with this policy, training and cleaning practice. Managers will identify an appropriate number of Local Equipment Co-ordinators who will be responsible for maintaining a local inventory of medical devices and equipment.

Managers will be responsible for identifying and arranging all relevant training required for all medical devices and equipment, with the support of the Local Equipment Coordinators.

In addition these managers will facilitate the safe use and storage of equipment across their services / localities, by ensuring processes are in place for identifying, maintaining, cleaning, storing and reporting faults.

3.6 The role of **Local Equipment Coordinators**, who have been identified by their line manager, is to ensure that the implementation of this policy and compliance with best practice can be overseen and monitored in all services that use medical devices and other equipment. Consequently, Local Equipment Coordinators will support their line managers in order to ensure that:

- All medical devices and equipment are procured following the process set out within the policy;
- All medical devices and equipment is recorded onto the ward / department asset register;
- Training is arranged and provided to staff for all new equipment purchased locally;
- Ensuring that update / refresher training is arranged and provided to staff for all existing equipment purchased locally according to the risk as described within the policy;
- Ensuring that training records are held locally for all staff who attend training provided either locally.
- All medical devices and equipment is appropriately maintained (either through MEMS, Livewell Estates Department or through a maintenance contract);
- Maintenance information on the ward / dept. asset register is reviewed and updated;
- Any incidents or problems identified relating to medical devices and equipment are reported in accordance with the Incident Reporting and Investigation Policy.

3.7 **All Staff** (this includes temporary or agency staff, contractors, students, externally hosted staff and others working within the service) have a responsibility to comply with the provisions of this policy, its related codes of practice as they are issued, the advice of their Line Managers and their professional code of conduct. All staff

are expected to report incidents and near misses that relate to the use of medical devices and other equipment in a timely manner according to the Incident Reporting Policy. They will be responsible for reporting any defects immediately and arranging for the isolation of the equipment and subsequent repair.

4 Definition

4.1 The MHRA's definition of a medical device is:

"any instrument, apparatus, appliance, material or health care product, excluding drugs, used for a patient or client for the purpose of:

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

5 Procurement of Medical Devices and Equipment

5.1 Any medical equipment or devices under £5000 (either single item cost or grouped low cost items) must be purchased following Livewell Southwest procurement process using local ward / Dept. / Service funds.

All requests for the purchase of medical devices or equipment over £5000 (either single item cost or grouped low cost items) should be made to the relevant Locality Manager or Head of Service following completion of the Medical Devices and Equipment Bid for Capital Funding form (Appendix B).

5.2 After an item is received from the supplier, it is the signatory's responsibility to ensure that the equipment is correct. It should immediately be sent or taken to MEMS for acceptance testing and registration if appropriate, (see section 10 or details of non MEMS items and maintenance arrangements). If the equipment is non-mobile then MEMS will visit on site.

5.3 No medical device is to be used until it has been accepted and registered by MEMS, or the appropriate department.

5.4 Any new electrical equipment purchased must have an installed date label attached – request via Estates Helpdesk. This will allow the equipment to be used for a period of 12 months before it requires PAT Testing.

5.5 Ensure the item is logged on the local asset register.

5.6 Each item purchased shall have a copy of the relevant manufacturer's user instruction data sheet. This shall accompany the item throughout its working life. Clinical protocols should make reference to the full use of the manufacturer's operating instructions. Please note, however, this instruction may actually be part of the labeling of a device.

5.7 **Donations of Medical Equipment**

5.7.1 The donation of medical equipment whether from charities, patients or their relatives will not be accepted by Livewell Southwest. This includes wheelchairs.

5.7.2 Funds raised by charities and friends of Livewell Southwest for the purchase of medical devices by the Livewell Southwest may be accepted. Devices subsequently purchased will be subject to the above procurement and registering procedures.

6 Inventory/Asset Register of Equipment

6.1 Local service managers are responsible for keeping a local data base of equipment, this must be reviewed and managed locally. Local Equipment Coordinators can support managers with this. This will enable:

a) A device that is subject to a recall to be traced in a timely fashion;

b) The service to assist MEMS and the LSW Estates Department in the process for statutory maintenance, safety checks and replacement/disposal programmes and planned audits;

c) Planned preventative maintenance to be carried out and recorded;

d) To reflect any staff or equipment changes.

7 Risk Driven Training

7.1 The Organisation requires that staff should only use equipment that they are competent and confident to use and that it is within the scope of their practice. Staff should not use equipment for which they have not received training.

Grading of Medical Devices for Risk & Training Purposes

a) **High Risk Device** - medical devices whose failure or misuse is reasonably likely to seriously injure or kill patient or staff.

Training for devices deemed as **High Risk** should be delivered by the manufacturer or designated trainer. Training should be annually or more frequently if the device is not used on a regular basis.

b) **Medium Risk Device** - medical devices whose misuse, failure or absence (i.e. out-of-service) with no replacement available would have a significant impact on patient care, but would not be likely to cause direct serious injury.

Training for devices deemed as **Medium Risk** may be taught by a person competent in the use of the equipment. Training for these devices should be on an annual basis where reasonably practical.

c) **Low Risk Device** - medical devices whose failure or misuse is unlikely to result in serious consequences.

A member of staff can learn from an experienced colleague or from the manufacturer's instruction manual for those items considered to be **Low**

Risk. Training should be on a regular basis for these devices.

7.2 Managers should identify the equipment and the users of that equipment within their areas of responsibility and identify their ongoing training needs. A user self-assessment form is attached as Appendix A, whilst not mandatory; some managers may find this helpful in making decisions regarding training.

7.3 Managers will record which levels of staff are authorised to use each piece of equipment. This will form the basis of the **training needs analysis**.

7.4 The training needs analysis must be recorded locally along with all associated training provided for each staff member. Training records that demonstrate those authorised to use equipment have been trained to the appropriate level based on the risk attached to the equipment may be required for investigations into incidents or claims.

7.5 Training needs for all staff should be identified at local induction and through Individual Performance Review and supervision processes. Agency or locum bank staff and students will be required to keep their portfolios/training logs up to date and available to be seen by the manager in charge of any area they are sent to work. Any training needs should be identified and supported.

7.6 The Corporate Risk and Compliance Team and / or the Manual Handling Advisor can advise managers regarding the allocation of a risk grade for all new equipment purchased

8 Safe Use of Equipment

8.1 To ensure the safe use of all medical devices staff must undertake the following before using any device:

a) Always visually check the device for signs of damage or incorrect setting before each use and ensure it is within service check dates.
b) If the device requires disposable attachments ensure that the correct ones for the device are used.
c) Do not use equipment you are not trained or competent to use.
d) Take responsibility for seeking training or declaring the lack of it to your line manager. Be familiar with the manufacturer's instructions, local user manual, etc, know where they are held and that they are readily available.
e) Ensure device is cleaned to an acceptable standard, and in accordance with the manufacturer's data sheet and Livewell Southwest Infection Prevention and Control Policies.

8.2 **Storage and Safekeeping of Medical Equipment**

When not in use, medical equipment must be suitably stored taking into account Health & Safety, Infection Prevention and Control Policies & manufacturer's instructions. The following should be considered:

a) Physical – temperature, humidity, safe from damage.
b) Security – locked cupboard/room.
c) Power supplies – maintain charged batteries, protect and look after leads/cables applicable to the device.

d) Segregation of clean and contaminated equipment.
e) Segregation of faulty and maintained equipment.
f) Accessibility – easy and ready to use access.

8.3 Any item that appears to be faulty or is awaiting repair must be taken out of service and a notice affixed stating, “Do not use” and quoting the action being taken. This notice should be dated and the name of the person removing should be noted clearly.

8.4 **What do I do when things go wrong**

Any incident involving the use of medical devices must be reported in line with the Livewell Southwest’s Incident Reporting and Investigation Policy and the current MHRA “Reporting adverse incidents and disseminating medical device alerts”, issued annually as a Device Bulletin. If in any doubt contact the Corporate Risk and Compliance Team.

8.5 Where a medical device is involved in an incident it must be suitably labelled, quarantined and stored securely until it is declared safe to use or disposed of.

9 Decontamination of Equipment

9.1 The Livewell Southwest Infection Prevention and Control Policy outlines the procedure for the safe use of medical devices this should be used in conjunction with the manufacturers and MEMS guidelines.

9.2 It is the user’s responsibility to ensure that medical equipment is properly cleaned/decontaminated before, during and after use.

9.3 When equipment is to be returned to a manufacturer, MEMS or Estates Department, the sender must ensure that it has been properly decontaminated and has a decontamination /fault report label attached with the necessary decontamination section completed. These labels are available on the organisations intranet or from the infection prevention and control team.

9.4 If an item of equipment is or could be contaminated internally and cannot be adequately cleaned then this fact must be reported on the decontamination/fault report label to whoever is to undertake the work.

9.5 It is an offence to send contaminated equipment through the postal or transport system.

9.6 The cleaning and decontamination of community equipment is the responsibility of the Service Provider and needs to be compliant with DoH-MHRA DB2003 (06) ‘Community Equipment Loan Stores’ 2003.

10 Single Use Items

10.1 Definition of Single Use Items

Definition of what is a single use item is not straightforward. Manufacturers have a responsibility under British and European Law to determine where a product

cannot be re-used for reasons of safety. These may include:

- A lack of appropriate cleaning/decontamination methods.
- Inability to provide the user with information on pre-use checks.
- Being unable to guarantee consistent performance during re-use.
- Concerns over control of infection.
- Lack of definition over the life span of the item.

Single use items have often contained limited or non-specific information about the use of the product, such as:

- "Single use" means that it can only be used once.
- "Do not re-sterilise" means it must not be cleaned/decontaminated for the purposes of re-use.
- "Single patient use" means that it might be suitable for re-use on the same patient.

If staff are in any doubt about the use of an item they must clarify it with the manufacturer before it is used/reused.

10.2 Packaging and Labeling

Is a symbol that may appear on packaging signifying that the product is intended for single use only and must not be re-used.

10.3 The External Standards

The Medical Devices Agency, which is an executive agency of the Department of Health, and is part of the Medicines and Healthcare Products Regulatory Agency (MHRA) re-issued a bulletin in August 2000 (originally issued in 1995) warning of The dangers of reusing single use items.

It states that:

- Devices designated for 'single-use' must not be reused under any circumstances.
- 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.

The bulletin above is now reinforced, by the implementation of the European Council's Medical Devices Directive, into UK law.

The Department of Health (HSC 1999/179) Action of this document requires that staff 'Never reuse medical devices for single-use.'

Under the Health & Safety at Work Act 1974 and Provision & Use of Work Equipment Regulations 1998 LSW would be committing an offence by simply re using a designated single-use item, regardless of whether it is safe.

10.4 Use of Medicines

Medicines must be considered as single use items unless the label and / or the supporting manufacturers guidelines clearly state that they have been prepared as multi-dose items. A risk assessment must be carried out (in conjunction with Pharmacy) for each individual product.

10.5 Exceptional Circumstances

In exceptional circumstances a decision might be taken to re-use items that have been identified as single-use. This will only be allowed to happen **once** a comprehensive risk assessment has been carried out at the point of use, **and** the Livewell Southwest Board, through the Operational Safety, Quality and Performance Committee, has agreed to accept responsibility on behalf of Livewell Southwest for any legal liabilities and/or associated risks that may arise.

The assessment should clearly lay out any risks to the patient.

Any risk assessments must be documented on the LSW Risk Register.

11 Maintenance and Repair of Equipment

11.1 It is of paramount importance that the ward/department inventory/asset register is kept up to date. It is the accuracy of this register that will ensure the regular scheduled maintenance of equipment in a timely manner, whether that is by the MEMS service, Livewell Southwest estates Department or other provider.

11.2 All devices will be maintained in accordance with the manufacturer's instructions and MEMS/other provider's advice. It is the department/unit/service managers' responsibility to ensure that approved maintenance is carried out at prescribed times and a record kept.

11.3 Managers should ensure that there are appropriate arrangements made for the maintenance and repair of equipment when the manufacturer's warranty expires.

11.4 **Medical Equipment Management Service (MEMS)**

The MEMS contract provides for the regular maintenance and repair of each item of medical equipment registered with them.

11.5 Medical devices used or intended to be used by any Livewell Southwest employees shall first be registered at Medical Equipment Management Service (MEMS) based at Derriford Hospital. Each device will have a label affixed showing a unique number and the due date of its annual inspection. If

electrical, this is also its PAT date.

11.6 MEMS are contracted to provide a wide reaching service to Livewell Southwest on all aspects of medical devices through an annual Service Level Agreement (SLA). It is therefore essential that MEMS be involved at all stages throughout the life of the equipment from procurement to disposal. This SLA will be reviewed annually by the Director of Finance.

11.7 **Removal of items from MEMS contracted repair**.(see also disposal section 15)

Items of equipment registered with MEMS that are, for whatever reason, no longer required, must be notified to MEMS and removed from local asset registers/inventories.

11.8 **Maintenance of Equipment not covered by the MEMS contract.**

Whilst the MEMS contract will provide maintenance and repair for the majority of equipment owned by the Organisation, some items, for instance beds, some physio equipment, fans, fridges etc will not fall within this contract. The ward/department inventory/asset register will identify the maintenance provider (either external maintenance contract or through LSW Estates Department).

11.9 It will be the responsibility of the **purchaser** to identify the maintenance requirements and provider as part of the procurement process. This will enable the purchaser of equipment to register it on arrival as appropriate.

12 Prescribing Medical Equipment (also see Section 13, Community Equipment).

12.1 Health and social care professionals are personally accountable when prescribing equipment for ensuring that service users and carers have received appropriate training and demonstration in the use and maintenance of the device provided (MDA Devices in Practice 2001).

12.2 Any person who prescribes medical equipment for use by a patient or carer must be qualified to do so and must ensure that due consideration is given to disability issues.

12.3 Any maintenance and repair arrangement that may be required during the issue period of the equipment must be made clear to the recipient at the time of issue in writing and comply with manufacturer's instructions. Written guidance must cover the following:

a) the name of the device
b) the safe operation and control of the device
c) how to check the device whilst in use
d) how to recognise a device failure or fault
e) what action is to be taken in the event of a failure or fault
f) individuals to be contacted in an emergency
g) suitable storage arrangements

12.4 Any instructions issued with the equipment must be adequate for the knowledge

level of the end user/carer and a signed receipt confirming their understanding must be held. These instructions should include methods of decontamination.

12.5 A local record must be kept of all equipment issued and returned, both for effective device accountability and to provide evidence that the device has been maintained. This ideally should be a computer-based system.

12.6 With regard to devices issued individually on long-term loan, Livewell Southwest remains accountable for the collection of these items when they are no longer needed. It is essential that individuals are aware of the role they play in the management of the devices.

12.7 Those clinicians responsible for the prescribing of medical devices for a patient's use will consider the ability of the user and the suitability of the device for the user.

13 Community Equipment (also refer to Section 12, Prescribing Medical Equipment)

13.1 It is the responsibility of the Community Equipment Service (CES) Manager to ensure that the CES Service Provider operates in accordance with the service specification and contractual agreement.

13.2 It is the responsibility of the CES Service Provider to ensure that adequate records are kept of all items of equipment that is loaned to a patient or carer.
These records should include:

a) Unique identification
b) Description – make/model
c) User/carer details, name & address
d) Maintenance requirements and dates
e) Issue and return dates
f) Signed receipts
g) Replacement due dates/equipment life cycle

13.3 Any person who prescribes medical equipment for use by a patient or carer must be qualified and appropriately trained. Clinicians must ensure that due consideration is given to disability issues and appropriate risk assessments are undertaken.

13.4 It is essential that service users and carers receive appropriate demonstration in the use and maintenance of the equipment and have been given appropriate written guidance which supports the use of the device. This guidance should include:

a) The name of the device
b) Operating instructions – manufacturers and care of the device
c) Acceptable and appropriate use of the equipment
d) Action to be taken by them in the event of a device failure or fault
e) Emergency contact details
f) Suitable storage arrangements

13.5 It is the responsibility of each clinical Service Manager to ensure that a record

of staff training is maintained for assessment, application and demonstration of equipment where appropriate.

13.6 There is an expectation that individual professional groups will have relevant core knowledge and understanding of the equipment that they are responsible for.

13.7 Any equipment used for assessment or short-term loan must be bagged during transit and returned to the store for decontamination in accordance with relevant Health & Safety and Infection Prevention and Control Policies. This also applies to equipment being taken and returned by clinicians to the satellite stores.

13.8 It is the responsibility of the CES Service Provider to maintain and repair equipment in accordance with the manufacturer's instructions and keep comprehensive records.

13.9 With regard to specialist equipment, it is the clinicians' responsibility to identify the equipment needed to meet the client/carer need and the Service Provider to source, procure, transport and fit as necessary.

13.10 Suitable storage facilities shall be provided by the CES Service Provider to store medical equipment in line with current H & S, Infection Prevention and Control Policies and manufacturer's instructions.

13.11 The Service Provider in accordance with the contract and Livewell Southwest policies will dispose of all medical equipment. Clinicians are to ensure that the Service Provider collects equipment for disposal and a record made.

13.12 Temporary loans of equipment may be necessary under certain circumstances but only within legislative guidelines.

14 Loaning Equipment within Livewell Southwest

14.1 It is the responsibility of local managers with support from their Local Equipment Coordinators to ensure that a record is kept of any equipment that is loaned to another ward or department by recording on the local asset register / inventory. This ensures both that the location of the equipment is always known and that the responsibility for it is transferred at time of loan.

14.2 Managers are responsible for the review of items out on loan on a regular basis to ensure that equipment that is no longer in use is returned to the original owner.

14.3 When the equipment is returned from loan the manager should ensure that it has been decontaminated and is functioning correctly before going into service and the asset register amended accordingly.

15 Loaning Equipment Outside of Livewell Southwest

15.1 No equipment shall be loaned outside of Livewell Southwest without approval of Locality Managers / Heads of Service. All such equipment will be recorded in the local asset register / inventory to ensure the equipment is returned and in an appropriate condition.

16 Devices on Loan from a Manufacturer or Other Source

16.1 Any device on loan from a manufacturer, supplier or another hospital should be subject to a written agreement that defines the device management requirements, responsibilities and liabilities.

16.2 Delivery, receipt and pre-use procedures for loaned equipment should be the same as for purchased equipment unless otherwise specified in the written agreement.

16.3 In addition equipment on loan to Livewell Southwest must not be transferred from the site that received it without first ensuring it is within the agreement of the supplier to do so.

17 Disposal of Equipment

17.1 Any item of equipment always remains a Livewell Southwest asset even when it is no longer required, redundant or beyond economic repair. Equipment that is clinically or technically obsolete or surplus may have some residual value. Such equipment shall be disposed of in a way that maximises the financial return to the Livewell Southwest.

17.2 No item that is registered at MEMS shall be disposed of without first referring to section 10.6 of this document.

17.3 Equipment no longer wanted by the Organisation and still in safe working order can, exceptionally, be offered to a charitable cause after getting approval from Locality Manager / Head of Service and an appropriate disclaimer for future liability signed, See Appendix D

17.4 All equipment for disposal shall be disposed of following discussion with the LSW Estates Department who will arrange via MEMs for it to be disposed of in accordance with the Livewell Southwest Waste (Safe Handling & Disposal of) Policy and the Waste Electrical and Electronic Equipment Regulations 2007 (WEEE).

18 Monitoring Compliance and Effectiveness

18.1 Local Managers / Heads of Service will ensure that annual audits of their local Asset Registers / Inventories are undertaken.

All policies are required to be electronically signed by the Lead Director. Proof of the electronic signature is stored in the policies database.

The Lead Director approves this document and any attached appendices. For operational policies this will be the Locality Manager.

The Executive signature is subject to the understanding that the policy owner has followed the organisation process for policy Ratification.

Signed: Director of Professional Practice, Safety & Quality

Date: 1st March 2016

Appendix A

Medical Devices and Equipment Self-Assessment - How Safe is Your Practice?

Before using a medical device or other piece of equipment, ask yourself the following questions:

	Yes	No
Do I know how to handle the medical devices in my unit?		
Have I been given appropriate training, instruction and supervision in order to use this piece of equipment safely?		
Was my competency to use this equipment safely assessed?		
Has the equipment been serviced and maintained appropriately and is this recorded?		
Do my junior staff colleagues know how to use equipment?		
Am I aware of the cleaning and/or decontamination procedure for this device and my responsibilities in this process?		
Can I safely use this equipment by myself?		
Do I know who to contact if there is a fault with the equipment in my organisation?		
Do I know how to report an adverse incident or near miss?		
Do I know who my MHRA Liaison Officer is?		
Do I have access to MHRA Device Bulletins of relevance to my area of practice and do I read and take note of Hazard and Safety Notices?		

Wherever “no” has been ticked, information/training/support is required.

It is your personal responsibility to report these shortfalls to your Line Manager.

From “MHRA Equipped to Care, 2000, a guide for health care professionals, support workers and managers”.

MEDICAL DEVICES AND EQUIPMENT BID FOR FUNDING

To be completed by relevant Service Manager – NOTE ALL BOXES MUST BE COMPLETED OTHERWISE THE FORM WILL BE RETURNED

TITLE OF BID:	**SERVICE MANAGER TITLE:**
DATE SUBMITTED:	**LOCALITY:**

1. Description of Equipment Required

2. Suppliers and Quotes – (please give all so that we have competitive information)

1.

2.

3.

4.

3. Maintenance Arrangements (Supplier maintenance contract / MEMS / LSW Estates Dept / Other)

Give details of maintenance arrangements

Is the maintenance cost included in the quotes above? **Y / N**
If not, give details of cost below:

4. Training Arrangements

Give details of training required – type, frequency and supplier

Is the training cost included in the quote? If not, give details of cost below:

5. Reason for this request: (e.g. replacement, increase in service users)	

6. Risks – give details (indicate the risk level for each risk domain identified using the NPSA Scoring Matrix):	*Risk Level – Low, Moderate, High*
Safety of Patients, Staff or Public:	
Quality / Complaints / Audit:	
Human Resources / Organisational Development / Staffing / Competence:	
Statutory Duty / Inspections:	
Adverse Publicity / Reputation:	
Business Objectives / Projects:	
Finance (including claims):	
Service / Business Interruption / Environmental Impact:	

7. Urgently Required Yes/No
Please give details

8. Consequences of Not Funding the Project:

9. Delivery Address

10. Any on-going revenue implications / savings?:

APPROVAL BY LOCALITY/DEPUTY LOCALITY MANAGER/HEAD OF SERVICE

Name: …… **Title:** ……

Signed: …… **Date:** ……

Appendix C
Local Equipment Coordinators Guidance

LOCAL EQUIPMENT COORDINATORS

ROLES AND RESPONSIBILITIES

The role of the Local Equipment Coordinators who have been identified by their line manager, is to ensure that their local team / service / department complies with the requirements of the Medical Devices and Equipment Management Policy and that the requirements of this policy are implemented at a local level – specifically:

- Ensure that all medical devices and equipment are procured following the process set out within the policy;
- Ensure that all medical devices and equipment is recorded onto the ward / department asset register / inventory;
- Ensure that training is arranged and provided to staff for all new equipment purchased locally;
- Ensure that update / refresher training is arranged and provided to staff for all existing equipment purchased locally according to the risk as described within the policy;
- Ensure that training records are held locally for all staff who attend training provided either locally or by external provider;
- Ensure that all medical devices and equipment is appropriately maintained (either through MEMS, Livewell Estates Department or through a maintenance contract);
- Ensure that maintenance information on the ward / dept. asset register is reviewed and updated;
- Ensure that any incidents or problems identified relating to medical devices and equipment are reported according to LSW Incident Reporting and Investigation Policy.

Appendix D

Disclaimer for Future Liability

Date

Livewell Southwest
Mount Gould Local Care Centre
200 Mount Gould Road
Plymouth
PL4 7PY

Waiver, Release and Assumption of Risk Agreement

Livewell Southwest has gifted the equipment described below to the organisation / individual(s) named below.

Equipment:

Organisation / Individual Name and Contact Details:

The organisation / individual named above will assume all risk associated with the use of the equipment listed above.

Agreement:

I agree to accept all possible known and unknown risk associated with using the equipment. I agree, to the fullest extent of the law, to indemnify and hold harmless and to waive any and all claims that I have or may have in the future against Livewell Southwest resulting from the use of the equipment. I agree to the fullest extent of the law to release, indemnify and hold harmless Livewell Southwest from any and all

liability for injury, loss, damage, death or expense that I or my organisation may suffer as a result use of the equipment, due to any cause or reason whatsoever, including, without limitation, any negligence or breach of contract in the manufacturing, assembling, design, maintenance, selection, sale, adjustment, modification of the equipment.

I have read and understood this agreement and I am aware that by accepting the equipment from Livewell Southwest, I am agreeing to all aspects of this agreement and that by doing so, I may be waiving certain rights, including the right to sue Livewell Southwest and / or its associated directors or employees.

Print Name:

Signature:

Date: