ME.02 – Management of Reusable Medical Devices and Equipment Policy

Document Summary
Reusable medical devices and equipment play an increasingly important role in the assessment and management of patients in clinical practice today. The Trust expects all staff (including staff working on behalf of the Trust) to adhere to the principles outlined in this policy before using any reusable medical devices or equipment.

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Date Ratified	April 2021
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Next Review Date	April 2026
Accountable Director	Director of Nursing
Document Author(s)	EBME Manager

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Document Submission Cover Sheet

Committee / Group Name: Infection Prevention Committee

Please choose **New Document** ○ **Revised Document** ◉

Type of Document	Policy	*If other state:*
Reason for submission ☒:	For Approval ☒	For Ratification ☒ For Noting ☐

Applicable to ☒: **Trust Wide** ☒

Division: Surgical ☐ Medical ☐ Integrated Care ☐ Clinical Support ☐

Directorate / Specialty *give detail* _____

Document Title: *(succinct & key word first)*	Management of Reusable Medical Devices and Equipment Policy		
Your Ref No:	ME.02	**Version:**	2.1
Author(s) Name:		**Designation:**	EBME Manager
Date submitted:	November 2020		

Reason for producing the document	Revision of existing policy
References used in document production	See references section
List of contributors *Detail name(s) and designation of contributors or those consulted*	Medical Devices Committee Infection Prevention Control Team Consultant Microbiologist
Review of document prior to submission *Detail name(s) and designation*	Environment and Information Manager & Lead Infection Prevention Nurse

For Quality and Safety Use Only

Content checked ☒	Date Email sent to author/secretary to add to committee agenda 15/02/2021

For Committee Use Only

On agenda for Meeting on: 23/03/2021

Meeting Outcome

Document for Approval: Infection Prevention Committee

Approved ☒	Committee Document Number assigned *(item number from Minutes)*: n/a Returned to Author by e-mail on n/a	
Not approved ☐	Feedback to author:	Sent by e-mail: Click here to enter a date.

Document for Ratification: Policy Review Group 23/04/2021

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Not Ratified ☐	Feedback to author:	Sent by e-mail: Click here to enter a date.

Document for Noting:	Noted ☐	No further action

Committee Comments:	

For Policies only – to go to Policy Team

Final version Word document, Cover Document and minutes to be sent to Policy Team

DOCUMENT HISTORY

Issue Status e.g. Draft or Final	Catalogue and Version Number	Document Title	Date	Actioned by: (Job Title)	Page/ Section/ Paragraph	Comments
New draft	ME02 V0.1	Management of Reusable Medical Devices and Equipment Policy	January 2018	EBME Manager	All	Revised policy total rewrite
Ratified	ME02 V1.0	Management of Reusable Medical Devices and Equipment Policy	January 2018	Medical Devices Committee	All	Ratified
Final	ME02 V2	Management of Reusable Medical Devices and Equipment Policy	Novembe r2020	EBME Manager	All	Reviewed, very minor changes and modified to fit new template
Final	ME02 V2.1	Management of Reusable Medical Devices and Equipment Policy	May 2021	EBME Manager	All	Revised 5.6 from Estates Department Helpdesk to Medical Engineering Helpdesk.

TABLE OF CONTENTS

1 SCOPE

This policy applies to all reusable medical devices and equipment used on Wye Valley NHS Trust premises or property and is applicable to all staff within Wye Valley NHS Trust. It also applies to reusable medical devices supplied by Wye Valley NHS Trust for use on patients in their own homes.

2 INTRODUCTION

Reusable medical devices and equipment plays an increasingly important role in the assessment and management of patients or clients in clinical practice today. The term “reusable medical devices and equipment” covers a broad range of products and can be defined as any instrument, apparatus, appliance, material or health care product, excluding drugs, used for a patient or client for the purpose of:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease.

2. Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap.

3. Investigation, replacement or modification of the anatomy or of a physiological process.

4. Investigations used in the vicinity of a patient or client.

Some examples of reusable medical devices and equipment are anaesthetic machines, scanners, surgical instruments, ECG monitors, pressure relief mattresses, ventilators, defibrillators, syringe drivers, volumetric infusion pumps, blood pressure systems, pulse oximeters, thermometers, glucose test meters, x-ray machines and wheelchairs.

3 STATEMENT OF PURPOSE

The Trust relies upon a large stock of reusable medical devices and equipment in order to carry out its primary function of patient care. This policy is based upon the requirements of the Medicines and Healthcare Products Regulatory Agency (MHRA) Device Bulletin DB 2006(05) ‘Managing Medical Devices’, the Healthcare Commissions Standards for Better Health, standard C4b, the NHS Litigation Authority (NHSLA) Risk Management Standards for Acute Trusts and the Care Quality Commission (CQC) Guidance, Outcome 11, as well as other national and international standards.

Wye Valley Trust will follow MHRA guidance and manufacturers/suppliers recommended ‘best practice’ in the management, use and decontamination of all reusable medical devices and equipment unless there is a specific, recorded and risk assessed reason for not doing so.

Within the Trust there are many pieces of equipment that fall within this definition. Usage is commonplace and often training is part of a professional’s education.

All staff must ensure they are competent in the appropriate and effective decontamination of the equipment in line with the manufacturer’s guidelines for the procedure and cleaning products used, and for ensuring the equipment is labelled as decontaminated appropriately afterwards.

4 DEFINITIONS

Reusable Medical Device or Equipment: 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.
- Investigations used in the vicinity of a patient or client.

5 DUTIES

The Trust has a structure that allows individuals to know where they assign responsibility into the organisation. In relation to reusable medical devices and equipment, the structure is as follows.

5.1 Chief Executive

The Chief Executive has overall responsibility but delegates work to specific 'directors'.

5.2 Director of Nursing (Director of Infection Prevention Control)

The Director of Nursing (Director of Infection Prevention Control) has to ensure the Trust has a safe system and process in relation to the management of reusable medical devices and equipment, including decontamination.

The Director of Nursing has to ensure the Trust has a safe system and process in regard to health and safety, including training in relation to reusable medical devices and equipment.

5.3 Director of Strategy

The Director of Strategy is the director with line management responsibilities through to the Electro Bio Medical Engineering Manager as well as the Executive Director responsible for all Estates functions.

5.4 Electro Bio Medical Engineering Manager (EMBE)

The EBME Manager has responsibility for ensuring the Trust has an up to date inventory of reusable medical devices and equipment, including details of any maintenance that has been carried out or is due.

5.5 Medical Engineers

The Medical Engineers carry out repairs and maintenance to ensure reusable medical devices and equipment are fit for purpose and detailed records are maintained on their database.

5.6 Medical Engineering Help Desk

The Medical Engineering Help Desk will enter requests for maintenance e.g. repairs, planned preventative maintenance or commissioning of new reusable medical devices and equipment, onto the database. The job request will then be assigned to a Medical Engineer electronically via the database.

5.7 Procurement Department

The Trust Procurement Department will notify the Medical Engineers and the Infection Prevention Team (IPT) of any pending purchases of reusable medical devices or equipment. The EBME manager and Procurement manager will meet regularly to discuss new medical devices and equipment purchases to try and ensure nothing new has been introduced without having gone through the property procedures.

5.8 Ward/Department Managers

Ward or department managers need to have an awareness and understanding that appropriate maintenance and decontamination has taken place on every piece of medical equipment for which they are responsible. They also need to make the equipment available for maintenance to take place and may also need to be responsible for ensuring that any contracted maintenance, not carried out by the Medical Engineers, is carried out.

Managers must ensure that all appropriate staff have received the appropriate training on the safe use and effective decontamination of the equipment.

5.9 Department User Representatives

Department User Representatives (DUR), as recommended by MHRA, need to be nominated for each department. The DUR will help to improve co-ordination between departments over the use and sharing of reusable medical devices and equipment and to assist in scheduling maintenance, with the EBME department, for their department area.

5.10 Infection Prevention Team

The Infection prevention service will support the procurement team and the EBME in reviewing the pre purchase questionnaire (PPQ), supplied by the Procurement Team, to clarify the decontamination requirements and confirm item suitability.

Infection prevention advice will be provided by the IPT following a review of the submitted PPQ completed by the department in advance of any reusable medical devices and equipment being purchased.

5.11 All Staff

All staff using reusable medical devices and equipment have a duty of care to ensure their actions do not compromise their patient(s), themselves or others.

The safety of patients and staff is paramount at all times. It is the responsibility of all users to ensure that medical equipment is used in such a manner that the patient(s), visitors or any other person is not put at risk.

1. All staff must ensure they are competent in the safe use and effective decontamination of any equipment they use.

2. All staff must take responsibility to seek training or declare lack of it by advising senior staff, clinical trainers and/or the resuscitation officer.

3. All staff must know where the user manual or training information is held for devices and equipment within the area they are working. Information may also be available via the intranet on the ‘Clinical User Manuals’ website or via the Medical Engineers (EBME).

If in doubt as to whether a reusable medical device or equipment has been maintained, contact the Medical Engineers on 01432 364440 or extension 4440 before using it.

No worker in this organisation should modify or alter the function or capability of a medical device or equipment. EBME staff are the only authorised personnel allowed to carry out modifications to reusable medical devices.

6 DETAILS OF THE POLICY DOCUMENT

6.1 Maintenance and Repair

This policy contributes to the Trust's compliance with the National Health Service Litigation Authority (NHSLA), Criterion 5 – Acute, Community and Non NHS Providers, Subsection 4 'Maintenance of Medical Devices and Equipment'. Reusable medical devices and equipment have to be maintained at regular intervals as laid down by manufacturers, suppliers or their agents and the Medicines and Healthcare Products Regulatory Agency (MHRA). Users have a duty of care under the Health and Safety at Work Act 1974 (HSWA 1974) to ensure that the reusable medical devices and equipment they use is in a good state of repair and that it is suitable for the purpose required of it.

It is essential that all reusable medical devices and equipment is safe for use on patients. All reusable medical devices and equipment must be accurately calibrated, where applicable, especially in relation to patient treatment or diagnosis. Advice on necessary standards can be provided by EBME. All routine 'planned preventative maintenance' (PPM) will include a function check and electrical safety test, where applicable. Accuracy and calibration checks may also be carried out, if applicable, and details logged on the appropriate technical procedure note (TPN) paperwork. If there is any doubt, contact the Medical Engineers immediately and withdraw the item from use, label it with a red 'Danger Do Not Use' label and inform the EBME helpdesk on 01432 364440 or extension 4440. The Medical Engineers will then respond accordingly with the appropriate action. Users must also try to accommodate the Medical Engineers or third party service personnel when it comes to accessing reusable medical devices and equipment for maintenance, be it at their bequest e.g. a breakdown or for scheduled PPM work. Key Performance Indicators (KPI's) will be drawn up and used as an 'assurance tool' which will be reviewed at the Medical Devices Committee (MDC).

6.2 Decontamination of Medical Equipment

All staff are required, in accordance with criterion 2 of the Health and Social Care Act 2008, to ensure they are decontaminating reusable medical equipment in the appropriate location, using the procedures and products compliant with manufacturers' guidelines and Trust policies. Staff must be competent in these procedures and the record keeping must be compliant and appropriate.

6.3 Inventory

A comprehensive database of reusable medical devices and equipment will be maintained within the EBME Department and the database will show clearly the frequency of maintenance required for each individual reusable medical device and equipment item, and who will carry out this work. Electronic records will be updated by the Medical Engineers every time any work is carried out on a reusable medical device or equipment. All paper records e.g. electrical safety test results, TPN, photos will be uploaded and stored electronically.

6.4 Purchase of New Reusable Medical Devices and Equipment

An important aspect of ensuring that risks are minimised with the use of new reusable medical devices and equipment is to ensure that staff are familiar with the equipment available. This can be achieved through training but also through standardising the reusable medical devices and equipment in the Trust. To achieve this, purchases of new reusable medical devices and equipment must conform to the Trust standard which is being achieved through Finance and Procurement Department mechanisms i.e. Capital Planning Equipment Committee (CPEC). Prior to the purchase of the equipment the IPT must be consulted with to ensure the manufacturers' recommendations are compatible with compliant Trust processes and products.

Items will not be authorised until IPT, EBME and Decontamination Lead (if appropriate) agree and sign off PPQ.

6.5 New Types of Reusable Medical Devices and Equipment

As technology advances and members of staff develop and learn new techniques, new types of reusable medical devices and equipment will be needed in the Trust to support these developments. In these cases, it is essential that all staff will be provided with the appropriate level of training by the relevant appointed trainer. Before introducing any new types of reusable medical devices and equipment the user must ensure that the Procurement Department and EBME Department are informed first. This will ensure suitable training for both users and maintenance personnel (if applicable) can be provided. Supporting documentation e.g. case of need forms, waivers, PPQ should be forwarded to the Procurement Department and EBME Department.

6.6 Reusable Medical Devices/Equipment for Use by Patients and/or Their Families

It may be part of a patient's clinical management that the patient and/or their families need to be trained in the maintenance of particular equipment. This must be done to suit the individual needs and requirements. Verbal instructions should be complemented by clearly written advice. Contact numbers of where advice and help can be sought, particularly in an emergency, must be given verbally and in writing to patients and their families. Information about how and where to return equipment for maintenance, if it is necessary for someone else to carry out e.g. Medical Engineers, external contractor, must also be completed.

6.7 Safety and Incidents

In the event of an incident occurring which involves a reusable medical device or equipment; this must be reported according to the Trust's Incident Management Policy (HS05).

All 'Medical Device Alerts' and 'Field Safety Notices' sent from the MHRA, manufacturers, etc. will be centrally dealt with through the Central Alerting System (CAS) Administrator.

EBME will analyse this information and, where relevant to reusable medical devices and equipment logged on their database, advise the Health and Safety Office.

EBME may receive manufacturer's safety or modification instructions and will ensure that they are implemented with appropriate urgency for any items of reusable medical devices and equipment for which they are responsible.

6.8 Disposal

At the end of the life of reusable medical devices and equipment, it is disposed of in a controlled manner. This will include:

a) Informing EBME of the disposal in order to keep their database accurate.

b) Arranging disposal with the appropriate department, e.g. EBME or Environmental Services, having first decontaminated the equipment in the appropriate manner and issuing a decontamination certificate with the equipment.

c) Where there is an inherent hazard in the equipment, such as defibrillators, that equipment is rendered harmless.

d) Where electrical equipment is involved it will conform to Waste Electrical and Electronic Equipment regulations. See IG.19 IT Equipment and Digital Disposal Policy.

e) Where a microbiological or chemical hazard exists, equipment is suitably decontaminated or otherwise safeguarded before disposal.

f) Where possible, residual value of equipment is retained through appropriate routes, such as through auctioning.

g) When equipment is disposed of, there is a process in place to remove liability from the Trust.

7 TRAINING

Medical devices must only be used or operated by a member of staff who has been suitably trained and who feels confident and is competent to do so (as per ME04. Medical Devices Training Policy).

The Trust recognises that it has a role to play in ensuring that members of staff are able to use the available reusable medical devices and equipment for the benefit of themselves and the patients in their care.

The training and update requirements for the use of reusable medical devices and equipment apply to all staff. This applies to permanent members of staff and temporary staff e.g. bank, agency or locum staff. No member of staff may operate any reusable medical device or equipment unless they and their immediate supervisor are confident that they are completely competent in its use.

Staff competency will be evaluated by a senior member of the ward or department team, or other competent person delegated to do so by the ward or department manager.

All staff must attend any training courses that the Trust requires before they use any reusable medical devices and equipment. Until they have successfully completed the identified training, and have been assessed as competent, they may only operate the reusable medical devices and equipment under supervision.

Staff must be trained in the decontamination processes required for the equipment to the appropriate level required for the individual equipment.

All staff are required to comply with the Health and Safety at Work Act 1974 (HSWA 1974) and the Provision and Use of Work Equipment Regulations and Lifting Operations and Lifting Equipment Regulations 1998 (PUWER-LOLER), which place a statutory requirement on employers and employees to ensure that they are trained to use any work based equipment. The importance of medical equipment training is also identified by the MHRA, NHSLA and the CQC. Reusable medical devices and equipment are work based equipment and are included in the Trust's mandatory training matrix.

8 MONITORING COMPLIANCE WITH THIS DOCUMENT

The table below outlines the Trust's monitoring arrangements for this document.

Aspect of compliance or effectiveness being monitored	Monitoring Method	Individual responsible for the monitoring	Frequency of the monitoring activity	Group/ committee which will receive the findings / monitoring report	Group / committee / individual responsible for ensuring that the actions are completed
Routine maintenance has been carried out on the Reusable Medical Devices and Equipment located in the ward or department.	The EBME manager and Head of EDC will physically inspect several random items in a ward or department to ensure the maintenance labels are in date	EBME manager and Head of EDC.	Quarterly.	Medical Devices Committee.	Medical Devices Committee.
Purchasing/Disposal of Reusable Medical Devices and Equipment	EBME manager and Head of Supplies will meet regularly to discuss new purchases. The EBME secretary will generate monthly reports on equipment that has been disposed of via the condemnation notices issued.	EBME manager and Head of Supplies.	Monthly.	Medical Devices Committee.	Medical Devices Committee.
EBME KPI's	The EBME manager will generate monthly reports on what equipment maintenance has been carried out.	EBME manager and his staff.	Monthly.	Medical Devices Committee.	Medical Devices Committee.
MHRA alerts, regarding Reusable Medical Devices and Equipment, received by the Trust are sent to EBME and other relevant staff and departments.	Central Alerting System (CAS)	Health and Safety administrator.	Daily.	Health and Safety Committee.	Health and Safety Committee.

9 REFERENCES/BIBLIOGRAPHY

Medicines and Healthcare Products Regulatory Agency DB2006(05) November 2006

Medicines and Healthcare Products Regulatory Agency One Liners Issue P1 October 2010

Medicines and Healthcare Products Regulatory Agency Equipped to Care 2000

Medicines and Healthcare Products Regulatory Agency DB2005(03) October 2005

Medicines and Healthcare Products Regulatory Agency DB2003(02) v2 November 2010

Medicines and Healthcare Products Regulatory Agency DB2006(03) v2 July 2006

Medicines and Healthcare Products Regulatory Agency DB2010(01) February 2010

The Healthcare Commissions Standards for Better Health

National Audit Office HC475 1998-99 June 1999

Health and Safety at Work Act 1974

Management of Health and Safety at Work regulations 1999

The Electricity at work Act regulations 1989

Control of Substances Hazardous to Health (COSHH) regulations 1999

Waste Electrical and Electronic Equipment (WEEE) regulations

93/42/EEC Directive concerning Medical Devices

90/385/EEC Directive concerning Active Implantable Medical Devices

Provision and Use of Work Equipment Regulations and Lifting Operations and Lifting

Equipment Regulations 1998 (PUWER-LOLER)

National Health Service Litigation Authority (NHSLA)

Care Quality Commission (CQC)

Department of Health Estates (DoHE)

10 RELATED TRUST POLICIES / PROCEDURES

Statutory and Mandatory Training Policy (HR.16)
Medical Device Training Policy (ME.04)
Decontamination Policy (ME.03)
Incident Management Policy (HS.05)
IT Equipment and Digital Disposal Policy (IG.19)

11 EQUALITY IMPACT ASSESSMENT

Please read EIA Guidance when completing this form.

Section 1

Name of Lead for Activity:	
Job Title:	EMBE Manager

Details of individuals completing this assessment	**Name**	**Job Title**	**Email Contact**
		Environment and Information Manager	
Date assessment completed		**20 November 2020**	

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title: Management of Reusable Medical Devices and Equipment Policy**			
What is the aim, purpose and/or intended outcomes of this Activity?	This policy details the definitions, duties and process for the management of reusable medical devices and equipment.			
Who will be affected by the development & implementation of this activity?	X X X X	Service User Patient Carers Visitors	X ❑ ❑ ❑	Staff Communities Other _____
Is this:	X Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?			
What information and evidence have you reviewed to help inform this assessment? (Please name sources, e.g. demographic information for patients / services / staff groups affected, complaints etc.)	None. The safety of Reusable Medical Devices and Equipment will affect all groups equally.			
Summary of engagement or consultation undertaken (e.g. who, and how, have you engaged with, or why do you believe this is not required)	None. The dangers of incorrectly used and maintained Reusable Medical Devices and Equipment pose risks to all.			
Summary of relevant findings				

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both

positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		✓		As above
Disability		✓		As above
Gender Reassignment		✓		As above
Marriage & Civil Partnerships		✓		As above
Pregnancy & Maternity		✓		As above
Race including Traveling Communities		✓		As above
Religion & Belief		✓		As above
Sex		✓		As above
Sexual Orientation		✓		As above
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		✓		As above
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		✓		As above

Section 4

What actions will you take to mitigate any potential negative impacts?

Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Time frame
None identified			

How will you monitor these actions?
N/A

When will you review this EIA? (e.g. in a service redesign, this EIA should be revisited regularly throughout the design & implementation)
Each time the policy is amended or reviewed.

Section 5

Please read and agree to the following Equality Statement

Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. WVT will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carers etc. and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics

Signature of person completing EIA:	
Date signed:	20th November 2020

Comments:	
Signature of Lead for this activity:	
Date signed:	20th November 2020
Comments:	