MEDICAL DEVICES MANAGEMENT POLICY

Policy Type	Non Clinical
Directorate	Corporate
Policy Owner	Director of Finance, Estates and IM&T
Policy Author	Medical Devices Co-Ordinator
Next Author Review Date	1st October 2023
Approving Body	Policy Management Sub-Committee 29th April 2020
Version No.	6.0
Policy Valid from date	1st April 2020
Policy Valid to date:	30th April 2024

'During the COVID19 crisis, please read the policies in conjunction with any updates provided by National Guidance, which we are actively seeking to incorporate into policies through the Clinical Ethics Advisory Group and where necessary other relevant Oversight Groups'

DOCUMENT HISTORY

(Procedural document version numbering convention will follow the following format. Whole numbers for approved versions, e.g. 1.0, 2.0, 3.0 etc. With decimals being used to represent the current working draft version, e.g. 1.1, 1.2, 1.3, 1.4 etc. For example, when writing a procedural document for the first time – the initial draft will be version 0.1)

Date of Issue	Version No.	Date Approved	Director Responsible for Change	Nature of Change	Ratification / Approval
12-08-08	1.0		Medical Devices Co-ordinator		
18-09-08	1.1		Medical Devices Co-ordinator	Update	
03-10-08	1.2		Medical Devices Co-ordinator	Update	
12-11-08	2.0		Medical Devices Co-ordinator	Approved at	IGC
	2.1		Medical Devices Co-ordinator	Endorsed at	Medical Devices Group
02-12-10	2.1		Medical Devices Co-ordinator	Endorsed at	Quality and Patient Safety Committee
21-12-10	2.2		Medical Devices Co-ordinator	Endorsed by	Service Delivery Executive Board
21-12-10	3.0	21 Dec 2010	Medical Devices Co-ordinator	Ratified by	Executive Board
Feb 2014	3.1		Medical Devices Co-ordinator	Update	
Feb 2014	3.1		Medical Devices Co-ordinator	Endorsed at	Medical Devices Group
Feb 2014	3.1		Medical Devices Co-ordinator	Endorsed at	Risk Management Committee
18-03-14	4.0	18 March 14	Executive Director of Nursing & Workforce	Update approved at	Policy Management Group
23-12-16	4.1		Medical Devices Co-ordinator	Update	
07-02-17	4.1		Medical Devices Co-ordinator	Endorsed at	Medical Devices Group
04-11-17	5.0	4 Nov 2017	Deputy Director of Nursing	Update	Exec-Led Corporate Governance & Risk Sub-Committee
18-12-19	5.1		Director of Nursing	Scheduled update	
29-01-20	5.1		Director of Nursing	Endorsed at	Medical Devices Group
29.04.20	6.0	29 April 2020	Director of Nursing	Approved via Chairs Action	Policy Management Sub-Committee
29.01.20	6.0	29 April 2020	Director of Finance, Estates and IM&T	12 month blanket policy extension due to covid 19 applied with author review date set 6 months prior to Valid to Date.	Quality & Performance Committee
18.05.20	6.0	29 April 2020	Director of Finance, Estates and IM&T	Extended policy uploaded and linked back with new cover sheet	Corporate Governance

NB This policy relates to the Isle of Wight NHS Trust hereafter referred to as the Trust

Contents

1 Executive Summary

The purpose of this document is to detail the Trust policy to achieve effective management of all medical devices. This policy is aimed at all staff who use medical devices and intended to ensure that they are used safely, competently and effectively for the best care of patients and to comply with the relevant external legislation and guidance.

2 Introduction

2.1 The aim of this policy is to ensure that there are systems in place to minimise the risks associated with the acquisition, use, maintenance, safety and management of medical devices across the Trust.

2.2 The Medical Devices Management Policy and procedures aim to ensure that whenever a medical device is used:

- It is suitable for its intended purpose.
- It does not represent a risk to patients and staff.
- Maintenance is managed and carried out to comply with the associated guidance, regulations and manufacturers recommendations.
- Relevant safety alerts and manufacturers bulletins are actioned promptly.

2.3 The procedures should be regarded as a guide to minimise to an acceptable level the risks associated with medical devices and equipment.

2.4 This policy has been developed in association with the Medical Devices Group and is a revised version of the previous Medical Devices Management Policy.

3 Definitions

CAS (previously known as SAB):
The Central Alerting System (CAS) is a web-based cascading system for issuing medical device alerts, patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care.
Alerts available on the CAS website include safety alerts, supply disruption alerts, CMO messages, drug alerts and Dear Doctor letters. Alerts are issued on behalf of the Medicines and Healthcare products Regulatory Agency, the NHS Improvement and the Department of Health.

CMO:
The Chief Medical Officer is the UK Government's principal medical adviser and the professional head of all medical staff in England.

Medical Devices:
The definition provided by the Medicines and Healthcare Products Regulatory Agency (MHRA) explains that ‘the term 'medical device' covers all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap. The range of products is very wide: it includes contact lenses and condoms; heart valves and hospital beds; resuscitators and radiotherapy machines; surgical instruments and

syringes; wheelchairs and walking frames - many thousands of items used each and every day by healthcare providers and patients.' A more comprehensive list can be found the MHRA web site. www.mhra.gov.uk

MHRA:
The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

4 Scope

4.1 This Medical Devices Management Policy is issued under the authority of the Chief Executive and will apply to all activities using medical devices and equipment.

4.2 This policy applies to all persons (staff, contractors, patients and members of the public) who may use or be affected by medical devices or equipment.

4.3 Although this policy is administered by the Medical Equipment Management Service, through consultation, relevant Trust stakeholders understand that they have a duty to manage devices and equipment to meet the requirements of this policy as a minimum.

4.4 Relevant Trust stakeholders may include any or all of the following:-

- All Trust staff involved in the purchase and use of medical devices and equipment.
- Stakeholders who arrange external contractors, to which this policy applies.

4.5 Where applicable this policy excludes medical devices and equipment which are, by agreement, used on Trust premises but not owned or maintained by the Trust (e.g. Dialysis machines in the Renal Unit which are owned, operated and maintained by Portsmouth Hospitals NHS Trust).

4.6 Specifically the use and maintenance of radiology equipment is governed by The Ionising Radiations Regulations 1999 (IRR99) and Ionising Radiation Medical Exposure Regulations (IRMER) 2000. Where applicable, compliance with this external legislation would take priority over this Trust policy.

5 Purpose

This policy aims to enable the safe and effective deployment, monitoring, maintenance, repair and control of medical devices and equipment throughout the Trust.

6 Roles and Responsibilities

6.1 Trust Board and the Chief Executive are responsible for ensuring that the policy contained within this document is applied throughout the Trust.

6.2 The Patient Safety Sub Committee is responsible for managing the risks identified by the Medical Devices Group.

6.3 The Medical Devices Group is responsible for identifying risks associated with medical devices.

6.4 The Medical Devices Co-ordinator is responsible for providing specialist advice, providing a co-ordinated medical device management system throughout the Trust and maintaining an inventory of re-usable medical devices and equipment.

6.5 All staff who are medical device users; are responsible for ensuring that the policy contained within this document and related procedures are adhered to.

7 Policy detail/Course of Action

7.1 **Procedures**

This policy is supported by the operational procedures listed below which are to be read in conjunction with this policy and will be subject to revision from time to time as required by changes in legislation, guidance and practice.

a. Selection, purchase and standardisation of equipment/devices.
b. Equipment maintenance.
c. Medical device training procedure.
d. Equipment Library.
e. Incident reporting.
f. Central Alerting System.
g. User manuals for medical equipment.
h. Single use medical devices.

The procedures listed above can be viewed on-line on the Medical Devices intranet webpage or by contacting the Medical Devices Co-ordinator.

7.2 **Annual Report**

An annual report shall be prepared for the Patient Safety Sub Committee and will include the following subjects:-

- Detail of the Trusts named CAS Liaison Officer.
- Report on incidents report to the MHRA.
- Report on Alerts received from the CAS and actions taken.
- Report on condition of medical devices and equipment.
- Report on training and competencies.
- Report on any areas of concern for planned preventative maintenance.

8 Consultation

The following groups were consulted:

- Medical Electronics Department.
- Medical Devices Group.

9 Training

This Medical Devices Management Policy does not have a mandatory training requirement or any other training needs but it is particularly important for all staff to be aware of the requirements of this policy. This policy will be publicised using the following methods:-

- Medical Devices intranet page.
- Trust intranet.

10 Monitoring Compliance and Effectiveness

10.1 The effectiveness of this Medical Devices Management Policy and its supporting procedures shall be monitored by the Medical Devices Group, Medical Devices Co-ordinator and others as named in the procedures.

10.2 Monitoring compliance will be measured using a variety of methods;

- An annual report for Patient Safety Sub Committee (as detailed in paragraph 7.2).
- Annual review of the Trusts medical device standardisation list at the Medical Devices Group.
- Bi-monthly reports to the Medical Devices Group on the Equipment Library plus medical device evaluations and purchases.
- Audits on up to 5% of maintenance, both in house and external contractors.

10.3 Any reduction in performance or areas of non-compliance will be passed to the Medical Devices Group for an action plan to be drawn up.

11 Links to other Organisational Documents

- Selection, purchase and standardisation of equipment/devices procedure
- Equipment maintenance procedure
- Medical device training procedure
- Equipment Library procedure
- Incident reporting procedure
- Central Alerting System procedure
- User manuals for medical equipment procedure
- Single use medical devices procedure
- Decontamination of Reusable Medical Devices Policy
- Electrical Services Safety Policy

- CQC - Key Lines of Enquiry; Safe, Effective.
- Managing Medical Devices – April 2014, MHRA 2015.
- Health and Social Care Act 2008, Regulations 2014 – Regulation 12 & 15.
- SI 1994/3017 Medical Device Regulations, the European Commission 1994.
- HC475 The Management of Medical Equipment in NHS Acute PCT's in England, National Audit Office 1999.
- Acute PCT's in England, National Audit Office 1999.
- A Safer Place for Patients: Learning to improve safety, National Audit Office 2005.
- Standards for better health, Department of Health 2004.
- Risk Management Standards: NHS Litigation Authority.
- Health and Safety at Work Act 1974. HMSO, 1974.
- The Ionising Radiations Regulations 1999. HMSO, 1999.
- The Ionising Radiation (Medical Exposure) Regulations 2000. Department of Health 2000.

12 References

The National Audit Office HC475 (1999) "The Management of Medical Equipment in NHS Acute PCTs in England The Stationary Office, London".

Medical Devices Agency (1998) "Medical Device and Equipment Management for Hospitals and Community-based Organisations MDA DB 9801 Medical Devices Agency, London".

Clothier report.

MDA DB9801 "Medical Device and Equipment Management for Hospital and Community-based Organisations".

DB9801 Supplement "Checking & Testing of newly delivered Medical Devices".

Health and Social Care Act (2008).

13 Appendices

Appendix A

Financial and Resourcing Impact Assessment on Policy Implementation

NB this form must be completed where the introduction of this policy will have either a positive or negative impact on resources. Therefore this form should not be completed where the resources are already deployed and the introduction of this policy will have no further resourcing impact.

Document title	**Medical Devices Management Policy**

Totals	**WTE**	**Recurring £**	**Non Recurring £**
Manpower Costs			
Training Staff	**0**	**0**	**0**
Equipment & Provision of resources	**0**	**0**	**0**

Summary of Impact:
This revised policy, combined with the associated procedures, will assist the Trust in achieving effective management of all medical devices and in complying with its legal and statutory obligations.

Risk Management Issues:

None identified.

Benefits / Savings to the organisation:
Reducing the risk of patient harm through medical device related incidents.

Equality Impact Assessment

- Has this been appropriately carried out? **YES**/~~NO~~
- Are there any reported equality issues? ~~YES~~/**NO**

If "YES" please specify:

Use additional sheets if necessary.

Please include all associated costs where an impact on implementing this policy has been considered. A checklist is included for guidance but is not comprehensive so please ensure you have thought through the impact on staffing, training and equipment carefully and that ALL aspects are covered.

Manpower	**WTE**	**Recurring £**	**Non-Recurring £**
Operational running costs			

Totals:	N/A		

Staff Training Impact	**Recurring £**	**Non-Recurring £**
Totals:	N/A	

Equipment and Provision of Resources	**Recurring £ ***	**Non-Recurring £ ***
Accommodation / facilities needed		
Building alterations (extensions/new)		
IT Hardware / software / licences		
Medical equipment		
Stationery / publicity		
Travel costs		
Utilities e.g. telephones		
Process change		
Rolling replacement of equipment		
Equipment maintenance		
Marketing – booklets/posters/handouts, etc		
Totals:	**N/A**	

- Capital implications £5,000 with life expectancy of more than one year.

Funding /costs checked & agreed by finance:	**N/A**
Signature & date of financial accountant:	**N/A**
Funding / costs have been agreed and are in place:	**N/A**
Signature of appropriate Executive or Associate Director:	**N/A**

Appendix B

Equality Impact Assessment (EIA) Screening Tool

Document Title:	Medical Devices Management Policy
Purpose of document	*This policy aims to enable the safe and effective deployment, monitoring, maintenance, repair and control of medical devices and equipment throughout the Trust.*
Target Audience	*All staff who use medical devices*
Person or Committee undertaken the Equality Impact Assessment	*Medical Devices Co-ordinator*

1. To be completed and attached to all procedural/policy documents created within individual services.

2. Does the document have, or have the potential to deliver differential outcomes or affect in an adverse way any of the groups listed below?

If no confirm underneath in relevant section the data and/or research which provides evidence e.g. JSNA, Workforce Profile, Quality Improvement Framework, Commissioning Intentions, etc.

If yes please detail underneath in relevant section and provide priority rating and determine if full EIA is required.

		Positive Impact	Negative Impact	Reasons
Gender	Men			*N/A*
	Women			*N/A*
Race	Asian or Asian British People			*N/A*
	Black or Black British People			*N/A*
	Chinese people			*N/A*
	People of Mixed Race			*N/A*

	White people (including Irish people)			*N/A*
	People with Physical Disabilities, Learning Disabilities or Mental Health Issues			*N/A*
Sexual Orientation	Transgender			*N/A*
	Lesbian, Gay men and bisexual			*N/A*
Age	Children			*N/A*
	Older People (60+)			*N/A*
	Younger People (17 to 25 yrs)			*N/A*
Faith Group				*N/A*
Pregnancy & Maternity				*N/A*
Equal Opportunities and/or improved relations				*N/A*

Notes:
Faith groups cover a wide range of groupings, the most common of which are Buddhist, Christian, Hindus, Jews, Muslims and Sikhs. Consider faith categories individually and collectively when considering positive and negative impacts.

The categories used in the race section refer to those used in the 2001 Census. Consideration should be given to the specific communities within the broad categories such as Bangladeshi people and the needs of other communities that do not appear as separate categories in the Census, for example, Polish.

3. Level of Impact

If you have indicated that there is a negative impact, is that impact:			
		YES	**NO**
Legal (it is not discriminatory under anti-discriminatory law)			
Intended			

If the negative impact is possibly discriminatory and not intended and/or of high impact then please complete a thorough assessment after completing the rest of this form.

3.1 Could you minimise or remove any negative impact that is of low significance? Explain how below:
3.2 Could you improve the strategy, function or policy positive impact? Explain how below:

3.3 If there is no evidence that this strategy, function or policy promotes equality of opportunity or improves relations – could it be adapted so it does? How? If not why not?	
Scheduled for Full Impact Assessment	Date:
Name of persons/group completing the full assessment.	
Date Initial Screening completed	