Policy		NHS Worcestershire Acute Hospitals NHS Trust

MEDICAL DEVICES POLICY INCLUDING EDUCATION AND TRAINING

Department / Service:	Medical Devices Committee	
Originator:	Mark Grimshaw Martina Morris	Technical Services Manager Service Lead – Safe Care
Accountable Director:	Helen Blanchard	Chief Nursing Officer
Approved by:	Technical Services Manager	
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Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust	
Target Departments	All	
Target staff categories	All	

Purpose of this document:

The purpose of this policy is to assist anyone who has responsibility for the management of medical devices in the Worcestershire Acute Hospitals NHS Trust.
This policy identifies the key responsibilities and duties of the providers of services and managers/staff in relation to the Trust's medical devices.

In addition, this policy is designed to ensure that all staff who are authorised to use medical devices, can do so in a safe and effective manner, appropriate to their role and that responsive and flexible medical devices training is available.

Key amendments to this Document:

Date	Amendment	By:
27/10/08	Addition of sub-sections to contents	M. Grimshaw
05/08/09	Addition of helpdesk contact details	M. Grimshaw
Sept 2010	Update maintenance , hire/loan equipment and monitoring sections – approved by Helen Blanchard, Director of Nursing & Midwifery, 13 Sept 2010	M.Grimshaw
July 2012	Revised policy, new section within maintenance, reporting committee and title changes	M.Grimshaw
June 2013	Policy merged with the Education and Training Policy for the Use of Medical Devices	M. Grimshaw and M. Morris
July 2015	Policy extended for 3 months whilst being reviewed	M. Grimshaw

Aug 2015	Document extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
November 2016	Currently no changes to the Medical Devices Policy and this will be reviewed early next year as part of the MTS Technical Services Review. Extended until 31st January 2017	Martin Long/Matthew Gilbert
Nov 2017	Document extended whilst under review	TLG
March 2018	Document extended for 3 months as approved by TLG	TLG
June 2018	Document extended for 3 months as approved by TLG	TLG
May 2019	Medical Devices committee have requested a complete re write of the policy in order to make it more user friendly. It was confirmed that the policy is still current in terms of its content and no immediate concerns	Ray Cochrane/Lisa Miruszenko
June 2020	Document extended for 6 months whilst under review	Ray Cochrane
February 2021	Document extended as per Trust agreement 11.02.2021	
Oct 23	Document extended whilst review undertaken	Ray Cochrane

References:

Medical Equipment Store Operational Policy
Guidelines on Point of Care
Decontamination Policy
Manual Handling Policy
Procedure for Reporting Extreme Clinical Incidents
Risk Assessment Policy
Procurement Policy
Novel Therapeutics Policy
Medical Devices Directive 93/42/EEC
Medical Devices Directive DB2006 (05) Managing Medical Devices
Medical Devices Directive DB2006 (04) Single Use Medical Devices: Implication and Consequence of Reuse
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Derbyshire Hospitals NHS Foundation Trust (2011) Trust policy and procedure for the competency and training requirements connected with medical devices.
Improving Patient Safety. National Patient Safety Agency (NPSA). (Available from http://www.npsa.nhs.uk/patientsafety/improvingpatientsafety/)
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The Medical Devices Regulations (2002) London, HMSO. (Available from http://opsi.gov.uk/si/si2002/20020618.htm)
The Medical Devices (Amendment) regulations (2003), London, HMSO. S.I. 2003/1697: (Available from http://www.opsi.gov.uk/si/si2003/20031697.htm)
The Provision and Use of Work Equipment Regulations (1998) London, HMSO. (Available from http://www.opsi.gov.uk/si/si1998/19982306.htm)
University Hospitals Birmingham NHS Foundation Trust (2012) Trust Procedure for Training in the Safe Use of Medical Devices

Oct 16	Further extension as per TMC paper approved 22nd July 2015	TMC

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1. Introduction

The policy is intended to establish the operational framework under which any medical device or equipment is managed, maintained and how education and training in the use of medical devices is delivered on Trust premises.

With reference to maintenance of medical devices there are a range of maintenance/workshop procedural documents that exist alongside the equipment databases for Siemens SMES and the Trust's EBME services that underpin this policy.

Keeping medical devices safe and effective requires a planned preventative maintenance and breakdown maintenance service to be carried out by competent persons.

In addition, it is a legal requirement for the Trust to ensure all medical equipment is safe for use and to this end appropriate maintenance regimes are both necessary and statutory.

Rapid changes in healthcare technology and clinical practice present particular challenges. Increased throughput of patients combined with more complex therapies are likely to impact on staff and increase pressures on staff working in healthcare. This is likely to result in:

- Acute care continuing to be complex and intensive, with a sustained growth in the sophistication of medical technology to support diagnosis, treatment and care.
- Continued growth in the capacity of the community and primary care infrastructures, providing acute and intermediate care through sophisticated methods of delivering care in the patient's home.
- A growth in skills required by clinical staff for using technical equipment.
- Patients becoming increasingly knowledgeable about their health needs and treatment options.
- Patients wishing to manage their conditions in the home environment requiring knowledge, preparation and support from healthcare professionals.

This policy sets out the roles and responsibilities of individuals, managers and relevant committees in the Trust with regard to the purchasing, maintenance, replacement and use of medical devices during normal work activity. In relation to education and training, the policy aims to ensure that staff who use medical devices can do so in a safe and effective manner, appropriate to their role, and to support staff in order to:

- Provide a clinical environment that promotes the delivery of safe, effective patient treatment.

- Ensure that the users of medical devices are fully conversant with their responsibilities, so that they may safely use any medical equipment appropriate to their role when authorised to do so.

- Establish a flexible and responsive training framework that will enable staff to use medical devices and disseminate training in a safe and effective manner.

- Achieve successful patient outcomes and in minimising harm to patients.

2. Scope of the Policy

This Policy applies to all medical devices/equipment used on Trust premises for diagnosis and/or treatment of disease, for monitoring patients and as assistive technology and staff who are authorised to use these medical devices.

3. Objective of this document

The purpose of this policy is to assist anyone who has responsibility for the management and use of medical devices in the Worcestershire Acute Hospitals NHS Trust. The Trust recognises that the successful implementation, use and maintenance of any medical device in today's healthcare environment is a crucial part of the Trust's business.

Its purpose is to ensure that:

- Medical devices are managed in accordance with the requirements of the Medical Devices Directive 93/42/EEC.
- Managers have the indicators to best practice for purchase, training and maintenance of medical devices and equipment.
- The arrangements for purchase, use and maintenance of medical devices and equipment are firmly embedded within the local framework for clinical governance and risk management.
- All medical devices and equipment are managed efficiently, safely and effectively in accordance with DB 2006 (05).
- All staff using medical devices understand their role in the purchase, management and safe use of medical devices and equipment.
- Framework for medical devices training is provided that meets the organisational needs in ensuring patient safety.
- Clearly defined objectives are in place for the provision of medical device training, which ensures the system is appropriately used.
- Individual users of medical equipment adhere to this policy and maintain their knowledge and skills. Each operator will have evidence of attendance at medical devices training and has a responsibility not to use medical devices unless authorised and competent to do so.

4. Definitions

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 or injury or investigation, replacement or modification of the anatomy or of a physiological process or used in the vicinity of a patient.

An authorised user is a member of staff who has been identified by the ward or department manager as being suitable to use the medical device and who can provide evidence of having received medical device use training and been assessed as competent in its use.

A Key Trainer is an authorised user of a specific device who has achieved a specialist level of competency and can train and assess the basic or proficient level of competency in others using that device.

Levels of Competency:

Basic competency (awareness level) = understands basic principles of medical devices. This applies to all medical devices that medical, nursing, midwifery, allied health professionals and ancillary staff may come in to contact with. This level of training is intended to provide a basic overview and understanding of the equipment, providing an awareness of the principles of the equipment. This level of training will be included in the next level (proficient or specialist training) or stand alone as training given for instance to healthcare support staff who would not be expected to operate the equipment clinically, but will need an appreciation of it for safety. Training may be provided by ward / department based key trainers or manufacturers.

Proficient competency (user level) = can safely and effectively use medical devices in the clinical area, and within boundaries of professional role. This applies to all medical devices that medical, nursing, midwifery, allied health professionals and ancillary staff may use or handle. This level of training is intended to provide comprehensive and detailed instruction in the use of the equipment, covering all aspects of the equipment including pre use testing, setting up, operation, user problems and decontamination. This will allow the staff to operate the equipment correctly and safely. Training may be provided by ward / department based key trainers or manufacturers.

Specialist Competency (user and trainer level) = can safely and effectively use medical devices and can train and assess others in the safe use of medical devices. This level of training is intended for those members of staff who have been designated as key trainers and who have completed the competency training for the equipment. This level of training allows the key trainer to train others. Key trainers must have been trained by the supplier /manufacturer. Key trainers will be expected to complete the Medical Devices Training Log **(Appendix 9)** when conducting in house training sessions and send this to the Safe Care Team who will forward it to the Training and Development Department.

5. General Policy Statements

It is the policy of Worcestershire Acute Hospitals NHS Trust (WAHT) to ensure medical devices/equipment is used and maintained in accordance with the latest guidance from manufacturers and MHRA.

The Trust Board acknowledges its responsibility for the safe and effective use of medical devices and has nominated the Chief Nursing Officer as the Board member responsible for the overall management of Medical Devices within the Trust.

The Trust will provide resources to ensure that the requirements of this policy are fulfilled and will include appropriate provision of suitable training and maintenance programmes.

The Trust will work towards ensuring that medical devices and other equipment are suitably deployed, maintained, monitored and controlled. The Trust will work towards ensuring that all medical devices and equipment purchased is procured in accordance with national guidelines and that there is adherence to requirement of legislation and the NHSLA standards.

The Trust will ensure that all Trust staff involved in the maintenance of Trust medical devices and equipment has the skills and resources necessary to ensure that the medical devices and equipment are maintained to the highest standards without compromising the safety of staff and patients.

The Trust will provide training programmes and appropriate systems for measuring competency of all staff that operate diagnostic, therapeutic or other specialised medical devices so that the medical devices can be used effectively and safely. Training needs must be identified through personal development programmes. This will enable all staff with individual requirements achieve safe working practices. The use of medical devices will be subject to the risk assessment process initiated and maintained by the Medical Devices Committee.

Unless there is an overriding clinical need, all medical devices will be obtained from preferred medical devices lists (makes and types), which the Supplies department will work towards generating in consultation with clinicians, Technical Services, HSDU, Infection Control, Manual Handling and other professionals deemed appropriate.

Medical device registers will be maintained in order that the Trust has an accurate database of its medical device and equipment assets. The registers will be maintained for general medical devices by Technical Services for the Alexandra hospital, Kidderminster and Aconbury sites and Siemens for the Worcestershire Royal Hospital. Surgical instrumentation will be recorded in the HSDU at the Alexandra hospital and the TSSU at Worcestershire Royal Hospital.

6. Roles and Responsibilities

6.1 The Role of the Chief Executive Officer

The Chief Executive Officer has overall responsibility for ensuring that medical devices are managed and used safely across the Trust.

6.2 The Role of the Chief Nursing Officer

The Chief Nursing Officer is designated with Board level responsibility for ensuring that medical devices are managed and used safely across the Trust.

As part of their role they must ensure that the NHSLA Standards and the Care Quality Commission's Essential Standards of Quality and Safety appertaining to medical devices are implemented and monitored accordingly.

The Chief Nursing Officer will advise the Trust Board of any issues relating to the safe use of medical devices.

6.3 The Role of Other Executive Director and Director Roles

The Director of Finance has responsibility for equipment replacement/ funding.

The Director of Asset Management and ICT has responsibility for the provision of equipment maintenance and providing reasonable resources to enable this work to be undertaken.

The Medical Director for Patient Safety has responsibility for ensuring that all medical staff adhere to this policy and understand the training and competency requirements.

6.4 The Role of Heads of Nursing/Matrons/Service Leads is to:

- Ensure that ward and department managers are aware and adhere to this policy and its requirements.

6.5 Users of medical devices must ensure that they:

- Ensure that they are competent in the use of medical devices and understand their responsibility for ensuring they acquire and maintain their own knowledge and skills and disseminate knowledge and skill to others who may need to use medical devices within their role. This includes:
    - Attending relevant medical devices training where a need has been identified.
    - Complete relevant training documentation to confirm they have received training.
    - Ensure they practice under direct supervision of a competent practitioner until their competency has been achieved successfully.
    - Ensure that they share any training records with their ward or department manager and their Key Trainers.
    - Ensure they maintain their competence and seek updates or further training in line with the code of conduct and this policy.
    - Adhere to the annual requirement of self-verification of competence.

The level of training required for each individual, and the frequency, will be identified as a result of the Training Needs Analysis carried out by the ward/department managers in each clinical area annually. Managers will establish what level of training each individual will need to achieve before being authorised to operate or handle a medical device.

- Are familiar with any instructions or labels associated with the use of equipment.

- Are aware of the cleaning/decontamination procedure for use with a particular medical device and the labelling as appropriate.

- Are aware of when the medical device was last serviced or formally inspected.
- Only use medical devices that have been authorised for use.
- Check equipment is safe and fit for its intended purpose before using.
- Is only used for its intended purpose as defined by the manufacturer.
- Report any defects to TECHNICAL SERVICES / SIEMENS / HSDU immediately and withdraw the device from use.
- Adhere to the risk assessment process for the use of the medical devices and equipment.

6.6 The Role of the Service Lead - Safe Care is to:

- Ensure that the training and education needs identified by managers relating to medical devices are responded to in an appropriate and timely manner.
- Lead the Safe Care Team in facilitating medical devices training days delivered by company or Key Trainers and by developing the Key Trainer network for high risk devices throughout the Trust.
- Ensure that any training records pertaining to medical devices are shared with the Training and Development Department who will record them on the Trust training record system.
- Ensure that advice, support and on-going training to Key Trainers is co-ordinated, in order to establish a network of users who have achieved a specialist level of competency in a specific device relevant to their area.
- Work with the Procurement Department / Medical Devices Committee to ensure that training needs are accurately and adequately considered during the procurement process.
- Provide reports twice annually on training and education to the Medical Devices Committee

6.7 The role of the Department Managers is to:

- Ensure that, where a life is defined by the manufacturer, robust management systems are in place so the device is not used beyond this limit.
- Ensure that all medical equipment owned by the Trust and used within their areas of responsibility comply with this policy.
- Manage MHRA safety notices in accordance with the SABS system.
- Identify situations and circumstances where potential incidents involving medical devices are most likely to occur and advise the Risk Services department accordingly.

- Develop and facilitate implementation of strategies to minimise user-related errors to reduce risk of untoward incidents and inform the Medical Devices Committee of these.

- Ensure that any untoward incident requiring reporting to Medicines and Healthcare products Regulatory Agency, MHRA) is done in accordance with Incident Reporting Policy. The device must be quarantined (see specific instructions in section 10.7 of this policy).

- Assist in devising protocols for using medical devices.

- Monitor the risk assessment process and make recommendations and modifications where appropriate.

- Liaise with Technical Services/Siemens/ HSDU on equipment related untoward incidents.

- Ensure that all staff understand the training and competency requirements for the safe use of medical devices.

- Keep an accurate record of all core and specialist medical devices used in their clinical area and staff who are authorised to use these devices. This must be reviewed annually or when a new medical device is introduced into the clinical area.

- Undertake a training needs analysis annually and inform the Safe Care Team of training needs pertaining to their area. In addition, they will review all training records as part of staff induction, return to work or as part of the annual Personal Development Review process.

- Ensure that the training and competency requirements are met by all their staff as described in this policy and that up to date records of staff training and competence are maintained.

- Ensure that only those staff who have been appropriately trained and authorised will operate any medical device.

- Nominate appropriate staff to undertake the role of Key Trainers and provide allocated time for training and assessing of staff.

- Ensure that relevant user information for equipment is updated, this may be delegated to the Key Trainer for each device.

- Ensure that staff do not modify or use medical devices in any way that is not authorised.

- Ensure that medical devices designed for reuse are safe to use before each procedure including sterilisation and disinfection procedures.

- Ensure that patients receive training and instructions on how to use medical devices, when issued by the Trust in the community in liaison with Community Services as appropriate.

- Ensure all staff follow advice or recommendations issued by the MHRA on equipment use.

- Advise of any changes, e.g. when equipment is transferred from its registered location.

- Ensure that the general actions below are followed:

- Liaise with TECHNICAL SERVICES / SIEMENS to decide maintenance issues where they have equipment on long-term hire.

- When equipment fails in use the device must be withdrawn from use and labelled stating date, nature of problem, name of individual reporting the failure and department to whom the problem was reported.

- Consulting with risk managers if there are Trust wide implications on a faulty piece of medical equipment.

- Untoward incidents are reported promptly and appropriately to line managers and Risk Services via the incident reporting form. Where equipment is involved in a serious untoward incident or near miss (a catastrophic or major event) involving a Patient, Visitor or member of staff, must be quarantined. See Incident Reporting Policy and Procedure for Reporting Extreme Clinical Incidents.

Ensure that the following preventative measures are adhered to wherever possible:

- Medical devices are assessed as appropriate before and during use and that there is, when necessary, a suitable record of the risk assessments and must notify the risk manager/health and safety officer of intended purchase prior to use.

- Ensure that clearly visible warning signs are on devices to indicate the nature of the hazard where there maybe a health and safety risk to staff, such as lasers.

- Make sure that the use of medical devices does not expose anyone to any hazards that may affect their health and or safety. These include:-

    - Any article or substance falling or being ejected from the device to include blood and body fluids.
    - Any rupture or disintegration of parts of the equipment.
    - Risk of fire or overheating from the equipment.
    - The release of any radiation, chemical, substance, dust, vapour, liquid such as glutaraldehyde, which may be stored in the device.

- Notify Technical Services/Siemens of changes in location and/or ownership or relevant medical devices which are on the inventory.

- All medical devices on loan or in use as part of a trial have a decontamination certificate.

- Manufacturers/suppliers instructions appertaining to particular devices are to be delivered to the relevant department by the Manufacturer/Supplier who will inform Siemens/Technical Services of this action.

6.8 The role of the Key Trainers is to:

- In conjunction with their ward or department manager and support from the Safe Care Team, act as a resource for issues relating to medical devices and actively promote and deliver training.

- Enter into an agreement with their manager to facilitate training and competency assessment on specific medical devices. Training for the Key Trainer will be facilitated via the Safe Care Team.

- Maintain their knowledge and disseminate training and updates in a timely and professional manner. The content of the training must be based on the manufacturers' guidance material, ensuring a consistent Trust wide approach.

- Maintain training records **(Appendix 9)** and medical devices resource folders and ensure that relevant user information for equipment is regularly updated.

- Ensure that potential users in their area who require authorisation or an update on the use of a medical device, have received appropriate training and been assessed as competent in its use. For medical devices classed as medium or high risk, Trust approved competencies must be used to provide evidence of staff competence. In the absence of the Trust approved competencies, the Competency Certificate in **Appendix 7** should be used to provide evidence of competence and must be completed following the training on a medical device until detailed competencies have been developed and approved. For medical devices classed as low risk, registered practitioners will be required to complete self-verification of competence located in **Appendix 8a**. Non-registered practitioners are not-permitted to carry out self-verification of competence and they must be assessed as competent in the use of medical devices by the Key Trainer in their clinical area as outlined in **Appendix 8b.** In the absence of the Key Trainer, the non-registered practitioner can be assessed as competent by a registered practitioner competent in the use of the medical device.

- Report staff who do not attend medical devices training to their managers.

- Carry out competency assessments and on successful completion will report to their manager that the user is competent to use a medical device. Copies of the completed competency forms **(Trust approved competencies or in the absence of Trust approved competencies the Competency Certificate located in Appendix 7)** will be maintained in the clinical area and copies of the training log **(Appendix 9)** will be sent to the Safe Care Team who will forward a copy to the Training and Development Department.

- To co-operate in matters pertaining to training, assessing, recording and monitoring in relation to the identified medical devices of their responsibility.

- Closely liaise with the Safe Care Team and inform the team of any problems relating to medical devices training.

Training on all medical devices shall be available at the following levels:

- **Medical Device Awareness level** – will be achieved after receiving training at medical devices training days or after receiving device training facilitated or delivered by the Key Trainer. This level is intended to provide a basic overview and understanding of the equipment, providing an awareness of the principles of the equipment, but will not authorise the users to operate the medical device.

- **Medical Device User level** – will be achieved after receiving training at medical devices training days or after receiving device training facilitated or delivered by the Key Trainer. For medical devices classed as medium or high risk, Trust approved competencies must be used to provide evidence of staff competence. In the absence of the Trust approved competencies, the Competency Certificate in **Appendix 7** should be used to provide evidence of competence and must be completed following the training on a medical device until detailed competencies have been developed and approved. For medical devices classed as low risk, registered practitioners will be required to complete self-verification of competence located in **Appendix 8a**. Non-registered practitioners are not-permitted to carry out self-verification of competence and they must be assessed as competent in the use of medical devices by the Key Trainer in their clinical area as outlined in **Appendix 8b.** In the absence of the Key Trainer, the non-registered practitioner can be assessed as competent by a registered practitioner competent in the use of the medical device. This level of training will authorise users to operate a medical device.

- **Key Trainer level** – will be achieved once an individual has undergone training described above and has been assessed as competent to safely and effectively use devices and train and assess others. They must have agreed with their ward or department manager to become a Key Trainer on medical devices for their clinical area. This level of training will authorise users to operate a medical device and teach others in its use.

  The training programme will be prepared by the Safe Care Team to ensure supply of appropriate training. The training programme will be made available Trust wide.

6.9 The role of the Technical Services/Siemens Manager:

- Siemens manager to be responsible for the maintenance of all medical equipment identified in the Bill of Quantities on the Worcester site identified on their database, including the equipment in the Medical Equipment Library.

- Technical Services manager to be responsible for the maintenance of medical equipment on the Alexandra hospital and Kidderminster sites. This includes the equipment in the Medical Equipment Library at the Alexandra hospital, the Aconbury East and West sites at Worcester and a few items within the Worcestershire Royal hospital. Reusable surgical instruments are the responsibility of HSDU/TSSU on their relevant sites.

- To ensure that all medical devices procured meet with European standards and carries the CE mark.

- To provide an inventory of all medical devices utilised across the Trust and will :

  - Ensure all medical devices are appropriately managed and maintained, an inventory of equipment will be kept and maintained by both Siemens and Technical Services. This will not include single use medical devices or surgical instruments; surgical instruments will be managed by HSDU/TSSU.
  - Ensure the inventory will be updated when additional or replacement equipment has been procured, when equipment has been condemned and is no longer in use and also when equipment has been transferred to another location.
  - Be responsible for the upkeep of the inventory on the Worcester site and will make it available (as read-only) to authorised users via the Trust's system.

6.10 The Role of the HSDU Manager is to:

- Ensure that all medical devices appropriate to the HSDU service whether procured/loaned or trialled, meet with the relevant European standards and carry the CE Mark.

- Ensure that all devices processed through the Trust Sterilisation and Disinfection Unit at Redditch or the Theatre Sterile Supply unit at Worcester Royal hospital are processed in accordance with the requirements of Production Quality Assurance Directive 93/42/EEC for Medical Devices, Annex V. (Known as the Medical Devices Directive)

- Provide advice on decontamination.

6.11 Non-Trust staff

All clinical staff working at the Trust and providing services in areas managed by the Trust, e.g. Locum, Third Party Agency and NHSP staff who are not substantively employed by the Trust, academic staff and students must adhere to this policy. Local induction to an area of work will identify and address the individual's medical devices training needs. A disclaimer located in **Appendix 10** must to be completed by the individual to indicate that they will not use any equipment they have not been trained and are not competent to use.

6.12 The role of the Manual Handling Advisors is to:

- Deliver Manual Handling training on Trust Induction to all staff as appropriate.

- Provide hoist training on their Risk Management up-date or department Manual Handling Training as appropriate.

- Ensure that medical devices within the remit of Manual Handling Policy are recommended and suitable for their intended purpose including reasonable maintenance and cleaning.

6.13 The role of the Procurement Department is to:

- Ensure that all purchasing staff involved in the procurement of medical devices are competent to undertake the tasks through understanding and meeting statutory requirements and applying best practice.

- Promote the use of the Medical Equipment Procurement Policy.

6.14 The role of Medical Devices Committee is to:

- Develop the Trust's Medical Devices Policy and other policies and procedures for the management of medical devices for clinical use from procurement through the equipment's life cycle from pre-purchase through to disposal.

- Review the process for the procurement and replacement of equipment.

- Report to the Executive Risk Management Committee (ERMC) twice annually, or as required. The ERMC will advise the Board on medical devices matters and related issues where relevant.

- Process appropriate requests for device acquisitions.

- Ensure that standardisation of medical device purchases is maintained as far as possible.

- Review the Training Needs Analysis as produced by each clinical area annually and monitor provision of training, attendance and staff competency records. Where challenges to adherence to the policy are identified, the Medical Devices Committee will seek to approve action plans to reduce the risk.

- Review feedback from the attendees of medical devices training.

- Review medical devices incidents.

- Review 'no fault found' reports.

- Review the completion of planned preventative maintenance.

7. Maintenance

7.1 General

Almost all maintenance is covered by either Siemens or Technical Services the exceptions are managed directly by departments usually in the case of specialist equipment, CT and MRI scanners as an example. This policy provides strategic guidance for the Trust with respect to maintenance however further detail is provided in the workshop procedures of both Technical Services and Siemens. Workshop procedures are operational documents and therefore subject to change as deemed necessary but always supportive of this strategic policy.

7.2 Planned Preventative Maintenance including Calibration

Planned preventative maintenance (PPM), including calibration, will be a statutory requirement in most cases. It will enhance the effectiveness and reliability of medical equipment and will be carried out at the appropriate frequency.

The level of PPM required is determined principally upon manufacturer's guidelines, MHRA guidance and where necessary locally by either Siemens or Technical Services based upon experience.

Siemens and Technical Services undertake PPM by either database schedule, area (specific wards/departments) or equipment store request. When PPM has been completed all equipment has a label attached stating "Next Test Due" with a date. It is the responsibility of the user to check this date before use and inform either Technical Services or Siemens if this date has passed. Siemens or Technical Services will arrange for PPM to be undertaken on the out of date equipment.

Non – PFI Planned Preventative Maintenance Introduction of Risk Centred Maintenance

Risk Centred Maintenance is to be employed in the non-pfi part of the Trust as part of an efficiency initiative and to make best use of available resources. The system is based upon a risk assessment of each equipment category and a frequency of maintenance assigned to that device accordingly.

For example, a device deemed as being high risk status would receive its' yearly service, a medium risk category would receive its service every 2 years and low risk every 3 years.

An example of a high risk category device would be a defibrillator, this is dormant until required on a relatively infrequent basis. The case for undertaking PPM is very clear as when needed it must operate correctly. A device that is in continuous use, however, where the effect of its failure in use is minimal could have a less frequent PPM schedule.

It is important to remember the complexity of a device does not determine its PPM schedule. A suction device on a resuscitation trolley is a critical device at a resuscitation event, requiring the same frequency as the defibrillator.

All devices are already risk assessed for maintenance and training purposes and the risk assessment process is reviewed by the medical devices committee. Once the risk assessment process is complete a decision can be made to reduce the frequency on medium and low risk equipment to every 2 and 3 years respectively. High risk equipment will receive yearly maintenance.

This initiative will allow for the best use of resources and increase turnaround on repair work which will reduce the overall associated risk with medical devices.

It is important at all times that staff must remove broken equipment from service immediately and report this to the appropriate helpdesk.

Arrangements for external PPM via the supplier or third party must be routed via Siemens/Technical Services to ensure only approved service organisations are used.

Ensure that the maintenance log of medical devices and work carried out on medical devices is kept up to date.

7.3 Medical devices with elapsed service dates

Where medical devices have an elapsed scheduled service date in excess of 2 years, the priority shall be raised to high, and if the location is known it shall be essential that this work is undertaken. If the medical devices cannot be located after a period of 3 years, the equipment shall be deemed as missing and shall be suspended from the active database. Should the equipment reappear, it shall be returned to the active database if appropriate and maintenance shall be resumed by Siemens or Technical Services.

7.4 Breakdown Maintenance

It is Trust policy that all medical equipment in use is free from any fault or defect and that all repair/maintenance is carried out to accepted standards by competent persons.

It is Trust policy that faulty or defective equipment is not and reported to either Siemens or Technical Services. Only upon their authorisation can the device be used until a repair is affected.

Faulty or defective equipment must be reported to Siemens/Technical Services as soon as possible using the following procedure:-

- At Worcestershire Royal Hospital Siemens will collect equipment that has been reported and has a decontamination label attached. At the Alexandra hospital, the Medical Equipment Store staff will complete a fault notice which will also state the equipment has been decontaminated before being given to Technical Services. At Kidderminster faulty equipment is logged with the Technical Services help desk as detailed below.
- Ensure equipment is decontaminated in accordance with Trust's Infection Control Policy for the Decontamination of Medical Devices.
- Ensure information is passed on to all who need to know, including any shift changes.

- The following details should be relayed to the helpdesk:

  Equipment type, i.e. Infusion Pump, Blood Pressure Monitor
  Make/Mode
  Serial Number
  Asset ID Number
  Precise nature of problem
  Any relevant access times

Helpdesk contact details are as follows:

For Worcestershire Royal hospital contact the Facilities helpdesk on ex 33333 and follow the prompt for option 2 (Siemens). For all non PFI locations please call Technical Services ex 44906.

7.5 User Maintenance

Where required, routine maintenance by the user ensures that devices continue to function correctly.

This may entail regular inspection as recommended in the manufacturer's user information. This should clearly show the routine tasks and how they should be carried out. Where necessary, these will include:

- Checking that it is working correctly before use
- Regular cleaning
- Specific daily/weekly checks
- Noting when it has stopped working properly or when obvious damage has occurred, and when discontinuing use
- Contacting the relevant servicing organisation

As well as manufacturer's guidance in-house training is provided, e.g. for checking resuscitation equipment, results of such checks should be recorded in the log books/kept with the equipment.

7.6 Maintenance of End-User Medical Devices

Statutory safety inspections will be carried out by Technical Services and Siemens prior to supplying or re-issuing equipment to end-users.

A valid tested label showing the date tested the next due date or an expiry "do not use after" date will be affixed to the equipment. This will help to make the end-users aware that the equipment needs returning to the hospital for re-testing.

This type of equipment is not under direct control or supervision normally afforded to hospital-based equipment. For this reason all wards and departments that loan out equipment must keep their own records and ensure that equipment can be traced and recalled for routine testing or when required.

7.7 Technical Services/Siemens will:

- Work towards standardisation of Medical Devices throughout the Trust.
- Ensure all medical devices on loan or in use as part of a trial will possess either a master indemnity or, an individual indemnity form where a master indemnity is not available, for the transfer of risk.
- When equipment is commissioned users will be either issued with the device instructions or these will be made accessible to users on the Trust intranet.
- Ensure there are arrangements for keeping track of instructions sent by manufacturers and for replacing them when relevant.
- Carry out acceptance tests and complete condemning procedures in accordance with MHRA recommendations:
- Inspect and certificate Pre-Purchase Questionnaires and Indemnities.
- Maintain a central inventory of medical equipment.
- Work towards a high standard of in-house service delivery.
- Monitor the quality of external service providers, via number of callouts/breakdowns.
- Manage all third party contracts appertaining to medical devices unless agreement with specialist departments is specifically requested.

Third party maintenance organisations need to be able to:

- Ensure competency in the repair or maintenance of the device.
- Gain access to appropriate medical devices to undertake repair and maintenance.
- Notify the Trust of any deviation to the maintenance repair or maintenance method.
- Take responsibility for the repair or maintenance.
- Wherever possible third party contractors should have their staff CRB checked and be able to provide evidence if requested.

8. Record Keeping

It is the Trust's policy to keep all records pertaining to the maintenance of medical equipment for 25 years wherever possible, or as directed by the Trust's Litigation Service. This is of particular importance with respect to litigation against the Trust and individuals.

The following records shall be kept by Siemens/Technical Services:

- Planned preventative maintenance records
- Breakdown maintenance records

It will be the responsibility of each ward/department Manager to ensure that copies of third party service report sheets are forwarded to Technical Services/Siemens.

A database will be maintained to incorporate maintenance records/reports against the relevant assets on a computerised database where reasonably possible, thus enabling full equipment service history to be maintained.

9. Procurement of Medical Devices including Devices that are Leased

In order to ensure best value for money, selection and acquisition for new medical devices should be co-ordinated through the Supplies Department.

This process must be adopted for any procurement of medical devices irrespective of the capital or programme that is funding the purchase (see Procurement Policy for more details).

This will include:-

- Donated equipment
- Equipment purchased through ward monies.

Pre-purchase assessment of other medical devices must be undertaken on all medical devices that are being considered for purchase that do not appear on the Trust's standard list. The following assessment criteria must be applied and will be done in conjunction with Users, Supplies, Technical Services/Siemens/HSDU, Manual Handling and the Infection Control Team as appropriate:-

- Clinical requirements
- Suitability for purpose
- Patient safety
- Maintenance implications
- Standardisation
- Staff health and safety implications (including infection control)
- Compatibility with existing equipment
- Decontamination
- Risk implications
- Estimated whole life costs including consumables and accessories
- Value for money
- CE Marking
- Other revenue costs such as consumables

9.1 Medical Devices on Hire/Loan/Trial

Any medical device that is part of a clinical trial does not have to be CE marked. However, it should have relevant documentation on its use which should incorporate user instructions and decontamination methods. Staff should refer to the Local Research Ethics Committee for use of a medical device as part of a clinical trial. (See also Novel Therapeutics Policy)

Technical Services will ensure that all relevant equipment is safety and acceptance tested and delivery is undertaken.

Any department loaning equipment to other Trusts/Hospitals must ensure that the receiving Trust/Hospital is supplied with instructions for use and a decontamination certificate. All devices will require further decontamination or sterilisation within the Trust before use.

Also refer to the Novel Therapeutics Policy for equipment or techniques that are new to the clinician or the Trust.

9.1.1 Powered Surgical Devices

- Technical Services / Siemens must be notified as soon as a decision is made to request or accept any medical devices on loan or hire. Technical Services / Siemens to record the medical devices on the loan register / database.

- All medical devices on loan should be clearly identified where appropriate using an “On Loan Label”. Any electrical medical devices must have an acceptance check before it is brought into use whenever possible.

- Loan of medical devices must be for a pre-defined period of time and must not be continuous as indemnity may expire and maintenance maybe required.

- If medical devices are subsequently to be purchased this should be done in consultation with Supplies, Technical

Services / PFI (Siemens / Investment committee) and HSDU where relevant.

9.1.2 Non Powered handheld devices

- Equipment borrowed or loaned by the Trust must be in consultation with the HSDU manager and sufficient notice given to undertake the necessary safe decontamination / sterilisation or maintenance work prior to use.

- Any loaned equipment must be accompanied by processing instructions and a comprehensive list of facilities required along with an inventory of every item supplied and a decontamination certificate. If the Trust cannot meet the processing requirements or any of the above is not supplied the instruments must not be processed or used.

- Equipment on loan or borrowed must be not be returned via a courier unless decontaminated prior to collection.

- For any equipment that is borrowed the Trust must complete a delivery note specifying the equipment, its purpose and the period of loan.

9.1.3 The Chief Executive is the authorised officer whose signature, and that of one other Director, is required to sign deeds when indemnity agreements are required, (not required where Master Indemnity exists). However, in day to day matters this responsibility is delegated to:

The Supplies Manager, HSDU Manager, Theatre Manager and Technical Services Manager.

When any equipment is borrowed by the Trust from a supplier an indemnity agreement must be signed between the Trust, (either Technical Services, Estates, HSDU or Supplies), and the company supplying the loan equipment using the “NHS Form of Indemnity – Form A”.

Indemnity for the purchase of equipment will form part of the formal procurement process. Should a tender be required, suppliers will be asked to provide information relating to indemnity. If a national or regional contract is being used to purchase the equipment, indemnity will have been discussed at initial tender stage by the contracting authority who will be able to supply you with these details upon request.

The Manager of the relevant service will retain copies of all completed forms.

10. Other Considerations

10.1 Storage

Equipment, along with relevant accessories, should be stored in a designated safe storage area and a record kept of medical devices inventory, repairs etc in accordance with the manufacturers recommendations where necessary.

10.2 Decontamination

Guidance on cleaning, disinfection and sterilising of the range of medical devices used within the Trust is given in the Decontamination policy.

10.3 Single Use Medical Devices

A single use medical device is to be used on an individual patient during a single procedure then discarded. These devices are not to be reprocessed or used on other patients. The Single Use Symbol on the packaging of medical devices means that the manufacturer:-

- Intends the device to be used once and then discarded.
- Considers the device is not suitable for use on more than one occasion.
- Has evidence to confirm that reuse would be unsafe.

The MHRA defines single patient use as more than one episode of use of a medical device on one patient; the device may undergo some re-processing between each use.

10.4 Specific Risks

There are medical devices that pose a significant risk to patients because of an adverse clinical outcome if it is used inappropriately. In these cases only those staff that have received training specific to the use of such medical devices are permitted to use it.

10.5 Replacement/Disposal

Consideration to replace Medical Devices should be taken when any of the following criteria apply:-

- Worn out beyond economic repair.
- Damaged beyond economic repair
- Unreliable (check service history)
- Clinically or technically obsolete
- Spare parts are no longer available
- More cost effective or clinically effective devices have become available.
- Unable to be cleaned effectively prior to disinfection and/or sterilisation
- Serious untoward incident resulting in serious injury or death
- On advice from MHRA

Medical devices can only be condemned by one of the following:

For disposal of medical equipment, please contact Technical Services/Siemens as to how to proceed.

10.6 Information/Instruction/Training

Anyone who uses medical devices shall have adequate information available to them in order that they can use the medical devices safely.

Some medical devices may have written instructions, supplied by manufacturers, attached to the device; others may require local rules to be established.

10.7 Incidents

Staff should refer to the Trust's Incident Reporting Policy and the Procedure for Reporting Extreme Clinical Incidents.

As a result of an incident resulting in a Medical Device being quarantined:

- Any equipment that is quarantined will be stored either in Technical Services Department or in exceptional circumstances the Health and Safety Manager's office.
- Equipment must not be given to the manufacturer unless there has been authorisation by the Health and Safety Manager, or the Technical Services Manager.
- Equipment must not to be given to the manufacturer in cases that involve the MHRA or other relevant body.
- Technical Services will allow equipment to be put back into use once the investigation has been completed and it is deemed safe for the equipment to be used again.
- Technical Services may require the manufacturer to be involved in the investigation but in any case the MHRA are the authorising officer for release of equipment either back into use or to be released back to the manufacturer for their investigation.
- Technical Services/Siemens must be sent a copy of the incident form if equipment has been involved in an incident or there is a problem with the device.
- Technical Services/Siemens will undertake a non-invasive check of the equipment for those devices that are involved in incidents so that any further tests to be done by the MHRA or Manufacturer are not compromised.
- Where incidents have serious repercussions, they must be reported to other agencies such as the MHRA by the Health and Safety Manager. In these circumstances medical devices must not be discarded but kept in a safe place and only handed over to a member of Trust staff. The incident should be reported immediately to the Health and Safety Manager so that the necessary follow up action is taken.

In all instances decontamination of equipment would normally be required prior to investigation service or repair HSG (93) 26. In serious incidents such as above or where devices are single use, decontamination or sterilisation may alter the material or operational characteristics of the device. This may severely hamper or render useless any subsequent investigation into the device failure. Advice should be taken from the infection control team / sterile services manager or Health and safety manager and should take account of the manufactures instructions or guidance.

Where contaminated items are to be transported on public roads they should do so in accordance with the Transportation of Dangerous Goods Act (ADR). Advice on packaging systems will need to be sought depending on the nature and size of the medical device.

11. Risk Classification

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

To facilitate this, the medical devices used in the Trust have been categorised into one of three groups:

- **High Risk -** Medical Devices that have the potential to cause serious consequences or death should they be used incorrectly or fail to function correctly.
- **Medium Risk -** Medical Devices that have would have a significant impact on patient care to cause temporary adverse health consequences should they be used incorrectly or fail to function correctly.
- **Low Risk -** Medical Devices that would be unlikely to cause any serious consequences should they be used incorrectly or fail to function correctly.

These categories provide a broad guideline. It is the responsibility of ward or department managers to identify through risk assessment if a medical device should be reassigned to a different risk category. In this event, the ward or departmental manager must inform the Medical Devices Committee. **See Appendix 5** for more information.

12. Training and Competency Assessment

12.1 Training requirements

Nursing, Midwifery, Allied Health Professionals and Ancillary Staff:
All new nursing, midwifery, allied health professionals and ancillary staff who will be operating medical devices as part of their role must not use them until they have received training and have been assessed as competent in their use. This training and competency assessment must be provided on induction to the clinical area.

Existing nursing, midwifery, allied health professionals and ancillary staff must have evidence of competency to prove that they are authorised to use a medical device and this must be stored in their personal files maintained by their ward or department manager. The self-verification of competence tool **(Appendix 8a)** must be completed annually by all registered practitioners for each medical device to provide evidence of on-going competence.

Non-registered practitioners are not-permitted to carry out self-verification of competence and they must be assessed as competent in the use of medical devices annually by the Key Trainer in their clinical area. **Appendix 8b** must be used for the assessment of their competence. In the absence of the Key Trainer, the non-registered

practitioner can be assessed as competent by a registered practitioner competent in the use of the medical device.

Medical staff:
New and existing medical staff will be required to sign a disclaimer **(Appendix 10)** to confirm that they will not use any medical device unless they are competent to do so. Identified training needs will be addressed via their Line Managers/Clinical Directors. Consultants will keep evidence of their competence in their Continuous Professional Development folders and the process will be reviewed as part of the annual Personal Development Reviews. The self-verification of competence tool **(Appendix 8a)** must be completed annually by all medical practitioners for each medical device to provide evidence of ongoing competence.

Trainee doctors are not permitted to use medical devices unsupervised and any evidence of training in the use of medical devices will be kept in their training portfolio/passport.

Other staff:
Specialist staff such as cardiology technicians and technical services department staff are outside the scope of this policy. This also includes scientists working in areas such as the Clinical Pathology department (laboratories and Biochemistry) as they are governed by the Clinical Pathology Accreditation.

12.2 Identification of Training Needs

Training needs will be identified by:

- Ward/Department Managers by reviewing the Training Needs Analysis annually and reporting the outcome to the Service Lead for Safe Care.
- A review of the Trust Training Needs Analysis by the Service Lead for Safe Care.
- A review of medical devices related incidents by the Medical Devices Committee.

In response to training needs identified:

- Programmes of pre-planned training will be provided across a range of medical equipment – either locally or Trust wide.
- Extended pre-planned training will be provided for those members of staff who have been designated as Key Trainers. This level of training will be developed and coordinated through the Safe Care Team.

12.3 Competency Assessment:

Initial competency assessment:
All staff must keep evidence of competency in the use of medical devices they are authorised to use. Initial training must be provided as part of their induction to the clinical area. For medical devices classed as medium or high risk, staff will be required to be assessed as competent in the use of the medical device by the Key Trainer in their clinical area. Trust approved competencies must be used to provide evidence of staff competence. In the absence of the Trust approved competencies, the Competency Certificate in **Appendix 7** should be used to provide evidence of competence and must be completed following the training on a medical device until

detailed competencies have been developed and approved. For medical devices classed as low risk, registered practitioners will be required to complete self-verification of competence located in **Appendix 8a** on induction to the clinical area. Non-registered practitioners are not-permitted to carry out self-verification of competence and they must be assessed as competent in the use of medical devices by the Key Trainer in their clinical area on induction to the clinical area. **See Appendix 8b.** In the absence of the Key Trainer, the non-registered practitioner can be assessed as competent by a registered practitioner competent in the use of the medical device.

Failure to attend training and provide evidence of attendance and competency will result in staff being unable to operate equipment as authorised users.

A copy of the attendance register from each training sessions organised by the Safe Care Team will be forwarded to the Training and Development Department. The ward or department managers and the Key Trainers will be responsible for maintaining accurate training records and evidence of staff competence in the use of medical devices within their areas. The training log in **Appendix 9** must be maintained for each locally delivered training and forwarded to the Safe Care Team who will forward a copy to the Training and Development Department.

On-going competency assessment:
All registered staff who will continue to use medical devices following the initial training, will be required to undertake self-verification of their competence **(Appendix 8a)** annually and provide evidence of this to their line manager as part of their Personal Development Review. Non-registered practitioners are not-permitted to carry out self-verification of competence and they must be assessed as competent in the use of medical devices annually by the Key Trainer in their clinical area and provide evidence of this to their line manager as part of their Personal Development Review (**Appendix 8b).** In the absence of the Key Trainer, the non-registered practitioner can be assessed as competent by a registered practitioner competent in the use of the medical device.

This must be provided for each medical devices staff use. If any aspects of the self-verification tool cannot be verified, training and assessment of competency must be sought prior to continuing to use the medical device.

12.4 Training update

The need for an update will be reviewed annually via the Personal Development Review process utilising the medical devices self-verification of competence form located in **Appendix 8a** for registered practitioners and **Appendix 8b** for non-registered practitioners. This process will identify any training needs as well as provide evidence of staff competence in using medical devices. Update training and competency re-assessment must be completed by staff who have not used medical devices for more than 6 months and those involved in an incident related to the incorrect use of a medical device. Infrequent users (e.g. 6 monthly or less) must undertake annual training and re-assessment of competency for each infrequently used medical device.

12.5 Non-compliance with training requirements

All line managers will be responsible for ensuring that all their staff can provide evidence of training and competence in the use of medical devices they are authorised to use. Should staff not attend the medical devices training that they have been booked on, the Training and Development Department or the Key Trainers will notify the manager who will be responsible for suspending the individual from using the medical device until they can provide evidence of training and competency assessment.

13. Introduction of new equipment

The trial or purchase of new equipment must take place with the approval of the Procurement Department / Medical Devices Committee and in adherence to the Procurement Policy.

There is an expectation that all users receive training from the manufacturer before the equipment is released into the clinical area. This training will be coordinated via the Safe Care Team and the training will be provided initially by the manufacturer. The provision of continued training will be determined by the Service Lead for Safe Care.

Trials of medical devices, approved by the Procurement Department / Medical Devices Committee, will be supported by the Safe Care Team where appropriate. This will ensure that training and support to clinical areas during the trial is provided.

Training for trials and purchase of new equipment will be provided in a flexible manner through a variety of forums, to facilitate adequate attendance.

In order to sufficiently meet the requirements of the training needs analysis, it may be necessary in specific circumstances to purchase the necessary training from external agencies.

14. Background

14.1 Equality Requirements

There are no equality issues in regard to this policy (see Appendix 1)

14.2 Financial Risk Assessment

Currently there is sufficient resource to support this policy for the next 12 months, so there is no financial risk associated with the policy. (see Appendix 2)

14.3 Consultation

All stakeholders have been involved in the production of this policy (see Appendix 3)

14.4 Approval Process

The policy will be presented to Trust Operational Committee for approval (see appendix 4)

15. Implementation

15.1 Plan for dissemination

The policy will be placed on the Trust intranet and can be found using the document finder facility.

15.2 Dissemination

All Trust staff will be informed of the revised policy and how to find it on the Trust intranet via the IT Noticeboard.

16. Monitoring and Compliance

Activity Monitored	Where	Audit / monitoring tool	Frequency	By whom	Report to	Frequency of reporting
Provide reports on training and education	Trust wide	Training plan Staff attendance records OLM records	Twice annually	Service Lead-Safe Care	Medical Devices Committee	Twice annually
Provide reports pertaining to the work led by the Medical Devices Committee	Trust wide	Report	Twice annually	Medical Devices Committee	Executive Risk Management Committee	Twice annually
Maintain clear record of training delivered locally	Trust wide – wards and departments	Local training log	Quarterly	Key Trainers	Service Lead – Safe Care	Quarterly
Completed annual training needs analysis and report finding to the Service Lead – Safe Care	Trust wide – wards and departments	TNA form held in each area	Annually	Ward / Department Managers	Service Lead – Safe Care	Annually
Review of training feedback from attendees	Trust wide	Training Evaluation forms	Quarterly	Service Lead-Safe Care Key Trainers	Medical Devices Committee	Quarterly Quarterly

Review of medical devices related incidents	Trust wide	Datix reports	Quarterly	Medical Devices Committee	Executive Risk Management Committee	Quarterly
Review of 'No Fault Found Reports' and other Medical Devices related reports raised at the Medical Devices Committee meetings	Trust wide	Reporting templates	Quarterly	Members of the Medical Devices Committee	Medical Devices Committee	Quarterly
Equipment audit of specialist departments	Specialist Departments (non-ward areas)	Audit tool	Annually	Department managers with support from Technical Services and Siemens	Siemens and Technical Services	Annually
Planned Preventative Maintenance	Trust wide	Database	Monthly	Technical Services and Siemens	Medical Devices Committee Executive Risk Management Committee	Twice yearly
Evaluate compliance in relation to the NHSLA Risk Management Standards	Trust wide	Trust Risk Register and Clinical Governance	Annually	Medical Devices Committee	Executive Risk Management Committee	Annually

17. Policy Review

This policy will be reviewed every two years and will be circulated for review and approval by the Medical Devices Committee and the Executive Risk Management Committee.

Contributors and Consultation to this Policy Include	
James Longmore	Director of Asset Management and Chair of Medical devices Committee
Medical Devices Committee	All members
Martina Morris	Service Lead – Safe Care
Jane Smith	Head of Nursing
Elaine Bethell	Tissue Viability
Mark Grimshaw	Technical Services Manager
Shaun Webb	Siemens
Heather Webb	Healthcare Standards Compliance
Jane Brown	Clinical Governance
Paul Graham	Health and Safety Manager
Heather Gentry	Lead Nurse Infection Control
Dave Thombs	Theatres
Steve Graystone	Medical Director for Patient Safety
Jeremy Thomas	Anaesthetist
Bev Edgar	Interim Director of HR
Sandra Berry	Head of Learning and Development Department
Execute Risk Management Committee	All members
Trevor Mason	Siemens Workshop Supervisor
Stephen Steward	Decontamination Lead and HSDU Manager

Appendix 1

Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document	Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	No	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
5.	**If so can the impact be avoided?**	n/a	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	n/a	
7.	**Can we reduce the impact by taking different action?**	n/a	

If you have identified a potential discriminatory impact of this key document, please refer it to Assistant Manager of Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Assistant Manager of Human Resources.

Appendix 2

Financial Risk Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration before progressing to the relevant committee for approval

Appendix 3
Plan for Dissemination of Key Documents

To be completed by the key document author and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Title of document:	Medical Devices Policy		
Date finalised:	06/08/13	**Dissemination lead: Print name and contact details**	Mark Grimshaw and Martina Morris
Previous document already being used?	**Yes**		
If yes, in what format and where?	In Policy format on Trust intranet		
Proposed action to retrieve out-of-date copies of the document:	Removal when replacement Policy is placed on intranet		

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Paper or Electronic**	**Comments**
Trust wide	Published on the Trust intranet	Electronic	
Trust wide	Daily update produced by the Communications Department	Electronic	

Dissemination Record - to be used once document is approved.

Date put on register / library of procedural documents		**Date due to be reviewed**	

Disseminated to: (either directly or via meetings, etc)	**Format (i.e. paper or electronic)**	**Date Disseminated**	**No. of Copies Sent**	**Contact Details / Comments**

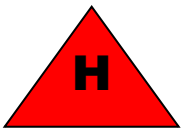
Appendix 4

Medical Equipment Risk Classification System

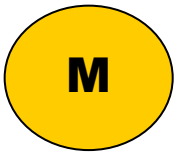
In order to reduce the risk associated with the use of medical devices, enable the Trust to prioritise medical device training the following risk categories have been established.

The risk categories have been developed using the Trust's risk matrix, based on likelihood and consequence. Advice has been sought from other Trusts and medical equipment professionals, including Siemens Healthcare and Technical Services. The risk categories will be included on the training needs analysis for all clinical areas and will enable ward/department managers to coordinate training in a timely manner.

The Medical Devices Committee is responsible for the final approval of medical device risk categories. The following list is not exhaustive but provides examples of categorisation.



High Risk Device. Competency based training and assessment required on induction prior to use. This can be accessed via planned training sessions arranged by the Safe Care Team or through Specialist and Key Trainers in the clinical area. Annual self-verification of competence required.



Medium Risk Device. Competency based training and assessment required on induction prior to use. This can be accessed via planned training sessions arranged by the Safe Care Team or through Specialist and Key Trainers in the clinical area. Annual self-verification of competence required.

Low Risk Device. Self-verification of competence (Appendix 7a for registered staff or 7b for non-registered staff) on induction. If training required, this can be accessed via planned training sessions arranged by the Safe Care Team or through Specialist and Key Trainers in the clinical area. Annual self-verification of competence required.

Appendix 5

List of Medical Devices

Equipment	H / M / L Risk
Anaesthetic Machines	H
Anaesthetic Gas Monitors	H
Baby Incubators	H
Blood Gas Analysers	H
Blood/Fluid Warmers	H
Cardiac Diagnostic Imaging	H
CPAP Devices	H
Defibrillators	H
Diathermy Units	H
Endoscopy Equipment	H
Glucose Analyzers	H
Haemodyalsis Equipment	H
Hoists (patient)	H
Infusion Devices	H
Lasers	H
Pacemakers - External	H
Respiration Apnoea Alarms	H
Resuscitation Equipment (all equipment located on resus trolley)	H
Ventilators	H
Beds - Electrical	M
Doppler-Blood Flow	M
ECG Recorders	M
Entonox Regulators	M
Humidifiers	M
Microscopes	M
Multiparameter Monitors	M
Nutrition Feed Pumps	M
Operating Tables	M
Patient Warmers	M
Peak flow meter	M
Physiotherapy Equipment	M
Pressure Relieving Equipment	M
Pulsoximeters	M
Thermometers-Electronic	M
Treatment Couches	M
Ultrasound Equipment	M
UV Therapy Units	M
Vital signs monitor	M
Breast Pumps	L
Laryngoscopes	L
Nebuliser pump	L
Ophthalmoscopes	L
Otoscopes	L
Oxygen/Air Flowmeters	L

Scales (patient)	L
Sphygmomanometer	L
Suction Units	L

Appendix 6

Medical Devices Competency Certificate

Staff Member:.....

Job Title:.....

Profession:.....

Ward / Department:.....

Type of Medical Device:.....

Model:.....

Assessment Criteria

No	Statement	Tick
1.	Received Trust approved training in the use of the medical device	
2.	Understands the purpose and function of the medical device	
3.	Understands the indications for the use of the medical device	
4.	Understands the contraindications for the use of the medical device	
5.	Demonstrates safe operation of the medical device	
6.	Demonstrates the ability to troubleshoot problems	
7.	Uses appropriate cleaning materials for decontamination of the medical device	
8.	Explains the correct procedure for reporting faulty medical device	
9.	Explain and understands the Trust Incident Reporting procedure	

This is to certify that .....has received Trust approved training and has been competency assessed on the safe use of the above medical device.
Assessor (Print name):.....

Date:.....

Assessor (Signature):.....

Staff Member (Signature):.....

Appendix 7a

Self-Verification of Competence Proforma- Medical Devices Registered Practitioners

N.B. As part of the self-verification of competence, the following criteria must be fully understood prior to medical device selection and application to the patient. If the following criteria cannot be completed then further training must be sought.

Staff Member:..... Job Title:.....

Profession:..... Ward / Department:.....

Medical device(s) this assessment refers to – please list:

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	Competency Statements	(Yes, No, N/A)
1.	I am authorised to use the above medical device(s).	
2.	I have access to the manufacturer's operational manual for the above medical device(s).	
3.	I understand the purpose and function of the above medical device(s).	
4.	I understand the indications for the use of the above medical device(s).	
5.	I understand the contraindications for the above medical device(s).	
6.	I am able to change the user calibration set up of the above medical device(s) if required.	
7.	I understand the automatic 'switch on test procedure' of the above medical device(s).	
8.	I am confident and competent to carry out any pre-use checks on the above medical device(s) if required.	
9.	I know how to safely and correctly connect the above medical device(s) to a patient.	

10.	I am able to explain to the patient what the above medical device(s) do and why they are being used.	
11.	I fully understand the purpose of the alarms that may occur on the above medical device(s).	
12.	I can effectively respond to any alarms that may occur on the above medical device(s).	
13.	I am able to recognise any operational malfunctions of the above medical device(s).	
14.	I know what action to take in the event of medical device failure.	
15.	I can safely disconnect and remove the above medical device(s) from service in the event of failure.	
16.	I am familiar with methods of reporting a defective medical device.	
17.	I am able to clean, decontaminate and prepare the above medical device(s) for future uses.	
18.	I am conversant with the Trust Untoward Incident Reporting procedure.	

Having answered 'YES' to all the questions above and taken in to account my personal assessment of competence in using the listed medical device(s), I declare that I am competent to use the listed medical device(s) without requiring further training.

Staff Member (Signature):.....Date:.....

To be completed annually as part of the Personal Development Review and a copy kept in the personal file.

Appendix 7b

Verification of Competence Proforma – Medical Devices
Non-Registered Practitioners

N.B. As part of the assessment of competence, the following criteria must be fully understood by the non-registered practitioner prior to medical device selection and application to the patient. If the following criteria cannot be completed then further training must be sought.

Staff Member:..... Job Title:.....

Profession:..... Ward / Department:.....

Medical device(s) this assessment refers to – please list:

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	Competency Statements	(Yes, No, N/A)
1.	The non-registered practitioner is authorised to use the above medical device(s).	
2.	The non-registered practitioner has access to the manufacturer's operational manual for the above medical device(s).	
3.	The non-registered practitioner understands the purpose and function of the above medical device(s).	
4.	The non-registered practitioner understands the indications for the use of the above medical device(s).	
5.	The non-registered practitioner understands the contraindications for the use of the above medical device(s).	
6.	The non-registered practitioner is able to change the user calibration set up of the above medical device(s) if required.	

7.	The non-registered practitioner understands the automatic 'switch on test procedure' of the above medical device(s).	
8.	The non-registered practitioner is confident and competent to carry out any pre-use checks on the above medical device(s) if required.	
9.	The non-registered practitioner knows how to safely and correctly connect the above medical device(s) to a patient.	
10.	The non-registered practitioner can explain to the patient what the above medical device(s) do and why they are being used.	
11.	The non-registered practitioner fully understands the purpose of the alarms that may occur on the above medical device(s).	
12.	The non-registered practitioner can effectively respond to any alarms that may occur on the above medical device(s).	
13.	The non-registered practitioner is able to recognise any operational malfunctions of the above medical device(s).	
14.	The non-registered practitioner knows what action to take in the event of medical device failure.	
15.	The non-registered practitioner can safely disconnect and remove the above medical device(s) from service in the event of failure.	
16.	The non-registered practitioner is familiar with methods of reporting a defective medical device.	
17.	The non-registered practitioner is able to clean, decontaminate and prepare the above medical device(s) for future uses.	
18.	The non-registered practitioner is conversant with the Trust Untoward Incident Reporting procedure.	

This is to certify that .....has been competency verified on the safe use of the listed medical device(s).

Assessor (Print name):..... Assessor (Signature):.....

Staff Member (Signature):.....
Date:.....

To be completed annually as part of the Personal Development Review and a copy kept in the personal file.

Appendix 8

Medical Devices Training Log

Medical Device:……

Ward / Department:……..

Key Trainer's Name (Print):……

Date of training	Candidate's name Print	Candidate's signature

Please send a copy of the populated form to the Safe Care Team and the Training and Development Department.

Appendix 9

Medical Devices Training Disclaimer for Medical staff, Locum and Agency Staff

Worcestershire Acute Hospitals NHS Trust is committed to providing high quality patient care within a safe environment. Medical devices provide a key role in the delivery of patient care. All users must be competent in the use of medical devices and have a professional responsibility for ensuring they acquire and maintain their own knowledge and skills.

In order to minimise risk, the Trust policy states that you do not use any medical device unless you are competent to do so.

Evidence of training and competence must be provided and if training is required this can be accessed via the Key Trainers in your department/specialty or Trust Medical Devices Training session.

Trainee doctors are not permitted to use medical devices unsupervised and any evidence of training in the use of medical devices will be kept in their training portfolio/passport.

It is the responsibility of all staff to make themselves aware of the Trust Policy for Medical Devices and the Trust Policy for Training and Education for the Safe Use of Medical Devices.

All staff must:

- Attend training where a need has been identified and in accordance with Professional Codes of Conduct.
- Ensure all records are maintained in their training or Continuous Professional Development portfolio.

I can confirm that I understand the above and will not use any medical device unsupervised if I am not competent to do so and I will maintain accurate records of training received

Name: …… Designation:……

Department: ……..

Signature: ……...Date:……