



Managing Medical Devices

Guidance for health and social care organisations

January 2021

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This document replaces DB 2006(05) and DB 2005(03)

Revision history

This version	Date published	Changes
V1.3	January 2021	Regulatory updates
V1.2	November 2020	Minor text changes Update of references Minor text changes to all sections Regulatory updates Remove tables and text boxes
V1.1	April 2015	Minor text changes to: Section 2.5 last paragraph. Section 3.4.2 added point Section 8 Section 8.2 6th paragraph Section 8.7 last paragraph (Note)

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1 Introduction

1.1 Aims of the guidance

The purpose of this document is to outline a systematic approach to the acquisition, deployment, maintenance (preventive maintenance and performance assurance), repair and disposal of medical devices.

It is intended primarily for people in hospital and community-based organisations that are responsible for the management of medical devices, to help them set up and develop systems that promote the use of the medical devices for safe and effective health care. Many of the principles of this guidance document may apply to all medical devices. However, not all sections may apply to implantable devices, and in vitro diagnostic (IVD) medical devices are covered in separate documents.

Medical devices play a key role in healthcare, vital for diagnosis, therapy, monitoring, rehabilitation and care. Effective management of this important resource is required to satisfy high quality patient care, clinical and financial governance, including minimising risks of adverse events. Good medical device management will greatly assist in reducing their potential for harm.

This guidance document updates and replaces previous guidelines published in:

- Managing Medical Devices Guidance for healthcare and social services organisations. April 2015
- Managing Medical Devices. Guidance for healthcare and social services organisations DB 2006 (05) November 2006
- Guidance on the safe and effective use of batteries and chargers for medical devices DB 2005 (03) October 2005.

In vitro diagnostic (IVD) medical devices are not within the scope of this document but we have separate guidance in the following publications:

- [Management of in vitro diagnostic medical devices](#)
- [Management and use of IVD point of care test devices](#)

Examples of medical devices are given below

This guidance document aims to:

- help healthcare organisations ensure the provision of adequate quantities of medical devices that are competently used by trained users, properly maintained and effectively managed to provide quality healthcare. The principles are summarised in Outcome 11 of the Care Quality Commission standards [1] CQC Regulation 15
- help healthcare organisations meet the Care Quality Commission's standards [1] (or equivalent) Regulation 15 on prevention of incidents by unsafe or unsuitable devices
- help healthcare organisations to plan and co-ordinate sustainable replacement programmes
- help healthcare organisations optimise cost, risk and performance of medical devices
- address strategies for ownership and use of medical devices
- provide balanced information to help groups developing local policy

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- identify relevant legislation
- identify sources of additional guidance.

The main topics cover the life-cycle management of medical devices:

- management of medical devices
- acquiring appropriate devices
- training
- maintenance and repair
- reporting adverse incidents
- decontamination
- decommissioning and disposal.

Examples of medical devices (not an exhaustive list)

Diagnosis or treatment of disease

Diagnostic laboratory device, X-ray machines, magnetic resonance imaging (MRI) scanners, vascular catheters, dressings, surgical instruments, syringes, hip replacement implants, standalone software for diagnosis including apps that are designed to diagnose

Monitoring of Patients

ECG, pulse oximeter

Critical Care

Infant incubators, blood-gas analysers, defibrillators, ventilators, vascular stents

Improve function and independence of people with physical impairments

Hoists, orthotic and prosthetic appliances, pressure care devices, walking aids, wheelchairs

Community-based healthcare

Dressings, domiciliary oxygen therapy systems, urine drainage systems

Emergency services (ambulances)

Stretchers, trolleys, defibrillators

1.2 Role of the MHRA

The role of the MHRA is to protect and promote public health and patient safety.

The MHRA undertakes market surveillance of medical devices on the UK market and takes decisions over the marketing and supply of devices in the UK.

The MHRA is responsible for the designation and monitoring of UK Approved Bodies.

Further guidance is available on [how the MHRA enforces the legislation on medical devices](#)

2 Systems of management

2.1 Management responsibility

Healthcare organisations should appoint a director or board member with overall responsibility for medical device management. There should be systems in place to ensure reporting of device issues including:

- the effectiveness of the medical devices management system
- the condition and performance of medical devices including device failures and issues; utilisation, performance, maintenance; repair and calibration history
- the execution of investment, replacement and disposal plans.

The management structure for medical devices should have clear lines of accountability up to board level. These lines of accountability should be extended, where appropriate, to include general practitioners, residential and care homes, community-based services, independent hospitals providing services for NHS patients, managed care providers, Private Finance Initiative (PFI) organisations and other independent contractors. It is important to establish who is accountable, and where there is a need for joint accountability arrangements.

Healthcare organisations should appoint Medical Device Safety Officers (MDSO). Part of the MDSO role is to report adverse incidents to the MHRA and other official agencies. The lines of accountability should include reference to the appointment of such safety officers [2].

Healthcare organisations should set out a long-term approach and objectives for the management of their medical devices, including strategic replacement and development equipment procurement planning.

This should include an overarching medical devices management strategy setting out medium to long term organisational requirements of assets taking account of cost, performance and risk across the entire equipment lifecycle. This strategic approach should also align with the responsible organisations overarching business / strategic plan.

2.2 Medical devices management group

Healthcare organisations should establish a medical devices management group to develop and implement policies across the organisation.

Membership of the group should depend on the requirements of each healthcare organisation but needs to be broad enough to address all the policy areas (see section 2.3). It needs appropriate representation from among the following groups of staff:

- clinical
- clinical / biomedical engineering
- clinical trainers
- management
- infection control
- decontamination lead
- risk management
- engineering
- maintenance
- IT and data support

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- purchasing
- medical device trainers
- medical device users
- MDSOs.

Where appropriate, the medical devices management group should include links with specialist groups dealing with specialised medical devices (for example laboratories, radiology and renal dialysis).

The group's role should be to:

- improve communication about medical devices within the organisation
- ensure involvement of clinicians, technical staff and users in relation to any proposed changes, including configuration settings relating to devices, where appropriate
- define persons responsible for device management tasks, training and safe device operation
- define and review the device management policy
- review incidents including governance issues relating to medical device management.

2.3 Device management policy

A device management policy should help to ensure that risks associated with the use of medical devices are minimised or eliminated. The medical devices management group should ensure that the policy addresses:

- responsibilities in relation to medical device management
- decontamination
- the equipment life cycle (including selection, acquisition, acceptance, maintenance, repair, monitoring, traceability and disposal/replacement) of all medical devices
- risk management including adverse incident reporting and actions required on National Patient Safety Alerts, MHRA safety messages and manufacturers' Field Safety Notices
- training and access to manufacturer's instructions
- records, including device inventory.
- outsourcing
- equipment deployment, tracking and utilisation
- equipment financing.

This policy should be regularly reviewed to ensure that, whenever a medical device is used, it is:

- suitable for its intended purpose
- used in line with the manufacturer's instructions
- traceable, where possible
- maintained in a safe and reliable condition, with associated records kept
- disposed of appropriately at the end of its useful life.

2.4 Records

Good record keeping is essential for the safe management of medical devices. All the aspects of medical device management covered within this guidance document require some degree of record keeping. The records should be maintained within one system wherever possible. For non-centralised records there should be suitable cross references between the various record systems.

Accurate and complete copies of records in paper or electronic form are required to be made available for future inspection, review and copying e.g. for CQC, internal audits, traceability, investigations.

The detail and complexity of the records depend on the type of device and usage during its lifetime. It should also include any specific guidance provided in the manufacturer's instructions and supporting information.

Records must be protected to ensure their accuracy is maintained and that any changes do not obscure previously recorded information. Procedures should include the ability to store securely to enable record retrieval throughout the retention period of records.

NHS Digital provides guidance on record management [3]

The device records should provide evidence of:

- a unique identifier for the device, where appropriate
- the purchase price of the equipment
- a full history, including date of purchase and where appropriate when it was put into use, deployed or installed
- any specific legal requirements and whether these have been met
- proper installation and where it was deployed
- schedule and details of maintenance and repairs
- the end-of-life date, if specified.

Healthcare organisations must ensure records are kept of training of users of medical devices. These should show that users:

- know how to use the device safely
- can carry out routine checks and maintenance
- have been trained and had relevant refresher training
- are confident and/or competent to use devices in their areas of work.

2.5 Deployment

Systems for managing medical devices need to take account of the different ways that the devices can be deployed. For example, devices can be:

- allocated to the department where they are used, which is given the responsibility for managing them. Examples include fixed installations, such as large X-ray machines and smaller critical care devices in some intensive therapy units
- allocated to device stores, pools or libraries, from which they are issued to users, as required. Examples include walking aids and frames issued by community stores and infusion pumps and ventilators in many healthcare organisations
- issued on long-term loan to an individual user for their use only. Examples include artificial limbs and wheelchairs.

Healthcare organisations should monitor equipment utilisation. Where a medical device is being under-used, consider whether it can be re-deployed in the hospital or healthcare organisation, either for the duration of its life or an interim period.

2.5.1 Department control

When the device is allocated to a department, individuals working in the department generally have primary responsibility for the way they treat the device and the state in which it is left. These responsibilities can also include performance checks before use and routine maintenance, such as charging batteries. It is essential that all individuals are aware of the medical device management system and the part that they play within the system to ensure that medical devices are managed correctly.

In many healthcare organisations some important aspects of device management, such as record keeping and scheduling maintenance, are often controlled outside of a department that has the primary responsibility for the use of the equipment. This may be a centralised device management group. It is essential that systems and procedures allow for the relevant details to be passed on to those responsible for the management of records for a device, and that users are aware that different departments within the organisation are responsible for maintenance. There may be significant advantages in terms of expertise and risk management in having a single medical device management group responsible for all types of medical devices and equipment within the organization.

2.5.2 Device stores, pools and libraries

In the community, routine device management may in practice transfer either to the end user or to a community healthcare worker. It is essential that all individuals are aware of the medical device management system and the part that they play within the system to ensure that medical devices are managed correctly.

In the acute setting, medical device libraries are more likely to retain responsibility for device management.

Best practice in the management of an equipment store/pool/library is characterised by a single use and return policy, unless equipment is booked out for multiple cases.

2.5.3 Devices issued individually on long-term loan

Some device management will transfer either to the individual end user or to a healthcare worker or other carer. However, it is essential to be clear about where responsibility lies for each aspect of management. This includes:

- decontamination procedures
- maintenance and associated records keeping
- availability of up-to-date instructions and other information, and passing to end users, where appropriate
- period and type of use
- device identification and traceability
- contact details (users and healthcare establishment).

The healthcare organisation remains accountable for collecting these items when they are no longer needed. It is essential that all individuals are aware of the medical device management system and the part that they play within the system to ensure that medical devices are managed correctly.

2.6 Monitoring and audit

Monitoring the organisation's performance on medical device management is important to minimise or eliminate risks to patients and staff.

Much of this activity should be by internal audit, as part of the organisation's governance arrangements. Healthcare organisations need to review their policies and systems for managing the use of medical devices regularly. This internal audit should be performed by the medical devices management group on a regular basis. An audit report should be submitted to the board.

This audit should also examine the organisation's policies and procedures for the safe acquisition, use, maintenance and repair, decontamination and disposal of medical devices against the checklists set out in this guidance. The audit should also check the storage procedures of records and assess current security measures that protect the integrity of the records. Record retrieval methods should also be audited.

Key indicators capable of showing improvements in medical devices management and/or providing early warning of risk should be used. The effectiveness and usefulness of these indicators should be reviewed regularly.

There will in addition be 'external' monitoring and audit components by organisations such as Care Quality Commission (CQC). The CQC will inspect against their Essential standards of quality and safety [1]. Healthcare organisations should consider benchmarking their management of medical devices with other healthcare organisations. This can help sharing of best practices.

2.7 Reporting adverse incidents (includes near misses)

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons. Any known problems associated with product design, documentation and common use related issues should also be reported, for follow up.

Report all adverse events relating to a device including user problems with a device, software failures, or problems with the instructions for use.

Reporting should be in line with the organisation's local policy and procedures. Staff should know who the healthcare organisation's Medical Device Safety Officer (MDSO) is and how they can be contacted. However, reports from individuals will be received by MHRA and investigated as appropriate.

Reporting is essential to ensure that lessons are learnt, and adverse events are not repeated. National reporting is essential to ensure that trends are spotted and appropriate action is taken across the country to help ensure the safe and effective use of medical devices, for example through safety messages. Unless the MHRA receives reports of all adverse events, emerging problems cannot be identified, continuing the risk of repeat events and patient harm.

Information from adverse incident reporting indicates that one of the factors that has the greatest impact on the safety of devices involve the instructions for use issued by the manufacturer, their availability and clarity. Other key safety factors include the design, the quality of training in the appropriate uses of devices and how well they are maintained and prepared.

Adverse incidents can be easily reported online through the Yellow Card scheme:
<https://yellowcard.mhra.gov.uk/>

MHRA

There are different ways for healthcare professionals to report a problem with a medical device if you're in [Scotland](#) or [Northern Ireland](#).

If you are in England or Wales, please report any problems with medical devices online using the [Yellow Card website](#).

Northern Ireland Adverse Incident Centre (NIAIC): niaic@health-ni.gov.uk

Incident Reporting and Investigation Centre (IRIC): nss.irc@nhs.scot

Recommendations for an effective management system

- a comprehensive, organisation-wide policy on the management of medical devices and a system in place, which ensure that all risks associated with the acquisition, deployment, use, monitoring, record integrity, reprocessing, maintenance, record generation and storage, decommissioning and disposal of medical devices are minimised.
- Board-level responsibility for medical devices management is clearly defined and there are clear lines of accountability throughout the organisation, leading to the board
- a medical devices group with representation from a wide range of staff
- a record of the current location of medical devices to facilitate a systematic approach to medical devices management and to target safety communications, or manufacturer's Field Safety Notices. Records of the action taken as a result should be maintained
- mechanisms to distribute manufacturer's Field Safety Notices, and MHRA safety information to the appropriate people in the organisation and to report incidents
- robust procedures to deal with all medical devices loaned within the organisation or to individual users. Independent contractors using medical devices have appropriate risk management systems in place and are aware of the overall policy and systems for medical device management within the healthcare organisation
- connectivity between the healthcare organisation's strategic plan and the 'on the ground' equipment lifecycle management activities
- an evidence-based and methodical decision-making framework to optimise decisions taken within each stage of the equipment lifecycle (see section 6)
- risk management as inherent in the management of medical devices.

3 Appropriate acquisition and selection of devices

3.1 Policy

Every healthcare organisation should ensure there is a policy or other mechanism for the acquisition and selection of appropriate devices for specific procedures.

Healthcare organisations should produce and manage the acquisition of medical devices through a multi-year investment and replacement plan. This plan should include a prioritised schedule of all short to long term medical devices requirements and should be monitored against appropriate risk assessment criteria.

The medical devices management group, or other mechanism, should ensure that local policy for the acquisition of medical devices address:

- safety, quality and performance, as well as all aspects of the acquisition cycle (see section 3.12)
- the need to ensure that the selection process considers care objectives and priorities of the healthcare organisation, and the needs of the patients.
- the process should consider whole life costs and follow national acquisition policy and recommendations, including any regional or national aggregation of procurement where this results in best value for money
- the need to ensure that the agreed acquisition requirement takes account of the needs and reasonable preferences of all interested parties, including those involved in use, commissioning, decontamination, maintenance and decommissioning
- consumables are cost effective for the life of the device, if applicable. This would include the cost of the device and its maintenance and the lifetime costs of consumables
- the mechanism for the acquisition and selection of appropriate devices for specific procedures.

The policy for procuring medical devices should be established in consultation with the professionals who will be prescribing, supplying or using these.

A healthcare organisation could be held responsible, under health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage, as a result of inappropriate purchase or prescription of a device.

The MHRA's publication *Devices in Practice* [4] includes a series of checklists that can help in the purchase, use and maintenance of medical devices, and training issues.

3.2 Methods of acquisition

In addition to purchasing and leasing, which are the most common methods of acquisition, there are other ways to acquire medical devices, including loans from manufacturers or other healthcare organisations and in-house manufacturing. Hospitals may loan each other devices to avert temporary problems; manufacturers may loan products as part of an evaluation or as an incentive to purchase associated products. In all cases, it must be clear from the outset who is responsible should a problem arise. The medical devices management group should be made aware of any loans.

Some larger clinical/biomedical engineering departments in healthcare organisations design and build medical devices for their own use. If the devices are supplied to another legal entity, then the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (**UK MDR 2002**) [5] apply. Organisations that manufacture medical devices but do not place them on the market (i.e. they are used only within the organisation or legal entity) should, as a matter of best practice, ensure that those devices are manufactured in accordance with the UK MDR 2002.

3.3 Factors to consider before acquisition

- Agree the requirements for the intended medical procedure and/or needs of the end user.
- Suitability for intended purpose/application by reviewing the manufacturer's description of the intended user, usage and the instructions for use, safety and performance information (including detailed specifications of the medical device), and comparing against the performance specifications contained within the acquisition requirement.
- Safety issues and any limitations on use.
- Software compatibility with archive systems, patient records etc.
- Electronic medical devices which process data need to be secure; the medical device is validated, as appropriate.
- Ease of use. Evaluate the ease of use and consider user experience and manufacturer's compliance with BS EN 62366-1:2015 Medical devices. Application of usability engineering to medical devices' [6] (please note this standard has not been designated to the UK MDR 2002 but represents best practice and therefore MHRA recommends it is adhered to over older versions). Has it been designed to minimise accidental misuse? How easy is it to misuse the device and what precautions are incorporated into the design to guard against misuse? Consider user experience feedback and evaluations from the expected clinical environment.
- Evaluate and assess the readability of manufacturer's instructions. Instructions for use (IFU) should be comprehensive but intelligible. Overly complex IFU may point to poor design that has not incorporated human usability as a key design goal.
- Availability, type and scope of training. What type of training is available e.g. face-to-face, electronic, e-learning, blended? Is it on-going? Is it training for users or maintainers or both? Does training include methods of decontamination?
- Advice and help. What advice services does the supplier offer and/or what user-help guides are incorporated in or with the system to assist the user with the operation of the device and of its suitability for use for specific procedures?
- Ensuring the operating/environmental conditions of the place where the device will be used are compatible with those of the device.
- Decontamination and disposal procedures, including ensuring the healthcare organisation is able to reprocess in line with the manufacturer's instructions (e.g. by trained technicians). The infection prevention team and decontamination lead should be consulted (see section 9).
- Pre-use set up, testing requirements, installation requirements and commissioning procedure (see section 5).
- The projected service life of the product and warranty details. In the long run, it could be cheaper to purchase a device which will last for 10 years but costs twice

as much as a device designed to last for only 3 years, as long as maintenance and replacement parts and consumables are available for the lifetime.

- Whole life costs: acquisition and operational, maintenance and consumable, training, risk, renewal and disposal costs.
- Medical devices may require routine user maintenance, planned preventive maintenance (e.g. by trained technicians) and ad-hoc maintenance, if faults occur. Many require periodic performance checks which may require specialist test equipment. Evaluate the user and planned maintenance recommendations for the device (including frequency and type). Evaluate the ease of breakdown maintenance, particularly in relation to how this will be provided and the response time provided by the supplier for breakdown maintenance. Ensure that all medical devices can be stored, maintained and serviced in line with the manufacturer's instructions for use. Consider all the costs associated with these before buying.
- Using profiles of existing devices. Before acquiring replacement devices, healthcare organisations should consider whether, with improved equipment management e.g. establishment of equipment libraries, they have sufficient inventory of existing devices to meet requirements.
- Rationalising the range of models versus diversity (see section 3.7).
- Reliability and previous performance.

3.3.1 The procedure for accepting new devices should also identify:

- Training needs
- Appropriate planned preventive maintenance and performance checks
- Technical support needs of users
- Whether risks associated with using a model for the first time have been minimised.

Some devices, such as medical gloves, dressings, catheters and syringes are delivered in bulk packs, so it would be inappropriate to check each one on delivery. For such consumable devices key issues are:

- Expiry dates are clearly shown on packaging, as required
- Appropriate marking for tracing lots, if there is a recall or modification required
- Instructions and safety information are available, as necessary
- Packaging is appropriate for storage
- Environmental conditions for storage are clear.

See also section 5.1.2

3.5 Modifying and changing use

Modifying existing devices or using them for purposes not intended by the manufacturer (off-label use) has safety implications. It may also count as manufacture of a new device under the UK MDR 2002 [5]. The original manufacturer's liability is limited and liability may be partly or wholly transferred to the organisation or person making the modifications, if the device is implicated in an adverse incident.

It is essential that modifications outside of the manufacturer's intended use are only considered as part of a fully documented risk management process within the healthcare organisation's risk management policy and procedures.

In specific cases, where it is deemed that using an alternative accessory to that specified by the device manufacturer would give improved benefits, then a risk assessment should be carried out to ensure that all components within a system are compatible and can be used safely, e.g. batteries, chargers, connectors.

If a device fails in use following replacement of a part with one not corresponding to the device manufacturer's specifications and this leads to the death or serious injury of a patient/user, there is a greater likelihood of the organisation responsible for medical device repair/maintenance being held liable for the injuries caused.

3.6 Safety performance and reliability

Points to consider

- Does the medical device have a UKCA, CE or CE UKNI mark? This is a legal requirement for medical devices.
- Is there any local knowledge or history of problems with the device or type of device?
- Do MHRA safety publications, manufacturer's advisory notices or other relevant publications identify issues related to the device?
- Have other users experienced problems and failures? Can the manufacturer provide evidence of reliability from other responsible organisations? Does the manufacturer claim compliance with relevant standards?

3.7 Rationalising the range of models versus diversity

Having a variety of models for the same purpose can increase the risk of operator's confusion, leading to misuse and complicating training requirements. Restricting purchase and stock holding to one type of device reduces these risks and can be financially advantageous.

However, reliance on a single model can also cause problems. The chosen model may prove unreliable or be subject to a manufacturer's recall. Sooner or later, the manufacturer is likely to withdraw the old model, as designs improve or the manufacturer may even cease trading.

There is particular risk of operator's confusion with devices that are superficially similar but have different applications, limitations, settings or operating procedures. If there is a need for different facilities or functions e.g. between infusion pumps for epidural and patient controlled analgesia (PCA) it may be better to choose completely different models.

3.8 Installation support services

- Is the installation to be carried out by manufacturer/supplier?
- What building and utility services are required? The adequacy of services needs to be established (e.g. the suitability of the electrical or piped gas supply).

- Is special decontamination, calibration or other associated equipment needed? Complex devices may need specialists to install and commission them.
- Does the device meet the required IT communication protocols, operating system etc.?
- Does the manufacturer endorse the installation of additional software e.g. virus checker?

3.9 Maintenance support services

Ensure that devices are regularly checked for functionality prior to use by the user in line with the manufacturer's instructions and throughout the expected lifetime of the device.

Points to consider

- Can the desired service provider maintain the device?
- How will the proposed contract or service level agreement deal with continuity of care? For example: on site repair, if needed.
- Are alternative devices available to cover periods when a device is being repaired or serviced?
- Are response times appropriate and guaranteed?
- What are the proposed servicing intervals? (Also, consider the types of checks and calibrations required between servicing intervals.).
- Are spares readily available, and for how long?
- Is service support guaranteed, and for how long?
- What information is available from the device manufacturer, e.g. circuit diagrams, preventive maintenance schedules, trouble-shooting guides, repair procedures, parts list, and special tools list?

3.10 Second-hand medical devices

Usage and service history should always be available for prospective purchasers before sale and then supplied with the device, at the point of sale.

As a minimum, there should be a:

- record of any reconditioning work carried out, including a record of replacement parts
- copy of all maintenance and servicing that have been carried out, including the name of the maintenance/servicing organisation
- record, type and frequency of usage over its working life
- fault log
- record of decontamination status
- date of installation

- tube usage (in the case of X-ray devices)
- helium level (in the case of MRI).
- Technical information supplied by the manufacturer (e.g. IFU, operators manual etc)

3.11 Documentation and monitoring

To reduce the possibility of inappropriate devices being purchased or prescribed it is essential that a full performance specification of the entire system is established before any purchases are made. For example, with battery powered device this must incorporate all elements, such as battery type, charger type, charging process, maintenance and use.

Once the selection process has identified the most suitable medical device, then the final terms and conditions covering all aspects of the acquisition should be agreed by all interested parties and documented. Only then should the contract be awarded, the purchase order raised, or the acquisition otherwise be cleared to proceed.

The acquisition should then be managed in accordance with the terms and conditions agreed, and the results of the acquisition and usage experience fed back into any subsequent acquisitions.

3.12 The acquisition cycle

Recommendations for acquiring equipment:

- Local acquisition policies and processes to be established with the involvement of the medical devices group within the organisation.
- The relevant advisory groups to be established and consulted.
- Safety, quality and performance considerations to be included in all acquisition decisions.
- The recommendations of the MHRA and other appropriate bodies to be considered for selection and acquisition.
- Ensure all acquisitions meet UK regulations.
- All developments, modifications and trials of devices to be carried out in accordance with the relevant legislation, guidance and risk management policy.
- Model ranges to be rationalised, where possible.
- Technical support, maintenance and repair systems, timescales and details of the lifetime of the device to be included.
- User experience to be fed back into the policy, process, future acquisitions and advisory groups.
- Organisations should identify how they can achieve savings through smarter procurement. Examples include identifying opportunities to aggregate spend, utilising national and/or local framework agreements and equipment standardisation.

4 Clinical investigations involving non-UKCA/CE/CE UKNI marked medical devices

The healthcare organisation's medical device management policy should cover situations where that organisation enters into agreements with a medical device manufacturer to take part in a pre-UKCA/CE/CE UKNI marking clinical investigation of a new medical device or wishes to conduct such a trial on a device manufactured in-house. That policy should include consideration of the following factors:

- Has the relevant ethics committee given approval for the study?
- Has the MHRA issued the manufacturer with a letter of no objection?
- Have the relevant healthcare professionals received adequate training?
- Are there arrangements in place to segregate the investigational devices from other UKCA/CE/CE UKNI marked medical devices and to ensure that the only healthcare professionals to use the investigational device are those named as clinical investigators in the application to the MHRA?
- Have patients who agreed to take part in the investigation done so only after providing fully informed consent?
- Has provision been made, where relevant, for decontamination, reprocessing, servicing, maintenance and disposal in conjunction with the sponsoring manufacturer?
- Does the agreement include criteria for stopping or curtailing the investigation or use?

5 Receiving a new device

5.1 Acceptance checks

Healthcare organisations should check that the specification of newly delivered devices matches the purchase order detail or tender specification.

Simple checks on delivery can save time and avoid trouble. Finding out that a device is broken or inappropriate, only when someone tries to use it for the first time, can delay or interrupt treatment, make it harder to establish when and where the problem arose and invalidate warranties.

5.1.1 Record keeping

The healthcare organisations should keep records of the order, the results of the delivery inspection, the individual device or batch identifier and any safety or functional tests.

It should always be recorded who carried these out, when and how, because:

- health and safety inspectors require records to be available
- a defence in a negligence case based on good device management can only be effective if records are available for the device involved
- recording the individual device or batch details on a validated and secure database means it can subsequently be traced for maintenance or for a manufacturer's recall/field correction, if necessary.

This should be part of the device life cycle that includes maintenance and traceability.

5.1.2 Skills required for, and scope of, checks and tests

Delivery checks should include:

- checking that the correct product, complete with usage and maintenance information and any relevant accessories, has been supplied
- ensuring that devices have been delivered in good condition and, where relevant, in good working order
- the manufacturer's instructions may specify particular testing, calibration or adjustment before a medical device is used for the first time. It may also be desirable to generate baseline data for comparisons, for example to show calibration drift during subsequent maintenance and to measure and record 'as new' reference values for electrical safety parameters.

Note: The tests listed in product safety standards, such as BS EN 60601-1 [7], are designed for type-testing and may damage the device under test, hence some are not suitable for pre-use or maintenance tests.

Checks and tests can only be effective if everyone carrying them out has appropriate training.

below is some basic guidance on what checks and tests should cover, and the skills required to carry them out. These checks will be dependent on device type.

See also section 3.4.3

Table 5.1 Basic guidance on delivery checks

Paperwork / database

- Is the device compatible with specification set out in the purchase order?
- Have the user, repair and maintenance information, compliance and calibration certificates, as well as test results been included, where relevant?
- Add device details, asset number and serial number on to device management records.
- Does the device (or any component part or accessory) need decontaminating before first use?
- Are the instructions for use appropriate?
- Does the device require validation?
- Are the Decontamination instructions appropriate?

Knowledge required

- Ordering system
- Inventory system
- Names and appearances of common medical devices
- Medical device documentation (Instructions for Use, certificates etc)
- Serial numbers and model identification codes

Visual inspection

- Check outer packaging is intact and undamaged
- Check for any damage apparent to the device on inspection
- Look for an appropriate expiry date, UKCA/CE/CE UKNI mark, UK Approved Body/Notified Body number, electrical class, lot number, quantity in pack, storage

information for unopened pack

Knowledge required

- Knowledge of areas to check for damage
- Familiarity with the appearance of product in good condition, common defects
- Knowledge of medical devices and their use
- Knowledge of electrical class symbols.

Configuration

- Configure the medical device to clinical requirements and ensure compatibility with all other equivalent medical devices in the healthcare organisation
- Agree configuration with clinical manager or director, documenting the decision with reasons, where appropriate.

Knowledge required

- Knowledge and understanding of the medical device and its clinical application
- Knowledge and understanding of the impact of configuration changes on clinical care
- Knowledge of how to configure this device.

Table 5.2 Basic guidance on safety and calibration checks

Functional

This may require more extensive checks by specialist staff for complex or specialist device.

- Does the device function in line with the manufacturer's information?
- Are accessories/parts included and compatible?
- Do indicators and displays function correctly in line with the manufacturer's information when powered up?*
- When powered up, does the device start when it should and do the dials and switches do what they say?*

Knowledge Required:

- For some devices, the skills required will be little more than basic training to allow the manufacturer's information to be followed.
- In cases where the manufacturer's instructions specify specialist assembly or manipulation, familiarity with the functions of the device and its components and accessories is required.

Electrical

- Are the mains leads, plugs and other connectors undamaged?
- Are the mains plugs compatible with the sockets used in the UK (BS 1363/A)? (Mains adapters should not be used on medical devices.)

Knowledge required:

Training in visual electrical safety inspection techniques.

Calibration and Measurement

Where appropriate, use test device to check:

- Accuracy of physiological measurements
- Dose delivery*

- Energy delivery*
- Accuracy of other outputs*

Knowledge required:

Tests should be carried out by an adequately trained and appropriately qualified person.

*only for active devices

For simple devices, bought with an adequately specified purchase order or tender system, pre-use testing may not be appropriate. Organisations may, however, wish to carry out random testing of samples at the delivery stage, as well as subsequent periodic checks.

5.1.3 Safety test limits

Acceptance tests should not exceed the bounds of normal use. They should not be type tests.

- Disassembly should be restricted to what is necessary for normal use and cleaning.
- Currents or voltages applied during tests should not exceed those occurring in normal use.
- Refer to BS EN 62353:2014* [8] for further information (please note this standard has not been designated to the UK MDR 2002 but represents best practice and therefore MHRA recommends it is adhered to over older versions).

Any test, in addition to those intended by the manufacturer and involving an abnormal stress, such as loading a hoist above its stated maximum working load, carries an unacceptable risk of causing permanent damage. It should not be carried out.

5.2 Special considerations

5.2.1 Risk assessment before first use

Healthcare organisations should have standard configuration sets for equipment, signed by a lead clinician and that equipment configuration is always verified before being put into service.

There may be additional risks associated with devices in the following categories which should be considered in the assessment process:

- Devices manufactured in-house
- Second-hand devices
- Devices lent by another responsible organisation
- Devices reissued to second or subsequent users
- Custom made devices for named patients
- Devices under clinical investigation

Risk assessment may mean local testing and the issue of a local safety certificate. A local safety certificate is intended to:

- Confirm that a device is safe and effective
- Set any necessary limits on its use.

5.2.2 Devices on loan from manufacturers

All devices on loan from manufacturers should be subject to a written agreement which defines the device management requirements, responsibilities and liabilities, including decontamination if applicable. See NHS Master Indemnity Agreement [9]. Delivery receipt and pre-use procedures for loan device should be the same as those for purchased device, unless otherwise specified in this written agreement.

5.2.3 Home use

Where the ownership and management of the device remain with the supplier, such as enteral feeding pumps, the manufacturer's pre-dispatch tests, combined with simple pre-use checks by those responsible for the care of the end user in the community, (e.g. community nurse), should provide adequate safety assurance. In this situation, record-keeping is the supplier's responsibility with input from the end user, as appropriate. For devices owned by healthcare services and loaned to end users in the community for use at home, the responsibility for ensuring that the device is delivered and is safe to use is the responsibility of the healthcare service. However, this may include an agreement for the end user to carry out basic assembly or safety checks before use.

For devices in the home and owned by the supplier, incident reporting to the MHRA is the responsibility of the supplier, once alerted by the user/carer. The local health provider that has purchased the service should also be notified by the supplier.

5.2.4 Installed devices

When a device needs to be installed, there should be a procedure in place for commissioning the installation, which has been agreed with the supplier and the healthcare organisation responsible for carrying it out. Installed devices need to take account of connecting to IT network, ensuring connectivity, configuration etc.

Particular attention should be given to connection to electrical power supplies. The electrical power installation should conform to the 18th Edition of the IET Wiring Regulations (in particular Section 710) [10].

Installation is required when any of the following occurs:

- Substantial assembly work will be required on-site
- There are permanent plumbing, electrical and gas pipeline connections
- The device needs to be permanently fixed in place.

Under the UK MDR 2002 [5], suppliers must provide instructions for installing a device and bringing it into use. Where appropriate, these instructions should include specifications for safety and performance checks.

A designated member of staff should oversee the commissioning process and take responsibility for deciding that it has been completed satisfactorily.

5.3 Legal requirements in relation to electrical safety testing

The Electricity at Work Regulations (EWR) [11] and the Health and Safety at Work etc. Act (HASAWA) [12] form the basis of programmes used by hospital technical staff for the regular electrical testing or inspection of portable electrical equipment. Carrying out a risk assessment may determine the need for either an inspection or electrical testing.

HASAWA imposes a duty on employers for:

- the provision and maintenance of plant and systems of work that are so far as is reasonably practicable, safe and without risks to health

- the provision of such information, instruction, training and supervision, as necessary.

The Electricity at Work Regulations state:

- 'no electrical equipment shall be put into use where its strength and capability may be exceeded in such a way as may give rise to danger'
- 'all systems shall be maintained so as to prevent, so far as is reasonably practicable, such danger'.

Healthcare organisations must have procedures to comply with the legislation. There is no specific legal obligation, or even guidance, requiring healthcare organisations to carry out any particular test, but there is a general duty to take necessary steps to protect staff and patients from danger. Healthcare organisations should implement electrical safety schedules to comply with this legislation. Risk assessments should be done to ensure that the tests carried out are appropriate or reasonably practical. These include pre-use testing of new devices (see section 5.1.3) in addition to subsequent maintenance tests.

6 Training

Healthcare professionals working for the organisation, as employees or contractors, have a professional duty to ensure their own skills and training remain up to date. The healthcare organisation should ensure that continuous professional development and training activities include the safe use of medical devices during annual staff appraisal.

Users, carers and prescribers need to carefully consider the content of all warnings of risks and the device should only be used and maintained in line with the manufacturer's instructions. If the manufacturer's instructions do not fully cover these points then please report to the MHRA, using the details in section 2.7.

The need for training depends on many factors including the device, and can involve end users, carers, professional users or other staff:

- Will it be required for all anticipated users, carers or staff?
- Will it be required for maintenance, repair and decontamination staff to enable them to carry out all their duties?
- Is the same model already in use and registered on a database for medical devices?
 - > If so, will refresher or update training be needed?
 - > If not, are new training and records needed?

6.1 Policy on training

A training policy should be developed by the medical devices management group.

Points to consider

- The need for adequate training programmes which may include generic and specific training and periodic review or retraining, as required.
- How will training be delivered (face-to-face, e-learning)?

- Is it competency based?
- Who should receive the training offered by the manufacturer or supplier? How will everyone else be trained, and by whom, and when?
- Inclusion of new staff, agency, on-call and locum staff and contractors and those involved in maintenance and repair services as appropriate.
- Continuing professional development.
- Training for service end users and carers. This may include written guidance and that the necessary checks and actions are taken in the event of failures or faults.
- Planned training before a new medical device is introduced to the organisation.
- Appropriate record keeping of training both centrally and by individuals.
- Access to manufacturer's instructions for all users.
- Have you considered future training needs for when those trained directly by the manufacturer/supplier change jobs?
- How will training updates be managed for device/software upgrades?
- How will end users or staff in the community be trained?

6.2 Training for device users

Any user of a device needs to understand how the manufacturer intends the device/equipment to be used, and how it normally operates to be able to use it effectively and safely. Training should include

- differences between models, compatibility with other products and any contraindications or limitations on use
- accessories and how they may increase or limit the use of the device
- use of controls
- displays, indicators, alarms etc.
- requirements for maintenance and decontamination, including cleaning, in line with the manufacturer's instructions and relevant local procedures
- be able to show end users how to use the device
- troubleshooting, including potential issues including those identified in safety advice from the MHRA, manufacturers and other relevant bodies
- be able to recognise device defects or when a device is not working properly and know what to do
- understand the importance of **reporting device-related adverse incidents** to the MHRA and be familiar with the organisations' reporting procedure (see section 2.7).

6.4 Training for repair and maintenance service providers

Individuals providing repair and maintenance services need to be adequately trained and appropriately qualified. This applies to directly employed staff, contracted services or others.

The training records of individuals involved should identify that they are appropriately trained to a level proportionate to the activities they are undertaking. See section 8.4.

6.5 Documentation

Evidence that suitable instructions and training were provided are needed, should a legal case be brought. Users of device should be asked to sign / electronically confirm statements confirming that they have received and understood written and / or oral instructions.

Details of training given should also be recorded. A simple test at the end of training to check that the information has been understood may also be included.

7 Instructions for use

7.1 The importance of effective instructions

Good clear instructions for use have a crucial role in the safe and effective use of devices. The manufacturer is responsible for supplying appropriate instructions, considering the knowledge and training of the intended user(s).

Clear responsibilities should exist for ensuring that the manufacturer's instructions are passed on to all users and, where appropriate, carers. The manufacturer's instructions may need to be supplemented with training.

When manufacturers update their information, healthcare organisations should have a protocol for keeping track of all sets of instructions they hold or have issued to users to enable replacement of existing instructions with revised versions. Consideration should be made to updating the content of relevant training.

Any shortcomings in the instructions should be reported to the MHRA as an adverse incident (see section 2.7).

7.2 Instructions for the end user

All necessary information on storage, pre-use checks, use, maintenance and cleaning should be passed on to the end user, including when the device is issued to a second or subsequent user.

A failure to pass on to the end user the manufacturer's original instructions may compromise the end user's ability to use the device safely, and may lay the healthcare organisation open to legal liability under:

- The Consumer Protection Act 1987 [13] (in the case of a medical device)
- The General Product Safety Regulations 2005 [14] (in the case of a consumer product not covered by other specific legislation)
- The Common Law of Negligence [15].

Some users or carers with particular disabilities or medical conditions may need additional instructions or training. For example, people who are visually impaired may not be able to easily read some forms of written information.

The healthcare organisation may also need to supply its own information to explain any additional administrative arrangements e.g. contact details for maintenance, consumables or spare parts.

Instructions may need to be written locally to cover whole systems where devices are used together with other device, such as connecting a blood analyser to a computer, to permit automatic updating of patient records.

If healthcare organisations draft their own instructions to supplement the manufacturer's instructions, consider consulting the manufacturer/supplier on their accuracy and suitability, before issue. See Table 7.1 for some potential difficulties with instructions.

7.3 Documentation

Evidence that suitable instructions and training were provided will be needed, should a legal case be brought. Records should be kept of who has received written device instructions.

- All users and prescribers should have access to the manufacturer's instructions.
- Records should be kept of who has received written device instructions.
- There must be a process for recording, tracking and updating the manufacturer's instructions.
- Any updates must be distributed to all relevant users of the device.
- Any manufacturer's instructions considered to be inadequate or ineffective should be reported to the MHRA (see section 2.7)

8 Maintenance and repair

8.1 Management policy for medical devices

The healthcare organisation's medical device management policy must cover the provision of maintenance and repair of all medical devices, including reconditioning and refurbishment. The healthcare organisation is responsible for ensuring their medical devices are maintained appropriately.

This includes:

- How each device should be maintained and repaired, and by whom
- Arrangements for maintenance and repair to be included as part of the assessment process
- Arrangements for the most suitable persons/providers to carry out the work
- Arrangements to ensure items subject to inspection, maintenance, repair or disposal should be decontaminated beforehand (see section 9)
- The timescale for planned maintenance
- The timescale for repairs to be completed
- Maintenance databases are validated for their intended use and functionality.

Where other regulations apply, Ionising Radiations Regulations 2017 [16] and The Lifting Operations and Lifting Equipment Regulations 1998 [17] for example, the tests

therein should be carried out in addition to the maintenance and testing recommended in the manufacturer's instructions for use (IFU) supplied with the device, not instead of.

The frequency and type of planned preventive maintenance should be specified, in line with the manufacturer's instructions and taking account of the expected usage and the environment which it is to be used.

8.1.1 Audit and review

Random audits should be carried out on all elements of maintenance, repair, record generation and storage to ensure that the correct procedures are in place and being adhered to. Audits should be carried out by staff with appropriate knowledge and experience of managing medical devices.

The healthcare organisation should also ensure that there is a mechanism to obtain regular feedback from all users of the device on the repair and maintenance process.

This should include the reporting of even apparently minor problems as these might lead to major failure unless remedied.

8.2 Choosing appropriate maintenance and repair services

The UK MDR 2002 [5] require a manufacturer to provide:

'all the information needed to verify whether the device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times'.

The following organisations and individuals can have a role in ensuring that medical devices are adequately maintained and repaired:

- manufacturer service organisation
- authorised service agents
- generic/third-party service providers
- in-house maintenance departments
- users.

The healthcare organisation should carry out a risk-benefit analysis before finalising the specification of any maintenance and repair services. Cost alone should not be the determining factor.

Where available, use a service provider or third-party repairer who complies with relevant quality system standards, such as European Standard BS EN ISO 13485:(2016) [18] or BS EN ISO 9001:(2015) [19]. These standards ensure their work is consistently of the nature and quality intended.

When selecting external maintenance contracts (OEM or third-party repairer), healthcare organisations should take time to fully consider which service level is the most appropriate to meet requirements. Consideration should be made against risk, performance and cost criteria.

A manufacturer may wish to supply and maintain devices exclusively to guarantee the standard of repair. Alternatively, a manufacturer may stipulate strict criteria on the training, equipment and resources of an in-house department or any third-party

repairer. See Tables 8.1 and 8.2. If these criteria are changed, it should be done so on the basis of a risk assessment.

Note: The term ‘third-party repairer’ does not apply to in-house healthcare maintenance facilities.

Points to consider:

- Do service providers have access to the necessary equipment and up-to-date and detailed maintenance records? Otherwise they may not be able to carry out the tasks safely and effectively.
- The track record of the service provider. How quickly can they provide a service? Will they loan devices whilst maintenance or repair is being carried out?
- What level of detail is needed in the records? It will vary with the type of device and may include, for example: calibration, preventive maintenance and troubleshooting.
- Are full details of the repair and maintenance procedures and spare parts available?
- Are consumable materials, such as adhesives or thread locking compounds, included?

Table 8.1 Comparison of in-house maintenance with an external provider

External provider

Advantages:

- Predictable costs.
- Possible to specify response times.
- Possible to specify equipment down times.
- Loan equipment.
- Often cheaper than manufacturer.
- Possible to have an on-site engineer to cope with breakdowns.
- Fewer external organisations to deal with.

Disadvantages:

- Hard to maintain fast response cover for critical care or high dependency breakdowns without additional costs.
- Equipment may need to be sent away for repair and servicing.
- Equipment loans may be required.
- May only be able to cover certain devices.
- Some devices may be excluded.
- Ensure manufacturers can train staff where appropriate.
- Possible lack of manufacturer’s information.

In House Maintenance

Advantages:

- Fast response possible for problem solving and breakdowns.
- In-house teams may be flexible in accessing equipment for scheduled preventive maintenance thus reducing down times.

- In-house equipment management departments can co-ordinate and manage an appropriate mix of in-house, manufacturer and third-party service

Disadvantages:

- Hard to maintain adequate stocks of spare parts across a wide range of devices.
- Special tools and test equipment may not be available.
- Specialist training costs can be high.
- Manufacturers are sometimes reluctant to provide training

Manufacturer

Advantages:

- Same build standard as
- original device, with modifications and updates incorporated.
- Assured access to spares.
- Remote diagnostics via computer network sometimes available.
- No problems with warranty/liability.
- Assured access to spares.
- Remote diagnostics via computer network sometimes available.
- No problems with warranty/liability.
- Availability of training for professional users.

Disadvantages

- Contracts with many separate manufacturers need to be negotiated and updated.
- Response times may be long, depending on the contract.
- Users may need long lists of helpline numbers.
- Problems with co-ordinating multiple contracts from the same manufacturer.

Note: If using an outside organisation, you need in-house expertise to monitor, audit and manage contracts.

8.3 The service contract

Any contractual agreement with a maintenance and / or repair service provider should specify the level and type of service required by the healthcare organisation and should include, where appropriate:

- reference to manufacturer's written instructions
- availability, source and traceability of spare parts
- notification of any changes, including the use of alternative spare parts or methods
- training of staff
- quality management systems
- requirement for adequate record keeping
- who is responsible under information governance when third parties and manufacturers are taking patient data from the premises
- use of sub-contractors
- response times

- loan devices
- disposal of obsolete devices, parts and waste.

Take specialist advice in drawing up contracts where specific legislation covers the process e.g. the radiation protection adviser in the preparation of service contracts for diagnostic X-ray device, as required by the Ionising Radiation Regulations 2017 [16] and for hoists or lifting device the Lifting Operations and Lifting Equipment Regulations 1998 [17]. See section 11, for other examples of legislation.

Guidance on a range of repair and maintenance contracts is available through the [NHS Supply Chain](#) and other frameworks.

8.4 Training and experience of repair and maintenance staff

Health and safety law [12] require employers to ensure employees are adequately trained. All service staff should be adequately trained and competent on devices and have sufficient work experience of the devices they repair and maintain.

Those without adequate training should not be allowed, nor should they attempt, to repair or maintain medical devices and equipment.

All those undertaking repair and maintenance should be able to produce written evidence of appropriate and up-to-date training, preferably as part of the documentation required by a quality management system. They should also be able to show that they are up to date on new maintenance techniques, consistent with the devices they are servicing.

8.4.1 Contracts with the manufacturer

Where contracts are placed with the manufacturer for repair and maintenance, the healthcare organisations should ensure that they are made aware of any changes in circumstances that may affect the repair or maintenance of their devices.

For example, if a manufacturer merges with, or is taken over by another organisation, the responsibility for repair and maintenance may transfer to the new organisation.

If the manufacturer ceases trading and an alternative service provider is not able to undertake the work in line with the manufacturer's instructions, the device may need to be disposed of. However, there may be circumstances where it is essential to keep a device in use. If this happens, a risk assessment of its continued use with service backup from another provider in line with the manufacturer's instructions must be completed, set against the consequences of the device not being available in the short or longer term.

Regularly review the situation to see if alternative arrangements can be made, including acquiring new or replacement devices and subsequent disposal of the original ones.

8.4.2 Subcontracted repair and maintenance

If any aspect of the repair or maintenance process is subcontracted, the healthcare organisation should ensure that:

- they are aware of those aspects of the repair that are being subcontracted
- the main service provider and the subcontractor have a contract, detailing the responsibilities of each party

- the service provider audits the subcontractor frequently to establish that it has the necessary expertise and resources, and that the work level meets the standard agreed between the service provider and the healthcare organisation
- they are notified of any changes in these arrangements.

8.5 Updating changes to manufacturers' instructions

Whoever provides maintenance and repair services should ensure that they are automatically alerted of any changes to repair or maintenance instructions and other essential safety information issued by the manufacturer, such as Field Safety Notices.

There may be changes to the design, or other information, which could affect safety or change the requirements for repair or maintenance, including recalls or safety measures and mandatory upgrades.

The records of the healthcare organisation and the service provider must show the version of the device currently in use and whether it has been upgraded, modified or repaired since it was supplied. This includes integral computer software.

This system should include all relevant guidance issued by the MHRA.

8.6 Spare parts and other components

There are several sources of spare parts:

- the device manufacturer
- other manufacturers
- healthcare organisations
- service providers
- pre-used.

8.6.1 Quality and compatibility with the device

Before purchasing equipment the purchaser should clarify with the manufacturer if there are any conditions imposed by them before they are willing to supply any spare part.

The contract between the healthcare organisation and the maintenance and / or repair service provider should clearly define the terms 'spare parts' and 'consumables' and ensure that their quality and compatibility match those supplied by the original device manufacturer.

To ensure that replacement parts are of the correct specification, purchase them either directly from the manufacturer or to the same specification.

When obtaining replacement spare parts from sources other than the manufacturer, you must take care to ensure that all aspects of the technical specification are met, including, for example: physical dimensions, material strength, mechanical properties and compatibility.

Any agreements to supply parts from sources other than those recommended by the manufacturer should be properly risk assessed, costed and documented, before a decision is made to buy them.

This should also include any effects on whole life costs: a cheaper part requiring more frequent maintenance may not be cost-effective in the longer term. There also

may be legal consequences for the healthcare organisation if a device failure, associated with the fitting of such a spare part, causes an injury or incident.

8.6.2 Reusing spare parts

Under normal circumstances, pre-used parts should not be used to repair a device. They may be acceptable in exceptional circumstances after a fully documented risk assessment.

The stresses and strains that the part has undergone will depend on many factors, such as: the length of time in service, age and repair or maintenance history. Pre-used parts may therefore increase the need for maintenance checks or reduce the overall life cycle of the device.

The failure of a part can have severe consequences for the end user. The part should not be reused if its previous history is unknown.

8.6.3 Traceability of spare parts

The healthcare organisation should ensure that they or the repair and maintenance service provider can:

- identify all spare parts replaced during the maintenance or repair of a device
- trace all critical parts back to the supplier.

This will permit ready identification of those devices containing parts that need to be repaired or recalled.

Not all spare parts are critical and the extent to which they need to be identified and related to the original piece of device will depend on several factors.

As a guide, a critical part is a component that might reasonably be expected to cause the failure of a piece of equipment, in such a way that affects its safety or effectiveness and consequently results in death or injury to a user, should it stop working.

8.6.4 Replacement batteries (see also Appendix)

Replacement batteries must provide the same power and lifecycle as those provided with the original device. If an inappropriate replacement battery is used, the device may not function or recharge properly, leading to increased risk to users or healthcare staff. The device manufacturer's specifications should always be followed with respect to replacement. Replacement battery packs may have to incorporate specific features such as active memory, current-limiting or capacity-indicating elements that interface with the medical device.

Note: The device manufacturer may upgrade the specification of the battery or pack during the lifetime of the device to allow improved performance. The latest instructions from the manufacturer of the specific device should be followed.

An organisation could be held responsible under health and safety law [12] and civil liability if a patient or member of personnel died or suffered personal injury or damage as a result of inappropriate replacement of batteries.

8.7 Repair and maintenance methods

The maintenance and repair service provider should have all the necessary testing, measuring and repair equipment and ensure that this is adequately maintained and calibrated, as required.

Test equipment, such as jigs, templates, and computer service and validated diagnostic software should be checked regularly to ensure that they can adequately demonstrate device safety.

Make sure that the service provider has identified and documented all risks, implemented a strategy to manage them, and has documented procedures in place detailing the repair and maintenance methods to safeguard device malfunctions and facilitate tracing of any subsequent parts recall.

Before bringing a device back into service, it should be adequately tested for electrical safety where applicable and for performance. The user should be informed of the results and any changes made to the settings of the device.

Professional users should be told, where applicable, about pass / fail criteria or anything that may adversely affect the treatment of a patient, for example increased radiation dose.

Note: A 'SERVICED' label should also include a due service date as clinical staff need to know the expected next service date in order to maintain patient safety. Service intervals for devices should range between 1 month and 2 years, depending on the device.

Table 8.3 Planned preventive maintenance checklist

Initial inspection

- Is the device clean?
- Does it need decontaminating?
- Note settings of controls.
- Inspect each element in line with manufacturer's instructions.

Parts replaced

- Note each item/part to be replaced.
- Record each items/part replaced, including details of source manufacturer and method of fitting.

Calibration

- Establish if any element/part requires calibration or re-calibration.
- Calibrate in line with the manufacturer's instructions.

Performance and safety

- Carry out performance tests against the manufacturer's specifications before and after maintenance.
- Consider if handover procedure is required.

Return to use

- Input all details on individual equipment record in the maintenance database.

- Check the device has its accessories, where appropriate, and is properly assembled.
- Return controls either to zero or to the settings noted at initial inspection.
- Stick on a dated, 'SERVICED' label noting the next date due and a note of any alterations in control settings

8.8 Routine maintenance by users

Routine maintenance by the user should ensure that the device continues to function correctly.

It entails regular inspection and care, as recommended in the manufacturer's user information or in local procedures. This should clearly show the routine tasks and how they should be carried out. Instructions for user maintenance of medical devices should be provided to the users. 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 then discontinuing use
- contacting the relevant servicing organisation.

Any problems the user finds can then be referred to a repair service. Minor changes that do not affect the safe working of the device can be recorded for attention during the preventive maintenance sessions.

Users may need to be trained to carry out routine maintenance. For example, they may require training on how to remove, change and insert batteries correctly in line with the manufacturer's instructions. They may also need to be warned about the dangers of substituting different battery types. See also Appendix.

8.9 Breakdowns

Even with comprehensive maintenance schedules, breakdowns may still occur.

To restore function as quickly as possible, it is often easiest to substitute a similar device, although this may require increased stock levels especially if equipment is not centrally managed. Substitution is not always possible for items such as large X-ray machines and specially adapted wheelchairs.

Increased stock levels can be set against the likely costs of, for instance, paying an external service provider or providing a similar in-house service for response cover 24 hours per day. Decisions will also depend on the level of service the healthcare provider wishes to provide for their patients and any associated costs for re-arranging clinic appointments etc.

Wherever possible, temporary repairs should be avoided but, if needed, the temporary repair should be carried out and all concerned should be informed of any special precautions or limitations on use, until a permanent solution is available.

This should be documented on the device records.

The device should be replaced or withdrawn from service as soon as possible and properly repaired, before it is used again.

8.10 Legal liabilities and Insurance

The healthcare organisations should take all reasonable steps to ensure that medical devices are repaired and maintained to a suitable standard. The extent of liability will depend on the specifics of the case, and what steps are taken to ensure that adequate repair and maintenance are carried out.

Healthcare organisations that modify devices and subsequently transfer them to another legal entity, such as another healthcare organisation, will also need to comply with the UK MDR 2002 [5].

Particular types of devices / equipment are covered by specific legislation and this may affect their maintenance requirements. Health and Safety legislation usually refers to the responsibilities of the employer, rather than the term 'healthcare organisation' used throughout this document. See section 11 for a list of relevant legislation.

The healthcare organisations should ensure that provider has adequate insurance or indemnity in place.

9 Decontamination

Healthcare organisations should keep patients, staff and visitors safe and have policies and systems in place to ensure that all reusable medical devices are properly decontaminated prior to use or maintenance, and that the risks associated with decontamination facilities and processes are well managed.

Decontamination requirements should be considered before reusable medical devices are acquired to ensure they are compatible with the decontamination procedures and equipment available. Decontamination pre-purchase questionnaires can be invaluable for auditing device decontamination issues, prior to purchase. The [Institute of Decontamination Sciences](#) have an example and information on how it can be accessed.

If the manufacturer's instructions appear inappropriate or incomplete, the organisation should report this to the MHRA as an adverse incident (see section 2.7).

Medical devices should be decontaminated and stored in accordance with legislation and best practice requirements, whilst following validated procedures (see Table 9.1). For further guidance see the Department of Health's document 'Management and decontamination of surgical instruments used in acute care' [20]. Devolved administrations may have their own guidance and should be contacted directly for advice.

Items subject to inspection, maintenance, repair or disposal, either on site or at the manufacturer's or agent's premises, should be decontaminated beforehand. Any loaned items being returned to a manufacturer or supplier should also be decontaminated (see Figure 9.1). Devices intended for single-use only do not require decontamination, except where they are implicated in an adverse incident and may need to be sent to the manufacturer for investigation. In this situation, contact the manufacturer to find out the most appropriate method of decontamination.

Once decontamination has been completed, the items should be labelled accordingly and a declaration of contamination status form/label completed (or sent electronically). See Figure 9.2 for an example form. This should be readily accessible to the recipient of the device.

10 Decommissioning and disposal of devices

10.1 Planning for replacement

A policy on removal from service is an essential part of device management. At some point, all devices will need to be replaced.

The expected life cycle of a device or piece of equipment should be held in the inventory record where appropriate, and regularly reviewed against the usage, maintenance and repair record, to see if the end date needs to be adjusted.

Heavy use or irregular maintenance may reduce the life cycle of a device but limited use may extend it.

A manufacturer's recall of a device will take precedence over other considerations.

10.1.1 Replacement criteria

Factors to consider include:

- whether the device is damaged or worn out beyond economic repair
- its reliability (check service history)
- clinical or technical obsolescence
- disposal due to contamination
- changes in local policies for device use
- absence of manufacturer/supplier support
- non-availability of correct replacement parts
- non-availability of specialist repair knowledge
- end users' opinions
- possible benefits of new model (features, usability, more clinically effective, lower running costs)
- lifecycle of the medical device
- redeployment
- utilisation profile – are additional units of equipment required or does the existing supply meet demand?
- equipment downtime
- disposal costs / revenue generation potential
- changes in clinical recommendations/standards
- new equipment technologies and / or technological obsolescence
- changes in service provision.

10.2 Decommissioning

Decommissioning aims to make devices safe and unusable, while minimising damage to the environment. Any device deemed unfit for use should be decommissioned.

It is advisable to contact the manufacturer at this stage for information on decommissioning. The manufacturer should be able to provide details of any environmental, disposal, recycling or structural requirements. If the manufacturer has ceased trading, contact the MHRA for further guidance.

Decommissioning should include decontamination, making the device safe and unusable. This is to ensure that an inappropriate person does not use the device and expose themselves and / or others to hazards.

For devices that are mobile or housed in general facilities, safety checks, such as power disconnection and cooling system disconnection, should be carried out.

Decommissioning larger installations often involves removal from a purpose-built room or surroundings. Decommissioning of device incorporating radioactive sources must be carried out in accordance with the Ionising Radiations Regulations [16].

10.2.1 Erasing stored data

If a device stores patient identifiable data, this should be certified as securely erased to an appropriate standard, such as BS ISO/IEC 15408 [21] and British HMG Infosec Standard 5, or IS5 [22], before disposal. Data on any device should be forensically unrecoverable, i.e. patient data must be over-written.

10.3 Disposal

Consult the manufacturer for the best methods of waste disposal. They should be able to provide details of the current techniques and processes applicable to their products.

The [Waste Electrical and Electronic Equipment Regulations](#) (WEEE) [23] primarily impose duties on 'producers', i.e. manufacturers and importers.

10.3.1 Examples of special waste

Some waste products need specialised disposal. Examples include:

- wastes containing certain metals (e.g. mercury above 3%, some batteries)
- oil wastes (including polychlorinated biphenyls – PCBs)
- wastes from coolants
- radioactive waste
- healthcare wastes from human or animal origin
- human waste from natal care, diagnosis, treatment or prevention of disease.

Where applicable, devices should be decontaminated before disposal or transfer to a third party, and supplied with a certificate of decontamination.

10.3.2 Transport of devices before disposal

When returning medical devices to the manufacturer at end of life, or when transporting devices, ensure that they are appropriately packaged and secured. Issues that should be addressed include: strength of packing materials, protecting sharp edges, ensuring the device is not damaged in transit etc.

Legislation applies to the transport of goods by road and rail:

- The Carriage of Dangerous Goods by Road Regulations [24]
- The Carriage of Dangerous Goods by Rail Regulations [25]
- Chemicals (Hazard Information and Packaging for supply) Regulations [26]
- The Radioactive Material (Road Transport) (Great Britain) Regulations [27].

Guidelines on transport by post are also provided by Royal Mail on their website: Prohibited goods – business customers [28].

10.4 Sale or donation for reuse

The UK MDR 2002 [5] apply to medical devices being sold for the first time. There is no legislation which specifically covers the resale or reuse of medical devices or equipment.

Note that devices not deemed to be safe for current patient use are therefore not safe for use by anybody to whom the device is donated. If the device is risk assessed as safe to use and working according to specification, it must be supplied with all relevant documentation (e.g. IFU, service history etc).

However, used medical devices are still required to be safe under other national provisions, including:

- Consumer Protection Act (Consumer Safety and Product Liability) [13]
- Sale and Supply of Goods Act [29]
- Health and Safety at Work Act [12]
- Trade Descriptions Act [30]
- The Electrical Equipment (Safety) Regulations [31]
- Unfair Contract Terms Act [32].

10.4.1 Liability issues

Before sale or transfer of ownership of medical devices, both parties should be clear about their legal liabilities. Legal advice should be obtained concerning general device types, such as walking frames or wheelchairs, and more specific advice for individual, larger devices such as X-ray machines.

Essential requirement 13b in Part II of the UK MDR 2002, Annex I (as modified by Part 2 of Schedule 2A to the UK MDR 2002) [5] requires the manufacturer to provide: 'all the information needed to verify whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all

It is good practice to apply this principle to the sale of used device or transfer of ownership, to ensure safety.

This information should be available for a prospective purchaser to view before sale and be supplied with the device on its completion.

On selling or donating used devices, as much as possible of the following information should be supplied with the device to the purchaser:

- a clear statement that the device is being resold/donated
- a certificate of decontamination
- the user manuals and training requirements
- full details of maintenance and servicing requirements
- service history and manual
- usage history
- quality assurance test details
- safety updates, including MHRA and manufacturer's documents that have been released since the medical device was first supplied.

If instructions, training and maintenance/repair information are not available, It is not recommended to pass the device to a new user until the appropriate documentation becomes available.

10.4.2 Refurbishment

A medical device supplied to a new owner after full refurbishment is covered by the UK MDR 2002 [5]. A new UKCA/CE/CE UKNI mark has to be affixed by the person or organisation that carries out the refurbishment.

The term reconditioning or 'refurbishment' is often used for the process of routine cleaning and maintenance, which precedes the re-issue of an item. This process is not generally considered 'full' refurbishment.

Full refurbishment

This term is used in the UK MDR 2002 [5] and applies to the re-manufacture and placing on the market of a device 'as new'. Devices that are fully refurbished and placed on the market are covered by the Medical Devices Regulations.

Full refurbishment will vary for a given device, but is generally considered to consist of:

- stripping into component parts or sub-assemblies
- checking their suitability for reuse
- replacement of components / sub-assemblies not suitable for reuse
- assembly of the replacement components or sub-assemblies, testing of the assembled devices against either original or revised release criteria
- the identification of the fully refurbished device, by appropriate means.

Additional guidance on what constitutes 'full refurbishment' of medical devices is given [here](#).

11 Legislation

This section gives examples of legislation that might apply to your organisation. It is not an exhaustive list.

- [Consumer Protection Act 1987](#) (Consumer Safety and Product Liability) [13]
- [Health and Safety at Work etc. Act](#) (HASAWA) 1974 [12]
- [Ionising Radiation \(Medical Exposures\) Regulations 2017](#) IR(ME)R
- [Ionising Radiations Regulations 2017](#)(IRR) [16]
- [Management of Health and Safety at Work Regulations](#) 1999
- Medical Devices Regulations 2002 (SI 2002 No 618, as amended) [5]
- Sale and Supply of Goods Act 1994 (Chapter 35) [29]
- The Common Law of Negligence: Law Reform (Contributory Negligence) Act 1945 [15]
- The Control of Substances Hazardous to Health Regulations 2002
- The Electrical Equipment (Safety) Regulations 1994 [31]
- The Electricity at Work Regulations 1989 [11]
- The Employers' Liability (Compulsory Insurance) Regulations 1998
- The General Product Safety Regulations 2005 [14]
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. Regulation 16 Safety, availability and suitability of equipment
- The Lifting Operations and Lifting Equipment Regulations 1998 [17]
- The Pressure Systems Safety Regulations 2000
- The Provision and Use of Work Equipment Regulations 1998
- The Waste Electrical and Electronic Equipment Regulations 2006 and The Waste Electrical and Electronic Equipment (Amendment) Regulations 2007 [23]
- Trade Descriptions Act 1968 [30]
- Unfair Contract Terms Act 1977 [32]

12 References and further information

12.1 References

A list of standards designated to the relevant legislation, including the UK MDR 2002, can be found here: <https://www.gov.uk/guidance/designated-standards>

1. Care Quality Commission. [Essential standards of quality and safety](#). 2010
2. NHS England and MHRA. [Improving medical device incident reporting and learning](#).
3. NHS Digital <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care/records-management-code-of-practice-for-health-and-social-care-2016>
4. MHRA. [Devices in Practice](#)
5. [Medical Devices Regulations 2002](#) (SI 2002, No 618, as amended)
6. BS EN 62366-1:2015 Medical devices. Application of usability engineering to medical devices
7. BS EN 60601-1-8:2007+A11:2017, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. 2007
8. BS EN 62353:2014 Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment. *Please note - this standard has not been designated under the UK MDR 2002*
9. Department of Health. [NHS Master Indemnity Agreement](#) July 2010
10. The 18th Edition. Requirements for electrical installations. IET Wiring Regulations.
11. [The Electricity at Work Regulations 1989](#)
12. [Health and Safety at Work etc. Act 1974](#)
13. [Consumer Protection Act 1987 \(Consumer Safety and Product Liability\) \(Chapter 43\). Part I: Product Liability, Part II: Consumer Safety](#)
14. [The General Product Safety Regulations 2005](#)
15. [The Common Law of Negligence: Law Reform \(Contributory Negligence\) Act 1945](#)
16. Ionising Radiations Regulations 2017
17. [The Lifting Operations and Lifting Equipment Regulations 1998](#)

18. BS EN ISO 13485:2016 Medical devices. Quality Management Systems. Requirements for regulatory purposes
19. BS EN ISO 9001:2015 Quality management system requirements
20. Department of Health. [Management and decontamination of surgical instruments used in acute care](#). 2013
21. [BS ISO/IEC 15408-1:2009](#) Information technology. Security techniques. Evaluation criteria for IT security Introduction and general model
22. HMG Information Assurance Standard No. 5 - Secure Sanitisation. Part of a larger family of IT security standards published by [CESG](#). If you have an nhs.net email address you can [register on the CESGIAP site](#) to access their policy and guidance documents.
23. [The Waste Electrical and Electronic Equipment Regulations 2006](#) as [amended in 2007](#)
24. [Carriage of Dangerous Goods by Road Regulations 1996](#)
25. [Carriage of Dangerous Goods by Rail Regulations 1994](#)
26. [Chemicals \(Hazard Information and Packaging for supply\) Regulations 2009](#)
27. [The Radioactive Material \(Road Transport\) \(Great Britain\) Regulations 2002](#)
28. Royal Mail. [Prohibited goods – business customers](#)
29. [Sale and Supply of Goods Act 1994](#) (Chapter 35)
30. [Trade Descriptions Act 1968](#)
31. [The Electrical Equipment \(Safety\) Regulations 1994](#)
32. [Unfair Contract Terms Act 1977](#)

12.2 Further reading

[The Special Waste Regulations 1996, SI1996 No. 972](#)

[The Management of Health and Safety at Work Regulations 1999 No. 3242](#)

Lee P, Thompson F & Thimbleby H (2012). 'Analysis of infusion pump error logs and their significance for healthcare,' British Journal of Nursing, 21(8):S12–S22 (IV Supplement)

BS EN 12182:2012, Assistive products for persons with disability. General requirements and test methods. 2012.

BS EN 12184:2014, Electrically powered wheelchairs, scooters and their chargers. Requirements and test methods

BS EN ISO 14971:2019, Medical devices. Application of risk management to medical devices

BS EN ISO 17664:2017, Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices

BS EN 62353:2014 Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment

IPEM. Report 95 Risk Management and its Application to Medical Device Management 2007, IPEM: York. ISBN 978 1 903613 33 7

IPEM. Report 97 Guide to Electrical Safety Testing of Medical Equipment: the how and why 2009, IPEM: York. ISBN 978 1 903613 36 8

12.3 Useful websites

Care Quality Commission
www.cqc.org.uk

Department for Business Innovation & Skills (BIS)
<https://www.gov.uk/government/organisations/department-for-business-innovation-skills>

European Association of Notified Bodies for Medical Devices
<http://www.team-nb.org>

Health and Safety Executive
<http://www.hse.gov.uk/>

NHS Supply Chain
<http://www.supplychain.nhs.uk/>

The Institute of Asset Management
<http://theiam.org/>

National Association of Medical Device and Equipment Trainers (NAMDET)
www.namdet.org

Computers and Human Interfacing with Medical Devices (CHI+MED)
<http://www.chi-med.ac.uk/>

The Institute of Physics and Engineering in Medicine
www.ipem.ac.uk

BSI shop website (for standards)
<http://shop.bsigroup.com/>

Websites accessed January 2020.

Appendix – batteries

A1 Battery maintenance

Batteries will naturally discharge over time. If they are not tested and regularly replaced or recharged, they may not operate correctly when required and may even become damaged, due to extensive discharge. For example, some patient monitors and infusion pumps have battery capacity indicators. If the batteries have not been charged in line with the manufacturer's instructions, the indicator itself may not give an accurate reading. This can result in the device shutting down unexpectedly. It should be used for guidance only.

The most important parts to maintaining battery function and life are:

- charging rechargeable batteries correctly in line with the device manufacturer's instructions
- using the correct charger
- keeping the terminals clean and free from debris
- checking connector cables, plugs and sockets.

This is particularly relevant for devices that are infrequently used, for example defibrillators.

Non-rechargeable batteries cannot be repaired if damaged, and should be replaced. Repairs to the outer case of a rechargeable battery may be possible in some circumstances, but should only be carried out by appropriately trained personnel. This may involve the battery being returned to the original manufacturer.

All devices with rechargeable batteries should be maintained and serviced in line with the manufacturer's instructions. This may require regular charging and discharging of the battery and use of specialist test equipment to check the output and condition of the battery or straightforward maintenance suitable for the end user to undertake.

Common issues

Batteries which no longer have any useable life should be removed from the device and replaced in line with manufacturer's instructions. When a device is not going to be used for a significant time, it may be beneficial to remove the batteries from the device.

All batteries must be treated with care to avoid physical damage.

Batteries should be subjected to as little environmental stress as possible. This includes storage or use outside the temperature range intended by the manufacturer, e.g. storage in vehicles or unheated outdoor storage. Batteries, wiring and connectors in medical devices which are left outdoors must be protected from damp to avoid corrosion of the case, contacts, terminals or connections. High ambient temperatures will reduce the capacity and life of the battery; low temperatures will reduce the ability of most batteries to deliver their rated output. Batteries should be stored in line with the manufacturer's instructions.

Batteries in implantable medical devices, such as pacemakers, require no specific maintenance other than voltage monitoring by the clinician in line with the pacemaker manufacturer's instructions, since they are sealed within the implant.

Incorrect output from a charger or an incomplete charging cycle could result in the battery being undercharged. This may result in a reduced time of operation of the device between charges. In other cases, incorrect output from the charger may result in overcharging with consequent deterioration of the battery performance and of the battery itself. The frequency with which batteries are charged depends on use.

Freestanding chargers should be positioned to allow a free flow of air into and out of the case venting or heat sinks. Chargers should not be covered or placed on long pile carpets. During the operation of charging, the charger should be close enough to the batteries and the mains socket to avoid strain on either of the leads. All usage should be in line with the manufacturer's instructions.

Chargers especially designed for non-rechargeable batteries are being marketed in the UK. Users should be aware that this charging process could be hazardous, and the recharged batteries have an extremely short shelf life. Batteries recharged in this way are not generally suitable for use in medical devices because of their unreliability.

An organisation could be held responsible under health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage as a result of supplying an inappropriate charging system.

Planned preventive maintenance should include inspections of:

- batteries
- chargers
- connector cables
- plugs
- sockets.

A2 Compatibility of power sources

During their design processes, manufacturers of medical devices set the specification of the battery, charger, all leads and connectors and the charging process, to ensure that the device operates correctly during normal use.

Manufacturers will also establish the detailed specification for maintenance and future replacements.

Batteries, chargers or processes that do not meet the specification set by the manufacturer can lead to incorrect operation or failure of the device. The user or others may be put at risk of:

- fire
- shock
- inhalation of fumes
- inappropriate treatment (e.g. misadministration of intravenous fluids via an infusion pump)
- malfunction of a device (e.g. patient hoist which does not operate as expected and leads to injury).

For applications where the chargers, batteries and leads are constantly disconnected and reconnected, it is essential that the plugs, leads and sockets have been designed to cope with multiple uses. Where repair services replace cables, plugs and sockets,

it should be in line with the manufacturer's instructions – the correct cable wiring configuration and plug or socket should be used.

If in a specific case it is deemed that the benefit of not using the battery, charger, connectors or charging process specified by the device manufacturer would give improved benefits then a risk assessment should be carried out and documented to ensure that all components within a system are compatible and can be used safely.

If a device fails in use following replacement of a part with one not corresponding to the device manufacturer's specification and this leads to the death or serious injury of a patient / user, there is a greater likelihood of the organisation responsible for setting up the components being held liable for the injuries caused. This liability is likely to be mitigated if a thorough, valid and documented risk assessment has been carried out.

The manufacturer's information should include, as a minimum:

- how to access the batteries
- how and when to charge
- how connections are marked to prevent incorrect fitting
- how to connect, disconnect and reconnect
- how to maintain and if necessary how to clean the connectors
- how to test the output of a battery or charger to ensure its performance is adequate
- when to replace batteries
- details of any fuses, overloads, circuit protection and what to do if any of these are activated
- guidance on battery replacement
- battery voltage and capacity
- battery type
- time to charge batteries depending on conditions of use or storage
- what maintenance is required including frequency for batteries, chargers, cables and connectors.