

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 and medical device training.

It is intended primarily for people in hospital and community based organisations that are responsible for the management of reusable 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 health care, 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. Unless medical devices are managed proactively, the same types of adverse incidents happen repeatedly. 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 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 in Table 1.

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 health care. The principles are summarised in Outcome 11 of the Care Quality Commission standards [1]
- help healthcare organisations meet the Care Quality Commission's standards [1] (or equivalent) 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
- 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.

Table 1 **Examples of medical devices** (not an exhaustive list)

Function	Examples
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
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. One way it does this is by regulating medical devices in the UK by ensuring they comply with the Medical Devices Regulations [2].

It aims to minimise the risk of new adverse incidents involving medical devices and reduce the likelihood of those that have already occurred from happening again. It achieves this through:

- Investigation of adverse incidents involving medical devices and equipment which may result in the issue of safety warnings and the provision of advice and guidance on safety and quality issues. For an up-to-date list of publications see [our website](#).

The typical causes of incidents with medical devices include:

- > inappropriate management procedures
- > inadequate servicing or maintenance
- > inappropriate use (including incompatible devices)
- > inadequate decontamination

MHRA

- > inadequate training (staff/users/carers)
- > inadequate instructions for use (IFU) or shortcomings in the design or manufacture.
- Acting as the UK competent authority, the regulator for the medical devices industry. The MHRA ensures that manufacturers meet UK legislation [2, 3]. This is by monitoring incidents, approval of clinical trials, audit of UK notified bodies, registration of manufacturers of class I medical devices, and compliance and enforcement action.

Note: Be aware that if the EU makes changes to the MDD, the guidance we give here may change.

Northern Ireland, Scotland and Wales

There is close co-operation between the MHRA and the devolved administrations of Northern Ireland, Scotland and Wales.

Responsibility for minimising the risk arising from the management and use of medical devices in Northern Ireland and Scotland is held by the devolved administrations. They may issue similar safety publications, although sometimes with different reference numbers.

In Northern Ireland, the Northern Ireland Adverse Incident Centre (NIAIC) conducts incident investigations; in Scotland the incident investigations are carried out by Health Facilities Scotland – Incident Reporting & Investigation Centre (HFS-IRIC). See 2.7 for contact details.

The MHRA investigates incidents in Wales. The Surgical Materials Testing Laboratory (SMTL) carries out lower risk incident investigations relating to a specific range of devices (www.smtl.co.uk).

The MHRA, as the competent authority for the whole of the UK, has the legal responsibility for regulatory matters so all regulatory breaches should be reported to us in the first instance.

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) or equivalent. MDSOs replace Medical Device Liaison Officers. 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 [4]. 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 strategies 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

- 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 MHRA's Medical Device Alerts 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, enable record retrieval throughout the retention period of records. Record changes must not obscure previously recorded information. The Department of Health provides guidance on record retention [5].

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 particular 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 particular 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 equipment is being under-utilised, consideration should be made to ascertain whether it can be re-deployed within 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 particular 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.

Example: During a recall of walking frames, some healthcare organisations found it difficult to locate devices as they did not record the batch number of the device on issue.

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) or equivalent 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 warnings. 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.

Our website contains details of how to report medical device adverse incidents. Adverse incidents can be easily reported online:

[Reporting adverse incidents involving medical devices](#)

Reports from Scotland should be sent to [Incident Reporting and Investigation Centre \(IRIC\)](#), email: nss.irc@nhs.net.

Reports from Northern Ireland should be sent to [Northern Ireland Adverse Incident Centre](#), email: NIAIC@dhsspsni.gov.uk.

For an effective management system we recommend that you should have:

- 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 comprehensive organisation-wide policy on the management of medical devices including: acquisition, deployment, use, monitoring, maintenance, decontamination and disposal.
- a record of the current whereabouts / location of medical devices to facilitate a systematic approach to medical devices management and to help establish the relevance of any particular Medical Device Alert (or other MHRA advice) or manufacturer's Field Safety Notice to the organisation. Records of the action taken as a result should be maintained.
- mechanisms to distribute manufacturer's Field Safety Notices, MHRA Medical Device Alerts, other MHRA safety guidance 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.
- 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 takes into account 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* [6] 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 Medical Devices Regulations [2] 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 Medical Devices Regulations.

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 needs 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 62366:2008 'Medical devices. Application of usability engineering to medical devices' [7]. 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.

- 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.

3.4 Choosing the correct device

3.4.1 Correct assessment and selection

Assessment of the device taking into account the end user's needs (including aspects ranging from technical operation of the device to comfort and noise) is essential to ensure the correct device is issued. In cases where a specific device would be unsuitable, because the user would not be able to operate it safely, a carer may assist the user. The device would therefore also have to meet the needs of the carer.

Assessment and supply or fitting of a device can take place in separate institutions and involve different people – prostheses are an example – and the fitter will sometimes need to refer patients back to the prescriber, if the device proves unsuitable. Ensuring that responsibility for choosing the most appropriate device is shared between relevant healthcare staff, the end user and the fitter can avoid these problems and reduce subsequent delays.

When medical devices are issued, it is essential that any residual risks concerning devices and their accessories are balanced against the anticipated benefits to the user or others. Where risks could not be removed during the design process, subsequent warnings of any residual risk should have been clearly displayed in the user instructions and product markings.

Example: Computer system aids device selection.

The request will not be accepted if the user's weight exceeds the stated maximum.

3.4.2 Suitability for intended purpose/application

The device chosen must meet the responsible organisation's performance specification, but unnecessary features may be a disadvantage.

Points to consider

- Whether the device is compatible with other devices and any medicinal products that it is likely to be used with.
- Whether the manufacturer intends the device to be used by those who will be using it.
- Whether the device is appropriate for the intended environment.

Examples of points to consider in the selection of wheelchairs

Will the user want to use it as a seat in transport?

Are the dimensions suitable for where it will be used? i.e. is it too big to safely drive through corridors of the house?

Will it be able to climb hills in the surrounding area?

Will extras such as kerb climber and anti-tippers be required?

Example: Entrapment

The mechanisms used to provide seat tilt, seat lift and backrest recline functions can pose an entrapment threat, in particular to fingers, toes and especially to inquisitive children. Trapping points can also be created when adjustable components such as reclining backrests are moved relative to fixed components such as armrests.

During the prescription process, consideration should be given to the user's physical abilities (e.g. eyesight and postural control) and the intended environment for the wheelchair, along with the manufacturer's guidance, to reduce the risks associated with trapping hazards.

Example: Powered wheelchairs

Some departments may have guidelines indicating that people who are visually impaired or who have severe epilepsy may be unable to use powered wheelchairs safely. But guidelines need to take account of the benefits, the individual circumstances, diagnosis and prognosis, so that particular end users, who could in fact use the powered wheelchair safely, are not unfairly denied.

Example: Support seating for severely disabled children

The prescription of the wrong device for severely disabled children can have permanently detrimental effects on the child, causing or worsening postural problems, skeletal deformity, etc. Transfers of the user to and from the seating, adjusting the seat and transport are all major points that may require input from the user's carer(s).

3.4.3 The procedure for accepting new devices should also identify:

- Any training needs
- Appropriate planned preventive maintenance and performance checks
- Technical support needs of users
- Whether risks associated with using a particular 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.

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 Medical Devices Regulations [2]. 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. See MDA/2010/001 [8] for further details.

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. See MDA/2010/001[8] for further details.

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.

Example: Chargers, batteries and leads that are constantly disconnected and reconnected have been designed to cope with such multiple use. Therefore you should select the plugs, leads and sockets that meet the manufacturer's specification.

3.6 Safety performance and reliability

Points to consider

- Is the medical device CE marked? CE marking is required for medical devices.
- Is there any local knowledge or past 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. See MDA/2010/001 [8] for further information, should these instructions are not followed.

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).

3.11 Documentation and monitoring

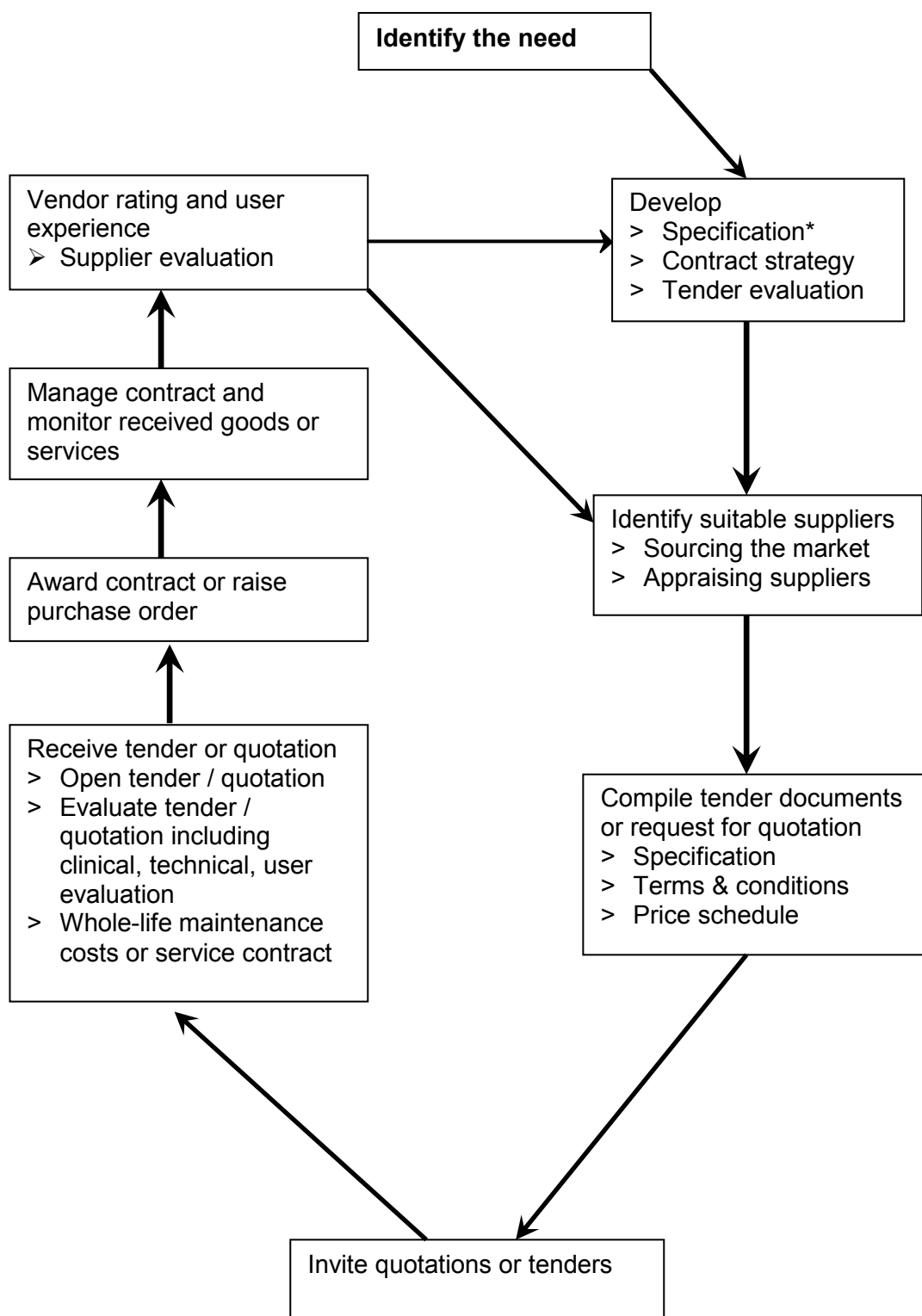
To reduce the possibility of inappropriate devices being purchased or prescribed it is essential that a full performance specification of the entire system is established before any purchases are made. For example, with battery powered device this must incorporate all elements, such as: battery type,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

Figure 3.1 Flow chart of the acquisition cycle



* consider software compatibility including archive systems and interchangeability with existing equipment.

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 in to service.

Some products should be risk assessed before first use, such as those listed in Table 5.3.

Table 5.3 Device requiring risk assessment before first use

Category	Examples
Devices manufactured outside the scope of the Medical Devices Regulations	In-house manufacture.
Device which has, or may have, been used before	<ul style="list-style-type: none"> • Bought second-hand. • Lent by another responsible organisation. • Device re-issued to second or subsequent users.
Devices within the scope of the Medical Devices Regulations, but not CE marked	<ul style="list-style-type: none"> • Custom-made for a named patient. • 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. See NHS Master Indemnity Agreement [11]. 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 BS 7671 (in particular Section 710) [12].

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 Medical Devices Regulations [2], 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) [13] and the Health and Safety at Work etc. Act (HASAWA) [14] 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.

Recommendations for receiving a new device

1. Check that the device matches the acquisition specification, is undamaged, is accompanied by all the necessary information and documentation, and that it is:
 - a) appropriately configured
 - b) supplied with appropriate accessories
 - c) supplied with appropriate consumables
 - d) supplied with appropriate instructions for use.
2. Make sure that the appropriate acceptance checks and tests have been carried out in accordance with risk assessment and legal requirements.
3. Where required, medical devices have been appropriately installed.
4. Details of the device and the manufacturer's instructions have been entered into the appropriate device monitoring and tracking systems.
5. Training needs have been identified and acted on.
6. For reusable devices, maintenance has been scheduled.

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.

Example: Training is a key element in device safety. Ensure adequate training programmes are in place for users. Ensure such training programmes are repeated regularly, where necessary. For example, all users of infusion systems were given a training log, as part of their individual record of continuing professional development (CPD). The training log was used to monitor end user training and to identify any remedy deficits. The log detailed: Dates of initial and refresher training, system(s) covered, trainer's endorsement.

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 professional users

Professional users need 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. Where relevant, they should:

- be aware of differences between models, compatibility with other products and any contraindications or limitations on use
- be able to fit accessories and to be aware of how they may increase or limit the use of the device
- be able to use any controls appropriately
- understand any displays, indicators, alarms etc.

- be aware of 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
- be aware of known pitfalls, 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).

6.3 Training for end users

End users need to understand the intended use and normal functioning of the device in order to use it effectively and safely. Where relevant, training should cover:

- Any limitations on use
- How to fit accessories and to be aware of how they may increase or limit the use of the device
- How to use controls appropriately
- The meaning of any displays, indicators, alarms etc., and how to respond to them
- Requirements for maintenance and decontamination, including cleaning
- Recognise when the device is not working properly and know what to do about it
- Understand the known pitfalls in the use of the device, including those identified in safety advice from the MHRA, manufacturers and other relevant bodies
- Understand the importance of reporting device-related adverse incidents to the MHRA (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.

Recommendations for training

- There is an organisation-wide policy on training regarding the safe use of medical devices.
- End users, carers, professional users or other staff are supported in attending training.
- End users, carers, professional users or other staff are made aware of and, where necessary, trained in adverse incident reporting requirements for medical devices.
- All professional users and contractors are trained in the safe operation of medical devices.
- All end users are given appropriate training in the safe and effective use of medical devices.
- Staff and contractors involved in providing maintenance, repairs and decontamination are adequately trained and appropriately qualified.
- Independent contractors using medical devices have appropriate risk management systems in place.

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 device. The manufacturer is responsible for supplying appropriate instructions, taking into account 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 (see Table 7.1 for examples) should be reported to the MHRA as an adverse incident (see section 2.7).

Table 7.1 Potential difficulties with instructions

Placement	Instructions can be printed on the device itself, or its immediate packaging, or supplied as a leaflet.
Content	Instructions must be clear and precise, and should include details of who to contact for specialist problem solving or guidance.
Print size	End users may be visually impaired.
Technical or difficult language	Instructions must be easy to understand and follow.
Translation from or into foreign language	This should be accurate and understandable.
Different versions	Manufacturers may have updated software/hardware. Need the right version to match the specific device.

Examples that show the necessity and benefit of appropriate training:

Example 1: Respiratory therapy devices – Instructions for Use

The MHRA was made aware of reports of incorrectly assembled respiratory therapy devices, where an expiratory pathway was not provided, resulting in the build-up of excessive pressures causing lung injury.

Users were advised to ensure that the manufacturer's instructions for use are followed, whenever respiratory therapy devices are connected to endotracheal or tracheostomy tubes. Also, the free passage of expired gases should be checked.

Example 2: Home dialysis – additional support

Patients using peritoneal dialysis device at home need more comprehensive backup than can be provided by written instructions. A 24-hour helpline gives access to expert advice, and home dialysis nurses can be called out to help in the patient's home.

Example 3: PEG removal

The MHRA received a report where following a 'cut-and-push' technique to remove a percutaneous endoscopic gastrostomy (PEG) tube, a remnant of the tube lodged in the small bowel and resulted in perforation and death. Only endoscopic removal of the PEG was recommended in the manufacturer's instructions.

Users were advised to ensure that the manufacturer's instructions for use were followed when using and removing these devices. Where endoscopic removal was not feasible, an appropriate risk assessment and patient follow-up should have been undertaken.

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 [15] (in the case of a medical device)

- The General Product Safety Regulations 2005 [16] (in the case of a consumer product not covered by other specific legislation)
- The Common Law of Negligence [17].

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.

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

Example: Attempt to attach instructions permanently to a hoist

A community store produced instructions on printed plastic cards which were clipped to hoists with a key ring. They were, however, generally missing when the hoists were returned. Ask end users not to remove the instructions, or make them very hard to remove.

Recommendations for 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 1999 [18] and The Lifting Operations and Lifting Equipment Regulations 1998 [19] for example, the tests therein should be carried out in addition to the maintenance and testing recommended in the manufacturer in the 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 in which it is to be used.

Example: Maintenance of trolleys and stretchers

A lack of planned preventive maintenance of trolley and stretcher wheels can lead to their failure and can affect the device's stability, potentially leading to patient's fall.

Ensure all trolleys are serviced and inspected in line with the manufacturers' instructions.

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 Medical Devices Regulations [2] 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 / third party repairer who complies with relevant quality system standards, such as European Standard BS EN ISO 13485:2012 [20] or BS EN ISO 9001:2008 [21]. 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. Healthcare organisations may also want to consider the potential savings opportunities that may be available through innovative approaches such as moving to multi-year contracts.

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 and 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 trouble-shooting.

- Are full details of the repair and maintenance procedures and spare parts available?
- Are consumable materials, such as adhesives or thread locking compounds, included?

Example: Third-party repair companies

When using third party repairers ensure that they have clear specifications that meet your requirements and where necessary carry out functional checks to ensure that the device meets the specification. Full traceability should be retained throughout this process. There should also be clarity of you receiving the same device back or receiving 'like for like'.

Example: Third-party repair companies

Many hospitals, particularly those making use of third-party repair companies, have found that their devices are sometimes returned containing parts not specified by the manufacturer. This may affect the performance. However, in-house repairers also sometimes fit inappropriate parts.

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

Maintenance / repair organisation	Possible advantages	Possible disadvantages
Outside organisations	<ul style="list-style-type: none"> • Predictable costs. • Possible to specify response times. • Possible to specify equipment down times. • Loan equipment. 	<ul style="list-style-type: none"> • 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.
In-house	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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.

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

Table 8.2 Comparison of third party with a manufacturer's servicing organisation

Maintenance/ repair organisation	Advantages	Disadvantages
Manufacturer	<ul style="list-style-type: none"> • 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. • Availability of training for professional users. 	<ul style="list-style-type: none"> • 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.
Independent third party	<ul style="list-style-type: none"> • Often cheaper than manufacturer. • Possible to have an on-site engineer to cope with breakdowns. • Fewer external organisations to deal with. 	<ul style="list-style-type: none"> • 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.

Note: If using an outside organisation, in house expertise to monitor, audit and manage contracts is required.

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 1999 [18] and for hoists or lifting device the Lifting Operations and Lifting Equipment Regulations 1998 [19]. 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 [14] requires 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.

Example: Hazards of inadequate training

Adequate training, even in simple tasks, avoids potential injury to patients. The legend in a generator control desk button was replaced in the wrong direction when the service provider changed a bulb. The legend showed the X-ray beam orientation as horizontal rather than vertical. A patient was subsequently set up for an X-ray under automatic exposure control in the wrong orientation.

Example: Hazards of inadequate training

After a series of adjustments by a service provider, a tilting X-ray table collapsed. Despite generic experience in maintenance procedures, experience and training did not cover the adjustments being attempted.

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.

Example: Wheelchair maintenance requires particular consideration

There must be a policy for wheelchair maintenance in hospitals and on loan in the community. Recommended periodic servicing and testing will not only vary between different types of wheelchair (e.g. manual or electric), but also on the type of usage and the user. A policy of checking every wheelchair at the same fixed interval is therefore unlikely to be appropriate. Some users spend 18 hours a day in their wheelchair, but only ever move a short distance, whilst others use their wheelchairs very frequently in different environments and others only use them occasionally for short periods.

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, such as Medical Device Alerts.

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 particular 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.

Example: A third party carried out the 'refurbishment' of defibrillator battery packs by replacing some of the internal cells but did not replace the original electronic components (thermistors). This produced unexpected depletion of the battery pack and inadequate advanced warning of failure of the defibrillator.

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 [14] 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 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 monthly to biannually, depending on the device.

Table 8.3 Planned preventive maintenance checklist

Heading	Notes
Service interval	In line with the manufacturer's recommendations, taking into account how much the device will be used.
Initial inspection	<ul style="list-style-type: none"> • Is the device clean? • Does it need decontaminating? • Note settings of controls. • Inspect each element in line with manufacturer's instructions.
Parts replaced	<ul style="list-style-type: none"> • Note each item/part to be replaced. • Record each items/part replaced, including details of source manufacturer and method of fitting.
Calibration	<ul style="list-style-type: none"> • Establish if any element/part requires calibration or re-calibration. • Calibrate in line with the manufacturer's instructions.
Performance and safety checks	<ul style="list-style-type: none"> • Carry out performance tests against the manufacturer's specifications before and after maintenance. • Consider if handover procedure is required.
Return-to-use	<ul style="list-style-type: none"> • 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.

Example: The MHRA received reports of dental hand pieces disintegrating during use. This was often caused by failure to follow the manufacturer's guidance on appropriate maintenance intervals.

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 Medical Devices Regulations [2].

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.

Recommendations on maintenance and repair

- All medical devices and items of medical equipment are to be maintained and serviced in line with the manufacturer's service manual and advice from external agencies e.g. Medical Device Alerts.
- Maintenance and repair providers should have a certified quality management system.
- Audit and user feedback systems are in place to frequently review the processes, policies and contracts.
- All staff involved in maintenance and / or repair are appropriately trained and qualified.
- Spare parts are of the correct specification and their quality and compatibility match those supplied by the original equipment manufacturer (OEM).
- Maintenance procedures are in line with manufacturer's maintenance instructions and timescales.
- All medical devices returned for servicing and repair are properly decontaminated.
- Where appropriate, ensure handover procedure completed.
- Organisations carrying out repairs and maintenance have adequate indemnity insurance.

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' [22]. Devolved administrations may have their own guidance and should be contacted directly for advice.

Table 9.1 Classification of infection risk associated with the decontamination of medical devices

Risk	Application of item	Recommendation
High	<ul style="list-style-type: none"> In close contact with broken skin or broken mucous membrane. Introduced into sterile body areas. 	Cleaning followed by sterilization.
Medium	<ul style="list-style-type: none"> In contact with mucous membranes. Contaminated with particularly virulent or readily transmissible organisms. Before use on immunocompromised patients. 	Cleaning followed by sterilization or disinfection. NB: Where sterilization will damage equipment, cleaning followed by high level disinfection may be used as an alternative.
Low	<ul style="list-style-type: none"> In contact with healthy skin. Not in contact with patient. 	Cleaning.

Example: A coroner reported a case of cross-infection caused by poor decontamination of laryngoscope handles. This has highlighted similar issues with the cleaning of laryngoscope blades. Ensure reusable laryngoscope blades are cleaned and sterilised between each patient use, following validated procedures. Single-use blades are to be used for one patient only and disposed of after use. See MDA/2011/096 [23].

Example: Reports have been received of a failure of dental instruments following use of inappropriate decontamination procedures. Ensure that the manufacturer's instructions are followed with regard to decontamination of reusable dental instruments. Further guidance has been published by the [Department of Health](#).

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.

Figure 9.1 Decontamination flow chart for devices that are being sent for investigation, repair or service

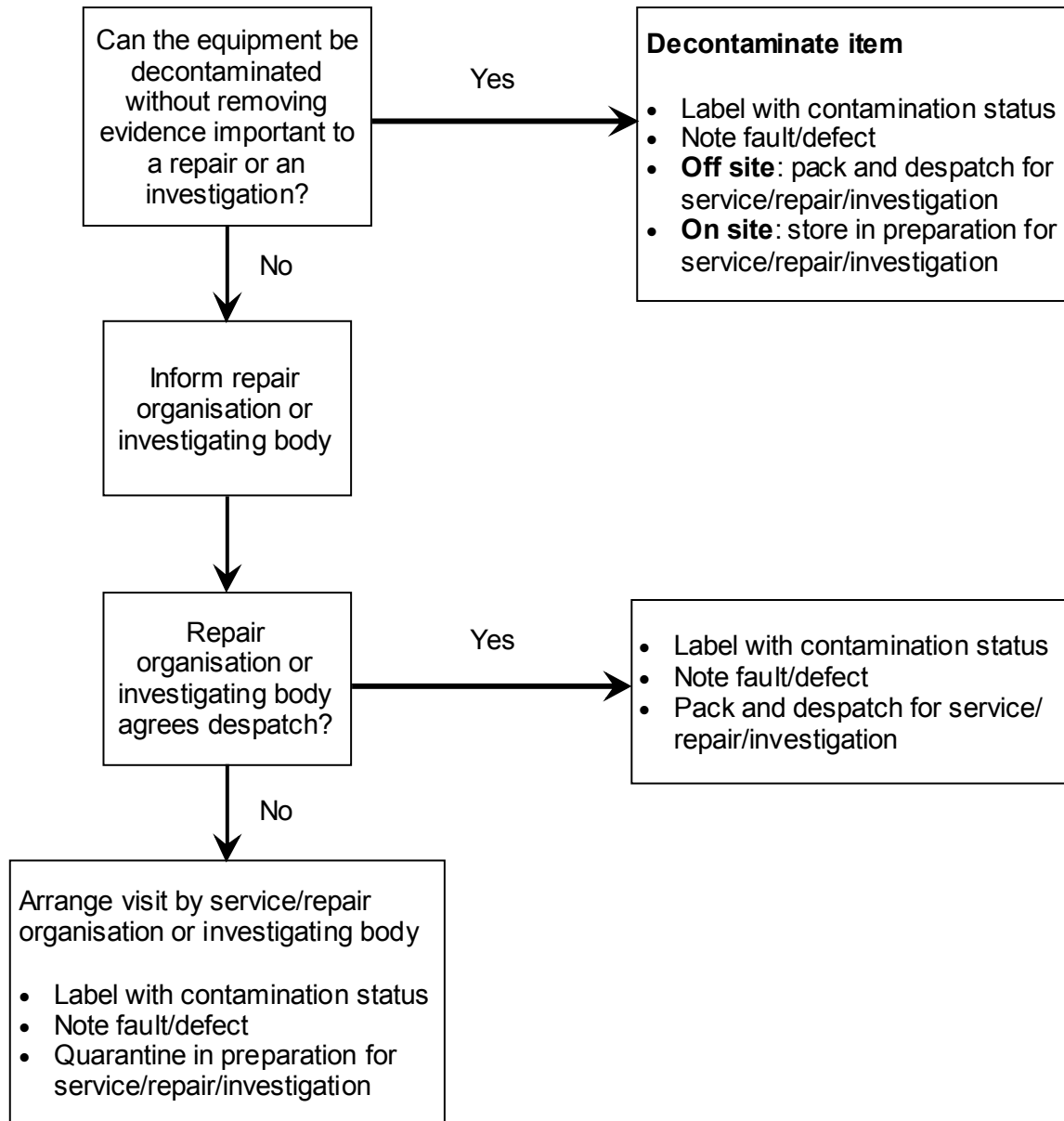


Figure 9.2 Sample form – declaration of contamination status

From (consignor): _____ Address _____ _____ _____ Reference _____ Emergency tel _____	To (consignee): _____ Address _____ _____ _____ Reference _____ _____
---	---

Type of equipment _____ Manufacturer _____

Description of equipment _____

Other identifying marks _____

Model no. _____ Serial no. _____

Fault _____

Is the item contaminated?	Yes* <input type="checkbox"/>	No <input type="checkbox"/>	Don't know <input type="checkbox"/>
* State type of contamination: blood, body fluids, respired gases, pathological samples, chemicals (including cytotoxic drugs), radioactive material or any other hazard _____			
Has the item been decontaminated?	Yes† <input type="checkbox"/>	No‡ <input type="checkbox"/>	Don't know <input type="checkbox"/>
† What method of decontamination has been used? Please provide details			
Cleaning _____			
Disinfection _____			
Sterilization _____			
‡ Please explain why the item has not been decontaminated? _____ _____			

Contaminated items should not be returned without prior agreement of the recipient

This item has been prepared to ensure safe handling and transportation:	
Name _____	Position _____
Signature _____	
Date _____	Tel _____

Recommendations on decontamination

- A local policy sets out the management and transport of medical devices from the point of use to the decontamination facility.
- All items subject to inspection, service, repair, or disposal should be decontaminated beforehand, following validated methods and procedures.
- Decontamination has been carried out in line with the manufacturer's instructions.
- All relevant members of staff have been fully trained in decontamination protocols [23, [IDSc](#)].
- It is illegal to send contaminated items through the normal post [31].
- Ensure that single use items are disposed of and not reused even if decontamination has been attempted.

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.

Example: Reports were received of instruments that had failed due to fatigue. Some of the devices had been in use for 15-20 years. Ensure that instruments are regularly checked for functionality prior to use and follow all of the manufacturer's recommendations regarding the expected lifetime of the instrument.

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, e.g. Creutzfeldt-Jakob (CJD) etc.
- 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 safe and making 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 [18].

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 [24] and British HMG Infosec Standard 5, or IS5 [25], 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 [26] 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.

Example: Implants with batteries (pacemakers, defibrillators, neuro-stimulators, drug pumps) should not be incinerated (as clinical waste) as it could result in explosion with possible injury to personnel and damage to the incinerator equipment.

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 [27]
- The Carriage of Dangerous Goods by Rail Regulations [28]
- Chemicals (Hazard Information and Packaging for supply) Regulations [29]
- The Radioactive Material (Road Transport) (Great Britain) Regulations [30].

Guidelines on transport by post are also provided by Royal Mail on their website: Prohibited goods – business customers [31].

10.4 Sale or donation for reuse

The Medical Devices Regulations [2] 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) [15]
- Sale and Supply of Goods Act [32]

MHRA

- Health and Safety at Work Act [14]
- Trade Descriptions Act [33]
- The Electrical Equipment (Safety) Regulations [34]
- Unfair Contract Terms Act [35].

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 of the Medical Device Directive [3] 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 times'.

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 may not be appropriate to pass the device to a new user.

10.4.2 Refurbishment

A medical device supplied to a new owner after full refurbishment is covered by the Medical Devices Regulations [2]. A new CE marking has to be affixed by the person or organisation that carries out the refurbishment.

The term reconditioning / '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 Medical Devices Regulations [2] 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 in the European Association of Notified Bodies for Medical Devices document 'Recommendation NB-MED/2.1/Rec 5' [36].

Recommendations for removal from service

- Medical devices and items of medical equipment are replaced, decommissioned and disposed of in line with an agreed policy.
- Before the sale or donation of medical equipment for reuse, the potential for future liability against the healthcare organisation should be considered.
- Disposal of waste should meet the applicable requirements for UK legislation.

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) [15]
- Health and Safety at Work etc. Act (HASAWA) 1974 [14]
- In Vitro Diagnostic Medical Devices Regulations [39]
- Ionising Radiation (Medical Exposures) Regulations 2000 [40]
- Ionising Radiations Regulations 1999 [18]
- Management of Health and Safety at Work Regulations 1999 [41]
- Medical Devices Regulations 2002 (as amended) [2]
- Sale and Supply of Goods Act 1994 (Chapter 35) [32]
- The Common Law of Negligence: Law Reform (Contributory Negligence) Act 1945 [17]
- The Control of Substances Hazardous to Health Regulations 2002 [37]
- The Electrical Equipment (Safety) Regulations 1994 [34]
- The Electricity at Work Regulations 1989 [13]
- The Employers' Liability (Compulsory Insurance) Regulations 1998 [38]
- The General Product Safety Regulations 2005 [16]
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. Regulation 16 Safety, availability and suitability of equipment [44]
- The Lifting Operations and Lifting Equipment Regulations 1998 [19]
- The Pressure Systems Safety Regulations 2000 [42]
- The Provision and Use of Work Equipment Regulations 1998 [43]
- The Waste Electrical and Electronic Equipment Regulations 2006 and The Waste Electrical and Electronic Equipment (Amendment) Regulations 2007 [26]
- Trade Descriptions Act 1968 [33]
- Unfair Contract Terms Act 1977 [35]

12 References and further information

12.1 References

1. Care Quality Commission. [Essential standards of quality and safety](#). 2010
2. [Medical Devices Regulations 2002](#) (as amended)
3. Medical Devices Directive ([MDD](#)) 93/42/EEC as amended [2007/47/EC](#)
4. NHS England and MHRA. [Improving medical device incident reporting and learning](#). March 2014
5. Department of Health. [Records Management: NHS Code of Practice](#). 2006
6. MHRA. [Devices in Practice](#)
7. [BS EN 62366:2008](#) Medical devices. Application of usability engineering to medical devices
8. MHRA. Medical devices in general and non-medical products [MDA/2010/001](#)
9. [BS EN 60601-1-8:2007](#), 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
10. [BS EN 62353:2008](#) Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment
11. Department of Health. [NHS Master Indemnity Agreement](#) July 2010
12. [BS 7671:2008](#) Requirements for electrical installations. IET Wiring Regulations. Seventeenth edition. 2011
13. [The Electricity at Work Regulations 1989](#)
14. [Health and Safety at Work etc. Act 1974](#)
15. [Consumer Protection Act 1987 \(Consumer Safety and Product Liability\) \(Chapter 43\)](#). Part I: Product Liability, Part II: Consumer Safety
16. [The General Product Safety Regulations 2005](#)
17. [The Common Law of Negligence: Law Reform \(Contributory Negligence\) Act 1945](#)
18. [Ionising Radiations Regulations 1999](#)
19. [The Lifting Operations and Lifting Equipment Regulations 1998](#)
20. [BS EN ISO 13485:2012](#) Medical devices. Quality Management Systems. Requirements for regulatory purposes

21. [BS EN ISO 9001:2008](#) Quality management systems. Requirements
22. Department of Health. [Management and decontamination of surgical instruments used in acute care](#). 2013
23. MHRA. Reusable laryngoscope handles - all models and manufacturers [MDA/2011/096](#)
24. [BS ISO/IEC 15408-1:2009](#) Information technology. Security techniques. Evaluation criteria for IT security Introduction and general model
25. 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.
26. [The Waste Electrical and Electronic Equipment Regulations 2006 as amended in 2007](#)
27. [Carriage of Dangerous Goods by Road Regulations 1996](#)
28. [Carriage of Dangerous Goods by Rail Regulations 1994](#)
29. [Chemicals \(Hazard Information and Packaging for supply\) Regulations 2009](#)
30. [The Radioactive Material \(Road Transport\) \(Great Britain\) Regulations 2002](#)
31. Royal Mail. [Prohibited goods – business customers](#)
32. [Sale and Supply of Goods Act 1994](#) (Chapter 35)
33. [Trade Descriptions Act 1968](#)
34. [The Electrical Equipment \(Safety\) Regulations 1994](#)
35. [Unfair Contract Terms Act 1977](#)
36. European Association of Notified Bodies for Medical Devices. Placing on the market of fully refurbished medical devices. [Recommandation NB-MED/2.1/Rec5](#)
37. [The Control of Substances Hazardous to Health Regulations 2002](#)
38. [The Employers' Liability \(Compulsory Insurance\) Regulations 1998](#)
39. [The In Vitro Diagnostic Medical Devices Regulations 2000](#)
40. [Ionising Radiation \(Medical Exposures\) Regulations 2000](#)
41. [Management of Health and Safety at Work Regulations 1999](#)
42. [The Pressure Systems Safety Regulations 2000](#)
43. [The Provision and Use of Work Equipment Regulations 1998](#)
44. [The Health and Social Care Act 2008 \(Regulated Activities\) Regulations 2010](#)

12.2 Further reading

MHRA. [Reporting Adverse Incidents Involving Medical Devices](#).

[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 12184:2009, Electrically powered wheelchairs, scooters and their chargers. Requirements and test methods

BS EN ISO 14971:2012, Medical devices. Application of risk management to medical devices

BS EN ISO 17664:2004, Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices

BS EN 62353:2008, 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 April 2014.

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.

Example A1: A battery-powered defibrillator apparently failed to deliver sufficient energy for effective treatment. On investigation, the batteries fitted were found to be in poor condition. No other fault with the device was found. Batteries should be checked routinely, in line with the device manufacturer's instructions.

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.

Example A2: A fatality occurred when an intra-aortic balloon pump failed during transportation of a patient in an ambulance. The device battery had not been maintained according to the manufacturer's instructions and a spare battery was not available. When transporting critically ill patients, ensure that a spare, fully charged battery pack is available during long journeys and that the battery status is checked in line with manufacturer's instructions.

Example A3: A powered medical device used during surgery, incorporating a strengthened (non-removable) case that housed the batteries, was dropped. This caused a hairline crack that went unnoticed. The device was then autoclaved which let in water/steam. When the device was subsequently used, the heat generated by the battery turned the water to steam which caused the case to burst.

Example A4: An infusion pump was used when transporting a patient between hospitals. Staff checked that the display on the pump said that the battery would last 4 hours (longer than the expected journey time), but the pump batteries expired after 90 minutes. On investigation, it was found that the manufacturer's instructions stated that the battery indication was not reliable until 5 minutes after switch on. This had not been noted in training.

Example A5: A user inserted the batteries the wrong way round in a portable audiometer. No one checked that the audiometer power light would not illuminate. This caused the device to short-circuit the batteries which then overheated and the current damaged internal wiring.

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.

Example A6: Powered wheelchair batteries being charged in a school classroom were not checked for condition and output during maintenance. The battery condition deteriorated over time and subsequent repetitive charging process led to gassing and emission of acid vapour which affected a number of children in a nearby classroom.

Example A7: A user forced a small, relatively fragile battery charger connector for a patient hoist into the socket the wrong way round, resulting in pin damage. The subsequent increased current through the plastic hand control burnt internal components and posed a risk of fire.

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).

Example A8: A manufacturer of a powered wheelchair did not adequately specify the charging connector to be used. A subsequent change in the material by the third party supplier of the plug terminals lead to overheating of the connector during charging.

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.

Example A9: A mobile pulse oximeter failed to indicate a low battery which could have led to a failure during transport. This was caused by the manufacturer failing to specify a sufficiently detailed charging regime for the device. As a result of reporting the issue to the MHRA, the manufacturer's instructions were modified to include a detail of when and how often the device should be charged.

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.

Example A10: A study of error logs carried out in a large NHS hospital [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)] showed that a number of infusion pumps had failed on battery during use and were used beyond the 'low battery' warning. Many of these failures went unreported. Follow-up checks identified a lack of mains sockets in clinical areas and a better stock rotation of devices that require charging was recommended. Infusion devices with accurate on-screen 'battery-life' indicators should also be considered. Medical device user logs can be a good source of information and can help identify trends and errors that often go unreported.