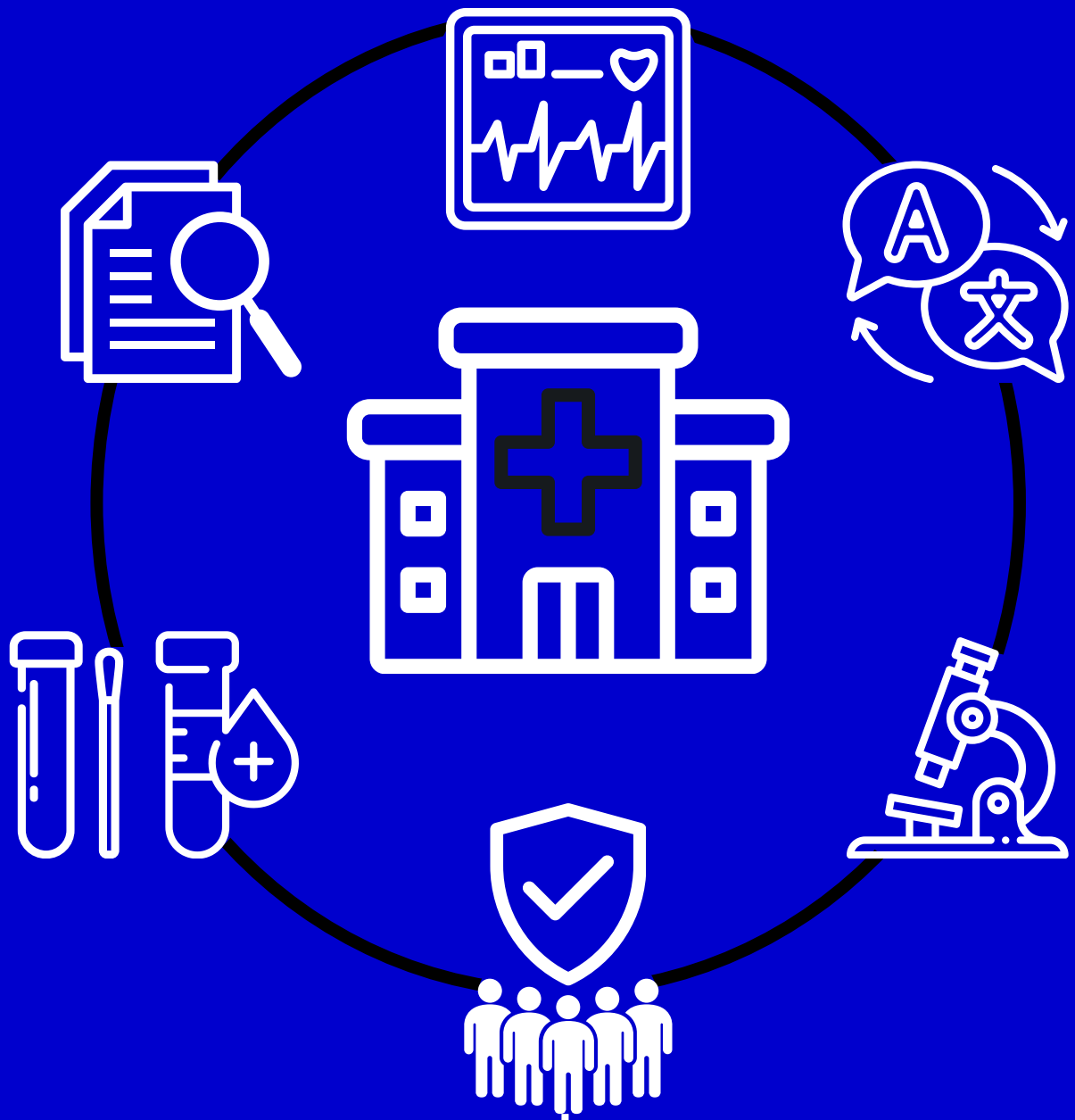
IMPERIAL

MedTechONE

MANAGING MEDICAL DEVICES: INTO THE NHS



MT1

COLLABORATIVE

www.imperial.ac.uk/medtechone/

IMPERIAL

MedTechONE

MANAGING MEDICAL DEVICES INTO THE NHS

DISCLAIMER

This information has been gathered from UK government guidance (August 2025). As such, this information may be subject to change.

A key aspect of the translation of medical devices is the pathway to getting a device into usage at hospitals. This process can be quite opaque, and isn't always widely known.

We've used the government policy guidance to create this resource, to give you a guide into the processes behind the scenes of medical device acquisitions in the NHS.

CONTENTS

CONTENTS

IMPERIAL

MedTechONE

INTRODUCTION

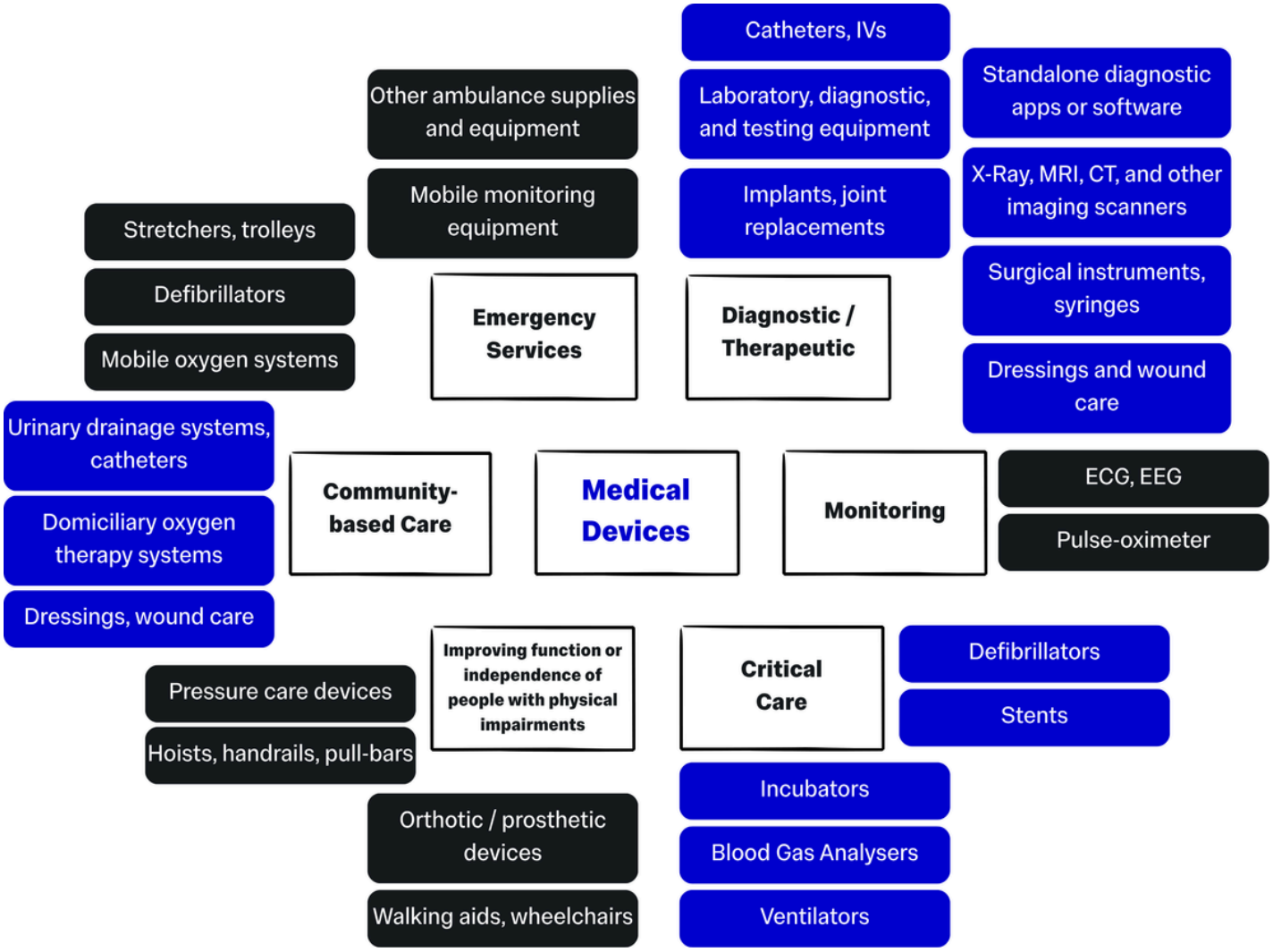
www.imperial.ac.uk/medtechone/

OVERVIEW

This resource covers the main categories of medical device acquisition, installation, and usage:

WHAT ARE MEDICAL DEVICES?

This guidance covers many types of medical device, including software and apps.



Medical devices within the NHS are regulated by the MHRA. The MHRA conducts market surveillance of medical devices within the UK and is the presiding regulatory body for decisions about the acquisition and supply of medical devices.

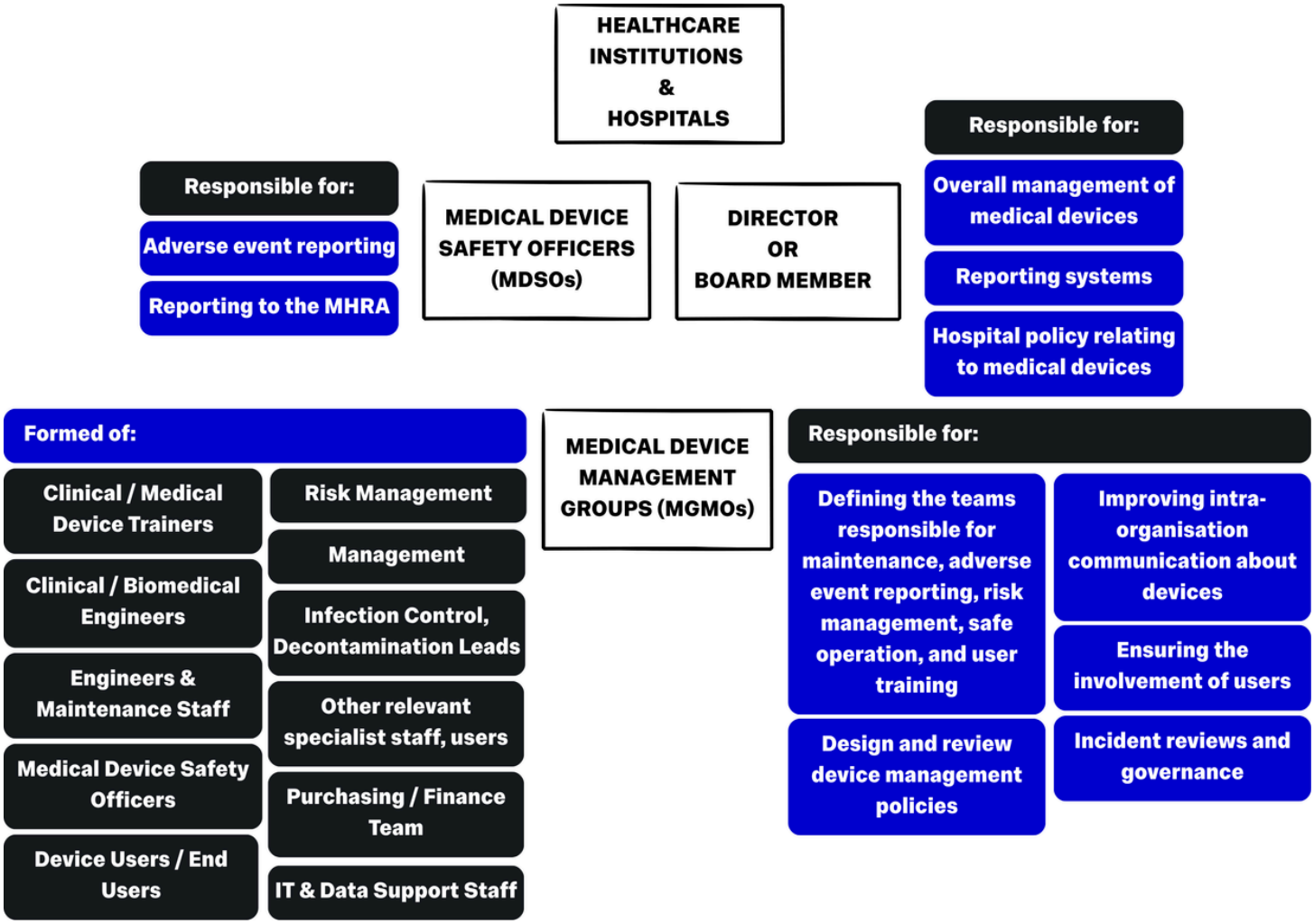
Hospitals will have long-term policies in place, covering acquisition, replacements, and development of medical devices. See if you can access a copy of the policy at the hospital you are working with, as it can help you understand their local policies on:

- Costs
- Clinical effectiveness of devices
- Acceptable performance and risk levels across the device life cycle
- Any relevant over-arching business and financial plans for the organisation

UNDERSTANDING HOSPITAL STRUCTURES

In the UK, hospitals will have set structures and hierarchies for all the people involved in the decision-making process for acquiring a new medical device or system.

As the manufacturer or supplier of a device, you will primarily be in contact with the Medical Device Management Group for that institution.



UNDERSTANDING HOSPITAL STRUCTURES

Policies created by a Medical Device Management Group will cover:

- Responsibilities in relation to device management
- Decontamination
- Equipment life cycle – Including selection, acquisition, acceptance, maintenance, repairs, monitoring, traceability, and disposal or decommissioning and replacement.
- Risk management, adverse event reporting, and lines of communication and responsibility. Plus actions and pathways relating to National Patient Safety Alerts, product recalls, MHRA Safety notices, and the manufacturer's Field Safety Notices.
- Training and access to manufacturer's instructions.
- Records, record keeping, device inventories.
- Outsourcing.
- Equipment financing.
- Device deployment, tracking, utilisation.

These policies will directly assess if a device is:

- Suitable for the intended purpose.
- Used in line with manufacturer instructions.
- Traceable (where possible).
- Maintained in a safe and reliable condition, with associated records maintained.
- Disposed of appropriately at the end of the life cycle, in accordance with Trust policy.

UNDERSTANDING HOSPITAL STRUCTURES

Who is responsible for the device?

Systems for managing medical devices will differ depending on the type of deployment that will apply to the device. Devices can be:

Allocated directly to the department where it will be used, thus the relevant department will be responsible for the management. This **most commonly applies to larger equipment** (such as imaging machines), and some smaller devices for critical / intensive care.

Allocated to device stores / libraries / pools from which they will be issued to users on request. **Common examples are mobility devices** (walkers, crutches, wheelchairs), and items like infusion pumps or ventilators.

Issued to a single user as a long-term loan, usually an individual user or patient. The **main examples are prosthetic limbs and wheelchairs.**

UNDERSTANDING HOSPITAL STRUCTURES

It is the hospital's responsibility to track device usage and utilisation. Devices that are under-utilised may be re-deployed elsewhere in the organisation or removed from circulation.

Note for product design: Incorporating record-keeping and identification aspects into device UIs can be useful e.g. areas where users can check the hospital-defined contacts for items like scheduled maintenance, as well as easily accessible asset tags or other identifying information. Risk-management is an inherent part of medical device management and should be considered at development.

In community care-based settings, the devices' management, maintenance and care will either be the responsibility of the end-user / patient, or the responsibility of a community worker.

For device libraries / pools, the device management and maintenance usually fall under the store's purview.

For devices issued on long-term loans, the device management will usually be split between the end-user (day-to-day management and maintenance) and a healthcare provider (scheduled maintenance, end of life cycle disposal, major repairs etc).

The responsibilities for each part will be defined at the start of the loan with regards to:

- Decontamination
- Maintenance and record-keeping
- Availability of up-to-date/updated instructions and care information
- Period and type of use
- Device identification and traceability
- Contact details (both users and healthcare establishments)

The healthcare institution always retains the responsibility for recovering the device at the end of the loan (or when they are no longer needed / fit for purpose).

IMPERIAL

MedTechONE

ACQUISITION OF NEW MEDICAL DEVICES

www.imperial.ac.uk/medtechone/

ACQUISITION & SELECTION OF DEVICES

Every healthcare organisation will have a policy in place for the selection and acquisition of medical devices, that usually includes a multi-year investment and replacement plan. It may include a short-to-long term schedule of medical devices, monitored against appropriate risk criteria.

Local acquisition policy will address:

- The clinical needs being addressed, and that the selection process considers care objectives, needs of patients, and the organisation's healthcare priorities.

- Safety, quality and performance, as well as the acquisition cycle as a whole.
- Whole life costs associated with the device, in line with national acquisition policy, guidance and recommendations. Considerations to value for money.
- Considerations for the needs and reasonable preferences of all involved parties, which includes both those involved in the use of the device, but also those involved in the general maintenance, upkeep, decontamination, and decommissioning of the device.
- Cost effectiveness of consumables relating to the device – includes the base cost of the device, and the lifetime cost of all related consumables.
- The mechanisms for the selection and acquisition of medical devices for specific procedures.

N.B. Healthcare organisations can be held legally responsible for any injury or death caused by inappropriate purchase, prescription or use of a device.

METHODS OF ACQUISITION

Most common acquisition methods:	Other acquisition methods:
Purchasing	Manufacturer Loan
Leasing	Loan from other healthcare institutions
	In-house manufacturing

Procedures for accepting new devices will identify:

- Training needs
- Appropriate planned maintenance and performance checks
- Technical support needs of users
- Minimisation of the risks of using a model/device for the first time.

As a first step, consider how your device fits into the existing hospital ecosystem.

FACTORS CONSIDERED PRIOR TO ACQUISITION

FACTORS CONSIDERED PRIOR TO ACQUISITION

SAFETY ISSUES & LIMITATIONS ON USAGE

Ensuring the designated area of operation for the device is suitable, ensuring the planned operating conditions are compatible with the device.

- Ease of use, user experience and manufacturer compliance with BS EN 62366-1:2015 Medical Devices
- **Ease of device misuse / accidental device misuse**
- **Mitigations in place / has it been designed to minimise misuse?**

Manufacturer's description of the intended user

AGREEMENT ON CLINICAL NEED

Usage and instructions for use

- **Safety and performance information**
- **Detailed specifications of the device**
- Comparison against the performance specifications defined in the acquisition requirements.

DEVICE LIFECYCLE

- **Projected service life cycle, length, and any applicable warranties.**
- **Costs of maintenance, repairs / spare parts, and consumables will be considered.** It may be cheaper for a hospital to buy a more expensive machine that lasts 10 years than a cheaper machine that only lasts 3 years (assuming repairs and consumables are of similar cost).

First set-up (pre-use set up), testing and calibration requirements, installation requirements, commissioning procedure.

Reliability and historic performance.

FACTORS CONSIDERED PRIOR TO ACQUISITION

FACTORS CONSIDERED PRIOR TO ACQUISITION

SUPPORT, MAINTENANCE & DECONTAMINATION

Evaluations of planned user maintenance, ad-hoc maintenance, and planned preventative maintenance, including:

- Periodic performance checks and any required specialist equipment.
- User/planned maintenance recommendations.
- Ease of breakdown maintenance and repairs – Including provision logistics and time frames.
- Ensuring the device can be stored, maintained and repaired in line with manufacturer requirements.

Decontamination and disposal procedures will be assessed to ensure that hospital processes are compatible with the manufacturer's guidelines. The hospital decontamination lead and infection prevention teams will be consulted on this area.

What advice or user help services do the manufacturer or supplier offer?
What user help guides are incorporated into the manufacturer's packet / into the device itself?
What does this information cover (user handling, usage guidance, suitability for specific procedures, operation manuals etc.)**?**

INSTRUCTIONS & TRAINING

Readability of manufacturer's instructions. Instructions for use should be comprehensive but also easily intelligible. Overly complex instructions for use are considered to indicate poor design, with a lack of consideration of human usage as a critical design goal.

Availability, type, and scope of required training. Is training required for both end users and maintenance, and does the training cover required decontamination procedures?

IT & DATA MANAGEMENT

Data and information security – Devices that process medical data must be secure and will be validated.

Software compatibility with patient record systems and archiving systems.

FACTORS CONSIDERED PRIOR TO ACQUISITION

When designing a medical device, **consider smaller factors that can improve the quality of the device and make the device more usable.**

For consumable items that are delivered in bulk (e.g. gloves, surgical dressings etc, where checking each one on delivery would be impractical), key considerations are:

- **Lot numbers / references are available on packaging** / easily identified, for tracing purposes e.g. for product recall, record keeping etc.
- **Instructions and safety information are readily available.**
- Expiry dates are shown on external packaging.
- **Packaging is appropriate for storage** and not excessive or cumbersome.
- Ideal **storage environment conditions are clearly marked** e.g. “Store in a cool dry place”.

SAFETY PERFORMANCE & RELIABILITY

It is a legal requirement for all medical devices placed on the UK market to be UKCA / CE marked.

The hospital will also assess any local history of issues with the device or similar devices, and will consider any issues that the device may face when in situ.

Part of these checks will cover MHRA safety publications, manufacturer advisory notices and relevant publications. **The hospital may also conduct a local level investigation into user experiences** with the device, or similar devices, encompassing any known problems or failures.

The manufacturer may be asked to provide evidence of reliability from other responsible organisations and will need to supply evidence of compliance with relevant regulatory standards.

Rationalising the range of models vs diversity

Hospitals consider the risk of **"operator confusion"** when acquiring devices. This means that **hospitals are unlikely to stock a variety of models for the same purpose/procedure.**

It is however, understood that there are risks to having only one model:

- A chosen model may be unreliable
- A single model will eventually go out of production/warranty/be unavailable for repairs/may be withdrawn by the manufacturer etc.

The main concern is models/devices that are superficially similar but that have differing, limitations, usages, restrictions, settings or operating procedures.

Key point: Designing medical devices that improve on existing models but limit the risk of operator confusion.

INSTALLATION SUPPORT SERVICES

Hospitals will balance the amount of work acquiring a new device requires, in contrast with staying with the current model or device. This includes assessing the support available for the physical installation of a device – this doesn't just mean large, commissioned devices but can include smaller devices.

Considerations will include:

- Is the installation carried out by the manufacturer/supplier?
- **What utility services are required?** e.g. Mains water, piped gas supply, electricity.
- **Are special practices required**, such as decontamination, calibration, or maintenance? Complex devices may need to be installed by a specialist.
- **Does the device meet IT protocols for digital safety, information security, and interfacing** with existing systems and records? Are there any operating systems requirements the device must meet?
- Can additional software like anti-viruses be installed?

The more information you can provide on these topics, the better. If your device will need to be installed by a specialist technician, or by a person from the manufacturer, you should be up front about the process so that it can be properly included in the discussion.

MAINTENANCE & SERVICING

After installation, but prior to first use, the device will be checked for functionality in line with the manufacturer's instructions.

Over the course of the life cycle of the device, the device will need maintenance or repairs. **During the acquisition process, hospitals assess how much impact the regular maintenance will have on the device's ability to operate**, and if service to patients will be interrupted or if it can be bridged during maintenance.

Hospitals will consider:

- **Can the desired service provider maintain the device?** This may be the manufacturer or a third party. Unless otherwise stipulated, the hospital will put the maintenance contract out to tender for an appropriate supplier.
- **What are the proposed time frames?** How strict are they / is there flexibility?
- **Continuity of care: Can the device be repaired on site?** Are there other options for the model when a device is being repaired or serviced? What is the availability of spare devices or parts?
- **Can the service provider guarantee response times and maintenance time frames?** Are the time frames appropriate and reasonable?
- **Are any calibrations or replacements required between official maintenance?** Are the instructions on user calibration clear?
- **How long is service support guaranteed?**
- **What information is available from the manufacturer / within the manufacturer instructions?** e.g. Maintenance schedules, preventative maintenance plans, troubleshooting guidance, repairs procedures, parts lists, spare parts and specialist repair tools?

FINALISING THE ACQUISITION & AWARDING THE CONTRACT

One of the final steps of acquisition is the drafting of a full performance specification of the entire system will be drafted prior to acquisition – this is part of the tendering process.

In addition, **“full” means full, and includes every single conceivable aspect of a device including items like batteries and charging procedures.** You must be prepared to draft and provide information on everything related to the device.

Once the performance specification is received and the device has been confirmed as an acquisition, **final terms and conditions will be drafted and will be accepted and signed by all parties concerned.** Only at this point will the contract officially be awarded to the supplier/manufacturer. The acquisition will then proceed according to the agreed terms, and any user feedback will be put towards future acquisitions/contract extensions.

IMPERIAL

MedTechONE

RECEIVING A NEW MEDICAL DEVICE

www.imperial.ac.uk/medtechone/

ACCEPTANCE CHECKS

The hospital will check that the received device and its specifications match that of the device on the purchase order and other acquisition information. The hospital will keep records of the delivery inspection and checks, as well as ordering records, individual device or batch numbers and identifiers, and the results of any safety and/or function tests, and a record of who carried out those tests.

Delivery checks will include:

- Checking that the correct product, complete with maintenance and usage information, and any relevant accessories, have been supplied.
- **Ensuring that the device is delivered in good condition**, and in good working order.
- **Reviewing the manufacturer's instructions, especially with regards to any calibrations, testing, or adjustments required prior to first use.** This may also require the generation of baseline data, e.g. "perfect working order" examples, to show calibration drift at subsequent maintenance, and to measure and record "at new" reference values for electrical safety records.

The person carrying out checks must be appropriately trained and qualified to conduct the relevant tests. **This may be a person on the delivery team, or it may be an assigned person from the hospital.** Additionally, acceptance tests should not exceed the bounds of normal usage – they are not stress tests.

ACCEPTANCE CHECKS

ACCEPTANCE CHECKS	
☐	Electrical testing e.g. PAT
☐	Damage checks (for transport induced damage)
☐	First use calibration
☐	Checking the quality of the instructions for use
☐	Adequacy of training
☐	Checking that the device received is the same as what was ordered, including model numbers
☐	Compatibility with the rest of the testing / diagnostic system, and with existing infrastructure
☐	Completeness checks - have all items and accessories been received as per the purchase order?

Consider including an Acceptance Check checklist in your shipping documents, or within the manufacturer's instructions. This way you can guarantee the device is received and checked to be in good condition, to the level of detail required.

TRAINING

Training policy for medical devices will be decided at a local level, but you should consider including the following in the manufacturer's guidance and instructions:

TRAINING

DELIVERY

Can the training for your device be covered within other generic training blocks, or does it require specific training?

How should periodic reviews, refreshers, and re-trainings be structured?

Is good training for this device usage competency-based?

Should training be undertaken prior to the device introduction to the hospital?

Will software changes / updates require additional training?

USERS

Who should be receiving the training directly from the manufacturer / supplier? And how will other people be trained?

How will other staff be trained? Including:

- New staff
- Agency staff
- On call / Locum / Contractors
- Staff responsible for maintenance and repairs
- Staff responsible for decontamination

How will training for service end users and patients be carried out? (Where applicable).

INFORMATION & RECORDS

Training record-keeping – Primarily the responsibility of the hospital

How will users access the manufacturer's instructions?

TRAINING

With regards to training users on device safety, it should be clear what:

- **Normal operation / usage looks like.**
- Differences exist between models, and what accessories and consumables are compatible with this model.
- Any **contraindications or restrictions** with regards to accessories and consumables.
- Requirements for maintenance, cleaning and decontamination are.
- **Troubleshooting** processes are available.
- **Device defects or failures look like** and how they should be handled / mitigated.
- The **process for reporting device-related adverse events** is e.g. reporting to the hospital and/or MHRA.
- Any **pass/fail functioning criteria** are, as they affect patient / user safety e.g. if X happens, it may cause additional doses of radiation etc.

IMPERIAL

MedTechONE

INSTRUCTIONS FOR USE

www.imperial.ac.uk/medtechone/

THE IMPORTANCE OF EFFECTIVE INSTRUCTIONS

Instructions for End Users

All information on:

- Storage,
- Pre-usage checks,
- Usage,
- Cleaning, and
- Maintenance

must be provided to the end user, **including where the device is passed on to a secondary user** e.g. the prescription of a prosthetic to a patient, the patient must receive all of the information.

The **manufacturer is responsible for supplying appropriate instructions**, and for considering the intended recipient, including their knowledge and training level (plus training required for the device usage).

Within the terms and conditions set at acquisition, **it should be made clear with whom the responsibility of making the instructions and training available lies.**

When information and instructions are changed or updated, they must be promptly rolled out to all device owners. Hospitals should have a competent set of records and methods of tracking historic versions of device instructions.

Shortcomings in instructions can be reported to the MHRA as an adverse incident.

THE IMPORTANCE OF EFFECTIVE INSTRUCTIONS

Failure to provide the manufacturer's original instructions may open the supplier, manufacturer, and the hospital to legal action in the event of injury to a user (regardless of if they are a clinical device user, or a patient). **It is important to note that some end users, including carers, those with disabilities, or those with communication needs, may require additional information, instructions and/or training.** It is prudent on the manufacturer's part to define these instructions and have them checked for accuracy and clarity to the relevant userbase during development – for example, instructions should be readily available in braille, for sight impaired users, but braille translations should checked for accuracy before being provided to users.

Instructions for Patients & Other End Users

The instructions provided to any end users must be detailed enough to cover, and in plain enough language that members of the public can understand:

- Differences between models and any cross-compatibilities.
- Accessories and how they increase / decrease the device's function.
- Use of controls, and the meaning of any lights, alarms, displays, or other indicators.
- Requirements for cleaning, general upkeep, decontamination, and maintenance.
- Basic device usage instructions, how to use the device.
- Basic troubleshooting guides.
- How to recognise a device defect, malfunction or other error, and what to do.
- Advice on the importance of reporting device defects, and who to report them to (either to the hospital who pass it on to the MHRA, or directly to the MHRA).

IMPERIAL

MedTechONE

MAINTENANCE & REPAIR

www.imperial.ac.uk/medtechone/

APPROPRIATE MAINTENANCE & REPAIR SERVICES

The UK MDR 2002 requires the 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 organisations that can have a role in the maintenance process, and in ensuring adequate maintenance include the:

- Manufacturer service organisation
- Authorised service agents or companies
- Generic third-party service providers
- In-house maintenance services/departments
- Users

The manufacturer may wish to be solely responsible for maintenance and repairs to ensure the quality of repairs. Alternatively, they may stipulate strict criteria on the training, equipment, and resources of in-house departments (or third-party service) with regards to the device.

APPROPRIATE MAINTENANCE & REPAIR SERVICES

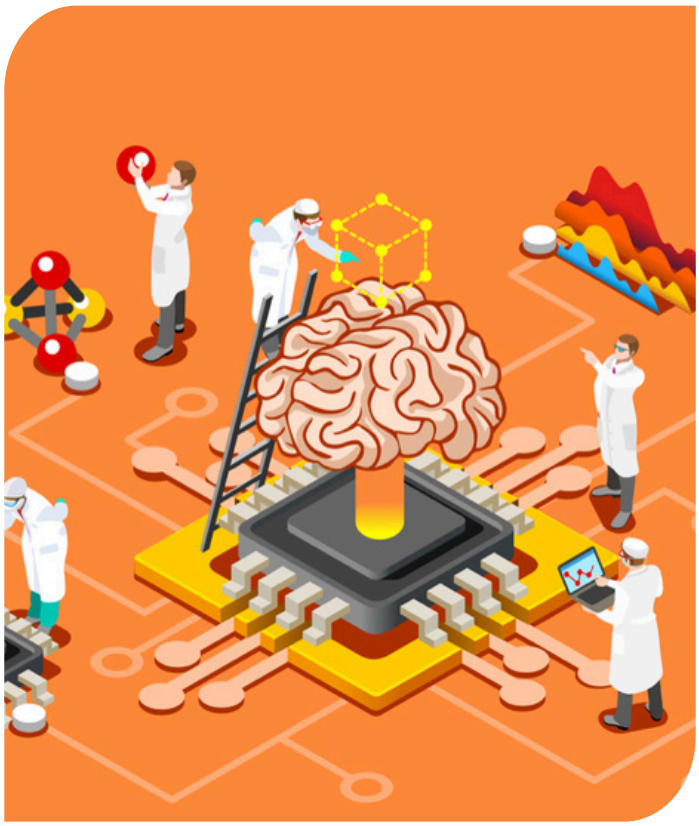
Points to consider:

- Do outside (non-manufacturer) services have **access to the necessary equipment and up-to-date maintenance records** to be able to carry out the maintenance safely and effectively?
- How quick is the service, and **can loan devices be provided** to cover the maintenance window?
- What level of detail is required within maintenance records? (May include calibration, preventative maintenance carried out, troubleshooting completed etc).
- **Are consumables like adhesives or proprietary cleaning solutions included?**
- **Are full instructions on maintenance and repairs available,** including procedures and spare parts? Includes defining what the manufacturer/supplier means by “spare parts”, and “repair” etc.

APPROPRIATE MAINTENANCE & REPAIR SERVICES

Any maintenance provider, including where that means the manufacturer or supplier, will be subject to a **contractual agreement defining the length and level of service**. It would include:

- Reference to the manufacturer's written instructions
- Availability, source, and traceability of new/spare parts
- Notifications of any changes and updates, such as new types of spare part or replacement structures
- Training of staff
- Quality Management Systems
- Record keeping requirements
- Use of sub-contractors
- Response times
- Disposal of obsolete devices, waste and parts
- Information Governance responsibilities where the maintenance of a device involves patient data or records leaving the hospital
- Loan devices and service continuation provisions



Specialist advice may be needed where specific legislation comes into play, or where there are other safety concerns such as radiation or x-rays (Ionising Radiation Regulations 2017).

APPROPRIATE MAINTENANCE & REPAIR SERVICES

Specialist advice may be needed where specific legislation comes into play, or where there are other safety concerns such as radiation or X-rays (Ionising Radiation Regulations 2017). Where contracts for maintenance and repairs rest with the manufacturer or supplier, the manufacturer is responsible for ensuring the hospital is made aware of any changes or issues that will affect the repair of their devices.

Refurbished, pre-used or second-hand spare parts should not be used to repair any device, except under special circumstances with contractual permission after the hospital carries out a full risk assessment.

Parts must absolutely never be re-used if their history and history of usage is unknown.

All spare or new parts used in a repair or regular maintenance must be documented and critical parts (those whose failure will present a safety risk to patients, or may damage the device, or may cause the device to cease function) must be able to be traced back to their original supplier. This is particularly relevant in case of a part/product recall.

Replacement batteries must provide the same power and life cycle as those originally supplied with the device. Using incorrect or inappropriate batteries can be dangerous and can damage devices. Any testing or benchmarking equipment should also be regularly checked and maintained to ensure it can still demonstrate optimal device outputs and safety.

“SERVICED” labels should include the date of the previous maintenance service, service personnel initials and the date of the next due maintenance service.

PLANNED PREVENTATIVE MAINTENANCE CHECKLIST

1 INITIAL INSPECTION

- [ ] Device cleanliness
- [ ] Decontamination required?
- [ ] Inspection of all elements in line with manufacturer instruction
- [ ] Note of settings controls (so any settings changed during cleaning can be put back for usage).

2 PARTS REPLACED

- [ ] Document each item/part to be replaced
- [ ] Include details of source manufacturer of any spare parts, and an overview of the method of installation/fitting

3 CALIBRATION

- [ ] Establish if any part requires calibration/re-calibration
- [ ] Calibrate in line with manufacturer instructions

4 PERFORMANCE & SAFETY

- [ ] Carry out performance tests according to manufacturer instructions before and after maintenance
- [ ] Check if any equipment handover procedures are required

5 RETURN TO USE

- [ ] Record all details of the maintenance in the designated maintenance record database, ensure you are making a record for the specific device (including any asset tags or IDs)
- [ ] Check the device has its accessories and is properly assembled
- [ ] Either return all controls to zero, or to the settings noted at initial inspection
- [ ] Adhere a “SERVICED” label noting the date of service, and the next prospective service date. Annotate with any alterations to settings.

IMPERIAL

MedTechONE

DECOMMISSIONING & DISPOSAL

www.imperial.ac.uk/medtechone/

DECOMMISSIONING

Decommissioning aims to make a device safe and completely non-functional for disposal.

Things to consider when devising instructions for decommissioning a device:

ENVIRONMENTAL CONSIDERATIONS
- BATTERIES
- BIODEGRADABLE MATERIALS
- CONTAMINATION & RADIATION
- RETAINED FLUIDS

DISPOSAL
- METHODS
- REQUIREMENTS
- SAFE HANDLING
- LOGISTICS

RECYCLING
- DONATION
- PARTS
- REFURBISHMENT
- SAFETY
- RELIABILITY

STRUCTURAL REQUIREMENTS
- DEVICE SIZE
- DANGEROUS PARTS OR MATERIALS
- LOGISTICS

DECOMMISSIONING

Decommissioning work includes decontamination and the removal of any hazards such as radioactive materials (which must be conducted in line with the Ionising Radiation Regulations 2017). For larger equipment this may also mean the disconnection of power and cooling systems.

Devices that incorporate the storage of patient data must be thoroughly erased and must be supplied with a certificate stating as such (along with any relevant information). Data must be erased to an appropriate standard, such as **BS ISO/IEC 15408**. Any remaining data must be forensically unrecoverable e.g. over-written.

It is prudent, as the manufacturer, to incorporate instructions for decommissioning ahead of time, so that any hospitals or centres using the technology are supported in the event that the company ceases trading.

Disposal

The manufacturer is responsible for providing information on how to appropriately dispose of used or decommissioned devices. This is in line with the Waste Electrical & Electronic Equipment Regulations.

You should also be considering if your device will involve the generation of any specialised waste, as this must be disclosed in both the instructions for use and in the instructions for disposal.

In cases where the manufacturer has ceased trading, **the hospital will contact the MHRA for advice.**

SPECIALISED WASTE

Some devices or components require specialised disposal methods. These could include:

TYPES OF SPECIALISED WASTE

Some devices or components require specialised disposal methods. This could include:

Items containing certain metals e.g. lithium batteries, or a device containing >3% mercury.

Oil wastes, including Polychlorinated Biphenyls (PCBs)

Human waste from natal care, and from diagnosis, treatment, or prevention of disease

Coolant Waste

Radioactive Waste

Clinical / biological waste of either human or animal origin

TRANSPORTATION

Where the device is returned to the manufacturer for disposal, **the manufacturer is responsible for providing information on how to pack the device for transport.** This should include information on:

- Strength of packing materials
- Packing sharp corners/edges
- How to ensure the device is not damaged in transit

Additionally, **transport instructions should adhere to current legislation for the transport of medical devices** including:

- The Carriage of Dangerous Goods by Road Regulations
- The Carriage of Dangerous Goods by Rail Regulations
- Chemicals (Hazard information and packaging for supply) Regulations
- The Radioactive Material (Great Britain: Road transport) Regulations

Sale or Donation for Reuse

The UK MDR 2002 applies to devices being sold for the first time, but **there are currently no regulations that cover secondary sale or donation of devices.**

This requires common sense behaviour – **if the device is currently not safe for patient use it is never safe to sell or donate.** Any used devices should be thoroughly risk assessed, and the risk assessment report should be included as part of the information for the sale.

RESALE & DONATION: REQUIREMENTS

Used medical devices are still required to be safe under other regulations, including the:

- Consumer Protection Act (Consumer Safety & Product Liability)
- Sale & Supply of Goods Act
- Health & Safety at Work Act
- Trade Descriptions Act
- The Electrical Equipment (Safety) Regulations
- Unfair Contract Terms Act

The device must always be included with all its information, from manufacturer instructions, calibration requirements, and maintenance requirements, to service and maintenance history, to any fault logs, decontamination certificates etc.

Prior to sale or donation, it is prudent for both parties to obtain legal advice, and to be sure about their legal obligations.

When selling or donating a device, alongside the above-mentioned information, there should be documentation provided that covers:

- A clear statement that the device is being resold/donated
- A decontamination certificate
- User manuals and training requirements
- Full details of maintenance and servicing requirements
- Service history and manuals
- Full usage history
- Quality Assurance test details
- Safety updates that have been released since the device's manufacture

If any aspects of the above are not available, it is not recommended to sell/donate the device.

REFURBISHMENT & FULL REFURBISHMENT

Refurbished devices are covered under the UK MDR 2002. As such, **a new UKCA/CE mark must be adhered to the refurbished device, affixed by the person or organisation that carries out the refurbishment**, after any required UKCA/CE assessments. (Refer to the UK MDR 20zx02 and other relevant legislation relating to UKCA/CE marking for more information).

Full Refurbishment refers to devices that are re-manufactured to be sold "as new" – These devices are also covered by the UK MDR 2002.

Full refurbishment may be different depending on the device, but is broadly considered to include:

- Stripping into components or sub-structures/assemblies.
- Checking their suitability for reuse.
- Replacement of any components/assemblies not fit for use.
- Assembly of replacement components/assemblies and subsequent testing for use against either original or revised (updated) criteria.
- The identification and marking of the refurbished device, as advised.

FURTHER READING & RESOURCES

Guidance Policy (UK GOV) 2021
https://assets.publishing.service.gov.uk/media/6089dc938fa8f51b91f3d82f/Managing_medical_devices.pdf

IVD Policy 2021
https://assets.publishing.service.gov.uk/media/60118464e90e0714311c38ce/Management_of_in_vitro_diagnostic_medical_devices.pdf

Management & Use of IVD POC Testing 2021
https://assets.publishing.service.gov.uk/media/601a8c988fa8f53fbdc27dcc/Management_and_use_of_IVD_point_of_care_test_devices.pdf

GLOSSARY

MDMG – Medical Device Management Group
MDSO – Medical Device Safety Officer

IMPERIAL

MedTechONE

CONTACTS

https://www.imperial.ac.uk/medtechone/

mt1-info@imperial.ac.uk

LinkedIn@MedTechONE