

# Devices in Practice

Checklists for using medical devices

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Medical devices play a crucial role in care and treatment. The number and variety of medical devices is vast and professionals handle a wide range of devices every day in their practice.

The Medicines and Healthcare Products Regulatory Agency is responsible for making sure that medical devices are safe and fit for purpose. We have published these checklists to provide a practical guide to using medical devices.

These checklists are for:

- health and social care professionals working in all areas including acute care, primary care, community care (or care at home), care homes, care homes with nursing and private healthcare systems
- health and social care organisations as they develop policies and protocols for the use and management of medical devices
- pharmacists in acute, primary care and social care settings
- voluntary and charitable organisations who provide devices direct to individuals or health and social care organisations.

Not all the checklists or the details will be relevant to every device but they are to prompt you to think about what needs to be done.

Our document '[Managing Medical Devices](#)' has more detailed guidance that includes procurement, maintenance and repair, and training.

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This document replaces the version published in 2008.

## 1 Examples of medical devices

The term 'medical device' covers a wide range of healthcare products other than medicines used every day in all healthcare settings.

A medical device is any product used in the:

- diagnosis, prevention, monitoring and treatment of disease or disability
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy, or of a physiological process
- control of conception.

We can't list all the different types of devices but the examples below give an idea of the range of products that are medical devices.

### **Used in the diagnosis or treatment of disease, or monitoring of patients:**

- anaesthetic machines
- blood glucose measuring devices
- chiropody and podiatry equipment
- CT scanners
- dental instruments, equipment and materials
- dressings
- endoscopes
- examination gloves
- intravenous (iv) administration sets and pumps
- nebulisers
- ophthalmic equipment
- pacemakers
- peak flow meters
- surgical instruments
- suction equipment
- syringes and needles
- ultrasound dopplers
- urinary catheters.

**Used in life support:**

- defibrillators
- patient monitors
- pulse oximeters
- ventilators.

**In vitro diagnostic medical devices and their accessories:**

- blood glucose measuring devices
- cholesterol test kits
- pregnancy test kits
- urine test strips.

**Used in general care:**

- adjustable beds
- patient hoists and other transfer equipment
- pressure relief equipment
- stoma care equipment.

**Equipment used by people with disabilities:**

- external prostheses and orthoses
- hearing aids
- incontinence aids
- prescribable footwear
- standing frames
- urine drainage systems
- walking aids
- wheelchairs and special support seating.

**Devices supplied by pharmacists:**

- condoms
- contact lens care products
- chlamydia test kits
- cholesterol test kits
- pregnancy test kits

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- sphygmomanometers
- thermometers
- stoma equipment
- urine test strips.

## **2 Safe use of medical devices**

Professionals in health and social care use medical devices themselves and also provide devices which are then used by others, such as users or carers. Professionals in health and social care are personally accountable when they use devices and therefore must ensure that they have appropriate training.

They are also personally accountable for ensuring users and carers have received appropriate training and know how to use the device that has been provided.

An individual healthcare professional who uses the device in a way not intended, or against the instructions of the manufacturer may be liable for any consequences.

Use this checklist to ensure that you use medical devices safely

**Before use: assessment**

- What are the clinical and social needs of the patients or clients?
- Which of the medical devices available best meets those needs?
- Has a risk assessment been done? Are the risks associated with this device acceptable and can they be minimised?
- If the device has been bought privately is the patient or client aware of their personal responsibility?
- If the medical device is to be used by patients and/or carers, have the following been taken into account:
  - physical capabilities eg manual dexterity
  - sensory capabilities eg vision, hearing, ability to understand and remember
  - previous experience with the medical device
  - the patient's or client's expectations
  - the environment in which device will be used.

**Before use: knowledge of device**

- Will the device be used in the way intended by the manufacturer?
- What are the limitations and contra-indications for use?
- Has the device been maintained in line with the manufacturer's instructions?
- Has the device been checked/calibrated after maintenance?
- Is the device within its expiry or use-by date?
- Who is authorised to carry out pre-use checks?
- Are there any signs of wear, damage or faults?
- Where can you get a replacement device?
- Do you know how to set up and use this device?
- Have you read the user instructions, and are they attached to the device, if this is possible?
- Have you been trained in its use?
- How was your competency to use this device assessed?
- Do you know how this device should perform and the monitoring that needs to be done to check its performance?
- Are you using the correct additional equipment, eg disposable infusion sets for an infusion pump?
- Do you know what to do if the device fails?
- Do you know how and to whom to report a device-related adverse incident?
- Has the device been modified? If so, has liability been checked with the manufacturer?
- In the case of devices purchased over the counter, have I advised the user to register with the manufacturer for ease of contact in case of urgent upgrades or recalls?

**During use**

- Have you documented the details (name and serial number) of the device being used?
- Does checking the medical device show it is working properly and to the manufacturer's specifications? Has this been documented?
- Do you know what to do if the device is not working properly?
- Have the regular checks of the device been recorded?
- Is the equipment still appropriate in the light of the patient or client's changing needs?

**After use**

- What cleaning and/or decontamination does the device need?
- Does the medical device show any signs of wear, damage or faults that should be reported?
- Does it need servicing, maintenance or repair?
- Were there any problems in using this device which should be noted and could be fixed for the future? Eg was any information missing from the manufacturer's instructions which would have been useful?
- If it is used in the home, how will the medical device be returned to the owner, disposed of, or safely stored?

### 3 Responsibilities of users and carers

Health and social care professionals will often provide medical devices to patients and carers. It is important to make sure that these groups of people have adequate information about the use of the device. Health and social care professionals are personally accountable for ensuring that users and carers have appropriate training in the use and maintenance of the device provided.

Individuals who buy a device over the counter or privately need to be made aware of their personal responsibility to ensure the device is appropriately used and maintained.

**Use this checklist to make sure that users and carers are fully aware of their responsibility for medical devices.**

- Has the user or carer been trained to use the device and assessed as competent?
- Have they been given written guidance on using the device?
- Does the guidance cover:
  - the name of the device
  - how to use the device and any accessories
  - their responsibility for checking the device while in use
  - the maintenance required and its frequency
  - recognition of device failure and fault
  - action to be taken in the event of a device failure or fault
  - their responsibility for reporting problems with the device to the supplier of the equipment
  - contact telephone numbers to use in an emergency, including out of hours
  - their responsibilities if they have bought the device themselves.

## 4 Record keeping

Good records are important in effective device management. Records should provide evidence of what the device is and where it came from, its serial or batch number, the maintenance record of the device and any training carried out on how to use it properly.

Paper-based systems can be used if you have only a few devices but a computer-based system is better if you have a number of devices.

### **Use this checklist to ensure your record keeping is adequate**

#### **Records should provide evidence of:**

- a unique identifier for the device, where appropriate
- 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.

#### **Your records should show that the end user:**

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

## 5 Reporting problems with devices

Sometimes a problem with a medical device can lead to an 'adverse incident'. We define this as 'an event which produces, or has the potential to produce, unwanted effects involving the safety of patients, users or other people'.

### **If there is an incident with a medical device:**

- Record the following:
  - manufacturer and model of the device involved (and any other details you can find)
  - details of the incident (how it happened and any effects on the people involved)
  - device settings
  - details of any error messages
  - date and time of the incident.
  
- Report the incident to the relevant manager and to the MHRA (or equivalent in Northern Ireland or Scotland).

The best way to report to us is through [our website](#).

We need to know about these problems so that we can investigate and take action to protect other patients and users.

You should also tell the manufacturer about it.

Even if you're not sure if the problem was caused by the medical device, tell us about it.