

HPRA



An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

MEDICAL DEVICES

Automated external defibrillators

Our
advice



www.hpra.ie

MEDICAL DEVICES

Automated external defibrillators

An automated external defibrillator (AED) is a medical device that analyses a person's heart rhythm and, when needed, delivers a shock to sudden cardiac arrest (SCA) victims who are in a shockable heart rhythm.

A defibrillator can play a potentially lifesaving role. Used correctly, it can improve a person's survival chances following SCA. Therefore, defibrillators need to be accessible and in good working order at all times in the event that they are needed for an emergency situation.

Traditionally AEDs have been operated by trained healthcare professionals such as GPs as well as those working in the ambulance and fire brigade services. As awareness of their benefits has grown, they are now widely used in community locations, such as sports facilities and shopping centres and often operated by members of the public.

The Health Products Regulatory Authority (HPRA) has published this leaflet to provide advice on selecting and purchasing an AED for use in a community setting. It also provides recommendations for maintaining the device after it has been purchased.

Where used in this leaflet, the term 'defibrillator' is specifically referring to the AED family of defibrillators and does not refer to other types of defibrillators such as implantable cardiac defibrillators.

Before you purchase a defibrillator

What to look for

- All medical devices must BY LAW display a CE mark. If a defibrillator has a CE mark then you can be assured that it should, when used and stored properly, work as intended and be safe.
- Accessories such as pads, used with a defibrillator to assess the patient and deliver therapy, are also medical devices. If supplied separately they must also bear the CE mark.
- Purchase your defibrillator from a trusted supplier who can provide the relevant support and traceability.



On a defibrillator, there should be a four digit number below the CE mark.

Storing the defibrillator

- Where you keep your defibrillator is critical to its performance. Inappropriate storage conditions can result in the defibrillator being unusable when needed and/or long term damage to the defibrillator and its accessories.
- Defibrillators and their accessories (such as pads, electrodes and battery) can be badly affected by the weather and other environmental conditions.
- The manufacturers of defibrillators and its accessories have confirmed that their products will perform under certain conditions. It is essential that you are aware of these conditions when deciding where to store the defibrillator.
- Check the manual of the defibrillator and its accessories to identify the conditions that can affect its performance, such as:
 - Storage temperature;
 - Exposure to moisture and damp (environmental humidity).

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- Check the area where the defibrillator will be stored and ensure it is suitable. You should consider:
 - Is the location heated? For example, although indoors, an entrance hall may not have a radiator.
 - Will the room be heated when not in use? For example, a sports hall that is only used on certain days.
 - Does the temperature or humidity level in the room vary significantly depending on the time of year?
 - Does the storage location ensure that the defibrillator is accessible?
- If the defibrillator is stored in an outdoor area where the temperature or humidity levels will fluctuate then it should be housed in a suitable cabinet or container. The cabinet should not just provide protection from rain but should also ensure it can be stored within the manufacturer's recommended conditions.
- Periodically confirm that the environmental conditions where the AED is located are within the manufacturer's recommendations e.g., measuring the temperature with a thermometer during colder periods is advisable.

Complete the training

- All users of defibrillators should complete a recognised training course where possible.
- It is important to ensure that the training provided is relevant to the defibrillator model that is used at your facility.
- Ensure that the names of trained users and their contact details are displayed near the defibrillator and that all staff, facility members and users are aware of those who can use the device.

After you purchase a defibrillator

Regular servicing and maintenance is crucial

- The user manual supplied with the defibrillator provides important information from the manufacturer about its use and maintenance.

- A defibrillator, like all medical equipment, must be used and maintained in accordance with the guidance given by the manufacturer.
- A copy of the manual should be stored with the defibrillator and be accessible AT ALL TIMES.
- Make sure you understand all of the information contained in the manual and any servicing or maintenance required. If in doubt, contact the manufacturer or their local distributor.
- A maintenance plan and schedule should be put in place. It is very important that someone familiar with the operation and storage of the defibrillator is given the task of keeping the plan up-to-date.
- The maintenance plan must also consider all accessories (pads, battery pack, electrodes, etc.) used with the defibrillator. The plan should also identify the different conditions of use that apply to the accessories, such as their shelf life or whether they are single use only.
- The maintenance schedule should detail the intervals at which checks should be completed on the device and its accessories as outlined in the manufacturer's instructions and also giving consideration to the environment of use. A record should be kept of the regular maintenance checks completed as part of the schedule.
- Ensure that all accessories are compatible with the defibrillator model.

Keep the defibrillator updated

- To make sure that all necessary maintenance, updates or changes can be carried out on your defibrillator, for example, it may require new software, it is important that it can be easily accessed at all times. You should therefore :
 - Complete and return all registration forms provided with the defibrillator;
 - Inform the manufacturer or local distributor of the location of the defibrillator as well as the address and the relevant contact details should they need to access it;
 - Keep these contact details up-to-date if the defibrillator is moved to a different premises or address

When you start to use a defibrillator

Check the status

- Your defibrillator has a status indicator that shows its current status. This is usually a light on the defibrillator and there may also be a voice prompt.
- Ensure you are familiar with this status indicator.
- The maintenance schedule for your defibrillator should include a log to record when the status of the defibrillator is checked. Ensure that each status check of the defibrillator is recorded in the log.
- Turning your defibrillator on and off repeatedly to confirm it is operating can run down its battery.

Periodic self tests

- A defibrillator performs self tests at regular intervals to verify it is ready for use. Some of the tests are automatic and do not require any action from the user, while some tests must be performed by the user to confirm the defibrillator is working properly.
- Make sure you have a clear understanding of the service tests performed by your defibrillator:
 - What is being tested?
 - How often are the tests carried out?
 - Are the tests automatic or do you need to do anything?
 - If your defibrillator indicates it has failed a test during maintenance CHECK THE USER MANUAL IMMEDIATELY and take the appropriate steps to identify the cause of the failure. Contact your local distributor or the manufacturer as soon as possible.

Effects of external factors

- The performance of your defibrillator can be affected by other external factors including electromagnetic interference.
- Known conditions that affect defibrillator performance should be detailed in the manual.
- Ensure the defibrillator is used away from any identified sources of interference.

Other Useful Information

This leaflet highlights some of the important issues that should be considered when purchasing, storing and maintaining an AED. It is not intended to be a guide on how to use a defibrillator nor does it replace or reduce the importance of your defibrillator manual and training. The following sources of information may also be of interest:

- **Irish Heart Foundation**
<https://irishheart.ie>
- **National Ambulance Service**
<http://www.nationalambulance.ie/>
- **Pre-Hospital Emergency Care Council**
<https://www.phecit.ie>

Relevant training courses may be found through the websites listed above.

How to report an incident to the HPRRA

If your defibrillator poses a risk to the health and safety of the patient, please report the problem to the manufacturer and to the HPRRA. You should report any unexpected problem or malfunction that may affect the patient's health or cause or contribute to an injury. For example, failure of the status indicator on the device to alert you that the device is not operating when in use.

You can report incidents to the HPRRA by filling in our online user report form on www.hpra.ie. If you would prefer to fill out a printed copy of the form, you can download it from our website or request a copy by phone or email.

The Health Products Regulatory Authority (HPRA)

Our role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products.

What does the HPRA do?

As the regulatory authority, we monitor the safety of all medical devices available in Ireland. Our aim is to make sure that these products do not compromise the health and safety of the patient or the person using them. We also work to ensure that medical device manufacturers comply with all safety regulations.

(The HPRA cannot provide advice on which medical devices you should buy.)

More information

This is one in a series of information leaflets that you can get from the HPRA and from our website: www.hpra.ie.



Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Phone: (01) 676 4971
Fax: (01) 634 4033
E-mail: devices@hpra.ie

www.hpra.ie