HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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HPRA calls for owners to check defibrillators

Over 900 machines urgently need updating

The Health Products Regulatory Authority (HPRA) today called on all organisations with automated external defibrillators (AEDs) to urgently check that the recommended safety and maintenance updates on their device have been undertaken. The HPRA is issuing this advice as it has identified some 940 defibrillators in Ireland, incorporating five particular models, where a corrective action remains outstanding. Updates to these AEDs are needed immediately to ensure that the devices will work as necessary in a life-saving situation. In addition, the HPRA warns that weather temperatures will affect a defibrillator's performance and all AED devices should be stored correctly and regularly checked during the winter months ahead.

The HPRA states that with the development of easier to use, automatic, portable and affordable defibrillators, there has been a significant increase in the number of AEDs in Ireland with sporting venues, schools, hotels, restaurants, businesses and shopping centres now having them on their premises in case of emergencies. It is estimated that there are up to 5,000 sudden cardiac deaths in Ireland each year with over 70% of all cardiac arrests occurring outside of the hospital environment. While AEDs can improve a person's survival chances following sudden cardiac arrest, the HPRA states that if the defibrillator is not maintained, stored or serviced correctly it may not work in an emergency. To ensure good working order at all times, correct storage and regular checks are required. Most importantly, the HPRA stresses that if an update or other action is identified and communicated by the manufacturer to the AED owner – through the publication and distribution of what is called a field safety notice (FSN) – then this should be undertaken immediately. Otherwise the AED may not work properly when it is needed. All field safety notices for defibrillators are also published on the HPRA website.

According to Anne Tobin, the HPRA's Medical Devices Vigilance Manager, there are many reasons why an AED may not work including the device requiring an upgrade as highlighted in a FSN which is outstanding; the batteries may be beyond their shelf life and not replaced; or the devices may not be stored and maintained correctly.

The HPRA is particularly concerned that for some 940 devices a corrective action which is required to enable them to work properly remains outstanding. This situation requires decisive action on behalf of the owners of these AEDs to respond to requests from the manufacturer or supplier of their device. Owners of AEDs also should ensure that the manufacturer has the correct contact details for them to allow the manufacturer inform them of the need for safety upgrades.

"It is estimated that there are some 10,000 AEDs in Ireland. We know that almost 950 of these have the potential to not work effectively in an emergency because a corrective action as deemed necessary by the manufacturer has not been completed. We know that the manufacturers concerned have attempted to contact the owners directly with some also using national advertising to highlight the importance of carrying out the required upgrade or battery check," says Ms Tobin. "We are urgently calling on defibrillator device owners to now check if they have an affected AED and where necessary to contact the manufacturer or supplier immediately to ensure the correction required for their defibrillator is carried out without further delay."

The 940 AEDs where corrective actions are needed to ensure they work effectively are:

AED Name	**Manufacturer**
Lifepak CR Plus	Physio Control Inc
Lifepak 1000	Physio Control Inc
AED Plus	Zoll
Samaritan PAD, 300, 300P	HeartSine
Samaritan 500P	HeartSine

"Even if an AED has received all the updates required, all owners should remember that as we enter the winter months it is critical they store their AEDs appropriately. Defibrillators and their accessories can be badly affected by the weather and other environmental conditions. The user manual supplied with an AED provides detailed information from the manufacturer about its use and maintenance and the HPRA's own advice leaflet highlights key issues around the purchase, care and use of AEDs. We urge people to read these and act upon the advice provided," she concludes.

The HPRA's guidance on AEDs includes:

- CE Mark – All medical devices including defibrillators must carry a CE mark which ensures that when used and stored properly, the device should work as intended and be safe.
- Review the product manual for the device and its accessories to identify the conditions that could affect its performance, such as:
    - Storage temperature;
    - Exposure to moisture and damp (environmental humidity).
- A copy of the manual should be stored with the defibrillator and be accessible AT ALL TIMES.
- 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.
- A defibrillator may need to be updated or changed during its time in use. For example, it may require new software.
- Regular servicing and maintenance is essential and must be carried out in accordance with the guidance given by the manufacturer.

The HPRA has a section on its website outlining the implicated AEDs that need corrective action. It has also published an advice leaflet on AEDs.

ENDS

FOR FURTHER INFORMATION

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ABOUT THE HEALTH PRODUCTS REGULATORY AUTHORITY

The Health Products Regulatory Authority (HPRA) protects and enhances public health and animal health by regulating medicines, medical devices and other health products. The products under its remit include human and veterinary medicines, medical devices, blood and blood components, tissues and cells, organs for transplantation and cosmetics.