750 DEFIBS NEED URGENT UPDATES

The Health Products Regulatory Authority claims that up to 750 automated external defibrillators in Ireland require urgent safety and maintenance updates, such as software upgrades or the replacement of an AED component.

As a result of ongoing post-market surveillance of the manufacturers, it has been deemed necessary by the Health Products Regulatory Authority (HPRA) to update this number of automated external defibrillators (AEDs).

These updates are needed immediately to ensure that the devices will work as necessary in a life-saving situation. If the AEDs are not appropriately updated, the devices across the seven affected models may not work as required in the event of an emergency.

Formerly the Irish Medicines Board (IMB), the HPRA is calling on all organisations in possession of an AED to check that their device is not one of the models affected by these outstanding actions.

The HPRA has a dedicated section on its website detailing the implicated AEDs that need corrective action. This information contains links to the manufacturers communications (titled Field Safety Notices) detailing the updates for the above models and manufacturers contact details.

The HPRA has also published its own safety notices in relation to various AEDs, links to which are on the AED webpage. It also has an advice leaflet on AEDs available to download online with printed copies also available to order.

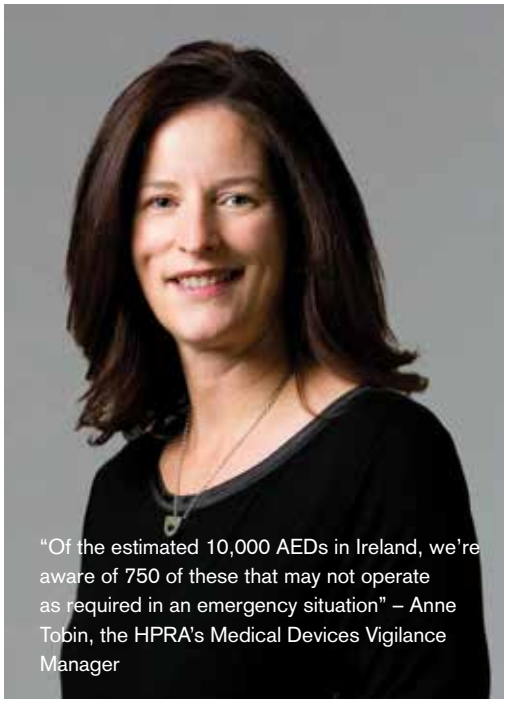
It is estimated that 70 percent of all cardiac arrests occur outside of the healthcare environment, where the correct operation of an AED may be a life-saving intervention. In addition to the updates, the HPRA is highlighting that all AED owners should ensure that their devices are stored correctly and regularly checked during the winter months.

Anne Tobin, the HPRA's Medical Devices Vigilance Manager said, "Of the estimated 10,000 AEDs in Ireland, we are aware of approximately 750 of these that may not operate as required in an emergency situation.

"We know that each of the AED manufacturers concerned are contacting the owners directly to gain access to the devices to ensure that the updates are completed. We are urgently calling on all device owners to check if they have one of the affected AEDs and, where necessary, to contact their manufacturer or supplier immediately to ensure the correction required is carried out without further delay."

Another key aspect to ensuring that these devices operate when required is good storage and maintenance according to the manufacturer's instructions.

Even if an AED has received all of the updates required, she said it's critical for owners to remember it's critical that AEDs are stored appropriately, during the winter months. "Defibrillators and their accessories can be badly affected by the weather and other environmental conditions," added Tobin.



"Of the estimated 10,000 AEDs in Ireland, we're aware of 750 of these that may not operate as required in an emergency situation" – Anne Tobin, the HPRA's Medical Devices Vigilance Manager

In recent years, defibs have become easier to use, automatic, portable and affordable, which has resulted in a significant increase in the number of AEDs in Ireland. Many Irish sporting venues, schools, hotels, restaurants, businesses and shopping centres now have the cardiac devices on their premises in case of emergencies.

All organisations with an AED on their premises should provide the manufacturer of their device with their correct contact details to ensure that the manufacturer can inform them of the need for safety upgrades if required.

In terms of the HPRA's guidance on AEDs, all medical devices including defibrillators must carry a CE mark to ensure the device should safely work as intended. It also recommends reviewing the product manual for the device and its accessories to identify conditions that could affect its performance.

AEDs models that require corrective actions:

AED NAME:	MANUFACTURER:
AED Plus	Zoll
Samaritan 300P	Physio-Control (formerly HeartSine)
Samaritan 500P	Physio-Control (Formerly HeartSine)
Lifepak 1000	Physio-Control
Lifepak CR Plus/Lifepak Express AED	Physio-Control
Fred Easyport	Schiller AG