

# Safety Notice

## Medical Devices

### Telefunken AED Models HR1 & FA1

Priority 2 – Warning



HPRA Safety Notice: SN2019(08)

Issue Date: 04 April 2019

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Defiteq International B.V.	V27086

#### ISSUE

In June 2016, the HPRA issued Safety Notice [SN2016\(15\)](#) on Telefunken AEDs, to highlight to users that the standby time of installed battery is **3 years**. The standby time begins once the battery is placed in the AED. In addition to the battery standby time there is a battery expiration date printed on the battery pack, which users must also be aware of and follow.

The HPRA is now aware that the CE certificate for Telefunken AEDs was suspended in July 2016 and subsequently withdrawn in April 2017. Without a valid CE certificate, a manufacturer may not place on the market its devices' and associated accessories. The manufacturer Defiteq International B.V. is uncontactable and appears to have ceased trading.

**Based on our available information, the HPRA recommends owners/users of Telefunken AEDs source an alternative device.** The current market performance of the device cannot be verified and the safe use of this device can no longer be assured. Furthermore, without valid market certification replacement batteries, pads and other accessories may no longer be placed on the market and any remaining stock (placed on the market prior to July 2016) may be approaching or have reached its expiration date.

## ACTION OR RECOMMENDATIONS

The HPRA advises that users:

- 1 Replace Telefunken AEDs in your possession.
- 2 Forward a copy of this safety notice to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.
- 3 Contact the HPRA with any concerns.

## TARGET GROUPS

Members of Public Community First Responders First Aid Organisations Sport Centres Work Places/Employers Nursing Homes	Carers Volunteer Ambulance Services Gyms Schools Retailers
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## BACKGROUND

The HPRA is issuing this Safety Notice to raise awareness of this issue. The HPRA is aware that 335 Telefunken AEDs have been placed on the Irish market but does not have end user information.

## HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority	Telephone:	+353-1-6764971
Kevin O'Malley House	E-mail:	<a href="mailto:devicesafety@hpra.ie">devicesafety@hpra.ie</a>
Earlsfort Centre	Website:	<a href="http://www.hpra.ie">www.hpra.ie</a>
Earlsfort Terrace		
Dublin 2		