

# Safety Notice

## Medical Devices

### Telefunken AED Model HR1 & FA1

#### Priority 2 – Warning

HPRA Safety Notice: SN2016(15)

Issue Date: 15 June 2016

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

#### ISSUE

The Health Products Regulatory Authority (HPRA) is aware of a small number of reports of battery issues relating to these devices. The HPRA would like to remind users of the importance of AED management. The Instructions For Use states that the standby time of batteries in these devices is 3 years.

#### ACTION OR RECOMMENDATIONS

The HPRA advises the following;

All users/owners of Telefunken AEDs should:

1. Have the device Instructions for Use readily available for device management.
2. Be aware that the device instructions for use indicates a 'standby time of the batteries' which is 3 years. This time starts once the batteries are placed into the device. Please ensure that you replace your batteries if they have been on standby in the machine for 3 years or longer.
3. Please note that batteries also have an expiry date. Batteries should not be used past their expiry date regardless of their standby time in the device.

4. Familiarise themselves with the device status display. Details can be found in the Instructions for Use.
5. Report any concerns regarding these devices to the HPRA.

## TARGET GROUPS

All users and owners of Telefunken AEDs

## BACKGROUND

The HPRA has recently been informed of a small number of complaints in relation to these devices, which appear to be related to the battery. The investigations into these complaints remain ongoing. Users are advised to report any concerns they may have about these devices to the HPRA.

A defibrillator can play a potentially lifesaving role. Used correctly, it can improve a person's survival chances following sudden cardiac arrest. 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. More information is available in the HPRA's information leaflet; [Automated external defibrillators - Our advice](#). This leaflet provides advice on selecting and purchasing an AED for use in a community setting as well as recommendations for maintaining the device after it has been purchased.

We advise all users to familiarise themselves with the service and maintenance requirements of the device and ensure that they are followed as required.

## MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Defiteq International B.V.  
Mispelhoefstraat 31B  
5651  
Eindhoven  
The Netherlands

Telephone: +31 653 23 23 13  
E-mail: [g.lindhout@defiteq.com](mailto:g.lindhout@defiteq.com)  
Website: <http://defiteq.com/en>

## 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	Fax:	+353-1-6344033
Earlsfort Centre	E-mail:	<a href="mailto:devicesafety@hpra.ie">devicesafety@hpra.ie</a>
Earlsfort Terrace	Website:	<a href="http://www.hpra.ie">www.hpra.ie</a>
Dublin 2		