HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

iPAD CU-SP1, iPAD CU-SP1 AUTO AEDs

Priority 2 – Warning

HPRA Safety Notice: SN2024(02) **Issue Date: 13th May 2024**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
CU Medical Systems, Inc.	CRN00F2M5

ISSUE
This safety notice contains important information in relation to a recall of automated external defibrillators (AEDs) from the Irish market. CU Medical Systems, Inc. has identified an issue with the battery meter of the iPAD CU SP1 and the iPAD CU-SP1 AUTO defibrillators that may result in the devices having insufficient battery energy to function. This could lead to failure to resuscitate a patient. CU Medical Systems, Inc. issued a field safety notice (FSN) in February 2024 advising of the safety issue and provided a list of affected serial numbers. **Potentially affected devices are being recalled and replaced.** Users are requested to **complete CU Medical's online registration form** to facilitate replacement of affected AEDs. **Registration of your affected device(s) must be completed before the 31st of May 2024**. The HPRA continues to engage with CU Medical Systems, Inc. and distributors/resellers in Ireland to ensure adequate awareness of this issue. The HPRA is publishing this safety notice to encourage users to register any iPAD CU-SP1 or iPAD CU-SP1 AUTO defibrillators currently available for use in Ireland.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Read the accompanying FSN and identify the model name(s) and serial number(s) of all CU Medical Systems, Inc. AEDs in your possession.

2 Complete the manufacturer's registration form and register **all** iPAD CU-SP1 and iPAD CU-SP1 AUTO AEDs by visiting https://tally.so/r/w2PalD without delay. Even if the serial number(s) of your device(s) does not appear in the Appendix of the FSN, it may still be eligible for replacement.

3 Report any safety issues associated with use of these devices to the manufacturer and to the HPRA.

TARGET GROUPS

Community First Responders	AED Managers

BACKGROUND

The iPAD CU-SP1 is a semi-automated external defibrillator and the iPAD CU-SP1 AUTO is a fully automated external defibrillator. Both AEDs are intended for use on patients suspected of suffering from sudden cardiac arrest.

The root cause of this issue relates to a software issue affecting software versions V1.00 – V1.41 for iPAD CU-SP1 devices and versions V1.00 – V1.10 for iPAD CU-SP1 AUTO devices.

The manufacturer has agreed to extend the scope of the recall and replacement action to all iPAD CU-SP1 and iPAD CU-SP1 AUTO devices with the software versions listed above that were supplied to the Irish market. This includes those AEDs that previously received a software update (via the UK distributor) to correct battery meter issues.

No complaints or incidents associated with this issue have been reported from the Irish market to date.

MANUFACTURER CONTACT INFORMATION

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

CU Medical Germany GmbH
Berliner Strasse 44
10713 Berlin
Germany

Telephone: +49 30 6781 7804
E-mail: service_IE@cu-europe.com

HPRA CONTACT INFORMATION	
All **adverse incidents** relating to a medical device should be reported to:	
Health Products Regulatory Authority Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2	Telephone: +353-1-6764971 E-mail: devicesafety@hpra.ie Website: www.hpra.ie