CU Medical Systems, Inc.

Rev 1: September 2018
FSN Ref: CU-FSN-22-06-01
FSCA Ref: CU-FSCA-22-06-01
Date of initial FSN: 22.06.2022
Date of updated FSN: 25.01.2023

Update to Previous Urgent Field Safety Notice issued 22nd June 2022.

Immediate Action Required – Product Recall

iPAD CU-SP1 / CU-SP1 Auto defibrillators

Introduction:

CU Medical Systems, Inc, the manufacturer of the iPAD SP1 defibrillator, has identified an issue with some of these devices. This issue means that a select batch of iPAD SP1's should have a software update ***as soon as possible***.

What is the reason for this revised FSN?
CU medical revised the FSN to avoid any customer confusion and achieve a higher customer feedback. This document includes more details in section "3.1 Step 4" (see page 9) and this introduction provides a general overview of the situation and emphasises the need for an urgent software update for all affected devices.

What is the issue?
When the battery in the iPAD is coming towards the end of its life, the battery meter could show that the battery contains more energy in it than it really has. This means that it is possible for the defibrillator to not have enough energy in it to deliver a shock when it is used.

What is the expected life of a battery?
A new battery is expected to last for five years from when it is inserted into the device. This is only if the device is left on standby and not used, and if frequent manual self-tests are not carried out. Using the device and carrying out manual self-tests will reduce the battery life to less than five years. If a device has a history of being used in an actual emergency it is likely that the battery energy is low. If the battery has been installed for longer than 3 – 4 years the battery energy could be low enough for the battery meter to show an inaccurate reading. For all affected devices, to ensure that the device operates correctly when needed, **you should arrange for the software update to be performed as quickly as possible** or purchase a new battery until such time as the software update can be performed.

How do I know if my device requires the update?
To determine if your device is affected, you should do two things;

1. Check the manufacture date of your device by looking at the label on the bottom of your device.
    a. If your device was manufactured between 01/05/2013 and 31/05/2018 it could be affected
2. Check what software version is installed on your device.
    a. To do this, press and hold the 'i' button for 2 seconds
    b. A voice prompt will tell you what the software version is. The software version is the first three digits of the nine digit number that is given.
    For example, if the device says "software version **1 4 0** 1 0 0 1 0 0", the software version is 1.40
    c. If your device has the following software versions, it requires an update:

    Semi-Automatic Devices (devices with an orange 'shock' button)
    Software versions 1.00 – 1.41 (and every version in between)

Fully-Automatic Devices (devices without an orange 'shock' button)
Software versions 1.00 – 1.10

How do I arrange for my device to have the update?

For the users in the UK
Please visit this website: https://www.upgrademydefib.co.uk/
You will be able to select a convenient date for your iPAD SP1 to be collected from you and to have the update applied.

For the users in Hungary or Ukraine
Please send an email to service@cu-europe.com

What should I do until my device has been updated?
It is important that you arrange to have your device updated as soon as possible. Until that time, please perform a manual self-test by removing and reinserting the battery. The device will ask you to press one or more buttons after you have reinserted the battery to complete the test. If the device passes the test, it will be able to operate for a minimum of 30 minutes and deliver a minimum of 10 shocks within the following 24 hours if required to do so. Please note however that the test result may change after 24 hours. If the device does not pass the test, you should *remove it from service until the update has been performed*. In this case it is likely that you will also need a new battery since the test failure suggest that the battery level is very low.

The following part of this document gives more detailed information about this issue.

For Attention of:

Persons responsible for / owners of defibrillators, manufactured by CU Medical Systems Inc. and distributed in **the UK** are requested to read this notice and visit the website detailed on page 4, to confirm this notice has been read and understood as soon as possible.

Persons responsible for / owners of defibrillators, manufactured by CU Medical Systems Inc. and distributed in **Hungary and Ukraine** are requested to read this notice and contact Manufacturer's Branch - CU Medical Germany GmbH, to confirm this notice has been read and understood as soon as possible.

Products Affected

Product Description	Model Number	UDI	Software versions in use in affected units
iPAD semi-automated external defibrillator	CU-SP1	0880943548100	V1.00 to V1.41
iPAD fully automated external defibrillator	CU-SP1 AUTO	0880943548048	V1.00 to V1.10

Explanation

iPAD CU-SP1 and CU-SP1 AUTO defibrillator units that possess BOTH the following conditions:

- are installed with software versions **V1.41 or lower** for CU-SP1, and **V1.10 or lower** for CU-SP1 AUTO device
  AND
- are set to either an English (British), Hungarian or Ukrainian language pack

have been identified as having a software issue that:

- overstates the battery status as 'full' - **although the battery energy condition is 'low'. '**Low' refers to the battery status in which the device is unable to operate.
- can cause the reported battery charge status to drop from 'full' to 'low' when the unit is switched on

Therefore, as affected units report a higher battery charge status than the actual battery energy condition, this means a unit is not ready to operate as intended when required in a patient resuscitation situation. If the energy condition is low, alternative CPR must be performed.

The issue can be resolved through application of a software update on behalf of the manufacturer.

Advice on actions to be taken

Persons responsible for / owners of defibrillators are required to identify and report affected units. Please therefore:

1. Determine the current software version installed by interrogating the unit. Please see

instructions on how to identify the software version later in this FSN.

2. Report affected units by visiting the website: http://www.ipad-aed.com/softwareupgrade, or contacting Manufacturer's Branch – CU Medical Germany GmbH, by 31st March 2023. Doing this means that you have read and understood this Field Safety Notice. If in doubt as to whether a unit is affected, please visit the website and report or contact Manufacturer's Branch – CU Medical Germany GmbH and report.

Further information and updates concerning this issue and the product recall are published on this website.

Any information you provide will only be used as part of this FSN and to facilitate any action required to upgrade your device with the latest software.

We apologise for any inconvenience caused by this issue.

Yours Sincerely,

CU Medical Systems, Inc.

Contact details of local representatives

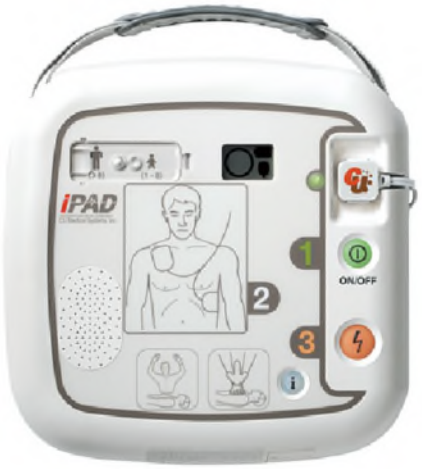
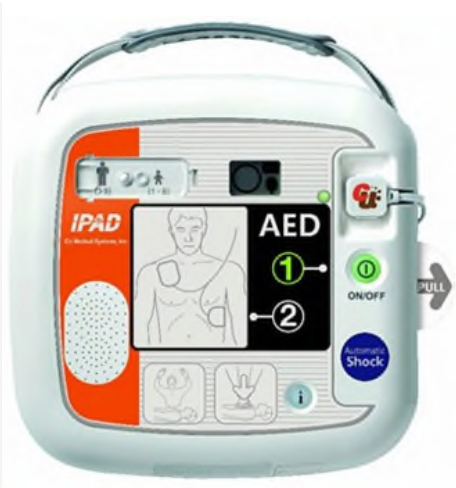
Corrective Action Hotline (UK Only):
Email: helpdesk@cumedical.services
Phone: +44 (0) 3330115704

Manufacturer's Branch: CU Medical Germany GmbH
E-mail: service@cu-europe.com
Address: Berliner Straße 44, 10713 Berlin Germany
Phone : +49 30 6781 7804
Fax : +49 30 6782 0901

UK Distributor: WEL Medical Ltd.
E-mail: recall@welmedical.com
Address: 1 Chancerygate Way, GU14 8FF Farnborough, United Kingdom
Phone: +44 (0) 1252 344007

Urgent Field Safety Notice (FSN)
iPAD CU-SP1 / CU-SP1 Auto defibrillators

Some CU-SP1, CU-SP1 AUTO defibrillators overstate the battery status as 'full' even when the battery energy condition is 'low'.

Information on Affected Devices	
1	**1. Device Types and Models**
	The CU-SP1 series is semi-automated external defibrillators (AED) and the CU-SP1 AUTO is a fully automated external defibrillator (AED). If connected to a patient, it automatically acquires and analyses the electrocardiogram (ECG) of the patient for the presence of Ventricular Fibrillation or Ventricular Tachycardia (also known as shockable rhythms).  Model Number: CU-SP1  Model Number: CU-SP1 AUTO
1	**2. Commercial name** IPAD
1	**3. Unique Device Identifier(s) (UDI)** **CU-SP1** 0880943548100 **CU-SP1 AUTO** 0880943548048
1	**4. Primary clinical purpose of devices** The CU-SP1 and CU-SP1 AUTO are to be used on patients that are suspected of suffering from sudden cardiac arrest with all of the following signs: a) No movement and no response when shaken b) No normal breathing

1	**5. Affected Software Version range**
	V1.00 – V1.41 for CU-SP1, and V1.00 – V1.10 for CU-SP1 AUTO (please note – CU-SP1 units with V1.42 or higher and CU-SP1 AUTO units with V1.11 or higher are not affected by the issue)
1	**6. Affected serial or lot number range**
	Devices using software versions as above **AND** set to English (British) or Hungarian or Ukrainian language packs. **Date of manufacture:** Potentially affected devices were manufactured between 01.05.2013 – 31.05.2018

Reason for Field Safety Corrective Action (FSCA)	
2	**1. Description of the product problem**
	The following issue has been reported in the UK to CU Medical Systems, Inc. due to abnormal operation in use. • A unit's battery meter reported battery status as fully charged • when the device was turned on, the battery meter then reported low battery status and the battery energy condition was also found to be low The problem has been identified as a software issue affecting CU-SP1 units operating with software version **V1.41 or lower** (software version V1.10 or lower for CU-SP1 AUTO) and have either English (British) or Hungarian or Ukrainian language pack set.
2	**2. Hazard giving rise to the FSCA**
	The battery meter displays full status, despite the real energy level of the battery being low. The device does not operate in this case.
2	**3. Probability of problem arising**
	We confirmed that this issue can only occur if the following conditions are met. 1. The remaining power of the battery is low. 2. The battery was not replaced after the battery alarm was triggered for the first time when the battery initially reached the 'low power' threshold.
2	**4. Predicted risk to patient/users**
	In the worst-case scenario, there is a risk that unit will be found to have insufficient battery energy to function, which consequently leads to an unsuccessful resuscitation of the patient, if no replacement defibrillator is available to be used.

2

5. Background on Issue

Abnormal device behaviour

Unexpected behaviour of some units, either during operation or in standby mode, has been reported to CU Medical.

- The battery status meter was displayed as 'full' but when the device was turned on, the battery meter immediately changed from 'full' to 'low'
- When the battery reached 'low', the issue described above could occur during all operations of the device, including self-tests.

Root cause

Root cause analysis has determined that this is a software issue confined to affecting software versions V1.00 - V1.41 for CU-SP1 and V1.00 - V1.10 for CU-SP1 AUTO, resulting from an overlap in the variable memory area. After the battery level was determined, the variable memory area was overlapped while loading an English (British) or Hungarian or Ukrainian language pack table. Due to this reason resulting in the battery status meter is displayed as 'full'.

Actions that prevent this from happening in future

Re-verification for all languages currently applied has confirmed that this issue only occurs in units set to English (British), Hungarian, or Ukrainian language packs.

We have confirmed during the debugging that this issue does not occur until the battery energy condition is low. It has also been confirmed that this problem does not occur if the battery is replaced promptly after a low battery alarm is displayed for the first time.

To correct this issue and prevent it from happening, installation of a software update is required.

The root cause is resolved in the software update that will applied through this product recall.

2

6. Other information relevant to FSCA

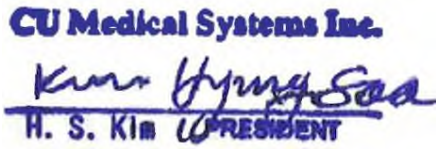
The root cause only can be eliminated by upgrading to the latest version of the software. Please visit the website below for further information or contact Manufacturer's Branch – CU Medical Germany GmbH.

http://www.ipad-aed.com/softwareupgrade

	Type of Action to mitigate the risk
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Return Device ☒ On-site device modification/inspection **Step 1 – Identify defibrillators Model CU-SP1 and CU-SP1 Auto.** The model number, the date of manufacture and the serial number are presented on the label on rear of unit.  **Step 2 – Interrogate the unit to identify the software version installed is V1.41 or earlier for CU-SP1 and V1.10 or earlier for CU-SP1 AUTO by following these** steps: One. Press i-button for 2 seconds to confirm the software version.  Two. The first 3 digits of 9 digits are the main software version. For instance, if the device utters **1 4 0** 1 0 0 1 0 0, **V1.40** is the software version. **Step 3 – If you are in the UK, please visit the website to arrange software update.** http://www.ipad-aed.com/softwareupgrade **If you are in Hungary or Ukraine, please contact Manufacturer's Branch – CU Medical Germany GmbH, to arrange software update.**

	Step 4 – Perform a self-diagnosis on the device Following the IFU, section 8.1, if the Buttons Test of the Battery Insertion Test or the Voice Prompt Test of the Battery Insertion Test fails, immediate battery replacement is required. Following the IFU, section 8.1, if the Power ON Test fails, replace the battery immediately. If the device passes the Battery Insertion Test (aka. BIT) or power-on test, the device is at least capable of handling one time of emergency operation with a guarantee of delivering 10 electric shocks and operating for 30 minutes within 24 hours. If the battery is close to be low battery, the result may change after the self-diagnostic test within 24 hours. A device that has not been upgraded should continue to be maintained. If the condition of the device is not checked regularly, it may become unusable in an emergency. Even if the device passes the BIT or power-on test, an immediate software upgrade is fundamentally required to correct the issue. For a device that has a history of use in an actual emergency or has been installed for longer than 3-4 years, it is highly likely that the battery energy is low. To ensure a safe use, please arrange a software upgrade at your earliest convenience or purchase a spare battery. Following the IFU, section 8.2, check all errors and warning messages – both any displayed symbol or vocal announcement. The main cause of errors and warning messages must be confirmed and resolved before using the device. Following the IFU 3.1 – Notice of Standard Package Contents, **an additional battery for replacement is the best way to prevent the worst case scenario.** If the device fails during an emergency, do not stop doing CPR until an alternative device is available. If you are not sure about the energy condition of your device, please contact us immediately for additional guidance.	
3.	2. By when should the action be completed?	The user should complete the action as soon as possible and no later than 3 (three) months after the FSN notification.
3.	3. Is customer Reply Required?	**YES** If you are in the UK, please visit the website: http://www.ipad-aed.com/softwareupgrade to register your details so that we may arrange the software upgrade. If you are in the Hungary or Ukraine, please contact Manufacturer's Branch – CU Medical Germany GmbH, to arrange software upgrade.

3.	**4. Action Being Taken by the Manufacturer** ☒ On-site device modification/inspection ☒ Software upgrade The cause of this issue has been identified and can be resolved with the software update. The manufacturer will install updated software on all affected devices. This software update will be performed by experienced engineers who have been trained by the manufacturer. All costs will be covered by the manufacturer. Dedicated E-Mail and telephone support will be available for immediate response to customer enquiries.	
3	5. By when should the action be completed?	By May 2023

	4. General Information*	
4.	1. FSN Type*	Follow-up
4.	2. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	3. Manufacturer information (For contact details of local representative refer to page 2 of this FSN)	
	a. Company Name	CU Medical Systems, Inc.
	b. Address	130-1, Donghwagongdan-ro, Munmak-eup,Wonju-si, Gangwon-do, Republic of Korea
	c. Website address	http://www.cu911.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. **YES**	
4.	5. List of attachments/appendices:	None
4.	6. Name/Signature	Kim, Hyung Soo Chief Executive Officer
		

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. *