

Urgent Field Safety Notice (FSN)

CU-SP1, CU-SP1 AUTO

Battery Meter Issue

For Attention of:

Distributors, resellers, and owners of a defibrillator manufactured by CU Medical Systems, Inc. located in the Republic of Ireland should read this field safety notice and check whether your device is one of the affected one with the attached serial number list on Appendix to take a necessary measure.

Contact details (name, e-mail, telephone, address etc.)
Corrective Action Hotline: Email: helpdesk@cumedical.services Phone 1: +44 (0) 333 011 5704 Phone 2: +44 (0) 1252 961 513
Branch: CU Medical Germany GmbH Address: Berliner Straße 44, 10713 Berlin Germany Phone: +49 30 6781 7804 Fax: +49 30 6782 0901 E-mail: service@cu-europe.com

Dear Valued Customer,

It has been found that some devices which have been sold in the Republic of Ireland show a symptom which needs correction. Therefore, CU Medical Systems has decided to initiate this corrective action by replacing the affected devices in Ireland to streamline the process and mitigate the risk as quickly as possible.

There was an issue with the battery meter on a specific batch of the CU-SP1 AED (Automated External Defibrillator) that may cause the battery level indicator to show a lower value than the true value. This notice is intended to inform you about:

- What the problem is
- Which devices are affected
- The actions planned by CU Medical to correct the problem

We request that you read this notice carefully and then fill out the urgent field safety notification electronic response form by **29.02.2024** to acknowledge that you have read and understood the contents of this notice, and to start the process to correct affected devices via product replacement.

Persons responsible for / owners of defibrillators manufactured by CU Medical Systems are required to identify and report affected units. Please therefore:

1. Identify the serial number and model name of your device, which are presented on the rear of the unit.
2. Check whether the serial number of your device is found in the serial number list on Appendix.
3. If your device is one of the affected units, fill an electronic form via <https://tally.so/r/w2PaID> no later than **29.02.2024** to confirm that you have read this field safety notice and understood its details. Based on the information provided in the form, we will respond to individuals as necessary.

CU Medical Systems Inc. apologises for any inconveniences caused by this problem.

Rev : Jan 2024
FSN Ref: CU-FSN-24-01-01
Yours Faithfully,

FSCA Ref: CU-FSCA-24-01-01

CU Medical Systems, Inc.

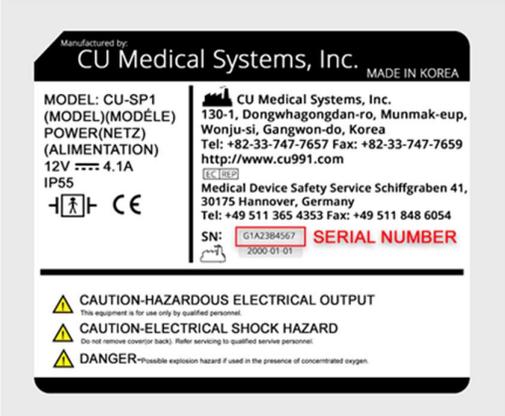
Urgent Field Safety Notice (FSN)

CU-SP1, CU-SP1 AUTO
 Battery Meter Issue

1. Information on Affected Devices*	
1	<p>1. Device Type(s)*</p> <p>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).</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p><CU-SP1></p> </div> <div style="text-align: center;">  <p><CU-SP1 AUTO></p> </div> </div>
1	<p>2. Commercial name(s)</p> <div style="text-align: center;">  </div>
1	<p>3. Unique Device Identifier(s) (UDI-DI)</p> <p>CU-SP1: 0880943548100 CU-SP1 AUTO: 0880943548048</p>
1	<p>4. Primary clinical purpose of device(s)*</p> <p>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:</p> <ul style="list-style-type: none"> a) No movement and no response when shaken b) No normal breathing
1	<p>5. Device Model/Catalogue/part number(s)*</p> <p>CU-SP1, CU-SP1 AUTO</p>
1	<p>6. Software version</p> <p>The software versions CU-SP1: V1.00-V1.41 and CU-SP1 AUTO: V1.00-V1.10 Language: British English, Hungarian, Ukrainian</p>
1	<p>7. Affected serial number</p> <p>Please refer to the serial number list on Appendix.</p>

2 Reason for Field Safety Corrective Action (FSCA)*	
2	<p>1. Description of the product problem*</p> <p>The following issue has been reported in the UK to CU Medical Systems, Inc. due to abnormal operation in use.</p> <ul style="list-style-type: none"> • 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 <p>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.</p>
2	<p>2. Hazard giving rise to the FSCA*</p> <p>The battery meter might display a lower battery level than the actual power contained in the battery. The lack of actual battery power might lead to a situation where the device becomes unable to analyse electrocardiogram of the patient.</p>
2	<p>3. Probability of problem arising</p> <p>It has been confirmed that this issue can only occur if the following conditions are met.</p> <ol style="list-style-type: none"> 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	<p>4. Predicted risk to patient/users</p> <p>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.</p>
	<p>5. Background on Issue</p> <p>Abnormal device behaviour</p> <p>Unexpected behaviour of some units, either during operation or in standby mode, has been reported to CU Medical.</p> <ul style="list-style-type: none"> • 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. <p>Root cause</p> <p>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'.</p> <p>Actions that prevent this from happening in future</p> <p>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.</p> <p>It has been confirmed during the debugging that this issue does not occur until the</p>

	<p>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.</p> <p>To correct this issue and prevent it from happening under the current circumstances, product replacement is ideal.</p>
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Type of Action to mitigate the risk*			
3.	<p>1. Action To Be Taken by the User*</p> <p style="text-align: center;"> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Return Device </p> <p>Step 1 – Identify the serial number and model name.</p> <p>The model name, date of manufacture and serial number are presented on the label attached on rear of the unit. Use this device information to fill the form.</p> <div style="text-align: center;">  </div> <p>Step 2 – Find the serial number in the serial number list on Appendix to see if your device is one of the affected units.</p> <p>Step 3 – Fill the electronic form by visiting https://tally.so/r/w2PaID to register your device.</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">2. By when should the action be completed?</td> <td>The user should complete the action no later than 2 months after the FSN notification.</td> </tr> </table>	2. By when should the action be completed?	The user should complete the action no later than 2 months after the FSN notification.
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3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">3. Is customer Reply Required? *</td> <td>Yes. If you are in the Republic of Ireland, please visit the website: https://tally.so/r/w2PaID to register your details so that we may arrange collecting your device and send the replacement unit.</td> </tr> </table>	3. Is customer Reply Required? *	Yes. If you are in the Republic of Ireland, please visit the website: https://tally.so/r/w2PaID to register your details so that we may arrange collecting your device and send the replacement unit.
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3.	<p>4. Action Being Taken by the Manufacturer</p> <p style="text-align: center;"><input checked="" type="checkbox"/> Other – Product Replacement</p> <p>The cause of the software error has been identified and a fix will be made available via product replacement. This product replacement will be done by CU Medical Germany GmbH in Berlin at no cost to the customer.</p>		
3	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">5. By when should the action be completed?</td> <td>By March 2024</td> </tr> </table>	5. By when should the action be completed?	By March 2024
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General Information*	
4.	1. FSN Type* New
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 1 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: Appendix – Serial Number List
4.	6. Name/Signature Kim, Hyung Soo Chief Executive Officer

Transmission of this Field Safety Notice	
	<p>to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.</p>

Appendix – Serial Number List

G1J48E0330	G1N05D0019	G1N09F0330	G1O11F0188	G1O34R0184	G1O49C013
G1J48E0369	G1N05D0022	G1N09F0350	G1O11F0189	G1O34R0187	G1O49C098
G1J48E0468	G1N05D0023	G1N09F0351	G1O11F0192	G1O34R0189	G1O49C114
G1J48E0627	G1N05D0031	G1N09F0356	G1O11F0193	G1O34R0209	G1O49C137
G1J48E0788	G1N05D0032	G1N09F0358	G1O11F0256	G1O34R0226	G1O49C208
G1J48E1433	G1N05D0042	G1N09F0364	G1O11F0284	G1O34R0230	G1O49C234
G1K33B0103	G1N05D0048	G1N20Y0242	G1O11F0298	G1O34R0242	G1O49C254
G1K33B0108	G1N05D0057	G1N40B0255	G1O11F0299	G1O34R0243	G1O49C257
G1L16D0357	G1N05D0085	G1N40B0281	G1O11F0366	G1O34R0248	G1O49C384
G1L25H0232	G1N05D0086	G1N40B0302	G1O11F0369	G1O34R0304	G1O52D005
G1L25H0278	G1N05D0088	G1N40B0312	G1O11F0380	G1O34R0325	G1O52D063
G1L25H0302	G1N05D0098	G1N40B0417	G1O11F0385	G1O34R0360	G1O52D108
G1L25H0316	G1N05D0130	G1N40B0424	G1O11F0395	G1O34R0377	G1O52D123
G1L25H0323	G1N05D0135	G1N43C0071	G1O11F0401	G1O34R0378	G1O52D133
G1L25H0342	G1N05D0146	G1N43C0075	G1O11F0417	G1O34R0381	G1O52D135
G1L42N0422	G1N05D0164	G1N43C0108	G1O11F0419	G1O34R0388	G1P06C068
G1L46R0169	G1N05D0167	G1N44D0359	G1O11F0425	G1O34R0392	G1P06C472
G1L46R0183	G1N05D0177	G1N45E0011	G1O11F0434	G1O34R0393	G1P07D139
G1L46R0448	G1N05D0199	G1N45E0105	G1O11F0438	G1O34R0421	G1P14I459
G1M02A0423	G1N05D0200	G1N45E0155	G1O11F0443	G1O42V0255	G1P15J060
G1M02A0426	G1N05D0202	G1N45E0163	G1O11F0460	G1O42V0280	G1P15J191
G1M02A0452	G1N05D0205	G1N45E0223	G1O11F0482	G1O42V0283	G1P17K395
G1M19J0262	G1N05D0222	G1N45E0231	G1O11F0491	G1O42V0284	G1P19L121
G1M19K0101	G1N05D0223	G1N45E0246	G1O11F0495	G1O42V0285	G1P19L446
G1M29Q0374	G1N05D0224	G1N45E0288	G1O11F0496	G1O42V0288	G1P21M006
G1M33R0021	G1N05D0304	G1N45E0302	G1O14G0499	G1O42V0313	G1P21M021
G1M33R0291	G1N05D0316	G1N45E0306	G1O18I0088	G1O42V0316	G1P21M031
G1M33S0002	G1N05D0355	G1N45E0313	G1O18K0396	G1O42V0387	G1P21M085
G1M33S0003	G1N05D0389	G1N45E0321	G1O22L0135	G1O42V0414	G1P25O056
G1M33S0015	G1N09E0023	G1N45E0327	G1O22L0486	G1O42V0415	G1P25O077
G1M33S0044	G1N09E0071	G1N45E0346	G1O26N0210	G1O42V0453	G1P25O079
G1M33S0046	G1N09F0046	G1N45E0358	G1O26N0216	G1O42V0456	G1P25O205
G1M33S0082	G1N09F0048	G1N45E0362	G1O29Q0254	G1O42V0457	G1P25O301
G1M33S0092	G1N09F0055	G1N45E0375	G1O29Q0260	G1O42V0458	G1P25O305
G1M33S0099	G1N09F0056	G1N45E0395	G1O29Q0262	G1O42V0480	G1P25O339
G1M33S0153	G1N09F0059	G1N45E0418	G1O29Q0263	G1O43W0006	G1P25O342
G1M33S0160	G1N09F0062	G1N45E0476	G1O29Q0264	G1O43W0045	G1P25O343
G1M33S0162	G1N09F0078	G1N45E0483	G1O29Q0273	G1O43W0077	G1P25O345
G1M33S0167	G1N09F0079	G1N46F0417	G1O29Q0280	G1O43W0078	G1P25O346
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G1M33S0315	G1N09F0209	G1O11F0027	G1O29Q0492	G1O43W0100	G1P25O398
G1M33S0323	G1N09F0210	G1O11F0036	G1O34R0003	G1O43W0101	G1P25O399
G1M33S0346	G1N09F0211	G1O11F0037	G1O34R0004	G1O43W0102	G1P25O400
G1M33S0349	G1N09F0212	G1O11F0038	G1O34R0011	G1O43W0106	G1P25O401
G1M33S0456	G1N09F0226	G1O11F0064	G1O34R0037	G1O43W0111	G1P25O405
G1M36U0282	G1N09F0227	G1O11F0067	G1O34R0088	G1O43W0118	G1P25O406
G1M36U0366	G1N09F0253	G1O11F0073	G1O34R0116	G1O43W0119	G1P25O407
G1N05C0171	G1N09F0255	G1O11F0076	G1O34R0127	G1O43W0121	G1P25O409
G1N05C0306	G1N09F0289	G1O11F0122	G1O34R0143	G1O43W0126	G1P25O411
G1N05C0390	G1N09F0291	G1O11F0124	G1O34R0147	G1O43W0169	G1P25O412
G1N05C0394	G1N09F0305	G1O11F0145	G1O34R0148	G1O43W0388	G1P25O418
G1N05D0018	G1N09F0308	G1O11F0152	G1O34R0149	G1O49C010	G1P25O420

G1P27P171	G1P27P239	G1P50G074	G1Q18Q148	G1Q23T400	G1Q25X297
G1P27P172	G1P27P251	G1Q02C450	G1Q18Q178	G1Q23T401	G1Q25X311
G1P27P173	G1P27P257	G1Q02C483	G1Q18Q180	G1Q23T449	G1Q25X315
G1P27P176	G1P30R439	G1Q02C498	G1Q18Q211	G1Q23T451	G1Q25X317
G1P27P180	G1P34U187	G1Q03D414	G1Q18Q257	G1Q23T455	G1Q25X329
G1P27P182	G1P35V081	G1Q18P226	G1Q18Q258	G1Q23T467	G1Q25X332
G1P27P183	G1P35V212	G1Q18P258	G1Q18Q264	G1Q23T468	G1Q25X345
G1P27P184	G1P35V494	G1Q18P261	G1Q18Q268	G1Q23U055	G1Q25X351
G1P27P199	G1P35V495	G1Q18P263	G1Q18Q269	G1Q23U136	G1Q25X353
G1P27P211	G1P36W310	G1Q18P288	G1Q20R465	G1Q23U154	G1Q25X355
G1P27P219	G1P42B243	G1Q18P383	G1Q23T365	G1Q23U167	G1Q25X356
G1P27P228	G1P42C029	G1Q18P455	G1Q23T385	G1Q23U289	G1Q30C326
G1P27P231	G1P42C253	G1Q18Q013	G1Q23T386	G1Q23U331	G1Q37I414
G1P27P232	G1P42C272	G1Q18Q018	G1Q23T387	G1Q23U375	
G1P27P233	G1P42C276	G1Q18Q040	G1Q23T388	G1Q25X272	
G1P27P234	G1P50G002	G1Q18Q063	G1Q23T390	G1Q25X281	
G1P27P238	G1P50G055	G1Q18Q068	G1Q23T394	G1Q25X294	