

## **Urgent Field Safety Notice** **CU-SP1, CU-SP1 AUTO**

For Attention of: owners of defibrillator manufactured by CU Medical Systems, Inc. located in the UK

CU Medical Systems is initiating a recall because the update provided as part of a previous corrective action (MHRA Ref.: 2021/002/001/601/002 – see information in appendix II), did not satisfactorily solve the issue.

CU Medical Systems has identified 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 visit the website address below by 31st July 2022 to acknowledge that you have read and understood the contents of this notice, and to start the process to correct all affected devices via a software re-install.

Further information concerning this issue will be published on the same website as it becomes available.

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

Yours Sincerely,

CU Medical Systems, Inc.

Contact details of local representative (name, e-mail, telephone, address etc.)

**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](mailto:service@cu-europe.com)

**Distributor: WEL Medical Ltd.**

Address: 1 Chancerygate Way, GU14 8FF Farnborough, United Kingdom

Phone: +44 (0) 1252 344007

E-mail: [servicing@welmedical.com](mailto:servicing@welmedical.com)

**Corrective Action Hotline:**

Email: [helpdesk@cumedical.services](mailto:helpdesk@cumedical.services)

Phone 1: +44 (0) 3330115704

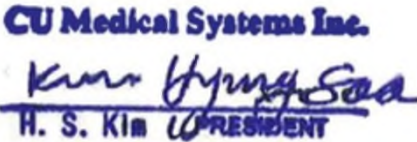
Phone 2: +44 (0) 1252 961 513

## **Urgent Field Safety Notice (FSN)** **CU-SP1, CU-SP1 AUTO**

<b>1. Information on Affected Devices*</b>	
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>&lt;CU-SP1&gt;</p> </div> <div style="text-align: center;"> <p>&lt;CU-SP1 AUTO&gt;</p> </div> </div>
1	2. Commercial name(s)
1	3. Unique Device Identifier(s) (UDI-DI)
.	0880943548100, 0880943548048
1	4. Primary clinical purpose of device(s)*
.	<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> <p>a) No movement and no response when shaken                  b) No normal breathing</p>
1	5. Device Model/Catalogue/part number(s)*
.	CU-SP1, CU-SP1 AUTO
1	6. Software version
.	The software versions CU-SP: V1.43-V1.50 and CU-SP1 AUTO: V1.21-V1.30
1	7. Affected serial or lot number range
.	<p>Target equipment: Total of 1365 devices.</p> <p>Please refer to the serial number list on the appendix.</p>

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	<p style="text-align: center;"><b>1. Description of the product problem*</b></p> <p>Since there were a large number of devices being manufactured for the UK between January 2020 and May 2020, CU Medical created a separate production line within the factory to help with production efficiency. In February 2020, an enhanced version of the CU-SP1 software was installed (version 1.43 for CU-SP1, version 1.21 for CU-SP1 AUTO). A reference voltage is used as part of the process to determine the battery level for the battery meter. It was confirmed that an error was made whilst inputting this voltage.</p> <p>When the update process is carried out in the factory, equipment is used that measures the reference value of the battery voltage and then compensates for it to ensure that the battery meter reads the correct level. Due to being unable to send an engineer and this equipment from Korea during the travel restrictions of Covid-19, CU Medical used software (from version 1.43 to version 1.50 for CU-SP1, from version 1.21 to version 1.30 for CU-SP1 AUTO) that automatically calibrates and compensates for the reference value of the battery voltage. It has subsequently been determined that this was not effective and the same symptom reoccurred.</p>
2	<p style="text-align: center;"><b>2. Hazard giving rise to the FSCA*</b></p> <p>The battery meter might display a lower battery level than the actual power contained in the battery, and this might lead to confusion.</p>
2	<p style="text-align: center;"><b>3. Probability of problem arising</b></p> <p>8 cases out of 1365 units were reported (0.58%). These 8 cases did not lead to any patient deceased incident. No rescue failure case was reported. However, all units might lead to users' confusion.</p>
2	<p style="text-align: center;"><b>4. Predicted risk to patient/users</b></p> <p>The risk to patients is mitigated since the battery meter displays less power than is actually contained in the battery. Even if the battery meter shows one bar flashing (low battery) there is 15% of the battery left, which will allow the device to deliver at least 10 therapeutic shocks and operate for at least 10 minutes. In addition, the daily self-tests are independent of the battery meter and will alarm the user if the battery level is too low to operate the device.</p>

<b>3. Type of Action to mitigate the risk*</b>			
<b>3.</b>	<p><b>1. Action To Be Taken by the User*</b></p> <p> <input checked="" type="checkbox"/> Identify Device              <input type="checkbox"/> Quarantine Device              <input checked="" type="checkbox"/> Return Device              <input type="checkbox"/> Destroy Device   <input type="checkbox"/> On-site device modification/inspection   <input type="checkbox"/> Follow patient management recommendations   <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)   <input type="checkbox"/> Other                      <input type="checkbox"/> None         </p> <p>Because the device will continue to operate as expected, no actions are required for the device other than arranging for the software update. The battery meter may show that it has less energy remaining in the battery than the actual energy in the battery. If you have one of the affected devices and the battery meter shows that there is little or no energy remaining in the battery, the battery should still be replaced as per the normal operating instructions.</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 30%;">2. By when should the action be completed?</td> <td>The user should complete the action no later than 2 months after he has been notified.</td> </tr> </table>	2. By when should the action be completed?	The user should complete the action no later than 2 months after he has been notified.
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3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 45%;">3. Is customer Reply Required? *</td> <td>Yes. Please visit the website (<a href="http://www.ipad-aed.com/safetynotice">www.ipad-aed.com/safetynotice</a>) to register your details so that we may arrange the software re-install.</td> </tr> </table>	3. Is customer Reply Required? *	Yes. Please visit the website ( <a href="http://www.ipad-aed.com/safetynotice">www.ipad-aed.com/safetynotice</a> ) to register your details so that we may arrange the software re-install.
3. Is customer Reply Required? *	Yes. Please visit the website ( <a href="http://www.ipad-aed.com/safetynotice">www.ipad-aed.com/safetynotice</a> ) to register your details so that we may arrange the software re-install.		
<b>3.</b>	<p><b>4. Action Being Taken by the Manufacturer</b></p> <p> <input type="checkbox"/> Product Removal                      <input checked="" type="checkbox"/> On-site device modification/inspection  <input checked="" type="checkbox"/> Software upgrade                      <input type="checkbox"/> IFU or labelling change  <input type="checkbox"/> Other    <input type="checkbox"/> None         </p> <p>The cause of the software error has been identified and a fix will be made available via a re-install. This software re-install will be done by a trained engineer with the correct equipment at no cost to the customer. We are going to install V1.51 for CU-SP1 and V1.31 for CU-SP1 AUTO.</p>		
3	<table border="1" style="width: 100%;"> <tr> <td style="width: 30%;">5. By when should the action be completed?</td> <td>By December 2022</td> </tr> </table>	5. By when should the action be completed?	By December 2022
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4. 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.
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>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)</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>

Please visit [www.ipad-aed.com/safetynotice](http://www.ipad-aed.com/safetynotice)

**Appendix I** – Serial Number List

**Appendix II** – Previous Corrective Action (MHRA Ref.: 2021/002/001/601/002)

G1J35A120	G1P19L208	G1Q02C259	G1R08E383	G1R29R427	G1R30S081	G1R30S178	G1R30S257
G1L4200464	G1P19L209	G1Q02C342	G1R14H278	G1R29R428	G1R30S082	G1R30S180	G1R30S258
G1L46R0410	G1P21M001	G1Q02C384	G1R14H475	G1R29R429	G1R30S087	G1R30S181	G1R30S259
G1M02A0309	G1P21M002	G1Q02C392	G1R14I217	G1R29R430	G1R30S088	G1R30S183	G1R30S261
G1M10F0115	G1P21M007	G1Q02C423	G1R25N246	G1R29R431	G1R30S090	G1R30S184	G1R30S262
G1M10F0148	G1P21M008	G1Q02C487	G1R25N492	G1R29R432	G1R30S091	G1R30S185	G1R30S265
G1M10F0151	G1P21M012	G1Q02C497	G1R25W360	G1R29R433	G1R30S092	G1R30S190	G1R30S268
G1M10F220	G1P21M055	G1Q03D176	G1R270136	G1R29R434	G1R30S093	G1R30S191	G1R30S269
G1M10G0248	G1P21M056	G1Q03D232	G1R29R297	G1R29R438	G1R30S094	G1R30S192	G1R30S270
G1M33R0220	G1P21M058	G1Q03D239	G1R29R316	G1R29R439	G1R30S096	G1R30S193	G1R30S273
G1M36T0139	G1P21M082	G1Q03D296	G1R29R318	G1R29R440	G1R30S100	G1R30S195	G1R30S277
G1M44A0457	G1P21M093	G1Q03D379	G1R29R319	G1R29R442	G1R30S101	G1R30S196	G1R30S280
G1N05C0284	G1P21M124	G1Q03D388	G1R29R322	G1R29R443	G1R30S103	G1R30S200	G1R30S281
G1N05D0376	G1P21M126	G1Q03D390	G1R29R324	G1R29R449	G1R30S111	G1R30S201	G1R30S282
G1N17K0120	G1P21M239	G1Q03D397	G1R29R325	G1R29R450	G1R30S114	G1R30S203	G1R30S283
G1N20Y0189	G1P21M305	G1Q03D399	G1R29R328	G1R29R451	G1R30S117	G1R30S205	G1R30S284
G1N34U0054	G1P21M343	G1Q03D406	G1R29R332	G1R29R455	G1R30S119	G1R30S207	G1R30S285
G1N45E0007	G1P21M345	G1Q03D413	G1R29R335	G1R29R459	G1R30S120	G1R30S208	G1R30S288
G1N45E0208	G1P250012	G1Q03D416	G1R29R338	G1R29R460	G1R30S121	G1R30S209	G1R30S290
G1N46F0241	G1P250045	G1Q05E083	G1R29R339	G1R29R461	G1R30S122	G1R30S211	G1R30S291
G1N47G0110	G1P250058	G1Q05E087	G1R29R340	G1R29R462	G1R30S123	G1R30S213	G1R30S294
G1002A0317	G1P250065	G1Q05E097	G1R29R341	G1R29R463	G1R30S124	G1R30S214	G1R30S296
G1002A0327	G1P250070	G1Q05E100	G1R29R342	G1R29R468	G1R30S125	G1R30S220	G1R30S297
G1010E0399	G1P250096	G1Q05E101	G1R29R343	G1R29R475	G1R30S126	G1R30S221	G1R30S298
G101810259	G1P250099	G1Q05E103	G1R29R348	G1R29R479	G1R30S127	G1R30S222	G1R30S301
G101810278	G1P250185	G1Q05E107	G1R29R349	G1R30S003	G1R30S128	G1R30S224	G1R30S302
G1034R0212	G1P250193	G1Q05E120	G1R29R353	G1R30S004	G1R30S129	G1R30S225	G1R30S304
G1034R0312	G1P250211	G1Q05E130	G1R29R363	G1R30S006	G1R30S130	G1R30S226	G1R30S306
G1042V0298	G1P250312	G1Q05E135	G1R29R364	G1R30S007	G1R30S133	G1R30S227	G1R30S307
G1042V0356	G1P250357	G1Q05E145	G1R29R367	G1R30S008	G1R30S134	G1R30S228	G1R30S308
G1042V0375	G1P250365	G1Q05E154	G1R29R369	G1R30S013	G1R30S137	G1R30S229	G1R30S315
G1042V0378	G1P250373	G1Q05E156	G1R29R372	G1R30S019	G1R30S140	G1R30S230	G1R30S316
G1043W0137	G1P250375	G1Q05E158	G1R29R375	G1R30S021	G1R30S141	G1R30S231	G1R30S319
G1049C096	G1P250500	G1Q05E161	G1R29R377	G1R30S026	G1R30S144	G1R30S233	G1R30S320
G1049C120	G1P27P185	G1Q05E163	G1R29R380	G1R30S028	G1R30S145	G1R30S234	G1R30S322
G1P03B448	G1P27P259	G1Q18Q055	G1R29R382	G1R30S029	G1R30S146	G1R30S235	G1R30S324
G1P14I228	G1P30R500	G1Q18Q063	G1R29R385	G1R30S032	G1R30S147	G1R30S237	G1R30S330
G1P14I276	G1P34U205	G1Q18Q130	G1R29R390	G1R30S034	G1R30S150	G1R30S238	G1R30S333
G1P14I283	G1P34U379	G1Q23T462	G1R29R391	G1R30S035	G1R30S152	G1R30S239	G1R30S334
G1P14I288	G1P35V288	G1Q23T465	G1R29R405	G1R30S036	G1R30S154	G1R30S240	G1R30S335
G1P14I350	G1P35V360	G1Q23U073	G1R29R407	G1R30S037	G1R30S155	G1R30S242	G1R30S338
G1P14I353	G1P35V373	G1Q23U098	G1R29R408	G1R30S044	G1R30S156	G1R30S244	G1R30S341
G1P14I476	G1P35V488	G1Q25X279	G1R29R412	G1R30S047	G1R30S157	G1R30S245	G1R30S343
G1P14I489	G1P36W171	G1Q37G184	G1R29R413	G1R30S049	G1R30S164	G1R30S247	G1R30S344
G1P17K343	G1P36W191	G1Q37G311	G1R29R415	G1R30S050	G1R30S166	G1R30S248	G1R30S345
G1P17K363	G1P42B204	G1Q37G351	G1R29R417	G1R30S071	G1R30S169	G1R30S249	G1R30S347
G1P17K381	G1P42B337	G1Q37H174	G1R29R422	G1R30S073	G1R30S170	G1R30S250	G1R30S348
G1P17K384	G1P42B378	G1Q46M266	G1R29R423	G1R30S074	G1R30S172	G1R30S251	G1R30S349
G1P19L162	G1P42B396	G1Q46M472	G1R29R424	G1R30S078	G1R30S174	G1R30S252	G1R30S351
G1P19L168	G1P42B463	G1R03C059	G1R29R426	G1R30S079	G1R30S176	G1R30S254	G1R30S352

G1R30S353	G1R30S456	G1R30T273	G1R34V244	G1R35W067	G1R35W295	G1R35W442	G1R36A217
G1R30S356	G1R30S457	G1R30T298	G1R34V246	G1R35W068	G1R35W304	G1R35W443	G1R36A221
G1R30S357	G1R30S459	G1R30T299	G1R34V256	G1R35W069	G1R35W305	G1R35W444	G1R36A222
G1R30S358	G1R30S460	G1R30T305	G1R34V260	G1R35W071	G1R35W308	G1R35W445	G1R36A225
G1R30S360	G1R30S461	G1R30T317	G1R34V267	G1R35W072	G1R35W310	G1R35W446	G1R36A226
G1R30S363	G1R30S462	G1R30T328	G1R34V271	G1R35W119	G1R35W313	G1R35W447	G1R36A230
G1R30S364	G1R30S463	G1R30T330	G1R34V273	G1R35W120	G1R35W315	G1R35W451	G1R36A233
G1R30S366	G1R30S464	G1R30T334	G1R34V274	G1R35W121	G1R35W317	G1R35W453	G1R36A234
G1R30S368	G1R30S465	G1R30T335	G1R34V275	G1R35W122	G1R35W321	G1R35W454	G1R36A236
G1R30S369	G1R30S466	G1R30T341	G1R34V276	G1R35W124	G1R35W325	G1R35W465	G1R36A238
G1R30S377	G1R30S467	G1R30T347	G1R34V277	G1R35W126	G1R35W326	G1R35W467	G1R36A239
G1R30S378	G1R30S468	G1R30T393	G1R34V278	G1R35W127	G1R35W327	G1R35W473	G1R36I066
G1R30S379	G1R30S470	G1R30T407	G1R34V279	G1R35W128	G1R35W330	G1R35W474	G1R36I301
G1R30S380	G1R30S471	G1R30T435	G1R34V280	G1R35W129	G1R35W331	G1R35W475	G1R36W035
G1R30S381	G1R30S473	G1R30T439	G1R34V282	G1R35W130	G1R35W337	G1R35W478	G1R36W061
G1R30S382	G1R30S474	G1R30T453	G1R34V287	G1R35W132	G1R35W338	G1R35W480	G1R36W306
G1R30S384	G1R30S475	G1R30T470	G1R34V289	G1R35W134	G1R35W339	G1R35W483	G1R36W418
G1R30S387	G1R30S477	G1R32X269	G1R34V365	G1R35W135	G1R35W342	G1R35W484	G1R36W431
G1R30S391	G1R30S480	G1R34A233	G1R34W273	G1R35W141	G1R35W344	G1R35W485	G1R36W448
G1R30S392	G1R30S481	G1R34U002	G1R35W001	G1R35W142	G1R35W345	G1R35W486	G1R36X079
G1R30S394	G1R30S482	G1R34U045	G1R35W002	G1R35W149	G1R35W347	G1R35W489	G1R36X082
G1R30S401	G1R30S484	G1R34U050	G1R35W004	G1R35W150	G1R35W350	G1R35W490	G1R36X085
G1R30S405	G1R30S485	G1R34U056	G1R35W005	G1R35W151	G1R35W351	G1R35W491	G1R36X095
G1R30S407	G1R30S486	G1R34U061	G1R35W007	G1R35W153	G1R35W352	G1R35W493	G1R36X098
G1R30S408	G1R30S488	G1R34U066	G1R35W008	G1R35W154	G1R35W353	G1R35W494	G1R36X099
G1R30S411	G1R30S491	G1R34U069	G1R35W009	G1R35W156	G1R35W354	G1R35W495	G1R36X104
G1R30S412	G1R30S492	G1R34U077	G1R35W010	G1R35W159	G1R35W355	G1R35W496	G1R36X105
G1R30S413	G1R30S494	G1R34U087	G1R35W012	G1R35W160	G1R35W358	G1R35W497	G1R36X106
G1R30S414	G1R30S495	G1R34U091	G1R35W013	G1R35W162	G1R35W360	G1R35W498	G1R36X111
G1R30S415	G1R30S496	G1R34U096	G1R35W015	G1R35W163	G1R35W363	G1R35W535	G1R36X112
G1R30S416	G1R30T002	G1R34U105	G1R35W016	G1R35W167	G1R35W366	G1R35X458	G1R36X113
G1R30S417	G1R30T005	G1R34U108	G1R35W017	G1R35W175	G1R35W373	G1R36A128	G1R36X115
G1R30s418	G1R30T009	G1R34U109	G1R35W019	G1R35W188	G1R35W374	G1R36A191	G1R36X117
G1R30S420	G1R30T011	G1R34U110	G1R35W020	G1R35W191	G1R35W378	G1R36A192	G1R36X121
G1R30S421	G1R30T017	G1R34U114	G1R35W021	G1R35W198	G1R35W381	G1R36A193	G1R36X123
G1R30S426	G1R30T018	G1R34U117	G1R35W022	G1R35W200	G1R35W403	G1R36A194	G1R36X126
G1R30S428	G1R30T126	G1R34U138	G1R35W023	G1R35W203	G1R35W404	G1R36A197	G1R36X128
G1R30S429	G1R30T127	G1R34U141	G1R35W024	G1R35W207	G1R35W407	G1R36A198	G1R36X133
G1R30S431	G1R30T138	G1R34U153	G1R35W025	G1R35W209	G1R35W408	G1R36A201	G1R36X138
G1R30S432	G1R30T139	G1R34V041	G1R35W026	G1R35W214	G1R35W409	G1R36A202	G1R36X139
G1R30S434	G1R30T145	G1R34V111	G1R35W028	G1R35W219	G1R35W412	G1R36A204	G1R36X237
G1R30S436	G1R30T149	G1R34V117	G1R35W034	G1R35W225	G1R35W414	G1R36A206	G1R36X266
G1R30S438	G1R30T154	G1R34V138	G1R35W035	G1R35W247	G1R35W415	G1R36A207	G1R36X269
G1R30S443	G1R30T156	G1R34V233	G1R35W036	G1R35W248	G1R35W420	G1R36A208	G1R36X271
G1R30S444	G1R30T159	G1R34V234	G1R35W053	G1R35W252	G1R35W431	G1R36A209	G1R36X272
G1R30S447	G1R30T161	G1R34V236	G1R35W059	G1R35W257	G1R35W433	G1R36A211	G1R36X273
G1R30S448	G1R30T164	G1R34V237	G1R35W060	G1R35W258	G1R35W434	G1R36A212	G1R36X274
G1R30S453	G1R30T171	G1R34V238	G1R35W063	G1R35W273	G1R35W435	G1R36A213	G1R36X275
G1R30S454	G1R30T237	G1R34V241	G1R35W064	G1R35W278	G1R35W439	G1R36A214	G1R36X276
G1R30S455	G1R30T262	G1R34V242	G1R35W066	G1R35W291	G1R35W441	G1R36A216	G1R36X277

G1R36x279	G1R36X378	G1R36X462	G1R40C051	G1R40C406	G1R46I006	G1R46I090	G1R46I196
G1R36X280	G1R36X379	G1R36X463	G1R40C052	G1R40C407	G1R46I009	G1R46I091	G1R46I199
G1R36X281	G1R36X382	G1R36X464	G1R40C053	G1R40C408	G1R46I011	G1R46I092	G1R46I200
G1R36X282	G1R36X383	G1R36X465	G1R40C054	G1R40C412	G1R46I012	G1R46I096	G1R46I202
G1R36X285	G1R36X384	G1R36X467	G1R40C055	G1R40C414	G1R46I013	G1R46I097	G1R46I203
G1R36X287	G1R36X387	G1R36X468	G1R40C059	G1R40C415	G1R46I014	G1R46I099	G1R46I205
G1R36X289	G1R36X389	G1R36X470	G1R40C060	G1R40C416	G1R46I015	G1R46I100	G1R46I206
G1R36X290	G1R36X390	G1R36X471	G1R40C062	G1R40C417	G1R46I017	G1R46I101	G1R46I207
G1R36X291	G1R36X392	G1R36X472	G1R40C063	G1R40C425	G1R46I018	G1R46I102	G1R46I216
G1R36X292	G1R36X394	G1R36X475	G1R40C065	G1R40C429	G1R46I019	G1R46I104	G1R46I217
G1R36x293	G1R36X396	G1R36X476	G1R40C066	G1R40C432	G1R46I023	G1R46I106	G1R46I221
G1R36X296	G1R36X398	G1R36X478	G1R40C068	G1R40C435	G1R46I025	G1R46I107	G1R46I225
G1R36X297	G1R36X400	G1R39W389	G1R40C069	G1R40C436	G1R46I026	G1R46I108	G1R46I226
G1R36X298	G1R36X407	G1R39W494	G1R40C070	G1R40C437	G1R46I028	G1R46I116	G1R46I227
G1R36X299	G1R36X409	G1R40C001	G1R40C071	G1R40C440	G1R46I029	G1R46I118	G1R46I228
G1R36X301	G1R36X410	G1R40C002	G1R40C079	G1R40C441	G1R46I030	G1R46I119	G1R46I230
G1R36X305	G1R36X412	G1R40C003	G1R40C083	G1R40C443	G1R46I031	G1R46I120	G1R46I231
G1R36X309	G1R36X413	G1R40C004	G1R40C084	G1R40C447	G1R46I032	G1R46I123	G1R46I233
G1R36X312	G1R36X414	G1R40C005	G1R40C085	G1R40C449	G1R46I033	G1R46I125	G1R46I234
G1R36X314	G1R36X416	G1R40C006	G1R40C087	G1R40C452	G1R46I035	G1R46I126	G1R46I238
G1R36X328	G1R36X418	G1R40C007	G1R40C088	G1R40C454	G1R46I036	G1R46I127	G1R46I240
G1R36X329	G1R36X419	G1R40C008	G1R40C089	G1R40C460	G1R46I037	G1R46I131	G1R46I243
G1R36X330	G1R36X421	G1R40C009	G1R40C340	G1R40C465	G1R46I038	G1R46I133	G1R46I244
G1R36X331	G1R36X424	G1R40C011	G1R40C353	G1R40C467	G1R46I040	G1R46I138	G1R46I254
G1R36X334	G1R36X425	G1R40C013	G1R40C357	G1R40C468	G1R46I041	G1R46I142	G1R46I255
G1R36X336	G1R36X426	G1R40C015	G1R40C359	G1R40C469	G1R46I042	G1R46I143	G1R46I259
G1R36X340	G1R36X427	G1R40C018	G1R40C364	G1R40C470	G1R46I046	G1R46I144	G1R46I260
G1R36X341	G1R36X429	G1R40C022	G1R40C367	G1R40C473	G1R46I047	G1R46I145	G1R46I262
G1R36X342	G1R36X431	G1R40C024	G1R40C369	G1R40C476	G1R46I049	G1R46I147	G1R46I263
G1R36X344	G1R36X432	G1R40C025	G1R40C372	G1R40C477	G1R46I050	G1R46I148	G1R46I264
G1R36X348	G1R36X433	G1R40C026	G1R40C374	G1R40C478	G1R46I052	G1R46I154	G1R46I265
G1R36X349	G1R36X435	G1R40C027	G1R40C375	G1R40C481	G1R46I053	G1R46I156	G1R46I269
G1R36X351	G1R36X436	G1R40C028	G1R40C377	G1R40C482	G1R46I054	G1R46I160	G1R46I270
G1R36X352	G1R36X437	G1R40C029	G1R40C378	G1R40C483	G1R46I058	G1R46I161	G1R46I271
G1R36X354	G1R36X439	G1R40C030	G1R40C379	G1R40C484	G1R46I059	G1R46I162	G1R46I272
G1R36X355	G1R36X440	G1R40C031	G1R40C380	G1R40C486	G1R46I060	G1R46I164	G1R46I274
G1R36X356	G1R36x441	G1R40C032	G1R40C381	G1R40C487	G1R46I063	G1R46I165	G1R46I275
G1R36X357	G1R36X443	G1R40C033	G1R40C383	G1R40C489	G1R46I070	G1R46I166	G1R46I277
G1R36X358	G1R36X444	G1R40C034	G1R40C384	G1R40C490	G1R46I071	G1R46I167	G1R46I280
G1R36X360	G1R36X445	G1R40C035	G1R40C385	G1R40C493	G1R46I072	G1R46I168	G1R46I281
G1R36X361	G1R36X446	G1R40C036	G1R40C386	G1R40C494	G1R46I073	G1R46I169	G1R46I283
G1R36X362	G1R36X448	G1R40C037	G1R40C387	G1R40C495	G1R46I075	G1R46I176	G1R46I284
G1R36X363	G1R36X451	G1R40C040	G1R40C389	G1R40C496	G1R46I077	G1R46I177	G1R46I286
G1R36x364	G1R36X452	G1R40C041	G1R40C390	G1R40C497	G1R46I078	G1R46I180	G1R46I287
G1R36X365	G1R36X454	G1R40C045	G1R40C394	G1R40C498	G1R46I079	G1R46I183	G1R46I292
G1R36X370	G1R36X455	G1R40C046	G1R40C397	G1R40C499	G1R46I084	G1R46I185	G1R46I294
G1R36X371	G1R36X457	G1R40C047	G1R40C398	G1R40C500	G1R46I085	G1R46I192	G1R46I296
G1R36X375	G1R36X458	G1R40C048	G1R40C399	G1R46I001	G1R46I086	G1R46I193	G1R46I297
G1R36X376	G1R36X459	G1R40C049	G1R40C400	G1R46I002	G1R46I088	G1R46I194	G1R46I298
G1R36X377	G1R36X461	G1R40C050	G1R40C405	G1R46I004	G1R46I089	G1R46I195	G1R46I299



G1R461300	G1R49M024	G1R49M380	G1R490372
G1R461303	G1R49M029	G1R49M385	G1R490373
G1R461305	G1R49M030	G1R49M388	G1R490378
G1R461307	G1R49M075	G1R49M394	G1R490380
G1R461309	G1R49M092	G1R49M403	G1R490381
G1R461312	G1R49M093	G1R49M406	G1R490382
G1R461315	G1R49M097	G1R49M411	G1R54V237
G1R461316	G1R49M098	G1R49M412	G1R56A209
G1R461317	G1R49M099	G1R49M417	G1R56I242
G1R461318	G1R49M100	G1R49M418	G1S03D084
G1R461319	G1R49M101	G1R49M422	G1S03D096
G1R461321	G1R49M115	G1R49M425	G1S03D105
G1R461322	G1R49M138	G1R49M426	G1S03D228
G1R461323	G1R49M152	G1R49M430	G1S03D436
G1R461325	G1R49M153	G1R49M431	G1S12L445
G1R461328	G1R49M155	G1R49M433	
G1R461329	G1R49M156	G1R49M444	
G1R461330	G1R49M158	G1R49M449	
G1R461331	G1R49M159	G1R49M456	
G1R461335	G1R49M160	G1R49M460	
G1R461336	G1R49M162	G1R49M462	
G1R461337	G1R49M164	G1R49M463	
G1R461340	G1R49M165	G1R49M464	
G1R48L106	G1R49M166	G1R49M466	
G1R48L113	G1R49M167	G1R49M467	
G1R48L117	G1R49M168	G1R49M468	
G1R48L120	G1R49M188	G1R49M469	
G1R48L362	G1R49M191	G1R49M471	
G1R48L372	G1R49M195	G1R49M472	
G1R48L389	G1R49M204	G1R49M473	
G1R48L401	G1R49M210	G1R49M475	
G1R48L403	G1R49M214	G1R49M476	
G1R48L404	G1R49M231	G1R49M477	
G1R48L405	G1R49M239	G1R49M478	
G1R48L408	G1R49M248	G1R49M479	
G1R48L418	G1R49M317	G1R49M500	
G1R48L421	G1R49M323	G1R490335	
G1R48L423	G1R49M324	G1R490336	
G1R48L424	G1R49M330	G1R490338	
G1R48L455	G1R49M332	G1R490340	
G1R48L461	G1R49M334	G1R490343	
G1R48L462	G1R49M335	G1R490344	
G1R48L465	G1R49M337	G1R490345	
G1R48L470	G1R49M350	G1R490346	
G1R48L472	G1R49M356	G1R490350	
G1R48L474	G1R49M360	G1R490353	
G1R48L482	G1R49M361	G1R490362	
G1R49M006	G1R49M364	G1R490363	
G1R49M009	G1R49M369	G1R490364	
G1R49M017	G1R49M378	G1R490366	



Dear Valued Customer,

CU Medical Systems has identified an issue with the battery meter on a specific batch of the iPad SP1 AED (Automated External Defibrillator) that may cause the battery meter to display lower energy level than is actually contained in the battery. This customer information letter 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 have reviewed our records and identified that you have been provided devices which may be affected by the attached Field Safety Notice. We kindly ask that you read this notice carefully and then visit the website address below by February 28th 2021 to acknowledge that you have read and understood the contents of this notice.

We will use the information provided to contact you and arrange correction of the affected devices via a software re-install.

Further information concerning this issue will be published on the same website as it becomes available.

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

Yours Sincerely,

CU Medical Systems, Inc.

**CU Medical Systems Inc.**

*Harkrark Ra*

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H.R.Ra / PRESIDENT

28.01.2021



<p><b>Affected Products</b></p>	<p>iPAD SP1 Semi-Automatic AED &amp; iPAD SP1 Fully Automatic AED Serial numbers listed in the Appendix.</p>
<p><b>Problem Description</b></p>	<p>An error was made during manufacturing on a limited number of devices. The effect of this is that when a new battery is inserted in the device, the battery meter reads that the battery is full, however within a short period of time – from a couple of weeks to a few months - the battery level meter drops suggesting that the battery has less power in it. Tests have concluded that there is no issue with the batteries themselves, but instead the issue is with the way that the battery meter reports the energy level.</p> <p>This issue does not cause any risk that the device will not work since there is actually more power in the battery than reported, and therefore the device will operate as expected.</p>
<p><b>How to identify affected products</b></p>	<p>The affected devices were manufactured between 01/01/2020 and 31/05/2020 and were sold in the UK &amp; Ireland between approximately 01/03/2020 and 31/12/2020</p> <p>The serial number of your device can be found on the label on the bottom of the device. This serial number should be checked against the list below.</p> <div data-bbox="751 891 1139 1263" data-label="Image"> </div>
<p><b>Advice on actions by customer/user</b></p>	<p>No actions by the user are required on the device. The device will continue to operate as expected. The battery meter may show that it has less energy remaining in the battery than the actual energy in the battery. If you have one of the affected devices and the battery meter shows that there is little or no energy remaining in the battery, the battery should still be replaced as per the normal operating instructions.</p> <p>Please visit the website (<a href="http://www.ipad-aed.com/safetynotice">www.ipad-aed.com/safetynotice</a>) to register your details so that we may arrange the software re-install.</p>
<p><b>Actions planned by the manufacturer</b></p>	<p>The cause of the software error has been identified and a fix will be made available via a software re-install. This software re-install will be done by a trained engineer at no cost to the customer.</p>
<p><b>Further information and support</b></p>	<p>Please visit the website address below for the latest information or if you have any questions or queries.</p>

Please visit; [www.ipad-aed.com/safetynotice](http://www.ipad-aed.com/safetynotice)

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