





Test Report issued under the responsibility of: KBW Inc.

1106, ACE pyeongchon tower 361, Simin-daero, Dongan-gu,
Anyang-si, Gyeonggi-do, Korea

TEST REPORT IEC 60601-1 Medical electrical equipment	
Part 1: General requirements for basic safety and essential performance	
Report Reference No.....:	KBW-2017-SM-319
Date of issue	2018-03-28
Total number of pages	176 pages
Testing Laboratory	KBW Inc.
Address	1106, ACE pyeongchon tower 361, Simin-daero, Dongan-gu, Anyang-si, Gyeonggi-do, Korea
Applicant's name	CU Medical Systems, Inc.
Address	130-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Republic of Korea
Test specification:	
Standard	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	CE Marking
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_1K (KBWTF-IEC60601-1 Ed 3.1(00))
Test Report Form Originator	UL(US) (KBW Inc. modified on 2017-09)
Master TRF	2015-11
Copyright © 2015 Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE), Geneva, Switzerland. All rights reserved.	
This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.	
This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.	
General disclaimer:	
The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.	



Test item description	Cardiac Defibrillator & Monitor	
Trade Mark	LiFEGAIN	
Manufacturer	Same as applicant's name and address	
Model/Type reference.....	CU-HD1	
Ratings.....	100-240 V~, 50-60 Hz, 1.4 A (for supply mains) or 14.4 Vdc, 5.0 Ah (Internally powered)	
Testing procedure and testing location:		
<input checked="" type="checkbox"/>	Testing Laboratory:	KBW Inc.
Testing location/ address	1106, ACE pyeongchon tower 361, Simin-daero, Dongan-gu, Anyang-si, Gyeonggi-do, Korea	
Tested by (name, function, signature)	SunYeol Yang / Project Handler	
Approved by (name, function, signature) ..	JuWuk Kim / Project Reviewer	

**List of Attachments (including a total number of pages in each attachment):**

Document No.	Documents included / attached to this report (description)	Total Pages
This test report includes the following documents:		
Annex A	IEC 60601-1-6 Test Report (Ref. No. KBW-2017-SM-319_A)	24
Annex B	IEC 60601-1-8 Test Report (Ref. No. KBW-2017-SM-319_B)	28
Annex C	IEC 60601-2-4 Test Report (Ref. No. KBW-2017-SM-319_C)	54
Annex D	IEC 60601-2-27 Test Report (Ref. No. KBW-2017-SM-319_D)	51
Annex E	IEC 60601-2-49 Test Report (Ref. No. KBW-2017-SM-319_E)	16
Annex F	ISO 80601-2-55 Test Report (Ref. No. KBW-2017-SM-319_F)	40
Annex G	ISO 80601-2-61 Test Report (Ref. No. KBW-2017-SM-319_G)	39
Annex H	IEC 80601-2-30 Test Report (Ref. No. KBW-2017-SM-319_H)	31
Attachments:		
Attachment 1	Photographs	12
Attachment 2	Construction diagram	4
Attachment 3	Label Information	5
Attachment 4	Component Licenses	3
Attachment 5	Specification of Transformer	46
Attachment 6	CIE/IEC 62471 Test Report	17
Attachment 7	IEC 62133 Test Report	69
Attachment 8	IEC 60529 Test Report	10
Attachment 9	Shock and Vibration Test Report	24
Attachment 10	User Manual	209