

TEST REPORT

1. Applicant

Name

: CU Medical System, Inc

Address

: 1647-1 Donghwa-ri Munmak-eup Wonju-si Gangwon-do (Seoul 220-801 Korea)

2. Products

Name

: Primary Lithium Battery pack

Model/Type

: CUSA1103BB

Manufacturer

: Healthwell Medical, Inc.

Serial Number

: -

3. Test Standard/Method : IEC 60086-4 (Third Edition): 2007

4. Test Results : Complied

5. Use of Report : -

6. Date of Application : 2012. 10. 16.

7. Date of Issue : 2012. 12. 21.

Tested by



Approved by



Jun Hyun Jong

PARK JONGKOO

Electrics & Electronics Technology Center

Electrics & Electronics Technology Center

The test results contained apply only to the test sample(s) supplied by the applicant, and this test report shall not be reproduced in full or in part without approval of the KTL in advance.

Korea Testing Laboratory



Summary of testing:**Tests performed (name of test and test clause):**

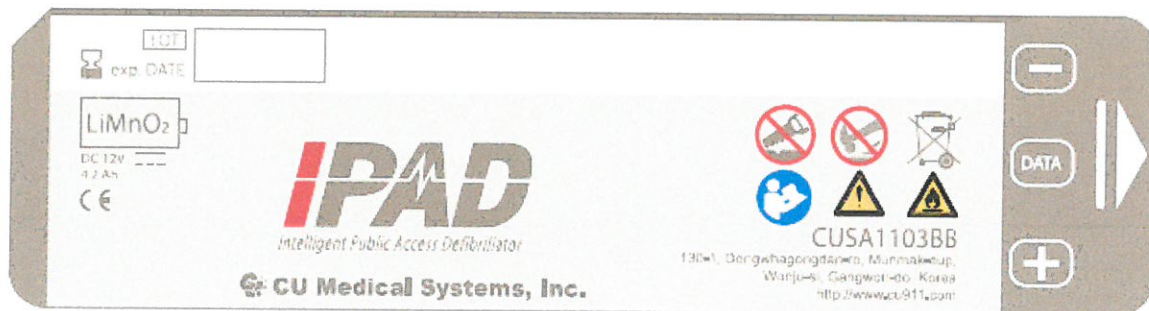
6.4.1 Test A: Altitude
 6.4.2 Test B: Thermal cycling
 6.4.3 Test C: Vibration
 6.4.4 Test D: Shock
 6.5.1 Test E: External short-circuit
 6.5.5 Test I: Abnormal charging
 6.5.6 Test J: Free fall
 6.5.7 Test K: Thermal abuse

Testing location:

KTL (Korea Testing Laboratory)
 222-13, Guro-3dong, Guro-gu, Seoul, 152-718, Korea

Summary of compliance with National Differences

- N/A

Copy of marking plate**List of Attachments**

- Remarks #1: Photographs

Test item particulars	
Classification of installation and use	N/A
Nominal Voltage	12 Vdc
Capacity	4200 mAh
Possible test case verdicts:	
- test case does not apply to the test object.....	N/A
- test object does meet the requirement	P (Pass)
- test object does not meet the requirement	F (Fail)
Testing	
Date of receipt of test item.....	2012-10-16
Date (s) of performance of tests.....	2012-10-16 to 2012-12-21
General remarks:	
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 testing laboratory. "(see Enclosure #)" refers to additional information appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report a comma / point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 6.2.5 of IEC60086-2:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided	☐ Yes ☒ Not applicable
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies): Healthwell Medical, Inc.	
130-2, Dongwhagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea	
General product information:	
1. CUSA1103BB is a primary lithium battery pack. 2. Cell connection of CUSA1103BB is 4 Serial 3 Parallel. 3. Otherwise specified, all tests have been carried out under temperature of $20 \pm 5^{\circ} \text{C}$. 4. The test samples are pre-production without serial numbers. 5. Throughout the test report, sample Numbers are designated as below. - Sample # 1-4: Undischarged - Sample # 5-13: Fully discharged	

IEC 60086-4			
Clause	Requirement + Test	Result - Remark	Verdict
4	Requirements for safety		P
4.1	Design consideration		P
	a) Abnormal temperature rise above the critical value		P
	b) Control of temperature increases in the battery		P
	c) Lithium cells and batteries shall be designed to relieve excessive internal pressure or to preclude a violent rupture under conditions of transport, intended use and reasonably foreseeable misuse.		P
4.2	Quality plan		P
	The manufacturer shall prepare a quality plan defining the procedures for the inspection of materials, components, cells and batteries during the course of manufacture, to be applied to the total process of producing a specific type of battery.		P
5	Sampling		P
5.1	General		P
5.2	Test samples	(See table 1)	P
6	Testing and requirements		P
6.1	General		P
6.1.1	Test application	(See 6.2)	P
	s: cell or single cell battery		N/A
	m: multi cell battery		P
6.1.3	Ambient temperature		P
6.1.4	Parameter measurement tolerances		P
6.1.5	Predischarge		P
6.1.6	Additional cells		N/A
6.2	Evaluation of test criteria		P
6.2.1	Short-circuit		P
6.2.2	Excessive temperature rise		P
6.2.3	Leakage		P
6.2.4	Mass loss		P
6.2.5	Venting		P
6.2.6	Fire		P
6.2.7	Rupture		P

IEC 60086-4			
Clause	Requirement + Test	Result - Remark	Verdict
6.2.8	Explosion		P
6.3	Tests and requirements – Overview	(See table 4 in the standard)	P
6.4	Tests for intended use See the standard		P
6.4.1	Test A: Altitude	(See appended Table 1 and Table 6.4.1 – 6.5.9) Mass loss(%) - Sample1: 0 - Sample2: 0 - Sample3: 0 - Sample4: 0 - Sample5: 0 - Sample6: 0 - Sample7: 0 - Sample8: 0	P
6.4.2	Test B: Thermal cycling	(See appended Table 1 and Table 6.4.1 – 6.5.9) Mass loss(%) - Sample1: 0.062 - Sample2: 0.062 - Sample3: 0.093 - Sample4: 0.062 - Sample5: 0.062 - Sample6: 0.062 - Sample7: 0.093 - Sample8: 0.093	P

IEC 60086-4			
Clause	Requirement + Test	Result - Remark	Verdict
6.4.3	Test C: Vibration	(See appended Table 1 and Table 6.4.1 – 6.5.9) Mass loss(%) - Sample1: 0 - Sample2: 0 - Sample3: 0 - Sample4: 0 - Sample5: 0 - Sample6: 0.031 - Sample7: 0 - Sample8: 0	P
6.4.4	Test D: Shock	(See appended Table 1 and Table 6.4.1 – 6.5.9) Mass loss(%) - Sample1: 0 - Sample2: 0 - Sample3: 0 - Sample4: 0 - Sample5: 0 - Sample6: 0 - Sample7: 0 - Sample8: 0	P
6.5	Tests for reasonably foreseeable misuse	(See appended Table 1 and Table 6.4.1 – 6.5.9)	P
6.5.1	Test E: External short-circuit	(See appended Table 1 and Table 6.4.1 – 6.5.9)	P
6.5.2	Test F: Impact		N/A
6.5.3	Test G: Crush		N/A
6.5.4	Test H: Forced discharge		N/A
6.5.5	Test I: Abnormal charging	(See appended Table 1 and Table 6.4.1 – 6.5.9)	P
6.5.6	Test J: Free fall	(See appended Table 1 and Table 6.4.1 – 6.5.9)	P
6.5.7	Test K: Thermal abuse	(See appended Table 1 and Table 6.4.1 – 6.5.9)	P

IEC 60086-4			
Clause	Requirement + Test	Result - Remark	Verdict
6.5.8	Test L: Incorrect installation		N/A
6.5.9	Test M: Overdischarge		N/A
6.6	Information to be given in the relevant specification		P
	a) PredischARGE current specified by the manufacturer		P
	b) Declaration whether the impact test or the crush test is more appropriate to simulate an internal short-circuit condition		N/A
	c) Maximum continuous discharge current specified by the manufacturer for test H; NOTE 1 Forced discharge of a cell can occur when it is connected in series with other cells and when it is not protected with a bypass diode. Where applicable, this should be reflected by the specification. and		N/A
	d) Abnormal charging current declared by the manufacturer for test I NOTE 2 Abnormal charging of a cell can occur when it is connected in series with other cells and one cell is reversed or when it is connected in parallel with a power supply and the protective devices do not operate correctly. Where applicable, this should be reflected by the specification.		P
7	Information for safety		P
7.1.1	Charge protection		P
7.1.2	Parallel connection		P
7.2	Safety precautions during handling of batteries		P
7.3	Packaging		P
7.4	Handling of battery cartons		P
7.5	Transport		P
7.5.1	General		P
7.5.2	Air transport	Shall be evaluated at final classification or regulation of transport.	N/A
7.5.3	Sea transport	Shall be evaluated at final classification or regulation of transport.	N/A
7.5.4	Land transport	Shall be evaluated at final classification or regulation of transport.	N/A
7.6	Display and storage		P

IEC 60086-4			
Clause	Requirement + Test	Result - Remark	Verdict
7.7	Disposal		P
8	Instructions for use		P
9	Marking		P
9.1	General		P
9.2	Small batteries		N/A

IEC 60086-4			
Clause	Requirement + Test	Result - Remark	Verdict

TABLE: Critical components information					
Object / part No.	Manufacturer/ trademark	Type / model	Technical data	Standard	Mark(s) of conformity ¹⁾
- Insulation:					
- Internal Wire	DaeYoungWire Co., Ltd.	1007	Min. V-2,	UL 758	UL
- Shrinkable Tube	DAEIL Industry Co.	PVC	0.1 mm	IEC60086-4	Tested in appliance
- Sponge Pad	Woo Sung Industry co.	SP1 (T, B, F, R)	EPDM 4 mm * 2mm * 0.3 mm	IEC60086-4	Tested in appliance
- Encapsulation:					
- Enclosure	LG chemical	AF312	ABS, V-0, 85 °C, Min thickness: 3.0 mm	UL 746	UL(E67171)
- temperature/current management devices					
- Thermal Fuse	SUNG WOO Industrial Co.	Thermal fuse / SW-102T	Functioning Trade Name : S.W.C. Type No. : SW – 102T Ratings : Rated voltage (250 V), Rated current (10 A) Rated Functions temperature (72°C)	UL60691	UL (E126429)
PCB	Various	Various	Min. V-1	UL94	UL
Cells (4 Serial 3 Parallel)	Panasonic	CR123A	Voltage : 3.0 V Capacity: 1400mAh Impedance: 1.0Ω	UL1642	UL
Supplementary information:					

IEC 60086-4					
Clause	Requirement + Test			Result - Remark	Verdict
	TABLE 1 and 6.4.1 – 6.5.9				P
Tests A-E	Cells and single cell batteries (10 samples to be tested)	Undischarged	10	-	N/A
		Fully discharged	10	-	N/A
	Multi cell batteries (4 samples to be tested)	Undischarged	4	A~D: NM, NL,NV, NC, NR, NE ,NF E: NT, NR, NE,NF	P
		Fully discharged	4	A~D: NM, NL,NV, NC, NR, NE ,NF E: NT, NR, NE,NF	P
Test F or G	Cells and single cell batteries	Undischarged	5 (Button and cylindrical)	-	N/A
		Fully discharged	10 (Prismatic)	-	N/A
	Multi cell batteries	Undischarged	No Battery tests required but the component cells shall have passed the test	UL 1642 approved	N/A
		Fully discharged		UL 1642 approved	N/A
Test H	Cells and single cell batteries	Undischarged	N/A	-	N/A
		Fully discharged	10	-	N/A
	Multi cell batteries	Undischarged	No Battery tests required but the component cells shall have passed the test	UL 1642 approved	N/A
		Fully discharged		UL 1642 approved	N/A
Test I to K	Cells and single cell batteries	Undischarged	5	-	N/A
		Fully discharged	N/A	-	N/A
	Multi cell batteries	Undischarged	5	I,K: NE, NF J: NV,NE,NF	P
		Fully discharged	N/A		N/A
Test L	Cells and single cell batteries	Undischarged	5 (+15)		N/A
		Fully discharged	N/A		N/A

IEC 60086-4					
Clause	Requirement + Test			Result - Remark	Verdict
Test M	Multi cell batteries	Undischarged	N/A		N/A
		Fully discharged	N/A		N/A
	Cells and single cell batteries	Undischarged	50% predischarged		N/A
		Fully discharged	75% predischarged		N/A
	Multi cell batteries	Undischarged	N/A		N/A
		Fully discharged	N/A		N/A
Supplementary Information: NC: No Short Circuit NE: No Explosion NF: No Fire NL: No Leakage NM: No Mass loss NR: No Rupture NT: No Excessive temperature rise NV: No Venting					

Remarks #1: Photographs

<Fig. #1>



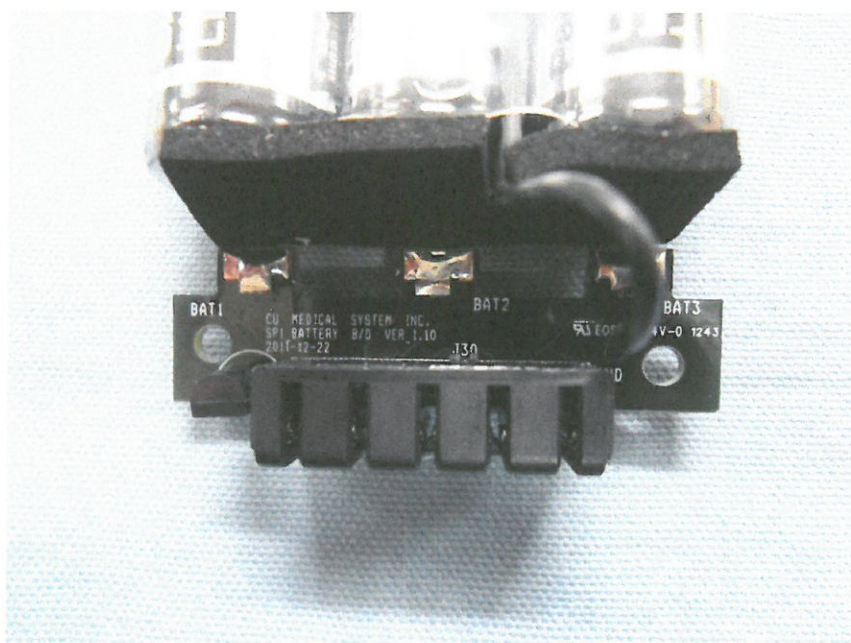
<Fig. #2>



<Fig. #3>



<Fig. #4>



<Fig. #5>

