



Attachment 9_Shock and Vibration Test Report

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TEST REPORT

Report No. : SGS-R18-0000-EN00
Order No. : TON-R18-0466
Applicant : CU Medical Systems, Inc.
Address : 130-1, Dongwhagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea
Product : Cardiac Defibrillator & Monitor
Model No. : CU-HD1
Date of Test : February 19, 2018 ~ March 27, 2018
Standard : Request of client
Test Result : Refer to Page 22
Use of Report : CB Progressive

This is certified that the above mentioned products have been tested for the sample provided by client.

Affirmation	Tested by Name : Jeong, Do-sic	Technical Manager Name : An, Hyo-kyung
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March 07, 2018

SGS Korea Co., Ltd. Dongtan Laboratory

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TQF-510-001_ver6

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Attachment 9_Shock and Vibration Test ReportReport No: SGS-R18-0000-EN00
Page : 3 / 24**1. Overview**

As requested by the client, this test was conducted on test sample according to the test specification presented by the client.

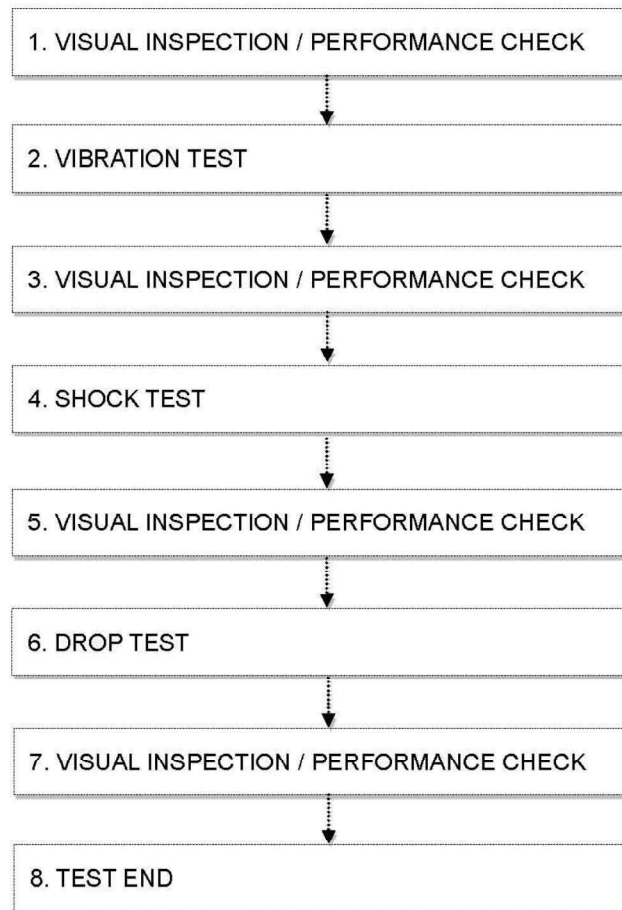
2. Product**2.1 Description**

- | | |
|--------------------|-----------------------------------|
| 1) Applicant | : CU Medical Systems, Inc. |
| 2) Manufacturer | : CU Medical Systems, Inc. |
| 3) Product | : Cardiac Defibrillator & Monitor |
| 4) Model | : CU-HD1 |
| 5) Serial No. | : - |
| 6) Sample quantity | : 1 EA |

2.2 Photograph

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The test be conducted in the following procedure.



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4. Test Condition & Test Result

4.1 Vibration test

Applicant	CU Medical Systems, Inc.	Dept. in charge	Reliability Test Team
Product	Cardiac Defibrillator & Monitor	Tester	Jeong, Do-sic (+82-31-240-6696)
Model	CU-HD1	Date	February 19, 2018
Serial No.	-		
Standard	Request of client	Page	6

(1) Test conditions

1) Test Type : Random

2) Frequency & Accelerometer

Frequency [Hz]	Accelerometer [m/s ² /Hz]	dB/octave
10 ~ 100	1	-
100 ~ 200	-	-7
200 ~ 2 000	1	-

3) Test time : 1 h 30 min in total (30 min in each axis)

4) Test axis : Transverse (X), Longitudinal (Y), Vertical (Z)

5) Sample condition : Unpackaged/Non operation

6) Sample quantity : 1 EA




(2) Environment conditions : (18 ± 1) °C, (37 ± 1) % R.H.

(3) Test procedures

- 1) Perform a visual inspection and an operational check for the specimen
- 2) Fix the specimen on the vibration table.
- 3) Operate the vibration tester.
- 4) Repeat from steps 1) to step 3) for each required axis.
- 5) Perform a final visual inspection and an operational check for the specimen.

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(4) Test photograph

Test axis	Test photograph
Vertical (Z)	
Transverse (X)	
Longitudinal (Y)	

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(5) Test equipment

Description	Manufacturer & Model	Serial number	The due date of next calibration	Calibration laboratory
VIBRATION TESTING SYSTEM	SHINKEN/G-0215NS	SG-4589	January 05, 2019	SICT
ACCELEROMETER	SHINKEN/V11-101S	1039	May 16, 2018	SICT

(6) Test result

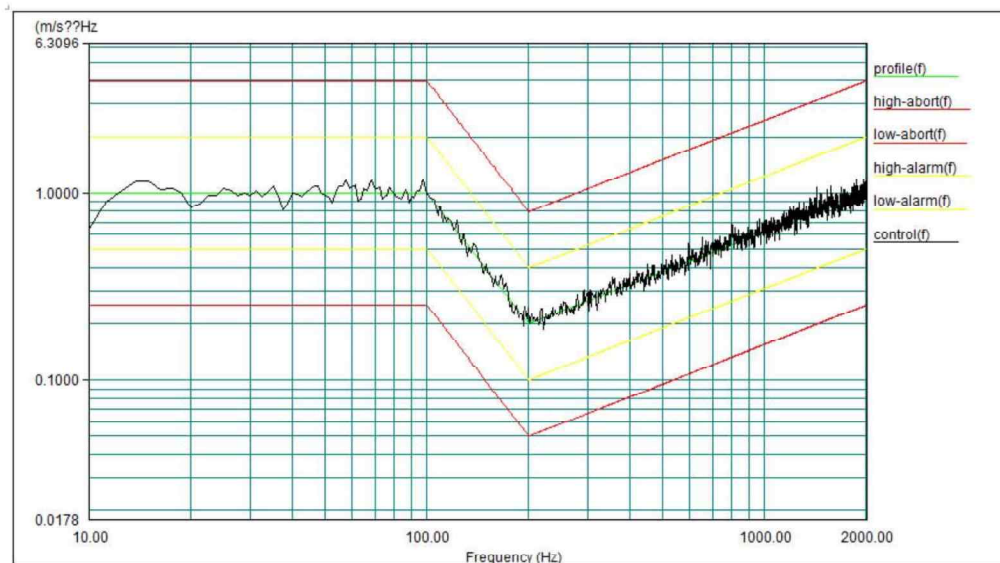
Check list	Test result
1. Visual inspection -. Mechanical damage such as deformation, loosening of screw, separation, crack, etc	No abnormal was found
2. Performance check -. Display output check	Refer to ※ Annex 1.

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※ Appendix 1. Vibration test Data _ Vertical (Z)

Control RMS: 36.448818 m/s² Full Level Elapsed Time: 00:30:00

Lines: 1600 Frame Time: 0.800000 Seconds

Demand RMS: 35.902779 m/s² Remaining Time: 00:00:00

DOF: 154 dF: 1.250000 Hz

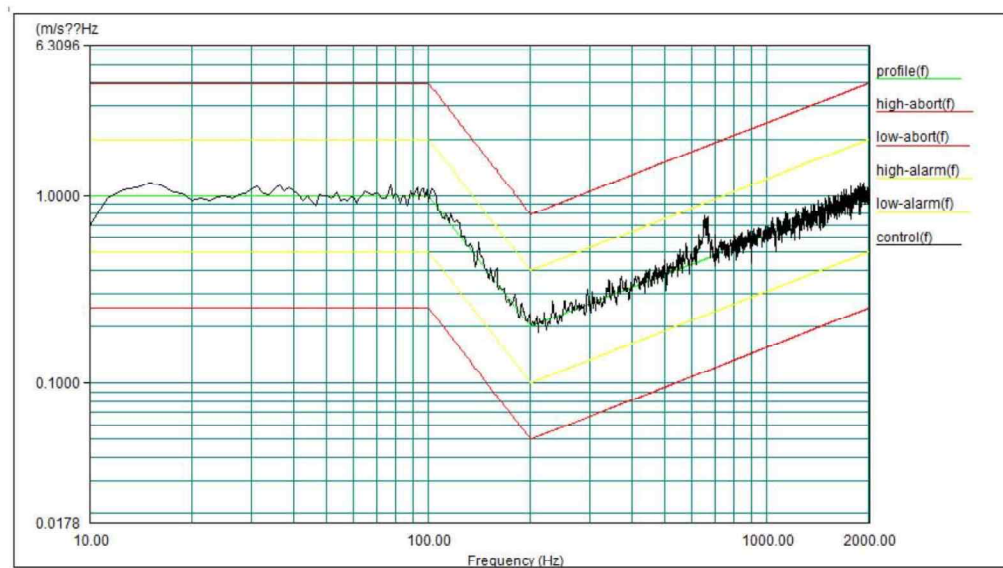
Data saved at 02:50:34 PM, Monday, February 19, 2018 Report created at 02:50:40 PM, Monday, February 19, 2018

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-. Vibration test Data _ Transverse (X)



Control RMS: 36.629372 m/s² Full Level Elapsed Time: 00:30:00

Lines: 1600 Frame Time: 0.800000 Seconds

Demand RMS: 35.902779 m/s² Remaining Time: 00:00:00

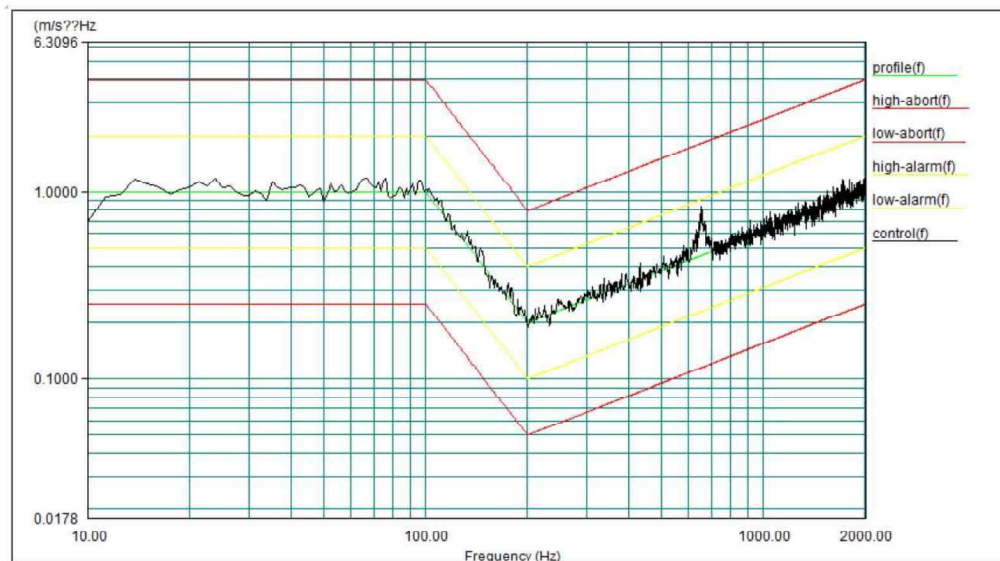
DOF: 154 dF: 1.250000 Hz

Data saved at 04:49:34 PM, Monday, February 19, 2018 Report created at 04:49:35 PM, Monday, February 19, 2018

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-. Vibration test Data _ Longitudinal (Y)



Control RMS: 36.638527 m/s² Full Level Elapsed Time: 00:30:00

Lines: 1600 Frame Time: 0.800000 Seconds

Demand RMS: 35.902779 m/s² Remaining Time: 00:00:00

DOF: 154 dF: 1.250000 Hz

Data saved at 03:48:29 PM, Monday, February 19, 2018 Report created at 03:48:29 PM, Monday, February 19, 2018

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4.2 Shock test

Applicant	CU Medical Systems, Inc.	Dept. in charge	Reliability Test Team
Product	Cardiac Defibrillator & Monitor	Tester	Jeong, Do-sic (+82-31-240-6696)
Model	CU-HD1	Date	February 19, 2018
Serial No.	-		
Standard	Request of client	Page	9

(1) Test conditions

- 1) Test Type : Half sine
- 2) Acceleration : 300 m/s²
- 3) Duration : 11 ms
- 4) Number of shocks : 18 times in total (±3 times in each axis)
- 5) Test axis : Transverse (X), Longitudinal (Y), Vertical (Z)
- 6) Sample condition : Unpackaged/Non operation
- 7) Sample quantity : 1 EA




(2) Environment conditions : (18 ± 1) °C, (37 ± 1) % R.H.

(3) Test procedures

- 1) Perform a visual inspection and an operational check for the specimen
- 2) Fix the specimen on the vibration table.
- 3) Operate the vibration tester.
- 4) Repeat from steps 1) to step 3) for each required axis.
- 5) Perform a final visual inspection and an operational check for the specimen..

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(4) Test photograph

Test axis	Test photograph
Vertical (Z)	
Transverse (X)	
Longitudinal (Y)	

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**(5) Test equipment**

Description	Manufacturer & Model	Serial number	The due date of next calibration	Calibration laboratory
VIBRATION TESTING SYSTEM	SHINKEN/ G-0205NSHD	SG-5301	December 12, 2018	SICT
ACCELEROMETER	SHINKEN/V11-101S	1039	May 16, 2018	SICT

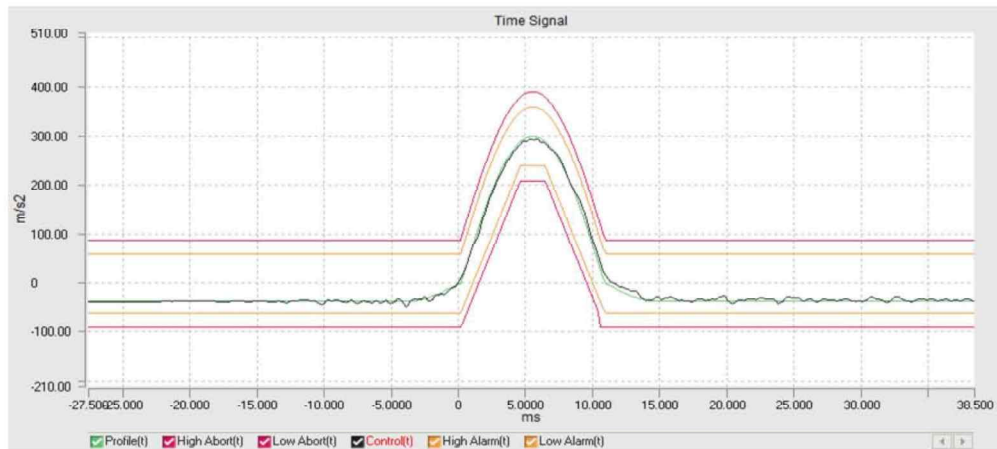
(6) Test result

Check list	Test result
1. Visual inspection -. Mechanical damage such as deformation, loosening of screw, separation, crack, etc	No abnormal was found
2. Performance check -. Display output check	Refer to ※ Annex 1.

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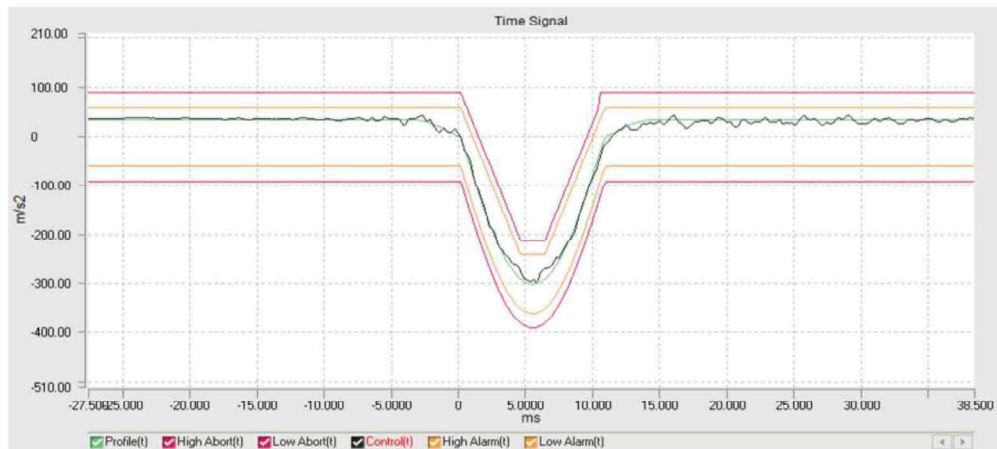
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※ Appendix 1. Shock test Data _ Vertical (Z)



Shock Type: Half Sine Mag: 300.00 m/s² Pulse Duration: 11 ms^{1/2}
Current level: 100 % Demand peak: 300.000 m/s² Control peak: 294.159 m/s²
Block Size: 1024 Frame Time: 0.1707 s dT: 0.000166667 s^{1/2}
Current Pulses: 3 Output pulses: 12 Remain pulses: 0^{1/2}
Data was saved as a file at time: 2018-3-27 AM 10:29:26^{1/2}

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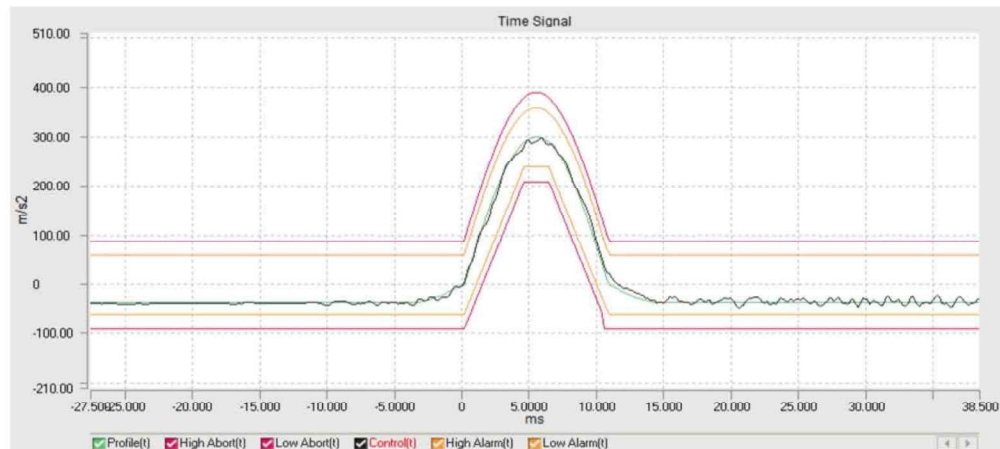
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Shock Type: Half Sine Mag: 300.00 m/s² Pulse Duration: 11 ms^μ
Current level: 100 % Demand peak: 300.000 m/s² Control peak: 297.383 m/s²
Block Size: 1024 Frame Time: 0.1707 s dT: 0.000166667 s^μ
Current Pulses: 3 Output pulses: 12 Remain pulses: 0^μ
Data was saved as a file at time: 2018-3-27 AM 10:29:34^μ

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-. Shock test Data _ Transverse (X)

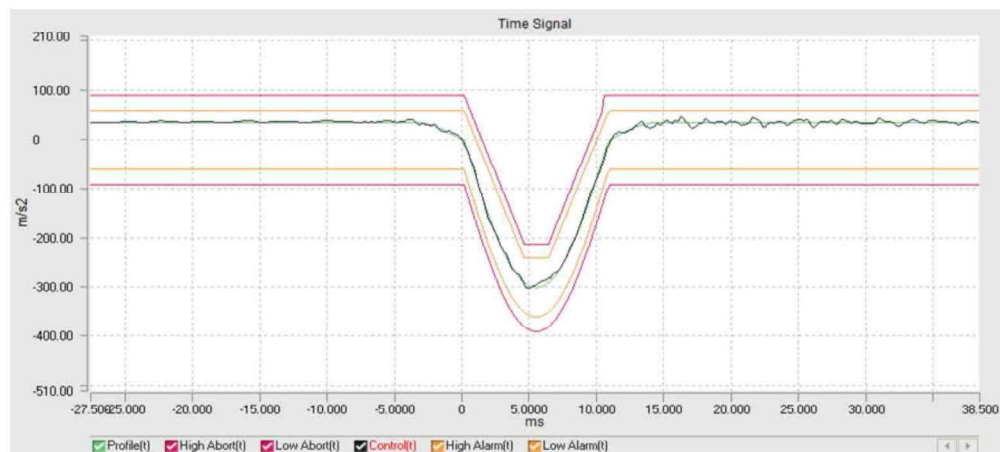


Shock Type: Half Sine Mag: 300.00 m/s^2 Pulse Duration: 11 ms⁺
Current level: 100 % Demand peak: 300.000 m/s^2 Control peak: 298.088 m/s^2
Block Size: 1024 Frame Time: 0.1707 s dT: 0.000166667 s⁺
Current Pulses: 3 Output pulses: 12 Remain pulses: 0⁺
Data was saved as a file at time: 2018-3-27 AM 10:06:53⁺



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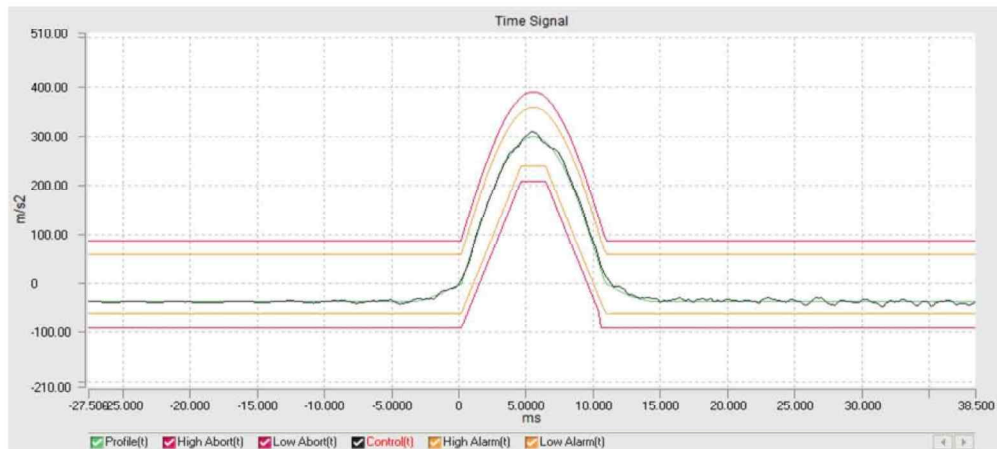


Shock Type: Half Sine Mag: 300.00 m/s² Pulse Duration: 11 ms^μ
Current level: 100 % Demand peak: 300.000 m/s² Control peak: 301.797 m/s²^μ
Block Size: 1024 Frame Time: 0.1707 s dT: 0.000166667 s^μ
Current Pulses: 3 Output pulses: 12 Remain pulses: 0^μ
Data was saved as a file at time: 2018-3-27 AM 10:07:20^μ

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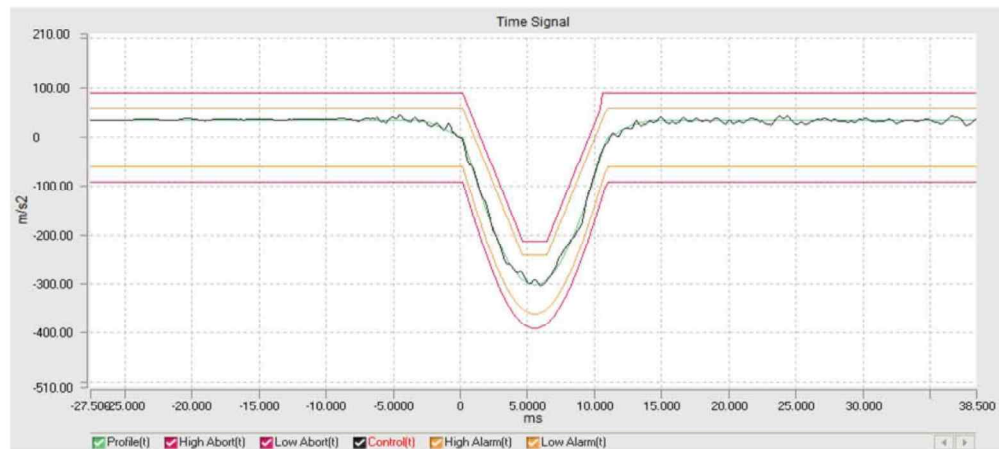
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-. Shock test Data _ Longitudinal (Y)



Shock Type: Half Sine Mag: 300.00 m/s² Pulse Duration: 11 ms^μ
Current level: 100 % Demand peak: 300.000 m/s² Control peak: 311.276 m/s²
Block Size: 1024 Frame Time: 0.1707 s dT: 0.000166667 s^μ
Current Pulses: 3 Output pulses: 12 Remain pulses: 0^μ
Data was saved as a file at time: 2018-3-27 AM 09:40:06^μ

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Shock Type: Half Sine Mag: 300.00 m/s² Pulse Duration: 11 ms^μ
Current level: 100 % Demand peak: 300.000 m/s² Control peak: 303.298 m/s²
Block Size: 1024 Frame Time: 0.1707 s dT: 0.000166667 s^μ
Current Pulses: 3 Output pulses: 12 Remain pulses: 0^μ
Data was saved as a file at time: 2018-3-27 AM 09:57:18^μ

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4.3 Drop test

Applicant	CU Medical Systems, Inc.	Dept. in charge	Reliability Test Team
Product	Cardiac Defibrillator & Monitor	Tester	Jeong, Do-sic (+82-31-240-6696)
Model	CU-HD1	Date	February 27, 2018
Serial No.	-		
Standard	Request of client	Page	2

(1) Test conditions

- 1) Drop height : 0.1 m
- 2) Drop orientation : 1 Faces
- 3) Number of drops : 1 times in total
- 4) Sample state : Unpackaged/Non-operation
- 5) Check time : Before, After the test
- 6) Sample quantity : 1 EA

(2) Environment conditions : (18 ± 1) °C, (37 ± 1) % R.H.

(3) Test procedures

- 1) Perform a visual inspection for the specimen.
- 2) Set the test height of drop.
- 3) Put the specimen on drop table.
- 4) Perform the drop.
- 5) Repeat from steps 3) to step 4) for each required surface.
- 6) Perform a final visual inspection for the specimen.

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(4) Test photograph



(5) Test equipment

Description	Manufacturer & Model	Serial number	The due date of next calibration	Calibration laboratory
STRAIGHT EDGE	EAGLE/2 000 mm	12062537-8	July 31, 2018	SICT

(6) Test result

Check list	Test result
1. Visual inspection -. Mechanical damage such as deformation, loosening of screw, separation, crack, etc	No abnormal was found
2. Performance check -. Display check	Refer to ※ Annex 1.



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※ Annex 1. Test result check

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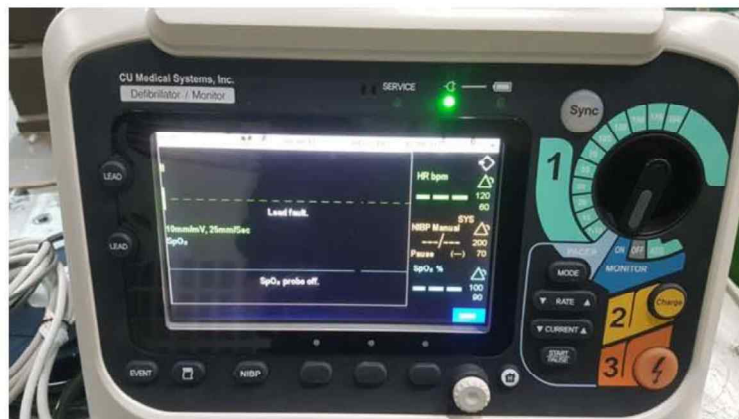
1. Performance check

Display check


Before
The
test



After
The
Test
(Vibration)



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Display check	
After The Test (Shock)	
After The Test (Drop)	