

EMC TEST REPORT

Test Report No. NC72107623.1 Rev B Date of issue: 22 September 2015

Product Name HD-S11-F2 Transmitter

Model 270-0196

Serial number tested 781058

Description Pressure, Biopotential, and Temperature 18MHz Transmitter

Test Date 29 June 2015

Manufacturer Data Sciences International
119 14th Street NW – Suite 100
St Paul MN 55112 USA

Issuing Laboratory TÜV SÜD America Inc
1775 Old Highway 8 NW, Suite 104
New Brighton MN 55112-1891 USA
Phone: 651 631 2487 / Fax: 651 638 0285

Test Result ☒ **Positive** ☐ **Negative**

TÜV SÜD America Inc reports apply only to the specific samples tested under stated test conditions. It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical components. TÜV SÜD America Inc shall have no liability for any deductions, inferences or generalizations drawn by the client or others from TÜV SÜD America Inc issued reports.

This report is the confidential property of the client. As a mutual protection to our clients, the public and ourselves, extracts from the test report shall not be reproduced except in full without our written approval. TÜV SÜD America's New Brighton, Taylors Falls, and Millville Labs maintain A2LA accreditation to ISO/IEC 17025 for the specific tests listed in A2LA Certificate #2955.11 as an Electrical Testing Laboratory.

TÜV SÜD America Inc and its professional staff hold government and professional organization certifications and are members of AAMI, ACIL, AEA, ANSI, IEEE, NARTE, and VCCI.

REVISION RECORD

REVISION	TOTAL NUMBER OF PAGES	DATE	DESCRIPTION
	20	07 August 2015	Initial Release
A	20	10 August 2015	Page 10: Test setup photos replaced.
B	20	22 September 2015	Pages 5 and 6: • Revised ANSI C63.4 reference to ANSI C63.10. • Revised remarks stating that no significant emissions detected to "All emissions were at the noise floor or more than 20dB below the limit."



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Appendix A

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EMC TEST REGULATIONS:

The tests were performed according to the following regulations:

FCC Part 15 Subpart C §15.209
IC RSS-210 Issue 8 Amendment 1
IC RSS-Gen Issue 4

LAB ACCREDITATION:

TÜV SÜD America's New Brighton, Taylors Falls, and Millville Labs maintain A2LA accreditation to ISO/IEC 17025 for the specific tests listed in A2LA Certificate #2955.11 as Electrical Testing Laboratories located at the following addresses:

Physical Location: 1775 Old Highway 8 NW, Suite 104
New Brighton MN 55112-1891 USA
Satellite Location: Oakwood Town Road
Millville MN 55957-0255 USA
Satellite Location 19333 Wild Mountain Road
Taylors Falls MN 55084 USA

ENVIRONMENTAL CONDITIONS IN THE LAB

Temperature:	Actual : 22-26°C
Atmospheric pressure	: 98-99kPa
Relative Humidity	: 55-62%

POWER SUPPLY UTILIZED

Power supply system :1.6 VDC

TEST EQUIPMENT

All measurement instrumentation is traceable to the National Institute of Standards and Technology and is calibrated according to internal procedure.

MEASUREMENT UNCERTAINTY

The test system for conducted emissions is defined as the LISN, tuned receiver or spectrum analyzer, and coaxial cable. The test system has a measurement uncertainty of ± 1.8 dB. The test system for radiated emissions is defined as the antenna, the pre-amplifier, the spectrum analyzer and the coaxial cable. The test system has a measurement uncertainty of ± 4.8 dB. All measurement instrumentation is traceable to the National Institute of Standards and Technology and is calibrated according to internal procedure.

SIGN EXPLANATIONS

☐ - not applicable
☒ - applicable

General field strength limits 0.009 – 30 MHz

FCC 15.209(a), FCC 15.209(c), IC RSS-210 2.5, RSS-Gen 7.2.5

Test summary

The requirements are: ■ - MET □ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.10: 2013

No unwanted emissions exceed the level of the fundamental.

Test location

TÜV SÜD America Inc, Taylors Falls, Large Test Site (Open Area Test Site)

Test distances

■ - 0.3 meters

■ - 1 meters

■ - 3 meters

□ - 10 meters

Test equipment

TUV ID	Model	Manufacturer	Description	Serial	Cal Date	Cal Due
WRLE02418	6502	Electro-Mechanics (EMCO)	Loop Antenna	2215	08-Sep-14	08-Sep-15
WRLE02534	ESHS-20	Rohde & Schwarz	EMI Receiver 9kHz-30MHz	837055/003	11-Aug-14	11-Aug-15

Cal Code B = Calibration verification performed internally. Cal Code Y = Calibration not required when used with other calibrated equipment.

Test limit

Frequency (MHz)	Field strength (μV/m)	Measurement distance (m)
0.009-0.490	2400/F(kHz)	300
0.490 - 1.705	24000/F(kHz)	30
1.705 - 30	30	30

The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector. The provisions in §§15.31, 15.33, and 15.35 for measuring emissions at distances other than the distances specified in the above table, determining the frequency range over which radiated emissions are to be measured, and limiting peak emissions apply to all devices operated under this part.

Test Data

Quasi-Peak data

Frequency (MHz)	Field strength (dBμV/m@0.3m)	Field strength (dBμV/m@1m)	Field strength (dBμV/m@3m)	Field strength (dBμV/m@30m)	Field strength (μV/m@30m)	Limit (μV/m@30m)
17.988	53.96	31.05	NF	-28.95*	0.0357*	30

NF Noise floor

* Extrapolated using 40 dB/decade falloff.

All emissions were at the noise floor or more than 20dB below the limit.

Radiated emissions in the frequency range of 10 kHz to 30 MHz, including the fundamental transmit signal, are measured using a receiver capable of quasi-peak/average/peak measurements and a magnetic loop antenna. The transmitter and loop antenna are rotated through 3 orthogonal axes in order to determine the maximum emission levels. If the signal cannot be measured at the specified limit distance, measurements are recorded at multiple distances nearer to the device and the final level mathematically extrapolated. Measurements between 150 kHz and 30 MHz are made with a 9 kHz resolution bandwidth. Measurements between 9 kHz and 150 kHz are made with a 200 Hz resolution bandwidth.

General field strength limits above 30 MHz

FCC 15.209(c), FCC 15.209(f), IC RSS-210 2.5, RSS-Gen 7.2.5

Test summary

The requirements are: ■ - MET □ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.10: 2013.

Test location

TÜV SÜD America Inc, Taylors Falls, Large Test Site (Open Area Test Site)

Test distance

3 meters

Test Equipment

TUV ID	Model	Manufacturer	Description	Serial	Cal Date	Cal Due
OWLE03202	EM-6917B	Electro-Metrics	Biconicalog Periodic	101	16-Oct-14	16-Oct-15
WRLE02673	85662A	Hewlett-Packard	Analyzer Display	2152A03687	08 Sep-14	08 Sep-15
WRLE03294	8566B	Hewlett-Packard	Spectrum Analyzer	2349A03098	08-Sep-14	08-Sep-15
WRLE02680	85650A	Hewlett-Packard	Quasi-Peak Adapter	2043A00343	08-Sep-14	08-Sep-15
WRLE10897	ZHL-1042J	Mini-Circuits	Amplifier Broadband AMP/ SMA QA1148002	NA	Code B 06-Feb-15	Code B 06-Feb-16
WRLE10863	N/A	TÜV SÜD America Inc	Test Companion Software Version 3.4.71	N/A	Code Y	Code Y

Cal Code B = Calibration verification performed internally.

Limit for transmitter

Frequency (MHz)	Field strength (μV/m)	Field strength (dBμV/m)	Measurement distance (m)
30 - 88	100	40	3
88 - 216	150	43.5	3
216 - 960	200	46	3
Above 960	500	54	3

The emission limits shown in the above tables are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz. Radiated emission limits in these three bands are based on measurements employing an average detector. When average radiated emission measurements are specified in this part, including average emission measurements below 1000 MHz, there also is a limit on the peak level of the radio frequency emissions. Unless otherwise specified, e.g., see §§ 15.250, 15.252, 15.255, and 15.509–15.519, the limit on peak radio frequency emissions is 20 dB above the maximum permitted average emission limit applicable to the equipment under test.

Test Data

Scan 30-1000MHz
DUT rotated 360°. Measurement antenna vertical & horizontal, 1-4m high
All emissions were at the noise floor or more than 20dB below the limit.

Occupied bandwidth

RSS-Gen 4.6.1

Test summary

The requirements are: ■ - MET □ - NOT MET

Test was performed in accordance with the article "The Measurement of Occupied Bandwidth" by Industry Canada's certification bureau.

Occupied bandwidth is 197.2 kHz

Test location

TÜV SÜD America Inc, Taylors Falls, Large Test Site (Open Area Test Site)

Test equipment

TUV ID	Model Number	Manufacturer	Description	Serial Number	Cal Date	Cal Due
WRLE10435	E4440A	Agilent	Spectrum Analyzer	MY44304483	30-Sep-14	30-Sep-15

Cal Code B = Calibration verification performed internally. Cal Code Y = Calibration not required when used with other calibrated equipment.

Test limit

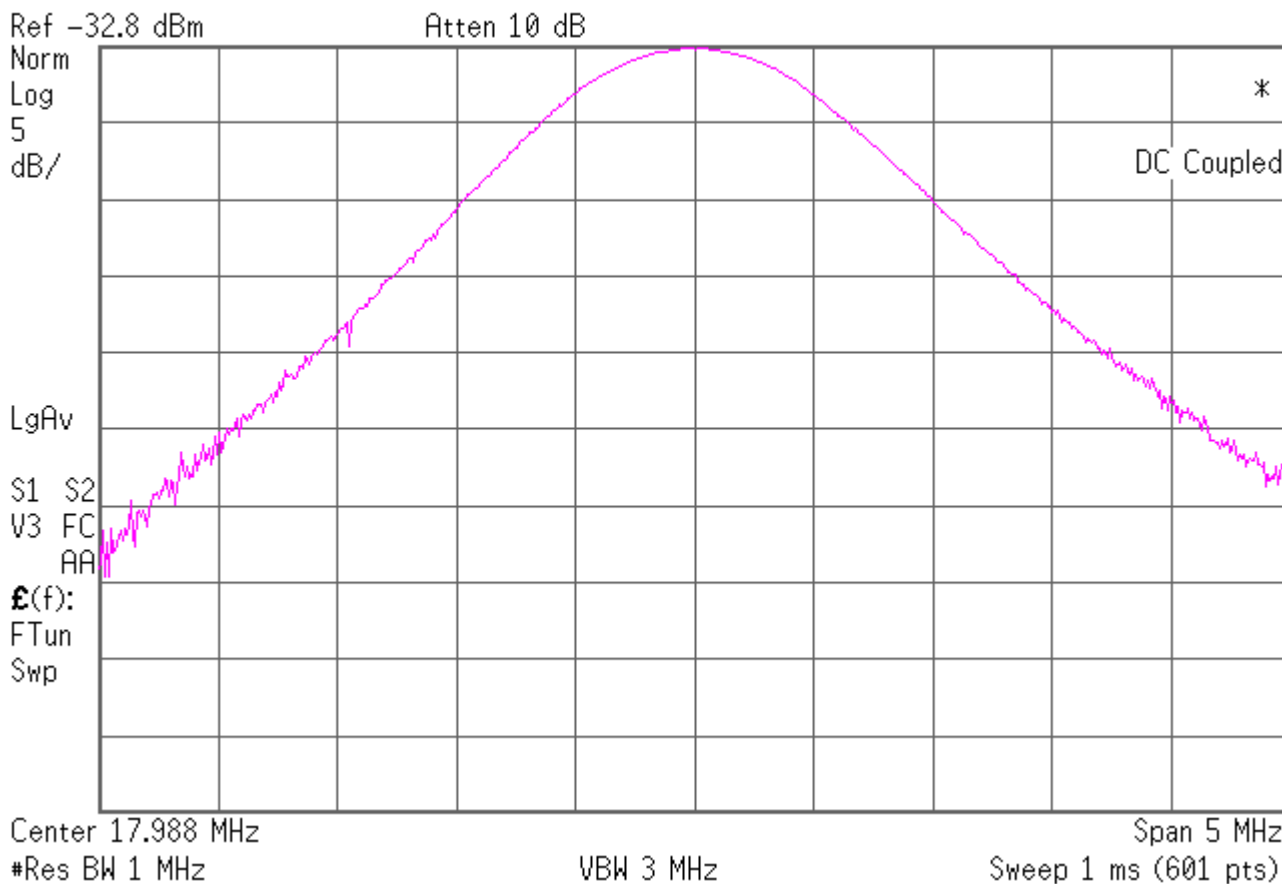
Not specified

Test data

Plot 1 of 2

✱ Agilent 11:16:16 Jun 29, 2015

R T



Plot 2 of 2 – occupied bw = 197.2 kHz

Agilent 11:19:16 Jun 29, 2015

R T

▲ Mkr1 197.2 kHz
-0.11 dB

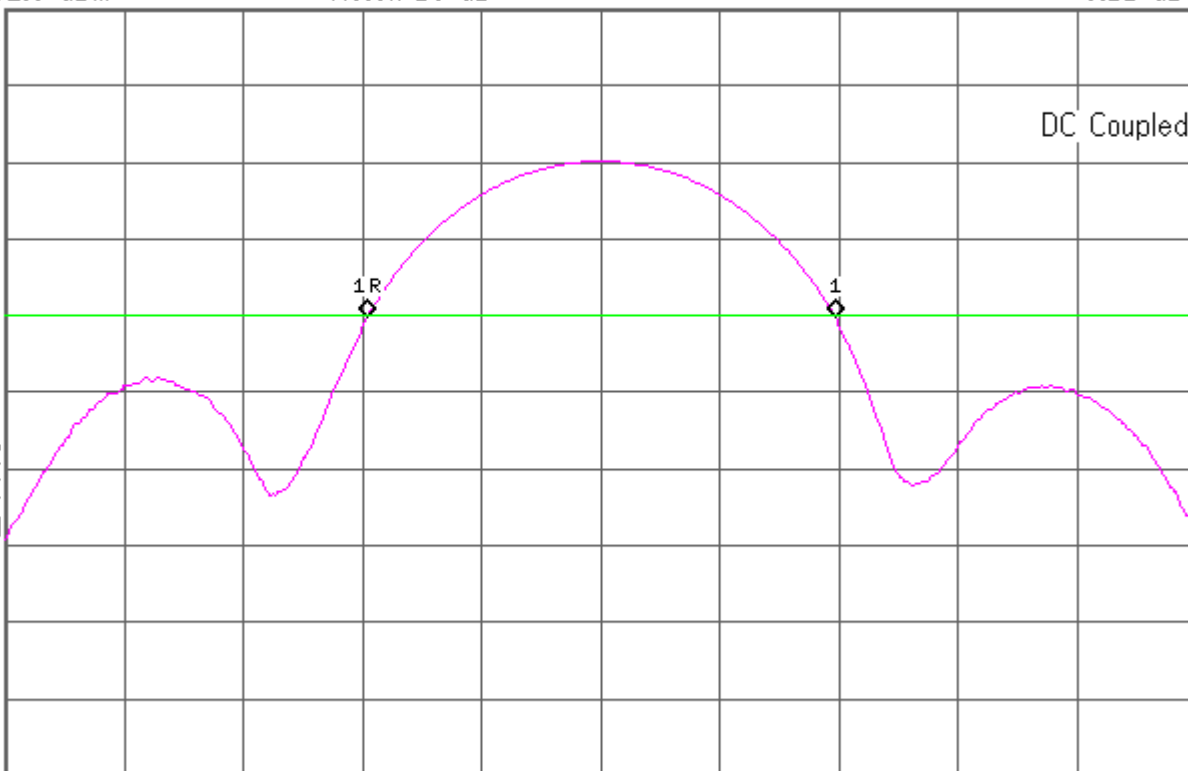
Ref -32.8 dBm

Atten 10 dB

Peak
Log
5
dB/

DC Coupled

DI
-52.8
dBm
LgAv
S1 S2
M3 FC
AA
£(f):
f>50k
Swp



Center 17.988 0 MHz

#Res BW 30 kHz

VBW 91 kHz

Span 500 kHz

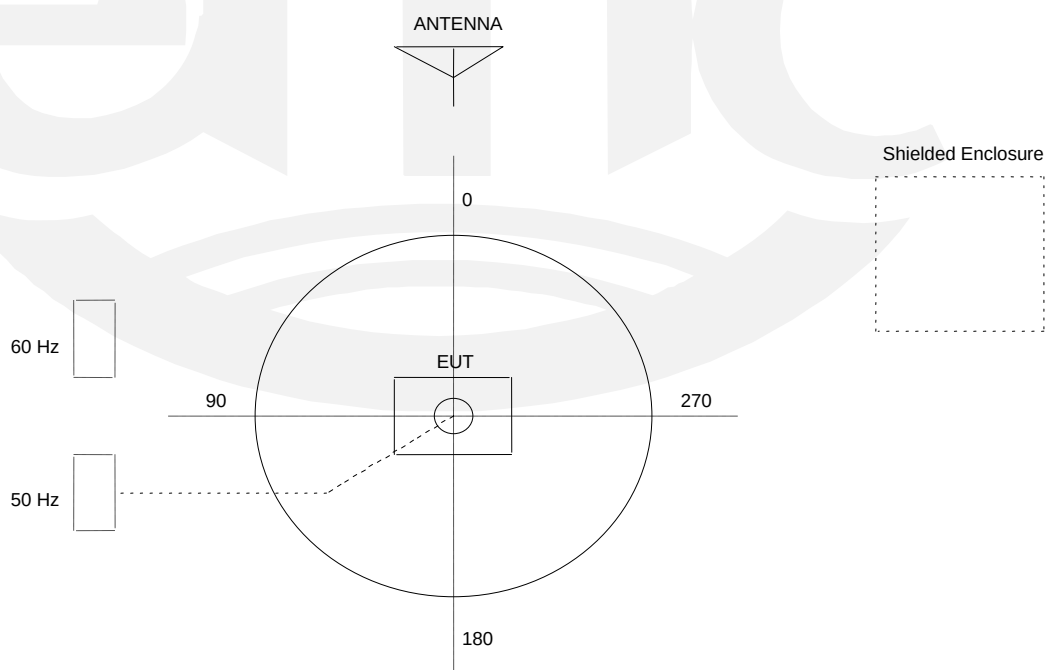
Sweep 1 ms (601 pts)

TEST SETUP FOR EMISSIONS TESTING

TÜV SÜD America Inc, Taylors Falls
Large Test Site

Notes:

1. Items shown in dotted lines are located on the floor below the test area. It is 5 meters vertically from the ground floor to the test area.
2. 50 Hz and 60 Hz are power panels for alternating current.
3. The antenna may be positioned horizontally 3 and 10 meters from the center of the turntable.
4. The circle is either a 6.7 meter or 1.2 meter diameter turntable.
5. A ground plane is in the plane of this sheet.
6. The test sample is shown in the azimuthal position representing zero degrees.



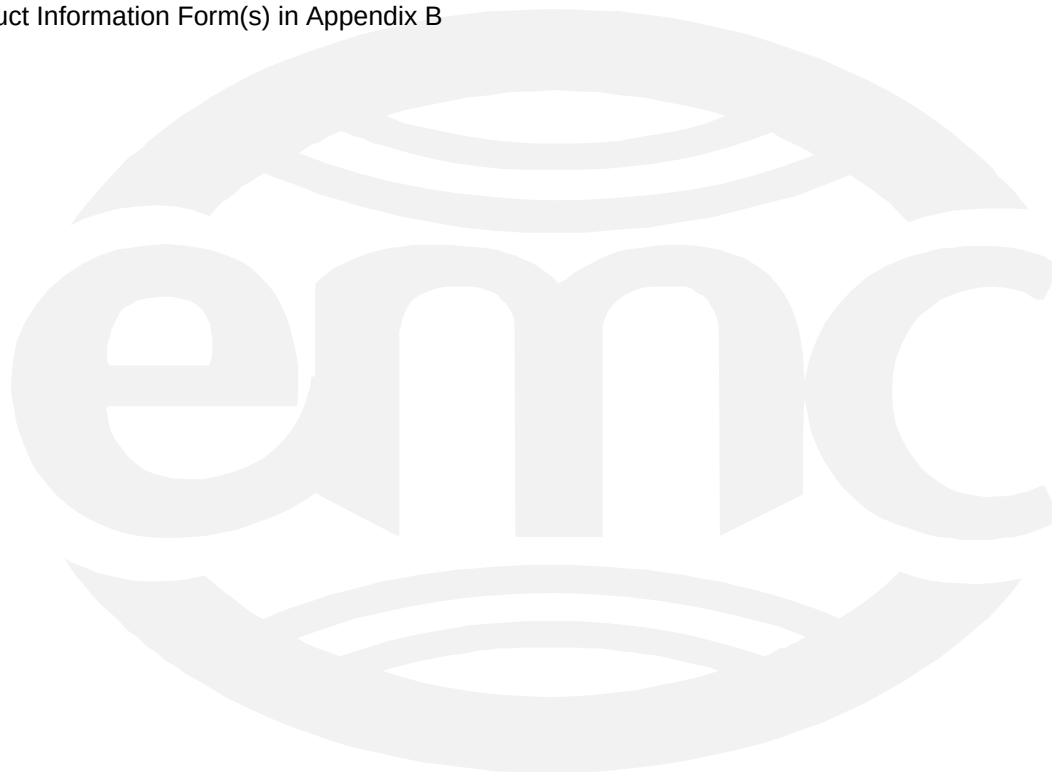
Equipment Under Test (EUT) Test Operation Mode:

The device under test was operated under the following conditions during testing :

- - Normal operating mode

Configuration of the device under test:

- - See Appendix A and test setup photos
- - See Product Information Form(s) in Appendix B



DEVIATIONS FROM STANDARD:

None.

GENERAL REMARKS:

None

Modifications required to pass:

- ☒ None
☐ As indicated on the data sheet(s)

Test Specification Deviations: Additions to or Exclusions from:

- ☒ None
☐ As indicated in the Test Plan

SUMMARY:

The requirements according to the technical regulations are

- ☒ - met and the device under test does fulfill the general approval requirements.
☐ - **not** met and the device under test does **not** fulfill the general approval requirements..

EUT Received Date: 29 June 2015
Condition of EUT: Normal
Testing Start Date: 29 June 2015
Testing End Date: 29 June 2015

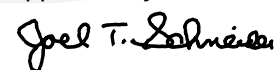
TÜV SÜD AMERICA INC

Tested by:



Greg S Jakubowski
EMC Test Engineer

Approved by:



Joel T Schneider
Senior EMC Engineer

Appendix A

Constructional Data Form





EMC Test Plan and Constructional Data Form

PLEASE COMPLETE THIS DOCUMENT IN FULL, ENTERING N/A IF THE FIELD IS NOT APPLICABLE. IF TESTING RESULTS IN MODIFICATIONS TO THE EQUIPMENT, PLEASE SUBMIT A REVISED TP/CDF INDICATING THOSE MODIFICATIONS.
NOTE: This information will be input into your test report as shown below. Press the F1 key at any time to get HELP for the current field selected.

Company: Data Sciences International (DSI)
 Address: 119 14th St NW Suite 100

 Contact: Perry Mills Position: Sr Research Fellow
 Phone: 651-481-7421 Fax: 651-481-7417
 E-mail Address: pmills@datasci.com

General Equipment Description -- NOTE: This information will be input into your test report as shown below.

EUT Description Pressure, Biopotential, and Temperature Transmitter
 EUT Name HD-S11-F2 Transmitter
 Model No.: 270-0196 Serial No.: 781058
 Product Options: None
 Configurations to be tested: Standard

Equipment Modification (If applicable, indicate modifications since EUT was last tested. If modifications are made during this testing, submit revised TP/CDF after testing is complete.)

Modifications since last test: None
 Modifications made during test: None

Test Objective(s): Please indicate the tests to be performed, entering the applicable standard(s) where noted.

- | | |
|---|---|
| ☒ EMC Directive 2004/108/EC (EMC)
Std: <u>EN 300-330-2</u> | ☐ FCC: Class ☐ A ☒ B Part <u>15</u> |
| ☐ Machinery Directive 89/392/EEC (EMC)
Std: _____ | ☐ VCCI: Class ☐ A ☐ B |
| ☐ Medical Device Directive 93/42/EEC (EMC)
Std: _____ | ☐ BSMI: Class ☐ A ☐ B (Separate Report) |
| | ☐ Canada: Class ☐ A ☐ B |
| | ☐ Australia: Class ☐ A ☐ B |
| | RTTE Directive |
| | IC RSS-210 Issue 7 |
| ☐ Vehicle Directive - 2004/104/EC (EMC)
☐ Other Vehicle Std: _____ | ☐ Other: <u>IC RSS-Gen Issue 2</u> |
| ☐ FDA Reviewers Guidance for Premarket Notification Submissions (EMC) | ☐ Ag Directive *2009/64/EC (EMC) |



EMC Test Plan and Constructional Data Form

Third Party Certification (contact TÜV for quote), if applicable (*Signature on last page required).

☐ Attestation of Compliance (AoC)*	☐ EMC Certification (used with Octagon Mark)*
☐ Statement of Compliance (SoC, previously CoC)* - All aspects of the essential requirements were assessed	
Protection Class (Req'd for AoC, SoC, EMC Cert. N/A for vehicles) ☐ Class I ☐ Class II ☐ Class III (Press F1 when field is selected to show additional information on Protection Class.)	
☒ FCC / TCB Certification	☐ Taiwan Certification
☐ Industry Canada / FCB Certification	☐ Korean Certification
☐ e-Mark Certification	

Attendance

Test will be: ☒ Attended by the customer ☐ Unattended by the customer

Failure - Complete this section if testing will not be attended by the customer.

If a failure occurs, TÜV SÜD America should:

- ☐ Call contact listed above, if not available then stop testing. (After hrs phone): _____
- ☐ Continue testing to complete test series.
- ☐ Continue testing to define corrective action.
- ☐ Stop testing.

EUT Specifications and Requirements

Length: 34mm Width: 16.5mm Height: 12.5mm Weight: _____

Power Requirements

Regulations require testing to be performed at typical power ratings in the countries of intended use. (i.e., European power is typically 230 VAC 50 Hz or 400 VAC 50 Hz, single and three phase, respectively)

Voltage: _____ (If battery powered, make sure battery life is sufficient to complete testing.)

of Phases: _____

Current (Amps/phase(max)): _____ Current (Amps/phase(nominal)): _____

Other Battery

Other Special Requirements

None

Typical Installation and/or Operating Environment

(ie. Hospital, Small Business, Industrial/Factory, etc.)

Research laboratory in business, academic institution or hospital.

EUT Power Cable

- ☐ Permanent OR ☐ Removable Length (in meters): _____
- ☐ Shielded OR ☐ Unshielded
- ☒ Not Applicable

EMC Test Plan and Constructional Data Form

EUT Interface Ports and Cables														
Type	Analog	Digital	During Test		Qty	Shielding		Termination	Connector Type	Port Termination	Length tested (in meters)	Removable	Permanent	
			Active	Passive		Yes	No							Type
EXAMPLE: RS232	☐	☒	☒	☐	2	☒	☐	Foil over braid	Coaxial	Metallized 9-pin D-Sub	Characteristic Impedance	6	☒	☐
none	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
	☐	☐	☐	☐		☐	☐						☐	☐
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EMC Test Plan and Constructional Data Form

EUT Software.

Revision Level: NA

Description:

Equipment Under Test (EUT) Operating Modes to be Tested -- list the operating modes to be used during test. It is recommended the equipment be tested while operating in a typical operation mode. FCC testing of personal computers and/or peripherals requires that a simple program generate a complete line of upper case H's. Provide a general description of all software, firmware, and PLD algorithms used in the equipment. List all code modules as described above, with the revision level used during testing. Consult with your TÜV Product Service Representative if additional assistance is required.

1. ON, (one operating mode only)
- 2.
- 3.

Equipment Under Test (EUT) System Components -- List and describe all components which are part of the EUT. For FCC & Taiwan testing a minimum configuration is required. (ie. Mouse, Printer, Monitor, External Disk Drive, Motherboard, etc)

Description	Model #	Serial #	FCC ID #
Pressure, Biopotential, and Temperature Transmitter	HD-S11-F2	781058	new



EMC Test Plan and Constructional Data Form

Support Equipment -- List and describe all support equipment which is not part of the EUT. (i.e. peripherals, simulators, etc)
This information is required for FCC & Taiwan testing.

<i>Description</i>	<i>Model #</i>	<i>Serial #</i>	<i>FCC ID #</i>

Oscillator Frequencies

<i>Manufacturer</i>	<i>Frequency</i>	<i>Derived Frequency</i>	<i>Component # / Location</i>	<i>Description of Use</i>
Discrete components	18.00MHz	18.00MHz	U3, L1, C4,C16	Transmit Frequency

Power Supply

<i>Manufacturer</i>	<i>Model #</i>	<i>Serial #</i>	<i>Type</i>
NA (battery)			☐ Switched-mode: (Frequency) _____ ☐ Linear ☐ Other: _____
			☐ Switched-mode: (Frequency) _____ ☐ Linear ☐ Other: _____

Power Line Filters

<i>Manufacturer</i>	<i>Model #</i>	<i>Location in EUT</i>
NA		



EMC Test Plan and Constructional Data Form

Critical EMI Components (Capacitors, ferrites, etc.)

Description	Manufacturer	Part # or Value	Qty	Component # / Location
None				

EMC Critical Detail -- Describe other EMC Design details used to reduce high frequency noise.

None required to prevent unintentional emissions since the device is physically small, battery powered, and very low power

PLEASE ENTER NAMES BELOW (INSERT ELECTRONIC SIGNATURE IF POSSIBLE)

Authorization (Signature Required if a Third Party Certification is checked on pg 1)

Customer authorization to perform tests
according to this test plan.

Date

Test Plan/CDF Prepared By (please print)

Date

EMC Block Diagram Form

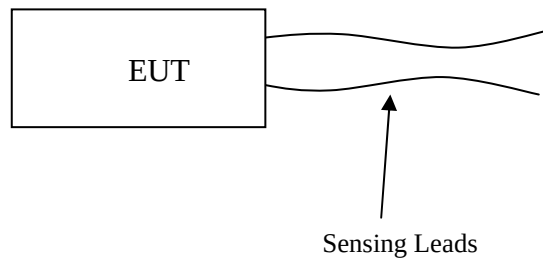
System Configuration Block Diagram -- Provide a line drawing identifying the EUT, simulators, support equipment, I/O cables, power cables, and any other pertinent components to be used during testing. Use a dashed line to separate the equipment in the testing field versus equipment outside testing field.

HD-S11-F2

The only device present during EMC testing the EUT. The EUT is a self contained transmitter including battery power and transmitting coil, so no other connections or equipment are required.

The EUT has only two modes (ON and OFF). No other equipment is required to determine the mode since the EMC test equipment is able to determine that it is in the ON mode.

Modulation of the EUT is not necessary since modulation does not affect average power or bandwidth. Therefore, no signal generator for modulation or connection to the sensing leads is necessary.

**Authorization Signatures**

Customer authorization to perform tests
according to this test plan.

Date

Test Plan/CDF Prepared By (please print)

Date