

# TEST REPORT

## FCC Part 15 Subpart C Section 15.249

## IC RSS-210 Issue 8

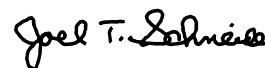
## IC RSS-Gen Issue 3

|                                           |                                                                                |
|-------------------------------------------|--------------------------------------------------------------------------------|
| MANUFACTURER'S NAME                       | Data Sciences International<br>119 14 <sup>th</sup> Street<br>St Paul MN 55112 |
| PRODUCT NAME                              | M-Series M-11 Physio Tel Digital implant transceiver                           |
| MODEL NUMBER(S) TESTED<br>FCC ID:MHAPTDM1 | M11-F1                                                                         |
| SERIAL NUMBER(S) TESTED                   | 726698                                                                         |
| PRODUCT DESCRIPTION                       | 909-921 MHz transceiver                                                        |
| TEST REPORT NUMBER                        | NC1402456.1                                                                    |
| TEST DATE(S)                              | 25-26 March 2014                                                               |

TÜV SÜD America Inc, as an independent testing laboratory, declares that the equipment tested as specified above conforms to the applicable EMC requirements of FCC Part 15 Subpart C Section 15.249 "Operation within the bands 902–928 MHz, 2400–2483.5 MHz, 5725–5875 MHz, and 24.0–24.25 GHz" and IC RSS-210 "Low-power Licence-exempt Radiocommunication Devices (All Frequency Bands): Category I Equipment" and IC RSS-Gen "General Requirements and Information for the Certification of Radiocommunication Equipment".

It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical characteristics. Any modifications necessary for compliance made during testing on the above mentioned date(s) must be implemented in all production units for compliance to be maintained.

Date: 28 April 2014



Location: Taylors Falls MN  
USA

Greg Jakubowski  
Senior EMC Technician

Joel T Schneider  
Senior EMC Engineer

Not Transferable

# EMC TEST REPORT

Test Report No. NC1402456.1 Date of issue: 28 April 2014

Product Name M-Series M-11 Physio Tel Digital implant transceiver

Model(s) Tested M11-F1

Serial No(s) Tested 726698

Product Description 909-921 MHz transceiver

Manufacturer Data Sciences International  
119 14<sup>th</sup> Street  
St Paul MN 55112

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.*

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## REVISION RECORD

| REVISION | TOTAL<br>NUMBER<br>OF PAGES | DATE          | DESCRIPTION     |
|----------|-----------------------------|---------------|-----------------|
|          | 25                          | 28 April 2014 | Initial Release |
|          |                             |               |                 |



## D I R E C T O R Y

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## EMC TEST REGULATIONS:

The tests were performed according to the following regulations:

FCC Part 15 Subpart C Section 15.249 Paragraph (a), (d)

FCC Part 15 Subpart C Section 15.207 Paragraphs (a)

FCC Part 15 Subpart B Section 15.109

IC RSS-210 Issue 8 Section A2.9 (a), (b)

IC RSS-Gen Issue 3 Sections 4.6.1, 7.2.5

## ENVIRONMENTAL CONDITIONS IN THE LAB

|                      |               |
|----------------------|---------------|
|                      | <u>Actual</u> |
| Temperature:         | : 20°C        |
| Atmospheric pressure | : 100kPa      |
| Relative Humidity    | : 35%         |

## POWER SUPPLY UTILIZED

Power supply system : 3 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  $\pm 1.8$  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  $\pm 4.8$  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

## Field strength of fundamental/harmonics

FCC 15.249(a), IC RSS-210 A2.9(a)

### Test summary

The requirements are: ☒ - MET ☐ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.4 2009, clause 8.2.3, 8.2.4. The implantable transmitter was tested in a body simulator.

Maximum field strength of the fundamental is 78.83 dB $\mu$ V/m (8.74 mV/m) at 915.384 MHz.

### Test location

☒ - Wild River Lab Large Test Site (Open Area Test Site)

☐ - Wild River Lab Small Test Site (Open Area Test Site)

### Test distance

☒ - 3 meters

### Test equipment

| TUV ID    | Model     | Manufacturer        | Description                            | Serial     | Cal Due          |
|-----------|-----------|---------------------|----------------------------------------|------------|------------------|
| WRLE03204 | EM-6917B  | Electro-Metrics     | Biconicalog Periodic                   | 102        | 30-May-13        |
| WRLE11146 | 85650A    | Hewlett-Packard     | Quasi-Peak Adapter                     | 2811A01299 | 04-Mar-14        |
| WRLE03295 | 85662A    | Hewlett-Packard     | Analyzer Display                       | 2349A06144 | 22-Apr-13        |
| WRLE02689 | 8566B     | Hewlett-Packard     | Spectrum Analyzer                      | 2416A00321 | 22-Apr-13        |
| WRLE02670 | 8447D     | Hewlett-Packard     | Preamplifier                           | 2443A03954 | Code B 20-Jan-14 |
| WRLE10527 | SL18B4020 | Phase One Microwave | Preamplifier 1 – 18 GHz                | 0001       | Code B 23-Jan-14 |
| WRLE02075 | 3115      | EMCO                | Ridge Guide Ant. 1-18 GHz              | 9001-3275  | 24-Feb-14        |
| WRLE10863 | N/A       | TÜV SÜD America Inc | Test Companion Software Version 3.4.71 | N/A        | Code Y           |

### Test limit

| Fundamental Frequency (MHz) | Field strength of fundamental mV/m | Field strength of harmonics $\mu$ V/m |
|-----------------------------|------------------------------------|---------------------------------------|
| 902-928                     | 50                                 | 500                                   |

Field strength limits are specified at a distance of 3 meters. The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except for the frequency bands above 1000 MHz. As shown in §15.35(b), for frequencies above 1000 MHz, the field strength limits in paragraphs (a) and (b) of this section are based on average limits. However, the peak field strength of any emission shall not exceed the maximum permitted average limits specified above by more than 20 dB under any condition of modulation.

Radiated emissions from the EUT are measured in the frequency range of 30 to 1000 MHz using a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with a 120 kHz / 6 dB bandwidth and quasi-peak detection and measurements above 1000 MHz are made with a 1 MHz RBW/VBW / 6 dB bandwidth and peak detection, 1 MHz RBW/ 10 Hz VBW for average detection. Table top equipment is placed on a non-conductive support 80 cm above the ground plane. Interface cables that are closer than 40 centimeters to the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators/testers (if used in this test) are routed through the center of the table and to a screen room located outside the test area. The antenna is positioned 3, 10 or 30 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT is rotated 360 degrees. The transmitter is rotated through 3 orthogonal axes to determine worst case.

### Test Data

see next page

### Measurement summary for limit1: FCC 15.249 <1GHz 902-928 3m (Qp)

| FREQ        | LEVEL (dBuV) | CABLE / ANT / PREAMP / ATTEN (dB) | FINAL (dBuV / m) | POL / HGT / AZ (m)(DEG) | FINAL (mV/m) | LIMIT (mV/m) |
|-------------|--------------|-----------------------------------|------------------|-------------------------|--------------|--------------|
| 915.384 MHz | 46.86 Qp     | 3.52 / 28.45 / 0.0 / 0.0          | 78.83            | V / 1.19 / 2            | 8.74         | 50           |
| 909.015 MHz | 76.46 Qp     | 3.51 / 28.3 / 30.4 / 0.0          | 77.87            | V / 1.20 / 6            | 7.82         | 50           |
| 920.85 MHz  | 75.26 Qp     | 3.53 / 28.57 / 30.4 / 0.0         | 76.96            | V / 1.14 / 8            | 7.04         | 50           |

Tx on, determine worst case orientation

DUT in dielectric fluid, 1/2" from bucket wall

DUT and its antenna vertical

|             |          |                          |       |              |        |     |
|-------------|----------|--------------------------|-------|--------------|--------|-----|
| 915.384 MHz | 46.86 Qp | 3.52 / 28.45 / 0.0 / 0.0 | 78.83 | V / 1.19 / 2 | -15.17 | n/a |
|-------------|----------|--------------------------|-------|--------------|--------|-----|

DUT and its antenna horizontal

maximized

|             |          |                          |       |               |        |     |
|-------------|----------|--------------------------|-------|---------------|--------|-----|
| 915.384 MHz | 45.68 Qp | 3.52 / 28.45 / 0.0 / 0.0 | 77.65 | H / 1.00 / 64 | -16.35 | n/a |
|-------------|----------|--------------------------|-------|---------------|--------|-----|

DUT and its antenna vertical for rest of test

### Measurement summary for limit1: FCC 15.209 >1GHz 3m av (Av)

| FREQ      | LEVEL (dBuV) | CABLE / ANT / PREAMP / ATTEN (dB) | FINAL (dBuV / m) | POL / HGT / AZ (m)(DEG) | FINAL (μV/m) | LIMIT (μV/m) |
|-----------|--------------|-----------------------------------|------------------|-------------------------|--------------|--------------|
| 4.577 GHz | 46.75 Av     | 8.62 / 32.44 / 43.93 / 0.0        | 43.88            | V / 1.10 / 342          | 156          | 500          |
| 4.545 GHz | 46.55 Av     | 8.59 / 32.39 / 43.97 / 0.0        | 43.56            | V / 1.10 / 345          | 151          | 500          |
| 2.746 GHz | 51.09 Av     | 6.24 / 29.09 / 43.66 / 0.0        | 42.76            | V / 1.00 / 0            | 137          | 500          |
| 4.604 GHz | 43.25 Av     | 8.65 / 32.49 / 43.9 / 0.0         | 40.48            | V / 1.10 / 336          | 106          | 500          |
| 5.492 GHz | 39.78 Av     | 9.55 / 33.89 / 43.12 / 0.0        | 40.1             | V / 1.00 / 0            | 101          | 500          |
| 2.763 GHz | 46.8 Av      | 6.26 / 29.13 / 43.68 / 0.0        | 38.5             | V / 1.00 / 353          | 84           | 500          |
| 2.727 GHz | 45.38 Av     | 6.22 / 29.05 / 43.64 / 0.0        | 37.01            | V / 1.00 / 0            | 70           | 500          |
| 3.661 GHz | 47.1 Pk      | 7.39 / 31.51 / 43.6 / 0.0         | 42.4             | V / 2.00 / 0            | 132          | 500          |

### Measurement summary for limit2: FCC 15.209 >1GHz 3m pk (Pk)

| FREQ      | LEVEL (dBuV) | CABLE / ANT / PREAMP / ATTEN (dB) | FINAL (dBuV / m) | POL / HGT / AZ (m)(DEG) | FINAL (μV/m) | LIMIT (μV/m) |
|-----------|--------------|-----------------------------------|------------------|-------------------------|--------------|--------------|
| 4.577 GHz | 52.1 Pk      | 8.62 / 32.44 / 43.93 / 0.0        | 49.23            | V / 1.10 / 342          | 289          | 5000         |
| 4.545 GHz | 52.15 Pk     | 8.59 / 32.39 / 43.97 / 0.0        | 49.16            | V / 1.10 / 345          | 287          | 5000         |
| 4.604 GHz | 50.95 Pk     | 8.65 / 32.49 / 43.9 / 0.0         | 48.18            | V / 1.10 / 336          | 256          | 5000         |
| 5.492 GHz | 47.25 Pk     | 9.55 / 33.89 / 43.12 / 0.0        | 47.57            | V / 1.00 / 0            | 239          | 5000         |
| 2.746 GHz | 54.9 Pk      | 6.24 / 29.09 / 43.66 / 0.0        | 46.57            | V / 1.00 / 0            | 213          | 5000         |
| 2.763 GHz | 51.65 Pk     | 6.26 / 29.13 / 43.68 / 0.0        | 43.35            | V / 1.00 / 353          | 147          | 5000         |
| 3.661 GHz | 47.1 Pk      | 7.39 / 31.51 / 43.6 / 0.0         | 42.4             | V / 2.00 / 0            | 132          | 5000         |
| 2.727 GHz | 49.2 Pk      | 6.22 / 29.05 / 43.64 / 0.0        | 40.83            | V / 1.00 / 0            | 110          | 5000         |

End scan 30 MHz - 10 GHz

## Spurious Radiated Emissions 30 - 9300 MHz

### FCC 15.249(d), IC RSS-210 A2.9(b)

#### Test summary

The requirements are: ■ - MET □ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.4 2003, clause 8.2.3, 8.2.4.

No spurious emissions were detected within 10 dB of the limit.

#### Test limits

Emissions radiated outside of the specified frequency bands, except for harmonics, shall be attenuated by at least 50 dB below the level of the fundamental or to the general radiated emission limits in §15.209, whichever is the lesser attenuation.

#### 15.209

| 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                        |

All measurements made at 3 meters. 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. Radiated emissions from the EUT are measured in the frequency range of 30 to 1000 MHz using a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with a 120 kHz / 6 dB bandwidth and quasi-peak detection and measurements above 1000 MHz are made with a 1 MHz RBW/VBW / 6 dB bandwidth and peak detection, 1 MHz RBW/ 10 Hz VBW for average detection. Table top equipment is placed on a non-conductive support 80 cm above the ground plane. Interface cables that are closer than 40 centimeters to the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators/testers (if used in this test) are routed through the center of the table and to a screen room located outside the test area. The antenna is positioned 3, 10 or 30 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT is rotated 360 degrees.

#### Test location

■ - Wild River Lab Large Test Site (Open Area Test Site)

#### Test distance

■ - 3 meters

#### Test Equipment

| TUV ID    | Model     | Manufacturer        | Description                            | Serial     | Cal Due          |
|-----------|-----------|---------------------|----------------------------------------|------------|------------------|
| WRLE03204 | EM-6917B  | Electro-Metrics     | Biconicalog Periodic                   | 102        | 30-May-13        |
| WRLE11146 | 85650A    | Hewlett-Packard     | Quasi-Peak Adapter                     | 2811A01299 | 04-Mar-14        |
| WRLE03295 | 85662A    | Hewlett-Packard     | Analyzer Display                       | 2349A06144 | 22-Apr-13        |
| WRLE02689 | 8566B     | Hewlett-Packard     | Spectrum Analyzer                      | 2416A00321 | 22-Apr-13        |
| WRLE02670 | 8447D     | Hewlett-Packard     | Preamplifier                           | 2443A03954 | Code B 20-Jan-14 |
| WRLE10527 | SL18B4020 | Phase One Microwave | Preamplifier 1 – 18 GHz                | 0001       | Code B 23-Jan-14 |
| WRLE02075 | 3115      | EMCO                | Ridge Guide Ant. 1-18 GHz              | 9001-3275  | 24-Feb-14        |
| WRLE10863 | N/A       | TÜV SÜD America Inc | Test Companion Software Version 3.4.71 | N/A        | Code Y           |

Cal Code B = Calibration verification performed internally.

**Test data** No spurious emissions detected within 10 dB of the limit.

## Receiver Radiated Emissions 30 - 9300 MHz

### FCC 15.109, IC RSS Gen Section 6

#### Test summary

The requirements are: ■ - MET □ - NOT MET

Testing was performed in accordance with the test procedure of ANSI C63.4 2003, clause 8.2.3, 8.2.4.

No receiver emissions were detected.

#### Test limits 15.109

| 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                        |

All measurements made at 3 meters. 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. Radiated emissions from the EUT are measured in the frequency range of 30 to 1000 MHz using a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with a 120 kHz / 6 dB bandwidth and quasi-peak detection and measurements above 1000 MHz are made with a 1 MHz RBW/VBW / 6 dB bandwidth and peak detection, 1 MHz RBW/ 10 Hz VBW for average detection. Table top equipment is placed on a non-conductive support 80 cm above the ground plane. Interface cables that are closer than 40 centimeters to the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators/testers (if used in this test) are routed through the center of the table and to a screen room located outside the test area. The antenna is positioned 3, 10 or 30 meters horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 meters, measurement scans are made with both horizontal and vertical antenna polarizations and the EUT is rotated 360 degrees.

#### Test location

■ - Wild River Lab Large Test Site (Open Area Test Site)

#### Test distance

■ - 3 meters

#### Test Equipment

| TUV ID    | Model     | Manufacturer        | Description                            | Serial     | Cal Due          |
|-----------|-----------|---------------------|----------------------------------------|------------|------------------|
| WRLE03204 | EM-6917B  | Electro-Metrics     | Biconicalog Periodic                   | 102        | 30-May-13        |
| WRLE11146 | 85650A    | Hewlett-Packard     | Quasi-Peak Adapter                     | 2811A01299 | 04-Mar-14        |
| WRLE03295 | 85662A    | Hewlett-Packard     | Analyzer Display                       | 2349A06144 | 22-Apr-13        |
| WRLE02689 | 8566B     | Hewlett-Packard     | Spectrum Analyzer                      | 2416A00321 | 22-Apr-13        |
| WRLE02670 | 8447D     | Hewlett-Packard     | Preamplifier                           | 2443A03954 | Code B 20-Jan-14 |
| WRLE10527 | SL18B4020 | Phase One Microwave | Preamplifier 1 – 18 GHz                | 0001       | Code B 23-Jan-14 |
| WRLE02075 | 3115      | EMCO                | Ridge Guide Ant. 1-18 GHz              | 9001-3275  | 24-Feb-14        |
| WRLE10863 | N/A       | TÜV SÜD America Inc | Test Companion Software Version 3.4.71 | N/A        | Code Y           |

Cal Code B = Calibration verification performed internally.

#### Test data

No receiver emissions were detected.

## 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 = 345.227 kHz

#### Test location

☒ - Wild River Lab Large Test Site (Open Area Test Site)

☐ - Wild River Lab Small Test Site (Open Area Test Site)

#### Test equipment

| TUV ID    | Model Number | Manufacturer | Description       | Serial Number | Cal Due   |
|-----------|--------------|--------------|-------------------|---------------|-----------|
| WRLE10435 | E4440A       | Agilent      | Spectrum Analyzer | MY44304483    | 20-Nov-14 |

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

#### Test limit

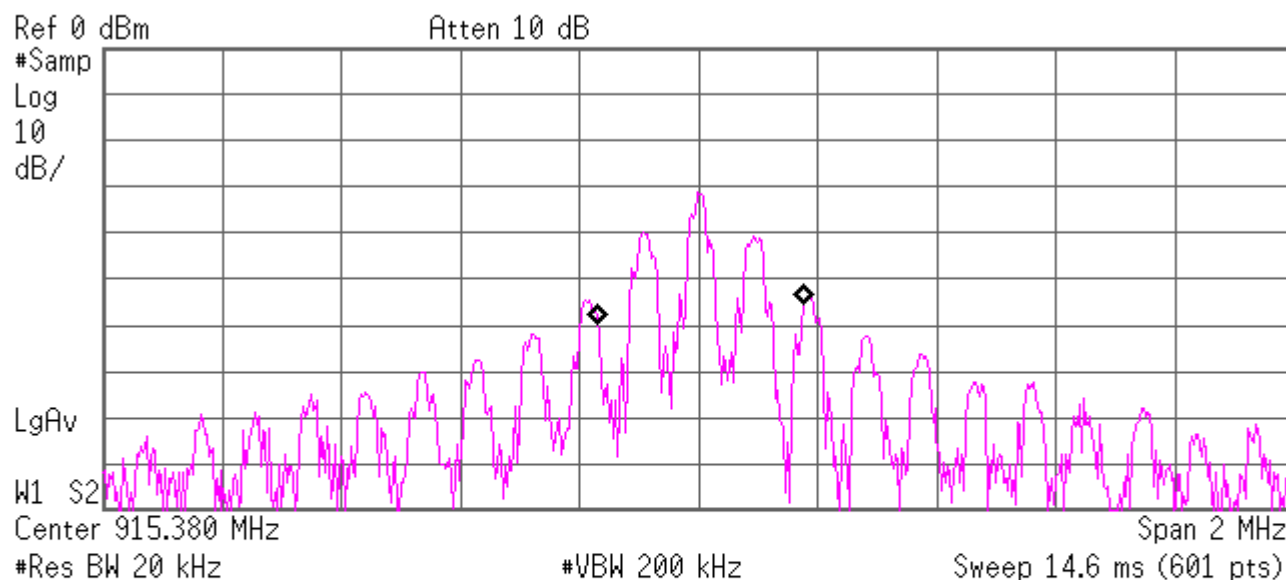
No limit specified

#### Test data

See following pages

Agilent 14:55:00 Mar 25, 2014

L



Occupied Bandwidth  
345.5227 kHz

Occ BW % Pwr 99.00 %  
x dB -26.00 dB

Transmit Freq Error 3.902 kHz  
x dB Bandwidth 391.968 kHz\*

## Conducted Emissions - AC Power Lines

FCC 15.207(a), IC RSS-Gen 7.2.4

### Test summary

The requirements are: ☐ - MET ☒ - NOT APPLICABLE

Testing was performed in accordance with the test procedure of ANSI C63.4 2003, clause 7.2

### Test location

☐ - Wild River Lab Large Test Site (Open Area Test Site)

☐ - Wild River Lab Small Test Site (Open Area Test Site)

### Test limits, dB $\mu$ V

| Frequency<br>(MHz) | dB $\mu$ V<br>Quasi Peak | dB $\mu$ V<br>Average |
|--------------------|--------------------------|-----------------------|
| 0.15 - 0.5         | 66 - 56*                 | 56 - 46*              |
| 0.5 - 5            | 56                       | 46                    |
| 5 - 30             | 60                       | 50                    |

\*Decreases with the logarithm of the frequency

Conducted emissions on the 50 Hz and/or 60 Hz power interface of the EUT are measured in the frequency range of 150 kHz to 30 MHz. The measurements are performed using a receiver, which has CISPR characteristic bandwidth (9 kHz resolution bandwidth) and quasi-peak/average detection, and a Line Impedance Stabilization Network (LISN), with 50  $\Omega$ /50  $\mu$ H (CISPR 16) characteristics. Table top equipment is placed on a non-conducting table 80 centimeters above the floor and is positioned 40 centimeters from the vertical ground plane (wall) of the screen room. In some cases, a pre-scan using a spectrum analyzer is initially performed on the units comprising the system under test to locate the highest emissions. Conducted emissions were measured on the Communication Link Controller, which powers the transceiver over Ethernet.

### Test data

Battery operated implantable – not applicable

### Equipment Under Test (EUT) Test Operation Mode:

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

- ☐ - Standby
- ☐ - Test program (H - Pattern)
- ☐ - Test program (color bar)
- ☐ - Test program (customer specific)
- ☐ - Practice operation
- ☒ - Normal operating mode – implantable transmitter tested in body simulator.

### 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:

- ☒ Implantable transmitter tested in body simulator.
- ☐ 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: 25 March 2014  
Condition of EUT: Normal  
Testing Start Date: 25 March 2014  
Testing End Date: 26 March 2014

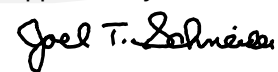
**TÜV SÜD AMERICA INC**

Tested by:



Greg Jakubowski  
Senior EMC Technician

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  
 Address: 119 14<sup>th</sup> St.  
St. Paul, MN 55112  
 Contact: Luke Strawn Position: Electrical Engineering Manager  
 Phone: 651-414-5493 Fax: \_\_\_\_\_  
 E-mail Address: lstrawn@datasci.com

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

EUT Description PhysioTel Digital Implant  
 EUT Name M-Series M-11 Implants  
 Model No.: Multiple (recorded on data sheet) Serial No.: Multiple (recorded on data sheet)  
 Product Options: M-11, M-01, M10, M00  
 Configurations to be tested: M-11 in constant output mode

### 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: \_\_\_\_\_  
 Modifications made during test: \_\_\_\_\_

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

- |                                                                                                                     |                                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> EMC Directive 2004/108/EC (EMC)<br>Std: _____                                              | <input checked="" type="checkbox"/> FCC: Class <input type="checkbox"/> A <input checked="" type="checkbox"/> B Part _____ |
| <input type="checkbox"/> Machinery Directive 89/392/EEC (EMC)<br>Std: _____                                         | <input type="checkbox"/> VCCI: Class <input type="checkbox"/> A <input type="checkbox"/> B                                 |
| <input type="checkbox"/> Medical Device Directive 93/42/EEC (EMC)<br>Std: _____                                     | <input type="checkbox"/> BSMI: Class <input type="checkbox"/> A <input type="checkbox"/> B (Separate Report)               |
| <input type="checkbox"/> Vehicle Directive - 2004/104/EC (EMC)<br><input type="checkbox"/> Other Vehicle Std: _____ | <input type="checkbox"/> Canada: Class <input type="checkbox"/> A <input type="checkbox"/> B                               |
| <input type="checkbox"/> FDA Reviewers Guidance for Premarket Notification Submissions (EMC)                        | <input type="checkbox"/> Australia: Class <input type="checkbox"/> A <input type="checkbox"/> B                            |
|                                                                                                                     | <input type="checkbox"/> Other: _____                                                                                      |
|                                                                                                                     | <input type="checkbox"/> 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).

|                                                                                                                                                                                                                                                                  |                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| <input type="checkbox"/> Attestation of Compliance (AoC)*                                                                                                                                                                                                        | <input type="checkbox"/> EMC Certification (used with Octagon Mark)* |
| <input type="checkbox"/> 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) <input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III<br>(Press F1 when field is selected to show additional information on Protection Class.) |                                                                      |
| <input type="checkbox"/> FCC / TCB Certification                                                                                                                                                                                                                 | <input type="checkbox"/> Taiwan Certification                        |
| <input type="checkbox"/> Industry Canada / FCB Certification                                                                                                                                                                                                     | <input type="checkbox"/> Korean Certification                        |
| <input type="checkbox"/> 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: \_\_\_\_\_ Width: \_\_\_\_\_ Height: \_\_\_\_\_ 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: 3.0V DC (If battery powered, make sure battery life is sufficient to complete testing.)  
Battery \_\_\_\_\_

# of Phases: \_\_\_\_\_

Current (Amps/phase(max)): \_\_\_\_\_ Current (Amps/phase(nominal)): \_\_\_\_\_

Other \_\_\_\_\_

### Other Special Requirements

### Typical Installation and/or Operating Environment

(ie. Hospital, Small Business, Industrial/Factory, etc.)  
Lab Equipment/ Controlled Environment

### 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                     |
| <b>EXAMPLE:</b><br>RS232       | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 2   | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Foil over braid | Coaxial        | Metallized 9-pin D-Sub | Characteristic Impedance  | 6         | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |
|                                | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |     | <input type="checkbox"/>            | <input type="checkbox"/> |                 |                |                        |                           |           | <input type="checkbox"/>            | <input type="checkbox"/> |

**EUT Software.**

Description:

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. Implant will be commanded by external hardware (CLC Version 0.1.24) to transmit at a constant output for ~ 4 minutes at a time.
- 2.
- 3.

| Description | Model # | Serial # | FCC ID # |
|-------------|---------|----------|----------|
| M-11 F1     | 43265   | 726698   |          |
| M-11 F2     | 43266   | 726702   |          |



## 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> |
|--------------------|----------------|-----------------|-----------------|
| CLC                |                |                 |                 |
| TRX                |                |                 |                 |
| Router             |                |                 |                 |
| Switch             |                |                 |                 |

### Oscillator Frequencies

| <i>Manufacturer</i> | <i>Frequency</i> | <i>Derived Frequency</i> | <i>Component # / Location</i> | <i>Description of Use</i> |
|---------------------|------------------|--------------------------|-------------------------------|---------------------------|
|                     |                  |                          |                               |                           |
|                     |                  |                          |                               |                           |
|                     |                  |                          |                               |                           |
|                     |                  |                          |                               |                           |
|                     |                  |                          |                               |                           |
|                     |                  |                          |                               |                           |

### Power Supply

| <i>Manufacturer</i> | <i>Model #</i> | <i>Serial #</i> | <i>Type</i>                                                                                                                        |
|---------------------|----------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------|
|                     |                |                 | <input type="checkbox"/> Switched-mode: (Frequency) _____<br><input type="checkbox"/> Linear <input type="checkbox"/> Other: _____ |
|                     |                |                 | <input type="checkbox"/> Switched-mode: (Frequency) _____<br><input type="checkbox"/> Linear <input type="checkbox"/> Other: _____ |

### Power Line Filters

| <i>Manufacturer</i> | <i>Model #</i> | <i>Location in EUT</i> |
|---------------------|----------------|------------------------|
|                     |                |                        |
|                     |                |                        |

**EMC Test Plan and Constructional Data Form****Critical EMI Components (Capacitors, ferrites, etc.)**

| <i>Description</i> | <i>Manufacturer</i> | <i>Part # or Value</i> | <i>Qty</i> | <i>Component # / Location</i> |
|--------------------|---------------------|------------------------|------------|-------------------------------|
|                    |                     |                        |            |                               |
|                    |                     |                        |            |                               |
|                    |                     |                        |            |                               |
|                    |                     |                        |            |                               |

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

PLEASE ENTER NAMES BELOW (INSERT ELECTRONIC SIGNATURE IF POSSIBLE)

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

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Customer authorization to perform tests  
according to this test plan.

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Date

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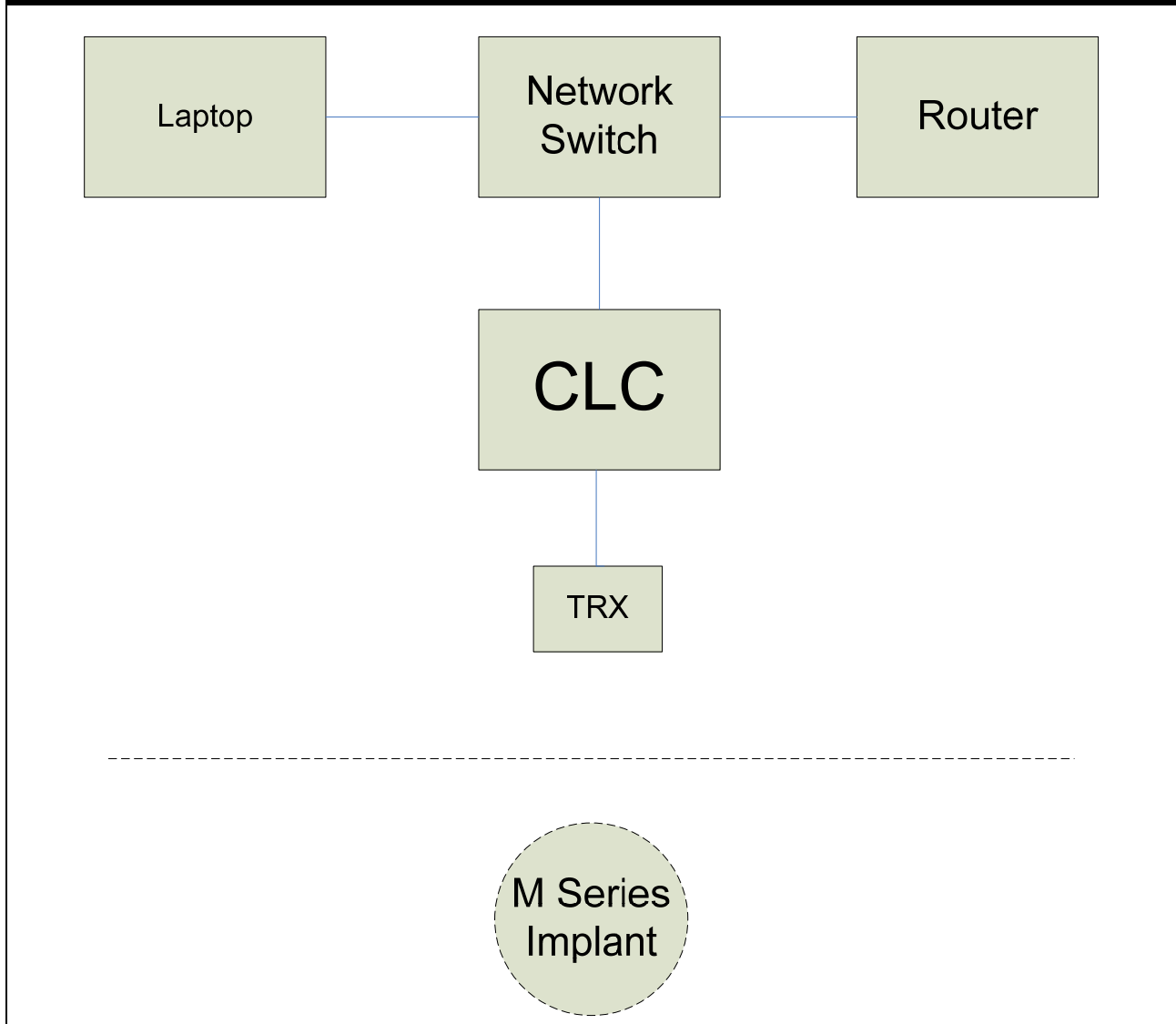
Test Plan/CDF Prepared By (please print)

---

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.

**Authorization Signatures**

\_\_\_\_\_  
Customer authorization to perform tests  
according to this test plan.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Test Plan/CDF Prepared By (please print)

\_\_\_\_\_  
Date