Murandi
Communications Ltd.
Innovative Radio Frequency Solutions

Spacelabs
Acceptance Test Plan for the Medical Telemetry Transmitter
Rev 6 – May 16, 2003

1. Table of Contents

2. Reference Documents

1. Spacelabs, Medical Ultraview Digital Telemetry Product Line Requirements for Patient-Worn Wireless Communication Sub-System, Draft – Jun 14, 2001.
2. Spacelabs Technical Specifications for the Medical Telemetry Transmitter, Rev 6, April 2003

3. Revision Notes

July 13,2001	Document changed from Draft to Rev1.
July 13,2001	Added additional testing to Frequency Deviation
July 13,2001	Added comment to Humidity Testing.
July 16,2001	Added specification for Data Rate test
July 16,2001	Included Delay Spread as part of Data Rate test
July 16,2001	Added Sec 5.4.2 System Integration Test
July 16,2001	Added Sec 6.6 Channel Selection Switch
Aug 21,2001	Changed document to Rev2 from Rev1.
Aug 21,2001	Added Sec 6.7 Lead Fault LED's
Aug 21,2001	Added Test for Channelization Sec.5.2.1
Aug 21,2001	Included note on Storage Temperature Sec. 5.3.
Jan 21,2002	Changed document to Rev3 from Rev2.
Jan 21,2002	Changed Sec 5.2.2 Radiated Spurious Emissions, Measurement Method grammar.
Dec 7, 2002	Changed document to Rev 4
Dec 7, 2002	Modified structure of document to match the updated Technical Specification. Section 6 was split into sections 6 to 8
Dec 7, 2002	Modified the Channelization method in section 5.2.1 to test invalid channels.
Dec 7, 2002	Modified the Data Rate test in section 5.2.1 by setting the failure limit to a 10% decrease in demodulated signal amplitude.
Dec 7, 2002	Modified Transmit Power test in section 5.2.2 to be performed with a modulated carrier.
Dec 7, 2002	Modified the Transmit Emissions test in section 5.2.2 to include the out of band measurements and to indicate the spectrum analyzer settings.
Dec 7, 2002	Added the test method for the Demodulated Pulse Width Jitter to section 5.2.2
Dec 7, 2002	Indicated the RBW of 1 MHz for the spectrum analyzer for the Absolute Delay measurement in section 5.2.2
Dec 7, 2002	Describe the test methods for the humidity, shock, vibration, altitude, ESD, EMF, and electromagnetic compatibility specifications in section 5.3
Dec 7, 2002	Section 5.4 was modified by removing subsection 5.4.2 for the Integrated Systems test. The Safety test was removed to match the change in the Technical Specification.
Dec 7, 2002	Section 6.1 was modified to describe all the tests required to verify the Low Battery Indicator.
Dec 7, 2002	Section 6.2 was modified to describe all the tests required to verify the Record Switch.
Dec 7, 2002	Section 6.3 was modified to describe all the tests required to verify the Channel Selection Switches.
Dec 7, 2002	Section 6.4 was modified to describe all the tests required to verify the Lead Fault Indicator LED's.
Dec 7, 2002	Section 7 was added to describe the verification of the Data Frame structure.
Dec 7, 2002	In section 8.3.1 the VCC_ECG pin test method was revised to include the specified current and voltage variation.
Dec 7, 2002	In section 8.3.2 the test method for the pins were revised to include the relation with the data frame.
Dec 7, 2002	In section 8.3.3 the test method for the pins were revised to include the relation with the data frame pulse widths. VREF was modified to describe the change from a voltage reference output to a voltage reference input

Dec 7, 2002	In section 8.3.4 the test method for the pins was revised to include the relation with the data frame.
Dec 7, 2002	In section 8.4 the test methods were revised to include functional requirement of the lines. Rver was added.
Feb 10, 2003	Changed document to Rev 5
Feb 10, 2003	Modified sections 8.3.1 to 8.3.3 due to the change in the ECG connectors and their pin-outs. The effect on the connector pin-outs was to reverse pins 1 to 5 and to reverse pins 6 to 9.
May 16, 2003	Changed document to Rev 6
May 16, 2003	Modified section 8.3 due to the changes in the Technical Specification that merged all the three ECG connectors into one.
May 16, 2003	Modified section 8.4 due to the changes in the Technical Specification that removed the DataSelect test point. The circuitry used to select between internal and external modulation data is now located within the test fixture.

4. Introduction

Specifications for the Medical Telemetry Transmitter are described in the Technical Specification. This document will describe how compliance with the technical specifications will be determined. This document together with the General Technical Specifications make up the Acceptance Test Specification and form the basis of determining whether or not the Medical Telemetry Transmitter meets the contractual obligations.

Measurement uncertainty will be added to the specification limits listed in the Technical Specification in order to determine the test limits.

5. Technical Specifications

5.1 Physical

Subject	**Measurement Method**	**Comments**
Housing and Mount	No test definition necessary. By inspection	
Weight	Weigh the RF board alone, fully populated and ensure it meets specification.	
Board Material	No test definition necessary. By inspection	
Board Area	No test definition necessary. By inspection	
Minimum Track Size	No test definition necessary. By inspection	
Minimum Track Spacing	No test definition necessary. By inspection	
Minimum Via Drill Size (After Plating)	No test definition necessary. By inspection	

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Subject	Measurement Method	Comments
Drill Accuracy	No test definition necessary. By inspection	
Standard Component	No test definition necessary. By inspection	
Maximum Component Height	No test definition necessary. By inspection	
ICT	No test definition necessary. By inspection	

5.2 Electrical Performance

5.2.1 General

Subject	Measurement Method	Comments
Frequency Range	No test definition necessary. Tested in conjunction with Maximum Transmit Power	
Modulation	No test definition necessary. By demonstration.	
Access Method	No test definition necessary. By demonstration.	
Channelization	Select a channel input by adjusting the DIP switch settings, power up the UUT and verify correct channel programming for all channels between 0 and 4095. Verify the RF output is disabled for all invalid channels.	The test will done at the band edges and at a random selection of valid and invalid channel settings.
Carrier Frequency Step Size	No test definition necessary. By demonstration.	
Carrier Stability	Transmit CW on mid channel and measure the output frequency with a spectrum analyzer, set to an appropriate setting. Verify that the frequency is within specification. The measurements are to be performed: • Over temperatures of 10°C, 30°C and 50°C. • Over the specified supply voltage variation The UUT should stabilize at the set temperature for 30 minutes before making the measurements.	
Channel Switching Time	With TX chain active program the synthesizer to switch between the low and high RF channels and back. Set the spectrum analyzer to the appropriate RF channel. Using the FM demodulator in zero span with a RBW of 1 MHz or greater, trigger the spectrum analyzer using the Synthesizer load enable, and verify that the output frequency is within +/-2ppm, in less than the specified time.	

Subject	Measurement Method	Comments
Frequency Deviation	Program the transmitter to transmit on mid channel. Apply positive and negative logic voltages to the TXData signal. Measure the change in RF output frequency using a spectrum analyzer in an appropriate setting, and ensure that it is within specification. The measurements are to be performed: • Over temperatures of 10°C, 30°C and 50°C. • Over the specified supply voltage variation The UUT should stabilize at the set temperature for 30 minutes before making the measurements.	
Data Rate	On mid channel input a baseband signal into the transmitter. Demodulate the RF carrier with a spectrum analyzer set to 100 kHz RBW. Increase the frequency of modulation up from DC. Note the frequency at which the amplitude of the demodulated signal decreases by 10%. Verify the data rate requirement was reached.	
Frame Length	No test necessary. By observation.	
Power Supply Voltages	Tested when testing Maximum Transmit Power and Frequency Deviation.	
Power Consumption	Put the UUT in the typical operating mode and measure current with an ammeter. Verify that the specified limits are met.	
Turn On Time Cold Start	By design the Transmitter hardware is expected to power up and be programmed such that data can be transmitted, well within specification.	

5.2.2 Transmitter Specific

Subject	Measurement Method	Comments
Transmit Power Conducted (50 Ω Load)	With the radio transmitting on a single frequency measure the maximum output power into a spectrum analyzer set to 1 MHz RBW. Verify the output power is within specification. The measurements are to be performed • Over the temperatures of 10° C, 30° C, and 50° C • Over the specified supply voltage variation • On Low, Mid and High channels.	
Transmit Emissions -conducted 50Ω load In band Adj. Channel Alt Channel Spurious(in band) Out of band	Using the “Adjacent Channel Measurement” function available on the Anritsu MS2602 spectrum analyzer, measure the transmit emissions in the Adjacent and Alternate channels while operating with the appropriate data rate and deviation. Measurements are to be made at the RF Antenna port. Verify that the emissions are within specified limits using a resolution bandwidth of 1 kHz and a channel bandwidth of 16 kHz for narrowband and 32 kHz for wideband. The detector on the spectrum analyzer should be set to ‘Peak’ to accurately measure the carrier power, and then 3 dB subtracted from the measurement to convert to the equivalent of a “sample” mode measurement. The in band spurious measurement is to be done with a 30 kHz RBW. The out of band measurements are to be measured with the following settings: CISPR BW below 1 GHz 1 MHz RBW above 1 GHz	

Subject	Measurement Method	Comments
Radiated Spurious Emissions	Set up the radio to transmit on low, mid and high channel, at a duty cycle and frame length specified in the Technical Specification. Terminate the RF antenna connector with a 50Ω load. a) Using a 100 kHz RBW, measure the emissions from 30 MHz to 1 GHz with appropriate conversion factors to convert to CISPR average measurements, path loss, and the effective receive antenna gain at various frequencies. Verify that all emissions in the restricted band meet and exceed specifications. b) Using a 1 MHz RBW, measure the average and peak emissions from 1 GHz to the 10^{th} harmonic with appropriate conversion factors to account for path loss and effective antenna gain at various frequencies. Verify that all emissions in the restricted band meet and exceed specifications.	A pre-scan test will be performed at Murandi. The final test will be performed at an approved FCC site
Demodulated Pulse Width Jitter	Tie the ECG vector inputs to 2.0V and demodulate the conducted RF output with a modulation analyzer that is set to a 100 kHz low pass filter. Feed the audio signal from the modulation analyzer into an oscilloscope. Trigger the oscilloscope off of the frame synchronization pulse and observe the maximum jitter on the falling edge of the vector pulse widths. The oscilloscope should be set to 1 second persistence and a 2 sweep average. Observe the maximum jitter over a 10 second period and verify the limit is met 9 times out of 10.	The 2 sweep average accounts for the filtering the receiver would perform on the ECG data.
Absolute Delay	Input a 500 Hz external baseband signal into the RF modulation input. Using a Spectrum Analyser set to 1 MHz RBW, demodulate the RF into the time domain. Trigger the SA from the base band signal and measure the delay to the point where the demodulated signal has settled to within 10% of its final value.	

5.3 Environmental

Subject	Measurement Method	Comments
Operating Temperature	Tested when testing Carrier Stability, Frequency Deviation and Maximum Transmit Power.	
Storage Temperature	By design. Murandi will provide data sheets to confirm design meets specification.	Murandi will provide data sheets to confirm design meets specification. Components that do not meet specification will be highlighted.
Operating Relative Humidity	Operate the unit at the specified maximums for humidity and temperature for 3 hours and verify the requirements for carrier stability, frequency deviation, and maximum transmit power are met.	Spacelabs will do integrated product testing.
Storage Relative Humidity	Store the unit at the specified maximums for humidity and temperature for 24 hours. Operate the unit within the normal operating range and verify the requirements for carrier stability, frequency deviation, and maximum transmit power are met.	Spacelabs will do integrated product testing.
Shock Resistance	Standard surface mountable components will be used throughout the design. Leaded parts, if any, will be securely fastened. Where practical, specifications will be checked to ensure that parts meet the shock and vibration specifications in the technical specification. Perform the drop test within fully assembled plastics and verify the demodulated waveform recovers within 5 seconds.	Spacelabs will do integrated product testing.
Vibration Resistance	Place the unit under the specified maximum for vibrations for the required amount of time and verify the demodulated waveform recovers within 5 seconds.	Spacelabs will do integrated product testing.
Altitude	Use an altitude chamber to simulate the maximum operating altitude and verify the unit meets the carrier stability, frequency deviation, and maximum transmit power. Place the unit under the simulated conditions for maximum storage altitude for 24 hours. Reduce the altitude to within the operating range and verify carrier stability, frequency deviation, and maximum transmit power specifications are met.	Spacelabs will do integrated product testing.

Subject	Measurement Method	Comments
ESD	Set the ESD gun to the appropriate levels and verify the operating and non-operating limits for conducted and over the air discharges. The test is to be done within the plastics.	Preliminary check will be done by Murandi and the final integrated product test will be done by SMI
EMF (radiated susceptability)	Generate the required field strength using a signal generator and dipole. The internal modulation of the signal generator can be set to the appropriate AM levels as specified. Sweep the generator over the specified range and verify the operating and non-operating limits.	Preliminary check will be done by Murandi. SMI will do the integrated product testing
Electromagnetic Compatibility	Generate the required magnetic field strength over the specified frequency range and verify the carrier stability, frequency deviation, and maximum transmit power specifications are met.	SMI will do the integrated product testing.

5.4 Other Requirements

Subject	Measurement Method	Comments
MTBF	As a general guideline, in order to ensure high reliability: • No device shall be operated at over 50% of its thermal rating under nominal operating conditions. • No device shall exceed its maximum thermal rating under worse case conditions	

6. User Interface

6.1 Low Battery Indicator

	Name	Measurement Method
1	**LED**	Reduce battery supply voltage until LED light begins flashing. Verify that voltage level is within the specifications. Verify the flash rate and duty cycle are within specification. Verify the LED is the desired color. Verify the current meets the specification.

6.2 Record Switch

	Name	Description
1	**SW3**	Verify that the record bit is cleared (status bit 32), inside the frame, by analyzing the baseband signal with a logic analyzer when the button is pressed. Verify the record bit is set when the button is released. The switch can be functionally verified with a patient monitor.

6.3 Channel Selection Switches

	Name	Description
1	**SW1_1**	Verify switch settings set transmitter to appropriate channel and that the correct channel number is inserted into the transmitted data frame. Can be functionally verified with a patient monitor.
2	**SW1_2**	See 1 above
3	**SW1_3**	See 1 above
4	**SW1_4**	See 1 above
5	**SW1_5**	See 1 above
6	**SW1_6**	See 1 above
7	**SW1_7**	See 1 above
8	**SW1_8**	See 1 above
9	**SW2_1**	See 1 above
10	**SW2_2**	See 1 above
11	**SW2_3**	See 1 above
12	**SW2_4**	See 1 above
13	**SW2_5**	Verify the appropriate unit type indicator is inserted into the transmitted data frame. Can be functionally verified with a patient monitor.
14	**SW2_6**	See 13 above
15	**SW2_7**	See 13 above
16	**SW2_8**	See 13 above

6.4 Lead Fault Indicator LED's

	Name	Description
1	**LED_RA**	Input a 5V logic low on the corresponding Lead Fault Logic interface line while also providing a 5V logic high on all remaining lines. Verify LED flashes accordingly. Verify the flash rate and duty cycle. Verify the LED color. Verify the current through the LED.

2	**LED_RL**	See 1 above
3	**LED_CH**	See 1 above
4	**LED_LL**	See 1 above
5	**LED_LA**	See 1 above

7. Structure of the Data Frame

Demodulate the RF carrier and use an oscilloscope or logic analyzer to capture 48 frames of data. Verify the data frame structure, timing and logic levels. Verify the proper control of the status bits, the pacer bit, and the pulse widths with relation to the applicable input lines. Note that these functions may be verified with other interface tests. The data frame structure can be functionally verified using a patient monitor.

8. Electrical Interface Specifications

8.1 RF Module to External Antenna

	Name	Measurement Method
1	**RF** (Antenna Feed)	Connect to Network Analyzer and measure the return loss. Verify that the performance is within specifications.
2	**GND** (Antenna Ground)	Measured in conjunction with above test.

8.2 Battery connector

	Name	Measurement Method
1	**BT1** (input)	Tested when testing Maximum Transmit Power.
2	**GND** (passive)	Tested when testing Maximum Transmit Power.

8.3 RF Module to Base Band Interface

8.3.1 ECG Interface (JP2)

	Name	Measurement Method
1	**RA** (input)	Input a High and a Low signal on this pin and use a logic analyzer to verify that the appropriate status bit is controlled correctly. The LED performance is verified with the Lead Fault Indicator LED test. To test the input impedance, insert a series resistor equal to the specified input impedance and verify that the decrease in voltage corresponds to Vdcload > ½ Vdcoc.
2	**Ch** (input)	Same test as RA.
3	**LA** (input)	Same test as RA.
4	**PACERF** (input)	Input a High and Low signal on this pin and verify the pacer bit is controlled correctly within the data frame. To test the input impedance, insert a series resistor equal to the specified input impedance and verify that the decrease in voltage corresponds to Vdcload > ½ Vdcoc.
5	**GND** (passive)	Verify low impedance to battery ground
6	**I** (input)	Input voltage values over the typical operating range and verify the pulse width within the data frame using an oscilloscope. Verify the operating range is met and the ratio of change in pulse width versus change in input voltage is met. To test the input impedance, insert a series resistor equal to the specified input impedance and verify that the decrease in voltage corresponds to Vdcload > ½ Vdcoc.
7	**III** (input)	Same test as I.
8	**AUX** (input)	Same test as I.
9	**RL** (input)	Same test as RA.
10	**LL** (input)	Same test as RA.
11	**VCC_ECG** (output)	Verify voltage is present and within specification with a resistive load that draws the specified current.
12	**GND** (passive)	Verify low impedance to battery ground
13	**VREF** (input)	To test the input impedance, insert a series resistor equal to the specified input impedance and verify that the decrease in voltage corresponds to Vdcload > ½ Vdcoc.
14	**II** (input)	Same test as I.
15	**IV** (input)	Same test as I.

8.3.2 SpO_2 Interface (JP4)

Pin	Name	Measurement Method
1	**SPO2** (input)	Input voltage values at over the typical operating range and verify the pulse width within the data frame using an oscilloscope. Verify the operating range is met and the ratio of change in pulse width versus change in input voltage is met. To test the input impedance, insert a series resistor equal to the specified input impedance and verify that the decrease in voltage corresponds to Vdcload > ½ Vdcoc.
2	**GND** (passive)	Verify low impedance to battery ground
3	**GND** (passive)	Verify low impedance to battery ground
4	**VCC5V** (output)	Measure the open circuit voltages and verify that Vout is within specification. To test the source impedance, terminate this pin with the specified source impedance and verify that Vload > ½ Voc.
5	**BT2** (output)	Verify direct connection to the battery.
6	**RECORDSW** (input)	Verify the proper control of the Record bit within the data frame with relation to this inputs logic. To test the input impedance, insert a series resistor equal to the specified input impedance and verify that the decrease in voltage corresponds to Vdcload > ½ Vdcoc.
7	**GND** (passive)	Verify low impedance to battery ground
8	**GND** (passive)	Verify low impedance to battery ground
9	**SPO2T1** (input)	Measure the open circuit voltages and verify that the Vout low and high are within specification. To test the source impedance, terminate this pin with the specified source impedance and verify that Vload > ½ Voc.
10	**SPO2T2** (input)	Measure the open circuit voltages and verify that the Vout low and high are within specification. To test the source impedance, terminate this pin with the specified source impedance and verify that Vload > ½ Voc.

8.4 Test and Manufacturing Test Points

	Name	Description
1	**GND** (passive)	Verify low impedance to battery ground
2	**ModOut** (output)	Measure the open circuit voltages and verify that the Vout low and high are within specification. To test the source impedance, terminate this pin with the specified source impedance and verify that Vload > ½ Voc. Tested in conjunction with the data frame verification.
3	**BT1** (input)	Verify low impedance to the positive terminal of the battery connector.
4	**BSLTX** (output)	Measure the open circuit voltages and verify that the Vout low and high are within specification. To test the source impedance, terminate this pin with the specified source impedance and verify that Vload > ½ Voc. Functionally verified when the microcontroller is programmed and the serial communication routine is performed.
5	**EXTMod** (input)	Verify the data present on this pin modulates the RF carrier. To test the input impedance, insert a series resistor equal to the specified input impedance and verify that the decrease in voltage corresponds to Vdcload > ½ Vdcoc.
6	**EnComm** (input)	Confirm the microcontroller enters communication mode with the setting of this pin. To test the input impedance, insert a series resistor equal to the specified input impedance and verify that the decrease in voltage corresponds to Vdcload > ½ Vdcoc. Functionally verified when the serial communication routine is performed.
7	**TEST** (input)	To test the input impedance, insert a series resistor equal to the specified input impedance and verify that the decrease in voltage corresponds to Vdcload > ½ Vdcoc. Functionally verified when the microcontroller is programmed.

8	**BSLRX** (input)	To test the input impedance, insert a series resistor equal to the specified input impedance and verify that the decrease in voltage corresponds to Vdcload > ½ Vdcoc. Functionally verified when the microcontroller is programmed and the serial communication routine is performed.
9	**RST** (input)	To test the input impedance, insert a series resistor equal to the specified input impedance and verify that the decrease in voltage corresponds to Vdcload > ½ Vdcoc. Functionally verified when the microcontroller is programmed.
10	**Rver** (passive)	Verify the impedance to ground depending on the board version.