

EXHIBIT B – Technical Report

FCC ID CM676A90343-WMTS

Measurement/Technical Report

Spacelabs Medical

Model 90343/90347 Digital Telemetry Transmitter

FCC ID: CM676A90343-WMTS

August 23, 2000

This report concerns (check one):		Original Grant <u>X</u>	Class II Change <u> </u>
Equipment Type: <u>Licensed Non-Broadcast Transmitter Worn on Body</u>		Rule Part: <u>47 CFR 95.1115</u>	
Note: <u>Part 95 Wireless Medical Telemetry Transmitter</u>			
Deferred grant requested per 47 CFR 0.457 (d)(1)(ii)?		Yes <u> </u> no <u>X</u>	
If yes, defer until:		<u> N/A </u> Date	
<u>Spacelabs Medical</u> agrees to notify the Commission by:		<u> N/A </u> Date	
of the intended date of announcement of the product so that the grant can be issued on that date.			
Report prepared by:		Northwest EMC, Inc. 22975 NW Evergreen Pkwy. Ste 400 Hillsboro, OR 97124 (503) 844-4066 Fax: (503) 844-3826	
Report No. SPAC0246			

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1.0 General Information

1.1 Product Description

Manufactured By.....Spacelabs Medical
Address.....15220 NE 40th Street, Redmond, WA 98073
Test Requested By: Steve Cantwell
Model.....Model 90343/90347 Digital Telemetry Transmitter
FCC ID..... CM676A90343-WMTS
Serial Number(s)347-001337
Date of Test.....August 23, 2000
Job Number SPAC0246

Prepared By:  Vicki Albertson, Technical Report and Documentation Manager		
Technical Review By:  Greg Kiemel, Director of Engineering	Approved By:  Dean Ghizzone, President	

1.1 Product Description - continued

This application is being submitted in support of an equipment authorization request for the Spacelabs Medical Model 90343 and 90347 Enhanced Digital Telemetry Transmitter (FCC ID CM676A90343-WMTS), in accordance with Part 95.1115 of the FCC rules for operation in the 608 to 614 MHz band. An application for this same device has also been submitted concurrently for authorization under Part 15.242 for operation in the 602 to 620 MHz band (reference FCC ID: CM676A90343-04). Both units are tuned in the factory, the only difference is that the EUT described in this application, will only operate in the 608 to 614 MHz band.

The Model 90343 is a multi-parameter biomedical telemetry transmitter that is used for the transmission of a patient's vital signs data, including the electrocardiogram (ECG), blood oxygen saturation (SpO₂), and non-invasive blood pressure (NIBP). This physiological data is encoded in a digital format and used to FSK-modulate a crystal controlled, RF carrier. This device is intended for use within the confines of medical facilities. It is not intended for off-premise vehicular use.

The Model 90347 transmitter is a lesser version of the 90343. It utilizes the same RF and ECG circuit boards, but lacks the SpO₂ circuit board and the NIBP interface, making it a singular parameter (ECG only) device.

This battery (9 volt alkaline type) powered UHF transmitter is worn by the patient. It operates on a 50 kHz system channel spacing. It utilizes unused UHF television channels from 608 to 614 MHz in accordance with 47 CFR 95.1115. The RF signal from this transmitter is radiated on one of the patient ECG lead wires, which, at a 3 meter distance, produces a field strength of approximately 64 millivolts per meter. . The allowable field strength for this class of device as authorized under the FCC Rules is 200 millivolts per meter at 3 meters.

This transmitter's RF design is based on Spacelabs Medical's Model 90340 UHF telemetry transmitter (FCC ID: CM676A90340), and has had the RF passive components sized for the higher UHF operation. The transmitted RF signal is received by a Model 90478 digital telemetry receiver. The receiver down-converts and demodulates the vital signs information to base band. Whereby they are processed for display in any of the Spacelabs Medical (SMI) Patient Care Management System (PCMS™) patient monitors.

Clocks/Oscillators Frequencies

RF BOARD (90343/90347)

- RF Carrier: 602 MHz to 620 MHz
- Fixed Crystal Oscillator: 150.5 to 155.0 MHz
- Watch Crystal 32 kHz
- Frame Rate 120 Hz
- Super Frame 2.5 Hz
- Low battery warning lamp 0.5 Hz

SpO₂ Board (90343 only)

- Processor crystal 32 kHz
- Processor clock 4.194 MHz
- A to D converter 2.45 MHz
- SpO₂ drive 1.024 kHz
- SpO₂ sample rate 1.048 MHz

1.2 Related Submittals/Grants

This product belongs to the same family of telemetry transmitters as the FCC ID CM67690340 and CM690343-05. The differences lie in the operating frequency range and increase of the output power to overcome a predicted increased path loss.

1.3 Tested System Details

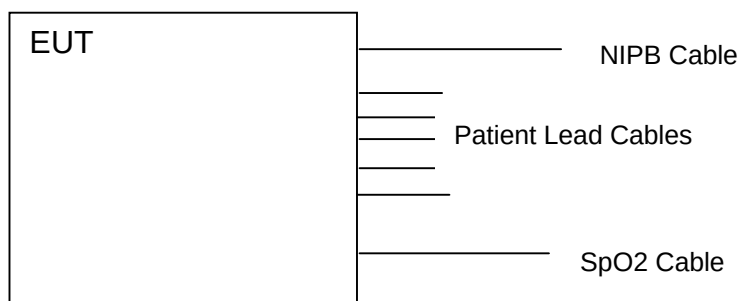
EUT and Peripherals

Item	FCC ID	Description and Serial No.
EUT	CM676A90343-WMTS	Spacelabs Medical Model 90343/90347 Digital Telemetry Transmitter, Serial #: 347-001337

Cables

Item	Description and Serial No.
ECG Lead Set	25.2 inches in length, unshielded. Part No. 012-0605-00.
SpO2 Adapter Cable	39 inches in length, unshielded. Part No. 700-0014-00.
NIPB Cable	58 inches in length, unshielded. Part No. 700-0015-00.

Figure 1: Configuration of Tested System



1.4 Test Methodology

Radiated testing was performed according to the procedures in ANSI C63.4 (1992).. Radiated testing was performed at an antenna to EUT distance of 3 meters, from 30 MHz to 6.5 GHz.

1.5 Test Facility

The Open Area Test Site (OATS) and conducted measurement facility used to collect the radiated and conducted data is located at

Northwest EMC, Inc.
14128 339th Avenue SE
Sultan, WA 98294
(360) 793-8675
Fax: 793-2536

The Open Area Test Site, and conducted measurement facility is located in Sultan, WA, at the address shown above. This site has been fully described in a report filed with the FCC (Federal Communications Commission), and accepted by the FCC in a letter maintained in our files.

Northwest EMC, Inc. is recognized under the United States Department of Commerce, National Institute of Standards and Technology, National Voluntary Laboratory Accreditation Program (NVLAP) for satisfactory compliance with criteria established in Title 15, Part 285 Code of Federal Regulations. These criteria encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987) as suppliers of calibration or test results. NVLAP Lab Code: 200059-0.

2.0 System Test Configuration

2.1 Justification

The EUT was operated at mid frequency (611 MHz) in the 608 MHz to 614 MHz band with a modulated carrier. Additional data was taken with transmit frequencies at 602 MHz and 620 MHz for the Part 15.242 application (filed concurrently, ref FCC ID CM676A90343-04) and is available upon request.

A new battery was installed prior to testing.

The patient RA ECG lead acts as the antenna and is normally attached between the EUT and a patient. However, attachment to the human body results in a significant change of impedance between the ECG leads. Test results vary from subject to subject, but signal field strengths at all associated frequencies are consistently lower when connected to the body than when configured with shorted test leads.

Shorted ECG patient leads have proven to be the worse case configuration for the 90343 and 90347 telemetry transmitters, and the most easily reproducible configuration. Test data was taken in this configuration.

The Model 90347 transmitter is a lesser version of the 90343. It utilizes the same RF and ECG circuit boards, but lacks the SpO2 circuit board and the NIBP interface, making it a singular parameter (ECG only) device. The absence of the SpO2 board in the 9037 effects the shielding of the RF board, so a larger shield is used on the RF board when it is installed in a 90347. Test data was taken with the RF board installed in both configurations – in the 90343 with a small shield, and in the 90347 with a large shield.

2.2 EUT Exercise Software

No special test software was employed during testing of the 90343/90347. The radio and ECG features of the 90343 and 90347 configurations are crystal controlled and do not require a software program to operate.

The only functional software/firmware is associated with the SpO2 board, an option that is unique to the 90343 configuration. Current release software was installed, Ver. 1.100.08.

2.3 Special Accessories

None

2.4 Equipment Modifications

The following modification was required to achieve EMI compliance:

- R7 increased to 6.99k ohms on RF printed circuit board assembly, P/N 670-09XX-XXX.

Please reference exhibit “P”, file name “Equipment Modifications Attestation Letter” for the manufacturer’s attestation statement

3.0 Antenna Information

The EUT uses a single antenna that is designed to ensure that no other antennas other than the one supplied by the grantee will be used with the device.

The design of the 90343/90347 transmitter relies upon the patient RA ECG lead to act as the device antenna. This is a stranded, unshielded wire that uses a DIN-safety molded rubber plug on the radio end and a snap fastener for the ECG pad at the patient end.

The connectors at both ends are standard medical designs that are intended to protect the patient and medical care-givers from unintentional electrical shock during defibrillation. The connectors also do not allow the user to connect any common RF signal amplification device to the transmitter.

Please reference exhibit “N”, file name “Patient Lead Photos.pdf”.

4.0 RF Exposure Compliance Requirements

The applicant confirms compliance with FCC rules that ensures the public is not exposed to radio frequency energy levels in excess of the Commission's guidelines (ref. 47 CFR 95.1125, 1.1307, 1.1310, 2.1091, and 2.1093. Also OET Bulletin 65, Supplement C).

While operating under Part 15.242, this exact same device is categorically excluded from routine evaluation for RF exposure due to its use, transmit frequency, and output power. The applicant was a key industry participant in the FCC rule making that led to the formation of the Wireless Medical Telemetry Service (WMTS). It is the applicant's position that the intent of the FCC rules is not to require SAR measurements for WMTS devices that also operate under 15.242, but only for those WMTS transmitters that operate at the higher frequency bands at higher power levels.

5.0 Information to User

Per 47 CFR 95.1109 (b), each device shall be labeled with the following statement: “Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.”

Due to the small size of the EUT, this information is placed in a prominent place in the manual (see page 5 of User Manual 1).

In addition, 47 CFR 95.1123 requires that “ the manufacturers, installers and users of WMTS equipment are cautioned that the operation of this equipment could result in harmful interference to other nearby medical devices.”

This information is covered in several locations in the manual (see pages 4 – 7 of User Manual 1).

Please reference exhibit “C”, file name “User Manual 1.pdf”.

6.0 Type of Emission

Per 47 CFR 95.1115 (c), the EUT complies with the requirement that “a wireless medical telemetry device may transmit any emission type appropriate for communications in this service, except for video and voice. Waveforms such as electrocardiograms (ECGs) are not considered video.”

The EUT has F1D emission. The EUT uses a digital, frequency shift keying modulation scheme with no sub-carriers.

The emission designator “F1D” was selected based upon the guidelines in 47 CFR 2.201: “F” designates an emission in which the main carrier is frequency modulated. “1” designates a single channel containing digital information without the use of a modulating sub-carrier (the applicant confirmed that no sub-carriers are used). “D” designates data transmission, telemetry. As detailed in the user manual, the device is used to transmit non-voice, non-video, biomedical telemetry.

7.0 Necessary Bandwidth

Per 47 CFR 2.202(c), the necessary bandwidth is calculated using Carson's Rule: $2M + 2D = 2(6000) + 2(6000) = 24000$. Where “M” is equal to the EUT's maximum modulation frequency in Hertz, and D is equal to the EUT's peak frequency deviation (i.e. half the difference between the maximum and minimum values of the instantaneous frequency).

Per 47 CFR 2.202(b), the necessary bandwidth is expressed “by three numerals and one letter. The letter occupies the position of the decimal point and represents the unit bandwidth”. The EUT's necessary bandwidth is expressed as “24K0”

Hence the EUT's emission designator is “24K0F1D”.

8.0 AC Powerline Conducted Emissions

Measurements to demonstrate compliance with the conducted limits are not required for devices which only employ battery power for operation and which do not operate from the AC power lines.

The EUT is battery operated and does not make provisions for battery chargers or any other connection to the AC power lines. Therefore, no AC powerline conducted emissions measurements were made.

9.0 Radiated Emissions

The field strength of radiated emissions shall meet the limits as defined in 47 CFR 95.1115.

The EUT was configured for continuous modulated operation at 611 MHz. Additional data was taken with transmit frequencies at 602 MHz and 620 MHz for the Part 15.242 application (filed concurrently, ref FCC ID CM676A90343-04) and is available upon request.

A new battery was installed prior to testing.

Since a larger shield is used on the RF board when it is installed in a 90347, testing was done with the RF board installed in both configurations – in the 90343 with a small shield, and in the 90347 with a large shield. The spectrum was scanned from 30 MHz to 6.5 GHz.

While scanning, emissions from the EUT were maximized by rotating the EUT, adjusting the measurement antenna height and polarization, and manipulating the EUT in 3 orthogonal planes (per ANSI C63.4:1992).

9.1 Results

Peak and quasi-peak measurements were made with a resolution bandwidth of 120kHz and a video bandwidth of 300kHz for measurements at or below 1GHz. Above 1GHz, a resolution bandwidth of 1MHz and a video bandwidth of 1MHz were used.

The field strength of the radiated emissions meets the limits as defined in 47 CFR 95.1115.

***The final radiated data may be referenced in Exhibit “E”,
file name “ Radiated Emissions.pdf”.***

10.0 Field Strength Calculations

The field strength is calculated by adding the Antenna Factor and Cable Factor, and subtracting the Amplifier Gain (if any) from the measured level. The basic equation with a sample calculation is as follows:

$$FS = RA + AF + CF - AG$$

where :

- FS = Field Strength
- RA = Measured Level
- AF = Antenna Factor
- CF = Cable Attenuation Factor
- AG = Amplifier Gain

Assume a receiver reading of 52.5 dBuV is obtained. The Antenna Factor of 7.4 and a Cable Factor of 1.1 is added. The Amplifier Gain of 29 dB is subtracted, giving a field strength of 32 dBuV/meter.

$$FS = 52.5 + 7.4 + 1.1 - 29 = 32 \text{ dBuV/meter}$$

$$\text{Level in uV/m} = \text{Common Antilogarithm} [(32 \text{ dBuV/m})/20] = 39.8 \text{ uV/m}$$

10.1 Measurement Bandwidths

Peak Data

150 kHz - 30 MHz	10 kHz
30 MHz - 1000 MHz	100 kHz
1000 MHz - 10000 MHz	1000 kHz

Quasi-peak Data

150 kHz - 30 MHz	9 kHz
30 MHz - 1000 MHz	120 kHz

11.0 Measurement Equipment

Instrument	Manufacturer	Model	Serial No	Cal Due
Spectrum Analyzer	Hewlett-Packard	8568B	2732A03810	07/19/01
Quasi-Peak Adapter	Hewlett-Packard	85650A	3303A01856	01/05/01
Spectrum Analyzer	Hewlett Packard	8593E	3710A02766	05/10/01
Antenna, Horn	EMCO	3115	9906-5818	12/08/00
Pre-Amplifier	AR	LN1000	19872	09/02/00
Pre-Amplifier	Hewlett Packard	83017A	3123A00288	09/02/00
Bicon Antenna	ARA	BCD-235-B	1042	01/07/01
Log Periodic Antenna	EMCO	3146	5060	01/07/01
Dipole Antenna	Roberts	A100	5116	01/10/01