

EXHIBIT B – Technical Report

FCC ID CM676A90343-04

Measurement/Technical Report

Spacelabs Medical

Model 90343/90347 Digital Telemetry Transmitter

FCC ID: CM676A90343-04

August 23, 2000

This report concerns (check one):		Original Grant <u>X</u>	Class II Change _____
Equipment Type: <u>Part 15 Low Power Communication Device Transmitter</u>		Rule Part: <u>47 CFR 15.242</u>	
Notes: <u>Biomedical Telemetry Transmitter</u>			
Deferred grant requested per 47 CFR 0.457 (d)(1)(ii)?		Yes _____ 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.			
Transition Rules Request per 15.37:		yes _____ no <u>X</u> _____	
If no, assumed Part 15, Subpart C for intentional radiators – new 47 CFR [10-1-92] provision.			
Report prepared by:		Northwest EMC, Inc. 22975 NW Evergreen Pkwy. Ste 400 Hillsboro, OR 97124 (503) 844-4066 Fax: (503) 844-3826	
Report No. SPAC0246.1			




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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.....CM676A90343-04
Serial Number(s) 343-001201, 343-001239, 347-001337
Date of TestAugust 23, 2000
Job Number SPAC0246.1

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 CM676A90343-04), in accordance with Part 15.242 of the Federal Communication Commission's Rules and Regulations.

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 602 to 620 MHz in accordance with 47 CFR 15.242. 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

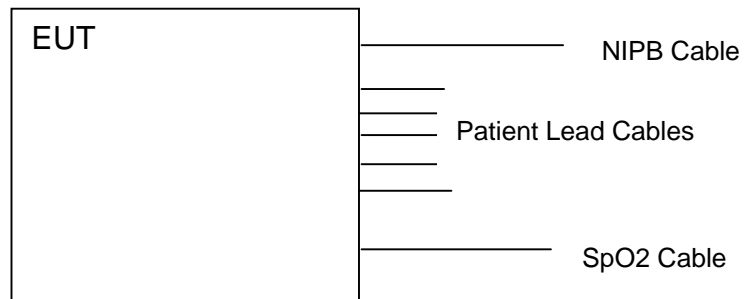
EUT and Peripherals

Item	FCC ID	Description and Serial No.
EUT	CM676A90343-04	Spacelabs Medical Model 90343/90347 Digital Telemetry Transmitter, Serial #s. 343-001201, 343-001239, 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 low, mid, and high transmit frequencies in the 602 MHz to 620 MHz band with a modulated carrier. 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 which 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

Per 47 CFR 15.203, 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 EUT meets the requirement that it be operated in a manner that ensures the public is not exposed to radio frequency energy levels in excess of the Commission's guidelines (ref. 47 CFR 15.242, 1.1307, 1.1310, 2.1091, and 2.1093. Also OET Bulletin 65, Supplement C).

The following is an excerpt from FCC Public Notice DA000912:

"It is important to note that the Commission's RF exposure rules apply to all facilities, operations and devices regulated by the Commission. While a given facility, operation or device might be categorically excluded from routine evaluation for RF exposure by Section 1.1307(b)(1) of our rules, it must still comply with the FCC's exposure guidelines."

The EUT is categorically excluded from routine evaluation for RF exposure due to its use, transmit frequency, and output power.

5.0 AC Powerline Conducted Emissions

Per 47CFR 15.207(d), 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.

6.0 Spurious Radiated Emissions

The field strength of the spurious emissions shall meet the limits as defined in 47 CFR 15.242.

The EUT was configured for continuous modulated operation at low, mid, and high transmit frequencies. Since a larger shield is used on the RF board when it is installed in the 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).

6.1 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 was used.

The field strength of the spurious emissions meet the limits as defined in 47 CFR 15.242.

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

7.0 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.

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

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

7.1 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

8.0 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