

EXHIBIT C Technical Report

FCC ID DV8LX5160

Measurement/Technical Report

Fukuda Denshi

Model LX-5160

FCC ID: DV8LX5160

March 12, 2001

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> Note: <u>Part 95 Wireless Medical Telemetry Transmitter</u>	Rule Part: <u>47 CFR 95.1115</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>Fukuda Denshi Co., Ltd.</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. FUKU0008		

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1.0 General Information

1.1 Product Description

Manufactured By.....Fukuda Denshi Tagajo Co.,Ltd.
Address.....2-6-8 Sakae, Tagajo, Miyagii, 985-0833 Japan
Test Requested By:Bob Steurer
Address:17725 NE 65th Street Redmond, WA 98052
Model..... LX-5160
FCC ID..... DV8LX5160
Serial Number(s) 00000001
Date of TestMarch 6, 2001 through March 9, 2001
Job Number FUKU008

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1.1 Product Description - continued

This application is being submitted in support of an equipment authorization request for the Fukuda Denshi Co., Ltd. Model LX-5160 Digital Telemetry Transmitter (FCC ID DV8LX5160), in accordance with Part 95.1115 of the Federal Communication Commission's Rules and Regulations. The Model LX-5160 is a multi-parameter biomedical telemetry transmitter that is used for the transmission of a patient's vital signs data from the patient monitor, including the electrocardiogram (ECG), and respiration (Resp). This physiological data is 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.

This battery (1.5 volt alkaline type) powered UHF transmitter is worn by the patient. It operates on a 12.5kHz system channel spacing. It utilizes unused UHF television channels from 608 to 614 MHz in accordance with 47 CFR 95 Subpart H. 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 with the transmitter set to maximum power. The allowable field strength for this class of device as authorized under the FCC Rules is 200 millivolts per meter at 3 meters. The transmitted RF signal is received by a Model LW-5560 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 Fukuda Denshi patient monitoring Systems.

Clocks/Oscillators Frequencies

- RF Carrier: 608 MHz to 614 MHz
- Reference for carrier frequency Fixed Crystal Oscillator: 2.4000 MHz
- Clock for Gate array : 84 kHz

1.3 Tested System Details

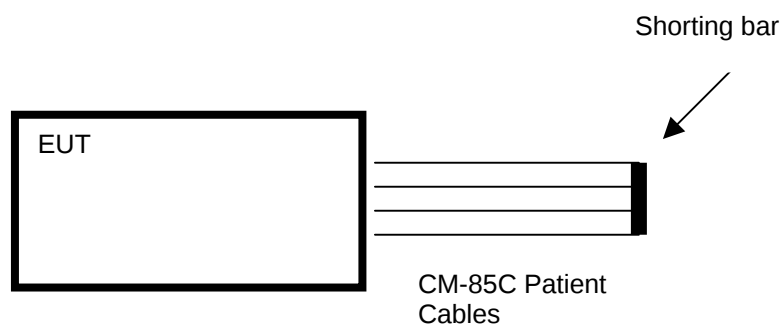
EUT and Peripherals

Item	FCC ID	Description and Serial No.
EUT	DV8LX5160	Fukuda Denshi Co. Model LX-5160, Serial No. 00000001.
Patient Simulator		Fukuda Denshi Co., Ltd., Patient electrode shorting bar.

Cables

Item	Description and Serial No.
Patient Cable	Patient Cable ~75 cm in length. Shielded cable x 4, Model No. CM-85C.

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, with the transmitter set to maximum output power.

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 608 MHz to 614 MHz band with a modulated carrier. At each frequency setting the transmitter was set to operate at maximum output power.

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 LX-5160 telemetry transmitters, and the most easily reproducible configuration. Test data was taken in this configuration using the patient electrode shorting bar.

2.2 EUT Exercise Software

No special test software was employed during testing of the LX-5160. The radio and Vital sign features of the LX-5160 configurations are crystal controlled phase lock loop.

2.3 Special Accessories

None

2.4 Equipment Modifications

No modification were required to achieve EMI compliance:

3.0 Antenna Information

The design of the LX-5160 transmitter relies upon the patient cable to act as the device antenna. This is a stranded, shielded wire that uses a unique molded plastic 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 “K”, file name “Patient Lead Photos.pdf”.

4.0 RF Exposure Compliance Requirements

The applicant confirms compliance with FCC rules that ensure 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. 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.” This information is prominently labeled on the exterior of the device and on page (1) of the user manual.

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 the user manual (page i).

Please reference exhibit “D”, file name “User Manual.pdf” and exhibit “E”, file name “FCC ID Label.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:

$$2M + 2D = 2(3500) + 2(1750) = 10.5 \text{ kHz.}$$

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).

The applicant specifies a maximum data rate of 7kBpS (7000 bits per second).

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 "10K5", hence the EUT's emission designator is "10K5F1D".

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 608, 610 and 614 MHz.

A new battery was installed prior to testing.

The spectrum was scanned from 30 MHz to 6.5 GHz for each of the above settings. 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 "F",
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

Description	Manufacturer	Model	Serial No.	Last Cal	Interval
Spectrum Analyzer	Hewlett-Packard	8568B	2732A03810	7/19/2000	12 mo
Spectrum Analyzer	Hewlett-Packard	8593E	3710A02766	5/10/2000	12 mo
Pre-Amplifier	ARA	LN1000	23497	5/1/2000	12 mo
Antenna, Log Periodic	EMCO	3146	9609-4646	1/18/2001	12 mo
Antenna, Bicon	EMCO	3104C	9608-4750	1/18/2001	12 mo
Quasi-Peak Adapter	Hewlett-Packard	85650A	3303A01805	7/19/2000	12 mo
Pre-Amplifier	Hewlett-Packard	83017A	3123A00288	10/2/2000	12 mo
Antenna, Horn	EMCO	3115	9307-4074	2/6/2001	12 mo