

# EXHIBIT C Technical Report

FCC ID DV8HLX561

# Measurement/Technical Report

**Fukuda Denshi**

**Model HLX-561**

**FCC ID: DV8HLX561**

**March 12, 2000**

|                                                                                                   |                                                                                                                         |                                  |                             |
|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|----------------------------------|-----------------------------|
| This report concerns (check one):                                                                 |                                                                                                                         | Original Grant <u>  X  </u>      | Class II Change <u>    </u> |
| Equipment Type: <u>Licensed Non-Broadcast Transmitter</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><br>Date       |                             |
| <u>Fukuda Denshi Co., Ltd.</u> agrees to notify the Commission by:                                |                                                                                                                         | <u>    N/A    </u><br>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.<br>22975 NW Evergreen Pkwy. Ste 400<br>Hillsboro, OR 97124<br>(503) 844-4066<br>Fax: (503) 844-3826 |                                  |                             |
| Report No. FUKU0007                                                                               |                                                                                                                         |                                  |                             |

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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 ..... Fukuda Denshi USA, Inc.  
17725 NE 65th Street, Redmond, WA, 98052  
Model.....HLX-561  
FCC ID..... DV8HLX561  
Serial Number(s) ..... 00000001  
Date of Test ..... March 6-9, 2001  
Job Number .....FUKU007

**Prepared By:**

*Vicki Albertson*

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Vicki Albertson, Technical Report and  
Documentation Manager

**Technical Review By:**

*Quantin Tolman*

**Approved By:**

*Donald White*

## 1.1 Product Description - continued

This application is being submitted in support of an equipment authorization request for the Fukuda Denshi Co., Ltd. Model HLX-561 Digital Telemetry Transmitter (FCC ID DV8HLX561), in accordance with Part 95.1115 of the Federal Communication Commission's Rules and Regulations. The Model HLX-561 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), blood oxygen saturation, (SpO2), invasive blood pressure (IBP), non-invasive blood pressure (NIBP), and temperature (Temp). This physiological data is encoded in a digital format and is 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 device is powered by the patient monitor to which it is attached. It operates on a 12.5kHz system channel spacing. It utilizes unused UHF television channels from 608 to 614 MHz in accordance with 47 CFR95 Subpart H. The RF signal from this transmitter is radiated from a permanently attached single whip antenna, which, at a 3 meter distance, produces a field strength of approximately 81 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. 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
- Processor crystal 16 MHz

## 1.2 Tested System Details

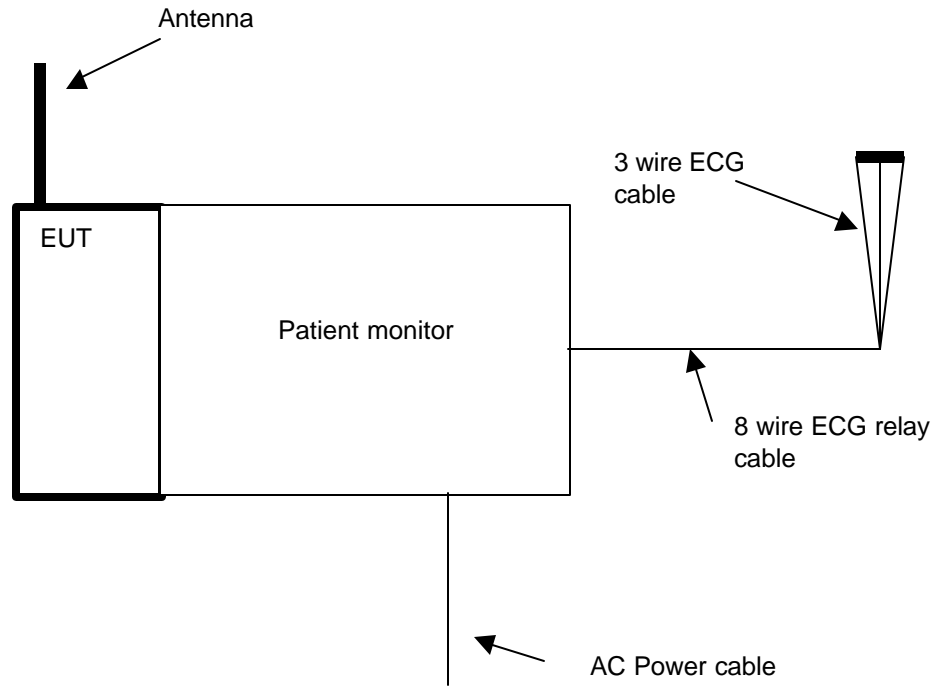
### EUT and Peripherals

| Item                                       | FCC ID    | Description and Serial No.                                                                                                                      |
|--------------------------------------------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| EUT<br>Patient Monitor<br>Patent Simulator | DV8HLX561 | Fukuda Denshi Co. Model HLX-561, Serial No. 00000001.<br>Fukuda Denshi Model DS-5100E, S/N 28100751<br>DNI Nevada, Inc., Model MedSim, S/N 2407 |

### Cables

| Item             | Description and Serial No.                                |
|------------------|-----------------------------------------------------------|
| ECG Relay Cable  | 325 cm. In length, 3 wire shielded cable, model no.CI-161 |
| ECG 3 Lead Cable | 75 cm. In length, 8 wire shielded cable                   |

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. The transmitter was set to maximum power for testing.

## **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 339<sup>th</sup> 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.

The EUT was connected to the Patient Monitor Model DS-5100E.

Shorted ECG patient leads have proven to be the worse case configuration for the DS-5100E/ HLX-561 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 HLX-561. The radio and Vital sign features of the HLX-561 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 EUT uses a fixed single whip antenna, part number FUKUDA 709, manufactured by Hidaka Denki Works Co., Ltd. This antenna has 0.4 dBi gain at 420-430 MHz. The antenna is permanently installed at the factory and is not serviceable by the user.

### 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, 2.1093, and 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 HLX-561 is a mobile transmitter which is categorically excluded from routine evaluation for RF exposure due to its use, transmit frequency, and output power. This device is not worn by patients. The separation between the device and patients exceeds 20 cm.

### 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 ii).

***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 Power Line Conducted Emissions

Measurements to demonstrate compliance with the conducted limits are required for devices which only employ AC power for operation and which operate from the AC power lines. The EUT is DC power operated thru the AC power operated patient monitor and which is connected to the AC power lines. Therefore, AC power line conducted emissions measurements were made on the patient monitor.

**Requirement:** Per 47 CFR 15.207, the radio frequency voltage that is conducted back onto the AC power line from the EUT, on any frequency within the 450 kHz to 30 MHz band, shall not exceed 250 microvolts.

**Configuration:** The AC power line conducted emissions were measured with the EUT operating in a frequency hopping mode typical of normal operation. The EUT was transmitting at its maximum data rate. The spectrum was scanned from 450 kHz to 30 MHz. The test setup and procedures were in accordance with ANSI C63.4-1992.

**Results:** Per 47 CFR 15.207, the radio frequency voltage that is conducted back onto the AC power line from the EUT, on any frequency within the 450 kHz to 30 MHz band, does not exceed 250 microvolts.

*The final conducted emissions data may be referenced in Exhibit "G",  
file name "Conducted Emissions.pdf"*

## 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.

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 Radiated and Conducted 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    |