

Test Report
for
Insulet Corporation
on the
Insulin Infusion Pump
Model: iXL
to
FCC Part 15 Subpart C, Section 15. 225

Deleted: M-803

Test Report #: 3050193
Date of Report: January 27, 2004

Project #: 3050193
Dates of Test: January 7, 20, 21, and 22, 2004

Total No of Pages Contained in this Report: 15

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FCC Part 15 Subpart C, Section 15. 225

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1.0 Summary of Tests

FCC RULE	DESCRIPTION OF TEST	RESULTS	REPORT PAGE
FCC §15.225	Fundamental Field Strength	Passed	7
FCC §15.209	Field Strength of Spurious Radiation	Passed	11
FCC §15.225	Frequency Stability Over Temperature	Passed	13

2.0 General Description

2.1 Product Description

The Insulet iXL Infusion Pump contains electronics for wireless transmission and reception of data, utilizing OOK modulation with a carrier frequency of 13.56 MHz. The system consists of a remote control and an insulin pump. The device is designed to transmit or receive data at rate of 2000 bits per second. A production version of the sample was received on January 7, 2004 in good condition.

The EUT has been tested at the request of

Company: Insulet Corporation
100 Cummings Center
Beverly, MA 01915
Name of contact: Mr. Mohsen Moghaddami
Telephone: (978) 299-0230
Fax: (978) 299-0301

2.2 Related Submittal(s) Grants

None.

2.3 Test Facility

Site 1C (Top Site) is a 3m and 10m sheltered emissions measurement range located in a light commercial environment in Boxborough, Massachusetts. It meets the technical requirements of ANSI C63.4-1992 and CISPR 22:1993/EN 55022:1994 for radiated and conducted emission measurements. The shelter structure is entirely fiberglass and plastic, with outside dimensions of 33 ft x 57 ft. The structure resembles a quonset hut with a center ceiling height of 16.5 ft.

The testing floor is covered by a galvanized sheet metal groundplane that is earth-grounded via copper rods around the perimeter of the site. The joints between individual metal sheets are bridged with a 2 inch wide metal strips to provide low RF impedance contact throughout. The sheets are screwed in place with stainless steel, round-head screws every three inches. Site illumination and HVAC are provided from beneath the ground reference plane through flush entry ports, the port covers are electrically bonded to the ground plane.

A flush metal turntable with 12 ft. diameter and 5000 lb. load capacity is provided for floor-standing equipment. A wooden table 80 cm high is used for table-top equipment. The turntable is electrically connected to the ground plane with three copper straps. The straps are connected to the turntable at the center of it with ground braid. The copper strap is directly connected to the groundplane at the edges of the turntable. The turntable is located on the south end of the structure and the antennas are mounted 3 and 10 meters away to the north. The antenna mast is a non-conductive with remote control of antenna height and polarization. The antenna height is adjustable from 1 to 4 meters.

All final radiated emission measurements are performed with the testing personnel and measurement equipment located below the ground reference plane. The site has a full basement underneath the turntable where support equipment may be remotely located. Operation of the antenna, turntable and equipment under test is controlled by remote controls that manipulate the antenna height and polarization and with a turntable control. Test personnel are located below the ellipse when measurements are performed, however the site maintains the ability of having personnel manipulate cables while monitoring test equipment. Ambient radiated emissions are 6 dB or more below the relevant FCC emission limits.

AC mains power is brought to the equipment under test through a power line filter, to remove ambient conducted noise. 50 Hz (240 VAC single phase), 60 Hz power (120 VAC single phase, 208 VAC three phase), and 60 Hz (480 VAC three phase) are available. Conducted emission measurements are performed with a Line Impedance Stabilization Network (LISN) or Artificial Mains Network (AMN) bonded to the ground reference plane. A removable vertical groundplane (2 meter X 2 meter area) is used for line-conducted measurements for table top equipment. The vertical groundplane is electrically connected to the reference groundplane.

2.4 Test Equipment and Support Equipment

Test Equipment

Description	Manufacturer	Model Number	ITS ID	Serial Number	Cal Due Date
Antenna	EMCO	3142	LOG1	9701-1116	10/17/2004
Temperature/Humidity Chamber	Bryant Manufacturing	TH-5S	SAF187	1207	07/16/2004
Loop Antenna	Empire	LP-105	LOOP2	905	06/02/2004
Loop Sensor	Solar Electronics	7334-1	SOL2	1898	06/05/2004
Spectrum Analyzer	Agilent	E7405A	None	US40240205	07/02/2004
EMI Receiver	Hewlett Packard	8546A	REC1	3650A00359	06/18/2004
10 Coaxial Cable	Alpha Wire	RG58/U	CBLBNC1	None	07/20/2004
Coaxial Cable	Alpha Wire	RG 214/U	10M In Floor	None	04/07/2004
Coaxial Cable	Alpha Wire	RG 214/U	CBL101	None	04/07/2004
Coaxial Cable	Alpha Wire	RG 214/U	CBL102	None	04/07/2004
Coaxial Cable	Alpha Wire	RG 214/U	CBL103	None	04/07/2004
Function Generator	Leader Electronics	LFG-1300S	None	7121065	09/22/2004
Antenna	Compliance Design	B100	ANT4A	3317	09/19/2004
Antenna	Compliance Design	B200	ANT4B	3245	09/19/2004
Antenna	Compliance Design	B300	ANT4C	3352	09/19/2004
DC Power supply	Agilent	E3620A	None	MY0003014	03/07/2004

Support Equipment

Description	Manufacturer	Model Number	Serial Number
None			

Cables

Quantity	Type	Length (m)	Shielding	Ferrite	Connector Type
None					

3.0 Fundamental Field Strength

FCC Part 15 Subpart C, Section 15.225

3.1 Test Procedure

The transmitter was placed on a wooden turntable. The measurement antenna was placed at a distance of 3 meters from the EUT. During the tests, the antenna height was at 1 meter above ground, and the EUT was rotated through 360 degrees and manipulated on three orthogonal axes in order to identify the maximum level of emissions from the EUT. A max hold function was used to determine maximum field strength levels.

Requirement: The fundamental field strength shall not exceed 10,000 $\mu\text{V/m}$ or 80 dB $\mu\text{V/m}$ at a test distance of 30 meters.

3.2 Test Results

Equipment Used: LOOP2, CBLBNC1, and REC1

Fundamental Field Strength From The Remote

Company: Insulet Corporation
 Engineer: Kouma Sinn
 Project #: 3053853
 Date: 1/7/04 & 1/23/2004
 Standard: FCC Part 15 Subpart C
 Section: 15.225
 Limit Distance: 3 meters
 Voltage/Frequency: 3VDC (batteries)
 Notes: Test was performed without groundplane

Location: 1C
 Pressure: n/a
 Temp: 20 deg. C
 Humidity: 23%
 Group: None
 Test Distance: 3 meters
 Frequency Range: 13.56 MHz

Model #: iXL (Remote)
 Serial #: EL0701
 Receiver: HP 8546A
 Antenna: LOOP2
 PreAmp: None
 Cable(s): CBLBNC1

Comment [I1]:

Ant. Pol. (V/H)	Frequency MHz	Reading dB(uV)	Antenna Factor dB(1/m)	Cable Loss dB	Pre-amp Factor dB	Distance Factor dB	Net dB(uV/m)	Limit dB(uV/m)	Margin dB	Pass/Fail
V	13.560	11.1	41.8	0.4	0.0	0.0	53.3	80.0	-26.7	Pass

Fundamental Field Strength From The Pump

Company: Insulet Corporation
 Engineer: Kouma Sinn
 Project #: 3053853
 Date: 1/7/04 & 1/23/2004
 Standard: FCC Part 15 Subpart C
 Section: 15.225
 Limit Distance: 3 meters
 Voltage/Frequency: 3VDC (batteries)

Location: 1C
 Pressure: n/a
 Temp: 20 deg. C
 Humidity: 23%
 Group: None
 Test Distance: 3 meters
 Frequency Range: 13.56 MHz

Model #: iXL (Pump)
 Serial #: EJ2538
 Receiver: HP 8546A
 Antenna: LOOP2
 PreAmp: None
 Cable(s): CBLBNC1

Ant. Pol. (V/H)	Frequency MHz	Reading dB(uV)	Antenna Factor dB(1/m)	Cable Loss dB	Pre-amp Factor dB	Distance Factor dB	Net dB(uV/m)	Limit dB(uV/m)	Margin dB	Pass/Fail
V	13.560	3.3	41.8	0.4	0.0	0.0	45.5	80.0	-34.5	Pass

4.0 Transmitter Characteristics

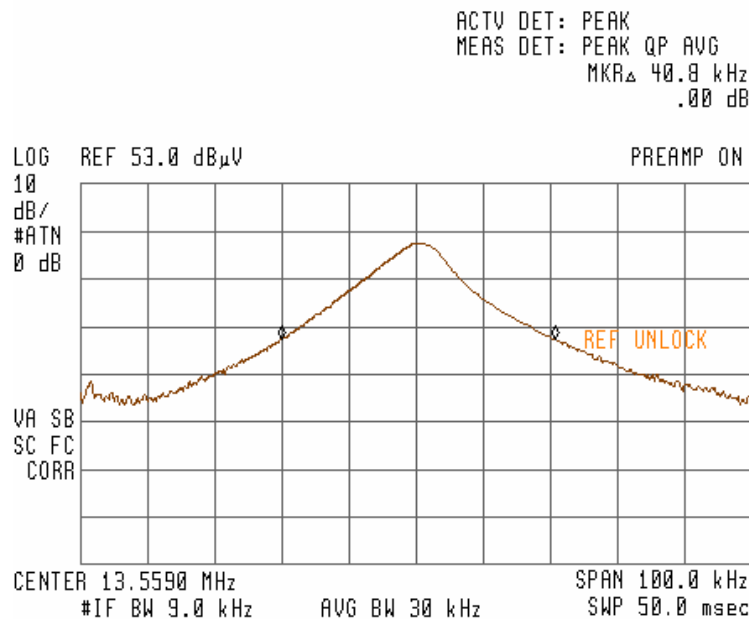
4.1 20 dB Bandwidth

The EUT was set to transmit in worst-case mode, and the bandwidth was measured using 9kHz resolution bandwidth.

Requirement: Section 15.225 of the FCC Part 15 Subpart C does not specify the bandwidth requirement. Measurement was taken for information purpose only.

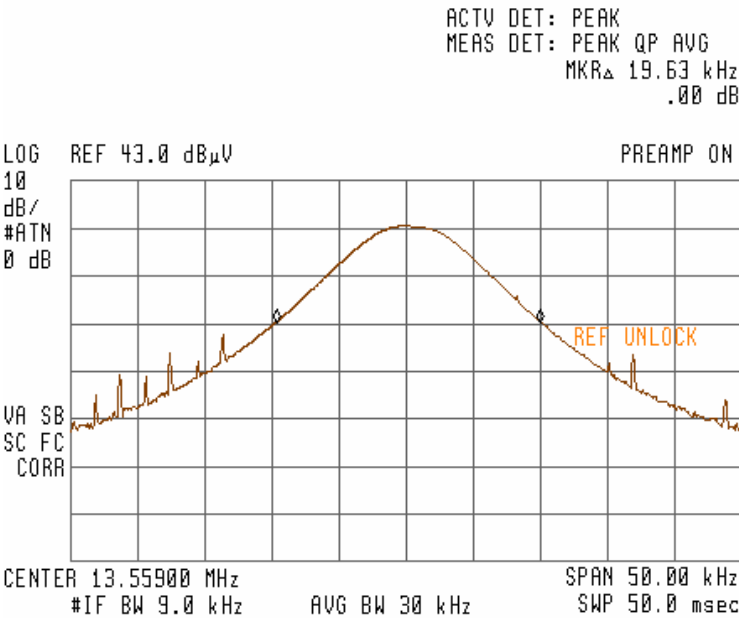
Remote

Frequency (MHz)	Bandwidth (kHz)	Limit (kHz)
13.5590	40.8	Not applicable



Pump

Frequency (MHz)	Bandwidth (kHz)	Limit (kHz)
13.5590	19.63	Not applicable



5.0 Field Strength of Spurious Radiation

FCC Part 15 Subpart B, Section §15.209

Deleted: 15.109

5.1 Test Procedure

The transmitter was placed on a wooden turntable. The measurement antenna was placed at a distance of 3 meters from the EUT. During the tests, the antenna height and polarization were varied, and the EUT was rotated through 360 degrees and manipulated on three orthogonal axes in order to identify the maximum level of emissions from the EUT. For measurements below 30 MHz the antenna was placed at 1 meter above ground and no ground plane was used. A max hold function was used to determine maximum field strength levels.

5.2 Test Results

Equipment: REC1, LOG1, LOOP2, CBLBNC1, SOL2, and Site 1C Floor Cable

Radiated Emissions / Interference

Company: Insulet Corporation Location: 1C Model #: iXL
Engineer: Kouma Sinn Serial #: EL0701
Project #: 3053853 Pressure: n/a Receiver: HP 8546A
Date: 1/7/04 & 1/23/2004 Temp: 20 deg. C Antenna: LOOP2 & SOL2below 30MHz, LOG1 above 30MHz
Standard: FCC Part 15 Subpart C Humidity: 23% PreAmp: None
Section: 15.225 Group: None Cable(s): CBLBNC1below 30MHz, Site 1C Floor above 30MHz
Limit Distance: 3 meters Test Distance: 3 meters
Voltage/Frequency: 3VDC (batteries) Frequency Range: 9kHz-1GHz
Notes: The pump and remote control were tested simultaneously

Deleted: 7.0 Line Conducted

Emissions¶

FCC § 15.107¶

7.1 Test Procedure¶

The test procedure is outlined in ANSI C63.4:1992S.¶

7.2 Test Results¶

The Part 15 requirements for this device are addressed in a separate report.¶

Results: Not required for Part 90. ... [1]

Ant. Pol. (V/H)	Frequency MHz	Reading dB(uV)	Antenna Factor dB(1/m)	Cable Loss dB	Pre-amp Factor dB	Distance Factor dB	Net dB(uV/m)	Limit dB(uV/m)	Margin dB	Pass/Fail
V	40.680	3.7	12.2	0.8	0.0	0.0	16.7	40.0	-23.3	Pass
V	150.000	5.3	8.6	1.5	0.0	0.0	15.4	43.5	-28.1	Pass
V	319.500	7.4	14.2	2.2	0.0	0.0	23.8	46.0	-22.2	Pass
V	408.400	12.0	16.4	2.6	0.0	0.0	31.1	46.0	-14.9	Pass
V	442.400	6.2	17.2	2.8	0.0	0.0	26.2	46.0	-19.8	Pass
V	466.900	4.7	17.9	2.9	0.0	0.0	25.5	46.0	-20.5	Pass
V	737.300	2.1	21.8	4.4	0.0	0.0	28.3	46.0	-17.7	Pass
V	368.650	5.0	15.9	2.5	0.0	0.0	23.4	46.0	-22.6	Pass

5.3 Configuration Photographs – Radiated Emissions



Spurious Test Setup, Front View



Spurious Test Setup, Back View

6.0 Frequency Stability vs Temperature
FCC Part 15 Subpart C, Section § 15.225**6.1 Test Procedure**

The equipment under test was connected to an external DC power supply and set to transmit at worst case duty cycle. The EUT was placed inside a temperature chamber. A cable for measuring the fundamental frequency was fed into the chamber through an opening insulated to minimize heat flow. After the temperature stabilized, the frequency of the fundamental was recorded from the analyzer.

Requirement: The frequency must not deviate by more than $\pm 0.01\%$ of the fundamental frequency over temperature variation of -20°C to $+50^{\circ}\text{C}$ at the nominal supply voltage.

6.2 Test Results

Equipment: Agilent Spectrum Analyzer

Company: Insulet Corporation

Engineer: Kouma Sinn

Project #: 3053853

Date: 01/22/04

Standard: FCC Part 15 Subpart C, Section 225

Location:

Detector:

Safety Lab

Peak

Model #: See below

Serial #: See below

Part #: See below

Receiver: Agilent

Description: Remote Serial No.: EL0701

Temp. Degree C	Maximum 3.0 Volts	Deviation	Minimum 2.25 Volts	Deviation	Pass/Fail
55.00	13.559230	0.000060	13.559220	0.000090	Pass
50.00	13.559195	0.000095	13.559220	0.000090	Pass
40.00	13.559220	0.000070	13.559245	0.000065	Pass
30.00	13.559325	0.000035	13.559295	0.000015	Pass
20.00	13.559290	0(nominal)	13.559310	0(nominal)	N/A
10.00	13.559255	0.000035	13.559290	0.000020	Pass
0.00	13.559350	0.000060	13.559315	0.000005	Pass
-10.00	13.559395	0.000105	13.559355	0.000045	Pass
-20.00	13.559355	0.000065	13.559335	0.000025	Pass

Description: Pump Serial No.: EJ2538

Temp. Degree C	Maximum 4.8 Volts	Deviation	Minimum 4.2 Volts	Deviation	Pass/Fail
55.00	13.559110	0.000045	13.558915	0.000215	Pass
50.00	13.559160	0.000005	13.559000	0.000130	Pass
40.00	13.559160	0.000005	13.559040	0.000090	Pass
30.00	13.558980	0.000175	13.559065	0.000065	Pass
20.00	13.559155	0(nominal)	13.559130	0(nominal)	N/A
10.00	13.559230	0.000075	13.559220	0.000090	Pass
0.00	13.559310	0.000155	13.559210	0.000080	Pass
-10.00	13.559200	0.000045	13.559180	0.000050	Pass
-20.00	13.559255	0.000100	13.559215	0.000085	Pass

Deviation based on 20 degrees C

Deviation allowed = +/-0.01%(13.559290) = 0.01355929

7.0 Frequency Stability vs. Voltage

Not applicable as the unit is powered from the battery. Testing was performed for information purpose only (see section 6.2 of this report for test results).

7.0 Line Conducted Emissions
FCC § 15.107

7.1 Test Procedure

The test procedure is outlined in ANSI C63.4:1992S.

7.2 Test Results

The Part 15 requirements for this device are addressed in a separate report.

Results: Not required for Part 90.
