



Nemko EESI, Inc.
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FCC, PART 15, SUBPART C

CERTIFICATION APPLICATION

For The Personal Pump Communicator (Transceiver)

Model: **MMT-313x**

FCC ID: OSU3132 (PENDING)

PREPARED FOR:

Medical Research Group

12744 San Fernando Road
Sylmar, CA 91342

PREPARED ON **NOVEMBER 1, 1999**

DOCUMENT NUMBER 99-207

This report has been prepared in accordance with all applicable requirements of ANSI C63.4-1992

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DOCUMENT HISTORY

REVISION	DATE	COMMENTS
-	11/01/99	Initial Release J. L. Griffin

NOTE: Nemko EESI, Inc. hereby makes the following statements so as to conform to Chapter 10 (Test Reports) Requirements of ANSI C63.4 (1992) "Methods and Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz":

- The unit described in this report was received at Nemko EESI, Inc.'s facilities on September 22, 1999. Testing was performed on the units described in this report September 22 - October 1, 1999.
- The Test Results reported herein apply only to the Units actually tested, and to substantially identical Units.
- This test report must not be used by the client to claim product endorsement by NVLAP or any agency of the U.S. Government.

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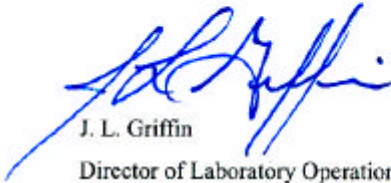
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CERTIFICATION

The Radio Frequency Interference (RFI) testing, data evaluation and this report have been prepared by Nemko EESI, Inc., an independent electromagnetic compatibility consulting and test laboratory.

The testing and data collection were accomplished in accordance with the requirements of the ANSI, C63.4-1992 standard and the applicable sections of FCC, Part 15, Subpart C for intentionally radiating equipment. Refer to the Administrative Summary for a description of the test sample.

I certify the data, data evaluation and equipment configuration herein to be a true and accurate representation of the sample's radio frequency interference emission characteristics, as of the test date(s), and for the design of the test sample utilized to compile this report.



J. L. Griffin
Director of Laboratory Operations

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1. ADMINISTRATIVE DATA AND TEST SUMMARY

1.1 Administrative Data

CLIENT: Medical Research Group
12744 San Fernando Road
Sylmar, CA 91342
(818) 362-8084
(818) 364-2647 – fax

CONTACT: Wayne Morgan (ext. 3310)

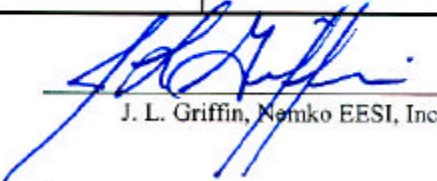
DATE(S) OF TEST: September 22 - October 1, 1999

TEST SPECIFICATION: FCC, Part 15, Subpart C, for intentional radiators
(low-power transmitters)

EQUIPMENT UNDER TEST (EUT): Personal Pump Communicator (Transceiver)
Model Number: MMT-313x
FCC ID Number (pending): OSU3132

EUT transmitter fundamental frequency: 262.144 kHz

<i>Specification</i>	<i>Frequency Range</i>	<i>Compliance Status</i>
FCC, CFR 47, §15.209 Radiated Emissions for Intentional Radiators	9 kHz – 30 MHz	PASS
FCC, CFR 47, §15.209, Class "B" Spurious Radiated Emissions	30.00 MHz - 1000 MHz	PASS


J. L. Griffin, Nemko EESI, Inc.

Please refer to the Test Results section of this report for further details.

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2. SYSTEM DESCRIPTION AND CONFIGURATION

2.1 Description of EUT's System

The Personal Pump Communicator (PPC) is part of an Implantable Insulin Delivery System (IIDS), which is a long-term, implantable medical device that delivers insulin to diabetic patients. The IIDS provides insulin delivery data that the patient and healthcare professionals can use to intensely manage diabetes.

A detailed description of the system can be found as an attachment to this report.

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2.1.1 Personal Pump Communicator (PPC) Description

A detailed description of the system can be found as an attachment to this report.

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2.1.2 Implant Unit (IU) Description

A detailed description of the system can be found as an attachment to this report.

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2.2 System Components and Power Cables

DEVICE	MANUFACTURER MODEL # SERIAL #	POWER CABLE
EUT - Personal Pump Communicator (Transceiver)	Medical Research Group MMT-313x UNK	N/A (Battery only)
Implant Unit	Medical Research Group MMT2007 UNK	N/A (Battery only)
Computer	Medical Research Group Windows-based Clone N/A	2m, unshielded, 18 AWG, 3-wire, IEC connector
Monitor	KDS VS-550 0495627935	2m, unshielded, 18 AWG, 3-wire, IEC connector
Keyboard	Keytronic K280W H904061714	N/A
Infrared Adapter	IR Ready Actisys N/A	N/A

2.3 System Components and Power Cables

CONNECTION	I/O CABLE
EUT to IR Adapter	(x2) 12' fiber optic cables
IR Adapter to Computer	2m, unshielded, 26 AWG, 9-wire, DB9 connectors
Computer to Keyboard	2m, unshielded, 26 AWG, 6-wire, PS/2 connector to hardwired
Computer to Monitor	1.5m, shielded, 24 AWG, 15-wire, DB15 connector to hardwired

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3. DESIGN MODIFICATIONS FOR COMPLIANCE

Device: Personal Pump Communicator (Transceiver)

Model: MMT-313x

No design modifications were made to the EUT during testing.

4. DESCRIPTION OF TEST SITE AND EQUIPMENT

4.1 Description of Open Area Test Site

The test site is located at 11696 Sorrento Valley Road, Suite F, San Diego, CA 92121. The site is physically located 18 miles Northwest of downtown San Diego. The general area is a valley 1.5 miles east of the Pacific Ocean. This particular part of the valley tends to minimize ambient levels, i.e. radio and TV broadcast stations and land mobile communications. The ten-meter site is located behind the office/lab building. It conforms to the normalized site attenuation limits and construction specifications as set in the EN 55022 (1987), CISPR 16 and 22 (1985) and ANSI C63.4-1992 documents. The site attenuation characteristics are verified for compliance every year and was last registered with the Federal Communications Commission on October 21, 1996, FCC Document Number 31040/SIT (1300B3).

4.2 Test Equipment

The following test equipment was used to collect data for this report. All devices used were of current calibration and of the type required in the applicable documents section of this report.

DEVICE TYPE	MANUFACTURE R	MODEL	ASSET #	CAL. DATE	CAL. DUE
Antenna, Biconical	EMCO	3104	128	6/23/99	6/23/00
Antenna, Loop	Electro-Metrics	ALR-25M	134	3/18/99	3/18/00
Quasi-Peak Adapter	Hewlett Packard	85650A	538	9/17/99	9/17/00
Spectrum Analyzer Display	Hewlett Packard	85662A	537	9/17/99	9/17/00
Spectrum Analyzer	Hewlett Packard	8566B	711	9/17/99	9/17/00
RF Preselector	Hewlett Packard	85685A	673	7/22/99	7/22/00

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5. DESCRIPTION OF TESTING METHODS

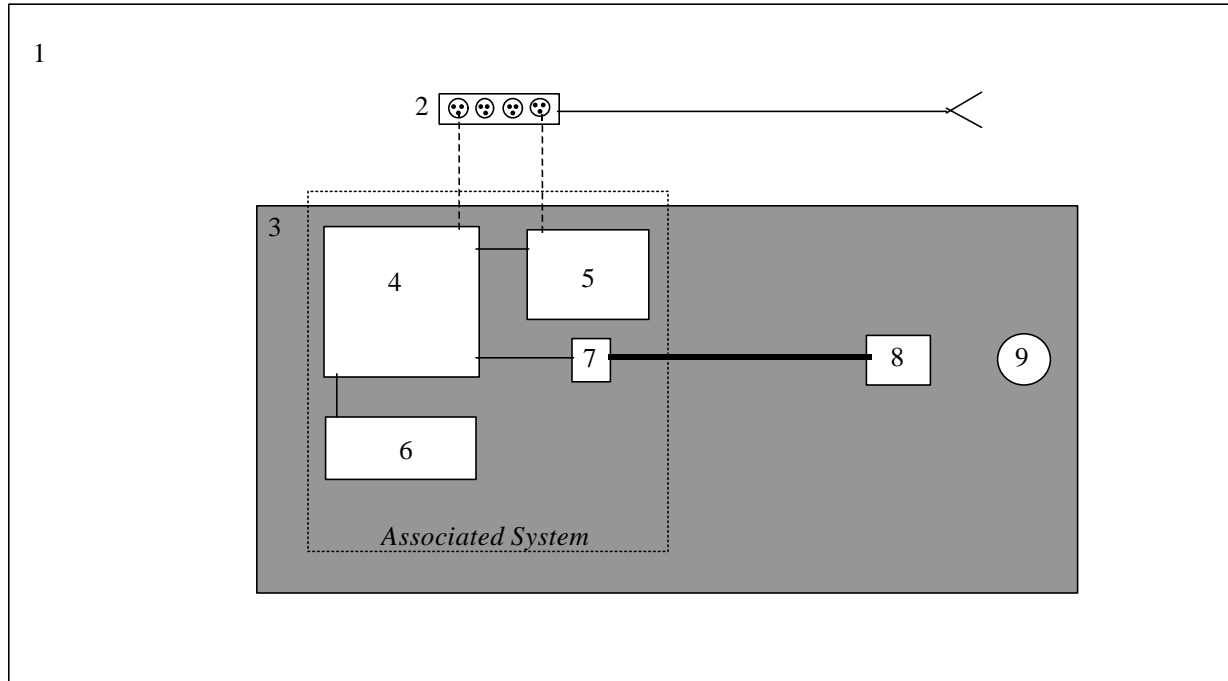
5.1 Introduction

As required in 47 CFR, Parts 2 and 15, the methods employed to test the radiated and conducted emissions (as applicable) of the EUT are those contained within the American National Standards Institute (ANSI) document C63.4-1992, titled "Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz." All applicable FCC Rule Sections that provide further guidance for performance of such testing are also observed.

For General Test Configuration please refer to Figure 1 on the following page.

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Figure 1. General Test Setup Drawing of EUT and Associated System



NOT TO SCALE

CONFIGURATION LEGEND

1. Test Laboratory
2. AC Power for Devices (120V, 60 cycles, single phase)
3. Non-Conducting table 80 cm above ground plane
4. Computer
5. Monitor
6. Keyboard
7. IR Device
8. EUT: Personal Pump Communicator (Transceiver)
9. Implant Unit

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5.2 Configuration and Methods of Measurements for Radiated Emissions

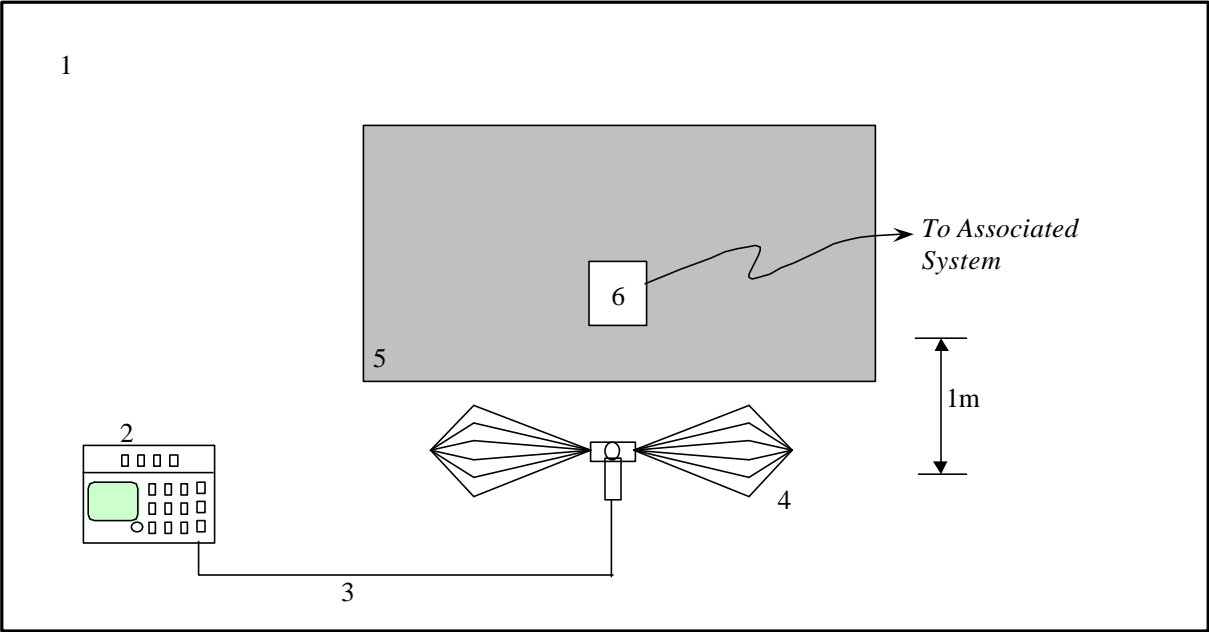
Section 8 of ANSI C63.4 determines the general configuration and procedures for measuring the radiated emissions of equipment under test. Initially, the primary emission frequencies are identified inside the test lab by positioning a broadband receive antenna one meter from the EUT to locate frequencies of significant radiation. Normally this is done inside a shielded chamber to eliminate ambients. Next, the EUT and associated system are placed on a turntable on an 10 meter open area test site (registered with the FCC in accord with its Rules and ANSI C63.4) and the receive antenna is located at a distance of ten or three meters from the EUT.

The EUT and associated system are configured to operate with a series of periodic transmissions, representing a "normally operating" mode. To ensure that the maximum emission at each discrete frequency of interest is observed, the receive antenna is varied in height from one to four meters and rotated to produce horizontal and vertical polarities, and the turntable is also rotated to determine the worst emitting configuration.

For Frequency ID and Radiated Emissions test configurations please refer to Figures 2 and 3 on the following pages.

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Figure 2. Frequency ID of Radiated Emissions Test Setup Drawing



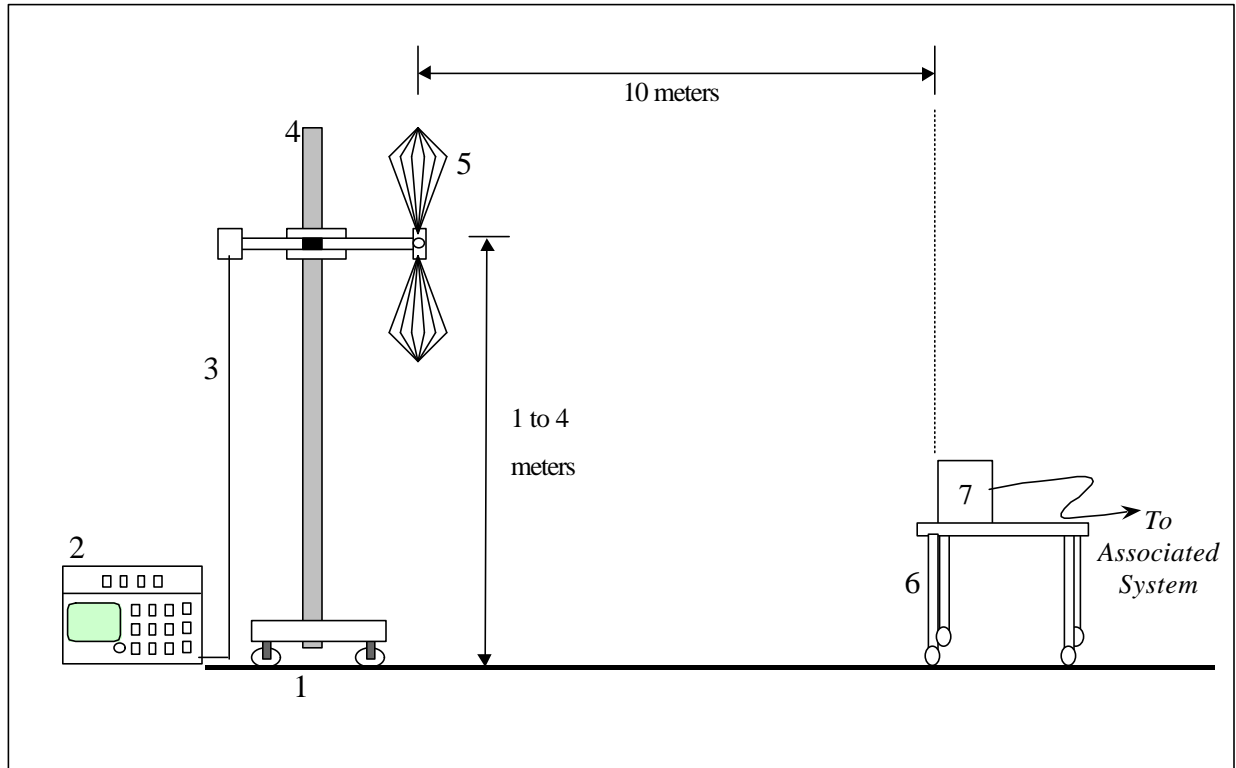
NOT TO SCALE

CONFIGURATION LEGEND

- 1. Test Laboratory
- 2. Spectrum Analyzer with Quasi-Peak Adapter
- 3. Coax interconnect from Antenna to Spectrum Analyzer
- 4. Receive Antenna (basic relative position)
- 5. Non-Conducting table 80 cm above ground plane
- 6. EUT: Personal Pump Communicator (Transceiver)

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Figure 3. Radiated Emissions Test Setup Drawing



NOT TO SCALE

CONFIGURATION LEGEND

1. Ground Plane (11 x 17 meters)
2. Spectrum Analyzer with Quasi-Peak Adapter
3. Coax interconnect from Receive Antenna to Spectrum Analyzer
4. Antenna Mast with motorized mounting assembly
5. Receive Antenna (basic relative position)
6. Non-Conducting table 80cm above ground plane
7. EUT: Personal Pump Communicator (Transceiver)

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5.3 Radiated Emission Field Strength

47 CFR sections §15.201, §15.203, §15.205, §15.209 specify the general emission specification limits and several specific parameter measures for low power transmitters operating in the frequency ranges. Compliance to the specific sections are listed below.

§15.203: The device under test has no external antenna. The user has no practical means to attach an external antenna

§15.205, §15.209: These sections specify the radiated emissions limits and restricted bands of operation. Please refer to the data sheets attached to this report for a tabulated list of the emission frequencies and their compliance status.

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6. TEST RESULTS

6.1 Radiated Emissions Test Data

Nemko EESI, Inc.
FCC, Part 15C, 15.209 Radiated Emissions Data Sheet
(10m Open Area Test Site)

Client: Medical Research Group
EUT: Tranceivers
Model #: MMT-2007 & MMT-313X

Conducted by: *M. L. K.*
Date of Test: 10-01-99
Test Distance, Amp. gain: 10 m, 59 dB

Frequency (MHz)	Spectrum Analyzer Reading at 10m (dB μ V)	Antenna Polori- zation (vertical or horizontal)	f_o	Amp. Gain & Cable Loss, Distance & Antenna Factor Correction for 10 m (dB μ V/m)	Total Interference Level at 10m (dB μ V/m)	Emission Spec. Limit at 10m (dB μ V/m)	Difference Margin (dB)
0.262	-3.1	v	f_o	42.4	-19.7	19.2	-38.9

Note: No additional harmonics (f_2 - f_{10}) of the fundamental frequency were observed within 10dB of the limit.

Test Conditions: Standard radiated emissions test set up on FCC registered open field site. The highest emissions for all antenna heights, polarities, and table orientations are the only emissions recorded.

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6.2 Spurious Radiated Emissions Test Data

Nemko EESI, Inc.
FCC, Part 15C, Section 15.209 Spurious Radiated Emissions Data Sheet
(10m Open Area Test Site)

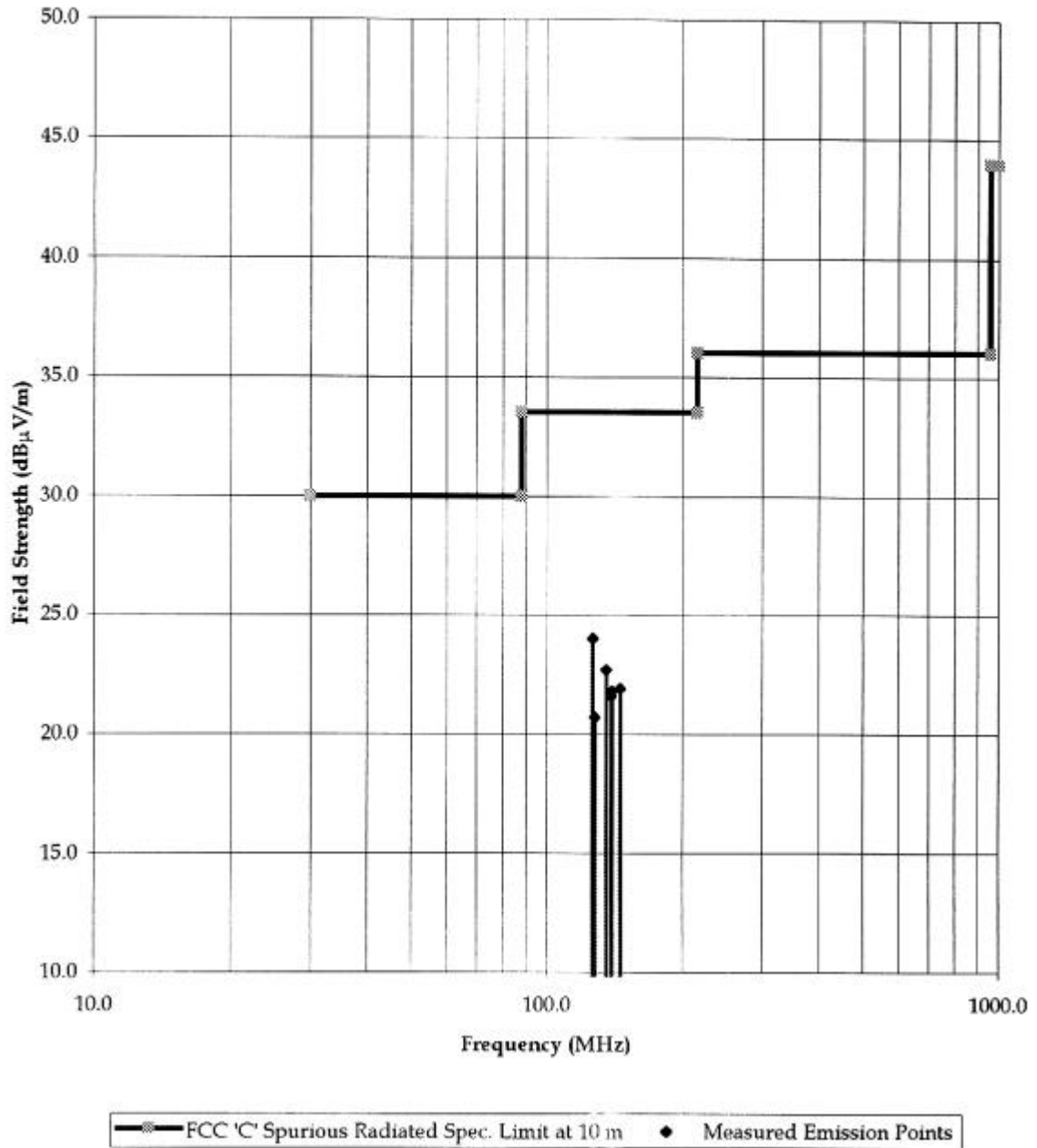
Client: Medical Research Group Conducted by: _____
EUT: Implantable Insulin Delivery System Date of Test: 09/22/99
Model #: MMT-2007 & MMT-313X (Boot Loader Mode) Frequency Range: 30-1000MHz

Frequency (MHz)	Spectrum Analyzer Reading (dBμV)	Antenna Polarization (V or H)	Amp. Gain & Cable Loss, Distance & Antenna Factor Correction for 10m (dB/m)	Total Interference Level Corrected for 10 m (dBμV/m)	Emission Spec. Limit at 10 m (dBμV/m)	Difference Margin (dB)
126.800	9.7	h	14.3	24.0	33.5	-9.5
127.980	7.0	v	13.7	20.7	33.5	-12.8
135.700	9.8	v	12.9	22.7	33.5	-10.8
139.280	8.6	v	13.0	21.6	33.5	-11.9
139.880	8.8	v	13.0	21.8	33.5	-11.7
146.100	7.9	v	14.0	21.9	33.5	-11.6

Test Conditions: Standard radiated emissions test set up on FCC registered open field site. The highest emissions for all antenna heights, polarities, and table orientations are the only emissions recorded.

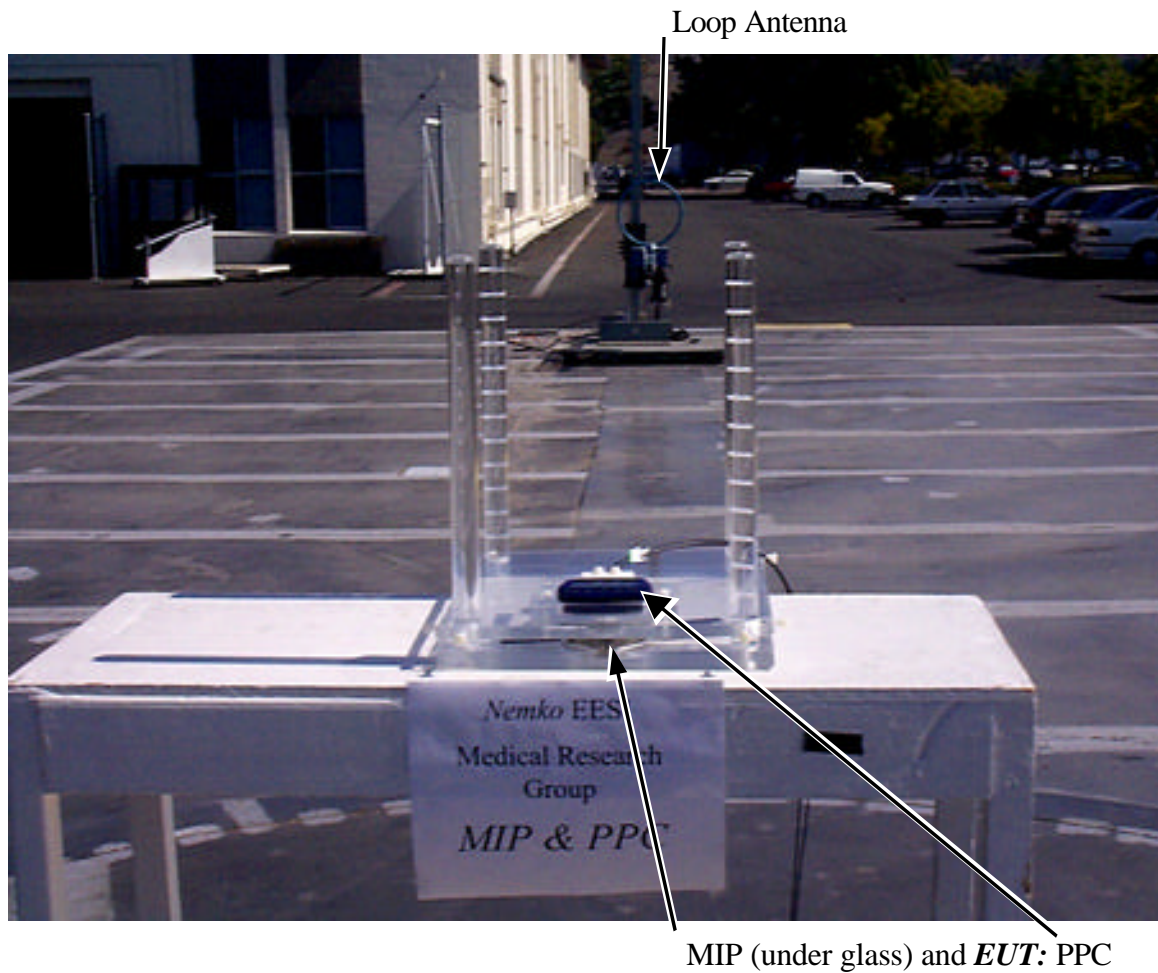
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Medical Research Group - Implantable Insulin Delivery System: MMT-
2007 & MMT-313X (Boot Loader Mode)
Radiated Emissions Profile (09/22/99) - Nemko EESI



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Figure 4. Radiated Emissions Test Configuration Photograph



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APPENDIX A

Conducted & Radiated Emissions Measurement Uncertainties

1. Introduction

ISO Guide 25(1990) and ANSI/NCSL Z540-1(1994) require that all measurements contained in a test report be “traceable”. “Traceability” is defined in the *International Vocabulary of Basic and General Terms in Metrology* (ISO: 1993) as: “the property of the result of a measurement... whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, *all having stated uncertainties*”.

The purposes of this Appendix are to “state the *Measurement Uncertainties*” of the conducted emissions and radiated emissions measurements contained in Section 5 of this Test Report, and to provide a practical explanation of the meaning of these measurement uncertainties.

2. Statement Of The Worst-Case Measurement Uncertainties For The Conducted And Radiated Emissions Measurements Contained In This Test Report

Table 1: Worst-Case Expanded Uncertainty "U" of Measurement for a k=2 Coverage Factor

Conducted Emissions Measurement Detection Systems	Applicable Frequency Range	"U" for a k=2 Coverage Factor	Applicable (If checked)
HP8568B Spectrum Analyzer with QPA and HP8447F Preamplifier	150 kHz - 30 MHz	+/- 3.0 dB	
HP8566B Spectrum Analyzer with QPA and Preselector	9 kHz - 30 MHz	+/- 2.9 dB	
Radiated Emissions Measurement Detection Systems	Applicable Frequency Range	"U" for a k=2 Coverage Factor	Applicable (If checked)
HP8568B Spectrum Analyzer with QPA & HP8447F Preamplifier	30 MHz - 200 MHz	+4.0 dB, -4.1 dB	
HP8568B Spectrum Analyzer with QPA & HP8447F Preamplifier	200 MHz-1000 MHz	+/- 3.5 dB	
HP8566B Spectrum Analyzer with QPA & Preselector	30 MHz - 200 MHz	+3.9 dB, -4.0 dB	✓
HP8566B Spectrum Analyzer with QPA & Preselector	200 MHz-1000 MHz	+/- 3.4 dB	✓
HP8566B Spectrum Analyzer with QPA & HP 8449A Preamplifier	1 GHz - 18 GHz	+2.5 dB, -2.6 dB	
HP8566B Spectrum Analyzer with QPA & HP8449A Preamplifier	18 GHz - 40 GHz	+/- 3.4 dB	

NOTES:

1. Applies to 3 and 10 meter measurement distances
2. Applies to all valid combinations of Transducers (i.e. LISNs, Line Voltage Probes, and Antennas, as appropriate)
3. Excludes the Repeatability of the EUT

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3. Practical Explanation Of The Meaning Of The Conducted And Radiated Emissions Measurement Uncertainties

In general, a "Statement of Measurement Uncertainty" means that with a certain (specified) confidence level, the "true" value of a measurand will be between a (stated) upper bound and a (stated) lower bound.

In the specific case of EMC Measurements in this test report, the measurement uncertainties of the conducted emissions measurements and the radiated emissions measurements have been calculated in accordance with the method detailed in the following documents:

- *ISO Guide to the Expression of Uncertainty in Measurement* (ISO, 1993)
- NIS 81:1994, *The Treatment of Uncertainty in EMC Measurements* (NAMAS, 1994)
- NIST Technical Note 1297(1994), *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results* (NIST, 1994)

The calculation method used in these documents requires that the stated uncertainty of the measurements be expressed as an "expanded uncertainty", U , with a $k=2$ coverage factor. The practical interpretation of this method of expressing measurement uncertainty is shown in the following example:

EXAMPLE:

Assume that at 39.51 MHz, the (measured) radiated emissions level was equal to +26.5 dB μ V/m, and that the $\pm 2\sigma$ (i.e. 95% confidence level) measurement uncertainty was ± 3.4 dB.

In the example above, the phrase "k = 2 Coverage Factor" simply means that the measurement uncertainty is stated to cover ± 2 standard deviations (i.e. a 95% confidence interval) about the measurand. The measurand is the radiated emissions measurement of +26.5 dB μ V/m at 39.51 MHz, and the 95% bounds for the uncertainty are -3.4 dB to + 3.4 dB. One can thus be 95% confident that the "true" value of the radiated emissions measurement is between +23.1 dB μ V/m and +29.5 dB μ V/m. *In effect, this means that in the above example there is only a 2.5% chance that the "true" radiated emissions value exceeds +29.5 dB μ V/m.*

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APPENDIX B

Nemko EESI, Inc.'s Test Equipment & Facilities Calibration Program

Nemko EESI, Inc. operates a comprehensive Periodic Calibration Program in order to ensure the validity of all test data. Nemko EESI's Periodic Calibration Program is fully compliant to the requirements of NVLAP Policy Guide PG-1-1988, ANSI/NCSL Z540-1 (1994), ISO 10012-1 (1993-05-01), ISO Guide 25 (1990), ISO-9000 and EN 45001. Nemko EESI, Inc.'s calibration program therefore meets or exceeds the US national commercial and military requirements [N.B. ANSI/NCSL Z540-1 (1994) replaces MIL-STD-45662A].

Specifically, all of Nemko EESI's *primary reference standard devices* (e.g. vector voltmeters, multimeters, attenuators and terminations, RF power meters and their detector heads, oscilloscope mainframes and plug-ins, spectrum analyzers, RF preselectors, quasi-peak adapters, interference analyzers, impulse generators, signal generators and pulse/function generators, field-strength meters and their detector heads, etc.) and certain *secondary standard devices* (e.g. RF Preamplifiers used in CISPR 11/22 and FCC Part 15/18 tests) are periodically recalibrated by:

- A Nemko EESI-approved independent (third party) metrology laboratory that uses NIST-traceable standards and that is ISO Guide 25-accredited as a calibration laboratories by NIST; or,
- A Nemko EESI-approved independent (third party) metrology laboratory that uses NIST-traceable standards and that is ISO Guide 25-accredited as a calibration laboratory by another accreditation body (such as A2LA) that is mutually recognized by NIST; or,
- A manufacturer of Measurement and Test Equipment (M&TE), if the manufacturer uses NIST-traceable standards and is ISO Guide 25-accredited as calibration laboratory either by NIST or by another accreditation body (such as A2LA) that is mutually recognized by NIST; or
- A manufacturer of M&TE (or by a Nemko EESI-approved independent third party metrology laboratory) that is not ISO Guide 25-accredited. (In these cases, Nemko EESI conducts an annual audit of the manufacturer or metrology laboratory for the purposes of proving traceability to NIST, ensuring that adequate and repeatable calibration procedures are being applied, and verifying conformity with the other requirements of ISO Guide 25).

In all cases, the entity performing the Calibration is required to furnish Nemko EESI with a calibration test report and/or certificate of calibration, and a "calibration sticker" on each item of M&TE that is successfully calibrated.

Calibration intervals are normally one year, except when the manufacture advises a shorter interval (e.g. the HP 8568B Spectrum Analyzer is recalibrated every six months) or if US Government directives or client requirements demand a shorter interval. Items of instrumentation/related equipment which fail during routine use, or which suffer visible mechanical damage (during use or while in transit), are sidelined pending repair and recalibration. (Repairs are carried out either in-house [if

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minor] or by a Nemko EESI-approved independent [third party] metrology laboratory, or by the manufacturer of the item of M&TE).

Each antenna used for CISPR 11 and CISPR 22 and FCC Part 15 and Part 18 radiated emissions testing (and for testing to the equivalent European Norms) is calibrated annually by either a NIST (or A2LA) ISO Guide 25-Accredited third-party Antenna Calibration Laboratory or by the antenna's OEM if the OEM is NIST or A2LA ISO Guide 25-accredited as an antenna calibration laboratory. The antenna calibrations are performed using the methods specified in Annex G.5 of CISPR 16-1(1993) or ANSI C63.5-1991, including the "Three-Antenna Method". Certain other kinds of antennas (e.g. magnetic-shielded loop antennas) are calibrated annually by either a NIST (or A2LA) ISO Guide 25-accredited third-party antenna calibration laboratory, or by the antenna's OEM if the OEM is NIST or A2LA ISO Guide 25-accredited as an antenna calibration laboratory using the procedures specified in the latest version of SAE ARP-958.

In accordance with FCC and other regulations, Nemko EESI recalibrates its suite of antennas used for radiated emissions tests on an annual basis. These calibrations are performed as a precursor to the FCC-required annual revalidation of the Normalized Site Attenuation properties of Nemko EESI's Open Area Test Site. Nemko EESI, Inc. uses the procedures given in both Subclause 16.6 and Annex G.2 of CISPR 16-1 (1993), and, ANSI C63.4-1992 when performing the normalized site attenuation measurements.