Engineering Change Notice (ECN)

QAFO 0001

Originated By:	Cottrill	Effective Date:	6-9-2014

Document Number	REVISION NEW	REVISION OLD	Initial Release Y/N	Document Title
EERE 0627	1.1	--	Yes	Model 4200 Patient Programmer Charger Conducted
EERE 0628	1.1	--	Yes	Model 4300 External Pulse Generator Conducted Transmit
EERE 0629	1.1	--	Yes	Model 4500 Clinician Programmer Conducted Transmit
EEEX 0230	1.1	--	Yes	EPG Engineering Exhibits for FCC Certification
EEEX 0231	1.1	--	Yes	CP Engineering Exhibits for FCC Certification
EEEX 0232	1.1	--	Yes	PFT Engineering Exhibits for FCC Certification
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				

Change Description

Initial release

Reason for Change (Justification)

This set of reports describes the RF Test Method and Conducted Transmit Power Output Test Results for the Model 4200 PPC, Model 4300 EPG, and Model 4500 CP.

The exhibits reflect information included for submission to FCC including for EPG (eeex 0230), CP (eeex 0231), and PFT (EEEX 0232).

1. Antenna Information [EPG & CP Only]
2. Internal Photos
3. Radio Block Diagram
4. Radio BOM [EPG & CP Only]
5. Radio Operational Description
6. Radio Schematic
7. Tune-up Procedure [EPG & CP Only]

Training Required per Approved Matrix		YES	x	NO (requires a brief rationale)

Rationale: Document type does not require training.

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Disposition of Material	
X	**No Material Affected** (Comments): Samples are representative of manufactured devices.
N/A	**Scrap** (Comments):
N/A	**Rework** (Instructions):
N/A	**Use As Is** (Justification):
N/A	**Other:** (Describe)

CURRENT CHANGE AFFECTS (If "Yes", list document number)			
☒ NO IMPACT (requires rationale)	Verification (Y/N) Doc.#:	Validation(Y/N) Doc.#:	Risk Management(Y/N) Doc.#:
☐ Documentation, Procedures, Forms and Work Instructions	Regulatory(Y/N) Doc.#:	Other: (Y/N) Doc.#:	Other: (Y/N) Doc.#:

"NO IMPACT" was selected please provide a brief justification rationale:

This engineering report is to ensure compliance with FCC regulations. It does not impact existing design verification, validation, risk management, or other regulatory submissions.

YES	NO	
n/a	n/a	One or more of the element(s) from "Current Change Affects" were selected which requires that effects of the change be described and the appropriate documentation to implement the change be provided.

"Current Change Affects" element(s) were selected which require the effects of the change be described below:

N/A

If changes affects a Device model, please list all affected model numbers below:

1	Model 4200 PPC	2	Model 4300 EPG	3	Model 4500 CP	4	N/A

REVIEW SIGNATURES				DATE	DIST
X	Document Author:	David Petsko	David A Petsko	6-9-14	
X	Director:	Mike Labbe		6/9/14	
X	Regulatory:	Doug Atkins	SEE ATTACHED SHEET	6-6-2014	
X	Quality:	KM Ahsan	SEE ATTACHED SHEET	6-6-14	
X	Engineering Manager:	Jeff Weisgarber	Jeffrey A Weisgarber	6/6/2014	
N/A	Executive Management:				
N/A	Marketing:				
X	Other:	Ben Cottrill		2014-June-6	

Processed By: RG Zay Date: 6/9/2014

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X	Engineering Manager:	Jeff Weisgarber		
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X	Other:	Ben Cottrill		

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N/A	Marketing:			
X	Other: Ben Cottrill			

Processed By: _____ Date: _____

Test Report	
Title: **Model 4500 Clinician Programmer Conducted Transmit Power Output Report**	
Document Number and Revision: **EERE 0629 Revision 1.2**	Page 1 of 3
Prepared By: Dave Petsko	Approved By:

1. Purpose

FCC Rules §2.1046 requires the conducted measurement of transmitter power output be included in the EMC test report documents submitted to the FCC for product certification. This document describes the RF Test Method and Conducted Transmit Power Output Test Results for Clinician Programmer (CP), Model 4500.

2. References

- 47 CFR § 2.1046(a)
- 1310-000062-07 / DS-0000-89-8 Rev 002-a Torpedo Clinician Programmer Schematic
- 1330-000051-04 / AP-0001-06-7 rev 004 ASBY PCB Torpedo Clinician Programmer
    - reworked per DA-0002-67-9 EEWI 0181 Clinician Programmer Board modification Work Instruction rev1.4.docx

3. RF Test Method

The 402-405 MHz conducted transmit power output of the Clinician Programmer, Model 4500 may be measured directly from the Murata MM8130-2600 RF Connector with Switch using a test coaxial cable and spectrum analyzer.

4. Equipment Used

Table 1 – List of Test Equipment

Equipment	Mfg.	Model	Cal ID	Cal Due
Spectrum Analyzer	Rohde Schwartz	FSL6	10055	8 NOV 2014
Coax Cable*	Johnson/Emerson	415-0033-012	NA	NA

5. Sample Information

A single sample was used for the Conducted Transmit Power Output Test as described in Table 2 below.

Table 2 – Sample Used

	CP Sample 1
Serial Number	FF00013
DBR	1565
Flash Memory Card, Application	5601-000017-00
Flash Memory Card, OS	5601-000014-03

5.1. Sample Traceability

Traceability records are defined for the sample including workflow/traveler, which includes reference to BOM revision, manufacturing procedures with revision number and component lot or serial numbers. A description of the methods and processes used to assemble/process the materials are recorded in the Minnetronix Development Build Record (DBR) so that the method and processes can be repeated if necessary. The DBR incorporates:

- DA-0001-89-5 ASBY Assembly Procedure for Torpedo Clinician programmer

- Revision information for BOMs
- Supplements for updates (e.g. software changes, any rework, etc.)

5.2. Sample Retention

Sample is retained at QIG's Cleveland facility.

6. Transmitter Power Output Test Results

The 402-405 MHz transmitter measured conducted power output data was recorded for low, medium, and high RF channels selected. The test results are shown in Figure 1 and recorded in Table 3. Test limits are not applicable per FCC §2.1046 requirements.

Figure 1 - Conducted Transmitter Power, Clinician Programmer, Model 4500

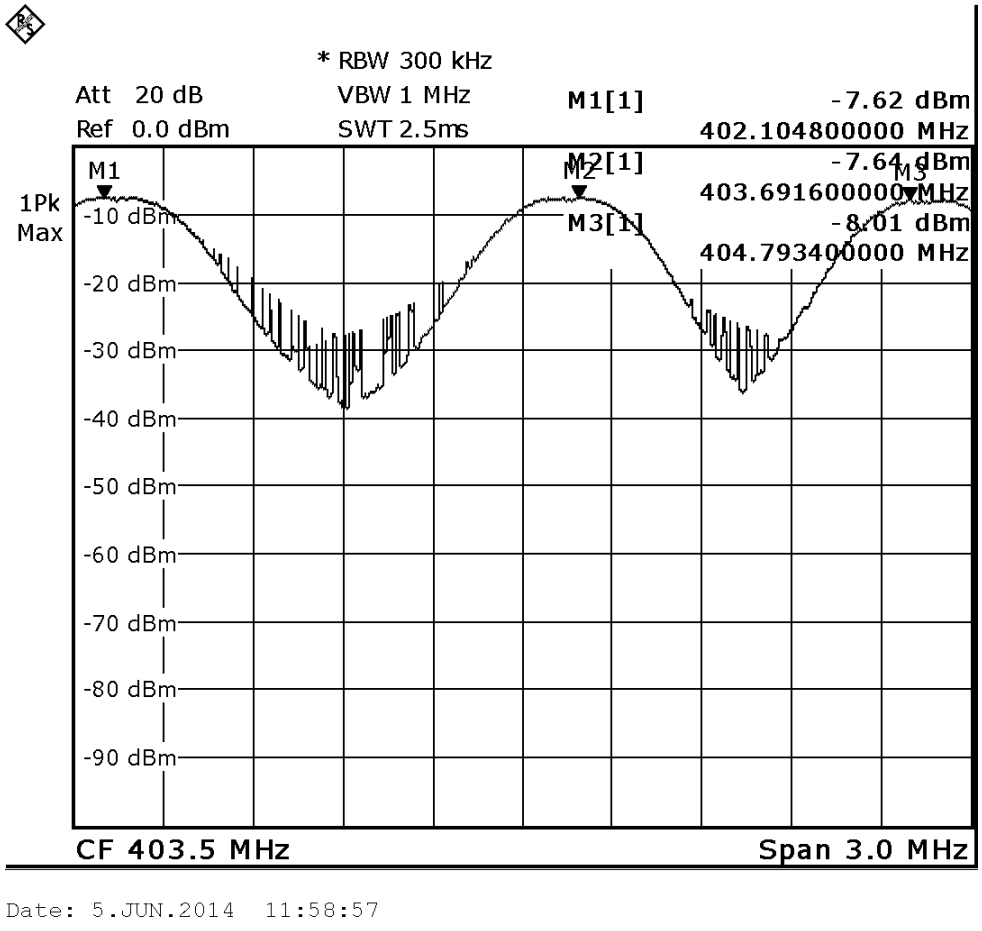

Table 3 – Clinician Programmer, Model 4500, Conducted Transmit Power Output

Transmit Power Setting 52	Channel 0	Channel 5	Channel 9
Frequency (MHz)	402.15	403.65	404.85
Power Output (dBm)	-7.32	-7.4	-7.71

* Coax Cable Insertion Loss – 0.3 dB

7. Revision History

Revision Level	Revision Description	ECN No#	Effective Date
1.1	Initial release	2333	06/09/14
1.2	Removed internal device photo.	2365	07/02/14