Engineering Change Notice (ECN)

QAFO 0001

Originated By:	Lisa Jorgenson	Effective Date:	7-2-2014

Document Number	REVISION		Initial Release Y / N	Document Title
	NEW	OLD		
EERE 0625	1.2	1.1	N	Model 4100 PoP conducted transmit power output report
EERE 0627	1.2	1.1	N	Model 4200 PPC conducted transmit power output report
EERE 0628	1.2	1.1	N	Model 4300 EPG conducted transmit power output report
EERE 0629	1.2	1.1	N	Model 4500 CP conducted transmit power output report
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				

Change Description

To remove the internal pictures in the body of the reports listed above

Reason for Change (Justification)

Change is requested by Northwest EMC based on their review of the reports. The reports show internal photos of the device and we have requested that internal photos be held confidential; however, test reports aren't eligible for confidential treatment.

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

Rationale: Employee training is not required to remove the internal pictures in the transmit power output report

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Disposition of Material	
X	**No Material Affected** (Comments):
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)

[X] 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:

The removal of internal pictures from these documents do not affect any documentation already released.

YES	NO	
	X	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	N/A	2	N/A	3	N/A	4	N/A

REVIEW SIGNATURES				DATE	DIST
X	Document Author	Lisa Jorgenson	LA	7-2-14	
X	Director:	Mike Labbe		7/2/14	
N/A	Clinical				
X	Regulatory	Doug Atkins		7-2-2014	
X	Quality:	KM Ahsan		7-2-14	
X	Engineering Manager:	Jeff Weisgarber	SEE ATTACHED SHEET	7-2-14	
N/A	Project Manager				
N/A	Executive Management:				
N/A	Marketing:				
X	Other:	Ben Cottrill	SEE ATTACHED SHEET	7-2-14	

Processed By: R.G Zenz Date: 7/2/2014

ECN # 2365

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Disposition of Material	
X	**No Material Affected** (Comments):
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)			
[X] NO IMPACT (requires rationale)	Verification (Y/N) Doc.#:	Validation(Y/N) Doc.#:	Risk Management(Y/N) Doc.#:
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X	Director:	Mike Labbe			
N/A	Clinical				
X	Regulatory	Doug Atkins			
X	Quality:	KM Ahsan			
X	Engineering Manager:	Jeff Weisgarber	Jeffry A. Weisgarber	7/1/2014	
N/A	Project Manager				
N/A	Executive Management:				
N/A	Marketing:				
X	Other:	Ben Cottrill		2014-Jul-2	

Processed By: _____ Date: _____

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 Patient Programmer Charger (PPC), Model 4200.

2. References

- 47 CFR § 2.1046(a)
- DS-0000-79-7 Torpedo Patient Programmer / Charger Schematic 001-a
- AP-0000-99-9 ASBY PCB Torpedo Patient Programmer / Charger 001-a

3. RF Test Method

The 402-405 MHz conducted transmit power output of the Patient Programmer Charger, Model 4200 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

	PPC Sample 1
PCB Serial Number	0013
PPC DBR #	Dbr1358, log1049
PPC Serial Number [EXID]	0x034569
SW Version	Custom EMC Test Software \ PWM, Antenna, MICS test apps, Torpedo\Software\PPC\Tools

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-0001-89-8 ASBY Assembly Procedure for Torpedo PPC Patient 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, Patient Programmer Charger, Model 4200

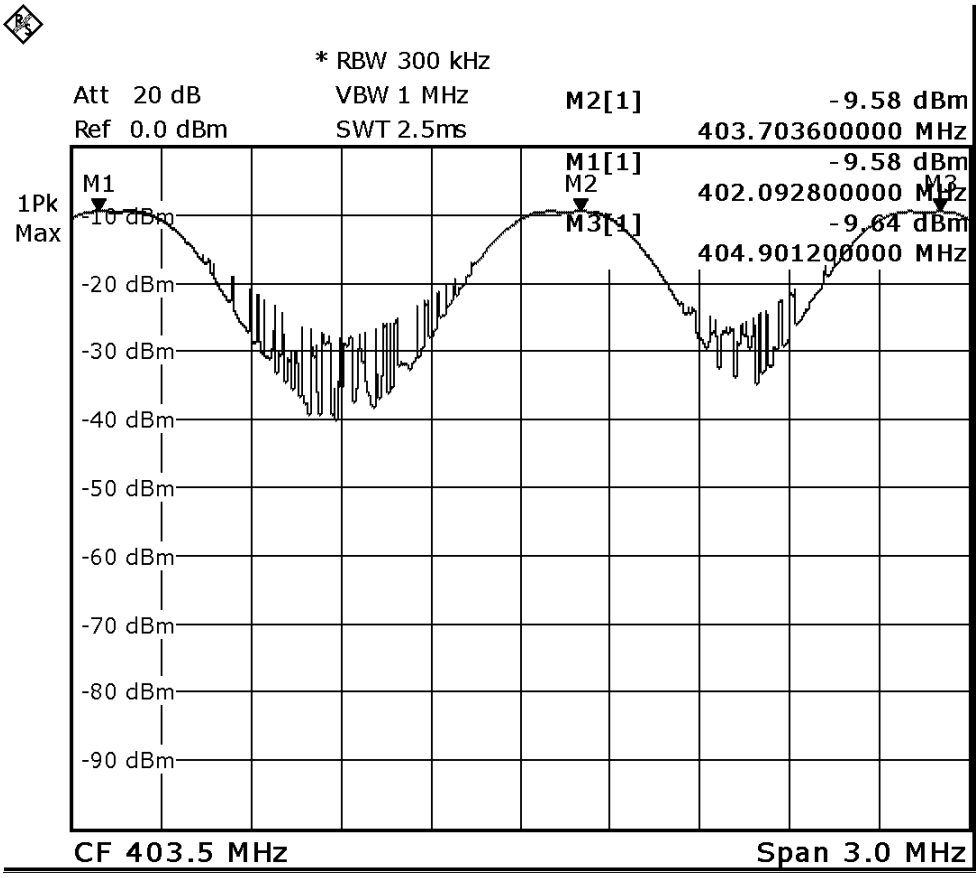

Table 3 – Patient Programmer Charger, Model 4200, Conducted Transmit Power Output

Transmit Power Setting 52	Channel 0	Channel 5	Channel 9
Frequency (MHz)	402.15	403.65	404.85
Power Output (dBm)	-9.28	-9.28	-9.34

* 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