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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N/A	Marketing:			
X	Other:	Ben Cottrill		

Processed By: _____ Date: _____

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X	Engineering Manager: Jeff Weisgarber			
N/A	Executive Management:			
N/A	Marketing:			
X	Other: Ben Cottrill			

Processed By: _____ Date: _____

Test Report

Title: **Model 4300 External Pulse Generator Conducted Transmit Power Output Report**	
Document Number and Revision: **EERE 0628 Revision 1.2**	Page 1 of 5
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 External Pulse Generator (EPG), Model 4300.

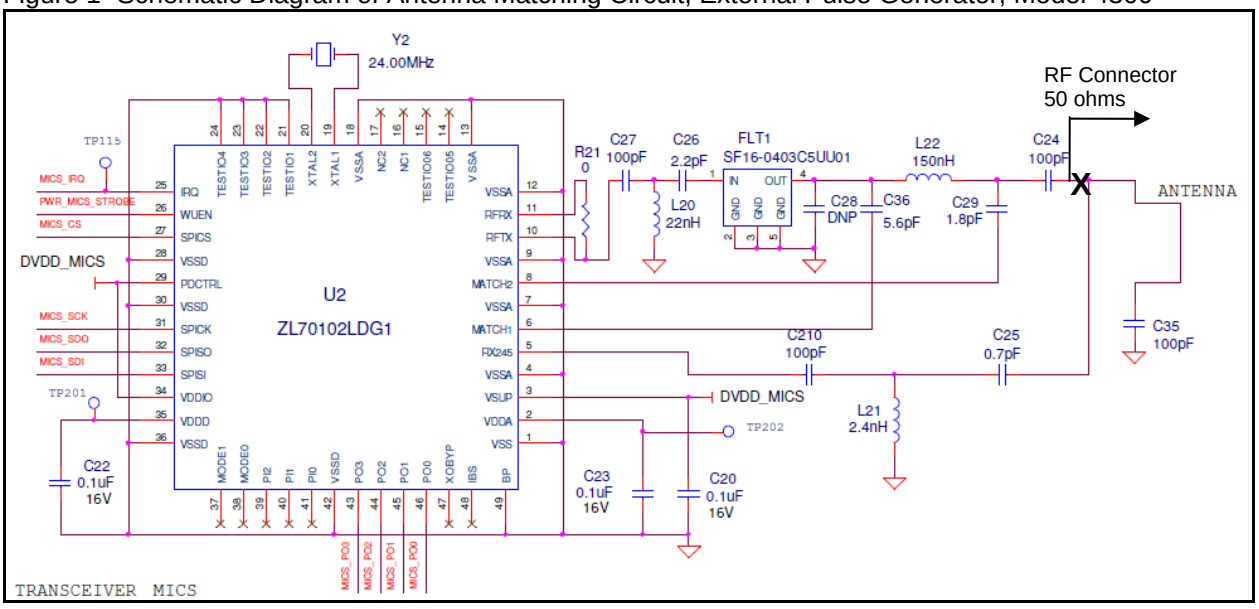
2. References

- 47 CFR § 2.1046(a)
- 1310-000060-03 EPG Schematic
- 1330-000053-03 EPG PCB Assembly Drawings / AP-0001-01-7 ASBY PCB Torpedo EPG 003-b

3. RF Test Method

The 402-405 MHz conducted transmit power output of the External Pulse Generator, Model 4300 may be measured directly by attaching a Murata MM8130-2600 coaxial connector with switch to the 50 Ohms I/O point of the PCB (EPG, Model 4300, Assembly Drawing 1330-000053) as shown in Figure 1.

Figure 1- Schematic Diagram of Antenna Matching Circuit, External Pulse Generator, Model 4300



The connector body (ground terminal) was soldered to the PCB ground flood area adjacent to capacitor C24. Capacitors C24 was turned CCW (90^0) such that C24 was disconnected from the. The open end of capacitor C24 was then soldered to the connector center conductor (hot terminal). (See the schematic location marked **X**). Finally, to impedance match FLT1 output to the 50 ohms (connector), inductor L22 was changed from 150nH to 36nH (Coilcraft part number 0402CS-36NXJL) and auto-tuned to peak signal strength using a Zarlink base station / PC running the QiG xCT application software revision 2.10.

Note: Attachment of the coaxial connector to the PCB assembly should be done by a trained electronics technician to allow for proper soldering and prevention of undue stress on the PCB solder connection (I.e. PCB pad area damage may easily occur).

The PCB is then connected to a spectrum analyzer via coax cable for measurement of transmitter conducted power output.

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

	EPG Sample 1
PCB Serial Number	0083
PCB Version	3.0
SW Version	R1.00.0005

5.1. Sample Traceability

The PCB certificate of compliance is attached in Appendix A - PCB Certificate of Compliance.

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 2 and recorded in Table 3. Test limits are not applicable per FCC §2.1046 requirements.

Figure 2 - Conducted Transmitter Power, External Pulse Generator, Model 4300

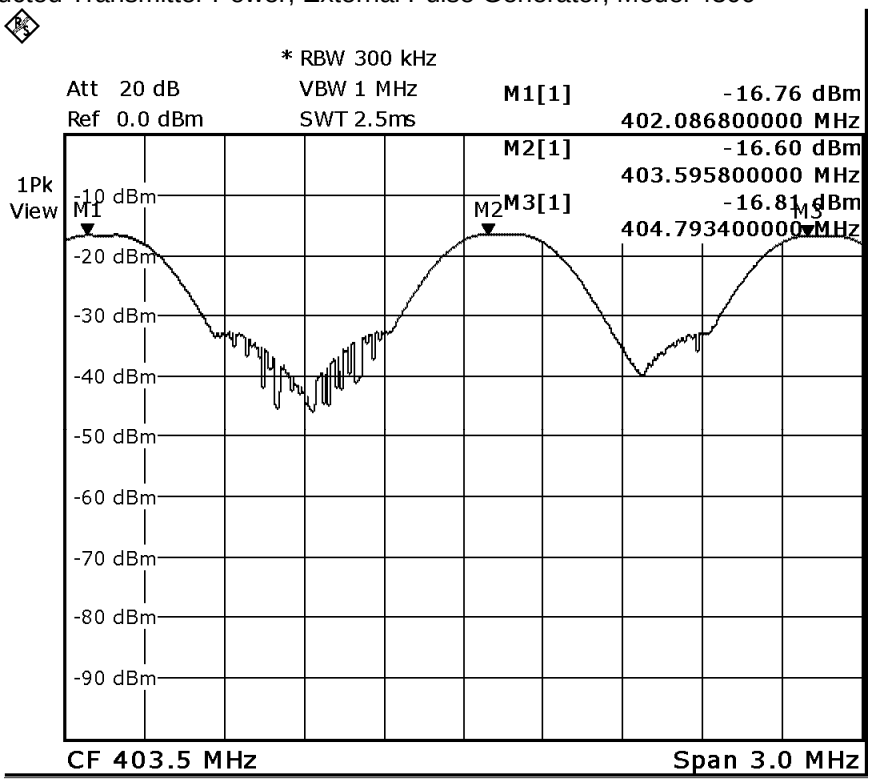


Table 3 – External Pulse Generator, Model 4300, Conducted Transmit Power Output

Transmit Power Setting 52	Channel 0	Channel 5	Channel 9
Frequency (MHz)	402.15	403.65	404.85
Power Output (dBm)	-16.46	-16.30	-16.51

* 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

8. Appendix A - PCB Certificate of Compliance

30062034

ei microcircuits

1031 Pahl Road Marikato, MN 56001 • Phone 507.345.5788 • FAX 507.345.7559 www.eimicro.com

Certificate of Compliance

Customer: QiG Group

Attention: QA Dept.

This document certifies that all materials and processes used in the manufacturing of this product are in compliance with the requirements of the customer supplied documentation.

Customer Part Number: 1330-000053

Customer Revision: 03

Product Description: EPG

Deviation from customers specifications, if any:

P.O. Number: 20190033

Lot Number/Date Code: 30062034 / 17 MAR 2014

Quantity: 24

Serial Number or Range: 0061-0084

Kalysta Rivera — Employee Name (Print)

Quality Engineer — Employee Title

[signature] — Employee Signature

3/6/14 — Date

A	121043	12/06/12	DW	DL
REV	ECO NO	DATE	DRFT	APP

SIP-10028-01

ei microcircuits
1651 Pahl Road • Mankato, MN 56001
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PACKING LIST

ORDER NUMBER	ORDER DATE	PAGE
20048250	3/7/2014	1

12172-03LF

BILL TO:
GREATBATCH, INC
10000 WEHRLE DRIVE
CLARENCE, NY 14031
Ship ID:

SHIP TO: QIG GROUP
1771 EAST 30TH STREET
CLEVELAND, OH 44114
UNITED STATES
Customer PO 20190033

CUSTOMER PURCHASE ORDER NO.	TERMS	SHIP VIA	FOB POINT
20190033	NET 30 DAYS	FED EX GROUND	MANKATO

ORDERED BY	SALES REPRESENTATIVE	ORDER DATE	OUR ORDER NO.	CUSTOMER ID
RC0	EI SALES	2/21/2014	20048250	GREAT

LINE NO.	DUE DATE	QTY ORDERED	QTY SHIPPED	U/M	UNIT	CUSTOMER PART NUMBER	REV	DESCRIPTION / COMMENTS	EIM PART NO.
01 01	3/7/2014	24	24	EA		1330-000053	03	GREAT EPG Board Assembly	12172-03LF
QTY:			PART NUMBER:					REVISION:	

NOTES:

Comments:

CERTIFICATE OF CONFORMANCE:
SELLER HEREBY CERTIFIES THAT ALL MATERIALS AND PROCESSES USED IN THE MANUFACTURE OF THIS SHIPMENT COMPLIES WITH REQUIREMENTS PER CUSTOMER SUPPLIED DOCUMENTATION. THIS INCLUDES BUILDING TO THE APPLICABLE CLASS OF CUR. REV STD IPC-A-610, DEFAULTING TO CLASS 2 AS PERMITTED. ELECTRONIC TRACEABILITY IS AVAILABLE UPON REQUEST BY PROVIDING A COPY OF THIS FORM.

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