

EXHIBIT T – Technical Report

FCC ID: PG6BA0T

Measurement/Technical Report

Biotronik, Inc., PG6BA0T

FCC ID: PG6BA0T

October 20, 2000

This report concerns (check one):		Original Grant <u> x </u>	Class II Change <u> </u>
Equipment Type: <u>MICS, Medical Implant Transmitter</u>		Rule Part: <u>47 CFR 95.603</u>	
Deferred grant requested per 47 CFR 0.457 (d)(1)(ii)?		yes <u> </u> no <u> X </u>	
If yes, defer until:		<u> N/A </u> date	
<u>Biotronik, Inc.</u> agrees to notify the Commission by:		<u> N/A </u> date	
of the intended date of announcement of the product so that the grant can be issued on that date.			
Report prepared by:		Northwest EMC, Inc. 22975 NW Evergreen Parkway, Suite 400 Hillsboro, OR 97124 (503) 844-4066 fax: (503) 844-3826	
Report No. MICR0001			

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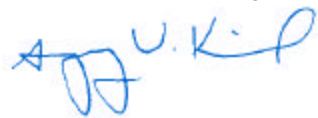
1.0 General Information

1.1 Product Description

Manufactured ByBiotronik, Inc.
Address..... 6024 SW Jean Rd. Building B, Lake Oswego, OR 97035
Test Requested By:..... Mark Johnson
Model.....Philos DR-T (a.k.a. Actros C-T)
FCC ID PG6BA0T
Applicable FCC Rule Part(s).....MICS, 47 CFR 95.603
Serial Number(s) 75103203-210
Date of Test October 19 - 20, 2000
Job NumberMICR0001

Prepared By:

Vicki Albertson, Technical Report and
Documentation Manager

Technical Review By:

Greg Kiemel, Director of Engineering

Approved By:

Donald Facteau, IS Manager

1.1 Product Description con't

The Equipment Under Test (EUT) is the Biotronik, Inc. Medical Implant Transmitter, Model Philos DR-T (aka Actros C-T). The transmitter is seeking authorization under the Medical Implant Communications Service (MICS, Part 95.603) as an ultra-low power transmitter. The transmitter is integral to a medical pacemaker and facilitates non-voice data communications with physicians. The pacemaker with the transmitter is a stand-alone device. It has an internal power source (lithium iodine battery).

The transmitter operates at 403.6 MHz, using FSK modulation with an occupied bandwidth of 46 kHz.

Please see the Operational Description, Exhibit "G", file name: Operational Description.pdf

Hardware Description:

- Clocks/Oscillators Frequencies: SAW stabilized oscillator that is operational at 403.6 MHz.
- Ports: None
- Antennas: Integral to the EUT. Information may be referenced in ***Exhibit "B", file name: Antenna Description.pdf***
- Frequency Range: 403.6 MHz
- Peak Conducted Output Power: 89.1 uW max (-10.5 dBm was used for SAR calculation)
- Modulation: FSK (non-voice, data only)
- Channel Bandwidth: 46 kHz
- Frequency Stability: 26.6 PPM
- Data rate: Information may be referenced in ***Exhibit "F", file name: Modulation Description.pdf***
- Emission Designator: F1D

1.2 Related Submittals/Grants

none

1.3 Tested System Details

EUT and Peripherals:

Item	Description and Serial No.
EUT	Biotronik, Inc. Model Philos DR-T (aka Actros C-T), FCC ID PG6BA0T, S/N 75103203-210
Human Torso Simulator Tank	Biotronik, Inc. Model None, S/N None

Cables:

Item	Length, shielding, and ferrites
Retrox Transvenous Active Fixation Leads	0.53 meters in length, unshielded, no ferrites.

Compliance testing was performed to the criteria stated in 47 CFR 95.605, which includes the requirement that a human torso simulator be used § 95.639 (f)(2)(i). This text fixture is used to simulate operation of the implant under actual operating conditions.

The physical dimensions of the tank are exactly as specified in § 95.639 (f)(2)(i). The container is plexiglass with a diameter of 30cm, height of 76cm, and wall thickness of 0.635cm. The exact orientation of the pacemaker within the tank is defined in this paragraph, and has been followed during this testing exactly.

The tank is filled with a biomaterial medium that matches the dielectric and conductivity properties of human muscle tissue at 403.6 MHz. This chemical formula is taken from the FCC reference in § 95.639 (f)(2)(ii) to the paper "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies". The chemical make-up used by Biotronik follows this reference precisely, and includes water, salt, sugar, and hydroxyethylcellulose (HEC). Further details can be found in the reference paper.

Pacemaker in human torso
simulator tank

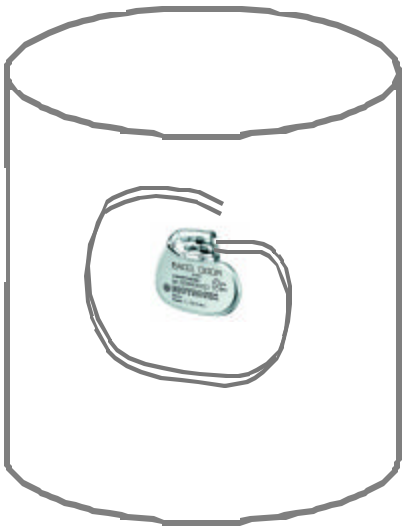


Figure 1: Configuration of Tested System

1.4 Test Methodology

ANSI C63.4 (1992) and 47 CFR Part 95

1.5 Test Facility

Northwest EMC, Inc.
22975 NW Evergreen Parkway, Suite 400
Hillsboro, OR 97124
(503) 844-4066
Fax: 844-3826

The semi-anechoic chamber, and conducted measurement facility used to collect this data is located at the address shown above. This site has been fully described in a report filed with the FCC, dated August 13, 1999, and accepted by the FCC in a letter dated August 30, 1999 (95296).

Northwest EMC, Inc. is recognized under the United States Department of Commerce, National Institute of Standards and Technology, National Voluntary Laboratory Accreditation Program (NVLAP) for satisfactory compliance with criteria established in Title 15, Part 285 Code of Federal Regulations. These criteria encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002 (ANSI/ASQC Q92-1987) as suppliers of calibration or test results. NVLAP Lab Code: 200059-0.

2.0 Technical Description

2.1 Type of Emission

The device has F1D emission.

2.2 Frequency Range

The device operates at a single frequency of 403.6 MHz .

2.3 Operating Power Level

The power output for the PG6BA0T device is fixed at the factory with no means for the user to change it. A conducted measurement of the implant transmitter power into a 50 ohm load gives a value of -16 dBm at the fundamental. The available power from the transmitter in a Pspice simulation is calculated to be -10.4 dBm. The calculated power delivered to a 50 ohm load would be -10.5 dBm. This shows good correlation (6 dB error) between the modeled result and the actual measured result, and furthermore it is noted that the error is conservative in that the modeled power is higher than the measured value.

2.4 DC Voltage and Current Applied

The nominal bias conditions on Q102 are a collector current $I_C = 450 \mu\text{A}$ and $V_{CE} = 1.4 \text{ V}$. The DC power dissipation on Q102 is $630 \mu\text{W}$.

2.5 Schematics and Parts List

Schematic diagrams of all circuitry and devices provided for determining and stabilizing frequency, for suppression of spurious radiation, for limiting modulation, and for limiting power are provided as separate attachments.

Schematics may be referenced in Exhibit "K", file name: "Schematics.pdf".

The Parts List may also be referenced in Exhibit "K", file name: "Schematics.pdf".

2.6 Block Diagram

A Block Diagram of all circuitry and devices provided for determining and stabilizing frequency, for suppression of spurious radiation, for limiting modulation, and for limiting power are provided as separate attachments..

Block Diagrams may be referenced in Exhibit "E", file name: "Frequency Block Diagram.pdf"

2.7 Circuit Description

A circuit description (relating to the block diagram) of all circuitry and devices provided for determining and stabilizing frequency, for suppression of spurious radiation, for limiting modulation, and for limiting power is provided as a separate attachment.

A circuit description may be referenced in Exhibit "G", file name: "Operational Description.pdf"

2.8 Tune-up Procedure

A description of the Tune-up procedure is provided as a separate attachment.

A Tune-up procedure may be reference in Section 8.5 of Exhibit “M”, file name: “Acceptance Test Procedure.pdf” The acceptance criteria for the tune-up procedure is found in Section 7.4 of Exhibit “N”, file name: “Acceptance Test Specification.pdf”

2.9 Description of Modulation System

A detailed description of the modulation system to be used, including the response characteristics (frequency, phase, and amplitude) of any filters provided, and a description of the modulating wavetrain, for the maximum rated conditions under which the equipment will be operated is provided as a separate attachment.

A description of the modulation system may be referenced in Exhibit “F”, file name: “Modulation Description.pdf”

2.10 FCC ID and Disclosure Policies

Per 47 CFR 95.1215, the Medical Implant Transmitters must be identified with a serial number. The FCC ID number may be place in the instruction manual and on the shipping container instead of being placed on the transmitter. In addition, the statement found in 47 CFR 95.1215(a) must be included with each transmitter.

Detailed descriptions of the FCC ID labeling method and disclosure statements are provided as a separate attachment. Please note that each transmitter is identified with a serial number.

A description of the FCC ID labeling method may be referenced in Exhibit “D”, file name: “FCC ID Label.pdf”. To view the serial number on the transmitter, reference Exhibit “I”, “External Photos.pdf”.

2.11 Modulation Characteristics

Reference 2.1047 (Audio characteristics not required for data transmitters), 95.1209, and 2.1033(c)(13)

Per 47 CFR 95.1209, non-voice data communications is permitted. The EUT utilizes FSK modulation for the purposes of communicating data to a physician. The emission designator “F1D” was selected based upon the guidelines in CFR 2.201: “F” designates an emission in which the main carrier is frequency modulated. “1” designates a single channel containing digital information without the use of a modulating sub-carrier (the applicant confirmed that no sub-carriers are used). “D” designates data transmission, telemetry or telecomm. As detailed in the “Modulation Description”, the device is used to transmit one way, non-voice data.

A description of the modulation system may be referenced in Exhibit “F”, file name: “Modulation Description.pdf”

2.12 Necessary Bandwidth

Reference 2.202(b)

The baseband data stream is filtered through R103 and D101. The nominal varactor capacitance is ~4 pF, giving a filter time constant of 4 μ s, or a 3 dB cutoff frequency of 40 KHz. The measured deviation of the SAW oscillator is typically 3KHz for a 2.4 V drive. Allowing the first 5 harmonics ($W=20$ KHz) for signal integrity, this yields a deviation ratio $\Delta = .15$. Carson's Rule predicts an occupied bandwidth of $2(\Delta + 1)W$ or 46 KHz.

Therefore the Form 731 states a necessary bandwidth of 46 kHz.

3.0 Occupied Bandwidth

Reference 47 CFR 95.633(e) and 2.1049

47 CFR 95.633(e)(1) specifies that the maximum authorized emission bandwidth is less than 300 kHz.

The emission bandwidth was made of the transmitted signal using a spectrum analyzer and the setup shown in Figure 2.1. The width of the modulated signal was measured 20 dB down relative to the maximum level of the modulated carrier.

Per 47 CFR 95.633(e)(3), the measurement should be made using a peak detector with a resolution bandwidth equal to approximately 1.0 percent of the emission bandwidth of the EUT. An emission bandwidth measurement was made using a 100Hz resolution bandwidth (no video filtering) and a peak detector. With these instrument settings, an emission bandwidth of 12.55 kHz was measured. This most closely satisfied the specified measurement criteria.

Clearly, it is important to use a RBW that is sufficiently narrow to plot the actual bandwidth of the signal and not the filter response curve of the spectrum analyzer. However, various plots were made using different frequency spans and resolution bandwidths in an attempt to not only satisfy the measurement criteria, but to also show that all emissions outside of the occupied band are greatly attenuated. Under no circumstances, is the emission bandwidth greater than or equal to 300 kHz.

3.1 Test Results

Reference Exhibit "R", file name: Occupied Bandwidth.pdf for the data plots.

4.0 Radiated Emissions

Reference 2.1053 & 90.635(d)

The Field Strength of Radiated Emissions was measured in the far-field at an FCC Listed Semi-anechoic Chamber up to 5GHz.

Spectrum analyzer and linearly polarized antennas were used to measure the effective radiated power (EIRP) of the fundamental, as well as unwanted radiated harmonics and spurious emissions.

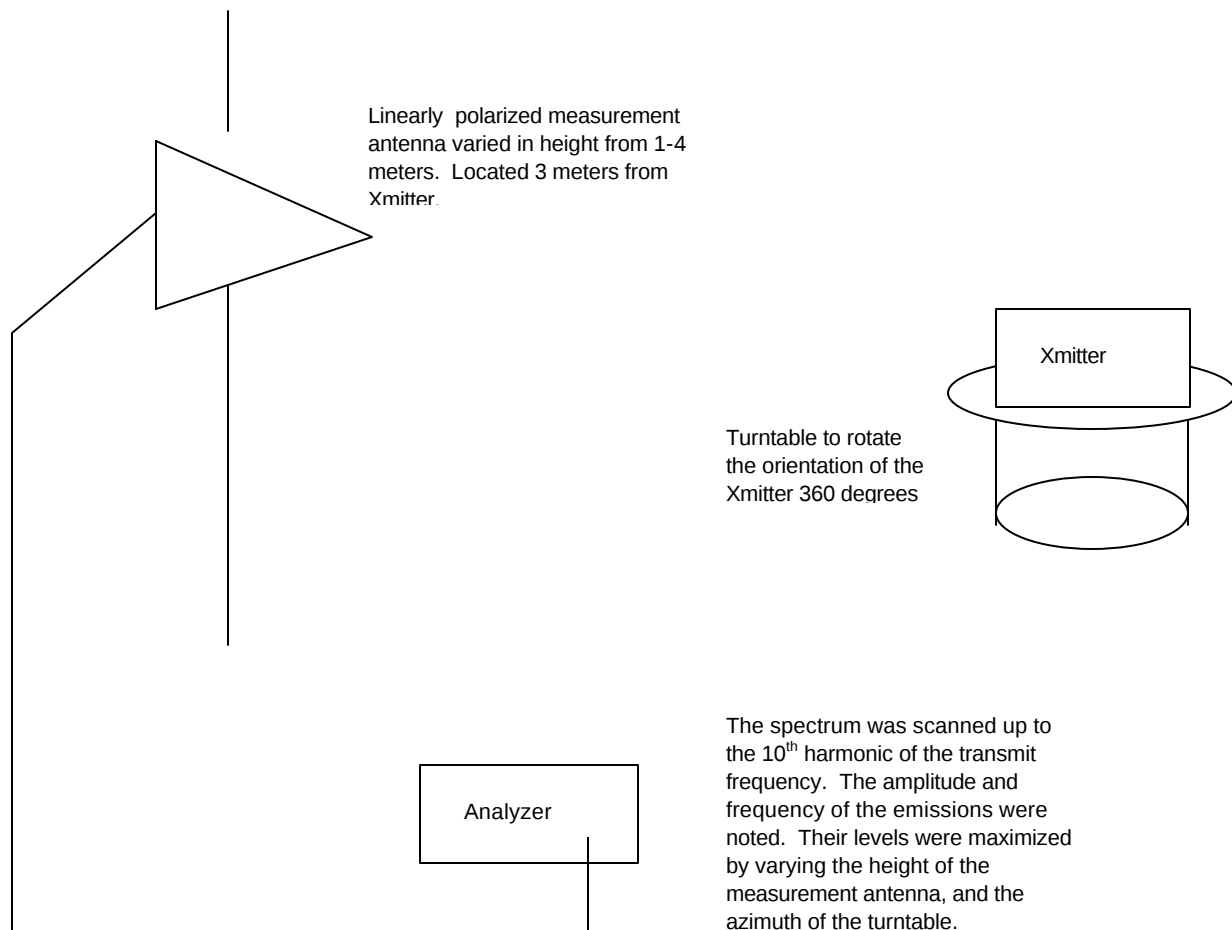
The orientation of the EUT and measurement antenna was manipulated to maximize the level of emissions.

The EUT was configured to transmit in a fixture that simulates the human torso. See Figure 1 for details of that configuration

Radiated Spurious Emissions Test Methodology

At an approved test site, the transmitter was placed in the human torso test fixture located on a remotely controlled turntable, and the measurement antenna was placed 3 meters from the transmitter. The turntable azimuth was varied to maximize the level of radiated emissions. The height of the measurement antenna was also varied from 1 to 4 meters. The amplitude and frequency of the emissions were noted.

Test Setup for Field Strength Measurements



4.1 Test Results

Reference Exhibit "Q", file name: "Radiated Emissions.pdf" for the data plots.

5.0 Frequency Stability

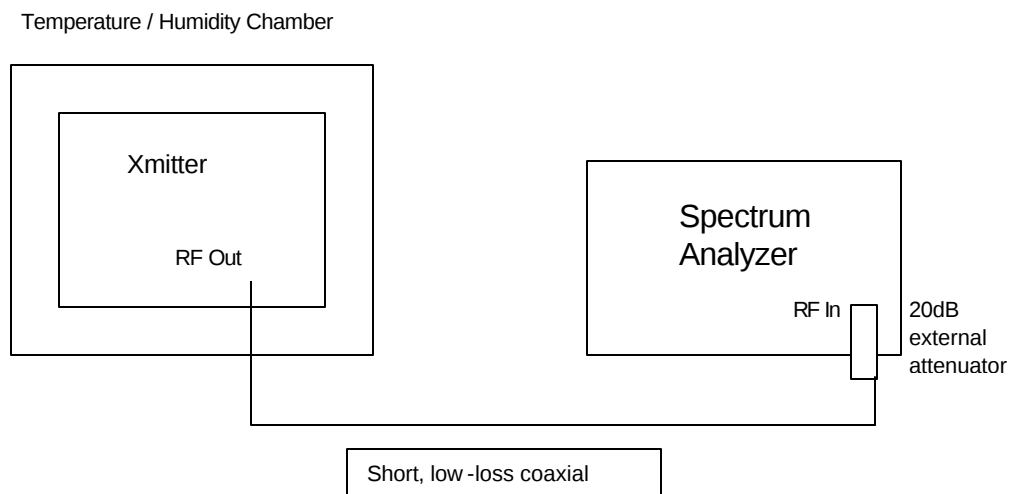
Reference 2.1055 & 95.628(e)

The Frequency Stability was measured at the RF output terminals using a spectrum analyzer. The spectrum analyzer is configured with a precision frequency reference that exceeds the stability requirement of the transmitter. T

The EUT was placed inside a temperature / humidity chamber with a low-loss coaxial cable connected to the spectrum analyzer outside of the chamber.

The transmit frequency was recorded at the extremes of the specified temperature range (+25° to +45° C) and at 5°C intervals.

Test Setup



5.1 Test Results

Reference Exhibit "P", file name: "Frequency Stability.pdf" for the data.

6.0 RF Exposure Compliance

The EUT meets the requirement that it be operated in a manner that ensures the public is not exposed to radio frequency energy levels in excess of the Commission's guidelines (ref . 47 CFR 1.1307, 1.1310, 2.1091, 2.1093, and 95.603(f)).

This application contains an exhibit with a report of the finite difference time domain (FDTD) computational modeling that shows compliance with FCC rules.

Reference Exhibit "S", file name: "SAR Analysis.doc" for the report.

7.0 Measurement Equipment

Instrument	Model	Serial No.	Calibration Due
Spectrum Analyzer	HP 8566B	2747A05213	01/19/01
Spectrum Analyzer	HP 8593E	3414U00634	07/01/01
Quasi-Peak Adapter	HP 85650A	2811A01353	01/19/01
Bilog Antenna	EMCO 3141	9906-1146	06/15/01
Pre-Amplifier	AR LN 1000A	25660	07/18/01
Pre-Amplifier	Miteq AMF-4D-005180-24-10	621707	07/18/01
Horn Antenna	EMCO 3115	9804-5441	07/10/01
Temp. / Humidity Chamber	Cincinnati Sub Zero ZH-32-2-2-H/AC	ZN9722620	10/31/01