



## TEST REPORT TO

FEDERAL COMMUNICATIONS COMMISSION CFR47 PART95 RSS-210 6.2.2(L3) 608-614 MHz (Medical Telemetry) Low Power Licensed Radio communication Devices Medical Telemetry Service Transceiver In the band 608-614 MHz

for

Philips Medical Systems Cardiac and Monitoring Systems 3000 Minuteman Drive Andover, MA 01810 978-659-2800

of

Patient Worn Device ECG/Sp02 Narrowband FM Transceiver

Model M2601B

on

#### 5/13/2004

Tested by

Signed original is on-file <u>at Phili</u>ps Medical Systems.

Andrew Mertinooke

Barry Wyshogrod 25-Aug-04

Reviewed by

Clifton P Brick

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Compliance Worldwide, Inc. – 357 Main Street – Sandown, NH 03873 (603) 887 3903 Fax 887 6445 http://www.cw-inc.com





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#### TEST DESCRIPTION

1. TEST OBJECTIVE

To test the Patient Worn Device with ECG and SpO2 transceiver Model M2601B to FCC Part 95 Rules and write a report.

2. E.U.T. DESCRIPTION

#### GENERAL

The Patient Worn Device with ECG and SpO2 Transceiver Model M2601B is an ECG and SpO2 monitoring device that provides an RF link to a monitoring station.

MODULATION SCHEME: FM

SERIAL NUMBERS: US41101374 608.0125 MHz US41101439 613.9875 MHz





# TEST RESULTS AND CONCLUSIONS

Rule Section	Requirement	Notes	Pass	Fail
95.1109(b)	Labeling	See Exhibits FCC Label Sample and Label Location.	1	
95.115(a)	Field Strength Limits		X	
95.115(b)	Undesired Emissions Limits		X	
95.115(c)	Emission Type	Transmits Data and ECG Waveform	X	
95.115(e)	Frequency Stability	Data Provided By Philips Medical	1	
95.1125	RF Safety	Statement and Technical Basis	1	

Note 1.) Exhibits provided by Philips for approval submission.





#### TEST RESULTS AND CONCLUSIONS

PRODUCT TESTED - Patient Worn Device ECG/Sp02 Transceiver

MODEL NUMBER - M2601B

#### RADIATED TEST RESULTS

The test results show that the emissions radiated from this equipment are in compliance with FCC Rules Part 95.

#### OCCUPIED BANDWIDTH & OUTPUT POWER

The test results show that the occupied bandwidth and output power of this equipment are in compliance with FCC Rules Part 95 .

#### CONDUCTED TEST RESULTS

N/A

#### ANALYSIS AND CONCLUSIONS

Based upon the radiated and conducted measurements we find that this equipment is within the limits of the FCC Rules Part 95. All results are based on a test of one sample, and represent other production units, only in as much as a sample represents other production units. If any significant changes are made to the unit, the changes shall be evaluated and a retest may be required.

**NOTES** (Special conditions unique to this test)

The EUT is battery Powered; no power line conducted testing applies.

A full investigation of the spectrum of this devices digital circuitry can be found in Test report 236-04B.





#### TEST PROCEDURES

- 1. TEST EQUIPMENT
  - A. HP 8546A (9 kHz 6.5 GHz) EMI Receiver w/ RF Filter Section, S/N 3704A00323 / 3650A00360. Calibration Date 1-16-2004, calibrated annually.
  - B. Com-Power Biconilog Antenna, Model AC220, S/N 25509. Calibration Date 7-17-2003, calibrated annually.
  - C. Electro-Metrics Double Ridged Guide Antenna, Model EM-6961, S/N 6337. Calibration Date: 6-24-2003, calibrated annually.
  - D. EMCO LISN, Model EM 3825/2, S/N 9109-1860. Calibration Date: 3-10-2004, calibrated annually.

## 2. FREQUENCY RANGE TO BE SCANNED.

A. Radiated Test from 30 MHz to 40 GHz (or the  $10^{th}$  harmonic of the highest frequency whichever is lower).

B. Conducted Test from 150 kHz to 30 MHz.





## 3. TEST PROCEDURES.

#### Radiated test procedure:

The EUT, associated cables and peripheral devices are placed on the supporting table and any support equipment is placed off the site. The EUT is turned on and any necessary operating or test software installed and allowed to warm up. The EUT is pre-scanned in our ferrite tile lined chamber where it is rotated 360 degrees and examined in both horizontal and vertical polarization, all emission frequencies are identified and recorded. The EUT is scanned, all frequencies identified in the chamber are investigated, as well as harmonic frequencies of the EUT. When an emission is found the emission is maximized by varying the bundle position of the connecting cables, the antenna height, the antenna polarization (vertical and horizontal) and the table orientation (360 degrees). The maximum reading is recorded and the next signal is searched for.

#### Conducted test procedure:

The power line of the EUT is connected to the LISN (Line Impedance Stabilization Network). A measurement of the emissions are made from the power line for both phase and neutral on the analyzer in the frequency range from 150 kHz to 30 MHz. The maximum readings are recorded for each phase.

All measurements are made according to the procedures defined in: "ANSI C63.4-1992 Standard Methods of Measurement of Radio Noise Emissions from Low-Voltage Electrical and Electronics Equipment in the Range of 9 kHz to 40 GHz, American National Standard for (ISBN 1-55937-215-5).





## FCC Part 95.1115 Test Limits

1. Part 95.1115(a)(2) Field Strength Radiation Limits (Quasi-Peak):

Frequency	Distance	Limit	Limit
MHz	meters	dBµV/m	µV∕m
608 614	3	106.0	200000

2. FCC Part 95.1115(b) Out-of-band emissions Limits (Quasi-Peak):

Frequency MHz	Distance meters	Limit dB <b>u</b> V/m	Limit UV/m
Below 960	3	46	200
Above 960	3	54*	500*

\*NOTE: Average Limits





# TEST FACILITY DESCRIPTION

Compliance Worldwide is located on 357 Main Street in Sandown, New Hampshire. The conducted and radiated test sites, located at C.W. are used for Federal Communications Commission (FCC) testing and Industry Canada Testing. A site description is on file with the FCC in Columbia, MD USA. Site information is also on file with Industry Canada, anyone wishing to review this Test Facility Description is referred to file number **IC 3023**. This is currently on file at Industry Canada, 1241 Clyde Avenue, Ottawa, ON K2C 1Y3.

The radiated site is a 3/10 meter indoor site with an enclosure for the product and a basement for the personnel, support equipment and test equipment.

The conducted site is part of a 16' x 20' x 12' ferrite tile chamber and uses one of the walls for the vertical metal wall required by EN 55022.

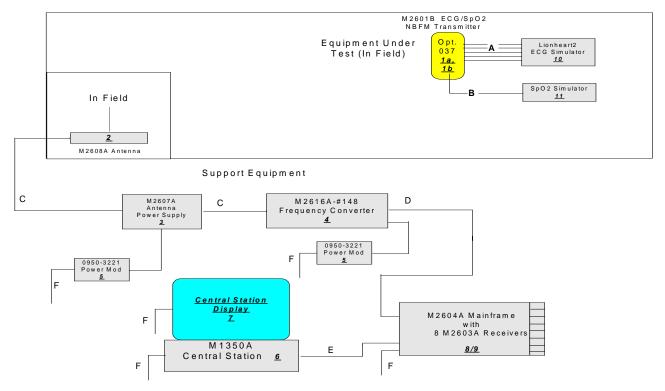
Both sites are designed to test products or systems 1.5 meter x 1.0 meter, floor standing or table top.





# TEST SET UP AND PERIPHERAL CONNECTION INFORMATION

Fig.1 M 2601B-NBFM Transmitter with SDN Telemetry System - FCC Part 15/95 Tests



See legend on next page.





## **EUT Hardware List:**

Block	Mfr.	Model /	Opt.(s)	Serial #	Description
#		Part #		(if available)	
1a	Philips	M2601B or	037, AAM,	US41101374	NBFM PWD w/SpO2
	-	862108/	S02		608.0125 MHz
		M4840-83003			RF Band 037 Check code 4882
1b	Philips	M2601B or	037, ABA,	US41101439	NBFM PWD w/SpO2
		862108/	AAM, S02		613.9875 MHz
		M4840-83003			RF Band 037 Check code 1440

## Support Equipment List:

Block #	Mfgr	Model / Part #	Opt.(s)	Serial # (if available)	Description
2	Philips	M2608A/ M2608-60000	N/A	4036A70575	Active Antenna
3	Philips	M2607A/ M2607-60006	ABA	4036A12174	Power Distribution for antenna system
4	Philips	M2616A/ M2616-60148	#148	4048A03003	Frequency Converter
5	Friwo	SDA5524G/ M2600-60008	N/A	NSN	Power Module, Universal
6	Philips	M3150A	N/A	US93280407	Central Station (HP D6723T)
7	HP	D1193A	N/A	JP32752364	Monitor
8	Philips	M2604A/ M2604-83100	ABA, OEU, C01	4146A11562	TeleFrame, Receiver Mainframe
9	Philips	M2603A/ M2603-83060	#007	4036A76071 4036A76072	Receiver, set to 460.0125 MHz, check code 2608 Receiver, set to 465.9875 MHz, check code 9113
10	Bio-Tek	Lionheart2	N/A	RN 125005	Multi-parameter patient simulator
11	DNI Nevada	OxiTest7	N/A	RN 125346	SpO2 simulator

## Cable List:

Block Item Letter	Part #	Shield? Y or N	Length	No. of Conductors (if avail.)	Termination	Function / Description
А	124 670	Y	1.5 m	5	PWD	5-lead ECG patient cable used with EASI
В	M1191A	Y	1.5 m	2	PWD	SpO2 Adult sensor
С	M1413-60101	Y	3 m/ 10	2	BNC	RG 6 BNC Cable, quantity = 2
			m			
D	M2616-60011	Y	3m	2	BNC/SMC	RG 405 Equivalent, quantity = 1
Е	M3180-60110	Y	4m	5	SDN I/O	SDN cable, Mainframe to Central Station, quantity=1
F	NA	Ν	2 m	3	NA	AC power cords

## **Test Equipment/Parts:**

Manufacturer	Model/Part Number	Recall/Serial Number	Description
Bio-Tek	LionHeart2	125005	Multi-parameter patient monitor
DNI Nevada	OxiTest 7	125346	SpO2 simulator

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## RADIATED TEST RESULTS

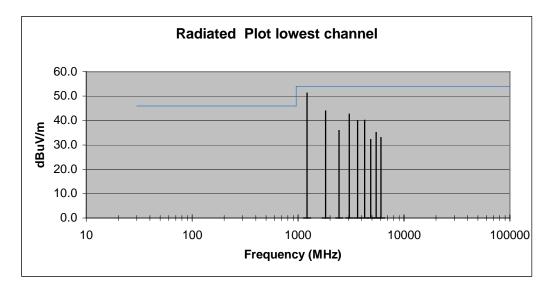
Frequency Range:	30 MHz - 14.5 GHz.
Measurement Distance:	3.0 Meters.
Bandwidth:	120 kHz, Per ANSI C63.4-1992.*
Detector Functions:	Peak, Quasi Peak
Table Height:	0.8 meters
Antenna Height Variation:	1 - 4 Meters.
Horizontal and Vertical Investigated,	worst case data shown.
*Measurement Bandwidth is 1 MHz above	960 MHz.

PLEASE SEE NEXT PAGE FOR RADIATED TEST DATA

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Radiated Data Log Plot lowest channel 608.0125 MHz

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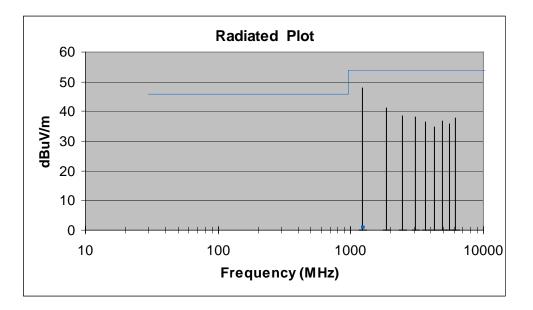
# Radiated Data Table lowest channel 608.0125 MHz

Frequency (MHz)	Peak Amp (dBuV/m)	Polarization (H/V)	Limit (dBuV/m)	Margin (dB)
1216	51.2	Н	54.0	-54.0
1824	43.9	Н	54.0	-54.0
2432	35.9	Н	54.0	-54.0
3040	42.5	Н	54.0	-54.0
3648	39.9	Н	54.0	-54.0
4256	40.1	Н	54.0	-54.0
4864	32.2	Н	54.0	-54.0
5472	35.0	Н	54.0	-54.0
6080	32.9	Н	54.0	-54.0

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Radiated Data Log Plot Highest channel 613.9875 MHz

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# Radiated Data Table Highest channel 613.9875 MHz

Frequency (MHz)	Peak Amp (dBuV/m)	Polarization (H/V)	Limit (dBuV/m)	Margin (dB)
1228	47.7	Н	54.0	-6.3
1842	41.0	Н	54.0	-13.0
2456	38.5	Н	54.0	-15.5
3070	38.2	Н	54.0	-15.8
3684	36.5	Н	54.0	-17.5
4298	34.6	Н	54.0	-19.4
4912	36.8	Н	54.0	-17.2
5526	35.8	Н	54.0	-18.2
6140	37.8	Н	54.0	-16.2

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## RADIATED OUTPUT POWER & OCCUPIED BANDWIDTH TEST RESULTS

Frequency Range:	608-614 MHz.
Measurement Distance:	3.0 Meters.
Bandwidth:	As Noted, Per ANSI C63.4-1992.
Detector Functions:	Peak
Table Height:	0.8 meters
Antenna Height Variation:	1 - 4 Meters.

Horizontal and Vertical Polarization Measurements Taken, Worst Case Reported.

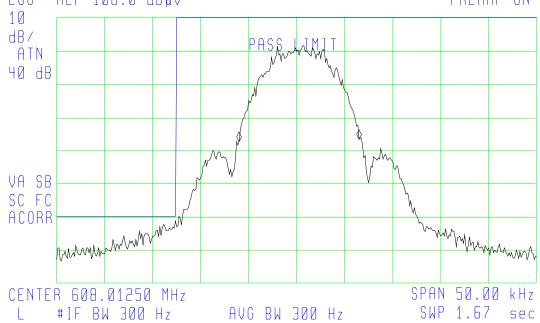
PLEASE SEE NEXT PAGE(S) FOR OCCUPIED BANDWIDTH RADIATED TEST DATA





Channel 0 Lower Band Edge / Bandwidth

(₯) 13:33:45 MAY 13, 2004 LOWER BAND EDGE 236-04 PHILIPS 2601B TX ACTV DET: PEAK MEAS DET: PEAK QP MKR<sub>△</sub> -12.50 kHz -.81 dBLOG REF 106.0 dBµV



Plot shows an occupied bandwidth of 12.5 kHz, and the emission contained within the band.

Frequency	26dB Bandwidth
(MHz)	(kHz)
608.0125	12.5

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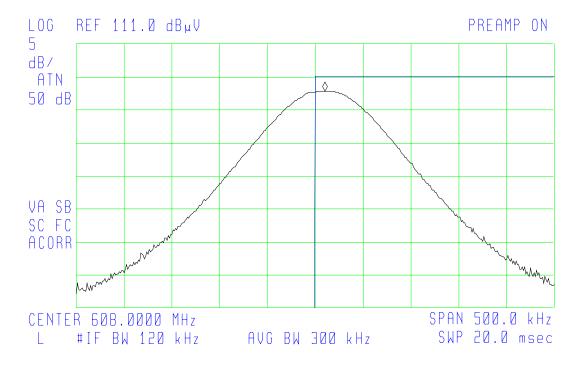




# Channel 0 Output Power Plot

(b) 13:48:53 MAY 11, 2004 LOW CHANNEL FEILD STRENGTH 236-04 PHILIPS M2601B

	608.0 104.1	
	104.0	
QP AVG	104.0	· · · · · · · · · · · · · · · · · · ·



Freq (MHz)	Polarization (H/V)	Peak Amp (dBuV/m)	QP Amp (dBuV/m)	QP Limit (dBuV/m)	QP Margin (dB)
608.0125	Н	104.1	104.0	106.0	-2.0

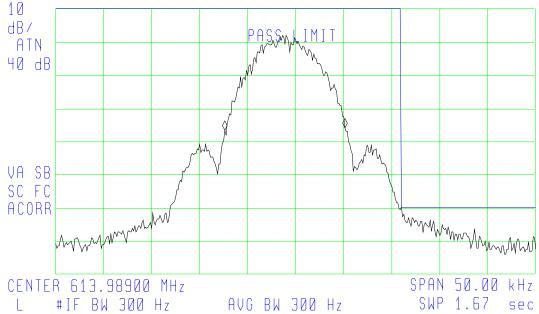
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Highest Channel Upper Band Edge / Bandwidth

(⑦) 13:41:35 MAY 13, 2004 UPPER BAND EDGE 236-04 PHILIPS 2601B TX ACTV DET: PEAK MEAS DET: PEAK QP MKR<sub>△</sub> -12.50 kHz -.70 dB
LOG REF 106.0 dBµV
PREAMP ON



Plot shows an occupied bandwidth of 12.5 kHz, and the emission contained within the band.

Frequency	26dB Bandwidth		
(MHz)	(kHz)		
613.9875	12.5		

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Upper Channel Output Power Plot

# (6) 14:29:51 MAY 11, 2004 HIGH CH FEILD STRENGTH 236-04 PHILIPS M2601B

ACTV DET: PEAK MEAS DET: PEAK QP AVG MKR 613.9825 MHz 102.84 dBµV



Freq (MHz)	Polarization (H/V)	Peak Amp (dBuV/m)	QP Limit (dBuV/m)	QP Margin
				(dB)
613.9825	Н	102.8	106.0	-3.2

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## NOTES AND COMMENTS

(Special conditions unique to this test)

A full investigation of the spectrum of this devices digital circuitry can be found in Test reports 236-04b

The EUT is battery Powered; no power line conducted testing applies.

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