VNUS™

Radio Frequency Generator
RFG*PLUS* Model RFG2 Service Manual

en

Table of Contents

Description 1
- Front and Rear Panel Layout 1
- System Overview 2
- UI Board 2
- Front Panel Interface Assembly (FPI) 3
- RF Board 3
- MMC/USB Assembly 3
- AC Power Board 3
- Isolation Barrier 3
- Operating Assumptions for VNUS RFG2 RF Generator 5

Basic Inspection and Checkout Procedure 5
- Visual Inspection 5
- Functional Inspection 5
- Power On Self Test 5
- Software Version 6

Electrical Safety Tests 6
- Electrical Safety Tests 220-240V 6
- Electrical Safety Tests 110-120V 7
- Electromagnetic Compliance 8

Biomedical Department Power Output Test 12

Power Delivery Verification 13

Alarm Priority 13

Error Codes 14

Service and Maintenance 16
- Cleaning and Disinfection 16
- Repairs and Returns 16
- Warranty 16
- Fuse Replacement 17

Technical Specifications 18
- Equipment Type 18
- Electrical 18
- RF Power Delivery Performance 18
- Tolerances 18

Description

Front and Rear Panel Layout

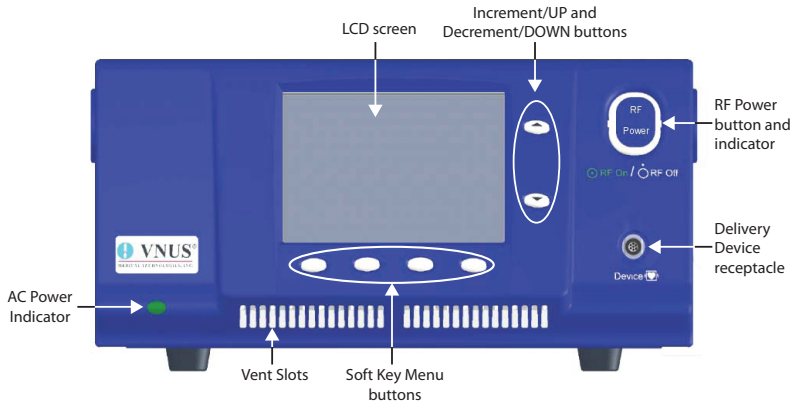


Figure 1: Front Panel

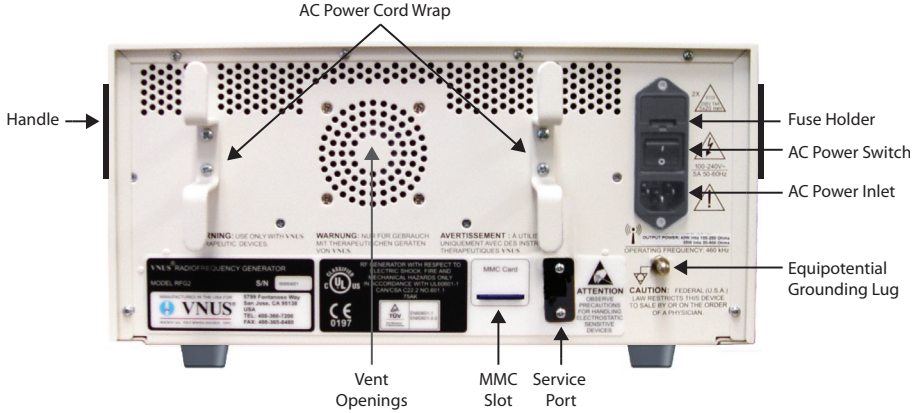


Figure 2: Rear Panel

System Overview

The VNUS RFG2 RF Generator supplies and controls the RF energy delivered to the RF Device. The RF Generator measures and displays RF output Power, load Impedance (Closure*RFS* only), and elapsed time of RF delivery. The RF Generator also interfaces with a sensor in the Device to provide a continuous display of measured Temperature during RF delivery.

The RF Generator consists of five main sections: UI Board, Front Panel Interface Assembly (FPI), RF Board, MMC/USB Assembly, and AC Power Board. A commercially available, medical grade, switching power supply is used to provide low-voltage power to supply the Generator's internal circuitry.

The major functional blocks of the VNUS RF Generator electronics are presented below in Figure 3.

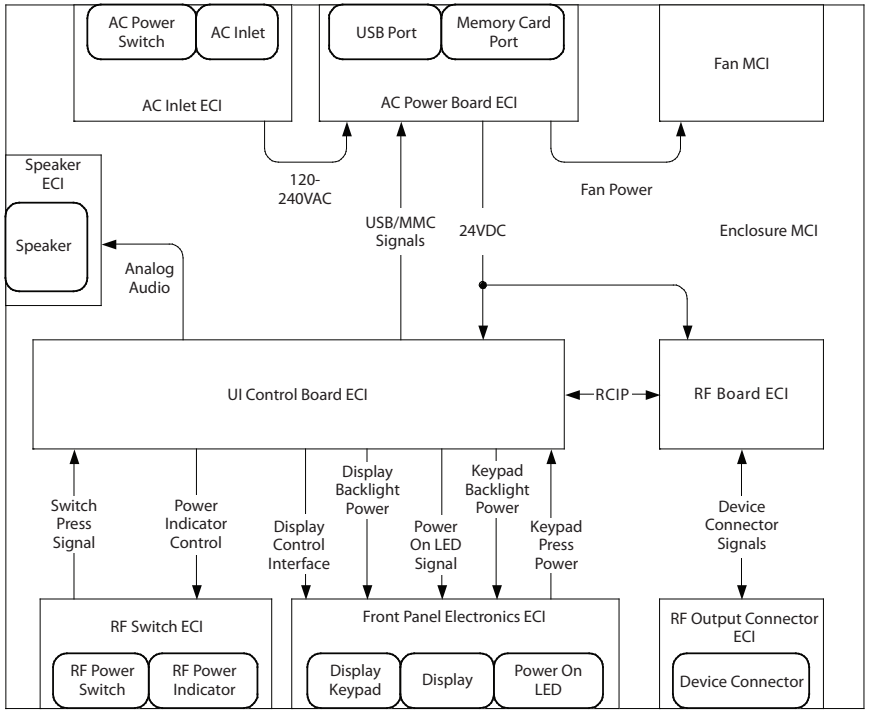


Figure 3: Block Diagram of the VNUS RFG2 Radiofrequency Generator

UI Board

All User Interface controls and indicators are managed and/or generated by the UI control circuitry. The UI Board is the large (app. 20"x5") PCB mounted vertically inside the chassis directly behind the LCD display. It controls all electronics that handle basic system operation and User Interface control. It also contains the RF Switch Circuitry for turning off/on RF power. In addition, the LCD Backlight Inverter (small 1"x4" PCB) is mounted to the UI Board. It is controlled by the UI Board and used for powering the 6.4" LCD display CCFL backlight tubes.

Front Panel Interface Assembly (FPI)

The Front Panel Interface Circuitry consists of 2 circuit boards (the UI Horizontal and UI Vertical keypad boards), and the RF switch circuitry, which is included on the UI board. The UI Horizontal and UI Vertical PCBs (also referred to as the keypad boards) contain the 6 general purpose keys and backlighting below (UI Horizontal Board) and to the right (UI Vertical Board) of the LCD display (as viewed from the front of the Generator). The RF Switch circuitry (contained on the UI Board) provides the switch and colored-backlighting for the RF on/off switch located on the right of the FPI (as viewed from the front of the Generator).

RF Board

The RF Generation Board generates a RF sinewave at 460.8 kHz, and provides the UI Board with measurements of delivered voltage, current and power. The RF Board controls the RF output by enabling RF generation and by controlling the amount of voltage delivered by the RF Board. The RF Board is the large (app. 8"x6") PCB mounted horizontally in the bottom of the chassis on the right side (as viewed from the front of the Generator). The RF Board controls all electronics that generate the RF power used to drive the device. Additional safety signals and control are provided by the UI Board through the 16 position IDC cable that runs between the UI and RF board.

MMC/USB Assembly

The MMC/USB Assembly is incorporated on the AC power board and refers to all MMC/USB related components. These components primarily consist of an MMC slot, a USB host controller, and filter components out on the AC Power Board. The UI processor (on the UI Board) controls the MMC and USB. The UI processor is connected to the components on the AC Power Board via the 14 position IDC cable in the left front corner (as viewed from the front of the Generator).

AC Power Board

The AC Power Board is the large (app. 8"x6") PCB mounted horizontally in the bottom of the chassis on the left side (as viewed from the front of the Generator). The AC Power Board controls the AC/DC power supply (and related circuitry) that generate 24 Volts to drive the system. The AC Power Board also monitors over-temperature conditions and drives the fan circuitry. The MMC/USB card slot, connector, and filter circuitry are also contained on this PCB.

Isolation Barrier

For the patient safety, an electrical isolation barrier is designed into the RF Board. The Isolation Barrier separates the Patient Connected side and the Non-Patient Connected side. There is 4000 VDC separation between AC Mains, Functional Grounds, Earth Ground and all exposed surfaces from patient contact. All devices (relay, transformer and opto-isolators) also have a minimum of 4000 VDC isolation between inputs and outputs.

The instantaneous voltage and instantaneous current of RF Output are fed back across the isolation barrier and input directly to an ADC.

Two power supplies, a +5V and a +2.5V supply are on the patient side of the isolation barrier. The capacity of the +5V supply is 50mA.

The isolated 5V supply is the source for the +2.5V supply. The output capacity of 25mA. It is used in the Patient Connected Circuitry.

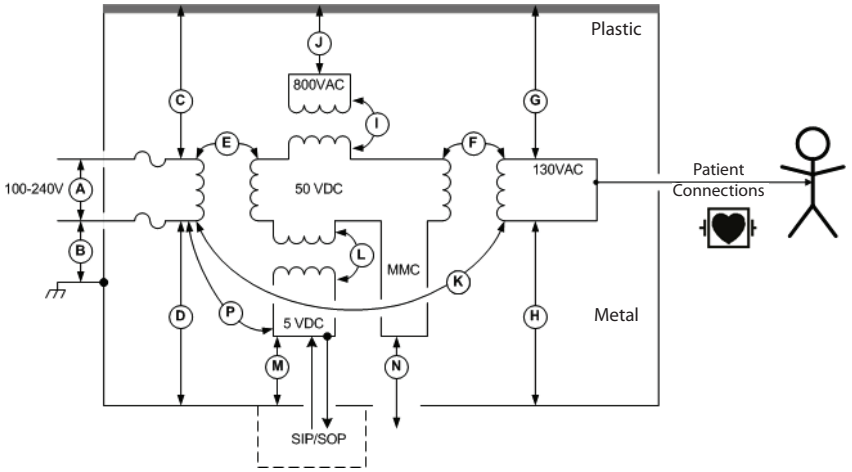


Figure 4: VNUS Radiofrequency Generator Grounding and Isolation Diagram

Table 1: Compliance Requirements for Isolation Barriers in Figure 4

Isolation	Type	Air Clearance (mm)	Creepage (mm)	Test Voltage
A	BOP (240 VAC)	1.6	3	1500
B	BI (240 VAC)	2.5	4	1500
C	DI (240 VAC)	5	8	4000
D	BI (240 VAC)	2.5	4	1500
E	DI/RI (240 VAC)	5	8	4000
F	DI/RI (130 VAC), BI (240 VAC)	5	8	4000
G	DI/RI (130 VAC), BI (240VAC)	5	8	4000
H	DI/RI (130 VAC), BI (240 VAC)	5	8	4000
I	17.g.5 Protective Impedance, Max EARTH leakage = 0.5mA			
J	DI/RI (1000 VAC)	18	32	7000
K	DI/RI (240 VAC)	5	8	4000
L	BI (240 VAC)	1.6	3	1500
M	Functional Only	na	na	na
N	Functional Only	na	na	na
P	DI/RI (240 VAC)	5	8	4000

Abbreviations in Table 1
Air Clearance - Shortest path in air between two conductive parts
BOP - Basic insulation between Parts of Opposite Polarity.
BI - Basic Insulation
Creepage - Shortest path along the surface of insulating material between two conductive parts
DI - Double Insulation
Functional Only - Insulation that does not perform a safety function
RI - Reinforced Insulation

Operating Assumptions for VNUS RFG2 RF Generator

- The RF Generator should be used only with a Hospital Grade power cord and plugged into only grounded, Hospital Grade AC sources.
- Class I, Type CF, Defibrillator-Proof Applied Part.
- Plastic and Metal Enclosure.
- Service Port is not user-accessible (factory use only). Service Port is covered by a plastic cover that can only be removed with a tool.
- Service Port is UL1950, 50VDC Normal/MAINS V in Single Fault Condition.
- Metal Enclosure is Protective Earth.
- Display has no touch screen, and sits behind protective plastic cover.
- Patient Connection is Bipolar Catheter.
- The display backlight operates off a DC to AC inverter. The input is 5 VDC and the output produces 335 V_{RMS}. The starting voltage is 1200 V_{RMS} and lasts for milliseconds until the bulb lights.
- Isolated Patient Connections include Device, Thermocouple, and ID Resistor.
- MMC is plastic of unknown insulation properties and is operator-accessible when device is powered.
- MMC pins are not user-accessible.

Basic Inspection and Checkout Procedure

Visual Inspection

- Inspect all external receptacle connectors for bent pins, foreign objects, damaged case and/or improper fit.
- Inspect the AC power cord for obvious physical defects or damage.

Functional Inspection

The VNUS RF Generator, RFG2 is designed to operate over line voltage range of 100-240 VAC, 50-60Hz, therefore no changes to the RFG2 are required when changing the mains voltage over this range. An appropriate power cord compatible with the outlet type in your area is required.

Plug power cord into power outlet, turn on main power to Generator. (Switch is located on the rear of unit).

Power On Self Test

Proper execution of the Power On Self Test internally verifies that the VNUS RF Generator is ready for operation.

Caution: The RF Generator enters Error Mode if it detects a failure during the Power On Self Test (POST) Mode. If any error messages occur indicating that the RF Generator is not safe to use, power off the unit and contact VNUS Customer Service.

During the Power On Self Test (POST), the RF Generator performs a number of internal self-tests of its software:

- Verifies integrity of system random access memory (RAM).
- Verifies contents of program read-only memory (ROM).
- Activates all visual indicators, including the LCD screen and the backlit **Soft Key Menu** buttons around the screen.
- Sounds Power On tone.
- Verifies operation of radiofrequency (RF) generation and measurement circuits.
- Displays a notice if POST must restore the factory default settings due to a corruption of persistent settings, such as screen brightness or tone volume settings.

Prior to using the RF Generator, observe that the screen, lights, and audible alarms cycle.

Software Version

The RF Generator's software release version will be displayed when the Power On Self Test is completed. The RFG2 enters Identification Mode as shown in Figure 5 below.



Figure 5: Identification Mode Showing Software Version

Electrical Safety Tests

The VNUS RF Generator has been thoroughly tested for isolation, leakage, and grounding integrity prior to shipment. Should it become necessary to perform these tests, the use of the appropriate test equipment, and knowledge of the appropriate sections of BS EN 60601-1:1990 +A1 +A2 which pertain to these tests is mandatory. VNUS Medical Technologies assumes no responsibility for damage to the instrument due to improper application of the tests below. If in doubt, consult the Safety Analyzer Users Manual or VNUS Medical Technologies prior to conducting the following tests.

Electrical Safety Tests 220-240V

A special test cable from VNUS is available for these tests. Please contact VNUS Customer Service for information on obtaining the Biomed Test Cable (TL100-119-02).

1. Set the line voltage to 264V and set the frequency to 50Hz. DO NOT EXCEED 280V!
2. Plug the line cord of the VNUS Generator into the leakage tester for all tests.
3. For source leakage and isolation tests, use the Biomed Test Cable to access patient connections. Short electrodes and thermocouple wires together for testing.
4. For the 25A test, connect the ROD-L leads to the chassis ground lug, and to the ground pin of the power cord.

WARNING! HIGH VOLTAGE! DO NOT TOUCH THE EQUIPMENT DURING THE ISOLATION TESTS!

Table 2: Electrical Safety Test Limits 240V

Parameter	Conditions	Passing
Input Voltage	Rated line + 10%	264V
Line Cord Resistance	N/A	< 100mΩ
25A chassis-cord gnd	10 seconds	< 100mΩ
Earth Leakage	Power Norm, GND OPEN	< 500 µA
Earth Leakage	Power Rev, GND OPEN	< 500 µA
Source Leakage, Applied Part	Power Normal, GND OPEN	< 10 µA
Source Leakage, Applied Part	Power Reversed, GND OPEN	< 10 µA
Iso Test, Applied Part	Power Normal	< 10 µA
Iso Test, Applied Part	Power Reversed	< 10 µA

Electrical Safety Tests 110-120V

1. Use the variable autotransformer and the DVM to set the line voltage to 132V. DO NOT EXCEED 140V!
2. Plug the line cord of the VNUS Generator into the leakage tester for all tests.
3. For source leakage and isolation tests, use the Biomed Test Cable to access patient connections. Short electrodes and thermocouple wires together for testing.
4. For the 25A test, connect the ROD-L leads to the chassis ground lug, and to the ground pin of the power cord.

WARNING! HIGH VOLTAGE! DO NOT TOUCH THE EQUIPMENT DURING THE ISOLATION TESTS!

Table 3: Electrical Safety Test Limits 120V

Parameter	Conditions	Passing
Input Voltage	Rated line + 10%	132V
Line Cord Resistance	N/A	< 100mΩ
25A chassis-cord gnd	10 seconds	< 100mΩ
Earth Leakage	Power Norm, GND OPEN	< 300 µA
Earth Leakage	Power Rev, GND OPEN	< 300 µA
Source Leakage, Applied Part	Power Normal, GND OPEN	< 10 µA
Source Leakage, Applied Part	Power Reverse, GND OPEN	< 10 µA
Iso Test , Applied Part	Power Normal	< 10 µA
Iso Test, Applied Part	Power Reversed	< 10 µA

Electromagnetic Compliance

Standards referenced in tables 4 and 5:

CISPR 11:2009 (Amended by A1:2010), Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement

IEC 61000-3-2:2009, Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)

IEC 61000-3-3:2008, Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current ≤ 16 A

IEC 61000-4-2:2008, Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test

IEC 61000-4-3:2008, Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test

IEC 61000-4-4:2004, Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test

IEC 61000-4-5:2005, Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test

IEC 61000-4-6:2008, Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields.

IEC 61000-4-8:2009, Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test

IEC 61000-4-11:2004, Electromagnetic compatibility (EMC) - Part 4-11: Testing and measuring techniques - Voltage dips, short interruptions and voltage variations immunity tests

Table 4: Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The RF Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the RF Generator should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The RFG2 must emit electro-magnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The RFG2 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 5: Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The RF Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the RF Generator should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors shall be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If disruption in power occurs, it may be necessary to reset the unit by disconnecting and reconnecting the catheter.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 5 s	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RFG2 requires continued operation during power interruptions, it is recommended that the RFG2 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be a levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the RFG2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE U_T is the a.c. mains voltage prior to application of the test level.			
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RF Generator is used exceeds the applicable RF compliance level above, the RF Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RF Generator. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 6: Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the RF Generator			
The RF Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RF Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RF Generator as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.1	0.1	0.2
.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Biomedical Department Power Output Test

VNUS has created a Biomedical Department Inspection Procedure for the testing of the VNUS RF Generator. This procedure outlines setting the VNUS Radiofrequency Generator up in concert with an ESU analyzer to verify temperature measurement, power output, and measurement of impedance.

A special test cable from VNUS is provided for this purpose. Please contact VNUS Customer Service for information on obtaining the Biomed Test Cable. (TL100-119-02 Cable, Biomed Test).

Set-up Procedure

- Check the RF Generator case exterior. The case exterior shall have no visible damage (e.g. dents, scratches, scaled off paint).
- Panel displays shall have no visible foreign material or damage.
- Inspect all external connectors/receptacles for bent pins, foreign objects, damaged case and/or improper fit.
- The AC power cord shall have no obvious physical defects or damage.
- Connect the RF Generator to the appropriate AC power supply and turn on main power, wait until the generator completes its self- test.
- Attach test cable to the generator.
- The front panel parameters should be:

Temperature:	~23°C (ambient temperature)
Impedance:	1999 Ω
Power:	0 W

- Clip ESU tester to red and black leads. Select 100 Ω impedance on ESU analyzer.
- Place red and yellow thermocouple wire in 37°C bath. Place reference thermometer in 37°C bath.

Test Method

- Verify that the bath temperature and ESU analyzer load impedance are indicated on the Temperature and Impedance displays.
- Depress the "RF Power" switch to initiate RF power sequence.
- Verify that the bath temperature, ESU analyzer load impedance, and power indicated on the Temperature, Impedance, and Power displays on the RF Generator are in agreement with the reference thermometer and the ESU analyzer.
- Turn off main power to the generator. Remove the modified Instrument Cable from the RF Generator, and AC power cord from the generator.
- In assessing the functionality of the RF Generator with any external measurement system such as an ESU Analyzer, the measurement tolerances of the ESU Analyzer for a given test must be added to the tolerances listed in the Tolerances section of this manual.

Power Delivery Verification

This test is intended to verify the ability of the VNUS RF Generator to deliver RF energy.

- Attach a Closure*FAST* catheter (model CF7-7-60 or CF7-7-100) to the generator.
- Fill a glass container with 0.9% saline solution heated to 37 ±3 °C (this simulates the temperature and impedance of blood in a blood vessel).
- Place the distal end of the catheter in saline such that the entire RF coil is covered by the saline.
- Press the RF Power button on the generator to enter ready mode.
- Press the Start RF button on the catheter to start RF treatment. Insure that the catheter coil is covered by the saline while RF power is being delivered.
- Verify that the generator delivers power and that the setpoint temperature is maintained during delivery.

Alarm Priority

The RF Generator will generate a tonal alarm for an alarm condition based on the power, temperature, and impedance feedback.

The RF Generator will enforce an alarm priority whereby an alarm message or tone takes priority over any other type of message or tone (i.e. advisory and informational).

During multiple message or tone conditions, the message or tone with the highest priority will take precedence as shown in Tables 7 and 8.

Table 7: Alarm Message Priority

Priority	Message
1 (Highest)	Alarm Message
2	Advisory Message
3	Informational Message

Table 8: Alarm Tone Priority

Priority	Tone
1 (Highest)	Button Acknowledge Tone
2	Invalid Tone
3	Alarm Tone
4	RF Stop Tone
5	Informational Tone
6	RF Start Tone
7	RF On Tone
8	RF Pullback Pause Tone
9	Power On Tone

Error Codes

If an error occurs, the RF Generator displays an error code. An error will be one of two types: unrecoverable or recoverable:

- **Unrecoverable errors** halt the RF Generator and require the operator to reset the RF Generator's AC Power to continue. If an unrecoverable error occurs, turn off the unit, wait a few seconds, and then turn on the unit. If the problem persists, contact VNUS Customer Service or a local distributor.
- **Recoverable errors** require the operator to respond to an error message or make a clinical decision.

Table 9: Error codes

Error Code	Description	Corrective Action
Error 1	Unexpected state.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 2	Unexpected event.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 3	A parameter value was incorrect.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 4	A queue overflowed.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 5	Unit not responding.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 6	Software version incorrect.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 7	Memory corruption detected.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 8	Resource conflict.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 21	RAM failure.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 22	UIC ROM failure.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 23	UIC watchdog failure.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 24	Operator-stored settings invalid. Default settings restored.	The operator should review the default RF Generator settings and make changes as desired.
Error 25	The inserted Multimedia Card (MMC) does not contain valid information or is missing files.	Turn off the unit, wait a few seconds, and then turn on the unit. If the error persists, try a different MMC.
Error 26	The inserted Multimedia Card (MMC) cannot upgrade this RF Generator because its serial number does not match.	Turn off the unit, wait a few seconds, and then turn on the unit. If the error persists, try a different MMC.
Error 27	The Multimedia Card (MMC) software update failed.	The RF Generator needs repair. Contact VNUS Customer Service or a local distributor.
Error 28	The inserted Multimedia Card (MMC) is not correctly formatted or is an invalid type.	Data logging will be disabled. No user action required.
Error 29	The RF Generator is unable to write data to the Multimedia Card (MMC).	Data logging will be disabled. No user action required.
Error 30	The inserted Multimedia Card (MMC) is full and no more data can be stored on it.	Data logging will be disabled. No user action required.
Error 31	The real-time clock stopped and has been restarted.	The operator should set the date and time. See the "RFG Setup Mode" section in the Operator's Manual for instructions.
Error 32	The inserted MMC card is not formatted.	Replace the MMC card.
Error 33	An Update Card was inserted after the unit was turned on.	To log data, insert a new card. To perform a software update, turn off the unit, wait a few seconds, and then turn on the unit.
Error 34	A UIC Software Task did not check in with the Task Monitor.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 35	The RFG2 has experienced more than five resets in one minute.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 36	A Software Stack became corrupt.	Turn off the unit, wait a few seconds, and then turn on the unit.
Error 37	The temperature of the RFG2 is above the specified operating temperature.	Allow the RFG2 to cool down before use.
Error 38	The temperature of the RFG2 is below the specified operating temperature.	Allow the RFG2 to warm up before use.
Error 39 - Error 485	Turn off the unit, wait a few seconds, and then turn on the unit. If the error persists, contact VNUS Customer Service.	

Service and Maintenance

Cleaning and Disinfection

Caution: Always unplug the AC Power cord prior to cleaning the RF Generator. Avoid spilling liquids into the RF Generator during cleaning. Avoid getting cleaning materials inside RF Device receptacle.

The RF Generator requires no scheduled maintenance other than cleaning external surfaces. It is recommended that the operator clean the unit prior to each use or as needed.

The recommended agents for cleaning RF Generator surfaces (not including the LCD screen) to prevent surface degrading or discoloration include the following:

- Five percent solution of household bleach (approximately 2,500 ppm Sodium Hypochlorite)
- Sporicidin®
- IPA 70/30

The recommended agent for cleaning the transparent, protective cover of the LCD screen is IPA 70/30.

RF Generator cannot be sterilized and must not enter a sterile surgical field.

Repairs and Returns

The RF Generator contains no operator-serviceable parts. The RF Generator must be either returned to the factory or repaired by qualified service personnel.

For RF Generator repairs or returns, call the VNUS Customer Service Department. See the back of this manual for contact information. A Customer Service Representative will assist the operator with obtaining service or returning the RF Generator, as appropriate.

The RF Generator must be unplugged before servicing.

WARNING: Do not remove the cover of the RF Generator, as there is a potential for electrical shock.

Warranty

For information about the RF Generator warranty and/or to obtain information about the availability of the VNUS Extended Warranty, contact VNUS Customer Service. See the back of this manual for contact information.

Opening the RF Generator by anyone other than an authorized VNUS technician voids the warranty.

Fuse Replacement

The RF Generator uses two 4A/250V, slo-blo, 5x20 mm fuses. In the event of a fuse failure, replace the fuses using the following procedure, as shown in Figure :

Caution: Fuses must be replaced with 4A/250V, slo-blo, 5x20 mm fuses. Using other fuses might damage the unit.

1. Disconnect the RF Generator's AC Power cord from the AC Power outlet.
2. Remove the slide-in fuse holder by inserting a small blade screwdriver into the slot located on the bottom side of the holder while activating the latch, and then pull out the holder by hand until the holder slides out.
3. Remove the holder completely by hand and replace the fuse(s).
4. Reinsert the fuse holder by pushing it with the thumb until the holder's front surface is flush with the power entry module's surface and the latch engages.

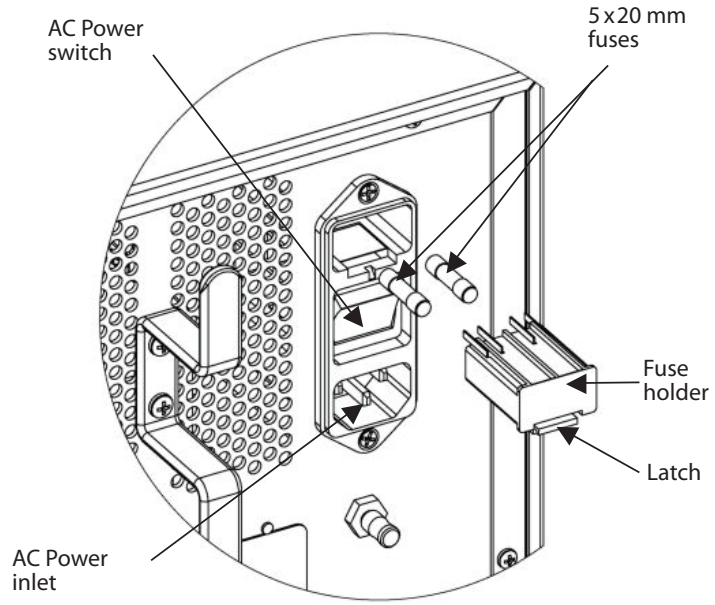


Figure 6: Fuse Replacement

Technical Specifications

Equipment Type

The Class I RF Generator is designed to work with Type CF, Defibrillator-Proof RF Devices. The RF Generator is designed to withstand an application of an external defibrillator while the RF Device is in use.

Electrical

The RF Generator:

- Operates from an AC Power source ranging from 100 to 240V RMS, 50 to 60 Hz.
- Includes a DIN 42801–compatible equipotential grounding lug that meets the ground bond requirements of UL 60601–1.

Should the supplied power cord need to be replaced to match another plug configuration, the replacement plug/cable/receptacle configuration must meet or exceed the following specifications:

100-120 VAC

- Cable: SJT16/3, IEC color code, maximum length 10 ft. (3 m)
- Plug: minimum 10 A - 125 VAC
- Unit receptacle: IEC female, minimum 10 A - 125 VAC

220-240 VAC

- Cable: H05VVF3G1.0 VDE, maximum length 10 ft. (3 m)
- Plug: minimum 6 A - 125 VAC
- Unit receptacle: IEC female, minimum 6 A - 125 VAC

RF Power Delivery Performance

The fundamental frequency of the RF signal is set at 460.8kHz.

Tolerances

Displayed Value	Range	Accuracy	Precision
Time	0:00 - 99:59 minutes:seconds	±1s	±1s
Temperature	10 - 130°C	±5°C	±19%
Power*	0.1 - 40 W	±20% (@ 25-1000 Ω)	±1% (@ 25-1000 Ω)
Impedance	10 - 1999 Ω	±15% or ±5 Ω, whichever is greater	±8%

* RF Power is measured on the isolated patient circuit and is the average Real Power. The RF Power capacity is also limited by the Maximum Power (W) setting of the connected RF Device. Please read the RF Device's Instructions for Use for more information.

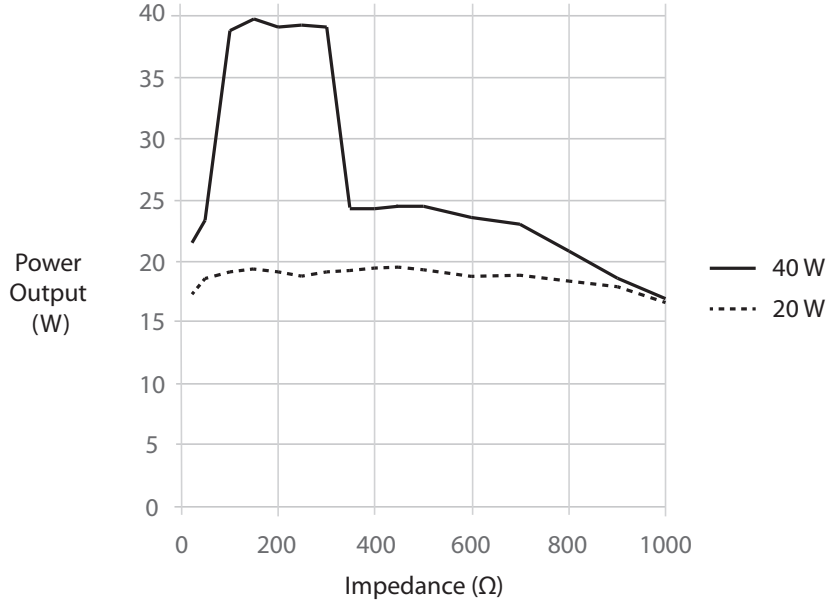


Figure 7: Power Output vs. Load Impedance

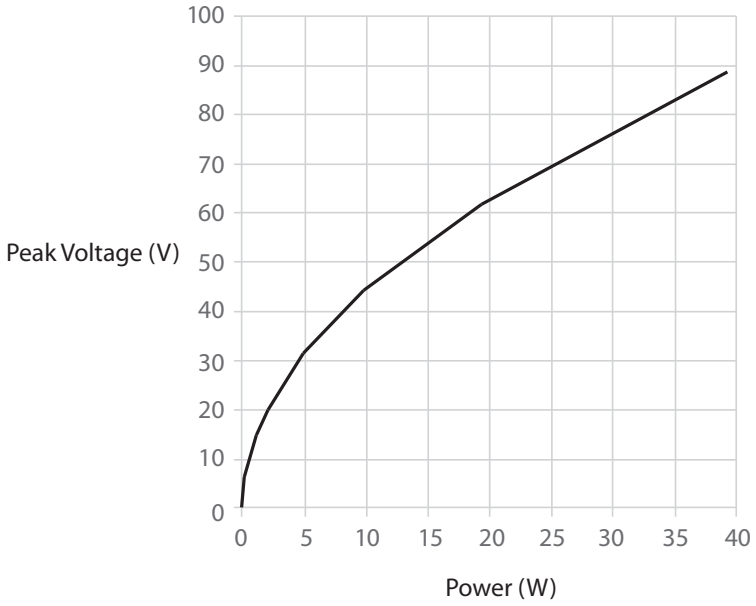


Figure 8: Peak Output Voltage vs. Power Output

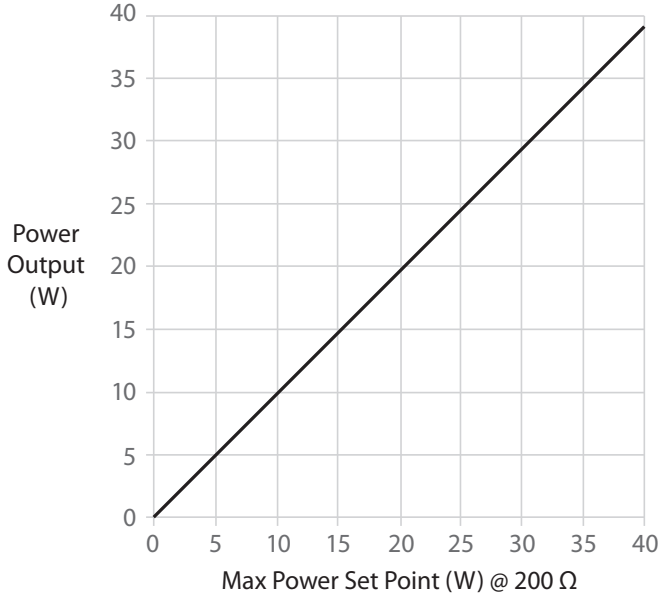


Figure 9: Power Output vs. Power Set Point

MEDICAL EQUIPMENT MODEL RFG2
WITH RESPECT TO ELECTRICAL SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL60601-1
CAN/CSA C22.2 NO.601.1
75AK

Rx ONLY

CE 0123

VNUS®
MEDICAL TECHNOLOGIES, INC.

RM 55-441-01 REV.C

5799 Fontanoso Way
San Jose, CA 95138 USA
Tel: +1-408-360-7200
Toll Free: +1–888–797–VEIN (8346)
Fax: +1-408-365-8470

EC REP
Covidien Ireland Limited,
IDA Business & Technology Park,Tullamore

Customer Service
Tel: +1-800-962-9888