Kimberly-Clark*

Pain Management Generator

PMG
V4.0

User's Manual

PMG-115	Basic
PMG-115-TD	Advanced
PMG-230	Basic
PMG-230-TD	Advanced

Kimberly-Clark

*Trusted Clinical Solutions**

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1 Introduction

The system presented in this User's Manual consists of the Kimberly-Clark* Pain Management Generator (PMG) (formerly known as the Baylis Pain Management Generator) and an optional pneumatic footswitch. For the user's convenience, the Kimberly-Clark* Pain Management Generator will be referred to in this User's Manual as the "Generator" or "PMG".

NOTE: *The PMG is also referred to as the Kimberly-Clark* Radiofrequency (RF) Generator on the packaging labeling.*

This User's Manual provides a description of the Generator, its controls and displays, and a sequence for its operation. This User's Manual also supplies other information of importance to the user. Do not operate the Generator before thoroughly reading this manual.

This User's Manual and the Generator screens can be made available in other languages. For further information U.S. customers please call Kimberly-Clark at 1-800-KCHELPS (800-742-1996), International customers please call +1-770-587-7200 for further information.

1.1 Glossary of Terms

Term	Definition
1-Shot	A possible value for the STIM RATE in the STIMULATION modes. If selected, only one stimulus pulse is delivered when the output is turned on.
Cannula	A metal tube that is electrically insulated along its length, with exception to an exposed tip from which electrical currents flow.
COOLED RF	A group of states specifically designed to allow for the use of water-cooled probes to allow more power to be dissipated in tissue, resulting in a larger lesion at a lower temperature.
Dispersive Electrode	An adhesive pad with a large electrically active surface area used in monopolar RF modes, as well as in certain Placement States. Often referred to as a "grounding pad", or as a "return electrode."
DONE	State of the Generator when RF energy has been terminated.
Footswitch	A pneumatic device that connects to the back of the PMG and allows hand-free starting and stopping of RF and Stimulation output.
IDL	Intradiscal Lesioning
IFU	Instructions For Use
Impedance	The effective resistance to the flow of current in a circuit.
Lesion	A localized pathological change in a bodily organ or tissue.
Mode	A group of states (usually READY, ON, and DONE) that comprise the machine steps necessary to complete a procedure. The modes for this Generator include: Current Stimulation, Voltage Stimulation, Auto Temp Lesion, Manual Power Lesion, Auto Pulsed Lesion, Manual Pulsed Lesion, Cooled RF, TransDiscal, RFA, and IDL.
Multi-RF	Multi-Radiofrequency
ON	State of the Generator when RF energy is applied to the probes and dispersive return electrode if applicable.
PDT A	The Peripheral Disc Temperature as relating to TDP A (TransDiscal* Probe A)
PDT B	The Peripheral Disc Temperature as relating to TDP B (TransDiscal* Probe B)
PMG	Pain Management Generator
POST	The state of the Generator when Power-On-Self-Tests are performed.
PULSE DUR	A setting that applies to VOLTAGE STIMULATION, CURRENT STIMULATION, AUTO PULSED LESION, and MANUAL PULSED LESION modes. In the STIMULATION modes, it describes the length of time of one stimulus pulse. In PULSED LESION modes (MANUAL AND AUTO) it describes the length of time of the RF pulse.
PULSE RATE	A setting that applies to AUTO PULSED and MANUAL PULSED modes. It describes the number of RF bursts of duration PULSE DUR and is measured in Hz.
Pump	Refers to Pain Management Peristaltic Pump Unit (TDA-PPU-1)
RAMP RATE – COOLED RF MODE	A setting that is adjustable in ADVANCED SETTINGS mode, and applies to COOLED RF mode. It is the rate at which the Generator heats to the SET TEMP.
RAMP RATE – IDL MODE	Setting that is adjustable in ADVANCED SETTINGS mode, and applies to IDL mode. It is the rate at which the Generator heats from the INITIAL TEMP to the SET TEMP.
RAMP RATE – TRANSDISCAL MODE	A setting that is adjustable in ADVANCED SETTINGS mode, and applies to TRANSDISCAL mode. It is the rate at which the Generator heats to the SET TEMP.
RAMP TIME –AUTO TEMP LESION AND AUTO PULSED LESION MODES	A setting that is adjustable in ADVANCED SETTINGS mode – LESION SETTINGS, and applies to the AUTO TEMP LESION and AUTO PULSED LESION modes. It is the rate at which the Generator heats to the SET TEMP.
RAMP TIME – RFA MODE	A setting that is adjustable in ADVANCED SETTINGS mode – RFA. It is the rate at which the Generator heats to the SET TEMP.
READY	State of the Generator where settings can be adjusted and other modes of operation can be chosen prior to RF application.

1.1 Glossary of Terms	
RF	Radiofrequency
RFA	Radiofrequency Annuloplasty
RF Probe	A slender, flexible surgical instrument used to deliver stimulation and RF output to bodily organs or tissues.
STANDBY	State of the Generator when a valid probe must be connected prior to proceeding to the applicable READY state for the probe.
STATE	A function of the Generator where a basic task is performed. For instance, the READY state for any mode allows settings to be changed and allows RF energy to be initiated. The states of the Generator include STANDBY, PLACEMENT, READY, ON, DONE, ADVANCED SETTINGS.
STIM RATE	A setting that applies to VOLTAGE STIMULATION and CURRENT STIMULATION modes. It describes the number of stimulus pulses delivered in a second, and is measured in Hz.
Stylet	A fine wire that is run through a cannula, to keep it stiff or clear of debris.
Switching Cable	Either of TDX-BAY-TSW (TransDiscal* Switching Cable) or PMX-BAY-RSW (RFA Switching Cable), used to aid in the placement of secondary probes or thermocouples.
TC	Thermocouple
TD	TRANSDISCAL
TDP	TransDiscal* Probe
TDP A	TransDiscal* Probe A
TDP B	TransDiscal* Probe B
TEMP	Temperature
Thermocouple	A thermoelectric device used to measure temperatures accurately, consisting of two dissimilar metals.
TRUE-TX Ramp Time Extension	A feature that will maintain the time at the Set Temperature and generate a notification if probes are in a configuration that prevents the set temperature from being reached in the specified Ramp Time.
Y-Cable	Any of TDX-Y-TSW-TDP (TransDiscal* Y-Cable), PMX-Y-RSW-RFA (RFA Y-Cable), or PMX-Y-BAY-ORA (IDL Y-Cable), resembling the characteristic shape of the letter "Y".

2 Indicated Use

Kimberly-Clark* Pain Management Generator Model PMG-115 Basic, PMG-115-TD Advanced (For Domestic Use) and Model PMG-230 Basic, PMG-230-TD Advanced (For International Use) are indicated for use to create lesions during neurological lesion procedures, and for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. The Kimberly-Clark* PMG is to be used in conjunction with separately approved probes.

- The Generator supplies up to 50 Watts of Radiofrequency energy at 460 kHz under power, voltage, or temperature control while continuously monitoring and displaying actual power or voltage delivered, measured probe temperature(s), time of power duration, and measured impedance. The use of a dispersive return electrode is specified in the accompanying IFUs of probes and cables.

The Generator is also intended to stimulate nerve cells by delivering low-frequency pulses in either voltage or current controlled modes to aid in probe placement.

The Generator is rated as Class 1, Type CF (rated for continuous operation) as per IEC-60601-1:2005.

Caution!

Rx Only: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

The Baylis Pain Management Brain Lesion Probe (PME-B), Cordotomy Probe (PME-C), and DREZ Probe (PME-D) are not licensed for use in Canada.

3 Warnings and Precautions

⚠ The safe and effective use of RF energy is highly dependent upon factors under the control of the operator. There is no substitute for a properly trained operating room staff. It is important that the operating instructions supplied with the Generator be read and understood before use.

3.1 Warnings

- **Read before use:** Do not operate the Generator before thoroughly reading this manual.
- **Improper line voltage selection may cause malfunction or damage to the instrument:** The Voltage Selector and Fuse Drawer must BOTH be set to the same voltage. They are located on the rear panel of the instrument (the fuse drawer is located in the power entry module). An improper voltage setting may result in Generator malfunction and potential instrument damage. The Voltage Selector is factory set and should not be changed by the user.
- **Risk of Fire:**
  - Do not use in the presence of flammable anesthetics, other flammable gases, near flammable fluids (such as skin prepping agents and tinctures), flammable objects, or with oxidizing agents. Observe appropriate fire precautions at all times.
  - Do not use this device in oxygen-enriched atmospheres, nitrous oxide (N_2O) atmospheres, or in the presence of other oxidizing agents.
- **Risk of RF burns to the patient:**
  - While using this device during a procedure, the patient should not be allowed to come into direct contact with grounded metal objects such as surgical table frame, the instrument table, etc. The use of antistatic sheeting is recommended for this purpose.
  - Place monitoring electrodes as far away from the treatment site as possible, to avoid burns or interference with other equipment. The use of needle monitoring electrodes (or other small-area electrodes) during RF output is not recommended. In all cases, monitoring systems incorporating HIGH FREQUENCY current limiting

devices are recommended.

- Use only with a Kimberly-Clark* or Baylis Pain Management Dispersive Electrode. Always select a dispersive electrode designed to be compatible with the available contact quality monitor.
- Unless a compatible Monitoring Dispersive Electrode is used with a Contact Quality Monitor, loss of safe contact between the Dispersive Electrode and the patient will not result in an auditory alarm.
- Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze.
- Failure of the Generator or accessories could result in an unintended increase of output power.
- Do not use the Multi-RF Module with the Baylis Pain Management Brain Lesion Probe (PME-B), Cordotomy Probe (PME-C), or DREZ Probe (PME-D).
- Do not use the Multi-RF Module with the Kimberly-Clark* or Baylis Pain Management Bipolar Adaptor (PMA-BP).
- **Interference with active implants**: During RF **output**, implanted devices such as pacemakers may be affected. Qualified advice should be obtained as necessary, to minimize the risk of injury from implanted device malfunction.
- **Interference with other equipment**: During RF **output** (lesion modes), the conducted and radiated electrical fields may interfere with other electrical medical equipment.

3.2 Precautions

- Do not activate the output of the Generator until the probe is properly positioned in the patient.
- In STIMULATION, LESION, COOLED RF, TRANSDISCAL and RFA modes, ensure that the dispersive return electrode is connected to the Generator and properly attached to the patient.
- In Multi-RF STIMULATION mode, connect one probe at a time to the Multi-RF module to display individual impedance readings for placement purposes.
- The entire area of the neutral electrode should be reliably attached to the patient's body and as close to the operating field as possible.
- The PMG may be used without a dispersive return electrode in some modes. Please refer to accompanying IFUs for related probes and cables.
- The activation tone and light are important safety features. Do not obstruct the activation light. Do not disable the activation audible tone.
- Do not remove the cover of the Generator, as there is a potential for electrical shock. Refer to authorized personnel for service.
- Use only the Kimberly-Clark* or Baylis pneumatic footswitch with the Generator.
- The mains power cord of the Generator must be connected to a properly grounded receptacle. Extension cords and/or adapter plugs must not be used.
- Do not wrap instrument cable around metal objects. Wrapping cables around metal objects may induce hazardous currents.
- The cables to the surgical electrodes should be positioned in such a way that contact with the PATIENT or other leads are avoided. Temporarily unused ACTIVE ELECTRODES should be stored in a location that is isolated from the PATIENT.
- Avoid high frequency output settings where the Maximum Output Voltage may exceed the rated accessory voltage.
- The output power should be as low as possible for intended purpose (applies to Manual modes).
- The application of the Neutral Electrode and its connections to be checked before selecting a higher output power.
- For surgical procedures where the high frequency current could flow through parts of the body having a relatively small cross sectional area, the use of BIPOLAR techniques may be desirable in order to avoid unwanted tissue damage.
- Perform regular inspections of all accessories, including electrosurgical cables and probes, for damage to insulations.
- Associated Equipment and Active Accessories should be selected that have a Rated Accessory Voltage equal to or greater than the Maximum Output Voltage.
- For information on the connection and disconnection of detachable parts and accessories, refer to the Instructions for Use for the corresponding probe or cable.
- Care should be taken to avoid the danger of ignition of endogenous gases.
- The PMG needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.
- Electronic equipment, including portable and mobile RF communications equipment, can affect the operation of the PMG. Operating non-essential equipment in the vicinity of the PMG should be avoided, if possible.
- The PMG should not be used adjacent to or stacked with other equipment. If the PMG must be operated adjacent to or stacked with other equipment, the PMG should be observed to verify normal operation in that configuration.
- Use of accessories, transducers and cables other than those specifically approved by Kimberly-Clark for use with the PMG may result in increased electromagnetic emissions or decreased electromagnetic immunity of the PMG.
- In Multi-RF Auto Temp mode, and in Multi-Cooled RF Auto Temp mode, maintain a minimum distance of 10 mm between probe tips and ensure that the probe tips do not touch.
- When using the PMG with the pump unit accessory (TDA-PPU) refer to the pump IFU for information on proper setup and operation.

4 Installation

Inspect the Generator for any signs of physical damage to the front panel, chassis or cover. **If any physical damage is found, DO NOT USE THE GENERATOR. CONTACT Kimberly-Clark for a replacement.** Kimberly-Clark must approve all returns.

4.1 Preparing the Generator for Use

- The Generator may be placed on a mounting cart or on any sturdy table or platform.
- Provide at least 10-15 cm of space behind the rear panel of the Generator for forced air-cooling. Do NOT obstruct the vents on the underneath of the Generator. Under continuous use for extended periods of time, it is normal for the top and rear panel to be warm.

4.2 Mains Power Cord

- The Generator is shipped with an approved hospital-grade mains power cord.
- Do not use extension cords or three-prong to two-prong adapters. The mains power cord assembly should be periodically checked for damaged insulation or connectors.

4.3 Generator Cleaning and Disinfection Instructions

- Use a mild detergent and damp cloth to clean the Generator cover, front panel, and power cable. The Generator cannot be sterilized. Do not allow fluids to enter the chassis. The Generator may be disinfected using a standard hospital alcohol solution applied with a cloth.
- Do not spray or pour liquids directly on the Generator.
- Non-flammable agents should be used for cleaning and disinfection wherever possible.
- Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of high frequency surgery.

4.4 When you get a new Generator

- When you open a box, you will find:
  - Generator
  - Power Cord
  - User's Manual

4.5 Generator Maintenance Schedule

- The Generator verifies calibration integrity during the Power-On-Self-Test (POST); maintenance is not required.
- For Cleaning and Disinfection Instructions, refer to 4.3 Generator Cleaning and Disinfection Instructions.

4.6 Compatible Accessories

- The Kimberly-Clark* PMG has been approved for use with all Kimberly-Clark* and Baylis accessories, transducers, and cables. This includes the PMX, PMP, PMC, PMF, TDX, TDP, TDI, TDA, CRX, and CRP line of products.

5 User Interface Overview

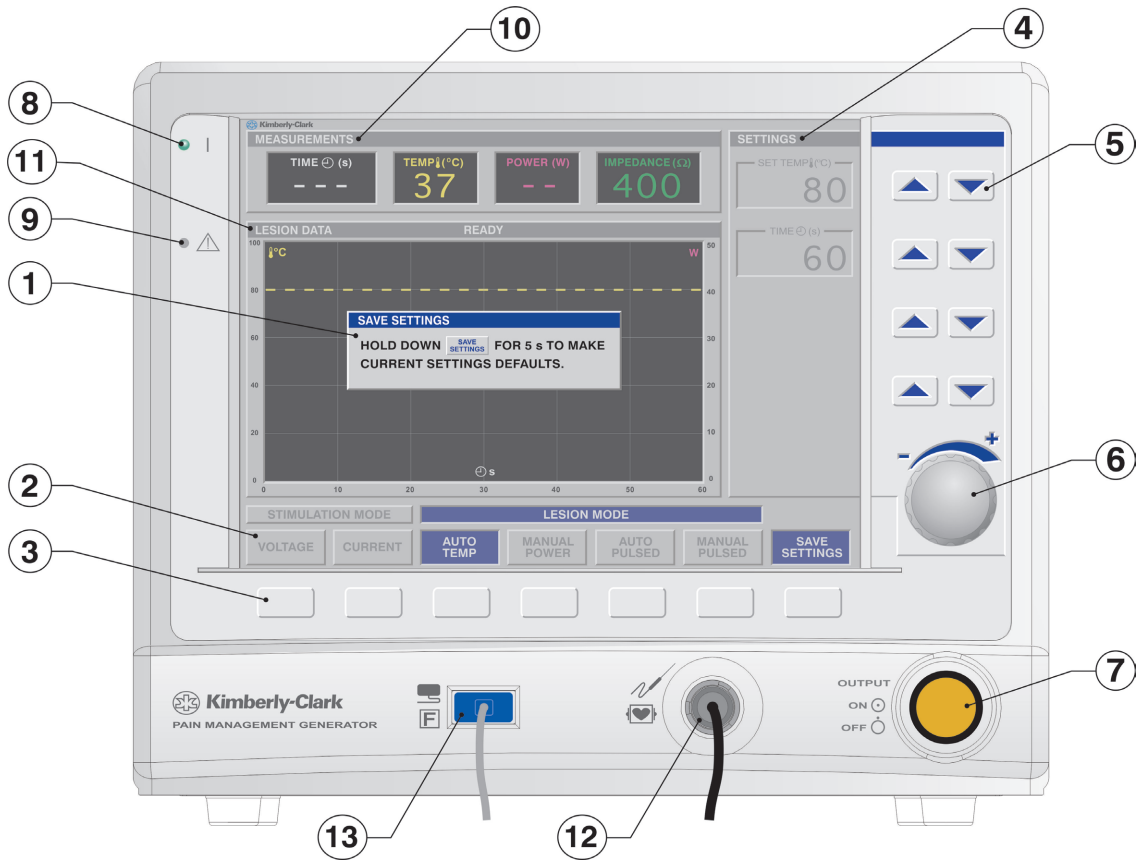


Figure 5-1 Generator front panel

5.1 Front Panel Displays, Controls, and Connections

- Descriptions of front panel features and their functions are given below. Please refer to *Figure 5-1* for location of each item on the front panel.

1. **Status Window:** This window is used to display messages (e.g., Error, Fault, Save Settings).
2. **Mode Function Labels:** These "labels" are part of the flat panel display and indicate the function of the associated Mode Function Key ③. Labels highlight to indicate the current operating mode. If no label is present, the associated button is not used in the present mode.
3. **Mode Function Keys:** These keys select and change the state of operation. For Kimberly-Clark* Pain Management Thermocouple RF probes, STIMULATION or LESION states are selected with a single press. In RFA mode, PLACEMENT or TREATMENT states are selected with a single press. In COOLED RF mode, STIMULATION or AUTO TEMP states are selected with a single press. In TRANSDISCAL mode, STIMULATION, PLACEMENT, or TREATMENT states are selected with a single press. The functions of these keys may vary between modes. The Mode Function Label ② above a key ③ always describes the key function.
4. **SETTINGS Window:** For each state (e.g., VOLTAGE STIMULATION, AUTO TEMP LESION, TRANSDISCAL TREATMENT, etc.), the adjustable settings are shown in the SETTINGS Window. Up to 5 SETTINGS are adjustable in each state, by using the Setting Adjustment Keys ⑤ and Rotary Encoder ⑥, to the right of the window.

5. **Settings Adjustment Keys:** The up ▲ and down ▼ buttons located to the right of the SETTINGS Window ④ are used for adjusting treatment settings in the upper 4 locations of the SETTINGS Window.
6. **Rotary Encoder:** This encoder is used for adjusting the bottom parameter in the SETTINGS Window. The parameter in the window depends upon the current mode.
7. **OUTPUT ON/OFF Button and Indicator:** This button controls STIMULATION, LESION, COOLED RF, TRANSDISCAL, RFA and IDL outputs. In STIMULATION modes, this button toggles the output on and off. In all other modes, this button control initiates or terminates RF output. The indicator is ON during RF delivery, and also when in the STIMULATION: ON state.
8. **POWER Indicator:** This green LED indicates that system power is on.
9. **FAULT Indicator:** This red LED indicates a system fault has occurred. System faults include: self-test failure, hardware protection (such as short-circuit shutdown), and software failure. Main power to the system must be cycled (off-on) to attempt recovery from a system fault.
10. **MEASUREMENTS Window:** Measured values for elapsed TIME, probe TEMPERATURE(S), RF POWER, RF VOLTAGE and/or IMPEDANCE are displayed during and after RF output in both STIMULATION and LESION states and during treatment states for COOLED RF, TRANSDISCAL, RFA and IDL modes. During all READY states (prior to RF output), TEMPERATURE and IMPEDANCE are displayed. In LESION READY states for AUTOTEMPERATURE, AUTOPULSED, MANUAL POWER, AND MANUAL PULSED, IMPEDANCE is displayed according to LOW/OK/HIGH range. In PLACEMENT states for TRANSDISCAL and RFA modes, only the IMPEDANCE between the probe and the dispersive return electrode will be displayed.
11. **Graph Window:** This window is used for graphing temperature, power and voltage data acquired during RF output in lesion states for ON states when in the LESION mode and treatment states when in COOLED RF, TRANSDISCAL, RFA and IDL modes. The horizontal axis is time ( ), corresponding to the treatment duration in the SETTINGS Window. The display will rescale if the TIME duration in the SETTINGS Window is modified. The vertical axis represents temperature (°C) and either power (W) or voltage (V).
12. **Connector Cable Connection:** This patient-isolated connection is for attachment of the connector cable for Kimberly-Clark* Pain Management Thermocouple probes.
13. **Dispersive Return Electrode Connection:** This patient-isolated connection is for attachment of a Kimberly-Clark* Pain Management Dispersive Electrode (PMA-GP-BAY).

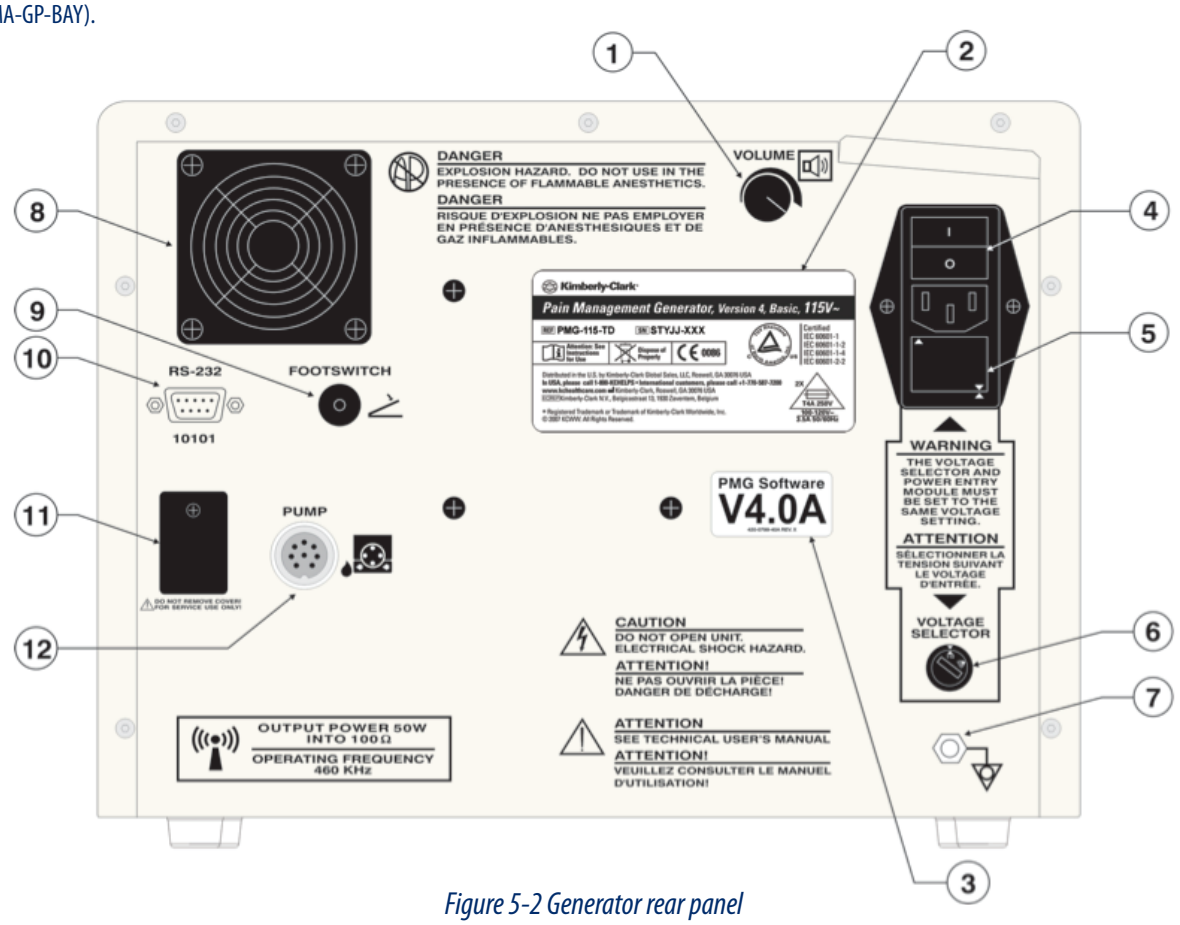


Figure 5-2 Generator rear panel

5.2 Rear Panel Displays, Controls, and Connections

- Descriptions of rear panel features and their functions are given below. Please refer to *Figure 5-2* for corresponding locations on the rear panel.

1. **Volume Adjustment:** This knob adjusts the volume of the system's audio output.
2. **Device Label:** This label indicates the model number of the Generator and includes contact information for Kimberly-Clark. The unique serial number of the Generator is marked on this label.
3. **Software Version Label:** This label indicates the PMG software version.
4. **AC MAINS SWITCH:** This switch controls the initial AC power input to the system, and is part of the power entry module, which integrates the AC power inlet and Fuse Drawer.
5. **Fuse Drawer:** The orientation of the fuse drawer, in conjunction with the AC CONFIGURATION SWITCH, determines the AC input voltage range (100-120V~ or 220-240V~). For each voltage setting the proper, corresponding fuses must be used, as indicated in the rear panel labeling.

6. **AC CONFIGURATION SWITCH:** The orientation of this switch, in conjunction with the Fuse Drawer, determines the AC input voltage range (100-120V~ or 220-240V~). Do not change the position of the voltage selector while the system is plugged in.
7. **Equipotential Ground Connection:** This connector is attached to the chassis/earth ground. It is intended for earth reference connection in environments where equipotential ground cabling is used.
8. **Fan:** A brushless DC fan is used to exhaust warm air from the Generator. The direction of airflow is outward from the rear panel.
9. **FOOTSWITCH Connection:** This pneumatic barb connects to the hose of the pneumatic footswitch. Like the OUTPUT ON/OFF switch, the FOOTSWITCH controls stimulus output in the STIMULATION modes and controls RF output in the LESION, COOLED RF, TRANSDISCAL, RFA and IDL modes. The action of the FOOTSWITCH differs from the OUTPUT ON/OFF switch: the FOOTSWITCH must be held down to continue delivery of stimulus pulses or RF energy.
10. **RS-232 Connection:** This is an isolated connection to a standard 9-pin COM port. It is provided for passive data acquisition, and cannot be used to control the system.
11. **RJ45 Connector:** Connection to be used by authorized service personnel only.
12. **Pump Module Interface Connector:** For attachment of authorized cooling pump unit only.

6 Factory Set Defaults

Factory Set Defaults			
Mode	**Settings**	**Adjustment Range**	**"Factory Set" Value**
VOLTAGE STIMULATION	STIM RATE	1-Shot, 2, 5, 10, 20, 50, 75, 100, 150, 180, 200 Hz	2 Hz
	PULSE DUR	0.1, 0.2, 0.5, 1.0 ms	1.0 ms
	VOLTAGE	0.0 –10.0 V	0.0 V
CURRENT STIMULATION	STIM RATE	1-Shot, 2, 5, 10, 20, 50, 75, 100, 150, 180, 200 Hz	2 Hz
	PULSE DUR	0.1, 0.2, 0.5, 1.0 ms	1.0 ms
	CURRENT	0.0 –10.0 mA	0.0 mA
AUTO TEMP LESION	SET TEMP	38° – 95°C	80°C
	TIME	15 – 600 s	75 s
MULTI-RF (TRUE-TX)	MAX RAMP TIME EXTENSION	DISABLE, 5–120 s, with 5 s interval	30 s
MANUAL POWER LESION	TEMP LIMIT	38° – 95°C	80°C
	TIME	15 – 600 s	75 s
	SET POWER	0 – 50 W	0 W
AUTO PULSED LESION	SET TEMP	38° – 95°C	42°C
	TIME	10 – 900 s	120 s
	PULSE DUR	10 – 100 ms, with 10 ms interval	20 ms
	PULSE RATE	1 – 10 Hz	2 Hz
MANUAL PULSED LESION	WARNING TEMP	38° – 95°C	42°C
	TIME	10 – 900 s	120 s
	PULSE DUR	10 – 100 ms, with 10 ms interval	20 ms
	PULSE RATE	1 – 10 Hz	2 Hz
COOLED RF	SET TEMP	30° – 90°C	60°C
	TIME	15 s–30 min	2 min 30 sec
MULTI-COOLED RF (TRUE-TX)	MAX RAMP TIME EXTENSION	DISABLE, 5–180 s, with 5 s interval	60 s
	SET TEMP	38° – 95°C	60°C
	TIME	15 s – 30 min with 15 s interval	2 min 30 sec
TRANSDISCAL	SET TEMP	30° – 90°C	BIPOLAR 50°C MONOPOLAR 60°C
	TIME	1 – 30 min	BIPOLAR 15 min MONOPOLAR 2 min 30 sec
RFA	SET TEMP	38° – 95°C	55°C
	TIME	1 – 30 min	10 min
IDL	SET TEMP	40° – 95°C	90°C
	TIME	30 s – 20 min	16 min 30 sec

7 Displays

7.1 System Initialization, Power-On-Self-Test (POST), and STANDBY States

- The System Initialization state is initiated when the system is turned on and it lasts about 40 seconds. The FAULT indicator normally lights during a portion of the System Initialization state.

Figure 7-1 System Initialization State Display

- The POST state is initiated after System Initialization is completed. It lasts about 30 seconds.

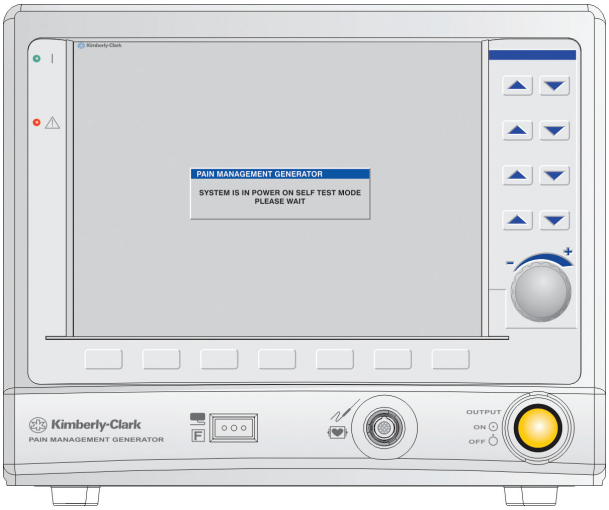


Figure 7-2 POST State Display

- The STANDBY state is initiated upon successful completion of the POST state.

Figure 7-3 STANDBY State Display

Displays and Indicators						
STATE	**PARAMETER**					
	RF/Stimulus Output		**FAULT indicator**		**RF/Stimulus Output ON/OFF indicator**	
	Status	**Description**	**Status**	**Description**	**Status**	**Description**
System Initialization	OFF	No RF or stimulus waveforms are generated.	OFF	Only Power On is illuminated during Initialization.	OFF	Only Power On is illuminated during Initialization.
Power-On-Self-Test (POST)		RF and stimulus waveforms are delivered into internal test loads.	ON	All indicators are illuminated during POST.	ON	All indicators are illuminated during POST.
STANDBY		The output is inactive.	OFF	(The FAULT indicator is used only in the POST and SYSTEM FAULT states.)	OFF	The indicator is not illuminated during this state.

STATE	**PARAMETER**					
	RF Audio Output		**Impedance Related Audio Output**		**Graph Window**	
	Status	**Description**	**Status**	**Description**	**Status**	**Description**
System Initialization	OFF	RF audio output is not generated during Initialization.	OFF	Impedance related audio output is not generated during Initialization.	N/A	No parameters are graphed during this state.
Power-On-Self-Test (POST)	ON-POST tone	A tone sounds for approximately 2 seconds to indicate that the system is active and is performing self-tests. The tone also serves as a test of the audio output.				
STANDBY	None	N/A			None	

STATE	**PARAMETERS**							
	Measurement Window		**Status Window**		**Available States**		**Available Settings**	
	Status	**Description**	**Status**	**Description**	**Status**	**Description**	**Status**	**Description**
System Initialization	N/A	No parameters are measured during this state.	None	N/A	None	No other modes are available during Initialization and POST states.	None	No settings are available during this state.
Power-On-Self-Test (POST)								
STANDBY	None		Active	"PLEASE ATTACH PROBE TO CABLE THEN ATTACH CABLE TO GENERATOR" message is displayed while in the STANDBY mode.		No operating modes are available until a probe is connected. The ADVANCED SETTINGS mode can be entered during the STANDBY state.		N/A

7.2 PLACEMENT State

- In the TRANSDISCAL mode, TREATMENT state is the default screen upon connection of a valid TransDiscal* Cable and probe, or when a TransDiscal* Y-Connecting Cable is used. The PLACEMENT state can be accessed from the STIMULATION or TREATMENT READY states. The PLACEMENT state cannot be accessed during the STIMULATION ON or TREATMENT ON states.

When in the PLACEMENT state:

- MEASURING TDP A is the default screen when the switching cable is set to Probe A, or when a TransDiscal* Y-Connecting Cable is used.
- MEASURING TDP B is the default screen when the switching cable is set to Probe B and BIPOLAR is enabled for use in the TRANSDISCAL mode, accessible from the ADVANCED SETTINGS mode.

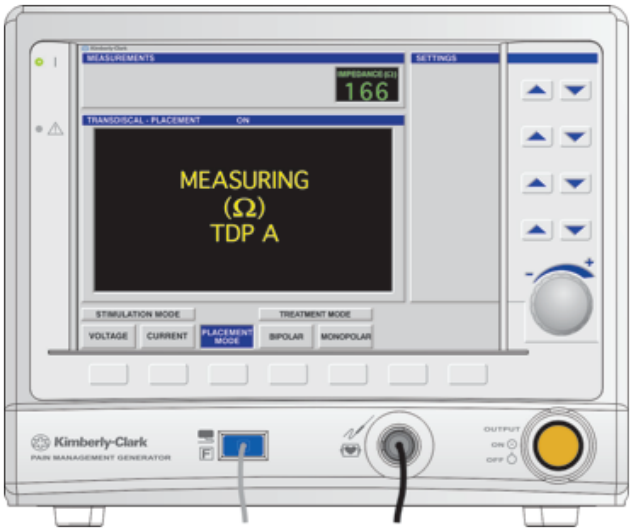


Figure 7-4 TDP A Placement Display

Displays and Indicators		
PARAMETER	**STATUS**	**DESCRIPTION**
RF/Stimulus Output	OFF	RF power is not delivered during this state.
FAULT Indicator	OFF	(The FAULT indicator is used only in the POST and SYSTEM FAULT states.)
RF/Stimulus Output ON/OFF Indicator	OFF	The indicator is not illuminated during this state, as there is no RF power delivery.
Measurement Window	ON	Active impedance measurement is displayed. The display will read HIGH for high impedances (e.g., open circuits).
Status Window	None	N/A
Available Modes	TREATMENT MODE None for RFA MODE – THERMOCOUPLE Placement state	In the Secondary Thermocouple Placement state, Treatment mode is not selectable. In the TDP A Placement state, Treatment mode is available. If the position of the switch on the Switching Cable changes to TDP B, the Generator changes to the TDP B Placement state, and the Treatment mode key is not selectable and the mode select key is greyed out. In the RFA Placement state, Treatment mode is available if the position of the switch on the Switching Cable concurs, or if only the RFA Y-Connecting Cable is used. If the position of the switch on the Switching Cable does not concur, TREATMENT mode is not selectable. When Treatment mode is selected, the Generator will enter the READY state of that mode. The Generator dynamically changes the selection availability of the Placement mode and Treatment mode key via monitoring the switch position in the switching cable, and displaying the appropriate text in the Graph Window.
Available Settings	None	N/A

STATE	**PARAMETER**					
	RF Audio Output		**Impedance Related Audio Output**		**Graph Window**	
	Status	**Description**	**Status**	**Description**	**Status**	**Description**
TDP A PLACEMENT	None	N/A	ON (Default**) OFF (if disabled)	Continuous audio output is generated for placement. Frequency of output is related to active impedance measurement. No audible tone if selected probe is an open circuit – replace with warning message. This feature can be disabled in the AUDIO SETTINGS state, accessible from the ADVANCED SETTINGS mode.	PLACEMENT MEASUREMENT	Indicates the system is measuring the selected probe impedance.
TDP B PLACEMENT						
RFA MODE - THERMOCOUPLE Placement						
RFA PLACEMENT						

*** Impedance Related Audio Output can be disabled in the AUDIO SETTINGS, accessible from the ADVANCED SETTINGS mode.*

7.3 READY States

- VOLTAGE STIMULATION Mode – READY state is the default upon connection of a Kimberly-Clark* Pain Management Thermocouple probe and cable.

Figure 7-5 VOLTAGE STIMULATION – READY Display

Figure 7-6 MULTI-RF VOLTAGE STIMULATION – READY Display

Displays and Indicators		
PARAMETER	**STATUS**	**DESCRIPTION**
RF/Stimulus Output	OFF	RF power is not delivered during the READY state. When Output ON/OFF is pressed, RF power is delivered and the Generator automatically transitions to the ON state. VOLTAGE STIMULATION – During the ON state, Voltage must be greater than 0.00 V for Stimulus pulses to be delivered. CURRENT STIMULATION – Stimulus pulses are not delivered during the READY state. During the ON state, Current must be greater than 0.00 mA for Stimulus pulses to be delivered. TRANSDISCAL AND COOLED RF TREATMENT – When Output ON/OFF is pressed; the Generator will enter the PRE-TREATMENT COOLING state.
FAULT Indicator	OFF	(The FAULT indicator is used only in the POST and SYSTEM FAULT states.)
RF/Stimulus Output ON/OFF Indicator	OFF	The indicator is not illuminated during the READY state, as there is no Stimulus/RF power delivery.
RF Audio Output	None	RF audio output is not generated during the READY state.

Displays and Indicators		
PARAMETER	**STATUS**	**DESCRIPTION**
Impedance Related Audio Output	OFF (Default**) ON (if enabled)	If enabled in ADVANCED AUDIO SETTINGS, impedance related audio output is generated.
Graph Window	Minimal	The time axis (⏲) is indefinitely scalable during the READY state, accommodating changes to treatment TIME. The dashed line denoting SET TEMP/TEMP LIMIT/WARNING TEMP will move according to changes made to the SET TEMP/TEMP LIMIT/WARNING TEMP value. TRANSDISCAL AND COOLED RF TREATMENT - Pump Status is displayed at the top of the Graph Window.
	STIMULATION READY display	Indicates the system is ready to generate stimulus pulses.
Measurement Window	Impedance Displayed	Impedance measurements are displayed for all attached thermocouples. In Multi-RF and Multi-Cooled RF modes, the displayed value is updated every second for each attached thermocouple.
Status Window	None	N/A

*** Impedance Related Audio Output can be disabled in the AUDIO SETTINGS, accessible from the ADVANCED SETTINGS mode.*

STATE	**PARAMETER**						
	Measurement Window		**Available States**		**Available Settings**		
	Status	**Description**	**Status**	**Description**	**Status**	**Description**	
VOLTAGE STIMULATION **CURRENT STIMULATION**	ON	Impedance measurements are displayed.	VOLTAGE STIMULATION CURRENT STIMULATION AUTO TEMP MANUAL POWER AUTO PULSED MANUAL PULSED SAVE SETTINGS	While in the READY state, other operating modes for Kimberly-Clark* Pain Management Thermocouple probes are available. When a different mode is selected, the Generator will enter the READY state of the new mode. The present SETTINGS can be saved as defaults by holding down the SAVE SETTINGS key. VOLTAGE/CURRENT STIMULATION – The setting is saved to the ADVANCED STIMULATION SETTINGS State, in the MOTOR and SENSORY toggle fields.	SELECT PROBE (Multi-RF)	Available Values	A, B, C or D
					STIM RATE	Range	1-Shot – 200 Hz
						Available Values†	1-Shot, 2, 5, 10, 20, 50, 75, 100, 150, 180 and 200 Hz
						Default**	2 Hz -OR- as set in ADVANCED STIMULATION SETTINGS State MOTOR
					PULSE DUR	Range	0.1–1.0 ms
						Available Values†	0.1, 0.2, 0.5 and 1.0 ms
						Default**	1.0 ms
					VOLTAGE / CURRENT	Range	0.00 – 10.0 V/mA (Only adjustable when STIM RATE is 1-Shot)
						Increment	0.01 V/mA
						Default**	0.00 V/mA (cannot be overwritten when the SAVE SETTINGS function is used)
					PRESETS	Toggle between MOTOR and SENSORY as specified in the STIMULATION SETTINGS state, accessible from the ADVANCED SETTINGS mode. Selecting a Preset modifies the STIM RATE.	

*** Defaults are factory-set, and are overwritten when the SAVE SETTINGS function is used.*

† Time Range set by user does not include factory-set PRE-TREATMENT COOLING Time (45 seconds) or POST-TREATMENT COOLING Time (10 seconds).

STATE	PARAMETER						
	Measurement Window		Available States		Available Settings		
	Status	Description	Status	Description	Status	Description	
AUTO TEMP LESION	ON	Temperature and Impedance measurements are displayed while Time and Power are not displayed (dashed lines replace values).	VOLTAGE STIMULATION CURRENT STIMULATION AUTO TEMP MANUAL POWER AUTO PULSED MANUAL PULSED SAVE SETTINGS	While in the READY state, other operating modes for Kimberly-Clark* Pain Management Thermocouple probes are available. When a different mode is selected, the Generator will enter the READY state of the new mode. The present SETTINGS can be saved as defaults by holding down the SAVE SETTINGS key. Multi-Cooled RF only supports AUTO TEMP LESION mode.	SET TEMP	Range	38° – 95°C
						Increment	1°C
						Default**	80°C
					TIME	Range	15 – 600 s
						Increment	1 s
						Default**	75 s
MANUAL POWER LESION					TEMP LIMIT	Range	38° – 95°C
						Increment	1°C
						Default**	80°C
					TIME	Range	15 – 600 s
						Increment	1 s
						Default**	75 s
					POWER LIMIT	Range	0 – 50 W
						Increment	N/A
						Default	0 W (Cannot be overwritten by SAVE SETTINGS function)
AUTO PULSED LESION					SET TEMP	Range	38° – 95°C
						Increment	1°C
						Default**	42°C
					TIME	Range	10 – 900 s
						Increment	1 s
						Default**	120 s
					PULSE DUR	Range	10 –100 ms
						Increment	10 ms
						Default**	20 ms
					PULSE RATE	Range	1 –10 Hz
						Increment	1 Hz
						Default**	2 Hz
MANUAL PULSED LESION					WARNING TEMP	Range	38° – 95°C
						Increment	1°C
						Default**	42°C
					TIME	Range	10 – 900 s
						Increment	1 s
						Default**	120 s
					PULSE DUR	Range	10 –100 ms
						Increment	10 ms
						Default**	20 ms
					PULSE RATE	Range	1 – 10 Hz
						Increment	1 Hz
						Default**	2 Hz

Note: *Multi-RF Manual Power and Manual Pulsed modes support 1 probe connected to the Multi-RF module.*

*** Defaults are factory-set, and are overwritten when the SAVE SETTINGS function is used.*

STATE	PARAMETER						
	Measurement Window		Available Modes		Available Settings		
	Status	Description	Status	Description	Status	Description	
COOLED RF TREATMENT	ON	The temperature of the Cooled RF probe(s) are displayed in the COOLED RF TEMP box. Impedance measurement between the Cooled RF probes are displayed. Time and Power are not displayed (dashed lines replace values).	VOLTAGE STIMULATION CURRENT STIMULATION SAVE SETTINGS	While in the READY state, Placement is available. When Placement mode is selected, the Generator will enter the READY state of that mode. The present SETTINGS can be saved as defaults by holding down the SAVE SETTINGS key.	SET TEMP	Range	38° – 95°C
						Increment	1°C
						Default**	60°C
					TIME	Range†	15 s – 30 min
						Increment	15 s (between 15 s and 5 min) 30 s (between 5 min and 30 min)
						Default**	2 min 30 sec
TRANSDISCAL TREATMENT		The temperature of the TransDiscal* probe(s) is displayed in the TRANSDISCAL TEMP box. The temperature of Peripheral Disc Temperature is displayed in the PERIPHERAL DISC TEMP box. Impedance measurement between TransDiscal* probes are displayed. Time and Power are not displayed (dashed lines replace values).	VOLTAGE STIMULATION CURRENT STIMULATION PLACEMENT MODE SAVE SETTINGS		SET TEMP	Range	30° – 90°C
						Increment	1°C
						Default**	BIPOLAR 50°C MONOPOLAR 60°C
					TIME	Range†	1 – 30 min
						Increment	30 s
						Default**	BIPOLAR 15 min MONOPOLAR 2 min 30 sec
RFA TREATMENT MODE		If enabled, Temperature of RFA and Thermocouple Probe are displayed. Impedance measurement for RFA is displayed. Time and Power are not displayed (dashed lines replace values). If the Thermocouple Probe is disabled via RFA SETTINGS in the ADVANCED SETTINGS state, that measurement is greyed out and the value replaced with dashed lines.	PLACEMENT MODE SAVE SETTINGS		SET TEMP	Range	38° – 95°C
						Increment	1°C
						Default**	55°C
					TIME	Range	1 – 30 min
						Increment	30 s
						Default**	10 min
IDL MODE		Temperature of IDL and Thermocouple Probe are displayed. Impedance measurement for IDL is displayed. Time and Power are not displayed (dashed lines replace values). If the Thermocouple Probe is disabled via IDL SETTINGS state, accessible from the ADVANCED SETTINGS mode, that measurement is greyed out and the value replaced with dashed lines.	SAVE SETTINGS	While in the READY state, other operating modes are not available. The present SETTINGS can be saved as defaults by holding down the SAVE SETTINGS key.	SET TEMP	Range	40° – 95°C
						Increment	1°C
						Default**	90°C
					TIME	Range	30 s – 20 min
						Increment	00:30 s
						Default**	16:30 min

*** Defaults are factory-set, and are overwritten when the SAVE SETTINGS function is used.*

† Time Range set by user does not include factory-set PRE-TREATMENT COOLING Time (45 seconds) or POST-TREATMENT COOLING Time (10 seconds).

7.4 ON States

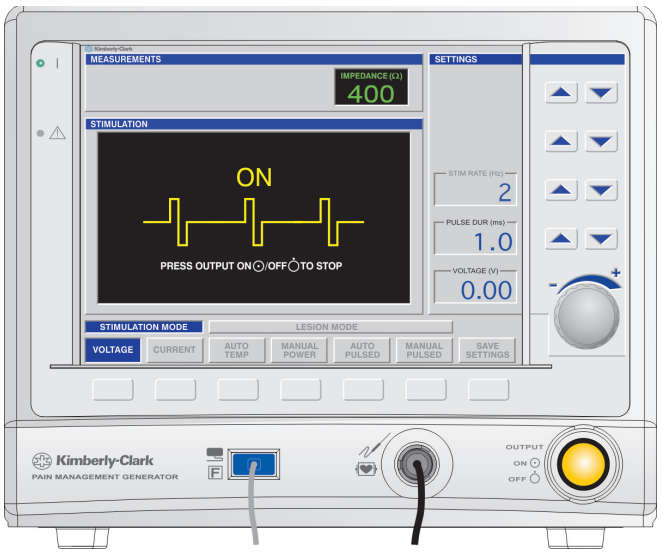


Figure 7-7 VOLTAGE STIMULATION – ON Display

Figure 7-10 MANUAL POWER LESION - ON Display

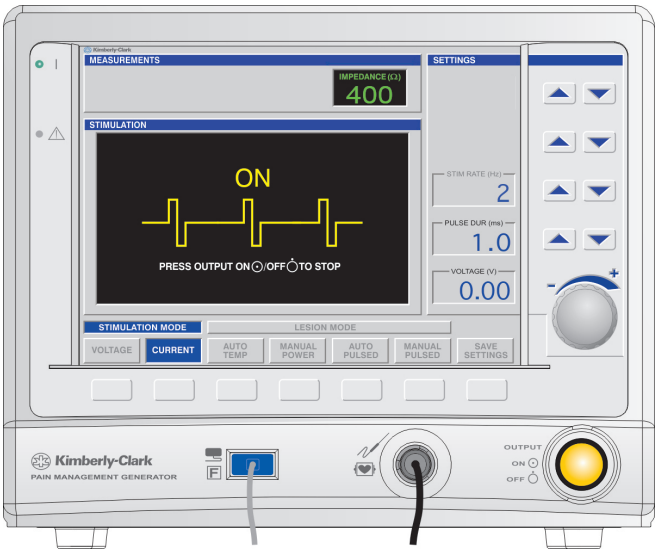


Figure 7-8 CURRENT STIMULATION – ON Display

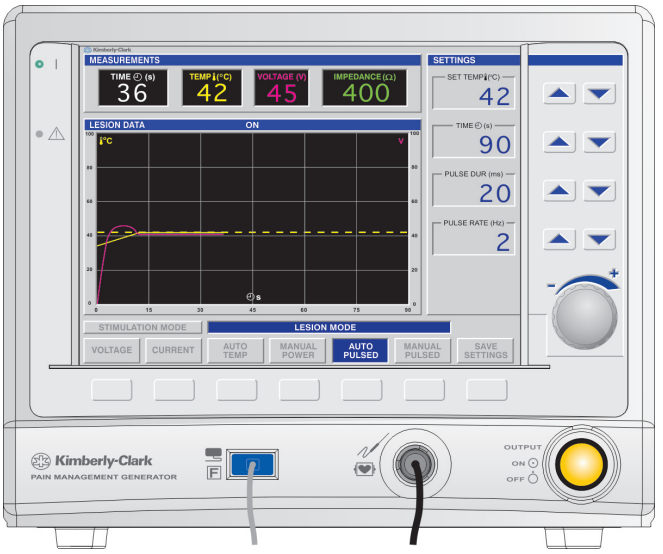


Figure 7-11 AUTO PULSED LESION – ON Display

Figure 7-9 AUTO TEMP LESION – ON Display

Figure 7-12 MANUAL PULSED LESION – ON Display

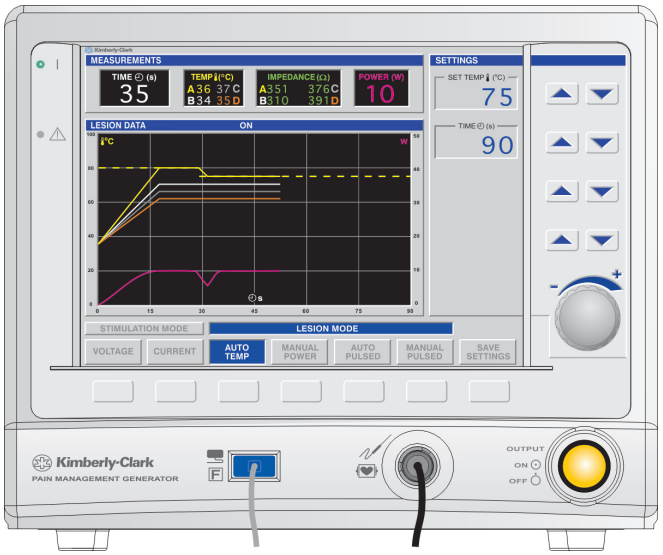


Figure 7-13 Multi-RF AUTO TEMP LESION – ON Display

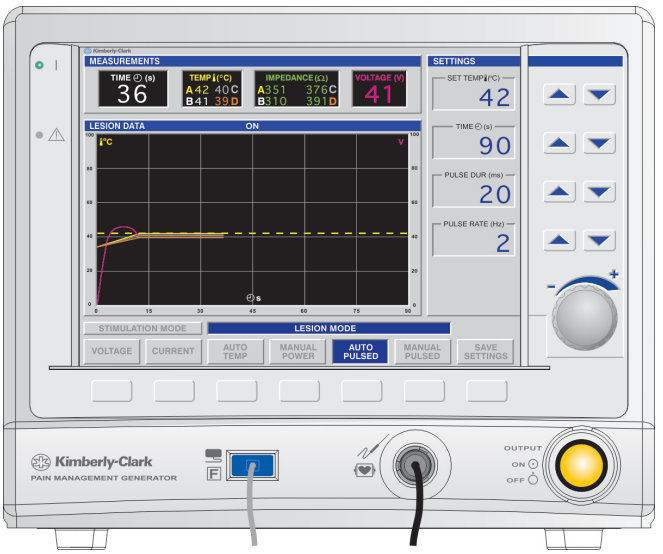


Figure 7-14 Multi-RF AUTO PULSED – ON Display

- COOLED RF AUTO TEMP AND TRANSDISCAL TREATMENT states consist of: PRE-TREATMENT COOLING, TREATMENT ON, and POST-TREATMENT COOLING, if enabled from ADVANCED SETTINGS.

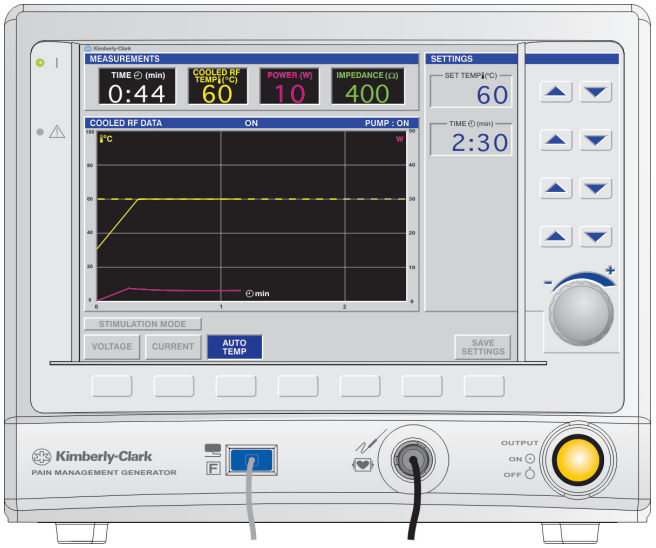


Figure 7-15 COOLED RF AUTO TEMP — ON Display

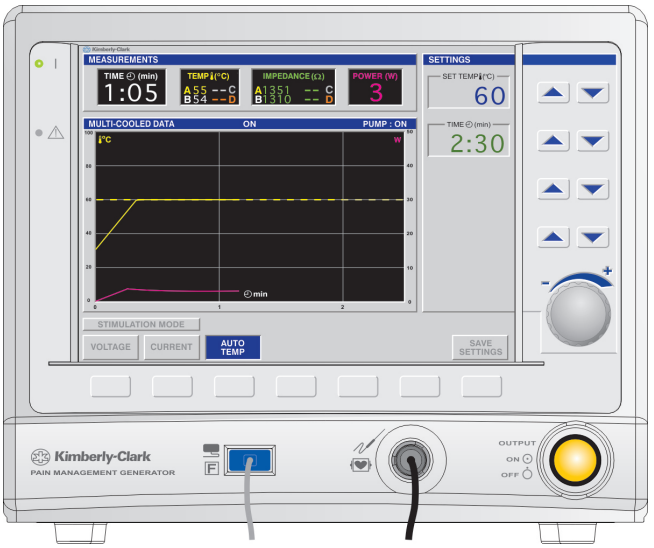


Figure 7-16 MULTI-COOLED RF — ON Display

Figure 7-17 TRANSDISCAL MONOPOLAR TREATMENT — ON Display

Figure 7-18 TRANSDISCAL BIPOLAR TREATMENT — ON Display

Figure 7-19 RFA MODE TREATMENT — ON Display

Figure 7-20 IDL MODE – ON Display (Secondary Thermocouple Disabled)

Displays and Indicators		
PARAMETER	**STATUS**	**DESCRIPTION**
RF/Stimulus Output	Stimulus Output ON	Stimulus pulses are delivered during the ON state.
	RF Output ON	RF power is delivered during the ON state. SET TEMP/TEMP LIMIT/WARNING LIMIT and treatment TIME remain modifiable during RF power delivery. COOLED RF AND TRANSDISCAL — RF power is delivered during the TREATMENT ON state. If the procedure is stopped while in TREATMENT ON state, the Generator enters POST-TREATMENT COOLING state if enabled in ADVANCED SETTINGS mode.
FAULT Indicator	OFF	The FAULT indicator is used only in the POST and SYSTEM FAULT states.
RF/Stimulus Output ON/OFF Indicator	ON	The indicator is illuminated during Stimulus pulse/RF power delivery.
RF Audio Output	ON	RF audio output is generated for RF power delivery. A tone is generated for two seconds at the conclusion of the procedure.
	None	RF audio output is not generated during Stimulus pulse delivery. A tone is generated for two seconds at the conclusion of the procedure.
Impedance Related Audio Output	OFF	Impedance related audio output is not generated during the ON state.
Graph Window	ON	Data is displayed. The time axis (◴) is indefinitely scalable during the ON state, accommodating changes to treatment TIME. The dashed line denoting SET TEMP/TEMP LIMIT/WARNING TEMP will move according to changes made to the SET TEMP/TEMP LIMIT/WARNING TEMP value. COOLED RF – graphed temperatures should be the maximum Cooled RF probe temperature. Pump Status is displayed at the top of the Graph Window. TRANSDISCAL – graphed temperatures should be the maximum TRANSDISCAL temperature and the maximum peripheral disc temperature, unless modified in TRANSDISCAL SETTINGS state, accessible from the ADVANCED SETTINGS mode. Pump Status is displayed at the top of the Graph Window.
	STIMULATION ON display	The waveform "flashes" to indicate the system is generating stimulus pulses.
Status Window	None	N/A

STATE	PARAMETER						
	Measurement Window		Available Modes		Available Settings		
	Status	Description	Status	Description	Status	Description	
VOLTAGE STIMULATION **CURRENT STIMULATION**	ON	Impedance measurements are displayed.	None	Other modes are not selectable while in the ON state, as indicated by the greyed-out mode key labels.	SELECT PROBE**	Range	A, B, C or D
						Increment	N/A
					STIM RATE**	Range	1-Shot –200 Hz
						Available Values†	1-Shot, 2, 5, 10, 20, 50, 75, 100, 150, 180 and 200 Hz
					PULSE DUR	Range	0.1 – 1.0 ms
						Available Values†	0.1, 0.2, 0.5 and 1.0 ms
					VOLTAGE/ CURRENT	Range	0.00–10.0 V/mA
						Increment	0.01 V/mA
AUTO TEMP LESION		All measurements are displayed.			SET TEMP	Range	38° – 95°C
						Increment	1°C
					TIME	Range	15 – 600 s
						Increment	1 s
MANUAL POWER LESION					TEMP LIMIT	Range	38° – 95°C
						Increment	1°C
					TIME	Range	15 – 600 s
						Increment	1 s
					POWER LIMIT	Range	N/A
						Increment	N/A
AUTO PULSED LESION					SET TEMP	Range	38° – 95°C
						Increment	1°C
					TIME	Range	10 – 900 s
						Increment	1 s
					PULSE DUR	Range	10 – 100 ms
						Increment	10 ms
					PULSE RATE	Range	1 – 10 Hz
						Increment	1 Hz
MANUAL PULSED LESION					VOLTAGE	Range	0 – 55 V
						Increment	5 V (between 0 and 30 V); 1 V (greater than 30 V)
					WARNING TEMP	Range	38° – 95°C
						Increment	1°C
					TIME	Range	10 – 900 s
						Increment	1 s
					PULSE DUR	Range	20 – 100 s
						Increment	10 ms
					PULSE RATE	Range	1 – 10 Hz
						Increment	1 Hz

*** STIM RATE may not be changed until Voltage/Current set to 0 V/mA or until Output OFF; SELECT PROBE may not be changed until Output OFF.*

† Available values may be limited to two frequencies if option selected in STIMULATION SETTINGS state, accessible from the ADVANCED SETTINGS mode.

STATE	PARAMETER						
	Measurement Window		Available Modes		Available Settings		
	Status	Description	Status	Description	Status	Description	
COOLED RF TREATMENT	ON	All measurements are displayed.	None	Other modes are not selectable while in the ON state, as indicated by the greyed-out mode key labels.	SET TEMP	Range	30° – 90°C
						Increment	1°C
					TIME	Range	15 s – 30 min
						Increment	15 s (between 15 s and 5 min) 30 s (between 5 min and 30 min)
TRANSDISCAL TREATMENT					SET TEMP	Range	30° – 90°C
						Increment	1°C
					TIME	Range†	1 – 30 min
						Increment	30 s
RFA MODE - TREATMENT		All measurements are displayed. If the Thermocouple Probe is disabled via RFA SETTINGS state, accessible from the ADVANCED SETTINGS mode, the measurement is greyed out and the value replaced with dashed lines.			SET TEMP	Range	38° – 95°C
						Increment	1°C
					TIME	Range	1 – 30 min
						Increment	30 s
IDL MODE		All measurements are displayed. **During ON state, SET TEMP should not be decreased below INITIAL TEMP in ADVANCED SETTINGS.** **During ON state, SET TIME should not be decreased below INITIAL TIME in ADVANCED SETTINGS.**			SET TEMP	Range	40° – 95°C
						Increment	1°C
					TIME	Range	30 s – 20 min
						Increment	30 s

† *Available values may be limited to two frequencies if option selected in STIMULATION SETTINGS state, accessible from the ADVANCED SETTINGS mode.*

7.5 DONE States

Displays and Indicators		
PARAMETER	**STATUS**	**DESCRIPTION**
Available Modes	HOLD DISPLAY	Other modes are not selectable while in the DONE or ON state, as indicated by the greyed-out mode key labels. In the DONE state, SAVE SETTINGS is replaced with HOLD DISPLAY, which has the function of holding the display. If selected, the HOLD DISPLAY button will read RELEASE DISPLAY and the button will flash. If the flashing RELEASE DISPLAY button is selected, the system shall return to the READY state. If the HOLD DISPLAY button is not selected, the system defaults to the ready state in 5 seconds. Settings are not adjustable while in the DONE state, the HOLD DISPLAY state, or the RELEASE DISPLAY state.

7.6 SAVE SETTINGS State

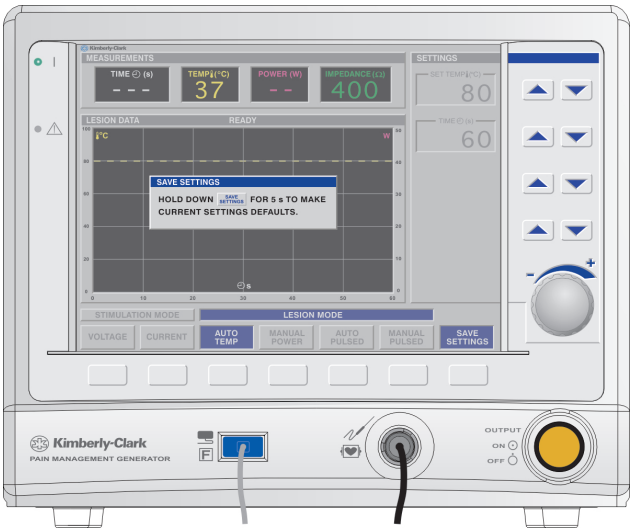


Figure 7-21 Save Settings Display

7.6.1 Example Display

- When the Save Settings button is pressed and held for 5 seconds the setting values in the current mode will become the new default values for those settings.

7.7 ADVANCED SETTINGS Mode

- The ADVANCED SETTINGS mode is accessible only from the STANDBY state.
- This state is entered by simultaneously pressing the upper-right Setting Adjustment Key [▼] and the lower-left Mode Select Key.

Displays and Indicators		
PARAMETER	**STATUS**	**DESCRIPTION**
RF/Stimulus Output	OFF	RF power is not delivered during the ADVANCED SETTINGS mode.
FAULT Indicator		(The FAULT indicator is used only in the POST and SYSTEM FAULT states.)
RF/Stimulus Output ON/OFF Indicator		The indicator is not illuminated during the ADVANCED SETTINGS mode.
Audio Output		Tone sounds briefly when saving settings.

Saving and Exiting	
SAVE SETTINGS**	Settings are stored, and the system transitions to the STANDBY mode.
CANCEL	The system transitions to the STANDBY mode without updating the settings.

*** Defaults are factory-set, and are overwritten when the SAVE SETTINGS function is used.*

7.7.1 ADVANCED SETTINGS Mode – STIMULATION SETTINGS State

When the ADVANCED SETTINGS mode is accessed, the Generator displays the default STIMULATION SETTINGS screen. Settings on this screen apply to both VOLTAGE and CURRENT STIMULATION.

- This mode allows the user to limit the quantity of selectable values in Stimulation Modes to two frequently used values.
- The stimulation rates may be adjusted to toggle between two values that are frequently used during treatment. The user may define these values here: MOTOR and SENSORY. If the LOCK AVAILABLE VALUES parameter is set to YES, it allows the user to toggle between the MOTOR and SENSORY stimulation rates. If it is set to NO, the user can view all values available for stimulation rates.
- The value stored in MOTOR is the default value upon entering Voltage or Current Stimulation Mode.
- If LOCK AVAILABLE VALUES is set to NO, and the user selects SAVE SETTINGS from either the Voltage or Current Stimulation Mode, MOTOR and SENSORY will be overwritten with the saved values.
- Since the VOLTAGE STIMULATION and CURRENT STIMULATION modes are available from the COOLED RF AUTO TEMP READY and TRANSDISCAL TREATMENT READY modes, any changes made to the VOLTAGE STIMULATION and CURRENT STIMULATION modes through ADVANCED SETTINGS also affects the VOLTAGE STIMULATION and CURRENT STIMULATION modes when accessed through COOLED RF and TRANSDISCAL modes.

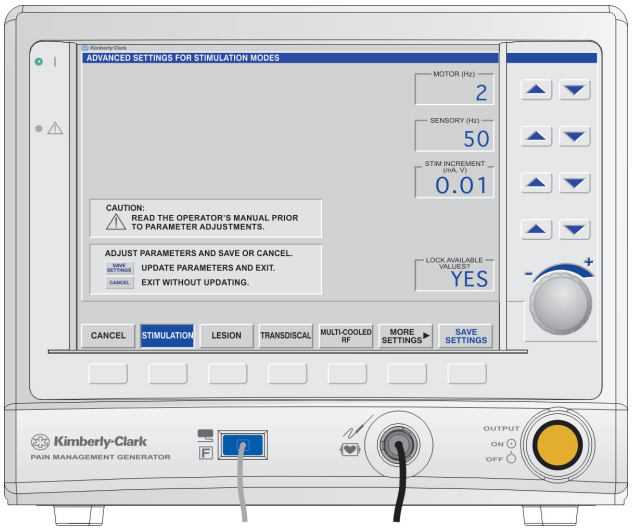


Figure 7-22 ADVANCED SETTINGS Mode – STIMULATION SETTINGS Display

Settings				
Affected Mode	**Parameter**	**DESCRIPTION**	**Available Values**	**Default Value****
STIMULATION Modes†	LOCK AVAILABLE VALUES?	Disable or enable selection of the MOTOR and SENSORY parameters. If "NO" is selected, the MOTOR and SENSORY parameters are greyed out and not selectable.	Yes/No	Yes
	MOTOR (Hz)	Rate at which Motor stimulus pulses are delivered.	1-Shot, 2, 5, 10, 20, 50, 75, 100, 150, 180 and 200 Hz	2 Hz
	SENSORY (Hz)	Rate at which Sensory stimulus pulses are delivered.	1-Shot, 2, 5, 10, 20, 50, 75, 100, 150, 180 and 200 Hz	50 Hz
	STIM INCREMENT	Minimum stimulus increment.	0.01, 0.02, 0.05, 0.10, 0.20 Volts or mAmps	

*** Defaults are factory-set, and are overwritten when the SAVE SETTINGS function is used.*

† STIMULATION Modes refers to both VOLTAGE AND CURRENT STIMULATION Modes.

7.7.2 ADVANCED SETTINGS Mode – LESION SETTINGS State

The following screen appears when LESION SETTINGS is selected from the ADVANCED SETTINGS Mode.

- This screen allows adjustment of the initial RAMP TIME taken by the AUTO TEMP LESION and AUTO PULSED LESION modes to attain the SET TEMPERATURE.
- This screen allows adjustment of POWER LIMIT in AUTO TEMP LESION and AUTO PULSED LESION modes.
- Changing RAMP TIME affects the portion of the total TIME spent at the SET TEMPERATURE.
- Lowering the RAMP TIME causes the Generator to attempt to reach the SET TEMPERATURE faster.
- MAX RAMP TIME EXTENSION is the maximum allowable duration for extension of the ramp time in Multi-RF and Multi-Cooled RF Auto Temp Lesion mode, to maintain a consistent Lesion Time. If all probes have not reached Set Temperature within the sum of this time and the specified Ramp Time, an error notification will be generated. This feature can be turned off by changing the setting to DISABLE.

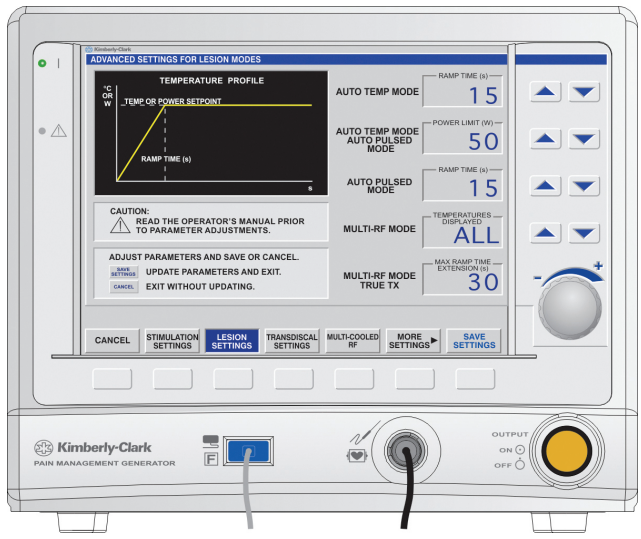


Figure 7-23 ADVANCED SETTINGS Mode — LESION SETTINGS Display

Settings					
Affected Mode	**Parameter**	**DESCRIPTION**	**Range/Units**	**Default Value**	**Increment**
Auto Temp LESION	RAMP TIME	Ramp-up interval to temperature set point.	10–60 s	15 s	1 s
AUTO TEMP LESION, AUTO PULSED LESION	POWER LIMIT	Maximum allowable power for temperature control.	1–50 W	50 W	1 W
AUTO PULSED LESION	RAMP TIME	Ramp-up interval to temperature set point.	5–60 s	15 s	1 s
MULTI-RF	TEMPERATURES DISPLAYED	Temperature displayed on screen in Multi-RF mode Measurement Window and Graph Display.	ALL/MAX	ALL	N/A
MULTI-RF (TRUE-TX)	MAX RAMP TIME EXTENSION	Maximum allowable duration for extension of ramp time. If all probes have not reached Set Temperature within this time, an error notification will be generated.	DISABLE, 5-120 s	30 s	5 s

7.7.3 ADVANCED SETTINGS Mode – TRANSDISCAL SETTINGS State

The following screen appears when TRANSDISCAL SETTINGS is selected from the ADVANCED SETTINGS Mode.

- This screen allows adjustment of the warning temperature threshold for the Peripheral Disc Temperature (PDT) by adjusting PERIPHERAL DISC WARNING TEMP.
- The Peripheral Disc Warning Temperature can be used as an aid during treatment. If either PDT A or PDT B exceeds the Peripheral Disc Warning Temperature, the rate of the Output ON tone increases (the tone is played more often).
- This screen allows adjustment of the RAMP RATE used by the TRANSDISCAL mode to attain the SET TEMPERATURE.
- Settings for two probes are selected with BIPOLAR mode.
- Settings for one probe are selected with MONOPOLAR mode.
- The maximum amount of power available can be adjusted by rotating the dial to change SET POWER LIMIT.

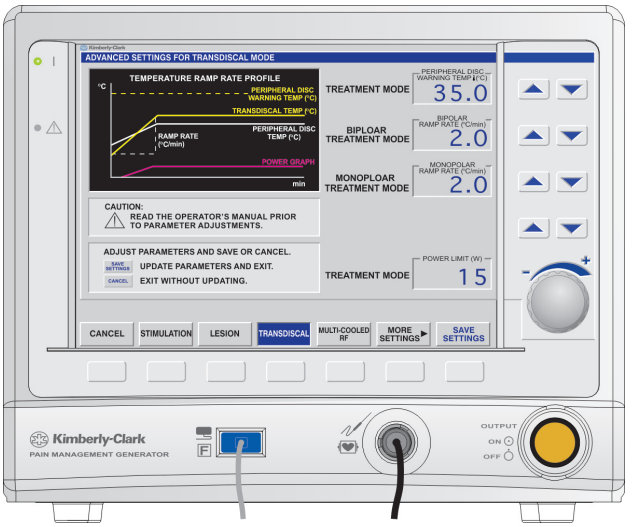


Figure 7-24 ADVANCED SETTINGS Mode – TRANSDISCAL SETTINGS Display

Settings					
Affected Mode	**Parameter**	**DESCRIPTION**	**Range/Units**	**Default Value**	**Increment**
Treatment Mode	PERIPHERAL DISC WARNING TEMP	Set point for the Peripheral Disc Temperature Warning.	30° – 60°C	45°C	0.5°C
	BIPOLAR RAMP RATE	Rate at which temperature increases from the INITIAL TEMP to the SET TEMP when two probes are used.	0.5° – 5°C/min	2°C/min	0.1°C/min
			5° – 10°C/min		5°C/min
			10° – 200°C/min		10°C/min
	MONOPOLAR RAMP RATE	Rate at which temperature increases from the INITIAL TEMP to the SET TEMP when two probes are used.	0.5° – 5°C/min	80°C/min	0.1°C/min
			5° – 10°C/min		5°C/min
			10° – 200°C/min		10°C/min
	POST TREATMENT COOLING	Select to enable or disable the option to go into POST TREATMENT COOLING after treatment.	ENABLE /DISABLE	ENABLE	N/A
Treatment Mode	POWER LIMIT	Maximum power available for temperature control.	1 – 50 W	25 W	1 W

7.7.4 ADVANCED SETTINGS Mode – MULTI-COOLED RF SETTINGS State

The following screen appears when MULTI-COOLED RF SETTINGS is selected from the ADVANCED SETTINGS Mode:

- This screen allows adjustment of POWER LIMIT in AUTO TEMP and AUTO PULSED modes.
- This screen allows adjustment of the initial RAMP RATE taken by the AUTO PULSED and AUTO TEMP modes to attain the SET TEMPERATURE.
- Changing RAMP RATE affects the portion of the total TIME spent at the SET TEMPERATURE.
- Raising the RAMP RATE causes the Generator to attempt to reach the SET TEMPERATURE faster.
- MAX RAMP TIME EXTENSION is the maximum allowable duration for extension of the ramp time in Multi-RF and Multi-Cooled RF Auto Temp Lesion mode, to maintain a consistent Lesion Time. If all probes have not reached Set Temperature within the sum of this time and the specified Ramp Time, an error notification will be generated. This feature can be turned off by changing the setting to DISABLE.

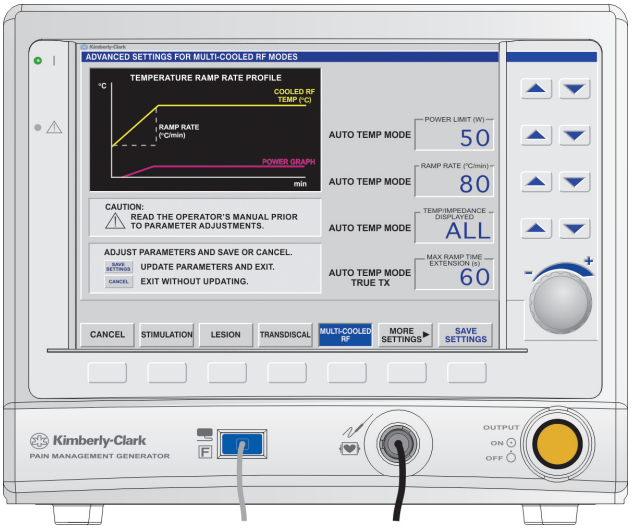


Figure 7-25 ADVANCED SETTINGS Mode — MULTI-COOLED RF SETTINGS Display

Settings					
Affected Mode	**Parameter**	**DESCRIPTION**	**Range/Units**	**Default Value**	**Increment**
AUTO TEMP LESION, AUTO PULSED LESION	POWER LIMIT	Maximum allowable power for temperature control.	1 – 50 W	50 W	1 W
AUTO PULSED LESION	RAMP RATE	Ramp-up interval to temperature set point.	0.5° – 5°C/min	80°C/min	0.1°C/min
			5° – 10°C/min		5°C/min
			10°–200°C/min		10°C/min
MULTI-COOLED RF	TEMPERATURE IMPEDANCE DISPLAYED	Temperature and Impedance displayed on screen in Multi-Cooled RF mode Measurement Window and Graph Display.	ALL/MAX	MAX	N/A
MULTI-COOLED RF (TRUE-TX)	MAX RAMP TIME EXTENSION	Maximum allowable duration for extension of ramp time. If all probes have not reached Set Temperature within this time, an error notification will be generated.	DISABLE, 5 – 120 s	30 s	5 s

7.7.5 ADVANCED SETTINGS Mode – COOLED RF SETTINGS State

The following screen appears when COOLED RF SETTINGS is selected from the ADVANCED SETTINGS Mode:

- This screen allows adjustment of the RAMP RATE used by the COOLED RF mode to attain the SET TEMPERATURE.
- The option to use POST TREATMENT COOLING after the active treatment has ended can be accessed by toggling the ENABLE/DISABLE Post Treatment Cooling control.
- The option to use one or two probes is accessible by adjusting NUMBER OF PROBES.
- The maximum amount of power available can be adjusted by rotating the dial to change SET POWER LIMIT.

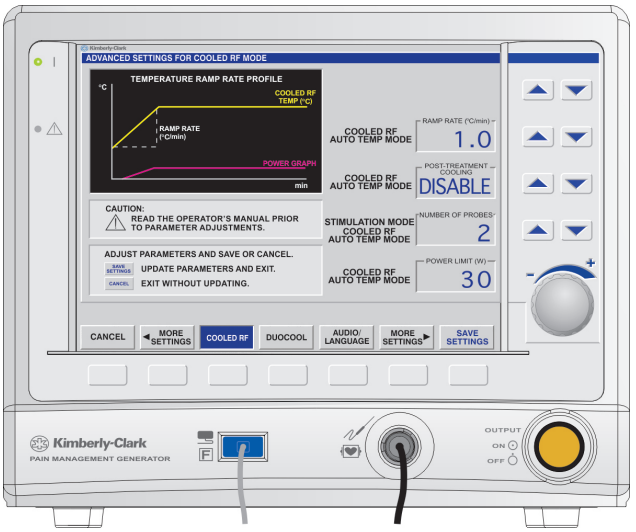


Figure 7-26 ADVANCED SETTINGS Mode – COOLED RF SETTINGS Display

Settings					
Affected Mode	**Parameter**	**DESCRIPTION**	**Range/Units**	**Default Value**	**Increment**
Cooled RF Auto Temp Mode	RAMP RATE	Rate at which temperature increases from the INITIAL TEMP to the SET TEMP.	0.5° – 5°C/min	80°C/Min	0.1°C/Min
			5° – 10°C/min		5°C/Min
			10° – 200°C/min		10°C/Min
	POST TREATMENT COOLING	Select to enable or disable the option to go into POST TREATMENT COOLING after treatment.	ENABLE/DISABLE	DISABLE	N/A
Stimulation Mode **Cooled RF Auto Temp Mode**	NUMBER OF PROBES	Number of Cooled RF Probes used.	1, 2	1	
Cooled RF Auto Temp Mode	POWER LIMIT	Maximum power available for temperature control.	1–50 W	25 W	1 W

7.7.6 ADVANCED SETTINGS Mode – AUDIO/LANGUAGE SETTINGS State

The following screen appears when AUDIO/LANGUAGE SETTINGS is selected from the ADVANCED SETTINGS Mode:

- The AUDIO/LANGUAGE SETTINGS state in the ADVANCED SETTINGS mode allows the user to enable/disable the impedance-related audio output during STIMULATION modes as well as during PLACEMENT and READY states (with exception to IDL mode).
- The AUDIO/LANGUAGE SETTINGS state also allows the user to select the language used for all screens, warning messages and error messages.
- Enabling Impedance Audio in All Stimulation Modes enables the tone in the Voltage and Current Stimulation – READY state.
- Enabling Impedance Audio in All Placement Modes enables the tone in the RFA and TransDiscal Placement Modes.
- Enabling Impedance Audio in All Ready States enables the tone in the Auto Temp, Manual Power, Auto Pulsed, Manual Pulsed, Cooled RF Auto Temp, TransDiscal Treatment Mode, and RFA Treatment Mode Ready States.
- For language changes to take effect, main AC power must be cycled OFF-ON.

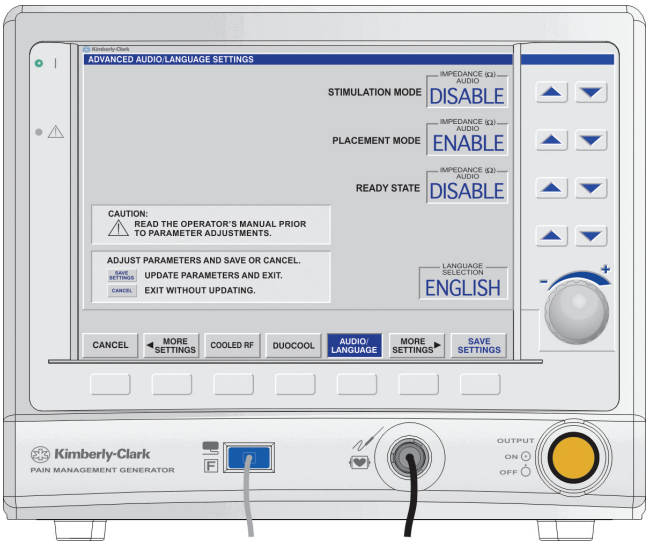


Figure 7-27 ADVANCED SETTINGS Mode — AUDIO/LANGUAGE SETTINGS Display

Settings					
Affected Mode	**Parameter**	**DESCRIPTION**	**Range/Units**	**Default Value**	**Increment**
STIMULATION Modes	IMPEDANCE AUDIO	Enable/Disable audio output in Stimulation modes.	ENABLE/DISABLE	DISABLE	N/A
Placement Mode				ENABLE	
All Modes except IDL		Enable/Disable audio output in all Ready States EXCEPT IDL READY STATE.		DISABLE	
LANGUAGE	Selects a language to display screens, error messages, and warning messages.	ENGLISH, ESPAÑOL, FRANÇAIS, ITALIANO, DEUTSCH.	ENGLISH	N/A	LANGUAGE

7.7.7 ADVANCED SETTINGS Mode – RFA SETTINGS State

The following screen appears when RFA SETTINGS is selected from the ADVANCED SETTINGS Mode:

- This screen allows the option of disabling the SECONDARY THERMOCOUPLE probe used in the RFA mode
  - If the SECONDARY THERMOCOUPLE is disabled, the corresponding temperature measurement window in RFA – TREATMENT Mode will be inactive.
- This screen allows adjustment of the initial RAMP TIME taken by the RFA mode to attain the SET TEMP.

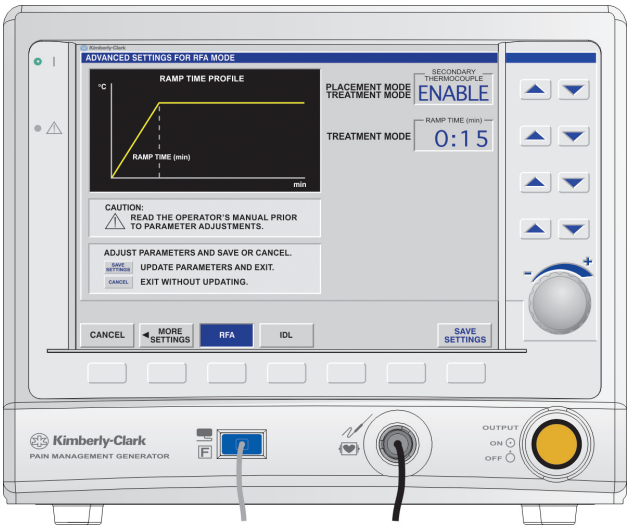


Figure 7-28 ADVANCED SETTINGS Mode — RFA SETTINGS Display

Settings					
Affected Mode	**Parameter**	**DESCRIPTION**	**Range/Units**	**Default Value**	**Increment**
Treatment Mode **Placement Mode**	SECONDARY THERMOCOUPLE	Enable/disable optional thermocouple	ENABLE/ DISABLE	ENABLE	N/A
Treatment Mode	RAMP TIME	Time in which temperature increases from the INITIAL TEMP to the PEAK TEMP	15 – 60 s; 1 – 10 min	15 s	1 s (for 15 – 60 s); 30 s (for 1 – 10 min)

7.7.8 ADVANCED SETTINGS Mode – IDL SETTINGS State

The following screen appears when IDL SETTINGS is selected from the ADVANCED SETTINGS mode:

- This screen allows the user to enable/disable the use of a secondary thermocouple probe as an aid by toggling ENABLE/DISABLE on the SECONDARY THERMOCOUPLE setting.
  - If the SECONDARY THERMOCOUPLE is disabled, the corresponding temperature measurement window in IDL Mode will be inactive.
- This screen allows adjustment of temperature profile parameters for the IDL mode, which are not available from the READY state. The INITIAL TIME, INITIAL TEMP, RAMP RATE, and POWER LIMIT are adjustable in this state.
- Changes to the INITIAL TIME and RAMP RATE affect the portion of the total TIME spent at the SET TEMP.
- Lowering the INITIAL TIME causes the Generator to attempt to reach the INITIAL TEMP more rapidly.

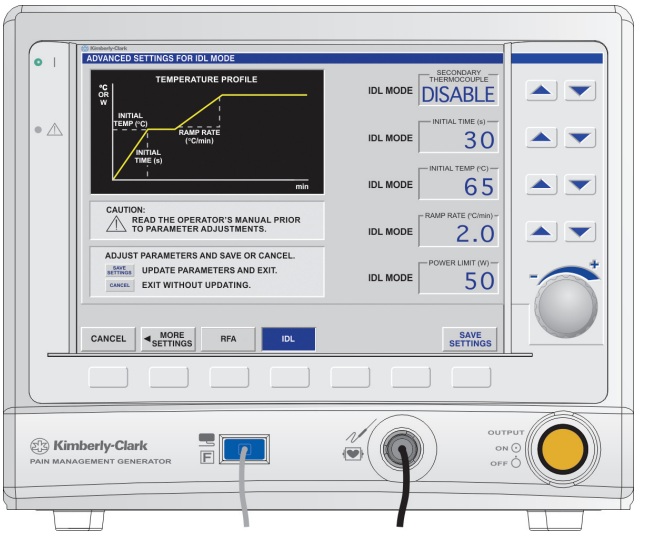


Figure 7-29 ADVANCED SETTINGS Mode — IDL SETTINGS Display

Settings					
Affected Mode	**Parameter**	**DESCRIPTION**	**Range/Units**	**Default Value**	**Increment**
IDL Mode	SECONDARY THERMOCOUPLE	Disable optional Thermocouple Probe	ENABLE/ DISABLE	DISABLE	N/A
	INITIAL TIME	Ramp-up interval to INITIAL TEMP set point	15 – 120 s	30 s	1 s
	INITIAL TEMP	Initial target for temperature ramping.	40° – 80°C	65°C	1°C
	RAMP RATE	Rate at which temperature increases from the INITIAL TEMP to the SET TEMP	0.5° – 5°C/min	2°C/min	0.1°C/min
	POWER LIMIT	Maximum power available for temperature control	1 – 50 W	50 W	1 W

7.8 Special Event States

7.8.1 Recoverable Errors

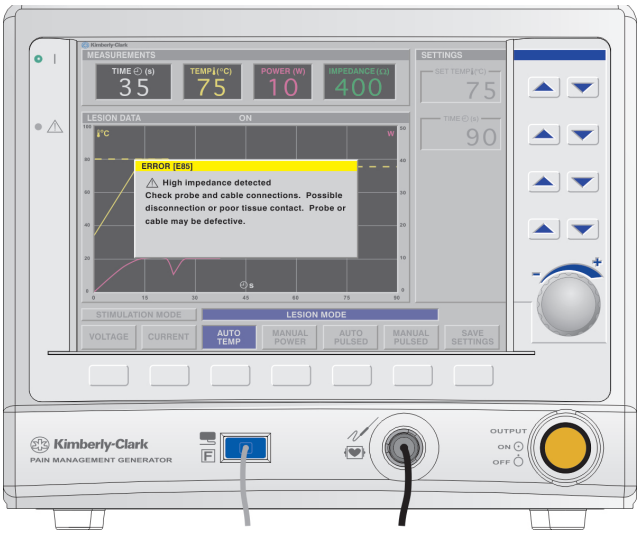


Figure 7-30 Recoverable Error Pop-Up Display

7.8.1.1 Display

- Yellow "error" indicator will display on screen.
- Error text will display in the center of the screen within the Status window.

7.8.1.2 Settings

- A 10-second time-out returns device to previous READY mode. If the probe and cable have been detached the Generator returns to the STANDBY state.
- Recoverable Error: measurement values are shown, and settings are greyed out.

7.8.2 Non-Recoverable Faults

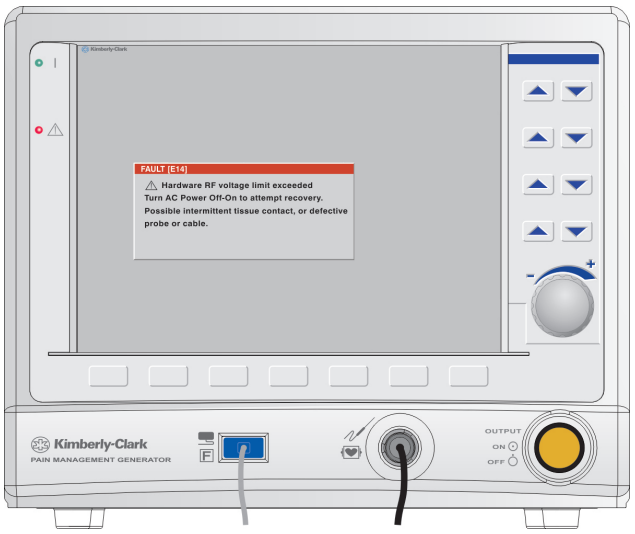


Figure 7-31 Non-Recoverable Fault Pop-Up Display

7.8.2.1 Display

- Red "error" indicator will display on screen.
- System Fault code will display in the center of the screen within the Status window.

7.8.2.2 Settings

- The main power On/Off switch needs to be cycled OFF then ON to attempt to clear the non-recoverable fault.

8 Technical specifications

8.1 Impedance Measurement

- Range 1 to 3000 Ohms (Ω), 1 Ω resolution
- Before and during lesion in LESION mode
- Before STIMULATION mode
- During TRANSDISCAL Placement mode
- During Cooled RF Auto Temp mode
- During TRANSDISCAL Treatment mode
- During RFA Placement mode
- During RFA Treatment mode
- During IDL mode

8.2 Stimulation

- Stimulation Amplitude Ranges: Voltage mode: 0.00-10 V, 0.01 V increment
  Current mode: 0.00-10 mA, 0.01 mA increment
- Stimulation rate: 1-Shot, 2, 5, 10, 20, 50, 75, 100, 150, 180 and 200 Hz
- Stimulation pulse duration: 0.1, 0.2, 0.5 and 1.0 ms

8.3 RF Output

- RF energy : 460.8 kHz ± 1 %, Quasi-sinusoidal
- Maximum power: 50 W (available into an impedance range of 60 Ω - 520 Ω, resistive.) Outside this range, the Generator reduces available power to comply with specified voltage and current limits.
- Applied part of patient circuit is not referenced to earth at high frequency.
- The maximum output of 50 W is restricted by:
  - Maximum voltage: 160 V_{rms}
  - Maximum current: 0.9 A_{rms}
  - Maximum peak voltage: 254 V (under normal operating conditions)
- Power output is available into loads of 25 Ω - 3000 Ω
- 100 Ω is the nominal "rated" load.

8.4 Measurement Accuracy (at time of manufacture)

- Power ±5 %, ± 0.25 W
- Impedance
  - 25 – 1000 Ω: ± 10 %, ±10 Ω
  - 1001 – 3000 Ω: ± 20 %±10 Ω
  - Multi-RF Mode: Accuracy subject to condition that impedances of all other probes are within 100 – 1000 Ω; accuracy defined at ambient temperature of 25°C.
- Temperature: ± 3°C for thermocouple probes
- Elapsed Time: ± 1 s/min

8.5 Software Shutdown Limits During RF Delivery or Stimulation

- Measured Impedance: < 25 Ω or > 3,000 Ω
- Measured Temperature: < 15°C, > 100°C, or
  > SET TEMPERATURE +5°C for 5 s, or
  > SET TEMPERATURE +10°C for 1 s
- Measured RF Power: > 55 W, or
  > SET POWER + 50 % + 5 W for 100 ms, or
  > SET POWER + 20 % + 5 W for 1 s
- Measured RF Voltage: > 180 V_{rms}
- Measured RF Current: > 0.9 A_{rms}

8.6 Hardware Shutdown Limits

- Measured RF Power: > 60 W
- Measured RF Voltage: > 200 V_{rms}
- Measured RF Current: > 1 A_{rms}
- Stimulation Current: > 40 mA
- Stimulation Voltage: > 11 V

8.7 Mechanical Specifications

- Size: 9.5 x 12.5 x 14.0" (24 x 32 x 35 cm) maximum
- Weight: 16.5 lb (7.5 kg) maximum (not including power cord or shipping box)
- Moisture protection rating: IPX0 (ordinary, per IEC601)

8.8 Environmental Specifications

- Operational temperature: 10°C to 35°C
- Storage & Transportation temperature: -40°C to 70°C
- Operation, Storage & Transportation Humidity: 20% to 95% non-condensing

8.9 Fuses

- 100 – 120 V~ / 60 Hz configuration: Replace mains fuses as marked: 4A/250V, T-lag, 5x20mm
- 220 – 240 V~ / 50 Hz configuration: Replace mains fuses as marked: 2A/250V, T-lag, 5x20mm
- When replacing fuses, ensure the integrity of the new fuses by inspecting for physical damage that could affect the function of the fuse.
- Use a precision slot drive screwdriver to remove the fuse drawer.
- Replace the fuses, and replace the fuse drawer.
- Ensure that the fuse drawer selection matches the value of the AC Mains Switch.
    - WARNING: A mismatch of fuse type, fuse drawer selection and AC Mains Switch can result in permanent damage to the Generator!

8.10 Line Input Ratings

- 3.5 A @ 100-120 VAC ~ 60 Hz
- 1.7 A @ 220-240 VAC ~ 50 Hz

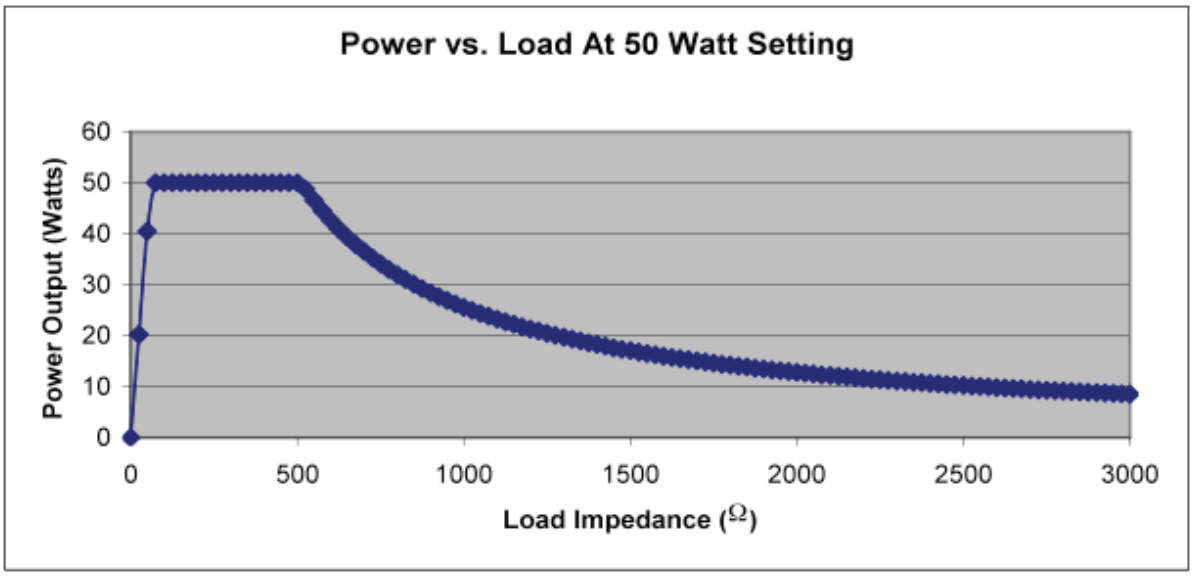
8.11 Footswitch Specifications

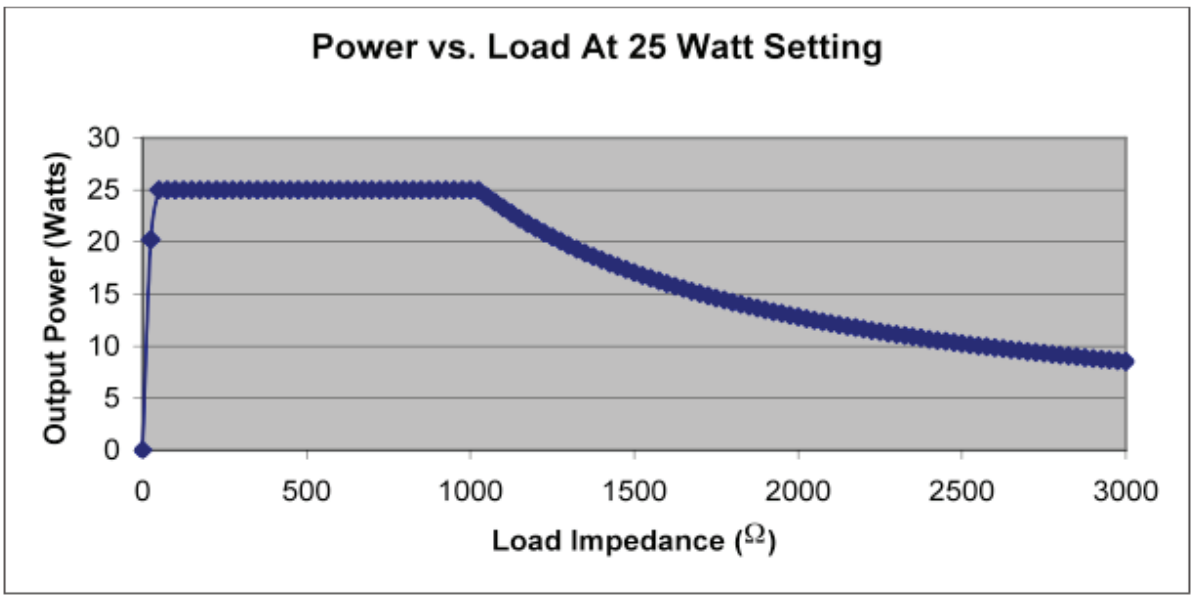
- Pneumatic

8.12 Rated Accessory Voltage (for Associated Equipment and Active Accessories)

- 160 V_{rms}

8.13 Output Power Graphs





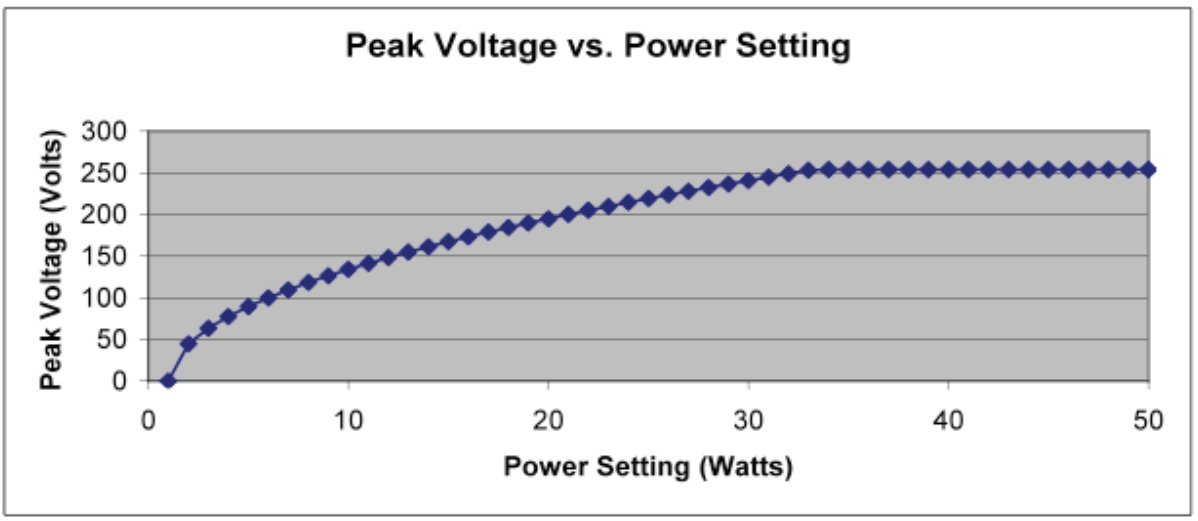


Figure 8-1 Power vs. Load and Peak Voltage

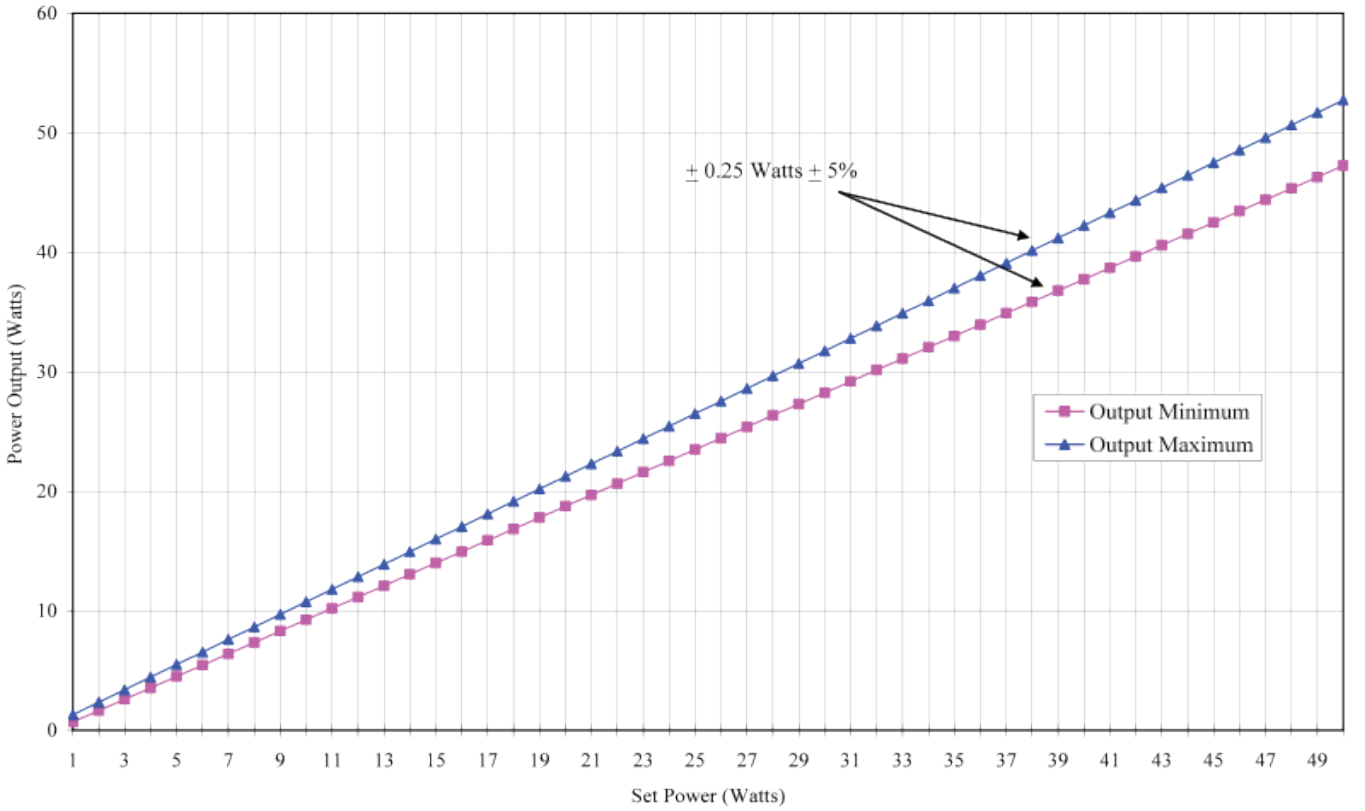


Figure 8-2 Set Power vs. Output Power

8.14 IEC Electrical Safety and EMC Specifications

Table 8-1 IEC Electrical Safety Specifications

Device Description	
Class I, Defibrillation proof Type CF Equipment, IPX0, not AP/APG	
Mode of Operation: Continuous	
Electrical Isolation	• Leakage current conforms to IEC 60601-1 • Dielectric withstanding voltage conforms to IEC 60601-1
EMC Emissions and Susceptibility: The Kimberly-Clark* Pain Management System has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2004. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This system generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instruction given below, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Portable and mobile RF communications equipment can affect medical electrical equipment.	

Table 8-2 IEC EMC Specifications (Emissions)

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Kimberly-Clark* Pain Management System is intended for use in the electromagnetic environment specified below. The customer or the user of the Kimberly-Clark* Pain Management System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 2	The Kimberly-Clark* Pain Management System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Kimberly-Clark* Pain Management System 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 B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 8-3 IEC EMC Specifications (Immunity)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Kimberly-Clark* Pain Management System is intended for use in the electromagnetic environment specified below. The customer or the user of the Kimberly-Clark* Pain Management System 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 should 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 ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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 cycles 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 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycles 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 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Kimberly-Clark* Pain Management System requires continued operation during power mains interruptions, it is recommended that the Kimberly-Clark* Pain Management System be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical commercial or hospital environment.
NOTE: *U_T is the AC mains voltage prior to application of the test level.*			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{rms} 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Kimberly-Clark* Pain Management System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = [1.17]\sqrt{P}$ $d = [1.17]\sqrt{P}$ 80 MHz to 800 MHz $d = [2.33]\sqrt{P}$ 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 meters (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: 
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 Kimberly-Clark* Pain Management System or any of its components are used exceeds the applicable RF compliance level above, the Kimberly-Clark* Pain Management System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating components or the entire Kimberly-Clark* Pain Management System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 8-4 IEC Recommended Separation of RF Communication Equipment

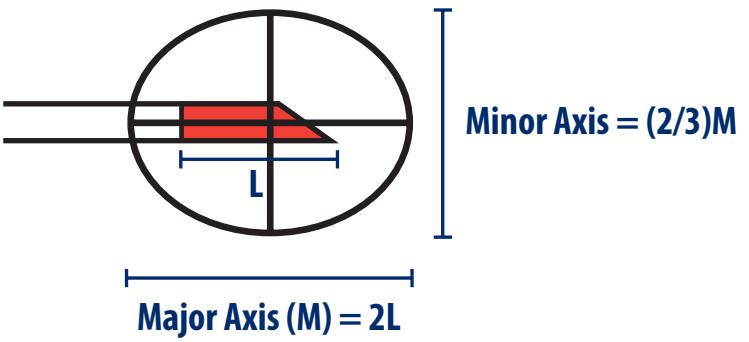
Recommended separation distances between portable and mobile RF communications equipment and the Kimberly-Clark* Pain Management System			
The Kimberly-Clark* Pain Management System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Kimberly-Clark* Pain Management System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Kimberly-Clark* Pain Management System 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 $d = [1.17]\sqrt{P}$	80 MHz to 800 MHz $d = [1.17]\sqrt{P}$	800 MHz to 2.5 GHz $d = [2.33]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined 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.*			

9 Standard RF Lesion Size

Lesion size and shape is determined by numerous factors including:

- cannula active tip length
- cannula active tip diameter
- impedance of tissue
- current intensity
- length of time that energy is applied

One published approximation method for lesion size and shape describes a lesion as a prolate spheroid in shape with the major axis = 2 x length of the active tip and the minor axis = 2/3 the major axis.[1] This approximation is valid for active tip lengths of up to 5 mm.



Eg: based on Active tip = 5 mm (0.197″)
Major axis = 10mm (0.394″)
Minor axis = 6.7mm (0.263″)

For active tip lengths in excess of 5 mm, the active tip diameter will primarily dictate the minor axis dimension of the lesion. The maximum minor axis dimension will not typically exceed 8 mm for 18 to 22 gauge cannulae.

Note: *In Multi-RF Auto Temp mode, maintain a minimum distance of 10 mm between probe tips and ensure that the probe tips do not touch. So long as this distance is maintained, all lesions formed will be non-contiguous.*

[1] ORGAN, L.W.: Electrophysiologic Principles of Radiofrequency Lesion Making. Appl. Neurophys. 39:69-76

10 Labeling Symbols

Alternating Current	
Attention: Consult accompanying documents	
Authorized Representative in the European Community	EC REP
Catalogue Number	REF
Connector Cable connection	
Consult Instructions for Use	
Dangerous Voltage	
Defibrillator-proof, Patient Isolated connections	
Isolated Patient Circuit	F
Dispersive Return Electrode connection	
Up	▲
Down	▼
Earth Ground	
Federal law (U.S.A) restricts this device to sale by or on the order of a physician	**Rx ONLY**
Footswitch	
Fuses	
Manufacturer	
Measured Temperature	
Non-Ionizing Radiation	
Output OFF	
Output ON	
Power OFF	
Power ON	
Pump Module Interface Connector	
Serial Number	**SN**
Time	
Please contact your distributor or the device manufacturer for recycling of this device	

Warranty

This warranty applies to customers in the United States only. Outside of the USA, contact your Kimberly-Clark sales representative.

Kimberly-Clark* warrants the products listed below against defects in both materials and workmanship to the registered owner at the time of purchase. All components of the Generator are covered by the warranty as described below, except the Cable and Probe Assemblies, which are covered in their own IFUs and have their own warranties.

This warranty does not apply to any unit that has been subject to misuse, neglect, improper installation or that which has been altered, adjusted, or tampered with by any person other than Kimberly-Clark authorized personnel.

If upon examination by authorized service personnel, it is determined that the malfunction is due to misuse or abuse, warranty provisions will not apply. An estimate of the cost of repair work will be given to the customer prior to servicing and repairing the unit.

The customer is responsible for returning the defective equipment to the factory at his or her own expense. The customer needs to get a return authorization number before shipping the unit back. Kimberly-Clark at its sole discretion can repair the unit or ship a new one. The units are to be shipped freight pre-paid for both the warranty period and out of warranty.

If, upon examination, it is determined that the fault had been caused by misuse or abnormal conditions of operation, the repairs will be billed to the customer as out-of-warranty repairs.

Instruments repaired under Kimberly-Clark standard repair program will be issued a thirty-day (30) warranty against defects in both materials and workmanship, provided the original warranty period has passed. Instruments submitted due to defects in materials and workmanship during the warranty period will be repaired at no charge to the customer.

The warranty set forth herein is exclusive and in lieu of all other warranties, remedies, obligations and liabilities of Kimberly-Clark, expressed or implied, including the implied warranties of merchantability and fitness for use and of consequential damages. These products are being sold only for the purpose described herein, and such warranty only runs to the purchaser. In no event shall Kimberly-Clark be liable for any breach of warranty in any amount exceeding the purchase price of the product.

No agent, employee or representative of Kimberly-Clark has the authority to bind the Company to any other warranty, affirmation, or representation concerning the instrument.

This warranty is valid only to the original purchaser of Kimberly-Clark products directly from a Kimberly-Clark* authorized agent. The warranty cannot be transferred or assigned by the original purchaser.

The warranty periods for components of the Kimberly-Clark* PMG are as follows:

Component	Warranty Period
For Domestic Use: RF Generator, PMG-115 (Basic) RF Generator, PMG-115-TD (Advanced) For International Use: RF Generator, PMG-230 (Basic) RF Generator, PMG-230-TD (Advanced)	1 year from shipment date
Footswitch, PMA-FS	90 days from shipment date

For servicing please contact Kimberly-Clark at:

1400 Holcomb Bridge Road
Roswell, GA 30076-2199

Email: InterventionalPain.KCHC@kcc.com

U.S. Customers: 800-KCHELPS (800-742-1996)

International Customers: +1-770-587-7200

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