

Version 2.1

Baylis RF Pain Management System



Stimulation
Standard RF — Auto & Manual
Pulsed RF — Auto & Manual
TD — TransDiscal™ System
RFA — RF Annuloplasty
IDL — Intradiscal Lesioning



Baylis Medical RF System for Pain Management

A Generator Designed for the Future of Pain Management

- Digital computerized system
- Software platform designed to incorporate future developments and new technologies
- Includes a variety of selectable languages
- Ability to change and save system settings
- Only relevant parameters displayed for each mode
- During each power up, self testing occurs to internally confirm parameters and calibration, ensuring they are within specification
- Flexible settings available in all Modes, allowing for modification before and during procedures

Available Generator Versions

PMG-115

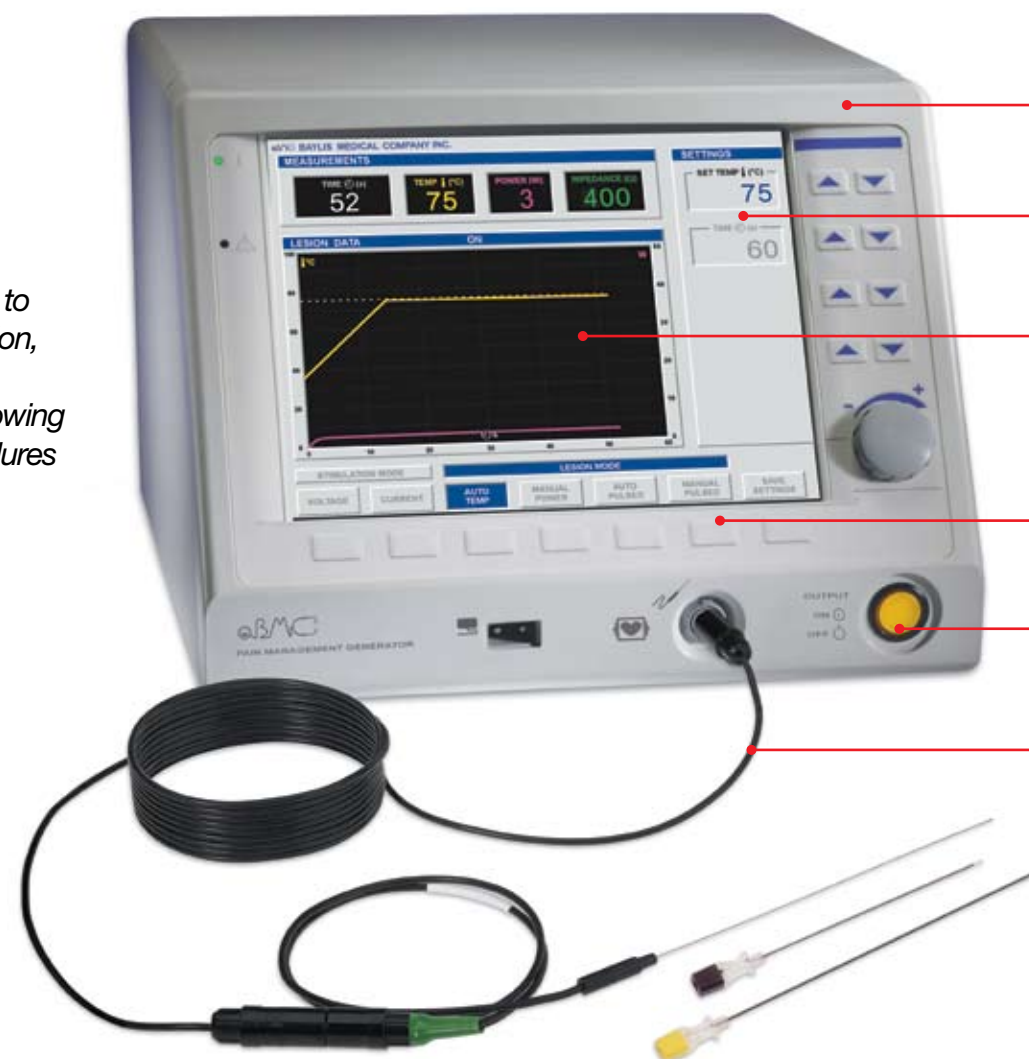
Modes included:

- Stimulation - Voltage and Current
- Standard RF - Automatic and Manual
- Pulsed RF - Automatic and Manual

PMG-115-TD

Modes included:

- Stimulation - Voltage and Current
- Standard RF - Automatic and Manual
- Pulsed RF - Automatic and Manual
- TD - TransDiscal™ System
- IDL - Intradiscal Lesioning
- RFA - RF Annuloplasty



Lightweight and portable

Context sensitive settings
Only relevant settings are displayed and active for each mode

Large, clear LCD screen
Real-time digital and graphical display of critical treatment data including temperature, time, power or voltage, and impedance

Mode selection
Soft-touch keys for selection of available modes

Single on/off switch
Button illuminates when output is on

Intelligent probe recognition
Generator identifies probe and displays only relevant information for each mode

Application Modalities



Stimulation

- Verify cannula placement using sensory and motor stimulation frequencies
- Adjustable stimulation rate and pulse duration
- Able to toggle between two frequently used stimulation frequencies
- Impedance measurement and audio tone are available to assist with probe placement
- Visual confirmation of stimulation output

Standard RF

- **Automatic Temperature Control:**
 - Programmable ramp time
 - One button touch to start the lesion energy application
 - Real-time graphical display of Temperature and Time throughout all procedures
- **Manual Power Control:**
 - Power is manually controlled to attain desired temperature

Pulsed RF

- **Automatic Temperature Control:**
 - Automatically deliver RF by adjusting voltage while maintaining the preset temperature
 - Voltage measurement is digitally and graphically displayed
 - A variety of pulse duration and pulse rate settings are available
- **Manual Power Control:**
 - Voltage is manually controlled to reach desired temperature or voltage

User Friendly Message

- The generator automatically recognizes potential problems
- Able to identify errors and display appropriate troubleshooting text message. This incorporated feature makes the system safe and easy to use
- Messages can be viewed in a variety of selectable languages

TransDiscal™ (TD)

- Uses two independently controlled, internally cooled probes to produce optimal bipolar RF lesions within the disc
- Impedance measurement and audio tone are available to assist with probe placement
- Easy to place introducers allow for a minimally invasive procedure

Intradiscal Lesioning (IDL)

- Programmable heating profile
- Compatible with electrothermal and disc decompression devices
- Additional temperature probe can be used to monitor the annulus temperature around the catheter and at the periphery of the disc

RF Annuloplasty (RFA)

- Flexible settings to allow choice of temperature profile
- Two temperature readings are displayed monitoring RFA probe tip temperature and annular temperature
- Impedance measurement and audio tone are available to assist with probe placement
- Compatible with RF Annuloplasty device



Accessories



RF Cannulae

- Available in a variety of lengths, gauges, and tip configurations
- Sure-grip hub
- Blue tactile indicator to identify direction of curve or bevel
- Color-coded for easy gauge identification
- Disposable

RadiOpaque™ Cannulae

- The marker on the RadiOpaque™ cannula is visible under fluoroscopy and indicates the beginning of the active tip

Neurological Probe Kit

- Cordotomy*
- DREZ*
- Thalamotomy
- Pallidotomy

* These kits include 4 spinal needles

Probe

- Durable and reusable
- Steam sterilizable
- Available in a variety of lengths and gauges
- Color-coded for easy gauge identification

Integra™ Probe/Cannula Combination

- Two-in-one, probe/cannula combination with a thermocouple, allows for stimulation, temperature and impedance monitoring
- Sterilized, ready to use
- Disposable

DataStream™ Data Recording Software

- Database software that records, saves, and prints detailed patient procedural reports



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Caution : Federal Law (USA) restricts the sale of these devices to or by the order of a physician.

Patents Pending and/or issued

Generator Specifications

Impedance Measurement

Range:	1 Ω to 3000 Ω, 1 Ω resolution (depending on mode)
Feature:	Before and during Stimulation mode Before and during standard RF treatment modes During TransDiscal™ Treatment and Placement modes Before and during IDL mode During RFA Placement mode Before and during RFA Treatment mode High and low impedance safety cut off

Stimulation

Stimulation Amplitude Ranges:	Voltage Mode: 0.0-10 V, 0.1 V increments Current Mode: 0.0-10 mA, 0.1 mA increments
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

RF Output

RF Energy:	460.8 kHz ±1 %, quasi-sinusoidal
Maximum Power:	50 W Maximum

Measurement Accuracy

Power:	±0.25 W, ±5 %
Impedance:	±10 Ω, ±10 %
Temperature:	±3 °C for thermocouple and thermistor probes
Elapsed Time:	±1 s/min

Timer

Standard RF Mode:	10 s - 300 s (depending on mode)
TransDiscal™ Mode:	1 - 30 min
IDL Mode:	30 s - 20 min
RFA Mode:	1 - 30 min

Mechanical Specifications

Size:	9.5" x 12.5" x 14.0" (24 cm x 32 cm x 35 cm) maximum
Weight:	16.5 lb (7.5 kg) maximum

Environmental Specifications

Operational Temperature:	10 °C to 40 °C
Storage Temperature:	-40 °C to 70 °C
Humidity:	20 % to 95 % noncondensing

PC Compatibility

RS232 port allows for data downloading with DataStream™ Data Recording Software