Boston Scientific
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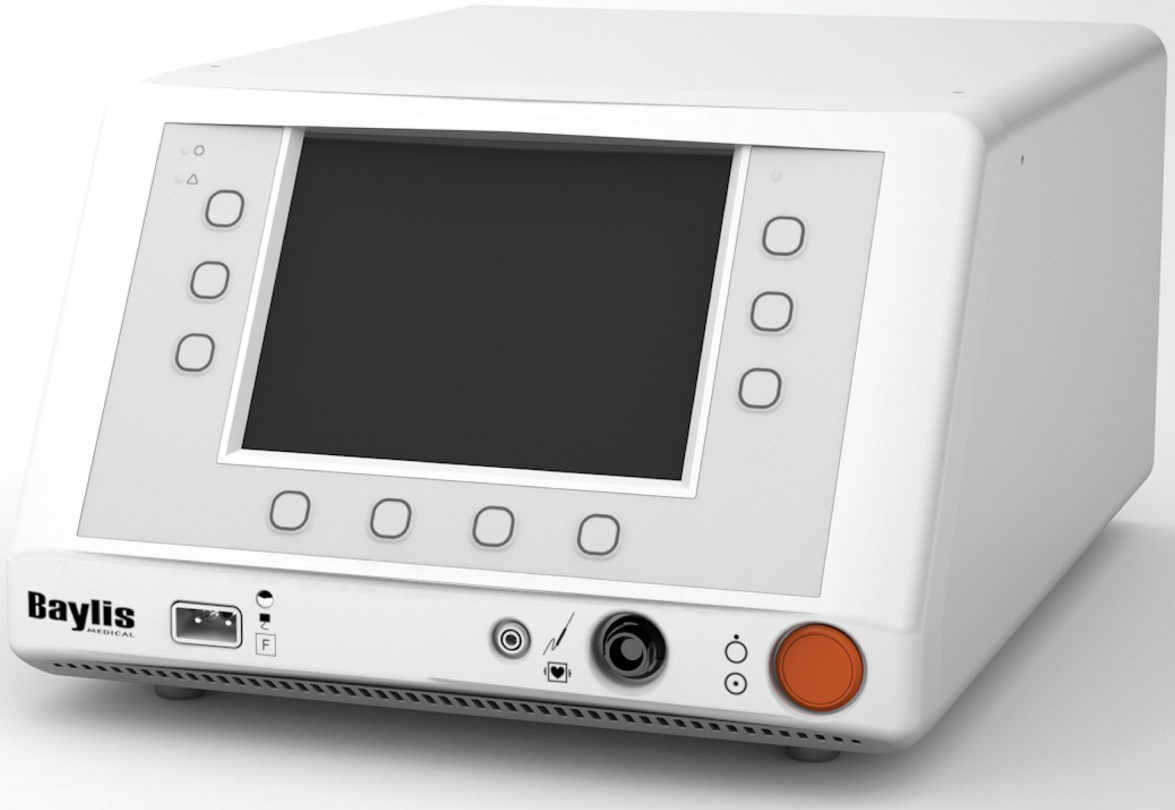
RFP-100A

RF Puncture Generator

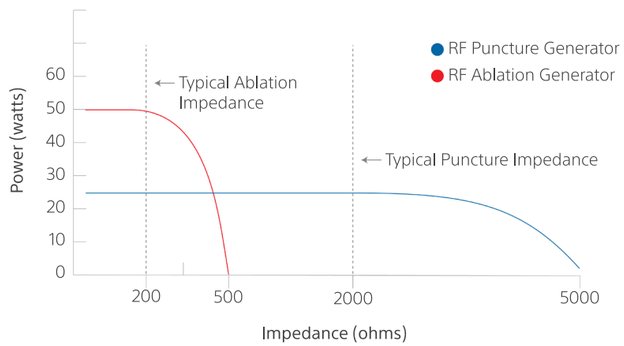


CONTROLLED TISSUE PUNCTURE USING RADIOFREQUENCY ENERGY

RFP-100A RF Puncture Generator*

RF Puncture vs. RF Ablation

Voltage Differences Between RF Puncture and RF Ablation



High impedance conditions are key to create a precise puncture in tissue with minimal surrounding damage. The RFP Generator is designed to function at high impedance, whereas a typical RFA Generator is not.

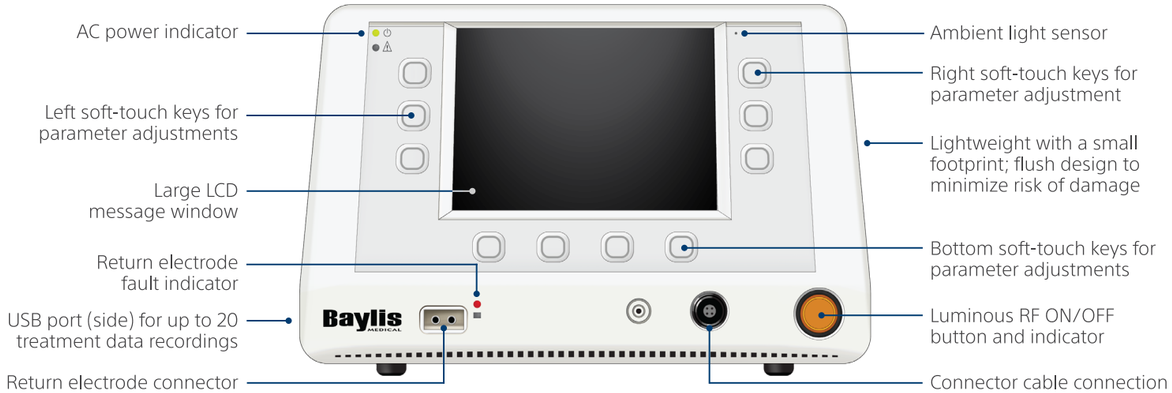
RF Puncture

Objective	To create a small opening in tissue
Occurs under these conditions	Low power (5-25 W)
	Short duration (1-3 s)
	High voltage (270-400 V)
Impedance range	2000-6000 Ω
Minimal collateral damage to surrounding tissue	

RF Ablation

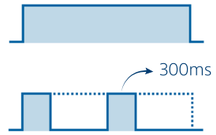
Objective	To create a lesion to destroy electrically conductive tissue
Occurs under these conditions	High power (30-50 W)
	Long duration (60-90 s)
	Low voltage (35-50 V)
Impedance range	150-300 Ω
Thermal destruction of surrounding tissue	

Features



Custom RF Settings

Use Constant Mode or Pulse Mode, and customize settings to your preference. Improved cutting ability enables shorter RF activation time.

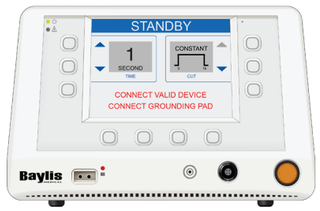


Constant Mode: Continuous RF delivery

Pulse Mode: 300 ms pulsed RF delivery per second

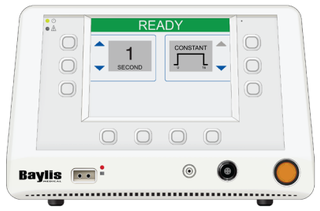
Intelligent Interface

Adjust settings in standby state. Automatic recognition of paired devices.



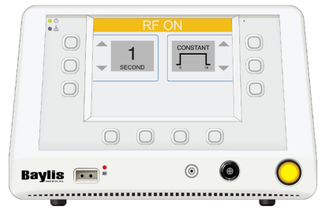
1 STANDBY

Connect grounding pad and connector cable. Generator automatically recognizes devices and makes available only appropriate modes.



2 READY

With all components connected, select desired Time and Cut settings. Using footswitch or RF ON button, initiate RF.



3 RF ON

Once RF ON button is pressed, generator enters “RF ON” state. Elapsed time is displayed during RF delivery. Screen will maintain until RF delivery concluded.

RFP-100A RF Puncture Generator

SPECIFICATIONS

Product Code	RFP-100A
RF Energy	468 kHz, Sinusoidal Maximum output power of 50 W
Duty Cycle	Durations from 300 or 1000 ms ± 5 ms
Count-up Timer	Settable from 1-10 s (Device dependent) Display resolution: 1 s
Dimensions	Width: 11.25 in (28.5 cm) Length: 15.6 in (39.6 cm) Height: 7 in (17.8 cm)

Weight	20 lb (9.1 kg)
Input Voltage	100-240 VAC
Current Rating	5.0 A, 50-60 Hz
Power Cord Length	10 ft

⚠WARNING: The RFP-100A RF Puncture Generator is designed and intended for use with RF transseptal solutions from Boston Scientific.

MULTI-PLATFORM DESIGN FOR MAXIMAL HOSPITAL VALUE

VersaCross™ RF Transseptal Solution

The VersaCross™ RF Transseptal Solution offers all-in-one versatility for transseptal and beyond in a single device.

NRG™ Transseptal Needle

The NRG™ Transseptal Needle is uniquely designed to assist the physician in gaining access to the left atrium.

SupraCross™ RF Solution

When the conventional solution may not be optimal, use SupraCross™ RF Solution to gain alternate access into the left atrium.

Baylis Medical Company Radiofrequency Puncture Generator RFP-100A

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The Baylis Medical Company Radiofrequency Puncture Generator & Footswitch (optional accessory) is to be used with separately approved radiofrequency devices in general surgical procedures to cut soft tissues.

CONTRAINDICATIONS: The BMC Radiofrequency Puncture Generator is not recommended for uses other than the indicated use.

WARNINGS: • The Generator is intended for use with separately cleared BMC RF Devices, BMC connector cables, and the accessory footswitch only. For respective devices/accessories, refer to individual IFUs for more information. • To avoid risk of electric shock, Generator must only be connected to supply mains with protective earth. • Do not remove the cover of the Generator. Removal of the cover may result in injury and/or damage to the Generator. • Laboratory staff and patients can undergo significant x-ray exposure during RF Puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • Place monitoring electrodes as far away from the surgical 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, incorporating high frequency current limiting devices are recommended. • Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze. • During RF output, implanted devices such as pacemakers may be affected. Qualified advice should be obtained as necessary, to minimize the risk from injury due to implanted device malfunction. • Devices should not be used in the presence of flammable materials, chemicals, and substances (anesthetics, oxygen, etc.). • No modification of Generator is allowed. Modification may result in patient or operator harm. • Generator failure can lead to neuromuscluar stimulation. • When using RF On/Off switch, the Generator can deliver RF energy without continuous depression of RF On/Off switch for the specified treatment time. Failure to specify correct treatment time could result in an unintended RF delivery.

PRECAUTIONS: • The Generator is intended for use with separately cleared BMC RF Devices, BMC connector cables and an optional accessory footswitch only. Ensure that the rated accessory voltage is equal to or greater than the Generator's maximum output voltage. • Read and follow the manufacturer's instructions for use of the return (dispersive) electrode. **Only use dispersive electrodes that meet or exceed IEC 60601-2-2:2017 requirements.** The entire area of the dispersive electrode should be reliably attached to the patient's body and as close to the operating field as possible. • The Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the BMC RF Device and dispersive electrode, particularly when operating the BMC RF Device. • During RF energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces or metal surfaces which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose. • The mains power cord of the Generator must be connected to a properly grounded receptacle to avoid the risk of electric shock. Extension cords, portable multiple socket outlets and/or adapter plugs must not be used. The mains power cord assembly should be periodically checked for damaged insulation or connectors. • Fluids pooled in the body depressions and cavities should be mopped up before RF energy is delivered. • There is a danger of ignition of endogenous gases (e.g., cotton and gauze saturated with oxygen may be ignited by sparks produced) during normal use of Generator. • The use of a smoke-plume extractor is recommended for the operator during RF procedures.

ADVERSE EVENTS: Adverse events that may occur while using the Generator include: • Atrial Fibrillation and/or Atrial Flutter • Myocardial Infarction • Sustained Arrhythmias leading to Ventricular Tachycardia • Neuromuscular stimulation • Electric shock • Thermal damage to tissue • Thromboembolic Episodes • Sepsis and Infection • Unintended Perforation

EP-1515603-AA

*Baylis Medical Company Radiofrequency Puncture Generator RFP-100A. Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

Boston Scientific
Advancing science for life™

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