

BAYLIS MEDICAL COMPANY RADIOFREQUENCY PUNCTURE GENERATOR

RFP-100A

ENGLISH
User's Manual



Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications.

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PREFACE

For the user's convenience, the Baylis Medical Company Inc. (BMC, or "Baylis Medical") Radiofrequency Puncture Generator (model: RFP-100A) will be referred to in this Operator's Manual as the "Generator". The Generator is to be used only with BMC radiofrequency (RF) devices that have been separately cleared for use with the Generator. These separately cleared BMC radiofrequency devices include, but are not limited to, the Nykanen Radiofrequency Wire, the *PowerWire*[™] Radiofrequency Guidewire, the *NRG*[™] Transseptal Needle, and the *VersaCross*[™] Radiofrequency Wire - they will generally be referred to in this Operator's Manual as the "BMC RF Device". The BMC RF Device is connected to the Generator through the appropriate BMC connector cable. The DuoMode[™] Cable serves as an extension cable that is used with the Generator, BMC RF devices and diagnostic equipment. The footswitch is an accessory to the BMC Radiofrequency Puncture Generator.

User covenants not to use the Generator in conjunction with any unauthorized products, items, consumables, disposables, equipment or parts.

User specifically agrees that Baylis Medical shall not be liable for damages, personal injury or death if the RF Generator is used in conjunction or with any unauthorized products, items, consumables, disposables, equipment or parts.

User specifically agrees that Baylis Medical shall not indemnify the Buyer for claims resulting in damages, personal injury or death if the RF Generator is used in conjunction or with any unauthorized products, items, consumables, disposables, equipment or parts.

User will not resell or redistribute the Generator to entities or persons, except with Baylis Medical's prior written consent.

The use of the BMC Radiofrequency Puncture Generator is fully described in this manual, including a description of the Generator, its controls, displays, and a sequence for its operation. In addition, other information of importance to the user is supplied. For specific instructions pertaining to the use of any one of the separately cleared BMC RF Devices, please refer to the instructions for use for the respective BMC RF Device.

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

SECTION 1: DEVICE DESCRIPTION

The Generator is a component of the Baylis Medical Company Radiofrequency (RF) Puncture System. The Generator is operated in conjunction with separately cleared BMC RF Devices, BMC connector cables such as (but not limited to) the RFX-BAY-TS, RFX-BAY-TS-12-SU or RFX-BAY-OTW-10-SU cables, an optional DuoMode Cable, a commercially available return (dispersive) electrode that meets or exceeds IEC 60601-2-2, and an optional accessory footswitch. The Generator delivers energy in a voltage-controlled monopolar mode between the BMC RF Device's distal tip electrode and the return electrode. Detailed information regarding the BMC RF Device is contained in a separate manual that accompanies each BMC RF Device.

The Generator produces continuous radiofrequency power output at a fixed frequency in the range of 450 kHz to 480 kHz in a monopolar mode. Connections for the Generator connector cable (which connects to the separately approved BMC RF Device) and a patient return electrode that meets or exceeds IEC 60601-2-2 are provided. Controls on the front panel allow the cut mode and the duration of the RF output to be set. In addition, on/off control of the output can be achieved through the optional accessory footswitch or through the dedicated front panel button. The elapsed time and the cut mode are displayed on the liquid crystal display (LCD) during RF energy delivery. An audible tone synchronized with the RF output is also produced during energy delivery. The Generator has several built-in safety features, such as device identification, alert messages, an automatic shut-off for out-of-range parameters or metal contact, and maximum voltage, current, and power limits.

The Generator has been tested for compliance with the following standards:

- IEC 60601-1
- IEC 60601-2-2
- IEC 60601-1-2

SECTION 2: INDICATIONS/CONTRAINDICATIONS


2.1. 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.

2.2. CONTRAINDICATIONS

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

SECTION 3: WARNINGS, PRECAUTIONS, AND ADVERSE EVENTS

 The safe and effective use of RF energy is highly dependent upon factors under the control of the operator. There is no substitute for 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

- DO NOT attempt to operate the Generator before thoroughly reading this User's Manual. It is vital that the operating instructions for the equipment be read, understood, and followed properly. For future reference, retain this User's Manual in a convenient, readily accessible place.
- 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.
- When the Generator is activated, conducted and radiated electrical fields may interfere with other medical and electrical equipment. Care should be taken to limit the effects that electromagnetic interference (EMI) produced by the Generator has on other equipment.
- 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.
- Do not attempt to perform an RF puncture with an initial cut setting other than that recommended by the BMC RF Device Instructions for Use. The cut setting (and therefore output power) should be as low as possible (as recommended for BMC RF device) to avoid any unintended result.
- Failure of the Generator could result in an unintended increase of output power.
- 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.
- Unless a compatible monitoring return electrode that meets or exceeds IEC 60601-2-2 is used with the contact quality monitor, loss of safe contact between the return electrode and patient will not result in an auditory alarm.
- The Generator should not be operated if the display area (LCD screen) is cracked or broken.
- Devices should be checked for exposed metal between shaft and handle, as well as check for any connection issues prior to use.
- 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.
- Flammable solutions may pool under the patients or in body depressions such as the umbilicus, and in body cavities such as the vagina.
- Generator failure can lead to neuromuscular 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.

3.2. 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.
- Ensure that the Generator connector cables and dispersive electrode cables are positioned in such a way that contact with the patient or other leads is avoided.
- Ensure the application and connections of dispersive electrode before selecting a higher output setting on generator.
- Temporarily unused Devices should be disconnected from the Generator, from the Connector Cable or they should be stored in a location that is isolated from the patient.
- It is recommended not to exceed the specified number of RF energy applications per BMC RF Device, as indicated within the BMC RF Device's specific instructions for use.
- Only physicians thoroughly trained in RF Puncture techniques, in a fully equipped catheterization laboratory, should perform RF Puncture procedures.
- 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 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.
- Apparent failure of the equipment to function properly at normal settings may indicate faulty application of the dispersive electrode or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication.
- Regularly inspect and test re-usable connector cables and accessory footswitch.
- Perform regular inspections of all system components, including separately cleared BMC RF Devices and BMC Connector Cables, for damage to insulations.
- Associated equipment and BMC RF Devices should be selected with a rated accessory voltage equal to or greater than the maximum output voltage of the mode it is to be used for.
- Baylis Medical Company relies on the physician to determine, assess, and communicate to each individual patient all foreseeable risks of the Generator.
- 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.
- Although the BMC RF Device and BMC Connector Cables are sterilized, the Generator is not. The Generator must not enter the surgical sterile field.

- 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.

3.3. 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

The BMC RF Device Instructions for Use should be consulted for any other adverse events that may be associated with use of that separately cleared device.

The Dispersive Electrode manufacturer's Instructions for Use should be consulted for any other adverse events that may be associated with use of that dispersive electrode.

SECTION 4: UNPACKAGING AND REPACKAGING

4.1. UNPACKAGING

The Generator's shipping carton contains all of the components identified below. Unpack the Generator and accessories carefully and visually inspect the front panel, chassis, or cover for damage. If any physical damage is found, **DO NOT USE THE GENERATOR. CONTACT** Baylis Medical Company for a replacement. Notify the carrier immediately if the shipment carton is damaged. Verify that the following items are received:

- | | |
|---|----------------------------|
| 1 | Generator |
| 1 | User's Manual |
| 2 | Hospital Grade Power Cords |

Read the Directions for Use in Section 7 of this manual very carefully and thoroughly. If there are any discrepancies or concerns, notify Baylis Medical Company. Store the shipping carton in a safe place for future use.

The Generator may be placed on a mounting cart or on any sturdy table or platform rated to hold at least 20 lbs. Do not obstruct the vents underneath and at the rear of the Generator.

WARNING: The Generator should not be used adjacent to or stacked with other equipment. If the Generator must be operated adjacent to or stacked with other equipment, the Generator should be observed to verify normal operation in that configuration.

Separately cleared accessory medical devices compatible with the Generator include BMC connector cables such as (but not limited to) the RFX-BAY-TS, RFX-BAY-TS-12-SU or RFX-BAY-OTW-10-SU cables, an optional DuoMode Cable (RFX-BAY-DUO-100A), a commercially available return (dispersive) electrode that meets or exceeds IEC 60601-2-2 and an optional accessory footswitch (RFA-FS). These devices are packaged separately.

4.2. REPACKAGING

If it is necessary to repack and ship the Generator, use the original shipping carton and packing materials to ensure that no breakage occurs. Disconnect all the cables and accessories and place them into the locations in the carton that are reserved for these components. Do not attempt to forcefully fit all the components into the carton.

SECTION 5: CONTROLS, DISPLAYS, AND CONNECTIONS

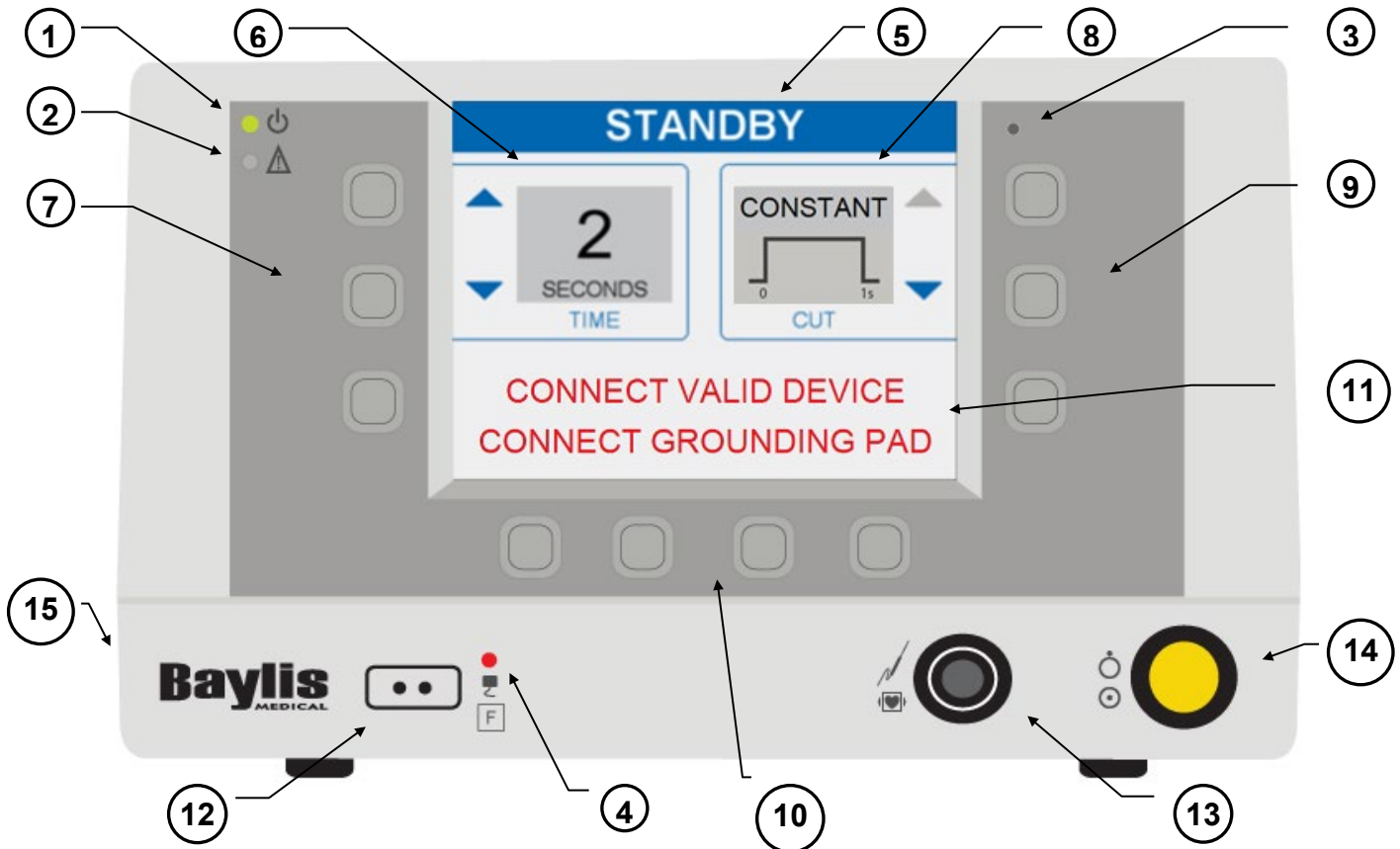


Figure 5-1 - Generator Front Panel

5.1. FRONT PANEL DISPLAYS, CONTROLS, AND CONNECTIONS

Descriptions of the front panel displays, controls, and connections are given below. Refer to Figure 5-1 - Generator Front Panel for their location.

- (1) **AC Power Indicator:** This green LED illuminates when the Generator is turned on.
- (2) **FAULT Indicator:** This red LED illuminates and flashes when a system ERROR has occurred. System errors include self-test failures, hardware protection errors, hardware measurement errors, and software failures. Mains power to the Generator must be cycled (off-on) to attempt recovery from a system error. Consult instructions for use.
- (3) **Ambient Light Sensor:** This sensor detects the ambient light level. Screen brightness is automatically adjusted according to ambient light level (bright (HIGH) in a bright room and dimmed (LOW) in a dim room).
- (4) **Return Electrode Fault Indicator:** The red LED illuminates when a return electrode is NOT connected to the generator OR when the measured impedance of a monitoring (dual foil) return electrode is greater than

150 ohm, indicating poor patient contact. Note: Only use return electrodes that meet or exceed IEC 60601-2-2 requirements.

- (5) **STATE Status Bar:** This window displays the current STATE of the Generator. The various Generator states and how they are related are shown in Figure 5-3 – Generator States Flow Chart.
- (6) **TIME Setting Window:** This window displays the desired RF output duration (in seconds). This window also displays the functions for the soft keys used to adjust the TIME setting.
- (7) **Left column soft keys:** These keys allow for parameter adjustment. Their function is displayed on the screen to the right of the soft key, when applicable. For example, the up ▲ and down ▼ arrows are displayed when the keys are to be used to increase or decrease a setting.
- (8) **CUT Setting Window:** This window displays the desired CUT mode. CUT modes are BMC RF Device specific and described in Section 0. The BMC RF Device’s instructions-for-use should be consulted for appropriate settings to use. This window also displays the function for the soft keys used to adjust the CUT setting.
- (9) **Right column soft keys:** These keys allow for parameter adjustment. Their function is displayed on the screen to the left of the soft key, when applicable. For example, the up ▲ and down ▼ arrows are displayed when the keys are to be used to increase or decrease a setting.
- (10) **Bottom row soft keys:** These soft keys have various functions. Each key’s function is displayed on the screen above the soft key when applicable.
- (11) **Message Window:** This window displays functional and informational messages when required.
- (12) **Return Electrode Connection:** This patient isolated connection is for attachment of an approved dispersive (return) electrode. **Only use dispersive electrodes that meet or exceed IEC 60601-2-2 requirements.** Either non-monitoring (single foil) or monitoring (dual foil) electrodes can be used.
- (13) **Connector Cable Connection:** This patient isolated connection is for the attachment of the RFP-100A connector cable. The user shall refer to the BMC RF Device instructions-for-use to select the proper connector cable model.
- (14) **RF ON/OFF Button and Indicator:** Upon press and release, this button initiates RF energy delivery when the Generator is in the READY state. This button terminates RF energy delivery when the Generator is in the ON state. The indicator in the button illuminates yellow when the Generator is in the ON state.
- (15) **USB Port (side):** When a USB memory stick is connected, treatment data from the last twenty (20) RF energy deliveries is downloaded. When left connected, data from subsequent RF deliveries is downloaded on a per treatment basis.

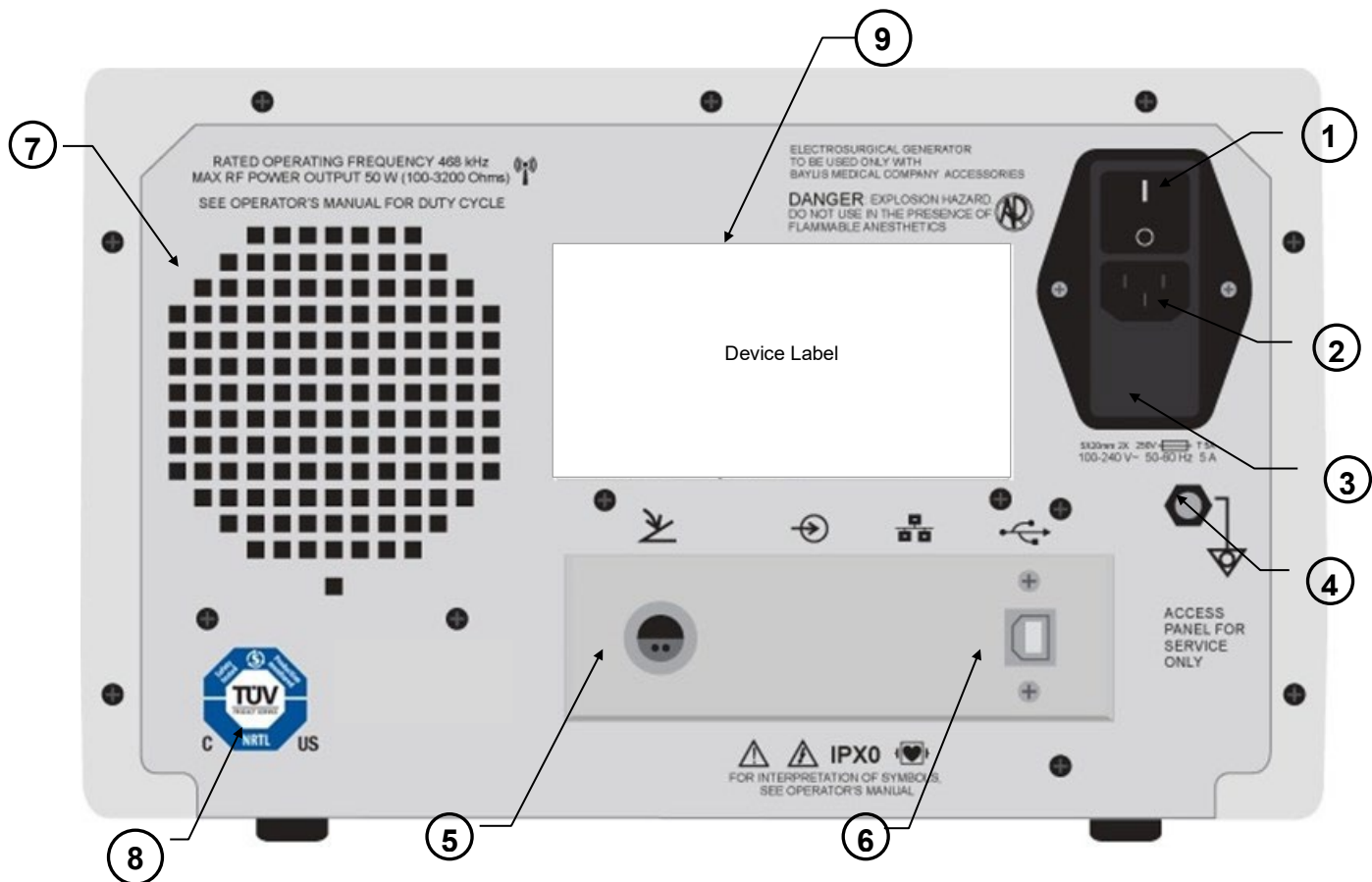


Figure 5-2 - Generator Rear Panel

5.2. REAR PANEL DISPLAYS, CONTROLS, AND CONNECTIONS

Descriptions of the rear panel displays, controls, and connections are given below. Refer to Figure 5-2 - Generator Rear Panel for their location.

- (1) **AC Mains Switch:** This switch controls the initial AC mains power input to the Generator. It is part of the power entry module which also contains the fuse drawer and AC power cord connector.
- (2) **AC Power Cord Connection:** This connection is for the attachment of a hospital grade power cord.
- (3) **Fuse Drawer:** This fuse drawer contains the fuses that protect the generator from excessive AC mains current.
- (4) **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.
- (5) **FOOTSWITCH Connection:** This connection is for the attachment of the FOOTSWITCH. Like the RF ON/OFF button, the FOOTSWITCH initiates and terminates RF energy delivery. However, its action is different than the RF ON/OFF button. The FOOTSWITCH must be pressed and held in the READY state to deliver RF energy and it must be released to terminate RF energy delivery.
- (6) **USB Connection (covered):** Connection to be used by authorized service personnel only.
- (7) **Fan:** A brushless DC fan is used to exhaust warm air from the Generator. The direction of flow is outward from the rear panel.
- (8) **TUV Product Service (c-us) Mark Label**
- (9) **Device Label:** This label indicates the model number, serial number, and manufacturer contact information. Symbols found on this label are described in Section 9.5.

Note: Any ports that are not captured in Figure 5-2 - Generator Rear Panel are non-functional and should not be used

5.3. GENERATOR STATES FLOW CHART

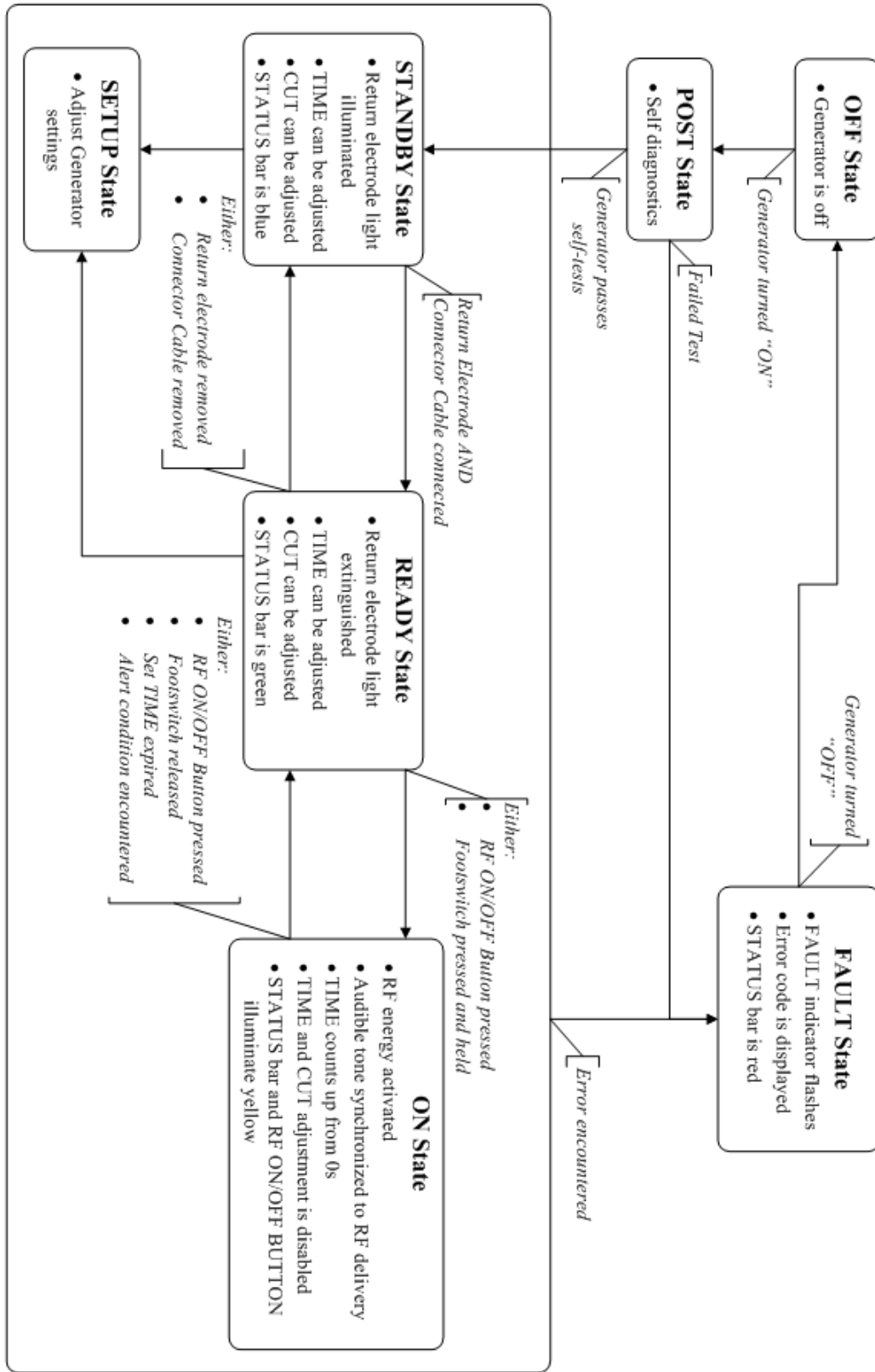


Figure 5-3 – Generator States Flow Chart

6.1. System Initialization and POST States

- The System Initialization state is initiated when the Generator is turned on. It lasts for approximately 40s.
- The AC Power Indicator is illuminated and a splash screen appears. The screen will go blank for approximately 20 seconds.



Figure 6-1- System Initialization Display

- The Power On Self Test (POST) state is initiated after System Initialization is complete. It lasts for approximately 10s.
- The FAULT indicator illuminates during POST.
- The Return Electrode Fault Indicator and RF ON/OFF indicator flash briefly during POST.
- A tone is sounded once POST is successfully completed.
- If the Generator does not complete POST, then an error will trigger (see FAULT state).
- The presence of the screen display, indicators and tone should be observed prior to operating the Generator.

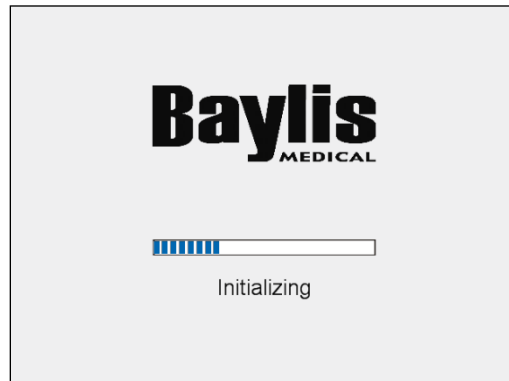


Figure 6-2- POST Display

6.2. STANDBY State

- The Standby State is initiated upon successful completion of the POST state.
- TIME and CUT settings can be adjusted with the left and right soft keys beside the arrows.
- Messages instruct the user to connect a Valid Device and Return Electrode (Grounding Pad).
- RF energy delivery cannot be initiated.

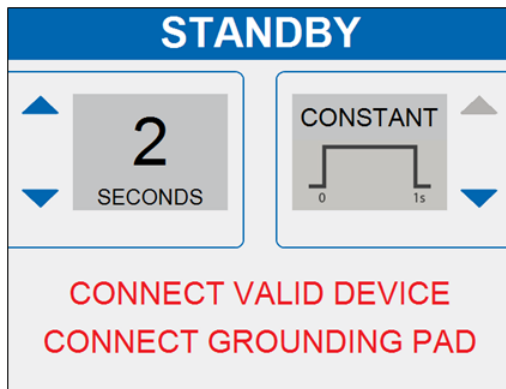


Figure 6-3- STANDBY State Display

6.3. READY State

- The Ready State is initiated when a Return Electrode (Grounding Pad) is connected AND a valid device is connected OR when RF energy delivery is terminated.
- TIME and CUT settings can be adjusted with the left and right soft keys beside the arrows.
- RF energy delivery can be initiated by either pressing the RF ON/OFF button or pressing and holding the FOOTSWITCH.

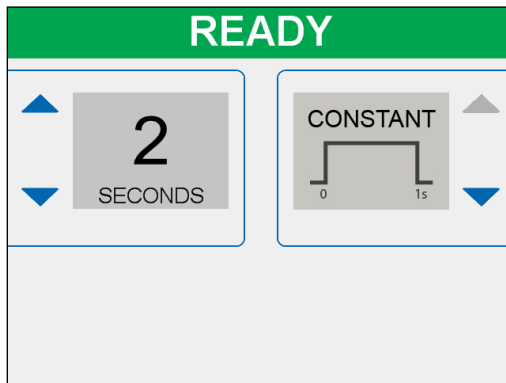


Figure 6-4a- READY State Display

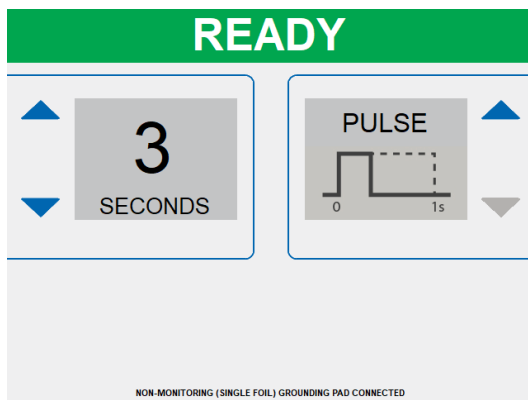


Figure 6-4b- READY State Display with Single Dispersive Electrode

6.4. ON State

- The ON State is initiated from the Ready State by either pressing the RF ON/OFF button OR by pressing and holding the FOOTSWITCH.
- TIME and CUT setting adjustment is disabled (adjustment soft key function is grayed out).

- Audible Tone synchronized with RF energy is heard.
- RF ON/OFF Indicator is illuminated in yellow.
- TIME counts up from 0 seconds.
- RF energy delivery is terminated by one of the following:
 - when the set TIME is reached
 - when the RF ON/OFF button is pressed
 - when the FOOTSWITCH is released
 - when there is an ALERT or ERROR condition.

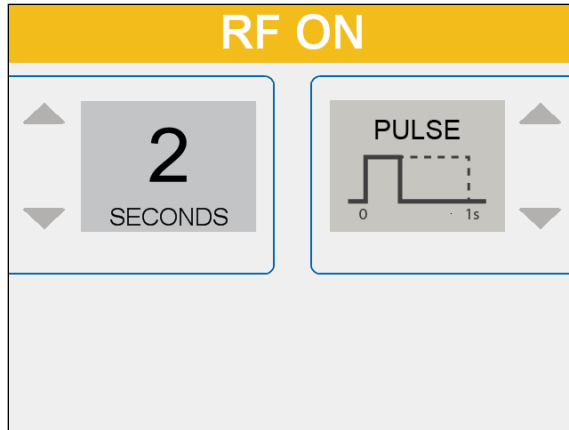


Figure 6-5- ON State Display

6.5. ALERT

- An ALERT is presented when an alert condition is met in STANDBY, READY, or ON States.
- An alert tone is sounded, “ALERT” is displayed in a red status bar, and a message with a code is displayed. See Section 9.3 for a list of ALERT codes and possible causes.
- The message is displayed until the “DISMISS” soft key is pressed or until five (5) seconds has elapsed, depending on the version of the generator.

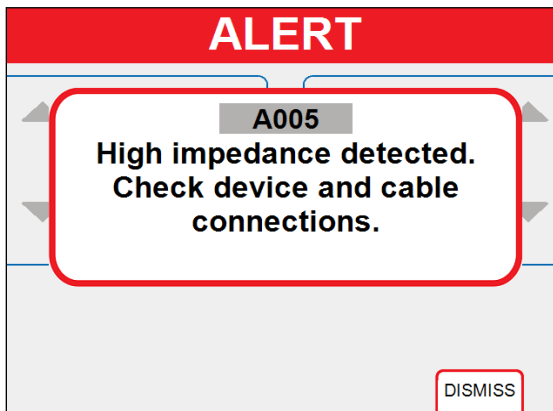


Figure 6-6- ALERT State Display

6.6. FAULT (ERROR) State

- The FAULT State is initiated when a system error has occurred.
- System errors include self-test failures, hardware protection errors, hardware measurement errors, and software failures.
- The user must record the error code and cycle main power (off-on) to the Generator to attempt recovery from a system error. Contact Baylis Medical Clinical support if error persists.
- A tone is sounded, “ERROR” is displayed in a red status bar, an error code is displayed, and the FAULT Indicator flashes red.
- If the Generator does not enter POST, then it will be considered as an error.

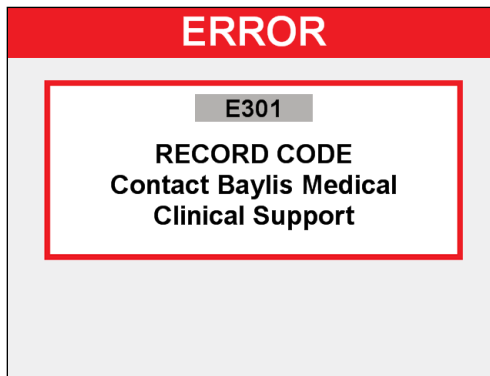


Figure 6-7- FAULT (ERROR) State Display

6.7. SETUP State

- The SETUP State is initiated when the user presses and holds for three (3) seconds:
 - the bottom-most soft key of the right column soft keys AND
 - the left-most soft key of the bottom row soft keys.
- The Generator setting to be adjusted is highlighted in **BLUE** and its value is black.
 - SELECT: The left soft keys are used to scroll through the settings.
 - CHANGE: The right soft keys are used to adjust the value of the highlighted setting.
- The SETUP State is exited and the settings are stored when “Save and Exit” is *pressed and held for three (3) seconds*. A tone sounds to confirm the settings were saved.
- The SETUP State is exited and the settings are NOT stored when “Cancel” is pressed.
- “Next” and “Back” soft keys change between the different SETUP screens.

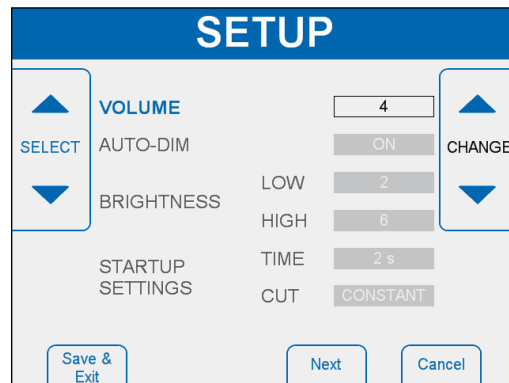


Figure 6-8- SETUP State Display - Page 1

| Parameter | DESCRIPTION | Range | Default Value | Increment |
|------------------|---|----------|---------------|-----------|
| VOLUME | Loudness level of the audible tones | 1 - 10 | 10 | 1 |
| AUTO-DIM | Automatic adjustment of screen brightness based on the ambient light level. When ON, the screen dims to BRIGHTNESS-LOW in low ambient light and BRIGHTNESS-HIGH in high ambient light. | ON – OFF | ON | N/A |
| BRIGHTNESS - LOW | Desired screen brightness level in low ambient light. | 1 – 10 | 2 | 1 |

| | | | | |
|-------------------------|--|-------------------|----------|------------|
| BRIGHTNESS - HIGH | Desired screen brightness level in high ambient light Screen brightness when AUTO-DIM is OFF. | 1 – 10 | 8 | 1 |
| STARTUP SETTINGS - TIME | Value for TIME setting when Generator is powered up | See Note 1 | 1s | See Note 1 |
| STARTUP SETTINGS – CUT | Value for CUT mode setting when Generator is powered up | Pulse or Constant | Constant | N/A |

Note 1: TIME can be set from 1s to 10s in increments of 1s. In addition, in certain units, if the CUT setting is Constant, TIME can also be set to 0.4s, 0.6s, or 0.8s.



Figure 6-9- SETUP State Display- Page 2

| Parameter | DESCRIPTION | Range/Units | Default Value | Increment |
|-------------------|---|--|---------------|----------------------------------|
| LANGUAGE | Selects a language to display screens, error messages, and warning messages. | ENGLISH, FRANÇAIS (FRENCH), DEUTSCH (GERMAN), NEDERLANDS (DUTCH) | ENGLISH | N/A |
| Software Versions | Displays current software versions. Not adjustable. | N/A | N/A | N/A |
| Generator S/N | Displays Generator serial number. Also found on rear device label. Not adjustable. | N/A | N/A | N/A |
| Time / Date | Displays Generator time and date. Adjustable by user. Not available in all versions of the Generator. | N/A | N/A | Standard Time and Date Increment |

SECTION 7: DIRECTIONS FOR USE

7.1. READ INSTRUCTIONS FOR USE

Do not operate the Generator or BMC RF Device before thoroughly reading their respective Instructions for Use. It is vital that the Instructions for Use for all the associated equipment is read, understood, and followed properly.

7.2. CONNECT GENERATOR POWER CORD

Connect the Generator Power Cord plug into a properly grounded AC electrical outlet. To ensure proper grounding, the Power Cord plug must be installed in an AC electrical wall outlet designated “Hospital Grade” or “Hospital Only”. **Never use an outlet without a grounding connection.**

Position the Generator for easy viewing of its front panel displays.

7.3. CONNECT FOOTSWITCH (OPTIONAL)

If the footswitch is to be used with Generator, it must be connected to the Generator rear panel. Line up the four (4) pin footswitch connector with the footswitch connection. Rotate the connector until it slides and clicks into place. A light tug on the cable can confirm that the connector is properly seated.

To disconnect the footswitch from the Generator, grasp the connector housing and gently pull it straight out of the receptacle. The connector housing slides backwards to disengage the locking mechanism.

Never disconnect the footswitch by pulling on the cable cord.

7.4. CONNECT CONNECTOR CABLE

Verify the BMC Connector Cable model specified by the BMC RF Device Instructions for Use. Connect the four (4) pin connector to the Connector Cable Connection on the Generator front panel. The connector on the Connector Cable that connects to the Generator is keyed. Gently line up the key while pushing in gently until the connector clicks firmly into the receptacle.

To disconnect the Connector Cable from the Generator, grasp the connector housing and gently pull it straight out of the receptacle. The connector housing slides backwards to disengage the locking mechanism.

Never disconnect the Connector Cable by pulling on the cable cord.

Do not twist the connector of the BMC Connector Cable while inserting or removing it from the Generator receptacle. Doing so may damage the pin connections.

Refer to the Connector Cable Instructions for Use for further details.

To connect the BMC RF Device to the BMC Connector Cable, please refer to the individual Instructions for Use of each BMC RF Device. Check for exposed metal between shaft and handle before use. Also check that there are no fit/connection issues between the Generator, BMC RF Device and BMC connector cable.

Note: Position the Generator near the table where the procedure is to be performed. The Generator may only be connected to recording systems providing patient electrical isolation in accordance with IEC 60601.

7.5. CONNECT THE DISPERSIVE (RETURN) ELECTRODE

Only use dispersive electrodes that meet or exceed IEC 60601-2-2 requirements. Connect the dispersive (return) electrode (also referred to as a grounding pad) connector to the Return Electrode Connection found on the Generator front panel. Line up the pins in the Generator receptacle with the sockets of the electrode connector and gently push the dispersive electrode connector until it sits firmly in place. To unplug, grasp the dispersive electrode connector and gently pull it out from the receptacle.

Before use, it is important to check the dispersive electrode’s sealed foil packaging for damage. Exposure to air, due to a damaged package, could cause the dispersive electrode to become dry and limit its capability to provide an appropriate return path for RF energy. Be sure the pad is moist and sticky to the touch before placing it on the patient. Do not attempt to relocate the patient dispersive electrode after its initial application. Electrode gel that is separate from and additional to any gel that is an integral part of the dispersive electrode is not required and should not be used.

The dispersive electrode should be placed on a well-vascularized, convex skin surface. Dispersive electrode placement on the thigh may be associated with higher impedance. Avoid scar tissue, bony prominence, adipose tissue, or any areas where fluid may pool. Shave, clean, and dry the application site as needed. Check for wrinkles or folds when applying the dispersive electrode, as they can inhibit adequate contact and decrease conductivity.

The Generator is equipped with a Return Electrode Fault Monitor that measures the impedance between the two conductors of the dispersive electrode. For a single foil electrode, the monitor will indicate a fault (the Return Electrode Fault Indicator will illuminate red) if either one or both of the conductors are faulty. For a dual foil electrode, the monitor will indicate a fault if the impedance between the conductors is greater than 150 ohms, which may indicate poor patient contact.

WARNING: Unless a compatible dual foil dispersive electrode is used **that meets or exceeds IEC 60601-2-2 requirements**, loss of safe contact between the dispersive electrode and the patient may not result in an auditory alarm.

When using a single foil dispersive electrode, a text string may appear at the bottom of the screen, indicating that monitoring for poor patient contact will not be available with this type of dispersive electrode. However, the user may still continue with the procedure.

7.6. TURN THE GENERATOR “ON”

Turn the Generator “ON” by pressing the rocker switch located on the Generator back panel to the “I” position. The Generator immediately performs a self-test of power generation, measurement, and control circuitry, as indicated by the progress bar on the display (POST state). If there are no errors, the Generator enters into the STANDBY state. If the self-test fails, a tone is sounded and the Generator enters into the FAULT state, where the red FAULT INDICATOR flashes and an error code is displayed.

If the FAULT state is entered (i.e. a system malfunction is detected during self-test), the Generator will not operate. To clear any malfunctions found during the self-test, the Generator power must be cycled (powered “OFF” and then back “ON”) with the self-test repeated. If the Generator fails again, the Generator will not function properly and the error code should be recorded. Baylis Medical Company should be contacted for service. The Generator will NOT operate unless the power on self-tests have been successfully completed.

If the dispersive electrode is disconnected or a dual foil dispersive electrode is not adequately applied, the Return Electrode Fault Indicator will illuminate red.

7.7. SET CUT MODE

Set the desired CUT mode as recommended by the BMC RF Device Instructions for Use, by using the right soft keys to increment ▲ or decrement ▼ through the settings.

Note: The CUT ▲/▼ soft keys are inoperative during RF power delivery.

7.8. SET TIME

Set the desired duration (in seconds) for RF power delivery, as recommended by the BMC RF Device Instructions for Use, by using the left soft key to increase ▲ or decrease ▼ the setting.

Note: The TIME ▲/▼ soft keys are inoperative during RF power delivery.

7.9. CONFIRM GENERATOR SETTINGS AND STATE

Prior to delivering RF energy to the BMC RF Device, first check that all the connections have been made properly and that the TIME and CUT settings are correct. The Generator should be in READY state if all connections have been properly made. Confirm that all of the requirements specified in the individual accessories’ Instructions for Use have been met. Only after all the above conditions are met should one proceed to deliver RF energy.

7.10. ACTIVATE RF ENERGY DELIVERY

RF energy delivery is activated when the RF ON/OFF BUTTON is pressed once or when the footswitch is pressed and held. Pressing the RF ON/OFF BUTTON again or releasing the footswitch before the timer elapses will terminate RF energy delivery. When RF power is delivered to the device, the Generator enters the ON state.

If interference with other equipment is suspected, reposition all cables being sure to keep Generator cables away from monitoring equipment cables.

7.11. DEACTIVATE RF POWER DELIVERY

RF energy delivery is terminated and the READY state is entered when either the timer elapses, when the RF ON/OFF BUTTON is pressed, or when the FOOTSWITCH is released during the ON state. The RF ON/OFF BUTTON will extinguish and the tone will no longer sound.

RF energy is also terminated with an ALERT or with an ERROR. If an ALERT terminated energy delivery, the alert message is displayed until the “Dismiss” soft key is pressed or until five (5) seconds has elapsed, depending on the version of the generator. The Generator enters READY state. If an ERROR terminated energy delivery, the error code is displayed, the FAULT Indicator flashes, and the Generator enters FAULT state. To attempt to exit the FAULT state, the Generator power must be cycled, after which the sequence of initializing steps must be performed again from Section 7.7.

Note: If an ERROR is encountered repeatedly, the Generator is not functioning properly and needs servicing; Contact Baylis Medical Company.

7.12. RE-APPLY RF POWER

To re-apply RF energy, repeat Steps 7.7 through 7.11. Confirm that the dispersive electrode is properly applied and connected before adjusting to a higher CUT setting.

7.13. PROCEDURE COMPLETE

When the Generator is no longer required, turn the Generator “OFF” by pressing the rocker switch located on the Generator back panel to the “O” position.

The BMC RF Device should be disconnected from the BMC connector cable. The BMC connector cable and return electrode should be disconnected from the generator front panel. The BMC RF Device, BMC connector cable and return electrode should be disposed of or stored as indicated in their instructions for use or according to the procedures for the institution.

If other connectors were used (e.g. footswitch, USB, etc), they should be disconnected as necessary to ensure safe storage of the Generator and accessories.

SECTION 8: SERVICE AND MAINTENANCE

The Generator requires no routine service or maintenance. Preventative maintenance can be performed annually such as cleaning and fuse replacement. If the Generator fails to operate when plugged into a proper AC power receptacle and the AC Mains Switch is turned “ON”, a fuse may have blown. Replace the fuse as described below or contact Baylis Medical Company for assistance. The Generator contains no user-serviceable parts. Disassembly and attempted repair by unqualified personnel may create a hazardous condition and will void the warranty. Annual preventative maintenance may include a test for electrical safety, check that the Dispersive Electrode Fault Indicator illuminates in the absence of a connection, and verification that the rear fan is operational.

WARNING: DO NOT remove the cover of the Generator. Removing the cover may result in personnel injury and/or damage to the Generator.

8.1. CLEANING

The outer surface of the Generator may be cleaned with a mild soapy solution. DO NOT immerse the Generator or its accessories in any liquid. Avoid caustic, abrasive or flammable cleaners and disinfectants. If disinfecting is required, 70% isopropyl alcohol or 5% solution of household bleach may be used to clean the outer surfaces. The Generator cannot be sterilized. Any flammable solvents used to wipe the Generator should be allowed to thoroughly dry before turning the Generator “ON”.

If the automatic dimming function of the display does not seem to be working, the ambient light sensor may be obstructed or dirty.

8.2. FUSE REPLACEMENT

1. Unplug the Power Cord from the Generator.
2. Use a precision slot screwdriver to remove the fuse drawer
3. Remove BOTH fuses from the fuse drawer and discard them.
4. Select TWO new fuses according to the following specifications:
5.0A/250V, Low breaking capacity, Slow Blow (or Time Lag), IEC markings
5. Ensure the integrity of the new fuses by inspecting for physical damage that could affect the function of the fuse. Replace if either or both look damaged.
6. Place the new fuses in the fuse drawer.
7. Return the fuse drawer back into the Generator in any orientation.

WARNING: Using different rated fuses than specified can result in permanent damage to the Generator!

8.3. DISPOSAL

For disposal of the Generator at the end of its service life, please contact Baylis Medical.

SECTION 9: SECTION 9: SPECIFICATIONS

9.1. TECHNICAL SPECIFICATIONS

| | | |
|-----------------------|--|-----------|
| Model number: | RFP-100A | |
| Description: | Class I, Defibrillation proof Type CF Equipment | |
| <u>Generator:</u> | | |
| RF Energy: | 468 kHz, Sinusoidal Maximum output power of 50 Watts* Maximum output current of 1.27 A * Maximum output voltage of 565.77 V * *Into resistive load range of 100-6000 ohms 300 ohm is the rated “nominal” load | |
| Duty Cycle: | Durations from 15 – 1000 ms \pm 5 ms (Device dependant) Repetition frequency of 1 Hz \pm 5%. Rest period of 3s is recommended between RF energy applications at 1000ms duty cycle. | |
| Measurement Accuracy: | Impedance Range | Accuracy |
| (Power and Impedance) | 100 – 1000 ohm: | \pm 10% |
| | 1000 – 3200 ohm: | \pm 15% |
| | 3200 – 6000 ohm: | \pm 20% |
| Count-up Timer: | Settable from 0.4-10 seconds (Device and CUT setting dependent) Display resolution: 1 second Accuracy: 0.1 second | |
| Dimensions: | Width: 11.25 inches (28.5 cm) Length: 15.6 inches (39.6 cm) Height: 7 inches (17.8 cm) | |
| Weight: | 20 lb. (9.1 kg) | |
| General: | | |

| | |
|-----------------------------------|--|
| Input Voltage: | 100-240 V~ |
| Current Rating: | 5.0A, 50-60 Hz |
| Fuse Rating: | 5.0A/250V, IEC, Slow Blow (Time Lag) |
| Power Cord Length: | 10 feet |
| Connector Cable | Keyed Quick Connect female 4 pin |
| Connection: | |
| Return Electrode | Standard male 2-pin for commercial pads |
| Connection: | |
| Recommended Dispersive Electrode: | Any commercially available return (dispersive) electrode that meets or exceeds IEC 60601-2-2 |
| Footswitch Connection: | Metal Keyed Quick Connect 4pin |
| RJ45 Cable Connector: | Standard RJ45 female Port Connector |
| Side USB Port: | Bulkhead mounting USB-A Connector |
| Rear USB Port: | Bulkhead mounting USB-B Connector |
| Line-In Connection: | Bulkhead BNC Connector |

Environmental:

Storage:

- Temperature: -20°C to 50°C. The unit should be gradually returned to the operating temperature range before use and stabilized for one hour before operation
- Relative Humidity: ≤90%, non-condensing
- Atmospheric Pressure: 500 to 1060 millibar

Operating:

- Temperature: 15°C to 40°C
- Relative Humidity: 15% to 90%, non-condensing
- Atmospheric Pressure: 700 to 1060 millibar

Leakage Current Measurements (No Fault Condition):

| | |
|---|----------|
| Device Source Current | < 10 uA |
| Dispersive Electrode Source Current | < 10 uA |
| Device Sink Current | < 10 uA |
| Dispersive Electrode Sink Current | < 10 uA |
| Enclosure Leakage (Ground Open, Power Normal) | < 300 uA |
| Enclosure Leakage (Ground Open, Power Reversed) | < 300 uA |

Dielectric Withstand (Hi-Pot) Test:

| | |
|--|------|
| Mains to Chassis (1500VAC, 1min) | PASS |
| Mains to Applied Parts (4,000 VAC, 1min) | PASS |

9.2. GENERATOR MODE SETTINGS

The CUT and TIME settings that are available to the operator are dependent on the Generator mode. The Generator mode is automatically selected when a BMC RF Device and its specified Connector Cable is connected to the Generator.

The table below provides the output parameters for each CUT and TIME setting available in each Generator mode.

- Mode 10 applications include the Nykanen Radiofrequency Wire and the *PowerWire* Radiofrequency Guidewire.
- Mode 12 applications include the *NRG* Transseptal Needle and the *VersaCross* Radiofrequency Wire

Table 9.2-1- CUT and TIME settings for each Generator Mode

| Mode # | CUT setting | Max Output Voltage (V _{rms}) | Pulse Duty Cycle (%) | Pulse Frequency (Hz) | max TIME (s) |
|--------|-------------|--|----------------------|----------------------|--------------|
| 10 | Constant | 300 | 100 | 1 | 3 |
| | Pulse | 400 | 30 | 1 | 10 |
| 12 | Constant | 270 | 100 | 1 | 3 |
| | Pulse | 270 | 30 | 1 | 10 |
| 14 | STX Low | 300 | 1.5 | 1 | 10 |
| | STX High | 350 | 1.5 | 1 | 10 |

OUTPUT ENERGY FIGURES

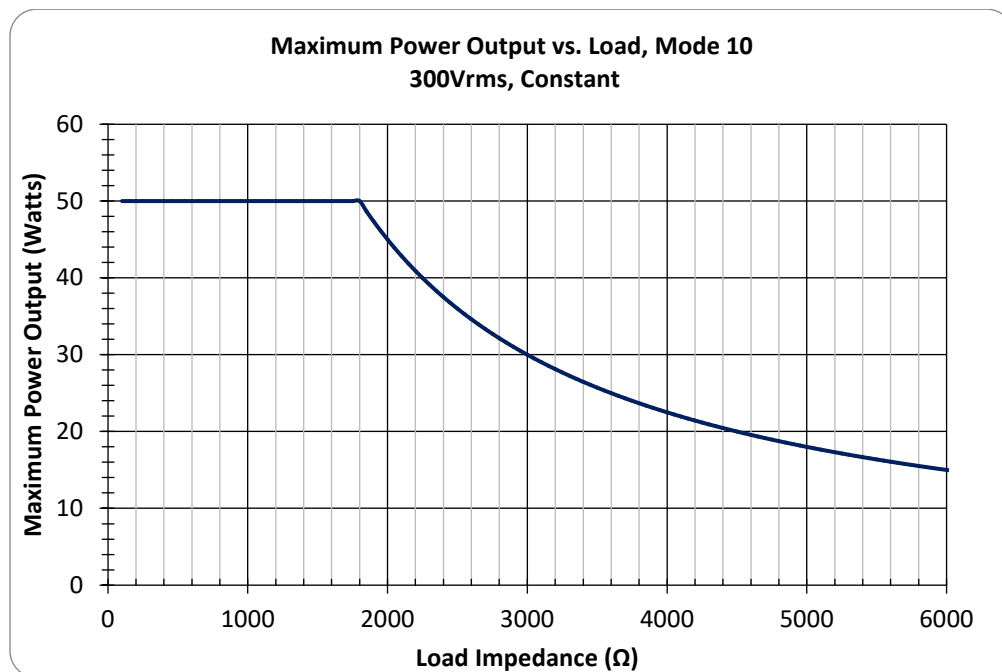


Figure 9-1 Maximum Power Output for Mode 10 Constant

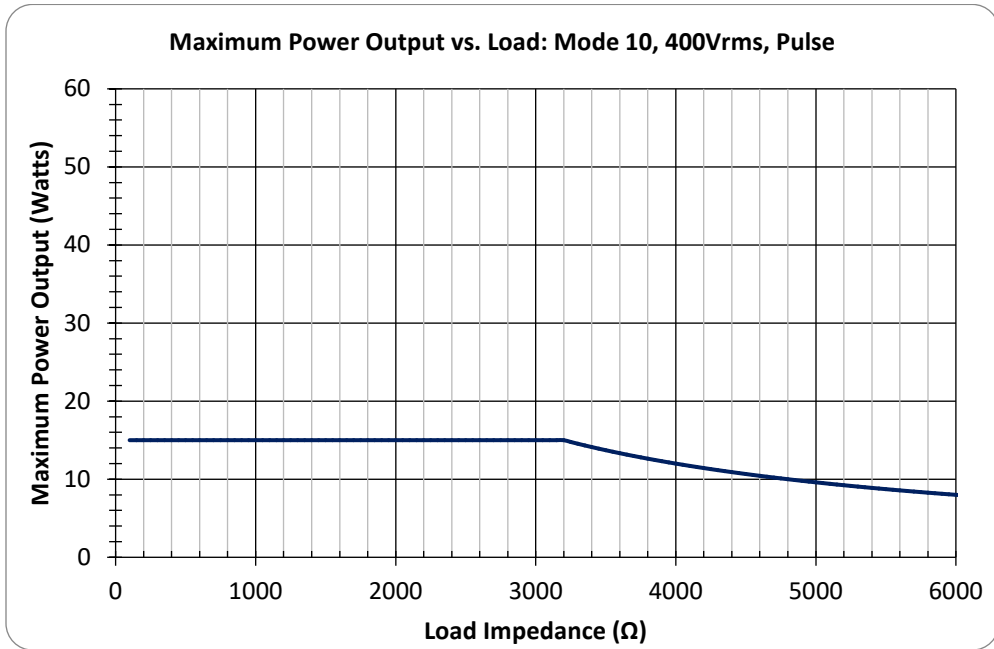


Figure 9-2 Maximum Power Output for Mode 10 Pulse

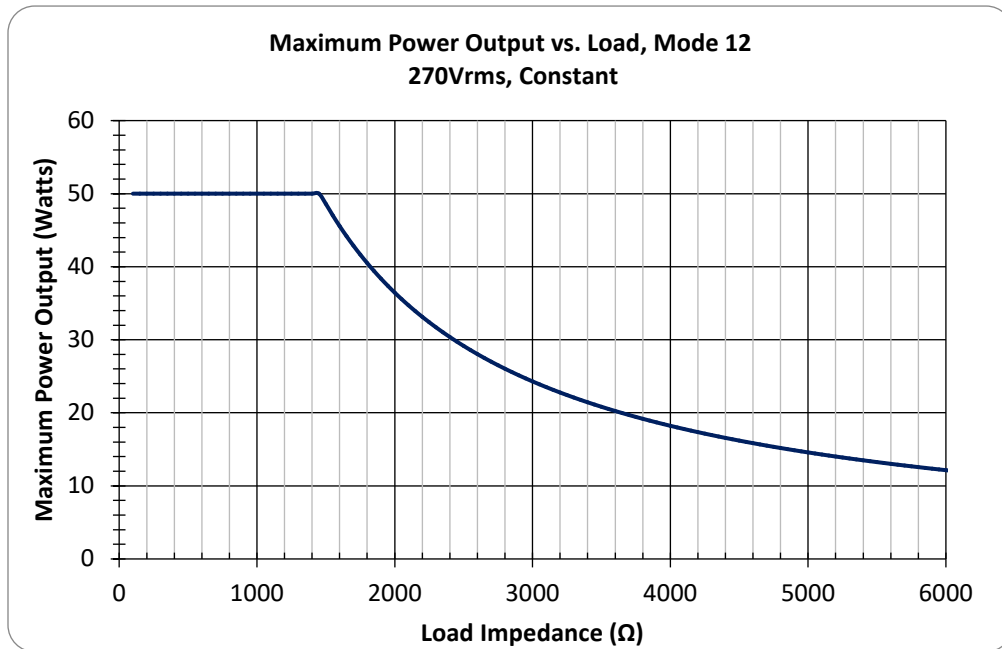


Figure 9-3 Maximum Power Output for Mode 12 Constant

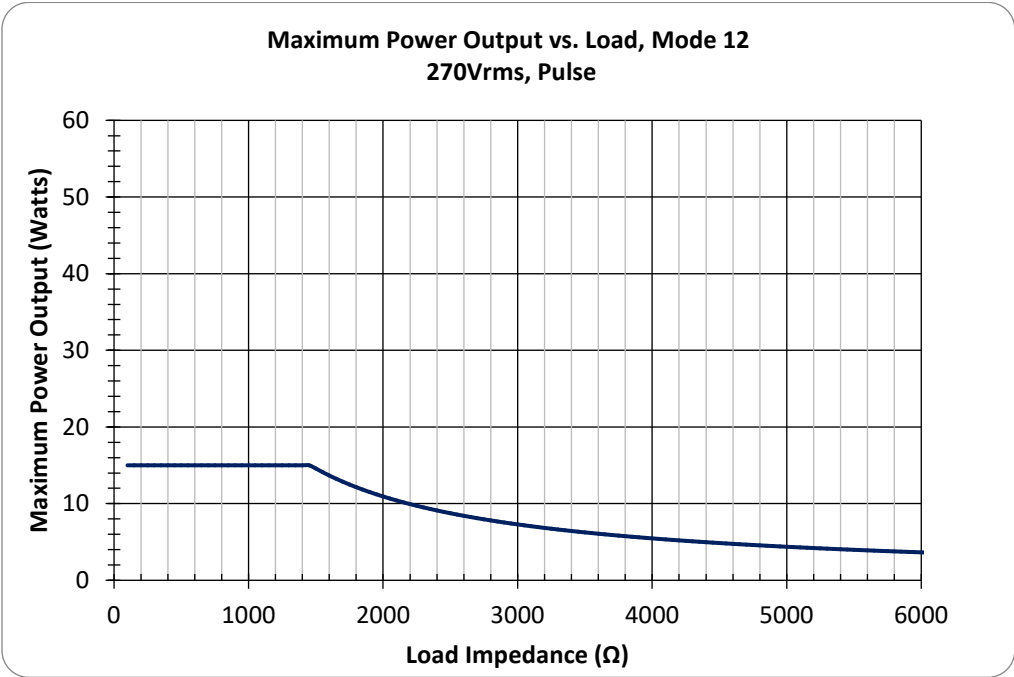


Figure 9-4 Maximum Power Output for Mode 12 Pulse

9.3. ALERT CODES

| Summary of Alert Codes, Displayed Text, and Description | | |
|---|---|--|
| Alert Code | Displayed Text | Description |
| A005 | High Impedance Detected. Check device and all cable connections | Greater than 6000 ohm measured during RF energy delivery. May indicate poor connection between Device and connector cable or poor patient contact with dispersive electrode. |
| A006 | Low Impedance Detected | Less than 100 ohm measured during RF energy delivery. Device may be in contact with a metal object. |
| A007 | Check ground pad contact with patient. Replace grounding pad if necessary. | Impedance between the conductors of a dual foil dispersive electrode is greater than 150 ohm. This may indicate poor patient contact. |
| A008 | Check ground pad contact with patient. Replace grounding pad if necessary. | Impedance between the conductors of a dual foil dispersive electrode is greater than 150 ohm. This may indicate poor patient contact. |
| A009 | Check ground pad contact with patient. Replace grounding pad if necessary. | Impedance between the conductors of a dual foil dispersive electrode is greater than 150 ohm. This may indicate poor patient contact. |
| A010 | Check all ground pad connections and ground pad contact with patient. | Open circuit between conductors of dispersive electrode connection. May indicate faulty dispersive electrode or poorly connected dispersive electrode. |
| A011 | Device ID has changed. | Error with connector cable may have altered Device specific settings. The connector cable should be checked for any problems. |
| A012 | Invalid device detected. Record alert code and contact Baylis Clinical Support. | Invalid or broken connector cable or device connected to the Generator. Replace connector cable and device. |
| A013 | Unsupported device detected. Record alert code and contact Baylis Clinical Support. | Device does not have supported output parameters. Replace connector cable and device. |
| A014 | Device connection lost. | Connector cable was disconnected or failed during RF energy delivery or authentication |
| A015 | Invalid device detected. Record alert code and contact Baylis Clinical Support. | Invalid connector cable or device connected to the Generator. Replace connector cable and device. If Alert persists, contact Baylis Medical. |
| A017 | The connected device conflicts with the current channel configuration. | Device parameters have been corrupted. Contact Baylis Clinical Support. |
| A018 | Device not connected | Either connector cable is not functioning or not connected when attempting to deliver RF energy. Check connector cable connection, replace connector cable if necessary. |
| A019 | Metal contact was detected. Reposition the device. | Metal contact detection feature has terminated RF energy delivery due to device proximity to metal. Reposition device before attempting to deliver RF energy. |
| A020 | The treatment time limit has been exceeded. | RF delivery longer than Time setting. If persists, contact Baylis Clinical Support. |
| A021 | The device is not ready for treatment. | RF ON/OFF button has been damaged or is stuck. If persists, contact Baylis Clinical Support. |

| Summary of Alert Codes, Displayed Text, and Description | | |
|--|---|--|
| Alert Code | Displayed Text | Description |
| A022 | The device is not ready for treatment. | Footswitch has been damaged or is stuck. Disconnect footswitch and deliver RF using RF ON/OFF button. Contact Baylis Clinical Support. |
| A023 | Treatment was terminated early. | RF delivery shorter than Time setting. If persists, contact Baylis Clinical Support. |
| A024 | Settings have changed according to device limits. | Time and Cut setting in Standby state were either out of range for a given Device or the Time setting was out of range for the desired Cut mode. Settings are automatically adjusted to maximum valid setting. |
| A025 | Settings have changed according to device limits. | Time and Cut setting in Standby state were either out of range for a given Device or the Time setting was out of range for the desired Cut mode. Settings are automatically adjusted to maximum valid setting. |
| A026 | Record Alert Code and contact Baylis Clinical Support. | Generator Setup settings have been lost. Settings have been reset to factory defaults. |
| A027 | An unknown failure occurred while exporting treatment data. | Export of treatment data failed. Check USB flash disk connection. If persists, contact Baylis Clinical Support. |
| A028 | Not enough space free to export treatment data. | USB flash disk is full. Free up space before attempting to obtain treatment logs. |
| A029 | Invalid device detected. Record alert code and contact Baylis Clinical Support. | Invalid connector cable or device connected to the Generator. Replace connector cable and device. |
| A030 | Record Alert Code and contact Baylis Clinical Support. | Handswitch Fault |
| A031 | Check connections between the cable and device. Reposition device, cable and grounding pad cable. | Patient Circuit Issue. Check and re-connect connections between Generator, cable and device. Ensure that the device cable and grounding pad cable are not crossing and are securely connected. If persists, contact Baylis Clinical Support. |

9.4. IEC ELECTRICAL SAFETY AND EMC SPECIFICATIONS

Table 9.4-1 IEC Electrical Safety Specifications

| | |
|--|--|
| Device Description | |
| Class I, Defibrillation proof Type CF Equipment, IPX0, not AP/APG | |
| Mode of Operation: Constant (Continuous) | |
| Electrical Isolation | <ul style="list-style-type: none"> Leakage current conforms to IEC 60601-1 Dielectric withstanding voltage conforms to IEC 60601-1 |
| <p>EMC Emissions and Susceptibility: The BMC Radiofrequency Puncture Generator has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This Generator 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.</p> | |

Table 9.4-2 IEC EMC Specifications (Emissions)


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

Table 9.4-3 IEC EMC Specifications (Immunity)

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|--|--|--|
| The BMC Radiofrequency Puncture Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the BMC Radiofrequency Puncture Generator should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact ±15 kV air | ±8 kV contact ±15 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 | 0 % UT for 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle and 70% UT for 25/30 cycles @ 0° 0 % UT for 250/300 cycles @ 0° and 180° | 0 % UT for 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle and 70% UT for 25/30 cycles @ 0° 0 % UT for 250/300 cycles | Mains power quality should be that of a typical commercial or hospital environment. If the user of the BMC Radiofrequency Puncture Generator requires continued operation during power mains interruptions, it is recommended that the BMC Radiofrequency Puncture Generator be powered from an uninterruptible power supply or battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of typical location in a typical commercial or hospital environment. |
| NOTE <i>UT</i> is the a.c. mains voltage prior to application of the test level. | | | |

Guidance and Manufacturer’s Declaration – Electromagnetic Immunity (continued)

The BMC Radiofrequency Puncture Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the BMC Radiofrequency Puncture Generator should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
|--|--|----------------------------|---|
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p> | <p>3 Vrms</p> <p>3 V/m</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the BMC Radiofrequency Puncture Generator including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = [1.17]\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = [2.33]\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |

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 BMC Radiofrequency Puncture Generator or any of its components are used exceeds the applicable RF compliance level above, the BMC Radiofrequency Puncture Generator 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 BMC Radiofrequency Puncture Generator.








^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 9.4-4 IEC Recommended Separation of RF Communication Equipment

| Recommended separation distances between portable and mobile RF communications equipment and the BMC Radiofrequency Puncture Generator | | | |
|---|---|---|--|
| <p>The BMC Radiofrequency Puncture Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BMC Radiofrequency Puncture Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and BMC Radiofrequency Puncture Generator as recommended below, according to the maximum output power of the communications equipment.</p> | | | |
| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter (m) | | |
| | 150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ | 80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ | 800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ |
| 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 |
| 50 | 8.25 | 8.25 | 16.50 |
| <p>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.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | |

9.5. LABELING AND SYMBOLS

| FRONT PANEL | |
|---|---|
| Defibrillator-proof, Patient Isolated connections |  |
| Dispersive (Return) Electrode connection; High Frequency Isolated Patient Circuit |  |
| Connector Cable connection |  |
| RF Output OFF |  |
| RF Output ON |  |
| AC Mains Power |  |
| USB-A Port |  |
| Set Time | TIME |
| Cut mode | CUT |
| Up |  |
| Down |  |

| REAR PANEL | |
|-----------------------------------|---|
| Power OFF |  |
| Power ON |  |
| Alternating Current |  |
| Caution |  |
| Dangerous Voltage |  |
| Equipotentiality and Earth Ground |  |
| Fuses |  |

| | |
|--|----------------|
| Footswitch connection | |
| Line in connection | |
| Ethernet Port | |
| USB-B Port | |
| Non-Ionizing Radiation | |
| Explosion Hazard. Do not use in the presence of flammable anesthetics. | |
| Manufacturer | |
| EU Authorized Representative | |
| Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. | Rx ONLY |
| Follow Instructions for Use | |
| Storage Conditions | |
| Temperature Limit | |
| Humidity Limitation | |
| Atmospheric Pressure Limitation | |
| Catalogue (Model) Number | |
| Serial Number, expressed as: YYMMDD-XXX, where “YYMMDD” is the lot manufacture date, and “XXX” is the unique identifier within the lot | |
| Only for EU member states: Use of this symbol indicates that the product must be disposed of in a way that complies with local and national regulations. For questions regarding recycling of this device please contact your distributor. | |

SECTION 10: LIMITED WARRANTIES AND DISCLAIMER

LIMITED WARRANTY – RF Generators (“Product”)

Baylis Medical Company Inc. (“BMC”, “Baylis”, “Baylis Medical” “Baylis Medical Company” or “Seller”), warrants the RF Generator and footswitch against defects in materials and workmanship to the registered owner at the time of purchase. All components of the RF Generator and Foot Switch are covered by the warranty as described below, except the connector cables, catheters, guide-wires, and accessories, which are covered in their own manuals and have their own warranties. Under this Limited Warranty, if any covered Product is proved to be defective in materials or workmanship, BMC will replace or repair, in its absolute and sole discretion, any such product, less any charges to BMC for transportation and labor costs incidental to inspection, removal or restocking of the Product. The length of the warranty is: (i) for the RF Generator, 1 year from shipment date, and (ii) for the Foot Switch, 90 days from shipment date.

This Limited Warranty applies only to new, original factory delivered Products that have been used for their normal and intended uses. BMC’s Limited Warranty shall not apply to BMC Products which have been resterilized, repaired, altered, or modified in any way and shall not apply to BMC products which have been improperly stored or improperly installed, operated or maintained contrary to BMC’s instructions. This warranty does not apply to any unit which has been subject to misuse, neglect, improper installation or that which has been altered, adjusted or tampered with by any person other than Baylis Medical authorized personnel. This Limited Warranty does not apply and will be null and void in whole and in part, if the RF Generator is used in conjunction or with any unauthorized products, items, consumables, disposables, equipment or parts.

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 Product to Baylis Medical at 5959 Trans-Canada, Montreal, Quebec, H4T 1A1 or to a specified address if different at his or her own expense. The customer shall obtain a return authorization number before shipping the unit back. Baylis Medical 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 Baylis Medical standard repair program will be issued a thirty-day 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 thirty-day warranty period will be repaired at no charge to the customer.

DISCLAIMER AND LIMITATION OF LIABILITY

THE LIMITED WARRANTY SET FORTH HEREIN IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, REMEDIES, OBLIGATIONS AND LIABILITIES OF BAYLIS MEDICAL, EXPRESSED OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE OR PURPOSE. ANY WARRANTY OTHER THAN SET FORTH HEREIN IS EXPRESSLY DISCLAIMED.

THE REMEDY SET FORTH HEREIN SHALL BE THE EXCLUSIVE REMEDY FOR ANY WARRANTY CLAIM, AND ADDITIONAL DAMAGES, INCLUDING CONSEQUENTIAL DAMAGES OR DAMAGES FOR BUSINESS INTERRUPTION OR LOSS OF PROFIT, REVENUE, MATERIALS, ANTICIPATED SAVINGS, DATA, CONTRACT, GOODWILL OR THE LIKE (WHETHER DIRECT OR INDIRECT IN NATURE) OR FOR ANY OTHER FORM OF INCIDENTAL, OR INDIRECT DAMAGES OF ANY KIND, SHALL NOT BE AVAILABLE. THESE PRODUCTS ARE BEING SOLD ONLY FOR THE PURPOSE DESCRIBED HEREIN, AND SUCH WARRANTY ONLY RUNS TO THE PURCHASER.

IN NO EVENT SHALL BAYLIS MEDICAL BE LIABLE FOR ANY BREACH OF WARRANTY IN ANY AMOUNT EXCEEDING THE PURCHASE PRICE OF THE PRODUCT. SELLER'S MAXIMUM CUMULATIVE LIABILITY RELATIVE TO ALL OTHER CLAIMS AND LIABILITIES, INCLUDING OBLIGATIONS UNDER ANY INDEMNITY, WHETHER OR NOT INSURED, WILL NOT EXCEED THE COST OF THE PRODUCT(S) GIVING RISE TO THE CLAIM OR LIABILITY. SELLER DISCLAIMS ALL LIABILITY RELATIVE TO GRATUITOUS INFORMATION OR ASSISTANCE PROVIDED BY, BUT NOT REQUIRED OF SELLER HEREUNDER. ANY ACTION AGAINST SELLER MUST BE BROUGHT WITHIN EIGHTEEN (18) MONTHS AFTER THE CAUSE OF ACTION ACCRUES. THESE DISCLAIMERS AND LIMITATIONS OF LIABILITY WILL APPLY REGARDLESS OF ANY OTHER CONTRARY PROVISION HEREOF AND REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY) OR OTHERWISE, AND FURTHER WILL EXTEND TO THE BENEFIT OF SELLER'S VENDORS, APPOINTED DISTRIBUTORS AND OTHER AUTHORIZED RESELLERS AS THIRD-PARTY BENEFICIARIES. EACH PROVISION HEREOF WHICH PROVIDES FOR A LIMITATION OF LIABILITY, DISCLAIMER OF WARRANTY OR CONDITION OR EXCLUSION OF DAMAGES IS SEVERABLE AND INDEPENDENT OF ANY OTHER PROVISION AND IS TO BE ENFORCED AS SUCH.

IN ANY CLAIM OR LAWSUIT FOR DAMAGES ARISING FROM ALLEGED BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, PRODUCT LIABILITY OR ANY OTHER LEGAL OR EQUITABLE THEORY, THE BUYER SPECIFICALLY AGREES THAT BMC SHALL NOT BE LIABLE FOR DAMAGES OR FOR LOSS OF PROFITS, WHETHER FROM BUYER OR BUYER'S CUSTOMERS. BMC'S LIABILITY SHALL BE LIMITED TO THE PURCHASE COST TO BUYER OF THE SPECIFIED GOODS SOLD BY BMC TO BUYER WHICH GIVE RISE TO THE CLAIM FOR LIABILITY.

Buyer covenants not to use the RF Generator in conjunction with any unauthorized products, items, consumables, disposables, equipment or parts.

Buyer specifically agrees that Baylis Medical shall not be liable for damages, personal injury or death if the RF Generator is used in conjunction or with any unauthorized products, items, consumables, disposables, equipment or parts.

Buyer specifically agrees that Baylis Medical shall not be held to any indemnification of the Buyer for claims resulting in damages, personal injury or death if the RF Generator is used in conjunction or with any unauthorized products, items, consumables, disposables, equipment or parts.

Buyer will not resell or redistribute Products to entities or persons, except with Baylis Medical's prior written consent.

No agent, employee or representative of Baylis Medical has the authority to bind the Company to any other warranty, affirmation or representation concerning the product.

This warranty is valid only to the original purchaser of Baylis Medical products which are directly purchased directly from a Baylis Medical authorized agent. The original purchaser cannot transfer the warranty.

The warranty periods for Baylis Medical products are as follows:

| | |
|------------------------------------|--------------------------------|
| RF Generator Baylis #: RFP-100A | 1 year from the shipment date |
| Foot Switch Baylis #: RFA-FS | 90 days from the shipment date |