COVIDIEN

Operation Manual

ClosureRFG™

Radiofrequency Generator

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parties hereby submit to the jurisdiction of the courts of the Commonwealth of Massachusetts.

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Chapter 1

Overview & General Features

Overview

Caution

U.S. federal law restricts the ClosureRFG generator to sale by or on the order of a physician.

Important

Prior to using the Covidien ClosureRFG radiofrequency generator, read this manual and review the warnings and cautions in it for important safety information.

The ClosureRFG generator is a product of Covidien. It is designed to provide controlled delivery of radiofrequency (RF) energy to RF catheters marketed by Covidien.

The ClosureRFG generator is for use with Covidien ClosureFast™ endovenous radiofrequency catheters and Covidien ClosureRFS™ endovenous radiofrequency stylets. Throughout this manual, the term "catheter" generally refers to both compatible ClosureFast catheters and ClosureRFS stylets that can be attached to the ClosureRFG generator.

Important

Please refer to the instructions for use included with the RF catheters for more information, such as clinical procedures, cautions, warnings, precautions, potential complications, and contraindications.

Additional technical details for the ClosureRFG generator are contained in Chapter 10, *Service & Maintenance*.

Indications for Use

The ClosureRFG generator is used with radiofrequency catheters intended for vessel and tissue coagulation.

Intended Use

The ClosureRFG radiofrequency generator supplies, measures, and displays RF output power, load impedance (ClosureRFS only), and elapsed time of RF delivery. The ClosureRFG generator also interfaces with a sensor in the catheter to provide a continuous display of measured temperature during RF delivery.

Equipment Type

The Class I ClosureRFG generator is designed to work with Type CF, defibrillator-proof RF catheters. The ClosureRFG generator will withstand an application of an external defibrillator while the RF catheter is in use.

Supported Accessories and Equipment

The ClosureRFG radiofrequency generator supports the following accessories

- Power cords as required for each geographical region
- The following RF treatment catheters
  - Covidien ClosureRFS endovenous radiofrequency stylets with cord length of 8 ft.
  - Covidien ClosureFast 7 cm endovenous radiofrequency catheters with cord length of 8 ft.
  - Covidien ClosureFast 3 cm endovenous radiofrequency catheters with cord length of 8 ft.

Important

The catheters listed above have a voltage rating that is higher than the maximum delivered by the ClosureRFG generator.

Refer to the RF treatment catheter's instructions for use for more information.

Caution

Use of unapproved RF delivery catheters or accessories may result in unanticipated performance, patient/operator safety hazard and increased emissions or decreased immunity.

- A USB drive for data export
- An SD data card to store generator treatment data (used for troubleshooting)
- A calibration test cable for connecting the ClosureRFG generator to a calibrated test load

Visual Indicators

The ClosureRFG radiofrequency generator includes the following visual indicators, not including the screen (see *Front Panel* on page 1-4)

- **RF Power:** Two software-controlled LEDs in the upper corners of the front illuminate blue when RF power is being delivered (RF power-delivery indicators)
- **AC Power Switch:** Indicates when the ClosureRFG generator is turned on

Audible Indicators

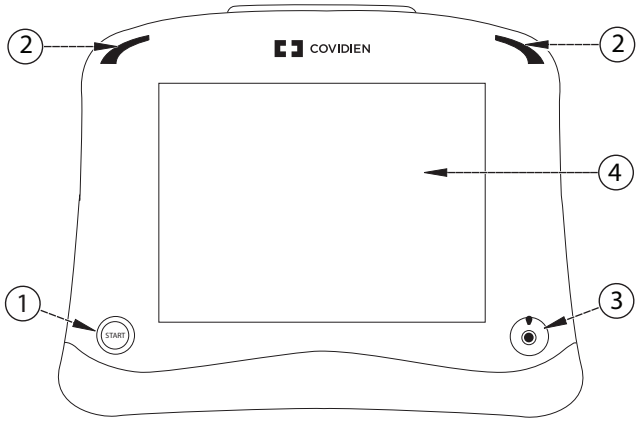
The ClosureRFG generator has audible indicators designed to alert the operator. Sound levels of alarm tones can be set to be compatible with the treatment environment.

- **Alarm, medium priority:** Three rapid, mid-frequency mixed tones
- **Informational:** Single short, high-frequency pure tone
- **RFS Advisory:** Two short informational tones
- **Power On:** Three ascending-scale pure tones
- **RF Start:** Single, long mid-frequency pure tone
- **RF Stop:** Single, long mid-frequency pure tone (Same as RF Start)
- **RF Ramp up:** Single, long, lower-volume mid-frequency pure tone
- **RF On:** Two short mid-frequency tones, the first at a higher frequency than the second
- **Valid key entry or button pushed:** Single short, high-frequency pure tone
- **Invalid entry:** Single short, low-frequency raspy tone

Important

Each button press produces a tone. If a button fails to sound, this indicates a button malfunction, and the ClosureRFG generator needs to be serviced.

Front Panel



The ClosureRFG radiofrequency generator front panel has the following buttons and indicators:

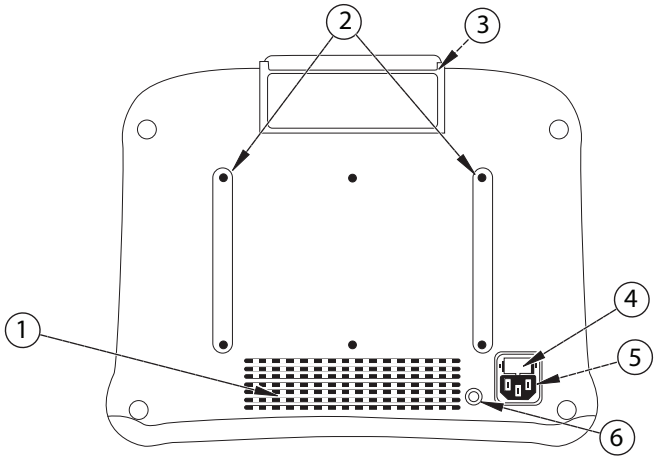
① **AC Power Switch:** Illuminates when AC power is provided to the ClosureRFG generator.

② **RF Power -Delivery Indicators:** Turns on when the ClosureRFG generator is first powered on, and when RF power is being delivered.

③ **Catheter Connector:** Receptacle for the catheter.

④ **Touch Screen:** Controls all functions of the ClosureRFG generator.

Rear Panel



The ClosureRFG radiofrequency generator rear panel includes these features:

① **Vent Openings:** Provide cooling air to the electronics. Do not block these openings.

② **AC Power Cord Wrap:** When the ClosureRFG generator is not in use, unplug the unit from the AC power source and wrap the cord around this wrap area.

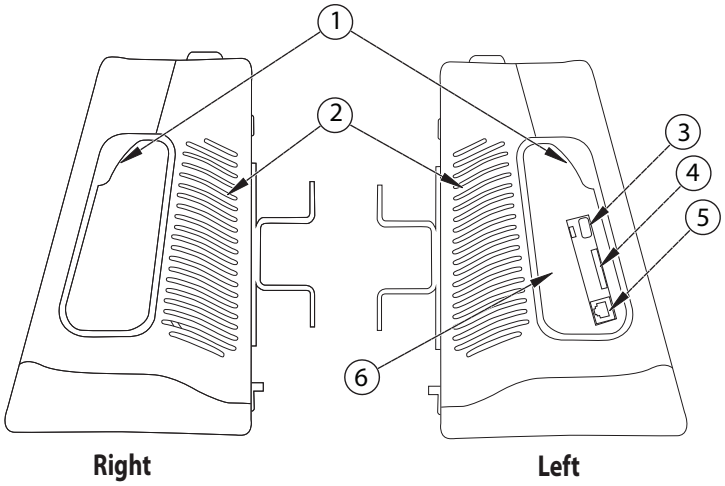
③ **Top Handle:** Best way to lift and carry the ClosureRFG generator.

④ **Fuse Holder:** Includes two 5A/250V, 5x20 mm fuses.

⑤ **AC Power Inlet:** Connects the AC power cord to the ClosureRFG generator.

⑥ **Equipotential Grounding Lug:** Provides a point for an auxiliary earth ground or ESD wrist-strap connection.

Side Panels



① **Handles**: The ClosureRFG radiofrequency generator has a handle on each side. Use these handles (or the top handle) while lifting or carrying the unit.

Caution

Be careful not to exert force to an attached USB device when picking up the ClosureRFG generator by the side handles.

② **Vent Openings:** Cooling air for the electronics.

③ **USB Slot:** Accepts a USB 2.0 device to export/store procedure data.

④ **SD Slot:** Accepts an SD card.

⑤ **Ethernet Service Port:** Used for calibration and repairs. For qualified service personnel only.

⑥ **Rubber Port Cover:** Provides a seal to limit liquid splashes getting into ports.

General Safety Guidelines

The safe and effective use of RF energy is highly dependent on factors under the operator's control. There is no substitute for properly trained staff. It is important to read, understand, and follow these directions.

The ClosureRFG radiofrequency generator is classified as an electrosurgical product. It must be operated in accordance with the guidelines in this section to ensure a safe environment and safe delivery of RF energy to the catheter. Failure to adhere to these guidelines might result in damage to the ClosureRFG generator and/or injury to the patient or user.

The ClosureRFG generator is for prescription use only. It is intended for use only by trained clinicians (operators) in a hospital or clinical environment.

The ClosureRFG generator contains no operator-serviceable parts. It must be returned to the factory for service.

Warnings and Safety Notices: Setting Up the ClosureRFG Generator

Warning

Electric Shock Hazard

- Do not use 3-to-2-prong grounding adapters.
- Always use an AC power center-tap configuration for 240 V single phase circuit.
- The ClosureRFG generator must only be connected to a supply mains with protective earth.
- Do not remove the cover of the ClosureRFG generator.

Fire and Explosion Hazard

- Do not operate the ClosureRFG generator in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Do not operate the ClosureRFG generator in contact with flammable materials, chemicals, or substances.
- Do not place active instruments near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical instruments that are activated or hot from use can cause a fire. When not in use, place electrosurgical instruments in a safety holster or safely away from patients, the surgical team, and flammable materials.
- Prevent pooling of flammable fluids and the accumulation of flammable or oxidizing gases or vapors under surgical drapes or near the surgical site. These fluids should be removed before use of electrosurgery.
- Use of electrosurgery may create arcing or embers that pose a fire hazard, especially in oxygen-enriched environments. Keep the device clean and free of all debris.

The ClosureRFG generator's performance may be affected by the use of portable and mobile communications equipment operating in near proximity. Refer to *Electromagnetic Interference (EMI)* on page 11-8 for more information.

Caution

Do not use the ClosureRFG radiofrequency generator if the AC power cord is damaged. Inspect the cord regularly for wear or damage. Damaged cords could result in patient or user injury.

The ClosureRFG generator produces high voltages on the catheter. Inspect all cables regularly for wear or damage. Discontinue use and discard the cable if damaged. Damaged cables could result in patient or user injury from electric shock.

Caution

Protect the ClosureRFG generator from exposure to extreme moisture to avoid electric shock and damage to the equipment.

To avoid unintentional burns, position the catheter away from the patient when the catheter is connected to the ClosureRFG generator but is not in use.

Important

The ClosureRFG generator is for use without a Neutral Electrode connection.

To allow generator heat to escape, verify that the ClosureRFG generator's vent openings, located on the sides and back of the unit, are not obstructed.

Avoid covering the speaker openings, to allow the operator to detect auditory tones.

Ensure the AC power switch on the front is accessible so that the ClosureRFG generator can be turned on and off.

Always refer to Covidien authorized personnel for service.

The ClosureRFG generator must be connected to an appropriate power source. Mains power quality should be that of a typical commercial or hospital environment.

If continued operation is required during power interruptions, the ClosureRFG generator must be powered from an uninterruptible power supply.

Warnings and Safety Notices: During RF Treatment

Warning

Use the ClosureRFG generator only with Covidien ClosureFast endovenous radiofrequency catheters or ClosureRFS endovenous radiofrequency stylets. DO NOT use catheters from any other manufacturer with the ClosureRFG generator as this may increase emissions, decrease immunity to interference, or injure the patient or user.

Be alert for potential interference with pacemakers and other active implants. In case of doubt, approved qualified advice should be obtained.

When the ClosureRFG generator is activated, the conducted and radiated electrical fields might interfere with other medical electrical equipment. Refer to *Electromagnetic Interference (EMI)* on page 11-8 for more information.

To prevent patient injury, always check if the measured temperature, impedance (RFS stylets), and RF power shown in the data display area are within safe operating ranges.

To avoid electric shock, while using the ClosureRFG radiofrequency generator, do not allow the patient to come into direct contact with grounded metal objects.

To avoid electric shock, avoid contact of cords and cables with the patient, leads, or other equipment.

Warning

Do not wrap the catheter cable around metal objects, as this might induce hazardous currents into the patient.

The ClosureRFG generator requires special precautions regarding Electromagnetic Compliance and needs to be installed and put into service according to *Electromagnetic Compliance (EMC)* on page 11-4.

ClosureRFG generator failure could result in an unintended increase in RF output.

Use of electrosurgery could result in neuromuscular stimulation resulting in patient injury.

Electrodes and probes for monitoring, stimulating, and imaging devices can provide paths for high-frequency current even if battery powered, insulated, or isolated at line frequency. The risk of burns can be reduced, but not eliminated, by placing these electrodes or probes as far away from the ablation site as possible. Protective impedance (Ω) incorporated into the monitoring leads may further reduce the risk of burns and permit continuous monitoring during RF energy delivery, Do not use needles as monitoring electrodes during procedures.

Caution

To prevent injury to the patient, do not start RF power until the catheter is properly positioned in the patient.

RF power activation tones and lights are important safety features. Do not obstruct indicator lights or the screen. Do not disable auditory tones.

The ClosureRFG generator should not be used adjacent to or stacked with other equipment. If adjacent use is necessary, the ClosureRFG generator should be observed to verify normal operation in the configuration in which it will be used.

Do not plug a wet catheter connector into a receptacle as it may damage the ClosureRFG generator.

Unpacking and Inspection of Components

Upon receiving the ClosureRFG radiofrequency generator, carefully unpack and inspect the items listed below:

- ClosureRFG generator without physical damage anywhere on the outside housing and screen
- Approved hospital-grade AC power cord, without cracks, frays, or any visible cord or plug damage
- CD-ROM, containing this operation manual

All damaged items must be repacked and returned to the Covidien Customer Service Department with prior approval. See *Repairs and Returns* on page 10-3 for contact information.

Chapter 2

ClosureRFG Generator Setup

Installation Requirements

Caution

The ClosureRFG radiofrequency generator must be installed and put into service according to the guidance provided in this document to ensure proper performance and its electromagnetic compatibility. If in doubt consult Covidien Customer Service or a local distributor.

The ClosureRFG generator should be used with only a hospital-grade power cord and plugged into only grounded hospital-grade AC sources.

The ClosureRFG generator requires an AC power source ranging from 100 VAC to 240 VAC, 50 Hz to 60 Hz, at 300 VA.

Mechanical Specifications

- Size: 26.7 cm H x 34 cm W x 17.3 cm D (10.5” x 13.4” x 6.8”)
- Weight: 6.8 kg (15 lb.) maximum

Location and Clearances

The ClosureRFG generator should be installed in a way that enables the operator to achieve optimal use, access all controls and view the operating screen.

Caution

Do not stack any items on top of the ClosureRFG generator. Doing so could damage the unit.

The ClosureRFG generator should not be used adjacent to other equipment. If stacked or adjacent use is necessary, the ClosureRFG generator should be observed to verify normal operation in the configuration in which it is used.

The ClosureRFG generator can generate EMI at any time. Refer to *Electromagnetic Interference (EMI)* on page 11-8 for cautions and warnings.

The ClosureRFG generator can be placed on any stable cart, table, or platform. Do not have it located so that it could fall onto a patient. It is recommended that a cart have conductive wheels and be rated to hold at least 6.8 kg (15 lb.). Refer to facility protocols and local ordinances for more information.

Provide at least 10 cm to 15 cm (4 in. - 6 in.) of space around the sides and back of the ClosureRFG generator for air circulation and cooling. After continuous use for extended periods of time, it is normal for the top to be warm.

The ClosureRFG generator cannot be sterilized and must not enter a sterile surgical field.

Essential performance for the ClosureRFG generator and associated catheters for electromagnetic compatibility is defined according to *Maximum Voltage Output* on page 9-3.

Applying AC Power

The ClosureRFG radiofrequency generator includes an approved hospital-grade AC power cord.

Prior to use, inspect the AC power cord, the AC power inlet, and the AC power outlet into which the unit plugs.

Caution

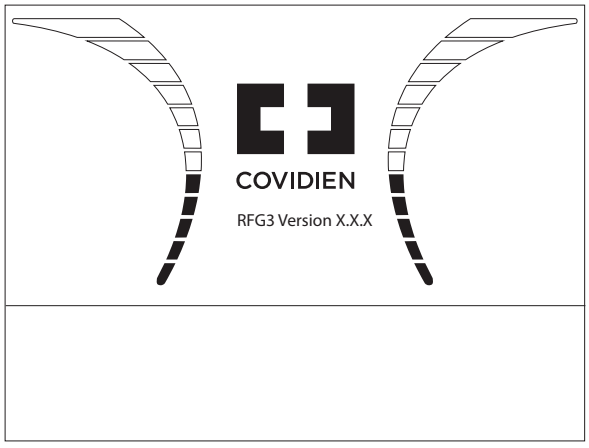
Do not plug the ClosureRFG generator into the AC power outlet if any of its surfaces appear to be cracked or damaged. Do not plug the ClosureRFG generator into a damaged outlet. Do not use a damaged AC power cord. Do not use extension cords, multiple portable outlets, or adapter plugs.

Observe the start-up sequence for correct behavior.

To turn on the ClosureRFG generator:

1. Plug the AC power cord into the AC power inlet at the back of the unit.
2. Plug the AC power cord into a grounded hospital-grade AC power outlet.
3. Push the AC power switch on the front panel to turn on the unit:
    - The AC power light illuminates green.
    - The RF power-delivery indicators flash and the screen turns white for a moment.
    - The Covidien logo appears, and the vertical arcs illuminate.

Covidien logo screen



4. The power-on tone sounds upon completion of a generator self-test.

Important

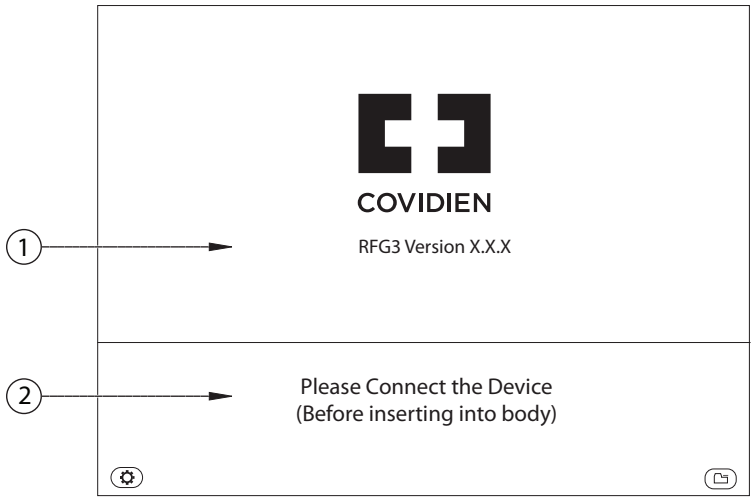
If the ClosureRFG generator fails to display the "Connect Device" message or sound the power-on tone, do not use the ClosureRFG generator. Refer to Chapter 8, *Troubleshooting*.

Standby Screen

When the system has powered up and no catheter is connected, the ClosureRFG radiofrequency generator displays "Please Connect the Device (before insertion into body)." The standby screen is shown in the following illustration.

The Options button (lower left) and Treatment History button (lower right) appear.

Power-on standby screen



The screen is divided into two areas with the data area above the message area.

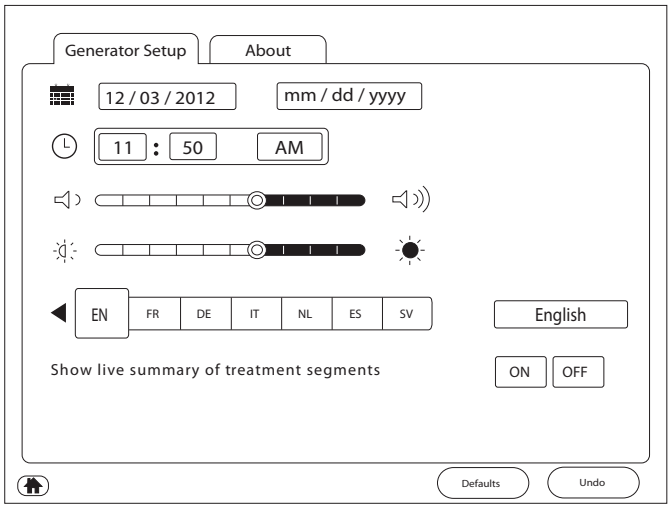
① The data area displays: measurements (temperature, power, impedance, and time); version and copyright; and treatment information.

② The message area displays: acknowledgements when a button is pressed; informational messages; instructions; and error messages [e.g., Please Connect the Device (Before inserting into body)].

Note: To ensure safe RF delivery, it is important to be familiar with how the ClosureRFG generator works, how to change desired settings, and how to interpret displays.

Press the **Options** button ⚙ on the lower-left side of the touchscreen. The Generator Setup screen will appear. When in the Generator Setup screen, the Options button is replaced by the Home button.

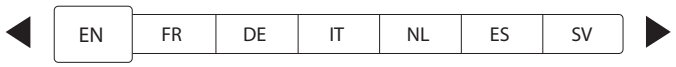
Generator setup screen



At any time

- Press the **Defaults** button (Defaults) to reset all settings except date/time to their factory settings.
- Press the **Undo** button (Undo) to undo any changes made since opening the Generator Setup screen.
- Press the **Home** button to accept the new settings and exit this screen.

Setting System Language



To select the language for the text in the displays

1. ◀ ▶ Press the Left- or Right-Arrow button to move the selection box in that direction along the selection bar,

   or

   [EN] Press the box for the language of choice. The selected language is shown in the text box at the right of the selection bar.

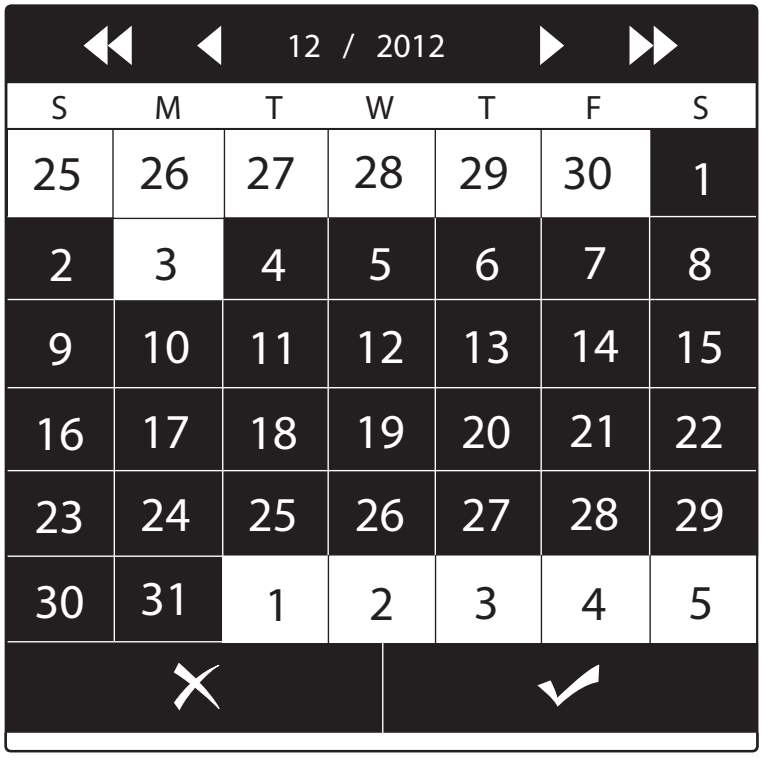
2. (Undo) To reject the language change, press the **Undo** button.

Setting System Date

12 / 03 / 2012

1. Press the Date button on the Generator Setup screen. A calendar is displayed.

Calendar screen



2. To change the **year**, press the left double-arrow button to decrease, or the right double-arrow button to increase.
3. To change the **month**, press the left single-arrow button to decrease, or the right single-arrow button to increase.
4. To change the **day**, press the number buttons on the number pad.
5. Press the **Green Check Mark** button to store the date and return to the Generator Setup screen.

   or

   Press the **Red X** button to return the date to the previous settings and return to the Generator Setup screen.

6. Press the **Date Format** button. The Date Format selection box is displayed.

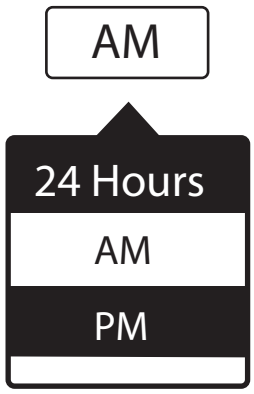
7. Press the row that displays the preferred date format.

Setting System Time

1. Press the hours or minutes button to change the corresponding value. A keypad is displayed.

2. Press the number buttons to set the hours or minutes.
3. Press the **Green Check Mark** button to save the entry, or **Red X** button to leave the pad without changes.

4. Press the **AM/PM/24 Hours** button to change between AM, PM, and 24-hour time.



5. Press the row that displays the preferred time format.

   Note: This system does not automatically adjust to Daylight Savings Time.

Adjusting Display Brightness

1. To change the brightness level:
   - Press the Brightness bar at the desired level, or
   - Press and drag the Slider button, or
   - Press the Dimmer or Brighter button.
2. To return the brightness to the previous setting, press the Undo button.

Adjusting Sound

1. To change the sound level:
   - Press the Sound Level bar at the desired level, or
   - Press and drag the Slider button, or
   - Press the Softer or Louder button.
2. To return the loudness to the previous setting, press the Undo button.

Total Treatment Summary Readout

Show live summary of treatment segments	**ON**	**OFF**

Press the ON or OFF button to select whether to display the summary on the screen during CLF catheter treatment.

Functional and Advisory Limits

Functional Limits: The ClosureRFG radiofrequency generator measures catheter and treatment parameters (temperature, impedance, RF power, and time) before and during RF treatment. These measured values must be within functional limits that are set to detect a catheter or generator malfunction before RF treatment can start or continue. The parameters are specific to the type of catheter attached.

If a value violates functional limits:

- RF treatment is prevented or stopped.
- An alarm tone (for high-temperature and high-power parameter functional limits) or an informational tone (for all other parameter conditions) sounds.
- During RF treatment, the gauge related to that parameter turns gray.
- An alarm message is displayed indicating the problem. The operator can press the Green Check Mark button, or allow it to clear itself in 30 seconds.
- Medium-priority errors also show the special icon ⚠ and sound a tone.

The operator must take some action (for example, acknowledge a prompt, replace the catheter) to clear the functional-limit violation.

Advisory Limits: If parameters are measured outside the advisory limits, but within the functional limits, a descriptive message appears and a tone sounds. Since these measurements are within the range of functional limits, treatment is still allowed.

Caution

Operation of the ClosureRFG generator during an advisory limits warning may cause suboptimal RF treatment. The ClosureRFG generator may not allow treatment to continue if the cause of the advisory message is allowed to persist.

- Advisory messages automatically clear when conditions causing the messages are gone.

Connecting a Catheter

Caution

Inspect the catheter cable for damage. If there is any, do not use the catheter.

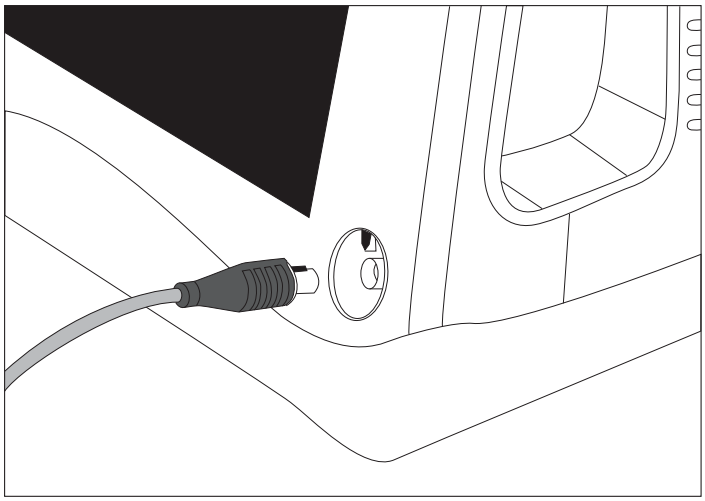
Damage could result to the catheter and the ClosureRFG radiofrequency generator if they are forced together when not aligned.

Important

The red mark on the ClosureRFG generator case must be aligned with the red raised line on the catheter connector before inserting it.

Insert the connector end of a Covidien ClosureFast endovenous radiofrequency catheter or Covidien ClosureRFS endovenous radiofrequency stylet into the receptacle on the front of the ClosureRFG generator.

Connecting a Device



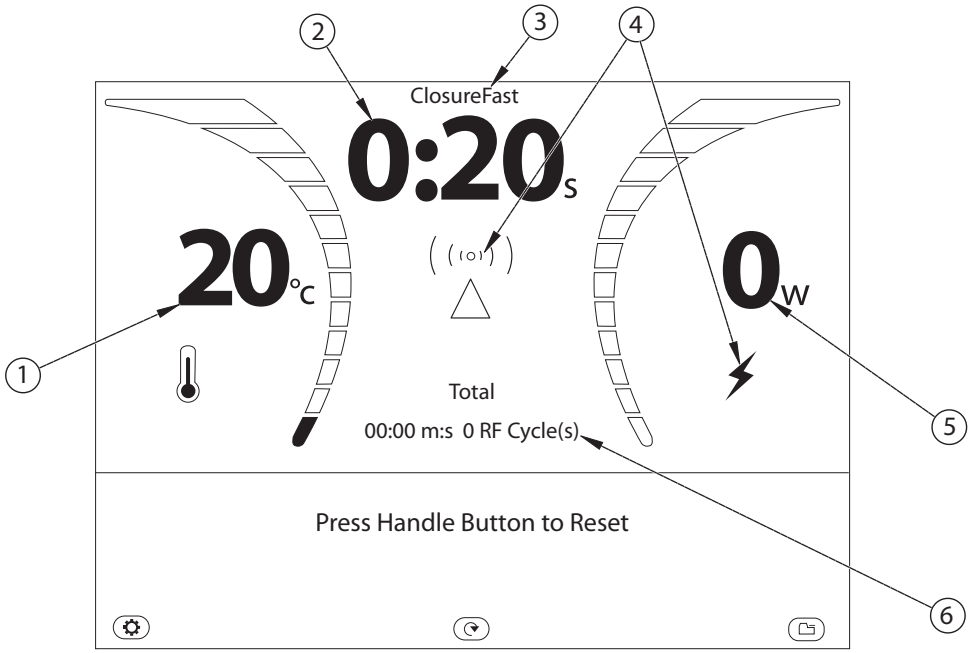
- If the catheter is unsupported, the message area shows, "The connected device is unsupported. Please connect another device."
- If the connected catheter is unknown or invalid, the message area shows, "The device is invalid."
- To disconnect a catheter, pull on only the connector, not the cable.

Chapter 3

Covidien ClosureFast Endovenous Radiofrequency Catheter Treatment

Ready-to-Treat Screen

ClosureFast ready screen



Whenever a Covidien ClosureFast Endovenous radiofrequency catheter is connected, this screen is present:

① **Catheter temperature:** Indicates current temperature of the catheter; it is not intended to measure patient body temperature.

② **Treatment Time:** Indicates, by counting down, the amount of time RF power has been delivered during the current RF treatment cycle. For CLF catheters, the preset treatment time is 20 seconds.

③ **Catheter Identifier:** "ClosureFast" is displayed.

④ **RF Ready Icons:** Indicates whether the ClosureRFG radiofrequency generator is ready to start RF treatment. When dark or gray, RF power is disabled due to a limit violation. When illuminated brighter, RF power is ready to be delivered to the catheter.

⑤ **RF Power:** Indicates RF power actively applied to the catheter.

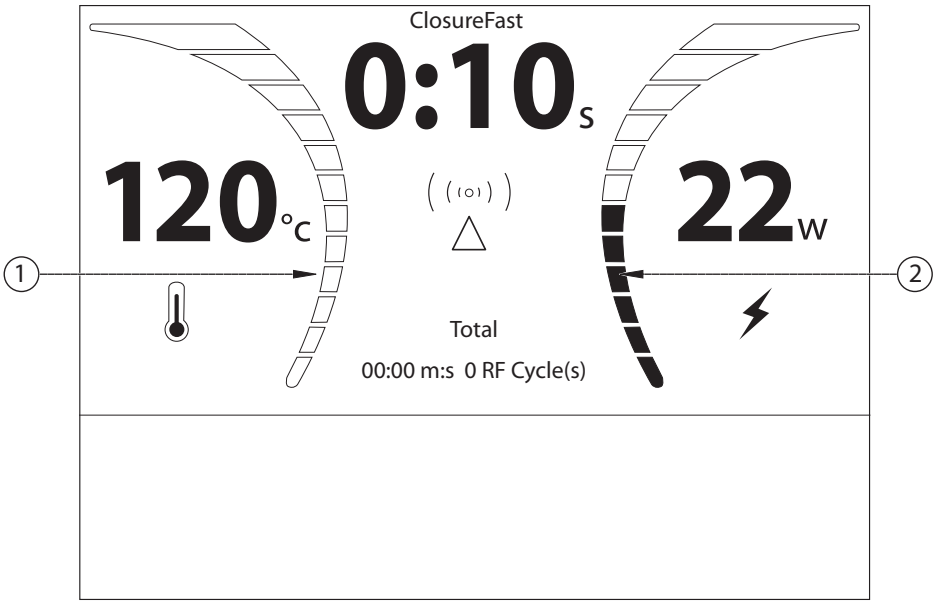
⑥ **Treatment Summary:** Indicates the total time and number of treatment cycles since reset, power on, or change of catheter, as minutes:seconds.

ClosureFast Catheter Gauges

Data Display with Gauges

Gauges indicate the measured parameter and whether the catheter's parameters (temperature and RF power) are within acceptable ranges. If a parameter is outside the advisory limits, its gauge brightens within the red area or lights only the blue area, a message is displayed, and a tone is sounded.

ClosureFast gauges during treatment



① The illumination of the **temperature** gauge segments:

- **Blue:** Cool; waiting for, or at the beginning of a heating cycle; or low during treatment
- **Blue-Green:** Within normal range after initial heating
- **Red:** Temperature above advisory or functional limit

② The illumination of the **power** gauge segments:

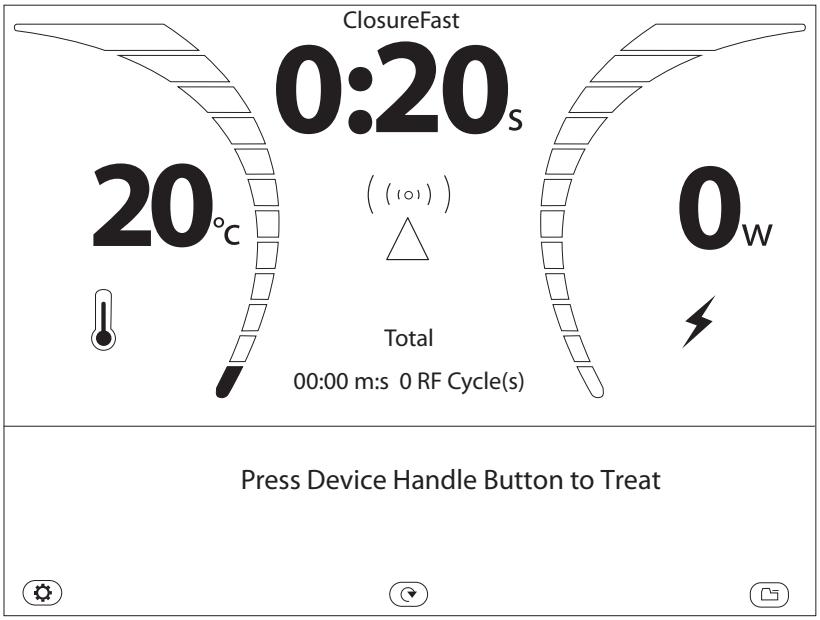
- **Blue:** Low but within limits
- **Blue-Green:** Within normal range
- **Red:** Power above advisory or functional limit

Note: For more information about these Limits, see *Functional and Advisory Limits* on page 2-8.

ClosureFast Catheter RF Treatment – Ready to Treat

The connected ClosureFast catheter displays the following screen. The ClosureRFG radiofrequency generator is ready to start treatment, as indicated by the green RF-ready icon.

Ready to treat with a ClosureFast catheter



Parameters of the catheter are checked before RF treatment is allowed. If the temperature and impedance are acceptable, the message "Press Handle Button to Treat" is shown.

Functional and Advisory Limits

Functional Limits with ClosureFast Catheters

- **Temperature:** Below 10° C and above 130° C for 1 second (calculated during the time the limit is exceeded).
- **Impedance:** Below 100 ohms for ClosureFast 7 cm, below 45 ohms for ClosureFast 3 cm, and above 300 ohms for 1 second. Measurements are not displayed.
- **RF power:** Above 60 watts for 1-5 seconds (calculated during the time the limit is exceeded).

Advisory Limits with ClosureFast Catheters

- **Temperature**
  - Below 30° C when starting RF treatment.
  - This occurs if the catheter hasn't been at 30° C or above since it was connected, implying it's not in the patient. The operator can override this warning.

    When the screen shows a Low Temperature warning, adjust the catheter or the application site if appropriate. Then, press the Green Check Mark button.
  - Below 100° C after several seconds of treatment. RF power stops before the countdown has completed. This likely indicates a condition of poor contact between the catheter and the tissue being treated (such as placement within the deep vein, or inadequate vessel exsanguination).
  - Falls below 118° C for more than 2 seconds after the setpoint temperature (120° C) is reached.
  - Above 125° C for 1-5 seconds (calculated during the time the limit is exceeded),

    Note: For more information, see *Functional and Advisory Limits* on page 2-8

Starting RF Treatment

Note: Review this section and *General Safety Guidelines* on page 10-1 before starting RF treatment.

Caution
Do not activate RF power until the catheter is properly positioned in the patient.

Important
Before starting RF treatment, thoroughly read the catheter's instructions for use. Confirm that the connected catheter matches the catheter type shown at the top of the Data Display area.
RF treatment can be stopped at any time, if necessary, by pressing the catheter handle button.

Note: The Treatment Summary, which is the accumulated time and cycles that the ClosureRFG radiofrequency generator applies power, can be displayed in the data area. Select this option in the Generator Setup screen.

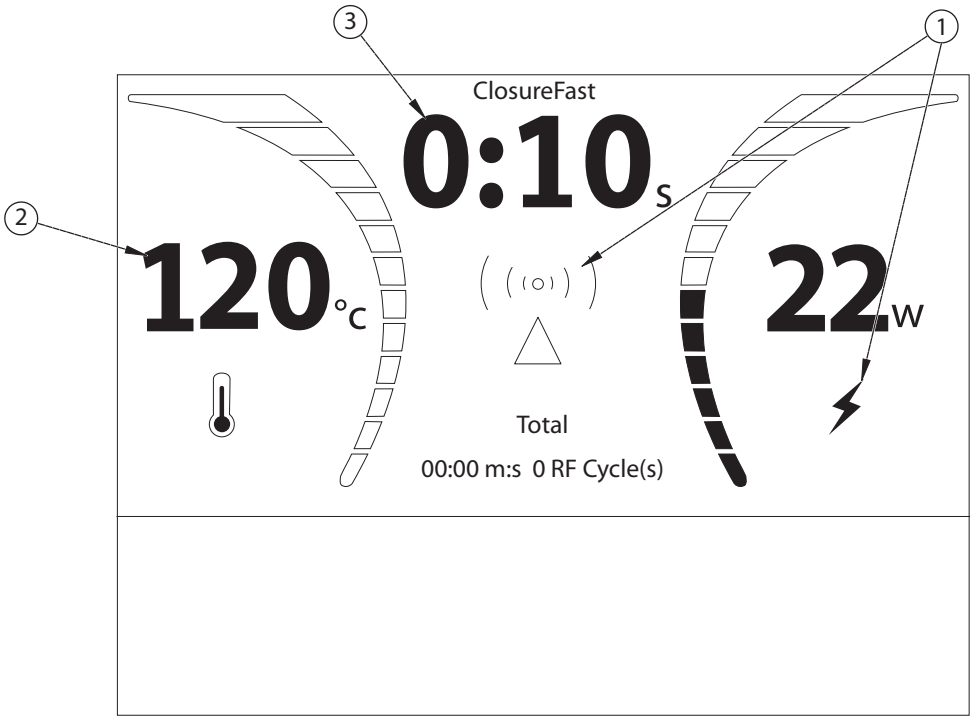
1. **Press the catheter handle button to start RF treatment.** This starts RF delivery, and changes the RF power icons to blue (1 in the following illustration). The RF-start tone sounds.
   a. The catheter temperature (2) increases toward the setpoint (120° C) and the timer (3) starts counting down.
   b. The RF ramp-up tone sounds for five seconds.

c. A message appears: "Device should reach target temperature in x seconds," with the time counting down.

d. When the setpoint is reached, the RF-on tone sounds every few seconds.

e. The ClosureRFG generator holds temperature at 120° C until the RF treatment time of 20 seconds has completed.

ClosureFast RF treatment in progress



2. RF delivery stops automatically when the 20-second RF treatment cycle is complete.

Warning

If RF treatment does not stop, disconnect the catheter to prevent injury to the patient.

The RF status icon changes from blue to green to indicate Ready to Treat again, and the timer resets to 20 seconds. Cumulative Treatment Summary messages appear in the message area:

a. "Press Device Handle Button to Treat"

b. "RF cycle completed at XXX°C YY W"

c. "Total Treatment Time = mm:ss, # RF Cycle(s)"

d. If the option has been selected in Generator Setup, this Treatment Summary is also displayed in the data area.

3. If additional treatment is needed,
   a. Reposition the catheter (and/or adjust compression) for the next RF treatment.
   b. Press the **catheter handle button** to start the next RF treatment.
4. Repeat step 3 until the procedure is completed.

Stopping RF Treatment

RF treatment stops automatically, since each cycle has a fixed time. If it's found necessary to stop RF treatment before the timer finishes, press the catheter handle button.

Note: See *Treatment Time Reset—Using the Same Catheter* on page 5-2 for an explanation of the treatment record.

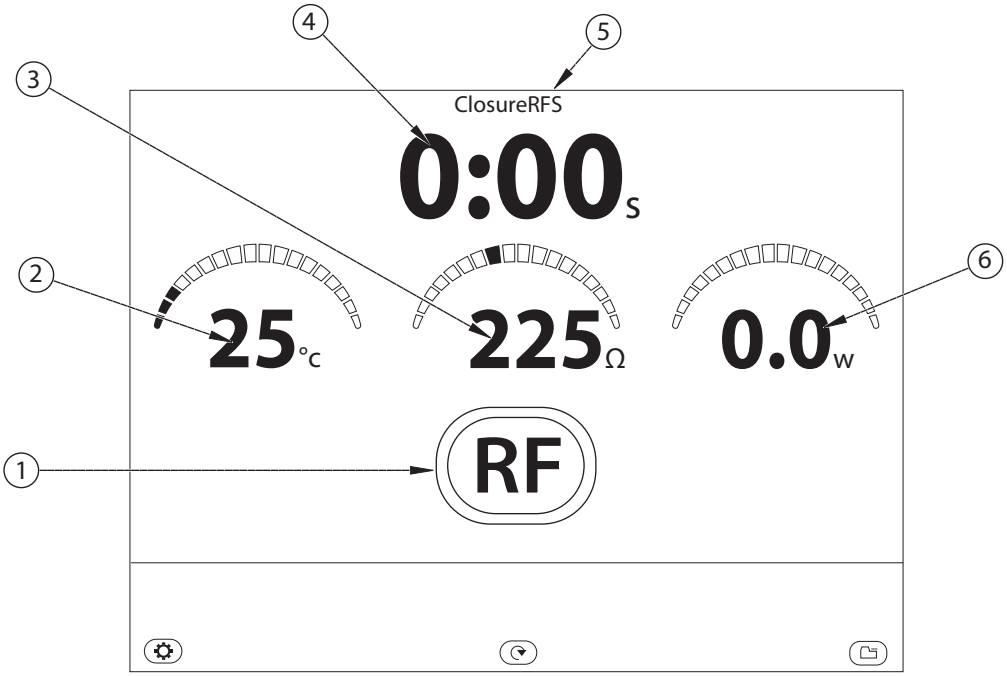
Note: See *Export—RF Treatment Data Storage* on page 5-3 for steps to export the treatment history.

Chapter 4

Covidien ClosureRFS Endovenous Radiofrequency Stylet Treatment

Ready-to-Treat Screen

ClosureRFS ready to treat screen



Whenever a ClosureRFS stylet is connected, this screen is present:

① **RF Start button:** Starts RF treatment. Changes to the blue RF Stop button when pressed.

② **Stylet temperature:** Indicates current temperature of the connected stylet; it is not intended to measure patient body temperature.

③ **Stylet impedance:** Indicates current impedance of the connected stylet

④ **Elapsed Treatment Time:** Indicates the amount of time RF power has been delivered during the current RF treatment cycle.

⑤ **Stylet Identifier:** "ClosureRFS" is displayed.

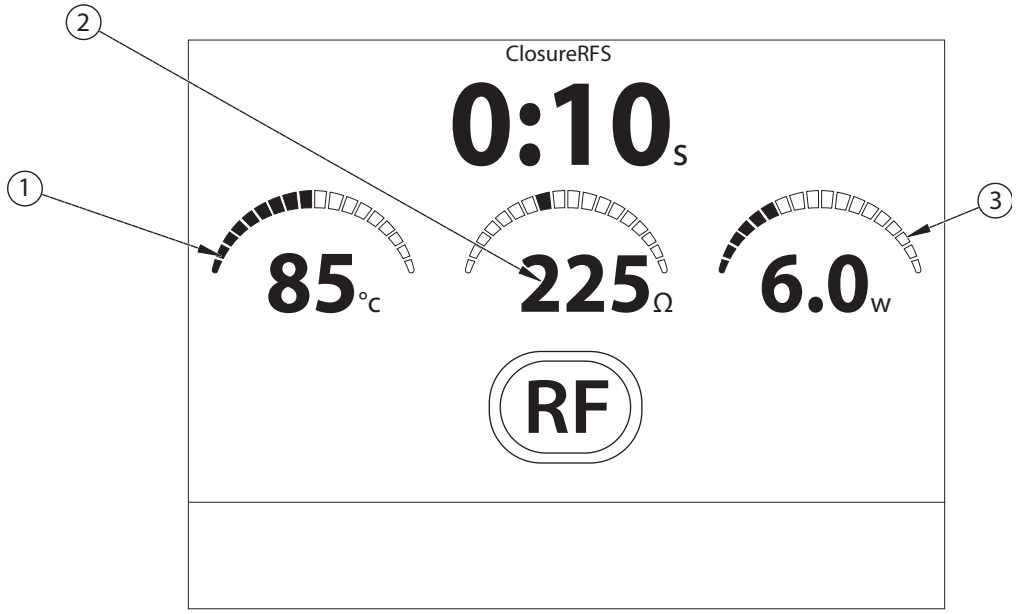
⑥ **RF Power:** Indicates RF Power actively applied to the stylet.

ClosureRFS Stylet Gauges

Data Display with Gauges

Gauges indicate the measured parameter and whether the stylet's parameters (temperature, impedance, and RF power) are within acceptable ranges. If a parameter is outside the advisory limits, its gauge brightens within the red area or lights only the blue area, a message is displayed, and a tone is sounded.

ClosureRFS gauges during treatment



① Illumination of the **temperature** gauge segments:

- **Blue:** Cool, waiting for, or at the beginning of a heating cycle; below advisory limit during treatment
- **Blue-Green:** Within normal range (after initial heating)
- **Red:** Temperature above advisory or functional limit

② Location of the bright **impedance** gauge segments:

- **Red-yellow (low end):** Below advisory or functional limit
- **Blue-Green:** Within normal range to advisory
- **Red:** Above advisory or functional limit

③ Illumination of the **Power** gauge segments:

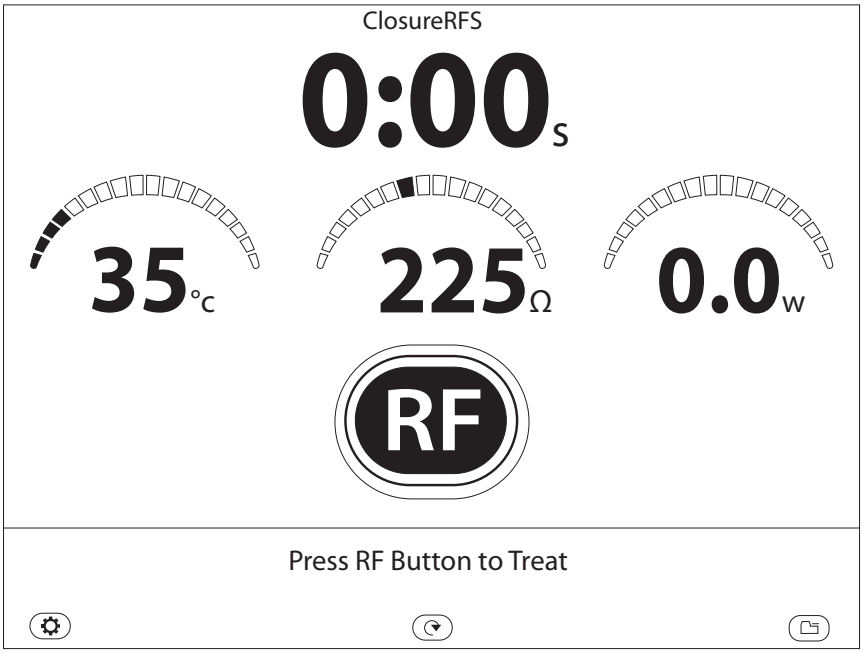
- **Blue and Blue-Green:** Within normal range to advisory
- **Red:** Above advisory or functional limit

Note: For more information about these limits, see *Functional and Advisory Limits* on page 4-3.

ClosureRFS Stylet RF Treatment—Ready to Treat

The connected ClosureFast stylet displays the following. The ClosureRFG radiofrequency generator is ready to start treatment, as shown by the green RF Start button.

Ready to treat with a ClosureRFS stylet



Parameters of the stylet are checked before RF treatment is allowed. If the temperature and impedance are acceptable, the message "Press RF Button to Treat" is shown.

Functional and Advisory Limits

Functional limits with ClosureRFS stylets

- **Stylet temperature:** below 10° C and above 110° C for 1-5 seconds (calculated during the time the limit is exceeded)
- **Impedance:** below 25 ohms and above 1000 ohms for 1 second
- **RF power:** above 7 watts for 1-2 seconds (calculated during the time the limit is exceeded)

Advisory limits for RF Treatment ClosureRFS stylets during treatment

- **Temperature:** below 80° C or above 92° C for 1-10 seconds (calculated during the time the limit is exceeded)
- **Impedance:** below 110 or above 400 ohms for 1-50 seconds (calculated during the time the limit is exceeded)
- **RF power:** above 5 watts for 1-3 seconds (calculated during the time the limit is exceeded)

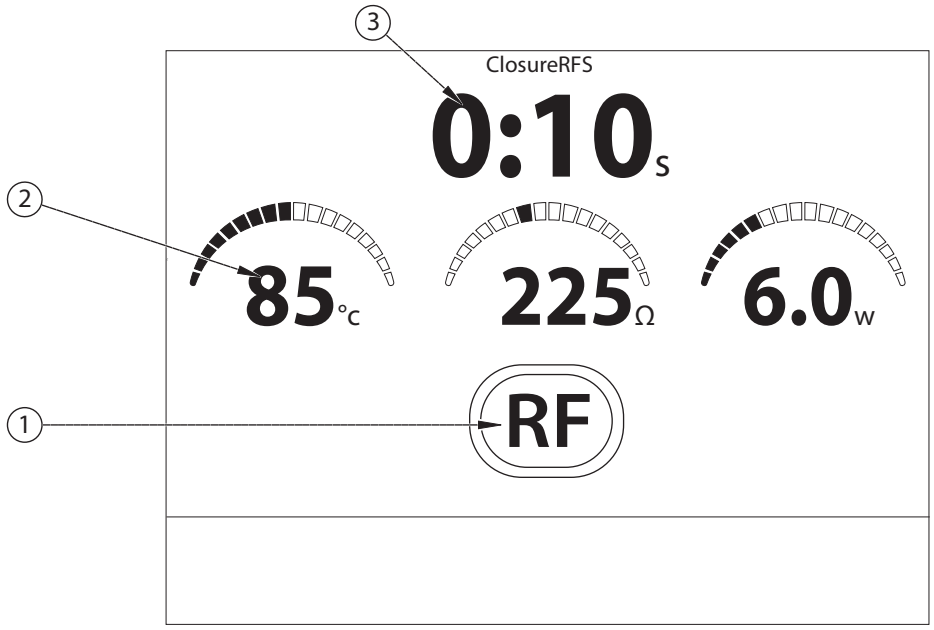
Starting RF Treatment

Caution
Do not activate RF power until the stylet is properly positioned in the patient.

Important
Review this section and *General Safety Guidelines* on page 1-6 before starting RF treatment.
Before starting RF treatment, thoroughly read the stylet's instructions for use. Confirm that the connected stylet matches the stylet type shown at the top of the Data Display area.
RF treatment can be stopped at any time, if necessary, by pressing the RF Stop button.

1. Press the **RF Button** (RF) on the screen to start RF treatment. This starts RF delivery, and changes the RF Start button face to blue, with a white border (1 in the following illustration). The RF start tone sounds.
   a. The stylet temperature (2 in the following illustration) increases towards the set point (85° C).
   b. The RF ramp-up tone sounds for several seconds.
   c. A message appears: "Device should reach target temperature in x seconds," with the time counting down.
   d. When the setpoint is reached, the RF ON tone sounds every few seconds.
   e. The ClosureRFG radiofrequency generator holds temperature at 85° C until treatment is stopped by pressing the RF Stop button.

ClosureRFS RF treatment in progress



2. During treatment, the RF advisory tone sounds every 60 seconds to aid in timing stylet movement.

Stopping RF Treatment

Warning

If RF treatment does not stop, disconnect the stylet to prevent injury to the patient.

1. When the procedure is done, press the **RF Stop** button (RF) on the screen to stop RF treatment.
   a. The RF Stop button changes from blue to the green RF Start button.
   b. The Treatment Timer (3 in the previous illustration) displays the time that RF power was applied to the stylet in this cycle.
   c. The data record (not shown on screen) will contain the total treatment time (identical to Treatment Time shown on the screen) and one RF treatment cycle.
   d. The screen displays "Press RF Button to Treat."

Important

Do this next step only if treatment was stopped with the intention to continue. The displayed cycle time will reset to zero and the total treatment time will continue to accumulate with further treatment.

2. If additional treatment is needed,
   a. Press the **RF Start** button (RF) on the screen.
   b. The screen's Treatment Timer resets to zero and starts counting up.
3. Move the stylet as directed in the stylet's instructions for use.
4. Press the **RF Stop** button (RF) on the screen to pause RF treatment, or when the procedure is finished.

   Note: The Treatment Timer displays the time for *only this cycle.*
5. Repeat steps 2-4 as needed.
6. When finished with the procedure, press the **Treatment History** button to obtain the total treatment time, which will be in the first data record on page 1.

Chapter 5

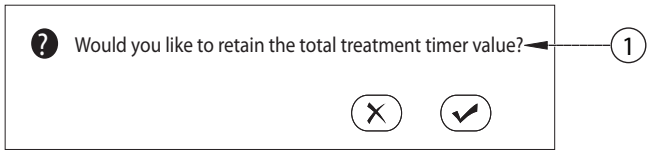
Treatment Times

Retain Total Treatment Timer—Connecting a New Catheter

When Used

- An RF treatment has been completed, either CLF or RFS.
- The catheter was unplugged and reconnected, or a new one of the same type connected.
- Power was not cycled on the ClosureRFG radiofrequency generator.

When a catheter is disconnected and the same or identical one reconnected, it will be used on either the same patient/patient site, or a new patient/patient site. The screen shows this question:



① Would you like to retain the total treatment timer value?

How

- **Same patient or site:** To continue adding to the previous timer value, press the **Green Check Mark** button. The ClosureRFG generator will behave as if the catheter had never been unplugged.
- **Different patient or site:** To reset the timer to zero, press the **Red X** button. This closes the current record (stores the accumulated treatment time and cycles), and opens a new data record for the next RF treatment.

Treatment Time Reset—Using the Same Catheter

When Used

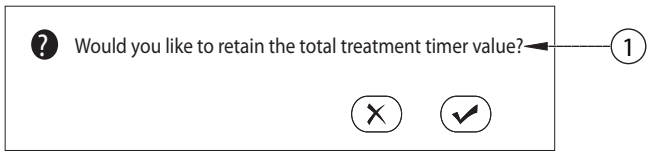
- An RF treatment has been done, either CLF or RFS.
- The catheter will be reused at a different patient site.
- The ClosureRFG radiofrequency generator was not power cycled.

RF treatment sometimes occurs at more than one site in a patient. If the operator wants to use the same catheter, and also wants a record of the treatment time at each site, the record for one site must be closed, and a new record for the next site opened.

How

To reset the RF treatment Timer to zero (and open a new record)

1. Press the **Reset Timer Value** button at the bottom of the screen. The screen prompts for confirmation.



   ① Would you like to retain the total treatment timer value?

2. Press the **Green Check Mark** button to reset the RF treatment timer, and open a new record.

   or

   Press the **Red X** button to cancel the reset, and continue with the current record.

   The timer will also be reset to zero and a new record opened with the following steps:

   a. Unplug the catheter and then reconnect, or connect another catheter of the same type.

   b. The screen prompts, "Would you like to retain the total treatment timer value?"

   c. Press the **Red X** button to not retain the Treatment Timer, and start a new treatment record. This will perform the reset.

      Note: Cycling power on ClosureRFG generator will also reset the timer and close the current record.

Export—RF Treatment Data Storage

Using Memory Cards

Memory Cards (USB devices and SD cards) can store data from recent procedures and log generator errors. The USB port is intended for the use only with a single, un-powered USB 2.0 storage device.Covidien supplies the SD card.

Caution
Proper ESD precautionary procedures should be used when handling, inserting, or removing a memory device. The USB and SD ports are for use only by trained personnel.
Do not insert a memory device during RF treatment.
Before handling the memory device, discharge any static electricity by touching the metal ground of the ClosureRFG radiofrequency generator (the ground lug on the back). Alternatively, use an ESD wrist strap to bond to the ClosureRFG generator's ground lug or to a known earth ground. This is important to avoid electrostatic discharge damage to the memory device.

All personnel who handle the memory device should receive an explanation of the ESD warning symbol and training in ESD precautionary procedures. This includes clinical/ biomedical engineering and health-care staff. At minimum, this training should include:

- An introduction to the physics of electrostatic charge
- The voltage levels that can occur in normal practice
- The damage that can be done to electronic components when equipment is touched by an operator who is electrostatically charged
- How and why to discharge one's body to earth or to the frame of the ClosureRFG generator, or bond oneself by means of a wrist strap to the ClosureRFG generator or to earth prior to handling the memory device

USB Devices

A USB device is used for saving RF-treatment summary data, as seen on the treatment-history screen.

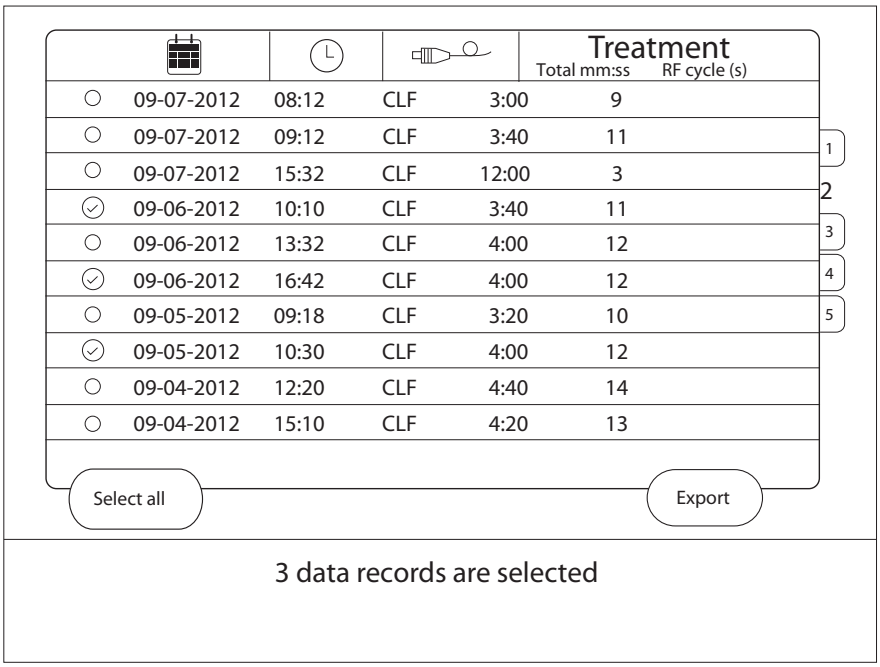
Export RF Treatment Data to USB

To export treatment summary data to a USB device

1. Use a tool, such as a small screwdriver, to carefully pry off the rubber port cover on the left side panel.
2. Insert any compatible USB media into the ClosureRFG radiofrequency generator USB port. Allow a few seconds as the system maps the USB device.
3. On the standby screen, press the Treatment History button  in the lower-right corner.

The treatment history screen appears.

Treatment history screen



There are up to 5 pages of history, which can be changed in the Generator Setup screen. The latest record is at the top of page 1. When entering this screen, all entries not exported so far are already selected.

4. Perform one of the following actions
   a. If the selection is correct, go to step 5, below
   b. To remove entries from export, press the circled checks on the left of the items.
   c. To add entries to export, press the open circles.
   d. Press **Select All** to select the complete list.
   e. Press **Select All** again to get a Clear All button, if needed.
5. Press **Export** to export the data to the USB.

   Note: The next time this screen is entered, all records not previously exported will be checked.

   Note: If the USB is full, or no records are selected, a message states "No records exported." Insert a different USB card or select records to export.
6. Remove the USB device
7. Insert another USB device, or attach the rubber port cover.

USB Data Structure

The file names on the USB are determined with this scheme:

YYMMDDHHMMSS.VPD

Where

- YY – last two digits of the year
- MM – month (1-12)
- DD – the day of the month (1-31)
- Time – Hour, minute, second in 24-hour format of when the export was done

The data format on the USB is 'CSV', which can be imported into a spreadsheet application, for example. The columns are: RF treatment date, RF treatment start time (24-hour format), type of catheter, total RF treatment time, and number of RF cycles.

Examples

2012-09-24,13:32,CLF,15:12,14

2012-09-23,16:32,RFS,5:12,1

SD Cards

The SD card stores ClosureRFG radiofrequency generator treatment data for troubleshooting (these records are not saved in the ClosureRFG generator if the SD card is not present). Logging occurs without notification to the operator. The data is accessible only to a qualified Covidien Service Representative.

Important

The SD card should be left in the ClosureRFG generator at all times. However, if necessary to remove/replace the SD Card:

1. Use a tool, such as a small screwdriver, to carefully pry off the rubber port cover on the left side panel.
2. Press the card in to unlatch it from the connector, and then pull the card out.
3. Insert another card if appropriate.
4. Attach the rubber port cover.
5. The screen shows the Not Installed icon if the SD card is not recognized  .

Chapter 6

Messages, Tones, and Responses

Condition and System Responses

Name	Action	User Action
High Temperature Advisory	Display: "Advisory: Temperature high" Sound: Informational Tone.	None required
Low Temperature Advisory	Display: "Advisory: Temperature low" Sound: Informational Tone.	None required
High Impedance Advisory	Display: "Advisory: Impedance high" Sound: Informational Tone.	None required
Low Impedance Advisory	Display: "Advisory: Impedance low" Sound: Informational Tone.	None required
Low Power Advisory	Display: "Advisory: Power low" Sound: Informational Tone.	None required
High Power Advisory	Display: "Advisory: Power high" Sound: Informational Tone.	None required
High Impedance Functional Advisory	Display: "Advisory: Impedance high. Check Connection." Sound: Informational Tone.	None required
Low Impedance Functional Advisory	Display: "Advisory: Impedance low. Replace catheter."Sound: Informational Tone.	None required
High Power And High Temperature Advisory	Clear any advisory message. Display: "Advisory: Temperature high, power high" Sound: Informational Tone.	None required
Low Power And High Temperature Advisory	Clear any advisory message. Display: "Advisory: Temperature high, power low" Sound: Informational Tone.	None required
High Impedance And High Temperature Advisory	Clear any advisory message. Display: "Advisory: Temperature high" Sound: Informational Tone.	None required

Name	Action	User Action
Low Impedance And High Temperature Advisory	Clear any advisory message. Display: "Advisory: Temperature high" Sound: Informational Tone.	None required
High Power And Low Temperature Advisory	Clear any advisory message. Display: "Advisory: Temperature low, power high" Sound: Informational Tone.	None required
Low Power And Low Temperature Advisory	Clear any advisory message. Display: "Advisory: Temperature low, power low" Sound: Informational Tone.	None required
High Impedance And Low Temperature Advisory	Clear any advisory message. Display: "Advisory: Temperature low" Sound: Informational Tone.	None required
Low Impedance And Low Temperature Advisory	Clear any advisory message. Display: "Advisory: Temperature low" Sound: Informational Tone.	None required
High Power And High Impedance Advisory	Clear any advisory message. Display: "Advisory: Power high" Sound: Informational Tone.	None required
Low Power And Low Impedance Advisory	Clear any advisory message. Display: "Advisory: Power low" Sound: Informational Tone.	None required
High Power And Low Impedance Advisory	Clear any advisory message. Display: "Advisory: Power high" Sound: Informational Tone.	None required
Low Power And High Impedance Advisory	Clear any advisory message. Display: "Advisory: Power low" Sound: Informational Tone.	None required
Low Power And High Temperature Advisory	Clear any advisory message. Display: "Advisory: Temperature high. Power low" Sound: Informational Tone.	None required
High Power Low Temperature And Low Impedance Advisory	Clear any advisory message. Display: "Advisory: Temperature low. Power high. Impedance high" Sound: Informational Tone.	None required
High Power High Temperature And Low Impedance Advisory	Clear any advisory message. Display: "Advisory: Temperature high. Power high. Impedance low" Sound: Informational Tone.	None required

Name	Action	User Action
High Power Low Temperature And High Impedance Advisory	Clear any advisory message. Display: "Advisory: Temperature low. Power high. Impedance high" Sound: Informational Tone.	None required
High Power High Temperature And High Impedance Advisory	Clear any advisory message. Display: "Advisory: Temperature high. Power high. Impedance high" Sound: Informational Tone.	None required
High Temperature Functional Limit	Clear any advisory message. Display: "Treatment Halted: Temperature high. Please press ✓ to continue." Sound: Audio Medium Alarm. Wait for User Acknowledgement.	User acknowledgement
Low Temperature Functional Limit	Clear any previous Advisory condition. Display: "Treatment Halted: Temperature low. Please press ✓ to continue." Sound: Informational Tone. Wait for User Acknowledgement.	User acknowledgement
High Impedance Functional Limit	Display: "Treatment Halted: Impedance high. Please press ✓ to continue." Sound: Informational Tone. Wait for User Acknowledgement.	User acknowledgement
Low Impedance Functional Limit	Display: "Treatment Halted: Impedance low. Please press ✓ to continue." Sound: Informational Tone. Wait for User Acknowledgement.	User acknowledgement
High Power Functional Limit	Display: "Treatment Halted: Power high. Please press ✓ to continue." Sound: Audio Medium Alarm. Wait for User Acknowledgement.	User acknowledgement
Low Power Functional Limit	Display: "Treatment Halted: Power low. Please press ✓ to continue." Sound: Informational Tone. Wait for User Acknowledgement.	User acknowledgement
Catheter Disconnected	Display: "Treatment Halted: Device disconnected. Please press ✓ to continue." message. Sound: Informational Tone. Wait for User Acknowledgement.	User acknowledgement
Advisory Catheter Broken	Display: "The connected device is broken. Please connect another device." Sound: Informational Tone. Wait for User Acknowledgement.	User acknowledgement. Replace catheter.

Name	Action	User Action
Functional Catheter Broken	Display: "Treatment Halted. Device Broken. Please press ✓ to continue." Sound: Informational Tone. Wait for User Acknowledgement.	User acknowledgement. Replace Catheter.
Seconds Within Target Temperature Range	Display: "XX seconds within target temperature range. Press handle button to treat. Total treatment time = MM:SS, YY RF cycle(s)"	None required
Low Temp Verify Catheter In Body	Sound: an invalid tone. Display: "Low Temp. Verify device is in body – Press ✓ to Confirm." Sound: Informational Tone. Wait for User Acknowledgement.	User acknowledgement
Adjust Compression Advisory	Display: "Advisory: Temperature low, power high. Adjust Compression." Sound: Informational Tone.	Adjust compression
Terminate ClosureFast Treatment	Display: "Target temperature not reached. RF cycle stopped at mm:ss, X°C, Y W. Press Device Handle Button to Treat." Sound: Informational Tone.	None required
Terminate ClosureFast Complete Cycle	Press Device Handle button to Treat. RF cycle completed at mm:ss, X°C, Y W. Z Total Treatment Time = mm:ss, N RF Cycle(s).	None required
Terminate ClosureFast Impedance	Display: "Treatment Halted: Non-uniform temperature. Adjust compression along heating element. SS Seconds within target temperature range." Sound: Informational Tone.	Adjust compression
ClosureFast Catheter Ready	Display: "Press Device Handle Button to Treat."	None required
ClosureRFS Catheter Ready	Display: "Press RF Button to Treat. Total Treatment Time = mm:ss."	None required
Treatment Summary Auto Selected	Display: "N records auto-selected since last export (date)."	None required
Treatment Summary N Records Selected	Display: "N records selected for export."	None required
Export In Process	Display: "Exporting in process, do not remove USB device."	None required
Treatment Summary Export Completed	Display: "Treatment summary data exported. Ok to remove USB device."	Remove USB device

Name	Action	User Action
Treatment Summary Export Failed	Display: "Treatment summary data export failed."	Use another USB device
USB Device Full	Display: "Device full. Please replace with another USB device." "No records exported."	Use another USB device
USB Not Installed	Display: "USB device is not installed." "No records exported."	Insert USB device
ClosureFast Treatment Ramp Up	Display: "Device should reach target temperature in XX seconds." Output RF ramp up tone.	None required
Confirm Discard	Display: "Would you like to retain the total treatment timer value?" Wait for User Acknowledgement.	User acknowledgement
Error Log Corruption	Display: "Error Log Corrupted. All error entries have been erased. Press OK to restart system." Wait for User Acknowledgement.	User acknowledgement. Generator restarts.
Non Recoverable Error	Display: "Error #ww. Press ✓ to restart." in the message area. Display: the error code only as part of this message. Display: Standby screen in the Data Area. Wait for User Acknowledgement. Restart generator.	User acknowledgement. Generator restarts.
Recoverable Error	Display: "Error #ZZ. Press ✓ to restart." in the message area. Display: the error code only as part of this message. Display: Standby screen in the Data Area. Sound: Informational Tone. Wait for User Acknowledgement.	User acknowledgement.
Unsupported Catheter	Display: "The connected device is unsupported. Please connect another device."	Replace catheter

Audible Signals

The ClosureRFG radiofrequency generator produces a audible signal for out-of-limit conditions based on the power, temperature, and impedance measurements.

During multiple message or tone conditions, the message or tone with the highest priority takes precedence, as shown in the following two tables.

Alarm settings are not configurable; an interruption of power will maintain the alarm setting.

Alarm Condition Priority

Priority	Alarm Condition
Medium	High-Power Functional Limit
Medium	High-Temperature Functional Limit

Alarm Priority Sound Pressure

Priority	Sound Pressure Level
Medium	>45 dB

Message Priority

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

Tone Priority

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

Chapter 7

Error Codes

If an error occurs, the ClosureRFG radiofrequency generator displays an error code. An error is one of two types: unrecoverable or recoverable.

- **Unrecoverable** errors stop the ClosureRFG generator from functioning and require the operator to acknowledge the condition. Once the operator presses the green check-mark, the ClosureRFG generator (itself or with assistance) cycles power to continue. If the problem persists, contact Covidien Customer Service or a local distributor.
- **Recoverable** errors require the operator to respond to an error message or make a clinical decision. After acknowledgement, the ClosureRFG generator returns to the last viewed screen.

Error codes

Error Code	Description	Corrective Action
1	Unexpected state.	Cycle system power and allow the POST testing to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
2	Unexpected event.	
3	A parameter value was incorrect.	
4	A queue overflowed.	
5	Unit not responding.	A communication cable within the unit has failed or is not installed correctly. Cycle power on the system and allow the POST testing to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
6	Software version incorrect.	Cycle system power and insert a USB device with the latest SW. Upgrade the system using the About tab. Cycle system power. If the system does not respond and/or the same error code is displayed, contact Covidien customer service
7	Memory corruption detected.	Cycle system power and allow the POST testing to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.

Error Code	Description	Corrective Action
8	Resource conflict.	Cycle system power and allow the POST testing to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
21	Memory failure.	
22	Memory failure.	
23	UIC watchdog failure	
24	Operator-stored settings invalid. Default settings restored.	Go to the Settings screen on the device and press the Defaults button. Cycle system power. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
25	The inserted USB device does not contain valid information or is missing files.	Cycle system power without the USB device installed. Allow the system to boot and then insert the USB device. If the error persists, use a known, valid USB device. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
26	The inserted USB device cannot upgrade this ClosureRFG generator because its serial number does not match.	Cycle system power without the USB device installed. Allow the system to boot and then insert the USB device. If the error persists, attempt to use a known, valid USB device. Verify that the serial number on the rear of the device matches the serial number given on the About tab of the Settings menu. If the serial numbers do not match and/or the same error code is displayed, contact Covidien customer service.
28	The inserted USB device is not correctly formatted or is an invalid type.	Cycle system power without the USB device installed. Allow the system to boot and then insert the USB device. If the error persists, attempt to use a known, valid USB device. Reformat the USB device by right clicking the device and selecting "format" on your PC. The device must be formatted to FAT32. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
29	The ClosureRFG radiofrequency generator is unable to write data to the USB device.	
30	The inserted USB device is full and no more data can be stored on it.	Remove the USB device, clear the data on the device and reinstall. Cycle system power and allow POST to complete.If the issue persists, try a different USB device. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
31	The real-time clock stopped and has been restarted.	Go to the Settings screen on the device and press the Defaults button. Cycle system power. After POST, re-enter the Settings screen and adjust the date and time as explained in *Setting System Time* on page 2-6. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.

Error Code	Description	Corrective Action
32	The inserted USB device is not formatted.	Cycle system power without the USB device installed. Allow the system to boot and then insert the USB device. If the error persists, attempt to use a known, valid USB device. Reformat the USB device by right clicking the device and selecting "format" on your PC. The device must be formatted to FAT32. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
34	A UIC Software Task did not check in with the Task Monitor.	Cycle system power and allow the system POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
35	The ClosureRFG generator has experienced more than five resets in one minute.	Unplug the system's power cord from the wall. Re-insert the plug into the wall receptacle and allow the system POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
36	A Software Stack became corrupt.	Cycle system power and allow the POST to complete. If the error persists, insert a USB device with the latest system SW. Upgrade the system from the About tab. Cycle system power. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
37	The temperature of the ClosureRFG generator is above the specified operating temperature.	Cycle system power allow the POST to complete. If the error persists, insert a known, working catheter and cycle system power again. Should the internal temperature of the device remain too high and the error persists, disconnect the power cord from the power source. Allow 30 minutes for the device to cool to ambient temperature. Re-attach the system to the power source and allow the unit to complete the POST. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
38	The temperature of the ClosureRFG generator is below the specified operating temperature.	Cycle system power and allow the POST testing to complete. If the error persists, insert a known, working catheter. Cycle the system power again. Should the internal temperature of the device remains too low and the error persists, allow the system to sit in an on state for a minimum of 30 minutes. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
39	Real Time Clock Failure.	Cycle system power and allow the POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.

Error Code	Description	Corrective Action
40	The installed SW is not compatible with the HW revision.	Cycle system power and insert a USB device with the latest system SW. Upgrade the system from the "About" tab. Cycle the system power again. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
41	The ClosureRFG generator unexpectedly reset.	Cycle system power and allow the POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
43	This error indicates that there is something wrong with the software.	Cycle system power and insert a USB device with the latest system SW. Upgrade the system from the "About" tab. Cycle system power again. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
44	This error indicates that error log was corrupt and has been cleared.	Remove the USB device, clear the data on the device and reinsert. Cycle system power and allow POST to complete. If the issue persists, reformat the USB device on your PC by right clicking the device and selecting "format." The device must be formatted to FAT32. If the issue is seen again, try a different USB device. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
45	The error occurs when the measure mode power is greater than 10 mW for more than 1 second.	Cycle system power and allow the POST testing to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
46	There is something wrong with the UIC Flash and the software was unable to correctly write data to it.	Cycle system power and insert a USB device with the latest system SW. Upgrade the system using the "About" tab. Cycle system power again. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
47	Touchscreen error.	Cycle system power and allow the POST testing to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.

Error Code	Description	Corrective Action
101	Temperature is too low.	Cycle system power and allow the POST to complete. If the error persists, insert a known, working catheter and cycle system power. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
102	Temperature is too high.	
103	Impedance is too low.	
104	Temperature and Impedance are too low.	
105	Temperature is too high and Impedance is too low.	

Error Code	Description	Corrective Action
106	Impedance is too high.	Cycle system power and allow the POST to complete. If the error persists, insert a known, working catheter and cycle system power. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
107	Temperature is too low and Impedance is too high.	
108	Temperature and Impedance are too high.	
109	Power is too low.	
110	Temperature and Power are too low.	
111	Temperature is too high and Power is too low.	
112	Impedance and Power are too low.	
113	Temperature, Impedance, and Power are too low.	
114	Temperature is too high. Impedance and Power are too low.	
115	Impedance is too high and Power is too low.	
116	Temperature and Power are too low. Impedance is too high.	
117	Temperature and Impedance are too low. Power is too high.	
119	Power is too high.	
120	Temperature is too low. Power is too high.	
121	Impedance is too low and Power is too high.	
122	Temperature and Impedance are too low. Power is too high.	

Error Code	Description	Corrective Action
123	Temperature and Power are too high. Impedance is too low.	Cycle system power and allow the POST to complete. If the error persists, insert a known, working catheter and cycle system power. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
124	Impedance and Power are too high.	
125	Temperature is too low. Impedance and Power are too high.	
126	Temperature, Impedance, and Power are too high.	
201	Temperature is too high.	
202	Temperature is too low.	
203	Impedance is too high.	
204	Impedance is too low.	
205	Power is too high.	
206	Power is too low.	
314	Task took too long to complete.	Cycle system power and allow the POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
350	Temperature exceeds a safety limit.	Cycle system power and allow the POST to complete. If the error persists, insert a known, working catheter. Cycle system power again. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
352	The catheter power exceeded the ClosureRFG radiofrequency generator Power Alarm Limit.	
354	The catheter voltage exceeded the ClosureRFG generator Voltage Alarm Limit.	
358	The catheter was disconnected while in Measure or Treatment Mode.	

Error Code	Description	Corrective Action
360	The HW Power limit was exceeded.	Cycle system power cycle and allow the POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
363	The output relay was open when it should have been closed.	
364	A broken thermocouple was detected.	Cycle system power and allow the POST to complete. If the error persists, insert a known, working catheter. Cycle system power again. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
450	Generator ROM Failure.	Cycle system power cycle and allow the POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
451	Generator RAM Failure.	
452	Generator Watchdog Failure	
455	Generator power supply temperature exceeds specification.	
457	The Catheter ID circuitry failed to correctly read the ID Calibration Load.	Cycle system power and allow the POST to complete. If the error persists, insert a known, working catheter. Cycle system power again. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
459	The calibration coefficients are corrupt.	Cycle system power cycle and allow the POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
460	Generator failed calibration check.	
461	The Primary Side Power Measurement and Catheter Side Power Measurement differ by more than the allowed value.	Cycle system power and allow the POST to complete. If the error persists, insert a known, working catheter. Cycle system power again. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
462	The Isothermal Reference and Isothermal Backup differ by more than the allowed value.	Cycle system power cycle and allow the POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.

Error Code	Description	Corrective Action
468	More than 5 resets occur within 1 minute. Could occur when operator repeatedly cycles RF treatment.	Unplug the system's power cord from the wall. Re-insert the plug into the wall receptacle and allow the system POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
469	The installed generator software is not compatible with the HW revision.	Cycle system power and insert a USB device with the latest system SW. Upgrade the system using the "About" tab. Cycle system power again. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
470	The ClosureRFG radiofrequency generator Output Relay is stuck closed.	Cycle system power cycle and allow the POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
471	The ClosureRFG generator Calibration Load Relay is stuck closed.	
472	The ClosureRFG generator Phase Offset is too large.	
473	The Safety Enable is not functioning correctly.	
474	The ClosureRFG generator Output RF Indicator is fault.	
475	The power supply is in error more than ±10%.	
476	The ClosureRFG generator High Speed ADC is saturate.	Cycle system power and insert a USB device with the latest system SW. Upgrade the system using the "About" tab. Cycle system power again. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
477	The ClosureRFG generator HW Power Limit is faulty.	Cycle system power cycle and allow the POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.

Error Code	Description	Corrective Action
478	The ClosureRFG generator SW is not able to control the isolated power supply enable.	Cycle system power and insert a USB device with the latest system SW. Upgrade the system using the "About" tab. Cycle system power again. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
479	RF Amplifier cannot be enabled.	Cycle system power cycle and allow the POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
480	The ClosureRFG generator's -15 V power supply has failed.	
481	The frequency source of the ClosureRFG generator is not correct.	
482	The ClosureRFG generator has too much offset in the catheter ID circuit.	Cycle system power and allow the POST to complete. If the error persists, insert a known, working catheter. Cycle system power again. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.
483	The uncorrected impedance of Catheter 28 is less than 1400 or greater than 1900 ohms.	
484	The uncorrected phase of Catheter 28 is less than –40 or greater than 0 degrees.	
485	The HZLT calibration coefficients are not valid.	Cycle system power cycle and allow the POST to complete. If the system does not respond and/or the same error code is displayed, contact Covidien customer service.

Chapter 8

Troubleshooting

Technical Assistance

To obtain technical assistance, contact Covidien Customer Service or a local distributor. See Chapter 10, *Service & Maintenance* for contact information.

The following sections suggest ways to troubleshoot three levels of problems: no power, RF treatment (procedure and catheter) problems, and generator functionality errors.

Generator Fails to Power On

If the ClosureRFG radiofrequency generator fails to power on, check for obvious conditions that may have caused the problem:

- Check the ClosureRFG generator for visible signs of physical damage.
- Check the power cord. Replace the power cord if you find exposed wires, cracks, frayed insulation, or a damaged connector.
- Verify that the wall outlet is supplying power.

Refer to Chapter 10, *Service & Maintenance* for more information.

RF Treatment Difficulties

During RF treatment, the ClosureRFG radiofrequency generator monitors the catheter's parameters (temperature, impedance, and RF power). Should one of these measurements be too high or too low, the ClosureRFG generator may stop RF treatment, sound an alarm, display an alarm message, and/or and flash this icon:

The following tables describe some situations that the operator might encounter. They do not include every possible situation that might occur.

Note: For more information, please refer to the catheter's instructions for use.

RF Treatment Difficulties – ClosureFast Endovenous Radiofrequency Ablation (RFA) Catheter

ClosureFast Catheter Difficulty	Possible Cause	Corrective Action
Unable to activate RF power	Body temperature not measured	Verify that the catheter has been inserted into the body and is properly positioned to begin RF treatment. Press the Green Check Mark button to proceed.
	Connected catheter is broken	Check the catheter connector to verify that it is plugged in properly and is not broken. Replace catheter.
	Temperature low; Tumescent fluid at room temperature surrounds tip of catheter	Verify that the catheter has been inserted into the body and is properly positioned to begin RF treatment. Press the Green Check Mark button to proceed.
Power high	Inadequate vessel exsanguination	Verify that the catheter is properly positioned. Check for flow, and employ or improve compression techniques as necessary.
Temperature low	Inadequate vessel exsanguination	Verify that the catheter is properly positioned. Check for flow, and employ or improve compression techniques as necessary.
	Saline in catheter connector	Check for presence of saline. If present, contact Covidien Customer Service. (Caution: Take care never to plug a wet catheter connector into the receptacle, as this may damage the ClosureRFG generator).
	Catheter, cable, or connector is damaged	Check all connections, cable, and the catheter for visible damage. Replace catheter.
	Temperature decreases as power is applied	Replace catheter.
Temperature high	Saline in catheter connector	Check for presence of saline. If present, contact Covidien Customer Service. (Caution: Take care never to plug a wet catheter connector into the receptacle, as this may damage the ClosureRFG radiofrequency generator).
Non-uniform temperature	Uneven compression across full length of heating element	Note catheter position with shaft markers. Check catheter and replace if damaged. If not damaged, insert catheter to desired location, Verify that the catheter is properly positioned. Employ or improve compression techniques as necessary.

ClosureFast Catheter Difficulty	Possible Cause	Corrective Action
Impedance low (not displayed)	Saline in catheter connector and/or receptacle	Check for presence of saline. If present, contact Covidien Customer Service. (Caution: Take care never to plug a wet catheter connector into the receptacle, as this may damage the ClosureRFG generator).
	Short circuit	Replace catheter.
Impedance high (not displayed)	Open circuit	Check catheter connection (disconnect and then re-connect).

RF Treatment Difficulties - ClosureRFS Endovenous Radiofrequency Stylet

ClosureFast Catheter Difficulty	Possible Cause	Corrective Action
Impedance low	Inadequate electrode-vein wall contact	Improve or employ vein compression techniques.
	Saline in device connector and/or receptacle	Check for presence of saline. If present, contact Covidien Customer Service. (Caution: Take care never to plug a wet catheter connector into the receptacle, as this may damage the ClosureRFG radiofrequency generator.)
	Short circuit	Replace stylet.
Impedance high	Coagulum formation on electrodes	Check stylet tip for coagulum and remove as required.
	Stylet not in contact with target tissue	Verify that the stylet is properly positioned.
	Open circuit	Check stylet connection (disconnect and then reconnect). Replace stylet.
Power high	Too much blood flow Pullback rate too fast	Check and improve exsanguination. Verify proper pullback rate.
Temperature low	Inadequate vessel exsanguination	Verify that the device is properly positioned. Check for flow, and employ or improve compression techniques as necessary.
	Pullback rate too fast	Verify proper pullback rate.
	Saline in device connector	Check for presence of saline. If present, contact Covidien Customer Service. (Caution: Take care never to plug a wet catheter connector into the receptacle, as this may damage the RF generator.)
	Stylet, cable, or connector is damaged	Check all connections, cable, and the stylet for visible damage. Replace stylet.
Temperature high	Saline in stylet connector	Check for presence of saline. If present, contact Covidien Customer Service. (Caution: Take care never to plug a wet device connector into the receptacle, as this may damage the RF generator.)

ClosureFast Catheter Difficulty	Possible Cause	Corrective Action
Unable to start RF treatment	Temperature and/or impedance parameter outside functional limits	Check stylet tip for coagulum and remove as required. Verify that stylet is properly positioned. Check stylet connection (disconnect and then re-connect).
	Temperature low; Tumescent fluid at room temperature surrounds tip of catheter	Verify that the catheter has been inserted into the body and is properly positioned to begin RF treatment. Press the Green Check Mark button to proceed.

Error Codes—Generator

If a ClosureRFG radiofrequency generator system error occurs, the screen displays an error code. An error is one of two types: unrecoverable or recoverable.

- Unrecoverable errors stop the ClosureRFG generator and the ClosureRFG generator must be power cycled
  - Turn off the unit, wait a few seconds, and then turn on the unit.
  - If the problem persists, contact Covidien Customer Service or a local distributor.
- Recoverable errors need only to be acknowledged when the error message appears on the screen. The ClosureRFG generator should function normally after acknowledgement.
- Recoverable errors may require the operator to respond to an error message or make a clinical decision.

Some errors require pressing the Green Check Mark button, after which the ClosureRFG generator will reboot.

Note: See Chapter 7, *Error Codes* for a list of all errors and their messages.

Chapter 9

Technical Specifications

Equipment Type

For ClosureRFG radiofrequency generator repairs or returns, call the Covidien Customer Service Department. The ClosureRFG generator may be returned to the factory.


The Class I ClosureRFG radiofrequency generator is designed to work with Type CF, Defibrillator-Proof RF catheters. The ClosureRFG generator is designed to withstand an application of an external defibrillator while the RF catheter is in use.

Electrical: ClosureRFG Generator

- Operates from an AC power source ranging from 100 V to 240 VAC, 50 Hz to 60 Hz, 5A.
- Includes a DIN 42801–compatible equipotential grounding lug that meets the ground bond requirements of UL 60601–1.
- USB: 2.0 devices only

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

100-120 VAC, 5 A

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

220-240 VAC, 5 A

- Cable: H05VVF3G1.0 VDE, maximum length 10 ft. (3 m)
- Plug: minimum 6 A - 240 VAC
- Unit receptacle: IEC female, minimum 6 A - 240 VAC

Conditions for Transporting and Storing the ClosureRFG Generator

-  Temperature between -20° C and 70° C
-  Relative humidity (non-condensing) between 10% and 90% for temperatures between -4° F and 104° F (-20° C and 40° C), and between 10% and 60% for temperatures between 104° F and 158° F (40° C and 70° C).
-  Ambient atmospheric pressure between 500 hPa and 1060 hPa

Conditions for Operating the ClosureRFG Generator

-  Temperature between 10° C and 40° C
-  Relative humidity (non-condensing) between 10% and 90%
-  Ambient atmospheric pressure between 700 hPa and 1060 hPa (equivalent to elevation between 3000 m and -300 m)

RF Power Delivery Performance

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

Measurement Tolerances

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

* RF power is measured on the isolated patient circuit and is the average power. The RF power capacity is also limited by the Maximum Power (W) setting of the connected RF catheter.

Note: Refer to the RF catheter's instructions for use for more information.

Maximum Output

Maximum Voltage Output

Device	Maximum Voltage* (Vpeak)	Load Ω	Crest Factor	Maximum Power* (Watts)
ClosureFast endovenous radiofrequency ablation (RFA) catheter 7 cm	206	100 - 300	1.7	40
ClosureFast endovenous radiofrequency ablation (RFA) catheter 3 cm	206	45 - 300	1.7	18
ClosureRFS endovenous radiofrequency stylet	125	110 - 400	1.6	6

***** Maximum voltage and power limited by software

The RFG3 Software is designed to limit the output control depending on the accessory being used. For example, ClosureFast endovenous radiofrequency ablation catheter 7 cm is limited to 40 W maximum, ClosureFast endovenous radiofrequency ablation catheter 3 cm is limited to 18 W maximum and ClosureRFS endovenous radiofrequency stylet is limited to 6 W maximum. The active load for maximum power output is 100 - 300 ohms for ClosureFast endovenous radiofrequency ablation catheter 7 cm, 45 - 300 ohms for ClosureFast endovenous radiofrequency ablation catheter 3 cm and 110 - 400 ohms for ClosureRFS endovenous radiofrequency stylet.

Duty Cycle

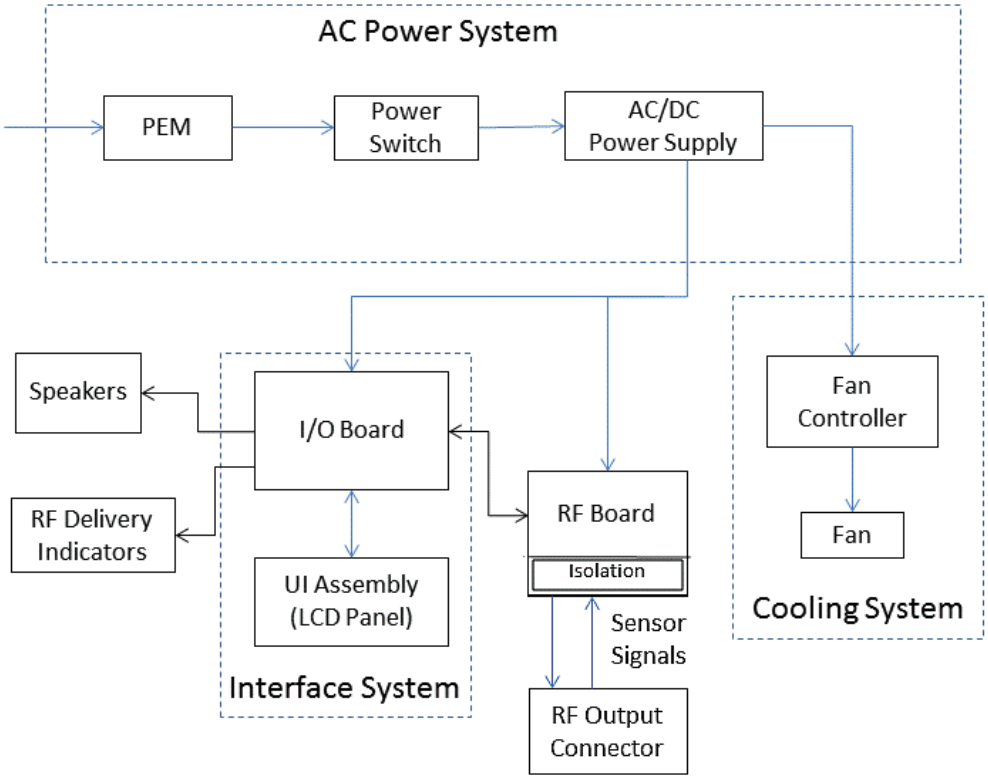
Mode	Duty Cycle
ClosureFast	60 s on / 2 s off
ClosureRFS	Continuous

System Overview

The ClosureRFG radiofrequency generator supplies and controls the RF energy delivered to the catheter. It measures and displays RF output power, load impedance (ClosureRFS only), and elapsed time of RF delivery. The ClosureRFG generator also interfaces with a sensor in the catheter to provide a continuous display of measured patient temperature prior to and during RF delivery.

The major functional blocks of the ClosureRFG generator electronics are presented below.

Major functional blocks of the ClosureRFG generator electronics



Description of Sub-systems

The major subsystems are:

- UI Assembly
- I/O Board
- RF Board
- AC Power System
- Cooling System

List of Circuit Boards

The ClosureRFG radiofrequency generator consists of six main PCBs which make up the five subsystems:

- UI Board (contains UI Processor and LCD Touch Screen electronics)
- I\O Board
- RF Board
- AC Power Supply
- Fan Controller
- RF Delivery Indicator PCB (Left and Right)

UI Board

The UI board contains the system processor, touch drivers, and touch screen interface. The UI board is a major component of the UI assembly that is mounted on the front of the chassis. It's is located inside a metal shield with the touch screen, and is accessible through the rear-door hatch. The UI assembly runs the ClosureRFG generator's system software stored in flash memory. It controls all electronics that handle basic system operation and the user interface, including all the system's audio and visual indicators.

I/O Board

The I/O board is the large (approximately 8.5" x 5.5") electronic assembly that mounts to the back of the UI assembly. It supplies 12 volts to the UI assembly and provides access to all the important signals coming from it. The I/O board provides the communication interface between the RF board and UI assembly and contains all the user accessible ports (Ethernet, SD Card, and USB). It provides interfaces for the system speakers, RF Delivery Indicators, and Power-ON LED.

RF Board

The RF board is the large (approximately 8"x 6") PCB mounted vertically on the rear panel of the inner metal chassis. It controls all electronics that generate the RF power used to drive the treatment catheters. Additional safety signals and control are provided by the I/O board through the 16 conductor cable that runs between them. The isolation circuitry for all patient connections is on this board.

AC Power Supply

A commercially available, medical grade switching power supply is used to provide low-voltage power to the ClosureRFG radiofrequency generator's internal circuitry. The AC Power Supply is the PCB assembly (approximately 5"x 3") mounted on the bottom of the inner metal chassis. It accepts 110-240 VAC, 50/60 Hz (nominal) and generates 24 volts to drive the RF-treatment system and 12 volts to drive the cooling system.

Fan Controller

The Fan Controller is a small (approx.1.7" x 0.9") PCB assembly mounted on the rear panel of the inner metal chassis. It measures the temperature inside the ClosureRFG generator and activates the fan when the temperature reaches the trip point. The fan controller keeps the fan on until the temperature drops to the shut-off set point, with a hysteresis of about 10° C.

RF Delivery Indicator PCB

The RF Delivery Indicator PCB assembly is a small (approximately 1.8" x 0.6") board that contains three blue discrete chip LEDs. There are two of these assemblies, mounted on the inner metal chassis on the top left and right corners of the touch display. The assemblies are mirror images and therefore not interchangeable.

General Description and Operating Conditions

Warning
Do not operate the ClosureRFG generator in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
Do not operate the ClosureRFG generator in contact with flammable materials, chemicals, or substances.

- The ClosureRFG radiofrequency generator should be used only with a hospital-grade power cord and plugged into only grounded, hospital-grade AC sources.
- Class 1, Type CF, Defibrillator-Proof Applied Part.
- Plastic and Metal Enclosure.
- Service Port is user-accessible but is for factory use only. Service Port is covered by a rubber cover that can only be removed with a tool.
- Metal Enclosure is Protective Earth.
- Patient Connection is Bipolar Catheter.
- Isolated Patient Connections include heating device, thermocouple, and ID resistor.
- The ClosureRFG generator cannot be sterilized and must not enter a sterile surgical field.
- The display has touch screen, with no protective plastic cover.
- The display backlight operates with 11 VDC at 150 mA. Over the display is a 4-wire resistive touch-sensitive mesh, which is a low-voltage (<3.4 V) sensing grid.
- SD and USB devices are typically plastic of unknown insulation properties and are operator-accessible when the ClosureRFG generator is powered.
- SD and USB pins are not user accessible.

- Activation time
  - ClosureFast catheter: 20 seconds (fixed)
  - ClosureRFS stylet: 2 to 8 minutes (variable, typical)
- An Ethernet communications port is provided for connecting the ClosureRFG generator to a PC for troubleshooting (Covidien authorized service only).

Environmental Conditions

Transportation and Storage

During transportation and storage, adhere to these guidelines:


Store the ClosureRFG radiofrequency generator at temperatures between -4° F and 104° F (-20° C and 40° C) and non-condensing relative humidity between 10% and 90% or temperatures between 104° F to 158° F (40° C and 70° C) and non-condensing relative humidity between 10% and 60%.


Ambient atmospheric pressure between 500 hPA and 1060 hPa.

When the ClosureRFG generator is not in use, unplug it from the AC power outlet and wrap the cord around the AC power cord wrap area.

Do not carry or lift the ClosureRFG generator by the AC power cord or catheter cables.


The chemicals from a broken LCD touch screen are toxic when ingested. Handle with care, especially if the LCD screen is broken. If chemicals from a broken LCD screen are accidentally ingested, obtain medical attention immediately.

Operation

Conditions for operating the ClosureRFG generator include the following:


Temperature between 50° F and 104° (F10° C and 40° C) and relative humidity (non-condensing) between 10% and 90%.


Ambient atmospheric pressure between 700 hPa and 1060 hPa (equivalent to elevation between 3000 m and -300 m).

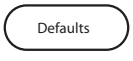
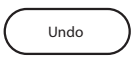

Protection against harmful ingress of water or particulate matter: classification IPX0 (susceptible to ingress).

Important
After removing the ClosureRFG generator or accessories from a storage environment, allow the generator and accessories to fully acclimate to the new environment before use.
Do not stack items on top of the ClosureRFG generator.

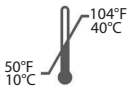
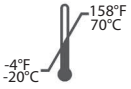
Common Symbols and Icons

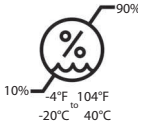
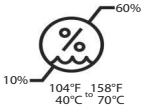
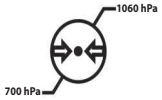
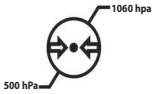
The ClosureRFG radiofrequency generator features a user-friendly interface with a large touchscreen used to control system functions. There are numerous warning and caution symbols, icons, and buttons (when pressed, cause an action) used throughout this manual by the ClosureRFG generator. The operator should be familiar with them and their meanings.

Symbols Used by the ClosureRFG Generator

Ω	Ohms (Impedance)		Reset Timer Value button
°C	Degrees Celsius (Temperature)		ClosureFast endovenous radiofrequency catheters: RF icon Treatment Status–RF not ready (gray), error condition
W	Watts (Power)		ClosureFast catheters: RF power icon Treatment Status–RF ready to start (green)
	Options button: Opens the Settings screen		ClosureFast catheters: RF power icon Treatment Status–RF is powered on to cause tissue heating (blue)
	Treatment History button: View and export data to a USB device		(Gray) ClosureRFS endovenous radiofrequency stylets: RF icon Treatment Status–RF not ready, error condition
	SD Card Not Installed Icon		(Green) ClosureRFS stylets: RF Start button Treatment Status–RF Ready (to start)
	Warning: (Yellow background) Alarm message displayed		(Blue) ClosureRFS stylets: RF Stop button Treatment Status–RF is powered on to heat tissue
	Home button: Exit various Settings screens		Reject/Cancel and Accept buttons
	Defaults button: In Settings, return selections to Default values		Undo button: In Settings, undo changes, go back to previous values

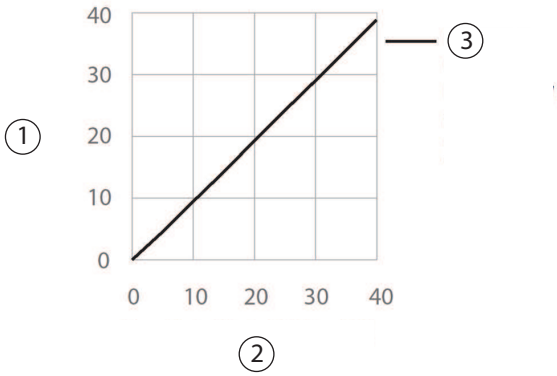
Symbols Used on the ClosureRFG Generator and Packaging

	Caution: Consult accompanying documents		Alternating Current
	Consult instructions for use		Equipotentiality
	RX only		The output is floating with respect to ground
	This side up		Fuses
	Fragile		Dangerous voltage
	Do not dispose in trash	**SD Card USB Device**	Storage device slots
	Explosion risk with flammable anesthetics		Electrostatic sensitive device (referring to USB, SD cards)
	Toxic chemicals		Temperature limitations, operation
	Keep dry		Temperature limitations, storage

	Defibrillation-proof type CF applied part		Humidity limitations, operation
	Humidity limitations, storage		Non-sterile
	Non-Ionizing Radiation		Atmospheric pressure limitations, operation
	Atmospheric pressure limitations, storage		Not made with natural rubber latex

Power Output Charts

Power Output vs. Output Control Settings at 200 Ω

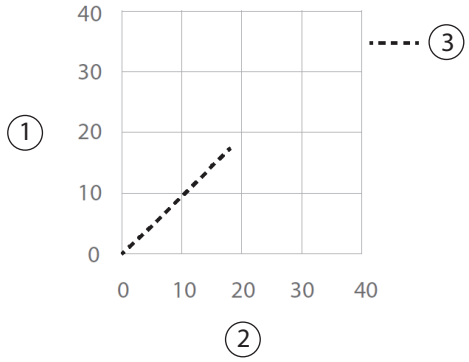


① Power output (watts)

② Power output control settings (watts)

③ ClosureFast endovenous radiofrequency ablation (RFA) catheter 7 cm

Power Output vs. Output Control Settings at 200 Ω

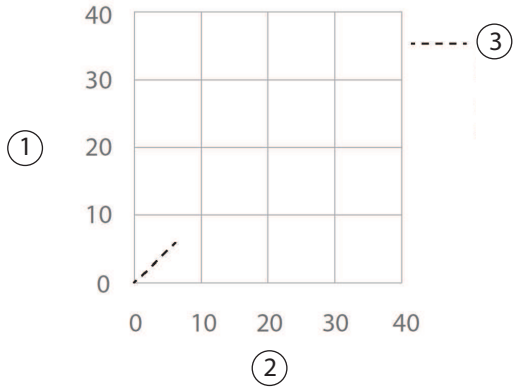


① Power output (watts)

② Power output control settings (watts)

③ ClosureFast endovenous radiofrequency ablation (RFA) catheter 3 cm

Power Output vs. Output Control Settings at 200 Ω

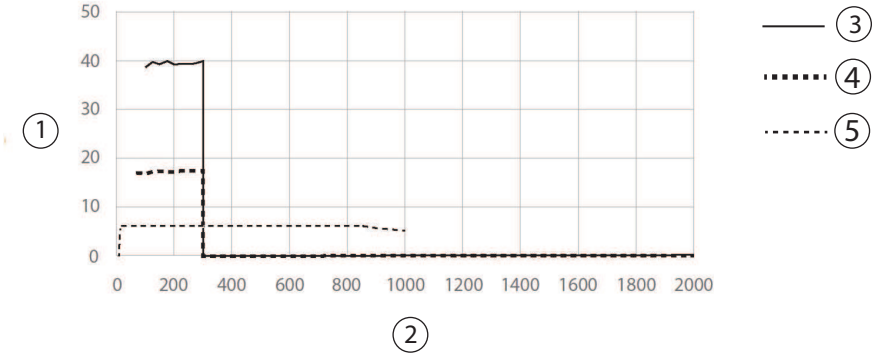


① Power output (watts)

② Power output control settings (watts)

③ ClosureRFS endovenous radiofrequency stylet

Maximum Power Output - Full Power Output Control Settings



① Power output (watts)

② Impedance (ohms)

③ ClosureFast endovenous radiofrequency ablation (RFA) catheter 7 cm

④ ClosureFast endovenous radiofrequency ablation (RFA) catheter 3 cm

⑤ ClosureRFS endovenous radiofrequency ablation (RFA) stylet

Chapter 10

Service & Maintenance

Maintenance

Important

There is no scheduled maintenance for the ClosureRFG radiofrequency generator. There are no calibrations. The ClosureRFG generator self-calibrates during POST.

The ClosureRFG generator needs no routine service other than cleaning and service activity required by the operator's institution. Qualified personnel should periodically inspect the ClosureRFG generator, and if service is necessary, contact Covidien.

Warning

The ClosureRFG generator contains no operator-serviceable parts. The case should not be removed. The ClosureRFG generator must be returned to the factory for service.

No modification of this equipment is allowed.

General Safety Guidelines

Review *General Safety Guidelines* on page 1-6.

In addition:

- The AC power switch on the front panel serves as the means of disconnection from supply mains. This switch also isolates the ClosureRFG generator electrically from the supply mains on both poles simultaneously.
- Using a power cord that does not meet the specifications in this Service and Maintenance section may present a potential for an electric shock or affect the performance of the ClosureRFG generator.

Environmental Conditions

Store the ClosureRFG radiofrequency generator at temperatures between -20° C and 40° C and non-condensing relative humidity between 10% and 90% or temperatures between 40° C and 70° C and non-condensing relative humidity between 10% and 60%.

Operate the ClosureRFG generator at temperatures between 10 ° C and 40 ° C and in non-condensing relative humidity between 10% and 90%.

Caution

Protect against harmful ingress of water or particulate matter. Generator classification: IPX0 (no protection).

Fuse Replacement

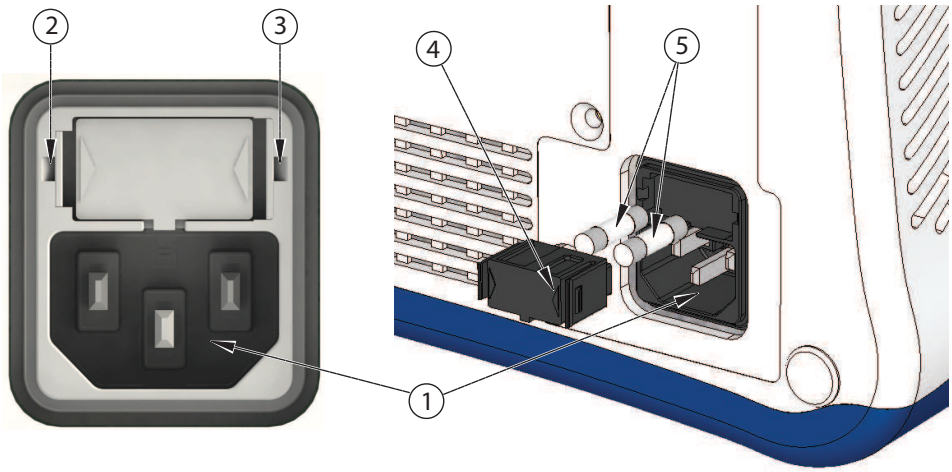
In the event of a fuse failure, replace the fuses using the following procedure, as shown:

Caution

Fuses must be replaced with 5 A/250 V, 5x20 mm fuses. Using other fuses might damage the unit.

1. Disconnect the ClosureRFG radiofrequency generator's AC power cord from the AC power inlet (1).

Fuse Replacement



2. Insert a small blade screwdriver into the small slot located on the left side of the holder (2) and pry the retaining clip out a small distance to loosen the latch.
3. Insert the blade into the small slot located on the right side of the holder (3) and pry the retaining clip out a small distance.
4. Pull the fuse holder drawer (4) out.
5. Replace the fuses (5).
6. Reinsert the fuse holder by pushing it until the holder's front surface is flush with the ClosureRFG generator surface and the latches engage.

Repairs and Returns

For ClosureRFG radiofrequency generator repairs or returns, call the Covidien Customer Service Department. The ClosureRFG generator may be returned to the factory.

Warning
Do not remove the cover of the ClosureRFG generator, as there is a potential for electrical shock.

Return for Repair

Call Customer Service for an Authorized Return Number and shipping instructions:

1-800-962-9888

Warranty

For information about the ClosureRFG generator warranty and/or to obtain information about the availability of the Covidien Extended Warranty, contact Covidien Customer Service.

Opening the ClosureRFG generator by anyone other than an authorized Covidien technician voids the warranty.

Cleaning and Disinfecting

The ClosureRFG radiofrequency generator requires no scheduled maintenance other than cleaning external surfaces.

Cleaning should be performed prior to each use. It may also be desirable to define cleaning intervals based on knowledge of the environment in which the ClosureRFG generator is used. Only personnel trained in the cleaning of medical devices should perform cleaning.

Caution
Always unplug the AC power cord prior to cleaning the ClosureRFG generator.
Do not immerse the AC power cord in water or other cleaning solution.
Avoid getting cleaning materials inside generator receptacles.
As with any AC-powered electrical device, care must be taken to prevent liquid from entering the ClosureRFG generator to avoid electrical shock hazard, fire hazard, or damage to electrical components.
Failure to follow the cleaning procedures described herein could result in hazards to users.

Touch Screen: The recommended agent for cleaning the surface is IPA in water, 70/30. Alcohol wipes and prep pads are acceptable.

Allow 15 minutes after cleaning for the excess cleaning agent to evaporate before turning on the ClosureRFG generator.

ClosureRFG generator surfaces (other than the touch screen): The recommended agents for cleaning, to prevent surface degrading or discoloration, are:

- Five percent solution of household bleach (approximately 0.25% Sodium Hypochlorite). Disinfecting wipes or pads that contain only Sodium Hypochlorite are acceptable.
- IPA in water, 70/30.

All surfaces, including the bottom side of the ClosureRFG generator and any surface on which it is placed, must be cleaned of any residues.

The ClosureRFG generator cannot be sterilized and must not enter a sterile surgical field.

Disposal

Follow local governing ordinances and recycling plans regarding disposal or recycling of components.

Important

The ClosureRFG radiofrequency generator includes a lithium battery. Do not incinerate or dispose of lithium batteries in general trash collection. Check state and local regulations dealing with the disposal of these materials.

Chapter 11

Electrical Safety Tests

The ClosureRFG generator has been thoroughly tested for isolation, leakage, and grounding integrity prior to shipment. The product has been tested for compliance with standards IEC 60601-1 and IEC 60601-2-2.

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

If these tests are necessary, it is mandatory that appropriate test equipment is used, and the tester has knowledge of the applicable electrical safety standards which pertain to these tests. Covidien assumes no responsibility for damage to the unit due to improper application of the following tests.

If in doubt, consult the Safety Analyzer User's Manual or Covidien prior to conducting the following tests.

Electrical Safety Tests 220-240 V

Warning

High Voltage Do not touch the equipment during the isolation tests.

1. Set the line voltage to 264 V and set the frequency to 50 Hz. Do not exceed 280 V.
2. Plug the line cord of the ClosureRFG radiofrequency generator into the leakage tester for all tests.
3. For source leakage and isolation tests, use the Biomed Test Cable to access patient connections. Short the electrodes and thermocouple wires together for testing.

4. For the 25 A test, connect the ROD-L leads to the chassis ground lug, and to the ground pin of the power cord.

Electrical Safety Test Limits 240 V

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

Electrical Safety Tests 110-120 V

Warning

High Voltage Do not touch the equipment during the isolation tests.

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

Electrical Safety Test Limits 120 V

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

Electromagnetic Compliance (EMC)

Standards referenced in tables on page 11-5 and page 11-6.

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

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

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

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

IEC 61000-4-3:2010, Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test

IEC 61000-4-4:2004 + A1:2010, Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test

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

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

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

Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The ClosureRFG radiofrequency generator is intended for use in the electromagnetic environment specified below. The customer or the user of the ClosureRFG generator should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	The ClosureRFG 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 ClosureRFG 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	

Electromagnetic Immunity

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

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

Separation Distances

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

Electromagnetic Interference (EMI)

The ClosureRFG radiofrequency generator has been tested for EMI emissions and susceptibility to emissions from other equipment according to established standards and limits.

Note: For electromagnetic compliance information, see *Electromagnetic Compliance (EMC)* on page 11-4.

The ClosureRFG generator might cause interference that can affect other equipment. Such interference would most likely occur during RF treatment mode, but could occur at any time.

The ClosureRFG generator is susceptible to EMI from other equipment. This could result in inaccurate RF power delivery and possible injury to the patient. Additionally, RF

treatment might stop or the unit might restart due to a non-repeating event, such as AC power surges, or power spikes.

Possible sources of EMI can include, but are not limited to, cellular phones, radio transmitters, motors, telephones, and lamps, as well as other medical equipment, such as electrosurgical products and defibrillators. EMI may be conducted through the AC power lines. Restrict the use of this equipment in the vicinity of the ClosureRFG generator.

If interference affects other equipment in the treatment area, move the other equipment or the ClosureRFG generator to a different location. Move the ClosureRFG generator cord and the catheter away from the susceptible equipment and its cords and cables.

Biomedical Department Inspection and Power Output Test

Note: The ClosureRFG radiofrequency generator performs an internal calibration during each start-up. No calibration is needed, and there are no internal adjustments to the RF power generator.

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

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

Set-up Procedure

- Check the ClosureRFG generator case exterior. The case exterior must have no visible damage (e.g., dents, scratches, peeling paint).
- The touch screen must have no visible foreign material or damage.
- Inspect all external connectors/receptacles for bent pins, foreign objects, a damaged case and/or improper fit.
- The AC power cord must have no obvious physical defects or damage.
- Connect the ClosureRFG generator to the appropriate AC power supply and turn on main power. Wait until the ClosureRFG generator completes its POST.
- Attach the test cable to the ClosureRFG generator.
- The front panel parameters should be:

  Temperature: ~23° C (ambient temperature)

  Impedance: 1999 Ω

  Power: 0 W

- Clip the ESU tester to the red and black leads.
- Select 100 Ω impedance on the ESU analyzer.
- Place the red and yellow thermocouple wire and the reference thermometer into a 37° C ± 3° C bath.

Test Method

1. Verify that the bath temperature and ESU analyzer load impedance are indicated on the temperature and impedance displays.
2. Press the RF Start button to start the RF power sequence.
3. Verify that the bath temperature, ESU analyzer load impedance, and power indicated on the temperature, impedance, and power displays on the ClosureRFG radiofrequency generator are in agreement with the reference thermometer and the ESU analyzer.
4. Turn off main power to the ClosureRFG generator. Remove the Test Cable and AC power cord from the ClosureRFG generator.
5. In assessing the functionality of the ClosureRFG generator with any external measurement system such as an ESU Analyzer, the measurement tolerances of the ESU Analyzer for a given test must be added to the tolerances listed for the ClosureRFG generator.

Power Delivery Verification

This test verifies the ability of the ClosureRFG radiofrequency generator to deliver RF energy.

1. Attach a ClosureFast catheter to the ClosureRFG generator.
2. Fill a glass container with 0.9% saline solution heated to 37° C ±3° C (this simulates the temperature and impedance of blood in a blood vessel).
3. Place the distal (heating element) end of the catheter in the saline such that the entire RF coil is covered. Insure that the catheter coil is covered by the saline before and during RF power delivery.
4. Press the catheter handle button on the handle to start RF treatment.
5. Verify that the ClosureRFG generator delivers power and that the setpoint temperature is maintained during delivery.

   Note: The heating element in the beaker of saline may not reach the setpoint temperature of 120° C. If so, completely and tightly wrap the heating element in a paper towel, and tape it closed. Immerse this assembly in the beaker, cover it completely with the saline solution, then return to step 4.

Chapter 12

Glossary of Terms

Advisory Limits - Limits on parameters, such as temperature, impedance, RF power, time, or a combination of these, outside of which RF treatment is not optimal and corrective action is suggested.

Alarm Tone - The alarm tone sounds when the unit detects an alarm condition for the connected catheter.

Catheter - An approved Covidien RF delivery or RF powered accessory that can be attached to the ClosureRFG radiofrequency generator.

Default - A value for a setting that is assigned automatically by the ClosureRFG generator. Default values remain in effect unless altered in the ClosureRFG Generator Settings screen.

Device - The term used in generator messages to refer to catheters and stylets.

EMC - Electromagnetic Compliance.

EMI - Electromagnetic Interference.

Functional Limits - Limits on parameters, such as temperature, impedance, RF power, time, or a combination of these, outside of which RF delivery will not start, or stops immediately.

Impedance - The effective resistance of the Covidien ClosureFast endovenous radiofrequency catheter heater, or the Covidien ClosureRFS endovenous radiofrequency stylet electrodes, expressed in ohms.

Informational Tone - The informational tone sounds if the unit detects that a parameter is between the advisory and functional limits for the connected catheter. It is also used during RF treatment and for button presses.

LCD - Liquid-Crystal Display, the touch screen.

Parameter - The measured quantities that govern the RF treatment algorithm—temperature, impedance, RF power, and/or time.

Persistent Settings - Operator-adjustable settings that retain their value when the ClosureRFG generator is turned off, such as screen brightness and tone volume settings.

POST - Power-On Self-Test.

Power Limit - Maximum RF power that the catheter can deliver.

Power Measurement - Current RF power being delivered.

Power Set Point - The desired RF power.

Procedure - All the cycles of an RF treatment at one site.

Record - The data stored for one RF treatment, or procedure. A record will have start date and time, the type of catheter (CLF or RFS), the treatment duration, and the number of cycles. A record is 'open' during a treatment for one or several cycles, and 'closed' when the ClosureRFG radiofrequency generator is power cycled, a different catheter type is connected, a 'Reset' is done, or a 'Retain' is not accepted.

Recoverable Error - An error condition that requires the operator to respond to an error message and/or make a clinical decision.

Reset (Treatment Timer) - To zero the accumulated time and cycle count to prepare for the next RF treatment. This is used only when a new patient site is to be treated with the same catheter. 'Reset' closes a record.

Retain (Treatment Timer) - To keep adding treatment time and cycles to the current (open) record. This is used when a catheter is reconnected, and the same site is to be further treated. 'Retain' continues to add cycles and time to an open record.

RF - Radiofrequency energy.

RF Treatment - Therapeutic RF delivery; the start-to-finish procedure for treating one site on a patient. It consists of one to several RF power delivery cycles, the data for which is stored in one record.

Settings - Operator-configurable controls in the Generator Setup screen.

Temperature Measurement - The current temperature at the catheter's point of RF delivery.

Temperature Set Point - The desired or target temperature.

Therapeutic RF - RF power levels delivered by a catheter that exceed 10 mW average power. This term is defined to distinguish between high RF power levels used for RF treatment and low levels used for parameter measurement before treatment.

Unrecoverable Error - An error condition that stops the ClosureRFG generator and requires the operator to cycle the ClosureRFG generator's AC power to continue.

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