Medtronic
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Operation Manual Update
ClosureRFG™ Radiofrequency Generator RFG3 Operation Manual
CD Part Number PT00054359

6 August 2019

Attention: Risk management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Healthcare Professional,

This notification is to provide you with important information regarding an update to the Operation Manual for the Medtronic ClosureRFG™ Radiofrequency Generator (RFG3). This issue does not affect the RFG3 device itself or its operation. This Operation Manual revision corrects six errors and adds clarity and/or corrects language in several sections of the manual (outlined in the enclosed document). The RFG3 maintains compliance to all applicable medical device safety standards. There are no other model numbers of Medtronic devices affected by this revision.

Through July 9, 2019, Medtronic has received zero (0) complaints as a result of these revisions.

Medtronic is not retrieving product from the field as no patient safety risk has been identified. Patients who have been, or will be, treated with RFG3 should continue to be managed according to your standard patient management protocols.

Customer Actions
Please complete the following actions:

- Review the Operation Manual Updated Language as provided in this letter and enclosed document.
- Store a copy of this letter and the enclosure with your current ClosureRFG™ Radiofrequency Generator RFG3 Operation Manual.
- Please share this information with healthcare professionals in your facility that use RFG3. Also share this information with any other organization where these devices may have been transferred.
- Complete the attached Customer Confirmation Form and return it as directed to confirm your receipt and understanding of this information

Please maintain a copy of this notice in your records. We are committed to patient safety and welcome any questions you may have regarding this communication. Please contact your Medtronic representative with questions.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,

[redacted]

Diana Teo
QRA Lead
SEA Region (Cluster 1)

[redacted]

Chloe Tan
QRA Lead
SEA Region (Cluster 2)

Enclosures:

1) *Appendix A*
2) *Customer Confirmation Form*

Appendix A

ClosureRFG™ Radiofrequency Generator RFG3 Operation Manual Updates:
Manual version PT00080736 replacing version PT00054359
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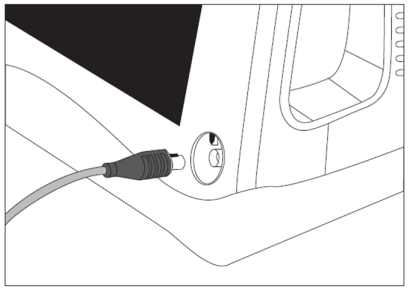
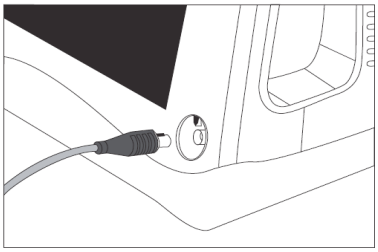
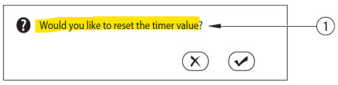
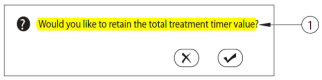
Location of Change	Updated Language (highlighted in yellow) Applies to new PT00080736	Old Language (highlighted in yellow) Applies to old PT00054359
Page 1-3, Chapter 1 Overview & General Features	"RF Ramp up: Repeating series of three short, lower-volume mid frequency pure tones" **Audible Indicators** 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:** Repeating series of three short, lower-volume mid-frequency pure tones • **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 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.	"RF Ramp up: Single, long, lower-volume mid-frequency pure tone" **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 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.
Page 2-9, Chapter 2 Closure RFG Generator Setup	"If the catheter is unsupported, the message area shows, "The connected device is unsupported. Please connect another device." Insert the connector end of a Medtronic ClosureFast endovenous radiofrequency catheter or Medtronic 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." • To disconnect a catheter, pull on only the connector, not the cable.	"If the connected catheter is unknown or invalid, the message area shows, "The device is invalid." Insert the connector end of a Medtronic ClosureFast endovenous radiofrequency catheter or Medtronic 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.

Page 5-2, Chapter 5 Treatment Times	"Would you like to reset the timer value?" 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 reset the timer value? 2. Press the **Green Check Mark** button to reset the RF treatment timer, and open a new record.	"Would you like to retain the total treatment timer value?" 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.

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<tr><th>Location of Change</th><th>Updated Language (highlighted in yellow) Applies to new PT00080736</th><th>Old Language (highlighted in yellow) Applies to old PT00054359</th></tr>
<tr>
<td>Page 6-2, Chapter 6 Messages, Tones, and Responses</td>
<td>“High Power Low Temperature And Low Impedance Advisory” “Advisory: Temperature low. Power high. Impedance low”.
<table>
<tr><th>Name</th><th>Generator Action</th><th>User Action</th></tr>
<tr><td>Low Impedance and High Temperature Advisory</td><td>Clear any advisory message.
Display: “Advisory: Temperature high”
Sound: Informational Tone.</td><td>None required</td></tr>
<tr><td>High Power and Low Temperature Advisory</td><td>Clear any advisory message.
Display: “Advisory: Temperature low, power high”
Sound: Informational Tone.</td><td>None required</td></tr>
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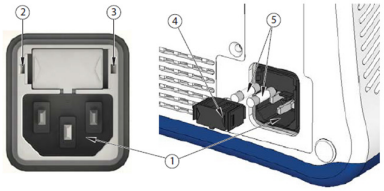
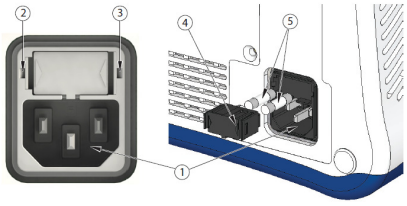
Page 10-1, Chapter 10 Service & Maintenance	"The **appliance inlet** serves as the means of disconnect from supply mains. Using a power cord that does not meet the specifications in **Chapter 9, Technical Specifications** may present a potential for an electrical shock or affect the performance of the ClosureRFG generator." **General Safety Guidelines** Review *General Safety Guidelines* on page 1-6. In addition: • The appliance inlet serves as the means of disconnect from supply mains. • Using a power cord that does not meet the specifications in Chapter 9, *Technical Specifications* may present a potential for an electrical shock or affect the performance of the ClosureRFG generator.	"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 electrical shock or affect the performance of the ClosureRFG generator." **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 electrical shock or affect the performance of the ClosureRFG generator.
Page 10-2, Chapter 10 Service & Maintenance	"Fuse must be replaced with 5 A/250 **V**, 5x20 mm fuses." **Fuse Replacement** In the event of a fuse failure, replace the fuses using the following procedure, as shown: **Precaution** 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).  2) Insert a small blade screwdriver into the small slot located on the left side of the holder (2) and pry the retraining 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.	"Fuses must be replaced with 5 A/250 A, 5x20 mm fuses." **Fuse Replacement** In the event of a fuse failure, replace the fuses using the following procedure, as shown: **Precaution** Fuses must be replaced with 5 A/250 A, 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).  2) Insert a small blade screwdriver into the small slot located on the left side of the holder (2) and pry the retraining 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.

NOTE:
- Additional minor changes (grammar, formatting and precise wording) were made for clarification that are not referenced above.
- In your geography, the updated Operations Manual language may differ slightly from the content of this communication based on the Operations Manual approved by local regulatory agencies, where required.

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ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
Physician / HCP/Distributors :	**Name:**
	Contact:
Address:	**Email:**
Phone no:	
E-mail:	

Please fill the below columns accordingly

By signing this form, I confirm that I have read and understood the Operation Manual Update Notification Letter, dated 6 August 2019, from Medtronic regarding the ClosureRFG™ Radiofrequency Generator RFG3 Operation Manual.

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the RFG3 listed above. There are other identifiers and/or lots affected globally and please verify with product owner if in doubt.

Name: _____ (print) Signature: _____ Stamp: _____ Date:_____

If you have any questions regarding this Notification Letter, please contact your Medtronic sales representative.