

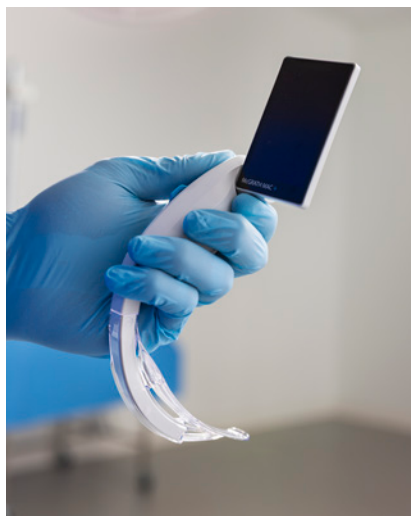
Medtronic

McGRATH™ MAC+ video laryngoscope

In-service guide



Unpacking, inspection, and initial setup for the McGRATH™ MAC+ video laryngoscope



- Unpack the laryngoscope and adjunct devices from their respective packaging and check for any visible signs of damage. In the event of signs of damage, do not use the damaged item and contact your Medtronic representative. Reference the enclosed quick start guides for component identification.
- Remove the camera cover from the distal end of the CameraStick™. The laryngoscope is supplied in a non-sterile state.
- Decontaminate the laryngoscope before first patient use, as instructed in the Cleaning and Disinfection section.
- Remove the protective cover from the cables, as applicable.
- The relay and cables can be cleaned prior to installing; however, these adjunct devices are not patient contacting and should only be surface cleaned, as instructed in the Cleaning and Disinfection section.
- It is recommended to charge the relay following unpacking, according to the instructions in the Charging the Relay section.
- If the OEM screen was purchased to optimize the streaming feature, unpack the OEM screen and any mounting and cable components and set up the screen for use. Alternatively, a compatible display already existing in the use environment can be used to stream.

Use



McGRATH™ MAC+ blade options:

McGRATH™ disposable blades sizes 1–4 feature a curvature similar to the traditional Macintosh blade profile; the McGRATH™ X blade features a hyperangulated curvature and is designed for difficult airways. These two styles of blades require different techniques for use.

Operation of the relay:

When the relay's battery is charged, the relay turns on and off by a single push of the power button. The relay alternatively powers on upon connection to a power source or PC. The relay can be used as a battery powered device to receive and store video and still image files wirelessly uploaded from the laryngoscope. The relay can be connected to the OEM screen or a compatible display in the use environment to enable streaming of the live video feed from the laryngoscope. Additionally, the relay can be connected to a PC to offload image and video files stored on the relay. See the Scenarios section of the relay quick start guide for recommended relay placement during use. More than one relay may be used at a time.

Charging the relay:

Charging is recommended following unpacking of the relay. Connect the relay to a power source (see specifications table for charging limits) using a USB-C cable to charge the relay's internal battery.

- The relay can either be powered by its rechargeable battery, or it can remain connected to a power source or PC using a USB-C cable during use. Charge the relay when battery charge becomes low (see the relay's quick start guide for graphical representation of battery indications). At a minimum, charge the relay once every three months.



Relay battery:

The relay's level of battery charge is displayed with battery indicator lights. Refer to the relay's quick start guide for graphic examples. Upon power on of the relay, the battery indicators will illuminate for five seconds, then turn off. Perform a quick press of the relay's power button to check the charge status during use.

- When charge is low, a single battery indicator will flash, indicating that the relay should be connected to a power source. If attempting to power the relay on when the battery is depleted, an indication of depleted battery will display then turn off, and the relay will not power on. See the Charging the Relay instructions to charge the relay.

ProxiLinq™ wireless connection technology (ProxiLinq™):

- ProxiLinq™ wirelessly connects the laryngoscope to one or more relays within the laryngoscope's line of sight. This enables seamless streaming and file upload activities without interfering with laryngoscopies in neighboring rooms. This ensures intentional in-room connection without needing to connect to Wi-Fi or Bluetooth.
- ProxiLinq™ is a closed system connection technology. No setup is required to utilize the ProxiLinq™ wireless connection technology; connection will automatically form between relays and laryngoscopes that are in the same room.
- ProxiLinq™ connection status is communicated using the ProxiLinq™ wireless connection icon on the laryngoscope's LCD screen, relay, and streaming graphical display. See the laryngoscope and relay quick start guides for graphical representations of the wireless connection states. ProxiLinq™ wireless connection is supported within a five meter distance between devices.

Stream:



- The relay enables wireless in-room streaming of the laryngoscope's live video feed by connecting it to the OEM screen or another compatible display in the use environment (see specification table). See the relay's quick start guide for graphical representations of setup and use of the streaming feature.
- Streaming setup:
 - Mount the relay to the OEM screen or compatible display with double-sided tape or another preferred method in a location within line of sight of the laryngoscope.
Note: For best connectivity, face the relay's wireless receiver in the direction of the laryngoscope.
 - Connect the relay to a power source with a USB-C cable (see specifications table). The relay will power on when connected to the power source. The relay must be connected to a power source to stream.
 - Connect the relay to the display with a micro-HDMI cable. A graphical screen will show on the display when the relay is set up correctly. Contact your local representative for additional supported video interfaces.
Note: To change the orientation of the streamed image between landscape and portrait, press and hold the relay's power button until the displayed image changes orientation (approximately three seconds).
- To begin streaming, power on the laryngoscope.
- The ProxiLinq™ wireless connection will automatically form between the laryngoscope and relay, as indicated by the ProxiLinq™ wireless connection icon on the laryngoscope, relay, and streaming graphical display. The live video from the laryngoscope will stream to the streaming display when wireless connection is established.

- A timer will show on the streaming display to indicate how long the laryngoscope has been powered on. The timer will reset if the laryngoscope is left stationary for more than 15 seconds or powered off.
- Power off the laryngoscope when the laryngoscopy is complete. Streaming will end upon powering off.

CaseCapture™ retrospective recording and still images:

- CaseCapture™ saves a video of the current laryngoscopy if selected and uploads the video to wirelessly connected relays. CaseCapture™ can be selected on the laryngoscope's LCD touchscreen at any time prior to powering the laryngoscope off. When selected, video feed from the time the laryngoscope was powered on will be saved. Video saving will stop when the laryngoscope is powered off, or when the CaseCapture™ button is selected a second time. The CaseCapture™ button can be selected additional times to save more video feed and update to a new stopping point if desired. The resulting video file will contain video feed from the time the laryngoscope powered on to this final stopping point. The video file both saves to the laryngoscope and automatically uploads to wirelessly connected relays.
- Still images captured by pressing the Still Image button also save to the laryngoscope and upload automatically to connected relays. See the relay's quick start guide for graphical representations of these features in use. Note that the streaming feature can be used concurrently to these features.

CaseCapture™ retrospective recording:

- Set up one or more relays in the desired location for the laryngoscopy, such as connected to a PC with a USB-C cable, free standing, or connected to a display for streaming.
Note: For best connectivity, face the relay's wireless receiver in the direction of the laryngoscope. See the relay's quick start guide for relay placement recommendations.
 - Power on the relay and laryngoscope and allow ProxiLinq™ wireless connection to automatically form between the devices, as indicated by the ProxiLinq™ wireless connection icon.
- Open the pull-out drawer by swiping up from the bottom edge or swiping to the right from the lower left edge of the laryngoscope's LCD screen.
- Select the CaseCapture™ video icon at any time during the laryngoscopy to save a video. When selected, the CaseCapture™ video icon will turn blue and a ring around the button will progress clockwise showing the length of video captured from the time the laryngoscope powered on. One full revolution represents one minute of video. When the drawer is closed, a CaseCapture™ indicator will display on the bottom edge of the screen to indicate that video has been selected to save.

Still image:

- To capture a Still image of the camera view, tap on the Still Image button on the pull-out drawer. A number will appear in the Still Image button indicating how many still images have been taken during this laryngoscopy.
When the drawer is closed, the number of still images captured will display on the bottom edge of the screen.
 - Slide the pull-out drawer down or to the left to close it. Alternatively, allow the drawer to automatically retract after five seconds.

CaseCapture™ retrospective recording and still image:

Upon powering off, the CaseCapture™ video and still image files will automatically save to the laryngoscope and upload to all relays wirelessly connected to the laryngoscope. No additional user interaction is needed to stop the video prior to powering off, though it can be selected to stop by tapping on the CaseCapture™ button a second time.

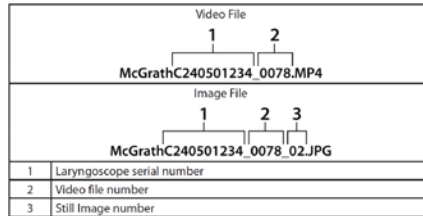
Relay file management:

Follow all local patient privacy regulations and hospital policies related to recording.

Relay file offload:

- See the relay's quick start guide for a graphical representation.
- To offload files from the relay, connect the relay to a PC with a USB-C cable.

- The relay will appear as a mass storage device called 'RELAY'. Locate and open this mass storage device on the PC to access stored files.
- Files are stored in folders based on the amount of time that has passed since the still image or video was originally captured on the laryngoscope. Still images and videos captured in the last 24 hours will be in the '0_24hrs' folder, still images and videos captured between 24 and 48 hours ago will be in the '24_48hrs' folder, and so on.
- Navigate to the desired files, then move the files to the desired PC storage location.
 - The naming convention for video and still image files are as follows:
 - Video file, 1 and 2
 - Image file, 1 and 3
 - 1. Laryngoscope serial number
 - 2. Video file number
 - 3. Still image number



- The video file number (2) increments for each power cycle and the still image number (3) increments for each still image captured during that power cycle.
- In the above example, these file names represent the single video and second still image captured during the 78th power cycle for laryngoscope with serial number C240501234.
- When file offload from the relay is complete, safely remove the relay from the PC.
- Video and still image files will be stored on the relay for up to seven days. After this time, these files will be automatically deleted.
Note: The time and date displayed for each video and still image file is arbitrary. Note: Files cannot be deleted, modified, or added to the relay from a PC. For instructions on how to manually delete files from the relay, see the delete files from relay file storage section.

Delete files from relay file storage:

- Video and still image files are automatically deleted from relay file storage after seven days, from the time the file was originally captured on the laryngoscope.
 - To manually delete all files from relay file storage:
 1. Power on the relay.
 2. After powering on, press and hold the relay power button for longer than 10 seconds.
 3. When the battery indicators start flashing, release the power button.
 4. Press and hold the relay power button again. The battery indicators will illuminate, then turn off in a waterfall sequence.
 5. When the waterfall sequence completes, release the power button. The relay will power off once the power button is released.
 - Note: Individual files cannot be deleted from relay file storage. Files cannot be deleted from the PC interface during file offload.

Laryngoscope settings allow users to:

- Configure video save options
- Recover backup files stored on a laryngoscope to a PC
- Manage the device, including deleting all video and still image files stored on the laryngoscope, updating software and restoring device defaults
- Access a QR code to a digital copy of this user manual and both quick start guides;
- Set the language for all text used in the laryngoscope's user interface. See the laryngoscope's quick start guide for a graphical representation of the settings menu.

Accessing settings:

- With the laryngoscope powered off, press and hold the power button.
- After a few seconds, a graphical image will be displayed on the laryngoscope's LCD screen. Continue to hold the power button.
- After a few more seconds, the settings menu will be displayed. Continuing to hold the power button, tap on the desired settings sub-section. Continue to hold the power button while navigating through the settings menu and features.



- To return to the previous screen, select the back arrow.
- Release the power button to exit settings and display the camera feed to the laryngoscope's LCD screen.
- Access save options from the main settings menu, select save options to configure video save settings.
 - Select CaseCapture™ automatically by default
 - While enabled, the CaseCapture™ settings feature automatically saves a video of every laryngoscopy to the laryngoscope and uploads it to wirelessly connected relays. CaseCapture™ can still be manually selected during a laryngoscopy to stop the video using the pull-out drawer as desired.
 - While disabled, CaseCapture™ must be manually selected during a laryngoscopy to save and upload a video to connected relays.
 - At receipt of this device, the CaseCapture™ setting is defaulted to disabled.
 - Backup: automatically save videos to backup storage on the laryngoscope
 - Backup saves a video of every laryngoscopy to a backup folder on the laryngoscope. Still image files will also be saved to the backup folder.
 - By default, backup video saving is enabled on this device.
 - Enabling backup will not automatically upload videos to connected relays. The CaseCapture™ feature should be used to upload videos to connected relays.
 - See the backup recovery section for instructions on recovering files saved to the laryngoscope using backup.



Backup recovery:

- See relay quick start guide for graphical representations.
 1. To recover backup video and still image files from the laryngoscope to a PC, navigate to laryngoscope settings according to the accessing settings instructions and select backup recovery.
 2. After entering backup recovery, the power button can be released. Note: Once the power button is released, access to the main settings menu is disabled.
 3. Connect a relay to a PC with a USB-C cable. The relay will automatically power on upon connection.
 4. Select continue on the laryngoscope's user interface. Then, proceed on the PC to copy desired files to the PC or other desired storage location as follows:
 - Once the ProxiLinq™ wireless connection forms between the laryngoscope and relay, the laryngoscope will appear on the PC as a mass storage device called 'McGRATH'.
 - Locate and open this mass storage device to access stored video and still image files.
 - Files are stored in folders called 'McGRATH' and 'backup'.
 - The McGRATH folder stores all still image files and any video files saved using CaseCapture™ during a laryngoscopy.
 - The backup folder stores backup still image and video files from every laryngoscopy if backup is enabled in laryngoscope settings.
 - Once in either the McGRATH or backup folder, files are stored in folders based on the amount of time that has passed since the still image or video was captured. Files follow the same naming convention as those saved to a relay. See the relay file offload section for information on the folder structure and file naming convention.
 - Navigate to the desired files, then copy the files to the desired PC storage location.



- When file recovery from the laryngoscope is complete, press the laryngoscope's power button, or safely remove the relay from the PC to exit backup recovery and power the laryngoscope off.
- Note: Video and still image files will be stored on the laryngoscope for up to seven days. After this time, these files will be automatically deleted.
- Note: The time and date displayed for each video and still image file is arbitrary.
- Note: Files cannot be deleted, modified, or added to the laryngoscope from a PC. For instructions on how to manually delete files from the laryngoscope, see the delete media section.

Delete media

- Video and still image files are automatically deleted from the laryngoscope after seven days.
- To manually delete all files from the laryngoscope, select manage device from the main settings menu, then select delete media.
 - Tap delete now to delete all video and still image files from the laryngoscope. Files cannot be individually selected for deletion.
 - Select delete to confirm deletion of all files or cancel to cancel deletion if desired.
 - When deletion is complete, select done to return to the main settings menu or release the power button to exit settings.

Update software:

Medtronic may provide platform software or firmware updates periodically. To inquire about updates, contact Medtronic or a local Medtronic representative.

Reset defaults:

- To reset laryngoscope defaults, select manage device from the main settings menu, then select reset defaults.
 - Select yes to confirm reset.
 - Once reset is complete, the laryngoscope will return to the manage device menu.

User manual:

From the main settings menu, select user manual to access a scannable QR code to view a digital copy of this user manual and the quick start guides.

Language selection:

- To change the language of all text used in the laryngoscope's user interface, select the language item from the main settings menu to access language options.
- Select the desired language.

Troubleshooting:

- Laryngoscope messages: For laryngoscope message examples, see the battery icons minutes available section of the laryngoscope's quick start guide. Normal screen (remaining hours and minutes of battery runtime available) 7-1.
 - Five minutes of battery runtime remaining on the battery (it is recommended to replace the battery) 7-2.
 - System error, this screen shows if there is a startup error including if there are zero minutes available on the battery 7-3.
 - Unknown minutes of battery runtime available (this is used after the zero minutes or if there is an internal error after startup) 7-4.
 - Dimmed, device is not sensing any motion. If it remains in this state, the device will turn off (after three minutes of no motion).
 - Flashing ProxiLinq™ wireless connection icon (wireless connection is forming between the laryngoscope and relay).
 - Solid ProxiLinq™ wireless connection icon (wireless connection has successfully formed between the laryngoscope and relay).

- ProxiLinq™ wireless connection icon with an 'X' through it (wireless connection error, wireless connection not available).
- Laryngoscope diagnostics: Contact your local representative for information regarding accessing device diagnostic data.

Laryngoscope troubleshooting:

- No image shown on screen or visible damage to the power button: Replace battery unit.
- If the image displayed on the screen is blurred:
 - Remove the blade and check that the image is clear. If necessary, wipe the camera at the end of the CameraStick™ with a lint-free wipe.
 - Replace the blade.
 - The performance of the McGRATH™ MAC+ connected video laryngoscope may be affected by the operation of nearby equipment that generates electromagnetic energy such as MRI or high-frequency (HF) surgical devices.
 - If unusual operation is observed, it may be necessary to take measures such as relocating, disabling, or shielding the nearby equipment.
 - If none of the above achieves positive results, contact your local representative for diagnostics and resolution. There are no serviceable parts inside the device.
- During use with MAC blade, if the camera system loses function and the LED remains functioning, the device can still be used as a direct view laryngoscope. During use with the MAC blade, a failure of the LED requires the removal of the video laryngoscope and an alternative device to be used.
- During use with the X blade™, any failure of the camera system or LED requires the removal of the video laryngoscope and an alternative device to be used.

Unexpected video interruption:

- Try to turn the device back on.
- Replace the battery unit.

File management:

- Files fail to automatically delete or move out of '0-24 hour' folder
 - Try powering the laryngoscope off and back on.
 - Contact your local representative for diagnostics and resolution. There are no serviceable parts inside the device.

Cleaning



The McGRATH™ MAC+ VL device and rechargeable battery should be cleaned and disinfected separately after unpacking and after each patient use. McGRATH™ blades are not intended to be cleaned or disinfected and should be disposed of after use according to local regulations.

Cleaning the McGRATH™ MAC+ VL device:

- To clean the device, use a quaternary ammonia and isopropyl alcohol wipe – for example a Super Sani-Cloth™ or equivalent.
 - **Cleaning** can be achieved through a single wipe down using the directions that follow.
 - **Intermediate-level disinfection** can be achieved by repeating the process outlined above using a new wipe, allowing the device to dry in between wipe downs.

- Remove the rechargeable battery prior to cleaning.
- Systematically work from the top to the bottom of the device, cleaning these areas:
 - Monitor
 - Monitor hinge
 - Rechargeable battery bay
 - Handle
 - Clip and heel area
 - Camera stick
 - Camera lens

The McGRATH™ MAC+ VL device and rechargeable battery should be cleaned and disinfected separately after unpacking and after each patient use. McGRATH™ blades are not intended to be cleaned or disinfected and should be disposed of after use according to local regulations.

- Ensure the surfaces remain thoroughly wet by continuously wiping for one minute.
- Once complete, visually inspect the device for visible soil. If any portion of the device is not visibly clean, repeat the cleaning steps using a new disinfectant wipe.

Cleaning the McGRATH™ rechargeable battery:

- To **clean** the rechargeable battery, use a 70% isopropyl alcohol wipe.
- For **intermedial level disinfection**, use a quaternary ammonia and isopropyl alcohol wipe – for example a Super Sani-Cloth™* or equivalent.
- Systematically work from the top to bottom of the rechargeable battery, cleaning these areas:
 - Carbon pill
 - Power contact
 - Clips
 - Lower rechargeable battery slot
 - Rechargeable battery cover
 - Tab
- Ensure the wipe comes in contact with all surfaces of the rechargeable battery for a minimum contact time of one minute.
- Once complete, visually inspect the rechargeable battery for visible soil. If any portion is not visibly clean, repeat the cleaning steps using a new wipe.

Cleaning the McGRATH™ Relay:

Using a 70% isopropyl alcohol wipe, clean the relay. Ensure that the 70% isopropyl alcohol wipe comes in contact with all surfaces of the relay. A minimum contact time of one minute on all surfaces is recommended.

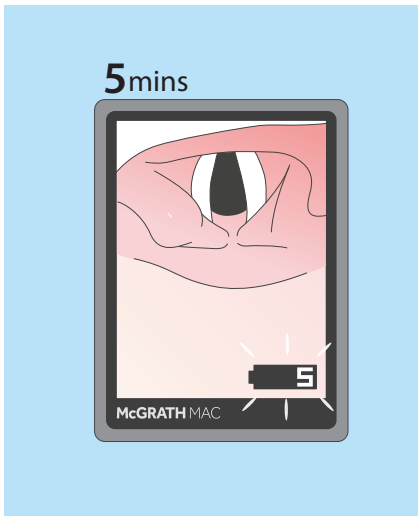
Relay disinfection:

Using a new 70% isopropyl alcohol wipe, disinfect the relay. Ensure that the 70% isopropyl alcohol wipe comes in contact with all surfaces of the relay. A minimum contact time of one minute on all surfaces is recommended.

Drying and storage:

- After cleaning and decontamination, the device, the rechargeable battery, and the relay should be air dried or wiped dry with a lint-free cloth.
 - The device and rechargeable batteries must be completely dry before use.
- Cleaned and decontaminated devices and rechargeable batteries should be packed immediately upon completion of the two-minute drying phase and should be stored in accordance with local guidelines.
 - The device and rechargeable batteries cannot be stored for reuse in their original packaging.
 - The rechargeable batteries can be stored in the charging station.
 - The maximum storage time of the rechargeable battery is three months. At least once every three months the battery needs to be discharged to zero minutes, and then fully recharged to 120 minutes. Failing to do so will decrease or even end the battery life.
 - Consider using the McGRATH™ MAC+ VL carry case for convenient storage.

Troubleshooting



Laryngoscope messages:

- For laryngoscope message examples see the battery icons minutes available section of the laryngoscope's quick start guide.
- Normal screen (remaining hours and minutes of battery runtime available).
- Five minutes of battery runtime remaining on the battery (it is recommended to replace the battery).
- System error, this screen shows if there is a startup error, including if there are zero minutes available on the battery.
- Unknown minutes of battery runtime available (this is used after the zero minutes or if there is an internal error after startup).
- Dimmed, device is not sensing any motion. If it remains in this state, the device will turn off (after three minutes of no motion).
- Flashing ProxiLinq™ wireless connection icon (wireless connection is forming between the laryngoscope and relay).
- Solid ProxiLinq™ wireless connection icon (wireless connection has successfully formed between the laryngoscope and relay).
- ProxiLinq™ wireless connection icon with an 'X' through it (wireless connection error, wireless connection not available).

Laryngoscope diagnostics:

- Contact your local representative for information regarding accessing device diagnostic data.



Laryngoscope troubleshooting:

- No image shown on screen or visible damage to the power button: Replace battery unit.
- If the image displayed on the screen is blurred:
 - Remove the blade and check that the image is clear. If necessary, wipe the camera at the end of the CameraStick™ with a lint-free wipe.
 - Replace the blade.
- The performance of the McGRATH™ MAC+ connected video laryngoscope may be affected by the operation of nearby equipment that generates electromagnetic energy such as MRI or high-frequency (HF) surgical devices.
- If unusual operation is observed, it may be necessary to take measures such as relocating, disabling, or shielding the nearby equipment.
 - If none of the above achieves positive results, contact your local representative for diagnostics and resolution. There are no serviceable parts inside the device.
- During use with MAC blade, if the camera system loses function and the LED remains functioning, the device can still be used as a direct view laryngoscope.
- During use with the MAC blade, a failure of the LED requires the removal of the video laryngoscope and an alternative device to be used.
- During use with the X blade™, any failure of the camera system or LED requires the removal of the video laryngoscope and an alternative device to be used.

Unexpected video interruption:

- Try to turn the device back on.
- Replace the battery unit.

File management:

- Files fail to automatically delete or move out of '0-24 hour' folder
 - Try powering the laryngoscope off and back on.
 - Contact your local representative for diagnostics and resolution.
There are no serviceable parts inside the device.

Flashing rechargeable battery icon with no minutes indicated:

- If the rechargeable battery icon is flashing and no numbers are displayed, this could indicate:
 - Zero minutes of rechargeable battery life remain.
 - An internal issue after startup.
- **Troubleshooting tip:**
 - Turn the device off and on again.
 - If this does not resolve the issue, turn the device off and replace the rechargeable battery unit.

No image on screen, or visible damage to the power button:

- In the event that no image is displayed on the screen, or if there is visible damage to the power button, this could indicate an issue with the rechargeable battery.
- **Troubleshooting tip:**
 - Replace the rechargeable battery unit.

Poor image quality:

- If the image displayed on the screen is blurred or fuzzy, the camera stick may need to be cleaned.
- **Troubleshooting tip:**
 - Remove the blade and check that the image is clear.
 - Wipe the camera at the end of the camera stick with a lint-free wipe.
 - Replace the blade.

Loss of camera system function:

- If the camera system loses function and the LED light source remains functioning, the device can still be used as a direct laryngoscope.

Loss of camera system function and LED:

- If the camera system and the LED light lose function, an alternate device should be used.

If you experience an issue that is not resolved through these troubleshooting tips, contact your local representative.

This material should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s).

Please note that the intended use of a product may vary depending on geographical approvals.

See the device manual(s) for detailed information regarding the intended use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.

For a MRI compatible device(s), consult the MRI information in the device manual(s) before performing a MRI.

If a device is eligible for eFU usage, instructions for use can be found at Medtronic's website manuals.medtronic.com.

Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

Medtronic products placed on European markets bear the CE mark and the UKCA mark (if applicable).

For any further information, contact your local Medtronic representative and/or consult Medtronic's websites.

Important: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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