Medtronic
Medical Surgical
Acute Care and Monitoring
6135 Gunbarrel Ave.
Boulder, CO 80301

Urgent Medical Device Removal and Correction

McGRATH™ MAC Video Laryngoscope

(Removal Item Codes 300-000-000, 300-200-000, Serial Numbers 366170 to 405673)

(Correction Item Code 301-000-000)

July 2024

Dear Risk Manager, Directors of Respiratory Care, Critical Care, Anesthesia and Emergency Medical Services:

The purpose of this notice is to advise you that Medtronic is issuing a voluntary removal for certain McGRATH™ MAC video laryngoscopes, item codes 300-000-000 and 300-200-000, serial numbers from 366170 to 405673, see Section 1. This notice also includes information related to an Addendum to the Instructions for Use (IFU) for item code 301-000-000, see Section 2.

Section 1:

Removal of Item Codes 300-000-000, 300-200-000

Item Code	GTIN	Description	Affected Serial Numbers
300-000-000	15060272980020	McGRATH™ MAC Video Laryngoscope	All serial numbers between 366170 to 405673
300-200-000	15060272980112	McGRATH™ MAC EMS Video Laryngoscope	

Customers should immediately discontinue use of these devices that are being removed. Customers should uninstall the McGRATH™ 3.6V battery assembly from these devices, dispose of it per local procedure and follow the instructions below for returning the devices that are being removed. This notice follows the receipt of two customer reports stating that the installed battery experienced a thermal event, which resulted in an explosion of the battery assembly before patient use. In one of these two instances, there were caregiver injuries.

Issue Description:

Our investigations of the customer reports are ongoing. To date, we have determined that the battery management system within the devices being removed (McGRATH™ MAC Video Laryngoscope device, item codes 300-000-000, 300-200-000) is not sufficient to mitigate against depletion of the battery voltage below the design threshold. Batteries that are depleted below the design threshold may increase the risk of the battery becoming unstable, which may lead to a thermal event[1] followed by a risk of explosion.

Risk to Health:

A thermal event[1] followed by a risk of explosion of the battery assembly can potentially cause caregivers and/or patients to experience burns, lacerations, tinnitus, hearing impairment and acoustic shock. The potential for a delay to treatment, respiratory failure, hypoxia, unspecified tissue injury, scar tissue, foreign body in patient or caregiver, tooth loss, and eye injury also exist. There also exists the potential for damage to surrounding equipment or surfaces.

[1] Thermal event is a condition in which the chemical reactions within the battery generate abnormally high temperatures.

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Patient Management:

There are no additional patient management recommendations that should be employed for patients where potentially affected devices were previously used.

Actions you should take:

- Immediately discontinue use of the devices being removed (300-000-000 and 300-200-000).
- Uninstall and dispose of the battery assembly from the devices being removed.
- Return the removed device (300-000-000 and 300-200-000) to Medtronic.
- Pass this notice on to all who need to be aware within your organization or to any organization where the potentially affected product with the specified serial numbers have been transferred or distributed.
- Please complete the enclosed Customer Confirmation Form **even if you do not** have affected inventory.

Section 2:

Labeling Correction for Item Code 301-000-000

Item Code	GTIN Number	Description
301-000-000	10884521823396 10884521776494	McGRATH™ MAC Video Laryngoscope (Next-Generation)

For customers of Next-Generation McGRATH™ MAC video laryngoscope devices, item code 301-000-000, this notice provides recommendations for good battery handling practices. Some of these recommendations are a reiteration of information contained in the McGRATH™ MAC Video Laryngoscope Instructions for Use (IFU). An IFU addendum is being issued which includes the important battery handling information listed below. **Note**: Next-Generation McGRATH™ MAC video laryngoscope devices (item code 301-000-000) **are not being removed** and are safe and effective for patient use. Next-Generation McGRATH™ MAC video laryngoscopes include an advanced battery management system that maintains the battery within intended voltage usage levels and renders them inoperable when the battery voltage falls below the device design threshold.

Important Battery Handling Information for Customers of Next-Generation Devices (301-000-000)

Medtronic is issuing an addendum to the McGRATH™ MAC Video Laryngoscope Instructions for Use (IFU). This addendum will include the following warnings regarding proper battery handling. Improper battery handling can increase the risk of a thermal event.

- McGRATH™ 3.6V battery assembly (340-000-000) is labelled with a "Use by date". Do not use a battery past the "Use by date".
- Refer to the product Instructions for Use (IFU) for proper battery storage conditions.
    - Any battery assemblies that have not been stored in these conditions should be disposed of per local guidelines.
- Do not use a battery assembly, installed or uninstalled, that has been dropped as it may have sustained internal damage that is not visible.
    - Dispose of any dropped battery assembly in accordance with your facility's procedure and replace with a new McGRATH™ 3.6V labeled battery assembly.

Actions you should take:

- Continue using Next-Generation McGRATH™ Video Laryngoscopes Next-Generation (301-000-000).
- Follow Important Battery Handling Information stated in the IFU and provided in this notice and maintain a copy of the addendum with the IFU for McGRATH™ MAC Video Laryngoscopes.
- Pass this notice on to all who need to be aware within your organization or to any organization where the potentially affected product with the specified serial numbers have been transferred or distributed.
- Please complete the enclosed Customer Confirmation Form **even if you do not** have affected inventory.

Additional Information:

Medtronic is communicating this information to the appropriate regulatory agency in your country.

Adverse reactions or quality problems experienced with this product should be reported to FDA and Medtronic:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call FDA (800) FDA-1088
- Call Medtronic Technical Support at 800-255-6774 option 1, then option 1.

We appreciate your prompt attention to this matter. We regret the inconvenience this may cause. If you have any questions regarding this communication, please contact your Medtronic Representative or Customer Service at 800-962-9888, Option 2.

Sincerely,

Enda Morrissey

Enda Morrissey
Senior Director, Quality
Acute Care and Monitoring

Enclosures:
Appendix A: Identifying Affected Devices
Appendix B: Customer Confirmation Form

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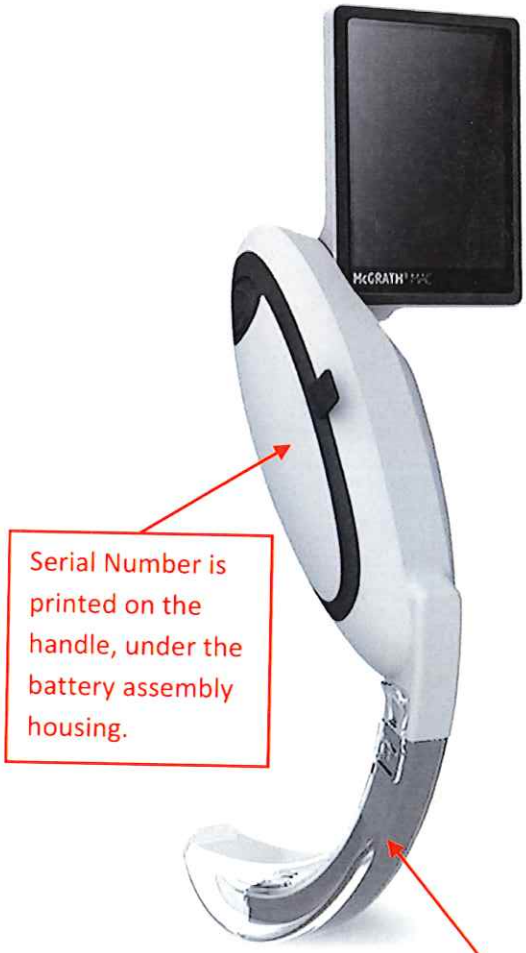
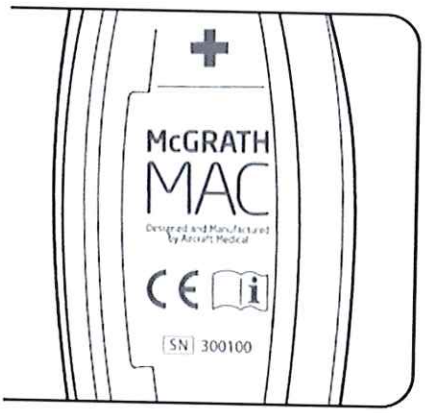
Appendix A:

IDENTIFYING AFFECTED DEVICES

Locate product information on product labels in your inventory

McGRATH™ MAC Video Laryngoscope, (300-000-000; Serial Numbers 366170 to 405673)





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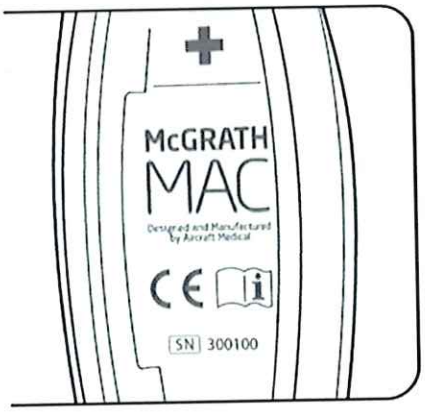
McGRATH™ MAC EMS Video Laryngoscope (300-200-000; Serial Numbers 366170 to 405673)

Back of McGRATH™ 3.6V battery - Use By Date

Serial Number is printed on the handle, under the battery assembly housing.

CameraStick™ (Metallic Gray)



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McGRATH™ MAC Video Laryngoscope, Next-Generation (301-000-000)

IFU Update Only

CameraStick™
(All one color)

Back of McGRATH™ 3.6V battery - Use By Date

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Customer Confirmation Form

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(Correction IFU Addendum 301-000-000)

For completion by Medtronic Customers Only – Please complete all fields below and return all pages immediately, even if you do not have any product to return.

By signing this form, I confirm that I have read the Urgent Medical Device Removal and Correction Notification Letter, dated July 2024, from Medtronic regarding removed McGRATH™ MAC Video Laryngoscope (Item Codes 300-000-000 and 300-200-000) and IFU Addendum (Item Code 301-000-000), and have taken appropriate action.

Please complete all applicable fields and sign the form as indicated below and email to rs.gmbfcamitg@medtronic.com.

Account Name: ___Atrium Medical Center_____

Account Number: ___0001796191_____

Account Signature: _____ **Date:** _____

Please fill in below the quantity of item code 300-000-000 and 300-200-000 product that you have in your existing stock and will be returning. Note: Next-Generation McGRATH™ MAC Video Laryngoscope devices (item code 301-000-000) are not being removed and are safe and effective for patient use.

Product Number	Serial number			RGA# (Contact us for #) rs.covidienfeedbackcustomerservice@medtronic.com

For additional serial numbers, please attach a list.

Refusal Section

- ☐ The above-mentioned facility is voluntarily rejecting participation in Medtronic's field action activity.
- ☐ The equipment has been decommissioned or condemned.
- ☐ The equipment's location is unknown.
- ☐ N/A

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Return Instructions:

- Identify and quarantine all affected McGRATH™ MAC Video Laryngoscope (Item Codes 300-000-000, 300-200-000).
- Product purchased directly from Medtronic please contact rs.covidienfeedbackcustomerservice@medtronic.com for Return Good Authorization (RGA).
- Replacements for returned affected product, serial number ranges from 366170 to 405673, will be issued based on the RGA number.
- If purchased from a distributor, contact your distributor directly to arrange for the return of the product back to your distributor.

Product Return Address: Return all affected product(s) in your inventory to:
Medtronic, Attn: Field Returns Dept., 195 McDermott Road, North Haven, CT 06473 USA.

Note: The addressee may continue to receive reminders of this notice until a response is received.

For questions, contact your Medtronic Representative or Customer Service at 800-962-9888 Option 2.