



PENTAX Medical  
 3 Paragon Drive  
 Montvale, New Jersey • 07645-1725  
 Toll-free: 800-431-5880 • Tel: 201-571-2300

May 23, 2017

**U.S. URGENT FIELD CORRECTION**  
**Notification of Update to Instructions for Use (IFU)**  
**Ultrasound Video Gastroscope Models EG-3670URK and EG-3870UTK**

Dear Valued Customer,

PENTAX Medical has become aware of an error in the Instructions for Use (IFU) for ultrasound video gastroscope models EG-3670URK and EG-3870UTK. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

**Affected Product Details:**

Product: Ultrasound Video Gastroscope Models EG-3670URK and EG-3870UTK  
 Instructions for Use: Z845 Revisions 13 and 14 (R13 and R14)

**Safety Instructions:**

Although no incidents related to this error have been reported to PENTAX Medical, please be informed about the following error and correction:

**Table 1:**

Page	Error	Correct
p70	WARNING: The <u>cleaning detergent solution should</u> remain in contact with the ALL internal channels and external endoscope surfaces for the time period recommended by the manufacturer of the disinfectant.	WARNING: The <u>disinfecting solution must</u> remain in contact with the ALL internal channels and external endoscope surfaces for the time period recommended by the manufacturer of the disinfectant.

**Customer Instructions:**

In order to ensure the proper use and cleaning of the affected PENTAX endoscopes, please have users read and carefully follow the IFU addendum that is included with this letter. If a new IFU is needed, please visit PENTAX Medical’s IFU portal (<https://ifu.pentaxmedical.com/welcome-to-pentax-medical/>). We invite you to contact your PENTAX Medical sales representative to arrange for training regarding these new procedures.

Also enclosed with this letter is a field correction response form. The form identifies the affected endoscopes (model and serial numbers) which have been sold to your facility. Please forward this letter and the enclosures to the department in which the above referenced items are in use. The end user of the affected products should complete this form and return it to PENTAX Medical.

**Contact Information**

If you have any questions regarding this action, please feel free to contact PENTAX Medical Customer Service.

Tel: 800-431-5880 (8:30 AM – 5:00 PM, Monday – Friday, EST)  
 Fax: 201-799-4063 (alternate 201-391-4189)  
 Email: [customeradvisories@pentaxmedical.com](mailto:customeradvisories@pentaxmedical.com)



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This corrective action is being made with the knowledge of the U.S. Food and Drug Administration.

PENTAX Medical regrets any inconvenience that may result from this action and appreciates your patience as we introduce these updated instructions. Please be assured that maintaining patient safety and quality is our utmost priority.

Sincerely,

PENTAX of America Inc.  
Director of Regulatory Affairs

Enclosures:  
Customer Response Form, Control Number MK-951  
Ultrasound Gastroscope IFU (Z845) Addendum, MK-958 Rev. A