Dear Valued Customer,

In April 2014, PENTAX Medical received clearances from the FDA for modifications to the Operation and Reprocessing Instructions for Use (IFU) for the 90-series of video colonoscopes and video gastroscopes (“Affected Endoscopes”). These revised instructions have not been included in product shipments since the time of these clearances.

PENTAX Medical is initiating this field action to provide customers that have purchased the Affected Endoscopes with the most recent Operation and Reprocessing IFUs. For your convenience, a USB flash drive is provided containing electronic copies of the Operation and Reprocessing IFUs and accompanying addenda and bulletins. These revised instructions should be implemented as soon as possible.

Some of the video colonoscope and video gastroscope models (see Table 2 below) have a forward water jet channel that requires an OE-C20 cleaning adapter. Customers who need OE-C20 adapters can purchase them from PENTAX Medical for affected endoscope models by requesting part number KUM-OEC20-FCA.

Revised Instructions
The instructions have been revised in the following manner:

- Operation IFU
  - Integrated all models of each family into the IFU
  - Modified the indications for use language to be consistent with similar products
  - Enhanced the explanation of the operation of the device
  - Revised and added cautions and warnings

- Reprocessing IFU
  - Included more specificity regarding reprocessing activities to aid in the proper method for reprocessing the endoscopes, including:
    - number of brush and rinse steps,
    - quantity of fluid volumes,
    - use of additional text, figures, cautions, and warnings
  - Integrated use of OE-C20 adaptor

Identification of Affected Endoscope Models
Table 1 provides an overview of the Affected Endoscope models, and the part number and revision of the historical and revised IFUs. The accompanying USB flash drive contains all the revised IFUs identified below. Please distribute only those IFUs which support the products owned by your facility.

### Table 1

<table>
<thead>
<tr>
<th>Affected Models</th>
<th>Historical Version of IFU’s</th>
<th>Revised IFU’s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Video Colonoscopes:</td>
<td>Z934 Owners IFU Z663 Reprocessing IFU</td>
<td>S017_R01 Operator IFU S022_R04 Reprocessing IFU No.388_R01 Addendum No.392_R00 Addendum D04-IFU-0001206 Rev. A Addendum MK-626 Rev. D Bulletin</td>
</tr>
<tr>
<td>EC-2990LI, EC-3490LI, EC-3490LK, EC-3490TLI, EC-3890LI, EC-3890LK, and EC-3890TLK</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Instructions Regarding Historical IFUs
Please ensure that user departments discard the prior versions of these Instructions for Use and ensure that all users read and carefully follow the revised Operation and Reprocessing IFUs to ensure the proper use and cleaning of the affected PENTAX endoscopes. We invite you to contact your PENTAX Medical sales representative to arrange for training regarding these new procedures.

Need for OE-C20 Cleaning Adapter
Table 2 is a chart of each 90-series video colonoscope and video gastroscope model, and whether that model has a forward water jet that requires an OE-C20 cleaning adapter.

<table>
<thead>
<tr>
<th>Video Colonoscopes</th>
<th>OE-C20 Adapter Required</th>
<th>Video Gastrosopes</th>
<th>OE-C20 Adapter Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC-2990LI</td>
<td>YES</td>
<td>EG-1690K</td>
<td>NO</td>
</tr>
<tr>
<td>EC-3490LI</td>
<td>YES</td>
<td>EG-2490K</td>
<td>NO</td>
</tr>
<tr>
<td>EC-3490LK</td>
<td>YES</td>
<td>EG-2790I</td>
<td>NO</td>
</tr>
<tr>
<td>EC-3490TLI</td>
<td>YES</td>
<td>EG-2990I</td>
<td>YES</td>
</tr>
<tr>
<td>EC-3890LI</td>
<td>YES</td>
<td>EG-2990K</td>
<td>YES</td>
</tr>
<tr>
<td>EC-3890TLK</td>
<td>YES</td>
<td>EG-3490K</td>
<td>YES</td>
</tr>
<tr>
<td>EC-3890TLK</td>
<td>YES</td>
<td>EG-3890TK</td>
<td>YES</td>
</tr>
</tbody>
</table>

Response Form
Enclosed with this letter is a Field Correction Response Form. The form identifies the Affected Endoscopes (Model and Serial Number) which have been sold to your facility. Please forward this letter and the enclosures to the relevant department in your facility so that they may review the information provided and complete the response form. Please note that you must return the completed form even if you do not have any IFUs to discard. Your local sales representative can assist you in completing this form. This information is essential in order to maintain recall effectiveness information required by FDA.

Contact Information
If you have any questions regarding this action, please feel free to contact Paul Silva, PENTAX Americas Recall Coordinator at:

Tel: 800-431-5880 ext. 2064 (8:30 AM – 5:00 PM, Monday – Friday, EST)
Fax: 201-799-4063 (alternate 201-391-4189)
Email: recall.coordinator@pentaxmedical.com

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,

Paul Silva
PENTAX of America Inc.
Director of Regulatory Affairs

Enclosures:
Customer Response Form, Control Number F04-REG-0001384
USB Flash Drive containing the Revised Instructions for Use, Control Number 7201-0100