10th Jan, 2012

Dear Valued Customer,

Our records indicate that you have received this product:
Bravo® pH Monitoring System, part number FGS-0312 (5-Pak) or FGS-0313 (Singles).

**Given Imaging is conducting a voluntary recall of Bravo® pH Monitoring devices. This recall is specific to lot numbers 11775Q through 17101Q.**

Please read this important information packet in its entirety. The enclosed directions require action on your part.

Given Imaging has received reports of failure of the Bravo capsule to attach to the esophagus or, alternatively, failure of the capsule to detach from the placement device. Upon investigation, Given Imaging determined that these failures have a combination of root causes including issues related to tolerances in certain manufacturing dimensions not being specified.

The reports of these issues have low rates of incidence and Given Imaging believes that there is low risk of injury to patients; however, occurrence of these failures may result in lengthened time for a Bravo procedure, esophageal injury, and/or the need for additional procedures.

In discovering these issues, Given Imaging has determined that the modification of some of the product tolerances within the specification ranges should decrease the likelihood of failures. These adjustments are incorporated into all Bravo product currently being manufactured.

**Given Imaging is also reiterating the importance of the rescue procedure, prior to removal of the device from the patient in any instance where there is resistance to removal of the device after capsule placement. When this condition occurs the practitioner is encouraged to break the handle which will release the device from the capsule.**

An “Attention” label on how to perform the rescue procedure (example included in this notice) and an updated User Manual are now being provided with all Bravo devices.
Finally, Given Imaging has also identified some instruction and technique-related adjustments that should have a positive impact on reducing incidences of failures. These include:

- Given Imaging has increased the minimum vacuum requirement for the vacuum pump from 510mmHg to 550mmHg. We have verified that this higher minimum is effective and safe.

- Given Imaging is recommending that users of all levels of experience consult with their Given Imaging representative for the latest information on proper administration techniques for Bravo use. Given Imaging has found that simple adjustments in hand position may positively affect procedure success.

Affected devices are all devices with lot numbers 11775Q through 17101Q. These devices were distributed between January 1, 2010 and December 31, 2011. Given Imaging will replace these Bravo devices at no charge.

This voluntary recall is being conducted with the knowledge of the FDA.

In order to ensure that the devices noted above are retrieved from your facilities, we request that you locate the devices as soon as possible and remove them from use. We also request that you identify the quantity of unused devices at the facility and return all of them to Given Imaging according to the instructions on the attached recall confirmation sheet. Please follow the enclosed directions carefully. If these devices are at other locations, please forward this information to them immediately.

We apologize for any inconvenience this may cause. Given Imaging continues to strive to provide the highest quality products and services that assist in meeting the needs of gastrointestinal diagnostics and monitoring.

Sincerely,
Given Imaging (Asia) Co. Ltd.
Please complete the following and return it to Given Imaging per the instructions below. All unused devices should be returned to Given Imaging.

Please fax this completed form to +852 2989 0899. No cover sheet is necessary.

Bravo® pH Monitoring System Recall Confirmation for:

Customer Number: ________ Customer Name: ____________________________

1. All unused Bravo pH Monitoring Systems with lot numbers 11775Q through 17101Q at the facility have been retrieved from all our locations within the facility, physically separated from products available for use, and removed (check one):

☐ YES ☐ NO Unused Product ☐ NO, explain:

____________________________________________________________

2. Fill in the quantity of these devices remaining at the facility.

Our records indicate that the following Bravo pH Monitoring System affected by this voluntary recall (products with lot numbers 11775Q through 17101Q) were shipped to this facility:

<table>
<thead>
<tr>
<th>Product</th>
<th>Quantity of Unused Devices Remaining at Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bravo® pH Monitoring System (5-Pak)</td>
<td></td>
</tr>
<tr>
<td>Bravo® pH Monitoring System (Single)</td>
<td></td>
</tr>
</tbody>
</table>

(If you have used all of either type of the affected devices please indicate “0” remaining for that type.)

If you have unused devices, we will provide you with material and instructions to return the devices to us at no cost to the facility once we receive this information. To receive credit for any unused devices, they will need to be returned.

3. The following is a REQUIRED FIELD. Confirmation Completed by:

_________________________________________ ________________________ ________________________ __________
Printed name Title Signature Date

www.givenimaging.com