Bravo® pH Monitoring System
Urgent Product Recall

{Address}

{Place}, 14.02.2012

Dear {Customer Name},

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

On behalf of Given Imaging {Name of Distributor} is conducting a voluntary recall of Bravo® pH Monitoring devices. This recall is specific to lot numbers starting at 11775Q through and including 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 oesophagus 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 products 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 starting at 11775Q through and including 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, the German BfArM and the {Name of local authority}.

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 {Name of Distributor} 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 and {Name of Distributor} continue to strive to provide the highest quality products and services that assist in meeting the needs of gastrointestinal diagnostics and monitoring.

We encourage you to report any adverse events or quality concerns with this product to {Name of Distributor}. As always adverse events may also be reported to the {Name of local authority}.

If you have any questions or require additional information, please contact {Name of Distributor} at the number listed below.

{Telephone number of Distributor}
Sincerely,

The {Name of Distributor} Management Team

Attachment: Delivery Device Recall Confirmation
Customer Bulletin

Please complete the following and return it to {Name of Distributor} per the instructions at the bottom of this form. All unused devices should be returned to {Name of Distributor}.

Please fax this completed form to {Fax # of Distributor}. No cover sheet is necessary.
OR
Scan and e-mail to {E-mail address of Distributor}.

Bravo® pH Monitoring System Recall Confirmation for:

Customer Number: {Customer Number} ***Customer Name:*** {Customer Name}

1. All unused Bravo pH Monitoring Systems with numbers starting at 11775Q through and including 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 Systems** affected by this voluntary recall (products with lot numbers **11775Q through 17101Q**) were shipped to this facility:

Product	***No. of Devices Shipped***	***Quantity of Unused Remaining at Facility***
Bravo® pH Monitoring System (5-Pak)	{#}	
Bravo® pH Monitoring System (Single)	{#}	

(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*

Customer Bulletin: Update to Vacuum Settings

Dear Customer,

This bulletin provides new specifications for verifying the proper operation of the Medela vacuum pump prior to performing placement of the Bravo pH capsule. The information is provided in three sections:

- Updated Bravo IFU information
- New process for setting up vacuum
- New label for vacuum pump adjustment knob

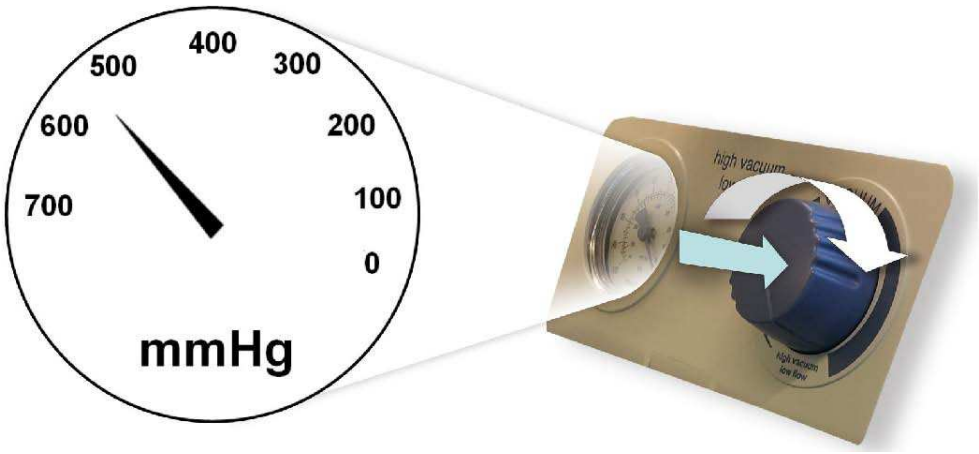
Updated Bravo IFU An updated version of the Bravo user manual is available in a miniCD format included in every Bravo pH capsule delivery device 5pack (FGS-312). Additionally, an electronic version of the document can be downloaded from the Given Imaging website using the following link:

http://given.com/bravo-manual

Click the link and, when prompted, select '**Save As**' to save the file to your computer. The Bravo user manual is updated to include the new vacuum setup process which has been modified to help ensure successful placement of the Bravo pH capsule.

Setting up the vacuum pump The minimum vacuum requirement for the vacuum pump has been updated from 510mmHg to 550mmHg. In order to verify that your vacuum pump meets these updated requirements, please perform the following test:

1. Ensure that the vacuum pump adjustment knob is turned fully to the maximum level. This is done by pushing the knob in and turning it clockwise as far as it would go. The adjustment knob should remain at the maximum setting at all times.

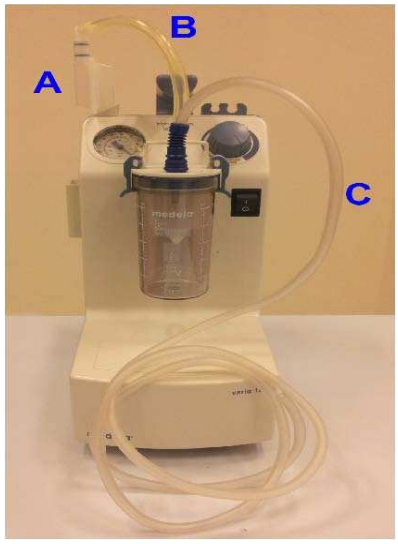


2. Connect the following components provided by Given Imaging
   - Filter (A)
   - Vacuum tube (B) connecting the filter to the canister
   - Vacuum tube (C) connecting the canister to the Bravo delivery device

Customer Bulletin: Update to Vacuum Settings

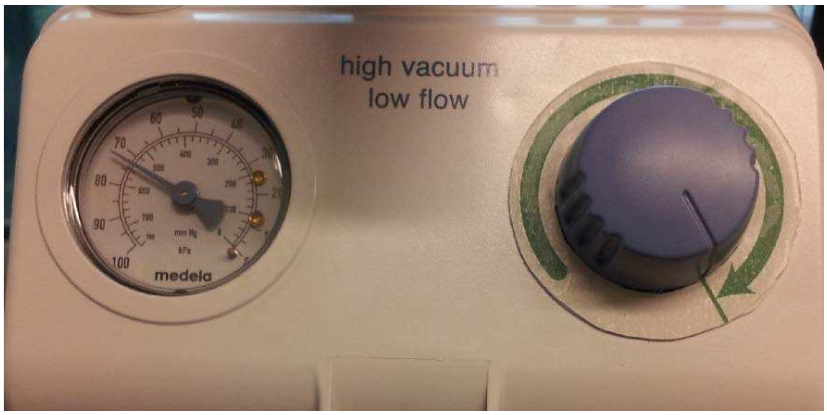
The components described above are provided by Given Imaging with each new vacuum pump or ordered directly from Given Imaging representative with FGS-0309

The image on the right displays the connection of the components to the vacuum pump and the Bravo delivery device.



3. Switch the vacuum pump on and Cover the tube with your finger. The vacuum gauge should read at least 575 mmHg. Remove your finger. The vacuum gauge should drop drastically (to zero or close to zero). If the vacuum unit complies with the above behavior, the vacuum unit is functioning properly. If the vacuum fails to reach 575 mmHg or fails to drop to close to zero, the vacuum unit should not be used. Contact customer support.

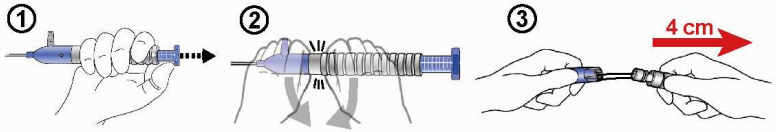
New label for vacuum pump adjustment knob The vacuum pump adjustment knob label supplied with this bulletin is designed to help ensure that the vacuum knob remains at the maximum setting. After completing the test above and verifying that the pump has passed, switch the vacuum pump off and affix the label (LBL149001 provided with each 5pack) on the vacuum pump as shown below.



Ensure that the indicator on the vacuum knob is aligned with the green arrow.

Attention!

If you feel any resistance when attempting to remove the catheter after fully raising the plunger with your thumb (1), disassemble the device by breaking the handle (2) and withdraw the gray portion of the handle a minimum of 4cm (3).
This will release the capsule and allow the removal of the catheter.
For more information read the Instructions for use.



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For more information read the Instructions for use.