

Fig. 1a Fig. 1b Fig. 1c

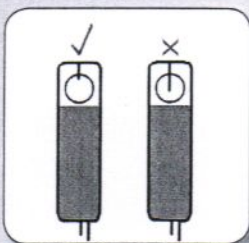


Fig. 2

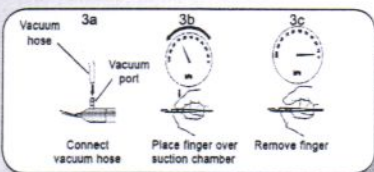


Fig. 3a Fig. 3b Fig. 3c

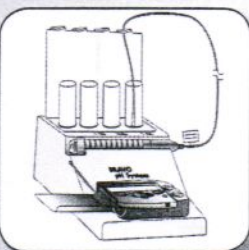
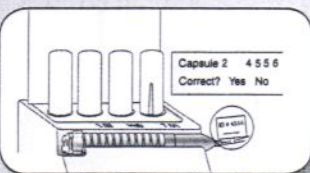


Fig. 4



Confirm that Capsule ID numbers match.

Fig. 5

1. Prepare the Calibration Stand

Verify that the pH buffers are at room temperature and have not expired. Fill the 4 tubes in the calibration stand half full. The fluid should be barely visible above the calibration stand tube holder.

- Tube 1: pH 7.01 buffer
- Tube 2: Sterile water
- Tube 3: pH 1.07 buffer solution
- Tube 4: Sterile water

2. Prepare the Bravo Delivery Device and Capsule

- Verify that the capsule is not expired, then carefully remove Bravo capsule and delivery device from the packaging. Remove clamshell, soaker bulb, and magnetic clip. (Fig. 1a, b)
- Check soaker bulb for fluid and set aside. If bulb is dry, contact Given Imaging Customer Support.
- Remove the magnetic clip and set aside. (Fig. 1c) Check chamber to ensure that trocar needle has not advanced. (Fig. 2)

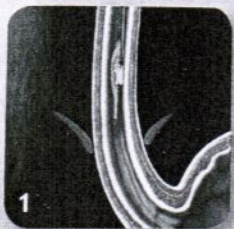
3. Prepare the Medela Pump

- Attach Medela Pump vacuum hose to delivery device. (Fig. 3a)
- Close off tissue chamber on Bravo capsule with thumb. Turn on pump, and ensure that vacuum level reaches at least 510 mmHg (68 kPa).
- Remove thumb from capsule. Vacuum level should drop by a minimum of 40 mmHg. (Fig 3b, c)

Note: Elevation affects maximum suction pressure of the Medela Pump.

4. Calibrate the Bravo Capsule

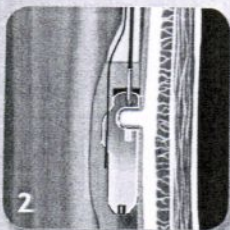
- Place the Bravo delivery device in the calibration stand with the catheter going to the right. Place capsule in pH 7.01 buffer and agitate to remove bubbles. **Note: When placing capsule into calibration tube, keep pH sensor clear of tube edge. Secure curved portion of delivery system behind retainer at top of calibration station. Soak capsule in pH 7.01 buffer solution for at least 10 minutes.** (Fig 4)
- Place a fresh AA lithium battery in Bravo Receiver and place it in the calibration stand. Verify the **Time** and **Date**, then go through the **SETUP** questions to select study options. Select **CAL** from main menu.
- The Receiver will display "Listening for Capsule" and a capsule ID number on the screen. This number **must match the number on the capsule** before continuing. (Fig 5) **Note: If Receiver is not able to identify the correct capsule ID number, refer to Instructions For Use.**
- The Receiver will display the message "Place in pH 7.01." Confirm that the capsule has been completely covered with pH 7.01 buffer for at least 10 minutes. Press **Enter** to start calibration. The Receiver will show percent of calibration completed.
- After 1-2 minutes, the Receiver will beep to indicate calibration in pH 7.01 buffer is complete and will then display the message "Place in pH 1.07." Before pressing **Enter**, rinse capsule in sterile water by agitating gently. Place capsule in pH 1.07 buffer. **Wait 30 seconds and then press Enter.**
- When the calibration is complete, the Receiver will beep and briefly display "Capsule 1 Calibrated."
- Check post-calibration values. Note pH reading in pH 1.07 buffer. **Without pressing Enter**, rinse capsule in sterile water and place in pH 7.01 buffer. Wait approximately 30 seconds for reading to stabilize and note pH reading. Post-Calibration values should be approximately the same as the buffer values.
- Press **Enter** and the Main Menu will appear. You are now ready to start the pH study. If the study will not start immediately, the capsule should remain in the pH 7.01 buffer, but must be used within 8 hours of calibration. **If start of pH study will be delayed by more than 30 minutes:**
 - Turn the Receiver off by holding power button down.
 - To start this pH study later in the day, turn Receiver back on by holding the power button down, bypassing **SETUP** and **CAL**, and going directly to **pH STUDY**.
 - With **pH STUDY** highlighted on Main Menu, press **Enter**. Press **Enter** again to start study. ***Recording*** will be displayed on the Receiver.



Step 1

Position Bravo pH capsule in the esophagus.

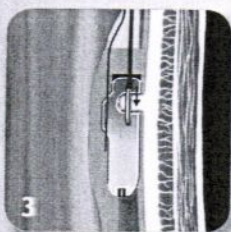
- Remove the capsule with delivery device from the pH buffer and rinse it in sterile water.
- Determine attachment location and mark it on the delivery device.
- Attach the vacuum hose to the handle.
- With the vacuum source turned off, carefully advance the delivery device to the desired location by passing it through the mouth with the capsule facing the patient's tongue.
- Stabilize the delivery device by holding it near the patient's mouth.



Step 2

Apply suction to draw a small amount of tissue into the capsule's suction chamber.

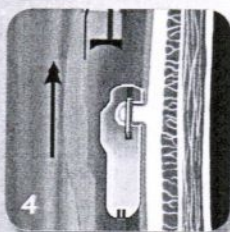
- Turn on the vacuum source and apply a minimum of 510 mmHg (68 kPa).
- After the vacuum level stabilizes, hold the delivery device in place for a full 30 seconds.



Step 3

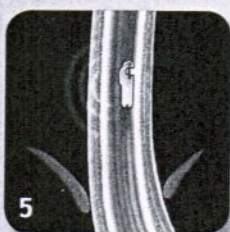
Attach capsule.

- Remove the safety tab from the Bravo handle.
- Press the plunger down with your thumb until it clicks into position; remove your thumb from the plunger.
- Using your thumb, rotate the top of the plunger clockwise 1/8th of a turn to release the capsule from the delivery device.
- Ensure that the white line is visible above the handle body. If not, use your thumb to raise the plunger until the white marking is visible.



Step 4

After ensuring the vacuum source is off, remove delivery system from the esophagus.



Step 5

Capsule immediately begins transmitting pH data.

- Verify that the Receiver is on and receiving data.



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6

1. Verify the DataLink is connected to the computer. (Fig. 1)
2. Turn on the computer and start the Polygram Net™ pH testing application software.
Note: Refer to the Polygram Net software User Guide for instructions on installing or starting the software.
3. Click the appropriate Bravo protocol from the **Home** tab in the Polygram Net software.
4. Enter the study details as necessary and click **Capture** in the Polygram Net software.
5. Open the Receiver door and turn the unit on by pressing the on/off button. The Receiver will ask you to confirm the correct time and date.
6. Press the **Enter** button to confirm the correct time and date. Place the Bravo pH Receiver in the DataLink.
7. Put the Receiver into **Send** mode by pressing the arrow keys until the **Send** option is highlighted. Press the **Enter** button. (Fig. 2)
8. The Receiver will display the message that it is "Initiating PC Connection." (Fig. 3)
9. In **Capture** view of the pH study in the Polygram Net software, click the red ● "Start Upload" button to initiate the upload process.
10. As the Receiver uploads pH data to the computer, the Receiver will display "Transferring Data." (Fig. 4)
11. When the data upload is complete, the Receiver will display "Transfer Successful." (Fig. 5)
Note: If the PC connection or data upload fails, refer to the Troubleshooting section of the Bravo pH Receiver User Guide.
12. The pH study will appear in **Capture** view in the Polygram Net software. Diary events and symptoms can be entered on this screen.
13. Click **Report** in the Polygram Net software to view and print the Bravo pH report.
14. Turn off the Receiver by pressing the power button and holding it for 2-3 seconds until the controller and patient displays turn off. Remove battery and store the Receiver for the next study. (Fig. 6)






BRAVO pH Patient Diary

Patient Instruction

The purpose of pH monitoring is to monitor the frequency and duration of gastroesophageal reflux during a normal day. It is important that you eat, drink, work and exercise as you normally would. Without carrying out your normal day, the test results may not reflect an accurate picture of your esophageal pH exposure.

DO NOT take any antacid (drugs such as Maalox, Mylanta, Tums, Roloids, Zantac, Tagamet, Pepcid, Axid, Prilosec, Nexium, Prevacid, Aciphex or Protonix) during your study unless instructed to by your physician.

Using the Patient Diary

Symptom Button	Symptom
	Heartburn
	Regurgitation
	Chest Pain

Record events (i.e. meals and sleep) in the patient diary using the time on the Receiver's display.

Using the Symptom Buttons

During the pH study symptoms (Heartburn, Regurgitation, Chest Pain) can be recorded in this diary or automatically recorded by pressing the appropriate symptom button.

To confirm that the button has been pressed, a green indicator light remains lit for 3 seconds and a beep is heard if this feature is turned on.

Receiver Out of Range

If the Receiver is too far from the Bravo Capsule, a beep will be heard for 30 seconds and the display will flash C1 or C2. Move the Receiver to your breastbone until the beep stops and the C1 or C2 is no longer visible.

If you have any problems or questions during your study, call _____ at _____.

At the completion of your pH study, return the Bravo pH Receiver and your diary to the Endoscopy/GI Lab on:

Manufactured by:



Medtronic A/S
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Phone +45 44 57 90 00
E-mail: gastro.mfd@medtronic.com
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BRAVO pH

diario de paciente

Instrucciones de paciente

El propósito de monitoreo del pH es vigilar la frecuencia y la duración de reflujo gastroesofágico durante un día normal. Es importante que usted come, bebe, trabaja y ejercer como lo haría normalmente. Sin efectuar su día normal, los resultados de la prueba no pueden reflejar una imagen precisa de su exposición del pH esofágico.

NO se tomar cualquier antiácido (medicamentos tales como Maalox, Mylanta, Tums, Roloids, Zantac, Tagamet, Pepcid, Axid, Prilosec, Nexium, Prevacid, Aciphex o Protonix) durante su estudio a menos que indique a su médico.

Usando los botones de síntomas

Usando los botones de síntomas durante los síntomas de estudio de pH (acidez, regurgitación, dolor de pecho) puede ser grabado en este diario o grabado automáticamente pulsando el botón apropiado del síntoma. Para confirmar que se ha presionado el botón, una luz de indicador verde permanece encendida durante 3 segundos y un sonido se oye si esta característica está activada

Utilizando los eventos de paciente diario

Button de sintoma	Síntoma
	Acidez
	Regurgitación
	Dolor de pecho

Apunte los eventos (comida, hora de dormir) en el diario de paciente usando la hora indicada en la pantalla del receptor.

Receptor de rango

Si el receptor está demasiado lejos de la cápsula de Bravo, se escucha un sonido durante 30 segundos y la pantalla parpadeará p1 o p2. Mover el receptor a su esternón, hasta que el sonido se detiene y la p1 o p2 ya no es visible. Si tienes cualquier problema o preguntas durante su estudio, llame a _____ al _____. En la realización de su estudio de pH, devolver el pH de Bravo receptor y su diario para el laboratorio de endoscopia/GI