Bravo® pH Monitoring System

User Guide
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FCC Compliance Statement
This device complies with Part 15 of the FCC. Operation is subject to the following two conditions:
1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

Rx Only

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Introduction

Description
The Bravo® pH Monitoring System is intended to be used for gastroesophageal pH measurement and monitoring of gastric reflux:

- First, a Bravo pH capsule is calibrated and the Bravo pH recorder (an ambulatory, programmable data recorder) is prepared.
- Using the delivery device, the capsule is positioned and attached in the patient’s esophagus, following either endoscopy or manometry.
- The data is collected by the capsule and transmitted to the recorder for the duration of the study.
- The data is then uploaded from the recorder to the software application on the PC or workstation. The software application is used to record, store, view, and analyze gastroesophageal pH data, enabling physicians to interpret study results.

Indications for Use
The Bravo pH Monitoring System is intended to be used for gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age. The Bravo pH capsule can be attached following either endoscopy or manometry. The AccuView and Reflux software applications are intended to record, store, view, and analyze gastroesophageal pH data.

Contraindications
Patients with bleeding diathesis, strictures, severe esophagitis, varices, obstructions, pacemakers or implantable cardiac defibrillators are contraindicated.

Warning
Patients are restricted from undergoing an MRI study for 30 days from the start of a pH study. The Bravo pH Monitoring System is not compatible for use in an MRI magnetic field. Use of the Bravo pH Monitoring System in an MRI magnetic field will result in damage to the system and possible patient injury.
Warnings and Precautions

- **Bravo pH capsule with delivery device**: Potential complications include, but are not limited to:
  - aspiration of the capsule if inadvertently pulled back up into the upper esophagus by the delivery device. There is a possibility that this may occur in a procedure in which the capsule did not attach to the esophageal mucosa.
  - tears or perforations in the mucosal and submucosal layers of the esophagus causing bleeding and requiring possible medical intervention.
  - **gastrointestinal endoscopy**: Potential complications include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, hypertension, respiratory arrest, and cardiac arrhythmia or arrest.
  - **nasal intubation**: Potential complications include, but are not limited to: sore throat, discomfort, and nasopharyngeal damage resulting in bleeding and soft tissue damage.
  - **Bravo pH capsule**: Potential complications include, but are not limited to:
    - discomfort associated with the capsule, or failure to detach from the esophagus within several days after placement, either of which may necessitate endoscopic removal.
    - premature detachment of the capsule.
  - The safety and efficacy of the Bravo pH capsule with delivery device has not been established for pediatric use on patients below the age of 4.
  - The Bravo pH capsule with delivery device is a single-use, disposable device. Reuse or any other misuse of a Bravo pH capsule with delivery device (such as sharp bending or kinking) results in an increased potential for damage to the delivery device and capsule, and possible patient injury.
  - Prior to use, all equipment for the pH study should be examined carefully to verify proper function.
  - Unauthorized maintenance by inadequately trained personnel would result in an unacceptable risk (e.g., excessive temperatures, fire, or explosion).
  - A thorough understanding of the technical principles, clinical applications and risks associated with the Bravo recorder is necessary before using this product. Read the entire manual before using the system for the first time.
  - No modification of this equipment is allowed.
  - Patients are restricted from undergoing an MRI study within 30 days of the pH study.
  - The Bravo capsule contains a trocar needle that is made of stainless steel. Use caution in patients with known sensitivities or allergies to the metals that are contained including chromium, nickel, copper, cobalt, and iron. The Bravo pH test lasts from 48 to 96 hours.
• Prior to the pH study, the patient should not eat or drink for a minimum of 6 hours.
• If excretion of the Bravo pH capsule from the patient has not been positively verified, and the patient develops unexplained postprocedure abdominal pain, vomiting, or other symptoms of obstruction, the patient should contact the physician for evaluation and possible abdominal X-ray.
• Undergoing an MRI while the Bravo pH capsule is inside the patient’s body may result in serious damage to the patient’s intestinal tract or abdominal cavity. If the patient did not positively verify the excretion of any Bravo pH capsule, the patient should contact the physician for evaluation and possible abdominal X-ray before undergoing an MRI examination.

Storage
Store all components in a controlled room temperature environment:
• capsules at 15–45 °C (59–113 °F)
• recorder at 0–40 °C (32–104 °F)

Electromagnetic Compatibility
Electrical equipment for medical use requires special electromagnetic compatibility (EMC) precautions and should be installed and serviced according to the documentation of device. Portable and mobile communication equipment can affect electrical equipment for medical use. For additional information on electromagnetic compatibility, see Electromagnetic Compatibility Declaration (EN / IEC 60601-1-2) on page 37.
Patient Information (Benefits and Risks)

Benefits
Bravo pH monitoring system provides a more tolerable and convenient way to evaluate your reflux symptoms when compared to catheter-based pH monitoring systems.

The capsule is temporarily attached to the wall of your esophagus. The capsule transmits pH information wirelessly to a small recorder that you wear. Data can be transmitted approximately 2 meters (6 feet), which means that you can take the recorder off to shower and sleep without interrupting the test.

You can engage in your usual activities during the test, which can provide your doctor with a more accurate picture of your acid exposure compared to data collected using catheter-based systems.

Risks
The Bravo pH test is not for everyone. If you have bleeding diathesis, strictures, severe esophagitis, varices, obstructions, a pacemaker, or an implantable cardiac defibrillator, you should not undergo a Bravo pH test. Additionally, because the capsule contains a small magnet, you should not have an MRI study within 30 days of undergoing the Bravo pH test.

Potential complications include, but are not limited to, the following events:
• perforation
• premature detachment of the pH capsule
• failure of the pH capsule to detach from the esophagus within several days after placement or discomfort associated with the pH capsule, requiring endoscopic removal
• tears in the mucosal and submucosal layers of the esophagus, causing bleeding and requiring possible medical intervention

Potential complications associated with gastrointestinal endoscopy include:
• perforation or hemorrhage
• aspiration
• fever or infection
• hypertension
• respiratory arrest
• cardiac arrhythmia or arrest

Note
All pH testing procedures carry some risks. This information should not be used as a substitute for talking with your doctor about diagnosis and treatment.
System Components

The Bravo pH Monitoring System consists of the following items:

1. Bravo pH recorder (referred to as recorder in this user guide)
2. case and shoulder strap
3. USB cable
4. charger
5. AccuView or Reflux software, delivered separately either on media or pre-installed on a bundled PC workstation (referred to as PC in this user guide)
6. Bravo pH capsule with delivery device (referred to as capsule in this user guide)
7. vacuum pump
8. pH 1.07 and pH 7.01 calibration buffer solutions
9. calibration stand
10. sterile water (to be supplied by the user)
System Workflow
When using the Bravo pH Monitoring System, you follow this general workflow:

1. **Charging the battery**: you can charge the recorder by connecting the supplied charger to an electrical outlet or by connecting the supplied USB cable to your PC.
2. **Recorder setup**: this includes setting the date and time and defining the default settings for studies. You only need to do it once (though values can be changed later as needed). See *Setting the Date and Time* on page 11.
3. **Calibration**: this includes making sure that the capsule is correctly reading the pH levels. You do this for every study. See *Calibrating Capsules* on page 13.
4. **Capsule placement**: this includes performing the procedure of positioning and attaching the capsule in the patient. See *Placing the Capsule* on page 21.
5. **Patient instructions**: this includes reviewing information about the study with the patient, such as instructions on using the recorder and filling out the patient diary. See *Reviewing Instructions with Patients* on page 26.
6. **Study duration**: this includes the patient wearing the recorder for the study duration.
7. **Data upload**: this includes transferring the study data from the recorder to the PC for analysis in the application software. See *Uploading pH Data* on page 28.

You must also become familiar with the basic workings of the recorder, including normal maintenance functions such as recharging and cleaning. See *Bravo pH Recorder* on page 7 and *Recorder Maintenance* on page 29.
Bravo pH Recorder

Description
The Bravo pH recorder is lightweight and compact. It fits into a case that comes with a strap and a belt clip. Patients wear the recorder (over the shoulder or attached to a belt) throughout the study period.

Backlight
The recorder has a backlit LCD screen and a row of symptom buttons. The backlight turns off automatically (select the backlight duration in Preferences). Pressing any key turns on the backlight. Only when the backlight is on can any of the recorder functions be used (for example, menu access for recorder setup, or symptom buttons for patient use).

Patient Buttons
When the recorder is placed in the case and is in record mode (that is, during a study), the on/off button and USB port are covered. The patient can use the three symptom buttons (Chest Pain, Regurgitation, and Heartburn) and the two event buttons (Meals and Supine) to record events during a study (see Figure 2).

* The default values of these buttons can be set in the software application.
During a study, the patient pushes any button to turn on the backlight. Once the backlight is on, pressing a symptom button causes a beep to occur, the button’s LED to light up briefly, and its icon is inverted briefly on the screen (see Figure 3). If the button is one of the event buttons, a beep occurs and the button’s LED starts blinking, indicating the event’s start time. The blinking continues until the patient presses the button again when the event ends. (That is, the patient presses any button to first turn on the backlight, and then presses the event button to signal the end of the event.)

![Regurgitation icon before and after pressing button.](image)

**Figure 3.** Regurgitation symptom icon as it appears on the recorder screen before and after pressing the button.

**Note**

Meal and Supine buttons can be used for patient input during the study.

When the recorder’s **PC Software** preference is set to RAPID pH, the Meal and Supine features are not supported. These buttons are located on the left and the right of the symptom buttons and are used only to navigate while setting up a study. Once a study recording has begun, the Meal and Supine buttons are disabled for patient use.

For details about selecting the software application, see *Choosing Study Settings* on page 11.

**Clinician Buttons and Menus**

You, the clinicians, have access to the menu to program the recorder for a study. The main menu appears after the welcome screen when the recorder is turned on.

While in the menu, you use the symptom buttons to navigate. The buttons have different meanings depending on the screen. For example, you may be prompted to press **Yes, No, Skip, Cancel**, etc. The recorder screen shows an arrow pointing to the appropriate button:

- **Escape/back.** Goes back (returns to previous level in the menu).
- **For the purpose of this document, ESC is used to indicate either escape/back button.**

- **Escape/back:** same functionality as the above.
- **In addition, it is also used to set the date and time.**
- **For the purpose of this document, ESC is used to indicate either escape/back button.**
Status LED
There is a small LED below the symptom buttons. The LED indicates the status of recorder by the color and duration or frequency of the flash.

<table>
<thead>
<tr>
<th>LED Status</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>off (no light)</td>
<td>Not recording any capsule transmissions. Data from previous study has been uploaded.</td>
</tr>
<tr>
<td>blinking blue</td>
<td>Receiving transmission from the paired capsule (recording).</td>
</tr>
<tr>
<td>blinking or steady red</td>
<td>A transmission error has occurred.</td>
</tr>
<tr>
<td>steady green</td>
<td>Study completed but data has not yet been uploaded to the software application.</td>
</tr>
<tr>
<td>blinking green</td>
<td>Data is being uploaded.</td>
</tr>
<tr>
<td>steady orange</td>
<td>User has pressed OK after calibration is completed message appeared on the screen.</td>
</tr>
</tbody>
</table>

General Guidelines
When working with the recorder:

- All values in Settings (for example, study duration, number of capsules) and Preferences (for example, date and time format and interface language) stay in effect for all studies until you change them.
• Fully recharge the battery before each study (see Charging the Recorder on page 10).
• Clean the recorder after each study (see Cleaning the Recorder on page 29).

Charging the Recorder
The recorder is delivered with the battery fully discharged. It must be recharged before using. A fully discharged recorder battery may take up to 7 hours to charge.
• Connect the recorder to the charger and plug it into an electrical outlet, or
• Connect the recorder to a USB cable and connect it to your PC. Do not use this method for charging more than one recorder simultaneously.

Turning the Recorder On and Off
1. Press and hold the on/off button (see Description on page 7) for 5 seconds until the recorder screen turns on.
   The recorder automatically performs an internal diagnostic check, which includes checking the batteries and verifying the time and date.
   • The recorder screen displays a brief welcome message showing the software and hardware versions.
   • If the battery is sufficiently charged and the time and date are available, the main menu is displayed.
   • If the date or time is not available, the recorder automatically displays the screen to set the date and time.
   • If the main battery is low, the recorder displays: Charge battery!

   Note
   The cursor’s default position shows the next logical step in your workflow. For example, if you have completed calibration, the cursor appears at Start Study. (You can move the cursor to select something else.)

2. To turn off the recorder, press and hold the on/off button for 2–3 seconds until Turn OFF the Recorder? appears on the recorder screen.

   Note
   The backlight remains on during Settings and Calibration processes. When recording or the main screen is displayed, the backlight turns off after the predefined time (default 30 seconds; see Choosing Study Settings on page 11). Press any key to turn it back on. If you are not sure if the recorder is turned on, press the on/off button once.
Setting the Date and Time
You must set the date and time the first time you turn on the recorder or if the battery has fully discharged. Once the date and time are set (and as long as the battery does not fully discharge), the recorder maintains the correct date and time, even when it is turned off. However, if the battery was fully discharged before turning the recorder on, the screen will automatically display the **Set Date/Time** screen.

To set the date and time:

1. The first part of the date (for example, the day field) is highlighted. Use ▼ below the ▲ icon displayed on the screen and ▲ (▲ on the screen) to change it to the correct date. Press ▼ (▼ on the screen) to move to the next field.
2. Repeat this process for the rest of the date (for example, month and year).
3. Repeat this process to set the time. When you are done, press **Enter**. You are returned to the main menu.

If time and date are correct, press **ESC** and return to the main menu.

Choosing Study Settings

1. From the main screen, select **Settings**. This screen appears:
2. Set the number of capsules as follows:
   a. With the cursor on **pH Capsules #1**, press **Enter**.
      - Use ▼ to select the number of capsules.
      - Press **Enter**. You move on to the next setting: **Study Duration**.
3. Set the study duration as follows:
   a. With the cursor on **Study Duration**, press **Enter**.
      - Use ▼ to select the study duration (24, 48, or 96 hours).

   **Note**
   The 96-hour option is only available if you are using AccuView or Reflux software as your PC software application.
c. Press Enter. You move on to the first screen of the next setting: **Show pH value of Preferences.**

   Note
   At any time you may select **Settings** from the Main screen and access **Preferences** to review and set the parameters.

4. The Preferences screen allows you to define settings that affect all studies.
   - **Show pH Value:** If **Yes**, the current pH value appears on the recorder screen during studies. If **No**, pH values are only displayed for the first 30 minutes of a study. The factory default is **No**.
   - **Button Beep:** If **Yes**, the recorder beeps when the patient presses a symptom button. The factory default is **Yes**.
   - **Capsule LED Blink:** If **Yes**, the recorder capsule LED blinks when the capsule signals are received. The factory default is **Yes**.
   - **Set Date/Time:** Once set, the recorder maintains the correct date and time. You should only have to change this again if there is a time change (for example, going on or off of Daylight Savings), or if the recorder battery is allowed to fully discharge.
   - **Date Format:** You can set the date format to **MM-DD-YY** or **DD-MM-YY**. The factory default is **MM-DD-YY**.
   - **Time Format:** You can set the time format to **12-hour (AM/PM)** or **24-hour (military)**. The factory default is **12-hour**.
   - **PC Software:** Select the software used to record, view, and analyze the data from studies. The choices are **AccuView** (factory default applies to Reflux software, as well) and **RAPID pH**.
   - **Language:** Select the language for the recorder interface. The choices are English, Danish, Dutch, Finnish, French, German, Italian, Norwegian, Portuguese, Spanish, and Swedish. The factory default is **English**.
   - **Backlight Duration:** Set the time that the recorder screen backlight stays on after a button is pressed. The choices are 15, 30 (factory default), 45, or 60 seconds.

5. To return one level up in the menu tree, press **ESC**.

   Note
   Once you have set preferences, you will not need to reset them unless:
   - you want to change something, or
   - the recorder battery is fully discharged.
Calibrating Capsules

Calibration is the process of making sure that the capsule is reading pH levels properly. You must go through calibration for each capsule.

**Note**
If you need to change the number of capsules or the study duration, select **Settings** from the main menu and make the necessary changes.

Existing Data

If data exists from a previous study and has not yet been uploaded, you must first do so before you can start calibration. The record screen shows the message: **Last study data not uploaded! To upload, connect to PC.**

- To stop calibration and upload the existing data, press **Cancel**. Follow the directions for your software application. (If you are using AccuView or Reflux software, see **Uploading pH Data** on page 28.) When the data is uploaded, start the new study again by selecting **Calibrate** from the main menu.

- To continue (overwrite the existing data without uploading it), press **Next** and then press **Yes** to confirm that you want to overwrite the last study data. The message **Clearing data...** appears, and then the recorder continues with the calibration process.

Starting Calibration

If the message about existing data does not appear, begin calibration as follows:

1. Select **Calibrate** from the main menu.
   
   The current settings (**Date/Time**, **# of Capsules**, and **Study Duration**) appear on the screen. Press **OK** to confirm or **Cancel** to return to the main screen.

   **Note**
   The backlight stays on during calibration, except during the 10-minute pre-soak stage.

   This message appears: **Place pH Capsule #1 in pH 7.01 and press Start to calibrate.**

2. Position the calibration stand on a level surface and place a clean calibration tube into each of the four holders. Place the recorder on the calibration stand (Figure 7).

3. Check the expiration date on the buffer fluid bottles (next to on the label).

4. Fill each of the four tubes in the calibration stand halfway (enough to be able to cover the capsule when it is inserted) as follows. The buffer solutions should be at room temperature (20–25 °C, 68–77 °F).
• tube 1: pH 7.01 buffer solution
• tube 2: sterile water
• tube 3: pH 1.07 buffer solution
• tube 4: sterile water

5. Check the expiration date on the capsule (next to on the label).

6. Without bending or kinking the delivery device, carefully remove the Bravo pH capsule with delivery device from the external shipping box and then from the inner pouch (Figure 4).

![Figure 4. Remove Bravo pH capsule with delivery device from pouch.](image-url)

7. Remove the capsule’s plastic cover, the reference sensor cover (soaker bulb cover), and the magnetic clip (Figure 5). Set the magnetic clip aside.

![Note](image-url)

Keep the magnetic clip at least 2 meters (6 feet) away from the delivery device so that it will not interfere with the capsule. If a procedure is delayed, you can replace the magnetic clip on the capsule to return it to an inactive state until needed. Do not discard the magnetic clip until after the procedure has been performed.
Figure 5. Remove Bravo pH capsule shipping components.

8. Check the soaker bulb for fluid and set aside.

**Note**

Even if the soaker bulb doesn’t show the presence of liquid, the capsule can calibrate as usual. Perform the capsule calibration as per instructions. If the capsule fails to calibrate, contact your customer support representative.
9. After opening the capsule package, make sure that the capsule trocar needle has not advanced (Figure 6).

![Figure 6. Make sure that the trocar needle has not advanced too far into the chamber.](image)

10. Without bending or kinking the delivery device, place the delivery device handle into the calibration stand (Figure 7).

![Figure 7. Delivery device in calibration stand.](image)

11. Carefully place the capsule into the pH 7.01 buffer solution calibration tube as indicated on the recorder screen.
12. Make sure that the capsule is completely covered with the buffer solution. Gently agitate the capsule to remove any air bubbles.

13. On the recorder, press **Start**. The recorder starts searching for the capsule’s signal. This message appears: *Waiting for pH capsule 1.*

14. When the recorder identifies the capsule, this message appears: *Does this pH capsule ID number match the delivery device number?*
   - The capsule ID is printed on the packaging label. If the ID matches, press **Yes**. If not, press **No** and the search begins again.
   - If the recorder still does not recognize the capsule or displays an error message, repeat the procedure. If the problem persists after three attempts, see *Recorder Troubleshooting* on page 32.

15. Press **Yes**. This message appears: *Initiating 10 minute pre-soaking.*

   **Caution**
   When placing the capsule into the calibration tube, do not allow either part of the pH sensor (the short silver-colored antimony and long clear reference sensor) to catch on the edge of the calibration tube, as this can damage the pH sensor. Avoid the tube edge while carefully lowering the capsule into the solution. *Any damage to the pH sensor will require the delivery device to be discarded before use.*

   **Caution**
   After agitating to remove air bubbles, do not move the capsule again or move the calibration stand during the calibration process.

16. Rinse the capsule in sterile water. Press **Next**. This message appears: *Place capsule #1 in pH 1.07 and press Start to calibrate.*

17. Place the capsule in the pH 1.07 solution and press **Start**.

**Note**
If you press **Skip**, the recorder goes directly to the next step, and the action (skipping pre-soak) is written to the recorder log.
If you did not skip (that is, if you pressed **Yes**), the backlight goes out. It automatically turns back on at the end of the 10 minute pre-soak period.

When the pre-soak period ends (or is canceled by pressing **Skip**), this message appears: *pH 7.01 calibrating.*

At the end of this calibration period, the recorder beeps and this message appears: *Rinse the pH capsule in sterile water and press Next.*

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At the end of this calibration period, the recorder beeps and this message appears: 

**pH capsule ID xxxx calibrated.** (where xxxx is the capsule ID).

**Caution**
If either part of the calibration process (pH 7.01 or 1.07) fails, see **Recorder Troubleshooting** on page 32.

18. Press **OK**. The calibration data is saved and the recorder main menu appears with the cursor ready at **Start study**.

**Note**
If you are performing a two-capsule procedure, the recorder guides you through the same calibration process for the second capsule. After the first capsule is calibrated, it can remain outside the buffer solutions for up to 60 minutes before use.

19. Proceed to **Performing a Bravo pH Study** on page 19.

**Note**
If you are not going to place the capsule in the patient immediately, return the capsule to the pH 7.01 buffer solution. It may remain there for up to 8 hours. **Rinse the capsule in sterile water before use.**
Performing a Bravo pH Study

The actions of performing the study (testing the vacuum, placing the capsule, and instructing the patient) should be performed in one continuous sequence as follows.

Setting up the Vacuum

1. Make sure that the vacuum flow knob is turned to maximum.

2. Connect the vacuum hose (supplied with the vacuum pump) to the vacuum port on the delivery device handle (Figure 8a).

3. With your gloved finger covering the suction chamber (Figure 8b), verify that the vacuum gauge reading is at least 550 mmHg. Make a note of the gauge reading.

   - **Note**
     At higher altitudes, the pressure readings may be lower. For different altitudes, use this table for the minimum recommended vacuum pressure. Contact customer support for additional information.

<table>
<thead>
<tr>
<th>Altitude</th>
<th>Minimum Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>feet</td>
<td>meters</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2000</td>
<td>610</td>
</tr>
<tr>
<td>4000</td>
<td>1220</td>
</tr>
<tr>
<td>6000</td>
<td>1830</td>
</tr>
</tbody>
</table>

4. Remove your finger from the suction chamber. Verify that the vacuum gauge reading drops (Figure 8c) by at least 50 mmHg (500 mmHg or lower).
5. Turn off the vacuum and detach the tubing from the delivery device.

6. Proceed to Starting Recording.

**Starting Recording**

1. If the recorder is turned off or in sleep mode, turn it on.

2. From the main menu, select **Start Study** and press **Enter**.

   If the recorder detects a conflict with the capsule ID, this message appears: **Capsule ID mismatch. Use pH capsule ID: xxxxx.** See **Recorder Troubleshooting** on page 32.

3. Verify that the recorder is recording pH values.

   **Note**
   
   The recorder screen shuts off after 60 seconds to conserve battery power. To turn on the recorder screen during a study, press any button.

4. Proceed to **Placing the Capsule** on page 21.
Placing the Capsule

1. Oral placement of the Bravo capsule can be performed either using:
   a. endoscopy: using an endoscope, determine the desired location for the capsule in the esophagus. Typically, the capsule is placed 6 cm (2.4 inches) above the squamo-columnar junction. Measure and record the distance traveled by the endoscope to the desired location.
   b. manometry: using a transnasal manometry catheter, determine the desired location for the capsule in the esophagus. Typically, the capsule is placed 5 cm (2 inches) above the proximal aspect of the landmarks (LES). Use a correction factor of approximately 4 cm to account for the longer pathway that the manometry catheter has to travel through the nasopharynx.

2. Remove the endoscope or manometry catheter from the patient.

3. With the vacuum off, complete the following steps:
   a. Remove the capsule from the buffer solution and rinse it in sterile water.
   b. Mark the distance determined in step 1 on the delivery device. The depth markings on the delivery device are indexed from the capsule’s pH sensor (Figure 9).
   c. Carefully advance the delivery device through the mouth (with the capsule facing the patient’s tongue) to the desired location in the esophagus.

![Caution]
If lubricants are used to ease placement insertion, do not cover the suction chamber with lubricant. This could interfere with the attachment of the capsule.

Figure 9. Capsule depth markings are indexed from pH sensor.
d. Holding the delivery device as straight as possible in a relaxed horizontal position, stabilize it by the patient’s mouth to make sure that it does not move.

**Warning**
Do not advance the delivery device into the trachea or lungs. Advancing the delivery device into the trachea or lungs can cause possible injury to the patient.

4. Endoscopically check the esophageal inlet to verify the desired placement of the delivery device in the esophagus. Carefully remove the delivery device immediately if it has entered the trachea.

5. After proper positioning of the delivery device:
   a. Attach the vacuum hose to the handle (Figure 8).
   b. Turn on the vacuum source and verify that the gauge reading is the same as you noted during vacuum setup.

**Caution**
- If the minimum vacuum level (550 mmHg) is not obtained, reposition the Bravo delivery device to achieve proper vacuum.
- Do not allow the delivery device to move during vacuum level acquisition. Failure to immobilize the delivery device can result in less than optimal attachment or non-attachment that will require the vacuum level acquisition process to be repeated.

6. After the vacuum level of at least 550 mmHg has been reached and the vacuum stabilizes, allow 30 seconds for the tissue to fill the suction chamber.

**Caution**
- Do not proceed without waiting a full 30 seconds. Failure to wait a full 30 seconds may result in insufficient or no tissue filling the suction chamber. This can result in the capsule not being securely attached or not attached to the patient’s esophagus.

7. Remove the safety tab:
8. Swiftly press the plunger on top of the handle all the way down until it stops at its locking position. This advances the trocar needle into the suction chamber (Figure 10).

---

**Warning**

Press down on the plunger with a swift and smooth motion to actuate the delivery device mechanism. Pressing down on the plunger too slowly may result in the capsule not properly attaching to the patient’s esophagus or not detaching from the delivery device.

Do not rotate the plunger while depressing it!

---

**Note**

- Your hand may feel the delivery mechanism actuate, and you may hear a click when this occurs.
- Remove your thumb after the plunger locks and before you begin rotating it 1/8 of a turn.

---

**Figure 10.** Attach the capsule to the patient’s esophagus.

9. Using your thumb, rotate the plunger from the side one-eighth (1/8) of a turn clockwise to release the capsule from the delivery device (Figure 11). The plunger springs up so that a white line is visible on the sixth rib of the plunger (Figure 12).

---

**Figure 11.** Release the capsule from the delivery device.
If the plunger does not automatically spring up, push it up gently with your thumb. These steps release the capsule from the delivery device.

Figure 12. Release the capsule from the delivery device, cont.

![Diagram showing release of capsule from delivery device]

Warning
Do not rotate or otherwise force the plunger beyond the white line on the barrel. Rotating or forcing the plunger beyond this may result in possible damage to the delivery device. This may also interfere with the detachment of the capsule from the delivery device, and cause possible injury to the patient.

Note
Following correct rotation of the plunger, the white marking should now be visible on the sixth rib of the plunger. If not, use your thumb to raise the plunger until the white marking is visible.

Warning
If problems occur with capsule detachment, see Delivery Device Disassembly Procedure on page 30.

10. Turn off the vacuum source. Remove the delivery device and discard it according to local waste management regulations.

Warning
Do not remove the delivery device from the patient with the vacuum source on. Removing the device with the vacuum source on can result in dislodgement of the capsule or possible injury to the patient’s esophagus.
11. At the clinician’s discretion, endoscopically confirm the capsule’s attachment.

**Caution**
Avoid contacting the capsule with the endoscope. Contact between the endoscope and capsule may result in the dislodgement of the capsule.

12. Confirm that the recorder is recording pH values and that the capsule status LED is blinking in blue.

**Note**
The recorder’s display turns off after 60 seconds to conserve battery life. Press any key to activate the recorder’s screen during a study.


**Stopping a pH Study**
The study completes automatically when the recorder no longer collects pH data and the recorder screen turns off. The study data is stored in the recorder until it is cleared.

To stop a study manually (before its intended completion):

1. Press the on/off button for several seconds until this message is displayed: *Are you sure you want to stop the pH study?*

2. Select your action:
   - If you select **No**, the study continues uninterrupted.
   - If you select **Yes**, this message is displayed: *Last study data not uploaded! To upload, connect recorder to PC.*

Remember: if you stop the study, you **must** upload the data to unlock the recorder before you can continue.
Reviewing Instructions with Patients

Review the following information with the patient.

1. Familiarize the patient with the recorder. Instruct the patient to press the appropriate button at the first sensation of the symptom (chest pain, regurgitation, or heartburn).

   **Note**
   The default meaning of recorder symptom buttons can be changed in the software application (AccuView or Reflux software). Refer to the software user guide for details. If you are using the buttons for other symptoms, make sure to explain the function of each symptom button to the patient.

   ![Figure 13. Default values of symptom buttons.](image)

2. Explain that the patient must first press any button to turn on the backlight, and then press the appropriate symptom or event button.

3. Show the patient that the indicator light on the symptom button (Figure 13) illuminates for 3 seconds confirming that a symptom button was pressed.

4. Explain the beep sound (if the recorder was programmed to beep when a symptom button is pressed).

5. Explain the use of the Patient Diary. Patients need to write down eating, lying down (supine), and other user-defined periods, using the time on the recorder’s screen for the start and end times.

   User-defined periods allow the patient to record a period of time when they are engaged in an activity that the physician determined may affect pH readings, such as smoking, exercising, or wheezing.

6. Instruct the patient to make sure that the recorder is always monitoring the capsule:

   *Bravo pH Monitoring System 26 User Guide*
• The patient must stay within 2 meters (6 feet) of the recorder during the study except, as necessary, for bathing. The recorder is not water resistant and should not be worn in the shower or in other wet environments.
• When resting or lying down, place the recorder on a night stand near the bed, the buttons turned toward the patient both for convenience of reaching it for possible symptom recording as well as for optimal reception.
• If a night stand is not near the bed, the patient should clip the recorder to the pillow, making sure the buttons face the patient.
• If the recorder is too far from the capsule, it beeps for up to 30 seconds and the capsule number icon disappears from the screen (1 for single-capsule procedures, 12 for double-capsule procedures). This indicates that the transmission from the capsule to the recorder has been interrupted. The patient should hold the recorder on the chest until 1 or 12 appears.
• This beep can also occur if there are other electronic or electrical devices operating at the same frequencies as the recorder. Instruct the patient to move away from these other devices; if the capsule number icon appears, the problem was caused by interference from another device.
• Instruct the patient to contact the doctor if 1 or 12 disappears from the recorder screen or if there are any problems or questions during the study.

7. Place the recorder in the case and show the patient how to adjust the shoulder strap.

**Warning**
The recorder must be worn over clothing.

If wearing the recorder with the shoulder strap, the patient must stay clear of moving equipment or machines that are potentially hazardous. If the strap becomes entangled with a moving part, it could cause the patient to be pulled into a dangerous position. This could result in possible patient injury.

Do not allow children to wear or play with the recorder shoulder strap either with or without the case. It is intended only for the prescribed use by an adult. Use of the shoulder strap by a child could result in possible injury. Instead, it is recommended to use the belt clip for children.

8. Instruct the patient about what to expect when the capsule detaches.

9. Instruct the patient to return the recorder at the completion of the study.
Uploading pH Data

1. Connect the Bravo recorder to your PC using the supplied USB cable.
2. Open AccuView or Reflux software by double-clicking the AccuView or Reflux software icon on your desktop.
3. Click Upload. A progress bar appears. Once the upload is complete, the Edit Information & Diary screen appears.
4. If more than one protocol is available for the Bravo pH capsule, select the desired one from the Protocol list.
5. Click OK.

Note
To perform multiple uploads from the same recorder, disconnect the recorder from the USB and reconnect it again between uploads.
Recorder Maintenance

Safety and Technical Checks
There are no required safety or technical checks, and no periodic maintenance for the recorder.

The recorder contains no serviceable components apart from the battery. If the recorder requires repair or is nonfunctional, contact customer support.

Cleaning the Recorder
Clean the recorder after each study.

1. Turn off the recorder.
2. Wipe the exterior surface of the recorder with 70–90% isopropyl alcohol.
3. Allow any alcohol to dry thoroughly before using the recorder.

Cleaning the Case and Strap
Wipe the case and strap with any commonly-used disinfectant.

Servicing the Battery
The recorder operates on one internal rechargeable lithium battery. When the battery has been recharged 275 times, a message appears on the screen reminding you to replace the battery.

Contact customer support to have the battery replaced.

Caution
Do not allow liquid to get into the recorder body or inside the front cover. The recorder is not fluid resistant. Allowing any liquid (alcohol, water, etc.) inside of the recorder can damage the recorder and cause it to malfunction.
Troubleshooting

Delivery Device Disassembly Procedure

If the capsule is attached to the patient’s esophageal tissue, but will not release from the delivery device, we recommend this procedure.

**Caution**
When performing the following steps to remove the capsule, it is **extremely** important to minimize movement of the capsule and the patient. Any movement could cause tissue injury at the site of the capsule attachment.

1. If available, insert an endoscope and confirm tissue has been pinned and the capsule has not been released from the delivery device. Use care when inserting the endoscope, and avoid force upon the capsule and the delivery device. Remove endoscope. If an endoscope is not available, proceed to step 2.

2. See Figure 14. Secure delivery device near biteblock or near nasal passage using a hemostat clamp. An assistant should continue to firmly hold the shaft of the delivery device with a hemostat until the release procedure (described below) is completed.

**Note**
For the following steps, moderate force may be needed to disassemble the Bravo delivery device handle.

**Warning**
During the disassembly of the handle, position the handle away from the patient’s face while protecting the patient’s mouth and nose, and away from the eyes of the patient and nearby staff. Plastic parts may break off during handle disassembly, resulting in possible injury to the patient and clinical staff.

*Figure 14. Delivery device secured at mouth (or nose, if applicable) using a hemostat with hand. Keep a firm grip on the hemostat throughout the release procedure.*
3. With gloved hands, place one hand onto the gray handle portion and one hand on the blue suction port part. Firm force may be needed to induce separation of the gray and blue parts. When the two parts have separated, go to step 4.

Note
Be careful not to transfer force or motion to the capsule portion of the delivery device.

![Figure 15. Break handle as indicated.](image)

4. See Figure 16. Withdraw the gray handle a minimum of 4 cm (about 1.5 in.). When performing this action, the wire that secures the capsule is also withdrawn and will automatically release the capsule.

Note
If it is difficult to withdraw the handle and you feel resistance, release the hemostat to allow the gray handle to be retracted. Make sure not to pull on the shaft to avoid transferring force to the capsule.

![Figure 16. Withdraw the gray handle 4 cm minimum. THIS ACTION WILL RELEASE THE CAPSULE. If the wires are difficult to withdraw, remove the hemostat. This will release the capsule at distal end.](image)

5. When the capsule releases from the delivery device, remove the delivery device from the patient.

6. If possible, use an endoscope to confirm that the capsule remained attached to the esophageal tissue.
Recorder Troubleshooting

Following is a list of problems you may encounter while operating the recorder. If you cannot resolve the problem with the solution provided, or you do not see the problem listed, contact your product customer support.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Startup</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recorder displays message:</td>
<td>General recorder problem.</td>
<td>Contact customer support to arrange servicing for recorder.</td>
</tr>
<tr>
<td><strong>ERROR</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recorder displays message:</td>
<td>Battery voltage low.</td>
<td>Contact customer support to arrange battery replacement for recorder.</td>
</tr>
<tr>
<td><strong>REPLACE BATTERY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recorder is locked (no buttons work) and displays message:</td>
<td>A study is done but the data has not yet been uploaded from the recorder.</td>
<td>Connect the recorder to the PC and follow the instructions on the recorder screen.</td>
</tr>
<tr>
<td><strong>Last study data not uploaded!</strong></td>
<td>To upload, connect recorder to PC.</td>
<td></td>
</tr>
<tr>
<td><strong>Calibration</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recorder displays message:</td>
<td>Calibration has already been performed but the calibration data has not yet been used in a study.</td>
<td>Perform the study with this calibration data or redo calibration.</td>
</tr>
<tr>
<td><strong>Calibration done. To use, press Cancel. To start new, press Yes.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recorder displays message:</td>
<td>Recorder battery is below 30% capacity.</td>
<td>Connect recorder to charger. Allow to fully recharge (may take several hours).</td>
</tr>
<tr>
<td><strong>Charge battery.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recorder displays message:</td>
<td>(various)</td>
<td>Press Help to display error message.</td>
</tr>
<tr>
<td><strong>Capsule 1 Calibration Error</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Error 1: Unexpected pH value</td>
<td>Capsule sends what appears to be a pH value, but it is outside expected range (pH 7.01 to 1.07).</td>
<td>For each of these calibration messages, try: 1. Replace buffer solution. 2. Try calibrating a new pH capsule.</td>
</tr>
<tr>
<td>Error 2: Slope too low</td>
<td>Difference in mV between signals read by capsule during calibration (that is, difference between pH 7.01 and pH 1.07 solutions) is lower than expected.</td>
<td>If error persists, contact customer support.</td>
</tr>
<tr>
<td>Error 3: Slope too high</td>
<td>Difference in mV between signals read by capsule during calibration is greater than expected.</td>
<td></td>
</tr>
<tr>
<td>Error 4: Signal unstable</td>
<td>Recorder cannot detect stable signal from capsule within 60 seconds during calibration.</td>
<td></td>
</tr>
<tr>
<td>Problem</td>
<td>Cause</td>
<td>Solution</td>
</tr>
<tr>
<td>---------</td>
<td>-------</td>
<td>----------</td>
</tr>
<tr>
<td>Recorder displays message: <em>Listening for caps...</em>, and does not progress further.</td>
<td>Capsule out-of-range.</td>
<td>Try each of these: &lt;br&gt;1. Move recorder closer to capsule. &lt;br&gt;2. Replace buffer solution. &lt;br&gt;3. Try calibrating a new pH capsule. &lt;br&gt;If error persists, contact customer support.</td>
</tr>
</tbody>
</table>

**Start Study**

| Recorder displays message: *Charge battery.* | Recorder battery is below 90% capacity. | Connect recorder to charger. Allow it to fully recharge (may take up to 7 hours). |
| Recorder displays message: *Settings for two capsules but only capsule xxxx found. Start recording?* | Recorder was configured for two-capsule study, but is now only detecting signal of one capsule. | If you continue recording, you will only collect data for the capsule identified in this error message. Otherwise, press ESC, perform calibration with another capsule, and continue. |
| Recorder displays message: *Capsule ID mismatch. Use capsule ID: xxxx.* | Capsule was not calibrated using this recorder, or there may be interference with another capsule in the area. | Try each of these: <br>1. Select the recorder that was calibrated to the capsule being used <br>2. Move recorder closer to capsule (place recorder on patient’s chest). <br>3. Remove patient from the area (100 meters) and try again. |

**Data Transfer**

| Recorder displays message: *Capsule ID mismatch. Use capsule ID: 0000.* | Calibration data is missing or invalid. | Recalibrate the capsule. Make sure that you get the message *pH capsule #1 calibrated.* |
| No pH display on recorder screen | Capsule out-of-range. | Move recorder closer to capsule. |
| Capsule not in contact with fluid. | Place capsule in buffer solution. |
Problem | Cause | Solution
---|---|---
Patient Interface | | |
Long beep and patient display flashes battery symbol | Battery low. | Recharge.
Long beep (up to 30 seconds) and the capsule indicator 1 or 2 disappears from the display | Signal from capsule lost. | Move recorder closer to capsule until capsule indicator reappears.
Signal from capsule lost. Move recorder closer to capsule until capsule indicator reappears. | Interference from 433 MHz electromagnetic sources. | Move recorder away from all possible sources of radio waves.
Indicator light does not blink when a symptom button is pressed | Indicator light or button not functioning. | Manually record symptoms. Contact customer support to arrange servicing for recorder.
Indicator light blinks but recorder does not beep when a symptom button is pressed | Recorder was programmed not to beep when symptom button is pressed. | Program recorder to beep when symptom button is pressed. See Choosing Study Settings on page 11.
Patient display does not show time | Battery is depleted. | Contact customer support to arrange battery service.
Patient display shows time, but not pH reading | Recorder was programmed not to display pH reading. | Reprogram recorder to display pH reading. See Choosing Study Settings on page 11.
Patient display shows Hi (H) pH level momentarily out-of-range (too high). | | Continue with study (no action required).
Patient display shows Lo (L) pH level momentarily out-of-range (too low). | | Continue with study (no action required).
Appendix A: Technical Data

Bravo pH Recorder

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Supply:</td>
<td>One lithium polymer battery (3.7 volt)</td>
</tr>
<tr>
<td>Size:</td>
<td>Height: 90 mm (3.5 in.)</td>
</tr>
<tr>
<td></td>
<td>Width: 100 mm (3.9 in.)</td>
</tr>
<tr>
<td></td>
<td>Depth: 30 mm (1.2 in.)</td>
</tr>
<tr>
<td>Weight:</td>
<td>150 g (5.3 oz)</td>
</tr>
<tr>
<td>Operating, Transporting, and Storage</td>
<td>Temperature: 0–40 °C (32–104 °F)</td>
</tr>
<tr>
<td>Operating and Storage Pressure:</td>
<td>520–790 mmHg</td>
</tr>
<tr>
<td>Operating, Transporting, and Storage</td>
<td>Humidity: Up to 85% relative humidity (noncondensing)</td>
</tr>
<tr>
<td>Number of Channels:</td>
<td>1 or 2 capsules</td>
</tr>
<tr>
<td>Symptom Buttons:</td>
<td>Chest pain</td>
</tr>
<tr>
<td></td>
<td>Regurgitation</td>
</tr>
<tr>
<td></td>
<td>Heartburn</td>
</tr>
<tr>
<td>Memory:</td>
<td>Code: 128 Kilobytes, 16 K Sram</td>
</tr>
<tr>
<td></td>
<td>Data: 8 Mbytes</td>
</tr>
<tr>
<td>Recording Time (study duration):</td>
<td>24, 48, or 96 hours (selectable)</td>
</tr>
<tr>
<td>Capsule Sampling Interval:</td>
<td>6 seconds, transmits every 12 seconds</td>
</tr>
<tr>
<td>Measuring Range:</td>
<td>pH level 1.0–8.0</td>
</tr>
<tr>
<td>Transmission of Data:</td>
<td>USB</td>
</tr>
<tr>
<td>Communication Frequency:</td>
<td>433.9 MHz</td>
</tr>
<tr>
<td>Bandwidth of the Receiving Section:</td>
<td>Maximum 600 KHz</td>
</tr>
<tr>
<td>Protection from Electric Shock:</td>
<td>Internally powered BF equipment</td>
</tr>
<tr>
<td>Mode of Operation:</td>
<td>Continuous</td>
</tr>
<tr>
<td>Water Ingress Protection:</td>
<td>Ordinary</td>
</tr>
<tr>
<td>Capsule Transmission Duty Cycle:</td>
<td>Every 12 seconds</td>
</tr>
</tbody>
</table>

Recorder Servicing

The recorder does not require routine servicing of internal components, unless the recorder becomes damaged. For service, contact the appropriate customer support representative.
USB Cable
  Length: 1 meter

Charger
  Input: 120 to 240 V (0.2 Amp, 50/60 Hz)
  Output: 5 V (1 Amp max, 5 W max)

Battery
  Weight <26 g
  Rated capacity 1150 mAh min, 1200 mAh typical
  Nominal voltage 3.7 V
  Max. operating voltage range 2.75 V to 4.2 V
  Expected cycle life 500 cycles
  Temperature range charge 0°C to 45°C
discharge -20°C to 60°C
  Humidity 65 ± 20% RH

FCC Compliance Statement
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
  • This device may not cause harmful interference, and
  • This device must accept any interference received, including interference that may cause undesired operation.

Declaration of Conformity

For additional information, contact Given Imaging.

Essential Performance of Bravo Recorder
Essential performance: < 0.5% missing frames (two-capsule procedure at 1 meter radius in a RF shielded room up to 96h recording).
Electromagnetic Compatibility Declaration (EN / IEC 60601-1-2)
This equipment has been tested and found to comply with EN / IEC 60601-1-2. Compliance with EN / IEC 60601-1-2 shows the equipment is reasonably protected against harmful interference in a typical medical installation. Tables 1, 2, and 3 apply to Given Imaging in-line powered and battery-powered external devices.

Caution
Bravo recorder needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Portable and mobile RF communications equipment can affect Bravo recorder.

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Bravo recorder as replacement parts for internal components, may result in increased emissions or decreased immunity of the Bravo recorder.

The Bravo recorder should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Bravo recorder should be observed to verify normal operation in the configuration in which it will be used.

Use of accessories, transducers, and cables with the Bravo recorder other than those specified may result in increased emissions or decreased immunity of the Bravo recorder.

The Bravo recorder may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

Table 1. Electromagnetic emissions
Bravo recorder is intended for use in the electromagnetic environment specified below. The customer or the user of Bravo recorder should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-ionizing electromagnetic emissions CISPR 11</td>
<td>Group 1 (Bravo pH recorder)</td>
<td>The Bravo recorder uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>Non-ionizing electromagnetic emissions CISPR 11</td>
<td>Class B (Bravo pH recorder)</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions EN 61000-3-2</td>
<td>Not Applicable (Battery-powered devices)</td>
<td>The Bravo recorder is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Voltage fluctuations/flicker emissions EN 61000-3-3</td>
<td>Not Applicable (Battery-powered devices)</td>
<td></td>
</tr>
</tbody>
</table>
### Table 2. Electromagnetic immunity

Bravo recorder is intended for use in the electromagnetic environment specified below. The customer or the user of Bravo recorder should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>EN 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD): EN 61000-4-2</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst: EN 61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>N/A</td>
<td>Not Applicable. Battery-powered device with signal line not longer than 1 meter.</td>
</tr>
<tr>
<td>Surge: EN 61000-4-5</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>N/A</td>
<td>Not Applicable. Battery-powered device with signal line not longer than 1 meter.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines: EN 61000-4-11</td>
<td>&lt;5% U&lt;sub&gt;T&lt;/sub&gt; (&gt;95% dip in U&lt;sub&gt;T&lt;/sub&gt;) for 0.5 cycle 40% U&lt;sub&gt;T&lt;/sub&gt; (60% dip in U&lt;sub&gt;T&lt;/sub&gt;) for 5 cycles 70% U&lt;sub&gt;T&lt;/sub&gt; (30% dip in U&lt;sub&gt;T&lt;/sub&gt;) for 25 cycles &lt;5% U&lt;sub&gt;T&lt;/sub&gt; (&gt;95% dip in U&lt;sub&gt;T&lt;/sub&gt;) for 5 sec</td>
<td>N/A</td>
<td>Not Applicable. Battery-powered device.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field: EN 61000-4-8 [All devices]</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
<td></td>
</tr>
</tbody>
</table>

*Bravo pH Monitoring System 38 User Guide*
Table 2. Electromagnetic immunity (continued)

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>EN 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3 Vrms</td>
<td>N/A (Battery-powered device with signal line not longer than 1 meter)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>150 kHz to 80 MHz</td>
<td>d = 1.2 \sqrt{P}</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V/m</td>
<td>(E_f) = 3 V/m</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80 MHz to 2.5 GHz</td>
<td>d = 1.2 \sqrt{P}</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>412.224 - 455.616 MHz range is exclusion band for the Bravo recorder in Rx mode. The Bravo recorder in Rx mode has no immunity against electromagnetic energy in this band in order to perform its intended function. The nearby electronic equipment may affect the system. Recommended separation distance: d = 1.2 \sqrt{P}, 80–800 MHz range. d = 2.3 \sqrt{P}, 800–2500 MHz range.</td>
</tr>
</tbody>
</table>

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Bravo System.

*a Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.
Bravo recorder is intended for use in an electromagnetic environment in which radiated electromagnetic disturbances are controlled. The customer or the user of the Bravo recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile communication equipment (transmitters) and the Bravo recorder as recommended below, according to the maximum output power of the communication equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of Transmitter W</th>
<th>80 to 412.224 MHz</th>
<th>412.224 to 455.616 MHz</th>
<th>455.616 to 800 MHz</th>
<th>800 MHz to 2.5 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>( d = 1.2 \sqrt{P} )</td>
<td>( d = 1.2 \sqrt{P} )</td>
<td>( d = 1.2 \sqrt{P} )</td>
<td>( d = 2.3 \sqrt{P} )</td>
</tr>
<tr>
<td>0.1</td>
<td>0.12</td>
<td>0.12</td>
<td>0.12</td>
<td>0.23</td>
</tr>
<tr>
<td>1</td>
<td>0.38</td>
<td>0.38</td>
<td>0.38</td>
<td>0.74</td>
</tr>
<tr>
<td>10</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
<td>2.3</td>
</tr>
<tr>
<td>100</td>
<td>3.8</td>
<td>3.8</td>
<td>3.8</td>
<td>7.4</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>23</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \( d \) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1:** At 80 and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

**NOTE 3:** In the band 412.224 to 455.616 MHz, Bravo recorder in Rx mode has no immunity against electromagnetic energy in order to perform its intended function. Nearby electronic equipment may affect the system. Immunity within this band is provided in upload mode of operation only.

Table 4. Transmitter requirements

<table>
<thead>
<tr>
<th>Description</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating frequency</td>
<td>433.9 MHz</td>
</tr>
<tr>
<td>Transmission type</td>
<td>Amplitude shift key (ASK)</td>
</tr>
<tr>
<td>Effective radiated power</td>
<td>29.7 µW</td>
</tr>
</tbody>
</table>
Bravo pH Capsule Specifications

**Materials**
- Cap: Makrolon®
- Shell: Makrolon®
- Reference sensor: Polyethylenterephthalat
- Filler material: 2 component epoxy

**Dimensions**
- Length: 28 mm
- Width: 6.5 mm
- Height: 6.0 mm

**Output & Transmission**
- EIRP: 17.6 µW (-47.53 dBm) at a 3-meter distance
- Format: Amplitude-shift keying
- Frequency: 433.92 MHz
- Rate: 60 ms every 12 seconds

**Storage & Operation**
- Storage temperature: 15–45°C (59–113 °F)
- Operation temp.: 20–45°C (68–113 °F)
- Storage humidity: Up to 85%
- Operation humidity: N/A
- Storage & operation pressure: 508–635 mmHg

Bravo pH Delivery Device Specifications

**Materials**
- Proboscis & Boot: Aliphatic, polyether-based TPU
- Nest: Acrylonitrile Butadiene Styrene
- Foam: Polyethelyne (PE)
- Tube: Polyamide (PA)
- Cable gauge: 2.4 mm (7 Fr)
# Appendix B: Symbols on Package Labeling

Refer to the device to see which symbols apply to this product.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conformité Européenne (European Conformity).</td>
<td>Keep dry</td>
</tr>
<tr>
<td>Fragile</td>
<td>Temperature limits</td>
</tr>
<tr>
<td>Caution</td>
<td>CSA mark</td>
</tr>
<tr>
<td>Consult the instructions for use</td>
<td>Expiration date</td>
</tr>
<tr>
<td>Lot number</td>
<td>Do not re-use</td>
</tr>
<tr>
<td>Serial number</td>
<td>FCC</td>
</tr>
<tr>
<td>Manufacturer address</td>
<td>IEC 60601-1/EN60601-1, Type BF Equipment</td>
</tr>
<tr>
<td>Direct current</td>
<td>Product number</td>
</tr>
<tr>
<td>Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.</td>
<td>Non-ionizing radiation (from wireless transmission)</td>
</tr>
<tr>
<td>Bravo pH capsules are MR unsafe</td>
<td></td>
</tr>
</tbody>
</table>

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*Bravo pH Monitoring System*  
*User Guide*