

# Medtronic

Bravo™ calibration-free reflux testing system




## Quick reference guide

Instructions for study uploading and diary entry

### To complete the recording:

When the study duration is complete, the recorder will automatically turn off. If you wish to end the study prior to the study duration elapsing, press and hold the **On/Off** button for several seconds. The message, "Are you sure you want to stop this study?" will be displayed. To stop the study, you must select **Yes** within three seconds. Otherwise, the recorder will stay in the recording mode.

### To upload the study:

- 1) Double-click on the Reflux Software desktop icon. 
- 2) Click on **Guide**, then **Next** for step-by-step instructions for uploading and reviewing a reflux study.
- 3) Press **Next** to upload study from the Recorder.
- 4) Press **Next** to open the Setup Event List window.
- 5) Select your patient's specific symptoms to be used for study analysis. To add a symptom to the list, type it into the white box with the drop-down arrow, then press the  button.
- 6) Use the drop down list  in the **Bravo Button Association** section to assign a symptom to each symbol, then press **Set As Default**.
- 7) Connect the recorder to the computer and press **Next** to upload the study from the recorder. When you see the "Edit Information & Diary" screen in the Reflux Software, you will know the transfer is complete.

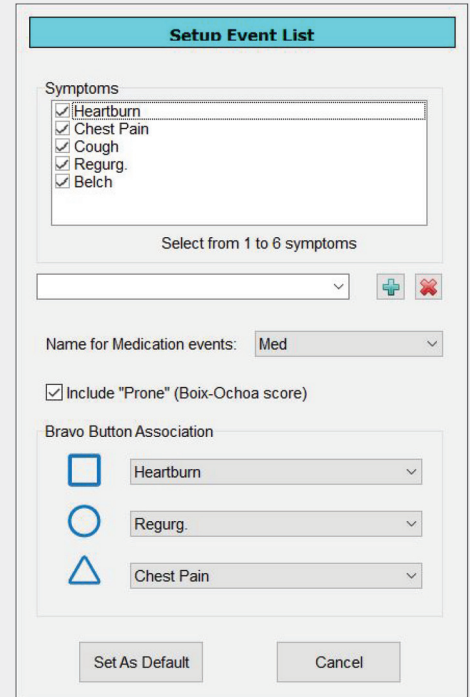
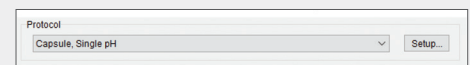
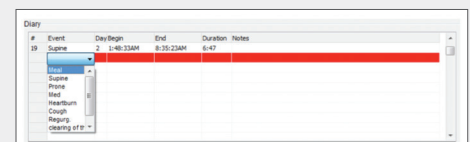
### To create and edit diary entries:

- 1) Enter the patient and other study information into the appropriate fields. Additions you make to the Study Information fields will be saved for future use in the drop-down list.
- 2) Verify the protocol matches the catheter used, and the desired analysis.
- 3) Corroborate all button press events in the Reflux Software diary against the patient's written diary. You can add diary events and symptoms via the text entry or the graphical user interface (GUI) method.

### Text entry method

The pull-down menu on the Event column allows you to select events (meals, symptoms, etc.), and you must manually enter day and time details. Note the following:

- **Symptom** and **Med** entries require only a **Begin** time; no **End** time is required.
- **Meals** and **Supine** events are durational, which require a Begin and End time.
- Incorrect time entries (e.g. a time is entered that is outside the period of the study data) will appear highlighted in red.
- To delete a diary entry, right click on the diary entry, select **Delete** and verify the deletion.

A screenshot of the 'Setup Event List' window in the Reflux Software. The window has a title bar 'Setup Event List' and a list of symptoms with checkboxes: Heartburn, Chest Pain, Cough, Regurg., and Belch. Below the list is a text box with a drop-down arrow and a plus sign button. There is a section for 'Name for Medication events:' with a dropdown menu set to 'Med'. A checkbox is checked for 'Include "Prone" (Boix-Ochoa score)'. Below that is the 'Bravo Button Association' section with three rows: a square button for 'Heartburn', a circle button for 'Regurg.', and a triangle button for 'Chest Pain'. At the bottom are 'Set As Default' and 'Cancel' buttons.A screenshot of a dropdown menu for 'Protocol'. The selected option is 'Capsule, Single pH'. There is a 'Setup...' button to the right.A screenshot of the 'Diary' table in the software. The table has columns for '#', 'Event', 'Day/Begin', 'End', 'Duration', and 'Notes'. The first row shows a 'Supine' event on Day 2 from 1:40:33AM to 8:35:23AM with a duration of 6:47. The event is highlighted in red. A dropdown menu is open over the 'Event' column, showing options like 'Supine', 'Prone', 'Meal', 'Heartburn', 'Cough', 'Regurg.', and 'clearing of B...'. The 'Event' column has a pull-down arrow.

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### GUI entry method

- Left-click the event to outline it in red, hover the cursor within the **Time Strip**, and left-click to place it at the specified time. You can adjust the time by moving the cursor into the lower grey portion of the **Time Strip** labeled **Adjust minutes**. To change the length of the time for an event, left-click and hold, then drag the edge of either end of the event.
- To deselect a red-outlined event button, left click the event button again.
- To delete or change an event, right-click on the event within the time strip and select **Delete** or **Change**, then verify your intention.
- Select **OK** at the bottom of the diary when finished editing.
- Click on **File>Save** to save the study to the Study Repository.

### To review the study

- 1) Review the pH trace(s) to determine if physiologically accurate and reflective of the patient's history. Ensure that:
  - a) The pH baseline is not consistently at or below pH 4 for a significant duration (possibly indicating catheter migration towards the stomach or capsule detachment).
  - b) The pH baseline is not consistently high.
- 2) Verify the study recording ended before the catheter was removed from the patient. If the catheter was removed before the end of the study recording, press **Exclude**. Then left-click drag the edges to encompass data from the beginning of catheter removal to the end of the study.
- 3) The study data review is complete. Press **Next** for the report creation steps.
- 4) Press **Next** to open the Report form, then:
  1. Review patient information and analysis data.
  2. Fill in the Procedure Description, Indications, Interpretation, Impressions, and Physician Signature.
  3. Press the **Create** button to open Create Report dialog.
  4. Select the information to be included in the Report document and create report.
  5. Press the **Close** button in the Report Form.
  6. Press **Save** to save the study in the Study Repository.

**Caution:** Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

#### Risk Information:

- Aspiration, tears or perforation in the mucosa, pain or discomfort (including chest pain) associated with the capsule, premature detachment, or failure to detach, which may necessitate endoscopic removal.
- The safety and efficacy has not been established for pediatric use on patients below the age of 4.
- Patients are restricted from undergoing an MRI study within 30 days of the start of a reflux study. Use of the Bravo™ reflux testing system in an MRI magnetic field will result in damage to the system and possible patient injury.
- Undergoing an MRI while the Bravo™ reflux 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™ reflux capsule, the patient should contact the physician for evaluation and possible abdominal x-ray before undergoing an MRI examination.
- The Bravo™ reflux capsule contains a trocar needle that is made of stainless steel. Use caution in patients with known sensitivities to the metals that are contained including chromium, nickel, copper, cobalt, and iron. Tests last from 48 to 96 hours.
- Gastrointestinal endoscopy: Potential complications include, but are not limited to: perforation, hemorrhage, aspiration, fever or 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.

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