A 3-Step Process

More patient satisfaction.
More confident diagnosis.
**Step 1 | Assess the pH Tracing**

The pH tracing is a graphical representation of the data that have been collected during the pH test to assess the pH tracing, review the patient history, visually inspect the data (diary and artifacts) and develop a preliminary diagnosis.

**A. Review the Patient History and Reason for the Bravo™ Reflux Testing System pH Test**

**B. Verify Diary Entry**

The software uses all of the diary information in calculations. If this information has not been entered...

- STOP!
- Do not interpret study until the entire diary (Meals, Supine & Symptoms) has been entered.
- Verify that the Meal and Supine times have been entered.
- Verify that the symptoms have been entered (indicated by a line and identified above the tracing).
- Note any artifacts (indicated by gray sections above graph corresponding with gaps in pH line). These will not be used in calculations.
- Verify that capsule did not detach during study. If detachment occurred, enter it as an “Ignore” event in the diary – see Example of Early Detachment on page 13.

**C. Review the Tracing**

- Look at the tracing in 12–16 hour segments. Observe acid reflux events (when red tracing line dips below blue pH 4 line) and consider:
  - Are there a large number of reflux events and/or symptoms?
  - Do reflux events occur during supine or upright periods, or both?
  - Do symptoms appear to be occurring in or around reflux events? (Symptom association is considered positive if the symptom occurs within two minutes of the reflux event. A more detailed view of the tracing may be required.)

**D. Form Preliminary Diagnosis**

- From this information, determine whether you believe the patient has acid reflux or not, based on how often and how long the tracing shows the pH < 4, and whether this occurs during daytime, nighttime or both.
- Step 2 will use the data from the study to affirm your preliminary findings.

**Step 2 | Affirm Preliminary Diagnosis**

The Reflux Tables and DeMeester Scores are used to affirm the preliminary diagnosis. Examine each 24-hour period separately, using the worst day for diagnosis, since the number of acid reflux episodes can vary from day to day.

**Step 3 | Associate Symptoms**

Symptom correlation is an important component of an accurate diagnosis. Evaluate the SAP & SI Tables to determine whether the symptoms are associated with reflux events.
Step 2 | Affirm Preliminary Diagnosis

The Reflex Table and DeMeester Scores are used to affirm the preliminary diagnosis. Examine each 24-hour period separately, using the worst day for diagnosis, since the number of acid reflux episodes can vary from day to day.

A. Examine Reflux Tables

Percent time spent in reflux is the single parameter which has been shown to best correlate with endoscopic damage. Normal is < 4.4% on the worst day.

B. Observe DeMeester Score

Normal = < 14.72 – Examine each 24-hour period separately, using the worst day for diagnosis.

DeMeester Score

The DeMeester Score is a method of adding weights to six common pH measurement parameters and presenting esophageal acid exposure data as a cumulative score. The score is then compared to data from normal individuals. The DeMeester Score takes into account and weights these six parameters:

1. Total percent time pH < 4.0
2. Percent time pH > 4.0 in the upright period
3. Percent time pH > 4.0 in the recumbent period
4. The total number of reflux episodes
5. The total number of reflux episodes longer > 5 minutes
6. Longest reflux (HH:MM)

DeMeester Normal = < 14.72 – Examine each 24-hour period separately, using the worst day for diagnosis, since the number of acid reflux episodes can vary from day to day.

C. Affirm Preliminary Diagnosis

Assure that Percent Time Spent in Reflux and the DeMeester Score for the worst day affirm the preliminary tracing diagnosis. If not, review Step 1 again and look for opportunities to reconcile the tracing with the Reflex Table and DeMeester Score.

Step 3 | Associate Symptoms

Symptom association is an important component of an accurate diagnosis. Evaluate the SAP & SI Tables to determine whether the symptoms are associated with reflux events.

A. Review SAP Calculations

The SAP calculates the probability that the observed association between symptoms and reflux events occurred by chance. SAP > 95% indicates that there is a < 5% probability that the observed symptom-to-reflux associations occurred by chance.

B. Review SI Calculations

The SI provides data on the strength of the association between symptoms and reflux events. SI > 50% is significant and indicates that > 50% of the observed symptoms were associated with reflux.

Symptom Index (SI)

The SI is defined as the number of times the symptom occurred when pH was < 4, divided by the total number of times the symptom was reported. The quotient is multiplied by 100 to give the percentage of symptom episodes that correlated with reflux. (There are drawbacks to the SI, in that it is insensitive to the number of reflux episodes.)
NORMAL CASE

Interpretation: Negative Study with Post-prandial Reflux

Step 1 | Assess the pH Tracing
- Meal & Supine times are entered
- Symptoms are entered and/or uploaded
- Artifacts (if any) are noted
- Capsule did not detach during study

Step 2 | Affirm Preliminary Diagnosis
- Percent Time Spent in Reflux when pH <4
- DeMeester Score is normal (< 14.72) on both days

Step 3 | Associate Symptoms
- SAP Table has no significant associations (values > 95%)
- SI Table has no associations (values > 50%), so it is not shown on report

Additional Physician Notes
- All values are normal
- Findings verify that cough is not caused by reflux
- Need to look for other cause of symptoms/other diagnosis

Day I - Worst Day

Day II

<table>
<thead>
<tr>
<th>Symptom Analysis (pH)</th>
<th>Heartburn</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of symptoms analyzed</td>
<td>7</td>
</tr>
<tr>
<td>No. of symptoms related to reflux</td>
<td>0</td>
</tr>
<tr>
<td>No. of symptoms not related to reflux</td>
<td>0</td>
</tr>
<tr>
<td>No. of reflux periods</td>
<td>25</td>
</tr>
<tr>
<td>Symptom severity index (SSI)</td>
<td>0.0</td>
</tr>
<tr>
<td>Symptom association prob. (SAP)*</td>
<td>77.8</td>
</tr>
</tbody>
</table>

* Probability that symptoms and reflux are not associated solely by chance, (>95% is significant)
**Step 1 | Assess the pH Tracing**
- Meal & Supine times are entered
- Symptoms are entered and/or uploaded
- Artifacts (if any) are noted
- Capsule did not detach during study

**Step 2 | Affirm Preliminary Diagnosis**
- Percent Time Spent in Reflux > 4.4% on both days
- DeMeester Score is > normal (14.72) on both days

**Step 3 | Associate Symptoms**
- SAP Table has associations (values > 95%)
- SI Table has associations (one with value > 50%)

**Additional Physician Notes**
- Further studies were done to check patient for delayed gastric emptying; studies were positive
- Patient had no history of diabetes
- After Bravo™ reflux testing system study, patient began a neurotransmitter antagonist and PPIs were stopped; improvement was noted
- Reflux was secondary to delayed gastric emptying

Interpretation: Positive Study with Upright Reflux

**History**
- Female patient with complaints of heartburn and regurgitation

**Table**

<table>
<thead>
<tr>
<th>Symptoms Analysis (pH)</th>
<th>Heartburn</th>
<th>Regurg.</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of symptoms analyzed</td>
<td>18</td>
<td>21</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Channel 1</th>
<th>Heartburn</th>
<th>Regurg.</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of symptoms related to reflux</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>No. of symptoms not related to Reflux</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>No. of reflux periods</td>
<td>112</td>
<td>122</td>
</tr>
<tr>
<td>Symptom index for reflux (%)</td>
<td>44.4</td>
<td>66.7</td>
</tr>
<tr>
<td>Symptom sensitivity index (SSI)</td>
<td>7.1</td>
<td>12.1</td>
</tr>
</tbody>
</table>

* Probability that symptoms and reflux are not associated solely by chance, (~95% is significant)
ABNORMAL NIGHTTIME CASE

Step 1 | Assess the pH Tracing

- Meal & Supine times are entered
- Symptoms are entered and/or uploaded
- Artifacts (if any) are noted
- Capsule did not detach during study

Step 2 | Affirm Preliminary Diagnosis

- Percent Time Spent in Reflux > 4.4% on both days
- DeMeester Score is > normal (14.72) on both days

Step 3 | Associate Symptoms

- SAP Table shows poor correlation of symptom (cough) which can also be seen on the tracing
- SI Table does not have cough association

Additional Physician Notes

- Patient proceeded to surgery

Interpretation: Positive Study with Supine Reflux

History

- Patient with a history of 4 cm hiatal hernia
- EGD positive for esophagitis
- Noted low LES pressure on esophageal manometry
- Testing done as pre-operative evaluation prior to surgery for reflux
**Interpretation: Positive Study for Reflux**

**History**
- Male patient with history of short-segment Barrett’s esophagus
- Complaints of mild heartburn — which was well controlled on PPI (bid)
- History of cough (to the point of “passing out”)
- Testing was done off medication
- Testing done for evaluation prior to surgical Nissen fundoplication

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**Step 1 | Assess the pH Tracing**
- Meal & Supine times are entered
- Symptoms are entered and/or uploaded
- Artifacts (if any) are noted
- Capsule did not detach during study

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**Step 2 | Affirm Preliminary Diagnosis**
- Percent Time Spent in Reflux when pH < 4
- DeMeester Score is > normal (14.72) on both days

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**Step 3 | Associate Symptoms**
- SAP Table shows no symptom association value > 95%
- SI Table shows heartburn is not associated with reflux (values < 50%)

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**Day I - Worst Day**

<table>
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<tr>
<th>symptom analysis (pH)</th>
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<th>Day II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measured time (min)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DeMeester score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td></td>
<td></td>
</tr>
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<td></td>
</tr>
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**Heartburn**

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<tr>
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<tr>
<td>Symptoms</td>
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</tr>
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<td></td>
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</table>

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**Symptom Analysis prob (SAP)**

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</table>

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*P value < 0.05 suggests that symptoms and reflux are not associated solely by chance.*
EXAMPLE OF EARLY DETACHMENT

Additional Physician Notes

- This study is an example of early detachment of the capsule prior to completion of 48 hours of recording.
  - The capsule remains in the stomach, as evidenced by pH levels of approximately 2.0.
  - During the meal period there is a rise in the pH to above 4, which is caused by buffering of the stomach acid by the meal and saliva.
  - Capsule leaves the stomach and enters the duodenum at approximately 12:00 on day three (as evidenced by pH ~ 7.0, indicating that capsule is reading alkaline pH).
  - REMEMBER: You MUST create an “Ignore” event from the point of capsule detachment to the end of the recording. Otherwise, the pH data captured during this period will be included in the software’s calculation.
  - There may still be enough data to provide an interpretation, depending on the amount of time that data was captured before the detachment. (In this case, the capsule detached after 30+ hours.)

You MUST create an “Ignore” event from the point of capsule detachment to the end of the recording. Otherwise, the pH data captured during this period will be included in the software’s calculation.
Risk Information: The risks of the Bravo™ reflux testing system include premature detachment, discomfort, failure to detach, failure to attach, capsule aspiration, capsule retention, tears in the mucosa, bleeding, and perforation. Endoscopic placement may present additional risks. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. Because the capsule contains a small magnet, patients should not have an MRI study within 30 days of undergoing the Bravo™ reflux test. Please refer to the product user manual or medtronic.com/gi for detailed information.

Reference: