Reflux Monitoring System

Catheter with pH and Impedance / Wireless pH Capsule

Definitive standard in GERD diagnosis
As the choices for diagnosing GERD proliferate, it can be really challenging to choose the right steps for clear diagnosis.

While empiric PPI therapy could be effective, it has a limited sensitivity of 78% and specificity of 54%.

The choices of Barium swallow, Endoscopy, Esophageal biopsy and other tests all have very specific indications and cause unnecessary discomfort for patients.

Ambulatory reflux monitoring (pH or Impedance-pH) is the only test that allow for determining the presence of abnormal esophageal acid exposure, reflux frequency and symptom association with reflux episodes.

Whether the choices of telemetry capsule or transnasal catheter, pH monitoring has excellent sensitivity (77-100%) and specificity (85-100%) in patients with erosive esophagitis, the added impedance monitoring could increase the sensitivity to 90% (from 70%) in cases with endoscopy-negative reflux symptoms.
Wireless pH Monitoring Capsule

Wireless pH monitoring capsule is the newest advance in ambulatory reflux monitoring.

A small capsule is delivered above the LES with a conveyer, then firmly attached to the mucosa via vacuum suction. The recording can last up to 96 hours. Data will be collected by the recorder through wireless transmission. The capsule will naturally drop from the mucosa and be excreted out.

Compact Design

Our capsule is one of the smallest in product volume in the competition, with the measurements of only 6.0*5.5*26.5mm and weights just 1.4 grams. The capsule support recording up to 96 hours data.

Intermission and Transmission

Sampling is fast and accurate (Every 3 Seconds), with double data protection. The transmission can be achieved within 3 meters, providing more comfort for patients. Supports USB for high-speed data download.

Setup and Calibration

You can use both your computer or the recorder to calibrate the capsule. Calibration is fast and easy.

Comfort and Utilization

Patient is free from nasal catheter, the delivering process, which uses depressurization is very straight forward, fast and painless.

Calculation and Report

Supports SI, SAP indication calculation.
Generates pH data analysis table, process Demeester rating automatically.

<table>
<thead>
<tr>
<th>Duration time (mmHg)</th>
<th>Total</th>
<th>Normal</th>
<th>Mild</th>
<th>Severe</th>
<th>Demeester</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reflux time (mmHg)</td>
<td>22.38 22</td>
<td>15.34 33</td>
<td>6.38 18</td>
<td>0.06 11</td>
<td>7.27 39</td>
</tr>
<tr>
<td>Longer reflux time (0 minutes)</td>
<td>66</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>The largest reflux time (5-6 mmHg)</td>
<td>3.66</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.66</td>
</tr>
<tr>
<td>Total reflux (%)</td>
<td>1.56 10</td>
<td>1.07 40</td>
<td>0.00 18</td>
<td>0.00 10</td>
<td>0.24 35</td>
</tr>
<tr>
<td>Percentage of the time under pH</td>
<td>6.7</td>
<td>1.2</td>
<td>0</td>
<td>0</td>
<td>5.6</td>
</tr>
</tbody>
</table>

Diagnosis Aid

The program indicate possible reflux episodes through intelligent analysis.

Acid reflux, pH < 4

Weak acid reflux, 4 < pH < 7
Reflex Monitoring System with pH/Impedance

Our catheter based reflux monitoring system support pH and impedance recording. Made from TPU (Thermoplastic Polyurethane), our catheter maintains rigid and flexible structure while keep industry leading small diameter, providing the best comfort and care for patients.

State of the art electrode technology provides quick 2-minutes calibration process, excellent measurement precision and long shelf life.

Data is recorded over a period of 24 hours then downloaded to workstation for further analysis.

Wide variety of catheter choices
- Slim catheter diameter as small as 2 mm.
- Comfortable and flexible material
- Up to 14 configuration of different length and sizes.
- High precision electrodes
- 2 Years long shelf life

Workstation Software
- Setup and Calibration guide
- Data import and analysis
- Perform various calculations including SI, SSI and SAP
- Custom and export reports.

Recorder
- 1 GB storage capacity for long-time recording
- 6 default record modes and 2 user-defined modes
- Compact and light, powered by one AA battery