

Anomalies in the digestive tracts are shaped by the sensation of internal organs, reflexive connection between the brain and intestines, and psychological effects. Motility assessment data revealing these factors is now becoming vital for clinical studies.

Regulatory Approval Reference Number

Isobar III
: 20900BZY00985000
Esophageal Manometry Catheter
: 20200BZZ00226000
Anal Manometry Kit
: 20100BZZ00922000



When a food bolus or gas enters, the digestive tract reacts to this stimulation with its motility represented as peristaltic reflex or intestinal reflex, and provides an organic sensation by transmitting a signal conveying the status of internal organs to the brain. Symptoms caused by abnormality of this function of digestive tract are called functional gastrointestinal disorders (FGID), pathology of which has gradually been revealed of late.

Isobar III is widely considered as one of the most effective means to assess the function of digestive tracts and has been valued as the sole means to diagnose IBS.

Isobar III

The main reservoir is capable of performing a single balloon application by itself. Using the external reservoir, it is possible to conduct a dual balloon application, the control and pressure detection of which are designed to be done by the main reservoir.

Main Reservoir

Power Source: AC100V 50/60Hz 85W
Dimension: W330×D530×H230mm
Weight: 30kg
Cylinder: 1300ml
Balloons: up to 1300ml; Step Accuracy: 0.04ml
Adjustable Pressure Range: 0 - 60mmHg; 0.1mmHg step pressure accuracy $\pm 2\%$
Volume Control of Balloons: feedback control with configured balloon pressure; keypad/external computer
Maximum Air Flow: 50ml/sec
Configuration Display: pressure and volumetric values; piston position; LED display with 40 characters
Port: 1 internal cylinder port; 2 pressure measurement ports (for external reservoir)
Analog Output: balloon pressure 20mmHg/V; balloon volume 250ml/V
Digital Input/Output: RS-232 9600 baud

External Reservoir (Dual Drive)

Power Source: AC100V 50/60Hz 85W
Dimension: W330×D530×H230mm; weight 12kg
Cylinder: 1300ml and 140ml
Balloons: up to 1300ml
Pressure/Volume Control: operated by main reservoir
Maximum Air Flow: 50ml/sec
Port: 1 external cylinder port; pressure measurement utilizes main reservoir ports

Remote Keypad

Controls: suction/distension of air within balloon
Cylinder Home Position: 2 channels each
Configuration: balloon pressure, speed settings
Hysteresis Setting: atmospheric correction
Volume Offset: 2 channels each
Safety Functions: emergency deflation, maximum volume/pressure setting



Isobar IIR



Remote Keypad

Isobar IIR

Designed for studies on mice, rats, ferrets, dogs, miniature pigs, sheep, etc.

Main Pump Unit

Power Source: AC100V 50/60Hz 78W
Dimension: W330×D530×H230mm; weight 20kg
Cylinder: 25 - 200ml; various step accuracy 0.04ml
Adjustable Pressure Range: 0 - 100mmHg; 0.1mmHg step pressure accuracy $\pm 2\%$
Volume Control of Balloons: feedback control with configured balloon pressure; keypad/external computer
Display: LED with 40 characters
Keypad Included

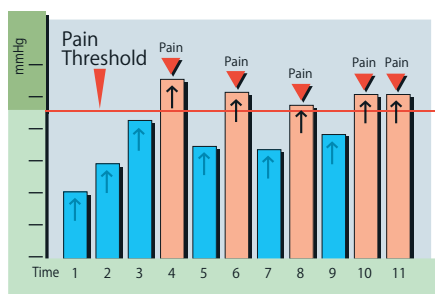
Method | Measurement of Colonic Sensation

Courtesy of Tohoku University; Prof. Shin Fukudo, Dr. Yasuhiro Sagami, Prof. Michio Hongo

There are two methods to stimulate the colon, one of which is based on pressure and the other on volume. Because of the various capacities of each subject's colon, the one using pressure is considered more objective.

1. Setting Stimulus Waveform

In this phase a pressure waveform which will be operated by the barostat is set. To conduct an accurate measurement, it requires an air injection at a fast rate of approximately 40ml/sec. and using any other device which is only capable of generating a slower rate may lead to an inaccurate result.



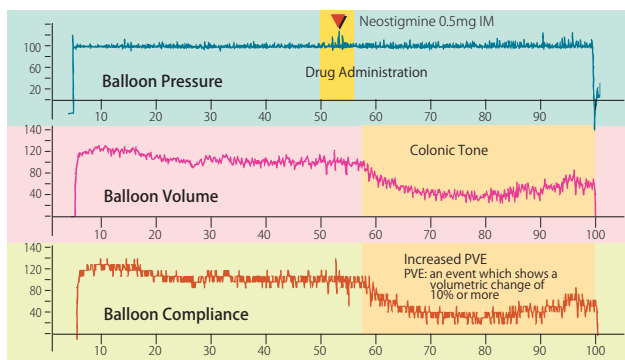
Pain threshold examination using computerized balloon stimulus

2. Measurement of Pain Threshold using Stimulation Test

The perception of pain reported by subjects is recorded during computerized ascending/descending pressure change within the balloon placed in the colon. It is recommended to set a period of each stimulus from 30 to 60 seconds, with an interval of 30 to 60 seconds. It is also recommended to gradually increase the pressure first and then repeatedly increase/decrease the pressure around the pain threshold reported by the subject.

Method | Measurement of Colonic Tone

Courtesy of Tohoku University; Prof. Shin Fukudo, Dr. Yasuhiro Sagami, Prof. Michio Hongo



Assessment of the efficacy of drug administration; a patient with functional constipation

This method applies some consistent low pressure to the colon to measure its colonic tone.

1. MDP (m1. Measurement of MDP (Minimal Distending Pressure))

MDP is the lowest value that the detection curve of colonic volume starts to detect respiratory fluctuations. This value is measured by applying pressure starting from 0 mmHg and then gradually increases by 1-2 mmHg.

2. Stimulation with Measurement Pressure

- The measurement begins with stimulation pressure set to MDP + 2 mmHg. MDP values vary among different subjects.
- In studies using fixed stimulation pressure, it is recommended to employ the value of 10-12 mmHg for the esophagus, and 6-8 mmHg for the stomach.

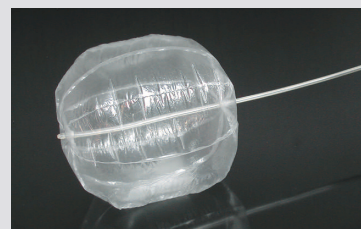
3. Starting the Measurement after Balanced State

Normally, it takes 15-20 minutes to reach a balanced state. If not, the study must be halted immediately and an attempt to release the gas potentially held in the subject's body should be made, as there is a possibility of gas leakage from the balloon.

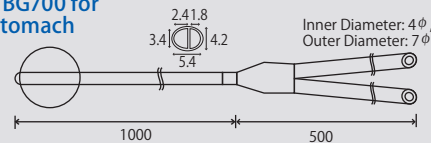
4. Analysis of Recorded Waveforms

Colonic volume decreases with colonic tone and increases with its relaxation. Fluctuations in the observed waveforms are studied after conducting a 15-minute baseline measurement. It is possible to measure not only long-term fluctuations but also phasic volume events (PVE), which indicate volumetric change equal to or more than 10% occurring in a short period of time.

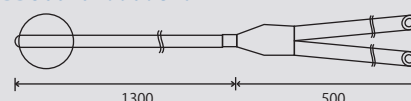
Barostat Balloons



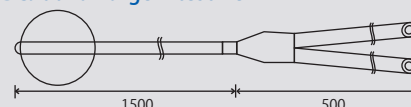
TBG700 for stomach



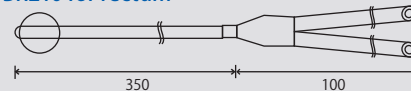
TBD500 for duodenum



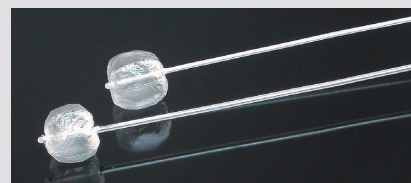
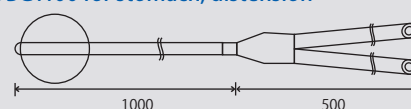
TBC900 for large intestine



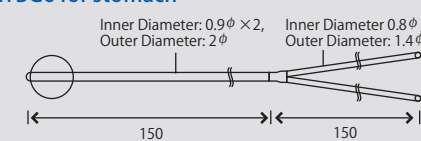
TBR210 for rectum



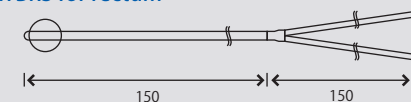
DBG1100 for stomach; distension



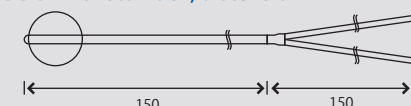
RTBG6 for stomach



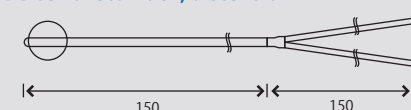
RTBR3 for rectum



RDBG12 for stomach; distension



RDBG5 for stomach; distension



STAR MEDICAL, INC.

5F Taiyo-Building 5-14-12 Nishinipori Arakawa-ku Tokyo 116-0013 Japan TEL:+81-3-5604-1641 FAX:+81-3-5604-1645
E-mail:starmedical@starmedical.co.jp http://www.starmedical.co.jp