

MANOalpha™

High Resolution Manometry System

Product Brochure



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Addressing the Rising Hygienic Concern

A matter of concern: the hygienic condition of reusable catheter

Inadequate cleaning between patient uses can result in the retention of blood, tissue and other biological debris (soil) in certain types of reusable medical devices.^{ref.1} According to the Spaulding Classification^{ref. 2}, manometry catheters can be categorized as semi-critical devices and require high-level disinfection. The hygienic state of reusable medical devices has emerged as a growing concern in public health. Therefore, HRM catheter reprocessing must meet necessary standards.

Automated reprocessing for High-Level Disinfection

The utilization of an automated reprocessing machine can effectively address the hygienic concern.

Standardization: The cleaning and disinfection process will be carried out consistently and according to predetermined protocols. This reduces the chance of human error and variability that can occur with manual cleaning.

Efficiency: Automated reprocessing machines are designed to perform the cleaning and disinfection process efficiently, reducing the time required compared to manual cleaning. This is particularly beneficial in busy healthcare settings where there is a need to process large numbers of instruments or medical devices.

Traceability: Built-in documentation systems can record important parameters such as cycle time, temperature, and chemical concentrations. This provides a reliable record for quality control, regulatory compliance, and traceability.

Validated solution for automated reprocessing

MANOalpha™ catheters are specifically designed and validated for cleaning and reprocessing using automated reprocessing machines. The catheter connector is equipped with a proprietary cover, making the entire catheter waterproof. This allows for immediate reprocessing after point-of-use treatment.

Reference:

1. US FDA. *Reprocessing of Reusable Medical Devices*. 10 Jan., 2013

2. Spaulding EH. *Chemical disinfection and antisepsis in the hospital*. *J Hosp Res* 1972; 9: 5 – 31

Introducing MANOalpHa™

Overview

MANOalpHa™ High Resolution Manometry System is intended to better map, measure and evaluate the esophageal and anorectal motility by providing accurate measurement, adaptive software, and automated reprocessing solution. It consists of the MANOalpHa™ central processor, reusable probe, calibration set and the optional portable cart with HD display screen and high-speed printer.



Advanced Hardware Features

Automated Reprocessing

- Meet the high-level disinfection standard
- Warranty: 3 years / 200 uses

Accurate Measurement

- Solid-state sensor without temperature drift
- Pressure calibration for obtaining valid data
- Up to 40 pressure sensors and 16 impedance sensors

Easy Operation

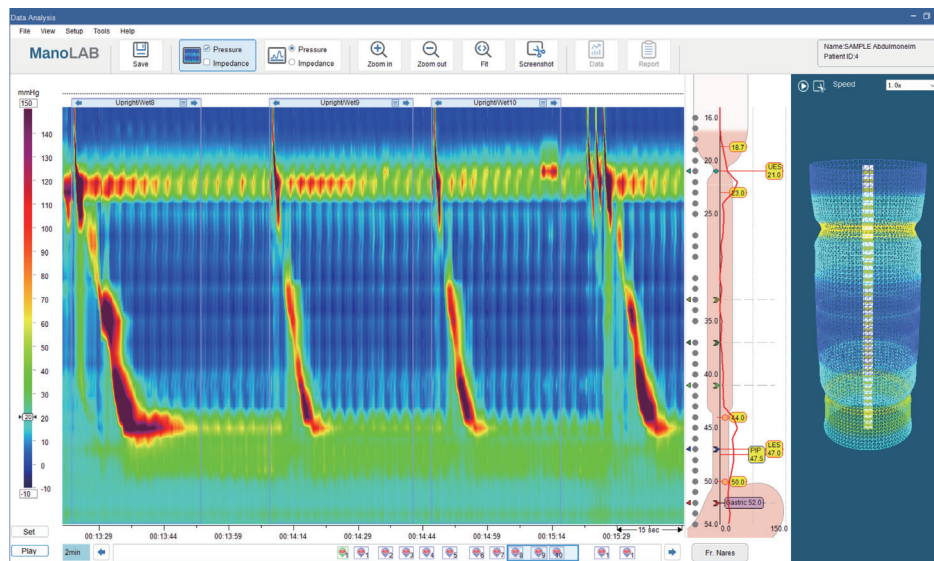
- Smaller diameter helps ease patient's discomfort
- Ergonomic designed probe handle
- All-in-one workstation. The whole procedure from calibration to report generation can be conducted at one portable cart.

Technical Specification	Central Processor	Probe (esophageal)	Probe (anorectal)
Size	360*260*90 mm [T=±10mm]	Φ 4.0 mm * 2035 mm	Φ 4.0 mm * 1667 mm
Weight	≤ 3000 g		
Voltage range	100-240V AC 50/60Hz		
Working current	≤ 1A		
Pressure collection / acquisition	Range: 0~300 mmHg Error: ±2% [100~300 mmHg] ±2 mmHg [0~100 mmHg] frequency: ≥100Hz	Range: 0~300 mmHg Error: ±2% [100~300 mmHg] ±2 mmHg [0~100 mmHg]	Range: 0~300 mmHg Error: ±2% [100~300 mmHg] ±2 mmHg [0~100 mmHg]
Impedance collection	Range: 0~10 KΩ Error: Error: ±60 Ω or ±5%, the larger one Frequency: ≥50 Hz		

Adaptive ManoLAB Software

ManoLAB software is a versatile tool for editing and navigation of your manometry study. Adapting to the latest Chicago Classification 4.0 and London Classification, ManoLAB provides the clinician with reliable and comprehensive data for the accurate assessment of esophageal and anorectal function.

To better enhance your experience, ManoLAB has been developed with intuitive features.

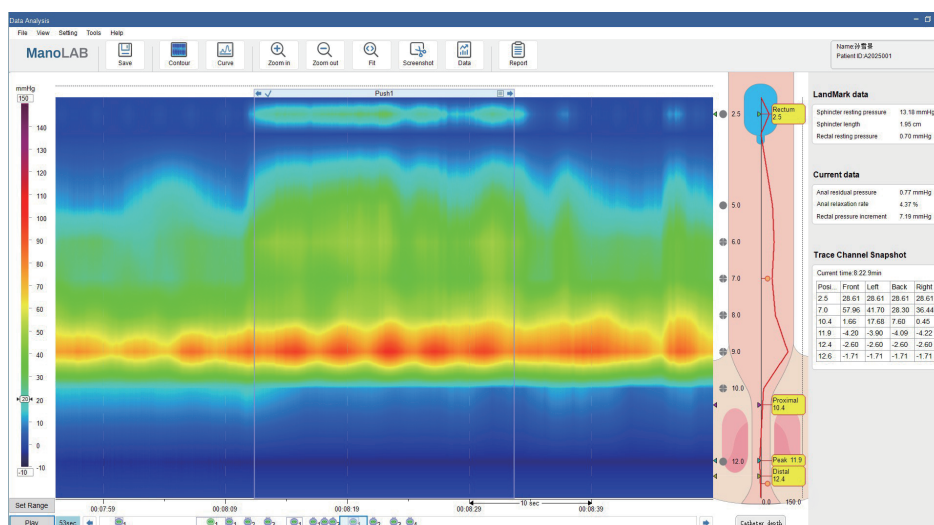


Thermo-compensation

For minimizing the deviation of collecting data, thermo-compensation process is added at the end of the measurement. It only takes 10-15 seconds.

Visual Instruction

This feature will guide user to complete the whole procedure step by step.



DICOM Integration

ManoLAB offers DICOM interface to connect the hospital's PACS for quick set-up.

User-friendly Interface

Flat designed interface allows you to navigate the interested individual event easily. Then double-click to access it for quick edit and confirm.

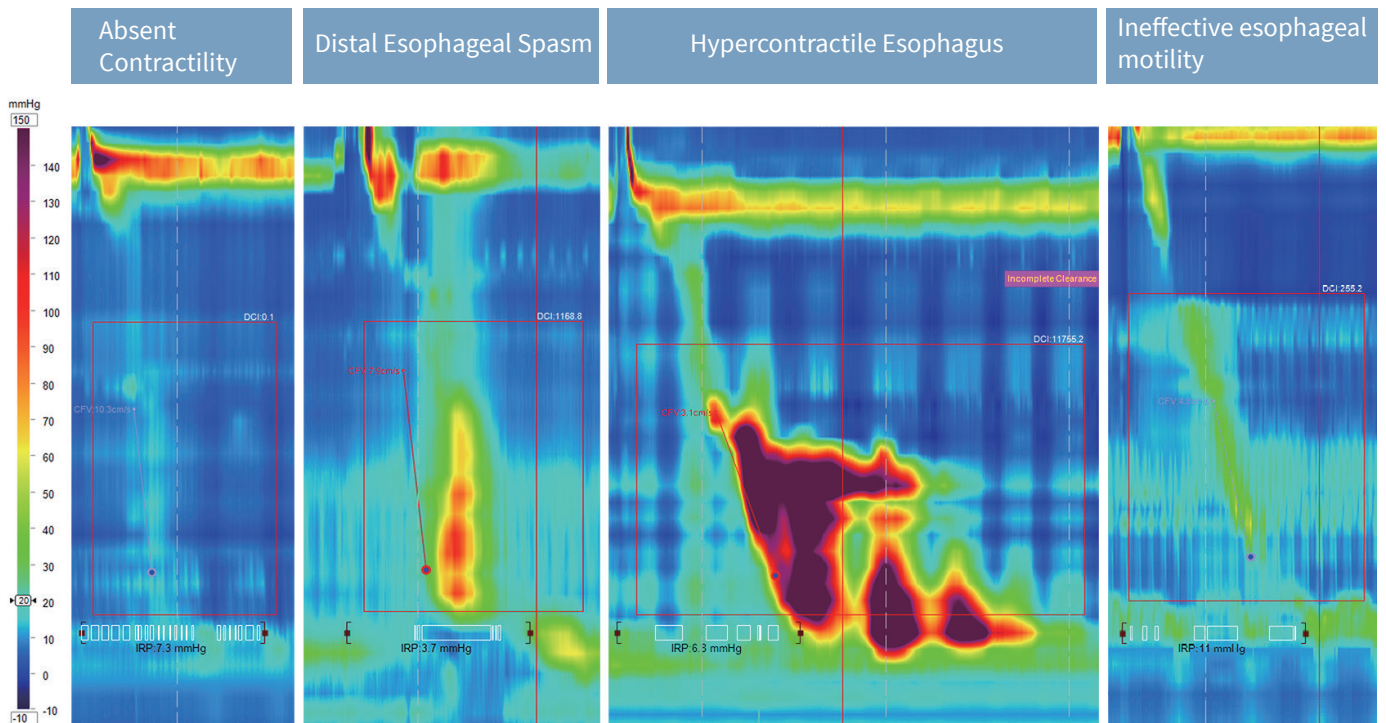
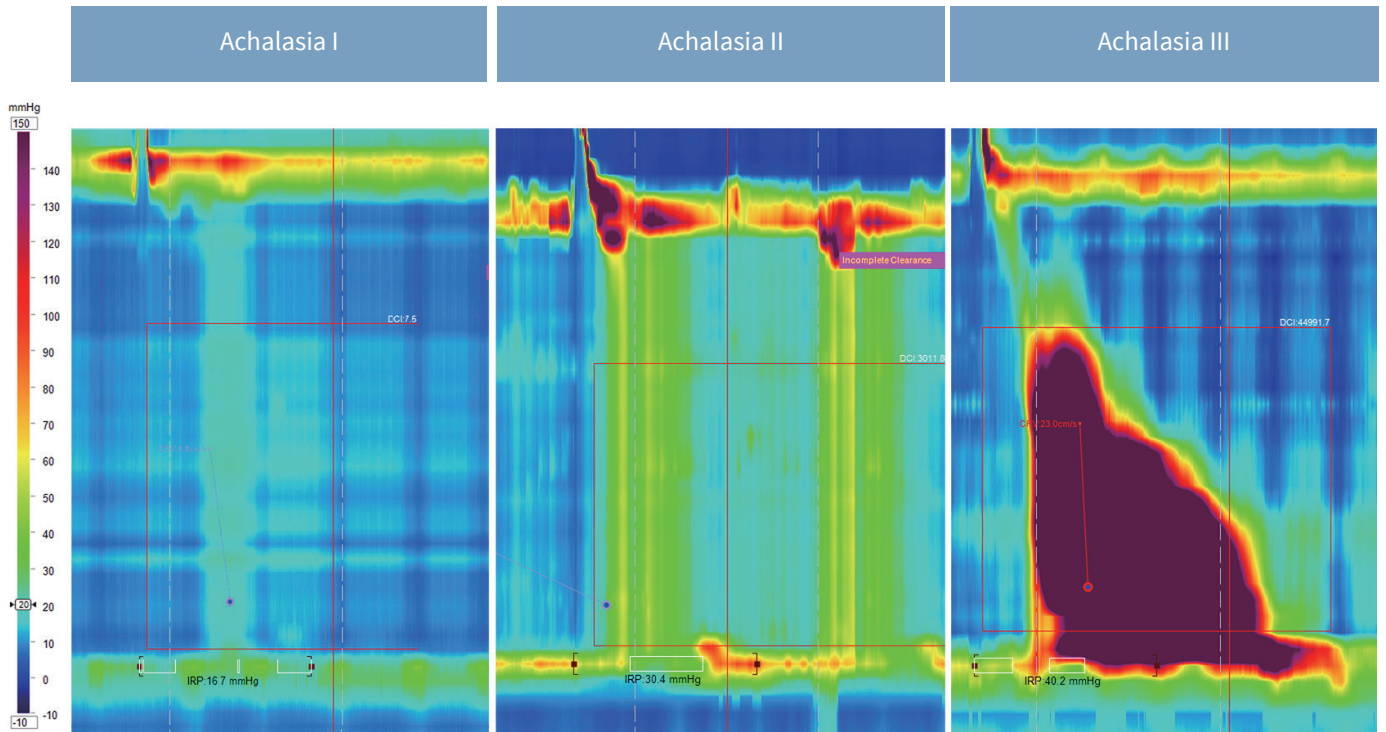
Automatic Recognition

Based on Chicago Classification and London Classification algorithms, all major parameters will be calculated automatically and listed right-hand at the meantime. All you need to do is to confirm or re-edit the result.

Standard HRM Protocol

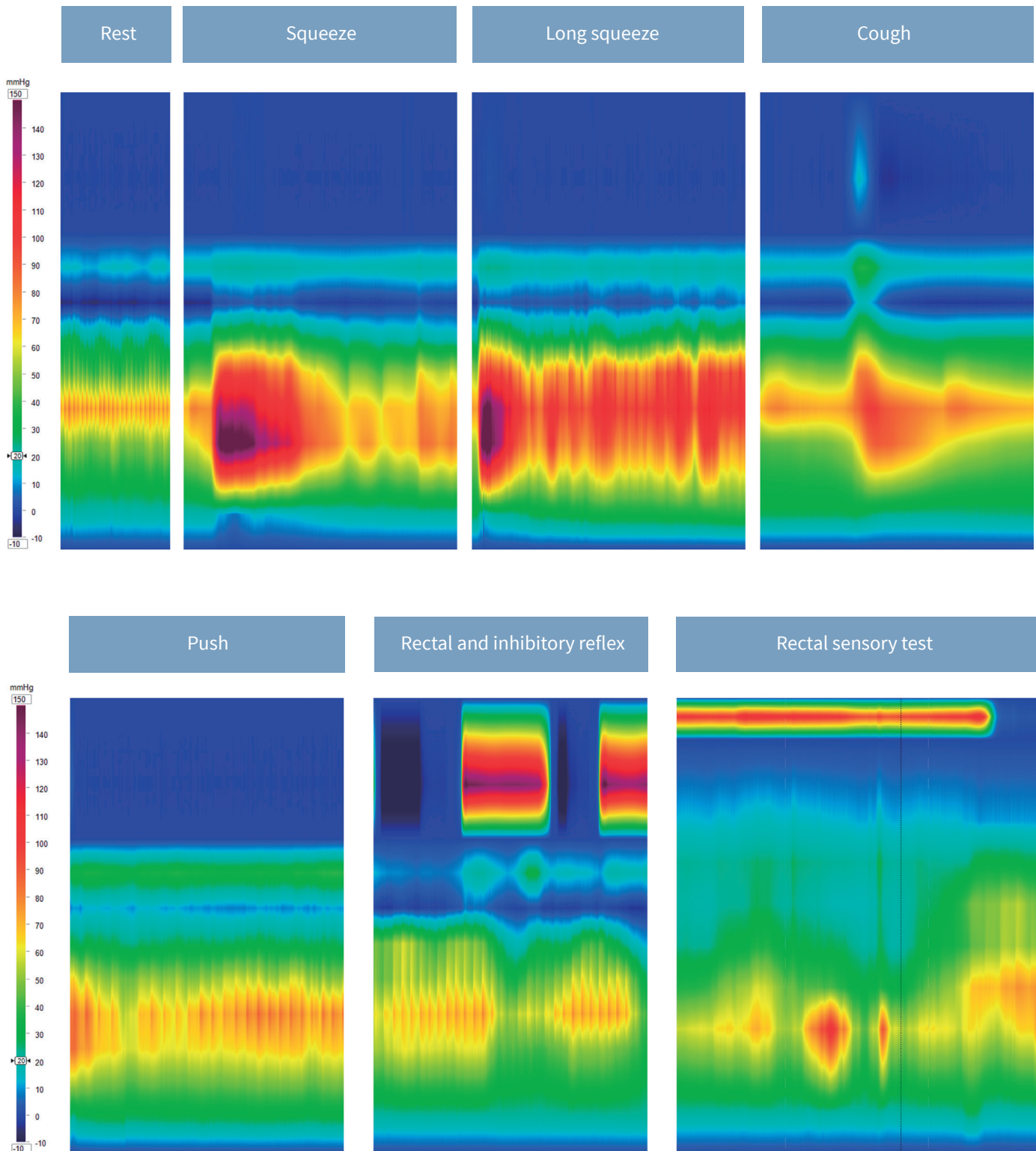
Reliable Diagnosis for Esophageal Manometry

The key HRM metrics and corresponding diagnostic thresholds are critical for disorder assessment. Algorithms based on the protocol of Chicago Classification 4.0 has been programmed in ManoLAB for reliable diagnosis. The typical esophageal motility disorders measured in upright position with MANOalPa™ are illustrated below.



London Classification for Anorectal Manometry

The MANOalpha™ HRAM System performs a comprehensive evaluation of anorectal function by recording intraluminal pressure activity along the anal canal and rectum during rest, squeeze, and simulated defecation. Through high-resolution spatiotemporal mapping, the system provides detailed visualization of sphincter function, rectoanal coordination, and rectal sensation.





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