

# MANOalpha™

High Resolution Esophageal Manometry System

Product Brochure



# MANOalpha™

## 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.<sup>ref.1</sup> According to the Spaulding Classification<sup>ref. 2</sup>, 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™ HREM

## Overview

MANOalpha™ High Resolution Esophageal Manometry System is intended to better map, measure and evaluate the esophageal 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

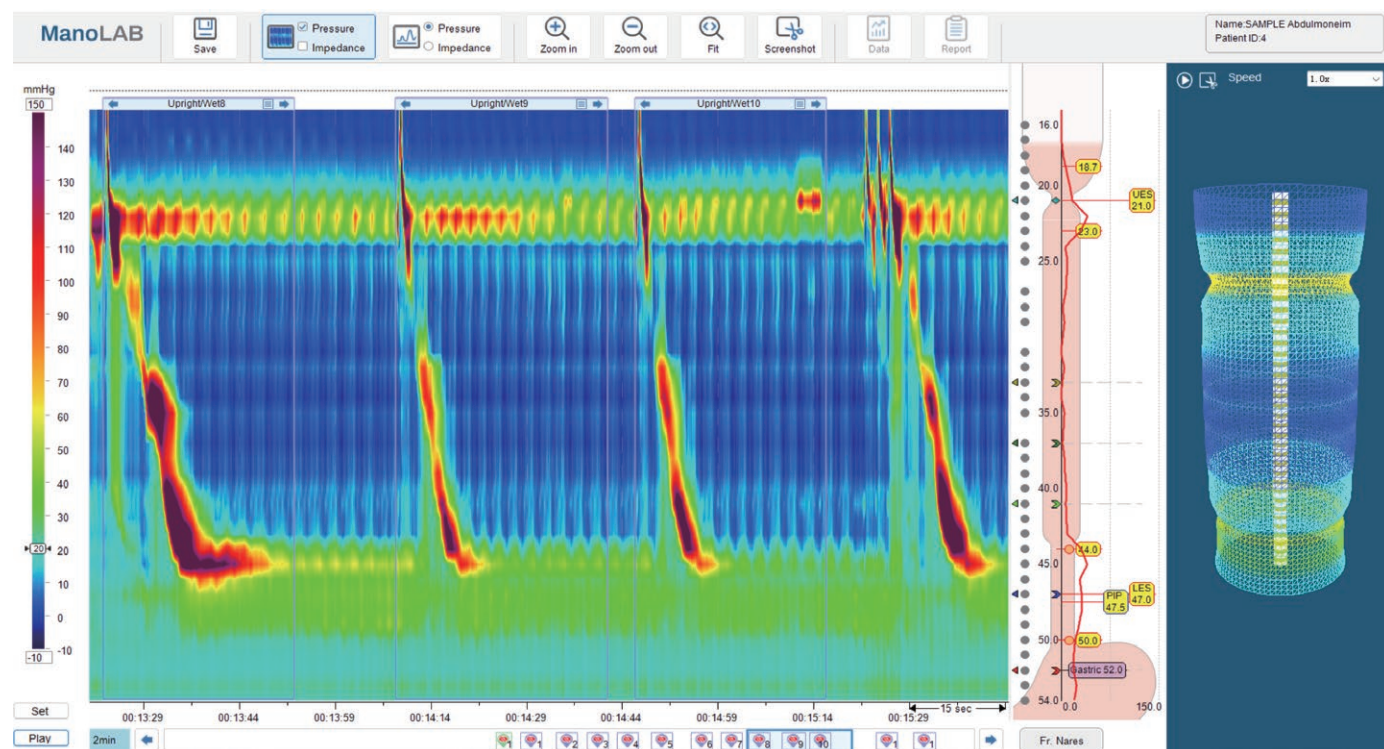
### Easy Operation

- 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
Size	360*260*90 mm [T=±10mm]	Φ 4.0 mm * 2035 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]
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, ManoLAB provides the clinician with reliable and comprehensive data for the accurate assessment of esophageal 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.

## 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 algorithms, all major parameters including IRP, DL and DCI will be calculated automatically and listed right-hand at the meantime. All you need to do is to confirm or re-edit the result.

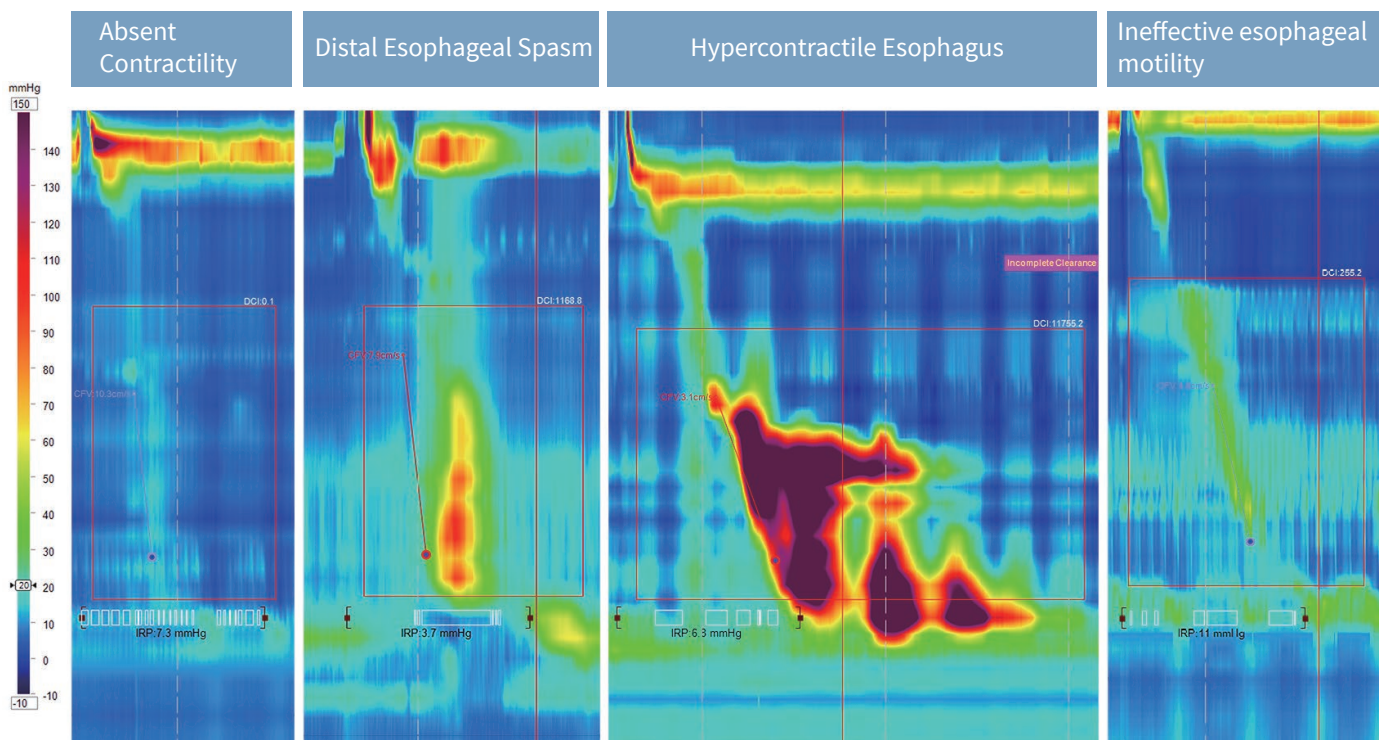
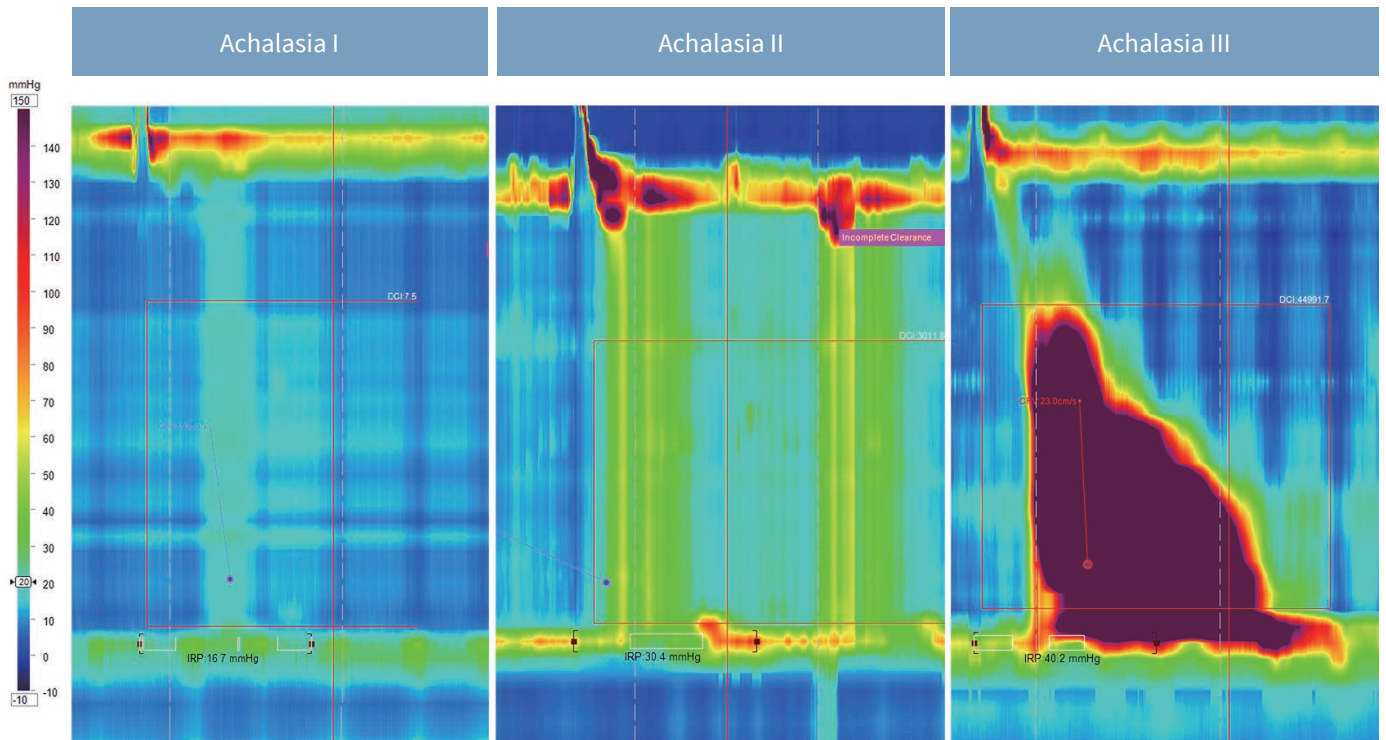
## DICOM Integration

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

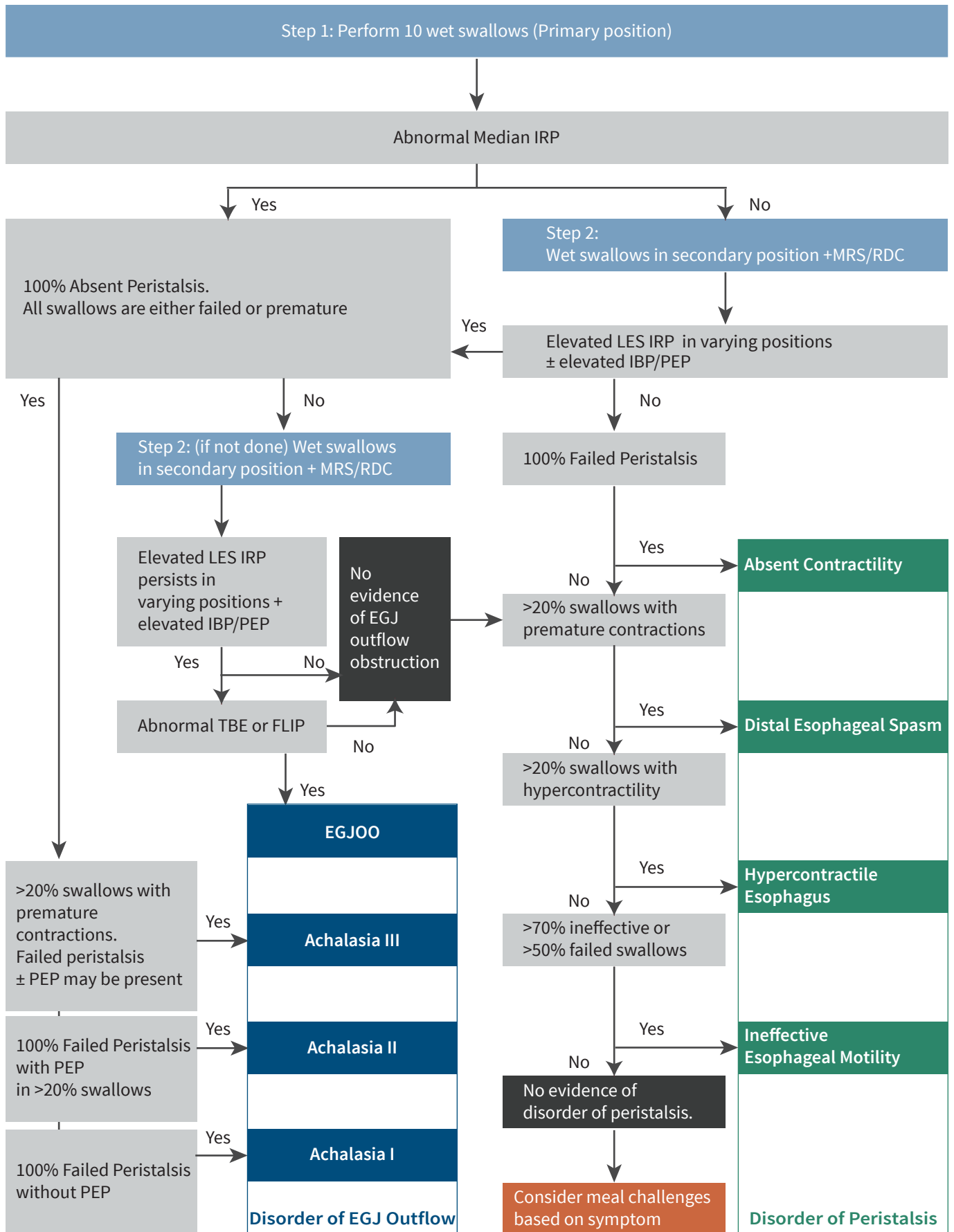
# Standard HRM Protocol

## Reliable Diagnosis

The key High Resolution Esophageal Manometry 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 MANOalpha™ are illustrated below.



# Hierarchical Classification Scheme<sup>ref3</sup>



Reference: 3. ESOPHAGEAL MOTILITY DISORDERS ON HIGH RESOLUTION MANOMETRY: CHICAGO CLASSIFICATION VERSION 4.0, *Neurogastroenterol Motil.* 2021 January ; 33(1): e14058.



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