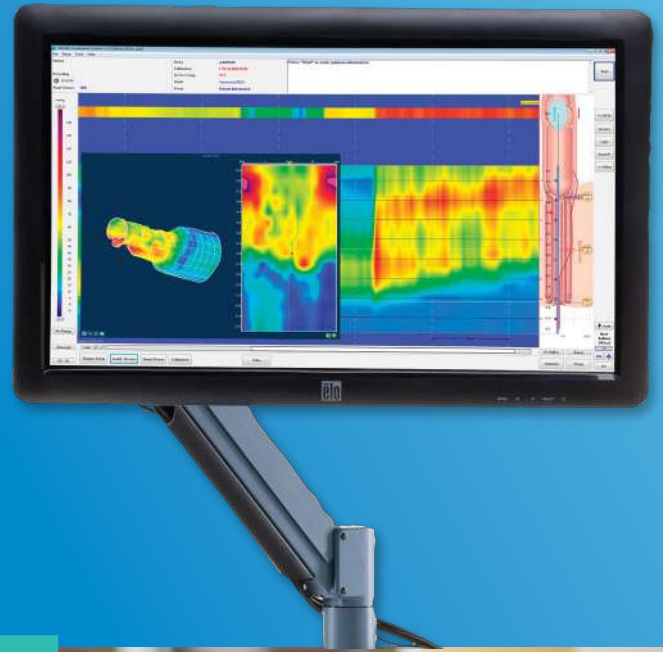


ANORECTAL MANOMETRY WITH GREATER CLARITY



MANOSCAN™ AR
anorectal manometry system

Medtronic

MANOSCAN™ AR anorectal manometry system

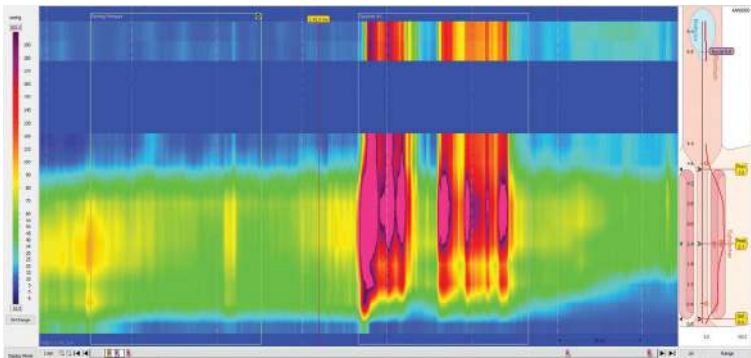
Anorectal manometry is the most widely used technique for the detection of abnormalities of sphincter function and/or rectoanal coordination.¹

In one setting a physician can comprehensively evaluate patients with fecal incontinence or constipation, including difficulty with defecation.¹ High resolution manometry can record and display detailed information simultaneously from the whole anal canal and distal rectum.¹

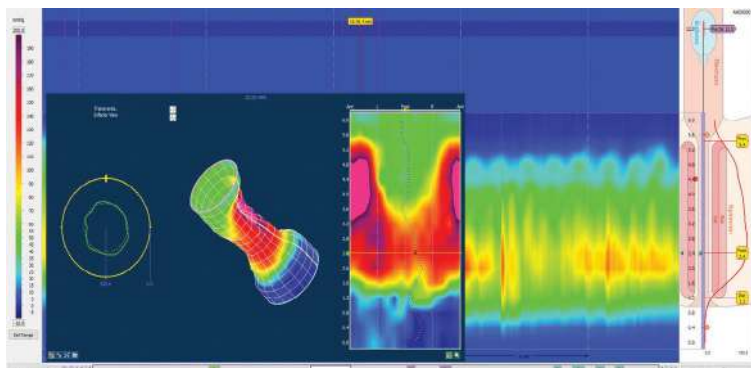
This high-resolution anorectal manometry also:

- Helps assess and quantify normal reflex pathways including relax, squeeze, and push functions of the anal sphincter muscles and rectum¹
- Helps identify patients who can benefit from biofeedback therapy
- Helps define functional weakness of the anal sphincter, diagnosis of dyssynergia, and abnormal rectal sensation

ManoScan™ AR 3D HRM system



Manoscan™ AR 3D HRM system
asymmetric anterior pressure



Manoscan™ AR 3D HRM system analytics

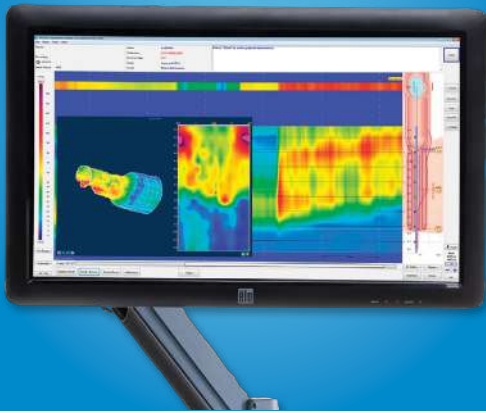
AR 3D HRM records point pressures longitudinally and radially from sensors mounted on a rigid probe with morphology represented in both two and three dimensions.¹

This three-dimensional imagery and topographical mapping enables increased diagnostic capabilities, such as the creation of physiological maps. Incorporating a single probe placement, the clinician can assess function and visualize symmetry of the anal canal.¹

Full featured workstation

This portable workstation system features:

- LCD flat panel touchscreen with articulating arm
- Modular data acquisition controller
- Windows™-based operating system
- LAN connection and WiFi-enabled
- Integrated catheter auto-calibration system
- Large lockable wheels
- Patient isolation transformer
- High-speed quality printer



Manoshield™ Disposable Catheter Sheath

Single-use sanitary catheter sheath helps prevent gross contamination of the catheter or probe to reduce manual cleaning efforts. These sheaths:

- Serve as a disposable protective outer cover that is removed and discarded immediately after procedure
- Reduce exposure of staff and equipment post-procedure, leading to decreased manual cleaning efforts
- Incorporate rectal compliance balloon for use with ManoShield™ AR and Manoshield™ AR 3D sheaths
- Meet CDC recommendation to use probe cover or condom to reduce the level of microbial contamination when one is available.²

Manoview™ Software

This intuitive suite of manometry study tools enables physicians to effectively identify motility disorders. The software features:

- Advanced tools that yield reliable measurement and comprehensive data analysis
- High-resolution and conventional displays for versatile, complete motility visualization
- Remote study capabilities when installed on any Windows™-based computer

Manoscan™ HRM Catheters

The Manoscan™ HRM catheters:

- Integrate with Manoshield™ disposable sheaths to minimize risk of cross-contamination
- Provide 5.6 cm length of continuous circumferential sensing with Manoscan™ AR probe, eliminating involuntary squeeze artifacts
- Displays high resolution data through 16 circumferential sensors by 16 longitudinal sensors generating 256 total measurement points



Procedure complications are rare but may occur. The risks of ManoScan™ AR high-resolution manometry include perforation or bleeding of the intestinal wall. Patients with previous rectal surgery, bowel inflammation, or bowel obstruction may have a higher risk for iatrogenic bowel perforation. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. The system is not compatible for use in an MRI magnetic field. Please refer to the product user manual or medtronic.com/gi for detailed information.

Indications

The ManoScan™ system provides mapping of pressures and, optionally, impedance within organs of the human gastrointestinal tract. These include the pharynx, upper esophageal sphincter (UES), esophagus, lower esophageal sphincter (LES), stomach, sphincter of Oddi, small bowel, colon, duodenum, and anorectal organs.

It is used in a medical clinical setting to acquire pressures and then store the corresponding data for visualization and analysis.

The real-time data as well as the analysis information can be viewed by medically-trained personnel for diagnostic and analytic purposes.

The ManoScan™ HRM modules provide high-resolution and/or 3D (three dimensional) display of the pressure and impedance data.

The ManoScan™ CLT module provides conventional line trace mapping of the pressure data and can be used as a stand-alone system or as a module of the ManoScan™ High-Resolution manometry system.

Contraindications

The use of the ManoScan™ system for anorectal manometry is contraindicated for patients with known anal stricture obstruction preventing insertion of the instrument

Risks

Anorectum insertion:

Potential adverse events associated with the use of the system and catheter insertion into the anorectum may include; discomfort, pain, minor bleeding, irregular heartbeat with dizziness, and perforation.

In rare instances, the catheter may curl during insertion and catheter position may move during the procedure.

Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur.

The system is not compatible for use in an MRI magnetic field.



References

1. Emma V. Carrington, S. Mark Scott, Adil Bharucha, et al. Advances in the evaluation of anorectal function the International Anorectal Physiology Working Group and the International Working Group for Disorders of Gastrointestinal Motility and Function. Nature Reviews Gastroenterology & Hepatology volume 15, pages 309–323.
2. Rutala WA, Weber DJ, The Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for disinfection and sterilization in healthcare facilities. 2008 Centers for Disease Control (CDC).

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