

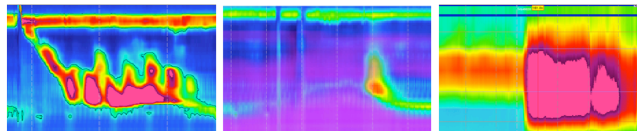
STANDARD OPERATING PROCEDURE

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High Resolution Anorectal Manometry (2D Medtronic Catheter)

SOP Title **How to perform High Resolution Anorectal Manometry
(2D Medtronic Catheter)**

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1. PURPOSE

This SOP is designed to enable clinicians and researchers involved in the clinical investigation of anorectal motor and sensory function, to correctly perform, record and analyse the findings acquired using the Medtronic High Resolution Anorectal Manometry 2 D Catheter.

2. INTRODUCTION

Anal manometry is the best established, most commonly performed test of anorectal sphincter function and recto- anal coordination.

The advent of high-resolution manometry utilizing a higher number of closely spaced pressure sensors with data presented as colour-contour pressure topography plots, has revolutionized the field of gastrointestinal motility.¹⁻⁴

3. SCOPE

This SOP applies to all clinical staff including nurses and investigators who participate in the running of clinical studies of anorectal motor and sensory testing.

4. SPECIFIC PROCEDURE DESCRIPTION

1. Equipment:

2D Solid State catheter Medtronic

Software: Mano View ARM current version, Medtronic

50 ml syringe

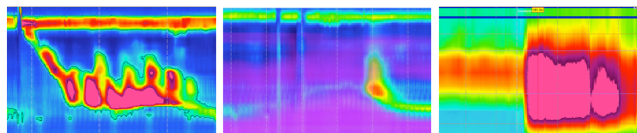
3 way tap

Alcohol wipes

Lucrication jelly

AR Balloon (Medtronic)

Tying material



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Optional:

One time use investigation sheaths for 2D catheter, Medtronic

2. Potential Hazards and Safe Handling

- Infection from unsuspected agents- HIV or Hepatitis faeces, blood or any other body fluids.

3. Safe handling

- Wear disposable gloves. Gloves can be changed as often as necessary during the procedure to prevent contamination of equipment.
- Observe waste segregation rules
- Alcohol gel can be used where necessary to clean hands.
- Wash hands after performing procedures

4. Contraindications

- Ongoing anal fissure
- Insufficient understanding of language to comply with instructions

5. Patient preparation

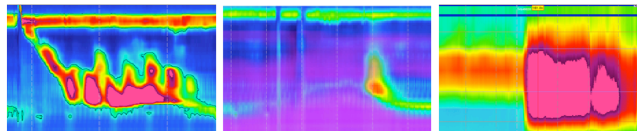
Patient of the patient prior to the test

Patients should be informed of the date of their test well in advance according to local practice. The requirement for a chaperone should be considered.

Patients should be asked to defecate before the appointment or 30 minutes prior to the test. If this is not possible a trans-anal wash-out or stimulant enema can be given.

Patient Preparation on Attendance

1. Confirm patient's details prior to starting the procedure.



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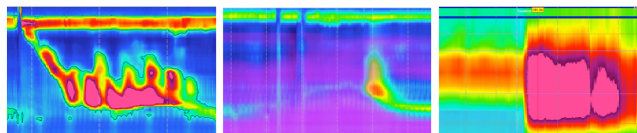
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2. Informed consent for the procedure should be obtained before the procedure according to local practice.
3. Explain in full detail the requirement of the test to the patient to allow for full cooperation during test procedures.
4. Inform the patient that they can withdraw consent at any time for the procedure.
5. Check for any allergies.
6. Review any medications that they may be taking.
7. Provide the patient with an opportunity to ask questions.
8. Ask the patient to change into a gown and remove underwear. Provide them with a sheet to cover the lower half of their body. It is also possible to provide colonoscopy pants for patient comfort.

6. Equipment Preparation

1. The High Resolution Anorectal Manometry catheter should be calibrated and Quality Control checked according to the manufacturers guidelines
2. Calibrate the HRM catheter including thermal compensation when required.
3. Ensure the catheter is correctly connected to the computer.
4. Place the catheter in the calibration chamber until the zero \longleftrightarrow are at the top of the chamber. Gently tighten the screw until the catheter is held in position by the chamber.
5. Open up the Mano View software
6. Select the correct catheter from the drop down menu or install new catheter if necessary.
7. Enter patient details "FILE→new patient". The patients details screen should display on screen. Enter patient details including the hospital number, referring physician and the test procedure operator name. Save all details and press OK.
8. Calibrate the probe. Select calibration, press zero channels and then click calibrate. The pressure in the calibration chamber should gently rise and fall. Click ok and the catheter should be now calibrated. On the right top of the



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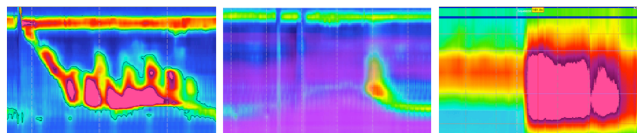
screen in the Mano View display page the catheter should read “calibrated”. If not the procedure should be repeated.

9. Once calibrated loosen the screw on the calibration chamber.
10. After calibration of the HR-ARM catheter the sheath including balloon or the balloon alone should be firmly stringed to the tip of the probe. A short inflation with 30 ml air should be performed to test for leakage.

Thermal compensation. Thermal compensation should be carried out once per 7 days. After entering the catheter number when the Mano View AR program is started a message on the screen will inform you if the catheter requires thermal compensation. Use a plastic calibration bowl and fill with warm tap water. Use the digital thermometer to ensure the temperature of the water is correct. Follow the instructions on the Mano View Programme for thermal compensation process.

7. Test Procedures

1. The patient should be positioned in the left lateral position (LLP). A digital rectal examination (DRE) should be carried out to check for faecal loading. A qualitative assessment of resting, squeeze and the defecation manoeuvre (bear down) should be carried out during the DRE. If the rectum is stool impacted the patient should be asked to empty his bowels or an enema should be given.
2. Lubrication jelly should be applied to the outside of the HR-ARM catheter. The HR-ARM catheter should then be carefully inserted into the rectum of the patient until the sphincter band is clearly visible on the monitor.
3. Allow for an approximate adaption period of 3 minutes before assessment of resting pressure. It is important to instruct the patient before that talking, laughing and moving will impact pressure measurement.
4. Press the “resting pressure measurement “ button to start recording resting pressure
5. Under verbal instruction and feedback of the operator the patient will be asked perform the following maneuvers:



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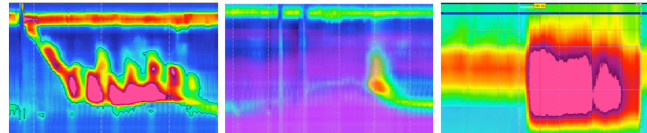
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1	Resting 60 seconds <i>“no talking with patient, no intervention”</i>
2	3 x Short squeeze (5 seconds) <i>“please squeeze in tight with the muscles around your bottom and hold until I say stop”</i> 30 sec rest between squeeze
3	1 x Long squeeze (30 seconds) <i>“please squeeze in tight with the muscles around your bottom. This time I would like you to hold on for 30 seconds, or as long as you can”. The patient should be encouraged to continue squeezing.</i> 60 sec rest after long squeeze
4	2 x Strong single cough 30 sec rest between cough
5	3 x Simulated defecation (push) 30 sec rest between push
6	1 x RAIR Fast balloon inflation, 30/60 mL in \pm 2 sec, Release air after 5 sec Repeat with larger volume if no reflex is observed (max 240 mL)

6. After RAIR testing **Rectal sensory testing** can be performed with the balloon at the tip of the catheter /or the balloon incorporated in the sheath. The balloon is inflated using the 50ml syringe attached to the catheter. The balloon is filled continuously with air and the patient asked to report “first sensation”, “urge” and “discomfort”. The investigator notes down the respective volumes in ml. The maximum volume of this balloon is 300ml.

8. Analysis and data processing



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1. HR –ARM: The studies are analysed with the inbuilt software (Manoscan AR, Medtronic)
2. Resting, squeeze and defecation manoeuvres are analysed by the program
3. Presence of the RAIR is reported
4. A report is automatically generated by the program after analysis is finished

5. INTERNAL AND EXTERNAL REFERENCES

1. Carrington EV, Heinrich H, Knowles CH, et al. Methods of anorectal manometry vary widely in clinical practice: Results from an international survey. *Neurogastroenterology & Motility* 2017;n/a-n/a.
2. Heinrich H, Sauter M, Fox M, et al. Assessment of Obstructive Defecation by High-Resolution Anorectal Manometry Compared With Magnetic Resonance Defecography. *Clin Gastroenterol Hepatol* 2015;13:1310-1317 e1.
3. Carrington EV, Scott SM, Bharucha A, et al. Expert consensus document: Advances in the evaluation of anorectal function. *Nat Rev Gastroenterol Hepatol* 2018;15:309-323.
4. Heinrich H, Misselwitz B. High-Resolution Anorectal Manometry - New Insights in the Diagnostic Assessment of Functional Anorectal Disorders. *Visc Med* 2018;34:134-139.