

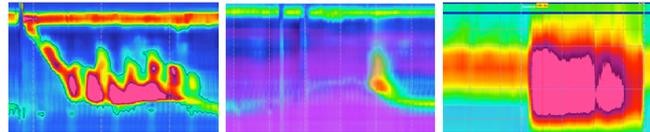
STANDARD OPERATING PROCEDURE

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High Resolution Anorectal Manometry (MMS Catheter)

SOP Title **How to perform High Resolution Anorectal Manometry
(MMS 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 MMS High Resolution Anorectal Manometry 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:

MMS Solid State catheter

MMS Software

MMS Manometry System

Bowl with hand warm water

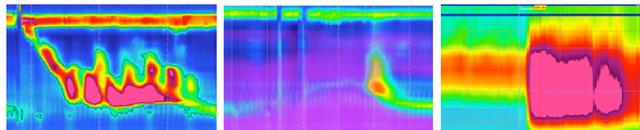
50 ml syringe

3 way tap

Lucrication jelly

Balloon (MMS)

Tying material



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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

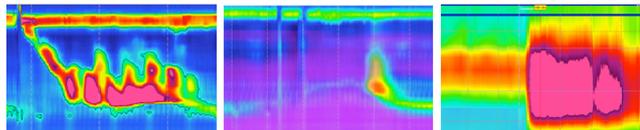
Patient of the patient prior to the test

Patients should be informed of the date of their test well in advance according to local practice. If the patients wishes a chaperone should be provided.

Patients should be asked to defecate before the appointment or 30 minutes prior to the test. If this is not possible a mini enema can be given.

Patient Preparation on Attendance

1. Confirm patient's details prior to starting the procedure.
2. Informed consent for the procedure should be obtained before the procedure according to local practice.



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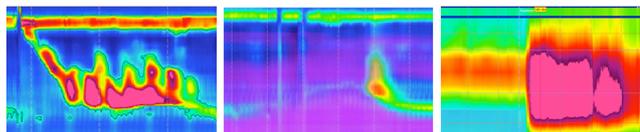
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3. Explain in full detail the requirement of the test to the patient to allow for full cooperation during test procedures.
4. Inform the patient that they can withdraw consent at any time for the procedure.
5. Check for any allergies.
6. Review any 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. Connect the solid state catheter to the CIM-AUX HRIM.
2. Fill a plastic bowel with body temperature distilled water of 37 degrees. Pre-wet the catheter as described in manual of the manufacturer (the minimum period is two minutes).
3. Press the Zero all button to zero all pressures (the pressure sensors must be covered with approx. 1 cm of water).
4. Remove the catheter from the bowel.
5. Quality check: touch the sensors softly one by one with a gloved hand and check the response on the screen.
6. Apply some lubricant to the balloon and insert the catheter gently in the anal canal of the patient. Position the balloon in the rectum of the patient.
7. Insert the catheter a little too deep and withdraw to prevent the balloon covering the sensors at the tip of the catheter.
8. Check the position on the screen. The anal canal should be in the middle of the screen with a couple of sensors in the rectum and a couple of sensors outside.
9. Ask the patient to cough to check the registration of the pressure channels.
10. You are ready for the investigation.



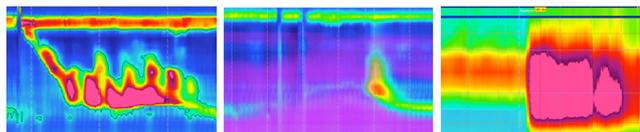
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7. Test Procedures

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. 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.
3. Press the “resting pressure measurement “ button to start recording resting pressure
4. Under verbal instruction and feedback of the operator the patient will be asked perform the following maneuvers:

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



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6	<p>1 x RAIR</p> <p>Fast balloon inflation, 30/60 mL in \pm 2 sec, Release air after 5 sec</p> <p>Repeat with larger volume if no reflex is observed (max 240 mL)</p>
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- After RAIR testing **Rectal sensory testing** can be performed with the balloon at the tip of the catheter. 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.

8. Analysis and data processing

- HR –ARM: The studies are analysed with the MMS software
- Resting, squeeze and defecation manoeuvres are analysed by the program
- Presence of the RAIR is reported
- A report is automatically generated by the program after analysis is finished

5. INTERNAL AND EXTERNAL REFERENCES

- 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.
- 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.
- 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.
- Heinrich H, Misselwitz B. High-Resolution Anorectal Manometry - New Insights in the Diagnostic Assessment of Functional Anorectal Disorders. *Visc Med* 2018;34:134-139.