

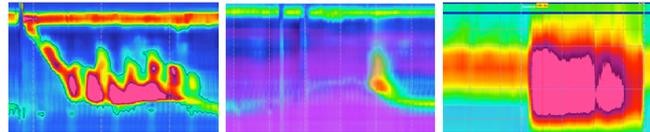
STANDARD OPERATING PROCEDURE

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High Resolution Anorectal Manometry (MMS Water Perfused Catheter)

SOP Title **How to perform High Resolution Anorectal Manometry
(MMS Water Perfused 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 Water Perfused 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 water perfused catheter

MMS Software

MMS Water perfused system Pump

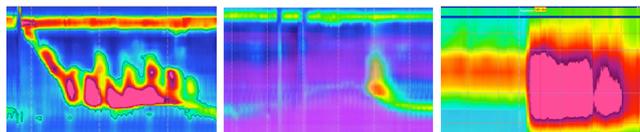
MMS Manometry system

50 ml syringe

3 way tap

Lucrication jelly

Balloon for Rectal Sensation testing (MMS)



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Tying material

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

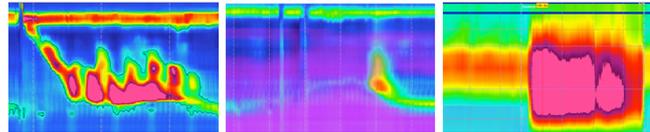
5. Patient preparation

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



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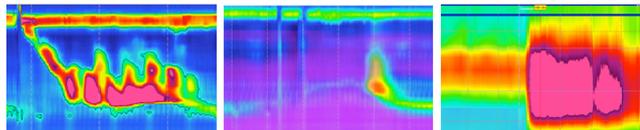
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1. Confirm patient's details prior to starting the procedure.
2. Informed consent for the procedure should be obtained before the procedure according to local practice.
3. Explain in full detail the requirement of the test to the patient to allow for 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. Check that the setup of the perfusion system is complete and correct. If applicable you have to connect the pressure transducers, the flow resistors (0.15 ml/min) and a water filter.
2. Remove lid and float from the water container.
3. Ensure that the inside of the water container is clean and fill the container with demineralized or distilled water which contains a biofilm reducing agent.
4. Put the float on the water and screw the lid on the water container; the tube must be placed through the hole of the float. Reconnect the tubes to the water container.
5. Connect the catheter to the pressure transducers (note: take care of the numbering of the channels specially look-a-likes 1-7 and 6-9).
6. Empty the balloon by squeezing all air out of the balloon. Connect the balloon filling lumen to the perfusion pump for automatic balloon inflation.
7. Put the catheter in the dish.
8. Start the pre-test of the HRAM investigation in the MMS software program. The software will switch on the perfusion pump.



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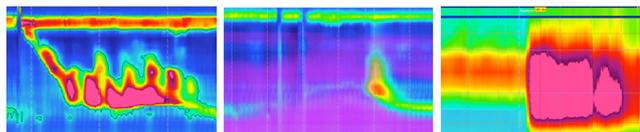
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9. Wait until the perfusion pump pressure equals the pressure as set in the investigation protocol (1000 mBar).
10. Wait 2 minutes until all lumen of the catheter are filled with water.
11. Inspect all wetted parts on air bubbles. Continue flushing if necessary.
12. Press the [Zero all after 10 seconds] button. Keep the catheter horizontal at the level of the anal verge (patient) to zero balance the pressures.
13. Quality check: Move the catheter vertically up 40 cm above the anal verge. All pressure channels should read ± 30 mmHg (40 cmH₂O)
14. 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.
15. Insert the catheter a little too deep and withdraw to prevent the balloon covering the sensors at the tip of the catheter.
16. 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.
17. Ask the patient to cough to check the registration of the pressure channels.
18. You are ready for the investigation.

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:



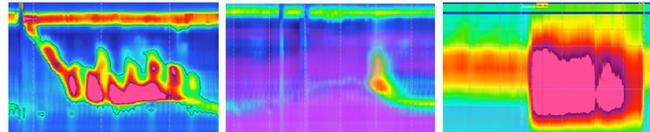
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| 1 | Resting 60 seconds <i>“no talking with patient, no intervention”</i> |
| 2 | 3 x Short squeeze (5 seconds) <i>“please squeeze in tight with the muscles around your bottom and hold until I say stop”</i> 30 sec rest between squeeze |
| 3 | 1 x 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) |

- 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.



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8. Analysis and data processing

1. HR –ARM: The studies are analysed with the MMS software
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.