

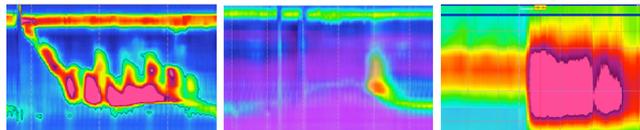
STANDARD OPERATING PROCEDURE

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High Resolution Anorectal Manometry (3D Medtronic Catheter)

SOP Title **How to perform High Definition Anorectal Manometry
(3D 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 Definition Anorectal Manometry 3D 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:

3D solid-state catheter Medtronic

Software: ManoView AR, ManoScan AR Acquisition, Medtronic

Medtronic manometric system: ManoScan 360 A120 + ManoScan3D A300

1 x 50 ml syringe

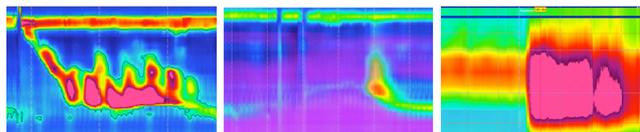
1 x 1 ml syringe

1 x stopcock

1 x "T" connector

1 x 5 ft jumper (clear tubing)

Lubrication jelly



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Single use clinical kit ManoShield AR 3D (containing: sheath with integrated balloon, antiseptic wipes, talc wipe and 2 ft jumper)

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

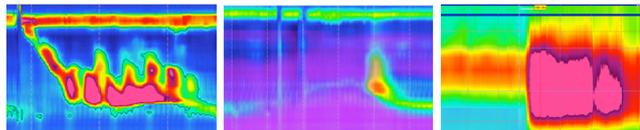
Patient of the patient prior to the test

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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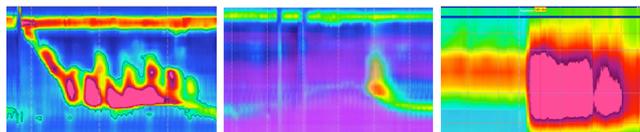
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2. Informed consent for the procedure should be obtained before the procedure according to local practice.
3. Explain in full detail the requirement of the test to the patient to allow for full cooperation during test procedures.
4. Inform the patient 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. If required catheter should be calibrated “In Vivo” (in warm tap water).
2. Connect the 3D catheter to the ManoScan3D A300 and connect the air tubes as indicated in the manual.
3. Open up the ManoScan AR Acquisition software
4. Select the correct catheter form the drop down menu or install new catheter if necessary.
5. 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.
6. Clean the catheter gently with the antiseptic wipe. Wait until the sensors are dry. Apply talc and put on the disposable sheath with the balloon.
7. Place the catheter in the calibration chamber and gently tighten the screw.
8. Fill the balloon with 1 ml of air and close all the taps. Ensure that there is no opened tap.



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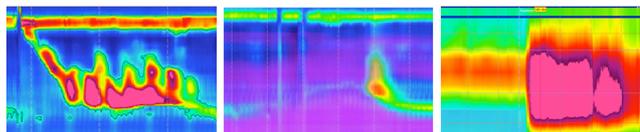
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9. Calibration process: Select calibration, press zero channels and then click calibrate. The pressure in the calibration chamber should gently rise and fall. Click ok and the catheter should be now calibrated. On the right top of the screen in the Mano View display page the catheter should read “calibrated”. If not the procedure should be repeated.
10. Once calibrated loosen the screw on the calibration chamber.

Calibration In Vivo. Thermal compensation should be carried out once per 7 days. After entering the catheter number when the ManoScan AR Acquisition 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 ManoScan AR Acquisition software for “Calibration In Vivo” calibration 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 catheter. The 3D catheter should then be carefully inserted into the rectum of the patient until the sphincter band is clearly visible on the monitor. Several cm of the distal rectum should be covered by the sensors.
3. Hold the catheter so that “posterior” marker is in the right place.
4. Click the “2D/3D” button to ensure that the whole span of anal canal and part of the rectum are covered by the sensors.
5. 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.



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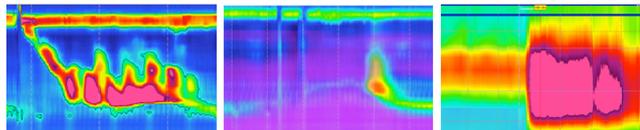
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6. Press the “Resting pressure measurement“ button to start recording resting pressure
7. Under verbal instruction and feedback of the operator the patient will be asked perform the following maneuvers:

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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) |

8. 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”



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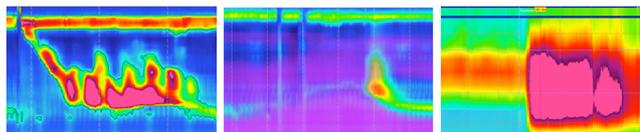
and “discomfort”. The investigator notes down the respective volumes in ml. The maximum volume of this balloon is 300ml.

8. Analysis and data processing

1. The results are analysed with the inbuilt software (ManoView AR, Medtronic)
2. Resting, squeeze and defecation manoeuvres are analysed by the program
3. Presence of the RAIR is reported.
4. 3D picture of the anal canal during rest, squeeze and bear down manoeuvres should be described by the investigator as inspected visually [5,11,12,20].
5. A report is automatically generated by the program after analysis is finished
6. If necessary, raw data can be obtained using the inbuilt function of the ManoView AR software for post-processing (Menu→ File→Save selected data). Post processing of the data can be done by external software programs to describe the 3D pressure profiles of the anal canal during rest, squeeze and bear down manoeuvres [6-26].

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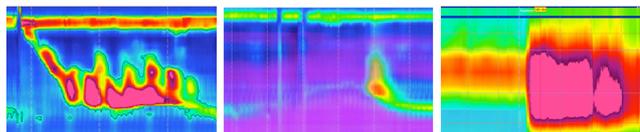


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