

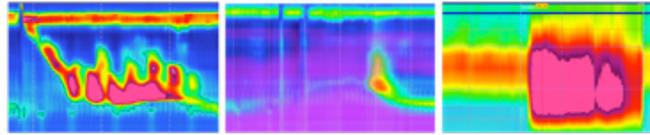
STANDARD OPERATING PROCEDURE

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Hand Held Short Protocol Barostat

SOP Title **How to perform Rectal Sensory Testing with a Hand Held Short Protocol Barostat**

Author	Dr. Henriette Heinrich	
Reviewed by	Prof. Mark Fox	



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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 of a short protocol hand held barostat.

2. INTRODUCTION

Rectal barostat is the gold standard for assessment of rectal volume, compliance and sensation. However the expense of the hardware and the time required for investigation via the electronic barostat are factors that confine this tool to the research setting. The short protocol hand held barostat offers a quick <10-minute assessment of rectal capacity (defined by rectal volume at 40mmHg distension pressure), compliance and sensation.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:

Oversized (e.g. 700ml) Barostat Bag and Catheter assembly (e.g. Mui Scientific)

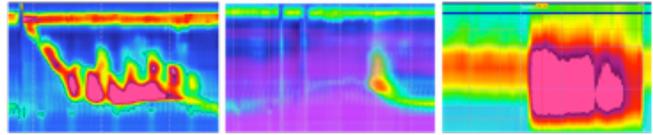
50 ml syringe

Two 3 way taps

Alcohol wipes

Lubrication jelly

Sphygmanometer (Electronic or hand held)



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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

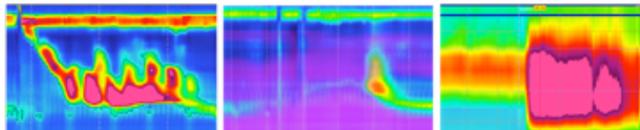
- Wear disposable gloves. Gloves can be changed as often as necessary during the procedure to prevent contamination of equipment.
- Observe waste segregation rules
- Alcohol gel can be used where necessary to clean hands.
- Wash hands after performing procedures

4. Contraindications

- Insufficient understanding of language to comply with instructions

5. Patient preparation

Patient of the patient prior to the test



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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

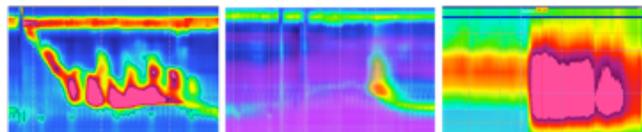
1. Confirm patient's details prior to starting the procedure.
2. Informed consent for the procedure should be obtained before the procedure according to local practice.
3. Explain in full detail the requirement of the test to the patient to allow for full cooperation during test procedures.
4. Inform 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 which a sheet to cover the lower half of their body. It is also possible possible to provide colonoscopy pants for patient comfort.

6. Equipment Preparation

1. Connect the Barostat bag to the sphygmomanometer and syringe via the three way taps. (see picture)
2. Empty the barostat bag completely via the syringe
3. Ensure that the sphygmomanometer is zeroed prior to use

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.



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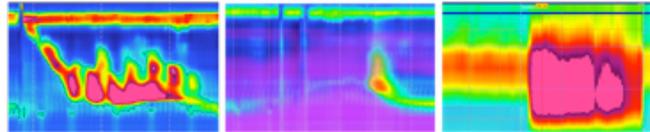
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2. The barostat bag should be lubricated and folded for insertion
3. The barostat should be carefully placed inside the patients rectum
4. Slowly start inflating the barostat bag using the 50 ml syringe, ensuring after each filling that no air can leave the balloon by ensuring correct position of the respective three way taps
5. Inflate the balloon until a supra-physiological level is reached on the sphygmomanometer in a conditioning sequence (40 mmHg intra-rectal distension pressure was used in studies).
6. This represents the rectal capacity (volume at a given intra-rectal distension pressure)
7. Deflate the barostat bag.
8. If the patient can not reach 40mmHg due to discomfort or pain, note the respective maximum pressure reached. At least >30mmHg is required for a stable assessment.
9. After deflating the bag completely slowly inflate the barostat bag until the patient notes the bag filling (“first sensation”)
10. Note down the respective volume at first sensation
11. Continue inflating the barostat bag until the patient reports a constant “urge” to defecate
12. Note down the volume at “urge”
13. Fill the barostat bag until the patients reports maximum discomfort
14. Note the volume at “maximum discomfort”. This can be greater than rectal capacity (i.e. greater than volume at 40mmHg distension pressure)
15. Remove half of the volume inflated and note down the pressure on the sphygmomanometer. This is an approximate measure of compliance (e.g. rectal capacity is 300ml, then deflate 150ml and measure pressure at this volume)
16. Completely empty the barostat bag
17. Remove the barostat bag from the rectum
18. The test is finished

8. Analysis and data processing

1. Express the volume thresholds for sensations as a percentage of rectal capacity at 40mmHg. Similar to measurement of sensation at a set pressure in the gold-standard barostat investigation, this allows comparison of rectal sensitivity between patients with different rectal capacity (normal 180-360ml, acquired during the conditioning sequence) ⁴
2. Compliance represents the pressure at half of the measured rectal volume



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5. INTERNAL AND EXTERNAL REFERENCES

1. Fox M, Thumshirn M, Fruhauf H, et al. Determinants of fecal continence in healthy, continent subjects: a comprehensive analysis by anal manometry, rectal barostat and a stool substitute retention test. *Digestion* 2011;83:46-53.
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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. Fox M, Thumshirn M, Fried M, et al. Barostat Measurement of Rectal Compliance and Capacity. *Diseases of the Colon and Rectum* 2006;49:360 - 370.