Agreed AGIP Guidelines for High-Resolution Anorectal Manometry (HR-ARM):

Equipment suggestions:

- Either a solid-state (reusable) or water-perfused (usually disposable) high-resolution anorectal manometry (HR-ARM) catheter should be used
- A maximum 10 mm inter-sensor spacing is recommended to allow pressures between sensors to be appropriately interpolated (estimation of a value between two known values) for display / analysis
- A minimum recording length of 8 cm is recommended to allow for assessment of both distal rectal and anal events
- For water-perfused catheters, perfusion rate should be kept to a minimum to limit the volume of water flowing within the anorectum during the procedure, but of sufficient rate to retain fidelity / accuracy of recording
- A standard (approximately 6 cm length x 4 cm width; maximum volume >360 ml) non-latex balloon should be mounted onto the catheter tip for assessment of rectal sensation and the rectoanal inhibitory reflex (RAIR)
- If possible, balloon inflation should be performed with an automated pump, to allow standardization of inflation speed (for sensation, recommended at 2 ml / sec)

Patient selection and preparation in advance of procedure:

- Patients should be assessed by a gastroenterologist or colorectal surgeon prior to referral for HR-ARM. Ideally, patients should undergo endoscopy +/- biopsies to exclude carcinoma or inflammatory conditions as the cause of symptoms, and to assess for structural abnormalities such as intussusception or stricture
- An information leaflet should be given to patients prior to attendance outlining preparation required, what to expect during the procedure, risks and post-procedure advice
- Patients should be informed of the date of their test well in advance
- Patients should be informed that they may continue to take their usual laxatives, enemas or suppositories (if necessary) prior to attendance
- If required, an advocate should be in attendance during the procedure

Patient preparation on attendance:

- The patient's details should be checked prior to starting the procedure
- The patient may be invited to open their bowels prior to starting the procedure. Enema administration to facilitate rectal emptying is not routinely recommended, although this can be considered in the context of faecal impaction
- A full and focused clinical history should be taken from the patient documenting relevant symptoms, associated past medical, surgical and obstetric history, and current medications
- The procedure should be explained in detail to allow informed consent and full co-operation during the test. The patient must be given the opportunity to have any questions or concerns they may have answered to their satisfaction before the procedure starts. The patient should be informed that they can withdraw consent at any time during the procedure
- Written consent may be taken, according to local guidelines

Equipment preparation:

- As per the 'BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy' (April 2017), before the start of each procedure the anorectal catheter (if reusable) should undergo a full cleaning cycle, unless last used and decontaminated within the preceding 3 hours. This should be undertaken by trained, competent staff. Relevant tracking details should be entered into an appropriate (catheter) cleaning log
- In the case of reusable catheters, it is important to ensure that the chosen disinfectant has been approved for decontamination by the catheter manufacturer
- Catheter calibration should be checked as per manufacturers' guidelines
- If required, the non-latex balloon should be adequately secured to the catheter, and inflation performed *ex vivo* to check for air leaks; if a leak is evident, the balloon should be re-secured to the catheter, and then re-tested
- The catheter should be zeroed at the start of every procedure

Performance of the procedure:

- The member of staff performing the procedure must either be fully trained and accredited in this procedure, or supervised by a fully trained and accredited practitioner
- Staff should wear appropriate protective clothing
- Ideally, a chaperone should be present during the procedure
- Each step of the procedure should be explained to the patient to ensure compliance
- The patient should be asked to lie down in the left lateral position with a sheet covering any exposed areas to ensure dignity
- If required, and performed by an appropriately trained and experienced practitioner, a digital rectal examination should be undertaken prior to HR-ARM, and documented with particular reference to:
  i) inspection of the perineum
     - excoriation
     - erythema
     - skin lesions
     - scars from previous surgery / perineal trauma
     - fistulae / external haemorrhoids
     - presence of mucosal prolapse / rectal prolapse on request to strain
  ii) digital rectal examination
     - palpable anal / rectal lesions
     - anal sphincter tone at rest
     - anal sphincter and puborectalis response on request to squeeze
     - anal sphincter and puborectalis response on request to strain
     - presence of stool within the rectum
     - presence of a rectocoele

  Any untoward sinister pathology noted incidentally during the procedure should be documented and the referring clinician informed without delay
- During digital rectal examination, a brief trial / tutorial of 'squeeze' and 'push' can be performed to ensure patient understanding prior to onset of the procedure
- After digital rectal examination, a minimum 5 minute period of rest should be allowed
- Lubrication gel should be applied to the catheter prior to commencement of the HR-ARM procedure to allow for comfortable insertion
- The HR-ARM catheter tip should be gently advanced through the anus into the rectum. If resistance is felt during insertion, pull back the catheter before re-

advancing. If catheter placement is problematic then do not continue to advance the catheter if discomfort is caused or if placement is overly difficult

- The catheter should be placed with the last 2 manometric sensors visible from the anal verge (to facilitate *post hoc* analysis), and preferably taped into position to prevent inadvertent movement during the testing protocol

- The following protocol should be performed, incorporating several manoeuvres:

(1) **Stabilisation** – a minimum of 3 minutes stabilisation period should be allowed. The patient should be asked to lie still, relaxed, without talking if possible. During this time it is useful to mark the limits of the anal canal for future reference;

(2) **Resting period** – a 1 minute period of measurement at rest should be taken, again with the patient relaxed and without talking. Any sudden movement (e.g. talking, coughing etc.) should be noted on the trace to prevent confusion during *post hoc* analysis;

(3) **Squeeze manoeuvre** – three squeezes, each of 5 seconds duration and separated by 30 second rest periods, should be performed in response to the (suggested) following command “please squeeze in tight with the muscles around your bottom and hold until I say stop”. A 30 second rest period should also be allowed following the third manoeuvre;

(4) **Endurance squeeze manoeuvre** – a single 30 second endurance squeeze should be performed in response to the (suggested) following command “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 during the 30 second period to aid compliance. A 60 second rest period should be allowed following this manoeuvre;

(5) **‘Push’ manoeuvre** – three 15 second pushes (simulated defaecation), each separated by a 30 second rest period, should be performed in response to the (suggested) following command “please push / bear down as if you were going to the toilet to open your bowels”. A 30 second rest period should be allowed following the third manoeuvre;

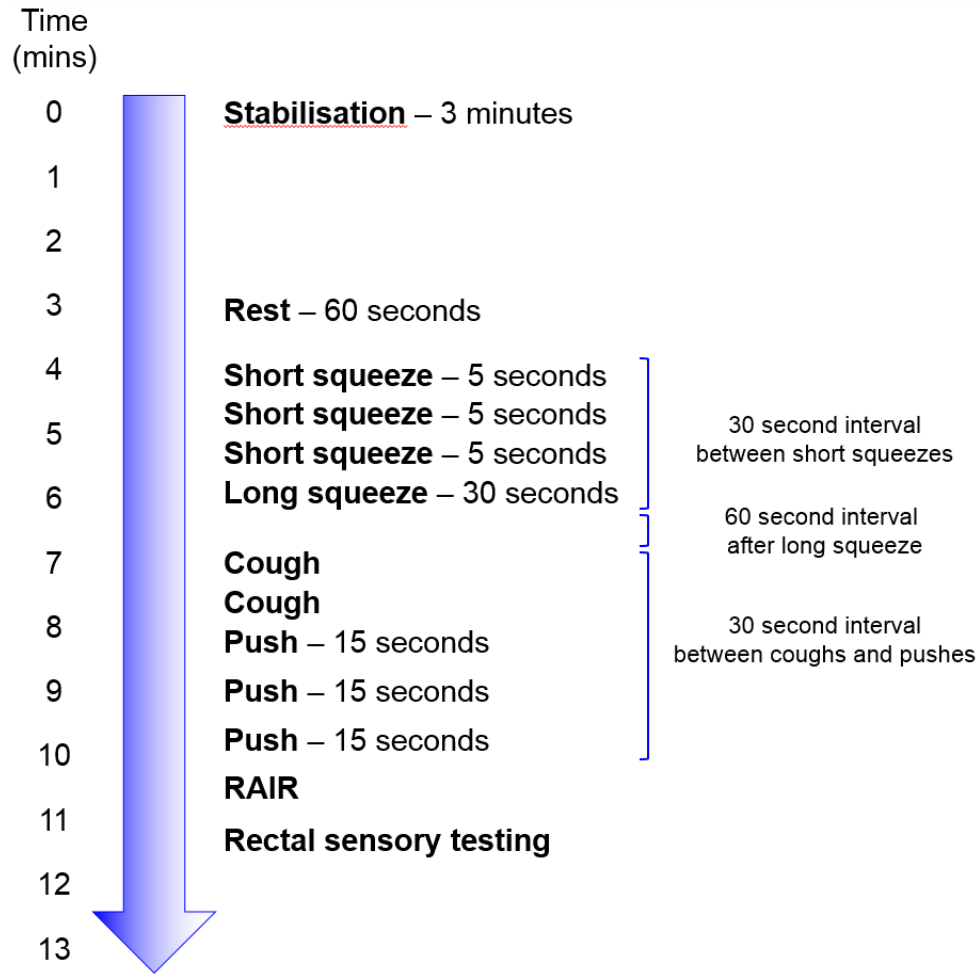
(6) **Cough manoeuvre** – two *single* coughs, separated by a 30 second rest period, should be performed, with the patient encouraged to cough as forcefully as possible. The patient should be instructed to refrain from coughing multiple times, as this impairs data interpretation. A 30 second rest period should be allowed following the second manoeuvre;

(7) **Rectoanal inhibitory reflex (RAIR)** – if this test is to be performed, the balloon should be inflated (ideally with an automated pump) at a rate of 30 ml/second to a volume of 60 ml. If the reflex is absent, increase the inflation volume in 60 ml increments (to a maximum of 240 ml) until the reflex is observed and sustained;

(8) **Rectal sensory testing** – rectal sensory testing should ideally be performed with an automated pump attached to the anorectal catheter. Using a ramp (continuous) inflation paradigm, the balloon should be inflated at a rate of 2 ml/second and the patient asked to report: (1) volume for first constant sensation, (2) desire to defaecate volume, and (3) maximum tolerated volume;

(9) **Rest period** – a final 30 second post-procedure period of rest should be recorded.

- At the end of the procedure, the catheter should be removed and a short period of recording performed *ex vivo* to ensure there has been no pressure 'drift' during the recording period
- The catheter should then be disconnected for decontamination purposes, and the recording saved for *post hoc* analysis.



Post-procedure practice:

- If a reusable catheter has been used, then a trained, competent member of staff needs to immediately clean the catheter as per the manufacturers' recommendations
- The cleaning details should then be entered into an appropriate catheter cleaning log
- If a single-use, water-perfused catheter has been used, it should be placed straight into an appropriate clinical waste bag for disposal
- The patient may either go home, or progress to other studies of anorectal / colorectal function within the same clinical appointment (e.g. endo-anal ultrasound, pudendal nerve terminal motor latencies, anal sensitivity testing, evacuation proctography, and gastrointestinal / colonic transit studies, as required)
- Analysis of the HR-ARM recording and subsequent reporting should be made by an appropriately trained and accredited practitioner, or under the supervision of a fully trained and accredited practitioner
- As no formal guidelines yet exist (expected early 2018), interpretation should be on the basis of comparison with an appropriate healthy volunteer dataset of suitable size
- Any complications noted during the study should be fully documented and appropriate follow-up provided if required