PATIENT DATA

1) Enter patient data completely
2) Tap “Set Up” button in left-hand column or “Next” button to advance

All that is needed to move forward is a patient ID number, but we recommend you fill out everything first, as you cannot go back and change info once the test has been completed. Once you have written an indication, doctor’s name, referring physician, it will populate a drop down list making the process easier as you go.

SET UP

1) Turn on FOB by pressing “On/Off” button and wait until “On” light appears on FOB
2) Tap “Bluetooth connect” button on screen
3) Wait for blue led on FOB to turn steady blue

The FOB should have 2 green lights and a blinking blue light in the middle, once the blue light becomes steady you are connected via Bluetooth properly.
4) Connect plug on catheter to FOB with arrows aligned
5) Connect ext. tube luer to catheter, other luer to FOB, and 3-way stopcock to 60cc syringe
6) Turn lever on FOB to Position 1 “OPEN” position
7) Select “2 Channel Catheter” or “5 Channel Catheter” and tap “FOB Connected”
8) Turn lever on FOB to Position 2 “PRIME” position (straight up and down)
9) Connect 5cc syringe loaded with 3cc of air to luer fitting on top side of FOB
10) Push in 3cc of air with syringe and then with plunger down remove 5cc syringe

After placing air into the sphincter balloons, you should take off the syringe and actually let air out of the balloons to normalize to the pressure in the room. After that, turn the lever to position 3 (facing towards the catheter) and that will close up the airlock to the sphincter balloons. *(YOU SHOULD COUNT UP TO 7 BEFORE TURNING THE LEVER TO POSITION 3)*
11) After syringe is removed, turn lever on FOB to Position 3 “Operate”, tap “Next”
12) Tap “PRIMED” on screen

13) Lubricate distal end of catheter, tell patient to relax, insert catheter to depth of 0 cm
14) For a 2-channel catheter no orientation is required
15) For a 5-channel catheter, orient “P” towards spine
16) Prime rectal balloon with 10cc of air from syringe, tap “Next”

Everything up to these steps should be done before you even see the patient. So when they arrive you can be ready to lube the catheter and place it in the patient. You should place the catheter into position “0” which is visible at the beginning of the blue portion of the catheter. You should place the 10cc of air into the rectal balloon after it is in the patient. At this point you will be completed with the set up.
**SYRINGE AND LEUR LOCK**

When filling the rectal balloon, you will be using the 60cc syringe and it is important to know how the leur lock functions. Here is a diagram explaining how it works:

**OPEN**

When the leur lock is “OPEN” you can place and remove air in the rectal balloon as needed during the tests. The blue lock shuts off the air flow the rectal balloon allowing you to switch the leur lock to the “CLOSED” position.

**CLOSED**

This is the leur lock in the “CLOSED” position. You can draw back air into the syringe without having to detach it. The blue lock once again closes the air flow between the syringe and the open air, it is important to close the lock before returning to the open position.
MEASUREMENT

RESTING- measuring resting pressures and high pressure zone

1) Hide patient screen from view, explain test is to measure anal canal resting pressure
2) Tell patient to relax and lie still, verify rectal and anal pressures are appropriate
3) Verify catheter depth is “0” at bottom of screen, tap “Start” to initiate a 10-sec trial
4) Relocate catheter to depth of “1” set depth to “1” at bottom of screen, tap “Enter” key
5) Tap “Start” to initiate a 10-sec trial
6) Relocate catheter to depth of “2” set depth to “2” at bottom of screen, tap “Enter” key
7) Tap “Start” to initiate a 10-sec trial
8) Determine High Pressure Zone by tapping “Review”, find HPZ and not catheter depth
9) Tap “Back to Tests”, set catheter depth to match HPZ depth and tap “Enter” key
10) To end Resting test, tap “Next Test” button, or tap any procedure on left-hand side of screen

With the catheter at position “0” you should run the resting test and be aware of the MAX line which is towards the bottom of the screen. Go back to the resting test for a second time. You should place the catheter into position “2” and run the same test again. Be aware of the MAX line again and whichever max is higher between position “0” “1” and “2” will be the High Pressure Zone (HPZ) and we will want to continue the rest of the tests from that position.
**SQUEEZE- measuring anal/sphincter squeeze pressures**

1) Hide patient screen from view, explain test is to measure anal canal squeeze pressure
2) Verify catheter position is set to HPZ (High Pressure Zone)
3) When “Start” appears, tap to begin first 20-sec measurement and tell patient to squeeze
4) When “Start” button reappears, tap it for new measurement and tell patient to squeeze
5) Repeat for total of 3 trials
6) To end Squeeze test, tap “Next Test” button or tap an procedure on left-hand side of screen

*You do not need to wait the full minute between the tests, if the patient is comfortable and ready to go you can enter the catheter position and run button will pop up and you can continue with the tests.*
SENSATION - measuring rectal sensation

1) Hide patient screen from view, explain test is to measure rectal sensation levels
2) Verify catheter position is at HPZ (High Pressure Zone)
3) When “Start” appears, tap to begin recording data
4) Slowly inflate rectal balloon until patient reports first sensation, immediately tap “First Sensation” button
5) Enter balloon volume in box on right side and tap “Enter” key. This records the volume
6) Continue filling until the patient reports normal urgency sensation, immediately tap “Normal Urgency” sensation button
7) Enter balloon volume in box on right side and tap “Enter” key. This records the volume
8) Continue filling until the patient reports strong urge sensation, immediately tap “Strong Urge” sensation button
9) Enter balloon volume in box on right side and tap “Enter” key. This records the volume
10) Continue filling until the patient reports MTV sensation. Immediately tap “MTV” sensation button. Note: some patients may not reach MTV and also stop for any pain experience during inflation.
11) Enter balloon volume in box on right side and tap “Enter” key. This records the volume
12) To end test, tap “Next Test” button, or tap any procedure on left-hand side of screen

We find that it is easier to just start the test and explain the steps as you go. So for your patients we like to say first alert us when you feel anything or a sense of fullness (hit the first sensation button and record the amount of air put into the catheter) when you feel like you have to go to the bathroom, but know you can wait (normal urge and record). Then record, when you absolutely have to go to the bathroom that can not be ignored (strong urge and record). Lastly, when the patient reports that they cannot continue due to the pressure from the inflated balloon (MTV and record)
STRENGTH
1) Position patient screen in view, explain strength training purpose & expectations
2) Verify catheter position is at HPZ, verify rectal balloon has original “Prime” fill of 10cc
3) Enter target duration of squeeze trials, set target squeeze pressure. Patient should be able to reach target 50-75% of the time. Tap “Run” to begin recording data
4) Tap “Squeeze” button to begin Strength trial. Tell patient to squeeze. The screen will show duration vertical lines and squeeze pressure goal line
5) When trial completes, tap “Pause” key to stop recording
6) Provide feedback to patient on strength and duration of contraction and correct contraction of abdominal wall muscles
7) Adjust strength trial duration, squeeze target, and vertical scale if necessary
8) Tap “Resume”
9) Tap “Squeeze” to initiate a new trial. Repeat for up to 50 squeeze trials
10) To show patient previous Strength trials, tap “Review” button on the left side of the screen; after review the history, return to strength training and continue

It is important the patient have a view of the screen. The goal is to ask the patient to engage/contract their sphincter to increase the Anal balloon pressure line (green). We set a goal line (pink) that is achievable for the patient 50-75% of the time. Instruct the patient to focus on “squeezing” their sphincter muscles. We do not want the patient “bearing down” or using abdominal/gluteal muscles to increase Rectum balloon pressure (blue line). It is important to teach the patient this difference. We are hoping over time to increase the max strength and duration of the hold for the patient’s. Repeat as necessary.
SENSORY

1) Ensure patient CANNOT see screen. Verify catheter position is at HPZ. Explain the purpose of sensory training is to put in a predetermined amount of air and check if it felt.

2) Instruct patient to squeeze & say “feel it” if they feel anything. Enter rectal balloon air volume. Use 50cc or a volume you are confident they will feel. Tap the “Run” key.

3) Tap “Start” button to begin first trial. Two response buttons appear: “Yes” and “None”.

4) Wait two seconds then inject the predetermined amount of air into the rectal balloon. Leave air in balloon for 1-2 seconds. If patient reports “felt it”, tap “Yes”. If not, tap “None”.

5) Adjust volume of air for the next trial and tap “Start” to begin. Repeat for up to 50 trials.

6) By decreasing volume of air on successive trials, you will arrive at the threshold for sensation. If threshold is greater than 15cc, put in air volumes slightly higher & some slightly lower than threshold on subsequent trials. Encourage patient to pay attention to weak sensations & provide feedback on improvements. Tap “next test” when done.

*It is important the patient NOT have a view of the screen. The goal is to increase the patient’s sensitivity of fecal matter in the rectum. We are trying to get the patient to sense/feel lower cc volumes. We set a goal line of 50cc and slowly lower it down with each subsequent trial. Once you have reached a threshold, try different varying degrees of air to train the sensitivity.*
URGE RESISTANCE

1) Ensure patient CANNOT see screen. Verify catheter position is at HPZ. Explain purpose of training is to teach them to use relaxation to counteract strong urge sensation and learn to tolerate larger volumes. Tell them what to expect.

2) Tap “Run” to start recording data

3) Tap “Start” to begin biofeedback training. This activates response buttons for “Normal Urge”, “Strong Urge”, & “MTV” slowly inflate RB until patient reports a sensation of Normal Urge or Strong Urge. It may be necessary to reload the 60cc syringe

4) When patient reports Urge sensation, immediately tap the appropriate button

5) Adjust RB balloon fill level to inflated volume and tap “Record”

6) Tap “Start” to reactivate response buttons. Continue to inflate RB until patient reports a Strong Urge. Tap “Strong Urge” button, adjust balloon fill meter, tap “Record”

7) Tap “Start”; remove 30cc from RB and check to see if the intensity of sensation has decreased from Strong Urge to Normal Urge. If so, tap “Normal Urge” button, adjust balloon fill meter, tap “Record”. Tap “Pause” to stop recording. Have patient practice deep breathing or other relaxation technique. Tap “Resume” to resume recording.

8) Tap “Start” to reactivate response buttons. Slowly inflate RB until patient reports Strong Urge again. Tap “Strong Urge” button, adjust balloon fill meter, tap “Record”

9) Tap “Start” ; remove 30cc from RB and check if intensity of sensation decreased from Strong Urge to Normal. If so, tap “Normal Urge” button, adjust balloon fill, tap “Record”

10) Tap “Pause” to stop recording. Have patient practice deep breathing or other relaxation technique. Provide feedback to patient on whether they are improving their tolerance for rectal filling. Repeat if desired.

11) Tap “review” button to show patient training session results
It is important the patient NOT have a view of the screen. The goal is to help patients “weather the storm”. Teaching the patient to relax when they reach the **Strong Urge** (have to go right now) and by removing the 30cc simulating the rectal wall relaxation we are showing the patient how to convert the go now situation into a **Normal Urge** (watching TV going at the next commercial) feeling. When the patient reaches the **Normal Urge** and **Strong Urge** levels teach them to engage/contract their sphincter muscles. This is teaching the patient to hold the bowel movement back to avoid accidents. The overall goal for this test is converting the **Strong Urge** to a **Normal Urge**. In a real life setting this will teach the patient skills so they are able to find a restroom and avoid an accident. Increased anal sphincter muscles strength may also help with these urge suppression exercises.
EXPEL FULL

1) Explain training to patient
2) Inflate distal balloon with an additional 50cc and confirm balloon volume
3) Instruct patient to “bear down” as if defecating
4) Confirm catheter position and tap “run/pause”
5) Adjust the anal and rectal targets to the desired values
6) Tap “Bear Down” and wait until the 20-second test completes
7) If more data required, enter balloon volume and tap “Bear Down” to repeat training of, if training is good, deflate balloon to original primed level of 10cc, enter Notes, and tap “review”

It is important the patient have a view of the screen. The goal is to help patients recruit the correct muscles during defecation. There is a Rectum balloon pressure line (blue) and a goal line (pink) along with an Anal balloon pressure line (green) and a goal line (pink). The idea is to set the rectal balloon pressure goal line high and the anal balloon pressure goal line low. Instruct the patient to bear down and tell the patient to relax their sphincter. This is teaching the patient not to “fight themselves” meaning bear down with their abdomen/rectal wall while holding back with their sphincter muscles. Teaching the patient to only use their abdomen/rectal wall during defecation will allow for easier defecation. This protocol may or may not be needed for patients with fecal incontinence.