



***mcompass*[®] Manometric Biofeedback Therapy System**

Instructions for Use / Operator Manual

The *mcompass*[®] Manometric Biofeedback Therapy System includes:



mcompass[®] Anorectal Manometry Fob



Medical Grade Tablet PC with
mcompass[®] Manometric Biofeedback Software



mcompass[®] 2-channel Biofeedback Catheter
or
mcompass[®] 5-channel ARM Catheter



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1. Introduction

This manual describes the safety precautions, features, use, and care of the Medspira *mcompass*[®] Manometric Biofeedback System. Please review this manual thoroughly before using the system. If you have any questions or comments on this manual or need any assistance with the use of the product, please contact Medspira at 1-800-345-4502 or visit <http://www.medspira.com>.

1.1 Information, Use of Symbols, and Cautions

This operator manual provides information on how to use the Medspira *mcompass* System. The user should read this guide before using the system.

Operators should understand the following symbols that may appear on Medspira products or in instructions for use and be aware of cautions and other information.

	WARNING or CAUTION: Alerts you to important operating considerations or potential condition that can be a risk for improper function or use of equipment.
	Consult Instructions for Use and any accompanying documents
	Federal law restricts this device to sale by or on the order of a physician.
	WEEE (Waste Electrical and Electronic Equipment). Complies with 2002/96/EC For disposal at the end of its useful life, please contact Medspira at 1-800-345-4502
	Federal Communications Commission notice (USA) This product contains Bluetooth Wireless Module FCC ID X3ZBTMOD2
	Indicates RF transmitter that applies electromagnetic energy This product contains Bluetooth Wireless Module FCC ID X3ZBTMOD2.
	Direct Current
	Compliance with Intertek testing for general product safety and emissions per UL 60601-1, IEC 60601-1-2:2007 and CAN/CSA C22.2 No. 60601-2:03
	Type B Equipment Human
	Indicates complies with RoHS directive
	Indicates quantity of contents in package (box, pouch, bag)
	This product is not made of or contain natural rubber Latex

	Catheters are for Single Use Only / Do Not Reuse
	Not Sterile. Do not sterilize. Sterilization may result in loss of proper function and/or could cause patient injury.
	Do not use if Use By Date printed on the product package has passed.
	Batch code
	Catalog number
	Part number
	Devices should be stored in a cool, dry location (-29 to 60° C).
	DANGER: This product contains Lithium-Ion Batteries. Do not open or expose to heat above 100 degrees C
	CAUTION: Do not submerge. Water protection rating = IPX0, no protection. Use damp soft cloth to clean and disinfect with standard cleansers including water, soap, or with quaternary ammonia / isopropyl alcohol or a germicidal disposable cloth. Cleaning is recommended after each use.
	CAUTION: Only properly trained professionals understanding the methods of anorectal manometry should attempt to use this system.
	In the unlikely event that the system creates smoke, sparks, or makes an unusually loud noise, or if the individual requires emergency assistance: <ul style="list-style-type: none"> • Stop the procedure if one is in progress. • Remove the individual from the room.



Class II equipment and internally powered equipment.

Type B human applied parts

Suitable for continuous operation

This product conforms to the requirements of UL STD 60601-1 and IEC STD 60601-1 and

CAN/CSA STD C22.2 No. 601.1-M90.

1.2 Indications

The Medspira *mcompass*[®] Manometric Biofeedback System is indicated for use with patients requiring anorectal and/or pelvic floor retraining and/or strengthening.

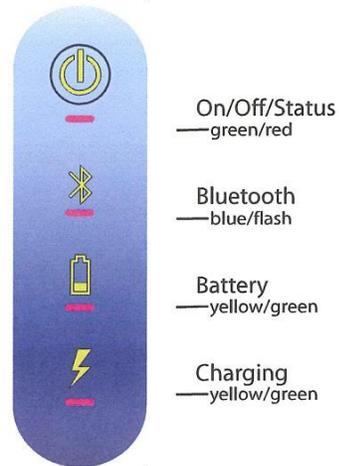
1.3 Pre-Use System Check & Operation Verification

Before using the system, visually check for any external damage. Do not use the system if the housing or connectors are cracked or broken.

Prior to using *mcompass*[®], fully charge the Tablet and Fob.

Turn on the Fob by tapping the On/Off Button for a couple of seconds and verify LED lights perform properly.

- **On/Off:** Green = On, No Light = Off
- **Bluetooth:** Flashing blue = Bluetooth search on
Solid blue = Bluetooth connected
No light = No paired device
- **Battery:** Green = Adequate battery power
Amber = Low battery power.
Note: Charge unit prior to use if amber light appears.
- **Charging Indicator:** No light = Not being charged
Yellow = Charging
Green = Fully charged
Yellow/Green alternating = Slowed charging process, keep connected



1.4 Safety Considerations

This manual contains detailed information on the setup, positioning, and use of the Medspira *mcompass*[®] Manometric Biofeedback System. The instructions should be read carefully and thoroughly before using this system.

Equipment Safety

- Personnel should observe all warnings and cautions that appear in these Instructions, Guides, or the user interface.
- The system is not suitable for use in the presence of flammable anesthetics in combination with air, oxygen, or nitrous oxide.
- This equipment is not protected against ingress of liquids.

Electrical and Mechanical Safety

The system consists of both electrical and mechanical components.

Only properly trained and qualified personnel should be authorized to service the system.

Reporting Incidents

Contact a Medspira Support representative at 1-800-345-4502 immediately to report an incident and/or injury to an individual, operator, or employee that occurred as a result of system operation. If an incident occurs as result of system operation, do not operate the equipment until an authorized investigation is conducted.

1.5 System Maintenance

There is no Routine or Preventive Maintenance required for the *mcompass*® System.

System components, including protective caps and covers, should be visually checked for any external damage. Do not use the system if the housing or connectors are cracked or broken.

If any damage or excessive wear is visible contact your Medspira Support representative for repair.

Any changes or modifications to the system are not allowed and may void your warranty.

1.6 System Cleaning

Cleaning is recommended after each use.



Detach the system from AC power before attempting to clean it.

- Do not re-attach after cleaning until the system has dried completely. Having the system attached to the AC power during cleaning or when it is wet may result in electrical shock.

Cleaning Instructions

- Verify all protective covers/caps are in place prior to cleaning.
- Do not inject fluids into the Fob – damage will occur.
- The system is NOT to be placed into any type of sterilizer.
 1. Clean the Fob with a clean damp cloth (do not immerse the Fob) using mild soap and water.
 2. Wipe with a clean dry cloth.
 3. Follow up with wipe down using a quaternary ammonia / isopropyl alcohol or a germicidal disposable wipe.
 4. Allow to fully air-dry before use.
- Store the system in a conditioned (cool and dry) space.

1.7 System Description and Operating Parameters

The *mcompass*® Manometric Biofeedback System is for patients who require a diagnostic test for anorectal function. To operate properly, the system will consist of a Fob, Tablet PC loaded with *mcompass*® Software, and a disposable single-use Balloon Catheter.

Operating range

Fob to Tablet PC maximum communications distance: 25 feet.

System Installation and Service

System software installation and configuration requires the services of a Medspira Support technician.

Power Supply

The power supplies for the Fob and Tablet PC units must be plugged into an AC wall power source when charging. The Fob will NOT function while plugged in and charging.

2. System Set Up

2.1 Preparing the System

Before each use, ensure that the battery indicators on the Fob and Tablet PC indicate an acceptable battery level and charge if necessary. The Fob and Tablet will not operate while charging.

Verify Fob to Tablet Bluetooth pairing. The Fob's blue light should be steady (see 1.3). Contact Medspira Support if the Fob and Tablet are not paired.

2.2 Tablet Initial Set Up

The mcompass® Manometric Biofeedback System includes easy to use software for completing various manometry tests. The following instructions are also displayed by the software.

Switching On the Tablet PC Power

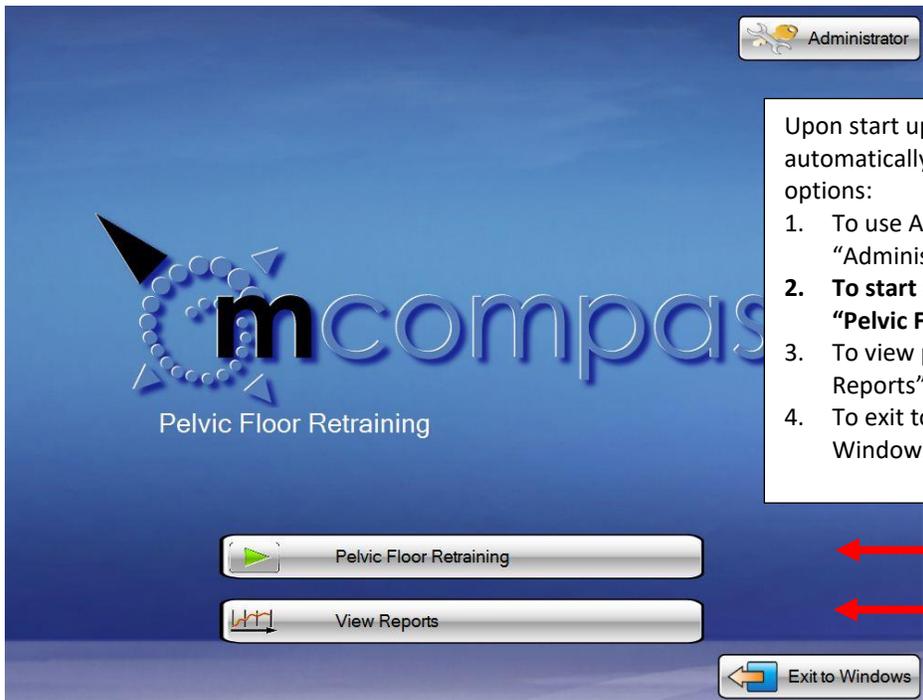
See specific Tablet PC operating instructions for proper use.

- Turn on the Tablet
- Allow for complete software start up prior to use
- Double tap the mcompass program icon → 

There are four screen options to choose from:

- Start Up Screen
- Administrator Screen
- Diagnostic Anorectal Manometry Login Screen
- View Reports Screen

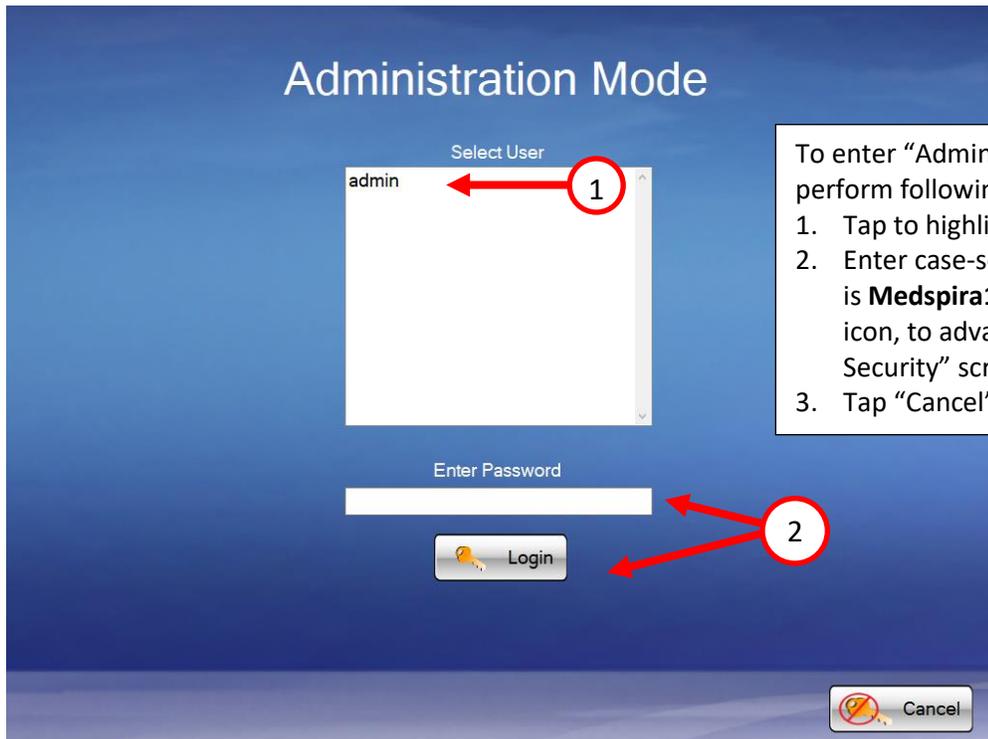
Start Up Screen



Upon start up, Medspira Start Up screen is automatically displayed providing four options:

1. To use Administrator functions, tap "Administrator" icon.
2. To start a Therapy Session, tap the "Pelvic Floor Retraining" icon.
3. To view previous tests, tap "View Reports" icon.
4. To exit to Windows, tap "Exit to Windows" icon.

Administrator Screen

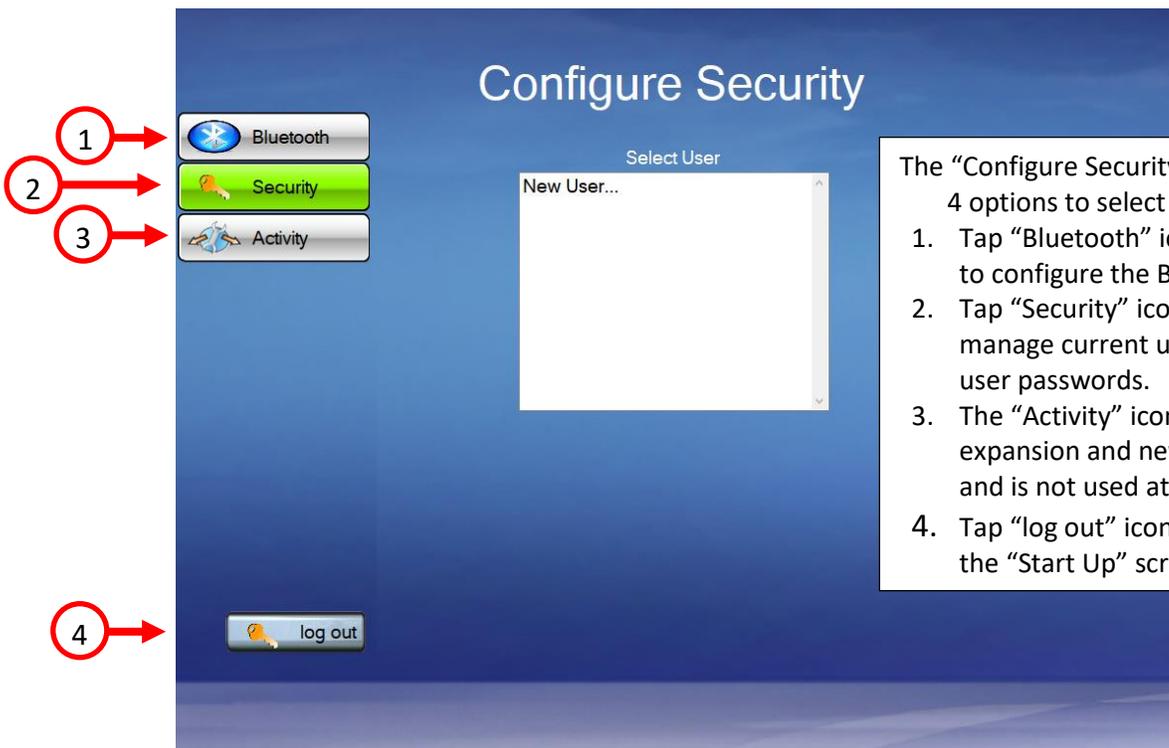


The screenshot shows the "Administration Mode" screen. At the top, it says "Administration Mode". Below that is a "Select User" dropdown menu with "admin" selected, indicated by a red circle with the number 1 and an arrow. Below the dropdown is an "Enter Password" text box. Below the text box is a "Login" button with a key icon, indicated by a red circle with the number 2 and an arrow. At the bottom right is a "Cancel" button with a red 'X' icon, indicated by a red circle with the number 3 and an arrow.

To enter "Administration Mode" screen, perform following:

1. Tap to highlight selected user.
2. Enter case-sensitive password (initial is **Medspira123**) then tap "Login" icon, to advance to "Configure Security" screen.
3. Tap "Cancel" icon returns you to

Configure Security Screen



The screenshot shows the "Configure Security" screen. On the left side, there are three icons: "Bluetooth" (1), "Security" (2), and "Activity" (3). In the center, there is a "Select User" dropdown menu with "New User..." selected. At the bottom left, there is a "log out" button with a key icon, indicated by a red circle with the number 4 and an arrow.

The "Configure Security" screen has 4 options to select from:

1. Tap "Bluetooth" icon allows you to configure the Bluetooth port.
2. Tap "Security" icon allows you manage current user and new user passwords.
3. The "Activity" icon is for future expansion and new applications and is not used at this time.
4. Tap "log out" icon returns you to the "Start Up" screen.

View Reports Screen

Note: To locate and view previous test(s), follow this section.

Report View Mode

Select User

user 1
admin

Enter Password

Login

Cancel

To enter Report View Mode Login screen perform following:

1. Tap to highlight username.
2. Tap on to “Enter Password” then tap “Login” icon to advance to “Select Report” screen.
3. Tapping “Cancel” icon returns you to “Start Up” screen.

Select Report Screen

Select Report

LastName	FirstName	PatientID	TestType	Date
xxxx		xxxx	DIAGNOSTIC	10/11/2022
xxx		xxx	DIAGNOSTIC	10/11/2022
		Test	DIAGNOSTIC	9/15/2022

Select File

View Report

log out

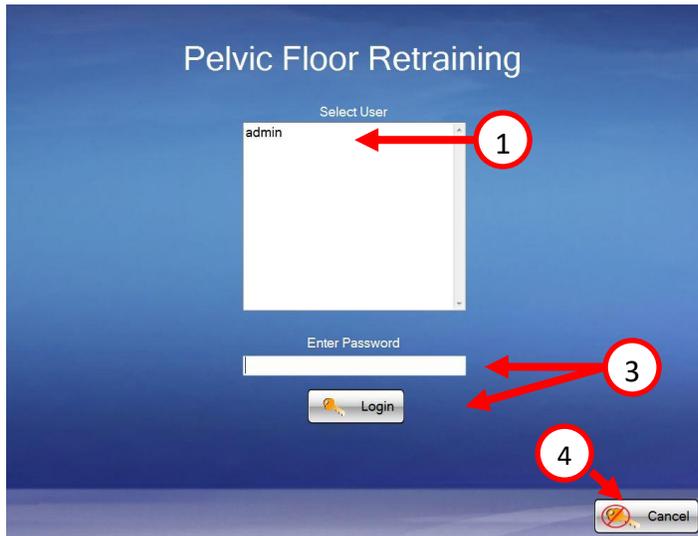
To select a report, perform following:

1. Tap to highlight selected report.
2. Tap “View Report” to open to report
3. Tap “log out” icon returns you to “Start Up” screen.

2.3 Patient Session Set-Up

Diagnostic Anorectal Manometry Login Screen

To Login, turn on Tablet. Swipe up. Enter Password.
Double tap the mcompass program icon →
Tap “mcompass Biofeedback” button



1. Tap to highlight User. Initial user is “Admin”. (Other users may be added in Administrator Screen.)
2. Open Tablet keyboard – tap “Keyboard” icon on screen.
3. Enter case-sensitive password. “Admin” password is **Medspira123**, then tap “Login” icon.
4. Tap “Cancel” icon to return to the “Start Up” Screen.

Note: The keyboard will hide automatically. Tap the icon in the lower right corner to pull it up again.

Enter Patient Data

Note: Steps 1 –19 may be performed before the patient is brought into the room for the test.

- Enter patient data completely
- Tap Next



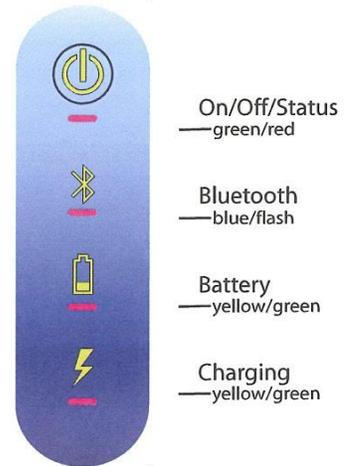
Only patient ID is required to proceed.

Note: Complete all desired fields before tapping Next, as you cannot go back and add/change information once test has been completed.

Once indications, doctor’s names, and referring physicians are entered, drop-down lists will be populated for ease of use.

Set Up – Bluetooth Connection

1. Make sure the Fob is charged and the charging plug is disconnected from the power source
2. Turn on the Fob by pressing “On/Off” button and wait until “On” light appears on Fob. All LEDs will be on for about 2 seconds.
3. You can proceed when you see steady green lights for On/Off and Battery, and one flashing blue light for Bluetooth.
4. Tap the “Connect Bluetooth” button on the screen
5. Wait for the flashing blue LED on the Fob to turn steady blue. This means you are connected to the Tablet.



6. Make sure the lever is in Position 1 “OPEN”



7. Tap Next on the screen



Note: If the Fob fails to connect through Bluetooth to Tablet, follow Tablet instructions.

The FOB should have 2 green lights and a blinking blue light in the middle, once the blue light becomes steady the Fob is connected via Bluetooth properly. If the Fob fails to connect through Bluetooth to the Tablet, follow the instructions outlined in our document labeled: Troubleshooting Issues with the FOB:

<https://medspira.com/support/anorectal-manometry-support/>

Set Up – Catheter Connection to Fob

NOTE: These steps must be performed in this order to obtain proper pressure readings.

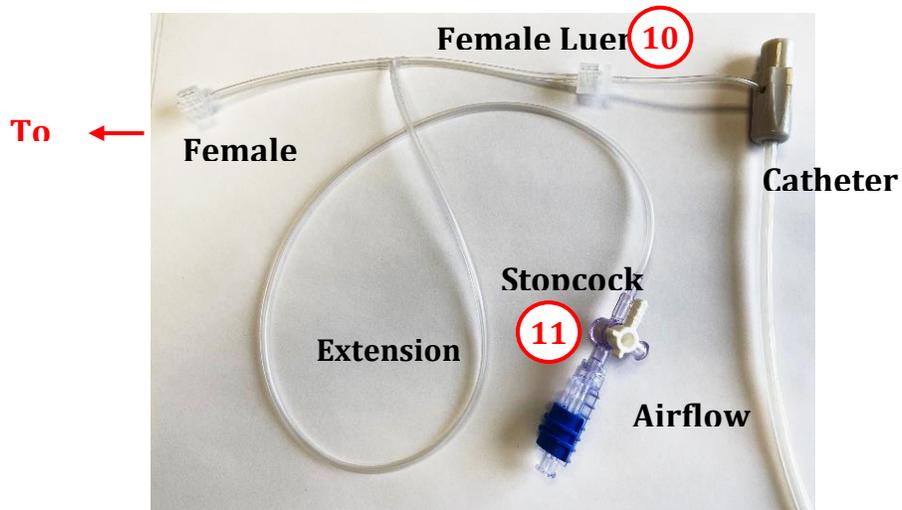
8. Tap “Fob Connected” to confirm Fob connection 
9. Connect catheter to the Fob by plugging in with arrows aligned

Line up the black triangle from the catheter to the blue triangle on the Fob and push it ALL the way in so that the arrow does not show.



NOTE: It does not snap or twist in place to connect or disconnect.

10. Connect the Extension Tube
 - One short end male luer connects to female luer on catheter
 - The other short end male luer connects to female luer on Fob



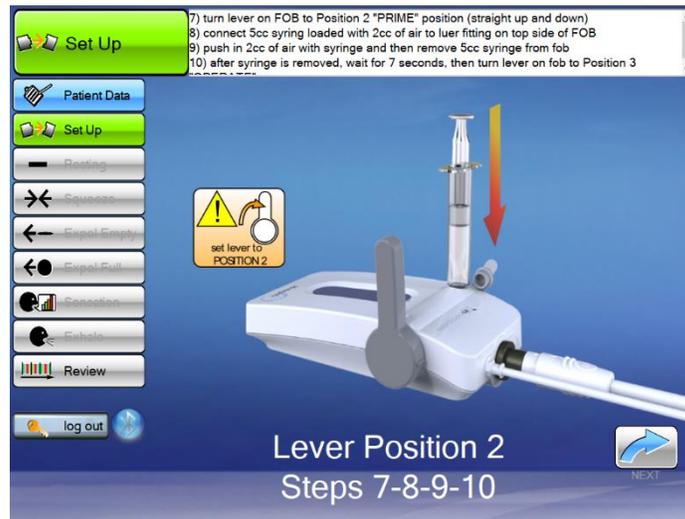
11. Connect large syringe to the Stopcock



Set Up – Priming the Fob

Test Set-Up continued

12. Move the lever on the FOB to Position 2 “PRIME” position (Straight up and down)
13. Load the 5cc syringe with **2cc** of air
14. Connect the 5cc syringe loaded with **2cc** of air to luer fitting on top of the FOB
15. Push in **2cc** of air with syringe
16. While holding thumb on syringe plunger, remove the 5cc syringe from the FOB



After placing air into the sphincter balloons, remove the syringe and let air naturally bleed out of the balloons to normalize to the pressure in the room (count to seven before moving the lever to position 3).

17. After the syringe is removed, move lever on the FOB to position 3 “OPERATE” and tap “NEXT”
Moving the lever to position 3 closes the airlock to the sphincter balloons
18. Replace protective cap for the 5cc syringe to prevent contamination
19. Tap “PRIMED” on the next screen



NOTE: Everything up to this point (steps 1-19) may be done prior to seeing the patient so when they arrive, you are prepared to begin the procedure.

3. Performing the Procedure

3.1 Prepare Patient for Testing

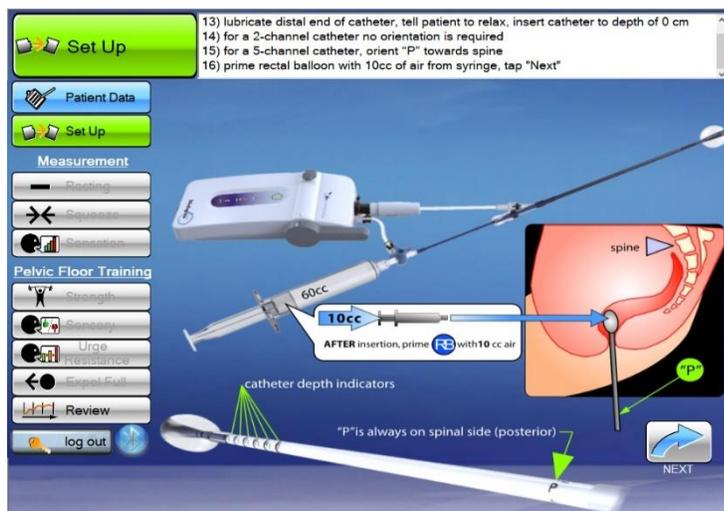
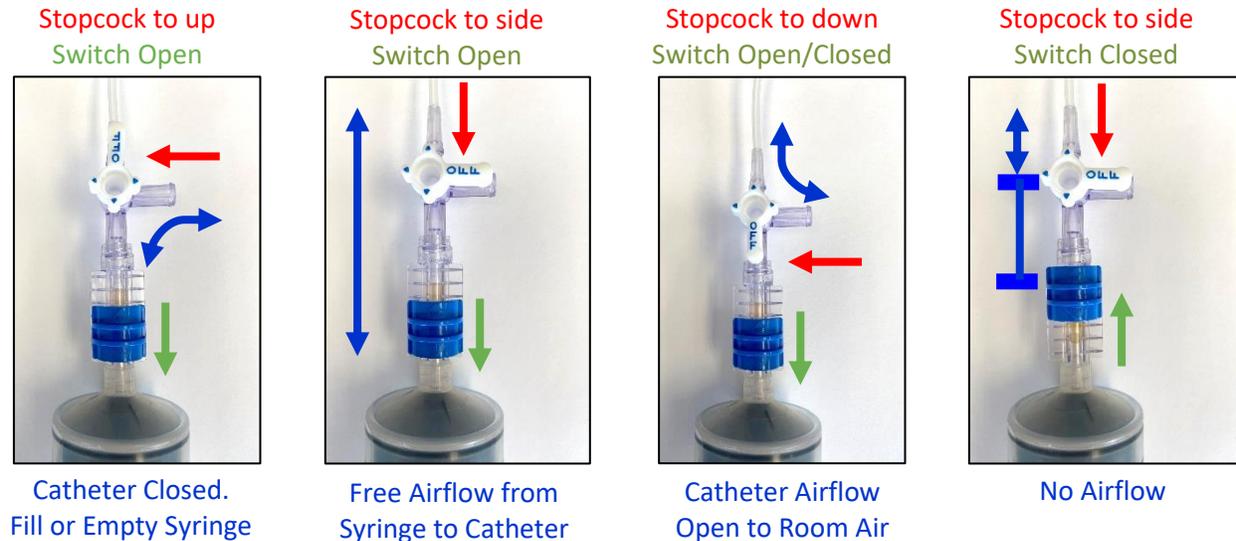
Note: Rectal air volumes are less when using a Petite 5-channel catheter (such as for pediatrics). These differences are highlighted in light blue.

Have the patient lie on their left side, knees raised toward stomach.

With the patient in position for the procedure,

- 1) Lubricate distal end of catheter device; instruct the patient to relax
- 2) Insert the catheter into the patient to position "0" on catheter verifying the letter "P" is in the proper orientation (toward the patient's back)
- 3) Using a large syringe, prime rectal balloon with 10cc of air [3cc for Petite Catheter], press "Next"
- 4) Lock the stopcock UP to the "Catheter Closed" position

How to Use the Stopcock:



At this point the Set Up is complete.

3.2 Resting Test

Resting Test – Measuring resting pressures and High Pressure Zone (HPZ)

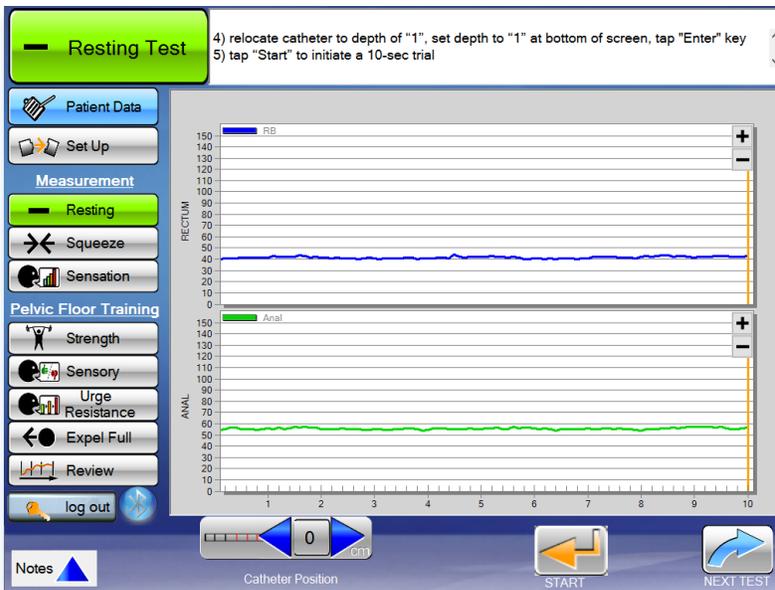
- 1) Hide patient screen from view, explain test is to measure anal canal resting pressure.
- 2) Tell patient to relax and lie still, verify rectal and anal pressures are appropriate.
- 3) Verify catheter depth is “0” at bottom of screen.
- 4) Tap “Start”  to initiate a 10-sec trial.
- 5) Relocate catheter to depth of “1” set depth to “1” at bottom of screen. Tap “Enter”  key.
- 6) Tap “Start”  to initiate a 10-sec trial.
- 7) Relocate catheter to depth of “2” set depth to “2” at bottom of screen. Tap “Enter”  key.
- 8) Tap “Start”  to initiate a 10-sec trial.
- 9) Determine High Pressure Zone (HPZ) by tapping “Review”. Find HPZ and note catheter depth.
- 10) Tap “Back to Tests”, set catheter depth to match the HPZ depth, and tap “Enter”  key.
- 11) To end Resting test, tap “Next Test” button, or tap any procedure on left-hand side of screen.

Determining the High Pressure Zone (HPZ) is required to properly perform the remaining tests.

With each Resting Test, at positions “0”, “1” and “2”, be aware of the MAX line which is near the bottom of the screen.

The highest MAX among positions “0”, “1” and “2” will determine the High Pressure Zone (HPZ).

Continue the rest of the tests from that HPZ position.



Use **CAUTION** when repositioning catheter depth in patient.

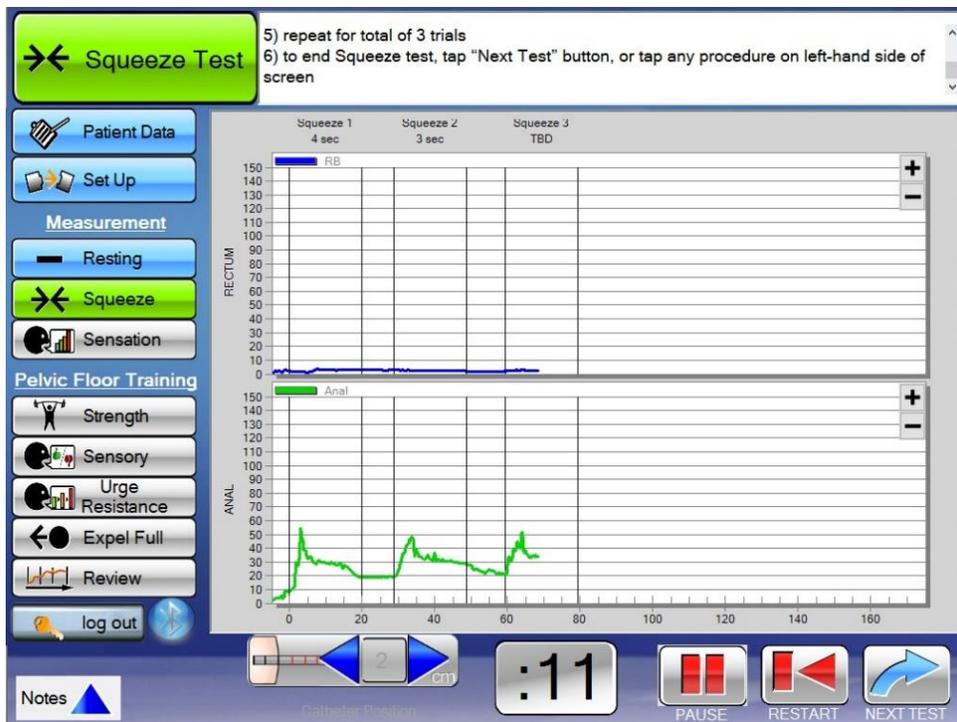
Note: Tap on the “Resting” icon at left to repeat the test at any time.

Note: At any time during any test notes may be added to the test report by tapping on the Note tab located on the lower left corner of the screen.

3.3 Squeeze Test

- 1) Hide the screen from patient view.
- 2) Explain this test is to measure anal canal squeeze pressure.
- 3) Instruct the patient to relax.
- 4) Verify catheter position is set to HPZ (*High Pressure Zone*) and tap “Run/Pause”.
- 5) Note: You may choose to tape the catheter to the patient to maintain its HPZ position.
- 6) When “Start” appears, tap to begin first 20-sec measurement, and tell patient to squeeze.
- 7) When “Start” button reappears, tap it for new measurement and tell patient to squeeze.
- 8) Repeat for total of 3 trials.
- 9) To end Squeeze test, tap “Next Test” button or tap a 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.



Perform 3 squeezes where the patient squeezes as hard as they can for 20 seconds. You will need to keep telling the patient to squeeze throughout the entire 20 seconds. You want them to not only squeeze hard but to hold it as long as possible. Tell the patient to squeeze like they are trying to hold in a bowel movement.

Note: Tap the “Squeeze” icon at left to repeat the test at any time.

Note: At any time during any test notes may be added to the test report by tapping the Note tab located on the lower left corner of the screen.

3.4 Sensation Test

- 1) Hide the screen from the patient view.
- 2) Explain the test to the patient. – You will be performing a series of 3 tests that are a continuation of each other, looking for the patient’s 1) first sensation, 2) normal urge to defecate, and 3) strong urge to defecate. You will be adding volume (making it bigger) to simulate a stool.
- 3) Tap the Green Arrow (run) button
- 4) Fill the large syringe with air
- 5) **Determine First Sensation Marker:**
 - Instruct the patient to state when they feel anything different (sensation), than they do with just the catheter in there right now.
 - Turn the stopcock to allow air to flow to the rectal balloon.
 - Start by pushing in 20ccs of air [5cc for Petite Catheter]. If the patient says nothing - continue to add 10cc [5cc for Petite] at a time. Once the patient has stated they feel the sensation, immediately tap the “First Sensation” button on the bottom of the screen.
 - Change the volume amount on the right-hand side to match the new current air volume in the rectal balloon.
 - Tap the “Enter”  key next to adjusted volume amount to auto-populate the information in the **First Sensation** box.
- 6) **Determine Normal Urge Marker:**
 - Instruct the patient to state when they feel like they need to have a bowel movement soon, but there is nothing urgent about it. (*For example, you are watching TV, but could easily wait until the next commercial break.*)
 - Continue to push air into the rectal balloon again. Slowly increasing the air volume, in the rectal balloon, by increments of 10ccs [5cc for Petite] at a time. Once the patient has stated they feel a desire to go, tap the “Normal Urge” box on the bottom of the screen.
 - Change the volume amount on the right-hand side to match the new current air volume in the rectal balloon.
 - Tap the “Enter”  key next to adjusted volume amount to auto-populate the information in the **Normal Urge** box.
- 7) **Determine Strong Urge Marker:**
 - Instruct the patient to state when they feel as if they can no longer hold in their bowel movement. (*For example, you have been holding it but just cannot hold it any longer.*)
 - Continue to push air into the rectal balloon again. Slowly increasing the air volume, in the rectal balloon, by increments of 10ccs [5cc for Petite] at a time. Once the patient has stated they feel the urgency, tap the “Strong Urge” box on the bottom of the screen.
 - Change the volume amount on the right-hand side to match the new current air volume in the rectal balloon.
 - Tap the “Enter”  key next to adjusted volume amount to auto-populate the information in the **Strong Urge** box.

Sensation Test Continued

- 8) **Determine MTV (Max Tolerable Volume) Marker – OPTIONAL** (Otherwise jump to Step 9)
 - It is NOT necessary to measure the final 'MTV level of this test. If the physician wants the additional data, this may be explained as testing for '**Total Capacity**'. For an example, express to the patient: 'Let me know when you feel that you just can't hold it anymore.'
 - Continue to push air into the rectal balloon again. Slowly increasing the air volume, in the rectal balloon, by increments of 10ccs [5cc for Petite] at a time. Once the patient has stated they feel the urgency, tap the "Strong Urge" box on the bottom of the screen.
 - Change the volume amount on the right-hand side to match the new current air volume in the rectal balloon.
 - Tap the "Enter"  key next to adjusted volume amount to auto-populate the information in the **MTV** box.
- 9) Remove all air from the rectal balloon and add back the baseline of 10ccs of air. Lock stopcock.
- 10) Tap "Next Test" on bottom left-hand side of screen to end the test.

Note: If needed, close the stopcock and refill the syringe with air to continue filling the rectal balloon.

Note: Catheter position icon is located at the bottom center of the display and is fixed during this test. The Balloon Fill icon is on the right side of display.

Note: After the test is complete return the rectal balloon to the original primed volume of 10cc's [3cc for Petite].

Note: Tap on the "Sensation" icon at left to repeat the test at any time.



CAUTION: Do not over inflate rectal balloon beyond the stated limit in the catheter's IFU. Rupture may occur if over inflated causing potential patient and/or system harm.

Note: At any time during any test notes may be added to the test report by tapping the Note tab located on the lower left corner of the screen.

4. PELVIC FLOOR RETRAINING

Four training exercises may be performed with the mcompass® Manometric Biofeedback System:

- **Strength**
- **Sensation**
- **Urge Resistance**
- **Expel Full**

After performing the Anorectal Manometry (ARM) tests, the referring physician should have provided the diagnosis and perhaps also the desired therapy path.

Clinical findings from ARM tests that may lead to each exercise being beneficial to a patient:

IF INDICATION IS	Chronic Constipation / Dyssynergia	Incontinence - Weak Sphincter	Incontinence - Hyposensitivity	Incontinence - Hypersensitivity
	<ul style="list-style-type: none"> • Weak rectal squeeze pressure during defecation. <u>or</u> • Insufficient anal relaxation – low or negative gradient. <u>or</u> • Expel full/empty tests show paradoxical muscle contraction during defecation. 	<ul style="list-style-type: none"> • Pressure values from anal squeeze test and resting test are below normal values. <u>or</u> • Anal squeeze duration is shorter than acceptable. 	<ul style="list-style-type: none"> • Rectal balloon volumes from sensation test are significantly <u>above</u> normal values. 	<ul style="list-style-type: none"> • Rectal balloon volumes from sensation test are significantly <u>below</u> normal values.
	↓	↓	↓	↓
EXERCISE TO PERFORM	Expel Full Exercise	Strength Exercise	Sensory Exercise	Urge Resistance Exercise
	To help the patient visualize muscle contractions associated with defecation and improve muscle strength and coordination abnormalities.	To help the patient increase pelvic floor strength and duration of squeeze in anal sphincter.	To help the patient lower the sensory threshold for stool in the rectum to a more normal level.	To help the patient increase their tolerance of larger volumes of stool in the rectum, converting strong urges into normal urges.
GOALS	<ul style="list-style-type: none"> • Rectal pressure > anal pressure (positive gradient) • Rectal pressure increase from baseline • Anal pressure decrease from baseline (resting) 	<ul style="list-style-type: none"> • > 100 mmHg max squeeze pressure • > 50 mmHg for 10 second duration of squeeze pressure • > 40 mmHg for resting pressure 	< 40 cc volume sensory threshold	> 120 cc volume strong urge threshold

Please note that this is a general guidance based on typical factors. Medical practitioners are expected to use their own best judgment.

4.1 Strength Exercise

- Biofeedback strength training highlights the importance of the clinician or therapist as a coach. Give the patient encouragement and praise.
- Many patients will not have good muscle isolation, strength, or the ability to squeeze for a 10 second duration at the first visit.
- Continue to work at each visit to achieve the strength training goals.

Strength Training Goals:

Goal of Training	Biofeedback Goal
Increase squeeze strength	Squeeze strength of 100mmHg or higher
Increase squeeze duration	Maintain at least 50 mmHg squeeze for at least 10 seconds
Increase resting pressure	Resting pressure at least 40 mmHg
Maintain constant rectal balloon pressure	Rectal balloon pressure does NOT increase greater than 10mmHg with squeeze

Perform the Exercise:

- 1) Position screen so patient can view it. Explain the strength exercise purpose & expectations.
 - *The goal is to increase the patient’s anal sphincter strength and hold duration.*
 - *Instruct the patient to focus on “squeezing” their sphincter muscles. The patient is not to be “bearing down” or using abdominal/gluteal muscles to increase rectum balloon pressure (blue line). It is important to teach the patient this difference.*
 - *Over time, their max strength and hold duration should increase.*
- 2) Verify catheter position is at HPZ. Also, verify rectal balloon has original “Prime” fill of 10cc [3cc for Petite].
- 3) Enter/verify the catheter position on the screen and tap “Enter”  key.
- 4) Enter a target duration (“Squeeze Secs”) for the first squeeze trials – something achievable.
- 5) Set target squeeze pressure (pink line) based on the patient’s earlier Squeeze Test. Patient should be able to reach the target 50-75% of the time.
- 6) Tap “Run” to begin recording data. There will be a 5 second delay before the “Squeeze” button appears.
- 7) Tap “Squeeze” button to begin Strength trial. Tell patient to squeeze. The screen will show duration vertical lines and squeeze pressures for both Rectal and anal muscles.
- 8) When trial completes, tap “Pause” key to stop recording.
- 9) Provide feedback to patient on strength and duration of contraction and correct contraction of abdominal wall muscles.
- 10) Adjust strength trial duration (perhaps in 2 second increments), increase squeeze target (based on the patient’s attainable pressure), and vertical scale if necessary.
- 11) Tap “Resume”.
- 12) Tap “Squeeze” to initiate a new trial. Repeat squeeze trials until fatigued. (Average is ~ 5-10 times.)
- 13) To show patient previous Strength trials, tap “Review” button on the left side of the screen. After reviewing the history, return to strength exercise and continue training.

Biofeedback Strength

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

Patient Data
 Set Up
Measurement
 Resting
 Squeeze
 Sensation
Pelvic Floor Training
Strength
 Sensory
 Urge Resistance
 Expel Full
 Review
 log out

RECTUM
 ANAL

Squeeze 1 8 sec Squeeze 2 9 sec Squeeze 3 TBD

RB
 Anal Goal

0 10 100 1000 PAUSE :07 REST

Catheter Position SQUEEZE SECS SQUEEZE TARGET

4.2 Sensory Exercise

Indications for Sensory Training:

- One or more bowel accidents that are larger than just staining that occurred with no warning or
- Abnormally high threshold for first sensation on ARM

Sensory Training Goals:

To increase the patient's sensitivity to fecal matter in the rectum and sense/feel lower volumes, such as < 40cc.

Perform the Exercise:

- 1) Position screen so patient CANNOT view it. Explain the sensory exercise purpose & expectations.
 - *The goal is to simulate a stool in the rectum and gradually increase the patient's physical sensitivity to that.*
- 2) Verify catheter position is at the High Pressure Zone (HPZ).
- 3) Instruct patient to say so as soon as they feel anything. Enter a rectal balloon air volume such as 50cc or a volume you are confident they will feel. Tap the "Run" key.
- 4) Tap "Start"  button to begin first trial. Two response buttons appear: "YES" and "NONE".
- 5) Wait two seconds then inject the predetermined amount of air into the rectal balloon. Leave air in balloon for 3-5 seconds. If patient reports they felt it, tap "YES". If not, tap "NONE".
- 6) Adjust volume of air for the next trial and tap "Start" to begin. Repeat until patient is fatigued.
- 7) 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 that the patient NOT have a view of the screen.

The goal is to increase the patient's physical sensitivity of fecal matter in the rectum.

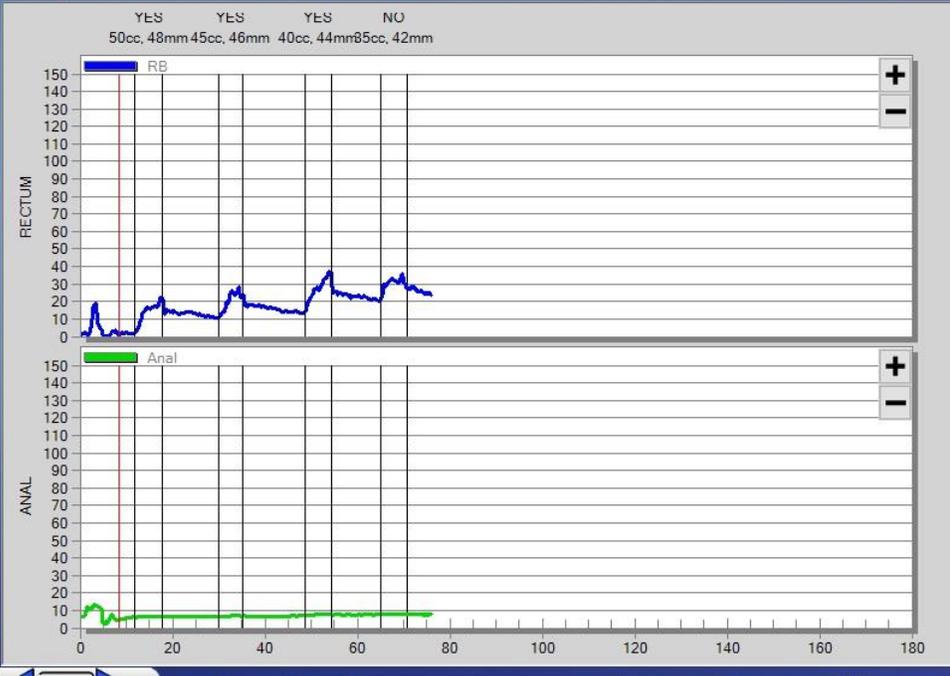
Do not let the patient know you are gradually reducing the volume. You are trying to get the patient to sense/feel lower cc volumes.

Set a goal line (perhaps 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 to occur at lower volumes and for the patient to feel sensation sooner.

Biofeedback Sensory

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.

- Patient Data
- Set Up
- Measurement
 - Resting
 - Squeeze
 - Sensation
- Pelvic Floor Training
 - Strength
 - Sensory**
 - Urge Resistance
 - Expel Full
 - Review
- log out



Notes

Catheter Position: 2 cm

Balloon Fill cc's: 35

PAUSE START NEXT TEST

4.3 Urge Resistance Exercise

Indications for Urge Resistance Training:

- One or more bowel accidents that are preceded by Strong Urge
or
- Abnormally low maximum tolerable volume on ARM (less than 100ml),
or
- Abnormally low urgency sensation (less than 80ml)

Urge Resistance Training Goals:

To improve control of strong urgency sensation and increase rectal capacity, such as > 120cc.

Perform the Exercise:

- 1) Position screen so patient CANNOT view it. Explain the exercise purpose & expectations.
 - *The goal is to teach them to use relaxation to counteract strong urge sensations and learn to tolerate larger volumes.*
- 2) All the air, except the 10cc [3cc for Petite] priming volume, should be removed from the rectal balloon before starting.
- 3) Verify catheter position is at the High Pressure Zone (HPZ).
- 4) Tap "Run" to start recording data.
- 5) Tap "Start"  to begin biofeedback training. This activates response buttons for "Normal Urge", "Strong Urge", & "MTV" (Max Tolerable Volume).
- 6) Slowly inflate the rectal balloon until patient reports a sensation of Normal Urge. It may be necessary to reload the syringe with more air.
- 7) When patient reports an Urge sensation, immediately tap the appropriate button.
- 8) Adjust rectal balloon fill level on the screen to the inflated volume and tap "Record".
- 9) Tap "Start"  to reactivate response buttons.
- 10) Continue to inflate rectal balloon until patient reports a Strong Urge. Tap "Strong Urge" button, adjust balloon fill meter, tap "Record".
- 11) Remove 10cc and have the patient try to relax and breathe for 5-10 seconds.
- 12) Tap "Start"  to reactivate response buttons.
- 13) Remove 30cc from rectal balloon 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".
 - If not (Strong Urge is still reported), wait for 5 seconds and repeat question.
- 14) Tap "Pause" to stop recording. Have patient practice deep breathing or other relaxation technique. Tap "Resume" to resume recording.
- 15) Return to Step 4 and repeat the training for as many trials as appropriate.
 - Provide feedback to the patient on whether they are improving their tolerance for rectal filling.
- 16) Tap "review" button to show patient training session results.

Urge Resistance Training Notes:

1. Pressing the Run button causes the balloon pressures to be displayed on the graph, but to initiate a trial you must press the Start button.

2. Pressing the Start button initiates a trial and puts a vertical line on the screen to show where you are starting. This causes the Sensory buttons (“Normal Urge”, “Strong Urge”, “MTV”) to appear. An important note is that unless the Start button is pressed to initiate a trial, the software will not be able to record the volume and pressure at the sensory threshold and will not be able to incorporate these into the reports.
3. As soon as the patient reports the sensation of urgency the clinician must immediately press the appropriate sensation button. This puts another vertical line on the graph and most importantly it holds the pressure at this point in a temporary file.
4. After pressing the sensation button, the clinician could actually reduce the volume of air in the rectal balloon without losing the ability to record the volume used at the point the sensation was reported. To record the volume at the point of sensation, the clinician has to change the rectal balloon fill ccs volume meter on the lower left and then press the Record button at the lower right-hand corner. This writes the volume and the pressure in the upper graph above the rectal balloon pressure. It writes the pressure from the temporary register and the volume you have just put in.
5. Although the software continues to record pressure in both balloons, the clinician will need to start a new trial to either find the next sensory threshold (strong urge after normal urge for example) or to have the patient try again after practicing relaxation. This would be done by tapping the Start icon again and repeating the process.
6. It is not necessary to provide biofeedback training on the threshold for Maximum Tolerable Volume (MTV). Instead, it is important to remind the clinician that after getting the patient to a threshold of Strong Urge, one should take some air out of the rectal balloon, have the patient relax for a minute or two, and then re-challenge them with another Strong Urge trial.

It is important that the patient NOT have a view of the screen. The goal is to help patients resist greater bowel pressures and suppress the immediacy of urges.

Teaching the patient to relax when they reach the Strong Urge (have to go right now) feeling and by removing the 30cc simulating the rectal wall relaxation, we are showing the patient how to convert the “go right now” situation into a Normal Urge (watching TV and 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 muscle strength may also help with these urge suppression exercises.

Biofeedback Urge Resistance

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

Patient Data

Set Up

Measurement

- Resting
- Squeeze
- Sensation

Pelvic Floor Training

- Strength
- Sensory
- Urge Resistance**
- Expel Full
- Review

log out

Notes

RECTUM

ANAL

RB

Anal

50cc, 48mm 70cc, 53mm 80cc, 55mm 80cc, 55mm

2 cm 80

PAUSE START

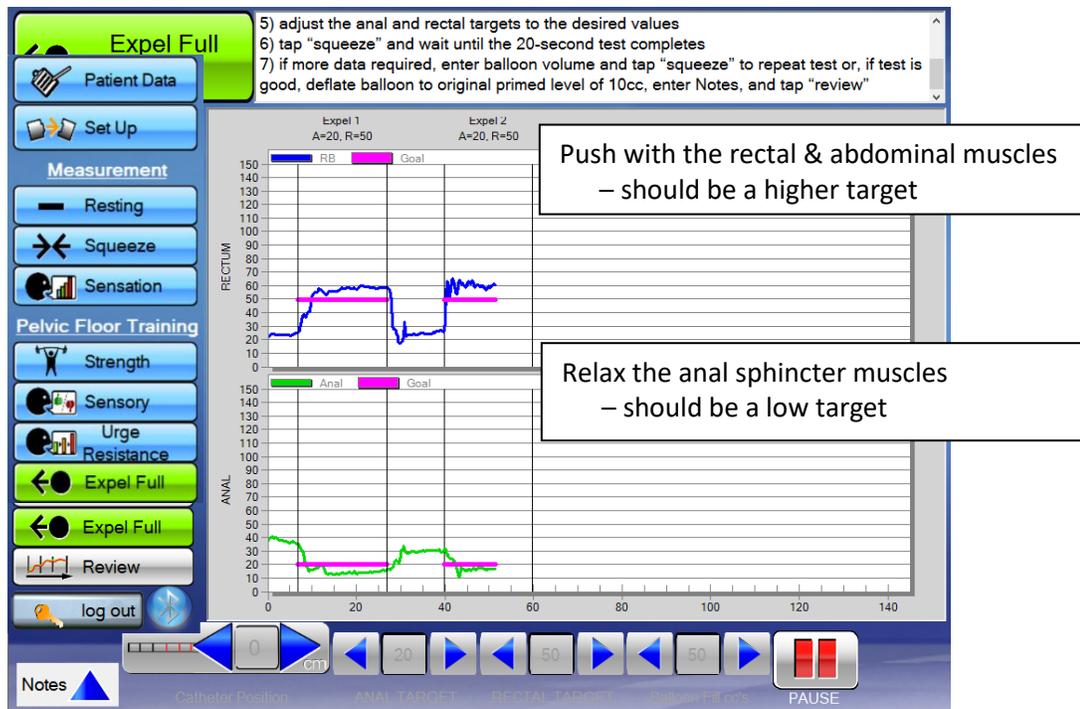
4.4 Expel Full Exercise

- 1) Position screen so patient CAN easily view it. Explain the exercise purpose & expectations.
 - *The goal is to teach them to use the proper abdominal/rectal wall muscles while also relaxing the anal sphincter to ease defecation.*
- 2) Inflate balloon with the same volume where First Sensation was experienced during the Sensation Test, plus (+) 10cc, and confirm balloon volume.
- 3) Adjust the anal and rectal targets to the desired values.
- 4) Tap the “Run” button.
- 5) Instruct patient to “bear down” as if defecating for 20 seconds.
- 6) Tap “Bear Down” and wait until the 20-second test completes. (Encourage the patient to maintain this effort for as long as they can.)
- 7) Deflate balloon to original primed level of 10cc [3cc for Petite].
- 8) Return to Step 3 to repeat for new trial. Repeat trials until patient is fatigued.
- 9) Enter Notes and tap “Review”.

It is important that 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 bearing 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.



Once you have completed the appropriate exercises, the patient is all done.

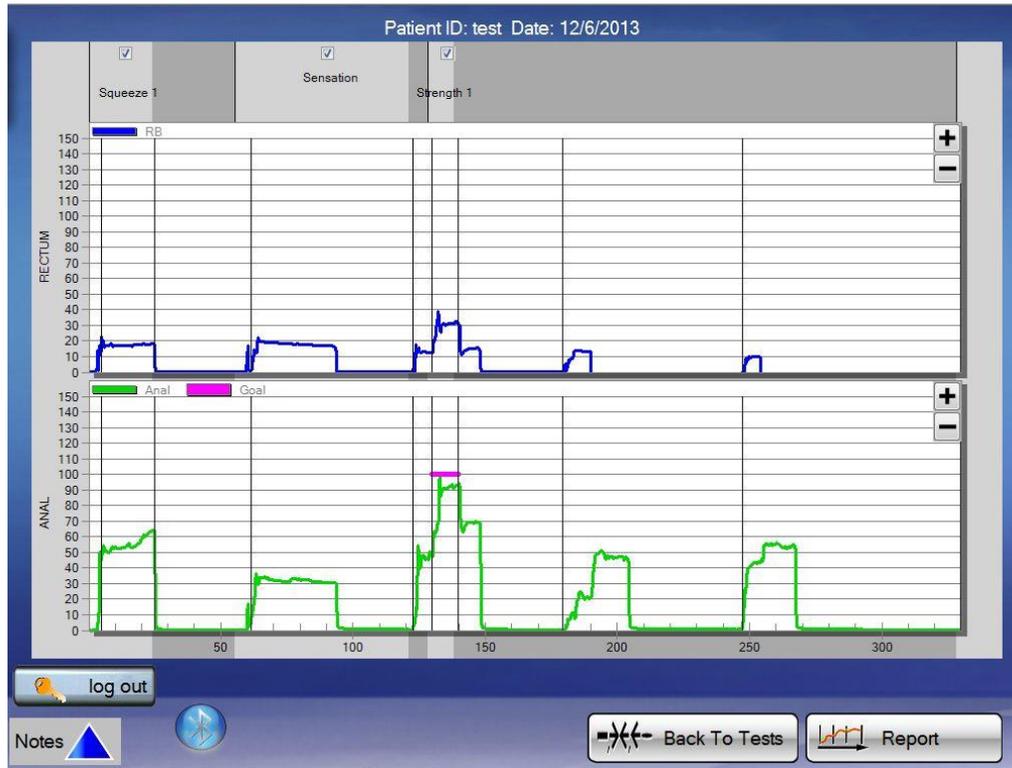
Catheter Removal Process

- 1) Remove all air from the catheter
- 2) Disconnect reusable extension tube from the catheter - *or* - Disconnect catheter assembly from Fob
- 3) Remove the catheter from the patient – You may place a glove over the top of the contaminated balloon to prevent further contamination
- 4) Safely dispose of the catheter

Clean Up Process

- 5) Clean all reusable components of the system with alcohol wipes
- 6) Return Fob handle to Position 1
- 7) Replace all three protective caps
- 8) Plug both Fob and Tablet into battery chargers for their next use

4.5 Review Screen



Once all desired tests and exercises are completed, select the “Review” icon to advance to the review screen. All completed tests are displayed.

Note: Check boxes are located at the top of the screen by the test description label. Keeping the box checked includes the data in the final report and calculations. Un-checking the box removes that specific test from the report and data calculations.

Note: You may zoom at any time by tapping on the screen with the pointer pen and dragging a box around the area. To un-zoom tap the button located on the pen shaft and touch the screen. A “Un-Zoom” icon appears, tap and the screen returns to the original format.

Upon reviewing the test data tap on the “Report” icon to generate the test report.

4.6 Run Report and Save File

Report Screen

mcompass Pelvic Floor Retraining

Patient:
Name: Physician: ***None Entered***
Patient ID: test Operator: ***None Entered***
Gender: Referring Physician: ***None Entered***
DOB/Age: Examination Date: 12/6/2013

Summary:

Resting¹	Biofeedback Strength (best trial)²	
Anal Mean (mmHg)	Anal Mean (mmHg)	84
	Anal Max (mmHg)	100
Squeeze²	RB Mean Pressure (mmHg)	29
Anal Mean (mmHg)	Squeeze Duration (sec)	7
Anal Max (mmHg)		
RB Mean Pressure (mmHg)	Biofeedback Sensory (best trial)⁴	
Squeeze Duration (sec)	RB Volume (cc)	

Sensation

Rectal Capacity (cc)	Biofeedback Urge Resistance (best trial)⁵	
	RB Volume (cc)	
	RB Mean Pressure (mmHg)	

Indications:
None Entered

Notes:
None Entered

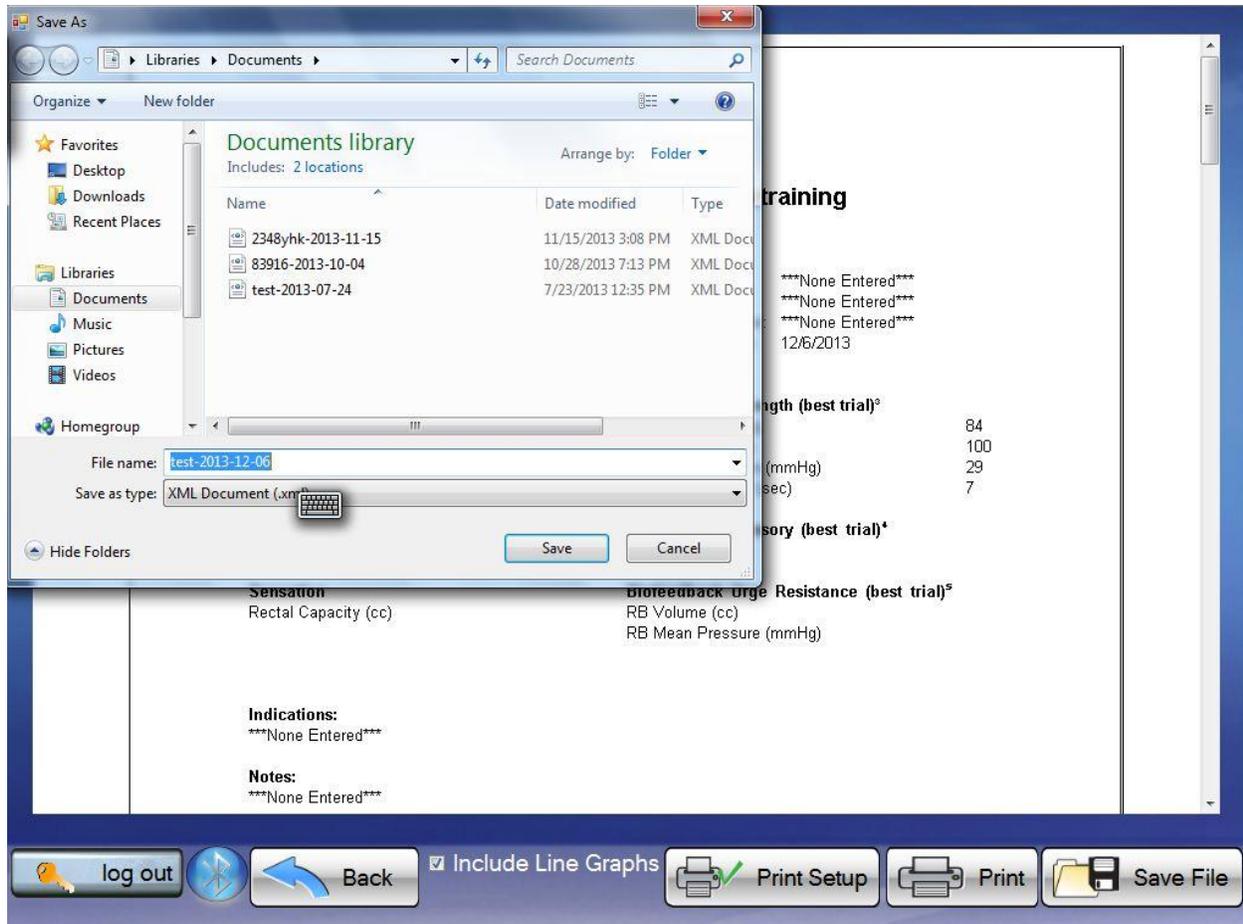
log out Back Include Line Graphs Print Setup Print Save File

1 2 3 4 5

Once the report screen icon is pressed a graphic display of the report is available for viewing on the screen.

This screen has five options to select from:

1. **log out** – this will return you to the Start Up Screen.
2. **Back** – this returns the user to the review screen. From the review screen the user may repeat tests or modify the selection of tests to be used in the final report.
3. **Print Setup** – this allows you to set your print format.
4. **Print** – this prints the displayed report.
5. **Save File** – this brings the user to the following screen:



From this screen, the user may name the file and save it for future transmission or review.

Note: All tests are automatically saved on the Tablet PC. These files are only viewable on the Tablet PC.

To email files to other Windows based PCs for viewing, use the “SAVE FILE” function on this screen.

- Select “SAVE FILE” to bring up the Windows Save As Screen as shown above. From here, save the file in any Windows File Folder. Enter the desired file name and select Save.
- The file can be emailed to any Windows based PC loaded with the *mcompass* software.

Note: All files are encrypted for patient protection. Files can only be viewed using *mcompass*® software by authorized users.

[Log Out](#)

5. Warranty & Repairs

Medspira LLC (Medspira) warrants to the original purchaser that new products will be free of defects in workmanship and material under normal use and service for a period of one (1) year from the date delivered to the end-user. Sale must be from Medspira directly or an authorized dealer. Customers or distributors are required to provide proof of date delivered. If the unit was provided for pre-purchase evaluation purposes, and is thereafter purchased by the end-user, warranty is calculated starting from the original delivery date to the customer. This warranty applies only to the original end-user of the product; warranty is non-transferable. Warranty is subject to change and may vary from product to product at sole discretion of Medspira.

During the warranty period, Medspira will repair a defective product under its Overnight Replacement Program. This Program includes free overnight shipping of loaner product, free repair of defective product, and free return shipping.

At its sole discretion, Medspira may choose to supply new or equivalent replacement product. The defective product must be returned to and received by Medspira within 10 calendar days, or the replacement product will be invoiced to the customer at full price. Overnight replacement requests must be received by Medspira by 1:00pm Central Time on normal business days.

This warranty includes the following items:

- *mcompass*® Anorectal Manometry Fob
- *mcompass*® Anorectal Manometry Diagnostic Software
- *mcompass*® Biofeedback Software
- *mcompass*® Tablet PC
- *mcompass*® Power Adapter

Excluded from this warranty and not warranted by Medspira in any manner, either express or implied, are: a) any product which has been disassembled, repaired, tampered with, altered, changed, or modified by persons other than Medspira's own authorized service personnel unless such repair by others is made with the written consent of Medspira; b) defects or damage to products resulting from wear, tear, misuse, negligence, improper storage, transit, line power fluctuations, any adverse environmental conditions, nonperformance of maintenance and care, consumable battery leakage, or use of non-approved accessories, consumables, or supplies; c) third party software and operating systems; d) any software that is being used on a system that has been corrupted by computer viruses, spy ware, or any third party software or device; e) software that is being used on unsupported operating systems and/or computer hardware; and f) associated consumables, including but not limited to catheters and batteries.

Warranty is subject to change and may vary by product at the sole discretion of Medspira.

This warranty is deemed to be the only warranty honored by Medspira in lieu of any and all warranties expressed or provided by any and all other merchants, distributors, companies or persons. No person or entity has authority to bind Medspira products to any warranty or guarantee except as specifically set forth herein.

The preceding warranty is the exclusive warranty and Medspira LLC makes no other warranty or representation of any kind whatsoever, express or implied, with respect to merchantability, fitness for a

particular purpose, or any other matter. The remedies stated in this warranty will be the exclusive remedies available to the customer for any defects or for damages resulting from any cause whatsoever, and without limitation.

In no event shall Medspira be liable for any consequential or incidental damages of any kind (including, without limitation, lost profits, business interruption, or lost information) arising out of your use of or inability to use the product.

NON-WARRANTY SERVICING

For non-warranty repairs, the customer is to contact Medspira for a Returned Goods Authorization (RGA) and ship their defective product to Medspira (at customer's expense). Medspira's Support team will assess the unit and advise the customer of the repair and shipping costs, which will be invoiced to the Customer. Upon customer's acceptance and authorization of the repair and shipping costs, the product will be repaired, the customer's invoice will be created, and the repaired product will be shipped back to Customer.

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