



***mcompass*[®] Anorectal Manometry Diagnostic System**

Instructions for Use / Operator Manual

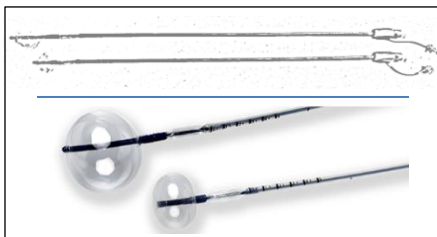
The *mcompass*[®] Anorectal Manometry Diagnostic System includes:



mcompass[®] Anorectal Manometry Fob



Medical Grade Tablet PC with
mcompass[®] Anorectal Manometry Software



mcompass[®] Anorectal Manometry Catheter
– Standard & Petite 5-Channel



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1. Introduction












This manual describes the safety precautions, features, use, and care of the Medspira *mcompass*[®] Diagnostic Anorectal Manometry 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*® Anorectal Manometry System is indicated for use with patients requiring anorectal pressure studies.

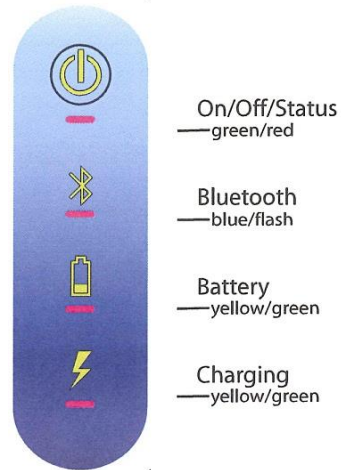
1.3 Pre-Use System Check & Operation Verification

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*® Anorectal Manometry 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*® Anorectal Manometry 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 Anorectal Manometry 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 diagnostic test, tap the "Diagnostic Anorectal Manometry" icon.
3. To view previous tests, tap "View Reports" icon.
4. To exit to Windows, tap "Exit to Windows" icon.

The screenshot shows the mcompass start-up screen with the following elements: the mcompass logo and 'Version: 1.08' in the center; an 'Administrator' button in the top right corner; and three buttons at the bottom: 'Diagnostic Anorectal Manometry', 'View Reports', and 'Exit to Windows'. Red arrows with circled numbers 1, 2, 3, and 4 point to these buttons respectively.

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. A red circle with the number "1" and an arrow points to the "admin" text. Below the dropdown is an "Enter Password" text box. A red circle with the number "2" and two arrows points to the "Login" button and the password box. At the bottom right, there is a "Cancel" button with a red circle and the number "3" and an arrow pointing to it.

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, there are three buttons: "Bluetooth", "Security", and "Activity". A red circle with the number "1" and an arrow points to the "Bluetooth" button. A red circle with the number "2" and an arrow points to the "Security" button. A red circle with the number "3" and an arrow points to the "Activity" button. 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 red circle and the number "4" and an arrow pointing to it.

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

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

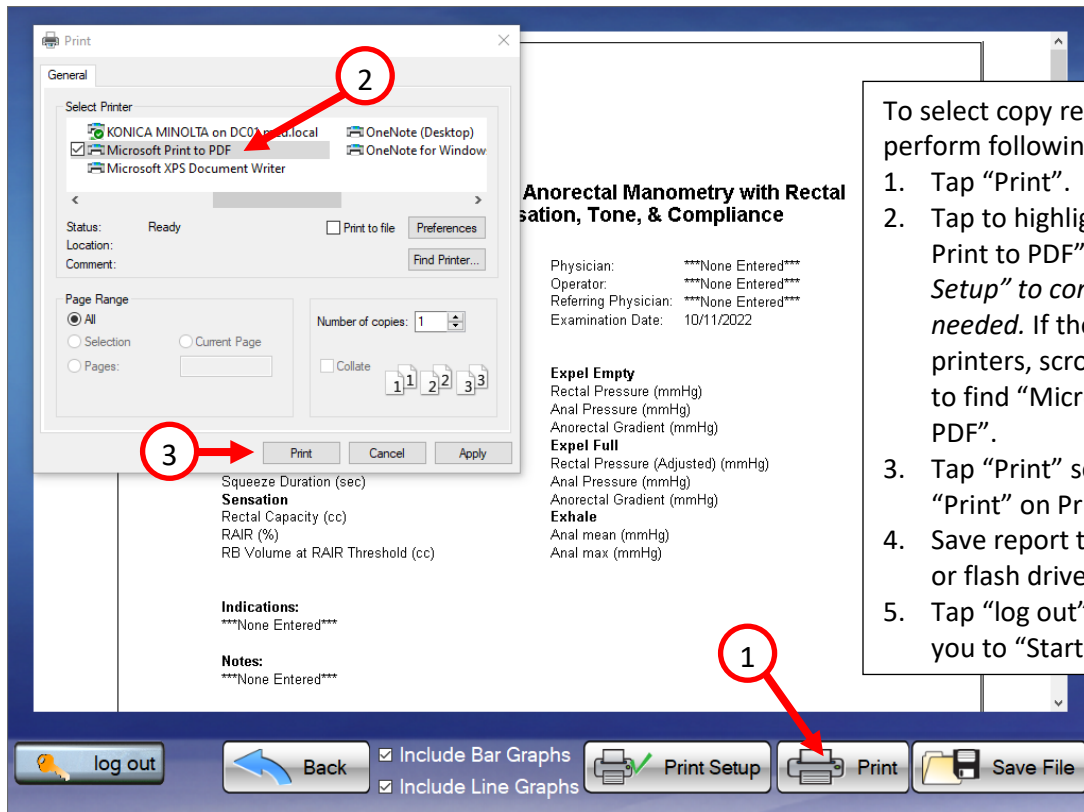
Select Report

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

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.

View, Save, & Print Report



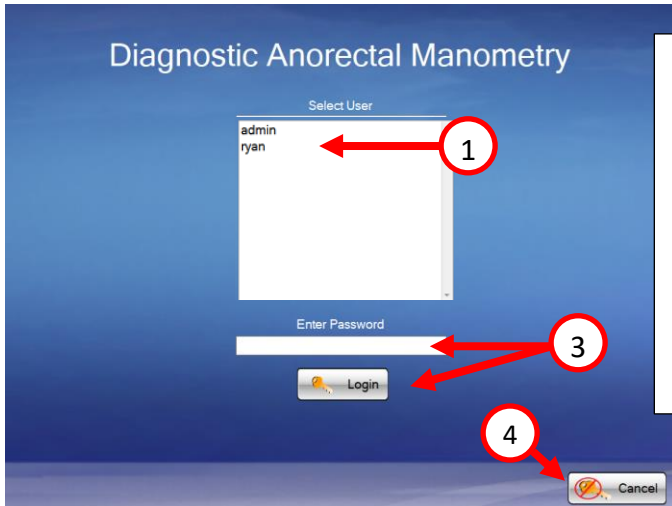
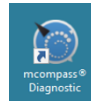
To select copy report in .PDF, perform following:

1. Tap "Print".
2. Tap to highlight "Microsoft Print to PDF". Tap "Printer Setup" to configure page if needed. If there are multiple printers, scroll left or right to find "Microsoft Print to PDF".
3. Tap "Print" screen, then "Print" on Print window.
4. Save report to area location or flash drive.
5. Tap "log out" icon returns you to "Start Up" screen.

2.3 Diagnostic Test Set-Up

Diagnostic Anorectal Manometry Login Screen

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




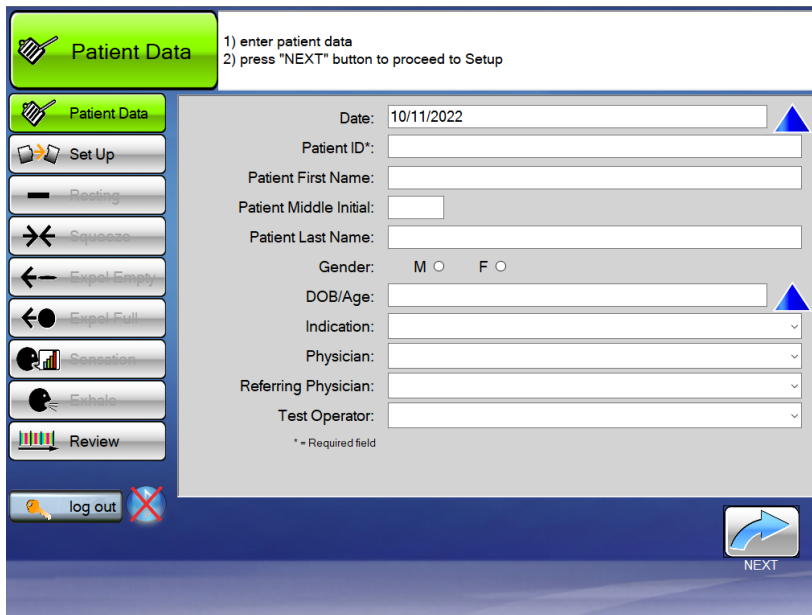
1. Tap to highlight User. Initial user is “Admin”. (Other users may be added in Administrator Screen.)
2. Open Tablet keyboard – tap “Keyboard” icon on screen.
3. Enter case-sensitive password. “Admin” password is **Medspira123**, then tap “Login” icon.
4. Tap “Cancel” icon to return to the “Start Up”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



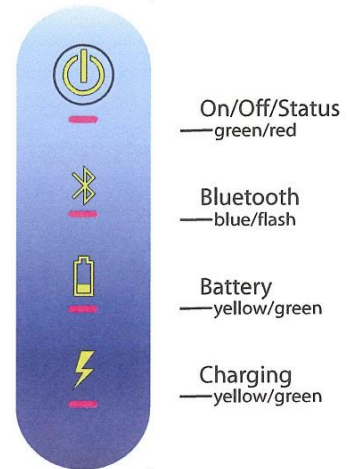
Only Patient ID is required to proceed.

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.

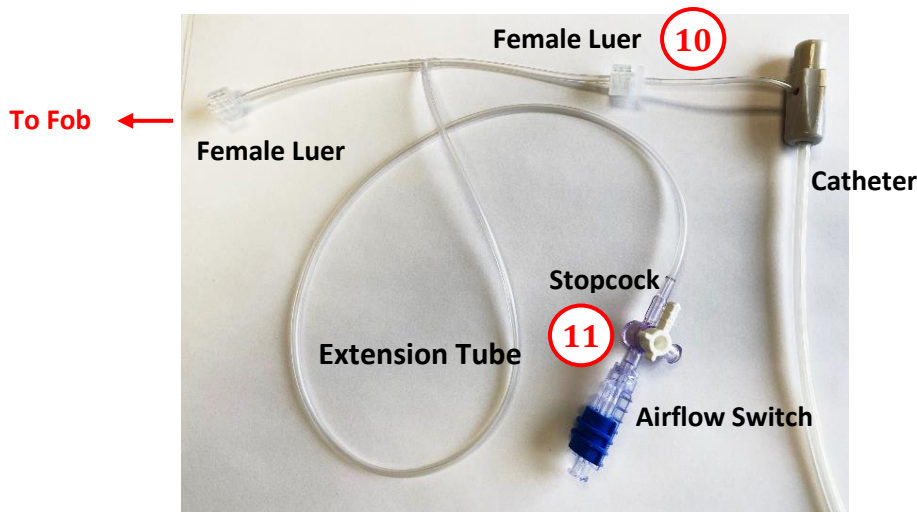
8. Tap “Fob Connected” to confirm Fob connection 
9. Connect catheter to the Fob by plugging in with arrows aligned

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

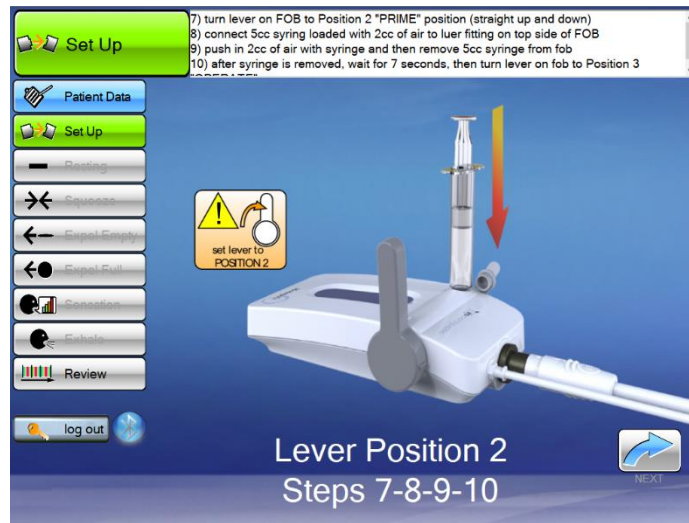


11. Connect Airflow Switch to 3-way Stopcock, and Connect large syringe to the Airflow Switch



Set Up – Priming the Fob

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

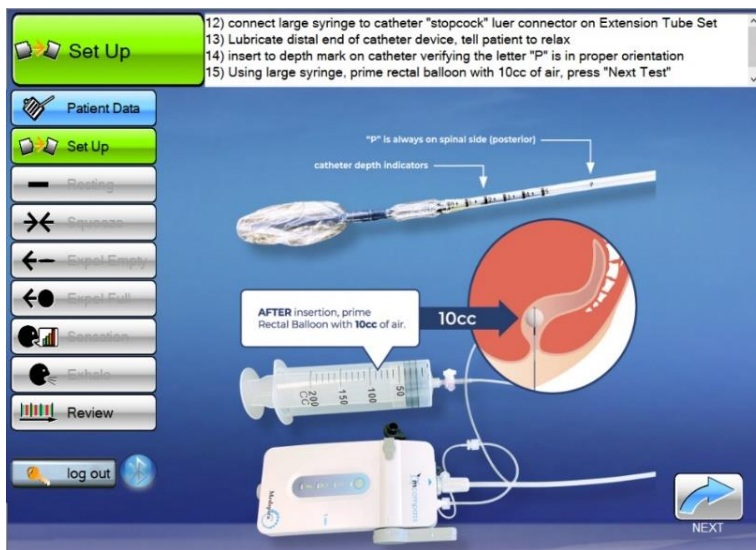
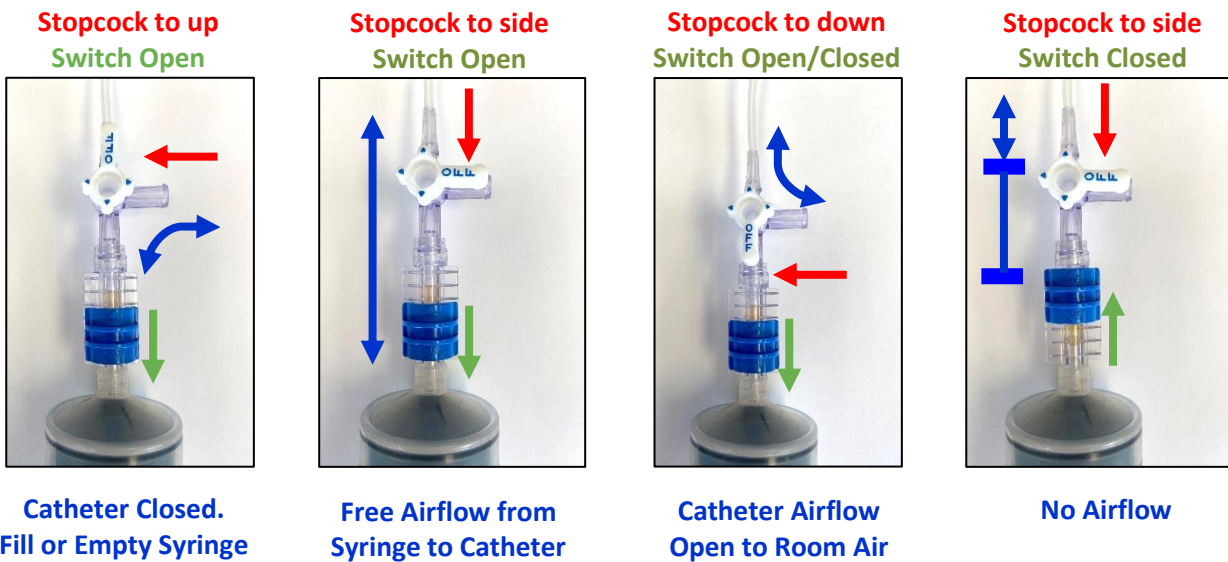
3.1 Prepare Patient for Testing

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 [3cc for Petite] of air, press "Next"
- 4) Lock the stopcock UP to the "Catheter Closed" position

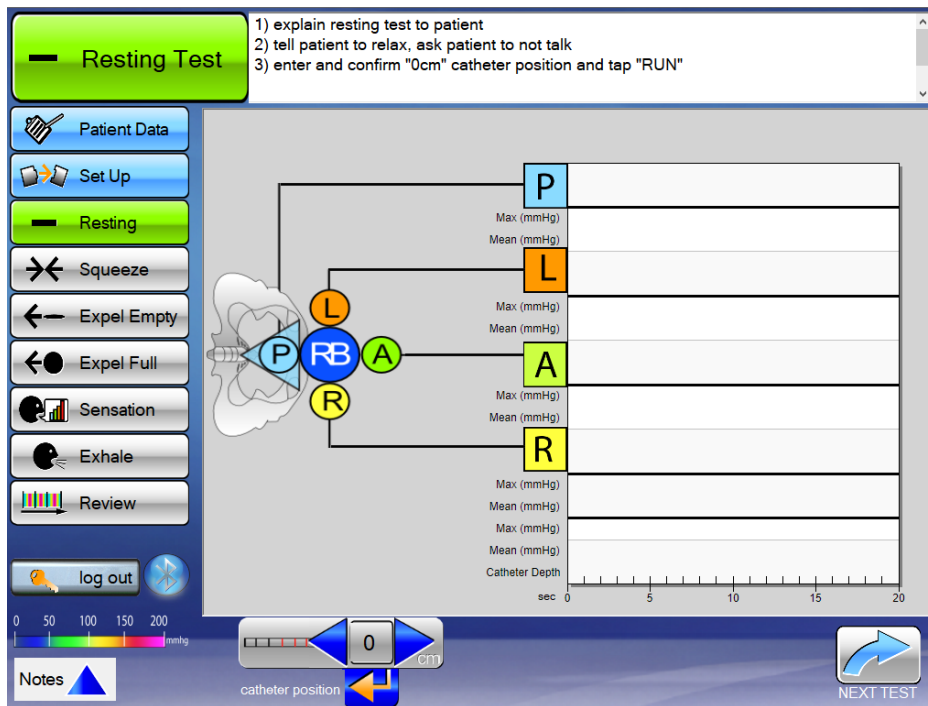
How to Use the Stopcock & Airflow Switch:



At this point, the Set Up is complete.

3.2 Resting Test

- 1) Explain test to the patient. – They are just to relax while you determine in what catheter position their anal sphincter strength is the greatest.
- 2) Instruct the patient to relax
- 3) Catheters have position (depth) markings. Position the catheter at “0”, enter position at bottom of screen, tap enter , and tap “Run/Pause”
 - NOTE:** The “run” icon will display five seconds after the catheter position is selected.
- 4) Let 20 second counter run to zero
- 5) Insert the catheter further into position “1”, enter position, tap enter , and tap “Run/Pause”
- 6) Insert the catheter further into position “2”, enter position, tap enter , and tap “Run/Pause”
- 7) Go to “Review”. Look for which ANAL MEAN is highest among the positions.
 - **This position is the High Pressure Zone (HPZ).**
 - **Continue all remaining tests from this HPZ position.**
- 8) *If the pressure increases through position “2”, repeat the test at position “3” (and “4”, “5” if necessary). Tap “Back to Tests” to repeat tests.*
- 9) Enter any Notes (if appropriate), then tap “Next Test”






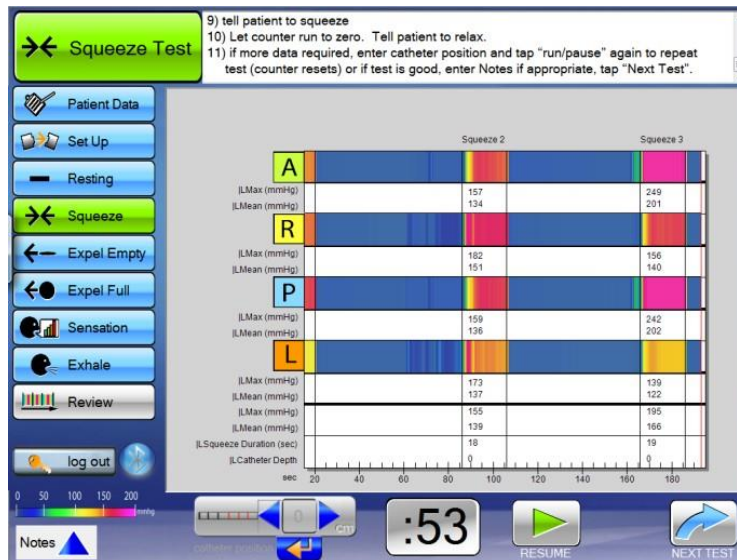
Use **CAUTION** when repositioning catheter depth in patient.

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) Explain the test to the patient. – They are to squeeze tight for as long and hard as they can, 3 times, simulating they are holding back a bowel movement.
 - 2) Check catheter position in the patient is in the High Pressure Zone (HPZ), verify position on the bottom of the screen, tap enter , and tap “Run/Pause”
 - 3) Instruct the patient to squeeze
 - 4) Let the counter run to zero. Ask the patient to relax; wait at least 30 seconds for patient to recover
- Repeat -**
- 5) Check catheter position in the patient is in the High Pressure Zone (HPZ), verify position on screen, tap enter , and tap “Run/Pause”
 - 6) Instruct the patient to squeeze
 - 7) Let the counter run to zero. Ask the patient to relax; wait at least 30 seconds for patient to recover
- Repeat -**
- 8) Check catheter position in the patient is in the High Pressure Zone (HPZ), verify position on screen, tap enter , and tap “Run/Pause”
 - 9) Instruct the patient to squeeze
 - 10) Let the counter run to zero. Ask the patient to relax; wait at least 30 seconds for patient to recover
 - 11) If more data required, check catheter position and tap “Run/Pause” again to repeat test (counter resets) or if test is good, enter Notes (if appropriate), then tap “Next Test”.


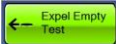


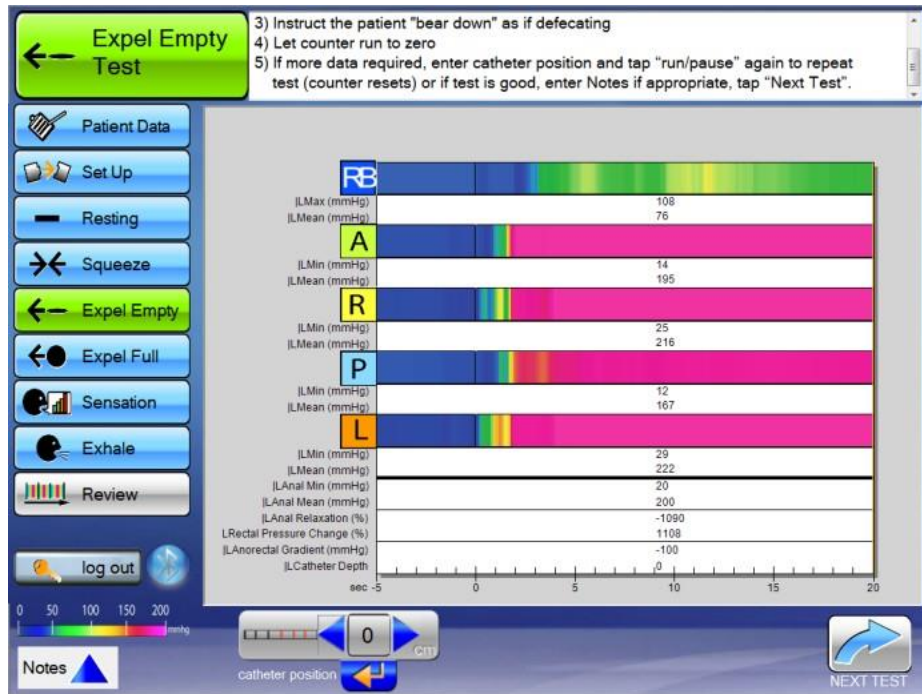
Perform 3 squeezes where the patient squeezes as hard as they can for 20 seconds. You will need to keep telling the patient to squeeze throughout the entire 20 seconds. You want them to not only squeeze hard but to hold it as long as possible. Tell the patient to squeeze like they are trying to hold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



1. Explain the test to the patient. – They are to “bear down” like they are trying to push out a stool.
2. Check catheter position in the patient is in the High Pressure Zone (HPZ), verify position on bottom of the screen, tap enter , and tap “Run/Pause”
3. Instruct the patient to bear down / push and keep pushing for 20 seconds.
4. Let 20 second counter run to zero. Tell the patient to relax.
5. Screen will move on to the “Expel Full Test”
6. If more data required, return to the Expel Empty Test  and repeat the test.
7. Enter Notes (if appropriate).

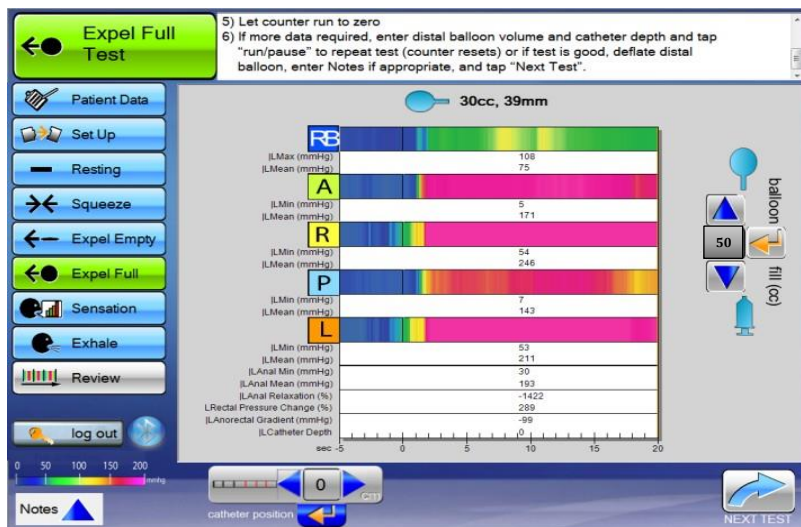


Note: Tap the “Expel Empty” icon at left  to repeat the test at any time.

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.

3.5 Expel Full Test


- 1) Explain the test to the patient. – Same exact test as the expel empty, except this time a small amount of air will be added to simulate stool in the rectum.
- 2) Fill the rectal balloon.
 - OPTION A1: **Standard Catheter - Ages ~ >6**: Inflate rectal balloon with 50cc. Lock the stopcock.
 - OPTION A2: **Petite Catheter - Ages ~<6**: Inflate rectal balloon with 10-40cc (**infant-child**). Lock the stopcock.
 - OPTION B: (**Recommended**): Ask the patient to say when they feel like there is stool in their rectum (sensation). Start by adding 20ccs (**10cc for Petite**) of air and add 10cc (**5cc for Petite**) at a time. When patient states they feel the sensation, add 10cc (**5cc for Petite**) more and lock the stopcock.
- 3) Enter the rectal balloon volume on the right (see “a” in diagram).
- 4) Check catheter position in the patient is in the High Pressure Zone (HPZ), verify position on bottom of the screen, tap enter , and tap “Run/Pause”
- 5) Instruct the patient to “bear down” as if defecating
- 6) Let counter run to zero
- 7) Screen will move on to the “Sensation Test”
- 8) If more data required, return to the “Expel Full”  test and repeat the test.
- 9) Open the stopcock, remove all but 10cc of air, and lock the stopcock.
- 10) Enter notes if appropriate and tap “Next Test”.



Before the test will run, you must make sure to enter the Catheter Position and enter the Amount of Air (“a”) you injected into the balloon. Then the Run button will appear.

Note: When complete, return the rectal balloon to the original primed volume of 10cc’s (**3cc for Petite**).

Note: Tap on the “Expel Full” 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.

3.6 Sensation Test

Note: Closing the Airflow Switch to maintain rectal pressure at each sensation mark is necessary to provide a meaningful Rectal Compliance Curve!

- 1) 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) desire to defecate, and 3) urgency to defecate. You will be adding volume (making it bigger) to simulate a stool.
- 2) Fill the large syringe with air
- 3) Ask the patient to relax for 7 seconds – this provides the resting pressure needed for the report
- 4) Tap the Green Arrow (run) button
- 5) **Determine First Sensation Marker:**
 - Instruct the patient to state when they feel as if there is stool in their rectum (Sensation).
 - Turn the stopcock to allow air to flow to the rectal balloon.
 - Start by pushing in 20ccs of air (**10cc for Petite**). If the patient says nothing - continue to add 10cc (**5cc for Petite**) at a time. Once the patient has stated they feel the sensation, close the Airflow Switch, and tap the sensation 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 yellow arrow next to adjusted volume amount to auto-populate the information in the **sensation** box.
- 6) **Determine Desire 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, could easily wait for the next commercial break.*)
 - Open the Airflow Switch and 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 desire, close the Airflow Switch, and tap the desire 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 yellow arrow next to adjusted volume amount to auto-populate the information in the **desire** box.
- 7) **Determine Urgency 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.*)
 - Open the Airflow Switch and 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, close the Airflow Switch, and tap the urgency 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 yellow arrow next to adjusted volume amount to auto-populate the information in the **urgency** box.

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



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.

8) **Determine Pain Marker – OPTIONAL** (Otherwise jump to Step 8)

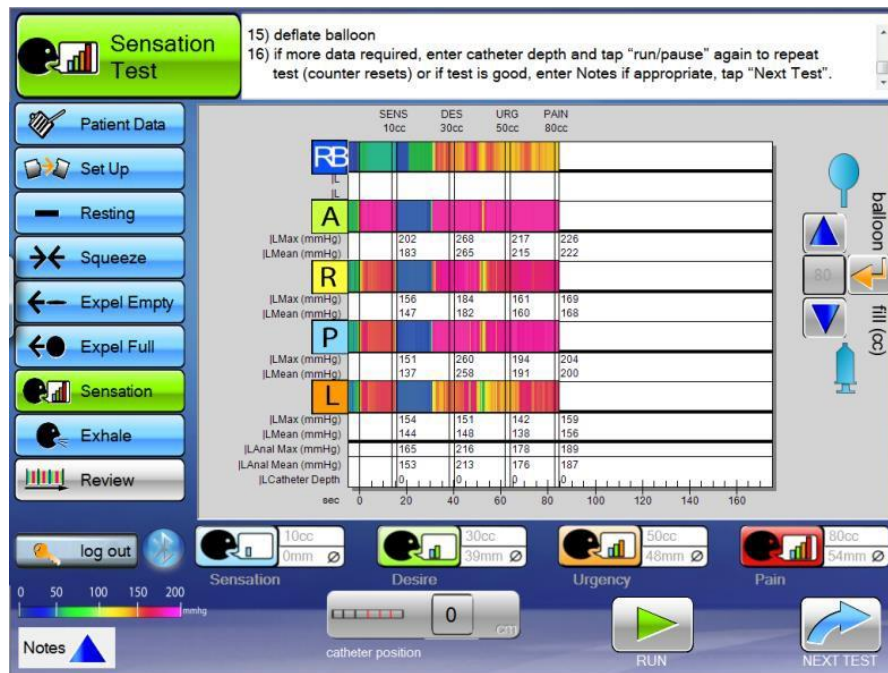
- Measuring to the ‘Pain’ level of this test is OPTIONAL. If the physician wants the additional data, this may be explained as testing for ‘**Total Capacity**’ rather than pain. For an example, express to the patient: ‘Let me know when you have a feeling that you can’t hold anymore.’
- Otherwise, you are done with the test.

9) Remove all air from the rectal balloon and add back the baseline of 10ccs **(3cc for Petite)** of air. Lock stopcock.

10) Tap “Test Review” on bottom left-hand side of screen. Let the information load. Once information has loaded, tap Report. On the first page of the report, the bottom left of the page, look for RAIR.

RAIR (RectoAnal Inhibitory Reflex)

A critical element of this test is reviewing the data and graphs after this test to determine the presence and amplitude of RAIR.



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: When 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.

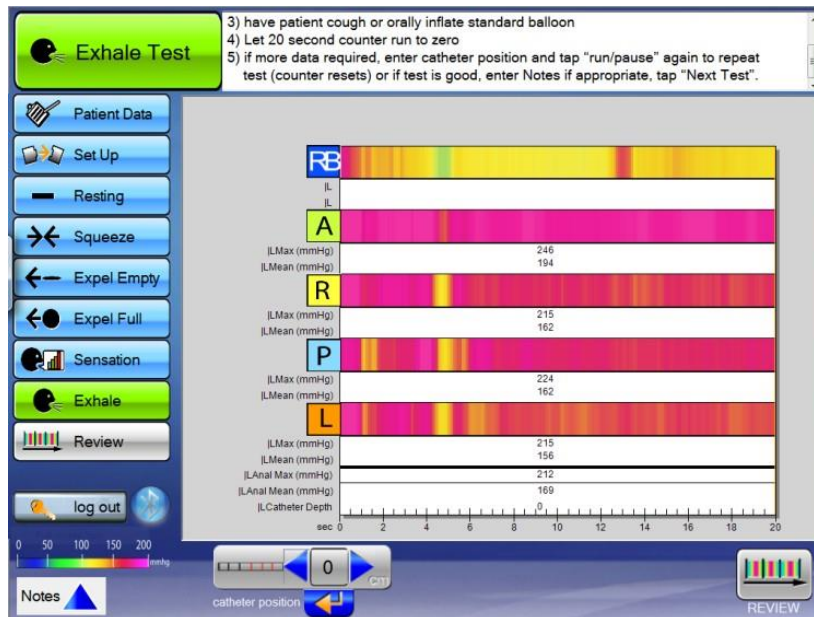


CAUTION: Do not over inflate rectal balloon beyond the stated limit in the catheter’s IFU. Rupture may occur if over inflated causing potential patient and/or system harm.

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.

3.7 Exhale Test

- 1) Explain the test to the patient. – They are to do a series (3 to 5) of good deep coughs or hard concentrated exhales (like blowing up a balloon) over 20 seconds.
- 2) Check catheter position in the patient is in the High Pressure Zone (HPZ), verify position at bottom of screen, tap enter , and tap “Run/Pause”
- 3) Have the patient cough, or exhale hard, or orally inflate a standard balloon
- 4) Let 20 second counter run to zero



To prevent a coughing fit, coach the patient to cough or exhale just once every several seconds.

Note: Click on the “Exhale” 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.

Once you have completed this test, the patient is all done.

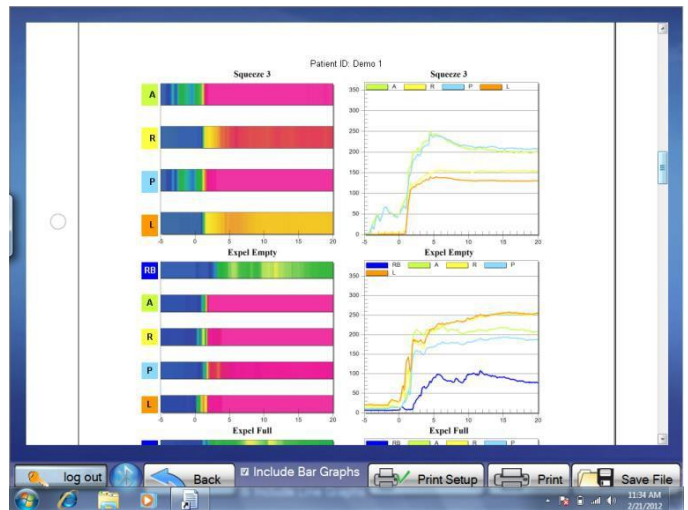
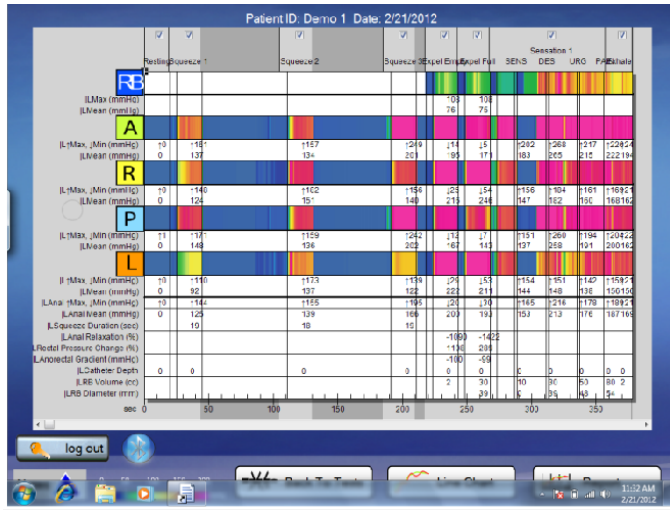
Catheter Removal Process

- 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

3.8 Review Screen



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

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: At any time, the user may switch between bar chart format and line chart format by tapping the icon located at the bottom of the screen.

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.

- This will populate a 6-8 page Report for interpretation.

3.9 Run Report and Save File

Report Screen

mcompass Diagnostic Anorectal Manometry with Rectal Sensation, Tone, & Compliance

Patient:
Name: _____ Physician: ***None Entered***
Patient ID: ARM TEST Operator: ***None Entered***
Gender: _____ Referring Physician: ***None Entered***
DOB/Age: _____ Examination Date: 1/6/2023

Summary:

Resting		Expel Empty	
Anal mean (mmHg)	-0	Rectal Pressure (mmHg)	1
Anal max (mmHg)	-0	Anal Pressure (mmHg)	-0
Squeeze		Anorectal Gradient (mmHg)	1
Anal mean (mmHg)	-0	Expel Full	
Anal max (mmHg)	-0	Rectal Pressure (Adjusted) (mmHg)	-19
Squeeze Duration (sec)	0	Anal Pressure (mmHg)	-0
Sensation		Anorectal Gradient (mmHg)	-19
Rectal Capacity (cc)	120	Exhale	
RAIR (%)	See Graph	Anal mean (mmHg)	-0
RB Volume at RAIR Threshold (cc)	See Graph	Anal max (mmHg)	-0

Rectal Compliance

120
110
100
90
80

time (cc)

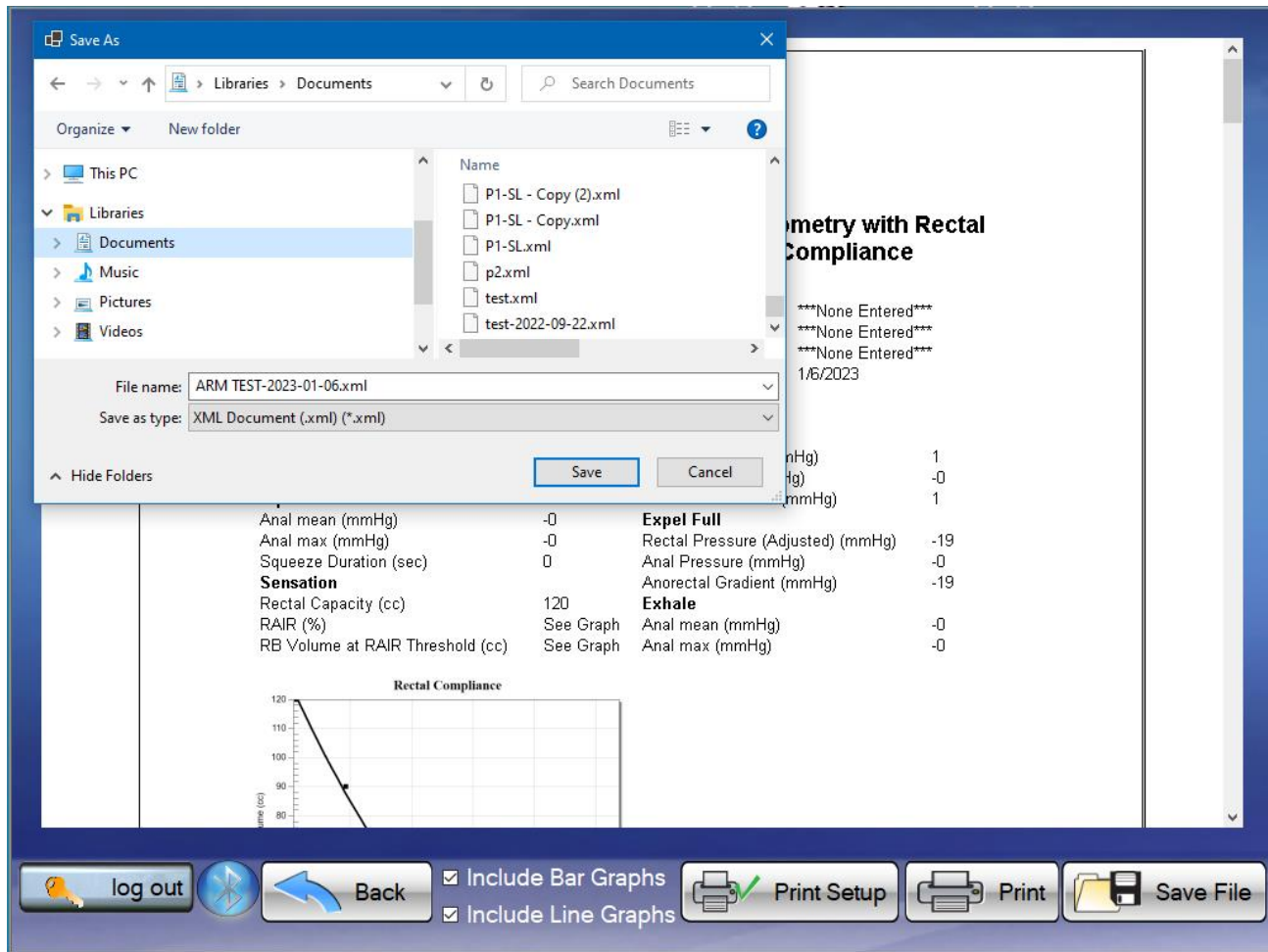
log out Back Include Bar Graphs Include Line Graphs Print Setup Print Save File

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](#)

4. 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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