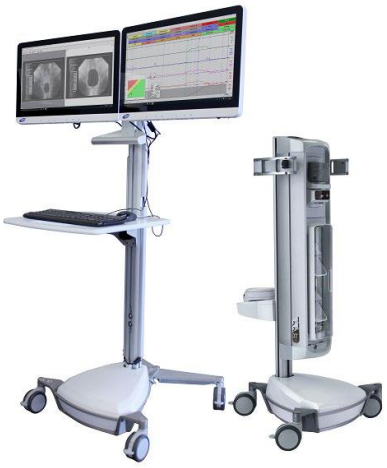
AQUARIUS®

XT/CT/LT/CTS Owner's Manual



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ABOUT THIS MANUAL

SYMBOLS

This manual provides important information to help in understanding the features and safe use of the device. The symbols outlined below highlight helpful tips and important cautions that will aide in guiding the reader through the manual.

CAUTION
Caution/warning symbol describes information that the user needs to know to prevent minor injury or product damage.

IMPORTANT
Important symbol describes important information about using the device.

NOTE
Note symbol describes additional information about the device.

1 INTRODUCTION AND GUIDELINES FOR USE

The LABORIE Next Generation Modular **AQUARIUS®** system is a fully wireless system providing mobility and ease-of-use. Procedures can be performed with the mountable modules and controlled by the **AQUARIUS®** software.

Connect to all devices from one central control hub (CHC). The wireless and battery-powered features of each device allow for improved system setup and use.

For warranty information and terms and conditions, visit the following website:
http://www.laborie.com/terms-and-conditions/

Figure 1: AQUARIUS Modules

1.1 INTENDED USE

1.1.1 AQUARIUS® SYSTEM

The **AQUARIUS®** LT, **AQUARIUS®** CT, and **AQUARIUS®** XT are diagnostic analyzer systems. The product is a data acquisition system for Urodynamics and peripheral diagnostics that records and displays physiological data from the patient. It is to be used as medical diagnostic equipment. Details are described as follows:

- Central Hub Computer: has a touch LCD as a new HMI and collects/synchronizes data from all procedure modules and sends data to PC. It also displays the device status and provides interface for calibration and pump setup.
- Pump Module: The pump on the Central Hub is used to infuse a patient's bladder with saline from an IV bag.
- Pressure transducers: These are the sensors for pressure measurement.
- EMG: Electromyography (EMG) transducer for measuring the raw and enveloped muscle activity.
- Urocap/Uroflow: Load cell transducer to detect volume and flow of liquid into a beaker.
- UPP Puller: Retracts a catheter at a constant speed from the patient.
- **Roam™** DX: Wireless Battery Powered EMG Measurement Device.
- PC: Computer which controls the system activity, displays, and stores data.

1.1.2 ANORECTAL MANOMETRY (ARM) SYSTEM

- LABORIE's ARM system is intended to measure physical parameters such as pressures and EMG of the terminal end of the digestive tract as it relates to Urodynamics, Incontinence, and the Pelvic Floor.

1.1.3 SPINNING DISK FLOW TRANSDUCER

The Flow Transducer is intended to sense voiding flow. It is used together with UDS devices for assessing voiding disorders.

1.2 TARGET POPULATION

- The major application of Urodynamics is the diagnosis of uncontrolled loss of urine (incontinence), abnormal urinary retention, neurological causes of Micturition disorders, or anorectal manometry.
- The major application of anorectal manometry (ARM) is to aid in the diagnosis of anorectal disorders and incontinence in men, women and children.

1.3 CONTRAINDICATIONS

⚠ WARNING: The AQUARIUS® system is contraindicated for any patient who is not a candidate for Urodynamic testing.

Catheters should not be used on patients who suffer from:

- Bladder infections
- Strictures in the urethra
- Prior to testing, a urinalysis and urine culture should be considered to rule out the presence of infection.

Single use, disposable catheters supplied by LABORIE Medical Technologies are "sterile", unless stated otherwise on the packaging label and instructions.

Reusable catheters are cleaned but ***not sterilized*** before shipping.

1.4 TARGET USERS

- Only medical professionals trained in Urodynamics should operate this device. The operator must read the Owner's manual entirely and refer to any additional training materials before using the device. Optional In-Service is available from LABORIE.
- To reduce the risk of cross-contamination or infection, physicians should be knowledgeable and qualified in applying the appropriate aseptic technique during the intended use of the device. The use of prophylactic antibiotics is at the discretion of the physician and the policies of the institution.
- To reduce the risk of serious patient injury, it is vital that physicians and clinicians performing Urodynamics studies on patients with a Spinal Cord Injury be prepared to recognize and treat *Autonomic Dysreflexia.*
- To reduce the risk of serious patient injury, it is vital that physicians and clinicians performing Urodynamics studies be prepared to recognize and treat symptoms associated with *vasovagal syncope (fainting) during Urodynamics procedures.*

Warnings related to Ureteral Catheterization can be referenced within the T-DOC instructions for use *(TDOC-UM01).*

1.5 WARNINGS AND PRECAUTIONS

⚠ PRECAUTION:

1. LABORIE equipment and accessories are licensed by Governments and approved by Safety Agencies to work with each other ONLY.
2. To prevent any risk of damage to the cart:
   - Do not lean on trays, accessories, monitors, main tower, or spine of any carts.
   - Monitor should be free of any obstacles. Do not hang anything on the monitor.
   - Do not suspend extra weight from the monitors.
   - Maximum weight on the work trays should not exceed more than 22 lbs. (10 kg).

CAUTION:

UNITED STATES FEDERAL LAW RESTRICTS THIS DEVICE TO SALE OR USE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.

⚠ *WARNINGS:*

READ CAREFULLY BEFORE USE!

1. ONLY LABORIE trained technicians may service the unit
2. LABORIE equipment and accessories are warranted to work with each other ONLY.
3. Do not use if device packaging has been opened, or damaged, or if it presents any fault due to improper transport, storage, or handling that could in any way hamper its use.
4. Ensure all wheels are locked during testing procedures to prevent injury to the patient. Do not lean on the equipment nor hang excessive weighted objects other than LABORIE standard accessories on the platform.
5. Exhibit caution when raising the PC & monitor from its lowest position as the mount may rise abruptly due to the strong springs used to counter-balance the weight.
6. Do not immerse the UDS equipment or any components in water or any other liquids.
7. Do not place your fingers inside the pump head when the pump rollers are moving.
8. LABORIE is not responsible for loss of patient files or test data. We recommend that you back up patient data on a regular basis.
9. DO NOT USE in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.
10. DO NOT USE electromyography (EMG) simultaneously with high frequency surgical equipment.
11. Do not operate the NXT System near shortwave or microwave therapy equipment as proximity may produce instability in the APPLIED PARTS.
12. Do not allow applied parts linked to a PATIENT CONNECTION, but not connected to the PATIENT, to contact other conductive parts including those connected to protective earth. Preserve the patient connection electrical isolation.
13. Use the AQUARIUS® with LABORIE equipment and accessories ONLY. Do not reuse single-use accessories. After use, dispose in accordance with local regulations.
14. Re-use, reprocessing or resterilization of disposables can lead to device failure and create a risk of cross-infection and/or cross transmission of infectious disease(s) from one patient to another.
15. Sterilization failure of reusable items prior to initial use or reuse can result in cross infection and/or cross-transmission of infectious disease from one patient to another.
16. DO NOT USE the AQUARIUS® in the presence of a magnetic resonance imaging system as the AQUARIUS® may contain ferromagnetic objects that pose a risk to the patient in the presence of a magnetic core. The strong magnetic field produced by the MRI may cause disruption of the system.
17. Always ensure the Transducer cup drain hole on the Spinning Disk Flow Transducer is unobstructed. If obstructed, clear away the obstruction before use.
18. Be aware that prolonged use of video capture may result in elevated temperatures at the rear of the AIO PC
19. To avoid the risk of electric shock, only connect this equipment to supply mains with protective earth.
20. Device intended for use in a clinical environment with controlled EMC standards to limit potential interference. The AQUARIUS® may be adversely affected by Bluetooth®, cellular or EMC interference.

Minimize interference from other Bluetooth devices by setting up all components of system in proximity to each other.

21. Only connect devices specified and approved by Laborie to the AQUARIUS® multiple socket outlets. Connecting any device not approved by LABORIE to the ME system alters the functional integrity of the product creating a safety risk.
22. Avoid altering or adding to AQUARIUS® medical electrical system. Any alteration to the AQUARIUS® system by an unauthorized party transfers responsibility for meeting ME system requirements from LABORIE to the altering party. Anyone connecting supplementary equipment to medical electrical equipment configures a medical system and is therefore responsible for ensuring that the system complies with the requirements for medical electrical systems, encompassed in the IEC 60601 series.
23. Batteries are not operator removable. Do not attempt to remove battery. All servicing of AQUARIUS system, components or attachments to be completed by LABORIE.
24. Do not place the printer in the patient environment unless it is powered via the Laborie provided Line Isolation Transformer (Separating transformer).
25. Only connect items that have been approved by Laborie to the system. Any additional connections become the responsibility of the operator and shall tested to meet the IEC 60601-1, ME SYSTEMS requirements.
26. There is the risk of electrical shock if the operator plugs in Non-ME Equipment (i.e. printer or laptop) directly into the MAINS supply that is intended to be powered by a Line Isolation Transformer (Separating transformer)
27. Do not touch the printer/laptop and the patient simultaneously.

NOTE: Local laws take priority over the above-mentioned requirements and warnings; if in doubt, consult your local Laborie representative or the technical service department.

2 CLEANING AND PREVENTIVE MAINTENANCE

IMPORTANT: Do not immerse the equipment or devices in water or any other liquids!

2.1 GENERAL CLEANING AND PREVENTIVE MAINTENANCE

- Always wear protective gloves when cleaning the equipment to prevent biological contamination.
- The AQUARIUS® system is non-immersible. The system and its modules, including the cart and its components, should be wiped down with a clean cloth dampened with a cleaning solution such as soap and water or as per hospital cleaning instructions.
- The EMG electrodes, tubing, disposable catheters, optional strap, and cartridges are intended for SINGLE PATIENT USE only. Do NOT re-use disposables.
- For the pressure transducers, clean any fluids or other foreign matter from the external surfaces of the transducers and cables using a slightly damp cloth and a mild detergent solution. Do not immerse. Do not use chlorine-based cleaning solutions/agents. Do not autoclave or EtO sterilize the transducer.
- Performing regular maintenance will reduce the need for repairs. Check the calibration every 6 months or whenever you suspect the transducers are off calibration to maintain optimal system performance.
- Pay close attention to the LED lights on each device. If they indicate a broken connection and/or low battery, then make sure that the connection is re-established, or the battery is fully charged. For information on LED lights refer to the Equipment Status and Light Signals section on page 29. Always charge the devices when alerted to do so by the system.

2.2 CARING FOR THE ROAM™ DX

- The **Roam™ DX** is not immersible. Wipe the outside only with soap and water or with a hospital-grade disinfectant.

IMPORTANT: Do not spray cleaning solution directly on or in the **Roam™ DX**.

- Clean the Roam™ DX holster with standard hospital wipes.
- The optional strap is disposable, non-sterile, and recommended for single use only.

NOTE:

- The insertion points of the EMG headstage/processor must be kept dry; never immerse the EMG into water or any liquids. The EMG headstage/processor can be wiped clean with a cloth dampened with soap or mild detergent and wiped dry immediately.
- LABORIE recommends charging and using the **Roam™ DX** at least once or twice a year to maintain optimal performance. If it will be placed in storage, make sure it is stored with the battery fully charged.

2.3 CARING FOR THE UROCAP V UROFLOWMETER

Follow the instructions below to clean the **Urocap™ V** of possible urine contamination. Always wear protective gloves when cleaning the equipment to prevent biological contamination.

IMPORTANT: Do not soak or immerse the **Urocap™ V** in water! Do not immerse or soak in water or in any other liquids (Figure 2).

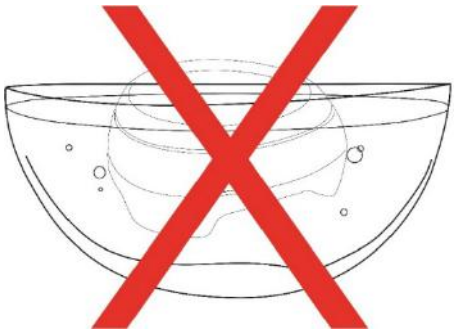


Figure 2: Do not Immerse

- The lid of the **Urocap™ V** is not removable.
- The **Urocap™ V** should be cleaned using a damp cloth with alcohol, soap, or disinfectant detergent (Figure 3). Store the **Urocap™ V** in a cool and dry area at room temperature. Refer to System Specifications on page 183.

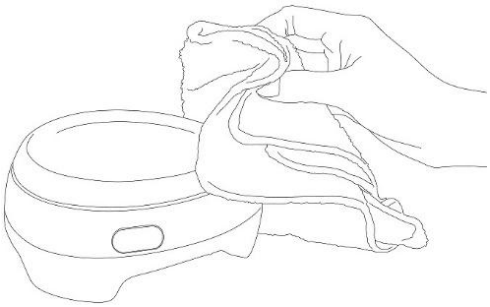


Figure 3: Cleaning the Urocap™ V

- Rinse and dry the Uroflow beaker after each use. Use Soap and water, or a mild detergent solution, for cleaning.
- Wipe the chair, Flowstand, and funnel clean with a cloth dampened with soap or mild detergent and wiped dry immediately. When cleaning the funnel, the maximum cleaning temperature should not exceed 80°C (176°F).

To check if the **Urocap™ V** is functioning, refer to page 12.

NOTE: Although the beaker is reusable, it will discolor over time and may need to be replaced.

2.4 CARING FOR THE SPINNING DISK FLOW TRANSDUCER

On a weekly basis, test the device for proper functionality. Inspect all cables and the sensor for cuts and other damage. If in doubt, send the device for service. No additional maintenance is required.

Clean the Flow Transducer at minimum once a week, preferably daily, to avoid deposits and odor. Clean the device as follows:

Quick Cleaning (Daily)

- Slowly pour approximately 1L of clean water into the funnel.
- Keep the disc running to flush the transducer cup.

Thorough Cleaning (Weekly)

1. Disconnect the Flow Transducer from the System.
2. Disconnect the jug, the funnel, and the disk from the Spinning Flow Transducer.
3. Use cleaning detergents appropriate for lavatory pans. Clean all the parts according to the detergent manufacturers' recommendations, including the inside and outside of the transducer cup.
4. Wipe off all parts with an appropriate disinfection solvent.

IMPORTANT: To avoid spill, do not tilt the Flow Transducer during cleaning with liquid in the transducer cup.

5. To avoid damage to the device, do not exceed the recommended cleaning temperatures for the different device components:

Funnel	Max 140°C / 284°F
Rotating Disk	Max 150°C / 302°F
Transducer cup	Max 100°C / 212°F
Disc Holder	Max 100°C / 212°F
Jug 1.5L, Steel	Max 200°C / 392°F
Jug 1L, White	Max 140°C / 284°F
Motor Housing	Max 100°C / 212°F

Table 1: Component Cleaning - Fluid Temperatures

6. After cleaning, rinse the components.
7. Reassemble the flow transducer.

IMPORTANT:

- Never immerse the connector into any liquid. Always keep it dry.
- Never remove the disk holder for cleaning.
- Never immerse any parts of the device in liquid (motor part/housing).

2.5 CARING FOR THE UPP PULLER

The UPP puller catheter guide and clamp have been designed so that they may be quickly disconnected, cleaned, and reprocessed to prevent cross contamination. Follow the instructions in this section to disassemble and reassemble the UPP parts for cleaning, disinfection, or sterilization.

IMPORTANT: It is extremely important to sterilize the Catheter Guide of the UPP puller. Failure to do so may result in cross-contamination if a new catheter contacts an unsterilized Catheter Guide and is used on a patient during testing.

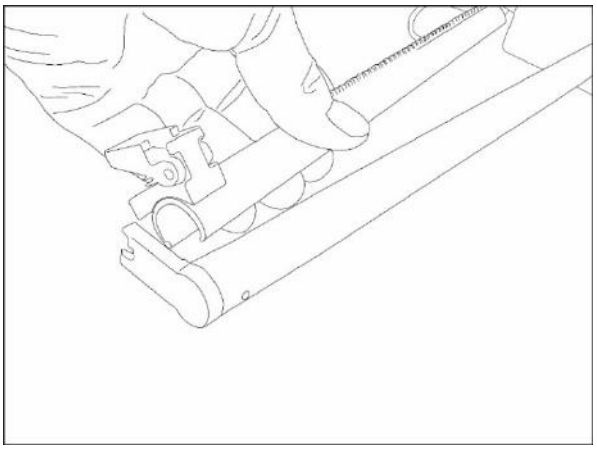


Figure 4: Disconnected Catheter Guide

WARNING:
Procedures That Will Damage the UPP Unit and Void the Warranty

- Autoclaving is not permitted. It will warp or destroy any other device or component.
- Do not immerse any connectors into any liquid. Always keep them dry.
- Do not use solvent or abrasive cleaning agents.
- Make sure that liquids do not enter the motor through apertures in the enclosure.
- Do not use Chlorine Bleach, Ammonia, Acetone, Methanol, Denatured ethyl alcohol, Mineral oil, or Iodine.
- The maximum service temperature is 100°C (212°F).

2.5.1 CLEANING AND DISINFECTION OF THE MOBILE CLAMP

After each procedure release the Mobile Clamp from the UPP and complete disinfection procedure.

2.5.1.1 HIGH-LEVEL DISINFECTION REAGENTS

The UPP components can be high-level disinfected using any of the **approved high-level disinfectant solutions** as per label instructions.

When selecting a high-level disinfectant, investigate the full properties and regulations. Strictly adhere to the instructions on the label.

The following disinfectants can be used:

- Aldehydes (Cidex®)
- Corsoline®
- Sporicidin®
- Chlorates (DiversolBX®)
- Sani-Cloth Plus or equivalent
- Dilute Bleach wipes – do not soak
- Alcohol is nearly inactive against certain organisms. 70% Isopropyl Alcohol cleaners may be used on the devices; however, higher level cleaners are recommended.

2.5.1.2 RELEASING THE MOBILE CLAMP

1. Click the **UPP Return** button then click the **UPP Stop** button. (Repeat this action until the mobile clamp is fully released from the motor body.)
2. Click the **UPP Stop** button to stop the motor.
3. Slide the mobile clamp down towards the catheter guide (Figure 5).

Figure 5: Mobile clamp moving toward catheter guide

4. Once the mobile clamp is flush to the catheter guide, twist the mobile clamp downwards (Figure 6).

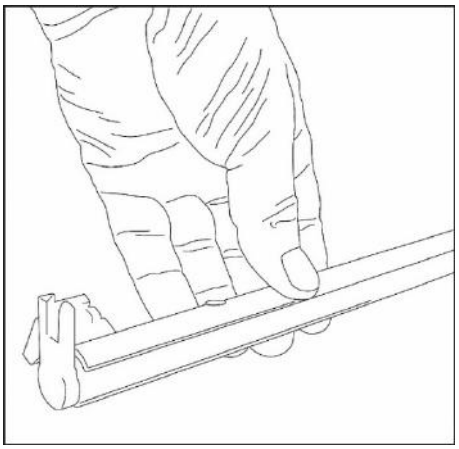


Figure 6: *Mobile clamp downwards*

5. Slide the mobile clamp completely off the nose tube. (Figure 7)
6. Clean and disinfect the mobile clamp.
7. Thoroughly rinse and dry the clamp.

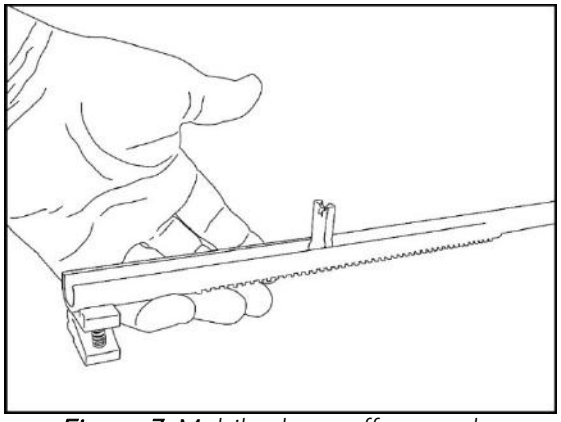


Figure 7: *Mobile clamp off nose tube*

2.5.2 Sterilization of the Catheter Guide

Follow the instructions provided to remove and sterilize the catheter guide.

2.5.2.1 Sterilization Reagents and Processes

NOTE: Components must be disassembled before sterilization.

The UPP puller components are compatible with the following sterilization processes:

- ETO
- Gas Plasma
- Peracetic Acid
- Instrument detergent or enzymatic instrument detergent
- Suggested Cleaning Solutions*:
    - KLENZYME (STERIS Corporation 1-800-548-4873)
    - ENDOZYME (The Ruhof Corp. 1-800-537-8463)

Follow the manufacturer's instructions.

*Reference to any specific brand name is not an endorsement of their efficacy.

2.5.2.2 Remove and Sterilize the Catheter Guide

1. Grasp the rounded section of the catheter guide with your thumb and forefinger as shown in Figure 8.

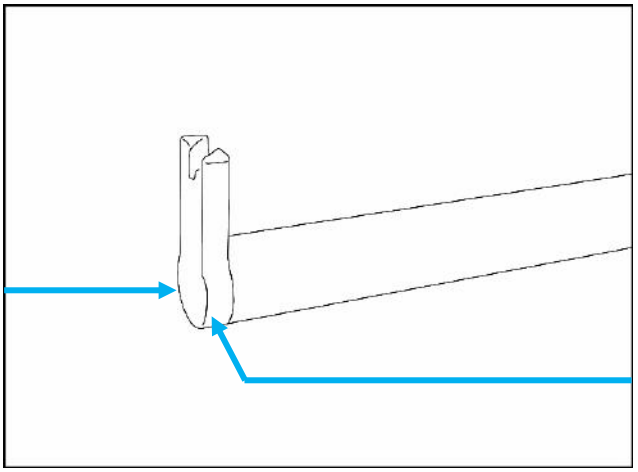


Figure 8: Catheter Guide Removal - Step 1

2. Pull the Catheter Guide out.
3. Sterilize the Catheter Guide using the recommended solutions.
4. Put the Catheter Guide back by pushing it into the nose tube.

NOTE: The tip has a silver ball that allows you to snap the Catheter Guide back into place and keep it at the correct position.

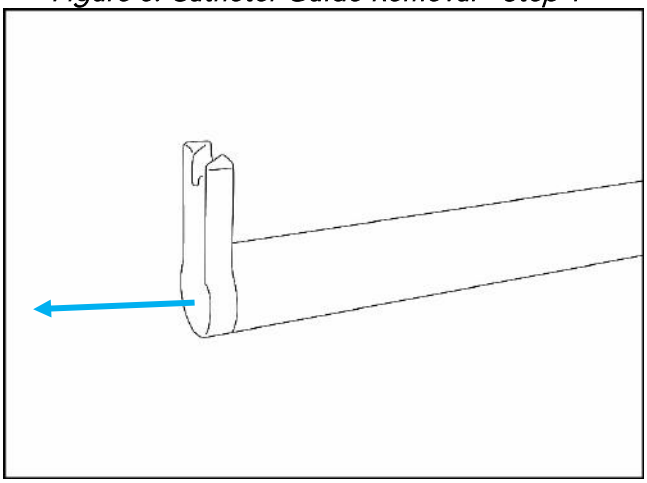


Figure 9: Catheter Guide Removal - Step 2

2.5.2.3 UPP REASSEMBLY

To Reattach the Catheter Guide:

Push the Catheter Guide back into the nose tube. The tip has a silver ball that allows you to snap the Catheter Guide back into place and keep it at the correct position.

To Reattach the Mobile Clamp:

1. Slide the mobile clamp onto the nose tube with the clamp facing downward (Figure 7).
2. Once passed the catheter guide, twist the mobile clamp upward.
3. Observe as the mobile clamp begins to move by itself up towards the motor body. The magnet on the end of the nose tube senses the approach of the mobile clamp and will place it back into the opening. It will stop moving by itself.
4. Click UPP Pull to ensure that the mobile clamp is securely in place.
5. Click UPP Stop.
6. Click UPP Return.

2.6 CARING FOR THE AIR-CHARGED TRANSDUCER/CABLE

The risk of patient to patient cross-contamination with sterile, single-use air-charged catheters using sterile technique is negligible. However, any procedure in high-risk settings with body fluids and skin-to-skin contact increases the risk of contamination of non-disposable components.

The following is recommended **after each patient use:**

- Air-charged catheters are single patient use only. Discard after use.
- Replace the tethered protective cap to the transducer housing via Luer Lock to protect the transducer.
- Spray or wet-wipe the transducer/cable with a hospital-grade, broad-spectrum disinfectant that covers standard potential pathogens as well as HIV, HBV, HCV, VRE, MRSA, MRSE, Pseudomonas and Mycobacterium.
- Wipe the transducer/cable until dry.

Refer to the General Cleaning and Preventive Maintenance section on page 5 for cleaning instructions for pressure transducers.

2.7 BATTERY - CHARGING AND PREVENTIVE MAINTENANCE

IMPORTANT! For proper and safe charging, use only USB cables provided by LABORIE.

2.7.1 CHARGING THE BATTERY

Urocap™ V:

Place the **Urocap™ V** on the charging bay/docking station on the cart or plug one end of the USB cable into the device and the other end into the medical grade power supply provided by LABORIE. This power supply can be plugged into a wall outlet; the **Urocap™ V** should be placed on the provided spacer to ensure it rests parallel to or flat against the ground.

It will take approximately 7.5 hours to fully charge the device (when not in use). When the **Urocap™ V** is sampling, it will take 9 hours for the device to fully charge.

NOTE: LABORIE recommends having the device plugged in or have at least 40% battery charge before the start of a test.

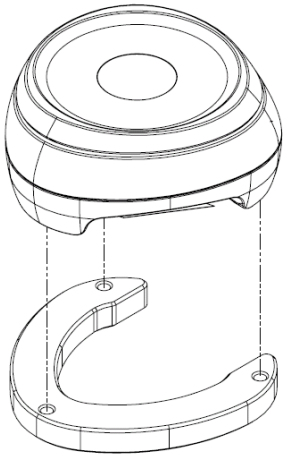


Figure 10: Urocap™ V Charging Spacer

Roam™ DX:

Place the **Roam™ DX** on the charging bay/docking station on the cart. Make sure it clicks into place to ensure a proper connection (a beeping sound signifies it is fully connected). It will take approximately 7.5 hours to fully charge the device (when not in use).
When the **Roam™ DX** is sampling, it will take 10.5 hours for the device to be fully charged.
When the LED light on the device is green it is fully charged.

NOTE: LABORIE recommends having the device plugged in or have at least 40% battery charge before the start of a test.

Figure 11: Roam™ DX Charging Bay

UPP:

Plug the USB cable from the UPP stand into the front USB port under the central pump hub to charge the UPP. It will take approximately 7.5 hours to charge (about 9 hours if sampling).
It is recommended to plug the UPP in at the end of every day to ensure a full charge for testing.

NOTE: LABORIE recommends having the device plugged in or have at least 40% battery charge before the start of a test. The equipment can still be used during battery charge time.

Figure 12: UPP

2.7.2 Battery Preventive Maintenance

- Do not step on, drop, drop in water, or puncture the battery. If misuse, abuse, or damage is suspected, or any form of mechanical damage to the casing is visible, then discontinue use and return the battery to LABORIE.
- If a sudden change in the battery's ability to hold a charge or a sudden change in battery lifetime is noticed, discontinue use and return the battery to LABORIE.
- It is recommended to charge all device batteries overnight to ensure proper function. Once the battery level drops to 40% charge, it is best to start recharging.

2.8 COMPUTER VIRUS PROTECTION

All computers purchased from LABORIE are virus-free before shipment and are installed with an antivirus program. It is the customer's responsibility to correctly use and maintain the anti-virus program to prevent virus problems. LABORIE is not responsible for any virus-related computer problems after point of delivery to the customer.

2.9 TREATING AND DISPOSING OF PRODUCT AFTER USE

- After use, discard the contaminated, plastic, single-use disposables and any packaging according to your institution's standard operating procedures on medical waste handling.
- For end of life product, waste electrical and electronic equipment should be collected separately and returned to the designated local recycling service.
- For end of battery life, disposal must be handled according to local regulations.
- Packaging waste should be collected separately for available national packaging collection and recycling services.

2.10 ENVIRONMENTAL CONSIDERATION OF WASTE DISPOSAL

It is important to dispose of waste (such as urine) properly to prevent environmental pollution. The waste should be disposed of in such a way that will not pollute the fresh water supply system — especially the drinking water system. Normally, this is not an issue in areas that have proper sewage systems with water treatment procedures. In this case, the most convenient way is to use these sewage systems.

2.11 PREVENTIVE MAINTENANCE – CHECKING CALIBRATION

Performing regular maintenance will reduce the need for repairs. As a step in maintaining optimal system performance check the calibration every 6 months or whenever you suspect the transducers are off calibration.

If the Uroflowmeter, the pump, the EMG, the UPP puller, the pressure transducers, and/or the infusion transducer are giving incorrect readings, try the following checkups before attempting to calibrate the system.

2.11.1 CHECK THE FLOW AND VOLUME OF THE UROCAP™ V UROFLOWMETER

Check Volume

1. Open the **AQUARIUS®** software and start a sample Uroflow test.
2. Put an empty beaker on the Uroflow transducer.
3. Select **Set Zeroes!**
4. Remove the empty beaker.
5. Fill a beaker with 500cc of water and place it on the Uroflowmeter.

The volume channel should display a volume of 500ml (+/- 5 ml). If the reading is above or below the 5ml threshold, then calibration is required. ***Once calibration is complete perform a re-check by following the instructions provided above.*** Contact LABORIE service for assistance if problems continue after the calibration and re-check.

Check Flow

1. Open the **AQUARIUS®** software and start a sample Uroflow test.
2. Put an empty beaker on the Uroflow transducer.
3. Select **Set Zeroes!**
4. Fill another beaker with 500cc of water.
5. Slowly and steadily pour the water from the filled beaker into the empty beaker. Try to keep the rate between 25 to 50 ml/second.

The volume channel should display a volume of 500ml (+/- 5 ml). If the reading is above or below the 5ml threshold, then calibration is required. ***Once calibration is complete perform a re-check by following the instructions provided above.*** Contact LABORIE service for assistance if problems continue after the calibration and re-check.

2.11.2 CHECK THE PUMP

Some reminders before pump check-up:

- If contrast is used for testing procedures, it should also be used for check-up and calibration procedures.
- Use only LABORIE recommended and approved tubing for accurate readings and measurements.

1. Prime the pump tubing.
2. Connect the pump tubing to a catheter and angle into an empty beaker.
3. Open the **AQUARIUS®** software and start a sample test.
4. Fill to a volume of 150 cc and stop the test.
5. Measure the volume.

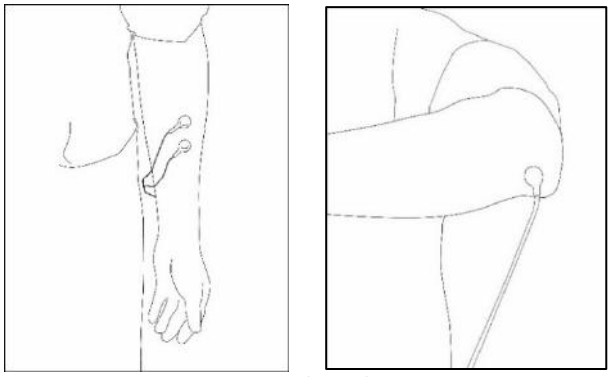
The volume channel should match the pump fill volume (+/- 10 ml). If the reading is above or below the 10ml threshold, then calibration is required. *Once calibration is complete, perform a re-check by following the instructions provided above.* Contact LABORIE service for assistance if problems continue after the calibration and re-check.

2.11.3 CHECK THE ROAM™ DX

2.11.3.1 CHECK EMG

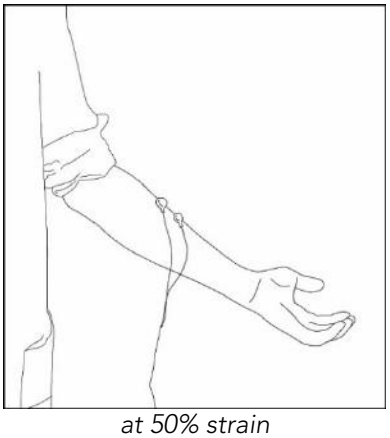
IMPORTANT: EMG leads tend to expire after six months of use; it is recommended that they be replaced every six months.

1. Open the **AQUARIUS®** software and start a sample test with an EMG channel.
2. Place two EMG electrodes, 1 inch apart, on your forearm (where the muscle flexes the most) and the third EMG patch on your elbow.
3. Keep your arm relaxed, palm open, and down to your side. You will notice minimal EMG activity.



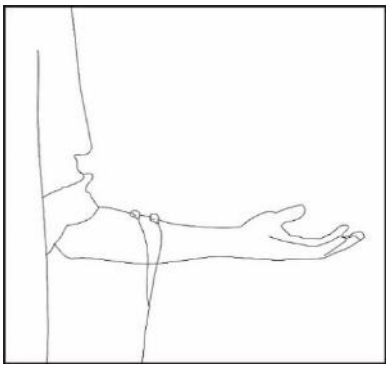
relaxed

4. Keep your palm open and lift your arm slightly (at a 45-degree angle) and hold the position to keep it at a constant rate. You will notice an increase in activity on the EMG channel.



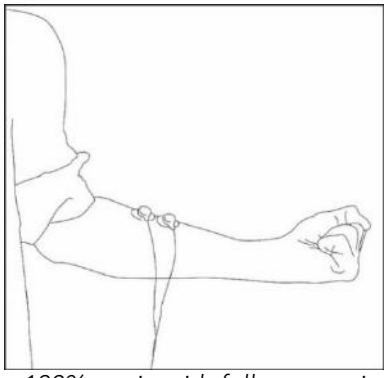
at 50% strain

5. Keep palm open and lift your arm further up until it is parallel to the floor. You will notice more activity on the EMG channel.



at 100% strain

6. Keeping your arm in the parallel position, clench your fist. You will see an increase in EMG activity on the EMG channel.
7. Unclench your fist and return to the relaxed position.
8. Check the EMG channel for activity.



at 100% strain with full contraction

Table 2: EMG Calibration Check

A sample reading can be seen here:

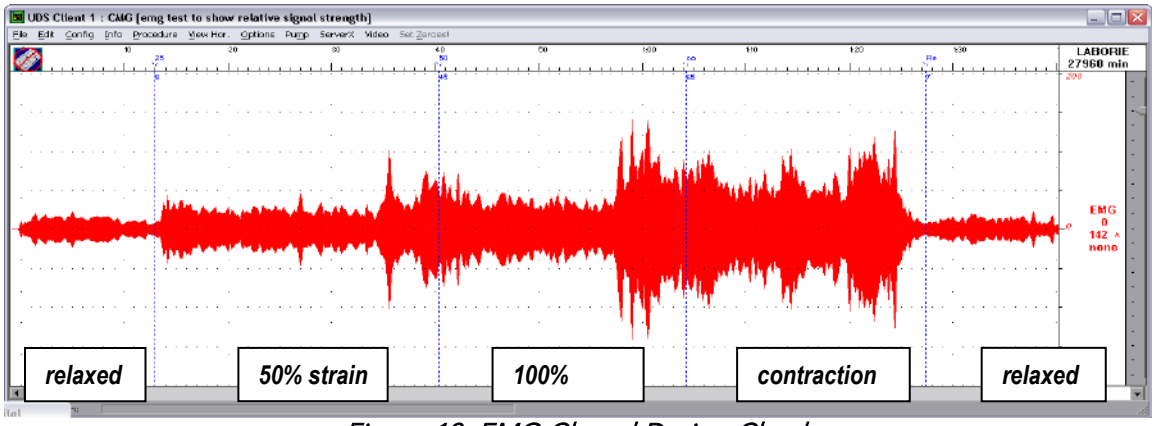


Figure 13: EMG Chanel During Check

If the EMG channel does not display any activity, then calibration is required. ***Once calibration is complete perform a re-check by following the instructions provided above.*** Contact LABORIE service for assistance if problems continue after the calibration and re-check.

2.11.3.2 CHECK THE PRESSURE TRANSDUCER USING T-DOC™

1. Switch the charger on the T-DOC to the **OPEN** position.
2. Connect the catheter to the charger and gently squeeze the balloon on the catheter to expel any air in the balloon.
3. Switch the charger to the **CHARGE** position.
4. Fill a standard graduated beaker with 1000ml of water.
5. Open the **AQUARIUS®** software and start a sample test with pressure channels.
6. Click **Set Zeroes**.
7. Dip the catheter into the beaker until the balloon on the catheter sits just below the water line. The pressure channel should read between 0 and 1 cmH_2O.
8. Carefully lower the catheter into the beaker until the tip gently touches the bottom of the beaker. Do not touch the sides of the beaker.
9. Hold the catheter in a steady position and wait for a reading on the pressure channel.

The pressure channel should display a reading of 15 cmH_2O (+/- 2 cmH_2O). If the reading is above or below the 2 cmH_2O threshold, then calibration is required. ***Once calibration is complete perform a re-check by following the instructions provided above.*** Contact LABORIE service for assistance if problems continue after the calibration and re-check.

2.11.3.3 CHECK THE PRESSURE TRANSDUCER USING WATER CATHETERS

1. Setup the water transducers as described in the Pressure Transducer Setup for Fluid-based Consumables section on page 25.
2. Connect the measurement tubing to the pressure channel of a water catheter, then prime the pressure channel.
3. Open the UDS120 software and start a sample test with pressure channels.
4. Align the catheter pressure hole with the center of transducer dome, Click **Set Zeroes**.
5. Raise the pressure hole of the catheter 15 cm above the center of transducer dome. Hold the catheter in a steady position and wait for a reading on the pressure channel.

The pressure channel should display a reading of 15 cmH_2O (+/- 2 cmH_2O). If the reading is above or below the 2 cmH_2O threshold, then calibration is required. ***Once calibration is complete perform a re-check by following the instructions provided above.*** Contact LABORIE service for assistance if problems continue after the calibration and re-check.

2.11.4 CHECK THE INFUSION TRANSDUCER

Ensure the saline bag does not touch any other mechanical component of the system (such as transducers, etc.) during the calibration check.

2.11.4.1 CHECK THE INFUSION TRANSDUCER USING THE UROFLOWMETER

Ensure the Uroflowmeter is checked and calibrated before checking the infusion transducer. To check the Uroflowmeter, refer to the Check the Flow and Volume of the Urocap™ V Uroflowmeter section on page 12.

1. Place a full infusion bag on the infusion transducer.
2. Place an empty beaker on the Uroflowmeter.
3. Open the **AQUARIUS®** software and start a sample test with a VH2O channel.
4. Click **Set Zeroes**.
5. Infuse 1000ml into the beaker on the Uroflowmeter. Read the volume channel to track infused volume.

The volume on the channel should match the volume emptied into the beaker. If there is a strong difference (+/- 10 ml) between the volume from the infusion bag and that of the volume displayed on screen, then a calibration is required. ***Once calibrated, perform a re-check with the instructions provided above.*** Contact LABORIE service for assistance if problems continue after the calibration and re-check.

2.11.4.2 CHECK THE INFUSION TRANSDUCER USING AN INFUSION BAG

1. Place a full infusion bag, with a declared volume of 1000ml at maximum, on the infusion transducer.
2. Open the UDS120 **Goby™** software and start a sample test.
3. Click **Set Zeroes**.
4. Remove bag and replace with an empty infusion bag.
5. Read the volume channel.

If there is a strong difference on the channel volume compared to the declared weight of the infusion bag, +/- 10ml, then calibration is required. ***Once calibrated, perform a re-check with the instructions provided above.*** Contact LABORIE service for assistance if problems continue after the calibration and re-check.

2.11.5 CHECK THE UPP PULLER

1. With a pencil, mark two points 50mm apart along the UPP puller shaft.
2. Open the **AQUARIUS®** software and start a sample UPP test.
3. Move the UPP to the distal (furthest) marker on the puller shaft.
4. Start a timer and then run the puller and measure the time it takes for the UPP puller to move to the proximal (closer) mark on the puller shaft.

The puller should stop at the proximal (closer) mark after 50 seconds (+/- 3 seconds). If the UPP puller does not move to the proximal mark in the required range of time, then calibration is required. ***Once calibration is complete perform a re-check by following the instructions provided above.*** Contact LABORIE service for assistance if problems continue after the calibration and re-check.

2.12 SAFELY MOVING THE CART

1. Before moving the cart, always make sure that all system components are disconnected from the main power source.
2. The cart should be in transport position before moving. Transport position consists of the following items:
   - All caster wheels should be unlocked.
   - Secure all loose parts and accessories.
   - Do not move the cart while connected to the main power source.
   - Do not move the cart while connected to separate accessories (furniture, etc.).
   - Monitors should be swiveled for maximum clearance when passing through doorways.
   - All drawers and doors should be closed and secure (if applicable).
   - All cables and tubes should be organized and contained to prevent trip hazards.
3. Maneuver the cart by grasping the cutout area on the keyboard tray. If there is no cutout, apply force horizontally to the highest tray with two hands.
4. Do not push the cart. Pull the cart as shown in *Figure 14* .

Figure 14: Safe movement of cart

5. Do not move the cart faster than average walking speed (1.4 m/s or 4.6 ft. /s).
6. Do not go over obstacles higher than 10 mm or 0.4 inches.

⚠ CAUTION: To prevent any risk of damage to the cart:

- Do not lean on trays, accessories, monitors, main tower, or spine of any carts.
- Monitor should be free of any obstacles. Do not hang anything on the monitor. Do not suspend extra weight from the monitors.
- Maximum weight on the work trays should not exceed more than 22 lbs. (10 kg).

3 SOFTWARE AND EQUIPMENT SETUP

3.1 SOFTWARE INSTALLATION

The **AQUARIUS®** software is installed prior to shipping. Only install the software if it has been accidentally uninstalled or if an upgrade is required. Installation instructions are available in the *Software Installation Guide* located in the LABORIE software disc.

NOTE: Some software features may be optional. Check with your LABORIE representative for details.

IMPORTANT: Do not upgrade any Microsoft Windows® 7 PC/laptop to Microsoft Windows® 10 OS as UDS systems and software provided by LABORIE are tested as a complete package and will not work correctly after such an update. Please contact your LABORIE support representative for more information.

3.2 STANDARD EQUIPMENT AND OPTIONAL ACCESSORIES

The **AQUARIUS®** is available in four models each with a Central Hub Computer (CHC) that houses the pump, connection ports for cables, and more. Verify that all ordered equipment and accessories have been received. Please contact LABORIE if there are any discrepancies between ordered and received equipment. Inspect the equipment for any visible signs of damage or mishandling. Notify the carrier immediately if damage is found.

NOTE: Save carrying cases and cartons to provide a convenient and safe way to return the equipment should service be required.

Refer to Table 3 for an overview of modules and parts available in each configuration:

AQUARIUS® LT	AQUARIUS® CT
○ Laptop ○ Keyboard/worksurface shelf ○ 1 **Roam™** DX (maximum) ⊖ AQUARIUS Central Hub Computer (CHC) ⊖ 1 Charging Bay for **Roam™** DX ○ Infusion transducer holder with drip cup (optional) ○ Pump - 4 roller ○ LIT (Isolation Transformer) ○ Uroflowmeter (**Urocap™ V** or Spinning Disk Flow Transducer) (separate charging plug supplied) ○ UPP Puller with Bracket or Stand (optional) ○ Sensor Array Extension Mount (optional) ○ Printer Shelf and Color Printer (optional)	○ All In One (AIO) PC ○ Keyboard/worksurface shelf ○ 2 **Roam™** DX ⊖ AQUARIUS Central Hub Computer (CHC) ⊖ 2 Charging Bays for **Roam™** DX ○ Infusion transducer holder with drip cup(optional) ○ Pump – 4 roller ○ LIT (Isolation Transformer) ○ Uroflowmeter (**Urocap™ V** or Spinning Disk Flow Transducer) (up to 2; separate charging plug supplied) ○ UPP Puller with Bracket or Stand (optional) ○ Sensor Array Extension Mount (optional) ○ Video (optional) ○ Printer Shelf and Color Printer (optional)
AQUARIUS® XT	**AQUARIUS® CTS**
○ All In One (AIO) PC ○ 2nd Monitor ○ AQUARIUS Tower and AQUARIUS Computer Workstation ○ Keyboard/worksurface shelf ○ 2 **Roam™** DX ⊖ AQUARIUS Central Hub Computer (CHC) ⊖ 2 Charging Bays for **Roam™** DX ○ Infusion transducer holder with drip cup (Optional) ○ Pump – 4 Roller ○ 2 LIT – one for workstation and one for tower (Isolation Transformers ○ Uroflowmeter (**Urocap™ V** or Spinning Disk Flow Transducer) (up to 2; separate charging plug supplied) ○ UPP Puller with Bracket or Stand (optional) ○ Sensor Array Extension Mount (optional) ○ Video (optional) ○ Printer Shelf and Color Printer (optional)	○ All In One (AIO) PC ○ Keyboard/worksurface shelf ○ 2 **Roam™** DX ⊖ AQUARIUS Central Hub Computer (CHC) ⊖ 2 Charging Bays for **Roam™** DX ○ Pump – 4 roller ○ LIT ○ Uroflowmeter (**Urocap™ V** or Spinning Disk Flow Transducer) (up to 2; separate charging plug supplied) ○ Wireless Color Printer ○ Infusion transducer holder with drip cup(optional) ○ UPP Puller with Bracket or Stand (optional) ○ Sensor Array Extension Mount (optional) ○ Video (optional)

Table 3: AQUARIUS® System Configurations

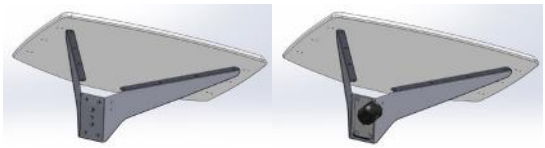
3.3 EQUIPMENT SETUP

3.3.1 CART SETUP

LABORIE recommends to setup the AQUARIUS® cart as follows:

1. Open shipping box.

2. For carts with shelves, lift and align shelf with screws and slide into position. Tighten screws using 1/8" hex key.

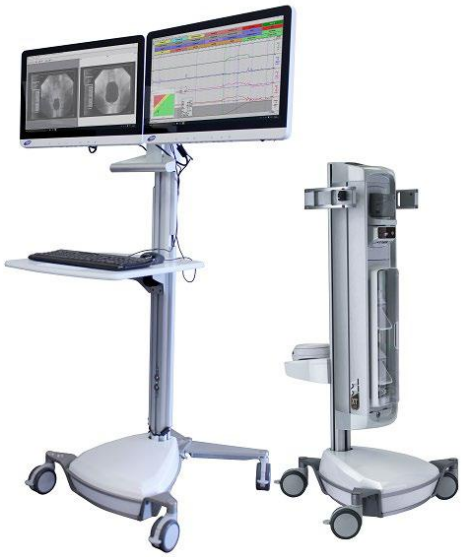


3. Place the plastic bottom cover on cart base.

4. Secure the power cord at the system base, located at the back of the cart, and connect the system power cable to an electrical outlet.

AQUARIUS LT

AQUARIUS CT



AQUARIUS XT

AQUARIUS CTS

Table 4: Cart Setup

3.3.1.1 RESET BUTTON

Use reset button to stop system. It will stop all moving components such as the pump and UPP as well as provide a reset to the digital portion of the Urodynamic processor. The system is designed to automatically stop or reset when the firmware is unresponsive after 5 seconds.

3.3.1.2 LOCKABLE WHEELS SETUP

Use the **AQUARIUS®** lockable wheels as follows:

IMPORTANT: Ensure all wheels are locked during testing procedures to prevent injury to the patient.

The **AQUARIUS®** system is equipped with built-in locking caster wheels, making it a mobile unit that can be moved from room to room. This is also a safety feature to ensure that the unit will remain securely in place and will not move during tests.

To lock the wheels, press down on the lever with the bottom of your foot (Figure 15). To unlock, push the lever up from underneath with the top of your foot.

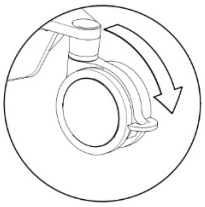
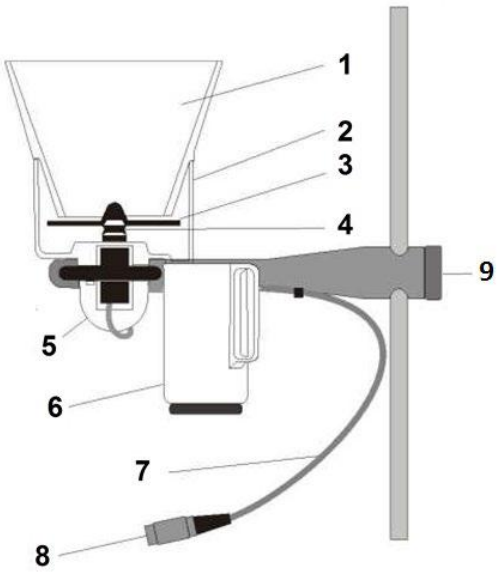


Figure 15: Lockable Wheels

3.3.1.3 SPINNING DISK FLOW TRANSDUCER SETUP

LABORIE recommends the Spinning Disk Flow Transducer setup as follows:



1 = Splash guard

2 = Transducer cup

3 = Rotating disk

4 = Disk holder

5 = Motor housing

6 = Jug (1.5L steel; 1L white)

7 = Motor cable

8 = Connector (connect to control box on the stand)

9 = Uroflow holder (turn the end of the holder clockwise to secure it tightly on to the stand)

NOTE: Ensure that all cables are organized and contained to prevent trip hazards.

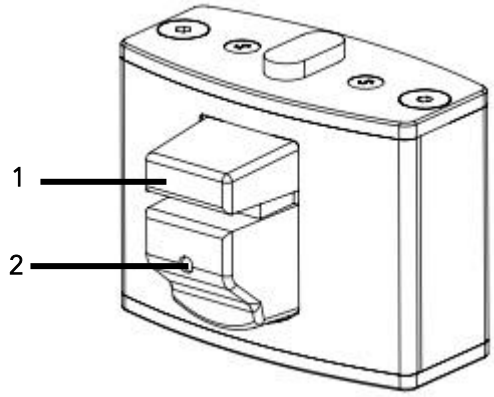
Table 5: Spinning Disk Flow Transducer Setup

3.3.1.4 FLOWSTAND

For assembly instructions see the ***AQUARIUS®*** *Flowstand User Assembly Instruction* booklet on the LABORIE Software Disc.

3.3.1.5 BUBBLE DETECTOR (OPTIONAL)

A bubble detector is connected the Central Hub Computer (CHC) to help detect air bubbles in the pump tubing. To set up the detection feature in the software, see page 180.



1 = Tubing from pump placed in groove

2 = LED light:

Green = no air bubbles

Red=air bubbles detected

NOTE: To avoid errors, make sure the pump tubing is pushed securely and completely into the groove.

3.4 UPP PULLER (OPTIONAL)

The battery powered UPP Puller mounted on the cart or on the puller stand can be used when performing urethral pressure profile tests. The UPP Puller consists of the Nose, the Motor Body, the Arm, and the Stand.

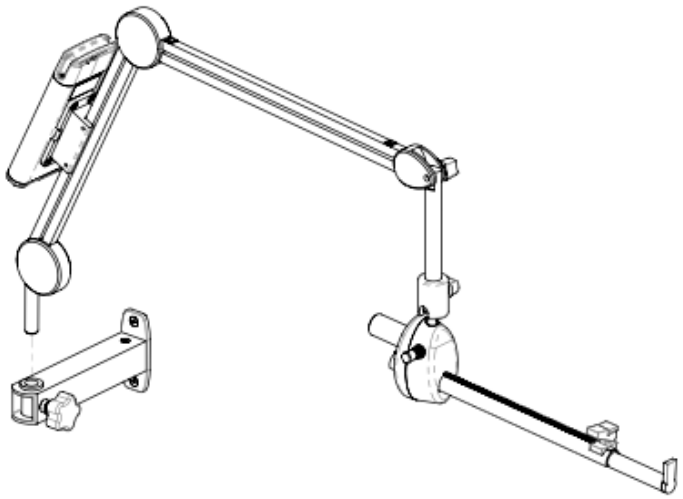


Figure 16: UPP Cart Mount

Figure 17: UPP stand

Remember to connect the UPP to the system. For more information on connection, see How to Add a Device to the System on page 36.

3.4.1 ASSEMBLE THE PULLER STAND (OPTIONAL)

To assemble the Puller Stand (UPP1006), prepare one 6mm and one 4mm HEX L-KEY.

1. Connect the Pole Assembly to the H-Base Assembly using the provided Washer M8, Split Washer M8, and Screw M8. Use the 6mm HEX L-Key to secure the screw (Figure 18).
2. Slide the Clamp Assembly into the post of the Puller Base Assembly and lock it in position with the Knob Screw provided. Use a 4mm Hex L-Key to insert the Puller into the Clamp Assembly (Figure 18).

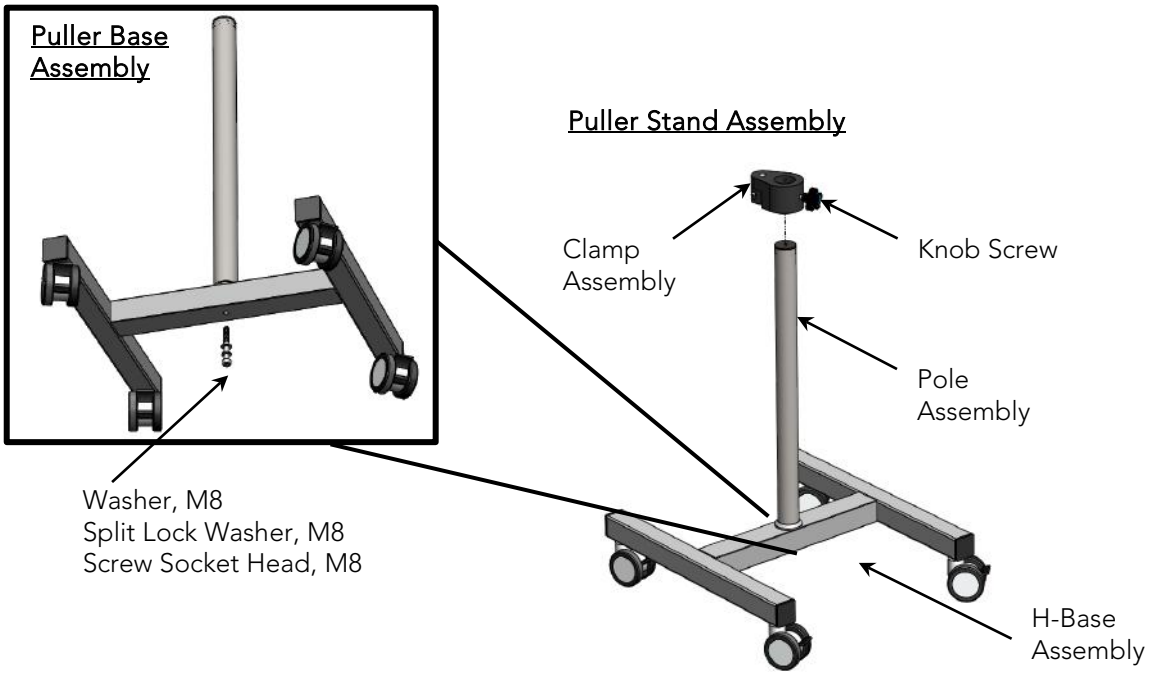


Figure 18: Puller Base and Puller Stand Assembly

3.4.2 Arm and Stand

The adjustable arm contains the electrical control pad (Figure 19). The UPP's speed setting is set in the UDS software program. The working range can be set for speeds varying from 0 to 3 mm/s.

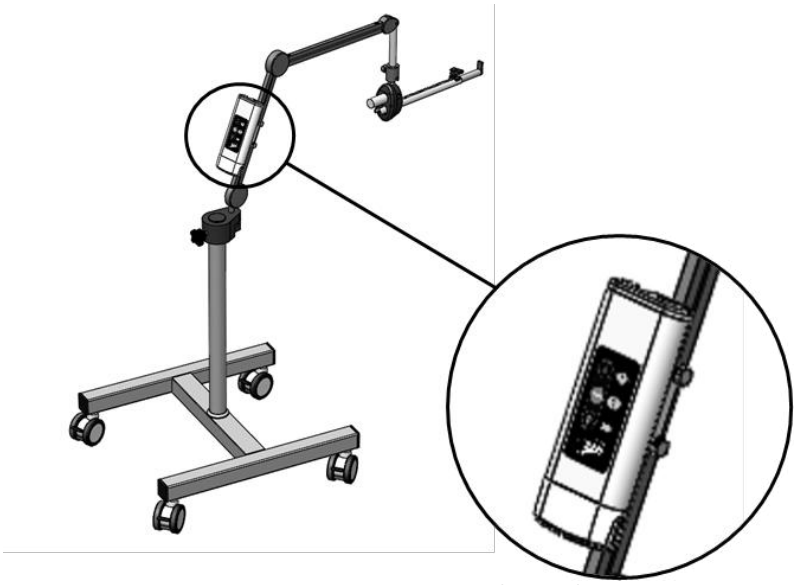


Figure 19: UPP Arm and Stand

3.4.3 Nose and Motor Body

Refer to Figure 20 below for an overview of the UPP Nose and Motor Body:

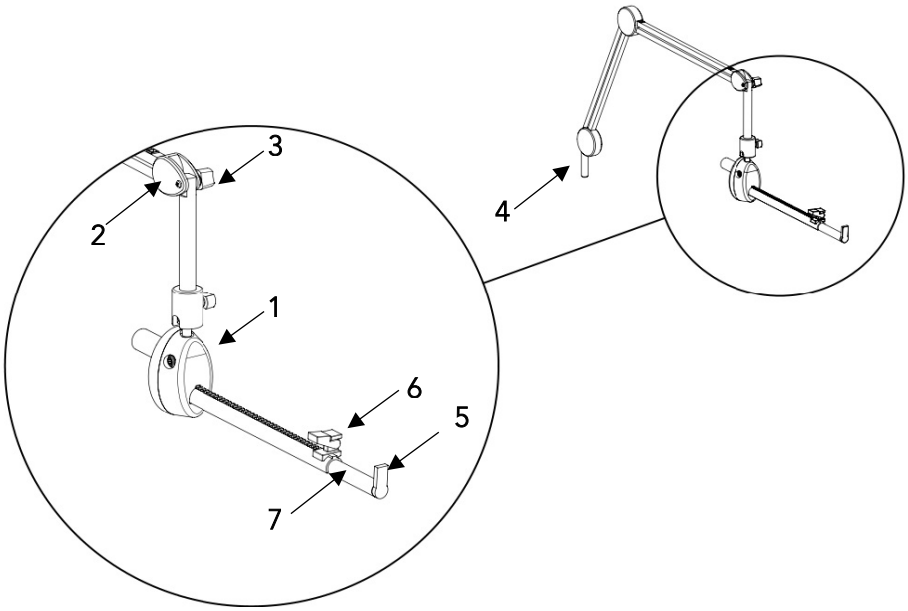


Figure 20: *UPP Nose Unit and Motor Body*

The **motor body** (1) is held by a **universal joint** (2) so that the system can be positioned to a preferred angle.
On the side of the universal joint is a **ball-joint knob** (3), which can be loosened to allow you to move and reset the nose unit in different directions. The power supply to the motor comes from a **cable** (4) extending from the adjustable arm. This cable is plugged into the side of the body.

The catheter is held and pulled via the nose section. It is guided through the **catheter guide** (5) and fixed at the **mobile clamp** (6). When the drive is engaged, the catheter will be pushed or pulled along the **nose tube** (7). For sterilization purposes, both the **catheter guide** and the **mobile clamp** may be removed.

3.5 UROCAP™ V AND SPINNING DISK FLOW TRANSDUCER SETUP

3.5.1 UROFLOW TRANSDUCER

The Flow Transducer is intended to sense voiding flow. It is used together with UDS devices for assessing voiding disorders.

The AQUARIUS system is compatible with the **Urocap™ V** and the Spinning Disk Flow Transducer. Once the Uroflow Transducer of choice and its accessories are removed from their packaging, setup the Uroflow Transducer, the chair, and the beaker. The Bluetooth technology built into the Uroflow Transducer provides the patient with a higher degree of privacy during voiding. The Uroflow Transducer, beaker, commode chair, and funnel can be set up in one room while the computer and printer are positioned in another room collecting and printing data.

IMPORTANT: It is critical the beaker is well centered on the **Urocap™ V.** Ensure that the beaker and the funnel are aligned but not touching.

1. Place the funnel on the plastic frame of the commode chair.
2. Carefully place the Uroflow transducer on the floor.
   a. If using a **Urocap™ V**, place a graduated beaker on top of the transducer (Figure 21).
   b. If using a Spinning Disk Flow Transducer, place the metal beaker under the flow transducer outlet (Figure 22).
3. Place the commode chair and funnel over the **Urocap™ V** and beaker or over the Spinning Disk Flow Transducer.

Figure 21: Urocap™ V Setup

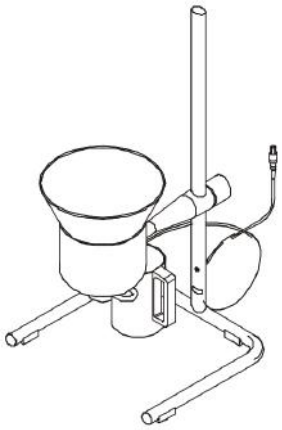


Figure 22: Spinning Disk Flow Transducer Setup

3.6 INFUSION VOLUME TRANSDUCER (OPTIONAL)

1. Ensure that the infusion transducer cable is connected to the Pump module.
2. Place a 1000 ml bag of sterile saline inside a pressure cuff. Hang the pressure cuff on the hook of the infusion transducer. Use an infusion pressure cuff for faster flow rate
3. Inflate the pressure cuff to 300 mmHg (when the red line appears on the pressure cuff gauge).
4. Connect an infusion line with a drip chamber to the saline bag.

IMPORTANT:

- Ensure that the infusion line is *not* pulled tight or else the transducer reading will not be accurate.
- The infusion transducer is calibrated for up to 1000 ml of sterile saline or water. If using a different medium, such as hypaque, re-calibration is required.
- The saline bag must not touch any other mechanical component of the system (such as transducers, etc.).

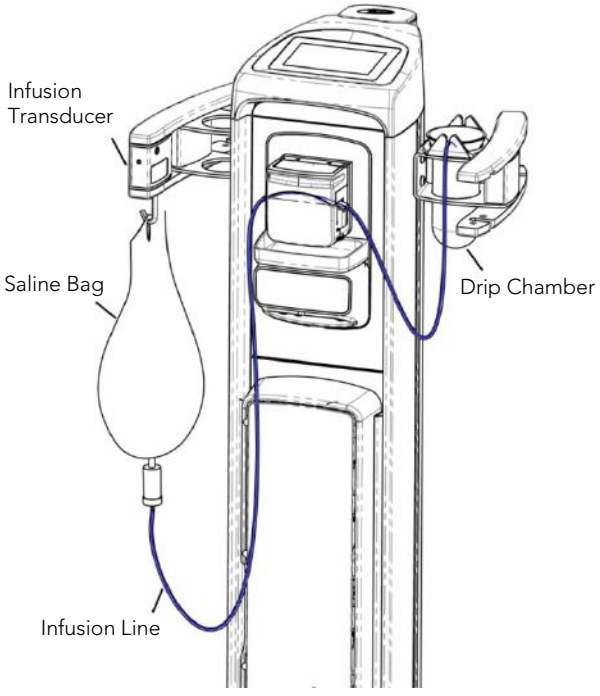


Figure 23: Infusion Transducer Connections

3.7 PUMP SETUP

Pump accuracy is not guaranteed if the pump tubing is used more than once. DO NOT run pump at a speed exceeding the limitation of the catheter and do not run pump at a high speed with a contrast medium.
To maintain patient safety during normal use, the pressure limit for the pump is preset to 150 cm H_2O and the volume limit is preset to 750mL.

1. Hang a bag of saline solution on the IV pole hook and insert pump tubing spike into the bag.
2. Flush the line completely.
3. Use the thumbwheel to close tubing and stop the flow.
4. Open pump head. Position compressible portion of pump tubing across rollers from left to right.
5. Close pump head.
6. Open the thumbwheel on the pump tubing.

3.8 ROAM™ DX SETUP FOR PRESSURE AND EMG

Roam™ DX Connections:

Insert the EMG cable into the **Roam™ DX** port labeled E2.

Attach the P1 cable to the port labeled "1" on the **Roam™ DX** and attach the P2 cable to the port labeled "2" and so on.

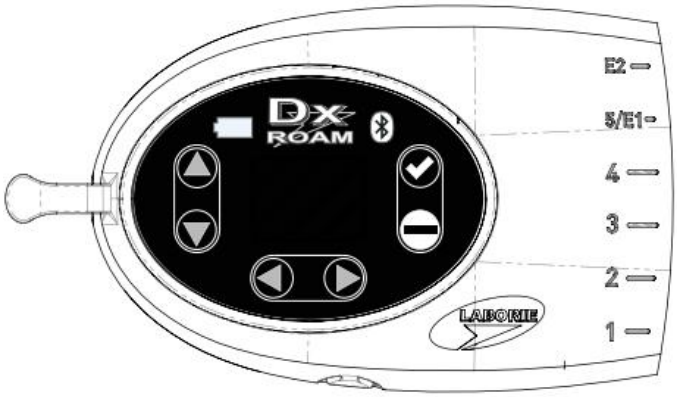


Figure 24: Roam™ DX

Roam™ DX Setup with a Patient:

If placed on the patient, position the **ROAM™ DX** either on a waist belt, on a lanyard, or on a waist strap. Alternatively, place the **Roam™ DX** on a nearby table/counter at level with the patient's waist (or higher). This will help prevent any liquid from dripping along the cables to the **Roam™ DX** device when the patient voids.

Figure 25: Roam Patient Setup

3.9 CONSUMABLES AND TRANSDUCER SETUP

3.9.1 PRESSURE TRANSDUCER SETUP FOR FLUID-BASED CONSUMABLES

To Set-up the Fluid-Filled Pressure Transducer for a test follow the instructions below. Refer to Figure 26 for a visual representation of the steps provided.

1. Take each pressure cartridge out of its package. Remove protective covers from the back and from the connector ends.
2. Slide a cartridge over each transducer until it clicks in place.
3. Attach pressure measurement tubing, with a three-way stopcock, to the lower (male) end of the pressure cartridge.
4. Attach a 10 ml sterile fluid filled syringe to the side port of the stopcock.
5. By turning the stopcock lever in appropriate directions, flush fluid from syringe through both the pressure cartridge and the pressure measurement tubing. Refer to Figure 20.

NOTE: Be sure that the stopper cap is always securely in place whenever the stopcock position is being changed. Always keep transducers level with the patient's symphysis pubis.

CAUTION: AIR BUBBLES must not be present in the system during testing.

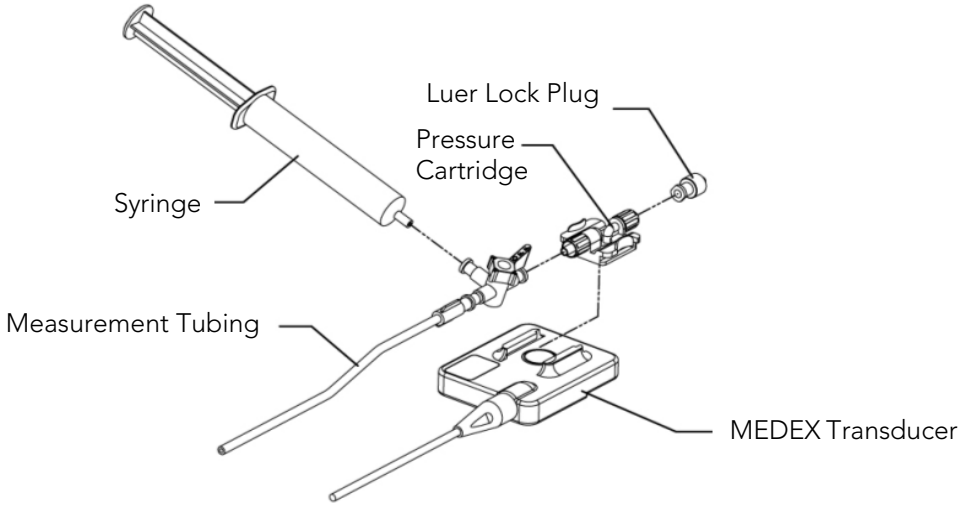


Figure 26: Pressure Transducer Setup

3.9.2 FLUID-FILLED PRESSURE TRANSDUCER CONNECTIONS - PRIMING

Do not plug in or unplug any transducers when a procedure is running. Always stop the procedure before plugging in or unplugging transducers. Follow the instructions provided to prime the transducer, pressure measurement tubing, and catheter:

1. Attach a 3-way stopcock with pressure measurement tubing to the bottom (male) connector of the pressure cartridge. Attach the opposite end of the pressure measurement tubing to the catheter. For TUB101 connect a 3-way stopcock to the tubing before linking to the pressure cartridge.
2. Attach a 3-way stopcock with pressure measurement tubing to the bottom (male) connector of the pressure cartridge. Attach the opposite end of the pressure measurement tubing to the catheter. For TUB101 connect a 3-way stopcock to the tubing before linking to the pressure cartridge.
3. Attach a syringe filled with water or saline to the stopcock.
4. Turn the stopcock "OFF" to the catheter (See Figure 27, Option B).
5. Remove the Luer lock plug from the top (female) connector of the pressure cartridge. Fill the pressure cartridge with water. Reattach the Luer lock plug.
6. Turn the stopcock "OFF" towards the Luer lock plug (See Figure 27, Option D).
7. Prime the pressure measurement tubing and the catheter.
8. Turn the stopcock "OFF" towards the syringe for pressure recording (See Figure 27, Option A).

Each option in Figure 27 indicates a stopcock position; arrows indicate lumens open to flow based on stopcock position while squared off arrows indicate off position.

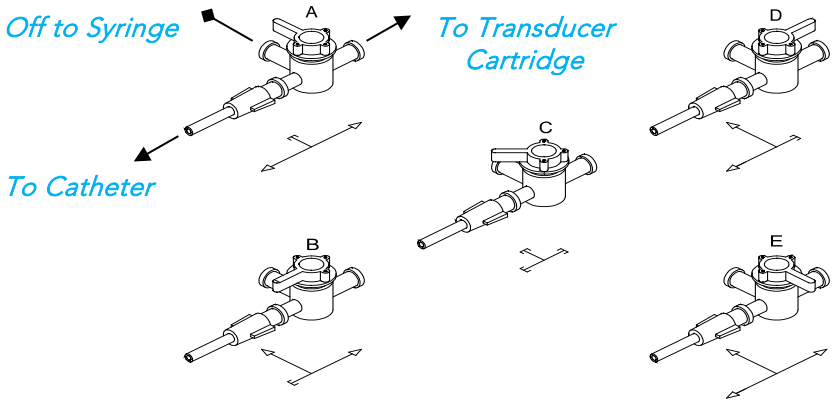


Figure 27: Stopcock Flow Directions

3.9.3 Catheter Setup

The following section is a reference guide to catheter setup and connection.

Ensure that only single-, dual-, and triple-lumen catheters supplied by LABORIE are used for Urodynamic tests involving the UDS System.

Do NOT use Foley catheters, as these catheters are not designed for pressure measurement, bladder infusion, or pressure recording. Do NOT use catheters on patients that suffer from bladder infections or strictures in the urethra.

3.9.4 Fluid-Filled Catheter Setup

3.9.4.1 Bladder Catheter Setup

Use a dual-lumen catheter to record bladder pressures:

1. Connect the infusion line to the bladder filling port of the catheter.
2. Connect the P1 measurement tubing to the vesical port of the catheter.

Use a triple-lumen catheter to simultaneously record urethral pressure and bladder pressures:

1. Connect the infusion line to the bladder filling port of the catheter.
2. Connect the P1 measurement tubing to the vesical port of the catheter.
3. Connect the P3 measurement tubing to the urethral port of the catheter.

3.9.4.2 Two Catheter Technique

To perform a Micturition test during which the patient will void with a vesical catheter in place, use two separate catheters: one narrow/small catheter for pressure measurement and a second for infusion only.

At the end of the filling portion of the study, the catheter used for infusion should be taken out and the catheter used for pressure measurement left in so that bladder pressure can be measured during voiding.

3.9.4.3 ABDOMINAL (RECTAL) BALLOON CATHETERS

Abdominal balloon catheters are used to measure abdominal pressure. Before connecting the balloon catheter to the measurement tubing, the balloon should be primed and be free of any air bubbles.

To prime a single-lumen catheter so it is free from air bubbles:

1. Fill a 20 cc syringe with 10 cc of sterile fluid.
2. Connect the syringe to the balloon catheter.
3. Hold the catheter vertically, in a "U" shape, with both ends facing up.
4. Draw back on the syringe to remove air from the rectal balloon.
5. Push on the syringe until the balloon fills with water.
6. Repeat Steps 4 and 5 until all air bubbles are removed from the balloon and the balloon is full of water.
7. Draw back on the syringe to deflate the balloon for insertion.
8. Depress the Syringe plundger to infuse water back into the catheter. Remove the syringe.
9. Connect the *primed* measurement tubing to the balloon catheter.

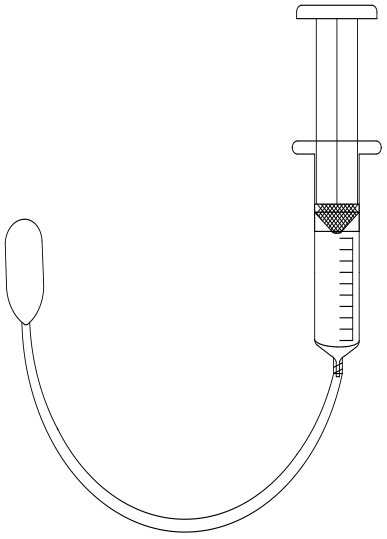


Figure 28: Abdominal Single-Lumen Balloon Catheter Priming

To prime a double-lumen catheter so it is free from air bubbles:

1. Connect the syringe to the longer port.
2. Open the venting port (the shorter port.)
3. Flush the catheter until there are no air bubbles in the balloon.
4. Cap the exhaust port.
5. Draw back on the syringe to deflate the balloon.
6. Clamp the end of the catheter that is to be connected to the measurement tubing.
7. Remove the syringe.
8. Connect the *primed* measurement tubing to the balloon catheter

To Insert a Single or Dual-Lumen Balloon Catheter:

1. Attach a syringe to the stopcock.
2. Insert the rectal balloon into the patient.
3. Turn the stopcock switch OFF to the transducer cartridge (A).
4. Fill the balloon with 1.5-3 cc's of water.
5. Turn the stopcock switch OFF to the syringe (B).

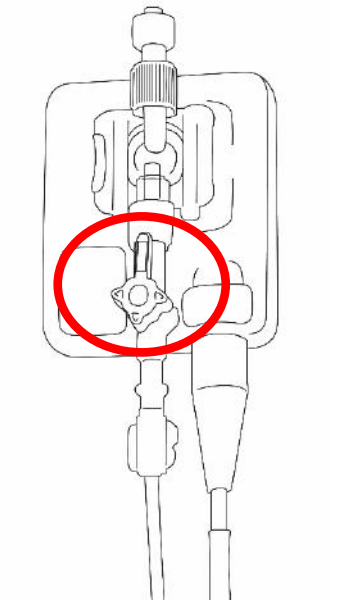


Figure 29: OFF to the Transducer Cartridge

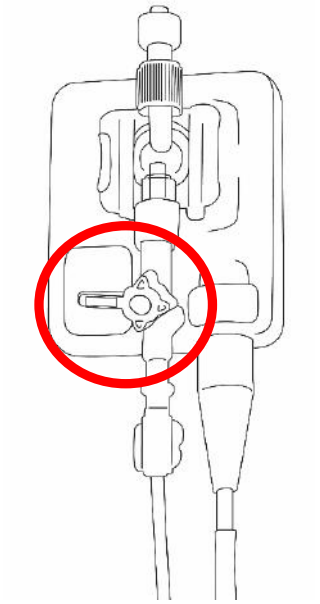


Figure 30: OFF to the Syringe

3.9.5 T-DOC AIR-CHARGED CATHETER SETUP

Follow the instructions provided to setup T-DOC Air-Charged Catheters and Transducers:

1. **Ensure Transducer Cables are connected to the machine.** Check that the charger is in the **OPEN** position.
2. Remove the protective cap from the pressure line and connect it to the matching Transducer Cable. Repeat for all pressure lines. Secure each connection by twisting the luer lock another ¼ turn.
3. Zero all catheters using the **Set Zeros** button in the software.
4. For each pressure transducer verify charging pressure by completing the following:
    a. Squeeze the associated balloon through the packaging to reduce the volume of residual air (use fingertips – not nails).
    b. Move the associated transducer slider to the charge position while still applying pressure.
    c. Remove fingertips and check reading. If pressure is ≤5 cm H2O, return the transducer slider to **OPEN.** If the pressure is >5 cm H2O, move the slider to OPEN and repeat.
5. Remove the catheter from the packaging by holding the catheter just below the Y-junction.
6. Coat the distal end of the catheter with a sterile, water-based lubricant and insert into the patient.
7. Tape the catheters as close to the insertion site as possible.
8. Ask the patient to cough to remove residual air from the balloon.
9. Slide the transducer to the **CHARGE** position. Remove tape and position urethral sensor at the desired point in the urethra, often at the highest-pressure area.
10. Connect the vesical catheter to the pump tubing.

NOTE: Ensure bladder and rectal pressures are within normal values. Have the patient cough and ensure the detrusor pressure (Pdet) is equal to zero and that both Pabd and Pves pressures are reacting appropriately. If Pabd is higher than Pves, reposition the Pabd catheter. Click the Equalize button on the UDS120 control panel.

11. Continue with the testing procedure when ready.

IMPORTANT: Do not plug in or unplug any transducers when a procedure is running. Always stop the procedure before plugging in or unplugging transducers. Ensure to consult Instructions for Use available with product.

3.9.6 EMG SETUP

Before the start of an EMG test:

- The electrodes should be connected to the 3 EMG leads
- The patient's anal area should be clean, dry, and free of hair.

Once the patient's skin is properly prepared, the electrodes may be applied.

- Place two electrodes peri-anally at the 10 o'clock and 2 o'clock position (or the 9 o'clock and 3 o'clock position), as close to the anal verge as possible and placed opposite each other.
- Place the third electrode on a bony prominence (such as the knee) or on a fatty portion of the inner thigh.

IMPORTANT: Ensure the electrodes are placed as close to the anal sphincter as possible or the EMG activity will be weak.

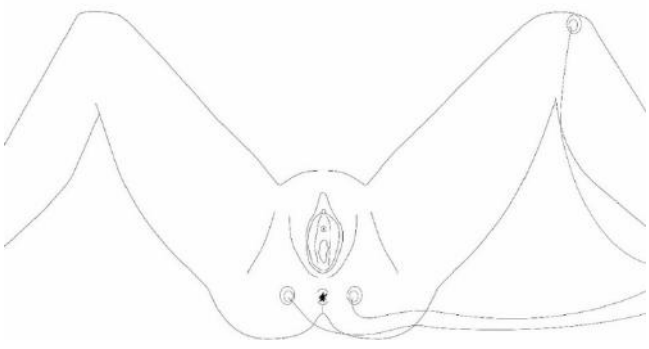


Figure 31: EMG Patch Placement.

NOTE: LABORIE recommends that each electrode be secured in place with an additional piece of surgical tape. If the electrodes detach, dry the skin and apply new surgical tape.

4 EQUIPMENT STATUS AND LIGHT SIGNALS

4.1 PUMP HUB

1 = Bluetooth Status indicator:

- **blue**= connected
- **green**= system at work but not connected
- **orange** = System fault
- **light off** = not connected

2 = Equipment Status Indicator:

- **green** = connected
- **blinking green** = connected and sampling
- **orange** = System fault
- **blinking orange** = not connected
- **light off** = system off

3 = Stop button:

- Press to stop pump
- Press and hold for 5 seconds to reset

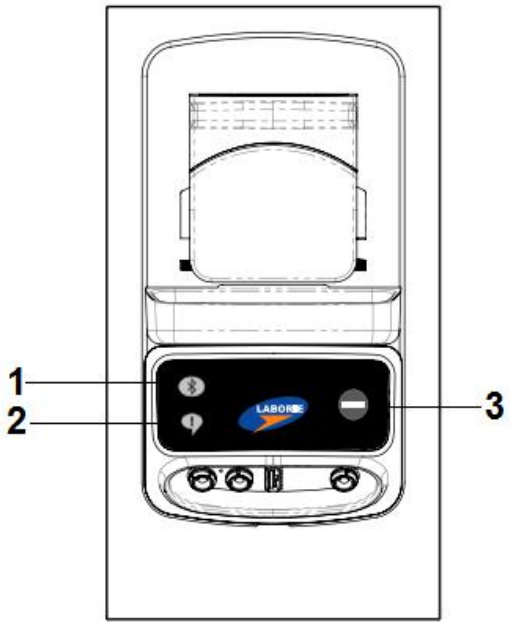


Figure 32: Pump Buttons and Indicators

1 = Infusion Transducer Connection:
Plug the infusion transducer cable into the port(s).

2 = USB port:
Connect the USB cable from the UPP or the **Urocap™ V** into the port.

3 = BDT:
Plug the cable from the bubble detector into this port.

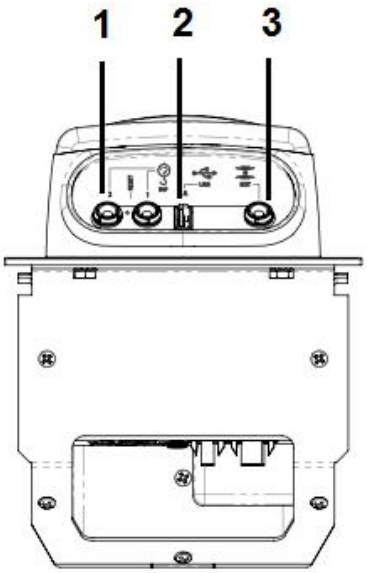


Figure 33: Pump Connections

4.2 ROAM™ DX

Refer to Figure 34 for identification of buttons and indicators available on the Roam™ DX.

1 = Toggle keys to move from screen to screen or setting to setting

2 = Start and stop buttons/ on-off power button (OK/Stop)

3 = Battery and Bluetooth status

4 = Message screen

For more information on the buttons and indicators described refer to Table 6.

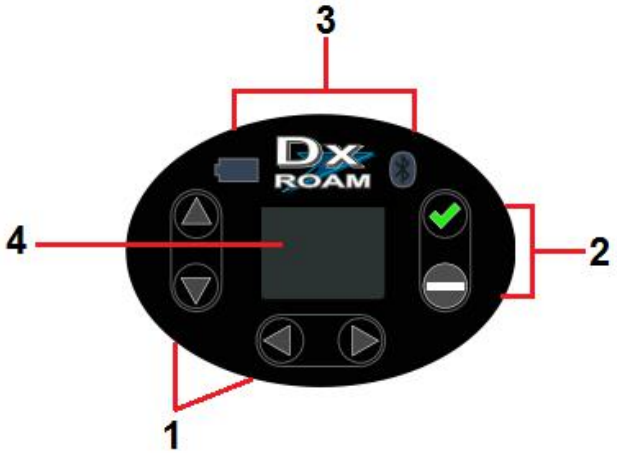


Figure 34: Roam DX Buttons and Indicators

*Toggle Keys (**1**):*	
Normal mode = Moving from one screen to another. **Changing settings mode** (*see screen descriptions on following pages*) = Moving from one line to another.	
Changing settings mode (*see screen descriptions on following pages)* = Increase/decrease selected value or scroll through options.	
*Start/Stop/OK (**2**):*	
Manual wake-up from hibernation. **Press** for 5 seconds to enter changing settings mode. **Single push** = Exit from changing settings mode.	
Press for 5 seconds to force device to hibernation mode. **Single push** = Exit from Changing Settings mode.	
*Battery and Bluetooth Status (**3**):*	
Solid green = External power connected; battery fully charged. **Solid green and orange** = External power connected; battery is charging. **Solid orange (no display, no response to keyboard)** = External power connected; battery is charging but battery level is still below critical. Just wait till battery is pre-charged. **Blinking green** = No external power. Battery is OK. **Blinking orange** = No external power. Battery is low. Connect external power immediately.	
OFF = Bluetooth channel is disconnected. **ON** = Bluetooth channel is connected. Every transmitted block forces this LED to blink.	

Message Screens (4):
Pressure sensor port status (P1, P2, P3, etc…) • If a field is empty, no function has been selected for this port (see Set up/Modify on page 65). • **E** means EMG is selected for this port. • Scroll bar displays current level of pressure signal. • "Stars" display the last calibration levels of this port: bottom for low level and top for high level. If both Stars are aligned at the border to the right, the port has not yet been calibrated. • Stars are blinking when device is sending EMG and pressure samples to UDS.
Port connection (USB or Bluetooth) • **PC Bond** = Check mark indicates that device is currently bonded to UDS. This icon is blinking when device is sending EMG and pressure samples to UDS • **BT** = Bluetooth Address • **Battery** = Displays current battery voltage (4.2 – full; 3.6 – empty) and charger status: Battery Full, Charging or Battery Powered (no external power)
System Information • **Unit** = **Roam™** serial number • **Ver** = Firmware version

Table 6: Functions of Roam Buttons and Indicators.

4.3 UROCAP™ V

The Urocap™ V LED indicators are described below. Refer to Figure 35 for the location of the LED Indicators on the device.

BT (Bluetooth)
blue = connected
green = system at work but not connected
orange = system fault
light off = not connected

Equipment status
green = connected
blinking green = connected and sampling
orange = System fault
blinking orange = not connected
light off = system off

Power
green = battery full and plugged into charger
blinking green= battery good
orange = charger plugged and battery charging; battery not fully charged
blinking orange = low battery; time to re-charge
light off = battery empty; re-charge

Figure 35: Front of Urocap™ V

The Urocap™ V buttons are described below. Refer to Figure 36 for the location of buttons on the device.

ON button = use to "wake up" Uroflowmeter

Reset button = Press and hold for 5 seconds or longer to bring to sleep


Figure 36: Bottom of Urocap™ V

4.4 UPP

The control pad on the UPP arm has buttons and indictors for use during a study as described below. Refer to Figure 37 for the location of buttons and indicators on the device.

1 = Arrows (up and down):
- Press UP to pull the arm
- Press DOWN return the arm

2 = UPP Stop button:
- Press to stop UPP
- Press and hold for 5 seconds or longer to bring to sleep

3 = Battery Status Indicator:
- **green** = battery full and plugged into charger
- blinking green = battery good
- **orange** = charger plugged and battery charging; battery not fully charged
- **blinking orange** = low battery; time to charge
- **light off** = battery empty; re-charge

4 = Bluetooth Status Indicator:
- **blue** = connected
- **green** = system at work but not connected
- **orange** = System fault
- **light off** = not connected

5 = Equipment Status Indicator:
- **green** = connected
- **blinking green** = connected and sampling
- **orange** = System fault
- **blinking orange** = not connected
- **light off** = system off

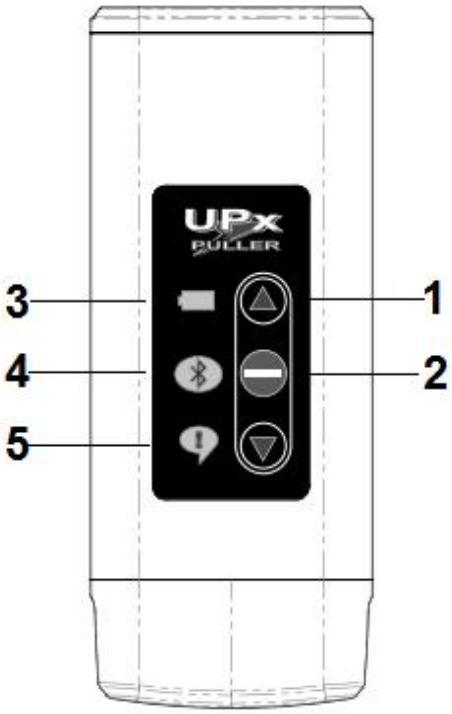


Figure 37: UPP Buttons and Indicators

NOTE: Closely monitor the battery level of the UPP when in use.

4.5 WIRELESS PRINTER SETUP

4.5.1 BEFORE YOU BEGIN

Ensure the following:
- The wireless network is set up and working properly.
- The printer and the computers that use the printer are on the same network (subnet).

While connecting the printer, you might be prompted to enter the wireless network name (SSID) and a wireless password.
- The wireless network name is the name of your wireless network.
- The wireless password prevents other people from connecting to your wireless network without your permission. Depending on the level of security required, your wireless network might use either a WPA passphrase or WEP key.

If you have not changed the network name or the security passkey since setting up your wireless network, you can sometimes find them on the back or side of the wireless router. If you cannot find the network name or the security password or cannot remember this information, see the documentation provided with your computer or with the wireless router. If you still cannot find this information, contact your network administrator or the person who set up the wireless network.

4.5.2 SET UP THE PRINTER ON YOUR WIRELESS NETWORK

To set up the printer on your wireless network use the Wireless Setup Wizard from the printer control panel to set up wireless communication.

1. On the printer control panel, from the Home screen, touch (Wireless).
2. Touch (Settings).
3. Touch Wireless Setup Wizard or Wi-Fi Protected Setup.
4. Follow the display instructions to complete the setup.

If you are already using the printer with a different type of connection, such as a USB connection, follow the instructions in the To Change Connection Method section on page 33 to set up the printer on your wireless network.

4.5.3 Print Using Wi-Fi Direct

Using Wi-Fi Direct, print wirelessly from a computer, smart phone, tablet, or other wireless-capable device—without connecting to an existing wireless network.

4.5.3.1 Guidelines For Using Wi-Fi Direct

- Ensure the computer or mobile device has the necessary software. If using a computer, make sure you have installed the HP printer software. If you have not installed the HP printer software on the computer, connect to Wi-Fi Direct first and then install the printer software. Select Wireless when prompted by the printer software for a connection type.
- Make sure Wi-Fi Direct for your printer is turned on.
- Up to five computers and mobile devices can use the same Wi-Fi Direct connection.
- Wi-Fi Direct can be used while the printer is also connected either to a computer using a USB cable or to a network using a wireless connection.
- Wi-Fi Direct cannot be used to connect a computer, mobile device, or printer to the Internet.

4.5.3.2 To Turn On Wi-Fi Direct

1. On the printer control panel, from the Home screen, touch (Wi-Fi Direct).
2. Touch (Settings).
3. If the display shows that Wi-Fi Direct is Off, touch the toggle button next to Wi-Fi Direct to turn it On.

4.5.3.3 To Change Connection Method

1. On the printer control panel display, from the Home screen, touch (Wi-Fi Direct).
2. Touch (Settings).
3. Touch Connection Method and then select Automatic or Manual.

4.5.3.4 To print from a wireless-capable computer (Windows)

1. Make sure you have turned on Wi-Fi Direct on the printer.
2. Turn on the computer's Wi-Fi connection. For more information, see the documentation provided with the computer.
3. From the computer, connect to a new network. Use the process you normally use to connect to a new wireless network or hotspot. Choose the Wi-Fi Direct name from the list of wireless networks shown such as DIRECT-**-HP ENVY 5000 series (where ** are the unique characters to identify your printer). Enter the Wi-Fi Direct password when prompted.

NOTE: To obtain the Wi-Fi Direct password, touch (Wi-Fi Direct) on the printer's control panel in the Home Screen.

4. Proceed to step 5 if the printer has been installed and connected to the computer over a wireless network. If the printer has been installed and connected to your computer with a USB cable, follow the steps below to install the printer software using the Wi-Fi Direct connection.
    a. Open the HP printer software. For more information, see Open the HP printer software (Windows) on page 15.
    b. Click Tools.
    c. Click Device Setup & Software, and then select Connect a new device.
    d. When the Connection Options software screen appears, select Wireless.
    e. Select your HP printer from the detected printer list.
    f. Follow the onscreen instructions.
5. Print your document.

4.5.4 Change the Connection Type

After you have installed the HP printer software and connected the printer to your computer or to a network, you can use the software to change the connection type (for example, from a USB connection to a wireless connection).

4.5.4.1 To change from a USB connection to a wireless network (Windows)

1. Open the HP printer software.
2. Click Tools.
3. Click Device Setup & Software.
4. Select Convert a USB connected device to wireless. Follow the onscreen instructions.

4.5.4.2 TO CHANGE FROM A WIRELESS CONNECTION TO A USB CONNECTION (WINDOWS)

Connect the printer and the computer with a USB cable. This USB port is at the rear of the printer.

NOTE: A USB connection between the computer and printer can only be used if these two devices are isolated from the patient environment to reduce the risk of electric shock to the patient. LABORIE always recommends the use of a wireless connection between the computer and printer.

5 USING THE MODULE TOUCHSCREEN

5.1 ICONS IN THE TOUCHSCREEN

Set up device connections, perform calibration, and adjust pump controls with the **AQUARIUS®** tower touchscreen.

Refer to Table 7 for an overview of touchscreen icons and their functions:

1 = DEVICE IDENTIFICATION:
Displays device type and connection status.


= wired connection


= Bluetooth connection

2 = DEVICE NAME and SERIAL NUMBER.

3 = POWER:
Displays power on or off to device.

4 = BATTERY:
Displays battery charge level.

5 = PC CONNECTION:


= wired PC connection


= wireless PC connection


= no PC connection; tap to turn OFF or restart the central hub computer.

6 = CALIBRATION:
Tap to open calibration procedure for each device. See page 44 for more information.

7 = PUMP CONTROLS: tap to open pump settings menu.
See page 38 for more information.

8 = SETTINGS: tap to add devices, remove devices, and configure connections.
See page 32 for more information.

9 = REMOTE CONTROL CONNECTION.

HOME
Tap to return to the Home (main) screen. Only visible when adding devices, removing devices, setting up pump controls, and calibration.

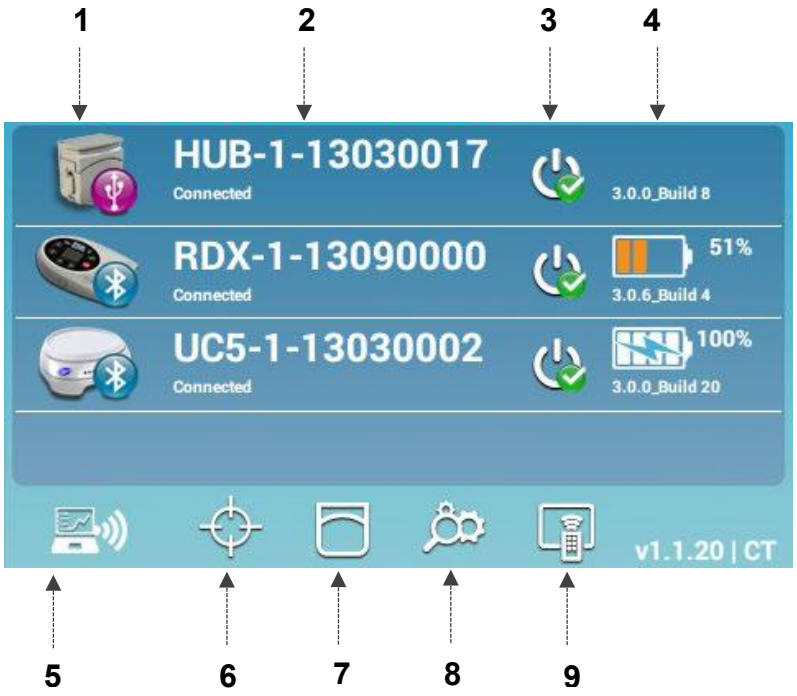


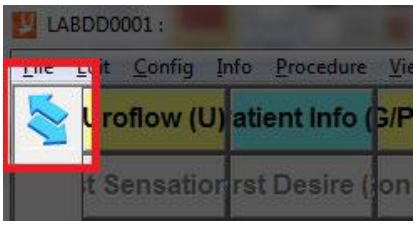
Table 7: Module Touchscreen Icons

5.2 SYSTEM STATUS MESSAGES

System status messages display the current status of the device modules configured with the system.

5.2.1 MESSAGES ON THE COMPUTER SOFTWARE

The following symbol indicates that the System and software are connected and functioning:



NOTE: There may be a 1 to 2-minute delay from when the software starts and when it establishes a connection to the system.

5.2.2 MESSAGES ON THE CHC TOUCHSCREEN

System Status messages are communicated per device on the CHC touchscreen. Look under the device serial number for status information. Table 8 below provides an overview of common system status messages:

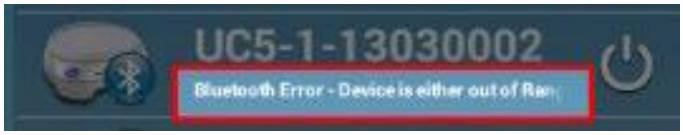
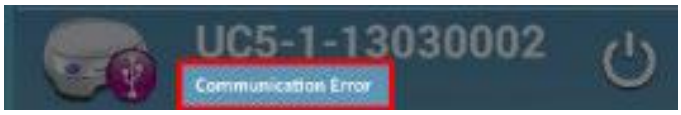
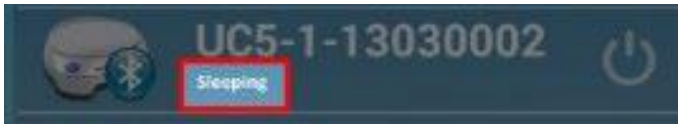
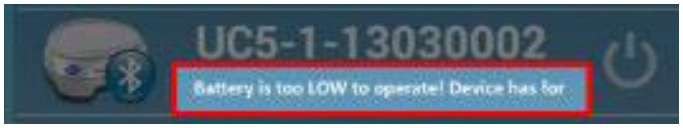
Bluetooth Error: This occurs when the Central Hub Computer (CHC) attempts to connect to the device module via Bluetooth but fails. The device may be out of range or the battery is depleted.	
USB Error: This occurs when the Central Hub Computer (CHC) attempts to connect to the device module via USB but fails. The device`s USB cable may not be plugged-in.	
Communication Error: This occurs when the Central Hub Computer (CHC) successfully connects via Bluetooth or USB but fails to communicate (Bond) with the firmware on the device module. Try resetting the power on the device module.	
Device Hibernation: This occurs when the Central Hub Computer (CHC) puts the device module into 'Sleep' mode. This is usually after 2 hours of inactivity. After 5 minutes, the LCD turns off. If the UDS software is running, it will put the device to sleep.	
Battery LOW Disconnect: This occurs when the device battery is very low. The firmware forces a disconnection. This will not occur if the USB charger is plugged-in. The status message scrolls across the screen.	
Battery LOW: This occurs when the device battery is very low. Recharge the battery.	
Battery SUSP: This occurs when the battery reaches a temperature above 45°C (113°F) or the power supply is not properly connected to the Central Hub Computer (CHC). This status message appears under the battery icon. Disconnect the **Roam™** DX from the power supply then reconnect. If the message still appears, contact LABORIE technical support.	

Table 8: CHC - System Status Messages

NOTE: System messages can be found in the Software's title bar.

5.3 USING THE TOUCHSCREEN FUNCTIONS

5.3.1 HOW TO ADD A DEVICE TO THE SYSTEM

Follow the instructions below to connect any additional devices including the **Urocap™ V** Uroflowmeters, UPP pullers, or **Roam™** DX.

NOTE: Make sure the UDS software is closed when connecting devices. Make sure to restart system after adding all NGM devices.

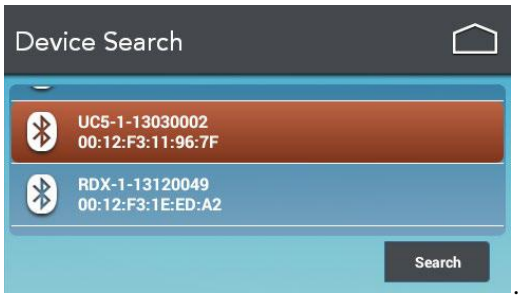
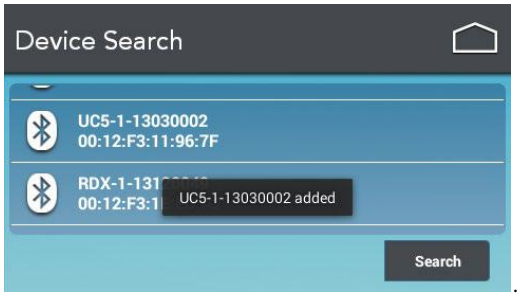
1. Tap the **Settings** Icon:	
2. Tap the **Add Device** option:	
3. Wait for the device search to complete in the *Device Search* window:	
4. Select the device for connection by tapping the search option that correlates with the serial number on the device:	
5. Tap **Yes** to add the device:	
6. A message will appear confirming addition of the device: 7. Repeat for any additional devices.	

Table 9: Adding Devices

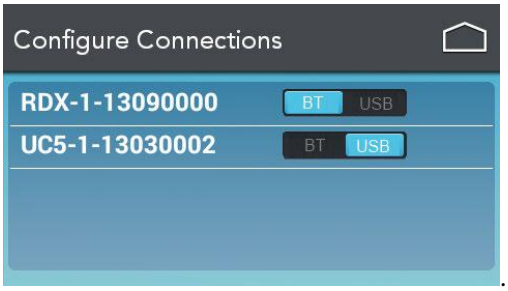
5.3.2 How to Remove a Device

1. Tap the **Settings** Icon:	
2. Tap the **Remove Device** option:	
3. Tap to select the devices to remove and then tap **Remove**:	
4. Repeat for any additional devices.	

Table 10: Removing Devices

5.3.3 How to Connect Devices

NOTE: Before connecting devices make sure the UDS software is closed and not running and the device is not connected via Bluetooth.

1. Tap the **Settings** Icon:	
2. Tap the **Configure Connections** option:	
3. Slide to select the type of connection for the devices listed, either Bluetooth or USB:	
4. Tap the **Home** icon at top left of the screen to go back to the home screen:	

5. The devices and their type of connections will be displayed:	

Table 11: Connecting Devices

5.3.4 How to Set Up Pump Controls

Control the pump speed during a UDS procedure or prime the pump to remove any bubbles from the Central Hub Computer (CHC). Before starting, make sure:

- Pump is calibrated.
- UDS software is running and a test procedure is selected containing pressures.
- Bubble Detector is setup for Auto Pump Stop during Priming (Optional).

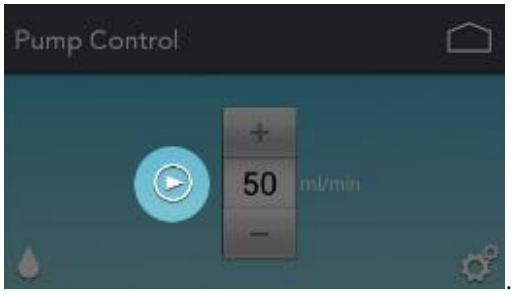
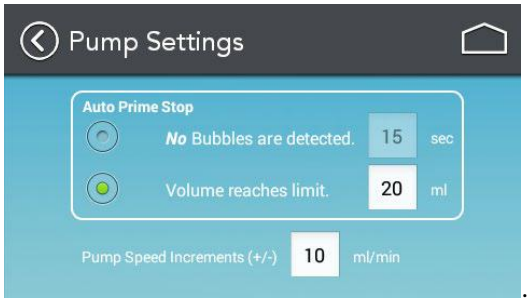
Using the Pump Controls:	
1. Tap the **Pump** Icon:	
2. Tap the **Play** button to start the pump:	
3. Tap the PLUS and MINUS buttons to increase or decrease the speed as necessary.	
Prepare Pump Settings	
1. Tap the **Settings** button on the lower right of the Pump screen to open the *Pump Settings* screen:	
2. In the *Pump Settings* screen, adjust the Bubble Detection threshold or the Volume Warning Limit for the pump. 3. Tap the edit box to type in the values.	
4. In the *Seconds* edit box, enter the time (in seconds) to alert the pump to stop when it no longer detects bubbles:	

Table 12: CHC - Pump Controls and Settings

5.3.5 CONNECT THE PC/LAPTOP TO THE SYSTEM

An important final step when setting up device connections is the linking of the PC/laptop to the AQUARIUS system.

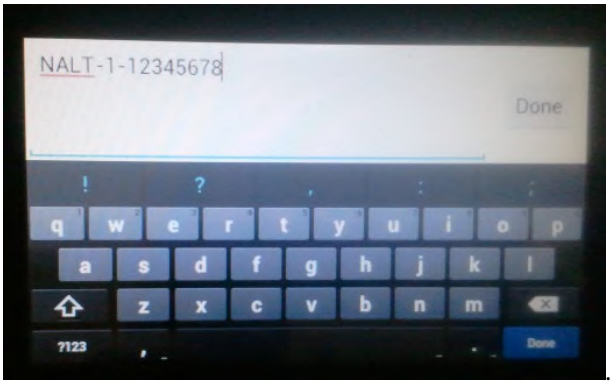
NOTE: Depending on the AQUARIUS model, screens and steps mentioned in this section will be slightly different from what you see with your system.

1. On the Central Hub Computer (CHC) home screen, tap the **Settings** Icon:

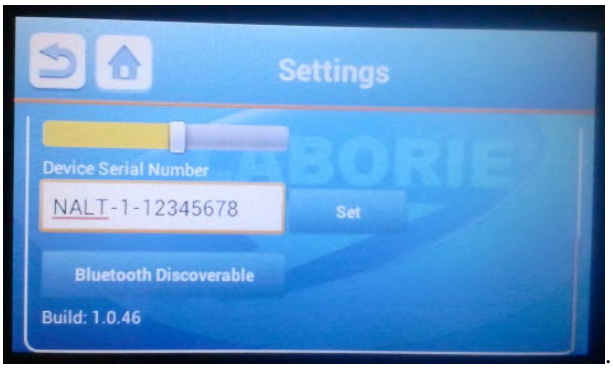
2. Scroll down to *the Device Serial Number* section. Tap the blank field and type the System serial number as it appears on the AQUARIUS cart device label (the label can be found on the bottom leg of the system):

3. Once the Device Serial Number has been entered press **Done:**

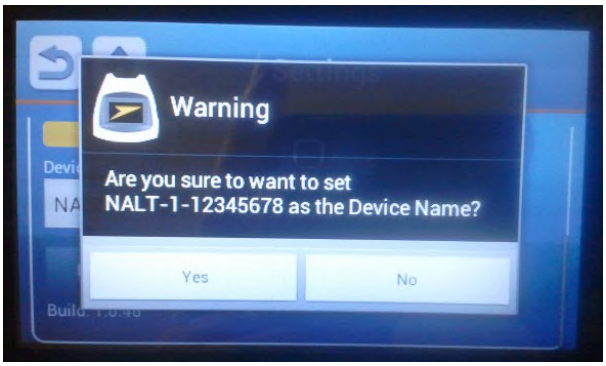
NOTE: The number should be in the format: *NAXX-1-YYMMZZZZ* where: *XX* = the system model type of *LT* or *CT* or *XT*; and *YYMMZZZZ* = all numerical digits. In the example above, the serial number entered is NALT-1-12345678.



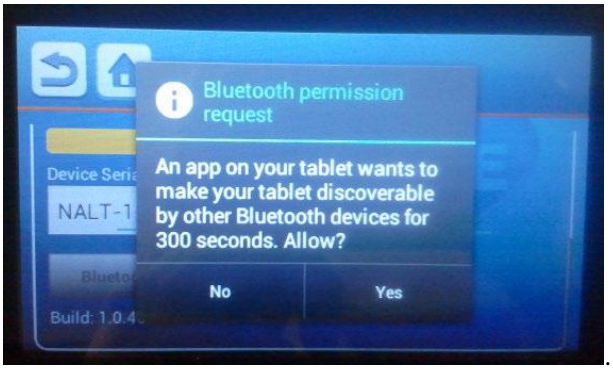
4. Tap the **Set** button:



5. Tap **Yes** to confirm the *Device Serial Number* is correct:

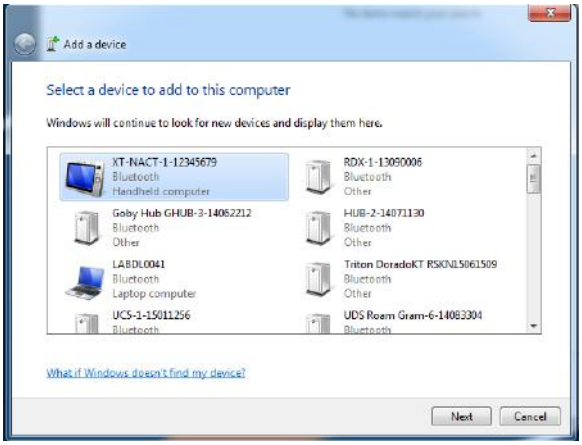


6. When ready to start pairing with the computer, tap **Bluetooth Discoverable** and then tap **Yes** in the resulting permission request screen:



7. Double-click the Bluetooth icon in the tool tray of the PC to pair to the system:

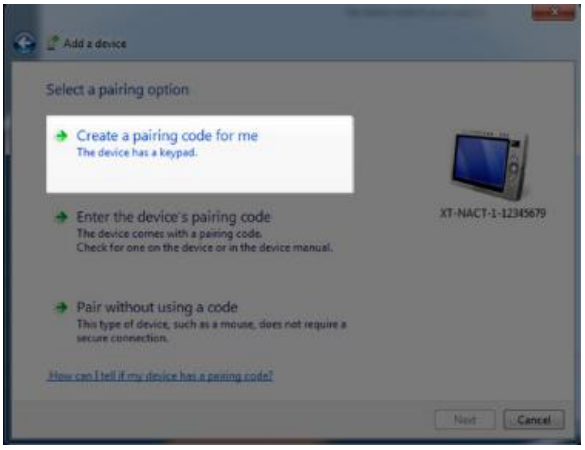
8. The *Add a device* window will load. Click **Add device** to begin searching for the AQUARIUS system. The AQUARIUS system name will appear as *XX-NAXX-YYYYYYYY* where: *XX* = the system model type *LT*, *CT*, or *XT*; and *YYYYYYYY* = all numerical digits. In the following example, the system chosen is *XT-NACT-1-12345679*:



Depending on the model type one of two options will appear:

a. If it is the **LT system,** then a passkey will be automatically generated as shown here. Tap **Pair** to continue.

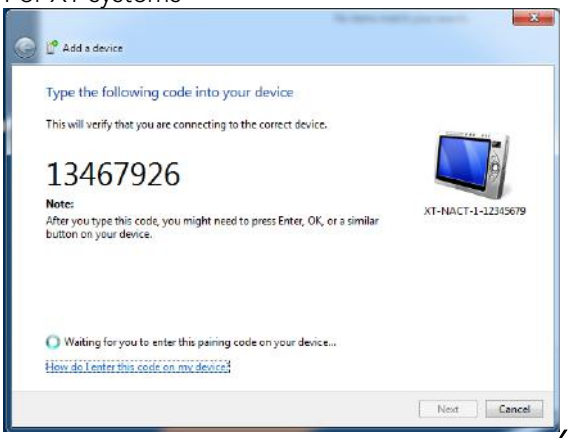
b. If it is the **CT** or **XT system,** then a passkey will need to be manually generated. Click **Create a pairing code for me** to continue.



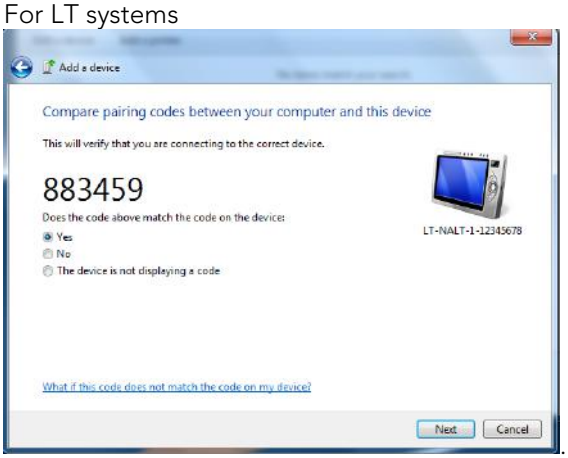
9. Once the passkey is generated, enter that passkey in the field on the Central Hub Computer (CHC) screen, then press next:

For LT systems, ensure the code on the Central Hub Computer (CHC) and the computer are the same; only then continue by selecting **Yes**. Then click **Next** to continue.

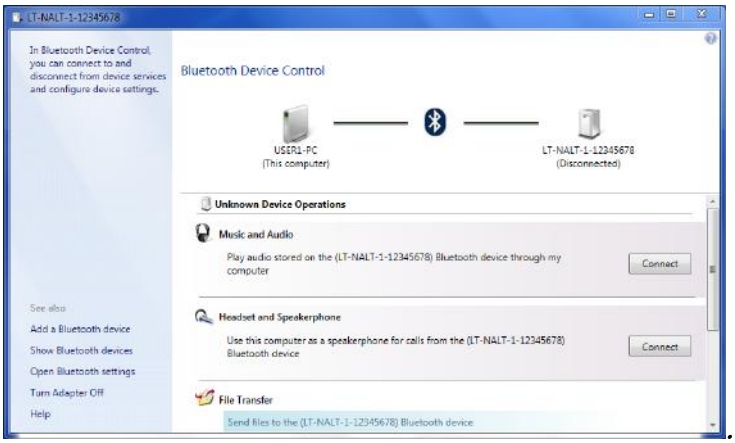
For XT systems



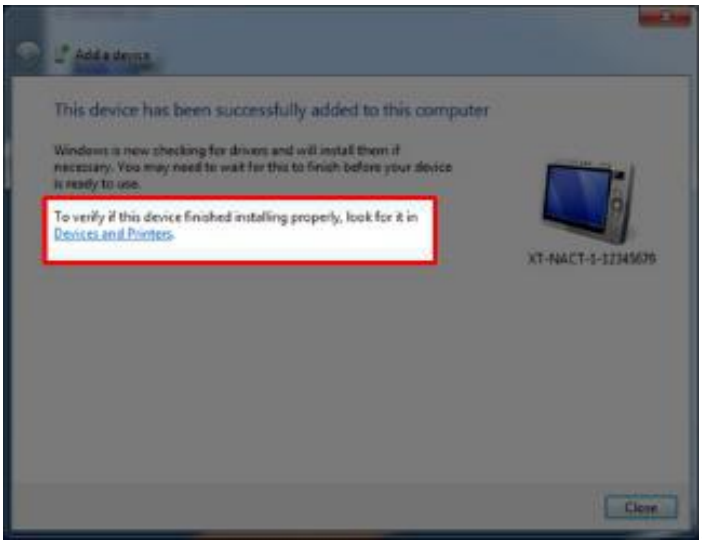
For LT systems



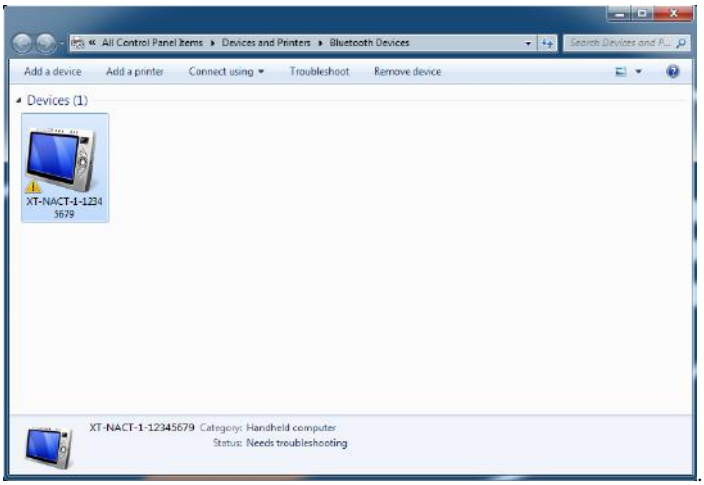
10. After clicking **Next**, the following window may appear. Close the window by clicking the ***X*** in the top-right corner. Do not make any changes under this window. Example window, LT-NALT-1-12345678:



11. When the *Add a device* window appears, click the **Devices and Printers** link to confirm that AQUARIUS® system has been added:.



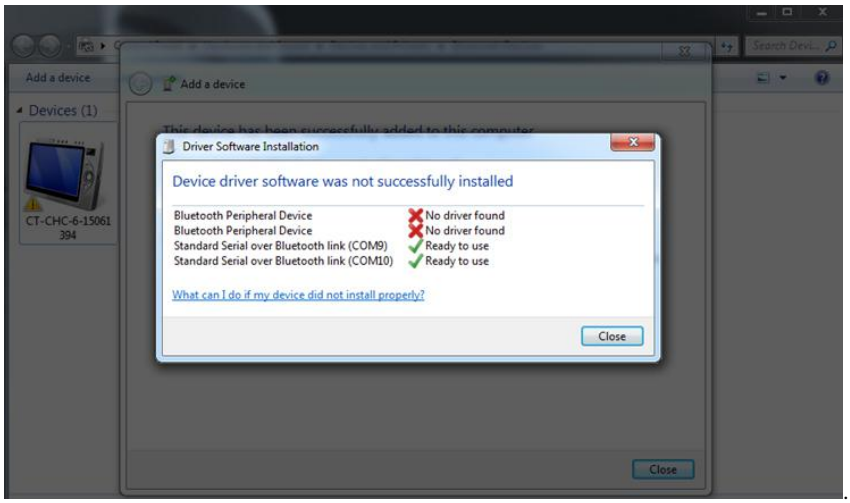
12. The AQUARIUS® system should appear under Bluetooth Devices as shown:



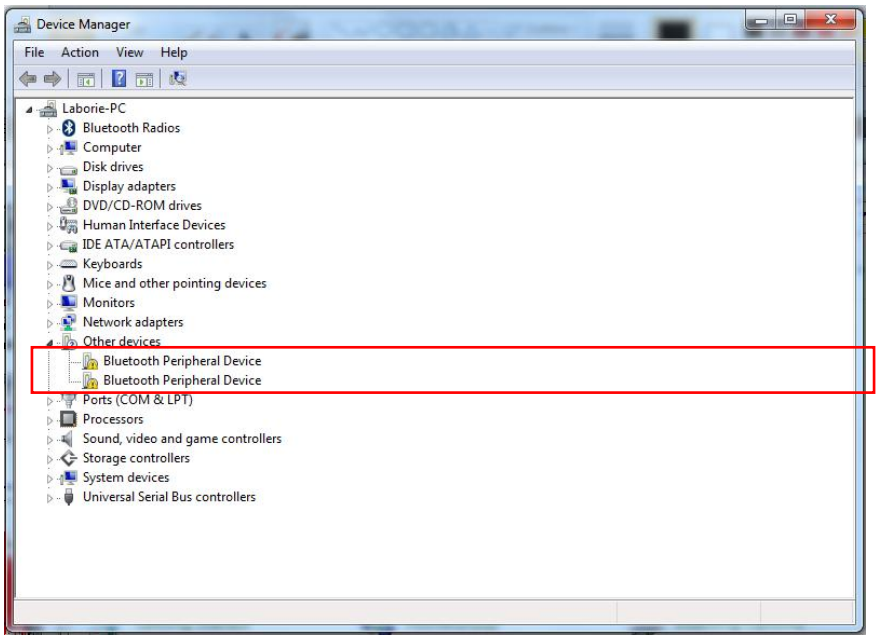
NOTE:

Disregard error messages regarding Peripheral Devices. These errors appear due to additional Bluetooth profiles that are available for use but are not recognized or used by the PC. This does not affect the functionality of the system or the Central Hub Computer (CHC). Refer to the two examples below of this error:

1. "Device driver software was not successfully installed" for Bluetooth Peripheral Devices. Refer to example provided:



2. Exclamation marks next to "Bluetooth Peripheral Device" under Device Manager. Refer to example provided:



Central Hub Computer (CHC) setup is complete.

Table 13: Connecting the PC or Laptop to the System

6 CALIBRATION

IMPORTANT:

- Do not plug or unplug any USB device from the Central Hub Computer (CHC) during the calibration procedure.
- Ensure that battery operated devices are either connected to their charger or fully charged before starting calibration procedures. Run the calibration procedure in one continuous process to ensure proper function.

6.1 HOW TO CALIBRATE FLOW AND VOLUME

6.1.1 CALIBRATE FLOW AND VOLUME WITH THE UROCAP™ V

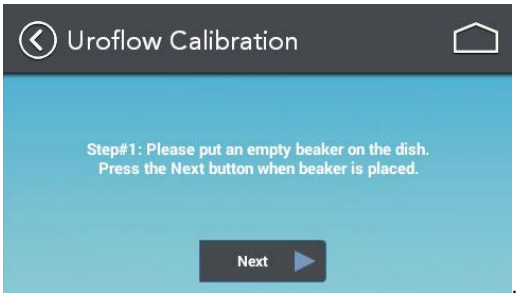
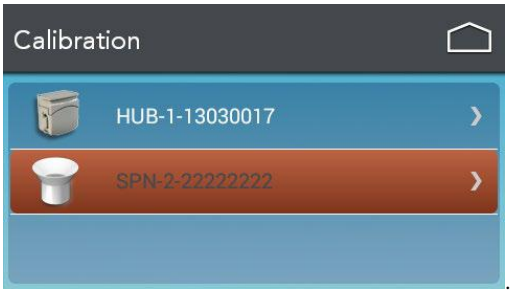
1. Tap the **Calibration** icon on the home screen:	
2. Tap the **UC5** device in the *Calibration* window:	
3. Listen for a `beep` from the Urocap™ V to signal it is ready for calibration. The touchscreen will display instructions for calibration of the device. 4. Follow the on-screen instructions to complete the calibration:	

Table 14: Calibrating the Urocap™ V

6.1.2 CALIBRATE FLOW AND VOLUME WITH THE SPINNING DISK FLOW TRANSDUCER

1. Tap the **Calibration** icon on the home screen:	
2. Tap the **Spinning Disk Flow Transducer** device:	

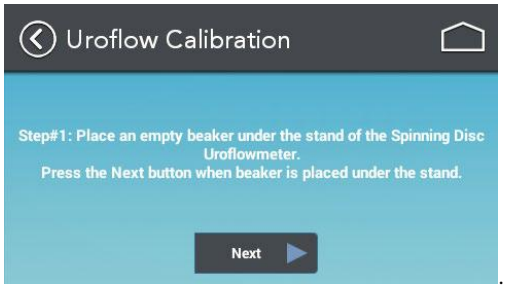
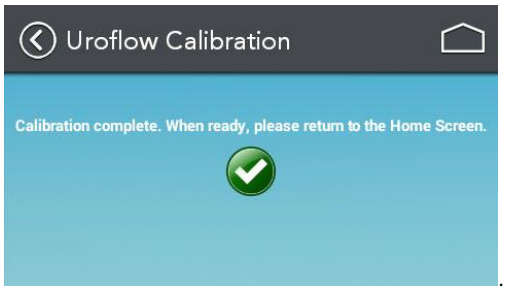
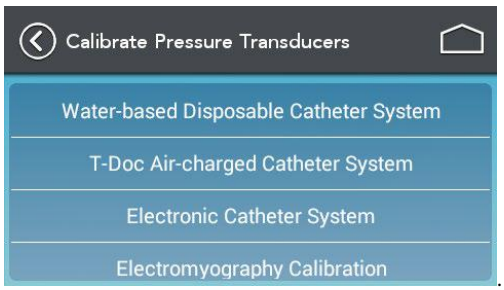
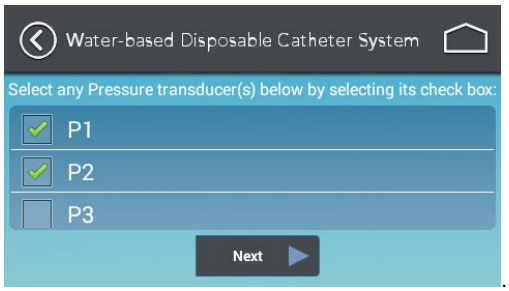
3. The Calibration will open for the Spinning Disk Flow Transducer. Follow the on-screen instructions to complete the calibration: NOTE: The **Next** button in the final screen does not need to be tapped. After 10 seconds of no flow, spinning disk will automatically complete calibration.	
2. When complete, tap the **Home** button to return to the Home screen:	

Table 15: Calibrating the Spinning Disk Flow Transducer

6.2 HOW TO CALIBRATE THE ROAM™ DX FOR PRESSURE AND EMG

Calibrate the Roam™ DX pressure and EMG channels. Ensure the transducers are securely connected to the device. Refer to the Consumables and Transducer Setup section on page 25.

6.2.1 CALIBRATE PRESSURE

1. Tap the **Calibration** icon on the home screen:	
2. Tap to select the **Roam™ DX** device.	
3. Tap to select the Catheter System set up for calibration:	
4. The calibration window for the selected Catheter System will load; in this example **Water-based Disposable Catheter System** has been selected. Tap the boxes correlating with the the transducer Channels being calibrated and tap **Next** to continue: NOTE: Scroll down the screen to see the other checkboxes (P4, P5)	

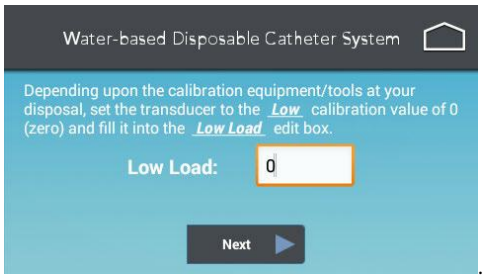
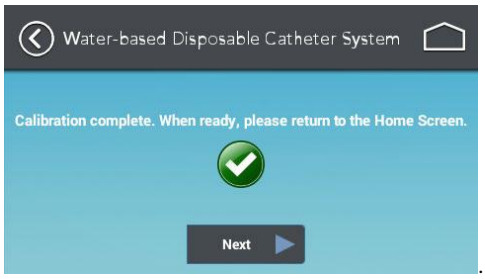
5. Type 0 (zero) in the low load box and tap **Next**:	
6. Continue calibration by following the on-screen instructions until the calibration complete window appears:	
7. Tap the **Return** button to go back to the *Calibrate Pressure Transducers* screen: 8. Repeat steps 2 to 7 for the other Transducer Types.	

Table 16: Calibrating Roam™ DX Pressure Channels and Transducers

6.2.2 CALIBRATE EMG

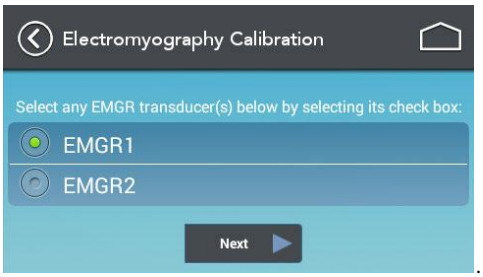
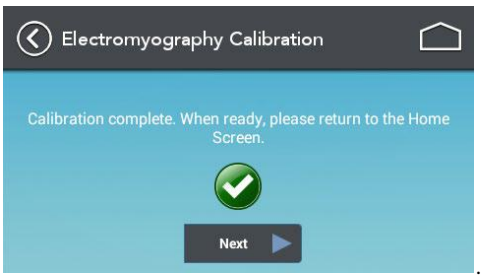
1. Tap the **Calibration** icon on the home screen:	
2. Select the **Roam™** DX device. 3. Tap to select **Electromyography Calibration**. The calibration window for Electromyography will load. 4. Tap to select **EMGR1** transducer and tap **Next** to continue:	
5. Short the EMG leads. The green progress bar moves when moving the leads. Tap **Next:**	
6. Wait for calibration to complete. Click **Next** to complete calibration for electromyography:	

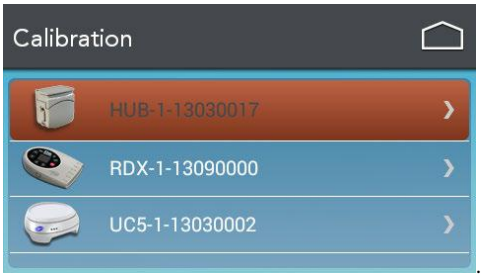
Table 17: Calibrating ROAM™ DX EMG Channel

6.3 HOW TO CALIBRATE THE PUMP

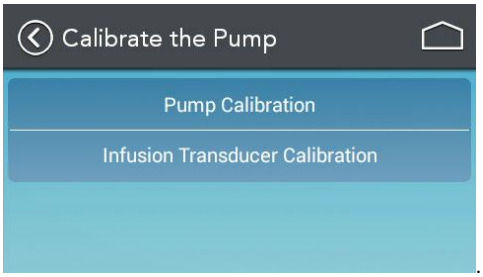
Calibrate the pump by assigning different Pump sets. A maximum of 10 sets are allowed.

1. Tap the **Calibration** icon on the home screen:

2. Tap to select the '**HUB'** device:



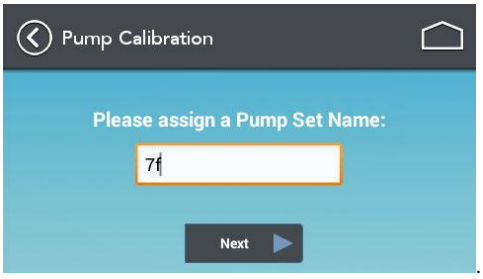
3. Tap to select the **Pump Calibration** option:



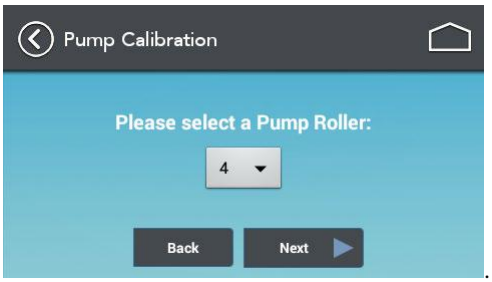
4. The **Pump Calibration** window will open. Tap the empty box and enter a calibration name. For example, Saline8f:

   This name is required to setup the pump for a test as outlined in the Pump Tab section on page 72.

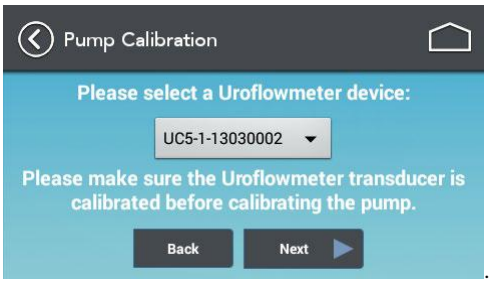
5. Tap **Next** to continue.



6. Select the pump roller from the combo box and tap **Next**:



7. Select a Urocap™ V device from the dropdown menu, then tap **Next** to continue:



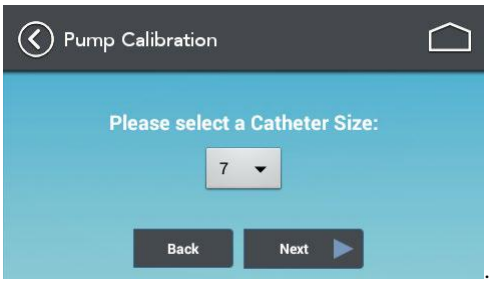
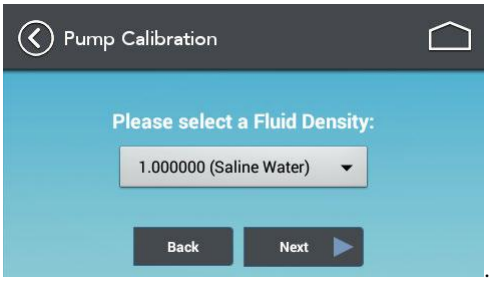
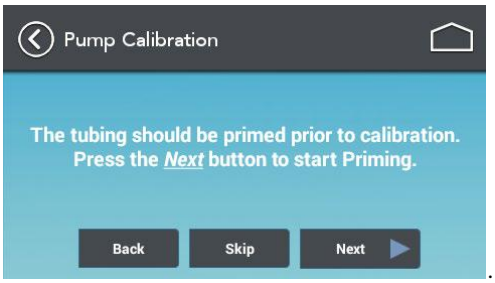
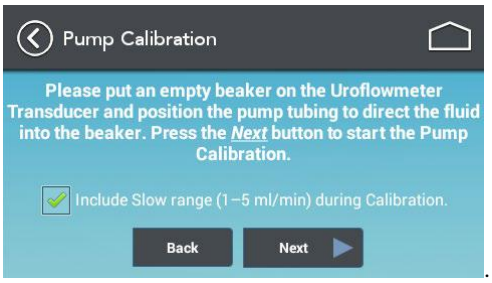
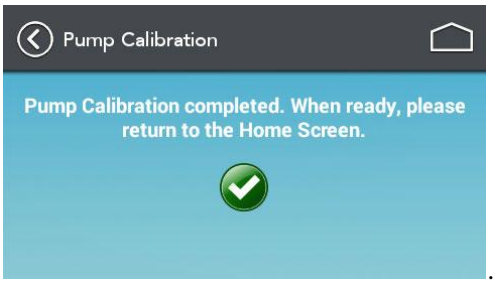
8. Select the correct catheter size from the listing, then tap **Next**:	
9. Select the fluid density from the combo box and then tap **Next**:	
10. Tap **Next** to start priming: NOTE: Tap **Skip** to go directly into calibration if desired.	
11. Tap OK to stop the pump and tap **Next** to continue:	
12. Follow the on-screen instructions to complete calibration: NOTE: During calibration there will be 8 calibration steps.	
13. Once complete, the pump calibration window will provide a confirmation message that calibration is complete: 14. Press the Home button to exit.	

Table 18: Calibrating the Pump

6.4 HOW TO CALIBRATE THE INFUSION TRANSDUCER

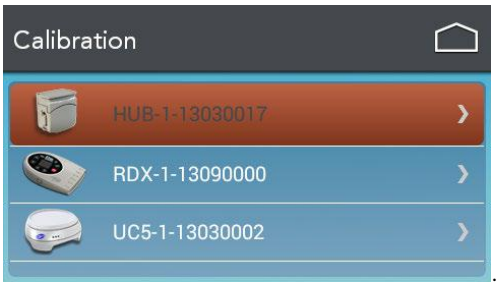
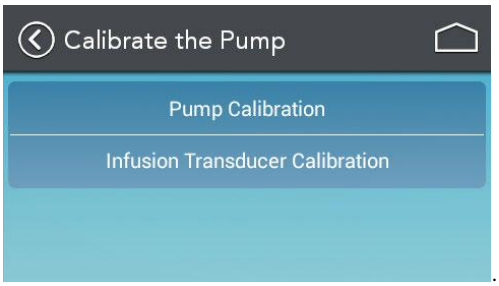
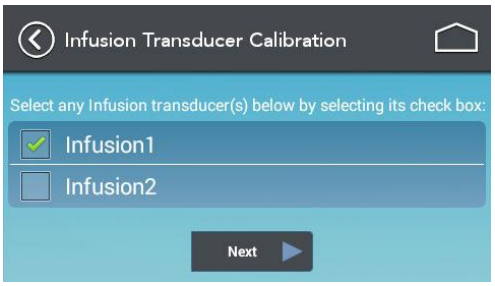
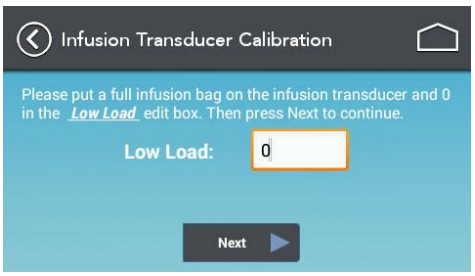
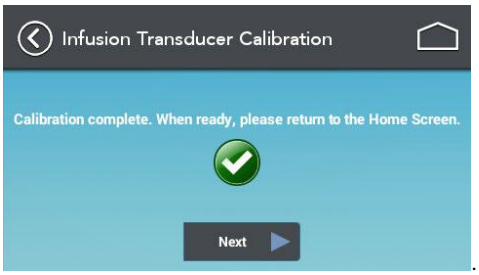
1. Tap the **Calibration** icon on the home screen:	
2. Tap to select the **'HUB'** device:	
3. Tap to select the **Infusion Transducer Calibration** option:	
4. Select a transducer and tap **Next**.	
5. Type in the *Low Load* value and then tap **Next**.	
6. Continue by following the on-screen instructions until calibration is complete:	

Table 19: Calibrating the Infusion Transducer

6.5 HOW TO CALIBRATE THE UPP PULLER

NOTE: Before starting UPP calibration, gather a ruler and pencil.

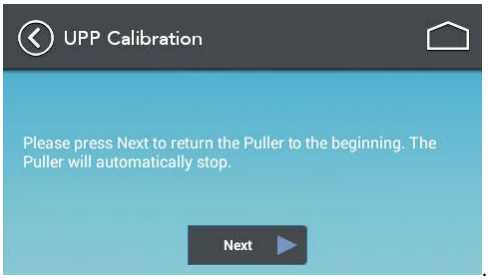
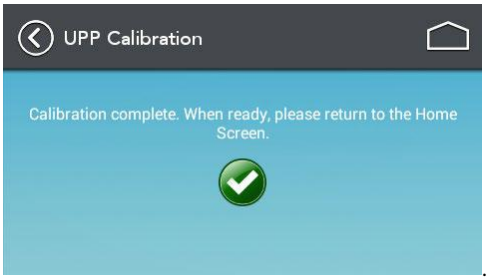
1. Tap the **Calibration** icon on the home screen:	
2. Tap to select the UPP device:	
3. Follow the on-screen instructions to complete the calibration:	
4. Tap the **Home** button to exit:	

Table 20: Calibrating the UPP Puller

7 SOFTWARE FEATURES AND FUNCTIONS

Double-click the **UDS** icon on the desktop to start the UDS software:

The AQUARIUS® software window will open. Refer to Figure 38 for identification of the main sections contained within the software window.

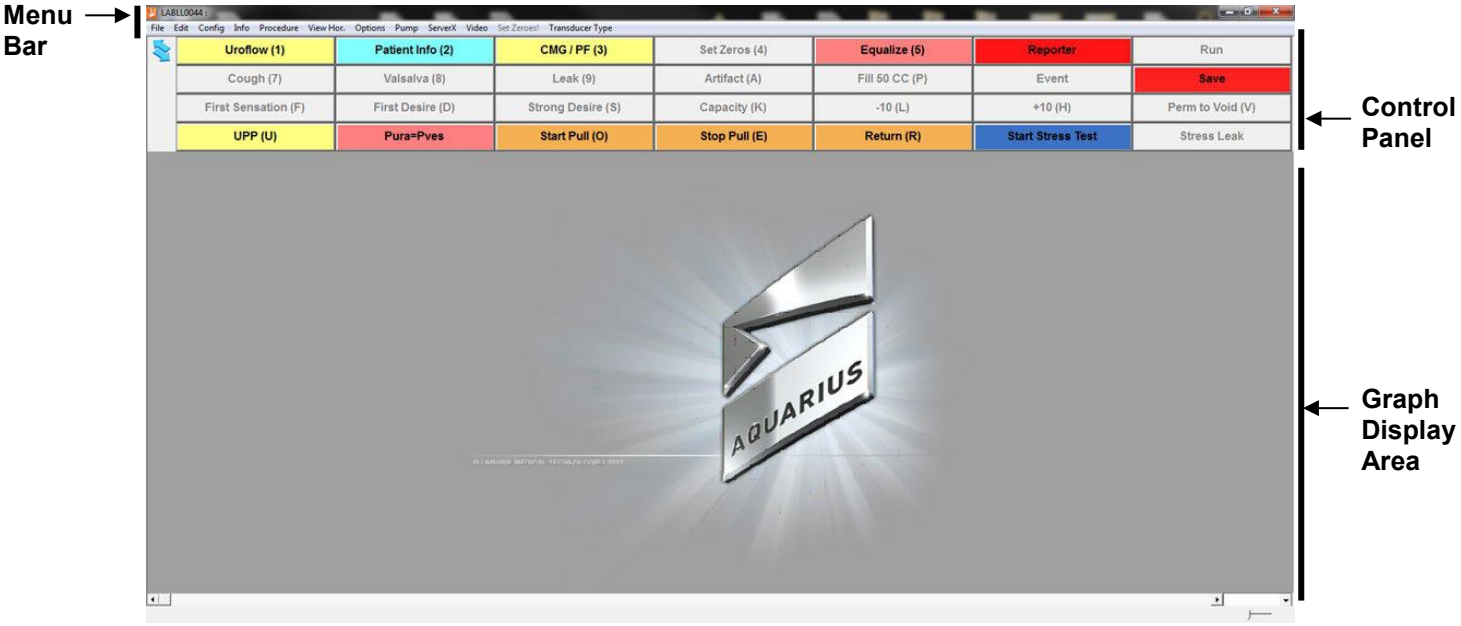


Figure 38: AQUARIUS Software Window

- **Menu Bar:** Click to access the features available for testing and analysis. The menus in the menu bar at the top of the **Goby™** software window contain items that allow you to view saved test files, customize the appearance of the control panel, create custom configurations, and view test summaries. The Menu bar contains the File, Configure, Info, Options, Video, View Horizontal, and Calibration Sets menus.
- **Control Panel:** Contains buttons for selection during Urodynamics procedures.
- **Graph Display Area:** Displays the scrolling graph during procedures, saved graph during review, and contains zoom level options.

NOTE: Device Icons are displayed on the CHC Touchscreen. Icons display equipment status. Any changes to the status will automatically appear on the CHC screen. For information on Device Status Icons refer to the Icons in the Touchscreen section on page 34.

The following subsections provide information regarding features available through the Control Panel, Graph Display Area, and Menus contained in the Menu Bar. In addition, this section provides information for VBN and ARM optional features.

7.1 DYNAMIC CONTROL PANELS

The UDS tests can be setup to open to a default control panel set each time the software starts. For more information on adding and configuring control panels, refer to the Control Panel Settings on page 115.

7.1.1 PRETEST

Use the Control panel to start the test. always enter patient information before starting a test. Once the patient information is entered, click the desired test button to open the Pretest screen (Figure 39).

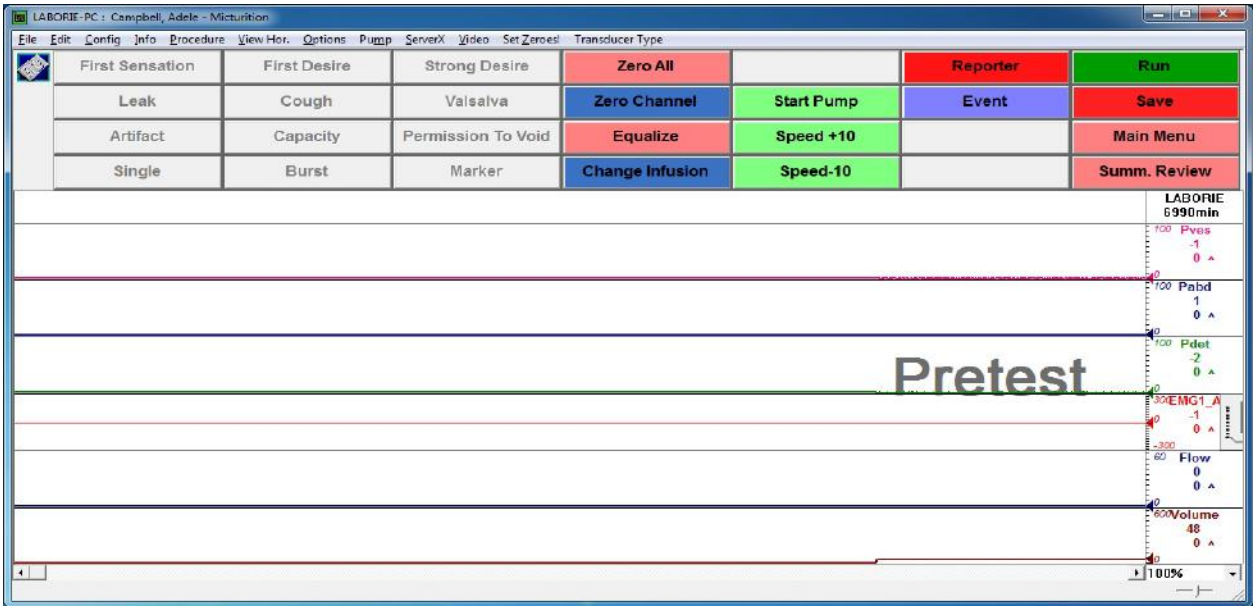


Figure 39: Pretest screen

The *Pretest* screen facilitates checks for proper catheter placement and verification of pressure responses before the start of a test. Data is not recorded while this screen is running.

- Click the **Summ. Review** button at any time to view the summary results of the test at that stage.
- Click **Return to Test** to go back to the test screen.
- Click the **Main Menu** button to return to the main welcome screen.

Refer to Figure 40 for reference:

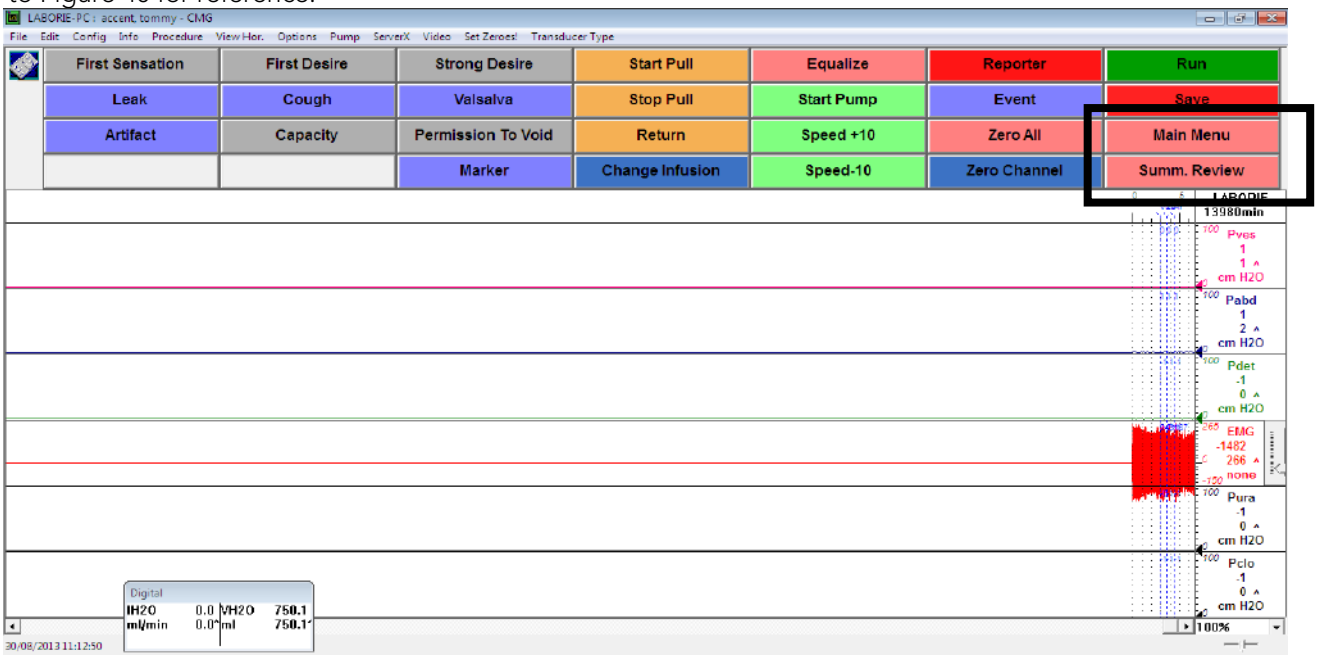


Figure 40: Pretest Window - Verifications

7.1.2 Zoom Button on Control Panel

Create and use a zoom button on the control panel for a more detailed look at a particular section of the graph.

NOTE: A test must be at least 3 minutes long for the zoom feature to work properly.

To setup the zoom button on the control panel follow the instructions below:

1. Begin by creating a **Zoom** button on the control panel (if not already created).
2. Click **Options** > **Control Panel Definition** and find an empty spot on the control panel to add the button.
3. Type the name under the ***Label*** column, the zoom value under the ***Definition*** column, and select the *Zoom* description under the listing in the third column (Figure 41).

NOTE: Zoom values are always set as 2X, 3X, 4X, etc… which corresponds to 2X=200%, 3X=300%, 4X=400% etc.

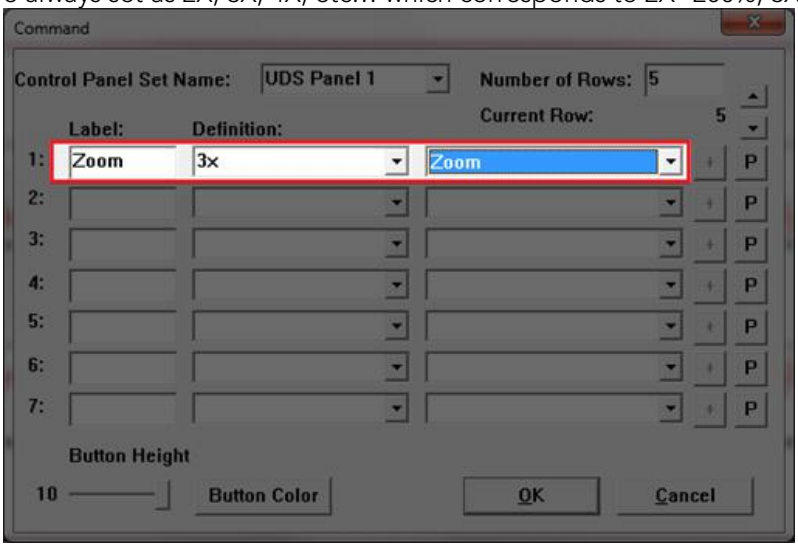


Figure 41: Command Window – Zoom Button Setup

4. Click **OK**.

To Zoom in on a portion of the graph follow the instructions below:

1. Press and hold the left mouse button and drag the cursor to highlight the area on the UDS graph to zoom. The area will be highlighted in black.
2. Click the **Zoom** button on the control panel to zoom in on the selected section.
3. Click the **Zoom Back** button to return to regular view.

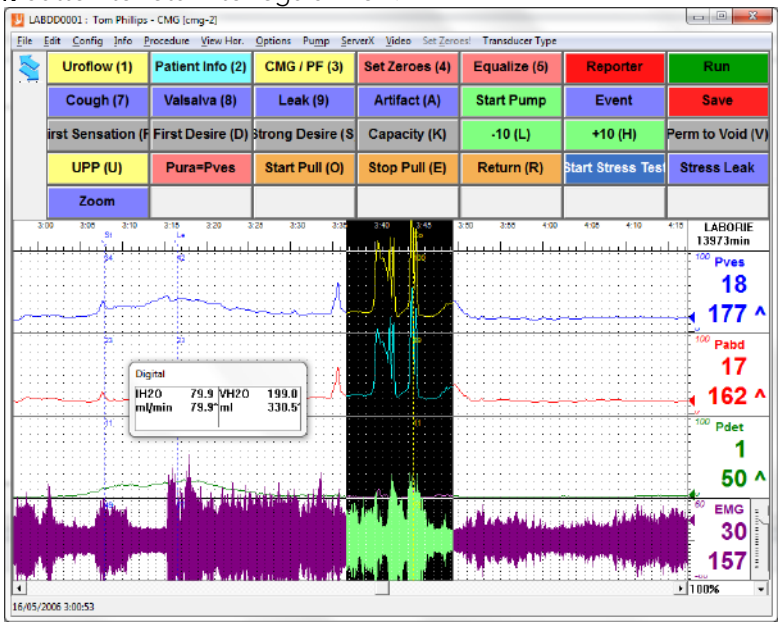


Figure 42: Zoom Feature

7.2 GRAPH DISPLAY AREA

7.2.1 HIDING/SHOWING CHANNELS

To hide any visible channels, right-click on the channel's line on the graph and then select the **Hide Channel** option in the resulting context menu. For example, to hide the *Volume* channel, right-click on the *Volume Channel's* line and select **Hide Channel** from the context menu (Figure 43). This can be repeated for as many channels as needed.

Figure 43: Hiding a Channel

To bring back the channel, right-click anywhere on the graph and select **Show Channels** and then select the channel name to make it visible again (Figure 44). Note that the channel will appear at the bottom of the graph.

Figure 44: Showing a Channel

7.2.2 MODIFYING CHANNELS

7.2.2.1 MODIFY CHANNEL TITLE AND UNITS

Change the channel title and units by simply clicking on them and typing in the new data.

To change a channel title:

1. Click a channel title. An edit box will appear above the channel title.
2. Type the new channel title into the edit box to replace the previous title and press **Enter.** The channel title of that channel will be changed.

Refer to Figure 45.

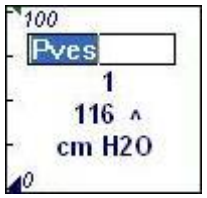


Figure 45: Channel Title

To change the channel units:

1. Click on a channel units. An edit box will appear above the channel units.
2. Type the new channel units into the edit box to replace the previous entry and press **Enter.** The channel units of that channel will be changed.

Refer to Figure 46.

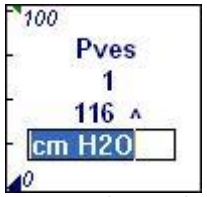


Figure 46: Channel Units

7.2.2.2 MODIFY CHANNEL SCALES

Change the channel scales (minimum and maximum) by simply clicking on them typing in the new data.

To change either the maximum and minimum scales:

1. Click on a channel scale. An edit box will appear above the channel scale.
2. Type the new channel scale into the edit box to replace the previous entry and press **Enter**. The channel scale of that channel will be changed.

Refer to Figure 54.

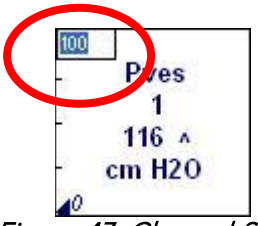


Figure 47: Channel Scale

7.2.2.3 CHANNEL VALUE MARKER

This feature displays the triangular channel value marker at the edge of the graph window to facilitate identification of the channel curve. The marker functions like a pen that draws the curves as the test is running. Refer to Figure 55.

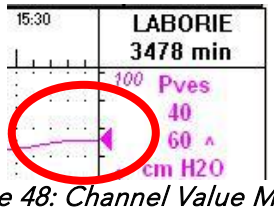


Figure 48: Channel Value Marker

7.2.2.4 DRAG/DROP CHANNEL ORDERING

Change the channel order quickly, in the Graph Display Area, without accessing the **Configuration** dialog box. For instructions on changing channel order in the **Configuration** dialog box refer to the Config Menu section, subheading Channels Settings Tab on page 66.

To change channel order using drag/drop mouse tool:

1. Right click on the channel information area. The channel information area displays the title of the channel. To use the drag and drop tool the user must right click the channel information area; do not select the graph portion of the display. A popup menu appears.
2. Select **Change Channel Order**. The mouse pointer will change to a hand.
3. Drag the channel information area of the channel being moved to its new position. Release the left mouse button. The channel changes order in accordance with selected positioning.
4. Repeat steps 2-3 for other channels selected for re-ordering.
5. After all channels are re-ordered, right-mouse click in the channel information area to show the popup menu and deselect the **Change Channel Order** menu item.

Refer to Figure 49.

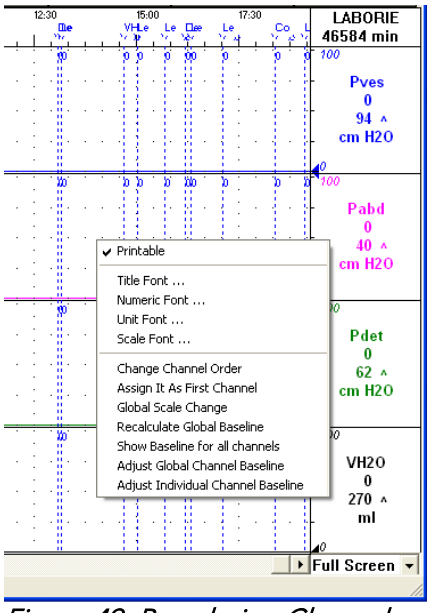


Figure 49: Reordering Channels

7.3 FILE MENU

The *File* menu is the first menu located on the menu bar at the top of the screen. It contains items that allow you to view saved files as well as contact information for the LABORIE support department.

7.3.1 Open

The *Open* feature on the *File* menu opens patient tests that have already been created.
Before opening a saved data file, be sure that any patient tests running are saved. Once the file is saved, opening a saved file automatically closes the old one.

To open a saved file:

1. Click **File** from the menu bar.
2. Select **Open**. The *Open Test* window will open (Figure 50).

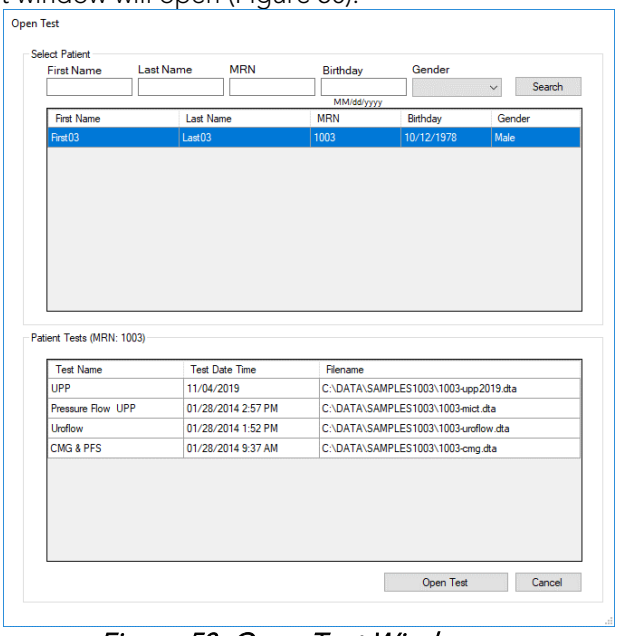


Figure 50: Open Test Window

3. Select the patient and then the file to be opened.
4. Click **Open Test** to open the file.

NOTE: Numbers always appear before letters when sorted in ascending order.

7.3.2 Open Scheduled Tests (optional – for i-LIST software users)

Retrieve the scheduled test information assigned to the local computer and/or for all computers for the day.
Click **File** > **Open Scheduled Tests** to launch the *Scheduled Test window:*

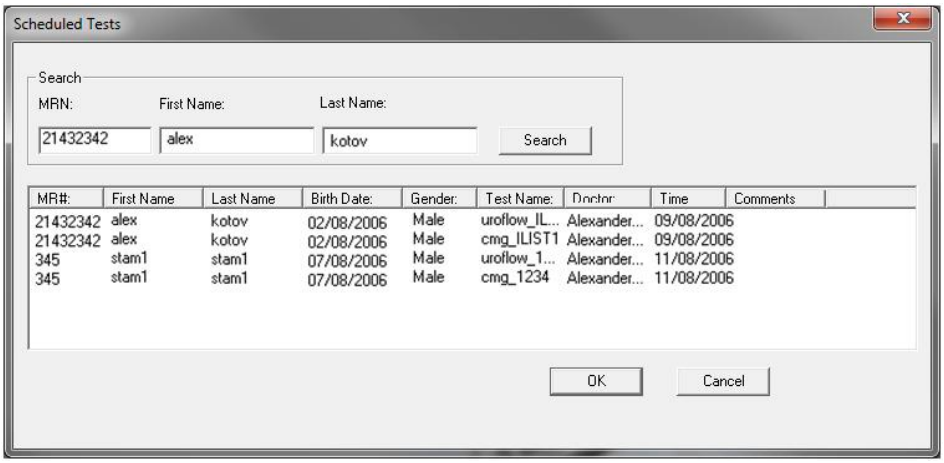


Figure 51: Scheduled Tests Window

- Search by name, MRN, or perform a general search to see all the tests in the i-LIST database.
- Select any test from the list and select **OK** to continue.

Patient Name and Doctor information cannot be changed.

7.3.3 Save As

The *Save As* feature is used to:

- Save a test for the first time.
- Resave a test using a different filename.
- Setup Patient File Security features (more information on this can be found in the Security Tab section on page 74).

When choosing a new file name, keep the following points in mind:

- The filename should not have been previously used.
- The filename should not contain punctuation marks.
- Establish a system for filing so that test data may be recognized and retrieved easily.

To assign a name to a file:

1. Click **File** from the menu bar.
2. Select **Save As** to open the *Save Test File* dialog box.

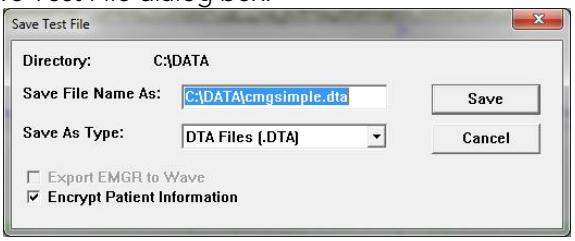


Figure 52: Save Test File Window

3. Click inside the text box and enter the desired filename using the keyboard. The file extension **.DTA** is automatically added to the filename.
4. If required, make sure that the *Encrypt Patient Information* box is selected.
5. Select the file type to save from the *Save As Type* list.
6. Click **Save**.

NOTE: All patient files are automatically stored in the c:\data directory. To change the directory, refer to File Saving Directory section on page 123

7.3.4 PRINT STUDY

Select the information for inclusion in the printed report through this window. At first print per test configuration, the Print Study option will navigate to the *Print Options* window. Use fields in the *Print Options* window to select print options. To change the font of a feature on the report, click the **font** button in the *Print Options window* and select the feature. Double-click the feature and select size and style. Click **OK** to confirm changes.

During the first print of a report for a specific test configuration, select preferred print options in the print menu and click the **Apply** button. Each time you print a report for this test configuration, the report will automatically print using options previously set. The *Print Options* window will no longer appear automatically when you click the **PRINT** button.

Click **File** from the menu bar and select **Print Study.** The **Print Options** window will appear (Figure 53).

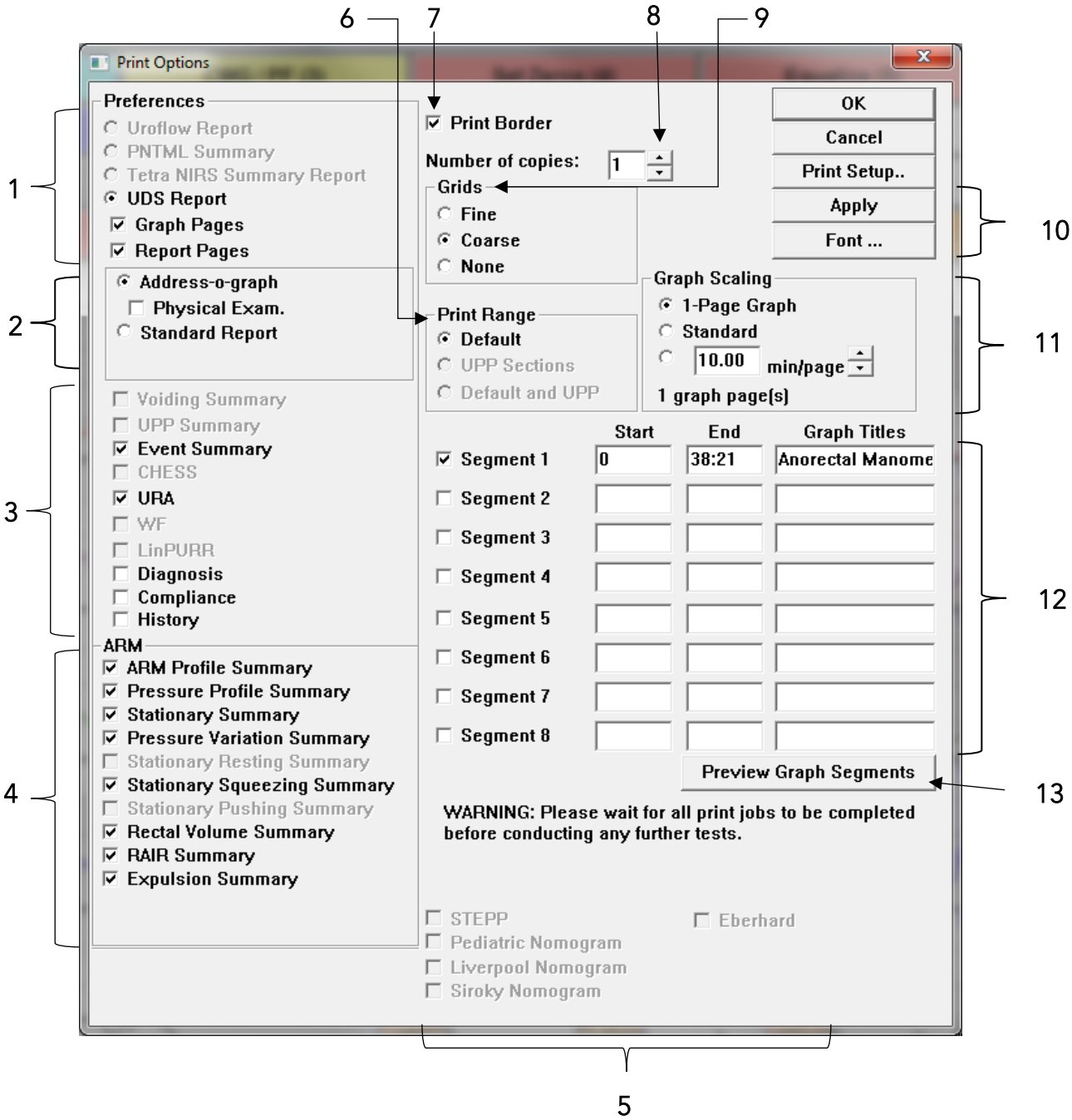


Figure 53: Print Options Window

Refer to the following figure and its accompanying legend to select printing options.

Number	Description	Print Output
(1) Preferences	Uroflow Report	One page voiding study report.
	PNTML Summary	Printout of PNTML (EVOX) tests. See the PNTML (EVOX) operating manual for more information.
	Tetra NIRS Summary	Not available with AQUARIUS® UDS software.
	UDS Report	Multi page complex study report.
	Graph Pages	Graph pages of UDS report.
	Report Pages	Report pages.
(2)	Address-o-graph	One to two page report style.
	Physical Exam.	Physical exam. section in address-o-graph report.
	Standard Report	Prints all information pertaining to study.
(3)	Voiding Summary	Uroflow Summary information.
	UPP Summary	UPP Summary information.
	Event Summary	Event Summary information.
	CHESS	CHESS Nomogram information.
	URA[1]	ICS Nomogram information.
	WF	Bladder Work Function information.
	LinPURR	Shafer's Nomogram information.
	Diagnosis	Patient Diagnosis information.
	Compliance	Prints compliance report information.
	History	Patient History information.
(4) ARM	ARM Profile Summary	ARM Summary table as part of the report pages (ARM option).
	Pressure Profile Summary	ARM Pressure Summary as part of the report pages (ARM option).
	Stationary Summary	ARM Stationary Summary as part of the report pages (ARM option).
	Pressure Variation Summary	ARM Pressure Variation Summary tables as part of the report pages (ARM option).
	Squeezing Summary	ARM Squeezing Summary table as part of the report pages (ARM option).
	Rectal Volume Summary	ARM Rectal Volume Summary as part of the report pages (ARM option).
	RAIR Summary	ARM RAIR Summary as part of the report pages (ARM option).
	Expulsion Summary	ARM Expulsion Summary as part of the report pages (ARM option).
(5) Nomograms and Summary Information	STEPP	N/A
	Eberhard	UPP Static and Stress curves and summary information as part of report pages.
	Pediatric Nomograms *(optional)*	This option is only available if the patient is between 3 – 16 years of age. Both the Voiding Summary screen and the Pediatric Nomogram option must also have been opened to enable this feature.
	Liverpool Nomogram *(optional)*	Optional feature for Uroflow procedures.

Number	Description	Print Output
	Siroky Nomogram *(optional)*	Optional feature for Uroflow procedures.
(6) Print Range	Default	Test from beginning to end.
	UPP Sections	UPP segments only.
	Default and UPP	Prints both options.
(7) Print Border Check box	Print Border	This feature will frame the graph with a simple line border.
(8) Number of Copies Control	Number of Copies	The default number of copies to print is one. Click on the combo box arrows to change the number of copies to be printed.
(9) Grids	Fine	Small grid squares on graph.
	Coarse	Large grid squares on graph.
	None	No grid squares.
(10) Apply and Font buttons	Apply	Click this button to set up a default configuration when printing each test.
	Font	The **Font** button can change the look of some of the items on the printed report. Once the **Font** button is clicked, double-click the name of the feature that will have a font change. Select the size and style and click **OK** to confirm the changes.
(11) Graph Scaling	1-Page Graph	Graph page is condensed into one page.
	Standard	Standard Graph pages printed out with no compression or expansion applied.
	Min/page	Selectable number of minutes per graph page. Use the scroll bar to adjust the desired number of minutes per page view.
(12) Graph Segments	Segments	Manually select up to 8 segments or sections of the graph to be printed as opposed to printing out the entire graph.
(13) Preview Graph Segments Button	Preview Graph Segments	Displays a sample of the graph printout.

For information on Print Setup, see page 62.
[1]Griffiths et al. (1989) Neurourology and Urodynamics 8:17-27.

*The URA may be difficult for first time **AQUARIUS®** users to interpret. The URA must be viewed on the screen before printing. Once the curve is viewed, the options in the dialog box become available.

Table 21: Print Options Descriptions

7.3.5 BATCH PRINT

Print multiple procedures together using the **Batch Print** feature. Select procedures from a particular day or from different time periods.

To access Batch Print for tests performed on the same day:

1. Click **File** from the menu bar and select **Batch Print**. The **Batch Print** window will appear (Figure 54).

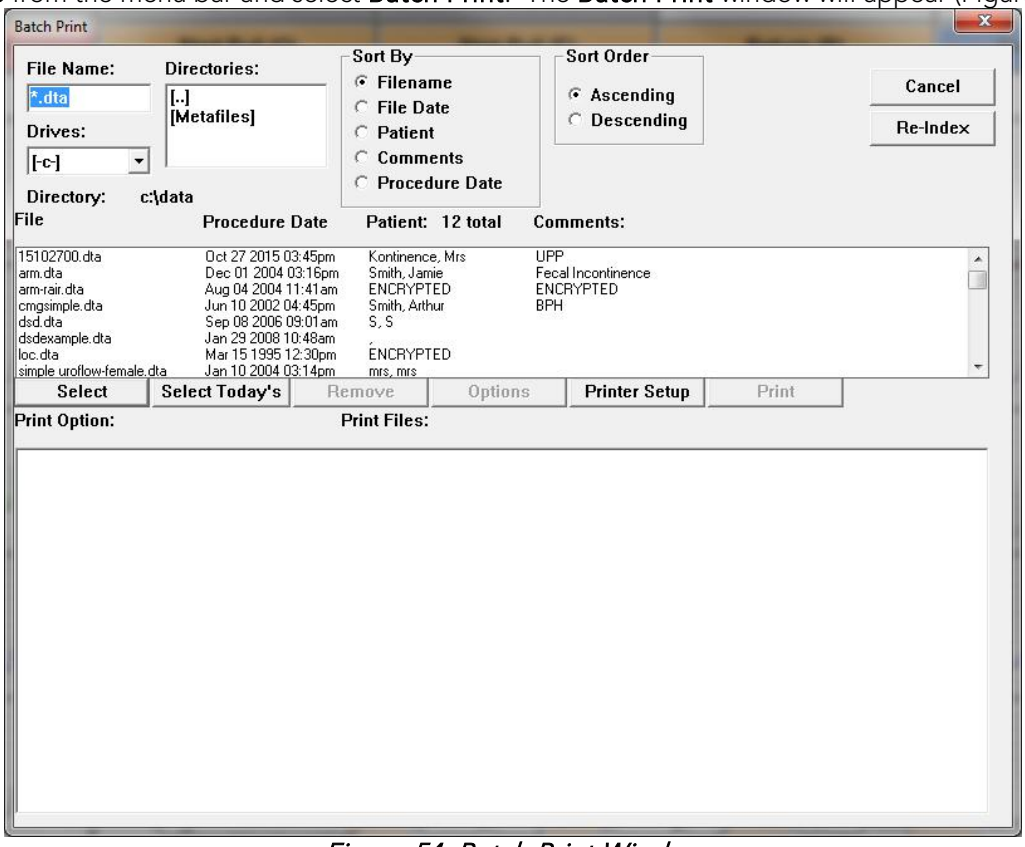


Figure 54: Batch Print Window

2. Click the **Select Today's** button. A dialog box appears indicating the number of data files that have been selected.
3. Click **OK**. The selected file(s) appear in the *Print Files* box at the bottom of the screen.
4. Click **Print**.

To access Batch Print for files which have been run on previous days:

5. Click **File** from the Menu bar and select **Batch Print**. The *Batch Print* window appears.
6. Select the files to be printed by double-clicking on each file or clicking on a file and pressing the **Select** button. The selected file will appear in the *Print Files* box at the bottom of the screen.
7. Click **Print**.

To cancel printing a file after it has been selected in the Print Files box:

1. Click on the file from the *Print Files* box in the *Batch Print* window.
2. Click **Remove**. The file name will disappear from the *Print Files* box and reappear in the *File List* box.

NOTE: The **Re-Index** option is only needed when an Index file is corrupt (A corrupt file means that the file is damaged. If the file is corrupt, a message box will tell you to use the Re-Index option). This option generates the index file that contains the patient's name, comments, file date, and the procedure date for quick look up. The Index file can be re-generated by re-indexing.

To access the Re-Index option:

1. Click the **Re-Index** button in the *Batch Print* window. The *Re-indexing Dialog box* appears.
2. Click **OK**. The file is automatically re-indexed.

7.3.6 PRINT SETUP

To access and adjust Print Setup options:

1. Click on **File** from the Menu bar and select **Print Setup**. The **Print Setup** window appears.
2. Set preferences:
    a. Select the appropriate printer in the *Printer Name* dropdown menu.
    b. Select the appropriate paper size in the source field.
    c. Select page orientation; click **Portrait**.
3. Click **OK**.

The changes made to the Printer setup will be applied to the printing process of the test.

Printer Properties: To change the printer options, please refer to the user's manual for the printer.

7.3.7 ABOUT UDS CLIENT

The *About UDS Client* window displays the contact information for LABORIE Technical Support and formulas used in Urodynamics. It also includes the software version number, the ServerX version number, the Firmware version number, and the VBN version numbers (if applicable). Use this window to create a fax cover sheet that can be sent to the LABORIE Support department for inquiries into any problems you may be experiencing with the equipment or software.

NOTE: The software version number is the same for single and multiple connections.

To access About UDS Client information:

1. Click **File** from the menu bar.
2. Select **About UDS Client**.
3. Use the window to review LABORIE contact information and system technical information.
4. Use the **Fax Cover** button to open the *Fax Cover Sheet* window (Figure 55).
   Use the available fields in this window to log information that will help the LABORIE Support team identify the problem and provide a solution. Click the **Print** button to print the cover sheet. Once it is printed, fax the sheet(s) to LABORIE Support with the fax number provided.

NOTE: The comments section has a maximum of 1024 characters.

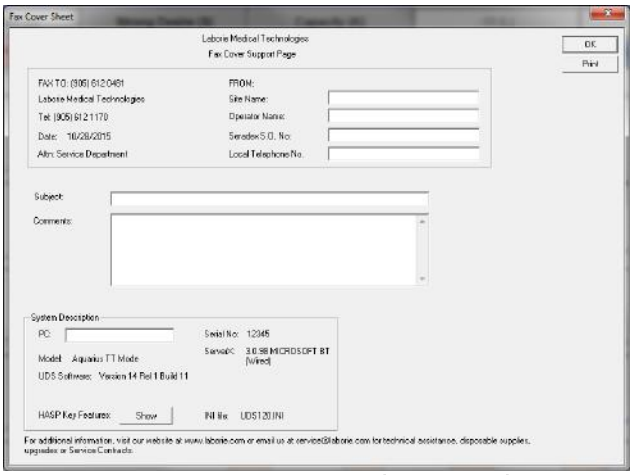


Figure 55: Fax Cover Sheet Window

NOTE: The **Update** button is only for use by the LABORIE Technical Support team.

7.3.8 IMPORT ASC

Importing and open test data saved in ASCII format using this feature.

7.3.9 IMPORT ICS

Import and open test data saved in ICS format using this feature.

7.3.10 EXIT

The **Exit** feature closes the UDS software.

7.4 EDIT MENU

The *Edit* menu provides access to features described in the following subsections.

7.4.1 MARK BLOCK

The Mark Block feature marks an image block (for example, a graph or graph segment) so that it can be copied and pasted into another application which supports Windows image pasting (for example: Microsoft Word, PowerPoint). This feature can also be used in the workstation mode.

NOTE: The Mark Block feature is not available when a test is running. Stop the test to enable this feature.

To mark an image block:

1. Open a saved test or stop the procedure if it is running.
2. Click **Edit** from the menu bar and select **Mark Block**. The cursor changes to a "+" symbol.
3. Select a section by dragging the + cursor from the top left corner to the bottom right corner (). The selected area will be highlighted. The section is ready for copying.This area is highlighted and is ready to be copied.

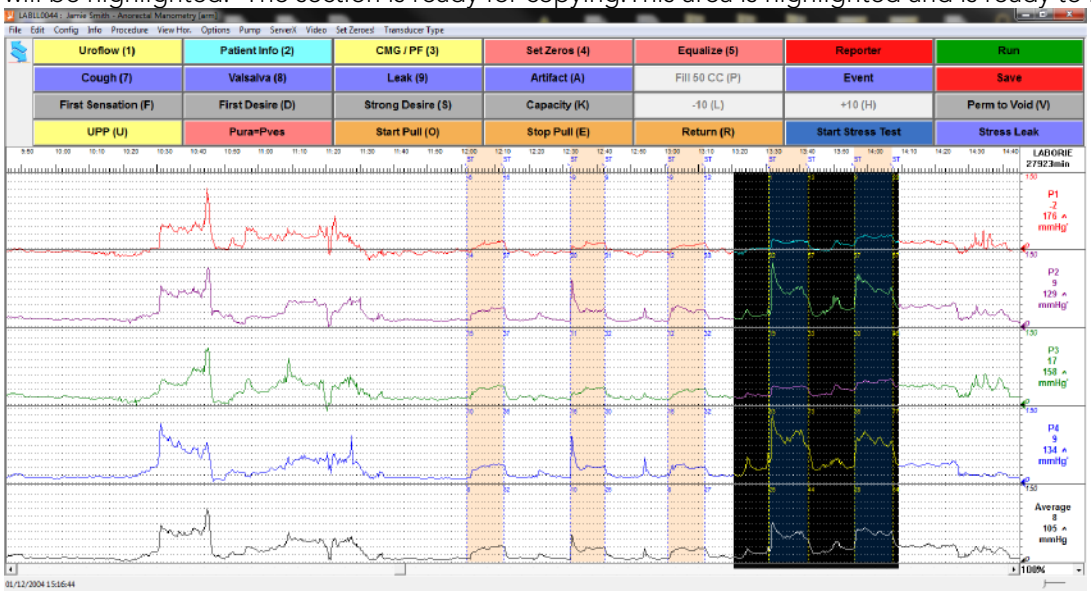


Figure 56: Mark Block Feature

Refer to the Copy section on page 63 for instructions on how to copy the marked area. To unmark a copy, refer to the Undo section on page 63.

7.4.2 COPY

Once an image block has been marked, it may be copied onto the clipboard for pasting into another Windows application. The clipboard is a temporary storage area that holds all marked items for the purpose of transferring data from one application to another in Windows. These marked items are not displayed on the screen.

To copy a test:

1. Mark the image block to be copied.
2. Click **Edit** from the menu bar.
3. Select **Copy**. The marked image block is copied into the clipboard until it is pasted into another application or deselected by using the **Undo** command.
4. Paste the marked image block into a document in Word, PowerPoint, Notepad, etc.

7.4.3 UNDO

The undo feature clears the selected (marked) image block. This menu item is only enabled if an image block has been selected.

To unmark a marked portion of a test:

After selecting an image block, click **Undo** from the *Edit* menu. The marked selection is unmarked.

7.4.4 Undo Set Zeroes

The undo set zeroes feature clears the settings of a previous zeroing operation.

To Undo the Set Zeroes of a Test:

1. Click **File** > **Undo Set Zeroes**.
2. Select **Undo**. The previous Set Zeroes operation is reversed.

7.4.5 Zoom – Selected Area and Back

Use the zoom function for a more detailed look at a section of the graph. The test must be at least 3 minutes long for the zoom feature to work.

1. Press and hold the left mouse button and drag the cursor to select an area on the UDS graph to zoom (Figure 57).

Figure 57: Zoom – Selected Area

2. Click Edit > Zoom Selected Area. The selected area is zoomed in and expands to fill the entire graph window (Figure 58).

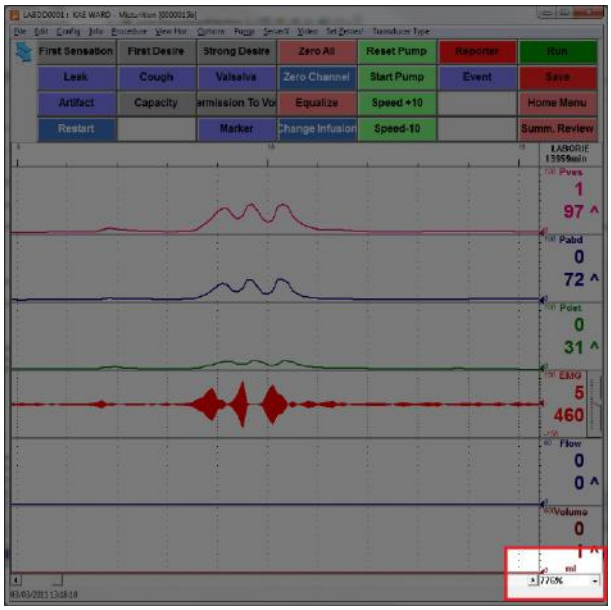


Figure 58: Selected Area Zoomed

3. Highlight an area of the zoomed graph again and select **Zoom Selected Area** to continue zooming in if necessary, *or* click **Edit** > **Zoom Back** to return to the original graph.

NOTE: A **Zoom** button can be created for one-click zoom-in to a preferred magnification level. Refer to the Zoom Button on Control Panel section on page 53 for more information.

7.5 CONFIG MENU

The *Config* menu contains items to help you set up files that can be loaded and used as standard configurations for testing. Clicking the *Config* menu title lists the following menu items:

7.5.1 OPEN

The *Open* feature serves a similar function as the control panel procedure buttons. Both controls load a test configuration to start a procedure. Select the test configuration file (*example*, CMG.cfg) and click **Open** to load the file using the *Open* feature.

7.5.2 SAVE AS

The *Save As* feature under the *Config* menu is used to save or redefine a configuration. Remember that a new file name should **not** include any punctuation marks. It is important that a system for filing be established so that test data may be recognized and retrieved easily. For example: A file may be named *Uroflow.CFG* for Uroflow studies or *CMG.CFG* for Cystometry.

To save a configuration with a different file name:

1. Click **Config** on the menu bar and select **Save As**. The *Save Test File* dialog box will appear (Figure 59).

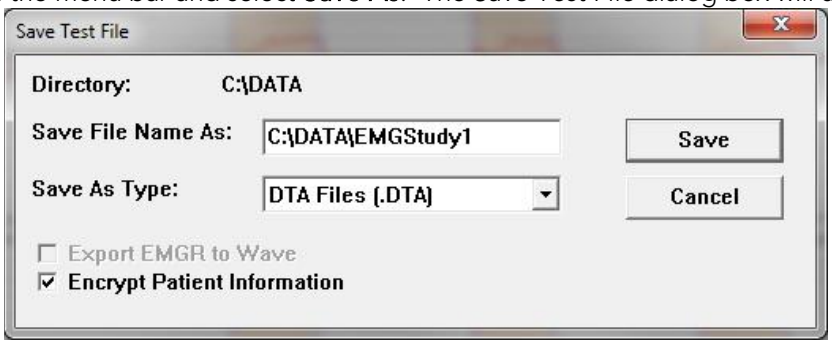


Figure 59: Save Test File Dialog Box

2. Enter the desired filename and click **Save**.

NOTE: The file extension ".CFG" stands for "configuration" and is automatically added to the configuration filename. Select the *Encrypt Patient Information* checkbox if you wish to encrypt patient information.
Set up/Modify. All of the test configuration files are automatically stored in the C:\CFG folder.

7.5.3 SETUP/MODIFY

Complete the following configurations using the *Set up/Modify* menu:

- Connect devices to a test configuration file
- Change data rate
- Change channel order
- Change channel title, scale, and units
- Change test name
- Add channels
- And more….

The configuration parameters tabs are divided into two major categories:

- **Channel parameters** configure individual channels and are found in the *Channel Settings* Tab.
- **Global parameters** customize the test format.

For access to Configuration:

Click **Config** from the menu bar and select **Set up/Modify** (Figure 60).

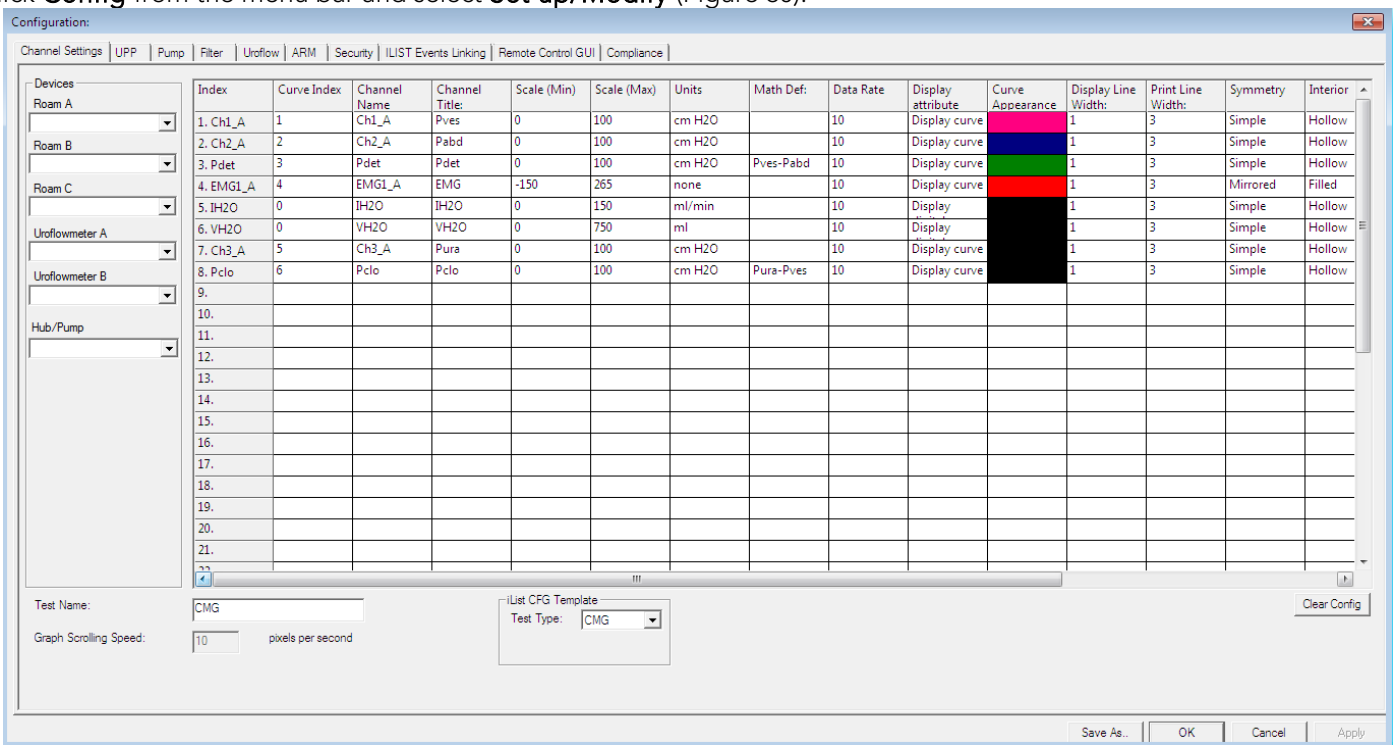


Figure 60: Configuration Window – Channels Settings

Before saving a new test configuration, use the **Clear Config** button to erase any changes made in this window and start again.

NOTE: To resize the columns or rows in the Configuration window for ease of reading information in the boxes, place the pointer on the shaded areas along the top or left side of the window. Move the pointer over the lines between the columns or rows until it changes to a double-ended arrow. Drag the arrow across to resize the columns, or up and down to resize the rows, until you get the right size for the column or row. Repeat resizing of the chart each time the Configuration window is opened.

The following section explains the parameters that can be changed and the procedures for performing these changes. After each change, press the **Apply** button to apply any changes made. Press **OK** to apply the most recent changes and to close the window.

7.5.3.1 CHANNELS SETTINGS TAB

Devices

Depending on the system, when a new test file is configured the devices belonging to the system will need to be linked with the new test file to ensure proper data recording.
Select the connected device from the Roam and Uroflowmeter drop down menus.

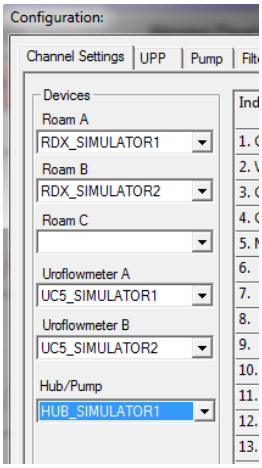


Figure 61: Channel Tab – Devices

NOTE: Devices must be set up before any other settings are configured in this screen. If at any time devices are removed or added to the system, the configuration tab needs to be updated with the newly added or removed device.

Curve Index, Channel Name, and Channel Title

The default transducer configuration displays: Uroflow, Pves, Pabd, Pdet, EMG, IH_2O, and VH_2O. Channels can be added or removed according to test requirements.

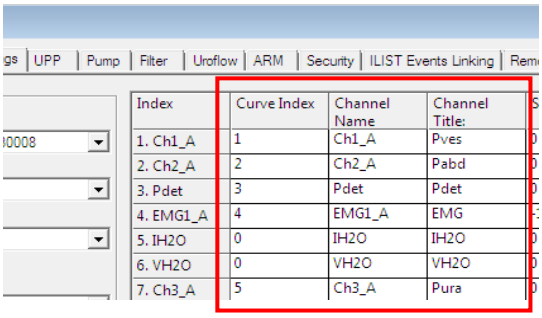


Figure 62: Curve Index, Channel Name, and Channel Title

To order channels:

1. Click in the *Curve Index* box of the channel requiring reordering.
2. Select the new positions from the dropdown menu. Repeat for all channels requiring reordering.

To remove a channel:

1. Click the box corresponding to the desired transducer.
2. In the *Channel Name* column, select **None** from the dropdown menu corresponding to the test channel being remove.
3. Click **OK** to remove the specified transducers from the graph.

To add a channel:

1. Click in the *Channel Title* box and select the desired transducer/channel for use.
2. Repeat until all the required transducers are selected and click **OK**.

Change the Channel Title for identification purposes by entering a new name in the *Channel Title* field. For example, if the default name "flow" is too vague, it may be replaced with "Uroflow."

To change the channel title:

1. Click in the *Channel Title* field box. The channel title is highlighted.
2. Enter a new *Channel Title*.

   Click **OK** to save the new *Channel Title*. The new name will display on the procedure graph.

NOTE: For curves, verify that the Display Curve in the Display Attributes section has been selected. A maximum of 8 curves can be displayed on the screen or on a printout.

Setting up CH5 and EMG1 Channel

IMPORTANT: The CH5 and EMG1 channels are the same port on the **Roam**™ DX and cannot be connected to the same **Roam™** DX device. If using one **Roam™** DX then configure either a CH5 or EMG1 for the test. Refer to Figure 63 for the warning that will appear if both channels are entered into the Channels Settings Tab for the same device.

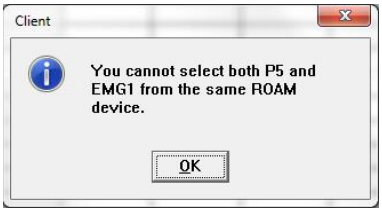


Figure 63: Roam EMG Connection Warning

Scale-Min/Max

Use the *Scale-Min/Max* column to specify a Scale range for the test curve.

To change the Maximum and Minimum scale:

1. Click on the **Scale (Min)** or **Scale (Max)** box of a channel.
2. Type the desired value for the Min and the Max using the keyboard. The new scale range will be displayed on the graph.

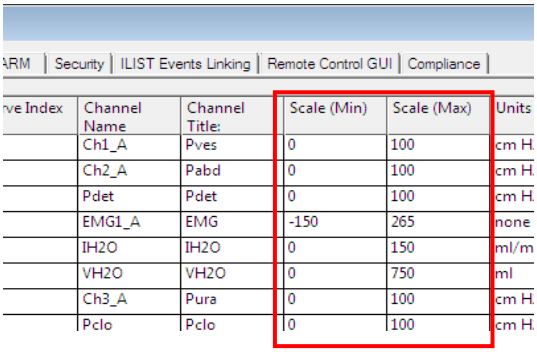


Figure 64: Scale Min/Max

NOTE: If the full-scale value entered is a lower number than the recorded peak value, the peak of the curve will be clipped off or extended into the curve above it, depending on the graph clipping Settings. For additional information on graph clipping, refer to the Graph Clipping section on page 125.

EMG Slider

The EMG channel box contains slider which allows the user to control Max and Min volumes without accessing the *Configuration* Window. (Figure 65).

Instead of manually adjusting the values, adjust the Max and Min scale values of the EMG channel using the slider. The slider control range is from (-10µV…+10 µV) to (-1000 µV...+1000 µV).

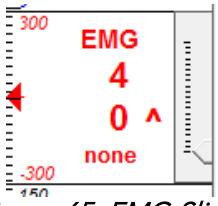


Figure 65: EMG Slider

Units

Use the *Units* column to set default units for each channel.

To change the scale units:

1. Click the **Units** box of a channel (Figure 66).
2. Open the drop-down menu for the **Units** combo box.

Select the desired unit. The unit change is displayed on the graph channel.

Math Def.

Use *Math Channels* to perform arithmetic operations between one or more channels. The math channels support basic arithmetic operations such as addition, subtraction, multiplication, division, and the parenthesis operator ().

For instance:
If you have the pressure channel labeled Pves calibrated in cmH2O and you wish to display the pressure in mmHg. Knowing 1mmHg = 1.36cmH2O, you can type the following in the Math Definition for the Math1 channel and change the units of Math1 channel to mmHg.

Pves / 1.36

Note that the channel label used in the math definition must exactly match the title of the channel used. In addition, combine the operators to make complex expressions like:

((Pves+100) - Pabd) / 1.36

To create a math channel:

1. Select **Config** > **Set up/Modify** > **Channels Settings**.
2. Select a new channel.
3. Select the **Curve Index** number.
4. Select **Math 1** under the **Channel Name** column.
5. Type the name of the math channel under the **Channel Title** column.
6. Select the **Units**.
7. Type the **Math Def** (Figure 66).
8. Verify the **Data Rate** as desired.
9. Select **Display Curve** under the **Display Attributes** column to show the curve on the screen.
10. Click **Apply**.

*Click **OK** to close the window.*

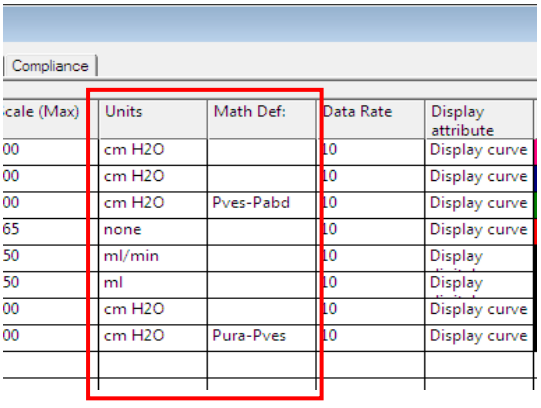


Figure 66: Channel Tab – Math and Units Channels

Data Rate

The Data Rate is the number of data points collected and stored per second during the recording process.
Variable High-Rate Sampling mode II: date rate 10 to 3000 Limitation: Multiple of 10
Variable High-Rate Sampling mode III: data rate 10 to 5000 Limitation: Multiple of 10

A higher data rate means the recorded curve has more data points, and therefore is more precise. However, higher data rate uses more memory storage. As a result, the maximum duration for the test is reduced.

To edit the data rate:

1. Click the **Data Rate** box corresponding to the specific channel. A **Data Rate** box will appear with a listing of data rates.
2. Select the desired value from the list. The new data rate is displayed on the graph.
3. Repeat for other channels (High Rate Sampling mode only).

Display Options

Display Attribute: Select to display the channel data as a curve on the graph or in the digital window.
Curve Appearance: Customize the channel color. Both the channel curve color and the channel information will be displayed (and printed on a color printer) in the new color.
Display Line Width: Make the channel curve thicker (in pixels) on the display by clicking the box under the **Display Line Width** column of the test channel and typing the desired display line width in pixels.
Print Line Width: Make the channel curve thicker (in pixels) on the print out only by clicking the box under the **Print Line Width** column of the test channel and typing the desired print line width in pixels.
Symmetry: Mirror a channel's curve to make a negative mirrored curve. Click the box under the **Symmetry** column for the test channel and select **Mirrored** or **Simple**.
Interior: Fill the area under the curve with the channel color.

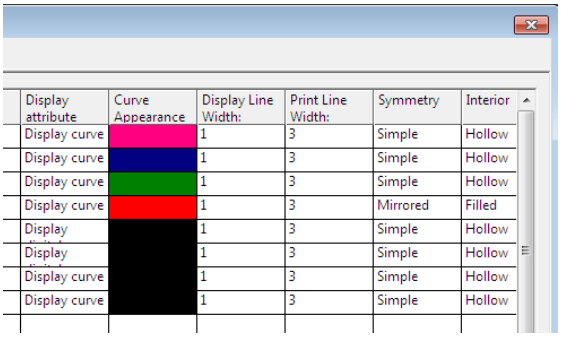


Figure 67: Channel Tab – Display Options

Use Filter

Use this feature to select curve filter options. Select to use a *Standard Filter*, use a *2 Second Filter*, use a *RealTime 2 Second Filter, or* not use a Filter. Apply the 2 Second Filter and the RealTime 2 Second Filter options to any pressure channel to remove any positive and negative spikes on the test curve.

Display Original

Use this feature to display the original graph if graph filters were applied.

Printable

Use this feature to see the graph on the printout of the test results.

i-LIST Channel

(for i-LIST Office Reporter users only)
Select the channels for inclusion in the data transfer from the UDS software to the i-LIST reports.

Test Name and Graph Scrolling Speed

The Channels tab provides Test Name and Graph Scrolling Speed Settings. Use the *Test Name* field to set the name of the test to facilitate search and retrieval.

Use the *Graph Scrolling Speed* field to set the scrolling speed for all curves. The *Scrolling Speed* controls the resolution of the curves. Values must be set between 2 and 10 pixels per second; the higher the number, the higher the resolution.

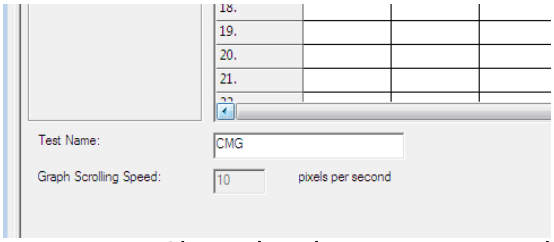


Figure 68: Channels Tab – Test Name and Scrolling Speed

To change a test name*:
Click the **Test Name** box and select the current test name. Type the new test name and click **OK**. Alternatively, type the new test name and set the Graph Scrolling Speed.

To set the Graph Scrolling Speed:
Click the *Graph Scrolling Speed* box and enter the number of pixels per second for the curve. Click **OK** to set the values.

*** NOTE for i-LIST Users**: The test name is vital to properly link to the patient database system. Please consult with LABORIE before changing the test name.

7.5.3.2 UPP TAB

Use the *UPP tab* to set the UPP Puller speed or calculate the UPP Distance Summary based on the distance a catheter is pulled with an attached sensor.

NOTE: Make sure to first select the **UPP** test button on the Control Panel before setting up this feature. Ensure the Distance Sensor has been calibrated

1. Connect the Distance Sensor/Catheter to Ch1.
2. Select the *Distance Sensor Channel* option. Select **Ch1** from the listing and click **OK** (Figure 69).

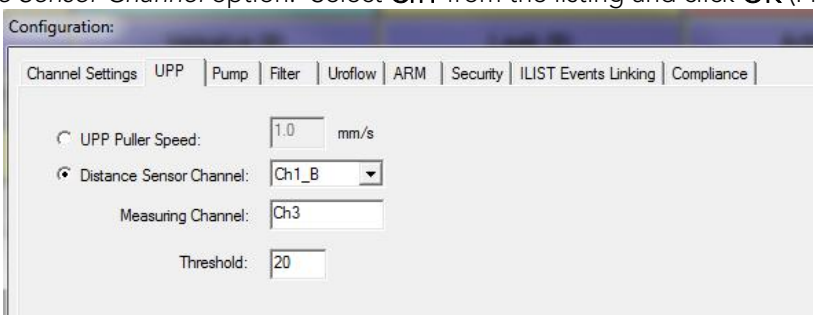


Figure 69: UPP Tab – Distance Sensor Channel

3. Run a UPP test and press the **UPP Stop** button to stop the test.
4. Click **Info** > **UPP Summary** to open the *UPP Summary* window (Figure 70).

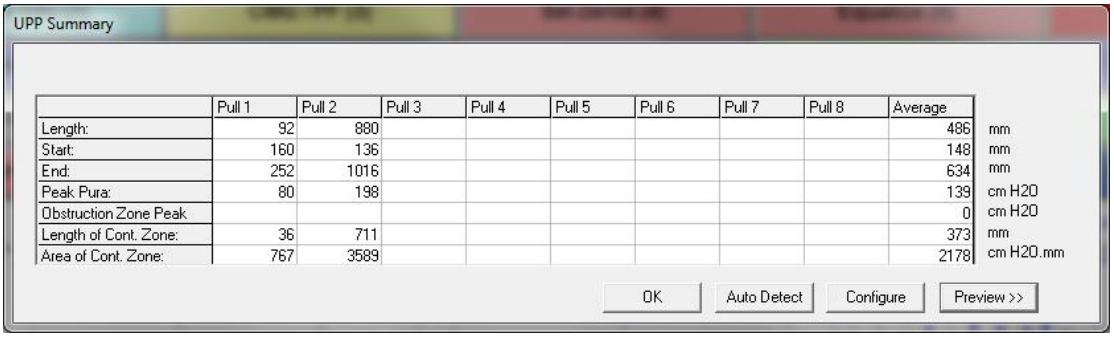


Figure 70: UPP Summary Window

5. Click the **Preview** button to display the *UPP Plots* (Figure 71). Click **OK** to close the screen.

NOTE: The **Preview** button is only available when using the *UPP Distance Summary* option.

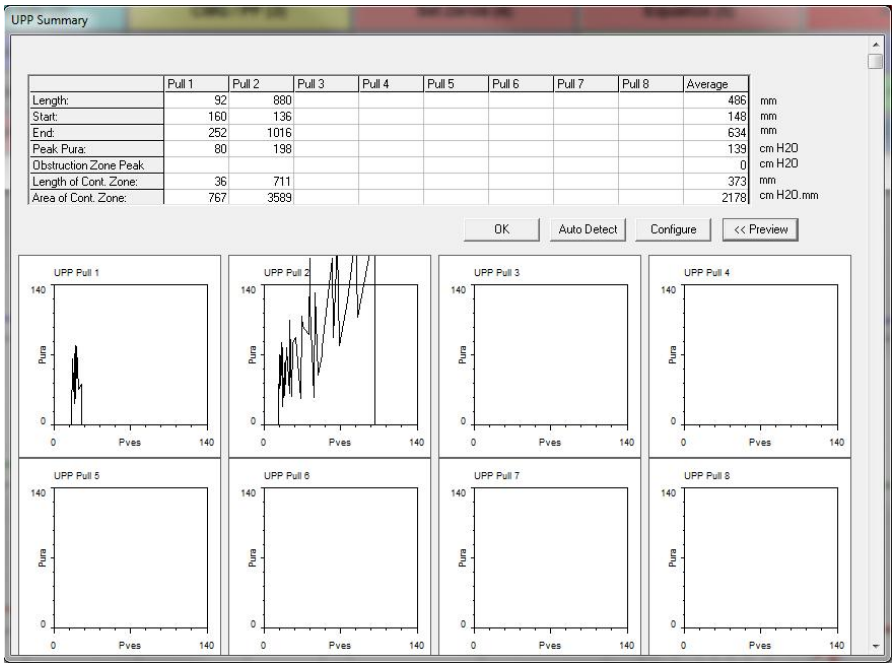


Figure 71: UPP Summary – UPP Plots

6. Print the results by clicking **File** > **Print Study** and selecting the *UPP Summary* option. Refer to an example of a UPP Summary Printout in Figure 72.

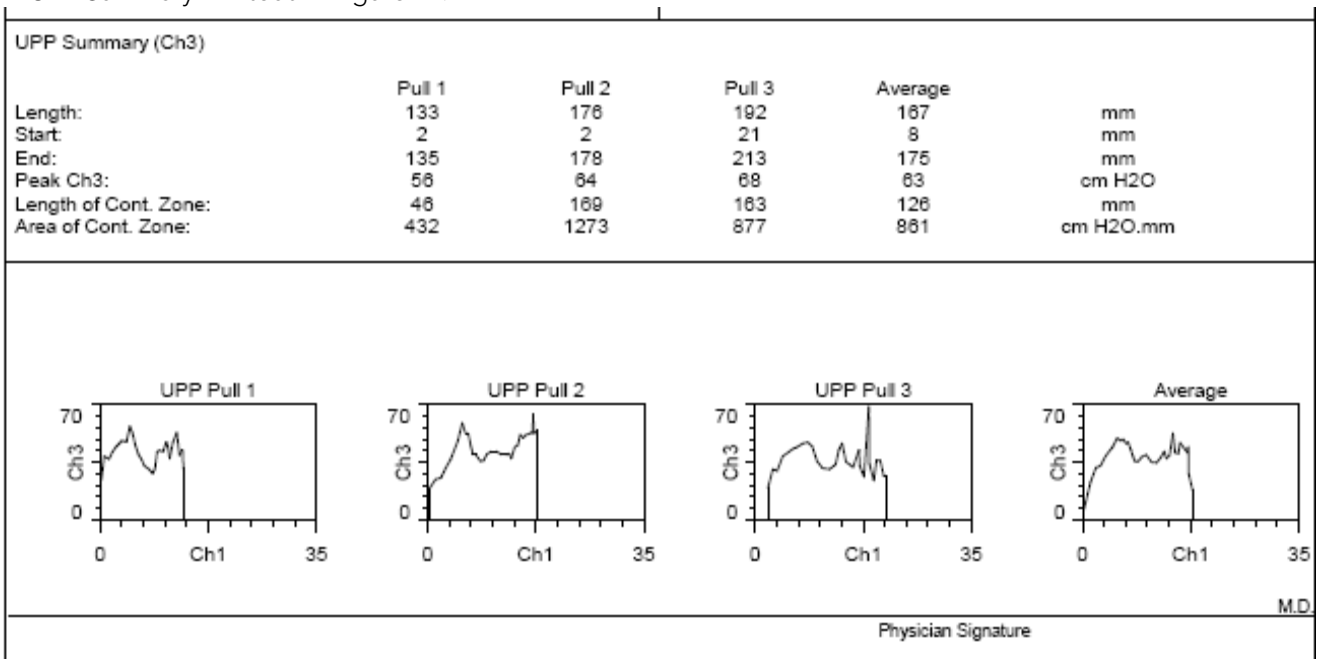


Figure 72: UPP Summary Printout

7. Once the UPP Distance Summary is complete, reconfigure UPP settings for speed. Click Setup/Modify to navigate to the *Configuration* window, select the *UPP Tab* and click **Configure;** select UPP Puller Speed option and run the UPP test.

7.5.3.3 PUMP TAB

Use the *Pump* tab to select the pump to use during a test and configure its settings. Settings include parameters for the pump such as fluid density and auto pump actions. Refer to

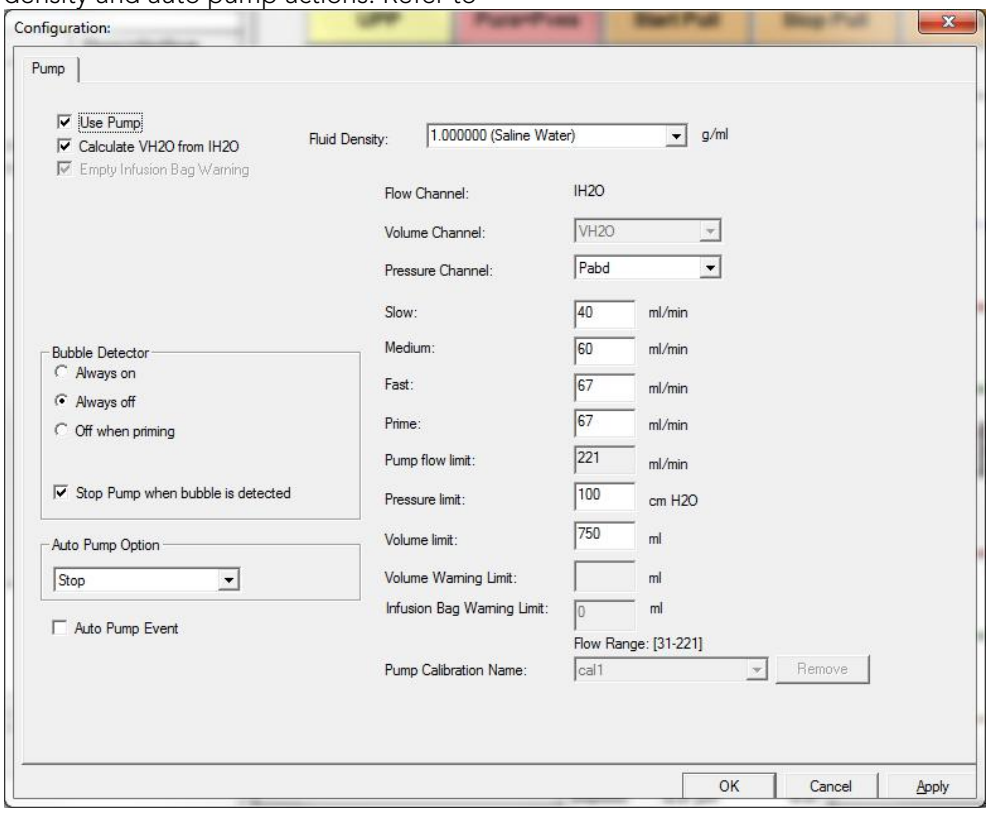


Figure 73: Configuration Window - Pump Tab

Refer to Table 22 below for a descriptions of settings and parameters available in the Pump Tab:

Feature	Function
Calculate VH2O from IH2O	When selected, the VH2O values are automatically calculated by the software based on the IH2O.
Empty Infusion Bag Warning	(valid only if Calculate VH2O from IH2O is not selected) When selected, the UDS software will automatically stop the pump and display the following warning message: **Infusion bag is empty!** when the Infusion transducer registers 5 ml or less of liquid in the infusion bag.
Volume Channel	Specifies the infusion volume channel
Pressure Channel	Specifies the channel used for pressure feedback. **NOTE:** this channel must not contain a math channel.
Slow (rate speed)	Determines the slow speed of the flow rate
Medium (rate speed)	Determines the medium speed of the flow rate
Fast (rate speed)	Determines the fast speed of the flow rate
Prime (rate speed)	Determines the prime speed of the flow rate **NOTE:** The Prime rate feature runs the pump at the speed set in the prime box in the Configure Pump screen. The default speed is 150 ml/min.
Pump Flow Limit	Specifies the max pump flow rate during calibration. **NOTE:** This setting cannot be changed manually in the UDS software.
Pressure Limit	Stops the pump if the pressure channel exceeds this limit. **CAUTION:** Do not exceed 150 cm H20

Feature	Function
Volume Limit	Stops the pump if the volume channel exceeds this limit. **CAUTION:** Do not exceed 750 ml
Volume Warning Limit	Displays a warning message when the infused volume reaches the specified limit.
Infusion Bag Warning Limit	When the value entered is greater than zero the UDS software will display the following warning message without stopping the pump: **Infusion bag is nearing empty!** When the infusion transducer registers the value equal or less than the value entered inside the Infusion Bag Warning Limit box but greater than the threshold value for the Infusion Bag is empty the warning is displayed. By default the threshold value is 5 ml.
Auto Pump Option Stop, Slow, Med, Fast	This option starts the pump at the selected pump speed when the test starts. Choose **Stop** if you do not want to use this option.
Auto Pump Event	This option records events automatically when the pump runs or stops. This option is enabled by default. Deselect the box to disable the feature.
Pump Calibration Name:	Select the appropriate calibration line from the dropdown list. The name contains all the information given during pump calibration on the Central Hub Computer (CHC).

Table 22: Pump Tab Settings Description

Set Up the Pump

1. Navigate to the *Channels Settings* tab in the *Configuration* window.
2. Ensure that the **Roam™** DX, Urocap™ V, and Pump combo boxes are selected for the corresponding channels.

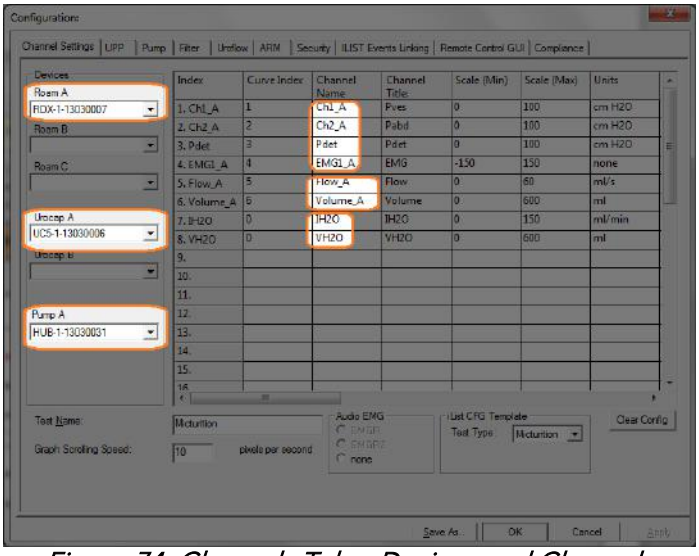


Figure 74: Channels Tab – Devices and Channels

3. Navigate to the *Pump* tab in the *Configuration* window
4. Select a Pump Calibration Name.
5. Enter values in the Slow, Medium and Fast fields.
6. Click **OK** to save changes and close the *Configuration* window.

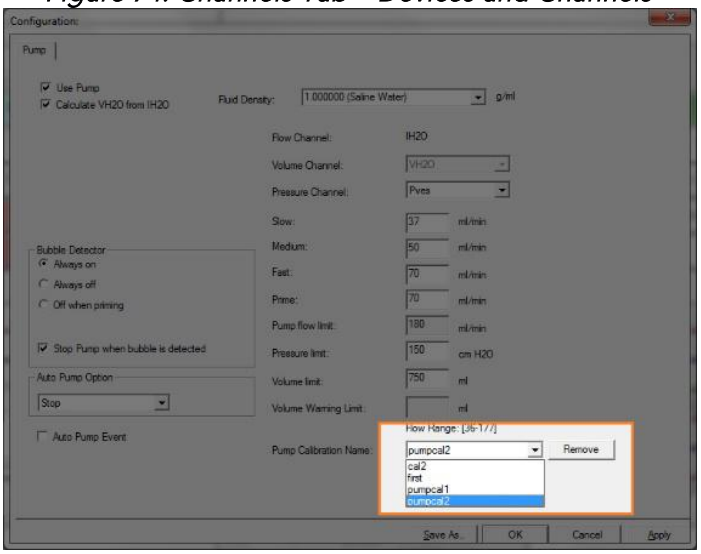


Figure 75: Pump Tab – Pump Calibration Name

7.5.3.4 FILTER TAB
Set the filter frequency under this tab.

7.5.3.5 UROFLOW TAB
Set the parameters for Uroflow such as auto Voiding Summary and auto printing under this tab. Refer to the Voiding Summary section on page 94 for more information.

7.5.3.6 ARM TAB
Set the channels that correspond to the ARM measurements under this tab. Run a four-channel ARM test or an eight-channel ARM test. For more information on setting up and performing ARM tests, refer to the Customizing the ARM Test section on page 164.

Select the *Enable Reverse Pump* option to activate the reverse pump button on the control panel.

7.5.3.7 SECURITY TAB
Set the security features to protect, or encrypt, a patient's name and information such as Medical Record Number, History, Diagnosis, Doctor's name, Clinic name, and Comments. Once encryption is set, only the software key that is associated to the patient file can see the decrypted information.

NOTE: This security feature needs to be set before you start running a test. Make sure that a software key is installed in your PC.

To encrypt patient information:

1. Click the ***Security*** tab.
2. Make sure that the *Enable Encryption of Patient Information* box is selected.
3. Click the **Add** button to add your key's serial number to the secure list.
4. Click **Apply** to save your selections.
5. Run your UDS test and save the test data.
6. In the **File** > **Save As** box, make sure that the *Encrypt Patient Information* box is selected.

Refer to Figure 76.

Once you save the patient information with encryption and if someone uses a virtual key that is not associated with the file, they will see the word *ENCRYPTED* in all the *Patient Information* fields.

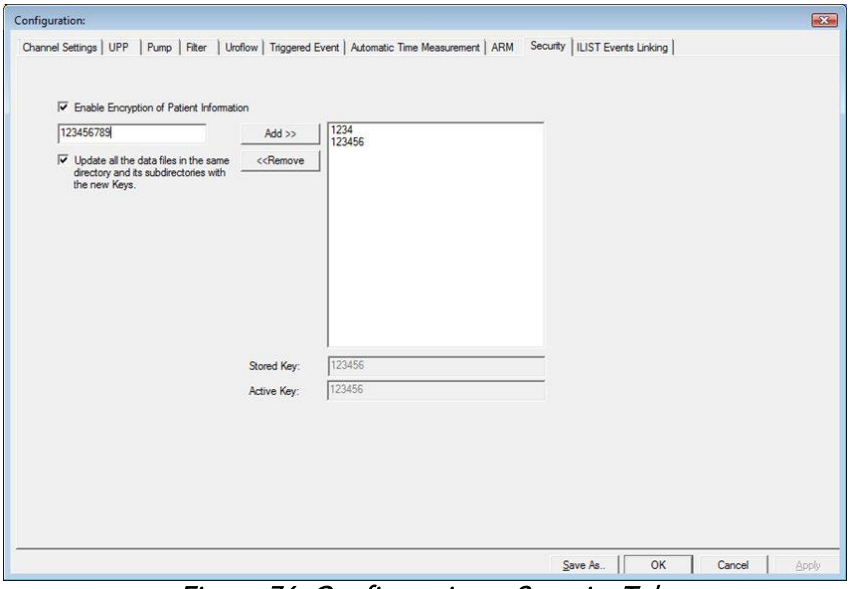


Figure 76: Configuration – Security Tab

To select all data files for encryption with a newly added serial key, even those already saved, select the *Update all the data files….* option.

7.5.3.8 I-LIST EVENTS LINKING TAB

Events that are not in the ***I-LIST Events Linking*** may not appear in some of the printed reports. Use the **iList Events Linking tab** to view available events.

Follow the instructions below to review event availability in the Event Summary:

1. In the software click **Config** > **Set up/Modify**.
2. Click the I-LIST Events Linking tab (Figure 77).

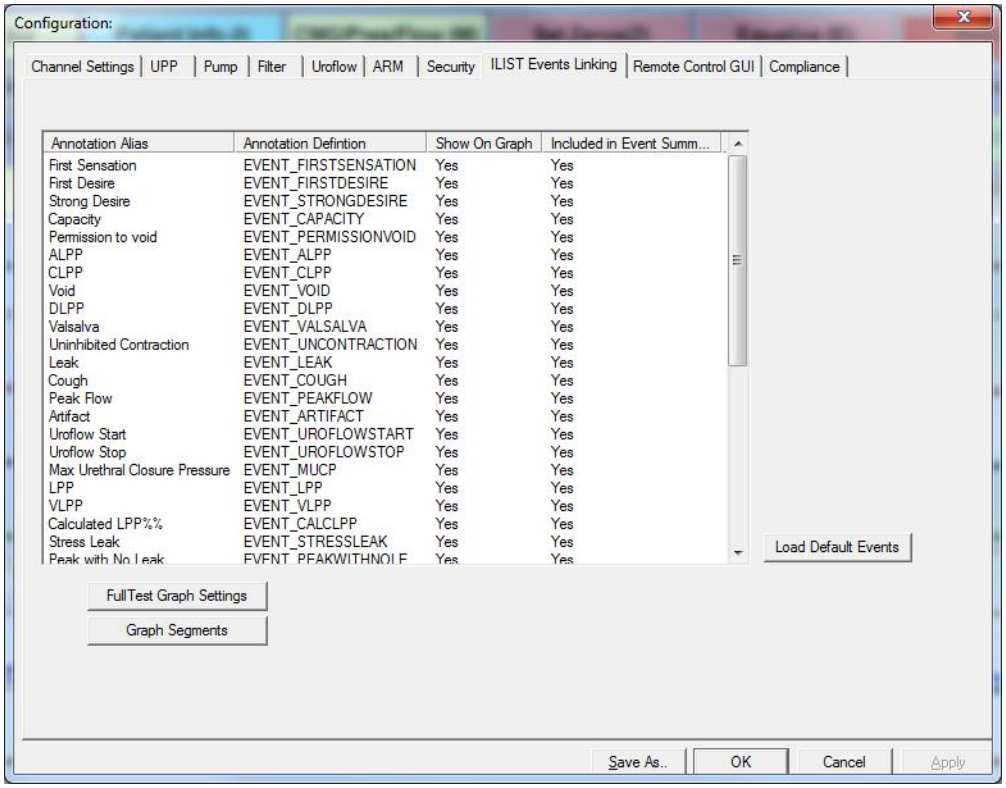


Figure 77: Configuration Window – ILIST Events Linking Tab

LIST Office Reporter will display only the events that appear in the list under this tab. Also, the *Annotation Alias* needs to exactly match what you mark on the UDS test in order to appear in the *Event Summary*.

If a new event is required or the software is being used with a language other than English, use the *Annotation Alias* listing located at the left most column of the **iLIST Events Linking tab** to add or translate an event name. Double click on the event name and change naming as needed. For example, the event *Strong Cough* is added to the list. Click the **Event** button on the control panel and the newly added event will appear in the *Event Annotation* window.

The *ILIST Events Linking* tab provides a listing of events in addition to **Load Default Events**, **Full Test Graph Settings**, and **Graph Segments** buttons.

- Click the **Load Default Events** button to add the standard **iList™** events to the listing.
- Click **Graph Segments** to customize the width, height and minutes per page for reports (Figure 78).

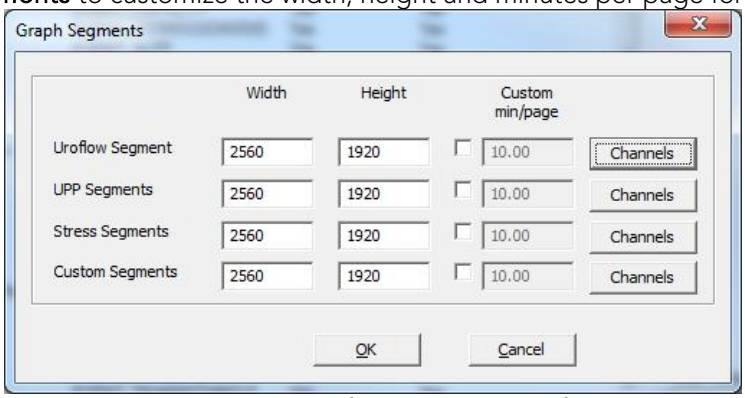


Figure 78: Graph Segments Window

- Select *Channels* to specify the channels to appear on the graph segment (Figure 79).

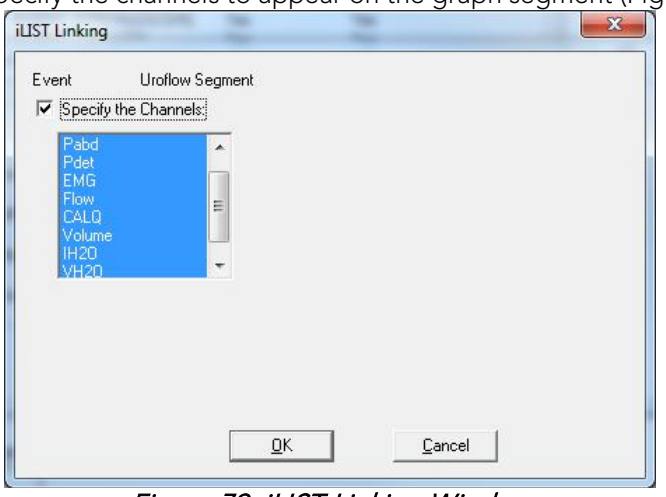


Figure 79: iLIST Linking Window

7.5.3.9 COMPLIANCE TAB

The **Compliance** tab, in the **Configuration** window, provides configuration options for automatically calculated **Bladder Compliance**. **Bladder Compliance** is commonly calculated from events in the filling stage of a study. Refer to the Bladder Compliance (Optional) section on page 105 for instructions on using automatically calculated **Bladder Compliance** and for information on accessing Bladder Compliance options from the *Info* Menu.

7.6 INFO MENU

The *Info* Menu contains items that that allow viewing of patient information as well as test summaries.

7.6.1 PATIENT INFORMATION

The details of a patient's file are easily added to and accessed through the *Patient Information* window.

To access the Patient Information box:

1. Click **Info** from the menu bar and select **Patient Info**. The *Patient Information* window appears.
2. Click in the **Patient** field and enter the patient's name.
3. Continue entering information into the fields available.
4. Click **OK**. The data entered in the Patient Information dialog box is saved and the Patient Information dialog box closes.

Refer to Figure 80 for a visual of the *Patient Information* window in the UDS software. Refer to Figure 81 for a visual of the *Patient Info* window in iList.

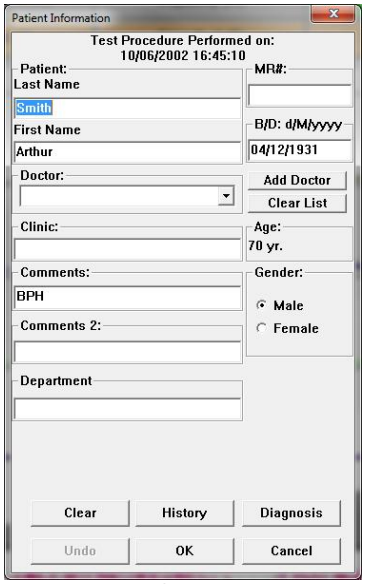


Figure 80: Patient Information Window – UDS

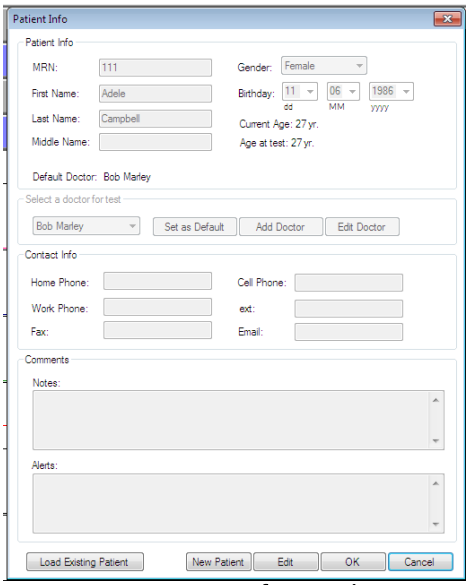


Figure 81: Patient Info Window – iList

IMPORTANT:

- Enter the patient's date of birth as month/day/year/, with one or two digits for the month or day and four digits for the year. For example: A patient born on September 8, 1972 would be entered as 09/08/1972 or 9/8/1972.
- Once the date of birth field is filled, the *Age* field automatically calculates from the date of birth to the date of the procedure. Pediatric patients, patients 16 years of age and younger, require additional setup. Refer to the Pediatric Information section on page 78 for more information.
- The *Gender* field selection informs statistical deviation information appearing in the *Voiding Summary*.
- The *Patient Name* field must be complete for the appropriate statistical deviation to print. Enter blank spaces into the **Patient Name** field if you do not want to enter a name.
- The *MR#* (medical record number) field keeps track of the patient's medical records, especially when names appear more than once.
- To add more than one doctor's name to the Doctor listing, enter a name and click the **Add Doctor** button. To remove names, click the **Clear List** button.
- If there is a change in any patient information in this window, you will need to save the CFG and/or DTA file again to confirm any changes.
- The *Patient Names* (first and last) fields can accommodate up to 44 characters.
- Medical record numbers cannot contain a back slash (\) or a forward slash (/).

7.6.2 PEDIATRIC INFORMATION

When entering information for a patient who is 16 years of age or younger, the *Patient Information* window will automatically adjust itself to allow for the addition of necessary information (Figure 82). Refer to overview of fields below:

- EBC: ***Bladder Capacity*** – shown in milliliters - automatically calculated using the formula: 30 x (Age + 1)[i].
- ATBC: ***Acceptable Total Bladder Capacity***. This limit is the maximum amount of fluid that can be infused into the patient according to bladder capacity at a given age. Calculated using the formula: ATBC = 16 x (Age of child in years) + 70 ml[ii].
- **Height:** add height in centimeters.
- **Weight:** add weight in kilograms.
- **Surface Area:** of the bladder - shown in square meters – automatically calculated based on height and weight.
- MPUR: ***Maximum Physiological Urinary Rate*** - shown in milliliters per minute – automatically calculated based on patient's height and weight.
- **Fill Rate:** fill rate of the pump.
  - *Current Pump Speed:* allows for selection of slow, medium, or fast fill rate
  - *Use MPUR (10% of EBC) for pump speed* and *Use ½ MPUR (5% of EBC) for pump speed*: automatically sets the ideal pump filling rate based on MPUR value.
  - *Sq.Root Bladder Volume*: automatically sets the ideal pump filling rate based on EBC value.

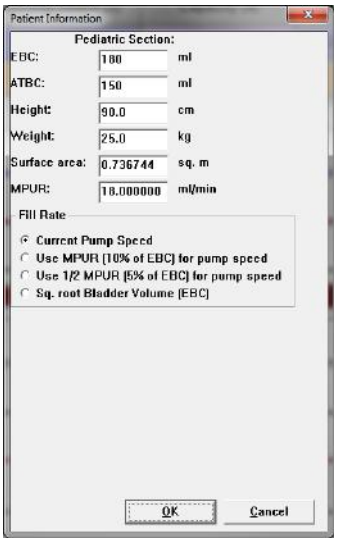


Figure 82: Patient Information Window

NOTE: To enable pediatric pump settings, select the test configuration (.cfg) file first then enter patient information. *MPUR* and *Sq Root Bladder Volume* fill rates can then be selected for the test.

7.6.2.1 VOLUME WARNING LIMIT

The **Volume Warning Limit** is used in the pediatric "Uro Mode" which applies to patients under 16 years of age. This limit is the maximum amount of fluid that can be infused into the patient according to bladder capacity at a given age.
The **Volume Warning Limit** is determined by Acceptable Total Bladder Capacity (ATBC.):

ATBC = 16 x (Age of child in years) + 70 ml.[ii]

The pump receives the information to calculate the ATBC from the data entered in the Patient Information dialog box.
NOTE: The ATBC is automatically calculated and cannot be changed.

If the infused volume exceeds the limit specified in the Volume Warning Limit box, a message appears.
IMPORTANT: After the warning appears, the pump does not automatically stop. It must be manually stopped.

7.6.3 HISTORY

Save a brief patient history with the study. The information in the History box is easily retrievable for future reference.

1. Click **Info** from the menu bar and select **History**. The History window will appear.
2. Enter helpful information about the patient.
3. Click **OK** to save the information.

NOTE: The **History** feature can also be accessed from the **Patient Information** dialog box (Figure 127).

7.6.4 DIAGNOSIS

The diagnosis feature holds notes made about a patient's condition after the test has been performed. Save the *Diagnosis* window with the test for future reference.

1. Click **Info** from the menu bar and select **Diagnosis**. The *Diagnosis* window will appear.
2. Enter information about the patient.
3. Click **OK** to exit. The information is saved when the file is saved.

NOTE: The Diagnosis feature can also be accessed from the Patient Information dialog box (Figure 127).

7.6.5 X-Y PLOT

The X-Y Plot can be used to calculate the urethral resistance factor (URA), the bladder work function (WF), the Linear Passive Urethral Resistance (LinPURR) graph, and CHESS functionality.
The formulas used to determine ICS Nomogram (URA) and WF are located in the appendix of the article.

7.6.5.1 ICS NOMOGRAM (URA)

The ICS Nomogram or URA (Urethral Resistance Factor) plot determines if a patient's urethra is obstructed or unobstructed by graphing the flow and Detrusor pressure (Pdet) curves of a pressure-flow test on the x- and y-axis respectively.

NOTE: A default delay factor of 0.8 seconds is used to account for any lag time before the Uroflow transducer in a pressure-flow test detects flow. It takes about 0.5 to 1.0 seconds for urine to travel through the urethra and into the Uroflow beaker. (*Refer to Dr. Griffith's article for more information).*

The URA Curve is a curve calculation based on the mathematical model of the equation. Please refer to the article by Dr. Derek Griffiths for more information.

Mathematical equations used for calculating the URA:

URA index:

The URA index is the y-intercept (Pdet intercept) of the following equation:

$$URA = \frac{\sqrt{4dQ^2 \times P\,\det^* + 1} - 1}{2dQ^2}$$

$$Pdet^* = \frac{\left(2dQ^2 \times URA + 1\right)^2 - 1}{4dQ^2}$$ at Maximum flow

Where:

d = 3.8×10^{-4}
Q = maximum flow
Pdet = Detrusor pressure
Pdet* = Detrusor pressure at maximum flow

To display the URA window:

1. Click **Info** > **X-Y plot**.
2. Select ICS Nomogram (URA). The URA Plot window will appear.

Refer to Figure 83.

- In the URA plot figure, the solid curve is *Flow vs. Pdet* and the dotted curve is *URA*.
- To cancel the URA option select **Exit!** in the URA Plot window.
- To display the URA Curve select **URA**.

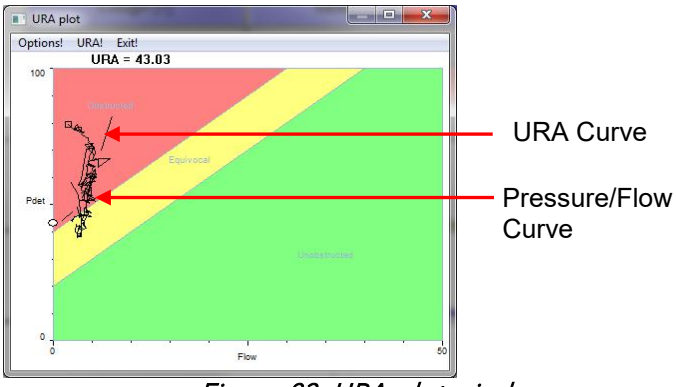


Figure 83: URA plot window

To change a channel name, threshold, or scale:

1. Click **Options!** from the *URA plot* window to launch the *X-Y Options* window.
2. Double-click in the text box of the name, threshold, or scale to be changed.
3. Type the appropriate modification.
4. Repeat until all parameter changes are complete.
5. Click OK to exit.

To specify the analyzing range:

1. Click **Options!** from the **URA plot** window to open the **X-Y Plot Options** window (Figure 84).
2. In the Segment section, click the **Change** button. Select the segment analyzing range by dragging the mouse pointer across the graph from left to right (Figure 85).
3. Click **Confirm**.
4. Click **OK**.

By default, the complete test is plotted on the graph and the scale is determined by the scale of the channels. This information is configured in the X-Y Plot options window.

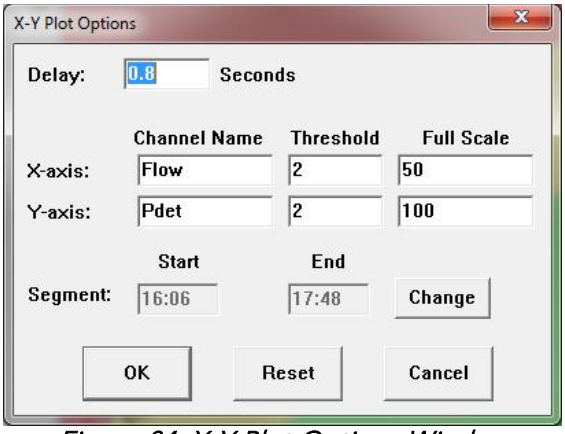


Figure 84: X-Y Plot Options Window

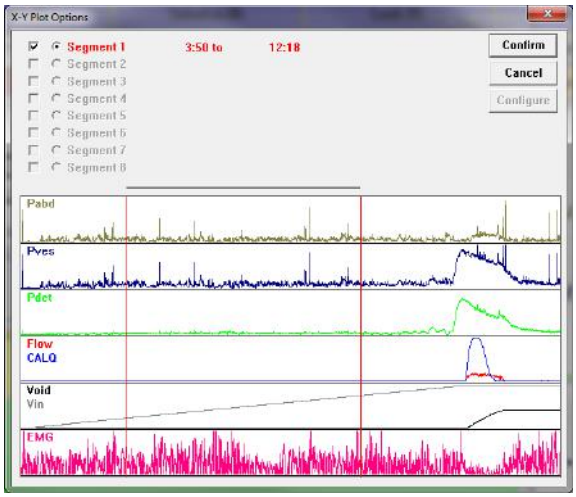


Figure 85: X-Y Plot Options – Change Segments

7.6.5.2 LinPURR

The LinPURR graph[iii] is based on the work by Dr. Werner Schäfer. The LinPURR (Linear Passive Urethral Resistance) feature is available after a Micturition (pressure-flow) test has been run. A LinPURR graph determines urethral resistance by comparing flow and pressure.

To open the LinPURR Graph:

1. Select the **Info** menu and select **X-Y Plot**.
2. Select **LinPURR**.

To cancel the LinPURR Option, select Exit! in the LinPURR window.

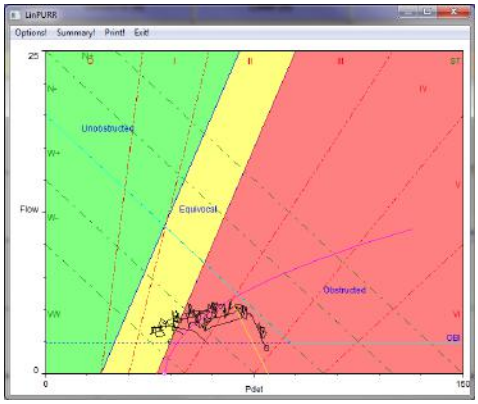


Figure 86: LinPURR Window

A complementary analysis of pressure/flow data can be made using Dr. Schäfer's techniques combined with Abrams/Griffiths. This representation is also in an X-Y format; however, the Flow and Pdet channels are plotted on the Y-axis and X-axis respectively.

To change the Parameters set for the LinPURR graph:

Click Options from the LinPURR window. The *PURR Options* window will load.

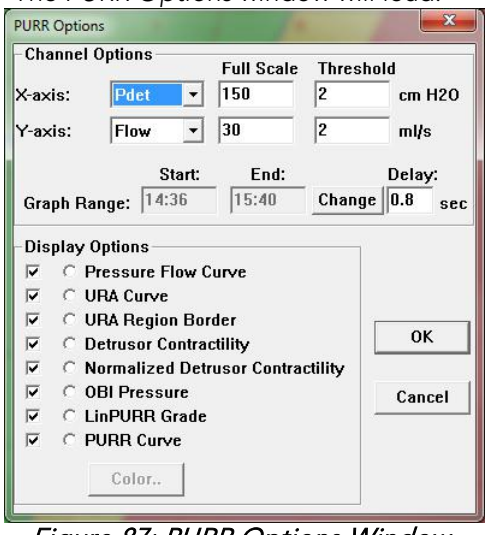


Figure 87: PURR Options Window

To change the Channel parameters or the Graph Range for the Lin PURR graph:

Refer to Figure 87 for a visual of the fields described.

Change the channel:

1. Click the drop-down button of the combo box beside the channel name to be changed.
2. Select the appropriate channel.

Change the Scale or Threshold:

1. Double click inside the appropriate text box.
2. Type a new value using the keyboard.

Change the Graph Range:

1. Click the Change button.
2. Select the new range.

Activate/Deactivate the Display Options:* Click the check box beside the appropriate option.
Color of Display: Select the Channel button. Press Color button.

* These Options are regions of discrimination to assist the clinician in categorizing the pressure/flow event.
The following list explains these regions:

- Pressure Flow Curve: This curve plots Uroflow and Pdet. It is similar to a URA curve, but LinPURR plots the pressure channel on a horizontal axis and the flow channel on a vertical axis.
- URA Curve: Please refer to page 79.
- URA Region Border: These lines on the graph divide the obstructed, unobstructed, and equivocal regions.
- Detrusor Contractility: Detrusor Contractility is displayed as six regions marked in a left-diagonal fashion by the following labels: VW, W-, W+, N-, N+, and S. The software looks at the dataset to determine the relative strength of the bladder using Pdet and Flow as factors.
- Normalized Detrusor Contractility: Normalized Detrusor Contractility represents the pressure at which the minimum "normal" bladder performance has been achieved on the Detrusor Contractility Scale. If this value is 0, then a minimum pressure has not been achieved.
- OBI Pressure: This pressure represents the point at (50% of Qmax+2.4ml/s.)
- LinPURR Grade: To perform a LinPURR Grade, use the following 2 above data points:
    - Pdet at max. Flow
    - Pdet at min. flow

The LinPURR plot can show a rough estimate of the relative grade (0 to VI.)
The digital parameters for LinPURR can be viewed from the LinPURR Summary box.

To access the LinPURR Summary Box:

Click **Summary** from the **LinPURR** window (Figure 86). The **LinPURR Summary** window appears.

To Change information in the LinPURR Summary Box:

To change any channel or pressure values in the boxes: Double-click the text box to be changed and type the new information using the keyboard.

To Change the LinPUUR Grade or Detrusor Contractility: Select the appropriate option.

To Save the information for printing: Click Save Diagnosis. The numerical results of the LinPURR calculation appear in the info-Diagnosis section of the software.

- Click the **Exit!** button to close the LinPURR Summary.
- Click the **Exit!** button in the **LinPURR plot** window to close the LinPURR Plot Window.

7.6.5.3 BLADDER WORK FUNCTION (WF)

The Bladder Work function[iv] is based on the work of Dr. Derek Griffiths. The Bladder Work Function feature is available after a Micturition (pressure-flow) test has been run. This feature calculates the bladder work function (also called bladder power) by using Pdet, Flow, and Bladder Volume.

To access the WF Plot:

1. Click **Info** and select **X-Y plot**.
2. Select **WF**. The WF plot is displayed and the complete test is plotted on the screen. The parameters can be changed in the **WF Configuration** window.
3. Select **Exit!** in the **WF Plot** window to close the **WF Plot** window.

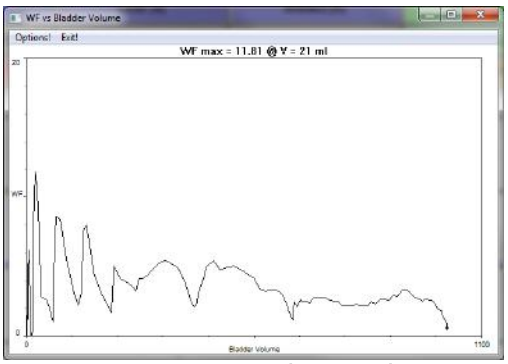


Figure 88: WF Plot Window

To change the Default Settings of the WF Plot using the WF Configuration Window:

1. Click **Options** from the WF window.
2. Change the range by using the **Change** button, if applicable.
3. Type any other changes using the keyboard.
4. Click **OK**.

By default, the Inflow Channel is the infused volume (VH2O) and the Outflow Channel is the voided volume (Volume). Usually the Inflow and Outflow volumes are equal in value; however, if a patient has a residual volume of urine in the bladder, the volumes will not be the same. Residual volume is the difference between the inflow and the outflow. It is automatically calculated and is displayed in the Residual Volume text box.

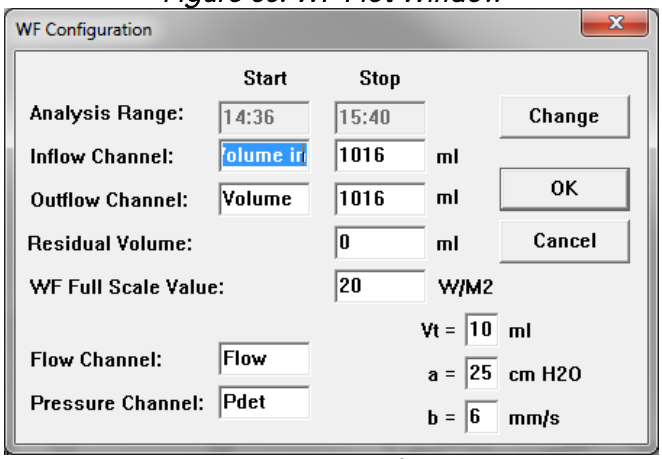


Figure 89: WF Configuration

Mathematical formulas used in this feature are listed here:

Bladder Power:

- WF= $\frac{(P\det + a)(v\det + b) - ab}{2\pi}$ (units: µW/mm^2)

Where: vdet = $\frac{Q}{2}\left(\frac{Vol + Vt}{4.188790205}\right)^{\frac{2}{3}}$

Variables and constants used in these equations are listed here:

- Q = maximum flow
- Pdet = Detrusor pressure
- Vol = bladder volume = infused volume-voided volume
- a = 25 cm H20
- b = 6 mm/s or 0.6 cm/s
- V = 10 ml

7.6.5.4 CHESS

The CHESS classification[v] is based on the work by Dr. K. Hofner. This feature will display a two-dimensional feature based on the independent values of *footpoint* (pvoid min) and *curvature* from the passive urethral resistance relation (PURR). The CHESS menu item is enabled only when there is a FLOW and PDET pressure.

To use the CHESS feature:

1. Run a test with Flow, Volume, and Pressure channels.
2. Stop the test.
3. Click **Info** > **Event Summary**. The **Event Summary** dialog box is displayed
4. Click **Info** > **X-Y Plot** > **ICS Nomogram (URA).**
5. Select **Info** > **X-Y Plot** > **CHESS**. The **CHESS Classification Scheme** dialog box will display.
6. Click File > Print Study. NOTE: Ensure that the URA and CHESS items are checked.
7. Click OK to print test.

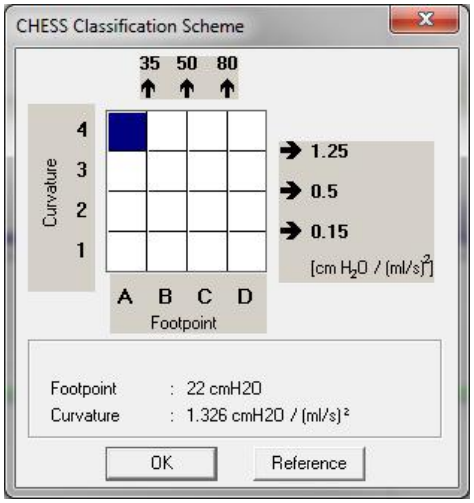


Figure 90: CHESS Classification Scheme Window

7.6.5.5 SIROKY NOMOGRAM

The Siroky Nomogram was developed to provide an accurate and reliable indication of outflow obstruction.[vi] The UDS software provided by LABORIE will help you compare the results of a patient's pre-therapy and post-therapy Uroflow test.

To view the Siroky Nomogram:

1. Start the UDS software and click **File** > **Open** to open a saved Uroflow test.
2. Click **Info** > **X-Y Plot** > **Siroky Nomogram** (Figure 91).

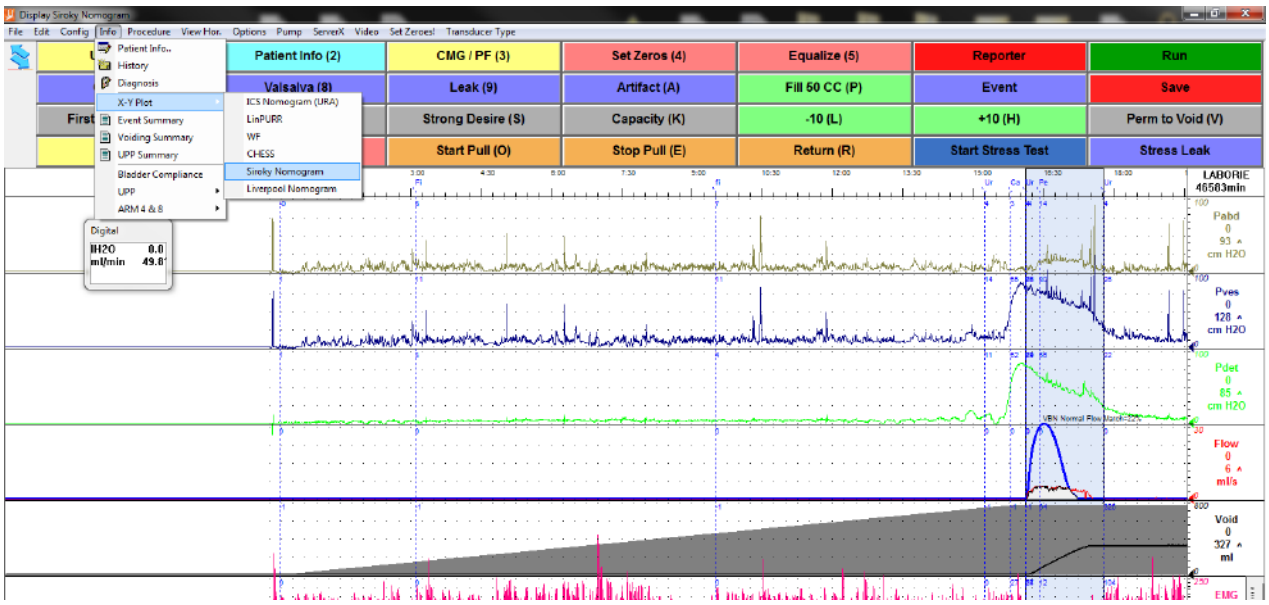


Figure 91: Access Siroky Nomogram

Once selected, the Siroky Nomogram window opens that contains the graphical representation of the Average and Maximum flow rates as developed by Siroky et al.

NOTE: The Siroky Nomogram is valid for male adult patients only.

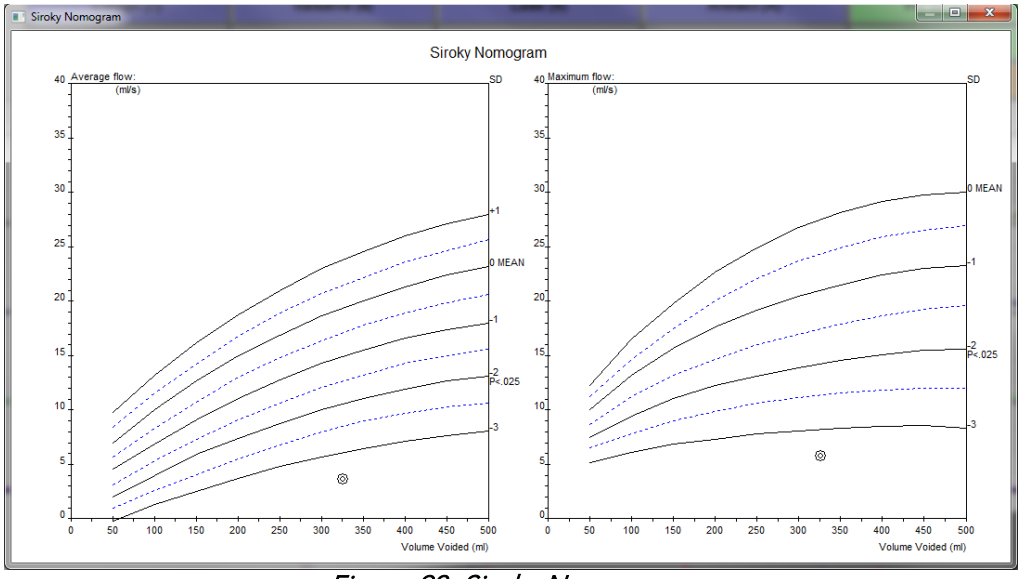


Figure 92: Siroky Nomogram

From here you can compare the average and maximum flow rates for the specific test. The plotted circles on the graph represent where the patient lies on the curve. Close the window to return to the UDS graph window.

7.6.5.6 LIVERPOOL NOMOGRAM

The Liverpool Nomogram was developed to provide an accurate and reliable indication of normal Uroflow rates.[vii] You can compare a patient's pre-therapy and post-therapy urinary flow rate with LABORIE's software and the built-in Liverpool Nomograms.

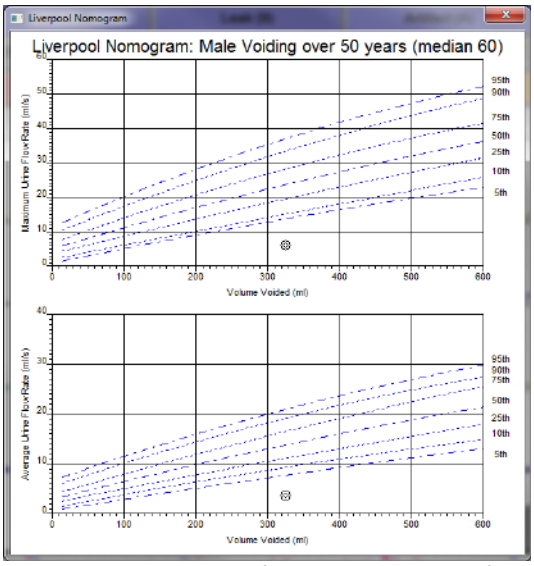


Figure 93: Liverpool Nomogram Window

To view the Liverpool Nomogram:

1. Start the UDS software and click **File** > **Open** to open a saved Uroflow test.
2. Click **Info** > **X-Y Plot** > **Liverpool Nomogram**.

Once you select the Liverpool Nomogram option, a window opens that contains the graphical representation of the Average and Maximum flow rates as developed by Siroky et al.

NOTE: The Liverpool Nomogram is valid for male and female adult patients only. Depending on the sex of the patient, the resulting Nomogram window will appear for either the male or female averages.

Compare the average and maximum flow rates for the specific test. The plotted circles on the graph represent where the patient lies on the curve.

Once you have viewed the graph, click the **X** in the upper-right corner to exit and return to the UDS graph window.

7.6.6 EVENTS

Add events throughout the test to record what occurs during the procedure. Events are automatically stored and displayed once added during a procedure. The summary of these events is available for reviewing through the *Info* menu in the *Event Summary* window.

Add events using the preconfigured Control Panel event buttons available by clicking the event button when the event occurs. Alternatively, left-click the graph window and select **Insert Event**. The **Event Annotation window** will load. Once selected an event marker will be shown on the Graph window.

7.6.6.1 ABOUT THE EVENT ANNOTATION WINDOW

The **Event Annotation** window contains a list of events that can be added to the graph.

- Access the **Event Annotation** window in two ways:
  - Click the **Event** button on the control panel.
  - Right-click anywhere on the graph and select the *Insert Event* option.
- If an event is already listed, then double-click the name to add it to the graph.
- To customize the event list:
  1. Click **Event** on the Control Panel.
     a. To delete an event from the list, select it and click the **Remove** button.
     b. To add a new event to the list, type it in the edit box and click the **Add** button.
  2. After all customizations are complete, click the **Save** button.
  3. Make sure the file name is correct and click **Save**.
  4. Click **Close** to close the list.
- Click the **Sort** button to sort the list alphabetically.
- Click the up and down arrows on the right-hand side to move an event up or down the list.

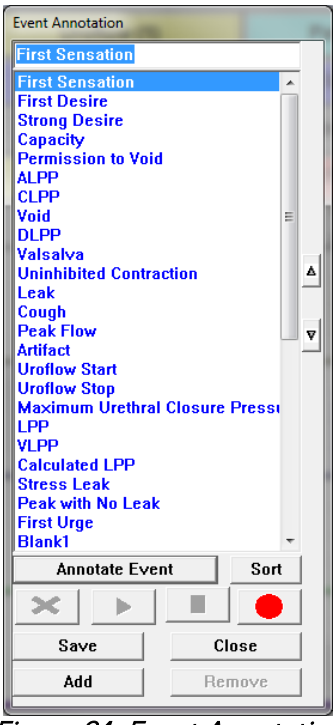


Figure 94: Event Annotation Window

7.6.6.2 DELETING OR RENAMING EVENTS – QUICK METHOD

To delete or rename an event on a graph, right-click on an event located on the graph and select the **Delete** or **Rename Event** option from the resulting menu as shown in Figure 95.

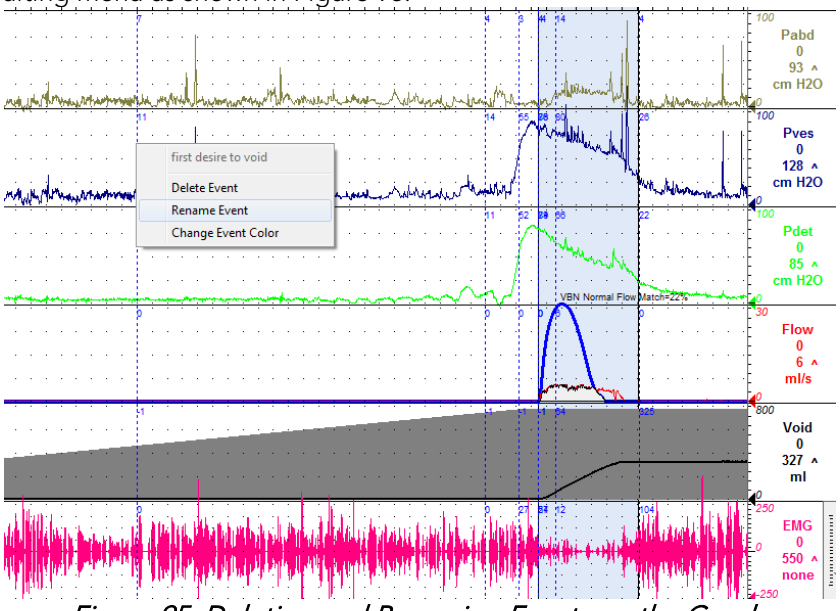


Figure 95: Deleting and Renaming Events on the Graph

7.6.6.3 PERMISSION TO VOID

Add the Permission to Void item to the event list of the **Annotation Window** to facilitate marking of the event during testing. Mark the Permission to Void Event on the graph to find the Maximum Filling Detrusor Pressure (Max Pdet) between the start of a test and the moment the patient voids.

With the Permission to Void event marker, the filling phase and the voiding phase segments will be included on the report when you select to print the study.

NOTE: If a *Permission to Void* event is added after the end of a Uroflow segment (each stop is automatically marked as **Ur** on the graph to signal the end of a segment), a message will appear asking for confirmation to remove the previous Uroflow segment as shown in Figure 96 below.

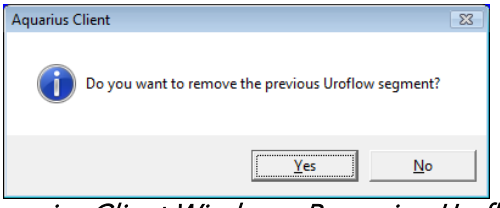


Figure 96: Aquarius Client Window – Removing Uroflow Segment

Click **Yes** to remove the marker or click **No** to keep the marker in the same spot.

7.6.6.4 STRESS EVENTS

The Stress Test and Stress Leak event buttons provide precise LPP (Leak Point Pressure) calculations which can be viewed in the Event Summary.

- Remember to attach the leak point detector to the catheter that will be measuring the pressure before starting the test.
- Click the **Stress Test** button in the *Control Panel* to start or stop the stress test calculation segment.
- Click the **Stress Leak** button to manually add a stress leak during the stress test detection phase.
- A *Calculated LPP* event is added to the graph when the stress test is stopped. This calculation is the change in Pves pressure from baseline (as found at Start Stress Test) to the point of leakage.
- When a test is stopped, a message box appears with options to select and help differentiate between a cough leak and a valsalva leak (Figure 97).

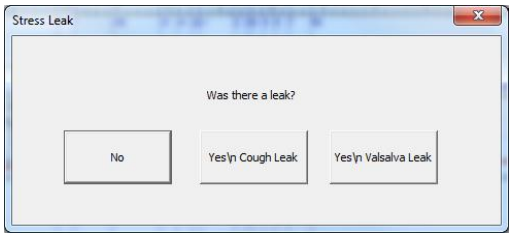


Figure 97: Stress Leak Message Box

- If ***No*** is selected, then a "peak with No Leak" event is added at the peak pressure value within the Stress Test segment.
- If ***Yes*** is selected, then a *Calculated LPP* event is also automatically added at the peak pressure value within the Stress Test segment along with the *Stress Leak* event.

To view the calculations, click **Info** > **Event Summary**.

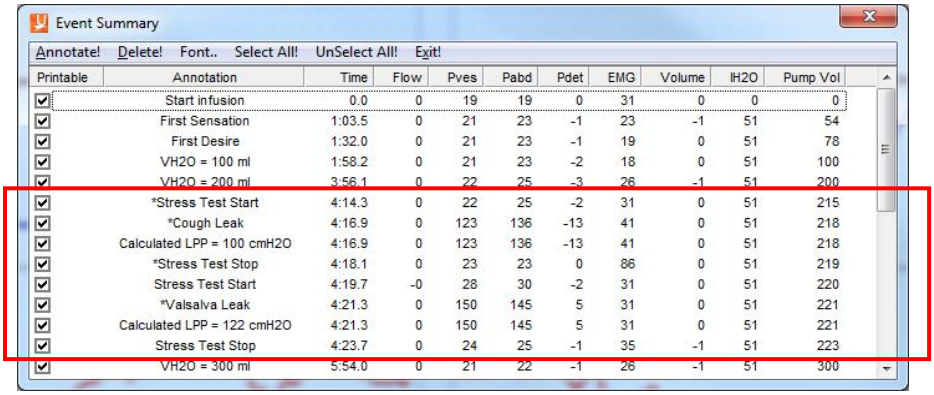


Figure 98: Event Summary Window – Stress Test Events

Stress events can also be recorded using the **Control Panel** instead of the *Annotation* window. Include **Valsalva** and **Cough Leak** Events in the Control Panel during configuration. Mark the events by clicking the assigned buttons during the test. Refer to Figure 99 for an example of a control panel configured for Stress events.

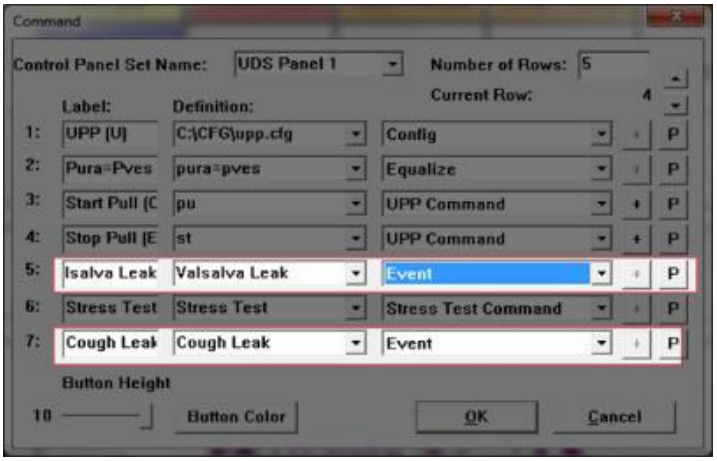


Figure 99: Control Panel Stress Events

7.6.6.5 AREA UNDER CURVE

The *Area Under Curve* feature calculates the area under the curve above a certain threshold for specific graph segments. Calculations can be viewed in the Event Summary.

Before using this feature, the **Area Start** and **Area End** events need to be configured for calculation *start* and *end* points. **Area Start** and **Area End events** configured using control panel buttons can only be used while a test is running, while the events added to the *Event Annotation* box can be used while a test is running or after a test is stopped or saved.

To configure Area Start and Area End buttons in the control panel:

1. Click Options > Control Panel Settings to open the control panel configuration window.

2. In the Command box, configure the Area Start* and Area End buttons.

* The Area Start button is set with the format AS:pressure channel:threshold value. In this example: AS:Pves:0 means that the area under the Pves curve above a threshold of 0 will be calculated (Figure 100).

3. Click OK to add the buttons to the control panel.

Refer to the Control Panel Settings section on page 115 for more information on configuring the control panel.

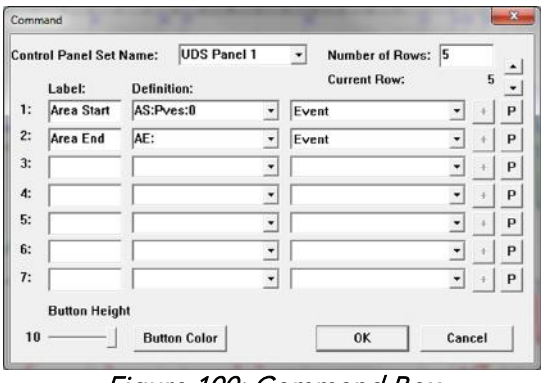


Figure 100: Command Box

To configure Area Start and Area End events in the Event Annotation box:

1. Select a test to run.
2. Click the **Event** button on the control panel to open the *Event Annotation* box.
3. Create the **Area Start** event by typing the format **AS:***pressure channel*:*threshold value.* In this example *AS:Pves:0* means that the area under the Pves curve above a threshold of 0 will be calculated (Figure 101).
4. Click **Add**.

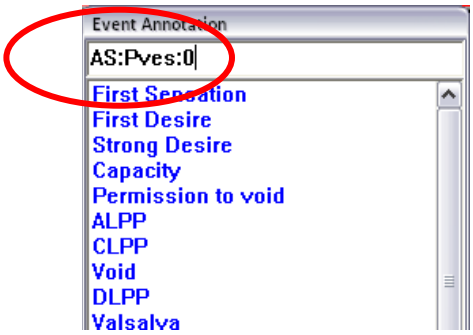


Figure 101: Event Annotation Window, "AS:"

1. Create the **Area End** event by typing **AE: (**make sure that a colon symbol **[:]**is typed after the AE).
2. Click **Add**.
3. Click **Close** to return to the test start window.

Refer to the About the Event Annotation Window section on page 86 for more information on the Event Annotation window.

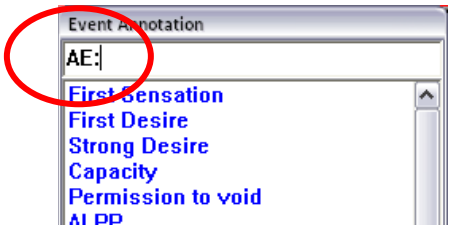


Figure 102: Event Annotation Window, "AE:"

To calculate the Area Under Curve during a test:

1. Click **Run** and then click **Zero All**.
2. When applicable, click the **Area Start** button on the control panel to establish the starting point of area calculation.
3. When applicable, click the **Area End** button to establish the end point of area calculation.
4. Complete the test and click **Info** > **Event Summary** to review the **Area Start** and **Area End** values.

To calculate the Area under Curve for a saved test or after a test is stopped:

1. When a test is stopped or a saved test is open, right click on the graph at the starting point of area calculation and select **Insert Event**.
2. Select the area start event named **AS:** in the list.
3. Click **Annotate Event.**
4. Move the cursor pointer to the end point of the calculation area and right-click on the graph.
5. Select **Insert Event.**
6. Select the area end event named **AE:** ***pressure channel*:*threshold value*** in the list.
7. Click **Annotate Event.** The area calculated will be appended to the Area End Event Annotation in the format *AE: Pves: xxxx* where *xxxx* is the calculated area.
8. Click **Info** and select **Event Summary** to review the **Area Start** and **Area End** values.

7.6.6.6 TRSS EVENTS

Add **TRSS** (*Tone, Reflex, Sensation, and Structure*) events to tests that are stopped or saved.

1. Right-click the graph to add a **TRSS** event and select **Insert TRSS Event**.
2. Select the **TRSS #** (Figure 103).

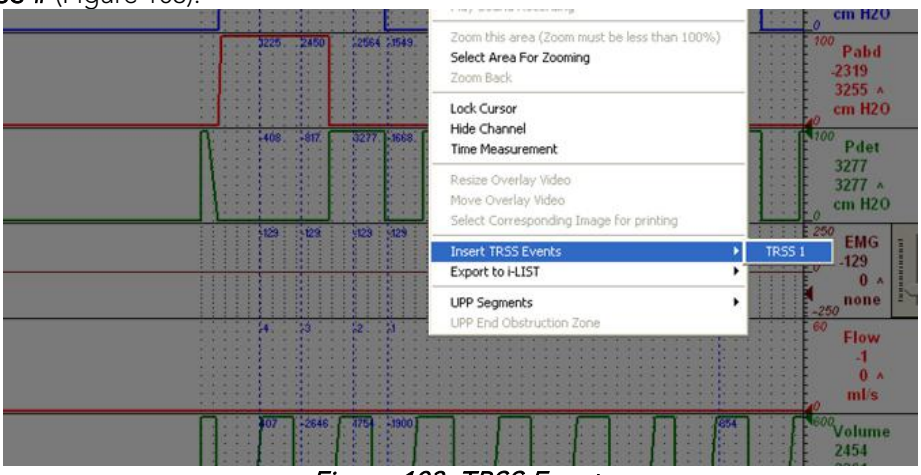


Figure 103: TRSS Events

3. Add **TRSS** events by left-clicking and dragging the cursor across to select the segment for TRSS calculation. Release the mouse button when area is selected.

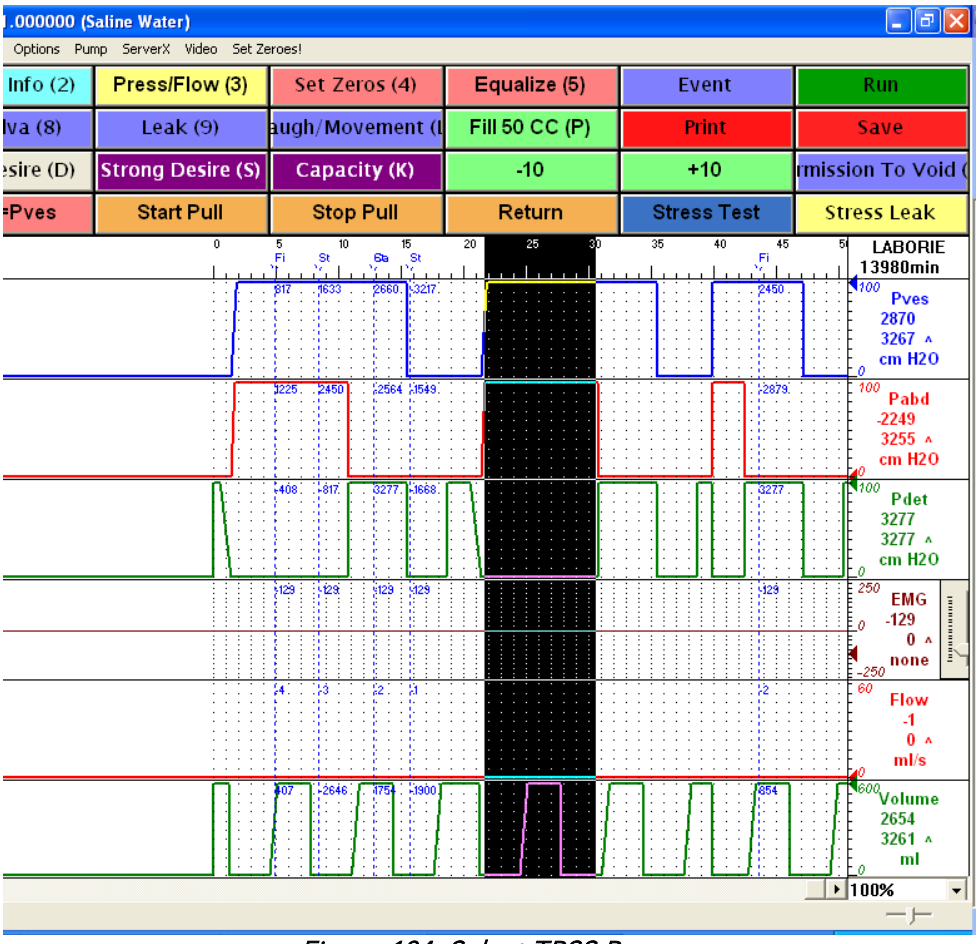
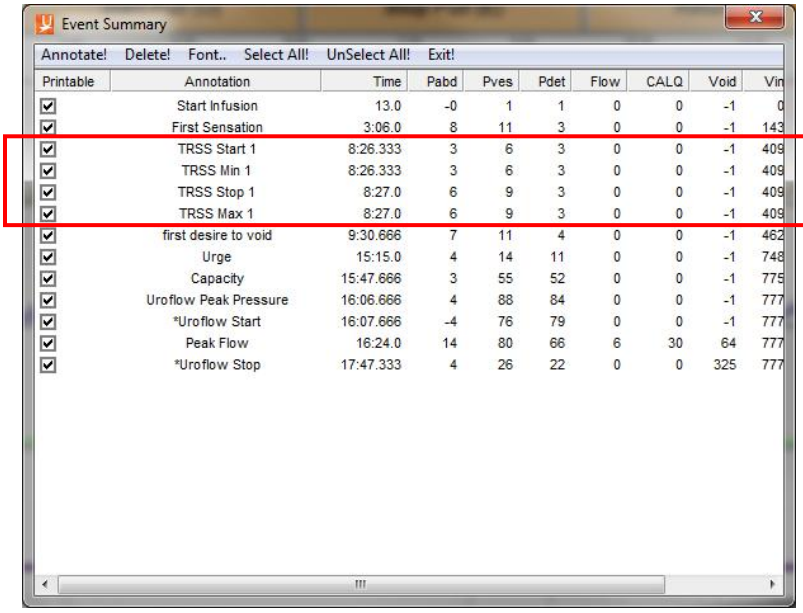


Figure 104: Select TRSS Range

4. The **TRSS Start** and **TRSS Stop** events are added to the graph and the **TRSS Event** values are visible in the *Event Summary* window.



Printable	Annotation	Time	Pabd	Pves	Pdet	Flow	CALQ	Void	Vin
☑	Start Infusion	13.0	-0	1	1	0	0	-1	0
☑	First Sensation	3:06.0	8	11	3	0	0	-1	143
☑	TRSS Start 1	8:26.333	3	6	3	0	0	-1	409
☑	TRSS Min 1	8:26.333	3	6	3	0	0	-1	409
☑	TRSS Stop 1	8:27.0	6	9	3	0	0	-1	409
☑	TRSS Max 1	8:27.0	6	9	3	0	0	-1	409
☑	first desire to void	9:30.666	7	11	4	0	0	-1	462
☑	Urge	15:15.0	4	14	11	0	0	-1	748
☑	Capacity	15:47.666	3	55	52	0	0	-1	775
☑	Uroflow Peak Pressure	16:06.666	4	88	84	0	0	-1	777
☑	*Uroflow Start	16:07.666	-4	76	79	0	0	-1	777
☑	Peak Flow	16:24.0	14	80	66	6	30	64	777
☑	*Uroflow Stop	17:47.333	4	26	22	0	0	325	777

Figure 105: Event Summary – TRSS Events

7.6.6.7 Opening Time Event

The **Opening Time** event calculates the time between the initial rise in bladder pressure, **Rise Pdet**, and **Uroflow Start**.

The mathematical definition for this is: Opening Time = Time at Flow Start – Time at Pdet rise

The **Rise Pdet** event is automatically placed between the **Permission To Void** and **Uroflow Start** events. The event is placed on the Pdet channel. Remember to verify the position of the event on the graph. It can be moved to another area of the graph if necessary.

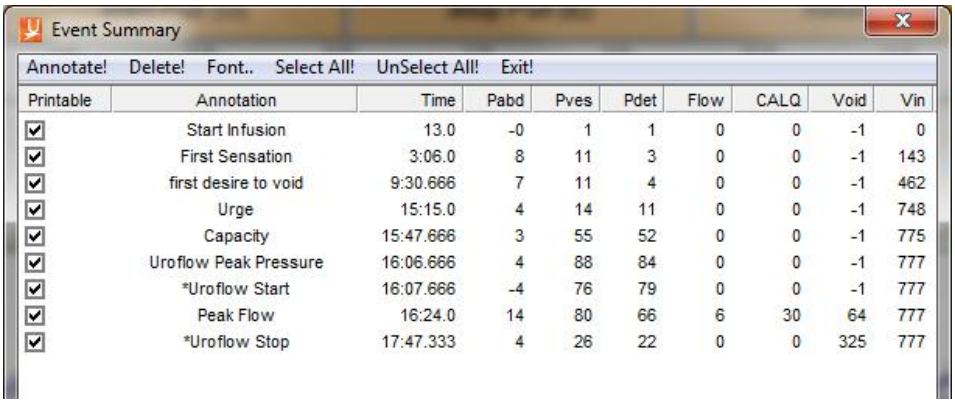
NOTE: that the physiological opening time may be approximately one second shorter than what is displayed.

Once the **Opening Time** event is added to the graph, it automatically activates the calculations associated with the event and the results are visible in the test report. Test reports, in the ***Filling phase Results*** section, will display the following information:

- Maximal Cystometric capacity (in ml): the value from VH2O at **Permission to Void**
- Incontinence during filling (in ml): the value of the Volume Channel at **Permission to Void**
- Bladder filling (Maximal cystometric capacity – Incontinence during filling) (in ml): value from Bladder Volume math channel or equivalent calculation in report.

7.6.7 EVENT SUMMARY

To view the *Event Summary* window:
Click **Info** > **Event Summary**. The events are listed in chronological order in the event summary as shown in Figure 106 below.



Printable	Annotation	Time	Pabd	Pves	Pdet	Flow	CALQ	Void	Vin
☑	Start Infusion	13.0	-0	1	1	0	0	-1	0
☑	First Sensation	3:06.0	8	11	3	0	0	-1	143
☑	first desire to void	9:30.666	7	11	4	0	0	-1	462
☑	Urge	15:15.0	4	14	11	0	0	-1	748
☑	Capacity	15:47.666	3	55	52	0	0	-1	775
☑	Uroflow Peak Pressure	16:06.666	4	88	84	0	0	-1	777
☑	*Uroflow Start	16:07.666	-4	76	79	0	0	-1	777
☑	Peak Flow	16:24.0	14	80	66	6	30	64	777
☑	*Uroflow Stop	17:47.333	4	26	22	0	0	325	777

Figure 106: Event Summary Window

In the *Event Summary* window double-click on an event to move to the point on the graph that corresponds to that event. The *Event Summary* window can be used to Annotate, Delete, and change the Font of events appearing within the on-screen display. The Event Summary window provides an overview of calculations gathered at the time the event was marked.

IMPORTANT: Always save the DTA file in order to keep the event annotation changes with the files.

7.6.7.1 CHANGING THE FONT

To change the appearance of the Event Summary window contents, select the font type and size by clicking the **Font** menu. This opens a *Font selection* window; set font t preferences. This only applies to the on-screen display and not to what is printed on the hardcopy report.

7.6.7.2 ADD OR CHANGE EVENT ANNOTATION

1. Click on an event and click the **Annotate!** button. The *Event Annotation* window will load (Figure 107).

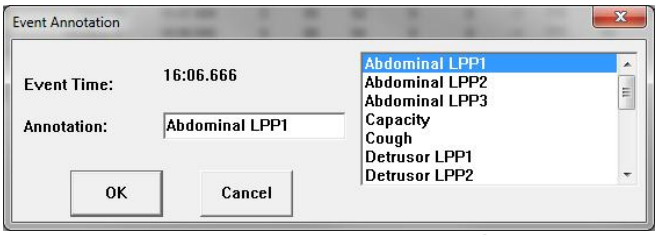


Figure 107: Event Annotation Window

2. Enter the text into the **Annotation field** or select an annotation the list.
3. Click **OK**. The *Event Annotation* window will close. Always save the CFG file in order to keep the event annotation changes with the files.

7.6.7.3 DELETING EVENTS FROM THE EVENT SUMMARY

1. Highlight the event. To highlight multiple events, hold down the Ctrl key while clicking on the events.
2. Click the **Delete!** button. The **Confirm Event Delete** message box will display.
3. Click **OK**. The events are deleted from the *Event Summary*.

7.6.7.4 EVENT LINE COLORING

To highlight an event placed on the graph, add a colored line to make it easily visible.

1. Open a test file if not already open.
2. Click **Info** > **Event Summary** to open the ***Event Summary*** window.
3. Click to select an event from the list, for example select the *First Sensation* event.
4. The selected event is automatically bolded on the graph (Figure 108). Close the ***Event Summary*** window.

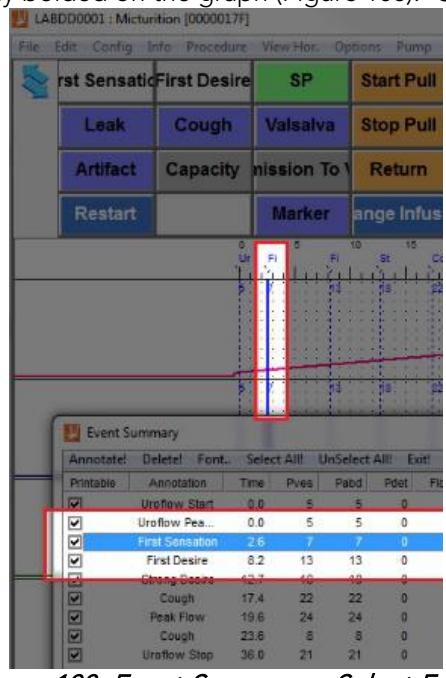


Figure 108: Event Summary – Select Event

5. Right-click the event on the graph to open the *context menu*.

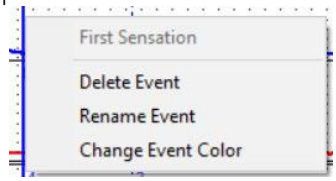


Figure 109: Select Event – Context Menu

6. Select **Change Event Color** to open the *color selection* window.
7. Select a new color from the available color boxes, for example change from blue to orange, and click **OK**. The event's line marking will change to the newly selected color.

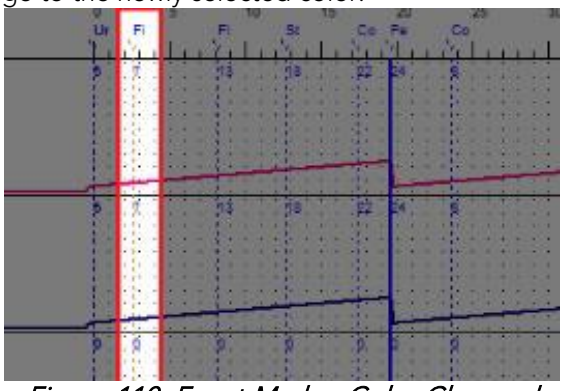


Figure 110: Event Marker Color Changed

8. Continue to change colors as preferred.

NOTE: If there are multiple instances of an event on the graph, the color change will be applied to all instances of the event. For example, if there are three *Cough* events on the graph and one is selected for color change, then the other two will also change color.

7.6.7.5 SELECTING/UNSELECTING EVENTS FOR PRINTING

The operator can select events and values for printing in the test results. To have all the events included on the test result printout click **Select All!** All events will be selected as shown in the *Printable* column where all boxes will be checked. To select specific events for inclusion click on check box in the *Printable* column. To exclude all the events from the printout, click **UnSelect All!**. Refer to the Printable column of Figure 106.

7.6.8 VOIDING SUMMARY

The *Voiding Summary* menu item applies only to tests involving Uroflow information like the Uroflowmetry and pressure-flow procedures. The Summary compares a patient's test results with normal values. Statistical deviations are calculated using these standards and are intended strictly for comparison purposes and should not be used solely for diagnostic purposes.

IMPORTANT: Since this comparison is based on patient gender, the gender must be correctly entered in the Patient Information dialog box. The software calculates the summary results only if the minimum voided volume is 55 ml.

To access the Voiding Summary:

Click **Info** from the menu bar and select **Voiding Summary**.

* BOOI, BCI, and BE references index values (see page 196 for definitions)

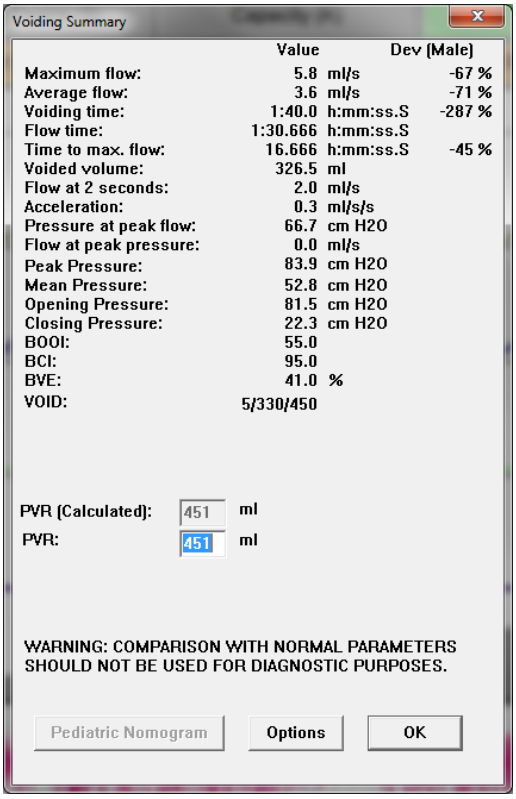


Figure 111: Voiding Summary Window

Voiding Summary Analysis

The Voiding Summary printout supplies a comparison to the Nomogram tables. They are provided for both male and female patients on the same printout. The comparison is provided in a percent difference from the table value. Following is the mathematical formula used in the calculations:

Peak Flow:
$$\frac{PeakFlow - PeakFlowMin(Volume, Sex)}{PeakFlowMin(Volume, Sex)} * 100\%$$

Mean Flow:
$$\frac{MeanFlow - MeanFlowMin(Volume, Sex)}{MeanFlowMin(Volume, Sex)} * 100\%$$

Flow Time:
$$\frac{TimeOfMicturitionMax(Volume, Sex) - FlowTime}{TimeOfMicturitionMax(Volume, Sex)} * 100\%$$

Time To Peak Flow:
$$\frac{TimeOfToMaxFlowMax(Volume, Sex) - TimeToPeakFlow}{TimeOfToMaxFlowMax(Volume, Sex)} * 100\%$$

These percent values are found in the patient statistics of the Voiding Summary printout. The M% represents the male values and the F% represents the female values.

⚠ WARNING: The comparison with normal parameters should not be used for diagnostic purposes. It is recommended to repeat the study if the total voided volume is inferior to 55 ml; normal parameters are not available below this volume. Statistic values cannot be given if the voided volume is less than 55 cc and more than 555 cc.

NOTE: Parameters of urinary flow were analyzed from 150 curves from subjects between 20 and 40 years old. The minimum normal for a given volume appears to be the most practical value with which to compare patient flow rate.

7.6.8.1 UROFLOW OPTIONS DIALOGUE BOX

The *Uroflow Options dialog box* is available from the *Voiding Summary Menu*. Click the **Options** button to launch the dialogue box. From the *Uroflow Options* ***Dialog Box*** you can:

- Customize how the **Voiding Summary** is calculated.
- Make changes to the channels and configuration parameters.

Refer to the following diagram and its legend to change any parameters in the *Uroflow Options Dialog Box*.

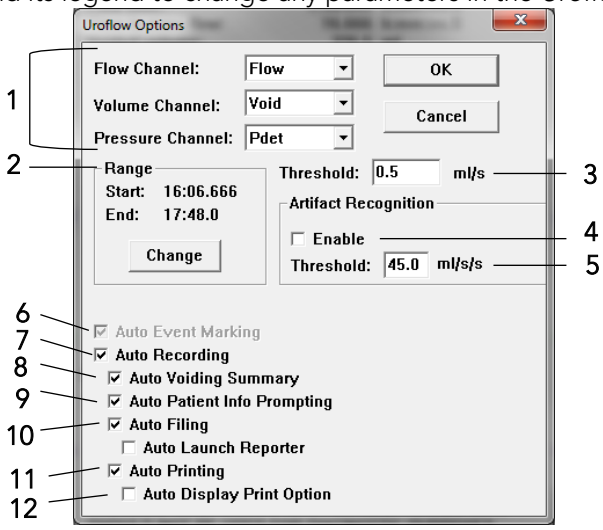


Figure 112: Uroflow Options Window

Number	Description
1	*Default channels:* Flow, Volume, and Pressure.
2	*Range*: Default range is from start to end of test.
3	*Threshold:* The minimum flow rate value used in calculating the Voiding Summary. Anything below this threshold is considered noise or insignificant flow. The minimum flow rate value used in calculating the Voiding Summary. Anything below this threshold is considered noise or insignificant flow.
4	*Enable Artifact Recognition:* Select check box to enable.
5	*Artifact Recognition Threshold*: Indicates the maximum acceptable change in Flow (acceleration) that is physiologically possible.
6	*Auto Event Marking:* Automatically adds events to graph.
7	*Auto Recording:* With Auto Recording on, tests are automatically started and stopped once the transducer senses fluid in the beaker.
8	*Auto Voiding Summary:* A Uroflow auto recording option to display Voiding Summary after a test is finished. Auto recording must be enabled for this to work.
9	*Auto Patient Info Prompting:* A Uroflow auto recording option to display the Patient Info window when a test is stopped. A Uroflow auto recording option to display the Patient Info window when a test is stopped.
10	*Auto Filing*: An auto recording option to save a file when a test is stopped.
11	*Auto Printing*: An auto recording option to print a file when a test is stopped.
12	*Auto Display Print Option:* An auto printing option to display print option before auto printing.

Table 23: Uroflow Options Window – Settings Description

To change a Channel:

1. Click the dropdown menu of the channel to be changed and a channel list will appear.
2. Select the appropriate channel name.

NOTE: Normally the default settings for threshold are not changed for performing Uroflowmetry on patients. Consult with your LABORIE representative for modifications to default settings.

The calculating channels may be replaced with other channels if the units are consistent in definition. **Example:** "Flow" may be replaced with another math channel depicting corrected flow rate.

To change the Time Range:

1. Click **Change**. The *Uroflow Options* window will appear for segment selection.

Figure 113: Uroflow Options Window – Time Range Selection

2. Click and drag the mouse pointer across the graph window from the start to the end of the Uroflow segment. A bold black line will run across the top of the box indicating the selection.
3. Release the mouse button and the start and end lines of the segment will be updated.
4. Click **Confirm** to save changes or click **Cancel** to cancel changes and return to the *Uroflow Options* window.

Artifact Recognition

This refers to the detection of non-physiological transducer readings. For example, if a patient kicks the transducer, the curve indicates a very high spike. The height of the spike is "unnaturally" high and therefore the UDS software recognizes the event as a deviation from what it considers a normal reading.

To enable the software to recognize Artifacts:

Select the **Enable Artifact Recognition** box and a checkmark will appear in the box indicating that the software will detect artifacts.

The Threshold check box in the Artifact recognition box indicates the speed of flow. The defaulted rate of flow is 45.0 ml/s/s. That rate means that if the speed of flow accelerates more than 45.0 ml/s/s, it is considered an artifact. When an artifact is detected, the Voiding Summary calculation will ignore the next set of data.

To change the Acceleration Rate Threshold for Artifact Recognition:

1. Double-click the *Artifact Recognition Threshold* box. The value in the text box is highlighted.
2. Enter a new value. The software recognizes the new value in the *Threshold text* box as the maximum rate of flow over which it considers an artifact.
3. Click **Confirm** to save changes or click **Cancel** to cancel changes and return to the *Voiding Summary* window.

Uroflow Auto Recording

The Uroflow Auto Recording feature is used for Uroflow or Pressure-Flow studies. It will automatically start a procedure.

This feature provides Auto Start, Auto Stop, and Auto Set Up of the next procedure. Selecting the *Auto Recording* option in the *Uroflow Options* window allows this feature. Once selected, choose other customizable auto options. The options are performed in the following order:

Options	Always On/Selectable	Description
Auto Beaker Detection	Always On	After selecting this procedure, it detects if a beaker is on the Uroflow transducer. If no beaker is put on, it will display the message *Beaker lifted up* in the title bar.
Auto Set Zeroes	Always On	Once a beaker is detected for eight consecutive seconds, zeroes are automatically set. If the beaker is lifted up after zeroes are set, detection will restart.
Auto Start	Always On	The test is automatically started if an increase in volume is detected after the beaker is settled.
Auto Stop	Always On	The test is automatically stopped 50 seconds after flow stops.
Auto Patient Info Prompting	Selectable	Automatically displays the Patient Info dialog box.
Auto Calculation	Always On	Automatically calculates the Voiding Summary.
Auto Voiding Summary	Selectable	Automatically displays the Voiding Summary window if Voiding Summary is valid.
Auto Filing	Selectable	Automatically saves the test in the form YYMMDDxx.QTA
Auto Printing	Selectable	Automatically selects the test for printing.
Auto Display Print Option	Selectable if Auto Printing on	Automatically displays the Print Option dialog box for confirmation/customization.
Auto Set up next test	Always On	Automatically sets up the next test.

Table 24: Auto Recording Options

Pediatric Nomogram (Optional)

The Pediatric Nomogram[viii] feature can be accessed from the Voiding Summary window. This is based on the work of Dr. Churchill at the Hospital for Sick Children in Toronto. The Nomogram is a plot of Peak Flow vs. Voided Volume and the center curve represents the Mean. The patient's flow data is represented by a circled dot on the graph. As a result, a normal flow curve is age and gender related.

NOTE: This feature is available only if the patient is between 3 to 16 years of age.

To access the Pediatric Nomogram Feature:

1. Click Pediatric Nomogram in the Voiding Summary window. The **Pediatric Nomogram** window will appear (Figure 114).

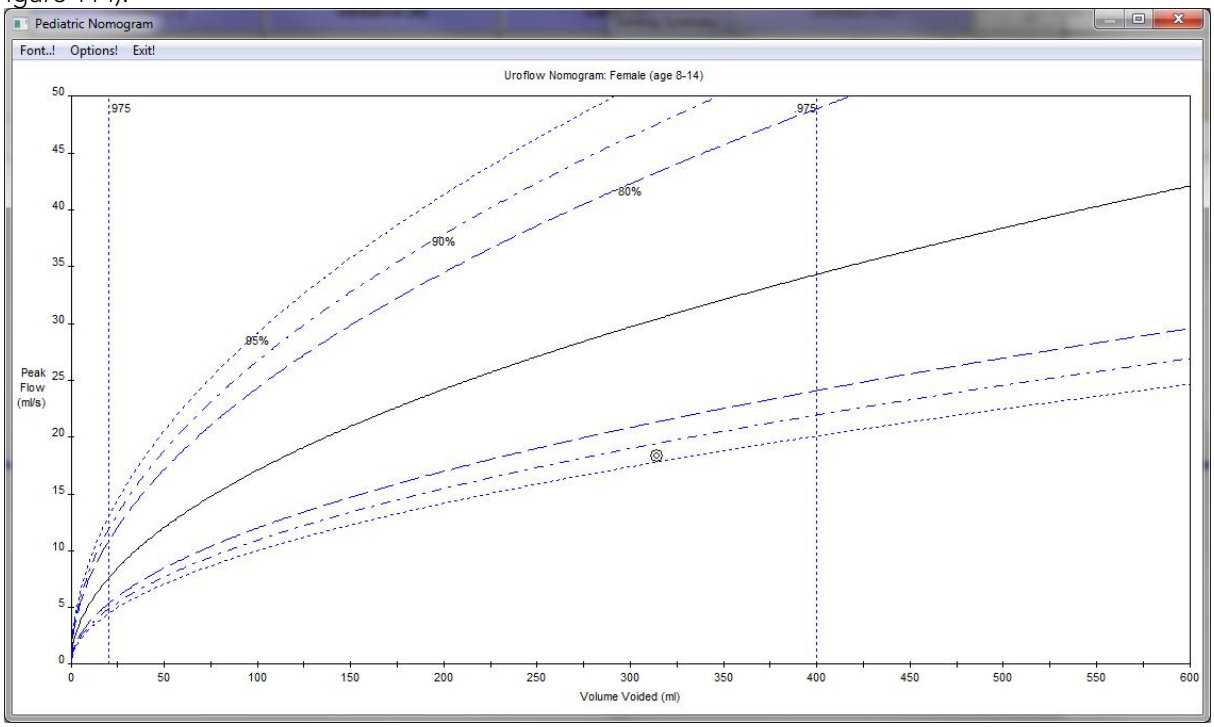


Figure 114: Pediatric Nomogram Window

2. View data in the **Pediatric Nomogram** and adjust settings as necessary in the window's toolbar.
    d. Change the font by using the *Font* menu.
    e. Change the scales by using the *Options* menu.
    f. Close the Pediatric Nomogram window by clicking **Exit!**.

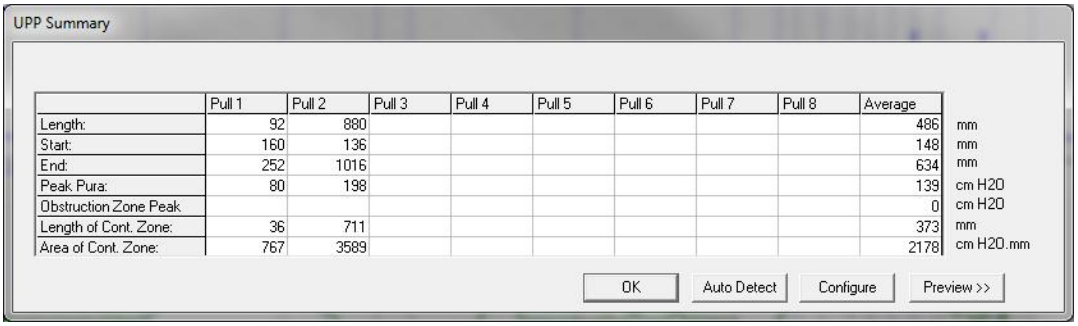
7.6.9 UPP SUMMARY

UPP start and stops are marked as events on the UDS screen. Pass the pointer over a UPP start or stop event and a ToolTip will display the event names (Figure 115). Reposition the event by clicking the line and moving it along the graph to a new location.

Figure 115: UPP Test Window – Event Markings

To open a UPP summary:

Click **Info** from the menu bar and select **UPP Summary**. The *UPP Summary* window will appear (Figure 116). Each column on the *UPP Summary* window represents a segment of the UPP test. From Pull start to Pull stop is one UPP segment or Pull 1. Additional Pulls are recorded in their own sequentially named columns (Figure 116).



	Pull 1	Pull 2	Pull 3	Pull 4	Pull 5	Pull 6	Pull 7	Pull 8	Average	
Length:	92	880							486	mm
Start:	160	136							148	mm
End:	252	1016							634	mm
Peak Pura:	80	198							139	cm H2O
Obstruction Zone Peak									0	cm H2O
Length of Cont. Zone:	36	711							373	mm
Area of Cont. Zone:	767	3589							2178	cm H2O.mm

Figure 116: UPP Summary Window

The UPP Summary window contains the following information:

- ***Length:*** Length of the urethra (functional length). The UDS software calculates the urethral length by multiplying the withdrawal rate by the period of the functional segment of the graph.

IMPORTANT: The recommended withdrawal speed is approximately one millimeter per second.

- *Start:* Starting time of the pull
- *End:* Terminating time of the pull
- *Peak Pclo:* Maximum urethral closure pressure
- *Obstruction Zone Peak:* Maximum pressure at observed obstruction (see page 101 for more information)
- *Length of the Continence Zone:* Distance between the bladder neck and the highest pressure point in profile
- *Area of the Continence Zone:* Area under the Length of Continence Zone

For information on the **Preview** button and its function, refer to the *Config* menu, UPP Tab on page 70.

To select and modify a segment for analysis:

1. Click the column heading (Pull 1, Pull 2, etc...) of a UPP pull. The start and stop times will be highlighted in green, and the graph on screen will scroll to the end position of the selected UPP pull.
2. Click the Auto Detect button to automatically adjust the start and end range *or* manually move one of the UPP start or stop events on the UDS screen. The events are updated on the screen and in the *UPP Summary* window.

NOTE: *Select up to eight segments for UPP calculation.*

To change the Puller Speed, Measuring Channel, and/or Threshold:

1. Click the **Configure** button on the UPP Summary window. The *UPP Config* box will appear.
2. Click the text box of the data field to be changed and enter the new data.
3. Click **OK**. The data fields are updated and the UPP Config dialog box closes.

Refer to the UPP Tab section in the *Config* Menu on page 70.

To print the UPP Summary:

1. Click **File** > **Print Study**.
2. Select **UPP Summary** from the *Preferences* section on the left side of the window.
3. Select **UPP Sections** from the *Print Range* section.
4. Select the desired segments.
5. Click **OK** to print.

Refer to the Print Study section on page 58 for more information on printing options.

Obstruction Zone Peak

Set the maximum pressure at an observed obstruction point. This setting will recalculate the peak pressure point.

To set the UPP obstruction zone:

1. Right-click inside a *UPP range on the graph* and the context menu will appear.
2. Select **UPP End Obstruction Zone** from the context menu (Figure 117).

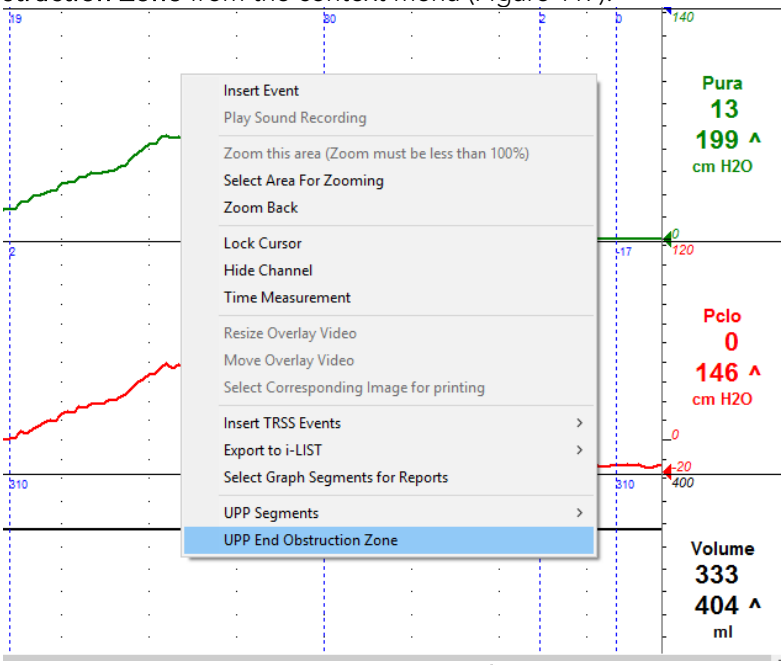


Figure 117: Context Menu – Obstruction Zone

3. The UPP obstruction zone will be marked on the graph as an event annotation in the format *UPPXeObstruction* (where *X* represents the UPP segment number). The original peak pressure event is recalculated between this new event and the UPP stop event, which becomes the UPP peak pressure for Functional Zone. A new peak event is also added called *Obstruction Zone Peak 1*. Refer to Figure 118.

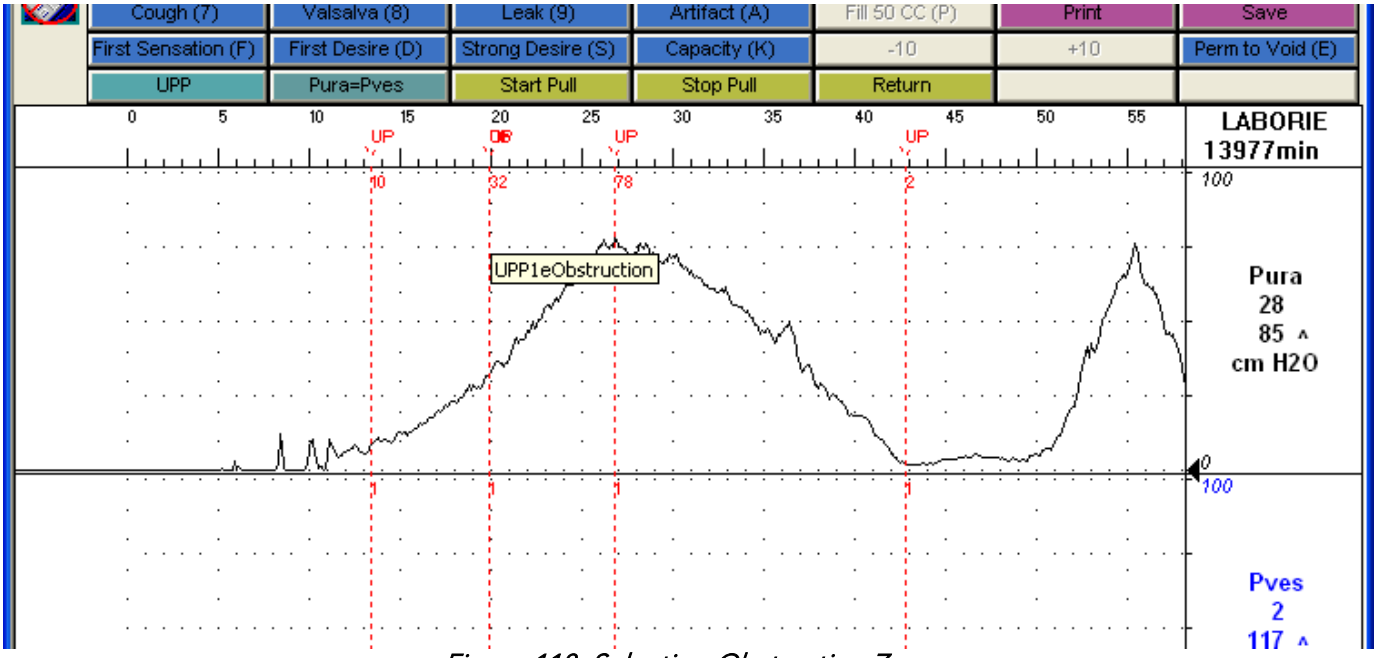


Figure 118: Selecting Obstruction Zone

4. Both peak events are movable. "Obstruction Zone Peak" parameters are shown in the UPP Summary as well as printed on the UPP Summary report.

Re-marking UPP Segments

The UPP segments mark automatically when using the **Start Pull** and **Stop Pull** Control Panel buttons to perform the UPP test. Each UPP performed with these Control Panel buttons creates three unique events on the graph named ***UPP Start X***, ***UPP Peak X***, and ***UPP Stop X*** (where *X* is the Pull #). The first UPP pull will be assigned number 1 with each additional Pull assigned a sequential number. UPP events for the first Pull will then be named UPP Start 1, UPP Peak 1, and UPP Stop 1 automatically (Figure 119).

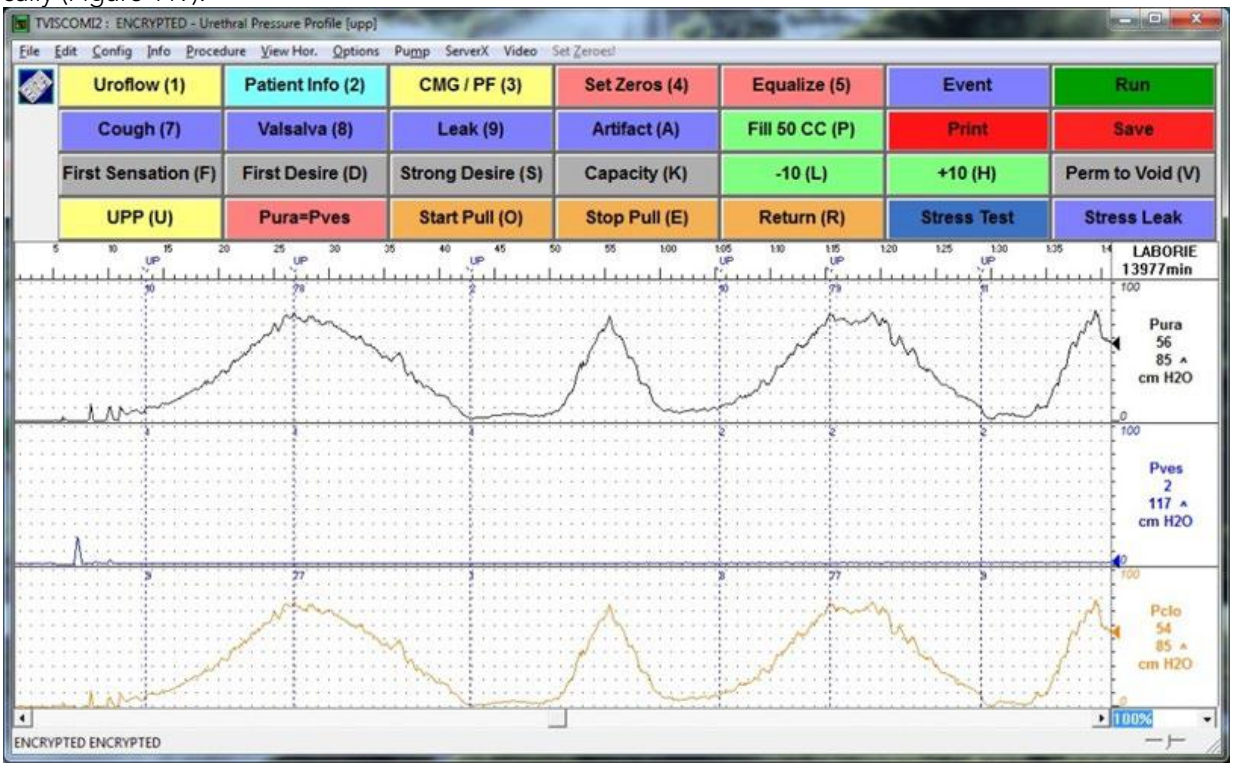


Figure 119: Urethral Pressure Profile Test

To re-mark the UPP Segments:

1. Remove the UPP Segment that requires re-marking:
    a. Right-click on the UDS graph to open a context menu.
    b. Click the *UPP Segments* option from the context menu to view all the UPP Pulls marked on the graph (Figure 120).

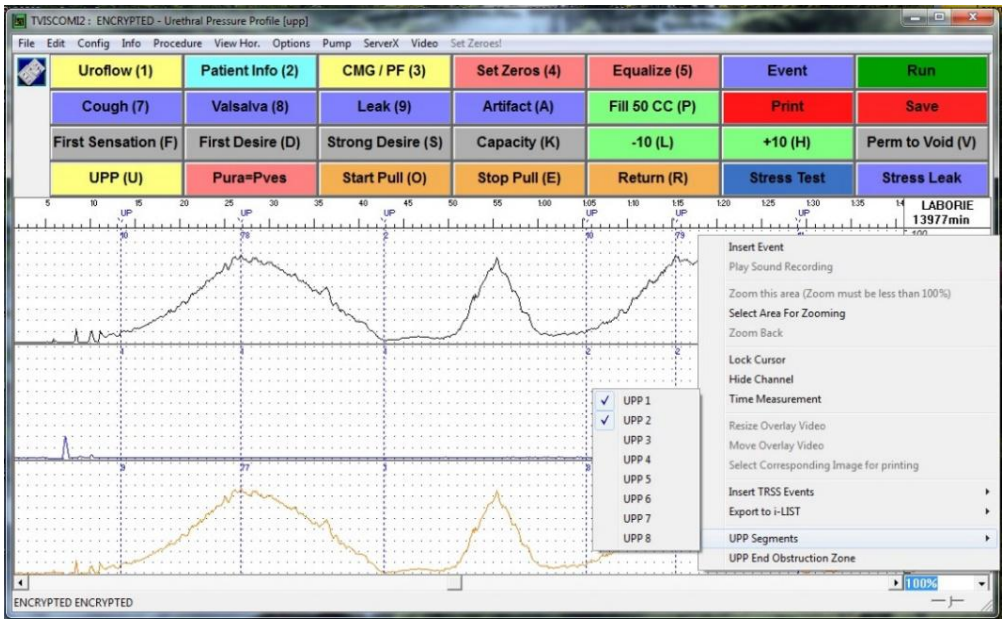


Figure 120: UPP Segments Menu

    c. Uncheck the UPP pull requiring re-marking and the event markings corresponding to that UPP pull will be removed from the graph. Figure 121 shows the removal of event markings for UPP1.

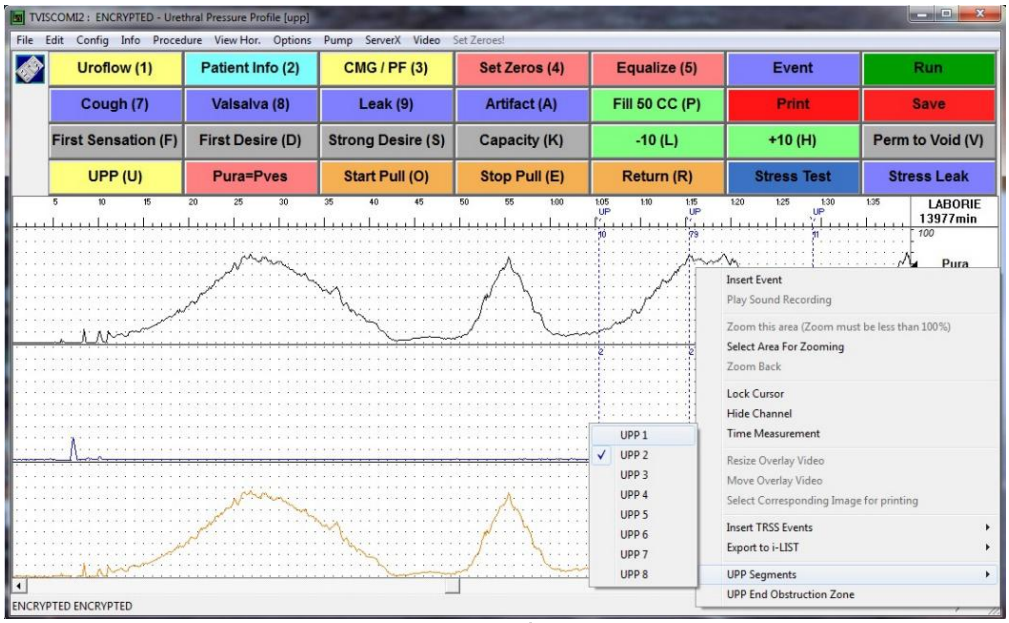


Figure 121:UPP Segment Window – Removing UPP Events

2. Select the UPP segment for re-marking. Left-click on the UDS Graph before the UPP pull requiring marking and drag the mouse to the end of the UPP pull to highlight the segment in black.

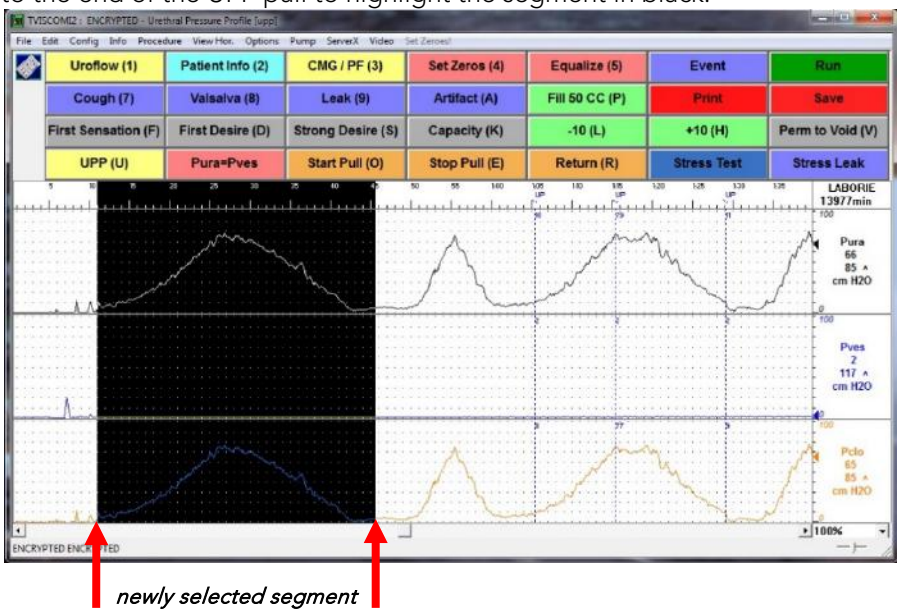


Figure 122: Marking a UPP Segment

3. Right-click on the highlighted section of the graph to open the context menu.
4. Click *UPP Segments* in the context menu and select an unused UPP Segment. *UPP Start*, *UPP Peak*, and *UPP Stop* events are added to the graph for that pull (Figure 124). Figure 123 shows remarking of UPP 1.

NOTE: Used segments are indicated by a check mark beside the segment name.

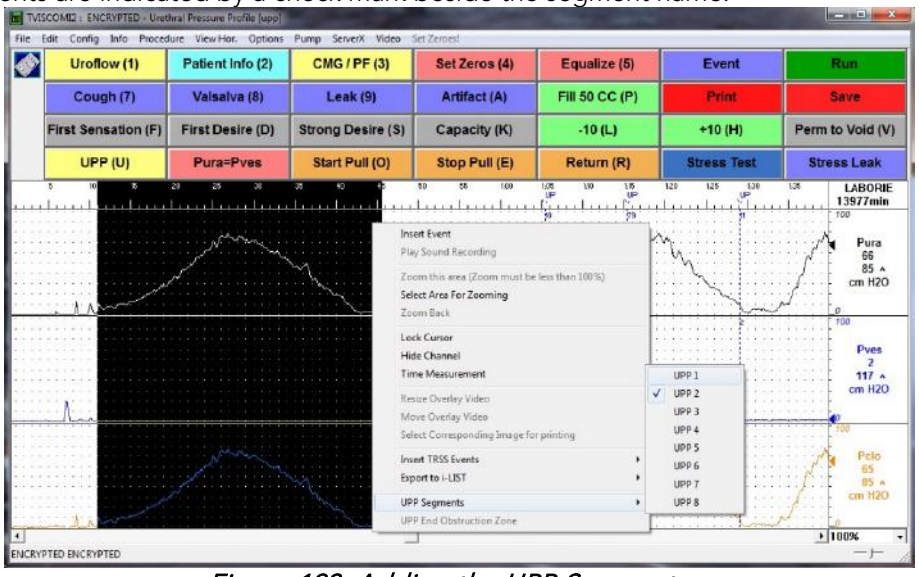


Figure 123: Adding the UPP Segment

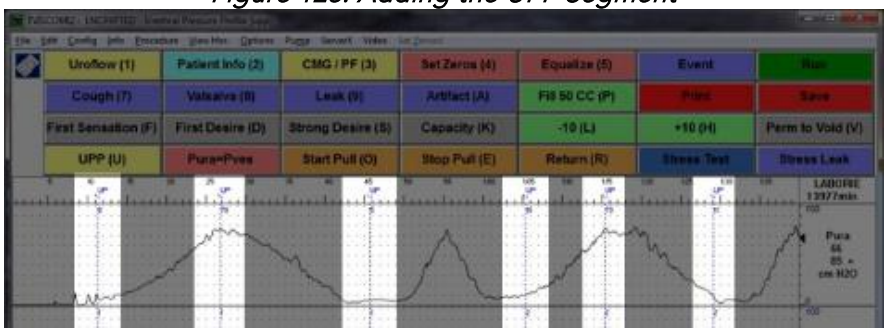


Figure 124: UPP Events Added

5. Verify the **UPP Summary** (found under the **Info** menu) is updated with the newly marked UPP pull information.

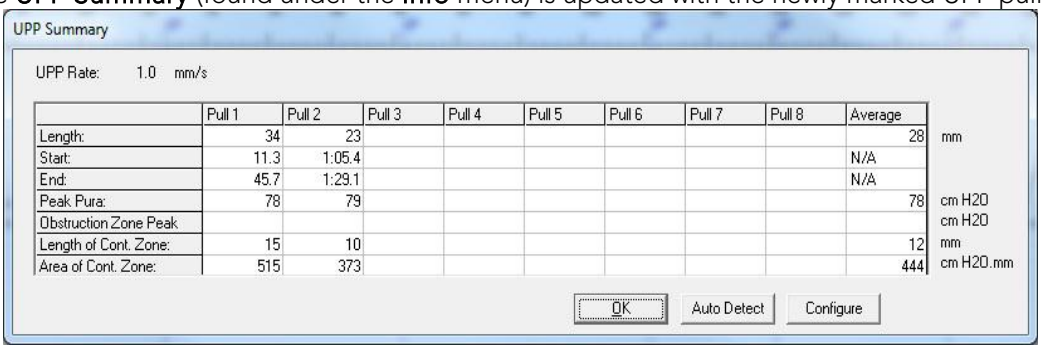


Figure 125: UPP Summary – Updated Segmens

7.6.10 BLADDER COMPLIANCE (OPTIONAL)

Bladder Compliance is commonly calculated using events from the filling stage of a study. The **Bladder Compliance** feature is available once a CMG or Micturition test has been performed. The feature enables the selection of study segments for analysis using the Bladder Compliance Calculation. The user can select marked events from any stage of the study.

NOTE: **Bladder Compliance** calculation/configuration can only be performed with English language software. The calculation results are expressed in *ml/cm H2O*.

Bladder compliance is calculated as:

$$\frac{\Delta VH20}{\Delta\ Pdet} = \frac{\text{change in bladder volume}}{\text{change in Detrusor pressure}}$$

Segment selection for calculation of **Bladder Compliance** can be completed manually or automatically. Manual selection must be completed through the *Info* menu. Automatic **Bladder Compliance** settings are available in the Configuration window which can be accessed through the *Info* Menu or the *Config* Menu. Refer to the Compliance Tab section on page 76 for more information on the *Configuration* window. Refer to subsections below for instructions on selecting segments for Bladder Compliance Calculation.

7.6.10.1 MANUAL BLADDER COMPLIANCE

Click the **Info Menu** and select **Bladder Compliance**. The *Compliance Measurement Range* window will appear. Each compliance measurement is defined by a start and end segment. The segments are differentiated by color.

Figure 126: Compliance Measurement Range Window

To Manually Select a Segment for Analysis:

1. The *Compliance Measurement Range widow* facilitates the manual selection of segments for Bladder Compliance calculation. Select a name assignment by checking one of the checkboxes from the segment list (ex. Segment 1).
2. Click and drag the pointer across the graph window from start to end of the desired segment. A bold black line will run across the top of the box, indicating the selection.
3. Release the mouse button. The "end" of the segment is selected. The time of the selection appears.
4. To modify the selected segment, reselect.
5. To keep the selection and return to the test click **Confirm**. The Compliance Calculation is displayed as an event in the Event Summary
6. To undo changes, deselect any segments and click **Cancel.** All changes are discarded, and the **Compliance Measurement Range** window will close.
7. To add additional segments for **Bladder Compliance calculation**, select a new segment name (ex. Segment 2) and repeat the procedure.

7.6.10.2 AUTO COMPLIANCE (OPTIONAL)

The **Auto Compliance** feature automatically calculates bladder compliance segments and calculations instead of having to manually select the segments from the graph. Click the **Configure** button in the *Compliance Measurement Range* window to open the Configuration window to the Compliance tab. The Configuration window can also be accessed from the *Config* menu, **Config** > **Configuration window** > **Compliance tab**; refer to the Compliance Tab section on page 76.

The Compliance tab provides three Compliance Methods: **Manual**, **Auto: Events**, and **Auto: Infusion / 100ml**. Refer to Figure 127 for a visual of the Compliance tab and its menus:

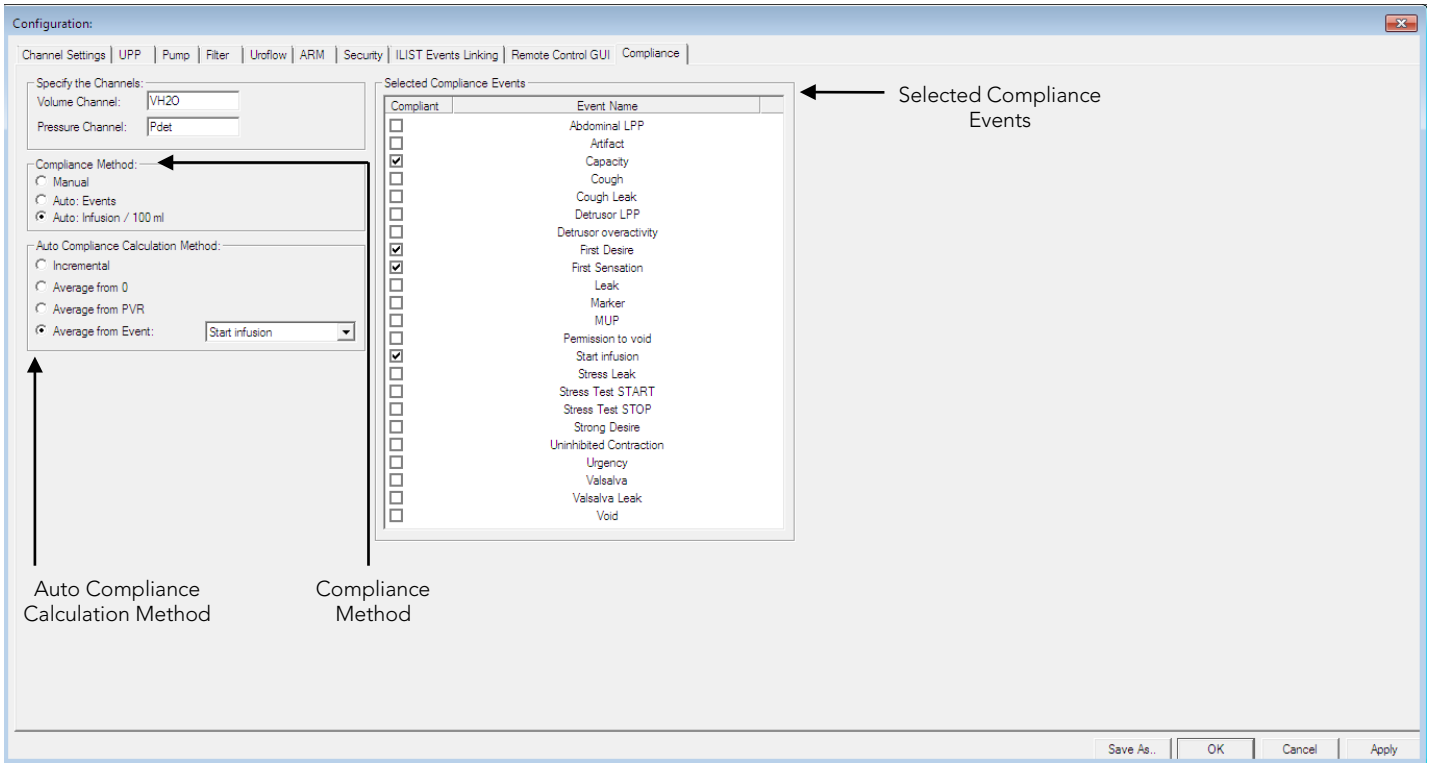


Figure 127: Configuration Window - Compliance Tab

Select Channels

Specify Volume and Pressure Channels (Figure 128).

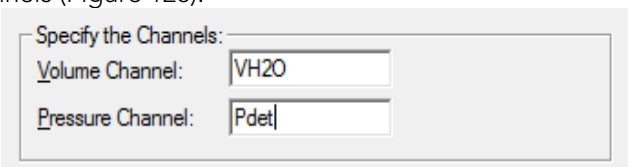


Figure 128: Compliance Tab – Specify Channels

NOTE: By default the change in volume is calculated from the VH20 channel and the change in pressure from the Pdet channel.

Select Auto Compliance Method

- **Manual** – Selection of this option will grey out **Auto Compliance Calculation Methods;** manually select the segments for calculation as instructed in the Manual Bladder Compliance section on page 105.
- **Auto: Events** – Selection of the **Auto: Events** option necessitates setup of the desired Auto Compliance Calculation Method.
- **Auto: Infusion/100mL** – Selection of this option sets Infusion volumes of 100mL as the auto compliance calculation reference points.

Refer to Figure 129.

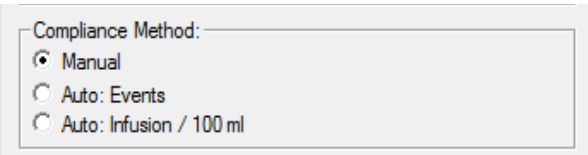


Figure 129: Compliance Tab – Compliance Method

Select the Auto Compliance Calculation Method

Auto compliance calculation methods allow the software to automatically create segments based on test events instead of requiring the user to manually select segments from the graph post study. For the software to automatically create segments, the user must set calculation start and calculation end events. The **Auto Compliance Calculation Method** menu allows the user to select the desired start point of the segments. The following options are available:

- **Incremental** – compliance segments are created between events selected from the *Selected Compliance Events* listing on the right-hand side of the screen.
- **Average from 0** – compliance segments are created from time zero of the test to the events selected from the *Selected Compliance Events* listing on the right-hand side of the screen.
- **Average from PVR** – compliance segments are created from the point where *VH20 = PVR* entered at the end of the pressure flow test (mL).
- **Average from Event** – Compliance segments are created from the test event selected from the dropdown menu.

Refer to Figure 130.

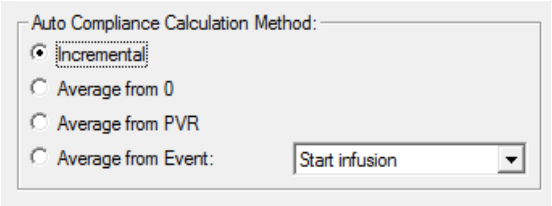


Figure 130: Compliance Tab – Auto Compliance Calculation Method

Select the Compliance Events.

For use with Auto compliance methods only. Use the **Select Compliance Events** menu to select the calculation end events. Select the checkbox of the desired events (Figure 131).

NOTE: Remember to save the configuration by clicking **Save As** then Save.

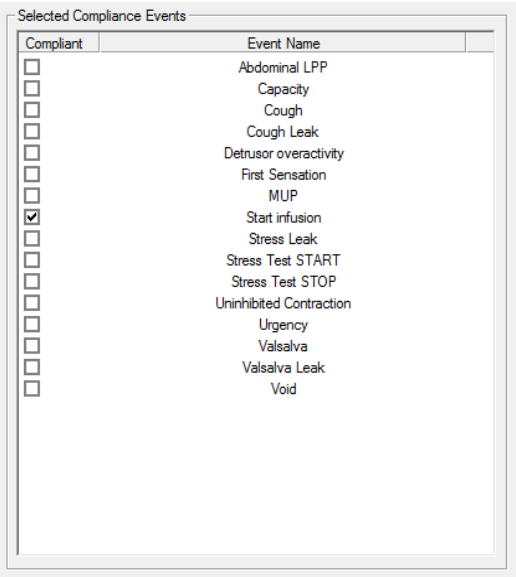


Figure 131: Compliance Tab – Select Compliance Events

7.6.11 UPP

This option contains optional software features such as Eberhard Curves and Pressure Transmission Ratio.

7.6.11.1 EBERHARD CURVES

The Eberhard feature measures the static and stress UPP profile for female patients. This feature in the UDS software is based on the work of J. Eberhard and P. Lienhard.[ix] A complete copy of this article is available upon request.

To access the Eberhard Curves Feature:

1. Click **Info** > **UPP**.
2. Select Eberhard Curves. The *Eberhard Curve Options* window will appear (Figure 132).

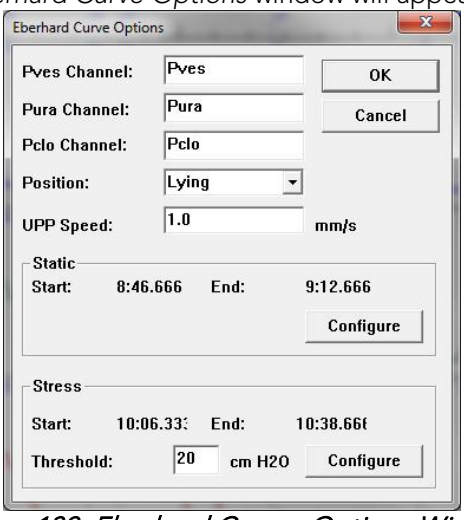


Figure 132: Eberhard Curves Options Window

3. Select the **Static** and the **Stress UPP** portions of the graph.
4. Click **OK.** The *Eberhard* window opens to display the curves along with Total Urethral Length, Pressures, Functional Urethral Length, and change information.

Configure Static UPP:

1. Click the **Configure** button in the *Static* section of the *Eberhard Curve Options* window to open the *Range Selection* window.
2. Select the range for calculating the static UPP Segment by clicking on the graph at the starting point of the range, holding the left mouse button down, and then dragging the mouse across the graph until you reach the end of the segment. Once the end of the segment is reached release the mouse button (Figure 133).

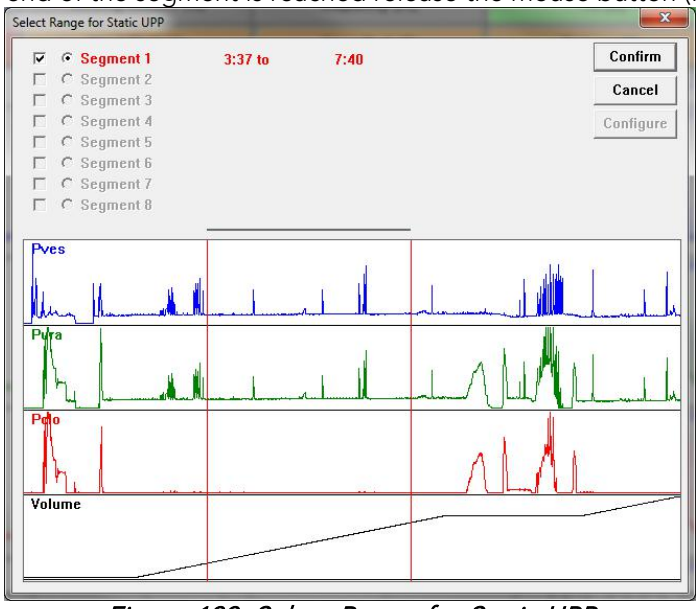


Figure 133: Select Range for Static UPP

3. The segment will be marked by red lines to the left- and right-side along with a black line across the top to highlight the selected portion of the graph. If the selected segment is incorrect, click **Cancel** and select a new segment.
4. Click **Confirm** to return to the *Eberhard Curve Options* window.

Configure Stress UPP:

1. Click the **Configure** button in the *Stress* section of the *Eberhard Curve Options* window to open the *Range Selection* window.
2. Select the range representing the dynamic UPP Segment by clicking on the graph at the starting point of the range, holding the left mouse button down, and then dragging the mouse across the graph until you reach the end of the segment. Once the end of the segment is reached release the mouse button.

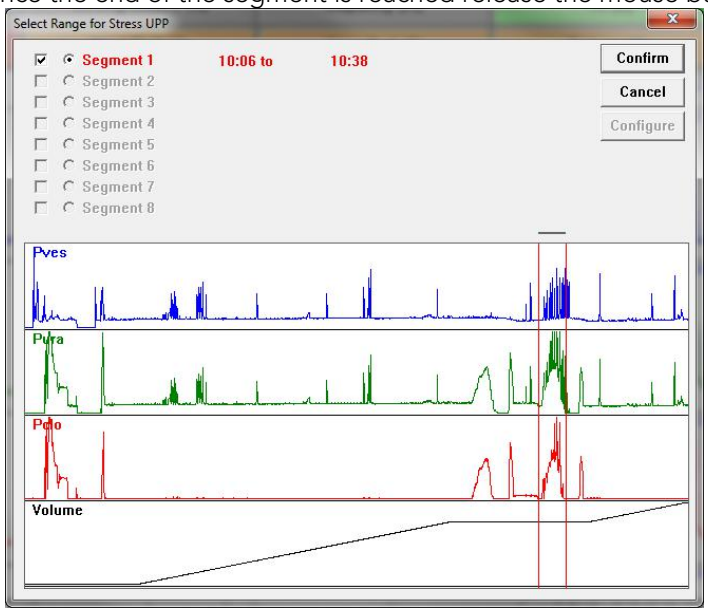


Figure 134: Select Range for Stress UPP Window

3. The segment will be marked by red lines to the left- and right-side along with a black line across the top to highlight the selected portion of the graph. If the selected segment is incorrect, click **Cancel** and select a new segment.
4. Click **Confirm** to return to the *Eberhard Curve Options* window.

Access Eberhard window

1. From the *Eberhard Curve Options* window click **OK, Info** > **UPP** > **Eberhardt Curve** > **OK**. The **Eberhard** window will open to display the curves along with *Total Urethral Length*, *Pressures*, *Functional Urethral Length*, and *change information* (Figure 135).

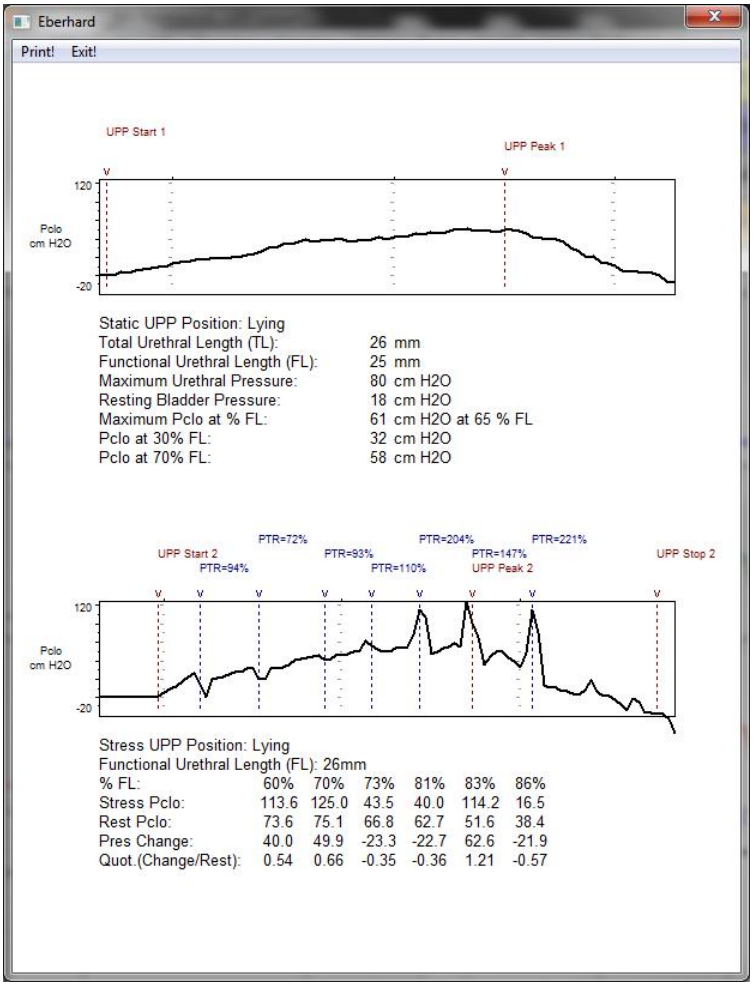


Figure 135: Eberhard Summary

2. Click **Print!** in the upper-left of the window to print a copy of the curve results.
3. Click **Exit!** to close the window.

7.6.11.2 Pressure Transmission Ratio

The Pressure Transmission Ratio (PTR) feature is available after a test with Pves and Pura is completed (For example, a UPP test). Pressure Transmission is a ratio of pressure that is "transmitted" from the bladder to the urethra during a cough. Pressure Transmission is calculated from the Pves and Pura channels.

The PTR formula is:

$$\%\ PTR = \frac{\Delta\ Pura}{\Delta\ Pves} \times 100\%$$

Where:

- Δ Pura refers to the change "from baseline" in urethral pressure during a cough
- Δ Pves refers to the change "from baseline" in vesicle pressure during a cough

Methods for Calculating PTR

In the Pressure Transmission window there are three methods provided for calculating PTR: **Basic PTR**, **UPP Segments**, **Manual PTR**. To launch the Pressure Transmission window, click **Info** > **UPP** and select Pressure Transmission.

Basic PTR:

The Basic PTR feature is the simplest method to identify coughs because this feature allows you to perform calculations for all coughs during the test. To configure Basic PTR follow the instructions provided below:

1. Click Info > UPP and select Pressure Transmission to launch the Pressure Transmission window (Figure 136).

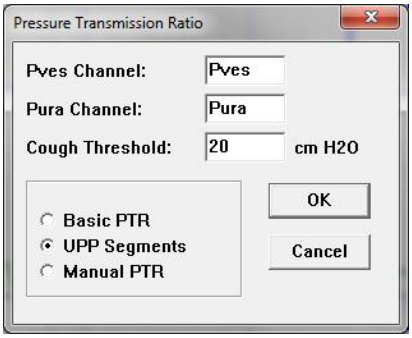


Figure 136: Pressure Transmission window

2. Select **Basic PTR** in the Pressure Transmission window and click **OK**. The **PTR Segment Selection** box will appear (Figure 137).

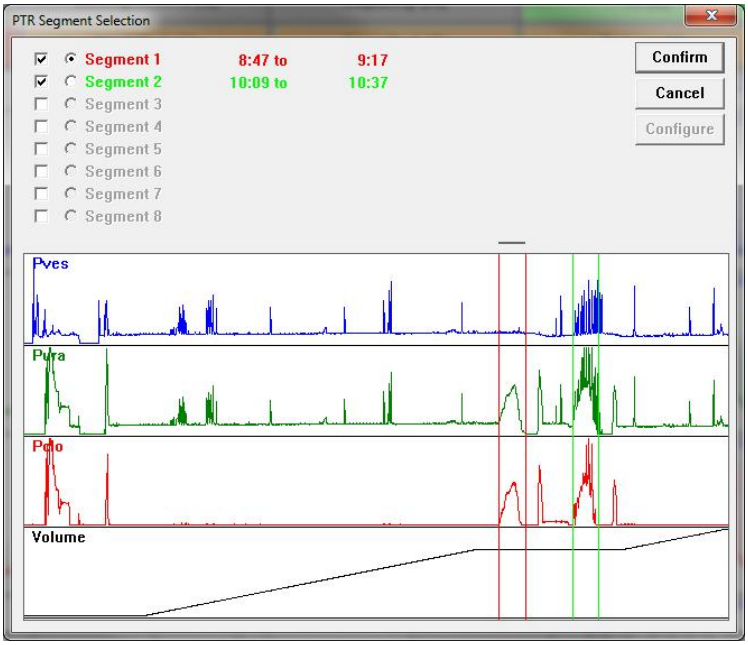


Figure 137: Basic PTR - PTR Segment Selection Box

3. Verify that the entire test is selected as a segment and click **Confirm**.
   NOTE: If more than one cough point exists in a study, LABORIE recommends to select separate segments instead of the entire test. Basic PTR allows the selection of up to three segments.
4. To modify selected segments, perform one of the following options in the **PTR Segment Selection** window then click **Confirm**:
   a. Click the **Auto Segment Detection** button to have the software modify the segment.
   b. Manually modify the segment by clicking and dragging the pointer across the graph window from the start to the end of the desired segment.

The system will automatically examine the Pves channel for any cough with an increase in pressure greater than 20cm H_2O(Cough threshold). These events are automatically marked and the pressure transmission ratio is calculated. Review the pressure transmission ration in the Event Summary.

If more than one cough point exists in a study, LABORIE recommends use of the segment selection feature. This allows selection of up to three segments of the study to be calculated for PTR.

PTR on UPP Segments

The **PTR on UPP Segment** feature is only available when UPP segments exist. Coughs will be calculated only for the UPP segments of the test.

To access UPP Segments:

The **UPP Segment** PTR feature is only available when UPP segments exist. Refer to the UPP Summary section on page 99 for information on UPP Segments. Coughs will be calculated only for the UPP segments of the test. To configure UPP Segments follow the instructions provided below:

1. Click **Info** > **UPP** and select **Pressure Transmission** to launch the **Pressure Transmission** window (Figure 136).
2. Click **UPP Segments** and then click **OK**. The **PTR Segment Selection** window will appear displaying UPP segment(s).
3. Select the segment check box.
4. Modify segments by performing one of the following options:
    a. Click the **Auto Segment Detection** button to have the software modify the segment. The "end" of the segment will be selected.
    b. Modify any segments by clicking and dragging the pointer across the graph window. Release the mouse button. The segment times will be updated.
5. Review selections.
    a. To remove changes, deselect any segment and click Cancel to return to the Pressure Transmission window.
    b. To keep changes click Confirm. The pressure transmission ratio will be calculated and the user will be returned to the test. To review data access the event summary.

Manual PTR

Manual PTR allows you to customize the cough point selection. It also allows each Pura and Pves peak to be zoomed in and modified accordingly. This is the most accurate method of calculating PTR. To configure Manual PTR follow the instructions provided below:

1. Click **Info** > **UPP** and select **Pressure Transmission** to launch the **Pressure Transmission** window.
2. Select **Manual PTR** from the **Pressure Transmission** window and click **OK**. The **Pressure Transmission** window closes.

2. Click on a peak in the Pves or Pura channel. A window appears with a close-up view of the peak and the value of its Peak, Base, and Height. The graphic representation will show a white bullet for start and end points on the graph.

3. **To adjust the Position of the Peak, Base, Height, and PTR in the window**:
    a. Click the white bullet to the left of the cough that indicates the starting point of the peak. Drag the bullet to the desired starting point. The starting point of the cough is modified. Repeat the same to change the end point of the cough to the right of the cough. The Peak, Base, and Height automatically recalculate.
    b. Click **Next** to adjust start and end points of the peak for the other channel (Pves or Pura).
    c. Review edits and once confirmed click **OK**. The window closes and the pressure transmission ratio is displayed as an event in the Evet Summary. To review data, refer to the Event Summary.

4. In the window described in step 2, click **OK** to manually select another cough point or click **Cancel** to return to the test.

7.6.12 ARM 4&8 (OPTIONAL)

Refer to the ARM 4 and ARM 8 Channel Test Results section on page 155.

7.7 VIEW HOR. MENU

The *View Horizontal* Menu provides resize options that will scale down or up the graphs shown in the scrolling graph section. The default zoom size is 1X or 100%.

NOTE: You can also set the zoom level by clicking the pop-up list located on the lower-right side of the UDS screen.

To modify zoom:

1. Click **View Hor.** from the menu bar. The **Zoom** dropdown menu will appear.
2. Click one of the settings. Refer to Table 25 to determine the appropriate scale. The test will scale to the size selected. The selected setting is saved when the test is saved.

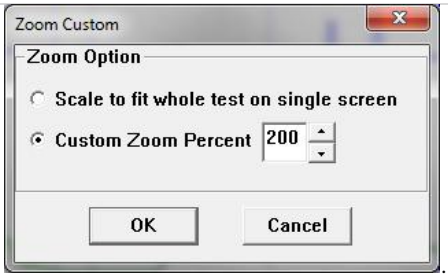
Setting	*Display*
25%	1/4 of the default zoom size
33%	1/3 of the default zoom size
50%	1/2 of the default zoom size
1X	Default zoom size
2X	Double the default zoom size
3X	Triple the default zoom size
4X	Quadruple the default zoom size
Full Screen	Whole test compressed on single screen
Full Screen On Stop	Whole test compressed on single screen once **Stop** button is clicked.
Custom	Zoom Custom box for whole test on single screen *OR* customized zoom preference between 1 – 500 %: 

Table 25: Horizontal Scaling

7.8 OPTIONS MENU

The *Options* menu activates and accesses miscellaneous functions of the software.

7.8.1 TEST RESTART

The Test Restart feature restarts a procedure from the beginning of the test. Sometimes when the patient coughs, sneezes, or kicks the transducer during a test, a re-evaluation is required.

To restart a test procedure:

- Click **Options** on the menu bar and select **Test Restart**.

7.8.2 TEST PLAYBACK

The Test Playback feature enables a pre-saved test to be viewed again like a recording. After the test is complete, it may be viewed by using the playback feature. The playback speed may be different from when it was recorded.

Click **Options** and select **Test Playback**. The test will play from the beginning of the test and runs until the procedure is over.

- To Pause the test, click **Stop**.
- To Resume playback, click **Test Playback**.
- To exit the playback mode, click **Options** then select Test Playback.

7.8.3 UROFLOW AUTO START

Another method of starting a test using the **Goby™** is selecting the Uroflow Auto Start option. It enables the recording process as soon as the **Urocap™ IV** detects the first flow of data. This selection is appropriate for Uroflowmetry studies in instances where the patient requires privacy before and during Micturition.

To set up Auto Start for a Uroflow test:

- Click **Options** from the menu bar and select **Uroflow Auto Start**.

7.8.4 CURSOR VALUE INDICATOR

The Cursor window displays the exact location of the mouse cursor and the values of each channel at that location. This feature is particularly useful for marking events and reviewing test data.

To access the Cursor window:

Click **Options** from the menu bar and select **Cursor Value Indicator** *-or-* Press the F9 key on the keyboard. This will launch he Cursor window (Figure 138).

To move the Cursor Window:

1. Click the title bar on the Cursor window.
2. Drag the window to the desired location on the screen.
3. Release the mouse button.

To cancel the Cursor Option:

- Click **Options** and select **Cursor Value Indicator** *-or-* Press the **F9** key on the keyboard.

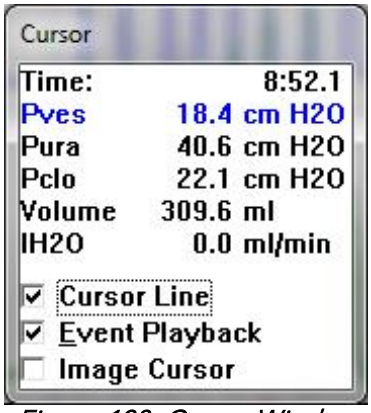


Figure 138: Cursor Window

7.8.5 DIGITAL VALUE INDICATOR

The Digital Value window displays the data of channels with digital attributes. While all channels will print as curves, the screen can display a maximum of eight channels at one time. If more than eight channels are used, additional channels may be displayed as digital or overlay. Digital channels are displayed in the Digital window, while curves of overlay channels are displayed on the channels in which they overlay.

To set the Digital Attributes of Channels:

1. Click Config > Set up/Modify.
2. Select the Display Digital attribute in the Display Attribute column.
3. If necessary, repeat for other channels.
4. Click OK.

To switch the Digital Window On/Off:

Click **Options** on the menu bar and select **Digital Value Indicator** *or* press **F8** on the keyboard.

7.8.6 Display Control Panel

The *Display Control Panel* menu items allows you to display or hide control panel buttons. The default mode is to display control panel buttons.

To remove the control panel function buttons, click Options > **Display Control Panel** and the buttons disappear (Figure 139). To restore control panel, click **Options** > **Display Control Panel** and the buttons will reappear.

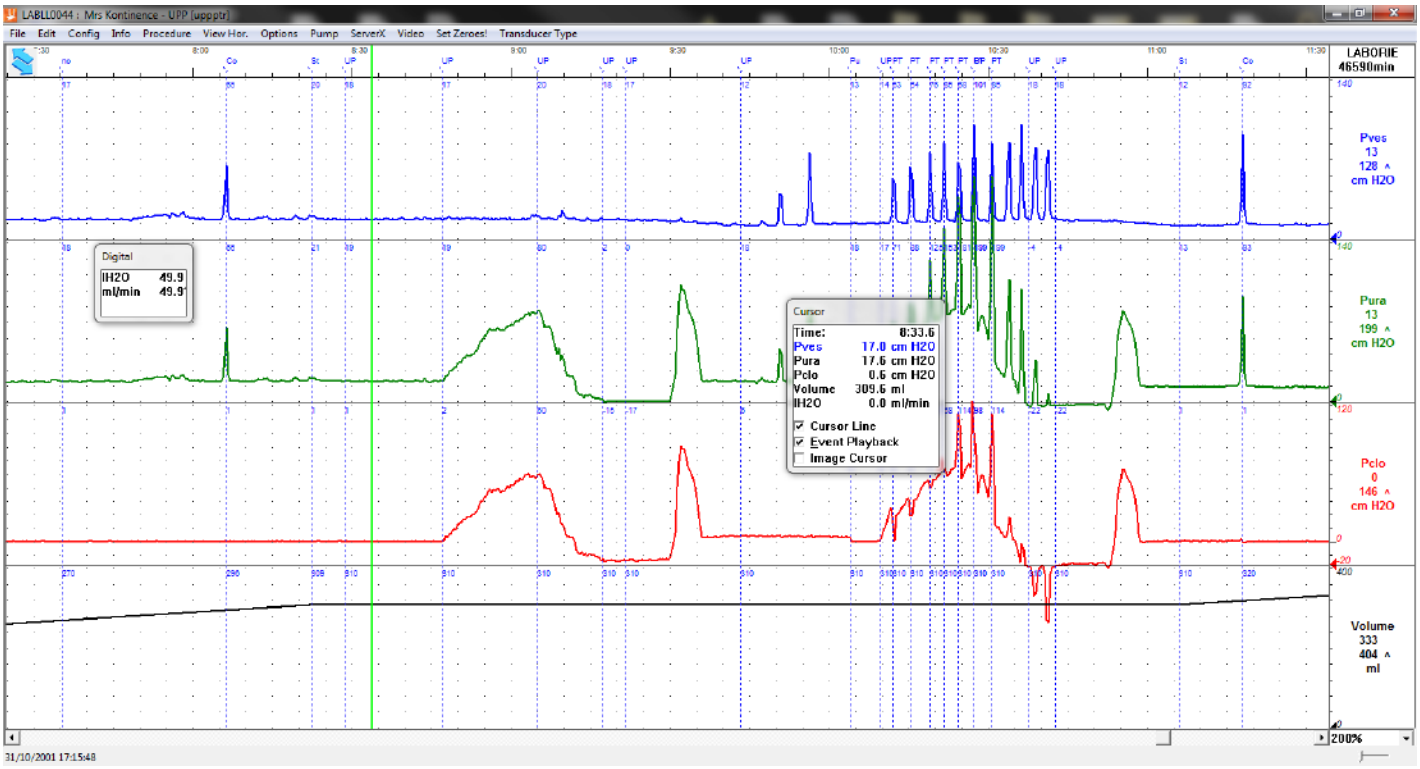


Figure 139: Scrolling Graph – Control Panel Hidden

7.8.7 Control Panel Settings

The easy accessibility of the Control Panel buttons is a convenient feature of the UDS software. The Control Panel Settings dialog box allows the Control Panel to be configured with various function buttons, and modifies the definitions that are assigned to event-type buttons.

There are seven Control Panel buttons on each row. The number of rows can be modified if desired. For a list of button labels and definitions, please refer to the last section in this chapter — Glossary of Control Panel Commands on page 119.

NOTE: There are seven buttons on each row; the last two buttons of the first and second rows are reserved for system use. You can program the rest of the buttons.

To configure the Control Panel:

The Control Panel provides quick access to events, tests and features during a study. There are five basic control panels already configured in the software. Custom control panels can be configured if desired. There are seven buttons in each control panel row; the number of rows can be modified if desired. Use the Command window to select the group of buttons available for procedures in the Control Panel.

To configure the Control Panel:

1. Click **Options** from the menu bar and select **Control Panel Settings.** The **Command** window will appear displaying the first row of Control Panel buttons (Figure 140).

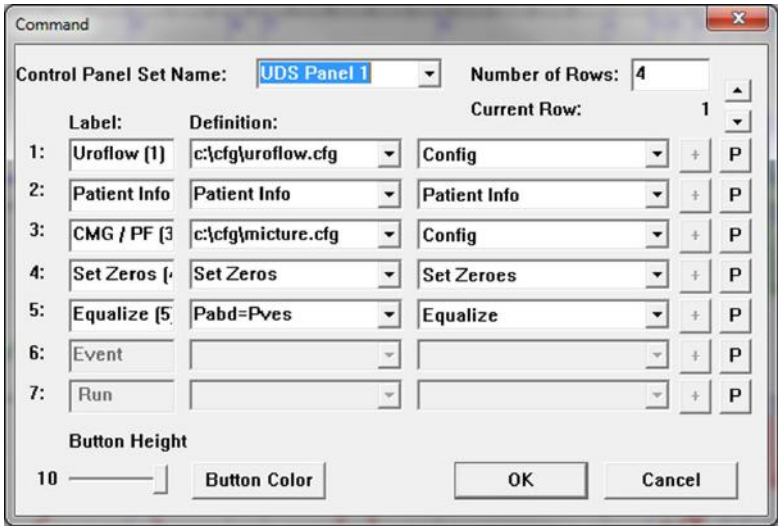


Figure 140: Command Window

2. Change the Label, Definition, and command type.
    a. To change the Name of the function button, double-click the entry in the label column and enter a new name (entered text will be displayed on the Control Panel button in the UDS Client screen).
    b. Change the definition for the button by clicking the appropriate box under the Definition column. Type the new definition into the field.

IMPORTANT: The meaning of the definition depends on the type of Control Panel Button.

    c. Change the command type by clicking on the drop-down arrow of the appropriate combo box. Select the appropriate function command type.

3. Click the down arrow of the **Current Row** field to move to the second row of buttons. Repeat configuration steps until Label, Definitions, and command type fields are set for all Control Panel buttons.
4. Click **OK** when all buttons are configured.

IMPORTANT: The Control Panel Set last used before the UDS software closes is saved as the Default Control Panel set and is automatically loaded when the UDS Client is restarted.

The Button Height slider can be used to adjust the size of the buttons in the Control Panel. Slide it to the right to increase the size of the button.

7.8.7.1 Multiple Control Panel Sets and Hot Key Configuration

Multiple Control Panel Sets can be set up in the UDS software. This allows multiple users to create their own customized Control Panel that can be selected for use before beginning testing. Up to sixteen Control Panel Sets can be set up in addition to the Default Control Panel Set.

To Configure New Control Panel Sets:

1. Click Options > Control Panel Settings.
2. Type in a new name in the Control Panel Set Name box. A maximum of 15 characters (including spaces) can be used for the name. To duplicate an existing configuration for customization, select the applicable control panel from the Control Panel Set Name box and enter a new name.
3. Customize the Control Panel buttons.
4. Click OK to save the Control Panel Set. The new settings are saved and ready for use.

To use another configured Control Panel Set:

1. Click **Options** > **Control Panel Settings** to launch the Control Panel Command box.
2. Click the drop-down button of the **Control Panel Set Name** box and select the appropriate name.
3. Click **OK**.

In addition to Control Panel Configuration, the **Hot Key** feature allows the creation a shortcut key combinations for control panel buttons.

To configure the Hot Keys:

1. Click **Options** > **Control Panel Settings.**
2. Click the **P** button next to the control panel button (Figure 140).
3. The *Properties* window will appear (Figure 141). Select a key combination that will correspond to the control panel button. In our example, we will apply a shortcut key combination of CTRL+R to the *First Sensation* button.
4. Click **OK**.

Mark the event during a test using either the control panel button or the shortcut key.

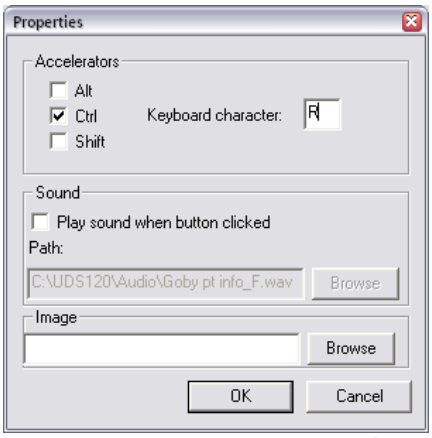


Figure 141: Properties Window

7.8.7.2 CONFIGURE BUTTON PROPERTIES

To configure control button properties, click the **P** button next to a Control Panel button in the *Command* window (Figure 85). The *Properties* window will load.

To Configure Sound:

Each button can be configured to play a unique sound when clicked.

NOTE: The sound card must be installed on the PC to use the Sound feature.

Open the Properties window by clicking the **P** button next to a Control Panel button. In our example the First Sensation button will have a sound file attached to it.

1. Select the **Play sound when button clicked** option from the *Sound* section of the *Properties* window.
2. Click **Browse** to retrieve the sound file.
3. Select the file and click **Open** to attach the file to the control panel button.
4. Click **OK** to exit the screen.

Control Panel

Select **Auto Load Control Panel Set Name** from the *Control Panel* section of the *Properties* window (Figure 142). Select an option from the dropdown menu. This setting will cause a default control panel to launch each time the configured control panel button is clicked.

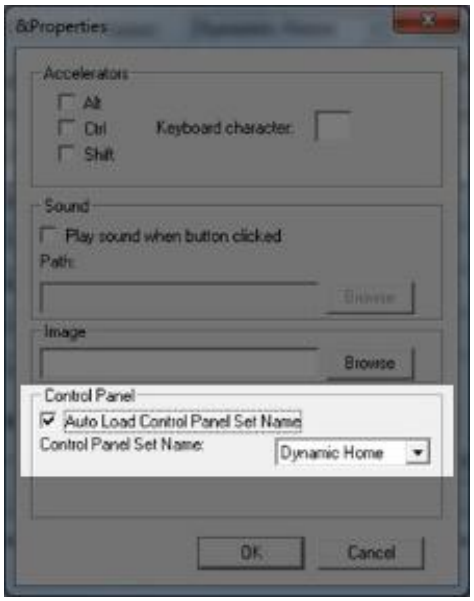


Figure 142: Set Auto Load Control Panel Set Name – Properties Window

Add an Image to a Control Panel Button

Add an image to a control panel button to make it easily distinguishable from other buttons.

To add an image to a button:

1. Click Options > Control Panel Settings.
2. Click the P button next to the control panel button. In this example we will add an image of a Uroflowmeter to the Uroflow button:

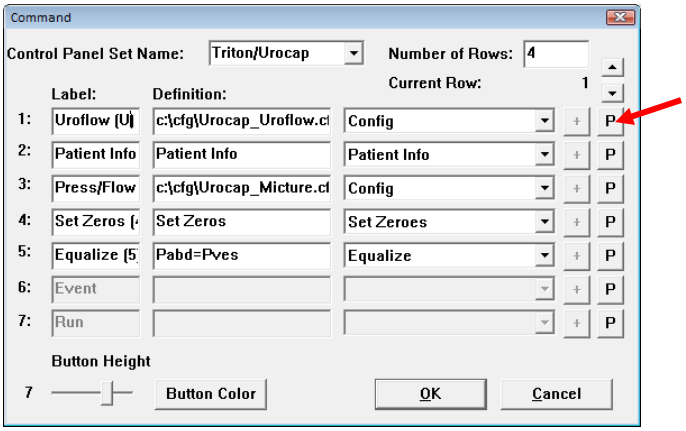


Figure 143: Uroflow Button Properties window

3. In the *Properties* window, click the **Browse** button in the ***Image*** section to select the image:

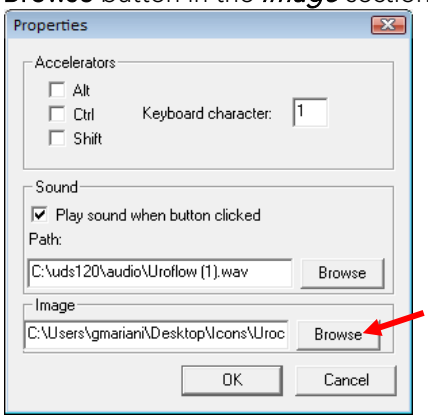
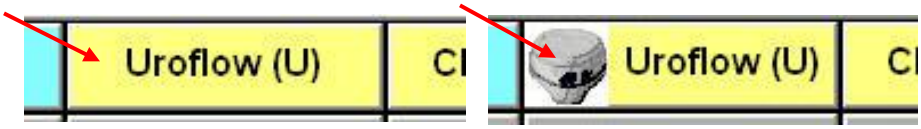


Figure 144: Adding Image to Label – Properties Window

4. Once the image is selected, click **Open** to add the image. The name of the image file will appear in the image field within the *Properties* window.
5. Click **OK** on the Properties window, and then click **OK** to close the Command window.

The image will now appear in the button on the control panel as shown in Figure 145:



Before *After*

Figure 145: Edited Uroflow Button

Customize Colors and Fonts

Click the **Button Color** button in the *Command* window to open the *Select Color* window. Choose the background color and font for individual Control Panel buttons as well as the color of the button names. Once complete click **OK** to save changes. The chosen colors and fonts will display on the main UDS screen.

To select the color and/or the text font for the buttons:

1. Click inside the colored box under the *Text* or *Button* column for the B*utton Type*. The *Color* window will appear.
2. Select the colors for the button and/or text.
3. Click the F button under the *Font* column and select the new font from the resulting font selection window.
4. Click **OK**.
5. Standardize coloring and fonts of all Control Panel buttons in the *Select Color* window. In the *All Buttons* section at the bottom of the window, select the button property to change. Click the rectangle next to the property to select the color or font. Click **OK** and exit the *Command* window. The chosen colors will display in the main UDS screen.

7.8.7.3 GLOSSARY OF CONTROL PANEL COMMANDS

Suggested Button Label	Definition	Type	Comments
First Sensation First Urge Capacity Valsalva Cough Area Start Area End	First Sensation First Urge Capacity Valsalva Cough AS:Pves:0 AE:	**Event** **Event - Unique**	Marks an event with the definition text as Event Annotation. An event that occurs only once and will replace any existing recorded event.
Uroflow CMG UPP Micturition	Full path of CFG file Example: c:\cfg\	**Config**	Opens a .cfg file.
Slow Fill Medium Fill Fast Fill XXX ml/min +YY ml/min -ZZ ml/min Reverse Slow Fill Reverse Medium Fill Reverse Fast Fill Start Pump Resume Pump §	SF MF FF SP=XXX (*where XXX is in ml/min)* SP+YY (w*here YY is the incremental rate)* SP-ZZ *(where ZZ is the decremental rate)* RSF RMF RFF Pumprunstop PumpRunStopResume	**Pump Command**	Controls the pump fill rate. Controls the reverse pump fill rate† Dynamic button to start/stop pump at medium fill speed. Used with speed control buttons. After the Stop Pump button is clicked the Resume Pump button is enabled.
Auto Start	N/A	**Auto Start**	Sets up Uroflow Auto Start
Set Zeroes	N/A	**Set Zeroes**	Sets all channels to zero. For setting EMG channel to zero see page 130.
Pura = Pves or Pabd = Pves	Channel X = Channel Y Example: Pura = Pves	**Equalize**	Sets the left channel value to the right.

Suggested Button Label	Definition	Type	Comments
UPP Return UPP Pull UPP Stop	IN *(returns the puller as fast as possible; for positioning the puller*) PU (*pulls at default UPP speed; stops when it reaches the tip*) ST (*stops the pull*)	**UPP Command*** **Refer to the UPP Puller manual for more information.**	Controls the UPP puller speed.
Start IC02 Stop IC02	ICO2=40 (*start CO2 infusion at 40 ml/min*) ICO2=0 (*stop CO2 infusion*)	**IC02 Command**	Pumps gas to fill bladder with CO_2.
Patient Info	N/A	**Patient Info**	Opens Patient Info window.
Rest Slow Waves MSP Compliance Expulsion *XX*cc	(rest) (waves) (max) (comp) (exp) (*XX*cc)	**ARM**	Controls Anorectal Manometry procedures. Refer to the **Anorectal Manometry (ARM) Feature** section on page 138 for more information.
Resting Profile Squeezing Profile Squeeze 5 cm Squeeze 4 cm Squeeze 3 cm Squeeze 2 cm Squeeze 1 cm Rest 5 cm Rest 4 cm Rest 3 cm Rest 2 cm Rest 1 cm 10 cc 20 cc 30 cc 40 cc 50 cc 60 cc 70 cc 80 cc 90 cc 100 cc 110 cc	RE SQP ST5 ST4 ST3 ST2 ST1 RT5 RT4 RT3 RT2 RT1 10cc 20cc 30cc 40cc 50cc 60cc 70cc 80cc 90cc 100cc 110cc **NOTE:** type as is; do not add a space between the number and "cc".	**ARM 4&8**	Controls Anorectal Manometry procedures performed with 4 or 8 pressure circumferential catheters. Refer to the **Anorectal Manometry (ARM) Feature** section on page 138 for more information.
Single Burst Manual Peak Image	Single Capture Burst Capture Manual Burst Peak Burst	**Image Event** **Image Event-Unique** **Peak Image Event**	Defines buttons for use with UDS Video Software. *Please refer to your video system's Owner's Manual for more information.*
Initialize Default Values Load File Save File	(vbninitialize) (vbnloadfile) (vbnsavefile)	**VBN**	Optional feature for bladder modeling. Controls the functions of the VBN feature.

Suggested Button Label	Definition	Type	Comments
Draw/Remove Calc Curves Interpretational Help Patient Info Global Values Bladder Settings Sphincter Settings Urethra Settings Select View Animation Control Box Change Aspect Ratio Curve Adjustments Other Options Transfer to VBN Close VBN Windows	(vbndrawremovecurves) (vbninterpretationalhelp) (VBNPatientFile) (VBNGlobalValues) (VBNBladder) (VBNSphincter) (VBNUrethra) (vbnchangeview) (vbncontrolanimation) (vbnaspectratio) (vbncurveadjustments) (vbnotheroptions) (vbnimportfile) (vbnclose)	*Please refer to the VBN section in this manual for more information.*	
Please refer to the i-LIST Manuals	Pre-set definitions	**i-LIST Config** **i-LIST Event** (*optional*) **i-LIST Command** **i-LIST Image Event** **i-LIST Event Unique**	Configures to the i-LIST software. Save the event into the i-LIST software. Send Command to i-LIST Save the event into the i-LIST software. Save the event into the i-LIST software.
Please refer to the Evox Owner's Manual	Pre-set definitions	**Evoked Potential**	N/A
Plot	Pre-set with the selections made when button is configured	**Plot**[f]	Click the plot button to open the Nomograms that are applicable to the test being performed.
Stress Test	Stress Test	**Stress Test Command**	For stress leak tests. Refer to the Stress Events section on page 87.
Main Menu	Main	**Load CP**	Sets the default control panel for each time the UDS software starts.
Summ. Review	PFReview	**Load CP**	View the summary results control panel to review the current test.
Zoom	2x 3x 4x	**Zoom**	Zooms in on the highlighted area of the graph when clicked.
No required button labels. Action is applicable to all button labels.	Cancel Settings of any Button Label	**None**	Cancel the control panel button action by selecting **None** in the button type field of the control panel.
*Additional UPP commands include:			

- PU XX (pulls the UPP puller XX millimeters at the default UPP speed; for example, PU 15 will pull the UPP for 15 mm at the default speed)
- PUH XX (pulls the UPP puller XX millimeters as fast as possible; used for positioning the UPP puller)
- IN XX (returns the UPP puller XX millimeters as fast as possible; used for positioning the UPP puller)

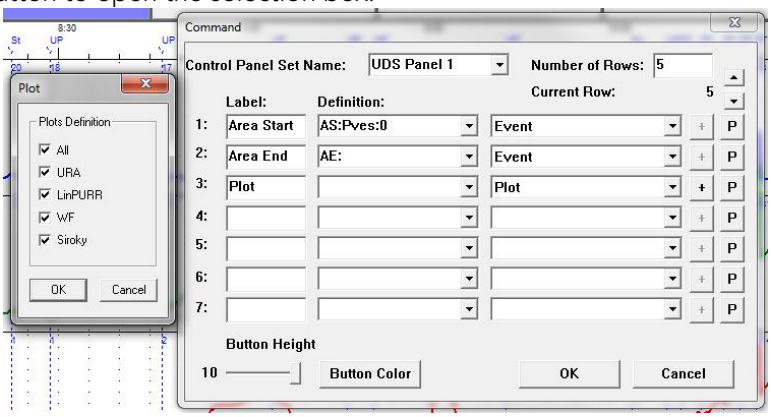
You can set the puller to automatically stop or pull at preset intervals with the click of a button. When a UPP Command is selected in the drop list and the definition is either PU or IN, a pop-up box appears and you can select the interval at which the puller will stop.

Click **OK** to set the interval.

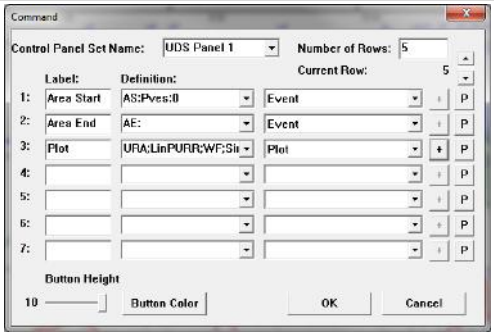
† The Reverse Fill pump feature runs the pump in reverse and is used during ARM testing when you want to quickly fill and then drain the large balloon that is used to provoke sensation. (If you program your pump commands as *ff, mf, and sf*, then you can add the *rff, rmf, and rsf*. If you program the commands as *fast fill, medium fill and slow fill*, then you can program the reverse as *reverse fast fill, reverse medium fill, and reverse slow fill.* **IMPORTANT! Reverse Fill is not a feature meant to drain the bladder! It is to be used only for the draining of the large balloon during ARM testing!**

ƒ To define the plots that will be displayed:

1. Select Plot from the drop list in the command window.
2. Click the plus (+) button to open the selection box.



3. Select All and click OK.
4. Type the word *Plot* under the Label column to name the button.



5. Click OK to set the button on the control panel.

NOTE: When the **Resume Pump** button is clicked it will restart the fill at the last used rate.

Table 26: Control Panel Commands

7.8.8 Enable Button Sounds

By default, button sounds and commands are audible in the software. To mute the sounds, click **Options** > **Enable Button Sounds** to deselect the option. Click **Options** > **Enable Button Sounds** to turn the sound on again if desired.

7.8.9 File Saving Directory

Use the File Saving Directory option to select the storage directory/folder for saving the UDS data files.

To change the Storage Directory:

1. Click Options on the menu bar and select File Saving Directory. The Change Data Directory window will appear.
2. Click Browse and select a new directory.
3. Click OK to close the *Browse for Folder* window.
4. Click the Create Dir. button to set the new directory.
5. Click OK to close the *Change Data Directory* window.

Refer to Figure 146.

Figure 146: Change Data Directory

7.8.10 Export Data

The Export Data option enables curve data to be exported in a text file format and used in another software program.

1. Click **Options** from the menu bar.
2. Select Export Data. The **Export** window will appear with the default export file name (xxxx.out) and the whole test selected.
3. To change the file name, enter a new name for the text file in the available field (Figure 147).
4. To change the export range, enter new start or end times in the available fields.

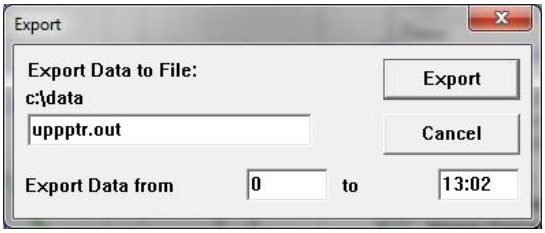


Figure 147: Export Window

5. Click **Export**. The text file is created and is ready to be imported into another software program (Figure 148).

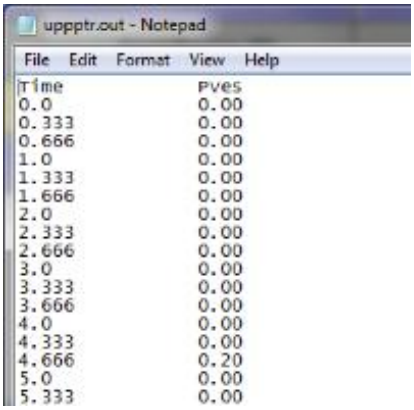


Figure 148: Exported Data - Notepad

7.8.11 EVENT DISPLAY OPTIONS

The event display options allow you to customize how events and peaks[OBJ].

To change how events and peaks are marked on a curve:

1. Click **Options** from the menu bar and select **Event Display Options**.
2. The **Event Display Options** window will load (Figure 149). Select preferred options and click **OK**.

   The **Guideline** option displays a dotted line.
   The **Annotation Abbreviation** option displays the first two letters of the Even Annotation.
   The **Channel Values** option displays the value of that event on each channel.

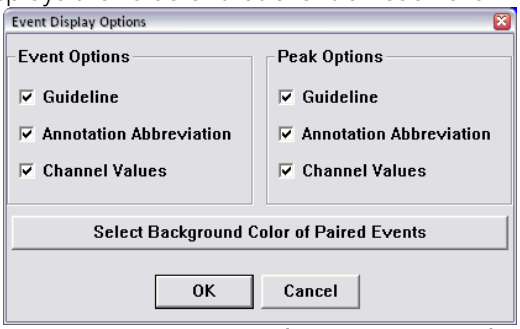


Figure 149: Event Display Options window

7.8.12 SELECTING BACKGROUND COLORS FOR EVENTS

This feature only applies to events configured with auto start and stop. The background of events' graphic range in the test selected can be highlighted using the **Select Background Color of Paired Events** button available on the *Event Display Options Menu* (Figure 149).

1. Click the **Select Background Color of Paired Events** button (Figure 149) to open the **Event Properties** window.
2. In the *Select Paired Event* dropdown menu, choose the type of test and select *Show region for this event* (Figure 150).

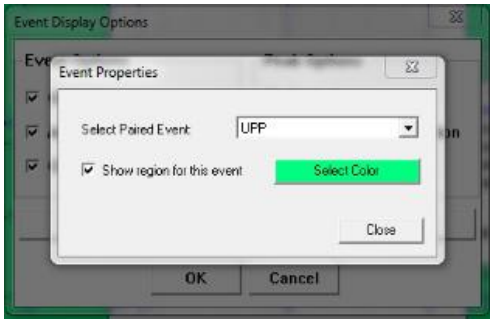


Figure 150: Event Properties – Select Paired Event

3. Click the **Select Color** button to open the color selection screen.
4. Select the background color for automatic events in the study.

5. Once the color is selected, click **Close** to exit *Event Properties* and then click **OK** to close the *Event Display Options* window. During the next test the graph will display a colored background where the events occur (Figure 151).

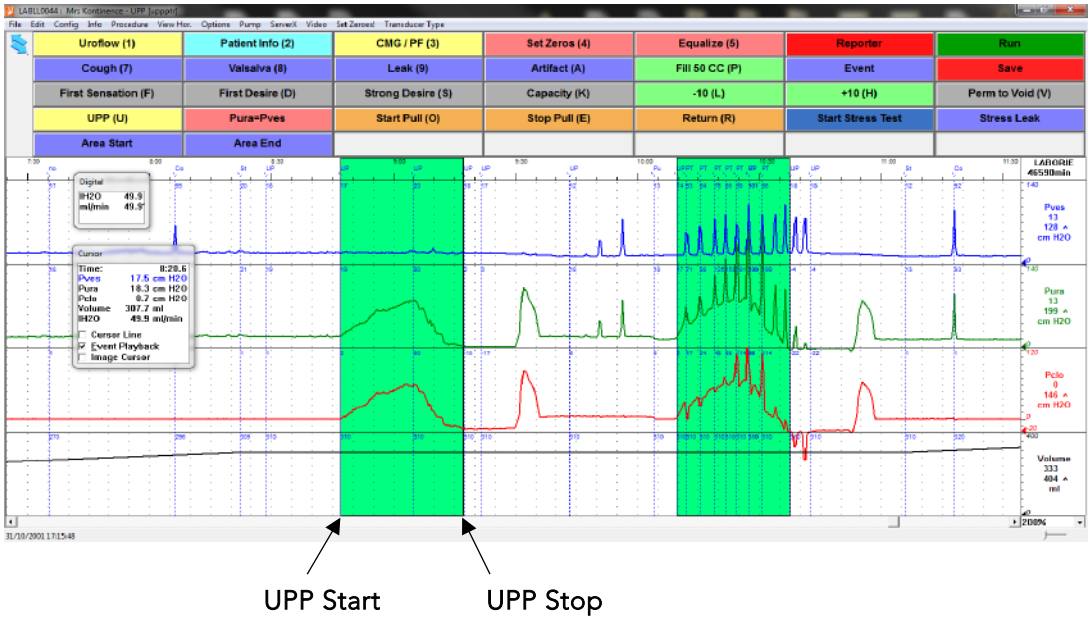


Figure 151: Auto Event Background Color

7.8.13 Auto Mark Peaks

The **Mark Peaks** feature automatically marks peak events for each channel once the test is complete.

- Click Options > Auto Mark Peaks to enable or disable the feature.

7.8.14 Auto Infusion Event

An Auto Infusion Event may be used in the filling phase of CMG or pressure-flow tests. It marks an event after every 100 ml of liquid is infused into the patient's body.

Click **Options** from the menu bar and select **Auto Infusion Event** to enable or disable the event. **The Auto Infusion Event** can **be configured prior to beginning testing or** while a test is running.

If events are displayed on the curve, the auto infusion event appears as a "VH" at the top of the curve. The Event Annotation in the Event Summary will read "VH2O = XXX ml".

To cancel the Auto Infusion Event option, click **Options** > **Auto Infusion Event**. For more information on displaying events, refer to the Events section on page 86.

7.8.15 Graph Clipping

The Graph Clipping option "clips" the top and bottom of a curve if it exceeds the display scales of a channel's display area. By default, this option is disabled and the curves can exceed the display area of a channel.
NOTE: The channel scale range determines the height of the curve.

To enable the Graph Clipping option:

1. Click **Options** from the menu bar.
2. Select **Graph Clipping**. The curves will appear flat if they exceeds the channel scale range.

Click **Options** > **Graph Clipping** to cancel the **Graph Clipping** option.

7.8.16 Smart Tracing

This feature allows the curves to be displayed like inked display where repeated data is re-inked. Lines that have repeated data will be displayed in a darker color. This feature is useful when a long test is compressed into a smaller display area.

7.8.17 Resize Overflow Screen

Maintains the graph lines in the graph channels.

7.8.18 IMAGE OVERLAY (OPTIONAL)

This is an optional feature in the UDS software. With Overlay, also called Image Overlay, you can run a live video image that will display under the graph on the UDS screen. This is available with the Video option of the software.

7.8.19 CHANGE INFUSION BAG

Use this menu item to replace an infusion bag during a CMG or Micturition test.
The system automatically detects when the infusion bag is empty or occluded and will display a message asking for directions to continue. Refer to the example in Figure 152.

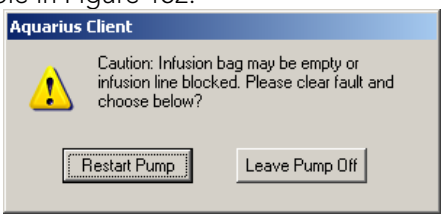


Figure 152: Infusion Bag Alert

To change the bag before the system provides the alert, select the *Change Infusion Bag* item under the ***Options*** menu.

To manually change the infusion bag during a test:

1. Click **Options** > **Change Infusion Bag**. The pump stops and the graph will continue to scroll. A message box appears asking you to change the infusion bag.
2. Click **OK**.
3. Replace the bag and reconnect the IV tubing.
4. Click **OK** to resume testing. The pump will continue with its normal activity.

7.8.20 AUDIO

This option contains the Audio Settings and Event Playback features.

Audio Settings (Optional Sound Feature)

This menu item is present only when the sound feature is enabled. Use this menu item to change sound recording parameters. To change the Sound Recording Parameters:

1. Click **Options** > **Audio** > **Audio Settings**.
2. Make changes.
3. Click **OK**.

Event Playback (Optional Sound Feature)

Use this menu item to turn on/off audio playback for sound events.

7.8.21 VBN

This option contains the VBN Settings and VBN Overlay features.

VBN Settings

If you have VBN enabled in the software, you can set the catheter size used so that the renderings in VBN are correct.

1. Click **Options** > **VBN** > **VBN Settings** to open the VBN settings window.

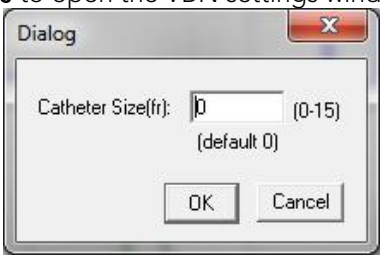


Figure 153: VBN Dialog Window

2. Type the size of the catheter (between 0 and 15) and click **OK**.

VBN – Normal Curve Overlay

This is a normalized Flow curve that is overlaid on the patient's Flow curve after a Uroflow or Pressure/Flow test. It provides a basis of comparison between the normal flow curve (for the patient's gender and voided volume) and the patient's actual

flow curve. The match to the normal curve is visible in the shaded area under the curve (Figure 154). The normal flow curve is recalculated if the gender entry is changed in the patient info screen.

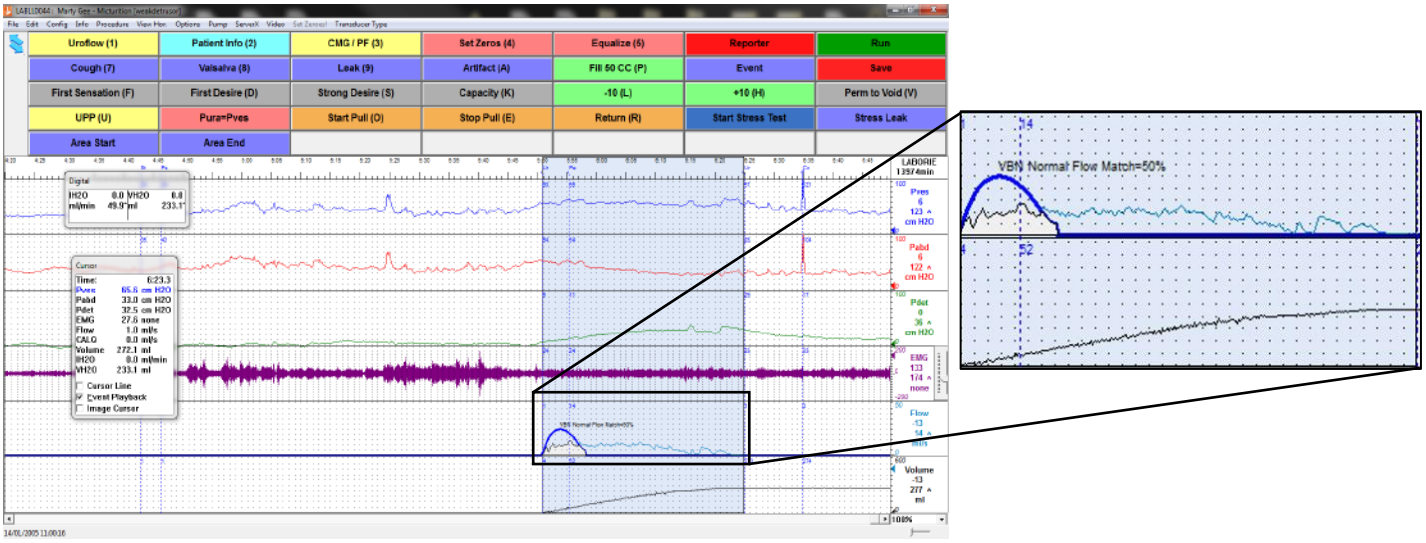


Figure 154: VBN Curve

By default, the VBN curve is visible once selected from under the *Options* menu. When *VBN – Normal Curve Overlay* is selected in the menu, a check mark will be displayed next to the item. To hide the curve, click **Options** > **VBN** >**VBN – Normal Curve Overlay**. The check mark will disappear.

7.8.22 I-LIST (OPTIONAL – FOR I-LIST SOFTWARE USERS ONLY)

The UDS Software will transfer the data to the i-LIST Message Queue.

To transfer data to iList from the scrolling graph:

1. Right-click on the graph and select the **Export to i-LIST** menu item.
2. Click on the name of the event to export (Figure 156).

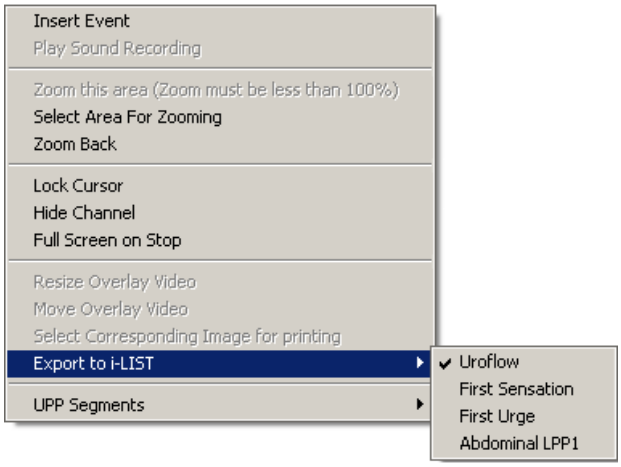


Figure 155: Export to i-List – Context Menu

3. Save the test file. The UDS software will automatically transfer files to the i-LIST Server.

To see if file transfer was successful:

1. Click **Options** > **i-List** > **MSMQ Monitor**.
2. Once the *i-List MSMQ Monitor* window is displayed, click **Options** > **Enable MSMQ Logging**.
3. A message of successful transfer and receipt is visible in the *i-List MSMQ Monitor* window (Figure 156).

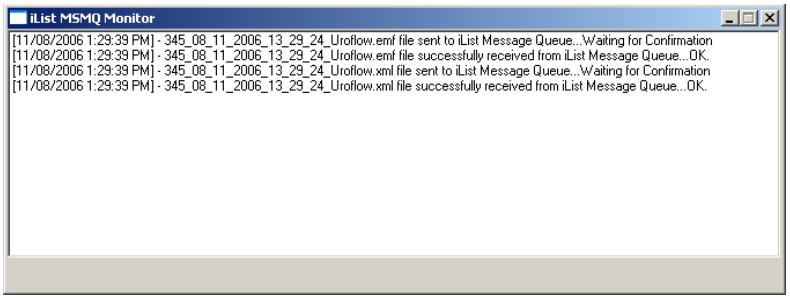


Figure 156: iList MSMQ Monitor

7.9 PUMP MENU

The *Pump* Menu provides access to configuration and filling controls.

7.9.1 CONFIGURE PUMP

Use the Configure Pump option to customize the pump options.

The Prime rate feature runs the pump at the speed set in the *prime box* in the *Configure Pump* screen. The default speed is 150 ml/min.

To configure the Pump:

1. Select **Configure Pump** from the ***Pump*** Menu. The Configure Pump screen will appear.
2. Select Customizations. Refer to Table 27 for descriptions of settings available.

Feature	Function
Volume Channel	Specifies the infusion volume channel
Pressure Channel	Specifies the channel used for pressure feedback
Slow (rate speed)	Determines the slow speed of the flow rate
Medium (rate speed)	Determines the medium speed of the flow rate
Fast (rate speed)	Determines the fast speed of the flow rate
Prime (rate speed)	Determines the prime speed of the flow rate
Pressure Limit	Stops the pump if the pressure channel exceeds this limit. **CAUTION:** Do not exceed 150 cm H20.
Pump Flow Limit	Specifies the max pump flow rate during calibration. **NOTE:** This setting cannot be changed manually in the UDS software.
Volume Limit	Stops the pump if the volume channel exceeds this limit. **CAUTION:** Do not exceed 750 ml.
Volume Warning Limit	Displays a warning message when the infused volume reaches the specified limit.
Auto Pump Option Stop, Slow, Med, Fast	This option starts the pump at the selected pump speed when the test starts. Choose **Stop** if you do not want to use this option.
Auto Pump Event	This option records events automatically when the pump runs or stops. This option is enabled by default. Deselect the box to disable the feature.

Table 27: Pump Configuration Options

3. Select **OK** to accept changes or select **Cancel** to exit without saving changes.

7.9.2 PRIME PUMP

Priming the pump removes all the air bubbles from the tubing, which may cause incorrect pressure readings.

7.9.3 SLOW FILL
Select this menu item to run the pump at the slow rate set in the *Configure Pump* window.

7.9.4 MEDIUM FILL
Select this menu item to run the pump at the medium rate set in the *Configure Pump* window.

7.9.5 FAST FILL
Select this menu item to run the pump at the fast rate set in the *Configure Pump* window.

7.9.6 STOP PUMP
Select this menu item to stop the pump.

Volume Warning Limit

The Volume Warning Limit is used in the pediatric "Uro Mode" which applies to patients under 16 years of age. This limit is the maximum amount of fluid that can be infused into the patient according to bladder capacity at a given age.

The Volume Warning Limit is determined by Acceptable Total Bladder Capacity (ATBC.)
ATBC = 16 x (Age of child in years) + 70 ml.

The pump receives the information to calculate the ATBC from the data entered in the Patient Information dialog box.

If the infused volume exceeds the limit specified in the Volume Warning Limit box, a message appears.

IMPORTANT: After the warning appears, the pump does not automatically stop. It must be manually stopped.

NOTE: The ATBC is calculated automatically and cannot be changed.

7.10 SERVERX MENU (OPTIONAL)
The *SERVERX* Menu provides access to ServerX features and system connection controls.

7.10.1 RESET CONNECTION
The Reset Connection feature resets the connection to the hardware. It should not be used during the test. It is intended for use only by qualified technical service personnel.

7.10.2 SHOW SERVERX WINDOW
The Show ServerX Window feature is to be used only by qualified technical service personnel.

7.10.3 CHOOSE BLUETOOTH
Use this menu item to select which **AQUARIUS®** system is connected to the software. The software will automatically connect to the same **AQUARIUS®** system when it is run the next time.

To select the system for connection:

1. Select **Server X** > **Choose Bluetooth**. The *Select a Bluetooth Server* window will open and search for all Bluetooth devices within range.
2. Select the name of the **AQUARIUS®** system from the list.
3. Enter the PIN number **LMTUDS94BT** (all capital letters) if prompted.
4. Click **OK**.

7.10.4 CONNECTION TYPE

Select the connection type option that matches the connection set up in the touchscreen settings, USB or Bluetooth (Figure 157). If the connection type is changed, then it must be changed in the touchscreen module software too.

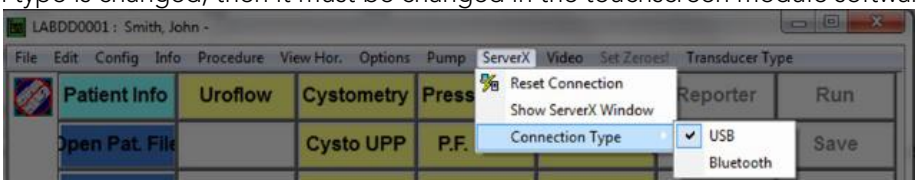


Figure 157: ServerX – Connection Type

When a connection is changed (such as switching from USB to Bluetooth and vice versa, exit then restart the software to enable the change.

7.11 VIDEO

Starts the video functions of the UDS software. Refer to the *Saturn Owner's Manual* for more information.

7.12 SET ZEROES! MENU

Set Zeroes is a menu located on the menu bar at the top of the screen. It is recommended that all transducers be zeroed before performing a test:

"Zero pressure is the value recorded when a transducer is open to the environment when disconnected from any tubes or catheters, or when the open end of a connected, fluid-filled tube is at the same vertical level as the transducer. Only then can a 'set zero' or 'balance' be performed."[x]

NOTE: The EMG channel must always be set to zero through this menu.

It is recommended to zero all transducers before performing a test.

To Set Zeroes before performing a test:

- Select **SET ZEROES!** from the Menu Bar in the *Goby Software* window. The *Set Zeroes* window will launch (Figure 158).
  - To set all transducers to zero, click **All**.
  - To zero a single transducer, click the button labeled with the transducer/channel name.
  - To set transducers to a specific value, click the **Advanced** button in the *Set Zeroes* Menu. Then click the option next to the transducer requiring the change. Use the keypad at the bottom of the window to set the specific value and click **Apply**.

NOTE: The **Advanced** button is only available when the test is stopped.

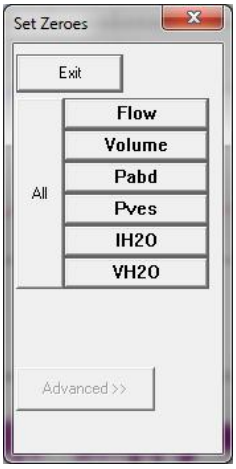


Figure 158: Set Zeros Window

7.13 TRANSDUCER TYPE

Select the type of transducer used with the system before a test starts to ensure proper data recording. Ensure the system has been calibrated to the transducer type selected.

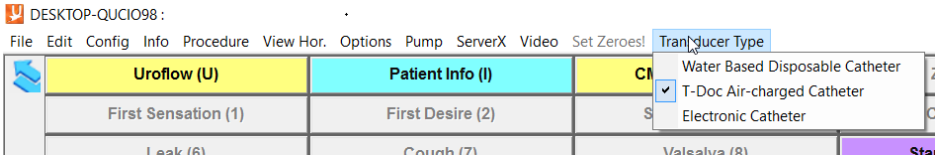


Figure 159: Transducer Type Menu

Use one type of transducer with the **Roam™ DX**; select either air-charged or water for all tests.

NOTE: A "transducer type" event will be added to the start of the graph when **Run** is clicked.

8 VBN FEATURE

VBN is an optional feature. Feature availability is dependent on system setup. Contact your LABORIE representative or call customer service to request this optional feature.

VBN is a mathematical model of the lower urinary tract and is based on the research and standards set by the members of the International Continence Society. VBN is a powerful and non-invasive tool to predict the aftereffects of surgery and/or prescribed treatment. The features available are dependent upon the VBN options installed on your system.

8.1 NORMAL CURVE OVERLAY

Calculate the normal flow (Q) curve to compare against the patient's actual flow (Q) Pves curve by overlaying the normal curve over the patients curve.

1. Click **File** > **Open** to open any Pressure/Flow .dta file or any file that has a *Flow/Q* channel.
2. Click **Options** >**VBN – Normal Curve Overlay**. When *VBN – Normal Curve Overlay* is selected in the menu, it will have a checkmark next to it.
3. Once *Normal Curve Overlay* has been selected, a blue curve representing the normal flow for the sex of the patient will be laid on top of the patient's actual flow curve.
4. Press F9 to enable the *Cursor* box. Move the mouse over the blue calculated curve and the patient's actual measured curve to observe the difference between the patient's flow and the normal flow.
5. Left click the bottom of the *Flow Channel* box (below the ml/s text) to change the channel label to the normal flow channel (CALQ). The label will become blue and say CALQ with a peak flow measurement in ml/s. This peak flow should be the value of the highest point on the normal flow curve.
6. Left click the box again to change the flow channel box from CALQ back to Flow.
7. Playback the test with the Normal Curve Overlay enabled to watch as the overlay is drawn.
8. Click **Options** >**VBN – Normal Curve Overlay** while it is selected to disable the overlaid curve.

8.2 VBN FULL AND VBN ANIMATION

Use the VBN Animation features to display a simulated model of the human bladder or display an animation of what the bladder might do with normal pressure and flow based on such factors as sex, catheter size (if any), and other forces. The control panel buttons associated with VBN are already loaded into the system.

VBN Full and **VBN Animation Only** versions have similar functionality except the VBN Animation version does not include the graph windows. Any functionality requiring a graph window is therefore not used in the VBN Animation version of the software.

To access the Control Panel:

1. Click **Options** > **Control Panel Definition**.
2. Select VBN from the *Control Panel Set Name* dropdown menu.
3. Click **OK**.
4. Click the **Transfer to VBN** button on the control panel to open the *VBN control panel*.

8.2.1 VBN CONTROL PANEL

When the VBN control panel loads, three rows of buttons will be displayed. The subsections below outline the functions on buttons available in the VBN Control Panel

Initialize Default Values

Click this button to open VBN windows and controls including controls to initialize VBN related variables to predefined default values. The controls available depend on the saved configuration of the VBN Control panel. If no customized layouts have been saved a default layout will launch (Figure 160).

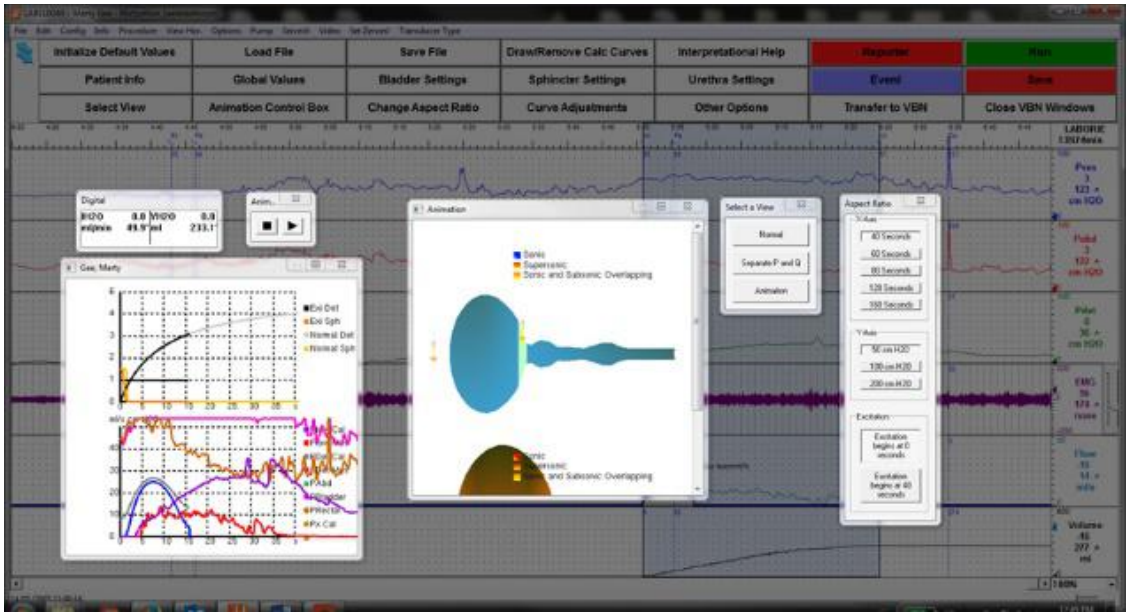


Figure 160: VBN Windows

Load File

Click this button to load a previous saved file in CAS format, which is the file format VBN uses to store tests.

Save File

Click this button to save the current VBN test in CAS format. VBN test can be retrieved using the **Load File** button.

Transfer to VBN

Use this button to import DTA files to the VBN component of the program.
Opened a pressure-flow DTA file from within the UDS software (**File** >**Open**) and press **Transfer to VBN** to import this test data to the VBN component of the program.

Draw/Remove Calculated Curves

Click this button to switch the display of the calculated pressure and flow curves on any open curve windows.

Interpretational Help

The **Interpretational Help** window is an important window in VBN.

It is responsible for controlling VBN's automatic interpretation features. With this feature, the software will automatically try and fit the calculated pressure and flow curves over the measured calculated pressure and flow curves by adjusting different VBN variables. It will then generate one or more solutions where the curves fit.

Select the **Together** button and the software will begin the process of trying to fit the curves. You can observe the calculations on any open graph or animation windows while the computer is trying different combinations of variables. Once the process is complete, a results window will appear showing any solutions.

If any solutions were discovered, the **Solution** value will change to 1. If more than one solution was discovered, use the -1 and +1 buttons to navigate between the different solutions.

Refer to Figure 161.

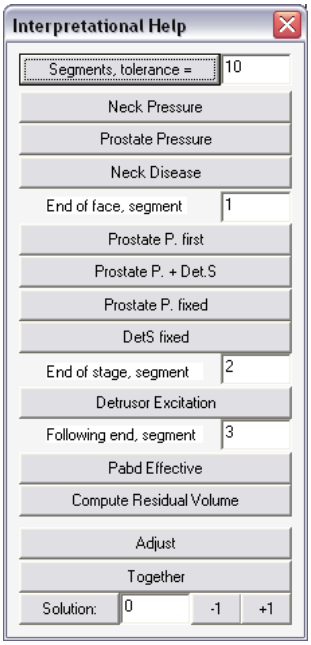


Figure 161: Interpretational Help

Patient Info

Click the **Patient Info** button to input or review patient information for the current test (Figure 162).

Adjust the gender of the patient by clicking the *Mr.* or *Mrs.* button. The equations used by VBN during its calculations are dependent on the sex of the patient, so this must be correctly entered before using the VBN function.

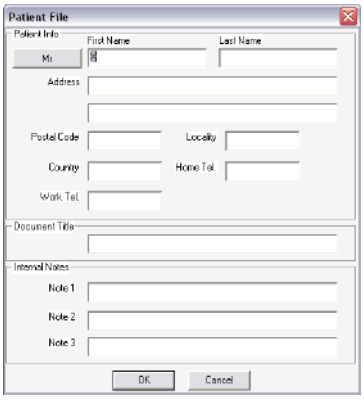


Figure 162: Patient File Window

Global Values

The **Global Values** window can be left open while you are performing other VBN features (Figure 163).

Use this window to observe measured values (for example, Volume Voided) to the values computed by the VBN software. This is especially useful when used in combination with the Interpretational Help feature, as you can compare how close the calculated values are to the original values for each solution.

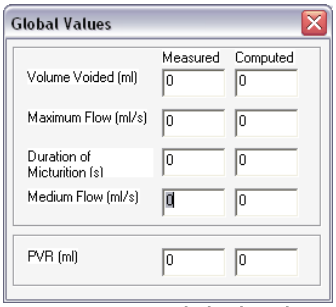


Figure 163: Global Values Window

Bladder

Click this button to open the **Bladder** window (Figure 164).

Adjust variables that affect the bladder such as Initial Volume, Detrusor Force, and so on. Some of these values will be automatically adjusted when using the Interpretational Help feature to discover solutions. From the *Bladder* window you can also input the initial volume inside the bladder, which has a significant effect on the calculations.

The following Settings are available in the *Bladder* window:

- **Detrusor Force:** A higher detrusor force will decrease the time it takes the patient to void, providing they are able to void at all.
- **Initial Volume:** The size of the bladder in the *Animation* window will change depending on the "Initial Volume". A greater initial volume also means it will take longer for the patient to void.
- **Time Of Break and Quality:** The patient should not be able to continue voiding much longer than the value (in seconds) of the "Time of Break" setting. How long the patient can continue voiding past this point depends on the "Quality setting".
- **Neck/Detrusor Coupling:** No observable effect for animation.

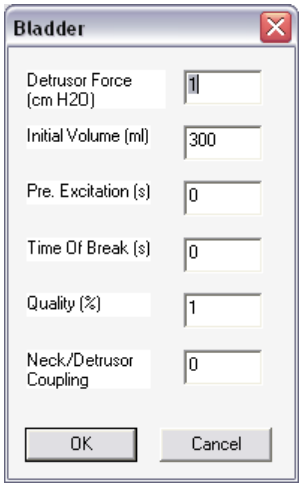


Figure 164: Bladder Window

Sphincter

Click this button to open the *Sphincter* window.
Use this to adjust variables that affect the Sphincter. Some of these values are automatically adjusted when using the Interpretational Help feature to discover solutions.

The following Settings are available in the *Sphincter* window:

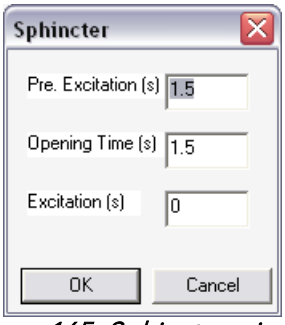


Figure 165: Sphincter window

- **Pre excitation:** For strong enough values, the voiding does not depend on it. For insufficient value the function of the sphincter is impaired, so continence is not achieved.
- **Opening Time:** The area of the urethra that the sphincter force effects will not open until this amount of time has passed. You will notice that Subsonic and Sonic forces will be in this area until the sphincter has opened.
- **Excitation:** Can influence how long it takes the patient to void, but it also depends on other settings.

Urethra

Click this button to open the *Urethra* window.
Use this feature to adjust variables that affect the Urethra. Some of these values are automatically adjusted when using the Interpretational Help feature to discover solutions. From the *Urethra* window select the size (in French units) of the catheter that is inserted into the urethra. This has a great impact on the calculations.

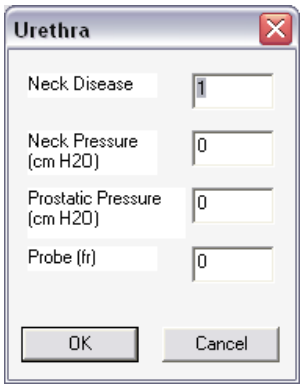


Figure 166: Urethra Window

The following Settings are available in the *Urethra* window:

- **Neck Disease:** A very low setting (for example: 0.1) will increase the time it takes the patient to void. You can observe the sonic/subsonic forces being located near the neck. No effect if greater than 0.2.
- **Neck Pressure (Male Only):** Increasing this value increases the pressure on the neck, which will increase the time it takes the patient to void.
- **Prostrate Pressure (Male Only):** Increasing this value increases the pressure from the prostate, which will increase the time it takes the patient to void.
- **Ura Comp. (Female Only):** Increasing this value will increase the time it takes the patient to void.
- **Urethra Area (Female Only):** Has an effect on the size of the Urethra. Will also affect the time it takes the patient to void.
- **Probe:** Sets the size of the probe (if any) inserted into the patient's urethra. A red bar will be visible in the animation window. A probe will greatly increase the amount of time it takes the patient to void.

Select View

Click this button to open the **Select a View** window (Figure 167).

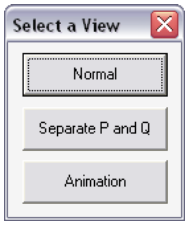


Figure 167: Select a View Window

This window provides access to *Normal, Separate P and Q, and Animation data representations.*

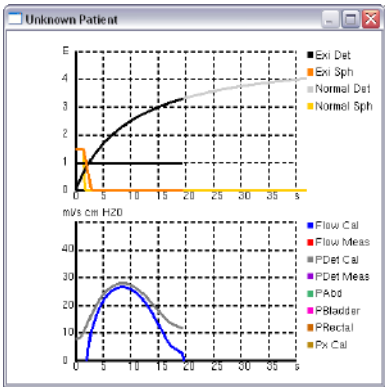


Figure 168: Normal

- Select the **Normal** button to open the Graph in its normal format (Figure 168).
- Select the **Separate P and Q** button to open a graph window that separates the pressure curves and the flow curves onto two different graphs (Figure 169).
- Select **Animation** to open the animation window (Figure 170).

NOTE: If using the Animation only version of VBN, the first two buttons will not be available.

These *Normal* and *Separate P and Q* graphing windows display several measured and calculated curves. Each curve has a corresponding label that matches its color. In both graphs, the top-most graph always displays curves relating to the Detrusor and Sphincter forces.

In the *Separate P and Q* window, the pressure and flow curves are separated into two different graphs. Use the scrollbar to view the different graphs.

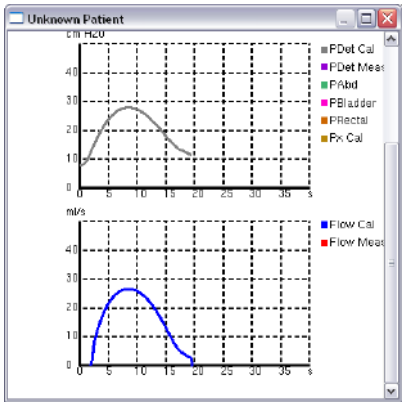


Figure 169: Separate P and Q

Animation Window

The *Animation* window displays a simulated model of the bladder for the current patient (Figure 170).

Adjustments to variables such as prostate pressure, size of catheter, initial volume, and the sex of the patient can be directly observed in this window.

When you are playing back an animation, this window displays the current flow rate, and the time that has elapsed at that stage of the animation. During an animation playback, the size of the bladder should gradually decrease provided the patient would be able to void during this simulation. The *Sonic* and *Supersonic* forces inside the urethra are also highlighted during the animation playback.

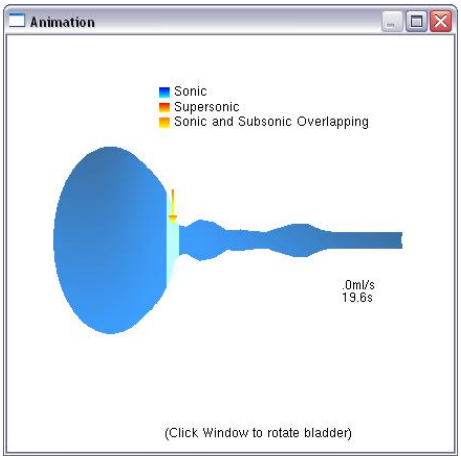


Figure 170: Animation window

Animation Control Box

Click this button to open the *Animation Control* Box (Figure 171).

Use the buttons on this window to control animation playback. Select the **Stop** button to reset the animation to the beginning stage, then select the **Play** button to begin playback. During the animation, use the **Pause** button to pause the playback.

Figure 171: Animation Control Box

Aspect Ratio

Click this button to open the *Aspect Ratio* window (Figure 172).

Use the controls in the *Aspect Ratio* window to adjust the aspect ratio of the X-axis and Y-axis on the graph windows. Use these controls to adjust the aspect ratio if the graph curves are out of range and going outside the bounds of the graph. This window also provides controls to set the excitation to either begin at 0 seconds or 40 seconds.

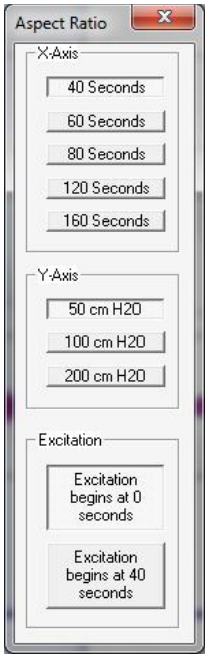


Figure 172: Aspect Ratio Window

Curve Adjustments

Click this button to open the *Curve Adjustments* window. Use this window, in combination with the *Normal Graph* window, to adjust the curves. Refer to Figure 173.

Under the *Curve to Adjust Option* select the curve to manipulate. Select a curve from the *Curve To Adjust* section and click the **Delete** button to delete an entire curve from the graph. Select the **Undo Delete** button to undo a previous deletion. To draw a curve directly on the graph, select the desired curve from the *Curve Adjustments* window, then click the normal graph window to draw a line from the beginning of the graph desired end point. To erase portions of the curve on the VBN graph, right click on the new endpoint of the curve. The curve will be erased from the end of the graph to the point selected.

Use the arrows in the *Move Curve* section to move the selected curve in the selected direction. This will show the effect that the abdominal pressure has on them.

The *Affinity* option allows you to multiply all the y-values of a selected curve by the amount entered to the field.

The Measured global values will be different based on the initial volume of the bladder. The other parameters take their standard value. While changing values in the windows the values in the *Global Values* window will change to reflect the other changes made.

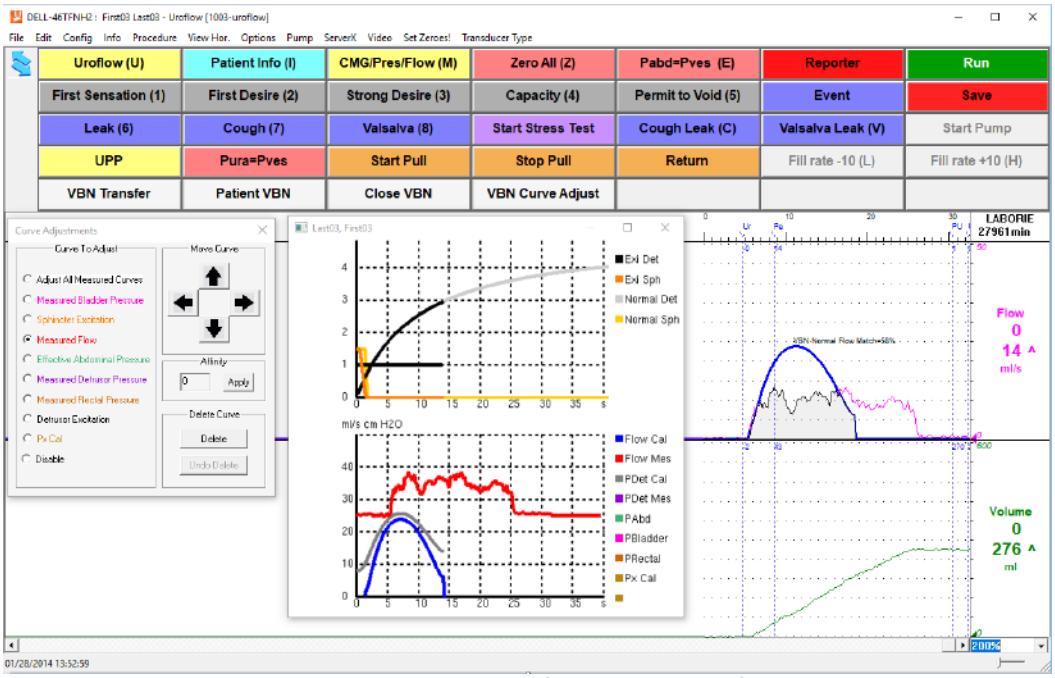


Figure 173: Curve Adjustments Window

Other Options

Click this button to open the *Other Options* window (Figure 174).
Enable or disable laws used during VBN's calculations. Some of these laws affect which calculations are used during *Interpretational help*.
From this window adjust the thickness of curves being displayed on the graph windows. Use the **Save** and **Restore** buttons to save the current window layout or to restore a previously saved window layout.

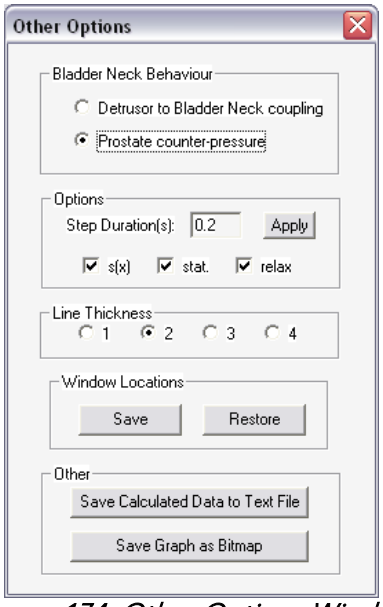


Figure 174: Other Options Window

Close VBN Windows

Select this button to close all VBN related windows. This is useful when you are done using VBN but wish to continue using another part of the UDS software.

9 ANORECTAL MANOMETRY (ARM) FEATURE

ARM is an optional feature. Availability is dependent on system setup. Contact your LABORIE representative or call customer service to request this optional feature.

The LABORIE Anorectal Manometry (ARM) feature is used to quantify the performance of the Anorectal mechanism. Anorectal function testing can provide useful information regarding the pathophysiology of disorders that affect continence and defecation or those that cause anorectal pain.

9.1 INTENDED USE

LABORIE ARM system is intended to measure the physical parameters such as pressures and EMG of the terminal end of the digestive tract as it relates to Urodynamics, Incontinence, and the Pelvic Floor.

9.2 TARGET POPULATION

The major application of ARM is to aid in the diagnosis of anorectal disorders and for evaluating abnormalities of the sphincteric mechanism. ARM has shown applicability in men, women, and children in the diagnosis of the following conditions or instances:

- Fecal Incontinence[xi,xii,xiii]
- Separating out the various types including:
- Pudendal nerve neuropathy[xiv]
- Sphincter lesions[xii]
- Overflow incontinence[xii]
- Can occur in diabetes mellitus[xv]
- Constipation[ix,x,xi]
- Chronic or otherwise[xvi,xvii,xviii]
- Pre- and post-operative care* for any procedure involving the sphincter apparatus[xi,xii]
- Fissure and fistula repair
- Colon-anal anastomoses
- Pouch operation
- Sphincter tightening
- Functional obstructive difficulties in defecation including[xii] :
- Paradoxical contraction of puborectalis muscle
- Anismus
- Spastic pelvic floor syndrome
- Megarectum
- Rectal inertia
- Internal rectal prolapse
- Assessing patients prior to and to facilitate biofeedback training of the evacuation and continence mechanisms[xi]
- Bowel symptoms resulting from systemic neurological disorders, such as multiple sclerosi[xix] and cerebrovascular accidents[xx]
- Congenital anomalies such as Hirschprung's disease[xxi] and imperforated anus[xxii]
- Encoporesis[xxiii]
- Collagen vascular disease (such as scleroderma)[xxiv]
- Trauma (accidental, obstetrical, or surgical injury)[xxv]
- Functional anorectal pain[xi,xxvi]

9.3 CONTRAINDICATIONS

The ARM system is contraindicated for any patient with one or more of the following conditions:

- Uncooperative patient
- Gastrointestinal (GI) bleeding
- Comatose

⚠ WARNING: Anorectal manometry should be performed with great care, especially in the early post-operative period following rectal surgery, or in those young and old patients who may not express or feel internal sensation during the examination, as these individuals may be at risk of bowel perforation. Great care should also be taken for those who have undergone surgery and/or radiotherapy due to rectal cancer at any time[xxvii xxviii xxix xxx xxxi] (*Appendix B – I: 16-20).* Park *et al.* (2008) recommend meticulous digital rectal examination preceding ARM for the detection of unsuspected anorectal abnormal lesions, and is necessary for patients with a history of rectal surgery. In addition, measuring maximum tolerable volume in the postoperative period should be omitted.

⚠ WARNING: Per the above warning, certain individuals may be at higher risk of bowel perforation during anorectal manometry, which may require surgical correction. Serious complications may occur in any surgery, which should be considered and communicated, to the patient, when assessing suitability for anorectal manometry testing.

9.4 SYSTEM STARTUP SEQUENCE

Power up the ARM enabled system in this sequence:

- ✓ Aquarius system tower
- ✓ Printer and Monitor
- ✓ PC
- ✓ UDS software

Failure to power up in this sequence could result in devices not being properly recognized.

9.5 USING ARM WITH AIR-CHARGED CATHETERS

Use the T-DOC Air-Charged ARM Catheter for ARM studies including Expulsion testing. Do NOT fill the sensory balloon beyond 450 c's for any given test. Do not exceed 300cc for pediatric patients. DO NOT put traction on or pull the T-DOC Air-Charged ARM Catheter out of the patient while the balloon is filled because the balloon may pull off from the catheter.

Equipment for ARM Testing

Required Equipment	Optional Accessories
• ARM 4 channel air- charged radial catheter with rectal balloon (CAT003 (4-Pressure)) • Syringe, provided by site • Four or eight pressure transducers/cables • AIO PC or laptop • Starter kit, pump tubing, catheters, beaker etc. (Will vary according to system setup) • Software CD containing ARM software and owner's manuals	• EMG unit and surface electrodes [CAB155, CAB154 or CAB153 (EMG cable) with ELE200 or ELE428 or ELE370&ELE365 (EMG electrodes)] • UPP Puller

Table 28: ARM Feature –Equipment for Air-Charged Catheters Setup

Contact your LABORIE representative to order replacement accessories.

9.5.1 Catheter and Transducer Setup and Connection

1. To set up the **Roam™** DX, the EMG, and the pump tubing on the AQUARIUS, refer to the Software and Equipment Setup section on page 18.
2. Make sure all transducers are in the **OPEN** position.

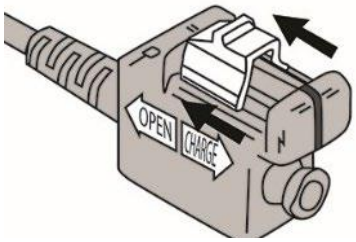
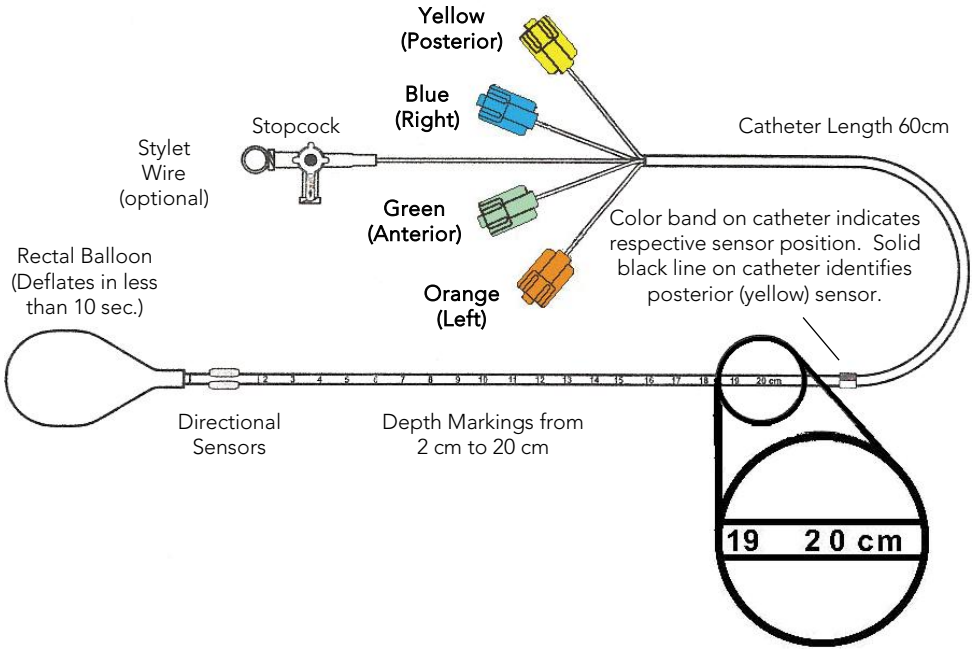


Figure 175: Transducer Cable – Open Position

3. Each directional sensor is identified by color. This color corresponds to the transducer/cable connection for ease of identification. Connect the color-coded transducer cables to the air-charged catheter by following the configuration shown in Figure 176.



Yellow P1 cable to POSTERIOR (yellow) catheter port

Blue P2 cable to the RIGHT (blue) catheter port

Green P3 cable to ANTERIOR (green) catheter port

Orange P4 cable to LEFT or (orange) catheter port

Figure 176: Air-Charged Abdominal Catheter – Connections

NOTE: The black line on the catheter indicates the "posterior" orientation. This line should be directly in line with the patient's spine during insertion. If the patient is on their left side, the line will be facing their back.

4. Gently squeeze then release each directional sensor to remove air. NOTE: This is not the large rectal balloon, but rather the four small directional sensors located directly beneath the rectal balloon.
5. Click **Set Zeros** on the software control panel.
6. Switch the transducer to the **CHARGE** position (Figure 177).

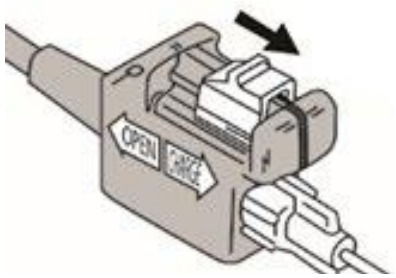


Figure 177: Transducer Cables – Charge Position

9.6 USING ARM WITH FLUID-FILLED SYSTEMS

Required Equipment	Optional Accessories
For a Fluid-filled Gravity Feed System: • ARM 4 or 8 channel water-perfused catheter with balloon [CAT006 (4-Pressure) CAT008 (8-Pressure)] • Pressure cartridge* (DIS125) • Measurement tubing (TUB101 or TUB102) • Pressure cuff (DIS302) • Syringe, supplied by the site • IV BAG • IV line • AIO PC or laptop computer • Equipment with built-in pump • Four or eight pressure transducers and cables • Starter kit (pressure cartridges, stopcocks, tubing, pump tubing, catheters, beaker etc. Will vary according to system setup) **Depending on the system, use a Nova dome (DIS103) instead of a pressure cartridge (DIS125).* *For a Fluid-filled with Constant Pressure Pump System:* • Syringe, supplied by site • 1 L Distilled water, supplied by site • 3-way stopcock (DIS431) • Pressure cartridge (DIS125 or DIS103) • Luer Lock Plug (DIS104) • Measurement tubing (TUB101 or TUB102) • ARM 4 or 8 channel water-perfused catheter with balloon CAT006 • (4-Pressure) CAT008 (8-pressure) • AIO PC or laptop computer • Equipment with built-in pump • Four or eight pressure transducers and cables • Starter kit (pressure cartridges, stopcocks, tubing, pump tubing, catheters, beaker etc. Will vary according to system setup)	• EMG unit and surface electrodes [CAB155, CAB154 or CAB153 (EMG cable) with ELE200 or ELE428 or ELE370&ELE365 (EMG electrodes)] • UPP Silent Drive Mechanical Puller (UPP1001)

Table 29: ARM Feature - Equipment for Fluid-Filled Systems

Contact your LABORIE representative for ordering replacement accessories.

9.6.1 TRANSDUCER SETUP AND CONNECTION

9.6.1.1 FLUID-FILLED TRANSDUCER SETUP USING GRAVITY SYSTEM

The Gravity Feed System is comprised of three subsets of equipment setups: IV bags, the pressure transducers, and the catheter.

The IV Bags

1. Place 4 cuffed (*if measuring 4 pressures*) or 8 cuffed (*if measuring 8 pressures**) saline or sterile water IV bags at the top of the IV pole.
2. Connect an IV line to each saline bag.

IMPORTANT: Keep the roller clamps closed when puncturing the bags.

3. Pump each pressure cuff to a minimum of 300 mmHg.
4. Prime each IV line.

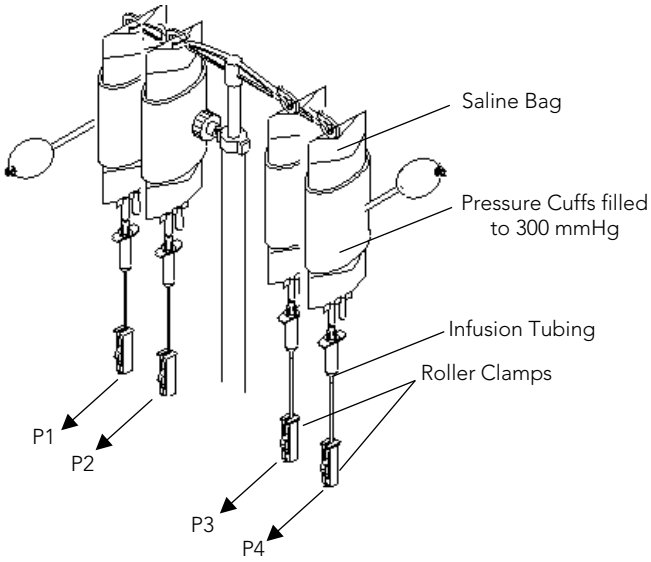


Figure 178: IV Bag Setup for 4 Pressures

Pressure Transducer Setup Using Transducer Cartridges
Refer to the Consumables and Transducer Setup section on page 25.

Fluid-filled Catheter Setup with Gravity System

Connect each catheter port to its corresponding pressure measurement tubing. For example, connect P1 on the catheter to the measurement tubing coming from the P1 transducer.

1. Open the drip on each IV line to 1 drop every 2-3 seconds to keep line flushed.
2. Hold the tip of the catheter level with the pressure transducer plate. Click **Set Zeroes**.

Refer to the Figure 179 below for a diagram of the fluid filled catheter channels from the distal end. The P1 channel is in line with the blue indicator line.

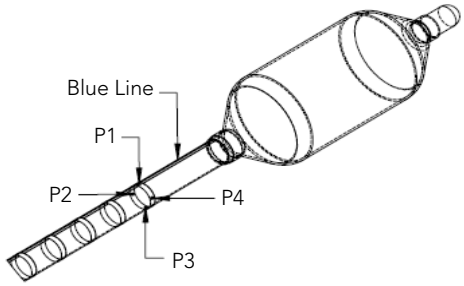


Figure 179: Fluid-filled catheter – Distal View of Channels.

EMG Setup

Refer to the EMG Setup section on page 28.

Pump Tubing Setup (optional)

Refer to the Pump Setup section on page 24.

9.7 USING ARM WITH ELECTRONIC CATHETERS

Standard Equipment	Optional Accessories
• ARM 4 or 8 channel radial catheter [CAT928 (4-Pressure) or CAT916 (8-Pressure)] • Rectal Balloon (CAT752) • Syringe, supplied by site • Surgical thread to attach balloon, supplied by site • AIO PC or laptop computer • Equipment with built-in pump • Four or eight pressure transducers/cables • Starter kit, pump tubing, catheters, beaker etc. (Will vary according to system setup)	• EMG unit and surface electrodes [CAB155, CAB154 or CAB153 (EMG cable) with ELE200 or ELE428 or ELE370&ELE365 (EMG electrodes)] • UPP Silent Drive Mechanical Puller (UPP1001) • Desktop printer with USB printer cable • USB Serial Converter (Direct cable option only) • RS-232 null modem cable (Direct cable option only)

Table 30: ARM Feature - Equipment for Electronic Catheters Setup

9.7.1 CATHETER SETUP

1. Connect the cables to the electronic catheters with Lemo cables; connect the S1 cable to P1, the S2 cable to P2, the S3 cable to P3 and the S4 cable to P4 until all connections are set. Refer to Figure 180 below showing cable and catheter connections:

Figure 180: Electronic Catheter – Distal View of Connections

2. Place the electronic catheter in a shallow water dish being careful not to submerge the electronic housing of the catheter.
3. Allow the catheter to sit in water for a minimum of 5 minutes, as the electronic sensors must stabilize prior to use.
4. Hold the sensors just below the water surface and click **Set Zeros**.
5. Let the catheters remain in the pan of water until ready for placement.

EMG Setup

Refer to the EMG Setup section on page 28.

Pump Tubing Setup (optional)

Refer to the Pump Setup section on page 24.

9.8 PERFORMING TESTS WITH THE ARM SYSTEM

IMPORTANT:

Notes Regarding Testing Procedures

- Prior to catheter insertion, **the rectal ampulla must be empty of all fecal debris**. Some doctors recommend that patients with constipation use an enema before coming in for the test.
- Place the patient in a left-lateral position with knees and hips flexed in or as close to a 90-degree position as possible. Above all, the patient must be resting comfortably and be willing and able to cooperate.
- Only 4-channel and 8-channel radial catheters are acceptable for use with the ARM software. If using linear catheters, then adjustments must be made to the software. Contact your LABORIE representative for more information.

Common Test Configurations

Test Name	Channel Title	Scale	Math Definition	Data Rate	Display Attribute
ARM4	P1 (or Posterior) P2 (or Right) P3 (or Anterior) P4 (or Left) Math1 (Average)	150mmHg 150mmHg 150mmHg 150mmHg 150mmHg	Null Null Null Null (P1+P2+P3+P4)/4 *or* (Posterior+Right+Anterior+ Left)/4	10points/s 10points/s 10points/s 10points/s 10points/s	Curve Curve Curve Curve Curve
ARM8	P1 (or Posterior) P2 (or Right Posterior) P3 (or Right) P4 (or Right Anterior) P5 (or Anterior) P6 (or Left Anterior) P7 (or Left) P8 (or Left Posterior) Math1	150mmHg 150mmHg 150mmHg 150mmHg 150mmHg 150mmHg 150mmHg 150mmHg 150mmHg	Null Null Null Null Null Null Null Null (P1+P2+P3+P4+P5+P6+P7+P8)/8 etc	10points/s 10points/s 10points/s 10points/s 10points/s 10points/s 10points/s 10points/s 10points/s	Curve Curve Curve Curve Curve Curve Curve Curve Curve
ARM4 with EMG	*ARM4 configuration plus:* EMG	-300uV to +300uV	Null	100points/s	Curve, mirrored, and filled
ARM8 with EMG	*ARM8 configuration plus:* EMG	-300uV to +300uV	Null	100points/s	Curve, mirrored, and filled
ARM4 using Integrated LABORIE pump	*ARM4 configuration plus:* IH2O VH2O	 150mL/min 600mL	 Null Null	 10points/s 10points/s	 Digital Digital
ARM8 using Integrated pump	*ARM8 configuration plus:* IH2O VH2O	 150mL/min 600mL	 Null Null	 10points/s 10points/s	 Digital Digital

Table 31: ARM – Common Test Configurations

9.8.1 Performing ARM Tests with a Radial Catheter

Eight different tests can be performed with LABORIE's ARM software:

Pressure Profiles using Control Panel Buttons

i) Resting Profile
ii) Squeezing Profile
iii) Pushing Profile (optional)

Pressure Profiles using Study Configurations

iv) Stationary Rest and Stationary Squeeze
v) Stationary Rest, Stationary Squeeze, and Stationary Push

Filling and Expulsion Studies

vi) RAIR (Rectoanal Inhibitory Reflex)
vii) Rectal Volume/Rectal Sensation
viii) Expulsion

9.8.2 Starting the ARM Software

The buttons and commands to run the ARM software are preloaded into the UDS software.

To access the ARM commands in the UDS software:

1. Click **Options** > **Control Panel Settings**. The *Command* window will be displayed.
2. Click the **Control Panel Set Name list** and select ARM 4&8.
3. Click **OK**. The **Control Panel** will display the buttons associated with ARM testing (Figure 181).

NOTE: The control panel for your software may have a different appearance than the examples shown here (such as colors, button size, etc.) To change the appearance of the control panel buttons, click the **Button Color** button in the *Command* window and make selections for appearance.

	ARM	Patient Info	Zero All	Resting	Squeezing	Event	Run
	5 cm Rest	4 cm Rest	3 cm Rest	2 cm Rest	1 cm Rest	Print	Save
	5 cm Squeeze	4 cm Squeeze	3 cm Squeeze	2 cm Squeeze	1 cm Squeeze	10 cc	20 cc
	30 cc	40 cc	50 cc	60 cc	70 cc	80 cc	90 cc
	Expulsion	RAIR	First Sensation	Urge	Max Tolerance		Cough
	Pull	Pull 1 cm	Stop Pull	Return			

Figure 181: ARM Control Panel

4. Click the **ARM** button to display the testing configuration.

9.8.3 Pressure Profiles using Control Panel Buttons

9.8.3.1 Profiles Setup

1. Gently insert the well-lubricated catheter 6cm beyond the anal verge with Channel 1 (S1) in the appropriate dorsal position. Use the markings on the catheter as a guide.
2. If using a mechanical puller, attach the distal (furthest) end of the catheter to the puller using the puller guides. Take note of UPP control buttons on the control panel for use with the mechanical UPP Puller (Figure 182).

ARM	Patient Info	Zero All	Resting	Squeezing	Event	Run
5 cm Rest	4 cm Rest	3 cm Rest	2 cm Rest	1 cm Rest	Print	Save
5 cm Squeeze	4 cm Squeeze	3 cm Squeeze	2 cm Squeeze	1 cm Squeeze	10 cc	20 cc
30 cc	40 cc	50 cc	60 cc	70 cc	80 cc	90 cc
Expulsion	RAIR	First Sensation	Urge	Max Tolerance		Cough
Pull	Pull 1 cm	Stop Pull	Return			

Figure 182: UPP Controls on the Control Panel

NOTE: The resting profile can be performed without the use of a puller. In this case, manually withdraw the catheter at an approximate speed of 1mm/s to ensure pressures are properly correlated to catheter position.

3. Refer to the instructions for the profile type required.

9.8.3.2 RESTING PROFILE

The resting profile provides a baseline with which all pressures will be compared against during ARM testing. It is imperative that the patient be able to relax during testing in order to allow the recording of true resting pressures. Refer to figure x for sample data of a resting profile:

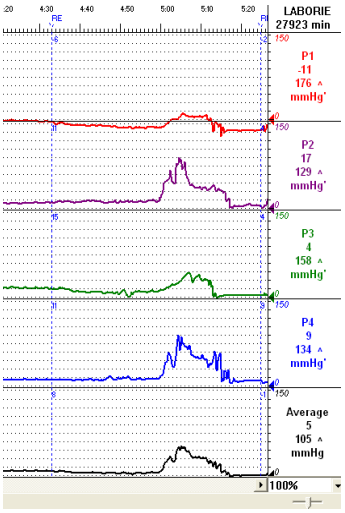


Figure 183: Sample Data of a Resting Profile

Follow the instructions provided to find the resting pressure profile:

1. Insert the catheter and prepare a mechanical puller as described in the Pressure Profiles using Control Panel Buttons
2. Profiles Setup section on page 145.
3. Allow the patient to relax for several minutes with the catheters inserted and positioned for the test. Allow as much time as necessary.

NOTE: The patient must remain as relaxed as possible throughout the procedure and should not move, talk, or cough during the withdrawal of the catheter.

4. Click **Resting** on the Control Panel to mark the start of the resting profile.
5. Click **Pull** on the Control Panel (Figure 182). The puller will slowly begin to remove the catheter at a set rate of 1mm/s.

NOTE: *Do not use the puller controls if manually withdrawing the catheter.* ***Withdraw the catheter very slowly****; it should take about 60seconds to go from 6cm to 0cm (1mm/s) or to when you can just observe the sensors. Do not completely remove the catheter from the body.*

6. Click the **Stop Pull** button to stop the puller when the sensors have passed the anal verge (Figure 182).
7. Click **Resting** again on the control panel to mark the end of the resting profile.

NOTE: The Resting Profile test should be performed at least twice to confirm a pressure pattern.

8. To perform a second resting profile, remove the catheter from the puller guides and manually re-insert the catheter to the initial starting position 6cm beyond the anal verge. Click **Return** on the control panel to setup the puller for the next profile (Figure 182).

IMPORTANT: The Puller must NOT be used for catheter reinsertion; doing so may result in injuries to the patient. Use the RETURN button on the control panel only to reposition the puller guide close to the tip of the puller.

9. Attach the distal (furthest) end of the catheter to the puller using the puller guides and repeat the above steps to perform a second resting profile.
10. Re-insert the catheter to proceed to the Squeezing Profile. If testing is complete, carefully remove the catheter.

9.8.3.3 SQUEEZING PROFILE

1. Insert the catheter and prepare a mechanical puller as described in the Pressure Profiles using Control Panel Buttons
2. Profiles Setup section on page 145.
3. Ask the patient to squeeze during the entire length of the catheter withdrawal.
4. Click **Squeezing** on the Control Panel to mark the start of the squeezing profile.
5. Click **Pull** on the Control Panel to start the pulling of the catheter (Figure 182).

NOTE: You do not need to use the puller controls if you are manually withdrawing the catheter.

6. Click Stop Pull to stop the puller when the sensors have passed the anal verge (Figure 182).
7. Click Squeezing on the Control Panel to mark the end of the test.

NOTE: The Squeezing Profile test should be performed at least twice to confirm a pressure pattern.

8. To perform a second squeezing profile, remove the catheter from the puller guides and manually re-insert the catheter to the initial starting position 6cm beyond the anal verge. Click **Return** on the control panel to setup the puller for the next profile (Figure 182).

IMPORTANT: The Puller must NOT be used for catheter reinsertion; doing so may result in injuries to the patient. Use the RETURN button on the control panel only to reposition the puller guide close to the tip of the puller.

9. Attach the distal (furthest) end of the catheter to the puller using the puller guides and repeat the above steps to perform a second resting profile.
10. Re-insert the catheter to proceed to the Squeezing Profile or Stationary Rest Profile. If testing is complete, carefully remove the catheter.

Refer to Figure 184 for sample data of a squeezing profile:

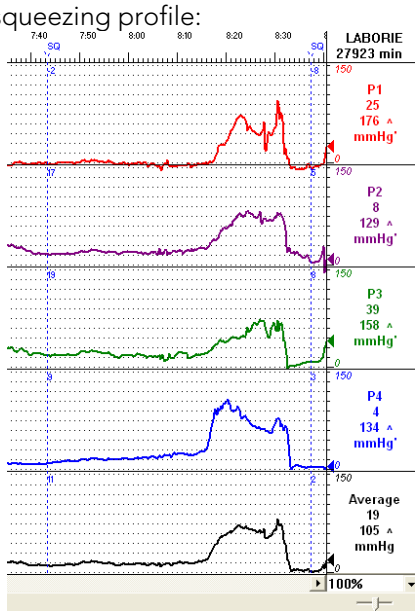


Figure 184: Sample data of a Squeezing Profile

9.8.3.4 PUSHING PROFILE

1. Insert the catheter and prepare a mechanical puller as described in the Pressure Profiles using Control Panel Buttons
2. Profiles Setup section on page 145.
3. Ask the patient to push during the entire length of the catheter withdrawal.
4. Click **Pushing** on the Control Panel to mark the start of the pushing profile.
5. Click **Pull** on the Control Panel; the puller will slowly begin to remove the catheter at a set rate of 1mm/s.

NOTE: Do not need to use the puller controls if manually withdrawing the catheter. **Withdraw the catheter very slowly**; it should take about 60seconds to go from 6cm to 0cm (1mm/s) or to when you can just observe the sensors. Do not completely remove the catheter from the body.

6. Click the **Stop Pull** button to stop the puller when the sensors have passed the anal verge.
7. Click **Pushing** again on the control panel to mark the end of the resting profile.

NOTE: The Pushing Profile test should be performed at least twice to confirm a pressure pattern.

8. To perform a second pushing profile, remove the catheter from the puller guides and manually re-insert the catheter to the initial starting position 6cm beyond the anal verge. Click **Return** on the control panel to setup the puller for the next profile.

IMPORTANT: The Puller must NOT be used for catheter reinsertion; doing so may result in injuries to the patient. Use the RETURN button on the control panel only to reposition the puller guide close to the tip of the puller.

9. Attach the distal (furthest) end of the catheter to the puller using the puller guides and repeat the above steps to perform a second resting profile.
10. Re-insert the catheter to proceed to the Squeezing Profile or Stationary Rest Profile. If testing is complete, carefully remove the catheter.

9.8.4 Pressure Profiles using Study Configuration

Refer to the figure below for Control Panel Buttons applicable to Rest, Squeeze, Push, Studies:

ARM	Patient Info	Zero All	Resting	Squeezing	Event	Run
5 cm Rest	4 cm Rest	3 cm Rest	2 cm Rest	1 cm Rest	Print	Save
5 cm Squeeze	4 cm Squeeze	3 cm Squeeze	2 cm Squeeze	1 cm Squeeze	10 cc	20 cc
30 cc	40 cc	50 cc	60 cc	70 cc	80 cc	90 cc
Expulsion	RAIR	First Sensation	Urge	Max Tolerance		Cough
Pull	Pull 1 cm	Stop Pull	Return			

Figure 185: ARM Control Panel – Study Buttons

9.8.4.1 Stationary Rest and Squeeze Study

The Stationary Rest and Squeeze Study are typically performed together; however, they can be performed as separate studies. Gently insert the well-lubricated catheter 6 *cm beyond the anal verge with Channel 1 (S1) in the appropriate and preferred dorsal position. Use the markings on the catheter as a guide.

Setup for Stationary Rest and Squeeze Study at 6 cm

To complete the studies at 5 cm, use the default buttons available. To start the Stationary Rest and Squeeze study at 6cm beyond the anal verge follow the steps below to configure control panel buttons before starting the test:

1. Click **Options** from the menu bar and select **Control Panel Definition.** The *Command* window will appear displaying the first row of **Control Panel** buttons.
2. Click the down arrow next to *Current Row* title and scroll down to a row that has blank button spaces. If needed add an entirely new row of buttons by changing the number in the box next to *Number of Rows*.
3. Create a button for **6 cm Rest**
   a. Under the *Label* column, type **6 cm Rest**.
   b. Under the *Definition* column type **SR6**.
   c. Click the dropdown menu on the third column and select **ARM**.
4. Locate another free button space to create a **6 cm Squeeze** button.
   a. Under the *Label* column type **6 cm Squeeze**.
   b. Under the *Definition* column, type **ST6**.
   c. Click the dropdown menu on the third column and select **ARM**.
5. Open the *Properties* window for each new button by clicking the PLUS (+) button .
6. Select *Automatically insert STOP event after* and enter a value in seconds. The default value is **10** seconds.
7. To add shading between start and stop events, select *show region for the ARM event,* and click the *Select Color* box to choose the color. Click **OK** to save changes and close the *ARM Event Properties* window (Figure 186).

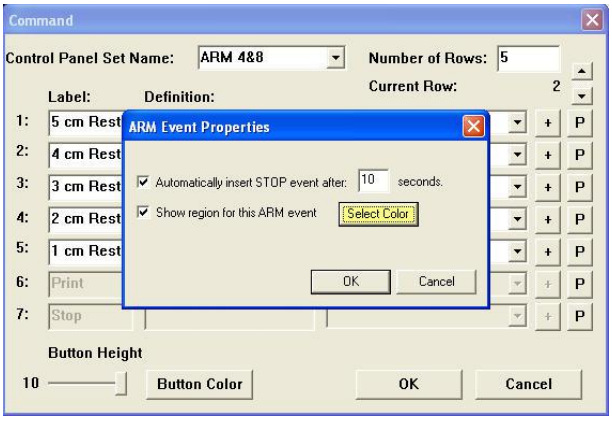


Figure 186: ARM Event Properties Window

8. Click **OK**. The two new control panel buttons will appear on the control panel.

Performing the Stationary Rest and Squeeze Study

1. Allow the patient to relax for several minutes, with the catheter inserted, in order to record true resting pressures.
2. Ask the patient to relax and click the **5 cm Rest** button to mark the start of the 5 cm resting period. If starting the test at 6 cm beyond the anal verge then click the **6 cm Rest** button instead. The control panel button will start flashing and a shaded area will scroll across the graph. After 10 seconds, the software will automatically mark the end of the resting period. The control panel button will no longer flash and the shading will stop.
3. Ask the patient to squeeze as hard as they can for 10 seconds. At the start of the squeeze click the **5 cm Squeeze** button, or the **6 cm Squeeze** button if starting at 6 cm beyond anal verge, and ask the patient to hold the squeeze for as long as the shading appears on the graph. After 10 seconds, the software will automatically mark the end of the squeeze period. The control panel button will no longer flash and the shading will stop. The patient should stop squeezing at this time.
4. Click the **Pull 1 cm** button on the control panel to withdraw the catheter 1 cm. Alternatively, manually pull the catheter out 1 cm. The catheter tip should now be 4 cm (or 5cm) from the anal verge.
5. Allow the patient to rest for at least 30 seconds before starting the next **Resting** segment.
6. Continue the testing by performing a **Rest** segment, a **Squeeze** segment, then withdrawing the catheter by 1 cm. Repeat this process, proceeding through the steps in 1 cm increments as programmed on the control panel. Complete a **Rest** segment and a **Squeeze** segment at 5cm (where applicable), 4 cm, 3 cm, 2cm, and 1 cm positions. Allow the patient to rest for at least 30 seconds after withdrawing the catheter per increment.
7. Once the Stationary Rest and Squeeze Study is complete, leave the catheter inserted to proceed to another ARM study (such as RAIR or Rectal Volume). The catheter will require repositioning depending on the next study performed. If testing is complete, carefully withdraw the catheter from the patient.

Refer to Figure 187 for sample data of a Stationary Rest and Squeeze Study. This example measures pressure beginning at 4cm from the anal verge. Alternating color patterns highlight the **Rest** segments and **Squeeze** segments.

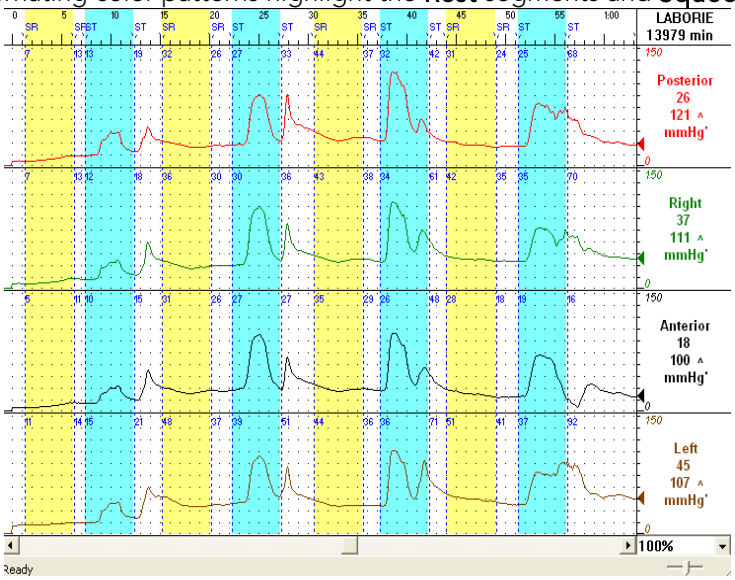


Figure 187: Stationary Rest and Squeeze - Sample Data

9.8.5 STATIONARY REST, SQUEEZE, PUSH STUDY

Gently insert the well-lubricated catheter 6 *cm beyond the anal verge with Channel 1 (S1) in the appropriate and preferred dorsal position. Use the markings on the catheter as a guide.

Setup for Stationary Rest and Squeeze Study at 6 cm

To complete the study at 5 cm, use the default buttons available. To start the Stationary Rest, Squeeze, Push Study at 6cm beyond the anal verge follow the steps provided below before starting the test:

1. Click **Options** from the menu bar and select **Control Panel Definition.** The *Command* window will appear displaying the first row of **Control Panel** buttons.
2. Click the down arrow next to *Current Row* and scroll down to a row that has blank button spaces. If required, add an entirely new row of buttons by changing the number in the box next to *Number of Rows*.
3. Create a button for **6 cm Rest**.
    a. Under the *Label* column, type **6 cm Rest**.
    b. Under the *Definition* column type **SR6**.
    c. Click the pull down arrow on the third column and select **ARM**.
4. Locate another free button and create a **6 cm Squeeze** button.
    a. Under the *Label* column type **6 cm Squeeze**.
    b. Under the *Definition* column, type **ST6**.
    c. Click the pull down arrow on the third column and select **ARM**.
5. Locate another free button and create a **6 cm Push** button.
    a. Under the *Label* column type **6 cm Push**.
    b. Under the *Definition* column, type **ST6**.
    c. Click the pull down arrow on the third column and select **ARM**
6. Open the ***Properties*** window for each button by clicking the PLUS (+) button.
7. Select *Automatically insert STOP event after* and enter a value in seconds. The default value is 10 seconds.
8. To add shading between the start and stop events, select *show region for the ARM event,* and click the *Select Color* box to choose the color (Figure 186). Click **OK** to save changes.
9. Click **OK**. The two new control panel buttons will appear on the control panel (Figure 188).

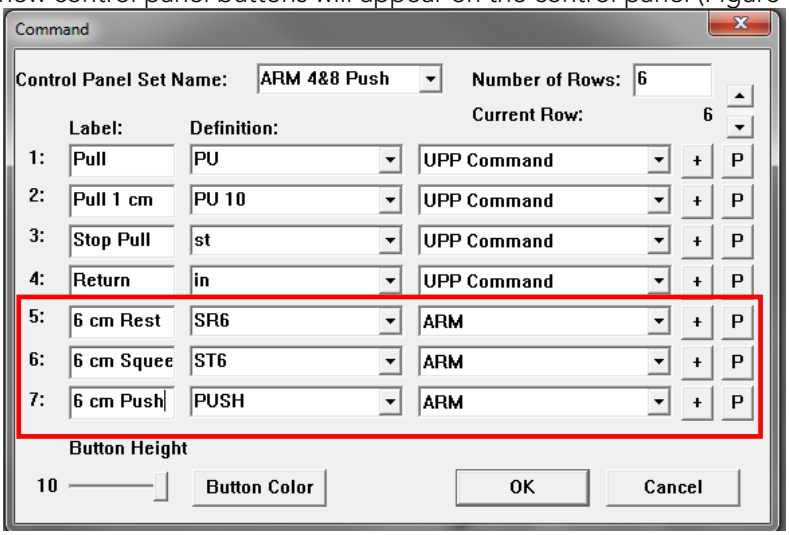


Figure 188: Command Window – Rest, Squeeze, and Push Events

Running the Stationary Rest, Squeeze, Push Study

1. Allow the patient to relax for several minutes, with the catheter inserted, in order to record true resting pressures.
2. Ask the patient to relax and click the **5 cm Rest** button to mark the start of the 5 cm resting period. If starting the test at 6 cm beyond the anal verge, then start with the **6 cm Rest** button instead. The control panel button will start flashing and a shaded area will scroll across the graph. After 10 seconds, the software will automatically mark the end of the resting period. The control panel button will no longer flash and the shading will stop.
3. Ask the patient to squeeze as hard as they can for 10 seconds. At the start of the squeeze click the **5 cm Squeeze** button, or **6 cm Squeeze** if starting at 6 cm beyond anal verge, and ask the patient to hold the squeeze for as long as the shading appears on the graph. After 10 seconds, the software will automatically mark the end of the squeeze period. The control panel button will no longer flash and the shading will stop. The patient should stop squeezing at this time.

4. Ask the patient to push to mimic an attempt to defecate. At the start of the push click the **5 cm Push** button or **6 cm Push** if starting at 6 cm beyond anal verge. The software will automatically mark the end of the push period. The control panel button will no longer flash and the shading will stop. The patient should stop pushing at this time.
5. Click the **Pull 1 cm** button on the control panel to withdraw the catheter 1 cm. Alternatively, manually withdraw the catheter out 1 cm. The catheter tip should now be 4 cm (or 5cm) from the anal verge.
6. Allow the patient to rest for at least 30 seconds.
7. Continue the testing by performing a **Rest** segment, a **Squeeze** segment, a **Push** segment, then withdrawing the catheter by 1 cm. Repeat this process, proceeding through the steps in 1 cm increments as programmed on the control panel. Complete a **Rest** segment, a **Squeeze** segment, and a **Push** segment at 5cm (where applicable), 4 cm, 3 cm, 2cm, and 1 cm positions. Allow the patient to rest for at least 30 seconds after withdrawing the catheter per increment.
8. Once the Stationary Rest, Squeeze, Push study is complete, leave the catheter inserted if proceeding to another study (such as RAIR or Rectal Volume). The required catheter position will depend upon the next test performed. If ARM testing is complete, carefully withdraw the catheter from the patient.

Refer to Figure 189 for Sample data of a Stationary Rest, Squeeze, Push Study:

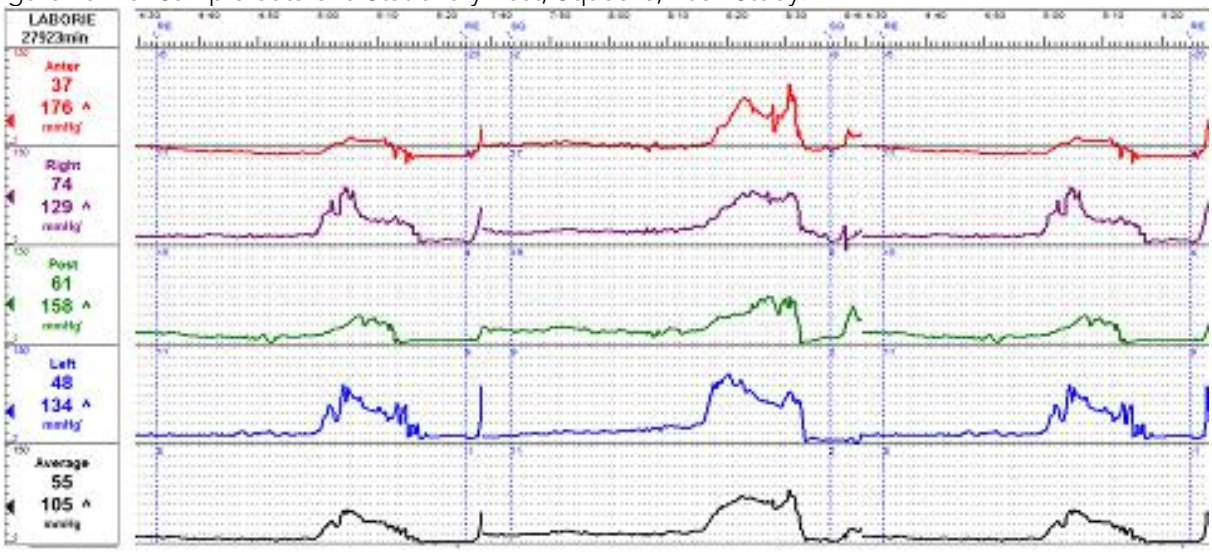


Figure 189: Sample data of a Stationary Rest, Squeeze, and Push Study.

9.8.6 Filling and Expusion Studies

Refer to Figure 190 for buttons used during the RAIR, Volume, and Expulsion studies.

ARM	Patient Info	Zero All	Resting	Squeezing	Event	Run
5 cm Rest	4 cm Rest	3 cm Rest	2 cm Rest	1 cm Rest	Print	Save
5 cm Squeeze	4 cm Squeeze	3 cm Squeeze	2 cm Squeeze	1 cm Squeeze	10 cc	20 cc
30 cc	40 cc	50 cc	60 cc	70 cc	80 cc	90 cc
Expulsion	RAIR	First Sensation	Urge	Max Tolerance		Cough
Pull	Pull 1 cm	Stop Pull	Return			

Figure 190: ARM Control Panel – RAIR, Volume, and Expulsion Buttons

9.8.6.1 RAIR (Rectoanal Inhibitory Reflex)

There are two different techniques to perform the RAIR study using the software's control panel functions.

RAIR Setup

1. Connect a 60 cc air-filled syringe to the ARM catheter's filling port.

NOTE: The balloon must be completely empty upon insertion

2. Gently insert a well-lubricated catheter into the patient. The catheter should be inserted to the point of highest resting pressure [HPZ] as previously recorded, or at approximately 3 cm. For example, if the HPZ was recorded at 2 cm, then place the catheter to the 2 cm marker.

RAIR - Technique #1:

1. Once Setup is complete, click the **10 cc** button on the control panel to mark the start of the event.
2. Inject 10 cc of air into the balloon and withdraw the 10 cc of air immediately. **NOTE:** The air should be withdrawn within 5 seconds of being introduced.
3. Click **10 cc** again to mark the event stop. A popup *window* will appear, select whether RAIR is present or absent from the dropdown menu (Figure 191).

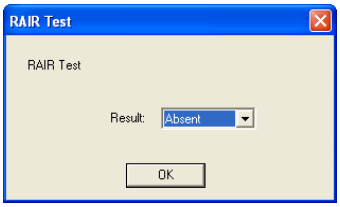


Figure 191: RAIR Absent or Present

4. If RAIR is not present, repeat these steps using greater increments of air such as 20cc, 30cc, and so on.
5. Leave the catheter in if proceeding to Rectal Volume testing. Alternatively, carefully remove the catheter if testing is complete.

Refer to figure x below for sample results of a RAIR study:

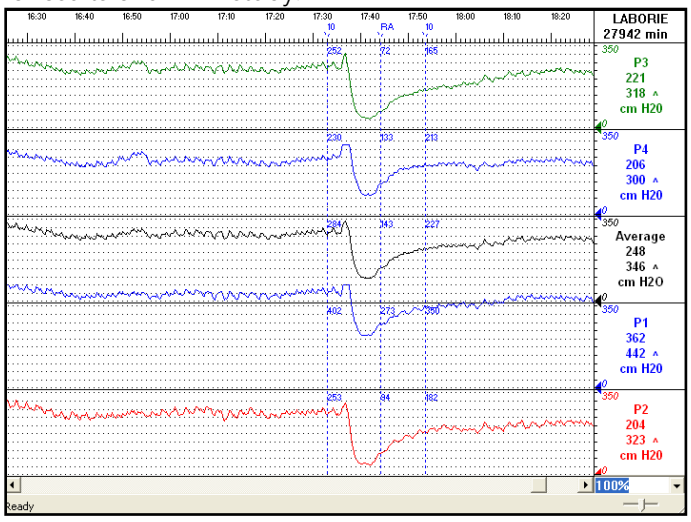


Figure 192: Sample results for a RAIR Study

RAIR - Technique #2:

1. Once setup is complete, click **RAIR** on the **control panel** to launch the *RAIR Test* window.
2. Select the volume at which the test will be performed from the *RAIR Test* window ().

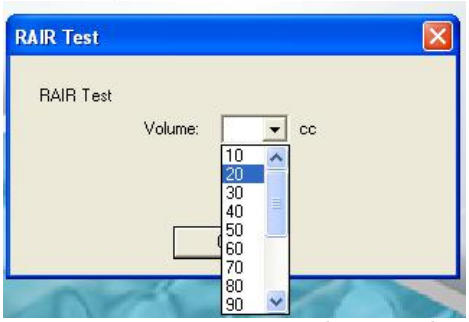


Figure 193: RAIR Test Window – Volume

3. Inject 10 cc of air into the balloon and withdraw the 10 cc of air immediately.

NOTE: The air should be withdrawn within 5 seconds of being introduced.

4. Click **RAIR** again to mark the stop event. A popup *win*dow will appear, select whether RAIR is present or absent from the dropdown menu (Figure 191).
5. If RAIR is not present, repeat these steps using greater increments of air such as 20cc, 30cc, and so on.
6. Leave the catheter inserted if proceeding to Rectal Volume testing. Alternatively, carefully remove the catheter if testing is complete.

RAIR Study Sample

Refer to Figure 194 below for sample results of a RAIR study:

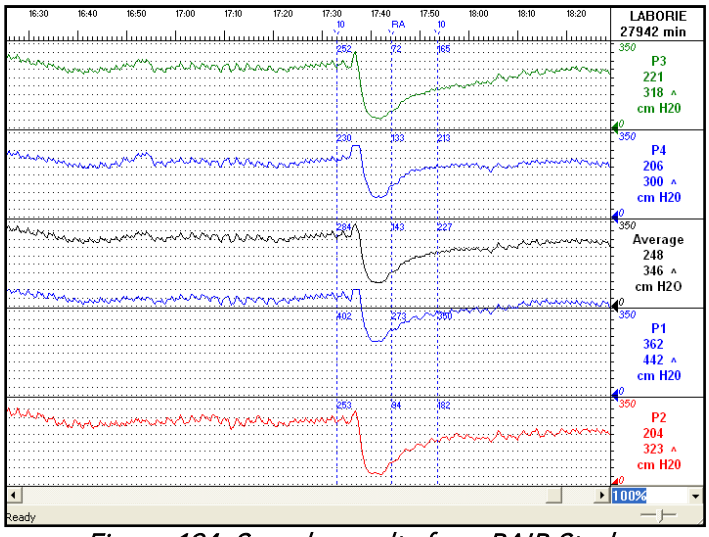


Figure 194: Sample results for a RAIR Study

9.8.6.2 RECTAL VOLUME USING FLUID AND A SYRINGE

If filling the rectal balloon manually with a syringe, use the software sensation buttons to prompt input of volumes observed at each sensation. Sensations include first sensation, urge, and max tolerance volumes.

Anorectal Summary - Volumes

1. Fill a 60cc Luer lock syringe with lukewarm water and attach it to the catheter's filling port.
2. Gently insert a well-lubricated catheter into the patient. The catheter should be inserted well beyond the anal verge (approximately 6 cm beyond the anus) where the area of highest pressure was previously recorded. The balloon will be positioned inside the rectum.

NOTE: The catheter should have a balloon fastened at the tip; the balloon must be completely empty upon insertion.

3. Gradually fill the rectal balloon with fluid.

NOTE: *If you release your grip on the syringe plunger, some of the infused fluid will go back into the syringe. Please keep a careful note of the volume within the syringe.*

4. When the patient feels the first sensation of fullness, click **First Sensation** on the control panel and then enter the infused volume when prompted.
5. Continue gradually filling the rectal balloon.
6. When the patient feels an urge, click **Urge** on the control panel and then enter the infused volume when prompted.
7. Continue gradually filling the rectal balloon
8. When the patient states they cannot hold any more, stop the pump and click **Max Tolerance** on the Control Panel and then enter the infused volume when prompted.
9. Leave the catheter in if proceeding to the Expulsion study. If proceeding to the Expulsion Testing, do not deflate the balloon, Turn the stopcock to the OFF position to prepare for Expulsion Testing. Alternatively, if testing is complete draw back on the syringe to empty the balloon then carefully withdraw the catheter from the patient.

Rectal Volume using Fluid and the Integrated LABORIE Pump

1. Setup the Pump Tubing with an IV bag of room temperature water. Connect the pump tubing to the catheter's filling port.
2. Gently insert a well-lubricated catheter into the patient. The catheter should be inserted so the rectal balloon is in the rectum. The catheter should be inserted well beyond the anal verge (approximately 6 cm beyond the anus) where the area of highest pressure was previously recorded. The balloon will be positioned inside the rectum.

NOTE: The catheter should have a balloon fastened at the tip; the balloon must be completely empty upon insertion.

3. Use the software controls to run the pump.
4. Gradually fill rectal balloon with fluid.
5. When the patient feels the first sensation of fullness, click **First Sensation** on the control panel.
6. Continue gradually filling the rectal balloon.
7. When the patient feels an urge, click **Urge** on the control panel.
8. Continue gradually filling the rectal balloon
9. When the patient states they cannot hold any more, stop the pump and click **Max Tolerance** on the Control Panel.
10. Leave the catheter inserted if proceeding to the Expulsion study. If proceeding to the Expulsion Testing, do not deflate the balloon. Turn the stopcock to the OFF position. Alternatively, if testing is complete use the reversible pump feature to remove fluid from the rectal balloon then carefully withdraw the catheter from the patient.

9.8.6.3 EXPULSION TEST

NOTE: *Position the patient in the left lateral decubitus position or move to a seated position over a commode chair to expel balloon.*

1. If the catheter balloon has not already been filled during Rectal Sensation testing, then fill the rectal balloon using a syringe to a standardized volume for the expulsion test (50mL recommended).
2. Click **Expulsion** to start the test.
3. Ensure that the patient is comfortable and then ask the patient to expel the balloon.
4. After approximately 1 minute, click on **Expulsion** again to end the test.
5. Enter the result, whether the patient expelled the balloon or not, and what fluid volume was used.

NOTE: If the VH2O channel is not specified in the test's Configuration file, enter the volume and response in the resulting message box. If the VH2O channel is added and specified in the test's Configuration file, the volume will be automatically read from the specified VH2O channel and the response will be displayed in the resulting message box.

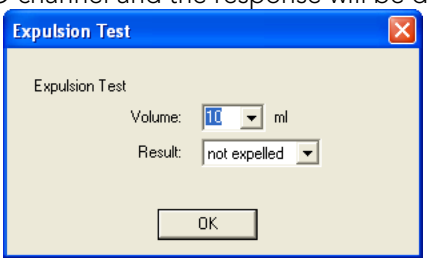


Figure 195: Expulsion Test Window – Volume and Result

6. If patient did not expel the balloon, remove some volume from the catheter and have patient try again to expel the balloon. Testing will end when the catheter is expelled. If the patient is unable to expel the balloon even when all the volume is removed, carefully withdraw the catheter.

9.9 ARM 4 AND ARM 8 CHANNEL TEST RESULTS

Once a test is performed, view the results for interpretation, analysis, and printing. The following summaries are available for ARM4 and ARM8:

Anorectal Summary	This summary provides a summary of all Anorectal Manometry tests performed Utilize this summary to preview and select data prior to report generation.
ARM Resting Profile	Summary of pressure data for one resting profile. Also contains summary of pushing data. 3D profile generation.
ARM Squeezing Profile	Summary of pressure data for one squeezing profile. 3D profile generation.
ARM Stationary Rest (1)	Summary of pressure data for each stationary rest position (6 cm, 5 cm, 4 cm, 3cm, 2 cm, and 1 cm). Refers to the first set of stationary rest pressure data.
ARM Stationary Rest (2)	Summary of pressure data for each stationary rest position (6 cm, 5 cm, 4 cm, 3cm, 2 cm, and 1 cm). Refers to the first set of rest pressure data and allows user to view two positions simultaneously.
ARM Stationary Squeeze (1)	Summary of pressure data for each stationary squeeze position (6 cm, 5 cm, 4 cm, 3cm, 2 cm, and 1 cm). Refers to the first set of stationary squeeze pressure data.
ARM Stationary Squeeze (2)	Summary of pressure data for each stationary squeeze position (6 cm, 5 cm, 4 cm, 3cm, 2 cm, and 1 cm). Refers to the first set of squeeze pressure data and allows user to view two positions simultaneously.
ARM Push Profile	Summary of pressure data for one pushing profile. 3D profile generation.

Table 32: ARM 4 and ARM 8 Test Result Summaries

9.9.1 ANORECTAL SUMMARY

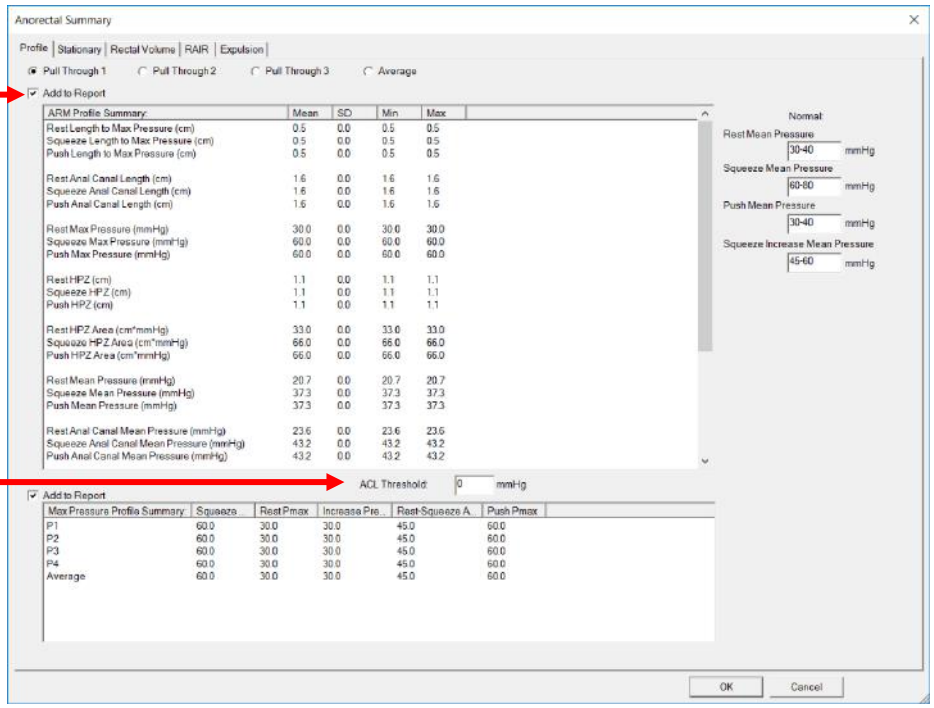
To access the *Anorectal Summary* window:

1. Click **Info** > **ARM 4 & 8**.
2. Select **Anorectal Summary**. The *Anorectal Summary* window will appear.

9.9.1.1 PROFILE TAB

Select the *Add to Report* box to add that section's data to the final report (and will also be transferred to *i-LIST™ Office Reporter*.

Enter the **Threshold** value. Default value is 0 (zero).



ARM Profile Summary

- **Rest / Squeeze Length to Max Pressure (cm):** Distance in centimeters from position of start of test until max pressure is reached.
- **Rest / Squeeze Anal Canal Length (cm):** Total length in centimeters of anal canal (the total distance between start and stop of test).
- **Rest / Squeeze Max Pressure (mmHg):** Maximum rest and squeeze pressures (mean, min, max, etc) in mmHg.
- **Rest / Squeeze HPZ (High Pressure Zone):** Sphincter length in centimeters where the pressure is greater than the (***Max Pressure*2/3***) of the segment.
- **Rest / Squeeze HPZ (High Pressure Zone) Area:** The sum of the area underneath the pressure curve where the pressure is greater than the (***Max Pressure*2/3***) of the segment (the Area of the HPZ is calculated in cm*mmHg).
- **Mean Pressure** = Average pressure in entire high-pressure zone (from START to STOP).
- **Anal Canal Length:** Length of anal canal in centimeters.
- **Anal Canal Mean Pressure**: Average Pressure in the Anal Canal Length zone.
- **Anal Canal Area**: Anal Canal Mean Pressure multiplied by the Anal Canal Length (Area in the Anal Canal Length zone)

NOTE: NOTE REGARDING CALCULATIONS:

The *Mean* value is the total sum of the calculated values of each channel divided by the number of channels used in the test.

- Formula: $\text{Mean} = \text{SUM}\ (Y_n) \div \text{Total number of channels used in test}$

Where: Y_n is the calculated value of the channel; *n* represents the channel number (which can be from 1 to 8).

The *SD* (standard deviation) is the square root of the sum of the calculated value of each channel minus the mean value, squared, and then divided by the total number of channels minus 1.

- Formula : $\text{SD} = \sqrt{\frac{\text{SUM}\ (Y_n - \text{Mean})^2}{(\text{total number of channels used in test} - 1)}}$

Where: Y_n is the calculated value of the channel; *n* represents the channel number (which can be from 1 to 8); and *Mean* is the value from the *Mean* column.

9.9.1.2 STATIONARY TAB

Refer to the Figure 196 below for a visual of the *Stationary Tab* in the *Anorectal Summary* window. The *Stationary Summary Circle Diagram*, *Pressure Variation*, *Stationary Resting Summary*, *Stationary Squeezing Summary*, and *Stationary Pushing Summary* options are available from the Stationary Tab.

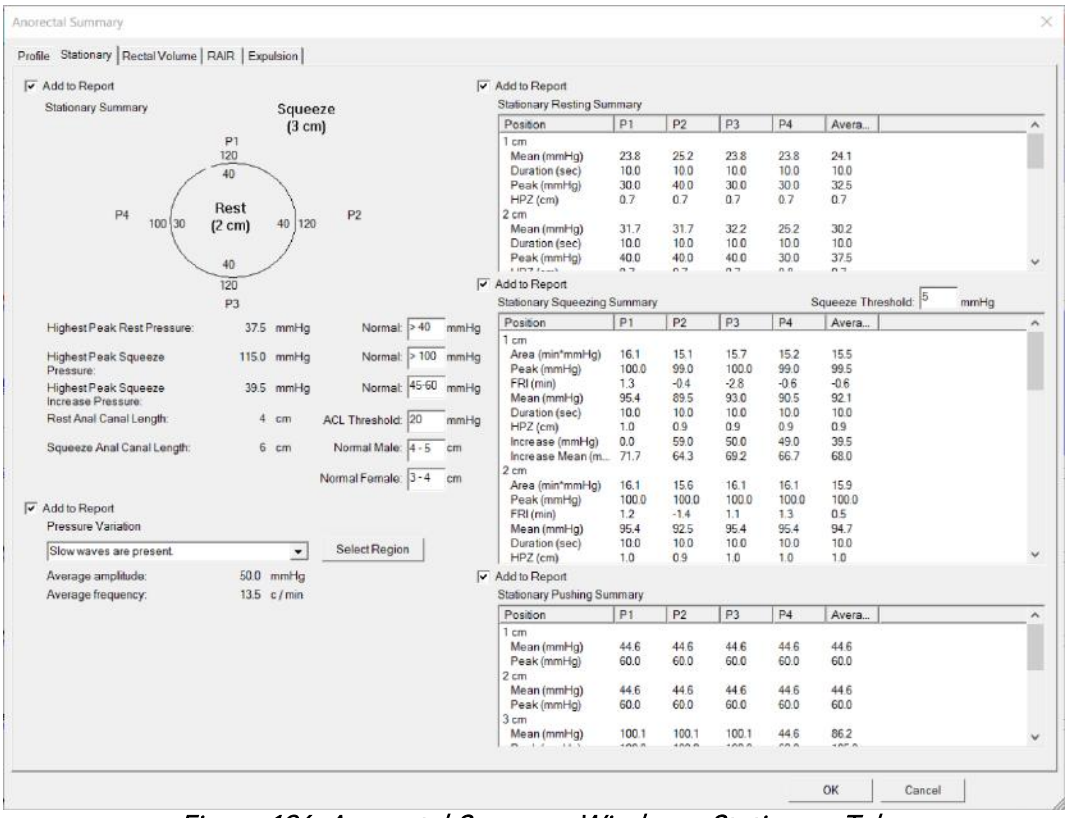


Figure 196: Anorectal Summary Window – Stationary Tab

Stationary Summary Circle Diagram:

- Outside Circle Values: Maximum Squeeze values at that position (mmHg).
- Inside Circle Values: Maximum Rest values at that position (mmHg).
- Highest Peak Rest Pressure: Maximum value in average channel for Peak Resting pressure.
- Highest Peak Squeeze Pressure: Maximum value in average channel for Peak Squeeze pressure.
- Highest Peak Squeeze Increase Pressure: Maximum value in average channel for Peak Increase pressure.
- Rest Anal Canal Length (cm): Displays the length of the anal canal. If the value at the start of the measurement is greater than the ACL Threshold then then 1 cm is added to the Rest Anal Canal Length.
- Squeeze Anal Canal Length (cm): Displays the length of the anal canal. If the value at the start of the measurement is greater than the ACL Threshold then then 1 cm is added to the Squeeze Anal Canal Length.

Pressure Variation:

- Pressure Variation dropdown: detects the presence or calculates the values associated with slow and ultra-slow waves. The dropdon menu provides various status options for the presence of slow and ultra-slow waves. Click the Select Region button and select the region on the graph where slow waves exist.
- Average Amplitude: The average pressure value in mmHg of the selected region.
- Average Frequency: The frequency in cycles/min of the pressure waves.

Stationary Resting Summary:

Displays all values relevant to Rest data dependent on position and specific sensor/lumen.

- Rest Mean Pressure: Average pressure during the Stationary Resting period.
- Rest Duration: Total time from Start to Stop of the Stationary Resting period.
- Rest HPZ (High Pressure Zone): The sum of the area underneath the pressure curve where the pressure is greater than the (***Max Pressure*2/3***) of the segment during the Stationary Resting period.
- Rest Peak: Peak pressure of the Stationary Resting period

Stationary Squeezing Summary:

Displays all values relevant to Squeeze data dependent on position and specific sensor/lumen.

- **Area:** Total area underneath the curve in min*mmHg.
- **Peak:** Maximum squeeze pressure in mmHg.
- **FRI (Fatigue Rate Index):** Value in minutes used to correlate to the fatigue rate of the sphincter. Calculated as the difference between max squeeze and max resting pressure (mmHg) divided by the slope of a line of best fit of the squeeze curve (mmHg / min).

Stationary Pushing Summary:

Displays all values relevant to Pushing data dependent on position and specific sensor/lumen.

- **Push Mean Pressure:** Average pressure during the Stationary Pushing period.
- **Push Peak:** Peak pressure of the Stationary Pushing period

9.9.1.3 RECTAL VOLUME TAB

Refer to the Figure 197 below for a visual of the *Stationary Tab* in the *Anorectal Summary* window.

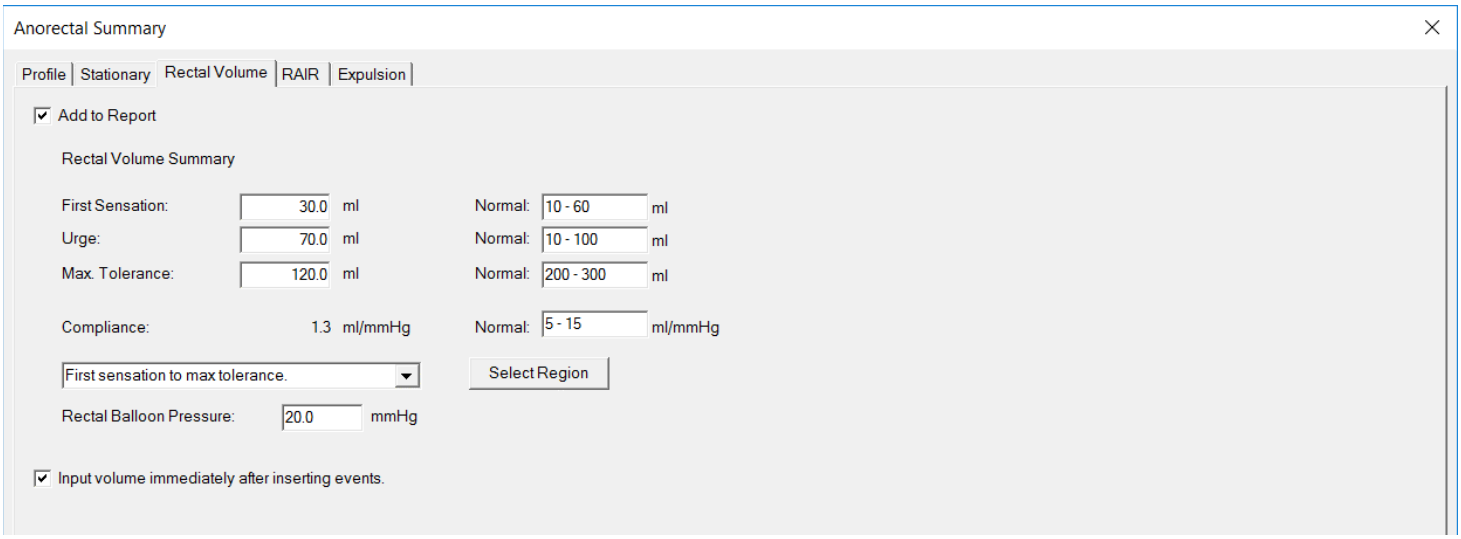


Figure 197: Anorectal Summary – Rectal Volume Tab

Select the *Add to Report* box to add that section's data to the final report. The data will also be transferred to *i-LIST™ Office Reporter* where applicable.

The following data options are found in the *Rectal Volume Tab:*

- **First Sensation:** The value in ml where the patient first felt rectal distention.
- **Urge:** The value in ml where the patient first felt the urge to defecate.
- **Max Tolerance:** The value in ml where the patient felt they could not tolerate further rectal distention.
- Compliance: (ONLY possible when Rectum Pressure is measured and is only available on select systems; to activate this, first map the "rectal pressure" row in the channel mapping section). Compliance, in mmHg, is the average change in pressure (mmHg)) as a result of a change in volume (ml) from first sensation to max tolerance. NOTE: compliance measurements are not possible with T-DOC air-charged catheters.

9.9.1.4 RAIR TAB

Refer to the Figure 198 below for a visual of the *Stationary Tab* in the *Anorectal Summary* window.

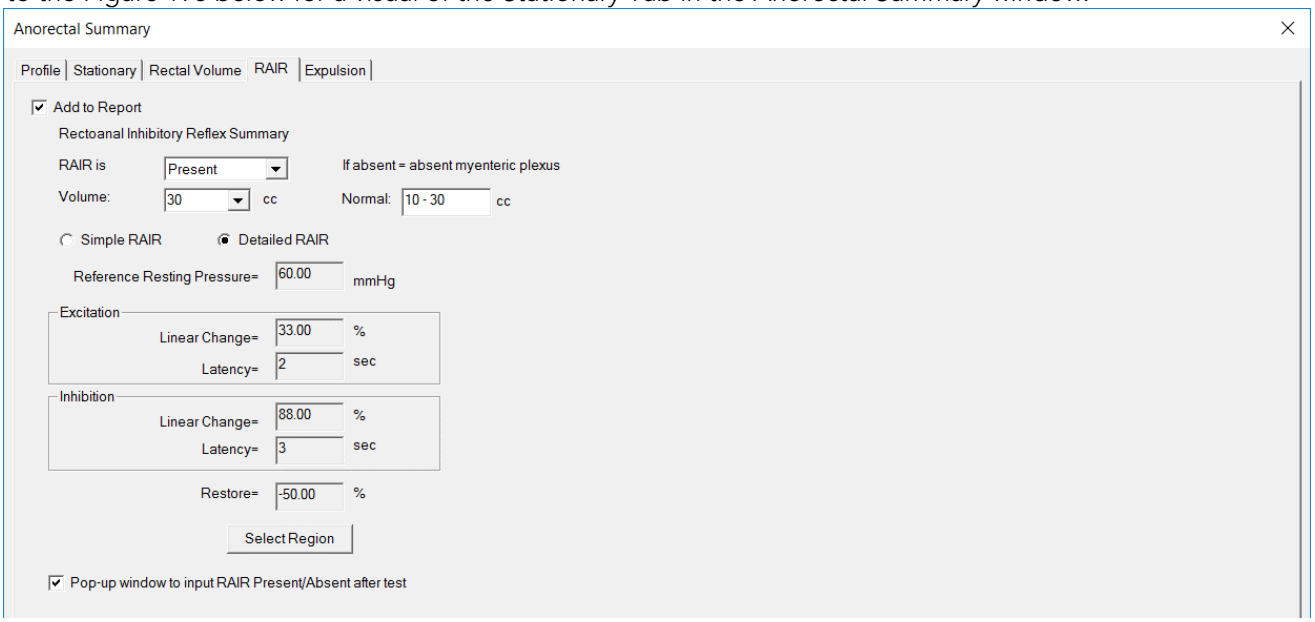


Figure 198: Anorectal Summary Window - RAIR Tab

The *Rectoanal Inhibitory Reflex Summary*, *Simple vs. Detailed RAIR*, *Excitation*, and *Inhibition* options are available in the *RAIR Tab*.

Select the *Add to Report* box to RAIR data to the final report. The data will also be transferred to *i-LIST™ Office Reporter* where applicable.

Rectoanal Inhibitory Reflex Summary

- **RAIR:** allows user to select whether RAIR is present or absent at given volume.
- **Volume:** Allows user to select which RAIR test to view and print with report.

Simple vs. Detailed RAIR:

- **Simple RAIR:** RAIR test used to only detect whether RAIR is present or absent.
- **Detailed RAIR:** Includes simple RAIR with the detailed data below.
- **Reference Resting Pressure:** Pressure in mmHg at which the RAIR test starts.

Excitation:

- **Linear Change:** Increase in Pressure in % (based on using the Reference Resting Pressure as 100%) during the initial rise in pressure associated with RAIR test.
- **Latency:** Time taken for the excitation response to occur post event initiation.

Inhibition:

- **Linear Change:** Decrease in Pressure in % (based on using the Reference Resting Pressure as 100%) during the main drop or pressure inhibition associated with RAIR test.
- **Latency:** Time taken for the inhibition response to occur post event initiation.

Pop-up window to input RAIR Present/Absent after test: Select whether the RAIR Present/Absent pop-up window is displayed after a test.

9.9.1.5 EXPULSION TAB

Refer to the Figure 198 below for a visual of the *Stationary Tab* in the *Anorectal Summary* window.

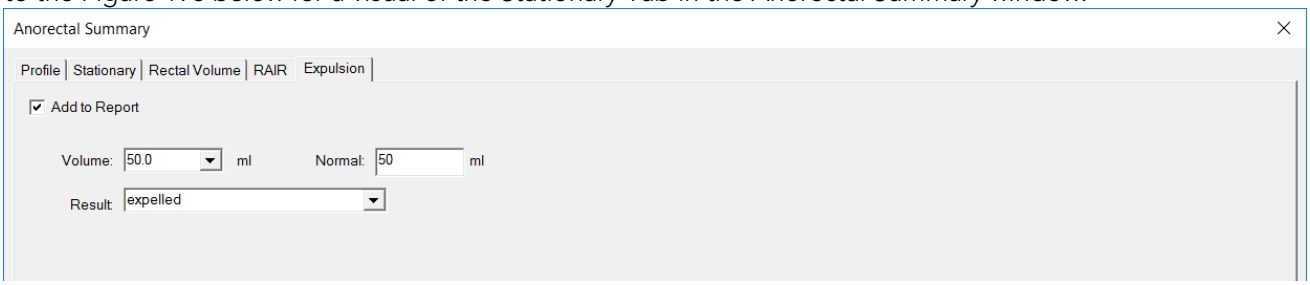


Figure 199: Anorectal Summary – Expulsion Tab

The following features are available in the *Expulsion Tab*:

- **Volume:** Select the catheter volume, in ml, at which the expulsion test was performed.
- **Result:** Select whether the balloon was expelled or not expelled by the patient.

Select the *Add to Report* box to add that section's data to the final report (and will also be transferred to *i-LIST™ Office Reporter*.

9.9.2 ARM RESTING, SQUEEZING, OR PUSHING PRESSURE PROFILE SUMMARIES

1. Click **Info** > **ARM 4&8**.
2. Select **Resting Profile**, **Squeezing Profile**, or **Pushing Profile**. The corresponding ARM profile window will display the pressure summary only.

NOTE:

In the following diagrams:
1 = Buttons to close the window or print the summary.
2 = Summary of the pressure profile. For resting profile, each pressure displayed is the pressure average over 5 mm; for squeezing and pushing profile, display of pressure summary for each position.
3 = Average pressure curve.

NOTE: For information on activating 3D plot imaging, contact your LABORIE representative.

a. The ARM Resting Profile example displays a pressure summary for the first resting profile. To view results for a second profile, open the Events Summary (**Info** > **Events Summary**) and delete the events marking the first profile. Refer to *ARM Stationary Resting Profile Summary* window in Figure 200.

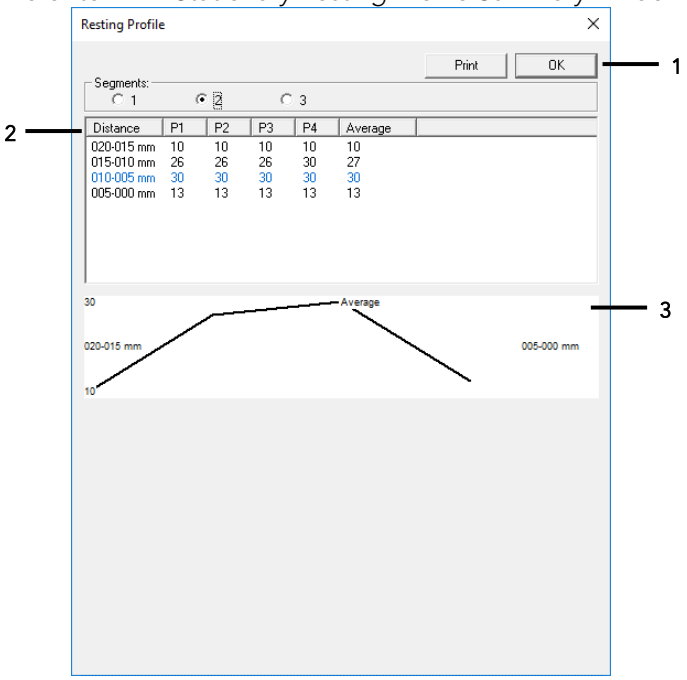


Figure 200: ARM Resting Profile 4 channel ARM Example

b. Refer to *ARM Stationary Squeeze Profile Summary* window in Figure 201.

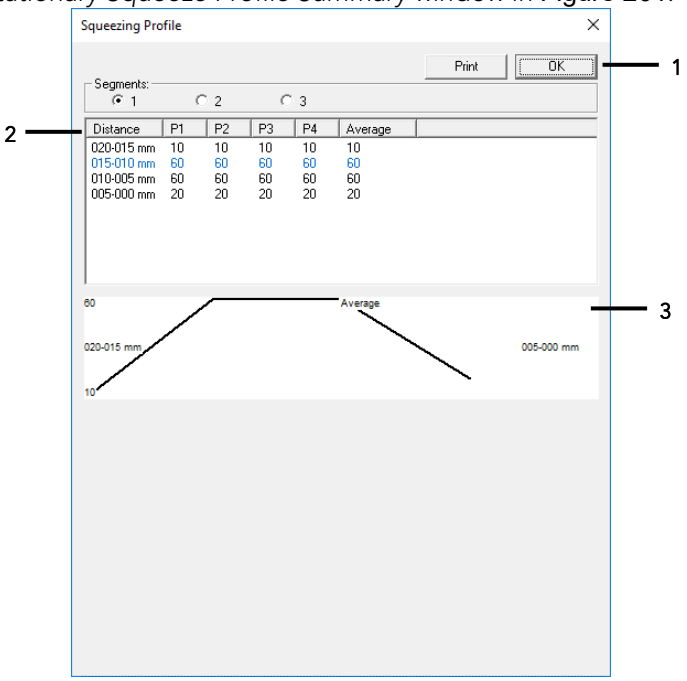


Figure 201: ARM Squeezing Profile Example

c. Refer to *ARM Stationary Pushing Profile Summary* window in Figure 202.

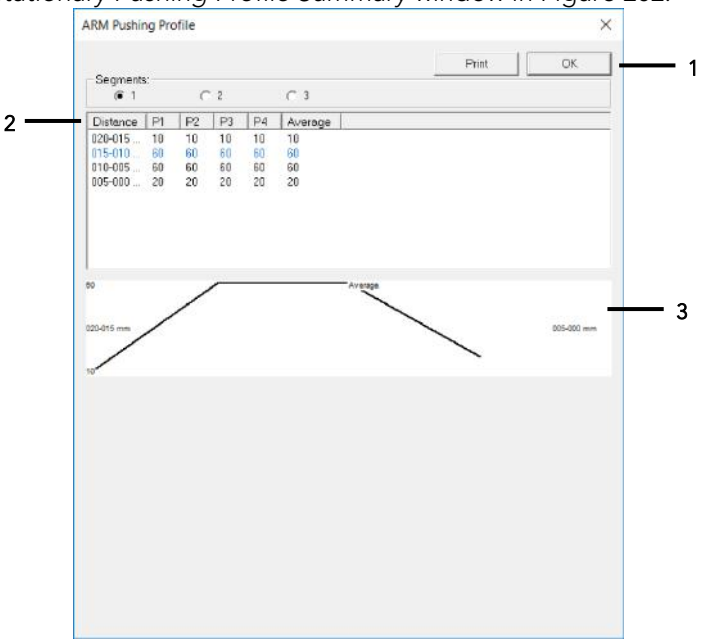


Figure 202: ARM Pushing Profile Example

9.9.3 ARM Stationary Resting, Squeezing, or Pushing Summaries

3. Click **Info** > **ARM 4&8**.
4. Select **ARM Stationary Rest**, **ARM Stationary Squeeze**, **or ARM Stationary Push**. The corresponding ARM profile window will display the summary.

NOTE:

In the following diagrams:
1 = Buttons to close the window or print the summary.
2 = Summary of the pressure profile. Entries are divided by seconds and display a pressure summary for each position.
3 = Average pressure curve.

NOTE: For information on activating 3D plot imaging, contact your LABORIE representative.

a. Refer to *ARM Stationary Rest Summary* Window in Figure 203.

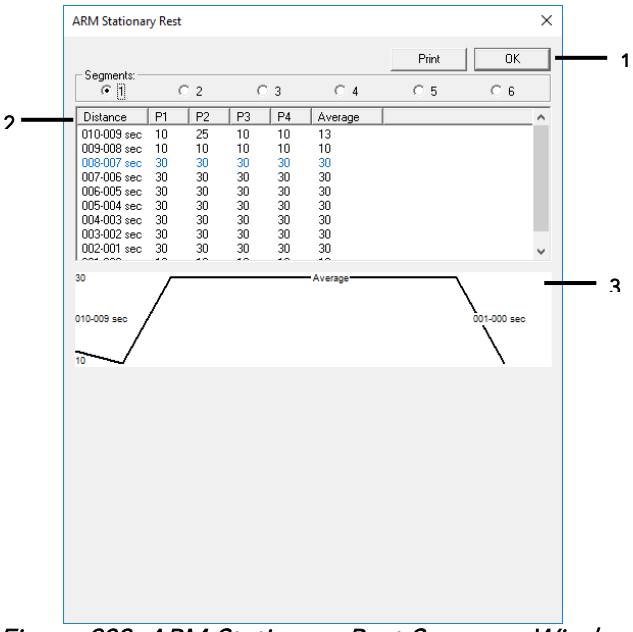


Figure 203: ARM Stationary Rest Summary Window

b. Refer to *ARM Stationary Squeeze Summary* window in Figure 204.

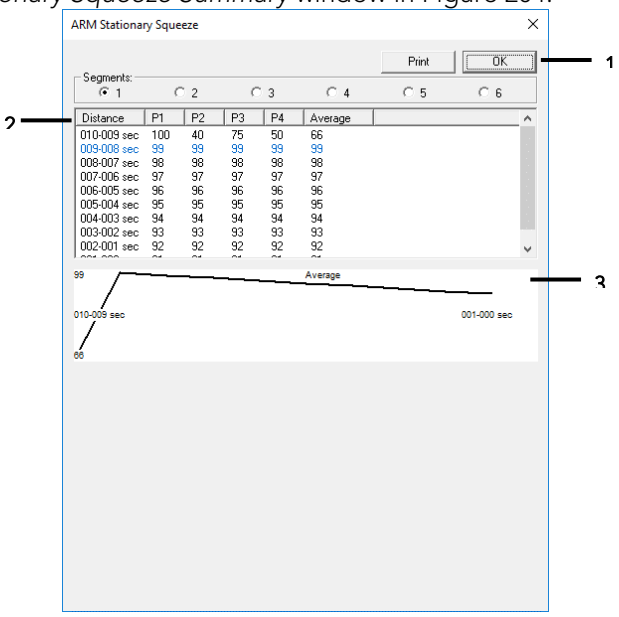


Figure 204: ARM Stationary Squeeze Summary Window

c. Refer to *ARM Stationary Push Summary* window in Figure 205.

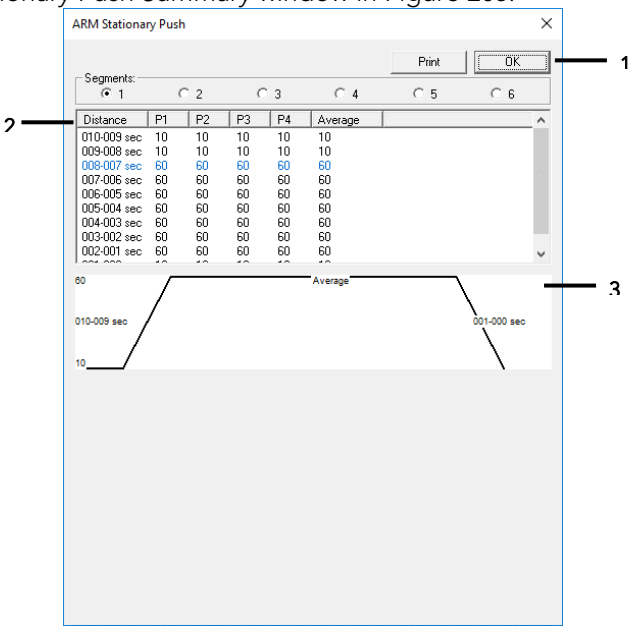


Figure 205: ARM Stationary Push Summary *Window*

9.10 PRINTING ARM TEST RESULTS

9.10.1 PRINTING TEST RESULTS THROUGH THE UDS SOFTWARE

Ensure that a test file is open in the UDS software. By default, if you have performed a specific test, such as RAIR, the software will suggest printing the associated *RAIR Summary*. If you have not performed a certain test, the associated print option will be inaccessible.

To access the UDS Software *Print Options* window, click **File** > **Print**. The **Print Options** dialog box will appear. Refer to the following figure (Figure 206). Select the summaries for inclusion in the printout and click **OK**.

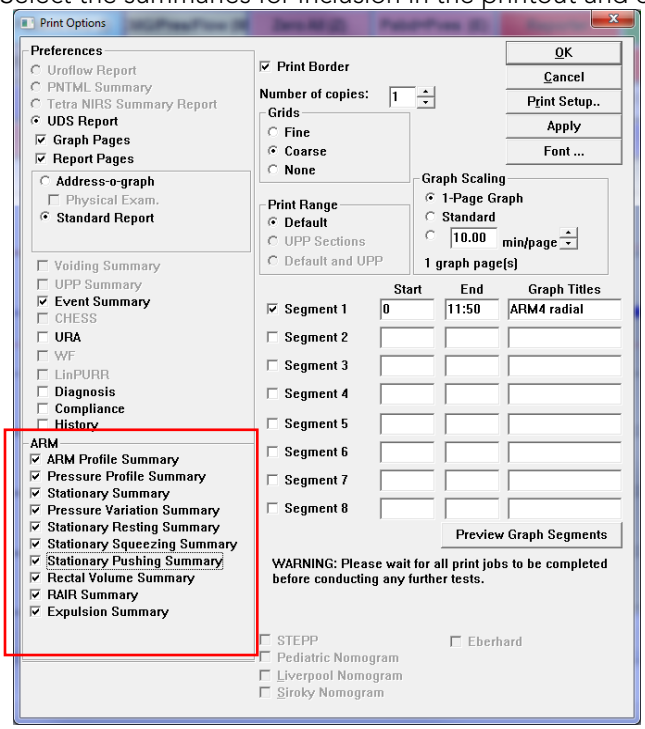
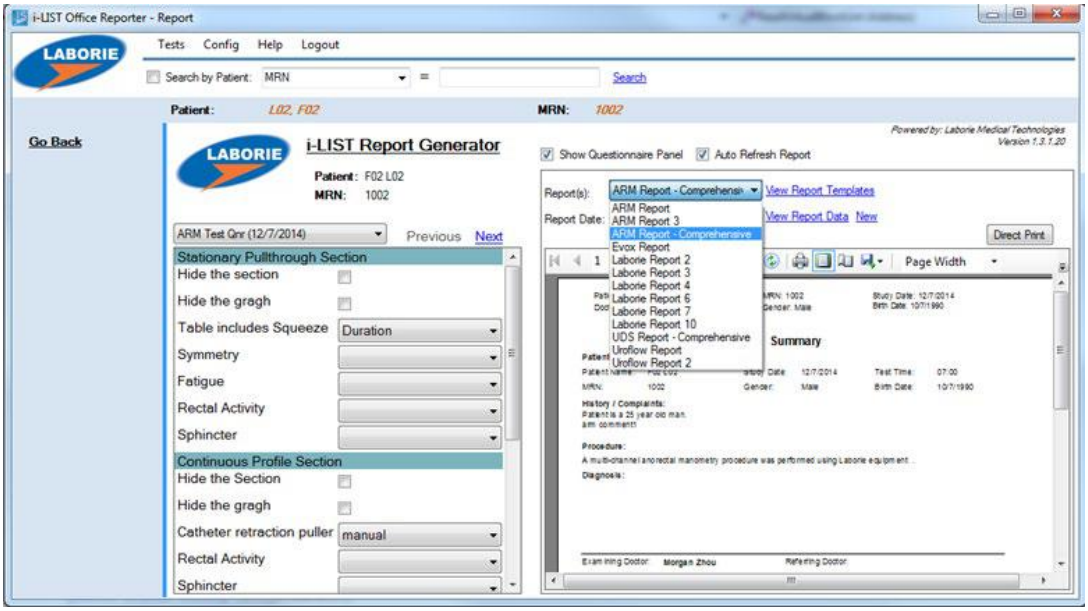


Figure 206: Print Options Window – ARM Section

For an overview of the ARM summaries listed on the *Print Options* window, refer to the Anorectal Summary section on page 155.

9.10.2 PRINTING TEST RESULTS THROUGH I-LIST OFFICE REPORTER

Once a test is run and complete, click the **Reporter** button on the UDS software control panel to open and print reports generated with the test data.



To print the report, click the **Print** icon on the toolbar in the *i-LIST Office Reporter* software.

NOTE: To print a saved test file, open the test file in the **File** > **Open** window of the UDS software and then click the **Reporter** button on the control panel to open the *i-LIST Office Reporter* software.

9.10.3 COMPREHENSIVE ARM REPORTS

A complete study report is available through the i-LIST Office Reporter application. Select the **ARM Report – Comprehensive** option in the reports(s) listing to obtain this type of report. This report contains items such as:

- Narrative-style summary of tests
- Graphs of test results
- Tables listing average values
- A graph printout of the test with event plots
- EMG assessment graph
- Pudendal nerve latency information
- Ultrasound images
- Answers to any questionnaires administered before the test

9.11 CUSTOMIZING THE ARM TEST

If modifying or creating a new test, click **Config** > **Setup/Modify** to open the *Configuration* window.

9.11.1 PART 1: SET CHANNELS FOR ARM STUDIES

1. Navigate to the *Channel Settings Tab*.
2. Configure four or eight pressure channels.
3. Configure one Math Channel as the average of all pressure channels. Pressure units are **cmH2O**, **mmHg**, or **mmHg'**. By default Pressure Channels are displayed in mmHg'. See following page for details of how to calibrate and use each unit of measure.
2. Configure EMG Channel(s) (optional).
3. Configure IH2O and VH2O (optional).
4. All other settings can remain as the default settings.
5. Click **Apply** and continue with setting up the ARM tab.

ARM Study Units

The following Arm Study units may be used for calibration:

- cmH2O: Calibrate pressure transducers in cmH2O and display data in cmH2O.
- mmHg: Calibrate pressure transducers in mmHg using a cmH2O to mmHg conversion. Data is displayed in mmHg.
  NOTE: 100mmHg = 136cmH2O
- mmHg': Calibrate pressure transducers in cmH2O and display data in mmHg using the software conversion unit mmHg'.

9.11.2 PART 2: SET UP ARM TAB

Navigate to the *ARM Tab* and select the channels that correspond to the ARM measurements recorded through testing. This tab is used to generate test result summaries, so the selections made here are important for accurate reporting (Figure 207).

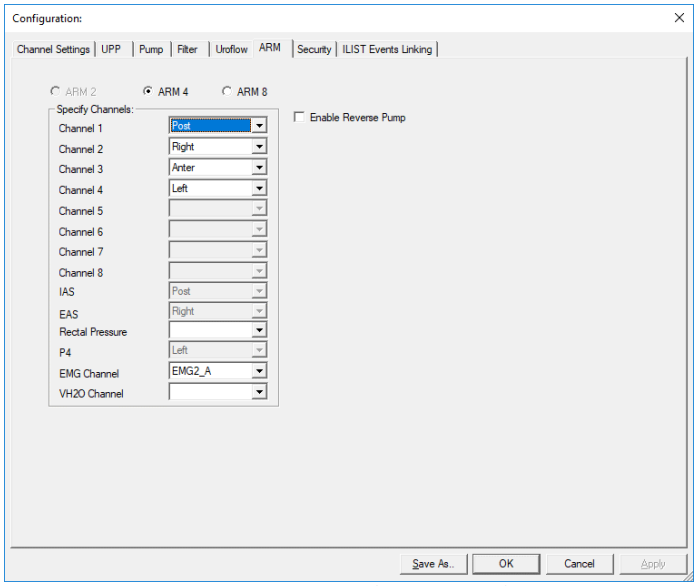


Figure 207: Example ARM Configuration for Four Pressures

Enable Reverse Pump for Balloon Filling

If using the pump, select the *Enable Reverse Pump* option in the *ARM Tab* to activate the reverse pump button on the control panel. The reverse pump button can be configured in the **Control Panel Settings** dialog box. Refer to the Glossary of ARM 4&8 Control Panel Commands on page 169 for button configuration options. Once the reverse pump button on the control panel is clicked, a warning message will appear requesting confirmation to continue (Figure 208).

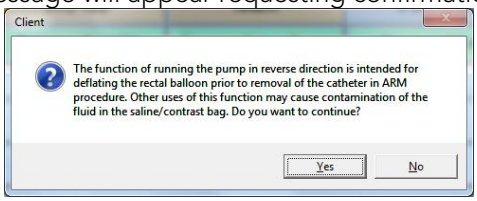


Figure 208: Reverse Pump Warning Message – Button Enabled and Clicked

Click **Yes** to continue or **No** to cancel. **The reverse pump action is intended only for deflating the rectal balloon before catheter removal. Do not run the reverse pump feature for any other actions.** A Start Infusion and Stop Infusion event will be added to the graph when reverse pump is started and stopped.

If the *Enable Revers Pump* options is not activated in the *ARM Tab* and the control panel button is clicked, an error message will appear:

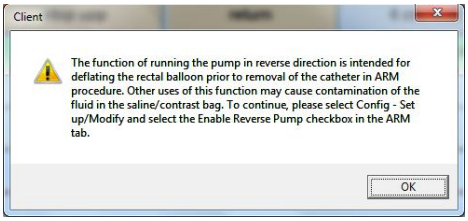


Figure 209: Revers Pump Error Message – Button Clicked, Not Enabled

9.11.3 PART 3: CONFIGURE THE CONTROL PANEL FOR ARM STUDIES

1. Click **Options** from the menu bar.
2. Select **Control Panel Settings.** The *Command box* will appear displaying the first row of Control Panel buttons.
3. Click the arrow next to the *Control Panel Set Name* and select **ARM 4&8**.

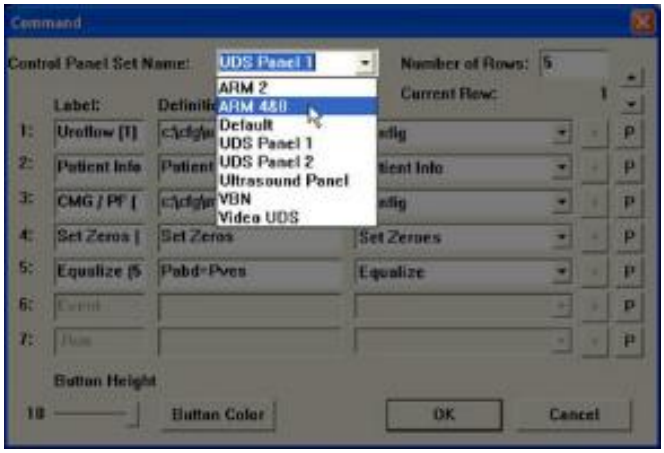


Figure 210: Control Panel Command Window - Selection for ARM

NOTE: The last two buttons of the first and second rows are reserved for system use. You can program the rest as needed.

ARM Properties

Each ARM button has a start and a stop event. Some of the ARM buttons can be configured to stop automatically after a specified time and to shade regions between start and stop events.

1. Open the Properties window by clicking the PLUS (+) button next to an ARM Control Panel button.
2. Select Automatically insert STOP event after and enter a value in seconds. The default value is 10 seconds.
3. To add shading between start and stop events, select show region for the ARM event, and click the Select Color box to choose the color.

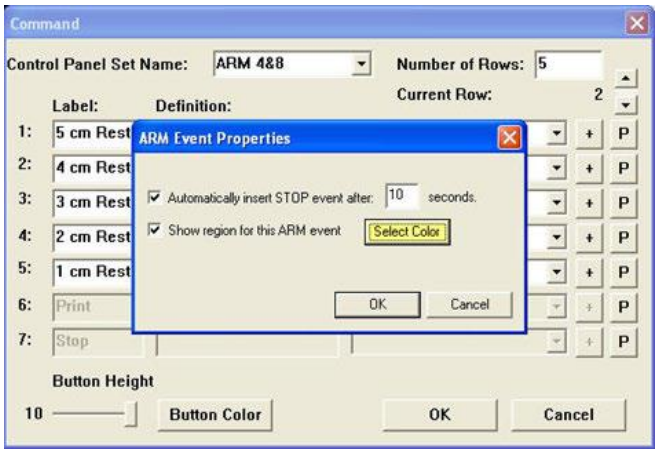


Figure 211: ARM Control Panel Buttons Properties Setup

4. Click OK to save changes.
5. Once saved, continue with the setup of the puller buttons (if you are using the Puller) or continue with the start of the ARM test.

9.11.4 CREATE CONTROL BUTTONS FOR THE MECHANICAL UPP PULLER (OPTIONAL)

Program control panel buttons to use the LABORIE Mechanical UPP Puller (UPP1001) and Controller (UPP1000 during the ARM test.

1. If there are no free button spaces under the ARM *Control Panel Set Name,* add a row of buttons by increasing the number in the **Number of Rows** box.
2. Select the down arrow next to *Current row* field to navigate to the newly created row.
3. Create a **Pull** button. The **Pull** button will pull the catheter at a specified rate once configured.
    a. Select the *Label* box and type ***Pull***.
    b. In the *Definition* box, type ***PU***.
    c. On the same row, in the third box, select **UPP Command** from the dropdown menu.
    d. On the same row, cclick the PLUS button [+] to set a fixed distance for stopping the puller.
4. Create the Pull 1 cm button. Move to the next line and type Pull 1 cm in the Label box, type PU 10 in the Definition box, and then select UPP Command in the listing. This button will command the puller to withdraw the catheter 1 centimeter (10mm) when clicked.
5. Create the Stop Pull button. Move to the next line and type Stop Pull for the label, ST for the definition and then select UPP Command in the listing. This button will stop catheter withdrawal.
6. Create the Return button. Move to the next line and type Return for the label, IN for the definition, and then select UPP Command. This button will move the puller guide forward.
7. Refer to Figure 212 for an example of completed setup.

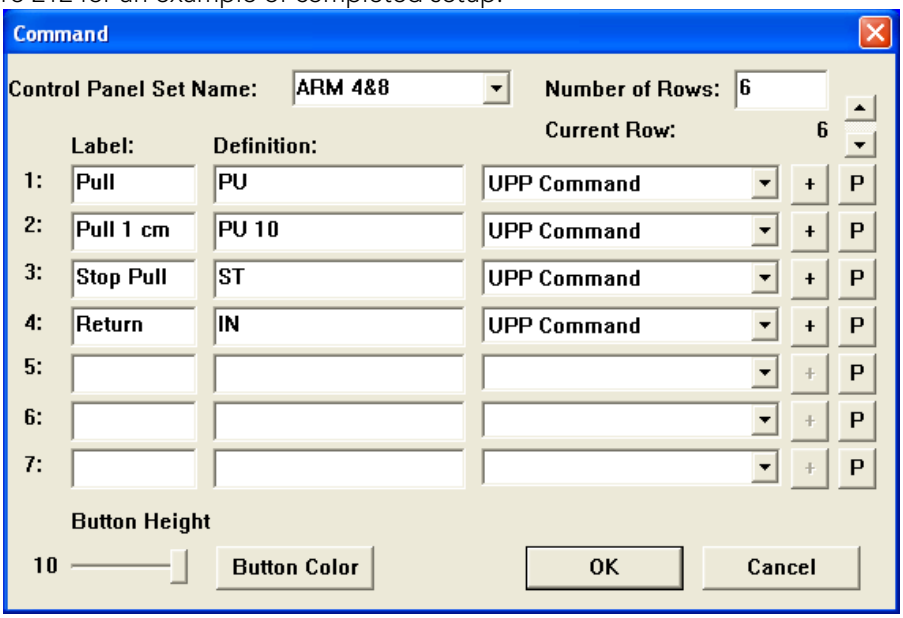


Figure 212: Control Panel Command Window – ARM 4& 8 UPP Commands

6. Click **OK**.
7. Continue with the setup of the sensation events.

9.11.5 CREATE FIRST SENSATION, URGE, AND MAX TOLERANCE EVENTS

If filling the rectal balloon manually with a syringe, the user must enter volumes at first sensation, urge, and max tolerance. To setup Sensation buttons to trigger the volume input request, click **Info** > **ARM 4&8** > **Anorectal Summary** and select the **Rectal Volume** tab. Select the *Input volume immediately after inserting events* option (Figure 213) and click **OK**. Click **Config** > **Save As** and assign a name to the file to make this a default setting. A message box will appear asking for input volume when *First Sensation*, *Urge*, or *Max Tolerance* events are selected.

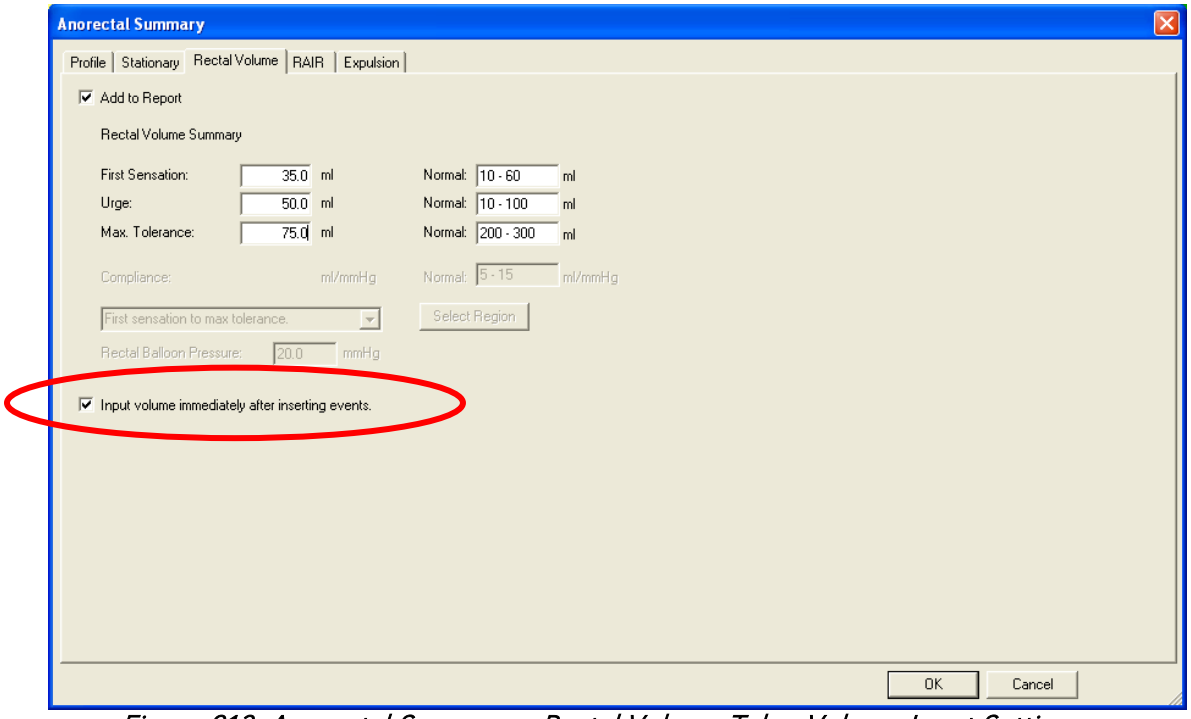


Figure 213: Anorectal Summary – Rectal Volume Tab – Volume Input Setting

When using the integrated pump, the volumes will be marked automatically with the sensation buttons. Ensure to specify the VH20 channel in the test's Configuration file then, follow the instructions below to enter sensations during an ARM test.

1. Click the **ARM** button on the Control Panel.
8. Click **Run** and let the test run for a few moments
9. Click the buttons labelled **First Sensation**, **Urge**, **and Max Tolerance**.
10. Click **Stop**.

9.11.6 GLOSSARY OF ARM 4&8 CONTROL PANEL COMMANDS

Suggested Button Label	Definition	Type
F*irst Sensation* *First Urge* Ma*x Tolerance*	*F*irst Sensation Ur*ge* *Maxi*mum Tolerance	**Event** Marks an event with the definition text as Event Annotation.
ARM 4 Radial ARM 8 Radial	Full path of CFG file Example: c:\cfg\	**Config** Opens a .cfg file.
Set Zeroes	N/A	**Set Zeroes** Sets all channels to zero.
Return Pull Pull *X* cm Stop Pull	IN *(returns the puller as fast as possible; for positioning the puller*) PU (*pulls at default Puller speed; stops when it reaches the tip*) PU *XX* ST (*stops the pull*)	**UPP Command (**Controls the puller speed) IN XX (*returns the puller XX millimeters as fast as possible; used for positioning the puller*) PU (*pulls the puller as fast as possible; used for positioning the puller*) PU XX *(pulls the puller XX millimeters at the default speed; for example PU 15 will pull the Puller for 15 mm at the default speed*)
Patient Info	N/A	**Patient Info** Opens Patient Info window.
Resting Squeezing Pushing 6 cm Push 5 cm Push 4 cm Push 3 cm Push 2 cm Push 1 cm Push 6 cm Squeeze 5 cm Squeeze 4 cm Squeeze 3 cm Squeeze 2 cm Squeeze 1 cm Squeeze 6 cm Rest 5 cm Rest 4 cm Rest 3 cm Rest 2 cm Rest 1 cm Rest 10 cc 20 cc 30 cc 40 cc 50 cc 60 cc 70 cc 80 cc 90 cc 100 cc 110 cc RAIR Expulsion Pushing	RE (*event for Resting Profile)* SQP (*event for Squeezing Profile)* *PUSH (event for Pushing Profile)* *SP6 (events for Stationary Study)* *SP5* *SP4* *SP3* *SP2* *SP1* ST6 ST5 (*events for Stationary Study)* ST4 ST3 ST2 ST1 SR6 SR5 (*events for Stationary Study)* SR4 SR3 SR2 SR1 10cc (*events for RAIR studies)* 20cc 30cc 40cc 50cc 60cc 70cc 80cc 90 cc 100cc 110cc RAIR E PUSH	**ARM** Controls Anorectal Manometry procedures performed with 4 or 8 pressure circumferential catheters.
Slow Fill Medium Fill Fast Fill XXX ml/min +YY ml/min -ZZ ml/min	SF MF FF SP=XXX (*where XXX is in ml/min)* SP+YY (*where YY is the incremental rate)* SP-ZZ *(where ZZ is the decremental rate)*	**Pump Command** Controls the pump fill rate.

Suggested Button Label	Definition	Type
Reverse Slow Fill Reverse Medium Fill Reverse Fast Fill	RSF RMF RFF	Controls the reverse pump fill rate†

† The Reverse Fill pump feature runs the LABORIE pump in reverse direction and can be used during ARM tests to quickly fill and then drain the large balloon used for evoking responses based on the sensation of rectum filling. Depending on the software version you are running, if you program your pump commands as *ff, mf, and sf*, then you can add the *rff, rmf, and rsf*. If you program the commands as *fast fill, medium fill and slow fill*, then you can program the reverse as *reverse fast fill, reverse medium fill, and reverse slow fill.*

IMPORTANT: Reverse Fill is not a feature meant to drain the bladder during Urodynamics testing! It is to be used only to drain the large balloon during ARM testing!

Table 33: ARM 4&8 Control Panel Commands

10 RUN UDS TESTS WITH AQUARIUS

10.1 UROFLOW TESTS

A Uroflow test is a measurement of the rate at which urine flows out of the body. It can be performed using the UDS software's auto-recording method, or it can be performed with manual control of the software.

10.1.1 UROCAP™ V SETUP FOR UROFLOW TEST

1. Gather the supplies needed for a Uroflow test. Ensure the battery of the **Urocap™ IV** is fully charged
2. Carefully place the **Urocap™ V** on the floor or on an approved Uroflow transducer stand. Positions a graduated beaker on top of the **Urocap™ V**.
3. Place the funnel on the plastic frame of the commode chair and position both over the **Urocap™ V** and beaker. Ensure that the beaker and the funnel are aligned but not touching.
4. Ensure that the computer is turned on, the device is connected, and the printer is turned on.
5. Start the UDS software and click the **Uroflow** button on the control panel corresponding to the **Urocap™ V**.
6. Once the Uroflow test enters the pretest screen, enter **Patient Information**.

NOTE: The **Uroflow** button is a customizable button and may be renamed. The connection icon next to the devices used during the study will not be visible for the length of the study.

10.1.2 RUN A UROFLOW TEST USING A UROCAP™ V

10.1.2.1 RUN A UROFLOW TEST: AUTO METHOD

1. Click the Uroflow button on the control panel. Ensure the button is configured to the appropriate configuration (CFG) file for a Uroflow test with the **auto-recording option** enabled.
2. Tap on the **Urocap™ V** to make sure it is responding.
3. The program will automatically begin to process the data when the transducer detects the start of flow. Alternatively, click the **Run** button to start the test.
4. Instruct the patient to void. If possible, leave the room to allow patient privacy.

CAUTION: Do not touch the beaker during voiding.

5. The graph will stop automatically 50 seconds after voiding has ended.
6. If desired, straight catheterize the patient or use a bladder scanner to obtain post-void residual measurement. When the *Uroflow Summary* screen appears enter the PVR value and click **OK.**
7. Click the **Save** button on the control panel to save the file or click **Reporter** to save, view, and print a test report in iList.
8. Empty the beaker and thoroughly wash for reuse.

10.1.2.2 RUN A UROFLOW TEST: MANUAL METHOD

1. Click the **Uroflow** button**.** Ensure the button is configured to the appropriate CFG file for a Uroflow test.
2. Tap on the **Urocap™ V** to make sure it is responding.
3. Click **Set Zeroes** on the control panel and click **Run** to start the test.
4. Instruct the patient to void. If possible, leave the room to allow patient privacy.

CAUTION: Do not touch the beaker during voiding.

5. When voiding is complete, click the **Stop** button**.**
6. If desired, straight catheterize patient or use a bladder scanner to obtain post-void residual measurement.
7. Click **Summ. Review button** on the control panel to view the *Uroflow summary* results. Then click **Return to Test** to continue. Type the post-void residual volume in the **PVR** box and click **OK.**
8. Click the **Save** button on the control panel to save the file or click **Reporter** to save, view, and print a test report in iList.
9. When the ***Save Test File*** box appears click the **Save** button in the box.
10. Empty the beaker and thoroughly wash for reuse.

10.1.3 SPINNING DISK FLOW TRANSDUCER SETUP

1. Gather the supplies needed for a Uroflow test. Ensure the Spinning Disk Flow Transducer is plugged into a wall outlet.
2. Ensure that the computer is turned on, the device is connected, and the printer is turned on.
3. Start the UDS software and click the **Uroflow** button on the control panel corresponding to the **Urocap™ V**.
4. Once the Uroflow test enters the pretest screen, enter **Patient Information**.

NOTE: The **Uroflow** button is a customizable button and may be renamed. The connection icon next to the devices used during the study will not be visible for the length of the study.

10.1.4 RUN A UROFLOW TEST USING A SPINNING DISK FLOW TRANSDUCER

1. Select the appropriate configuration (CFG) file for a Uroflow test. To use automated features ensure **auto-recording options** are enabled.
2. Confirm that the top right button of the Control Panel is green and displays "Run."
3. Confirm that the LED light on the Spinning Disk's control box is green and blinking.
4. Instruct the patient to void. If possible, leave the room to allow patient privacy. The program will automatically begin to process the data when the Spinning Disk Flow Transducer detects the start of flow. Alternatively, click the **Run** button to start the test.
5. The graph will stop automatically 50 seconds after voiding has ended. Alternatively, select the **Stop** button to stop the study.
6. If desired, straight catheterize patient or use a bladder scanner to obtain post-void residual measurement.
7. Click **Summ. Review button** on the control panel to view the *Uroflow summary* results. If automatic features are enabled the *Uroflow Summary* screen will appear automatically. Enter the PVR value and click **OK.**
8. Click the **Save** button in the control panel to save the file or click **Reporter** to view and print a test report.
9. Empty the beaker and thoroughly wash for reuse.

10.2 CMG TEST OR MICTURITION (PRESSURE/FLOW)

The purpose of running a CMG test is to determine whether the bladder and its surrounding tissues are functioning correctly. The CMG test involves filling the bladder and determining the Detrusor pressure Pdet = Pves – Pabd (the difference between the pressure inside the bladder (Pves) and the pressure inside the abdomen (Pabd)).

- Calibrate all transducers before running the test.
- Operators should be knowledgeable and qualified in applying the appropriate aseptic technique during the intended use of the device.

10.2.1 RUN A CMG/MICTURITION TEST WITH AIR-CHARGED CATHETERS

1. Gather supplies needed for testing (catheters, beaker, commode chair, funnel, cable transducers, etc.).
2. Turn on and connect all equipment required for the study.
    a. Turn on the computer and the printer. Start the software.
    b. Ensure the **Roam™ DX** and **Urocap™ V** are connected to the software and at full battery.
    c. Connect the transducer cables to the **Roam™ DX** and the catheters to the transducer cables. Connect the primed infusion line to the filling lumen on the vesical catheter. Ensure the compressible portion of the Infusion Pump Tubing is inserted through the pump.
3. Click the **CMG/PF** button on the control panel and enter the patient's information if necessary.
4. Check that the chargers of the transducer cables are in the **OPEN** position.
5. Click the **Zero All** button on the control panel.
6. Position the patient in the supine or lithotomy position with legs in stirrups for catheter insertion.
7. Insert the Air-Charged Catheters into the patient.

NOTE: Bladder catheter placement for women is 8-10 cm for single sensor and 12-14 cm. For men insert Bladder catheters 8cm plus penile length. Place the abdominal catheter rectally 10 -15cm, past any stool, along the anterior wall of the rectum.

IMPORTANT: These are approximate guidelines. Ensure that the catheter sensor is fully inserted into the bladder without over insertion.

8. Prepare the patients skin and apply EMG patches; the patient's skin should be clean, dry, and free of hair. Ensure electrodes are snapped onto the 3 EMG leads. Place two electrodes peri-anally at the 10 o'clock and 2 or 3 o'clock positions. Place the third electrode on a bony prominence such as the patient's hip bone or knee.

9. Switch the transducers to the **CHARGE** position to record true internal pressures. When recording two pressures during a CMG or Pressure/Flow test, Pves and Pabd should be fairly equal and Pdet should be at or near zero.
10. Ask the patient to cough to confirm catheter positioning. When recording two pressures at the same time, the cough will show equal deflection on both channels.

NOTE: If Pabd is higher than Pves, try repositioning the Pabd catheter. If repositioning does not work, ask the patient to cough to confirm that both pressures are reacting appropriately.

11. Select the applicable calibration file for a CMG/Micturition test then click the **Run** button on the control panel.
12. Click the **Start Pump** button to start the pump and begin filling the bladder.
13. Mark relevant events using buttons available in the control panel (for example: *First Sensation*, *First Desire* and so on). Encourage the patient to give feedback on sensation or urge.
14. Click **Stop Pump** to stop infusing when the patient is full and click **Capacity** on the control panel to mark the event.
15. Click the **Permit to Void button and** ask the patient to void through the commode chair into the **Urocap™ V** beaker (with catheters in place).
16. Click the **Stop** button when finished and then click the **Save** button on the control panel to save the test file.
17. Print the results of the test if desired.
18. Remove the catheters, EMG patches, and pump tubing and dispose in accordance to hospital/clinic procedures.
19. Empty and thoroughly wash the beaker for reuse.

10.2.2 RUN A CMG / MICTURITION TEST USING FLUID-FILLED CATHETERS

1. Gather supplies needed for testing (catheters, beaker, commode chair, funnel, transducers, etc.).
2. Turn on and connect all equipment required for the study.
    a. Turn on the computer and the printer. Start the *UDS120 GOBY* software.
    b. Ensure the **Roam™ DX** and **Urocap™ V** are connected to the software and at full battery.
    c. Prime the transducers pressure cartridges, measurement tubing, and pump tubing.
    d. Click the **CMG/Micturition** button on the control panel. Ensure all the pressure transducers are responding. Press the 100 mm Hg button on the pressure transducer cartridge and tap the beaker on the Uroflow transducer. **NOTE:** 100 mm Hg = 136 cm H20.
3. Position patient in the supine or lithotomy position with legs in stirrups for catheter insertion.
4. To zero the transducers, first adjust the pressure cartridges to the height of the patient's bladder. Turn the stop cocks "OFF" to the cartridges, remove the stopper caps, and select **Set Zeroes** on the Control Panel. Replace the stopper caps and turn the three-way stop cocks "OFF" to the syringe.
5. Set up and prime the catheters in accordance with device specific instructions for use.
6. Insert the Bladder and Abdominal Catheters. Tape catheters as close to the insertion site as possible.
7. Connect the pressure measurement lines and pump tubing to the appropriate catheter ports and cables.
8. Prepare the patients skin and apply EMG patches; the patient's skin should be clean, dry, and free of hair. Ensure electrodes are snapped onto the 3 EMG leads. Place two electrodes peri-anally at the 10 o'clock and 2 or 3 o'clock positions. Place the third electrode on a bony prominence such as the patient's hip bone or knee.
9. Ask the patient to cough in order to verify that the channels are responding.
10. Select the Calibration file for the CMG/Micturition test and then click the **Run** button on the control panel.
11. Click the **Start Pump** button to start the pump and begin filling the bladder.
12. Mark relevant events using the buttons available on the control panel (for example: ***First Sensation***, ***First Desire*** and so on). Encourage the patient to give feedback on sensation or urge.
13. Click **Stop Pump** to stop infusing when the patient is full and click **Capacity** on the control panel to mark the event.
14. Click the **Permit to Void** button and ask the patient to void through the commode chair (with catheters in place) into the **Urocap™ V** beaker.
15. Click the **Stop** button when finished and then click the **Save** button on the control panel to save the test file.
16. Print the results of the test if desired.
17. Remove the catheters, EMG patches, and pump tubing and dispose in accordance to hospital/clinic procedures.
18. Empty then thoroughly wash the beaker for reuse.

10.3 UPP TESTS

A UPP test is used to measure the length of the urethra and to measure the pressure within the urethra. An optional UPP Puller may be used in conjunction with the UDS Software to run a UPP test. To setup the UPP stand refer to the Assemble the Puller Stand (Optional) section on page 21.

IMPORTANT: The UPP puller is intended for catheter withdrawal only!

- Calibrate all transducers before running the test.
- Operators should be knowledgeable and qualified in applying the appropriate aseptic technique during the intended use of the device.

10.3.1 RUN A UPP TEST USING AIR-CHARGED CATHETERS

1. Gather supplies needed for testing (catheters, cable transducers, pump tubing, etc.).
2. Turn on and connect all equipment required for the study.
    a. Turn on the computer and the printer. Start the software.
    b. Ensure the **Roam™ DX** and the UPP puller are connected to the software and at full battery.
    c. Connect the transducer cables to the **Roam™ DX** and the catheters to the transducer cables. Connect the primed infusion line to the filling lumen on the vesical catheter. Ensure the compressible portion of the Infusion Pump Tubing is inserted through the pump.
3. Click the **UPP** button on the Control Panel.
4. If the UPP button is not visible click **Options** > **Control Panel Settings** and select the ***PressureFlowUPP*** control panel set.

NOTE: The connection icon next to the devices used during the study will not be visible for the length of the study.

5. Check that the chargers of the transducer cables are in the **OPEN** position.
6. Click the **Zero All** button on the control panel.
7. Invite the patient to take the test. Enter Patient Information.
8. Position the patient in the supine or lithotomy position with legs in stirrups for catheter insertion.
9. Insert a triple-lumen catheter into the patient's bladder.

NOTE: Bladder catheter placement for women is 8-10 cm for single sensor and 12-14 cm. For men insert Bladder catheters 8cm plus penile length. Place the abdominal catheter rectally 10 -15cm, past any stool, along the anterior wall of the rectum.

IMPORTANT: These are approximate guidelines. Ensure that the catheter sensor is fully inserted into the bladder without over insertion.

10. Switch the transducers to the **CHARGE** position to record true internal pressures.
11. Click **Run** on the Control Panel.
12. If required, infuse the desired volume into the bladder using the pump.
13. Once ready, stop the pump.
14. Click **Start Pull** (or press **F6** on the keyboard) and the UPP puller will begin to remove the catheter from the patient's bladder at the preset speed.

NOTE: If you do not have a UPP puller, pull the catheter out manually at a slow and steady rate. Watch the cm markers on the catheter; it should take a count of 10 to go from one marker to the next [pulling at 1mm/sec]. When the Pura and Pclo curves rise, Pves should remain stable indicating that the sensor is traveling through the urethra.

15. When the Pura sensor on the catheter has been pulled out from the urethra, Pura returns to 0, select **Stop Pull** (or press **F6)**.
16. Select the **Return** button to set up the UPP for the next catheter pull. Reinsert the catheter.

NOTE: The catheter must be reinserted manually, not using the UPP puller.

17. Click the **Stop** button when finished and then click the **Save** button to save the test file.
18. Print the results of the test if desired.
19. Remove the catheters, EMG patches, and pump tubing and dispose in accordance to hospital/clinic procedures.

10.3.2 RUN A UPP TEST USING WATER-FILLED CATHETERS

1. Gather supplies needed for testing (catheters, transducers, pump tubing, etc.).
2. Turn on and connect all equipment required for the study.
    e. Turn on the computer and the printer. Start the *UDS120 GOBY* software.
    f. Ensure the **Roam™ DX** and UPP Puller are connected to the software and at full battery.
    g. Prime the transducers pressure cartridges, measurement tubing, and pump tubing. Click the **UPP** button on the Control Panel. If the UPP button is not visible click **Options** > **Control Panel Settings** and select the ***PressureFlowUPP*** control panel set.
    h. Ensure all the pressure transducers are responding. Press the 100 mm Hg button on the pressure transducer cartridge and tap the beaker on the Uroflow transducer. **NOTE:** 100 mm Hg = 136 cm H20.

NOTE: The connection icon next to the devices used during the study will not be visible for the length of the study.

3. Position patient in the supine or lithotomy position with legs in stirrups for catheter insertion.
4. To zero the transducers, first adjust the pressure cartridges to the height of the patient's bladder. Turn the stop cocks "OFF" to the cartridges, remove the stopper caps, and select **Set Zeroes** on the Control Panel. Replace the stopper caps and turn the three-way stop cocks "OFF" to the syringe. Set the zeroes with the perfusion line dripping at 1 drop every 2 to 3 seconds
5. Set up and prime the catheter in accordance with device specific instructions for use.
6. Invite the patient to take the test. Enter Patient Information.
7. Position the patient in the supine or lithotomy position with legs in stirrups for catheter insertion.
8. Insert a triple-lumen catheter into the patient's bladder.
9. Click **Run** on the Control Panel.
10. If required, infuse the desired volume into the bladder using either the pump or the Infusion Transducer.
11. Once ready, stop the pump or close the roller valve on the infusion line. i.e. stop the pump line and not the UPP drip line.

NOTE: If you do not have a UPP puller, pull the catheter out manually at a slow and steady rate. Watch the cm markers on the catheter; it should take a count of 10 to go from one marker to the next [pulling at 1mm/sec]. When the Pura and Pclo curves rise, Pves should remain stable indicating that the sensor is traveling through the urethra.

12. When the Pura sensor on the catheter has been pulled out from the urethra, Pura returns to 0, select **Stop Pull** (or press **F6)**.
13. Select the **Return** button to set up the UPP for the next catheter pull. Reinsert the catheter.
14. Click the **Stop** button when finished and then click the **Save** button to save the test file.
15. Print the results of the test if desired.
16. Remove the catheters, EMG patches, pressure tubing, transducer cartridges and pump tubing and dispose in accordance to hospital/clinic procedures.

11 TROUBLESHOOT AND SERVICE

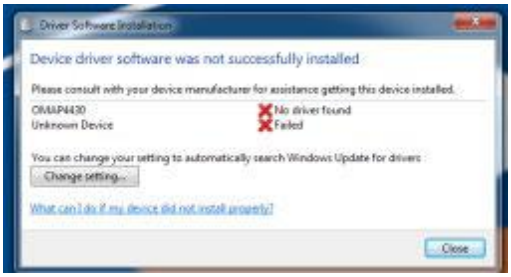
If problems continue, contact LABORIE's Service team at 1-800-333-1039 or email service@laborie.com.
Follow the instructions provided in the table below for troubleshooting steps.

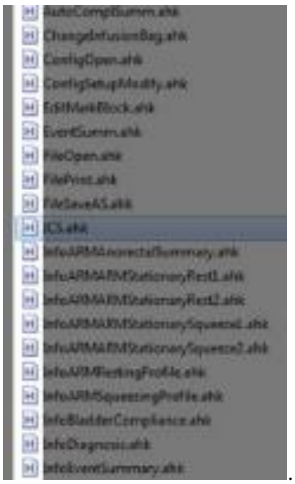
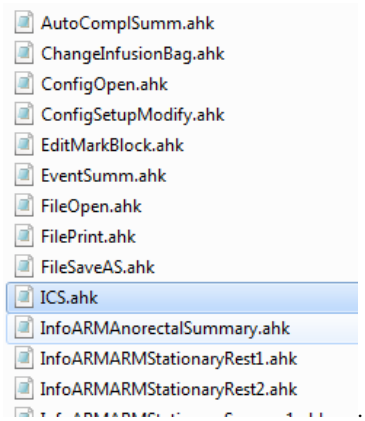
Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
ALL DEVICES		
No response from the devices?	No power on electrical outlet?	Plug the system into a known working electrical outlet.
	Damaged power cord?	Unplug the system and contact LABORIE for a replacement power cord.
	Power cord is not connected properly?	Ensure the power cord is secure at the base of system and at the electrical outlet.
	Devices are not connected in software?	Connect the devices to the system. Refer to the Using the Module Touchscreen on page 34.
	Wrong connection type?	Make sure the correct connection type (either Bluetooth or USB) is selected under the *Connection Type* sub-menu. Refer to the Connection Type section on page 130.
Computer or Printer cannot power on?	No power on electrical outlet? Damaged power cord? Power cord not connected properly?	Ensure electrical outlet is working, power cords are not damaged, and all power cords are secure at both ends.
USB power is connected but the orange Battery LED displaying on the device. There is no icon on the screen and no response from keyboard?	Battery is empty?	Wait (up to 30 minutes) until the battery is charged enough for wake-up.
No external power is connected and cannot wake-up ROAM™ using OK button or Bluetooth connection?	Battery voltage is below wake-up level?	Wait (up to 30 minutes) until the battery is charged enough for wake-up.
Device displays partial charge when the battery is fully charged (i.e. was left in charger for more than 5 hours)?	Need to restart?	Restart entire system.
EMG		
EMG reading is too high/low?	EMG channel scale is not optimized?	Adjust the scale by clicking on the scale values and typing in new values.
	Electrodes are wet or generally not sticking?	Shave the area if necessary and wipe dry. Apply a good amount of tape to keep moisture out.
	Detached electrode?	Re-attach electrode.

Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
	Water/urine leaked all over the electrodes?	Dry the area with a towel and replace the electrodes.
No spike response in EMG and baseline is flat?	Electrodes are not picking up the proper muscle group?	Move either one or both measuring electrodes (the ones attached to the red leads) closer together.
EMG response is too high and the channel is saturated?	Electrodes are not picking up the proper muscle group?	Move either one or both measuring electrodes (the ones attached to the red leads) a little farther apart.
PRESSURES		
Pressure not responding?	Position of catheters?	Check position and adjust as necessary.
	Catheters are not securely connected to the cables?	Check connections and adjust as necessary.
	Zeroes are not set properly?	Reset zeroes.
	Catheter is kinked?	Replace catheter if necessary.
	Using water-based disposables?	Flush lines and reset zeroes. Make sure all stopcocks are in the correct position. Refer to the Consumables and Transducer Setup on page 25.
PUMP		
Pump not running?	Pump is not Calibrated?	Calibrate Pump.
	Pump pressure limit reached?	Reset P1 (Pves) to zero. Check for kinks in the bladder catheter.
	Volume limit exceeded?	Reset VH_2O Channel to Zero and try again.
	Pump calibration incorrect?	Recalibrate the pump.
	Pump rate set at 1ml/min?	Close UDS software and wait one minute. Then, restart the software.
Pediatric pump settings incorrect?	Pediatric pump settings switch to adult pump settings?	Follow the steps provided below to set up pump speeds for pediatric patients, 1. Open a Cystometry test (or any test file using a pump). 2. Enter patient information for pediatric patient. Enter *Height* and *Weight* to view the calculated MPUR. Select the **Use MPUR for pump speeds** option under the *Fill Rate* section. 3. Click **Save**. 4. Click **Yes**. 5. Click **Run** and then click **Start Pump** on the control panel. 6. Click Info then click Patient information. 7. Click **OK**. 8. Re-select **Use MPUR for pump speeds**. Click **OK** to load the correct MPUR speeds for the test.

Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
UROCAP™ V		
Uroflowmeter signal shows vibration and/or spike patterns?	Plastic beaker is touching the flow funnel?	Reposition the Uroflowmeter and re-check.
	Patient touched the Uroflowmeter with their feet?	Ask patient to remain calm during procedure. Refer to Uroflow Options Dialogue Box, Artifact Recognition section on page 97 for information on filtering non physiological spikes.
	Floor is unsteady?	Move to a more solid foundation.
Incorrect flow or volume readings?	Beaker is not properly seated on Uroflowmeter dish?	Adjust the beaker position.
	Funnel is touching the beaker?	Adjust the commode chair or the Uroflowmeter.
	Incorrect beaker in use?	Use beakers supplied by LABORIE ONLY.
Error message on screen reads: "Calibration Failure…(Flow out of range.)"	Water poured quickly into beaker?	Pour water slowly and at a steady rate.
	More than 500mL poured into beaker?	500mL of water must be poured into the beaker.
Error message on screen reads: "Calibration Failure…(Volume delta out of range.)"	Less than 500mL of water poured into beaker?	500mL of water must be poured into the beaker.
BLUETOOTH CONNECTION		
Unable to connect via Bluetooth?	Connection broken?	Reduce the distance between the device and the computer. The maximum distance between the processor and the computer can be up to 10 meters (33 feet). Remove any physical barriers like walls, posts, doors, or people.
Unable to connect devices to Bluetooth at first setup?	Connection broken?	Reconnect devices: 1. Click the Bluetooth button on the device to "wake up" the device and re-establish a connection. 2. Wait 5 minutes. 3. If the button press does not re-establish a connection, then press the system reset button on the tower to restart the entire system. 4. Once restarted wait for all connections to reset.
Unable to connect to PC via touchscreen?	Connection broken?	Reconnect devices in the touchscreen: 1. First disconnect all Bluetooth devices via the touchscreen. 2. Restart the software and establish a connection to the PC. Refer to the Connect the PC/Laptop to the System section on page 39. 3. Reconnect all Bluetooth devices via the touchscreen. Refer

Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
EVENTS		
A "transducer change" event is marked on the graph?	Cable connected/disconnected from device?	This action is marked on the graph to help distinguish it from an actual signal received during testing. It is also marked when the **ROAM™ DX** device goes through an auto-recovery process.
SOFTWARE ERROR MESSAGES - iList Reporter		
Error message: "Error Code: 66a (Can't install KB2160841)" appears?	.NET Framework file needs repair.	To repair .NET Framework File: 1. Click Start > Control Panel > and double-click Add or Remove Programs. *Alternatively,* click Start > Control Panel > Programs > Programs and Features. 2. In the resulting list, right-click the *Microsoft .NET Framework 4 Client Profile* file and select **Change** *or* select **Uninstall/Change.** 3. Select to **Repair** the file and wait for the repair to complete before continuing. 4. Restart the computer.
UDS report not transferring to i-LIST Office Reporter?	Make sure i-LIST MsgQListener is running.	To Check MsgQListener: 1. Close all open programs. 2. Make sure i-LIST Message Queue Listener is running by clicking **Start** > **Programs** > **Laborie** > **i-LIST MsgQListener**. 3. Restart the computer and attempt to send a report to i-LIST Office Reporter. If unsuccessful try the solution below.
	Install Windows Updates	To Install Windows Updates: 1. Close all open programs. 2. Click **Start** > **Control Panel** and double-click **Windows Updates** -OR- Click **Start** > **All Programs** > **Windows Updates**. If there are updates waiting for installation, install them and then restart the computer. 3. Once restarted, attempt to send a report to i-LIST Office Reporter. If unsuccessful try the following solution to repair the .NET file.
	Repair .NET Framework File	To repair .NET Framework: 1. Click Start > Control Panel > and double-click Add or Remove Programs. *Alternatively,* click Start > Control Panel > Programs > Programs and Features. 2. In the resulting list, right-click the *Microsoft .NET Framework 4 Client Profile* file and select Change *OR* select Uninstall/Change 3. Select to Repair the file and wait for the repair to complete. 4. Restart the computer and continue with sending a UDS report to i-LIST Office Reporter.

Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
Error message appears after system restart stating devices not found: 		Do not click anywhere on the screen. Wait for message to disappear. Once message is gone continue with regular use.
PC		
PC does not power on?	Power interruption due to power outage?	After power interruption follow the steps below: 1. Unplug the power cable from the power brick. 2. Press and hold the power button on the computer for 5 seconds. 3. Wait for the lights over the power brick to switch-off. 4. Plug the power cable back into the power brick. 5. Press the power button on the computer to switch the PC on again.
PRINTER		
Printer LED does not light up?	Printer power cable unplugged?	Plug in the printer power cable and try again.
	Printer is not turned on?	Turn on the printer by pressing the printer power button.
Printer Error LED on steady or flashing?	Printer paper is out?	Load the printer paper.
	Printer cover is open?	Close the cover of the printer.
	Printer is out of ink?	Replace the printer cartridges.
	Printer paper is jammed or mis-fed?	Correct paper problem then, press paper feed button.
BUBBLE DETECTOR		
Red light on sensor lit even though bubbles are not visible	Pump tubing is not inserted securely?	Make sure the pump tubing is placed securely into the groove on the sensor.

Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
CONTROL PANEL		
Script buttons (Uroflow Summary, Summary Review, etc…) stopped working?	Program file for formatting buttons is not set properly?	The program used for formatting script buttons must use the AutoHotKey**.ahk** format. To verify the program is correct follow these steps: 1. Go to **C:\UDS120** and open the **HK** folder. 2. Make sure the file format icons are set to the AutoHotKey application as shown to the right:  3. If the icons are not set to the AutoHotKey application, for example they are in the Notepad format (as seen to the right) then you must change it to the AutoHotKey application:  4. Right-click on any line and select **Properties**. In the *Opens with* section click the **Change** button and select the *AutoHotKey Unicode* application in the resulting window and then click **OK**:  5. The *Opens with* section will display the AutoHotKey application. 6. Click **OK**.

Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
TOUCHSCREEN		
Touchscreen on tower frozen?	Need to reset?	Press the reset button on the Central Hub Computer (CHC) for 5 seconds to reset the system:  .

Table 34: Troubleshooting

NOTE: The Laborie Aquarius LT, CT, CTS and XT are designed to be used as stand-alone cart systems, with the only mains power supply connection going through the LABORIE medical-grade power supply (LIT) in the base of the cart. Do not connect it to any other devices unless the whole system is outside the patient environment or the other device has its own medical grade power supply.

12 END-USER SOFTWARE LICENSE AGREEMENT

Find licenses and terms for LABORIE products and services in the following locations:

End User License Agreement: http://www.laborie.com/eula/

Terms and Conditions: http:// http://www.laborie.com/terms-and-conditions/

13 APPENDIX

APPENDIX A. SYSTEM SPECIFICATIONS

EQUIPMENT SPECIFICATIONS

For proper operation, the device requires mains power 110 VAC or 240 VAC.

AQUARIUS® Carts	AQUARIUS® CT CART: SINGLE DISPLAY L = 36" (90.0cm) W = 26" (66.0cm) H = 60-71" (153.0-180cm) AQUARIUS® XT TOWER L = 24" (60.0cm) W = 26" (66.0cm) H = 48" (120.0cm) AQUARIUS® XT PC CART: DUAL DISPLAY L = 36" (90.0cm) W = 34.5" (88.0cm)* H = 60-71" (153.0-180cm) *operational width described - can pivot to pass through doors. AQUARIUS® LT L = 32" (81.0cm) W = 26" (66.0cm) H = 48" (120.0cm) AQUARIUS® CTS L = 36" (90.0cm) W = 26" (66.0cm) H = 65" (165.0cm)
Operating Conditions	Temperatures: 15°C to 35°C Humidity: 20% to 80% relative humidity Pressure: 700 hPa to 1014 hPa (up to 2000 m)
Transport and Storage Conditions	Temperature: -29°C to 60°C Humidity: uncontrolled to 85% relative humidity
Pump Hub P/N: PMP1000	Output Channels: 2 Infusion / 1 Bubble/1 USB type A/ 1 USB type B
Roam™ DX P/N: RMX1000	Dimensions: 5.5"(14cm) L X 3.6"(9.3cm) W X 1.6"(3.9) H Weight: 0.60 lbs (0.27kg) Pressure Range: -50 to +350 cmH20; EMG Range: 0 to 1000uV Output Channels: 4 Pressure / 1 EMG / 1 Pressure/EMG Sampling Rate (each channel): Pressure= 50Hz max.; EMG=5000Hz max. / 10 – 100 Hz (increments of 10Hz)
Urocap™ V P/N: TRA1002	Dimensions: 6.3"(16.0cm) L X 6.3"(16.0cm) W X 2.6"(6.6cm) H Weight: 0.95lbs (0.43kg) Flow Range: 0 to 50mL/s; Volume Range: 0 to 1000mL Output Channels: Flow; Volume Sampling Rate: Flow=100Hz max.; Volume=100Hz max.
UPP (arm and stand) P/N: UPP1001 and UPP1000	Dimensions: 23.5"(59.7cm) L X 23.5"(59.7cm) W X 35.6"(90.4cm) H Arm extension: 30 » (76cm) Luxo: Extension 36.0" (91.5cm) / Weight: 3.3 lbs. (1.5kg) Speed: 0 to 3 mm/s
Maximum load for printer shelf and workstation shelf	22 Lbs. (10kg)
Spinning Disk Flow Transducer	Width*: 16" (400mm)

P/N: 9034K0103	Depth*: 19" (485mm) Height*: 29-36" (735-925mm) Weight*: Less than 7.61 lbs (Less than 3.5 kg) Cable length*: 122" (310cm) Number of Channels: 1 Power Supply: Power consumption: max 1.0A; Input: 24 V DC/1.0 A; Output: Tacho Accuracy: Refer to the Accuracy of the main device. Storage / Transportation: • Temperature -40° to +70°C (-40° to 158°F) • Humidity 10% to 100%rh (including condensation) • Atmospheric pressure 700 Pa to 1060 Pa Operating Conditions: • Temperature +10° to +40°C (50° to 104°F) • Humidity 30% to 75% • Atmospheric pressure 700 Pa to 1060 Pa Jug Volumes: Steel jug 1.5L; White jug 1L *values include the stand

Table 35: AQUARIUS® Specifications

T-DOC Air-Charged Catheters Conditions

Operating Conditions:	15°C (59°F) to 40 °C (104°F)
Storage Temperature:	-25°C (-13°F) to +50°C (122°F)

Anorectal Manometry (ARM)

Test Capabilities	Stationary Rest & Squeeze Pushing Rectal Volumes Rectoanal Inhibitory Reflex (RAIR) Balloon Expulsion
Calculations	Rectal Compliance (mL/mmHg) RAIR Inhibition and Excitation Characteristics Resting, Average and Max Pressures (mmHg) Fatigue Rate Index (min) Anal Canal Length (cm) or High Pressure Zone (cm) Ultra Slow Wave Analysis Pressure Area Functions
Catheters	T-DOC Air-Charged -> 4 channel radial Unisensor Electronic -> 4 channel radial -> 8 channel radial MUI Water Perfused -> 4 channel radial -> 8 channel radial Rectal pressure measurement available for specific options
Accuracy	Pressure: +/- 5% EMG: +/- 6% Volume using infusion transducer: +/- 10%

Table 36: ARM Capabilities and Accessories

CLASSIFICATIONS

Classifications	Class I Type BF Applied Part Mode of Operation: Continuous Equipment not suitable for use in the presence of a Flammable Anesthetic Mixture with Air or Oxygen or Nitrous Oxide.

Table 37: AQUARIUS® Classifications

Spinning Disk Flow Transducer

Classifications	Degree of protection against electric shock: *Type BF (Body Floating):* Applied part provides a specific degree of protection against electric shock, particularly in regard to the amount of current leakage that is allowed. The applied part is mechanically isolated (floating). Not intended for direct cardiac application. Degree of protection against harmful ingress of water: IP33 Degree of safety in presence of inflammable anesthetics: The device is not intended for use with anesthetic gases mixed with air, oxygen or nitrous oxide. Danger of electrical ignition. Mode of operation: Continuous / intermittent operation.

Table 38: Spinning Disk Flow Transducer Classifications

TYPE BF APPLIED PARTS

- EMG/CMG
- Pressure transducers

APPENDIX B. SYMBOLS AND LABELING

EC REP Authorized Representative in the European Community (5.1.2)[1]: Indicates the manufacturer's device representative in the European Community.	SGS SGS certification - certified to U.S. and Canadian safety standards.	Date of Manufacture (5.1.3)[1]: Indicates the date of device manufacture.	Manufacturer (5.1.1)[1]: Indicates the device manufacturer.	Consult Instructions for Use (5.4.3)[1]: Manufacturer recommends consultation of Instructions for Use.	Read Operator's Manual (M002)[4]: Indicates user must refer to Owner's/Operator's Manual.
LOT Lot - Batch Code (5.1.5)[1]: Indicates the batch or lot code for identification and tracking purposes.	REF Catalogue Number (5.1.6)[1]: Indicates the device model or catalogue number.	SN Serial Number (5.1.7)[1]: Indicates unique device serial number for device traceability.	Type BF Applied Part (Table D.1, 20)[2]: Identifies a type BF applied part complying with IEC 60601-1.	Use-by Date (5.1.4)[1]: Indicates date after which use is prohibited.	STERILE Sterile (5.2.1)[1]: Indicates a sterile device.
STERILE EO Sterilized Using Ethylene Oxide (5.2.4)[1]: Indicates method of sterilization used as ethylene oxide.	STERILE R Sterilized Using Irradiation (5.2.4)[1]: Indicates method of sterilization used as irradiation.	Alternating Current (Table D.1, 1)[2]: Indicates use of Alternating Current.	Direct Current (Table D.1, 1)[2]: Indicates use of Direct Current.	Non-ionizing Electromagnetic Radiation (5140)[5]: Radio Frequency (RF) Transmitting Device Indicates presence of RF transmitters.	Keep Dry (5.3.4)[1] Indicates a device requiring protection from moisture.
Do Not Re-Use (5.4.2)[1]: Medical device intended for single use, on a single patient, during a single procedure.	Safety Label, No Pushing (P017)[3]: To prohibit pushing against a specified device.	Safety Label, No Sitting (P018)[3]: Indicates sitting on the identified surface is prohibited.	Humidity Limitation (5.3.8)[1]: Indicates the humidity range to which the medical device can be safely exposed.	Temperature Limit (5.3.7)[1]: Indicates the temperature limit to which the medical device can be safely exposed.	Atmospheric Pressure Limitation (5.3.9)[1]: Indicates the atmospheric pressure range to which the medical device can be safely exposed.
Protective Earth, Grounding (Table D.1, 7)[2]: Identifies any terminal intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of protective earth electrode.	Not for general waste. This product is designated for separate collection at an appropriate collection facility in accordance with WEE Directive. Dispose of in accordance to local regulations.	General Battery (5001B)[4]: Identifies a device related to the power supply by battery.	General Warning Sign (W001)[3] Indicates a general warning.	MAX 10kg Safety Label, Safe working Load 10kg	MAX 1kg Safety Label, Safe Working Load 1kg
MAX System Safe Working Load	**Device Stop/Reset** button: Press and hold for 3 seconds to reset. Press and hold for 5 seconds or longer to bring to sleep.	Direction of Pump Flow	(01)00627825003728 (11)200311 (21)NAXT-X-2003ZZZZ GS1 DataMatrix for Unique Identification (01) Global Trade Item Number (11) Date of Manufacture (21) Serial Number	Importer (3725)[4]: Indicates the entity that imports the medical device.	

1. EN ISO 15223-1 Medical Devices – Symbols to be used with medical device, labels, labelling and information to be supplied – Part 1: General Requirements.
2. CAN/CSA-C22.2 No. 60601-1:14 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
3. BS EN ISO:2012+A6:2016 Graphic symbols – Safety colours and safety signs – Registered safety signs (ISO 7010:2011).
4. ISO 7000:2014 – Graphic Symbols for Use on Equipment – Registered Symbols.
5. IEC 60417 – Graphic Symbols for Use on Equipment.

NOTE: Sterility symbols are applicable to consumbale devices only. Refer to consumable device instructions for use for complete symbol and instructional overview.

Table 39: Symbols Glossary

PRODUCT LABELS

- Device label can be found on the cart leg:

APPENDIX C. ELECTROMAGNETIC COMPATIBILITY (EMC)

This equipment has been tested and found to comply with the limits for:

IEC 60601-1-2:2014 (Ed4.0)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 61000-3-2:2009	Limits for harmonic current emissions (equipment input current =16 A per phase)
IEC 61000-3-3:2013	Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current =16 A per phase and not subject to conditional connection
IEC 61000-4-2:2008	Testing and measurement techniques –Electrostatic discharge immunity test
IEC 61000-4-3:2010	Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test. Ed 3.2.
IEC 61000-4-4:2012	Testing and measurement techniques – Electrical fast transient/burst immunity test
IEC 61000-4-5:2005	Testing and measurement techniques - Surge immunity test
IEC 61000-4-6:2003+A1:2004+A2:2006	Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields
IEC 61000-4-8:2009	Testing and measurement techniques – Power frequency magnetic field immunity test
IEC 61000-4-11:2004	Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests
CISPR 11:2010	Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement
CISPR 22:2008	Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement

To prevent Bluetooth disconnection, limit the wireless interference from other devices or equipment, like microwaves, Wi-Fi, cordless/wireless technology at 2.4 GHz.

1. *These limits are designed to provide reasonable protection against harmful electromagnetic or other interference in most installations. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful electromagnetic or other interference, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:*
    - *Reorient or relocate **AQUARIUS®** unit.*
    - *Increase the separation between **AQUARIUS®** unit and the affected equipment.*
    - *Connect the non-medical system equipment into an outlet on a circuit different from that to which the **AQUARIUS®** unit is connected.*
    - *Consult the dealer or experienced technical personnel for help.*

WARNING! Changes or modifications not expressly approved by LABORIE could void the user's authority to operate the equipment.

2. *This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.*
3. *This device contains: **FCC ID: PVH0946 IC: 5325A-0946.***

Table 40: Electromagnetic Compatibility

IEC 60601-1-2:2014 Table 1 Requirements

The Aquarius Urodynamic Analyzer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Aquarius Urodynamic Analyzer System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The Aquarius Urodynamic Analyzer System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Aquarius Urodynamic Analyzer System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning**: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re- orienting or relocating the Aquarius Urodynamic Analyzer System or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Table 41: Electronic Emissions

IEC 60601-1-2:2014 Table 2 Requirements:

The Aquarius Urodynamic Analyzer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Aquarius Urodynamic Analyzer System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±2kV, ±4kV, ±8 kV and ±15kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100 % dip in U_T) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 70% U_T (30% dip in U_T) for 25 cycles 0% U_T (100% dip in U_T) for 5 seconds	<5% U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Aquarius Urodynamic Analyzer System requires continued operation during power mains interruptions, it is recommended that the Aquarius Urodynamic Analyzer System be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 42: Electromagnetic Immunity

IEC 60601-1-2:2014 Table 4 Requirements:

The Aquarius Urodynamic Analyzer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Aquarius Urodynamic Analyzer System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms for ISM bands.	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Aquarius Urodynamic Analyzer System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{p}$ 150kHz to 80Hz $d = 1.17\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2.7 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710/745/78 0 MHz 28 V/m 810/870/93 0 MHz 28 V/m 1720/1845/ 1970 MHz 28 V/m 2450 MHz 9 V/m 5240/5500/ 5785 MHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a)Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Aquarius Urodynamic Analyzer System is used exceeds the applicable RF compliance level above, the Aquarius Urodynamic Analyzer System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Aquarius Urodynamic Analyzer System b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 43: Electromagnetic Immunity – Radio Frequency Communications

IEC 60601-1-2:20014 Table 6 Requirements:

Recommended separation distances between portable and mobile RF communications equipment and the Aquarius Urodynamic Analyzer System

The Aquarius Urodynamic Analyzer System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Aquarius Urodynamic Analyzer System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aquarius Urodynamic Analyzer System as recommended below, according to the maximum output power of the communications equipment.

⚠ WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Aquarius system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter** (m)		
	150 kHz to 80 MHz $d = 1.17\ \sqrt{p}$	**80 MHz to 800 MHz** $d = 1.17\ \sqrt{p}$	**800 MHz to 2.5 GHz** $d = 2.33\ \sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 44: Separation Distances

APPENDIX D. COMMONLY USED TEST CONFIGURATIONS

Test Name	Channel Titles	Scale	Math Definition	Data Rate	Display Attribute
Uroflowmetry	Flow	40ml/s	Null	5points/s	Graphical
	Volume	600ml	Null	5points/s	Graphical
Cystometry with EMG	Pves	100cmH2O	Null	5points/s	Graphical
	EMG	400(none)	Null	5points/s	Graphical
	IH2O	200ml/min	Null	5points/s	Graphical
	VH2O	1000ml	Null	5points/s	Graphical
Advanced CMG	Pves	100cmH2O	Null	4point/s	Graphical
	Pabd	100cmH2O	Null	4point/s	Graphical
	Pdet	100cmH2O	PvesPabd	4point/s	Graphical
	EMG	400(none)	Null	4point/s	Graphical
	IH2O	200ml/min	Null	4point/s	Digital
	VH2O	1000ml	Null	4point/s	Digital
Simple Pressure/Flow	Pves	100cmH2O	Null	3points/s	Graphical
	Flow	40ml/s	Null	3points/s	Graphical
	Volume	1000ml	Null	3points/s	Graphical
Advanced Pressure/Flow	Pves	100cmH2O	Null	3points/s	Graphical
	Pabd	100cmH2O	Null	3points/s	Graphical
	Pdet	100cmH2O	PvesPabd	3points/s	Graphical
	Flow	40ml/s	Null	3points/s	Graphical
	Volume	1000ml	Null	3points/s	Digital
	IH2O	200ml/min	Null	3points/s	Digital
	VH2O	1000ml	Null	3points/s	Digital
	EMG	400(none)	Null	3points/s	Graphical
UPP	Pura	150cmH2O	Null	5points/s	Graphical
	Pves	150cmH2O	Null	5points/s	Graphical
	Pclo	150cmH2O	PuraPves	5points/s	Graphical

Table 45: Test Configurations

APPENDIX E. APPENDIX E. GLOSSARY OF TERMS AND ACRONYMS

TERMS[xxxii] USED IN URODYNAMICS TESTING


Notations in italics indicate usage specific to LABORIE's Urodynamic testing protocols.

- abdominal pressure: (Pabd) the pressure surrounding the bladder, usually measured via rectum or vagina.
    - *Standard channel on CMG or pressure/flow studies, measured in cmH2O.*
- abdominal leak point pressure: (ALPP) the intravesical pressure at which there is leakage of fluid from the bladder caused by increasing abdominal pressure by straining or coughing. ALPP less than 60cmH2O pressure is considered intrinsic sphincter dysfunction. ALPP greater than 90cmH2O pressure can indicate urethral hypermobility, and shows a low risk of intrinsic sphincter dysfunction.
    - *Standard annotation in Event Menu, often on Control Panel.*
- acontractile detrusor: (formerly arreflexic bladder) absence of detrusor contraction under Urodynamic evaluation.
- area under the curve: a calculation of the area contained by the curve of a urethral pressure profile.

- bladder pressure: (Pves, intravesical pressure) pressure within the bladder.
    - *standard channel on CMG, pressure/flow, or UPP tests, measured in cmH2O.*

- calibration: "checking calibrations" -verifying the accuracy of measurements.
- recalibrate: a procedure to correct or improve the accuracy of measurements.
- capacity: notation of the sensation at which the patient feels he/she can no longer delay voiding. This is the point at which permission to void is given.
    - *Standard annotation in Event Menu, often placed on the Control Panel.*
- closure pressure: (Pclo) the calculated value that reflects the difference between urethral pressure and bladder pressure. Pura–Pves=Pclo. Pclo less than 20cmH2O pressure can indicate intrinsic sphincter dysfunction.
    - *Standard channel in a UPP test, measured in cmH2O.*
- cystometrogram: (CMG) the graphical recording of bladder pressures. Most commonly used to refer to general Urodynamic studies.
    - *Standard will include Pves, Pabd, Pdet, EMG and display volume infused and infusion rate.*

- detrusor: muscle layer surrounding bladder.
- detrusor leak point pressure: detrusor pressure at which urine leakage occurs.
    - *in the absence of either a detrusor contraction OR increased abdominal pressure.*
    - Most often seen in neurologically impaired patients such as spinal cord injury. DLPP greater than 40cmH2O pressure can lead to upper urinary tract damage.
- detrusor overactivity: characterized by involuntary detrusor contractions during the filling phase of Urodynamics – either spontaneous or provoked.
- detrusor overactivity incontinence: incontinence as a result of involuntary detrusor contraction.
- detrusor pressure: (Pdet) the calculated pressure measurement reflecting that component of total intravesical pressure that is generated by the detrusor muscle. Pves-Pabd=Pdet.
    - *Standard on CMG or pressure/flow tests, measured in cmH2O.*

- electromyogram: the measurement of nerve activity – in Urodynamics to monitor sphincter muscle activity.
- enuresis: involuntary loss of urine, usually subcategorized as nocturnal enuresis meaning involuntary loss of urine during sleep.

- filling phase: (storage phase) often used to describe the CMG portion of a Urodynamic examination, this phase ends prior to voiding.
- filling rate: the recommendation by ICS is greater than the predicted maximum filling rate (calculated at body weight in kg divided by 4). Defined as between 10100ml/min, the typical filling rate during Urodynamics with adults is 50-60ml/min.
    - *Usually displayed as a digital channel during CMG or pressure/flow tests, measured in ml per minute.*
- first desire to void: during Urodynamics, the feeling that would lead the patient to pass urine at the next convenient moment, but voiding can be delayed.
    - *Standard annotation in Event Menu, often on Control Panel.*

- first sensation of filling: during Urodynamics, the feeling when he/she is first aware of bladder filling. The reported sensation of "coldness" (secondary to room temperature infused fluid) is not usually considered the first sensation.
    - *Standard annotation in Event Menu, often on Control Panel.*
- frequency: the complaint of voiding too often by day.
- functional profile length: the length of the urethra along which the urethral pressure exceeds bladder pressure
    - *calculated within a UPP segment, displayed in mm, as length of continence zone.*

- hesitancy: difficulty initiating voiding.

- idiopathic detrusor overactivity: (formerly "detrusor instability") incontinence due to an involuntary detrusor contraction with no defined cause.
- incompetent urethral closure mechanism: when the urethra allows leakage of urine in the absence of a detrusor contraction.
- incontinence: the involuntary loss of urine. May be further defined as: stress incontinence, urge incontinence, mixed (both stress and urge) incontinence, nocturnal enuresis, and situational incontinence.
- International Continence Society: (ICS) "The primary interest of the International Continence Society is to study storage and voiding function of the lower urinary tract, its diagnosis and the management of lower urinary tract dysfunction, and to encourage research into pathophysiology, diagnostic techniques and treatment." This group sets standards for Urodynamic testing followed by Laborie Medical Technologies ULC's training programs.
- intravesical pressure: (Pves) pressure measured within the bladder. Note that pressure within the bladder can come from two sources – pressure from the body (Pabd) and pressure from the muscle surrounding the bladder (Pdet). Formerly known as "total intravesical pressure".
    - *Standard channel on CMG, pressure/flow, and UPP tests, measured in cmH2O.*
- intrinsic sphincter dysfunction: (ISD) is usually indicated by maximum urethral closure pressure less than 20cmH2O pressure, or ALPP less than 60cm H2O pressure.

- leak point pressure: (LPP, ALPP, VLPP, CLPP) the intravesical pressure at which involuntary urine leakage in noted during increased abdominal pressure, in the absence of a detrusor contraction. Ex: leakage noted during Urodynamics when patient is asked to cough or bear down. This can be notated with the modifier of A for abdominal, V for Valsalva, or C for cough, but all are technically "leak point pressures".
    - *Referred to in cmH2O pressure.*
- lower urinary tract symptoms: (LUTS) these may include frequency, urgency, incontinence, nocturia, recurrent urinary tract infections, and many others.

- maximum cystometric capacity: (capacity) the volume at which the patient can no longer delay voiding. During Urodynamics, this is usually the point at which permission to void is given.
    - *Measured in ml, this is a standard annotation in Event Menu, often on Control Panel.*
- maximum urethral closure pressure: (MUCP) the maximum difference between urethral pressure and intravesical pressure. During Urodynamics, this is measured on the Pclo channel, and can be recorded independently or during a urethral pressure profile.
    - *Measured in cmH2O.*
- maximum urethral pressure: (MUP) maximum pressure of the measured profile.
    - *Measured in cmH2O.*
- micturition study: a pressure/flow study. This study includes pressure measurements such as Pves and Pabd as well as Uroflow measurements. This allows documentation of the relationship between the pressure generated during the voiding event and the resultant flow rate and pattern.

- neuropathic detrusor overactivity: (formerly hyperreflexia) detrusor overactivity where there is a relevant neurological condition.
- nocturia: complaint that patient must wake one or more times to void.
- nocturnal enuresis: the complaint of loss of urine during sleep.
- normal detrusor function: allows bladder to fill with little or no change in pressure, with no involuntary contractions despite provocation.

- permission to void: annotation placed at time of reported sensation of bladder capacity, recommended by ICS to document when patient was told to allow voiding. This helps differentiate between contractions that are involuntary, and contractions that are voluntarily generated to initiate voiding.

- phasic detrusor overactivity: a characteristic wave form, which may or may not lead to incontinence post-void residual: (PVR) the volume of urine left in the bladder after voiding.
- pressure/flow study: (Micturition study) a Urodynamic study that includes pressure measurements such as Pves and Pabd as well as Uroflow measurements. This allows documentation of the relationship between the pressure generated during the voiding event and the resultant flow rate and pattern.
    - *Standard will include: Pves, Pabd, Pdet, EMG, Flow, Volume voided, and digital display of volume infused and infusion rate.*
- pump rates: using the pump, the rate at which fluid is infused into bladder during Urodynamic testing.
    - *See" filling rate" for recommendations.*

- sensation: in Urodynamics, the reported sensations during testing such as first sensation, first desire, strong desire, and sense of reaching bladder capacity.
    - *These are recorded as annotations, in the Event Menu and usually on the Control panel.*
- stress urinary incontinence: (SUI) the symptom of a loss of urine associated with exertion, often with cough or sneeze. This is considered a complaint unless proven through urodynamics, when it then is known as Urodynamic stress incontinence (formerly genuine stress incontinence).
- strong desire to void: described as the persistent desire to void without fear of leakage.
- subtracted pressure: usually referring to the difference between total intravesical pressure and abdominal pressure – Pdet.
    - *Pves-Pabd=Pdet.*

- terminal detrusor overactivity: a single involuntary detrusor contraction occurring at capacity, which cannot be suppressed and results in incontinence, usually resulting in emptying of bladder.
- total profile length: not generally accepted as a useful parameter. This is the length of the urethra measured from where the sensor enters the urethra to where the sensor exits the body.

- uninhibited: acting without conscious inhibition – often used to describe a bladder contraction which the patient is unable to suppress.
- urethra: the tube leading from the bladder to the outside of the body.
- urethral pressure: (Pura) the pressure needed to just open a closed urethra.
    - *Measured in cmH2O.*
- urethral pressure profile: (UPP) the pressures recorded throughout the length of the urethra, measured by withdrawing the catheter at a slow known rate (recommended: 1mm/sec). Most accurately done using a mechanical puller.
    - *Standard will include: Pves, Pura, and Pclo.*
- urethral relaxation incontinence: leakage due to urethral relaxation in the absence of raised abdominal pressure or a detrusor contraction.
- urgency: a sudden, compelling desire to void.
    - *If reported during Urodynamic testing, this can be annotated.*
- urge incontinence: symptom of incontinence associated with a strong compelling desire to void.
- Urodynamic stress incontinence: (formerly genuine stress incontinence, SUI, or stress incontinence) the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction.

- valsalva: the attempt to forcibly exhale with a closed glottis – often used to increase intra-abdominal pressure.
    - *Used to provoke stress incontinence, can be annotated as VLPP.*
- voiding phase: (emptying phase) often used to describe the portion of a Urodynamic evaluation that records both pressures and flow parameters during a voiding event, this would immediately follow the "filling phase".

ABBREVIATIONS

Common abbreviations used in this manual:

- CHC: Central Hub Computer
- CFG: software configuration file
- HMI: Human Machine Interface

CALCULATIONS

- BOOI = pdetQmax – 2Qmax[xxxiii]
- BCI = pdetQmax + 5Qmax[xxxiii]
- BVE = (VV/BC) x 100[xxxiii]

COMMON URODYNAMICS ACRONYMS

- ALPP: Abdominal leak point pressure
- BOOI: Bladder outlet obstruction index[xxxiii]
- BCI: Bladder contractility index
- BVE: bladder voiding efficiency
- CLP: Cough leak point pressure
- CMG: Cystometrogram
- DLPP: Detrusor leak point pressure
- DSD: Detrusor sphincter dyssynergia
- EMG: Electromyogram
- FUL: Functional urethral profile length
- ICS: International Continence Society
- IH2O: Rate of fluid infusion during
- ISD: Intrinsic sphincter dysfunction (or deficiency)
- LinPURR: linear passive urethral resistance (*Nomogram available in UDS software*)
- LPP: Leak point pressure
- LUTS: Lower urinary tract symptoms
- MCC: Maximum cystometric capacity
- MUCP: Maximum urethral closure pressure
- MUP: Maximum urethral pressure
- NGB: Neurogenic bladder Pabd Abdominal pressure
- Pabd: Abdominal pressure
- Pclo: Closure pressure
- Pdet: Detrusor (or subtracted) pressure
- Pura: Urethral pressure
- Pves: Intravesical pressure
- PVR: Post-void residual
- SUI: Stress urinary incontinence
- UDC: Uninhibited detrusor contraction
- UPP: Urethral pressure profile
- URA: Urethral resistance factor - Nomogram
- VH2O: Volume infused during CMG
- VLPP: Valsalva leak point pressure
- VS: Valsalva
- VUR: Vesico-ureteral reflux

APPENDIX F. APPENDIX F: ARM VALUES

MEAN VALUES RANGE[xxxiv]

Degree of Continence	Number of Patients (F:M)	Resting Pressure (mmHg)	Squeeze Pressure (mmHg)	Rectal Sensory Volume (mL)	Volume for Reflex Relaxation
Complete incontinence	39 (35/4)	51 (20-100)	88 (36-200)	31 (5-120)	18 (10-50)
Partial incontinence	89 (72/17)	62 (18-144)	123 (0-420)	27 (5-23)	20 (5-50)
Seepage and soilage	42 (24/18)	62 (18-169)	178 (0-395)	40 (10-100)	21 (0-60)
Normal (controls)	**35 (19/16)**	**88 (43-164)**	**204 (62-380)**	**19 (5-60)**	**19 (10-40)**
Chronic constipation	41 (30/11)	88 (30-139)	173 (60-390)	43 (10-120)	25 (10-50)

Table 46: Arm Values – Mean Values Range

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