

Goby



Owner's Manual

Operation, Care, and Maintenance



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CANADA



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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 aid 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

LABORIE's **Goby™** system is a simple and easy-to-use Urodynamic Analyzer system. **Goby™** gives patients the freedom to move with less cables/wires and smaller testing devices.

For warranty information and terms and conditions, visit www.laborie.com

1.1 GETTING STARTED

To prepare the **Goby™** system before performing any Urodynamics procedures:

1. Set up the system hardware. (see page 15)
2. Configure test files (if necessary). (see page 38)
3. Turn on components and any other accessories.
4. Start the Urodynamics procedure(s).

1.2 LEARNING ABOUT THE GOBY™ SYSTEM

To learn about the features and how-to of the **Goby™** system, read the following documents or sections of this manual:

- **Goby™** quick start guide (provided with the equipment shipment and on the software disc.)
- Software features and functions (Refer to the [Software Features and Functions](#) section on page 31)
- How to perform Urodynamics tests with the **Goby™** (see pages 80 to 83)

1.3 INTENDED USE

The **Goby™** system is a Urodynamic Analyzer system that is intended to quantify the pressure, flow and EMG characteristics of the lower urinary tract. Using the available transducers, the system can be used for performing standard Urodynamic tests such as Uroflow, CMG, UPP, and Micturition studies.

The major application of Urodynamics is the diagnosis of uncontrolled loss of urine (incontinence), abnormal urinary retention, or neurological cases of Micturition disorder. The device is intended to be used as medical diagnostic equipment.

1.4 CONTRAINDICATIONS



The **Goby** 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 or strictures in the urethra.

Single-use, disposable catheters provided by LABORIE are "sterile", unless stated otherwise on the packaging label and instructions. Prior to testing, a urinalysis and urine culture should be considered to rule out the presence of infection.

Reusable catheters are cleaned but not sterilized before shipping.

1.5 TARGET USERS

1. Only technicians and physicians 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.
2. To reduce the potential for discomfort during the procedure and/or transient discomfort, dysuria and hematuria, technicians and physicians should explain any additional risks of the procedure to the patient.
3. 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*. Physicians must monitor patients with Autonomic Dysreflexia at least 2 hours after resolution of the episode.
4. To reduce the risk of cross-contamination or urinary tract 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.
5. 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 TDOC IFU (*TDOC-UM01*).

1.6 WARNINGS AND PRECAUTIONS

PRECAUTIONS:

1. LABORIE equipment and accessories are licensed by Governments, approved by Safety Agencies and warranted to work only with each other.
2. Do not exceed the maximum load marked on the adjustable shelf of 2 kg and the static shelf of 10kg.

CAUTION:

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

SYSTEM WARNINGS:

READ CAREFULLY BEFORE USE!

1. **DO NOT USE** in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
2. **DO NOT USE** electromyography (EMG) simultaneously with high frequency surgical equipment.
3. **DO NOT** operate the Goby System near shortwave or microwave therapy equipment as proximity may produce instability in the APPLIED PARTS.
4. **DO NOT** allow applied parts linked to a PATIENT CONNECTION, but no connected to the PATIENT, to contact other conductive parts including those connected to protective earth. Preserve the patient connection electrical isolation.
5. **DO NOT** place your fingers inside the pump head when the pump rollers are moving.
6. **DO NOT USE** the **Goby™** in the presence of a magnetic resonance imaging system as it 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.
7. **DO NOT ATTEMPT TO OPEN OR REPAIR** the **Goby™** system components by yourself or by an unauthorized party. ONLY LABORIE-trained technicians may service the **Goby™** system components.
8. Do not clean or service the **Goby™** System or components while in use with a patient.
9. Batteries are not operator removable; do not attempt to remove batteries from the **Goby™** system components. All servicing of **Goby™** system, components or attachments to be completed by LABORIE.
10. Exposure to ESD may cause the system to RESET.
11. LABORIE is not responsible for loss of patient files or test data. LABORIE is strongly recommended to back up patient data on a regular basis.
12. Ensure all castor wheels are locked during testing procedures to prevent injury to the patient. **DO NOT** lean anywhere on the system or its devices. The devices are not designed to support the weight of a person.
13. To prevent possible injury to the patient, always use the UPP puller with the UPP puller adaptor.
14. Re-use, reprocessing or re-sterilization 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. **DO NOT** immerse the **Goby™** equipment or any components in water or any other liquids.
16. Always position the **Goby™** to facilitate ease of access to all electrical connections and plugs. The device operator must be able to disconnect the device in case of emergency quickly and safely.
17. To avoid the risk of electric shock, only connect this equipment to supply mains with protective earth.
18. Only connect devices specified and approved by LABORIE to **Goby™** 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.
19. Avoid altering or adding to the **Goby™** medical electrical system. Any alteration to the **Goby™** 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.
20. Do not place the printer in the patient environment unless it is powered via the LABORIE provided Line Isolation Transformer (Separating transformer).
21. Only connect items that have been approved by LABORIE to the system. Any additional connections become the responsibility of the operator and require testing to meet the IEC 60601-1, ME SYSTEMS requirements.
22. 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).
23. Do not touch the printer/laptop and the patient simultaneously.

SYSTEM IMPORTANT INFORMATION

1. Use the **Goby™** with LABORIE equipment and accessories only. Do not reuse disposable devices. After use, dispose in accordance with local regulations. 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.
2. The built-in pump is designed for use with water, saline or hypaque solutions only.
3. To prevent cross-contamination, waist belts and lanyards are made of machine washable materials and should be washed with hot water and dried between uses.
4. To prevent the IV pole from dropping when mounted on the cart, ensure the pole is installed securely into the pole mount and ensure the locking mechanism is securely fastened in place.
5. Be aware that prolonged use of video capture may result in elevated temperatures at the rear of the AIO PC.
6. Device intended for use in a clinical environment with controlled EMC standards to limit potential interference. **Goby™** 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.

SYSTEM SAFETY COMPLIANCE

1. To prevent unexpected exposure to radiation, the device has been tested against EN 60601-1-2 EMC standards.
2. To prevent exposure to potential electric shock, the device meets and exceeds the insulation breakdown specifications for EN 60601-1, EN 60601-1-2 EMC standards & CSA 22.2 medical standards.
3. Warning symbols on all labels comply with EN ISO 15223-1 and EN 1041.
4. To prevent external injuries, patients and equipment operators are protected from moving parts of the pump roller head by limiting the torque of the motor.

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 GOBY™ SYSTEM – CARE AND MAINTENANCE


2.1 GENERAL CARE, CLEANING, AND PREVENTIVE MAINTENANCE

IMPORTANT:

- Always wear protective gloves when cleaning the equipment to prevent biological contamination.
- **EMG electrodes, tubing, disposable catheters, and transducer cartridges are intended for SINGLE PATIENT USE only. Do NOT re-use disposables.**
- The **Goby™** system is **non-immersible**. The system including the **Urocap™ IV** and the **Goby™ Hub** should be wiped down with a clean cloth dampened with a cleaning solution such as soap and water or as per hospital cleaning instructions. Refer to the [Caring for the UDS Roam](#) section on page 8 for a reagents list applicable to cleaning the **UDS Roam™**.
- Do not sterilize the **Goby™** system components.
- Performing regular maintenance will reduce the need for costly repairs. Check all transducer calibration of the **Goby™** every 6 months or whenever you suspect the transducers are out calibration.

Pay close attention to the LED lights on each device. If they indicate a broken connection and/or low battery, make sure that the connection is re-established and fully charge the battery. Refer to the [LED Lights](#) section on page 27.

2.1.1 Caring for the UDS Roam

 **IMPORTANT:** The **UDS Roam** is **not immersible**. Wipe the outside of the device with soap and water or with a hospital-grade disinfectant from the compatibility list below. **DO NOT SPRAY CLEANING REAGENTS DIRECTLY ON OR IN THE UDS ROAM.**

The UDS Roam is compatible with the following cleaning and disinfection reagents:

- Hypochlorite wipes (Clorox or equivalent)
- QUAT wipes (Sani-Cloth or equivalent)
- Hydrogen Peroxide wipes (Diversey Oxivir Tb or equivalent)
- Aldehyde wipes (Kohrsolin FF or equivalent)
- Isopropanol 70%

Ensure the reagents are used for at least the contact time stated in the reagent instructions. Do not use reagents for more than twice the stated contact time.

NOTE: LABORIE recommends charging and using the **UDS Roam™** 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.

The UDS Roam can be set up for use with a patient using a waist belt, lanyard, or holster. To prevent cross-contamination, waist belts and lanyards are made of machine washable materials that should be washed with hot water and dried between uses. The holster can be cleaned with standard hospital wipes.

To check if the **UDS Roam™** is functioning correctly, refer to the [Check the UDS Roam™](#) section on page 12.

2.1.2 Caring for the Urocap™ IV Uroflowmeter

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

! **IMPORTANT:** Do not soak the Urocap™ IV in water! Do not immerse in water or in any other liquids!

- The Urocap™ IV Uroflowmeter has an immersion protection rating of IP54 for ingress of water. This means that the enclosure of the Uroflowmeter can handle splashes of water and liquid from any direction, but it is not protected against total immersion into water or any other liquids. This complies with IEC 60529 standards.
- Never soak or immerse the Urocap™ IV in water or any other liquids (Figure 1).

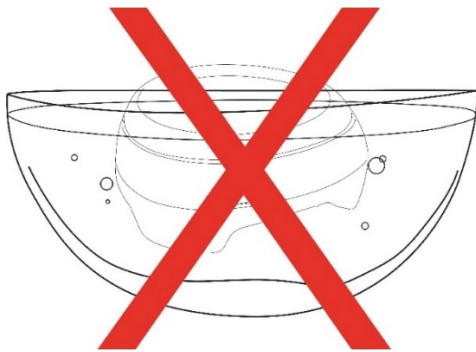


Figure 1: Do not Immerse

- The lid of the **Urocap™ IV** is not removable.
- The **Urocap™ IV** should be cleaned using a damp cloth with alcohol, soap, or disinfectant detergent (Figure 2).

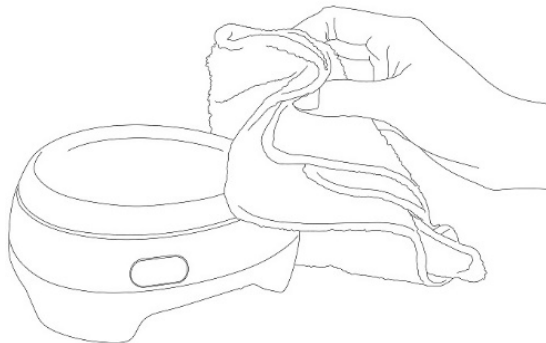


Figure 2: Cleaning the Urocap™ IV

- Store the **Urocap™ IV** in a cool and dry area at room temperature. Refer to the [Specifications](#) section on page [101](#).
- After each use rinse the Uroflow beaker. Soap and water, or a mild detergent solution can be used for cleaning. **NOTE:** Although the beaker is reusable, it will discolor over time and may need to be replaced.

To check if the **Urocap™ IV** is functioning correctly, see the [Check the Flow and Volume of the Uroflowmeter](#) section on page [11](#).

2.1.3 Caring for the Goby™ Hub

Before beginning cleaning procedure, disconnect the **Goby™ Hub** from power, stop the pump, power off the unit, and disconnect the pump cable.

Wipe the **Goby™ Hub** with a clean cloth dampened with water and mild detergent. Ensure to remove pump tubing from the pump and dispose at the completion of each test. If fluid spills in the pump head, use a mild solution of detergent and water to clean the pump. Remove the pump door from the pump head and wash both sections thoroughly. The pump can be removed from the **Goby™ Hub** by turning the pump head counterclockwise 45° and sliding the pump forward; place safely aside. Reassemble any disassembled parts and store the **Goby™ Hub** in a cool and dry area at room temperature. Refer to the [Specifications](#) section on page 101.

WARNING:

- Do not use strong detergent reagents as they may damage the surface finish of the pump's metal and plastic casing.
- Do not immerse the **GOBY™ Hub** or its pump head in cleaning solution.
- Do not use excessive force when removing the pump door. Once removed from the pump head place the pump door safely aside. Dropping the pump door may cause scratches and damage.
- The tubing set which is used with the pump system during Urodynamic measurements is intended for *single use only*. It should not be cleaned and reused.

To check if the pump is functioning properly, see the [Check the Pump](#) section on page 11.

2.1.4 Caring for the Cart and its Components

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.

2.1.5 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. 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 steps should be performed **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, MSRA, MSRE, Pseudomonas and Mycobacterium.
- Wipe the transducer/cable until dry.

To check if the pump is functioning properly, see the [Check the Pump](#) section on page 11.

2.2 BATTERY - CHARGING AND PREVENTATIVE MAINTENANCE

2.2.1 Charging the Battery

The **Urocap™ IV** and the **UDS Roam™** each contain rechargeable batteries. The battery status is visible in the Device Manager. For information on battery status messages, see the [Equipment Status Indicators and Buttons](#) section on page 27.

- To charge the **Urocap™ IV** plug one end of the power supply cord into the device and the other end into an electrical outlet.
- To charge the **UDS Roam™**, place the **UDS Roam™** securely into the **Goby™ Hub**. Ensure that the **Goby™ Hub** is connected to a power source. Plug one end of the power supply cord into the bottom of the **Goby™ Hub** and the other end into an electrical outlet. Switch the **Goby™ Hub** ON with the power switch at the bottom. Use Input and Output Cables and Cords provided by LABORIE only.

NOTE:

- It will take approximately 5 hours to fully charge the devices.
- When the LED light on the device is green it is fully charged.
- The equipment can still be used while charging.
- When placed in the Hub the UDS Roam will show an increase in EMG noise.

2.2.2 Battery - Preventative 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.

2.3 COMPUTER VIRUS PROTECTION

All computers purchased from LABORIE are virus-free before shipment and are installed with the Norton™ 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.

2.4 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.

2.5 ENVIRONMENTAL CONSIDERATION OF WASTE DISPOSAL

Since the **Goby™** System is designed to perform Uroflow studies using the **Urocap™ IV**, 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. In areas that have sewage systems with water treatment procedures, the most convenient means of disposal is to use these sewage systems.

2.6 PREVENTIVE MAINTENANCE – CHECKING CALIBRATION

Performing regular maintenance will reduce the need for repairs. Check the transducer calibration every 6 months or whenever you suspect the transducers are out of calibration. If the Uroflowmeter, the pump, the **UDS Roam™**, the EMG, the pressure transducers, the UPP puller, and/or the Infusion Transducer appear to be giving incorrect readings, try the following checkups before attempting to calibrate the system.

2.6.1 Check the Flow and Volume of the Uroflowmeter

2.6.1.1 Check Volume

1. Open the UDS120 **Goby™** 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.*** Contact LABORIE service for assistance if problems continue after the calibration and re-check.

2.6.1.2 Check Flow

1. Open the UDS120 **Goby™** 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.

2.6.2 Check the Pump

Some reminders before pump check-up:

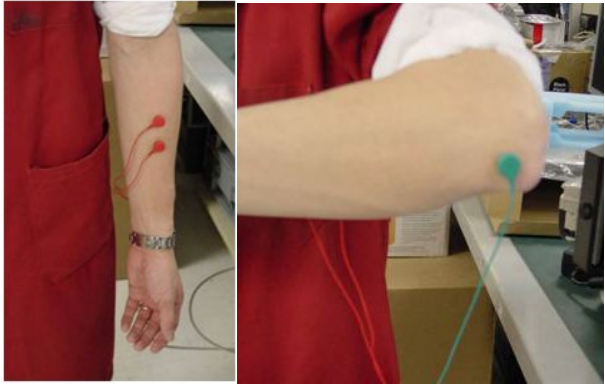
- If contrast is used for testing procedures it should also be used for check-up and calibration procedures.
- Use only LABORIE recommended and approved tubing for accurate readings and measurements.
 1. Prime the pump tubing.
 2. Set up the pump tubing with catheter to pump into an empty beaker.
 3. Open the UDS120 **Goby™** 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.

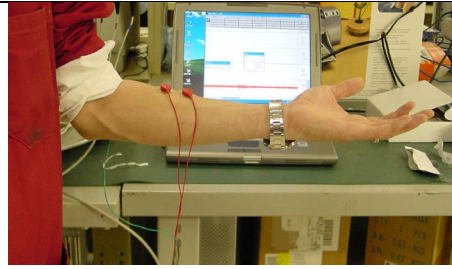
2.6.3 Check the UDS Roam™

2.6.3.1 Check the EMG

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

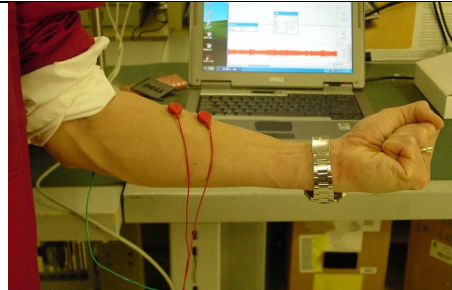
<ol style="list-style-type: none"> 1. Open the UDS120 Goby™ software and start a sample test with an EMG channel. 2. Place two EMG electrodes, 1 inch apart, on your forearm (where the muscle flexes the most) and the third EMG patch on the elbow of the same arm. 3. Keep your arm relaxed, palm open, and fully extended. You will notice minimal EMG activity. 	 <p style="text-align: center;">EMG Placement</p>
<ol style="list-style-type: none"> 4. Keep your palm open flex the arm slightly until it reached a 45-degree angle. Hold the position to keep it at a constant rate. You will notice an increase in activity on the EMG channel. 	<p style="text-align: center;">at 50% strain</p>

- Keep palm open and flex arm to a 90 degree angle, until it is parallel to the floor. You will notice more activity on the EMG channel.



at 100% strain

- Keeping your arm in the 90 degree position, clench your fist. You will see an increase in EMG activity on the EMG channel.
- Unclench your fist and return arm to the fully extended position.
- Check the EMG channel for activity.



at 100% strain with full contraction

A sample reading can be seen here:

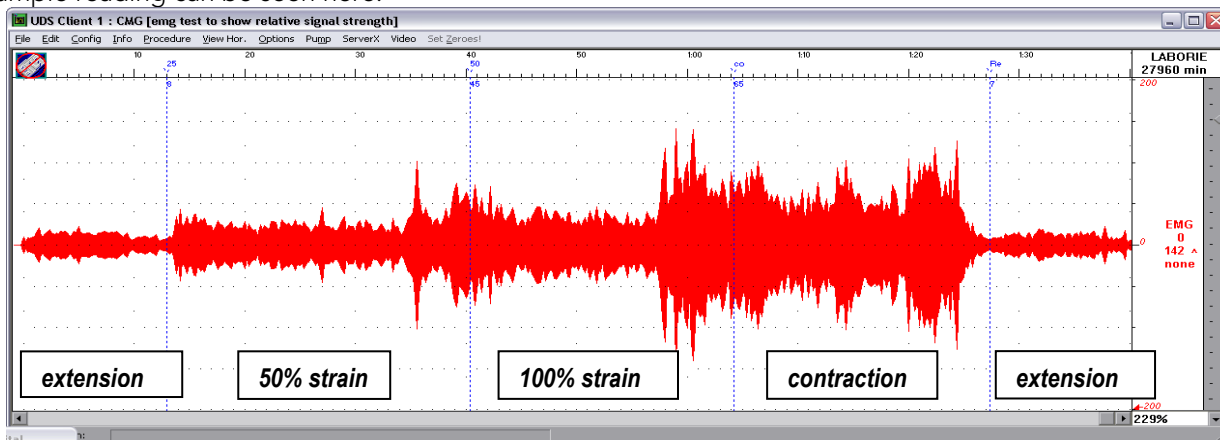


Figure 3: EMG Chanel during Check

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.

2.6.3.2 Check the Pressure Transducers Using T-DOC™

- Connect the T-DOC™ Reusable Cable to the UDS Roam™.
- Switch the charger on the T-DOC to the **OPEN** position.
- Connect the catheter to the charger and gently squeeze the balloon on the catheter to expel any air in the balloon.
- Switch the charger to the **CHARGE** position.
- Fill a standard graduated beaker with 1000ml of water.
- Open the UDS120 Goby™ software and start a sample test with pressure channels.
- Click **Set Zeroes**.
- 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 cmH₂O.
- 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.
- 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 cmH₂O (+/- 2 cmH₂O). If the reading is above or below the 2 cmH₂O 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.

2.6.3.3 Check the Pressure Transducers Using Water Catheters

1. Setup the water transducers as described in [Fluid-Filled Pressure Transducer Setup](#) section on page 20.
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 cmH₂O (+/- 2 cmH₂O). If the reading is above or below the 2 cmH₂O 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.

2.6.4 Check the Infusion Transducer

2.6.4.1 Check the Infusion Transducer Using the Uroflowmeter

Ensure the Uroflowmeter is checked and calibrated before following the instructions below to check the Infusion Transducer. To check the Uroflowmeter, see the [Check the Flow and Volume of the Uroflowmeter](#) section on page 11.

1. Place a full infusion bag on the infusion transducer.
2. Place an empty beaker on the Uroflowmeter.
3. Open the UDS120 **Goby™** 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 measured in the Uroflowmeter and that of the volume displayed on screen, 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.

2.6.4.2 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.

2.6.5 Check the UPP Puller

1. With a pencil, mark two points 50mm apart along the UPP puller shaft.
2. Open the UDS120 **Goby™** 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 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 repeating the instructions provided above.** Contact LABORIE service for assistance if problems continue after the calibration and re-check.

3 SET UP GOBY™ EQUIPMENT AND ACCESSORIES

Check that all ordered equipment and accessories have been received. 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 has been found. LABORIE recommends saving carrying cases and cartons to provide a convenient and safe way to return the equipment should service be required.

3.1 EQUIPMENT CHECKLIST

The main components of the **Goby™** system are the **Urocap™ IV** Uroflowmeter, the **UDS Roam** pressure recorder, and the **Goby™** Hub. The following are required to setup the **Goby™** system for Urodynamics:

Standard Equipment

- ✓ UDS Roam™ (wireless battery-powered pressure and EMG measurement device)
- ✓ Urocap IV (Wireless Uroflowmeter)
- ✓ **Goby™** Hub (Wireless pump and UDS Roam docking station)
- ✓
- ✓ Power supplies
- ✓ Power cables
- ✓ Catheters (air-charged or fluid-fill)
- ✓ Beakers
- ✓ Commode chair and funnel
- ✓ EMG gel patch electrodes
- Software disc, quick start guide, configuration guide, and owner's manual

Optional Equipment

- ✓ Laptop
- ✓ Infusion Transducer
- ✓ Waist belt and holster or lanyard for UDS Roam
- ✓ Printer shelf (*optional*)
- ✓ Cart (*optional*)
- ✓ UPP Silent Drive Puller and mounting clamp (*optional*)
- ✓ Bluetooth® key and drivers if using non-Laborie computer/laptop (*optional*)
- ✓ Pressure transducer cartridges (*optional*)
- ✓ IV pole and hook (*optional*)
- ✓ IV pole mounting clamp
- ✓ LIT (Line Isolation Transformer) box

3.2 ASSEMBLE SYSTEM COMPONENTS

3.2.1 Assemble the UDS Roam with the Goby™ Hub

Follow the instructions provided to assemble the UDS Roam™ with the **Goby™** Hub:

- Insert the EMG cables to the **UDS Roam™** cartridge with the ground cable connecting to the center opening marked with the ground symbol. Attach the P1 cable into the port labeled "1" on the cartridge; P2 cable into the port labeled "2" on the cartridge and so on (Figure 4).

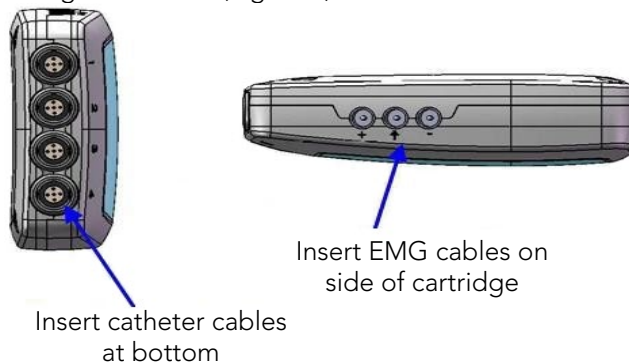


Figure 4: UMS Roam Connections Setup

- Place the UDS Roam cartridge into the **Goby™** Hub and make sure the connector at the bottom of the UDS Roam cartridge clicks securely into place into the **Goby™** Hub (Figure 5).

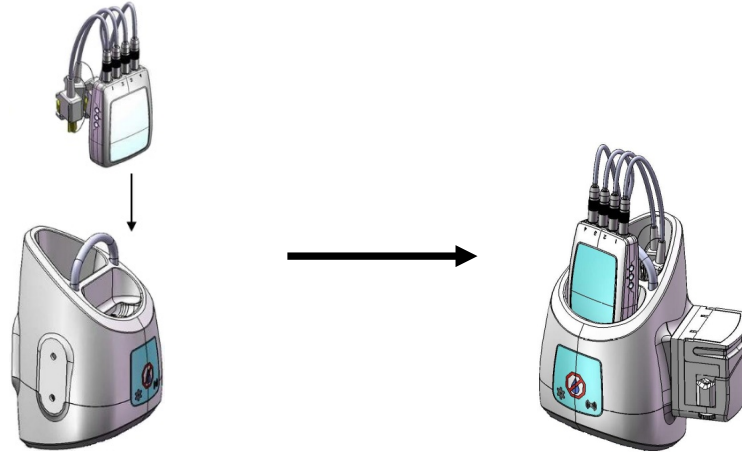


Figure 5: Connecting the UDS Roam to the Goby™ Hub

NOTE: The UDS Roam, transducers, and consumables may be setup with a patient using the belt and holster. Refer to the [How do I attach the UDS Roam™ to a patient?](#) guidance in the [Quick Reference and FAQ](#) section.

3.2.2 Assemble Goby™ with Cart

Follow the instructions provided to assemble the Goby™ with Cart:

- Place the **Goby™** Hub into the IV mount and lock in place using the gold screw. Clamp the mount on the IV pole at the desired height.
- Plug the power supply cord of the cart into an electrical outlet.
- Place the **Urocap™ IV** on the floor as needed for tests. Plug into the power supply to begin charging.
- (Optional) Insert the UPP puller securely into the clamp on the IV pole. Plug the UPP cable into the rectangular connector at the bottom of the **Goby™** Hub.
- The IV pole is not designed to support the weight of the system. Do not lift the cart or table by holding the IV pole.
- To prevent possible injury to the patient, exercise caution when adjusting IV pole height during a procedure.

Refer to Figure 6 for identification of each component described in the setup.



Figure 6: Goby™ with Cart Setup

3.2.3 Assemble Goby™ on a Tabletop

Follow the instructions provided to assemble the Goby™ on a Tabletop:

- Attach the foot mount onto the **Goby™** Hub using the opening behind the power switch of the **Goby™** Hub as the insertion point (Figure 7). **Do not insert the foot into the other Goby™ Hub openings.**

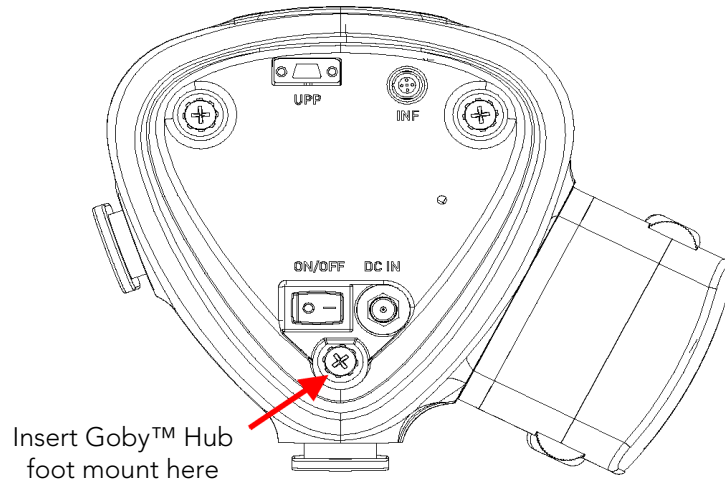


Figure 7: Goby Hub – Foot Mount Insertion Point

- Place the **Goby™** Hub with the **Goby™** Hub foot onto the tabletop. Attach the IV pole tabletop mounting clamp securely to the edge of the table (Figure 8). Place the IV pole into the clamp and secure the IV pole with the thumbscrew.

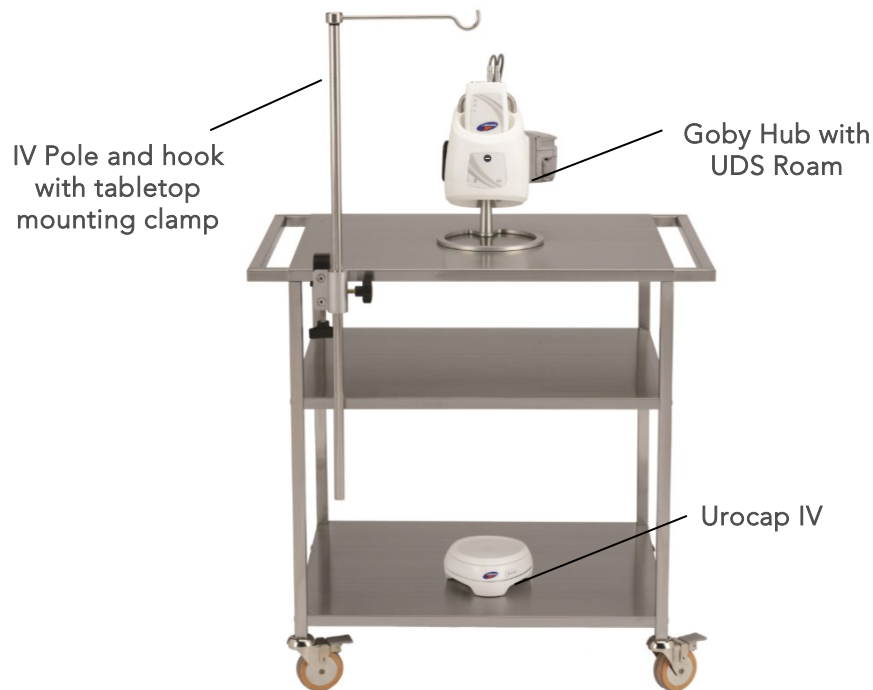



Figure 8: Goby™ on Tabletop Setup

 **NOTE:** LABORIE recommended that a table with a minimum 1.5" thickness and edge of 1" be used to mount the IV pole.

- Place the **Urocap™ IV** on the floor as needed for tests.
- (Optional) Attach the UPP puller to the tabletop with the mounting clamp. Plug the UPP cable into the rectangular connector at the bottom of the **Goby™** Hub.

3.2.4 Assemble Goby™ on an IV Pole

Follow the instructions provided to assemble the Goby™ on an IV Pole:

- Attach the **Goby™** Hub to the IV pole. Unfasten the thumbscrew on the mounting clamp and place it around the IV pole; place it on the center tube for increased stability. Tighten the thumbscrew to secure into place. Insert the **Goby™** Hub into the clamp by sliding either the back or side mount on the **Goby™** Hub into the slot of the clamp. It is locked into place with the gold-colored pin screw.
- If removal of the **GOBY™** Hub is necessary, gently pull out the pin screw and slide the **GOBY™** Hub up and out. Adjust the height of the **Goby™** Hub as necessary.

IMPORTANT: Do not adjust the height of the IV pole clamp with the **Goby™** Hub still inserted into the mount. First remove the **Goby™** Hub and then perform adjustments as necessary.

- Place the **Urocap™ IV** on the floor and use as needed for tests.

Refer to Figure 9 for identification of each component described in the setup.

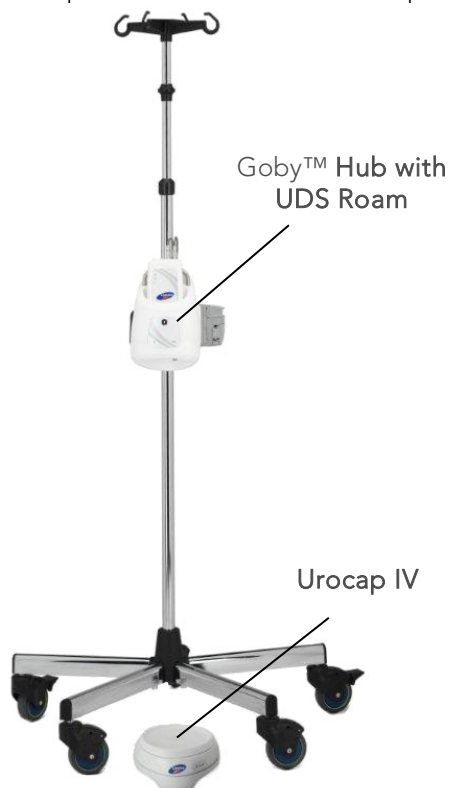



Figure 9: Goby™ with IV Pole Setup

3.2.5 Set up the Pump

To ensure patient safety, do not exceed a pressure of 150cmH₂O or a volume of 750mL in the pump settings.

DO NOT ADJUST the IV pole with an infusion bag/bottle on the hook. Always remove the infusion bag/bottle before making IV pole adjustments.

1. Insert the pump tubing spike into a 1000ml bag of saline solution.
2. Flush the line completely.
3. Clamp the line shut and hang the bag on the IV pole hook.
4. Open pump door. Position the compressible portion of pump tubing across rollers from left to right.

 **NOTE:** the soft portion of the pump tubing should be placed at the left edge of the pump head; be careful not to pinch tubing between V-shaped clamps on either side of the rollers.

5. Close pump door.
6. Open the roller clamp on the pump tubing.

3.2.6 Set up Infusion Transducer (optional)

To set up the infusion transducer follow the instructions provided below. Refer to Figure 10 for a representation of completed set-up.

1. Place the infusion transducer on the IV pole.
2. Connect the infusion transducer cable to the circular-shaped connector at the bottom of the **Goby™** Hub.
3. Place a 1000 ml bag of sterile saline inside a pressure cuff. Hang the pressure cuff on the hook of the infusion transducer. LABORIE recommends the positioning of the IV pole at least 30 cm above the patient table.
4. Inflate the pressure cuff to 300 mm Hg (when the green line appears on the pressure cuff gauge).
5. Connect an infusion line to the saline bag. Use a basic solution set with a drip chamber.
6. Tape the infusion line to the IV pole between the drip chamber and the roller clamp (flow control valve). Ensure there is excess tubing between the tape and the drip chamber. If the tubing is pulled tight then it will produce inaccurate readings. Connect the other end of the infusion line to the filling port on the catheter.

! **IMPORTANT:** The infusion transducer is calibrated for up to 1000 ml of sterile saline or water. Re-calibration is required for use of different mediums such as hypaque. See the [Calibrate the Infusion Transducer](#) section on page 92 for information on calibrating the Infusion Transducer.

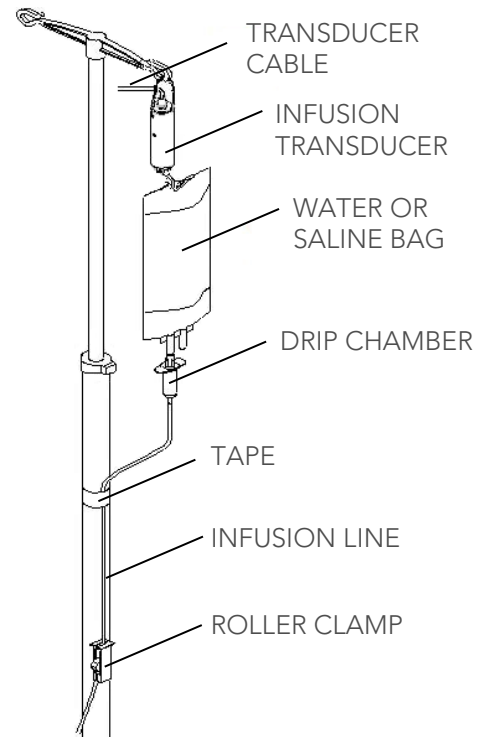


Figure 10: Infusion Transducer Setup

3.2.7 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 11).
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 11).

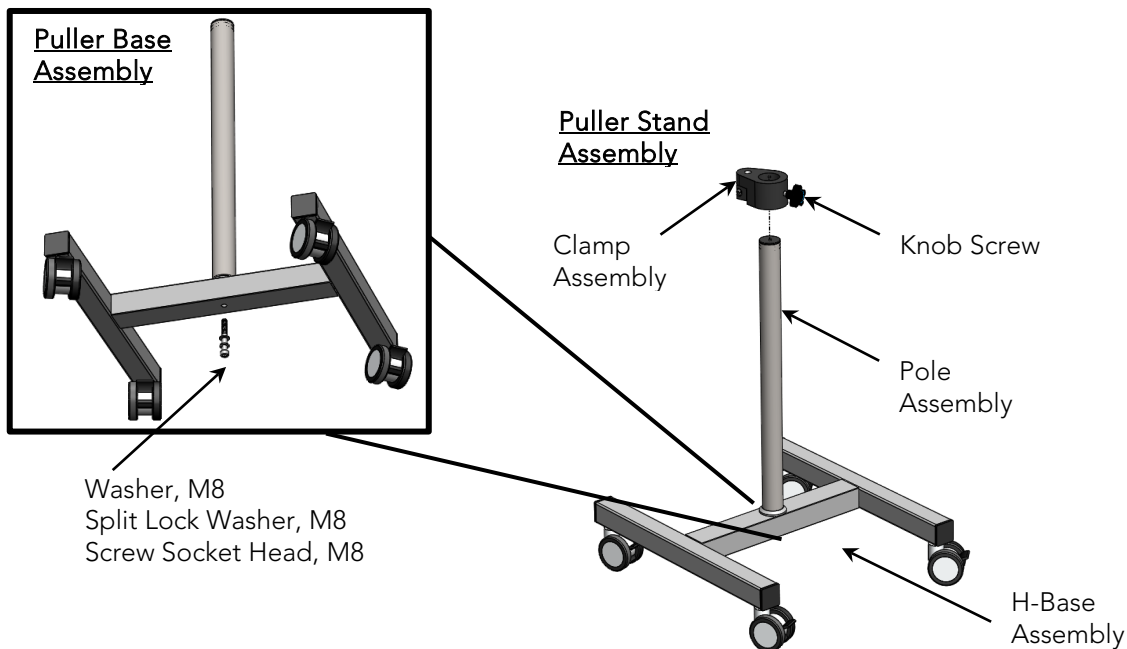


Figure 11: Puller Base and Puller Stand Assembly

3.2.8 Set up Ambulatory Remote Control (optional)

If a remote control (COM762) is used for ambulatory Uroynamics testing, first set up the remote control for patient use and then instruct the patient on how to use the remote during a procedure.

Insert the event marker cable attached to the remote into the UDS Roam port labeled “4” (Figure 12).

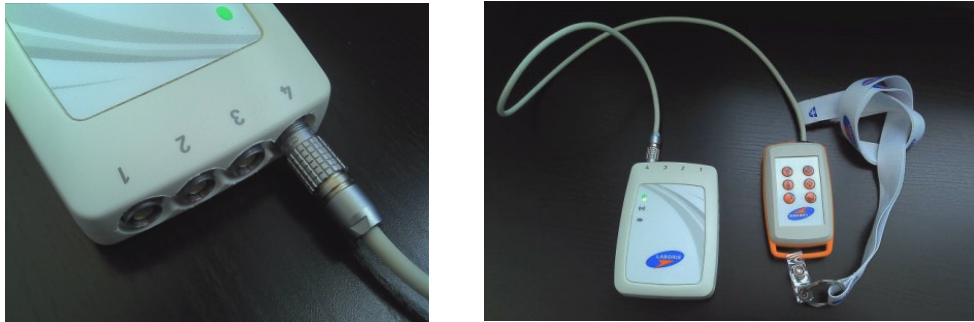


Figure 12: Connecting the Remote Control to the UDS Roam


Refer to the [Setting Up the Remote Control and UDS Roam for Ambulatory Testing](#) section on page 84.


3.3 CONSUMABLES AND TRANSDUCER SETUP

3.3.1 Fluid-Filled Pressure Transducer Setup

To Set-up the Fluid-Filled Pressure Transducer for a test follow the instructions below. Refer to Figure 13 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 14: Stopcock Flow Directions.

 **NOTE:** Be sure that the stopper cap is always securely in place whenever the stopcock position is being changed.

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

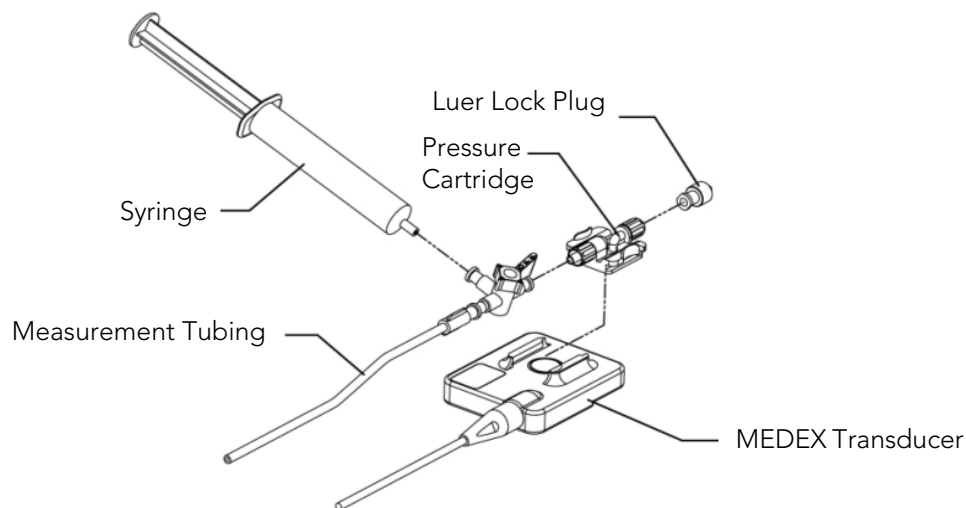


Figure 13: Fluid-Filled Pressure Transducer Setup

3.3.2 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.
2. Attach a syringe filled with water or saline to the stopcock.
3. Turn the stopcock "OFF" to the catheter (See Figure 14, Option B).
4. 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.
5. Turn the stopcock "OFF" towards the Luer lock plug (See Figure 14, Option D).
6. Prime the pressure measurement tubing and the catheter.
7. Turn the stopcock "OFF" towards the syringe for pressure recording (See Figure 14, Option A).

Each option in Figure 14 indicates a stopcock position; arrows indicate lumens open to flow based on stopcock position while squared off arrows indicate off position.

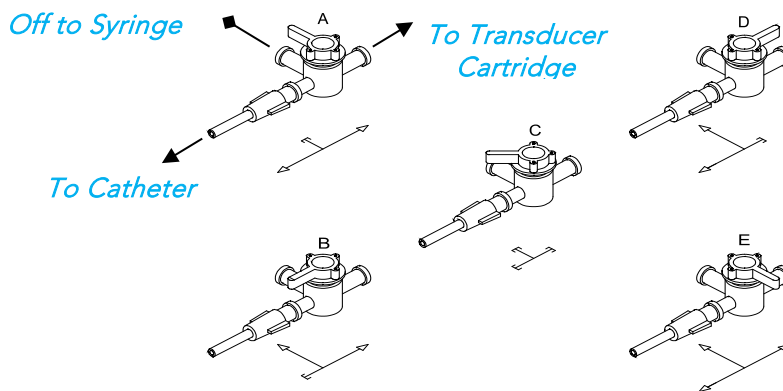



Figure 14: Stopcock Flow Directions


3.3.3 T-DOC Air-Charged Catheter and Transducer 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 (P_{det}) is equal to zero and that both P_{abd} and P_{ves} pressures are reacting appropriately. If P_{abd} is higher than P_{ves}, reposition the P_{abd} 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.

3.3.4 EMG Patches

Once the patient's skin is properly prepared, apply EMG patches as directed below.

-  **NOTE:** The patient's anal area should be clean, dry and free of hair.
1. Snap the electrode patches onto the 3 EMG leads.
 2. Place two electrodes peri-anally at the 10 o'clock and 2 or 3 o'clock positions. Place as close as possible to the anus for pelvic floor muscle readings. Place the third electrode on a bony prominence such as the patient's hip bone or knee (Figure 15).

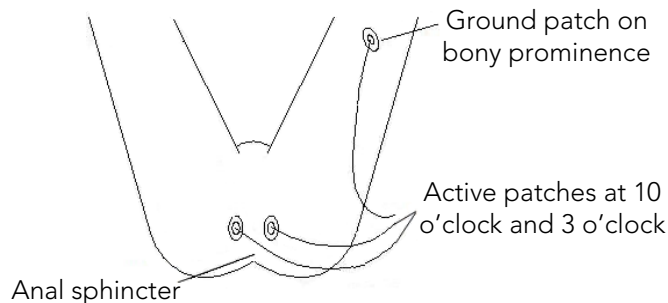


Figure 15: Electrode Placement Diagram

3. Secured each electrode with an additional piece of surgical tape. If the electrodes detach, dry the skin and apply new surgical tape.

3.4 WIRELESS PRINTER SETUP

3.4.1 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.

3.4.2 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 display to set up wireless communication.

1. On the printer control panel display, 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 Change the connection type on page 24 to set up the printer on your wireless network.

3.4.3 Print Using Wi-Fi Direct



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

3.4.3.1 Guidelines for Using Wi-Fi Direct



- Make sure your computer or mobile device has the necessary software.
 - If you are 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.

3.4.3.2 To Turn on Wi-Fi Direct


To Turn on Wi-Fi Direct on the printer

1. On the printer control panel display 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.

To Change Connection Method on the Printer

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

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.
4. **NOTE:** To obtain Wi-Fi Direct password, on the printer control panel display, from the Home screen, touch  (Wi-Fi Direct).
5. Proceed to step 6 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.
6. Print your document.

3.4.4 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).

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.

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 recommends that a wireless connection is used between the computer and printer at all times.

3.5 CONNECT GOBY™ DEVICES

The **Goby™ Device Manager** window allows you to connect the **Goby™** system components to the software. Once the connections are established in this window, the equipment will automatically connect each time the computer and/or equipment is powered on.

1. Ensure that the Bluetooth dongle is plugged in to the computer.

2. Double-click the Goby™ Device Manager icon  on the computer desktop.
3. The Goby™ Device Manager window will display the status of the Goby™ equipment (Figure 16).

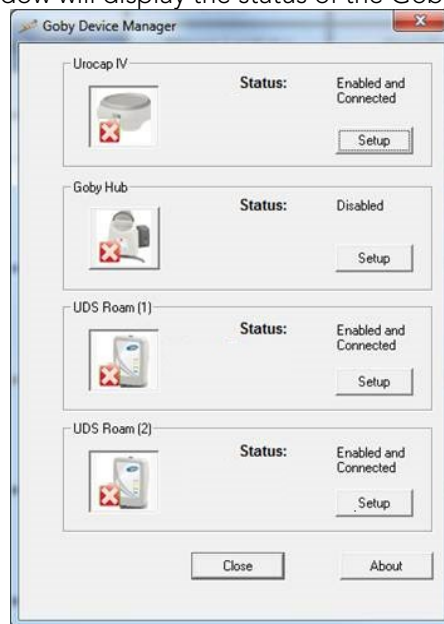


Figure 16: Goby Device Manager – Components Disconnected

4. Click **Setup** to connect the equipment (Figure 17).

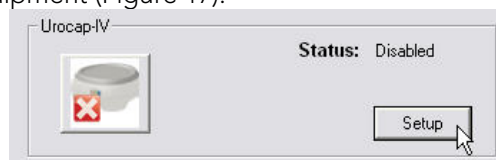


Figure 17: Launching Setup window

1. In the **Urocap™ Setup** window, click the **Device Search** button to start locating the Uroflowmeter that needs to be connected to the system (Figure 18). If the device is not found, click **Cancel** in the *Bluetooth Device Server* window and click **Device Search** again.
- 2.

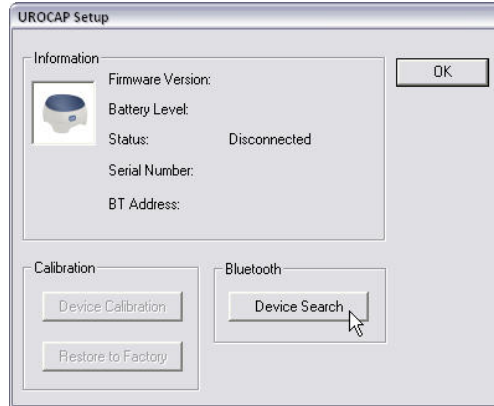


Figure 18: Launching Device Search

3. Wait for the **Urocap™** to be located. When the **Urocap™** appears in the *Bluetooth Device Server* window, highlight the name and then click **OK** (Figure 19).



Figure 19: Selecting Urocap™ IV Device

4. When a connection is established, the Bluetooth address and serial number fields will display the device information (Figure 20).

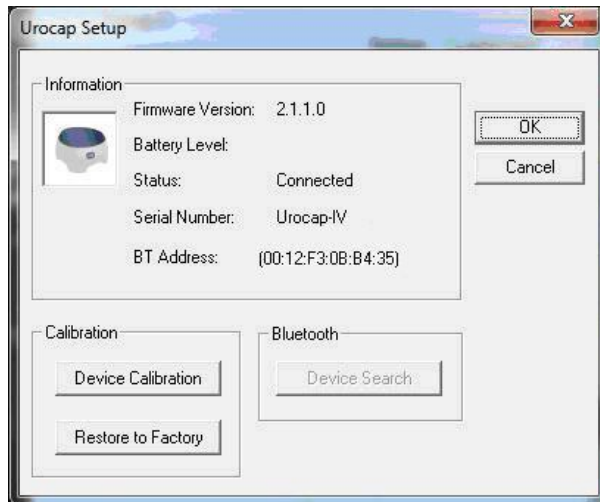


Figure 20: Urocap Setup –Connected

5. Click **OK** to go back to the **Goby™ Device Manager** window.
6. Repeat the steps provided to connect the **Goby™ Hub** and the **UDS Roam** to the system.

7. In the *Device Manager* window click the device button for the **Urocap™ IV**, the **Goby™ Hub**, and the **UDS Roam™**. Wait for the connection to establish and finalize as exemplified in Figure 21.

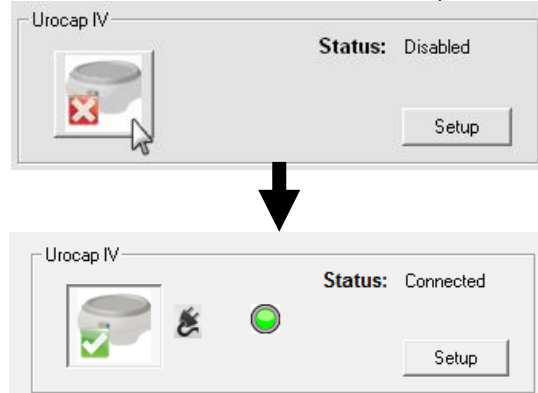


Figure 21: Finalizing Connection in the Device Manager

When all devices are connected and functioning, the Goby Device Manager window will look similar to Figure 22:

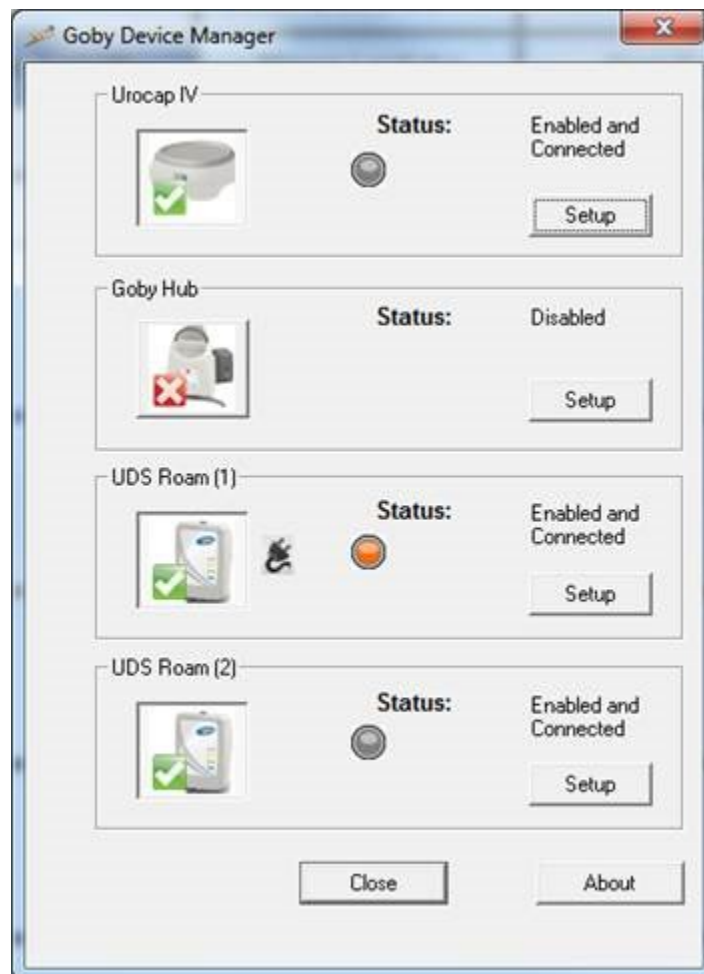


Figure 22: Goby Device Manager Window

! **IMPORTANT:** Do not plug or unplug devices, pair or unpair Bluetooth devices, while the Goby system is in use with a patient.

4 EQUIPMENT STATUS INDICATORS AND BUTTONS

4.1 LED LIGHTS

Once the components are assembled and plugged in, the LED lights on the UDS Roam™, the Urocap™ IV, and the Goby™ Hub will flash their connection status. The LED lights for each device are located on the front of the device. The status is also displayed in the Device Manager. Please see an overview of LED light signal statuses in Table 1 below:













		
<p> BT (Bluetooth) blue = connected green = system at work but not connected orange = system fault light off = not connected</p> <p> Equipment status green = connected blinking green = connected and sampling orange = System fault blinking orange = not connected light off = system off</p> <p> 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 charge light off = battery empty; re-charge</p>	<p> BT (Bluetooth) blue = connected green = system at work but not connected orange = system fault light off = not connected</p> <p> Equipment status green = connected blinking green = connected and sampling orange = System fault blinking orange = not connected light off = system off</p> <p> 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 charge light off = battery empty; re-charge</p>	<p> BT (Bluetooth) blue = connected green = system at work but not connected orange = System fault light off = not connected</p> <p> Equipment status green = connected blinking green = connected and sampling orange = System fault light off = not connected</p> <p> = pump/Goby™ stop button</p>

Table 1: LED Light Signals of Goby Components

4.2 ICON INDICATORS

Icon indicators in the **Goby Device Manager** window will display the status of a device in addition to battery status. The battery status is shown as a LED icon in the center of the window.

4.2.1 Connection Status

Table 2 provides an overview of the status icons provided in the Device Manager Window with instructions on how to proceed based on the connection status indicated:


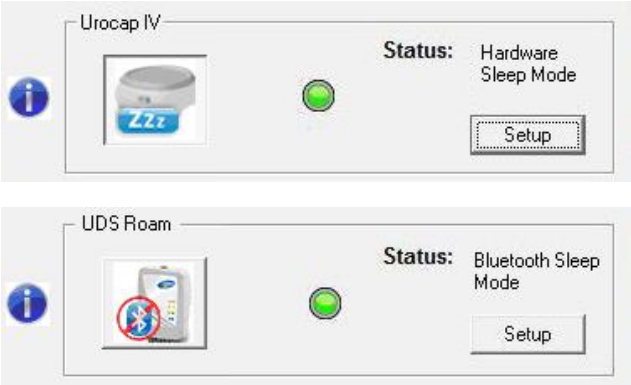

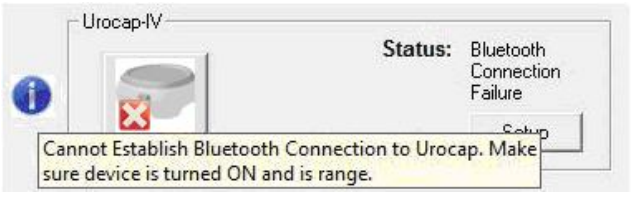

	<p>When devices are connected and functional a green check mark will appear next to the device picture.</p>
	<p>After a period of inactivity, when the devices are connected but not in use, the device will go to "sleep" to conserve battery power.</p> <p>The device will auto activate from <i>Hardware Sleep Mode</i> once a new study is started by clicking the Run button located on the Control Panel.</p> <p>To restart the device in <i>Bluetooth Sleep Mode</i>, click the Wake-up button on the control panel.</p>
	<p>If there is a connection failure, re-connect the equipment. Click the device button to reconnect. If the device does not connect after this attempt, follow the steps provided in the Connect Goby™ Devices section on page 24.</p>
	<p>If an information bubble icon  is displayed next to the device icon, place the mouse cursor over it to read the message and follow the instructions.</p>

Table 2: Device Manager Status Icons

Table 3 describes device icon indicators for Ambulatory Monitoring:



<p>This icon displays when ambulatory recording has stopped and data is ready for downloading:</p> <p>For instructions on downloading data, refer to the Ambulatory Monitoring section on page 84.</p>	
<p>This icon indicates that ambulatory recording has begun:</p>	

Table 3: Ambulatory Device Icons

4.2.2 Battery Status

Table 4 provides an overview of the battery status provided in the Device Manager Window indicating with instructions on how to proceed based on the battery status indicated:

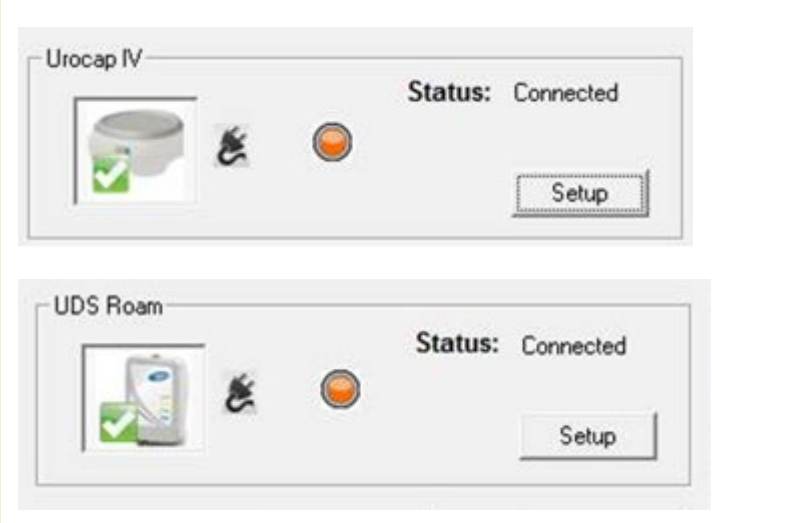


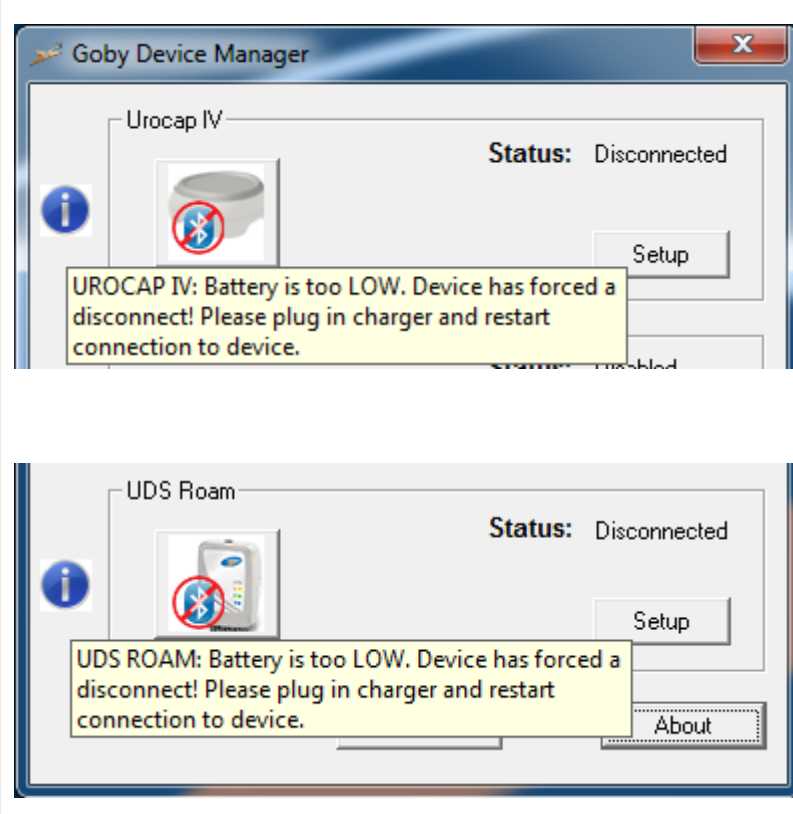


 <p>The screenshot shows two device panels. The top panel is for 'Urocap IV' and the bottom panel is for 'UDS Roam'. Both show a green battery icon, a plug symbol, and a green LED indicator. The status for both is 'Connected'. A 'Setup' button is visible in each panel.</p>	<p>The battery status will display in the Device Manager window in addition to the device LED indicators. The LED light color on the device will be the same as the color displayed in the Device Manager window.</p> <p> NOTE: the plug symbol  signifies that the device's battery is being charged.</p>
 <p>The screenshot shows the 'Goby Device Manager' window. The top panel for 'Urocap IV' and the bottom panel for 'UDS Roam' both show a red battery icon, a plug symbol with a red 'X', and a red LED indicator. The status for both is 'Disconnected'. A yellow tooltip message is displayed over the Urocap IV device: 'UROCAP IV: Battery is too LOW. Device has forced a disconnect! Please plug in charger and restart connection to device.' An information bubble icon (i) is visible on the left of each panel.</p>	<p>Before the battery power is completely drained, for either the Urocap™ IV or the UDS Roam, the device's LED lights will flash orange as outlined in the LED Lights section on page 27.</p> <p>When the battery power reaches total power depletion, the device will disconnect from the system and the status messages (as illustrated on the left) will be displayed in the Device Manager window. Place the mouse cursor over the information bubble icon  to find more information. To restart the connection, follow the steps provided in the Connect Goby™ Devices section on page 24.</p> <p> NOTE: If either the Urocap™ IV or the UDS Roam shutdown due to low battery while a test is in progress, the graph will stop scrolling and an event named <i>Urocap™ IV Low Battery Shutdown</i> or <i>UDS Roam Low Battery Shutdown</i> will be marked on the graph. Stop the test, plug the device into the charger, and reconnect as described in the Connect Goby™ Devices section on page 24.</p>

Table 4: Battery Status in the Device Manager

4.3 DEVICE CONNECTORS AND BUTTONS

Connections ports and buttons at the bottom of the Goby™ Hub and Urocap™ IV provide different functions. Refer to Figure 23 and Figure 24.

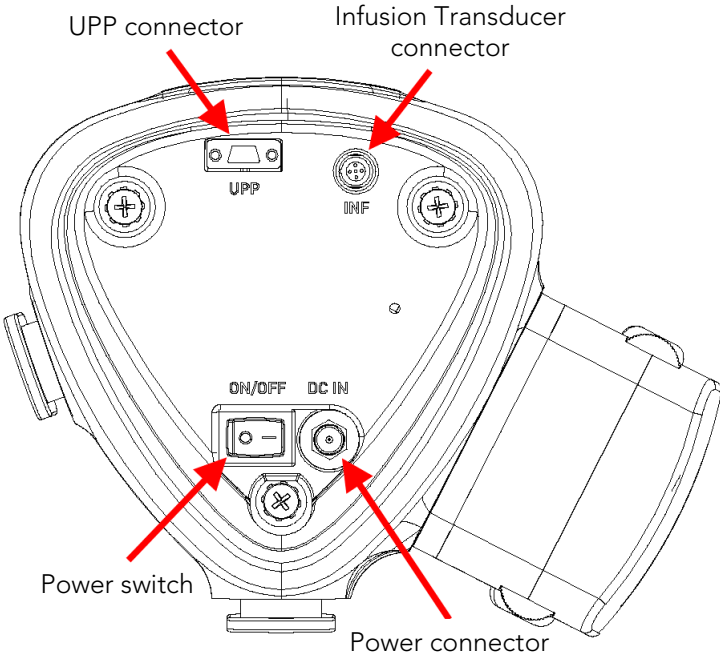
 <p>The diagram shows the bottom view of the Goby™ Hub. It features four main components labeled with red arrows: the UPP connector at the top left, the Infusion Transducer connector at the top right, the Power switch at the bottom left, and the Power connector at the bottom right. The Power switch is labeled 'ON/OFF' and the Power connector is labeled 'DC IN'. There are also two circular ports with plus signs on the left side and one on the right side.</p>	<p>UPP connector: plug the UPP cable into this port.</p> <p>Infusion transducer connector: plug the infusion cable into this port.</p> <p>Power connector: plug the power cable into this port</p> <p>Power switch: turns the Goby™ Hub power on/off.</p>
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Figure 23: Goby™ Hub bottom view

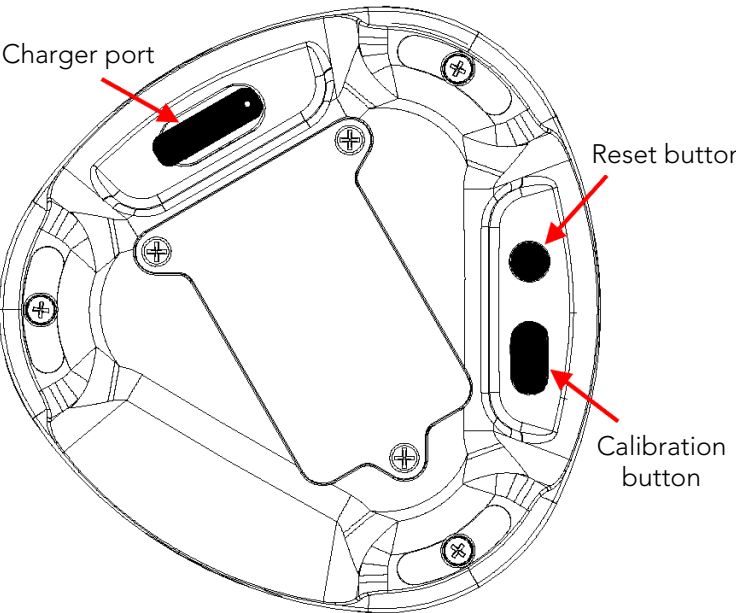
 <p>The diagram shows the bottom view of the Urocap™ IV. It features three main components labeled with red arrows: the Charger port at the top left, the Reset button at the top right, and the Calibration button at the bottom right. The Charger port is a rectangular slot with a tab on the left side. The Reset button is a small circular button, and the Calibration button is a larger rectangular button.</p>	<p>Charger port: lift the tab to reveal the charging port. Insert the charger cable into this port.</p> <p>Reset button: press to reset system firmware. To be pressed only when equipment status light is orange and other methods of troubleshooting do not resolve connection issues.</p> <p>Calibration button: press to apply settings during the calibration process. This behaves the same way as the Apply button in the software.</p>
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Figure 24: Urocap™ IV bottom view

5 SOFTWARE FEATURES AND FUNCTIONS



Double-click the UDS120 Goby™ shortcut icon on the computer desktop UDS120 Goby to open the Goby™ software. Please refer to the descriptions below for functions available on the Goby software window (Figure 25).



Figure 25: Goby 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.
- **Device Status Icons:** Icons display the equipment status. Any changes to the status will automatically appear here. To view device status changes and perform any re-connections, double click the icon which will open the Goby Device Manager window. For information on Device Status Icons refer to the [Equipment Status Indicators and Buttons](#) section on page 27.
- **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.

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 Pediatrics Setup, Remote Control setup, iList, and Video.

5.1 CONTROL PANELS

The UDS tests can be set to open to a default control panel set each time the software starts. For more information about adding and configuring control panels see the [Control Panel Settings](#) section on page 71

5.1.1 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. Begin by creating a **Zoom** button on the control panel (if not already created):

1. Click **Options > Control Panel Definition** and find an empty spot on the control panel to add the button.
2. 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.
3. Click **OK**.
4. Press and hold the left mouse button and drag the cursor to highlight the particular area on the UDS graph to zoom.
5. Click **Zoom** button on the control panel.
6. Click the **Zoom Back** button to return to regular view.

5.2 GRAPH DISPLAY AREA

5.2.1 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 26). This can be repeated for as many channels as needed.

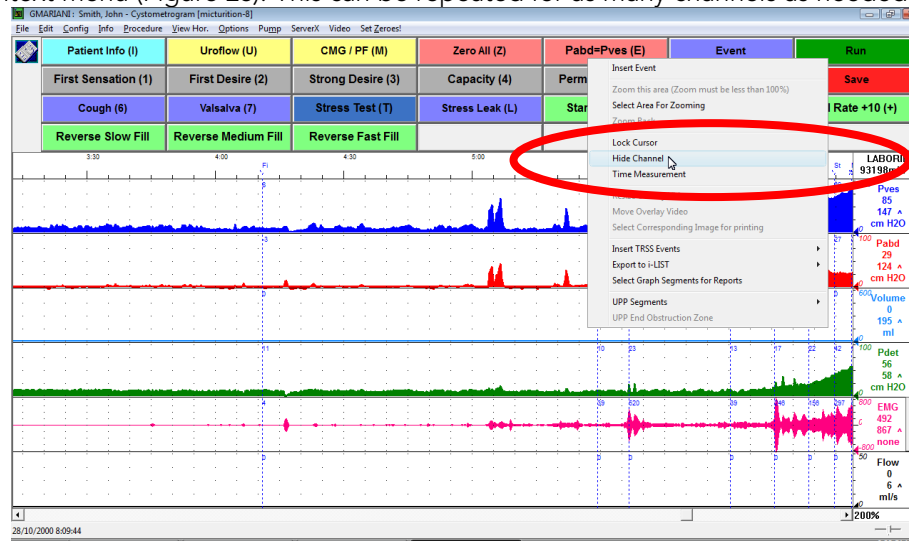


Figure 26: Hiding a Channel

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 27). Note that the channel will appear at the bottom of the graph.

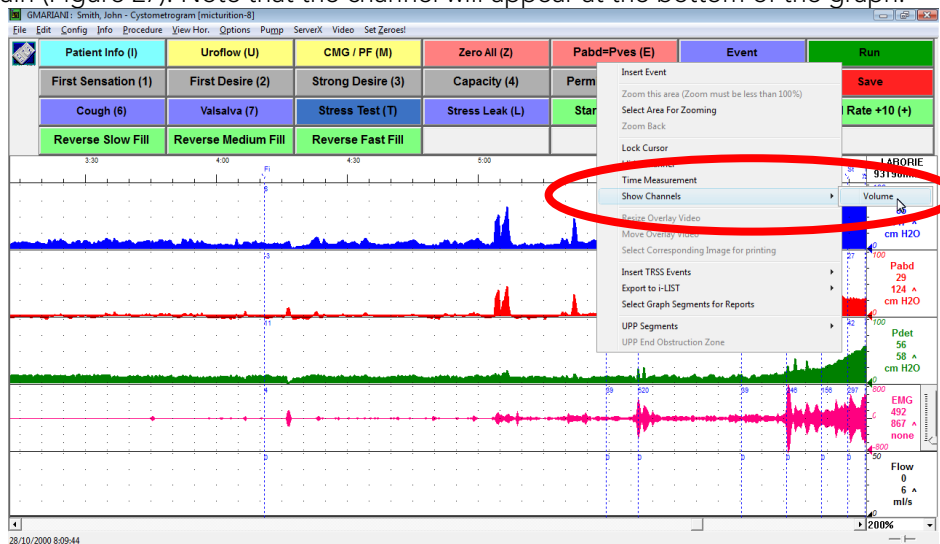


Figure 27: Showing a Channel

5.2.2 Modifying Channels

5.2.2.1 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 will be changed.

Refer to Figure 28.

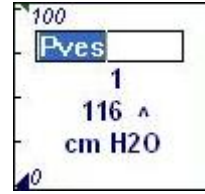


Figure 28: Channel Title

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 will be changed.

Refer to Figure 29.

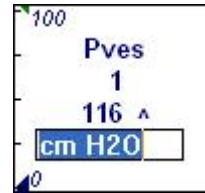


Figure 29: Channel Units

5.2.2.2 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 scale:

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 will be changed.

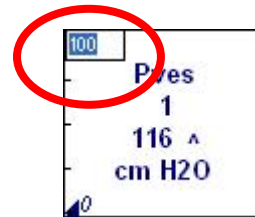


Figure 30: Channel Scale

5.2.2.3 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.

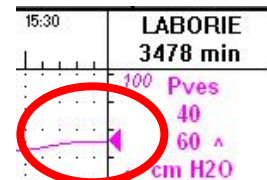


Figure 31: Channel Value Marker

5.2.2.4 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 Channel Settings Tab on page 38.

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 will appear.
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 and 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 32.

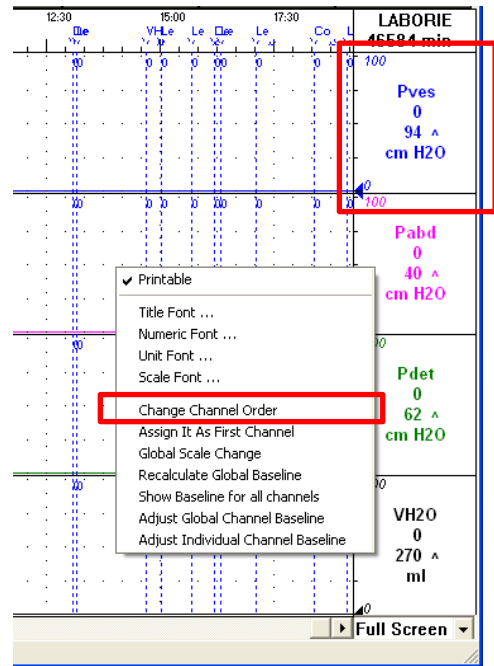


Figure 32: Reordering Channels

5.3 FILE MENU

The **File** menu contains items that allow you to view saved files as well as contact information for the LABORIE support department.

5.3.1 Open

Select **File > Open** to open and view any saved test files.

Click on a patient name to view all tests associated with that particular patient.

To view a test, click on the test name in the lower-half of the window and then click **Open Selected Test**. Refer to Figure 33.

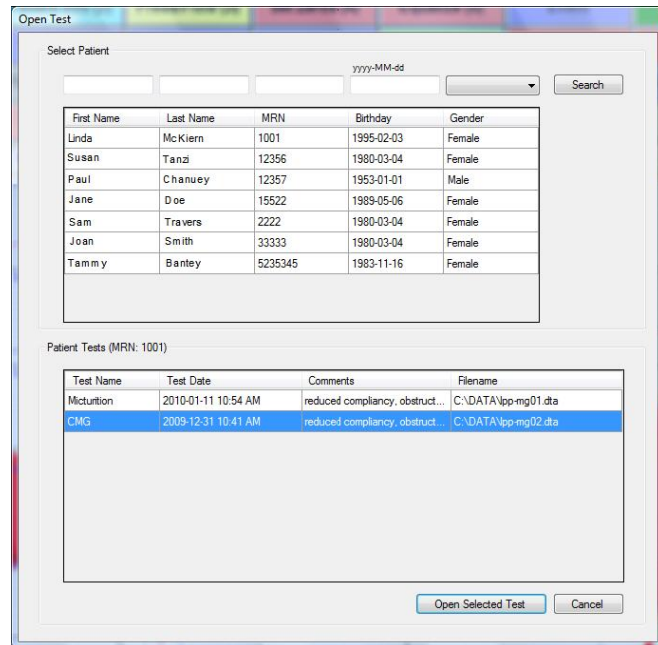


Figure 33: Open Test Window

5.3.2 Open From Data File

Select **File > Open From Data File** to view tests that are saved in the DATA folder on your computer.

- Data Files can be conveniently sorted according to Filename, Procedure Date, File Date, Patient and Comments fields.
- The **Re-Index** button updates the information stored in the Data Files.
- The **Save Listview** button allows you to save a copy of the file list in notepad.
- The **Set Directory** button allows you to see the location of the directory where all test data is saved.

Refer to Figure 34.

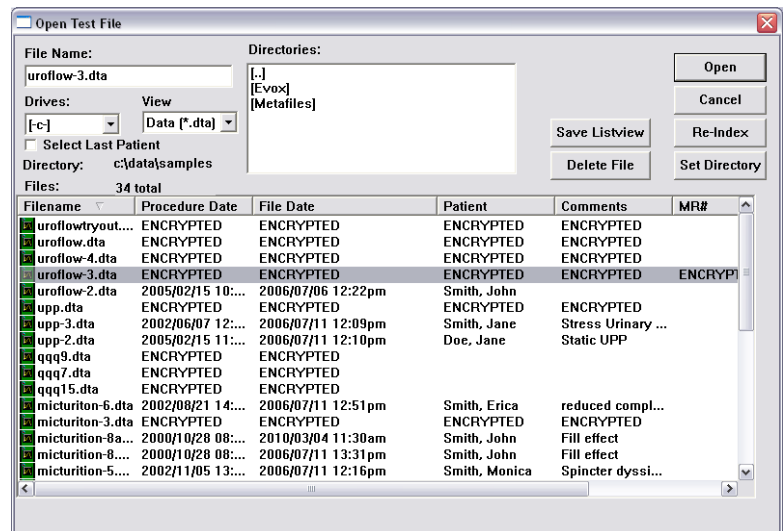


Figure 34: Open Test File Window

5.3.3 Save As

Select **File > Save As** to:

- Save a test for the first time.
- Resave a test using a different filename.
- Set up Patient File Security features by selecting the *Encrypt Patient Information* box.

Refer to Figure 35. This window can also be launched by clicking the **Save** button on the control panel.

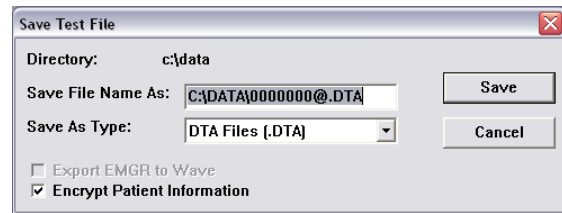


Figure 35: Save Test File Window

5.3.4 File Saving Directory

The File Saving Directory option allows the user to select the storage directory/folder for saving the UDS data files. Select **File > File Saving Directory** to access the window.

- To change the directory:
 - i. Click **Browse** and select a new directory.
 - ii. Click **OK**.
 - iii. Click the **Create Dir.** button to set the new directory.
 - iv. Click **OK**. The software will remember the Data Directory chosen for saving data files for the next save.

Refer to Figure 36.


 **NOTE:** File Saving Directory can also be selected from **Options > File Saving Directory**. To avoid loss of data during a test, the Goby software automatically backs up test data every 1 minute.



Figure 36: Change Data Directory Window

5.3.5 Print Study

Use this window to select the information to include in printed reports. This window will allow the printing of saved UDS Data files.

The first time you print a report for a specific test configuration, click **File > Print Study** and select your preferred print options in the print menu and click the **Apply** button. Each time you perform a test with this configuration, the report will automatically print when the **PRINT** button is clicked. The print menu will no longer appear, and it will print with your preferred settings each time.

More information on the options available in this window can be found on page 110 of the Appendix.

Report preview is not available in UDS software. To Print and Preview reports using iLIST refer to the [Print a Test](#) section on page 88.

5.3.6 Batch Print (optional feature)

Batch Printing allows the printing of multiple procedure reports at once (for example, during a particular day or at different time periods). Select **File > Batch Print** to open the window.

- To batch print tests performed on the same day click **Select Today's** and then click **OK**.
- To batch print files that have been run on previous days select the files to be printed by double-clicking on each file or clicking on a file and clicking the **Select** button.
- The **Re-Index** option is only needed when a 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.

5.3.7 Print Setup

Use this window to select the printer for printing data and reports. The selected printer will be the default until changed.

5.3.8 About UDS Client

The About UDS Client dialog box displays the information for contacting LABORIE Technical Support as well as formulas used in Urodynamics. It also includes the software version number, the Firmware version number, and the device name.

Click the **Fax Cover** button to open the Fax Cover sheet window that can be sent to the Support department for inquiries into any problems you may be experiencing with the equipment or software. Once you have filled in the information, click the **Print** button to print the cover sheet and fax to the support department.

5.3.9 Exit

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

5.3.10 Ambulatory Configuration Manager

When the **Ambulatory** button is clicked on the control panel, the test procedure automatically converts to ambulatory mode. In the resulting screen:

- select the UDS Roam used for recording pressures
- click **Select Configuration** to choose the test's configuration file
- click **Select Patient** to enter patient information
- click **Observe** to verify pressures and Set Zeroes as necessary
- click **Start Recording** to begin the ambulatory monitoring.
- Click download to download data from the test.

Refer to Figure 37 .

For instructions on running an Ambulatory monitoring test, refer to the [Ambulatory Monitoring](#) section on page 84.

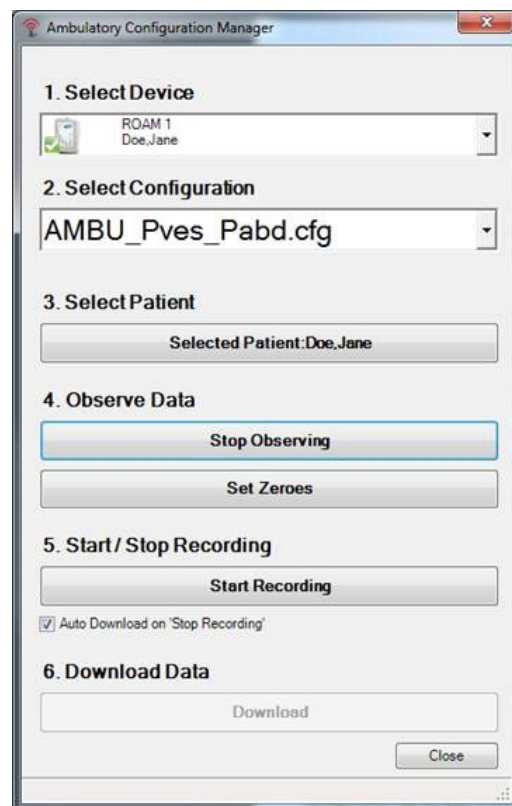


Figure 37: Ambulatory Configuration Manager

5.4 EDIT MENU

5.4.1 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.
2. Click **Edit > Zoom Selected Area**. The selected area is zoomed in and expands to fill the entire graph window.
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

5.5 CONFIG MENU

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

5.5.1 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.

5.5.2 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 filename:

1. Click **Config** on the menu bar and select **Save As**.
2. **Save Test File** dialog box will appear.
3. Enter the desired filename and click **Save**.

 **NOTE:** All test configuration files are automatically stored in the C:\CFG folder. Select the *Encrypt Patient Information* checkbox to encrypt patient information.


5.5.3 Set up/Modify

Select **Config > Set up/Modify** to configure test files and features. The configuration window will load.

5.5.3.1 Channel Settings Tab

Use the *Channel Settings* tab to select which channels will be displayed on the graph, the channel colors, and the channel order (Figure 38).

Once a file is set up, type a name into the *Test Name* box and click **Save As** to save the configuration.

 **NOTE:** Some of the features listed may not be available with your software.

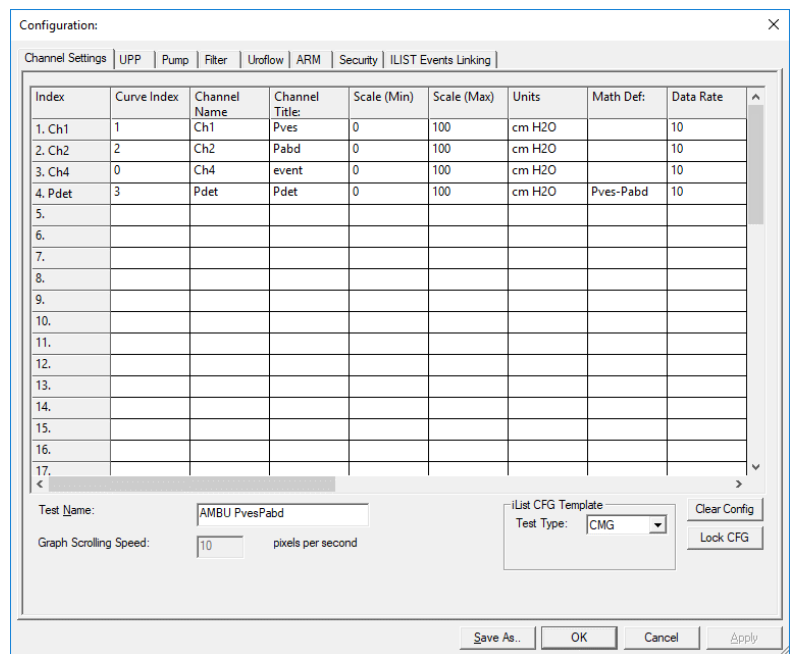


Figure 38: Configuration – Channel Settings Tab

To perform the following actions, locate the feature in the column header and select the box aligned with the appropriate channel:

- To change the *Channel Order*, click the **Curve Index** box of the channel to be moved and select its position on the graph.
- To change the *Channel Title*, click in the **Channel Title** box and type a new channel title name.
- To change the *Minimum* and *Maximum* scale, click the **Scale (Min)** or **Scale (Max)** box of a channel and type the desired value for the **Min** and the **Max** values.

- To change the scale units, click the *Units* box of a channel and then click the down arrow beside the *Units* combo box to select the desired unit.
- *Math Channels* can be used to perform arithmetic operations between one or more channels. The math channels support basic arithmetic operations (e.g. addition, subtraction, multiplication and division) and the parenthesis operator.
- VBN feature allows for the overlay of Normal Flow Match information. Utilize the CALQ Math Channel to overlay VBN information (Normal Flow Match) over the flow channel.
- To change the channel color, double-click the box under the *Curve Appearance* column and select the new color in the *Color* dialog box. Click **OK** when selected.
- *Display Line Width* feature allows the user to make the channel curve thicker (in pixels) on the display. Click the box under the *Display Line Width* column of the test channel and type the desired display line width in pixels.
- *Print Line Width* feature allows the user to make the channel curve thicker (in pixels) on the printout only. Click the box under the *Print Line Width* column of the test channel and type the desired *Print Line Width* in pixels.
- *Symmetry* feature allows the user to mirror a channel's curve making a negative mirrored curve. Click the box under the **Symmetry** column for the selected channel and select **Mirrored** or **Simple**.
- *Interior* feature allows the user to fill the area under the curve with the same color as the channel background color.
- The *Printable* option allows the user to see the graph curves on the test results printout. Select **Printable** to include the curve in a printout.
- *Curve Overlay* allows the user to display up to 5 channel curves on the same graph on the display and print out.

Unlock CFG in Channel Settings

To aid in the prevention of accidental overwriting of test configuration the software provides a lock/unlock function in the **Configuration** window.

IMPORTANT: All configuration files provided in the UDS120 software are locked at installation. Only unlock if you are sure of the modifications required.

Click **Config > Set up/Modify** to open the configuration file list and select a configuration file that needs modification. Click the **Unlock CFG** button. Click **Yes** in the resulting warning message to continue. Make changes as needed and when complete click the **Lock CFG** button. Click **Yes** in the resulting warning message to lock the configuration file (Figure 39).

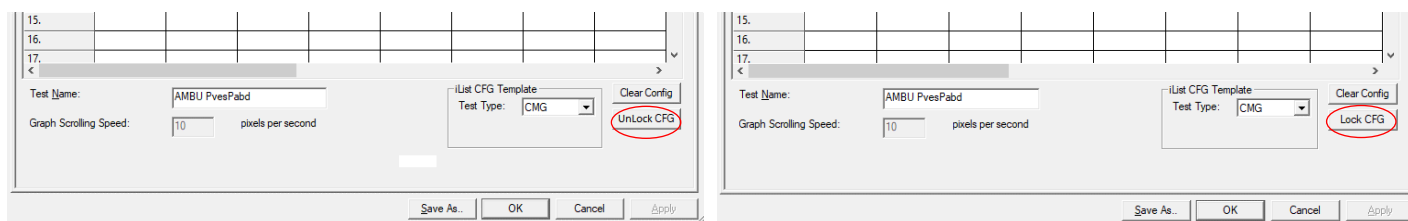



Figure 39: Lock and Unlock CFG


5.5.3.2 UPP Tab

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

1. Connect the Distance Sensor/Catheter to Ch1.

 **NOTE:** Make sure the Sensor has been calibrated first.

2. Select the Distance Sensor Channel option (Figure 40).
3. Select Ch1 from the listing.
4. Click **OK**.

 **NOTE:** Make sure you first select the **UPP** test button on the Control Panel before setting up this feature.

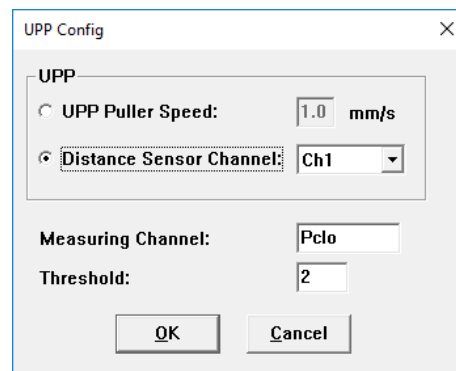



Figure 40: UPP Configuration Window

5.5.3.3 Pump Tab

Use the pump tab to set the parameters for the pump such as auto pump actions and volume limits (Figure 41). Table 5 provides a description of features available in the Pump tab.

 **NOTE:** The fluid density selection must match with the fluid density used to calibrate the equipment. Refer to the [Calibrate the Pump](#) section on page 90.

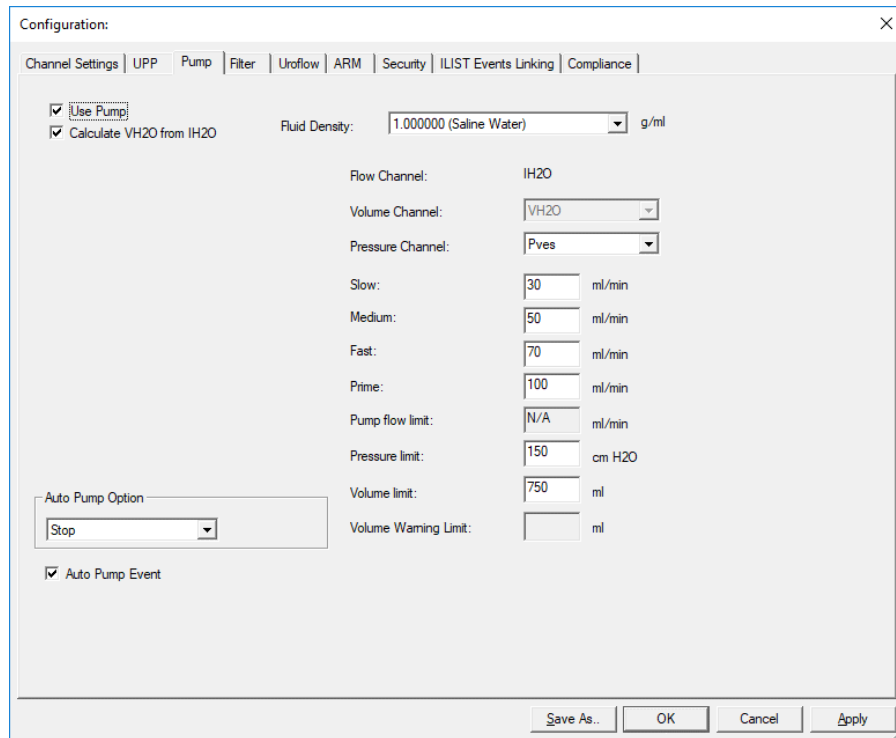


Figure 41: Configuration – Pump Tab


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. 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 H2O.
Volume Limit	Stops the pump if the volume channel exceeds this limit. CAUTION: Do not exceed 750 ml.
Volume Warning Limit [‡] (see following section for more information)	Displays a warning message when the infused volume reaches the specified limit.
Auto Pump Option <ul style="list-style-type: none"> • 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. Select the box to enable the feature.

NOTE: If pump is set to zero while a test is running, the pump speed will also need to be reset.

± 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 Minimal Acceptable Total Bladder Capacity (MATBC.)

MATBC = 16 x (Age of child in years) + 70 ml.ⁱ

 **NOTE:** The MATBC is calculated automatically and cannot be changed.

The pump receives the information to calculate the MATBC 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.

Table 5: Pump Tab Feature Functions

5.5.3.4 Filter Tab

Set the filter frequency under this tab.

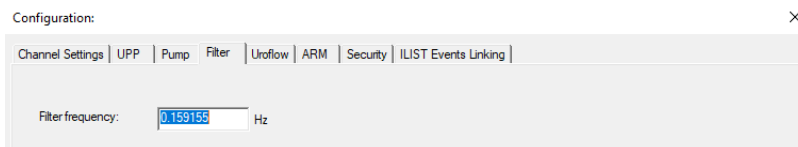


Figure 42: Configuration Window – Filter Tab

5.5.3.5 Uroflow Tab

Set the parameters for Uroflow such as auto Uroflow summary and auto printing under this tab.

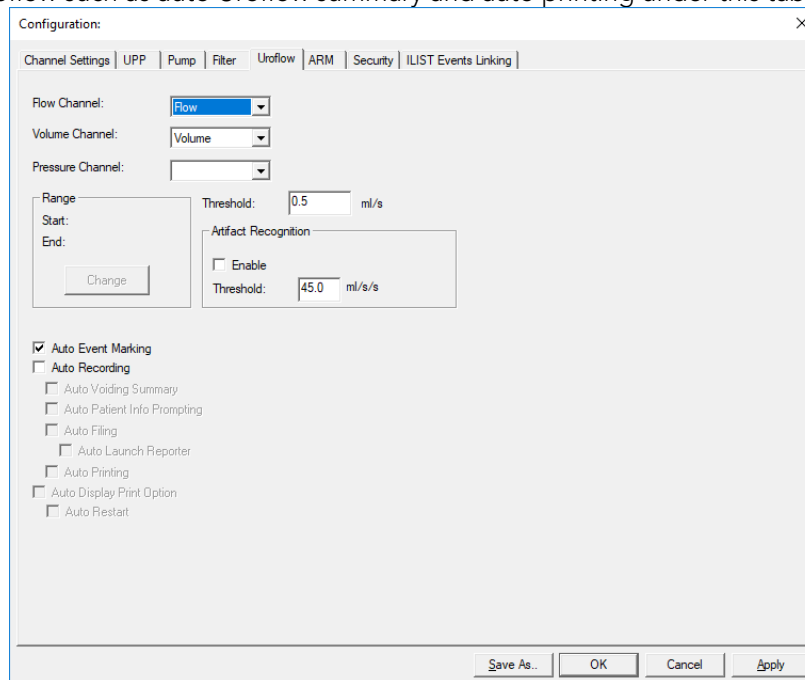



Figure 43: Configuration Window – Uroflow Tab

Auto event settings may also be accessed through the Voiding Summary window. Refer to the [Voiding Summary](#) section on page 60.


5.5.3.6 ARM Tab

Set the channels that correspond to Anorectal Manometry measurements under the Arm Tab. For more information on setting up and performing ARM tests with the Goby system, please refer to the *ARM Owner's Manual*.

 **NOTE:** select the *Enable Reverse Pump* option to activate the reverse pump button on the control panel.

5.5.3.7 Security Tab

Under this tab you can 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 virtual key that is associated with 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 virtual key is installed on 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 44.

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.

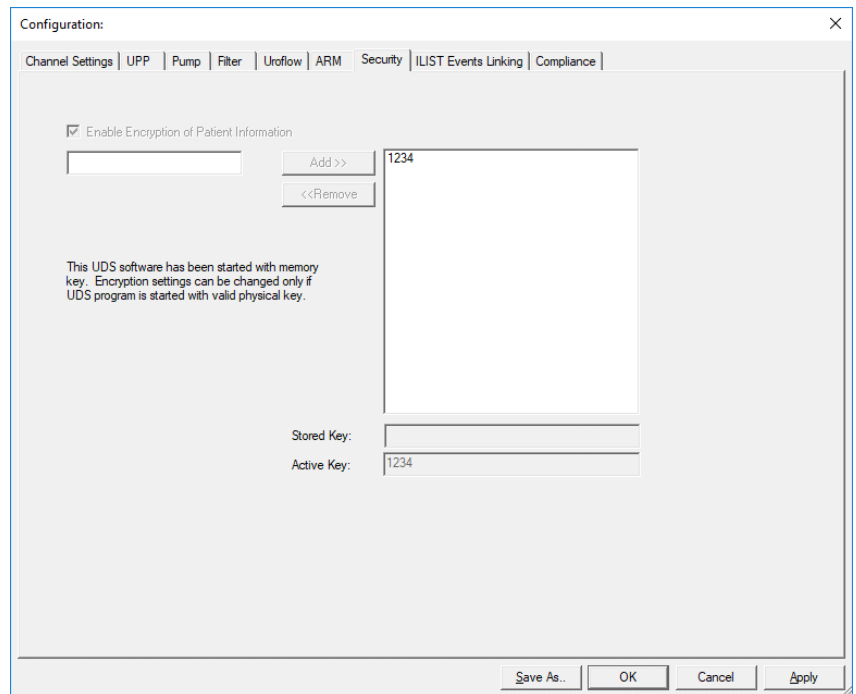



Figure 44: Configuration – Security Tab

5.5.3.8 iList™ Events Linking Tab

Events that are not in the *ILIST™ Events Linking* may not appear in 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 Goby software click **Config > Set up/Modify**.
2. Click the *ILIST™ Events Linking* tab.

 **NOTE:** Click the **Load Default Events** button to add the standard iList™ events to the listing (Figure 45).

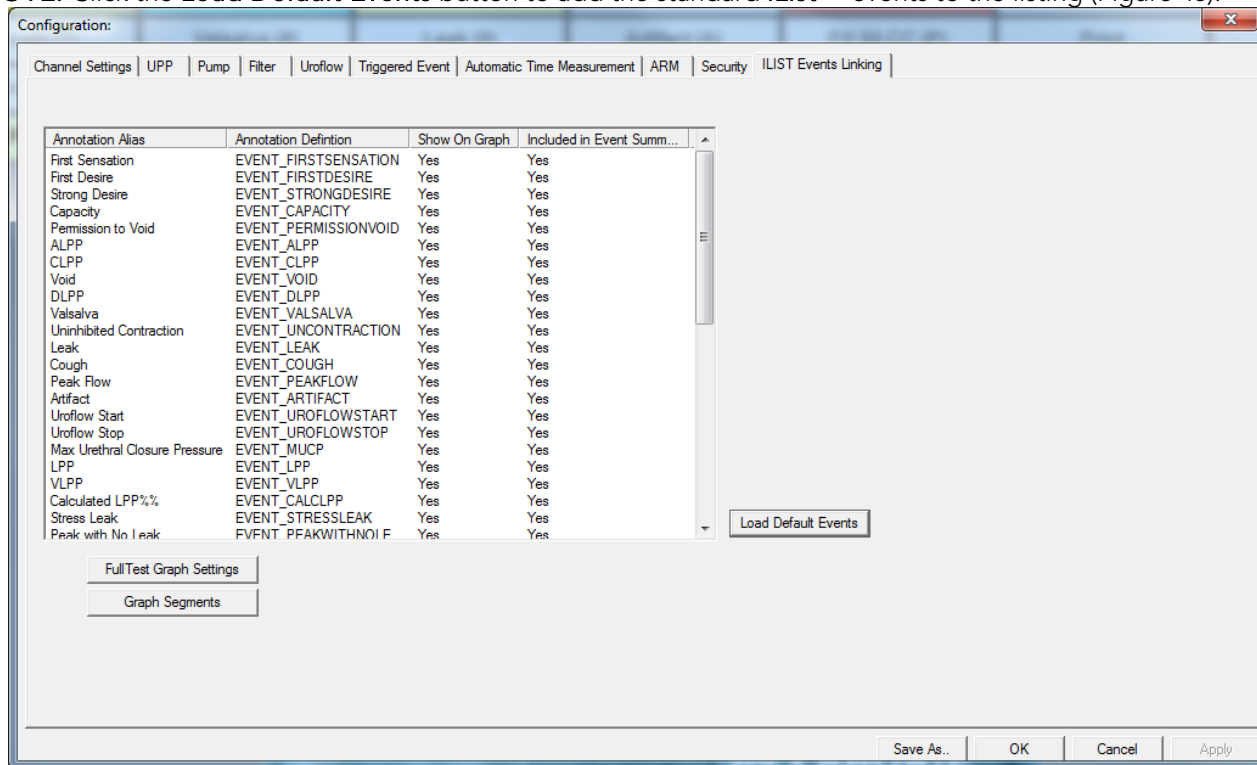


Figure 45: Configuration – iList Even Linking Tab

iList™ Office Reporter will display only the events that appear in the list under this tab. The **Annotation Alias** needs to match the event naming used in 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. Refer to the [Events](#) section on page [55](#) for more information on the *Event Annotation* window.

5.5.3.9 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 [68](#) for instructions on using automatically calculated **Bladder Compliance** and for information on accessing Bladder Compliance options from the **Info Menu**.

5.6 INFO MENU

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

5.6.1 Patient Info

The details of a patient's file are easily added to and accessed through the *Patient Information* window (Figure 46). Add information as necessary and click **OK** when complete.



NOTE: If a previous patient's information is still visible in this form, click **New Patient** and then enter the necessary information. Click **OK** when complete.

If you already know that the patient is in the system, click the **Load Existing Patient** button and select the patient in the resulting list.

Figure 46: Patient Info Window

5.6.2 Pediatric Patient 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 47). Refer to overview of fields below:

- **EBC: Bladder Capacity** – shown in milliliters - automatically calculated using the formula: $30 \times (\text{Age} + 1)^{\text{ii}}$.
- **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: $\text{ATBC} = 16 \times (\text{Age of child in years}) + 70 \text{ ml}^{\text{iii}}$.
- **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. For more information on pump fill rates for pediatric patients, refer to the [Pump Tab](#) section on page 40.
 - *Current Pump Speed*: allows for selection of slow, medium, or fast fill rate
 - *Use MPUR (10% of EBC) for pump speed and Use 1/2 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 47: 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.

5.6.2.1 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.):

$$ATBC = 16 \times (\text{Age of child in years}) + 70 \text{ ml.}^{iv}$$

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.

5.6.3 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 authorized for use by Dr. Derek Griffith^v and are located in the appendix of the published article.

5.6.3.1 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 Uroflowmeter detects flow in a pressure-flow test. It takes about 0.5 to 1.0 seconds for urine to travel through the urethra and into the 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 Griffith for more information.

Mathematical equations used for calculating the URA are listed here:

URA index:

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

Where:

$$d = 3.8 \times 10^{-4}$$

Q = maximum flow

Pdet = Detrusor pressure

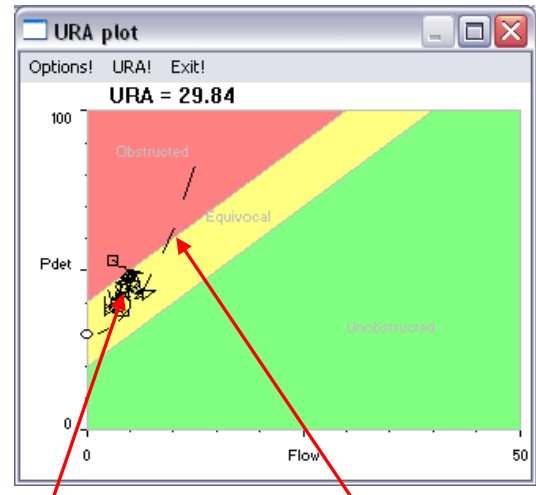
Pdet* = Detrusor pressure at maximum flow

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

$$P_{det}^* = \frac{(2dQ^2 \times URA + 1)^2 - 1}{4dQ^2} \quad \text{at Maximum flow}$$

To display the URA window:

1. Click **Info > X-Y plot**.
 2. Click **ICS Nomogram (URA)**. The URA Plot window will appear. Refer to Figure 48.
- 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**.



URA Curve Pressure/Flow Curve

Figure 48: URA plot window

To specify the analyzing range:

1. Click **Options!** from the **URA plot** window to open the **X-Y Plot Options** window.
2. Click the **Change** button.
3. Select the segment analyzing range by dragging the mouse pointer across the graph from left to right.
4. Click **Confirm**.
5. Click **OK**.

Refer to Figure 49.

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.

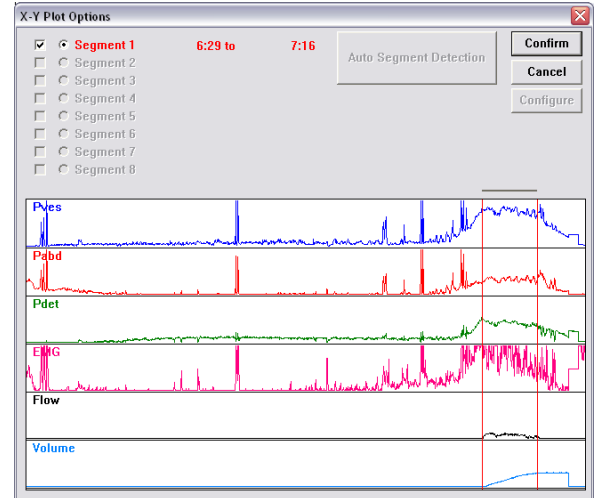


Figure 49: X-Y Plot Options

To change a channel name, threshold, or scale:

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

5.6.3.2 LinPURR

The LinPURR graph^{vi} 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 access the LinPURR Graph:

1. Select the **Info** menu and select **X-Y Plot**.
2. Click **LinPURR**. The LinPURR graph is displayed.

To cancel the LinPURR option select **Exit!**.

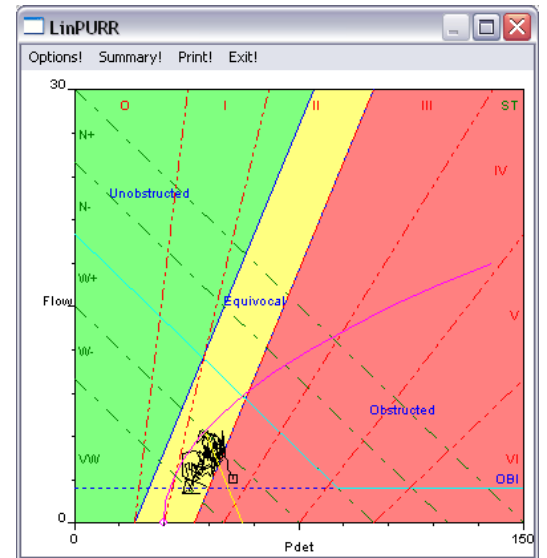


Figure 50: LinPURR Window

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 access the Parameters for the LinPURR graph:

Click **Options** from the LinPURR window. The LinPURR Options box will appear.

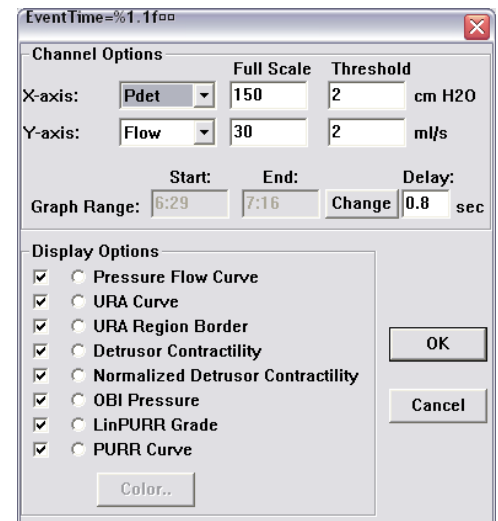


Figure 51: LinPURR Options Box

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

Refer to Figure 51 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 45.
- **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 50). The **LinPURR Summary** window will appear.

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 LinPURR Grade or Detrusor Contractility: Select the appropriate option.

To Save the information for printing: Click Save Diagnosis. The numerical results of the LinPURR calculation will 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.

5.6.3.3 Bladder Work Function (WF)

The Bladder Work function^{vii} 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 > X-Y plot > WF**. The WF plot is displayed and the complete test is plotted on the screen (Figure 52).

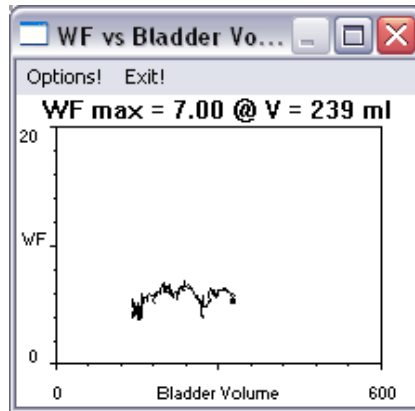


Figure 52: WF Plot

2. Select **Exit!** in the **WF Plot** window to close the **WF Plot** window.

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

1. Click **Options** from the WF window. The WF Configuration window will appear (Figure 53).

Figure 53: WF Configuration 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. Refer to Figure 53 above.

Mathematical formulas used in this feature are listed here:

Bladder Power:

$$\frac{(P_{det} + a)(v_{det} + b) - ab}{2\pi}$$

- WF= (units: W/mm²)

Where:

- $v_{det} = \frac{Q}{\text{quals}} \left(\frac{Vol + Vt}{4.188790205} \right)^{\frac{2}{3}}$

Variables and constants used in these equations are listed below:

- Q = maximum flow
- Pdet = Detrusor pressure
- Vol = bladder volume = infused volume-voided volume
- a = 25 cm H2O
- b = 6 mm/s or 0.6 cm/s
- V = 10 ml

5.6.3.4 CHES

The CHES classification^{viii} 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 CHES menu item is enabled only when there is a FLOW and PDET pressure.

1. Run a test with Flow, Volume, and Pressure channels.
2. Stop the test.
3. Click **Info > X-Y Plot > ICS Nomogram (URA)**.
4. Select **Info > X-Y Plot > CHES**. The CHES Classification Scheme window will appear (Figure 54).
5. Click **OK** to exit.

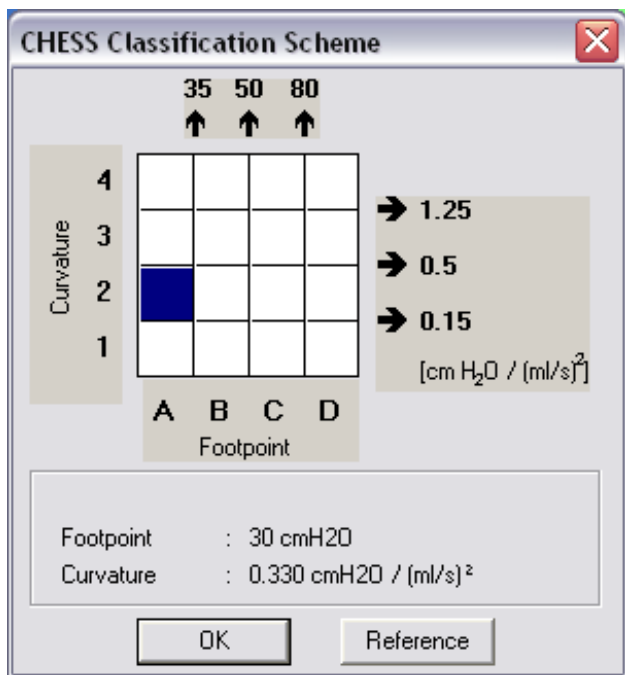



Figure 54: CHES Classification Scheme Window

5.6.3.5 Siroky Nomogram

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

To view the Siroky Nomogram click **Info > X-Y Plot > Siroky Nomogram**.

Once you select the Siroky Nomogram option, a window opens that contains the graphical representation of the Average and Maximum flow rates as developed by Siroky et al (Figure 55).

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

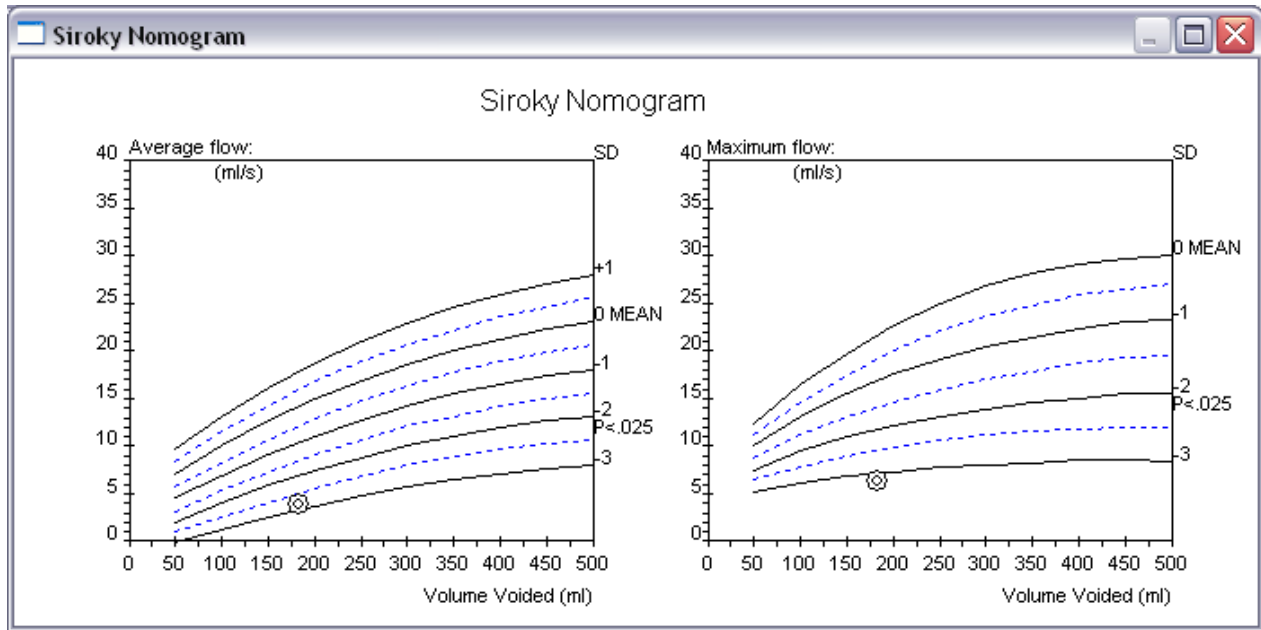


Figure 55: Siroky Nomogram Window

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.


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

5.6.3.6 Liverpool Nomogram

The Liverpool Nomogram was developed to provide an accurate and reliable indication of normal Uroflow rates.^x Compare a patient's pre-therapy and post-therapy urinary flow rate against the built-in Liverpool Nomograms.

To view the Liverpool Nomogram click **Info > X-Y Plot > Liverpool Nomogram**.

A window will open that contains the graphical representation of the Average and Maximum flow rates as developed by Siroky et al (Figure 56).

 **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.

From here, 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. Click the X in the upper-right corner to exit and return to the UDS graph window.

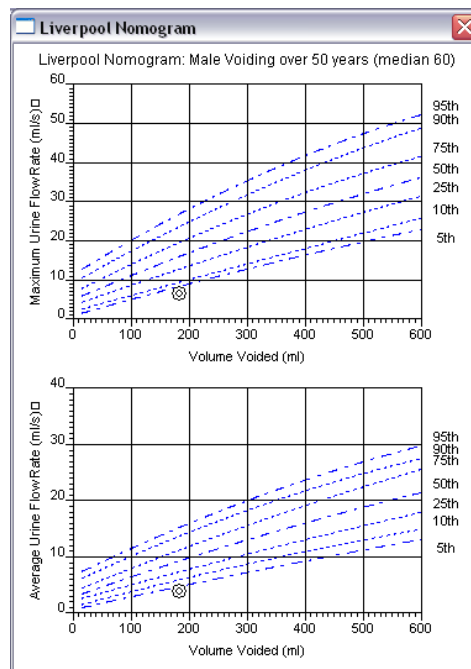


Figure 56: Liverpool Nomogram Window

5.6.4 UPP

5.6.4.1 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.^{xi} 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 57).

Figure 57: 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.

5.6.4.2 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:

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

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 58).

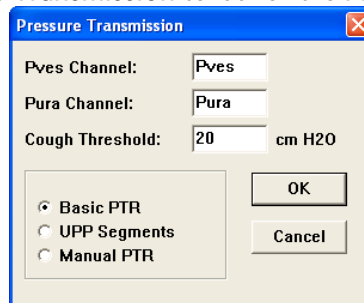



Figure 58: Pressure Transmission window

2. Select **Basic PTR** in the Pressure Transmission window and click **OK**. The **PTR Segment Selection** box will appear (Figure 59).



Figure 59: 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 H₂O(Cough threshold). These events are automatically marked and the pressure transmission ratio is calculated. Review the pressure transmission ration in the Event Summary.

PTR on UPP Segments

The **UPP Segment** PTR feature is only available when UPP segments exist. Refer to the [UPP Summary](#) section on page 64 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 58).
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.

5.6.4.3 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.

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 0, click **OK** to manually select another cough point or click **Cancel** to return to the test.

5.6.5 Events

Add events throughout the test to record what happened during the procedure. Events are automatically stored and summarized once added during a procedure. The summary of these events is available for reviewing through the info menu in the Event Summary Window. Refer to the [Event Summary](#) section on page 58.

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.

5.6.5.1 About the Event Annotation Window

The **Event Annotation** window contains a list of events that can be added to the graph (Figure 60).

- 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.

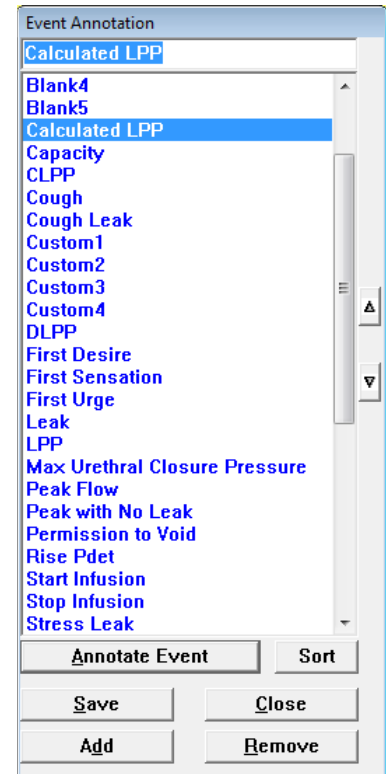


Figure 60: Event Annotation Window

5.6.5.2 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 61 below.

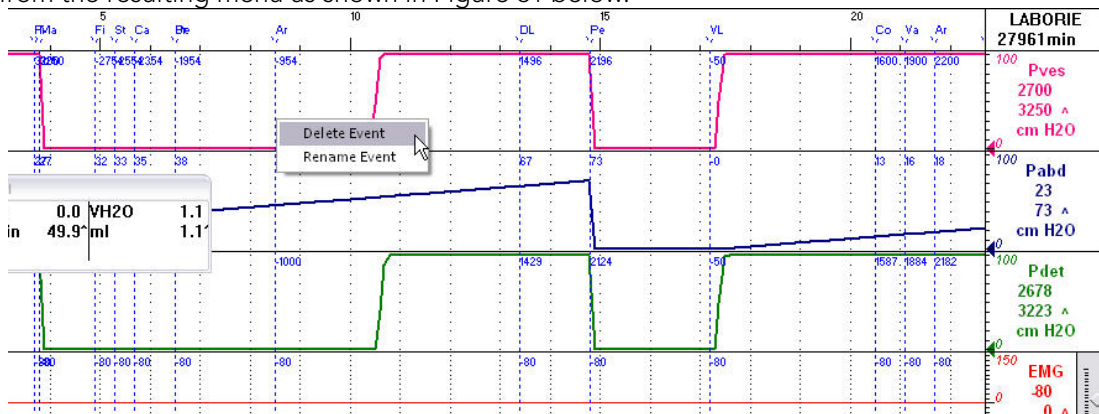



Figure 61: Deleting and Renaming Events on the Graph

5.6.5.3 Permission to Void Event

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 62 below.

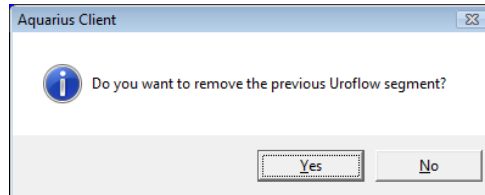


Figure 62: Aquarius Client Window – Removing Uroflow Segment

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

5.6.5.4 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 63).

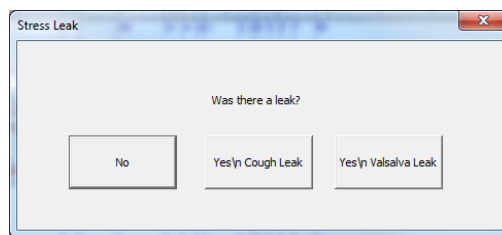


Figure 63: Stress Leak Message Box

- 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**.

Printable	Annotation	Time	Pves	Pabd	Pdet	EMG	Flow	Volume
<input checked="" type="checkbox"/>	First Sensation	4.9	817	1225	-408	-129	-4	407
<input checked="" type="checkbox"/>	Stress Test START	8.4	1633	2450	-817	-129	-3	-2646
<input checked="" type="checkbox"/>	*Stress Leak	12.8	2660	-2564	3277	-129	-2	1754
<input checked="" type="checkbox"/>	Calculated LPP = 1026 cmH2O	12.8	2660	-2564	3277	-129	-2	1754
<input checked="" type="checkbox"/>	Stress Test STOP	15.7	-3217	-1549	-1668	-129	-1	-1900

Figure 64: Even Summary – Calculated LLP

5.6.5.5 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 65).

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

Refer to the [Control Panel Settings](#) section on page 71 for more information on configuring the control panel.

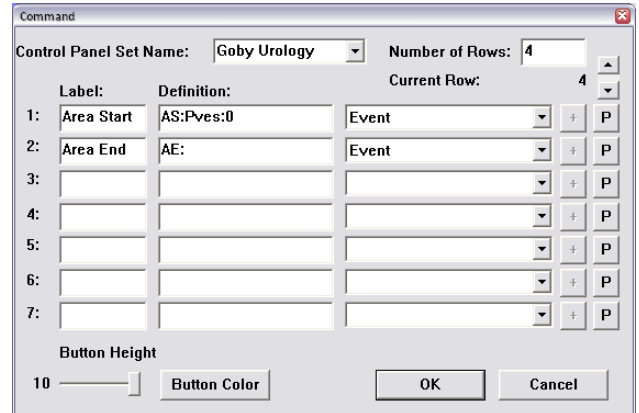


Figure 65: Command Box

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 66).
4. Click **Add**.

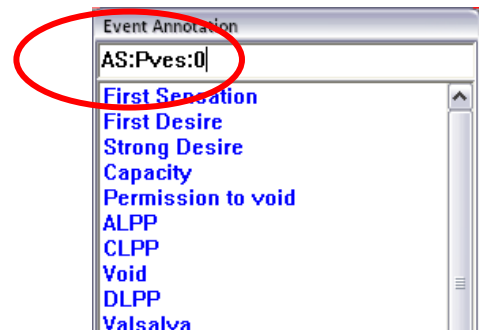


Figure 66: Event Annotation Window, "AS:"

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

Refer to the [About the Event Annotation Window](#) section on page 55 for more information on the Event Annotation window.



Figure 67: 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.

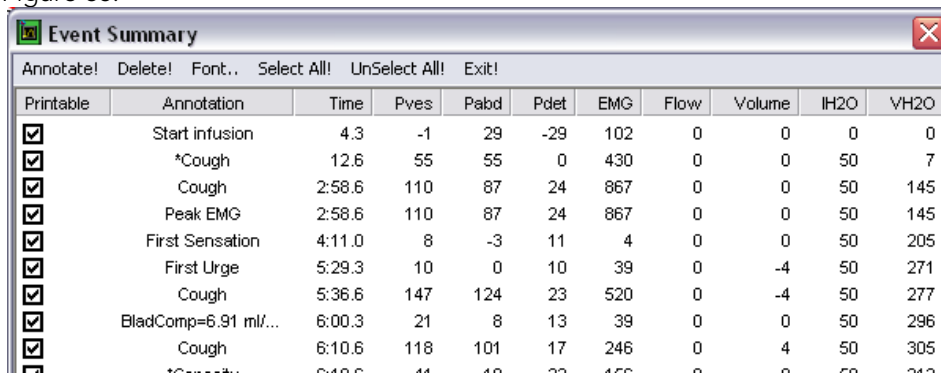
To calculate the Area under Curve for a saved test or after a test is stopped:

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.

5.6.6 Event Summary

To view the *Event Summary* window:

Click **Info > Event Summary**. The events recorded during the test are listed in chronological order in the **Event Summary** window as shown in Figure 68.



Printable	Annotation	Time	Pves	Pabd	Pcdet	EMG	Flow	Volume	IH2O	VH2O
<input checked="" type="checkbox"/>	Start infusion	4.3	-1	29	-29	102	0	0	0	0
<input checked="" type="checkbox"/>	*Cough	12.6	55	55	0	430	0	0	50	7
<input checked="" type="checkbox"/>	Cough	2:58.6	110	87	24	867	0	0	50	145
<input checked="" type="checkbox"/>	Peak EMG	2:58.6	110	87	24	867	0	0	50	145
<input checked="" type="checkbox"/>	First Sensation	4:11.0	8	-3	11	4	0	0	50	205
<input checked="" type="checkbox"/>	First Urge	5:29.3	10	0	10	39	0	-4	50	271
<input checked="" type="checkbox"/>	Cough	5:36.6	147	124	23	520	0	-4	50	277
<input checked="" type="checkbox"/>	BladComp=6.91 ml/...	6:00.3	21	8	13	39	0	0	50	296
<input checked="" type="checkbox"/>	Cough	6:10.6	118	101	17	246	0	4	50	305

Figure 68: Event Summary Window

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.

5.6.6.1 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 where you can set the font to your preference. This only applies to the on-screen display and not what is printed on the hardcopy report.

5.6.6.2 Add or Change Event Annotation

1. Highlight an event and click **Annotate!**
2. The **Event Annotation** window will load. Type the text in the text box or pick from the list.
3. Click **OK**.

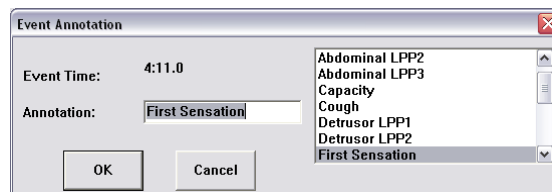


Figure 69: Event Annotation Window

5.6.6.3 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 **Delete!**
3. Click **OK** (Figure 70). Highlighted events are deleted from the Event Summary.

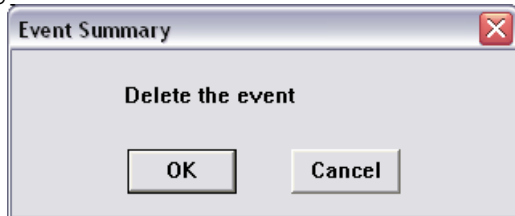


Figure 70: Event Summary – Confirm Deletion

5.6.6.4 Move to Event

Once you are in the *Event Summary* window double-click on an event to move to the point on the graph that corresponds to that event. *Always save the DTA file in order to keep the event annotation changes with the files.*

5.6.6.5 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 68.

5.6.7 Voiding Summary

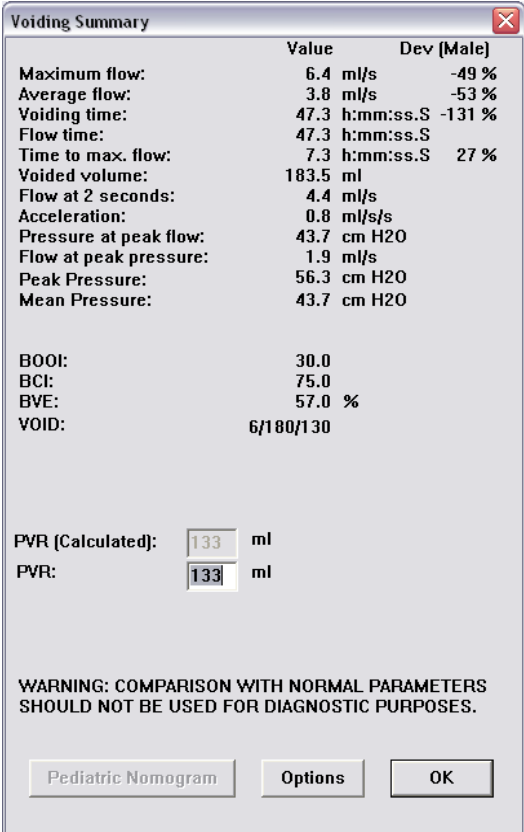
The **Voiding Summary** applies only to tests involving Uroflow information like the Uroflowmetry and pressure-flow procedures. The Summary compares a patient's test results with the normal values. Refer to Table 19: Parameters of Uroflowmetry – 80 Males or Table 20: Parameters of Uroflowmetry – 50 Females in the [Appendices](#) section starting on page [101](#). 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*.

To access the *Voiding Summary*:

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

The *Voiding Summary* printout supplies a comparison to the Nomogram tables (Figure 71). They are provided for both male and female patients on the same printout.



	Value	Dev [Male]
Maximum flow:	6.4 ml/s	-49 %
Average flow:	3.8 ml/s	-53 %
Voiding time:	47.3 h:mm:ss.S	-131 %
Flow time:	47.3 h:mm:ss.S	
Time to max. flow:	7.3 h:mm:ss.S	27 %
Voided volume:	183.5 ml	
Flow at 2 seconds:	4.4 ml/s	
Acceleration:	0.8 ml/s/s	
Pressure at peak flow:	43.7 cm H2O	
Flow at peak pressure:	1.9 ml/s	
Peak Pressure:	56.3 cm H2O	
Mean Pressure:	43.7 cm H2O	
BOOI:	30.0	
BCI:	75.0	
BVE:	57.0 %	
VOID:	6/180/130	
PVR (Calculated):	133 ml	
PVR:	133 ml	
WARNING: COMPARISON WITH NORMAL PARAMETERS SHOULD NOT BE USED FOR DIAGNOSTIC PURPOSES.		
Pediatric Nomogram Options OK		

Figure 71: Voiding Summary Window

The comparison is provided in a percent difference from the table value. The following is the mathematical formula used in the calculations:

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

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

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

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

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.

5.6.7.1 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.

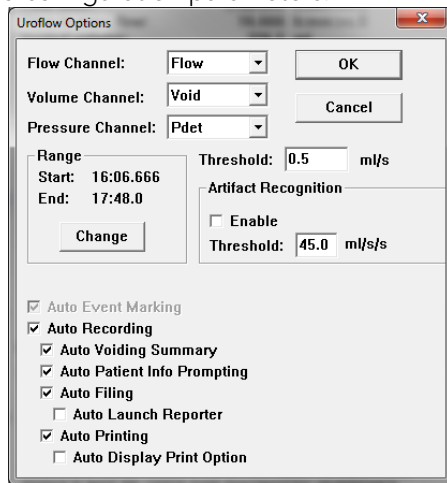


Figure 72: Uroflow Options Dialogue Box

Refer to the descriptions in the following list for parameters which can be changed in the *Uroflow Options Dialog Box*.


- **Default channels:** Flow, Volume, and Pressure.
- **Range:** Default range is from start to end of test.
- **Threshold:** The minimum flow rate value used in calculating the Voiding Summary. Anything below this threshold is considered noise or insignificant flow.
- **Enable Artifact Recognition:** Select check box to enable.
- **Artifact Recognition Threshold:** Indicates the maximum acceptable change in Flow (acceleration) that is physiologically possible.

- **Auto Recording:** With Auto Recording on, tests are automatically started and stopped once the transducer senses fluid in the beaker.
 - **Auto Event Marking:** Automatically adds events to graph.
 - **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.
 - **Auto Patient Info Prompting:** A Uroflow auto recording option to display the *Patient Info* window when a test is stopped.
 - **Auto Filing:** An auto recording option to save a file when a test is stopped.
 - **Auto Launch Reporter:** For **iList™** users, select also to automatically start **iList™** Office Reporter to generate a report.
 - **Auto Printing:** An auto recording option to print a file when a test is stopped.
 - **Auto Display Print Option:** An auto printing option to display print option before auto printing.

The instructions below provide information on how to adjust each of the parameters in the *Uroflow Options Dialogue Box*.

To Change Default Channels:

1. Click the Channel box beside the channel requiring adjustment 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 as long as 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 Segment Selection* window will appear.
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. The start and end lines of the segment are updated.
4. **Confirm** or **Cancel** the selected segment by clicking the appropriate option. The *Uroflow Options Segment Selection* window closes, returning to the *Uroflow Options Dialogue Box*.

To Enable the Software to Recognize Artifacts:

In the *Uroflow Options dialogue box*, select the **Enable Artifact Recognition** box. A checkmark will appear in the box indicating that the software will detect artifacts. Artifact Recognitions refers to the detection of non-physiological transducer readings.

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 UDS120 GOBY software recognizes the event as a deviation from what it considers a normal reading.

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:

1. Double-click the **Artifact Recognition Threshold** box. The value in the text box will be highlighted.
2. Enter a new value using the keyboard. The software will recognize the new value in the Threshold text box as the maximum rate of flow. Any values over this maximum rate will be considered an artifact.
3. When exiting the Uroflow Options dialogue box, click **OK** to save changes or **Cancel** to cancel changes. The *Uroflow Options* window closes and returns to the *Voiding Summary* window.

To Enable Uroflow Auto Recording:

Select the **Auto Recording** option in the **Uroflow Options dialogue box**

The **Uroflow Auto Recording** feature is used for Uroflow or Pressure-Flow studies. It will automatically start a procedure without the need to click buttons. This feature provides Auto Start, Auto Stop, and Auto Set Up of the next procedure. Once this feature is made available, you can select other customizable options.


Uroflow Auto Recording options are performed in the order described in Table 6:

Options	Always On/Selectable	Description
Auto Beaker Detection	Always On	After selecting this procedure, it detects if a beaker is on the Uroflowmeter. If no beaker is put on, it will display the message <i>Beaker lifted off</i> 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 Uroflow Summary	Selectable	Automatically displays the <i>Voiding Summary</i> 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 6: Uroflow Auto Recording – Order of Actions

5.6.7.2 Pediatric Nomogram

The Pediatric Nomogram^{xiii} feature can be accessed from the *Voiding Summary* window. This feature 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 73).

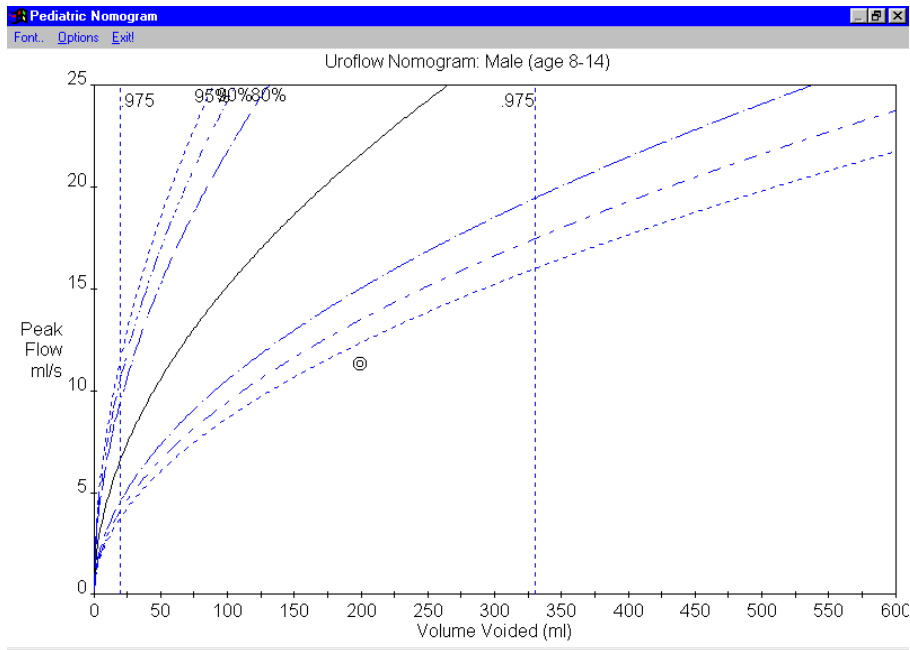


Figure 73: Pediatric Nomogram Window

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

5.6.8 UPP Summary

The UPP (Urethral Pressure Profile) test allows a clinician to assess and determine a patient's urethral length and resistance. Once the urethral pressure and the vesicle pressure data are obtained, the software can provide a UPP summary.

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

To Open the UPP Summary window:

Click **Info** from the menu bar and select **UPP Summary**. The *UPP Summary* window will appear (Figure 74). 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.

UPP Summary										
UPP Rate: 1.0 mm/s										
	Pull 1	Pull 2	Pull 3	Pull 4	Pull 5	Pull 6	Pull 7	Pull 8	Average	
Length:	26	23	21	21					22	mm
Start:	1:21.0	2:06.0	2:45.5	3:32.0					N/A	
End:	1:47.0	2:29.5	3:06.5	3:53.0					N/A	
Peak Pura:	48	65	60	51					56	cm H2O
Obstruction Zone Peak										cm H2O
Length of Cont. Zone:	13	11	13	9					11	mm
Area of Cont. Zone:	404	316	449	230					350	cm H2O.mm

Figure 74: 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.
- *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

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. 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.

5.6.8.1 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 75).

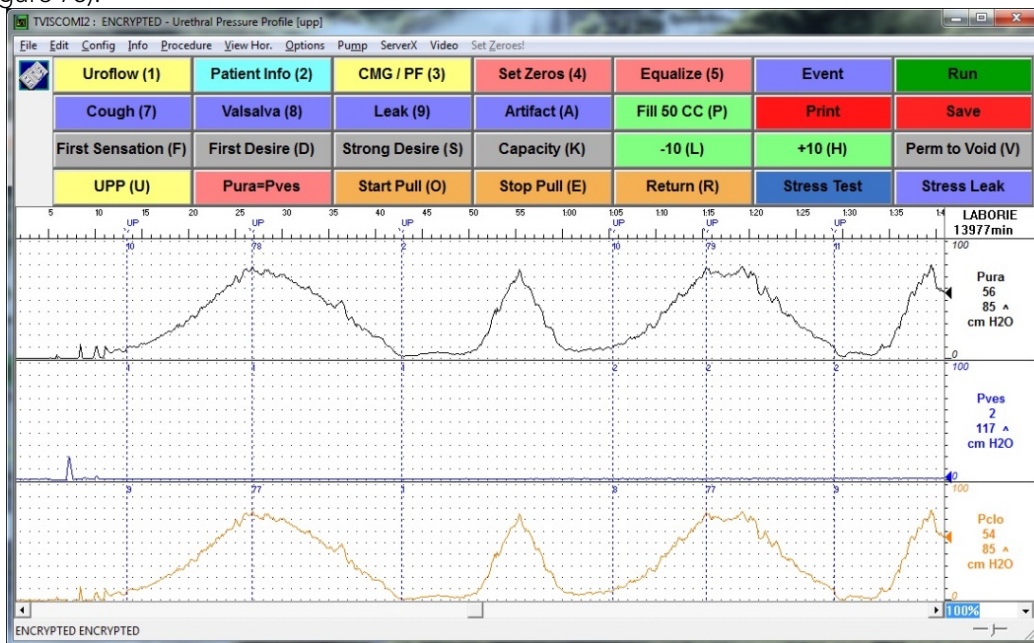


Figure 75: Urethral Pressure Profile Test

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 76).

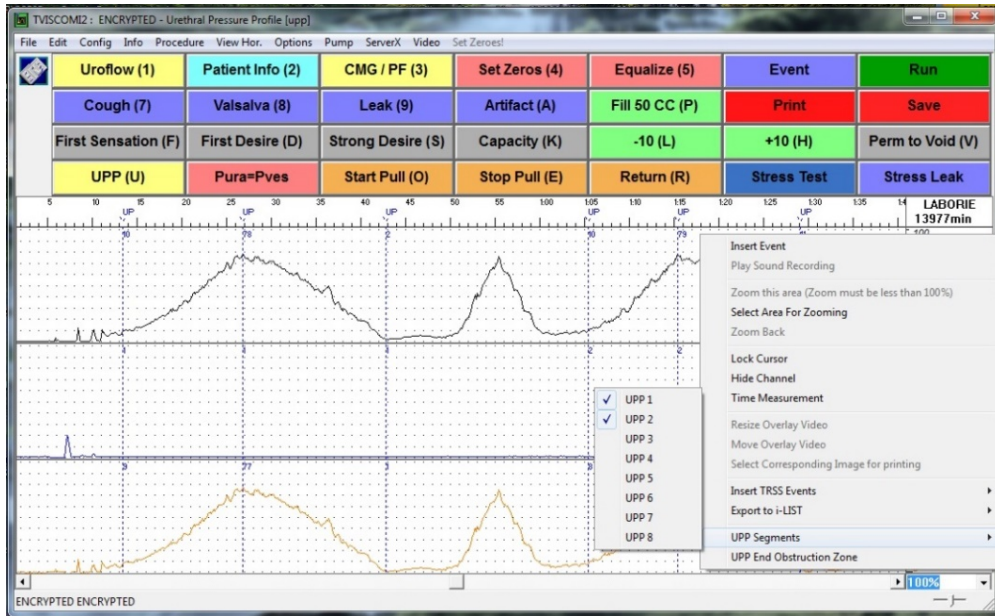


Figure 76: UPP Segments Menu

- c. Uncheck the UPP pull requiring re-marking and the event markings corresponding to that UPP pull will be removed from the graph. Figure 77 shows the removal of event markings for UPP1.

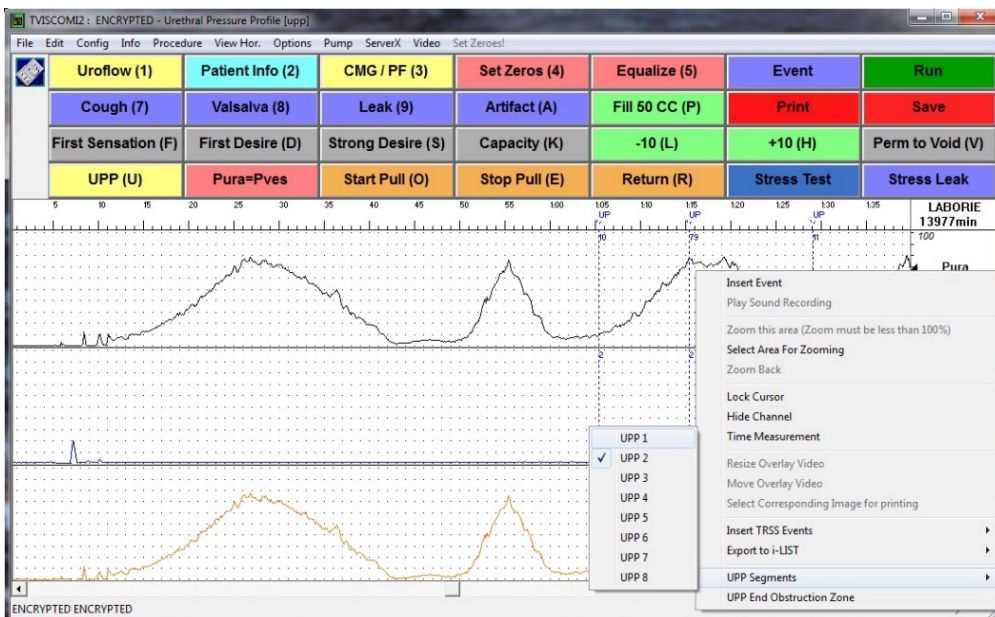


Figure 77: UPP Segment Window – Removing UPP Events

- 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.

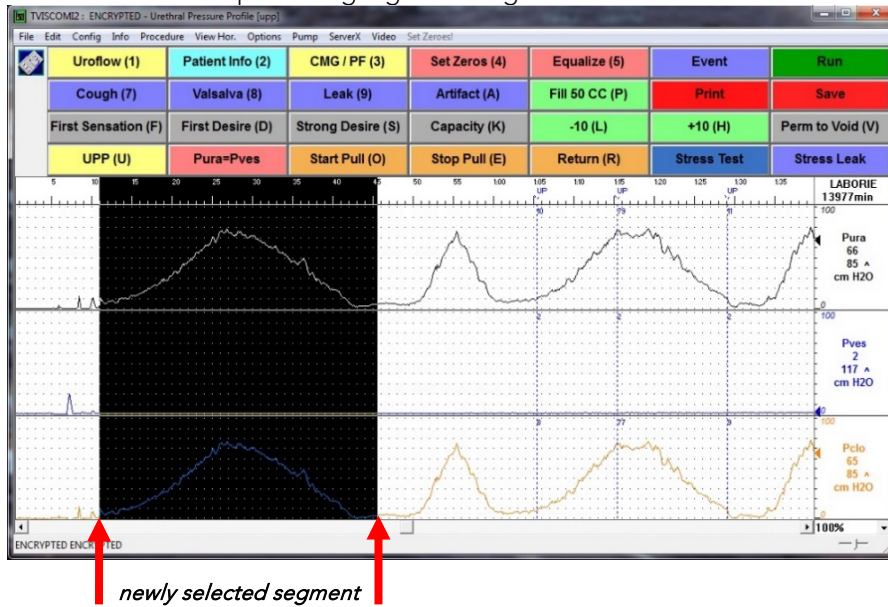


Figure 78: Marking a UPP Segment

- Right-click on the highlighted section of the graph to open the context menu.
- 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 79 shows remarking of UPP 1 which was removed in step 1.

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

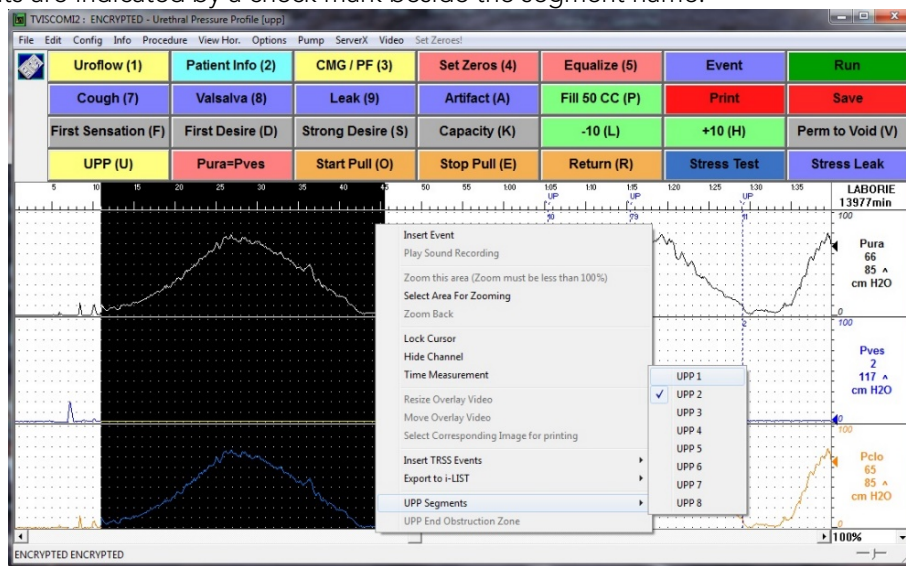


Figure 79: Adding the UPP Segment


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

UPP Summary									
UPP Rate: 1.0 mm/s									
	Pull 1	Pull 2	Pull 3	Pull 4	Pull 5	Pull 6	Pull 7	Pull 8	Average
Length:	34	23							28 mm
Start:	11.3	1:05.4							N/A
End:	45.7	1:29.1							N/A
Peak Pura:	78	79							78 cm H2O
Obstruction Zone Peak:									cm H2O
Length of Cont. Zone:	15	10							12 mm
Area of Cont. Zone:	515	373							444 cm H2O.mm

Figure 80: UPP Summary – Updated Segment

5.6.9 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:

$$\frac{\Delta V_{H2O}}{\Delta P_{det}} = \frac{\text{change in bladder volume}}{\text{change in Detrusor pressure}}$$

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 [Set up/Modify](#) section on page 38 for more information on the *Configuration* window. Refer to subsections below for instructions on selecting segments for Bladder Compliance Calculation.

5.6.9.1 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.

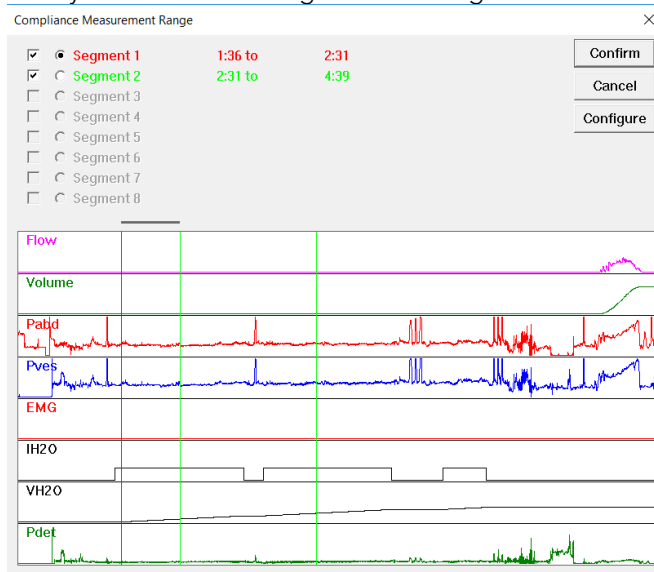


Figure 81: Compliance Measurement Range Window

To Manually Select a Segment for Analysis:

1. The *Compliance Measurement Range* window 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 will be selected. The time of the selection appears.
4. To modify the selected segment, reselect range.
5. To keep the selection and return to the test click **Confirm**. The Compliance Calculation will be 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.

Auto Bladder Compliance

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 > Set up/Modify > Compliance tab**; refer to the [Compliance Tab](#) section on page 43.

The *Compliance* tab provides three Compliance Methods: **Manual**, **Auto: Events**, and **Auto: Infusion / 100ml**. Refer to Figure 82 for a visual of the *Compliance* tab and its menus:

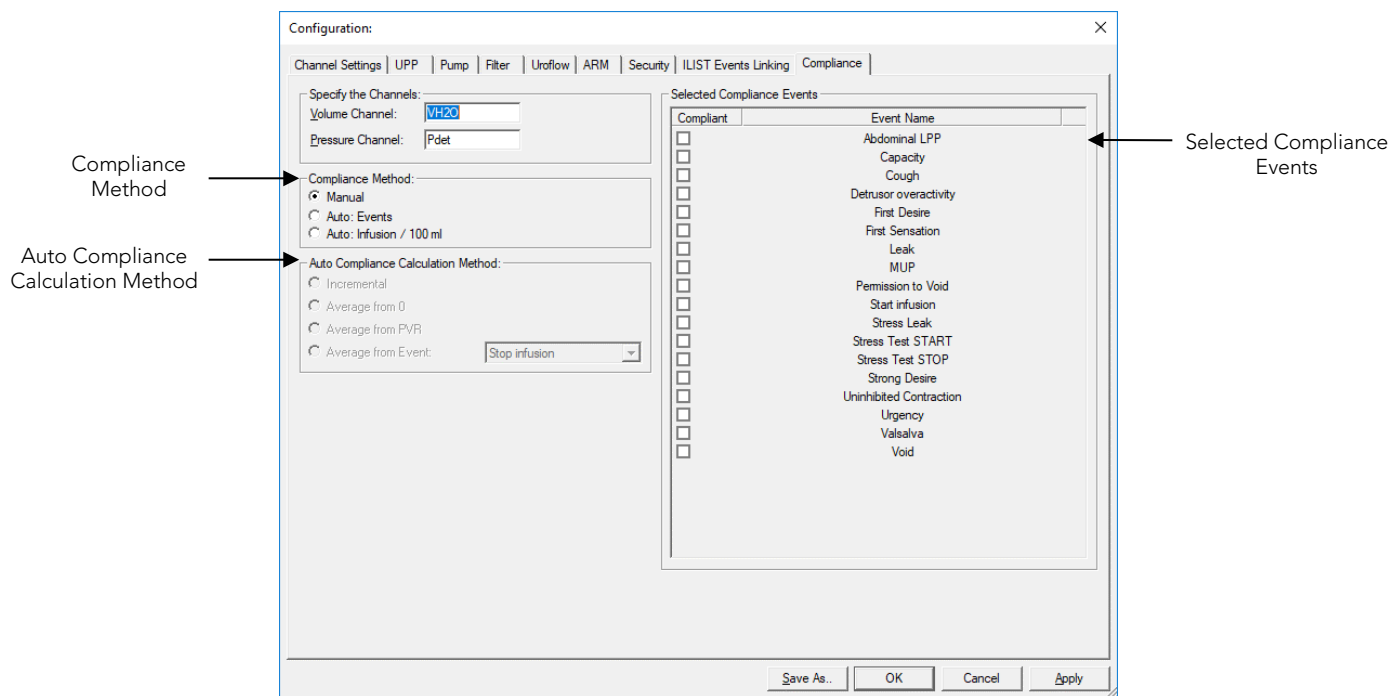


Figure 82: Compliance Window

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 68.
- **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.

Select 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.

Once the calculation start event is selected in *Auto Compliance Method*, select calculation end events using the *Select Compliance Events* menu.

Select Compliance Events

Use the **Select Compliance Events** menu to select the calculation end events. Select the checkbox of the desired events. Press **OK** to save changes to compliance settings.

5.7 VIEW HORIZONTAL MENU

The *View Horizontal* Menu provides resize options that will scale down or up the graphs shown in the scrolling graph section. To select specific areas of the graph for closer inspection, refer to the [Zoom – Selected Area and Back](#) on page 37.

5.8 OPTIONS MENU

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

5.8.1 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**.

5.8.2 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 plays 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**.

 **NOTE:** Audio is not available during playback at 2X speed or faster.

5.8.3 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**.

5.8.4 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 > Cursor Value Indicator** or Press the F9 key on the keyboard. This will launch the *Cursor* window (Figure 83).

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 > Cursor Value Indicator** or press the **F9** key on the keyboard.

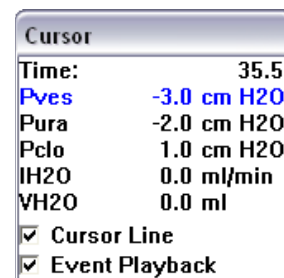


Figure 83: Cursor Window

5.8.5 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 > Digital Value Indicator** or press **F8** on the keyboard.

5.8.6 Control Panel Settings

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 84).

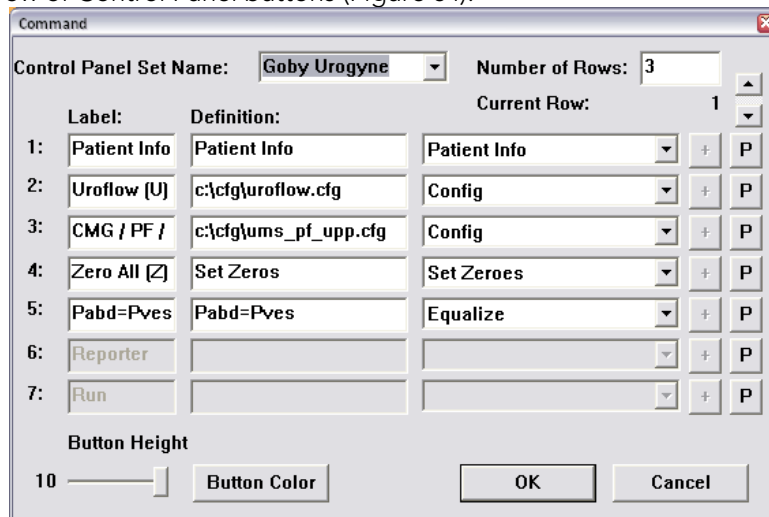


Figure 84: Command Window

2. Change the Label, Definition, and command type.
 - a. To change the Name of the function button, double-click the label of the button 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 type of function 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.

5.8.6.1 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 84).
3. The *Properties* window will appear (Figure 85). 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.

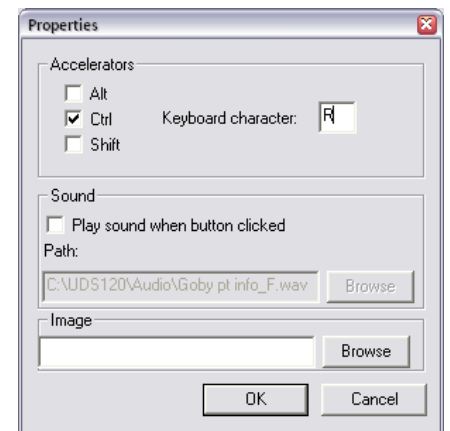


Figure 85: Properties Window

5.8.6.2 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:

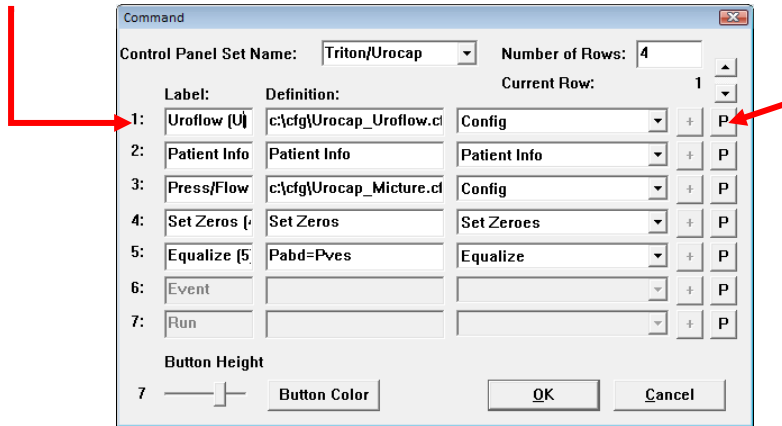


Figure 86: Uroflow Button Properties window

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

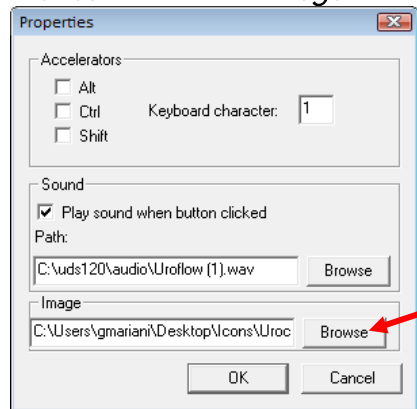


Figure 87: Adding Image to Label – Properties Window

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 88:

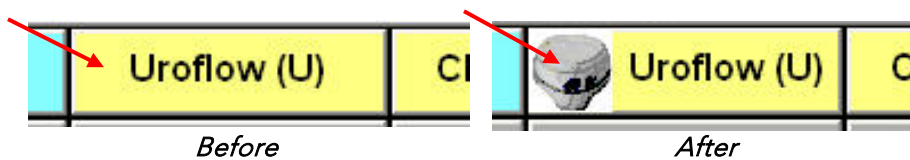


Figure 88: Edited Uroflow Button

5.8.6.3 Customize Colors and Fonts and Adjust Button Size

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 *Button 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**.

Standardize coloring and fonts of all Control Panel buttons in the *Select Color* window (Figure 89). 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.

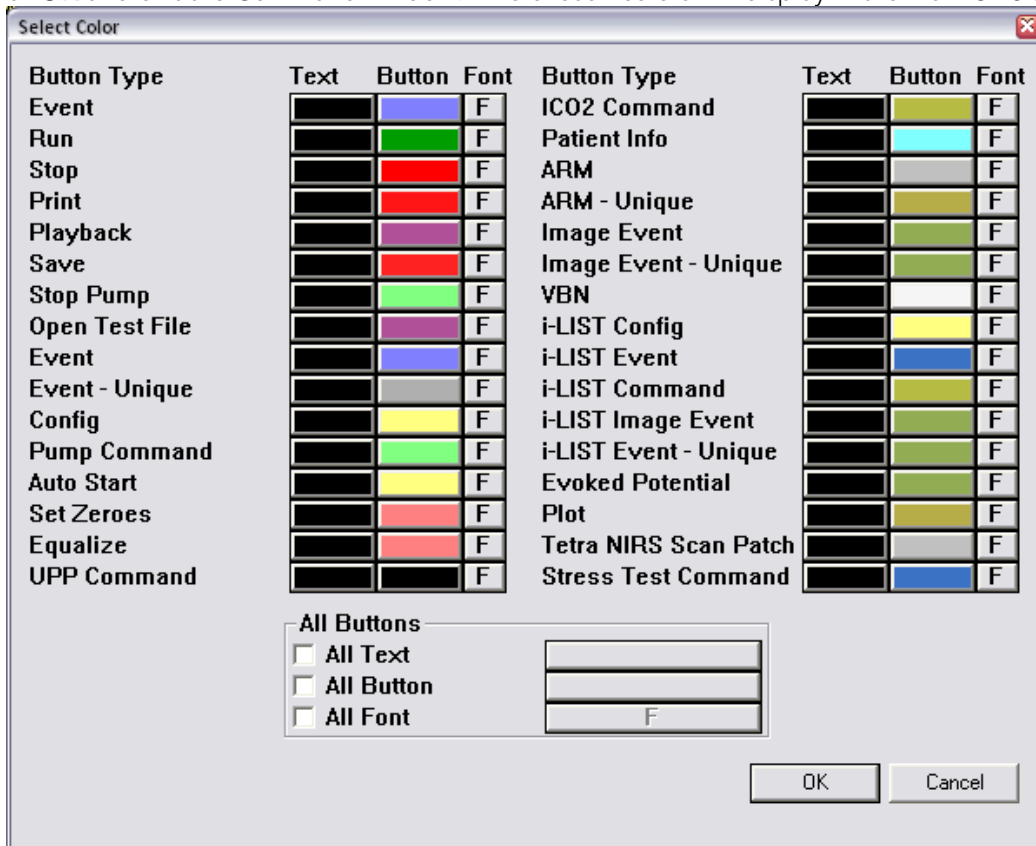


Figure 89: Select Color Window

The *Button Height* slider on the *Command* window 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 (Figure 86).

5.8.6.4 Types of Control Panel Commands

The following table lists the types of control panel buttons available for the Goby™ software. Note that the button names (labels) in the chart are suggestions and can be re-named.

Button Label	Definition	Type	Comments
First Sensation First Desire Capacity Valsalva Cough	First Sensation First Desire Capacity Valsalva Cough	Event	Marks an event with the definition text as Event Annotation.
		Event - Unique	An event that occurs only once and will replace any existing recorded event.
Uroflow CMG Micturition	Full path of test CFG file	Config	Opens a .cfg file.
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.
Resume Pump	PumpRunStopResume	Pump Command	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.
Zero All	N/A	Zero All	Sets all channels to zero.
Pura = Pves or Pabd = Pves	Channel X = Channel Y Example: Pura channel = Pves channel	Equalize	Sets the left channel value to the right.
Patient Info	N/A	Patient Info	Opens Patient Info.
Plot	Pre-set with the selections made when button is configured	Plot[†]	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 56 for more information.
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.

Button Label	Definition	Type	Comments
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.

† NOTE : To define the Nomogram plots that will be displayed follow the instruction provided below.

1. Select **Plot** from the drop list in the *Command* window.
2. Click the plus (+) button to open the selection box.
3. Select **All** in the *Plot Window* and click **OK**.
4. Name the button.
5. Click **OK** to save changes to the control panel.

Refer to Figure 90.

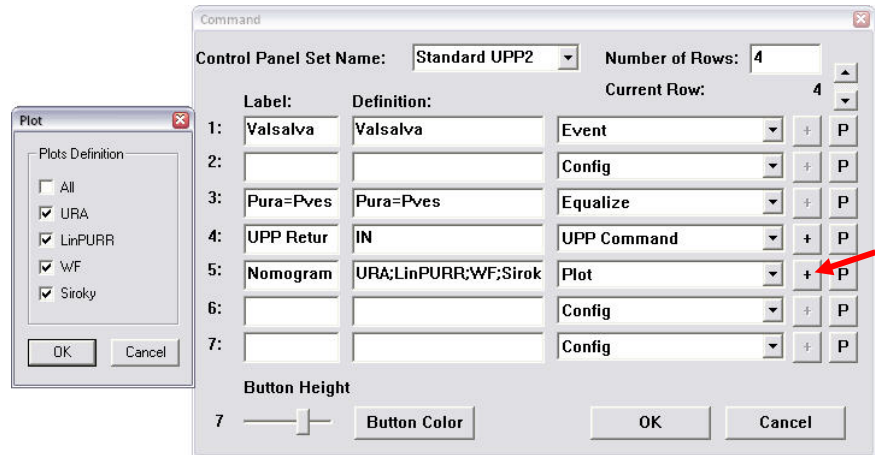
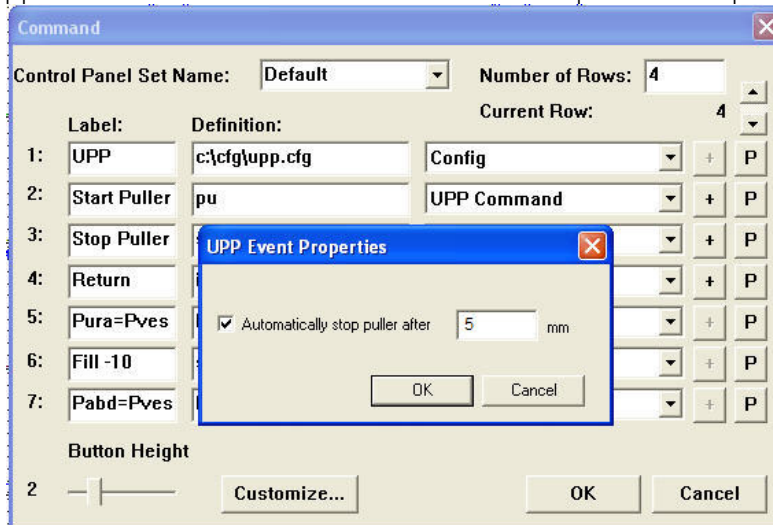


Figure 90: Command Window – Selecting Plots

*NOTE 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)

Set the puller to automatically stop or pull at preset intervals with the click of a button using the Additional UPP commands listed above. When a UPP Command is selected in the Label drop down list and the definition is either PU or IN, a pop-up box appears for selection of the intervals at which the puller will stop.



- Click **OK** to set the interval.

Table 7: Control Panel Commands

5.8.7 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.

5.8.8 Event Display Options

Utilize event display options to customize how events and peaks are marked on the curve.

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 91). 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.

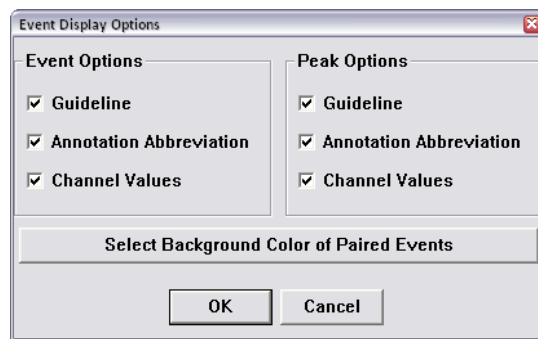


Figure 91: Event Display Options window

5.8.9 Select Background Color 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 91).

1. Click the **Select Background Color of Paired Events** button (Figure 91) 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 92).

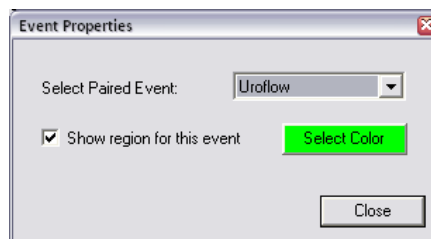


Figure 92: Event Properties – Select Paired Event

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.

5.8.10 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.

5.8.11 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 *Event Summary* on page 55.

5.8.12 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 exceed the channel scale range.

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

5.9 SET ZEROES! 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 (Figure 25). The Set Zeroes window will launch (Figure 93).
 - 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 while a test is running.

5.9.1 Undo Set Zeroes

The **Undo Set Zeroes** feature clears the settings of a previous zeroing operation.

To Undo the **Set Zeroes** action for a test, click **Undo Set Zeroes** from the *File* menu and select **Undo**.

The previous Set Zeros operation will be reversed.

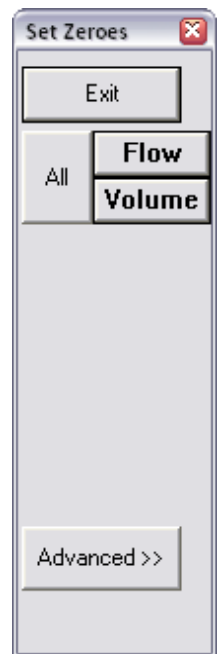


Figure 93: Set Zeroes Window

6 HOW TO RUN TESTS

This section provides instructions on how to run tests with the **GOBY™** System. For more information on equipment or accessories setup, refer to the [Set Up Goby™ Equipment and Accessories](#) section on page 15.

6.1 UROFLOW TEST

A Uroflow test is a measurement of the rate at which urine flows out of the body. It can be performed with the UDS120 Goby software's automatic method or it can be performed through manual use of the software.

NOTE: Make sure the battery of the **Urocap™ IV** is fully charged before the start of the test.

6.1.1 Urocap IV Setup for Uroflow Test

1. Gather the supplies needed for a Uroflow test. (Beaker, commode chair, funnel, etc...).
2. Carefully place the **Urocap™ IV** on the floor or on an approved Uroflow transducer stand.
3. Gently position a graduated beaker on top of the **Urocap™ IV**.
4. Place the funnel on the plastic frame of the commode chair and position both over the **Urocap™ IV** and beaker. Ensure that the beaker and the funnel are aligned but not touching.
5. Turn on the computer and then turn on the printer.

6.1.2 Run a Uroflow Test

6.1.2.1 Run a Uroflow Test: Auto Method

1. Complete Urocap IV Setup as instructed in the [Urocap IV Setup for Uroflow Test](#) section on page 80.
2. Invite the patient to get ready to take the test.
3. Start the *UDS120 GOBY* software.
4. Click the **Uroflow** button on the control panel.
5. Confirm that **Auto Recording Mode** is displayed in the blue title bar above the graph.
6. Tap on the **Urocap™ IV** to make sure it is responding.
7. Notify the patient that the test is set to proceed. 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.



CAUTION: DO NOT TOUCH the beaker during voiding.

8. Wait for the patient to finish voiding. The graph will stop automatically 50 seconds after voiding has ended.
9. When the *Patient Information* screen appears enter any required information and click **OK**.
10. Straight catheterize the patient to obtain post-void residual measurement (PVR), then remove the catheter. When the *Uroflow Summary* screen appears, enter the PVR value and click **OK**.
11. Click the **Save** button on the control panel to save the test or click **Reporter** to save, view, and print a test report in iList.
12. Empty the beaker and thoroughly wash for reuse.

6.1.2.2 Run a Uroflow Test: Manual Method

1. Complete Urocap IV Setup as instructed in the [Urocap IV Setup for Uroflow Test](#) section on page 80.
2. Invite the patient to get ready to take the test.
3. Start the *UDS120 GOBY* software and
4. Click the **Uroflow** button on the control panel.
5. Click **Set Zeroes** on the main menu bar.
6. Click the **Run** button to start the test.
7. Instruct the patient to void. If possible, leave the room to allow patient privacy.

CAUTION: DO NOT TOUCH the beaker during voiding.

8. When voiding is complete, click the **Stop** button.
9. Straight catheterize the patient to obtain a PVR measurement, then remove the catheter.
10. Click **Info**, then **Voiding Summary**. Enter the PVR measurement into the associated box and click **OK**.
11. Click the **Save** button on the control panel to save the test or click **Reporter** to save, view, and print a test report.
12. Empty the beaker and thoroughly wash for reuse.

6.2 CMG/PF TEST


The purpose of running a CMG/PF 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 $P_{det} = P_{ves} - P_{abd}$ (the difference between the pressure inside the bladder (P_{ves}) and the pressure inside the abdomen (P_{abd})).


NOTE: Make sure the batteries on the devices are fully charged before the start of the test.

6.2.1 Run a CMG/PF Test


6.2.1.1 Run a CMG/PF Test Using 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 *UDS120 GOBY* software.
 - b. Turn on the **Goby™ Hub** with the power switch located at its base and ensure it is connected in the software. Ensure the **UDS Roam™** and **Urocap™ IV** are connected to the software and at full battery.
 - c. Connect the transducer cables to the **UDS Roam™** 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. Tape catheters as close to the insertion site as possible. The **UDS Roam™** may be attached to the patient with the optional belt and holster; refer to page [95](#).
9. 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.
10. Switch the transducers to the **CHARGE** position to record true internal pressures. When recording two pressures during a CMG or Pressure/Flow test, P_{ves} and P_{abd} should be fairly equal and P_{det} should be at or near zero.
11. 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 P_{abd} is higher than P_{ves} , try repositioning the P_{abd} catheter. If repositioning does not work, ask the patient to cough to confirm that both pressures are reacting appropriately.

12. Select the *Calibration Set* and then click the **Run** button on the control panel. Refer to the [Calibration Sets Menu](#) section on page [79](#) for instructions on selecting Calibration Sets.
13. Click the **Start Pump** button to start the pump and begin filling the bladder.
14. 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.
15. Click **Stop Pump** to stop infusing when the patient is full and click **Capacity** on the control panel to mark the event.
16. Click the **Permit to Void** button and ask the patient to void through the commode chair into the **Urocap™ IV** beaker (with catheters in place).
17. Click the **Stop** button when finished and then click the **Save** button on the control panel to save the test file.
18. Print the results of the test if desired. See the [Print a Test](#) section on page [88](#) for more information.
19. Remove the catheters, EMG patches, and pump tubing and dispose in accordance to hospital/clinic procedures.
20. Empty and thoroughly wash the beaker for reuse.

6.2.1.2 CMG/PF 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. Turn on the **Goby™ Hub** with the power switch located at its base and ensure it is connected in the software. Ensure the **UDS Roam™** and **Urocap™ IV** are connected to the software and at full battery.
 - c. Prime the transducers pressure cartridges, measurement tubing, and pump tubing.
 - d. Click the **CMG/PF** 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 H₂O.
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 Set* and then click the **Run** button on the control panel. Refer to the [Calibration Sets Menu](#) section on page 79 for instructions on selecting Calibration Sets.
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™ IV** 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.

6.3 RUN A UPP TEST

A Urethral Pressure Profile (UPP) test is used to measure the length of the urethra and the pressure within the urethra. An optional UPP puller device 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 19. Refer to the *UPP Silent Drive Puller Owner's Manual* for more information about the setup and use of the UPP puller.



NOTE: Make sure the battery is fully charged before the start of the test.

6.3.1 Setup for UPP Test

1. If utilizing the UPP Silent Drive Puller, ensure that the device is set up correctly. Refer to the *UPP Silent Drive Puller Owner's Manual* for more information.
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. Turn on the **Goby™ Hub** with the power switch located at its base and ensure it is connected in the software. Ensure the **UDS Roam™** and **Urocap™ IV** are connected to the software and at full battery.
 - c. Prime the pressure transducer cartridges, pressure measurement tubing and pump tubing.
3. Ask the patient to void or perform a Uroflow test if required.
4. Insert catheters according to device specific Instructions for Use.
5. Tape the catheters as close to the insertion site as possible and ensure the catheter is connected to the applicable transducer pressure cartridge. The **UDS Roam™** may be attached to the patient with the optional belt and holster; refer to page 95.
6. Click the **UPP** button on the control panel and add the patient's information if necessary. Click **Run** then infuse.
7. Click **Start Pump** to infuse a minimum of 50cc into the bladder. Once the bladder is filled to the desired volume, click **Stop Pump**.
8. Confirm placement of the Pura sensor just proximal to the bladder neck. Withdraw the catheter at a moderate rate. When Pura begins to rise, stop withdrawing and return the catheter *slightly* back into the bladder. This will place the sensor proximal to the bladder neck, which is a good place to start the slow withdrawal.

6.3.2 Run a UPP Test

6.3.2.1 UPP Test with the UPP Silent Drive Puller

1. Once the UPP Test setup is complete, place the catheter into the guide and clamp of the UPP puller arm.
2. Click **Start UPP**. The catheter will be withdrawn from the bladder at a rate of 1mm/second. Notice when Pura and Pclo start to rise; Pves should remain stable indicating that the sensor is traveling through the urethra.
3. When the Pura sensor on the catheter has reached the end of the urethra (as indicated by the Pclo reaching zero), click **Stop UPP**.
4. Click **Return** to set up the puller for the next catheter pull. The UPP Puller will return to the start position.



IMPORTANT: If the catheter is removed from the patient do not use the UPP Puller to re-insert the catheter.


5. Click **Stop** when finished, then click the **Save** button on the control panel. Print the results of the test if desired. See the [Print a Test](#) section on page 88 for more information.
6. Remove the catheters and dispose in accordance to hospital/clinic procedures.
7. The UPP puller must be thoroughly cleaned and disinfected. See the *UPP Silent Drive Puller Owner's Manual* for information about cleaning and disinfecting.


6.3.2.2 UPP Test with a Manual Pull

1. Once the UPP Test setup is complete, click **Start UPP**.
2. Begin withdrawing the catheter VERY slowly. 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.
3. When Pclo returns to 0, stop pulling.
4. Click **Stop UPP**. Reinsert the catheter to either repeat the UPP or click Stop to finish the test.
5. Click Save button on the control panel; print the results of the test if desired.
6. Remove the catheters and dispose in accordance to hospital/clinic procedures.
7. The UPP puller must be thoroughly cleaned and disinfected. See the *UPP Silent Drive Puller Owner's Manual* for information about cleaning and disinfecting.

6.4 AMBULATORY MONITORING

The Ambulatory Monitoring feature allows the **UDS Roam™** to monitor pressure and EMG data separate from the software once setup. The **UDS Roam™** will store information while the test is recording, at completion of test the data must be downloaded into the software for analysis.

 **NOTE:** The **UDS Roam™** can run for 1 voiding cycle (3 hours) or 2 to 3 voiding cycles (4 to 6 hours). Fully charge the **UDS Roam™** and calibrate the remote control buttons.

 **IMPORTANT:** The Ambulatory Monitoring feature is available for remote ambulatory users only.

6.4.1 Setting Up the Remote Control and UDS Roam for Ambulatory Testing

Use the remote control to add events to the graph during tests. Once the buttons are configured click the button as the events occur and they will be recorded on the graph. Press and hold the configured buttons for at least 1 second.

6.4.1.1 Part 1: Calibrate P4

1. Plug the Ambulatory Remote into Channel 4 (P4) of the **UDS Roam™**.
2. Double-click the **UDS Roam** icon in the main window to open the *Goby Device Manager* window:

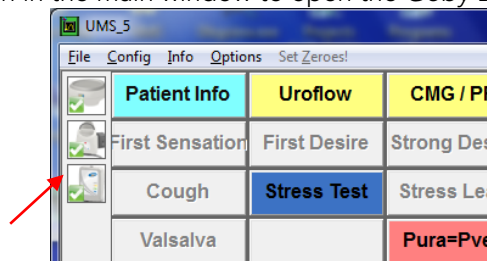


Figure 95: Goby Device Manager Window – Calibrate Remote Control and UDS Roam

3. Click the **Setup** button to launch the *Setup* window. Click the **Device Calibration** button.
4. Select **P4** for calibration as the **Ambulatory Remote** connects to channel 4 of the **UDS Roam™**.
5. Type 0 into the *Low Load* box and click the **Apply** button (Figure 96).

NOTE: do not press any event buttons on the remote.

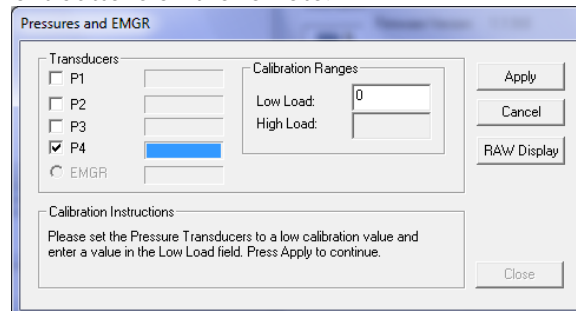


Figure 96: Device Calibration – Pressures and EMGR Window

6. Click the **RAW Display** button. Press each button on the remote control and make note of the button that has the lowest RAW value when pressed. **NOTE:** The button with the lowest RAW value is usually button 6.
7. Type 130 in the *High Load* box (Figure 97).

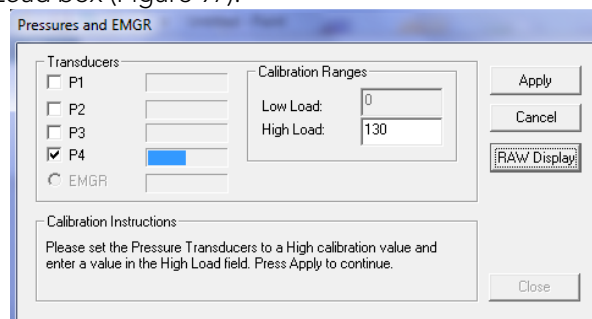


Figure 97: Device High Load Calibration – Pressures and EMGR Window

- Press the button on the remote control with the lowest RAW value (as found in step 6) and click **Apply**. The Pressures and EMGR window will close.

6.4.1.2 Part 2: Configure File Settings for Remote Detection Algorithm

- Click the **CMG/PF** button on the Software Control Panel.
- Click **Config > Setup/Modify** to launch the *Configuration* window.
- Click the *Channel Settings* tab and then click the **Clear Config** button.
- Add **Ch4** to the channel settings with the following data and click **OK**. (as shown in Figure 98)

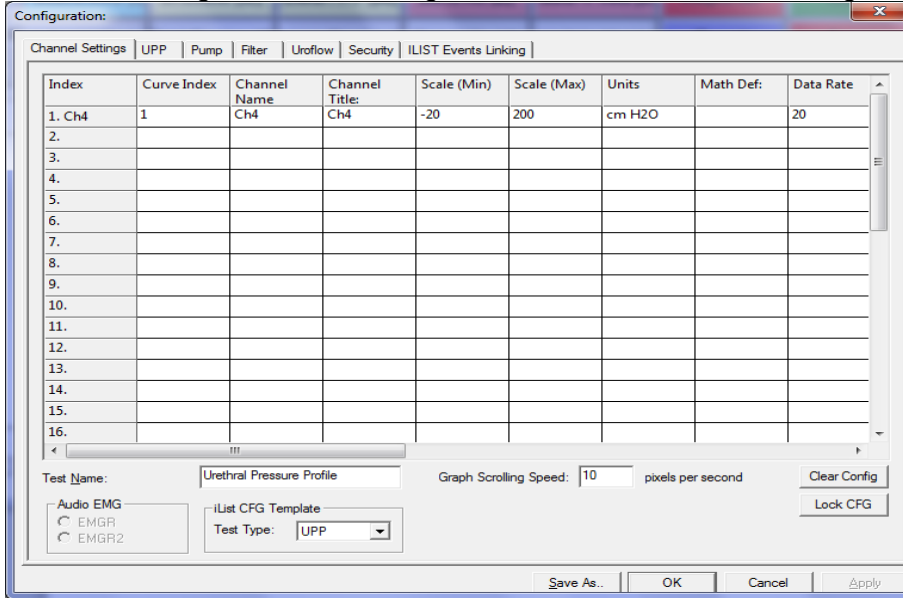


Figure 98: Configuration Window – Channel Settings

- Run a sample test and press the remote buttons one by one, starting with Button (1). Each instance will be marked on the graph as an event providing a relative CH4 value. Take note of the order you press the buttons.
- On the graph, right-click on the first event to open the context menu as shown in Figure 99. Click **Calibrate Remote Button Events > Button (1)** from the context menu. Repeat for all other buttons using their correlating events.

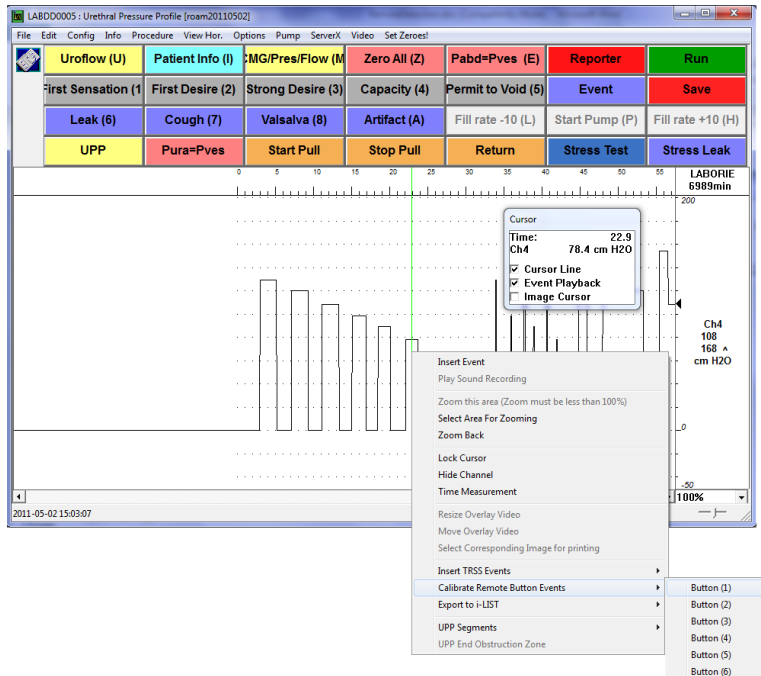


Figure 99: Calibrate Remote Button Events

6.4.1.3 Part 3: Configure the Buttons

1. Click **Options > Remote Button Events Settings** to configure the buttons on the remote for use during a test (Figure 100).




Figure 100: Remote Button Events Window

2. Select an action for each button from the drop down menu next to each button number.
3. Click **OK** to set the button actions.

A printable copy of the remote button functions screen is available in the *Intake and Voiding Diary* PDF document found on the LABORIE software disc. Write in the name of the event next to each button to help keep track of which event is configured for each button.

6.4.2 Running an Ambulatory Monitoring Test

1. Click the **Ambulatory** button on the UDS120 control panel: 
2. In the resulting *Ambulatory Configuration Manager*, select the **UDS Roam™** device that will record the data from the drop-down menu under section 1.
3. Ambulatory testing can be performed with two separate **UDS Roam™** devices on two separate patients at the same time. When setting up the test ensure to select a different **UDS Roam™** device for each patient.
4. Select the configuration file to use for the ambulatory test from the drop-down menu under section 2.
5. Select the patient name under section 3.
6. Click **Observe** under section 4 to view the *Pretest* window for verification of pressures. Refer to Figure 101.

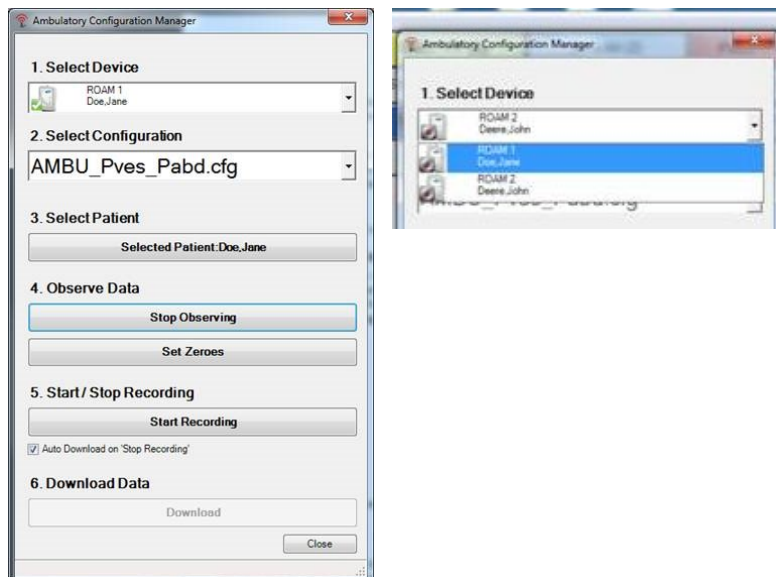


Figure 101: Ambulatory Configuration Manager Window

- Ensure catheters are inserted as per the [T-DOC Air-Charged Catheter and Transducer Setup](#) section on page 21. LABORIE recommends the use of T-DOC Air-Charged for Ambulatory Monitoring to allow for freedom from the Urodynamic System. With transducers in the open position, **Set Zeroes** to atmospheric pressure. The test graph will begin scrolling in **Pretest** mode but will not record data as shown in Figure 102 below; adjust catheters as needed. The LED Bluetooth light on the **UDS Roam™** will light up to signal a connection has been made.

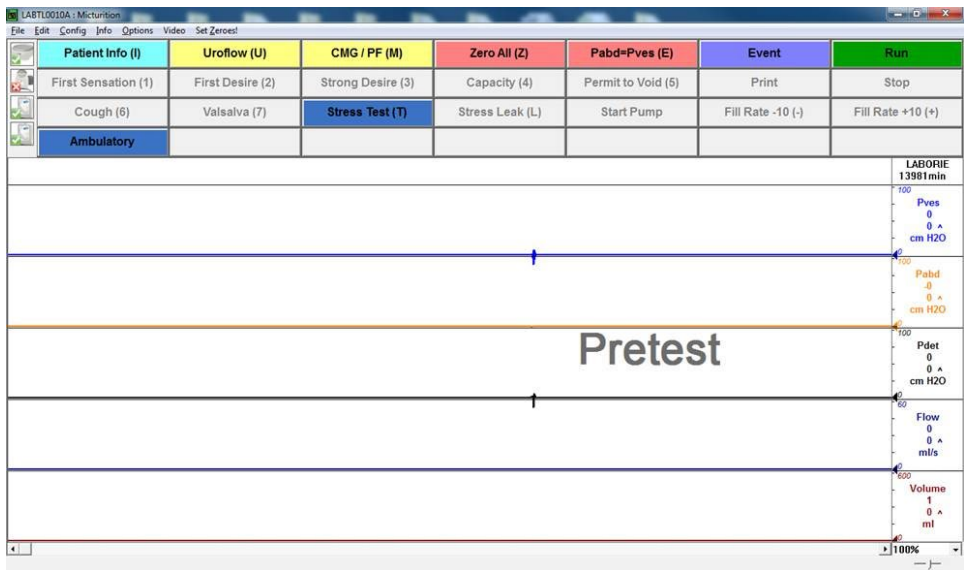


Figure 102: Ambulatory – Pretest Window

- Click **Start Recording** under section 5 of Figure 101 to start ambulatory monitoring. Alternatively, ambulatory monitoring can be started outside of the observation mode by clicking **Stop Observing**, then clicking **Start Recording**. The **UDS Roam™** icon will alert that it is in recording mode:
- The patient is now in ambulatory mode and pressure recording begins. Click **Close** to exit the *Ambulatory* window (Figure 101).



NOTE: LABORIE recommends to enter *Observe* mode once every hour to check catheter placement.

- To enter observe mode, click the **Ambulatory** button on the UDS120 control panel, click **Observe** and wait for the Bluetooth connection to be established. All pressures are being recorded at this point as well as during the pressure check.
- Once Ambulatory recording is complete download all information by clicking the **download button** in section 6 of Figure 101.

Provide the patient with the *Intake and Voiding Diary* PDF document found on the LABORIE software disc to help record events.



NOTE: when data is downloaded, it is erased from the storage memory of the **UDS Roam™** and copied over to the PC. The **UDS Roam™** icon will signal if information is still stored in its memory by displaying the following icon in the *Ambulatory Configuration Manager* screen:



6.5 PRINT A TEST

Once the test is complete, click the **Reporter** button on the software control panel to open and print the report. To print a saved test file, open the test file using the *File* Menu. Click **File > Open** to launch the *Open Test* window then, select the patient file. Click the **Reporter** button on the control panel to open the **iList™ Office Reporter** software.

iList™ Office Reports contain information gathered from the *Patient Info* screen as well as the saved test files. Report templates are associated with the type of UDS test performed. For example, if you select a report template to view Uroflow test results then **iList™ Office Reporter** will use that template for each Uroflow report unless otherwise configured. Refer to the [Print Study](#) section on page 36.

The **iList™ Office Reporter** main window has a standard layout. Figure 103 provides an overview of sections in the **iList™ Office Reporter** main window:

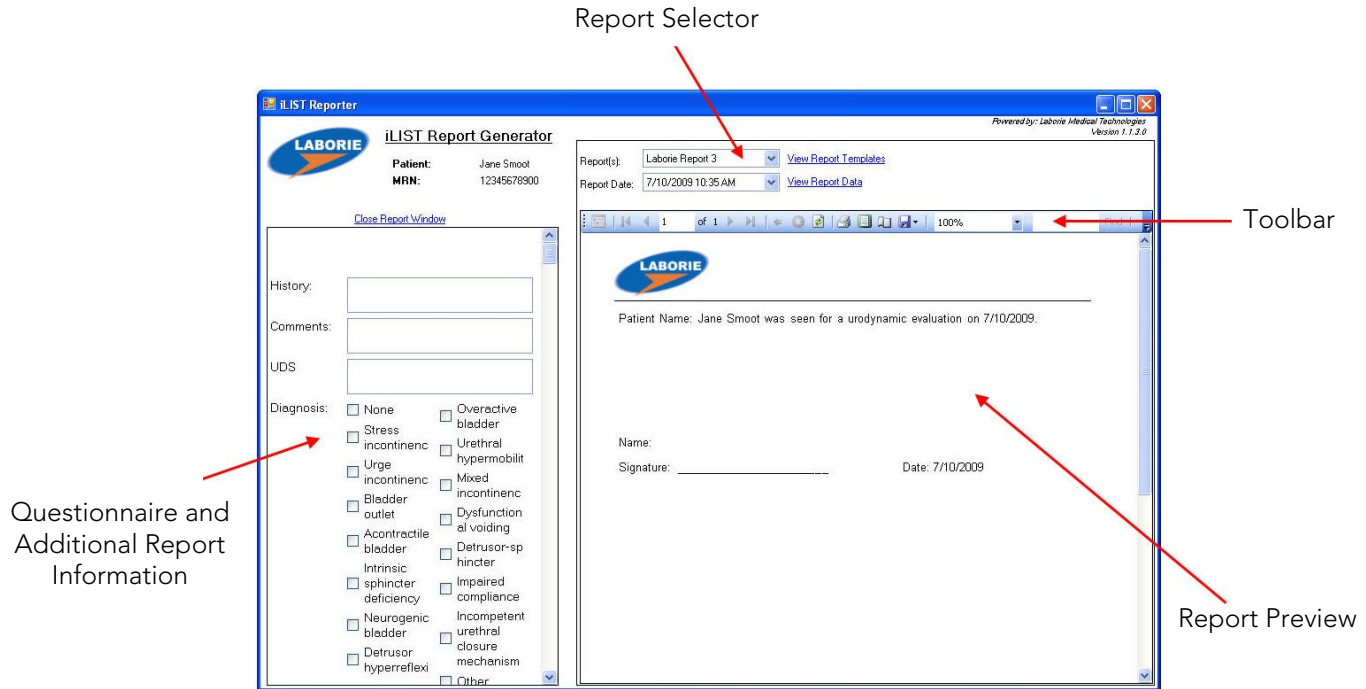


Figure 103: iList Reporter Reading Guide – Main Window

Description of **iList™ Office Reporter** sections:

- The **Questionnaire and Additional Report Information** section allows for the input of comments to the final report.
- The **Report Selector** is a listing of the report formats available for the test file. You can also select the report based on the type of test performed.
- The **Toolbar** contains quick access buttons for functions such as exporting files, page layout, quick print, navigation arrows, etc.
- The **Report Preview** Window section displays test results for the patient's visit in the selected report format

To select a report template, click the name in the *Report(s)* Selector and select an option from the drop-down menu.

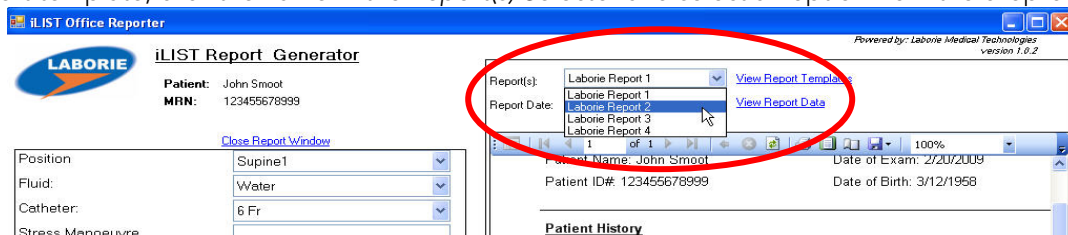



Figure 104: iList Reporter – Report Template

To print a report, click the **Print** icon  on the toolbar in the **iList™ Reporter** software.

7 CALIBRATION

To calibrate the **Urocap™ IV**, the **UDS Roam™**, the pump on the **Goby™ Hub**, the infusion transducer, or the UPP Puller, open the *Goby Device Manager* window and select the appropriate device.

IMPORTANT: Plug the **Urocap™ IV**, the **UDS Roam™**, and/or the **Goby™ Hub** into their chargers before beginning calibration. Make sure the cart is on a level surface and the wheels are locked.

The power switch for the **Goby™ Hub** is located at the bottom of the Hub. For an overview of connections for the **Urocap™ IV** and the **Goby™ Hub** see the Device Connectors and Buttons section on page 30.

7.1 CALIBRATE THE UROCAP™ IV UROFLOWMETER

1. Plug the **Urocap™ IV** into the charger and plug the charger into an outlet.
2. Start the UDS120 Goby software and double-click the **Urocap™ IV** icon in the main window to open the *Goby Device Manager* window (Figure 105).
3. Click the **Setup** button in the *Urocap* section to launch the *Urocap™ Setup* window. Click the **Device Calibration** button (Figure 106).

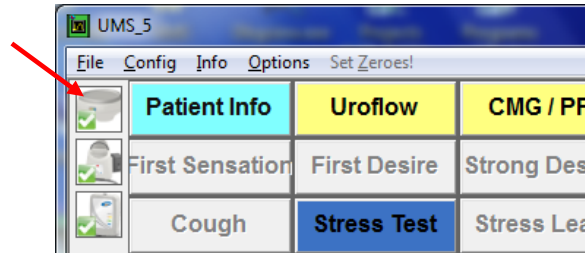


Figure 105: Access Goby Device Manager – Urocap IV

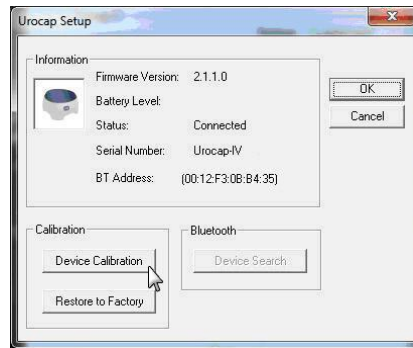


Figure 106: Urocap Setup – Device Calibration

4. Place an empty beaker on the **Urocap™ IV** and then click **Apply** in the *UROCAP4 Calibration* window (Figure 107).
5. Follow the on-screen instructions to complete the calibration.
6. Click **Close** once calibration is complete.

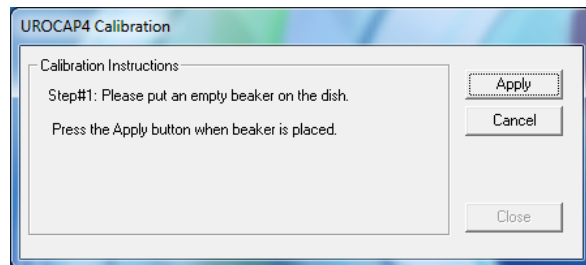


Figure 107: UROCAP4 Calibration Window

7.2 CALIBRATE THE PUMP

1. Switch ON the Goby™ Hub.
2. Start the UDS120 Goby software and double-click the **Goby™ Hub** icon in the main window to open the *Goby Device Manager* window (Figure 108).

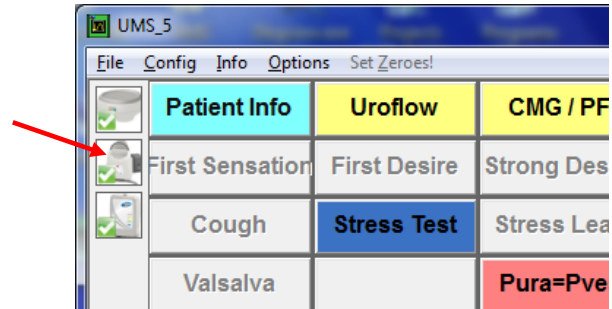


Figure 108: Access Goby Device Manager – Goby™ Hub

3. Click the **Setup** button to launch the *Goby Hub Setup* window. Click the **Device Calibration** button (Figure 109).



Figure 109: Goby Hub Setup Window

4. Select the *Pump* option under the *Pump Section* (Figure 110).
5. Set up the pump tubing. Refer to the [Set up the Pump](#) section on page 18.
6. Type in the **Calibration Name**. The name will be used when selecting a calibration set before running a test.



NOTE: Do not use commas in Calibration Names.

7. Select the *Fluid Density* and the *Catheter Size* that will be used during the Pump calibration and enter their values in the appropriate fields.
8. Follow the on-screen instructions to complete the calibration.

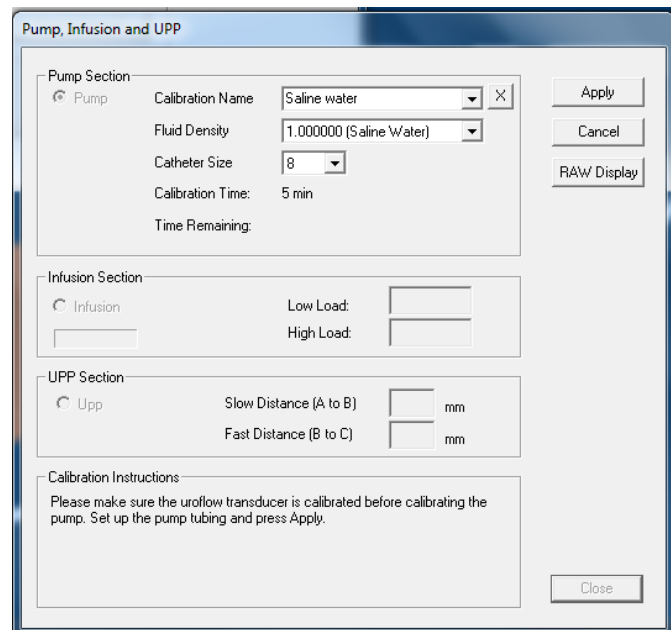


Figure 110: Pump, Infusion, and UPP Calibration Window

7.3 CALIBRATE THE UDS ROAM™ FOR EMG, PRESSURE TRANSDUCERS, AMBULATORY REMOTE, AND/OR ACCUTAK

1. Switch ON the Goby™ Hub .
2. Start the UDS120 Goby software and double-click the UDS Roam™ icon in the main window to open the Goby Device Manager window (Figure 111).

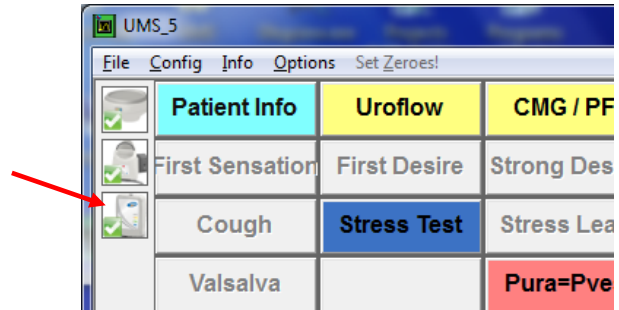


Figure 111: Access Goby Device Manager – UDS Roam™

3. Click the **Setup** button to launch the UDS Roam Setup window. Click the **Device Calibration** button (Figure 112).

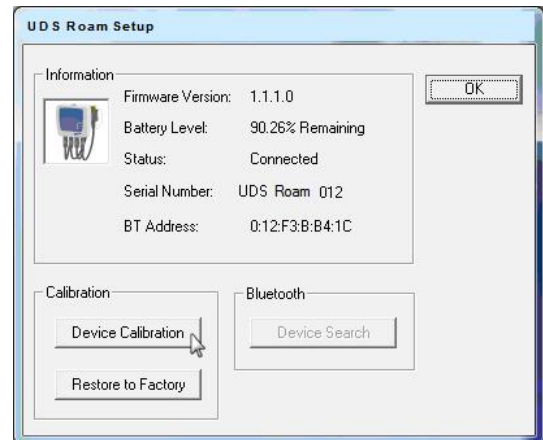


Figure 112: UDS Roam Setup Window

4. Select the pressures and/or EMG to calibrate under the Transducer heading by checking the applicable box (Figure 113).
5. Follow the on-screen instructions to complete the calibration

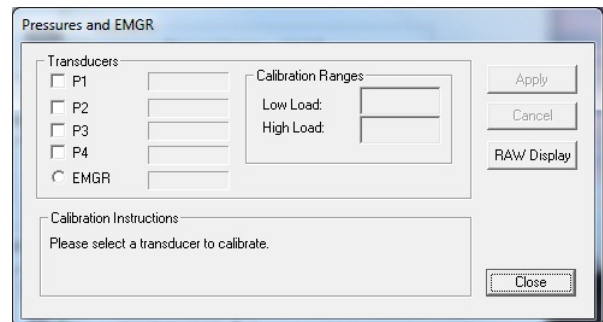


Figure 113: Pressures and EMGR Calibration Window

7.4 CALIBRATE THE INFUSION TRANSDUCER

1. Plug the infusion transducer cable into the connector at the bottom of the **Goby™ Hub**.
2. Switch ON the **Goby™ Hub**.
3. Start the UDS120 Goby software and double-click the **Goby™ Hub** icon in the main window to open the *Goby Device Manager* window (Figure 108).
4. Click the **Setup** button in the *Goby™ Hub* section to launch the *Setup* window. Click the **Device Calibration** button (Figure 109).
5. Select **Infusion** under the *Infusion Section* option (Figure 114).
6. Place a full infusion bag on the infusion transducer.
7. Follow the on-screen instructions to complete the calibration.

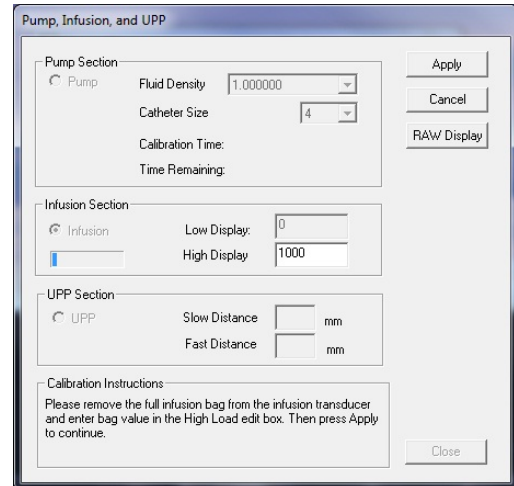

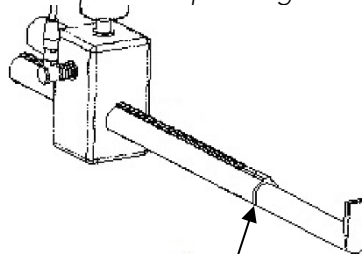


Figure 114: Pump, Infusion, and UPP Calibration Window – Infusion Section

7.5 CALIBRATE THE UPP

1. Gather a sharpened pencil for marking purposes and a ruler with millimeter (mm) markings.
2. Plug the UPP cable into the connector at the bottom of the **Goby™ Hub**.
3. Switch ON the **Goby™ Hub**.
4. Start the UDS120 Goby software and double-click the **Goby™ Hub** icon in the main window to open the *Goby Device Manager* window (Figure 108).
5. Click the **Setup** button in the *Goby™ Hub* section.
6. In the *Setup* window click the **Device Calibration** button (Figure 109).
7. Click **UPP** under the *UPP Section* option (Figure 115).
8. Follow the on-screen instructions to complete the calibration.

 **NOTE:** When marking distances on the puller, mark the edge of the mobile clamp that stops along the nose tube.



Mark edge where
clamp stops along
nose tube

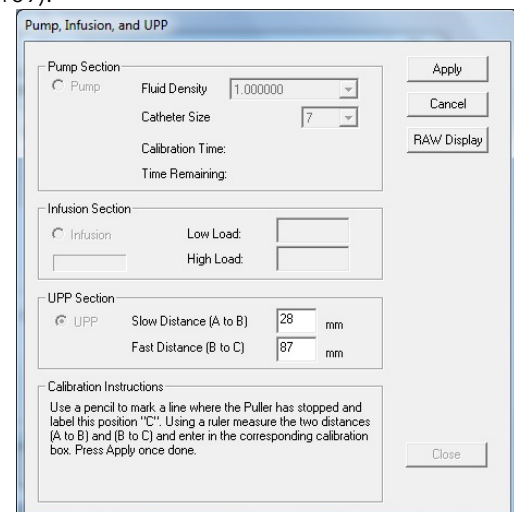


Figure 115: Pump, Infusion, and UPP Calibration Window – UPP Section

7.6 RESTORE FACTORY CALIBRATION

Not available.

8 QUICK REFERENCE AND FAQ

8.1 EQUIPMENT

How do I check that all equipment is connected?

Check equipment connection in one of two ways:

- a. The equipment's LED lights provide indication of the device's status. Refer to the [LED Lights](#) on page [27](#) for a table listing LED light status.
- b. Open the **Device Manager** and verify that connections are enabled. Refer to the [Icon Indicators](#) section on page [28](#).

How do I lock/unlock the wheels on the cart or tabletop?

To lock the wheels, press down on the lever with the bottom of your foot (Figure 116).

To unlock, push the lever up from underneath with the top of your foot.

Remember! To prevent injury to the patient always lock all wheels before beginning testing procedures.

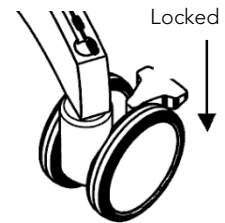


Figure 116: Wheels – Locking Mechanism

How do I adjust the height of the cart shelf?

CAUTION! Remove any items (laptop, etc.) from the shelf before making height adjustments.

- Loosen the black knob located underneath the shelf counter-clockwise to enable height adjustment.
- Adjust as needed and then tighten the knob firmly when desired height is reached to secure the shelf in place.

How do I know when I need to charge the devices?

The equipment's LED lights as well as the *Device Manager* window indicate equipment status. Refer to the [LED Lights](#) on page [27](#) for a table listing LED light status. It will take approximately 5 hours to fully charge the device.

IMPORTANT: As soon as you see the blinking orange LED on either the **Urocap™ IV** or the **UDS Roam™**, plug in the device's charger to avoid losing connection to the system.

How do I charge the devices?

See the [Battery - CHARGING and Preventative Maintenance](#) section on page [10](#) for information about charging the devices.

Can I still use the device(s) while the battery is charging?

Yes, the **Urocap™ IV** and the **UDS Roam™** can still be used while charging.

How do I attach the UDS Roam™ to a patient?

Attach using the provided belt and holster:

- Thread the belt into the **UDS Roam™** holster.
- Place the **UDS Roam™** into the holster and secure into place.
- Secure the belt around the patient's waist with the **UDS Roam™** cables extending downward (Figure 117).



Figure 117: UDS Roam Holster and Belt Setup

- Secure the transducer cables onto the belt utilizing the VELCRO bottom.
- Connect the catheters to the cables.
- You can also use the optional lanyard to place the Roam around the patient's neck.

How do I attach the Goby™ Hub to the IV pole?

Unfasten the thumbscrew on the mounting clamp and place it around the IV pole; place it on the center tube for increased stability. Tighten the thumbscrew to secure into place. Insert the **Goby™ Hub** into the clamp by sliding the **Goby™ Hub** back mount or side mount into the slot of the clamp. Lock in place using the gold-colored pin screw. To remove the **Goby™ Hub** mount, gently pull out the pin screw and slide the **Goby™ Hub** up and out. Adjust the height of the **Goby™ Hub** as necessary.

! **IMPORTANT:** To prevent damage, remove the **Goby™ Hub** from the mounting clamp before adjusting the placement of the clamp on the IV pole.

How do I stop the pump?

Press the grey button on the front of the **Goby™ Hub** if you need to stop the pump at any time during a test (). Alternatively,



lift the pump head to release the tubing from the pump.

How do I stop the UPP?

Press the grey button on the front of the **Goby™ Hub** if you need to stop the UPP at any time during a test. Alternatively, manually remove the catheter from the UPP clip.

8.2 SOFTWARE

A message appears saying a device is in "sleep mode". What do I need to do?

Click the **Run** or **Wake up** button on the control panel and wait for connection to resume before using the device.

A message appears saying there is a device connection failure. What do I need to do?

Open the Goby™ Device Manager window by clicking the button of the disconnected device and wait for the connection to be re-established. If a connection is not established, follow the instructions provided in the [Connect Goby™ Devices](#) section on page 24 to connect the devices. If reconnection is not successful, restart the computer and try the reconnection steps again.

How do you connect to the Goby™ system after unplugging and then plugging back in one of the devices? Do I need to re-start the computer?

Re-starting the computer is not required. Re-connect the device by restarting the **Goby™ Device Manager**.

- Locate the **Goby™ Device Manager** icon in the System Tray; right-click the icon and select **Exit** (Figure 118).

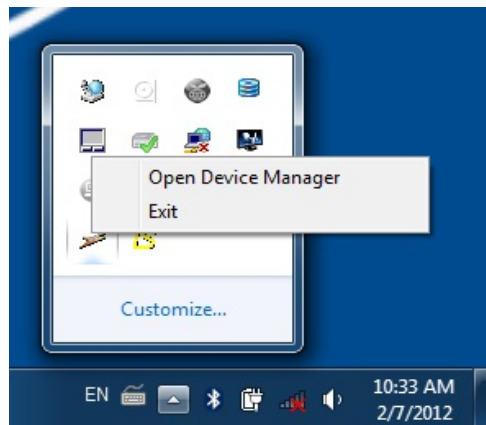


Figure 118: Opening the Device Manager Through the Quick Access Toolbar



- Wait 5 - 10 seconds, and then double-click the **Goby™ Device Manager** shortcut icon on the desktop. This will reload the Goby Device Manager in the system tray.
- Double-click the new instance of the **Goby™ Device Manager** in the system tray to open the *Goby™ Device Manager* window; verify all devices are connected.
- **Close** the utility.

9 TROUBLESHOOT

Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
ALL DEVICES		
No response from the devices?	No power on electrical outlet?	Plug system into a known working electrical outlet.
	Damaged power cord?	Unplug system and contact LABORIE for replacement power cord.
	Power cord not connected properly?	Ensure power cord is secure at the base of system and at the electrical outlet.
	Devices not connected in software?	Connect the devices to the system. Refer to the Connect Goby™ Devices section on page 24 for more information.
	Bluetooth devices paired/unpaired or plugged/unplugged while Goby software running?	Reconnect the devices as described on page 24. Remember: do not plug or unplug devices, or pair or unpair Bluetooth devices, while the Goby system is in use.
Device(s) disconnected while test in progress?	Battery power low or completely drained?	Follow these steps to reconnect: <ol style="list-style-type: none"> 1. Click Stop on the control panel. 2. Plug in the disconnected device's battery charger and plug the charger into an electrical outlet. Make sure connections are secure. 3. Open the <i>Goby Device Manager</i>. 4. Click the device icon with the <i>Disconnected</i> status and wait for the Device Manager to connect to the device again. The status will change to <i>Connected</i> and it will also display it is in charging mode. 5. Close the <i>Device Manager</i> window and click the Run button on the control panel to continue from the point where the test stopped.
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.
EMG		
EMG reading too high/low?	EMG channel scale not optimized?	Adjust scale by clicking on the scale values and typing in new values.
	Electrodes are wet or generally not sticking?	Shave area if necessary and wipe dry. Apply a good amount of tape to keep moisture out.
	Detached electrode?	Re-attach electrode.
	Water/urine leaked all over the electrodes?	Dry the area with a towel and replace the electrodes.
	UDS Roam™ placed in Hub?	EMG reading will increase when placed in the Goby™ Hub for charging and when in use.

Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
No spike response in EMG and baseline is flat?	Electrodes 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 channel saturated?	Electrodes 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 not securely connected to cable?	Check connections and adjust as necessary.
	Zeroes not set properly?	Reset zeroes.
	Catheter 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 CMG/PF Test Using Fluid-filled Catheters section on page 82.
PUMP		
Pump not running?	Pump not calibrated? Calibration is incorrect?	Calibrate Pump. Refer to the Calibration section on page 89.
	Pump pressure limit reached?	Reset P1 (Pves) to zero. Check for kinked bladder catheter.
	Volume limit exceeded?	Reset VH ₂ O Channel Zero and try again.
UROCAP™ IV		
Uroflowmeter signal does not respond?	Urocap™ IV improperly connected?	Connect the Urocap™ IV to the system. See page See the Connect Goby™ Devices section on page 24 for more information.
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 the Uroflow Options Dialogue Box, To Enable the Software to Recognize Artifacts : subsection on page 62 for information on filtering non physiological spikes
	Floor is unsteady?	Move to a more solid foundation.
Incorrect flow or volume readings?	Beaker not properly seated on Uroflowmeter dish?	Adjust beaker position.
	Funnel is touching beaker?	Adjust commode chair or 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.


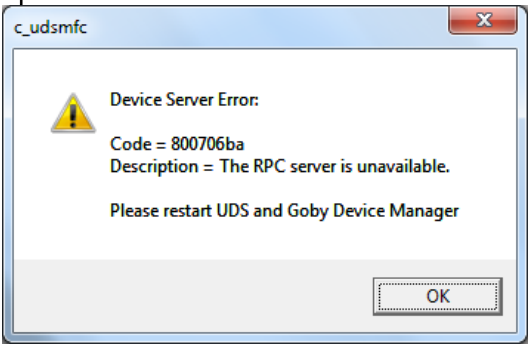
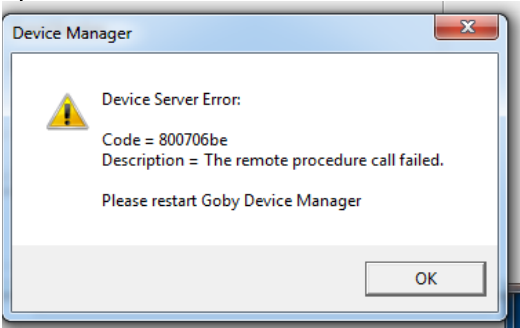
Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
	More than 500mL poured into beaker?	500mL of water must be poured into beaker to calibrate.
Error message on screen reads: "Calibration Failure...(Volume delta out of range.)"	Less than 500mL of water poured into beaker?	500mL of water must be poured into beaker to calibrate.
BLUETOOTH CONNECTION		
Unable to connect via Bluetooth?	Connection broken?	Bluetooth must be turned on by clicking the device icon in the Goby Device Manager.
		Reduce the distance between the device and the computer. The maximum distance between the processor and the computer is up to 10 meters (33 feet).
		Remove any physical barriers like walls, posts, doors, or people.
Blue screen appears when I connect the Bluetooth USB adapter?	Adapter unplugged?	Restart the computer. Remember: do not plug or unplug devices, or pair or unpair Bluetooth devices, while the Goby system is in use.
SOFTWARE ERROR MESSAGES		
Error message displays "devices are not connected" as shown below: 	Goby Device Manager not running?	Click the link in the error message to open the Goby Device Manager or restart the Goby Software.
	Devices not connected?	Click the link in the error message to open the Goby Device Manager and reconnect the devices. Alternatively, click OK to close the error message and click the Wake up button on the control panel.
	Configuration file not set?	<ol style="list-style-type: none"> 1. Click Config > Set up/Modify. 2. Check that the channels in the <i>Channel Name</i> column match those listed in the error message. If not, select the correct name in the <i>Channel Name</i> listing. 3. Click Apply then click OK.
	Configuration file set but message still appears?	<ol style="list-style-type: none"> 1. Click OK. 2. Click the Run or Wake up button on the control panel to resume connections.


Figure 119: Error Message – Device connections

Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
<p>Received following message when the software opens:</p>  <p>Figure 120: Error Message – RPC Server Unavailable</p>	<p>Software opened too soon after computer turned on?</p>	<p>Close the <i>Goby Device Manager</i> and the <i>UDS120 Goby</i> software. Wait one minute and then re-open the Device Manager and the software to re-connect.</p>
<p>Received following message when the software opens:</p>  <p>Figure 121: Error Message – Remote Procedure Call Failed</p>	<p>Bluetooth dongle not plugged in?</p>	<p>Click OK and close the software. Plug in the Bluetooth dongle into a USB port and wait for the blue light to turn on. Re-open the software to continue.</p>
<p>Received error message stating: "Connection to device not established".</p>	<p>Software opened too soon after computer turned on?</p>	<p>Close the <i>Goby Device Manager</i> and the <i>UDS120 Goby</i> software. Wait one minute and then re-open the Device Manager and the software to re-connect.</p>
<p>iList™ Reporter</p>		
<p>Error message: "Error Code: 66a (Can't install KB2160841)" appears?</p>	<p>.NET Framework file needs repair</p>	<ul style="list-style-type: none"> • Click Start > Control Panel > and double-click Add or Remove Programs. – OR – Click Start > Control Panel > Programs > Programs and Features. • In the resulting list, right-click the <i>Microsoft .NET Framework 4 Client Profile</i> file and select Change OR Uninstall/Change • Select to Repair the file and wait for the repair to complete before continuing. • Restart the computer.
<p>UDS report not transferring to iList™ Office Reporter?</p>	<p>Make sure i-LIST MsgQListener is running.</p>	<ul style="list-style-type: none"> • Close all open programs. • Make sure iList™ Message Queue Listener is running by clicking Start > Programs > Laborie > i-LIST MsgQListener. • Restart the computer and attempt to send a report to i-LIST™

Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
		Office Reporter. If unsuccessful try the solution below.
	Install Windows Updates	<ul style="list-style-type: none"> • Close all open programs. • 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. • 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	<ul style="list-style-type: none"> • Click Start > Control Panel > and double-click Add or Remove Programs. -OR- Click Start > Control Panel > Programs > Programs and Features. • In the resulting list, right-click the <i>Microsoft .NET Framework 4 Client Profile</i> file and select Change OR select Uninstall/Change • Select to Repair the file and wait for the repair to complete. • Restart the computer and continue with sending a UDS report to iList™ Office Reporter.
i-LIST Window does not appear when the Select Patient button is clicked from under Ambulatory window.	Patient file must contain Doctor information.	<ul style="list-style-type: none"> • Make sure Patient Information file contains a doctor's name.
PRINTER		
Printer LED does not light up?	Printer power cable unplugged?	Plug in printer power cable and try again.
	Printer not turned on?	Turn on printer by pressing printer power button.
Printer Error LED on steady or flashing?	Printer paper out?	Load printer paper.
	Printer cover open?	Close cover of printer.
	Printer out of ink?	Replace printer cartridges.
	Printer paper jam or mis-feed?	Correct paper problem then press paper feed button.

Table 8: Troubleshooting

If problems continue, contact the LABORIE Service team at 1-800-333-1039 or email service@laborie.com.

 **NOTE:** The LABORIE Goby CT and CT PC 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.

10 APPENDICES

APPENDIX A: SPECIFICATIONS

For proper operation, the device requires mains power 110 VAC or 240 VAC.

Transportation and Storage Conditions:	Temperature: -29°C to +60°C Humidity: uncontrolled to 85% relative humidity
Operating Conditions:	Temperature: +15°C to +35°C Humidity: 20% to 80% relative humidity Pressure: 700 hPa to 1014 hPa (up to 2000m)
Goby™ Hub (GBH001)	Dimensions: 7.6”(19.3cm) L X 6.0”(15.2cm) W X 8.6”(21.8cm) H Weight: 3.7lbs (1.7kg) Volume Range : 0 to 1500mL; Flow Range: 5 to 140mL/min Output Channels: Volume (VH2O), Speed (IH2O) Sampling Rate: 20 Hz Charger: Connect to SL Power Electronics Corp. ME60A1241F01 PSU only.
UDS Roam™ (PLM001)	Dimensions: 4.0”(10.2cm) L X 2.8”(7.1cm) W X 1.0”(2.5) H Weight: 1.0 lbs (0.5kg) Pressure Range: 0 to 320 cmH2O; EMG Range = +/-1000uV Output Channels: 4 Pressure, 1 EMG Sampling Rate: Pressure=20Hz; EMG=1200Hz Charger: Connect to Sager Electronics Inc. Model: ME20A0540F02 or Goby™ Hub only.
Urocap™ IV (TRA851)	Dimensions: 6.3”(16.0cm) L X 6.3”(16.0cm) W X 2.6”(6.6cm) H Weight: 0.7lbs (0.3kg) Flow Range: 0 to 50mL/s; Volume Range: 0 to 1500mL Output Channels: Flow; Volume Sampling Rate: Flow=20Hz; Volume=20Hz Charger: Connect to SL Power Electronics Corp. Model: ME20A0540F02 PSU only.
Cart (CAR1000 or CAR1002)	CAR1000 Dimensions: 28.5”(72.4cm) L X 25.4”(64.5cm) W X 42”(106.7cm) H CAR1000 Weight: 46kg CAR1002 Dimensions: 28.5”(72.4cm) L X 25.4”(64.5cm) W X 59.4”(150.9cm) H CAR1002 Weight: 56kg  NOTE: CAR1000 is applicable to Goby™ CT cart configuration. CAR1002 is applicable to Goby™ CT PC cart configuration. Contact LABORIE for more information on Goby System configurations.
IV Pole (IVP605)	Dimensions: Stem + base: 55” (140cm)

Table 9: GOBY™ Specifications

AMBULATORY DEVICES SPECIFICATIONS

UDS Roam™ – Ambulatory (COM762)	Dimensions: 4.0”(10.2cm) L X 2.8”(7.1cm) W X 1.0”(2.5) H Weight: 0.3 lbs (0.1kg) Pressure Range: -50 to 200 cmH2O; EMG Range = +/-1000uV Output Channels: 4 Pressure, 1 EMG Sampling Rate: Pressure=20Hz; EMG=1200Hz
Power Supply (POW041) with 110V Power Cord (POW005)	Input: 100-240V, 50/60Hz, 0.5A / Output: 5V, 3A
Power Supply Battery	Li-Pol or Li-Ion, 1590mAh, 3.7V Charging Time = 5 hrs. max.



Table 10: Ambulatory Specifications

CLASSIFICATIONS

IEC 60601-1:	Class I Equipment Type BF Applied Parts
Mode of Operation:	Continuous; Equipment not suitable for use in the presence of a Flammable, Anaesthetic Mixture, with Air, or Oxygen, or Nitrous Oxide.
Degree of Protection:	<p>The Urocap™ IV uroflowmeter enclosure is classified IP54 according to degree of protection against ingress of water and particulate matter as per the test requirements of IEC 60529. With this IP (<i>International Protection</i>) rating, it means that the Urocap™ IV uroflowmeter enclosure:</p> <ul style="list-style-type: none"> • Protects users using tools 1.0 mm or larger from accessing hazardous parts, and protects equipment from ingress of dust (signified by the rating code 5). • Protects equipment from the harmful effects of water splashing from any direction (signified by the rating code 4). <p>NOTE: the IP rating will be visible on the device label per uroflowmeter model.</p>

Table 11: GOBY™ Classifications

APPENDIX B: SYMBOLS AND LABELING

 <p>Authorized Representative in the European Community (5.1.2): Indicates the manufacturer's device representative in the European Community.</p>	 <p>SGS certification - certified to U.S. and Canadian safety standards.</p>	 <p>Date of Manufacture (5.1.3)¹: Indicates the date of device manufacture.</p>	 <p>Manufacturer (5.1.1): Indicates the device manufacturer.</p>	 <p>Consult Instructions for Use (5.4.3): Manufacturer recommends consultation of Instructions for Use.</p>	 <p>Read Operator's Manual (M002): Indicates user must refer to Owner's/Operator's Manual.</p>
 <p>Lot - Batch Code (5.1.5)¹: Indicates the batch or lot code for identification and tracking purposes.</p>	 <p>Catalogue Number (5.1.6): Indicates the device model or catalogue number.</p>	 <p>Serial Number (5.1.7)¹: Indicates unique device serial number for device traceability.</p>	 <p>Type BF Applied Part (Table D.1, 20)²: Identifies a type BF applied part complying with IEC 60601-1.</p>	 <p>Use-by Date (5.1.4): Indicates date after which use is prohibited.</p>	 <p>Sterile (5.2.1): Indicates a sterile device.</p>
 <p>Sterilized Using Ethylene Oxide (5.2.4)¹: Indicates method of sterilization used as ethylene oxide.</p>	 <p>Sterilized Using Irradiation (5.2.4)¹: Indicates method of sterilization used as irradiation.</p>	 <p>Alternating Current (Table D.1, 1)²: Indicates use of Alternating Current.</p>	 <p>Direct Current (Table D.1, 1)²: Indicates use of Direct Current.</p>	 <p>Non-ionizing electromagnetic Radiation (5140)²: Radio Frequency (RF) Transmitting Device Indicates presence of RF transmitters.</p>	 <p>Keep Dry (5.3.4)¹: Indicates a device requiring protection from moisture.</p>
 <p>Do Not Re-Use (5.4.2)¹: Medical device intended for single use, on a single patient, during a single procedure.</p>	 <p>Safety Label, No Pushing (P017)³: To prohibit pushing against a specified device.</p>	 <p>Safety Label, No Sitting (P018)³: Indicates sitting on the identified surface is prohibited.</p>	 <p>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.</p>	 <p>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.</p>	 <p>General Battery (5001B)⁴: Identifies a device related to the power supply by battery.</p>
 <p>General Warning Sign (W001)³: Indicates a general warning.</p>	 <p>Safety Label, Safe working Load 10kg</p>	 <p>Safety Label, Safe Working Load 2kg</p>	 <p>System Safe Working Load</p>	 <p>Direction of Pump Flow</p>	 <p>Device Stop button</p>
 <p>Humidity Limitation (5.3.8)¹: Indicates the humidity range to which the medical device can be safely exposed.</p>	 <p>Temperature Limit (5.3.7)¹: Indicates the temperature limit to which the medical device can be safely exposed.</p>	 <p>Atmospheric Pressure Limitation (5.3.9)¹: Indicates the atmospheric pressure range to which the medical device can be safely exposed.</p>	 <p>GS1 DataMatrix for Unique Identification (01) Global Trade Item Number (11) Date of Manufacture (21) Serial Number</p>		

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 consumable devices only. Refer to consumable device instructions for use for complete symbol and instructional overview.

Table 12: Symbols Glossary

Labels can be found on the devices as follows:




Label Description	Label Placement
Goby Urodynamic Analyzer Systems	
Goby™ Hub, Wireless Pump & UDS Roam™ Docking Station	
UDS Roam, Wireless Battery Powered & EMG Measurement Device	

Table 13: Label Locations

APPENDIX C: ELECTROMAGNETIC COMPATIBILITY (EMC)

This equipment has been tested and found to comply with the limits for:

IEC 60601-1-2:2014(Ed.4)	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and 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
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: 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

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 **Goby™** unit.
 - Increase the separation between **Goby™** unit and the affected equipment.
 - Connect the non-medical system equipment into an outlet on a circuit different from that to which the **Goby™** 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***

IEC 60601-1-2:2014 Table 1 Requirements

<p>The Goby Urodynamic Analyzer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Goby Urodynamic Analyzer System should assure that it is used in such an environment.</p>		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The Goby 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	<p>The Goby 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:</p> <p>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 Goby Urodynamic Analyzer System or shielding the location.</p>
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Table 14: Table 1 Requirements - Electromagnetic Environment

IEC 60601-1-2:2014 Table 2 Requirements:

The Goby Urodynamic Analyzer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Goby 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 Goby Urodynamic Analyzer System requires continued operation during power mains interruptions, it is recommended that the Goby 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 15: Table 2 Requirements – Electromagnetic Environment – Guidance

IEC 60601-1-2:20014 Table 4 Requirements:


The Goby Urodynamic Analyzer System is intended for use in the electromagnetic environment specified below. The customer or the user of the Goby 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 Goby 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 Goby Urodynamic Analyzer System is used exceeds the applicable RF compliance level above, the Goby 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 Goby Urodynamic Analyzer System			
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 16: Table 4 Requirements – Electronic Environment – Guidance

IEC 60601-1-2:20014 Table 6 Requirements:


Recommended separation distances between portable and mobile RF communications equipment and the Goby Urodynamic Analyzer System			
<p>The Goby 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 Goby Urodynamic Analyzer System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Goby Urodynamic Analyzer System as recommended below, according to the maximum output power of the communications equipment.</p> <p> 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 Goby system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p>			
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
<p>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.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Table 17: Table 6 Requirements – Separation Distance

APPENDIX D: PRINT STUDY OPTIONS

Click **File Menu > Open > Print Test** to access the *Print Test* window. Refer to the table below for an overview of the options available in in Goby UDS120 Software:

Description	Print Output
Preferences: Uroflow Report	1-page voiding study report.
Preferences: UDS Report	Multi page complex study report.
Preferences: Graph Pages	Graph pages of UDS report.
Preferences: Report Pages	Report pages.
Standard Report	Prints all information pertaining to study.
Voiding Summary	Uroflow Summary information.
UPP Summary	UPP Summary information.
Event Summary	Event Summary information.
CHESS	CHESS Nomogram information.
URA	ICS Nomogram information.
WF	Bladder Work Function information.
LinPURR	Shafer's Nomogram information.
Diagnosis	Patient Diagnosis information.
History	Patient History information.
Pediatric Nomograms <i>(optional)</i>	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 <i>(optional)</i>	Optional feature for Uroflow procedures.
Siroky Nomogram <i>(optional)</i>	Optional feature for Uroflow procedures.
Print Border	This feature will frame the graph with a simple line border.
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.
Grids: Fine	Small grid squares on graph.
Grids: Coarse	Large grid squares on graph.
Grids: None	No grid squares.
Print Range: Default	Test from beginning to end.
Print Range: UPP Sections	UPP segments only.
Print Range: Default and UPP	Prints both options.
Apply	Click this button to set up a default configuration when printing each test.
Graph Scaling: 1-Page Graph	Graph page is condensed into one page.
Graph Scaling: Standard	Standard Graph pages printed out with no compression or expansion applied.
Graph Scaling: Min/page	Selectable number of minutes per graph page. Use the scroll bar to adjust the desired number of minutes per page view.
Segments	Manually select up to 8 segments or sections of the graph to be printed as opposed to printing out the entire graph.
Preview Graph Segments	Displays a sample of the graph printout.
Font	Opens a window that allows you to set the font for each section of the report. Double-click the name of the feature to change its font. Select the size and style and click OK to confirm the changes.

Table 18: Report Options Descriptions

NOTE: UPP Segments will appear when changing "Print Range" from "Default" to "Default and UPP" as shown below:

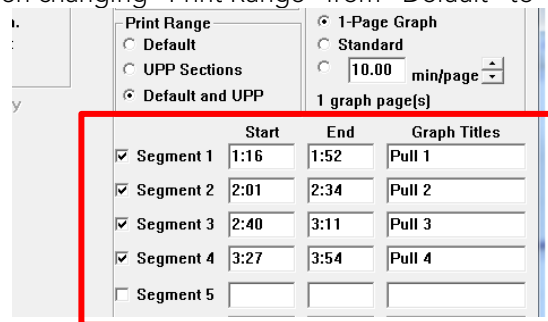


Figure 122: Print Range – UPP Segments

APPENDIX E: NOMOGRAM TABLES FOR UROFLOWMETRY^{xiii}

Parameters of Uroflowmetry in 80 Normal Males												
Vol (cc)	Peak Flow			Average Flow			Time to Max Flow			Time of Micturition		
	Max	Aver	Min	Max	Aver	Min	Max	Aver	Min	Max	Aver	Min
60	22.4	14.3	6.2	13.3	8.0	2.7	7.3	4.0	0.7	14.9	8.6	2.2
70	23.0	14.9	6.8	13.8	8.5	3.2	7.6	4.3	1.0	15.4	9.1	2.7
80	23.6	15.5	7.4	14.3	9.0	3.7	7.9	4.6	1.2	16.0	9.6	3.2
90	24.2	16.1	8.0	14.8	9.5	4.2	8.1	4.9	1.6	16.5	10.1	3.7
100	24.8	16.7	8.6	15.3	10.0	4.7	8.4	5.1	1.8	16.9	10.6	4.2
110	25.4	17.3	9.2	15.7	10.4	5.1	8.6	5.4	2.1	17.4	11.1	4.7
120	25.9	17.8	9.7	16.2	10.9	5.6	8.9	5.6	2.3	17.9	11.5	5.1
130	26.4	18.3	10.2	16.6	11.3	6.0	9.1	5.8	2.5	18.3	12.0	5.6
140	26.9	18.8	10.7	17.1	11.8	6.5	9.3	6.0	2.7	18.8	12.4	6.0
150	27.4	19.3	11.2	17.5	12.2	6.9	9.5	6.2	2.9	19.2	12.8	6.5
160	27.9	19.8	11.7	17.9	12.6	7.3	9.7	6.4	3.1	19.6	13.3	6.9
170	28.4	20.3	12.2	18.3	13.0	7.7	9.8	6.5	3.3	20.0	13.7	7.3
180	28.8	20.7	12.6	18.7	13.4	8.1	10.0	6.7	3.4	20.4	14.1	7.7
190	29.3	21.2	13.1	19.1	13.8	8.5	10.1	6.9	3.6	20.8	14.5	8.1
200	29.7	21.6	13.5	19.4	14.1	8.8	10.3	7.0	3.7	21.2	14.9	8.5
210	30.1	22.0	13.9	19.8	14.5	9.2	10.4	7.1	3.9	21.6	15.2	8.9
220	30.5	22.4	14.3	20.1	14.8	9.5	10.5	7.3	4.0	22.0	15.6	9.2
230	30.9	22.8	14.7	20.5	15.2	9.9	10.7	7.4	4.1	22.3	16.0	9.6
240	31.2	23.1	15.0	20.8	15.5	10.2	10.8	7.5	4.2	22.7	16.3	10.0
250	31.6	23.5	15.4	21.1	15.8	10.5	10.9	7.6	4.3	23.1	16.7	10.3
260	31.9	23.8	15.7	21.5	16.2	10.9	11.0	7.7	4.4	23.4	17.0	10.7
270	32.2	24.1	16.0	21.8	16.5	11.2	11.0	7.8	4.5	23.7	17.4	11.0
280	32.6	24.5	16.4	22.0	16.7	11.4	11.1	7.8	4.6	24.1	17.7	11.4
290	32.9	24.8	16.7	22.3	17.0	11.7	11.2	7.9	4.6	24.4	18.1	11.8
300	33.2	25.1	16.9	22.6	17.3	12.0	11.3	8.0	4.7	24.8	18.4	12.0
310	33.4	25.3	17.2	22.9	17.6	12.3	11.3	8.0	4.8	25.1	18.7	12.4
320	33.7	25.6	17.5	23.1	17.8	12.5	11.4	8.1	4.8	25.4	19.1	12.7
330	34.0	25.9	17.8	23.4	18.1	12.8	11.4	8.2	4.9	25.8	19.4	13.0
340	34.2	26.1	18.0	23.6	18.3	13.0	11.5	8.2	4.9	26.1	19.7	13.4
350	34.5	26.4	18.3	23.9	18.6	13.3	11.5	8.2	5.0	26.4	20.0	13.7
360	34.7	26.6	18.5	24.1	18.8	13.5	11.6	8.3	5.0	26.7	20.4	14.0
370	34.9	26.8	18.7	24.3	19.0	13.7	11.6	8.3	5.0	27.1	20.7	14.3
380	35.1	27.0	18.9	24.6	19.3	14.0	11.6	8.4	5.1	27.4	21.0	14.7
390	35.4	27.2	19.1	24.8	19.5	14.2	11.7	8.4	5.1	27.7	21.4	15.0
400	35.6	27.4	19.3	25.0	19.7	14.4	11.7	8.4	5.1	28.1	21.7	15.3
410	35.7	27.6	19.5	25.2	19.9	14.6	11.7	8.4	5.2	28.4	22.0	15.7
420	35.9	27.8	19.7	25.4	20.1	14.8	11.8	8.5	5.2	28.7	22.4	16.0
430	36.1	28.0	19.9	25.5	20.2	14.9	11.8	8.5	5.2	29.1	22.7	16.3
440	36.3	28.2	20.1	25.7	20.4	15.1	11.8	8.5	5.2	29.4	23.1	16.7
450	36.5	28.3	20.2	25.9	20.6	15.3	11.8	8.6	5.3	29.8	23.4	17.0
460	36.6	28.5	20.4	26.1	20.8	15.5	11.9	8.6	5.3	30.1	23.8	17.4
470	36.8	28.7	20.6	26.2	20.9	15.6	11.9	8.6	5.3	30.5	24.1	17.8
480	36.9	28.8	20.7	26.4	21.1	15.8	11.9	8.6	5.4	30.9	24.5	18.1
490	37.1	29.0	20.9	26.5	21.2	15.9	11.9	8.7	5.4	31.2	24.9	18.5
500	37.2	29.1	21.0	26.7	21.4	16.1	12.0	8.7	5.4	31.6	25.2	18.9
510	37.3	29.2	21.1	26.8	21.5	16.2	12.0	8.7	5.4	32.0	25.6	19.3
520	37.5	29.4	21.3	27.0	21.7	16.4	12.0	8.8	5.5	32.4	26.0	19.7
530	37.6	29.5	21.4	27.1	21.8	16.5	12.1	8.8	5.5	32.8	26.4	20.1
540	37.7	29.6	21.5	27.2	21.9	16.6	12.1	8.8	5.6	33.2	26.8	20.5
550	37.9	29.8	21.7	27.4	22.0	16.7	12.2	8.9	5.6	33.6	27.3	20.9

Table 19: Parameters of Uroflowmetry – 80 Males

<i>Parameters of Uroflowmetry in 50 Normal Females</i>												
Vol (cc)	Peak Flow			Average Flow			Time to Max Flow			Time of Micturition		
	Max	Aver	Min	Max	Aver	Min	Max	Aver	Min	Max	Aver	Min
60	23.6	14.6	5.5	13.8	7.9	2.0	6.4	3.9	1.4	12.7	8.1	3.4
70	24.9	15.8	6.8	14.8	8.8	2.9	6.5	4.0	1.5	13.0	8.3	3.7
80	26.0	17.0	7.9	15.7	9.7	3.8	6.6	4.1	1.6	12.3	8.6	3.9
90	27.1	18.1	9.0	16.5	10.6	4.6	6.7	4.2	1.7	13.5	8.9	4.2
100	28.1	19.1	10.0	17.3	11.4	5.4	6.8	4.3	1.8	13.8	9.1	4.5
110	29.1	20.1	11.0	18.1	12.1	6.2	6.9	4.4	1.9	14.1	9.4	4.7
120	30.0	21.0	11.9	18.8	12.9	6.9	7.0	4.5	2.0	14.4	9.7	5.0
130	30.9	21.8	12.8	19.5	13.6	7.6	7.2	4.7	2.1	14.6	10.0	5.3
140	31.7	22.6	13.6	20.1	14.2	8.3	7.3	4.8	2.3	14.9	10.3	5.6
150	32.4	23.4	14.3	20.8	14.8	8.9	7.4	4.9	2.4	15.2	10.6	5.9
160	33.1	24.1	15.0	21.3	15.4	9.5	7.5	5.0	2.5	15.5	10.9	6.2
170	33.3	24.7	15.7	21.9	16.0	10.1	7.7	5.2	2.6	15.8	11.2	6.5
180	34.4	25.3	16.3	22.4	16.5	10.6	7.8	5.3	2.8	16.1	11.5	6.8
190	34.9	25.9	16.8	22.9	17.0	11.1	7.9	5.4	2.9	16.4	11.8	7.1
200	35.5	26.4	17.4	23.4	17.5	11.5	8.1	5.5	3.0	16.8	12.1	7.4
210	36.0	26.9	17.9	23.8	17.9	12.0	8.2	5.7	3.2	17.1	12.4	7.7
220	36.4	27.4	18.3	24.2	18.3	12.4	8.3	5.8	3.3	17.4	12.7	8.0
230	36.8	27.8	18.7	24.6	18.7	12.8	8.4	5.9	3.4	17.7	13.0	8.4
240	37.2	28.2	19.1	25.0	19.1	13.2	8.6	6.1	3.6	18.0	13.4	8.7
250	37.6	28.5	19.5	25.3	19.4	13.5	8.7	6.2	3.7	18.4	13.7	9.0
260	37.9	28.9	19.8	25.7	19.7	13.8	8.8	6.3	3.8	18.7	14.0	9.3
270	38.2	29.2	20.1	26.0	20.0	14.1	9.0	6.5	3.9	19.0	14.3	9.7
280	38.5	29.5	20.4	26.2	20.3	14.4	9.1	6.6	4.1	19.3	14.7	10.0
290	38.8	29.8	20.7	26.5	20.6	14.7	9.2	6.7	4.2	19.7	15.0	10.3
300	39.1	30.0	21.0	26.8	20.8	14.9	9.3	6.8	4.3	20.0	15.3	10.6
310	39.3	30.3	21.2	27.0	21.1	15.1	9.4	6.9	4.4	20.3	15.6	11.0
320	39.6	30.5	21.5	27.2	21.3	15.3	9.5	7.0	4.5	20.6	16.0	11.3
330	39.8	30.8	21.7	27.4	21.5	15.5	9.6	7.1	4.6	21.0	16.3	11.6
340	40.0	31.0	21.9	27.6	21.7	15.7	9.7	7.2	4.7	21.3	16.6	11.9
350	40.3	31.2	22.2	27.8	21.8	15.9	9.8	7.3	4.8	21.6	16.9	12.3
360	40.5	31.4	22.4	27.9	22.0	16.1	9.9	7.4	4.9	21.9	17.3	12.6
370	40.7	31.7	22.6	28.1	22.2	16.2	10.0	7.5	5.0	22.3	17.6	12.9
380	40.9	31.9	22.8	28.2	22.3	16.4	10.1	7.6	5.1	22.6	17.9	13.3
390	41.2	32.1	23.1	28.4	22.4	16.5	10.2	7.7	5.2	22.9	18.2	13.6
400	41.4	32.4	23.3	28.5	22.6	16.7	10.2	7.7	5.2	23.2	18.6	13.9
410	41.7	32.6	23.6	28.6	22.7	16.8	10.3	7.8	5.3	23.6	18.9	14.2
420	41.9	32.9	23.8	28.8	22.8	16.9	10.4	7.9	5.4	23.9	19.2	14.5
430	42.2	33.2	24.1	28.9	23.0	17.0	10.4	7.9	5.4	24.2	19.5	14.9
440	42.5	33.5	24.4	29.0	23.1	17.2	10.4	7.9	5.4	24.5	19.8	15.2
450	42.8	33.8	24.7	29.1	23.2	17.3	10.5	8.0	5.5	24.8	20.2	15.5
460	43.2	34.1	25.1	29.3	23.3	17.4	10.5	8.0	5.5	25.1	20.5	15.8
470	43.6	34.5	25.5	29.4	23.5	17.5	10.5	8.0	5.5	25.4	20.8	16.1
480	44.0	34.9	25.9	29.5	23.6	17.7	10.5	8.0	5.5	25.7	21.1	16.4
490	44.4	35.3	26.3	29.7	23.7	17.8	10.5	8.0	5.5	26.0	21.4	16.7
500	44.9	35.8	26.7	29.8	23.9	18.0	10.5	8.0	5.5	26.3	21.7	17.0
510	45.3	36.3	27.2	29.9	24.0	18.1	10.5	7.9	5.4	26.6	22.0	17.3
520	45.9	36.8	27.8	30.1	24.2	18.3	10.4	7.9	5.4	26.9	22.2	17.6
530	46.5	37.4	28.4	30.3	24.3	18.4	10.4	7.9	5.3	27.2	22.5	17.8
540	47.1	38.0	29.0	30.4	24.5	18.6	10.3	7.8	5.3	27.5	22.8	18.1
550	47.7	38.7	29.6	30.6	24.7	18.8	10.2	7.7	5.2	27.7	23.1	18.4

Table 20: Parameters of Uroflowmetry – 50 Females

APPENDIX F: CALCULATIONS

- $BOOI = p_{det}Q_{max} - 2Q_{max}^{xiii}$
- $BCI = p_{det}Q_{max} + 5Q_{max}^{xiii}$
- $BVE = (V/BC) \times 100^{xiii}$

APPENDIX G: END-USER SOFTWARE LICENSE AGREEMENT

EULA: <http://www.laborie.com/eula/>

Terms and Conditions: <http://www.laborie.com/terms-and-conditions/>

APPENDIX H: GLOSSARY

TERMS^{xiv} USED IN URODYNAMICS TESTING

NOTE: Notations in italics indicate usage specific to LABORIE's Urodynamic testing protocols

- **abdominal pressure:** (P_{abd}) 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*
- **acocontractile 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:** (P_{ves} , 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:** (P_{clo}) the calculated value that reflects the difference between urethral pressure and bladder pressure. $P_{ura} - P_{ves} = P_{clo}$. P_{clo} 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 P_{ves} , P_{abd} , P_{det} , 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. $P_{ves} - P_{abd} = P_{det}$.
 - *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 that all Laborie Medical training follows.
- **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 is 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 has to 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 urodynamically, 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”.

COMMON URODYNAMICS ACRONYMS

- ALPP: Abdominal leak point pressure
- BOOI: Bladder outlet obstruction index^{xv}
- 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 UDS120 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

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