

UROCAP™ IV

Owner's Manual



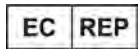
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CANADA



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ABOUT THIS MANUAL

As you read through the manual, you will find information on how to configure features in the **Urocap™ IV** software, as well as information on care and maintenance of the **Urocap™ IV** system.

Throughout the manual you will also find specially marked sections that emphasize important reminders and information to help you understand the features of the system, as marked here:

	<p>CAUTION</p> <p>Provides information users need to know in order to prevent minor injury or product damage.</p>
	<p>IMPORTANT</p> <p>Provides important information regarding use of device or software</p>
	<p>NOTE</p> <p>Provides useful information or reminders while operating the device or software.</p>

1 INTRODUCTION

LABORIE's Urocap™ IV is a simple and easy-to-use Uroflowmeter with built-in comparative studies. These studies, along with other unique features, will deliver highly accurate Uroflowmetry recordings that are easy to produce and interpret. An added feature is the built-in Bluetooth® technology — providing you with the ease and flexibility of wireless connection to perform all your Uroflowmetry procedures.

Uroflowmetry (Uroflow) is a standard Urodynamic test, whereby the urine flow rate and volume are measured. Uroflowmetry is used to verify or disprove patient symptoms via scientific methodology. It is a prerequisite for you, as a user of this equipment, to understand the basic measuring principles and techniques of Uroflowmetry analysis.

The purpose of this manual is to familiarize you with the installation, use, and operation of the **Urocap™ IV** Uroflowmeter.

For further information or technical service, please contact your local LABORIE sales representative or contact LABORIE.

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

1.1 GENERAL DESCRIPTION

The **Urocap™ IV** uses Uroflowmetry as a form of Urodynamic testing. The urinary flow rate and volume are measured and the results, in general, are used to verify or disprove patient symptoms via scientific methodology. Data acquisition occurs as the transducer collects and processes data, which is displayed via the **Urocap™ IV** software application. It prints the data in graphical form through the **Urocap™ IV** software or the i-LIST™ Office Reporter software, and is followed by a calculated Voiding Summary.

1.2 MAIN FEATURES

Features include:

- Hardcopy printout of Uroflow report including:
 - Patient information section
 - Uroflow graph including Flow and Volume channels
 - Voiding Summary
- On-site calibration
- Software interface with real-time graph scrolling

1.3 CAUTIONS AND WARNINGS



READ CAREFULLY BEFORE USE

CAUTION

United States Federal Law restricts this device to sale or use by, or on the order of, a licensed physician.



GENERAL SYSTEM WARNINGS:

- 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.
- The **Urocap™ IV** system and associated devices are intended for indoor use only and under the following standard operating conditions:
 - Temperature: +10°C to +40°C (50°F to 104°F)
 - Humidity: 30% to 75% relative humidity (non-condensing)
 - Pressure: 700 to 1060 hPa
- Physicians and technicians **MUST** inform patient of any potential risks of the procedure including potential discomfort, dysuria and hematuria.
- **DO NOT USE** in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- 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.
- **DO NOT STAND** anywhere on the system or its devices. The devices are not designed to support the weight of a person.
- **DO NOT** immerse the **Urocap™ IV** equipment or any components in water or any other liquids.
- **DO NOT USE** the **Urocap™ IV** 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.
- **DO NOT ATTEMPT TO OPEN OR REPAIR** the **Urocap™ IV** system components by yourself or by an unauthorized party. **ONLY Laborie-trained technicians** may service the **Urocap™ IV** system components.
- **LABORIE equipment and accessories** are licensed by Governments and approved by Safety Agencies to work **with each other ONLY**.
- LABORIE equipment and accessories are warranted to work with each other **ONLY**.
- No modification of this equipment is allowed.
- **DO NOT STERILIZE** the **Urocap™ IV** system components.
- Use Input and Output Cables and Cords provided by LABORIE only.
- Exposure to ESD may cause the system to RESET.
- To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth to prevent damage or injury.

- Connecting electrical equipment to a multiple socket outlet effectively leads to creating a medical electrical system and can result in a reduced level of safety.
- The **Urocap™ IV** system must be positioned in such a way to provide unobstructed access to the power cord connector in the event of a required emergency stop.
- Do not place the printer in the patient environment unless it is powered via the Laborie provided Line Isolation Transformer (Separating transformer).
- Only connect items that have been approved by Laborie to the system. Any additional connections become the responsibility of the operator and shall be tested to meet the IEC 60601-1, ME SYSTEMS requirements.
- 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)
- Do not touch the printer/laptop and the patient simultaneously.



General System Important Information

- Before the procedure, verify that the **Urocap™ IV** system components and software are functioning properly.
- LABORIE is not responsible for loss of patient files or test data. It is strongly recommended to back up patient data on a regular basis.
- To avoid the potential of incorrect data reporting, always verify all remote events are downloaded with data.
- Avoid accidental contact between connected but unused applied parts and other conductive parts including those connected to protective earth to prevent damage or injury.
- Do not plug or unplug devices, or pair or unpair Bluetooth devices, while the **Urocap™ IV** system is in use.
- Calibration should be checked at least every six (6) months or whenever there is a suspicion that the calibration is incorrect. ONLY calibrate the transducers if necessary.
- To ensure proper system use, follow the equipment setup instructions in the Equipment Setup section in this manual.
- To avoid disruption, ensure the **Urocap™ IV** uroflowmeter is plugged in to a power outlet during test procedures.
- It is important that the beaker is well centered on the Urocap uroflowmeter and does not touch the funnel.

DO NOT TOUCH the beaker during voiding and ensure the patient does not touch or move the beaker during a procedure.

- In case of device connection/Bluetooth connection interruption, reconnect the devices as outlined in this manual
- To avoid the risk of device connection interruption, reduce the distance between the device and the computer. The maximum distance between the processor and the computer can be up to 10 meters (33 feet). Also, remove any physical barriers like walls, posts, doors, or people.
- To reduce the risk of equipment connection failure, the software contains built-in algorithms that add checksum (CRC) protocols to data transmissions. In the event the data received is not correct, an alert message is displayed to the user.



General System Safety Compliance

- 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.

1.4 INTENDED USE

The **Urocap™ IV** Uroflowmetry analyzer is intended to quantify the flow characteristics of the lower urinary tract. Using the available transducer, the system can perform standard Uroflowmetry studies. Uroflowmetry is a standard Urodynamic test that is often used as a screening test before moving on to more advanced Urodynamic studies such as Pressure or Micturition. The **Urocap™ IV** is intended for use in Uroflowmetry studies that measure both flow rate and voided volume and is intended for use by a qualified practitioner only.

1.5 TARGET POPULATION

The major application of Urodynamics (including Uroflowmetry) is the diagnosis of uncontrolled loss of urine (incontinence) or abnormal urinary retention.

1.6 CONTRAINDICATIONS

 The **Urocap™ IV** Uroflowmetry analyzer is contraindicated in any patient who is not a candidate for Uroflowmetry testing.

2 CLEANING AND MAINTENANCE

At times, the **Urocap™ IV** will become dirty due to urine contamination and cleaning is required. Always wear protective gloves when cleaning the equipment to prevent biological contamination.



DO NOT SOAK THE **UROCAP™ IV** IN WATER. DO NOT IMMERSE IN WATER OR ANY OTHER LIQUIDS.



Figure 1 – Do not immerse the Urocap™ IV

- The **Urocap™ IV** Uroflowmeter has a rating of IP54 for ingress of water. This means that the enclosure of the device is able to handle splashes of water and liquid from any direction, but is not protected against total immersion into liquids. Never soak or immerse the **Urocap™ IV** into liquids.
- The lid of the **Urocap™ IV** is not removable. Attention must be paid to prevent damage.
- The **Urocap™ IV** should be cleaned using a damp cloth with alcohol, soap or disinfectant detergent.

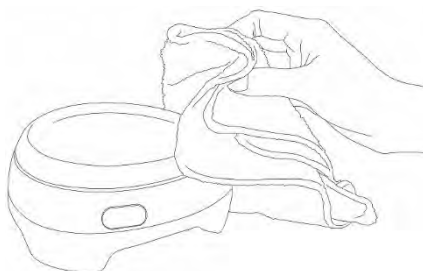


Figure 2 – Cleaning the **Urocap™ IV**

- The unit should be stored in a cool, dry area at room temperature.
- The Uroflow beaker should be rinsed and dried after use. Soap and water or a mild detergent solution can be used for cleaning.



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

- Performing regular maintenance will reduce the need for costly repairs. Check the transducer calibration of the **Urocap™ IV** every 6 months, or whenever you suspect the transducer is off calibration.
- Pay close attention to the LED lights on the device. If they indicate a broken connection and/or low battery, make sure that the connection is re-established or battery is fully charged.

3 BATTERY: CHARGING AND MAINTENANCE

3.1 CHARGING THE BATTERY

The **Urocap™ IV** contains a rechargeable battery. To charge:

1. Lift the tab on the bottom of the **Urocap™ IV** to reveal the charging port (A).
2. Plug one end of the charging power supply cord into the charger port on the bottom of the device and the other end into an electrical outlet.
3. When LED light on the device is green, it is fully charged.

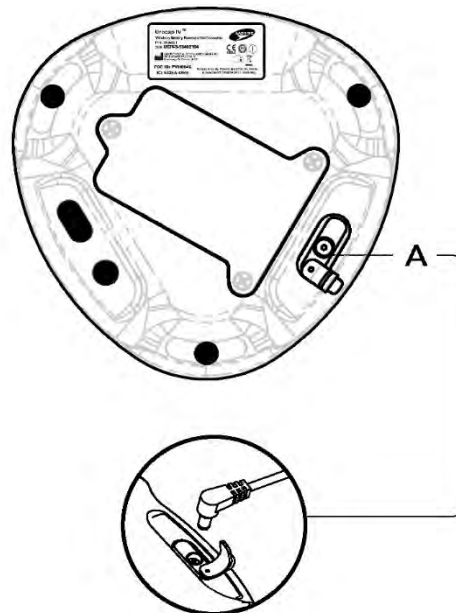


Figure 3 – **Urocap™ IV** charging port location



The equipment can be used while charging

3.2 PREVENTATIVE MAINTENANCE

- Do not step on, drop, immerse in water, or puncture the battery. If misuse, abuse or damage is suspected – or any form of mechanical damage to the casing is visible – discontinue use and contact LABORIE service.
- If there is a sudden change to the battery's ability to hold a charge or a sudden change in battery life is noticed, discontinue use and contact LABORIE service.

3.3 TREATING AND DISPOSING OF PRODUCT AFTER USE

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

3.4 ENVIRONMENTAL CONSIDERATION OF WASTE DISPOSAL

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

4 DEVICE SETUP

4.1 PERFORM AN EQUIPMENT CHECK

Verify 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. Carrying cases and cartons should be saved to provide a convenient and safe way to return the equipment should service be required.

Refer to the following table for a list of standard and optional equipment.

EQUIPMENT	DESCRIPTION
A white, bowl-shaped device with a circular opening on top and two small buttons on the front. Urocap IV Uroflowmeter (TRA851)	The Urocap™ IV uses a weight transducer to measure both volume and flow rate. A beaker is placed on top of the transducer. When urine is collected in the beaker, the transducer detects the change in weight and the Uroflow procedure starts.
A rectangular power supply unit with a power cord attached to one side. Urocap IV Power Supply (POW044)	The power supply and charger provides power to the uroflowmeter. For medical safety it is the only supply to be used for this device.
A power cord with a standard three-prong electrical plug on one end and a connector for the device on the other. Power Cords (POW005 [110V] or POW740 [220V])	To conform to medical standards, the power cable is of a medical grade accepted by hospitals. The plug portion of the cord will vary depending on which country the unit is delivered to or by customer request.


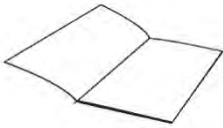
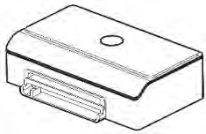


 <p>Beaker (DIS900 x 5)</p>	<p>The type of plastic beaker included with the package is the only recommended beaker to be used with the system.</p>
 <p>Urocap™ IV Standalone Quick Start Guide (MAN400)</p>	<p>Quick start guide provides brief overview of system functions.</p> <p>Owner's manual provides full set of instructions for use for devices, accessories, and software.</p>

Table 1 – Standard Equipment

EQUIPMENT	DESCRIPTION
 <p>Wireless Printer</p>	<p>The wireless printer connects to mobile devices via WIFI and provides a printout of test results. Please speak with a Laborie representative to learn about the recommended printer for your region.</p>
 <p>Commode Chair (CHA181) and Funnel (CHA102)</p>	<p>The folding commode chair and funnel are both made of sturdy materials.</p>
 <p>Uroflow Stand (MSM1065 – wheeled) or MSM1075 (locked)</p>	<p>The uroflow stand provides added protection from artifact when used under a commode chair. It can be used for male studies for voiding in a standing position.</p>

STANDARD	OPTIONAL
<ul style="list-style-type: none"> • Urocap™ IV Uroflowmeter • Power supply and charger • Power cables • Beakers • Commode chair and funnel • Software disc containing software, and owner's manual, and quick start guide • Laptop provided by LABORIE 	<ul style="list-style-type: none"> • Printer • Uroflow stand • Bluetooth® key and drivers if using non-LABORIE provided computer/laptop • i-LIST HL7 integration package

Table 2 – Optional Equipment

4.2 SET UP EQUIPMENT

Once the **Urocap™ IV** and accessories are removed from their packaging assemble the **Urocap™ IV**, the chair, and the beaker for testing. Connect the power supply to the **Urocap™ IV** and plug the power supply into an electrical outlet.

The Bluetooth technology built into the **Urocap™ IV** provides the patient with a higher degree of privacy during voiding. The **Urocap™ IV**, the beaker, the commode chair and funnel can be set up in one room while the laptop and printer can be in another room collecting and printing data.

4.3 INSTALL SOFTWARE

If not already installed on the laptop, please refer to the *System Installation Guide for Laborie UDS Systems with Windows 10®* on the LABORIE software USB to install the **Urocap™ IV** standalone software.

4.4 CONNECT UROCAP™ IV TO SOFTWARE

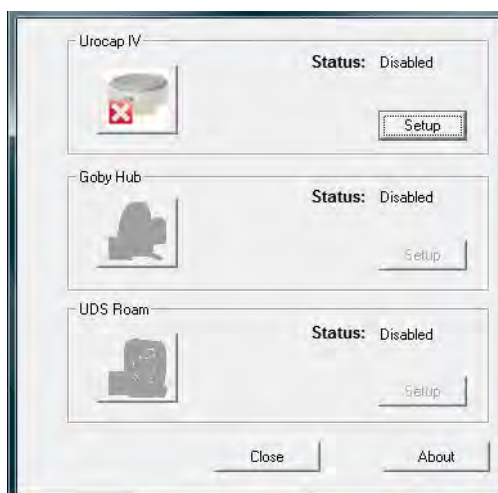
The **Urocap™ IV Device Manager** window allows you to connect the **Urocap™ IV** to the software. Once the connection is established in this window, the equipment will automatically connect each time the computer is powered on.

1. Make sure the Bluetooth dongle is plugged in to the computer.
2. Double-click the ***Urocap™ IV Device Manager*** icon on the computer desktop.



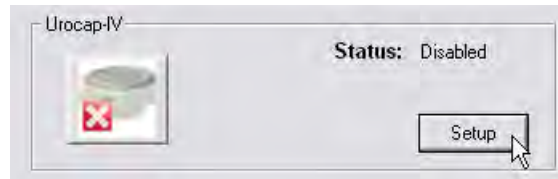
The **Urocap™ IV** Device Manager window will display the status of the **Urocap™ IV** equipment.

Note: The Goby Hub and UDS Roam are not required for this connection.



3. Make sure the **Urocap™ IV** Uroflowmeter is near the computer.

- Click Setup to connect the equipment.



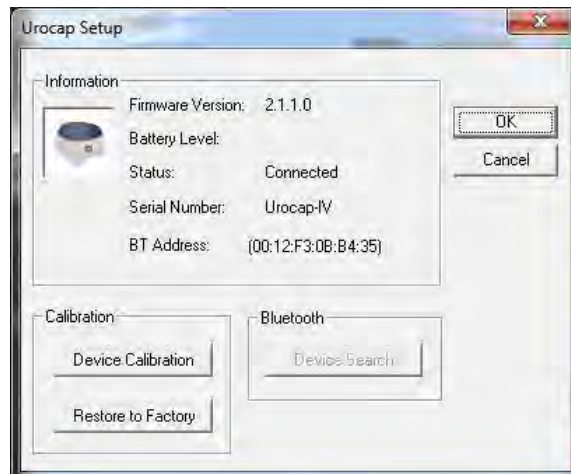
- In the Urocap Setup window, click the Device Search button to start locating the Uroflowmeter that needs to be connected for the system.
- Click Cancel in the Bluetooth Device Server window.
- Click Device Search again.



- Wait for the Urocap to be located. When the Urocap is located in the Bluetooth Device Server window, highlight the name and then click OK.



When a connection is established, the Bluetooth address and serial number fields will display the device information.



- Click OK to go back to the **Urocap™ IV** Device Manager window.

10. In the Device Manager window click the **Urocap™ IV** device button and wait for the connection to establish and finalize.

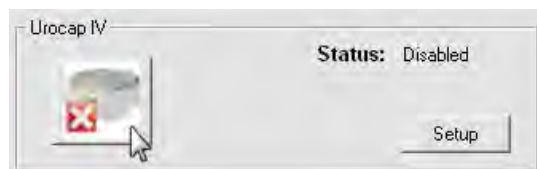
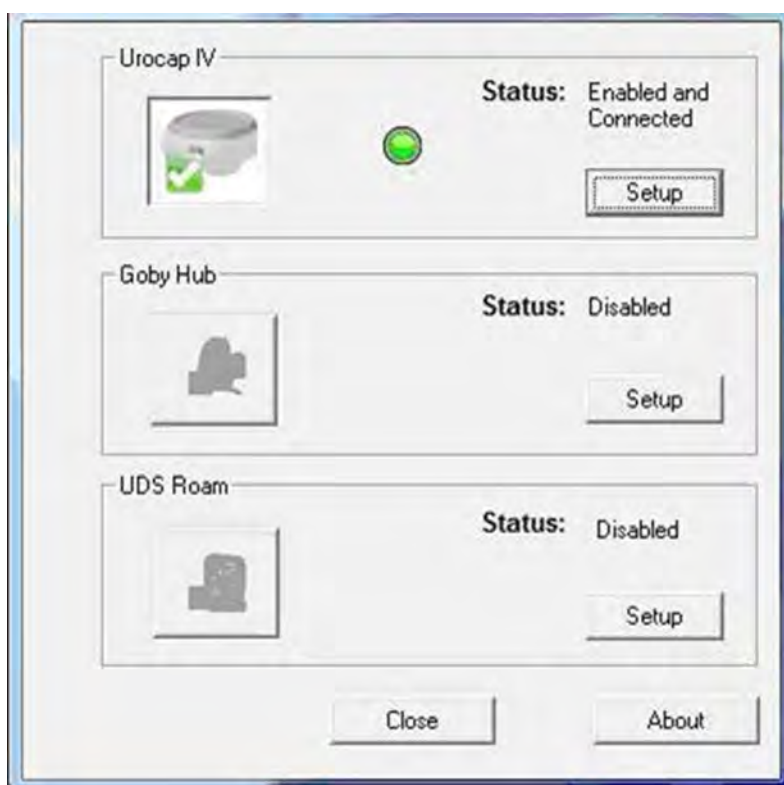


Table 3: Connecting Urocap™ IV to the Software

When the **Urocap™ IV** is connected and functioning, the **Urocap™ IV** Device Manager window will look similar to this:



4.5 WIRELESS PRINTER SETUP

4.5.1 BEFORE YOU BEGIN

Ensure the following:

- The wireless network is set up and working properly.

- The printer and the computers that use the printer are on the same network (subnet).

While connecting the printer, you might be prompted to enter the wireless network name (SSID) and a wireless password.



- The wireless network name is the name of your wireless network.
- The wireless password prevents other people from connecting to your wireless network without your permission. Depending on the level of security required, your wireless network might use either a WPA passphrase or WEP key.

If you have not changed the network name or the security passkey since setting up your wireless network, you can sometimes find them on the back or side of the wireless router.

If you cannot find the network name or the security password or cannot remember this information, see the documentation provided with your computer or with the wireless router. If you still cannot find this information, contact your network administrator or the person who set up the wireless network.

4.5.2 SET UP THE PRINTER ON YOUR WIRELESS NETWORK

To set up the printer on your wireless network use the Wireless Setup Wizard from the printer control panel 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 20 to set up the printer on your wireless network.

4.5.3 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.

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.

To Turn On Wi-Fi Direct

1. On the printer control panel display, from the Home screen, touch  (Wi-Fi Direct).

2. Touch  (Settings).
3. If the display shows that Wi-Fi Direct is Off, touch the toggle button next to Wi-Fi Direct to turn it On.


To Change Connection Method

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

To Print From a Wireless-Capable Computer (Windows)

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

Enter the Wi-Fi Direct password when prompted.

NOTE: To obtain Wi-Fi Direct password, on the printer control panel display, from the Home screen, touch  (Wi-Fi Direct).

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

5. Print your document.

4.5.4 CHANGE THE CONNECTION TYPE

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

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.

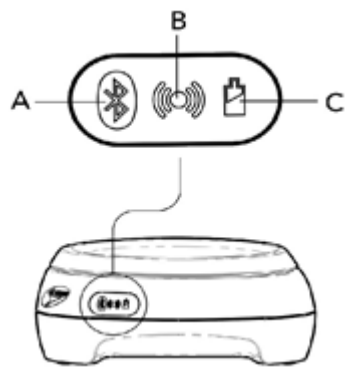
Note: A USB connection between the computer and printer can only be used if these two devices are isolated from the patient environment to reduce the risk of electric shock to the patient. Laborie highly recommends that a wireless connection is used between the computer and printer at all times.

5 DEVICE FEATURES AND FUNCTIONS

5.1 LED LIGHTS

The **Urocap™ IV** contains LED lights that indicate its battery and connection status. Equipment status can also be checked in the **Urocap™ IV** Device Manager window.

Once the components are assembled and connected, the LED lights on the **Urocap™ IV** will flash their connection status. The LED lights are located on the front of the device.



A. Bluetooth Icon

- a. Blue: Connected or Sleep Mode
- b. Green: System at work but not connected
- c. Orange: System fault
- d. Light OFF: Not connected

B. Equipment Status

- a. Green: Connected
- b. Blinking Green: Connected and sampling
- c. Orange: System fault
- d. Blinking Orange: Not connected
- e. Light OFF: System OFF or sleep mode

C. Battery Power

- a. Green: Battery full and plugged in
- b. Blinking Green: Battery good
- c. Orange: Charger plugged in and battery charging.
- d. Blinking Orange: Low battery, time to charge
- e. Light OFF: Battery empty

5.2 CONNECTION STATUS

Icon indicators in the **Urocap™ IV** Device Manager window will also display the status of the **Urocap™ IV**. The colored circle in the middle of the screen displays the battery status.

	When connected and functional, a green check mark will appear next to the Urocap™ IV picture and will display its connection status.
	After a period of inactivity, when the Urocap™ IV is connected but not in use, it will go to "sleep" to conserve battery power. To restart the device when in <i>Hardware Sleep Mode</i> , click the Run button. To restart the device when in <i>Bluetooth Sleep Mode</i> , click the Wake up button on the control panel.
	When there is a connection failure, you will need to re-connect the Urocap™ IV . Click the device button to re-connect. If the device does not connect after this attempt follow the steps starting on page 50 for more information

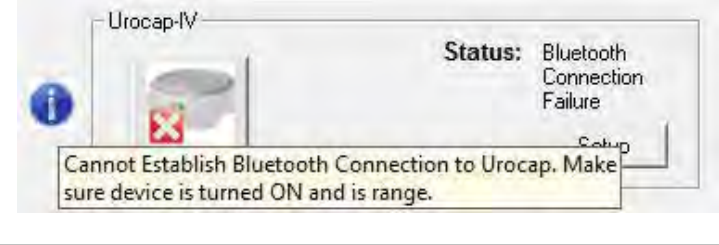

	<p>If an information bubble icon  is displayed next to the device icon place the mouse cursor over it to read the message and follow the instructions.</p>
---	---

Table 4 – Device Manager System Status Indicator Icons

5.3 BATTERY STATUS


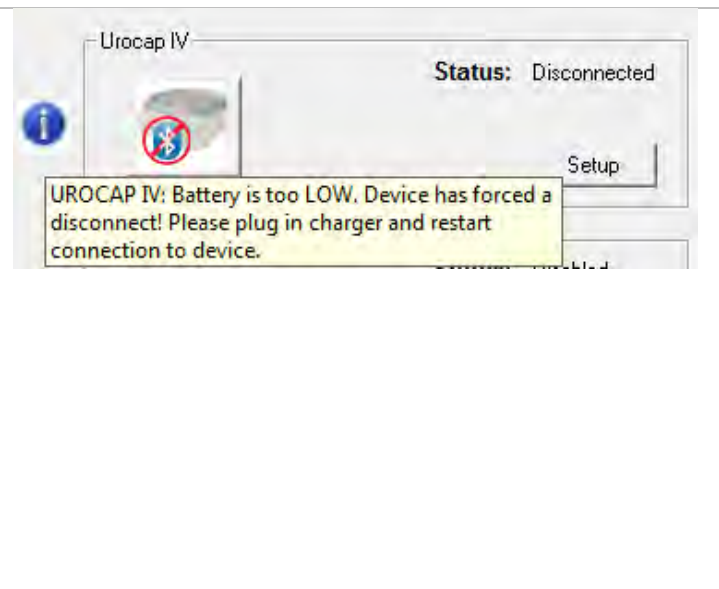

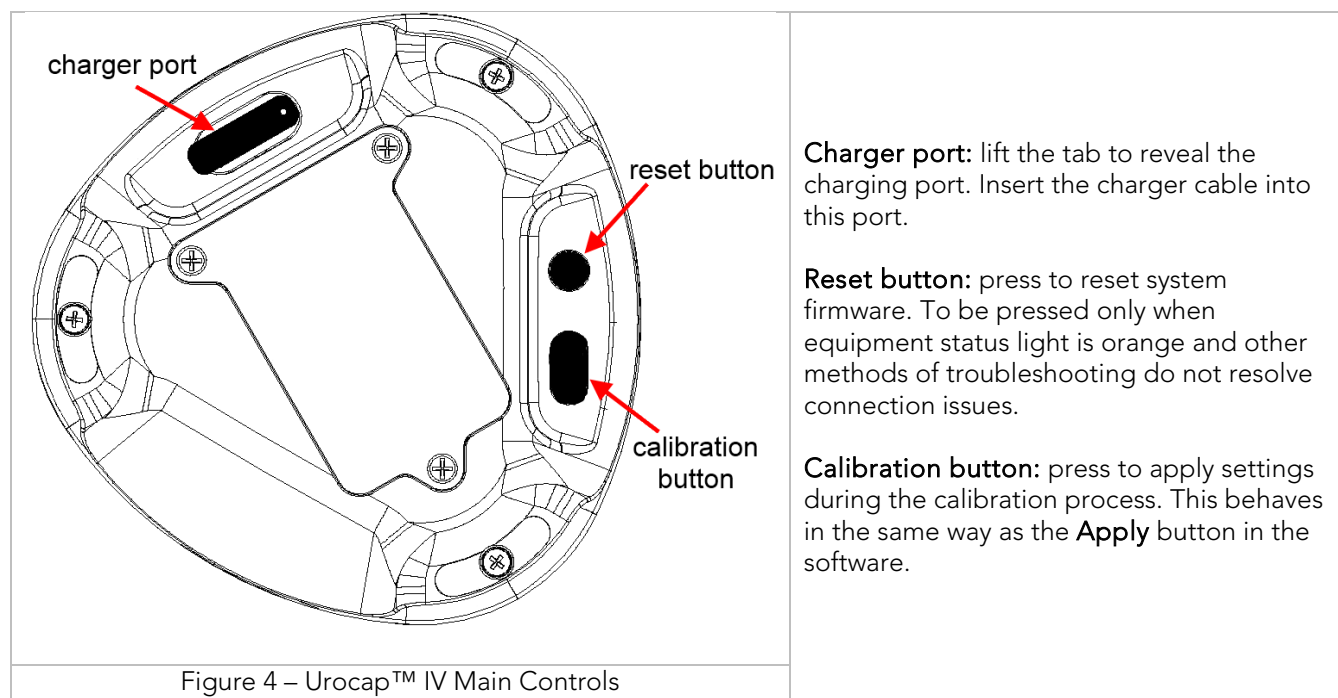
	<p>The battery status will also display in the Device Manager window and the LED light color on the device will be the same as the color displayed in the Device Manager window.</p> <p>NOTE: the plug symbol signifies that the device's battery is being charged.</p>
	<p>Before complete drainage of the battery power, the device's LED lights will flash the battery power status (as outlined on page 22). When the battery reaches total power drainage, the device will be disconnected from the system and the status message (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 on page 49.</p> <p>NOTE: If battery power drainage occurs while a test is in progress, the graph will stop scrolling and an event named <i>UrocapIV Low Battery Shutdown</i> will be marked on the graph. Stop the test, plug the device into the charger, and reconnect as described on page 13.</p>

Table 5 – Device Manager Battery Status indicator Icons

5.4 DEVICE CONNECTOR AND SYSTEM RESET BUTTON



6 SOFTWARE FEATURES AND FUNCTIONS



Double-click the **Urocap™ IV** shortcut icon on the computer desktop to open the **Urocap™ IV** software.

The menus in the menu bar at the top of the **Urocap™ IV** software window contain items that allow you to view saved test files, to customize the appearance of the control panel, and to view test summaries.



- **Menu Bar:** Click to access the features available for testing and analysis.
- **Device Status:** displays the connection status of the **Urocap™ IV**. Any changes to the status will automatically appear here. Double click the icon to open the *Device Manager* window to investigate status changes and to reconnect.
- **Control Panel:** contains buttons for selection during procedures
- **Graph Display Area:** displays the scrolling graph, saved graphs, and contains zoom level options.

6.1 QUICK START

- Click the **Uroflow** button to manually control the software.
- Click the **Uroflow Auto Start** button to automatically start the test and print results.
- Click the **Uroflow Auto Recording** button to automatically start, stop, and open the *iLIST Reporter* software.

6.2 FILE MENU

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

6.2.1 OPEN

Select this 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**.

6.2.2 OPEN FROM DATA FILE

Select this 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.

6.2.3 SAVE AS

Click this 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 as shown in Figure 5 – Save Test File.

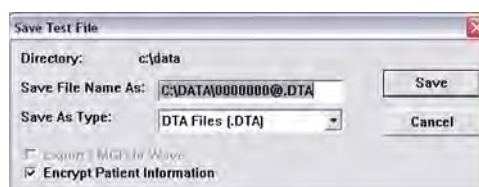


Figure 5 – Save Test File Window

6.2.4 FILE SAVING DIRECTORY

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

To change the directory:

- Click **Browse** and select a new directory.
- Click **OK**.
- Click the **Create Dir.** button to set the new directory.

Click **OK**.



Figure 6 – Change Data Directory Window



After saving to the new directory, the software will remember the location for the next time

6.2.5 PRINT STUDY

Select the information in this window to include in a printed report.

The first time you print a report for a specific test configuration, 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.

6.2.6 BATCH PRINT (OPTIONAL FEATURE)

Batch Printing allows you to print multiple procedure reports at once (for example, during a particular day or at different time periods).

- **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.**

6.2.7 ABOUT UDS CLIENT

The About UDS Client dialog box displays the information for contacting Laborie's Technical Support team 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 then fax the sheet to LABORIE's support department.

6.2.8 EXIT

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

6.3 CONFIG MENU

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

6.3.1 SAVE AS

The **Save As** feature saves or redefines a test file configuration linked to the **Uroflow** button on the control panel. Remember that a new file name should **not** include any punctuation marks. This file can then be used for testing when the **Uroflow** button on the control panel is clicked.

For example: A configuration file may be named *Uroflow1.cfg* for Uroflow studies and used as the basic file for all Uroflow tests.



The *Uroflow.cfg* file name is the default file pre-loaded on the software and should not be changed.



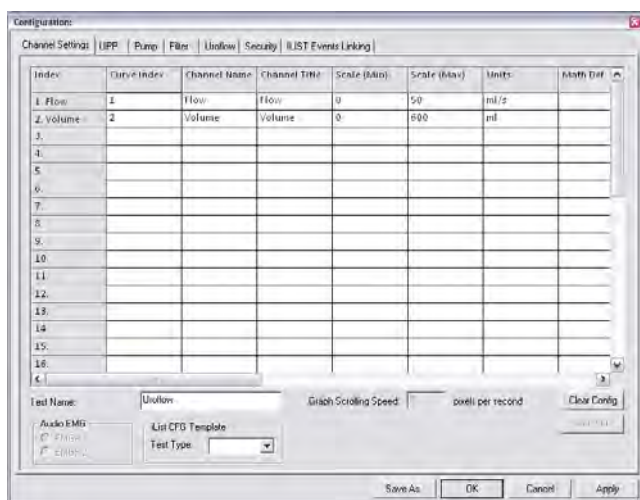
Select the *Encrypt Patient Information* checkbox if you wish to encrypt patient information.

6.3.2 SET UP/MODIFY (OPTIONAL)

Select this to configure new test files and features. An automatic start of the Uroflow test (**Auto Start**) is the default setting when the **Uroflow** button on the control panel is clicked.

To set up another type of test to be used when the Uroflow button is clicked use the configuration options under the **Channel Settings** tab and the **Uroflow** tab.

CHANNEL SETTINGS



Under the **Channel Settings** tab you can select which channels will be displayed on the graph, the channel colors, and the channel order.

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

Figure 7 – Configuration Window

- 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 *Maximum* and *Minimum* 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.
- 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.
- Line widths can also be modified to be thicker or thinner. Select specific widths for either display on screen (*Display Line Width*) or appearance on printouts (*Print Line Width*).
- *Symmetry* allows you to mirror a channel's curve to make a negative mirrored curve. Click **Mirrored** to create a mirrored curve.
- *Interior* allows you to fill the area under the curve with the same color as the channel color selection.
- The *Printable* option allows you to see the graph curves on the test results printout. Select **Printable** to include the curve in a printout.
- *Curve Overlay* allows you to display up to 5 channel curves on the same graph on the display and print out.

UROFLOW

Under this tab, you can set the parameters for Uroflow such as auto Uroflow summary and auto printing.

SECURITY

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 to the patient file can see the decrypted information.**



This security feature needs to be set before you start running a test, and make sure that a virtual key is installed in your PC.

To encrypt patient information:

1. Click the **Security** tab.
2. Make sure that the *Enable Encryption of Patient Information* box is selected.
3. Type the serial number of the virtual key into the field under *Enable Encryption of Patient Information*.
4. Click the **Add** button to add the serial number to the secure list.
5. Click **Apply** to save selections.

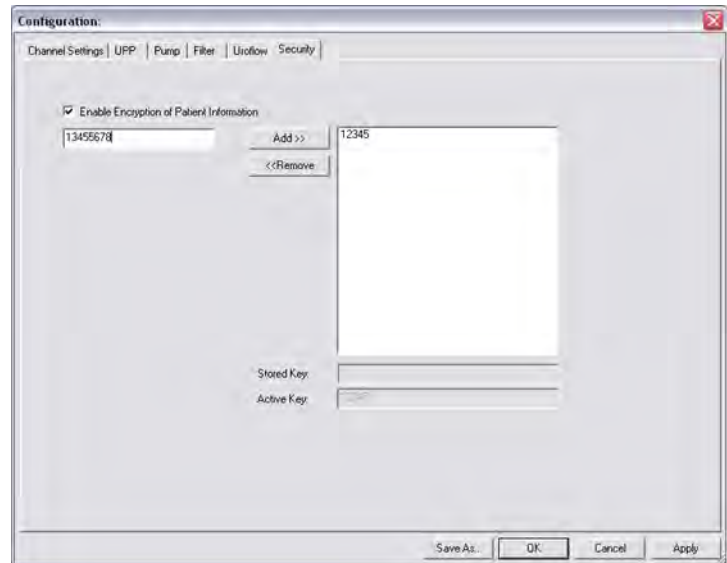


Figure 8 – Configuration Window, Security Tab

Once a UDS test is performed, remember to select the *Encrypt Patient Information* box in the *Save As* window.

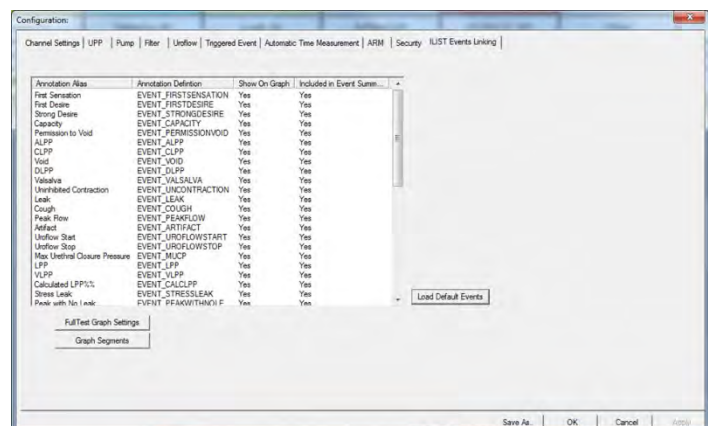
Once you save the patient information with encryption, if someone uses a virtual key that is not associated with the file they will see the word *ENCRYPTED* in all the *Patient Information* fields.

ILIST EVENTS LINKING

Events that are not in the *ILIST Events Linking* may not appear in some of the printed reports.

Try the following to check if an event is available in the Event Summary:

1. In the software click **Config > Set up/Modify**.
2. Click the *ILIST Events Linking* tab.
3. (optional) Click the **Load Default Events** button to add the standard iLIST events to the listing.



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

If you need to add an event, or if you are using the software with a language other than English, then you will need to add or translate the Event name in the *Annotation Alias* listing on the left-hand side. Click on the event name once, then click on the name again, and then type in the word as needed. For example, the event *Strong Cough* is added to the list. If we then click the **Event** button on the control panel, the newly added event will appear in the *Event Annotation* box.

6.3.3 UNLOCK CFG

To prevent the accidental overwriting of test configuration files, this option will let you lock/unlock configuration files.



All configuration files provided in the UDS120 software are locked at installation. Only unlock if you are sure of the modifications to be made.

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.

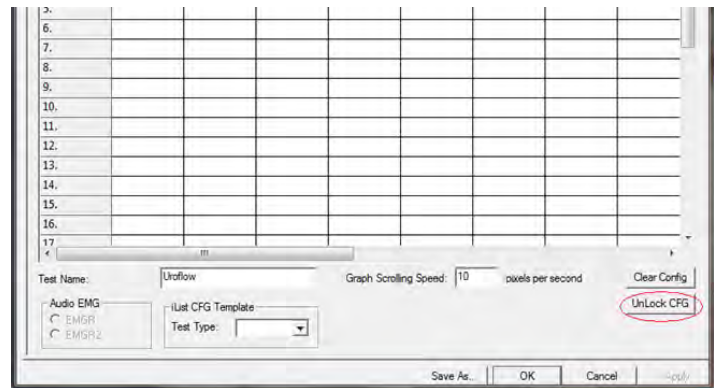


Figure 9 – Unlock CFG

Make changes as needed and when complete click the **Lock CFG** button.

Click **Yes** in the resulting warning message to lock the configuration file.

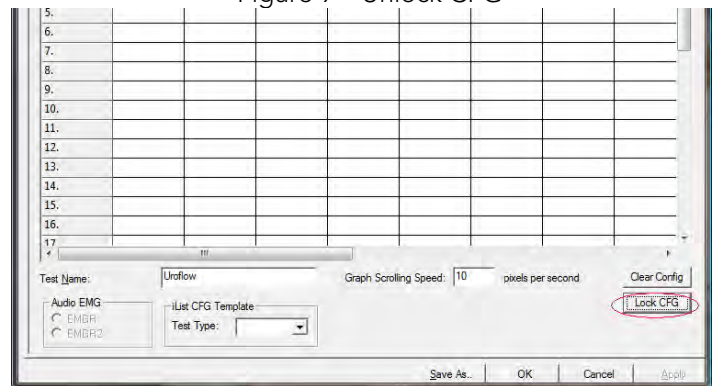
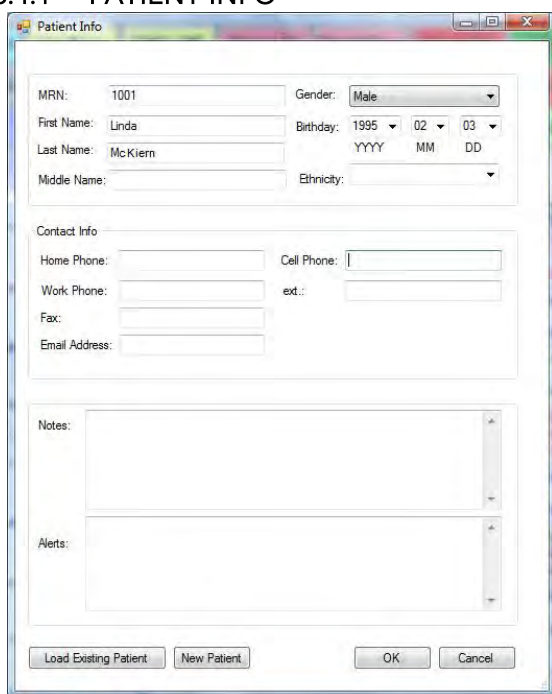


Figure 10 – Lock CFG

6.4 INFO MENU

The **Info** menu contains items that allow you to view patient information as well as test summaries.

6.4.1 PATIENT INFO



The details of a patient's file are easily added to and accessed through the Patient Information dialog box. Add information as necessary and 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.

If the patient is under 16 years of age then another patient information screen will open, click **Cancel** to continue with the test.

Figure 11 – Patient Information Window



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.

6.4.2 X-Y PLOTS

This menu contains the Nomograms for comparing Uroflow rates and outflow obstruction.

SIROKY NOMOGRAM (OPTIONAL)

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

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

The Siroky Nomogram contains the graphical representation of the Average and Maximum flow rates as developed by Siroky et al.



The Siroky Nomogram is valid for male adult patients only.

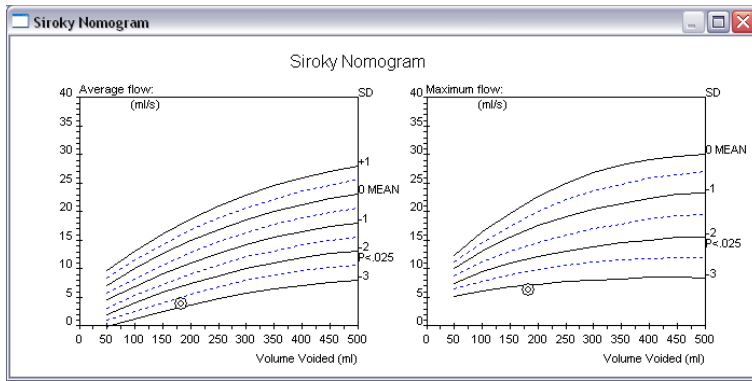


Figure 12 – Siroky Nomogram Window

LIVERPOOL NOMOGRAM (OPTIONAL)

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

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

The Liverpool Nomogram contains the graphical representation of the Average and Maximum flow rates as developed by Siroky et al.



The Liverpool Nomogram is valid for male and female adult patients only. Depending on the patient's gender, the resulting Nomogram window will appear for either the male or female averages.

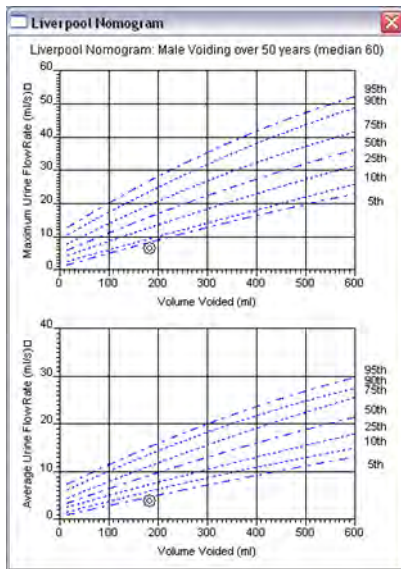


Figure 13 – Liverpool Nomogram Window

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.

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.

PEDIATRIC NOMOGRAM (OPTIONAL)

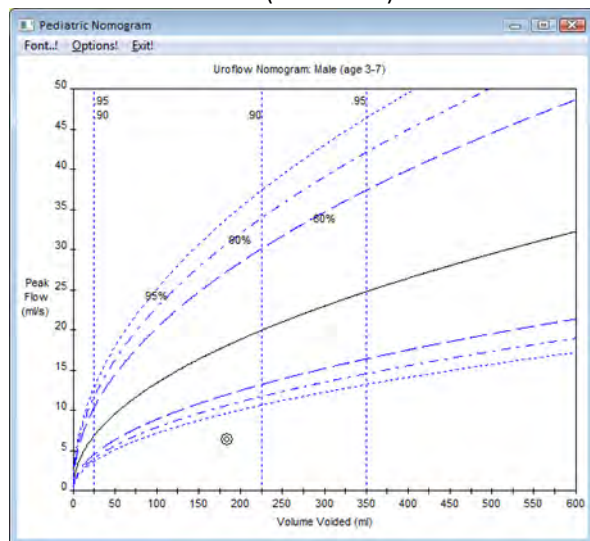


Figure 14 – Pediatric Nomogram Window

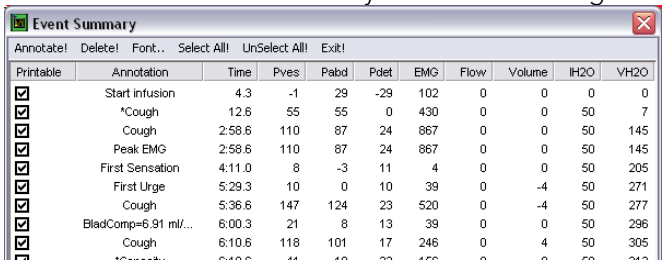
The Pediatric Nomogram is based on studies conducted by Dr. Churchill at the Hospital for Sick Children in Toronto, Ontario, Canada.

The studies concluded that a normal flow curve is related to age and gender. Each Nomogram is a plot of *Peak Flow* (y-axis) versus *Volume Voided* (x-axis). The center solid curve represents the *Mean*.

The plotted circles on the graph represent where the patient lies on the curve.

6.4.3 EVENT SUMMARY

You can add events throughout the test to record what happens during the procedure. Events are automatically stored and summarized when you register the markings. The summary of these events is available for review at a later time. You can add events by use of the Control Panel event buttons or by right mouse click on the graph window when you want to add the event. An event marker will be shown on the Graph window. Refer to the following table for different event markers.

TASK	STEPS
To add an event using a pre-configured Control Panel button during the test	<ul style="list-style-type: none"> Click the Control Panel event button when the event occurs.
To add an event that is not listed on the Control Panel:	<ol style="list-style-type: none"> Click the button labeled Event in the Control Panel when the event occurs. Event Annotation dialog box opens with the event list. If the event to be added is available in the event list, double-click it. If it is not on the list, type it in the edit box at the top of the window and press the ENTER key on the computer keyboard.
To view the Event Summary	<ul style="list-style-type: none"> Click Info > Event Summary to list in chronological order. 
Add or change event annotation	<ol style="list-style-type: none"> Highlight an event and click Annotate! Type the text in the text box or pick from the list. Click OK.

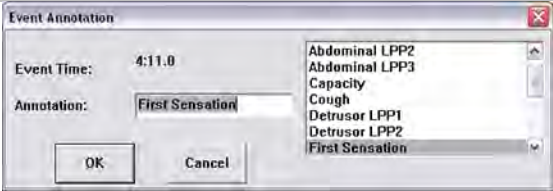
	 <p>The Event Annotation dialog box contains the following fields and list:</p> <ul style="list-style-type: none"> Event Time: 4:11.0 Annotation: First Sensation List of events: Abdominal LPP2, Abdominal LPP3, Capacity, Cough, Detrusor LPP1, Detrusor LPP2, First Sensation Buttons: OK, Cancel
Deleting events from the Event Summary	<ol style="list-style-type: none"> 1. Highlight the event. (To highlight multiple events, hold down the Ctrl key while clicking on the events.) 2. Click Delete! 3. Click OK.
Deleting or renaming events	To delete or rename an event on a graph, right-click on an event located on the graph and select an option from the resulting menu.
Selecting/Unselecting events for printing	<p>You can also have the events and values printed on the printout of the test results. To have all the events printed on the printout click Select All!</p> <p>To exclude all the events from the printout, click UnSelect All!</p>
Move to event on the graph	Once you are in the Event Summary window, you can double-click on an event and have the graph move to the point that corresponds to that particular event.

Figure 15 – Using and Adapting Event Markers



If you would like to change the appearance of the Event Summary window contents you can 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.

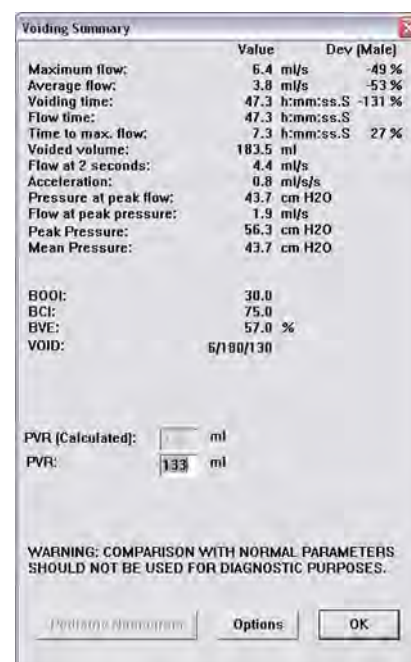
6.4.4 VOIDING SUMMARY

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

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. They are provided for both male and female patients on the same printout.



The Voiding Summary window displays the following data:

	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:	6/190/130	
PVR [Calculated]:	ml	
PVR:	133 ml	
WARNING: COMPARISON WITH NORMAL PARAMETERS SHOULD NOT BE USED FOR DIAGNOSTIC PURPOSES.		
<input type="button" value="Printout Information"/> <input type="button" value="Options"/> <input type="button" value="OK"/>		

Figure 16 -- Voiding Summary Window

The comparison is provided in a percent difference from the table value. 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.



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 less than 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.



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

6.4.5 UROFLOW OPTIONS

From the Uroflow Options box you can:

- Customize how the summary is calculated.
- Make changes to the channels and configuration parameters.

TO CHANGE PARAMETERS:

1. Click **Options** located in the **Voiding Summary** box.
2. Refer to the following list to change any parameters in the Uroflow Options dialog box.

PARAMETER	DESCRIPTION
Default Channels	Flow and Volume
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.
OEM Uroflow Transducer	Original Equipment Manufacturer (for optional non-Laborie Uroflow transducers).
Auto Event Marking	Automatically adds events to graph.

Auto Recording	With Auto Recording on, tests are automatically started and stopped once the transducer senses fluid in the beaker.
Auto Voiding Summary	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	Automatically starts <i>i-LIST Office Reporter</i> when a test is saved.
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.

Table 6 – Parameters Available in the Uroflow Options Dialogue Box

TO CHANGE A CHANNEL:

1. Click the Channel box beside the channel to be changed. *Result:* A channel list appears.
2. Select the appropriate channel name. *Result:* The selected channel name appears in the channel field.

The calculating channels may be replaced with other channels as long as the units are consistent in definition.



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

TO CHANGE THE TIME RANGE:

1. Click **Change**. *Result:* The Uroflow Options segment selection window appears.
2. Click and drag mouse pointer across the graph window from the start to the end of the Uroflow segment. *Result:* A bold black line runs across the top of the box indicating the selection.
3. Release the mouse button. *Result:* The start and end lines of the segment are updated.
4. Perform **one** of the following procedures:
 - a. Click Confirm to confirm selected segment.
 - b. Click Cancel to cancel the selected segment.

6.5 OPTIONS MENU

The **Options** menu contains helpful functions of the **Urocap™ IV** software.

6.5.1 TEST RESTART

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

To restart a test procedure: Click **Options** on the menu bar and select **Test Restart**.

6.5.2 TEST PLAYBACK

The playback feature enables a pre-saved test to be played back as if it is being recorded. After the test is complete, it may be viewed by using the playback feature. However, the playback speed may be different from that when it was recorded.

Click **Options** and select **Test Playback**

- To pause the test, Click Stop.

- To resume playback, Click Test Playback.
- To Exit the playback mode, Click Options and select Test Playback.

6.5.3 UROFLOW AUTO START

This feature starts the recording process as soon as the **Urocap™ IV** detects the first flow. 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**.

6.5.4 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:

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

To move the Cursor Window:

- Click the title bar on the **Cursor** window.
- Drag the window to the desired location on the screen.
- Release the mouse button.

To cancel the Cursor Option:

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

6.5.5 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 only a maximum of eight channels at one time. If more than eight channels are used, additional channels may be displayed as digital or overlay. Digital channels are displayed in the Digital window, while curves of overlay channels are displayed on the channels in which they overlay.

To set the Digital Attributes of Channels:

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

To switch the Digital Window On/Off:

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

6.5.6 CONTROL PANEL SETTINGS

The Control Panel Settings dialog box allows you to select the group of buttons available for procedures. There are 5 basic control panels set in the software when first installed, however other panels can be configured if desired. There are seven control panel buttons on each row; the number of rows can be modified if desired.

To configure the Control Panel:

1. Click **Options** from the menu bar and select **Control Panel Settings**.

2. Configure the control panel using the table below.
3. Click the down arrow of the Current Row to move to the second row of function buttons.
4. Click **OK** when all buttons are configured completely.

TASK	STEP
<i>Name of the function button:</i>	<p>Double-click the Label text box of the button. (The entered text will be displayed on the Control Panel button in the UDS Client screen.)</p> <p>Enter the name of the function button using the keyboard.</p> <p>Repeat until all the function buttons are labeled appropriately.</p>
<i>Definition of the name on the function button:</i>	<p>Click in the appropriate text box under the Definition column.</p> <p>Enter the new definition using the keyboard.</p> <p>Repeat until the definitions for all items on the Control Panel are complete.</p>
<i>Type of function button:</i>	<p>Click on the down arrow of the appropriate combo box to the right of each button's function.</p> <p>Select the appropriate function command type.</p> <p>Repeat until the type of all function buttons in the row are set.</p>

Table 7 – Configuring Control Panel Settings

TYPES OF CONTROL PANEL COMMANDS FOR THE **UROCAP™ IV** SOFTWARE

The following table lists the types of control panel buttons available for the **Urocap™ IV** software. Note that the button names (labels) in the chart are suggestions and can be named any way you prefer.

Button Label	Definition	Type	Comments
First Sensation	First Sensation	Event Event - Unique	Marks an event with the definition text as Event Annotation.
First Desire	First Desire		
Capacity	Capacity		An event that occurs only once and will replace any existing recorded event.
Valsalva	Valsalva		
Cough	Cough		
Uroflow	Full path of test configuration file. For example c:\cfg\Uroflow1.cfg.	Config*	Opens a .cfg file.
Auto Start	N/A	Auto Start	Sets up Uroflow Auto Start.
Zero All	N/A	Zero All	Sets all channels to zero.
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.
		None	Cancels a button function.

Table 8 – Control Panel Commands

IMPORTANT NOTE!** If you configure a particular test file under **Config > Set up/Modify** for use in Uroflow testing then it will need to be added to the control panel. The software is set to use the preconfigured file that automatically starts when the Uroflow button is clicked. To change the file used make sure that the correct file name is typed into the Definition box and that the correct selections are set in the ***Uroflow Options tab.

† NOTE:

To define the plots that will be displayed:

1. Select **Plot** from the drop list in the command window.
2. Click the PLUS (+) button to open the selection box.
3. Select **Siroky** and click **OK**.
4. Name the button in the *Label* column.
5. Click **OK** to set the button on the control panel.

MULTIPLE CONTROL PANEL SETS AND HOT KEY CONFIGURATION

Multiple Control Panel Sets can be set up in the UDS software, which will allow two or more users to use the same equipment but each having a customized Control Panel. Up to 16 Control Panel Sets can be set up in addition to the Default Control Panel Set.

The Hot Key configuration feature allows you to create a shortcut key combination for a particular control panel button.

<i>To Configure Multiple Control Panel Sets:</i>	<ol style="list-style-type: none">1. Click Options > Control Panel Settings.2. Type in a new name in the Control Panel Set Name box.3. Customize the Control Panel buttons to your liking.4. Click OK to save the Control Panel Set.
<i>To use another configured Control Panel Set:</i>	<ol style="list-style-type: none">1. Click Options > Control Panel Settings.2. Click the drop down button of the Control Panel Set Name box and select the appropriate name.3. Click OK.
<i>To add a new Control Panel set by duplicating the settings of an existing Control Panel set:</i>	<ol style="list-style-type: none">1. Click Options > Control Panel Settings.2. Click the drop-down button of the Control Panel Set Name box and select the name of the Control Panel set to be copied.3. Type over the displayed Control Panel Set Name with a new name.4. Make any additional changes to the Control Panel Set.5. Click OK.
<i>To configure the Hot Keys:</i>	<ol style="list-style-type: none">1. Click Options > Control Panel Settings.2. Click the P button next to the particular control panel button.3. Select a key combination that will correspond to a particular function of 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.

Table 9 – Configuring Control Panel Sets



The PLUS (+), MINUS (-), and EQUAL (=) keys can also be used for the Hot Key configurations.

ADD AN IMAGE TO A CONTROL PANEL BUTTON

An image can be added to a control panel button to make it easily distinguishable from the others.

To add an image to a button:

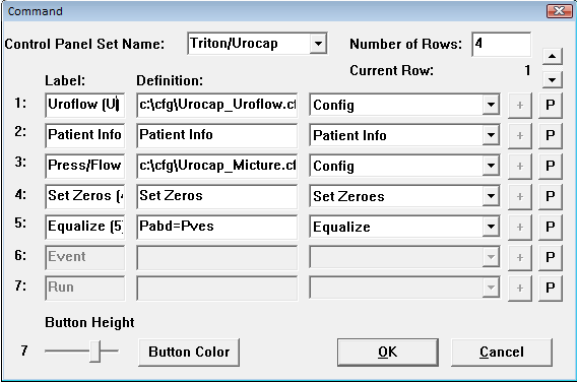
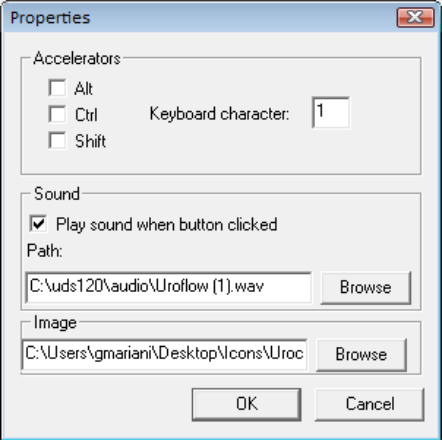
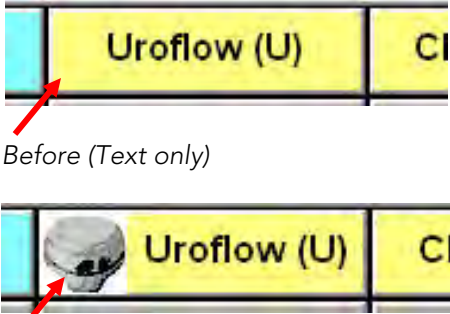
<div>1. Click Options > Control Panel Settings.</div> <div>2. Click the P button on the line of the control panel button to which an image will be added. In our example we will add an image to the Uroflow button:</div>	<div></div>
<div>3. In the <i>Properties</i> window, click the Browse button in the <i>Image</i> section to locate the image. Our picture in this example will be a picture of the Uroflowmeter.</div>	<div></div>
<div>4. Once the image is found, click Open to add the image name to the blank line in the <i>Properties</i> window.</div>	
<div>5. Click OK, and then click OK again to close the window. The image will now appear in the button on the control panel.</div>	<div></div> <div>Before (Text only)</div> <div>After (Uroflowmeter image with text)</div>

Table 10 – Adding an Images to Control Panel Buttons

CUSTOMIZE COLORS AND FONTS AND ADJUST BUTTON HEIGHT

Click the **Button Color** button in the *Command* window to open the *Select Color* window. You can choose the background color and font for individual Control Panel buttons as well as the color of the button names.

Once you have made your selections click **OK** to set them. The chosen colors and fonts will display once you exit the Command window and return to the main UDS screen.

To select the button color and/or the text font:

1. Click inside the colored box under the *Text* or *Button* column for the particular button type.
2. Select the colors you want for the button and/or text.
3. Click the **F** button next to the button type under the *Font* column and select the font you would like for the button from the resulting font selection window.
4. Click **OK**

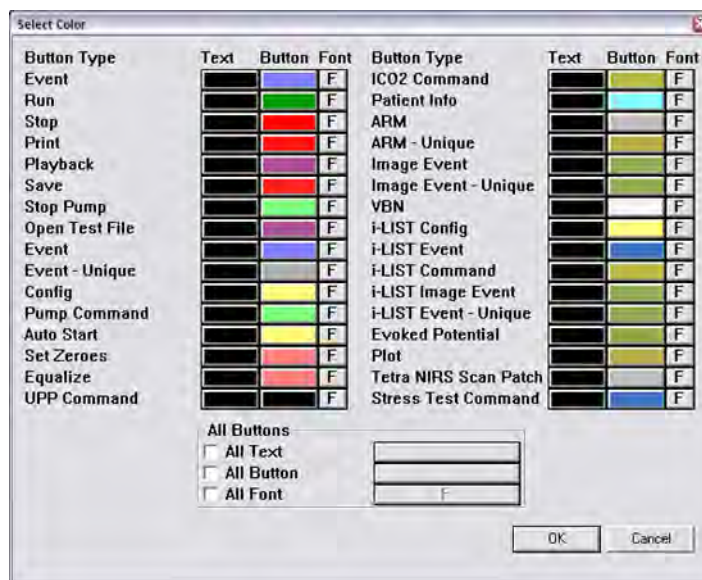


Figure 17 – Select Color Window

You can also select to have *all* Control Panel buttons with the same color and font. In the *All Buttons* section at the bottom of the window, select the button property to change and then click the rectangle next to the property to select the color or font. The chosen colors will display once you click **OK** and exit the Command window and return to the main UDS screen.

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

AUTO MARK PEAKS

The Mark Peaks feature automatically marks peak events for all channels when the test is stopped.

Click **Options > Auto Mark Peaks** to enable Mark Peaks.

Click **Options > Auto Mark Peaks** to disable Mark Peaks.

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.

Click **Options** from the menu bar.

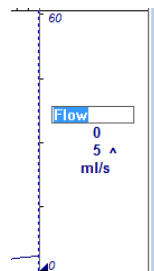
Select Graph Clipping.

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

MODIFYING GRAPH APPEARANCE (OPTIONAL SOFTWARE FEATURES)

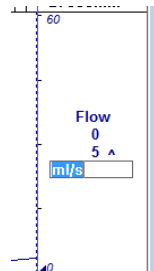
To change a channel name:

Click directly on the channel name.
Type a new channel name and press Enter on the keyboard.



To change the channel units:

Click directly on the channel unit.
Type the new channel units and press Enter on the keyboard.



To change either the maximum and minimum scale:

Click directly on the channel scale value.
Type the new channel scale value and press Enter on the keyboard.

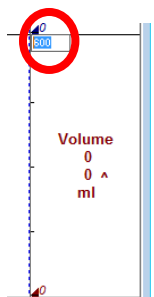


Table 11 – Modifying Graph Appearance

To change the order of the channels:

1. Right-click directly on the channel area and select **Change Channel Order** from the resulting pop-up menu.
2. *Result:* The mouse pointer changes to a hand-shaped cursor.
3. Left-click and drag the channel to be moved over another channel and release the mouse button.
4. Repeat step 2 for any other channels.
5. Right-click directly on the channel area to and select **Change Channel Order** again from the pop-up menu to set the changes in place.

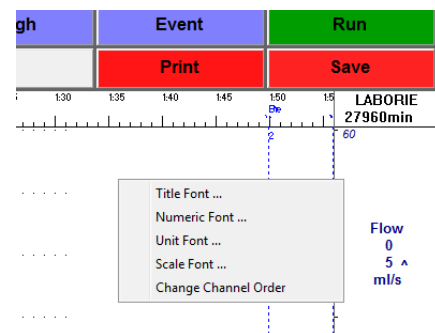


Table 12 – Adapting Channel Order

To move an event to a new location:

1. Move the mouse pointer over the guideline of an event.
2. Left-mouse click on the event guideline. If multiple events are in the area, a dialog box opens to help select the specific event to move. Select the event to be moved and click OK.
3. Move the double-arrow pointer to another position on the graph.
4. Left-click and then click the Yes button to move the event.

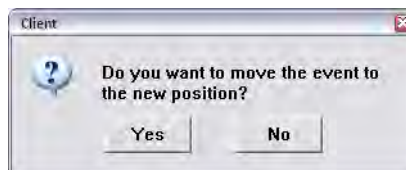


Table 13 – Adjusting Event Marker Location

To change one or more fonts for displaying channel information:

1. Right-click directly on the channel information area.
2. Select one of the *Title Font*, *Numeric Font*, *Unit Font* or *Scale Font* menu items.
3. Pick the font from the resulting *Font* selection window and click **OK** to set the changes.

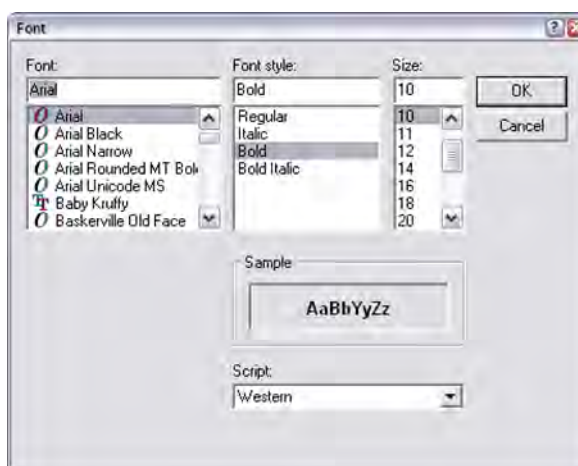


Table 14 – Adjusting Channel Font

SET ZEROES

Click this to zero channels as needed.

7 RUN A UROFLOW TEST

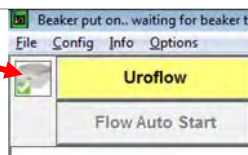
A Uroflow test is a measurement of the rate at which urine flows out of the body. It can be performed with the software's automatic method or it can be performed with manual control of the software.



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

7.1 AUTO METHOD

STEP	
1	Gather the supplies needed for a Uroflow test. (Urocap™ IV , beaker, commode chair, funnel, and straight catheter).
2	Plug the power cord into an electrical outlet.
3	Place the funnel on the plastic frame of the commode chair.
4	Carefully place the Urocap™ IV on the floor or on an approved Uroflow transducer stand.
5	Gently place a graduated beaker on top of the Urocap™ IV .
6	Place the commode chair and funnel over the Urocap™ IV and beaker. Make sure the beaker and the funnel are aligned but not touching.
7	Turn on the computer and then turn on the printer.
8	Invite the patient to get ready to take the test.
9	Double-click the Urocap™ IV shortcut icon on the computer desktop.
10	Make sure the Urocap™ IV is connected.
11	Click the Uroflow Auto Recording button on the control panel.
12	Confirm that all channels display zero values.
13	CAUTION! DO NOT TOUCH the beaker during voiding.
14	Instruct the patient to void; provide privacy if possible.
15	The graph will start scrolling once flow is detected and will automatically stop 50 seconds after voiding ends.
16	When the <i>Patient Information</i> screen appears, enter information, as necessary, and click OK.
17	Straight catheterize patient to obtain post void residual measurement. Remove the catheter.
18	When the <i>Voiding Summary</i> screen appears enter the PVR value and click OK.



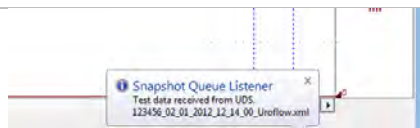


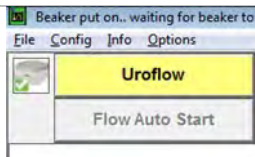

19	Wait for the data to be transferred to the <i>i-LIST™ Office Reporter</i> application.	
20	In the fields on the left side of the screen, enter information to include in the printed report.	
21	Click the printer icon to print the report.	
22	Empty the beaker. It can be thoroughly washed and reused.	

Table 15 – Performing a Uroflow Study using Automatic Flow Detection

7.2 MANUAL METHOD

STEP		
1	Gather the supplies needed for a Uroflow test. (Urocap™ IV , beaker, commode chair, funnel, and straight catheter).	
2	Plug the power cord into an electrical outlet.	
3	Place the funnel on the plastic frame of the commode chair.	
4	Carefully place the Urocap™ IV on the floor or on an approved Uroflow transducer stand.	
5	Gently place a graduated beaker on top of the Urocap™ IV .	
6	Place the commode chair and funnel over the Urocap™ IV and beaker. Make sure the beaker and the funnel are aligned but not touching.	
7	Turn on the computer and then turn on the printer.	
8	Invite the patient to get ready to take the test.	
9	Double-click the Urocap™ IV shortcut icon on the computer desktop.	 Urocap IV
10	Make sure the Urocap™ IV is connected.	
11	Click the Uroflow button on the control panel.	
12	Click Set Zeroes. Click Run to start the test.	
13	CAUTION! DO NOT TOUCH the beaker during voiding.	
14	Instruct the patient to void; provide privacy if possible.	
15	When voiding is complete click Stop.	
16	Straight catheterize patient to obtain post void residual measurement. Remove the catheter.	
17	Click Info and Voiding Summary. Enter the post-void residual volume in the PVR box.	

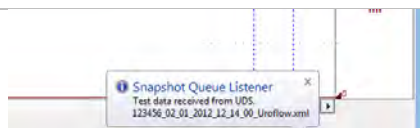
18	Click the Save button to name and save the test.	
19	Wait for the data to be transferred to the <i>i-LIST™ Office Reporter</i> application.	
20	In the fields on the left side of the screen, enter information to include in the printed report.	
21	Click the printer icon to print the report.	
22	Empty the beaker. It can be thoroughly washed and reused.	

Table 16 – Performing the Uroflow Study Utilizing Manual Start

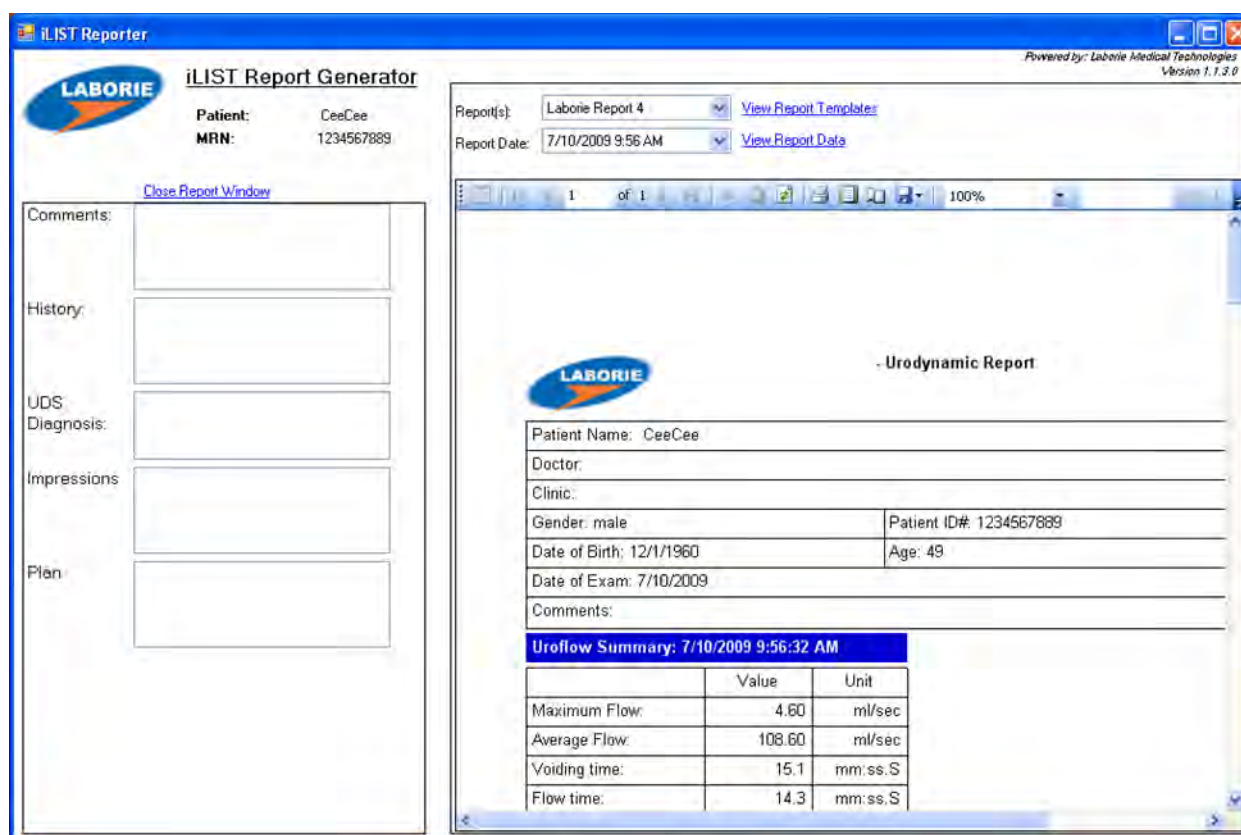
8 PRINT A TEST

Once a test is run and complete, click the **Print** button on the control panel (if auto start Reporter is not active) to open and print reports generated with the test data.

Select the items to include in the printout and click **OK** when ready.

8.1 PRINTING FROM ILIST OFFICE REPORTER

If printing reports from within the *i-LIST Office Reporter* software is preferred, add comments and select items to include in the report from the available templates.



iLIST Report Generator

Patient: CeeCee
MRN: 1234567889

Report(s): Laborie Report 4 [View Report Template](#)
Report Date: 7/10/2009 9:56 AM [View Report Data](#)

Urodynamic Report

Patient Name: CeeCee
Doctor:
Clinic:
Gender: male Patient ID#: 1234567889
Date of Birth: 12/1/1960 Age: 49
Date of Exam: 7/10/2009
Comments:

Uroflow Summary: 7/10/2009 9:56:32 AM

	Value	Unit
Maximum Flow:	4.60	ml/sec
Average Flow:	108.60	ml/sec
Voiding time:	15.1	mm:ss.S
Flow time:	14.3	mm:ss.S

Figure 18 – *iList Office Report* Main Window

The main window contains the same general layout for each type of report. *iLIST Office Reports* contain information gathered from the *Patient Info* screen as well as the saved test files from the **Urocap™ IV** software.

Report templates are associated with the type of 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.

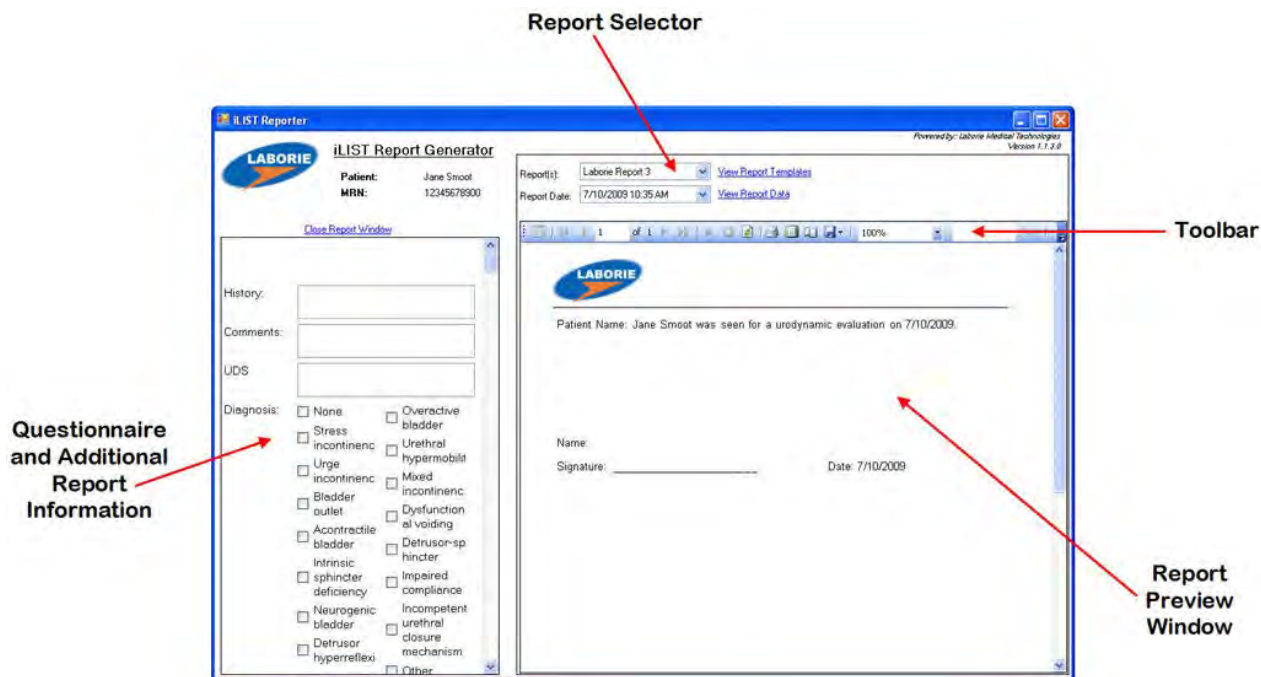


Figure 19 – iList Office Report Section Overview

- The **Questionnaire and Additional Report Information** section allows for the input of any answers or comments to the final report.
- The **Report Selector** is a listing of the types of reports you can select to view for the particular 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, arrows for going through pages of the report, etc...
- The **Report Preview Window** section contains test results for a particular patient's visit in the actual report format

To select a report template click the name in the *Report(s)* heading and click a selection from the listing.

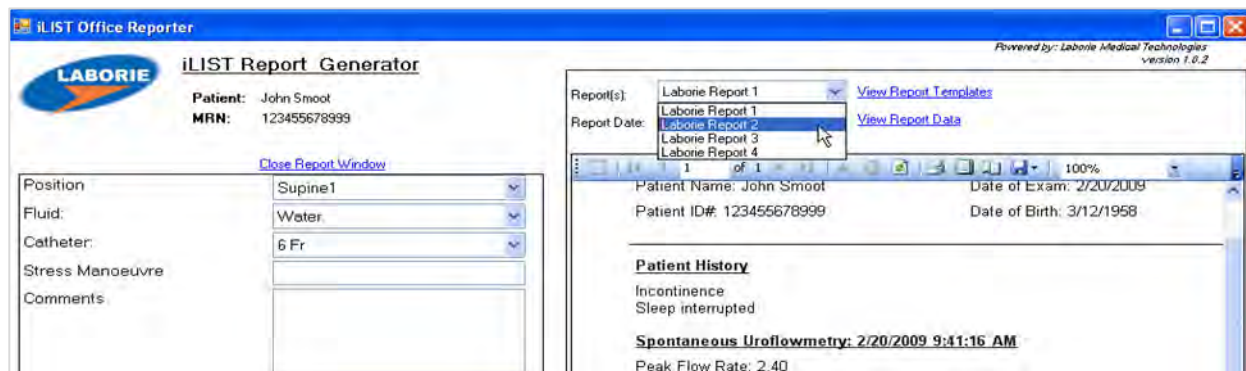



Figure 20 – Selecting Report Template

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

9 CALIBRATION


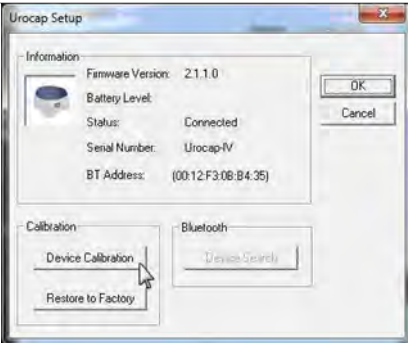
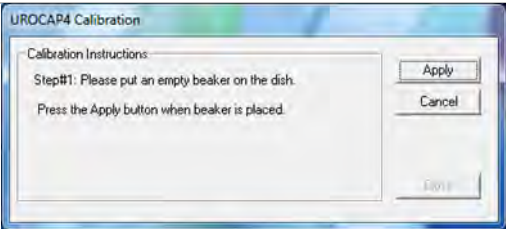
STEP		
1	Plug the Urocap™ IV into the charger and plug the charger into an outlet.	
2	Start the UDS120 Goby software and double-click the Urocap™ IV icon in the main window to open the Urocap™ IV Device Manager window.	
3	Click the Setup button in the Urocap section.	
4	In the Urocap Setup window click the Device Calibration button.	
5	Place an empty beaker on the Urocap™ IV and then click Apply .	
6	Follow the on-screen instructions to complete the calibration.	
7	Click Close when calibration complete.	

Figure 21 – Calibrating the Urocap™ IV with UDS120

10 QUICK REFERENCE AND FAQ

How do I check that the Urocap™ IV is connected?

You can check equipment connection one of two ways:

- The equipment's LED lights alert you of its status.
- Open the **Device Manager** and see if connections are enabled.

How do I know when I need to charge the Urocap™ IV?

The LED lights on the **Urocap™ IV**, as well as the Device Manager window, will alert you of the device's battery status. See Section 5.1 for a chart listing LED light status.

How do I charge the Urocap™ IV?

See Section 3.1 for more information about charging the devices.

Can I still use the Urocap™ IV while battery is charging?

Yes, the **Urocap™ IV** can still be used during charge time.

The battery power LED on the Urocap™ IV is starting to blink orange (indicating low power). Should I continue using it or should I charge it right away?

As soon as you see the blinking orange LED, plug in the device's charger to avoid losing system connections.

A message appears saying the Urocap™ IV is in "sleep mode". What do I need to do?

Click the **Run** button on the software control panel and wait for the connection to resume before use.

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

Open the **Urocap™ IV Device Manager** window, click the **Urocap™ IV** button icon and wait for the connection to be re-established. If a connection is not established, follow the instructions starting on page 10 to manually connect the **Urocap™ IV** to the software.

11 TROUBLESHOOTING

11.1 UROCAP™ IV

SYMPTOM(S)	POSSIBLE CAUSE(S)	CHECK/ CORRECTIVE ACTION(S)
No response from Uroflowmeter	No power on electrical outlet	Plug into a known working outlet
	Damaged power cord	Unplug and contact LABORIE for replacement cord
	Power cord not connected properly	Ensure power cord is secure at base of device and at the outlet.
	Devices not connected in software	Connect devices to the system.
	Bluetooth devices unpaired/paired or plugged/unplugged while running software	Reconnect the devices
Uroflowmeter disconnects while test is in progress	Battery power low or completely drained	<ol style="list-style-type: none">1. Tap STOP2. Plug in the disconnected device's battery charger and plug charger into an electrical outlet. Ensure connection is secure.3. Open the Urocap™ IV Device Manager.4. Click the device icon with the disconnected status, and wait for the Device Manager to connect to the device again. The status will change to Connected and it will also display it is in charging mode.5. Close the Device Manager window and click the Run button on the control panel to continue from the point where the test stopped.
Computer or printer does not power on	No power or power cord connected improperly	Ensure electrical outlet is working, power cords are not damaged and all cords are secure at both ends.

Uroflowmeter signal does not respond	Urocap™ IV improperly connected	Connect the Urocap™ IV to the software
Uroflowmeter signal shows vibration and/or spike patterns	Plastic beaker is touching funnel	Reposition the Uroflowmeter and check again.
	Patient has touched uroflowmeter with their feet	Ask patient to remain calm during procedure
	Floor is unsteady or uneven	Move to a more solid foundation
Incorrect flow or volume readings	Beaker not properly seated on dish	Adjust beaker position
	Funnel is touching the beaker	Adjust commode chair or Urocap™ IV
	Incorrect beaker is in use	Use beakers supplied by LABORIE only
Error message on screen reads: "Calibration Failure...(Flow out of range)"	Water was poured into beaker too quickly	Pour water slowly and at a steady rate
	More than 500 ml poured into beaker	500 ml must be poured into the beaker
Error message on screen reads: "Calibration Failure...(Volume delta out of range)"	Less than 500 ml of water poured into the beaker	500 ml must be poured into the beaker

Table 17 – Troubleshooting Urocap™ IV Usage

11.2 BLUETOOTH CONNECTION

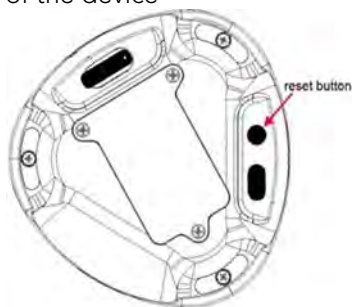
SYMPTOM(S)	POSSIBLE CAUSE(S)	CHECK/ CORRECTIVE ACTION(S)
Unable to connect via Bluetooth	Broken connection	Press the system reset button on the bottom of the device
		
		Ensure Bluetooth is on by clicking the device icon in the Urocap™ IV Device Manager
		Reduce the distance between the device and the computer (maximum distance is 10m/33') Remove physical barriers such as walls or people

Table 18 – Troubleshooting Bluetooth Connectivity

11.3 SOFTWARE ERROR MESSAGES


SYMPTOM(S)	POSSIBLE CAUSE(S)	CHECK/ CORRECTIVE ACTION(S)
Error message displays “Devices are not connected”	Urocap™ IV Device Manager not running	Click link in the error message to open the Urocap™ IV Device Manager. -or- 1. Click OK . 2. Close Urocap™ IV software. 3. Open the Urocap™ IV Device Manager software. 4. Open the Urocap™ IV software again.
	Configuration file not set	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	1. Click OK . 2. Click the Run or Wake up button on the control panel to resume connections.
Error message when software opens	Software opened too soon after computer was turned on	Close the Device Manager software. Wait several minutes and re-open the software to reconnect

Table 19 – Understanding Error Messages

11.4 PRINTER

SYMPTOM(S)	POSSIBLE CAUSE(S)	CHECK/ CORRECTIVE ACTION(S)
Printer LED not lit up	Power cable unplugged	Plug in printer power cable and try again
	Printer not turned on	Turn on printer by pressing power button
Printer error LED on or flashing	Printer paper out	Load printer paper
	Printer cover open	Close printer cover
	Printer out of ink	Replace printer cartridges
	Printer paper jam or misfeed	Correct paper problem and press paper feed button

Table 20 – Troubleshooting Printer Usage

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

Note: The Laborie Urocap IV has a medical grade power supply available for the laptop, but the desktop printer is not medically isolated and must not be used within the patient environment or directly connected to the laptop if the laptop is within the patient environment.

12 APPENDICES

APPENDIX A. SPECIFICATIONS AND SYSTEM INFORMATION

Upon request, LABORIE will make available any circuit diagrams, component part lists, and other technical documentation directly related to the Urocap™ IV.

Urocap™ IV (TRA851)	<p>Dimensions: 6.3"(16.0cm) L X 6.3"(16.0cm) W X 2.6"(6.6cm) H</p> <p>Weight: 0.7lbs (0.3kg)</p> <p>Flow Range: 0 to 50mL/s; Volume Range: 0 to 1500mL</p> <p>Output Channels: Flow; Volume</p> <p>Sampling Rate: Flow=20Hz; Volume=20Hz</p> <p>Charger: Connect to SL Power Electronics Corp. Model: MW172KB0540F02 or ME20A0540F02 PSU only.</p> <p>Power Supply: POW044 - 5V, 3A</p>
Transportation and Storage Conditions	<p>Temperature: -29°C to +60°C</p> <p>Humidity: 10% to 85% relative humidity</p> <p>Pressure: 500 hPa to 1060 hPa</p>
Operating Conditions	<p>Temperature: +10°C to +40°C (50°F to 104°F)</p> <p>Humidity: 30% to 75% relative humidity (non-condensing)</p> <p>Pressure: 700 hPa to 1060 hPa</p>

Table 21 – Equipment 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> <p>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).</p> <p>Protects equipment from the harmful effects of water splashing from any direction (signified by the rating code 4).</p> <p>NOTE: If applicable to your uroflowmeter model, the IP rating will be visible on the device label.</p>

Table 22 – Classification

APPLICABLE STANDARDS AND DIRECTIVES

Directive: MDD Directive 93/94/EEC

Standards:

- EN 60601-1
- EN 60601-1-2
- EN 60601-1-6
- UL 60601-1
- ANSI/AAMI ES 60601-1:2005/AS:2010
- EN 62366
- EN 62304
- EN ISO 14155
- EN ISO 15223-1
- EN ISO 14971
- CAN/CSA C22.2 No. 601.1 – M90
- CAN/CSA C22.2 No. 60601-1:08
- ISO 13485

Table 23 – Applicable Directives and Standards

Please refer to the EC Declaration of Conformity for latest product related standards.

APPENDIX B. SYMBOLS AND LABELING

SYMBOLS GLOSSARY



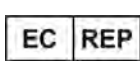













	LABORIE Logo		Consult Instructions For Use
	Authorized Representative in the European Community		CE Mark – European Compliance Symbol
	SGS Certification – certified to U.S and Canadian Safety Standards		Read Operator's Manual
	Serial Number		Manufacturer
	IP Rating		Date of Manufacture
	Do Not Immerse		Not for general waste. Dispose of in accordance to local regulations.
	Alternating Current		Direct Current
	Direction of pump flow		Radio Frequency (RF) Transmitting Device

Table 24 – Symbols Glossary

Labels are placed as follows:

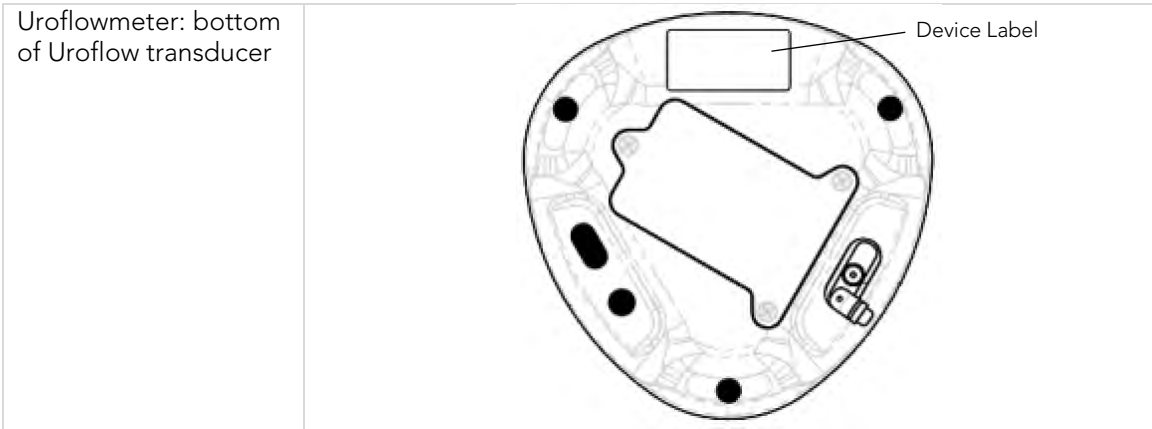
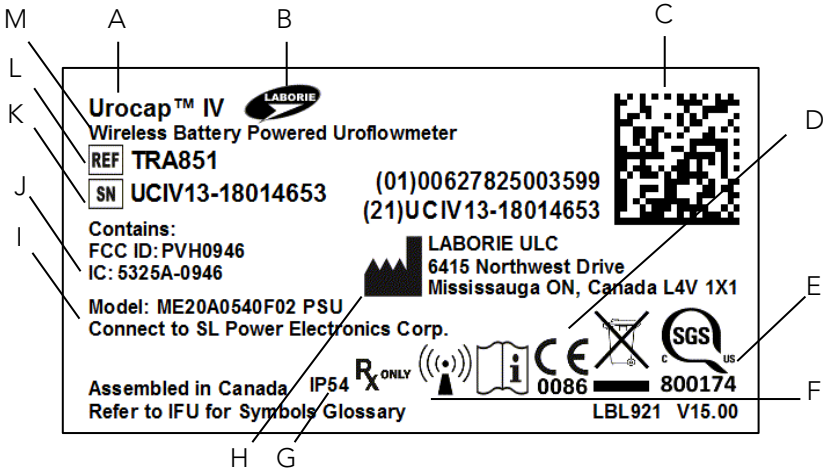


Table 25 – Label Placement

Each label may contain some or all of the following:



A	Device name	B	Company Logo
C	GS1 Barcode with GTIN (01) Global Trade Item Number (21) Serial Number	D	Notified body CE mark
E	Safety Certification Mark	F	EN ISO symbols group
G	IP Rating**	H	Manufacturer Information
I	Power Supply input	J	Radio Equipment codes
K	Device Serial Number*	L	Device Part Number
M	Device Description		

*XXX-X = product ID code and build number; YY = last 2 digits of year of manufacture; MM = month of manufacture; ZZZZ = label sequence.

**May be applicable; dependent on device build number

Table 26 – Label Reading Guide

APPENDIX C. ELECTROMAGNETIC COMPATABILITY (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 61000-4-6:2003+A1:2004+A2:2006	Testing and Measurement Techniques – Immunity to Conducted Disturbances, Induced by Radio-Frequency Fields.
IEC 61000-4-8: 2009	Testing and measurement techniques – Power frequency magnetic field immunity test
IEC 61000-4-11: 2004	Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests

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 the **Urocap™ IV**
 - Increase the separation between **Urocap™ IV** system and affected equipment
 - Connect the non-medical system equipment into an outlet on a circuit different from that to which the Urocap IV system is connected.
 - Consult the dealer or experienced technical personnel for help.



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.

APPENDIX D. TABLES OF GUIDANCE AND DECLARATION REGARDING ELECTROMAGNETIC IMMUNITY



- The use of accessories, transducers, and cables other than those specified by LABORIE may result in increased EMISSIONS or decreased IMMUNITY of the **Urocap IV®**
- The **Urocap IV®** needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this EMC section.
- The following connectors have applied the ESD testing exemption:
 - None
- Pins of connectors identified with the ESD warning symbol should not be touched and connections should not be made to these connectors unless ESD precautionary procedures are used.
- Ensure ESD precautionary measures such as proper grounding, use of antistatic straps, use of antistatic sprays or solutions for wiping, and antistatic floor mats and table mats are in place.
- It is strongly recommended that all staff involved receive an explanation of the ESD warning symbol and training in ESD precautionary procedures.
- The minimum contents of an ESD precautionary procedure training should include:
 - An introduction to the physics of electrostatic charge.
 - The voltage levels that can occur in normal practice and the damage that can be done to electronic components if they are touched by an operator who is electrostatically charged.
 - An explanation should be given of methods to prevent build-up of electrostatic charge and how and why to discharge one's body to earth or to the frame of the equipment or bond oneself by means of a wristband to the equipment or the earth prior to making a connection.
- Portable and mobile RF communications equipment can affect the **Urocap IV®**.
- This equipment/system is intended for use by health care 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 reorienting or relocating the equipment or shielding the location.
- The equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

IEC 60601-1-2: 2014 - TABLE 1 REQUIREMENTS

Urocap IV® is intended for use in the electromagnetic environment specified below. The customer or the user of the **Urocap IV®** should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 1	The Urocap IV® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Urocap IV® is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Warning: This equipment/system is intended for use by health care 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 device or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

Table 27 – Electromagnetic Environment Emissions Requirements, Compliance, and Guidance

IEC 60601-1-2:2014 – TABLE 2 REQUIREMENTS

The **Urocap IV** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Urocap IV** 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 UT = 120/230 Vac	0% UT (100 % dip in UT) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 70% UT (30% dip in UT) for 25 cycles 0% UT (100% dip in UT) for 5 seconds	<5% UT (>95 % dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.

		(>95% dip in UT) for 5 sec	
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 UT is the a.c. mains voltage prior to application of the test level.			

Table 28 – Electromagnetic Environment Immunity Requirements, Compliance, and Guidance

IEC 60601-1-2: 2014 – TABLE 4 REQUIREMENTS

The **Urocap IV®** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Urocap IV®** 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 Urocap IV including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17 \sqrt{p} \text{ 150kHz to 80Hz}$ $d = 1.17 \sqrt{p} \text{ 80 MHz to 800 MHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 2.3 \sqrt{p} \text{ 800 MHz to 2.7 GHz}$ <p>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</p> <p>Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol:</p> 

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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 29 -- Electromagnetic Environment Immunity Requirements, Compliance, and Guidance for RF Transmitting Devices

IEC 60601-1-2: 2014 – TABLE 6 REQUIREMENTS

Recommended separation distances between portable and mobile RF communications equipment and the **Urocap IV®**.

The **Urocap IV®** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Urocap IV®** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Urocap IV®** as recommended below, according to the maximum output power of the communications equipment.



WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Aquarius system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.17 \sqrt{p}$	80 MHz to 800 MHz $d = 1.17 \sqrt{p}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
<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 30 – Separation Distance Requirements

APPENDIX E. END USER LICENSE SOFTWARE AGREEMENT

Find licenses and terms for LABORIE products and services in the following locations:

End User License Agreement: <http://www.laborie.com/eula/>

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

APPENDIX F. PRINT OPTIONS FOR UDS120 GOBY SOFTWARE FOR UROCAP™ IV

Print Options

Preferences

- ☐ Uroflow Report
- ☐ PNTML Summary
- ☐ Tetra NIRS Summary Report
- ☒ UDS Report
- ☒ Graph Pages
- ☒ Report Pages

Standard Report

- ☒ Voiding Summary
- ☐ UPP Summary
- ☒ Event Summary
- ☒ Compliance
- ☐ STEPP
- ☐ Pediatric Nomogram

Print Border ☒

Number of copies: 1

Grids

- ☐ Fine
- ☒ Coarse
- ☐ None

Print Range

- ☒ Default
- ☐ UPP Sections
- ☐ Default and UPP

Graph Scaling

- ☒ 1-Page Graph
- ☐ Standard
- 1.00 min/page

1 graph page(s)

	Start	End	Graph Titles
<input checked="" type="checkbox"/> Segment 1	0	1:49	Uroflow
<input type="checkbox"/> Segment 2			
<input type="checkbox"/> Segment 3			
<input type="checkbox"/> Segment 4			
<input type="checkbox"/> Segment 5			
<input type="checkbox"/> Segment 6			
<input type="checkbox"/> Segment 7			
<input type="checkbox"/> Segment 8			

Preview Graph Segments

WARNING: Please wait for all print jobs to be completed before conducting any further tests.

OK **Cancel** **Print Setup..** **Apply** **Font ...**

Figure 22 – Print Options Window

DESCRIPTION	PRINT OUTPUT
Preferences: Uroflow Report	1 page voiding study report.
Preferences: UDS Report	Full UDS Report
Preferences: Graph Pages/Report Pages	Graph pages of UDS report with Report pages.
Standard Report	Prints all information pertaining to study.
Voiding Summary	Uroflow Summary information.
Event Summary	Event Summary information.
Compliance	Prints compliance calculations

DESCRIPTION	PRINT OUTPUT
Pediatric Nomogram <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	Prints test from beginning to end.
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	Click to display a sample of the graph printout. Drag the cursor over a section of the graph to include as a segment and then click Confirm to include in the printed report.
Font	Opens a window that allows you to set the font for each section of the report. Double-click the titles to set the font.

Table 31 – Print Preferences Options

APPENDIX G. NOMOGRAM TABLES FOR UROFLOWMETRY – MALE

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 32 – Nomogram Tables – Male

APPENDIX H. NOMOGRAM TABLE FOR UROFLOWMETRY – FEMALE

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	21.9	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 33 – Nomogram Tables - Female

APPENDIX I. GLOSSARY

TERMS USED IN URODYNAMIC TESTING

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

enuresis: involuntary loss of urine, usually subcategorized as nocturnal enuresis meaning involuntary loss of urine during sleep.

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

frequency: the complaint of voiding too often by day.

hesitancy: difficulty initiating voiding.

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 training follows.

lower urinary tract symptoms: (LUTS) these may include frequency, urgency, incontinence, nocturia, recurrent urinary tract infections, and many others.

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.

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.

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.

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.

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.

COMMON ACRONYMS

- ALPP: Abdominal leak point pressure
- BOOI: Bladder outlet obstruction indexⁱⁱⁱ
- BCI: Bladder contractility index
- BPH: Benign prostate hyperplasia
- 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

ⁱ Siroky MB, Olsson CA, and Krane RJ. The Flow Rate Nomogram: II.Clinical Correlation. J Urol 1980;123:208-10.

ⁱⁱ Haylen BT, Ashby D, Sutherst JR, Frazer MI and West CR. Maximum and Average Urine Flow Rates in Normal Male and Female Populations – the Liverpool Nomograms. British Journal of Urology. (1989). 64:30-38.

ⁱⁱⁱ A Cannon. AW Thomas, E Bartlett, J Ellis-Jones, L Chambers and P Abrams. BLADDER CONTRACTILITY AND VOIDING EFFICIENCY IN MEN WITH BLADDER OUTLET OBSTRUCTION TREATED CONSERVATIVELY AND BY TURP. Bristol Urological Institute, Bristol, United Kingdom. Informally discussed posters, ICS 2000 Tampere.