UROCAP™ IV LIGHT

Owner's Manual

LABORIE Headquarters
6415 Northwest Dr., Unit 10
Mississauga, Ontario, Canada L4V 1X1
Tel: 905.612.1170
Fax: 905.612.9731

LABORIE USA
400 Avenue D, Suite 10
Williston, Vermont, USA 05495
Tel: 1.800.522.6743
Fax: 1.802.878.1122

LABORIE Europe/International

EC REP

Medical Measurement Systems B.V.
Colosseum 25
7521 PV Enschede
The Netherlands
Tel.: +31.53.4803700
Fax: +31.53.4803701

www.laborie.com

Document Number: UCL-UM01-V10.00 / MAN1017
Version: 11.00
Release Date: April 14, 2020

Laborie Medical Technologies Canada ULC
6415 Northwest Drive, Unit 10
Mississauga ON L4V 1X1
CANADA

CE 2797

CONTENTS

LIST OF FIGURES

LIST OF TABLES

ABOUT THIS MANUAL

As you read through the manual, you will find information on how to configure features in the Urocap™ IV Light (UDS Light) software, as well as information on care and maintenance of the Urocap™ IV Light 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:

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

1 INTRODUCTION

LABORIE's Urocap™ IV Light System is focused on allowing patient privacy, while providing the nurse or doctor the ability to monitor the uroflow. The procedure is recorded on an Android device (also called a mobile device) and then printed through a wireless inkjet printer on a full-size page.

The high-level system overview is shown in Figure 1 – System Overview.

Figure 1 – System Overview

1.1 GENERAL DESCRIPTION

Urocap™ IV Light, with wireless technology, is a portable Uroflowmetry instrument that provides a non-invasive measurement of urinary flow rate and volume. The device consists of a wireless Uroflowmeter, a light-weight tablet, and various accessories that provide measurement-related information.

Urocap™ IV Light is a quick, accurate, reliable and easy-to-use Uroflowmetry instrument. Investigation begins automatically when the patient begins voiding and displays graphically on the Urocap™ IV Light (UDS Light) software application. When the patient stops voiding, the software intelligently detects voiding completion and prompts the user to print the study. It prints the data in graphical form and is followed by a calculated voiding summary.

1.2 INTENDED USE

The Urocap™ IV Light Uroflowmetry analyzer is intended to quantify the urine flow characteristics in 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 Light Wireless Battery Powered Uroflowmeter is intended for use in Uroflowmetry studies that measure both flow rate and voided volume of urine. The system is intended for use as medical diagnostic equipment by a qualified practitioner only.

1.3 INDICATIONS FOR USE

The major application of urodynamics (including uroflowmetry) is the diagnosis of uncontrolled loss of urine (incontinence), abnormal urinary retention, or neurological causes of micturition disorders.

1.4 CONTRAINDICATIONS

The Urocap™ IV Light is contraindicated in any patient who is not a candidate for uroflowmetry testing.

1.5 MAIN FEATURES

Some of the features include:

- Urocap™ IV Light (UDS Light) Software: The Urocap™ IV Light (UDS Light) Software combines touch technology and streamlined workflow to enhance procedure simplicity.
- Urocap IV Hardware: The Urocap IV Uroflowmeter is custom molded and water protected (IP54) to help improve hygiene and simplify cleaning. Indicator lights provide connection status and battery level to help guide the user.
- Wireless and Modular Design: The combination of battery power and Bluetooth® technology eliminate power plugs, allow easy portability and setup flexibility.
- Variable Mounting Options: The universal mobile device mount is designed to accommodate different clinical environments. Mounting options include a desktop, wall, or IV Pole.
- Reporting: Clear and concise reports generate seamlessly following a Uroflow study. Allows physician to quickly review flow particulars and helps to diagnose abnormalities in voiding patterns.
- Security: The universal mobile device mount provides security for your device from theft by locking it in place with screws. Optionally, a device lock can be used to provide added security.
- Optional Accessories: Enhance the system to make your workflow easier with a height-adjustable Uroflow stand, Commode Chair, and device lock.

1.6 PRECAUTIONS 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.

PRECAUTIONS

- LABORIE equipment and accessories are licensed by governments and approved by safety agencies to work with corresponding LABORIE accessories and equipment ONLY.
- LABORIE is not responsible for loss of patient files or test data.

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.
- Do not use if the 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 immerse the equipment or any components in water or any other liquids.
- Use ONLY input and output cables and cords provided by LABORIE.
- Do not attempt to open, modify, or repair the system components yourself or through an unauthorized party. ONLY LABORIE-trained technicians may service the system components.
- DO NOT LEAN on the system or its devices. The devices are not designed to support the weight of a person.
- DO NOT STERILIZE the Urocap™ IV Light system components.
- Do not alter or add to the Urocap™ IV Light medical electrical system. Any alteration to the Urocap™ IV Light system by an unauthorized party transfers responsibility for meeting ME system requirements from LABORIE to the altering party. Anyone connecting supplementary equipment to ME equipment configures a medical system and is therefore responsible for ensuring that the system complies with the requirements for medical electrical systems, encompassed in the IEC/EN 60601 series. Do not install or remove software from the tablet provided by LABORIE.
- Do not upgrade the tablet's Android operating system without authorization from LABORIE.
- To reduce the risk of serious patient injury, it is vital that physicians and clinicians performing urodynamic studies on patients with a Spinal Cord Injury be prepared to recognize and treat Autonomic Dysreflexia. Proper patient screening before urodynamic testing and continued monitoring for spikes in blood pressure and pulse during test procedures is also required. If a rise in blood pressure or other symptoms are detected, the bladder must be emptied immediately. Raise the patient's head if not already in a sitting position. Physicians must monitor patients with Autonomic Dysreflexia at least 2 hours after resolution of the episode.
- To reduce the risk of serious patient injury, it is vital that physicians and clinicians performing urodynamic studies be prepared to recognize and treat symptoms associated with vasovagal syncope (fainting) during urodynamic procedures.

- DO NOT USE the Urocap™ IV Light 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.
- To prevent potential shock hazard, the printer is wireless and should be placed in area away from the patient. Do not place the printer in the patient environment unless it is powered via a Laborie approved Line Isolation Transformer (Separating transformer).
- There is a risk of electrical shock if the operator plugs in Non-ME Equipment (i.e. printer or laptop) that is intended to be powered by a Line Isolation Transformer (Separating transformer) directly into the MAINS supply.
- Do not touch the printer or the tablet and the patient simultaneously.

IMPORTANT FOR GENERAL SYSTEM USE:

- To ensure proper system use and to prevent the receival of incorrect readings from the Urocap™ IV Light device, follow the equipment setup instructions in the Device Setup section on page 15 of this manual.
- Always wear protective gloves.
- It is important that the beaker is well centered on the Urocap™ IV Light, 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 the procedure.
- DO NOT TOUCH OR KICK the beaker during settling.
- To avoid disruption, ensure the Urocap™ IV Light is plugged in to a power outlet during test procedures.
- To avoid the risk of device connection interruption, reduce the distance between the uroflowmeter and the tablet. The maximum distance between the uroflowmeter and the tablet is 10 meters (33 feet).
- To further reduce the risk of software communication interruption, it is recommended to keep the devices plugged in during test procedures.
- To prevent misdiagnosis from an unqualified user, the software auto-detects for any unexpected range in calibration. In addition, LABORIE offers user training sessions and technical support.
- To prevent tripping, all parts and accessories, including cables and cords, related to the Urocap™ IV Light system should be kept appropriately tidy to ensure a safe environment.
- Make sure hands and fingers are away from pinch point. Pinch point may occur when operating the swivel function between the tablet and the mount.
- Calibration should be checked at least every six (6) months or when calibration inaccuracy is suspected. ONLY calibrate the Urocap™ IV Light if necessary.
- To prevent possible misuse or improper installation of equipment an Owner's Manual and Quick Reference Card are provided with each shipment. The software is designed to be intuitive and straight forward featuring built-in animation to help guide the user.

GENERAL SYSTEM NOTES

TO PREVENT EXTERNAL INJURY TO PATIENT OR USER:

- Follow mounting assembly instructions provided to prevent the device from falling off the wall mount.
- A semi permanent adhesive disc is provided with the mounting kit to secure the swivel mount to the tablet. Magnets are provided to secure the device on the swivel to the mounting bracket and three (3) locking screws are provided to secure the mounting bracket to tabletop, wall, or pole.
- The recommended mounting hardware is provided with each shipment.
- A 15-degree mounting tolerance is built into the wall mount design. The mounting configuration has been successfully tested to 4X maximum weight load.
- Hardware for cable management is provided to prevent a tripping hazard.
- To prevent the device mount stand from falling from the tabletop utilize mounting holes and hardware provided to secure the stand to the tabletop. Rubber feet are provided in the bracket design as an addition prevention against the device falling from the tabletop.

TO PREVENT IMPROPER CONNECTION OF POWER SUPPLY TO DEVICE:

- Connectors have a locking mechanism which provides tactile feedback to the user.
- The software does not allow for studies to be performed when the Urocap™ IV Light battery is below 40% charge and/or the tablet battery is below 15% charge.

TO PREVENT DAMAGE TO DEVICE OR SYSTEM:

- Custom packaging is designed to securely hold individual components during shipping.

TO FURTHER REDUCE THE RISK OF SOFTWARE COMMUNICATION INTERRUPTION:

- The UDS Light software confirms communication link to the Urocap™ IV Light firmware. If the communication link is interrupted the UDS Light software will initiate reconnection. If the reconnection attempt is unsuccessful, an error message displays in the UDS Light software notifying the operator.
- The software records all data in live mode so that data collected before loss of connection is saved.

TO PREVENT LOSS OF DATA:

- If a report fails to print, a reprint button is available to correct the problem and to reprint the previous study.
- When multiple tablets are connected to one printer, a reprint button is available to reprint the study.
- The printed report includes the date and time when the study was completed as well as the date and time when the report was printed. This can be used to correlate patient data with patient visit times.

TO PREVENT DATA BREACH:

- The device mount features an additional lock to secure the device from theft.
- The software only saves the test data and not any patient information.

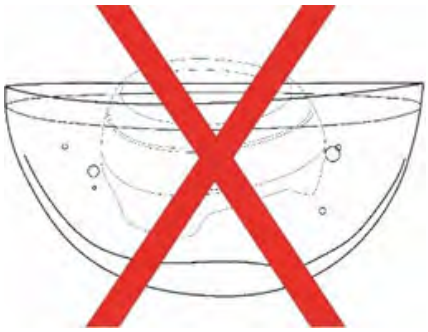
NOTE: local laws take priority over the above-mentioned requirements and warnings; if in doubt, consult your local LABORIE representative or the technical service department.

2 CLEANING AND MAINTENANCE

2.1 CLEANING THE UROCAP™ IV LIGHT

The Urocap™ IV Light will become dirty due to urine contamination and cleaning will be required. Always wear protective gloves when cleaning the equipment to prevent biological contamination.

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



- The Urocap™ IV Light Uroflowmeter has a rating of IP54 for ingress of water. This means that the enclosure of the device can 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 Light into liquids.
- The lid of the Urocap™ IV Light is not removable. Attention must be paid to prevent damage.
- The Urocap™ IV Light should be cleaned using a damp cloth with alcohol, soap, or disinfectant detergent.

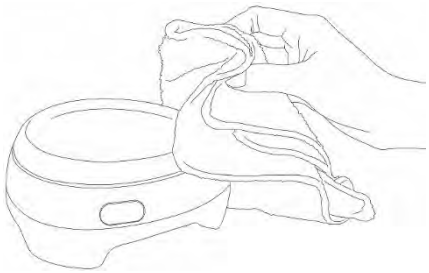


Figure 2 – Cleaning the Urocap™ IV Light

- 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.

- The chair, Flowstand and funnel can be wiped clean with a cloth dampened with soap or mild detergent and wiped dry.

When cleaning the funnel, the maximum cleaning temperature should not exceed 80˚C (176˚F)

2.2 MAINTAINING THE UROCAP™ IV LIGHT

- Performing regular maintenance will reduce the need for costly repairs. Check the transducer calibration of the Urocap™ IV Light 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 that battery is fully charged.
- Refer to manufacturer's instructions for cleaning and maintenance of the tablet.

3 BATTERY: CHARGING AND MAINTENANCE

3.1 CHARGING THE BATTERY

Lift the tab on the bottom of the Urocap™ IV Light to reveal the charging port (A).

Plug one end of the power supply cord into the charger port on the bottom of the device and the other end into an electrical outlet.

When the 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 BATTERY 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 a sudden change is noticed to the battery's ability to hold a charge or a sudden change in battery life, 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

As the Urocap™ IV Light 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 sewage systems with water treatment procedures. In this case, the most convenient way is to use these sewage systems.

4 DEVICE SETUP

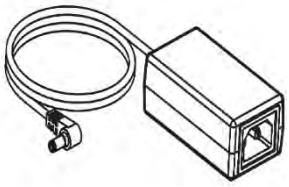
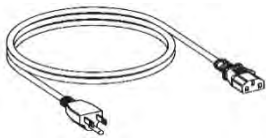
To get up and running as quickly as possible, the following sections will outline the recommended setup procedures.

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 tables for a list of standard and optional equipment.

4.1.1 STANDARD EQUIPMENT

EQUIPMENT	DESCRIPTION
 Urocap™ IV Light Uroflowmeter (UCL2000)	The Urocap™ IV Light 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.
 Urocap IV Power Supply (POW044)	The power supply and charger provide power to the uroflowmeter. For medical safety it is the only power supply to be used for this device.
 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.
 Tablet (COM805)	The Tablet is provided with a medical grade power supply, USB cable, and adaptor. The tablet connects to the Urocap™ IV Light and the printer to record Uroflow test procedures. It is provided pre-loaded with the Urocap™ IV Light (UDS Light) software (LAB2000).

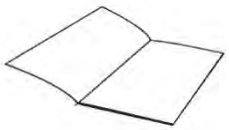
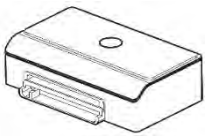
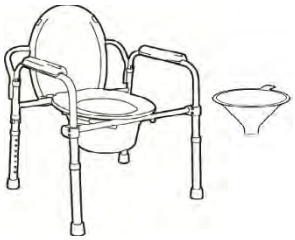
 Mobile Device Mount Kit (MSM1103)	The mobile device mount, swivel mount, provides stability when using the tablet in either a table-mounted or wall-mounted configuration. Please refer to the **Mobile Device Mount Setup** section on page **47** for setup instructions. Assembly guide MAN1011 is provided with the Mobile Device Mount Kit and outlines the procedure for attaching the mount to the tablet.
 Beaker (DIS900 x 5)	The plastic beaker included with the system is the only recommended beaker for use with the system.
 Urocap™ IV Light Setup Guide (MAN1013) and Quick Reference Card (MAN1019)	The setup guide and quick reference card provide brief overviews of system functions. The owner's manual provides complete instructions for use of devices, accessories, and software.

Table 1 – Standard Equipment

4.1.2 OPTIONAL EQUIPMENT

EQUIPMENT	DESCRIPTION
 Wireless Printer	The printer connects to the tablet via WIFI and provides a printout of test results. Please contact your LABORIE Customer Service representative for LABORIE recommended printers available per geographic location.
 Commode Chair (CHA181) and Funnel (CHA102)	The folding commode chair and funnel are both made of sturdy materials. The commode chair and funnel facilitate uroflowmetry studies in a seated position.

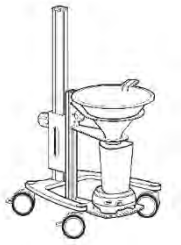
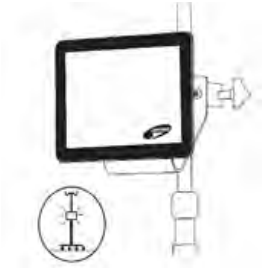
 Uroflow Stand (MSM1065 – wheeled) or MSM1075 (locked)	The uroflow stand provides added protection from artifact when used under a commode chair. It can be used for male voiding studies in a standing position.
 Mobile Device Lock (COM520)	The Mobile Device Lock is a combination lock for the mobile device to provide added security. It attaches to the tablet via the security slot and anchors to a desk, table, or fixed structure.
 C-Clamp IV Pole Clamp Kit (MSM1109)	The C-Clamp provides stability when the tablet is mounted on an IV pole. Refer to the **Mobile Device Mount Setup** section on page **47** for setup instructions. The Assembly guide MAN1012 is provided with the C-Clamp IV Pole Clamp Kit and outlines procedures for attaching the mount to the tablet.

Table 2 – Optional Equipment

4.2 SET UP EQUIPMENT

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

The recommended setup is illustrated in Figure 4 – Equipment and Room Setup.

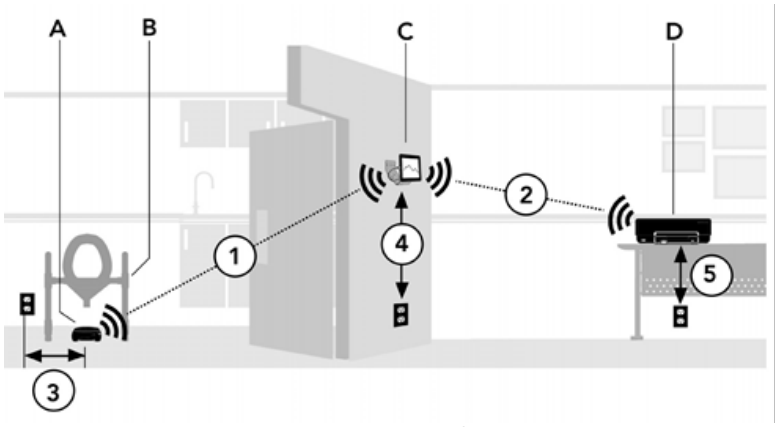


Figure 4 – Equipment and Room Setup

If applicable, set up the Urocap™ IV Light (A), the commode (B), the tablet (C) and the printer (D) as shown. Keep the distance between the Urocap™ IV Light and the tablet (1), and the distance between the tablet to the wireless printer (2) to less than 10 metres (33 feet).

The Urocap™ IV Light can still be used while it is plugged in and charging.

The maximum distance between the Urocap™ IV Light and an electrical outlet (3) is 5 metres (17 feet). The maximum distance between the tablet and an electrical outlet (4) is 3 metres (10 feet). The maximum distance between the wireless printer and an electrical outlet (5) is 2 metres (6 feet).

4.3 SET UP THE MOBILE DEVICE MOUNT

The mount can be secured to a wall, placed on a table, a cart, or fixed to an IV pole. The optional allen key and security lock provide an added level of security when using the mount. If not already assembled, refer to the assembly guides provided with the shipment or refer to Mobile **Device Mount Setup** section on page **47** of this Owner's Manual.

4.4 CONNECT THE TABLET AND THE PRINTER

The procedure for connecting the tablet and the printer only needs to be performed if the tablet and printer do not automatically connect when turned on for the first time.

4.4.1 TABLET SETUP

The tablet contains the Urocap™ IV Light (UDS Light) software, which is used with the Urocap™ IV Light system. This software runs as the default home application.

Unpack the tablet from the manufacturer's packaging and turn on the device. The Urocap™ IV Light (UDS Light) software will display.

1. To set language preference, follow the steps provided in the **Language** section on page **27**.
2. To connect the Urocap™ IV Light to the software follow the steps provided in the **Add Device** section on page **25**.

The Urocap™ IV Light serial number is printed on the label on the bottom of the device. The serial number will be required to connect the device to the software. Please refer to Error! Reference source not found. on page Error! Bookmark not defined. for the location of the serial number.

3. To calibrate the Urocap™ IV Light follow the steps provided in the **Calibration** section on page **30**.
4. If not already completed, attach the tablet to the device mount.

4.4.2 WIRELESS PRINTING VIA WI-FI DIRECT

Method 1:

1. From the printer home screen, tap the wireless direct icon and make a note of the Wi-Fi direct name and password.

Figure 5: Printer Controls

2. Tap the settings icon in the lower left corner
3. In the Wi-Fi Direct settings menu, tap the button on the right side to turn on Wi-Fi direct.
4. Tap the back icon to return to the Wi-Fi direct screen.
5. Press OK.
6. In the UDS Light software, tap the System Settings Icon.
7. Tap Printer Settings from the list.
8. In the Android Printer Settings window, select HP Print Service Plugin, then the OK button to turn on the HP Print Service Plugin. Ensure that ONLY the HP Print Service Plug-in is turned ON. Turn OFF any other services.
9. Tap the three dots in the top right corner and access Settings.
10. Scroll down to Wi-Fi Direct and tap the slider on the right to turn Wi-Fi Direct ON.
11. Go back to the UDS Light software home screen by tapping the Home button. The device is now ready to perform a study.

12. When a study is printed from the UDS Light software, the printer may be selected from the list in the top left corner of the HP Print Service Plugin.

Figure 6: Select Printer, Printing Via Wireless Direct

4.4.3 WIRELESS PRINTING VIA EXISTING WI-FI NETWORK

Method 2:

On the printer, go to Settings > Network Setup >Wireless Setup Wizard.

1. Select the wireless network you wish to connect to and authenticate.
2. Note the printer's IP address after a connection is established.
3. Connect the tablet to Wi-Fi.
4. When a study is printed from the UDS Light software, the printer may be selected from the list in the top left corner of the HP Print Service Plugin.

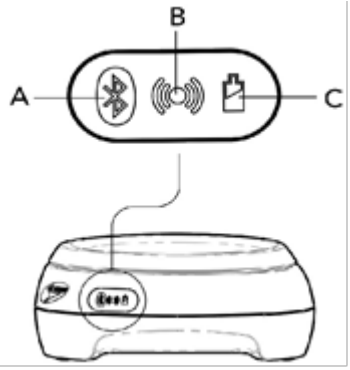
Figure 7: Selecting Printer, Printing Via Existing WI-FI Network

*LABORIE recommends the use of specific printers with the Urocap™ IV Light System based on compatibility testing. Please contact your LABORIE customer service representative for recommended printer specifications and availability per geographical location. It is possible to connect other printers; however, LABORIE does not warrant their functionality with this system.

5 HARDWARE

5.1 LED LIGHTS

The LED lights on the side of the Urocap™ IV Light display device status. Refer to Figure 14 for information on the meaning of the LED colors and behaviors.



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

Figure 8: LED Light Signals

5.2 DEVICE CONNECTOR AND SYSTEM RESET BUTTON

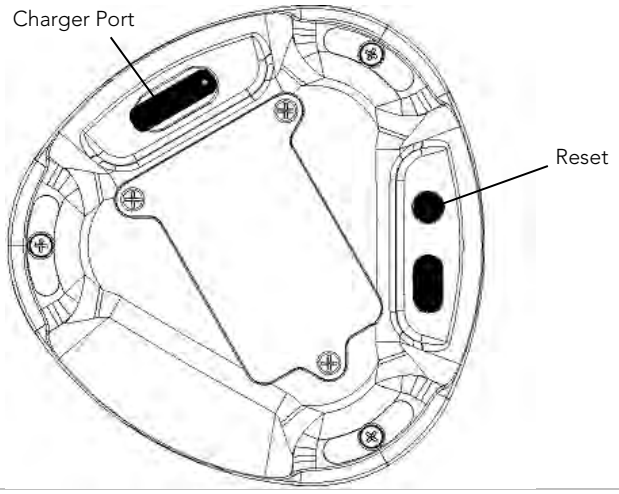


Figure 9 – Urocap™ IV Main Controls

Charger port: lift the tab to reveal the charging port. Insert the charger cable into this port.

Reset button: press to reset the system firmware. To be pressed only when equipment status light is orange and other methods of troubleshooting do not resolve connection issues.

6 SOFTWARE FEATURES AND FUNCTIONS

The Urocap™ IV Light system functions utilizing the Urocap™ IV Light device, a tablet provided with UDS Light software, and a printer for printing studies.

6.1 TABLET HOME SCREEN

Once the Tablet is powered-on, the UDS Light software will automatically launch to the home screen. The home screen provides access to all the features and functions for Uroflowmetry testing and for setting up configurations.

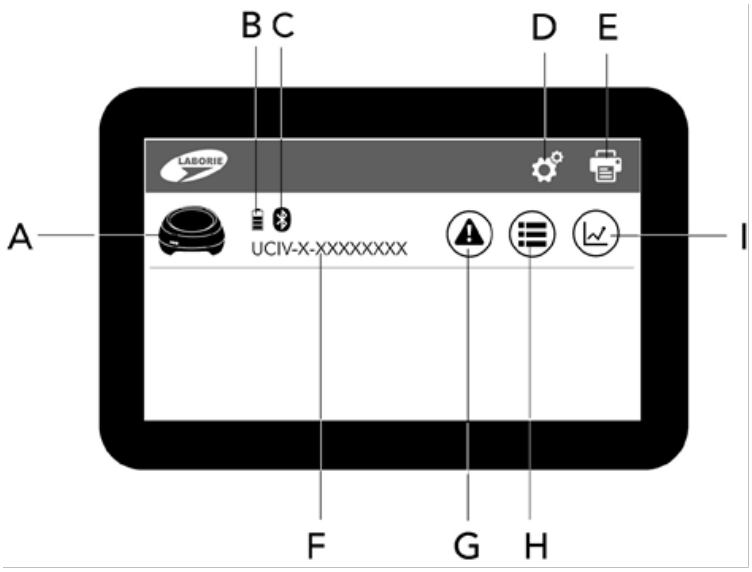


Figure 10 – Urocap™ IV Light (UDS Light) Home Screen Guide

Refer to the following table for a description of the icons found on the home screen:

ICON	FUNCTION	
A	Urocap™ IV Light Connection Status – Displays the connection status between the device and the software. Any status changes automatically appear here.	
		Connected and functioning.
		Hardware disconnect – tap icon to reconnect.
		Hardware sleep mode – conserves battery power. Tap icon to reconnect.
B	Battery Status – Displays the battery level of the Urocap™ IV Light.	
		Battery full – Battery level is 75-100%.
		Battery good – Battery level is 50-75%.

		Battery not fully charged – Battery level is 25-50%.
		Battery low, time to charge – Battery level 0-25%.
		Battery empty, recharge now – Battery level is 0%.
		Power plugged in, battery charging.
C	Bluetooth connection status. Only visible if connected.	
D	System settings - Tap open options screen to add/remove Urocap™ IV Light devices as well as to set time, date, and language.	
E	Reprint Last Test – Tap to print test results from last recorded test. The symbol will appear once a test is completed.	
F	Device Name – Displays the name of the Urocap™ IV Light device in use. The name can be the serial number or a custom name.	
G	User Notification – Provides feedback and only appears when a notification is available. Tap to read system message.	
H	Device Options – Tap to open options screen to start calibration or set device name.	
I	Study Space – Tap to start a test.	
	Home Button – Tap to return to main home screen.	

Table 3 – Home screen Icons

6.2 STUDY SPACE

To launch the study space screen, tap the 'Study Space' icon located on the home screen as shown in Figure 11.

Figure 11 – Opening Study Screen

Along with the scrolling graph visible on the main area of the screen, the beaker status, volume value and test progress are all visible along the right-hand side of the screen. Please refer to Figure 12 for a representation of the Study Space Screen.

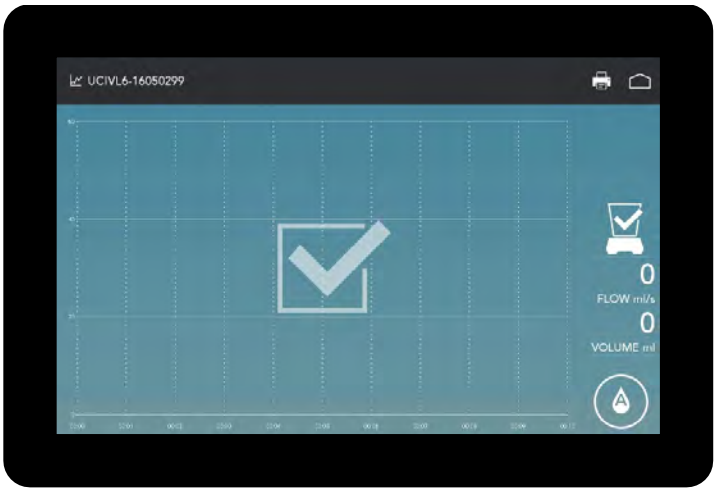


Figure 12: Study Space Screen Shot – Ready to Begin Study

The following table provides descriptions of the icons displayed during a test study.

ICON	FUNCTION
	Solid Color – Beaker off.
	Blinking – Beaker settling.
	Beaker Ready/ Zero.
	Study in progress/ Flow detected.
	Study complete, Volume ≥ 500 ml.
	Study complete, Volume < 500 ml.
	Test is ready to start.
	Autostart is ready to detect flow (Auto mode).

	Stop test – tap to manually stop the test recording.
	Tap to start a new study.

Table 4 – Study Screen Icons

6.3 SYSTEM SETTINGS

To launch the System Settings Screen, tap the 'System Settings' icon on the home screen. From this screen the user may add devices, remove connected devices, change the on-screen language, and set time and date through the system settings.

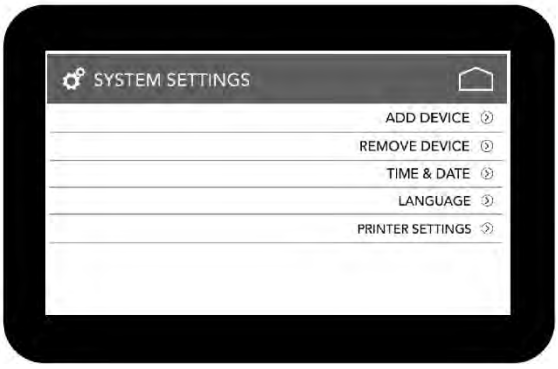


Figure 13 – System Settings Screen

6.3.1 ADD DEVICE

- Tap the 'Add Device' option under System Settings and wait for the Bluetooth search to locate the available Urocap™ IV Light devices

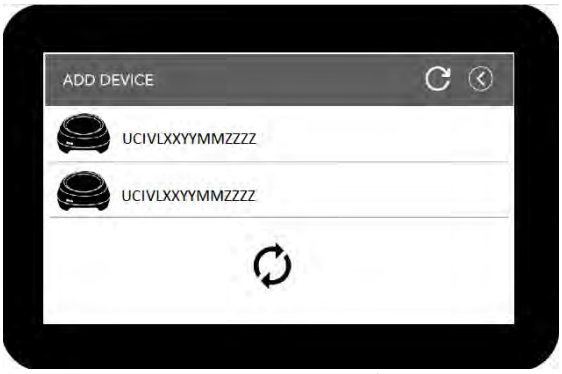


Figure 14 – Device Search Screen

- Tap the line with the correct Urocap™ IV Light Serial Number to add the device.
- Click 'Yes' in the resulting pop-up window asking to confirm the selection.
- Wait for the connection to be established.
- During the connection of the Urocap™ IV Light device, the Bluetooth pairing request pop-up window may appear. It is important to wait for the window to automatically close (it usually occurs within 10 seconds; he timing depends on the tablet's operating system) before continuing. Refer to Figure 15 – Bluetooth Pairing Window.

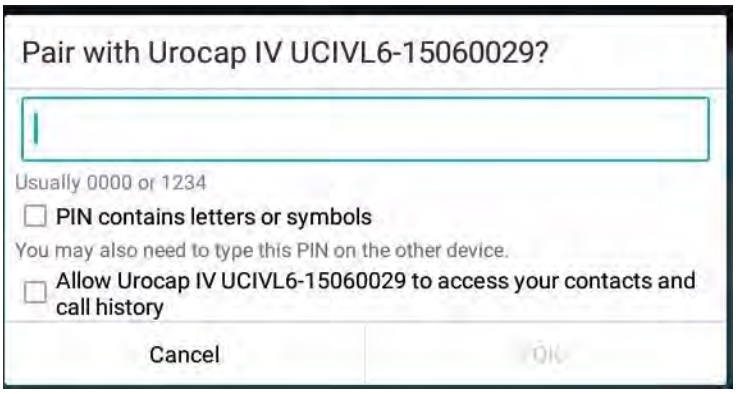


Figure 15 – Bluetooth Pairing Window

6.3.2 REMOVE DEVICE

- To remove a connected Urocap™ IV Light device, it must first be disconnected on the home screen. If the device is not already disconnected, tap the Urocap icon on the home screen to disconnect. The icon will shift status to disconnect as represented in Figure 16.

Figure 16 – Disconnected – Urocap Icon

- Tap the Remove Device option under System Settings.
- From the list of devices tap the minus symbol next to the name of the device to remove it from the UDS Light software and tap 'Yes' when asked to confirm removal.
- Wait for the system to take away the selected device from the list.

6.3.3 TIME & DATE

Tap the Time & Date option under the System Settings to set the preferred time and date format by tapping the available options on screen.

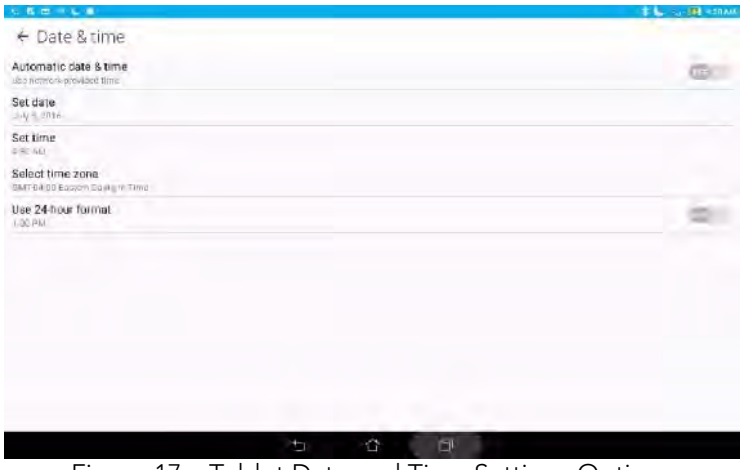


Figure 17 – Tablet Date and Time Settings Options

Any changes made here will only display in the tablet and not in the UDS Light software.

6.3.4 LANGUAGE

The UDS Light software supports: English, French, Polish, Italian, Spanish, Russian, Chinese (Simplified), Japanese, Portuguese, Dutch, German, Swedish, Croatian, Czech, Danish, Finnish, Icelandic, Latvian, Lithuanian, Norwegian, Romanian, Serbian, Slovak, and Slovenian.

To change the language, tap the language option under system settings and select the preferred language.

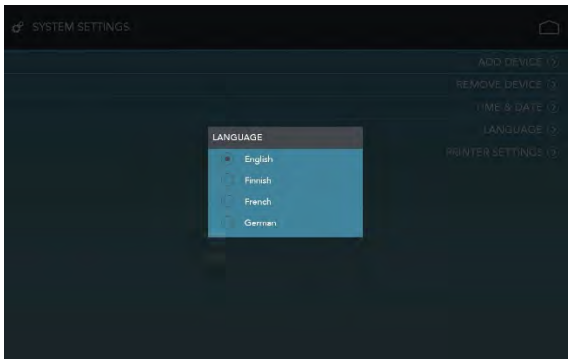


Figure 18 – Software Language Selection Screen

Chinese (Simplified)	中文 (简体字)
Croatian	Hrvatski
Czech	Ceština
Danish	Dansk
Dutch	Nederlands (Nederland)
English	English (Canada); English (United Kingdom); English (United States)
Finnish	Suomalainen
French	Français (Canada); Français (France)
German	Deutsch
Icelandic	Icelandic
Italian	Italiano
Japanese	日本語
Latvian	Latvijas
Lithuanian	Lietuvos
Norwegian	Norsk
Polish	Polski
Portuguese	Português
Romanian	Româna
Russian	Русский
Serbian	Српски
Slovak	Slovenský
Slovenian	Slovenski
Spanish	Español (España)
Swedish	Svenska

Table 5 – Software Language Options

6.4 DEVICE OPTIONS

Tap the device options icon on the home screen to access calibration and device name features. The screen also lists details of the device, including part number, serial number, and firmware build.

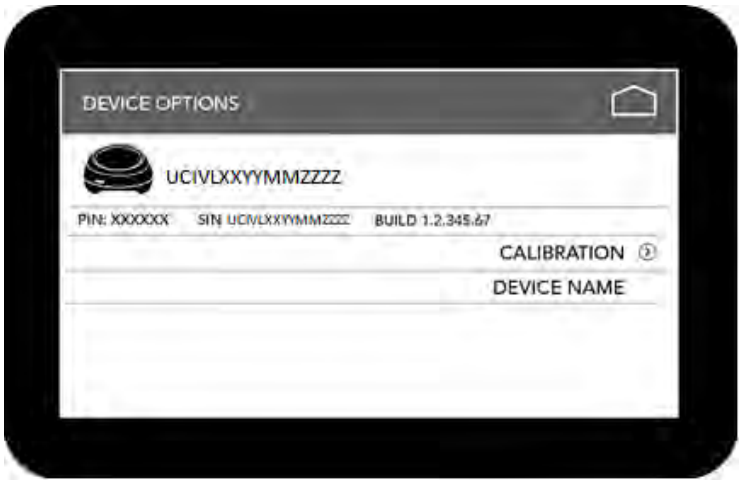


Figure 19 – Device Options Screen

6.4.1 DEVICE NAME

By default, the device serial number is set as the device name. The device can be renamed for easy identification by tapping the 'Device Name' option on the System Settings screen and then tapping the 'Device Name' option.

In the resulting field, type the new device name (Figure 20). A maximum of 15 characters can be used for a device name; some special characters are not accepted. Tap OK when complete.

Figure 20 – Renaming the Urocap™ IV Light Device

If the name field is left empty, the software will automatically add the device serial number to the empty field.

7 RUNNING A UROFLOW TEST

Run a uroflow test with the Urocap™ IV Light System to measure the rate at which urine flows out of the body.

Ensure the battery of the Urocap™ IV Light is at least 40% charged or plugged in before beginning the test.

The device allows for only one test to be recorded at a time.

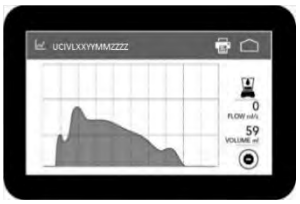
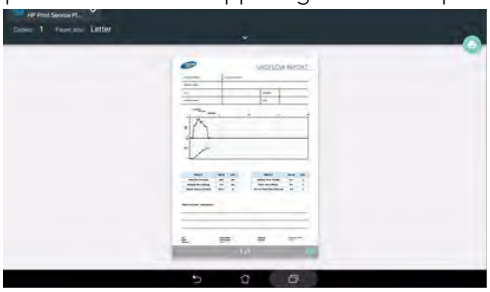
Step	Description
1	Gather the supplies needed for the uroflow test: Urocap™ IV Light, tablet, beaker, commode chair and funnel.
2	Place the funnel on the plastic frame of the commode chair.
3	Carefully place the Urocap™ IV Light on the floor or on an approved uroflow transducer stand.
4	Place the commode chair and funnel over the Urocap™ IV Light and beaker. Ensure the beaker and funnel are aligned but not touching.
5	Turn on the tablet and the printer.
6	Tap the study space icon located on the tablet home screen.
7	Gently place an empty graduated beaker on top of the Urocap™ IV Light and wait for the beaker to settle. Do not touch the beaker during settling or voiding
8	The beaker status icon will display a checkmark when the system is ready to start a test.
9	Instruct the patient to get ready for the test.
10	Instruct the patient to void; provide privacy if possible.
11	Observe as the graph starts scrolling once flow is detected. The graph will automatically stop 50 seconds after voiding ends. 
12	When the print window appears, tap the 'Print' icon in upper-right corner to print a copy of the tests results. 
13	Once the printout is complete, write in patient information and any additional notes as needed.
14	Empty the beaker. Test is complete.

Table 6 – Running a Uroflow Test

8 CALIBRATION

Calibration can be performed using a static weight or by pouring water into a beaker.

1. Plug the Urocap™ IV Light into the charger and plug the charger into an outlet (if the battery is not fully charged).
2. Tap the 'device options' icon on the home screen, and then tap the 'calibration' option as shown below.

Figure 21 – Calibrating the Urocap™ IV Light

3. Select the preferred calibration method by tapping either the weigh or water calibration option to start calibration.

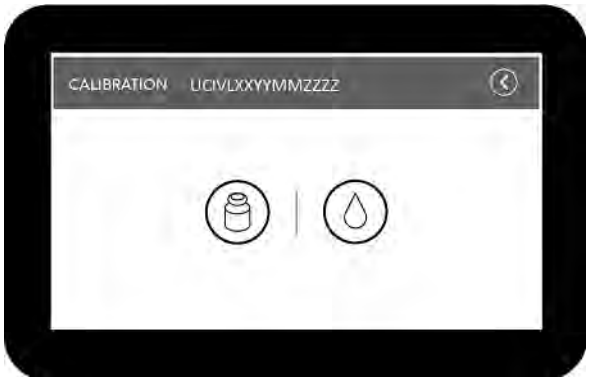


Figure 22 – Select Calibration Method

4. Follow the on-screen instructions to complete calibration. Once the calibration icon is selected, the process follows one of two paths: by weight or by water.

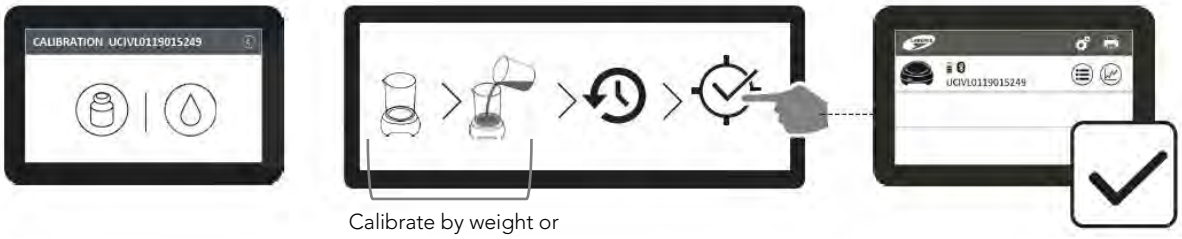


Figure 23 – Calibration Process

9 QUICK REFERENCE AND FAQ

How do I check that the Urocap is connected?

The equipment's LED lights will alert you of its status.

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

The LED lights on the Urocap™ IV Light as well as on the software's home screen will alert you of the battery status.

How do I charge the Urocap™ IV Light?

See Section 3 for more details.

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

Yes, the Urocap™ IV Light can be used while it is charging.

The battery LED on the Urocap™ IV Light is blinking orange. Should I continue using it or charge it right away?

As soon as you see the blinking orange LED indicating low power, plug in the device to avoid losing system connections.

The Urocap™ IV Light is switched to sleep mode. What do I need to do?

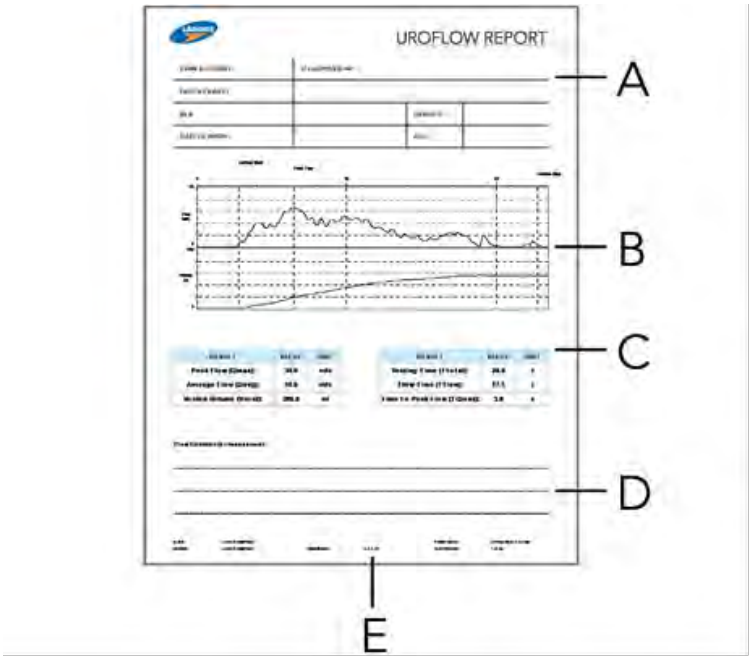
a. *Plug in the charger (if necessary) and tap the 'sleep mode' icon.* 

b. *Tap the icon again and wait 60 seconds for reconnection to occur.*

The Urocap™ IV Light is switched to disconnect mode. What do I need to do?

a. *Plug in the charger (if necessary) and tap the 'disconnected mode' icon.* 
b. *Tap the icon again and wait 60 seconds for reconnection to occur.*

How do I read a printout of a study?



A Patient information section. Write in any patient information as necessary.

B Graph Section including:

- Study printout if up to 15 minutes
- Indicators to highlight Qmax, Uroflow Start, Uroflow Stop A Qura flow rate graph and volume voided graph
- A y-axis scale where flow scale = 50 ml/s and volume voided scale = ml*
- Automatically calculated x-axis max scale to ensure the entire study is stretched across paper width if study duration is greater than 2 minutes.

C Results listed in table format:

- Peak Flow (Qmax): the maximum measured value of the flow rate in ml/s.
- Average Flow (Qavg): voided volume divided by total flow time.
- Voided Volume (Vvoid): total volume voided during the micturition process.
- Voiding Time (Ttotal): total time from start of flow to end of flow.
- Flow Time (Tflow): total time where flow was greater than zero.
- Time to Peak Flow (TQmax): elapsed time from onset of flow to maximum flow.

D Notes section

E Timestamp of printout

*Scale:

- 0-500 ml if voided volume ≤ 500 ml;
- 0-1000 ml if voided volume falls between 500 ml and 1000 ml;
- 0-1500 ml if voided volume > 1000 ml.

Can I use my own printer?

LABORIE has tested and recommends using only the supplied printer. Any other printers can be used at the owner's risk.

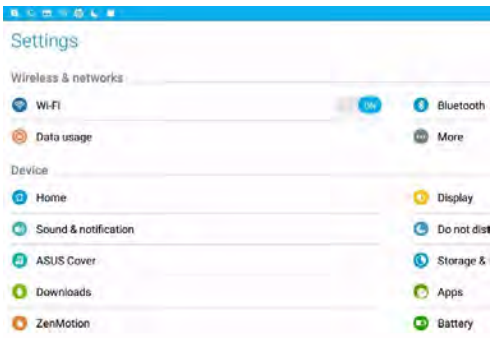
Can I use my own tablet?

No. The Urocap™ IV Light application is available only from LABORIE and will arrive pre-installed on tablet supplied by LABORIE only.

10 TROUBLESHOOTING

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

10.1 TABLET

SYMPTOM(S)	POSSIBLE CAUSE(S)	CHECK / CORRECTIVE ACTION(S)
Tablet does not connect to printer.	Is the WIFI on the tablet connected to another network?	Ensure the tablet is only connected to the Printer WIFI direct.
Tablet cannot power on.	Is the Power button not pressed?	Press and hold the power button for 10 seconds and release. At times, it may requires pressing and holding for up to 30 seconds.
	Is the Device out of power? Is the battery drained?	Plug in the device and allow it to charge.
Tablet does not show the study screen button.	The Urocap™ IV Light has not properly paired with the tablet?	Remove the Urocap™ IV Light device, then add the device again (as outlined on page 25).
	Is the Urocap™ IV Light charged or plugged in?	The Software will not open the study screen if the Urocap™ IV Light battery is below 40% and not plugged in.
Tablet is in the camera mode/screen. 	Camera icon tapped/ selected?	The tablet camera can sometimes be engaged by swiping down from the top of the screen and selecting the camera icon. To exit camera mode, select the Home button on the device.
Urocap™ IV Light (UDS Light) software does not automatically appear when the device is turned on?	Is home application setting correct?	1. Select the App Drawer icon on the Home screen.  2. Scroll through the apps and select the Settings icon.  3. Select the Home menu item.  4. Select Urocap™ IV Light (UDS Light) application

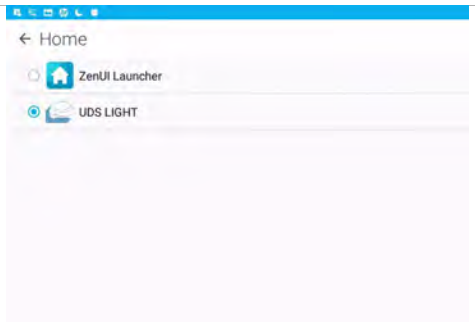
		 5. Click the Home button on the tablet to set the Urocap™ IV Light (UDS Light) application as the Home application.

Table 7 – Troubleshooting Tablet Usage

10.2 BLUETOOTH CONNECTIONS

SYMPTOM(S)	POSSIBLE CAUSES	CHECK/CORRECTIVE ACTION(S)
Unable to connect via Bluetooth.	Connection is broken.	Press the system reset button on the bottom of the Urocap™ IV Light device.
		Reduce the distance between the Urocap™ IV Light and the tablet. The maximum distance between the Urocap™ IV Light and the tablet is up to 10 metres (33 feet).
		Ensure there is an unobstructed line of sight between the Urocap™ IV Light and the tablet.
		Ensure the Bluetooth connection is turned ON in the tablet system settings.

Table 8 – Troubleshooting Bluetooth Connectivity

10.3 PRINTER

SYMPTOM(S)	POSSIBLE CAUSES	CHECK/CORRECTIVE ACTION(S)
Printer power LED is not lit up.	Printer power cable is unplugged.	Plug in cable and try again.
	Printer is not connected.	Turn on printer by pressing power button
Printing does not work.	The tablet is not connected to the WIFI direct connection.	Ensure HP wireless direct is turned on and, if necessary, security is enabled. Up to five computers and tablets can use the same HP wireless direct connection. HP wireless direct can be used while the printer is also connected to a computer using USB cable or to a network using a wireless connection.
	Accidentally tapped outside printing window.	Tap the reprint last test icon.
Printer error LED on or flashing.	Printer paper out.	Load printer paper
	Printer cover open.	Close cover of printer
	Printer out of ink.	Replace printer cartridges
	Paper mis-feed or jam.	Correct paper problem, press paper feed button.
Error message displays 'Incorrect printer cartridge' or 'Printer cartridge problem'.	Printer cartridge requires a check.	Resolve by reseating, cleaning or replacing the cartridges.

Table 9 – Troubleshooting Printer Usage

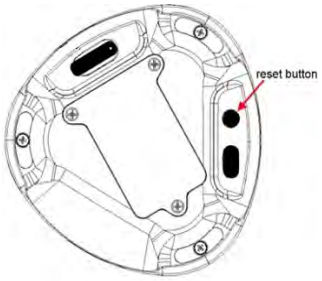
Note: The Laborie Urocap™ IV Light has a medical grade power supply available for the laptop, but the desktop printer is not medically isolated and must not be used within the patient environment or directly connected to the laptop if the laptop is within the patient environment.

10.4 UROCAP™ IV

SYMPTOM(S)	POSSIBLE CAUSES	CHECK/CORRECTIVE ACTION(S)
No response from uroflowmeter.	No power from electrical outlet.	Plug into a known working electrical outlet.
	Damaged power cord.	Unplug and contact LABORIE for replacement power cord.
	Power cord not connected properly.	Ensure power cord is secure ant the base of the uroflowmeter and at the electrical outlet.
	Devices not connected in the software.	Connect/add the device to the system.
Uroflowmeter disconnected while test in progress.	Battery power is low or completely drained.	1. Tap STOP. 2. Plug in the disconnected device's battery charger and plug charger into an electrical outlet. Ensure connection is secure. 3. Tap device icon with the disconnected status and wait for the reconnection of the device.
Uroflowmeter signal shows vibration and/or spike patterns.	Plastic beaker is touching the flow funnel.	Reposition the Uroflowmeter and check again.
	Patient had touched the uroflowmeter with their feet.	Ask patient to remain calm during procedure.
	Floor is uneven, or surface is unsteady.	Move to a more solid foundation.
Incorrect flow or volume readings	Beaker not seated properly on uroflowmeter disc.	Adjust beaker position.
	Funnel is touching beaker.	Adjust commode chair or Urocap™ IV Light.
	Incorrect beaker in use.	Use beakers supplied by LABORIE ONLY.
	Uroflowmeter requires calibration.	Calibrate the Urocap™ IV Light and restart test.

Table 10 -- Troubleshooting Urocap™ IV Usage

10.5 USER NOTIFICATION MESSAGES

SYMPTOM(S)	POSSIBLE CAUSES	CHECK/CORRECTIVE ACTION(S)
A message appears on-screen saying there is a communication error.	Interference between the Urocap™ IV Light and the tablet.	1. Press the reset button on the bottom of the device 
	Urocap™ IV Light and/or tablet are out of range.	2. Plug in the Urocap charger (if necessary) and tap the Urocap icon on the software screen. The icon will change to disconnect mode.

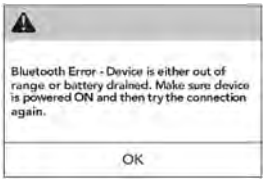
	Reset button pressed unintentionally.	 3. Tap the icon again and wait 60 seconds for reconnection to occur
Bluetooth error 	Interference between Urocap™ IV Light and tablet. Urocap™ IV Light and/or tablet out of range.	1. Ensure that the Urocap™ IV Light is within working range of the mobile device. 2. Tap the Urocap icon. The icon will change to disconnected mode.  3. Tap the icon again. Wait 60 seconds for reconnection to occur.
Low battery shutdown	Insufficient battery power.	1. Plug in the Urocap™ IV Light charger and tap the Urocap icon in the software. Icon will change to disconnected mode. 2. Tap icon again. Wait 60 seconds for reconnection to occur.

Table 11 – Understanding Notifications

11 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 Light System.

Transportation and Storage Conditions	Temperature: -29°C to +60°C Humidity: uncontrolled to 85% relative humidity
Operating Conditions	The system and associated devices are intended for indoor use only under the following standard operating conditions: Temperature: +10°C to +40°C Humidity: 35% to 75% relative humidity Pressure: 700 hPa to 1060 hPa (up to 2000m)
Urocap™ IV Light (UCL2000)	Size: 16.0 cm (6.3") L X 16.0 cm (6.3") W X 6.6 cm (2.6") H Weight: 0.3 kg (0.7 lbs) Flow Range: 0 to 50 mL/s; Volume Range: 0 to 1500 mL Output Channels: Flow; Volume Sampling Rate: Flow = 20 Hz; Volume = 20 Hz Charger: Connect to SL Power Electronics Corp. Model: MW172KB0540F02 or ME20A0540F02 PSU only. Power Supply: POW044 - 5V, 3A Urocap™ IV Light External Materials: ABS PA-765 Battery Enclosure Materials: Lexan BPL1000 Polycarbonate
Android Tablet (COM805)	Size: 251.6 mm (9.9")H X 172 mm (6.77")W X 7.9 mm (0.31")D Weight: 490 g (17.28 oz.) Connectivity: Micro USB, 3.5mm headset jack; Bluetooth, WIFI Charger: Connect to GlobTek, Inc. Power Supply Model # WR9QA1200USBNMEDRVB only.
Battery Mode	Urocap™ IV Light Recharge time – Five hours to fully recharge when not in use Continuous run – at least 14 hours with fully charged battery Tablet Recharge time – Six hours to fully recharge when not in use Standby mode – minimum 24 hours with fully charged battery Continuous run – Minimum of 3 hours with fully charged battery
Mobile Device Mount	Metal Bracket Size: 96.1 mm (3.78") H X 102 mm (4.00") W X 133 mm (5.22") Depth Weight: 500 g (17.6 oz.) Rotating Device Mount Size: 65.1 mm (3.78") H X 102 mm (4.00") W X 65.1 mm (5.22") Depth Weight: 50.0 g (1.80 oz.)
Folding Commode Chair (CHA181)	560 mm (22.25") W X 470 mm (18.50") Depth X 620 mm (24.0") to 87.0cm (34.0") H Weight: 5.9 kg (13 lbs.); Weight limit: 160 kg (350 lbs.)

Funnel (CHA102)	Size: 28.6 cm (11.25”) L; Diameter To Rim: 29 cm (11.4”)
Flow Stand	Wheeled Stand (MSM1065) Size: 395 mm (15.6”) L X 520 mm (20.5”) W Height with funnel: 440 - 795 mm (17.3 - 31.3”) Fixed Stand (MSM1075) Size: 395 mm (15.6”) L X 520 mm (20.5”) W Height with funnel: 420 - 775 mm (16.5 - 30.5”)
Printer	Please contact your LABORIE Customer Service representative for printer specifications available per geographic location.
Mobile Device Lock (COM520)	Cable length: 1.80 m (5.9’)

Table 12 – Equipment Specifications

CLASSIFICATION

IEC 60601-1:	The system is connected to the mains via an external power supply unit (PSU) and is classified as Class 1, portable equipment with no patient applied parts and intended for continuous operation. Alternately the system can be powered via its internal battery pack and classified as internally powered equipment.
Classification of Installation and Use:	Portable; Class I (via PSU); Internally Powered Equipment (Battery Mode).
Degree of Protection:	The Urocap™ IV Light 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 (International Protection) rating, it means that the Urocap™ IV Light uroflowmeter enclosure: • Protects users using tools 1.0 mm or larger from accessing hazardous parts and protects equipment from ingress of dust (signified by the rating code 5). • Protects equipment from the harmful effects of water splashing from any direction (signified by the rating code 4). NOTE: If applicable to your uroflowmeter model, the IP rating will be visible on the device label.

Table 13 – Classification

DIRECTIVES AND STANDARDS

Directive: MDD Directive 93/42/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 1041
- EN ISO 14971
- CAN/CSA C22.2 No. 601.1 – M90
- CAN/CSA C22.2 No. 60601-1:08
- ISO 13485

Table 14 – Applicable Directives and Standards

APPENDIX B. SYMBOLS AND LABELING

LABORIE Logo	SGS 800174 SGS Certification – certified to U.S and Canadian Safety Standards	CE Mark – European Compliance Symbol	Not for general waste. This product is designated for separate collection at an appropriate collection facility in accordance with WEE Directive. Dispose of in accordance to local regulations.
Manufacturer (5.1.1)[1]: Indicates the device manufacturer.	Date of Manufacture (5.1.3)[1]: Indicates the date of device manufacture.	Consult Instructions for Use (5.4.3)[1]: Manufacturer recommends consultation of instructions for use.	EC REP Authorized Representative in the European Community (5.1.2)[1]: Indicates the manufacturer's device representative in the European Community.
REF Catalogue Number (5.1.6)[1]: Indicates the device model or catalogue number.	SN Serial Number (5.1.7)[1]: Indicates unique device serial number for device traceability.	Non-ionizing electromagnetic Radiation (5140)[2]: Radio Frequency (RF) Transmitting Device Indicates presence of RF transmitters.	(01) 1 0627825 00595 8 (11) 200228 (21) UCIVLBBYYMMZZZZ GS1 DataMatrix for Unique Device Identification: (01) Global Trade Item Number (11) Date of Manufacture (21) Serial Number
Importer (3725)[3]: Indicates the entity that imports the medical device.	1. EN ISO 15223-1 Medical Devices – Symbols to be used with medical device, labels, labelling and information to be supplied – Part 1: General Requirements. 2. IEC 60417 – Graphic Symbols for Use on Equipment. 3. ISO 7000:2014 – Graphic Symbols for Use on Equipment – Registered Symbols.		

Table 15 – Symbols Glossary

PRODUCT LABELS

Labels are located as follows:

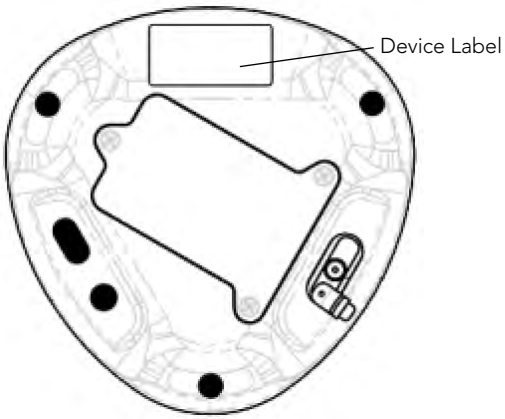
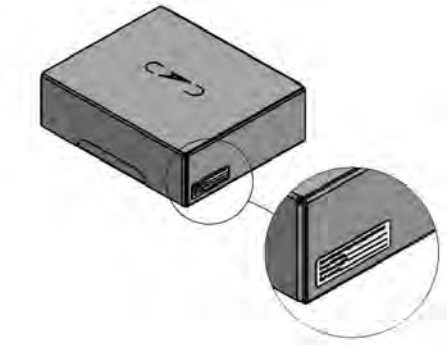
System Device Label: located on the underside of part number UCL2000	
Kit: located on the side of the product package carton	
Tablet: on back cover of device	 Tablet

Table 16 -Label Placement

APPENDIX C. ELECTROMAGNETIC COMPATABILITY (EMC)

Standards to which conformity is declared:

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 Light
    - Increase the separation between Urocap™ IV Light system and affected equipment
    - Connect the non-medical system equipment into an outlet on a circuit different from that to which the Urocap™ IV Light system is connected.
    - Consult the dealer or experiences 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 Light.
- The Urocap™ IV Light 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 Light.
- 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 Light is intended for use in the electromagnetic environment specified below. The customer or the user of the Urocap™ IV Light 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 Light 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 Light 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 17– Electromagnetic Environment Emissions Requirements, Compliance, and Guidance

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

The Urocap™ IV Light is intended for use in the electromagnetic environment specified below. The customer or the user of the Urocap™ IV Light 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 (>95% dip in UT) for 5 sec	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.
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 18 -- Electromagnetic Environment Immunity Requirements, Compliance, and Guidance

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

The Urocap™ IV Light is intended for use in the electromagnetic environment specified below. The customer or the user of the Urocap™ IV Light 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 Light including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{p}$ 150kHz to 80Hz $d = 1.17\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2.7 GHz Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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 19 -- 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 Light.

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

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

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 20 – Separation Distance Requirements

APPENDIX E. END USER SOFTWARE LICENSE AGREEMENT

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

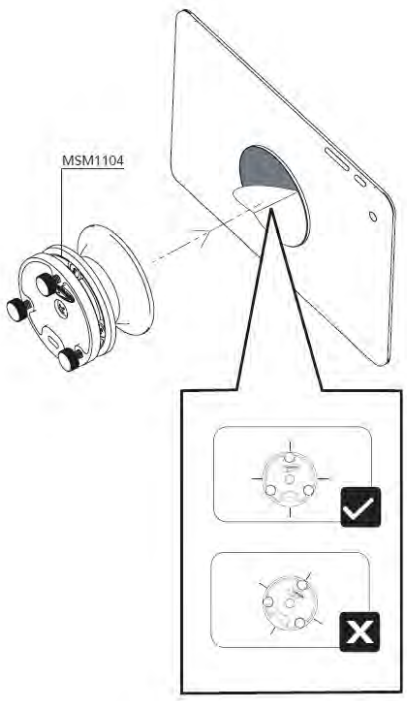
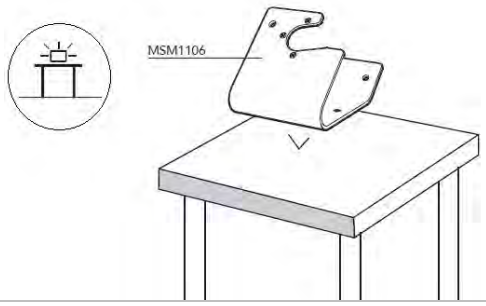
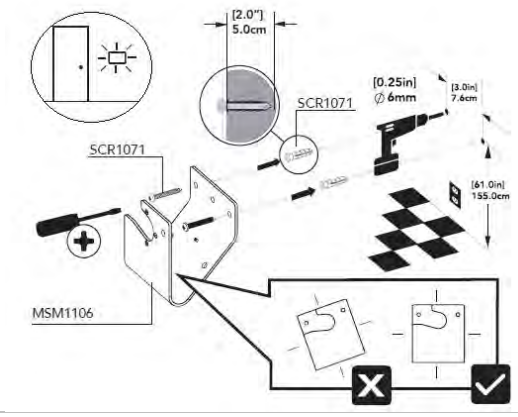
End User License Agreement: http://www.laborie.com/eula/

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

APPENDIX F. MOBILE DEVICE MOUNT SETUP

Follow the steps provided below to setup the tablet with the mobile device mount.

Tabletop or Wall-Mounted Configurations:

1. 	Adhere the adhesive disk to the tablet. Remove the adhesive backing paper from the exposed side and attach the plate of the swivel mount. Ensure the knobs on the swivel mount are properly positioned before adhering.
2. 	OPTION A: Place the mount stand on top of a table or counter and fasten with the supplied screws.
	OPTION B: Fasten the mount stand to a wall with the supplied screws. Position screws at least 155 cm (61") from the floor and keep them 7 cm (3") apart. Ensure stand is properly aligned.

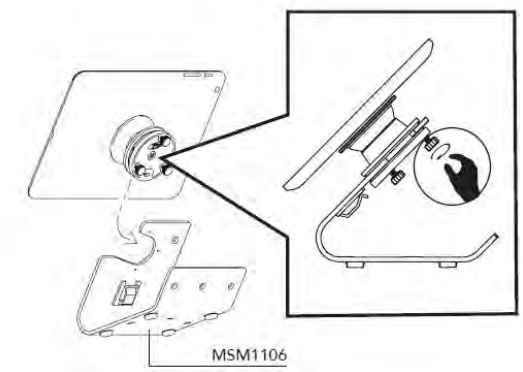
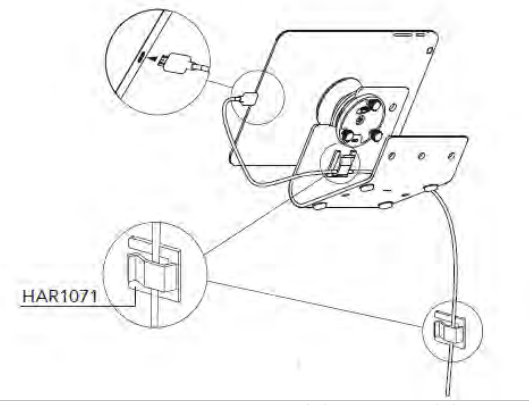
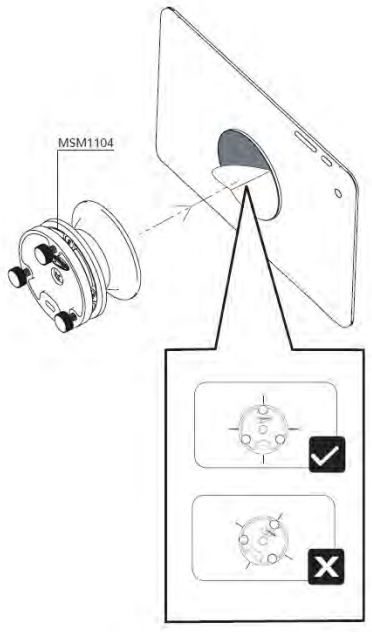
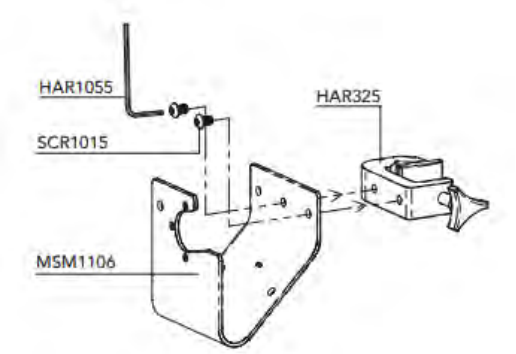
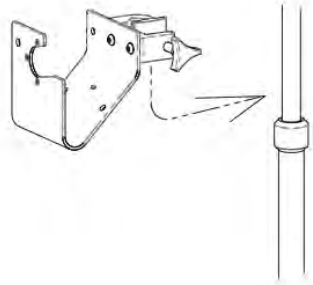
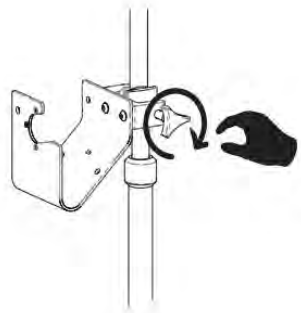
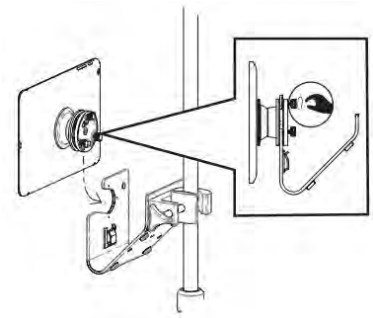
3.  	Slide the assembled mount onto the stand. You may need to loosen the knobs on the base in order to fit the mount onto the stand.
4.  	Plug the USB cable into the tablet. Use the clip on the back of the stand to keep the cable neatly in place.

Table 21 – Table Top or Wall Mount Setup Instructions

Pole Configuration:

1.  	Adhere the adhesive disk to the tablet. Remove the adhesive backing paper from the exposed side and attach the swivel mount. Ensure the knobs on the swivel mount are properly positioned.

2.  	Attach the C-Camp to the mount stand with the supplied screws.
3. 	Position the assembled clamp onto the IV pole.
4. 	Tighten the knob of the clamp to secure it into place.
5. 	Slide the assembled mount onto the clamp. You may need to loosen the knobs on the base to fit onto the stand.

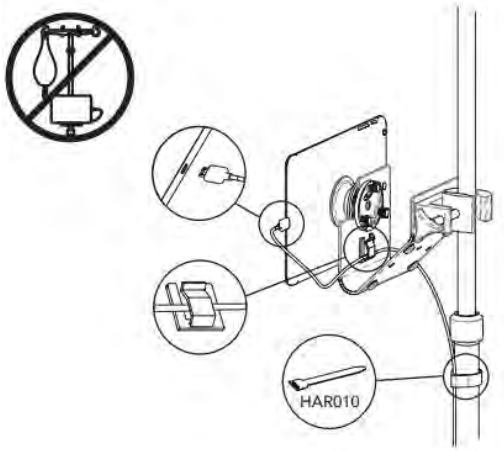
6.  	Plug the USB cable into the tablet. Use the clips located on the back of the stand and on the IV pole to keep the cable neatly in place. Never mount the mobile device on an IV pole that will use IV bags.

Table 22 – Mobile Device Mount, Pole Configurations Setup Instructions

APPENDIX G. COMPLIANT CABLES AND ACCESSORIES

Urocap™ IV Light uroflow transducer
Tablet (mobile device)
Tablet DC power cord (10 ft./3.0 m)
Urocap™ IV Light Power Cord (17 ft./5.0 m)

Table 23 – Cables and Accessories

APPENDIX H. 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 index[i]
- 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] A Cannon. AW Thomas, E Bartlett, J Ellis-Jones, L Chambers and P Abrams. BLADDER CONTRACTILICITY 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.