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# NXT Go

## Owner's Manual

Version A

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# 1 Introduction

The LABORIE NXT Go system is a partially wireless capable system providing mobility and ease-of-use in the field of Urodynamics. It allows studies to be performed with mountable modules and is controlled by the LABORIE Synergy software. The wireless and battery-powered features allow for improved system setup and use. For information on warranty and terms and conditions, visit http://www.laborie.com/terms-and-conditions/.

*Figure 1: NXT Go*

## 1.1 Intended Use

The NXT family are medical device systems used for Urodynamics and pelvic floor assessment. These systems can display, record, and store data such as vesical, urethral, and abdominal pressures, urine flow and volume, and pelvic floor EMG from the patient for diagnostics purposes only.

## 1.2 Indications of Use

The NXT Urodynamics System is indicated for urologic diagnostic testing to aid in the diagnosis of urine storage and voiding disfunction diseases including:

- Urinary incontinence and retention
- Bladder outlet obstructions
- Neurogenic bladder dysfunction
- Other complex voiding/urine storage problems

This device is indicated for use under the direction of licensed and trained health care professionals.

# 1.3 Equipment Intended Use

Refer to the descriptions below for a breakdown of intended use per module.

**Standard Equipment**

- NXT Go Pump Hub with NXT Go Infusion Hook: Wired device which uses a peristaltic infusion pump to fill a patient's bladder with saline and/or contrast.
- Urocap NXT: Wired or wireless and battery powered device which measures volume and flow rate of urine.
- Roam NXT: Wired or wireless and battery powered detachable module that connects to the PIM NXT.
- PIM NXT: Device which is powered by the Roam NXT to measure pressure and electromyography.
- Laptop PC: Computer which controls the system activity and displays and stores data.
- Synergy: Application software which runs on the PC to control the system activity and display, and store data.
- Bluetooth Dongle NXT: Allows wireless communication between modules and the system.
- Remote Control NXT: Wireless and battery powered device which allows control of the system from a distance.

**Optional Equipment**

- Printer: Allows hardcopy reports to be created.
- UPP Puller NXT: Wired or wireless and battery powered device which controls and measures speed and distance during a Urethral Pressure Profile.

**Accessories**

The accessories of the equipment are as follows:

- Catheters, Electrodes, Tubing, Pressure Transducers: Disposable or reusable items used for infusion and to measure pressure from the patient.
- Commode, Procedure Chair: Supports patient and facilitates position changing throughout the procedure.
- Flow Stand, IV Pole, Carts, Stands, Trolleys: provides mountable surfaces for standard equipment and accessories.
- SmartSense Barcode reader: Allows consumable device information to be recorded by the system.

# 1.4 Contraindications

None known.

# 1.5 About this Manual

The NXT Go Owner's Manual is intended to provide important information and instruction regarding the use of the NXT Go System.

## 1.5.1 Manual Symbols

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

| Symbol | Description |
|---|---|
|  | Caution/warning symbol describes information that the user needs to know to prevent minor injury or product damage. |
|  | Important symbol describes important information about using the device. |
|  | Note symbol describes additional information about the device. |

# 1.6 Software and Equipment

## 1.6.1 Software Install

Synergy software is installed prior to shipping. The supported operating system for Synergy Software is Microsoft Windows® 10.0. For the end-user software license agreement, visit http://www.laborie.com/terms-and-conditions/end-user-software-license-agreement/

**IMPORTANT:**

- Ensure that Windows automatic updates are always enabled.
- LABORIE strongly recommends that BitLocker remain enabled on the NXT system to comply with the HIPAA standard regarding data privacy and security.
- Ensure that an antivirus program is always enabled. For more information about the use of antivirus programs, refer to the Computer Virus Protection section on page 90.
- Do not upgrade any Microsoft Windows® 10.0 PC or laptop to any other version of Microsoft Windows®. The UDS Urodynamics system and software provided by LABORIE are tested as a complete package and will not work correctly after updating the operating system. Contact your LABORIE support representative for more information.
- Changes to the Windows Group Policies may prevent the NXT system from operating correctly. Before making any Group Policy changes, contact your LABORIE support representative for guidance to confirm if changes can be safely made.
- To install any updates for the Synergy software, contact your LABORIE support representative for guidance.
- Access Synergy **Software Version**, **Serial Number**, **System Fingerprint**, and **GS1** information by navigating to the System Settings window under the Settings icon  . Refer to the Overview of Icons in the Title Bar section on page 47 for instructions on accessing the System Settings.

## 1.6.2 Standard Equipment and Optional Accessories

Prior to use, 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 is found.

**NOTE:** LABORIE recommends keeping the carrying cases and cartons provided with the devices to use during transport if the equipment must be sent in for service.

Standard NXT System Configuration:

| NXT Go | Standard Equipment |
|---|---|
|  | Computer: Laptop PC<br>Printer: Inkjet<br>Pump Hub: NXT Go Pump Hub with NXT Go Infusion Hook<br>Uroflowmeter: Urocap NXT (1)<br>UDS: Roam NXT (1) with PIM NXT for T-DOC or Fluid<br>Electronic Medical Records (EMR): Add-on feature<br>UPP Puller NXT: Add-on Equipment |

*Table 1: NXT System Configuration – Standard Equipment*

# 1.7 Warnings and Precautions

**Precautions:**

| |
|---|
| Prior to Urodynamic testing, a urinalysis and urine culture should be considered to rule out the presence of infection. |
| Care should be taken when performing a Urodynamic study on patients with:<br>○ The presence of a bladder infection<br>○ Strictures in the urethra |
| LABORIE is not responsible for loss of patient files or test data. LABORIE recommends that the user backup patient data on a regular basis. |
| LABORIE equipment and accessories are licensed by Governments, approved by Safety Agencies, and warranted to work only with each other. |
| The Roam NXT and the PIM NXT are not intended for long-term direct patient contact. If the devices must be attached to a patient, place gauze or another material between the devices and the patient's skin. |

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

**⚠Warnings:**

| |
|---|
| The NXT Urodynamic System contains magnets which can interfere with control of a pacemaker or ICD (Implanted cardioverter-defibrillator). Follow instructions from the manufacturer of such devices and ensure that the Roam NXT, Urocap NXT and charger cable connectors are always kept at a sufficient distance from any implanted device. |
| Only LABORIE trained technicians may service the unit. |
| Do not use if the device packaging has been opened, damaged, or if it presents any fault due to improper transport, storage, or handling that could in any way hamper its use. The NXT System is intended for install by trained personnel ONLY. |
| Do not immerse the NXT System or any of its modules in water or any other liquids. |
| Do not place your fingers or any body parts inside the pump when the pump rollers are moving. |
| Do not use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. |
| Do not use electromyography (EMG) simultaneously with high frequency surgical equipment. |
| Do not operate the NXT System near shortwave or microwave therapy equipment as proximity may produce instability in the APPLIED PARTS. |
| Do not allow applied parts linked to a PATIENT CONNECTION, but not connected to the PATIENT, to contact other conductive parts including those connected to protective earth. Preserve the patient connection electrical isolation. Do not place the printer in the patient environment. |
| Do not reuse single-use accessories. After use, dispose of single-use accessories in accordance with local regulations. |
| Re-use, reprocessing, or resterilization of disposables can lead to device failure and create a risk of cross-infection and/or cross transmission of infectious disease(s) from one patient to another. |
| NXT System Accessories are not intended to be defibrillation-proof. |
| Improper processing of reusable items prior to initial use or reuse can result in cross infection and/or cross-transmission of infectious disease from one patient to another. |
| Risks associated with catheterization increase immediately after urethral or bladder surgery. The performance of Urodynamic studies with post-operative patients is at the discretion of the physician. |
| Medical care professionals performing Urodynamic studies should be prepared to recognize and treat symptoms associated with ureteral catheterization, *vasovagal syncope* (fainting), and *Autonomic Dysreflexia*. |
| To avoid potential patient injury never clean or service any module or component of the NXT System while in use with a patient. |
| The use of the Medical Electrical equipment is restricted to one patient at a time. |
| Do not use the NXT System in the presence of a magnetic resonance imaging system as the NXT System may contain ferromagnetic objects that pose a risk to the patient in the presence of a magnetic core. |

| |
|---|
| To avoid risk of electric shock, do not touch the pogo pins located inside the Urocap NXT Charging Hub or the Urocap NXT Wall Charger. |
| To avoid the risk of electric shock, only connect this equipment to a mains power supply with protective earth. |
| This device is intended for use in a clinical environment with controlled EMC standards to limit potential interference. The NXT System may be adversely affected by Bluetooth, cellular, or EMC interference. Minimize interference from other Bluetooth devices by setting up all modules of the system in proximity to each other. |
| Electromagnetic Interference in the form of electrostatic discharge or radiated emissions can cause the NXT System components to temporarily disconnect. Components may require a power cycle before operation can resume after exposure to these electromagnetic interferences. |
| Only connect devices specified and approved by LABORIE to the NXT System. Connecting any device not approved by LABORIE to the Medical Electrical (ME) system alters the functional integrity of the product creating a safety risk. |
| Do not connect any multiple socket-outlets or extension cords to the NXT GO System or any of its components |
| Always position the NXT System to facilitate ease of access to all electrical connections and plugs. The device operator must be able to disconnect the device quickly and safely in case of an emergency. |
| Do not alter or add to the NXT medical electrical system. Any alteration to the NXT 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 make changes or modifications to the PIM NXT for TDOC and its radiators. Changes to intentional or unintentional radiators not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. |
| Batteries are not operator replaceable (except for in the Remote Control NXT). Do not attempt to remove the battery. All servicing of the NXT System, modules, or attachments must be completed by LABORIE authorized personnel. |

**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 Quick Start

To prepare for a typical study, follow the steps provided below.

1. Setting Up the Equipment
2. Gathering Supplies and Equipment
3. Preparing the Urocap NXT
4. Preparing the NXT Go Pump Hub
5. Preparing the Roam NXT
6. Preparing the UPP Puller NXT
7. Setting Up Consumables and Preparing the Patient

## 2.1 Setting Up the Equipment

1. Unpack the NXT Go Pump Hub, Roam NXT, Patient Interface Module NXT (PIM NXT), and Urocap NXT from their shipping boxes. Unpack the UPP Puller NXT. For information on the NXT Go Pump Hub, Roam NXT, PIM NXT, Urocap NXT, NXT Infusion Hook, Remote NXT, or UPP Puller NXT refer to the Hardware section on page 96.

**IMPORTANT:** Lock all wheels of the pole or table used for equipment setup. Ensure all wheels are locked during testing procedures to prevent injury to the patient.

2. If utilizing the UPP Puller NXT assemble and mount the UPP Puller NXT according to the instructions provided in the Preparing the UPP Puller NXT section on page 22. For information on charging the UPP Puller NXT refer to the UPP Puller NXT – Charging the Battery section on page 107.
3. Connect the PIM NXT to the Roam NXT. For instructions on how to connect these devices, refer to the Replacing the PIM NXT section on page 102.
4. Connect the Roam NXT and the Urocap NXT to the PC using the NXT Magnetic Pogo Pin Cable and the USB to Binder Cable Adapter to pair the devices. Once paired unplug the devices for wireless use.
5. Hang the NXT Go Infusion Hook on an IV Pole. Connect the NXT Go Infusion Hook to the NXT Go Pump Hub. Connect the NXT Go Power Cord to the NXT Go Pump Hub and the NXT Go Power Supply, then connect to supply mains. Use the NXT Go USB Cable to connect the NXT Go Pump Hub to the laptop PC. Refer to Figure 77 for a visual of inputs on the NXT Go Pump Hub.

   For information on the NXT Go Pump Hub, refer to the NXT Go Pump Hub section on page 98. For information on charging the Roam NXT, refer to the Roam NXT—Charging the Battery section on page 103. For information on charging the Urocap NXT, refer to the Urocap NXT—Charging the Battery section on page 106.

   Refer to the Maintenance and Service section on page 75 for information on cleaning and maintaining the modules, including all system check intervals and procedures for verifying the integrity of the system.

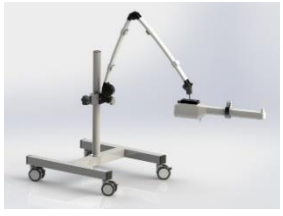
6. Turn on the laptop PC by pressing the power button . Double click the Synergy Icon to launch the Synergy Login Page.

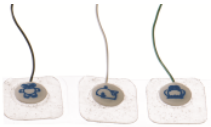
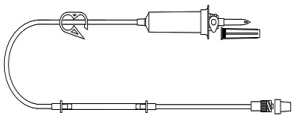
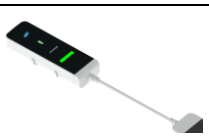
7. Login to Synergy by inputting the account **User Name** and **Password**, assigned during system install, into the Synergy Login Page. The Synergy Main Window will load. Refer to Figure 33: Synergy Main Window Reading Guide. Ensure to update access information from initial system install. Refer to the User Access Control section on page 42 for more information on logging in to Synergy and accessing controls.

# 2.2 Gathering Supplies and Equipment

Prior to beginning a Urodynamics study, the user should ensure that the following supplies and equipment have been gathered and prepared for use during the procedure.

**IMPORTANT:** Place the required supplies on a table or tray for easy access when preparing the patient for full Urodynamic testing.

<table>
<tr><td colspan="2">Procedure Specific items:</td></tr>
<tr><td colspan="2">• Straight catheter<br>• Catheterization supplies such as cleansing swabs, lubricant, etc.<br>• Saline bag<br>• Exam gloves<br>• Tape<br>• Preparation tray</td></tr>
<tr><td colspan="2">System Specific Items:</td></tr>
<tr><td>  <br>NXT Go Pump Hub (DCX2101)</td><td>  <br>NXT Go Infusion Hook (MSM1185)</td></tr>
<tr><td>  <br>Urocap NXT (UCX2001)</td><td>  <br>Remote Control NXT (RCX2001)</td></tr>
<tr><td>  <br>Roam NXT (ROX2001) & PIM NXT for T-DOC (PIX2211)</td><td>  <br>Roam NXT (ROX2001) & PIM NXT for Fluid (PIX2231)</td></tr>
<tr><td>  <br>Urocap NXT Stand with Funnel (MSM1172 & CHA1000)</td><td>  <br>UPP Puller NXT (UPX2001) and UPP Stand (UPP1006)</td></tr>
</table>

| | |
|---|---|
|  Commode Chair (CHA181 or CHA171) and Funnel (CHA102) |  Snap-on electrodes (ELE428) and cable (CAB1091, CAB1092, CAB1103, CAB1104) |
|  Inkjet Printer supplied by Laborie |  Beaker (UD575) |
|  T-DOC NXT Abdominal Catheter (CATT3A17) |  T-DOC NXT 7FR Single and Dual Sensor Bladder Catheters (CATT3BXXX part number series) |
|  Single, Dual, and Triple Lumen Bladder Fluid NXT Catheters (DLC-6D-RFID, DLC-7D-RFID, CDLC-6D-RFID, CDLC-7D-RFID, 9021P5892-RFID) |  Abdominal Pressure, Fluid NXT Catheters (9021P4592-RFID, 9021P4522-RFID) |
|  Pressure Measurment Tubing (TUB101) |  Disposable Cartridge and Luer Lock (DIS130) |
|  Medex LogiCal® Pressure Transducers (Medex TRA60X) |  Pressure Cuff for Perfusion for fluid UPP Only (DIS302) |
|  Clamp for Medex Pressure Transducers (BRA230) Bracket for 3 Medex Pressure Transducers (BRA405) |  PIM NXT for Fluid to Medex Transducer Cables (CAB1093) |
|  Infusion Pump Tubing for Laborie NXT Systems (TUBPTNXT or TUB500-RFID) |  Roam NXT to PIM NXT Connector Cable (CAB2111) |

| | |
|---|---|
|  UPP Puller NXT Cable (CAB1109) |  USB to Binder Cable Adapter (CAB1117) |
|  NXT Magnetic Pogo Pin Cable, Binder Termination, 3m Length (CAB1081) |  Power Supply, Medical Grade, Class II Wall Plug (POW1033) |
|  NXT Go Power Cord (POW006) |  NXT Go USB Cable (CAB1056) |
|  NXT Go Power Supply (POW1043) |  Roam NXT Mounting Bracket (MSM1153) |
|  NXT Go IV Pole Bracket (MSM1062) |   NXT GO Carrying Case (PKG1091) |



# 2.3 Preparing the Urocap NXT

To prepare the Urocap NXT for use:

1. Ensure that the Urocap NXT is charged and ready to use.
2. Place the funnel on the plastic frame of the commode chair.
3. Carefully place the Urocap NXT transducer on the floor.
4. Place the graduated beaker on top of the transducer.
5. Place the commode chair and funnel over the Urocap NXT and beaker.

*Figure 2: Urocap NXT Setup*

**NOTE:** For setup instructions using the Urocap NXT Stand refer to MAN1000.

**IMPORTANT**: Ensure all preparation steps are completed before starting a study in Synergy.

# 2.4 Preparing the NXT Go Pump Hub

To prepare the NXT Go Pump Hub:

1. Place the device on a stable surface where it will not be a tripping hazard.
2. Connect the NXT Go Infusion Hook to the NXT Go Pump Hub.
3. Connect the NXT Go Pump Hub to supply mains using the NXT Go power cord and the NXT Go power supply.
4. Connect the NXT Go Pump Hub to the computer using the NXT Go USB cable.

Refer to the NXT Go Pump Hub section on page 98 for connection points on the NXT GO Pump Hub and to the Infusion Pump Tubing Setup section on page 24 to setup the pump.

# 2.5 Preparing the Roam NXT

- Ensure the Roam NXT is charged. LABORIE recommends charging the device overnight to ensure optimal battery power for a full day of procedures.
- Confirm that the Roam NXT and PIM NXT are connected securely. The PIM NXT and the Roam NXT must be connected to function. For information on the Roam NXT and the PIM NXT, refer to the Roam NXT section on page 100.

# 2.6 Preparing the UPP Puller NXT (Optional)

Ensure the UPP Puller NXT is charged. LABORIE recommends charging the device overnight to ensure optimal battery power for a full day of procedures. Refer to the UPP Puller NXT section on page 107 for instructions on how to charge the device. Confirm that the UPP Puller NXT is fully assembled and securely mounted.

## 2.6.1 Assembling the UPP Puller NXT

Identify removable parts to begin assembly of the UPP Puller NXT. The UPP Puller NXT nose separates from the motor through a locking mechanism located at its base (Figure 3). Fit the nose onto the motor with the locking mechanism in the unlocked position. Once the couplers have self-aligned lock the mechanism (Figure 4). If disassembly is required, unlock the mechanism and pull the nose away from the motor.

*Figure 3: UPP Nose Locking Mechanism*

*Figure 4: Connect the UPP Motor and Nose*

The UPP nose features the removable Catheter Guide and Catheter Clamp (Figure 5). Attach the Catheter Guide and Catheter Clamp to the appropriate connection point. The Catheter Guide and Catheter Clamp use magnets to connect and disconnect from the nose.

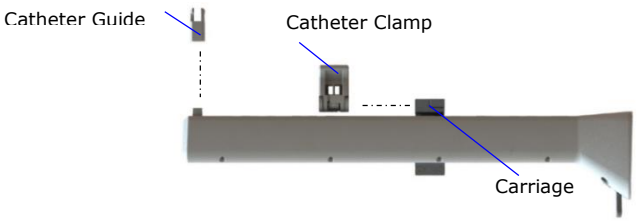



*Figure 5: Left Profile – Removable Parts*

**IMPORTANT:** Removal of the Catheter Clamp may expose a sharp piece of metal protruding from the hinge. Take care when handling.

To mount the UPP Puller NXT, slide the Pole Clamp onto the post of the UPP Stand. Ensure that the yellow bushing is facing upwards. Lock it in position with the Rubber Knob Screw located on the Pole Clamp. Loosen the thumb screw on the Pole Clamp and place the UPP Puller NXT Arm Clamp Insert into the clamp's yellow bushing (Figure 6).

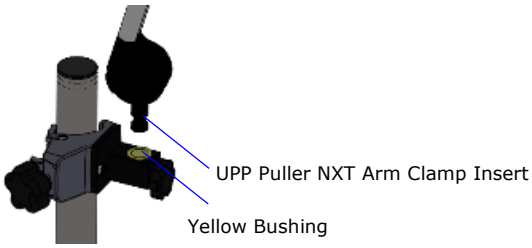



*Figure 6:Connect UPP Puller NXT Arm Clamp and the Pole Clamp*

Tighten the thumbscrew to complete mounting. To adjust any of the joints on the UPP Puller Arm, loosen the thumbscrews, adjust, and retighten. Refer to Figure 7.

**IMPORTANT:** Loosen the thumbscrews only as much as is required to complete adjustments. Avoid removing the thumbscrews from the UPP Puller NXT Arm.

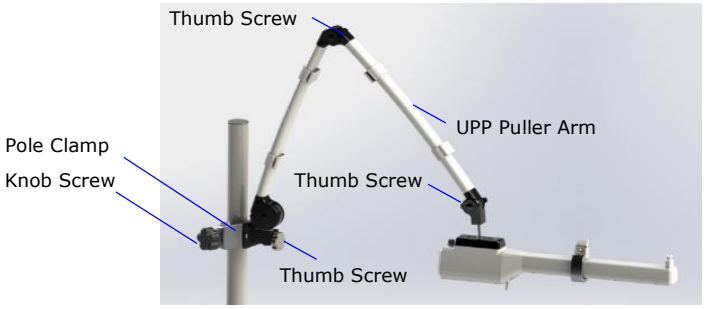



*Figure 7: Mounting the UPP Puller NXT*

## 2.6.2 Assembling the UPP Puller NXT Stand

To assemble the Puller Stand (UPP1006), prepare one 6mm and one 4mm HEX L-KEY. Connect the Pole Assembly to the H-Base Assembly using the provided Washer M8, Split Washer M8, and Screw M8. Use the 6mm HEX L-Key to secure the screw (Figure *8*).

*Figure 8: Assembling the UPP Stand*

# 2.7 Setting Up Consumables and Preparing the Patient

Synergy uses **Consumable Traceability** to track consumables used during studies. Prior to beginning consumable setup, ensure to start a study. For instructions on starting the study refer to the Start Study Button section on page 61.

Complete consumable and patient setup in the preview phase of the study. Catheters and tubing must be scanned into Consumable Traceability to proceed from the preview phase. Consumable information will show in the **Consumable Traceability** tab available in the **Preview** window once entered or scanned. For more information on **Consumable Traceability** refer to the Procedure – Preview Phase section on page 62.

## 2.7.1 Infusion Pump Tubing Setup

LABORIE Infusion Pump Tubing is intended for single use only. Do not re-use, reprocess, or resterilize pump tubing. Use of the Infusion Pump Tubing outside of its intended use may affect pump accuracy. Do not run the pump at a speed exceeding the limitation of the catheter.

**IMPORTANT**:

- Always use only LABORIE Infusion Pump Tubing to ensure a properly and accurately functioning system.
- Catheters, the saline bag, and the Infusion Pump Tubing are consumables intended for single use with a single patient only; they must be replaced after every use.
- To maintain patient safety during normal use, the maximum pump speed is preset to 150ml/min.
- Always refer to the Instructions for Use provided with the consumable deployed for information on proper use of the device.

To setup the pump tubing, follow the steps provided below:

1. Scan the SmartSense tag, located on the packaging, against the reader located on the NXT Go Pump Hub by holding proximity for 3 seconds. Refer to the NXT Go Pump Hub section on page 98 for a visual of the SmartSense tag reader.
2. Hang a bag of saline solution. Refer to the Infusion Volume Transducer section on page 100. Insert the pump tubing spike into the bag.
3. Close the tubing clamp to block the tubing and to stop the flow.
4. Squeeze and release the flexible drip chamber until fluid flows.
5. Open the tubing clamp and flush the line completely.
6. Open the pump door and position the compressible portion of the pump tubing across the rollers; close the pump door.

**NOTE:** Do not stretch the compressible portion of the pump tubing during insertion as the pump controls the tautness of the tubing insert.

To remove air bubbles from the pump tubing with Synergy, click the **Prime Pump Tube On** button. Click the **Prime Pump Tube Off** button to turn off the pump. Synergy automatically displays pump activation markers.

7. Attach the luer connector of the tubing to the fill connection of a prepared catheter.

#### 2.7.1.1 Replacing the Pump Tubing

To replace the pump tubing:

1. Close the tubing clamp.
2. Disconnect the pump tubing from the catheter.
3. Remove the pump tubing spike from the bag and empty the saline bag.
4. Open the pump door and remove the pump tubing. Discard the pump tubing according to your institution's standard operating procedures on medical waste handling.
5. Setup the new pump tubing as described in the Infusion Pump Tubing Setup section above.

### 2.7.2 Setting Up Catheters and Transducers

The NXT system is compatible with LABORIE T-DOC Air Charged Catheters and Fluid NXT Catheters equipped with SmartSense tags. Refer to the Gathering Supplies and Equipment section on page 19 for a list of compatible catheters.

#### 2.7.2.1 T-DOC Air Charged Catheters

To setup the T-DOC Air Charged Catheters for use with the NXT, follow the steps below.

**IMPORTANT:** Always reference the Instructions for Use provided with the consumable deployed for device specific information and instructions.

1. Ensure the PIM NXT for T-DOC is connected to the Roam NXT. A solid green light bar on the Roam NXT indicates that the device is ready for use. For additional information on connecting the PIM NXT to the Roam NXT, refer to the Replacing the PIM NXT section on page 102.
2. Position the patient in a supine or lithotomy position.
3. Open the catheter pouch and coat the distal end of the device with a water-based lubricant before inserting the catheter into the patient.

**For female patients**: Insert vesical (Pves) catheter 8-10 cm for single sensor, 12-14 cm for dual sensor. Insert abdominal (Pabd) catheter into the rectum 10-15 cm, past any stool that may be present, along the anterior wall of the rectum. Alternatively, insert vaginally in the posterior fornix, just behind the cervix, at the level of the cul-de-sac of Douglas.

**For male patients:** Insert vesical (Pves) catheter 8 cm plus penile length. Do not force if resistance is met. Insert abdominal (Pabd) catheter into the rectum 10-15 cm, above the prostate, past any stool that may be present, along the anterior wall of the rectum. Tape the catheter as close to the insertion site as possible.

4. Remove the protective caps from the catheter connectors, lift the doors on the PIM NXT, insert the connectors into the PIM NXT, and push gently until they lock. Verify that all catheters are connected properly by giving a gentle tug on the catheter connector. Do not pull catheter lumens. Close any doors of the PIM NXT which are not in use to seal the empty transducer channels from dirt or debris.

**IMPORTANT:** The catheter connectors are color coded blue (Pves), red (Pabd), and yellow (Pura) per industry standard.

*Figure 9: Catheters Connected to PIM NXT*

5. Verify that the catheter appears in the consumable traceability window in Synergy. If the catheter does not register in Synergy, disconnect the catheter and reconnect.
6. Confirm positioning of the catheter using the Synergy interphase. Ask the patient to cough to confirm the catheter's positioning. When recording two pressures at the same time, the cough will show equal deflection on both channels (Figure 22). With Auto Cough detection activated, Synergy will mark these deflections as coughs automatically; refer to Customizing Control Panel on page 58 for more information.

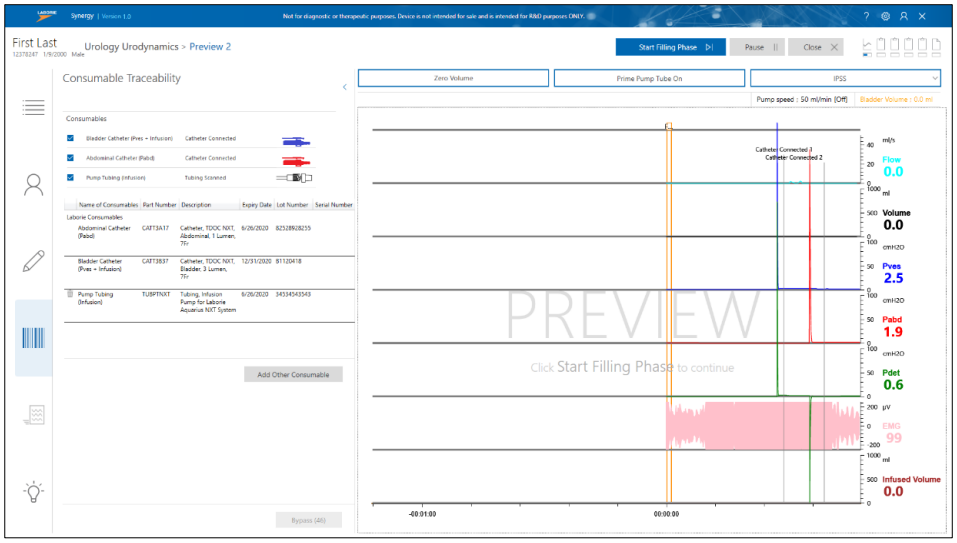



*Figure 10: Pressure Flow Preview Phase*

**IMPORTANT:** T-DOC Air-Charged Catheters are intended for single-use. Synergy will not recognize a catheter that has previously been registered in the software after the allotted two hours to complete Urodynamic testing.

7. Once preferred catheter placement is confirmed, connect the Infusion Pump Tubing to the filling lumen on the vesical catheter or filling catheter. Ensure all air bubbles have been removed from the Infusion Pump Tubing and that the Infusion Pump has been properly primed before connecting the line to the filling lumen on the vesical catheter or filling catheter.

Refer to the T-DOC Air-Charged Catheters section on page 108 for information on T-DOC catheters.

## 2.7.2.2 Roam NXT, PIM NXT for Fluid, and Transducer Setup

1. Ensure the PIM NXT for Fluid is connected to the Roam NXT. A solid green light bar on the Roam NXT indicates that the device is ready for use. For additional

information on connecting the PIM NXT to the Roam NXT, refer to the Replacing the PIM NXT section on page 102

2. Use the PIM NXT for Fluid to Medex Transducer Cables to connect the pressure transducers to the Pressure Channel Connectors on the PIM NXT for Fluid (Figure 11).

*Figure 11: Roam NXT, PIM NXT for Fluid, and Pressure Transducer Connected*

**IMPORTANT:** The Pressure Channel Connectors on the PIM NXT for Fluid are color coated blue for Pves, yellow for Pura, and red for Pabd. The channel color coated green is capable of Pves, Pura, or Pabd measurements.

3. Use Medex clamps and brackets to mount the pressure transducers on the NXT Hoop or an IV pole at the patient's waist height or higher.
4. Remove disposable cartridges from their packages. Remove protective covers from the back and from the connector ends of the cartridges. Slide a cartridge over each transducer until it clicks in place (Figure 12).
5. Aseptically remove pressure measurement tubing from its package and attach the three-way stopcock to the lower (male) end of the pressure cartridge.
6. To prime the cartridge and the pressure measurement tubing, attach a sterile fluid filled syringe to the side port of the stopcock.

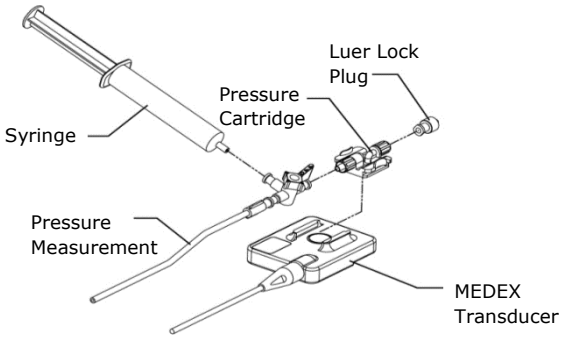



*Figure 12: Transducer Setup*

7. Turn the stopcock lever in the appropriate directions to flush fluid from the syringe through both the cartridge and the pressure measurement tubing (Figure 13).

**NOTE:** Always secure the cartridge stopper cap whenever changing the stopcock lever's position.

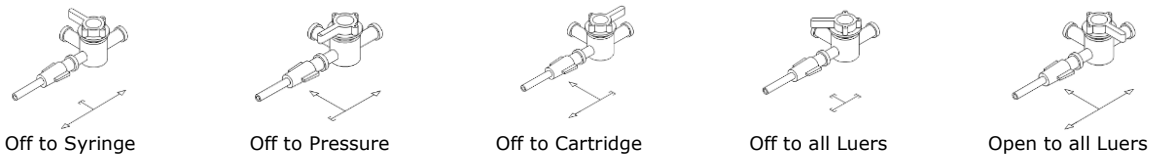



*Figure 13: Stopcock Lever Positions*

### 2.7.2.3 Bladder Fluid NXT Catheters

1. Scan the SmartSense tag located on the catheter's packaging. Ensure the catheter is logged into the Synergy **Consumable Traceability** window.
2. Aseptically remove the catheter from its package and apply a light film of water-based lubricant to the distal end. Catheterize the patient.

   **For female patients**: Insert the Bladder Fluid NXT catheter 8-10 cm for single sensor, 12-14 cm for dual sensor.

   **For male patients:** Insert the Bladder Fluid NXT catheter 8 cm plus penile length. Do not force if resistance is met.
3. Connect the catheter to the corresponding Pura or Pves Pressure Channel Connector's pressure measurement tubing.
4. Attach a sterile fluid filled syringe to the side port of the pressure measurement tubing's stopcock. Ensure to purge air from the disposable cartridge, pressure measurement tubing, and catheter lumens. Refer to Figure 13.

**NOTE:** If using perfusion, set up a second IV bag with a pressure cuff to maintain constant flow.

### 2.7.2.4 Abdominal Fluid NXT Catheters

1. Scan the SmartSense tag located on the catheter's packaging. Ensure the catheter is logged into the Synergy **Consumable Traceability** window.
2. Aseptically remove the catheter from its package and open all luer caps. Attach a four-way stopcock to the Pabd pressure lumen.
3. Fill a 10cc syringe and attach it to the side luer of the stopcock. Hold the catheter so that the balloon is pointing upward.
   a. For the dual lumen catheter, infuse solution from the filled syringe into the catheter to force the air inside the catheter to ascend then discharge out of the purge lumen. After all air has been removed from the catheter, close the luer cap on the purge lumen. Collapse the balloon by withdrawing the fluid from the catheter with the syringe.
   b. For a single lumen catheter, ensure to fill a 10cc syringe with 5-7cc of solution. Hold the catheter so that the balloon is higher than the stopcock. Open the stopcock to the syringe and the catheter and aspirate all air from the balloon. Infuse 4-5cc of solution into the catheter to slightly distend the balloon. Repeat aspiration and infusion until no air remains in the balloon.
4. Finish preparation with the balloon collapsed and the stopcock off to all luers.
5. Apply a light film of water-based lubricant to the balloon and insert the catheter.

   **For female patients:** Insert the Abdominal Fluid NXT catheter into the rectum 10-15 cm, past any stool that may be present, along the anterior wall of the rectum. Alternatively, insert vaginally in the posterior fornix, just behind the cervix, at the level of the cul-de-sac of Douglas.

   **For male patients:** Insert the Abdominal Fluid NXT catheter into the rectum 10-15 cm, above the prostate, past any stool that may be present, along the anterior wall of the rectum.
6. Open the stopcock to the syringe and the catheter and infuse approximately 1-1.5cc of solution.

7. Slowly open the stopcock to the luer where the pressure measurement tubing will be attached. Connect the tubing to the stopcock as the meniscus forms on the stopcock luer. Take care not to lose fluid from the catheter.
8. At the beginning of the study the abdominal pressure must equal vesicle pressure in Synergy. If Pabd is higher than Pves, slowly open the stopcock to the free luer connector and allow a drop of solution to escape. Repeat until Pabd equals Pves. If Pabd is lower than Pves, open the stopcock to all luers and use the syringe to add a few drops of solution. When Pves and Pabd are equal, Pdet will be 0cm $H_20$.
9. Turn the stopcock off to the syringe and instruct the patient to cough to verify continuity and pressure transmission.

## 2.7.3 Placing the EMG Patch Electrodes

1. Enter consumables information into the **Consumable Traceability** section in the **Preview** phase.
2. Place two electrodes peri-anally at the 10 o'clock and 2 o'clock position (or at the 9 o'clock and 3 o'clock position), as close to the anal verge as possible (Figure 14) .Place the third electrode on a bony prominence (such as the knee) or on a fatty portion of the inner thigh.

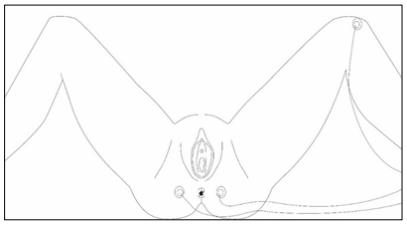


*Figure 14: EMG Patch Electrode Placements*

3. Gather all tubing/wires and secure them to the patient's thigh with tape.
4. Connect the EMG cable to the PIM NXT as shown in Figure 15 below.

*Figure 15: EMG Cable Connected to PIM NXT*

## 2.7.4 Performing Roam NXT Patient Setup

For ease of movement and accessibility during Urodynamic procedures, the Roam NXT may be mounted on an IV Pole (Figure 16) or on the procedure chair. When mounting the Roam NXT, always ensure the clamping mount is securely fastened.

*Figure 16: Roam Mounted on IV Pole*

# 3 How to Perform a Study

To perform a typical study, follow the instructions provided.

1. Starting a Study
2. Running the Study
    i) FreeFlow Study
    ii) Urology Urodynamic Study
    iii) Cystometry Study
    iv) Tests
3. Finishing the Studies
4. Printing the Study Result (Optional)

## 3.1 Starting a Study

1. Ensure that the computer and printer are turned on.
2. Start the Synergy application, and login using your credentials. A successful login will load the Synergy Main window. For information on how to login to the Synergy application, refer to the Login section on page 42.
3. Ensure that all devices required for the study are ready (i.e. fully charged). Refer to the Hardware section on page 96 for instructions on charging the NXT System modules.
4. Verify that all devices required for the study are connected to the NXT System either via Bluetooth technology or USB cable. The Bluetooth Dongle NXT must be connected to complete all studies available in Synergy.

a) In the title bar of the Synergy software, click the **Settings** icon, and then click the **Device Manager** option; the **Device Manager** window will pop-up as shown in the figure below.

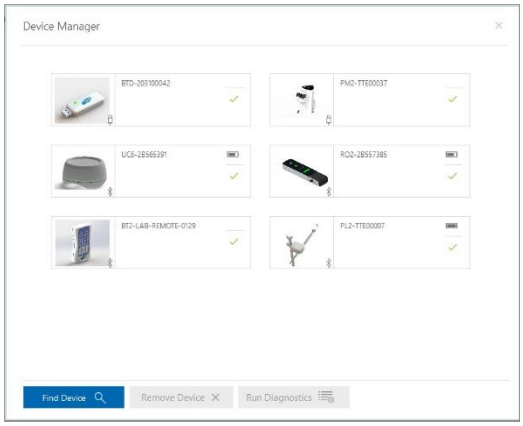



*Figure 17: Device Manager Window*

b) In the **Device Manager** window identify the Bluetooth Dongle NXT, Urocap NXT, Roam NXT, Pump NXT, and UPP Puller NXT and verify each device is properly connected as indicated by a green checkmark.

c) To connect the Remote Control NXT, ensure the remote control is active then click the **Search for devices** button. This will cause the **Find Devices** window to pop-up (Figure 18). Select the Remote Control NXT and click the **OK** button.

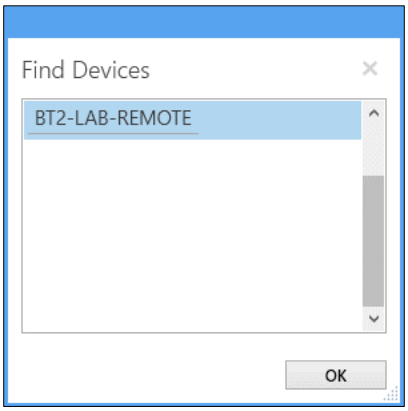



*Figure 18: Find Devices Window*

5. Choose the patient from the **Patients** section.
   a) If the patient already exists in the system, select the patient and proceed to the next step.
   b) To add a new patient, click the **New Patient** button in the **Patients** section. Enter the patient information in the **Patient Details** section under the **Info** tab (Figure 35) and click the **Save** button to save the new patient details. If required, input any relevant past medical history under the **History** tab. Once the patient has been added, select the patient and proceed to the next step.

**NOTE:** The following fields are mandatory for completing new patient setup**: First**, **Last**, and **Birth Date**.

6. To begin the study, ensure a patient is selected in the **Patients** section. Within the **Patient Details** section, select any applicable symptoms under the **Symptoms** tab immediately prior to starting the study. Symptoms are not automatically saved in the patient details section. Symptoms are saved in the study report. Next, select the applicable study under the **UDS** tab and click the **Start Study** button.

**IMPORTANT**: Patient and test option must be selected to access the **Start Study** Button. If the **Start Study** Button remains inaccessible after this step, verify that all devices required for the study type are connected in the **Device Manager** and that all hardware channels are set.

For more information on troubleshooting study start and workflow configuration, refer to the Study Management section on page 55.

# 3.2 FreeFlow Study

A FreeFlow study provides a measurement of the rate at which urine flows out of the body. It can be performed using the Urocap NXT and Synergy software provided as part of the LABORIE NXT system.

**NOTE**: Before beginning the FreeFlow Study ensure that you have completed the tasks outlined in the Gathering Supplies and Equipment section on Page 19.

## 3.2.1 Starting the FreeFlow Study

Start the FreeFlow study as described in the Starting a Study section on page 30.

The FreeFlow study requires the use of the Urocap NXT and Bluetooth Dongle NXT. Ensure that the Urocap NXT device is ready to use (i.e. fully charged with the beaker in place). For information on preparing the Urocap NXT, refer to the

Preparing the Urocap NXT section on page 21.

## 3.2.2 Performing a FreeFlow Study

### 3.2.2.1 Preview Phase

1. The **Preview** phase begins as represented in Figure 19. For information about the icons in the Preview phase, refer to the Procedure – Preview Phase on page 62.

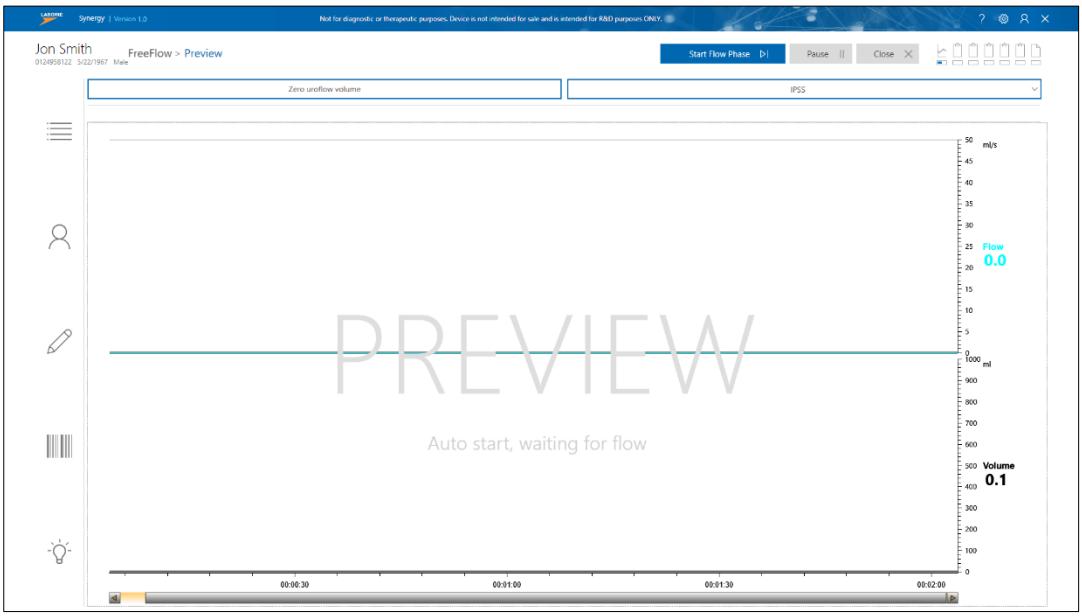



*Figure 19: FreeFlow Preview Phase*

**NOTE:** Questionnaires are available through the questionnaire drop down menu and may be completed at any time during or after the study. Scroll through the menu and select the preferred study. A questionnaire window will appear alongside the study window. Press **OK** or **Close** to exit the questionnaire window. Refer to the Questionnaire section on page 65 for an overview of the questionnaires available.

2. Click the **Zero Volume** button to prepare the Urocap NXT and then click the **Start Flow Phase** button to start the study and move to the **Flow** phase.

**NOTE:** Pause the study by clicking the **Pause** Pause button and resume the study by clicking the resume button.

### 3.2.2.2 Flow Phase

1. Instruct the patient to void. The Synergy application will automatically start to record data when the transducer detects the start of the flow.

**NOTE:** To shift the position or empty the urine beaker during the Flow Phase, click the **Change Urine Beaker** button. A popup window will appear, and the study will pause. Once the action is complete, click **Continue** on the popup window to resume.

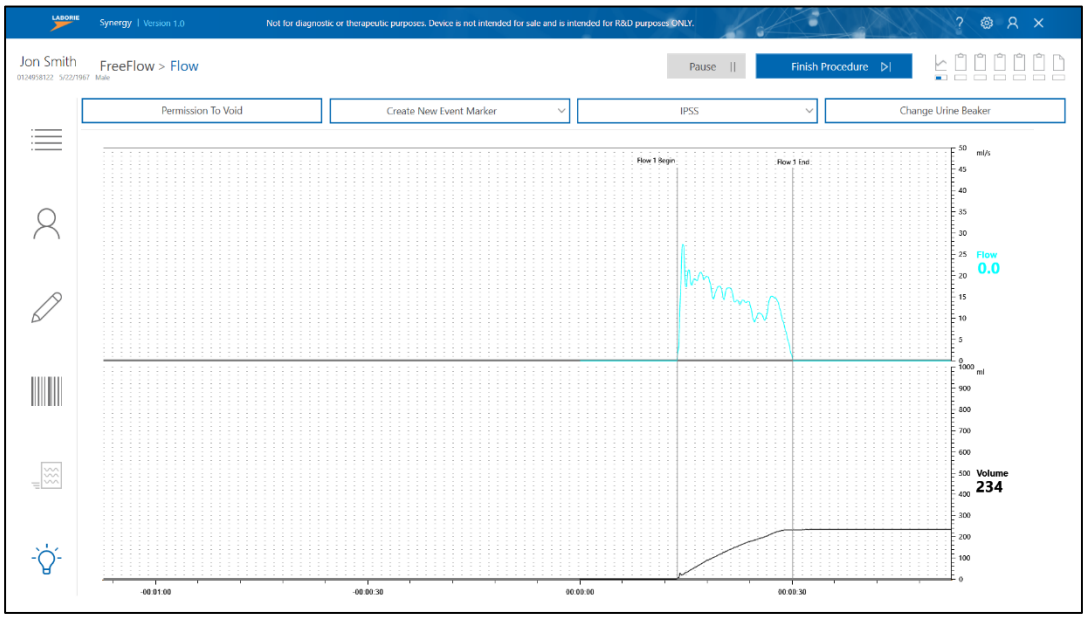



*Figure 20: FreeFlow Record Phase*

2. The flow phase will stop 60 seconds after voiding ends.
3. **A Post Voided Residual** window (Figure 21) will pop-up. Select the preferred method of capturing Post Voided Residual (PVR), meaning the amount of fluid remaining in the bladder at the completion of the voiding phase. Use of the PVR functions is at the discretion of the overseeing physician.
    a. **Calculated PVR** selection automatically provides the difference between infused volume and voided volume.
    b. **Drainage PVR** selection allows the operator to pour drained fluid into the Urocap NXT to measure PVR.

**IMPORTANT**: Do not empty the Urocap NXT beaker before adding PVR fluid drained from patient bladder. If the beaker is filled to capacity utilize **Calculated PVR** or **Input PVR** options.

    c. **Input PVR** selection allows the operator to input the PVR measurement calculated by a separate measurement device.

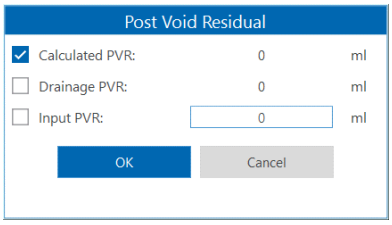



*Figure 21: Post Voided Residual Window*

4. Click OK on the **Post Void Residual** window to save data and advance to the Report. Pressing **Cancel** skips the PVR window.

**NOTE:** Post Voided Residual may also be entered and edited in the Report.

### 3.2.2.3 FreeFlow Report

1. A preview of the FreeFlow Report will be generated using the default (**UDS**) configuration settings (Figure 22). The user can apply the default configuration for the report or customize the report. For information on customizing the report, refer to the Reports section on page 65.

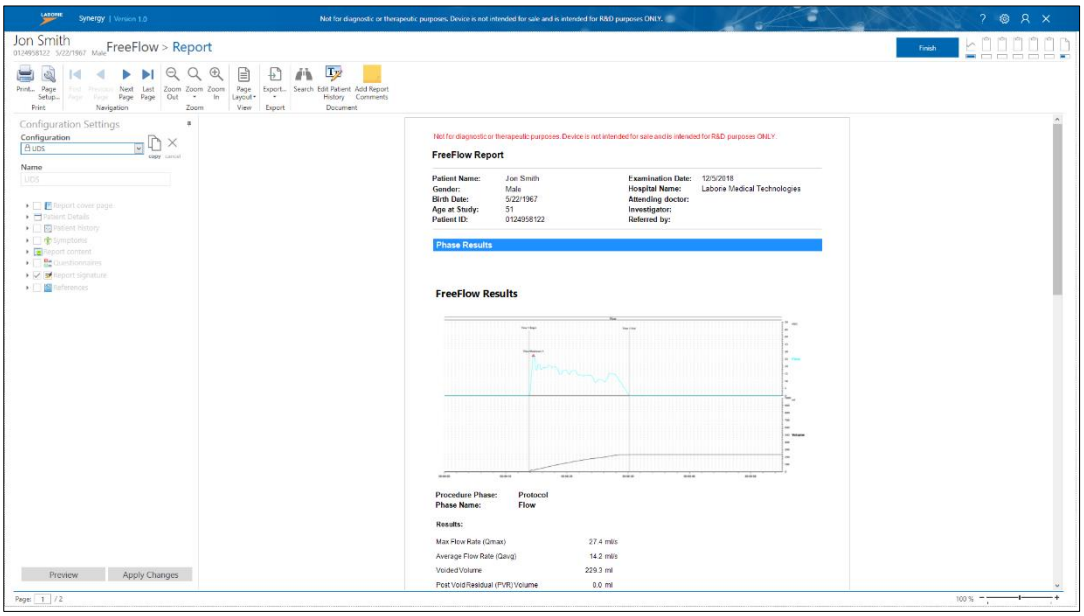



*Figure 22: FreeFlow Preview Report*

2. Click the **Finish** button. The report will appear under the **Studies** tab in the **Patient Details** section.
3. The operator may begin a secondary test with the same patient, under the guidance of the overseeing physician, or continue to Finish the Study.

**NOTE:** Reference the Finishing the Studies section on page 41 and the Printing the Study Result (Optional) section on page 41 for instructions on completing the study.

# 3.3 Urology Urodynamic Study

The Urology Urodynamic Study is a urologic diagnostic test that provides aid in the diagnosis of urine storage and voiding disfunction. The Urology Urodynamic Study includes a FreeFlow test and a Pressure Flow test. A Pressure Flow test involves filling the bladder and determining the Detrusor pressure Pdet = Pves – Pabd (the difference between the pressure inside the bladder (Pves) and the pressure inside the abdomen (Pabd)).

**NOTE:**

- Before beginning the Urology Urodynamic Study, ensure to review the Gathering Supplies and Equipment section on page 19.
- Operators should be knowledgeable and qualified in applying the appropriate aseptic technique during the intended use of all devices required for the study.

## 3.3.1 Starting a Urology Urodynamic Study

Start the Urology Urodynamic study as described in the Starting a Study section on page 30.

The study requires the use of the Urocap NXT, Roam NXT, NXT Go Pump Hub, and Bluetooth Dongle NXT. Ensure all modules are connected in the Synergy Software. Ensure that the Urocap NXT and Roam NXT are fully charged. The Synergy Software will recognize the PIM NXT and the Roam NXT as one device under the title Roam NXT.

## 3.3.2 Performing a Urology Urodynamic Study

### 3.3.2.1 Preview and Flow Phase

1. Once the Urology Urodynamic study starts, the **Preview** phase for the FreeFlow test will begin. For instructions on performing a FreeFlow test, refer to the Performing a FreeFlow Study section on page 32.

2. When the FreeFlow test is complete, navigation of the **Post Voided Residual** window is completed, Synergy will automatically transfer to the Pressure test **Preview 2** window. Press the **Zero Volume** button to prepare the Urocap NXT for the **Voiding** phase.

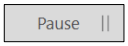
### 3.3.2.2 Preview 2 Phase

**Preview 2** begins the Pressure test, the second part of the Urology Urodynamic Study. Complete patient and consumables setup during this phase. Refer to the Setting Up Consumables and Preparing the Patient section on page 24. Once patient and pump setup are complete proceed to the **Filling Phase.**

### 3.3.2.3 Filling Phase

1. Click the **Start Filling Phase** button 

. The **Filling phase** window will display.

**NOTE:** Pause the study by clicking the Pause 

button and resume the study by clicking the resume  button.

2. If necessary, the Pabd channel value can be set to equal the Pves channel value by pressing the **Equalize Pdet** button.
3. Click the **Pump On** button to start the Infusion Pump and begin filling the bladder. Click **Smart Pump Up** or **Smart Pump Down** buttons to increase or decrease the pump speed, respectively.

**NOTE:** To change the infusion bag click the **Change Infusion Fluid** button. A popup window will appear, and the study will pause. If desired, update the Fluid Density setting using the dropdown menu available on the popup window and click **OK** to resume the study. Fluid density options must be configured in the **Workflow Configuration** window before starting the study. Refer to the Customizing Workflows section on page 56.

4. Encourage the patient to give feedback on sensation or urge. Mark relevant events (e.g.: **First Sensation, First Desire, Strong Desire**, etc.) by clicking the **First Sensation** drop-down menu and selecting the relevant event. Refer to Figure 23.

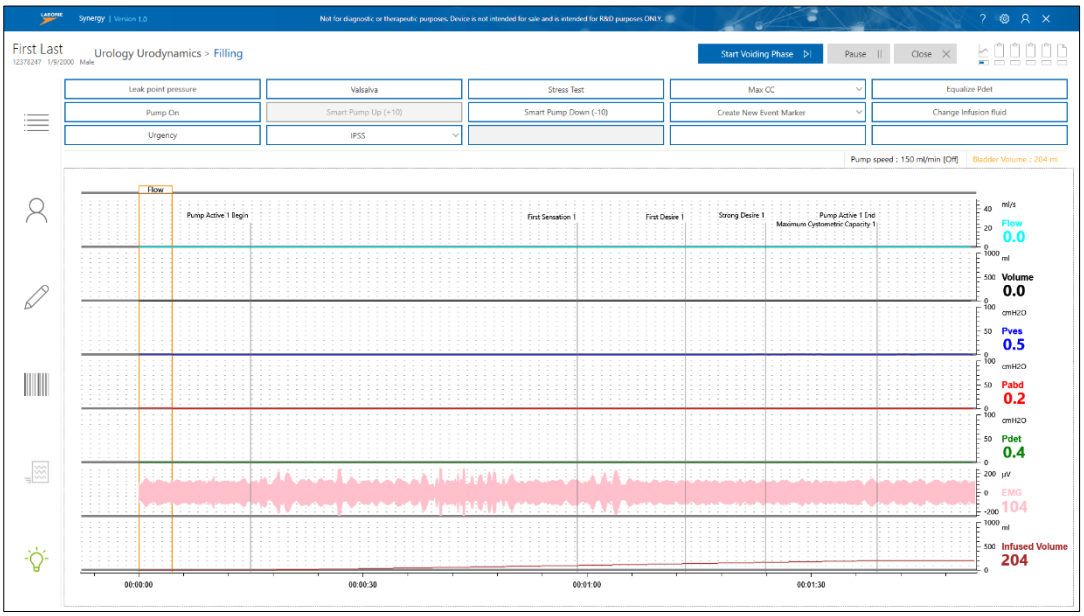



*Figure 23: Pressure Flow Filling Phase*

5. When the patient starts to feel discomfort or fullness, stop the Infusion Pump by clicking the **Pump Off** button in the Synergy software. Click the **Start Voiding Phase** button to move to the next phase.

⚠ **Caution:** Infusion can be stopped at ALL TIMES by pressing the grey pump stop button on the NXT Go Pump Hub, by opening the pump door, or by disconnecting the filling tube from the catheter or the water bag.

### 3.3.2.4 Voiding Phase

The **Voiding** phase will begin (Figure 24). Click the **Permission To Void** button and ask the patient to void through the commode chair into the Urocap NXT setup. See

1. Preparing the Urocap NXT for a reference image of the Urocap NXT Setup. If the patient fails to void re-click the **Permission to Void** button to create a new marker; this action will shift the previous marker to 'Attempt to Void'.

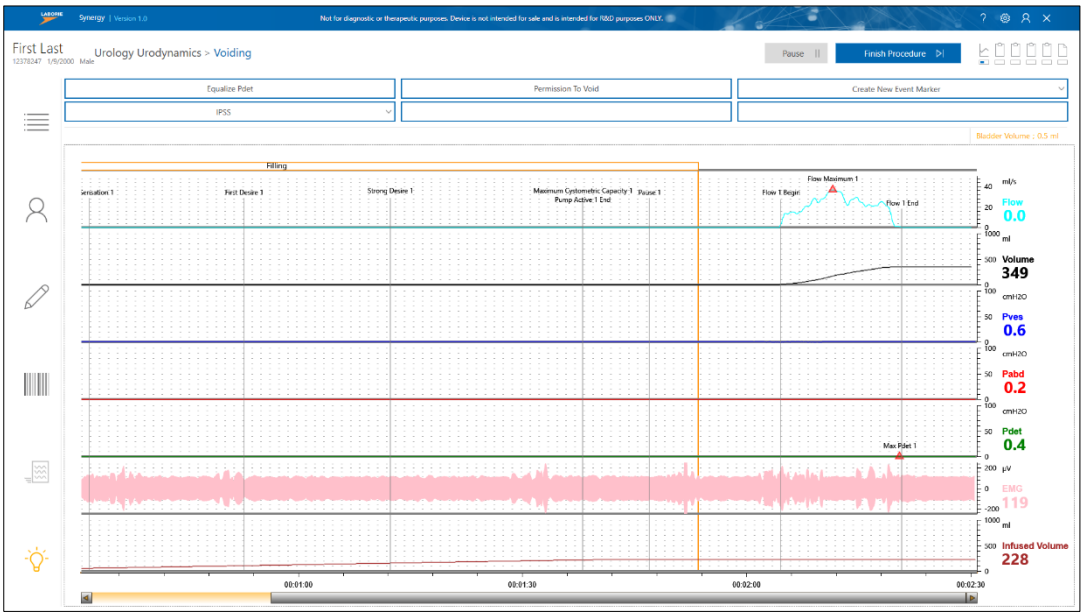



*Figure 24: Pressure Flow Voiding Phase*

2. The voiding phase will stop 60 seconds after voiding ends.
3. **A Post Voided Residual** window (Figure 21) will pop-up. Select the preferred method of capturing Post Voided Residual (PVR), meaning the amount of fluid remaining in the bladder at the completion of the voiding phase. Click **OK** to move to the Report.

### 3.3.2.5 Urology Urodynamics Report

1. A preview of the Pressure Flow Report will be generated using the default (UDS) configuration settings. The user can apply the default configuration for the report or customize the report. For information on customizing the report, refer to the Reports section on page 65.
2. Click the **Finish** button to close the report. The report will then appear under the **Studies** tab in the **Patient Details** section.
3. The operator may begin a secondary test with the same patient, under the guidance of the overseeing physician, or continue to finish the study.

# 3.4 Cystometry Study

A Cystometry study involves filling the bladder and determining the Detrusor pressure Pdet = Pves – Pabd (the difference between the pressure inside the bladder (Pves) and the pressure inside the abdomen (Pabd)). The Cystometry study provides one phase to complete filling and voiding. This allows the user flexibility in procedure structure.

## 3.4.1 Starting the Cystometry Study

Start the Cystometry study as described in the Starting a Study section on page 30.

The study requires the use of the Urocap NXT, Roam NXT, NXT Go Pump Hub, and Bluetooth Dongle NXT. Ensure all modules are connected in the Synergy Software. Ensure that the Urocap NXT and Roam NXT are fully charged. The Synergy Software will recognize the PIM NXT and the Roam NXT as one device under the title Roam NXT.

## 3.4.2 Performing the Cystometry Study

### 3.4.2.1 Preview phase

Complete patient and consumables setup during this phase. Refer to the Setting Up Consumables and Preparing the Patient section on page 24. Once patient and pump setup are complete proceed to the **Cystometry Phase.**

### 3.4.2.2 Cystometry phase

1. Click the **Start Cystometry Study** button.
2. Click the **Pump On** button to start the Infusion Pump and begin filling the bladder. Click **Smart Pump Up** or **Smart Pump Down** buttons to increase or decrease the pump speed, respectively.

**NOTE:** To change the infusion bag click the **Change Infusion Fluid** button. A popup window will appear, and the study will pause. If desired, update the Fluid Density setting using the dropdown menu available on the popup window and click **OK** to resume the study. Fluid density options must be configured in the **Workflow Configuration** window before starting the study. Refer to the Customizing Workflows section on page 56.

3. Encourage the patient to give feedback on sensation or urge. Mark relevant events (e.g.: **First Sensation, First Desire, Strong Desire**, etc.) by clicking the **First Sensation** drop-down menu and selecting the relevant event.
4. When the patient starts to feel discomfort or fullness, stop the Infusion Pump by clicking the **Pump Off** button in the Synergy software.

**Caution:** Infusion can be stopped at ALL TIMES by pressing the grey pump stop button on the NXT Go Pump Hub, by opening the pump door, or by disconnecting the filling tube from the catheter or the water bag.

Click the **Permission To Void** button and ask the patient to void through the commode chair into the Urocap NXT setup. See

5. Preparing the Urocap NXT for a reference image of the Urocap NXT Setup. If the patient fails to void re-click the **Permission to Void** button to create a new marker; this action will shift the previous marker to 'Attempt to Void'. If the

**Permission to Void** button is selected in error, delete the event and continue "filling phase" activities by pressing the **Pump On** button.

6. The Cystometry phase will stop 60 seconds after voiding ends. Alternatively click the **Finish Procedure** button.
7. **A Post Void Residual** window will pop-up. Select the preferred method of capturing Post Voided Residual (PVR), meaning the amount of fluid remaining in the bladder at the completion of the voiding phase. Click **OK** to move to the **Review** phase.

#### 3.4.2.3 Review and Report Phases

Review study data and adjust markers in the Review phase. Click the **Report** button to proceed to the Cystometry Report. Customize and save report layout.

# 3.5 Tests

The following tests can be completed within Urodynamic studies that provide a **Filling** or **Cystometry** phase.

## 3.5.1 Stress Test

1. Commence the stress test once the patient's bladder had been infused with 150-200ml of fluid. Position the patient so that the meatus, the urinary opening, is easily observed.
2. Select the **Stress Test** toggle button to begin the stress test. Clicking the **Stress Test** toggle button will automatically stop the pump.
3. If a leak is observed select the **Leak** button to mark the event.
4. Select the **Stress Test** toggle button again to end the stress test. A pop-up window will appear showing a suggested designation for the stress test.
5. Synergy automatically assigns each stress test based on events marked within the range. To change the assigned type designation, select the option and press **OK** (Figure 25). Changing the designation will add or remove the events marked in the stress test.


*Figure 25: Stress Test Designation Window*

6. Repeat the test after every 150ml to 200ml infused until stress incontinence is documented or ruled out.
7. Finish the selected study.

## 3.5.2 Urethral Pressure Profile

To start a Urethral Pressure profile (UPP) follow instructions provided in the Customizing Workflows section on page 56 on adding a UPP phase to a study or select a study template that contains a UPP phase. Ensure to complete patient and consumables setup as instructed in the Setting Up Consumables and Preparing the Patient section on page 24.

### 3.5.2.1 Manual Urethral Pressure Profile

To complete a Manual Urethral Pressure Profile, follow the instructions below:

1. In the UPP phase, confirm the positioning of urethral pressure sensor (Pura) just proximal to the bladder neck. To position the sensor, manually withdraw the catheter at a moderate rate. When Pura begins to rise, stop withdrawing and return the catheter slightly back into the bladder.
2. Select the **Rest Profile** toggle button to start the rest profile.
3. Begin manually withdrawing the vesical catheter very slowly, pulling at approximately 1mm/second by using the measurement marking on the catheter. Vesical pressure should remain stable while urethral pressure and closure pressure (Pclo) rises and falls indicating that the sensor is travelling through the urethra.
4. When Pclo returns to zero, stop pulling and reselect the **Rest Profile** toggle button to end the profile.
5. Reinsert the catheter and position just proximal to the bladder neck to complete a Stress Profile using the **Stress Profile** toggle button. Once the required number of profiles is complete, finish the selected study.

### 3.5.2.2 Mechanical Urethral Pressure Profile

For a Mechanical Urethral Pressure Profile, ensure that the UPP puller NXT is connected in the **Device Manager** window. Select the **Puller** option and set the **Puller Speed** under **Profile Settings** in the **Workflow Configuration** window before starting the test. To complete a Mechanical Urethral Pressure Profile, follow the instructions below:

1. In the UPP phase, confirm positioning of the urethral pressure sensor (Pura) just proximal to the bladder neck. To position the sensor, manually withdraw the catheter at a moderate rate. When Pura begins to rise, stop withdrawing and return the catheter slightly back into the bladder.
2. Ensure that the UPP Puller is in the start position. If the **Rest Profile** and **Stress Profile** buttons are greyed out in the Synergy Control Panel, click the **Puller Return** button to return the UPP Puller to the start position.
3. Feed the catheter through the Catheter Guide and use the Catheter Clamp to secure the catheter to the UPP Puller NXT.
4. Select the **Rest Profile (On)** toggle button to start the rest profile. The UPP Puller will begin pulling at the speed selected in the Workflow Configuration.

**NOTE:** UPP Puller NXT speed can only be adjusted in the **Workflow Configuration** window prior to starting the test.

5. Select the **Rest Profile (Off)** toggle button to mark the end of the profile. Click the **Puller Return** button to return the UPP Puller NXT to the start position.
6. Manually reinsert the catheter and position just proximal to the bladder neck to complete a Stress Profile.

7. Select the **Stress Profile (On)** toggle button to start the stress profile. The UPP Puller will begin pulling at the speed selected in the **Workflow Configuration** window.
8. Select the **Stress Profile (Off)** toggle button to mark the end of the profile. Click the **Puller Return** button to return the UPP Puller NXT to the start position.
9. Manually reinsert the catheter and position just proximal to the bladder neck to repeat the profile. Once the required number of profiles is complete, finish the selected study.

# 3.6 Finishing the Studies

1. When all tests have been completed, remove any catheters and EMG patches from the patient and dispose of them in accordance with hospital/clinic procedures. Ensure to deflate Abdominal Fluid NXT Catheter Balloons before removal.
2. Empty the beaker. The beaker should then be thoroughly washed and reused. Refer to the Maintenance and Service section on page 75 for further information.
3. Remove and dispose of the Infusion Pump Tubing and any other consumables used during the study.

# 3.7 Printing the Study Result (Optional)

1. Select the patient from the **Patients** section, on the main screen, and click the **Studies** tab in the **Patient Details** section.
2. Click the **Report** button. The report window will then be displayed using default configuration as shown in the figure below.
3. Ensure that the printer is turned on and connected to the system. Click the **Print**  icon to display the **Print** pop-up window and click the **OK** button to print the report.

**NOTE:** The user may also print the report at the end of the study once all data has been recorded. A preview of the report is generated, the user can apply changes to the report and then click the **Print** icon.

# 3.8 Troubleshooting

- For FAQs and troubleshooting tips, refer to the Troubleshooting Guide section on page 91. If problems cannot be resolved, contact the LABORIE Service team at 1-800-333-1039 or email service@laborie.com.

# 4 Synergy Software

This section provides an overview of Synergy software functions and features based on standard workflow:

1. Accessing Synergy
    i. User Access Control
    ii. Sections and Icons in the Main Window
2. Overview of Synergy Setup Features Required to Start a Study
    i. Patient Management
    ii. Study Management
3. Overview of Synergy Functions Available During a Study
    i. Workflow Steps
4. Study Process Review
    i. UDS Intelligence



## 4.1 User Access Control

### 4.1.1 Login

To login to Synergy, follow the steps below.

1. Double-click the Synergy shortcut icon on the desktop or launch the Synergy application from the LABORIE Dashboard. The Synergy Login Page will be displayed (Figure 26). Upon first login ensure to accept the **End User License Agreement**.
2. Input account **User Name** and **Password** into the Synergy Login Page. Initial access information will be set up during system install. Users must update all access information upon first use; do not use generic or universal login credentials. Additional access accounts may be created by utilizing the **User Setup** function**.**

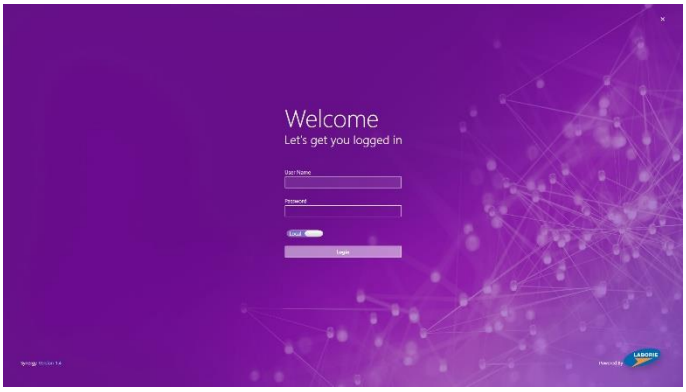



*Figure 26: Synergy Login Page*

A successful login will display the Synergy Main Window. For an overview of features available on the Main Window, refer to the Sections and Icons in the Main Window section on page 46.

**IMPORTANT**: Do not leave the computer unattended once login is completed. LABORIE recommends that the user manually lock the computer before leaving the computer workstation.

## 4.1.2 Creating User Accounts

Synergy facilitates four basic account structures: Local Admin, Local User, Domain Admin, and Domain User. Local Accounts are managed within Synergy by Local Admins. Domain accounts are intended to link to the Active Directory of the user institution; if creating domain accounts, ensure that all roles within Synergy align with the Active Directory User Group roles of the user institution.

### 4.1.2.1 User Account Setup and Password Reset

To create a new account in Synergy, the user must have a Local Admin or Domain Admin account. To create new user accounts, follow the instruction provided below.

1. Click the Admin icon located on the Synergy title bar and select **User Setup** (Figure 33)**.**

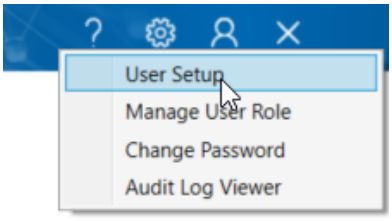



*Figure 27: Accessing User Setup Application*

2. The User Setup window will popup (Figure 28). To create a new account, input **Username, Password, First Name, Last Name, and Email.** Select **Local Admins** or **Local Users** under the **Role** section to set account type. Press **OK** to complete account setup**.**

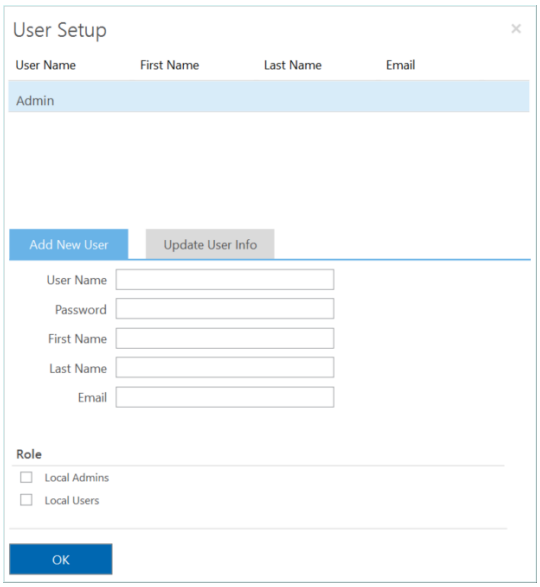



*Figure 28: User Setup Window*

3. To reset the password of an active account, select the existing account from the user list. Under the **Update User Info** tab, enter the new password and press **OK** (Figure 29).

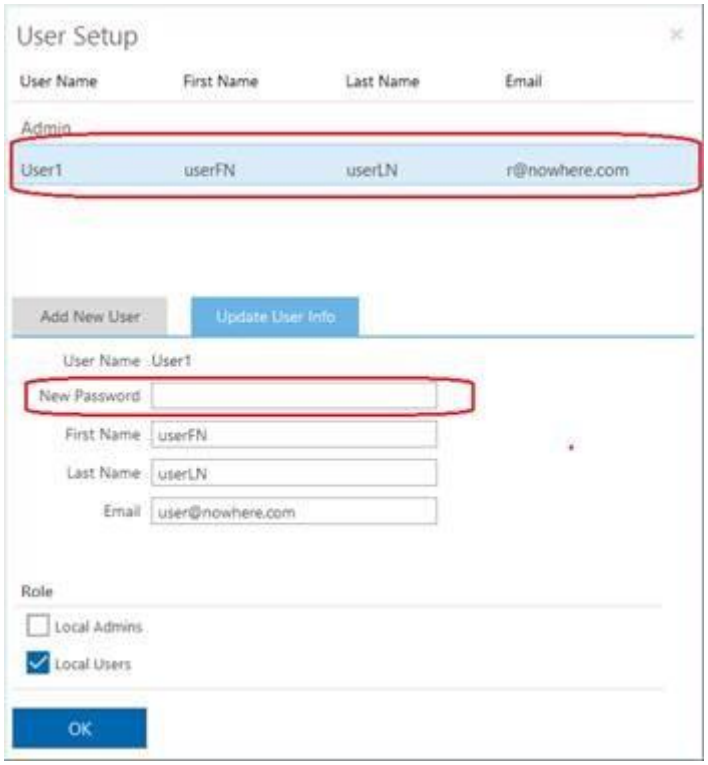



*Figure 29: Password Reset*

**NOTE**: Local and Domain Users may reset their own passwords ONLY. Local or Domain Admin access is required to reset password information for other users.

### 4.1.2.2 Managing User Role

All Synergy account types have pre-set permissions that control which function users may access based on user roles. Local and Domain Admins may manage user role permissions with the **Manage User Role** window. Follow the instructions provided below for managing user roles.

1. Click the Admin icon located on the Synergy title bar and select **Mange User Role** (Figure 30).

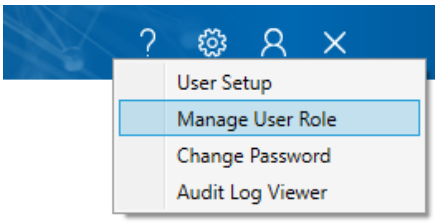



*Figure 30: Accessing the Manage User Role Application*

2. The **Manage User Role** window will pop-up (Figure 31). To create a new role, press **Add**.

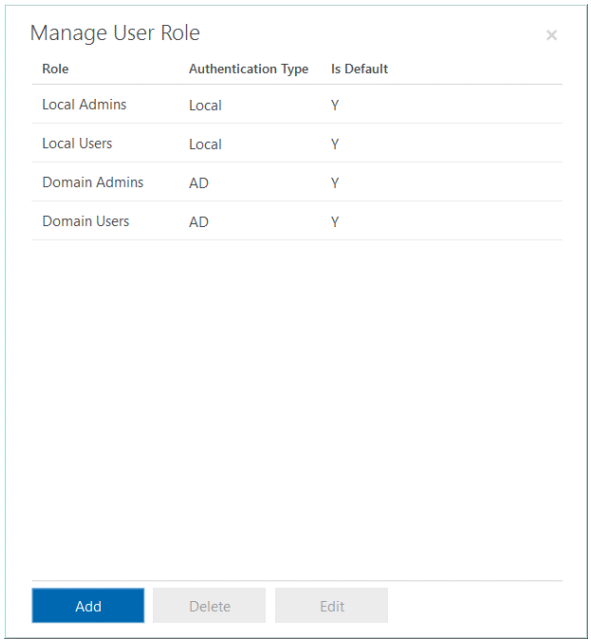



*Figure 31: Manage User Role Window*

3. Create a new role by entering a new title in the **Role** category and selecting an **Authentication Type** from the dropdown menu (Figure 32). Select all the functions desired for access by the new user role, and press **Save**.

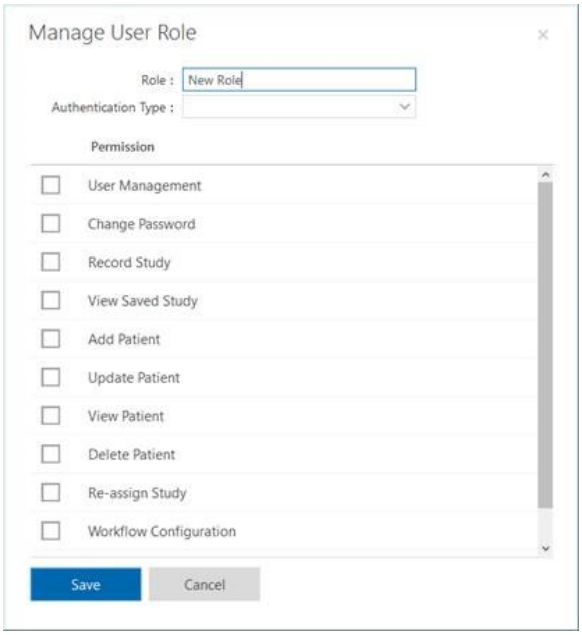



*Figure 32: Adding New User Role*

4. To reassign the account role, click the Admin icon located on the Synergy title bar and select **User Setup > Update User Info Tab.** Select the newly created role; press **Save**.

# 4.2 Sections and Icons in the Main Window

This section overviews the various features accessible from the Main Window.

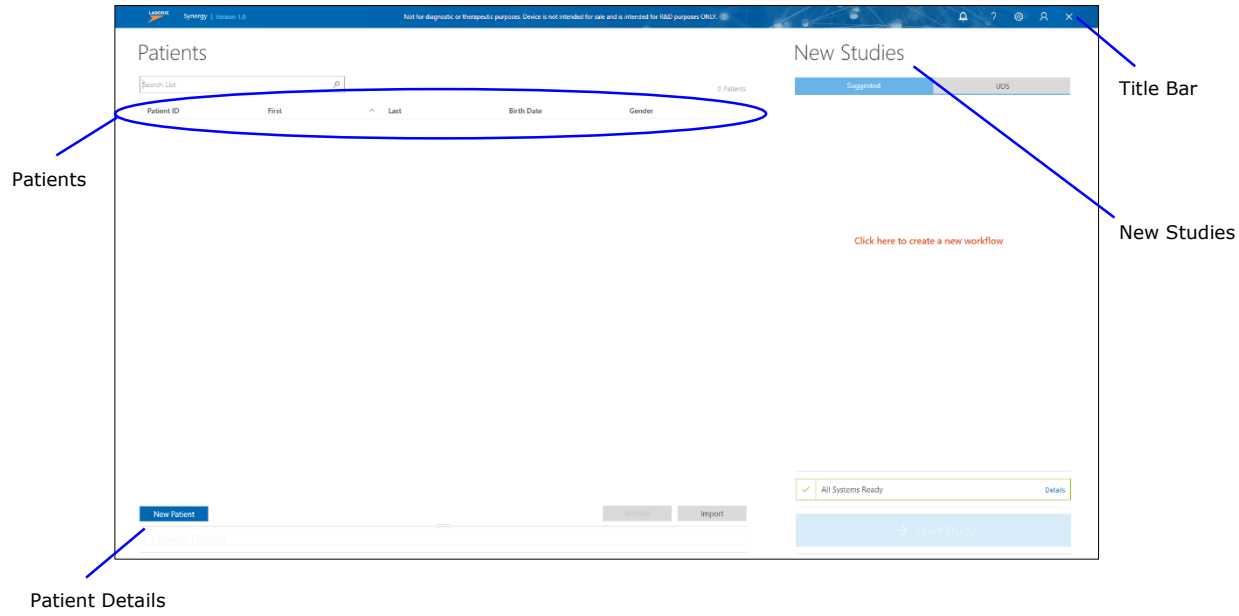



*Figure 33: Synergy Main Window Reading Guide*

### 4.2.1 Overview of Sections

A brief overview of the sections in the **Main Window** is provided in Table 2. Refer to Figure 33 for a visual guide showcasing the location of all sections described.

| Section Name | Section Description |
|---|---|
| **Patients** | Lists all the patients. Add a new patient, delete patient, and search for a required patient. |
| **Patient Details** | Edit the patient information, enter relevant medical history, select symptoms, displays previously conducted studies, and allows you to reassign a study. |
| **New Studies** | Displays all configured studies under **Suggested** and **UDS** tabs accordingly. |
| **Title Bar** | Contains icons that allow you to access **Help file**, **Settings**, **Admin Profile**, and **Close Application**. |

*Table 2: Synergy Main Window Section Overview*

### 4.2.2 Overview of Icons in the Title Bar

A brief description of the icons located on the **Title Bar** in the **Main Window** is provided in Table 3 below. Refer to Figure 33 for a visual guide showcasing the location of all sections described.

| Icons | Description |
|---|---|
| **Notifications** | Click this icon to view to view system notifications and error messages. |
| **Help** | Click this icon to launch the help file. |
| **Settings** | Click this icon to access **System Settings**, **Device Manager**, **Patient Settings**, **Database Management** and **Workflow** options. |
| **Admin** | Click this icon to access **User Setup**, **Manage User Role**, **Change Password**, and **Audit Log Viewer**. |
| **Close** | Click this icon to close the Synergy application. |

*Table 3: Title Bar Icon Overview*

#### 4.2.2.1 Settings

The options under the **Settings** icon are described in Table 4 below.

| Options | Description |
|---|---|
| **System Settings** | Contains **System Information** and **System Configuration** options. |

| | |
|---|---|
| **Device Manager** | Displays the **Device Manager** window. |
| **Patient Settings** | Contains **Patient Display Settings**, **Deleted Patients**, **Attending Doctors**, **Investigators**, **Referrals**, and **Patient Groups** options. |
| **Database Management** | Contains **Archive Patients**, **Import Patients**, and **Deleted Patients** options. |
| **Workflow** | Contains **Editor**, **Import Custom Workflow**, and **Export Custom Workflow**. Editor displays the **Workflow Configuration** page; create new workflows and set hardware channels. |

*Table 4: Settings Options Overview*

#### 4.2.2.2 Admin

The options under the **Admin** icon are described in Table 5 below.

| Options | Description |
|---|---|
| **User Setup** | Displays the **User Setup** window; you can add new users (for Local accounts), and update user information (for Local users). |
| **Manage User Role** | Displays the **Manage User Role** window. |
| **Change Password** | Displays the **Change Password** window; you can change the Synergy login password. |
| **Audit Log Viewer** | Displays the **Audit Log Details** table which contains the event logs (for Synergy software) on the local machine. |

*Table 5: Admin Options Overview*



# 4.3 Patient Management

## 4.3.1 Patients

The **Patients** section in the Main Window (Figure 34) lists all patient files and allows the user to:

- Add a new patient
- Delete a patient
- Search for a required patient
- Reassign a study
- View Patients entered through EMR

For information on performing any of the listed tasks, refer to the instructions provided below.

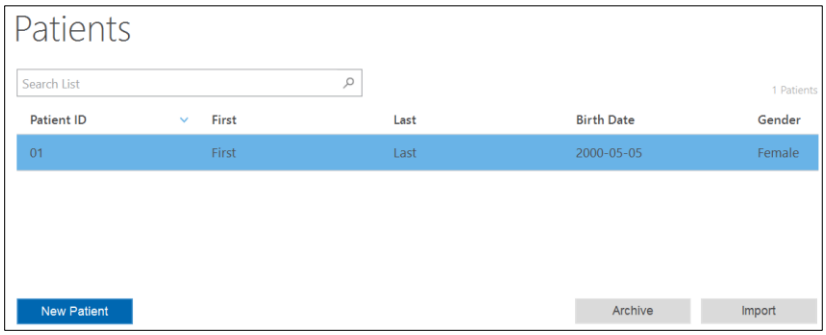



*Figure 34: Patients Section*

### 4.3.1.1 Adding a New Patient

1. Click the **New Patient** button in the **Patients** section.
2. Enter the patient details in the **Patient Details** section under the **Info** tab (Figure 35).
3. Click the **Save** button under the **Info** tab to save the patient details.
4. If required, enter the relevant past medical history under the **History** tab. Synergy will automatically save information entered.

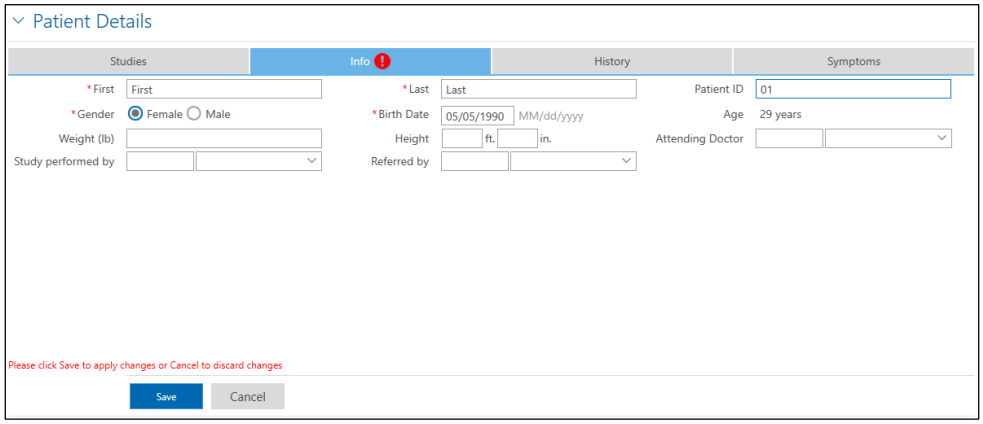



*Figure 35: Default Patient Details*

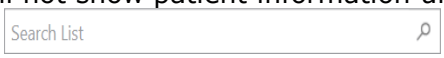
**NOTE:** Fields in the **Patient Details** section can be customized through the **Patient Settings** window. Click the **Settings** Icon > **Patient Settings** > **Patient Display Settings**. Fields can be customized for the **Patients** section and the **Patient Details**. Mandatory fields are marked with a red asterisk.

### 4.3.1.2 Deleting Patient Data

1. Select the patient in the **Patients** section and right-click to open the context menu. Select **Delete <<Patient Name>>** option.
2. A **User Notification** window will appear. Click the **Ok** button to proceed.

**NOTE**: Deleted Patients can be restored from the Database Management window.

### 4.3.1.3 Searching for a Required Patient

The **Patients** section will not show patient information until a search is initiated. Use the **Search List** search box 

located in the **Patients** section to search for a required patient. Enter an asterix "*" to view all patients, a plus sign "+" to view the last entered patient, or an element of the patient's name to view a specific patient. All fields provided in the **Patients** section are searchable.

### 4.3.1.4 Exporting Patient Data

Patient data can be exported from the system in different forms (e.g. PDF, HTML, RTF, DOCX, XLS, XLSX, Image) to a computer. Follow the instruction provided below to export patient data.

1. Select the patient from the **Patents** section.
2. Open the report from **Patient Details**.
3. Click the export icon, the **Export Document** window will be generated.

**NOTE:** The export Export... drop-down icon can be used to select the required format to export the report. The **Export Document** window will be generated (Figure 36).

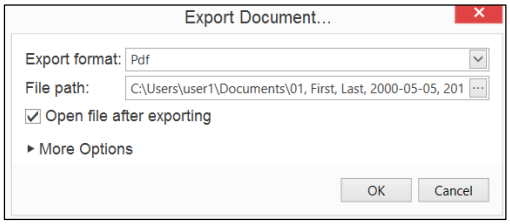



*Figure 36: Export Document Window*

4. Select the required format, file path, and other required options. Click the **OK button**.

### 4.3.1.5 Reassigning Study

The reassign function allows the user to transfer study results from one patient to another if the wrong patient was selected. Exercise caution when using this functionality.

1. Select the patient in the **Patients** section. Select the study to reassign under the **Studies** tab in **Patient Details** section. Right-click on the study and select the **Reassign Study** option.
2. Select the appropriate patient to reassign the study within the **Patients** section. Right-click and select **Reassign Study to <Patient Name>** option. A **User Notification** window will pop-up.
3. Click the **Ok** button to confirm the reassignment of the test.
4. To cancel reassignment, right click on the patient and select the **Cancel** option.

**NOTE:** If the study being re-assigned was previously sent to Electrical Medical Records, contact the EMR vendor and request the deletion of the previously sent report. Synergy will provide a warning message requesting confirmation of action when re-assigning a study previously sent to EMR.

## 4.3.1.6 View Patients Entered through EMR

The **Patient** section will show an icon indicating patients entered through the Electronic Medical Records (EMR) functionality in the EMR column (Figure 37).

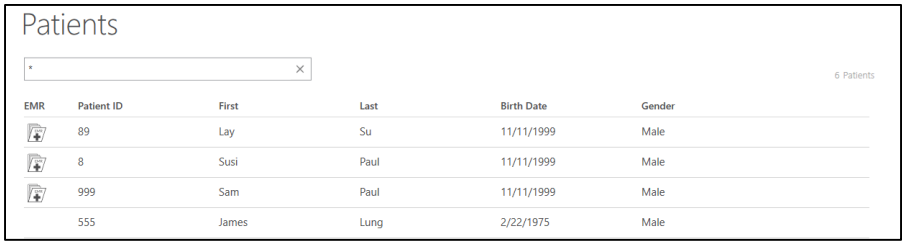



*Figure 37: Patient List - EMR*

By default, this EMR column is not visible. To make it visible, navigate to **Settings** > **Patient Display Settings.** By default, the **EMR** field will be off. Select **Table** in the table options column and click **Save** (Figure 38)**.**

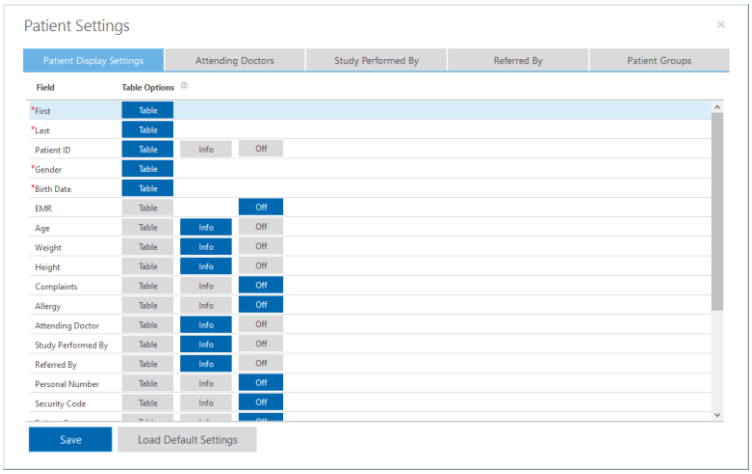



*Figure 38 Patient Settings – EMR*

**NOTE:** EMR is an add-on feature that must be configured to interact with Synergy. Contact LABORIE Service for information on EMR.

## 4.3.2 Patient Details

The **Patient Details** section (Figure 35) in the Main Window allows the user to:

- View previously conducted studies under the **Studies** tab
- View EMR status: report successfully sent or report not sent .
- Create or edit patient information under the **Info** tab
- Enter relevant medical history under the **History** tab
- Select symptoms under the **Symptoms** tab

**NOTE:** All studies, including partial studies, will be stored under patient details once the study has started. Studies closed during the first preview phase will not be saved.

### 4.3.2.1 Symptoms

The patient symptoms are available under the **Symptoms** tab (Figure 39), and can include:

- Involuntary Leakage on Effort/Exertion
- Involuntary Leakage associated with urgency and also effort/exertion
- Post-Prostatectomy Leakage
- Urgency with Involuntary Leakage
- Low Capacity
- High Capacity
- Frequency
- Urgency without Leakage
- Decreased Bladder Sensation
- Increased Bladder Sensation
- Absent Bladder Sensation
- Feeling of incomplete bladder emptying
- Weak/intermittent stream
- Post-void dribbling
- Hesitancy
- Straining to Void
- Position-dependent Micturition
- Dysuria (Painful Voiding)
- Vaginal Prolapse Symptoms
- Polyuria
- Nocturia
- Enuresis
- Pelvic Pain

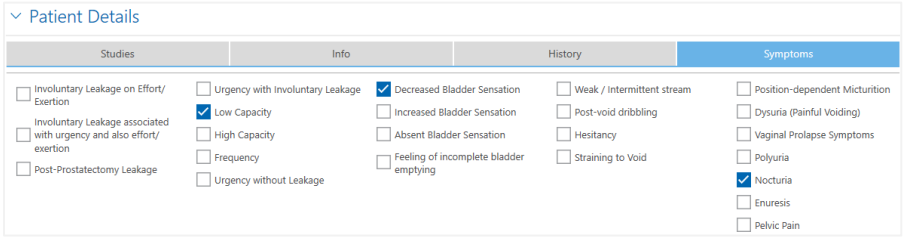



*Figure 39: Patient Details – Symptoms Tab*

Select all symptoms that are relevant to the patient only once ready to start the study. Selected symptoms will be documented in the study report; symptoms are not saved in the Patient Details section.

## 4.3.3 Database Management

Navigate to the Toolbar and select **Settings** > **Database Management**. From this option select **Archive Patients**, **Import patients,** or **Deleted Patients** to launch the **Database Management** window.

### 4.3.3.1 Archiving Patients

Patient data can be archived into an encrypted file on the computer system or on an external hard drive. Follow the instructions below for archiving patient data.

1. Select the patients for archiving. All patients available in the database will appear in this window. To select patients individually, select individual check boxes. To select all patients select the checkbox located on the header (Figure 40).

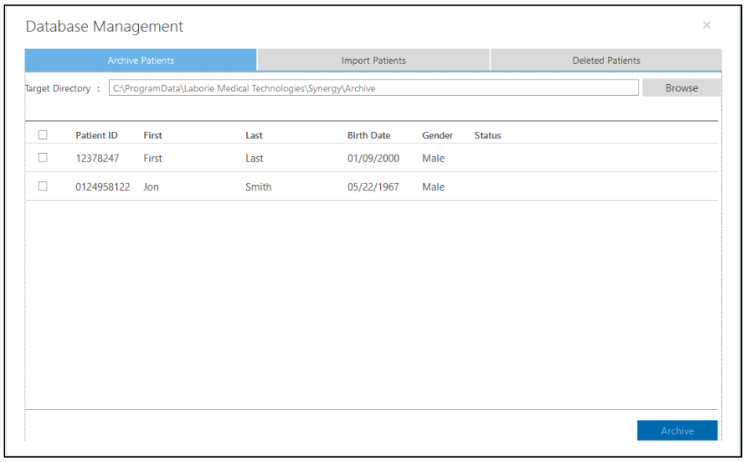



*Figure 40: Database Management – Archive Patients*

2. Ensure the Target Directory lists the desired location for patient archive. To select a different location, click the **Browse** button. Click **OK** to save changes or click **Cancel** to exit. By default, each time patients are archived a new folder will be created in the selected location.
3. Click the **Archive** button. A pop-up window will appear to confirm a successful archive. Archive status will also be displayed under the status column.

**IMPORTANT:** Once a patient is archived, data associated with the patient cannot be updated through EMR data transfer until the patient is restored.

### 4.3.3.2 Importing Archived Patient Data

Archived patient data can be imported to the Synergy software if that patient data is not already present in the Synergy database. Synergy will not allow for the duplication or overwriting of patient information.

1. Select the **Import Patients** tab in the **Database Management** window.
2. Click the **Browse** button and select an archived folder. All patients archived in this folder will be displayed in the **Database Management** window.
3. Select patients for import by using the provided checkboxes.

4. Click the **Import** button. A pop-up window will appear to confirm a successful import.

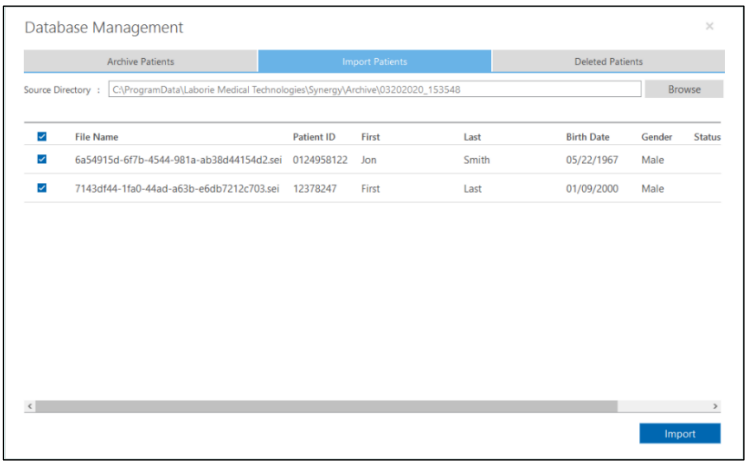



*Figure 41: Database Management – Import Patients*

## 4.3.3.3 Restore or Permanently Delete Patient Data

When a Patient is deleted from the **Patients** section, it can be restored from the **Database Management** window.

1. Select the **Deleted Patients** tab in the **Database Management** window (Figure 42).

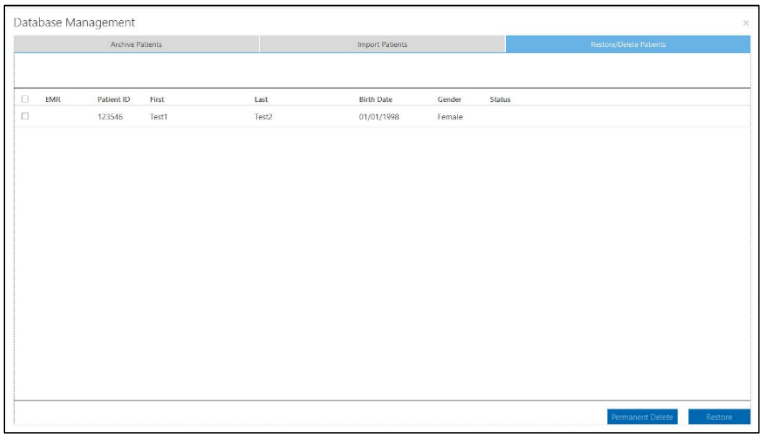



*Figure 42: Database Management – Deleted Patients*

2. Select the patients for data restore using the check boxes provided. To select patients individually, select individual check boxes. To select all patients, select the checkbox located on the header.
3. Click the **Restore** button; a User Notification window pops-up, click the **OK** button to restore the selected patients or the **Cancel** button to exit.

To permanently delete patients in the **Database management** window, select patients using the check boxes provided or select all patients using the checkbox located on the header. Click **Permanent Delete**. Exhibit caution when using this feature as this information cannot be restored.

# 4.4 Study Management

## 4.4.1 Workflows

Synergy Workflows control the structure and content of each study. Each Workflow has standard **Workflow Steps**: Procedure, Questionnaire, Report, and Review. Workflows vary by the phases contained in the default configuration of their **Procedure** workflow step. Access Workflow settings in the **Workflow Configurator** window by navigating to **Settings** > **Workflow** > **Editor**. The following workflow templates are available from the **Workflow Configurator** window:

- FreeFlow
  - Two phase procedure for uroflowmetry
  - Preview and Voiding
- Flow-EMG
  - Two phase procedure for uroflowmetry combined with EMG
  - Preview and Voiding
- Urology Urodynamics
  - Five phase procedure for standard Urodynamics
  - Preview, Voiding, Preview 2, Filling, Voiding
- Urogynecology 2P Urodynamics
  - Six phase procedure for Urodynamics with UPP using a single pressure bladder catheter
  - Preview, Voiding, Preview 2, Filling, Voiding, UPP
- Urogynegology 3P Urodynamics
  - Five phase procedure for Urodynamics using a single pressure bladder catheter
  - Preview, Voiding, Preview 2, Filling, Voiding
- Cystometry
  - Two phase procedure for Urodynamics with a combined filling and voiding phase called Cytometry
  - Preview and Cystometry

The workflows described above reflect default workflow templates. Setup workflows to appear under the **New Studies**, **UDS** tab on the Synergy Main window by creating copies or customizations of the workflow templates. Refer to instructions provided in the Customizing Workflows section on page 56.

To start a study, workflows must appear in the **New Studies** section of the Main Window.

**UDS** tab

Upon initial install Synergy will not show any workflows under the **UDS** tab. Studies are added to the **UDS** tab once workflow templates are copied, customized, then saved in the **Workflow Configurator** window.

**Suggested** tab

Studies are suggested based on patient file inputs such as patient symptoms and patient history. Scientific references are available in the help menu of Synergy.

**NOTE:** Studies must be shown in the **UDS** tab to be suggested.

## 4.4.2 Customizing Workflows

The **Workflow Configuration** window has three main sections: **Workflow** drop down menu, **Workflow Steps**, and **Settings Tabs**. To customize workflows or add workflows to the **UDS** tab, begin by creating a copy of the workflow template.

1. Click **Settings** > **Workflow** > **Editor** in the title bar to launch the **Workflow Configuration** window (Figure 43).

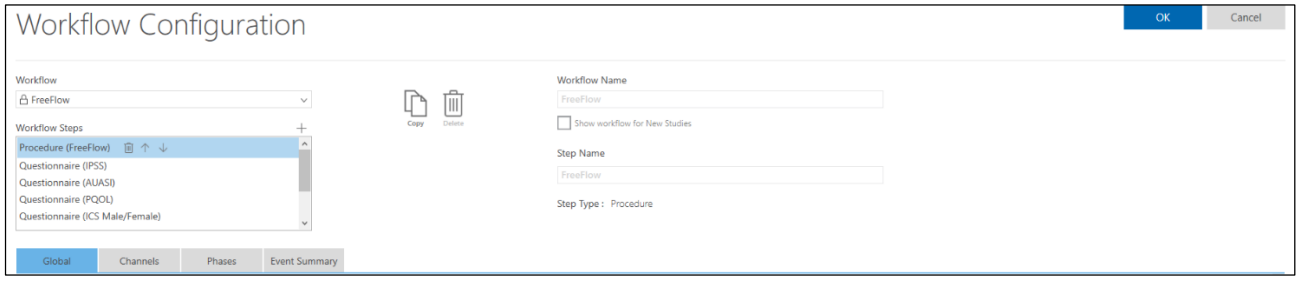



*Figure 43: Workflow Configuration Window – Channels Tab*

2. Select the workflow template to edit from the **Workflow** drop down menu and click the **Copy** icon. This will unlock editing options for the **Workflow Steps** and **Settings Tabs**.
3. Rename the workflow under the **Workflow Name** option.

**NOTE:** The name of the workflow, default or customized, will be shown on the header of the study phases and on the final report.

4. Ensure that the **Show workflow for New Studies** option is selected. To add the workflow to the **UDS** tab on the Synergy Main window click **OK** or continue customization.

Configure custom workflows by completing the following steps:

1. Customize workflow step naming by selecting a step under **Workflow Steps** and assigning a new name under **Step Name** if desired. Update **Workflow Steps** layout by using the plus +, up/down ↑ ↓, and delete icons provided.
2. Select **Procedure** from under **Workflow Steps**. Customize **Global**, **Channel**, **Phase**, and **Event Summary** settings by using the corresponding tabs available.
    a. The **Global** settings tab provides settings standard across the default workflows. These settings customize the view of the graph and its channels during a study. Set preferences for features such as **Urocap Noise Reduction Level** and **Profile Settings**.
        i. Use the **Urocap Noise Reduction Level** feature to detect and smooth chart spikes caused by environmental noise. Contact LABORIE Service for guidance on option selection.
        ii. Select UPP method, Manual Pull or Puller, using **Profile Settings**. If using the Puller method ensure to set Puller Speed. To run a UPP ensure a default workflow is selected that contains a UPP phase, such as Urogynecology 2P Urodynamics or Urogynecology

3P Urodynamics. Alternatively create a custom workflow by adding a UPP phase to the default workflow templates provided.

b. The **Phases** setting tab allows for customization of auto and manual event markers per phase and of phase layout.

   i. Refer to the Customizing Control Panel section on page 58 for information on customizing event markers.

   ii. The **Phases** tab provides a phase layout for the workflow selected. Update phase layout for custom workflows by using the plus +, up/down ↑ ↓, and delete 🗑 icons provided. Rearrange or delete phases under the **Protocol** heading by clicking on the phase heading and using the appropriate icon to complete the change. To add a phase, Select the **Protocol** heading and click the plus button. Select the desired phase from the popup window and click **OK** (Figure 44).

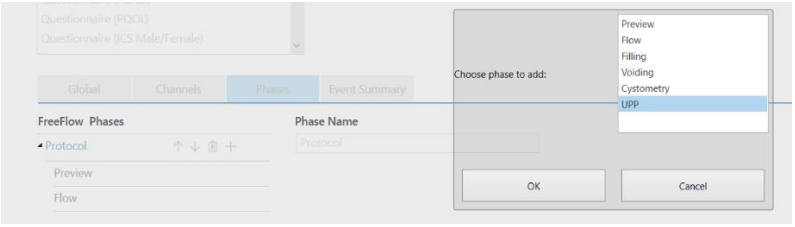



*Figure 44: Adding a Phase to a Custom Workflow*

   iii. Adjust **Fluid Density** in the **Phases** tab by entering a new value. The **Fluid Density** setting is available in the filling, voiding, and UPP phases. If updating **Fluid Density** settings, ensure to update in all relevant phases. Fluid density can be changed during a study using the **Change Infusion Fluid** button to fluid densities previously saved to the workflow. Click the fluid density dropdown menu to view previously saved fluid densities.

c. The **Channels** settings tab provides settings for hardware channels. Refer to the Accessing Hardware Channels section on page 60.

d. The **Event Summary** settings tab displays events for inclusion in the event summary. Select events for inclusion using the checkboxes provided. View event summary in the Review and Report of the completed study.

3. Select **Questionnaire** or **Review** under the **Workflow Steps**. Enable or disable automatic execution under the **Settings** tab.
4. Select **Report** under the **Workflow Steps**. Customize **Landscape Graph Scaling** settings by selecting scaling by **Number of Pages** or **Time per Page**.
5. Click the **OK** button to save the workflow.

#### 4.4.2.1 Workflow Step Settings Tabs

The following settings tabs are available under the **Procedure Workflow Step**:

- **Global**: Graph Settings, Channel Settings, Other Settings, EMG Settings, Profile Settings

- **Channels**: Channel Name, Channel Position, Channel Type, Unit, ScaleMax, ScaleMin, Color, Hardware channel, Chartdown Sampler
- **Phases**: Phase Name, Visible Channels, Channel Values Shown Separately, Workflow Additional Configuration Items, Additional Status Bar Items, Fluid Density Settings, Control Panel
- **Events Summary**: Select Event Names for inclusion in the **Event Summary** and view **Marker type**.

The following settings tab is available under the **Questionnaire Workflow Step**:

- **Settings**: Automatically Execute Questionnaire

The following setting tab is available under the **Report Workflow Step**:

- **Settings**: Silent Report Execution, Landscape Graph Scaling

The following setting tab is available under the **Review Workflow Step**:

- **Settings**: Automatically Execute Review, Control Panel

#### 4.4.2.2 Customizing Control Panel

The control panel is a customizable space available in each study phase window providing control buttons that allow the user to place study markers, control the pump, and perform other additional tasks. Buttons available in the control panel are standardized per study phase for default workflows. Customize buttons per study phase using custom workflows.

**IMPORTANT**: Workflows cannot be re-configured while a study is in progress. All workflow settings must be adjusted prior to beginning a study.

To customize the control panel, first create a custom workflow as instructed in the Customizing Workflows section on page 56. Then follow the instructions below to customize the control panel per study phase:

1. Click the **Phases** tab on the **Workflow Configuration** Window. Select a phase to customize from those listed. Scroll down to the control panel section located at the bottom of the window. Refer to Figure 45.

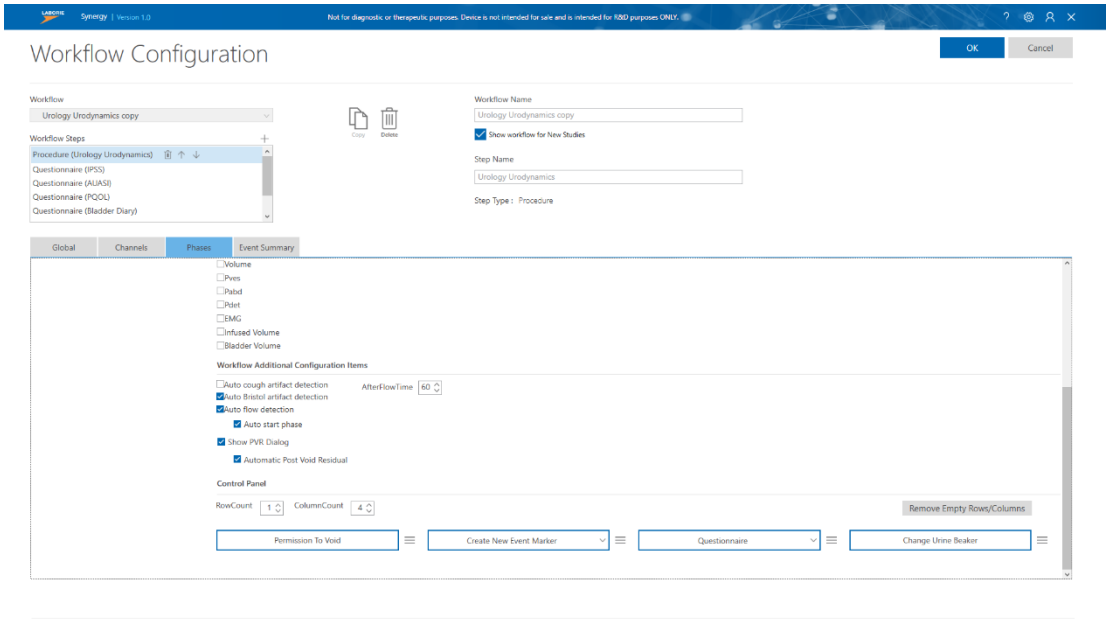



*Figure 45: Workflow Configuration Window - Control Panel*

2. Verify that the desired number of Control Panel buttons are provided. Use the **Row Count** and **Column Count** fields to increase or decrease the number of buttons shown in the control panel.
3. To add or change a button's label, click on the button to launch the **select action for button** window (Figure 46). Select the label of choice and press **OK**. To remove a button label, click the button to be adapted and select **Empty Button** in the action window; click **OK** to implement the change.

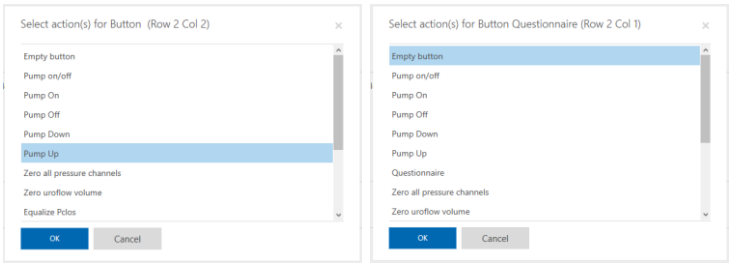



*Figure 46: Action Window – Adding, Changing or Emptying Button Label*

4. To customize the appearance of buttons, click the **Options** icon ☰ located beside the button. A window will appear where minor button functions and appearance may be adjusted (Figure 47). Options include button caption, colors, and connectivity. Once edits are complete click **OK.**

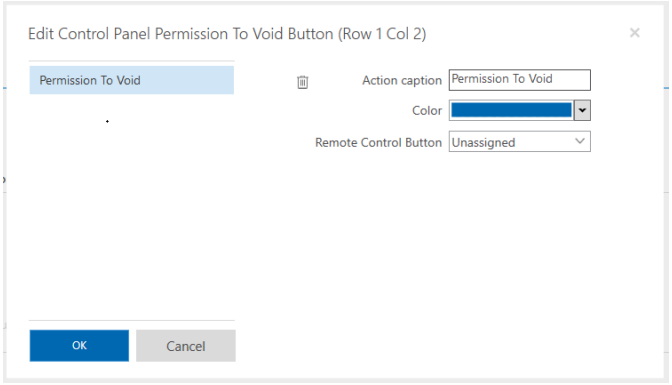



*Figure 47: Edit Control Panel Button*

5. Click the **OK** button located at the top of the **Workflow Configuration** window to implement all changes to the custom workflow.

## 4.4.2.3 Accessing Hardware Channels

To access hardware channels, click the **Settings** icon in the title bar, and then click **Workflow** > **Editor**. Select the required workflow then navigate to the **Channels** tab.

If hardware channels are not set correctly, a red exclamation point icon will appear on the **Channels** tab as shown in Figure 48.

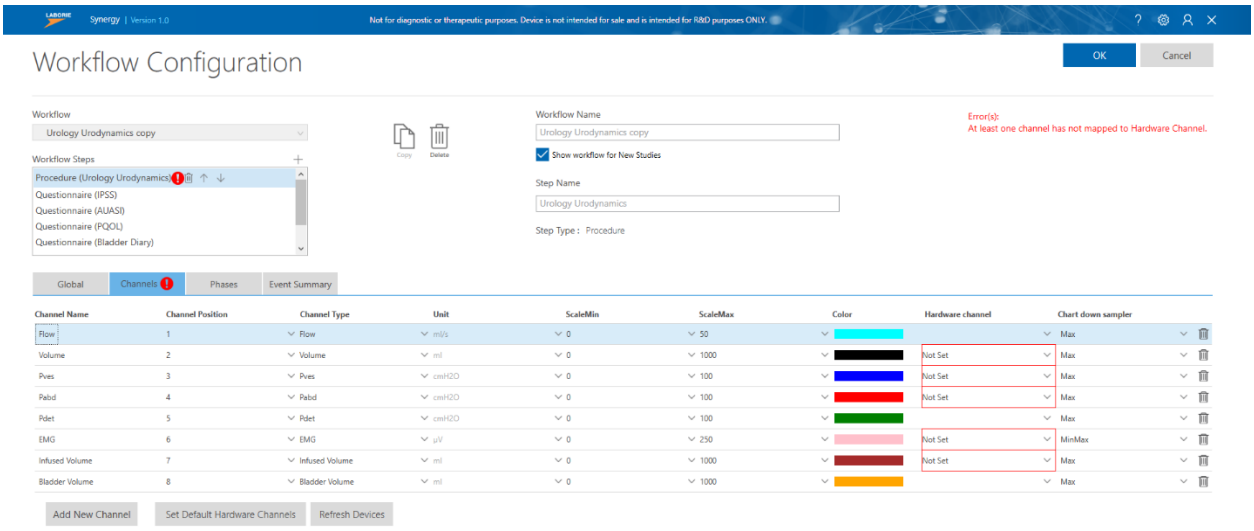



*Figure 48: Workflow Configuration with Hardware Channel Error*

To set hardware channels, first ensure to select the required **Workflow** option from the **Workflow** dropdown menu. Click the **Channels** tab and confirm the presence of all desired phases. Click the **Set Default Hardware Channels** button. Click the **OK** button to save changes and proceed to start study.

### 4.4.3 Start Study Button

The **Start Study** button (Figure 49) launches Synergy into the Preview Study phase.

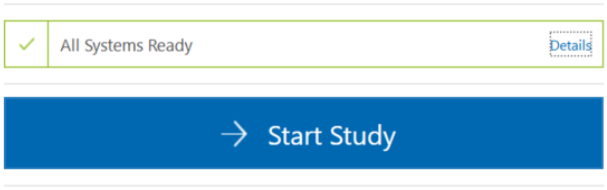



*Figure 49: Start Study Button*

Once all study inputs are received the button will shift to blue. When greyed out the button cannot be activated. Hover the curser over the **Start Study** button to activate tool tip functionality which will suggest troubleshooting options, as shown in Figure 50.


*Figure 50: Start Study Button Tool Tip*

**NOTE:** Always ensure patient and study of choice are selected and that all hardware channels and devices are linked before attempting to start a study.

**IMPORTANT**: The Synergy software will not allow the user to begin a study if the Roam NXT or Urocap NXT have under 15% battery charge available. To activate the start study button when the device battery is below 15%, connect the device to the applicable charging hub.

Connect the Urocap NXT to power using the NXT Magnetic Pogo Pin Cable; Urodynamic studies cannot be completed with the Urocap NXT seated within the NXT Hoop. Refer to the Urocap NXT section on page 105 for information on using the NXT Magnetic Pogo Pin Cable.

## 4.5 Workflow Steps

Studies in Synergy have standard workflow steps for users to complete. Standard workflow steps are **Procedure**, **Questionnaire**, **Report**, and **Review**. These steps can be customized and viewed through the **Workflow Configuration** window. Refer to the Customizing Workflows section on page 56.

The **Procedure** workflow step has a different phase breakdown depending on the type of study selected. Refer to the Workflows section on page 55 for phase break down per study workflow.

This section provides an overview of workflow steps, their phases, and their functions from the start to the completion of the study.

To proceed through the workflow steps and their phases, utilize the icons described below in Table 6:

| Icon | Button Description |
|---|---|
| Next | Allows the user to proceed to the next phase of the study. During a Urodynamic study the 'Next' icon will be accompanied by the title of the next study phase. |
| Pause | Allows the user to pause the study. |
| Resume | Allows the user to resume the study. |
| Close | Allows the user to close the phase window. |

*Table 6: Synergy Navigation Icons*

## 4.5.1 Procedure – Preview Phase

When a study is started, the **Preview** phase begins the **Procedure** workflow step. This phase facilitates all patient set-up activities.

### 4.5.1.1 Slide Sidebar

The slide sidebar provides access to patient, device, and quality process information throughout the study using quick access icons. Table 7 below provides an overview of each icon's functionality.

| Slide Sidebar Icon | Button Description |
|---|---|
| Patients | Displays the Patients section. |
| Patient Details | Displays the Patient Details. |
| History | Displays the Patient History. |
| Consumable Traceability | Displays the Consumable Traceability. For more information on Consumable Traceability, refer to the Consumable Traceability section on page 62. |
| Quality Control Check | Displays the Quality Control Check section which lists the modules, module statuses, and tasks which must be completed throughout the study. For more information, refer to the UDS Intelligence section on page 71. |
| Quick Results and Nomograms | Displays Quick Results and Nomograms for reference throughout the study. For more information, refer to the Quick Results and Nomograms section on page 67 |

*Table 7: Slide Sidebar Icon Overview*

## 4.5.1.2 Consumable Traceability

During the **Preview** phase, the user will need to enter each of the consumables applicable for the study under the **Consumable Traceability** window.

- The user can do this by either scanning the SmartSense tag on the product using the registration systems embedded in the NXT Go Pump Hub and the PIM NXT for TDOC, or by manually entering the required information. Any information entered for the consumables will be displayed in the **Consumable Traceability** window (Figure 51).
- During scanning of the consumable, the Roam NXT (connected to the PIM NXT) or the NXT Go Pump Hub will provide auditory feedback emitting a single beep to indicate scan in process, with an additional single beep for a successful scan or an additional 2 beeps for a failed scan.

**IMPORTANT:** Auditory feedback is not intended to act as a standalone indicator or as an alert for consumable scanning status. Operators must verify that consumables have successfully scanned into consumable traceability by verifying their addition in the **Consumable Traceability** window.

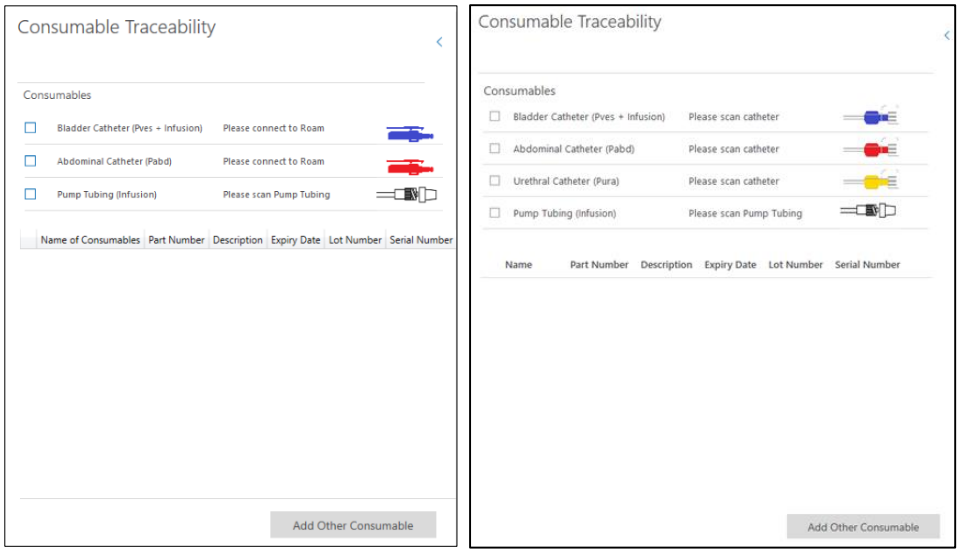



*Figure 51: Consumable Traceability –Air-Charged and Fluid Catheters*

Consumables are classified as automatic and manual. Follow the instructions provided below for scanning different types of consumables:

1. Automatic consumables (e.g. the Pves Catheter, Pabd Catheter, or Vinf Catheter enabled with a PIM connector) are automatically recorded when the catheters are inserted into the PIM NXT. Verify that the catheter appears in the **Consumable Traceability** window.

**IMPORTANT:** Automatic consumables cannot be manually entered into Consumable Traceability; they must be scanned by the PIM NXT.

2. Manual consumables (e.g. Pump Tubing, Extension Tubing, Pressure Measurement Tubing, Fluid NXT Catheters, or other supplies required for the study) must be either scanned using the registration system embedded in the NXT Go Pump Hub, or the required information must be manually entered in the **Consumable Traceability** window.

a. To use the scanner, hold the SmartSense tag located on the consumable's packaging in proximity to the scanner located on the NXT Go Pump Hub for 3 seconds. Verify that the consumable appears in the **Consumable Traceability** window.

b. To manually enter data into Synergy, press the **Add Other Consumable** button. In the manual consumable entry window, enter the **Name of Consumable**, **Type of Consumable**, **Expiry Date**, **Lot Number**, and **Serial Number** of the applicable consumable and click **Save** (Figure 52).

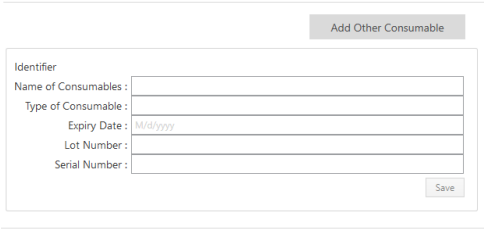



*Figure 52: Manual Consumable Traceability*

**NOTE:** If consumable registration fails consult Synergy screen for error codes indicating reason for failure.

**IMPORTANT:** Synergy will not recognize catheters or infusion pump tubing that have previously been registered in the software for other patients. Synergy allots catheters and infusion pump tubing two hours of activity once registered. Synergy considers consumables as registered to a specific patient once the user proceeds to the recording phases with the submitted consumables.

## 4.5.2 Procedure – Recording Phases

Once setup activities are complete, move to the recording phases of the **Procedure** workflow step. During the Recording phases, data received during the study is recorded. The Recording phases are **Flow**, **Filling**, and **Voiding**.

- As each Synergy channel records data, during the recording phases, it is displayed on screen as a continuous curve and as a digital value.
- Each Synergy channel is assigned its own color by default. To adapt the color of each channel, click the Channel Name to launch the editing window. Click on the assigned color and select a new color. Press **Ok** to save changes (Figure 53).

**NOTE:** The channel color can be changed during all workflow steps or configured in the workflow before beginning the study.

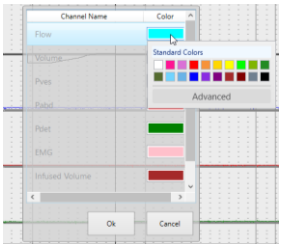



*Figure 53: Change Channel Color*

- In the **Flow** and **Voiding** phases, the Synergy software will automatically start to record data when the Urocap NXT detects the start of the flow. The **Voiding** phase will stop 60 seconds after voiding ends by default. The user may also click the **Next** icon to proceed to the next step.
- Events are marked on the graph as they are entered by the user or automatically generated by the software. They can be moved, deleted, or inserted during recording or during review once the study is complete. Some special events cannot be moved as they reflect a fixed point (e.g. pump on/off).
- All marks entered by the user are implemented through buttons located on the Control Panel. Any specialized buttons required for the study must be configured through workflow customization. Default workflows provide a range of default buttons commonly used for Urodynamics. For workflow customization refer to the Customizing Workflows section on page 56.
- Use the **Create New Event Marker** button located on the Control Panel to mark events during the test not previously assigned their own button. Markers entered in this field will be stored in a dropdown menu for future use.
- During the study, the user may click the **Pause** 

button to pause the study and click the **Resume**  button to resume the study.

## 4.5.3 Questionnaire

The **Questionnaire** workflow step provides optional questionnaires to aid in better understanding patient problems and the study being conducted. The user may choose to pose the questions to the patient or skip and proceed to the Report step.

**NOTE:** The Questionnaires are available for selection in the Procedure and Review workflow steps. Select the desired questionnaire to start the **Questionnaire** workflow step.

The following questionnaires are available:

- ICS Male/Female Questionnaire
- 24 Hour Bladder Diary
- International-Prostate Symptom Score (I-PSS)
- American Urological Association Symptom Index (AUA-SI)
- Prolapse Quality of Life (P-QOL)

To customize or check default questionnaires provided during a study, access the Workflow Configuration Window. Refer to the Customizing Workflows section on page 56.

## 4.5.4 Reports

Generate a report for the study in the **Report** workflow step. The default template used for reports is titled **UDS**. The user cannot edit the settings of the default report template; however, additional templates customized by the user can be created, as detailed below.

### 4.5.4.1 Editing

To edit the data fields in a report, a copy of the default configuration must be created within the **Configuration Settings**. Once a copy exists, any desired changes can be made to the copy.

To create a copy of the report,

1. Select the patient from the **Patients Section** in the Main Window, refer to Figure 34 for a visual reference. Open the report from the **Patient Details** section. The report will automatically generate in conformance to the **UDS** report configuration.
2. Press the copy button located beside the **Configuration** title (Figure 54). If desired, change the title of the new report configuration under the **Name** category.

**NOTE:** New report configurations will be saved by Synergy once applied and may be selected from the **Configuration** dropdown bar for future formatting.

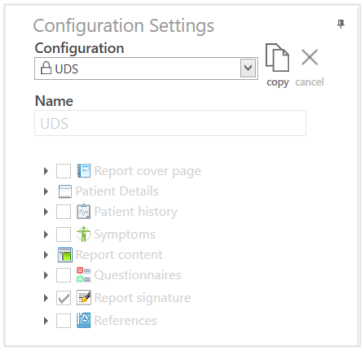



*Figure 54: Configuration Settings – Editing the Report*

3. To adapt the report content, enable or disable various data fields by clicking the checkbox next to the required data field in the **Configuration Settings**.
4. The position of some data fields in the report may be moved using the **Up** and **Down** buttons. To move a data field, select the applicable field.
   The  arrow marks will appear beside the selection. Click the appropriate arrow mark to move the data field, depending upon the desired direction.
5. Click the **Preview** button to view any changes that were implemented. To complete updates to the report, press the **Apply Changes** button. To exit the **Report** workflow step, press the **Finish** button.

## 4.5.4.2 Adding Comments

This option allows the addition of comments as a section in the report. To add comments to the report, follow the steps provided:

1. Select the **Add Report Comments** button 

located in the toolbar. This will launch the **Comments** window (Figure 55).

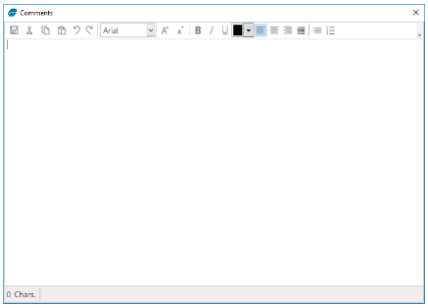



*Figure 55: Comments Window*

2. Enter any comments in the window and select the save icon on the **Comments** window's toolbar.
3. Ensure the **Comments** option is checked under **Report content** in the **Configuration settings**. To edit comments from the **Configuration Settings**, open the Comments dropdown menu and select the **click to enter text!** option. This will open the **Comments** window.

   The Comments dropdown menu includes a secondary dropdown called Header title. Open the dropdown and select the **click to enter text!** option to assign a heading to the comments section of the report (Figure 56).

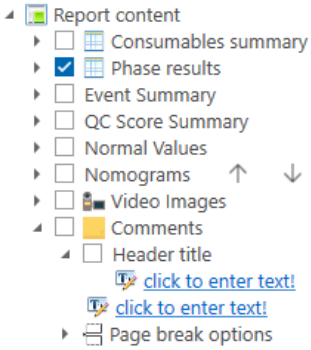



*Figure 56: Comments and Header Title Drop Down Menus*

4. Click the **Apply Changes** button to save changes to the report.

## 4.5.4.3 Quick Results and Nomograms

Quick Results and Nomograms generated by Synergy are intended for use as quick references complementary to the complete study data.

- Study results are calculated from the data recorded by NXT system transducer channels during the procedure; values are rounded to a single decimal place for user viewing. Calculations and nomograms are calculated using the raw data collected during the study, not from the rounded values provided for ease of reading.
- Nomograms are graphical representations of particular results from the procedure.
- Nomograms may be generated through the Report content drop down menu 

. Check the **Nomograms** option and **Apply Changes** to add this feature to the report. Nomograms are intended as a summary analysis only.
- Quick Results and Nomograms may be viewed during the study on the Slide Sidebar under the associated icon .

## 4.5.4.4 Normal Values

**Normal Values** is a data field available for activation within report customization. The **Normal Values** field is intended to provide an expected range of values for different events which may occur during the study (Figure 57).

1. By default, the **Normal Values** field will be unchecked in the **Configuration Settings** for the report.
2. To enable the **Normal Values** field,
   a) Select the required configuration copy, and then expand the **Report content** option by clicking the arrow beside the title: 
   b) Click the checkbox beside the **Normal Values** field to enable this function.
   c) To save the changes to the report, click the **Apply Changes** button.

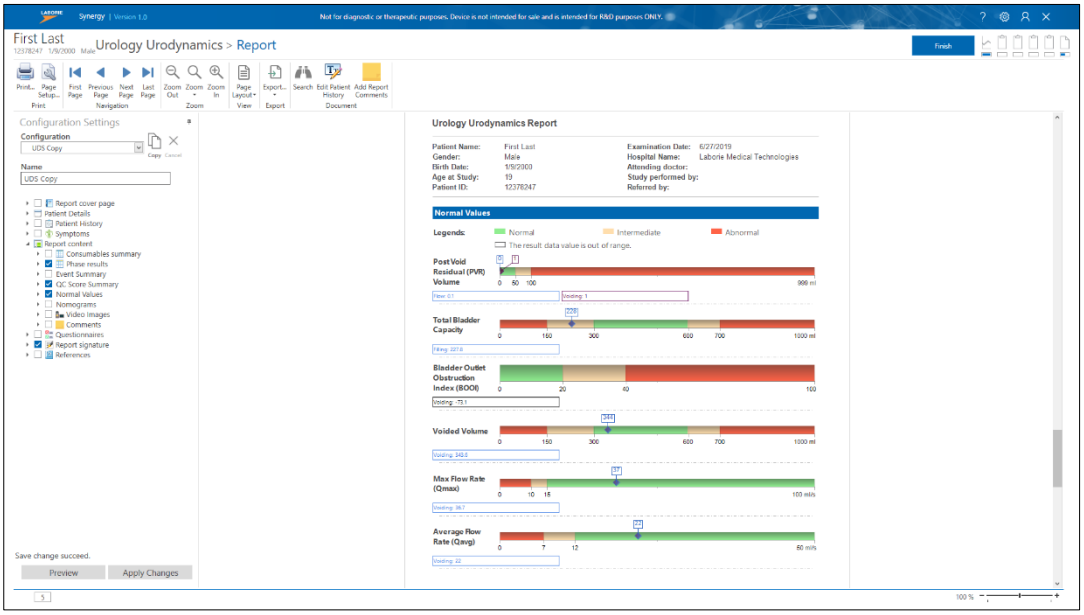



*Figure 57: Normal Values*

## 4.5.4.5 Sending Reports to EMR

Open the report from the **Patients** section or from the **Reports Workflow Step** and click the **Send to EMR** button 

on the report ribbon bar. This icon will only be visible if the user has an EMR license enabled. When the **Send to EMR** button is clicked, Synergy validates if the EMR service is running. If the service is running Synergy will send the report to the EMR System. If the EMR service has stopped, Synergy will display a notification message. All studies in Synergy can be sent to an EMR system if an EMR license is enabled.

Synergy displays a progress indicator while waiting for acknowledgement from the EMR system. Synergy will wait for 10 seconds, then display a message asking if the user wants to continue waiting. This 10 second wait time is configurable and can be increased if needed from Synergy application configuration file. After 60 seconds from the time the report was sent to EMR, the process will timeout and show an **Export Failed** dialog if no acknowledgement had been received from EMR system (Figure 58).

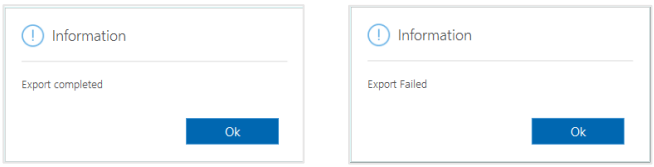



*Figure 58: EMR Sending Status*

**NOTE:** The **Send to EMR** button will not be accessible when using the **Preview Changes** feature to view report configuration. Click **Apply Changes** on the report **Configuration Settings** panel to access the **Send to EMR** button.

## 4.5.5 Review

The Review workflow step allows the user to assess the information recorded during the study. To review the study, select the patient in the **Patients** section, click the **Studies** tab in the **Patient Details** section, and click the **Review** button; the **Review** window will then load (Figure 59).


*Figure 59: Review – FreeFlow Study*

While in the **Review** window, the user can:

Access, edit, and review content in the Slide Side Bar.

- Review UDS Intelligence Score and Quick Results.
- Edit patient details and patient history.
- Select images for inclusion in the report.
- Edit **Study Configuration** settings using the **Review Editor** available under the **Settings** icon. Limited settings are available in the review phase.

Review and Edit information in the Graph section.

- Use the red marker to move, add, or delete events in the graph. Left click on a marker and drag to move it to a new position. Right click on the location where a marker is required and select the **Marker Type** from the resulting menu to insert an event marker. Right click the event marker and select **Delete Marker** to remove an event marker from the graph.

**NOTE:** fixed events, such as pump markers, cannot be moved or deleted from the graph.

- Use the vertical red marker to zoom in on a specific portion of the graph. Left click and drag the red marker to select the portion of the graph to expand. Use the **Previous Zoom** button in the control panel to return to the previous magnification or click **Zoom 100%** to view the full graph.
- Move the phase boundaries in the graph. Phase boundaries are markers that show where each phase of the test started and ended. Follow the instructions below:

  a) Press the Ctrl + Shift keys together. This will cause the **Review** window to grey out.
  b) Move the vertical red marker to the phase boundary line, click and then drag the phase boundary line to the desired location on the graph.
  c) Verify that all changes are saved.

Once review of the study is complete and changes are saved, click the **Close** button to return to the main window. Alternatively, click the **Report** button to load the Report window beside the Review window in split screen. To exit the review section of the split screen, click the **Close** button. To exit the report section of the split screen, click **Finish.**

# 4.6 UDS Intelligence

## 4.6.1 Quality Control (QC)

The UDS Intelligence capabilities within Synergy allow the software to provide feedback on user adherence to required standards and procedures throughout the study.

The **Quality Control** window can be accessed by selecting the Quality Control Icon on the Slide Sidebar at any time during the study. The quality feedback provided in the Quality Control window will vary based on the workflow step.

### 4.6.1.1 Pre-test Quality Control

During the **Preview** Phase of the Procedure workflow step, the **Quality Control** window will display **Pre-test Quality Control**.

1. **Pre-test QC** displays the modules which must be completed to prepare the NXT system for the recording phases of the study. The user can expand each module to show actions required for submodules by using the plus/minus boxes.
2. The color of the module indicates its status. If a submodule requires attention the main module will reflect this in its assigned status (Figure 60).
    a. If the color of the module is red, action is required. Grey submodules are provided to give guidance on how to resolve requirements; for additional information, hover the curser over the red modules.
    b. An amber colored module indicates a recommended action.
    c. Green indicates the completion of all actions for the setup of the module.
    d. Blue submodules provide recommended actions regarding patient set-up.

See Figure 60 below for examples of the color coding of the modules in the preview phase.

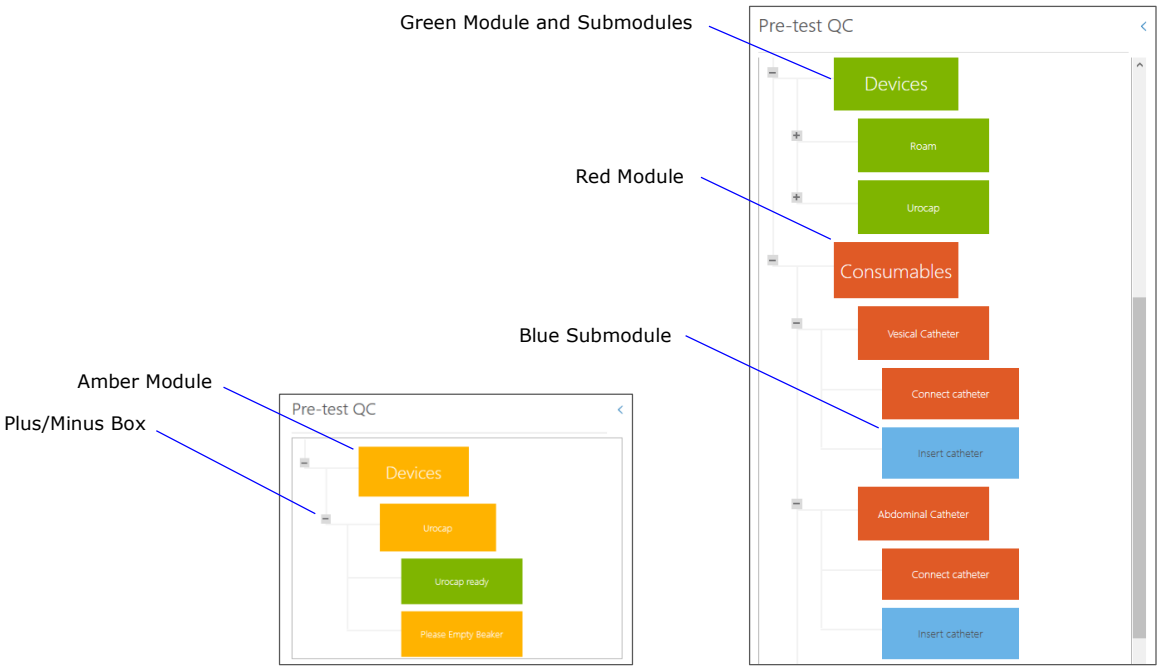



*Figure 60: Pre-test QC*

### 4.6.1.2 Protocol Guidance

During the **Recording** phases of the **Procedure** workflow step, the Quality Control window will display **Protocol Guidance**. Two protocol fields are provided: **Total Score** and **Phase Score** (Figure 61). The Quality Control icon will shift colors as the phase score evaluation changes. The Protocol Scores are color coded in accordance with QC Score values. Green signifies an **excellent score**, Amber a **good score**, and blue a **fair score**.

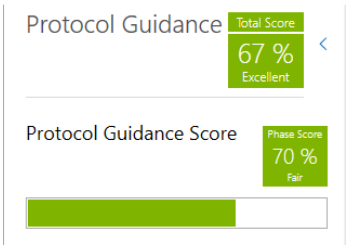



*Figure 61: Protocol Guidance - Total Score and Phase Score*

Refer to QC Score and QC Score Summary on page 73 for an overview of how QC score is calculated.

### 4.6.1.3 UDS Intelligence in the Review Workflow Step

Compiled features of UDS Intelligence can be referenced in the Review workflowstep. Select the Quality Control Icon from the Slide Sidebar. From this window the **Protocol Guidance**, **Pre-test Quality Control**, and **QC Score** can be reviewed for each phase of the study such as flow, Filling, and Voiding. Navigate the window by selecting the tab corresponding with the phase requiring review (Figure 62).

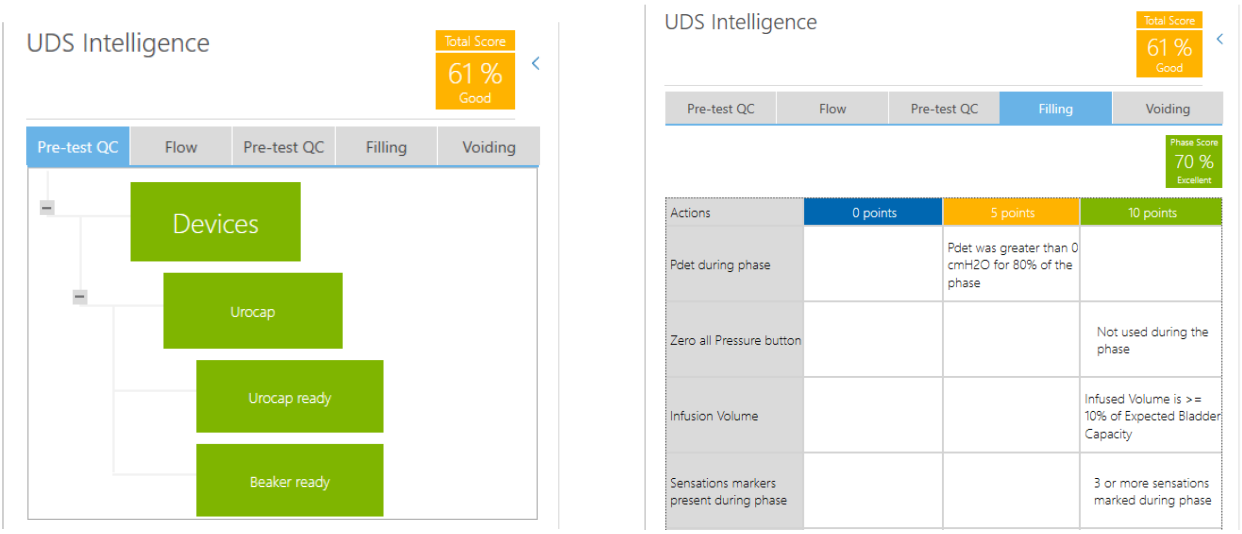



*Figure 62: Protocol Guidance and QC Score in the Review Phase*

## 4.6.2 QC Score and QC Score Summary

The QC Score is an aggregated estimate of the quality of the workflow tasks performed while conducting a study.

The QC Score can be viewed in a summary at the end of study **Report** or from the Quality Control icon in the Slide Sidebar. By default, the **QC Score Summary** field will be unchecked in the **Configuration Settings** of the report (Figure 63).

To enable the **QC Score Summary** field in the report:

1. Create a new report copy or select a previously created report copy from the configuration dropdown menu.

**NOTE:** Refer to the Reports section on page 65 for more information on creating report copies.

2. Expand the **Report content** option by clicking the arrow beside the title, Report content.
3. Click the checkbox beside the **QC Score Summary** field to enable this function.
4. To save changes to the report, click the **Apply Changes** button.

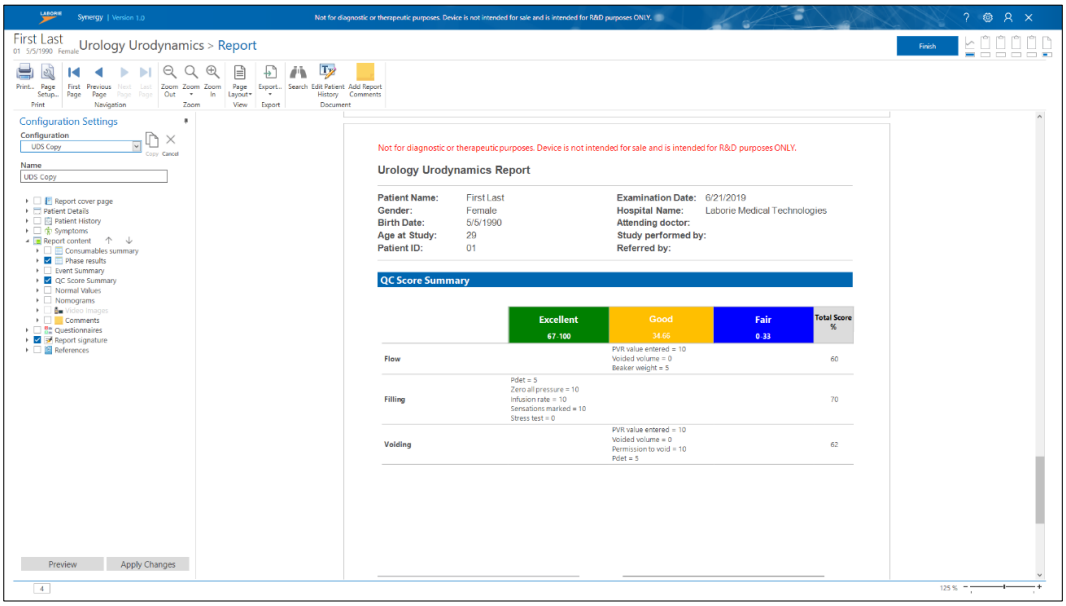



Figure 63: QC Score Summary

**The QC Score Summary**, accessible through the study report and review phase, provides an overview of points earned for each action per study phase. Table 8 below explains how the QC Score is allotted per phase:

| Flow Phase | Blue=0 points | Yellow=+5 points | Green=+10 points |
|---|---|---|---|
| Volume Voided Pediatric | No uroflow volume recorded | Volume voided > 0 | Volume voided ≥ 50% EBC |
| Volume Voided Adult | No uroflow volume recorded | Volume voided > 0 | Volume voided > 150 ml |
| PVR | No PVR value entered | Not Possible | Any PVR value, including 0 ml |
| Beaker | Beaker not empty at start of flow (Beaker weight >= 25 gm) | Beaker empty at start of flow (Beaker weight < 25 gm) | Not Possible |

| Filling Phase | Blue=0 points | Yellow=+5 points | Green=+10 points |
|---|---|---|---|
| Pdet | Pdet > 0 cmH2O < 80% of phase | Pdet > 0 cmH2O > 80% of phase | Pdet > 0 cmH2O continuously |
| Zero All Pressure | Used during Filling | Not Possible | Not used during Filling |
| Infusion Pump Pediatric | Infused Volume < 10% EBC | Not Possible | Infused Volume ≥ 10% EBC |
| Infusion Pump Adult | Infused Volume < 10% EBC | Not Possible | Infused Volume ≥ 10% EBC |
| Sensations | None marked | 2 marked | 3+ marked |
| Stress Test | Not Possible | Performed @ Vinf > 150 ml | Max Pves > 30 cmH2O if Leak, >60cmH2O if no leak |
| Pre-test QC (Out of Scope) | Not performed | Performed but not passed | Baseline & Cough passed |
| Cough Check (Out of Scope) | Not performed | Done at least once after FS | Done every 100-150 ml infused |

| Voiding Phase | Blue=0 points | Yellow=+5 points | Green=+10 points |
|---|---|---|---|
| Volume Voided Pediatric | No uroflow volume recorded | Volume voided > 0 | Volume voided ≥50% EBC |
| Volume Voided Adult | No uroflow volume recorded | Volume voided > 0 | Volume voided >150ml |
| Permission to void | Not marked | Not Possible | Marked |
| Pdet | Pdet > 0 cmH2O < 80% of phase | Pdet > 0 cmH2O > 80% of phase | Pdet > 0 cmH2O continuously |
| PVR | No PVR value entered | Not Possible | Any PVR value, including 0 ml |

*Table 8: QC Score Allotment Process*

**NOTE:** Scientific references are available in the **Help Menu** of Synergy. Click the **Help** icon available in the title bar of the main window to launch the **Help Menu**.

# 5 Maintenance and Service

## 5.1 Cleaning and Disinfection

### 5.1.1 General Cleaning and Disinfection

This section provides limitations and recommendations for the cleaning and disinfection processes to be performed by the user on the standard modules of the NXT System. See the Equipment Intended Use section on page 13. Synergy is an application software. It does not require reprocessing. The Bluetooth Dongle is not intended for reprocessing.

Surfaces of the standard equipment intended for reprocessing should be cleaned and/or disinfected following the reprocessing procedures outlined in the following sections, beginning on page 75:

- General Cleaning and Disinfection
- Cleaning and Disinfection Preparation
- Cleaning
- Disinfection
- Completing Cleaning and Disinfection

#### 5.1.1.1 Cleaning and Disinfection Reagents

The standard modules of the NXT System intended for reprocessing, excluding the laptop PC, are compatible with the following cleaning and disinfection reagent:

- **Ammonia based wipes**

⚠ **CAUTION:** LABORIE has not evaluated the use of cleaning/disinfection reagents which do not appear above. Use of unapproved reagents could damage the NXT system and should be avoided. Do not use wipes containing bleach. For questions on the compatibility of a reagent which is not listed above, contact LABORIE.

**IMPORTANT:** Ensure the reagents are used for at least the contact time stated in the reagent instructions. Do not use reagents for more than twice the stated contact time. Do not allow reagents to pool on any part of the NXT System or in the charging cradles.

The manufacturer of the laptop PC has declared the device to be compatible with the following reagent:

- **70% isopropyl alcohol (final concentration by volume) on a moistened microfiber cloth.**

Refer to the latest instructions provided on the manufacturer's website for the laptop PC prior to beginning cleaning: https://www.dell.com/support/article/en-ca/sln308919/guidance-for-keeping-your-dell-technologies-equipment-clean?lang=en

#### 5.1.1.2 Cleaning and Disinfection Frequency

- **Cleaning –** After each use, all devices should be visually inspected and cleaned to remove any debris or soiling.

- **Disinfection –** Devices should be disinfected in accordance with the frequency defined below.
  - Roam NXT, PIM NXT, Urocap NXT, UPP Puller NXT: Perform disinfection after the device has contact with the patient's skin, contact with a contaminated catheter, or after contamination has been observed (e.g. presence of urine on the device), or, at minimum, daily.
  - NXT Go Pump Hub and PC: Perform disinfection of the device, at minimum, once a week.

#### 5.1.1.3 Methods and Tools

- All cleaning and disinfection should be performed using moistened cloths and a soft bristle brush.
- No additional tools are required for cleaning or disinfection.
- Inspect the Computer, NXT modules, and peripherals for physical damage or wear and tear prior to cleaning.
- Ensure the charging contacts for all modules are wiped free of debris and contaminants.
- Optional reusable accessories used in conjunction with the NXT System should be cleaned and/or disinfected according to the instructions contained in their device specific Instructions for Use. Refer to the Introduction section on page 12 an overview of standard equipment and accessories.

⚠ **CAUTION:** No abrasive tools should be used. Do not spray the cleaning reagents on the NXT System components, modules, accessories, or peripherals. Do not autoclave the NXT System components, modules, accessories, or peripherals or clean them with sharp tools or abrasives. Do not immerse the NXT System components, modules, accessories, or peripherals. Do not immerse electrical connectors in water or other liquids.

### 5.1.2 Cleaning and Disinfection Preparation

To begin cleaning or disinfection preparation, complete the following:

1. Put on gloves and safety glasses.
2. Obtain the module for cleaning and select the cleaning wipes.
3. Put on any other specific personal protective equipment recommended by the wipe's manufacturer.
4. Ensure a stable surface is available to place any modules or parts that may need to be separated from the NXT System during the cleaning and disinfection process in the designated reprocessing area.

#### 5.1.2.1 Containment and Transportation

Transport the soiled device individually in a closed container to a designated cleaning and disinfection area.

- Do not transport the device in a container with other devices.
- Do not soak the device prior to cleaning.

#### 5.1.2.2 Urocap NXT Preparation

**IMPORTANT**: Ensure that the plug is fully inserted to avoid fluid ingress. Refer to Figure 88: Urocap NXT Controls.

#### 5.1.2.3 Roam NXT and PIM NXT Preparation

To prepare for cleaning or disinfection, remove the belt clips from the Roam NXT and the PIM NXT. Refer to the Removing and Attaching the Clip section on page 103 for instructions on removing the clip.

When performing cleaning or disinfection, the Roam NXT and PIM NXT can be separated by unfastening the screw holding the Roam NXT and the PIM NXT together. Disconnection of the Roam NXT and PIM NXT is not required for cleaning or disinfection. For more information on separating the Roam NXT and the PIM NXT refer to the Removing the PIM NXT section on page 102.

Identify the PIM NXT model in use. Ensure to close the transducer doors on the PIM NXT for T-DOC.

**IMPORTANT:** Do not attempt to clean the inside of the PIM NXT for T-DOC transducer channels as this may damage the delicate measurement elements. This area should not require cleaning as it is protected by the transducer doors while not in use or by the catheter connector during Urodynamic study. If dirt or debris is observed in the transducer channels as a part of daily inspection, Contact LABORIE for service and/or disposal instructions.

If contamination is observed near the transducer channels during or post procedure, follow the instructions provided in the Cleaning the Roam NXT and PIM NXT section on page 78 to remove contamination from this area of the device.

### 5.1.3 Cleaning

Follow the instructions provided in this section to manually clean the NXT System and peripherals.

**IMPORTANT:** No method of automated cleaning or disinfection has been validated for the NXT System or its modules. None of the NXT modules, Computer, or peripherals are sterilizable or autoclavable. Refer to the manufacturer's instructions for how to clean the laptop computer.

#### 5.1.3.1 Cleaning the Urocap NXT

This section provides instructions for cleaning the Urocap NXT and its accessories. Ensure that the vent plug is inserted into the open vent hole, then follow the instructions provided in the Performing Manual Cleaning section on page 79 to clean the Urocap NXT, being certain not to apply excessive force to the top of the Urocap NXT.

**IMPORTANT:** Excessive force applied to the top of the Urocap NXT, where the beaker is placed, during cleaning or handling can damage the measurement apparatus.

If the area around the battery cover ventilation holes on the Urocap NXT becomes soiled, this portion of the device should be cleaned as follows:

1. Remove the vent plug if connected.

2. Visually inspect the vent hole for soiling. If soiling or debris is observed, gently wipe the affected area with a cleaning wipe. Take care to prevent any excess cleaning reagent from entering the vent hole.
3. Repeat as necessary using a fresh wipe or the clean side of the existing wipe until the affected area is visibly clean. If visible soil persists, use a soft bristle brush to gently brush away or loosen the remaining soil, then wipe again using a fresh wipe.
4. Wipe the area with a dry, lint free cloth. Ensure the area is dry to the touch.
5. Re-insert the vent plug.

Cleaning the Urocap NXT Accessories and Urocap NXT Stand:

- Rinse and dry the beaker after each use. While the beaker can be reused, it will discolor over time and may need to be replaced.
- When cleaning the funnel, the maximum cleaning temperature should not exceed 80°C (176°F).
- Refer to MAN1000 for instructions on cleaning the Urocap NXT Stand.

### 5.1.3.2 Cleaning the Roam NXT and PIM NXT

To clean the Roam NXT and PIM NXT, follow the instructions provided in the Performing Manual Cleaning section on page 79.

If the area on the PIM NXT for T-DOC normally covered by the transducer doors becomes soiled, this portion of the device should be cleaned as follows:

1. Open the transducer doors.
2. Visually inspect the transducer doors and their hinges for soiling. If soiling or debris is observed, carefully remove the transducer doors and place safely aside. If no soiling or debris is observed proceed without removing the doors.
3. Gently wipe the affected area with a cleaning wipe taking care to avoid the transducer channels. Take care to prevent any excess cleaning reagent from entering the transducer channels. Wipe each transducer door to remove soiling and debris.
4. Repeat as necessary using a fresh wipe or the clean side of the existing wipe until the affected area is visibly clean. If visible soil persists, use a soft bristle brush to gently brush away or loosen the remaining soil, then wipe again using a fresh wipe.
5. Wipe the area with a dry, lint free cloth. Ensure the area is dry to the touch.
6. Reattach, if removed, and close the transducer doors.

The transducer doors should only be kept open when reprocessing the area normally covered by the transducer doors. Once reprocessing of this area is complete, close the transducer doors to ensure that the transducer channels are not exposed to any liquids during any additional processing.

### 5.1.3.3 Cleaning the NXT Go Pump Hub and the NXT Go Infusion Hook

To clean the outer surface area of the NXT Go Pump Hub and the NXT Go Infusion Hook follow the instructions provided in the Performing Manual Cleaning section. To clean the Infusion Pump NXT rollers, located on the NXT Go Pump Hub (Figure 64), open the pump door and wipe each roller with an approved cleaning reagent. Refer to the Cleaning and Disinfection Reagents section on page 75.

*Figure 64: Pump Rollers*

### 5.1.3.4 Cleaning the UPP Puller NXT

Prior to beginning the cleaning procedure ensure to separate the UPP Puller NXT nose from the motor. Remove the Catheter Guide and the Catheter Clamp and clean them separately. Refer to the Assembling the UPP Puller NXT section on page 22 for a visual of how these parts are assembled and disassembled.

To clean the UPP Puller NXT Nose, Catheter Guide, and Catheter Clamp, follow the instructions provided in the Performing Manual Cleaning section on page 79.

If soiling is observed on the UPP Puller NXT arm or motor, wipe the surface with a fresh cleaning wipe to remove soiling. Take care not to remove the o-ring from the motor coupler while wiping (Figure 65).

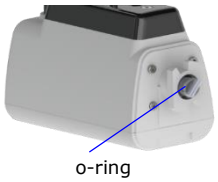



*Figure 65: Cleaning the Area Between Motor and Nose*

### 5.1.3.5 Performing Manual Cleaning

This section covers the cleaning method for the Remote Control NXT, and peripherals.

For the Roam NXT, PIM NXT, Urocap NXT, NXT Infusion Pump, NXT Go Pump Hub and UPP Puller NXT, ensure to refer to the device specific cleaning sections starting on page 77 for guidance on when and where to apply the cleaning procedure described below.

1. Ensure to review General Cleaning and Disinfection, Cleaning and Disinfection Preparation, Cleaning, and Completing Cleaning and Disinfection sections fully before beginning cleaning.
2. Turn off and disconnect all power to the NXT System or NXT module.

3. Remove any visible soiling by hand immediately after the completion of a study using a dry, soft, lint free cloth.
4. Gently wipe down the surface of the Computer, NXT module, or peripherals using a fresh cleaning wipe to remove visible soil.
5. Use a fresh wipe to thoroughly wet the external surfaces of the device. Wipe around cables, edges, cracks, crevices, corners, and hard-to-reach areas. Ensure that all surface areas and connectors have been in contact with the wipe.
6. Repeat as necessary until surfaces are visibly clean. If visible soil persists, use a soft bristle brush to gently brush away or loosen the remaining soil, then wipe the device again using a fresh wipe.
7. Wipe the modules, and peripherals with a dry, lint free cloth. Ensure the device is dry to the touch before using the device in a procedure.
8. Visually inspect the units in standard office lighting to ensure they are clean. If the inspection determines the devices to not be visually clean, the user should repeat the cleaning cycle.
9. Perform visual inspection of all units for corrosion, discoloration, pitting, or cracking. Contact LABORIE for service and/or disposal instructions if the unit is observed with these defects.

**NOTE**: There are no rinsing steps required for the cleaning or disinfection processes.

## 5.1.4 Disinfection

### 5.1.4.1 Performing Manual Disinfection

1. To disinfect the device, follow the cleaning instructions allowing the surface to remain wet for the required contact time as listed on the product label of the cleaning solution. Ensure to refer to module specific disinfection instructions.
2. Ensure the device is dry to the touch before using it to perform another study.
3. Once disinfection is complete, confirm that each module is working correctly by verifying calibration. Refer to the Verifying Calibration section on page 84 for calibration instructions per module.

**IMPORTANT**: Refer to Urocap NXT specific disinfection instructions in the Disinfecting the Urocap NXT section on page 80. Refer to Roam NXT and PIM NXT specific disinfection instructions in the Disinfecting the Roam NXT and PIM NXT section on page 81. Refer to the Disinfecting the UPP Puller NXT section on page 81.

### 5.1.4.2 Disinfecting the Urocap NXT

To disinfect the Urocap NXT, follow the instructions provided in the Performing Manual Cleaning section on page 79 allowing the surface to remain wet for the required contact time listed on the product label of the cleaning solution.

Disinfect the area around the battery cover ventilation holes on the Urocap NXT following the instructions below:

1. Remove the vent plug if connected.
2. Gently wipe the affected area with a cleaning wipe to remove soiling and debris. Take care to prevent any excess cleaning reagent from entering the vent hole. Allow the surfaces to remain wet for the required contact time listed on the product label of the cleaning solution.

3. Repeat this process, if necessary, using either a fresh wipe or the clean side of the existing wipe until the affected area is visibly clean.
4. Re-insert the vent plug.

#### 5.1.4.3 Disinfecting the Roam NXT and PIM NXT

To disinfect the Roam NXT, PIM NXT for T-DOC, and PIM NXT for Fluid, follow the instructions provided in the Performing Manual Cleaning section on page 79 allowing the surface to remain wet for the required contact time listed on the product label of the cleaning solution. For any parts that may contact the patient's skin, such as belt clips, complete a rinse step to aid in the removal of reagent residuals. Use a clean, lint free cloth that has been moistened with purified water to wipe the part. Repeat for a total of three rinses.

Disinfect the area of the PIM NXT for T-DOC normally covered by the transducer doors following the instructions below:

1. Remove the transducer doors and place safely aside.
2. Gently wipe the affected area with a cleaning wipe taking care to avoid the transducer channels. Take care to prevent any excess cleaning reagent from entering the transducer channels. Wipe each transducer door to remove soiling and debris. Allow the surfaces to remain wet for the required contact time listed on the product label of the cleaning solution.
3. Repeat this process, if necessary, using either a fresh wipe or the clean side of the existing wipe until the affected area is visibly clean.
4. Reattach and close the transducer doors.

#### 5.1.4.4 Disinfecting the UPP Puller NXT

Prior to beginning disinfection procedure, ensure that the UPP Puller NXT nose is separated from the motor. Remove the Catheter Guide and the Catheter Clamp and disinfect separately. Refer to the Assembling the UPP Puller NXT section on page 22.

To disinfect the UPP Puller NXT nose, Catheter Guide, and Catheter Clamp, follow the instructions provided in the Performing Manual Cleaning section on page 75 allowing the surface to remain wet for three minutes or for the required contact time listed on the product label of the cleaning solution.

### 5.1.5 Completing Cleaning and Disinfection

Follow the instructions provided below to complete the cleaning and disinfection process.

#### 5.1.5.1 Reconnect and Reassemble

- If previously disassembled, reassemble the Roam NXT and PIM NXT by inserting the PIM NXT into the Roam NXT collar until it is flush. Screw together re-using the screw supplied with the device. Ensure not to overtighten the screw.
- Reattach PIM NXT and Roam NXT belt clips. Refer to the Removing and Attaching the Clip section on page 103.
- If previously disassembled, reassemble the UPP Puller NXT by connecting the motor and the nose. Reattach the Catheter Guide and the Clamp. Refer to the Assembling the UPP Puller NXT section on page 22.
- Ensure to close the pump door.

To use the system after cleaning or disinfection, re-connect power to the system, dock devices, and follow the instructions provided for normal use.

#### 5.1.5.2 Packaging and Storage

Devices may be packaged flat in a clean, anti-static box or wrapped in a lint free cloth post-cleaning or disinfection. Do not stack devices on top of each other and ensure that devices are not pressed against each other or against the container. If the box has multiple units, use a divider to ensure no contact with other devices.

Refer to the Appendix on page 110 for Storage Conditions.

For long term storage, LABORIE recommends that the Roam NXT and the Urocap NXT be fully charged prior to storing. Press the "Reset" button on the module to cause the device to go into long-term sleep mode. To wake up the modules after storage, pair them with the laptop PC. Refer to the Hardware section on page 96.

# 5.2 Preventive Maintenance

## 5.2.1 General Maintenance

This section provides instructions on maintenance activities which can be performed by the user on various modules of the NXT System. The following sections, beginning on page 82, should be referenced for device specific information.

- Caring for the Interlocked Roam NXT
- Caring for the Urocap NXT

**NOTE**: Module batteries are not user replaceable, except for the Remote Control NXT. Contact LABORIE Service for battery replacement if required. Refer to the Hardware section on page 96 for an equipment overview and instructions on charging batteries.

#### 5.2.1.1 Caring for the Interlocked Roam NXT & PIM NXT

Inspect the Roam NXT and PIM NXT to ensure there are no signs of visible deterioration of the device prior to using them for a Urodynamics Study. General guidelines for caring for these devices are provided below:

- If a transducer door or belt clip breaks, is damaged or lost, contact LABORIE Service for a replacement.
- EMG recording cables should be replaced either at sign of wear or annually.
- The PIM NXT should be replaced every two years to sustain recording quality.
- As a part of regular maintenance, inspect the PIM NXT for T-DOC transducer channels for any obstructions, dirt, or debris. Any objects inserted into the PIM NXT transducer channels other than the intended catheter connector may cause damage and channel obstruction.
- If an object is trapped inside the cavity, do not insert a catheter into that channel until the object is removed.
- If small objects or an O-ring get stuck inside the charging cavity, turn the cavity upside down and gently shake the PIM NXT to remove the object.
- Do not attempt to remove any lodged objects from the PIM NXT for T-DOC transducer channels with a tool. Do not attempt to clean or remove dirt or debris from the transducer channels. Contact LABORIE Service for repair or replacement.

### 5.2.1.2 Caring for the Urocap NXT

Ensure the Urocap NXT cover is not displaced or stretched after completing the cleaning or disinfection process.

- If the cover of the Urocap NXT becomes displaced, gently apply pressure around its circumference to ease the cover back into place.
- If the device's rubber feet are lost or damaged, contact LABORIE Service for a replacement.
- If the device's vent plug is lost or damaged, contact LABORIE Service for a replacement. Avoid moisture or fluids near this area until a replacement vent plug is received.

### 5.2.1.3 Caring for the UPP Puller NXT

Inspect the UPP Puller NXT to ensure there are no signs of visible deterioration of the device prior to using it for a Urodynamics Study.

- If the device's Catheter Guide or Catheter Clamp are lost or damaged, contact LABORIE Service for a replacement.
- If the UPP Puller Arm Clip is lost or damaged, contact LABORIE Service for a replacement.

# 5.3 Verifying Calibration

LABORIE recommends users verify calibration annually, or when any module has been shaken, dropped, or transported between sites, to confirm system accuracy.

**IMPORTANT:** NXT System modules do not require user calibration as the system modules are provided calibrated. If verification procedures reveal a calibration malfunction, contact LABORIE Service for a replacement device.

## 5.3.1 Urocap NXT – Verifying Calibration

To setup verification of calibration for the Urocap NXT, follow the steps provided below.

**NOTE:** To complete the calibration procedure prepare one LABORIE beaker and 500ml of tap water.

1. Login to the Synergy software.
2. Connect the Urocap NXT to the Synergy software and set up the hardware channels.

### 5.3.1.1 Checking the Absolute and Relative Weight

To begin calibration verification, check the total weight measured on the Urocap NXT without a beaker:

a) Place the Urocap NXT on a level surface and let it settle for 20-30 seconds.

b) Click the **Settings** icon in the title bar, then click **System Settings** > **Device Manager** option. The **Device Manager** window will pop-up.

c) Click the **Urocap NXT** option, then click the **Run Diagnostics** button. The device diagnostics window will pop-up (Figure 66).

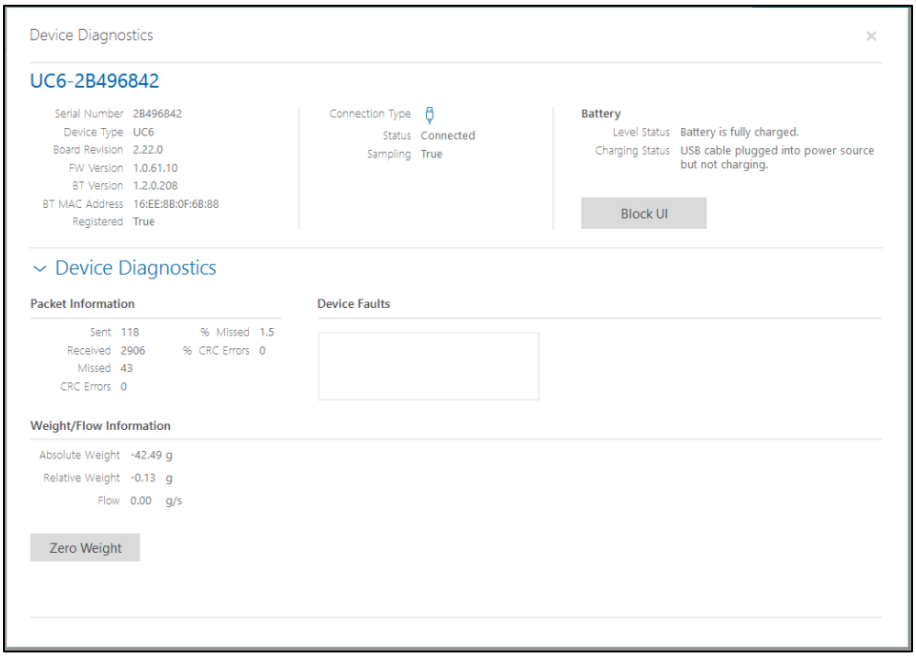



*Figure 66: Urocap NXT – Device Diagnostics*

d) Press the **Zero Weight** button.

e) The **Relative Weight** for Urocap NXT should measure at 0.0g +/- 2g immediately following zeroing. To verify calibration, check the absolute and relative weight with water.

f) The **Absolute Weight** should measure 0.0g +/- 1kg.

#### 5.3.1.2 Checking the Relative Weight with Water

To complete calibration verification for the Urocap NXT, check the relative weight with water:

a) Take a beaker and place it on the Urocap NXT. Wait 10s. Press the **Zero Weight** button.

b) Add 500 ml of water to the beaker.

c) Verify that the **Relative Weight** for the Urocap NXT in the diagnostic window is 500.00 g +/-3% as exemplified in Figure 67.

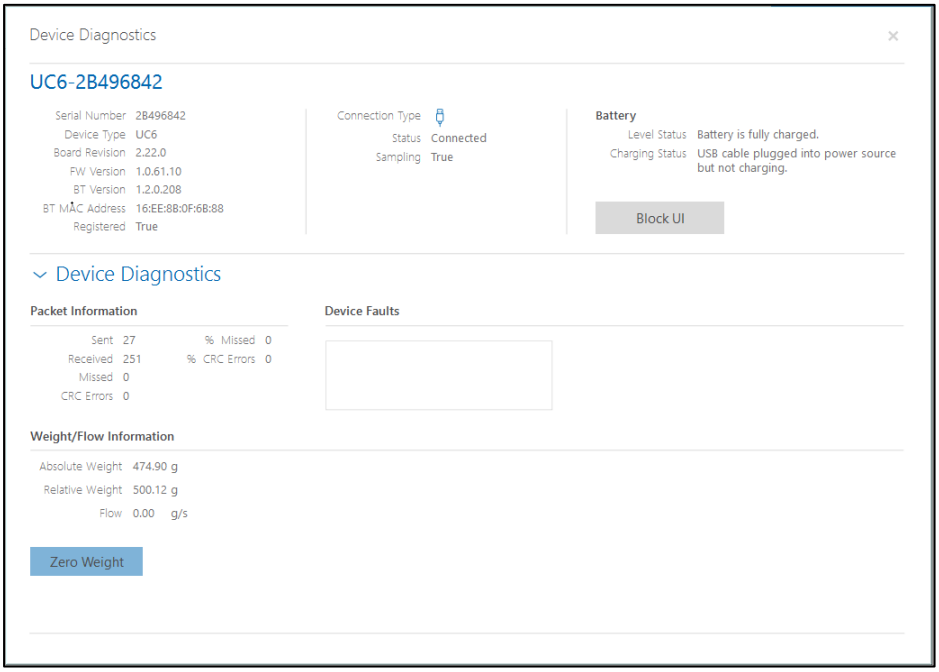



*Figure 67: Urocap NXT – Device Diagnostics with Water*

## 5.3.2 Roam NXT – Verifying Calibration

To setup verification of calibration for the Roam NXT:

1. Login to the Synergy software.
2. Ensure the PIM NXT is connected to the Roam NXT. Ensure to connect the PIM NXT that corresponds with the consumable type in use.
3. Connect the Urocap NXT, Roam NXT, and the Infusion Pump NXT to the Synergy software and setup the hardware channels.

### 5.3.2.1 Verifying EMG Capability

To begin verifying calibration for Roam NXT EMG capability, gather one calibrated signal generator (capable of generating sinusoidal waves at 10Hz-200 µV) with one alligator cable, three Touchproof 1.5mm connectors, and one EMG input cable. To complete calibration verification:

a) Setup a signal generator; prepare to create a sine wave with 10 Hz, and 200 µV.

b) Connect the touchproof connectors to the signal generator using the alligator cable.

c) Connect the EMG input cable to the connection point located on the PIM NXT.

d) Insert touchproof connectors into the EMG input cable. Refer to Figure 68 for a visual representation of the signal generator and the Roam NXT setup.

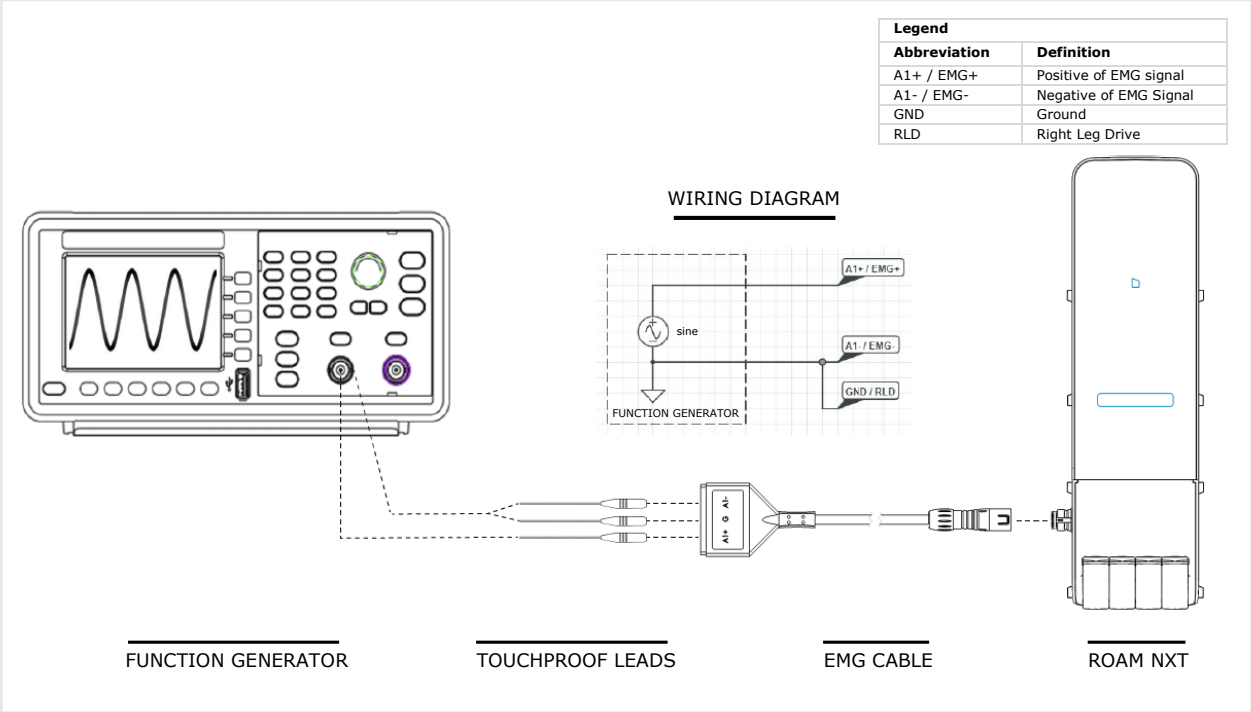



*Figure 68: Wiring Diagram – EMG Calibration Verification with a Waveform Generator*

e) Once the signal generator and the Roam NXT are connected as displayed in Figure 68, begin generation of a sine wave with 10 Hz, and 200 µV.

f) Select a patient file created for verification purposes from the **Patient** section, choose the **Urology Urodynamics** test under the UDS tab, and click the **Start Study** button; the **Preview** phase will begin.

g) Verify that the graph in the preview phase shows EMG as a 200µ sine wave.

#### 5.3.2.2 Verifying Pressure Measurement Capability

To begin verifying calibration for the PIM NXT transducers, gather one Cylinder at least 25 cm tall and one NXT Catheter. To complete calibration verification:

a) Fill a cylinder with 20cm of water.

b) Coil the NXT Catheter inside the cylinder so that all pressure ports touch the bottom of the cylinder.

c) Connect the catheter to the relevant PIM NXT channel.

d) Click the **Settings** icon in the title bar, then click the **System Settings > Device Manager** option. The **Device Manager** window will pop-up.

e) Click the **Roam NXT** option, then click the **Run Diagnostics** button. The device diagnostics window will pop-up (Figure 69).

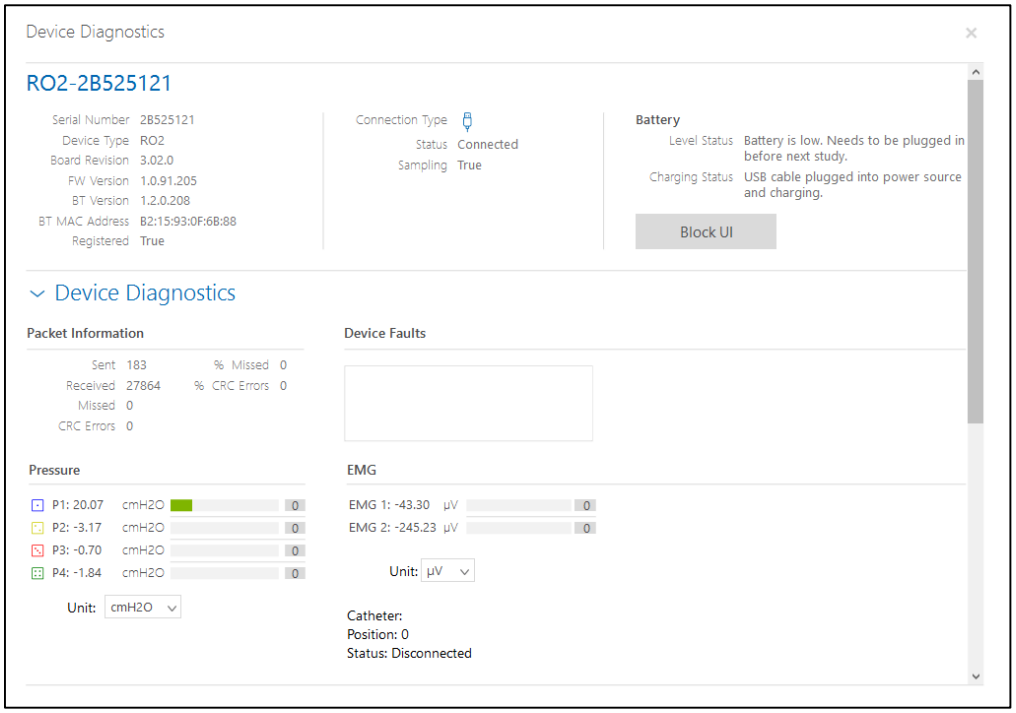



*Figure 69: Roam NXT – Device Diagnostics*

f) The Pressure should be approximately 20cm of water +/-3%. Repeat for each channel.

### 5.3.3 NXT Go Pump Hub and Volume Transducer – Verifying Calibration

To set up verification of calibration for the Infusion Pump NXT, located on the NXT Go Pump Hub, and the Infusion Volume Transducer, located in the NXT Go Infusion Hook, follow the instructions below:

1. Login to the Synergy software.
2. Ensure the Infusion Pump NXT is connected to the Synergy software.

### 5.3.3.1 Checking the Total Weight without a Saline Bag

To begin calibration verification, measure the total weight of the Infusion Pump NXT and Infusion Volume Transducer without a saline bag:

a) Setup the Infusion Volume Transducer without a saline bag.

b) Click the **Settings** icon in the title bar, then click **System Settings** > **Device Manager** option. The **Device Manager** window will pop-up.

c) Click the **Infusion Pump NXT** option, then click the **Run Diagnostics** button. The device diagnostics window will pop-up (Figure 70).

d) Press the **Zero** button.

e) The Total Weight should measure as zero immediately after zeroing. To complete calibration verification, check the total weight with a saline bag.

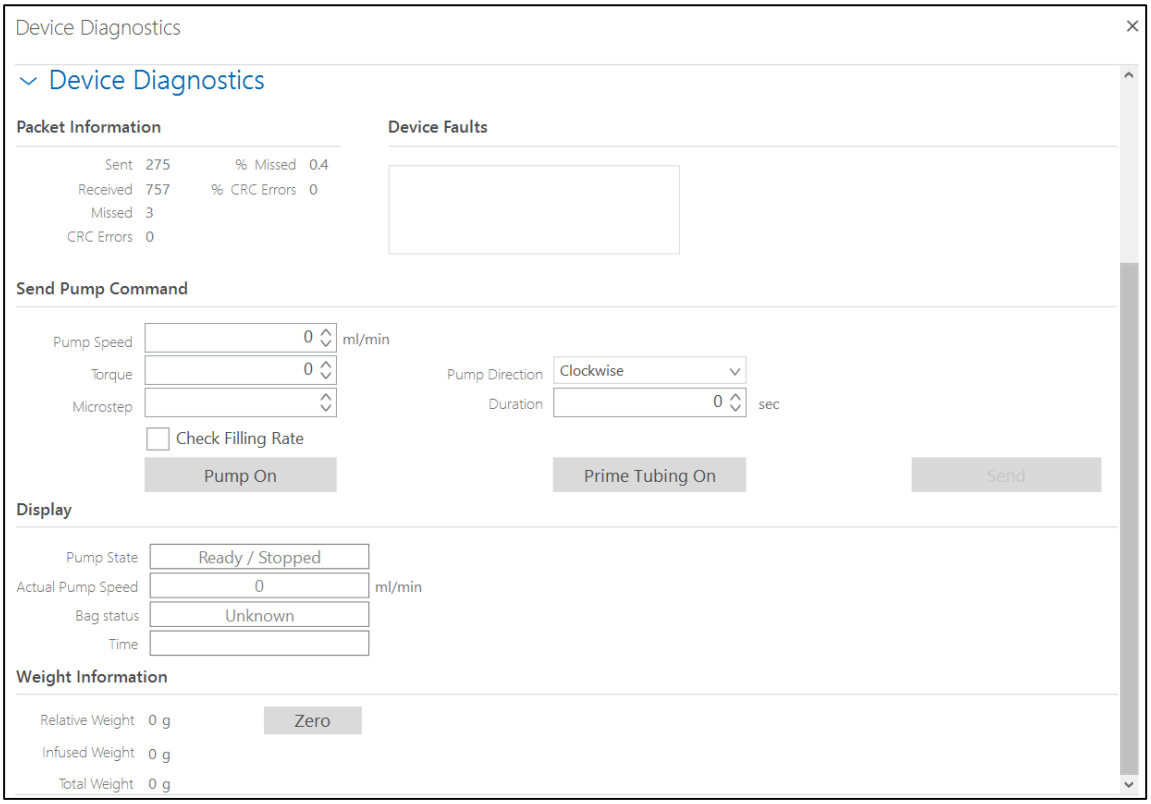



*Figure 70: Infusion Pump NXT Diagnostics Window*

### 5.3.3.2 Checking the Total Weight with a Saline Bag

To complete calibration verification, check the total weight of a 500mL saline bag:

a) Press the **Zero** button.

b) Measure the weight of the saline bag using an external measuring device.

c) Setup the Infusion Volume Transducer with the saline bag.

d) The Total Weight in the diagnostic window should be the previously measured weight +/- 5%.

# 5.4 Configuration

## 5.4.1 NXT Go Electrical Isolation Diagram

Refer to the diagram shown below in Figure 71 for a visual representation of the NXT Go electrical isolation from mains supply. For further information regarding electrical isolation, contact LABORIE Service.

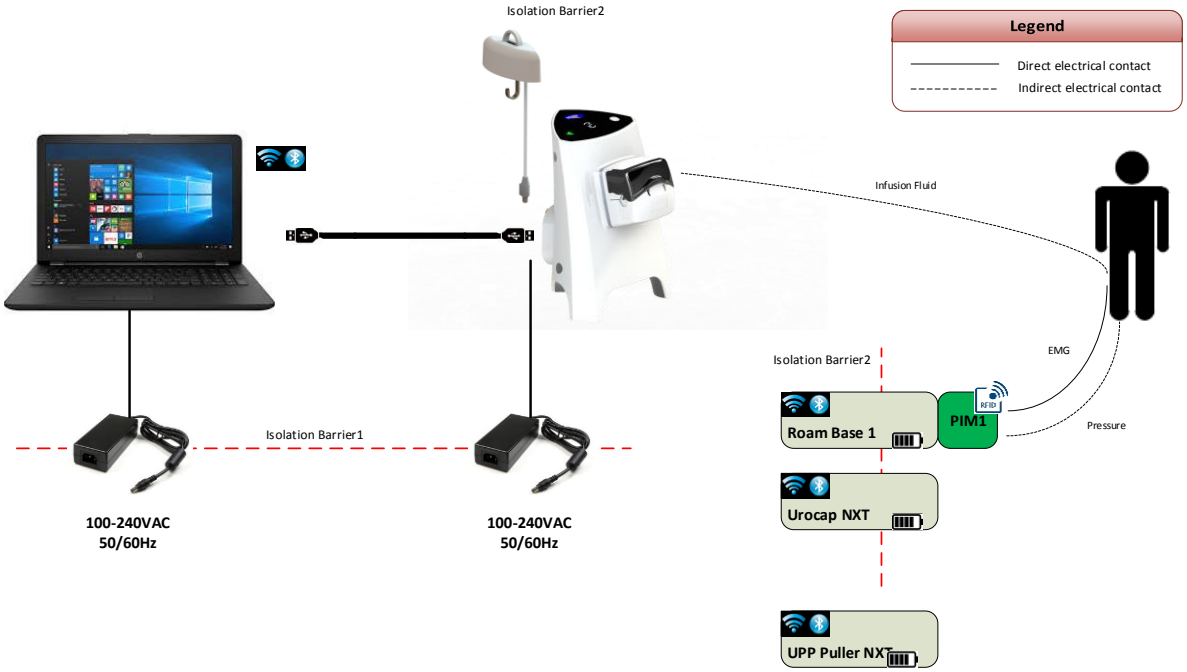



*Figure 71: NXT Go Isolation Diagram*

## 5.4.2 Roam NXT and Wall Charger Isolation Diagram

Refer to the diagram shown below in Figure 72 for a visual representation of the method to isolate the Roam NXT from supply mains when configured with a wall charger. For further information regarding electrical isolation, contact LABORIE Service.

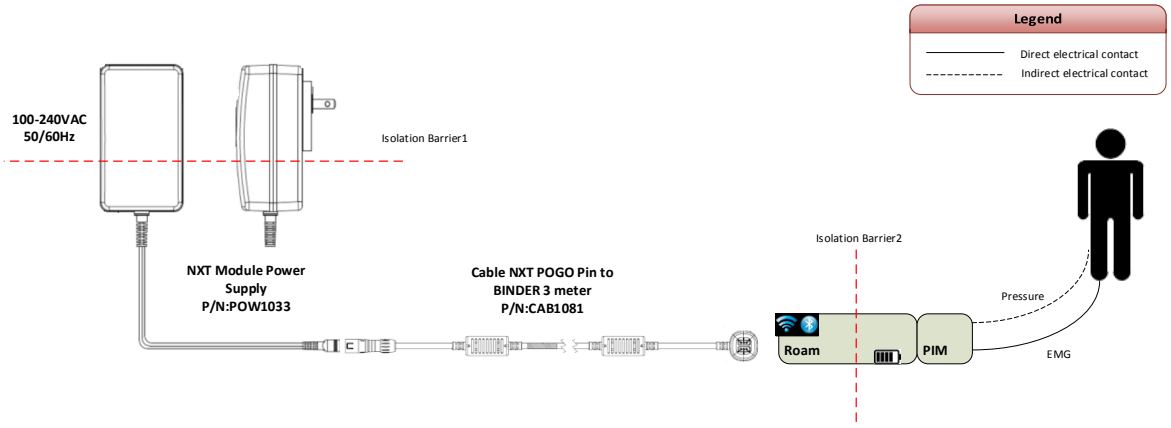



*Figure 72: Roam NXT and Wall Charger Isolation Diagram*

### 5.4.3 Urocap NXT and Wall Charger Isolation Diagram

Refer to the diagram below in Figure 73 for a visual representation of the method to isolate the Urocap NXT from supply mains when configured with a wall charger. For further information regarding electrical isolation, contact LABORIE Service.

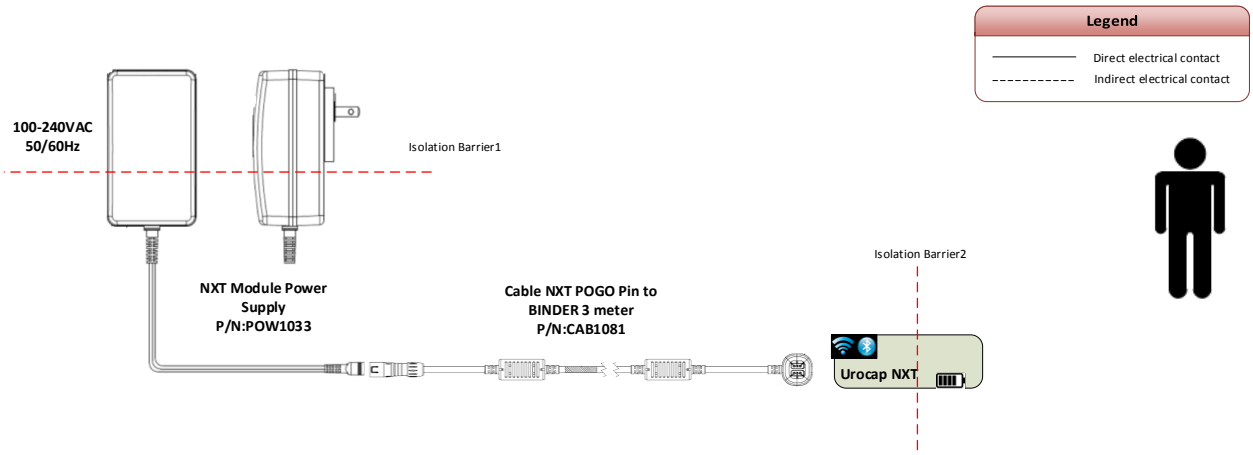



*Figure 73: Urocap NXT and Wall Charger Isolation Diagram*

### 5.4.4 UPP Puller NXT and Wall Charger Isolation Diagram

Refer to the diagram below in Figure 74 for a visual representation of the method to isolate the UPP Puller NXT from supply mains. For further information regarding electrical isolation, contact LABORIE Service.

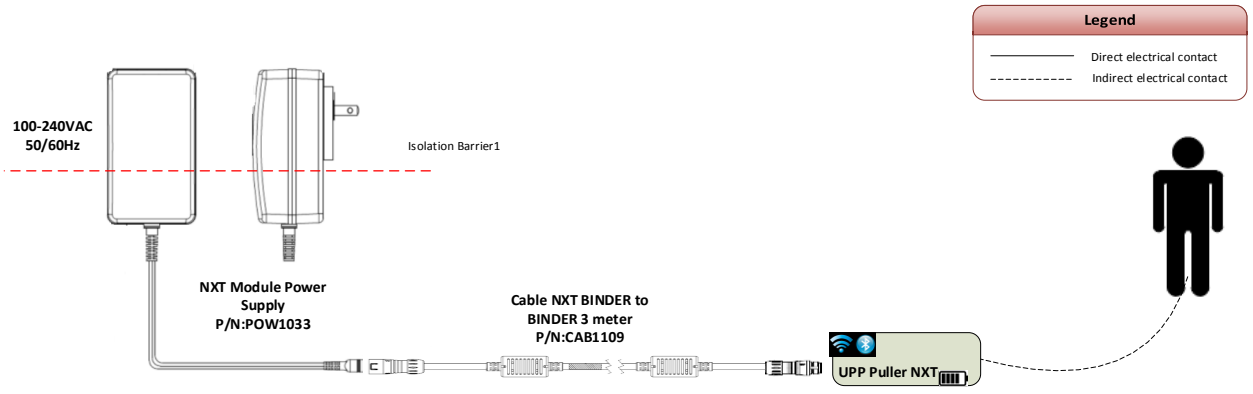



*Figure 74: UPP Puller NXT and Wall Charger Isolation Diagram*

## 5.5 Computer Virus Protection

Each computer purchased from LABORIE is verified to be virus-free prior to shipment and is installed with an antivirus program. It is the customer's responsibility to correctly use and maintain the antivirus program. Customers may use an alternative antivirus program at

their own risk. LABORIE **does not** certify alternative antivirus programs for use with the NXT System. LABORIE is not responsible for any virus-related computer problems after delivery of the computer to the customer.

# 5.6 Disposing of Product After Use

The NXT System equipment and disposables should be disposed of in the following manner:

- Contaminated single-use disposables: Discard these products according to the standard operating procedures on medical waste handling at the institution of use.
- Waste Electrical and Electronic Equipment (WEEE): Ensure any waste electrical and electronic equipment is collected separately and returned to the locally designated recycling service for these types of products.
- Batteries: Dispose of any end-of-life batteries according to local regulations.
- Packaging waste: Ensure any packaging waste is collected separately for available national packaging collection and recycling services. Packaging is 80% recyclable/renewable by weight.

# 5.7 Environmental Consideration of Waste Disposal

The NXT System is designed to perform Urodynamics. LABORIE recommends disposing of waste generated from these studies, such as urine, properly to prevent environmental pollution. The waste should be disposed of in such a way that it will not pollute the fresh water supply system, especially the drinking water system. In areas that have sewage systems with water treatment procedures, the most convenient means of disposal is to use these sewage systems.

# 5.8 Backups

Synergy software automatically backs up data to its database at regular intervals. The user can also archive patient data to an external hard drive. For information on archiving patient data, refer to the Database Management section on page 53.

# 5.9 Troubleshooting Guide

| Symptoms | Possible Cause(s) | Corrective Action(s) |
|---|---|---|
| **All Devices** | | |
| No response from the devices? | No power on electrical outlet? | Plug system into a known working electrical outlet. |
| | Damaged power cord? | Unplug system and contact LABORIE for replacement power cord. |
| | Power cord not connected properly? | Ensure power cord is secure at the base of system and at the electrical outlet. |

| Symptoms | Possible Cause(s) | Corrective Action(s) |
|---|---|---|
| | Devices not connected in software? | Reconnect the devices to the system through the USB cables provided. Consult **Device Manager Window** to confirm device connection. |
| Computer or Printer cannot power on? | No power on electrical outlet? | Ensure electrical outlet is working, power cords are not damaged, and all power cords are secure at both ends. |
| | Damaged power cord? | |
| | Power cord not connected properly? | |
| **EMG** | | |
| EMG reading too high/low? | EMG channel scale not optimized? | Set EMG scale in the Workflow Configuration for Pressure flow. |
| | Electrodes are wet or generally not sticking? | Shave area if necessary and wipe dry. Apply a good amount of tape to keep moisture out. |
| | Detached electrode? | Re-attach electrode. |
| | Water/urine leaked over the electrodes? | Dry the area with a towel and replace the electrodes. |
| No spike response in EMG and baseline is flat? | Electrodes are not picking up the proper muscle group? | Move either one or both measuring electrodes (the ones attached to the red & black leads) closer together. |
| EMG response is too high and channel saturated? | Electrodes not picking up the proper muscle group? | Move either one or both measuring electrodes (the ones attached to the red & black leads) closer together. |
| EMG reading is too high or channel saturated? | Mains frequency pickup? | Check the measurement electrodes and quality of patient ground. |
| **Pressure** | | |
| Pressure not responding? | Position of catheters? | Check position and adjust as necessary. |
| | Catheters are not securely connected to the PIM NXT? | Check connections and adjust as necessary. |

| Symptoms | Possible Cause(s) | Corrective Action(s) |
|---|---|---|
| | Zeroes not set properly? | Reset zeroes in Preview workflow step. |
| | Catheter kinked? | Replace catheter if necessary. |
| **Pump** | | |
| Pump not running? | Pump pressure limit reached? | Reset Pves to zero. Check for kinked bladder catheter. Ensure Pump pressure does not exceed 150 ml/min. |
| | Pump settings? | Check Pump and Infusion lines. Check if Pump door is closed. Check if Pump tubing is inserted correctly. |
| **Urocap** | | |
| Uroflowmeter signal shows vibration and/or spike patterns? | Plastic beaker is touching the flow funnel? | Reposition the Uroflowmeter and re-check. |
| | Patient has touched the Uroflowmeter with their feet? | Ask patient to remain calm during procedure. |
| | Floor is unsteady? | Move to a more solid foundation. |
| | Urocap NXT is recording environmental pressure changes? | Unplug the vent plug from the Urocap NXT air vent located on the bottom of the unit. |
| | | Activate the **Urocap Noise Reduction Level**. Click **Settings** > **Workflow** > **Editor** to launch the **Workflow Configuration window** then, select the **Global Tab**. **The Urocap Noise Reduction Level** feature provides three options: **None**, **Narrow**, or **Wide**. Consult LABORIE Service for guidance on setting selection. |
| Incorrect flow or volume readings? | Beaker is not properly seated on the Uroflowmeter dish? | Adjust beaker position to ensure beaker is placed flat in the center of the Uroflowmeter. |
| | Beaker placed or adjusted during study? | Ensure that the beaker is placed on the Uroflowmeter before starting the study. |
| | Funnel is touching the beaker? | Adjust commode chair or Uroflowmeter. |

| Symptoms | Possible Cause(s) | Corrective Action(s) |
|---|---|---|
| | Incorrect beaker in use? | Use beakers supplied by LABORIE only. |
| **Bluetooth Connection** | | |
| Unable to connect via Bluetooth? | Connection broken? | Reduce the distance between the device and the computer. The maximum distance between the processor and the computer can be up to 10 meters (33 feet).<br>Clear any physical barriers between the device and the computer. |
| Unable to connect devices to Bluetooth at first setup? | Connection broken? | Press the Reset button on the device to "wake up" the device and re-establish a connection; wait for few minutes. |
| **PC** | | |
| PC does not power on? | Power interruption due to power outage? | • Unplug the power cable from the power brick.<br>• Press and hold the power button on the computer for few seconds (until you hear a beep sound).<br>• Plug the power cable back in to the power brick.<br>• Press the power button on the computer to switch the PC back on again. |
| **Printer** | | |
| Printer LED does not light up? | Printer power cable unplugged? | Plug in printer power cable and try again. |
| | Printer not turned on? | Turn on printer by pressing printer power button. |
| Printer Error LED on steady or flashing? | Printer paper out? | Load printer paper. |
| | Printer cover open? | Close cover of printer. |
| | Printer out of ink? | Replace printer cartridges. |
| | Printer paper jammed or misfed? | Clear the jammed paper and then press the paper feed button. |

| Symptoms | Possible Cause(s) | Corrective Action(s) |
|---|---|---|
| **Software** | | |
| Valsalva readings are being marked automatically as coughs. | When performing Valsalva procedure, patient is triggering a sharp rise in pressure resembling a cough spike? | Activate Bristol cough marker in the workflow configuration.<br>Click on **Settings**>**Workflow Settings**>**Phases**. Create a copy of the workflow. In each study phase scroll to the **Workflow Additional Configuration Items** subtitle and de-select **Auto Cough artifact detection**.<br>Select **Auto Bristol artifact detection** and save changes to custom Workflow. Use the new custom workflow to complete test with the patient.<br>For more information on custom workflows refer to the Study Management<br>Workflows section on page 55. |

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

### 5.9.1 Software Error Messages

If the following error messages are displayed in Synergy software, contact the LABORIE Service team at 1-800-333-1039 or email service@laborie.com:

- Hardware Failure
- Device is not ready for another process
- Data could not be written to EEPROM
- Data could not be read from EEPROM
- SD card error
- Study map full
- SD card full
- SD card not present
- SD card faulty

# 6 Hardware

## 6.1 Laptop Personal Computer

For information on the specifications of the laptop personal computer provided with the NXT System, refer to Table 15: Equipment Specifications in the Appendix section beginning on page 110.

## 6.2 Bluetooth Dongle NXT

The Bluetooth Dongle NXT, as shown in Figure 75, allows modules such as the Roam NXT and Urocap NXT to wirelessly communicate with the NXT system.

*Figure 75: Bluetooth Dongle NXT*

## 6.3 Remote Control NXT

The Remote Control NXT (Figure 76) is a battery powered device which connects to the computer wirelessly via Bluetooth technology. This device allows the user to control the NXT System from a distance.


*Figure 76: Remote Control NXT Membrane Icons*

The Remote NXT key icons and their functionalities are described in Table 9 below.

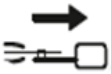
| Key Icon | Function | | Key Icon | Function |
|---|---|---|---|---|
|  | Begin Recording | |  | Pump Speed Increase |
|  | Stop Active Hardware | |  | Pump Speed Decrease |
| FS | First Sensation Marker | |  | Pump On/Off |
| FD | First Desire to Void Marker | |  | Balance/Equalize 1 |
| SD | (Standard) Normal Desire to Void Marker | |  | Balance/Equalize 2 |
| MC | Maximum Capacity Marker | |  | Zero All Pressures |
|  | Cough Marker | |  | Stress Profile On/Off |
|  | Valsalva Marker | |  | Rest Profile On/Off |
|  | Urgency Marker | |  | Puller Return/Stop |
|  | Leak Marker | |  | Record Video Burst |
| 1-4 | User Custom 1-4 | |  | Video Burst Start/Stop |
| 5-8 | User Custom 5-8 | |  | Record Video Snapshot |

*Table 9: Remote Control NXT Icons*

## 6.3.1 Remote Control NXT LED Signals

The Roam NXT contains a LED light to convey status of device. Table 10 provides descriptions of LED indications per color.

| **LED Status** | **Description** |
|---|---|
| Blinking Blue | Connecting through Bluetooth technology. |
| Solid Red | Disconnected. |
| Solid Purple | Idle mode. |
| Green | Indicates touch key input. |
| Blinking Green | Indicates the Remote Control NXT is losing connectivity. |

*Table 10: Remote Control NXT LED Signals*

### 6.3.2 Remote Control NXT Battery Replacement

To replace the Remote Control NXT battery:

1. Use a Philips screwdriver to unscrew the two screws on the battery door at the back of the Remote NXT.
2. Remove the used battery and replace it with the new battery. Ensure that there is correct battery contact orientation. Always use 3xAAA batteries.
3. Place the screws in the two screw holes on the battery door and tighten the screws to secure the battery door using a Philips screwdriver.

## 6.4 NXT Go Pump Hub

The NXT Go Pump Hub (Figure 77) includes: the Infusion Pump NXT, pump controls, and the SmartSense tag reader. Refer to the diagram below for key parts and controls.


*Figure 77: NXT Go Pump Hub*

The NXT Go Pump Hub must be connected to the power supply, the laptop, and the NXT Go Infusion Hook to function. Ensure the NXT Go Pump Hub appears in the **Device Manager**.

### 6.4.1 Infusion Pump NXT

The Infusion Pump NXT on the NXT Go Pump Hub is used to fill the patient's bladder with fluid during Urodynamic Study. The maximum pump rate of the Infusion Pump NXT for 7 French catheters is 70ml per minute.

The interface on the NXT Go Pump Hub provides access to pump stop control, the SmartSense tag reader, and LED indicator lights (Figure 78).

| | |
|---|---|
| LABORIE | LABORIE LOGO Indicator |
| | Pump stop button |
| | Pump status arrow |
| | SmartSense tag reader |

*Figure 78: Status of the Pump*

For information on setting up the pump tubing, refer to the Infusion Pump Tubing Setup section on page 24.

#### 6.4.1.1 NXT Go Pump Hub Indicator Lights

Table 11 indicates the different statuses for the NXT Go Pump Hub. The NXT Go Pump Hub must be connected to the power supply to function.

| | LABORIE Logo status indicator | Pump Status Arrow |
|---|---|---|
| **NXT Go Pump Hub** | Blinking White: Firmware upgrade is in progress | Blinking White: Firmware upgrade is progress (Synchronized blinking with Laborie Logo) |
| | Solid White: Standard | Slow breathing green: System is ready<br>Fast breathing green: System is pumping |
| | | Slow breathing amber: System is not ready |

*Table 11: NXT Go Pump Hub Indicator Signals*

# 6.5 NXT Go Carrying Case

Use the NXT Go Carrying case to transport the NXT Go components.

1. Place the NXT Go components into the carrying case. Refer to Figure 79 for the placement of each component.

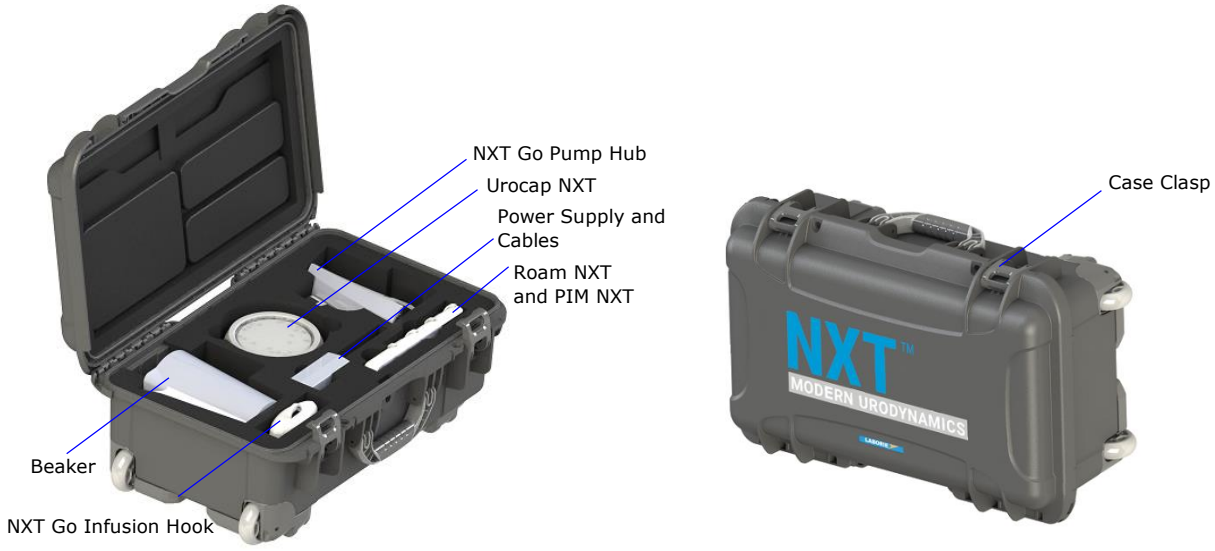



*Figure 79: NXT Go Carrying Case*

2. Close the lid and secure the two clasps prior to transporting.

# 6.6 Infusion Volume Transducer

The infusion volume transducer is a part of the NXT Go Infusion Hook. The transducer allows Synergy to measure the fluid used to infuse the bladder during a Urodynamic study. The infusion volume transducer (Figure 80) is setup as follows:

1. Hang the NXT Go Infusion Hook from an IV Pole. Ensure the NXT Go Infusion Hook connector cable is attached to the NXT Go.
2. Hang a 1000 ml bag of sterile saline or water on the NXT Infusion Hook.
3. Connect the Infusion Pump Tubing to the saline bag.

**IMPORTANT**:

Ensure that the infusion line is not pulled tight or the transducer reading will not be accurate.

Do not allow the saline bag to touch any other mechanical component or module of the system. The saline bag must free hang from the NXT Go Infusion Hook to allow the transducer to measure an accurate weight.

*Figure 80: Infusion Volume Transducer on IV Pole*

The infusion transducer is calibrated for up to 1.5kg of fluid. Ensure the **Fluid Density** setting captured in the workflow aligns with the fluid type being used. Fluid density must be set in the workflow configuration prior to beginning the study. Refer to the Customizing Workflows section on page 56.

# 6.7 Roam NXT

The Roam NXT is a wireless capable module intended to be connected to the detachable PIM NXT models. Together, the devices are used to record pressure and EMG during Urodynamic study. The PIM NXT must be connected to the Roam NXT to facilitate functionality of both devices. The devices may be connected directly or by using the Roam NXT to PIM NXT Connector Cable.

## 6.7.1 PIM NXT

The PIM NXT is the connection point for patient pressure and EMG inputs. Ensure to select the PIM NXT model that facilitates use of the pressure catheters deployed, PIM NXT for T-DOC or PIM NXT for Fluid.

### 6.7.1.1 PIM NXT for T-DOC

The PIM NXT has four transducer channels for use with T-DOC NXT catheters and two EMG input ports to connect to EMG accessories such as patches, fine wires, and needles.

The PIM NXT houses SmartSense tag readers in each transducer channel to scan catheters upon insertion of the catheter connector into each channel. Refer to the Consumable Traceability section on page 62 for more information on scanning catheters into Synergy software.

Figure 81 below displays an interlocked Roam NXT and PIM NXT and indicates key parts and controls.

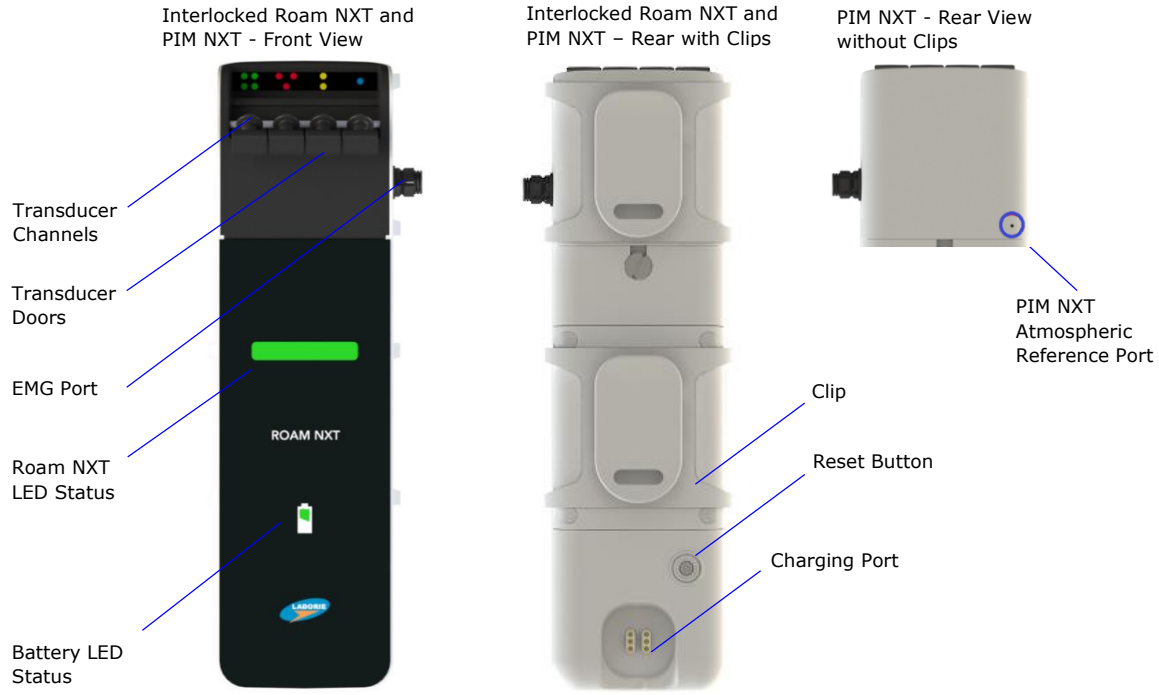



*Figure 81: Roam NXT and PIM NXT Controls - Front and Back*

### 6.7.1.2 PIM NXT for Fluid

The PIM NXT for Fluid has four Pressure Channel Connectors for use with the PIM NXT for Fluid to Medex Transducer Cables and NXT fluid catheters. The PIM NXT for Fluis provides two EMG input ports to connect EMG accessories such as patches, fine wires, and needles. Figure 82 below displays the Roam NXT, PIM NXT for Fluid, Transducer Cables, Pressure Transducers, and Disposable Cartridges interlocked and indicates key parts and controls.

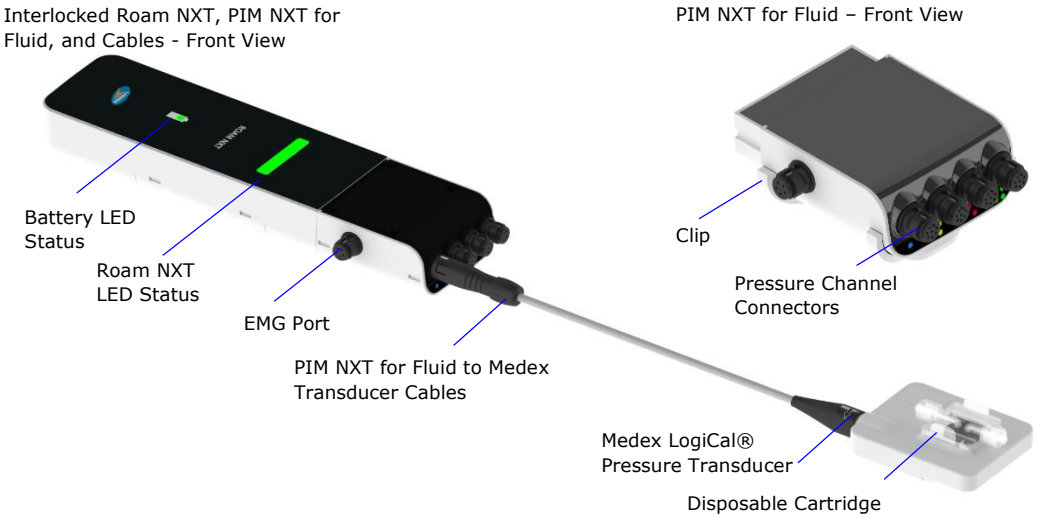



*Figure 82: Roam NXT and PIM NXT for Fluid Controls*

## 6.7.2 Replacing the PIM NXT

Follow the instructions provided below for replacing the PIM NXT.

**IMPORTANT:** The PIM NXT is not intended to be interchangeable during regular use. When the PIM NXT is connected, directly or through use of the Roam NXT to PIM NXT Connector Cable, to the Roam NXT it should only be detached for cleaning or maintenance.

### 6.7.2.1 Removing the PIM NXT

To remove the PIM NXT, follow the instructions provided below.

1. Use a flat head screwdriver to loosen the screw(s) connecting the PIM NXT and Roam NXT without fully detaching.
    a. When directly connected, loosen the screw located at the back of PIM NXT.
    b. When using the connector cable, loosen the screw located at the joint of the connector cable with the PIM NXT and the joint of the connector cable with the Roam NXT.
2. Gently pull the PIM NXT away from Roam NXT base until it disconnects from the base (Figure 83).

*Figure 83: Roam NXT with a Detached PIM NXT*

### 6.7.2.2 Attaching New PIM NXT

To attach a new or existing PIM NXT, follow the instructions provided below.

- Using a flat head screwdriver, loosen the screw(s) used to connect the PIM NXT and Roam NXT without fully detaching.

a. To directly connect the PIM NXT (Figure 84) and the Roam NXT, fit the loosened screw through the slot in Roam NXT base.

*Figure 84: PIM NXT (with screw and belt clip)*

b. To use the connector cable (Figure 85), fit the loosened screw on the PIM NXT through the slot in the cable connector and fit the loosened screw on the cable connector through the slot in the Roam NXT.

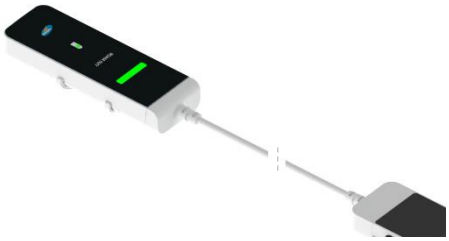


*Figure 85: PIM NXT and Roam NXT with the Connector Cable*

2. Ensure all connections are fully inserted, then retighten the screws.

#### 6.7.2.3 Removing and Attaching the Clip

Individually press a single prong of the clip sideways across the Roam NXT until it clicks out of the latch. Repeat with all four prongs of the clip and pull the clip away from the Roam NXT.

To attach the clip, gently slide the prongs into their latches which will produce an auditory click. Ensure that the clip is securely fastened before using the clip or mounting the Roam NXT. Follow the same instructions to attach or detach the clip located on the PIM NXT (Figure 86).

*Figure 86: Removing the Roam NXT and PIM NXT Clips*

### 6.7.3 Roam NXT—Charging the Battery and Pairing

Charge the Roam NXT by using the supplied wall charger and the NXT Magnetic Pogo Pin Cable.

1. Attach the binder connector to the connector on the wall charger.
2. Connect the wall charger to a power supply.
3. Attach the Magnetic Pogo Pin connector to the Roam NXT.

Pair the device by using the USB cable adapter and the pogo pin cable to connect the device to the laptop PC. Once the device displays in the Synergy **Device Manager**, disconnect the cable from the laptop and the laptop PC.

Table 12 indicates the different statuses for the Roam NXT and its battery. LABORIE recommends for the user to have the device plugged in, or for the device to have at least 1-2 hours of battery charge before beginning a test. Always connect the Roam NXT device to the wall charger at the completion of working hours to ensure full charge for the next study period.

| | Battery Status  | Roam NXT Status  |
|---|---|---|
| **Roam NXT** | Flashing Green: Charging, not at full capacity<br>(When removed from the charger the indicator will change to amber if charge is insufficient) | Green: Ready to use (for at least 2 hours of recording) |
| | Solid Green: Charged (Battery charging complete; plugged in and at full capacity) | |
| | Solid Amber: Low (Battery capacity sufficient for at least 1 hour of recording) | Amber: Not ready to use.<br>Connect the Roam NXT to the wall charger. |
| | Flashing Amber: Very Low (Battery capacity sufficient for at least 1/2 an hour of recording) | |
| | Lack of Illumination: Empty/Sleep mode (No declared battery capacity) | Lack of Illumination: Device inactive or in sleep mode; not ready to use.<br>Device will go into sleep mode 1 hour after system shutdown. Return the Roam NXT to the charger or use the USB cable to pair to the PC. |

*Table 12: Roam NXT LED Signals*

Roam NXT Charging Guidance:

The device battery shall charge from "very-low" to "charged" in less than 5 hours when in charge only mode or within 8 hours if charging while acquiring data. "Charged" is battery capacity sufficient for more than or equal to two hours of recording and "very-low" is battery capacity sufficient for at least one-half hour of recording.

# 6.8 Urocap NXT

The Urocap NXT with wireless technology (Figure 87) is a portable Uroflowmeter that provides a non-invasive and accurate measurement of urinary voiding functions.

- The Urocap NXT is intended to be used to quantify the flow characteristics of the lower urinary tract. Using a built-in transducer, the system performs standard Uroflowmetry studies that measure both flow rate and voided volume.

*Figure 87: Urocap NXT*

- The Bluetooth technology built into the Urocap NXT provides the patient with more privacy during voiding. Bluetooth connection allows the Urocap NXT, the beaker, the commode chair, and the funnel to be set up in one room while the computer, printer, and study operator can be in another room collecting and printing data.
- The Urocap NXT features air vents along its base. The center air vent should be plugged during cleaning to avoid fluid ingress. During a study the plug should be removed to allow external and internal pressures to equalize.

Figure 88 indicates the location of key controls on the Urocap NXT:

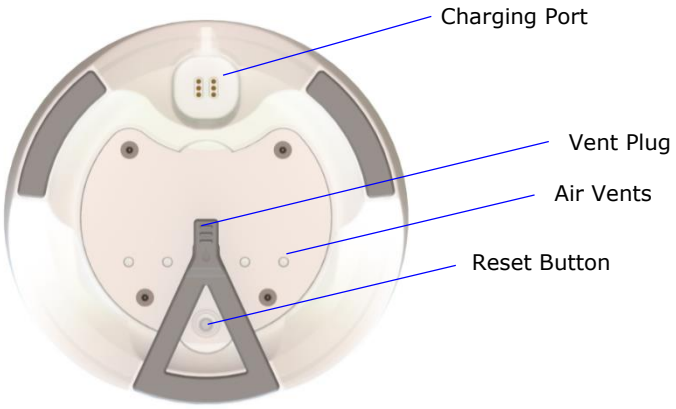



*Figure 88: Urocap NXT Controls*

### 6.8.1 Urocap NXT—Charging the Battery and Pairing

Charge the Urocap NXT by using the supplied wall charger and the NXT Magnetic Pogo Pin Cable.

1. Attach the binder connector to the connector on the wall charger.
2. Connect the wall charger to a power supply.
3. Attach the Magnetic Pogo Pin connector to the Urocap NXT.

Pair the device by using the USB cable adapter and the pogo pin cable to connect the device to the laptop PC. Once the device displays in the Synergy **Device Manager**, disconnect the cable from the laptop and the laptop PC.

The table below indicates the status of the Urocap NXT and its battery.

| | Urocap NXT Status  |
|---|---|
| **Urocap NXT** | Green: Ready to use<br>Yellow: Not ready to use, commence charging<br>Lack of Illumination: Device inactive or in sleep mode; not ready to use.<br>Device will go into sleep mode one hour after system shutdown. Return the Urocap NXT to the charger or use the USB cable to pair to the PC. |

*Table 13: Urocap NXT LED Signals*

LABORIE recommends for the user to have at least 1-2 hours of battery charge on the Urocap NXT prior to the start of a test or to complete the test with the Urocap NXT plugged in using the NXT Magnetic Pogo Pin Cable. Always return the device to the Urocap NXT Charging Hub at the completion of working hours to ensure full charge for next study period.

Urocap NXT Charging Guidance:

The device battery shall charge from "low" to "charged" in less than 5 hours when in charge only mode or within 8 hours if charging while acquiring data. "Charged" is battery capacity sufficient for more than or equal to one hour of recording and "low" is battery capacity not sufficient for one hour of recording.

# 6.9 UPP Puller NXT

The UPP Puller NXT supports the completion of Urethral Pressure Profile Studies. The UPP Puller NXT consists of the motor, nose, arm, and pole clamp. The UPP Puller NXT comes with a wall charger and the UPP Puller NXT Cable for charging or pairing. The Puller NXT pole clamp allows the UPP puller to be mounted on the UPP Stand or IV Pole. Refer to Figure 89 for an overview of important parts and controls.

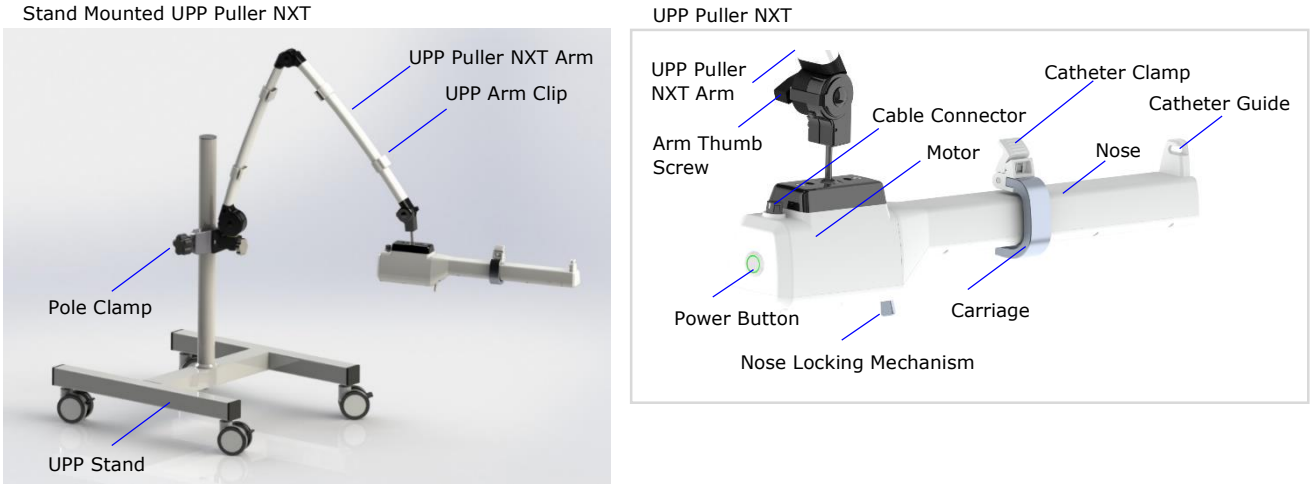



*Figure 89: UPP Puller NXT Key Parts and Controls.*

## 6.9.1 UPP Puller NXT – Pairing

Use the UPP Puller NXT Connector Cable with the USB to binder adapter cable to connect the UPP Puller NXT to the NXT Go laptop PC. The UPP Puller NXT will power on and will appear in the Synergy **Device Manager** window. Once the Bluetooth connection is established the cable can be disconnected for wireless use.

## 6.9.2 UPP Puller NXT – Charging the Battery

Charge the UPP Puller NXT by using the supplied wall charger and the UPP Puller NXT Cable.

1. Attach the binder connector to the connector on the wall charger.
2. Connect the wall charger to a power supply.
3. Attach the UPP Puller NXT Cable to the Cable Connector located on the UPP Puller NXT Motor.

Table 14 indicates the different statuses for the UPP Puller NXT and its battery. The device battery shall charge from "very-low" to "charged" in less than 4 hours when in charge only mode or within 8 hours if charging while acquiring data. "Charged" is battery capacity sufficient for more than or equal to one hour of recording and "very-low" is battery capacity sufficient for less than one hour of recording. Always connect the UPP Puller NXT to the wall charger at the completion of working hours to ensure full charge for the next study period. If the UPP Puller will not be used for an extended period, ensure to power off the device. To power off the device, press and hold the Power button until the LED light turns off.

| | Battery Status | UPP Puller NXT Status |
|---|---|---|
| |  |  |
| **UPP Puller NXT** | Breathing Green: Sufficiently charged or charging. | Breathing Green: Ready<br>Breathing Green - Fast: Sampling or actuator is in motion. |
| | Breathing Amber: Battery is low (less than 60 minutes of operation). | Breathing Amber: Puller is not ready for sampling or motion.<br>Breathing Blue: Firmware upgrade is in progress.<br>Solid Red: Fault<br>Lack of illumination: Puller is sleeping or shut off. |
| | Lack of illumination: Empty/Sleep mode (No declared battery capacity) | |

*Table 14: UPP Puller NXT LED Signals*

# 6.10 T-DOC Air-Charged Catheters

The T-DOC NXT Air-Charged Catheter series are part of the next-generation LABORIE systems designed for use during Urodynamic studies (Figure 90).

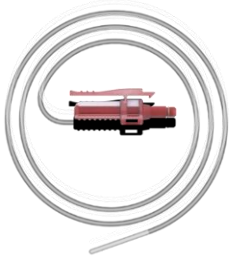


*Figure 90: T-DOC NXT Air-Charged Catheter*

- The T-DOC Air-Charged Catheters are single-use catheters intended for Urodynamic pressure monitoring. T-DOC Air-Charged Catheters are provided sterile and must not be re-used, reprocessed or resterilized.
- The T-DOC Air-Charged Catheters feature a connector developed for use with the PIM NXT.
- The connector is inserted into the charging cavity on the PIM NXT, and a small amount of air is pumped through the catheter lumen(s) into the air balloon located at the distal end of the catheter. A tactile click indicates that the connector is securely locked in the PIM NXT.
- When external pressure is applied to the balloon, the pressure transducer registers this pressure differential and sends the data to the Roam NXT. For information on how to setup the T-DOC Air-Charged Catheters, refer to the Setting Up Consumables and Preparing the Patient section on page 24.

- To disconnect the catheter from the PIM NXT, press down on the thumb tab and gently pull the connector from the PIM NXT.
- T-DOC catheters provide the option of an integrated infusion lumen that connects to the LABORIE Infusion Pump Tubing. Each catheter connector contains a SmartSense tag that allows the user to scan information into the Synergy software facilitating consumable traceability.
- The connectors are color coded as per industry standard (Figure 91)—blue(Pves), red(Pabd), and yellow(Pura).

*Figure 91: T-DOC NXT Catheters – Color Coding*

- The PIM NXT uses an equivalent color-coding strategy to allow the user to match color coded transducers to catheters of the same color (Figure 92). The PIM NXT features an additional green transducer channel that can be used for vesical, abdominal, or urethral measurement.

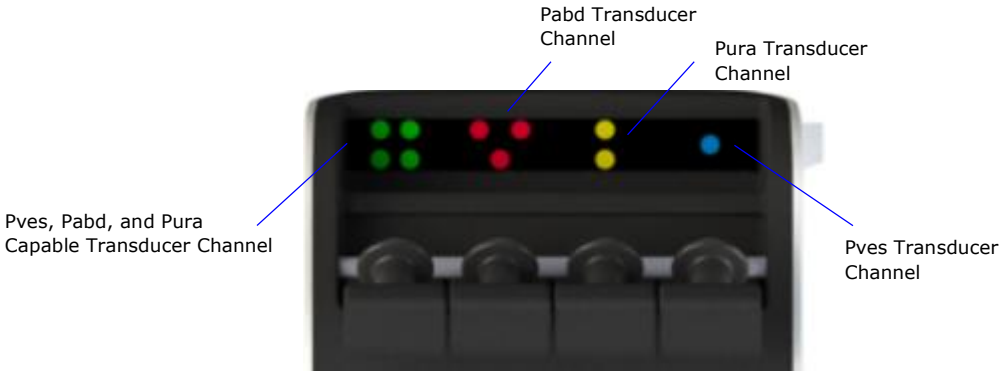



*Figure 92: PIM NXT Color Coded Transducer Channels*

**IMPORTANT:** Place all required supplies on a table or tray for easy access when preparing the patient for full Urodynamic testing. Refer to the Gathering Supplies and Equipment section on page 15 for more information.

# 6.11 EMG Electrodes

The following EMG patches are required for the user to perform a Urology Urodynamic study: Snap-on electrodes (ELE428) and cable (CAB1091, CAB1092, CAB1103, CAB1104).

For information on how to place the electrodes, refer to the Placing the EMG Patch Electrodes section on page 29.

# 6.12 Commode

The Commode Chair (CHA181 or CHA171) and Funnel (CHA102) are required equipment for performing a FreeFlow or Urology Urodynamic study. Further information on how to setup the commode chair, funnel, and Urocap NXT, can be found in the Gathering Supplies and Equipment section on Page 19.

# 7 Appendix

## Appendix A: System Specifications

### Equipment Specifications

| | |
|---|---|
| **NXT Go Power Requirements** | For proper operation, the system requires main power 120-240 VAC, 50/60Hz.<br>POW1043: PSU, Medical Grade, 24V, 1.33A AC/DC<br>POW006: Power Cord, 110V, 18AWG, 10ft, 125V, 10A<br>CAB1056: Cable, USB 2.0 Hi Speed A/B, 6ft Long with Ferrites |
| **Operating Conditions** | Temperature: +10° C to +40° C<br>Humidity: A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa<br>Pressure Range: 700hPa to 1060hPa |
| **Transport Conditions** | Temperature: -30° C to +60° C<br>Humidity: up to 95 ± 5% RH Non-Condensing<br>Pressure Range: 700hPa to 1060hPa<br>***IMPORTANT**: The LABORIE recommended transport conditions (-10° C to +40° C, 20% to 80% RH Non-Condensing) are labelled on the outside of the packaging. Laborie tests to more extreme conditions to ensure this product can withstand any unexpected conditions which may arise.*<br>*Laborie has not performed testing to verify system functionality when transported outside of the limits provided* |
| **Storage Conditions** | Temperature: -20° C to +40° C<br>Humidity: up to 85 ± 5% RH Non-Condensing<br>Pressure Range: 700hPa to 1060hPa<br>***IMPORTANT**: LABORIE has not performed testing to verify system functionality when stored outside of the limits provided.* |
| **Laptop PC** | Computer: Dell Mobile Precision Workstation 3550<br>Screen: 15.6", 1920x1080<br>CPU: i5-10310U with Intel UHD Graphics 620<br>RAM: 16GB, 2X8GB, DDR4 2666Mhz<br>HDD: 512 GB SSD<br>OS: Windows 10 Enterprise LTSC 2019 64 bit Multilanguage |

| | |
|---|---|
| | Ports: 3x USB, 1x USB-C, 1 HDMI, 1 Ethernet, Micro SD<br>Wireless: Wireless LAN 802.11 ac Dual Band<br>Bluetooth: Laborie Bluetooth Dongle required<br>Audio: Internal speakers, Headphone & Microphone<br>Conference: Integrated Webcam with microphone<br>Keyboard: 102/3 keys with function keys & number pad<br>Variants: USA, UK, Canadian bilingual, Spanish QWERTY, French AZERTY, German QWERTZ<br>Battery: Up to 4 hours<br>Dimensions: 24 x 36 x 1.5 cm, 1.9kg, 9.5 x 14 x 0.6”, 4.1lbs |
| **NXT Go Pump Hub**<br>**P/N: DCX2101** | Dimensions: 147mm L X 137mm W X 185mm H<br>Weight: 2kg<br>Output Channels: 1 Infusion / 1 USB Type B<br>Power Supply: 24V, 1.33A AC/DC<br>Flow Rate Range: 1mL/min to 150 mL/min<br>Infused Weight: 0g to 1500g (±5% of actual value or ±10g whichever is greater)<br>IP Rating Compliance: IPX3<br>Type BF Applied Part: N/A<br>External materials: Aluminum 6061, Cycoloy C6200-111, Dow Corning QP1-250, Polyester EBG187L, Stainless Steel, Zinc Plated Steel, IXEF 1022, Grilamid LV-5H, Nickel-plated Neodymium, Santoprene 101-64, Desmopan DP 9370AU |
| **NXT Go Infusion Hook**<br>**P/N: MSM1185** | Dimensions: 104mm L X 46mm W X 80mm H<br>Weight: 0.25kg<br>Output Channels: 1 Weight<br>Infused Volume: 0mL to 1500mL (±2% of actual value or ±10mL whichever is greater)<br>IP Rating Compliance: IPX0<br>Type BF Applied Part: N/A<br>External materials: Aluminum 6061, Cycoloy C6200-111, Stainless Steel, PVC, Desmopan DP 9370AU |

| | |
|---|---|
| **Roam NXT**<br>**P/N: ROX2001** | Dimensions: 154mmx65mmx38mm<br>Weight: 229 g<br>Power Supply: 5VDC, 1.5A max<br>IP Rating Compliance: IP47<br>Type BF Applied Part: EMG/CMG, Pressure transducers<br>External Materials: Cycoloy C6200-111, Makrolon, Dow Corning, Elastosil 3003/70 A/B, Gold-plated brass, Lexan 8010 Film, Loctite. |
| **PIM NXT for T-DOC**<br>**P/N: PIX2211** | Dimensions: 76mmx72mmx26mm<br>Weight: 90g<br>Pressure Range: -70 to +400 cmH20; EMG Range: ±1mV<br>Output Channels: 4 Pressure /2 EMG<br>Bandwidth: Pressure= 20Hz; EMG=0.5Hz to 1kHz<br>IP Rating Compliance: IP47<br>Type BF Applied Part: EMG/CMG, Pressure Transducers<br>External Materials: Cycoloy C6200-111, Elastosil 3003/70 A/B, Gold-plated brass, Hardened Steel, Lexan 8010 Film |
| **PIM NXT for Fluid**<br>**P/N: PIX2231** | Dimensions: 86mmx70mmx26mm<br>Weight: 75g<br>Pressure Range: -40 to +400cmH2O; EMG Range: ±1mV<br>Output Channels: 4 Pressure / 2 EMG<br>Bandwidth: Pressure = 25Hz; EMG = 0.5Hz to 1kHz<br>IP Rating Compliance: IP47<br>Type BF Applied Part: EMG/CMG, Pressure Transducers<br>External Materials: Cycoloy C6200-111, Gold-plated brass, Lexan 8010 Film |
| **Urocap NXT**<br>**P/N: UCX2001** | Dimensions: 150mmx150mmx80mm<br>Weight: 700g<br>Flow Range: 0 to 50mL/s; Volume Range: 0-2L<br>Output Channels: 1 Weight<br>Measured Weight Range: 0 to 2000g<br>Bandwidth: Flow=1Hz max.; Volume=5Hz.<br>IP Rating Compliance: IP47<br>External Power Supply: 5VDC, 1,5A max<br>Internal Power Supply: Li-Polymer Battery, 3.7V, 2400mAh |

| | |
|---|---|
| | Type BF Applied Part: N/A<br>External Materials: Dow Corning QP1-250, Cycoloy C6200-111, Elastosil 3003/30 A/B, Gold-plated Brass, Loctite 401 & 242<br>***IMPORTANT**: LABORIE cannot guarantee the IP47 rating unless the vent plug is inserted into the open vent hole.* |
| **UPP Puller NXT**<br>**P/N: UCX2001** | Dimensions: 18”(45.7cm) L X 2.5”(6.4cm) W X 4.5”(11.4cm) H<br>Weight: 1.8 lbs. (0.82kg)<br>Arm extension: 32” (81.3cm)<br>Speed: 0 to 2 mm/s<br>IP Rating Compliance: IP54<br>Supported catheter sizes: 4.5-12 French<br>External materials: Cycoloy C6200-111, Aluminum 6061-T6, POM-C, Dow Corning QP1-250, Stainless Steel, TPE, Fluoroelastomer Rubber |
| **Remote NXT**<br>**P/N: RCX2001** | Dimensions: 65mmx36mmx119m<br>Weight: 100g<br>Internal Power Supply: 3x AAA batteries<br>IP Rating Compliance: IPX0<br>Type BF Applied Part: N/A<br>External Materials: Cycolac GPM5500S, Autotex 2F 157 |
| **Bluetooth Dongle**<br>**P/N: BTX2001** | External Power Supply: 5VDC, 35mA max<br>IP Rating Compliance: IPX0<br>Type BF Applied Part: N/A |
| **Accessories** | External Materials<br>Funnel: Cycolac Resin, Acrylonitrile-butadiene-styrene terpolymer<br>Beaker: Polypropylene<br>Commode: Powder-coated Steel and Plastic<br>EMG Cable (CAB1091, CAB1092): Polyamide and Thermoplastic Elastomer<br>EMG Cable (CAB1103, CAB1104): PVC, Polyolefin, PA |

*Table 15: Equipment Specifications*

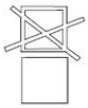
# Classification and Applicable Directives

| | |
|---|---|
| **Classifications** | Class I Type BF Applied Part<br>Mode of Operation: Continuous<br>Equipment not suitable for use in the presence of a Flammable Anesthetic Mixture with Air or Oxygen or Nitrous Oxide. |
| **Applicable Directives and Standards** | • IEC 60601-1:2012<br>• CAN/CSA C22.2 No. 60601-1:14<br>• AAMI/ANSI ES60601-1:2005/(R)2012 + A1:2012<br>• EN 60601-1:2006/A1:2013<br>• IEC 60601-1-6:2006 + A1:2013<br>• IEC 60601-2-49:2011<br>• CAN/CSA C22.2 No. 60601-2-49:11 (R2016)<br>• IEC 60601-1-2:2014<br>• CAN/CSA-C22.2 NO. 60601-1-2:16<br>• EN 60601-1-2:2015<br>• IEC 62304:2006 + A1:2015<br>• EN 62304:2006/AC:2008<br>• IEC 62366-1:2015<br>• EN 62366:2008<br>• IEC 62133:2012 |
| **Related Standards** | • TIR57:2016<br>• ANSI/UL 2900-1:2017<br>• ISO 15223-1:2016<br>• IEC TR 62354:2014<br>• ISO/IEC 17025:2017 |

*Table 16: Classifications and Directives*

# Appendix B: Symbols Glossary

| | | | | | |
|---|---|---|---|---|---|
| EC REP<br>Authorized Representative in the European Community (5.1.2)[1]:<br>Indicates the manufacturer's device representative in the European Community. | SGS<br>SGS certification - certified to U.S. and Canadian safety standards. |  <br>Date of Manufacture (5.1.3) [1]:<br>Indicates the date of device manufacture. |  <br>Manufacturer (5.1.1)[1]:<br>Indicates the device manufacturer. |  <br>Consult Instructions for Use (5.4.3)[1]:<br>Manufacturer recommends consultation of Instructions for Use. |  <br>Read Operator's Manual (M002)[3]:<br>Indicates user must refer to Owner's Manual. |
| LOT<br>Lot - Batch Code (5.1.5) [1]:<br>Indicates the batch or lot code for identification and tracking purposes. | REF<br>Catalogue Number (5.1.6)[1]:<br>Indicates the device model or catalogue number. | SN<br>Serial Number (5.1.7)[1]:<br>Indicates unique device serial number for device traceability. |  <br>Class II Equipment (Table D.1, 9) [2]:<br>Identifies Class II Medical Electrical Equipment. |  <br>Type BF Applied Part (Table D.1, 20) [2]:<br>Identifies a type BF applied part complying with IEC 60601-1. |  <br>Use-by Date (5.1.4)[1]:<br>Indicates date after which use is prohibited. |
| STERILE<br>Sterile (5.2.1)[1]:<br>Indicates a sterile device. | STERILE R<br>Sterilized Using Irradiation (5.2.4)[1]:<br>Indicates method of sterilization used as irradiation. |  <br>Alternating Current (Table D.1, 1)[2]:<br>Indicates use of Alternating Current. |  <br>Direct Current (Table D.1, 1) [2]:<br>Indicates use of Direct Current. |  <br>Non-ionizing electromagnetic Radiation (5140) [5]:<br>Radio Frequency (RF) Transmitting Device<br>Indicates presence of RF transmitters. |  <br>Keep Dry (5.3.4)[1]<br>Indicates a device requiring protection from moisture. |
|  <br>Power Off (Table D1, 13) [2]:<br>Indicates power off control. |  <br>Power ON (Table D.1, 14) [2]:<br>Indicates a stable position power 'on' control. |  <br>Do Not Re-Use (5.4.2) [1]:<br>Medical device intended for single use, on a single patient, during a single procedure. |  <br>Safety Label, No Pushing (P017) [3]:<br>To prohibit pushing against a specified device. |  <br>Safety Label, No Sitting (P018)[3]:<br>Indicates sitting on the identified surface is prohibited. |  <br>Safety Label, No Stepping on Surface (P019) [3]:<br>To prohibit stepping on a specified surface. |
|  <br>Humidity Limitation (5.3.8) [1]:<br>Indicates the humidity range to which the medical device can be safely exposed. |  <br>Temperature Limit (5.3.7) [1]:<br>Indicates the temperature limit to which the medical device can be safely exposed. |  <br>Fragile, handle with care (5.3.1) [1]:<br>Indicates the medical device can be broken or damaged by not handling carefully. |  <br>This way up (0623) [4]:<br>Indicates the direction which the box should remain oriented (stored or shipped) to avoid potential damage to the device. |  <br>Handle with Care<br>(No Associated Standard)<br>Indicates the medical device can be broken or damaged by not handling carefully |  <br>General Battery (5001B) [4]:<br>Identifies a device related to the power supply by battery. |

| | | | | | |
|---|---|---|---|---|---|
|  <br>Do Not Stack (2402) [3]:<br>Indicates the items shall not be vertically stacked, either because of the nature of the transport packaging or the nature of the items themselves. |  <br>Protective Earth, Grounding (Table D.1, 7)[2]:<br>Identifies any terminal intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of protective earth electrode. |  <br>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. |  <br>General Warning Sign (W001) [3]<br>Indicates a general warning. |  <br>Safety Label, Safe Working Load 1kg |  <br>Safety Label, Safe working Load 10kg |
|  <br>System Safe Working Load |  <br>Safety Label, Pinch Point |  <br>Direction of Pump Flow |  <br>Device Stop button | **EMG**<br>Safety Label, EMG<br>Identifies connection point for electromyography. | (01)00627825011617<br>(11)190516<br>(21)NXTP-XXXXXXXX<br>GS1 2D Data Matrix<br>(01) GTIN<br>(11) Date of Manufacture<br>(21) Serial Number |

1. EN ISO 15223-1 Medical Devices – Symbols to be used with medical device, labels, labelling and information to be supplied – Part 1: General Requirements.
2. CAN/CSA-C22.2 No. 60601-1:14 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
3. BS EN ISO:2012+A6:2016 Graphic symbols – Safety colours and safety signs – Registered safety signs (ISO 7010:2011).
4. ISO 7000:2014 – Graphic Symbols for Use on Equipment – Registered Symbols.
5. IEC 60417 – Graphic Symbols for Use on Equipment.

**NOTE:** Sterility symbols are applicable to consumable devices only. Please refer to consumable device Instructions for Use for complete symbol and instructional overview.

*Table 17: Symbols Glossary*

# Medical Device Label Placement

Refer to Figure 93 below for the location of the Medical Electrical System label for the NXT Go.

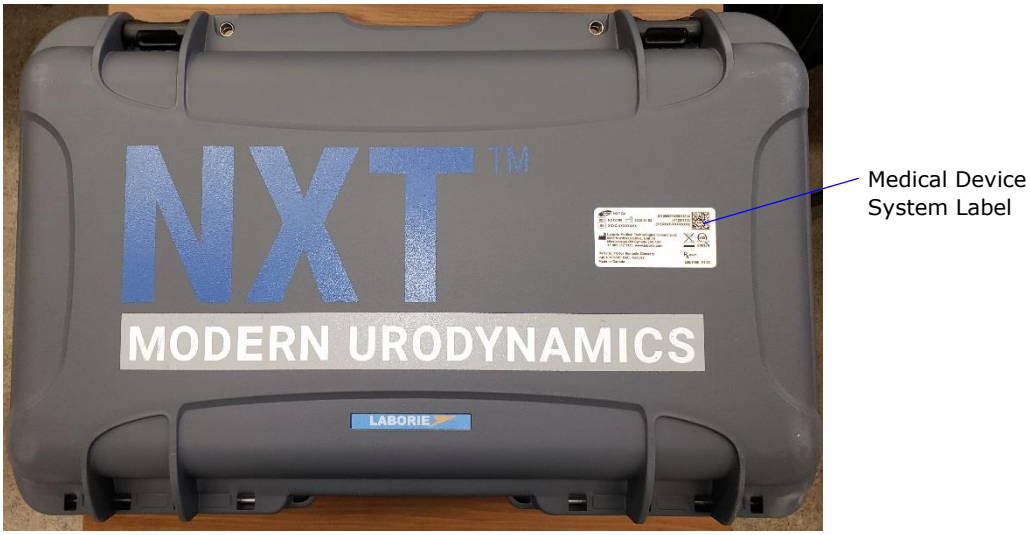



*Figure 93: NXT Go System Label Placement*

# Appendix C: Electronic Compatibility (EMC)

The NXT needs special precautions regarding EMC (Electro Magnetic Compatibility) and needs to be installed and put into service according to the EMC information provided in this manual.

For EM compliance, it is important to only use catheters and accessories as supplied or recommended by LABORIE. Contact LABORIE for approved catheters.

Recommendations for actions to assure that the NXT remains safe regarding EM disturbances:

1. The equipment should be visually inspected regularly for damaged cables and connectors. Damaged cables should be replaced.
2. If the NXT system is used in a location near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, it may be necessary to take preventive actions for reducing the EM interfering level (for instance by shielding the investigation room).

The NXT system contains Bluetooth wireless modules which intentionally receive and transmit RF electromagnetic energy in the 2.4 GHz ISM frequency band.

| Guidance and Manufacturer's Declaration—Electromagnetic Emissions | | |
|---|---|---|
| The NXT measurement system is intended for use in the electromagnetic environment specified below. The customer or the user of the NXT measurement system should assure that it is used in such an environment.<br>When the NXT system is exposed to electromagnetic (EM) disturbances, the system may show abnormal behavior. For instance, the measured traces may become obscured, the software may crash or, in case of very high-level transient voltage events like for instance ESD, parts of the system may even become defective. | | |
| Emission Test | Compliance | Electromagnetic Environment Guidance |
| RF emissions<br>CISPR 11 | Group 1 | The NXT 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<br>CISPR 11 | Class A | The EMISSIONS characteristics of the NXT make it suitable for use in industrial areas and hospitals (CISPR 11 class A).<br>If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. |
| Harmonic emissions<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | Complies | |

*Table 18: Guidance and Manufacture's Declaration – Electromagnetic Emissions*

| Guidance and Manufacturer's Declaration—Electromagnetic Immunity | | | |
|---|---|---|---|
| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment — Guidance |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact<br>±15 kV air | ±8 kV contact<br>±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<br>IEC 61000-4-4 | ±1 kV for input/output lines<br>±2 kV for AC and DC powerlines | ±1 kV for input/output lines<br>±2 kV for AC and DC powerlines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±1 kV differential mode<br>±2 kV common mode | ±1 kV differential mode<br>±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0% $U_T$ (100% dip in $U_T$) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.<br><br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><br>0% $U_T$ (100 % dip in $U_T$) for 5 secs | 0% $U_T$ (100% dip in $U_T$) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.<br><br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><br>0% $U_T$ (100 % dip in $U_T$) for 5 secs | Mains power quality should be that of a typical commercial or hospital environment. If the user of the NXT requires continued operation during power mains interruptions, it is recommended that the NXT be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Note: $U_T$ is the AC mains voltage prior to application of the test level. | | | |

| Guidance and Manufacturer's Declaration—Electromagnetic Immunity | | | |
|---|---|---|---|
| Immunity test | IEC 60601 Test level | Compliance Level | Electromagnetic Environment—Guidance |
| Conducted RF IEC 61000-4-6<br><br>Radiated RF IEC 61000-4-3 | 3 Vrms 150 kHz to 80 MHz<br>6Vrms for ISM bands<br><br>3 V/m<br>80 MHz to 2,7 GHz<br><br>27 V/m<br>385 MHz<br><br>28 V/m<br>450 MHz<br><br>9 V/m<br>710/745/780 MHz<br><br>28 V/m<br>810/870/930 MHz<br><br>28 V/m<br>1720/1845/ | 3 Vrms<br><br>3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the NXT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance**<br>d = 1,17 P<br>d = 1,17 P 80 MHz to 800 MHz<br>d = 2,33 P 800 MHz to 2,7 GHz<br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br>The EMG channel is (fairly) sensitive to conducted and radiated RF. Disturbance of the EMG trace is possible at and below the specified test level. It may be necessary to relocate the NXT or to apply shielding.<br>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 near the equipment marked with the following symbol: |

| | | | |
|---|---|---|---|
| | 1970 MHz<br><br>28 V/m<br>2450 MHz<br><br>9 V/m<br>5240/5500/<br>5785 MHz | |  |

**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 NXT is used exceeds the applicable RF compliance level above, the NXT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NXT.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

*Table 19: Guidance and Manufacturer's Declaration – Electromagnetic Immunity*

| Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the NXT | | | |
|---|---|---|---|
| The NXT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NXT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NXT as recommended below, according to the maximum output power of the communications equipment.<br>⚠ **WARNING**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the NXT 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 Hz<br>$d=1{,}17\sqrt{P}$ | 80 MHz to 800 MHz<br>$d=1{,}17\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d=2{,}33\sqrt{P}$ |
| 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 meters(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.<br>**Note 1**: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>**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 Distances between Portable and Mobile RF Communications Equipment and the NXT*

# Transmitter and Wireless Compliance Statements

This device complies with part 15 of the FCC Rules. This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science, and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions: (1) This device may not cause interference. (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil contient des émetteurs / récepteurs exemptés de licence qui sont conformes aux RSS exemptes de licence d'Innovation, Sciences et Développement économique Canada. Le fonctionnement est soumis aux deux conditions suivantes: (1) Cet appareil ne doit pas causer d'interférences. (2) Cet appareil doit accepter toute interférence, y compris celles susceptibles de provoquer un fonctionnement indésirable de l'appareil.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.