glean™
modern urodynamics

Glean Urodynamics System

Owner's Manual

Operation, Care, and Maintenance

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ABOUT THIS MANUAL

SYMBOLS

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

 CAUTION

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

 IMPORTANT

Important symbol describes important information about using the device.

 NOTE

Note symbol describes additional information about the device.

1 INTRODUCTION

1.1 DEVICE DESCRIPTION

The Glean Urodynamics System (GUS) is indicated for standard Urodynamic tests such as Uroflow (UF), Cystometrogram (CMG), Urethral Pressure Profile (UPP), and Micturition Studies (MS).

GUS consists of the following three physical component elements: Sensor, Insertion Tool, and Uroflowmeter, as well as the following three software applications: Glean Mobile App (Clinician), Glean Mobile App (Patient), and Glean Web App. The patient may use the Glean Mobile App as a digital voiding diary, logging fluid input, leakage, urgency, and other urological symptoms. The clinician may use the Glean Mobile App to prepare the Sensor for insertion, log symptoms, and download data. The Glean Web App may be used by clinicians to view and analyze data.

The Sensor can be inserted through the urethra into the bladder using the Insertion Tool. Once inserted, the Sensor has a Removal String that hangs out of the urethra to enable removal of the Sensor. The Sensor may stay in the bladder for the entire duration of monitoring while collecting data. The Sensor stores data that may be wirelessly transmitted to the Glean Mobile App (Clinician) once it is removed from the body.

The Uroflowmeter is used to measure voided volume and flow. The Glean Mobile App (Clinician) wirelessly receives data from the Uroflowmeter after the patient has completed a voiding cycle.

Data from the Glean Mobile App (Clinician and Patient) is synchronized wirelessly in the cloud and made available for review, analysis, and interpretation by trained clinicians using the Glean Web App. After the clinician has completed analysis and interpretation, they may use the Glean Web App to generate the report documenting the Urodynamic findings.

1.1.1 Sensor

- The Sensor (Figure 1) is a long, flexible tube with rounded ends and a removal string.
- The Sensor is designed to be inserted into the bladder through the urethra using the Insertion Tool.
- The Sensor contains a battery and flexible electronic circuit board with a microprocessor, software, pressure sensor and memory to store data.
- The Sensor is designed to curl into a circular shape once inserted in the bladder to ensure the Sensor stays in the bladder until removal is desired.
- When desired, the clinician may remove the Sensor by gently pulling on the Removal String. This will pull the Sensor out of the body through the urethra.
- The Sensor can collect data for the duration of Urodynamic monitoring..
- The Sensor is a one-time use disposable device and designed for use under the supervision of a trained clinician.

Figure 1. Sensor

1.1.2 Insertion Tool

- The Insertion Tool (Figure 2) is used to insert the Sensor in the patient's bladder.
- The Insertion Tool is comprised of two components: the Sheath and the Advancer.
- Once the Sensor is placed in the bladder, the Sheath and Advancer may be removed leaving the Removal String hanging out of the urethra.

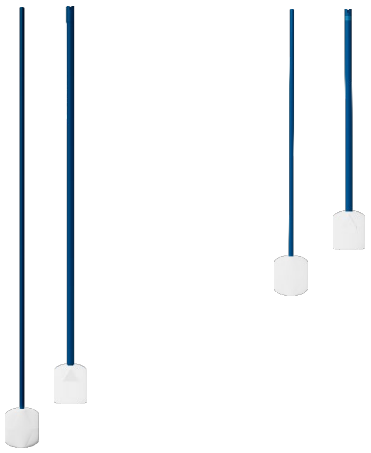


Figure 2. Insertion Tool - Advancer and Sheath (male-left; female-right)

1.1.3 Uroflowmeter

- The Uroflowmeter (Figure 3) measures the voided volume and flow of urine when a patient voids into the urine collection cup.
- The Uroflowmeter is designed to work with commonly available commodes and funnels that may assist users in properly collecting the urine.

Figure 3. Uroflowmeter

1.1.4 Software – Glean Mobile Apps (Clinician and Patient) and Glean Web App

- The Glean Mobile App (Clinician) is used by the clinician to prepare the Sensor for insertion.
- During the period of monitoring, the patient may use the Glean Mobile App (Patient) to complete a digital voiding diary. The patient may log fluid input, leakage, urgency, and other urological symptoms.
- After monitoring is complete, the clinician may use the Glean Mobile App (Clinician) to download data from the Sensor.
- The Glean Mobile App (Clinician) is used to download data from the Uroflowmeter.
- Data from the Glean Mobile App (Clinician and Patient) is synchronized in the cloud and available for review, analysis, and interpretation by a trained clinician using the Glean Web App.
- Once complete, the clinician may use the Glean Web App to generate a Urodynamics report.

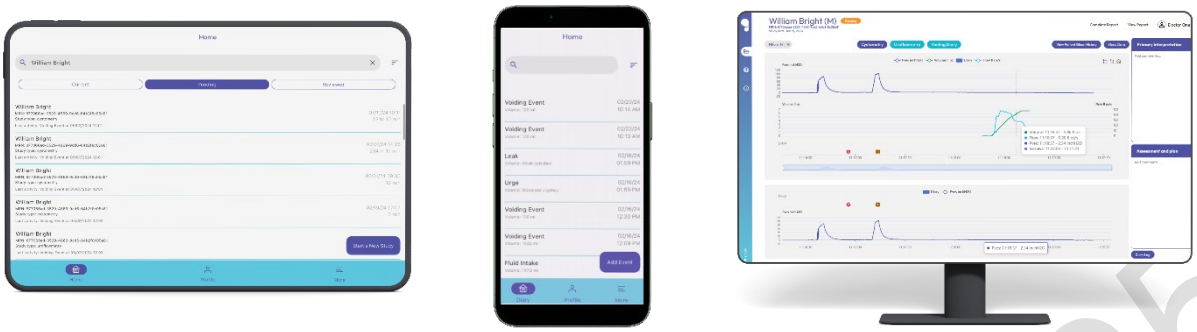


Figure 4: Software (Clinician App, Patient App, Web App)

1.2 GETTING STARTED

To prepare the GUS before performing any Urodynamics procedures:

1. Remove the Uroflowmeter from the packaging and ensure it goes into Awake state by pressing and holding the Button LED on the front of the Uroflowmeter.
2. Clean the Uroflowmeter and charging puck according to instructions in section 4.1.1 Caring for the GUS Uroflowmeter and Charger before ihitial use.
3. Place the Uroflowmeter on the charging puck to charge.
4. Ensure required items in Table 1 are obtained and set up.
5. Ensure mobile devices are connected to wireless internet and desktops are connected to internet.
6. Ensure users have proper access to the Glean Mobile App and Web App.
7. After steps 1 – 6 are complete, the GUS is ready to begin the Urodynamics procedure(s).

Bright Uro Equipment	Customer Provided Equipment
✓ Uroflowmeter ✓ Charging Puck ✓ Power cables ✓ Sensor and Insertion Tool ✓ Uroflowmeter Quick Start Guide ✓ Owner's manual	✓ Laptop or computer for use with the Glean Web App ✓ Mobile device (tablet/phone) for use with the Glean Mobile App ✓ Disposable urine collection cup ✓ Commode chair and funnel ✓ Materials required for aseptic insertion technique (such as a Foley Catheter Insertion Kit). ✓ Water-based lubricant and/or lidocaine gel. ✓ Biohazard bags

Table 1. Required Equipment

1.2.1 How Supplied

1.2.1.1 Sterility

The Sensor and Insertion Tool are provided STERILE (ethylene oxide [EO] sterilization). The sterile packaging should be inspected for visible damage prior to use. Do not use if damage is suspected. Do not reuse or attempt to re-sterilize.

1.2.1.2 Contents

GUS may be provided as two separate packages. One package contains the Sensor and Insertion Tool and a separate package contains the Uroflowmeter.

The Uroflowmeter package contains the following components:

- Uroflowmeter (ME Equipment, no applied parts) - IP54 rated
- Uroflowmeter Wireless Charger - IP54 rated
- Uroflowmeter Charger AC/DC Adapter (Manufacturer // PN: HDP Power// HDP12-MD-WUSB-4) (no ingress protection. Keep away from wet areas)
    - Input ratings: 90~264VAC, 47~63Hz, 12W max
    - Charger rated voltage, power: 5V, 5W

(The combination of the Uroflowmeter Charger and AC/DC Adapter make up the ME System)

The Sensor and Insertion Tool package contains the following components:

- Sensor (Type BF Applied Part)
- Insertion Tool (Sheath and Advancer)

The Glean Mobile App can be downloaded directly from the Google Play™ store for Android products and Apple App Store™ for iOS products. The Glean Web App can be accessed at gleanuds.com
The mobile apps can be downloaded directly from the Google Play™ store for Android products and Apple App Store™ for iOS products.

1.2.1.3 Additional Required Items

- Laptop or computer for use with the Glean Web App
- Mobile device (tablet/phone) for use with the Glean Mobile App
- Urine collection cup
- Commode chair and funnel
- Materials required for aseptic insertion technique (such as a Foley Catheter Insertion Kit)
- Water-based lubricant and/or lidocaine gel
- Biohazard bags

1.2.2 Device Inspection

Inspect each device and packaging to verify that no damage or defects exist. If the device is expired, damaged or if the sterile barrier has been compromised (e.g., hole in device packaging), do not use the device.

1.2.3 Device Storage

- Store the kits at room temperature.
- Avoid direct sunlight.

1.3 LEARNING ABOUT THE GLEAN URODYNAMICS SYSTEM (GUS)

To learn about the features and how-to of the Glean Urodynamics System, read the following documents or sections of this manual:

- GUS Uroflowmeter Quick Start Guide (provided with the equipment shipment)
- GUS Training Videos (may be accessed at gleanuds.com/training)
- Software Features and Functions (see 7 SOFTWARE FEATURES AND FUNCTIONS on page 18)
- How to Run Tests – CMG/PF Test, Uroflow Test, and Data Analysis (see 8 HOW TO RUN TESTS – CMG/PF TEST, UROFLOW TEST, AND DATA ANALYSIS on page 25)

1.4 INTENDED USE / INDICATIONS FOR USE

The Glean Urodynamics System (GUS) is a Urodynamic Analyzer System that is intended to quantify the pressure and flow characteristics of the lower urinary tract. The system can be used to perform standard Urodynamic tests such as Uroflow, Cystometrogram (CMG), Urethral Pressure Profile (UPP), and Micturition Studies.

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

1.5 CONTRAINDICATIONS

- Use of GUS is contraindicated for any patient who is not a candidate for Urodynamic testing.
- The Sensor should not be used on patients who suffer from symptomatic urinary tract infections. Prior to testing, a urinalysis and urine culture should be considered to rule out the presence of infection.
- The Sensor should not be used on patients who suffer from a major stricture in the urethra.
- Single-use, disposable Sensors and Insertion Tools provided by Bright Uro are “sterile,” unless stated otherwise on the packaging label and instructions.
- The GUS Sensor and Insertion Tool are for use on adult patients only.

1.6 TARGET USERS

- Only technicians and clinicians trained in Urodynamics should operate this device. The operator must read the

Owner's Manual entirely and refer to any additional training materials before using the device.

- To reduce the potential for discomfort during the procedure and/or transient discomfort, dysuria and hematuria, technicians and physicians should explain any additional risks of the procedure to the patient.
- To reduce the risk of serious patient injury, it is vital that clinicians performing Urodynamics studies on patients with a Spinal Cord Injury be prepared to recognize and treat Autonomic Dysreflexia. Clinicians must monitor patients with Autonomic Dysreflexia for at least 2 hours after resolution of the episode.
- To reduce the risk of cross-contamination or urinary tract infection, clinicians should be knowledgeable and qualified in applying the appropriate aseptic technique during the intended use of the device. The use of prophylactic antibiotics is at the discretion of the clinician and the policies of the clinic/institution.
- To reduce the risk of serious patient injury, it is vital that technicians and clinicians performing Urodynamics studies be prepared to recognize and treat symptoms associated with vasovagal syncope (fainting) during Urodynamics procedures.

1.7 WARNINGS AND PRECAUTIONS

PRECAUTIONS

⚠ Bright Uro equipment and accessories are licensed by Governments, approved by Safety Agencies, and warranted to work only with each other.

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

⚠ SYSTEM WARNINGS

⚠ DO NOT USE GUS in the presence of a magnetic resonance imaging (MRI) system as it may contain ferromagnetic objects that pose a risk to the patient in the presence of a magnetic core. The strong magnetic field produced by the MRI may cause disruption of the system.

⚠ DO NOT ATTEMPT TO OPEN OR REPAIR GUS components by yourself or by an unauthorized party. ONLY Bright Uro trained technicians may service GUS components.

⚠ Batteries are not operator removable; do not attempt to remove batteries from the GUS system components. All servicing of the GUS system, components or attachments are to be completed by Bright Uro.

⚠ Exposure to electrostatic discharge (ESD) may cause GUS to FAIL.

⚠ Bright Uro is not responsible for loss of patient files or test data.

⚠ Re-use, reprocessing or re-sterilization of disposables can lead to device failure and create a risk of cross-infection and/or cross transmission of infectious disease(s) from one patient to another. The Insertion Tool and Sensor are provided as single use, disposable devices and are intended to be discarded after use.

⚠ DO NOT immerse the GUS Uroflowmeter or other reusable system components in water or any other liquids. Only use approved cleaning agents to clean the Uroflowmeter as outlined in this Owner's Manual.

⚠ WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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

SYSTEM IMPORTANT INFORMATION

1. Use GUS with Bright Uro equipment and accessories only. Do not reuse disposable devices. After use, dispose in accordance with local regulations. Do not use if device packaging has been opened, or damaged, or if it presents any fault due to improper transport, storage, or handling that could in any way hamper its use.
2. Device intended for use in a clinical environment with controlled electromagnetic compatibility (EMC) standards to limit potential interference. GUS may be adversely affected by Bluetooth®, cellular or EMC interference. Minimize interference from other Bluetooth devices by setting up all components of system in proximity to each other. Placement of GUS Sensor on a patient's upper torso should be avoided to minimize any possibility of electromagnetic interference with active implantable devices such as ICD's and pacemakers.

3. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A).

4. Frequency: The system radios operate in the 2.4 GHz ISM (Industrial, Scientific, Medical) band. This band specifically ranges from 2.400 to 2.4835 GHz. Bandwidth: The system radios use a frequency-hopping spread spectrum, where it occupies a channel with a bandwidth of 2MHz. Modulation: BLE primarily uses Gaussian Frequency Shift Keying (GFSK) modulation. Effective Radiated Power: +0dBm

5. The appliance coupler or AC/DC power adapter is not used as an isolation means. The Uroflowmeter isolation is reinforced through plastic and is decoupled to the charger. The 2 means of protection come from the plastics around the charger and the uroflowmeter. Also, the uroflowmeter does not have an applied part and does not contact the patient during normal use. The operator touches the device during use and charge. Therefore, the protection is means of operator, not patient.

. SYSTEM SAFETY COMPLIANCE

1. To prevent unexpected exposure to radiation, the device has been tested against EN 60601-1-2 EMC standards.

2. To prevent exposure to potential electric shock, the device meets and exceeds the insulation breakdown specifications for IEC 60601-1:2005 & A2:2020; EN 60601-1:2006 & A2:2021; ANSI/AAMI ES60601-1:2005 & A2:2021;.

3. To prevent radiofrequency electromagnetic interferences, the device meets and exceeds the specifications for IEC 60601-1-2:2014 & A1:2020; EN 60601-1-2:2015 & A2:2021

4. Warning symbols on all labels comply with ISO 7000, EN ISO 15223-1, and ISO 20417.

5. MRI Safety: The Sensor is ***MR unsafe***. The Sensor should be removed before imaging or treatment.

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

2 ADVERSE EVENTS/RESIDUAL RISKS

2.1 POTENTIAL ADVERSE EVENTS/RESIDUAL RISKS

Possible complications associated with the use of GUS are similar to those associated with other methods of Urodynamics and include, but may not be limited to:

- Autonomic Dysreflexia (for individuals with spinal cord injury)
- Bladder or Urethral Spasms
- Change in Urinary Frequency
- Discomfort
- Injury to the Lower Urinary Tract (LUT) and/or Genitals
- Urinary Urgency
- Urinary Incontinence

- Urinary Retention
- Urinary Tract Infection
- Urinary Tract Inflammation or Irritation
- Broken Sensor Removal String
- Sensor Fracture

2.2 DEVICE-RELATED ADVERSE EVENTS REPORTING

Any device-related adverse event or other incident regarding GUS should be immediately reported to Bright Uro. To report an event or incident, email: support@brighturo.com.

3 PATIENT COUNSELING INFORMATION

The physician should review the risks and benefits with the patient. Patients with a history of urethral strictures or frequent urinary tract infections should be monitored closely.

4 GLEAN URODYNAMICS SYSTEM—CARE AND MAINTENANCE

4.1 GENERAL CARE, CLEANING, AND PREVENTIVE MAINTENANCE

IMPORTANT:

- Always wear protective gloves when cleaning the equipment to prevent biological contamination.
- GUS Sensors and Insertion Tools are intended for SINGLE PATIENT USE only. Do NOT reuse disposables.
- The Uroflowmeter and Uroflowmeter Charger are reusable components intended for multipatient use and repeated use. Thoroughly clean the Uroflowmeter and Charger prior to first use and immediately after each patient use to minimize the risk cross-contamination between patients and infection during patient care.
- The Uroflowmeter and Uroflowmeter Charger components of GUS are non-immersible. The Uroflowmeter and Charger should be wiped down with a clean cloth dampened with a cleaning solution such as soap and water or as per hospital cleaning instructions.
- Do not sterilize the GUS components.
- Performing regular maintenance will reduce the need for costly repairs.
- Pay close attention to the LED lights on each device. If they indicate a broken connection and/or low battery, make sure that the connection is reestablished and fully charge the battery. Refer to 6.1 LED LIGHTS on page 17.
- If an object weighing 5lbs or over is accidentally dropped on the Uroflowmeter surface or the uroflowmeter appears to be giving incorrect readings, run the following checkups.
    - Follow the instructions in section 8.1.9 to Start a new uroflowmetry study
    - Fill the container with 100cc of water and complete the study.
    - Verify that the measured volume is correct once the data is downloaded on the Mobile App.
    - Repeat the steps above using 500cc of water.

If any of the observed readings is incorrect, please contact the BrightUro customer support for further instructions.

4.1.1 Caring for the GUS Uroflowmeter and Charger

The instructions that follow specify how to clean the GUS Uroflowmeter and Charger of possible urine contamination. Thoroughly clean the Uroflowmeter and Charger prior to first use and after each patient's use. Always wear protective gloves when cleaning the equipment to prevent biological contamination

IMPORTANT: Do not soak the GUS Uroflowmeter or Charger in water! Do not immerse in water or in any other liquids! Follow the cleaning instructions precisely to thoroughly clean the Uroflowmeter!

- The GUS Uroflowmeter and Charger has an immersion protection rating of IP54 for ingress of water. This means that the enclosure of the Uroflowmeter and Charger can handle splashes of water and liquid from any direction, but it is not protected against total immersion into water or any other liquids. This complies with IEC 60529 standards.
- After every use, inspect the uroflowmeter or charger for any sign of damage or wear. If any is present, then contact the BrightUro customer support.
- The Glean Uroflowmeter and Charger should be cleaned thoroughly using the following steps:
    - Separate the Uroflowmeter and Charger from each other and the AC Adapter.
    - Set the Uroflowmeter to Asleep state by pressing and holding the Button LED on the front of the device.
    - Wipe the Uroflowmeter and Charger. Potential cleaning solutions in clinic include:

- A cloth dampened with quaternary ammonium germicidal disinfectant solution
- Soap
- Disinfectant Detergent

- Allow the Uroflowmeter and Charger to dry before use.
- Inspect the Uroflowmeter and Charger for any visible organic materials or urine stain. If any is present, repeat the cleaning process above again. There shall be no visible stain or organic materials on the surface of the uroflowmeter.

- WARNING: DO NOT SUBMERSE THE UROFLOWMETER OR CHARGER IN ANY FLUID. DOING SO MAY DAMAGE OR DESTROY THE DEVICE.

- Store the Glean Uroflowmeter and Charger in a cool and dry area at room temperature.
- Calibration: Return the Uroflowmeter annually to Bright Uro for recalibration. Contact Bright Uro to schedule this service as required.

4.1.2 Reuse Instructions for Uroflowmeter and Uroflowmeter Charger

The Uroflowmeter and Charger have a use life of 15,000 cycles based on successful validation testing of reprocessing and reuse of the device under normal use conditions. This number of reuse cycles is estimated based on 20 uses per day over 1 year period which is approximately equal to 5000 uses/year. If you expect the number of uses to exceed this estimate, please notify Bright Uro customer support. Note that the number of reuse cycles is dependent on full compliance with the care and maintenance instructions and directions for use of the Uroflowmeter specified in this manual.

To verify that the Uroflowmeter is ready for each reuse:

- Follow the cleaning instructions in Section 4.1.1 prior to first use and immediately after each patient use.
- After each use, inspect the Uroflowmeter and Charger for any sign of damage or wear. If any is present, then contact the Bright Uro customer support immediately.
- Charge the Uroflowmeter using the Charger as described in Section 5.2.
- While switching the Uroflowmeter from the Asleep to Awake state prior to use, the device will automatically run a Power On Self-Test to check the performance of the device. If the Uroflowmeter shows abnormal LED patterns, follow the instructions in Section 11 (Troubleshoot). If the problem persists, contact Bright Uro customer support.

4.2 BATTERY—CHARGING AND PREVENTATIVE MAINTENANCE

4.2.1 Charging the Battery

The GUS Uroflowmeter contains rechargeable batteries. The battery status is indicated by the Button LED on the front of the Uroflowmeter. For information on battery status, see 6 EQUIPMENT STATUS INDICATORS AND BUTTONS on page 17.

To charge the GUS Uroflowmeter:

- Plug the power cable of the Uroflowmeter Charging Puck into an electrical outlet.
- Place the GUS Uroflowmeter securely onto the Charging Puck.
- Confirm that the Uroflowmeter button LED shows that the device is being charged.

NOTE:

- When the Button LED on the device is BLUE, it is charging.
- The Uroflowmeter is the only rechargeable device in the Glean Urodynamics System.
- The Uroflowmeter can be used while charging.

4.4 TREATING AND DISPOSING OF PRODUCT AFTER USE

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

- Packaging waste should be collected separately for available national packaging collection and recycling services.

4.5 ENVIRONMENTAL CONSIDERATION OF WASTE DISPOSAL

Because the GUS is designed to perform Uroflow studies using the Uroflowmeter, it is important to dispose of waste (such as urine) properly to prevent environmental pollution. The waste should be disposed of in such a way that will not pollute the freshwater supply system—especially the drinking water system. In areas that have sewage systems with water treatment procedures, the most convenient method of disposal is to use these sewage systems.

4.6 PREVENTIVE MAINTENANCE—CHECKING CALIBRATION

Proper regular maintenance of the uroflowmeter will maximize the life of the product. The uroflowmeter must be calibrated every 12 months. If you suspect that the uroflowmeter is giving incorrect readings, please contact the Bright Uro customer support team.

Return the Uroflowmeter annually to Bright Uro for recalibration. Contact Bright Uro to schedule this service as required. The Uroflowmeter and accessories has been designed and rated for an expected service life of 3 years with proper regular maintenance. The Uroflowmeter has use life of and been successfully tested for 15,000 cycles under normal use conditions.

5 SET UP THE GLEAN URODYNAMICS SYSTEM (GUS)

Upon receiving the Glean Urodynamics System, inspect the equipment for any visible signs of damage or mishandling. If damage has been found, notify the carrier immediately. Bright Uro recommends saving carrying cases and cartons to provide a convenient and safe way to return the equipment should service be required.

5.1 SENSOR SETUP

The Sensor and Insertion Tool are intended for SINGLE PATIENT USE only. Do NOT reuse disposables. To set up the GUS Sensor for Urodynamics and to run a CMG/PF Test, refer to 8.1 CMG/PF TEST on page 25.

5.2 UROFLOWMETER SETUP

The Uroflowmeter and its Charging Puck are the only reusable components of GUS. The following are required to set up the GUS Uroflowmeter for Urodynamics:

- Charge the Uroflowmeter by placing it on its Charging Puck.
- For normal use, place the Uroflowmeter on a flat and reasonably level floor as needed for tests.
- Place an unused urine collection cup on the Uroflowmeter. Ensure the urine collection cup is placed inside the silicon ring as indicated in Table 2.
- To awake the Uroflowmeter from sleep mode, press and hold the button on the front of the device for at least 3 seconds.
- To put the Uroflowmeter to sleep mode from Awake mode, press and hold the button on the front of the device for 3 seconds.
- To run a Uroflow Test refer to 8.1.9 Run a Uroflow Test on page 38.

Figure 5. Urine Collection Cup Placement

6 EQUIPMENT STATUS INDICATORS AND BUTTONS

6.1 LED LIGHTS

The LED light for the GUS Sensor is located in the middle of the unit. The LED lights for the GUS Uroflowmeter are located on the front of the device. Table 2 provides a description of LED light locations.

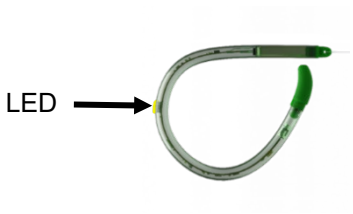
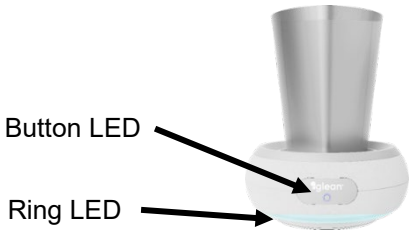
GUS Sensor	GUS Uroflowmeter
	

Table 2. Device LED Light Locations

6.1.1 Sensor LED Patterns

The Sensor LED will flash after the power button is pressed for at least 3 seconds while it is pairing via Bluetooth. Once paired, the Sensor will stop flashing. The Sensor will continue flashing for 150 seconds if it is not paired with a Bluetooth device.

6.1.2 Uroflowmeter LED Patterns

Device State	Ring LED	Button LED
OFF	OFF	OFF
ON	Pulsing	Pulsing
ON – Bluetooth Connected	Pulsing	Solid
ON – Collecting Data	Solid	Solid

Table 3. Uroflowmeter Device State LED Patterns

⚠ WARNING: If the Button LED displays a Triple ORANGE Flash, then conditions have not been met to enter acquisition mode (e.g. battery state critical, Bluetooth not connected, session available, Power On Self-Test failed).

⚠ WARNING: If the Button LED displays a Single ORANGE Flash, then the Power On Self-Test failed. Put the device into Asleep state and switch to Awake state again. If the problem persists, contact Bright Uro.

Battery State	Button LED
CHARGING	BLUE
NORMAL	WHITE
LOW	PINK
CRITICAL	ORANGE

Table 4. Uroflowmeter Battery State LED Patterns

NOTE: If the battery state is LOW or CRITICAL, place the Uroflowmeter on the charging puck.

7 SOFTWARE FEATURES AND FUNCTIONS

This section provides instructions on how to navigate the GUS Software – Glean Web App and Mobile Apps. For more information on the software, refer to 1.1.4 Software – Glean Mobile Apps (Clinician and Patient) and Glean Web App on page 10.

7.1 ACCESSING THE GLEAN APPS

Users can access the Glean Web App at gleanuds.com. The Glean Mobile App can be downloaded directly from the Google Play™ store for Android products and Apple App Store™ for iOS products.

7.1.1 Access the Glean Web App

Navigate to the Glean Web App at gleanuds.com

7.1.2 Install the Glean Mobile Apps

1. Login to mobile device.
2. Navigate to the Android/iOS App Store.
3. Search for the “Glean UDS” mobile app.
4. Download the Glean Mobile App.
5. Open the Glean Mobile App and allow the app to use Bluetooth.

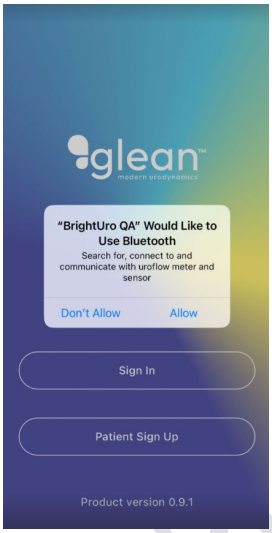


Figure 6. Glean Mobile App Bluetooth Connection

6. Create an account or login using account information.

7.2 LOGIN TO THE GLEAN MOBILE OR WEB APPS

Users can log into the Glean Mobile or Web Apps with account information.

1. Open the Glean Mobile or Web Apps.
2. Enter user email.
3. Enter user password.
4. Click “Sign In” to login.

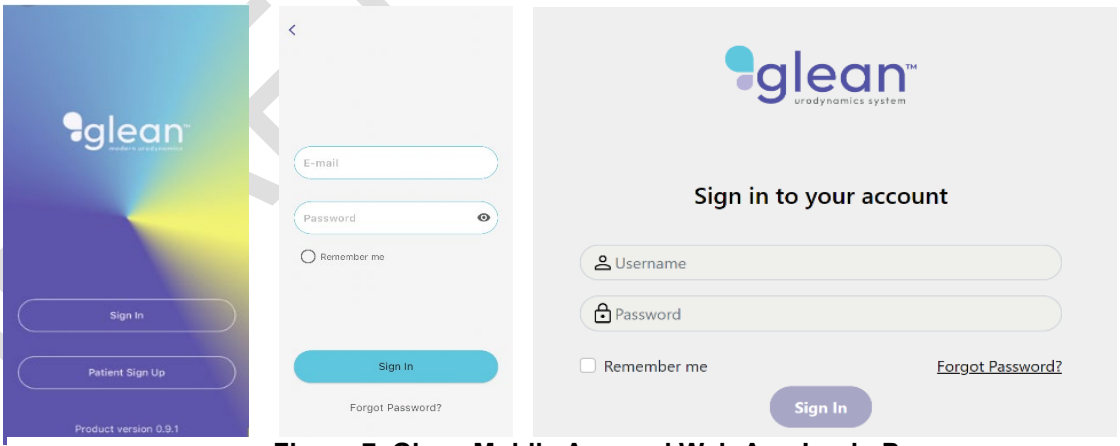


Figure 7. Glean Mobile App and Web App Login Page

NOTE: If a device is provided to patients by the clinic, ensure the patient is logged out of account upon returning the device. Accounts will be automatically logged out after 30 minutes of inactivity.

7.3 CREATE USER ACCOUNTS

Clinic Admins (Referred to as Tenant in the Glean Web App) will create accounts for designated personnel to support GUS procedures.

1. Login to the Glean Web App (Admin).

2. Navigate to the desired account page (Admin/CP/Patient) using the three bars icon on the top left.

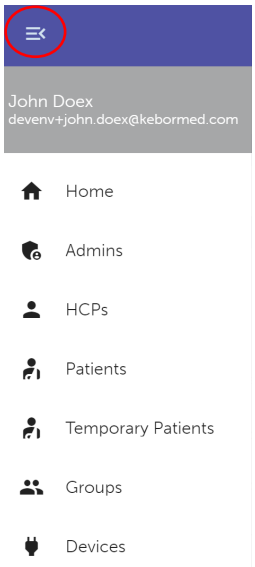


Figure 8. Navigate to Account Page

3. Select the three dots icon at the top right and click “CREATE.”

Figure 9. Create an Account

4. Enter the required information and click “SUBMIT.

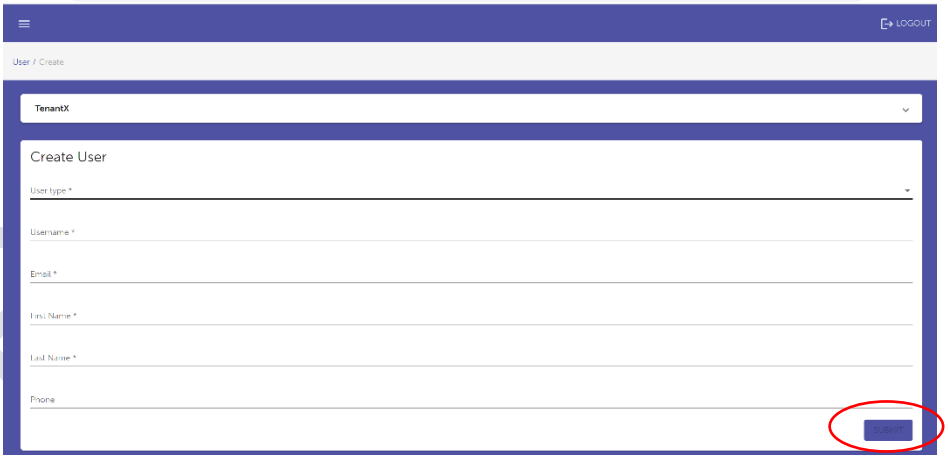


Figure 10. Enter Account User Information

7.4 DELETE USER ACCOUNTS

Clinic Admins may use the web portal to delete user accounts as required.

1. Login to the Glean Web App (Admin).

2. Navigate to the desired account page (Admin/HCP/Patient).

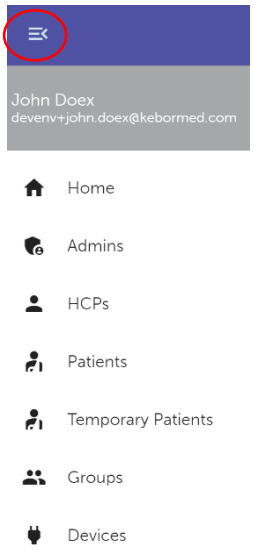


Figure 11. Navigate to Account Page

3. Locate the user account and click “VIEW.”

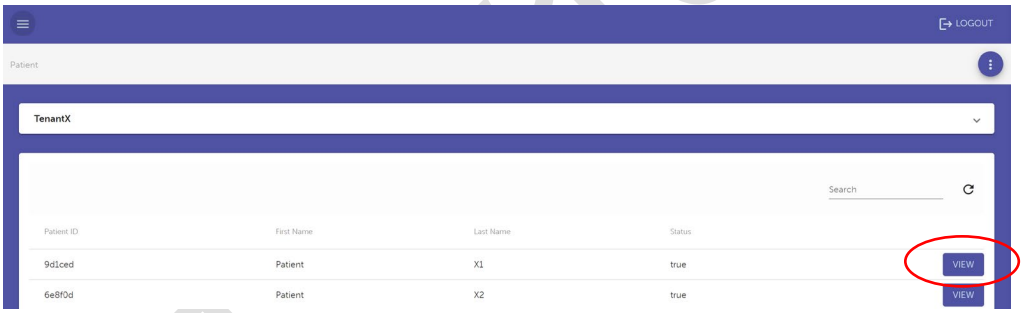


Figure 12. View User Account

4. Select the three dots icon at the top right and click “DELETE.”

Figure 13. Delete User Account

5. Click “YES” to delete user account.

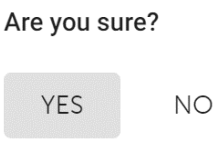


Figure 14. Confirm Deletion of User Account

7.5 RESET PASSWORD

Admin or users may reset a password for a Glean account.

7.5.1 Admin

1. Login to the Glean Web App (Admin).
2. Navigate to the desired account page (Admin/HCP/Patient).

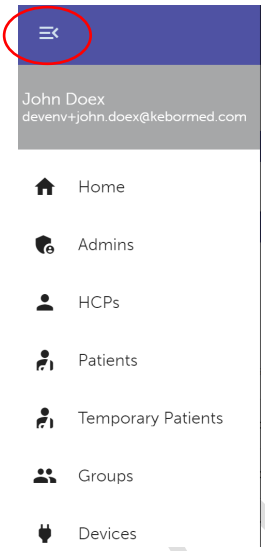


Figure 15. Navigate to Account Page

3. Locate the user account and click “VIEW.”

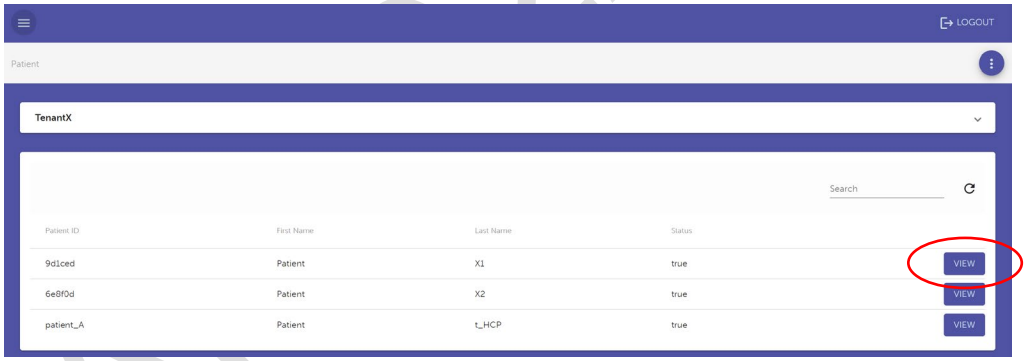


Figure 16. View User Account

4. Select the three dots icon at the top right and click “RESET PASSWORD.”

Figure 17. Reset Password

5. Observe the success message at bottom of screen saying, “Email successfully sent.”

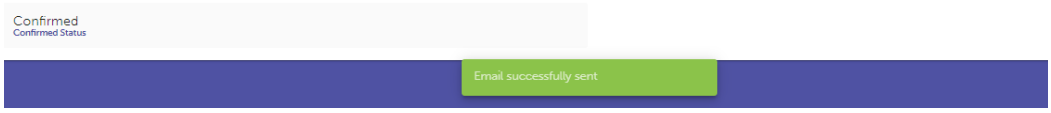


Figure 18. Reset Password Email Successfully Sent

7.5.2 User

1. Open the Glean Mobile or Web App.
2. Select “Forgot Password?”

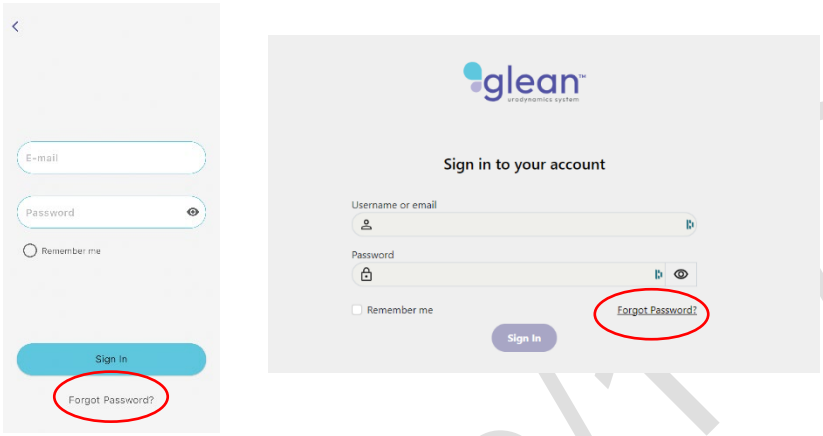


Figure 19. Forgot Password

3. Enter user email and click “Send” or “Submit.”

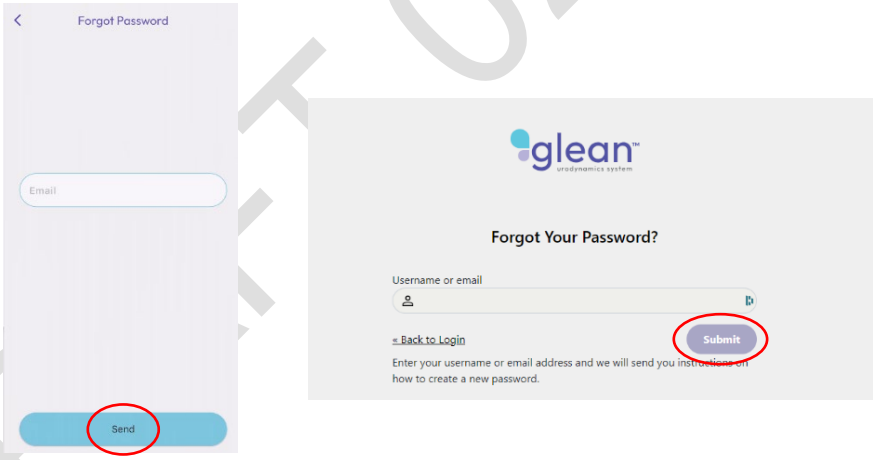


Figure 20. Send Email to Reset Password

4. Click on verification link in email.
5. Enter a new password.
6. Login to the Glean Mobile or Web App using the new password.

7.6 ADD A PATIENT PROFILE IN THE GLEAN ADMIN PORTAL

Use the Glean Admin portal to ensure the correct patient information is uploaded for future Urodynamics evaluation.

1. Obtain patient information needed for entry into the Glean Web App (Admin).
2. Login to the Glean Web App (Admin).

3. Select the three bars icon and click on “Patients.”

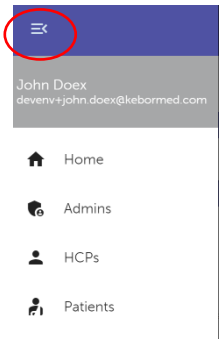


Figure 21. Patient Account Page

4. Select the three dots icon and click “CREATE.”

Figure 22. Create Patient Account

5. Enter the patient information and click “SUBMIT.”

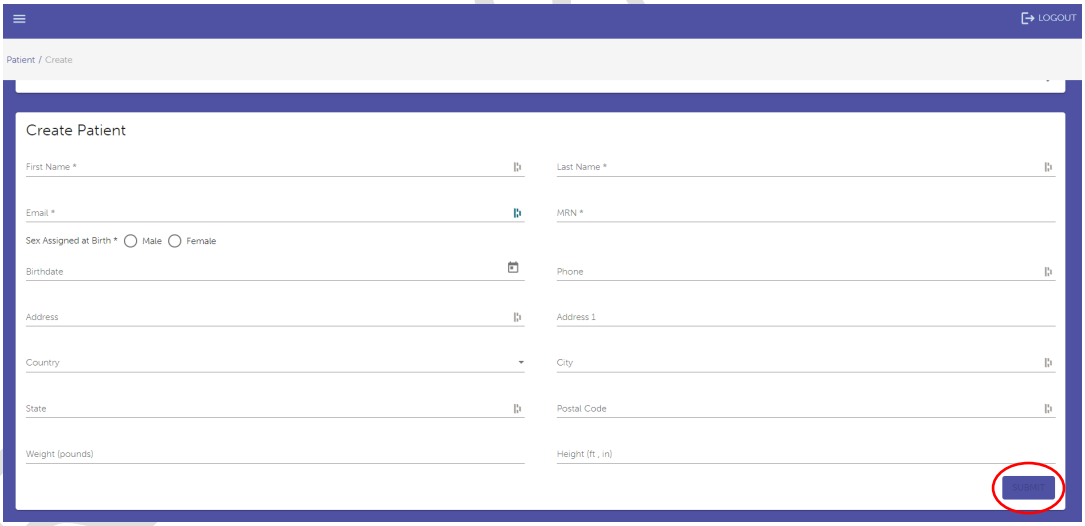


Figure 23. Enter Patient Information

6. Observe the green pop-up window at the bottom of the screen to confirm patient entry.

NOTE: If a patient’s email is already in the system but not associated with a clinic, a pop up will ask “Do you want to invite this patient to your clinic?” Select “OK”, and an email will be sent to the patient to ask if they would like to associate with the clinic. Have the patient accept the invitation to be associated with your clinic.

8 HOW TO RUN TESTS – CMG/PF TEST, UROFLOW TEST, AND DATA ANALYSIS

This section provides instructions on how to run tests with the GUS. For instructional videos on how to run tests with GUS, visit gleanuds.com/training. For more information on equipment or accessories setup, refer to 1 INTRODUCTION on page 9.

8.1 CMG/PF TEST

The purpose of running a CMG/PF test is to determine whether the bladder and its surrounding tissues are functioning correctly. The CMG test involves allowing the bladder to fill in a natural, antegrade manner and determining the vesical pressure, Pves, via the GUS Sensor.

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

8.1.1 Prepare the patient for aseptic insertion.

8.1.2 Instill lubricant in the urethra.

Instill lubricant with or without lidocaine in the urethra if needed based on clinical judgement.

8.1.3 Prepare the Sensor for data collection.

1. Inspect labeling to select the proper sensor for the patient's gender (male or female).
2. Open the outer box and remove pouch. Do not open the pouch or remove the Sensor from the pouch at this step.
3. Login to the Glean Mobile App (Clinician).
4. Select "Start a New Study."

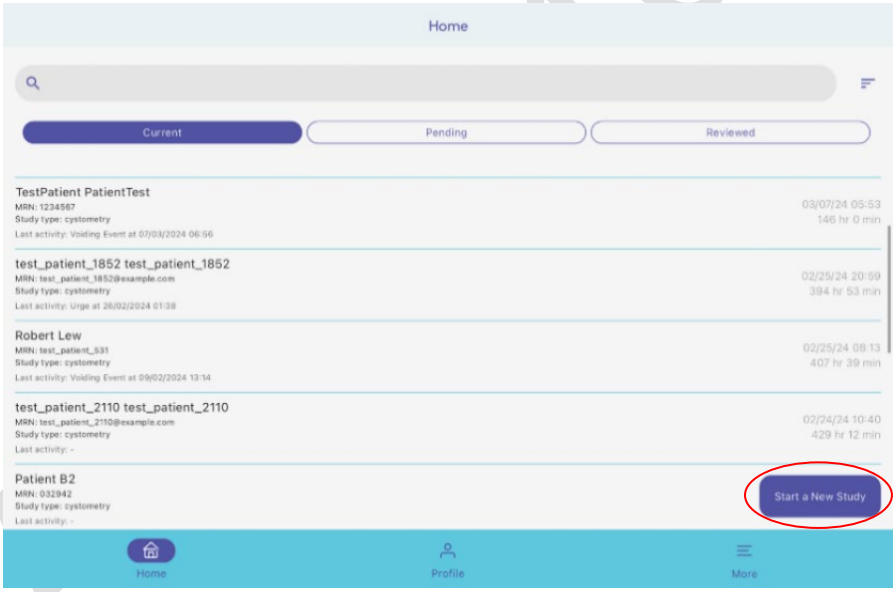


Figure 24. Start a New Study

5. Select the correct patient.

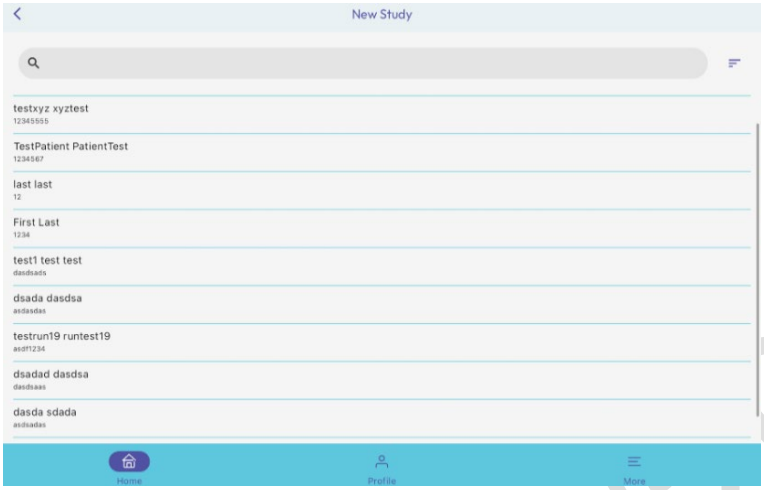


Figure 25. Select a Patient

6. Confirm the patient's information.

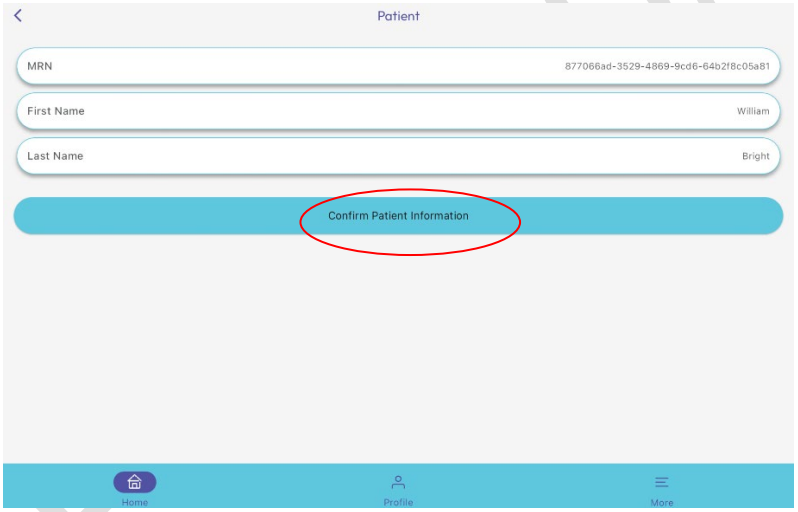


Figure 26. Confirm Patient Information

7. Confirm the patient's information and select "Start Study."

Figure 27. Start Study

8. Select “Add Events or Devices.”

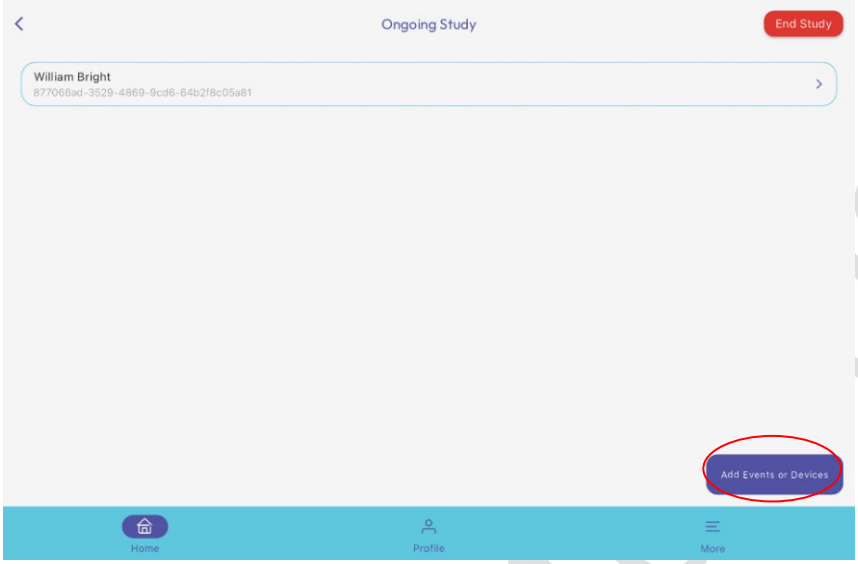


Figure 28. Add Events or Devices

9. Select “Add Sensor.”

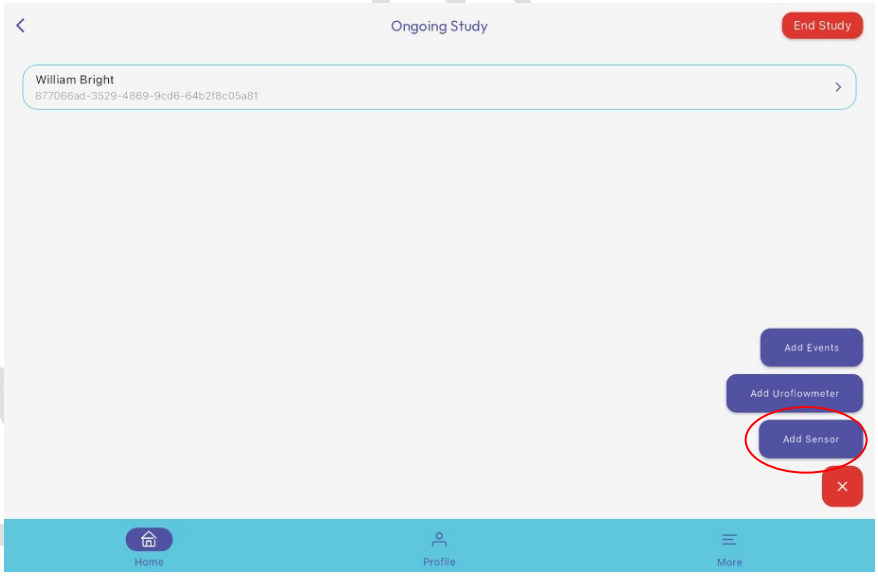


Figure 29. Add Sensor

10. Press and hold the Sensor button for >3 seconds while inside the packaging to power on the sensor and click “Next” when complete. When the sensor is powered on you will see the LED flashing.

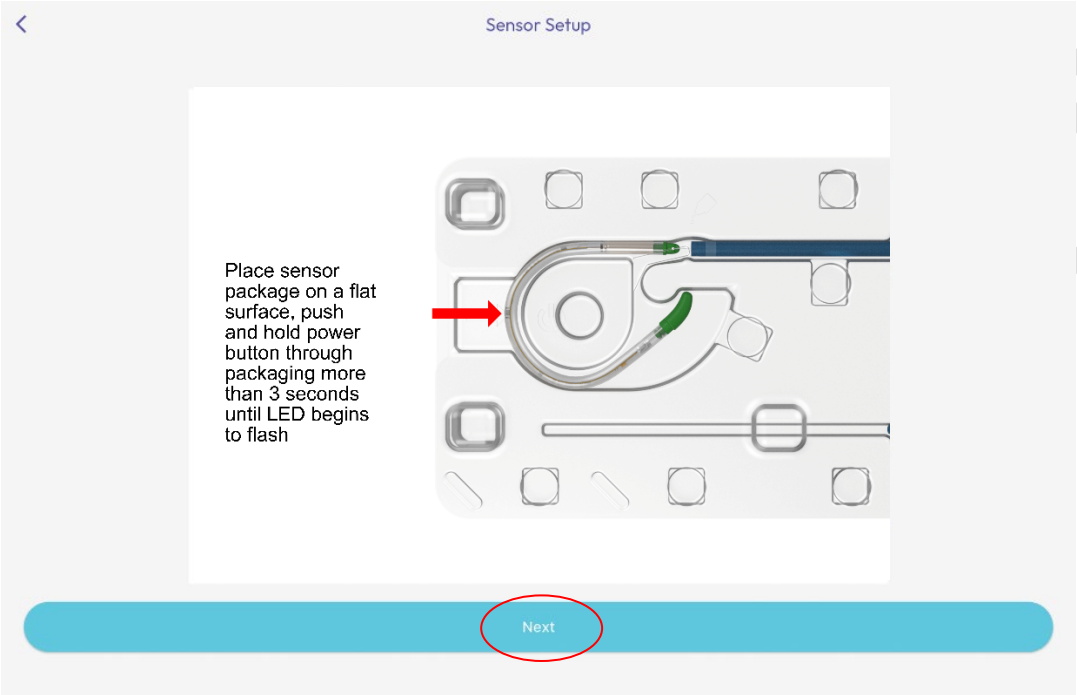


Figure 30. Power On the Sensor

11. Scan the QR code on the plastic tray through the pouch and allow the Glean Mobile App to access your camera.

Figure 31. Scan the QR Code

12. Enter the PIN from the label near the QR Code. Once bonded, click “Setup Sensor.”

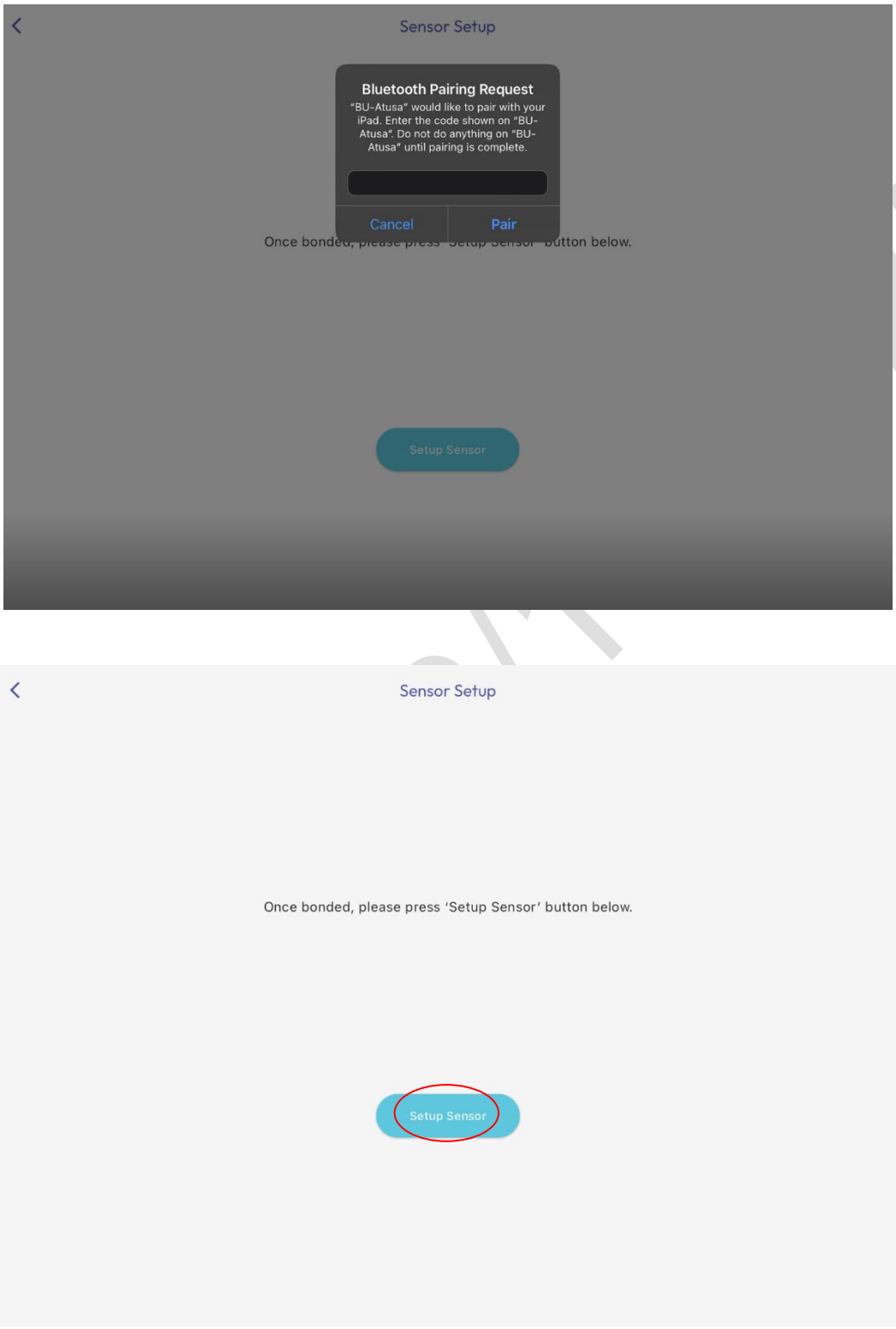


Figure 32. Enter PIN and Setup Sensor

13. Follow the instructions to calibrate the Sensor by leaving the Sensor on a flat surface. Click “Done” when calibration steps are complete.

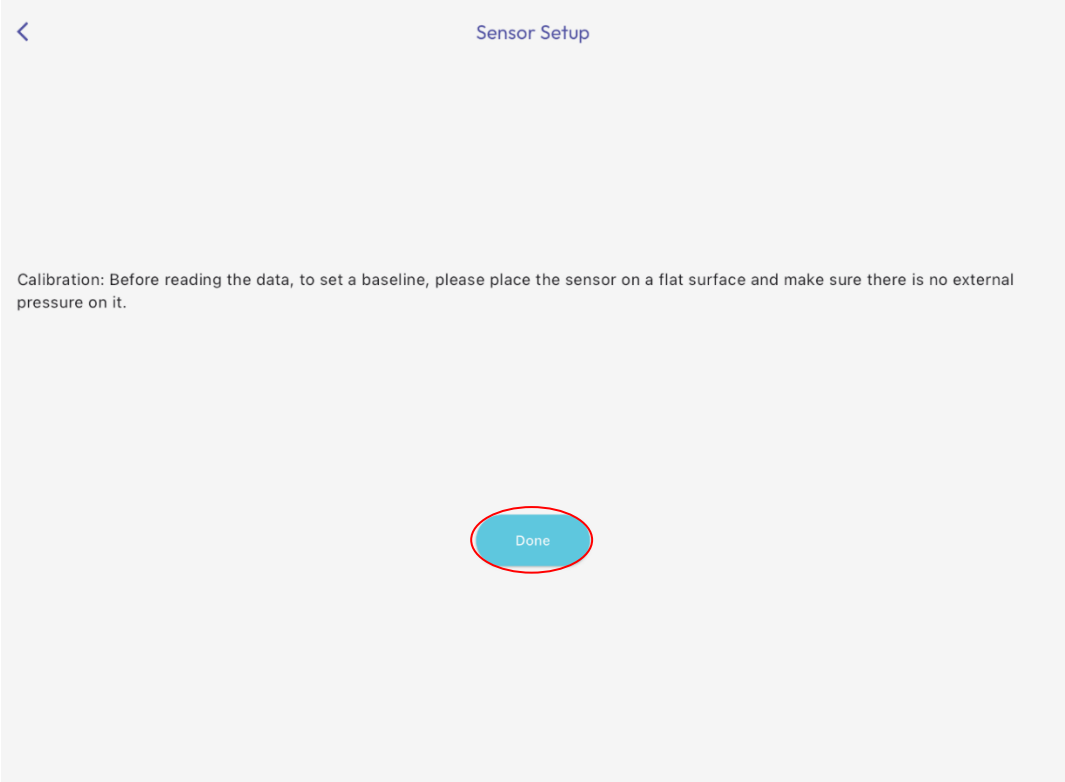


Figure 33. Calibrate the Sensor

NOTE: A pop-up message will tell you if the Sensor is not functional and to discard. If this occurs, repeat the steps in 8.1.3 with a new Sensor.

8.1.4 Load the Sensor in the Sheath.

1. Peel the pouch open using the chevron end.
2. Gently drop the tray onto a flat surface.
3. Prepare for aseptic insertion (wash hands, put on sterile gloves, gather any additional items needed for a sterile field, etc.).
4. Open the plastic tray lid.
5. Apply lubricant to the entire length of the Sensor with specific focus on the space between the Sensor endcap and the Sheath.
6. Grab the Removal String and place in line with sheath so that it is hanging over the edge of the plastic tray.
7. Gently close the tray lid ensuring that each snap is properly seated, especially around the Sensor.
8. Using the left hand to hold the tray still, gently pull the Removal String until the sensor is fully loaded into the Sheath.
9. Open the plastic tray lid and lift the Sheath out of the plastic tray.
10. Inspect the Sensor tip to ensure proper alignment and seating of the Sensor and Sheath locking feature.
11. If necessary, apply gentle pressure to rotate and seat the Sensor into the Sheath locking feature.

8.1.5 Deploy the Sensor in the bladder.

8.1.5.1 Male Patient

1. Apply gentle traction to the tip of the penis to straighten the urethra.
2. Grasping the body of the Sheath, insert the tip of the Sensor into the urethra.
3. While maintaining traction on the penis, gently advance the Sheath ensuring not to push past any significant resistance.
4. Continue advancing the Sheath until the handle of the Sheath is near the tip of the penis.
5. Gently withdraw the Sheath approximately 2-4 centimeters.

6. Use one hand to grasp the handle of the Sheath and the other hand to pick up the Advancer.
7. Insert the Advancer and push to deploy the Sensor.
8. Continue pushing the Advancer until the handle meets the handle of the Sheath.
9. Gently withdraw the Advancer and confirm placement with visual observation of urine flow.
10. If urine does not flow, maintain the positioning of the Sheath and wait at least 20 seconds to observe urine flow.
11. If urine still does not flow, remove the Sheath then remove the sensor and reattempt insertion with a new Sensor once the patient's bladder has filled.
12. Gently remove the Sheath ensuring not to pull the Removal String.
13. Secure the Removal String to the patient's body using tape (or similar materials such as Tegaderm).
14. Click "Deployment Complete" or "Deployment Failure" on the Glean Mobile App (Clinician) when Sensor deployment is completed/failed (Figure 34).

8.1.5.2 Female Patient

1. Separate the labia to expose the urethra.
2. Grasping the body of the Sheath, insert the tip of the Sensor into the urethra.
3. Continue advancing the Sheath until approximately ½ of the Sheath is inside the patient's body.
4. Use one hand to grasp the handle of the Sheath and the other hand to pick up the Advancer.
5. Insert the Advancer and push to deploy the Sensor.
6. Continue pushing the Advancer until the handle meets the handle of the Sheath.
7. Gently withdraw the Advancer and confirm placement with visual observation of urine flow.
8. If urine does not flow, maintain the positioning of the Sheath and wait at least 20 seconds to observe urine flow.
9. If urine still does not flow, remove the Sheath then remove the sensor and reattempt insertion with a new Sensor once the patient's bladder has filled.
10. Gently remove the Sheath ensuring not to pull the Removal String.
11. Secure the Removal String to the patient's body using tape (or similar materials such as Tegaderm).
12. Click "Deployment Complete" or "Deployment Failure" on the Glean Mobile App (Clinician) when Sensor deployment is completed/failed (Figure 34).

NOTE: If at any time you feel resistance do NOT force the Insertion Tool. You may need to apply more lubrication before continuing insertion.

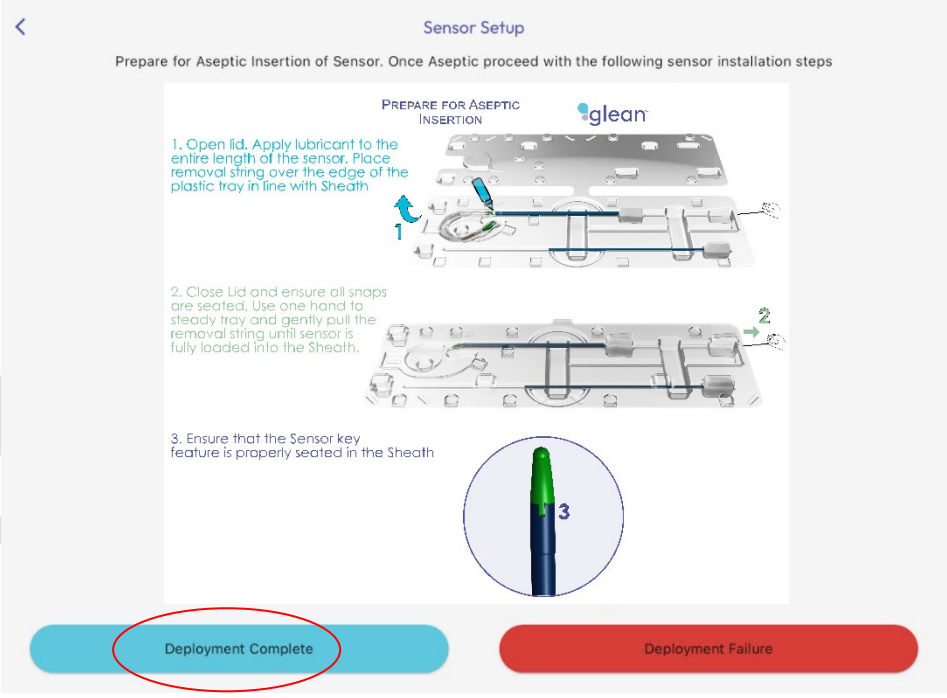


Figure 34. Sensor Deployment Complete or Failure

8.1.6 Log events using the Glean Mobile App (Clinician).

1. Login to the Glean Mobile App (if not already logged in).

2. If desired, perform any series of guided maneuvers based on patient history, symptom presentation, and goals for urodynamic evaluation.
3. Use the Glean Mobile App (Clinician) to select the correct patient for the ongoing study and select “Add Events or Devices.”

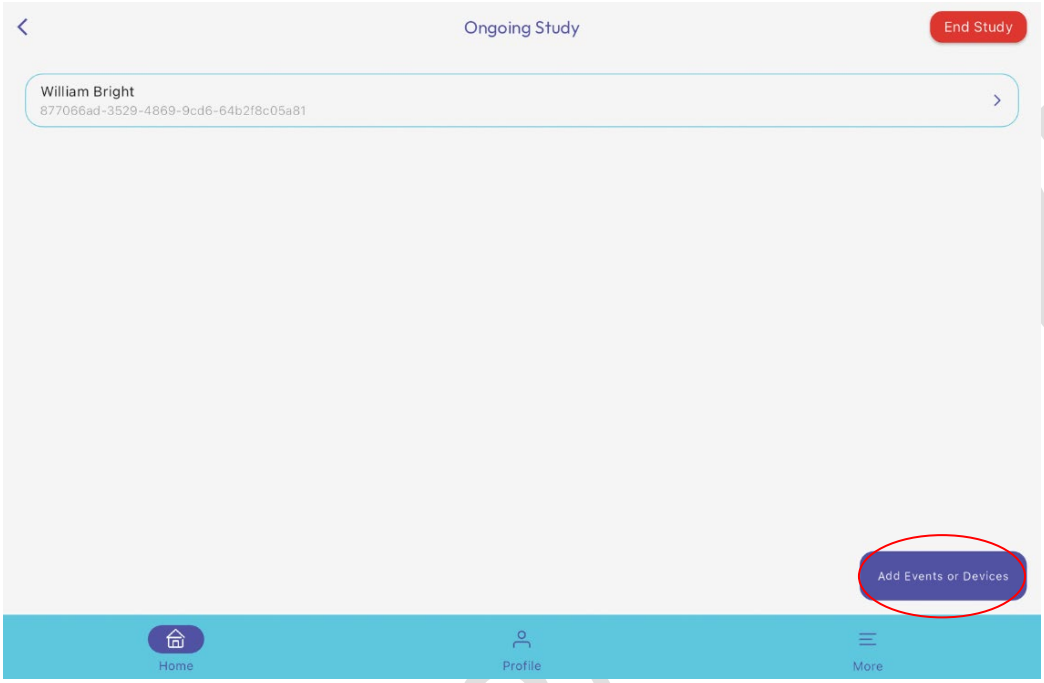


Figure 35. Add Events or Devices

4. Select “Add Events.”

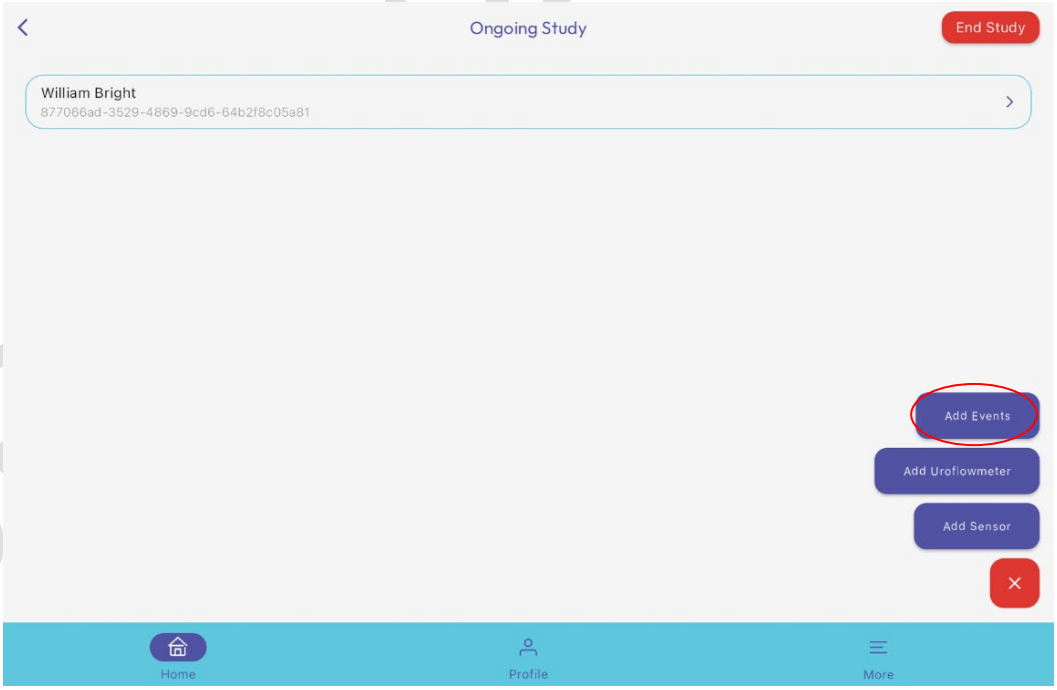
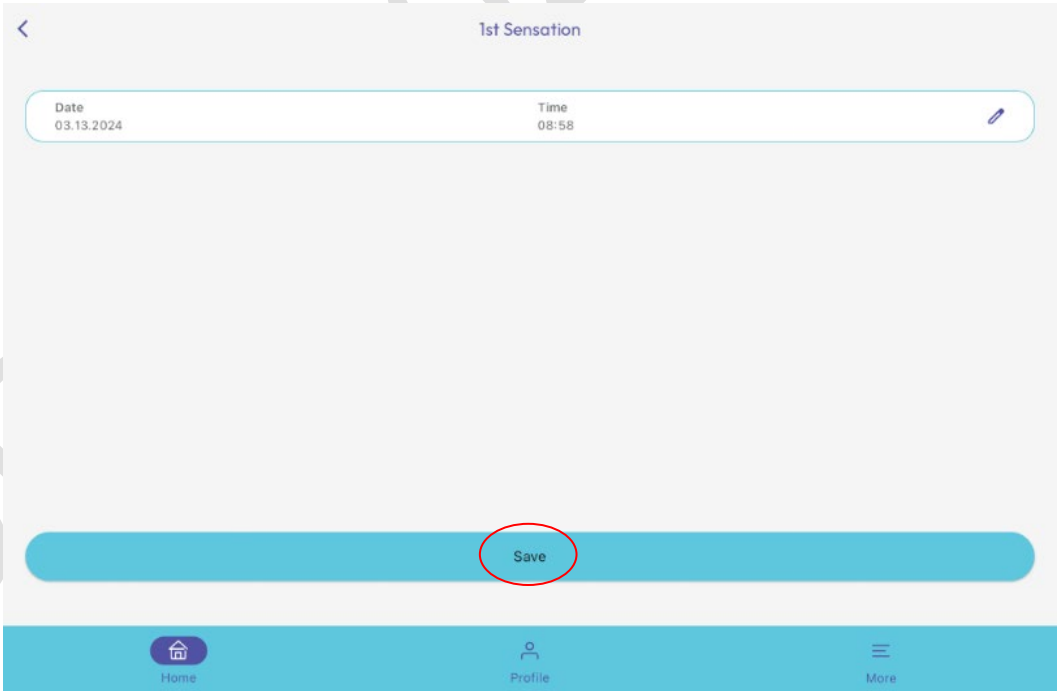


Figure 36. Add Events (Clinician)

5. Select the desired event (Cough, Valsalva, PVR, 1st Sensation, 1st Desire, Strong Desire, Voiding Event, Leak, Fluid Intake, Urge, Others) and guide the patient to perform maneuver if necessary.

Figure 37. Select Appropriate Event (Clinician)

6. Confirm the event details and enter required information. Select “Save.” Examples of 1st Sensation and Leak are shown below in Figure 37.



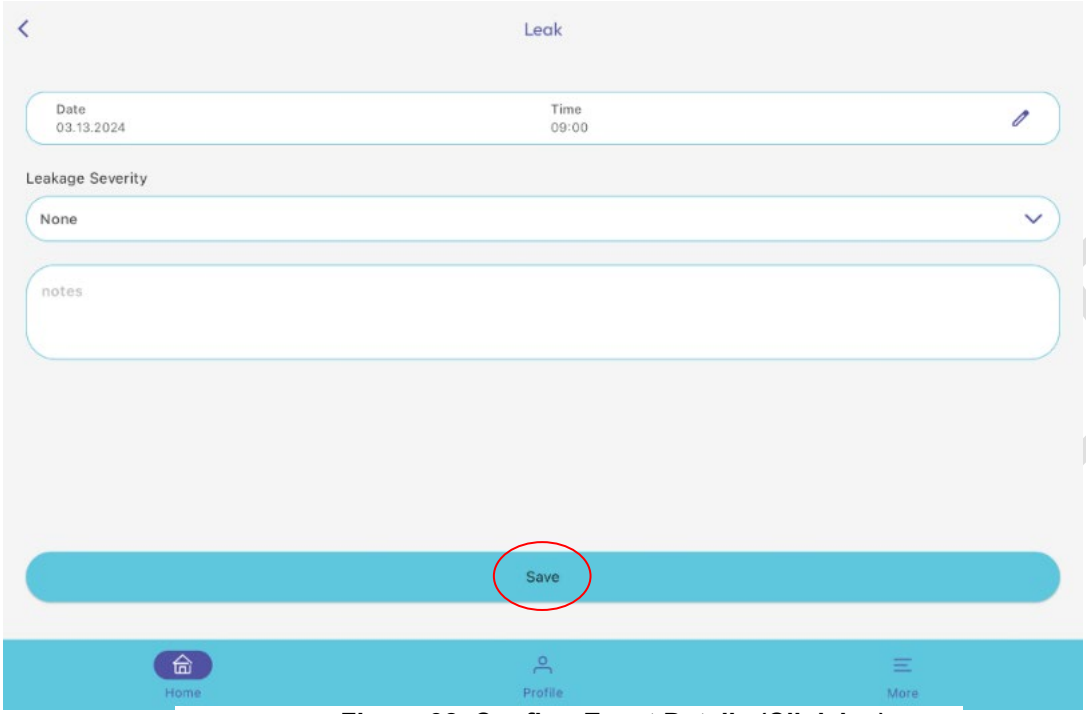
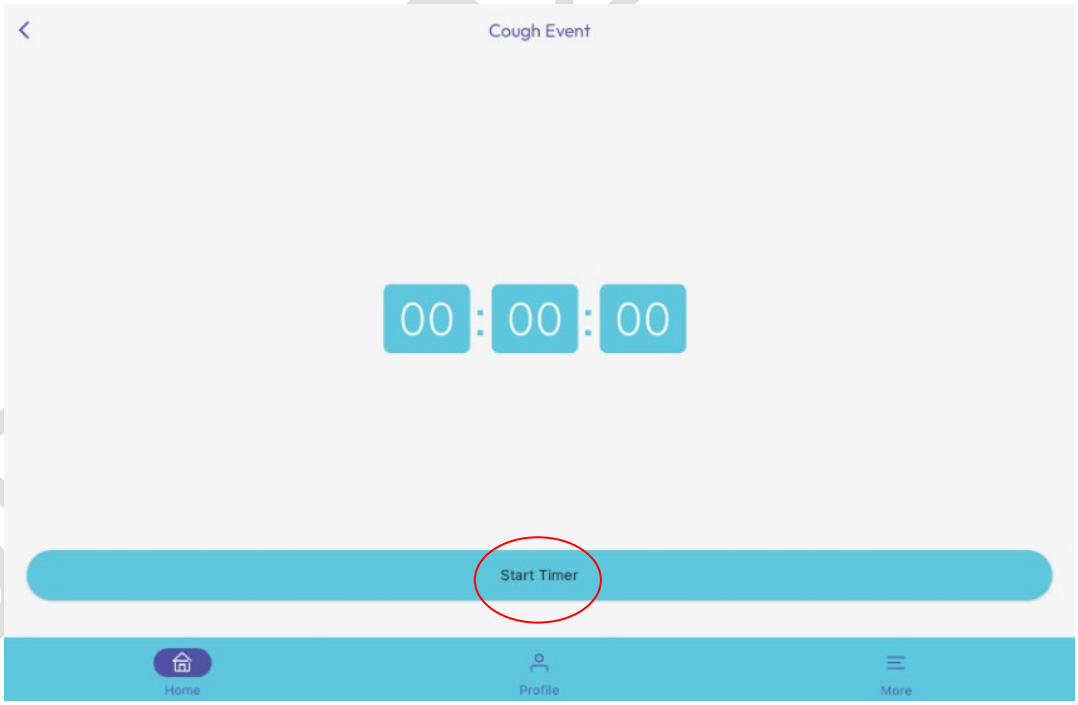


Figure 38. Confirm Event Details (Clinician)

7. To log a Cough or Valsalva, ask the patient to perform maneuver after you click “Start Timer.” Click “Stop Timer” when patient is finished performing maneuver. An example of Cough is shown below in Figure 38.



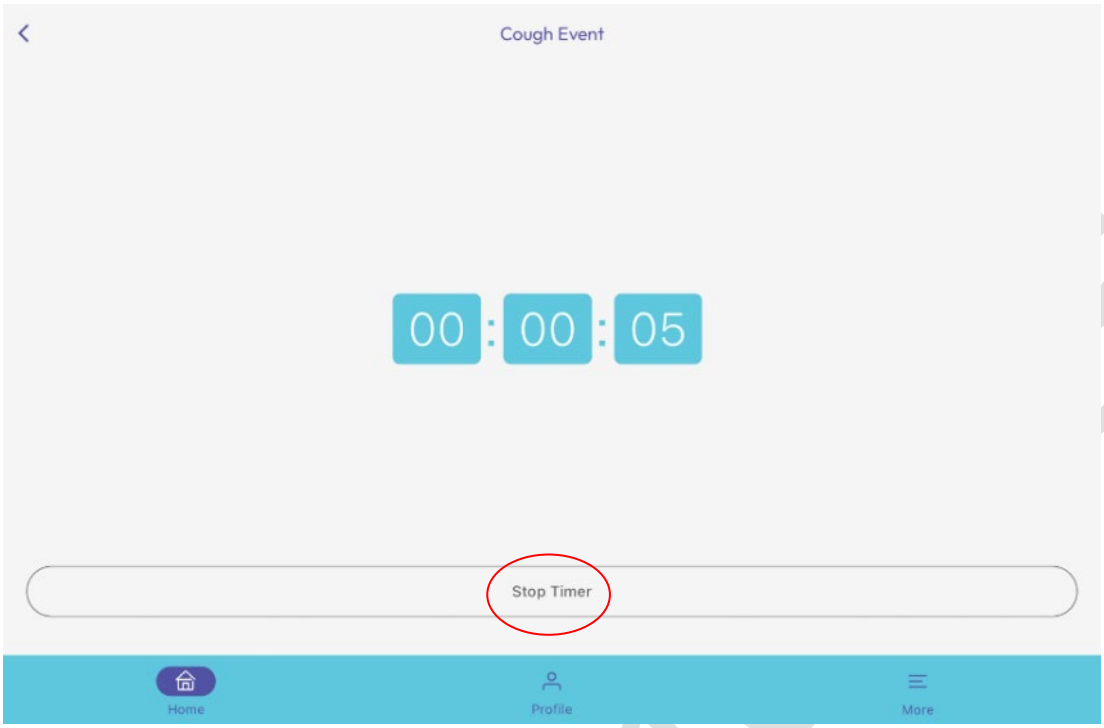


Figure 39. Event Timer

8. For all other maneuvers, attempt to log the event and press the event button at the same time as when the patient is performing the maneuver.
9. Repeat steps 7-8 for each maneuver that is necessary given the patient's history and symptom presentation.
10. Edit the date and time of each event by selecting an event from the Ongoing Study page and then selecting the pen icon. An example for editing the date and time is shown in Figure 40. After selecting the pen icon, you can modify the time or other data fields and save the changes. To do this, it will require a comment to justify the change to the event.
11. To delete an event, hold your finger on the event for at least one second and select "yes" to delete the event.

8.1.7 Instruct the patient to log symptoms during ambulatory monitoring.

1. If desired, have the patient log symptoms during the ambulatory monitoring period.
2. Ensure the patient has downloaded the Glean Mobile App to their smartphone or provide the patient with a device that has the Glean Mobile App installed. If preferred, the patient may use a pen and paper to log symptoms. A Symptom Log template is available at gleanuds.com/diary.
3. Ensure the patient has logged into the Glean Mobile App with the proper account information.
4. Educate the patient on how to log events (refer to Chapter 11.1.8 on page 27 for details on how to log events using the Glean Mobile App (Patient)).

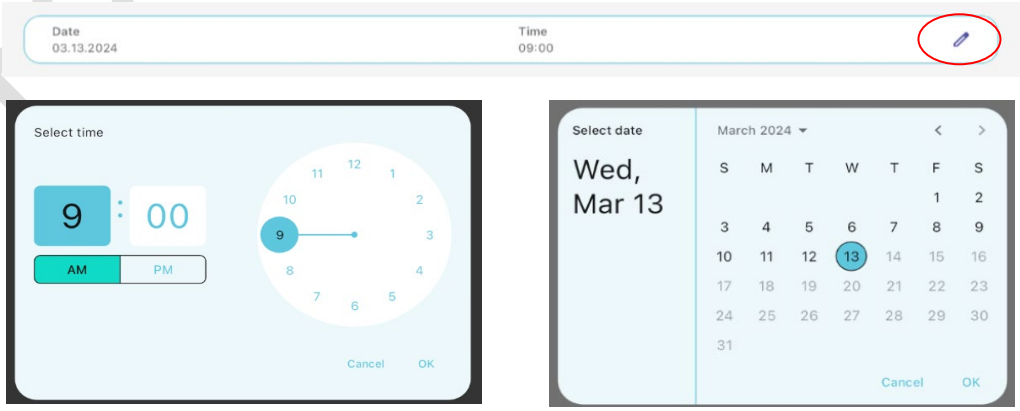


Figure 40. Edit Event (Clinician)

5. Instruct the patient to return to the exam room when they have a strong desire to void.

8.1.8 Train the Patient to use the Glean Mobile App (Patient).

1. Login to the Glean Mobile App (Patient).
2. Select “Add Event.”

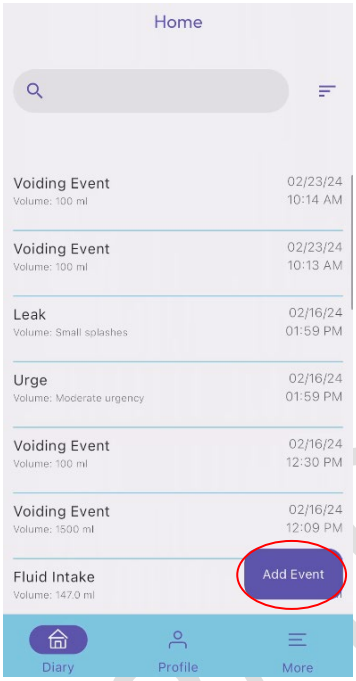


Figure 41. Add Event (Patient)

3. Select event type (leak, urge, fluid intake, voiding event) and enter data.

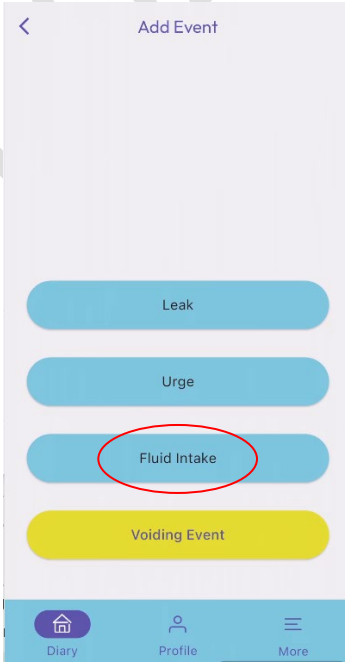


Figure 42. Select Event Type (Patient)

4. Enter required information. Select “Enter” then “Save” to complete data upload.

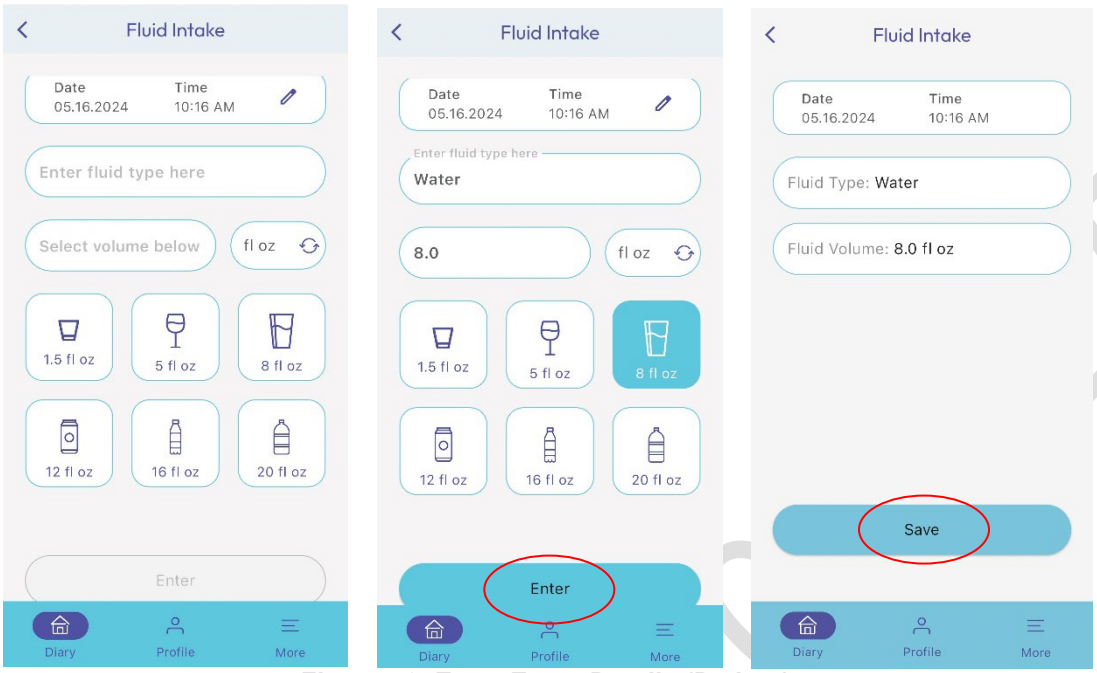


Figure 43. Enter Event Details (Patient)

5. Edit a logged event by selecting an event from the home page and clicking “Edit” or by clicking on the pen icon when entering the data.

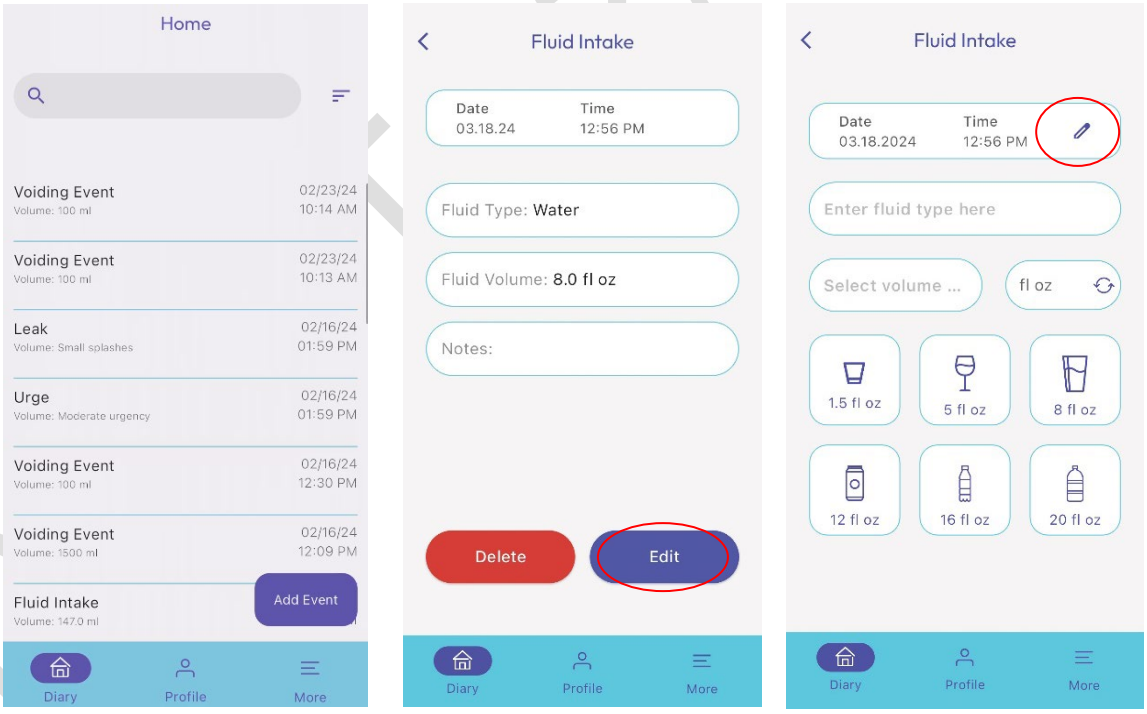


Figure 44. Edit Event (Patient)

6. Delete a logged event by clicking “Delete.”

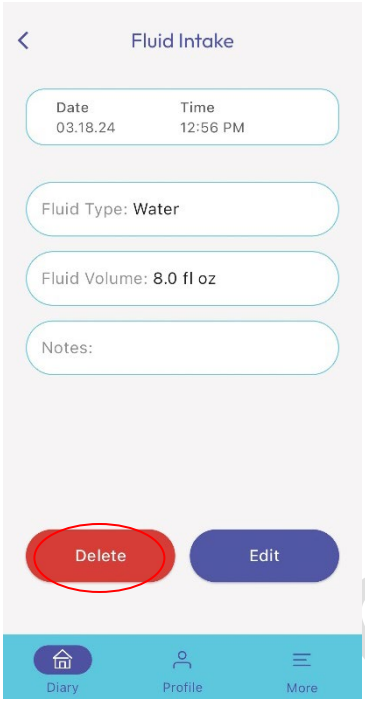


Figure 45. Delete Event (Patient)

8.1.9 Run a Uroflow Test

A Uroflow Test is a measurement of the rate at which urine flows out of the body. It can be performed using the Glean Mobile App (Clinician). A Uroflow Test may be conducted as a standalone test, when a Sensor is not in use, or as part of a CMG/PF Test when a Sensor has been deployed in the patient. To begin a Uroflow Test:

NOTE:

- Make sure the battery of the GUS Uroflowmeter is fully charged before starting the test.
- Press the Button LED once to start acquisition and storage. To stop data acquisition and storage, press the Button LED once.
- The Uroflowmeter will stop recording data automatically after 30 minutes.
- The Uroflowmeter Bluetooth wireless connection interface will support connectivity to an external mobile device that is up to 0.5 m away.

WARNING: No part of the ME EQUIPMENT shall be serviced or maintained while in use with a PATIENT

8.1.9.1 Prepare the Uroflowmeter for data collection.

1. Gather the supplies needed for a Uroflow Test (urine collection cup, commode chair, funnel, etc.).
2. Carefully place the GUS Uroflowmeter on the floor.
3. Gently position a urine collection cup on top of the Uroflowmeter. Ensure the urine collection cup is placed as indicated in Figure 50.
4. Place the funnel on the plastic frame of the commode chair and position both over the Uroflowmeter and receptacle. Ensure that the urine collection cup and the funnel are aligned, but not touching.
5. Login to the Glean Mobile App (Clinician).
6. If adding Uroflowmetry to an existing study, select the ongoing study from the active studies list and go to Step 9.

7. If required, select “Start New Study.”

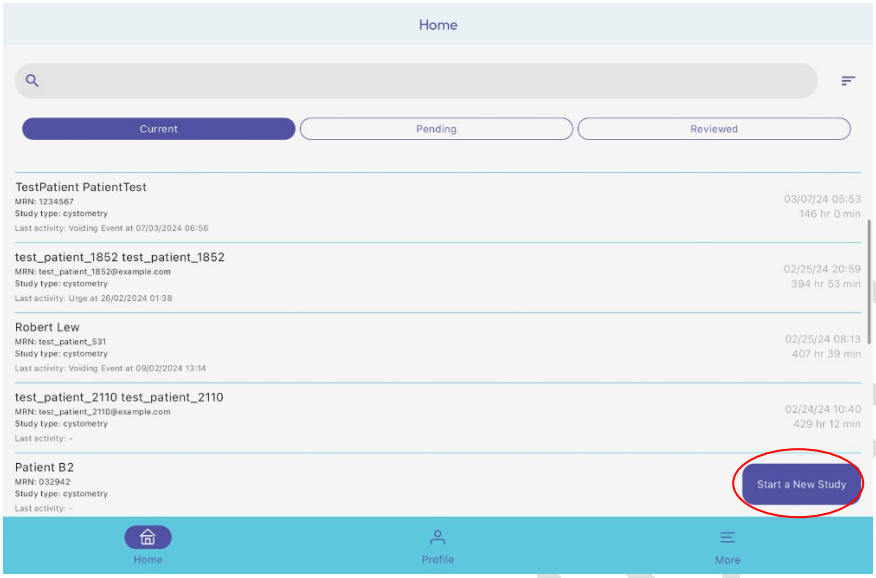


Figure 46. Start a New Study

8. Select the desired patient profile, confirm the patient information, and start the study if necessary.

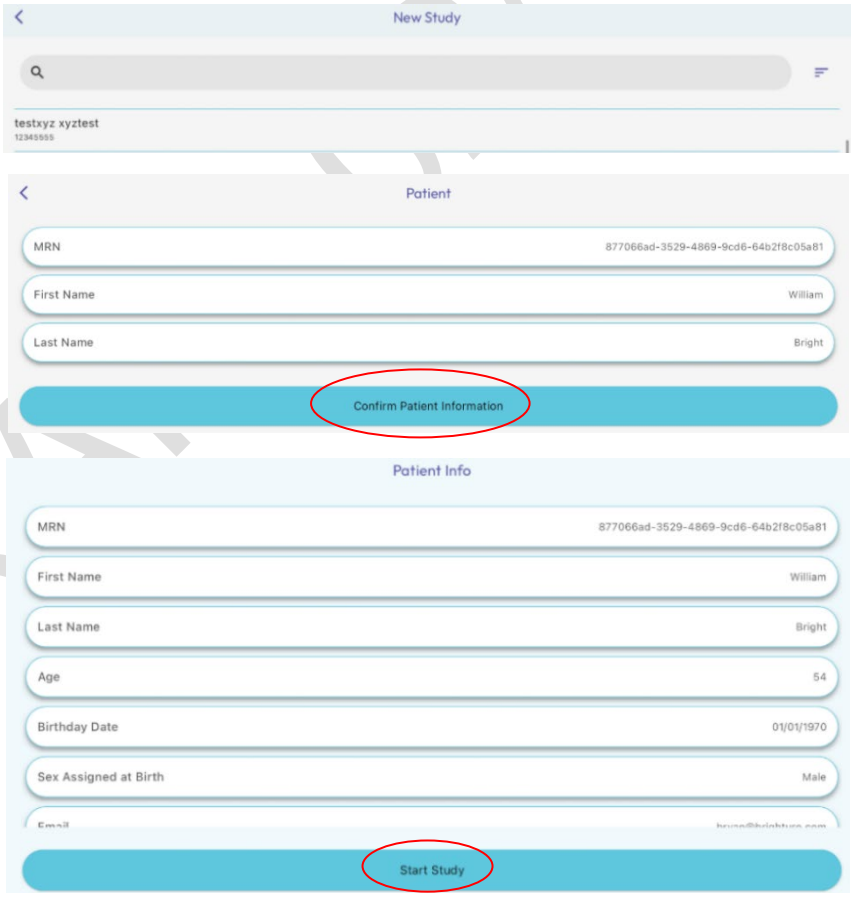


Figure 47. Select a Patient, Confirm Patient Information, and Start Study

9. Select “Add Events or Devices.”

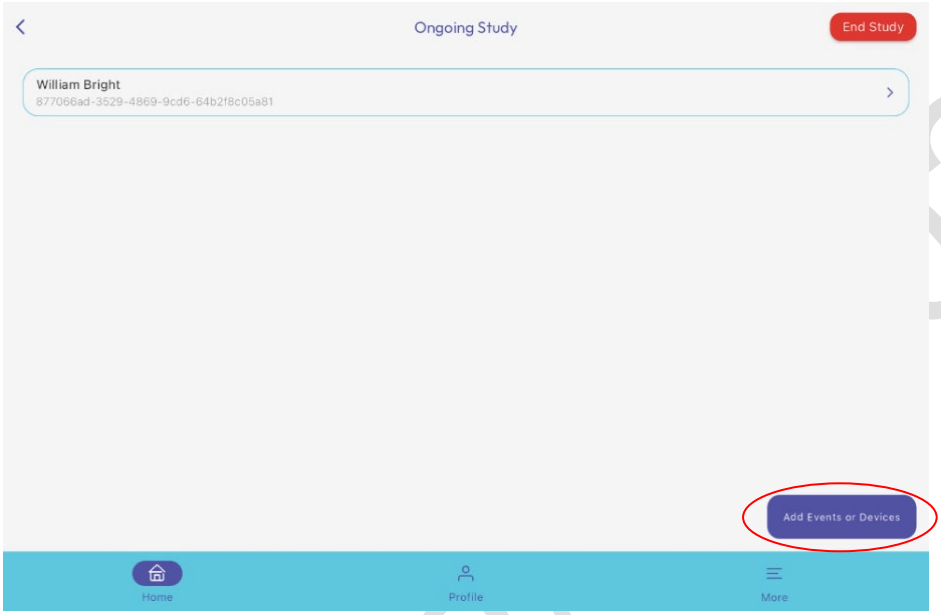


Figure 48. Add Events or Devices

10. Select “Add Uroflowmeter.”

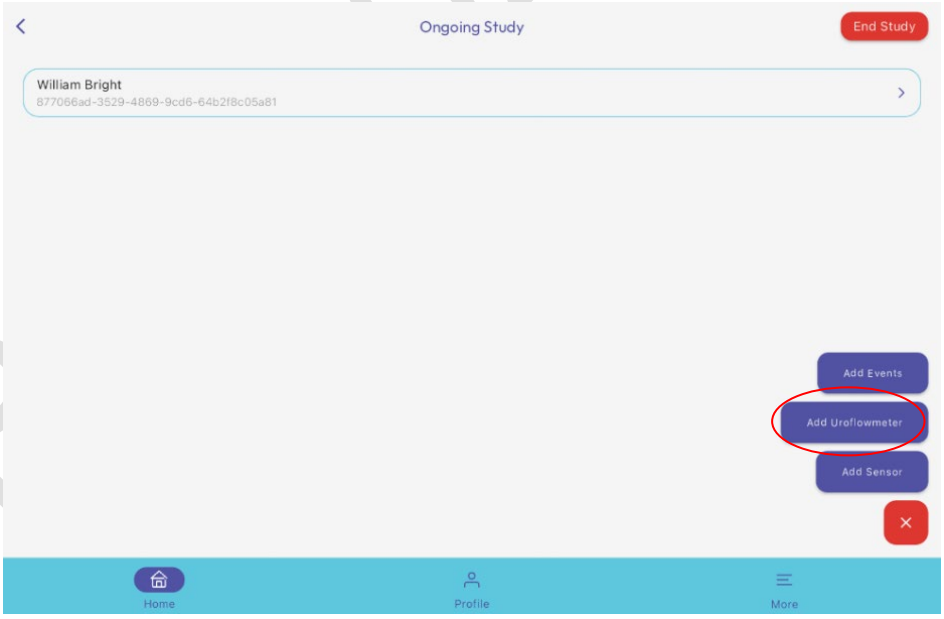


Figure 49. Add Uroflowmeter

11. If required, wake the Uroflowmeter by pressing and holding the button for at least 3 seconds and click “OK” when complete.

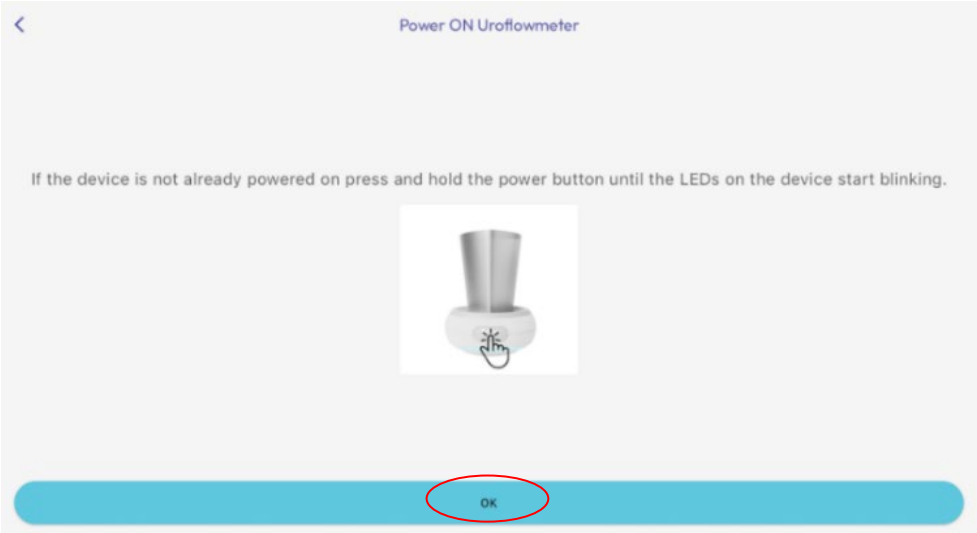


Figure 50. Set the Uroflowmeter to Awake state

12. Scan the QR code on the Uroflowmeter or Quick Start Guide.

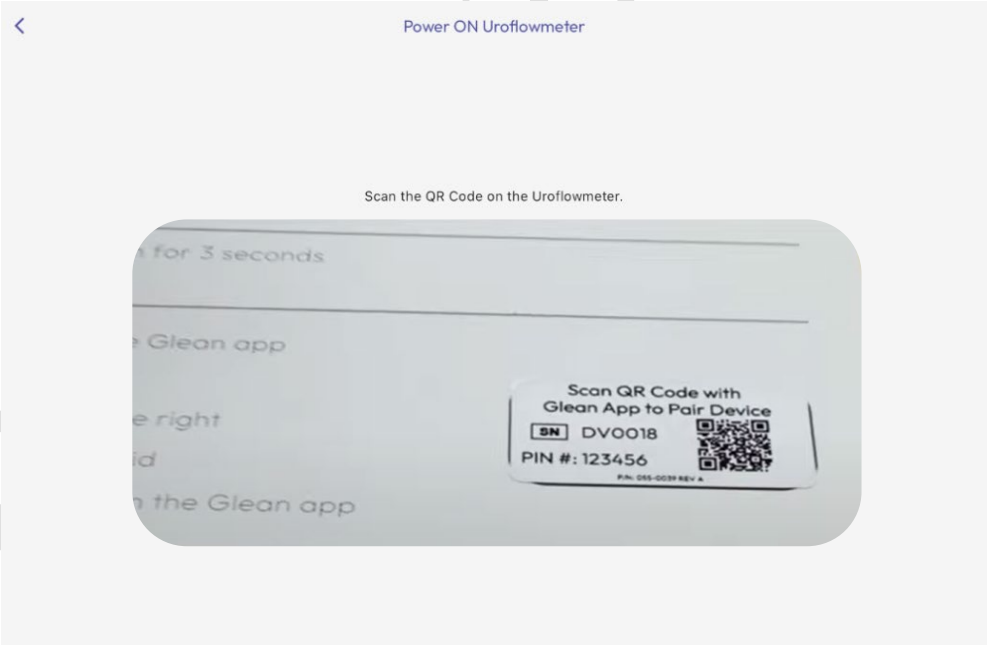


Figure 51. Scan QR Code on Uroflowmeter

13. If required, enter the PIN near the QR code.

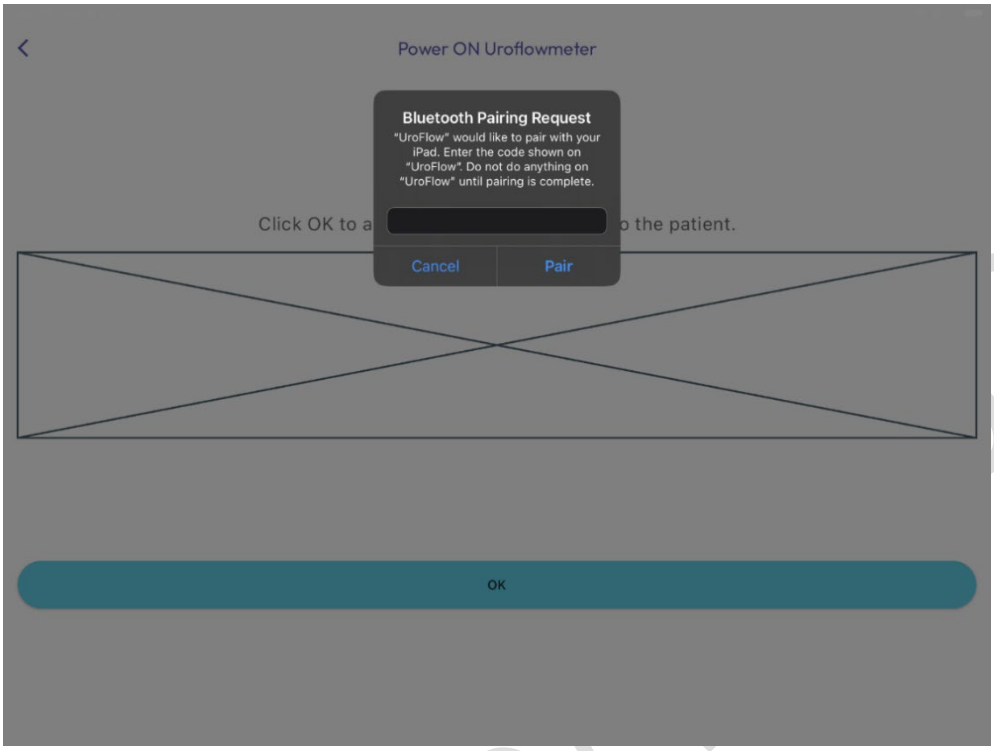


Figure 52. Enter Uroflowmeter PIN

14. Click “OK” to associate the Uroflowmeter with the patient profile.

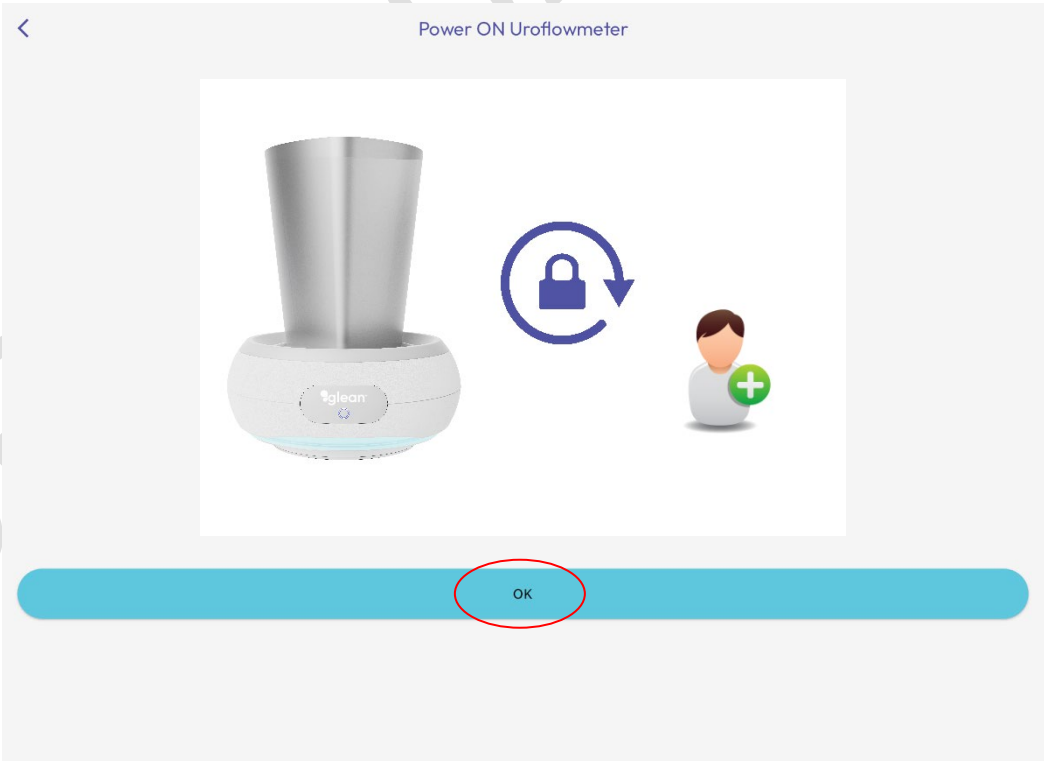


Figure 53. Associate Uroflowmeter with Patient

15. Click “Connect” then ‘Start Uroflowmetry’ to start collecting Uroflowmeter data.

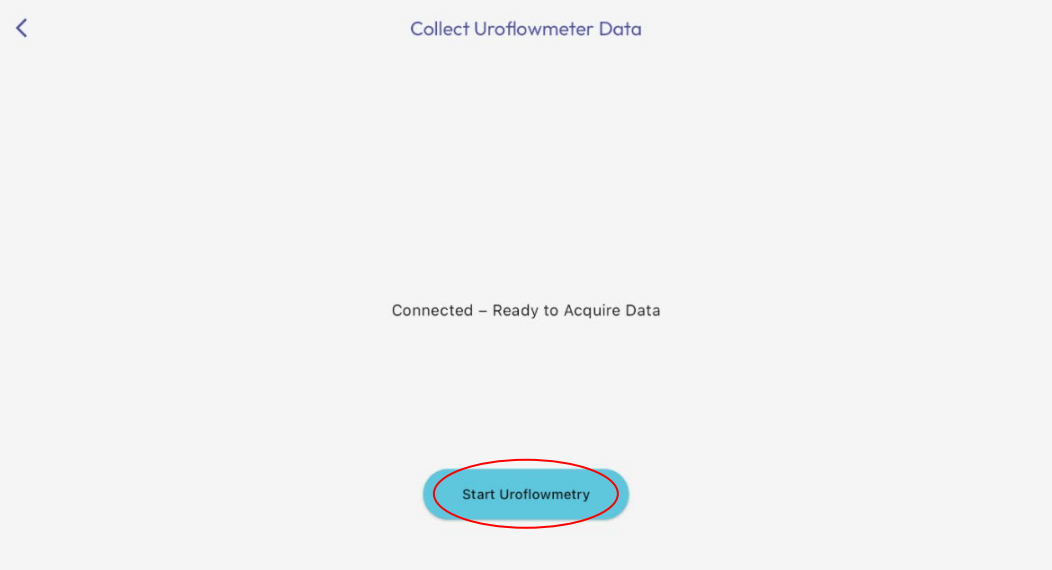


Figure 54. Start Uroflowmetry

NOTE: If you lose Bluetooth connection during the void then you will need to repeat steps 5 – 14 after the void is complete to download the data to the patient profile, which may include stopping the study.

8.1.9.2 Instruct the patient to void.

1. Instruct the patient not to touch or kick the urine collection cup before, during or after voiding.
2. Tell the patient to void into the collection cup until they feel their bladder is empty and to notify clinic staff once complete.

CAUTION: DO NOT TOUCH the urine collection cup during voiding.

8.1.9.3 Download the data from the Uroflowmeter.

1. Click “Stop Uroflowmetry” to stop data acquisition from the Uroflowmeter.

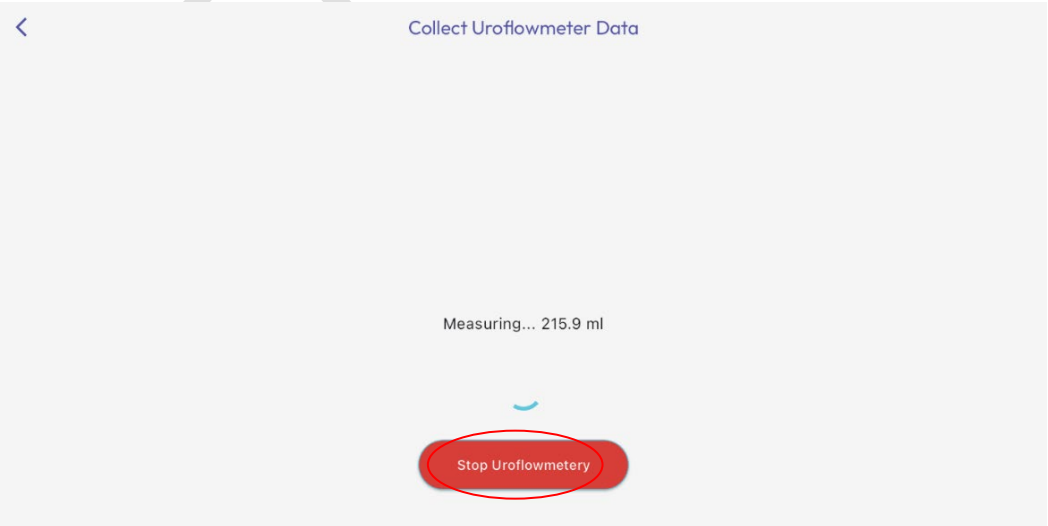


Figure 55. Stop Uroflowmetry

2. Click “Download” to download the Uroflowmetry data.

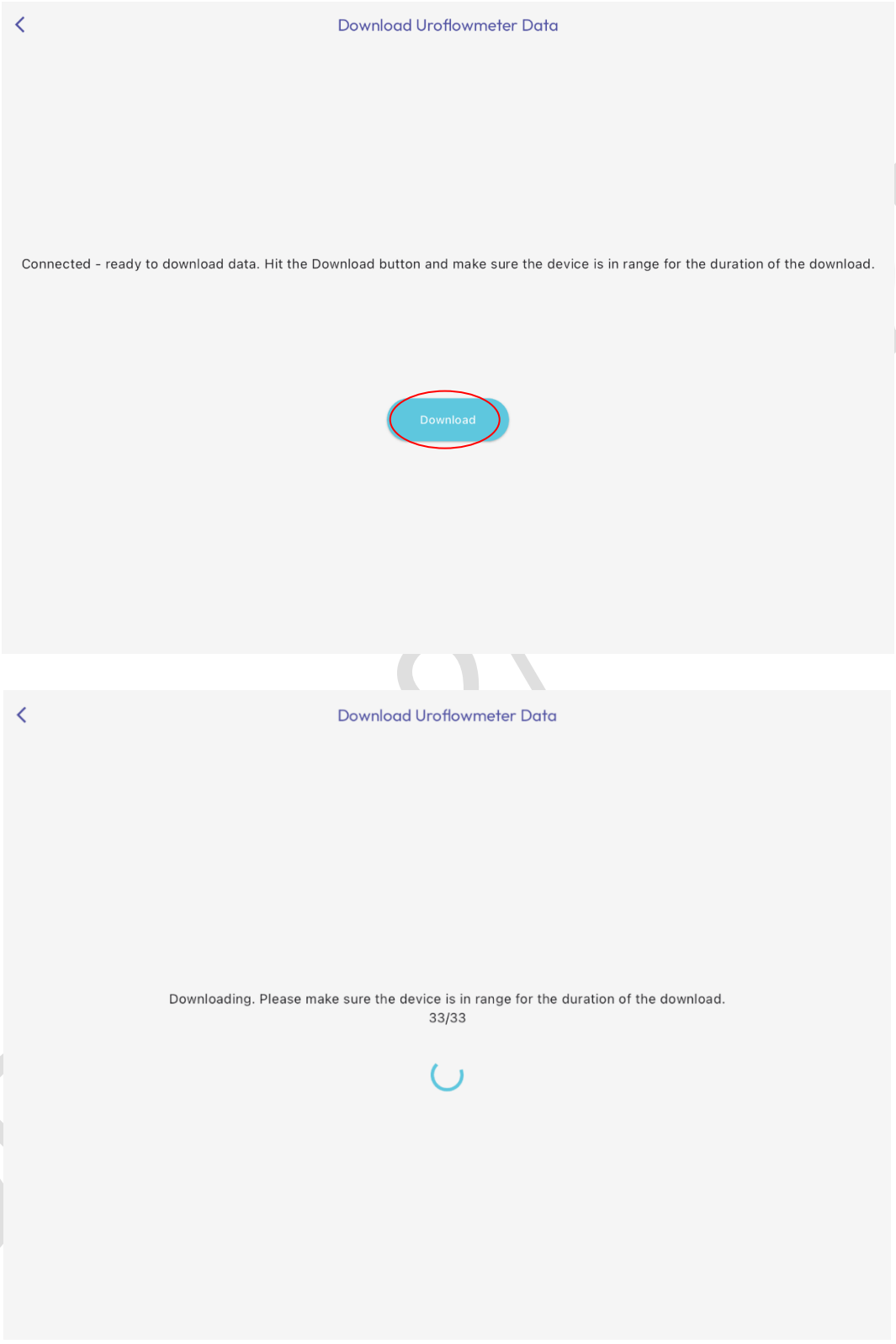


Figure 56. Download Uroflowmetry Data

3. View Uroflowmetry data and select “Confirm” to upload to the patient record.

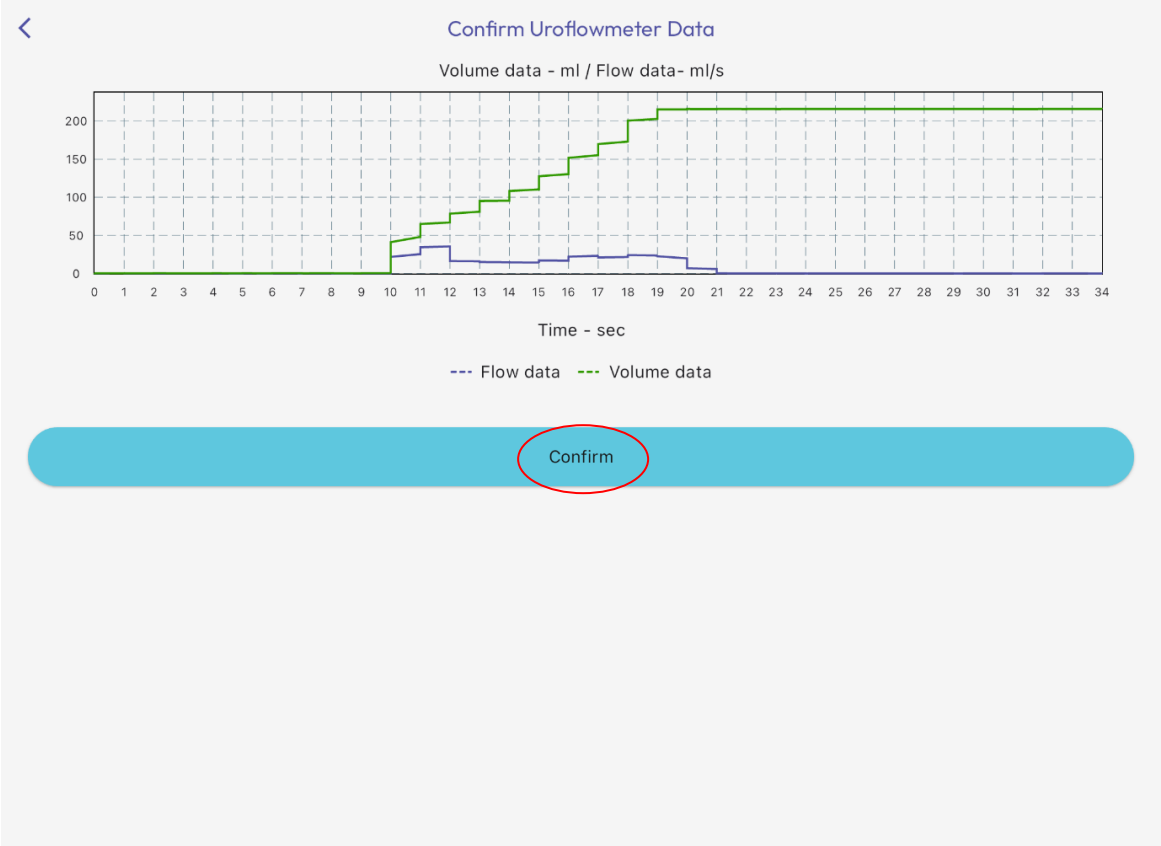


Figure 57: Confirm Uroflowmetry Data

8.1.10 Measure PVR using preferred method.

1. If desired, measure PVR using preferred method.
2. Log bladder volume as an event titled “PVR” in the Glean Mobile App (Clinician).

8.1.11 Prepare the patient for Sensor removal.

1. Have the patient remove clothing.
2. Have the patient assume a comfortable position for Sensor removal.

8.1.12 Remove the Sensor from the bladder.

1. Gently remove any material used to secure the Sensor Removal String.
2. Gently pull the removal string until the Sensor is completely out of the body.
3. Place the Sensor in a biohazard bag and close the bag.

No⚠ In the event of sensor removal string breakage or fracture of the sensor in vivo, remove the entire sensor per Standard of Care followed at urodynamics facility for removal of objects from the bladder using standard techniques and equipment such as cystoscopes and snares or graspers.

8.1.13 Urethral Pressure Profile (UPP)

If desired, Urethral Pressure Profile testing may be performed with Glean using a Manual Pull.

1. Ensure the patient has at least 50 mL of urine in the bladder.
2. Gently remove any material used to secure the Sensor Removal String.
3. Pull the Removal String very gently until you begin to feel resistance at the bladder neck.
4. Once you feel resistance from the Sensor at the bladder neck begin pulling very slowly. Continue to watch the Sensor as you remove it from the body and attempt to pull at a rate of approximately 1 mm per second.
5. Place the Sensor in a biohazard bag and close the bag.

8.1.14 Download data from the Glean sensor.

1. Select the correct patient profile from Glean Mobile App (Clinician) for the ongoing study.

2. Select "Add Events or Devices"

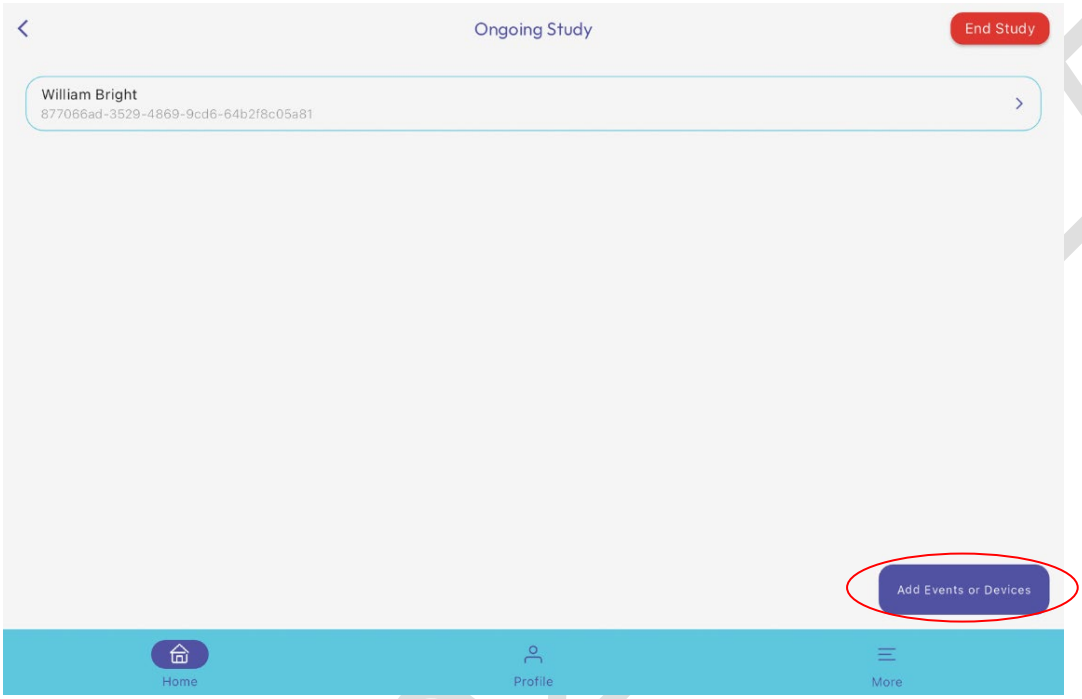


Figure 58. Add Events or Devices

3. Select "Download Sensor Data"

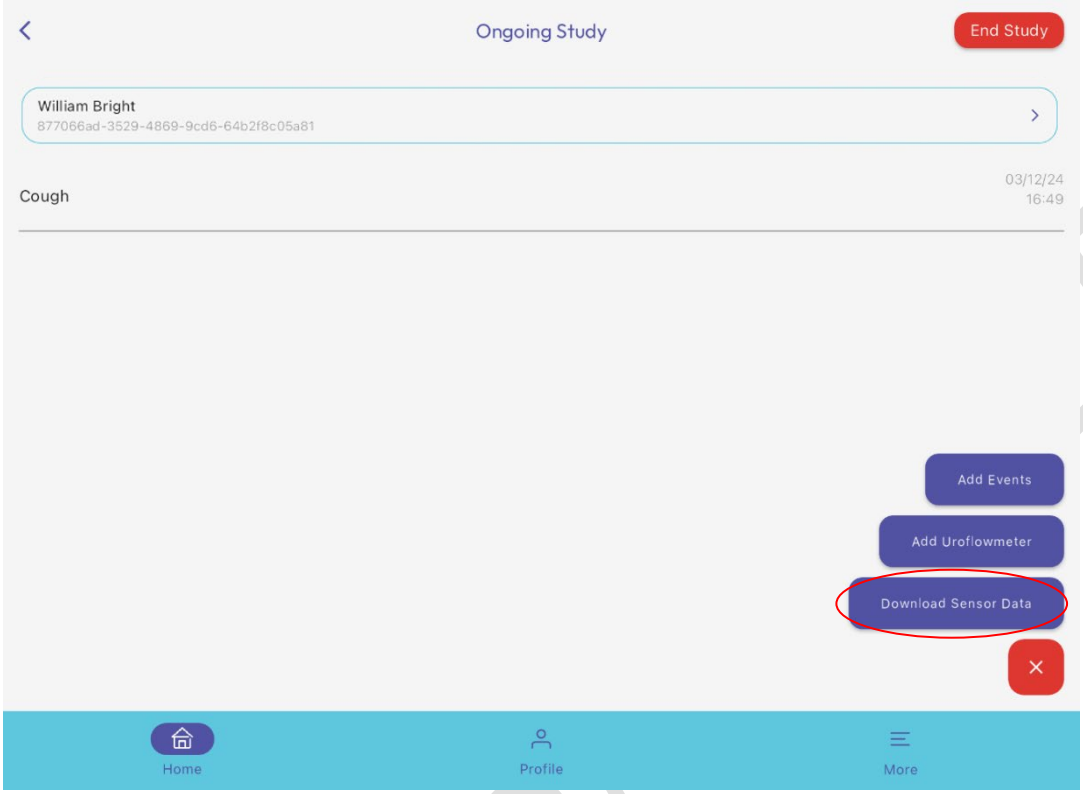


Figure 59. Select Download Sensor Data

4. Press and hold the sensor button for at least three seconds until the LED begins to flash.
5. Select "Connect."

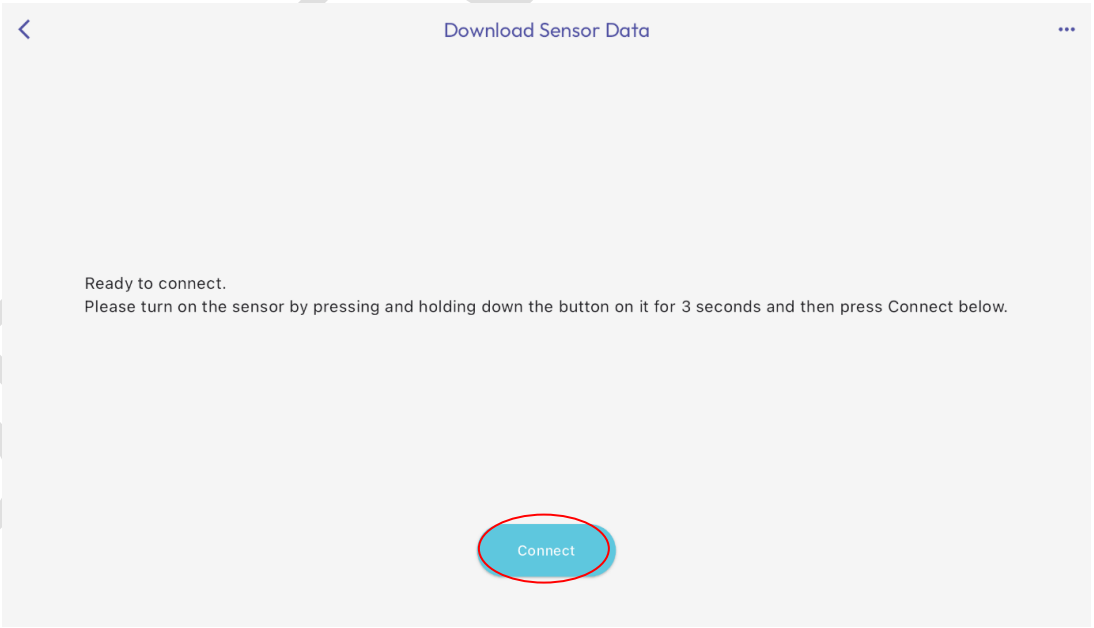


Figure 60. Connect Sensor to Download Data

6. Select "Download" and keep the Sensor near the mobile device until the data download is complete.

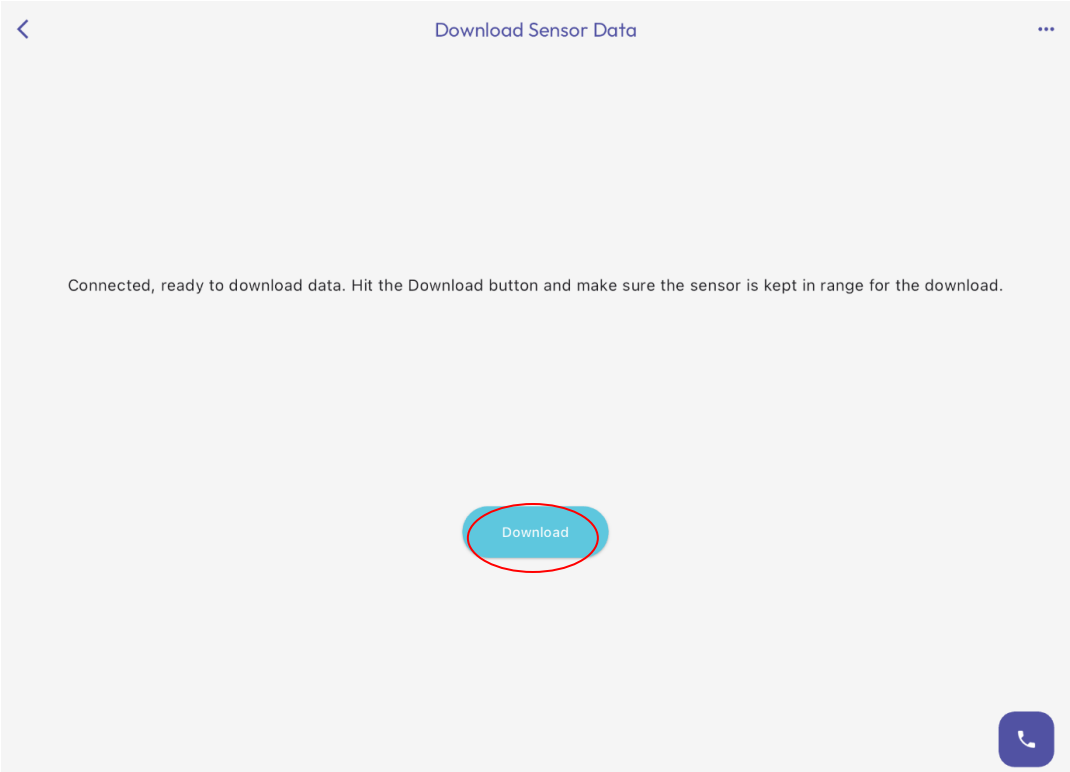


Figure 61. Connect Sensor to Download Data

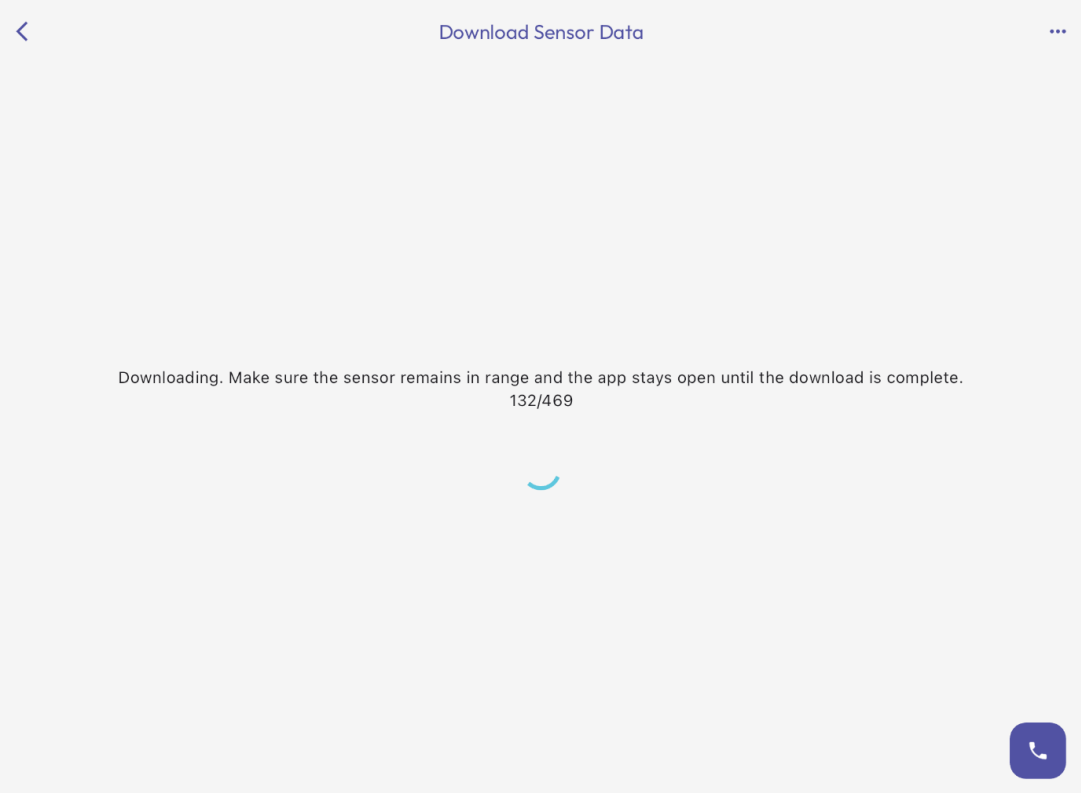


Figure 62. Download Sensor Data

7. View Sensor data and select "Confirm" to upload data to the patient record.

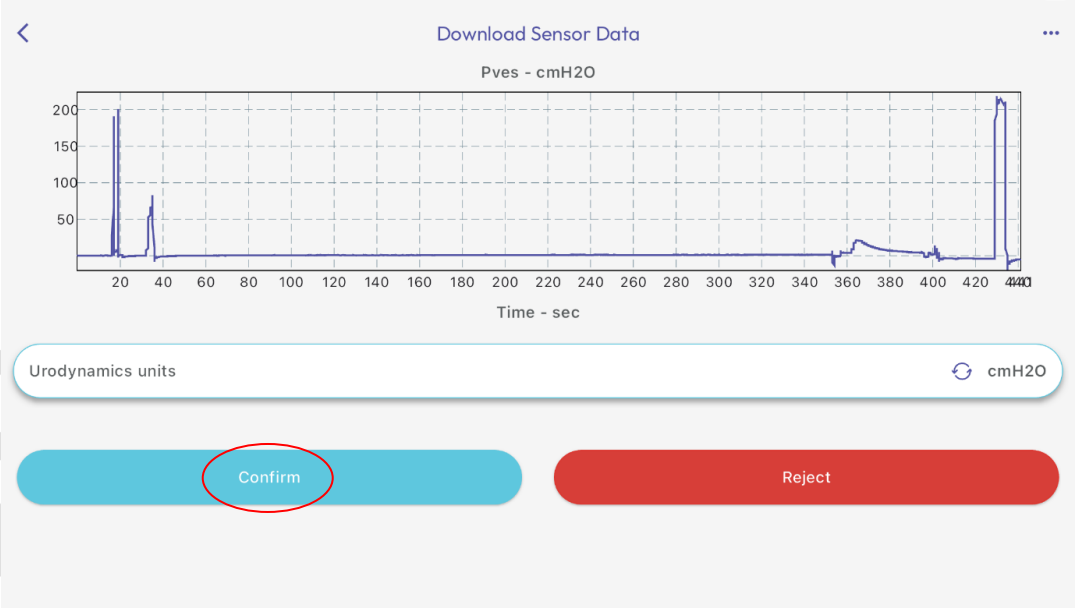


Figure 63. Confirm Sensor Data

8. Dispose of the Sensor according to clinic guidelines.

8.2 ANALYZE THE DATA USING THE GLEAN WEB APP

Health Care Providers may analyze GUS data using the Glean Web App.

8.2.1 Login to the Glean Web App (Clinician).

8.2.2 Select the desired patient and study.

1. Current or pending studies will appear under the Studies Overview page in the default homepage view. Select the desired patient and study by clicking on the desired row

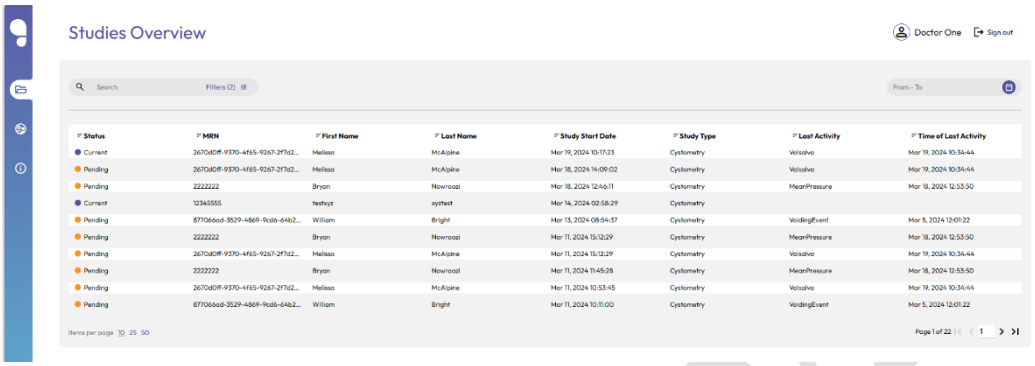


Figure 64. Studies Overview

2. To view all patients, select the patient icon on the left to view the list of patients.
3. Identify the correct patient using name or MRN and click “Studies.”

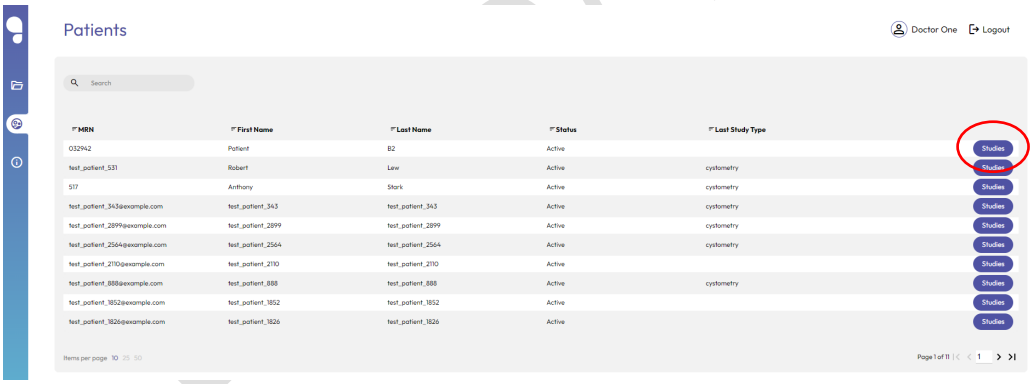


Figure 65. Select Patient Studies

4. Confirm the date/time of the study and the type of study then click on the desired row.

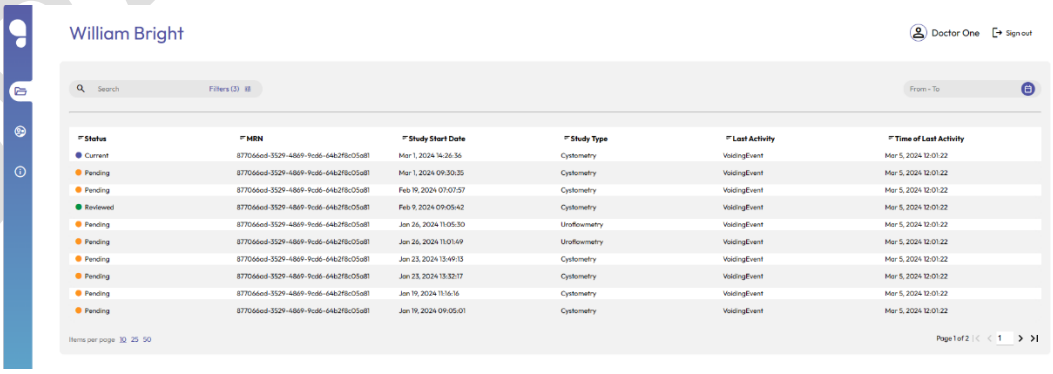


Figure 66. View Patient Studies

5. The study data will open to be viewed.

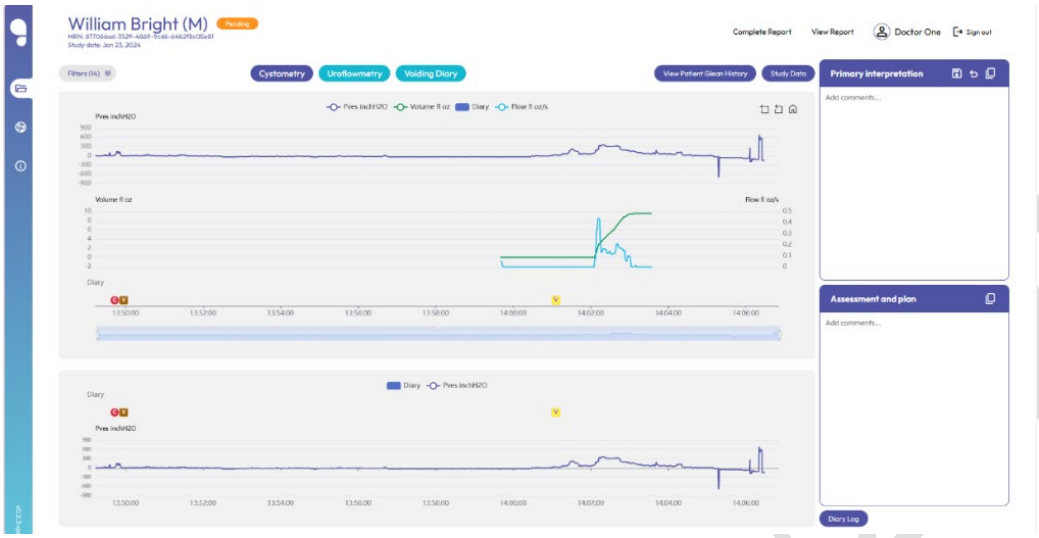


Figure 67. View Study Data

8.2.3 Analyze Urodynamics data.

1. Visually review Urodynamics data.
2. Adjust or modify view as required for detailed analysis.

8.2.4 Adjust the x-axis for Urodynamics data.

1. Determine area of interest.
2. Select the + Zoom icon at the top right of the viewing area.
3. Drag the box over desired area of interest to zoom in.

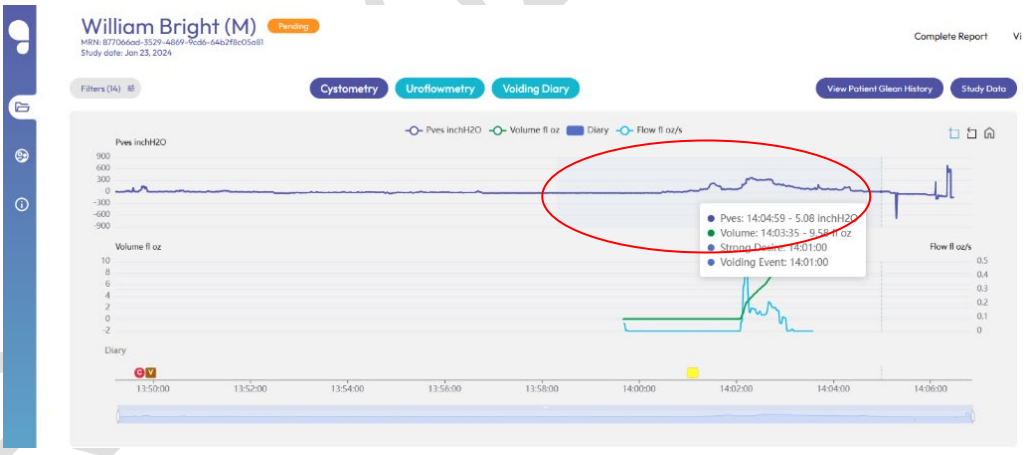


Figure 68. Drag Zoom Box

OR

1. Determine area of interest.
2. Adjust the left side of sliding view window to set the left limit for desired area of interest.

3. Adjust the right side of sliding view window to set the right limit for desired area of interest.

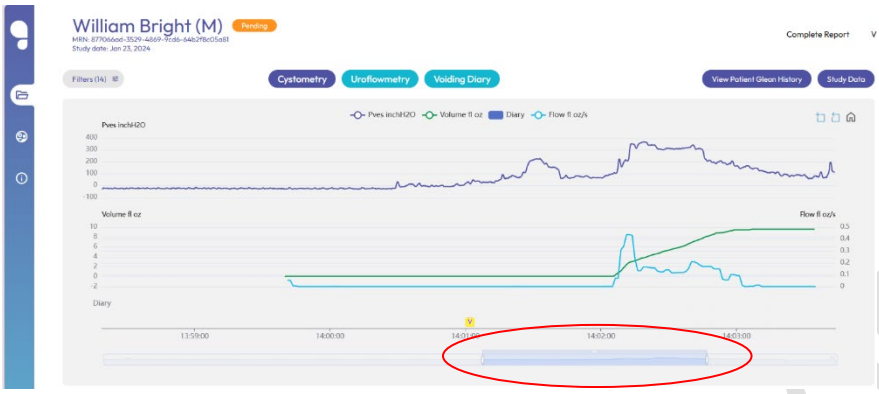


Figure 69. Adjust Sliding View Window

OR

1. Identify event of interest (e.g. cough, leak, void).

Figure 70. Select Event of Interest

2. Click on event of interest. The view will automatically zoom to center event with buffer on each side.

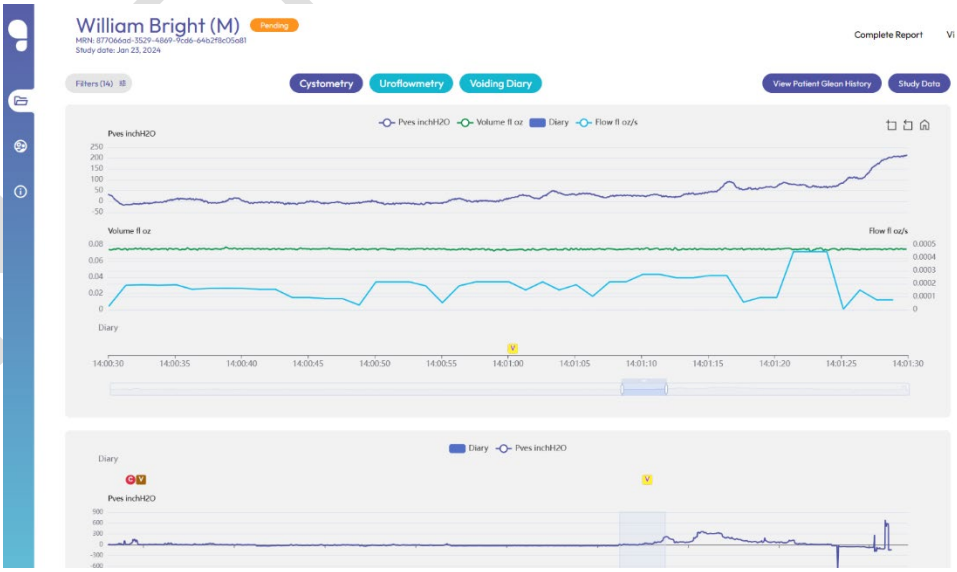


Figure 71. View Event of Interest

8.2.5 Adjust the y-axis for Urodynamics data.

1. Determine area of interest.
2. Adjust x-axis to zoom in to area of interest. See Chapter 11.2.4 on page 41 for instructions on how to adjust the x-axis.
3. Software will automatically adjust to minimum and maximum pressure levels in area of interest.

8.2.6 Select multiple events of similar type.

1. Navigate to the Uroflowmetry or Voiding Diary tab.

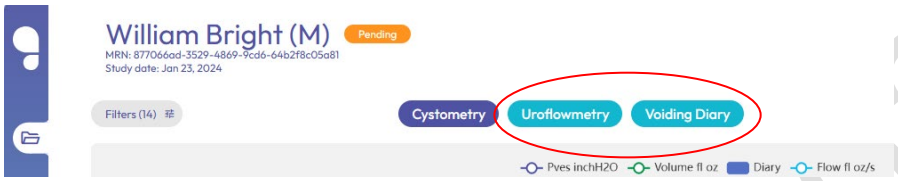


Figure 72. Uroflowmetry and Voiding Diary Tabs

2. Select the desired events from the table in the bottom viewing area.

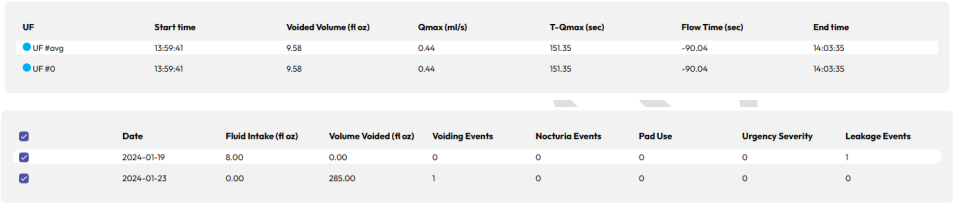


Figure 73. Select Events of Similar Type

3. Unselect events to be removed from the visual display and analysis.

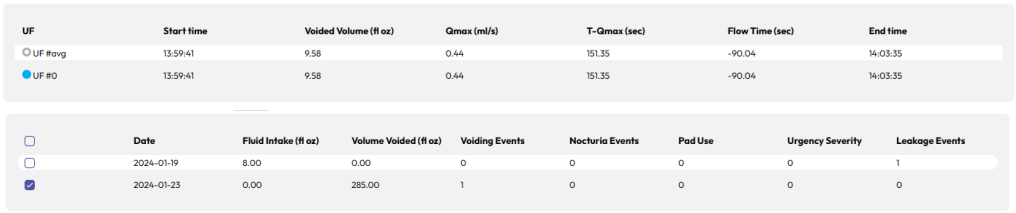


Figure 74. Unselect Events of Similar Type

8.2.7 Draft notes for interpretation, assessment, and plan.

1. Type notes in text window for “Primary interpretation.”

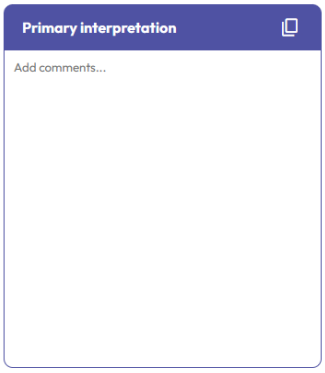


Figure 75. Draft Primary Interpretation

2. Type notes in text window for “Assessment and plan.”

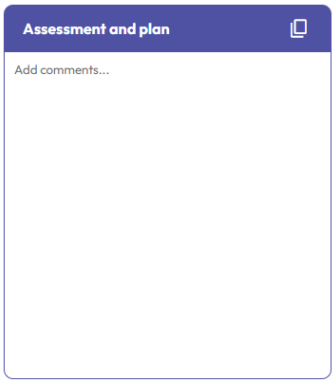


Figure 76. Draft Assessment and Plan

3. Select the copy icon to copy text for use outside of the Glean Web App.

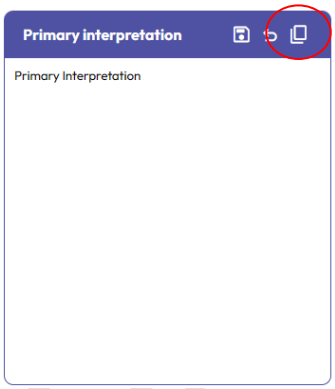


Figure 77. Copy Notes

4. To save the notes, select the save icon or click outside of the notes text box to autosave.

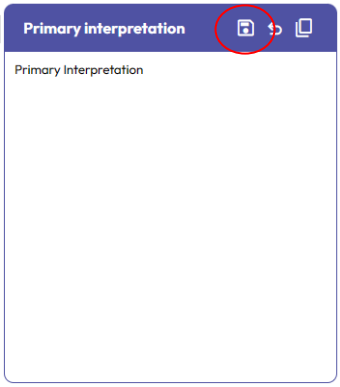


Figure 78. Save Notes

8.2.8 Export the Urodynamics report.

1. Complete analysis and notes for the Urodynamics evaluation.
2. Confirm report accuracy.
3. Select “Complete Report.”

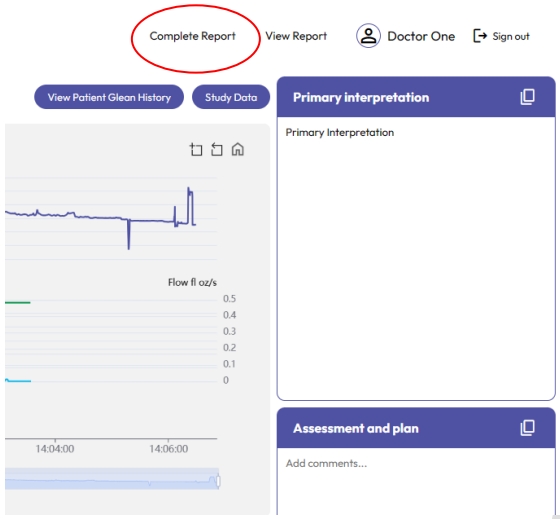


Figure 79. Complete Urodynamics Report

4. Select “View Report.”

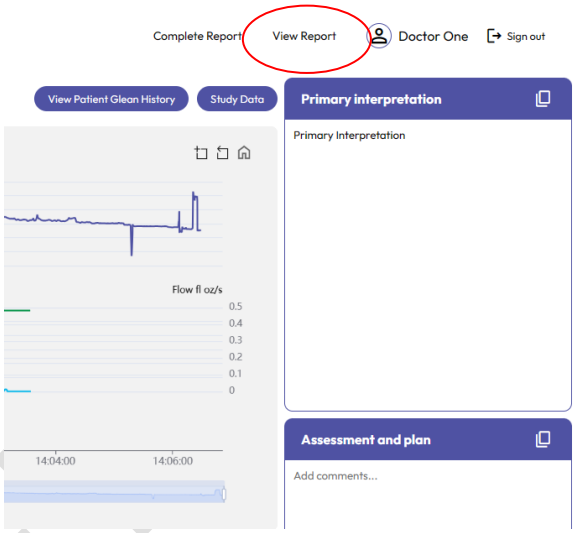


Figure 80. View Urodynamics Report

5. Select “Print Report.”

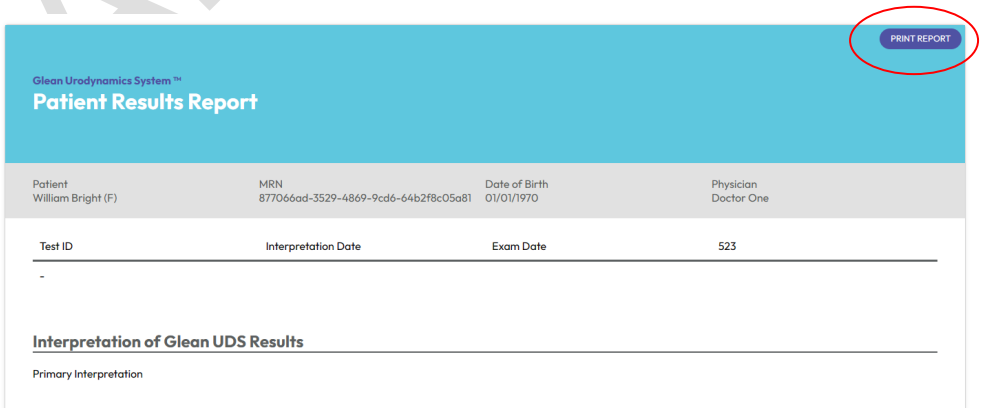


Figure 81. Print Urodynamics Report

6. Select desired destination for printing of report or “Save as PDF” and confirm file location.

8.2.9 Utilize filtering to adjust view of Urodynamics data.

1. Click on “Filters” in the top left.

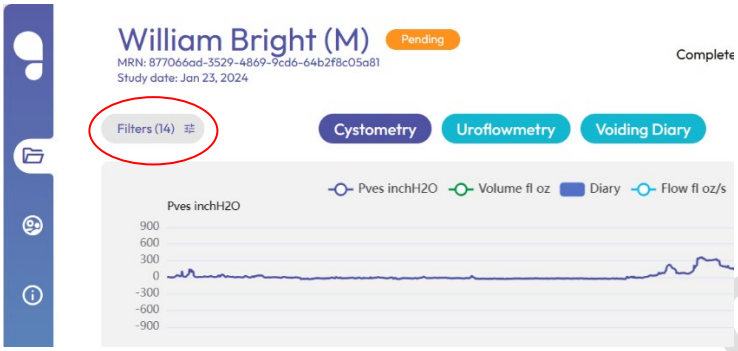


Figure 82. View Filters

2. Determine desired events or desired filtering methods.

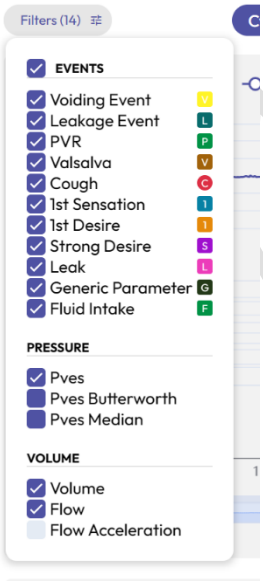


Figure 83. Select Filters

3. Select desired events/filters to display data in view.
4. Unselect event/filters to hide data from view.

8.2.10 View the Glean patient history.

1. Login to the Glean Web App (Clinician).

2. Select a patient record and study.

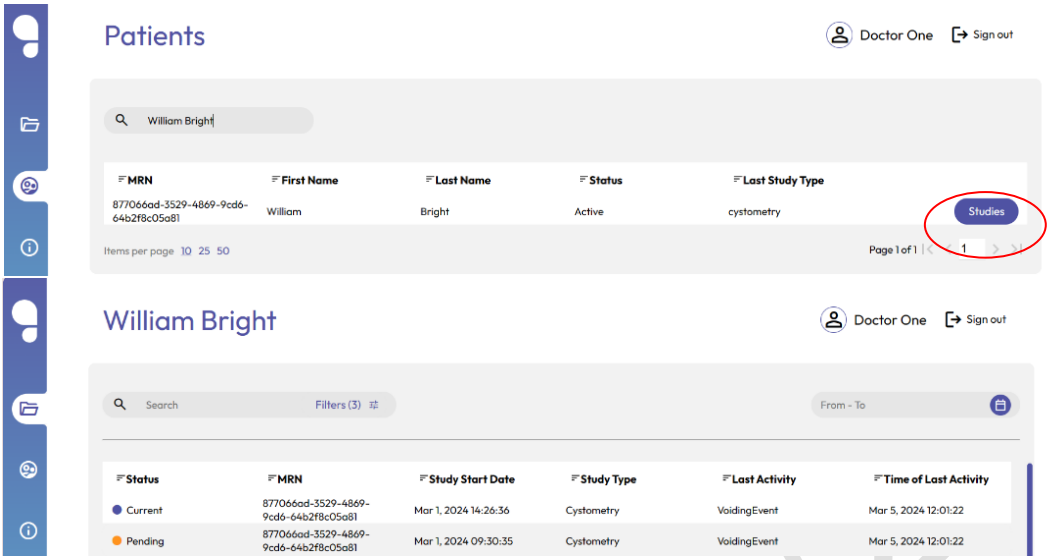


Figure 84. Select Patient Record and Study

3. Select “View Patient Glean History.”

Figure 85. View Glean Patient History

8.2.11 View detailed Urodynamic study data.

1. Login to the Glean Web App (Clinician).
2. Select a patient record and study.

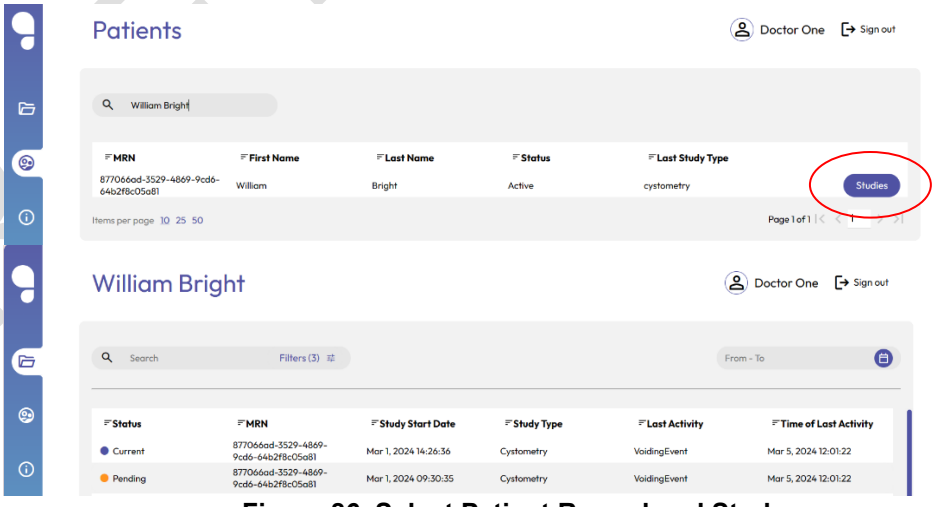


Figure 86. Select Patient Record and Study

3. Select “Study Data” to see detailed parameters of Urodynamics and Uroflowmetry exams.

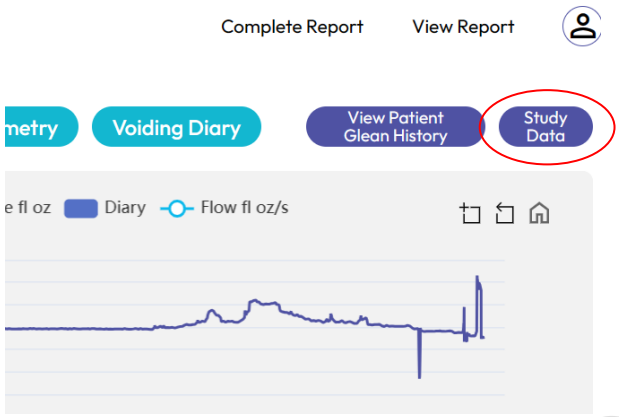


Figure 87. View Study Data

8.2.12 Adjust Glean Web App settings.

Users may select or unselect settings to adjust the view of urodynamics data.

1. Login to the Glean Web App (Clinician).
2. Select the user icon at the top right of the screen and click on “Settings.

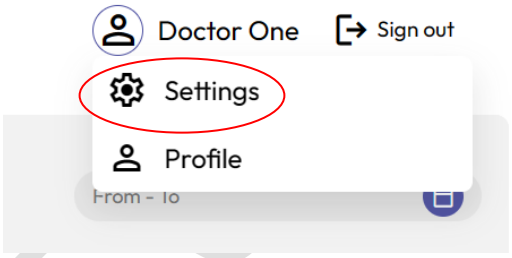


Figure 88. Glean Web App Settings

3. Adjust the user settings to accommodate the preference of the user and click “Save Settings.”

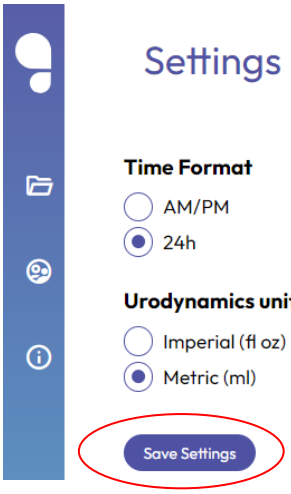


Figure 89. Adjust Glean Web App Settings

4. Click “Yes” to confirm your changes.

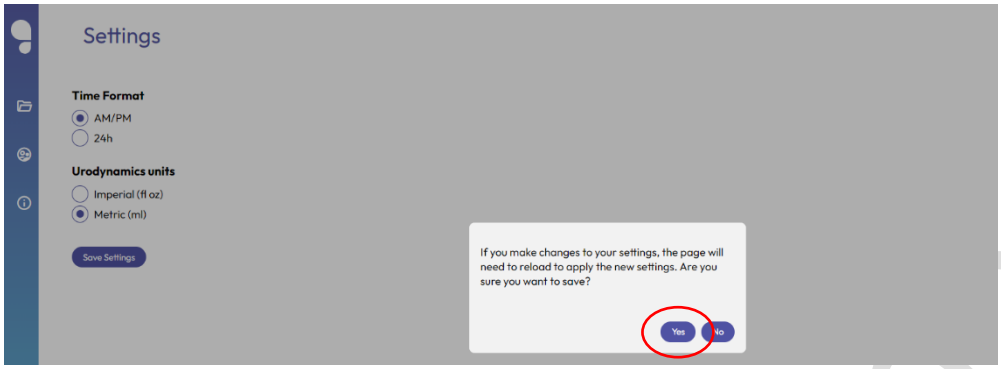


Figure 90. Confirm Settings Changes

9 CALIBRATION

Return the Uroflowmeter annually to Bright Uro for recalibration. Contact Bright Uro to schedule this service as required.

10 FAQ

How do I know when I need to charge the Uroflowmeter?
The GUS Uroflowmeter's LED lights indicate equipment status. If the Button LED is pink or orange, charge the Uroflowmeter. The Uroflowmeter is charging when the Button LED turns blue.

Can I use the Uroflowmeter while the battery is charging?
Yes, the GUS Uroflowmeter can be used while charging.

What should I do if the Removal String falls out of the Insertion Tool prior to loading the Sensor into the Insertion Tool?
Use graspers or forceps to pull the Removal String through the Sheath while maintaining a sterile field or use a new Sensor.

Can I use a dilator to assist in inserting the Sensor?
Yes, you may use a dilator to assist in inserting the Sensor if necessary, based on clinical judgement.

How do I know if the Sensor is properly deployed in the bladder?
The Sensor is properly deployed in the bladder if urine flows through the Sheath after Sensor deployment.

Is the Sensor transmitting Bluetooth data through the body?
The Sensor only connects via Bluetooth before insertion and after removal. The data is stored on the Sensor while it is indwelling in the body.

How do I dispose of the Sensor?
The Sensor is a single use device. Dispose of the Sensor according to local guidelines.

Are mobile devices and desktops provided by Bright Uro?
Bright Uro does not provide mobile devices or desktops. Clinics can utilize any available mobile devices and desktops.

11 TROUBLESHOOT

Symptom(s)	Possible Cause(s)	Check/Corrective Action(s)
SENSOR AND INSERTION TOOL		
Sensor LED is not flashing after pressing and holding power button for at least 3 seconds	Power button not pressed firmly	Firmly press and hold the power button for at least 3 seconds. Ensure proper finger placement on the power button.
	Sensor battery died	Use a new Sensor.
Unable to load the Sensor in the Insertion Tool	Removal String broken	Use a new Sensor.
	Sensor not aligned with locking feature	Twist the Insertion Tool while maintaining aseptic technique to align the locking feature with the Sensor.
	Lubricant not applied to Sensor	Apply lubricant over the entire Sensor and continue loading.
	Lid not closed over Sensor and Insertion Tool prior to loading	Close lid over Sensor and Insertion Tool and continue loading.
Unable to insert device into bladder	Sheath met with resistance	Gently advance the Sheath during insertion. Do NOT push past significant resistance. Reattempt or stop device insertion based on clinical judgement.

Unable to deploy Sensor in bladder	Urine did not flow through the Sheath	Maintain the positioning of the Sheath and wait at least 20 seconds to observe urine flow. If urine still does not flow, remove the Sheath then remove the sensor and reattempt insertion with a new Sensor once the patient's bladder has filled.
	Advancer met with resistance	Gently advance the Advancer during Sensor deployment. DO NOT push past significant resistance. Withdraw both the Sheath and Advancer together 2-3 cm then continue deployment. Reattempt or stop device insertion based on clinical judgment.
Unable to connect Sensor to Glean Mobile App (Clinician) to start CMG/PF Test.	Sensor LED not flashing	Press and hold the power button for at least 3 seconds until the LED begins to flash.
	Unable to scan QR code	Lay the Sensor packaging on a flat surface. Ensure the QR code is completely visible and rescan.
	Unable to connect via Bluetooth	Reattempt to connect. If still unable to connect, use a new Sensor.
Unable to connect Sensor to Glean Mobile App (Clinician) to download data.	Sensor LED not flashing	Press and hold the power button for at least 3 seconds until the LED begins to flash.
	Unable to connect via Bluetooth	Reattempt to connect. If still unable to connect contact Bright Uro.
UROFLOWMETER		
Uroflowmeter will not go into Awake state	Uroflowmeter not charged.	Place the Uroflowmeter on the Charging Puck and plug the power cable into an electrical outlet.
	Button LED not pressed firmly.	Press and hold the Button LED on the front of the device for at least 3 seconds.
Abnormal LED patterns	Conditions have not been met to enter acquisition mode	Ensure the device is fully charged. Set the Uroflowmeter to Asleep state and back to Awake mode, then reconnect.
	Power On Self-Test failed	Set the Uroflowmeter to Asleep state and back to Awake mode again.
Unable to connect Uroflowmeter to Glean Mobile App (Clinician) to start Uroflow Test	Unable to scan QR code	Place the device on a flat surface. Ensure the QR code is completely visible and rescan.
	Unable to connect via Bluetooth	Forget device in Bluetooth setting of mobile device then reconnect with PIN.
	Uroflowmeter has previous data pending download.	Download data to correct patient profile and reattempt connection for new test.
	Uroflowmeter not powered on.	Press and hold the Button LED on the front of the device to switch the device to Awake state.
	Uroflowmeter not charged.	Place the Uroflowmeter on the Charging Puck and plug the power cable into an electrical outlet.

Unable to connect Uroflowmeter to Glean Mobile App (Clinician) to download data	Uroflowmeter associated with different patient.	Ensure the Uroflowmeter being used is associated with the correct patient.
	Uroflow Study has not been stopped.	Stop study then download data.
	Uroflowmeter not powered on.	Press and hold the Button LED on the front of the device to set the device into Awake state.
	Uroflowmeter not charged.	Place the Uroflowmeter on the Charging Puck and plug the power cable into an electrical outlet.
SOFTWARE		
Unable to log in to Glean Mobile App or Web App	Incorrect password	Reset password and reattempt log in. If still unable to log in, contact clinic admin.
Unable to access the Glean Mobile or Web Apps	Unable to open Glean Mobile App	Power off and on mobile device or delete and redownload the app.
	Incorrect web address	Ensure navigation to correct web address via log in page located at gleanuds.com.

Table 5. Troubleshooting

Error Message	Location	Corrective Action(s)
WEB / MOBILE APP		
Could not get your token	Landing page	Unable to retrieve service token to complete your registration. Please contact the Bright Uro Service team for registration assistance.
MOBILE APP		
Connection failed	Sensor Setup page	Reattempt to connect. If still unable to connect contact Bright Uro Service team.
There was an issue uploading sensor data to the cloud.	Data Download page	Wait for 2-3 minutes and reattempt to upload the sensor data to the cloud. If unsuccessful after 3 attempts, contact the Bright Uro Service team.
Error trying to read the QR Code	Scan Device QR Code	Make sure there is good lighting, the QR code symbol is completely visible, and the camera lens is clean. Reattempt to read the QR code
Unknown issue.	Sensor Setup page	Record the steps taken to get the error and contact the Bright Uro Service team.
Could not remove the Event	Edit Event page	Log out of the current session. Close the Glean UDS App and login to start a new session, then reattempt to remove the event. If the error persists, check the troubleshooting section or contact the Bright Uro Service team.
Error trying to save information	Add Event page	Log out of the current session. Close the Glean UDS App, and login to start a new session. Then reattempt to add the event. If the error persists, check the troubleshooting section or contact the Bright Uro Service team.

Error trying to delete your account	Patient Profile page	Contact the Bright Uro Service team for a possible solution.
Error trying to make the request.	Reset Password page	Log out from the current active session and close the Glean UDS App. Start a new browser and login to start a new session. Reattempt to reset the password. If the error persists, check the troubleshooting section or contact the Bright Uro Service team.
You must fill your Email.	Sign In/ Login page	Verify the correct email is entered.
You must provide your password.	Sign In/ Login page	Make sure the password field is filled out.
Limited or no internet connectivity.	Sign In/ Login page	Make sure you have an active internet connection and try to login again.
One event already has this name.	New Event Type (Others)	Use different event name that has not been used before and try again.
You cannot create an empty field event	New Event Type (Others)	Make sure all the required fields are filled out prior to creating the event.
You need to choose a Type	New Event Type (Others)	Make sure the event type is filled out.
Email address cannot exceed 64 characters after the "@"	New Event Type (Others)	Make sure to use a valid email address.
Email exceeds maximum length	New Event Type (Others)	Make sure to use a valid email address.
The selected hour cannot be in the future	New Event Type (Others)	Make sure to enter the valid time.

Table 6. Error Messages

If problems continue, contact the BRIGHT URO Service team at +1 (949) 216-0873 or by email at support@brighturo.com.

12 APPENDICES

APPENDIX A: TECHNICAL DATA

Model	Glean Urodynamics System
Classification EN 60601-1	- Applied part, Type BF - IP54 Rated - Pollution Degree Classification – 2 (Products classified with a pollution degree of 2 are typically intended for use in environments where only non-conductive pollution occurs. However, temporary conductivity caused by condensation may happen occasionally.)
Mode	Continuous Operation
Sterilization	Ethylene Oxide (EO) Sterilization (Sensor and Insertion Tool only)
Operating Conditions	+10 °C (50 °F) to +40 °C (104 °F)(Sensor and Insertion Tool) +15 °C (59 °F) to +35 °C (95 °F) (Uroflowmeter) 20% to 80% Relative Humidity, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa (all devices)
Operating Atmospheric Pressure	700 hPa - 1014 hPa (up to 2,000 m)
Transport and Storage Conditions	+20 °C (68 °F) to +25 °C (77 °F) (Sensor and Insertion Tool, storage) 0 °C (32 °F) to +60 °C (140 °F) (Sensor and Insertion Tool transport) -30 °C (-22 °F) to +60 °C (140 °F) (Uroflowmeter, storage) -30 °C (-22 °F) to +60 °C (140 °F) (Uroflowmeter, transport) Uncontrolled to 85% Relative Humidity, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa, and 100 hPa to 1,060 hPa (Sensor and Insertion Tool) Uncontrolled to 85% Relative Humidity, non-condensing (Uroflowmeter, storage and transport) **NOTE**: Manufacturer considers that there is no hazard if device is used immediately after storage.
Weight	0.3 lbs (150 g)
Dimensions (H X W X D)	Uroflowmeter: 3” (76.2 mm) H x 7.5” (190.5 mm) W x 7.5 (190.5 mm) D

Table 7. GUS Specifications

APPENDIX B: CLASSIFICATIONS

IEC 60601-1:	Class II Equipment Type BF Applied Parts
Mode of Operation:	Continuous; Equipment not suitable for use in the presence of a Flammable, Anaesthetic Mixture, with Air, or Oxygen, or Nitrous Oxide.
Degree of Protection:	The GUS Uroflowmeter enclosure is classified IP54 according to degree of protection against ingress of water and particulate matter as per the test requirements of IEC 60529. With this IP (International Protection) rating, it means that the Uroflowmeter enclosure: • Protects users using tools 1.0 mm or larger from accessing hazardous parts, and protects equipment from ingress of dust (signified by the rating code 5). • Protects equipment from the harmful effects of water splashing from any direction (signified by the rating code 4). NOTE: the IP rating will be visible on the Uroflowmeter label.

Table 8. GUS Classifications

APPENDIX C: SYMBOLS AND LABELING

	Consult Instructions for Use		Sterilized using ethylene oxide
	Warning		Non-Sterile
	Do not use if package is damaged		Date of Manufacture
	Consult Instructions for Use		Manufacturer
	Not made with natural rubber latex		Authorized Representative in the European Community
	Consult the instructions for use for important cautionary information such as warnings and precautions		Contents of box or container
	Strong Magnetic field		Quantity
	Keep dry		Lot number of product
	Keep out of direct sunlight		Catalog number of product
	Single use only		Serial number of product
	Humidity limitation		Use by Date (Expiration date of product)
	Upper Limit of Temperature		Atmospheric pressure limitation
	Temperature limits		Requires Disposal per Waste Electrical and Electronic Equipment Directive
	Type BF Applied Part		Peel open pouch at marked corner
	Prescription use only		Direct Current
IP54	Ingress Protection Rating		Class II (2) Equipment

	Unsafe in MRI Environments		

1. ISO 15223-1 Medical Devices – Symbols to be used with medical device, labels, labelling and information to be supplied – Part 1: General Requirements.
2. ISO 7010 Third Edition 2019-07 Graphical symbols – Safety colors and safety signs – Registered safety signs
3. ISO 7000 Sixth edition 2019-07 Graphical Symbols for Use on Equipment – Registered Symbols.
4. IEC 60417 – Graphic Symbols for Use on Equipment.

NOTE: Sterility symbols are applicable to single-use devices only.

Table 9. Symbols Glossary

Labels can be found on the devices as follows:

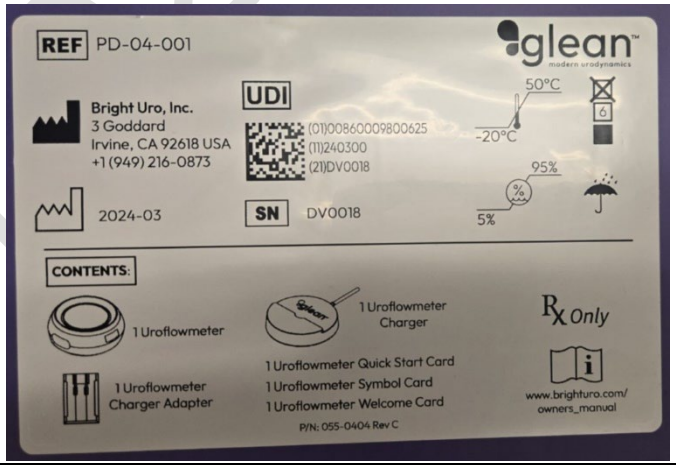
Label Description	Label Placement
GUS Sensor and Insertion Tool	
GUS Uroflowmeter	

Table 10. Label Location

APPENDIX D: ELECTROMAGNETIC COMPATIBILITY (EMC)

This equipment has been tested and found to comply with the limits for:
IEC 60601-1-2:2020(AMD+1), IEC 60601-2:40:2016 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

CISPR 11	Industrial, scientific, and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics
IEC 61000-3-2	Limits for harmonic current emissions (equipment input current = 16 A per phase)

IEC 61000-3-3	Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current = 16 A per phase and not subject to conditional connection
IEC 61000-4-2	Testing and measurement techniques – Electrostatic discharge immunity test
IEC 61000-4-3	Testing and measurement techniques – Radiated, radiofrequency, electromagnetic field immunity test. Ed 3.2.
IEC 61000-4-39	Testing and measurement techniques – FID Magnetic Proximity Fields
IEC 61000-4-4	Testing and measurement techniques – Electrical fast transient/burst immunity test
IEC 61000-4-5	Testing and measurement techniques – Surge immunity test
IEC 61000-4-6	Testing and Measurement Techniques – Immunity to Conducted Disturbances, Induced by Radio-Frequency Fields.
IEC 61000-4-8	Testing and measurement techniques – Power frequency magnetic field immunity test
IEC 61000-4-11	Testing and measurement techniques – Voltage dips, short interruptions, and voltage variations immunity tests
Clause 5	Identification, Marking and Documents

Table 11. Electromagnetic Compatibility

1. These limits are designed to provide reasonable protection against harmful electromagnetic or other interference in most installations. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful electromagnetic or other interference, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
   - Reorient or relocate GUS Uroflowmeter unit.
   - Increase the separation between GUS Uroflowmeter unit and the affected equipment.
   - Connect the non-medical system equipment into an outlet on a circuit different from that to which the GUS Uroflowmeter unit is connected.
   - Consult experienced technical personnel for help.

⚠ WARNING: Changes or modifications not expressly approved by Bright Uro could void the user's authority to operate the equipment.

2. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

3. 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.
4. The Uroflowmeter contains FCC ID: PVH0946 IC: 5325A-0946
5. Sensor FCC ID: 2BHMUGUS1000

IEC 60601-1-2:2020 Table 1 Requirements

The GUS is intended for use in the electromagnetic environment specified below. The customer or the user of the GUS should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The GUS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The GUS meets the conducted and radiated performance requirements for non-life supporting equipment and meets the harmonic emissions, voltage dips and variations and voltage fluctuation (flicker) requirements for non-life supporting equipment pursuant to CISPR 11, Al & A2, and IEC 61000-3-3. The GUS is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re- orienting or relocating the device or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Table 12. Table 1 Requirements—Electromagnetic Environment

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

The GUS is intended for use in the electromagnetic environment specified below. The customer or the user of the GUS should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±2 kV, ±4 kV, ±8 kV and ±15 kV Air	±8 kV Contact ±2 kV, ±4 kV, ±8 kV, ±15 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

The GUS is intended for use in the electromagnetic environment specified below. The customer or the user of the GUS should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Voltage Dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100 % dip in U_T) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 70% U_T (30% dip in U_T) for 25 cycles 0% U_T (100% dip in U_T) for 5 seconds	<5% U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency Magnetic Field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 13. Table 2 Requirements—Electromagnetic Environment—Guidance

IEC 60601-1-2:2014 Table 4 Requirements:

The GUS is intended for use in the electromagnetic environment specified below. The customer or the user of the GUS should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms for ISM bands.	3 Vrms	Professional healthcare Environment WARNING: Portable and mobile RF communications equipment such as diathermy, electrocautery, and RFID equipment may affect the device. The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the screen should be observed to verify normal operation while operating. The device may temporarily experience a disruption in function while near devices that emit strong radiated fields. Basic safety will not be impacted. If undesirable effects are observed, try one of the following: 1. Reorient or relocate the other equipment. 2. The Uroflowmeter and Sensor are internally powered and will not be impacted

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			by conducted emissions while running on battery. 3. While charging, connect the other equipment into an outlet on a circuit different from that to which the Uroflowmeter is connected to. 4. Consult Bright Uro for help.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710/745/780 MHz 28 V/m 810/870/930 MHz 28 V/m 1720/1845/1970 Mhz 28 V/m 2450 MHz 9 V/m 5240/5500/ 5785 MHz	3 V/m	Professional Healthcare Environment WARNING: Portable and mobile RF communications equipment such as diathermy, electrocautery, and RFID equipment may affect the device. The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the screen should be observed to verify normal operation while operating. The device may temporarily experience a disruption in function while near devices that emit strong radiated fields. Basic safety will not be impacted. If undesirable effects are observed, try one of the following: 1. Reorient or relocate the other equipment. 2. The Uroflowmeter and Sensor are internally powered and will not be impacted by conducted emissions while running on battery. 3. While charging, connect the other equipment into an outlet on a circuit different from that to which the Uroflowmeter is connected to. 4. Consult Bright Uro for help.

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

Table 14. Table 4 Requirements—Electronic Environment—Guidance

WARNING: Per IEC 60601-1-2, ed 4.1, portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the Glean system Uroflowmeter or Sensor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE: If the measured field strength at the location where the device is used exceeds the aforementioned compliance level, the device should be monitored to ensure it is functioning properly. Should unusual performance characteristics (i.e., no data acquisition when expected) be observed, additional measures may be required, such

as changing the alignment or location of the device. Also, see the Troubleshooting section for help with troubleshooting.

Transmitter and Receiver Product Specifications:

The Uroflowmeter and Sensor devices intentionally transmit and receive RF energy for communication. The Uroflowmeter uses Wireless Power Transfer (WPT) for charging.	
Parameter	**Specification**
Tx/Rx Frequencies	2.402 to 2.480 GHz
Max Power Output	1.0 mW EIRP
Modulation	BLE1M-GFSK
WPT Frequency	100 kHz

Table 15. Transmitter and Receiver Product Specifications

The expected functions and performance of the Glean Urodynamics System are listed in the table below along with what to expect if the functions or performance are lost or degraded due to electromagnetic disturbances. Note that the probability of harm associated with an electromagnetic disturbances has been mitigated to low with multiple design risk control measures and verification testing to IEC 60601-1-2 for basic safety and Essential Performance.

Expected Device Function/ Performance	**What to expect if the functions/performance are lost or degraded due to electromagnetic disturbances**
Quantification of the pressure and flow characteristics of the urinary tract	Electromagnetic disturbance causes inaccurate measurement of pressure and flow characteristics, leading to incorrect diagnosis or delay of procedure/diagnosis.
Inability to download recorded data from the sensor	Electromagnetic disturbances or interference from other wireless equipment disrupts the data download process leading to delay of procedure/diagnosis.
Inability to establish wireless connection to the sensor or uroflowmeter	Electromagnetic disturbances or interference from other wireless equipment prevents connection to the sensor or uroflowmeter leading to delay of procedure/diagnosis.

APPENDIX E: END-USER SOFTWARE LICENSE AGREEMENT

EULA, Terms and Conditions: www.gleanuds.com/EULA

APPENDIX F: GLOSSARY

TERMS[i, ii] USED IN GLEAN URODYNAMICS TESTING

NOTE: Notations in italics indicate usage specific to Bright Uro's Glean Urodynamics System protocols.

Abdominal leak point pressure: the intravesical pressure at which urine leakage occurs due to increased abdominal pressure in the absence of a detrusor contraction.

- *Measured in cmH2O*

Acontractile detrusor: absence of detrusor contraction under Urodynamic evaluation.

Area under the curve: a calculation of the area contained by the curve of a urethral pressure profile.

Bladder pressure: (Pves, intravesical pressure) pressure within the bladder

- *Measured in cmH2O*

Cystometry: the measurement of the pressure-volume relationship of the bladder during filling. Measurements obtained during cystometry include bladder sensations, compliance, bladder capacity and the presence or absence of detrusor overactivity (DO). The graphical recording of the bladder pressure and volume over time is referred to cystometrogram (CMG).

- *GUS bladder pressure is recorded as Pves in the Glean Web App*

Detrusor overactivity: characterized by involuntary detrusor contractions during the filling phase – either spontaneous or provoked.

Detrusor overactivity incontinence: incontinence due to an involuntary detrusor contraction.

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

Filling phase: (storage phase) often used to describe the CMG portion of a Urodynamic examination, this phase ends upon to voiding.

First desire to void: during Urodynamics, the feeling that would lead the patient to pass urine at the next convenient moment, but voiding can be delayed.

- *This can be recorded as an event labeled "1st Desire" in the Glean Mobile App (Clinician)*

Frequency: the complaint of voiding too often by day.

Functional profile length: the length of the urethra along which the urethral pressure exceeds bladder pressure, calculated within a UPP segment, displayed in mm, as length of continence zone

Hesitancy: difficulty initiating voiding.

Idiopathic detrusor overactivity: (formerly "detrusor instability") incontinence due to an involuntary detrusor contraction with no defined cause.

Incompetent urethral closure mechanism: when the urethra allows leakage of urine in the absence of a detrusor contraction.

Incontinence: the involuntary loss of urine. May be further defined as: stress incontinence, urge incontinence, mixed (both stress and urge) incontinence, nocturnal enuresis, and situational incontinence.

- *This can be recorded as an event labeled "Leak" in the Glean Mobile App (Clinician and Patient)*

International Continence Society: (ICS) "The primary interest of the International Continence Society is to study storage and voiding function of the lower urinary tract, its diagnosis and the management of lower urinary tract dysfunction, and to encourage research into pathophysiology, diagnostic techniques and treatment."

- *This group sets standards for Urodynamic testing that all Bright Uro training follows.*

Intravesical pressure: (Pves) pressure measured within the bladder. Note that pressure within the bladder can come from two sources – pressure from the abdomen (Pabd) and pressure from the muscle surrounding the bladder (Pdet). Formerly known as "total intravesical pressure".

- *GUS intravesical pressure recorded in CMG, pressure/flow, and UPP tests, measured in cmH2O*

Intrinsic sphincter dysfunction: (ISD) is usually indicated by maximum urethral closure pressure less than 20 cmH2O pressure, or ALPP less than 60 cmH2O pressure.

Leak point pressure: (LPP, ALPP, VLPP, CLPP) the intravesical pressure at which involuntary urine leakage is noted during increased abdominal pressure, in the absence of a detrusor contraction.

- *Measured in cmH2O*

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

Maximum cystometric capacity: (capacity) the volume at which the patient can no longer delay voiding. During Urodynamics, this is usually the point at which permission to void is given.

- *Measured in ml*

Maximum urethral pressure: (MUP) maximum pressure of the measured profile.

- *Measured in cmH2O*

Micturition study: a pressure/flow study. This study includes pressure measurements such as Pves and Uroflow measurements. This allows documentation of the relationship between the pressure generated during the voiding event and the resultant flow rate and pattern.

- *The results of the GUS pressure/flow study may be viewed in the Glean Web App*

Neuropathic detrusor overactivity: (formerly hyperreflexia) detrusor overactivity where there is a relevant neurological condition.

Nocturia: the complaint that patient has to wake from sleep during the night one or more times to void.

Nocturnal enuresis: the complaint of loss of urine during sleep.

Normal detrusor function: the detrusor allows the bladder to fill with little or no change in intravesical pressure, with no involuntary contractions despite provocation.

Permission to void: Time at which clinician allows patient to void as denoted by an annotation placed at time of reported sensation of bladder capacity, recommended by ICS to document when patient was told to allow voiding. This helps differentiate between contractions that are involuntary, and contractions that are voluntarily generated to initiate voiding.

- *This can be recorded as an event labeled "Voiding Event" in the Glean Mobile App (Clinician and Patient)*

Phasic detrusor overactivity: Intermittent detrusor overactivity which occurs during filing, which may or may not lead to incontinence.

Post-void residual: (PVR) the volume of urine left in the bladder after voiding.

- *This can be recorded as an event labeled "PVR" in the Glean Mobile App (Clinician)*

Retention: a non-painful bladder, which remains palpable or percussible after the patient has passed urine. Such patients may be incontinent.

Sensation: in Urodynamics, the reported sensations during testing such as first sensation, first desire, strong desire, and sense of reaching bladder capacity.

- *These can be recorded as events in the Glean Mobile App (Clinician)*

Stress urinary incontinence: (SUI) the symptom of a loss of urine associated with exertion, often with cough or sneeze. This is considered a complaint unless proven urodynamically, when it then is known as Urodynamic stress incontinence (formerly genuine stress incontinence).

Strong desire to void: described as the persistent desire to void without fear of leakage.

- *This can be recorded as an event labeled "Strong Desire" in the Glean Mobile App (Clinician).*

Terminal detrusor overactivity: a single involuntary detrusor contraction occurring at capacity, which cannot be suppressed and results in incontinence, usually resulting in emptying of bladder.

Uninhibited: acting without conscious inhibition – often used to describe a bladder contraction which the patient is unable to suppress.

Urethra: the tube leading from the bladder to the outside of the body.

Urethral pressure: (Pura) the pressure needed to just open a closed urethra.

- *Measured in cmH2O*

Urethral pressure profile: (UPP) the pressures recorded throughout the length of the urethra, measured by withdrawing the Sensor at a slow known rate (recommended: 1mm/sec).

- *Measured in cmH2O*

Urethral relaxation incontinence: leakage due to urethral relaxation in the absence of raised abdominal pressure or a detrusor contraction.

Urgency: the complaint of a sudden compelling desire to pass urine which is difficult to defer.

- *This can be recorded as an event labeled "Urge" in the Glean Mobile App (Clinician and Patient)*

Urge incontinence: symptom of incontinence associated with a strong compelling desire to void.

Urinary tract infection: finding of microbiological evidence of significant bacteriuria and pyuriaxii usually accompanied by symptoms such as increased bladder sensation, urgency, frequency, dysuria, urgency urinary incontinence, and/or pain in the lower urinary tract.

Urodynamic stress incontinence: (formerly genuine stress incontinence, SUI, or stress incontinence) the involuntary leakage of urine during increased intravesical pressure, in the absence of a detrusor contraction.

Valsalva: the attempt to forcibly exhale with a closed glottis – often used to increase intra-abdominal pressure.

- *Used to provoke stress incontinence, can be recorded as an event labeled "Valsalva" in the Glean Mobile App (Clinician)*

Voiding phase: (emptying phase) often used to describe the portion of a Urodynamic evaluation that records both pressures and flow parameters during a voiding event, this would immediately follow the "filling phase".

- *This can be recorded as an event labeled "Voiding Event" in the Glean Mobile App (Clinician and Patient)*

APPENDIX G: ACRONYMS

- CMG: Cystometrogram
- GUS: Glean Urodynamics System
- LUTD: Lower urinary tract dysfunction
- LUTS: Lower urinary tract symptoms
- MS: Micturition study
- PFS: Pressure/flow studies
- Pves: Intravesical pressure
- PVR: Post-void residual
- UF: Uroflowmetry
- UPP: Urethral pressure profile
- UTI: Urinary Tract Infection

APPENDIX H: CYBERSECURITY-RELATED INFORMATION

The cybersecurity information contains system configurations and policies that are utilized and adopted by BrightUro for the GleanUDS product. The GleanUDS Delivery system diagram is depicted in the figure below.

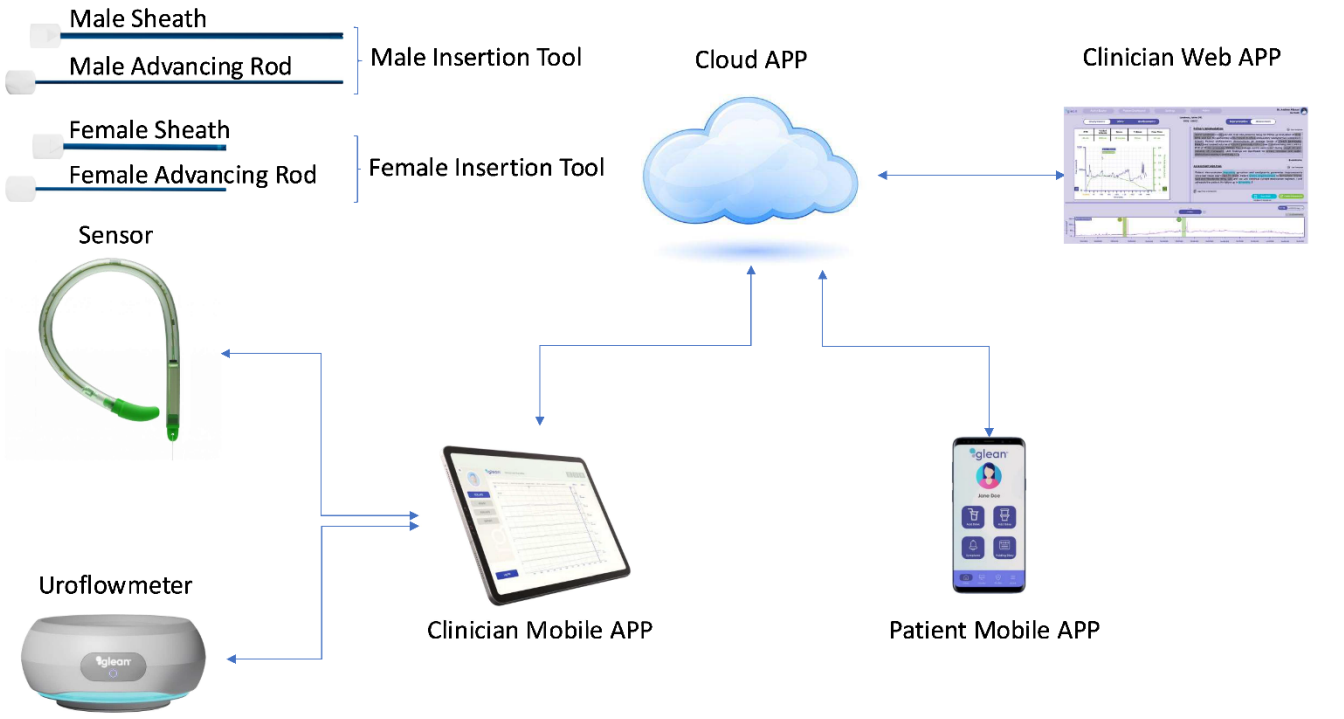


Figure 91: GleanUDS Delivery System Diagram

FIREWALL PROTECTION:

The web application is protected by a Web Application Firewall (WAF) at the infrastructure level, which filters and monitors incoming HTTP/S traffic to prevent common web application attacks (e.g., SQL injection, cross-site scripting). Additionally, Network Security Groups (NSGs) are used to control inbound and outbound traffic at the network layer (Layer 3/4), allowing for precise control over access to cloud resources. As a result, users do not need additional firewall protection on their local devices specifically for interacting with this application.

However, we recommend that users still enable the built-in firewall on their personal devices (e.g., Windows Defender Firewall, macOS Firewall) to protect against other network threats unrelated to this platform.

ANTI-MALWARE SOFTWARE:

While our platform leverages Azure's cloud-based security measures (e.g., anti-malware and threat detection at the infrastructure level), we recommend that users install and maintain up-to-date anti-malware software on their personal devices to protect against local threats (e.g., viruses, spyware, and ransomware). Reputable anti-

malware solutions that offer real-time scanning and automatic updates are highly recommended to ensure full protection.

PASSWORD POLICY:

To ensure the security of user accounts, the following password policy is in place for all web and mobile applications:

- Minimum password length of 10 characters.
- Use of at least one uppercase letter, one lowercase letter, one number, and one special character.
- Passwords must not be reused for at least the last five changes.
- Enable two-factor authentication (2FA) for enhanced account security (Optional)

BACKUP AND RESTORE FEATURES AND PROCEDURES TO RESTORE AUTHENTICATED CONFIGURATIONS

The system is designed to perform regular backups and restore data based on the configuration of high-availability systems. These backups use AES 256-bit encryption, ensuring that data is both protected and restorable when needed. Azure, by default, uses AES 256-bit cipher in CBC mode with a 256-bit key. The key is encrypted using a symmetric key stored in the Azure Key Vault. Authentication is necessary to access and restore configurations, with role-based authorization controls in place to restrict access to authorized personnel. Additionally, the system ensures that only authenticated and authorized users can restore configurations to a known, validated state, helping ensure that post-restoration configurations align with security policies. The procedures ensure continuity of care and minimize downtime, restoring critical functionalities efficiently.

There is no critical data that resides in the system which the Mobile or Web applications are running on. All of the data is securely stored in the Azure cloud. The regular backup method for Mobile App or personal computer systems include backup of the GleanUDS Mobile and Web Application configuration data.
The recorded data in the GleanUDS uroflowmeter is downloaded and stored in the cloud after a study session is completed. The data is automatically erased from the device once it is stored in the cloud. Hence, there is no requirement to backup any data in the device.

METHODS FOR RETENTION AND RECOVERY OF DEVICE CONFIGURATION BY AN AUTHENTICATED AUTHORIZED USER

The system follows a data retention policy that maintains configuration data for a period of 15 years. During this time, authenticated and authorized users can recover configuration settings through a role-based authentication system. Critical configurations and associated data are securely stored in encrypted backups that are accessible only to authorized personnel. In compliance with security best practices, recovery procedures require verification of the user's credentials to prevent unauthorized access to sensitive data. Automated backup routines ensure up-to-date configurations are available for recovery, ensuring minimal disruption to critical device operations.

The recorded data in the GleanUDS uroflowmeter is downloaded and stored in the cloud after a study session is completed. Hence, the recorded data retention and recovery follows the overall system practice.

HIGH-LEVEL DESCRIPTION OF DEVICE FEATURES PROTECTING CRITICAL FUNCTIONALITY (E.G., BACKUP MODE, DISABLING PORTS/COMMUNICATIONS)

The system implements a variety of protective features to ensure critical functionality is maintained, even during abnormal conditions. These include firewall configurations, mutual TLS (mTLS) encryption, Web Application Firewall (WAF), and role-based authorization. For instance, Azure Network Security Groups (NSGs) control both inbound and outbound traffic, while WAF and Distributed Denial of Service (DDoS) protections prevent malicious traffic from disrupting critical operations. The WAF specifically helps by filtering, monitoring, and blocking malicious HTTP/S traffic to the application. Unused ports and communication channels are disabled by default, minimizing the system's exposure to potential threats.

DESIGN RESPONSE TO ANOMALOUS CONDITIONS (E.G., SECURITY EVENTS, NOTIFICATIONS, LOGGING)

The system is designed to support real-time monitoring and vulnerability scanning tools to detect and respond to anomalous conditions.

Security events are logged and can be configured to notify authorized users in real-time, providing actionable insights. This ensures the system remains resilient to threats and supports detailed logging for post-incident analysis.

FORENSIC EVIDENCE CAPTURE (LOG FILES) FOR SECURITY EVENTS

The system captures comprehensive forensic evidence in the form of log files, stored centrally and securely. These logs include detailed records of user actions, changes to configurations, and logs generated by various system components, including Kubernetes clusters, firewalls, databases, and other critical infrastructure. Log files are stored in a centralized third-party service such as Azure Monitor or Log Analytics, and they are secured using encryption to prevent unauthorized access. The log files are kept for a specified period to comply with regulatory requirements and can be consumed by automated analysis software like Intrusion Detection Systems (IDS) or Security Information and Event Management (SIEM) platforms for advanced security event analysis. Logs are archived and managed in compliance with data retention policies, ensuring that relevant forensic evidence is available for future investigations if needed.

SOFTWARE DEPENDENCIES FOR VULNERABILITIES MONITORING

BrightUro works with a 3rd party provider to monitor any potential new vulnerabilities in any of the dependency libraries or software that is part of the GleanUDS system. Additionally, the GleanUDS cloud system can integrate with tools like Azure Security Center or similar solutions to monitor for security events such as configuration changes, unauthorized login attempts, and network anomalies.

SOFTWARE/FIRMWARE UPDATES

The Glean UDS Mobile App will be made available through the Apple AppStore and Google PlayStore. Users will receive notification on their devices when updates to the Mobile App is available for installation. At which time, the user will have the option to install the updated software on their devices.

The firmware on the Glean UDS Uroflowmeter can only be updated by BrightUro's trained service personnel. Instructions on returning the uroflowmeter device to BrightUro's service center is provided in the Glean Owner's Manual. BrightUro will send out notifications to customers when there are updates available to the firmware. The Glean UDS sensor firmware is not updateable.

BrightUro will provide security patches or software updates for the Glean UDS product during the lifetime of the product.

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