



Glean Urodynamics System

Patient Manual



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ABOUT THIS MANUAL

SYMBOLS

This manual provides important information to help you understand the features and safe use of the device. The symbols outlined here highlight helpful tips and important cautions that may help you as you read through the manual.



CAUTION

Caution/warning symbol describes important information 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.

INTRODUCTION

This manual contains instructions about how to use the Glean App. Your doctor may ask you to use this app as a part of different tests they perform to help them understand what is going on with your bladder and lower urinary tract.

Clinicians often perform Urodynamic tests to assess Lower Urinary Tract Dysfunction, identify the cause of the Lower Urinary Tract Dysfunction, and help to select the best treatment for your condition. For many of these tests, your Clinician will measure the pressure in your bladder and the flow of urine when your bladder is filling and when you empty your bladder. While you are completing these tests, your Clinician may ask you how you are feeling and whether you are experiencing symptoms. The Glean App allows you to digitally log your symptoms using a smartphone or tablet. This information may help the clinician to better understand what is happening in your bladder during your test.

INSTALLING THE GLEAN MOBILE APPLICATION

This section provides instructions on how to download and install the Glean App.

ACCESSING THE GLEAN APP

The Glean App can be downloaded directly from the Google Play™ store for Android products and Apple App Store™ for iOS products.

INSTALLING THE GLEAN APP

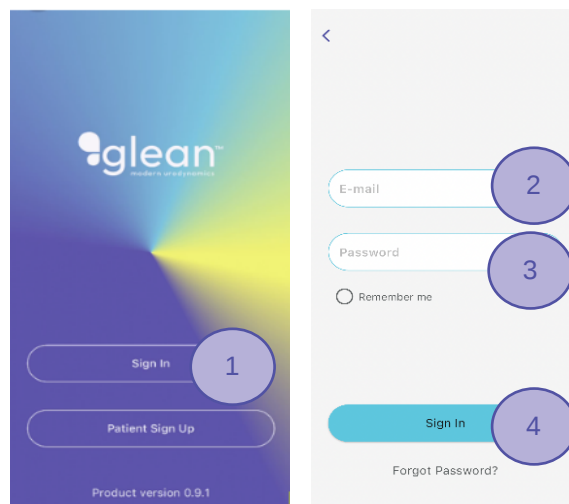
1. Login to your mobile device.
2. Navigate to the Android/iOS App Store.
3. Search for “Glean UDS”.
4. Download and install the Glean App.

CREATE A PASSWORD

1. Your clinic will add you as a patient using your email.
2. You will receive an email to create a password for your Glean account.
3. Click on the link in your email and create your password.

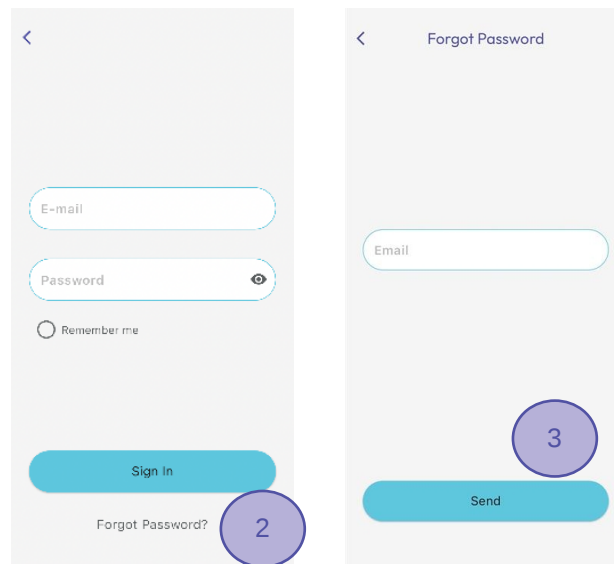
LOGIN TO THE GLEAN APP

1. Open the Glean App and select “Sign In”.
2. Enter your email.
3. Enter your password.
4. Click “Sign In”.



RESET YOUR PASSWORD

1. Open the Glean App.
2. Select “Forgot Password?”
3. Enter your email and click “Send.”
4. Click on the verification link in your email.
5. Enter a new password.
6. Login to the Glean App using the new password.

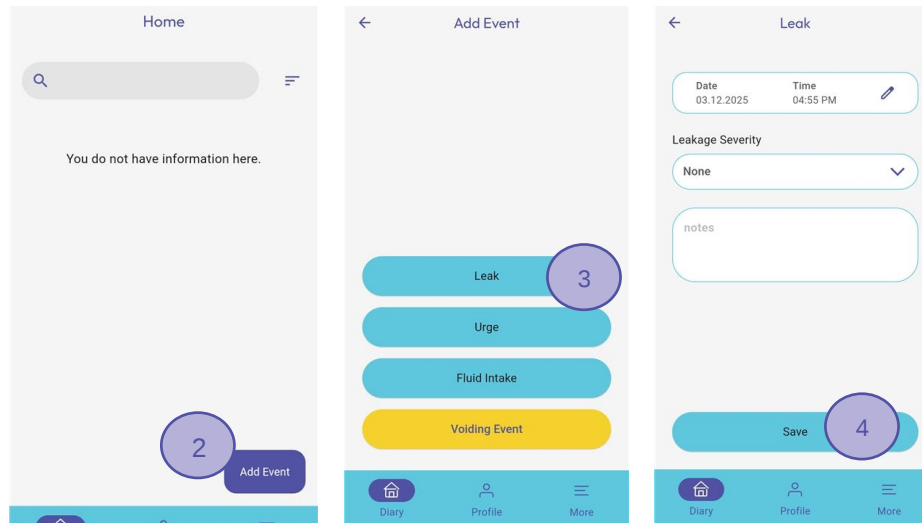


HOW TO USE THE GLEAN APP DURING YOUR TEST

This section provides instructions on how to use the Glean App during your Urodynamics Exam.

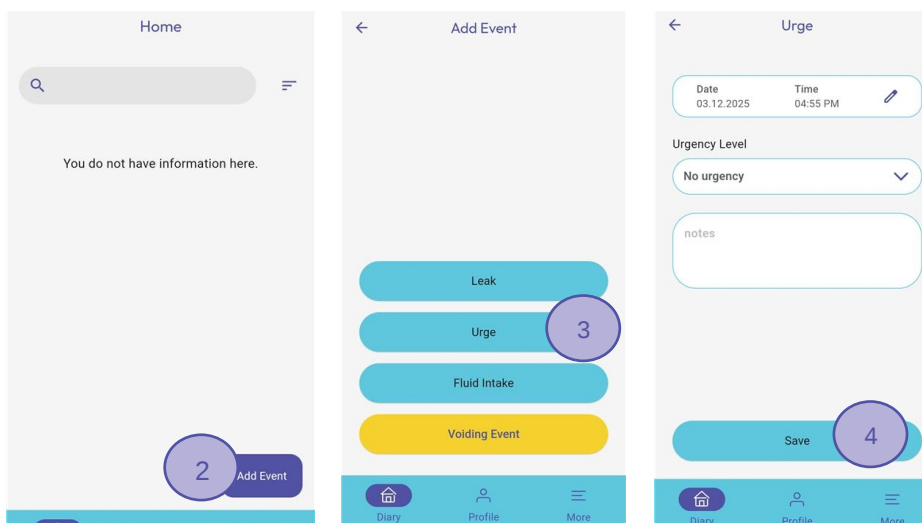
LOG AN EVENT (LEAK)

1. Login to the Glean App.
2. Select “Add Event.”
3. Select “Leak.”
4. Enter required information. Select “Save” to complete data upload.



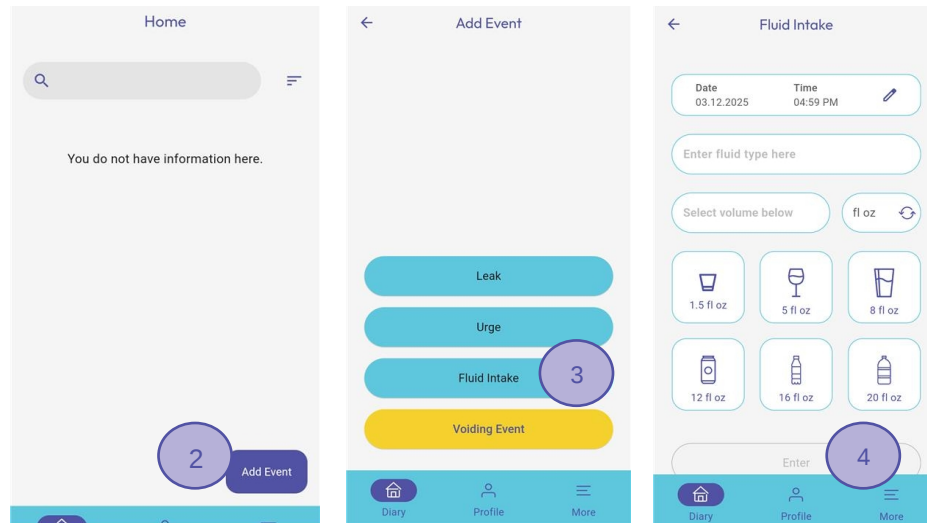
LOG AN EVENT (URGE)

1. Login to the Glean App.
2. Select “Add Event.”
3. Select “Urge.”
4. Enter required information. Select “Save” to complete data upload.



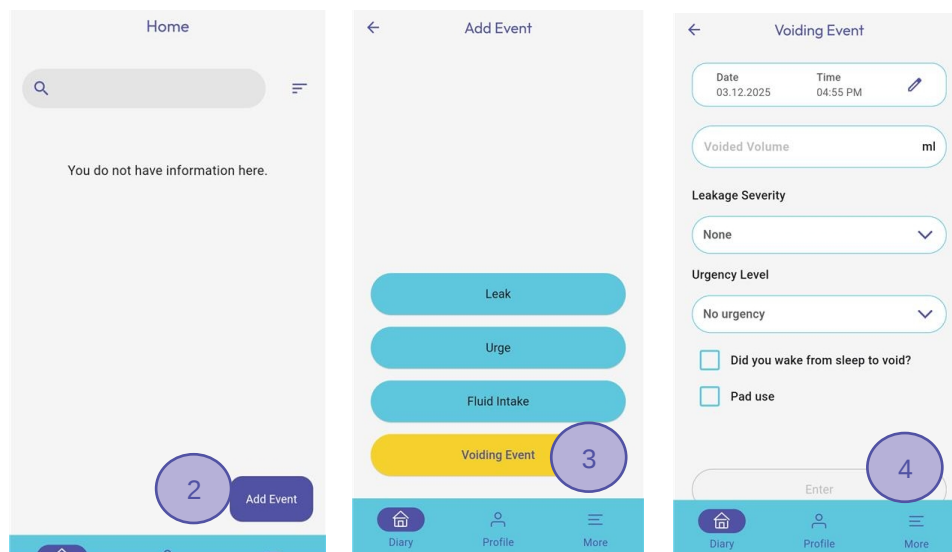
LOG AN EVENT (FLUID INTAKE)

1. Login to the Glean App.
2. Select “Add Event.”
3. Select “Fluid Intake.”
4. Enter required information. Select “Enter” then “Save” to complete data upload.



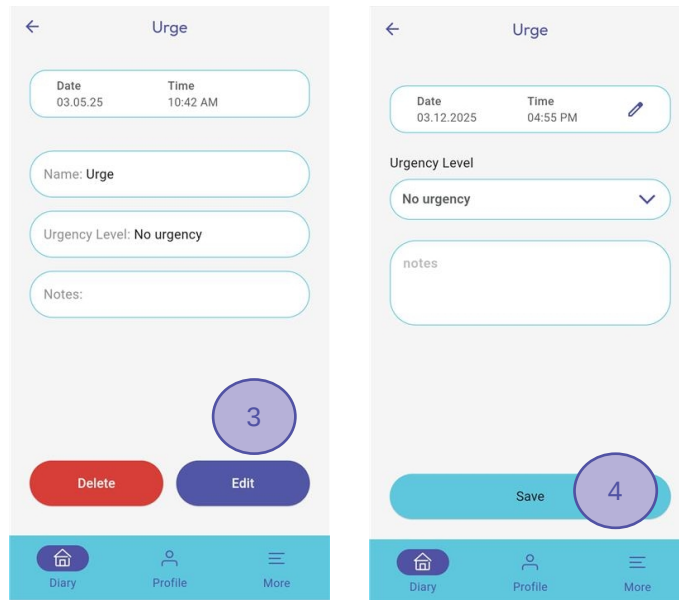
LOG AN EVENT (VOID)

1. Login to the Glean App.
2. Select “Add Event.”
3. Select “Voiding Event.”
4. Enter required information. Select “Enter” then “Save” to complete data upload.



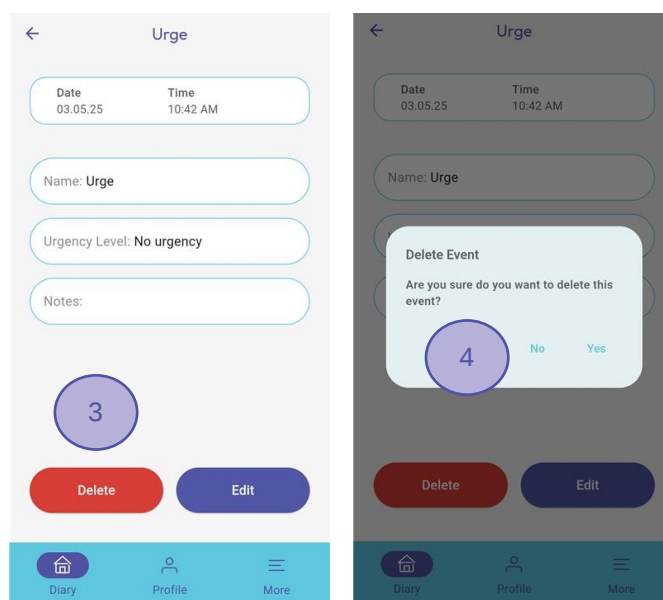
EDIT AN EVENT

1. Login to the Glean App.
2. Select the event you would like to edit.
3. Click “Edit” to edit the event.
4. Add a note and select “Save” to complete data upload.



DELETE AN EVENT

1. Login to the Glean App.
2. Select the event you would like to delete.
3. Select “Delete” to delete the event.
4. Select “Yes” to confirm the deletion.



CONTRAINDICATIONS

If you have (or think you have) any of the following conditions, please notify your clinician because this may mean you should NOT be tested using Glean.

- Glean is not recommended 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 (a urinary tract infection may include symptoms such as a fever, burning sensation when you urinate, cloudy or strong-smelling urine, or other common symptoms of urinary tract infections). Before testing, your clinician should take a urine sample and test it to rule out the presence of infection.
- The Sensor should not be used on patients who suffer from a major stricture in the urethra (narrowing of the urethra).
- The use of the Glean Urodynamics System is not recommended in patients with Stage 4 prolapse (when one or more organs drop from their position and cause a bulge that protrudes from the vagina).
- The use of the Glean is not recommended if you can't feel or sense when you leak (incontinence - involuntary urination).

ADVERSE EVENTS

The following is a list of potential adverse events and risks that may occur for patients using Glean. Possible complications associated with the use of Glean 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 whose nervous system reacts to pain or discomfort below the level of spine injury with a sudden spike in blood pressure)
- Bladder or Urethral Spasms (involuntary muscle contractions)
- Broken Sensor Removal String
- Change in Urinary Frequency (changes in how often you need to urinate)
- Discomfort
- Dysuria (discomfort or pain during when you pee)
- Hematuria (blood in the urine)
- Injury to the Lower Urinary Tract (LUT) and/or Genitals
- Sensor Fracture (breaking)
- Urinary Urgency (a sudden strong, immediate need to pee)
- Urinary Incontinence (loss of bladder control resulting in leakage of urine)
- Urinary Retention (inability to empty your bladder)
- Urinary Tract Infection (when harmful bacteria enter your urinary system leading to symptoms such a fever, a burning sensation when you pee, cloudy or strong-smelling urine, or other common symptoms of infection).
- Urinary Tract Inflammation or Irritation (swollen or irritated bladder or urethra causing discomfort or a burning sensation when you pee).



DEVICE-RELATED ADVERSE EVENTS REPORTING

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

WARNINGS AND PRECAUTIONS FOR PATIENTS



SYSTEM WARNINGS

-  DO NOT USE Glean 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.
-  Bright Uro is not responsible for loss of patient files or test data.



SYSTEM SAFETY COMPLIANCE

MRI Safety: The Sensor is **MRI 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.

Approved By:
[\(CO-669\) Patient and Owner's Manual Updates](#)

Description
Patient manual updated to add size of the device, add a single channel description to the device description, and add an updated clinical summary. Owner's manual added more detailed information on how to use the app and pictures of the app interface, updated contraindications and warning language for clarity.

Justification
Changes add information about the device for use by the user and patient.

Assigned To:	Initiated By:	Priority:	Impact:
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