Manuals+ — User Manuals Simplified.

iUFlow ART-003 Perfect Bladder Tracking Uroflowmetry and Real time Data User Manual

Contents

iUFlow ART-003 Perfect Bladder Tracking Uroflowmetry and Real time Data

Product Information

iUFlow is a Uroflowmeter designed for bladder monitoring at home. It measures urination (voiding) volume and flow rate when used in conjunction with the iUFlow mobile device app. It eliminates the need for direct handling of urine and captures volume and flow rates wirelessly with clinical grade accuracy. The device comes with a bowl, sensor, rinse container, and user manual.

Intended Purpose

The iUFlow Uroflowmeter is intended to be used for measuring urination (voiding) volume and flow rate when used in conjunction with the iUFlow mobile device app.

Product Usage Instructions

Part 1: Set-up the iUFlow device and App

1. Download the app from the App Store or Google Play.
2. Open the app and complete the sign-up process.
3. Remove the parts of iUFlow from the packaging.
4. Place the iUFlow Bowl upside down on a flat rigid surface.
5. Align the unlock icon on the bowl with the orange dot on the sensor and rotate clockwise until it snaps into the locked position.
6. Place iUFlow device on the toilet bowl under the seat.
7. Make sure your iUFlow is stable with all 3 flaps touching the bowl between the bowl and the toilet seat, and the bottom of the sensor of the iUFlow does not touch the water inside the toilet.
8. Pour 1 glass of water into the device before first use.
9. Use the provided rinse container to rinse and store the device when not in use.

Part 2: Use iUFlow device and app

1. Make sure that iUFlow device blue light is blinking.
2. Urinate into iUFlow device.
3. Wait for the urine to drain and for the green light to stop.
4. When the indication light is Blue-Red-Blue it is OK to rinse the device by pouring a glass of water in.
5. On your smartphone, turn on Bluetooth and start iUFlow app.

6. If the iUFlow device is nearby, a green check mark appears at the top left-hand corner of the screen when connected.

7. Tap SYNC.

8. Wait for the recorded measurements to be downloaded into your diary.

Find the comprehensive user manual at
http://iuflow.com/iuflow-manual/

Video instructions can be found at
http://iuflow.com/start

Know your iUFlow

iUFlow is a Uroflowmeter for bladder monitoring at home which eliminates the need for direct handling of urine. With iUFlow, there is no need to write down the urination volume; an easy to use app captures volume and flowrates wirelessly with clinical grade accuracy for you to send by email to your physician!

Package contains

- 1 Bowl
- 1 Sensor
- 1 Rinse container
- 1 User Manual

Intended purpose:
For measurement of urination (voiding) volume and flow rate when used in conjunction with iUFlow mobile device app.

Part 1: Set-up the iUFlow device and App

Downloading & installing iUFlow® app
You can download and install iUFlow® app to your smart mobile device using the Apple App Store or Google Play Store. The app is downloaded the same way as other Apps on your smart mobile device. iUFlow® app is free of charge and is customized for your smart mobile device.

*Downloading the app requires data connectivity.
Scan the QR code according to your mobile device:

Alternatively, you can download the app from the App Store at the following link: **luflow.com/iOS**
Or
Download the app from Google Play at the following link: **iulfow.com/android**
Then, open the app and complete the sign-up process

Set-up your iUFlow

Remove the parts of iUFlow from the packaging
Place the iUFlow Bowl upside down on a flat rigid surface as shown below. Align the unlock icon on the bowl with the orange dot on the sensor and rotate clockwise until it snaps into the locked position. When locked the orange dot aligns with the lock sign.

Place iUFlow device on the toilet bowl under the seat
Make sure your iUFlow is stable with all 3 flaps touching the bowl between the bowl and the toilet seat, and the bottom of the sensor of the iUFlow does not touch the water inside the toilet.
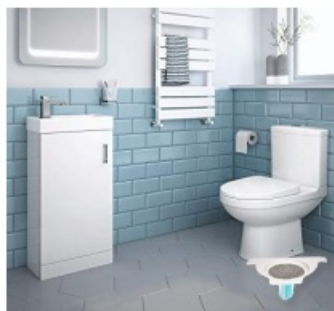
Before first use

Pour 1 glass of water into the device.

Rinse container

Use the provided rinse container to rinse and store the device when not in use.

Part 2: Use iUFlow device and app

Indication
Make sure that iUFlow device blue light is blinking.

Urinate into iUFlow device
Wait for the urine to drain and for the green light to stop.

Note: iUFlow is a standalone device, there is no need to have the app running while using it.

Rinse

When the indication light is Blue-Red-Blue it is OK to rinse the device by pouring a glass of water in.

iUFlow indicator lights

Blue (blinking)
Ready to measure.
Tip: Two quick blinks indicate Bluetooth is connected.

Blue-Red-Blue (blinking)
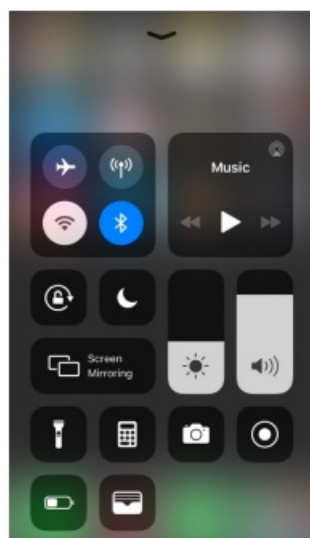Waiting for a rinse.

Green (blinking)
Recording session

Red
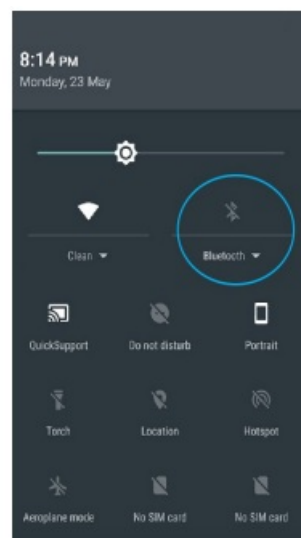Battery is too low to measure. or contact support. **assist@kesemhealth.com**

Download sessions into your phone
On your smartphone, turn on Bluetooth and start iUFlow app. If the iUFlow device is nearby, a green check mark appears at the top left hand corner of the screen when connected.

iPhone   Android

Note:
Do not need to manually pair the iUFlow by searching the device. iUFlow will automatically connect when Bluetooth is enabled on the smart device.

Tap SYNC

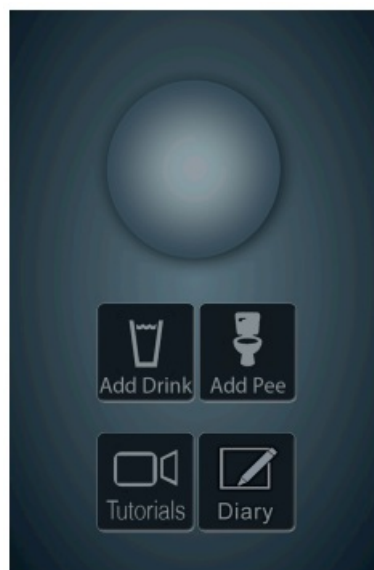Wait for the recorded measurements to be downloaded into your diary.

Once you see the notice "Sessions download is completed", all sessions from iUFlow device are stored in your phone.

iUFlow Screens : Diary

Open diary
On the main screen, tap the Diary button.

Edit
Tap Edit to modify or delete an event

Note: iUFlow can store up to 60 sessions, a good practice is syncing everyday or 2nd day.

Date	Pee	Drink	Leak	Urge
06 Mar, 20 (4)	1667	1893	1	2
16:31		200		
16:22		591		
16:22	976		1	
16:21		376		Juice
16:14		150		
16:13		200		
16:08				💩 3 Norma
16:06		376		Juice
16:06	150			
12:54	392		2	3
12:53	149			3
06 Jan, 20 (7)	1479		1	

Edit Session
You can add or edit the information in the diary to include any leakage or urgency you experienced.
Leakage* before getting to the toilet Urgency* to go to the toilet.
Add a short note (optional)
Tap the Save button.

‹ Back   **Add Pee**   Save

Today   TIME: **Now** 🕐

Volume Voided: **120** (ml)

LEAKAGE:
(0) (1) (2) (3) (4)

URGENCY:
(0) (1) (2) (3) (4)

Description

Save

Leakage: Unintentional loss of urine. Inability to hold urine in the bladder due to loss of voluntary control over the urinary sphincters resulting in the involuntary passage of urine.
Urgency: A sudden compelling desire to pass urine.

DOs and DON'Ts

Note
Repeat this for every urination over 24 or 48 or 72 hours as advised by your healthcare provider.

Recommended
Female position: Make sure both feet are flat on the floor. Your behinds should be at the back of the toilet seat and may touch iUFlow device. You can do several practice runs before starting your formal diary.
Other household members should not urinate into iUFlow.

Attention

- Do not strain with urination.
- Do not move your body during urination.
- Handle with care. Do not shake, drop etc. the device at any time.
- Make sure no hair goes into iUFlow.
- Do not drop toilet paper into iUFlow.
- Do not defecate (poop) into iUFlow.
- Do not place any items, toys, materials etc. into iUFlow.
- Do not spit or spill water into iUFlow during urination.
- Avoid using iUFlow if any of the above occurred, as it may not work properly.
- Always rinse the iUFlow after a recording session using the provided rinse container and cold water before storing.
- Certain medication and constipation may affect the accuracy of the uroflowmeter readings.

Flow feature

iUFlow measures the volume, speed and time of urination.
Results are then used by your doctor to compare your urine flow rate with values considered normal for your age and sex.
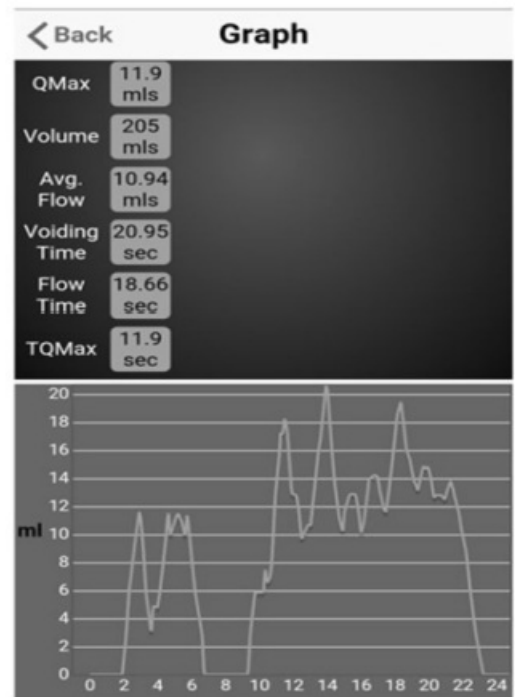The flow measurement will help determine how your lower urinary tract is functioning.

In Diary

1. Choose event(s) to show chart
2. Tap on the chart button

Date		Pee(ml)	Drink(ml)	L
20-10	(3)	580		
☐ 03:03		205		
☐ 02:55		100		
☑ 02:54		275		
19-10	(3)	200	750	:
☐ 09:42			375	
☐ 03:12		200		:
☐ 03:12			375	
18-10	(23)	6510		

QMax	11.9 mls
Volume	205 mls
Avg. Flow	10.94 mls
Voiding Time	20.95 sec
Flow Time	18.66 sec
TQMax	11.9 sec

iUFlow Screens : Add Pee

Missed a urination into iUFlow?

Add Pee
On the main screen, tap the Add Pee button
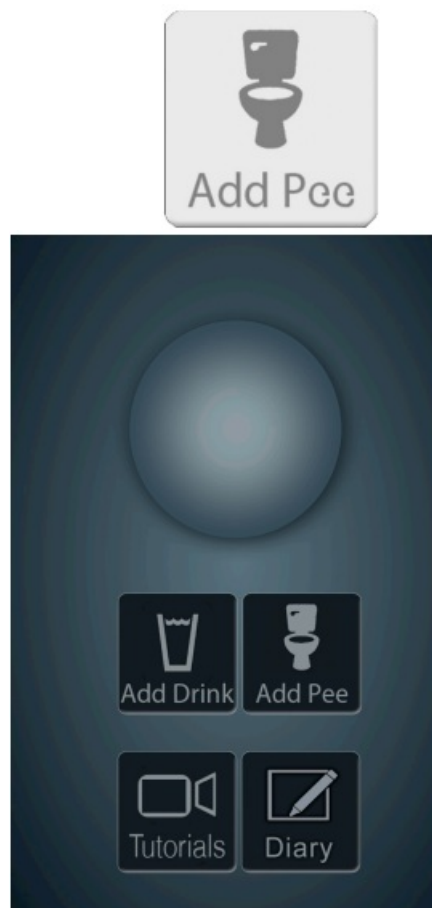
Enter the correct amount.

Indicate to what degree you had:

- Leakage before getting to the toilet
- Urgency to go to the toilet.
- Mark the urine colour (optional) Add a short note (optional).
- Tap the Save button.

Add Pee
On the Add Pee screen, tap the Add Poo button (top right)

Choose the correct type (1-7 scale)

Add a short note (optional).

Tap the Save button.

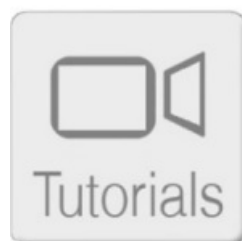| 3 | | A sausage shape with cracks in the surface | Normal |
4		Like a smooth, soft sausage or snake	Normal
5		Soft blobs with clear-cut edges	Lacking fiber
6		Mushy consistency with ragged edges	Mild Diarrhea
7		Liquid consistency with no solid pieces	Severe Diarrhea

Description

Save

Watch tutorials

Video tutorials
On the main screen, tap the Tutorials button
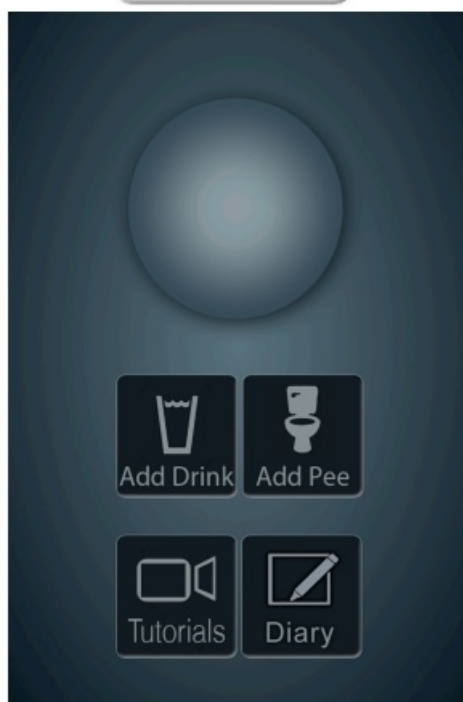
Choose the title
you would like to play

Tap Play

Questions and Answers

How do I contact support?
You can email support on **assist@kesemhealth.com**

Phone:

USA: +1 (949) 966 0180

Questions?
Check online at iUFlow frequently asked questions
http://iuflow.com/frequently-asked-questions/

Kesem Health Pty Ltd,
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345, Lincoln Hill Rd, Shrewsbury, VT 05738 USA

Email: rob@13485cert.com
Tel: +1.802.281.4381; +1.802.258.1881

Part 3: Product information

iUFlow is comprised of

- The iUFlow device: The hardware device (Bowl + Sensor) placed on the toilet bowl under the toilet seat (for sitting position) to measure the volume and the flowrate of urination by a user throughout the voiding; capable of connecting to a mobile device via Bluetooth (e.g. Smartphone); and
- The iUFlow application software: A mobile device application ("app") that collects data from the iUFlow device, analyses the data utilizing an algorithm and stores it.

Operating conditions

- Temperature range: 120C – 300C
- Altitude: 0 – 2000 m
- Shelf life: 2 years from the date of manufacture
- Product life:
- iUFlow (Pro): 4 weeks from first use or 60 urination sessions
- iUFlow (XL): 10 weeks from first use or 300 urination sessions

Usage limitations

- Use only when installed onto a western style toilet (The height between the seating surface (rim) of the toilet bowl to the lowest point (water surface) is 130mm or more.
- For urine only.
- Ensure the water level of toilet does not touch the bottom of the sensor.
- Do not use in a moving vehicle (e.g. plane, train, ferry).
- Use only with iUFlow app.

Supported devices

iUFlow supports iOS 8 or later and Android 5 (Lollipop) and above.
The mobile devices that are officially compatible are these:

iOS
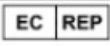
- iPhone 6 / 6S / SE / 6 Plus / 6S Plus
- IPhone 7 / 7 Plus / iPhone 8 / 8 Plus

- iPhone X / XR / XS / XS Max
- iPhone 11 / Pro / Pro Max
- IPhone 12 / Mini / Pro / Pro Max
- IPhone 13 / Mini / Pro / Pro Max
- iPad (2018 – 2021)
- iPad Air (2019 – 2021)
- iPad Mini (2018 – 2021)
- iPad Pro (2018 – 2021)

Android

- Google Pixel 2 / Pixel 2 XL
- Google Pixel 3 / Pixel 3 XL
- Google Pixel 4 / Pixel 4 XL
- LG G5 / G6 / G7 / G8
- Motorola Moto G5 / G6 / G7 / G8
- Samsung Galaxy S6 / S7 / S8
- Samsung Galaxy S9 / S10 / S20 / S21
- Samsung Galaxy Z
- Samsung Galaxy Plus models
- Samsung Note 5 / 8 / 9 / 10 / 20 / 20U

Symbols glossary

Symbol	Meaning
MD	Medical Device
UDI	Unique Device Identifier
SN	Serial Number
	Refer to user manual
	Date of manufacture
	Manufacturer
	Expiry date
(1)	Single user multiple use
	Do not use if the package is opened or damaged
CE	CE mark
	Temperature limit within which the device can be safely used
===	Direct current only
	Protect from moisture
EC REP	Authorised representative in European Union
	Do not dispose of with landfill
	Can be broken or damaged if not handled carefully
	Information website

Specifications

iUFlow measuring accuracy and specifications

iUFlow measures uroflowmetry parameters in a single urination event by a user with the following accuracy;
Volume measurement:

- Measuring range: 50 to 750 ml (Total Flow Volume)
- Accuracy: +/- 5% or +/- 10 ml (Whichever is greater)
  Flowrate measurement:
- Measuring range: 5 to 50 ml/s
- Accuracy: +/- 5% or +/- 1 ml/s (Whichever is greater) iUFlow also measures and records the urination flowrate as it varies throughout the urination event. For each urination event, the user can access a graph showing the flowrate (ml/s) as a function of time (seconds) as well as the following parameters:
- The total flow duration (i.e. Voiding time, Flow time) (seconds);
- The average flowrate (ml/s);

- The highest instantaneous flowrate (i.e. Qmax) (ml/s); and
- The time to the highest instantaneous flowrate (i.e. TQmax) (seconds).

Energy exchange

iUFlow neither delivers energy to the user's body, nor does it extract energy from the user's body in any way or form.

iUFlow, however, includes one CR2032 battery (non-replaceable) to power its electronics. The battery and the electronics are housed in a secure sealed compartment which is insulated so as to prevent any contact with the user. iUFlow is designed so that the electronics compartment is NOT exposed to water and/or urine.

Substance exchange

iUFlow neither delivers any substance to the user's body, nor does it extract any substance from the user's body. iUFlow is activated by urine from the user; however, that urine is not extracted by the device, but rather flows naturally as in everyday life urination.

Cleaning:

Clean the device after use using clean cold water only.

- Pour 240ml (or 8 fl oz) of clean water into the bowl and allow to drain into the toilet.
- Do not wash with detergents.
- Do not immerse product in water.

Storage:

- The unit will self-drain when positioned correctly on the toilet.
- Important: Allow unit to fully air dry before storage.
- Store at 12-300C (53-860F)

Servicing and adjustment:

- The iUFlow contains no user-serviceable components.
- No adjustment is required.
- This device contains a non-rechargeable battery. Do not recharge.

Disposal of the iUFlow device:

- Separate the bowl from the sensor by turning the sensor clockwise to align the orange dot with the unlock sign (see page 4).
- Dispose of the sensor safely and according to the local procedures for household hazardous waste.
- Recycle the iUFlow bowl with normal household recycling waste..
  Do not remove the covers of the device components. Only perform maintenance procedures specifically described in this user manual.
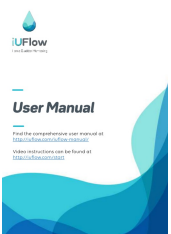
Potential risks of use

3.0v
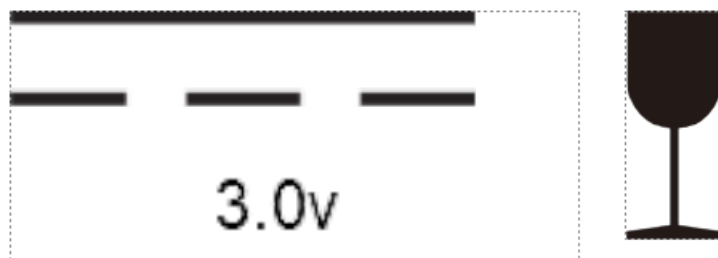
Revision history

Revision	Date of	Change Control	Description of Revision change Number
1.0		N/A	New document
2.0		N/A	First use instructions added.
3.0	27/03/2018	N/A	Updated content as required by TGA, FDA and MDD.
3.1	23/07/2018	N/A	Rearranged the content of the user manual according to some user feedback.
3.2	04/10/2018	N/A	Minor corrections as per recommendations from external audit stage 1.
3.3	09/11/2018	N/A	Minor corrections according to the DHF-003 Traceability Matrix.
4.0	27/02/2019	N/A	Minor corrections to be more compliant with regulatory requirements
5.0	23/01/2020	KHQMS-249	Minor corrections, changes in iUFlow device indicator colours.
5.1	26/05/2020	N/A	Minor corrections
5.2	01/10/2020	N/A	New AER and RP information, updated compatible smart devices list and some other minor corrections.
5.3	23/09/2021	N/A	Minor corrections
5.4	21/01/2022	N/A	Added clarification notes on pages 8 and 11

Controlled Document

Documents / Resources

iUFlow User Manual Find the comprehensive user manual at http://iuflow.com/uflow-manual Video instructions can be found at https://iuflow.com/start	**iUFlow ART-003 Perfect Bladder Tracking Uroflowmetry and Real time Data** [pdf] User Manual ART-003 Perfect Bladder Tracking Uroflowmetry and Real time Data, ART-003, Perfect Bladder Tracking Uroflowmetry and Real time Data, Tracking Uroflowmetry and Real time Data, Real time Data

References

- ^{iUF} **iUFlow- voiding bladder diary on the App Store**
- ^{iUF} **iUFlow**
- ^{iUF} **Start iUFlow - Uroflow - Urine Flow Test @home. A Perfect Flow Diary**
- ^{iUF} **Bladder Diary by iUFlow - Apps on Google Play**

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