

# INSTRUCTIONS FOR USE

**Model name: SU-UFM-001**

**Product name: proudP Urine Flow Tracker**

SHIFU-02 Rev.5.2

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## **1. Introduction**

### **1.1 proudP Urine Flow Tracker**

Urine Flow Tracking can be easily done at home with proudP installed on compatible smartphones. The proudP is a standalone mobile application for tracking urinary health. It is designed to give convenience of measuring voided volume and urine flow rate just by listening to the voiding sound with natural settings at home without any extra device but your smartphone. It uses the microphone in the smartphone to record the sound of voiding and transmits it to the cloud server where our acoustic AI technology analyzes the voiding sound to calculate the results and then send the information back to the app. The analyzed results are saved on the cloud server and can be reviewed on the proudP app of any mobile device you sign into with your proudP account.

This gives you more opportunities to do the urine flow test at home whenever you need to empty your bladder without any additional hardware but the smartphone. No need to struggle with Bluetooth pairing with extra devices on the toilet nor cleaning a device. You avoid the inconvenience and discomfort of having to keep your bladder full while you travel to a urologist to do a conventional urine flow in the physical device at the doctor's office.

The ease of testing and ability of collecting multiple series of reliable data at home using proudP is intended to be auxiliary to the physician's professional judgment for risk assessment and early detection of complications through providing an additional full daily picture of urinary health in natural settings.

proudP is available to anyone who wants to check the speed and volume of urine flow. In addition, if your doctor has a proudP Clinic Account, your uroflowmetry data can be sent to the doctor's proudP Dashboard automatically whenever you conduct the measurement so that the physician can review your data remotely. (You enter the doctor's Clinic Code into proudP to share your data with their account.)

### **1.2 Indication For Use**

proudP Urine Flow Tracker is a mobile application intended for measuring voided volume of urine and urine flow rate using the sound recorded by microphone in mobile devices.

This device can be used for assessment of voiding function. This device can be used at the office or at home, but it must be used in a quiet bathroom environment with minimal ambient noise. This device is intended for patients over 18 years of age.


The analyzed data from proudP is designed to support the clinical decision by healthcare professionals. It is not intended to be a primary diagnosis tool.

proudP is not intended to be, and should not be taken to be, nor do they replace, (I) professional medical advice, screening, diagnosis, or treatment, (II) the practice of medicine, or (III) the provision of medical care. Please do not rely on the results provided by proudP to assess your health; instead, you should consult with your doctors or another qualified healthcare professional in all matters relating to your health.

### 1.3 Description and Features of proudP

#### 1.3.1 Menu symbols in proudP

Symbol	Title	Description
	About	Shows the application software version, UDI, terms of use, privacy policy, intended use, and the manufacturer information.
	Contact Us	Direct message submission to the technical help desk at Soundable Health, Inc.
	Finish	The button to finish recording the voiding sound.
	Glossary	Glossary with regards to urology.
	Home	Displays the latest measurement record.
	How to measure	A set of illustrated user guides describing how to perform measurement with proudP.
	Insights	The history of measurement records provided in the form of voiding diary.
	Menu	Open more options.
	Profile	proudP account information entered do create account, password and passcode set up, and optional personal detail fields to be filled up, such as clinic code, patient ID, height, and weight.
	Sign Out	Sign Out from proudP account.
	Start	The button to start recording the voiding sound to do the measurement.
	Symptom Scores	Provides the menu to take I-PSS, MSHQ-EjD, CPSI, IIEF, or OABSS tests.

	Your Doctor	Optional menu to connect with doctor to update your data on your physician's proudP Dashboard, if and only if the doctor is within proudP network
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### 1.3.2 Features



No.	Part	Function
(1)	Measurement	Initiate measurement
(2)	Home	Check latest measurement records
(3)	Insights	Check previous measurement records
(4)	View	Displays the latest measurement record

(5)	Menu	Provide Profile, Symptom Score Questionnaires, What proudP does, How to measure, Glossary, and Contact Us, option to sign out, and About Us.
(6)	Notifications	Provide notification messages

#### 1.4 User Requirements

The following are required to do measurement with proudP.

- Own any of compatible smartphones enlisted with iOS 11 or later version:  
<https://www.proudP.com/compatible-devices>
- A valid email address for registration and future password management. Registration is available using your Facebook, Google, or Apple account.
- Stable network connection over Wi-Fi or Cellular data network.
- Capability of standing in front of the toilet, in case of male users.
- Have a quiet bathroom at home that the vent fan can be turned off.
- Sitting style flush toilet with water filled up. Urinals in public restrooms are not compatible with proudP.
- Able to find or prepare a spot to place the phone 3 feet from the toilet water, in case of male users.
- Able to understand and follow the instructions to capture the voiding sound.
- Valid clinic code provided by physicians which can be entered through “your doctors” is an option if you want your doctor to remotely monitor your measurement data. If you want to experience this feature but your physician does not have the clinic code or not coming up, please contact us at [support@soundable.health](mailto:support@soundable.health)

## 2. How to use proudP

### 2.1 Download and create proudP account

- Search proudP on the Apple App Store.
- After downloading, open the app and create a proudP account to get started.
- Please note that creating a strong password helps protect your sensitive measurement data. Your password should have at least 8 characters, including at least one lower-case letter, one upper-case letter, one digit, and a special character (i.e., !@#\$%^&\*~\_). This will be only required if you delete the app and install again, or switch to a new phone. Also, you can always reset your password with your email by tapping “Forgot Password”.
- Enter the clinic code if you have one. By entering the clinic code, your measurement records will be automatically showing up on the physician’s proudP Dashboard so that your physician will be able to monitor your data remotely. Please note that this is optional.
- Make sure to give access for using the microphone when you tap START button to record your flow. This allows proudP to capture the voiding sound. Not giving the permission to use a microphone will block you recording the sound of voiding to get the uroflowmetry data.

## 2.2 Measurement Environment

proudP is designed for use at home with natural settings. proudP requires to be used at a quiet environment. proudP works with a sitting style flush toilet filled up with water. proudP is fine tuned to give the best results when the phone is placed properly, and the sound of human voiding is recorded.

### 2.2.1 Find the best bathroom environment

- There is a suitable spot to place the phone 3 feet from the toilet water
- The vent fan can be turned off to remove the noise interference.
- Able to keep the door and window closed to block the everyday noise, such as washer/dryer, furnace, chatter, tap water, TV/Radio and all.
- Sitting style flush toilet installed.
- The toilet is filled up with enough water.

### 2.2.2 Plan and determine where to place the phone

- Make sure the microphone is pointing to the toilet. The microphone is at the bottom side of your phone, the part closer to your mouth when talking over the phone.
- Place the phone 2-3 feet away from the toilet water surface.

**\*Tip: Note that placing the phone too close doesn't help to capture voiding sound.**

## 2.3 How to measure with proudP

You found the quiet bathroom, turned the vent fan off, closed the door, and determined where to place the phone. Now is the time to start recording your urine flow.

Step 1. Find a quiet bathroom with a sitting-style flush toilet filled with water.

Step 2. Limit noise interference: turn off the vent fan, and close the bathroom door to reduce noise from the furnace, laundry, TV/radio, etc.

Step 3. Launch the proudP app.

Step 4. Place the phone 3 feet from the toilet.

Step 5. Position the microphone towards the toilet bowl. The microphone is at the bottom of your phone, near your voice when you talk on the phone. Make sure nothing is between the microphone and the toilet bowl, such as the toilet lid.

Step 6. Push the START button in proudP.

Step 7. Aim at the water, not the side of the bowl.

Step 8. Press the FINISH button *\*before\** flushing the toilet or washing your hands.

Step 9. Then flush the toilet

## 2.4 How to check the measurement records

### 2.4.1 Home

Home tab provides you with the latest measurement record.

- a. After completing measurement, tap on the home tab and move to the home screen.
- b. Home screen shows the latest result of measurement.

- Result of the latest measurement shows flow rate graph, voided volume, maximum flow rate, average flow rate, and voiding time.
- The results of your Symptom Scores are also shown at the bottom. Scroll down to review the history of uroflow measurement or symptom questionnaire scores.

#### 2.4.2 History

The History tab provides you the functionality of exploring the measurement history.

- Tapping on the History tab on the bottom of the screen leads to the History screen.
- History screen shows the results of measurements for today as following
  - Graph of results measured today: graphic representation of voided volume and maximum flow rate measured today.
  - Total times voided and total voided volume measured today.
  - List of Voids Today: shows the list of events (measurement time, maximum flow rate, and voided volume) measured today. Tapping on the event leads to a screen showing detailed results of each event.
- Browse through tabs on the upper part of the screen to view measurements by event, daily, weekly, monthly, yearly.
  - EVENT tab: detailed results of the latest event (uroflow graph, voided volume, maximum flow rate, average flow rate, voiding time)
  - DAY tab: Graphic representation of today's measurements and list of events measured today
  - WEEK tab: Graphic representation of this week's measurements
  - MONTH tab: Graphic representation of this month's measurements
  - YEAR tab: Graphic representation of this year's measurements
- Use '<' or '>' button to move to previous or next event, day, week, month, or year.

#### 2.4.3 Symptom Score Questionnaires

a. Tapping on the top right menu then selecting the Symptom Scores button leads to the "Questionnaires" screen.

- Symptom Scores includes the following internationally standardized questionnaire:
  - IPSS (International Prostate Symptom Score)
  - MSHQ-EjD (Male Sexual Health Questionnaire Ejaculatory Dysfunction Short Form)
  - CPSI (National Institutes of Health Chronic Prostatitis Symptom index)
  - IIEF (International Index of Erectile Function)
  - OABSS (Overactive Bladder Symptom Score)

- c. Tap on the START button to answer the questionnaire you wish to take.
- d. On the shown questions, choose the answer that is pertinent to your most current state of health.
- e. Once the questionnaire is completed, the score will be shown, which is calculated by an internationally standardized method.

### 3. Warnings and Cautions

#### 3.1 Warnings

**DO NOT** use non-compatible devices.

**DO NOT** use it if you are a male and do not have capability to stand while voiding.

**DO NOT** share your proudP account with others.

**DO NOT** hold the phone while measuring with proudP if you are a male. It should be placed 3 feet from the toilet water.

**DO NOT** place the phone behind the toilet lid.

**DO NOT** place the phone at the commode.

**DO NOT** block the microphone while measuring with proudP.

**DO NOT** use if your smartphone hearing aid application is running.

**DO NOT** use if your smartphone Live Listen application is running.

**DO NOT** use a urinal.

**DO NOT** use a urine cup.

**DO NOT** use anything other than the common sitting style flush toilet.

**DO NOT** use a toilet without water.

**DO NOT** use it if the toilet is filled up with toilet paper.

**DO NOT** keep your phone inside your pocket while using proudP.

**DO NOT** change your medication without talking to your doctor.

#### 3.2 Cautions

**Make sure to read the instructions** to know how to keep tracking your urine flow right and find out more you need to know.

**Have a smartphone ready to use proudP**, the mobile application is running on smartphones. It is intended only for people who own a smartphone and are familiar with smartphone applications.

**Check out if your smartphone is working with proudP**. The devices enlisted at the following link are supported. <https://www.proudP.com/compatible-devices>

**To get the best accurate result**, keep hydrated and use proudP whenever it is time to empty the bladder. Keep it in mind to carry your iPhone when heading to the toilet. But no need to get stressed out of forgetting it, just do it another time.

**Keep the Wi-Fi or cellular data network turned on** to receive the analyzed data. Network connection is required to transmit the voiding sound and uroflowmetry data extracted from the sound.

**The performance can be affected by room acoustics**, the distance of the smartphone placement, the direction of its microphone, the type of toilet, and background noises. Please do measurement according to the instructions described in this manual.

**Use proudP on sitting style flush toilets,** urinals at the public restrooms are not working with proudP. DO NOT use urinals with proudP.

**Check out the water level of the toilet.** proudP listens to the voiding sound hitting the water in the toilet. Toilets with low levels of water, or toilets filled up with toilet paper are not working with proudP.

**Follow all instructions included in this manual.** Following the instructions by placing your phone at the right spot and recording the sound of voiding only will give you the best accurate result.

**Be careful not to drop your phone into the toilet.** In the case of male users, holding the phone 3 feet higher from the toilet is not the proper way of measuring with proudP. Place the phone 3 feet from the toilet water.

**Keep the microphone clear.** Best to have your phone near and clear of any obstructions. Keep your phone out of your pocket.

**It is recommended to have your bladder full enough before taking the test to get meaningful maximum flow rate.** This gives the insight of the bladder capacity and maximum flow rate. Since it is not easy to know how much the bladder is filled up, no need to stress out but good to know.

**Testing over 18 years old is recommended.** Effectiveness in children and youth under the age of 18 have not been established.

#### 4. Maintenance

Enable the lock screen feature to protect the data created and stored using this software. And do not share your proudP account with others.

Use the PASS CODE enable & lock feature with proudP App. You can enable this security feature via MENU > Profile > Setup Passcode.

Keep up to date to the latest version of the proudP App.

#### 5. Troubleshooting

Trouble	UI Indicator	Possible reason	Solution
Unable to get readings.	"Results Not Available"	1) There might be background noise that humans cannot recognize but the machine does. 2) The placement of the phone is too close or too far. 3) The microphone is blocked by something. 4) Measurement is not done using a sitting style flush toilet. 5) Voided time is too short to analyze. (less than 5 seconds)	1) Find a quiet bathroom where the everyday noise can be blocked. 2) Place the phone at the right spot as guided. Male, 3 feet away from the toilet. 3) Clear out the microphone. Avoid using BT accessories while testing. 4) Use a sitting style flush toilet with water filled up.

		<p>6) The toilet bowl is filled up with toilet paper.</p> <p>7) Using a non-compatible device.</p> <p>8) Holding the phone while voiding instead of placing it at the right spot.</p> <p>9) Flushed the toilet before tapping the FINISH button.</p> <p>10) No network connection established.</p> <p>11) A hearing aid is connected to your smartphone and in use.</p> <p>12) The Live Listen function is currently turned "on"</p>	<p>5) Feel free to skip testing if voiding ends shortly.</p> <p>6) Flush the toilet. Do it another time.</p> <p>7) Do not use non-compatible devices.</p> <p>8) Male users are suggested to bring in a bar stool or chair to place the phone if there is no suitable spot.</p> <p>9) Flush the toilet after tapping the FINISH button.</p> <p>10) Enable Wi-Fi or cellular data networks.</p> <p>11) Disconnect your hearing aid from your device</p> <p>12) Turn the Live Listen function "off."</p>
Unable to log in.		<p>1) Unstable network</p> <p>2) Wi-Fi or cellular data network disabled.</p> <p>3) Temporary server connection failure.</p>	<p>Enable Wi-Fi or cellular data network.</p> <p>Restart the phone by pressing the volume up key and the power key at the same time for 5 seconds.</p>
Keep displaying "Pending analysis"	"Pending..."	<p>1)Using a non-compatible device</p> <p>2) Unstable network</p> <p>3) Wi-Fi or cellular data network disabled.</p> <p>4) Temporary server connection failure.</p>	<p>Once the network connection stabilizes, the results will be displayed. Make sure the Wi-Fi or cellular data network setting is enabled. Try shutting down the app and launching again or log out and log in again.</p>
Nothing happens by tapping the START button.	"App does not have permission to use the microphone."	<p>Must give permission to use the microphone.</p>	<p>Go to Settings &gt; proudP &gt; Microphone to give the permission</p>
Could not get confirmation code after pressing "Forget password"	No email received.	<p>Signing up with invalid email address will not allow you to receive any email to get confirmation code.</p>	<p>Make sure to sign up using a valid email address.</p>

Any other problems.	The application version differs from that of the installed proudP and the App store one.	1) Not updated to the latest released application. 2) Disabled to receive notification for PRIVY application.	Go to Settings > Notifications > proudP > Enable to allow notifications
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## 6. Specification

Items	Specifications
Range for flow rate	0 to 50 mL/s
Range for voided volume	10 to 1000 mL
Minimum and maximum duration of flow recording	5.5 ~ 180 seconds
Sampling rate	20 Hz

## 7. Glossary

Terms	Descriptions
Average Flow Rate	Average (AVG) rate of urine flow over time
BPH	Benign Prostatic Hyperplasia, as known as enlarged prostate.
Encouraged Max Flow Rate	Normal values of maximum flow rate vary depending on age and sex. In men, urine flow declines with age while women have less change over time. Also, maximum urine flow rate is strongly correlated with voided volume.
Encouraged Voided Volume	150 ~400 ml is the recommended range of voided volume. It may vary and depend on one's functional bladder capacity.
Urine Flow Rate	It is the speed of urine calculated by dividing the volume of the urine by the time duration
I-PSS Score	International Prostate Symptom Score. Set questions about voiding symptoms to understand the severity.
Max Flow Rate	The peak value of urine flow rate over a certain time window.
OABSS Score	Overactive Bladder Symptom Score.
Symptom Score	A questionnaire to understand how bothersome the urinary symptoms are and to monitor how the progress goes.

Uroflowmetry	Uroflowmetry is a diagnostic test used to measure the flow of urine during urination. The speed of urine flow is calculated as milliliters of urine passed per second.
Voided Volume	The total volume expelled via the urethra.
Voiding	To empty your bladder, as known as peeing.
Voiding Diary	A tool used to better understand the incontinence symptoms. It's about tracking and knowing how much and when you have fluid intake, how much and when you urinate, how much and when you feel the urge to urinate, and how much and when you have leakage by journaling that information.
Voiding Time	The total duration of voiding.

## 8. Customer Support

Please contact Soundable Health, Inc. if you need assistance or any proudP related concerns. For more information please visit: <https://www.soundable.health>  
 Technical Help Desk: [support@soundable.health](mailto:support@soundable.health)  
 Direct contact to the help desk via the Contact Us menu from proudP App.

## 9. Revision History

Date	Revision	Reason for Change
07-17-2019	SU-UFM-001 Rev.0	Initial Release
05-18-2021	SU-UFM-001 Rev.1	Updated to reflect UI changes
03-28-2022	SU-UFM-001 Rev.2	Updated to reflect UI, specification changes.
09-30-2022	SU-UFM-001 Rev.3	Minor typo correction, reflect UI enhancement and feature update.
10-06-2022	SU-UFM-001 Rev.4	Minor Typo correction
01-03-2023	SU-UFM-001 Rev.4.1	Updated address of manufacturer
11-01-2023	SU-UFM-001 Rev.4.2	Updated address of distributor
04-09-2024	SU-UFM-001 Rev.4.3	Updated the name of manufacturer
04-11-2024	SU-UFM-001 Rev.5	Updated to reflect graphic UI and logo changes
05-10-2025	SU-UFM-001 Rev.5.1	Minor typo correction
06-10-2026	SU-UFM-001 Rev.5.2	Updated safety information