

iPeeWell Uroflowmeter

INSTRUCTIONS FOR USE

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1. INTENDED USE

The iPeeWell Uroflowmeter (model: IUFM1) is a medical device of the IM class according to the EU MDR, intended for non-invasive **measurement of urine volume, urination time, flows and other** urination parameters.

It **shows the functioning of the lower urinary tract**. The device itself does not make diagnoses. It is intended to detect deviations in the way of urination, which may indicate a possible medical condition and thus warn the user that they can seek medical care in time. It is also helpful in keeping urination diaries.

The medical device is intended for use **by medical personnel in health care institutions** (urologist, uro-gynecologist, family doctor, other medical personnel trained in uroflowmetry) **and/or lay people** (men, women and children under parental supervision) **in the home environment**. With the use and more measurements in the home environment, the interpretation of the results can be more accurate and the treatment more effective when the results are used as an additional tool in diagnostics by urologists and uro-gynecologists. The device is used in the home environment: when the user has problems with urination; when he wants to monitor the condition of the urinary tract during the use of certain medications or after surgery; and for preventive purposes.

The device works together with an application for smart devices (phones, tablets) or PCs, which serves to start and display reports. The companion app is not required for basic safety and essential performance. It is intended exclusively for (indoor) indoor use. Not for implantation or oral use.

The measuring range of the device is up to 1000ml, exceeding the overload limit (the maximum total weight is 1500g – 150%F·S) can permanently damage it if, for example, the collection jug along with the urine is too heavy. During use, it is necessary to pay attention to the warnings of the application and the instructions that users must strictly follow, as improper use endangers the user's safety, data reliability and the operation of the device.

The device itself **does not make a diagnosis, only indirectly indicates the presence and severity of problems with urination**.

⚠ Users should carefully read the instructions for use and all warnings in the manual. Otherwise, patient safety, data security and the usefulness of the data obtained may be compromised.

2. OPERATION

2.1. VARIANTS

The device is intended for professional and lay use. There are two variants. The variant for home use (iPeeWell Uroflowmeter HOME) allows you to display basic parameters (read the chapter on interpreting reports). The variant for professional use (iPeeWell Uroflowmeter PRO) in combination with the desktop application allows you to display all the parameters (described in the chapter on interpretation) and faster use when changing users of uroflowmetry. The mobile application is adapted for use by one user and works with both variants.

⚠ Please read the "Warnings" section carefully and follow the instructions!

2.2. SWITCHING ON/OFF AND POWER SUPPLY

Turn on the device by connecting the power supply that is part of the device to the mains voltage (the technical specifications describe the permissible models). The device does not have a sleep mode – it is always ready for measurement with an active RF receiver/transmitter waiting for commands. Do not use it continuously for a long time (several weeks). After use, turn it off by disconnecting the power. If you close the app, the connection is disconnected, but the device is still working.

2.3. SELECTION OF A COLLECTING JUG

The collection jug must have a flat base and must lie stably on the device. The recommended weight is up to 150g. The recommended jug (not included in the kit) is one that does not pose a risk to the user: stable, sturdy, waterproof, wide at the top, flat below, without sharp edges and easy to clean. The diameter of the upper surface of the device is 12 cm – we recommend a jug with as large a contact surface as possible. The recommended volume is ≥2000 ml to prevent overflow. After the first use with the device, the jug is no longer suitable for other purposes. Follow local hygiene standards and label it accordingly. The jug must not touch the surroundings during the measurement, nor must it be touched by the user (the device measures the weight on it)!

2.4. INSPECTION PRIOR TO (FIRST) USE ⚠

Be sure to inspect the device before use. Check the integrity of the power supply, cable and housing, and the intactness/cleanliness of the gap between the housing sections. Gently remove the protective cover on the underside of the appliance (see section "Storage"). After removal, let the device stand still for a few minutes. Calibrate it if necessary. Never turn the device on/off in less than 15 seconds – it may cause the electronics to malfunction and thus void the warranty. When you plug in the device, the LED light will turn on. The light turns off when the device is ready to work or turn off. In the meantime, the preparation and control of the operation of the device is carried out. If an error occurs, the application notifies the user.

2.5. WIRELESS COMMUNICATION

The device uses Bluetooth BLE 4.2 (frequencies 2,402–2,480 GHz) for data transmission (communication via electromagnetic waves). BLE stands for Bluetooth Low Energy. When transmitting, the amount of energy emitted complies with the regulations, which is ensured by the manufacturer of the microcontroller assembly, Espressif Systems Co., LTD, and the testing performed.

During measurements, communication is minimal, and after measurement, there is a short-term transfer of the measurement data made. If the app is not connected, the device is still emitting RF waves. If the connection is too poor or non-existent, the app will display an appropriate notification on the screen. The application itself also requires access to the internet in order to check for updates and security checks (it does not transmit user's health data).

2.6. DEDICATED SMART DEVICE APP

An app on your mobile device connects to your device. For Bluetooth connection, enable location services (used to locate the device and is not used to track the user). The application is used to connect, manage and display measurements. On mobile devices, it keeps the screen active, so close the app after use to save battery. The application can be found on the manufacturer's website (see section "links").

2.7. DEDICATED DESKTOP APPLICATION

You can connect to the device using a dedicated desktop program that is used to connect, manage, and display measurements. The PC/laptop must have Bluetooth connectivity capability. Some older USB Bluetooth adapters do not recognize or work with the device. In this case, use another newer adapter. The application is located on the manufacturer's website (section "links") and guides you through the installation itself.

2.8. VIGILANCE

Any serious incident that has occurred in relation to a device shall be notified to the manufacturer (info@ipeewell.com) and to the competent authority of the Member State in which the user is established.

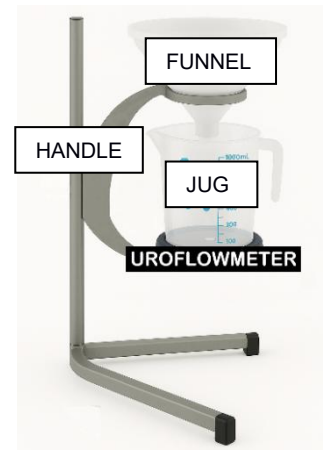
3. HOW TO USE

⚠ Before the first use, be sure to read the section "Inspection before the first use". Calibration is described in the section "Calibration". The device works precisely exclusively on a horizontal base.

Any installation or use error may affect the accuracy of the measurements. Ensure cleanliness, stability and the absence of interference in the environment of the device. Don't miss a single step. Always follow the instructions in the "warnings" section. When the power is turned on, the LED lights up temporarily and goes out after a successful start. **NEVER PAIR THE OPERATING SYSTEM WITH A "FLOWSCALE" DEVICE!** If you do pair, delete it, otherwise the device will not work. The app itself finds the device and connects to it. Read about how the apps work in the relevant sections.

3.1. INSTALLATION / USAGE ENVIRONMENT

For optimal device performance and accurate results, follow these steps. The Uroflowmeter is intended for use in a home healthcare environment and in a professional healthcare facility (clinic/healthcare facility - in the outpatient setting). Avoid environments with RF emitting devices (such as magnetic resonance imaging, chargers, active HF surgical equipment). You can use it in all environments that meet the environmental requirements (environment, temperature, humidity, EMC) and the intended use. Connect it to a stable AC power source. Install the device exclusively on a horizontal, non-slip, non-foamy, clean and dry surface. Do not place it on textile substrates (e.g. clothing, fabrics or toilet covers). The collection jug must have a flat bottom and must lie stably on the device. Keep the device away from magnetic devices, wireless communication devices (cell phones, transmitters), large metal objects, and electrical appliances. The substrate should not vibrate, as vibrations interfere with measurements. Avoid prolonged exposure to UV rays (e.g. sunlight) as they can cause a yellowish tint to the housing. Also, do not expose the device to temperatures higher than those specified in the technical data.



Example of use with or without funnel

It is recommended that the device be used in the bathroom, or more precisely on the toilet, mainly to facilitate the emptying of urine from the collection jug and cleaning after the measurement. In order to maintain the accuracy of the measurements, it is not recommended to use them outside, open spaces or in drafts.

INSTALLATION HEIGHT: the device together with the jug must be at a distance of no more than 20 cm from the urethra outlet. Install so that the liquid does not leak out of the jug and does not bounce off the walls.

ADDITIONAL ENVIRONMENTAL PRECAUTIONS

- Ensure the device is protected from dust/lint (e.g., towels, toilet covers, clothing fibers) and keep the housing gap free of particles.
- Avoid direct sunlight and strong heat sources; do not place the device on heated floors or next to radiators.
- Avoid use in strong drafts (open windows/ventilation outlets) that can disturb the urine stream and affect collection.
- Keep pets, pests, and children away during use and storage to prevent tipping, impact, cable pulling, and contamination.

3.2. MEASUREMENT PROCEDURE

First, place an empty collection jug on the machine. Launch the app that connects to the device on its own. Make sure that the user information is filled in correctly. Wash your hands before measuring. Trigger the measurement via the measure button in the app. During measurement, the LED light on the device lights up. When it goes off, the measurement is downloaded to the application and displayed. Save the measurement. Empty the jug.

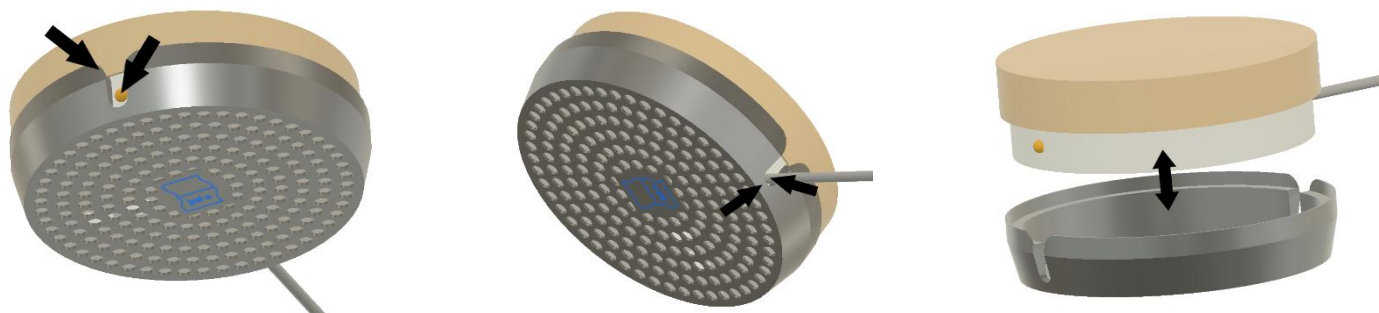
3.3. END OF USE

⚠ After the measurement, it is necessary to disconnect the device from the power source, as long-term power supply shortens its life. After the measurement, it is necessary to remove the collection jug from the device so that the measuring body is not damaged or stretched due to prolonged load. If it is used to manage a mobile application (phone, tablet...), it is necessary to turn off Bluetooth and location services. Storage is described separately. **If following happens: the application is uninstalled, the storage is deleted, the device breaks down or the device is factory reset, all saved reports and settings may be permanently lost, so it is necessary to make regular backups!**

3.4. STORAGE

When storing, be careful to twist the power cord as little as possible and never pull it. Clean your device by following the instructions in the cleaning section. Do not squeeze or weigh down the device, as this may damage the measuring body. Store it in dry rooms on a flat surface, in the dark (avoid UV rays). Temperature conditions for storage are specified in the technical specifications. Once a year, connect the device to the power supply. Read the section on warnings. The device is for indoor use and storage.

The **PROTECTIVE COVER** (Figures 1-3) is located on the underside of the appliance to protect it from being squeezed during transport or storage. The book symbol at the bottom of the lid reminds you to read the instructions and remove the lid before use. Gently remove the lid before use, and gently put it back on before storing.



Figures 3.1-3.3: Protective cover

TEMPERATURE ACCLIMATIZATION BETWEEN USES

If the device has been stored or transported outside the operating temperature range (5-40°C), allow it to reach the operating range and ensure it is completely dry (no condensation) before use. No special warm-up is required beyond the startup self-test; the device is ready when the LED indicates completion of startup (Section 2.4).

3.5. CLEANING

Use minimal to medium disinfection for cleaning. Do not pour liquids on the device. Liquid can penetrate the electronics and destroy it. First, gently remove the dirt mechanically, then clean the device with a damp cloth (<45°C). You can use a non-corrosive cleaning agent (soap). Then wipe the device with a dry cloth and air dry. In a clinical

setting, isopropyl alcohol (maximum 50%) can be used for a short time. The cleaning agent must be removed from the device.

The device is designed for use in a dry environment. Do not expose directly to liquids, steam or jets of water. It is not intended to be cleaned with running water or immersed! The device is not waterproof and is not intended for use near liquids or damp surfaces.

If liquid enters the appliance, switch it off immediately, turn it upside down to drain the liquid and air dry it (facing at a 45° angle). After that, we recommend a service inspection. The device is intended for indoor use. Keep it clean and dry. It is necessary to remove any foreign objects from the gaps (if there are, the device must be recalibrated). Always follow all instructions in the technical specifications and instructions for use.

It is necessary to avoid: strong solvents such as acetone, ammonia, chlorine compounds or hydrogen peroxide (decompose, discolour, deform the device), long-term UV disinfection, autoclaving, exposure to high temperatures (above 50°C), steam sterilization. When cleaning, it is necessary to avoid rubbing too hard and putting pressure on the device due to possible overloading of the measuring body. If the device comes into contact with urine or other liquids, it must be cleaned.

Cleaning frequency and handling between uses

For home use (single patient): After every measurement: empty the jug, rinse it, and clean it according to local hygiene practice. Wipe the device's top surface with a damp cloth and dry it. If any urine or liquid contacts the device: clean immediately as described above and allow to dry completely before the next use or storage.

For professional use / multiple patients: Use a dedicated collection jug per patient (or a disposable/replaceable collection solution as per local hygiene rules). Do not share an uncleaned jug between patients. Contamination with urine: clean and disinfect the external surfaces of the device (wipe method only) and allow to dry before the next patient. If contamination is suspected, use gloves and follow your facility's infection control procedures.

Between uses: store the device clean and dry, with the protective cover installed (Section 3.4).

3.6. WHEN NOT TO USE THE DEVICE / CONTRAINDICATIONS

There are no absolute contraindications. Relative contraindications are: inability to follow the instructions for conducting the examination, insertion of a catheter into the bladder and autonomic dysreflexia. Also note the section on warnings. Do not use the device unless it has been inspected before use and calibrated.

3.7. WHEN TO SEE A DOCTOR?

See a doctor immediately or as soon as possible (regardless of the results shown by the device, always consult a doctor) if:

1. Use the device as recommended by your doctor: If your doctor has advised you to use this uroflowmeter, consult your doctor regularly about the frequency of measurements, interpretation of results, and next steps. Show them the reports generated by the device. Your doctor will give you the best advice on how to use the information in the context of your overall medical condition.

2. Notice deviations from normal values or app alerts: - If the device reports values that deviate from the reference values, or if you receive specific alerts from the device. Even if you're feeling well, it's important to have your doctor evaluate these measurements. - If your measurements are consistently outside the expected reference values, even if the deviations are not large. - If you notice a sudden or significant change in your measurements compared to the previous ones, even if the new values are still within the reference range.

3. You have symptoms, regardless of the measurement results: If you are experiencing any of the following or other symptoms, regardless of what the uroflowmeter measurements show: Pain or burning sensation during urination. More frequent urination than usual. Urgent and sudden feeling of the need to urinate. Difficulty initiating urination or interrupting the flow of urine. Feeling of an incompletely emptied bladder. Weak jet of urine. Blood in the urine. Sudden leakage of urine (incontinence) or worsening of existing incontinence. Fever, chills or back/lower abdominal pain that may indicate a urinary tract infection. Any other new or worrying changes in your urination habits or general well-being.

4. You are unsure or anxious: If you are unsure about the results of the measurements or how to interpret them. If you have any questions or concerns about your urinary health.

Remember: Regular medical checkups are key to staying healthy. This device is a device that can help you keep track, but it is your doctor who can make a diagnosis and prescribe the appropriate treatment.

3.8. CALIBRATION

Procedure is intended for periodic calibration to ensure the accuracy of measurements. It is recommended every 50 measurements or once a month (whichever comes first). Repeat calibration after dropping, squeezing/overloading, getting wet, or otherwise damaging the device (in addition to other necessary additional measures described in these instructions). The device is calibrated during production. Calibration procedure - first prepare the calibration weight (recommended weight 200g or 500g with accuracy according to the OIML M2 standard); Install your device in the

appropriate location (see "Installation") and turn it on and connect to the app. Then, follow the instructions in the "Calibrate" section of the app you're using.

The app will automatically alert you to the necessary calibration after a certain number of measurements. Don't ignore these warnings - calibration maintains accuracy.

3.9. MAINTENANCE PLAN

The device does not have a special maintenance regime. Before each use, follow the instructions in the "inspection before use" section. Periodic calibrations are required (section calibration). It is necessary to take care of following the instructions and warnings. The main concern is the correct storage of the device, proper use with respect to the physical conditions of storage and use. Exposure to UV rays should be avoided. Care for cleanliness.

Birthdate:1960-06-15

Your email:Your email:

User name:Anonymous

Language:English

Male gender☒

I have the device☒

Use ounces (oz)☐

Use speech☐

Use Sign in Form☐

Change Sign in data

Calibration, time and density

Reset

Export PDF

Change consent

Instructions for use

When to visit doctor?

Delete settings

Cancel

OK

Figure 4.2: Settings



Figure 4.3: Basic screen (left and right)

4. INSTALLATION AND USE OF THE MOBILE APPLICATION WITH THE DEVICE

4.1. INSTALLATION OF THE APPLICATION AND FIRST LAUNCH

The app is available for mobile devices. You can install the application from the manufacturer's website (see section "links"). After installation, an application icon will appear on the screen (Figure 4.1).



Figure 4.1: iPeeWell Uroflowmeter app icon

4.1.1. STARTUP, PERMISSIONS AND SETTINGS

When you first launch the app, it will ask you for the permissions listed below, which you need to confirm in order to work. We suggest that you confirm permissions to use "While using the app".

- Using Bluetooth (to connect to the device).
- Access files on a mobile device (to save and open files).
- Access to the microphone or permission to record audio (for voice control of the application - optional).
- Access location or search for nearby devices (to find a device).

If you had Bluetooth turned off before launching the app, you'll see a greeting message on your screen: "Waiting for Bluetooth connection." Turn on Bluetooth in your smart device or the app itself turns it on (depending on the version of the operating system). When Bluetooth is turned on, the operating system offers you pairing or connection to surrounding devices. **DO NOT PAIR THE OPERATING SYSTEM WITH "flowscale"!** If you do this by mistake, you must delete the pairing in the settings of your operating system. Otherwise, the device will not work.

Every time you launch the app, it will ask you for your username and password. The default user name is "u" and the password is "p". You can change them in the settings by clicking on the "Change login details" button. When you lose your password, click on "I forgot my password".

The first time you launch the app, you'll see consents to use. After confirmation, you will be presented with the settings page (figure 4.2). You can also access the settings in a different way by pressing the button in the upper right part of the screen (figure 4.3 - gear).

First, select the appropriate language. Enter your first name, last name and your year of birth. We also recommend that you enter your e-mail, which is used exclusively for occasional notification of promotions/discounts/improvements. If you are a man, confirm this in the menu. Confirm that you have the device. If you want the app to start searching for your device after this

step, you need to close the app and restart it. To use voice control, check "use speech." If you no longer want to use application protection with a username and password, tick "use login form". Please also read the privacy and consent policy information.

- The "calibration and time" button opens the calibration settings (see the calibration section).

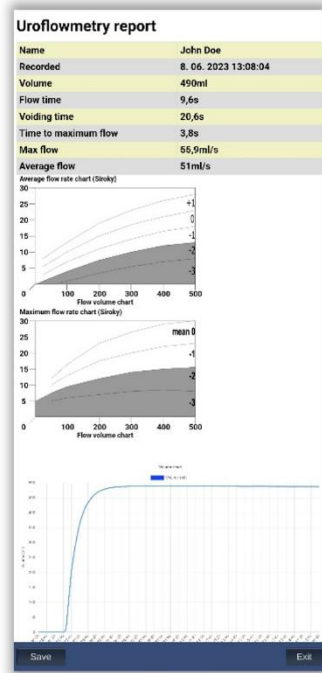


Figure 4.4: Uroflowmetry report

- The "reset" button will send a command to reset the device.

- The "change consent" button will delete your consent to use the app.

- The "export PDF" button will open the file browser with which you select the report and export it as PDF.

- The "instructions for use" button will open a link to the electronic instructions for use in the external browser.

- The "delete settings" button deletes all settings and closes the application. Restarting the app starts with a new consent and settings. The permissions themselves in the operating system can only be revoked in the operating system settings.

4.2. MEASUREMENTS

After each subsequent launch of the application, a text will appear at the bottom of the screen indicating the status of the connection to the device: "Search...", "Connecting...", others, and finally "Ready for action..."

After that, you are greeted by a basic screen that says "start measuring" (figure 4.3 left). If you have selected "use speech" in the application settings, you will be greeted by a screen that says "voice activation" (figure 4.3 on the right).

When the basic screen appears, the appliance is ready. Start the measurement by pressing a button. When using speech, then indicate the beginning ("measure", "start", "začni"). During the measurement, the current measurement step (e.g., "measurement") will be displayed at the bottom of the screen. After urination, the device waits an additional 5-30 seconds (adjustable) to prevent premature termination

of the measurement (section "Waiting after urination").

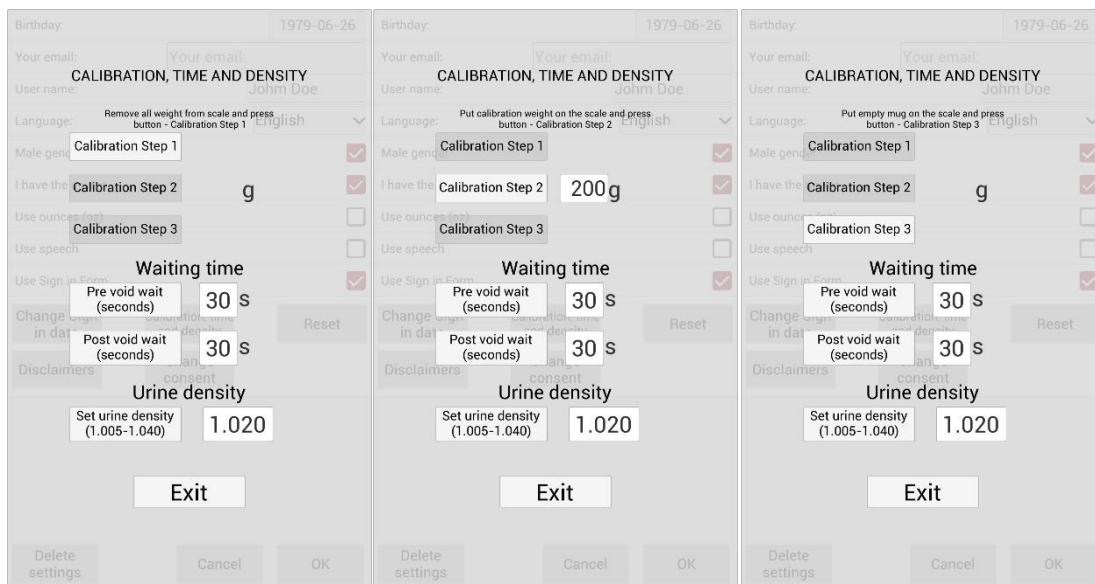
This is followed by the generation and display of the uroflowmetry report (Figure 4.). Here you have the following options:

1. "Exit" closes the measurement report.
2. "Save" saves the measurement to your smart device.

4.3. BUTTONS ON THE HOME SCREEN

On the basic screen (Figure 4.3), the following buttons are located next to the button for performing measurements:

1. **Settings** – a picture of the gear in the upper right corner. More in the "Settings" section.
2. **Read** – read the last measurement from the device's temporary memory. If the device is reset or the power is interrupted, the temporary memory is deleted and such reading fails.
3. **Open** – to open saved records. More in the section "view archive".
4. **Exit** – closes the application. The app does not turn off bluetooth and location when exiting. This can be done manually. Read the "end of use" section.



Figures 4.5-4.7: Calibration – three steps

type in the weight of the weight used (the maximum safe weight allowed by the measuring body is 1000g), then press the button. Wait about 30 seconds, then the third button becomes available - "Calibration Step 3". Remove the weight and install the collection jug on the device. Press. Wait a few seconds. This step completes the calibration.

4.5. SETTING THE TIME TO WAIT FOR URINATION AND THE TIME AFTER URINATION

In the settings menu, press the "Calibration, Time and Density" button. Both settings are located below the calibration (Figures 5-7). They determine the time in seconds (5-30 seconds) that the device waits for the start of urination and the time after the last excreted urine before the device completes the measurement. With each additional urine output, the program counter resets. The recommended time is 10-20 seconds.

4.6. SETTING THE URINE DENSITY

In the settings menu, press the "Calibration, Time and Density" button. Both settings are located below the calibration and time setting (Figures 4.5-4.7). The density of urine is between 1,005-1,040. The default value is 1.020. If you drink a lot, the density is lower. If you're not sure, leave it at the default value.

4.7. VIEWING ARCHIVE

On the home screen, pressing the "open" button opens the file browser – saved uroflowmetry reports. On some devices, three folders appear; the measurements are in the files folder. Select the file and open it. The file names are composed as follows: the number before the underscore represents the sequence number of the measurement in the current day, and after the underscore is the date of the measurement in the format yyyyymmdd (year, month, day). For example, "3_20240131".

5. INSTALLATION AND USE OF THE DESKTOP APPLICATION FOR UROFLOWMETRY

The desktop app is intended for professional users.

INSTALLATION: The program is located on the manufacturer's home page. You can find links to the app in the "links" section. There is also a video on the manufacturer's website, where we guide you through the steps described below. Download the desktop app for your PC. Run the installation file. The application will be installed under "C:\iPeeWellDesktopApp". During installation, select the option to create a shortcut on the desktop.

Allow the app to access the internet (allow it to pass through the firewall), as well as access to the Bluetooth connection. Grant the app administrator rights if the program asks you to. In case of slow performance, disable the antivirus scan of the directory/folder in which the program is installed.

START: Double-click the icon on the desktop. The first launch of the application takes a bit more time, as the application needs to prepare additional files and folders for its operation. It will create a folder "UroflowFiles" on the desktop.

LICENSE: A license form is displayed on the first start. Send us the code from the top row of the pop-up window. All letters are capitalized. Distinguish between zeros and the letters O. Enter the code we send you in the bottom line.

4.4. CALIBRATION, TIME AND DENSITY
In the settings menu, press the "Calibration, time and density" button. Calibration images (Figures 4.5-4.7) will be displayed. Remove all weight from the device, and then press the "Calibration Step 1" button. Wait until the second button becomes available - "Calibration Step 2". Place the weight in the middle of the device,

Confirm by clicking enter.

⚠ The license code is tied to the hardware of the computer. Do not change the composition of the computer!

LOGIN: The login form appears at startup. The default username is "u" and the password is "p". If you wish, check the box on the sign-up form to save your username.

5.1. MENU

Files:

- New: The new measurement clears the form and makes it ready for a new user.
- Open: Allows you to open saved uroflowmetry reports. CTRL+O is a shortcut.
- Save: Save report which is displayed. CTRL+S is a shortcut.
- Make PDF: Saves report as a PDF report file.
- Print: Opens the print dialog. CTRL+P is a shortcut.
- Export CSV: Saves report as a CSV report file.
- Exit: closes the program.

Options:

- Calibration: device calibration menu with settings for waiting time to urinate and time after urination (5-30 seconds). You can also set the use of urine density and its setting. This allows for additional accuracy of measurements. The calibration procedure is the same as for the mobile version of the program (Calibration section).
- Theme: Dark and light.
- Language: The language of the user interface.
- Units: grams or ounces.
- Sound effects: additional sound notifications and effects.
- Speech commands: manage the start of measurements with speech (English only: begin, start, go, measure).
- Join development: allows us to quickly eliminate any errors - it sends performance data to our servers. By default, it's off.
- Logging: Records application usage (»LOG.txt" in the "UroflowFiles" folder on your desktop) in a file. If you have problems with the app, you can send it to us so that we can fix the bugs in the app.
- Sign-in dialog: enables protection against unauthorized insights or data protection. You can change your username and password. If you lose your password, please read our FAQ.
- Reports: Display the baseline and extended spectrum of urination parameters in reports. For advanced users.
- Permanent connection: if connection with the device is lost, the app tries to reconnect.

Help:

- About - about the author.
- EULA / Privacy policy.
- Check for updates – the ability to enable/disable automatic checking for program updates.

5.2. TABS

- UROFLOW: the main tab for your work. Displays individual reports.
- DOCUMENTS: provides access to useful documents for patients and eIFU.
- DONATIONS: describes the benefits of home uroflowmetry and allows for volunteer support.
- ANALYSIS: Displays multiple reports from your disk at the same time for easy comparison.

5.2.1. MAIN TAB – UROFLOW

Patient information. Here you enter the surname and first name of the person being investigated. Choose if it is a male person. Birthday – Must be in the format DD/MM/YYYYY, such as 14/03/1977. The index is the number of the subject on your outpatient records. "Check" – the button checks the validity of the specified data.

All feedback from background processes is displayed at the bottom of the program – the information bar.

"Clear Screen" clears the patient's current health data and clears the measurement from the screen.

To work with the device, you must first connect to it. Click on the link button at the bottom of the "connect". If you don't connect within 15 seconds of clicking, try again. After the connection, additional buttons become available:

"Measure" starts the measurement. If you have enabled voice commands, voice recognition begins when you click the measurement button.

"Read" downloads the last measurement from the device (it is possible until you take a new measurement or turn off the device).

"Save" stores the displayed report to disk.

"Print" prints the displayed report. Reports are saved with the extension ".avif".

"Make PDF" stores the displayed report to disk in a PDF format.

6. WEAK SIGNAL

In case of a poor Bluetooth signal, a notification of a bad signal is displayed (e.g. too much distance to the device, ambient interference). At a distance of up to 10m, a sufficient signal is expected for a good connection. Warnings need to be read.

7. PRIVACY POLICY AND END USER LICENSE CONSENT

Take a look at the links:

- <https://www.ipeewell.com/app-privacy-policy/>

- <https://www.ipeewell.com/eula/>

8. WARNINGS AND PRECAUTIONS!

Precautions in the event of changes in performance

If you notice unusual measurement behaviour (unexpected values, frequent errors, unstable readings, repeated connection loss, or physical damage), take the following actions:

- Stop the measurement, remove the jug, and disconnect the power.
- Inspect the device and power supply for damage, liquid ingress, dirt, or foreign objects in the housing gap.
- Ensure correct installation: horizontal, stable, non-vibrating surface; the jug must not touch surrounding objects; do not touch the device during measurement.
- Move the device away from potential electromagnetic sources and repeat the measurement.
- Perform calibration as described in Section 3.8.
- If the problem persists, stop using the device and contact the manufacturer's service (Section 15).

Precautions regarding reasonably foreseeable environmental conditions

Use the device only within the environmental conditions specified in Section 3.1 and 8. In addition:

- Do not use the device in a wet environment, near splashing water, steam, or aerosols (e.g., next to a shower).
- Protect the device from dust, lint, hair, small particles, and insects; these can enter the housing gap and affect accuracy.
- Avoid direct sunlight and other strong light/heat sources; prolonged UV exposure can discolor the housing and heat can affect performance.
- Keep the device away from pets and children. Prevent pulling of the cable, tipping, impact, or contamination.

Degree of accuracy claimed (measuring function)

The device has a measuring function. The claimed accuracy for volume and flow measurements is stated in Section 12 and applies only when the device is used as instructed (correct installation, within operating conditions, and calibrated).

WARNING: Strangulation/tripping hazard (cables)

Route the power cable to avoid loops and do not leave excess cable length accessible. Keep cables out of reach of children. Do not allow children to play with the cable. Disconnect the device from mains when not in use.

WARNING: Use only specified accessories and materials

Use only the power supply and other accessories/materials specified in these instructions. Use of non-specified accessories, detachable parts, cables, or power supplies can cause improper operation, inaccurate results, increased EMC emissions/decreased immunity, or safety hazards.

WARNING: Do not interconnect with other equipment not described in these instructions

Do not connect this device to other equipment, ports, or systems unless explicitly described in this IFU. Use only the dedicated iPeeWell mobile/desktop applications for communication. Do not use third-party software to control the device.

WARNING: Do not modify the equipment.

Do not open, modify, or repair the device. Any modification or unauthorized repair can lead to inaccurate measurements, electrical hazards, and loss of compliance. Modifications void the warranty.

The user is responsible for the correct use of the device in accordance with the instructions. Instructions which, if not followed, could lead to property damage, serious injury or death to the user or others. The device does NOT make diagnoses and is NOT a substitute for professional medical opinion, examination, or treatment. The report itself is not the only basis for diagnosis or therapy. The information obtained by using this device is for informational purposes only. DO NOT change your treatment or medication schedule based on the measurements of this device without first consulting your physician. The manufacturer shall not be liable for damage resulting from improper use, misinterpretation of information without medical advice, or use contrary to the intended use and warnings. Compliance with the warnings falls within the requirements of the intended use! By following the instructions, the safety and efficiency of the device is taken care of. This includes these warnings and other instructions. When installing and connecting the device, it is necessary to comply with all local laws and regulations. In addition to the warnings and instructions in these instructions, it is also necessary to agree to the privacy policy and end user's licence agreement (present on company's website). The decorative print (optional) on the top of the device is intended solely for aesthetic appearance and does not affect the performance or accuracy of measurements. Print wear does not affect the operation of the machine.

Pay attention to the application's warnings during use!

The device must be protected from moisture, liquids, dust, small particles, dirt, UV radiation, chemical and physical influences! These may destroy the device, which may lead to property damage and/or bodily injury/malfunction. The device must not fall. Despite the absence of visible changes, the fall can cause irreversible internal damages, e.g. of the measuring body. Falls void the warranty. The device is not dust resistant and is not waterproof. Ingress of the substance can cause inaccurate operation and possibly irreversible damage that can endanger the health of the user! The device is a reusable medical device intended for indoor use and is not for military purposes. Careful handling is required, as it is a measuring device. The value of the displayed measurements and the operation are significantly influenced by the regularity and accuracy of the calibration, as well as the loads and the wear and tear of the measuring element. A large number of gears and storage of the device, as well as bending the cable, shortens the service life. Pay special attention to the cord so that you don't get tangled in it or stumble. It is important that the device is on a horizontal, dry, clean, non-slip, solid surface on which the oscillation or vibration of the environment does not affect the device. The device should not be touched during the measurement for the sake of accuracy. The expected accuracy is written in the technical data. We advise caution to avoid property damage or bodily harm, both to yourself and to others. THE MANUFACTURER AND THE SELLER ARE NOT LIABLE FOR ANY MATERIAL DAMAGE AND/OR PERSONAL INJURY! The manufacturer and/or the seller do not assume any liability for damage resulting from unintended or incorrect use.

The use of the applications is at your own risk! The manufacturer is not responsible for any malfunctions of the device on which the application is installed. The same warnings apply to apps that work in conjunction with your device. Internet access is not required for the basic operation of the application (it is only necessary to search for updates, send messages/logs to the manufacturer, access to user manuals).

Like all electronic devices, this device is susceptible to malfunctions from static electricity.

While the LED light on the device is on, the device should not be disconnected from the power supply. Never turn the device on and off the power supply in less than 15 seconds, as this may damage the device's memory, cause irreparable defects and void the warranty.

The device is not resistant to falls - the failure of the measuring body occurs before the failure of the case. Dropping the device will void the warranty. In the chapter "Basics of report interpretation" you will find basic knowledge with which you will be able to interpret reports, as many years of experience are required for proper professional interpretation of reports. If you are unsure, consult your doctor!

Stop using the device if you notice any **damage, deformation, or degradation of the material** (e.g., cracks, broken parts, deviation of the cover or housing), **instability of the device**, unusual sounds, or **abnormal measurement behaviour**. In this case, do not reuse the device and contact the manufacturer's service centre.

Any serious incident that has occurred in relation to a device shall be notified to the manufacturer and to the competent authority of the Member State in which the user is established.

Warnings continue in the next chapter!

9. WARNINGS AND INFORMATION - ELECTROMAGNETIC COMPATIBILITY

The iPeeWell uroflowmeter uses Bluetooth BLE wireless communication. The iPeeWell uroflowmeter complies with IEC 60601-1-2:2014+A1:2020. Emissions: CISPR 11, Group 1, Class B. RF energy is only used for data transmission (indoor operation). Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The listed models are suitable for use in all establishments, including domestic establishments, those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Immunity: In accordance with IEC 60601-1-2 for HOME HEALTHCARE ENVIRONMENT.

For more accurate measurement results and good wireless performance, place the device away from other (electro)magnetic devices (like MRI), wireless communication devices (mobile phones, transmitters), large metal objects and electrical appliances (HF emitting devices, chargers). The essential performance is the correct acquisition and storage of measurement data. During EMC testing, the correct measurement and transmission of the current value at 1Hz within the specified accuracy limits is considered representative of the essential performance.

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 iPeeWell Uroflowmeter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic compatibility - since the key functionality of the device is the correct measurement and calculation of urine volume, flow rates and other uroflowmetry parameters, in case of electromagnetic interference the user can expect: interruption of the Bluetooth connection, delay in data transmission, temporary inoperability of the application or a request to repeat the measurement! If a warning about a poor connection or measurement error appears, repeat the measurement at a less disturbed time and/or also change the environment (increase the distance to or remove RF sources, move the device)! **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. After use, turn off the device and, if necessary, turn off Bluetooth and location services on the mobile device.

Select a stable AC power source (100-240V AC) for the power supply, as unstable voltage may affect the operation of the device. Use only the supplied power supply. Unauthorized repairs will void the warranty. Use of other power supplies may result in malfunction or safety risks. **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. Do not cover the power supply and use device only in a dry environment!

Detailed information on electromagnetic compatibility can be found in the EMC MEASUREMENTS chapter.

Examples of devices/sources that can cause electromagnetic interference

Examples include (not exhaustive):

- Mobile phones and tablets, cordless phones, Bluetooth devices, Wi-Fi routers/access points.
- Two-way radios/walkie-talkies, amateur (ham) radios, nearby base stations or high-power transmitters.
- Microwave ovens, induction cooktops, large motors, switching power supplies/chargers, wireless power transfer (Qi) chargers.
- RFID/NFC readers, anti-theft gates (EAS), metal detectors.
- In clinical environments: MRI systems, diathermy/HF surgical equipment, electrocautery devices.

If interference is suspected, increase separation distance, remove or switch off the source if possible, and repeat the measurement.

10. ERRORS AND FREQUENTLY ASKED QUESTIONS (FAQ)

Visit: www.ipeewell.com/uroflowmeter-faq/ or <https://www.ipeewell.com/ipeewell-uroflowmeter-pogosta-vprasanja/>

10.1. The device does not work!

10.1.1. Check if you have turned on the device.

10.1.2. Check that the power supply is working. Use a stable AC voltage source.

10.1.3. Turn the Uroflowmeter off and on again. Close and restart the app.

10.1.4. In the event of RF interference on other devices, it is desirable to try the following: use the Uroflowmeter device in another location; increase the distance between the equipment and the receiver; consult with a dealer or radio/TV professional.

10.1.5. Read carefully the section on device installation and the section on warnings.

10.2. The proposed measurements do not make sense!

- 10.2.1. Check if you have removed the protective cover ("storage" section).
- 10.2.2. Check that the appliance is correctly installed (base, horizontal, location) and properly calibrated.
- 10.2.3. Check that there are no surrounding interfering factors that interfere with the measurements.
- 10.2.4. Do not touch the device during the measurement.

10.3. The program does not find a device!

- 10.3.1. Make sure you have turned on your device.
- 10.3.2. Check if the smart device itself (without our app active) is already connected/paired with the Uroflowmeter device. Remove the Bluetooth bond in the operating system.
- 10.3.3. Check Power Management Settings (in Windows): USB Power Management: Windows can put USB devices into sleep mode to save power. Disable USB selective disconnect settings: Go to Control Panel → Hardware and Sound → Power Options → Change Plan Settings → Change Advanced Power Settings. Locate the USB settings → USB Selective Interrupt Setting and set it to Disabled.
- 10.3.4. The memory of the Windows operating system may become saturated, and the bluetooth module begins to work incorrectly. Restart your computer.
- 10.3.5. Certain bluetooth modules are not able to connect to the iPeeWell Uroflowmeter. If your module reports the RSSI value as a positive number, it will most likely not work with a uroflowmeter. Try to swap/exclude it and use another one.

10.4. The device has changed color!

- 10.4.1. Due to the properties of the housing material, it changes colour slightly when exposed to UV rays. It's a natural phenomenon. Discoloration is best known in the white case, which can turn yellow.

10.5. Invalid measurement

- 10.5.1. If the measurement is very short, the program will indicate that the measurement is invalid. If you still want to show or see it, increase the waiting time after micturition.
- 10.5.2. If the flow is very poor (<3 ml/s), the device will not correctly detect the onset of urination and will report an invalid measurement.
- 10.5.3. Switch off the appliance for 15 seconds.
- 10.5.4. If both did not work, perform calibration.

10.6. I forgot my login username and password

- 10.6.1. Click on the forgotten username or password button on the sign-in box.
- 10.6.2. Or send an email to support@ipeewell.com with the subject "UROFLOW APP PASSWORD RESET" and tell us your license code in the text and attach the file "iPeeWell.doo", which is located in the "UroflowFiles" (desktop) or "Files" (mobile devices) folder.

10.7. The device has fallen into the toilet

- 10.7.1. Read the section on cleaning.

10.8. Measurements are made under the wrong name or under another person

- 10.8.1. If the measurement is still on the device, correct the user's name and click read. Save.
- 10.8.2. If the first solution does not work, open the file, correct the username and click save. Delete the wrong file.

10.9. Certain functions in the mobile application do not work

- 10.9.1. The mobile application requires permissions to operate: file access, location, bluetooth, microphone. New versions of Android only ask for permission once. If you denied permissions on the first launch, you need to change the permissions using the operating system itself or uninstall the application and reinstall it.

10.10. I have a question that is not here

- 10.10.1. Visit the link above where we record all the questions of our users.

ERROR

The device controls its operation. Applications report errors to the user. These are:

ERROR 1: The data is still being processed after the measurement was made and is not ready to be transferred. The request must be repeated.

ERROR 2: This error may occur if the power supply is faulty or insufficient, if the load cell or the wire connection to it has failed, and if the analogue-to-digital converter has malfunctioned. In this case, first change the power outlet. If the error still occurs, the device will need to be serviced.

ERROR 3: No measurement data. This occurs when there is a processing and transmission request, but no new measurement data is present.

ERROR 4: The reported weight is over the limit. A data transfer error has occurred. The data transfer request must be repeated.

ERROR 5: The measured weight is over the limit. There was an overload! The device will no longer work properly! It is necessary to have the device serviced or buy a new one!

LED SIGNALING

When switched on, the LED light will turn on transiently and turn off when the device is ready to measure. Constantly lights up during measurement.

11. BASICS OF REPORT INTERPRETATION AND COMMON CURVES

With the knowledge given below, you will be able to interpret the reports in an indicative way. "Indicative" because the correct professional interpretation of reports requires many years of experience. In case of uncertainty, consult your urologist! You can get more uroflowmetry knowledge on our website. With a sufficient number of applicants, our company also provides workshops on reading uroflowmetry results.

Basic parameters:

- **Gender** - the most important parameter! Women have short urethra and no prostate. The nomograms shown are for men (warning shown)!
- **V or Vvoid** - Volume (ml) - the total amount of excreted urine collected in the measuring device during the measurement.
- **Artefacts** - These occur when you touch a collection jug or uroflowmeter during measurement. This spoils the measurement.
- **Interruptions** - information about interruptions during urination.
- **Curve shape** - interrupting, waving, bell-shaped or with a plateau.
- **Description** of the shape of the curve, flows, and the presence of interruptions and artifacts.

Extended parameters:

- **Age** - a very important parameter, as age has a great influence on flows (especially in men)
- **Qave or Qavg** - Average flow rate (ml/s) - This is the average of the total flow during the time of urination.
- **Qmax** - Maximum flow rate (ml/s) - Maximum flow rate achieved during urination.
- **T100 or Tvoid** - Time of urination (seconds) - The time it takes a person to urinate. This includes the time of the intermediate interruptions of the stream.
- **Tflow** - Flow time (seconds) - the time spent between the onset of the stream and the end of the stream.
- **TQmax** - Time to maximum flow - the time from the occurrence of the stream to the maximum flow. It's normally $<1/3$ Tvoid.
- **Hesitation time** (seconds) - the time between the decision to urinate and the appearance of the stream.
- **Interval time** (seconds) - the total time during urination when there is no stream. The difference between Tvoid and Tflow. These interruptions are normally absent or few, so Tvoid is almost equal to Tflow.
- **VT10** - Volume at 10% of the time of urination (ml) - the time that shows the strength of the bladder and the patency of the lower urinary tract.
- **VT50** - Volume at 50% of the time of urination (ml) - the time that shows the strength of the bladder and the patency of the lower urinary tract. Normal $>50\%$ Vvoid.
- **Qr ratio** - the ratio between Qave and Qmax. A high ratio is present in prolonged and/or obstructive urination. Maximum 1.
- **TQ ratio** - the time-flow ratio between Tvoid and Qmax (s^2/ml). A high ratio is present in prolonged and/or obstructive urination.
- **DTAT ratio** - the ratio of time to Qmax and time after Qmax. A delayed peak indicates an altered function of the bladder and/or bladder neck.
- **Duration of Qmax** or duration of plateau (s) - the time of persistence of stream power at Qmax.
- **Time after TQmax** (seconds) - The time after reaching the maximum flow to the end of urination.
- **Waviness** - information about the presence of waviness of the curve.

High or prolonged Qr, TQ and Qmax insistence time speak for the presence of a plateau. Meanwhile, the short Qr, TQ, and mean DTAT speak in favor of the presence of a bell curve.

Approximate normal average values of **Qave urine flows by age:**

4-7 years: is 10ml/s

8-13 years: boys 12ml/s, girls 15ml/s

14-45 years: men 21ml/s, women 18ml/s

46-65 years: men 12ml/s, women 18ml/s

66-80 years: men 9ml/s, women 18ml/s

Conditions that must be met for the evaluation of uroflowmetry: at least 150ml of urine excreted, no artifacts, no jet circulation!

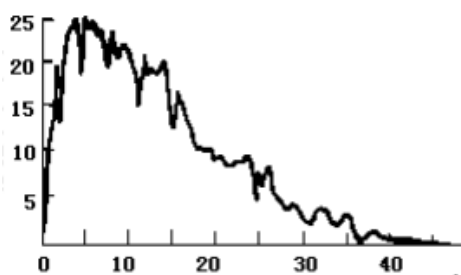
Obstruction is a term for obstacle. If the Qmax is >20ml/s, there is very likely no obstruction. At flows between 15-20 ml/s, there is a low probability of the presence of obstruction, but the clinical picture should be taken into account. At flows between 10-15ml/s, the presence of obstruction is suspected. However, at <10ml/s flows, the obstruction is usually severe. It can be a malfunction of bladder contractions or a poor contraction of the bladder. The bladder could have been underfilled. At a flow rate of <10ml/s, 70% is specific to be an obstruction of bladder outflow. The tests need to be repeated several times.

Diseases in which **flows are low**: neurogenic bladder, spinal cord defects, diabetes, larger bladder tumor, narrowing of the bladder neck, advanced prostate cancer, narrowing of the urethra, urine leakage, inflammation of the bladder and others.

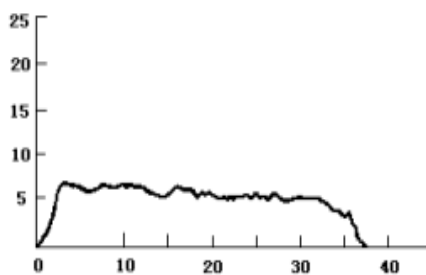
Drugs with a greater impact on results: anticholinergics, alpha blockers, drugs for reducing the prostate, drugs with an effect on nerves...

Typical flow curve layouts:

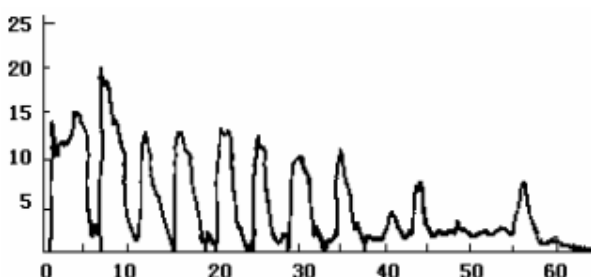
Normal Curve (Good Flow, Fast Peak):



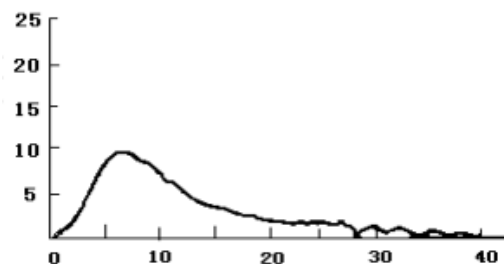
Obstructive curve (e.g. narrowing of the urethra) (plateau):



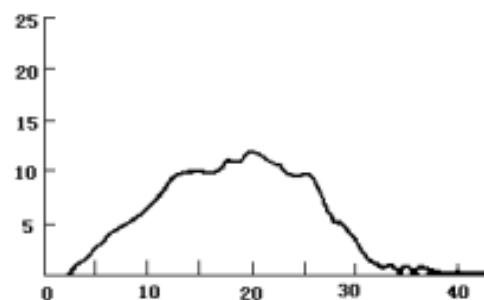
Spinal cord defect (wavy curve):



Elongated and obstructive curve (e.g. enlarged prostate) (lower, elongated curve):



Change in the muscles of the bladder, neck of the bladder (delayed peak):



12. UROFLOWMETER SPECIFICATIONS AND REQUIREMENTS

The device is made of state-of-the-art semiconductor elements and is manufactured in accordance with EU regulations and standards. It is a reusable medical device intended for indoor use.

The device is designed in accordance with ICS standards.

Degree of accuracy claimed (measuring function)

Flowrate and Volume accuracy: $\leq 1\%$

Accuracy is valid only when used on a horizontal, stable surface, within the operating environmental conditions, and after calibration as described.

Other specifications:

Model: IUFM1

Analog-to-digital conversion: 24-bit 10Hz

Recording the minimum flow rate: $\leq 0.1\text{ml/s}$

Flow range: 0-50ml/s

Volume range: 0 - 1000ml (0 – 33.8 oz.).

Overload limit: 1500g (150% F·S).

Measurement time: 0-10 minutes (Time to wait for the start/end of urination 5-30 s)

Ingress protection (IP code): IP21

Device classification (IEC 60601-1): protection class: Class II; Applied part: none.

Power supply: 5V/0.5A. Only prescribed power supplies may be used.

External dimensions (ΦxH): 120x37mm without power cord and power supply

Casing: Biodegradable 3D printed PLA/PLA+ (polylactic acid)

Communication: Bluetooth LE[®] 2402-2480MHz 5,29dBm, PCB antenna 3,26dBm, standard 4.2

Environment: for indoor use; not for use in water

Operating temperature: 5 - 40°C (41-104°F)

Storage and transport temperature: -25°C - +50°C (-13-122°F)

Humidity (operation, storage, transport): 10-90%, no condensation

Pressure (operation, storage, transport): 70kPa - 106kPa

Color: basic white. Printable top area of the device: $\Phi \leq 120\text{mm}$.

The weight of the entire device: 182g(device) + 108g(power supply) = 290g

Soldering electronics: lead-free.

Expected service life

Expected service life: 5 years under normal use and maintenance as described in this IFU. Service life can be shortened by overloads, drops/impact, liquid ingress, exposure to extreme temperatures, and repeated bending/twisting of the power cable.

Prescribed/Permitted Power Adapters:

Manufacturer Friwo, series models FOX6-XM, input: 100-240V~, 50/60Hz, output: 5V= at least 1A, with IPX2 Fox adapter, compliance: IEC/EN 60601-1, IEC/EN 60601-1-11 (2×MOPP).

Minimum hardware and software requirements of the PC application:

- Dual-core processor at least 2.3 GHz
- 4 GB RAM; 1 GB hard drive/SSD
- Operating system (minimum): Windows 10/11 (.NET 8 or newer back compatible)
- Bluetooth BLE 4.2 or newer back compatible
- Internet access (app updates, communication with the manufacturer, electronic instructions for use)
- Screen resolution 1920 x 1080; DPI setting to 100%

Minimum hardware and software requirements of the smartphone / tablet mobile application:

- Quad-core processor at least 2GHz
- 2 GB RAM; 200 MB flash
- Operating system: Android 12 (API 31), Apple iOS 16 (all .NET 8 or newer)

- Bluetooth BLE 4.2 or newer back compatible
- Internet access (updates, recording application crashes, communication with the manufacturer, electronic instructions for use)
- Screen resolution 720 x 1280
- the application must be allowed to operate: access to the Internet, Bluetooth, storage, location, microphone (voice control)

13. WASTE DISPOSAL



Packaging is disposed of among the waste, separately by type of material. Cardboard and cardboard are disposed of as waste paper, and foils as secondary raw materials. (The following applies in the EU and countries with separate collection of secondary raw materials.) Waste devices must not be disposed of as household waste! Every consumer is legally obliged to dispose of old devices in a collection for electronic devices / for further professional recycling and thus prevent negative impacts on the environment.

Potentially biohazardous parts and accessories

Parts and accessories that may be contaminated with urine (e.g., the collection jug and any items used to handle/clean it) shall be treated as potentially biohazardous and disposed of according to local regulations. Lay users must contact their local authorities to determine the proper method of disposal of potentially biohazardous parts/accessories, as applicable.

14. WARRANTY LIMITATIONS

iPeeWell d.o.o. offers a limited warranty for the device for one year from the date of purchase. In the case of an over-the-counter purchase, it is necessary to attach proof of purchase when claiming the warranty. The warranty can only be claimed by the original or primary purchaser. The warranty is not transferable to subsequent purchasers or owners. The warranty covers defects in materials and/or workmanship of the device. The warranty does not cover defects, deterioration or damage resulting from alteration, improper or unreasonable use or maintenance, use outside of intended use, failure to follow instructions, abuse, accident, neglect, exposure to excessive humidity, temperature, pressure, fire, lightning, voltage surges or other natural phenomena. The Limited Warranty does not cover damage, deterioration or damage as a result of installation, any unauthorized tampering with the product, any repair by an unauthorized person, or other causes unrelated to the defect in the materials used and/or the workmanship of the device. Without limiting the exclusion conditions set forth herein, iPeeWell d.o.o. does not warrant that the device, including and without limitation the technology or electronic components of the device, will not become obsolete or maintain compatibility with other products or technique/technology that may be used with the device. The company iPeeWell d.o.o. can repair or replace the product according to its own assessment.

15. LINKS AND ADDITIONAL INFORMATION



Website: <https://www.ipeewell.com/>

FAQ: <https://www.ipeewell.com/uflowmeter-faq/>

Windows App: <https://www.ipeewell.com/uflow/desktopapp/>

Mobile App: <https://www.ipeewell.com/uflow/mobileapp/>

eIFU: <https://www.ipeewell.com/documents/>

E-mail: support@ipeewell.com



16. MANUFACTURER AND SERVICE

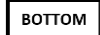
Production and service facilities are located at the company's headquarters. Consultation regarding the service is possible via e-mail servis@ipeewell.com. Service is recommended when there is a malfunction of the device (FAQ - errors), liquid ingress or other unforeseen use or deviations.

iPeeWell d.o.o., SERVICE, Celovška 14, 3000 Celje, Slovenia

17. DOCUMENT VERSION

- Version 1/20251010: First version. Slovenian and English languages.
- Version 2/20260110: Additional warnings. For ISO60601 adapted use environment. Added IFU precautions (performance change/environment), additional WARNING statements, cleaning between uses, expected service life, EMC interference sources, and biohazard disposal guidance. First edition in French.

18. EXPLANATION OF THE SYMBOLS USED

	Conformity symbol CE / Declaration of conformity according to the applicable European directives
	Reference, product name
	Serial number
	Name and address of the manufacturer
	Date of production of medical device.
	This product is subject to WEEE directive 2002/96/EC. Contact your local authority for information about disposal and recycling. Parts need to be disposed separately.
	Operating temperature: 5 - 40°C (41-104°F). Storage and transport temperature: -25°C – +50°C (-13-122°F).
	Humidity (operation, storage, transport): 10-90%, no condensation.
	Pressure (operation, storage, transport): 70kPa – 106kPa.
	Special storage/handling conditions: keep dry.
	Indicates the authorized representative in the European Community/ European Union: name and address.
	Fragile, handle with care. Indicates a medical device that can be broken or damaged if not handled carefully.
	Consult instructions for use or consult electronic instructions for use.
	Caution.
	Website where patient can obtain additional information.
	Medical device
	Unique device identifier
	Our symbol: This marks the bottom of the device.
OPERATION	Our symbol: Conditions to be met for operation.
STORAGE & TRANSPORT	Our symbol: Conditions to meet for storage and transport of the device.

19. EMC MEASUREMENTS

The iPeeWell uroflowmeter model IUFM1 is intended for use in the electromagnetic environment specified below. The customer or the user of the model should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The listed model use 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 B	The listed model is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

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

Enclosure Port			
Immunity test	Test Condition	IEC 60601 Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 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%.
Radiated RF EM fields and Proximity fields from RF wireless communications equipment IEC 61000-4-3	10 V/m; 80 MHz – 2,7 GHz; 80% AM 1kHz	10 V/m	Mains power quality should be that of a typical HOME healthcare environment.
	385 MHz (18 Hz PM); 27 V/m	27 V/m	
	450 MHz (FM +/-5 kHz deviation 1 kHz sine); 28 V/m	28 V/m	
	710 MHz (217 Hz PM); 9 V/m	9 V/m	
	745 MHz (217 Hz PM); 9 V/m	9 V/m	
	780 MHz (217 Hz PM); 9 V/m	9 V/m	
	810 MHz (18 Hz PM); 28 V/m	28 V/m	
	870 MHz (18 Hz PM); 28 V/m	28 V/m	
	930 MHz (18 Hz PM); 28 V/m	28 V/m	
	1720 MHz (217 Hz PM); 28 V/m	28 V/m	
	1845 MHz (217 Hz PM); 28 V/m	28 V/m	
	1970 MHz (217 Hz PM); 28 V/m	28 V/m	
	2450 MHz (217 Hz PM); 28 V/m	28 V/m	
	5240 MHz (217 Hz PM); 9 V/m	9 V/m	
	5500 MHz (217 Hz PM); 9 V/m	9 V/m	
	5785 MHz (217 Hz PM); 9 V/m	9 V/m	
RATED power frequency magnetic fields IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a HOME healthcare environment.

Proximity magnetic fields IEC 61000-4-39	30 kHz; CW; 8 A/m	8 A/m	RFID, WPT, and similar equipment should not be used closer than the recommended separation distance of 15 cm from any part of the device, including cables.
	134,2 kHz; PM 2,1 kHz; 65 A/m	65 A/m	
	13,56 MHz; PM 50 kHz; 7,5 A/m	7,5 A/m	

The listed model is intended for use in the electromagnetic environment specified below. The customer or the user of the listed model should ensure that it is used in such an environment.			
Input a.c. power PORT			
Immunity test	Test Condition	IEC 60601 Compliance level	Electromagnetic environment - guidance
Electrical fast transient/bursts IEC 61000-4-4	± 2 kV 100kHz Repetition frequency	± 2 kV	Mains power quality should be that of a typical HOME healthcare environment.
Surges IEC 61000-4-5	± 0,5 kV, ±1 kV; Line-to-line	± 0,5 kV, ±1 kV	Mains power quality should be that of a typical HOME healthcare environment.
Conducted RF induced by RF fields IEC 61000-4-6	3 Vrms in 150 kHz - 80 MHz 6 Vrms in ISM and Amateur Radio Bands b) 80% AM 1kHz	3 Vrms in 150 kHz - 80 MHz 6 Vrms in ISM and Amateur Radio Bands	Mains power quality should be that of a typical HOME healthcare environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U _T ; 0°,45°,90°,135°,180°,225°,270°,315° 0% U _T ; 0° 0% U _T ; 70% 0% U _T ; 0%	0,5 Cycles 1 Cycle 25/30 Cycles (50/60Hz) 250/300 Cycles (50/60Hz)	Mains power quality should be that of a typical HOME healthcare environment. If the user of the listed models requires continued operation during power mains interruptions, it is recommended that the above listed model is powered from an uninterruptible power supply.
Comment: a) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS. b) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.			

The listed model is intended for use in the electromagnetic environment specified below. The customer or the user of the listed model should ensure that it is used in such an environment.			
Signal input/output parts PORT			
Immunity test	Test Condition	IEC 60601 Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 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/bursts IEC 610004-4 (a)	± 1 kV 100 kHz Repetition frequency	N/A	Mains power quality should be that of a typical HOME healthcare environment.

Surges IEC 61000-4-5 (b)	±2 kV Line-to-ground	N/A	Mains power quality should be that of a typical HOME healthcare environment.
Conducted RF induced by RF fields IEC 61000-4-6 (d)	3 Vrms in 150 kHz - 80 MHz 6 Vrms in ISM and Amateur Radio Bands c) 80% AM 1kHz	3 Vrms in 150 kHz - 80 MHz 6 Vrms in ISM and Amateur Radio Bands	Mains power quality should be that of a typical HOME healthcare environment.
Comment: a) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded. b) This test applies only to output lines intended to connect directly to outdoor cables. c) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz. d) SIP/SOPS whose maximum cable length is less than 1 m are excluded.			

20. WARRANTY CARD

iPeeWell Uroflowmeter warranty card

device type: iPeeWell Uroflowmeter,
model: IUFM1,
Warranty period: 12 months

Warranty statement

We declare:

That the product will work flawlessly during the warranty period if you follow the instructions provided. To provide service maintenance and necessary spare parts for the product during the warranty period. That during the warranty period, we will ensure that defects and deficiencies are eliminated at our own expense within a period that will not exceed 45 days. A product that is not repaired within the specified period will be replaced with a new one at your request. To claim the warranty, it is necessary to attach an invoice with information about the buyer (name and surname, street and number, postal code and city, country, telephone, e-mail) and a description of the defect.

The warranty is valid from the day of purchase of the product, which you prove with an invoice.

The warranty expires if it has been established that the previous repair was carried out by an unauthorized person. That is, if non-original parts were installed. The warranty does not apply to mechanical damage and malfunctions resulting from improper connection or improper use. The warranty does not apply if the limitations of the warranty are not observed, which are written in the instructions for use.

Find attached EU declaration of conformity.

Manufacturer/name and address: iPeeWell d.o.o., Celovška 14, 3000 Celje, Slovenia

Authorized representative/name and address: /

We declare with full responsibility that:

Product: iPeeWell Uroflowmeter _____

Type/model: IUFM1

Serial number: _____

Complies with provisions of low voltage devices.

RoHS: 2011/65/EU

Safety: IEC 60601-1, IEC 60601-1-11, EN 60068-2-27, EN 60068-2-64, IEC/EN 60529

Health: (EU) 2017/745 (MDR)

EMC IEC/EN 60601-1-2, EN 301 489-1 V2.2.3, EN 301 489-17 V3.2.4

Radio: EN 300 328 V2.2.2, 2014/53/EU RED

Use: 2012/19/EU WEEE, EN ISO 15223-1

Place and date of issuer name, surname and signature of authorized person:

Rok Rodič, director

Celje, 23.3.2026; iPeeWell d.o.o.



iPeeWell d.o.o.
Celovška 14, 3000 Celje,
Slovenia



iPeeWell UROFLOWMETER® -
INSTALLATION AND USE
INSTRUCTIONS