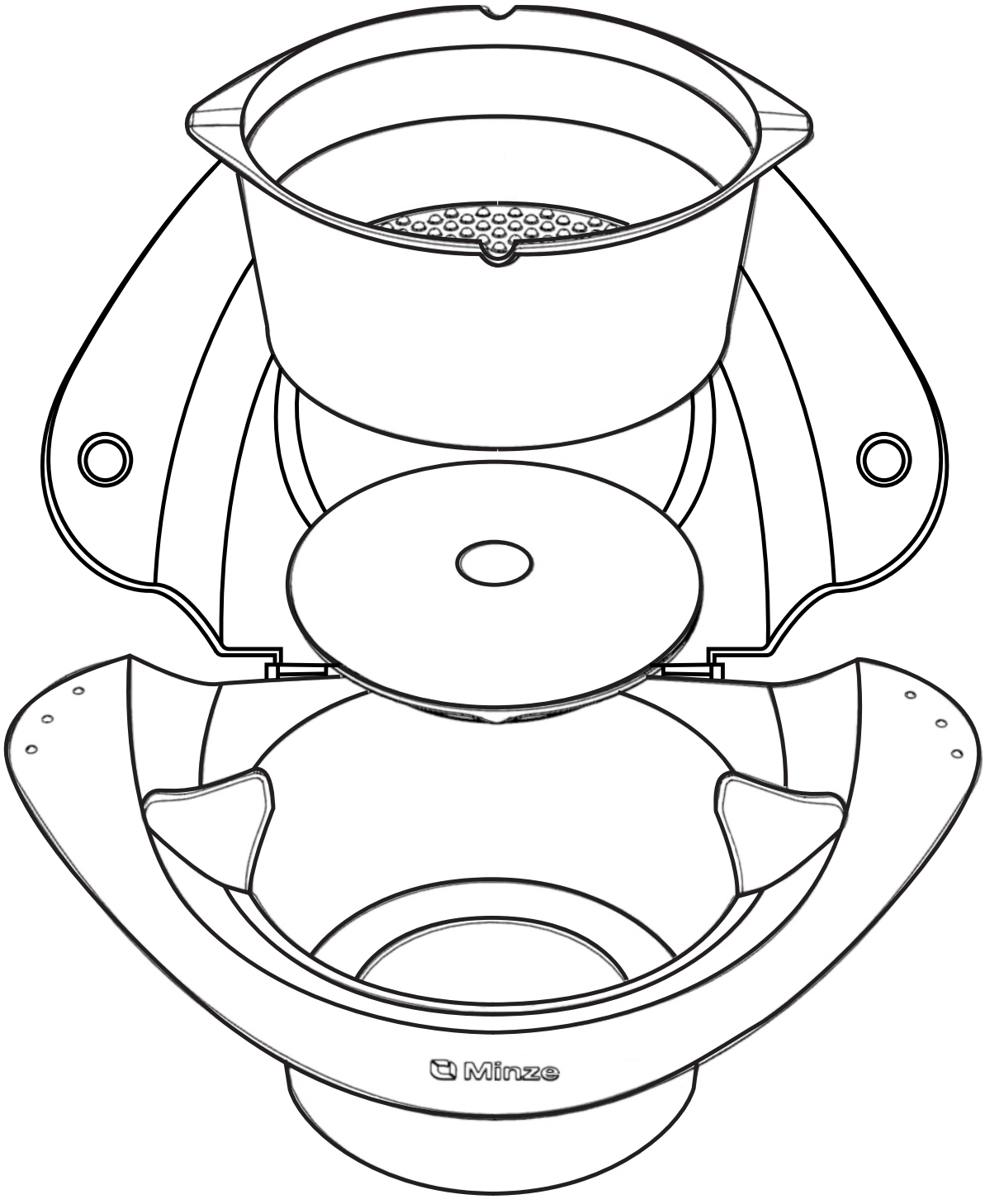
MINZE UROFLOW

v4 EN / August 2020

Installation and Operating Instructions
Read this manual before use



Minze
health at home

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1 / INTRODUCTION TO MINZE UROFLOW

1.1 / INTENDED USE

Minze Uroflow is a system intended to help a patient maintain a digital voiding diary and capture his uroflow curves without professional supervision (e.g. at their own home) or with professional supervision (e.g. in a conventional setting at a hospital). The measurements will be used by the clinician during diagnosis and treatment and for long-term monitoring for children (potty-aged) and adults (female and male) suffering from voiding disorders.

Minze Uroflow does not diagnose or recommend treatment. The collected and presented data will aid the clinician in making a diagnosis or providing treatment.

1.2 / INTENDED USER PROFILES

Minze Uroflow is intended to be used by professional users and lay users.

Professional user
The professional users are clinicians and assistants. Clinicians should have a medical degree and experience in the diagnosis, monitoring and treatment of patients with urologic conditions using uroflowmetry and voiding diaries. Assistants should have a medical certification or nursing degree and experience in the operational process of diagnosis, monitoring and treatment of patients with urologic conditions using uroflowmetry and voiding diaries: manipulating, collecting data, cleaning, etc.
All professional users must read this manual prior to using the system. Failure to comply with these instructions for use may compromise the performance of the device.

Lay user
The lay users are adult and paediatric (potty-trained) patients suffering from lower urinary tract symptoms; and caregivers. Adult patients and caregivers supervising a (paediatric) patient should have received and read the patient manual prior to using the system. Failure to comply with these instructions for use may compromise the performance of the device.

The images in this manual are used for explanatory purposes. Your product version may differ from these images, due to updates. However, functionalities are the same. You can find the latest updates and more detailed information/ instructions on www.minzehealth.com.

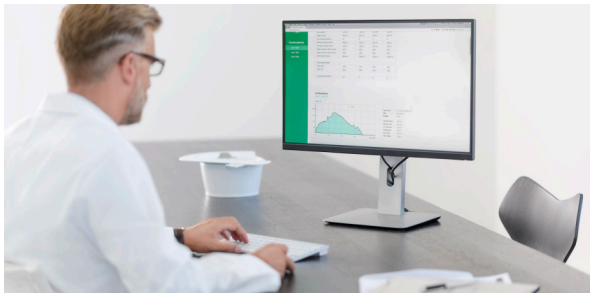
1.3 / OVERVIEW

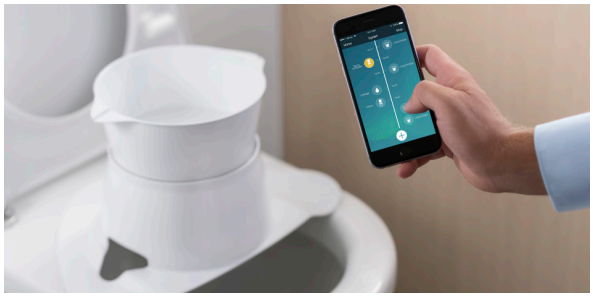
Hospiflow

Minze Hospiflow is a combination of a uroflowmeter with accessories, a hospital mobile application and an online portal. A clinician can investigate the lower urinary tract system of a patient by using the uroflowmeter and accessories – a peehat and cup – in the hospital. The hospital app makes it possible to manage the different uroflowmeters in use in the hospital (connection status, battery level, etc.). The uroflowmetry data then gets sent to the online portal, where it can be linked to the correct patient to consult the data.

Homeflow

Minze Homeflow is a combination of a uroflowmeter with accessories, a patient mobile application and an online portal. A clinician can prescribe the uroflowmeter and accessories – a peehat and cup – to a patient to use it at home in order to receive more information about his/her lower urinary tract system. The patient has to answer some questions in the app with every void registered like urge, incontinence and liquid intake. This way the patient app makes it possible to link uroflowmetry data to voiding diary data. The data is then send to the online portal, where the clinician can remotely consult the patient's data.





Online clinician portal (left); Minze uroflowmeter with accessories on a normal toilet and Minze Flow app (right).

1.4 / SYSTEM DESCRIPTION

The Minze Uroflow uses Bluetooth Low Energy (BLE) technology and internet connection (Wi-Fi or mobile telecommunication, e.g. 3G, 4G, ...) to wirelessly send data from the uroflowmeter (through BLE) to the Minze Flow application and from there to the online clinician portal (through an internet connection). The operating system on the smartphone or tablet that runs the Minze flow app can either be iOS or Android.

The Minze uroflowmeter uses weight transducer technology (load cell) to measure volume and calculate flowrate over time. It also contains a presence detection sensor, allowing it to automatically go from stand-by modus to awake modus whenever a user comes near or grabs it. Next to that it contains an accelerometer sensor to detect excessive movement or a drop during use. Lastly it uses Near Field Communication (NFC) to perform patient authentication. The cup contains a NFC tag, which can be read out by NFC reader inside the uroflowmeter.

Minze uroflowmeter (left); NFC-tag on the bottom of the cup (middle); NFC reader inside the uroflowmeter (right)

1.5 / BOX CONTENTS

There are two types of Minze Flow delivery boxes: the **full set box** and the **single patient cups box**. There is also a **box that needs to be prepared for the patient in case of a Homeflow assessment.**

***Full set box** (all parts are reusable)*

1 x Uroflowmeter (with 4 AA Alkaline batteries inside)

1 x Minze Peehat

1 x Shield

1 x Minze Hospiflow cup (white)

1 x Minze Uroflow - Installation and Operating Instructions

1 x Minze Homeflow - Patient Manual

Single patient cups box

24 x Minze Homeflow cups (transparent)

x 24

Box to prepare for the patient (in case of a Homeflow assessment)

1 x Uroflowmeter (with 4 AA Alkaline batteries inside)

1 x Minze Peehat with shield

1 x Minze Homeflow cup (transparent)

1 x Minze Homeflow - Patient Manual

⚠ CAUTION — ***Only use the accessories described in the Minze Uroflow manual: the Minze peehat and the Minze Hospiflow or Homeflow cups. The uroflowmeter will not register a void if other accessories are used.***

⚠ **WARNING** — ***Explain the patient that the uroflowmeter contains batteries that do not need to be changed! He/she should never open the uroflowmeter battery lid. If the battery lid is opened, urine or water can enter and damage the uroflowmeter.***

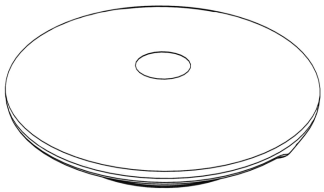
⚠ **WARNING** — ***Explain the patient that the shield must always be attached to the peehat and properly closed when registering a void.***

2 / TECHNICAL INFORMATION MINZE UROFLOWMETER

2.1 / OPERATING REQUIREMENTS

There are some operating requirements you should be aware of before using the Minze uroflowmeter:

- Operating temperature: +5°C to +40°C (+41°F to +104°F)
- In case the temperature during transport is outside the operational temperature range, ***let the uroflowmeter adapt to room temperature for at least one hour before use.***
- Humidity: 15% to 90%, non-condensing
- Atmospheric pressure: 70 kPa to 106 kPa



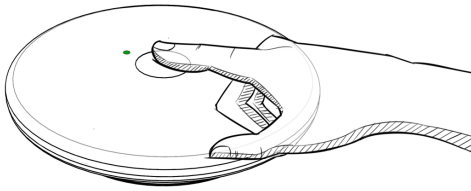
2.2 / TURN ON THE UROFLOWMETER

Shortly press the button ***once*** to turn on the uroflowmeter. A green light will turn on:

Steady green light: The uroflowmeter is turned on and ready to be used

Blinking green light: The uroflowmeter is turned on and ready to be used, but not (yet) connected to a phone (or gateway).

After turning on the uroflowmeter it will go into stand-by modus.



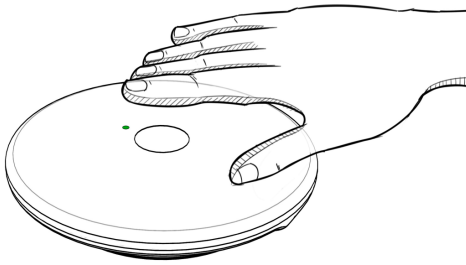
2.3 / UROFLOWMETER IN STAND-BY MODUS

In stand-by modus the green light is turned off, but when you approach or grab the uroflowmeter the green light will turn on again, indicating the uroflowmeter is ready to be used.

The uroflowmeter will be in stand-by modus for:

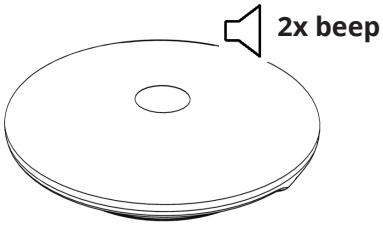
- ***30 minutes*** in case of a Homeflow assessment. It will automatically turn itself off after 30 minutes.
- ***4,5 hours*** after every void in case of Hospiflow.

If the light does not go on, the uroflowmeter is turned off. Turn it on again to use it!



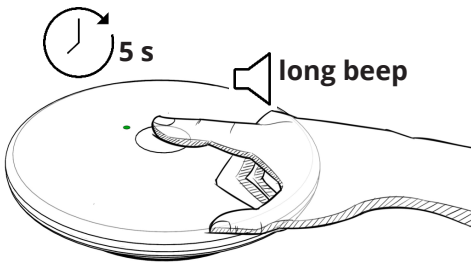
2.4 / SUCCESSFUL MEASUREMENT

When a measurement was successfully registered the uroflowmeter will double beep.

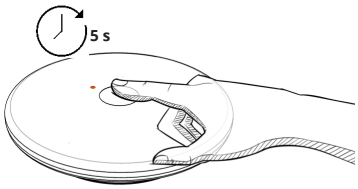


2.5 / TURN OFF THE UROFLOWMETER

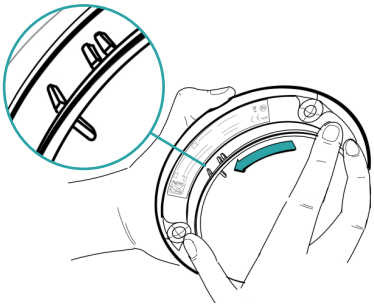
To save on battery, turn off the uroflowmeter when you are done using it. To turn off the uroflowmeter press the button (you will hear a first beep and the steady green light turns on); keep pressing for 5 seconds (you will hear a second beep and the steady green light will turn off); release the button (you will hear a long beep) and it is turned off.



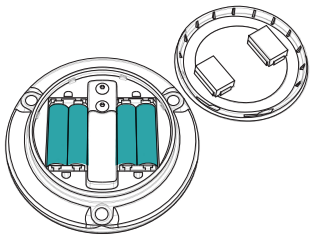
2.6 / LOW BATTERY LEVEL



- When you press the button and ***a steady orange light shows for 5 seconds***, the uroflowmeter is out of battery and will turn itself automatically off.
  The battery level is too low to use the uroflowmeter. It is time to change the batteries. To do so, perform the following steps:

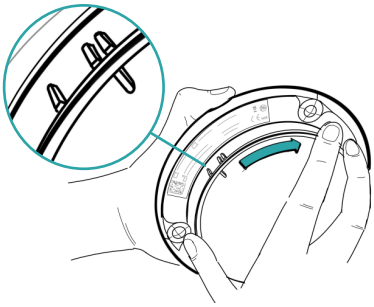


1/ Open the battery lid: turn it counterclockwise until the ***I-marking***



2/ Remove the old batteries and dispose of them in accordance with internal policies and local regulations.

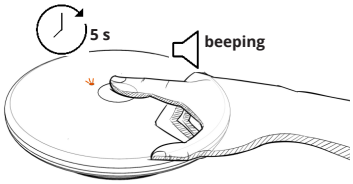
3/ Place four new AA Alkaline batteries in the battery compartment. Make sure you respect the polarity markings when placing the batteries.
Respect internal policies regarding battery usage and purchase, but never use expired batteries!



4/ Place the battery lid back: turn it clockwise until the ***II-marking.*** Make sure the ***battery lid seal*** (silicone O-ring) is in position!

2.7 / SERVICE AND MAINTENANCE

The Minze uroflowmeter is ***factory calibrated*** and doesn't need to be recalibrated during its expected service life under normal conditions and handling as described in this manual. The uroflowmeter has a self-check and calibration-check feature in case abnormal conditions and/or handling would result in an ***internal defect or a calibration malfunction, so:***



- the user gets notified by a ***blinking orange light together with a beeping sound for 5 seconds;***
- and the uroflowmeter turns itself automatically off to avoid incorrect measurements with a defective device.

WARNING ***Do not attempt to repair or modify the Minze uroflowmeter on your own. If you have any issues, please contact Minze Health or a representative. You can find the latest contact details on www.minzehealth.com***

2.8 / TECHNICAL SPECIFICATIONS

UROFLOWMETER CHARACTERISTICS

General

- Weight sensor (load cell): measures voided volume and calculates flow
- Dimensions: 142 mm (diameter) x 30 mm (height)
- Weight: 365 g
- Housing material: PC 2458 (hard parts) and Kraton G1645 M Polymer (soft parts)
- Degree of protection: IP 65
- Label material: top coated polyester (thermal transfer; permanent acrylic adhesive)
- Electronics solder: lead free
- Bluetooth: version 5

Battery

- Replaceable batteries: 4 x AA Alkaline
- Battery life in case of Homeflow use: 1 year
- Battery life in case of Hospiflow use: 3 months

Accessories

Holder: peehat for both men and women

- Material: PC 2458

Cup: 1200 ml capacity

- Material: ABS (Homeflow cups)
- Material: PC 2458 (Hospiflow cups)

TRANSPORTATION, STORAGE AND OPERATION REQUIREMENTS UROFLOWMETER

Transportation and storage temperature

- -25°C to +5°C (-13°F to +41°F),
- +5°C to +35°C (+41°F to +95°F) at a relative humidity up to 90%, non-condensing, or
- +35°C to +70°C (+95°F to 158°F) at a water vapor pressure up to 50hPa

Site requirements

- Operating temperature: +5°C to +40°C (+41°F to +104°F)
- Humidity: 15% to 90%, non-condensing
- Atmospheric pressure: 70 kPa to 106 kPa

MEASUREMENT SPECIFICATIONS

Volume

- Range: 0 – 1000 ml
- Resolution: 1 ml
- Accuracy: within ±3% of full scale (1000 ml, i.e. ± 30ml)
- Sampling rate: 20 Hz

Flow rate

- Range: 0 – 50 ml/s
- Resolution: 1 ml/s
- Accuracy: within ±5% of full scale (50 ml/s, i.e. ± 2.5 ml/s)
- Sampling rate: 20 Hz

Void duration

- Max time recording: 180s

CLASSIFICATION/APPROVAL

- MDD, Medical Device Directive 93/42/EEC, Class I(m) medical device.
- IEC 60601-1 (Medical Electrical Equipment)
- IEC 60601-1-2 (EMC)
- IEC 60601-1-6 (Usability)
- IEC 60601-1-11 (Home Healthcare Environment)
- IEC 60529 (Degrees of Protection Provided by Enclosure – IP Code)
- EN 301 489 (Electromagnetic Compatibility and Radio Spectrum Matters)
- EN 980 (Symbols for use in the labelling of medical devices)
- EN 1041 (Information supplied by the manufacturer of medical devices)
- EN ISO 10993-1 (Biological evaluation of medical devices)
- EN 301 489 – 1/17 (Compliance to article 3.1b of the RED 2014/53/ED)

3 / PERFORM HOMEFLOW AND HOSPIFLOW ASSESSMENTS

The images in this manual are used for explanatory purposes. Your product version may differ from these images, due to updates. However, functionalities are the same. You can find the latest updates and more detailed information/instructions on www.minzehealth.com.

3.1 / GET STARTED WITH THE MINZE PORTAL

Together with the shipment of your Minze Uroflow box, your organization and a first user for the Minze clinician portal will already be set up. Open your browser and visit **portal.minzehealth.com**. Log in with your (temporary) personal credentials, which you received by e-mail. After logging in, go to the ***patients page***.

To visit the Minze clinician portal, following internet browsers are supported for at least as long as the service life of the device: Google Chrome version 45 (or higher), Internet explorer version 11 (or higher), Firefox version 51 (or higher), Safari version 10 (or higher). For the best user experience we advise you to keep your browser up to date.

Navigate through the portal

Use the top right menu to navigate through the different pages:

Hospiflow: gather in-hospital uroflowmetry measurements with Hospiflow cups (see further).

Patients: manage the patients linked to your organisation.

Settings: manage organisation specific settings (users, license, Hospiflow cups,...).

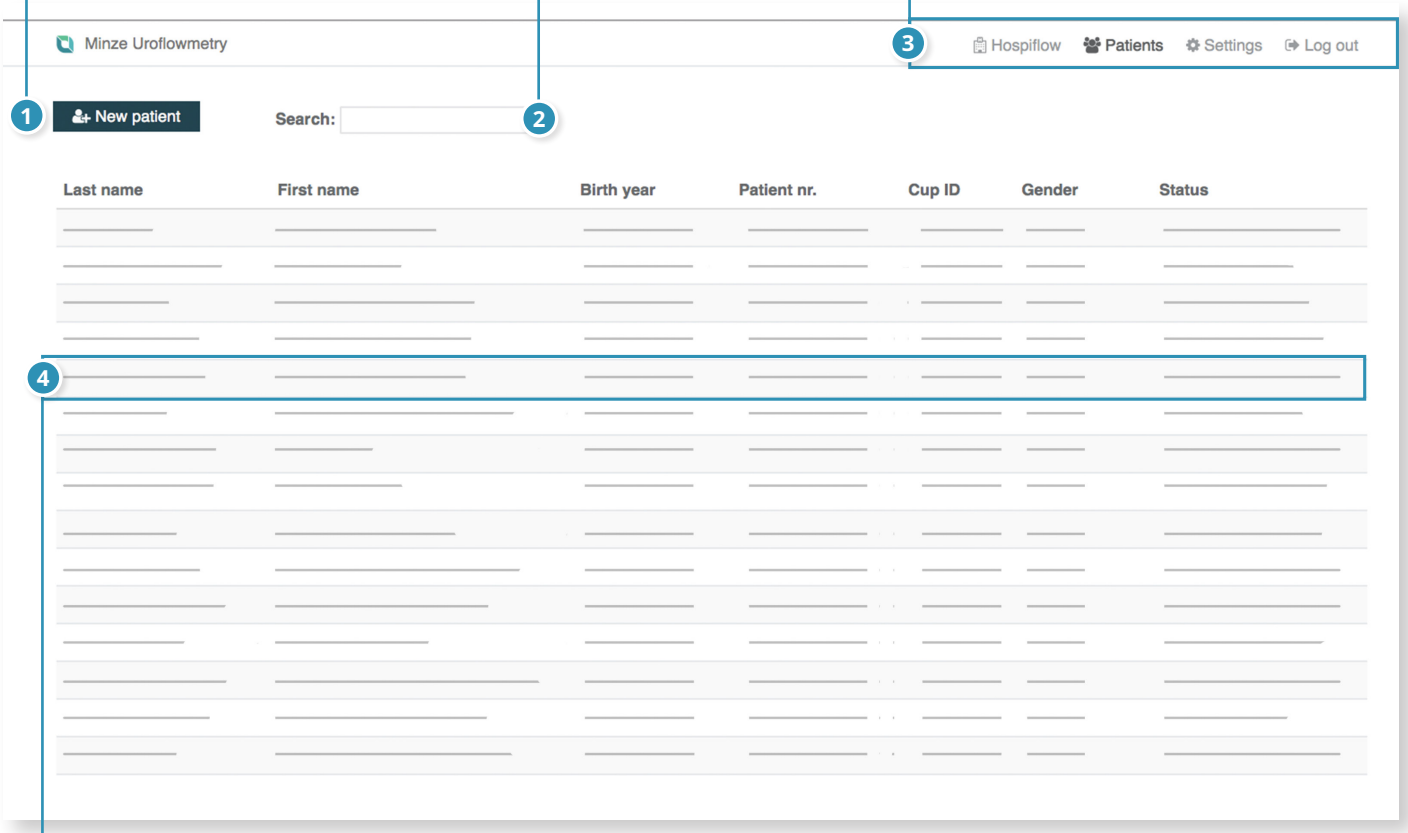
Log out: log out from the Minze portal.

Add new patients

Add new patients to the portal. Click on the button and fill in the requested patient information to create a new patient.

Search for patients

Search for a patient by their last name, first name, patient N°, etc.



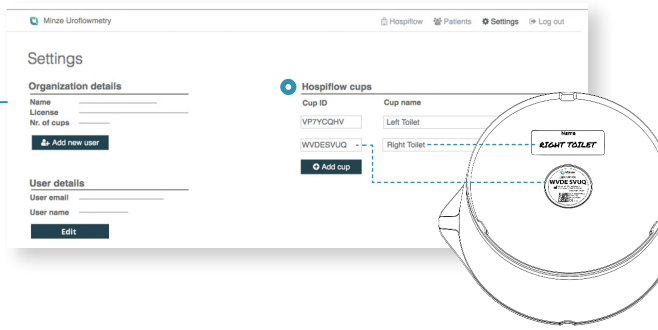
Go to a patient profile

Select a patient by clicking on his/her name to open the patient profile, where you can:

Create Homeflow assessments for that patient (see further).

Analyse Homeflow and Hospiflow assessments performed by that patient (see further).

3.2 / GATHER HOSPIFLOW MEASUREMENTS



1. LINK HOSPIFLOW CUPS TO ORGANISATION *(only one time)*

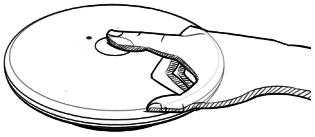
Go to the settings page to assign **white Hospiflow cups to your organisation using the cup ID** (at the bottom of the cup). The measurements on the Hospiflow page are **grouped** by the Hospiflow cups.

Tip: Give the cup a "friendly" name and write it in the name field at the bottom of the cup.

2. REGISTER A VOID WITH THE UROFLOWMETER AND ACCESSORIES

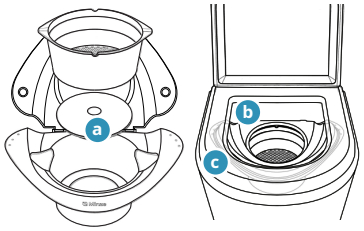
1

Before voiding, make sure the uroflowmeter is turned on. ***Push the button shortly once*** and check if the green light turns on.



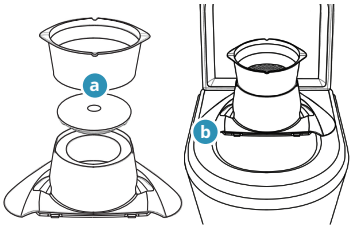
Assemble correctly (SITTING)

a. Place the uroflowmeter in the peehat and put the cup on top.
b. Close the shield of the peehat.
c. Hang in the toilet underneath the toilet lid.



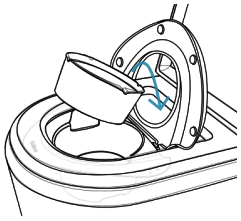
2 ***Assemble correctly (STANDING)***

a. Place the uroflowmeter on the peehat and put the cup on top.
b. Put the assembly on top of the toilet seat.



3

Lift the cup or wait 1 minute after voiding to ***end and save the measurement***. Empty and rinse it afterwards.



WARNING ***The shield must always be attached to the peehat, properly closed and placed underneath the toilet seat when registering a void (sitting). Never sit directly on the shield.***

WARNING ***The uroflowmeter must always be placed in the center of the peehat without touching the inner edge of the peehat opening at the bottom.***

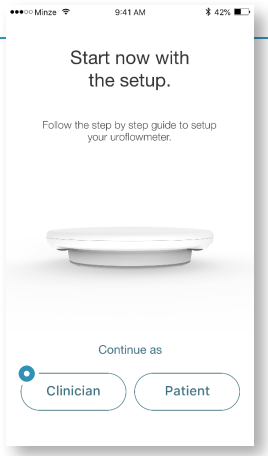
3. MEASUREMENTS SENT TO THE MINZE PORTAL THROUGH THE MINZE FLOW APP

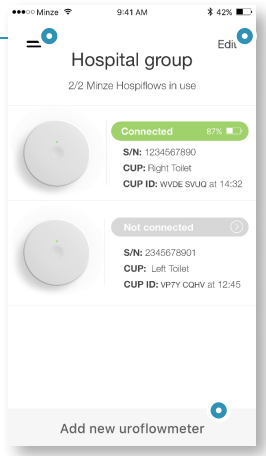
Make sure you **continue as clinician**, you will have to login using the same credentials as the ones you use for the clinician portal.

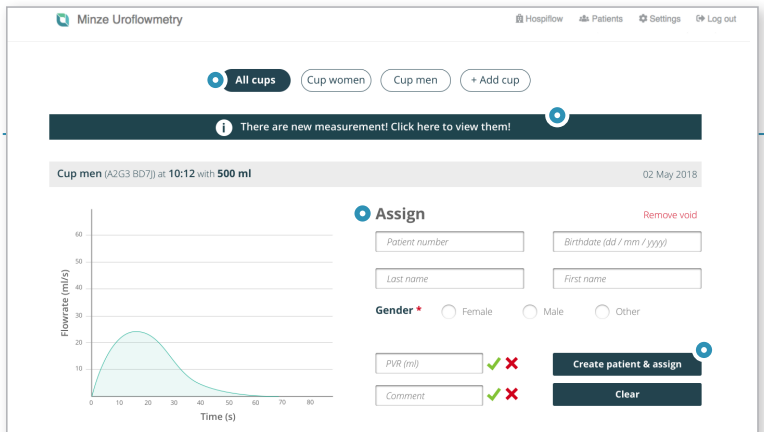
In the app you can **manage uroflowmeters** for Hospiflow sessions: uroflowmeter(s) overview, add/edit uroflowmeters and use the hamburger menu for more settings.

Measurements are **automatically sent** via the app or gateway (Bluetooth) to the portal (internet). In case Bluetooth or internet connection got lost, the app will notify and guide you. The measurement is saved on the uroflowmeter until it is succesfully sent.

The patient and clinician app are both within the same Minze Flow app. You can download it on the Play store for Android devices or on the App store for iOS devices. You need at least iOS 8.2. or Android 4.4. to run the app and your device should have Bluetooth. These operating systems will be supported for at least the service life of the device. We strongly recommend to keep your operating system up to date.







4. ASSIGN MEASUREMENT TO PATIENT

The Hospiflow measurements are sorted by time. To **assign a measurement to a patient**, fill in the requested patient information. New patients will be registered to the portal during the assignment of a measurement. Existing patients can be selected from a result list corresponding to the provided input.

3.3 / GATHER HOMEFLOW MEASUREMENTS

1. CREATE HOMEFLOW ASSESSMENT

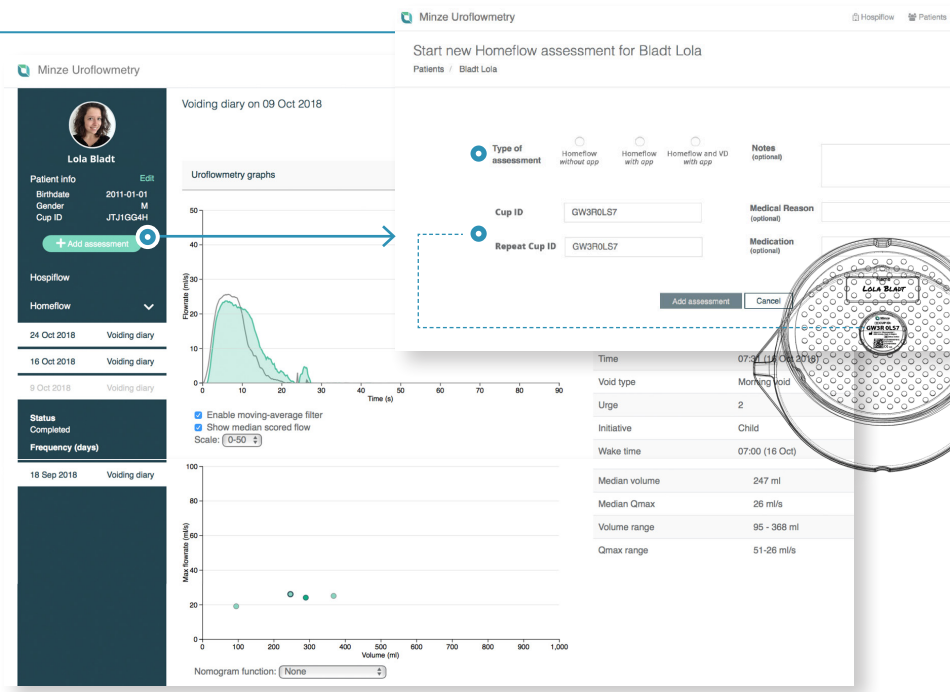
Press the **add assessment button** and fill in the required assessment information.

Select an assessment type:

- ***Homeflow without app*** / Register voids at home during a couple of days.
- ***Homeflow with app*** / Register voids at home during a couple of days.
- ***Homeflow and voiding diary with app*** / Register every void, drink and leakage during 24-hour cycles *(from morning void of one day to morning void of the next day).*

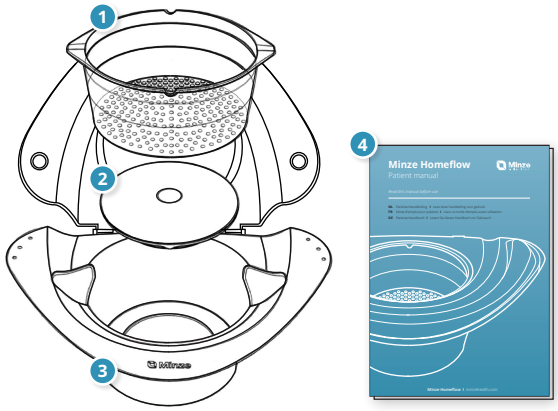
Link a Homeflow cup (transparent) to the patient using the cup ID (at the bottom of the cup). Once the patient is linked to this Homeflow cup, all voids registered with this cup will end up on this patient's profile. The patient is not bothered with a username and password, because the NFC-tag contains his/her unique credentials.

Tip: Write the patient's name in the name field at the bottom of the cup.



⚠ CAUTION ***In case a Homeflow cup gets lost or broken, it can be replaced with a new one in the patient's profile by changing the cup N°. An already assigned cup can never be reassigned to someone else. The Homeflow cups are single patient cups.***

2. SEND PATIENT HOME



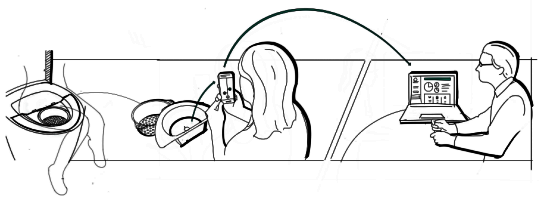
Make sure you provide every patient with:

1. **Transparent Homeflow cup linked to the patient**
2. **Uroflowmeter with batteries inside** (green light when you turn it on; no orange blinking light)
3. **Minze Peehat with shield**
4. **Minze Homeflow - Patient manual**

The patient manual explains step by step how to correctly capture data during an assessment and how to use the uroflowmeter, accessories and patient app. The patient app additionally provides extra information to guide him/her through the assessment: quick tutorials, reminders,...

Because steps are often the same for the different assessment types, the patient manual is bundled for all types of assessments. We recommend you to go through this small patient manual with the patient. It is beneficial that you are aware as a clinician of what the patient has to do at home, so you can give additional verbal instructions.

3. GET THE DATA FROM THE PATIENT'S HOMEFLOW ASSESSMENT



The Homeflow measurements are ***automatically sent via the patient's app*** (Bluetooth) to the patient's profile in the Minze portal (internet).

In case of patients without an app all measurement are saved on the uroflowmeter. You can upload the Homeflow measurements to the patient's profile using the Minze Flow app (hamburger menu) logged in as a clinician or using the gateway.

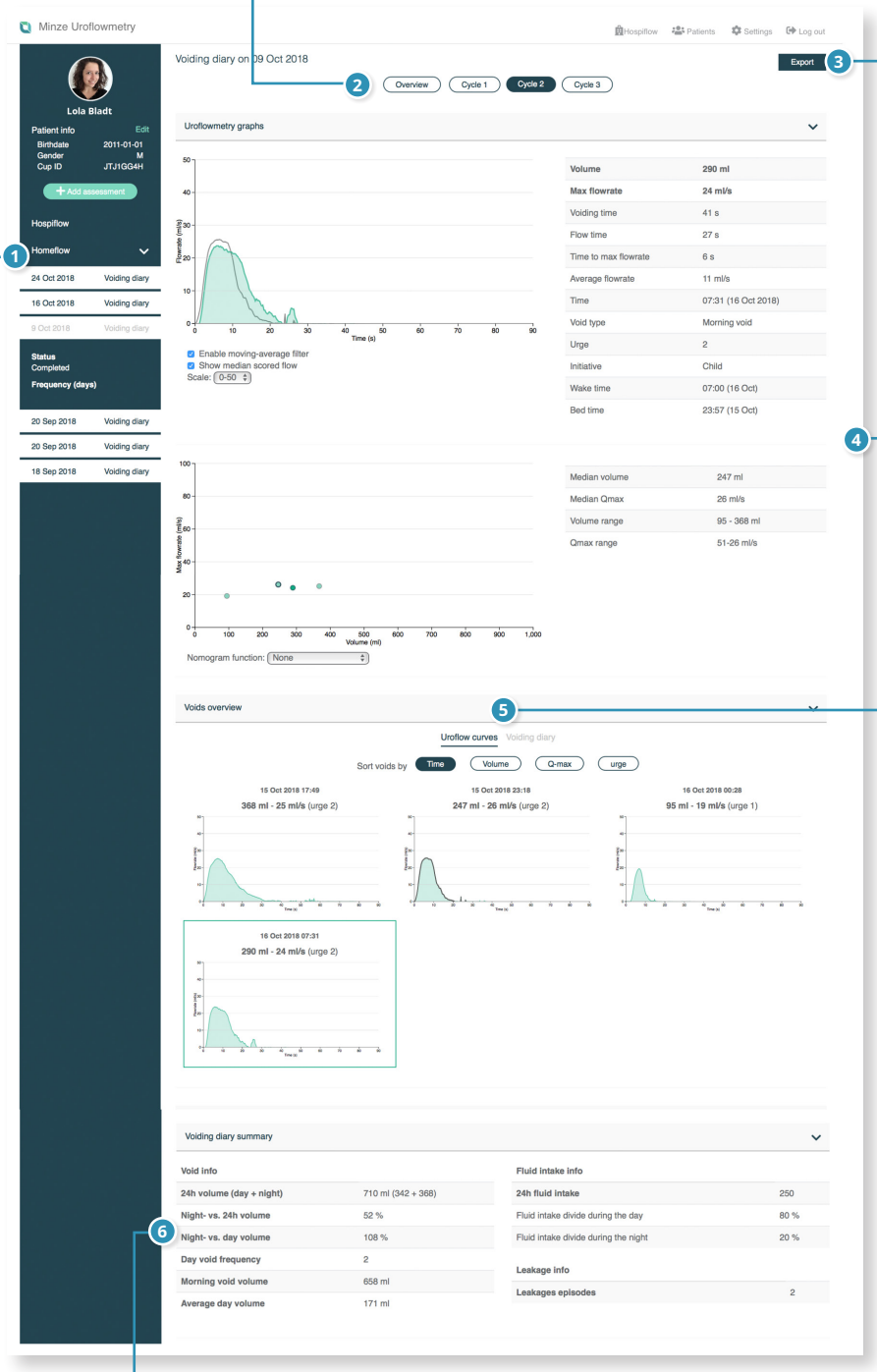
3.4 / ANALYSE HOSPIFLOW AND HOMEFLOW ASSESSMENTS ON THE ONLINE MINZE PORTAL

Select assessment

In the left bar of the patient's profile page you can see the assessment history of the patient. The assessments all mention a type (**Hospiflow or Homeflow**) and date. Select the assessment you want to analyse the data from.

Overview and cycles (in case of voiding diary)

In case of a voiding diary, you can select if you want to see the data of a **specific cycle or an overview of all cycles**. The data are shown in different fields (uroflowmetry graphs, voids overview, etc.). You can hide or reveal the data in every field via the "˅".



Export to PDF

Export all the data from the assessment to a PDF file by pressing this button.

Uroflowmetry graphs

A flowrate-time graph (uroflow curve) is shown with ***detailed uroflowmetry and voiding diary parameters*** next to it. The selected or most recent void is shown.

A max. flowrate – voided volume graph is shown with ***summarizing uroflowmetry data*** next to it. Every dot in the graph represents a void. You can ***select a dot in this graph*** to update the uroflow curve above with the newly selected void.

Voids overview

Uroflowcurves view

An overview of all the uroflow curves is shown, which you can ***sort by time, volume or urge***. You can ***select a uroflow curve*** to update the uroflowmetry graphs above with the newly selected void.

Voiding diary view

In case of a voiding diary you can also choose to get an overview of the voids, drinks and leakages in a standard ***voiding diary table.*** You can ***select a void out of this table*** to update the uroflowmetry graphs above with the newly selected void.

Automated voiding diary summary (in case of a voiding diary)

An automated voiding diary summary is calculated per cycle, providing more detailed voiding diary parameters.

4 / CLEANING AND DISINFECTING INSTRUCTIONS

The Minze uroflowmeter and accessories are Non-critical Patient-care Items that require a low-level to intermediate disinfection. This manual gives you a recommended way of cleaning and disinfecting the Minze uroflowmeter and accessories, but always check in with your internal cleaning procedures in the hospital.

Clean and disinfect when necessary (check in with internal procedures), but ***at least when receiving it back after Homeflow use*** and at the ***end of a Hospiflow session day***. The recommended cleaning and disinfecting procedure has the following steps:

1/ Rinse in cold water (<43°C) to remove gross debris.

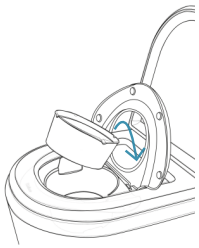
2/ Scrub with an enzymatic detergent only to remove visible soil.

3/ Rinse thoroughly with cold water (<43°C). Check for visible soil. Repeat cleaning if soil is still visible.

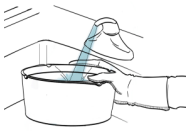
4/ ***Disinfect with alcohol 70% - 90%*** (use a spray or wipe, but ***do not immerse the uroflowmeter in alcohol***) with a contact time of at least 1 minute.

5/ Dry with a dry clean cloth or let it air-dry.

After every void during a Hospiflow session you should at least:



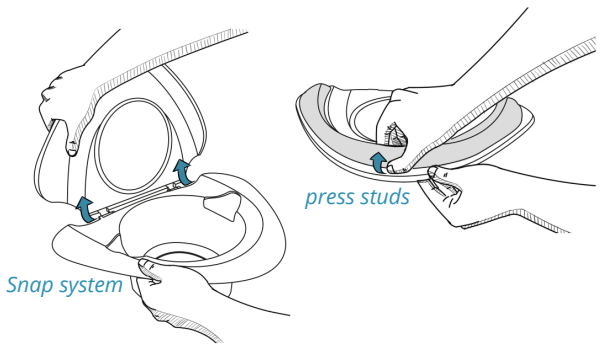
1/ Empty the cup in toilet

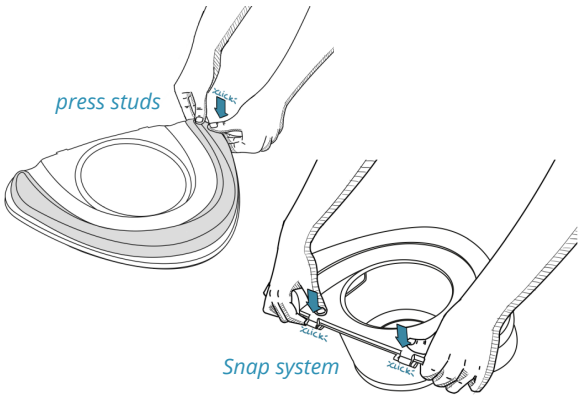


2/ Rinse it with cold water (< 43° C)

3/ Dry it with a dry clean cloth or let it air-dry

Apply the same cleaning steps for the accessories. You can take off the shield ***(snap system)*** and detach the cushion on top of it ***(press studs)*** to clean more thoroughly.





⚠ WARNING ***Never allow water to get inside the Minze uroflowmeter to prevent damage to the system, e.g. do not remove the battery lid when cleaning the device.***

⚠ CAUTION ***Store the uroflowmeter and accessories in a dry, dust-free and clean environment between uses.***

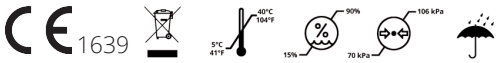
⚠ CAUTION ***Always attach the shield back to the peehat (snap system) after cleaning.***

5 / TROUBLESHOOTING MINZE UROFLOW

Can't find a solution for your problem? Visit www.minzehealth.com for the latest updates on troubleshooting or contact Minze Health or a representative.

Problem	*Symptom*	*Remedy*
Uroflowmeter dropped in toilet	Uroflowmeter slipped/fell in the toilet.	*Clean, dry and disinfect immediately. Visually examine for damage.*
Damaged uroflowmeter housing and/or accessories	Visual damage (dents, broken parts, deformation, deep scratches, holes, etc.) to the uroflowmeter or accessories.	*Do not attempt to repair or modify the Minze uroflowmeter and/or accessories on your own. Please contact Minze Health or a representative. You can find the latest contact details on www.minzehealth.com.*
Cannot log in to clinician portal	You do not know or cannot remember your login credentials for the Minze clinician portal.	*You should have received your login credentials via e-mail (the e-mail address entered during onboarding or when adding a new user). In case you forgot it, press the "Forgot password" button. A new e-mail with new credentials will be sent to your e-mail address.*
Measurement not uploaded to clinician portal	A void was registered with the uroflowmeter but cannot be found in the clinician portal.	*Check the following:* • *Connected to the internet* • *Bluetooth connection established between uroflowmeter and app/gateway* • *Uroflometer turned on (If not, it cannot register)* • *Uroflowmeter and accessories correctly assembled (if not, it cannot register)*
Measurement assigned to wrong patient	During a Hospiflow session a measurement got assigned to the wrong patient.	*Use the "reassign" button in case a measurement was assigned to the wrong patient.*
Patient has lost his/her personal Homeflow cup	Patient already has a Homeflow cup N° linked to him/her, but lost the cup.	*During the creation of a new assessment, the cup N° linked to the patient is shown, but can also be edited by overwriting it. You can only use Homeflow cups which are not yet linked to a patient.*
Cannot login as professional user	You do not know how to login as a professional, which credentials to use or forgot your credentials.	*Continue as Clinician in the Minze Flow app and login. Use the same credentials as those you use to login to the clinician portal. You should have received your login credentials via e-mail (the e-mail address entered during onboarding or when adding a new user). In case you forgot it, press the button Forgot password. A new e-mail with new credentials will be sent to your e-mail address.*
Cup error message	In the clinician section of the app a cup error message is shown, e.g. "Not a Hospiflow cup".	1. *Make sure you are not using a Homeflow cup (transparent). Only use Hospiflow cups (white)!* 2. *Make sure you assigned the Hospiflow cup to Hospiflow sessions via the clinician portal.*
Patient cannot start using Homeflow	The patient cannot start a Homeflow assessment via the Minze Flow app. A message says there are currently no assessments.	*Make sure you created an assessment for the patient and linked a Homeflow cup to him/her.*

6 / WARNINGS AND CAUTIONS



The safety information in this appendix is intended for:
- users performing investigations by using the Minze Uroflow system (e.g. the clinician);
- users who install, test and maintain the Minze Uroflow system.

Before working with the Minze Uroflow measurement system and its manual, please take notice of the safety information as described in this appendix. The Minze Uroflow is a prescribed device to be used only by:
- clinicians and other specialists;
- individuals who have been trained and authorized by a clinician or a medical institution and are under the supervision of a clinician.

The Minze Uroflow must be purchased under the supervision of a clinician.

The Minze uroflowmeter can only be used and stored indoor at temperatures between +5°C and +40°C (+41°F to +104°F), at a humidity between 15% and 90%, non-condensing and at an atmospheric pressure between 70 kPa and 106 kPa. The Minze uroflowmeter must be used and stored in a dry, dust-free and clean environment.

Minze will not give any guarantee or take any responsibility for any Minze Uroflow part which has been opened, adjusted or replaced by clinic personnel.

Although precautions have been taken to prevent malfunctions due to abnormal environmental conditions and/or abnormal handling, such malfunction can occur in some circumstances.

Abnormal environmental conditions include, but are not limited to:
- any condition other than specified in the manual;
- (electro-)magnetic fields caused by X-ray equipment, (radio-)transmitters, radar equipment, etc.;
- electro static discharge;
- main disturbances;
- extreme temperatures, pressures, humidity, dust, etc.

Abnormal handling includes, but is not limited to:
- any handling other than specified in the manual;
- rough handling.

Provided such or similar conditions do not occur, the Minze Uroflow will prove to be durable and reliable.

The following signs are printed in this manual indicating important warnings and precautions. It is crucial to pay good attention to these warnings and precautions to provide patient safety and to prevent damaging the equipment.

WARNING ***A warning is a statement that alerts the user to the possibility of injury or other adverse reactions associated with the use or misuse of the device.***

CAUTION ***A caution is a statement that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such malfunctions include device malfunction, device failure, damage to the device or damage to other property.***

6.1 / UNPACKING

⚠ CAUTION See the packing list to check if all items are present.

6.2 / INSTALLATION

⚠ **WARNING** Safety can be violated if the Minze uroflowmeter shows visible damage.

⚠ **WARNING** No modifications of the Minze uroflowmeter and accessories are allowed.

⚠ **WARNING** Do not attempt to open the Minze uroflowmeter, besides opening the battery lid.

⚠ CAUTION To achieve an effective and safe set-up, the Minze Uroflow needs to be installed and put into service in accordance with the information provided in this manual.

6.3 / THE COMPUTER AND SMARTPHONE/TABLET

⚠ **WARNING** The computer (and its peripherals) and the smartphone/tablet connected to the Minze Uroflowmeter must comply with the latest version of one of the following standards: the IEC 60950, EN 60950 or UL 60950.

6.4 / MINZE UROFLOWMETER

⚠ **WARNING** The Minze uroflowmeter is not intended to be used in the presence of anaesthetic products.

⚠ **WARNING** Do not try to remove the silicone O-ring from the uroflowmeter and do not swallow it. Removing it would allow liquids to enter the Minze uroflowmeter, permanently damaging the electronics.

⚠ **WARNING** Damaged or degraded uroflowmeter housing and/or accessories can affect patient/operator safety and product performance and accuracy. Do not attempt to repair or modify the Minze uroflowmeter and/or accessories, but contact Minze Health or a representative. You can find the latest contact details on www.minzehealth.com.

⚠ CAUTION Do not drop or throw the Minze uroflowmeter. Do not apply excessive force or drop items on it. This can permanently damage it.

⚠ CAUTION Avoid touching or kicking the Minze uroflowmeter or urine container (cup) during a measurement.

⚠ CAUTION Never try to remove parts from the Minze uroflowmeter by pulling them, unscrewing them or using sharp tools.

6.5 / ENERGY SOURCE

⚠ **WARNING** Only use 4 AA Alkaline batteries as energy source for the Minze uroflowmeter. Do not use any other energy sources.

⚠ **WARNING** Always recycle batteries according to local regulation. Improper disposal of batteries may create an environmental contamination hazard.

6.6 / INVESTIGATIONS

WARNING Investigation procedures as described in the Minze Uroflow manual do not pretend to be complete. How an investigation is performed and how the results are interpreted and the actual diagnosing, remains under all circumstances the responsibility of the clinician performing the investigation. The description of investigation proceedings is only included to serve as an example to discuss the use of the various markers and the various transducers to reduce risks involving wrong treatment of a patient.

WARNING Safety can be violated if, for example, the device:
- shows visible damage;
- fails to perform the intended measurement;
- has been subjected to prolonged storage under unfavorable conditions;
- has been subjected to severe stresses in transit;
- has been handled by unqualified personnel.

WARNING In the very rare case of a patient getting an allergic reaction during the use of Minze Uroflow, immediately stop the use of it for this patient.

CAUTION The reuse of a single patient cup for another patient leads to measurement data ending up with the wrong patient (the previous one), because a single patient cup can never be reassigned to another patient on the online portal.

CAUTION The Minze uroflowmeter complies with applicable national and international standards for electromagnetic interference. As a precaution to avoid interference issues, please do not extensively use a smartphone/tablet (calling, downloading, surfing, streaming, playing games, ...) when registering a void with the Minze uroflowmeter.
Although interference issues caused by external sources are not expected, please avoid excessive use of heat sources near the uroflowmeter.

6.7 / CLEANING

WARNING Never allow water to get inside the Minze uroflowmeter to prevent damage to the system.

CAUTION Only use enzymatic detergent to manually clean the Minze uroflowmeter and accessories. Never use other chemicals or techniques to prevent damage to the system.

CAUTION Only use alcohol 70%-90% to manually disinfect the Minze uroflowmeter and accessories. Never use other chemicals than alcohol or other techniques than manually disinfecting (e.g. high temperature) to prevent damage to the system.

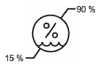
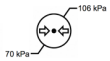
CAUTION Do not use excessive amounts of water to clean the Minze uroflowmeter to prevent damage to the electronics.

6.8 / SAFETY REGULATIONS

Minze uroflowmeter:
- Protection Class: internally powered.
- Applied part: NA.
- Ingression protection: IP 65.

7 / EXPLANATION OF SYMBOLS

The list below gives an explanation of the symbols on the Minze Uroflow.

CE 1639	Declaration of conformity according to the applicable European directives
REF	Reference, product name.
SN	Serial number.
	Name and address of the manufacturer.
	Use by date YYYY-MM (year – month)
	Consult instructions for use.
IP 65	Protected against ingress of dust (dust tight) and protected against water jets from any direction.
	This product is subject to WEEE directive 2002/96/EC. Contact your local authority for information about disposal and recycling. Batteries and uroflowmeter need to be disposed separately.
Contains FCC ID: SH6MDBT42Q	The Minze Uroflowmeter contains a radio module which is FCC full modular approved.
	Special storage/handling conditions: store/use the Minze Uroflowmeter at temperatures between +5°C and +40°C (+41°F to +104°F).
	Special storage/handling conditions: store/use the Minze Uroflowmeter at a humidity between 15% and 90%, non-condensing.
	Special storage/handling conditions: store/use the Minze Uroflowmeter at an atmospheric pressure between 70 kPa and 106 kPa.
	Special storage/handling conditions: keep the Minze Uroflowmeter dry.

8 / WARRANTY

Minze NV (hereinafter referred to as “Minze”) warrants the Minze Uroflowmeter, Minze Uroflowmeter parts, the Minze Flow application and Minze Software (hereunder commonly referred to as “Product”) against defects in materials and workmanship under normal use and service in accordance with Minze published guidelines for a period of one (1) year from the date of Purchase by the end-user purchaser from Minze or its authorized resellers. Minze published guidelines include but are not limited to information contained in technical specifications, instructions for use or short instructions for use. This warranty is only given to the original purchaser of the Product.

Minze further warrants the Product to meet the technical specifications as stated in these instructions for use for a period of one (1) year from the date of Purchase by the end-user purchaser from Minze or its authorized resellers.

This warranty does not cover damage caused by accident, abuse or neglect due to the misuse of the product. This limited warranty is non-transferable. Unauthorized attempts to open, repair or modify the Product will void this warranty. The use of the Product with accessories or other products not authorized by the manufacturer; or failure to maintain the Product in accordance with the manufacturer’s recommended procedures; or any cause other than the intended normal use of the Product can void the warranty.

Minze or its authorized resellers will repair or replace, at no charge, Products needed for such warranty service. The purchaser shall return the defective Product to Minze or its authorized resellers at Minze’s instructions and costs. In the event of a Product recall, market withdrawal, safety alert or similar action necessitated by the failure of the Product to operate in accordance with the technical specifications, caused by an act or omission (whether intentional or unintentional) of Minze (collectively, a “Recall”), Minze shall repair or replace such Product or take related action and pay all reasonable costs related to such action. A Recall is defined to be a systematic effort to locate and recall Products in the possession of users, distributors or sales representatives and repair or preplace those Products or take related actions.

9 / ELECTROMAGNETIC COMPATIBILITY (EMC) COMPLIANCE

Information for accompanying documents in the scope of IEC60601-1-2.

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

Guidance and manufacturer's declaration

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The Minze Uroflow complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is safe to operate it in the presence of high-frequency surgical equipment; however, it is good practice to avoid using the Minze Uroflow near other equipment.

Electromagnetic emissions

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

Emission test	Compliance	Guidance
RF emissions CISPR 11	Group 1	The Minze Uroflow uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Minze Uroflow 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity

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

Immunity test	IEC 60601 Test level	Compliance	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	4 kV, 8 kV contact 2 kV, 4 kV, 8 kV, 15 kV air	4 kV, 8 kV contact 2 kV, 4 kV, 8 kV, 15 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	Not applicable
Surge IEC 61000-4-5	Not applicable	Not applicable	Not applicable
Voltage dips, short interruptions, and voltage variations on power-supply IEC 61000-4-11	Not applicable	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Not applicable	Not applicable	Not applicable

Electromagnetic immunity

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

Immunity test	IEC 60601 Test level	Compliance	Guidance
Conducted RF IEC 61000-4-6	Not applicable	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Minze Uroflow including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. ***Recommend separation distance*** d = 1.2 √P d = 1.2√P 80MHzto800MHz d = 2.3√P 800MHzto2.5GHz where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with he following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM 1 kHz 10 V/m 80 MHz - 2.7 GHz 80% AM 1 kHz	3 V/m 80 MHz - 2.7 GHz 80% AM 1 kHz 10 V/m 80 MHz - 2.7 GHz 80% AM 1 kHz	

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Minze Uroflow is used exceeds the applicable RF compliance level above, the Minze Uroflow should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Minze Uroflow.

2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Minze Uroflow

The Minze Uroflow is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Minze Uroflow can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Minze Uroflow as recommended below, according to the maximum output power of the communications equipment.

Output Power of Transmitter in Watt	Separation distance according to frequency of transmitter in meter		
	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.5GHz d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Minze
health at home

Minze N.V.
Offerandestraat 1, 2060 Antwerp
Made in Belgium

Minze Uroflow
CE 1639

Minze Uroflow - Installation and Operation Instructions
v4 EN / August 2020