

Instructions For Use

v4 EN/ February 2025

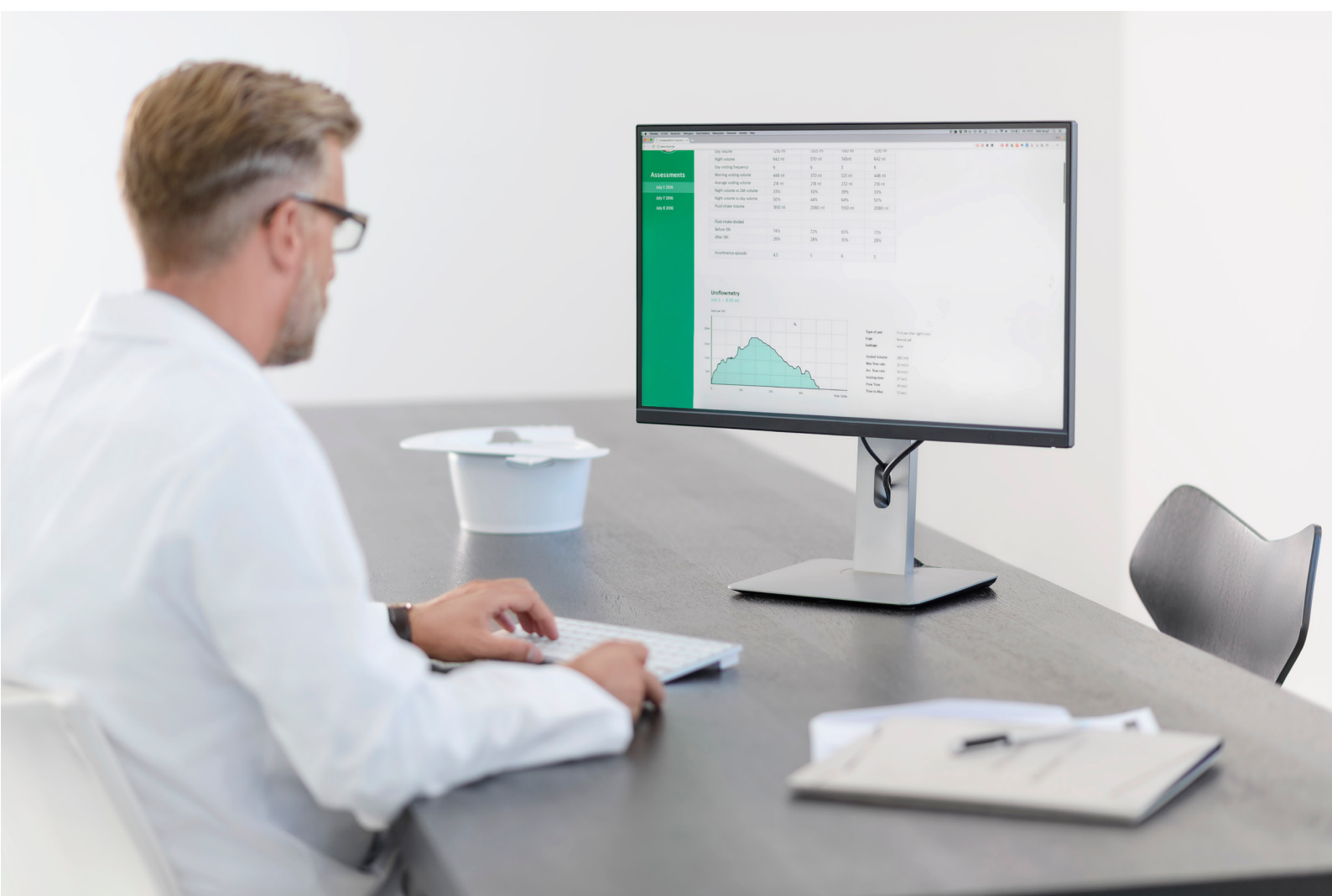


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1 / INTRODUCTION TO MINZE PLATFORM

1.1 / INTENDED USE

The Minze Platform is a medical device (software) intended to capture physiological and non-physiological patient information from an in clinic or home environment. Information is collected either through manual entry and/or via compatible hardware devices and accessories. This information is used to assist in decisions with diagnosis, for therapeutic purposes and to provide lifestyle advice and behavioral therapy techniques for patients with lower urinary tract symptoms.

1.2 / INTENDED USER PROFILES

A. Professional users: healthcare professionals, clinicians and assistants, with a medical degree, medical certification or nursing degree.

B. Lay users: The lay users are individuals suffering from lower urinary tract symptoms or their caregivers. No specific education is required, but a minimum reading level is required (8th grade). They must be able to use a smartphone and download/install/use simple mobile phone applications.

1.3 / CLINICAL BENEFIT

There is no direct clinical benefit. The collected urological parameters (via hardware or software) are used to inform clinical management to support in decisions with diagnosis, for therapeutic purposes and to provide lifestyle advice and behavioral therapy techniques for patients suffering from lower urinary tract symptoms. Any potential indirect clinical benefit is dependent on the clinician's decision, not the Minze Urology System itself. Decisions on surgeries and/or other invasive treatments should never be based on the outcome of Minze's software alone.

1.4 / OVERVIEW USE CASES

Hospiflow

Minze Hospiflow is a combination of a uroflowmeter with accessories, a hospital mobile application (or Minze gateway) and the Minze Dashboard. A clinician can investigate the lower urinary tract system of a patient by using the uroflowmeter and accessories – a pee-hat 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 is then visualized at the Minze dashboard, 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 the Minze Dashboard. A clinician can prescribe the uroflowmeter and accessories – a pee-hat 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 visualized at the Minze Dashboard, where the clinician can remotely consult the patient's data.

Diary Pod Automated bladder diary

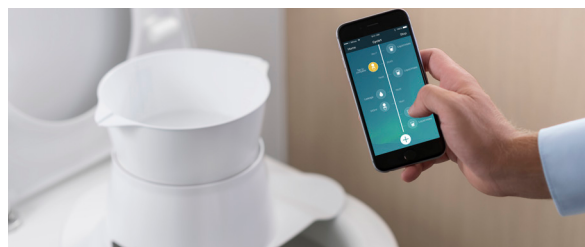
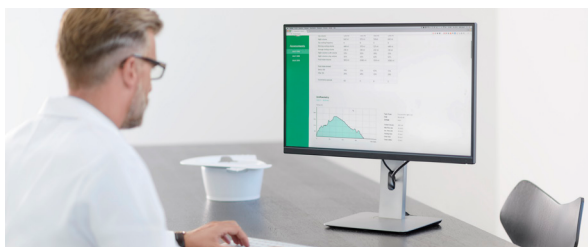
Minze Diary Pod is a combination of a Diary Pod device, a patient mobile application and the Minze Dashboard. A clinician can prescribe an automated bladder diary to a patient to use at home in order to receive accurate and reliable bladder diary information. The patient has to answer some questions in the app with every void registered through the Diary Pod like urge, incontinence and liquid intake. The data is then visualized at the Minze Dashboard, where the clinician can remotely consult the patient's data.

Digital bladder diary and symptom questionnaires

A digital bladder diary and symptom questionnaire is an assessment collected through a patient mobile application only, without hardware. A clinician can prescribe a digital bladder diary to a patient to use at home in order to receive bladder diary information. The patient has to answer some questions in the app with every void registered in the app like urge, incontinence and liquid intake. The data is then visualized at the Minze Dashboard, where the clinician can remotely consult the patient's data.

Personalized therapeutic recommendations

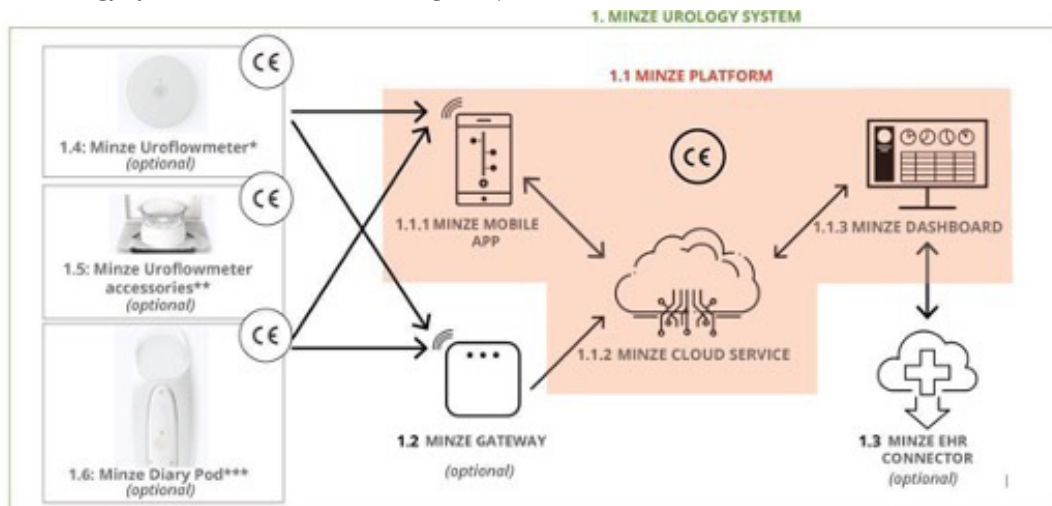
A patient can receive therapeutic recommendations based on their bladder diary and/or questionnaire results. These recommendations can be assessed in the patient facing part of the Minze Dashboard.



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

1.5 / SYSTEM DESCRIPTION

The Minze Urology system contains the following components:



1.2 The Minze Gateway is a device that enables wireless or wired network connectivity. It acts as a bridge between Minze uroflowmeter or Diary Pod and a network infrastructure, facilitating secure data transmission and communication to the Minze platform. The Minze Gateway does not alter, modify, or process the transmitted data; it only enables the transfer between connected devices and the network.

1.3 Minze EHR connector is an optional non-medical software add-on which enables communication between the Minze Cloud Service and the HCP's Electronic Medical Record (EMR) system. The Minze EMR connector does not alter, modify, or process the transmitted data.

1.4 Minze Uroflowmeter is an optional separate Medical Device, classified as Class 1m and covered in separate Technical Documentation and CE Certificate.

1.5 Minze Uroflowmeter accessories is a separate Medical Device, classified as Class 1, always used together with the Minze Uroflowmeter.

1.6 Minze Diary Pod is a Medical Device Class 1, covered in a separate Technical Documentation and CE Certificate. It's optional to the 1.1 Minze Platform.

The Systems contains the Minze Platform (1.1) as only mandatory component, the other components are optional. Minze Sensors (1.4 / (1.5+1.6)) connect either to the Mobile App or the Gateway via Bluetooth Low Energy to upload data, which is forwarded to the Minze Cloud Service (1.1.2) for processing and storage.

The Minze Platform is compatible with Minze hardware devices. The Minze hardware devices and Minze Platform (Minze Cloud Service, Minze Mobile App, Minze Dashboard) use as means of communication Bluetooth Low Energy (BLE) technology and internet connection (Wi-Fi or mobile telecommunication, e.g. 3G, 4G, ...). These technologies are used to wirelessly send data from the Minze Hardware device (through BLE) through the Minze Mobile App, further to the Minze Cloud Service for storage and data processing, and from there to the Minze Dashboard to be visualized to the professional user (through an internet connection). The operating system on the smartphone or tablet that runs the Minze Mobile App can either be iOS or Android.

Minze platform works with support accessories and tools: computer/laptop, mouse, keyboard and display monitor, smart phones, Minze EHR connector, and Minze Gateway,

2 / TECHNICAL INFORMATION MINZE PLATFORM

2.1 / SYSTEM REQUIREMENTS

- Minze supports the following mobile operating systems: iOS 15 (or more recent), Android 9 (or more recent) with access to the Google Play store and Apple App store.
- Internet browser: Google Chrome (at least version 134.0.6998.23 or more recent), Microsoft Edge (at least version 133.0.3065.82 or more recent), Firefox (at least version 135.0.1 or more recent), Safari (at least version 17.6 or more recent). For the best user experience, the user is advised to keep the browser up to date.
- Minze Platform requires a stable broadband internet connection: minimum 100 megabit per second ethernet connection, 2.4 GHz over wireless connection.
- Support hardware to access Minze Platform is required to be compatible with the recommended mobile operating systems and internet browsers.
- The Minze Platform is only accessible through the recommended browsers, app stores and mobile operating systems. Not through a physical medium like a CD, memory stick or other storage device.

2.2 / MAINTENANCE, UPDATES & LIFETIME

iOS and Android users should update their app through the Play Store like any other application. The Play and iOS Store send notifications when a new required version is available. The lifetime of the Minze Platform is 5 years.

2.3 / DATA PROTECTION & GDPR

At Minze, industry state-of-the-art measures are implemented to protect safety of data and data privacy. A variety of measures are taken to ensure that user data is secured. The Minze platform is encrypted by TLS version 1.2 or higher, no data is stored on the Minze Dashboard, patient identifiable information and medical data are stored separately in the Minze Cloud. All the processed data are pseudonymized and encrypted, using HTTPS TLSv1.2 encryption in transfer and the AES-256 encryption algorithm at rest.

2.4 CLASSIFICATION/APPROVAL

- MDR, Medical Device Regulation 2017/745, Class IIa medical device.
- EN ISO 14971:2019 Medical devices - Application of risk management to medical devices
- EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - part 1: general requirements
- IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical device
- IEC 62304:2006/A1:2015 Medical device software - Software life cycle processes

3 / PERFORMING HOSPIFLOW, HOMEFLOW, AUTOMATED AND DIGITAL BLADDER DIARY ASSESSMENTS

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

3.1 / GET STARTED WITH THE MINZE PORTAL

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

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.

Navigate through the Minze Dashboard

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.

Search for patients

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

The screenshot shows the 'Minze Internal' dashboard with a top navigation bar containing 'Hospiflow', 'Homeflow', and 'Patients' (selected). A 'New patient' button is highlighted with a blue circle and the number 1. A search bar is highlighted with a blue circle and the number 2. A table of patients is shown with columns: Last name, First name, Birth year, Patient nr., and Gender. The first row is highlighted with a blue circle and the number 4. The table contains 15 rows of patient data.

Last name	First name	Birth year	Patient nr.	Gender
Andrews	Frank	05/04/1932	19320405005	Male
Brookes	Edward	08/03/1970	19700308008	Male
Brown	Stephanie	16/03/1955	19550316024	Female
Clark	Jim	30/12/2003	20031230098	Male
Collins	Tom	09/07/1948	19480709891	Male
Darnell	Daisy	24/05/1963	19630524007	Female
Finick	Meredith	06/11/1945	194511106203	Female
Harvey	Bob	02/09/1924	19240902087	Male
Matthews	William	06/01/1975	19750106098	Male
Smith	Michael	12/01/1962	19620112001	Male
Tarich	Lucy	07/01/1998	19980107003	Female
Winson	David	28/08/1982	19820828672	Male

Go to a patient profile

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

Create remote monitoring assessments for that patient (see further).

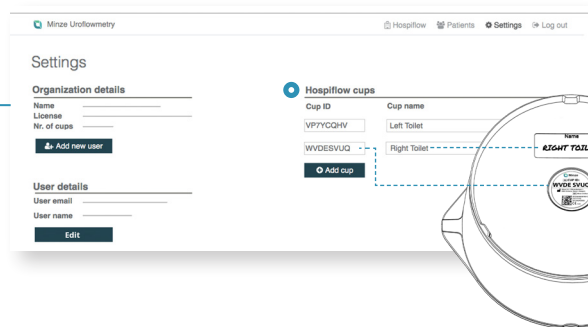
Analyse remote monitoring assessments performed by that patient (see further).

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 the organisation** using the **cup ID** (at the bottom of the cup). The measurements on the Hospiflow page are **grouped** by the Hospiflow cups.

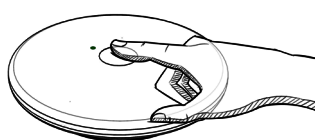
Tip: Give the cup a “friendly” name and write it in the name field at the bottom of the cup.



2. REGISTER A VOID WITH THE UROFLOWMETER AND ACCESSORIES

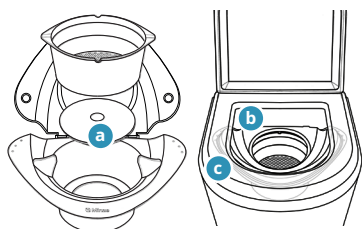
1

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)

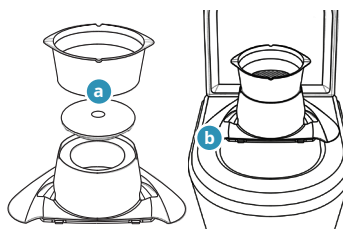
- a. Place the uroflowmeter in the pee-hat and put the cup on top.
- b. Close the shield of the pee-hat.
- c. Hang in the toilet underneath the toilet lid.



2

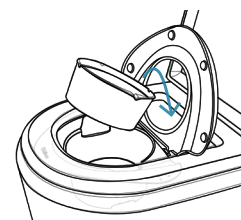
Assemble correctly (STANDING)

- a. Place the uroflowmeter on the pee-hat 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.



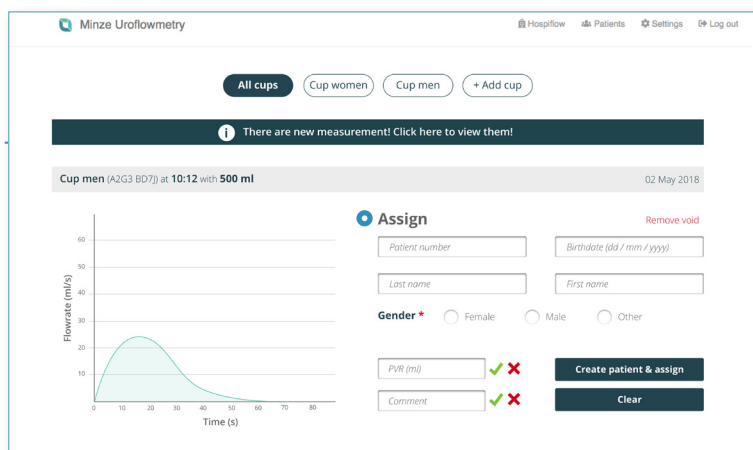
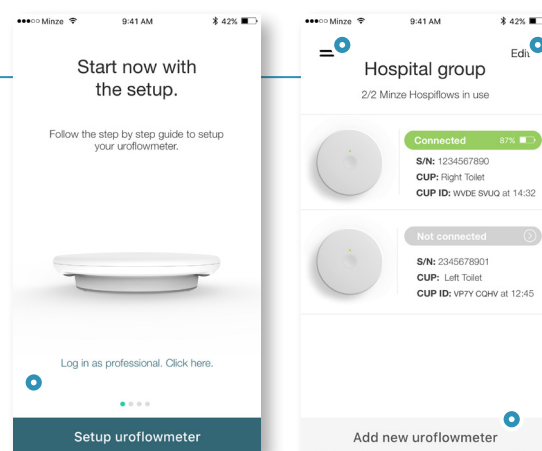
3. MEASUREMENTS SENT TO THE MINZE DASHBOARD THROUGH THE MINZE MOBILE APP

Make sure to **continue as clinician**: login using the same credentials as the ones used for the clinician portal.

In the app, the uroflowmeters for Hospiflow sessions can be **managed**: uroflowmeter(s) overview, add/edit uroflowmeters and the hamburger menu to access 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 provide guidance. The measurement is saved on the uroflowmeter until it is successfully sent.

The patient and clinician app are both within the same Minze Mobile app. The Minze Mobile app can be downloaded on the Play store for Android devices or on the App store for iOS devices. At least iOS 8.2. or Android 4.4. is required To run the app, a device with at least version iOS 8.2. or Android 4.4 and Bluetooth is required. These operating systems will be supported for at least the service life of the device. It is strongly recommended to keep the device 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

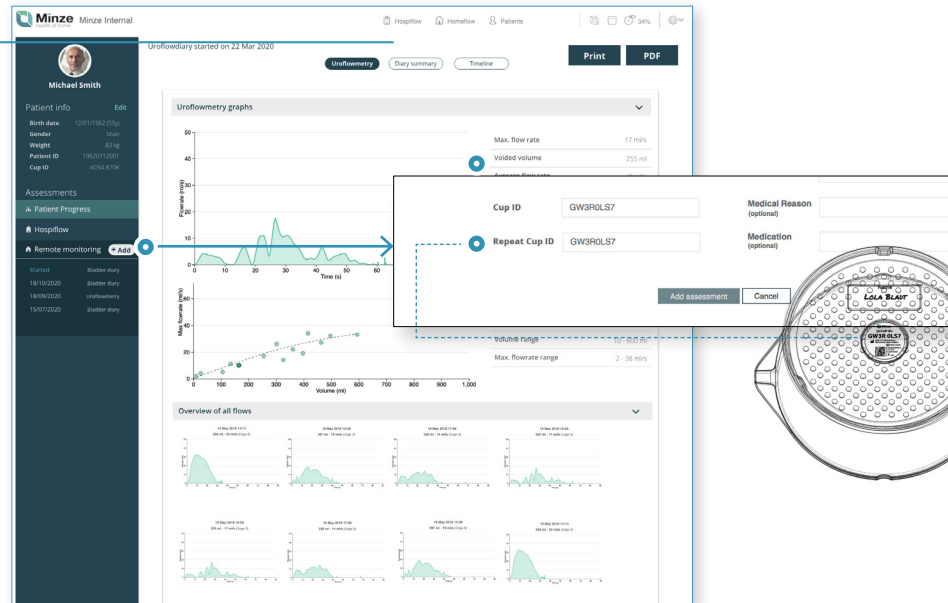
Select the **add remote monitoring** and fill in the required Homeflow assessment information.

Select an assessment type:

- **Uroflowmetry only** / Register voids at home during a couple of days.
- **Uroflow diary** / Register every void, drink and leakage during 24-hour cycles (from morning void of one day to morning void of the next day).

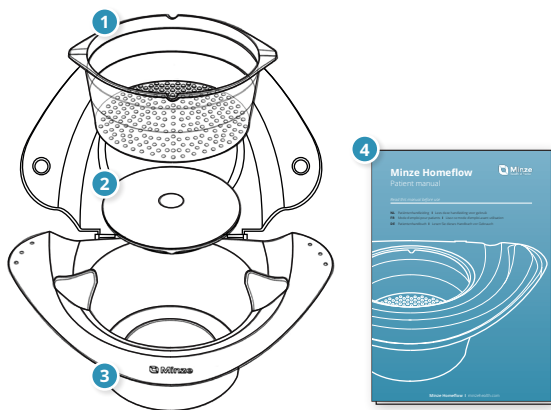
Link a Homeflow cup (transparent) to the patient using the cup ID (at the bottom of the cup). Once the patient is linked to this Homeflow cup, all voids registered with this cup will end up on this patient's profile. The patient is not bothered with a username and password, because the NFC-tag contains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

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



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



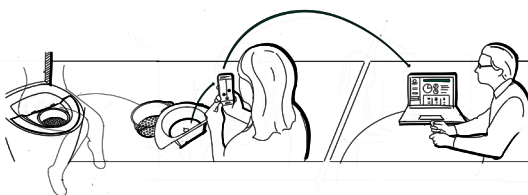
Make sure to provide every patient with:

1. **Transparent Homeflow cup linked to the patient**
2. **Uroflowmeter with batteries inside** (green light when it is turned 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 the clinician is aware what the patient has to do at home, so additional verbal instructions can be given if needed.

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



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

Select assessment

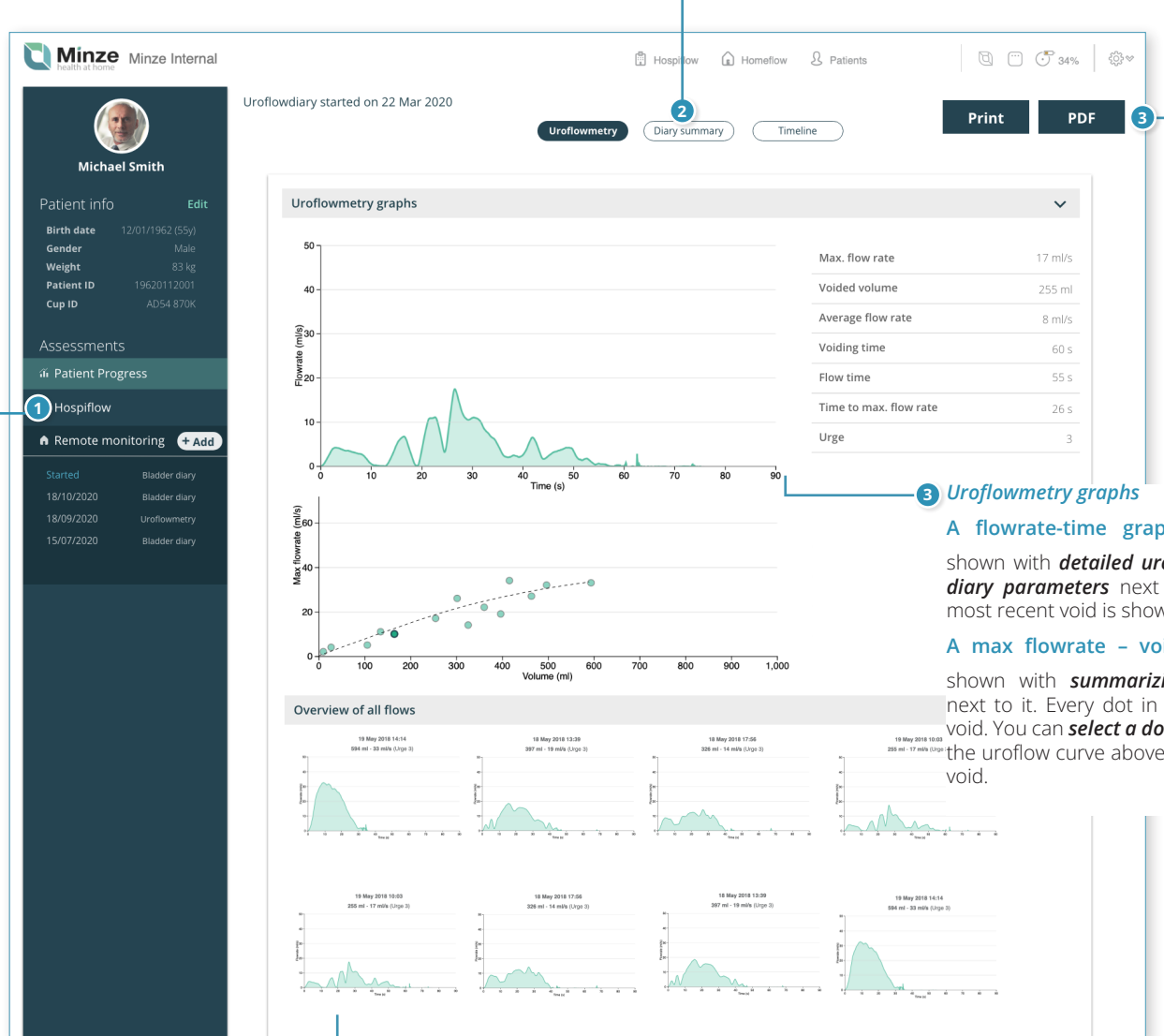
In the left bar of the patient's profile page, the assessment history of the patient can be found. The assessments mention a type (**Hospiflow, Uroflow Diary, uroflowmetry only or voiding diary**) and date. Select the assessment to analyse the data.

Overview and cycles (in case of voiding diary)

In case of a voiding diary, select the data of a **specific cycle or an overview of all cycles**. The data are shown in different fields (uroflowmetry graphs, voids overview, etc.). The data in every field via the "arrow icon" can be hidden or revealed..

Export to PDF

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



Voids overview

Uroflowcurves view

An overview of all the uroflow curves is shown, which can be **sorted by time, volume or urge**. A uroflow curve can be selected to update the uroflowmetry graphs above with the newly selected void.

Voiding diary view

In case of a voiding diary, an overview of the voids, drinks and leakages in a standard voiding diary table is displayed. A void out of this table can be selected to update the uroflowmetry graphs above with the newly selected void.

3.4 / GATHER VOIDING DIARIES

A voiding diary is the objective recording and documentation of the bladder function. To keep a voiding diary, the user needs to record their voiding habits for at least 2 days.

1 / CREATE AN AUTOMATED OR DIGITAL BLADDER DIARY ASSESSMENT

There are three types of voiding diary assessments: an assessment using the Minze Diary Pod, an assessment without the Minze Diary Pod, and one where only voided volumes are tracked. This needs to be selected in the Minze dashboard by the clinician.

Home assessment details	Home assessment details
Type of device and assessment*  ☒ Bladder diary ☐ Void volume only ☐ Digital bladder diary (no hardware)	Type of device and assessment*  ☐ Bladder diary ☐ Void volume only ☒ Digital bladder diary (no hardware)

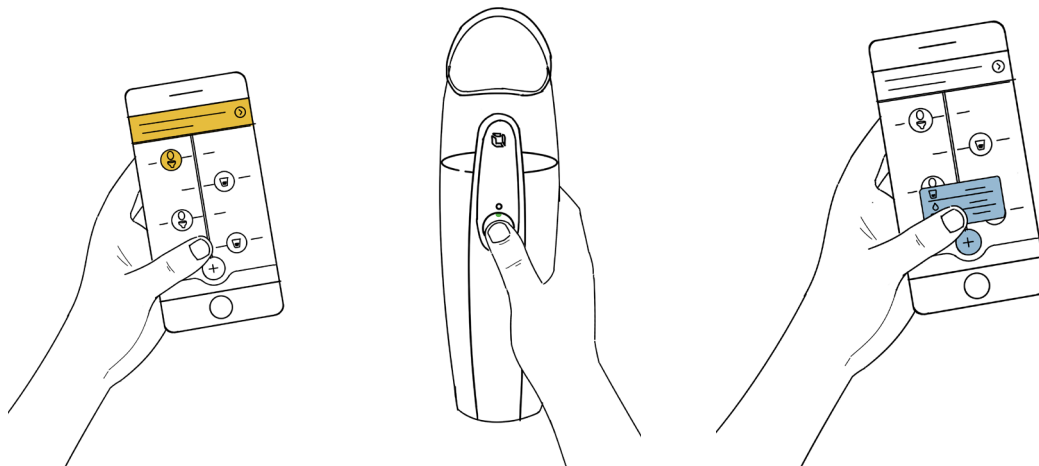
Next to the Diary Pod, there are 3 options where the clinician can choose from.

2 / SEND PATIENT HOME, PATIENT KEEPS A BLADDER DIARY

The patient uses the Minze Diary Pod with the Minze Mobile App, and patient manual. Some important remarks related to Bladder Diaries:

- ! Voiding diaries are kept in cycles: a cycle starts from a morning void and ends with the morning void of the next day!
- ! The recommended cycle duration is typically between 2 to 7 days, which may or may not need to be consecutive. However, adherence to the clinician's instructions is always essential.
- ! Register all voids using the Minze Diary during a cycle.
- ! The Minze Diary can connect to the Minze Flow app to provide additional information related to the void. When using the Minze app, also record your fluid intake and leakages in the app.

Using the Minze Mobile App:

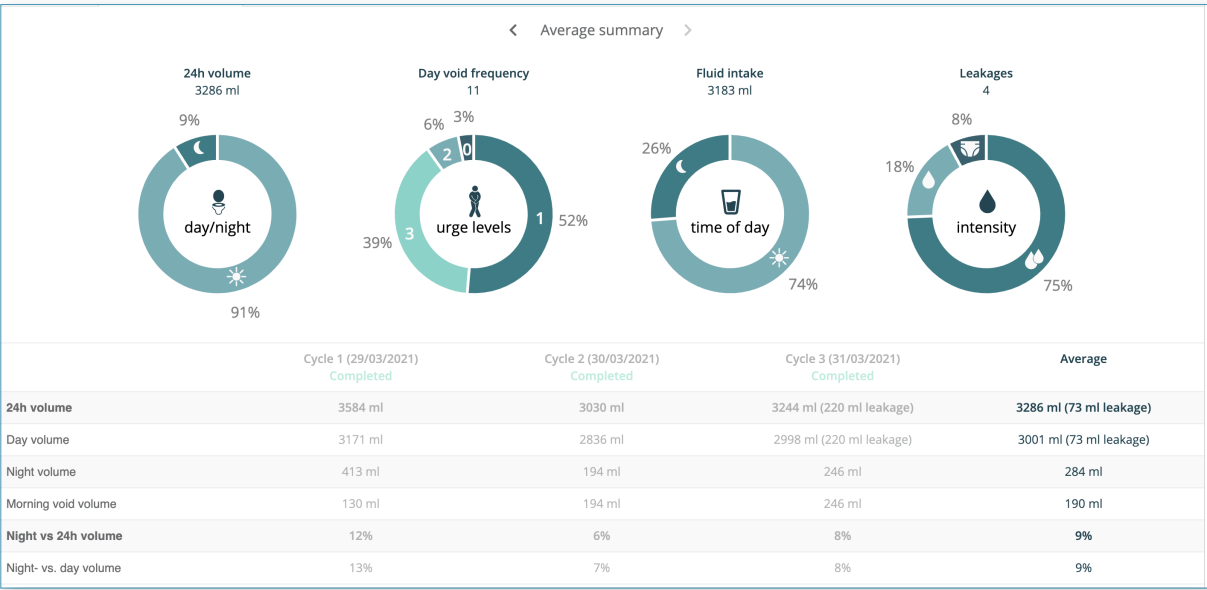


Answer the voiding diary questionnaire by selecting the void coming from the Diary Pod or by adding the void manually. In case of the Diary Pod, make sure the phone's bluetooth is on and the Minze Diary Pod is within range. Press the button again to try to reconnect with the app.

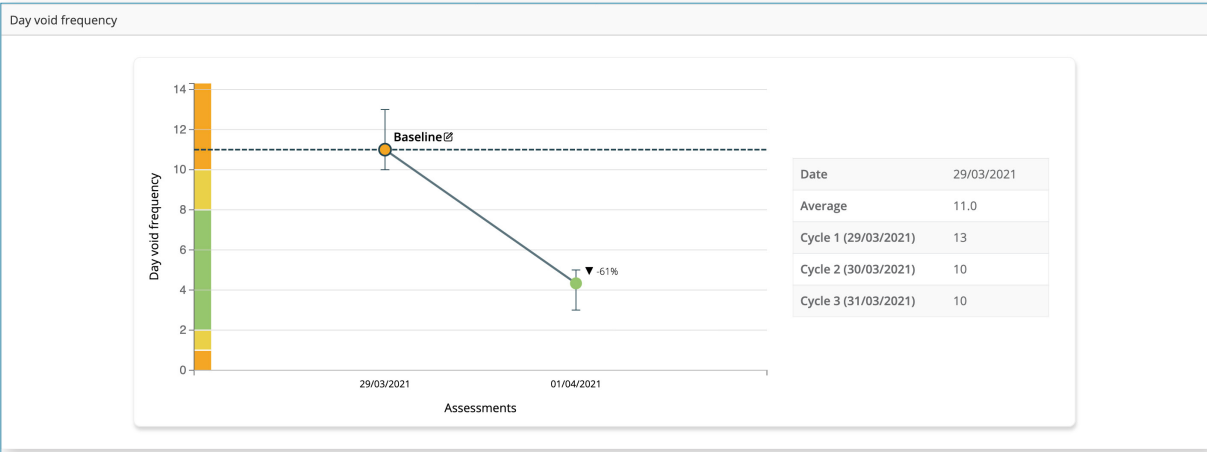
Use the "+" button in the app to complete the bladder diary by adding drinks and leakages to your diary timeline. Answer the questionnaire related to the event that is being added.

3 / ANALYSE VOIDING DIARY ASSESSMENTS ON THE MINZE DASHBOARD

The data collected by the Minze voiding diary gives an overview of voiding and drinking trends over a period of time (cycles). The data can be accessed either via the Minze dashboard.



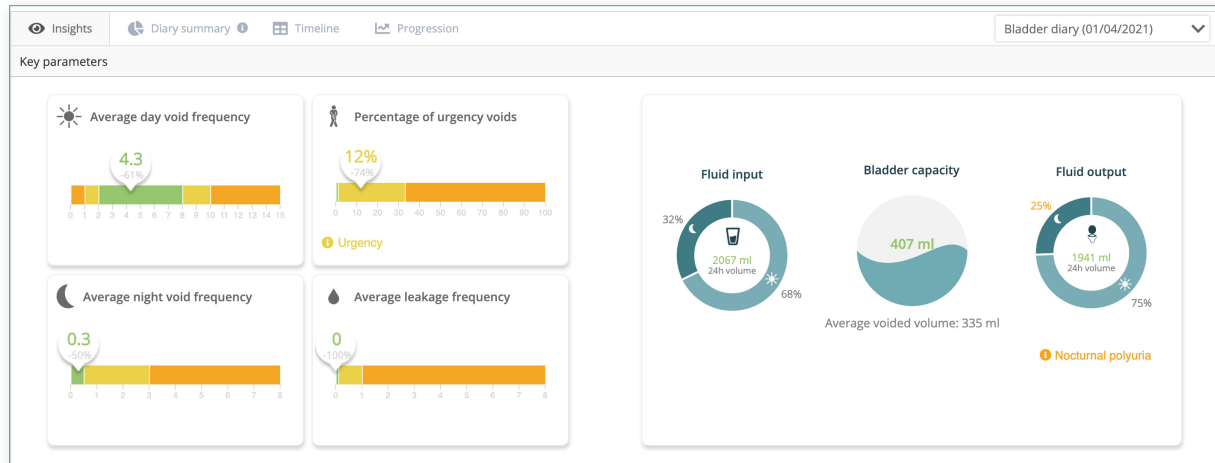
Access data via the Minze Dashboard. Users who make use of the Minze Dashboard, can access the data there. Make sure to create a patient and an assessment first. Link the Minze Diary ID to the patient in order for the data to automatically and in real-time end up on his or her patient profile.



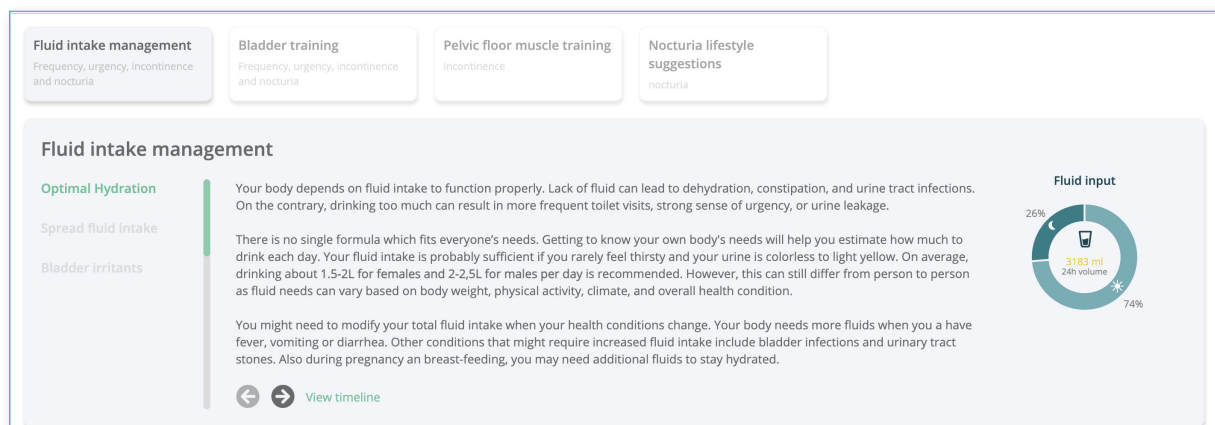
In the Minze Dashboard, the clinician can track patient progress for multiple relevant parameters like day void frequency, average day volume, etc

4 / LIFESTYLE ADVICE AND BEHAVIORAL THERAPY TECHNIQUES FOR PATIENT WITH LOWER URINARY TRACT SYMPTOMS.

Following completion of a bladder diary, users gain access to a simplified dashboard presenting a synopsis of their diary outcomes. Furthermore, evidence-based lifestyle advice and behavioral methods, collectively termed conservative therapy, are offered. These encompass fluid intake management, bladder training, pelvic floor exercises, and nocturia lifestyle suggestions. The clinician retains the option to enable or disable this feature as needed.



Based on international guidelines, simplified dashboard of the bladder diary results. This can be made available to the patient.



Based on international guidelines, evidence and guideline-based lifestyle advice and behavioral methods. This can be made available to the patient.

5 / WARNINGS & PRECAUTIONS

This section is intended for:

- users performing investigations by using the Minze Platform (e.g. the clinician)

There are no warnings and precautions for the Minze Platform.

No residual risks have been identified which are required to be communicated to the user and/or other person under warning and precaution.

6 / EXPLANATION OF SYMBOLS

The list below gives an explanation of the symbols on the Minze Platform



Declaration of conformity according to the applicable European directives



Reference, product name.



Serial number.



Name and address of the manufacturer.



Medical Device



Unique Device Identification (UDI)

7 / NOTICE



Any serious incident that has occurred in relation to the device should be reported to Minze and the competent authority of the Member State in which the user and/or patient is established.



Minze N.V.
Lange Gasthuisstraat 29/15, 2000 Antwerp
Made in Belgium



**Minze Platform -
Installation and Operation
Instructions**
v3 EN / March 2024



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latest version of this document