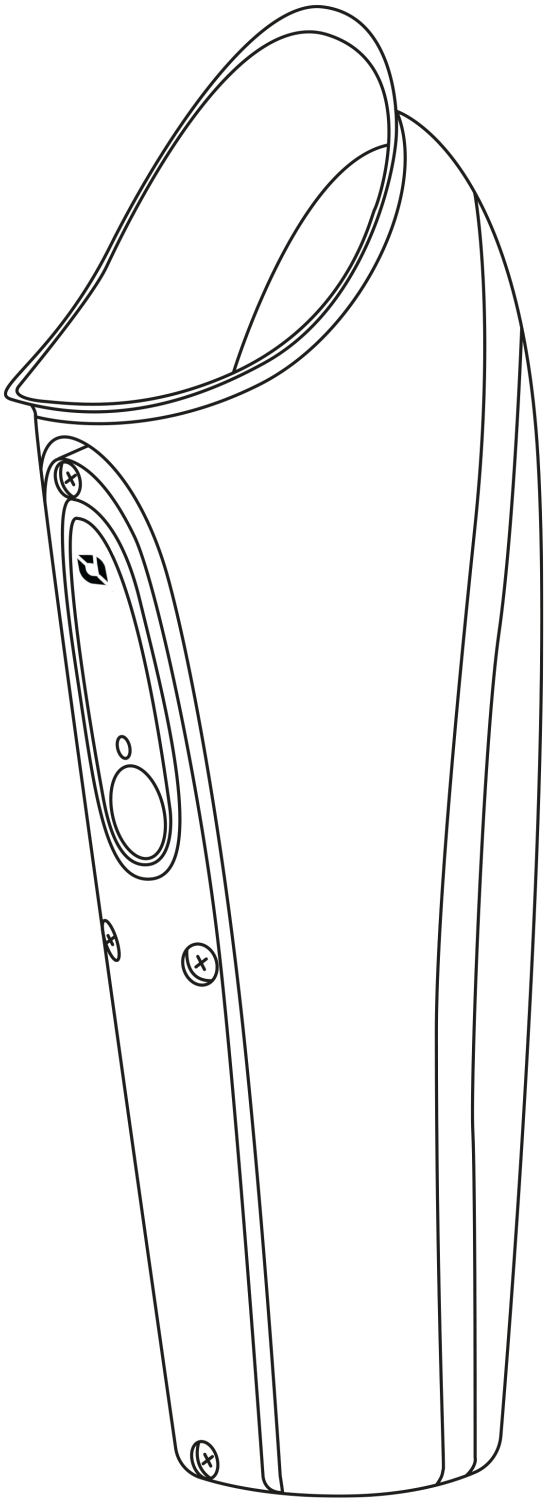
MINZE DIARY

v4 EN / June 2021

Instructions for use

Read this manual before use



Minze
health at home

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1 / INTRODUCTION TO MINZE DIARY

1.1 / INTENDED USE

Minze Diary is a device intended to automatically track voided volume trends over a time period to assist patients in keeping a bladder diary. The Minze Diary is used without the need for professional supervision (e.g. at the home of the patient).

The Minze Diary device does not diagnose or recommend treatment.

1.2 / INTENDED USER PROFILES

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

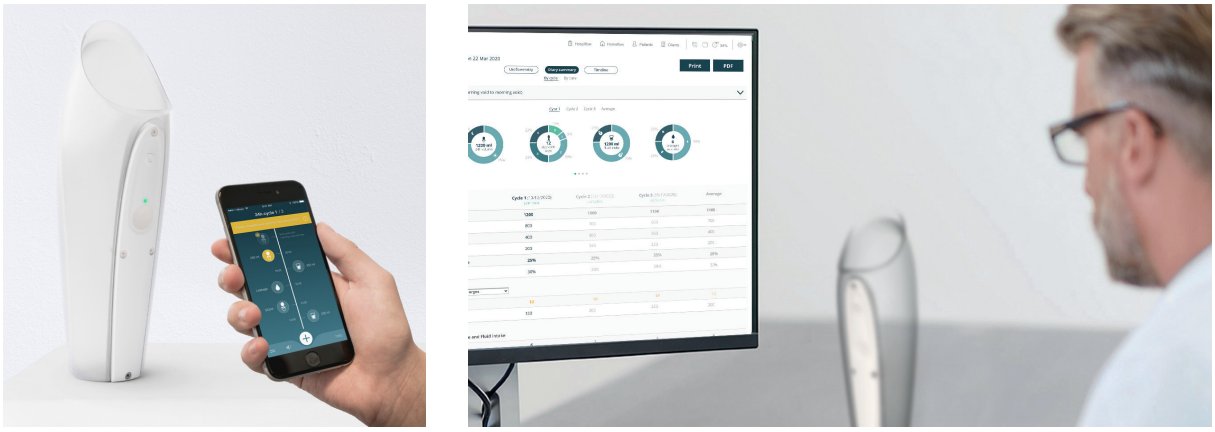
Professional user
The professional users are clinicians and assistants. Clinicians should have a medical degree and experience using bladder diaries for the diagnosis, monitoring and treatment of patients with urologic conditions.
Assistants should have a medical certification or nursing degree and experience in the operational process of diagnosis, monitoring and treatment of patients with urologic conditions using bladder diaries: explanation to the patient, collecting and processing the data,...
The Minze Diary device is compatible with the Minze health software products.

Lay user
The Minze Diary is intended to be used by toilet-trained children, adults and elderly of all genders. Lay users should be mentally competent or assisted by a mentally competent supervisor/caregiver.
The lay users can be healthy individuals or patients suffering from lower urinary tract (LUT) symptoms/dysfunctions, including neurogenic LUT dysfunctions. Healthy individuals use the Minze Diary as an informational tool in the context of staying hydrated and drinking enough water (general purpose). Patients use it in the context of screening, diagnosis and monitoring of their LUT symptoms (medical purpose).
The Minze Diary device is not sterile. Patients who underwent a procedure or have another form of injury in the genital area should contact their clinician before use.

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

Minze Diary is a portable, single-patient device to track voided volume trends during bladder diary cycles (from morning void to morning void the next day). It can be used by clinicians to receive more objective information about a patient's lower urinary tract system. It is possible to use the Minze health software products (Portal and app) to manage and assess the bladder diary assessments. The Minze patient app can be used to assess the data and add additional information, like urge, incontinence and fluid intake. The Minze Diary can be used for general purposes or medical purposes. In case of general purposes, healthy individuals can use it as an informational tool in the context of staying hydrated and drinking enough water. In case of medical purposes, clinicians can use it in the context of diagnosis and monitoring of patients with lower urinary tract conditions.



Minze Diary device is compatible with the Minze health software products: the Minze patient app (left) and Clinician Portal (right)

1.4 / SYSTEM DESCRIPTION

The Minze Diary uses capacitance technology to measure height in the receptacle and convert it to volume indications. It also contains an accelerometer sensor to correct for a horizontal angle when holding the receptacle. Additionally it can detect excessive movement or a drop during use.

The Minze Diary uses Bluetooth Low Energy (BLE) technology to wirelessly send data from the device to the Minze App. The operating system on the smartphone or tablet that runs the Minze Flow app can either be iOS or Android.

1.5 / CONTENT

The Minze diary is a portable, single-patient device. The measuring unit and electronics (battery, memory,...) are all integrated in the receptacle and permanently affixed.
The battery doesn't need to be changed during the expected service life of the product under normal conditions and handling as described in this manual.

Minze Diary - Receptacle (transparant part) with permanently affixed measuring unit and electronics (white part)

⚠ CAUTION

Never try to remove parts from the Minze Diary by pulling them, unscrewing them or using sharp tools. Doing this could permanently damage the device.

2 / TECHNICAL INFORMATION MINZE DIARY

2.1 / OPERATING REQUIREMENTS

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

- 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
- In case the environmental conditions during transport or storage were outside the specified ranges of operation, ***let the device adapt to operating conditions for at least 15 minutes before use.***

2.2 / USER INTERFACE

The user interface of the Minze Diary exists out of a button and light. By shortly pressing the button you activate the device, indicated by the light going on. The device will assess what to do depending on the situation:

- If there is liquid inside of the receptacle, it will register the liquid level, indicated by: a slow blinking light (registering), followed by a steady light for 5 seconds (processing) and finally a double blink light (successfully registered and saved to memory)
- If there is a smartphone with the Minze app nearby (within bluetooth range), it will connect to it. If there are voids in memory, they will be sent to the app.
- If there is no liquid inside the receptacle and no smartphone with app nearby, the device will go to sleep mode after a few minutes.

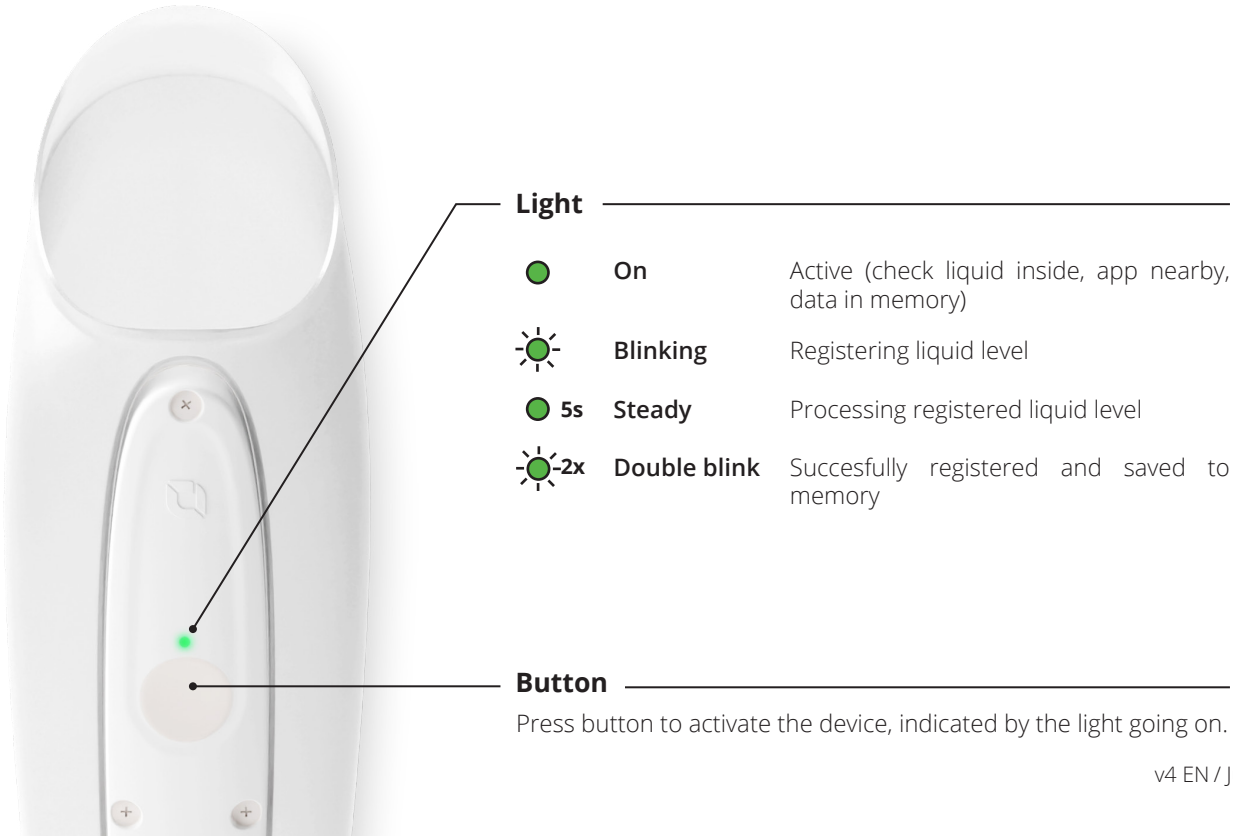
2.3 / OUT OF BATTERY

When the Minze Diary is out of battery, the light will not turn on anymore when pressing the button. The batteries are non-rechargeable and non-replaceable, do not make any attempt to recharge or replace them! However, under normal conditions and handling as described in this manual, the battery should last at least as long as the expected service life of the product (up to 1000 voids).

2.4 / SERVICE AND MAINTENANCE

The Minze Diary 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.

⚠ CAUTION ***Never attempt to recharge or replace the batteries; and never attempt to repair or modify the Minze Diary on your own. If you have any issues, please contact Minze Health or a representative. You can find the latest contact details www.minzehealth.com.***



2.5 / TECHNICAL SPECIFICATIONS

DEVICE CHARACTERISTICS

General

- Technology: Capacitance to measure height in the receptacle and convert it to volume indications
- Dimensions: 250mm (height) x 100mm (depth) x 70mm (width)
- Weight: 100 g
- Housing material: PE (receptacle), ABS (cover hard plastic), TPE (cover soft plastic)
- Degree of protection: IP 65
- Label material: top coated polyester (thermal transfer; permanent acrylic adhesive)
- Electronics solder: lead free
- Bluetooth: version 5

Battery

- CR2032 button cell (non-rechargeable and non-replaceable)
- Shelf life: 4 years
- Expected service life: Device can register up to 1000 voids before it runs out of battery

Specifications

- Unisex usage: Can be used by men, women and children
- Volume capacity: Collect up to 600ml; measure up to 500ml
- Volume indications: within the greater of ±10ml or ± 10% (in regard of the scope of the intended use)

TRANSPORTATION, STORAGE AND OPERATION REQUIREMENTS DEVICE

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
- In case the environmental conditions during transport or storage were outside the specified ranges of operation, **let the device adapt to operating conditions for at least 15 minutes before use.**

CLASSIFICATION/APPROVAL

- MDD, Medical Device Directive 93/42/EEC, Class I medical device.
- EN 60601-1 (Medical Electrical Equipment)
- EN 60601-1-2 (EMC)
- EN 60601-1-6 (Usability)
- EN 60601-1-11 (Home Healthcare Environment)
- EN 60529 (Degrees of Protection Provided by Enclosure – IP Code)
- EN 301 489 (Electromagnetic Compatibility and Radio Spectrum Matters)
- EN 301 489 – 1/17 (Compliance to article 3.1b of the RED 2014/53/ED)
- EN ISO 15223-1 (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)

3 / PERFORM A BLADDER DIARY ASSESSMENT

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 / KEEP A BLADDER DIARY WITH THE MINZE DIARY

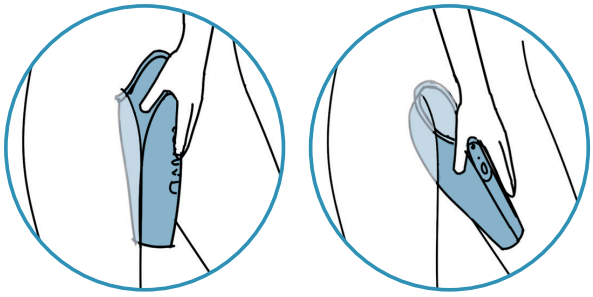
A bladder diary is the objective recording and documentation of the bladder function. To keep a bladder diary, the user needs to record their voiding habits during a couple of days. Some important remarks:

- Bladder diaries are kept in cycles: a cycle starts from a morning void and ends with the morning void of the next day!
- The amount of cycles you need to keep is normally 3, which can be, but don't have to be consecutive. However, always do as the clinician requested.
- 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.

3.2 / REGISTER A VOID USING THE MINZE DIARY

1. Urinate in the receptacle

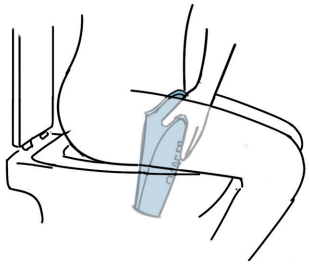
First, find a position and orientation of the Diary Pod that feels most natural and comfortable. For women it is advised to position it closely against the body, so all urine properly runs in.



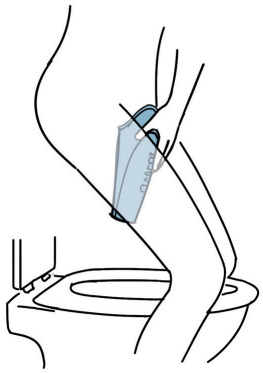
If your urine stream is strongly angled to the back (e.g. women with prolapse), you can try to orient the receptacle in the opposite direction.

Next, choose a comfortable voiding posture: standing, sitting, squatting,...

Standing

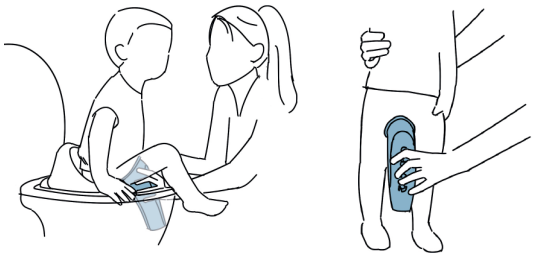


Sitting

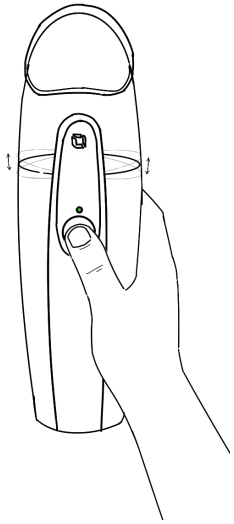


Squatting

If you are assisting people (e.g. children), choose the most comfortable position: sitting or standing. Make sure you collect all urine. Definitely with girls/women, you have to make sure the receptacle is properly placed against their private parts.



2. Register the liquid level



After collecting the urine in the receptacle, press the button to register the liquid level. The light will go on.

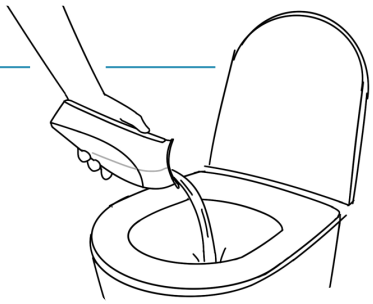
A slow blinking light indicates the device is registering. Try to hold it still (or place it on a flat surface), in order for the liquid level to be stable.

2s Once the level is stable and registered, the light will go steady, indicating the device is processing the data.

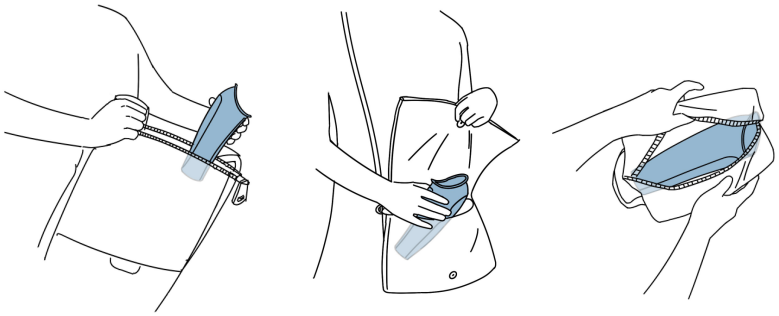
2x When the level is successfully registered and saved to memory, the light will double blink.

3. Empty the receptacle

Empty the receptacle and clean it afterwards (see next chapter for cleaning instructions).

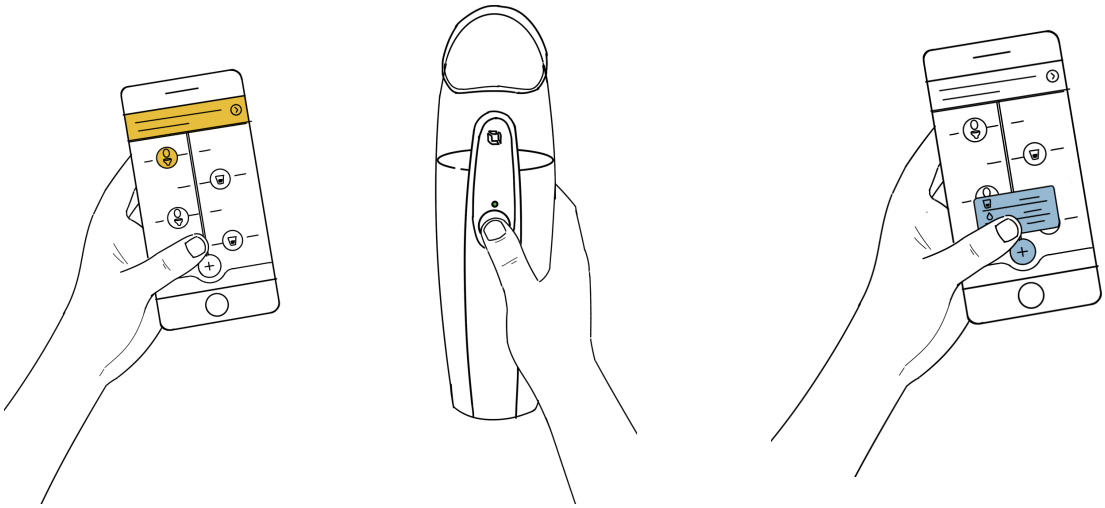


4. Store away



The Minze Diary is made to be easily stored away, also when living an active life. It fits in a backpack, a purse, a toiletry bag,...

3.3 / USE THE MINZE FLOW APP

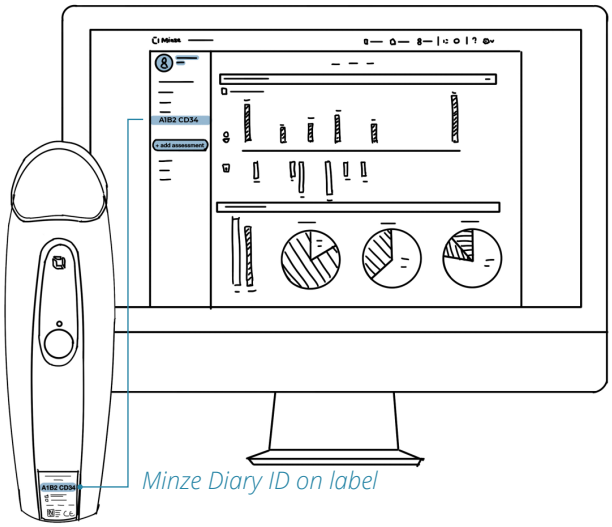


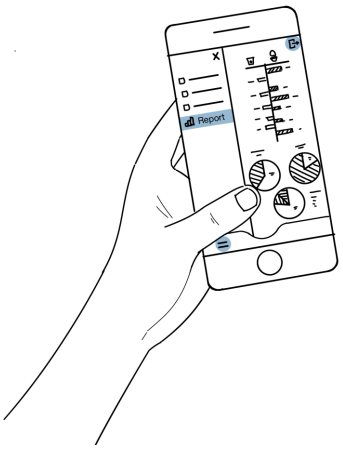
If a smartphone with the Minze Flow app is nearby, the device will automatically connect and a notification of a new void should appear. Answer the bladder diary questionnaire by selecting the void. Make sure your phone's bluetooth is on and the Minze Diary device is within range. Press the button again to try to reconnect with the app.

Use the "+" button in the app to complete your bladder diary by adding drinks and leakages to your diary timeline. Answer the questionnaire related to the event you're adding.

3.4 / ACCESS THE BLADDER DIARY DATA

The data collected by the Minze Diary gives an overview of voiding and drinking trends over a period of time (cycles). The data can be accessed either via the Minze Clinician portal or the Minze app.





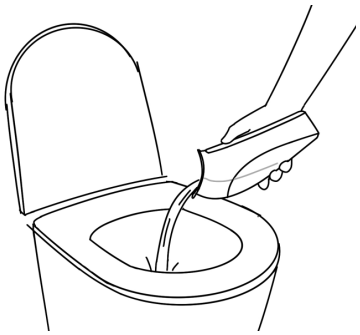
Access data via the Minze Clinician Portal
Users who make use of to the Minze Clinician Portal, can access the data there. Make sure to create a patient and an assessment first. Link the Minze Diary ID to the patient in order for the data to automatically and in real-time end up on his or her patient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

Access data via the Minze Flow App
There is an option in the Minze Flow app to export a report and send it to an e-mail address. The user has the option to print or share this report with other people, like a clinician.

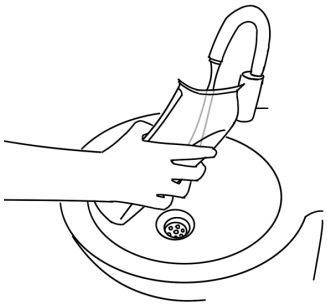
4 / CLEANING INSTRUCTIONS

The Minze Diary is a single-patient use device and a Non-critical Patient-care Item. In order to keep the device clean during use (single-patient), follow the recommended cleaning and disinfecting (low-level to intermediate) instructions in this manual. Always check in with internal procedures.

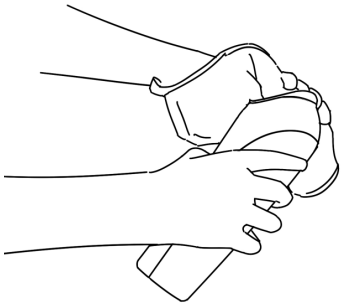
After every void, you should at least:



1/ Empty the receptacle

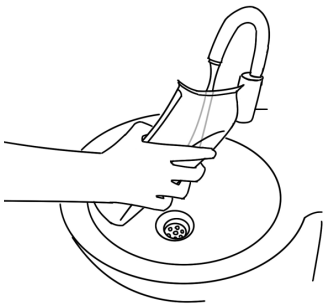


2/ Rinse it with cold water (< 43° C)

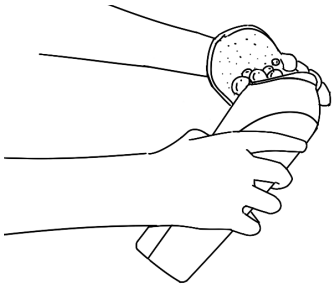


3/ Dry it with a dry clean cloth or let it air-dry

At the end of bladder diary cycle, it is recommended to:

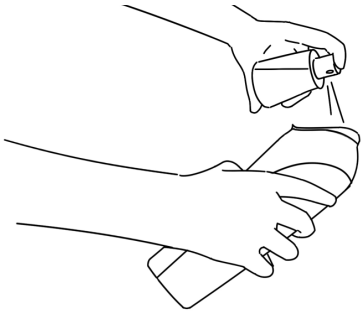


1/ Rinse in cold water (<43°C) to remove gross debris.



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) with a contact time of at least 1 minute.

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

⚠ CAUTION ***To prevent water damage to the system/electronics: never immerse the Minze Diary for several minutes in water or other liquids; and never use excessive amounts of water to clean the device.***

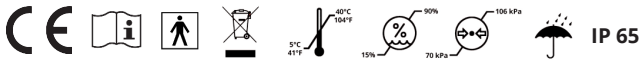
⚠ CAUTION ***Store the Minze diary in a dry, dust-free and clean environment between uses.***

5 / TROUBLESHOOTING MINZE DIARY

Can't find a solution for your problem? Found a bug, suggest an improvement or report an issue with the product?
Visit the Minze Help Center or contact Minze Health or a representative for assistance. You can find the latest details on www.minzehealth.com (support page).

Problem	*Symptom*	*Remedy*
Device dropped in toilet	Device slipped/fell in the toilet.	*Clean, dry and disinfect immediately. Visually examine for damage.*
Visual damage to device	Dents, broken parts, deformation, deep scratches, holes, etc.	*Do not attempt to repair or modify the Minze Diary. Please contact Minze Health or a representative. You can find the latest contact details on www.minzehealth.com.*
Void not successfully registered	After pressing the button, the light is slowly blinking (registering), but this is not followed by a steady light and double blink.	*Check/try the following:* • *Is the volume inside the receptacle very small (only just filling the bottom surface or less)? If so, the volume is too small to be registered. Please add this void manually in the app using the "+" button.* • *Are you shaking/moving when trying to register? The device needs a more or less stable liquid level in order to successfully register. Try to keep the device in a stable position. If you fail to hold the device more or less stable, put it on a surface (toilet, table, shelf,...).*
Device doesn't activate	Light doesn't go on when pressing the button	*Either your device got damaged by abnormal handling/ conditions or the device is out of battery (beyond its service life). Do not attempt to repair or modify the Minze Diary. Please contact Minze Health or a representative. You can find the latest contact details on www.minzehealth.com.*
Device doesn't connect with Minze app	In the app a message is shown that there is no connection established with the Minze Diary device. Voids saved in memory don't appear on the timeline.	*Make sure:* • *Bluetooth is turned on (and location in case of Android users) on your smartphone.* • *Your smartphone is connected to the internet (WiFi or cellular connection, like 3G or 4G).* • *You pressed the button on the Minze Diary device and the light turned on.*
Bladder diary data not uploaded to Minze Clinician portal	Clinicians making use of the Minze Clinician portal don't see the data arriving on the patient's profile.	*Make sure:* • *You added the patient in the portal (patient overview page).* • *You created a bladder diary assessment for that patient (patient profile page).* • *You linked the Minze Diary ID to the patient (during assessment creation).* • *The patient used the Minze app and properly established connection (bluetooth and internet).*

6 / CAUTIONS



The cautions in this appendix are intended for:
- professional users performing investigations by using the Minze Diary (e.g. the clinician);
- lay users or caregivers supervising someone (e.g. children); healthy users or patients.

Please take notice of the cautions as described in this appendix. In case the Minze Diary is used for its medical purposes, it should 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 Diary 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 Diary must be used and stored in a dry, dust-free and clean environment. In case the environmental conditions during transport or storage were outside the specified ranges of operation, let the device adapt to operating conditions for at least 15 minutes before use.

Minze will not give any guarantee or take any responsibility for any Minze Diary part which has been opened, adjusted or replaced.

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 Diary will prove to be durable and reliable.

There are no generally known conditions in the home healthcare environment that can unacceptably affect the basic safety and essential performance of the device. There are only precautions to be taken to prevent damaging the device. The following sign is used in this manual indicating important precautions:

⚠ 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 / GENERAL

⚠ CAUTION To achieve an effective and safe usage, the Minze Diary needs to be used in accordance with the information provided in this manual.

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

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

⚠ CAUTION Product performance can be violated if the device:
- shows visible damage;
- fails to perform the intended use;
- has been subjected to prolonged storage under unfavorable conditions;
- has been subjected to severe stresses in transit;
- has been handled by unqualified personnel.

⚠ CAUTION If the device shows visible damage or changes in the performance, stop using it and contact your doctor or healthcare professional.

⚠ CAUTION The reuse of a Minze Diary device for another patient/user is not allowed to avoid the risk of cross-contamination and mixing up data.

⚠ CAUTION Investigation procedures as described in the 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.

⚠ CAUTION Keep the Minze Diary and its packaging out of reach of children and let children only use it under supervision of an adult. This is to avoid abnormal handling by children which could affect their safety and/or damage the system: e.g. to avoid the danger of suffocation (packaging) and of swallowing small parts in case of misuse (unscrewing parts, broken parts,...).

⚠ CAUTION Keep the Minze Diary out of reach of pets, pests and other animals to avoid damage to the system.

⚠ CAUTION In the very rare case of an allergic reaction during use of the Minze Diary, immediately stop using it and contact your doctor or healthcare professional.

⚠ CAUTION Do not press the receptacle excessively hard against the skin to avoid a very rare chance of injury.

6.2/ ELECTRONIC DEVICE

⚠ CAUTION Never attempt to recharge or replace the batteries; and never attempt to repair or modify the Minze Diary on your own. This is to avoid the danger of ingestion of the battery.

⚠ CAUTION The Minze Diary is considered electronic waste (e-waste). Always recycle according to local regulations. Improper disposal of e-waste may create an environmental contamination hazard.

⚠ CAUTION The Minze Diary 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 Diary.

Although interference issues caused by external sources are not expected, please avoid excessive use of heat sources near the device.

⚠ CAUTION Only use the Minze Flow app to establish Bluetooth connection with the Minze Diary. Do not try to connect using other equipment or other mobile applications.

⚠ CAUTION The smart device(s) connected to the Minze Diary must comply with the latest version of one of the following standards: the IEC 60950, EN 60950 or UL 60950.

6.3/ CLEANING

⚠ CAUTION To prevent water damage to the system/electronics: never immerse the Minze Diary for several minutes in water or other liquids; and never use excessive amounts of water to clean the device.

⚠ CAUTION Only use enzymatic detergent to manually clean the device. Never use other chemicals or techniques to prevent damage to the system.

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

⚠ CAUTION Store the Minze diary in a dry, dust-free and clean environment between uses.

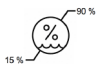
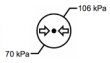
6.4 / SAFETY REGULATIONS

Minze Diary:

- Protection Class: internally powered.
- Type BF applied part: Part of Medical Electrical Equipment that in normal use necessarily comes into physical contact with the patient for Medical Electrical Equipment or Medical Electrical System to perform its function.
- Ingression protection: IP 65.

7 / EXPLANATION OF SYMBOLS

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

CE	Declaration of conformity according to the applicable European directives
REF	Reference, product name.
SN	Serial number.
	Name and address of the manufacturer.
	Type BF applied part Patient isolation from electrical shock.
	Read 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. Device needs to be disposed as electronic waste according to local regulations.
Contains FCC ID: Y86-DA14531MOD	The Minze Diary device contains a radio module which is FCC full modular approved.
	Special storage/handling conditions: store/use the Minze Diary device at temperatures between +5°C and +40°C (+41°F to +104°F).
	Special storage/handling conditions: store/use the Minze Diary device at a humidity between 15% and 90%, non-condensing.
	Special storage/handling conditions: store/use the Minze Diary device at an atmospheric pressure between 70 kPa and 106 kPa.
	Special storage/handling conditions: keep the Minze Diary device dry.

8 / WARRANTY

Minze NV (hereinafter referred to as “Minze”) warrants the Minze Diary device (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 Diary 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 Diary near other equipment.

Electromagnetic emissions

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

Emission test	Compliance	Guidance
RF emissions CISPR 11	Group 1	The Minze Diary 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 Diary 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 Diary is intended for use in the electromagnetic environment specified below. The customer or the user of the Minze Diary 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 Diary is intended for use in the electromagnetic environment specified below. The customer or the user of the Minze Diary 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 Diary 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 Diary is used exceeds the applicable RF compliance level above, the Minze Diary should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Minze Diary.

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 Diary

The Minze Diary is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Minze Diary can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Minze Diary 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

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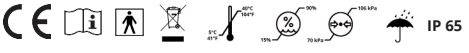
Offerandestraat 1, 2060 Antwerp
Made in Belgium

Minze Diary



Minze Diary -
Instructions for use
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