

Lutastic[®]+



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Lutastic+ Instructions For Use
V1 EN September 2025
Scope: Lutastic+ app v1.0.0 and higher

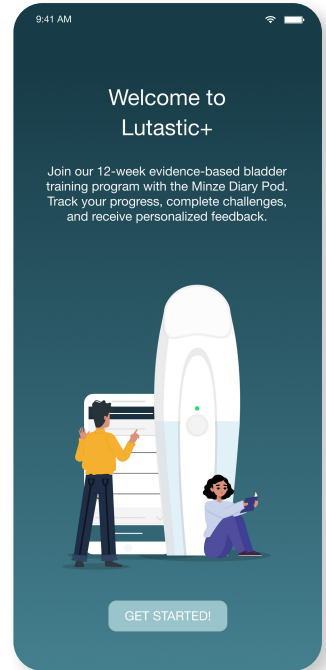
1. Getting started

Welcome to Lutastic+

Lutastic+ is a digital therapy for men with lower urinary tract symptoms. It guides you step by step through a 12-week program divided into six modules, developed in line with urological guidelines. You'll have one year of access, so you can continue using Lutastic+ for long-term support beyond the 12-week program.

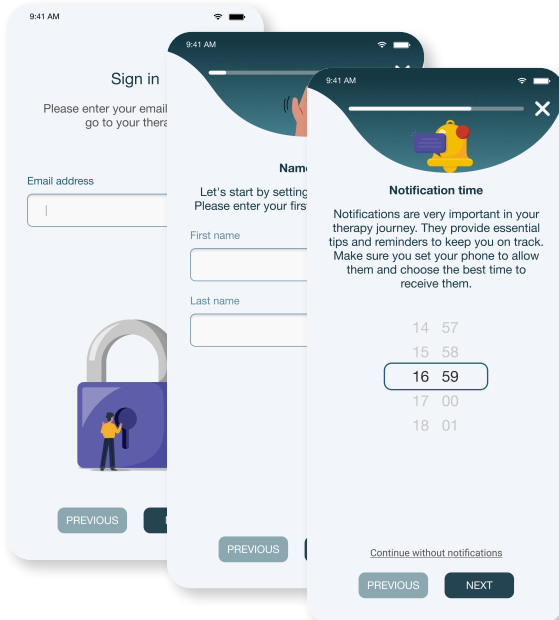
Download Lutastic+

Search for Lutastic+ in the App Store (iPhone) or Google Play Store (Android). Download and open the app.



Onboarding

Once you open the app, you'll be guided through a short onboarding process.



! Allow notifications!

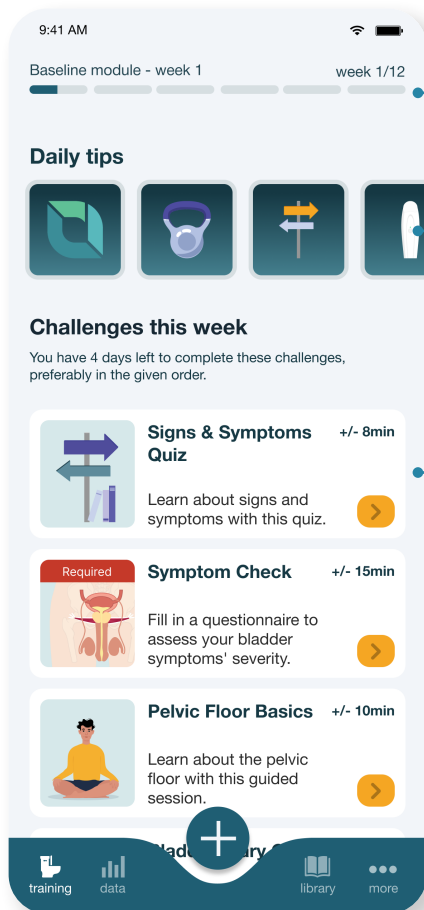
You'll be asked to allow notifications. Please make sure to click yes, as these reminders are an essential part of your therapy. You can choose a time of day that suits you best for receiving them.

2. Therapy overview

2.1. The home screen explained



After onboarding, you will arrive at your home screen, also called the training tab. The training program lasts 12 weeks, divided into 6 modules (Baseline, Crash Course, Routine Training, Progress Check, Refresh Training, Final Check).



Progress bar

The progress bar shows your current therapy week and module.

Daily tips

Each day, you receive a short tip at the time you selected in the onboarding. Tips include practical advice, quick quizzes, motivational content, or key takeaways. They take just a few minutes but help to keep your therapy top of mind.

Challenges per module

Each module contains a set of challenges to complete within that module's timeframe (ranging from 1 to 3 weeks). You choose how to fit them into your days—either spread them out or do several on the same day—but try to follow the order shown (top to bottom). Some challenges can also be scheduled so you can complete them at a convenient time.

! Program flow

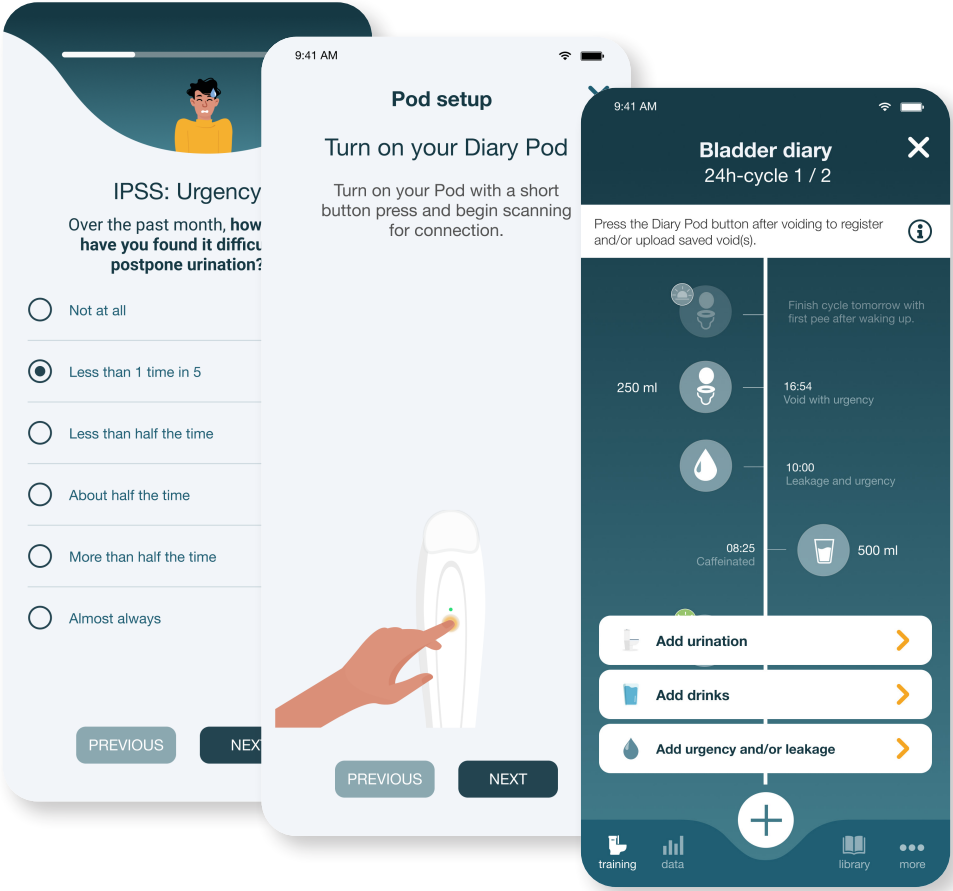
The Lutastic+ program runs automatically over 12 weeks, moving from one module to the next. Only the first module (Baseline) pauses until you complete the Symptom Check and Bladder Diary. So no worries if your Diary Pod hasn't arrived yet or you need a little more time.

2.2. Challenges explained

Challenges are at the core of the program. Each one has a time estimate, starts with a short introduction, and then guides you step by step. On a high level, these challenges fall into three main categories: symptom monitoring, education, and building habits.

Symptom monitoring challenges

Symptom monitoring challenges take place mainly in the Baseline, Progress Check, and Final Check modules. These include completing a symptom check, setting up your Diary Pod, and recording a bladder diary. They are important to understand your symptoms and to see how you progress.



Required

Symptom Check
+/- 15min



Fill in a questionnaire to assess your bladder symptoms' severity.

>

The **symptom check** uses validated symptom questionnaires to show whether your symptoms are mild, moderate, or severe.

The **Pod setup & intro** helps you connect your Diary Pod, understand how it works, and try a test measurement. It records the time and amount of urine when you press the button after urinating.



Pod Setup & Intro
+/-15min

Connect your Diary Pod and try it out.

>

Required

Bladder Diary
2 days



Keep a 2-day bladder diary using the Diary Pod.

>

During the **2-day bladder diary**, record each urination with the Diary Pod and log drinks, urgency, and leakages with the + button in the app. Start with your first morning urination after waking up and continue until the first morning urination on the 3rd day.

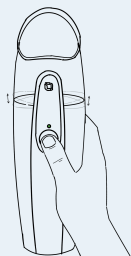
! Required challenges

The symptom check and bladder diary are required in the first module. So don't worry if your Pod hasn't arrived yet—the therapy will pause until you complete them.

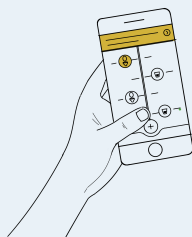
How to use the Diary Pod for challenges in the app



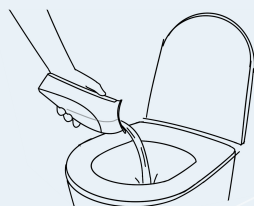
Urinate in the Diary Pod



Press the button after urinating



Open the app to check your measurement



Empty and clean the Diary Pod

⌘ Bluetooth needs to be on for Diary Pod challenges.

Phone not nearby? Don't worry, the Pod has a memory and stores your data when you press the button. It stays active for 10 minutes and will sync automatically once your phone reconnects. If more than 10 minutes have passed, just press the button again to sync.

Education challenges

Education challenges are especially central in the Crash Course module but appear in other modules as well. These challenges use interactive quizzes and guided sessions.



Signs & Symptoms Quiz +/- 8min
Learn about signs and symptoms with this quiz.

Quizzes are fun, interactive and educational—you just answer the questions, no preparation needed. Each answer unlocks part of an article, and by the end you’ve read the whole piece.

Guided sessions are interactive lessons where you’ll learn about topics such as the pelvic floor, urge suppression, dribble prevention, or voiding basics. You’ll learn and practice at the same time.



Pelvic Floor Basics +/- 10min
Learn about the pelvic floor with this guided session.

9:41 AM



Lower urinary tract symptoms
Difficulty starting to urinate, feeling the urge to go described as a symptom?

☐ Incomplete bladder emptying

☐ Hesitancy

☐ Post-void dribbling

☐ Intermittency

PREVIOUS

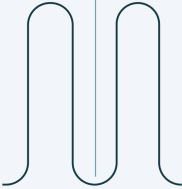
NEXT

9:41 AM

1. Short contractions

This exercise helps build awareness and strength. Contract your muscles for 2 seconds as the line goes up, then relax for 2 seconds as it goes down. Click “Next” to try.

contract relax



PREVIOUS

NEXT

Building habits challenges

Building habits challenges becomes the main focus in the Routine Training and Refresh Training modules. Here you'll find challenges such as pelvic floor training, bladder control, and the lifestyle log.



Pelvic Foundations +/- 15min
Strengthen your core and pelvic floor in this training session.

Pelvic floor training sessions uses animations to guide you through pelvic floor and core exercises, which become more challenging as you progress.

The bladder control challenge helps you gradually stretch the time between toilet visits. You record two urinations with the Pod to start and stop a timer, using urge suppression techniques to hold on longer.



Bladder Control +/- 1hour
Train your bladder to hold on longer using urge suppression techniques.



Lifestyle Log 1 day
Put the fluid intake tips into practice and pick one day to log.

The lifestyle log brings your daily habits into focus with tips on fluid intake, evening routines, and voiding techniques. Choose one day to track your drinks, toilet visits, urgency, and leakages using the + button, and see how lifestyle influences your bladder health.

9:41 AM

Bent Knee Lift and Extend

Go!



30



HOW TO

- Lie on your back with knees bent flat on the floor.
- Lift one leg towards your chest the knee bent, then extend it straight out. Alternate between legs.

Increase intensity: Use both legs simultaneously.

9:41 AM

Bladder control

Cancel

00 : 38 : 04

First pee 08:47 - 210

Second pee

Hold on as long as you can!

Can't hold it any longer? Pee into the Diary Pod, press the button on the Pod to stop the timer, and check your results.



9:41 AM

LIFESTYLE LOG

×

Drinks to avoid!

Skip coffee, alcohol, and soda in the evening. Try alternatives like flavored water, herbal tea, or a 0.0% drink. Stop drinking fluids 1-2 hours before bed.



NEXT

2.3. Menu guide

At the bottom of your screen you'll find the main menu. This gives you access to all parts of the app: the training tab, the data tab, the library, and the more tab.



This is your home screen. Here you'll find your daily tips, challenges, and progress bar. It's the main place where you'll follow your therapy day by day.



Here you can view your data from symptom checks, bladder diaries, bladder control challenges, and lifestyle logs, shown in charts with explanations.



The library is your knowledge base. Here you can find all the articles that support the therapy and revisit daily tips from previous modules.



This is where you'll find your personal settings. You can update your profile, adjust your notification preferences, check your Diary Pod connection, and consult the privacy policy.

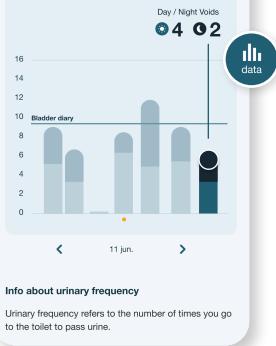
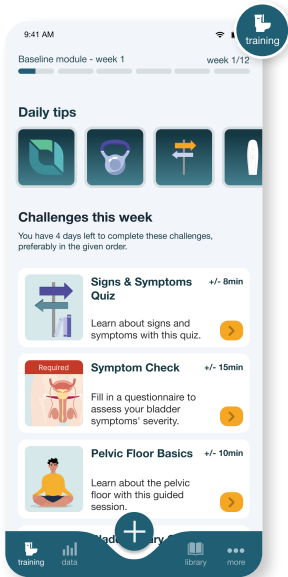


In the middle you'll see the + button, which you can use to add drinks, urinations, leakages and/or urgency episodes. When you're not logging, this button turns into a confetti button—tap it anytime for a motivational boost.

Just above the menu, you'll find a link to see all challenges of the 12-week program. This lets you redo challenges or catch up on ones you may have missed.

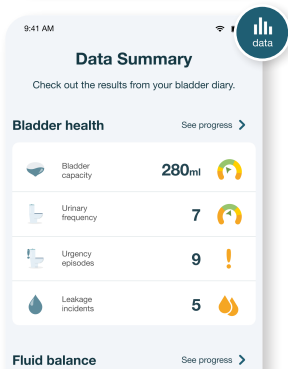
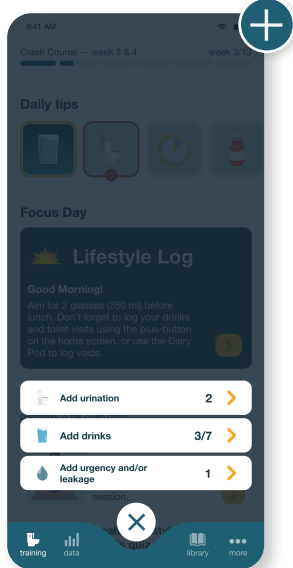
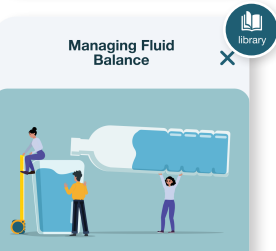
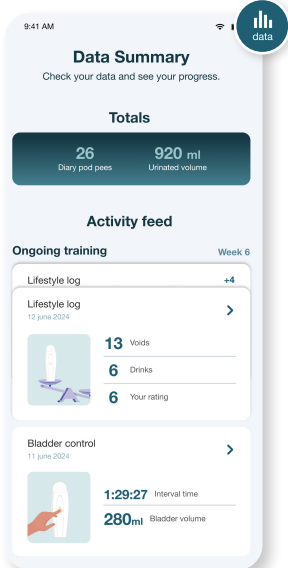
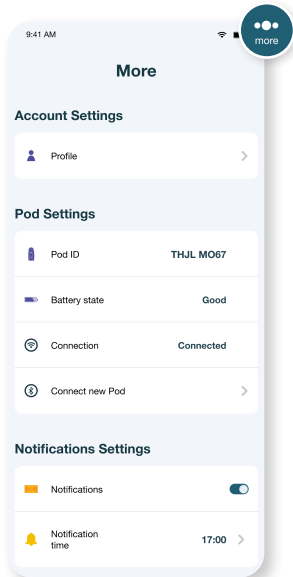
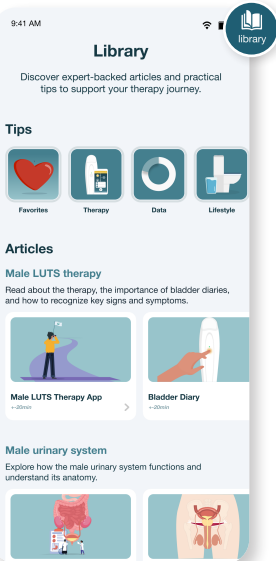
See all challenges of the 12-week program >





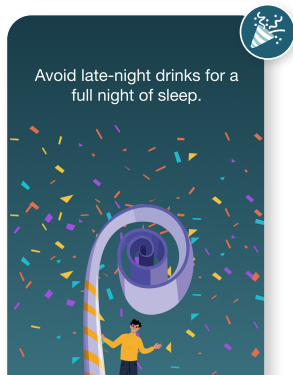
Info about urinary frequency

Urinary frequency refers to the number of times you go to the toilet to pass urine.



Optimal hydration

Your body can only store a certain amount of water or salt. If you have too much of either, your body will get rid of the excess in your urine, leading you to produce more urine. Urine overproduction can result in more frequent toilet visits, larger urine volumes, a strong sense of urgency, and urine leakage. Younger people usually get rid of excess water and salt during the day, but your body changes as you get older; you may start to experience nocturia, a need to urinate that wakes you up at night. Lack of fluid can also be a problem, as it can lead to dehydration, constipation, and urine tract infections.



3. Safety information

Intended use

Lutastic+ is a mobile health software application intended for use by adult male patients with lower urinary tract symptoms (LUTS) to support self-management of their condition by providing lifestyle advice and behavioral modification techniques, with the purpose of alleviating symptoms and improving quality of life.

Intended user

The intended user of Lutastic+ are the lay users.

The lay users are male patients suffering from lower urinary tract symptoms who were diagnosed by a physician with BPH (ICD-10 N40) and/or overactive bladder (ICD-10 N32.8). Patients use it in the context of self-management of their voiding and storage symptoms. 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.

Target population

The Lutastic+ mobile application is developed for men:

- who are at least 18 years old,
- who were diagnosed with BPH (ICD-10 N40) and/or overactive bladder (ICD-10 N32.8), and are under the supervision of a doctor or healthcare professional,
- who are physically and mentally able to carry out behavioral and physiotherapeutic exercises independently,
- who are able to speak and write German, Dutch or English fluently and
- capable of operating a smartphone or tablet.

Contra-indications

The Lutastic+ mobile application is not suitable for people with:

- Bladder dysfunction / symptoms that have not been clarified by a doctor / are unclear - such as for example visible blood in the urine, suspected cancer in the bladder or pelvic area or suspected urinary tract stones.

Warning & precautions

There are no specific warnings for using Lutastic+. However, the following precautions apply:

- The application must only be used following prescription by a qualified physician.
- The application is not a substitute for medical advice; patients should not change medication or therapy without consulting their physician.
- If symptoms significantly worsen, new symptoms appear, or in case of health concerns, the patient should consult their physician.

No residual risks have been identified which are required to be communicated to the user.

4. Technical information

System requirements

- Lutastic+ requires the following mobile operating systems: iOS version 16 or later, or Android version 10 or later.
- Devices must have access to the Apple App Store or Google Play Store.
- Users are required to keep their mobile operating system up to date to ensure compatibility, performance, and security.
- A stable internet connection (via Wi-Fi or mobile data) is required for cloud communication and data synchronization.
- Users must use hardware that supports Bluetooth Low Energy (BLE) version 4.1 or higher to enable wireless data transmission from the compatible medical hardware device.
- Lutastic+ is only available via official digital distribution platforms: Apple App Store and Google Play Store
- The application is not distributed via physical media such as CDs, USB drives, or other external storage.

Maintenance, updates & lifetime

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

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 software is encrypted by TLS version 1.2 or higher, 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.

Classification / approval

- MDR, Medical Device Regulation 2017/745, Class I 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
- IEC 82304-1:2016 Health software Part 1: General requirements for product safety

Explanation of symbols



Declaration of conformity according to the applicable European regulations



Reference,
product name



Serial
number



Name and
address of the
manufacturer



Medical
device



Unique Device
Identification



Read instructions
for use

Therapy program

Lutastic+ is a digital therapy for male lower urinary tract symptoms. It offers a 12-week program based on urological guidelines, with one year of access.

Challenges

Every module brings challenges that teach you useful lifestyle tips, help you build habits, and guide you in training your bladder.

Diary Pod

The Diary Pod is central to the therapy. It measures your urination volume and timing, offering objective data and progress insights.

Daily tips

Every day you'll get a short tip: practical advice, a quiz, motivational content, or a key takeaway. It only takes a few minutes and helps you stay on track.



Notice

Any serious incident that has occurred in relation to the device should be reported to support@minzehealth.com and the competent authority of the Member State in which the user is established.

For the latest version of this IFU, please check e-ifu.minzehealth.com