

Instructions For Use



HELLO, WELCOME TO STARLING!

My name is Dr. Kunj Sheth and I am a practicing Urologist at Stanford University. As a physician, I have seen many patients that have expressed their frustration with the current standard of urinary tract infection (UTI) diagnosis and management. Like many of my colleagues in the field, I run a very busy surgical practice and have often wondered if there were more convenient ways for patients to not only monitor their bladder health at home, but get in touch with a clinician in a timely manner if needed.

The UrinDx device was created to meet the demands of those who wanted a better way to monitor their bladder health at home. After years of innovation and development, we have designed a new way for you to stay up to date on your bladder health, stay in touch with your healthcare providers, and stop flushing valuable information down the toilet! Together, my hope is that we can vastly improve the standard and quality of care you receive when it comes to UTI management.

Please let us know how this product works for you, and feel free to ask us any questions you may have. Email us at support@starlingmedical.com.



Kunj Sheth

Kunj Sheth, MD

Pediatric Urologist

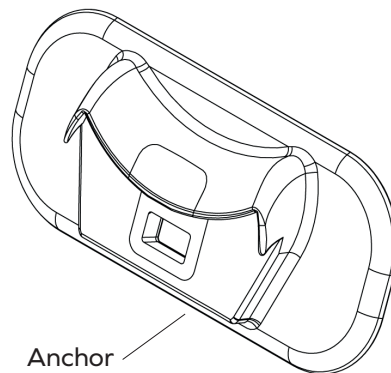
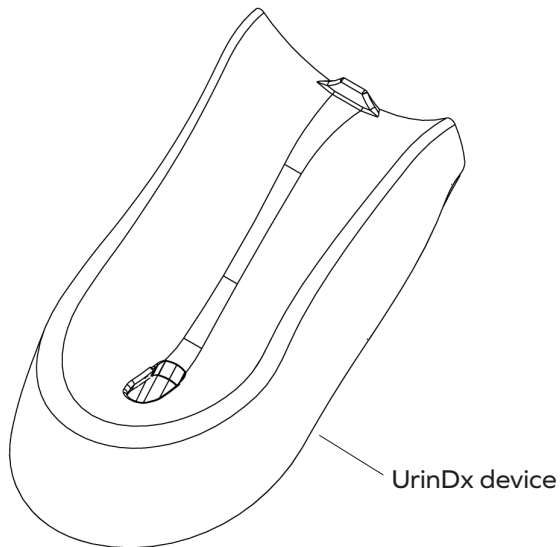
Consulting Clinical Director, Starling Medical

<https://starlingmedical.com/>

TABLE OF CONTENTS

Package Contents	1
Device Description	2
Intended Use	3
Before Use	4
Instructions for Use	5
Cleaning Instructions	9
Specifications and Disposal	10
Safety and Compliance	11
General Symbols	12

WHAT'S IN YOUR KIT?



Anchor UDI: 00860010249017
UrinDx device UDI: 00860010249000
Full Assembly UDI: 00860010249024

***Note:** Thoroughly read all instructions. Observe all warnings, cautions and precautions noted through these instructions. Failure to do so may result in complications, serious injury, or device damage.

DEVICE DESCRIPTION

UrinDx (*ur-index*) is a small, reusable device whose primary function is to seamlessly blend into the daily bathroom routine of any user. With just a quick scan of your urine, UrinDx uses light-based spectroscopy to track changes in the composition of your urine, identifying characteristics of specific molecules and groups of molecules that may indicate signs of various pathologies.

Take urinary tract infections (UTIs), for example. Did you know that some UTIs are caused by bacteria that produce a molecule called nitrites? Well, UrinDx is able to measure changes in the absorption characteristics associated with nitrites at various wavelengths of light as urine flows through the device. Starling then compiles changes in these absorption characteristics and others over time into a holistic score called the UrinDx Score. This score is indicative of changes in various biomarkers of interest like nitrites in your urine, giving you a snapshot of your urinary health.



INTENDED USE

For In Vitro Diagnostic Use and Single Patient Use. Please note, UrinDx is intended only for the identification of nitrite levels in urine and is not intended to diagnose specific conditions. Please speak with your doctor about your results.

GENERAL WARNING

- Use only as directed. Misuse may lead to injury.
- ☒ **DO NOT** attempt to modify the device in any way.
- The device should only be used by adults or with adult supervision.
- ☒ **DO NOT USE** the device for anything other than urine (blood, stool, saliva, ect).
- ☒ **CAUTION** The UrinDx device emits UV and IR light. **DO NOT** look directly into the channel of the device while in use, eye irritation may result. Please note, the colored lights seen on the outside are not UV or IR.
- This device has not been evaluated for use with Pressure Assist Toilet Systems.

PRECAUTIONS

- Upon removal from the package, inspect the device to ensure no damage is present. If any (scratches, color change, etc.) are present on the device, contact Support and do not continue with installation or use.
- ☒ **DO NOT** expose the device components to harmful cleaning agents or solvents.
- ☒ **DO NOT** stick anything into the channel of the device.
- ☒ **DO NOT** fully submerge the device in water. The device is safe for use in the toilet and should not be harmed by flushing water

The Starling Medical Application will contain personal information about your urine health and it is recommended that you create a pin or passcode for the smart phone used with the device. Do not share this information with anyone you have not authorized to know your protected health information.

BEFORE USE

Visit <http://www.help.starlingmedical.com/en> or the Help Center on the Starling Medical app for FAQs, Troubleshooting, and demo videos.



PREPARATION

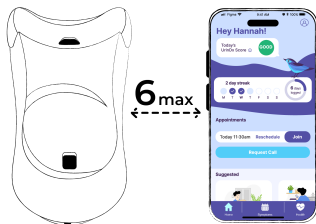
1. Please ensure you have a smart phone (minimum IOS 16 or Andriod 8 version) readily available for set up with access to the internet.
2. Please ensure your toilet is clean.

APPLICATION SET-UP

1. Prior to receiving your device, you will receive an onboarding email with the subject line "WELCOME TO STARLING". Within this email there will be a link to download and launch the app.
 - a. If you cannot find the onboarding email or do not have email capabilities on your smart phone, download the Starling Medical mobile application from the App Store on your iPhone or the Google Play store on your Android phone. Search for "Starling Medical". Once downloaded, navigate from "Get Started" to "Request a New Link" Click this and enter the requested information and will be texted a link to confirm your identity.
2. Once downloaded you will be prompted to turn on your bluetooth settings, allow notifications and allow location sharing.
3. Once you have confirmed the necessary settings and permissions, you may proceed to *Set up the UrinDx Device*. You can follow the instructions in the Starling Medical App for setting up the UrinDx as well.

SET UP THE URINDX DEVICE

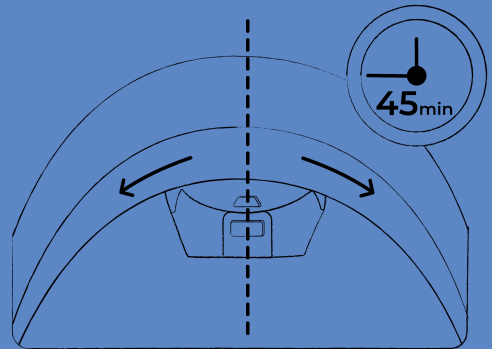
1. Remove UrinDx device and provided anchor from the shipping box. Inspect the UrinDx device and anchors for damage.
2. **Ensure your smart phone with the downloaded app is open and within 6 feet of the UrinDx device during the entire set up process.**



1. **Slowly and carefully** pull the battery pull tab away from the device. The tab should be removed completely. Pulling the battery pull tab will power on the device and it will automatically begin pairing with your smart phone. The light will blink blue showing that it is looking to pair with your nearby smart phone.
 - a. The device will blink blue for 1 minute and will turn off if it does not recognize a nearby device. Check your settings to ensure bluetooth is enabled.
 - b. If the light is off it means the device went into power saving mode. To retry pairing, cover the top of the UrinDx device with your hand and wait for the blue light to turn back on.
2. Once the device is paired with your smart phone, it will begin an internal check of its sensors. Several colored lights will blink during this phase.
 - a. If the device is not working as intended, the light will blink red.
 - b. Please contact Starling Support for troubleshooting.
3. Once the device has confirmed it is ready for installation, the light will turn green. Please proceed to *Install the Anchor*.

INSTALL THE ANCHOR

1. Choose a toilet which you use first thing in the morning.
2. With soap and water, wipe the front part of the inside of the toilet bowl, just under the rim, where the device will be installed. Wait 1 minute for the bowl to dry before installing the adhesive anchor. [see figure below]
3. Once the toilet surface is clean and dry, peel the adhesive and place the anchor in the front of the toilet. DO NOT get the adhesive wet as it will not remain sticky. Ensure the topmost edges on either side are touching the underside of the toilet rim.
4. Firmly press and hold the anchor to the toilet for 30 seconds.
5. Do not touch the anchor or use the toilet for 45 minutes to ensure the anchor is adequately adhered to the toilet.
6. After **45 minutes** you may install the UrinDx device onto the anchor. Slide the topmost connecting tab of the device into the anchor. Press the UrinDx device into the anchor to slot the lower tab and fully connect UrinDx to the toilet.
7. Device is now ready for use!



INSTRUCTIONS FOR USE

EVERYDAY USE

1. Bring your bluetooth enabled smart phone that has been paired with UrinDx to the bathroom with you. Your phone needs to be within at least 6 feet of the UrinDx device in order to use the device.
2. Once fully installed, UrinDx will automatically go into “Power Saving” mode. The device wakes up from “Power Saving” mode based on a change in ambient light in the room. Turn on the bathroom light in order to wake up the device from “Power Saving” mode.
 - a. Turning on or off a bathroom light, and/or sitting on or standing above the toilet when your shadow covers the device will wake it up.
3. Once the device moves from “Power Saving” mode to “Looking For User” mode, it will blink blue. A calibration will immediately occur once the device recognizes you via your smart phone.

Troubleshooting Tips

- *The device will blink blue for 1 minute and will turn off if it does not recognize a nearby device.*
 - *If the device light switches from blinking blue to blinking red, there was an error in calibration. Please contact Starling Support to troubleshoot.*
4. After a successful calibration, the device light will turn a solid green indicating it is ready to be used.
 5. Sit down on the toilet (to avoid splashing) and urinate into the funnel of the device. The solid green light will begin blinking when it recognizes urine passing through.
 6. Once you are finished using the toilet, flush the toilet as normal.
 7. Results will be shown in your Starling App within 24 hours. Enable notifications to know when results have been processed.

INSTRUCTIONS FOR USE

UNDERSTANDING THE URINDX SCORE

With the accompanying Starling Medical app, you can easily monitor your UrinDx Score and receive alerts if your urine shows characteristics of elevated nitrite levels, which can be used in the aid of screening for a urinary tract infection (UTI). Plus, your score will continue to improve in accuracy the more you use UrinDx. During the first week, try to use UrinDx multiple times a day so your score is more representative of your health.

It's important to note that while UrinDx can help identify early warning signs, it is not a replacement for your healthcare provider. But, with UrinDx, you'll be one step closer to taking control of your urinary health!

So, what does your UrinDx Score mean?

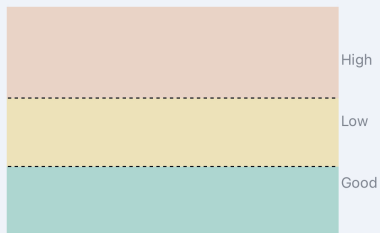
The score is divided into three zones: Good, Low Risk, and High Risk.

The **Good** zone indicates that your nitrite levels are likely low and stable.

The **Low Risk** zone serves as an early warning sign that your nitrite levels could be increasing. At this stage we recommend you speak with your Starling nurse for recommendations on potential lifestyle changes that could be used to lower your risk of a UTI.

The **High Risk** zone indicates your nitrite levels are likely much higher than your established baseline. A telehealth appointment with a Starling nurse will be scheduled directly through the Starling Medical app to confirm any symptoms and to connect you with downstream clinical care.

UrinDx Score



In summary, UrinDx is an easy-to-use and consumer-friendly medical device that empowers you to monitor changes in your urine composition. With UrinDx and the Starling Medical app, Now UrinControl Of Your Health!

CLEANING INSTRUCTIONS

CLEANING PRECAUTIONS

- ☒ **DO NOT** stick anything into the channel of the device. This may damage the device.
- ☒ **DO NOT** leave the UrinDx device submerged in water. If the device is fully submerged in the water, please discontinue use and contact support@starlingmedical.com
- ☒ **DO NOT** use hot water to clean the UrinDx device. Water can be warm to the touch, but not hot.
- Ensure all components are thoroughly rinsed and free from soap and residue before storage or use.
- Harsh chemical disinfectants or cleaning agents should not be used and may deteriorate the device materials.

CLEANING INSTRUCTIONS

1. Pull UrinDx up and away from the anchor until it detaches and remove it from the toilet. Leave the anchor in the toilet.
2. Rinse UrinDx with soap and water.
3. Allow for water to drain through the internal channel from the funnel. If a block is suspected, rinse the internal channel from the bottom to remove any debris. Repeat as necessary

TOILET CLEANING INSTRUCTIONS

1. Pull UrinDx from away from anchor until it detaches and remove from toilet. Leave anchor in toilet.
2. Clean toilet as you normally would, using a toilet brush and standard household cleaning products.

SPECIFICATIONS

- **Operating Temperature (Indoor):** 35.6 F to 113 F (2 to 45 C)
- **Storage Temperature (Indoor):** 35.6 F to 86 F (30 C) max
- **Pollution Degree:** 2
- **Maximum Operating Humidity:** 85% RH
- **Battery Nominal Voltage:** 3.6 Volts
- **Battery Capacity:** 2400 mAh
- **Number of Batteries:** 2 ER14505
- **Total Device Weight:** 300g
- **Maximum Storage and Operating Altitude:** 200m
- **Ingress Protection:** IP66

Dimensions (in) LxWxH

Anchor: 2.5 x 5.5 x 0.74

UrinDx: 4.86 x 5.5 x 0.74

Starling Medical, Inc reserves the right to make technical changes.

DISPOSAL

Dispose of the device in accordance with your local recycling and waste disposal practices and requirements for products containing lithium batteries.



Starling Medical, Inc.
7505 Fannin St.
Houston TX 77054
USA

SAFETY & COMPLIANCE

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body.

SAFETY

IEC 61010-1:2010 Ed.3+A1 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements

IEC 61010-2-101:2018 Ed.3 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment

Waterproof according to **IP66**

ELECTROMAGNETIC COMPATIBILITY (EMC)

47 CFR Chapter 1 - FCC Part 15 - Radio Frequency Devices - Subpart B Unintentional Radiators

47 CFR Chapter 1 - FCC Part 15 - Radio Frequency Devices - Subpart C / RSS-257 Intentional Radiators (Bluetooth Low Energy Transmitter)

GENERAL SYMBOLS

Symbols	Title	Symbols	Title
	Patient Information Website		Serial Number
	Unique Device Identifier		Do not use if package is damaged
	Manufacturer		Consult instructions for use
	Date of Manufacture		IVD
	Batch Code (Lot)		Non-Sterile
	Catalogue Number		Bluetooth
	LTE		Caution

Abbreviations: UTI (Urinary Tract Infection), UDI (Unique Device Identifier), FAQ (Frequently Asked Questions)

CONTACT US

If you have questions about the Starling Medical app or UrinDx, please reach out to the Support Team.

Email: support@starlingmedical.com

Phone: 800-343-5346

Chat with us on the Starling Medical app on the bottom of your home screen or on the blue bubble on the bottom right hand side of our website <https://starlingmedical.com>