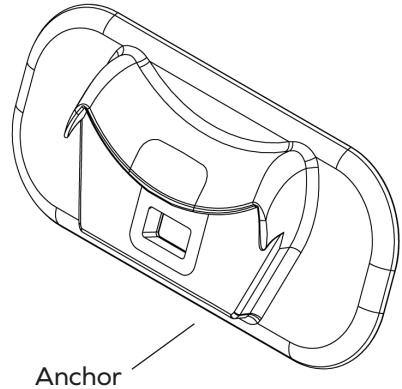
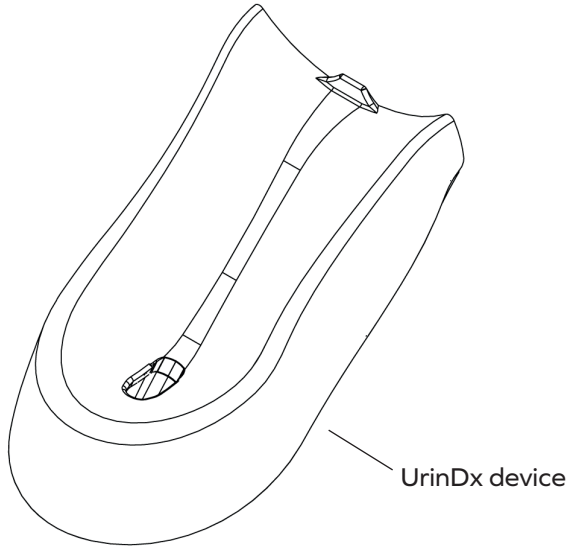


Instructions For Use



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-in-dex*) 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 spectrophotometry to track changes in the composition of your urine, identifying characteristics of specific molecules and groups of molecules that may indicate potential risk of infection or signs of pathology.

For example, take a urinary tract infection (UTI). UrinDx is able to measure a molecule called nitrites in your urine and compile the changes over time into a holistic score called the **UrinDx Score**.

You may easily access your score on the Starling application after several days of use, giving you a snapshot of your urinary health.



BEFORE USE

- Have your smartphone ready with the downloaded Starling application.
- With your smartphone's camera, scan the QR code below to **watch the Beginners Guide video** to get familiarized with the installation process.



- We recommend selecting a toilet you use first thing in the morning.
- Please make sure your toilet is clean.
 - With household cleaning supplies, clean the front part of the inside of the toilet bowl, just under the rim, where the device will be installed.

SET UP THE URINDX DEVICE

Make sure your smartphone with the downloaded application is open and within 6 feet or less of the UrinDx device during the entire set up process.

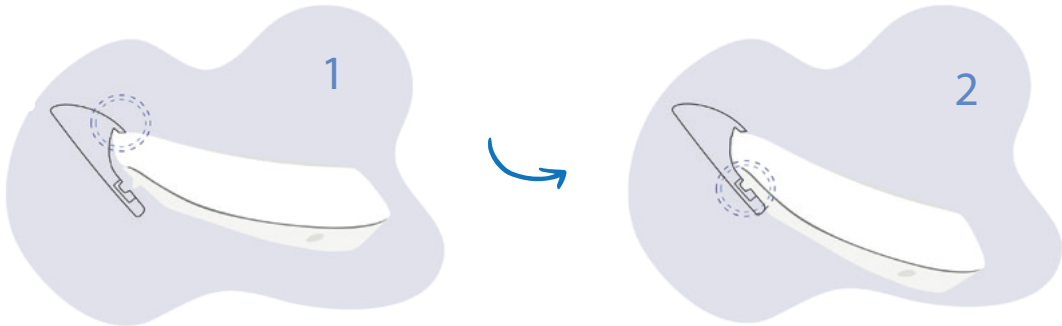


1. Remove the UrinDx device and anchor from the box.
2. Inspect the device and anchor for damage.
3. Once out of the box, pull the battery pull tab away from the device. It will automatically begin pairing with your smartphone and show a blinking blue light.
 - *The device will blink blue for 30 seconds and will turn off if it does not recognize a nearby device. Check your settings to ensure Bluetooth is enabled.*
 - *If the blue 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.*
4. Once the device is paired with your smartphone, it will begin an internal check of its sensors. Several multicolored lights will blink during this phase.
 - *If you see a blinking red light, the device is not working as intended. Please contact the Support team for troubleshooting.*
5. The device's light will turn solid green to confirm it is ready for installation.

INSTALL THE ANCHOR

DETERMINE CORRECT POSITION

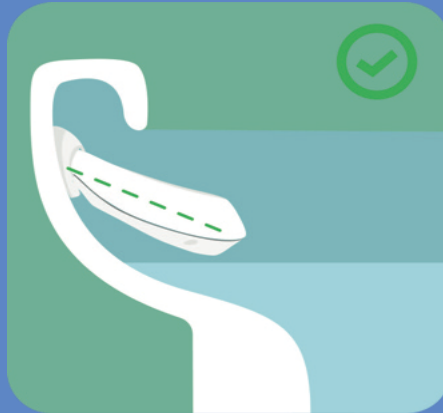
1. Dry the cleaned toilet area with a paper towel and then wipe down the area with the provided alcohol swab.
2. To determine the correct position of your anchor, connect the UrinDx device to the anchor by sliding the top of the device up into the anchor overhang and then press the UrinDx device down towards the anchor to click in the lower tab.



INSTALL THE ANCHOR

3. Hold the now connected anchor and UrinDx inside the toilet bowl keeping these factors in mind:

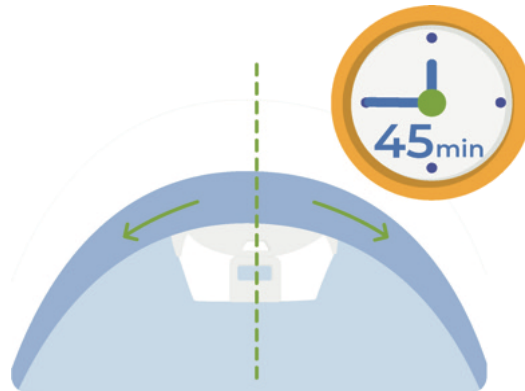
- When looking down at your toilet bowl, UrinDx should be centered.
- The anchor is downstream of flush holes and **not** covering them.
- The angle of the device should slope down slightly.
 - I. AVOID the angle being too steep, causing the UrinDx to touch the water level.
 - II. AVOID UrinDx pointing up, preventing UrinDx from draining.



INSTALL THE ANCHOR

PLACE ANCHOR

4. When confident in the location of the anchor, peel off the adhesive anchor backing. Place the anchor in the desired location and disconnect UrinDx from the anchor.
 - DO NOT get the adhesive wet, as it will not remain sticky.
5. Firmly press and hold the anchor to the toilet for 30 seconds.
6. Do not touch the anchor or use the toilet for 45 minutes to ensure the anchor is adequately adhered to the toilet.
7. After **45 minutes** you may install the UrinDx device back onto the anchor.
8. The device is now ready for use!



INSTRUCTIONS FOR DAILY USE

1. Bring your smartphone to the bathroom and open the Starling application.
2. UrinDx will wake up from power saving mode based on a change in light in the room. Turn on the bathroom light and lift up the toilet lid in order to wake up the device.
3. A blinking blue light (looking for user mode) will quickly turn into a calibration (multicolored sensor check).
4. The device light will turn a solid green indicating it is ready to be used.
5. To avoid splashing, sit down on the toilet and urinate into the funnel of the device. Another set of multicolored lights will begin when the device recognizes urine passing through.
6. The device will blink green when it is sending your data to your smartphone.
7. Once you are finished, flush the toilet like you normally would.

INSTRUCTIONS FOR DAILY USE



1. Bring your smartphone to the bathroom and open the Starling application.
2. Wait for the solid green light on the device.
3. Pee!

UNDERSTANDING THE URINDX SCORE

With the accompanying Starling application, you can easily monitor your UrinDx Score and receive alerts if your urine shows characteristics of elevated nitrite levels. During the first week, try to use UrinDx multiple times a day so your score is more representative of your health.

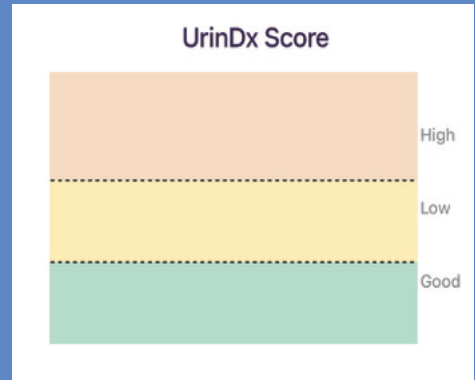
The UrinDx Score is divided into 3 sections:

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 application to confirm any symptoms and to connect you with downstream clinical care.

It's important to note that while UrinDx can help identify early warning signs, it is not a replacement for your healthcare provider.



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 contact support@starlingmedical.com
- ⊗ **DO NOT** use hot water to clean the UrinDx device. Water can be warm to the touch, but not hot.
- ⊗ **DO NOT** remove the white sticker on the inferior aspect of the device.
- ⊗ **DO NOT** use a brush over the white sticker area. This may damage the device.
- 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.

DEVICE & TOILET CLEANING

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.
4. Clean toilet as you normally would, using a toilet brush and standard household cleaning products.

INTENDED USE

For In Vitro Diagnostic Use and Single Patient Use. Please note, UrinDx is intended only for the identification of nitrite levels in the 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.
- The device should only be used by adults or with adult supervision.
- The device has not been evaluated for use with Pressure Assisted toilet systems.
- ⊗ **DO NOT** attempt to modify the device in any way.
- ⊗ **DO NOT** use the device for anything other than urine (blood, stool, saliva, etc).
- ⊗ **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 multicolored lights seen on the outside are not UV or IR.

PRECAUTIONS

- Upon removal from the package, inspect the device to ensure no damage (scratches, cracks, etc) is present. If any damage is present, 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.
- ⊗ **DO NOT** remove the white sticker on the bottom part of the device.

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) L x W x H

Anchor: 2.5 x 5.5 x 0.74

UrinDx: 4.86 x 5.5 x 0.74



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

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.

GENERAL SYMBOLS

	Caution		Date of Manufacture		LTE		Bluetooth
	Unique Device Identifier		Batch Code (Lot)		Catalog Number		
	Manufacturer		Serial Number		In Vitro Diagnostic Medical Device		

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 6 1010-1:2010 Ed.3+A1 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use
- Part 1: General Requirements

IEC 6 1010-2-101:2018 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)

WE ARE HERE TO HELP



Have questions?

- Go to **www.starlingmedical.com** and chat with us using the blue bubble on the bottom right hand side of your screen.
- Send an email to support@starlingmedical.com
- Call us at 800-343-5346
- Chat with us on the Starling app
- Visit <http://www.help.starlingmedical.com/en> or the Help Center on the Starling application for FAQs, Troubleshooting, and demo videos.

