

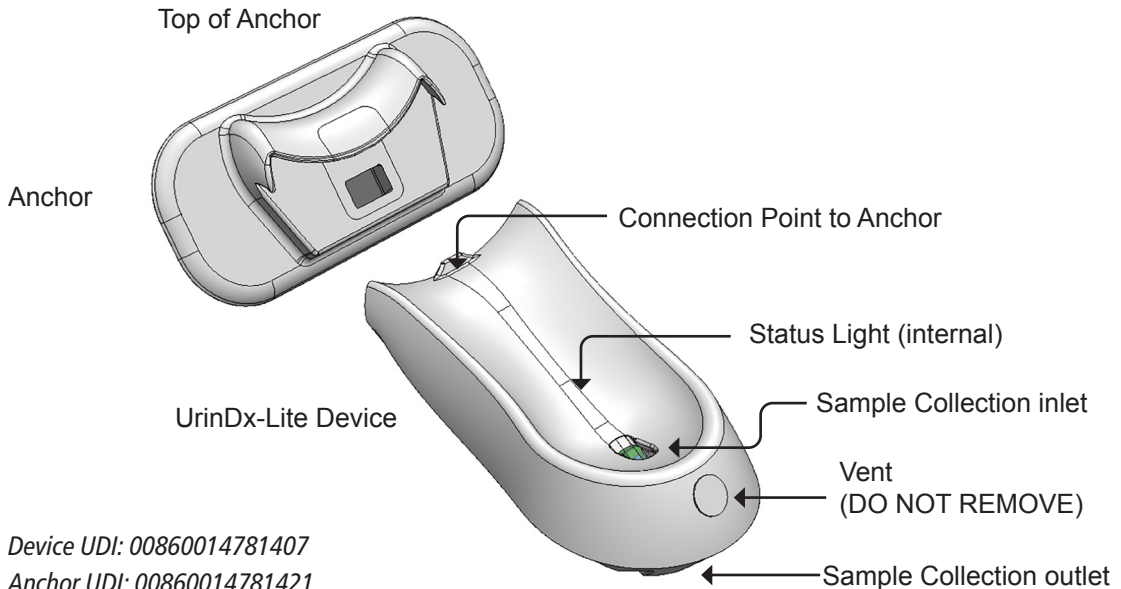
Instructions For Use



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GETTING TO KNOW URINDX-LITE



Device UDI: 00860014781407

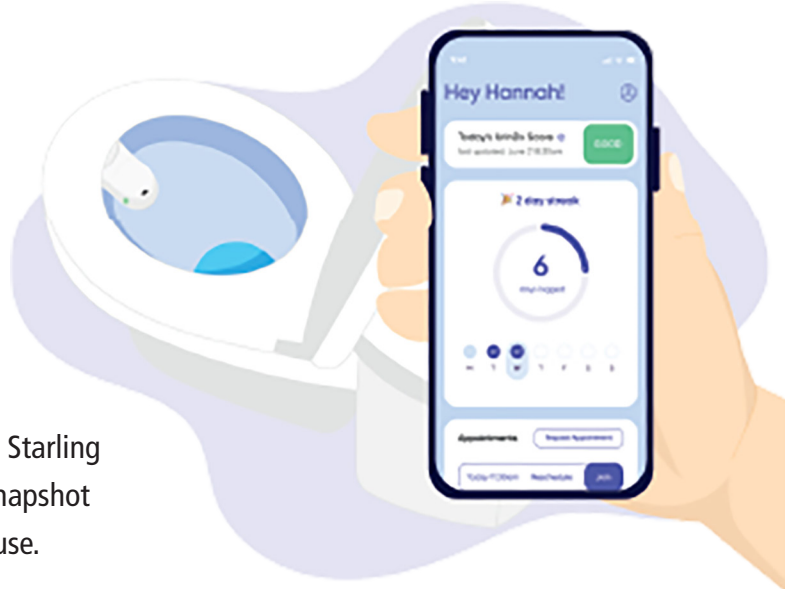
Anchor UDI: 00860014781421

Full Assembly UDI: 00860014781414

**Note: Thoroughly read all instructions. Observe all warnings, cautions, and precautions noted through these instructions. Failure to do so may result in loss of device benefits, complications with use, and device damage.*

DEVICE DESCRIPTION

UrinDx-Lite (ur-in-dex) is a small, reusable device whose primary function is to monitor urinary function while seamlessly blending into the daily bathroom routine of any user. With just a quick scan of your urine, UrinDx-Lite uses spectrophotometry to track changes in the composition of your urine, to evaluate your risk of urinary disorders.



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

APP INSTALLATION

- Scan the QR Code on below or on the Quickstart Guide to download the Starling app from the App Store or Google Play.



Scan to Download

- Open the app and, when prompted, allow Location Sharing and Bluetooth Access.
- The Starling mobile application will walk you through the device setup.

INSTALL THE ANCHOR

PREPARE YOUR TOILET

(We recommend selecting a toilet you use first thing in the morning)

1. Please make sure your toilet is clean.

- Using household cleaning supplies, clean inside of the toilet bowl, focusing on the front area just under the rim.

2. After cleaning, wipe down the front of the toilet bowl with the provided alcohol wipes and ensure it is fully dry.

- DO NOT flush the toilet after this step prior to completion of the install procedure.



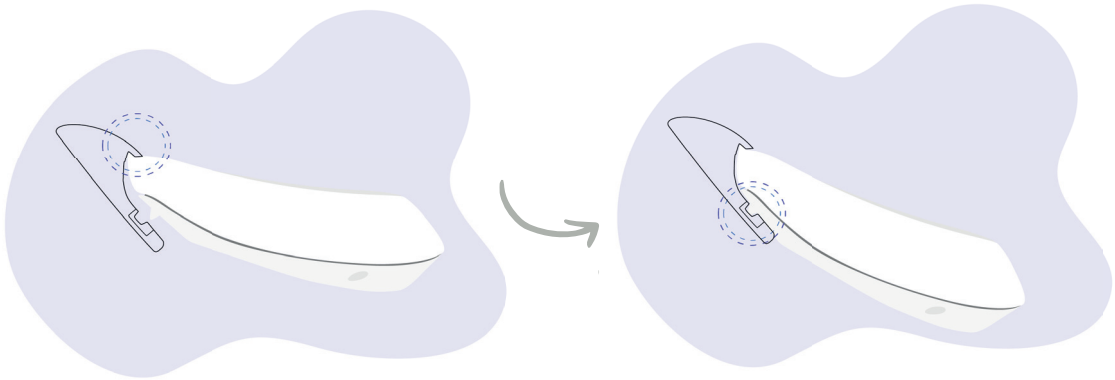
(Optional) watch the Beginners Guide video to get familiarized with the installation.

INSTALL THE ANCHOR

MOUNTING URINDX-LITE TO THE ANCHOR

To determine the correct anchor position in your toilet, connect the UrinDx-Lite device to the anchor by:

1. Sliding the top of the device up into the anchor lip.
2. Pressing the UrinDx-Lite device down towards the bottom of the anchor to engage the device into the anchor.

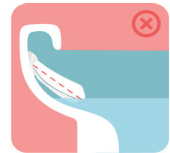
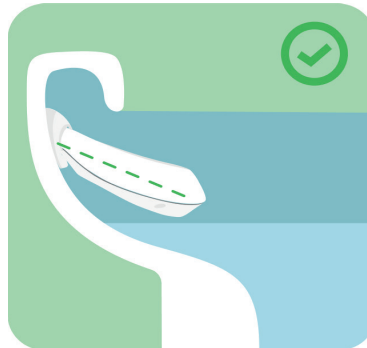


INSTALL THE ANCHOR

DETERMINE CORRECT POSITION

Before removing the adhesive backing, position the now connected anchor and UrinDx-Lite keeping these factors in mind:

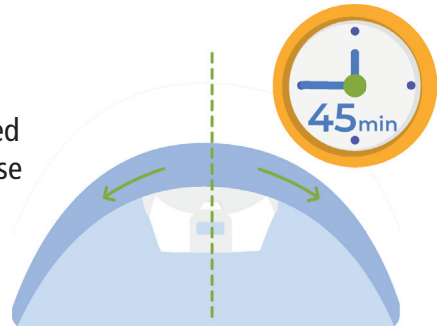
1. Center the device to the front of the toilet under the toilet lip.
2. Ensure the device angle is adequate.
 - i. Angle should NOT be too steep to touch the toilet water.
 - ii. The rear of the device should NOT stick up past the anchor height.
3. Ensure the anchor does not block the toilet flush holes.



INSTALL THE ANCHOR

PLACE ANCHOR

1. When confident in the position of the anchor, disconnect the anchor from the device and peel off the adhesive anchor backing.
 - DO NOT get the adhesive wet, as it will not remain sticky.
2. Place the anchor firmly into place.
3. Press and hold the anchor firmly in place for 60 seconds.
4. Press the edges of the anchor to ensure adequate adherence.
 - If the anchor center or edges are not well adhered after these steps, continue to press firmly on those areas for an additional 60 seconds.
5. DO NOT flush the toilet or clip in the device until 45 minutes have passed.



CONNECTING TO URINDEX-LITE

FIRST USE - TURNING ON THE DEVICE

1. Locate the power button on the underside of the device.
2. Press and hold the power button for at least 5 seconds.
 - A. When a blue light is visible, the device has turned on.
3. Ensure the device is within 3 ft of your phone and the Starling app is installed and open on your smartphone.

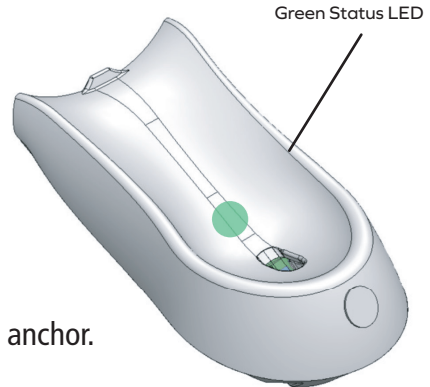


Power Button

CONNECTING TO URINDX-LITE

CONNECTING TO YOUR DEVICE

1. Open the Starling App on your smartphone.
2. Keep the device within 3ft from your smartphone.
3. When powered on, the device will automatically scan to connect to the Starling App.
4. When connected, the device will flash green. This designates a successful connection.
5. You can now clip the UrinDx-Lite onto the installed anchor.



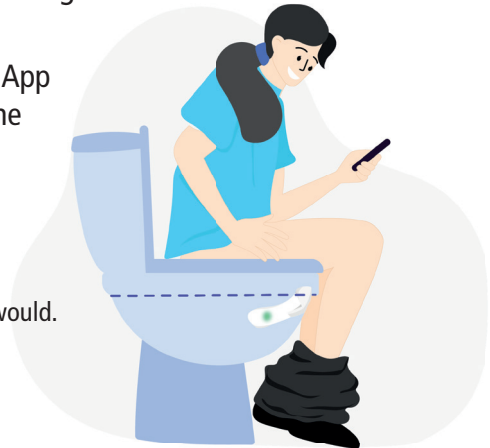
HOW TO USE URINDX-LITE

CAPTURING A SAMPLE

1. To capture a sample, take your smartphone with you to the bathroom.
2. Open the Starling App.
3. Follow any on screen instructions for using your device.
4. Sit down on the toilet and urinate into the funnel of the device.
5. Multicolored lights will begin scanning your urine.
6. The device will blink green and blue when it is sending your data to your smartphone.
7. Once the sample has been received, the Starling App will show the latest sample date and time and the UrinDx Score will be updated.

TIPS





- Avoid splashing by sitting down when using the device.
- After collecting a sample, flush the toilet like you normally would.
- For further information and guidance see the in app help articles and FAQ's.
- Trouble? Reach out to us in the App.





HOW TO USE URINDX-LITE

WHAT DO THE LIGHTS MEAN?

Everyday Use

Color	Animation	Interval	Description
 Blue	Solid	5 seconds	Device is powered on or reset
 Green	Pulsing	< 30 seconds	Ready to capture your sample
 Red/Green/Blue	Alternating	5 seconds	Capturing your sample
 Blue/Green	Alternating	5 seconds	Sample was successfully captured and sent to the Starling app

Other

Color	Animation	Interval	Description
 Red	Solid	5 seconds	Device fault - please contact customer support
 Red	Solid	20 seconds	The UrinDx light may be blocked, please remove the device from the anchor and wash with soap and water

You can flush your toilet at anytime during these light sequences EXCEPT for during Red/Green/Blue.

UNDERSTANDING THE URINDX SCORE

With the accompanying Starling mobile app, you can easily monitor your compliance. If allowed by your health care provider, you will also see your UrinDx Score and receive alerts if your urine shows characteristics of elevated turbidity. Urine Turbidity refers to the visual clarity or cloudiness of a urine sample. High turbidity indicates the presence of particles that make the urine look opaque, rather than clear. During the first week, try to use UrinDx multiple times a day so your score is more representative of your health.

If you experience symptoms at any time, please contact your care coordinator regardless of your UrinDx score.

The UrinDx Score is divided into 3 sections:

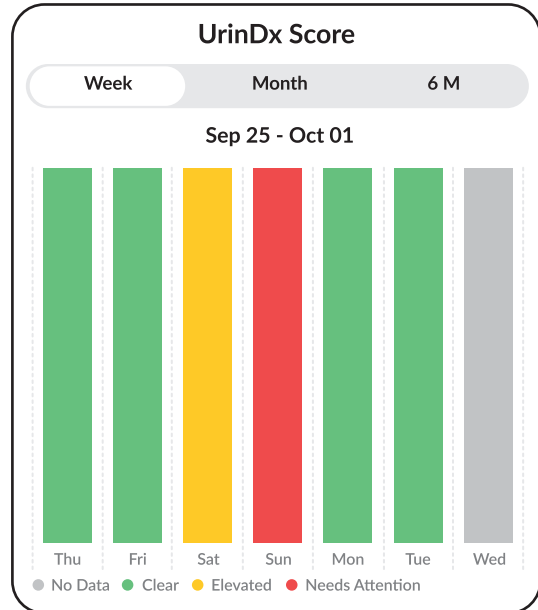
The **Clear** result indicates that your urine is clear and your urinary health is likely good.

The **Elevated** result serves as an early sign that your urine is becoming cloudy and could indicate decreasing urinary health if it persists. At this stage, we recommend you speak with your care coordinator for recommendations on preventative care that could lower your risk. Your care coordinator can be contacted through the phone number they provided you with at the start of the program.

UNDERSTANDING THE URINDX SCORE

The **Needs Attention** zone indicates your urine is turbid and may indicate risk for a urinary disorder. A care coordinator will contact you to confirm any symptoms and to connect you with downstream clinical care if needed.

It's important to note that while UrinDx-Lite 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-Lite device submerged in water.
- ⊗ **DO NOT** use hot water to clean the device. Water can be warm to the touch, but not hot.
- ⊗ **DO NOT** remove any stickers from the device.
- ⊗ **DO NOT** use a brush over the stickers. This may damage the device.

When cleaned, ensure all components are thoroughly rinsed and free from soap and residue before storage or use.

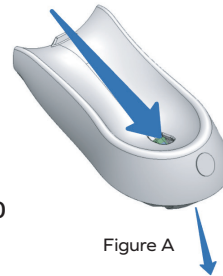
Harsh chemical disinfectants or cleaning agents should not be used and may deteriorate the device materials.

CLEANING INSTRUCTIONS

CLEANING PRECAUTIONS

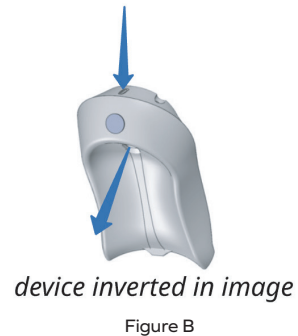
GENERAL CLEANING

1. Remove the device from the anchor before cleaning.
DO NOT REMOVE THE ANCHOR.
2. Rinse the device with soap and water. Allowing for water to drain through the collection funnel (Figure A).
3. Clean your toilet as you normally would, using a toilet brush and standard household cleaning products.



CLEANING BLOCKAGES

1. Clean out blockages from the collection funnel by flowing water through the sample collection outlet (Figure B).



Please remember to wash your hands after handling and cleaning your device.

INTENDED USE

The device is intended to measure the turbidity of a urine sample and provide an assessment of urine clarity. The results can be used in the evaluation of urinary disorders. The device is intended for prescription use and is suitable for use in both clinical laboratory and point-of-care settings.

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 stack or store the device close to other electrical equipment.
- Portable RF communications equipment, including antennas, can affect medical electrical equipment, UrinDx-Lite should be used no closer than 30cm (12-inches) to any part of a medical electrical equipment, including cables specified by the manufacturer.

INTENDED USE

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 any stickers from the device.
- ⊗ **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-Lite 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 multi-colored lights seen on the outside are not UV or IR.

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:** 2600 mAh
- **Number of Batteries:** 2 IMR14500
- **Total Device Weight:** 300g
- **Maximum Storage and Operating Altitude:** 200m
- **Ingress Protection:** IP66
- **Bluetooth Low Energy (BLE):**
 - Frequency Band: 2.402 GHz - 2.480 GHz
 - 40 Channels Total
 - 2 MHz Spacing
 - 3 Advertising Channels: 2402, 2426, 2480 MHz
 - Modulation: GFSK (1msps, optional 2msps)
- **Dimensions (in):**
 - Anchor: 2.5 x 5.5 x 0.7
 - UrinDx-Lite: 4.9 x 5.5 x 0.8











Starling Medical, Inc.
2450 Holcombe Blvd, Suite 1320
Houston, TX 77021, USA

DISPOSAL

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

GENERAL SYMBOLS

 REF	Catalog Number		Manufacturer	 MD	Medical Device
 UDI	Unique Device Identifier		Date of Manufacture		Consult Instructions for use
 LOT	Batch Code (Lot)		Bluetooth		

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 & COMPLIANCE

TESTED FOR COMPLIANCE TO:

- **IEC/EN 60601-1-2:2014/2015+AMD1:2020** - Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance.
- **47 CFR Chapter 1 - FCC Part 15** - Radio Frequency Devices - Subpart B - Unintentional Radiators

TEST LEVELS

IEC/EN 60601-1-2

- **CISPR 11 Radiated Emissions** - Class B, Group 1
- **IEC/EN 61000-4-2 Electrostatic Discharge** - $\pm 8\text{kV}/\pm 15\text{kV}$ Air
- **IEC/EN 61000-4-3 Radiated EF Fields** - 10V/m (80MHz - 2.7GHz)
- **IEC/EN 61000-4-8 Power Frequency Magnetic Field** - 30A/m (50 or 60 Hz)
- **IEC/EN 61000-4-39 Proximity to Magnetic Fields** - 30kHz (8A/m), 134.2 kHz (65 A/m), 13.56 MHz (7.5 A/m)

FCC Part 15B

- **15.109 Radiated Emissions** - 30MHz to 1 GHz

IP Testing

- **Tested to IP66** - No ingress or Dust allowed, Powerful Jets (12.5mm test nozzle diameter)

WE ARE HERE TO HELP

HAVE QUESTIONS?

Go to www.starlingmedical.com and chat with us using the blue bubble on the bottom of your screen.

Email support@starlingmedical.com

Call 800-343-5346

See our Help Center on the Starling mobile application for FAQs, Troubleshooting, and demo videos.

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MAR-001 Rev B