CarePath® System

Patient Instructions For Use

IDUROLOGY

6016 Brookvale Lane
Knoxville, TN 37919

CarePath System
Urine Flow Device

Find us on the World Wide Web at:
www.i-ourology.com

Caution: Federal law restricts this device to sale by or on the order of physician.

Contents

Glossary

Term	Definition
CarePath device	The hand-held device measures urine flow and transmits data securely to your healthcare provider
CarePath system	The CarePath device, storage pouch, and accompanying documents
Caution	Important notification or instruction regarding a hazardous situation which can cause material damage or lead to minor or moderate injury
Note	Indicates important information that is necessary for proper device operation
LED	Light Emitting Diode (i.e. the color-changing light in the CarePath device handle)
QRG	Quick Reference Guide
Void / Voiding	Urinate / Urinating
Wake Up & Bedtime hours	The daily schedule you set up with your healthcare provider during which the CarePath system will expect to see your urination data
Warning	Important notification or instruction regarding a hazardous situation which can cause a serious or fatal injury

1 Introduction to the CarePath System

General Description

The CarePath system facilitates evaluations measuring urine output. It consists of the CarePath device, accompanying documents, and training. The system:

- Measures and calculates flow rate and volume from urination data
- Automatically transmits urination data to a secure location
- Creates and provides uroflow reports to healthcare providers

The intended operator of the CarePath device is the patient. The CarePath system has no user-serviceable components. This system is not to be serviced or maintained by the user. The intended environments are hospitals, clinics, doctor's offices and the patient's home.

CarePath Indications for Use

The CarePath System is indicated for use any time a voiding diary or uroflow is ordered by a prescribing physician.

CarePath Contraindications

There are no known contraindications for the CarePath System.

CarePath System Components

- CarePath device
- Storage pouch
- Quick Reference Guide (QRG)

Risks and Benefits

The CarePath system provides greater accuracy for tracking urine output and associated data. There are no known risks when the device is used as instructed.

2

Getting Started with the CarePath System

Your healthcare provider has determined a uroflow evaluation is necessary for identifying your current urination patterns in your normal environment. CarePath provides a low-impact method of tracking your daily routine.

Your healthcare provider relies on the information provided by the system. It is important to use it as instructed. Contact your healthcare provider if the system is not working as expected or was used in a way other than instructed.

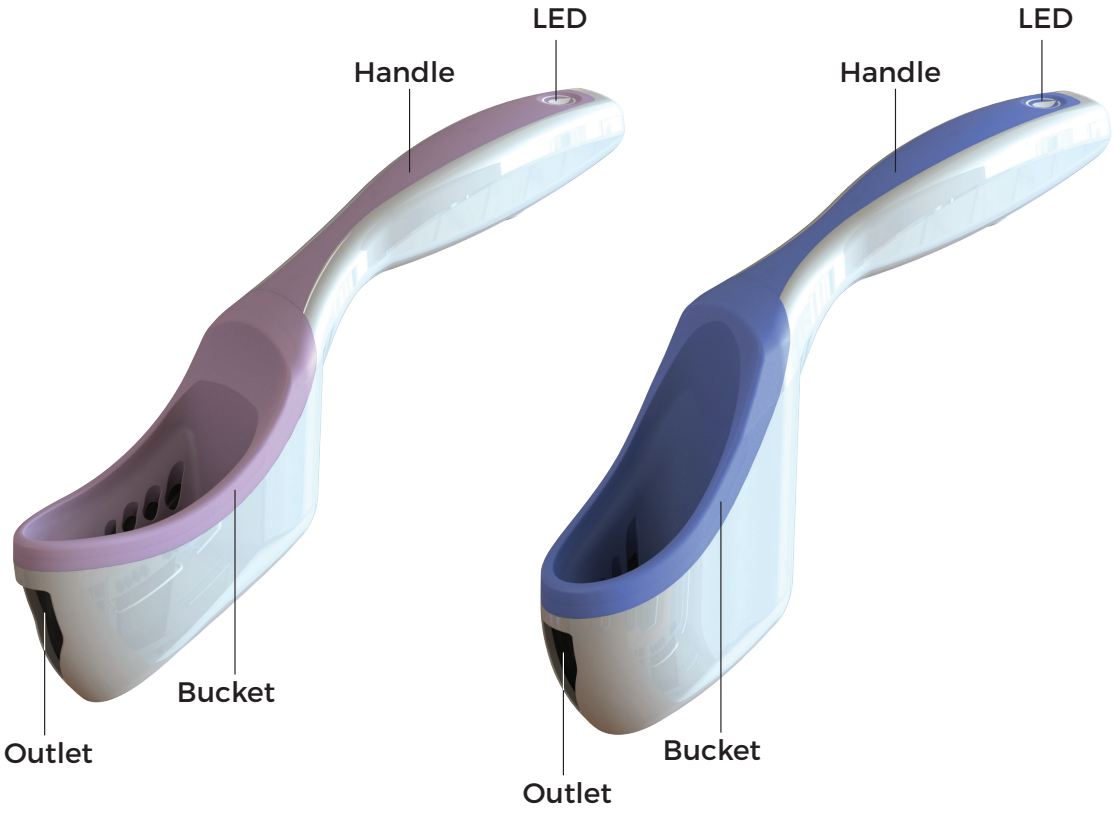
The CarePath Device

Note: Is intended for a single patient's repeated use.

Note: Do not detach the disposable receptacle from its handle.

Note: Is specifically designed for both male and female anatomies.

Caution: Do not attempt to replace the battery or open the CarePath device case. It contains no parts that require user maintenance.



The CarePath Device - female design (left) and male design (right)

CarePath Device LED / light states

- **Outlet** - Where the urine exits
- **Bucket** - Catches the urine
- **Handle** - Aids in positioning the device
- **LED / light** - Communicates correct orientation

1. Green - Correctly oriented for data collection.

2. Yellow - Incorrectly oriented. Adjust the angle of the device until the LED / light turns green.

3. Red - Device issue. DO NOT use. Please call your patient navigator at (865) 693-4800.

3 Using Your CarePath Device

Before you begin your home evaluation, read all of the instructions in this document. Follow all directions provided by your healthcare provider.

Warning: To avoid the risk of fire, electric shock, or burns, do not crush, incinerate, put in dishwasher, put in microwave, or heat the device above 212˚F (100˚C). **Do not store the CarePath device in your car or in any environment where excessive heat is possible.**

Caution: Do not use the device in temperatures outside the range of 41˚F to 104˚F (5˚ to 40˚C), since it may not provide accurate data.

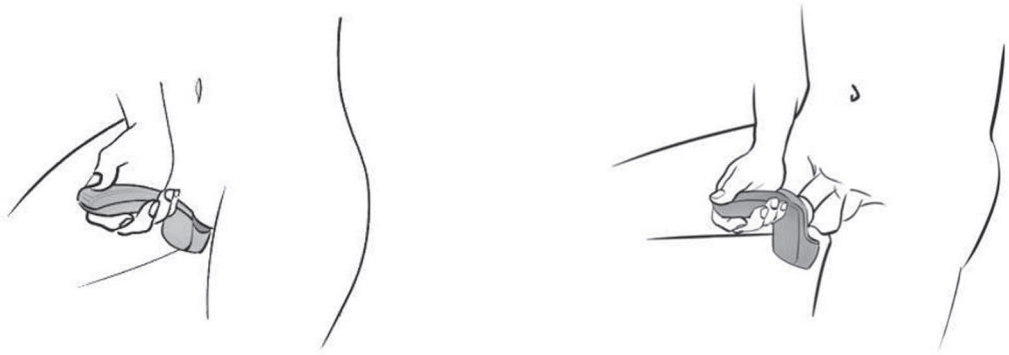
Recording a Urination

Note: Data is automatically sent with each urination.

Note: Cellular coverage can affect the rate of data transfer.

During your evaluation, use the CarePath device every time you urinate, following these steps:

1. For females, sit on the toilet. For males, you may either sit or stand.
2. Remove the CarePath device from its storage pouch.
3. For women, the device should be touching your body. For men, the device should be held close to your body as shown on page 8.
4. Adjust the angle of the handle until the LED/light at the end of the handle is steady green. Try to keep the LED/light steady green throughout the duration of your urination.
5. Urinate into the device. Urine will flow through the bucket and exit the outlet into the toilet.



Expected use positions- female (left) and male (right)

6. After your urination stream is ended, tilt the outlet in the device slightly downward to ensure it is completely drained into the toilet.

7. Rinse the device in water only and return it to the black storage pouch. You may lay your device out to dry before placing it in the storage pouch, if desired.

4 Caring for Your CarePath Device

Cleaning Your CarePath Device

To clean your CarePath device, rinse it in water only. When you have rinsed your CarePath device, place it back in your storage pouch until its next use.

Caution: To clean your CarePath device, rinse it in water only. Do not use any other method of cleaning since it may affect the accuracy of the device.

Storing Your CarePath Device

Use the provided storage pouch for protecting your CarePath device between uses.

Disposal

Do not dispose of the CarePath device.

5 Returning Your CarePath Device

When your uroflow evaluation is complete, please return the CarePath device to I/O Urology in the box it arrived in by following the instructions provided in the box.

6 Getting Help

Note: Contact your patient navigator at (865) 693-4800 with any questions or concerns regarding use or care of your CarePath device.

Frequently Asked Questions

Below are frequently asked questions (FAQ) about the CarePath system. If your question is neither answered here nor in the remainder of this guide, please contact your patient navigator or I/O Urology technical support.

Will I be contacted throughout my CarePath evaluation?

A patient navigator will review your real-time urination activity and may contact you during your CarePath evaluation.

Does my patient navigator follow my urination data every day during the uroflow evaluation?

YES - every time CarePath is used the urination information is sent automatically to your patient navigator.

This urination data is reviewed daily by your patient navigator and feedback, instructions and educational videos from your provider will be sent to you by text or phone at the appropriate time during the evaluation.

What if I need to get in touch with my navigator?

If you have any questions about using CarePath, please call your navigator at (865) 693-4800.

What happens if I forget to use the CarePath device when I urinate?

You cannot manually enter a urination. Simply use CarePath the next time you urinate and your evaluation will progress.

Customer Service

If you have any information about the product, please call CarePath's Technical Support Number +1 (865) 693-4800, Monday through Friday, between 7:00 a.m. and 5:00 p.m., Central Time, U.S.A.

Manufacturer

I/O Urology Corp.
6016 Brookvale Lane, Knoxville, TN 37919
Ph: +1(865) 693-4800
www.i-ourology.com

7 Technical Information

CarePath Device Specifications

Battery:	Lithium-Ion Rechargeable
Service Life:	5 years from date of manufacture
Full Charge Battery Life:	24 days under normal use conditions
Data Recording Time:	24 hours under normal use conditions before data upload needed
Degree of Ingress Protection:	IP22 (Protected from water spray less than 15 degrees from vertical)
Protection against Electrical Shock:	Internally powered medical equipment
Degree of Protection:	Type BF Applied Part
Mode of Operation:	Continuous

- Biocompatibility requirements have been met for the biological evaluation of the CarePath device and its component materials that come into contact with the human body.
- This CarePath device has no essential performance (if the device is compromised there is no unacceptable risk to the user (patient and professional users).
- The CarePath device contains no serviceable parts or components for users (patient and professional users) or service personnel.

Warning: No modification of this equipment is allowed.

Warning: Do not attempt to charge the CarePath device. The CarePath device does not require charging during your evaluation and can only be charged by I/O Urology using a specialized CarePath charger.

Test	Standard to Which Device Conforms
Product Safety	AAMI/ANSI/ES 60601-1
Home Use Safety	AAMI/IEC 60601-1-11
Electromagnetic Compatibility (EMC)/ Electromagnetic Immunity (EMI)	AAMI/IEC 60601-1-2
Battery	IEC 62133; UL 1642; UN38.3
Biocompatibility/Toxicity	ISO 10993-1; ISO 10993-5; ISO 10993-10

Environmental Conditions for Use & Storage

The CarePath device is intended for storage and operation in a room-temperature environment.

Condition	Temperature	Relative Humidity (non-condensing)	Standard to Which Device Conforms
Operating	+5˚C to +40˚C	15% - 93%	70 – 106 kPa
Storage	-20˚C to +60˚C	15% - 93%	70 – 106 kPa
Transport	-20˚C to +60˚C	15% - 93%	70 – 106 kPa

Electromagnetic and Other Interferences

The CarePath system has been tested and deemed in conformance with the relevant requirements in EN 60601-1-2 Class B for Electromagnetic Compatibility (EMC).

Caution: The CarePath system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Technical Information section of this User Guide.

Warning: The CarePath system should not be used adjacent to or stacked with other electromagnetic equipment. If adjacent or stacked use with other electromagnetic equipment is necessary, verify that the CarePath system operation is normal in the configuration(s) in which it will be used.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CarePath system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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