

CarePath System

Instructions for Professional Use

I/O Urology Corp.
730 Quail Hollow Dr.,
Elizabethton, TN 37643
Ph: +1-423-647-2222
www.i-ourology.com



CarePath System

Urine Flow Device

© 2020 I/O Urology Corp.

All rights reserved. No part of this document may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission from I/O Urology Corp..

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 a physician.

Contents

1	<i>Introduction to the CarePath System</i>	<i>6</i>
	Components for the Professional User	6
	Components for the Patient	6
	The Assembled CarePath Device.	6
	Handle LED / light Indications.	7
2	<i>CarePath System Clinical Details</i>	<i>8</i>
	Intended Use	8
	Indications for Use.	8
	Contraindications	8
	Get Started	8
	Office Uroflow.	8
	Voiding Diary	9
	Home Uroflow	10
	Voiding Diary + Home Uroflow	10
3	<i>CarePath Basic Procedures</i>	<i>11</i>
	Install the Base Station.	11
	Charge the CarePath Device.	12
	Assemble the CarePath Device	12
	Create a New Study	13
	Download Mobile App	16
	Return a Device	18
	Disassemble & Clean a Device.	19

4	<i>CarePath Reports</i>	20
	View Patient Report	20
	View Study Status	21
	Physician Portal	22
5	<i>Service, Storage and Disposal</i>	23
	Environmental Conditions for Use & Storage	23
	Disposal of CarePath Components	23
6	<i>Assistance & Troubleshooting</i>	24
	Assistance	24
	Tablet App Troubleshooting.	24
	Mobile App Troubleshooting	25
	Customer Service	26
7	<i>Technical Information</i>	27
8	<i>Symbols Glossary</i>	38

Glossary

Term	Definition
CarePath device	The CarePath handle with the disposable installed, which measures and calculates flow rate and volume from raw void-related data and transmits this data securely to your healthcare provider
CarePath mobile app	A mobile application for Android and Apple smart phones providing a low-impact method of tracking daily fluid intake and voiding routine while using the CarePath device
CarePath system	The CarePath device, storage pouch, mobile app, and accompanying documents
Caution	Important notification or instruction regarding a hazardous situation which can cause material damage or lead to minor or moderate injury
Day Mode	Mobile app state during which you will receive messages from the CarePath system until you indicate you are going to bed for the night
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)
Night Mode	Mobile app state during which you will not receive messages from the CarePath system until you indicate you are awake for the day
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 void data
Warning	Important notification or instruction regarding a hazardous situation which can cause a serious or fatal injury

1 Introduction to the CarePath System

The CarePath system facilitates studies measuring urine output. It includes the CarePath device, a mobile app, a tablet app, a base station, and accompanying documents. The system:

- ◆ Measures and calculates flow rate and volume from raw void-related data
- ◆ In the case of a voiding diary, collects study related patient inputs
- ◆ Automatically transmits raw void-related data to a secure location
- ◆ Generates and provides void-related reports to professional users
- ◆ Can create comparison reports between patient studies

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.

Components for the Professional User

- ◆ CarePath base station and power supply
- ◆ CarePath device handles and disposables
- ◆ CarePath tablet and tablet app
- ◆ CarePath web portal

Components for the Patient

- ◆ CarePath device (handle with disposable attached)
- ◆ Storage pouch
- ◆ Quick Reference Guide
- ◆ Mobile app (voiding diary studies only)

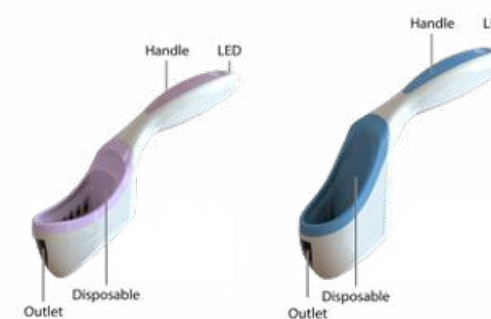
The intended operator of the CarePath device is the patient. The intended operator of the CarePath base station, tablet and tablet app is the Professional User. The CarePath system has no user-serviceable components. This system is not to be serviced or maintained by the user.

The intended environments are hospitals, clinics, doctor's offices and the patient's home.

The Assembled CarePath Device

Caution: CarePath has distinct designs for the male and female anatomy. Provide the proper device to patients, based on anatomy.

Caution: Do not attempt to replace the battery or open the CarePath device case. The CarePath device contains no user-serviceable parts.



Female device (left) and Male device (right)

- ◆ **Outlet**—Releases urine stream
- ◆ **Disposable**—Receives urine stream
- ◆ **Handle**—Provides method to orient device
- ◆ **LED**—Communicates correct orientation

Handle LED / light Indications

On base station:

- ◆ **Flashing Green**—Charging
- ◆ **Solid Green**—Fully Charged

After removing from base station:

- ◆ **Flashing Yellow**—Ready for a disposable to be attached.
- ◆ **Flashing Green**—Valid disposable is attached and the device is ready for patient assignment.
- ◆ **Flashing Red**—Invalid disposable is attached; remove disposable and attach a new disposable of the appropriate gender matching the handle.

During patient use:

- ◆ **Green**—Correctly oriented for data collection.
- ◆ **Yellow**—Incorrectly oriented. Adjust the angle of the device until the LED / light turns green.

Errors:

- ◆ **Flashing Red**—Do not assign to patient. Place on the base station. If red LED/light persists, contact your I/O Urology representative for service, repair, or replacement.
- ◆ **Solid Red**—Device issue. Place on the base station. If red LED/light persists, contact your I/O Urology representative for service, repair, or replacement.

Note: The CarePath device contains rechargeable batteries. These are self-monitored for end of life and battery issues. The LED will turn red and the handle will no longer be usable after 5 years from the date of manufacture or if a battery issue/battery degradation is detected.

2 CarePath System Clinical Details

Intended Use

The CarePath System provides void-related data to healthcare providers to enable health-related diagnoses and track patient progress during treatment. It includes both disposable and reusable components which are reprocessed by the healthcare provider.

Indications for Use

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

Contraindications

There are no known contraindications for the CarePath system.

Get Started

Studies fall into four discrete categories as described below. You can generate reports for each study and, as long as the studies are of the same type, you can generate comparison reports of the studies to refine your assessment.

Note: The CarePath device collects void data and streams it to the Cloud for validation and calculation of flow rate and volume, both stored as HIPAA-compliant information.

Office Uroflow

An office uroflow study is a single event that provides you with a single data set for use in assessment. An office uroflow study includes the following tasks:

1. Create a new study for the patient on the CarePath tablet app.
2. Assemble the CarePath device (p. 11).
3. Assign the CarePath device to the patient (p. 12).
4. Provide the CarePath device in a storage pouch and the accompanying Quick Reference Guide (QRG) to the patient, after reviewing the use and cleaning instructions from the QRG with the patient.
5. Have the patient void into the CarePath device in a designated office facility.
6. Have the patient return the CarePath device.
7. Complete the return process on the CarePath tablet app, disassemble and clean the device (p. 17-18), and place the CarePath handle back on the base station.
8. View the report of the void on the CarePath tablet app (p.19).

Voiding Diary

A voiding diary is an off-site study that provides you with up to three days of records of fluid intake and urinary output. The three days do not have to be consecutive.

The voiding diary requires patients to either use a mobile app in conjunction with the device, or to manually document all fluid intake, void-related information such as urgency, and leaks for the three days. The patient qualitatively assesses each void.

The voiding diary also captures waking and sleeping patterns for the same time frame to categorize the data. The CarePath device calculates the time-of-occurrence, duration, volume, and flow rate of each patient void event.

A voiding diary study includes the following tasks:

1. Create a new study for the patient on the CarePath tablet app.
2. Assemble the CarePath device (p. 11).
3. Assign the CarePath device to the patient (p. 12).
4. Provide the CarePath device in a storage pouch and the accompanying Quick Reference Guide (QRG) to the patient, after reviewing the use and cleaning instructions from the QRG with the patient.
5. **Practice Day:** Encourage the patient to use the CarePath device 1-2 times on the same day they receive their device. This data does not count toward the voiding diary study. The practice day allows the patient to familiarize themselves with the process before starting the study.
6. After the Practice Day, the prescribed study will begin. The patient will void into the CarePath device at home or alternate facility, based on the normal daily patient routine.

7. Upon completion of the voiding diary, have the patient return the CarePath device.
8. Complete the return process on the CarePath tablet app, disassemble and clean the device (p. 17-18), and place the CarePath handle back on the base station.
9. View the report of the CarePath voiding diary study on the CarePath tablet app (p. 19).

Note: The CarePath device collects void data and streams it to the Cloud for validation and calculation of flow rate and volume, both stored as HIPAA-compliant information.

Home Uroflow

The home uroflow study is an extended study that provides you with a custom set of void data. You establish the timing for void data collection with the patient. This study is limited to a maximum of one month in duration.

The home uroflow study includes the following tasks:

1. Determine the appropriate times for void data collection.
2. Create a new study for the patient on the CarePath tablet app.
3. Assemble the CarePath device (p.11).
4. Assign the CarePath device to the patient (p. 12).
5. Provide the CarePath device in a storage pouch and the accompanying Quick Reference Guide (QRG) to the patient, after reviewing the use and cleaning instructions from the QRG with the patient.
6. Have the patient void into the CarePath device at home or alternate facility, based on the normal daily patient routine.
7. Upon completion of the study, have the patient return the CarePath device.
8. Complete the return process on the CarePath tablet app, disassemble and clean the device (p. 17-18), and place the CarePath handle back on the base station.
9. View the report of the home uroflow study on the CarePath tablet app (p. 19).

Voiding Diary + Home Uroflow

Repeat the steps of the Voiding Diary, but during assigning select the Voiding Diary + Home Uroflow study option. The patient will complete the study as if it was a regular voiding diary.

The difference is that in the end, you will get a voiding diary report and a uroflow report.

3 CarePath Basic Procedures

Install the Base Station

CarePath provides you with a base station that can charge the batteries of up to four CarePath device handles simultaneously. The following items are included in the CarePath base station box:

- ◆ One (1) CarePath base station
- ◆ One (1) 12V AC/DC wall plug power supply

To install the base station, follow the instructions below.

1. Remove the base station and power supply from the packaging
2. Carefully inspect each item as it is unpacked for any signs of damage that may have occurred during shipment.
3. Do not attempt to set up the base station if anything is damaged or defective.
4. Plug the power supply into the back of the base station
5. Plug the power supply into your standard AC power outlet, universal power supply or power strip based on your institution's policies.

Warning: Only use the approved power supply with the base station or the base station/power supply could overheat or shock the user.

Warning: If there is damage to the power supply, contact your CarePath representative for an approved replacement and stop using the base station immediately. Use of a damaged or unapproved power supply can cause the base station / power supply to overheat or shock the user.

Warning: Always position the base station so the power supply is accessible in case the base station needs to be disconnected (unplugged) from AC power during an emergency.

Note: A green LED on the front of the base station base station indicates that it is properly installed.

Caution: Firmware updates will be completed by your CarePath Representative using the USB port on the base station. This USB port is only to be used by CarePath Representative for this purpose.

Charge the CarePath Device

You must fully charge each handle on a base station prior to device assembly and assignment to a patient.

1. Place a device handle into a base station cradle
2. When the handle LED/light is solid green (fully charged), it is ready to be used.

Warning: Use only a CarePath base station with CarePath device handles and only charge CarePath device handles on a CarePath base station or the base station could overheat.

Caution: The CarePath base station and device may become hot during charging. Do not touch the charging area on the base station or hold the device for longer than 1 minute directly after charging, or you could be burned.

Assemble the CarePath Device

CarePath has distinct designs for the male and female anatomy. Select matching color-coded handles and disposables: pink for the female anatomy, blue for the male anatomy.

Assemble the disposable to the handle as part of the process of creating a new study for the patient.

1. Select a charged, anatomy specific CarePath handle from the base station.
2. Select a matching anatomy specific, color-coded CarePath disposable.
3. Hold the handle with the colored portion up as shown.
4. Hold the matching color-coded disposable in the other hand with the colored portion up as shown.

5. Slide the flat surface of the disposable down onto the matching flat surface of the handle until the disposable locks into place.



Assemble the CarePath Device (cont.)

Note: You cannot interchange anatomically different handles and disposables.

Note: Once a handle and disposable interlock, you cannot separate them without the key.

Note: The disposable is meant to be used by a single patient for multiple voids during a single study.

Create a New Study

Once the CarePath device has been assembled, it's time to create a new study and assign the device to the patient.



Tablet App home screen

1. On the home screen, press New Study.
2. On the New Study: Login screen, log in to the CarePath system. The system may attempt to utilize facial recognition to log in a registered

user. Alternately, you can provide your CarePath username and password.

Note- for the tablet do not include "@carepathreports.com"

3. On the New Study: Patient Information screen,



enter the patient data as shown below.

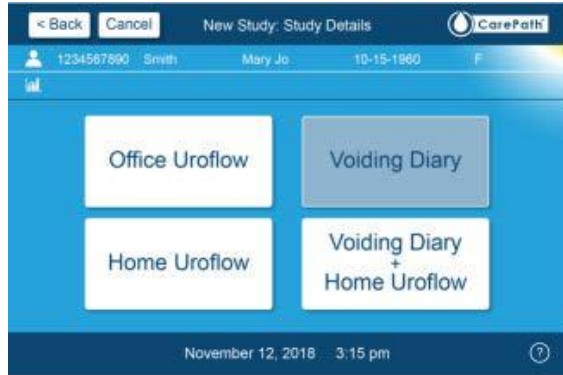
Tablet App patient information screen

Medical Record #	Enter the patient medical record number.
Last Name	Enter the patient last name.
First Name MI	Enter the first name and middle initial.
Date of Birth	Enter the date of birth using MM-DD-YYYY format.
Sex	Press either M for male or F for female.

4. Once you have entered the patient information, press Next.

Create a New Study (cont.)

- On the New Study: Study Details screen, select a study type, such as the voiding diary study.



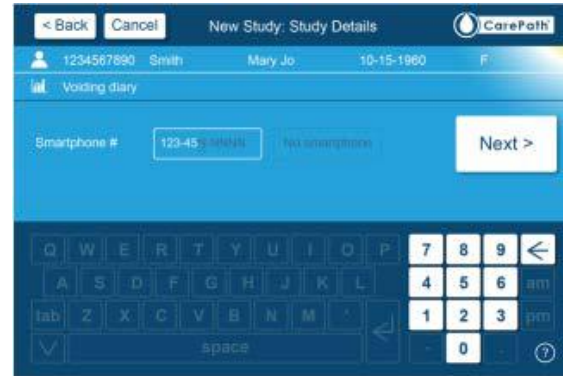
Tablet App study details screen

Note: If you have already assigned a device to the patient for an office uroflow study and you want to assign the CarePath device to the patient for another study, you must press Yes to the question: Reuse currently assigned Device?



Tablet App study details confirmation screen

- For the voiding diary study, complete the required screen.



Tablet App phone number entry screen

- Enter the patient's smartphone number or select No Smartphone if the patient will not be using the Mobile App, then press Next.
- Enter normal waking and bedtime hours, such as 6 am to 10 pm, then press Next.
- For male uroflow studies, enter the patient's AUA-SI value related to prostate symptoms, then press Enter.

Note: This screen will not appear for Uroflow studies.

Note: The AUA symptom index is calculated based on patient symptom severity for prostate function. Symptoms qualify as mild for scores of 0 to 7, moderate for scores of 8 to 19, and severe for scores of 20 to 35.

Create a New Study (cont.)

- Follow the graphic instructions on the New Study: Assign Device screen to assemble the device.



Tablet App device assembly screen

- Register the CarePath device ID, following the graphics on the screen by holding the handle against the tablet and level with the top right corner of the tablet until the tablet emits a tone.

Note: If you do not hear a tone, reposition the handle, repeating until you hear a tone.

- On the New Study: Assign Device screen, review the patient and study details listed beneath the header and choose one of the following actions for uroflow studies:

Submit	Press to finish linking the CarePath device to the patient, then press Submit.
Edit Details	Press to modify the patient data you entered for the CarePath device, then return to this screen and press Submit.



Tablet App device submission screen

- Provide the CarePath device in a storage pouch and the accompanying Quick Reference Guide (QRG) to the patient, after reviewing the use and cleaning instructions from the QRG with the patient. Make the patient aware of the warnings/cautions and expected use positions by the patient below.

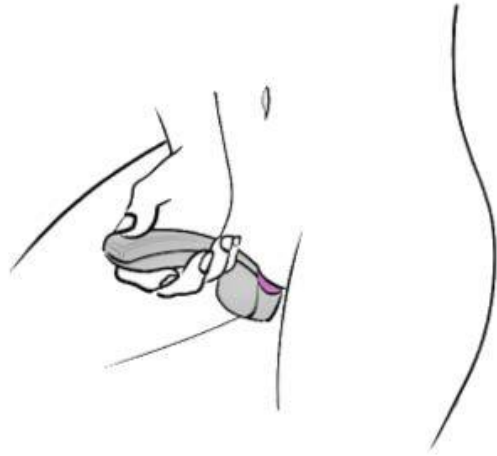
Warning: To avoid the risk of fire, electric shock, or burns, do not crush, incinerate, put in dishwasher, put in microwave, or heat the device above 212°F (100°C). Do not store the CarePath device in your car or in any environment where excessive heat is possible.

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

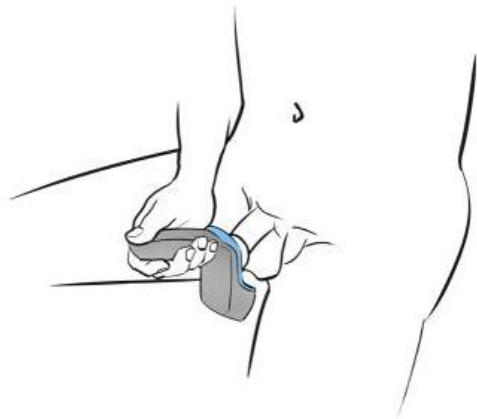
Caution: To clean your CarePath device, rinse it in water only. Do not use any other method of cleaning since it may affect the accuracy of the device.

Create a New Study (cont.)

The following are expected patient use positions of the device for males and females.



Expected female use





Expected male use

Download Mobile App

The mobile app is only used for voiding diaries. The CarePath mobile app requires a smartphone; using Safari on iPhone or Chrome on Android.

You will be prompted to assist the patient with the download and installation of the mobile app on their smartphone.




Caution: The CarePath mobile app installation is associated with a single voiding diary study. If the patient requires a second voiding diary study, the patient must delete the earlier study app, then reinstall the new study app.

1. When the device is successfully associated with the patient's study, a registration link is texted to the patient's smartphone. The phone number associated with the patient's smartphone was manually entered earlier during the Patient Information input process on the tablet app (p. 13).
2. Have the patient check their text messages and click the CarePath registration link.
3. Have them select either the menu option for an Apple smart phone or an Android smart phone, based on their smartphone type.
4. For an Apple smartphone, have the patient press the  option.
5. For an Android smartphone, have the patient press the  option.

Note: If there is a delay between registering the device and selecting the activation link, the user may need to follow additional steps to receive an activation code before completing the steps above.

Download Mobile App (cont.)



For Apple iPhone users, have the patient follow the sequence of prompts from the QRG:

1. At the prompt to add the CarePath mobile app to the homescreen, press  at the bottom of the screen.
2. Scroll to the  icon to Add to Homescreen and press.
3. Press Add. If desired, move the CarePath App button to a more convenient location.
4. Have the patient press  to open the CarePath mobile app.
5. Confirm home screen is displayed.



Mobile App home screen

For Android smartphone users, have the patient follow the sequence of prompts from the QRG:

1. At the prompt to add the CarePath mobile app to the homescreen, press the vertical ellipses ().
2. Press Add to homescreen.
3. Press Add. If desired, move the CarePath App button to a more convenient location.
4. Have the patient press  to open the CarePath mobile app.
5. Confirm home screen is displayed.



Mobile App home screen

Return a Device

After the patient brings the device back, process the return using the tablet app. The Return process closes out the study and allow reports to be generated.

1. On the tablet app home screen, press Return Device.



Tablet App home screen

2. Follow the graphic instructions on the Return Device screen to return the device.



Tablet App return device screen

Note: If you do not hear a tone, reposition the handle, repeating until you hear a tone.

Disassemble & Clean a Device

Prepare device for cleaning:

1. Put on disposable gloves.
2. Remove soiled device from bag. Dispose of bag.
3. Release the disposable portion of the device from the re-usable handle by inserting the CarePath key and rotating it 90 degrees either clockwise or counterclockwise.
4. Separate the disposable from the handle by sliding them apart.
5. Dispose of disposable portion per your institution's policies.

Clean device:

6. Completely clean all of the exposed surfaces of the handle by wiping with a CaviWipe™ towelette.
7. Dispose of used towelette per your institution's policies.
8. Inspect device to ensure no visible soil remains. If visible soil remains, repeat cleaning steps.

Disinfect after cleaning:

9. Using a new CaviWipe™, wipe entire surface with towelette, ensuring that the surface is thoroughly wet. Special care should be taken to ensure that the seams on the side of the handle as well as the indentation at the bottom of the handle are effectively wiped.
10. Ensure that entire surface remains visibly wet for 3 minutes, repeating use of CaviWipe™ towelettes as required.
11. Dispose of used towelette(s) per your institution's policies. Remove and dispose of gloves.

Note: The cleaning and disinfection processes described here are validated processes per TIR30 and TIR12.

Warning: The surface must remain wetted for 3 minutes for proper disinfection.

4 CarePath Reports

Reports fall into two categories:

- ◆ **Single study reports**—Use to view a single study for a specific patient. Single study reports include voiding diary reports, home uroflow reports, and office uroflow reports.
- ◆ **Comparison study reports**—Use to view up to three studies for a specific patient. This is only allowed with up to three of the same study type.

View Patient Report

1. On the home screen of the tablet app or web portal, press View Reports.



Tablet App home screen

2. You may need to log in before continuing.
3. Search for the desired study by medical record #, patient name, or date of birth.
4. Select the correct patient.
5. Scroll through the patient's available studies, then either press a single study tab from the study tabs or select up to three like-studies for a comparison report.
6. Choose from one of the following actions:
 7. To print a single or comparison report, press Print.
 8. To save a single report, press Save.
 9. To exit the report view, press Done.

Note: If printing has not been set up at your facility, contact your I/O Urology representative.

View Study Status

Studies will only appear on the study status screen if there is something wrong with the study.

There are three possible study statuses: Device Overdue, Device Issue, Study Issue.

1. On the home screen of the tablet app or web, press View Reports.

Note: On the top right corner of the View Reports button, there is a blue area with a notification number. The number indicates the number of study status items.

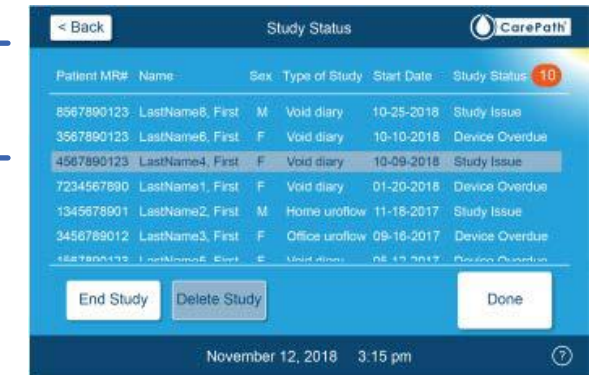


Table App home screen

2. Press Study Status.
3. Select the study of interest

From here you have three options:

- ◆ **End Study**—This will close the study and create a report
- ◆ **Delete Study**—Data associated with the study will be inaccessible.
- ◆ **Done**—No change will be made to the selected study status.



Tablet App study status screen

Physician Portal

The physician portal allows the physician to view CarePath information on a web browser (Chrome, Microsoft Edge, Firefox, or Safari). It can be used for remote patient monitoring, to view reports and data for active and closed studies, view individual void data or change your password.

1. Navigate to: CarePathReports.com
2. Login: Click the login button in the upper right corner. Use your full CarePath username including “@carepathreports.com”

Note: The website will temporarily switch to Microsoft's login page, once your credentials are entered it will return to the CarePath portal.

3. Finding a Patient: Type in the patient's medical record number and click enter.
4. Reports: Locate the report column. To view, print, or download a report, select the appropriate icons.
5. Individual Void Data: From the Study Reports page, select the icon in the Void Detail column to go to the Void Detail page for that study. Then, locate the report row. To view, print, or download a report, select the appropriate icons.
6. User Profile: To log out or change your password click on the profile icon, then select the appropriate button.

5 Service, Storage and Disposal

Service

The CarePath System contains no user-serviceable components. This system is not to be serviced or maintained by the user (patient and professional user) or service personnel.

Useful Life

The CarePath device has a useful life of 5 years from date of manufacture.

Environmental Conditions for Use & Storage

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

Condition	Temperature	Relative Humidity (non-condensing)	Atmospheric Pressure
Operating	+5°C to +40°C	15% - 93%	70 – 106 kPa
Storage	-20°C to +60°C	10% - 100%	50 – 106 kPa
Transport	-20°C to +60°C	10% - 100%	50 – 106 kPa

Disposal of CarePath Components

CarePath Disposable

After the patient has completed the prescribed study and returned the used device to the healthcare provider's office, the used disposable may be disposed of as regular trash material. These disposables are not considered infectious waste per the OSHA Bloodborne Pathogen Standard, which considers urine a non-regulated body fluid.

CarePath Device

When the CarePath device has reached the end of its useful life it should be disposed of separately, not as unsorted municipal waste.

The rechargeable (lithium-ion) battery inside the CarePath device handle is classified as a hazardous material. The U.S. Environmental Protection Agency (EPA) classifies these spent lithium batteries as “Universal Waste” and they must be disposed of accordingly.

The CarePath device handle also contains electronic parts like printed circuit boards, which are classified as “Electronic Waste”. Electronic waste in certain states can be classified as “Universal Waste” and has specific regulations that must be followed for disposal.

If you need information on these disposal systems, please contact your local waste administration. If you require information on collection and disposal of your CarePath device please contact I/O Urology.

6 Assistance & Troubleshooting

Assistance

If you have any questions regarding the use of this product, please call CarePath's Technical Support Number +1 (423) 647-2222, Monday through Friday, between 7:00 a.m. and 5:00 p.m., Central Time, U.S.A.

Tablet App Troubleshooting

Messages pop up on the Tablet App to communicate information or to alert you to conditions that require your attention.

Message	What it means	What to do
Login Error	There was an issue logging in: wrong password, wrong username or both.	Double check your login credentials and try again. In case of repeated failures, contact your CarePath Representative.
System Error	An internal error with the CarePath system occurred.	Retry last operation. In case of repeated failures, contact your CarePath Representative.
Patient already in study	A patient is already a part of a study and cannot be assigned to a new one.	Close the open study and try again.
Patient already in study with phone number	A patient is already enrolled in a study with the phone number.	Ensure the phone number is correct, or close the existing open study.
Patient not currently in study	An issue occurred while trying to re-use a device.	Start a new study for the patient.
Handle not assigned to clinic	The handle you are using is not assigned to the same clinic as this tablet.	Contact your CarePath Representative.
Handle End of Life	The handle has reached its end of battery life, and can no longer support a full study.	Recycle handle and use new handle for study.

Tablet App Troubleshooting (cont.)

Messages pop up on the Tablet App to communicate information or to alert you to conditions that require your attention.

Message	What it means	What to do
Handle is not ready to be used in a study	The handle not ready to be assigned to a study, for one of several reasons.	Place handle on charger and restart study creation. In case of repeated failures, contact your CarePath Representative.
Sex mismatch	Handle sex does not match patient sex.	Ensure the sex of the device, disposable, and study is consistent. Replace the entire handle if necessary.

Mobile App Troubleshooting

Messages pop up on the Mobile App to communicate information or to alert the patient to conditions that require their attention.

Message	What it means	What to do
Invalid phone number	The phone number is not associated with an open study	The patient should retry their phone number and confirm their correct phone number was used during study setup.
Invalid activation code	The activation code is not associated with an open study	The patient should retry the activation code they received.
No internet connection / Error connecting to server	Currently the Mobile App cannot upload data due to lack of internet connectivity.	The patient should wait and data will be automatically sent when the connection is available.

Customer Service

If you have any information about the product, or a patient reports information to you, please call CarePath's Technical Support Number +1 (423) 647-2222, Monday through Friday, between 7:00 a.m. and 5:00 p.m., Central Time, U.S.A.

Manufacturer

I/O Urology Corp.

730 Quail Hollow Dr., Elizabethton, TN 37643

Ph: +1 423-647-2222

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:	16 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: Charge device batteries using only the CarePath base station provided by I/O Urology .

Test	Standard to Which Device Conforms
Product Safety	AAMI/ANSI/ES 60601-1: 2005; (R) 2012 +A1, +A2
Home Use Safety	AAMI/IEC 60601-1-11: 2015
Electromagnetic Compatibility (EMC)/ Electromagnetic Immunity (EMI)	AAMI/IEC 60601-1-2: 2014
Battery	IEC 62133: 2012; UL 1642; UN38.3
Biocompatibility/Toxicity	ISO 10993-1: 2009; ISO 10993-5: 2009; ISO 10993-10: 2010

CarePath Base Station Specifications

Protection against Electrical Shock:	Class II Equipment
Power Supply:	AC/DC wall plug power supply Class II, Input: 100-240 Vac, 50-60Hz Output: 12 Vdc @ 2 Amp
Mode of Operation:	Continuous
Degree of Ingress Protection:	IPx0

- ◆ The CarePath base station has no essential performance (if the device is compromised there is no unacceptable risk to the user (professional users)).
- ◆ The CarePath base station contains no serviceable parts or components for users (professional users) or service personnel. 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.

Warning: No modification of this equipment is allowed.

Warning: Only use power supply provided by I/O Urology .

Note: The CarePath base station can be isolated from mains power by disconnecting (unplugging) the AC/DC wall plug power supply from the AC power outlet.

Test	Standard to Which Device Conforms
Product Safety	AAMI/ANSI/ES 60601-1: 2005; (R) 2012 +A1, +A2
Electromagnetic Compatibility (EMC)/ Electromagnetic Immunity (EMI)	AAMI/IEC 60601-1-2: 2014

Applied Part

The CarePath device will touch the patient during the normal use and is treated as an Applied Part. The CarePath device meets all requirements of a type BF Applied Part.

Biocompatibility

Biocompatibility requirements have been met for the biological evaluation of the CarePath system and its component materials that come into contact with the human body.

Protection Against Ingress of Solids and Liquids

The CarePath device has an Ingress Protection rating of IP22. This means that the device is protected from water spray less than 15 degrees from vertical the enclosure. The CarePath base station has an Ingress Protection rating of IPX0.

Information on Electromagnetic and Other Interferences

The CarePath device has been tested and deemed in conformance with the relevant requirements in EN60601-1-2 Class B for Electromagnetic Compatibility (EMC). The CarePath base station has been tested and deemed in conformance with the relevant requirements in EN60601-1-2 Class A 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: The CarePath base station is intended for use by healthcare professionals only. The base station may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.

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.

FCC Interference Statement

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.

Changes or modifications not expressly approved by I/O Urology could void your authority to operate the equipment.

Electromagnetic Compatibility (EMC) Compliance

The CarePath device 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. The CarePath device 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 the CarePath device does cause harmful interference to radio or television reception, which can be determined by turning the equipment of 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

The CarePath base station has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. The CarePath base station generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of the CarePath base station in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Warning: The CarePath device must not be co-located or operating in conjunction with any other antenna or transmitter.

Radio Wave Exposure and Specific Absorption Rate (SAR) Information

This SAR (Specific Absorption Rate) limit as dictated by the FCC is 1.6W/kg averaged over 1 gram of tissue. The CarePath device has been tested against this SAR limit to maintain compliance with FCC RF exposure requirements.

The CarePath device complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.

FCC Identifiers

CarePath Device

- ◆ FCC ID: 2AVN910631 (LTE Cat-M1 cellular module)
- ◆ FCC ID: 2AVN910632 (CarePath Device)

CarePath Base Station

- ◆ FCC ID: 2AVN910633

Care Path Device - Information on the Radio Subsystem

The CarePath device contains the following radio frequency transmitters:

Model	Type and Frequency Characteristics
LTE Cat-M1 Model: nRF9160	700 – 2200 MHz 1.4 MHz bandwidth
NFC RFID Model: ST25R95	13.553 – 13.567 MHz Modulation ASK (Amplitude Shift Keying)

CarePath Device Emissions Compliance

Guidance and manufacturer's declaration - electromagnetic emissions		
The CarePath device is intended for use in the electromagnetic environment specified below. The user of the CarePath device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF Emissions (CISPR 11)	Group 1	CarePath device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions (CISPR 11)	Class B	The CarePath device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 6100-3-3	Not Applicable	

CarePath Device Immunity Compliance

Guidance and manufacturer's declaration – electromagnetic immunity – Enclosure Port		
The CarePath device is intended for use in the electromagnetic environment specified below. The user of the CarePath device should assure that it is used in such an environment.		
Immunity test	Compliance Test Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches)
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See next table below	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches)
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

CarePath Device Immunity Compliance (cont.)

Guidance and manufacturer's declaration – electromagnetic immunity						
Compliance Test Levels for Enclosure Port Immunity to RF wireless communications equipment						
Test frequency (Mhz)	Band	Service *	Modulation	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation ** 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460; FRS 460	FM +/- 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation ** 18 Hz	0.2	0.3	9
810 870 930	800 - 960	GMS 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	Pulse modulation ** 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE BVand 1, 3, 4, 25; UMTS	Pulse modulation ** 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth; WLAN 802.11 b/g/n; RFID 2450; LTE Band 7	Pulse modulation ** 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11a/n	Pulse modulation ** 217 Hz	0.2	0.3	9

* For some services, only the uplink frequencies are included.
 ** The carrier is modulated using a 50% duty cycle square wave signal

CarePath Base Station Emissions Compliance

Guidance and manufacturer's declaration - electromagnetic emissions		
The CarePath base station is intended for use in the electromagnetic environment specified below. The user of the CarePath base station should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF Emissions (CISPR 11)	Group 1	CarePath base station uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions (CISPR 11)	Class A	The CarePath base station is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Harmonic emissions IEC 61000-3-2	Class A	WARNING: The CarePath base station is intended for use by healthcare professionals only. The base station may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.
Voltage fluctuations/flicker emissions IEC 6100-3-3	Complies	

CarePath Base Station Immunity Compliance

Guidance and manufacturer's declaration – electromagnetic immunity – Enclosure Port		
The CarePath base station is intended for use in the electromagnetic environment specified below. The user of the CarePath base station should assure that it is used in such an environment.		
Immunity test	Compliance Test Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches)
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table above	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches)
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.






CarePath Base Station Immunity Compliance (cont.)

Guidance and manufacturer's declaration – electromagnetic immunity – Power and Signal Ports		
The CarePath base station is intended for use in the electromagnetic environment specified below. The user of the CarePath base station should assure that it is used in such an environment.		
Immunity test	Compliance Test Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV AC and DC power ports ± 1 kV signal ports 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surges Line-to-ground IEC 61000-4-5	Not applicable	The CarePath base station is intended to be supplied by a secondary IEC 60950 compliant AC/DC power supply.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V a) 0,15 MHz – 80 Mhz 6 V a) in ISM bands between 0,15 MHz and 80 MHz b) 80 % AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey c), should be less than the compliance level in each frequency range. Interference may occur near equipment marked with the following symbol:
Voltage dips IEC 61000-4-11	Not applicable	The CarePath base station is intended to be supplied by a secondary IEC 60950 compliant AC/DC power supply
Voltage interruptions IEC 61000-4-11	Not applicable	

8 Symbols Glossary

Physical Packaging and Labeling

The following symbols may appear on the CarePath system labeling or packaging.

Symbol	Standard	Title	Meaning
	ISO 15223-1	Consult Instructions for use (Ref # 5.4.3)	Indicates the need for the user to consult the Instructions for use.
	ISO 15223-1	Keep Dry (Ref # 5.3.4)	Medical device needs to be protected from moisture
IP22	IEC 60529	Protected against solid foreign objects of 12.5 mm \AA and greater. Protection against vertically falling water drops when enclosure tilted up to 15°.	Protected against finger sized objects. Protected against dripping water when tilted up to 15 degrees from specified orientation.
	ISO 60417	Type BF Applied Part (Ref # 5333)	Identifies a type BF applied part complying with IEC 60601-1.
	ISO 60417	Class II equipment (Ref # 5172)	Double insulation or reinforced insulation for protection against electric shock
	ISO 7000	Temperature limit (Ref #0632)	Indicates the temperature limits to which the medical device can be safely exposed.














Mobile App Labeling

The following symbols may appear in the CarePath Mobile App. For more information about the Mobile App, see Chapter 3 of this document (p. 11-19) and the CarePath Patient User Guide.

	Fluids		Next page
	Void		Previous page
	Bladder leak		Urgency / Urgency rating
	Onboard help		Mild urgency
	Drops		Moderate urgency
	Wet		Severe urgency
	Soaked		Activity
	None / No cause		Small drink (4-8 oz.)
	Apple / iOS device		Medium drink (10-14 oz.)
	Android / Google device		Large drink (16-20 oz.)
	CarePath Mobile App logo		X-Large drink (24-32 oz.)
	Add to homescreen (Apple / iOS device)		More (Android / Google device)
	Share (Apple / iOS device)		

Tablet App Labeling

The following symbols may appear in the CarePath Tablet App. For more information about the Tablet App, see Chapter 3 and 4 of this document (p. 11-19, 20-21).

	New study		Onboard help
	Patient reports		Previous page
	Patient report count		Next page
	Return device		Patient study count
	Patient information		Success / Complete
	Problem with device or system: See accompanying on-screen message		Patient report: A parameter or multiple parameters are outside the expected range
	Successful device scan		

Index

A

Assembling 12-13
Assigning 15

B

Base Station
Installing 11
Charging devices 12

C

CarePath system
Overview 6
Components 6
Clinical details 8
Cleaning 19
Customer service 25

D

Disinfecting, *see* Cleaning
Disassembling 19
Disposal 22
Downloading 16-17

F

FCC Information 29,30

G

Glossary
of terms 5
of symbols 34-36

L

Labeling 34-36
Lights
on CarePath Device 7

M

Mobile app 6, 16-17

O

Office uroflow, *see* Uroflow

P

Patient components 6

R

Reports 20-21
Returning 18

S

Storage 22
Symbols
Physical 27
Mobile app 28
Tablet app

T

Tablet App
Technical information
Troubleshooting

U

Uroflow study
at home 10
in-office 8

V

Voiding diary study 9
Voiding diary + uroflow 10

This page intentionally left blank

I/O Urology Corp. 730 Quail Hollow Dr. ■ Elizabethton, TN 37643 ■ Ph: +1 423-647-2222 ■ www.i-ourology.com