CarePath System

Patient User Guide

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UROLOGY

CarePath System

Urine Flow Device

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Find us on the World Wide Web at:

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

Contents

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

General Description

The CarePath system facilitates studies measuring urine output. It consists of the CarePath device, a mobile app, accompanying documents, and training. 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
- Creates and provides void-related 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 System Components

- CarePath device
- Storage pouch
- Quick Reference Guide (QRG)
- Mobile app (voiding diary studies only)

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. There are no known contraindications for the CarePath system.

2 Getting Started with the CarePath System

Your healthcare provider has determined a study is necessary for identifying your current voiding patterns in your typical environment. CarePath provides a low-impact method of tracking your daily routine using the following resources:

♦ A CarePath device

♦ Mobile app (voiding diary studies only)

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.
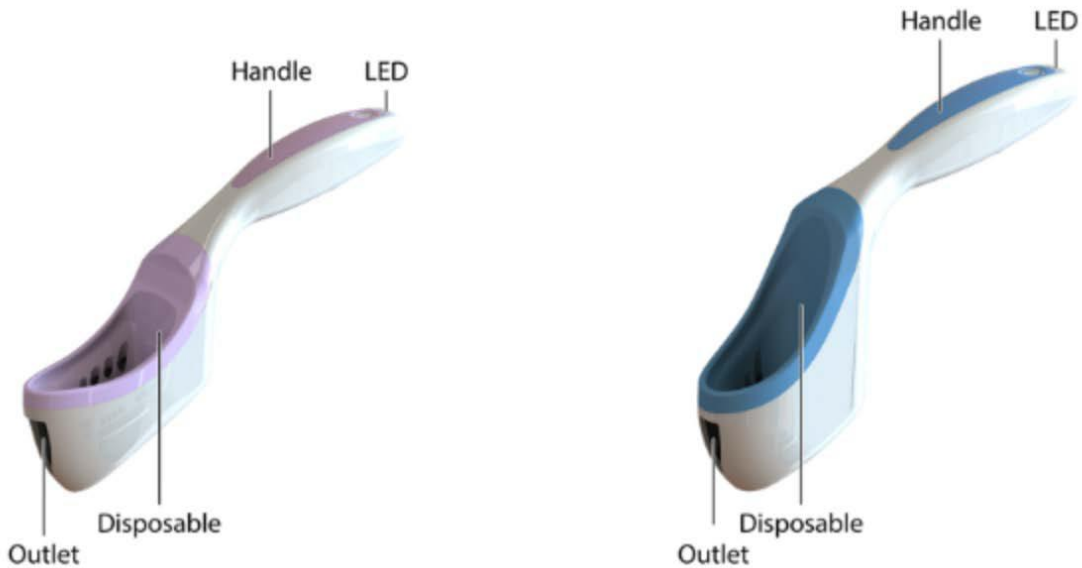
The CarePath Device

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

Note: Do not attempt to separate the disposable receptacle from the handle.

Note: CarePath has distinct designs for the male and female anatomy.

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

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

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

CarePath Device LED / light states

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. Return device to your healthcare provider.

The CarePath Mobile App

The CarePath mobile app provides you with a low-impact method of tracking your daily fluid intake and voiding routine while using the CarePath device. It links your specific CarePath device to the mobile app on your smart phone.


Note: **If you do not have a smart phone, or have issues with mobile signal reception, discuss the manual voiding diary option with your healthcare provider. You will need to record your daily fluid intake, void urgency, and any leakage manually. You will still use the CarePath device to record voiding times and voiding volume.**

The user-friendly interface provides you with basic recording prompts during the day and also identifies your nighttime routine. It allows you to record three types of data:

1. Your fluid intake by general volume

2. Your level of voiding urgency

3. Any bladder leakage you may experience

Mobile App overview

- ◆ **Back Button**—Press to access prior screen.
- ◆ **Help**—Press to access user help.
- ◆ **Date**—Displays the current date.
- ◆ **Menu Options**—Select a menu option from the home screen to add a voiding diary entry.
- ◆ **Study Day**—Displays the day number of the home study.
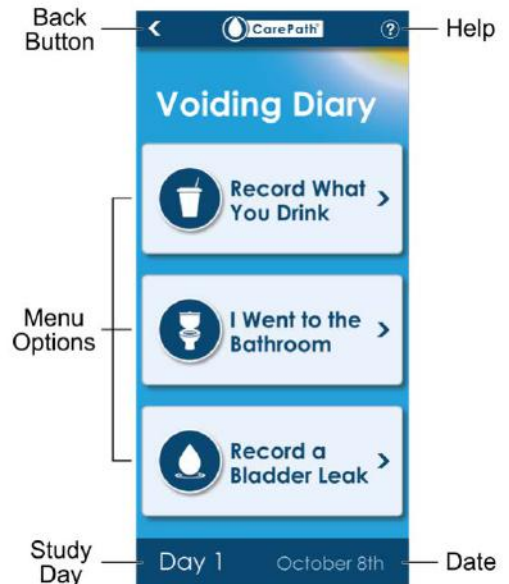
3 Using Your CarePath Device and Mobile App

Before you begin your home study, 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.

Starting with Your Practice Day

The day you receive your CarePath device from your healthcare provider is called your "Practice Day". The Practice Day allows you to become familiar with using the CarePath device without the data affecting the study your healthcare provider prescribed.

Follow the instructions in the Quick Reference Guide (QRG) or on p.14 of this guide to void into the CarePath device once or twice on your Practice Day. Don't worry, the data won't affect the study. Take your time to become familiar with the LED lights (p.8) and holding the device in the correct orientation (p.14) for data collection.

The Practice Day allows you to try out the CarePath device and get familiar with the process before starting your study.

Your prescribed study will begin the day after your Practice Day.

Installing the CarePath Mobile App

Note: Browsers update frequently, if issues are found with these instructions that prevent installation, contact your healthcare provider for assistance. Only use Safari for iPhones and Chrome for Androids.

Note: The following sections apply only if you are using the CarePath mobile app on a smart phone.

Note: If you do not have your phone with you during your visit, but plan to use the mobile app, you may need to enter your phone number and an activation key that will be texted to you after clicking the activation link.

If you brought your smart phone with you to your appointment, your healthcare provider will assist you in adding the CarePath mobile app to your smart phone. If not, you must add the app before you can begin your home study.

Here are the tasks to add the CarePath mobile app to your smart phone:

1. You'll receive a text message on your smart phone with a unique and secure link to install the mobile app.

♦ If you do not receive a text message with a CarePath link, contact your healthcare provider.

2. Press on the link to open a web browser with instructions for installing the mobile app.

♦ You might also be asked to enter your phone number to receive an activation code before installing the app. This activation code will be automatically sent to you as a text message.

3. Select the appropriate option for an Apple smart phone or an Android smart phone, based on your phone type.

♦ For an Apple smart phone, press the option.

♦ For an Android smart phone, press the option.
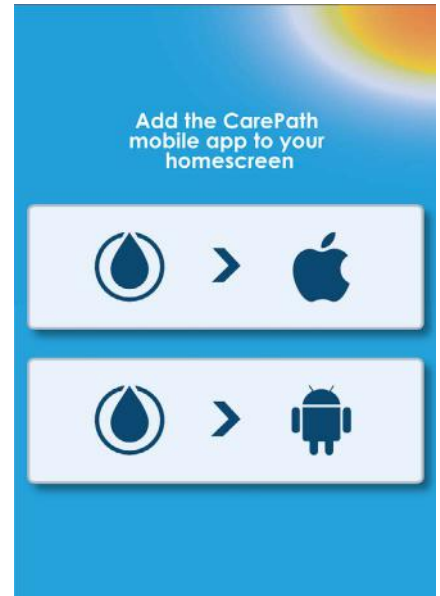
Installing the CarePath Mobile App (cont.)

For Apple iPhone users, follow the 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. Press ◉ to open the CarePath mobile app.

5. Confirm home screen is displayed.

Mobile App home screen

For Android smartphone users, follow the 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

Making an Entry in Your Mobile App

Typically, your healthcare provider will ask you to make an entry in the CarePath mobile app each time you drink fluid, each time you void, and each time you experience a bladder leak. Most entries should occur when you are active during the day. If you awaken to void during your sleep period, you may choose whether to wait until morning to make a diary entry or to make the entry at the time of occurrence.

Day 1 of the Voiding Diary study should begin with your first morning void of the day following receipt of the CarePath device.

For example: Your healthcare provider sent you home with a device on Wednesday. Day 1 of your Voiding Diary starts with your first void on Thursday morning.

Use the following procedures in the order that you find most natural until it is time to return the CarePath device to your healthcare provider.
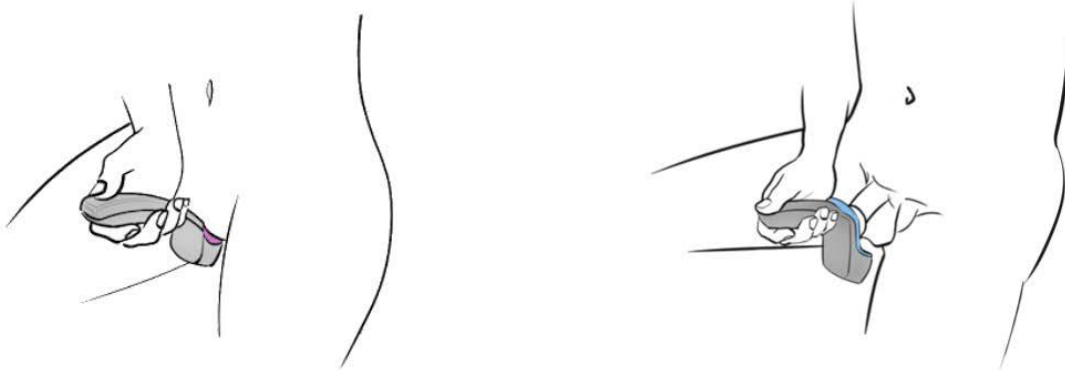
Recording a Void

Note: **Data transmission automatically occurs for each void.**

Note: **You may enter void information into the mobile app only after a void has been received. Cellular coverage can affect the rate of data transfer. You will receive a text message reminder after the data is received.**

For each scheduled study day established with your healthcare provider, you must use the CarePath device and mobile app every time you void. Here are the tasks for recording a void.

1. Sit on the toilet. This is important for both women and men.

2. Remove the CarePath device from its storage pouch.

3. Bring the device to your body according to your anatomy. For women, the device should be touching your body. For men, the device can either be touching you or held close to your body as shown below.

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

Recording a Void (cont.)

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 void.

5. Urinate into the device. Urine will flow through and out the outlet in the front of the device into the toilet.

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 its storage pouch. You may lay your device out to dry before placing it in the storage pouch, if desired.

8. You'll **receive a text message on your smart phone** when it's time to enter information about your void.

♦   If you try to enter information before it's time, you might get a "*No Void Data*" error, so wait for the text message.

9. Using your smart phone, press ⭕ to open the CarePath mobile app.

10. Press **I Went to the Bathroom**.

11. Select one of the two options, **Convenience** or **Urgency**, depending on why you used the bathroom.

♦   If you selected "*Urgency*", you will be asked about how the urgency felt, whether you experienced any leakage, and whether you needed to change your protection.

12. Finally, you will be asked if you want to record if you've had **anything to drink**.

13. You will be returned to the home screen once you are done.

You successfully recorded a void.

Remember to follow these steps throughout your scheduled study.

Recording Your Fluid Intake

For each scheduled study day established with your healthcare provider, use the mobile app to track what you drink. Here are the tasks for recording your fluid intake.

1. Using your smart phone, press ⦿ to open the CarePath mobile app.

2. Press **Record What You Drink**.

3. Select one of the four options, depending on how much you had to drink: **Small**, **Medium**, **Large**, or **X-Large**. It's not important what you drank (e.g. water, soup, coffee, melted ice cream, etc.) but rather the overall quantity. Do your best to estimate.

4. Press **Done** when you have made your selection.

5. You will be returned to the home screen once you are done.

You successfully recorded your fluid intake.

Remember to follow these steps throughout your scheduled study.

Recording a Bladder Leak

Note: Data transmission automatically occurs for each entry.

For each scheduled study day established with your healthcare provider, make a special diary entry for bladder leaks that you have not already recorded as part of a void entry. Here are the tasks for recording a bladder leak.

1. Using your smart phone, press ⬤ to open the CarePath mobile app.

2. Press **Record a Bladder Leak**.

3. Select one of the three options, depending on what you felt was the primary cause for your bladder leak (if any): **No Cause**, **Activity**, or **Urgency**.

   ♦ If you selected "*Activity*" , you will be asked about the specific activity.

   ♦ If you selected "*Urgency*", you will be asked about how mild or severe the urgency felt.

4. Finally, you will be asked about the amount of leakage and whether you needed to change your protection.

5. You will be returned to the home screen once you are done.

You successfully recorded a bladder leak.

Remember to follow these steps throughout your scheduled study.

Understanding Day & Night Modes

For each scheduled study day established with your healthcare provider, the CarePath mobile app sends you messages during the Wake Up and Bedtime hours you set up with your healthcare provider. You are not expected to use the mobile app after you go to bed.

First thing in the morning and just before you go to bed, the mobile app will ask you several questions.

Upon Wake Up

1. Record your void following the steps in the Recording a Void section (p. 14-15).

2. The mobile app will ask you whether you are getting up for the day or not.

3. Answer "*Yes*" or "*No*".

♦ If you answer "*No*", the mobile app will stay in Night mode and will not start a new study day.

4. If you answer "*Yes*", the mobile app will enter Day mode and start a new study day.

5. You will be asked about your most urgent void during the night (which might be your morning void).

Before Bedtime

1. Around the bedtime hour you established with your healthcare provider, you will be asked by the mobile app if this is your last void before bed.

2. Answer "*Yes*" or "*No*".

♦ If you answer "*No*", the mobile app will stay in Day mode and will continue to gather your data for that day.

3. If you answer "*Yes*", the mobile app will enter Night mode and will not send you messages until morning.
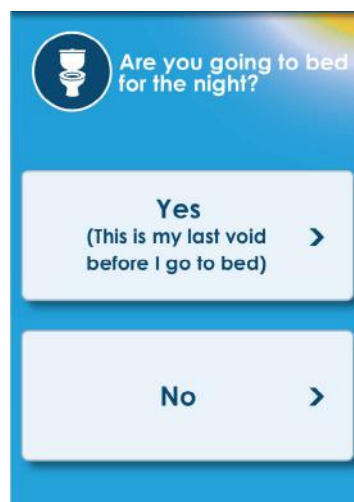
4 Caring for Your CarePath Device

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. Follow the steps in Chapter 5 (p. 20) and return it to your provider at your next scheduled appointment.

5 Returning Your CarePath Device

Your healthcare provider will contact you and let you know you are done and when you can return the device.

Once your healthcare provider has let you know it's time to return your device, return it to its storage pouch, and take it to your next scheduled appointment.

6 Getting Help

Note: **Contact your healthcare provider with any questions or concerns regarding use or care of your CarePath device.**

Mobile App Troubleshooting

Messages pop up on the CarePath mobile app to communicate information or to alert you to conditions that require your attention.

Message	What it means	What to do
Invalid phone number	The system did not recognize the phone number you entered.	You should retry your phone number. If you continue to receive this message, contact your healthcare provider.
Invalid activation code	The system did not recognize the CarePath activation code you entered.	You should retry the CarePath activation code you received in your text messages. If you continue to receive this message, contact your healthcare provider.
No internet connection / Error connecting to server	Currently the Mobile App cannot send or receive data due to lack of internet connectivity.	You don't need to do anything. Your CarePath device will automatically send and receive data when the internet connection is available.

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 healthcare provider or I/O Urology technical support.

Does it matter what time I record what I drink?

No, the CarePath system just cares about total daily volume, but do your best to record what you drink throughout the day.

Do I need to record what I drank?

No, the CarePath system just cares about how much, not what you drank.

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

You cannot manually enter a void. Do your best to remember to use the device every time you void.

How do I add the CarePath mobile app to my home screen?

See Chapter 3 (p. 10-12) of this guide.

Depending on your phone settings, you might need to scroll down or to one side to see the options; when in doubt, search online or consult the phone manual.

How do I know when it's time to return the CarePath device?

See Chapter 5 (p. 20) of this guide.

Your healthcare provider will contact you and let you know you are done and when you can return the device.

Why can't I open the CarePath mobile app anymore?

When the CarePath system has collected enough data per your healthcare provider's instructions, you will no longer be able to open the mobile app.

Customer Service

If you have any information about the 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.

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: Do not attempt to charge the CarePath device. The CarePath device does not require charging during your study and can only be charged by your healthcare provider using a specialized CarePath charger.

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

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.**

8 Symbols Glossary

Mobile App Labeling

The following symbols may appear in the CarePath mobile app. For more information about the mobile app, see Chapter 2 (p. 7-9) and Chapter 3 (p. 10-18) of this 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.)

Mobile App Labeling (cont.)

	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)		

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