



Stream Dx Uroflowmeter

User Manual

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1 Introduction

1.1 Stream Dx Uroflow System

The Stream Dx Uroflow System includes both a device (Stream Dx Uroflowmeter) and a secure web portal (Stream Dx Cloud) which provides urine voiding reports for physicians. The device consists of two parts, the containment Sleeve, and the Electronic Base (also referred to as a Puck Assembly). The Sleeve and Electronic Base combine to create the Uroflowmeter.

The Stream Dx Uroflow System is designed to allow physicians to order a device to be sent to a patient for use in the comfort of the patient's home. Data collected by the in-home device can be used to create a voiding diary which includes volume, flow rate, and time of voiding events.

When a patient is finished using the device for the designated time, they will dispose of the Sleeve and return the Electronic Base using a prepaid envelope. Once the device is returned to a Stream Dx facility, data on the device is uploaded to the Stream Dx Cloud and is used to generate a uroflow report.

The uroflow report includes:

- An overall and daily summary of all voids.
- A Liverpool Nomogram.
- An International Prostate Symptom Score (I-PSS) Survey, provided by the patient.
- Line graphs with superimposed uroflow traces for visualizing flow patterns by time period. The time periods are: all voids, 6am to 2pm, 2pm to 10pm and 10pm to 6am. Each of the line graphs feature an overall average flow trace for visualization.
- Histograms for visualizing distribution of max volume, max flow rate, and average flow rate among all the voids.
- A voiding diary containing summaries for each void.

The Stream Dx Uroflowmeter is primarily intended to capture voiding data in the patient's home and provide the data to physicians as an aid in developing or monitoring treatment plans. The ability to capture urine flow data outside the clinic in an environment more natural to the patient can lead to improved quality of data, improved patient convenience, improved clinic workflow, and a larger amount of data available to the physician, leading to greater statistical significance in diagnosis.

There is one model of the Stream Dx System: Version 1.

1.2 Intended Use

The Stream Dx Uroflowmeter is intended to electronically collect adult male patient voiding data to assist in the diagnosis of Lower Urinary Tract Symptoms (LUTS). This device is intended for home use.

Stream Dx will calculate a patient's flow rate and their maximum voided volume based on recorded data. This information will be provided to the patient's provider by Stream Dx.

The data obtained from the Stream Dx Uroflowmeter is meant to be used exclusively as a tool to aid in the diagnosis of a condition. It is not intended to be used alone as the sole method of diagnosis.

1.3 Safety Information

The Stream Dx User Manual is intended for physician instruction of the Stream Dx Uroflowmetry System. Safety information can be found in Appendix A.

1.4 User Requirements

To use the Stream Dx Uroflowmeter, a patient needs to meet the following requirements:

- Physically capable to urinate while standing.
- Cognitively able to follow the instructions.
- Willing to use and return the device promptly.
- Correct contact information is provided (Address and Phone Number).
 - Email address if available.

A patient and/or caregiver should be capable of pressing the start button to start and stop data recording, adding the Pre-fill Cup of water into the device, emptying out the device, and rinsing the inner part of the cup when finished. Physicians are encouraged to verbally instruct patients on how to use the device. Instructions will be included with every order (See Section 4). No environmental restrictions are currently in place for use location.

1.5 About this Manual

The Stream Dx User Manual is intended for all providers performing investigations with the Stream Dx Uroflow System.

This manual provides you with detailed information concerning:

- Clinic Registration (Chapter 2)
- Ordering a Stream Dx Uroflowmeter for Patient Use (Chapter 3)
- Patient Explanation and Instruction (Chapter 4)
- Device Return and Disposal (Chapter 5)
- Maintenance and Troubleshooting (Chapter 6)
- Navigating the Stream Dx Data Portal (Chapter 7)
- Technical Specifications (Chapter 8)

The Stream Dx Instruction Manual (trifold pamphlet) is intended for patients using Stream Dx Uroflowmetry System in a home setting.

Feedback on this manual

Stream Dx welcomes your feedback to improve our manuals. Please send your questions and comments to Stream Dx at support@streamdx.com.

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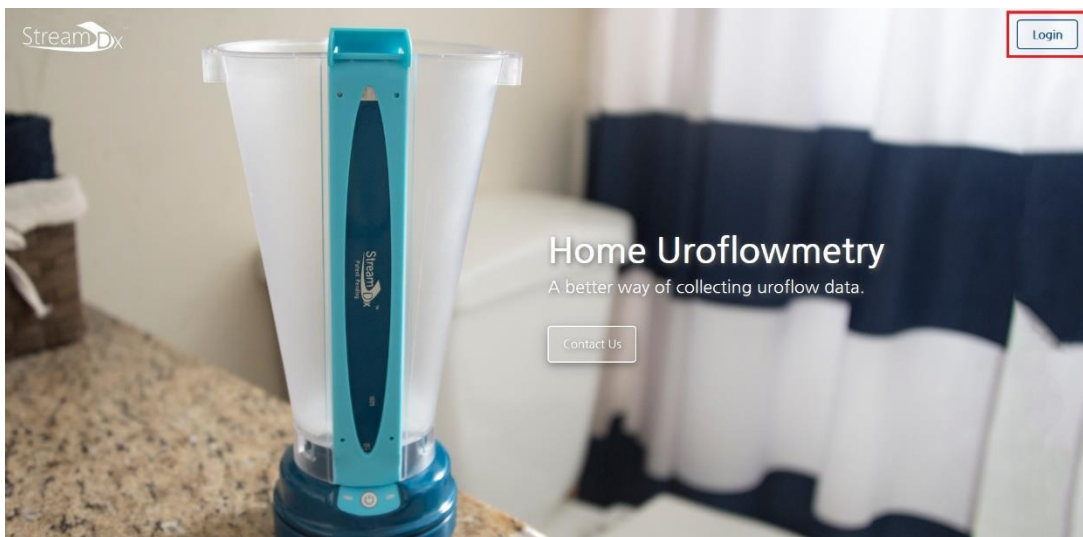
Stream Dx Uroflowmeter User Manual
Device Model: SDX01
Device Version: V001
Document Number: SDX1-5005-04
Document Revision: B

2 Clinic Registration

2.1 Creating an Account

A clinician must create an account with Stream Dx before ordering a Stream Dx Uroflowmeter.

1. Use a web browser to visit <https://streamdx.com>. We recommend using Google Chrome for accessing our data portal.
2. On the top right corner of the page, click the Login button.



3. This will bring you to the Login Page. Click the Clinic Registration link to begin creating an account.
4. Follow the instructions on the page to create your clinic account.
 - Your username may be the same as your email.
 - A Stream Dx Sales Rep Code is required to finish the registration process. If you do not have a Sales Rep Code, please call Stream Dx at 385-549-8060 and one will be provided to you.

3 Ordering a Stream Dx Uroflowmeter for Patient Use

3.1 Patient Registration

1. Log into your clinic account.
2. On the patient list, click on the Register New Patient Button.
3. Enter in the patient information on the Register New Patient page and click submit.
 - The patient's address must be an address which the United States Postal Service (USPS) delivers to.
4. A successful registration of the patient will bring you back to the Patient List page and the newly registered patient should show up in the list.

3.2 Ordering a Stream Dx Uroflowmeter

1. To order a device for a registered patient, click on the Order Device button on the same row in which the patient name appears.
 - An order device button can also be found on the Patient's History page.
2. Make sure the Patient's shipping and contact information is current and submit the order.
 - A patient who currently has an order in progress cannot be ordered a new device until the order in progress has been completed. The system prevents more than one device being ordered for the same patient at any given time.
 - The patient should receive a confirmation email once the order has been placed. This email will include a link to an instructional video on how to use the Stream Dx Uroflowmeter.

3.3 Instructing the Patient

Inform the patient that they will be receiving a call from Stream Dx to confirm their address and phone number prior to shipment of the device. The device will arrive approximately 2-3 business days after a patient's address and number has been confirmed.

Go over the information covered in Section 4 Patient Explanation and Instruction with the patient.

An I-PSS survey will be included when the patient receives the Stream Dx Uroflowmeter. Ask the patient to complete the I-PSS Survey and return it back to Stream Dx with the return package.

4 Patient Explanation and Instruction

4.1 Explanation to the Patient

When ordering a Stream Dx Uroflowmeter for a patient, the clinic must explain the use and return instructions to the patient.

Please refer to Section 4.2 to view the Patient Instructions for Use and review them with the patient. Answer any questions regarding the use of the device with the patient.

Review the procedure below with the patient. This procedure is to be repeated every time they record a void.

1. Place the Stream Dx Uroflowmeter on a toilet lid such that the power button is facing towards you. If a closed toilet lid is not available, place the Stream Dx device on a level surface at a height that is comfortable for urinating into the device.
2. Press the power button on the Stream Dx Uroflowmeter and ensure that the green light is flashing, indicating that it is recording data.
3. Completely fill a Pre-Fill cup (included in the package) with water and pour slowly into the device. This step must be completed before every voiding event.
4. Urinate into the Stream Dx Uroflowmeter and aim towards the target on the inside of the sleeve. Do not pick up the device while urinating into the device.
5. When finished, push the power button once more to stop recording and to turn off the device.
6. Empty the urine into the toilet and rinse the inside of the Sleeve with tap water.
7. Store the empty device in the upright position next to the toilet for next use.

Emphasize to the patient the importance of using the Pre-Fill cup and keeping the device undisturbed on the level surface when in use. The data collected may not be usable if the device is used incorrectly.

Review Section 5 with the patient for instructions on cleaning, disposal of the sleeve and return of the electronic base prior to sending the Stream Dx Uroflowmeter home with the patient.

Inform the patient that it is acceptable to start a recording and terminate if they are unable to void. This will not affect their test or the ability for the device to record a future void.


Refer to Section 6.3.2 for an explanation of status LED lights and review these with the patient.

4.2 Patient Instructions for Use


The following two-sided, trifold pamphlet will be sent to the patient as instructions on how to use the device. The pages included here are for reference only and should remain with the instruction manual. The instruction manual is also available in Spanish (not pictured).

RETURNING


1 Hold onto electronic base and twist off the empty sleeve.




3 Place the electronic base in the pre-paid return envelope.




2 Dispose of the sleeve and cups in the trash.



4 Place the envelope in your mailbox or drop off at a USPS office.





Instruction Manual

READ BEFORE USE


Watch video at streamdx.com/patient-video

For any problems or questions, please call **385-549-8060**


HOW TO USE (Use for 7 days, or as recommended by physician)

FREQUENT QUESTIONS


1 On a level surface, turn on. Wait for green LED blink only.




4 Urinate into device. Do not pick up during use.




2 Before each use, fill small cup full with water.




5 Before picking up the device, turn it off.



3 When green LED is blinking, slowly pour in water over 3-5 seconds.¹



6 Empty and rinse the inside with water only. Empty after finished.²




How long should I use the device?
After receiving the device, **begin to use immediately** as often as possible for 7 days or as prescribed.

Do I need to prefill the device with water every time I use it?
Yes, make sure the green LED is blinking **before** prefilling the device.

Can I pick up the device to urinate into it?
No, the device should remain on a level surface until you are finished urinating.

TROUBLESHOOTING

BOTH GREEN AND RED LED BLINKING
The device is not on a level surface. Place it on a level surface.



For any other issues, call the StreamDx support line at 385-549-8060.

² Do not rinse the exterior of the device. Wipe the exterior with a dry tissue if necessary.

¹Do NOT throw away small measuring cup until you send the device back.

SDX1-5005-03.01.D

4.3 I-PSS Survey

An I-PSS (International Prostate Symptom Score) survey will be provided to each patient who receives a Stream Dx Uroflowmeter. Instruct patients to fill out the survey and return to Stream Dx. I-PSS surveys returned by patients will be included in the final reports for each order. A Spanish version of the I-PSS survey is printed on the reverse side of the page.

4.4 Items Provided to the Patient

Each Stream Dx Uroflowmeter package will include the following items:

Identifier	Item	Quantity
1	Stream Dx Disposable Sleeve	1
2	Stream Dx Electronic Base	1
3	Pre-Fill Cup	2
4	Return Envelope	1
5	I-PSS Patient Survey	1
6	Instructions for Use	1



5 Device Return and Disposal

5.1 Return of Stream Dx Electronic Base

1. The patient should twist the top Sleeve portion (Counter-clockwise when looking down into the Sleeve) off of the electronic base.
2. The Stream Dx Electronic Base should be placed in the pre-paid return envelope along with the I-PSS survey and sealed closed. The patient may drop off the pre-paid return envelope at any USPS mailbox or USPS office.

5.2 Disposal of the Stream Dx Sleeve

1. The patient may dispose of the Sleeve in the trash once they are finished with it.

6 Maintenance and Troubleshooting

6.1 Introduction

This chapter contains information regarding the maintenance and troubleshooting of the Stream Dx Uroflowmeter.

6.2 Maintenance: Home Cleaning and Sensor Care

The Stream Dx Uroflowmeter is clean and ready to use when it is sent to the patient; the Sleeve is new and the electronic base has been disinfected. The patient should follow the instructions below to maintain the Uroflowmeter during the testing period.

1. After disposal of urine, rinse the inside of the device with tap water.
 - External parts of the device can be wiped clean with a tissue or cloth.
2. Store in the upright position in preparation for the next use.
3. DO NOT remove the Sleeve from the Electronic Base between uses. The separation of device components should only be completed once, at the end of the use period.
4. If the Sleeve is accidentally removed from the Electronic Base, attempt to reconnect the Sleeve to the Electronic Base. If you have difficulties or the device is not functioning as expected, call the Stream Dx support line at 385-549-8060.

6.3 Troubleshooting

6.3.1 Stream Dx Uroflowmeter Does Not Function

If the Stream Dx Uroflowmeter is not functioning as expected, call the Stream Dx support line at 385-549-8060 and a customer support agent will assist in troubleshooting or replacing the device.

6.3.2 Explanation of the Status LEDs

The Stream Dx Uroflowmeter contains two status LEDs for status indication. The LED on the left is green and the LED on the right is red, see image below. Please refer to the table below for descriptions of each status indication.



Green (Left) LED	Red (Right) LED	Indication
Off	Off	Stream Dx Uroflowmeter is not functioning. Possible reasons: <ul style="list-style-type: none"> • Device is off • Device has run out of battery. (Less likely)
Flashing Green	Off	The device has been activated and is ready to record.
Flashing Green 3 times after Button is pushed	Off	The device has successfully saved the recorded data and is entering low power mode.
Flashing Green	Flashing Red	Device is not on a level surface. Please place device on a level surface. Red light will turn off when the device is at a satisfactory tilt.
Off	Solid Red	Device is not functioning correctly. Please contact Stream Dx.
Off	Flashing Red 3, 5, or 7 times and shutting off.	Device is not functioning correctly. Please contact Stream Dx.
Flashing Green 3 times and turns off, independent of button push.	Off	Device has timed out. The device will automatically turn off 5 minutes after the Button has been pressed. The device will still be ready to record data after the Button is pressed again.

6.3.3 Damage to Device

Prior to use, visually inspect the device for damage. If any damage is seen, such as cracked or broken plastic components, do not use the device. Contact Stream Dx directly at 385-549-8060 and notify us of the issue.

If you suspect the device has been damaged during use, do not use the device. Contact Stream Dx directly at 385-549-8060 and notify us of the issue.

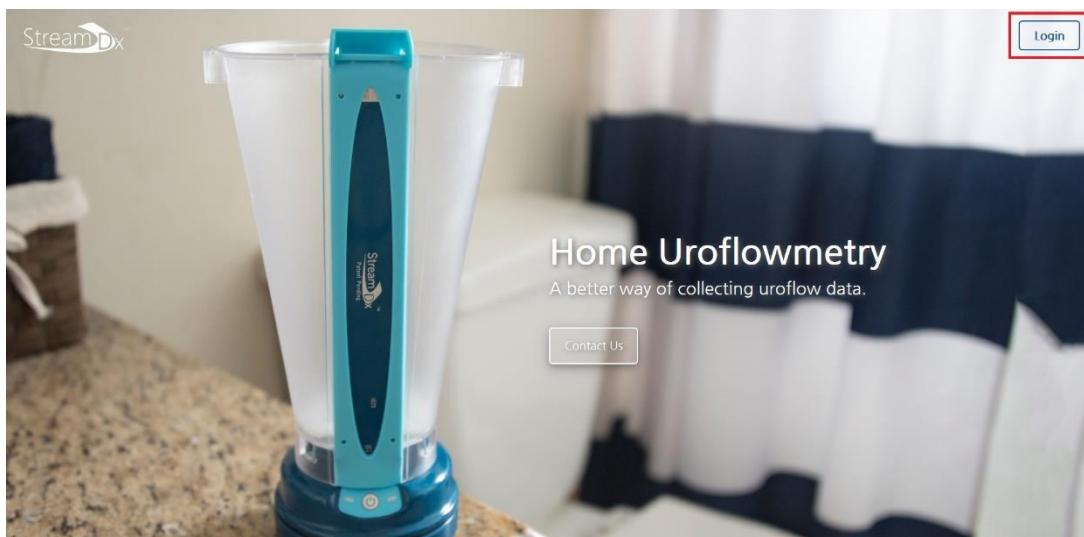
7 Navigating the Stream Dx Data Portal

7.1 Introduction

This chapter describes how to access patient uroflow reports and other features.

7.2 Accessing Patient Reports

1. Use a web browser to visit <https://streamdx.com>. We recommend using Google Chrome for accessing our data portal.
2. On the top right corner of the page, click the Login button.



3. Log in by entering in your username and password.
4. To go to a patient's history page, click on the row the patient appears on in the patient list.
5. If the patient has completed Stream Dx Uroflow Testing and a report is available, you can click on show report to view the report or update the report to classify each individual void.

7.3 Viewing In-Progress Orders

1. On the Patient's History page, click on the In-Progress tab to view any orders which are currently in progress for the patient. There is a progress bar which allows visibility to see the current step the order is on while Stream Dx is obtaining the uroflow report.

- You will not be able to order a second device for any patients who have any orders currently in progress.

7.4 Other Website Features

Physicians will be able to update account details such as payment and contact information using the website. To update these settings, click on the My Account drop down and click on the Settings button.

8 Technical Specifications

8.1 Website

Stream Dx recommends using Google Chrome as your browser for accessing the Stream Dx Web Portal.

8.2 Stream Dx Uroflowmeter

The Stream Dx Uroflowmeter measures flow rate by using a capacitive fluid height sensor as opposed to the more common method of using weight-based or spinning disc sensors. The fluid height sensor is durable and can be shipped to patients. One limitation of most uroflowmeters is that excessive movement of the device during a void can invalidate the void. Regarding the Stream Dx Uroflowmeter, a voiding event occurring less than 15 minutes following a previous void can invalidate the newly collected void. The Stream Dx System will detect these issues and notify the physician when test results are excluded. For best results, instruct the patient to place the Stream Dx Uroflowmeter on a flat, closed toilet lid such that the opening of the Stream Dx Uroflowmeter is around groin height. Ensure that the Stream Dx Uroflowmeter is as level as possible during use.

The Stream Dx Uroflowmeter is made up of two components, the Electronic Base and Sleeve. The device is fully assembled when shipped to the patient. At the end of the testing period, the patient will twist off the Sleeve to remove it from the Electronic Base (See Patient Instructions for Use). The patient is instructed to discard the Sleeve and return the Electronic Base to Stream Dx using a pre-paid envelope included with the original shipment. If the Sleeve is removed prior to the end of the study, it is recommended that the patient attempt to replace the Sleeve. If the Uroflowmeter is not working as expected, contact Stream Dx for further instruction.

The Stream Dx Uroflowmeter is battery powered and does not connect to an external power supply.

Technical Specifications		
Dimensions:	Height: 9.62 inches Electronic Base Width: 3.53 inches Sleeve Length (including spout): 5.38 inches	
Mass:	356 grams	
Transportation Temperature and Storage Conditions	Temperature: +10°C to +40 °C Humidity: 30%-75% non-condensing relative humidity.	
Operating Conditions	Temperature: +10°C to +40 °C Humidity: 30%-75% non-condensing	
Range	Flow	Volume
	0-25 mL/s	25-700 mL
Accuracy	Flow	Volume
	+/-2.5 mL/s	+/- 30 mL
Maximum volume	700 mL	
Recording time	10 Hours	
Battery life	A minimum of 10 hours in active mode and 160 hours in standby mode.	
Frequency Band of Transmission	The Stream Dx Uroflowmeter includes a Bluetooth Chip which operates in the frequency band of 2.4 GHz.	

8.3 Classification

Type BF Applied Part, approved for continuous operation in non-oxygen rich environments

ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1

IEC 60601-1-11:2015

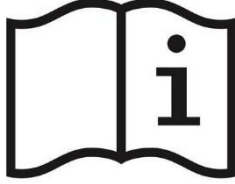






CAN/CSA-C22.2No. 60601-1:14

CAN/CSA-C22.2No. 60601-11:15

Appendix A - Safety Information

- Do not submerge the Stream Dx Uroflowmeter
- The Stream Dx Uroflowmeter is not intended for use with flammable agents or harsh chemicals.
- The Stream Dx Uroflowmeter is not intended for use in oxygen rich environments
- Portable and mobile RF communications equipment can affect the Stream Dx Uroflowmeter.
- The Stream Dx Uroflowmeter should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary then the Stream Dx Uroflowmeter should be observed to verify normal operation in the configuration in which it is used.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
- Intended for urine collection/measurement only and is intended for indoor use only with the conditions specified in Section 8 of this document.
- Do not use the device if the packaging has been opened or damaged.
- Improper use of the device using accessories other than what is provided with the device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation
- 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 Stream Dx Uroflowmeter. Otherwise, degradation of the performance of this equipment could result.
- The data obtained from the Stream Dx Uroflowmeter is meant to be used exclusively as a tool to aid in the diagnosis of a condition. It is not intended to be used alone as the sole method of diagnosis.

Appendix B - Explanation of Symbols

	Consult Instructions for Use
	Type BF Applied Part
	Manufacturer
	Bluetooth logo
	Catalogue Number
	Lot Code
	Button used to start and end recording of a voiding event

Appendix C – Applied Parts



Applied Parts	Type	Probability of contact	Duration of contact
Sleeve	Type BF	100%	<1 minute per use x up to 50 uses/day
Electronic Base	Type BF	100%	<1 minute per use x up to 50 uses/day