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Document code: SDX1-10003-01
Model: SDX01
Version: V001
Date of release: 01 March 2019
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1 Introduction

1.1 Stream Dx Uroflow System

The Stream Dx Uroflow System includes both a device and a secure web portal which provides urine voiding reports for physicians. The Stream Dx Uroflow system is designed to allow physicians to order a device and have it sent to a patient for use in the comfort of the patient’s home. The in-home device can collect a voiding diary which includes volume, flow rate, and time of voiding events over a five-day period.

The device consists of two parts, the containment “Sleeve,” and the electronic “Puck.” The Sleeve and Puck combine to create the urine collection vessel. When a patient is finished using the device for the designated time, they will dispose of the Sleeve and return the Puck using a prepaid envelope. The data will be uploaded to the Stream Dx Cloud once the device arrives at the Stream Dx facility and the reports will be generated as soon as the data is uploaded. The uroflow reports include a super trace of all flow traces, a Liverpool nomogram, an IPSS survey (if provided by the patient), three super traces of flow rates broken down by time, daily volume voiding diaries, a coding summary, and graphs representing each individual uroflow.

Stream Dx is primarily intended to capture data in the patient’s home and provide the data to physicians as an aid in developing treatment plans. The ability to capture urine flow data outside the clinic will lead to improved quality of data (due to collecting data in a more natural environment), 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 disorders. 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 caregiver 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's 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, no special skills are required. A patient and/or caregiver should be capable of filling the Pre-Fill Cup, pressing the start button to start and stop data recording, emptying out the device, and rinsing the inner part of the cup when finished. Physicians are recommended 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's Manual is intended for all physicians performing investigations with the Stream Dx Uroflow System.

This manual provides you with detailed information concerning:

- Physician Registration (Chapter 2)
- Ordering a Stream Dx Device for Patient Use (Chapter 3)
- Patient Use, Return, and Disposal of the Stream Dx Device (Chapter 4)
- Maintenance and Troubleshooting (Chapter 6)
- Technical Specifications (Chapter 8)

The Stream Dx Quick Start Guide is intended for the patient using Stream Dx Uroflowmetry system in a home setting.
Feedback on the manual

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

2.1 Creating an Account

A clinician must create an account with Stream Dx before receiving 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 Physician Registration link to begin creating an account.
4. Follow the instructions on the page to create your physician account.
   • Your username may be the same as your email.
   • A Stream Dx sales rep code is required to finish the registration process.
3 Ordering a Stream Dx Device for Patient Use

3.1 Patient Registration

1. Log into your physician account.


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’s roster page and the newly registered patient should show up in the roster.
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 appears on.
   - An order device button can also be found in the Patient’s History page.

2. Review that the Patient’s shipping and contact information are current and submit the order.
   - A patient who currently has an In-Progress order cannot be ordered a new device until the In-Progress order has been completed.
   - 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 device.
3.3 Instruct the Patient

Inform the patient that the device will arrive approximately 2-3 business days after a device has been ordered. Go over the information covered in Section 4 Patient Explanation and Instruction with the patient.

An IPSS survey will be provided to the patient when they receive the Stream Dx Uroflowmeter. Ask the patient to complete the IPSS Survey and return it with the return package at the end of their study. Refer to Section 4.3 for a sample of the IPSS Survey.
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.

Explain the procedure the patient is expected to follow for each void to record data.

1. Close the toilet seat and lid.

2. Place the Stream Dx Uroflowmeter on the 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 nearby such that the top of the device is around the groin area.

3. Press the power button on the Stream Dx Uroflowmeter and ensure that the green light is flashing, indicating that it is recording data.

4. 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.

5. Urinate into the Stream Dx Uroflowmeter and aim towards the target on the inside of the sleeve.

6. When finished, push the power button once more to stop recording and to turn off the device.

7. Empty the urine into the toilet and rinse the Sleeve with tap water.

8. 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 not prefilled or if the device is not level during use.
Review Section 6 with the patient for instructions on cleaning, return and disposal of the device 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 study.

Refer to Section 6.3.3 for an explanation of status LED lights and review these with the patient.
4.2 Patient Instructions for Use

The following pages 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.
4.3 IPSS Survey

An IPSS survey will be provided to each patient which receives a Stream Dx Uroflowmeter. Instruct patients to fill out the survey and return to Stream Dx. IPSS surveys returned by patients will be included in the final reports for each order.

### International Prostate Symptom Score (I-PSS)

<table>
<thead>
<tr>
<th>In the past month:</th>
<th>Not at All</th>
<th>Less than 1 in 5 times</th>
<th>Less than Half the time</th>
<th>About Half the time</th>
<th>More than Half the Time</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Incomplete Emptying</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How often have you had the sensation of not emptying your bladder?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Frequency</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How often have you had to urinate less than every two hours?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Intermittency</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How often have you found you stopped and started again several times when you urinated?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Urgency</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How often have you found it difficult to postpone urination?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Weak Stream</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How often have you had a weak urinary stream?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Straining</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How often have you had to strain to start urination?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Nocturia</td>
<td>Now</td>
<td>1</td>
<td>Time</td>
<td>2</td>
<td>Times</td>
<td>3</td>
</tr>
<tr>
<td>How many times did you typically get up at night to urinate?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total IPSS Score:** 

1-7: Mild  
8-19: Moderate  
20-35: Severe

### Quality of Life Due to Urinary Symptoms

<table>
<thead>
<tr>
<th>Delighted</th>
<th>Pleased</th>
<th>Mostly Satisfied</th>
<th>Mixed</th>
<th>Mostly Dismissed</th>
<th>Unhappy</th>
<th>Terrible</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.4 Items provided to the Patient

Each Stream Dx Uroflowmeter package will include the following items:

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Item</th>
<th>Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Stream Dx Disposable Sleeve</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>Stream Dx Puck</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>Pre-Fill Cup</td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>Return Envelope</td>
<td>4</td>
</tr>
<tr>
<td>1</td>
<td>IPSS Patient Survey</td>
<td>5</td>
</tr>
<tr>
<td>1</td>
<td>Instructions for Use</td>
<td>6</td>
</tr>
</tbody>
</table>
5 Device Return and Disposal

5.1 Return of Stream Dx Puck

1. The patient should twist the top Sleeve portion off of the Puck.

2. The Stream Dx Puck should be placed in the pre-paid return envelope along with the IPSS 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 cleaning, return and disposal of the Stream Dx Uroflowmeter.

6.2 Maintenance: Home Cleaning and Sensor Care

The device is clean and ready to use when it is sent to the patient. The patient should follow the instructions below to maintain the Stream Dx device 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 cloth and water.

2. Store in the upright position in preparation for the next use.

3. DO NOT remove the Sleeve from the Puck between uses. The separation of device components should be completed only once, at the end of the use period.

4. If the Sleeve is accidentally removed from the Puck, attempt to reconnect the Sleeve to the Puck. 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. Please refer to the table below for descriptions of each status indication.

<table>
<thead>
<tr>
<th>Green (Left) LED</th>
<th>Red (Right) LED</th>
<th>Indication</th>
</tr>
</thead>
</table>
| Off              | Off            | Stream Dx Uroflowmeter is not functioning. Possible reasons:  
|                  |                | • Device is off  
|                  |                | • Device has run out of battery (Highly unlikely). |
| 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  | Off            | The device has been activated and is ready to record. |
| 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 times and shutting off. | The sleeve has been disconnected from the puck. 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.

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 the recorded patient voids with the Stream Dx Uroflowmeter and other features.

7.2 Accessing Patient Studies

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 roster.

5. If the patient has completed a Stream Dx Uroflow study 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 Devices in Use

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.
   - You will not be able to order a second device for any patients who have an In-Progress order.

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 commonly method of using weight-based sensors. The fluid height sensor is durable and able to be shipped to patients. One limitation of this device is that excessive movement of the device during a void can invalidate the test results. Also, a void event occurring less than 15 minutes after a previous void can also create invalid test results. The Stream Dx System will detect these issues and notify the physician. 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.

The Stream Dx Device is made up of two components, the Puck and Sleeve. When the patient receives the device, the two are already assembled together. Following the study period, the Sleeve will be removed from the Puck by the patient by twisting the Sleeve off of the puck (See Patient Instruction for Use). If the Sleeve is removed prior to the end of the study, it is not recommended that the patient attempt to replace the Sleeve. Contact Stream Dx for further instruction.

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

<table>
<thead>
<tr>
<th>Technical Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dimensions:</strong></td>
</tr>
<tr>
<td>Height: 9.62 inches</td>
</tr>
<tr>
<td>Puck Width: 3.53 inches</td>
</tr>
<tr>
<td>Sleeve Length (including spout): 5.38 inches</td>
</tr>
<tr>
<td><strong>Mass:</strong></td>
</tr>
<tr>
<td>356 grams</td>
</tr>
<tr>
<td><strong>Transportation Temperature and Storage Conditions</strong></td>
</tr>
<tr>
<td>Temperature: +10°C to +40 °C</td>
</tr>
<tr>
<td>Humidity: 30% -75% non-condensing relative humidity.</td>
</tr>
</tbody>
</table>
### Operating Conditions

<table>
<thead>
<tr>
<th></th>
<th>Temperature:</th>
<th>Humidity:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+10°C to +40°C</td>
<td>30% - 75% non-condensing</td>
</tr>
</tbody>
</table>

#### Range

<table>
<thead>
<tr>
<th>Flow</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-25 mL/s</td>
<td>25-700 mL</td>
</tr>
</tbody>
</table>

#### Accuracy

<table>
<thead>
<tr>
<th>Flow</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>+/-2.5 mL/s</td>
<td>+/- 30 mL</td>
</tr>
</tbody>
</table>

#### 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 has a frequency band of reception of 2.4 GHz. The preferred frequency band of 2.4 GHz and has a bandwidth of the receiving section of the Stream Dx Uroflowmeter in those bands.

### 8.3 Classification/approval

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

- 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 Uroflowmetry Device is not intended for use with flammable agents.
- The Stream Dx Uroflowmetry Device is not intended for use in oxygen rich environments
- Portable and mobile RF communications equipment can affect the Stream Dx Uroflowmetry Device.
- The Stream Dx Uroflowmetry Device should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary then the Stream Dx Uroflowmetry Device 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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="i" /></td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td><img src="image" alt="TUVRheinland" /></td>
<td>TUV certification – TUV Rheinland certified this product to U.S. safety standards.</td>
</tr>
<tr>
<td><img src="image" alt="Person" /></td>
<td>Type BF Applied Part</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Bluetooth" /></td>
<td>Bluetooth logo</td>
</tr>
<tr>
<td><img src="image" alt="Catalogue Number" /></td>
<td>Catalogue Number</td>
</tr>
<tr>
<td><img src="image" alt="Lot Code" /></td>
<td>Lot Code</td>
</tr>
<tr>
<td><img src="image" alt="Button" /></td>
<td>Button used to start and end recording of voiding event.</td>
</tr>
</tbody>
</table>
## Appendix C – Applied Parts

<table>
<thead>
<tr>
<th>Applied Parts</th>
<th>Type</th>
<th>Probability of contact</th>
<th>Duration of contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sleeve</td>
<td>Type BF</td>
<td>100%</td>
<td>&lt;1 minute per use x up to 50 uses</td>
</tr>
<tr>
<td>Puck</td>
<td>Type BF</td>
<td>100%</td>
<td>&lt;1 minute per use x up to 50 uses</td>
</tr>
</tbody>
</table>