# FloPoint Elite Uroflow System



User's Manual



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# **Important Information**

#### **Product Description**

The study of urine discharge rate, or uroflowmetry, is recognized by the medical community to be valuable in the determination of comparative urological function.

The advanced technology in the FloPoint Elite Uroflow System provides an accurate and convenient method to help assess bladder function. The FloSensor contains a disk that spins at a constant speed. When a flow of urine hits the disk, the motor must work harder to maintain the disk spinning at that same speed with the added weight of the urine. The FloSensor measures the amount of power needed to maintain the disk's original speed and uses that measurement to calculate the urine flow rate. The FloSensor also records the total amount of urine discharged by the patient. This data can be analyzed using the ScanPoint® with QuickPrint software to determine how quickly or slowly the patient urinated, any interruptions or changes in the flow, and the total volume of the patient's bladder.

## **Intended Use Warnings and Cautions**

The FloPoint Elite Uroflow System should be used only by individuals who have been trained and authorized by a physician or the institution providing patient care. All users must read this entire *User's Manual* prior to using the FloPoint Elite Uroflow System.

<u>Do not attempt to operate this instrument until you thoroughly understand all instructions and procedures in this manual.</u> Failure to comply with these instructions may compromise the performance of the device and the reliability of its measurements. For the most current version of this *User's Manual*, please visit the Verathon® web site at: http://www.verathon.com/manuals.htm.

#### **Statement of Prescription**

United States federal law restricts the FloPoint Elite Uroflow System to use by, or on the order of, a physician. This statement is required per 21 Code of Federal Regulations (CFR) 801.109.

**NOTE:** It is standard practice to have medical staff authorize the use of the FloPoint Elite Uroflow System within its intended use throughout an institution. Individual prescriptions for use are not required.

#### Statement of Intended Use

The FloPoint Elite system is intended for uroflowmetry exams: the measurement and analysis of urine discharge rate and volume. The FloSensor is placed in a toilet bowl with a disposable funnel placed on top, which directs the urine flow into the sensor. The patient may void into the sensor from either a standing or sitting position. Uroflowmetry data gathered by the FloSensor is transmitted to the ScanPoint Remote via wireless radio link. When used in conjunction with ScanPoint with QuickPrint software, a report containing the ICS values for uroflowmetry may be generated for the patient's medical record.

#### **Contraindications**

None

To assure safe and reliable operation for the use and the patient, please read and heed the following warnings and cautions.

## WARNINGS and CAUTIONS:

To assure safe use and accurate results when using the FloPoint Elite Uroflow System be aware of the following conditions:

#### Read and understand all procedures prior to use.

Before using the FloPoint Elite Uroflow System, you must read and understand all the instructions and procedures in this *User's Manual*. Failure to comply with the instructions may affect the safety of the patient, clinician, and/or the accuracy of the exam results. For the most up-to-date version of the *User's Manual*, go to

http://www.verathon.com/manuals.htm.

#### Clean the instrument after every use.

To ensure the reliability of the FloSensor, it is imperative that you clean the FloSensor with a typical disinfecting bathroom cleaner after every use.

When cleaning FloPoint Elite Uroflow System components, do not use any products containing ammonia.

#### Sterilization.

Do not sterilize this instrument.

#### Power Supply.

Only connect the FloPoint Elite AC adapter to power sources consistent with the input specifications shown on the adaptor label.

#### Risk of fire and/or explosion.

Do not use the FloPoint Elite Uroflow System in the presence of flammable anesthetics.

#### Risk of device damage:

Do not allow any foreign objects fall onto or into the device. Only expose the unit to fluids as directed for uroflow measurements and cleaning.

Do not subject the FloPoint Elite Uroflow System to mechanical vibration, dust, or shock.

Do not store or use the FloPoint Elite Uroflow System near heat sources such as radiators. Do not operate this device in temperatures below 10°C (50°F) or above 35°C (104°F). Do not store this device in temperatures below -10°C (14°F) or above 35°C (95°F).

Assure that the FloPoint Elite Uroflow System is situated in an area with proper ventilation.

To comply with IEC 60601-1 and national electrical codes, the FloCharger must be wall-mounted as described in this manual.

Never cover the FloCharger or FloSensor with any cloth or other object that might interfere with proper ventilation.

Do not store or operate the FloPoint Elite Uroflow System near equipment or devices that generate strong electro-magnetic fields.

Do not place any heavy objects on top of the FloSensor or FloCharger.

#### Hazardous materials present. Assure proper disposal.

The FloPoint Elite Uroflow System may contain lead, batteries, and other environmentally hazardous materials. When the FloPoint Elite Uroflow System has reached the end of its

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useful service life, return the device, and related accessories to a Verathon® Service Center for proper disposal. Alternatively, follow your local protocols for hazardous waste disposal.

#### Assure proper computer system configuration.

When using the FloPoint Elite Uroflow System with ScanPoint® software, your computer must be minimally certified to EN / IEC / CSA / UL 60950 or 60101-1 standards. This configuration ensures that compliance to the EN/IEC 60601-1-1 system standard is maintained. Anyone connecting additional equipment to the FloPoint Elite Uroflow System signal input port or signal output port configures a medical system, and is therefore responsible for ensuring that the system complies with IEC 60950 or EN/IEC 60601-1-1 (if in the vicinity of patients). If you need assistance, contact your biomedical staff, Verathon Medical representative, or the Verathon Medical Customer Care Department at 1.800.331.2313.

#### Assure proper distance from patient.

The ScanPoint Remote docking station and the computer used to access online ScanPoint image archives (if used) must be placed outside the patient vicinity (more than six feet (2 meters) from the patient). Refer to EN/IEC 60601-1 for the definition of patient vicinity.

#### Risk of injury or device damage.

Keep long hair and loose clothing away from the FloSensor. Keep foreign materials such as toilet paper and metal out of the FloSensor.

**Do not flush FloPoint Elite funnels down the toilet.** Dispose of them as you would other medical waste.

#### Service.

The FloPoint Elite Uroflow System should be serviced by authorized service personnel when:

- The AC power cord or plug has been damaged.
- Objects have become trapped in the instrument.
- The instrument has been exposed to rain or moisture other than that consistent with use as directed.
- The instrument does not appear to operate normally or exhibits a marked change in performance.
- The instrument has been dropped or the enclosure damaged.

The FloPoint Elite Uroflow System does not contain any user-serviceable components. The user should not attempt to service the instrument beyond the procedures provided in this manual, unless directed by Verathon service personnel. All other servicing should be referred to authorized service personnel.

If at any time you require assistance with your FloPoint Elite Uroflow System, contact Verathon Medical Customer Care at 800.331.2313 (Canada and US only) or 425.867.1348.

# Introducing the FloPoint® Elite Uroflow System

## **Product Description**

FloPoint Elite Uroflow System measures and records a patient's pattern of urinary flow, allowing physicians to quickly assess the mechanics of flow and to diagnose abnormalities in voiding patterns (e.g., obstructed or restricted flow, superflow, etc.). The advanced technology in the FloPoint Elite Uroflow System provides an accurate and convenient method to assess bladder function. The FloSensor rapidly and accurately records both the flow rate and the total amount of urine discharged by the patient. These measurements are transmitted via radio link to a remote handset, which in turn interfaces with ScanPoint® with QuickPrint software, allowing data storage, diagnostic analysis, and report generation.

The FloPoint Elite Uroflow System has a small footprint, making it easy and unobtrusive to use and store. The FloSensor, the heart of the FloPoint Elite system, is lightweight and designed to fit in a standard toilet bowl during an exam. Between uses, it stows discreetly in the FloCharger, which also recharges the FloSensor battery.

## FloPoint Elite Uroflow System Parts and Features

The main features of the FloPoint Elite Uroflow System and ScanPoint Remote are illustrated in Figure 1.

**Handles Funnel Box** Latch Clamshell **FloSensor** Microphone LCD display Start button **FloPoint Elite** Mounting Reset **Bracket** button **FloCharger** ScanPoint Remote in the **ScanPoint Docking Station** FloCharger LED

Figure 1. FloPoint Elite Uroflow System Components and Features

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The FloSensor fits into a standard toilet bowl and measures a patient's urine flow rate and volume. The ScanPoint® Remote gathers patient data measured by the FloSensor and transmits it to the ScanPoint host computer allowing further analysis and reporting options. The Remote also tracks other diagnostic information about the internal functioning of the FloSensor.

Part Name	Purpose
Handles	Provide a means for carrying the FloSensor, suspend the FloSensor in the toilet bowl, and support the disposable funnel.
FloSensor	Measures urine volume and flow rate.
Latch	Allows the FloCharger housing to be closed securely.
Clamshell	Protects the FloSensor and FloCharger from dust and contaminants when not in use.
FloCharger	Recharges the FloSensor battery
FloPoint Elite Mounting Bracket	Attaches to the wall, securely holding the FloCharger and a funnel box 3 feet (0.914 m) or more above the floor.
Funnel Box	Contains 40 disposable funnels for attachment to FloSensor during uroflow exams.
ScanPoint Remote	Acts as a remote control for starting/stopping the FloSensor. Its LCD display communicates exam and device status to the user. The FloSensor transmits exam data to the Remote via a wireless radio link. The Remote, in turn, downloads this data to a computer with ScanPoint with QuickPrint software.
Start/Stop button	Starts/stops FloSensor functions for exams and calibration.
LCD display	Displays measurement data and device status.
Microphone	Records voice annotations.
Reset button	A recessed button on the back of the Remote that re-activates the Remote when it does not self-activate. Occasionally when the Remote battery has been completely discharged, you may need to reset the Remote before it can be used again.

## **ScanPoint Label Writer (Optional Printer)**

The ScanPoint Label Writer is an optional component of the FloPoint Elite System. It prints patient exam data on self-adhesive labels (approximately 2.5" x 6") that can be attached to a patient record. The parts and features of the ScanPoint Label Writer are shown in (Figure 2).

**Bottom View** Top/Side View Top cover Label roll USB connector DC power Platen connector release **0** Label feed path Θ and tear bar Label spool Form-feed Cable button and LED Label eject channel button

Figure 2. ScanPoint® Label Writer Parts and Features

The ScanPoint Label Writer is a direct thermal printer and does not use toner, ink cartridges, or a ribbon. Instead, it uses heat from a thermal print head to print on specially treated labels.

- The Form-feed button on the front of the printer advances a single label.
- The Label eject button is used to remove labels from the printer when changing rolls
- The LED status light allows you to visually determine the current state of the printer:
  - Solid blue Power is on and the printer is ready.
  - Flashing blue Labels are not loaded properly or label spool is empty.

#### ScanPoint Online

ScanPoint with QuickPrint software is included with your FloPoint Elite system. During an exam, data is gathered from the FloSensor by the ScanPoint Remote. The Remote, in turn, downloads this data to the ScanPoint host computer allowing patient record storage, further diagnostic analysis, and report generation.

ScanPoint Online is an innovative service that enhances and expands the capabilities of the FloPoint Elite Uroflow System.

ScanPoint Online allows you to:

View exam measurements and graphs from patient exams.

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- Print exam results for patient records and for reimbursement (if applicable) using your choice of report format.
- Save a PDF copy of the exam report that can be imported into other electronic medical record systems.
- Save and store images online allowing you to access patient records from any Internet-enabled computer (HIPAA compliant).
- Take advantage of ScanPoint® automatic file backup service.
- Ensure the optimum accuracy of your FloPoint Elite system by calibrating online, in a matter of minutes, and as often as you wish.
- Take advantage of automatic software upgrades.

## **ScanPoint Premium Warranty Total Customer Care<sup>SM</sup> Plan**

The Premium Warranty Total Customer Care Plan includes ScanPoint Online, insures your device against damage, theft and loss, provides free next-day loaners, and pays all shipping charges.

# **Getting Started**

The previous section provided introductory information about the FloPoint Elite Uroflow System. This section provides information on how to set up your FloPoint Elite Uroflow System prior to first use.

## **Required Equipment**

In addition to the components included with your FloPoint Elite system (see "FloPoint Elite Uroflow System Parts and Features" beginning on page 16), highly recommended equipment includes:

 A Windows® computer with a high-speed Internet connection. (Computer hardware, software and operating system requirements can be found on page 120.)

**NOTE:** To use ScanPoint Online, a Windows computer with an Internet connection is required.

 Adobe® Acrobat® Reader®, for viewing and printing reports (see "Step 3: Installing Adobe® Acrobat® Reader" on page 25).

## **Getting Started**

To assure successful set up and operation of your FloPoint Elite Uroflow System, follow these seven steps in the order given:

- **Step 1.** Unpack the FloPoint Elite components and related accessories. Instructions begin on page 21.
- **Step 2.** Attach the Mounting Bracket to the wall and attach the FloCharger to the Mounting Bracket. Instructions begin on page 25.
- **Step 3.** Install Adobe Acrobat Reader. Instructions begin on page 26.
- **Step 4.** Install ScanPoint with QuickPrint software on your PC. Instructions begin on page 26.
- **Step 5.** Set your ScanPoint with QuickPrint user preferences. Instructions begin on page 33.
- **Step 6.** Install FloPoint devices (ScanPoint Docking Station and optional Label Writer) using the Windows Install New Hardware Wizard. Instructions begin on page 39.
- **Step 7.** Charge the ScanPoint Remote and FloSensor batteries. Instructions begin on page 44. **NOTE:** The FloSensor and the Remote should arrive from the factory already charged.

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## **Step 1: Unpack the Box and Check the Components**

Set the shipping container right side up and carefully open the top flaps (do not insert anything sharp through the top of the box). Remove the contents and verify that you have received everything listed below. If anything is missing or damaged, notify your authorized Verathon Medical representative or Verathon Medical Customer Care Department at 1.800.331.2313.

#### **Part and Part Number**

## **Name and Description**



#### FloSensor with Handles

Measures urine volume and flow rate. The Handles suspend the FloSensor inside the toilet.

#### 0570-0175



## FloCharger with Clamshell

Stores the FloSensor and recharges the batteries.





#### FloPoint® Elite Mounting Bracket

Attaches to the wall, securely holding the FloCharger and a box of funnels 3 feet (0.914 m) or more above the floor.

0800-0337

## **Name and Description**



#### ScanPoint® Remote

Acts as a remote control to start and stop the FloSensor, displays information on flow measurements and device status, records voice annotations, and transmits data to a ScanPoint host computer when placed in the ScanPoint Docking Station (below).

0570-0174



## **ScanPoint Docking Station**

Transmits data from the ScanPoint Remote to the ScanPoint host computer and recharges the Remote batteries.

0570-0168



#### ScanPoint with QuickPrint Installation CD

Produces reports based on the data gathered during an exam and submitted by the ScanPoint Remote.

0900-1238



## FloPoint Elite In-Service CD

Includes FloPoint Elite User's Manual and Quick Reference Cards.

0900-1445



## **Box of Paper Funnels**

Help direct the urine flow toward the FloSensor.

Box contains 40 funnels.

0800-0297

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## **Name and Description**



#### **Activation Tool**

Use to press the Reset button on the ScanPoint® Remote if the Remote needs to be reactivated.

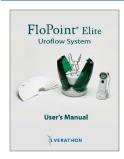
0130-0181



#### Lanyard

Attaches to the ScanPoint Remote, if desired, to assist with placement of the Remote in proximity to the FloSensor.





#### **User's Manual**

FloPoint Elite Uroflow System User's Manual (this manual).

0900-1442



## **FloPoint Elite Mounting Bracket Template**

Aids in attaching the Mounting Bracket to the wall.

0900-1557

## **Name and Description**



#### FloPoint Elite Quick Reference Card

Provides a summary of essential user instructions.

0900-1443



# FloPoint Elite Calibration Quick Reference Card

Provides instructions for the FloPoint Elite calibration procedure.

0900-1444

#### **ScanPoint Label Writer**

If you ordered a ScanPoint Label Writer, the following items are included:

## **Part and Part Number**

#### **Name and Description**



## **ScanPoint Label Writer**

Prints exam results on adhesive label media.

0570-0178



#### **USB** Cable

Connects the ScanPoint Label Writer to the ScanPoint host computer.

0600-0233

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#### **Name and Description**



#### **Label Writer Power Cord**

Connects the Label Writer power adaptor to a wall outlet.

0600-0232



#### **Power Supply**

Connects the power cord to the Label Writer.

0275-0002



#### Roll of Labels

Labels in roll format properly sized for the ScanPoint® Label Writer.

0125-0446

# Step 2: Attach the Mounting Bracket to the wall and attach the FloCharger to the Mounting Bracket.

- For an installation of the FloCharger in the patient vicinity to comply with IEC 60601-1 and the National Electric Code in the United States and the Canadian Electric Code in Canada, no part of the FloCharger cord must be lower than 3 feet above the floor. Use the cord wrap underneath the FloCharger to protect the unused portion of the cord. Any other installation method will jeopardize compliance of the FloPoint Elite system with IEC 60601-1 and the NEC or CEC and will therefore void any warranties (implied or otherwise) offered by Verathon Medical for the instrument.
- WARNING: Install the FloCharger Mounting Bracket at a height of at least 3 feet (10 meters) above the floor.
- WARNING: Use the cord wrap underneath the FloCharger to protect the unused portion of the cord.
- WARNING: Installation of a FloCharger that does not use the Mounting Bracket or alternate protection of the cord will not be compliant with the Medical-Electrical Safety Standard (IEC 60601-1). Alternate protection requires that the cord be 3 feet (10 meters) above the floor and not easily accessible by a patient.

- **NOTE:** The installation kit is compatible with dry-wall construction. If the wall material differs, an alternate mounting system must be used.
- 1. Attach the Mounting Template to the wall such that the bottom of the template is level and 3 feet (914 cm) above the floor.
- At each of the four marked locations, press the tip of the anchor into the drywall using a #2 Phillips screwdriver. Drive anchor clockwise until anchor stops flush with the wall. Insert the screw into the anchor. Tighten the screw leaving 1/4" of thread exposed on which to hang the bracket.
- 3. Hang the bracket on the four screws and tighten the screws. The Mounting Bracket should be held securely flush with the wall.
- 4. Measure the distance from the bracket to the outlet. On the FloCharger, wrap any power cord in excess of that length on the cord-wrap recess underneath the FloCharger. If necessary, use adhesive tape to keep the cord in place.
- 5. Mount the FloCharger on the four posts of the Mounting Bracket. Start by getting one post into one charger foot, then place the other 3 feet on the posts. Push the FloCharger down until it is fully seated on the posts.
- Attach the correct prongs into the AC adapter. The FloPoint Elite system is compatible with power systems world-wide and a set of prongs for various systems are included with the AC adapter. The prongs will click into place and be held securely.
- 7. Plug the AC adapter into the socket. The FloCharger is now ready to charge. The FloSensor and the ScanPoint® Remote should come from the factory already charged. After the initial charge, recharge the batteries whenever they are low or completely drained.

## Step 3: Installing Adobe® Acrobat® Reader

ScanPoint with QuickPrint uses Adobe Acrobat Reader (version 6.0 or higher) to print labels and patient reports. If Acrobat Reader software is not already installed on your computer, you can obtain a free copy at the Adobe Web site: http://www.adobe.com. Follow the links for Acrobat Reader. After installing the Acrobat Reader software, you must run the program once to accept the End User License Agreement in order to use Acrobat Reader for printing reports.

## Step 4: Install ScanPoint with QuickPrint

#### IMPORTANT!

You must have Administrator privileges to install ScanPoint with QuickPrint.

The dialog boxes displayed on your computer may differ slightly from those illustrated in the following procedures. If so, follow the instructions in the dialog boxes displayed on your screen.

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To use the ScanPoint® Online service, you need to install the ScanPoint with QuickPrint software included on the installation CD. The software creates links on your Start menu and desktop to ScanPoint with QuickPrint, ScanPoint online help, the ScanPoint online manual, and the Verathon® Web site.

**NOTE:** Review the following information before beginning installation of the ScanPoint with QuickPrint software.

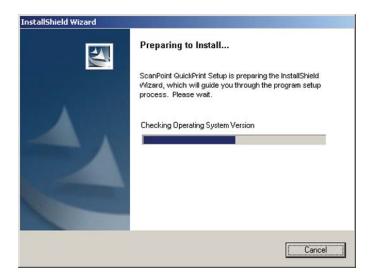
- Verify that your computer meets the minimum requirements for this software installation. (See "Computer Hardware and Software Requirements" on page 120.)
- You must have Administrator privileges on your computer to install this software.
- The dialog boxes displayed on your screen may differ slightly from those illustrated in the following steps. In this case, follow the instructions in the dialog boxes displayed on your screen.
- Do not plug in any new hardware devices (Label Writer, Docking Station, etc.) before installing ScanPoint with QuickPrint. If you have already plugged one in, cancel the Add New Hardware dialog box and disconnect the device(s) before proceeding.
- Important: Make sure you have the latest service pack and critical updates for the version of Windows that you are running. To find recent security updates, visit Windows Update. (From your Internet Explorer browser window, select Tools > Windows Update.

#### Installing ScanPoint with QuickPrint Software

1. To begin, place the installation CD into your computer's CD drive. The Install Shield Wizard should start automatically.

**NOTE:** If the Install Shield Wizard does NOT open automatically:

- a) Double click the My Computer icon on your desktop.
- b) Double click your CD drive icon or name.
- 2. The Preparing to Install screens will open.





Followed by the ScanPoint® with QuickPrint InstallShield Wizard dialog box.

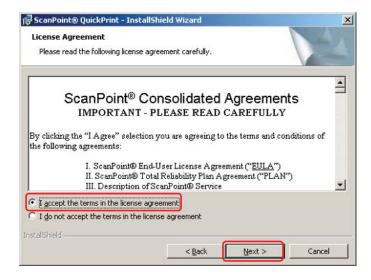
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#### Click NEXT.



3. The ScanPoint® with QuickPrint license agreement is displayed. You must accept the agreement to continue with installation.

Click the I ACCEPT THE TERMS IN THE LICENSE AGREEMENT radio button. Click Next.



4. The Setup Type dialog box is displayed.



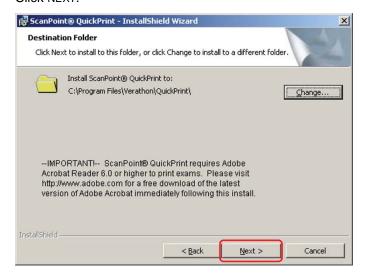
If you have a ScanPoint® Label Writer: Select the COMPLETE radio button.

If you do not have a ScanPoint Label Writer: Select the CUSTOM radio button. The next dialog box lists the features that will be installed. Clear the check for installing the Label Writer.

Click NEXT.

- 5. The Destination Folder dialog is displayed. You may:
  - Accept the default location (no action is required).
  - Change the location: Click the CHANGE button. Enter or browse to the desired location and click OK to return to the Destination Folder dialog.

#### Click NEXT.

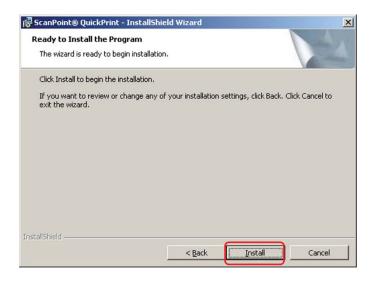


**NOTE:** ScanPoint with QuickPrint requires Adobe® Acrobat® Reader 6.0 or higher to print exams. Please visit http://www.adobe.com for a free download of

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the latest version of Adobe® Acrobat® immediately following the installation of the ScanPoint with QuickPrint software.

6. The Ready to Install the Program dialog is displayed. Click INSTALL.

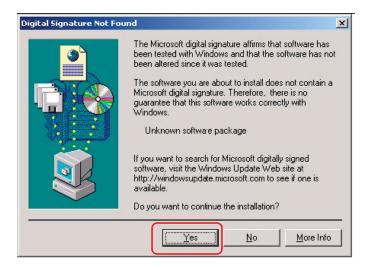


During installation, a Microsoft® Warning dialog box is displayed stating that Microsoft has not yet tested this software for compatibility with the Windows® XP and Windows 2000 operating systems. However, Verathon® has tested the ScanPoint with QuickPrint software and hardware drivers rigorously and is confident that they are fully compatible with both Windows XP and Windows 2000.

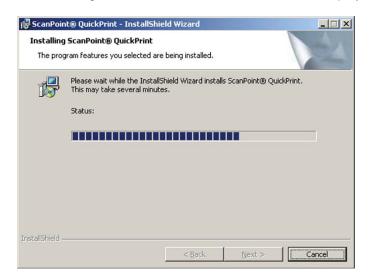
Click CONTINUE ANYWAY if this button is displayed.



7. The Digital Signature dialog is displayed (Windows 2000 only). Click YES to continue installation.

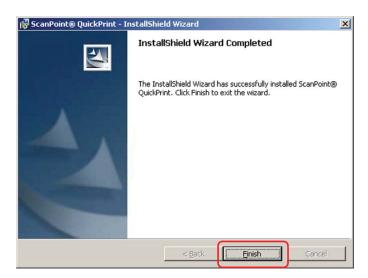


8. The Installing ScanPoint® with QuickPrint screen is displayed.



9. When the installation is complete, the InstallShield Wizard Completed dialog box is displayed. Click FINISH.

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10. The ScanPoint® with QuickPrint software installation is complete. ScanPoint with QuickPrint starts automatically and the QuickPrint Preferences Wizard opens.



Click NEXT to set your ScanPoint user preferences.

## **Step 5: Setting ScanPoint User Preferences**

Once you have installed ScanPoint with QuickPrint, and your FloPoint Elite devices, you can use the QuickPrint Preferences Wizard to customize QuickPrint settings.

The following procedure shows you how to use the Preferences Wizard to set up your initial preferences. If at any time you want to change a specific setting, go to the Tools menu, select PREFERENCES, and click on the appropriate tab. For information on the Preferences dialog boxes, see "Changing Your Preferences" on page 77.

To set up your user preferences:

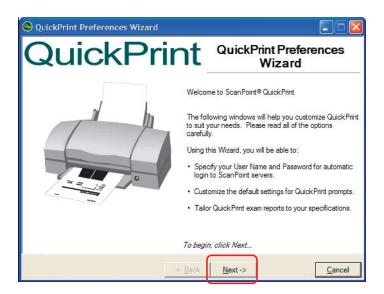
1. Open ScanPoint® with QuickPrint by double-clicking the ScanPoint icon in your system tray (the area next to your clock in the bottom right corner of your screen).



If ScanPoint with QuickPrint is not running, double-click the ScanPoint with QuickPrint icon on your desktop, or click the START button and select

Programs > Verathon® > ScanPoint with QuickPrint > ScanPoint with QuickPrint.

 The first time you run ScanPoint with QuickPrint, the Preferences Wizard will start automatically. Otherwise, from the Tools menu, select "Preferences Wizard" to open the first dialog box.

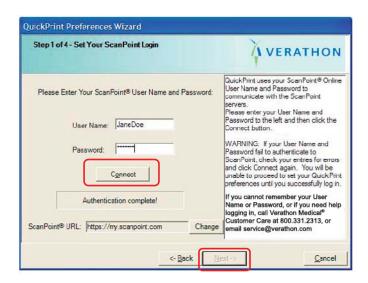


- 3. Click NEXT to open the Set Your ScanPoint Login dialog.
- 4. Enter the User Name and Password provided to you by Verathon and click CONNECT.

**NOTE:** If you did not receive a ScanPoint User Name and Password, please contact Verathon Medical Customer Care at 1.800.331.2313.

In a few moments, the status box will indicate that ScanPoint authentication is complete.

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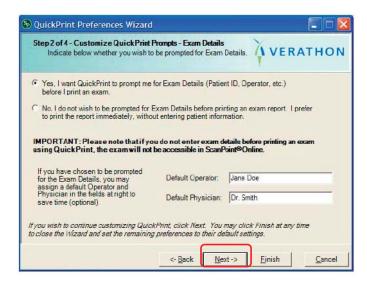
5. Click NEXT to open the Customize QuickPrint Prompts dialog.

**NOTE:** Do not change the default ScanPoint® URL in this dialog unless requested to do so by the Verathon Medical Customer Care Department.

**NOTE:** This ScanPoint User Name and Password will apply every time you log in to Windows using your current user account. There is no time-out period: the User Name and Password you enter will remain active until you change them. For information on changing your ScanPoint user profile, see "Changing Your Preferences" on page 77.

- 6. Indicate whether you want QuickPrint to prompt you for exam details (Patient ID, Patient Name, Gender, Position, Normal Void, Operator, and Physician) before transmitting exam results.
  - If you choose to be prompted for exam details, you can enter default names for the operator (who performed the exam) and physician (who ordered the exam) in the Default Operator and Default Physician text boxes. The names you enter will automatically appear in the Operator and Physician text fields after each exam. You will be able to overwrite the default names before printing the exam results.
  - If you choose not to be prompted for exam details, QuickPrint will automatically print each exam without prompting you for exam details. Blank spaces will appear in the printed exam report for you to fill in the Patient ID, Patient Name, Gender, Position, Normal Void, Operator, and Physician.

**NOTE:** These exams will not be available for future access in ScanPoint.

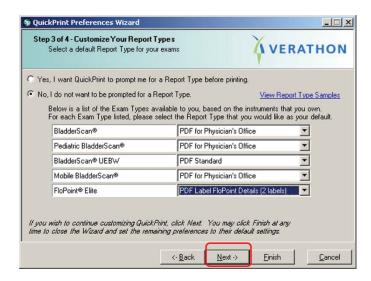


When you finish filling in the dialog box, click NEXT to open the Customize Your Report Types dialog.

- 7. Choose whether you want QuickPrint to prompt you to choose a report type each time an exam is performed. To view samples of each report type, click the VIEW REPORT TYPE SAMPLES link on the right side of the dialog box.
  - To have QuickPrint prompt you to choose a report type each time an exam is performed, choose the YES, I WANT QUICKPRINT TO PROMPT ME FOR A REPORT TYPE BEFORE PRINTING radio button.
  - If you do not want to be prompted to choose a report type each time you print an exam, choose the No, I DO NOT WANT TO BE PROMPTED FOR A REPORT TYPE radio button.
- 8. Choose the default report type you want to use from the drop-down menus.

**Important!** If you do not enter the Patient ID and Operator before printing an exam, you will not be able to access the exam later in ScanPoint<sup>®</sup>.

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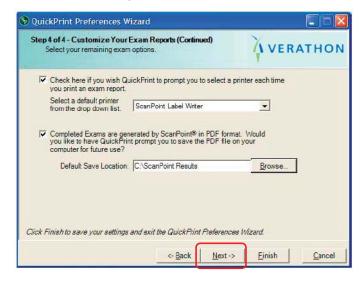
Click NEXT to open the last Customize Your Exam Reports dialog.

9. If you want QuickPrint to ask you to specify the printer each time you print an exam report, click the top radio button.

Select a default printer from the options in the drop-down menu.

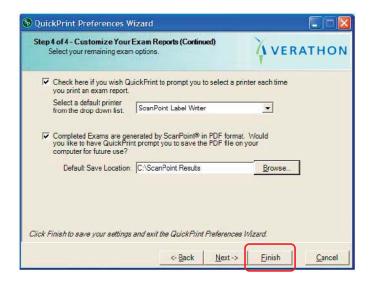
If you want QuickPrint to save the exam report in PDF format (opened in Adobe Acrobat Reader) each time it prints an exam, place a check mark in the bottom check box. The PDF can be incorporated into a patient's electronic medical record.

If you wish, enter a default location on your computer for saving exams in the Default Save Location text box. You will always be able to specify a different location to save a specific exam.



Click NEXT. The Preferences Wizard Complete dialog box is displayed.

10. Click FINISH to exit the Preferences Wizard. For more information on Preferences settings, see "Changing Your Preferences" on page 77.



#### **About User Profiles**

Your User Name and Password are associated with the User Profile you requested from Verathon® when you purchased your FloPoint Elite instrument. The ScanPoint® features available to you depend on your user profile.

There are three common types of ScanPoint user profiles:

- Administrative Users have access to all ScanPoint features. Administrative
  users can prepare new exams, upload exam results, accept or reject exam
  results, view past exams, and calibrate FloPoint Elite instruments.
- Clinical Users can prepare new exams, upload exam results, accept or reject exam results, and view past exams. Clinical users cannot calibrate FloPoint Elite instruments.
- Technical Users can calibrate FloPoint Elite instruments, but cannot prepare new exams, upload exam results, accept or reject exam results, or view past exams.

Each time a user logs in to a Windows® computer with ScanPoint, QuickPrint automatically connects to ScanPoint using the user profile they entered in the Preferences Wizard or Preferences dialog box. To prevent unauthorized access to patient data in the ScanPoint system, Verathon recommends setting a screen saver password, or locking the computer when not in use. For more information on recommended security precautions, go to the ScanPoint with QuickPrint Help menu and choose Security Best Practices.

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If you need to change user profiles or assign new users at any time, please contact your Verathon Medical representative or the Verathon Medical Customer Care Department at 1.800.331.2313.

## Step 6: Installing FloPoint Elite Devices

In order for your FloPoint Elite peripheral devices (ScanPoint® Docking Station and optional Label Writer) to function properly, they must be installed using the Microsoft Found New Hardware Wizard.

You will need to complete a separate wizard for each device.

IMPORTANT!

The dialog boxes displayed on your computer may differ slightly from those illustrated in the following procedures. If so, follow the instructions in the dialog boxes displayed on your screen.

#### **Installing the ScanPoint Docking Station**

**NOTE:** The ScanPoint Docking Station has a USB connector (Figure 3). To make sure that you have the ScanPoint Docking Station, check that it has a USB connector and that the label on the bottom says, "ScanPoint Docking Station."

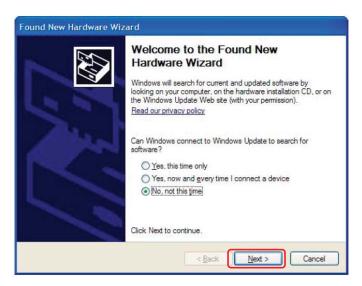


Figure 3. The ScanPoint Docking Station has a USB Connector.

1. Turn the computer on. Plug the ScanPoint Docking Station into any available USB connector on your computer.

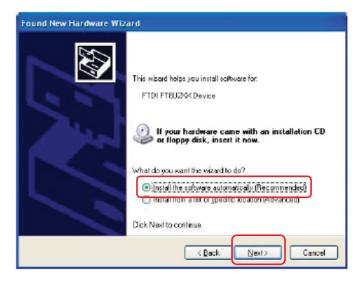
The Found New Hardware Wizard is displayed.

#### Click NEXT.



2. The second New Hardware Wizard screen is displayed.

Select the Install the software automatically radio button and click Next to install the drivers for the hardware automatically.



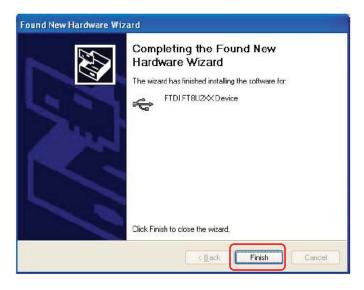
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3. A warning is displayed stating that Microsoft has not yet tested this software for compatibility with the Windows XP and Windows 2000 operating systems. However, Verathon Inc. has tested the ScanPoint® with QuickPrint software and hardware drivers rigorously and is confident that they are fully compatible with both Windows XP and Windows 2000.

Click CONTINUE ANYWAY.



4. When driver installation is complete, a dialog box is displayed to tell you the installation was successful. Click FINISH.



#### Setting up the ScanPoint Label Writer

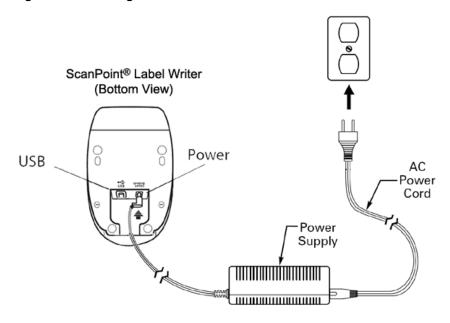
**NOTE:** This procedure is required only if your order includes the ScanPoint Label Writer.

#### **Connecting the Label Writer to Power**

Refer to Figure 4

- 1. Plug the power cord into the power supply.
- 2. Plug the power supply into the power connector on the bottom of the printer.
- 3. Plug the other end of the power cord into a power outlet near the ScanPoint® host computer.

Figure 4. Connecting the ScanPoint Label Writer to Power



- 4. Plug the USB cable into the USB port on the bottom of the printer.
- Insert the power and USB cables through the cable channel and set the printer down.
- 6. Connect USB cable to any available USB port on your computer **ONLY when prompted to do so during software installation.**

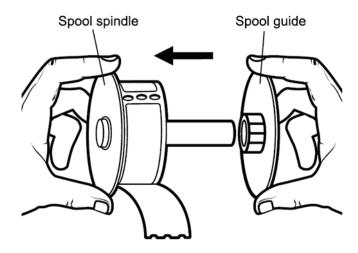
#### **Installing a Roll of Labels**

- Press the form-feed button to eject the labels that protected the Label Writer during shipment.
- 2. Open the top cover and remove any packing material inside the label compartment.
- 3. Remove the label spool.

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4. Hold the spool spindle in your left hand and place the label roll on the spindle so that the labels feed from underneath and the left edge of the label roll is flush against the side of the spool (Figure 5).





5. Place the spool guide onto the right side of the spool and press the guide tightly against the label roll, leaving no gap between the roll and the spool.

**NOTE:** The roll of labels must fit snugly against both sides of the label spool, with no gaps, so that the labels do not become misaligned as they feed through the printer.

6. Align the left edge of the label with the left edge of the label feed slot and insert the label into the slot (Figure 6).

Figure 6. Inserting a Label into the Label Feed Slot



7. The Label Writer feeds the labels, stopping at the beginning of the first label. If the Label Writer stops without feeding the label, make sure the label is fully inserted and then press the form-feed button. Close the top cover.

#### **Connect the Label Writer to Your Computer**

- 1. Make sure that:
  - The Label Writer is set up and plugged into a power outlet as described in the previous paragraphs.
  - Your computer is turned on and the ScanPoint<sup>®</sup> Installation CD is in your computer's CD drive.
- 2. Plug the Label Writer's USB connector into any available USB connector on your computer. The Install New Hardware Wizard will start up automatically.
- 3. Follow the on-screen directions for installing new hardware as with the ScanPoint Docking Station.

## Step 7: Charge the Batteries

The FloSensor and the ScanPoint Remote should come from the factory already charged. After the initial charge, recharge the batteries whenever they are low or completely drained.

#### **Charging the ScanPoint Remote Battery**

Use the ScanPoint Docking Station to charge the ScanPoint Remote.

The ScanPoint Docking Station is a dual-purpose device:

- It transmits exam data stored in the Remote to the ScanPoint host computer via a USB connection.
- It charges the Remote battery (NOTE: To charge the Remote, the computer must be turned on).

#### To charge the ScanPoint Remote battery:

**NOTE:** The ScanPoint software and ScanPoint Docking Station drivers must already be installed. See "Step 4: Install ScanPoint with QuickPrint" on page 26 for instructions on performing those tasks.

- 1. Make sure the ScanPoint Docking Station is connected to the ScanPoint host computer via its USB connector and that the computer is turned on.
- 2. Set the Remote in the Docking Station. The battery icon on the Remote display will scroll from empty to free to indicate that the Remote is charging.
- 3. Leave the Remote in the Docking Station until the battery icon displays a minimum of two segments.

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**NOTE:** Fully charging the battery may take up to 6 hours.

Remote

Battery icon shows a fully charged battery

ScanPoint Docking Station

Figure 7. ScanPoint Remote Battery Icon

## **Charging the FloSensor Battery**

- 1. Make sure the FloCharger AC adapter has been plugged into a wall outlet.
- 2. Seat the FloSensor on the FloCharger base. The FloCharger LED will alternate orange and green to indicate that the FloSensor battery is charging.
- 3. When the FloCharger LED is solid green, the FloSensor battery is fully charged and the FloSensor is ready for use.

NOTE: Fully charging the FloSensor battery may take up to 6 hours.

## **Displays, Controls, and Indicators**

## ScanPoint® Remote Display Icons

The following table illustrates and describes the ScanPoint Remote display icons.

#### **ScanPoint Remote Display Icons**

# Icon Meaning Battery power level: Four segments: The battery is fully charged. One segment: The battery is nearly depleted and should be charged at once. Scrolling segments: The battery is charging. Blank display: The Remote is in sleep mode. After clicking the Start button to start an exam, a series of rotating arrows indicate that the FloSensor is warming up. The warm up period lasts approximately 15 seconds. When complete, the Remote plays a "chirp up" and the display shows a zero (below). The Remote is ready to receive exam data from the FloSensor. During an exam the Remote displays the flow rate, in ml/s, 12 currently being measured by the FloSensor. When an exam is completed, either because the Start button on the Remote was clicked or because the FloSensor detected the end of flow, the display cycles through four different screens: The first screen displays for one second and indicates that the VOL next display will be the volume in ml. The volume in ml is displayed for two seconds. If the voided 352m volume is greater than one liter, "> 999ml" is displayed.

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Icon	Meaning
PF Î	The third screen indicates that the following screen will display the peak flow rate in ml/s.
77 <sub>Î</sub>	Peak flow rate in ml/s is displayed for two seconds
	The Remote is ready to record an annotation, a voice recording is in progress (icon flashes), or the Remote is saving voice annotation data (icon flashes)
ERR	ERR - followed by a number from 1-10 indicates an error in FloSensor and/or Remote function. A list of error codes appears in the Troubleshooting section on page 91.
45 <b>♣</b>	When the Remote is placed in the ScanPoint® Docking Station, it automatically downloads saved exam data. The display indicates the progress of the download.
192	Digits indicate days remaining before the next required calibration. <b>NOTE:</b> ScanPoint will give you a warning message 20 days before the calibration expires.
000	If the calibration has expired, the "setting sun" icon is displayed. Three flashing zeros provide an additional reminder that the FloSensor calibration has expired.
1-3 <del>-</del>	When calibrating the FloSensor, you have up to three attempts to get a successful calibration. (Usually, a calibration is successful on the first attempt.) This display shows the current attempt number completed and the total possible number, e.g. "one of three."
3-3-	After the third calibration attempt, or after the first successful calibration, the display shows "3 - 3" to indicate that all necessary attempts are complete. If the calibration was successful, all four arrows are displayed.

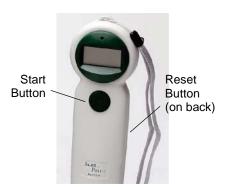
#### ScanPoint® Remote Buttons

The ScanPoint Remote has two buttons. The Start button, below the display, controls all the Remote operations and functions. The Reset button, in a recess on the back of the Remote, is used only to reactivate the Remote in case it will not resume normal operation.

Use the Start button as follows:

#### Press and Release the Button:

- Wakes up the Remote when it's sleeping. (If no icons are visible on the display, the Remote is sleeping).
- If the Remote is awake and within range of the FloSensor, a single press and release will create a radio link between the FloSensor and the Remote. The Remote will automatically record any data being transmitted by the FloSensor.
- If the Remote is collecting data from the FloSensor, a single click will stop the transmission.



#### **Pressing the Button Twice:**

- Wakes up the Remote when it's sleeping. (If no icons are visible on the display, the Remote is sleeping).
- If the Remote is awake and within range of the FloSensor, press the button twice to stop the FloSensor motor. (To restart the FloSensor, either press and release the Start button, or place the FloSensor on the FloCharger and then remove it again.)

#### Press and Hold:

- Record an annotation: If the Remote has an exam stored in memory, press and hold the Start button to record an annotation.
- Check calibration: If the Remote does not have exam data stored in memory, press and hold the Start button to see how many days are remaining before the required calibration.

#### **ScanPoint Remote Audio Cues**

The Remote speaker plays back voice annotations and emits several different audio cues to indicate the system status as follows:

**Chirp:** The Remote is ready to measure urine flow.

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**Chirp Down:** The urine flow has ended and the Remote has stopped receiving data from the FloSensor.

## **High-pitched Repeating Beep:**

The Remote is not receiving data from the FloSensor. This alert is triggered if data transmission from the FloSensor is interrupted for 0.2 seconds. This condition is likely due to radio interference and can usually be remedied by moving the Remote closer to the FloSensor. The Remote must be used within 3 meters of the FloSensor.

#### Siren Chirp:

During calibration, the siren chirp sounds after a successful calibration. At this point, the Remote must be returned to the ScanPoint® Docking Station to complete the calibration process.

#### **Error Chirp:**

During calibration, the error chirp plays after a change in calibration. Another calibration must be performed to confirm the change in calibration.

During exam start up, the error chirp will sound if the Remote cannot make contact with the FloSensor.

## FloSensor Indicators

The FloSensor contains a beeper that communicates device status. The FloSensor will sound a beep under following conditions:

- Motor starts
- Motor stops
- Every 3 seconds when the FloSensor and the Remote are in radio contact and are ready to measure and record a uroflow exam. This can signal to the patient that it is okay to begin voiding.

**NOTE:** The clinician should advise patients that the FloSensor will beep every 3 seconds to indicate normal operation and is not a cause for concern.



**FloSensor** 

## **FloCharger Indicators**

The FloCharger contains an LED that communicates charging status as follows:

- **Solid green:** The FloSensor is fully charged and ready for use.
- Alternating green and orange: The FloSensor is charging.
- Solid red: The FloCharger has stopped charging. There is either some foreign metal object in the FloCharger or the FloCharger or FloSensor may be malfunctioning.

In this case, remove the FloSensor from the charger. Make sure there is nothing in either the charger or in the hole on the sensor and then try charging again. If the problem persists, call Verathon Medical Customer Care to arrange a replacement.

No light: The FloCharger is unplugged.



FloCharger LED

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# **Performing an Exam**

## Preparing for the Exam

#### Before you begin the exam:

- 1. Make sure you are familiar with the parts of the FloPoint Elite system (see FloPoint Elite Uroflow System Parts and Features on page 16).
- 2. Make sure you have performed all the steps in the setup procedure described in the "Getting Started" which begins on page 20.
- 3. Check the Remote battery icon to make sure the battery has sufficient power. If the battery icon appears less than 25% full, return the Remote to the ScanPoint® Docking Station until the battery is fully charged.
- 4. You can save 8-10 different exams on the ScanPoint Remote by voice annotating the exams. It may be helpful to decide on the patient information you wish to record on each voice annotation before you begin the exam (see page 54 for details). At the end of the workday, you can download the saved exams via the Docking Station into ScanPoint with QuickPrint software.

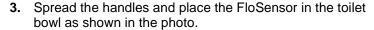
## **Performing an Exam**

1. Pick up the Remote from the ScanPoint Docking Station and a funnel and bring both items to the restroom. Set both items on the counter while preparing the FloSensor.

#### 2. Prepare the FloSensor.

Put on a pair of gloves and lift the toilet seat. Using the handles, remove the FloSensor from the FloCharger clamshell. The FloSensor will beep and the motor will start spinning. The FloSensor will take 15 seconds to warm up to operating speed.

**NOTE:** If you try to stop the FloSensor during the warm-up by using the Remote, it will not work until after the warm-up is complete.



#### 4. Place the funnel on top of the FloSensor.

Place the funnel on top of the FloSensor as shown in the photo. Press the tabs on the funnel under the handles to hold the funnel in place.

Put the seat down or leave it up depending on the preference of the patient.

Remove and dispose of your gloves.





## 5. Prepare the ScanPoint® Remote.

Press and release the Start button on the Remote. The FloSensor will perform a set of internal self-test to ensure proper functioning.



If the FloSensor motor is warming up, the Remote will display circling arrows for approximately two and a half minutes.



Next, the Remote will display a zero and sound a "chirp up" to indicate that the FloSensor and Remote are ready to perform an exam.



**NOTE:** To indicate that it is ready and waiting, the FloSensor will beep every 3 seconds until it detects urinary flow. Advise the patient that the beeping is normal and not a cause for concern.

**NOTE:** If the FloSensor detects no urinary flow for 20 minutes, the FloSensor motor will shut down to preserve battery life. When the Remote button is pushed to start an exam, the motor will re-start.

- **6.** To assure the most accurate measurement, instruct the patient to urinate onto the funnel wall closest to the front of the toilet. The patient should not urinate directly onto the FloSensor.
- 7. Leave the Remote within 10 feet of the FloSensor for example, using the supplied lanyard, you can hang the Remote on a hook in the restroom or just outside the restroom door.

**NOTE:** The Remote will emit a high-pitched beep if it begins to lose radio contact with the FloSensor.

#### 8. Ending the Exam.

When the patient is finished, pick up the Remote and press the button once to end the exam. The Remote play will play a "chirp down" to signal the end of the exam. The FloSensor motor will continue to run for 20 minutes to provide time for cleaning.

**NOTE:** The exam will end automatically if no flow is detected for 3 minutes.

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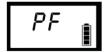
After the exam has ended, the Remote display will cycle through a series of four informational screens:



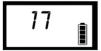
"VOL" Displays for one second indicating that the following screen will display the total voided volume measured in ml.



Total volume of urine voided displays for 2 seconds. If the total is greater than one liter, "> 999 ml" is displayed.



"PF" displays for one second indicating that the following screen will display the peak flow rate measured in ml/s.



Peak flow rate measured in ml/s displays for 2 seconds..

#### 9. Prepare the cleaning solution.

While the patient is performing the exam, prepare 2 liters of cleaning solution (see instructions on page 55).

#### 10. Save the exam by recording a voice annotation (optional).

After the patient completes the exam, you can record additional information about the patient to be stored with the exam results.

Recording a voice annotation saves the exam in memory on the ScanPoint® Remote. The Remote can store a total of 8-10 voice-annotated exams, depending on the length of the voice annotations.

By voice annotating and saving each exam, you can wait to download the exams from the ScanPoint Remote into ScanPoint with QuickPrint software until the end of the workday.

For instructions on how to download saved exams from the ScanPoint Remote, please refer to "Completing a Voice Annotated Exam" on page 63.

## **Recording a Voice Annotation**

After performing an exam, you can record additional information about a patient to be stored with the exam results.

#### To record a voice annotation:

 Press and hold the Start button until you hear a beep (about three seconds). The recording icon is displayed. Continue to hold the button until you have finished recording the annotation.



2. The microphone is located just above the display. Hold the microphone approximately 6 inches (15 cm) from your mouth when you are recording the annotation, and speak clearly.

Be sure to include all relevant exam information, such as patient ID, age, gender, date and time, position (sitting or standing), whether or not the void was typical for that patient, and the name of the person performing the exam.

A total of 10 seconds of recording time is available. If you exceed 10 seconds, the Remote will beep to indicate that recording has stopped.

- 3. When you have finished recording the annotation, release the Start button. The Remote will beep to indicate that recording has stopped.
- 4. The Remote will automatically play back the annotation.
  - If you wish to re-record your annotation, start over at the first step in the annotation procedure. You must begin re-recording within 5 seconds after playback has stopped.
  - If the annotation is satisfactory, the Remote stores the annotation in flash memory.
- 5. At this point the Remote is ready to start the Quick Clean procedure.

Cleaning procedures are described in detail in the next section of this manual beginning on page 55.

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# **Cleaning and Maintenance**

#### WARNING! Possible device damage.

Failure to heed the following warnings may cause device damage not covered by the FloPoint Elite warranty.

- **IMPORTANT:** When cleaning FloPoint Elite components, do not use any products that contain ammonia.
- Do not subject any FloPoint Elite device to steam sterilization or ethylene oxide sterilization.
- Cleaning products containing bleach can tarnish the FloSensor handles. Tarnish can be readily removed using stainless steel cleaner.

## **FloSensor Cleaning Procedures**

#### Quick Clean Procedure - Perform After Every Exam

- 1. While a patient is performing an exam, prepare two liters of cleaning solution: a 10% solution of non-abrasive disinfecting cleaner, such as chlorine bleach or an organic acid.
- After the exam is completed, put on a pair of gloves, remove and dispose of the paper funnel from the top of the FloSensor and verify that the FloSensor is still running.

**NOTE:** Do not flush the paper funnel down the toilet. Dispose of it as appropriate for medical waste.

If the FloSensor is not running, click the button on the Remote to restart the FloSensor.

**NOTE:** If the Remote is holding onto an exam, first record a voice annotation to save the exam data and then press the button to start the FloSensor.

- 3. Flush the toilet to eliminate any urine.
- 4. After the toilet finishes flushing, pour the two liters of cleaning solution through the FloSensor. Flush the toilet again.
- 5. Remove the FloSensor from the toilet, dry it with a clean paper towel and place it back on the FloCharger. The FloCharger LED will begin to alternate orange/green to indicate charging. Close the clamshell doors
- 6. Remove and dispose of your gloves.

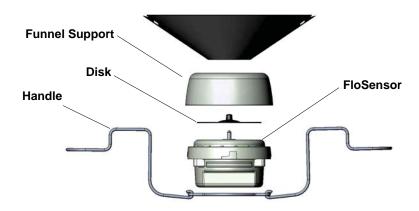
### **Solid Material Cleaning Procedure**

If any solid material enters the FloSensor, the top portion of the FloSensor may be disassembled to facilitate cleaning.

#### CAUTION! Risk of equipment damage.

The FloSensor disk is fragile. Take care to avoid damaging the disk while the funnel support is separated from the FloSensor. Do not drop or bump the FloSensor or lay it on its side while it is disassembled.

Figure 8. FloSensor Components



- 1. Put on a pair of gloves.
- Remove and properly dispose of the funnel. Do not flush it down the toilet.
- Check to see if the FloSensor motor is still running. If the motor is still running, press the button on the Remote twice to stop the motor. Verify that the motor has stopped running.
- 4. Remove the funnel support by turning it counter-clockwise and lifting it away from the FloSensor disk.

## **CAUTION!** Risk of personal injury and/or equipment damage.

Unless care is taken to stop the FloSensor motor, the FloSensor disk may still be spinning when the funnel support is removed. Take care to avoid injury and debris dispersion. Do not remove the funnel support if the sensor disk is still spinning.

- 5. Remove the solid material. Clean the FloSensor and the funnel support using a disinfecting cleaner.
- 6. Replace the funnel support by carefully seating it on the FloSensor and turning it clockwise to lock. Take care not to contact the sensor disk during this process.
- 7. Remove and dispose of your gloves.

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## **FloCharger Cleaning Procedure**

- 1. Unplug the FloCharger AC adapter from the mains (wall outlet).
- 2. Remove the clamshell from the FloCharger base.
- 3. Dry any liquid remaining in the charging well.
- 4. Using a disinfecting wipe, clean all the surfaces of the FloCharger.
- 5. Replace the clamshell on the FloCharger base.
- 6. Plug the FloCharger back into the wall outlet.

## ScanPoint® Remote Cleaning Procedure

To clean the Remote, use a germicidal wipe or a soft cloth dampened with IPA (70% isopropyl alcohol) to wipe the surfaces of the Remote until it is thoroughly cleaned.

## **Label Writer Cleaning and Maintenance**

The ScanPoint Label Writer is designed to provide long and trouble-free service, while requiring very little maintenance. The Label Writer will provide the best possible performance if you follow the setup instructions that appear on page 39.

To keep your Label Writer printer working properly, you should clean it from time to time. Dusting the outside of the printer occasionally will help keep foreign matter from getting inside the printer. However, it is still a good idea to periodically perform some basic interior maintenance.

You can easily clean your Label Writer printer using the following items:

- Lint-free cloth.
- Isopropyl alcohol, diluted dishwashing detergent, or diluted glass cleaner. (If you use glass cleaner, make sure it does not contain ammonia.)
- Small, soft brush, such as a paint brush.

#### Cleaning the Exterior and Interior of Your Printer

- 1. Turn off the printer and disconnect the power cord.
- 2. Use the lint-free cloth to wipe the exterior of the printer. Remove dirt and smudges with one of the cleaning solutions mentioned above.
- 3. Open the top cover.
- 4. Use a small, soft brush/cotton swab to whisk away paper dust and other stray particles from the inside of the printer.
- 5. Remove the roll of labels to clean under the roll.

If you have a Label Writer cleaning card, follow the instructions printed on its packaging and feed it through the printer mechanism.

- 6. Reconnect the power cord and turn on the printer.
- 7. Reload the roll of labels and close the top cover.

## **Regular Inspections and Maintenance**

Verathon® recommends that the FloPoint Elite system be calibrated once a year. For more information, please refer to the Calibration section in this manual and contact Verathon Medical Customer Care at 1.800.331.2313 (US and Canada only). International customers, please refer to the contact information on page 21).

#### **Weekly Inspections**

Once a week, you should inspect the FloPoint Elite for physical faults or cracks. Any apparent cracks or faults in the FloSensor, FloCharger, or ScanPoint® Remote must be referred to an authorized FloPoint Elite Service Center or your local FloPoint Elite distributor

**IMPORTANT!** If you see any physical faults or cracks in the instrument, discontinue use immediately and contact your local Verathon Medical representative or the Verathon Medical Customer Care Department at 1.800.331.2313.

## **Repairing FloPoint Elite Instruments**

The FloPoint Elite Uroflow System components: ScanPoint Remote, FloSensor, and FloCharger, and ScanPoint Docking Station, are completely sealed. There are no user-serviceable components. Verathon does not make available any type of circuit diagrams, component parts lists, descriptions, or other information that would be required for repairing the device and related accessories.

Premium Warranty Total Customer Care<sup>™</sup> Plan customers have access to loaner units and free shipping options which vary according to plan.

If you have any questions, please contact your local Verathon Medical representative or the Verathon Medical Customer Care Department at 1.800.331.2313.

## **Instrument Disposal**

The FloPoint Elite Uroflow System and related devices may contain lead, batteries, and other environmentally hazardous materials. When the FloPoint Elite Uroflow System has reached the end of its useful service life, return the device and related accessories to a Verathon Service Center for proper disposal. Alternatively, follow your local protocols for hazardous waste disposal.

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# Managing Exam Results in ScanPoint® with QuickPrint

## Starting ScanPoint with QuickPrint

Once ScanPoint with QuickPrint is installed, it starts automatically every time you turn on your computer. There is no need for you to open it manually. You can verify that ScanPoint with QuickPrint is open and running by confirming the presence of the ScanPoint icon in your system tray (in the lower right corner of your screen near the clock).

ScanPoint with QuickPrint stays in the background and becomes active only when you place a FloPoint Elite instrument that is holding exam information into the ScanPoint Docking Station (the ScanPoint Docking Station must be connected to the computer's USB port).

If ScanPoint with QuickPrint is running in the background, you can open it manually by double-clicking the ScanPoint icon in your system tray.

If ScanPoint with QuickPrint is not running, you will not see the ScanPoint icon in the system tray. To open it, either double-click the ScanPoint QuickPrint icon on your desktop or open the Start menu and select:

Programs > Verathon > ScanPoint with QuickPrint > ScanPoint with QuickPrint.

#### ScanPoint with QuickPrint Windows Icons

The ScanPoint with QuickPrint window displays a status box and if appropriate, a message icon (Figure 9).

ScanPoint® QuickPrint \_ | | X **Status** View Tools Help Box nistrative User - mfgad **Status** Indicator Prepare New Exam Instrument name Instrument Details 0570-0174 5310701 Serial: Next Calibration: 9/12/2008 12:46:58 PM

Figure 9. QuickPrint Window with Status Box and Message Icon

Message Indicator

Status Box symbols have the following meanings:

Item	Meaning
Status Indicator	Possible symbols are:
	<b>Blue exclamation point:</b> QuickPrint is waiting for you to input information.
	Green check mark: The instrument is ready to use.
	<b>Red stop sign:</b> The instrument is performing a process such as transmitting information to ScanPoint.
Instrument image	A picture of the instrument that is currently transmitting data to the computer.
Instrument name	The name assigned to the instrument. You can rename the instrument by clicking on the name and entering a new one.

## **Using Multiple ScanPoint Docking Stations**

If you have more than one FloPoint Elite instrument with multiple Remotes and ScanPoint Docking Stations, you will see one status box for each available device. The currently active instrument is indicated by a solid border around the status box. To communicate with a different instrument, click its instrument image in the appropriate status box.

#### The Message Indicator

This icon indicates the number of ScanPoint messages you have waiting to be viewed. To view the messages, click the icon. If there is more than one message, you will be able to move through a scrollable list of message headings. The messages are "Read Only." You cannot create a text reply, although you can select YES / NO buttons, as appropriate.



## **Completing an Unannotated Exam**

Perform the following steps to complete an exam only if you *did not* enter a voice annotation.

If you did enter a voice annotation, see "Completing a Voice-Annotated Exam" on page 63.

**NOTE:** The following procedure assumes that you have performed an exam as described in Performing an Exam beginning on page 51.

#### If You Did Not Enter a Voice Annotation

 Place your Remote into the ScanPoint Docking Station connected to your computer. Exam results are automatically transmitted to ScanPoint. As the exams are being transmitted to ScanPoint, the Remote display shows the percentage of the data that has been transferred.



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#### IMPORTANT! Unsaved exam data could be lost.

If the battery is low or the ScanPoint® Remote goes into sleep mode (after 20 continuous minutes of non-use or charging), unsaved exam data is lost.

2. If you chose not to be prompted for exam information when you set your user preferences, the instrument automatically transmits the exam data.

When the transmission is complete, QuickPrint prints the results according to the user preferences you previously selected.

**NOTE**: You can view sample report formats at the end of this section or by going to the Help menu and selecting Report Type Samples.

3. If you chose to be prompted for information when you specified your user preferences, the Exam Details dialog box appears, displaying the prompts you requested.

**NOTE:** Depending on the prompts you requested, the dialog box you see may differ from the following illustration (Figure 10).

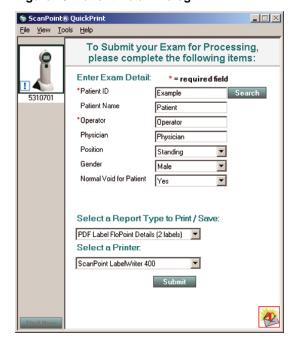


Figure 10. Patient Detail Dialog

4. Enter the appropriate information according to the following table:

## **IMPORTANT!** Required fields.

Fields marked with a red asterisk (\*) are required in order for the exam to be available later in ScanPoint®.

Item	Meaning
Patient ID*	The unique code you use to identify this patient. If you don't know the Patient ID code, press the SEARCH button to display a list of the codes you have assigned to your patients.
Patient Name	The patient's name as it appears in your records.
Operator*	The person performing the exam.
Physician	The patient's primary health care provider.
Select Gender	The patient's gender.
Select Position	The patient's position during the exam (standing or sitting).
Select Normal Void	"Yes" if the patient feels that the void was representative of his/her routine voiding.
Select a report type to print	Click the down arrow (▼) at the right of the text box to select the type of report you wish to print.
	<b>NOTE:</b> You can view sample report formats starting on page 71 or by going to the Help menu and selecting Report type samples.
Select a printer	Click the down arrow ( $\overline{}$ ) at the right of the text box to select the printer for the report.

5. When the dialog is complete, click the SUBMIT button. The information is transmitted to ScanPoint and the report is printed.

For more information on viewing and printing past exam results in ScanPoint, see "Viewing Exam Results in ScanPoint Online" beginning on page 66.

## Reprinting an Exam

After printing the exam results through QuickPrint, you can print them again with the same or different printer or report format.

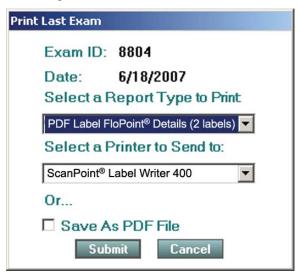
NOTE: You can reprint the most recent exam from QuickPrint. Use ScanPoint to print

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older past exams. See "Viewing Exam Results in ScanPoint® Online" beginning on page 66 for more information on printing saved exam results from ScanPoint.

## To Reprint the Most Recent Exam Results

- 1. Place the Remote used to take the exam in the ScanPoint Docking Station.
- 2. From the QuickPrint File menu, select PRINT LAST EXAM.
- 3. The Print Last Exam dialog prompts you for the report type and printer. Complete the dialog and click SUBMIT.



## **Completing a Voice-Annotated Exam**

**NOTE:** If you did not add a voice annotation to the exam, refer to "Completing an Unannotated Exam" on page 60.

 Place the Remote in the ScanPoint Docking Station connected to your computer. Exam results are automatically transmitted to ScanPoint. As the exams are being transmitted to ScanPoint, the Remote display shows the percentage of the data that has been transferred.



After all the exam data are downloaded, the ScanPoint New Exam Results window opens (Figure 11).

**VERATHON** New Exam Results Point<sup>®</sup> Bladder Monitor Click the column heading to sort BladderScan® UEBW Mobile BladderScan® Patient ID Patient N Wednesday, June 20, 2007 10:09:31 AM BVI9400 Enter Details Pediatric Wednesday, June 20, 2007 10:10:10 AM BVI9400 Enter Details BladderScan® Wednesday, June 20, 2007 9:52:51 AM FloPoint(R) Elite Enter Details View Exam Results New Exams Past Exams Wednesday, June 20, 2007 9:44:23 AM FloPoint(R) Elite Enter Details Example Patient Friday, May 25, 2007 1:44:00 PM Bladder Mass Operator <u>Available</u> Wednesday, June 20, 2007 9:41:00 AM Bladder Mass Example Patient Operator Available Bladder Monitor Example Patient Wednesday, June 20, 2007 9:57:00 AM Bladder Volume Operator <u>Available</u> Assignment Calibration Wednesday, June 20, 2007 9:42:00 AM Bladder Volume Example Patient Operator Available verathon.com Help Example Patient Wednesday, June 20, 2007 9:35:13 AM FloPoint(R) Elite Operator Available Wednesday, June 20, 2007 9:42:48 AM FloPoint(R) Elite Example Patient Operator Available Example Patient Wednesday, June 20, 2007 9:35:00 AM Pediatric Bladder Volume Operator Available Wednesday, June 20, 2007 9:36:00 AM Pediatric Bladder Volume Example Patient Operator <u>Available</u>

Figure 11. New Exams Results Window

2. In the ScanPoint New Exam Results window, any exams that have not yet been viewed in ScanPoint are displayed.

By default, the exams are arranged in order by Patient ID. To arrange the exams in a different order, click the appropriate column heading. For example, to arrange the exams in order by Exam Date, click the Exam Date column heading. The exams are listed in order from oldest to most recent. To reverse the date order, click the Exam Date column heading again.

3. In the Exam Result column, exams that display an ENTER DETAILS link have a voice annotation but are missing required exam details.

To complete exams with missing details, Click the ENTER DETAILS link corresponding to the desired exam. A blank Patient information dialog will open (Figure 12).

4. Click the LISTEN button to play the annotation. You can replay the annotation as many times as necessary.

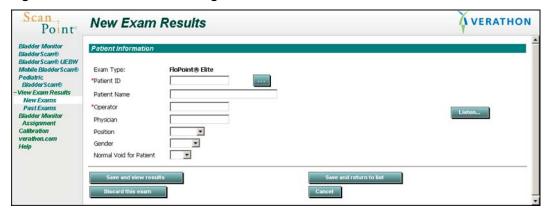


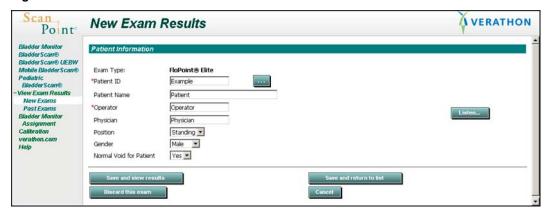
Figure 12. New Exam Results Dialog

5. Fill out the dialog fields according to the information in this table (Figure 13):

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Item	Meaning
Patient ID*	The unique code you use to identify this patient. If you don't know the Patient ID code, press the SEARCH button to display a list of the codes you have assigned to your patients.
Patient Name	The patient's name as it appears in your records.
Operator*	The person performing the exam.
Physician	The patient's primary health care provider.
Gender	The patient's gender.
Position	The patient's position during the exam (sitting/standing)
Normal Void	"Yes" if the patient feels the void is typical of their normal pattern.

Figure 13. Patient details added to an exam record



6. To save your entries and return to the New Exam list, click the SAVE AND RETURN TO LIST button or the SAVE AND VIEW RESULTS button. This exam will remain in the New Exams list until you view the results.

To delete the exam and return to the New Exams list, click the DISCARD THIS EXAM button.

**NOTE:** For more information on viewing and printing results in ScanPoint, see "Viewing Exam Results in ScanPoint Online" on page 66.

7. When you are finished, close the ScanPoint window by clicking the  $\boxtimes$  in the upper right corner of the window.

## **Viewing Exam Results in ScanPoint Online**

QuickPrint automatically prints the current exam results from your instrument. To view or print previous exam results, you must use ScanPoint Online.

The information in this section explains how to view, approve, and print exam results in ScanPoint Online.

You can use any computer with an Internet connection to open ScanPoint Online and view and print exam results. However, no matter which computer you use, you can view only exams performed at your facility and saved in your facility's ScanPoint account.

#### **Starting ScanPoint Online**

To start ScanPoint Online, choose the appropriate procedure:

#### Starting ScanPoint Online -ScanPoint with QuickPrint is already installed:

- Open the QuickPrint window by double-clicking the ScanPoint icon in the system tray.
- 2. Start the ScanPoint system by clicking the SCANPOINT button in the QuickPrint window or by selecting LAUNCH SCANPOINT from the View menu.

# Starting ScanPoint Online - ScanPoint with QuickPrint is not installed:

- Open your Internet Explorer browser and navigate to the ScanPoint Web site at http://my.scanpoint.com.
- In the Sign In dialog box, enter the User Name and Password assigned to you by Verathon<sup>®</sup>.
- Click the SIGN IN button to open the initial ScanPoint window.

Exam results are divided into two categories: New and Past.

#### New:

These are exam results that have been transmitted to ScanPoint Online from QuickPrint but not yet viewed. Using ScanPoint Online, you can review these exams and accept or reject them. Once viewed, the exams are automatically moved to the Past Exams list.

New Exams that have an ENTER DETAILS link in the Exam Result column have voice annotations but are missing exam details. When viewing these exams, you can listen to the voice recording associated with the exam, enter exam details, and view the results. For more information, see "Completing a Voice-Annotated Exam" on page 63.

 Past: Exam results that have already been reviewed in ScanPoint and that have been accepted or rejected.

#### **Viewing Exam Results**

#### 1. Click NEW EXAMS:

On the ScanPoint menu, at the left side of the window, click NEW EXAMS. (You

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may need to expand the View Exam Results menu to see this option.). The New Exam Results page will open (Figure 14).

**N** VERATHON New Exam Results Point<sup>®</sup> Bladder Monitor Olick the column heading to sort BladderScan® Patient ID Patient Name BladderScan® UEBW Mobile BladderScan® Pediatric BladderScan® BVI9400 Wednesday, June 20, 2007 10:09:31 AM Enter Details Wednesday, June 20, 2007 10:10:10 AM FloPoint(R) Elite Wednesday, June 20, 2007 9:52:51 AM Enter Details View Exam Results Enter Details New Exams Past Exams
Bladder Monitor
Assignment
Calibration Example Patient Friday, May 25, 2007 1:44:00 PM Bladder Mass Operator Available Wednesday, June 20, 2007 9:41:00 AM Bladder Mass Example Operator Example Patient Wednesday, June 20, 2007 9:57:00 AM Bladder Volume Operator Available Example Wednesday, June 20, 2007 9:42:00 AM Bladder Volume verathon.com Example Patient Wednesday, June 20, 2007 9:35:13 AM FloPoint(R) Elite Operator Available Wednesday, June 20, 2007 9:42:48 AM FloPoint(R) Elite Pediatric Bladder Volume Wednesday, June 20, 2007 9:35:00 AM Example Patient Operator Available Example Wednesday, June 20, 2007 9:36:00 AM Pediatric Bladder Volume Operator Available Refresh

Figure 14. New Exam Results Page

#### 2. Sort and review exam data:

Exam results are sortable. By default, exam results are displayed in order by the Patient ID number. To arrange the exams in a different order, click in the appropriate column heading. For example, to sort the exams by date, click the Exam Date column heading. By default, the exams are listed in order from the oldest at the top to the most recent at the bottom. To reverse the date order, click the Exam Date heading again.

#### 3. Open an Exam Details page:

Click the AVAILABLE link to the right of the exam you want to view. A new window will open containing the exam results (Figure 15).

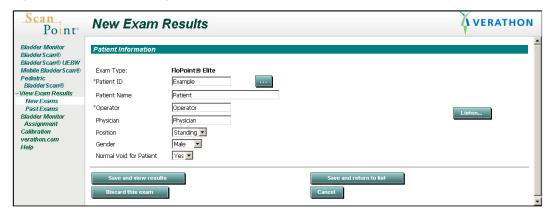


Figure 15. Exam Details Page

### 4. Accept or Reject the Exam

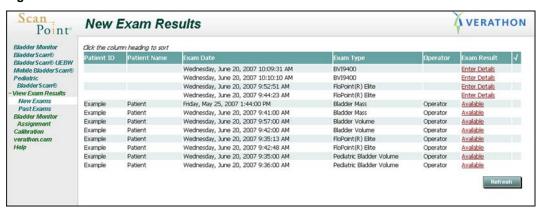
You can accept, reject, or print the exam results according to the instructions in the following table.

То	Do this
Accept the results of a new exam	Click the CLOSE button at the bottom of the exam result page. Or, click the ⊠ in the upper right corner of the exam result window.
Reject the results of a new exam	Enter a reason for rejecting the exam in the Reject Reason text box at the bottom of the exam result page. Then click REJECT button.
Print the exam details and scan images	At the bottom of the exam result page, click the     PRINTABLE PAGE link. A new window appears displaying     the exam report as it will print.
	<ol><li>At the top of the page, click the PRINT THIS PAGE link. The Windows Print dialog box will open.</li></ol>
	3. Select the appropriate options and click OK to send the page to the printer.

#### 5. Reviewed Exams are moved to the Past Exams list

Once an exam has been viewed, a check mark is displayed next to its entry in the last column of the New Exam Results list (Figure 16). When you refresh the ScanPoint window, any viewed exams disappear from the list.

Figure 16. New Exam Results



#### **Viewing Past Exams**

Once an exam has been viewed in ScanPoint, it is automatically moved to the Past Exams list.

1. On the ScanPoint menu at the left of the window, click PAST EXAMS. The Patient Exams History screen is displayed (Figure 17).

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Point

Bladder Monitor
Bladder Scan® UEBW
Mohite Bladder Scan® UEBW
Mohite Bladder Scan®
Pediatric
Bladder Scan®
Wew Exams
Bladder Monitor
Assignment
Calibration
verathon.com
Help
Log Off

Patient Exams History

VERATHON

Verathon

\*denotes a required field

Submit

Submit

Figure 17. Patient Exams History screen - Search by Patient ID

To see a patient's past exams, enter the appropriate Patient ID in the Patient ID
text box and click SUBMIT. Alternatively, to choose from a list of IDs used at your
institution, click the SEARCH button and then click on the appropriate Patient ID.

A list of viewed exams with the Patient ID you selected will appear (Figure 18).

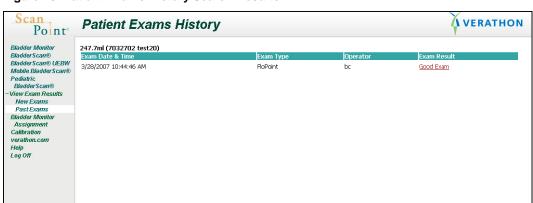


Figure 18. Patient Exams History Search Results

- 3. To view an exam result, click the link in the Exam Result column next to the appropriate exam.
  - Accepted exam results will display a Good Exam link.
  - Rejected exam results will display a Failed Exam due to user rejection link.
- 4. Follow the instructions in the previous table to view or print these results.

## FloPoint Elite Reports in ScanPoint with QuickPrint

FloPoint Elite exam results in ScanPoint with QuickPrint (Figure 19) are divided into three sections with different kinds of information in each section:

#### Information:

Category	Description
Exam Date and Time	The date and time the exam was performed.
Patient ID	The patient's ID as entered into ScanPoint with QuickPrint.
Patient Name	The patient's name as entered into ScanPoint with QuickPrint.
Operator	The instrument operator for this exam, as entered into ScanPoint with QuickPrint.
Physician	The supervising physician for this exam, as entered into ScanPoint with QuickPrint
Gender	The patient's gender
Position	The patient's voiding position - sitting or standing
Normal Void for Patient	Yes / No

#### Measurements

Measurement	Description
Peak Flow	Measured in ml/s
Average Flow	Measured in ml/s
Time to Peak Flow	Measured in seconds
Voided Volume	Measured in ml
Flow Time	Measured in seconds
Pattern	Intermittent, for example
Void time	Measured in seconds

## Graphs

- Flow Rate: Flow Rate (in ml/s) over Time (in seconds)
- Voided Volume: Voided Volume (in ml) over Time (in seconds)

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## **Report Type Samples**

There are two different styles of reports provided by the FloPoint Elite system:

- A summary report that provides only the peak flow measurement.
- A detailed report that provides all measurements described above.

#### **Past Exams and Voice Annotated Exams**

Past exams and voice annotated exams must be printed through the ScanPoint On-Line interface. Both the summary and the detailed reports have been formatted to fit on a sheet of 8.5"x11" paper in portrait orientation (Figure 19).

#### To print a past exam or voice annotated exam:

- 1. After opening the exam results, click on either the Summary or the Detail links to open a preview of the printed report.
- 2. Once the preview is open, click on the Print This Page link to print the report to your printer.

#### **Exams without Voice Annotation**

Exams without voice annotation may be printed directly through QuickPrint to a sheet of 8.5" x 11" on your local or network printer, or to labels available with the ScanPoint Label Writer (Figure 24). Your QuickPrint preference settings will let you select which report format you want to print and what printer to use.

NOTE: The Label Report cannot be printed from ScanPoint Online.

#### **Printing Results from the Last Exam Performed**

The last exam performed by your FloPoint Elite may be re-printed through the QuickPrint interface by clicking the PRINT LAST EXAM button. QuickPrint reports may be printed to a sheet of 8.5" x 11" on your local or network printer, or to labels available with the ScanPoint Label Writer. Use QuickPrint preference settings to select the desired report format and printer.

Information Exam Date & Time: Wednesday, June 20, 2007 9:35:13 AM Patient ID: Example Patient Name: Patient Operator: Physician: Operator Physician Exam Overview Gender: Position: Normal Void for Patient: Measurements Peak Flow: 20.0 ml/s Average Flow: Time to Peak Flow: 9.4 1.3 Voided Volume: Flow Time: 4.0 Pattern: Void Time: Continuous 4.0 s Images 40-35-30-20-15-10-Time (s) 40 35-25-20 10-Time (s) Customer comments Result: Good Exam FloPoint Summary FloPoint Details

Figure 19. ScanPoint Online Detail Report

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20· 15· 10·

Physician Signature:\_

0570-0175 | 7040602 | 87893

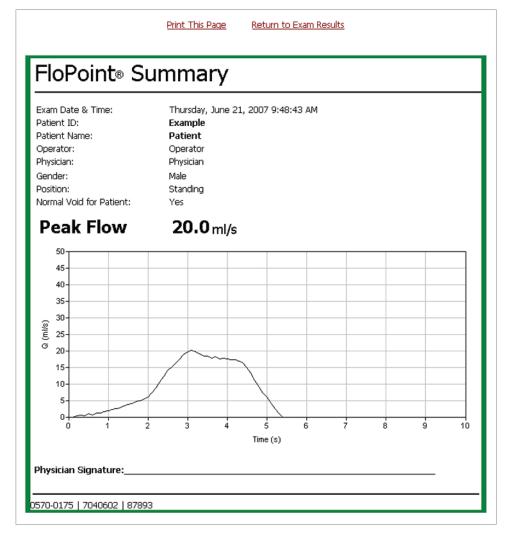
Print This Page Return to Exam Results FloPoint® Details Exam Date & Time: Thursday, June 21, 2007 9:48:43 **Peak Flow:** 20.0<sub>ml/s</sub> Average Flow: Patient ID: Example 9.4<sub>ml/s</sub> Patient Name: Patient 3.05 Time to Peak Flow: Operator: Operator Voided Volume: 51<sub>ml</sub> Physician: Physician 5.4<sub>s</sub> Flow Time: Continuous Pattern: Void Time: 5.4s Gender: Male Position: Standing Normal Void for Patient: Yes 45 40-35 30-25 20-15 10-Time (s) 50-45-40-35. Volume (ml) 30-25

Figure 20. ScanPoint Online Detail Report Preview

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Time (s)

Figure 21. ScanPoint Online Summary Report Preview



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Verathon® ScanPoint® Exam Results FloPoint ® Results **Peak Flow**  $20.0 \, \text{ml/s}$ Exam Date & Time June 21, 2007 9:48 AM Average Flow 9.4ml/s Time to Peak Flow Patient ID Example 3.0s51ml Patient Name Patient Voided Volume Operator Operator Flow Time 5.4s Physician Physician Pattern Continuous Void Time 5.4s Gender Male Standing Position Normal Void for Patient Yes 35-25-Time (s) 50 -45 -30 -25 -Physician Signature \_ 0570-0175 | 7040602 | 87893

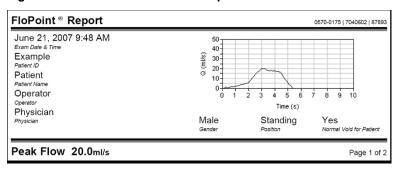
Figure 22. QuickPrint Full Page Detail Report

Verathon®ScanPoint® Exam Results

Figure 23. Quick Print Full Page Summary Report

FloPoint ® Results Summary Exam Date & Time Thursday, June 21, 2007 9:48 AM Patient ID Example Patient Name Patient Operator Operator Physician Physician Gender Male Position Standing Normal Void for Patient Peak Flow 20.0 ml/s Q (ml/s) 25-20 Time (s) Physician Signature . 0570-0175 | 7040602 | 87893

Figure 24. QuickPrint Detail Label Report



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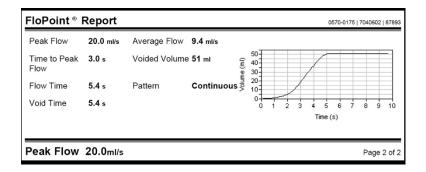
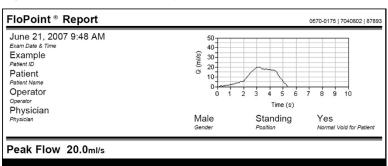


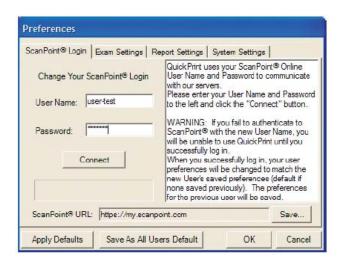
Figure 25. QuickPrint Summary Label Report



# **Changing Your Preferences**

The Preferences dialog box allows you to set your ScanPoint login information, QuickPrint prompts, default information and print settings, and preferred warnings. You can also use the Preferences Wizard to set many of your preferences — see "Step 5: Setting ScanPoint User Preferences" on page 33.

1. From the Tools menu, choose Preferences. The Preferences dialog box is displayed.



- 2. Consult the following table for the Preferences you can set up or change. When you are finished setting your preferences, click the OK button to save your changes and exit the Preferences dialog box, or:
  - Click the APPLY DEFAULTS button to reset all your Preferences to their default settings.
  - Click the SAVE AS ALL USERS button to set the Preferences settings for all users on your computer.
  - Click CANCEL to cancel any changes you have made.

То	Do this
Log in to ScanPoint or	Click the ScanPoint Login tab.
change from one user profile to another.	<ol> <li>Enter the User Name and Password assigned to you by Verathon<sup>®</sup>.</li> </ol>
	3. Click CONNECT.
	<b>NOTE:</b> This ScanPoint User Name and Password will apply every time you log in to Windows using your current user account. There is no time-out period: the User Name and Password you enter will remain active until you change them.
Change the URL of the ScanPoint Web site.	<b>NOTE:</b> Do not perform this procedure unless instructed to do so by the Verathon Medical Customer Care Department.
Have QuickPrint prompt	Click the Exam Settings tab.
you for exam details after each exam.	<ol><li>Indicate which prompts you want displayed for each exam by placing a check mark in the appropriate check boxes.</li></ol>
	<ol><li>If desired, in the Default Operator text box, enter the name you want to appear automatically in the Operator text box.</li></ol>
	<ol> <li>If desired, in the Physician text box, enter the name you want to appear automatically in the Physician text box.</li> </ol>
	<b>NOTE:</b> You can always overwrite these default names for a particular exam
	5. Choose a default printer for printing exams.
	<b>NOTE:</b> You will be able to change printers for a particular exam only if you place a checkmark in the Prompt for Printer check box.

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То	Do	this
Specify default names for the Operator and Physician text boxes in the Exam Details dialog box.	1.	Click the Exam Settings tab.
	2.	Place a check mark in the Prompt for Exam Details check box.
<b>.</b>	3.	In the Default Operator text box, enter the name you want to appear automatically in the Operator text box.
	4.	In the Physician text box, enter the name you want to appear automatically in the Physician text box.
		<b>NOTE:</b> You can always overwrite these default names for a particular exam.
Specify a default printer.	1.	Click the Exam Settings tab.
	2.	Click the down arrow (▼) on the right side of the Default Printer check box and choose the printer you want.
	3.	If you do not place a check mark in the Prompt for Printer check box, this printer will be used every time you print a new exam.
Have ScanPoint with	1.	Click the Exam Settings tab.
QuickPrint prompt you to save a PDF (a printable copy of the exam) after each exam.	2.	Place a check mark in the Prompt to Save Exam PDF check box.
	3.	If desired, enter a default location for saving exams in the Default Save Location text box. You will always be able to override this setting for a specific exam.
Have ScanPoint with	1.	Click the Report Settings tab.
QuickPrint prompt you for a report type.	2.	Place a check mark in the Prompt for Report Type check box.
	3.	To specify a default report type for each FloPoint Elite device you have available, click the down arrow (▼) to the right of the text box and select the appropriate type.
View sample report types.	1.	Click the Report Settings tab.
	2.	Click the View Report Type Samples link.
		You can also view report samples in this manual, starting on page 71.

То	Do this
Specify a default report for each exam type.	1. Click the Report Settings tab.
	<ol> <li>Click the down arrow (▼) to the right of the appropriate instrument text box and select the appropriate report type.</li> </ol>
	If you do not place a check mark in the Prompt for Report Type check box, these report types will be used every time you print a new exam.
Change the location for updates to ScanPoint with QuickPrint.	<b>NOTE:</b> Do not perform this procedure unless instructed to do so by an authorized Verathon <sup>®</sup> representative.
	<ol> <li>Click the System Settings tab.</li> </ol>
	<ol><li>In the Update URL text box, enter the new Web site location given to you by Verathon.</li></ol>
Turn on or turn off specific warning messages.	Click the System Settings tab.
	<ol><li>Place a check mark in the check box(es) next to the warning(s) you want to receive.</li></ol>

# **Exiting QuickPrint or Hiding the QuickPrint Window**

You can close the QuickPrint window without exiting the program, or you can exit QuickPrint completely.

## Closing the QuickPrint Window without Closing ScanPoint

To hide the QuickPrint window, do one of the following:

- Click the minimize button in the upper right corner of the QuickPrint window.
- Go to the File menu and select CLOSE. The QuickPrint window closes. The ScanPoint icon visible in your system tray indicates that the program is still running.

### To Exit QuickPrint Completely

- If a QuickPrint dialog box is currently displayed, go to the File menu and select EXIT.
- If a QuickPrint dialog box is not currently displayed, right-click the QuickPrint icon in the system tray and select EXIT.

A dialog box appears asking you to confirm that you want to exit QuickPrint. Click ok.

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# **Calibration**

To make sure the FloSensor is providing accurate measurements, it must be calibrated every 12 months.

The entire calibration process takes approximately 15 minutes.

You can calibrate the FloSensor as often as you like; you do not have to wait for the next scheduled calibration date. However, at a minimum, you should calibrate the FloSensor every 12 months.

**NOTE:** If your facility has signed up for the ScanPoint® Online Service Plan, you will automatically receive the Calibration Fluid 4-pack and a Calibration Quick Reference Card approximately 30 days before your FloSensor requires calibration (Figure 26).

Figure 26. FloPoint Elite Calibration Fluid and Calibration Quick Reference Card.



## **Calibration Fluid Pouch**

Pouch containing unique fluid for use in calibrating the FloPoint Elite instrument.

0800-0331



FloPoint Elite Calibration Quick Reference Card:

Provides instructions for the FloPoint Elite calibration procedure.

0900-1444

# **Determining the Number of Days until Required Calibration**

- 1. Clear the Remote of saved exam data by placing it in the ScanPoint Docking Station and saving the exam data to ScanPoint.
- 2. Remove the Remote from the ScanPoint Docking Station. Press and hold down the Start button for at least five seconds. The LCD screen displays the "setting

sun" icon and the number of days until the required calibration date - 120 in the illustration below.



**NOTE:** When the Remote displays and **000** calibration is required.

When there are 20 days remaining before the next required calibration, a warning message appears in ScanPoint® with QuickPrint (Figure 27).

The following instrument(s) require calibration within 20 days.

Part Number Serial Number Next Calibration Date 0570-0154 1072 2006/3/23 0570-0167 5064 Expired 0570-0154 7379 2006/3/24

Figure 27. ScanPoint Calibration Warning Message

#### To view the date for the next scheduled calibration:

- 1. Place the Remote in the ScanPoint Docking Station.
- 2. In ScanPoint with QuickPrint, go to the View menu and select Instrument Details. The Instrument Details dialog will open (Figure 28).

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Figure 28. Instrument Details Dialog

The last two lines of information in the dialog provide the date of the last calibration and the date of the next required calibration.

3. Click the green RETURN TO INSTRUMENT OVERVIEW button to close the dialog and return to the Instrument Overview (Prepare New Exam) pane.

# Calibrating the FloSensor using ScanPoint with QuickPrint

To make sure the FloPoint Elite FloSensor is providing accurate measurements, it must be calibrated every 12 months. The entire calibration process takes approximately 15 minutes.

- 1. Place the Remote in the ScanPoint® Docking Station. From your desktop, open QuickPrint by double-clicking the QuickPrint Icon.
- 2. The Calibrate Instrument screen will open. Click the CALIBRATE button on this screen to begin configuring the Remote for the calibration procedure.
- 3. When Configuration is complete, take the ScanPoint Remote, a Funnel, three pouches of Calibration Fluid (available from Verathon®), the Calibration Pouch Nozzle and the FloSensor to the toilet.

4. Put on a pair of gloves. Install the FloSensor in the toilet bowl as you would for an exam.

> Place the funnel on top of the FloSensor and push the tabs under the handles to hold it securely in place.





5. Pick up the Remote and press and release the button once to begin the calibration process. The FloSensor will take 15 seconds to warm-up before it will be ready to perform an exam. The Remote will chirp indicating that the FloSensor is ready to measure the calibration flow.

While the FloSensor is warming up, plug the Nozzle into the Calibration

Ready to calibrate

Fluid Pouch.

- 6. When the Remote chirps to indicate readiness, slowly pour the contents of one pouch of Calibration Fluid onto the side of the funnel closest to the front of the toilet. The flow rate should be between 10 – 20 ml/s as measured continuously by the Remote.
- 7. When the pouch is empty, press and release the button to end the calibration. Depending on the readout on the Remote display, the calibration was either successful (go to step 8), or unsuccessful (go to step 9).

#### If the Calibration was Successful

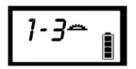
8. If the calibration was successful, four arrows and "3 - 3" are displayed. The Remote plays a "siren" chirp indicating that it should be returned to the ScanPoint® Docking Station to complete the calibration process. Please proceed to step 10.



Successful calibration

#### If the Calibration was Unsuccessful

9. If the Calibration was unsuccessful, the Remote will emit an error beep. The calibration process allows for a maximum of three calibration attempts. Return to step 6 and repeat the calibration process from there. After three unsuccessful calibration attempts, please proceed to step 10.



The display shows the current attempt number and the total allowable number of attempts possible, in this case, "one out of three."

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## **Completing Calibration**

 When you have completed a successful calibration—or when three calibration flows have been attempted—return the FloSensor to the FloCharger and flush the toilet.

Remove your gloves and return the Remote to the ScanPoint® Docking Station for re-configuration.

- 11. **If the calibration was successful:** When the Remote is returned to the Docking Station, it will upload the calibration data to ScanPoint. ScanPoint verifies the calibration, assigns a new calibration date to the FloSensor, and reprograms the Remote with the exam software. This process should take a minute or so. When the software upload is complete, please proceed to step 13.
- 12. **If the calibration was unsuccessful:** When the Remote is returned to the Docking Station, it will upload the calibration data to ScanPoint. In ScanPoint, click "Return to Instrument Overview" in the upper right corner. From the Instrument Overview screen, click "Submit".

NOTE: The Remote will be reprogrammed with the exam software and you may continue to use your FloPoint Elite Uroflow System, but the instrument is still NOT calibrated. Please contact Verathon Medical Customer Care for assistance at 1.800.331.2313.

13. If calibration was successful, click the link to print a Certificate of Calibration (Figure 29). The calibration process is now complete.

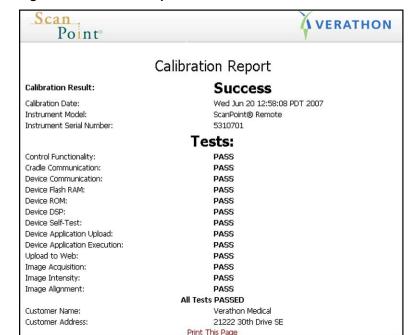


Figure 29. Calibration Report

# **Troubleshooting**

# **Help Resources**

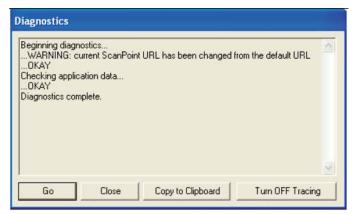
Verathon® provides an extensive array of customer care resources, described in the table below.

You can obtain copies of this manual, Quick Reference Cards, and clinical studies and view training videos by accessing the Verathon Web site at **www.verathon.com** or by contacting your Verathon Medical representative. A complete listing of contact information is provided on page 95.

Resource	Description
FloPoint Elite Quick Reference Cards	Summary of procedures for using the FloPoint Elite Uroflow System.
FloPoint Elite User's Manual	Refer to the troubleshooting suggestions that begin on page 86 for solutions to common problems.
www.verathon.com	The Verathon Web site (www.verathon.com) provides the latest user manuals, quick reference cards, clinical studies, and training videos.
	To find the latest FloPoint Elite information, from the Verathon Home page, select "FloPoint Elite."
ScanPoint® Install CD	ScanPoint with QuickPrint software.
FloPoint Elite In-Service CD	Includes FloPoint Elite User's Manual and Quick Reference Cards.
ScanPoint Help	From your ScanPoint application, select <b>Help</b> from the toolbar at the top of the ScanPoint window.
ScanPoint Online	ScanPoint Online provides:
	<ul> <li>Access to real-time troubleshooting from Verathon.</li> </ul>
	The ability to calibrate the instrument online.
	<ul> <li>Software upgrades, when available.</li> </ul>
	<ul> <li>HIPAA-compliant automatic data backup and archiving.</li> </ul>
ScanPoint Diagnostics	This ScanPoint tool checks your system and lets you know of any problems or needed updates (Figure 30).
	To access this information, from the ScanPoint menu select <b>Tools</b> > <b>Diagnostics</b> .

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Figure 30. ScanPoint® Diagnostics



Resource	Description
Premium Warranty Total Customer Care <sup>sm</sup> Plan	A Verathon® insurance plan that provides all the benefits of ScanPoint Online (preceding paragraph) plus:
	<ul> <li>Instrument insurance: A perpetual warranty against outdated technology with free upgrade / replacement when your device is no longer manufactured.</li> </ul>
	<ul> <li>Free loaner program.</li> </ul>
	<ul> <li>Free shipping.</li> </ul>
Phone support	In North America, call: 1.800.331.2313. International customers, please refer to the list of Customer Care phone numbers on page 21.

# **Diagnosing Problems**

## **ScanPoint Problems**

Issue / Problem	Answer
How can I improve my system's security and privacy?	To view recommended security and privacy practices, from the ScanPoint Help menu and select "Security Best Practices."

Issue / Problem	Answer
When I insert the ScanPoint disk into the CD drive, the installation	If the installation screen does not automatically open when you insert the ScanPoint CD, you can start installation this way:
screen does not appear.	<ol> <li>On the Windows taskbar, click Start &gt; Run. The Run dialog will open.</li> </ol>
	<ol><li>Type: D:\setup.exe (where D is the name assigned to the CD drive) and click Ok.</li></ol>
I can't access the ScanPoint Web site.	Check your Internet connection.
I can't start ScanPoint.	Exit all open Internet Explorer windows and restart the program.
I can't log onto ScanPoint.	You may have mistyped your login name and password.
ooun ome	Try entering them again making sure that they are spelled correctly and that you are using upper and lower case letters as appropriate.
	If you can't remember your login name or password, click <b>Get help with sign in</b> .
My ScanPoint session has expired.	Your ScanPoint session has timed out because it was idle for over 12 hours. You must log in again.
Why do some text boxes have red asterisks (*)?	A red asterisk indicates that the text box cannot be left blank. You are required to enter text in any field marked with a red asterisk.
I can't find the exam results I want.	Make sure the exam was transmitted to your account and not someone else's. If it was transmitted to your account but you still can't find it, one of the following conditions may apply:
	<ul> <li>ScanPoint may not have validated the exam yet.</li> <li>Wait a few minutes and try again.</li> </ul>
	<ul> <li>The exam results may have already been viewed. If so, go to the Past Exams menu and request the results again.</li> </ul>
A security warning appeared on my screen.	You may be trying to run an outdated version of ScanPoint, or the driver ScanPoint needs is not available. If either is true, click <b>Yes</b> in the security warning dialog box.

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Issue / Problem	Answer
Why do I get an error message saying that I must enter a positive number?	A minus sign ( – ) cannot be the first character in any ScanPoint® text box. Re-enter the digits without the minus sign.
An error message appeared on the ScanPoint screen.	Click the HELP button on any ScanPoint screen and follow the directions provided.  If you still have questions, contact the Verathon Medical Customer Care Department at 1.800.331.2313.
My account has expired.	Contact Verathon® at 1.800.331.2313 to reactivate your account.
I can't access some menu options.	You can access only the features for which you have signed up.

# **ScanPoint Remote Problems**

Issue / Problem	Answer
The Remote does not recognize the FloSensor. Or, the FloSensor is not communicating with the Remote.	<ul> <li>Make sure you are within 3 meters (10 feet) of the FloSensor.</li> </ul>
	<ul> <li>Make sure the FloSensor battery is charged and the Remote battery is charged.</li> </ul>
The Remote does not turn on.	The Remote battery may need to be charged.
	<ol> <li>Place the Remote in the ScanPoint Docking Station (make sure the computer is turned on) for up to 8 hours.</li> </ol>
	<ol> <li>If the scrolling battery icon does not appear after 2 hours, press the Reset button on the rear of the Remote.</li> </ol>
	<ol> <li>For more information about charging the Remote, see "Charging the ScanPoint Remote Battery" on page 44.</li> </ol>

Issue / Problem	Answer
The ScanPoint® Remote isn't working.	<ul> <li>Make sure the Remote is seated properly in the ScanPoint Docking Station.</li> </ul>
	<ul> <li>Make sure the Remote battery is charged.</li> </ul>
	<ul> <li>If the Remote is charged but still won't turn on, press the Reset button on the back of the Remote using the activation tool provided with you FloPoint Elite system.</li> </ul>
	If the Remote is still not functioning properly, contact Verathon Medical Customer Care at 1.800.331.2313.
The ScanPoint Remote won't communicate with ScanPoint.	Check the connections between the ScanPoint Docking Station and the USB connector on your computer.
	If the Remote is still not functioning properly, contact Verathon Medical Customer Care at 1.800.331.2313.
The ScanPoint Remote	It is normal for the Remote to beep when:
beeped.	<ul> <li>It is beginning or ending a process.</li> </ul>
	<ul> <li>It is entering sleep mode to conserver battery life.</li> <li>Press any button to "wake up" the Remote.</li> </ul>
	<ul> <li>Battery power is low and the Remote needs to be recharged. (See "Charging the ScanPoint Remote Battery" on page 44.)</li> </ul>
	<ul> <li>Radio contact is weak. Move the Remote closer to the FloSensor.</li> </ul>

# **Error Messages**

Message	Answer
User's comments may not be empty during exam rejection.	Enter a reason for the rejection in the Reason text box.
Exam already has exam data uploaded. Please start another exam.	You have already transmitted the results of the exam. You may conduct a new exam, if desired.
This field may not be empty.	You must make an entry into the appropriate text box. It cannot remain blank.

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Message	Answer
You must enter a positive number.	A minus sign ( – ) cannot be the first character in any ScanPoint® text box. Re-enter the digits without the minus sign.

# **Error Codes**

Code	Meaning	Resolution
Err 1	FloSensor did not respond to Self- Test Request from ScanPoint Remote.	Charge the FloSensor.
Err 2	FloSensor did not respond to a stop exam request from ScanPoint Remote. Exam information is complete and a new exam could be started.	Reset FloSensor by placing it on the FloCharger.
Err 3	The calibration exchange between the FloSensor and the ScanPoint Remote failed.	Repeat the calibration. If it still fails, upload data to ScanPoint and call Verathon Medical Customer Care.
Err 4	At least 1 second of continuous data was lost due to a radio communication failure.	Alert on ScanPoint Remote indicates loss of radio data. Move ScanPoint Remote closer to the FloSensor during an exam. If alert comes after patient has completed voiding, there will be no impact on exam result.
Err 5	The ScanPoint Remote failed to write a value to the FloSensor flash.	Repeat the operation. (Not a function performed by customers. Call Verathon Medical Customer Care.)
Err 6	The ScanPoint Remote failed to read a value from the FloSensor flash.	Repeat the operation. (Not a function performed by customers. Call Verathon Medical Customer Care.)
Err 7	The FloSensor battery has insufficient charge to perform an exam.	Charge the FloSensor.

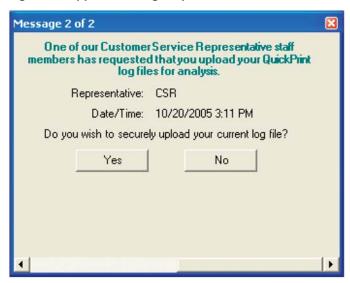
Code	Meaning	Resolution
Err 8	The FloSensor motor is moving too slowly and could no longer be controlled.	Check the FloSensor for something blocking the motor. If necessary, remove the funnel retainer and clean the FloSensor (see page 56). Re-assemble and attempt the exam again. If the problem persists, contact Verathon Medical Customer Care.
Err 9	The FloSensor is requiring too much current to control the speed.	Either the flow rate is too high or there is something preventing the motor from moving. Remove the funnel retainer and clean the FloSensor (see page 56). Reassemble and attempt the exam again. If the problem persists, contact Verathon Medical Customer Care.
Err 10	The FloSensor internal temperature is too high.	Let the FloSensor cool off and attempt to perform another exam. If the problem persists, contact Verathon Medical Customer Care.

# **Application Log**

If you are experiencing problems, the Customer Care Department at Verathon Medical may send you a message requesting permission to view your application log (Figure 31).

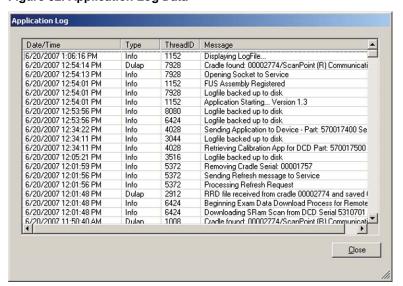
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Figure 31. Application Log Request



The application log is a record of all the actions ScanPoint® has performed. No patient data is included. You can preview your application log by going to the **View** menu and selecting **Application Log**. Figure 32 shows a typical application log

Figure 32. Application Log Data



# Warranty

Verathon Medical warrants the FloPoint Elite Uroflow System against defects in material and workmanship as long as it is covered by the Premium Warranty Total Customer Care<sup>SM</sup> Plan. This warranty does not cover equipment sold as used.

Pursuant to this warranty, a service center authorized by Verathon® will repair or replace units that prove to be defective during the warranty period.

This warranty does not apply if the unit was misused or modified by anyone other than a service center authorized by Verathon.

The unit must be used in accordance with the instructions contained in this manual. Consumable items are not covered in this warranty and should be used in conformance with Verathon product specifications.

For further details, consult your Premium Warranty Total Customer Care<sup>SM</sup> Plan. Warranty conditions may differ in some countries outside the United States. Contact your local distributor for warranty terms.

# **Disclaimer of Additional Warranties**

There are no understandings, agreements, representations of warranties expressed or implied (including warranties of merchantability or fitness for a particular purpose) other than those set forth in the preceding Warranty section. The contents of this manual do not constitute a warranty.

Some states disallow certain limitations on applied warranties. The purchaser, user, and patient should consult state law if there is a question regarding this disclaimer. This information, descriptions, recommendations, and safety notations in this manual are based upon Verathon's experience and judgment with the FloPoint Elite as of March 2010. The contents of this manual should not be considered to be all-inclusive, or to cover all contingencies.

The physician who directs the use of the FloPoint Elite Uroflow System at the institution where it is in use is responsible for keeping current with clinical research in uroflowmetry.

Please direct any questions or problems concerning uroflowmetry, using the instrument, or the interpretation of data to the responsible physician.

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# **Contacting Verathon®**

The team at Verathon is committed to modernizing healthcare delivery by putting patients first. Our products support healthcare professionals by providing the reliability, utility, and excellence. For additional product and company information, visit the Verathon Web site at www.verathon.com. If you have any questions or comments about Verathon products and services, please contact us at:

**Corporate Headquarters (USA)** 

Verathon Incorporated 20001 North Creek Parkway Bothell, WA 98011

USA

EC Rep

**Verathon Medical B. V. (Europe)** 

Willem Fenengastraat 13 1096 BL Amsterdam The Netherlands Toll free: 800.331.2313 (US & Canada Only)

Tel: 425.867.1348 Fax: 425.883.2896 Web: www.verathon.com

Email: customerservice@verathon.com

Tel: +31 (0) 20 210 30 91 Fax: +31 (0) 20 210 30 92

Email: customerserviceeu@verathon.nl

# **Clinical Application**

## **Definitions, Indications, and Output**

#### **Definitions**

Uroflowmetry is a diagnostic test in which the patient urinates into a flow sensor connected to a recording device that produces a plot of urine flow rate versus time (the "uroflow curve"). Most uroflow systems measure urine flow rate by continuously weighing the urine as it fills a catch vessel and calculating the rate of increase in urine weight. By contrast, the FloPoint Elite FloSensor contains a disk that spins at a constant speed. When a flow of urine hits the disk, the motor must work harder to maintain the disk spinning at that same speed with the added weight of the urine. The FloSensor measures the amount of power needed to maintain the disk's original speed and uses that measurement to calculate the urine flow rate. The FloSensor also records the total amount of urine discharged by the patient.

#### **Indications**

In general, uroflowmetry is used as a screening test to determine which patients with symptoms or clinical conditions involving the lower urinary tract should be referred for further workup (e.g., urodynamics, cystography). The most common clinical application of uroflowmetry is to provide an objective indication of a low urine flow rate caused by bladder outflow obstruction — especially in males with symptoms suggestive of benign prostatic hypertrophy. Uroflowmetry is also often included in the workup of females with urinary incontinence.

## Clinical Condition or History Suggestive Of:

- High bladder outlet resistance. Examples include prostatism (the most common indication), lower urinary tract infection and previous lower urinary tract surgery.
- A decompensated bladder or weak detrusor contraction.
- Neurologic impairment of voiding. Examples include multiple sclerosis and spinal cord injury.

## **Specific Signs and Symptoms:**

- Prolonged or interrupted voiding.
- High residual urine.
- Manually assisted voiding (e.g., by applying pressure to the lower abdomen).
- Excessive straining required to void.

### **FloPoint Elite Output**

The FloPoint Elite Uroflow System plots urine flow rate in ml/second versus time in seconds. Several measurements are taken from the FloPoint Elite curve, either manually by the clinician, or automatically by a digital processor.

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# **FloPoint Elite Exam Interpretation**

### **Limitations and Specific Clinical Applications**

A reduced urine flow rate can be caused by either a bladder outlet obstruction or by detrusor hypocontractility. In turn, bladder outlet obstruction can be due either to an anatomical abnormality (e.g., prostatic hypertrophy) or a neurological abnormality (e.g., detrusor-sphincter dyssynergia caused by multiple sclerosis). Therefore, by itself, uroflowmetry cannot determine the cause of a reduced flow rate.

However, many clinicians with uroflowmetry experience contend that uroflowmetry can provide useful clinical information by itself, particularly in men. For example, Boone and Kim² state that if a patient complains of a reduced flow of urine, but there are no other signs or symptoms of voiding dysfunction and uroflowmetry is normal, it is unlikely that further urodynamic testing will reveal an abnormality. Chapple and MacDiarmid³ state: "Simple uroflowmetry by itself is adequate investigation for uncomplicated prostate-mediated bladder outflow obstruction in over 60% of patients. McLoughlin, et al⁵ found that an abnormally reduced maximum urine flow rate is a reliable indicator of obstruction in over 90 percent of men with prostatic symptoms. Also, Abrams¹ and Sand and Ostergard³ state that in female patients with urinary incontinence an abnormally high flow rate and short duration void sometimes provides a useful suggestion of detrusor instability and/or abnormally reduced outlet resistance.

## **Quantitative Measurements**

Figure 33 diagrams the measurements taken from the FloPoint Elite curve. Table 1 summarizes the definitions and normal results of these measurements.

#### **Flow Rates**

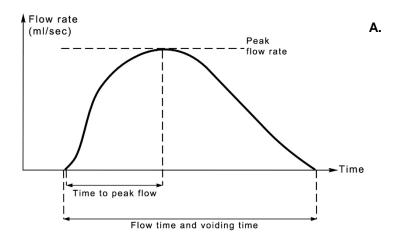
Both maximum and average urine flow rates are strongly dependent on voided volume and the patient's age and sex.

**NOTE:** In subsequent FloPoint Elite Report Charts (Figure 33 through Figure 42), flow rate is represented by the letter Q.

#### Figure 33. Measurements Taken From the FloPoint® Elite Curve

**A.** Measurements of the continuous uroflow curve. Average flow rate (not shown) is calculated by divided total volume voided by flow time. **B.** Measurements of flow time and voiding time from an

intermittent uroflow curve.



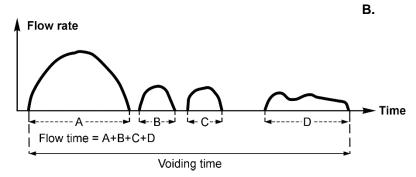


Table 1. Measurements from the FloPoint® Elite Curve (see Figure 33)

MEASUREMENTS	DEFINITION	NORMAL RESULTS
Peak Flow Rate	Maximum measured flow rate excluding dribble-produced or other spikes.	Depends on age, sex and voided volume. Rarely exceeds 40 ml/sec. Clinical significance is questionable with irregular flow patterns.
Average Flow Rate	Voided volume divided by flow time.	Typically is about half of Peak Flow.
Voiding Time	Total duration of the micturition, including interruptions.	Averages about 10 seconds with 100 ml voided volume and 25 seconds with 400 ml voided volume. No "normal limits" defined.

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MEASUREMENTS	DEFINITION	NORMAL RESULTS
Flow Time	Total duration of measurable flow.	Equal or nearly equal to voiding time. A flow time that is significantly shorter than the voiding time indicates an abnormal intermittent FloPoint® Elite pattern.
Time to Peak Flow	Time from flow onset to peak flow.	About 30 percent of voiding time. Has no clinical significance with irregular flow pattern.

#### Measurements Related to FloPoint® Elite Curve Patterns

Time to peak flow rate, flow time and voiding time do not provide the same quantitative "normal" versus "abnormal" results as do flow rates. However, as discussed in the next section, these measurements can provide useful indications of the FloPoint Elite curve's shape.

#### Continuous/Regular Patterns:

 Normal: A normal FloPoint Elite pattern is a smooth unbroken, bell-shaped curve with peak flow occurring relatively early. (Time to peak flow averages about 30% of total flow time.) Figure 34 shows an example of a normal uroflow curve.

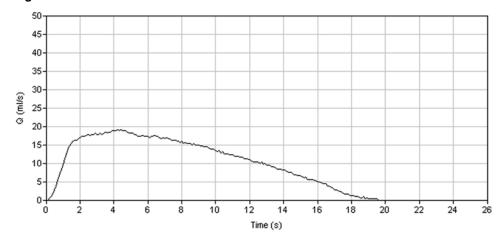


Figure 34. Normal Uroflow Curve

• Superflow: Figure 35 shows an example of a "superflow" pattern. This pattern is characterized by a very high flow rate - usually greater 40 ml/sec. - and a very short flow time. A superflow pattern is usually seen in females. It

suggests decreased outlet resistance and/or detrusor instability, hence may be associated with urinary incontinence.  $^{2,\,6}$ 

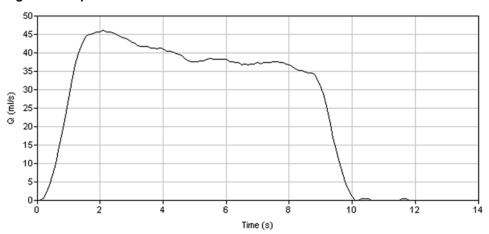
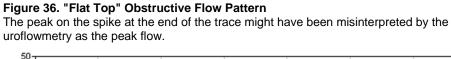
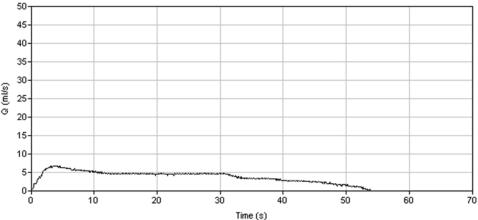


Figure 35. Superflow Pattern

# Obstructive:

Patterns suggestive of bladder outlet obstruction (BOO) are characterized by a prolonged flow time during which a large part of the total voided volume is voided at a constant low flow rate. Figure 36 and Figure 37 show examples of "obstructive" flow patterns.





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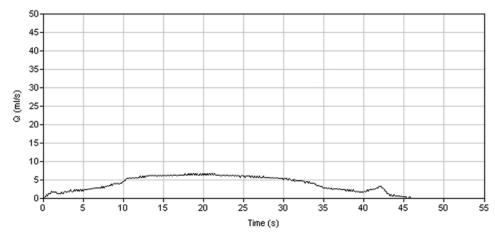


Figure 37. Rounded Top Obstructive Flow Pattern

#### **Irregular Patterns**

With the exception of an occasional terminal spurt (e.g., Figure 36) or one or two secondary voids in a normal man, irregular flow patterns are always either abnormal or artifactual. There are two types of irregular flow patterns: a "fluctuating" flow pattern, in which the repeated downward deflections do not fall below a measurable flow rate, and an "intermittent" flow pattern characterized by the occurrence of interruptions of varying durations between voiding episodes. Figure 38 shows an example of a fluctuating flow pattern caused by abdominal straining: Figure 39 shows an example of an intermittent flow pattern caused by detrusor-sphincter dyssynergia.

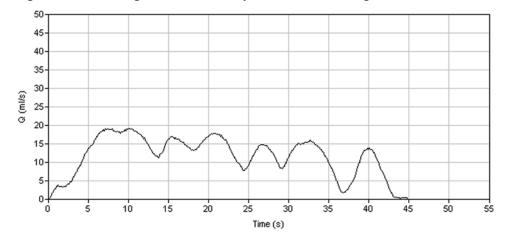


Figure 38. Fluctuating Pattern Caused by Abdominal Straining

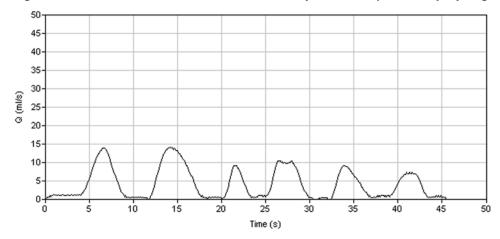


Figure 39. Abnormal Intermittent Pattern, Caused By Detrusor Sphincter Dyssynergia

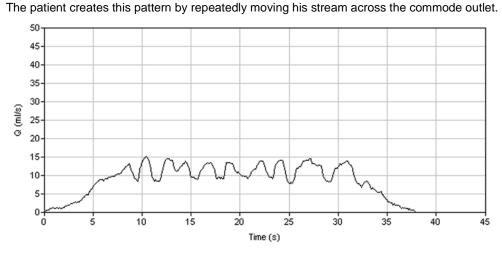
### **Clinical Significance**

Whether an irregular uroflow pattern or urethral sphincter relaxation are lost causing the detrusor to push intermittently against a contracted urethral sphincter, irregular traces can also be caused by fluctuating or poorly sustained detrusor contractions, which are generally seen in patients with a neurological abnormality – most commonly multiple sclerosis.<sup>1</sup>

#### **Artifactual Causes**

As discussed previously, irregular traces can be caused by a male patient moving his stream across to the collecting funnel ("cruising") or intermittently squeezing the tip of the penis or foreskin during voiding.¹ Figure 40 and Figure 41 show examples of these two types of artifactual irregular patterns. Anxiety, as might be caused by the unfamiliar laboratory environment, can also cause an irregular trace in normals.

Figure 40. Artificial Fluctuating Pattern



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50 45 40-35 30 Q (ml/s) 25 20 15 10 30 35 10 15 20 25

Figure 41. Artificial "Squeezing" Pattern

The patient creates this pattern by repeatedly obstructing urine flow by squeezing his foreskin or penis.

# Using Flow Time and Voiding Time to Help Identify the Curve Pattern

A long time to peak and a long flow time can help confirm a subjective impression of an "obstructive" flow pattern.

Time (s)

Comparing flow time with total voiding time provides a quantitative indication of an interrupted flow pattern's severity – the greater the difference between voiding and flow times, the more severe the interruption.

## **Summary of Diagnostic Significance**

Table 2 summarizes the diagnostic significance of abnormal FloPoint Elite test results.

**Table 2. Diagnostic Significance of FloPoint Elite Results** 

CURVE SHAPE		PEAK TIME TO MAXIMUM	VOID TIME	CONCLUSION	
Pattern	Shape	1.2011			
Continuous	Flat ("obstructive" pattern)	Low	Shortened (Peak flow may be difficult to identify.)	Prolonged	Outlet obstruction*
Continuous	Rounded ("obstructive" pattern)	Low	Variable	Normal	Detrusor under- activity
Continuous	High Peak short duration and ("superflow" pattern)	High	Shortened	Shortened	Detrusor instability and/or normal or reduced output resistance

CURVE SHAPE		PEAK FLOW	TIME TO MAXIMUM	VOID TIME	CONCLUSION
Pattern	Shape	FLOW	WAXIWOW		
Irregular**	Fluctuating	Variable	No significance	No significance	Voluntary abdominal straining.
					Detrusor- sphincter dyssynergia.
					Dysfunctional voiding
Irregular	Interrupted	Variable	No significance	No significance	Same as fluctuating pattern. Possibly a more severe condition.

<sup>\*</sup> In female, rule out stress urinary incontinence and lower urinary tract infection.

#### **Artifacts and Pitfalls**

Following are some events and conditions that can lead to misinterpretation of FloPoint Elite test results.

## "Spikes" or Rapid Fluctuations in the Curve

There are several potential causes of spikes in the FloPoint Elite curve that can lead to misinterpretation. The most common of these are: (1) mechanical disturbance of the flow sensor and, (2) straining either during (Figure 42) or at the end (Figure 38) of the void.

The most significant misinterpretation that can be caused by spikes is mistaken identification by an automatic processor of a spike peak as the void maximum.<sup>1,2,4,6</sup> Figure 42 shows examples of such a computer misinterpretation (solid arrow). In situations such as this, the clinician must override the computer's interpretation and read the maximum manually from a smooth portion of the uroflow trace (open arrow in Figure 42).

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<sup>\*\*</sup> In male, rule out "cruising", (variable stream direction) and intermittent squeezing of penis or foreskin.

Figure 42. Artifactual uroflow peak produced by a spike

The (black arrow) identifies an artifactual spike that the uroflowmetry reads as the flow peak. The correct peak flow (open arrow) must be read manually by the interpreter.

#### Low and High Voided Volumes

When total voided volumes are below 150 ml, "normal" flow rates become so low as to make the test an insensitive indicator of an abnormally low flow rate. At voided volumes of over 600 ml, the bladder may become decompensated, thereby producing an artifactually low flow rate. Therefore, it is important to avoid voided volumes below 150ml and above 600ml. If such volumes are encountered, the test should be repeated.

Time (s)

# **Test Technique**

Incorporating the following into the FloPoint Elite test procedure will materially enhance both the efficiency with which the test is done and the clinical utility of the test's results:

- 1. The void should be performed with a comfortably full bladder. To accomplish this, the patient should be instructed to drink approximately 2 pints of fluid two hours before appearing for his or her appointment and to not void prior to arriving at the clinic. Alternatively, the patient might be questioned about the fullness of his bladder upon arriving for his appointment and instructed to drink water immediately if the bladder is empty. As noted above, voids of more than 600 ml or less than 150 ml should be repeated as the patient's bladder has refilled.
- 2. Instruct the patient to void in a position that he or she is most used to (usually standing for a male, sitting for a female).
- 3. A male should be instructed to direct the stream to the location marked on the funnel and to maintain constant stream direction throughout the void.

## **Reimbursement Information**

### **Physician Participation Requirement**

During the performance of FloPoint Elite uroflowmetry, "direct physician supervision" is required. This means that the physician must be present in the office suite (not necessarily in the room when the procedure is performed), and immediately available to furnish assistance and direction throughout the performance of the procedure.

#### **Procedure Codes**

There are only two procedure codes to use for the performance of FloPoint® Elite uroflowmetry:

51736: Simple uroflowmetry (uroflowmetry performed by the use of stop-watch flow rate or a mechanical Uroflow System).

51741: Complex uroflowmetry (uroflowmetry performed using calibrated electronic equipment).

#### **Diagnosis Codes**

Table 3 lists diagnosis codes that can be entered into a claim for FloPoint Elite uroflowmetry reimbursement. Diagnosis codes for uroflowmetry that are acceptable to regional reimbursement bodies differ by region. Therefore, specific regions may not authorize uroflowmetry reimbursement for all listed diagnosis.

Table 3. Diagnosis Codes Used with FloPoint® Elite

DIAGNOSIS	CODE
Equina syndrome with neurogenic bladder	344.61
Atony of Bladder	596.4

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DIAGNOSIS	CODE
Bladder Neck Obstruction (acquired)	596.0
Hypertonicity of bladder	596.51
Low bladder compliance	596.52
Paralysis of bladder	596.53
Neurogenic bladder NOS	596.54
Detrusor sphincter dyssynergia	596.55
Other functional bladder disorder	596.59
Urethral stricture due to unspecified infection	598.00
Traumatic urethral stricture	598.1
Postoperative urethral stricture	598.2
Other specified causes of urethral stricture	598.8
Urethral stricture, unspecified	598.9
Hypertrophy of prostate (BPH)	600.0
Retention of urine, unspecified	788.20
Incomplete bladder emptying	788.21
Other unspecified retention of urine	788.29
Urinary incontinence, unspecified	788.30
Urge incontinence	788.31
Stress incontinence, male	788.32
Mixed incontinence	788.33
Incontinence w/o sensory awareness	788.34
Post-void dribbling	788.35
Nocturnal enuresis	788.36
Continuous leakage	788.37
Other urinary incontinence	788.39
Urinary frequency (micturition)	788.41
Polyuria	788.42
Nocturia	788.43
Splitting of urinary stream (intermittent)	788.61
Slowing of urinary stream (weak)	788.62

## **REFERENCES**

- 1. Abrams, P., Uroflowmetry, <u>Urodynamics</u>, 22nd ed. London, Springer-Verlag, 1997, pages 20-39.
- 2. Boone T.B. and Y. H. Kim, Chapter 4, Uroflowmetry, in Nitti, V. D. (ed), <u>Practical</u> Urodynamics, Philadelphia, W. B. Saunders, 1998, pages 28-37.
- 3. Chapple, C.A. and S. A. MacDiarmid, <u>Urodynamics Made Easy</u>, Chapter 3 Urodynamic Techniques: Flow Rate, New York, W.B. Saunders, 2000, pages 26-32.
- 4. Grino, P., B., et al, Maximum urinary flow rate by uroflowmetry: automatic or visual interpretation, J. Urol, 149, 339-341, 1993.
- 5. McLoughlin, J., et al, Symptoms versus flow rates versus urodynamics in the selection of patients for prostatectomy, <u>Brit. J. Urol.</u> 66, 303-305, 1990.
- 6. Rivas, D. A. and M. B. Chancellor, Chapter, 5, Uroflowmetry, in Blaivis, J., and M. Chancellor, (eds.), <u>Atlas of Urodynamics</u>, Baltimore, Williams & Wilkins, 1996.
- 7. Sand, P. K. and D. R. Ostergard, <u>Urodynamics and the Evaluation of Female Incontinence</u>, A <u>Practical Guide</u>, Chapter 3, Uroflowmetry in the Female, London, Springer-Verlag, 1995.

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# **Parts and Accessories**

# FloPoint® Elite Uroflow System Components

The following components are included with your FloPoint® Elite Uroflow System with ScanPoint® with QuickPrint system.

# **Part and Part Number**

# Name and Description



### **FloSensor**

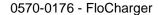
Measures urine volume and flow rate. The handles suspend the FloSensor inside the toilet.

0570-0175 - FloSensor



## FloCharger with Clamshell

Stores the FloSensor, recharges the batteries, and resets the measuring device to zero.





# FloPoint Elite Mounting Bracket

Attaches to the wall, securely holding the FloCharger and box of funnels 3 feet (0.914 m) or more above the floor.

0800-0337

# **Part and Part Number**

# **Name and Description**



#### ScanPoint® Remote

Acts as a remote control to start and stop the FloSensor, displays information on flow measurements and device status, and records voice annotation.

0570-0174



# **ScanPoint Docking Station:**

Transmits data from the ScanPoint Remote to the ScanPoint host computer and recharges the Remote batteries.

0570-0168

To order any of the above parts, contact your authorized Verathon Medical Sales Representative or contact the Verathon Medical Customer Care Department at 1.800.331.2313.

# **FloPoint Elite Uroflow System Accessories**

The following accessories are included with your FloPoint Elite Uroflow System with ScanPoint with QuickPrint system.

## Part and Part Number

## **Name and Description**



## ScanPoint with QuickPrint Installation CD

Produces reports based on the data gathered during an exam and submitted by the ScanPoint Remote.

0900-1238



#### FloPoint Elite In-Service CD

Includes FloPoint Elite User's Manual and Quick Reference Cards.

0900-1445

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# **Part and Part Number**

# **Name and Description**



## **Box of Paper Funnels**

Help direct the urine flow toward the FloSensor.

Box contains 40 funnels.

0800-0297



#### **Activation Tool**

Use to press the Reset button on the ScanPoint® Remote if the Remote needs to be reactivated.

0130-0181



# Lanyard

Attaches to the ScanPoint Remote, if desired, to assist with placement of the Remote in proximity to the FloSensor

0264-0008



FloPoint Elite Setup and Use Quick Reference Card

Provides a summary of essential operator instructions.

0900-1443



## **FloPoint Elite Calibration Quick Reference**

Provides instructions for the FloPoint Elite calibration procedure.

0900-1444

## **Part and Part Number**

## **Name and Description**



FloPoint Elite Mounting Bracket Template
Aids in attaching the Mounting Bracket to the wall.

0900-1557

To order any of the above parts, contact your authorized Verathon Medical Sales Representative or contact the Verathon Medical Customer Care Department at 1.800.331.2313.

## Other FloPoint Elite Uroflow System Accessories

The following accessories are not included with your FloPoint Elite Uroflow System with ScanPoint® with QuickPrint system.

#### **Part and Part Number**

## Name and Description



## **Calibration Fluid Pouches**

Pouch containing unique fluid for use in calibrating the FloPoint Elite. The Calibration Fluid Pouches are shipped with the Calibration Kit.

0800-0331

#### ScanPoint Label Writer and Related Components



ScanPoint Label Writer (optional)
Prints exam results.

0570-0178

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## **Part and Part Number**

## **Name and Description**



#### **USB Cable**

Connects the ScanPoint® Label Writer to the ScanPoint host computer.

0600-0233



## **Switching Power Adapter**

Connects the Label Writer to the wall outlet.

0275-0002



#### Roll of Labels

Labels in roll format properly sized for the ScanPoint Label Writer.

0125-0446



#### **Power Cord**

Connects the FloCharger to the wall outlet to charge the FloSensor battery.

0600-0232

To order any of the above parts, contact your authorized Verathon Medical Sales Representative or contact the Verathon Medical Customer Care Department at 1.800.331.2313.

## **Specifications**

## **Symbol Directory**

The following table illustrates and explains the symbols that may appear on the FloPoint Elite Uroflow System components and/or packaging. These symbols indicate the FloPoint Elite system compliance with international and national standards and regulations.

#### **Symbol**

#### Meaning



Underwriters Laboratories mark of certification of the FloPoint Elite uroflow system (which consists of the FloSensor, the FloCharger with Clamshell, the FloPoint Elite Mounting Bracket, the ScanPoint Remote and the ScanPoint Docking Station) with respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA 22.1 No. 601.1. System configuration with accessory Model No.0570-0178 (ScanPoint Label Writer) was not part of the UL investigation. Accessory equipment connected to the analog and digital interfaces must be in compliance with the nationally harmonized IEC standards (i.e. IEC 60950 for data processing equipment, IEC 60065 for video equipment, IEC 61010-1 for laboratory equipment, and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible for ensuring the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, please consult the technical services department or your local representative.



IEC 348 symbol indicating "Attention: consult accompanying documentation."



Marked in accordance with Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) (solid bar indicates product was put on the market after 13 August 2005).



Class II equipment protected throughout by double insulation or reinforced insulation.



Type BF applied part with EN/IEC-60601-1.

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Symbol	Meaning
CE	CE marked in accordance with the Medical Device Directive (MDD).
C Us	Canadian Standards Association (CSA) mark of certification to United States standards for electromedical equipment.
+35C	Ambient temperature range for Storage Conditions (-10 to +35 $^{0}$ C)
	Atmospheric pressure range for Storage Conditions (50 to 106 kPa)
0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 /	Relative Humidity for Storage Conditions (20 to 95%)

## **Standards and Regulations Compliance**

Verathon® certifies that all units are in compliance with all applicable international and national standards and regulations, including but not limited to the following:

Specification	Standard	
Electromagnetic compatibility standards	IEC 60601-2, ICES-001	
Safety Standard	IEC 60601-1	
Health Insurance Portability and Accountability Act (HIPAA)*		

<sup>\*</sup>For details on Verathon compliance with privacy rules, please refer to the information in the QuickPrint Help menu (select "Privacy Agreement").

#### **Electromagnetic Effects**

There are no restrictions on the use of FloPoint Elite Uroflow System due to its electromagnetic characteristics. Both the emissions from FloPoint Elite and the susceptibility of this instrument to interference from other sources are within prescribed limits of all applicable standards at the date of manufacture. The emissions test procedure that was used is specified in EN/IEC55011: 1991 for Group 1, Class A equipment (per EN/IEC60601-1-2, 36.201.1.7).

Verathon declares that this FloPoint® Elite uroflow system is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. The declaration of conformity may be consulted at www.verathon.com/FloPoint\_Elite.htm.

This ISM device complies with Canadian ICES-001. Cet appareil ISM est conforme à la norme NMB-001 du Canada.

**NOTE:** This equipment 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. This equipment 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 this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off 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.

Modifications to this equipment not expressly approved by Verathon® could void the user's authority to operate the equipment

FloPoint Elite Uroflow System is suitable for use in industrial, scientific, and medical (ISM) environments, and in domestic environments under the jurisdiction of a health care professional. An indication of adverse electromagnetic effects from FloPoint Elite Uroflow System on another electronic device would be a degradation of performance in the other device when the devices are operated simultaneously. If such interference is suspected, separate the two devices as much as possible, or discontinue simultaneous operation, if practical, and contact Verathon.

The FloPoint Elite Uroflow System will operate normally in the proximity of other potential interference sources, and has demonstrated immunity at a field strength of 3 V/m (per EN/IEC 60601-1-2, 36.202.2.1). You do not need to take any other precautions regarding exposure in reasonably foreseeable environmental conditions to magnetic fields, pressure, or variations in pressure, acceleration, or thermal ignition sources.

#### **Health Insurance Portability and Accountability Act**

To address the growing concern about the protection and confidentiality of an individual's medical information, Verathon has taken the following measures to ensure the safe delivery and storage of all information that is maintained, used, and presented by the ScanPoint system:

- All ScanPoint system communications across the Internet are transmitted using the Secure Socket Layer (SSL) protocol and the 128-bit Data Encryption Standard (DES).
- All Patient Health Information (PHI) specific data stored within the ScanPoint database is encrypted.
- The ScanPoint Web site infrastructure is housed by a Tier-1 Network Service Provider (NSP) that meets the SAS/70 certification.

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- Within the NSP, the ScanPoint equipment is located in a "locked, steel cage" structure, removing access from even the NSP's personnel.
- Verathon has enacted all policies and procedures outlined in HIPAA to protect our internal network from unauthorized access.

Verathon has taken these actions to meet HIPAA's Privacy and Security requirements and shall continue to monitor any changes in these laws to insure all precautions are taken to protect PHI. For further information on how Verathon manages access to PHI, refer to the Verathon Business Associate Agreement (0003-0138).

## **FloCharger**

Item	Specification
Input Voltage	100 – 240 V AC RMS
Input Frequency	47 – 63 Hz
Input current	0.8 A max
Input connection	Employs direct plug-in AC prongs for wall outlets.
Insulation	Class II with double insulation to each terminal.
Testing	To EN/EN/IEC 60601-1 requirements
Water Ingress	Rated at IPX0 (not protected against ingress of water)
Compliance	UL and CSA equivalent standards

## **FloSensor**

Item	Specification
Sensory Type	Spinning Disk
Battery type	Lithium Ion. 14.4 V, 2200 mAh
Battery life	A fully charged battery can perform approximately 30 exams within a 24-hour period.
Charging Method	Charge the FloSensor using the FloCharger installed on the Mounting Bracket.
Charging Time	No more than six hours from an empty battery to a full charge.
Water Ingress	Rated at IPX7 (Water tight for 30 minutes at a depth of 1 m)

## ScanPoint® Remote

Item	Specification
Battery type	Lithium Ion. 4.2 V, 700 mAh
Battery life	A fully charged battery can perform approximately 30 exams within a 24-hour period.
Charging Method	Charge the FloSensor using the ScanPoint® Docking Station connected to the USB port of a computer compliant with IEC 60950 or IEC 60601-1.
Charging Time	No more than eight hours from an empty battery to a full charge.
Water Ingress	Rated at IPX0 (not protected against ingress of water)

## **ScanPoint Docking Station**

Condition	Specification
Use	Indoor
Water Ingress	Rated at IPX0 (not protected against ingress of water)
Computer Regulatory Compliance	The computer must minimally comply with the requirements of IEC 60950 and preferable with the requirements of IEC 60601-1.
Computer Connection	USB 1.1
Design	Decoupled transformer at 200 mA at 4.2 V (25 kHz)
Water Ingress	IPX0

## **Accuracy Specifications**

The accuracy specifications assume the instrument is being used according to the instructions provided by  ${\sf Verathon}^{\tiny{\textcircled{\tiny 0}}}.$ 

Specification	Description
Flow rate measurement	$\pm$ 3% $\pm$ 1 ml/s (as measured by Verathon accuracy measurement test)

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Specification	Description
Volume measurement	$\pm$ 5% $\pm$ 5 ml/s (as measured by Verathon accuracy measurement test)
Maximum Flow Rate	50 ml/s
Maximum volume measure	2 liters

## **Operating Conditions**

All components of the FloPoint Elite Uroflow System are designed to function properly within the following specifications:

Condition	Value
Use	Indoor
Ambient Temperature Range	+10 - +35° Celsius (50 - 95° Fahrenheit)
Atmospheric pressure range	70 kPa - 106 kPa
Relative humidity	30% - 75% non-condensing

## **Storage Conditions**

All components of the FloPoint Elite Uroflow System are designed to withstand the following storage conditions:

Condition	Description
Storage	Indoor
Ambient Temperature Range	-10 - +35° Celsius (14 - 95° Fahrenheit)
Atmospheric pressure range	50 kPa - 106 kPa
Relative humidity	20% - 95% non-condensing

## **Radio Specifications**

The FloSensor and ScanPoint® Remote communicate via a radio frequency that operates in the 2.4 GHz ISM (Industrial, Scientific, Medical) band with a range of 3 meters (10 feet). FloPoint Elite Equipment complies with the specifications contained in FCC Part 15.

Parameter Description	Condition	Value
RF Frequency Range		2.402 - 2.479 GHz
Range		Up to 3 meters (10 feet)

## **Computer Hardware and Software Requirements**

To use ScanPoint with QuickPrint, your computer must meet the following hardware and software requirements:

**NOTE:** ScanPoint® with QuickPrint works only with Microsoft® Internet Explorer® 6.0 or later.

ScanPoint with QuickPrint is not compatible with Apple® Macintosh® computers.

Requirement	Minimum	Recommended
Processor	PC with 800 MHz processor	PC with 2.0 GHz processor
Video display	Video card and monitor capable of 800 x 600 resolution.	Video card and monitor capable of 1024 x 768 resolution.
USB Ports*	Two USB 1.1 ports	Two USB 2.0 ports*
Hard drive	200 Mb of available space	5 Gb of available space
Memory	512 Mb	1024 Mb
Internet access	256k DSL	512k DSL, cable modem, T1 line or other high-speed connection

<sup>\*</sup>Two ports are needed if both the ScanPoint Docking Station and the Label Writer will be used.

## **Operating System and Software Requirements**

Requirement	Minimum	Recommended
Operating system	Microsoft Windows 2000 Professional with Service Pack 2	Microsoft Windows 2000 Professional with Service Pack 4 or Windows XP with the latest service pack.
Browser	Microsoft Internet Explorer version 6.0	Microsoft Internet Explorer version 7.0

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Requirement	Minimum	Recommended	
Microsoft .NET Framework	.NET® Framework version 2.0 (This software is installed with ScanPoint with QuickPrint.)	.NET Framework version 2.0 with the latest Microsoft® updates installed.	
Adobe® Acrobat Reader®	Adobe Acrobat Reader 6.0	Adobe Acrobat Reader 7.0*	

<sup>\*</sup>Available for free download from www.adobe.com.

**NOTE:** For ScanPoint with QuickPrint to function properly, Microsoft Internet Explorer 6.0 or later must be installed. ScanPoint will not function with any other browsers such as Netscape® and Firefox. ScanPoint QuickPrint is **not compatible** with Microsoft Windows Vista.

## **Label Writer Specifications**

The ScanPoint® Label Writer meets the following specifications:

Condition	Description
Print method	Direct thermal
Print resolution	300 dots per inch (118 dots per mm)
Maximum print width	2.25" / 56 mm
Maximum media width	2.44" / 62 mm
Interface	USB 2.0 full speed printer class device
Average print head life	2,000,000 linear inches (over 31 miles) / 50,800 linear meters
Printer power requirements	24 VDC 1.75 A
Regulatory approvals	CSA, FCC, UL

**NOTE:** System configuration with accessory Model No.0570-0178 (ScanPoint Label Writer) was not part of the UL investigation. Accessory equipment connected to the analog and digital interfaces must be in compliance with the nationally harmonized IEC standards (i.e. IEC 60950 for data processing equipment, IEC 60065 for video equipment, IEC 61010-1 for laboratory equipment, and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible for ensuring the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, please consult the technical services department or your local representative.

# **Mounting Bracket and Related Equipment Specifications**

Mounting Bracket	Description
Mounting bracket material	16 guage 304 stainless steel
Weight (mounting bracket alone)	6.5 lb (2.95 kg)
Weight (mounting bracket plus funnels, charger, and sensor	13 lb (5.9 kg)

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# Glossary

Term	Meaning
Activate	When the ScanPoint® Remote battery has been completely discharged, you may need to activate, or reset, the Remote before you can use it again. The Remote can be reactivated by pressing the recessed Reset button on the back of the unit using the supplied Activation Tool.
Activation Tool	The small tool used to depress the Reset button on the back of the Remote (see "Activate" above).
Annotation	A brief voice recording made on the ScanPoint Remote providing exam details.
Average Flow	The average flow rate during flow intervals measured in ml/s. This calculation does not include the time between intervals.
Calibration	Checking the accuracy and function of your FloPoint Elite by comparing it with a known standard.
ScanPoint Docking Station	The unit that transmits exam data from the Remote to the ScanPoint host computer, and when the computer is turned on, also charges the Remote battery.
Continuous (Pattern)	There was one flow interval detected during the exam.
Detailed Report	This report contains all ICS values and prints on two labels or a single sheet of 8.5 x 11" paper. It contains: the date and time of the exam, patient ID, patient name, operator ID, physician, gender, position and indicator for whether or not this was a normal flow for the patient, peak flow measurement, average flow measurement, voided volume, flow time measurement, void time measurement, pattern measurement, chart of flow rate vs. time, chart of cumulative volume vs. time, part number and serial number of the FloSensor, and the ScanPoint exam ID. See also Summary Report.
FloCharger	The FloPoint Elite base unit that provides a storage and transportation unit for the FloSensor and also recharges the FloSensor batteries.
FloSensor	The central component of the FloPoint Elite system, it contains a rotating disc for measuring urinary flow rate and volume

Term	Meaning
Flow Interval Ends	The end of a flow interval is identified by two consecutive samples with a flow rate less that 0.2 ml/s.
Flow Interval Starts	The start of a flow interval is identified by two consecutive samples with a flow rate greater than 0.5 ml/s. The actual start of the interval is selected to be the sample prior to the identifying samples where the flow rate is at least 0.2 ml/s.
Flow Time	The total amount of time in seconds during which flow is being measured. In the case of intermittent flow, this value will be smaller than the Void Time as this value does not include the time between intervals where there is no flow.
HIPAA	Health Insurance Portability and Accountability Act, enacted by the US Congress in 1996.
	Title II of HIPAA, the Administrative Simplification provisions (AS), requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. The AS provisions also address the security and privacy of health data. The standards are meant to improve the efficiency and effectiveness of the nation's health care system by encouraging the widespread use of electronic data interchange in the U. S. health care system.
ICS	International Continence Society. An international association of medical professionals whose purpose is to study storage and voiding function of the lower urinary tract, its diagnosis and the management of lower urinary tract dysfunction, and to encourage research into pathophysiology, diagnostic techniques and treatment.
Intermittent (Pattern)	There were two or more flow intervals detected during the exam (see also Continuous and Undetermined).
LCD screen	The LCD (liquid crystal display) screen on the ScanPoint® Remote that displays flow measurements, instrument status, and other exam settings and information.
New Flow Interval Starts	A new flow interval is identified by a Flow Interval Start that is at least 0.25 seconds after the previous Flow Interval End.
Peak Flow	Peak flow rate measured in ml/s. The value of the peak flow detected by the FloSensor (see also Average Flow).
QuickPrint	The program that process exams and prints the results.

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Term	Meaning
ScanPoint® Remote	The remote control unit that receives exam data from the FloSensor via radio contact and transmits the exam data to the ScanPoint host computer via ScanPoint Remote Docking Station.
ScanPoint Image Management Technology	The software and online service provided by Verathon® that prints exam results, maintains patient records, displays flow diagrams from exams, downloads software updates, and calibrates the FloPoint Elite.
ScanPoint with QuickPrint	ScanPoint with QuickPrint is a software program installed on your computer that communicates with ScanPoint Online to help you quickly and easily download and print FloPoint Elite measurements.
Sleep mode	When the FloSensor and/or ScanPoint Remote shuts down to conserve energy. Press the ScanPoint Remote button to "wake up" the device.
Summary Report	Provides only peak flow measurement and prints on a single label or a single sheet of 8.5 x 11" paper. The Summary Report contains the date and time of the exam, patient ID, patient name, operator ID, physician, gender, position and indicator for whether or not this was a normal flow for the patient, peak flow measurement, chart of flow rate vs. time, part number and serial number of the FloSensor, and the ScanPoint exam ID. See also Detailed Report.
Time to Peak Flow	The amount of time, measured in seconds, between the start of the first interval of flow to the maximum measured flow rate.
Undetermined (Pattern)	There were no flow intervals detected in the exam (see also Continuous and Intermittent).
Void Time	The total amount of time in seconds from the start of the first interval to the end of the last interval, including all the time between intervals where flow is not measured.
Voided Volume	The total volume of urine measured by the FloSensor in ml.

