INTERSON

We revolutionize imaging devices

ViewBladder 10

Assessing Bladder Volume

User Guide

Equipment Manufacturer
Interson Corporation
7026 Koll Center Parkway, Suite 201
Pleasanton, CA 94566 USA
Phone: 925.462.4948
Fax: 925.462.4833
Email: support@interson.com
Website: www.interson.com

EC Representative EC REP
MediTech
Maastrichterlaan 127
NL-6291 EN Vaals
Netherlands
Phone: +31.43.306.3320
Fax: +31.43.306.3338

CE 0197

This user guide is applicable to but not limited to the following probes:

3.5 MHz General Purpose (GP/AB)

Table of Contents

1. Introduction

Congratulations on your purchase of the ViewBladder 10, the tablet based ultrasound imaging system to easily assess bladder volume. Please review this user guide before you begin scanning. Contact Interson or your sales representative if you have any questions.
Note: There is also an embedded Help Guide in the ViewBladder 10 software, as well as context-sensitive video help.

The sale of this item is subject to regulation by the U.S. Food and Drug Administration and state and local regulatory agencies.

2. Minimum System Requirements

- Computer Operating System: Windows 7
- Minimum processor: 1.5 GHz
- Minimum RAM: 2 GB RAM
- USB 2.0 port

3. Warnings, Safety Information

3.1. Meaning of Signal Words

In this User's Manual, the signal words "Warning" and "Caution" are used regarding safety and important instructions. All users of the ViewBladder 10 Probe System must understand the meanings of these signal words. These signal words and their meanings are as follows

Signal Word	Meaning
 **WARNING**	Indicates a potentially hazardous situation which, if not avoided, could cause injury or harm to the equipment.
 **CAUTION**	Indicates a potentially hazardous situation which, if not avoided, may result in minor injury or harm to the equipment.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in property damage.
	Type BF Equipment

3.2 Meaning of Safety Symbols

	"Attention", refer to User's Manual
	"Consult Instructions for Use"

3.3. General Cautions and Warnings

CAUTION

Probes must be cleaned after each use. Cleaning the probe is an essential step prior to effective disinfection. Follow the manufacturer's instructions when using disinfectants.

WARNING

Do not allow sharp objects, such as scalpels or cauterizing knives, to touch probes or cable.

WARNING

Equipment not suitable for use in the presence of flammable mixtures.

WARNING

If the probe is used with other devices, current leakage may increase and electric shock may be caused. It is the user's responsibility to ensure safety when the probe is to be used with other devices. If safety cannot be ensured, use of the probe with other devices is not allowed.

WARNING

The use of a "Non-Medical" grade AC Adapter could potentially cause harm to the system, the probe, the operator and/or the patient.

3.4. Operator Qualifications

The medical professional operating the ViewBladder 10 system must have a general knowledge of the use of ultrasound imaging devices and imaging protocols.

Connect the probe to the USB port prior to turning on the tablet.

Do not use in the presence of flammable anesthetics or other flammable materials.

Interson probes use very low acoustic power output, and ultrasound imaging has been found, in many studies, to be safe when used correctly. However, as with all medical procedures, risks and benefits must be weighed. It is important to use the lowest power settings and the shortest scan times possible while attaining the needed clinical information.

3.5. Care and Handling of Probes

Although Interson probes are very durable, reasonable care must be taken to avoid damaging them. Handle the membrane on the tip of the probe and the cable attachment at the other end of the probe with care. Keep the probe membrane away from sharp objects to avoid damage. Clean and store the probe in a manner to protect the membrane. Do not put stress on or use the cable to carry the probe, as this may damage the probe and /or the cable. Your probe should give you many years of reliable service if these simple precautions are followed.

3.5.1. Cleaning and Disinfection

WARNING

Always disconnect the ultrasound probe from the host computer system before performing maintenance or cleaning. Always follow the manufacturer's instructions when cleaning and disinfecting probes and biopsy guide adapters. Do not use a surgeon's brush when cleaning probes. The use of even soft brushes can damage the probe.

3.5.1.1 Probe Cleaning

1. Wear protective gloves when performing the cleaning process.
2. Disconnect the probe from the system.
3. Remove any sheaths, biopsy guide adapters, and biopsy needle guides.
4. Discard sheaths (sheaths are a single-use item) in a biohazard container.
5. Use a soft cloth lightly dampened in a mild soap or compatible cleaning solution to remove any particulate matter or body fluids that remain on the probe or cable.
6. To remove remaining particulates, rinse with water up to probe's USB cable connection.
7. Wipe with a dry cloth; or wipe with a water-dampened cloth to remove soap residue, and then wipe with a dry cloth.

3.5.1.2 Probe Disinfecting

A 10-6 reduction in pathogens should be reached following the disinfecting procedures in this manual and using the following recommended solutions. The following disinfectants are recommended because of both biological effectiveness (as qualified through the FDA 510(k) process) and their compatibility with Interson ultrasound product materials.

Solutions	Country	Type	Active ingredient	FDA 510(k)
Cidex®	USA	Liquid	Gluteraldehyde	K934434
Cidex Plus®	USA	Liquid	Gluteraldehyde	K923744

1. Wear protective gloves when performing the disinfecting procedure.
2. Check the expiration date on the solution that is being used. Use only solutions that are within the expiration date.

WARNING

The type of tissue it will contact during use dictates the level of disinfection required for a device. Ensure that the solution strength and duration of contact are appropriate for disinfection. Be sure to follow the manufacturer's instructions.

WARNING

Using a non-recommended disinfection solution, incorrect solution strength, or immersing a probe deeper or for a period longer than recommended can damage or discolor the probe and will void the probe warranty.

WARNING

Do not immerse probes longer than one hour. Probes may be damaged by longer immersion.

WARNING

Disinfect probes using only liquid solutions. Using autoclave, gas (EtO), or other non-Interson-approved methods will damage the probe and void the warranty.

1. Mix the disinfection solution compatible with the probe according to label instructions for solution strength. A disinfectant qualified by the FDA 510(k) process is recommended.
2. Immerse the probe into the disinfection solution per the manufacturer's recommendations of duration.
3. Follow the instructions on the disinfection label for the duration of probe immersion.
4. Using the instructions on the disinfectant or sterilization label, rinse the probe up to the point of immersion, and then air dry or towel dry with a clean cloth.
5. Examine the probe for damage such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the probe and contact a customer service representative.

3.6. Surface Cleaning

The tablet surface can be easily cleaned using a microfiber towel or other soft wipe. If needed, rubbing alcohol or another mild cleaner can be used, however never apply cleaner directly to the tablet surface. Dampen the microfiber towel with the cleaner. Do not saturate the towel.

3.7. Surface Disinfection

The tablet surface can be disinfected using the cleaners identified in 3.5.1.2 Probe Disinfecting. Do NOT immerse the tablet and never spray the disinfectant directly on the tablet surface. Spray a conservative amount onto a towel, being careful not to saturate the towel.

3.8. Acoustic Energy

The effects of acoustic energy on human tissue have been widely reviewed and are still under investigation. Therefore, it is recommended that diagnostic ultrasound output power be set to the lowest possible levels in accordance with the principle of ALARA (As Low As Reasonably Achievable). See section 6 of this manual for Acoustic measurements.

3.9. Electromagnetic Compatibility (EMC)

The Interson GP, EC & SP family of USB powered ultrasound probes have completed and passed EN 60601-1-2: 2007 standard.

3.10. Prescription Device Statement

CAUTION

US Federal law restricts this device to sale by or on the order of a physician.

3.11. Training

This ViewBladder 10 system is intended to be used by trained medical professionals only. The system's functions are described in this manual and are also available through the ViewBladder 10 system software Help Menu.

4. General

This user guide is for the Interson ViewBladder 10 system. Prior to using the system, become familiar with the operating instructions in this guide.

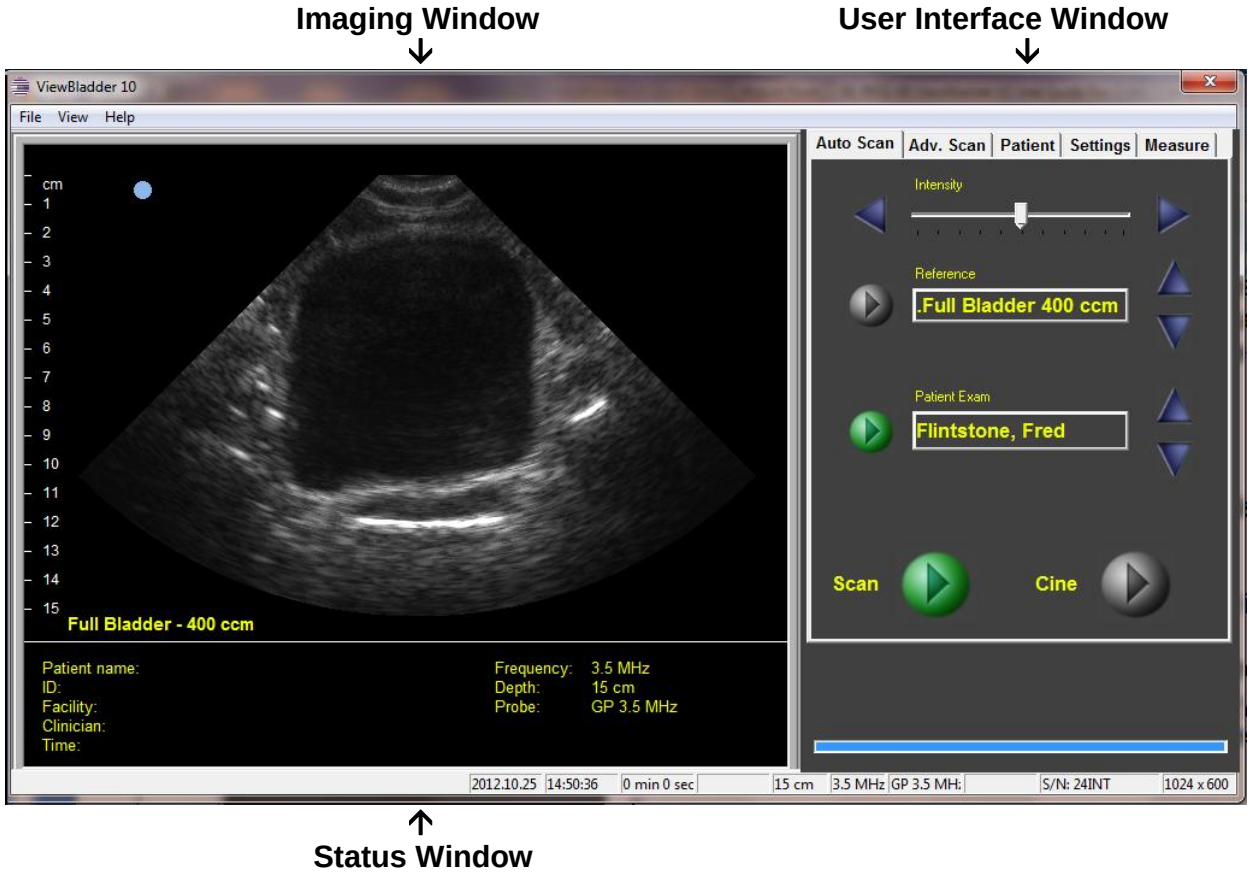
5. ViewBladder 10 Display

The ViewBladder 10 screen is divided into three major sections: Imaging Window, Status, Window, and User Interface Section.

On the upper left side is the Imaging Window**.** The Imaging Window displays the ultrasound scan, and includes measurements, calculations, and annotations. You can perform a bladder volume measurement by simply swiping the height and width on any frozen bladder image. Place your finger on the top edge of the bladder and swipe down to the bottom edge to measure the height. Similarly, place your finger on the left edge and swipe to the right edge to measure the width. The calculated volume is now displayed on the left of the screen.

Directly below the Imaging Window is the Status Window. If you have started a patient exam, the left hand column shows all of the details about the patient. The right hand column shows information about the probe and its settings.

On the right side of the screen is the User Interface Window. It contains a number of tabs to start patient exams, adjust the image, input patient and exam information, set preferences, and perform measurements and calculations. Each of these tabs and their functions are described in detail in this User Guide.



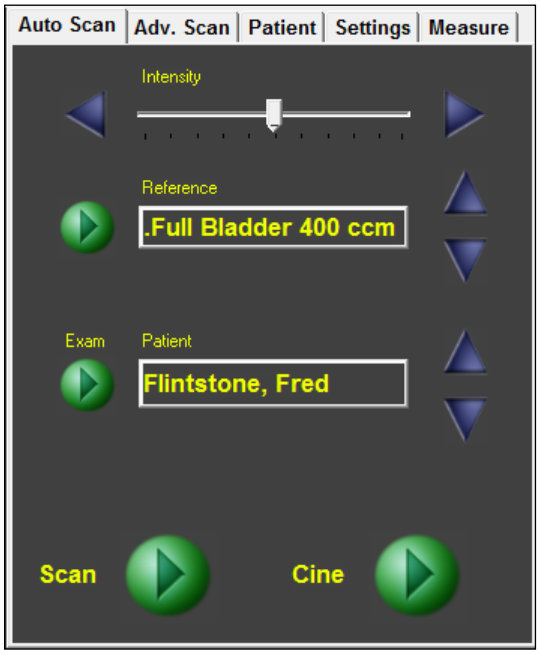
Note the blue dot on the upper left side of the image. This blue dot corresponds to the scan / freeze and image orientation button on the probe. The radiologist's convention is that the orientation mark on the image identifies the patient's right side or the patient's head. The image can be flipped and/or inverted in the ***Settings*** *tab.*

6. ViewBladder 10 User Controls

The User Interface Section on the right side of the screen contains five tabs: **Auto Scan, Adv. Scan, Patient, Settings,** and **Measure.** Each of these tabs has its own page in this user guide. Video help and embedded help are also available for each of these tabs. To access **Video Help**, select a tab and then use the **Help** pull down in the upper left corner of SeeMore and select **Video Help**. To access embedded help, select **Help** in the upper left corner of SeeMore and select **Help Topics**.

6.1. Auto Scan Tab

The **Auto Scan** tab is the default view. You may adjust intensity, select and display reference images, and start an exam for a specific patient.



Intensity adjusts the brightness of the image. It is typically best to leave the slider in the center of the range.

Reference images can be displayed using the green play button or the up and down blue arrows. By comparing your patient's bladder to one of the reference images you can easily asses the state of your patient to be full, empty or partial

The Patient Exam automatically collects and saves images, volume measurement data, and a single-page report.

The following steps will guide you through acquiring a Bladder Volume using three distance measurements. First you will acquire a transverse image of the bladder to measure the height and width of the bladder. Followed by a mid-sagittal scan to measure the thickness.

In the Measure tab you can select from either Bladder Volume 3D or Bladder Volume. Bladder Volume displays the volume using only the height and width from the transverse scan. If you are performing a two dimension Bladder Volume measurement, you will skip steps 7, 8, and 9.

1. From the Auto Scan tab, press on the up and down Patient Exam arrows to scroll through the Patient list to select a specific patient.
2. Press the green Patient Exam button to begin the exam. The button will change to yellow and then inactive grey while you are in the exam.
3. Follow the on-screen instructions to acquire the transverse image. Position the probe on the centerline of the patient's stomach just above the pubic bone with the probe's blue button pointed to the patient's right side. Start the scan by briefly pressing either the blue button on the probe or the large green Scan button on the screen.
4. Make minor adjustments to probe position to obtain the largest, most optimal bladder image.
5. Freeze the image by pressing the blue button on the probe or the yellow pause Scan button on the screen.

6. After freezing the image, measure the height of the displayed bladder by placing your finger on one edge of the bladder and swiping to the opposite side. Similarly measure the width. If you feel you did not optimally place your finger, double tap to remove the current measurement and then swipe your finger again.

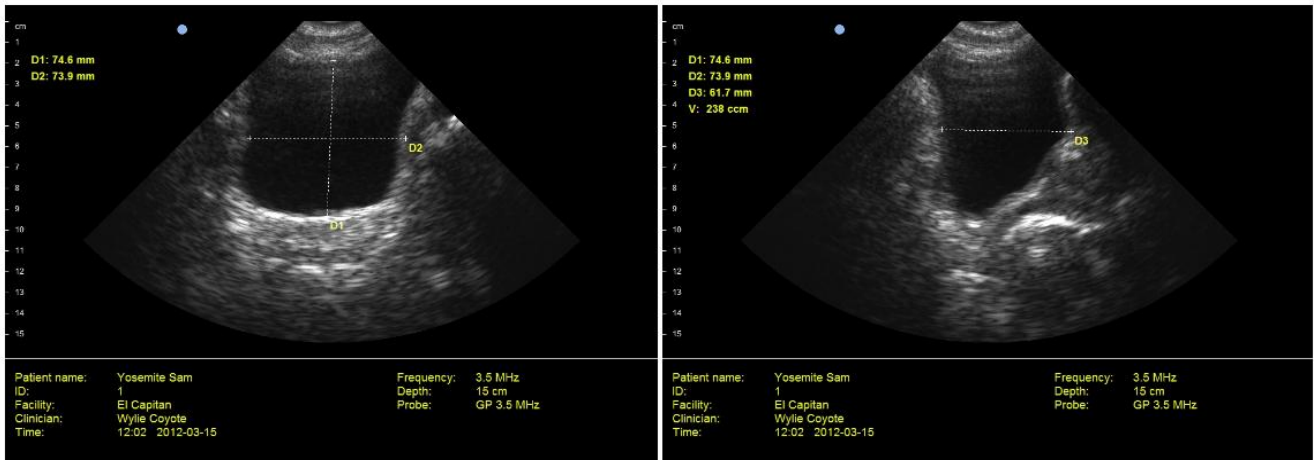
7. Follow the onscreen prompts, displayed in yellow beneath the patient exam box, to take the mid-sagittal scan. By rotating the probe 90 degrees you will be viewing the thickness of the bladder. Start the scan and then freeze when you have the optimal bladder image.

8. You should see a black ultrasound shadow on the right edge of the scan. This is the patient's pubic bone.

9. Measure the thickness of the bladder by placing your finger on the edge of the bladder and swiping to the opposite side. The mid-sagittal bladder image is often displayed at a slight angle, either up or down. Therefore to make the most accurate measurement, always measure the thickness at the appropriate angle.

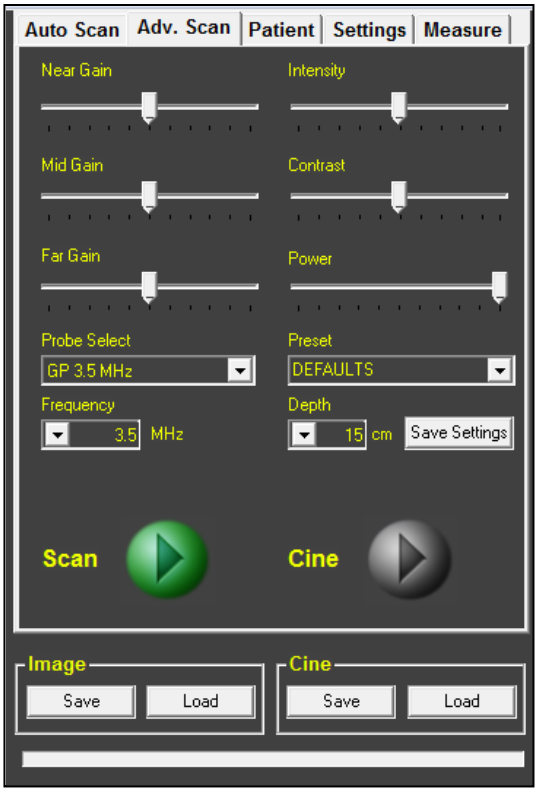
10. ViewBladder 10 will calculate and display the bladder volume. If you find you did not optimally place your finger, double tap to remove the volume calculation and the distance measurement. Repeat the distance measurement.

11. Press the yellow pause button near the Patient Exam box to end the patient exam and automatically generate and save the report.



6.2. Advanced Scan Tab

The **Adv. Scan** tab provides the complete ultrasound controls. This tab is typically only used if you are using ViewBladder 10 to analyze abdominal structures other than the bladder.



In the right hand column of sliders you can adjust the **Intensity** and **Contrast**. Typically you will leave these in the center. **Power** controls the probe's pulse power. Typically you will leave this at the maximum. If the displayed image is saturated, you may get a better image by lowering the pulse power.

In the left hand column of sliders you can adjust the three gains. The typical starting point is with all three gains in the center. **Near Gain** adjusts the first third of the image. **Mid Gain** adjusts the middle third, and **Far Gain** the last third. If the technique of starting with all gains in the middle doesn't seem to give you a good image, adjust all gains to the minimum (left), move pulse power to maximum (right) and intensity and contrast in the middle. Now raise the **Near Gain** until the first third of the image is just below saturation. Now, similarly, adjust **Mid Gain** and then the **Far Gain**.

Probe Select identifies all connected probes and enables you to select which probe you would like to use.

Preset enables you to select from an included preset of ultrasound parameters.

A specific preset contains: Intensity, Contrast, Near Gain, Mid Gain, Far Gain, Frequency, Depth, and Power. The list of available presets changes based on the probe that is selected. To save a new preset, type a new name over an existing preset name (no spaces allowed) and select **Save Settings**. To delete a preset, select the preset name and then press **delete** on the keyboard.

Frequency allows you to select from available pulse frequencies. Pulse frequencies are probe specific, and as such, different probes may have different pulse frequencies. As image resolution is better at higher frequencies, always use the highest pulse frequency that allows you to scan to your desired depth.

Depth changes the displayed depth range. Depth ranges are dependent on the probe selected and the selected pulse frequency.

Scan starts and stops the scan. The scan button on the probe and the keyboard's space bar will also start and stop the scan.

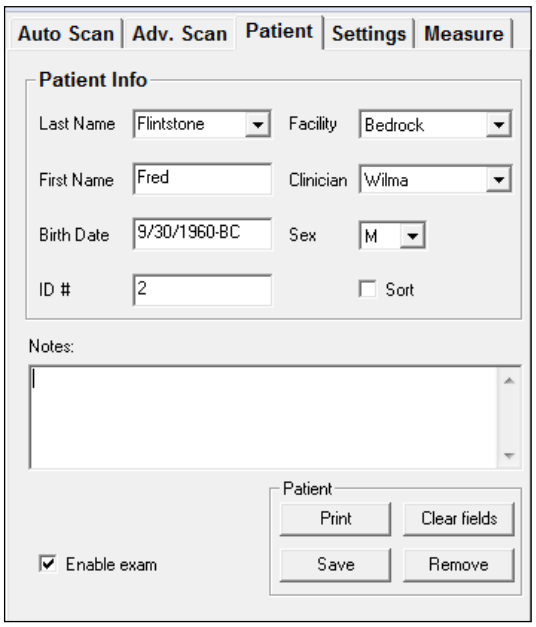
ViewBladder 10 automatically saves the most recent frames. After stopping a scan the most recent frames can be replayed by pressing the **Cine** play button. The number of frames that are automatically saved in the Cine frames buffer can be set in the **Settings** tab.

Image Save stores the current displayed frame of native format scan data and also a jpeg with measurements and annotations. **Image Load** recalls a saved frame of native format scan data.

Cine Save stores the buffer of most recent scan frames. **Cine Load** recalls a previously saved buffer of the most recent scanned frames.

6.3. Patient Tab

The **Patient** tab is where new patients are entered prior to starting an exam.



A new patient can be entered or an existing patient can be edited. After editing or entering the patient information, select **Save** and follow the prompts to add as a new patient or edit the current patient. New patient information can be typed over current information, or **Clear Fields** will clear all displayed information without deleting a patient from the database. To delete a patient from the database select **Remove**.

Facility and **Clinician** are selected and saved with the patient data. They are entered and edited in the **Settings** tab.

Sort alphabetically sorts the database by **Last Name**. If **Sort** is not checked, patients are displayed in the order they were entered.

Patient Exams are initiated and completed from the Auto Scan tab.

After an exam is completed, **Print** will print a single page report for the selected patient **Last Name**. The report is driven from a customizable template. To modify the report template refer to page 14. The standard template prints a single page report of the patient information and includes the transverse and sagittal scans that were automatically saved while performing the patient exam from the AutoScan tab.

The patient data file can be edited outside of ViewBladder 10.

Navigate to the Patient Data folder in Documents/SeeMore.

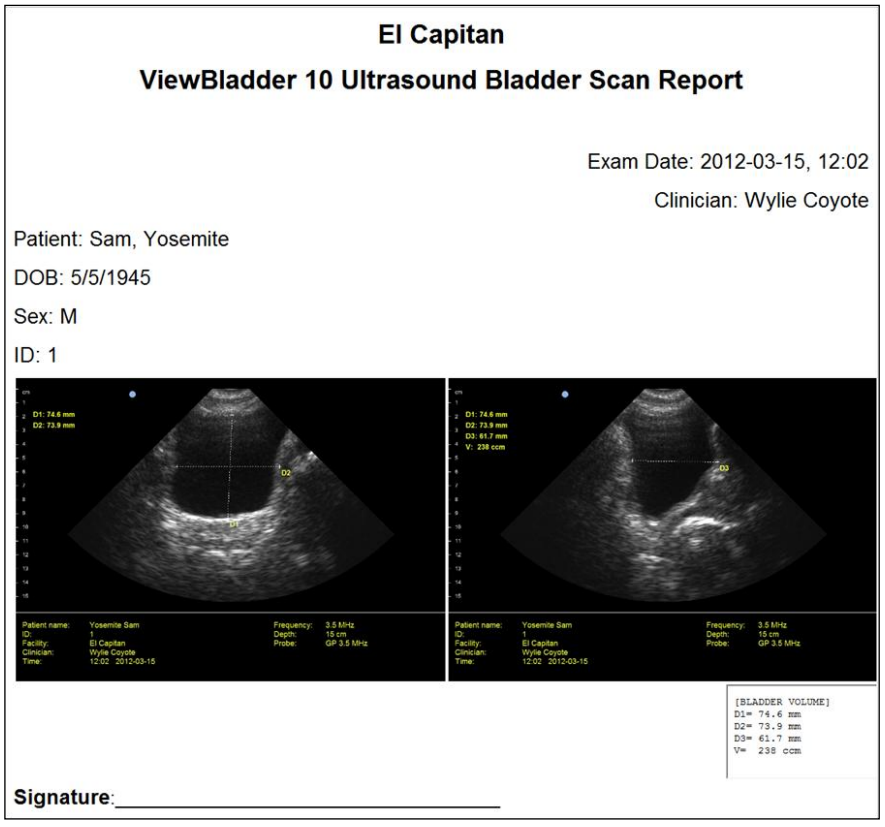
Make a copy of PatientsDataFile.csv

Open and edit PatientDataFile.csv

Be careful to save to the comma separated value format.

Open ViewBladder and be sure you can scroll through all patients.

If you need to recall the original file, rename the copy that you made earlier to PatientDataFile.csv



El Capitan

ViewBladder 10 Ultrasound Bladder Scan Report

Exam Date: 2012-03-15, 12:02

Clinician: Wylie Coyote

Patient: Sam, Yosemite

DOB: 5/5/1945

Sex: M

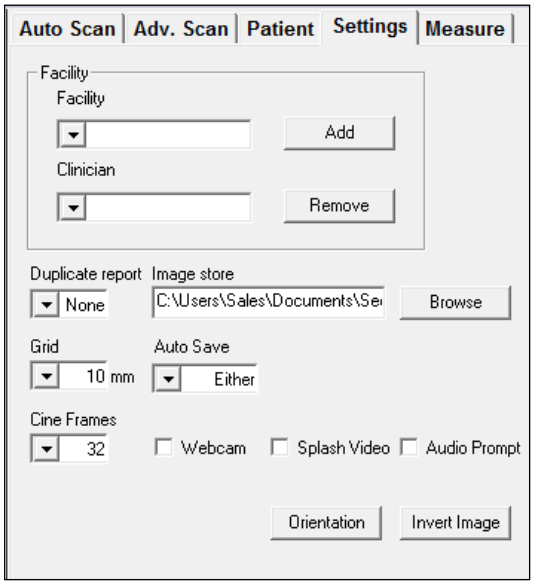
ID: 1

[BLADDER VOLUME]
D1= 74.6 mm
D2= 73.9 mm
D3= 61.7 mm
V= 238 ccm

Signature:_____

6.4. Settings Tab

The **Settings** tab is used to configure the functions of SeeMore.



In the **Facility** block you can **Add** and **Remove** either **Facility** or **Clinician** names. To remove a name, highlight the facility or clinician name and select **Remove**.

To add a new name, type over an existing name and select **Add**. The previous entry is not edited, the new entry is added.

Duplicate report lists any connected storage drives and allows you to select a duplicate location to store a copy of the patient exams as they are taken.

Image Store specifies the default location to store images that are not associated to a patient exam. **Image Save** or **Cine Save** will save to this specified location. There is typically no need to change this default directory.

Grid displays reference marks on the left side of the Image Window.

Auto Save specifies whether the space bar or the probe button automatically saves images to the patient's folder during an exam.

Centerline displays a reference line in the center of the image.

A **Biopsy Guide** reference line can be displayed if an endocavity probe is the specified probe.

Cine Frames allows the user to specify the number of frames that are buffered for replay. 32, 64,128 or 256 may be selected. As the frame rate is approximately 15 frames per second, these equate to approximately 2, 4, 8, and 16 seconds of buffered frames.

Webcam outputs a webcam to Windows. This feature outputs the SeeMore Image Window as a webcam, allowing you to send a real-time image to a remote location. You can select this webcam in Skype or another video transport.

Splash Video enables an included video to be played when SeeMore starts.

Audio Prompt enables included audio measurement prompts to be played during a bladder volume calculation.

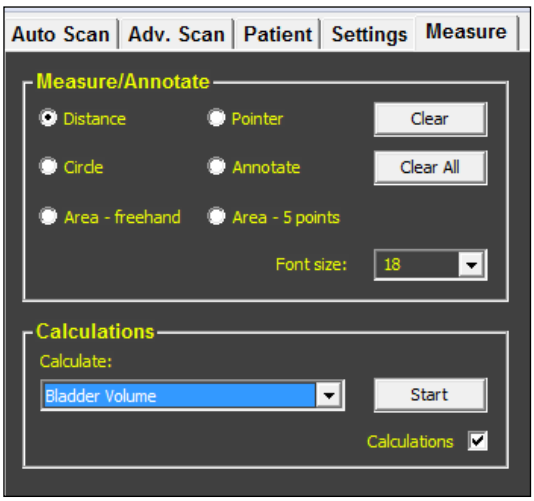
Display scaling controls the size of the SeeMore application window. Enter a value between the displayed numbers and follow the prompts. As the image data set is 800 x 512, for any image window that is larger than 800 x 512, extrapolated pixels are added in to develop the image. Therefore the smallest image window will provide the clearest image. Always set **Display scaling** to the smallest value that still allows you to see the image and adequately do your procedure.

Orientation flips the image right and left.

Invert Image flips the image up and down.

6.5. Measure Tab

The **Measure** tab is used to add measurements and annotations to an image, as well as perform Bladder Volume and Bladder Volume 3D calculations. Contact Interson for additional calculations that can be added to your system. Prostate Volume, Crown Rump, Gestational Sac, Femur Length, Head Circumference, Abdominal Circumference, and Bi-Parietal Diameter are available.



There are four types of measurements available.

Distance is invoked by placing your finger on a starting point and dragging your finger to the end point and then lifting your finger.

Similarly, a perfect **Circle** can be drawn. Place your finger at one edge of the circle and drag your finger to the other edge of the circle.

To draw a random shape use **Area-freehand**.

To draw a smooth shape, use **Area - 5 points** and select five points on the image. ViewBladder 10 will smoothly connect the five points.

Annotate and **Pointer** are used to label items on the image.

Font Size can be changed to suit your preference.

Clear removes the most recent measurement or annotation one at a time.

Clear All removes all calculations, measurements, and annotations.

To enable calculations, select the white box in the **Calculations** window. There are two calculations available in ViewBladder 10. Use the **Calculate** pull down to select either Bladder Volume or Bladder Volume 3D. Bladder Volume uses the height and width of a transverse bladder scan to estimate bladder volume. Bladder Volume 3D adds a thickness measurement from a mid-sagittal scan to the height and width measurements from the transverse scan. Bladder Volume 3D use the industry-standard Height x Width x Thickness x 0.7 to estimate the bladder volume.

Pressing **Start** begins the calculation procedure and provides text prompts underneath the calculations window.

7. Saving, Viewing, and Printing Images / Reports

There are a variety of ways to save, view, and print images from the ViewBladder 10 application. As saved images are also stored in the jpeg format, they can be viewed and printed with a variety of Windows applications. These are in addition to the Patient Report which automatically saves both the transverse and mid-sagittal images with patient and calculation information. This Patient Report is printed using the Print button on the Patient tab.

Saving

There are many ways that images can be saved. At the bottom of each control tab, on the left, is the Image Save function. This automatically saves the current frame as a backscatter image, (raw data). Image Save also automatically saves the current image frame as a jpeg and includes any added measurements, calculations and annotations.

Viewing

To review jpeg images, close ViewBladder 10 and click on the desktop folder labeled Patient Data. You can navigate to a patient's folder and display a specific .jpg image. Images that were not saved to a patient folder can be found in the Patient Data/_Stat Images folder.
To review backscatter images, in the ViewBladder 10 application, click on the Load Image button at the bottom of the Adv.Scan tab. Navigate to the Patient Data/_Stat Images folder and select a saved .bs image. The current image in the imaging window will be replaced by the retrieved image data. You can use the gain controls to adjust the image. You can add measurements and annotations and then resave the image as a jpeg for printing.

Printing Images and Patient Exam Reports

Jpeg images can be printed to any available Windows supported printer.
You can use Windows and any installed graphics program to open and print any previously saved jpeg image. Navigate to the Patient Folder using the shortcut on the desktop and select the .jpg file that you would like to print.
You can also print the Image and Status Window using the File pull down in the upper left corner of the ViewBladder 10 application window.
Patient Exam reports are printed by using the Print button in the Patient tab. Reports are printed using a customizable template. To modify the report template close ViewBladder 10 and navigate to the Documents/SeeMore Data/Settings folder and make a copy of report-template-calc.html file. You are now ready to modify the report template. Open report-template-calc.html using Notepad. Make your edits and perform file save. Open ViewBladder and take a new patient exam. Test your template by printing the report for this new exam. If you need to, you can always rename the copy of the report template that you made earlier to return to the original report template.

Saving and Viewing Reference Images

High resolution reference images are included in the Reference Data folder. These reference images are displayed on the Auto Scan tab and are used to compare your patient's bladder to typical bladder volumes. By comparing to these reference images you can alleviate the need to make measurements of bladder volume. You can edit or add annotations of your clinic's protocol to the included reference images or to your clinic specific reference images and save them in the Reference Data folder. Additionally if you save a video or jpg with the same name as the reference image in the Reference Data folder, it can be displayed by single tapping the reference image when the reference image is displayed from the Auto Scan tab. Additionally, the settings that were used to take a reference image are automatically invoked, thereby alleviating the need to adjust or determine any settings prior to scanning your patient.

8. Electromagnetic Compatibility

Like other medical equipment, Interson USB Ultrasound Probes require special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), Interson USB Ultrasound Probes must be installed and operated according to the EMC information provided in this manual.
The Interson USB Ultrasound Probes have been designed and tested to comply with IEC 60601-1-2: 2002 requirements for EMC with other devices.

CAUTION

Portable and mobile RF communications equipment may affect the normal function of the Interson USB Ultrasound Probes.

CAUTION

Do not use cables or accessories other than those provided with the Interson USB Ultrasound Probe, as this may result in increased electromagnetic emissions or decrease immunity to such emissions.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions & Immunity					
Interson USB Ultrasound Probes are intended for use in the electromagnetic environment specified below. The customer or the user of the Interson USB Ultrasound Probe should ensure that it is used in such an environment.					
Environmental Phenomena	**Test In Accordance to**	**Level**	**Criteria**	**Basic Standard**	**Notes**
Radiated Emissions	EN60601-1-2	Group 1 Class a	Under Limit	CISPR 11	Measure at 5 meters
Electrostatic Discharge	EN60601-1-2	±2kV ±4kV ±8kV contact discharge ±2kV ±4kV ±8kV air discharge	36.202.1 (j)	EN61000-4-2	Apply to all accessible components
Radiated Immunity	EN60601-1-2	80MHz-2.5GHz 3V/m 80%@1kHz	36.202.1 (j)	EN61000-4-3	Expose all parts of EUT to field
EFT I/O Only	EN60601-1-2	±2kV 5/50 5kHz	36.202.1 (j)	EN61000-4-4	None
Conducted Immunity I/O Only	EN60601-1-2	0.15 – 80MHz 3Vrms 80%@1kHz	36.202.1 (j)	EN61000-4-6	None

Guidance and Manufacturer's Declaration: Electromagnetic Immunity
Interson's USB Ultrasound Probes are intended for use in the electromagnetic environment specified below. The customer or the user of the Interson USB Ultrasound Probe should ensure that it is used in such an environment.
Field strength form fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, armature radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Interson USB Ultrasound Probe is used exceeds the applicable RF compliance level, the Interson USB Ultrasound Probe should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Interson USB Ultrasound Probe system.

9. Storage

When the Probe is not being used, it should be stored in a clean, dry area.

CAUTION

Do not use cables or accessories other than those provided with the Interson USB Ultrasound Probe, as this may result in increased electromagnetic emissions or decrease immunity to such emissions.

Do not store the probe in the shipping case. It may become a source of infection.

To prevent damage to the probe, do not store in areas where it might be exposed to:

- *Excessive vibration*
- *Excessive dust & dirt*

Store the probe under the following ambient conditions:

- *Temperature: -10°C to 50°C (14°F to 122°F)*
- *Relative Humidity: 20% to 80% (no condensation)*
- *Atmospheric pressure: 700 hPa to 1060 hPa*

10. Transportation

Never carry the probe by the cable. The cable could disconnect from the probe allowing it to drop and possibly damaging the probe.
Never bend the USB cable in a tight radius. This could result in damage to the cable.

Transport the probe under the following ambient conditions:

- Temperature: -10°C to 50°C (14°F to 122°F)
- Relative Humidity: 20% to 80% (no condensation)
- Atmospheric pressure: 700 hPa to 1060 hPa

When transporting the probe to a different field location or being returned for repair and/or maintenance, use the disinfected carrying case or enclosure that the probe was originally packaged in. Call Interson for an RMA number before returning a probe for evaluation and possible repair. If the original package is not available, pack in such a way that the probe is protected.

11. Care of the USB Probe

USB probe(s) and their cables are completely sealed units. The probe may be submersed in water up to the cable during normal use.

DO NOT OPEN ANY PROBE

Be careful when handling the USB probe. If the USB probe dropped on a hard surface it can be damaged.

DO NOT DISCONNECT or REMOVE USB CABLE

Be sure to keep the USB probe plug dry at all times.

The probe should be cleaned after every use. Regularly check the transducer housing and front face for cracks, as this may cause a loss of fluid which would impair the performance of the probe. Regularly check the cable for cuts, cracks, and kinks. This could also impair the performance of the probe.

Cleaning
Ensure the USB probe is at room temperature, rinse off any visible contamination (such as scanning gel or biological substances) with a detergent and tap water at a maximum of 40°C (104°F). Do not use water at temperatures below 10°C (50°F). Dry with a sterile cloth.

Maintenance
Periodic testing and maintenance of the Interson USB ultrasound probe is NOT required.

⚠ **WARNING**

Do not use cables or accessories other than those provided with the Interson USB Ultrasound Probe, as this may result in increased electromagnetic emissions or decrease immunity to such emissions. Users of this USB probe(s) have an obligation and responsibility to provide the highest degree of infection control possible to patients, co-workers and themselves. To avoid cross contamination, follow all infection control policies established for the office, department or hospital as they apply to personnel and equipment.

12. Disposal

1. Contact Interson Corporation before disposing of the probe.

2. Concerning the WEEE label:
   The following information is for EU member states:
   The use of this symbol indicates that this product should not be treated as household waste.
   By ensuring that this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste-handling of this product. For more information concerning the return and recycling of this product, please consult Interson Corporation.

Appendix A - Software Installation

ViewBladder 10 is delivered with the software already installed in the tablet.
These software installation instructions only apply if you would like to load the software onto another Windows 7 computer.

Email sales@Interson.com to get a copy of the ViewBladder 10 software.

Do NOT plug in the USB ultrasound probe until the software has been fully installed.

Software installation:

1. Plug in the Memory Stick to one of the computer's USB 2.0 ports.
2. Navigate to the location that contains the file **ViewBladder 10 Setup.exe**
3. Click on the icon **ViewBladder 10 Setup.exe**
4. Follow the on-screen instructions - click **Next** when prompted.
5. When installation is complete, click **Finish**.
6. Do *NOT* launch the ViewBladder application - the drivers need to be installed.
7. Connect the ultrasound probe to an available USB 2.0 port.
8. Wait for the first driver to install. Windows 7 will confirm the installation.
9. Launch the ViewBladder application using the shortcut on the desktop.
10. The second driver will install. Windows 7 will confirm the installation.
11. ViewBladder 10 will now launch and you are ready to scan.

Appendix B - Interson Probe System Specifications

Imaging Mode	B Scan
Functions	• Standard USB Port (2.0) connectivity • Multiple freeze method: button on probe, keyboard, or soft key on screen • Zoom with enhanced resolution (4 times over sampling) • Auto Image saves on Freeze
Image Resolutions	0.1 to 2.0 mm resolution *
Gray Shades	True 256 (8 bits) shades of gray
Sector Size	50, 60, or 90 degree sector *
Transducers	High Bandwidth, single element: 3.5 MHz, 5 MHz, 7.5 MHz, 12 MHz, 15 MHz, and 24 MHz *
Depth Selections	3, 5, 6, 10, 15, and 20 cm depths *
Measurements	Distance, area, volume measurements
Signal Processing	• TGC controls, near, mid and far • Contrast and image intensity controls • Frame averaging • Interpolation
Archive Functions	• Exam data • Cine buffer range 32-256 frames • Open system architecture
Power Supply Requirements	DC 5.0 V at 500 mA (max) obtained from the USB 2.0 port
Environmental	• Max operating temperature: 40°C (104°F) • Min operating temperature: 10°C (50°F) • Operating humidity range: 20-80% non-condensing
Storage Temperature	-10°C to 50°C (14°F to 122°F)

*Probe Dependent

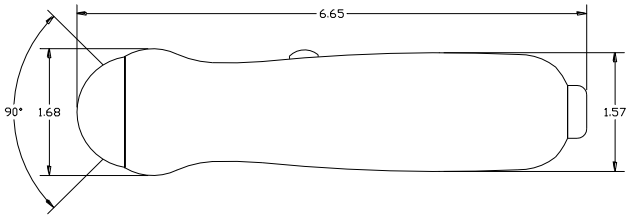
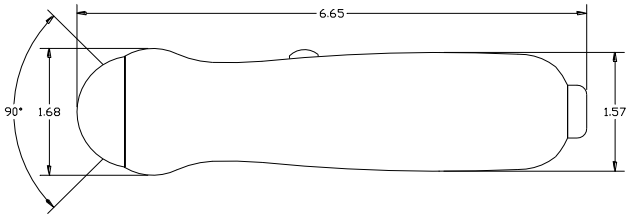
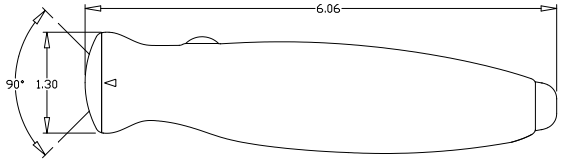
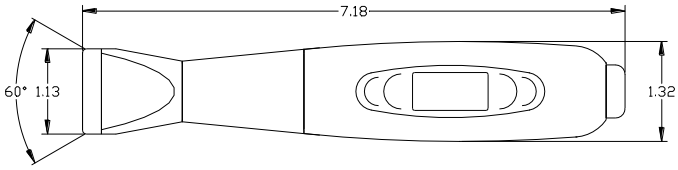
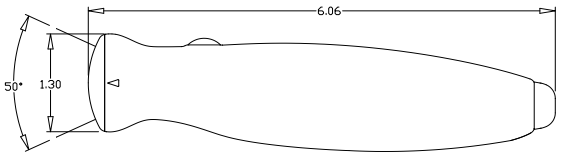
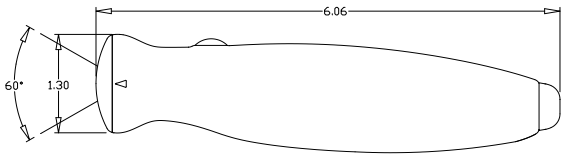
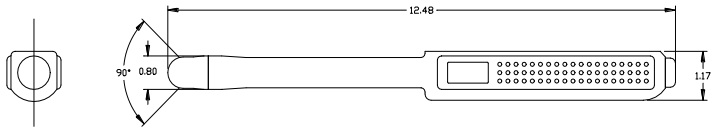
Appendix C - Computer System Specifications

Open System Architecture	System Specification Requirements for PC, Tablet, or Laptop
Processor	1.5 GHz or higher
Memory	2 Gigabyte or more
Video Chipset	Intel 815EM or higher performance equivalent, NVIDIA recommended
Video Memory	Up to 16 MB SDR or equivalent
Display	XGA 1024x768 or greater
Digital Ports	2 USB 2.0 Port(s) (full speed)
Keyboard	83 Keys or equivalent
Mouse	Touchpad, Laser Mouse, or USB Mouse or equivalent
AC Adapter	Medical Grade
Battery Type	PCGA-BP2R or equivalent
Operating System	Windows 7
Software	Interson Corporation – USB ultrasound version 2.0.01 or Higher
Warranty	1 year for the ultrasound probe
Special Options	N/A

WARNING

Do not use cables or accessories other than those provided with the Interson USB ultrasound probe, as this may result in increased electromagnetic emissions or decrease immunity to such emissions.
The use of a “Non-Medical” grade AC Adapter could potentially cause harm to the system, the probe, the operator and/or the patient.

Appendix D - Interson Probes and their Applications

Description	Product Design	Product Targeted Use
USB PROBE GP 3.5 MHz AB 3.5 MHz		**Human - Abdominal** Focal Point - 7.5 mm Max depth – 20 cm Patient contact area - 35 mm Displayed depth – 10 cm, 15 cm, 20 cm
USB PROBE GP 5.0 MHz AB 5.0 MHz		**Human - Abdominal** Focal Point – 6 mm Max depth – 20 cm Patient contact area - 32 mm Displayed depth – 10 cm, 15 cm, 20 cm
USB PROBE SP 7.5 MHz PI 7.5 MHz		**Human Superficial Anatomy** Focal Point - 2.0 cm Max depth - 10.0 cm Patient contact area - 20.0 mm Displayed depth – 5 cm, 10 cm
USB PROBE MV 12.0 MHz		**Human Vascular - Phlebotomy** Focal Point - 0.5 cm Max depth - 3.0 cm Patient contact area - 29.0 mm Displayed depth - 3.0 cm
USB PROBE NV 12 MHz		**Human Near Field Vascular** Focal Point - 0.5 cm Max depth - 3.0 cm Patient contact area - 29.0 mm Displayed depth - 3.0 cm
USB PROBE SR 7.5 MHz VA 7.5 MHz		**Human Superficial Anatomy** Focal Point - 2.0 cm Max depth - 10.0 cm Patient contact area – 20 mm Displayed depth – 3 cm, 5 cm, 6 cm, 10 cm
USB PROBE EC 7.5 MHz EB 7.5 MHz		**Human Endocavity Trans-Vaginal OB/GYN** Focal Point - 2.5 cm Max depth - 10 cm Patient contact area – 21 mm Displayed depth – 5 cm, 10 cm

Appendix E - Summary of the Acoustic Quantities

Summary of the acoustic quantities (GP 3.5 MHz / AB 3.5 MHz)							
Index	*MI*	*TIS*	*TIS*	*TIS*	*TIB*	*TIB*	*TIC*
Mode	-	Scanning	Non-scanning	Non-scanning	Scanning	Non-scanning	-
			A_{aprt} =1 cm²	A_{aprt} >1 cm²			
Acoustic working frequency (MHz)	3.30	3.30	NA	NA	3.30	NA	NA
Output power (mW)	38.8	38.8	NA	NA	38.8	NA	NA
Bounded output power (mW)	38.8	38.8	NA	NA	38.8	NA	NA
Attenuated output power (mW)	11.3	11.3	NA	NA	11.3	NA	NA
Spatial-peak temporal-average intensity (mW/cm2)	13.5	13.5	NA	NA	13.5	NA	NA
Attenuated spatial-peak temporal-average intensity (mW/cm2)	3.98	3.98	NA	NA	3.98	NA	NA
Peak-rarefactional acoustic pressure (MPa)	1.66	1.66	NA	NA	1.66	NA	NA
Attenuated peak-rarefactional acoustic pressure (MPa)	0.896	0.896	NA	NA	0.896	NA	NA
-1 2 dB output beam area (cm2)	2.27	2.27	NA	NA	2.27	NA	NA
Equivalent aperture diameter	1.7	1.7	NA	NA	1.7	NA	NA
Depth for *TIS*	0	0	NA	NA	0	NA	NA
Depth for *TIB*	0	0	NA	NA	0	NA	NA
Depth at max. attenuated pulse-intensity integral	5.43	5.43	NA	NA	5.43	NA	NA
Supplementary information: B-Mode only with 90 degree scan angle, 15 Hz scan rate and 256 lines per scan							

Summary of the acoustic quantities (GP 5.0 MHz / AB 5.0 MHz)							
Index	*MI*	*TIS*	*TIS*	*TIS*	*TIB*	*TIB*	*TIC*
Mode	-	Scanning	Non-scanning	Non-scanning	Scanning	Non-scanning	-
			A_{aprt} =1 cm²	A_{aprt} >1 cm²			
Acoustic working frequency (MHz)	3.66	3.66	NA	NA	3.66	NA	NA
Output power (mW)	38.2	38.2	NA	NA	38.2	NA	NA
Bounded output power (mW)	38.2	38.2	NA	NA	38.2	NA	NA
Attenuated output power (mW)	14.1	14.1	NA	NA	14.1	NA	NA
Spatial-peak temporal-average intensity (mW/cm2)	18.7	18.7	NA	NA	18.7	NA	NA
Attenuated spatial-peak temporal-average intensity (mW/cm2)	6.92	6.92	NA	NA	6.92	NA	NA
Peak-rarefactional acoustic pressure (MPa)	2.22	2.22	NA	NA	2.22	NA	NA
Attenuated peak-rarefactional acoustic pressure (MPa)	1.35	1.35	NA	NA	1.35	NA	NA
-1 2 dB output beam area (cm2)	1.13	1.13	NA	NA	1.13	NA	NA
Equivalent aperture diameter (cm2)	1.2	1.2	NA	NA	1.2	NA	NA
Depth for *TIS*	0	0	NA	NA	0	NA	NA
Depth for *TIB*	0	0	NA	NA	0	NA	NA
Depth at max. attenuated pulse-intensity integral	3.93	3.93	NA	NA	3.93	NA	NA
Supplementary information: B-Mode only with 90 degree scan angle, 15 Hz scan rate and 256 lines per scan							

Summary of the acoustic quantities (SP 7.5 MHz / PI 7.5 MHz)							
Index	*MI*	*TIS*	*TIS*	*TIS*	*TIB*	*TIB*	*TIC*
Mode	-	Scanning	Non-scanning	Non-scanning	Scanning	Non-scanning	-
			A_{aprt} =1 cm²	A_{aprt} >1 cm²			
Acoustic working frequency (MHz)	4.72	4.72	NA	NA	4.72	NA	NA
Output power (mW)	16.5	16.5	NA	NA	16.5	NA	NA
Bounded output power (mW)	11.4	11.4	NA	NA	11.4	NA	NA
Attenuated output power (mW)	10.6	10.6	NA	NA	10.6	NA	NA
Spatial-peak temporal-average intensity (mW/cm2)	62.2	62.2	NA	NA	62.2	NA	NA
Attenuated spatial-peak temporal-average intensity (mW/cm2)	40.3	40.3	NA	NA	40.3	NA	NA
Peak-rarefactional acoustic pressure (MPa)	3.10	3.10	NA	NA	3.10	NA	NA
Attenuated peak-rarefactional acoustic pressure (MPa)	2.49	2.49	NA	NA	2.49	NA	NA
-1 2 dB output beam area (cm2)	0.64	0.64	NA	NA	0.64	NA	NA
Equivalent aperture diameter (cm)	0.90	0.90	NA	NA	0.90	NA	NA
Depth for *TIS* (cm)	0	0	NA	NA	0	NA	NA
Depth for *TIB* (cm)	0	0	NA	NA	0	NA	NA
Depth at max. attenuated pulse-intensity integral (cm)	1.33	1.33	NA	NA	1.33	NA	NA
Supplementary information: B-Mode only with 90 degree scan angle, 15 Hz scan rate and 256 lines per scan							

Summary of the acoustic quantities (SR 7.5 MHz / VA 7.5 MHz)							
Index	*MI*	*TIS*	*TIS*	*TIS*	*TIB*	*TIB*	*TIC*
Mode	-	Scanning	Non-scanning	Non-scanning	Scanning	Non-scanning	-
			A_{aprt} =1 cm²	A_{aprt} >1 cm²			
Acoustic working frequency (MHz)	4.75	4.75	NA	NA	4.75	NA	NA
Output power (mW)	17.7	17.7	NA	NA	17.7	NA	NA
Bounded output power (mW)	13.4	13.4	NA	NA	13.4	NA	NA
Attenuated output power (mW)	11.5	11.5	NA	NA	11.5	NA	NA
Spatial-peak temporal-average intensity (mW/cm2)	55.4	55.4	NA	NA	55.4	NA	NA
Attenuated spatial-peak temporal-average intensity (mW/cm2)	36.2	36.2	NA	NA	36.2	NA	NA
Peak-rarefactional acoustic pressure (MPa)	2.80	2.80	NA	NA	2.80	NA	NA
Attenuated peak-rarefactional acoustic pressure (MPa)	2.27	2.27	NA	NA	2.27	NA	NA
-1 2 dB output beam area (cm2)	0.64	0.64	NA	NA	0.64	NA	NA
Equivalent aperture diameter (cm)	0.90	0.90	NA	NA	0.90	NA	NA
Depth for *TIS* (cm)	0	0	NA	NA	0	NA	NA
Depth for *TIB* (cm)	0	0	NA	NA	0	NA	NA
Depth at max. attenuated pulse-intensity integral (cm)	1.30	1.30	NA	NA	1.30	NA	NA
Supplementary information: B-Mode only with 60 degree scan angle, 18 Hz scan rate and 256 lines per scan							

Summary of the acoustic quantities (EC 7.5 MHz / EB 7.5 MHz)							
Index	*MI*	*TIS*	*TIS*	*TIS*	*TIB*	*TIB*	*TIC*
Mode	-	Scanning	Non-scanning	Non-scanning	Scanning	Non-scanning	-
			A_{aprt} =1 cm²	A_{aprt} >1 cm²			
Acoustic working frequency (MHz)	4.60	4.60	NA	NA	4.60	NA	NA
Output power (mW)	23.5	23.5	NA	NA	23.5	NA	NA
Bounded output power (mW)	19.8	19.8	NA	NA	19.8	NA	NA
Attenuated output power (mW)	12.4	12.4	NA	NA	12.4	NA	NA
Spatial-peak temporal-average intensity (mW/cm2)	35.7	35.7	NA	NA	35.7	NA	NA
Attenuated spatial-peak temporal-average intensity (mW/cm2)	18.9	18.9	NA	NA	18.9	NA	NA
Peak-rarefactional acoustic pressure (MPa)	3.16	3.16	NA	NA	3.16	NA	NA
Attenuated peak-rarefactional acoustic pressure (MPa)	2.30	2.30	NA	NA	2.30	NA	NA
-1 2 dB output beam area (cm2)	0.64	0.64	NA	NA	0.64	NA	NA
Equivalent aperture diameter (cm)	0.9	0.9	NA	NA	0.9	NA	NA
Depth for *TIS* (cm)	0	0	NA	NA	0	NA	NA
Depth for *TIB* (cm)	0	0	NA	NA	0	NA	NA
Depth at max. attenuated pulse-intensity integral (cm)	2.0	2.0	NA	NA	2.0	NA	NA
Supplementary information: B-Mode only with 90 degree scan angle, 15 Hz scan rate and 256 lines per scan							

Summary of the acoustic quantities (MV 12.0 MHz / NV 12.0 MHz)							
Index	*MI*	*TIS*	*TIS*	*TIS*	*TIB*	*TIB*	*TIC*
Mode	-	Scanning	Non-scanning	Non-scanning	Scanning	Non-scanning	-
			A_{aprt} =1 cm²	A_{aprt} >1 cm²			
Acoustic working frequency (MHz)	6.39	6.39	NA	NA	6.39	NA	NA
Output power (mW)	0.72	0.72	NA	NA	0.72	NA	NA
Bounded output power (mW)	0.27	0.27	NA	NA	0.27	NA	NA
Attenuated output power (mW)	0.69	0.69	NA	NA	0.69	NA	NA
Spatial-peak temporal-average intensity (mW/cm2)	3.64	3.64	NA	NA	3.64	NA	NA
Attenuated spatial-peak temporal-average intensity (mW/cm2)	3.49	3.49	NA	NA	3.49	NA	NA
Peak-rarefactional acoustic pressure (MPa)	1.45	1.45	NA	NA	1.45	NA	NA
Attenuated peak-rarefactional acoustic pressure (MPa)	1.42	1.42	NA	NA	1.42	NA	NA
-1 2 dB output beam area (cm2)	0.38	0.38	NA	NA	0.38	NA	NA
Equivalent aperture diameter (cm)	0.70	0.70	NA	NA	0.70	NA	NA
Depth for *TIS* (cm)	0	0	NA	NA	0	NA	NA
Depth for *TIB* (cm)	0	0	NA	NA	0	NA	NA
Depth at max. attenuated pulse-intensity integral (cm)	0.10	0.10	NA	NA	0.10	NA	NA
Supplementary information: B-Mode only with 60 degree scan angle, 15 Hz scan rate and 256 lines per scan							

Appendix F - Interson USB Probes - Indications for Use

Interson USB Probes **Clinical Application**	GP 3.5 MHz / AB 3.5 MHz	GP 5.0 MHz / AB 5.0 MHz	SP 7.5 MHz / PI 7.5 MHz	MV 12 MHz / NV 12 MHz	SR 7.5 MHz / VA 7.5 MHz	EC 7.5 MHz / EB 7.5 MHz	ER 7.5 MHz / ES 7.5 MHz	ER 12.0 MHz / ES 12.0 MHz
Ophthalmic								
Fetal	●	●						
Abdominal	●	●	●					
Intra-Operative (Specify)								
Intra-Operative Neurological								
Pediatric		●	●	●	●			
Small Organ	●	●	●	●	●		●	●
Neonatal Cephalic		●	●					
Adult Cephalic								
Cardiac		●						
Transesophageal								
Trans-Rectal						●	●	●
Trans-Vaginal						●		
Trans-Urethral								
Intra-Vascular								
Peripheral -Vascular			●	●	●			
Laparoscopic								
Muscular-Skeletal Conventional			●		●			
Muscular-Skeletal Superficial			●		●			
Others (Specify)								

1. <u>USB Transducer GP 3.5 MHz / AB 3.5 MHz</u> This device is a hand-held, single element, mechanical sector probe intended for transcutaneous use with the INTERSON USB ULTRASOUND PROBE SYSTEM. The nominal operating frequency is 3.5 MHz. In B-mode the transducer operates over a 35 mm area as an end-firing probe. This device is intended for use with the INTERSON USB ULTRASOUND PROBE SYSTEM for the transcutaneous imaging of neonatal, abdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc., to aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria.

2. USB Transducer GP 5.0 MHz / AB 5.0 MHz:
This device is a hand-held, single element, mechanical sector probe intended for transcutaneous use with the INTERSON USB ULTRASOUND PROBE SYSTEM. The nominal operating frequency is 5.0 MHz. In B-mode, the transducer operates over a 32 mm area as an end-firing probe. This device is intended for use with the INTERSON USB ULTRASOUND PROBE SYSTEM for the transcutaneous imaging of neonatal, abdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc., to aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria.

3. USB Transducer SP 7.5 MHz / PI 7.5 MHz:
This device is a hand-held, single element, mechanical sector probe intended for transcutaneous use with the INTERSON USB ULTRASOUND PROBE SYSTEM. The nominal operating frequency is 7.5 MHz. In B-mode the transducer operates over a 20 mm area as an end-firing probe. This device is intended for use with the INTERSON USB ULTRASOUND PROBE SYSTEM for the transcutaneous imaging of neonatal, abdominal organs and structures including the gastrointestinal tract, kidney, bladder, etc., peripheral vessels, and small organs to aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria.

5. USB Transducer MV 12.0 MHz / NV 12.0 MHz:
This device is a hand-held, single element, mechanical sector probe intended for transcutaneous use with the INTERSON USB ULTRASOUND PROBE SYSTEM. The nominal operating frequency is 12 MHz. In B-mode the transducer operates over a 29 mm area as an end-firing probe. This device is intended for use with the INTERSON USB ULTRASOUND PROBE SYSTEM for the transcutaneous imaging of peripheral vessels and as small organs to aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria.

6. USB Transducer SR 7.5 MHz / VA 7.5 MHz:
This device is a hand-held, single element, mechanical sector probe intended for transcutaneous use with the INTERSON USB ULTRASOUND PROBE SYSTEM. The nominal operating frequency is 7.5 MHz. In B-mode the transducer operates over a 29 mm area as an end-firing probe. This device is intended for use with the INTERSON USB ULTRASOUND PROBE SYSTEM for the transcutaneous imaging of peripheral vessels and small organs to aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria.

7. USB Transducer EC 7.5 MHz / EB 7.5 MHz:
This device is a hand-held, single element, mechanical sector probe intended for transcutaneous use with the INTERSON USB ULTRASOUND PROBE SYSTEM. The nominal operating frequency is 7.5 MHz. In B-mode the transducer operates over a 21 mm area as a side-firing probe. This device is intended for use with the INTERSON USB ULTRASOUND PROBE SYSTEM for the transcutaneous imaging of endocavity, etc. and small organs to aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria.

Appendix G - Patient Privacy and Confidentiality

There are important steps you can take to safeguard your data.
Ultrasound images, patient data files, and reports may include identifying patient information. HIPAA regulations and other patient privacy and regulatory standards require that users take reasonable care to protect this information.

It is important that you comply with your own hospital or clinic HIPAA guidelines regarding privacy and safeguarding patient information. Ask yourself these questions: What would my liability be if someone stole my laptop, computer, or storage device? What would I do if my computer hard drive crashed? Ultimately, it is the user's responsibility to assure the security of their data.

Several strategies may be used to protect data:

1) Control the computer and storage devices at all times. They should be locked up when not under direct control of user.
2) Limit access to the computer to authorized users
3) Password protect computer – require login.
4) Password protect any folders or files that include patient information. This should have adequate encryption to prevent unauthorized viewing.
5) Regularly back up your data and store in a safe place.

Note: Interson ViewBladder 10 software does not include electronic signature control and is not meant to substitute for an electronic medical record.

Appendix H - Interson Customer Warranty

Interson (“the Company”) warrants that the SeeMore USB Ultrasound Imaging Probe (the "Product") will perform in accordance with its specifications, and is free from material and manufacturing defects. Loss or damage caused by misuse or abuse is not covered by this warranty.

The Company agrees to replace or correct any defects or errors in the Product for a period of one (1) year from the date of purchase from an authorized Interson dealer. The Company's sole liability and the exclusive remedy shall be, at the Company's option, the repair or replacement of the Product.

The Company makes no additional representations or warranties, express or implied, regarding the Product and/or its use. By way of example, but not of limitation, the Company makes no representations or warranties of merchantability or fitness for a particular purpose. Purchaser assumes the responsibility for the selection of the Product as being adequate for and appropriate for purchaser's purposes.

In no event will the Company be liable for any special, incidental, indirect or consequential damages whatsoever arising out of the use of or inability to use the product, even if the company has been advised of the possibility of such damages.

The warranty does not extend to defects to: (i) the Product arising out of material or workmanship not provided or furnished by the Company; (ii) the Product resulting from abnormal use of the Product or use in any manner other than as specified in the Product's operating manual; (iii) components or parts warranted by another party;(iv) parts which are subject to normal wear and tear, including, but not limited to, cables, cable connectors, or switches.

Product may be returned only upon issuance of a Return Materials Authorization ("RMA") number by the Company. The RMA number must appear on all packages and paperwork.

All shipping costs incurred in shipping Product to the Company for warranty and non-warranty repair will be borne by the purchaser.

The Product must be sent pre-paid freight, and clearly marked "Attention: Service."

Please include the nature of the problem along with all contact information.

EC REP

EC Representative
MediTech
Maastrichterlaan 127
NL-6291 EN Vaals
Netherlands
Phone: +31.43.306.3320
Fax: +31.43.306.3338

Interson Corporation MediTech
7026 Koll Center Parkway
Suite 201
Pleasanton, CA 94566
Tel: 925.462.4948
Fax: 925.462.4833
Email: support@interson.com
www.interson.com

Appendix I - Warranty and Extended Warranty Registration

Interson probes come with a standard one-year warranty. You can register your ViewBladder 10 system online at http://www.interson.com/registration or make a copy of this form, fill out your information, and mail to Interson.

Extended Warranty

An extended warranty may be purchased for up to two additional years.

This protection includes: repair of damaged probes as well as elective yearly maintenance. We clean, calibrate, and repair as may be necessary. Interson pays return domestic shipping. International customers may incur additional return shipping charges.

Extended warranty must be purchased within 30 days of ownership.

To register your system for an extended warranty: copy this page, fill out your information, and send to Interson with payment.

Customer _____

Address _____

Address _____

City _____ State ____ Zip _____

Phone _____ E-mail _____

Purchase Date _____

Additional One year coverage: $400 USD per system; tablet + probe

Additional Two years coverage: $800 USD per system; tablet + probe

Tablet or probe model name	Serial Number	Year(s) additional coverage (circle one)	
		1 Year	2 Years
		1 Year	2 Years
		1 Year	2 Years
		1 Year	2 Years

Amount enclosed: _____

Interson Corporation
7026 Koll Center Parkway
Suite 201
Pleasanton CA 94566
Tel: 925.462.4948
Fax: 925.462.4833
Email: support@interson.com
www.interson.com