INTERSON

We revolutionize imaging devices

SeeMore

USB Ultrasound

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

Information in this document is subject to change without notice.

CE 0197

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

3.5 MHz General Purpose (GP/AB)
5.0 MHz General Purpose (GP/AB)
7.5 MHz Small Parts (SP/PI)
7.5 MHz Endocavity (EC/EB)
7.5 MHz Vascular (SR/VA)
7.5 MHz Endorectal (ER/ES)
12.0 MHz Endorectal (ER/ES)
12.0 MHz Micro-Vascular (MV/NV)

Table of Contents

1. Introduction

Congratulations on your purchase of the Interson USB Ultrasound Imaging Probe, the ultrasound imaging probe that plugs into the USB port of your computer. 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 SeeMore software.

Note: *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, 8
- Minimum processor: 2.5 GHz
- Minimum RAM: 4 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. These signal words and their meanings are as follows. All users of the Interson Ultrasound Probe System must understand the meanings of these signal words.

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

	Follow Operating Instructions
	“Attention”, refer to User’s Manual

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 EN 60601-2 approved AC Adapter could potentially cause harm to the system, the probe, the operator and / or the patient.

WARNING

Do not touch the USB probe System’s USB cable connector and the patient simultaneously.

WARNING

USB Probe System is not to be used with HF surgical equipment.

WARNING

Do not submerse USB Probe System in water

WARNING

No modification of this equipment is allowed. Attempting to modify or service the equipment may result in safety hazards and performance degradation and / or failure.

3.4. Symbology

The following symbols may be used on Interson labeling:

SN	Symbol for “Serial Number”
REF	Symbol for “Part Number”
	Symbol indicating the “date of manufacture”
	Type BF Equipment
	Follow Operating Instructions

3.5. Operator Qualifications

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

Do not plug in the ultrasound probes until the software has been fully installed. See software installation guide in Appendix A, page 18.

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.

A drape or probe covering may be used. Ultrasound does not penetrate through air, so you must apply scanning gel on the inside of the drape, as well as on the outer surface of the drape.

3.6. 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. Store the probe in its padded case. This will protect the probe and the delicate scanning membrane. Do not put stress on, or use the cable to carry the probe, as this may damage the probe and cable. Your probe should give you many years of reliable service if these simple precautions are followed.

3.7. Cleaning and Disinfection

WARNING

Always disconnect the ultrasound probe system from the host computer before performing maintenance or cleaning.

WARNING

Always follow the manufacturer's instructions when cleaning and disinfecting probes and biopsy guide adapters.

WARNING

Do not use a surgeon's brush when cleaning probes. The use of even soft brushes can damage the probe.

3.8. Probe Cleaning

The USB Ultrasound Probe System is capable of withstanding, without damage or deterioration of the safety provisions, the cleaning and/or disinfecting process specified in this manual and the instructions for use.

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.

3.9. 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 solution is used.
3. 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 times. Do not use heat or radiation to sterilize. This will permanently damage the probe and void the warranty.

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. Examine the probe for damage such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, abandon disinfection, discontinue use of the probe, and contact a customer service representative.
2. Mix the disinfecting solution, that is 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 disinfecting solution per the manufacturer's recommendations of duration. Do not immerse any part of the probe's cable or cable connector.
3. Follow the instructions on the disinfectant 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.

3.10. Surface Cleaning

Refer to “Probe Cleaning” (3.7, page 5)

3.11. Surface Disinfection

Refer to “Probe Disinfecting” (3.8, page 6)

3.12. Acoustic Energy

The effects of acoustic energy on human tissue are currently 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.

3.13. Electromagnetic Compatibility (EMC)

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

3.14. Prescription Device Statement

CAUTION

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

WARNING

The sheath may contain natural rubber and talc, which may cause allergic reactions. For more information, see the FDA’s March 29, 1991, Medical Alert on latex products.

3.15. Training

This USB probe system is intended to be used by trained medical professionals only.
The specific probe functions are described in this manual and are also available through the SeeMore system software Help Menu.

4. General

This user guide is for the Interson USB probe system. Prior to using the probe, become familiar with the operating instructions in this guide. The USB probe system is a unique concept where the ultrasound system is built entirely into the probe. This USB probe system allows the user to image in real-time and review cine or freeze-frame images on the screen in B-Mode scan format.

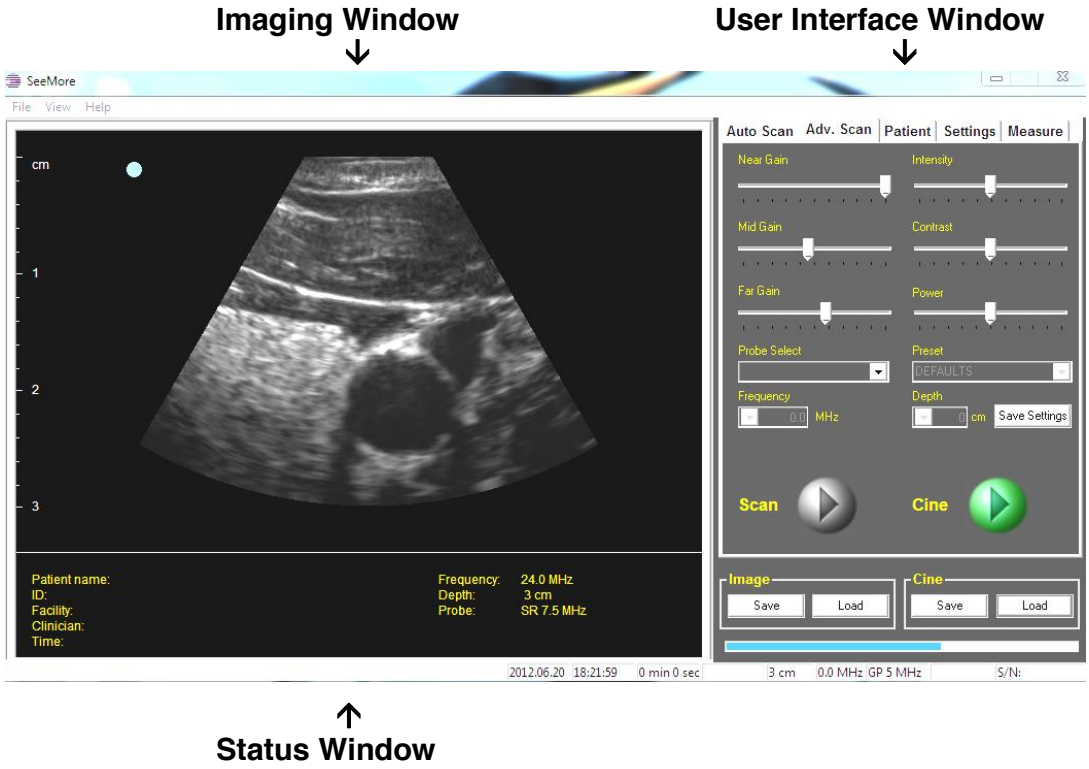
WARNING

Prior to patient evaluation, inspect the USB Ultrasound Probe System for any physical damage such as leaking fluid and/or cracked and/or broken: membrane; housing; strain relief; stand-by switch; USB cable. If physical damage exists, do not use for patient evaluation and return to Interson for service evaluation.

5. SeeMore Display

The computer monitor screen is divided into three major sections:

On the left side is the **Imaging Window** and **the Status Window.** The **Imaging Window** displays the ultrasound scan, and includes measurements, calculations and annotations. The **Status Window** displays patient information for the active exam and details 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 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.



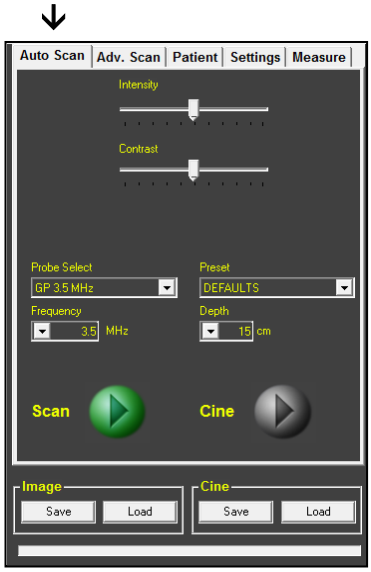
*Note the blue dot on the upper left side of the image. This blue dot corresponds to the scan / freeze and image orientation button on the probe. The radiologist's convention is that the orientation mark on the image identifies the patient's right side or the patient's head. The image can be flipped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

6. SeeMore 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 Quick Start Guide. Video 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 select different presets and adjust basic functions such as depth, frequency, intensity and contrast from this tab



You may adjust the **Intensity** and **Contrast**. It is typically best to leave these in the center.

Probe Select identifies all connected probes and enables you to select which probe you would like to use. Select the pull down arrow to view the list of connected probes

Preset enables you to select from any included presets 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. Presets are saved and deleted in the **Adv. Scan** tab.

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 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.

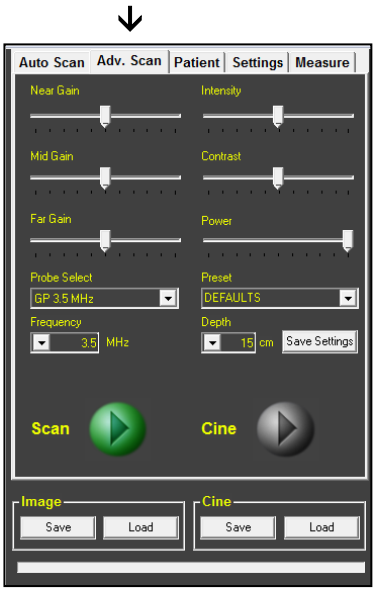
SeeMore automatically saves the most recent frames. After stopping a scan the most recent frames can be replayed by pressing the **Cine** play button. The number of frames that are automatically saved in the cine frames buffer is selected in the **Settings** tab.

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 raw scan data.

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

6.2. Advanced Scan Tab

The **Adv. Scan** tab has the same functionality as the **Auto Scan** tab**,** as well as the capability to adjust the image's gains and pulse power, and save presets.



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, **Power** will be at the maximum unless the image is saturated with the **Gains** centered.

In the left hand column of sliders you can adjust three gains. Start with all three gains in the center. If the image is saturated, lower the **Power**. Lower **Power** typically provides better images when imaging a bladder or fetus. **Near Gain** adjusts the first third of the image. **Mid Gain** adjusts the middle third, and **Far Gain** the last third. An alternative adjustment method is to adjust all gains to the minimum (left), pulse power to maximum (right), and intensity and contrast in the middle. Now, increase the **Near Gain** until the first third of the image is just below saturation. Similarly, adjust the **Mid Gain**, and finally the **Far Gain**.

Probe Select identifies all connected probes and enables you to select which probe you would like to use. Only one probe can be active at a time.

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 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.

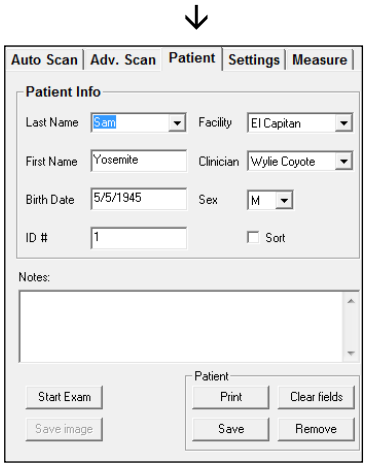
SeeMore automatically saves the most recent frames. After stopping a scan the most recent frames can be replayed by pressing the **Cine** play button. The number of frames that are automatically saved in the Cine frames buffer can be set in the **Settings** tab.

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 raw scan data.

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

6.3. Patient Tab

The **Patient** tab is where new patients are entered and selected prior to starting an exam. New patient information can be typed over current information, or **Clear Fields** will remove all displayed information without deleting a patient from the database.



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.

Facility and **Clinician** are selected and saved with the patient. 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.

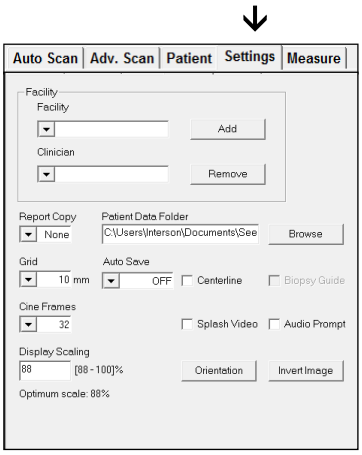
Start Exam posts the current patient information to the Status Window and makes a patient folder in the Documents/SeeMore Data/Patient Data directory. Images and calculations are stored to this folder. Start and then stop/freeze a scan. You may use either the **Scan** button on the screen, the button on the probe, or the keyboard space bar. Images are saved each time **Save Image** is pressed.
Prior to pressing **Save Image**, you may scroll to a specific image by using the arrow keys on the keyboard or the scroll wheel on the mouse.
You may add measurements, annotations, and calculations prior to pressing **Save Image**.
To end a patient exam press **Stop Exam**.

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. The standard template prints a single page report of the patient information and the first four saved images. The report template may be modified to arrange text and images and to modify the number of images that are included in the report. Contact Interson or your distributor to learn how to modify the report template.

Images, calculations and measurements that are conducted here in the **Patient** tab are automatically associated with a specific patient if **Start Exam** has been pressed. To make a calculation or measurement that is not associated with a specific patient select the **Measure** tab; make calculations and measurements, and optionally save and print single images.

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 C**linician** 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.

Report Copy lists any connected storage drives and allows you to select a location to store a duplicate copy of patient exams.

Patient Data Folder specifies the location for patient data and exams. You can select Browse and modify the default location. By specifying a network folder, SeeMore will automatically make all patient folders in, and send all patient data to, the network location.

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. The default is **OFF** as the user has much more control over which image to save using **Save Image,** after selecting **Start Exam** in the Patient tab.

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 selected probe.

Cine Frames allows the user to specify the number of frames that are buffered for replay. 32, 64,128, 256, 512, 1024 or more may be selected. As the frame rate is approximately 15 frames per second, these equate to approximately 2, 4, 8, 16, 32, or 64 seconds of buffered frames. The maximum number of Cine Frames depends on your installed memory and is automatically set on SeeMore startup. The keyboard arrow keys or the mouse wheel will scroll through cine frames.

Splash Video enables an included video describing the features and capabilities of SeeMore to be played when SeeMore starts.

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

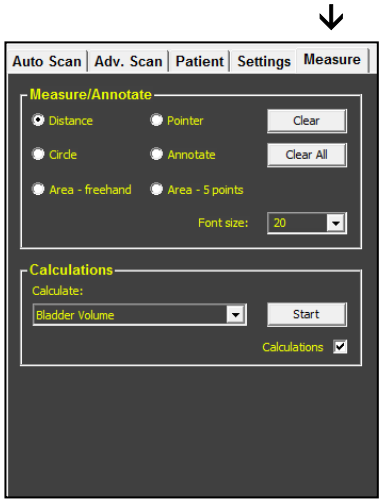
Display Scaling controls the size of the SeeMore application window. The optimal scale percentage is automatically calculated. Setting display scaling larger than optimal, will cause Windows to add pixels to the image data. The clearest image is obtained with the smallest scaling. Enter a value, press return, close and reopen SeeMore to change the display scaling.

Orientation flips the image right and left. Radiologist's convention is the orientation mark identifies the right side or head of a patient.

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 any included calculations. If calculations are not included, contact Interson about available calculations. Bladder Volume, Prostate Volume, Crown Rump, Gestational Sac, Femur Length, Head Circumference, Abdominal Circumference, and Bi-Parietal Diameter are all available.



There are four types of measurements available:
Distance is invoked by either placing and dragging your finger, or simply left click and drag on the image window. Similarly, a perfect **Circle** can be drawn, or a random shape with **Area-freehand**. To draw a smooth shape, use **Area – 5 points** and select five points on the image. SeeMore 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.

If calculations are available they can be selected using the **Calculate** pull down. Pressing **Start** provides text prompts underneath the calculations window. If a patient exam is open, the calculation images will be saved to the patient folder. If not, you can save the image with calculations, measurements, and annotations by using **Image Save** from the **Auto Scan** or **Adv. Scan** tab**.**

Statement of Accuracy

Accuracy of distance measurements are displayed in the table below:

GP USB Probe Family	± 5 % or ± 5 mm, whichever is greater
SP USB Probe Family	
EC USB Probe Family	

7. Saving, Viewing, and Printing Images

There are a variety of ways to save, view, and print images from the SeeMore application. As saved images are also stored in the jpeg format, they can be viewed and printed with a variety of Windows applications.

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.

If a patient exam is started, images can be saved automatically in the patient folder whenever you freeze the image with either the probe button or space bar. This **Auto Save** feature is configured in the **Settings** tab.

If a patient exam has been started, you can save images using **Save Image** just below the **Start Exam** button. Refer to the **Patient** tab and **Patient** tab **Video Help.**

Viewing

To review jpeg images, minimize or close SeeMore and click on the desktop folder labeled Patient Data. You can select and open a specific .jpg image.

To review backscatter images, in the SeeMore application, click on the **Load Image** button at the bottom of any control tab. Select a specific .bs image. The current image in the imaging window will be replaced by the retrieved image data.

You can use the gain controls and intensity and contrast to adjust the image. You can add measurements and annotations and then resave the image as a jpeg for printing.

Printing

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 you would like to print.

You can also print the Image Window using the **File** pull down in the upper left corner of the SeeMore application window.

If you have taken a patient exam, you can print the exam by selecting the patient by last name in the Patent Tab and then selecting **Print** from the Patient control box.

Viewing Reference Images

High resolution reference cine files are included in the Patient Data/_Stat Images folder. These reference images are included for you to compare your technique and to assure you are getting optimum image quality from your system.

Click **Load Cine** file button and double click the cine image file that you want to review. To single step through a cine loop, use the arrow keys on the keyboard or scroll wheel on the mouse. You can adjust intensity and contrast, and perform measurements on any displayed image.

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: 2007 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 from 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.

CAUTION

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 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. When returning for repair, there is no need to use the original package, pack in such a way that the probe is protected. This will help to control the shipping costs. Contact Interson to obtain a Return Material Authorization number and the best packaging method prior to sending a probe in for evaluation and possible repair.

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.

WARNING

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 - SeeMore Software Installation

Do NOT plug in the USB ultrasound probe(s) 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. Please open, read, and print the file READ ME for detailed instructions regarding installation. Also print the files SeeMore Installation.pdf and XVID Installation.pdf
3. Click on the icon **SeeMoreSetup *x.yy.zz*.exe**
4. Follow the instructions per SeeMore Installation.pdf.
5. Per the READ ME instructions, click on XVID.exe
6. Follow the instructions per XVID Installation.pdf.
7. Remove the Memory Stick and store it in a safe place.
8. Do *NOT* launch the SeeMore application - the drivers need to be installed.
9. Connect the ultrasound probe to an available USB 2.0 port.
10. Wait for the first driver to install. Windows 7 will confirm the installation.
11. Launch the SeeMore application using the shortcut on the desktop.
12. The second driver will install. Windows 7 will confirm the installation.
13. The SeeMore application 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 VDC, ± 5% at 500 mA (max) 2.5 watts (max) obtained from the USB 2.0 port
Environmental	• Max operating temperature: 35°C (95°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

WARNING

The use of a non EN 60601-2 approved AC Adapter could potentially cause harm to the system, the probe, the operator and / or the patient.

WARNING

The use of non ISO 10993 series of standards off-the-shelf Ultrasound Transmission Gel could potentially cause harm to the system, the probe, operator and / or the patient.

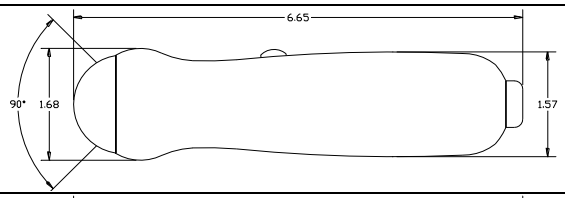
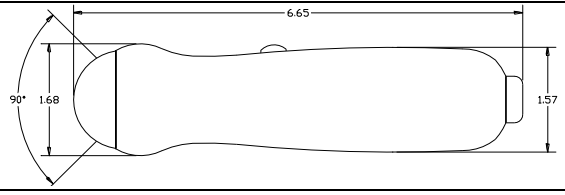
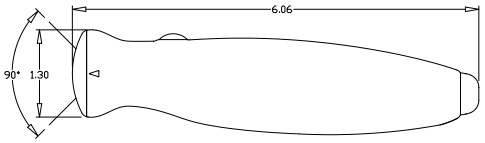
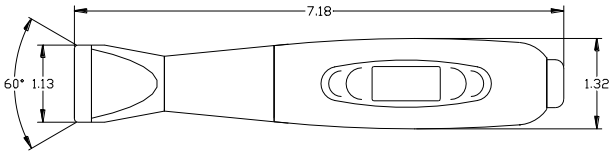
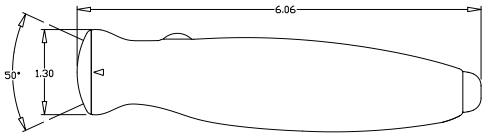
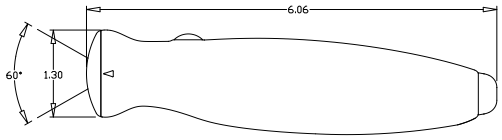
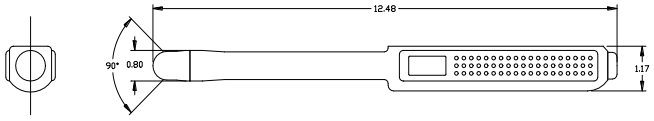
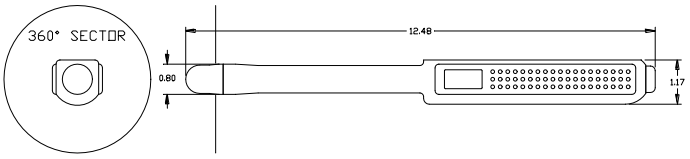
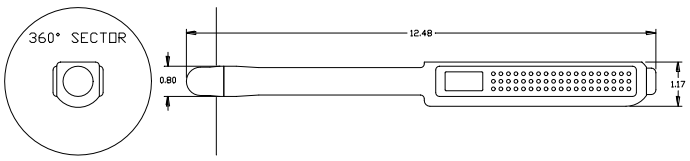
Appendix C - Computer System Specifications

Open System Architecture	System Specification Requirements for PC, Tablet, or Laptop
Processor	2.5 GHz or higher
Memory	4 Gigabyte or more
Video Chipset	Intel 815EM or higher performance equivalent, NVIDIA recommended
Video Memory	Up to 16 MB SDR or equivalent
Display	12.1" TFT 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	Outline Drawing	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, 15, 20 cm
USB PROBE GP 5.0 MHz AB 5.0 MHz		**Human Abdominal** Focal Point - 6 cm Max depth - 20 cm Patient contact area - 32 mm Displayed depth - 10, 15, 20 cm
USB PROBE SP 7.5 MHz PI 7.5 MHz		**Human Superficial Anatomy** Focal Point - 2.0 cm Max depth - 10 cm Patient contact area - 20 mm Displayed depth - 3, 5, 6, 10 cm
USB PROBE MV 12.0 MHz		**Human Vascular / Phlebotomy** Focal Point - 0.5 cm Max depth - 3 cm Patient contact area - 29 mm Displayed depth - 3 cm
USB PROBE NV 12 MHz		**Human Near Field Vascular** Focal Point - 0.5 cm Max depth - 3 cm Patient contact area - 29 mm Displayed depth - 3 cm
USB PROBE SR 7.5 MHz VA 7.5 MHz		**Human Superficial Anatomy** Focal Point - 2.0 cm Max depth - 10 cm Patient contact area - 20 mm Displayed depth - 3, 5, 6, 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 - 3, 5, 6, 10 cm
USB PROBE ER 7.5 MHz ES 7.5 MHz		**Human Endocavity Trans-Rectal 360** Focal Point - 2 cm Max depth - 10 cm Patient contact area - 64 mm Displayed depth - 3, 5, 6, 10 cm
USB PROBE ER 12.0 MHz ES 12.0 MHz		**Human Endocavity Trans-Rectal 360** Focal Point - 1.8 cm Max depth - 6 cm Patient contact area - 64 mm Displayed depth - 3, 5, 6 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 (ER 7.5 MHz / ES 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 (ER 12.0 MHz / ES 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)	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 * Based on comparative analysis							

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 SeeMore Probes - Indications for Use

SeeMore 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	●	●						
Trans-esophageal								
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.

4. USB Transducer MV 12.0 MHz / NV 12.0MHz:
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.

5. 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.

6. 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.

7. <u>USB Transducer ER 7.5 MHz / ES 7.5 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 7.5 MHz. In B-mode the transducer operates over a 60 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.

8. <u>USB Transducer ER 12.0 MHz / ES 12.0 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 12.0 MHz. In B-mode the transducer operates over a 60 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 provide adequate encryption to prevent unauthorized viewing.
5) Regularly back up your data and store in a safe place.

Note: Interson/SeeMore 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.

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

Appendix I - Warranty and Extended Warranty Registration

Interson probes come with a standard one-year return-to-factory warranty. You can register your probe(s) 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 probes 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: $300 USD per probe

Additional Two years coverage: $600 USD per probe

Probe Model Name / Part Number	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