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SeeMore

USB Ultrasound

Instructions For Use

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Information in this document is subject to change without notice.

CE 2797

This Instructions For Use is applicable to but not limited to the following probes:

3.5 MHz General Purpose (GP)

12.0 MHz Endorectal (ER)

7.5 MHz Vascular (SR)

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, European Union and state and local regulatory agencies.*

2. Device

2.1 Commercial Name:

Interson USB Ultrasound Probe System

2.2 Generic Name:

Diagnostic Ultrasound System and Accessories

2.3 Prescription Device Statement

CAUTION

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

2.4 Device Description

The Interson USB Ultrasound Probe System is a self-contained portable, multiple-mode, and multiple-application ultrasound imaging system. The system contains an ultrasound generator/receiver, analog to digital converter, microcontroller, control logic, USB 2.0 interface and control offering a full complement of conventional operating modes, software-based parameter controls, and recording. The selection nine transducers to be offered with the system permits a wide range of clinical applications including fetal heart, abdomen, OB/GYN, vascular, extremity, pediatric, cardiac, neonatal cephalic, urology, and ophthalmology. With these general areas of intended use, the various transducers adapt the system for the specific imaging tasks.

Nine different models of the USB Ultrasound Probe System are available and any two may be connected at the same time to a USB 2.0 port. In addition to the initial operational settings for each USB Ultrasound Probe System are preprogrammed in the system. User-customized parameter settings for each USB Ultrasound Probe System may be inserted by the operator and stored for recall as needed via the system control panel. Customization includes transmit power, images controls selection, and Time Gain Compensation (TGC). Controls are also provided to select display format and to utilize the Cine function.

The Interson USB Ultrasound Probe System is a B-Mode scanner and supports a wide variety of applications. It is an ultrasound scanner, which provides high resolution, and high penetration performance. Probes are supported in frequencies from 3.5 MHz to 48.0 MHz. These probes can be applied to a variety of fields such as fetal, abdomen,

OB/GYN, vascular, extremity, pediatric, cardiac and urology. The Interson USB Ultrasound Probe System provides various measuring functions. It can measure distances and calculate areas, circumferences and volumes, as well as calculate the date of delivery by using biparietal diameter (BPO), head circumference (HC), abdominal circumference (AC), femur length (FL), crown rump length (CRL), and gestational sac (GS). Prostate and bladder volume calculations are also available. Biopsy guidelines are provided on screen to assist in the collection of tissue samples. The Operating Modes of the Interson USB Ultrasound Probe System is B-Mode, The Interson USB Ultrasound Probe System supports the Cine function (capable of storing up to 32 to 1024 sequential images). Management of patient history is possible by image-storage function.

For more information on Interson Probe System refer to Appendix B, and for more information on Interson Probe System Specification refer to Appendix D.

2.5 Indications for Use

Please refer to Appendix F.

2.6 Contraindications

None

2.7 Clinical Benefit

The expected clinical benefits of Interson USB ultrasound probe System are related to the device's intended purpose to aid in the diagnosis of diseases or conditions via imaging visualization and fluid flow analysis of the target tissue. The use of portable ultrasound imaging such as Interson USB ultrasound probe System significantly reduces the need for hospital visits, making the process more convenient for patients.

3. Minimum System Requirements

- Computer Operating System: Windows 7, 8
- Minimum processor: 2.5 GHz
- Minimum RAM: 4 GB RAM
- USB 2.0 port

Please refer to Appendix C – Computer System Specification for more detail.

4. Warnings, Safety Information

4.1. Meaning of Signal Words

In this User's Manual, the signal words such as "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.
	Type BF Equipment (B = body, F = floating applied part).
	Follow Operating Instructions
	"Attention", refer to User's Manual

4.2. 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

Do not insert the probe connector into any USB ports other than those on your computer or tablet.

WARNING

The use of a AC adapters which have not been tested for electrical safety could potentially cause harm to the system, the probe, the operator and/or the patient. Interson recommends that you use only the AC adaptor supplied by the manufacturer of your computer or tablet. Such adaptors should display certification of electrical safety testing. If you are using a battery-operated system you can disconnect the AC adapter to obviate this warning.

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 (high frequency) 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.

WARNING

Health care providers who maintain or transmit health information are required by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the European Union Data Protection Directive (95/46/EC) to implement appropriate procedures: to ensure the integrity and confidentiality of information; to protect against any reasonably anticipated threats or hazards to the security or integrity of the information or unauthorized uses or disclosures of the information.

Please refer to Appendix H – Patient Privacy and Confidentiality.

4.3. 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 (B = body, F = floating applied part)
	Follow Operating Instructions
CE 2797	Affixed to a Class 1 device requiring verification by the Notified Body of sterilization or measurement features, or to a Class IIa, IIb or III device requiring verification or auditing by the Notified Body to applicable Annex(es) of 93/42/EEC and 2017/745.
	Equipment manufacturer
	“Attention”, refer to User’s Manual
EC REP	EC Representative
	TUV Rheinland of North America, Inc, cTUVus Certification
MD	Medical Device

5. Healthy Scanning Guidelines

WARNING

Use of an ultrasound system may be linked to musculoskeletal disorders (MSDs).

Use of an ultrasound system is defined as the physical interaction between the operator, the ultrasound system, and the transducer.

WARNING

When using an ultrasound system you may experience occasional discomfort in your hands, fingers, arms, shoulders, eyes, back, or other parts of your body. However, if you experience symptoms such as constant or recurring discomfort, pain, throbbing, aching, tingling, numbness, burning sensation, or stiffness, do no ignore these warning signs. Promptly see a qualified health professional. Symptoms such as these can be linked with MSDs. MSDs can be painful and may result in potentially disabling injuries to the nerves, muscles, tendons, or other parts of the body. Examples of MSDs include carpal tunnel syndrome and tendonitis.

5.1 Position the System

- Promote comfortable shoulder, arm and hand posture.
- Minimize eye strain, adjust the angle of the system/display to minimize glare from the overhead or outside lighting.
- When the exam/procedure allows, position the system within reach.
- Minimize neck strain, if using a stand, adjust the stand height such that the display is at or slightly below eye level.

5.2 Position Yourself

- Support your back during an exam/procedure:
    - Use a chair that has support for your lower back.
    - Use a chair that adjusts to your work surface height and promotes a natural body posture.
    - Use a chair that allows for quick height adjustments.
    - Always sit or stand in an upright manner. Avoid bending or stooping.

- Minimize reaching and twisting:
    - Use a bed that is height adjustable.
    - Position the patient as close to you as possible.
    - Face forward. Avoid twisting your head or body.
    - Move your entire body front to back and position your scanning arm next to or slightly in front of you.
    - Stand for difficult exams to minimize reaching.

- Promote comfortable shoulder and arm postures for your scanning arm:
    - Keep your elbow close to your side.
    - Relax your shoulders in a level position.
    - Support your arm using a support cushion or pillow, or rest it on the bed.

- Minimize neck bending and twisting:
    - Position the ultrasound system/display directly in front of you.

- Promote comfortable hand, wrist, and finger postures for your scanning arm:
    - Hold the transducer lightly in your fingers.
    - Minimize the pressure applied on the patient.
    - Keep your wrist in a straight position.

5.3 Take Breaks

Minimizing scanning time and taking breaks can be very effective in allowing your body to recover from physical activity, which can help you avoid any MSDs.

- Plan your work so there are breaks in between ultrasound exams.
- Avoid sustaining the same posture by varying your head, neck, body, arm and leg positions.

5.4 Exercise

Targeted exercises can strengthen muscle groups, which may help you avoid MSDs. Contact a qualified health professional to determine stretches and exercises that are right for you.

6. 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.

WARNING

To avoid risk of injury, 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.

7. 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.

8. 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.

8.1. 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.

2 Wear protective gloves when performing the cleaning process.

3 Disconnect the probe from the system.

4 Remove any sheaths, biopsy guide adapters, and biopsy needle guides.

5 Discard sheaths (sheaths are a single-use item) in a biohazard container.

6 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.

7 To remove remaining particulates, rinse with water up to probe's USB cable connection.

8 Wipe with a dry cloth; or wipe with a water-dampened cloth to remove soap residue, and then wipe with a dry cloth.

8.2. 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	K924434
Cidex Plus®	USA	Liquid	Gluteraldehyde	K923744
Sporicidin®	USA	Liquid	Gluteraldehyde	K922262
Resert™ XL HLD	USA	Liquid	Hydrogen peroxide	K080420

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

WARNING

The level of disinfection required for a device is dictated by the type of tissue it will contact during use. To avoid infection, ensure the disinfectant type is appropriate for the equipment. For information, see the disinfectant label instructions and the recommendations of the Association of Professional in Infection Control and Epidemiology (APIC) and the U.S. Food and Drug Administration (FDA).

WARNING

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

For more information on probe warranty please refer to Appendix H and Appendix I.

WARNING

Disinfect probes using only Interson-approved methods. Using autoclave, gas (EtO), heat or radiation to sterilize or other non-Interson-approved methods will permanently damage the probe and void the warranty.

For more information on probe warranty please refer to Appendix H and Appendix I.

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.
3. Immerse the probe up to the cable in the disinfecting solution per the manufacturer's recommendations of duration. Do not immerse any part of the probe's cable or cable connector.

4. Using the instructions on the disinfectant or sterilization label, rinse the probe up to the point of cable, and then air dry or towel dry with a clean cloth.

8.3. Surface Cleaning

Refer to “Probe Cleaning”

8.4. Surface Disinfection

Refer to “Probe Disinfecting”

9. 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 Appendix E of this manual for Acoustic measurements.

10. Electromagnetic Compatibility (EMC)

The Interson USB powered ultrasound probes have completed and passed EN 60601-1-2.

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 requirements for EMC with other devices.

See Appendix J of this manual for EMC test details.

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.

11. 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.

12. Getting Started

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.

12.1 Install Software

Please refer to Appendix A.

12.2 Transducer Preparation

WARNING

Some transducer sheaths contain natural rubber and talc, which can cause allergic reactions in some individuals. For more information, see the FDA's March 29, 1991, Medical Alert on latex products.

Acoustic coupling gel must be used during exams.

12.3 General Use

Apply a liberal amount of gel between the transducer and the body.

12.4 Invasive or Surgical Use

WARNING

To prevent contamination, the use of sterile transducer sheaths and sterile coupling gel is recommended for clinical applications of an invasive or surgical nature. Do not apply the transducer sheath and gel until you are ready to perform the procedure.

12.4.1 Installing Sheaths

Note: Interson recommends the use of market-cleared, transducer sheaths for intracavitary or surgical applications. To lessen the risk of contamination, install the sheath only when you are ready to perform the procedure.

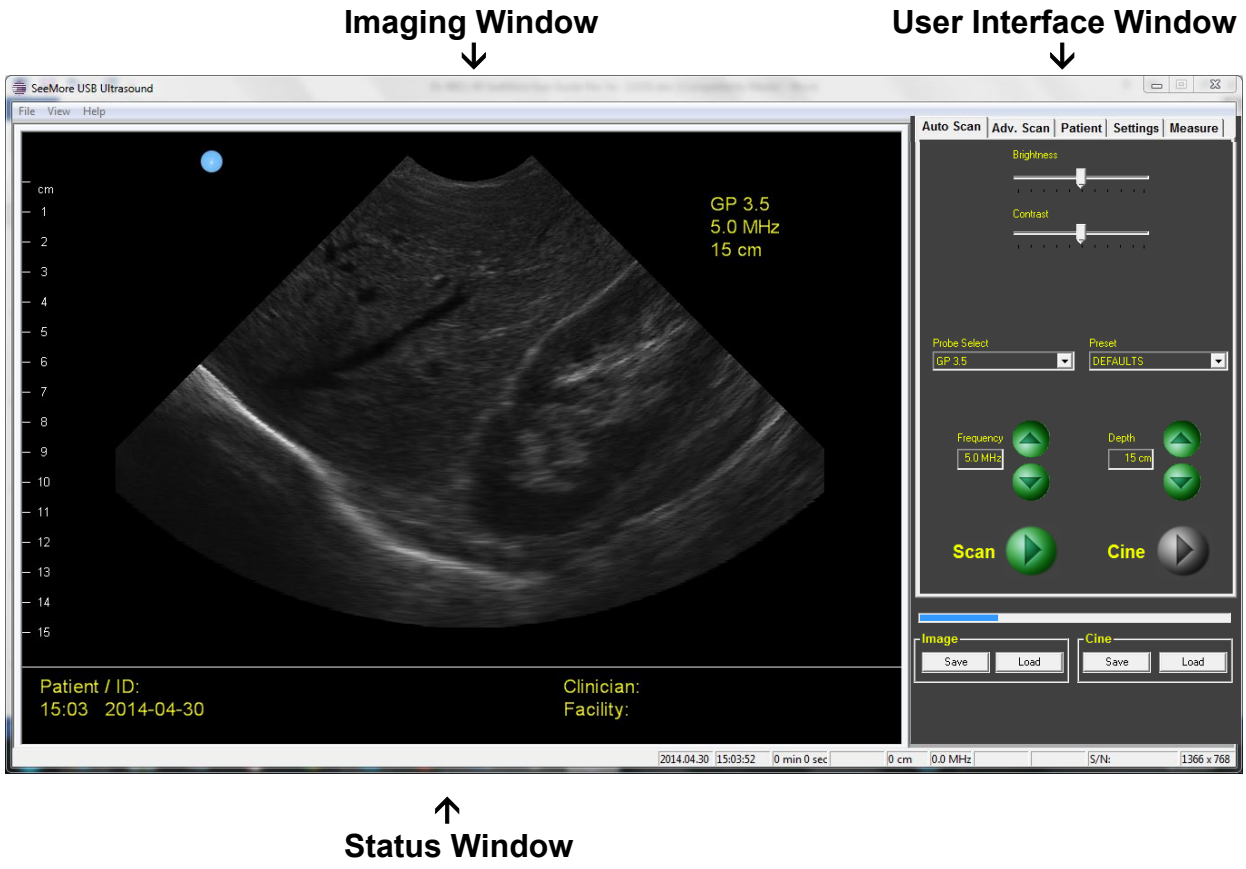
1. Place gel inside the sheath.
2. Insert the transducer into the sheath.

3. Pull the sheath over the transducer and cable until the sheath is fully extended.
4. Secure the sheath using the bands supplied with the sheath.
5. Check for and eliminate bubbles between the face of the transducer and the sheath. If any bubbles are present between the face of the transducer and the sheath, the ultrasound image may be affected.
6. Inspect the sheath to ensure there are no holes or tears.

13. 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, the probe and probe settings, and includes added measurements, calculations and annotations. The **Status Window** displays patient information for the active exam. 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.*

14. 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**. ***Section 14 is for the SeeMore version 4 user interface. For SeeMore version 2 user interface refer to Appendix I.***

14.1 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 selected probe.

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.

14.2 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 **Brightness** 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 selected probe.

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.

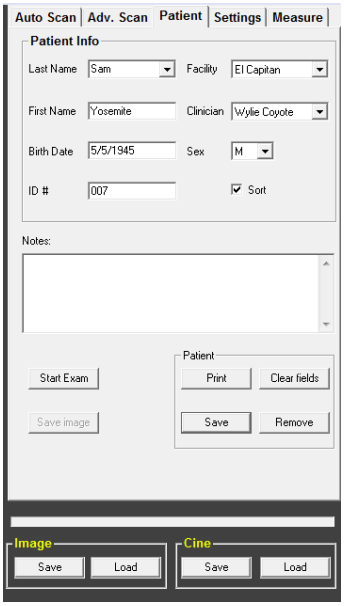
SeeMore automatically saves the most recent frames. After stopping a scan the most recent frames can be replayed by pressing the **Cine** play button. The number of frames that are automatically saved in the Cine frames buffer can be set in the **Settings** tab.

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.

14.3 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. After pressing **Start Exam**, 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 to the patient folder each time **Save Image** is pressed.

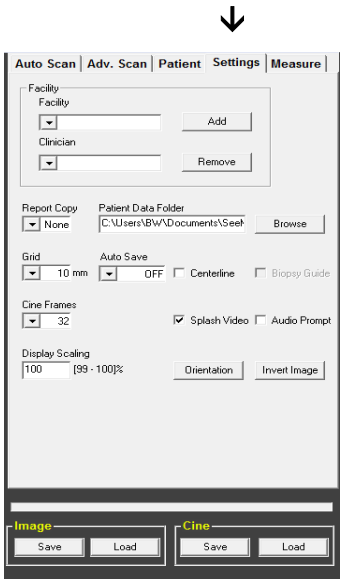
Prior to pressing **Save Image**, you may scroll to a specific image by using the arrow keys on the keyboard or the scroll wheel on the mouse. You may add measurements, annotations, and calculations prior to pressing **Save Image**. To end a patient exam press **Stop Exam**.

After pressing **Stop Exam**, **Print** will print a single page report for the selected patient's **Last Name**. The patient 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 using the **Image Save** at the bottom of any page.

14.4 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.

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 after selecting **Start Exam** in the Patient tab and then use **Save Image**, just under the **Start Exam** button.

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 each Cine frame.

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 default is 100%. If you desire to modify the size of the SeeMore application window, enter a value, press return, and then close and reopen SeeMore to respect the new display scaling.

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

Invert Image flips the image up and down.

14.5 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 five 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. **Angle** is invoked by placing three points on the image window. The second point is the angle's vertex.

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 (using **Start Exam** from the **Patient** tab), the calculations and 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 bottom of any control tab**.**

Statement of Accuracy

Accuracy of distance measurements are ± 5 % ± 5 mm.

15. 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 including 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 instructions and the **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 **Image Load** 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 adjust the gain controls, and intensity and contrast for 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 .jpg 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 a patient exam, you can print the exam by selecting the patient's last name in the Patient Tab and then select **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, at the bottom of each control tab and double click the Cine image file that you want to review. To single step through each frame of a Cine loop, use the arrow keys on the keyboard or scroll wheel on the mouse. You can adjust the gains, as well as intensity and contrast, and perform measurements on any displayed image.

16. Storage

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

⚠ CAUTION

Disinfect the probe before use. To avoid it from becoming 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*

17. 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 carrying case or enclosure that the probe was originally packaged in.
- Call Interson for an RMA (Return Material Authorization) number before returning a probe for evaluation and possible repair.
- When returning for repair, return probe in original package. If the original package is not available, contact Interson for the best packaging method prior to sending a probe in for evaluation and possible repair.

18. 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 is dropped on a hard surface it can be damaged.

DO NOT DISCONNECT or REMOVE USB CABLE FROM THE PROBE

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. Please refer to section 7 (Cleaning and Disinfection) for more detail.

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

⚠ 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.

19. 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.

20. Troubleshooting

If a problem is experienced with the USB probe, try the suggestions as listed below:

- **No Image:**
  - Disconnect the Probe; exit program and turn off computer.
  - Turn on the computer, reconnect the Probe and Restart the program.

- **Image not clear:**
  - Adjusting the **Image Controls** on the right of the screen by changing Gains, Intensity (brightness) and Contrast.

- **Error messages:**
  - Repeat all steps listed in “No Image”.

21. Customer Service

If unable to find the solution by using this manual or **Help** command, contact Interson customer service or local Interson distributor.

Prepare to call customer service:

To receive the fastest possible resolution of a problem, have the following information available when calling 925-462-4948 or e-mailing support@interson.com:

- Serial number, product name and model.
- Purchase date on the invoice.
- Conditions under which the problem occurred.
- Error messages that have been displayed.
- Operating system version number.

Taking the probe(s) to service partner:

If advise to take the USB probe(s) to service partner, be sure to provide the service partner with the information listed in “Prepare to call customer service”.

22. Adverse Event Reporting

Report any serious incident that occurs in relation to the Ultrasound Probe System to Interson Corporation and to the competent authority of the country in which the user and patient are established.

23. Glossary of Terms

- **USB Images:** The raw, unprocessed data obtained from the scanner.
- **Cine:** Shorthand for “Cine Buffers”.
- **Cine Buffers:** Stored image frames that record a history of a scanning session. The more image frames, the longer the history that may be saved and played back.
- **FPS:** Frames per Second.
- **JPEG:** Joint Photographic Experts Group. Commonly used to refer to an image file format defined by this group.
- **KB:** Kilobytes (2^{10} = 1024 bytes).
- **MB:** Megabytes (2^{20} = 1048576 bytes).
- **Pixel:** Picture Element; the smallest unit of display on a monitor.
- **USB:** Universal Serial Bus. A standard for connecting peripherals to computers.

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.
3. Click on the icon **SeeMoreSetup *x.yy.zz*.exe**
4. Follow the instructions per SeeMore Installation.pdf.
5. Remove the Memory Stick and store it in a safe place.
6. Do *NOT* launch the SeeMore 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 will confirm the installation.
9. Launch the SeeMore application using the shortcut on the desktop.
10. The second driver will install. Windows will confirm the installation.
11. 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 • Auto image save 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, 7.5 MHz, 12 MHz*
Depth Selections	2 cm through 24 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 32-1024 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: 50°C (122°F) • Min operating temperature: -10°C (14°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 AC adapters which have not been tested for electrical safety could potentially cause harm to the system, the probe, the operator and/or the patient. Interson recommends that you use only the AC adaptor supplied by the manufacturer of your computer or tablet. Such adaptors should display certification of electrical safety testing. If you are using a battery-operated system you can disconnect the AC adapter to obviate this warning.

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

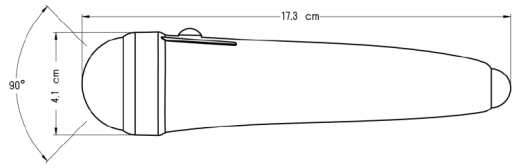
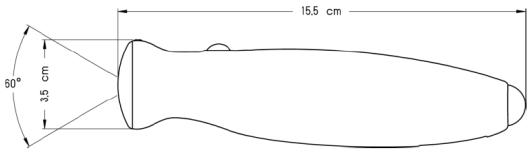
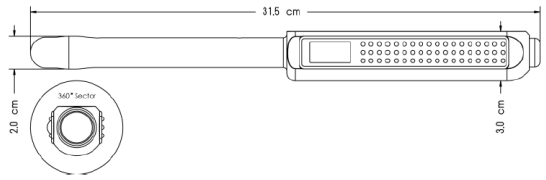
Open System Architecture	System Specification Requirements for PC, Tablet, or Laptop
Processor	2.5 GHz or higher
Memory	4 Gigabyte or more
Video Chipset	Intel 815EM or higher performance equivalent, NVIDIA recommended
Video Memory	Up to 16 MB SDR or equivalent
Display	12.1" TFT XGA 1366x768 or greater
Digital Ports	2 USB 2.0 Port(s) (full speed)
Keyboard	83 Keys or equivalent
Mouse	Touchpad, Laser Mouse, USB Mouse, or equivalent
AC Adapter	Medical Grade
Battery Type	PCGA-BP2R or equivalent
Operating System	Windows 7, 8
Software	Interson Corporation – USB ultrasound version 4.0.02 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

See Appendix F for the Indications for Use for each probe.

Model	Product Design	Specifications
GP 3.5 MHz		Focal Point: 7.5 mm Max depth: 24 cm Patient contact area: 35 mm Displayed depth: 10 - 24 cm
SR 7.5 MHz		Focal Point: 2.0 cm Max depth: 10 cm Patient contact area: 12 mm Displayed depth: 3 – 10 cm
ER 12.0 MHz		Focal Point: 1.6 cm Max depth: 6.0 cm Patient contact area: 64 mm Displayed depth: 4 – 10 cm

Appendix E - Summary of the Acoustic Quantities

Table 1: Summary of Acoustic quantities: GP 3.5 MHz Probe

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.50	0.61		0.61		0.29
Index component value				0.61	0.61	0.61	0.61	
Acoustic Parameters	$p_{r,a}$ at z_{MI}	(MPa)	0.90					
	P	(mW)		38.84		38.84		38.84
	$P_{1\times1}$	(mW)		38.84		38.84		
	z_s	(cm)			N/A			
	z_b	(cm)					N/A	
	z_{MI}	(cm)	5.43					
	$z_{pii,a}$	(cm)	5.43					
	f_{awf}	(MHz)	3.30	3.30		3.30		3.30
Other Information	prr	(Hz)	3840.0					
	srr	(Hz)	15.0					
	n_{pps}		1					
	$I_{pa,a}$ at $z_{pii,a}$	(W/cm2)	68					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$	(mW/cm2)	3.98					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm2)	13.50					
	p_r at z_{pii}	(MPa)	1.66					
Operating control conditions	90 degree scan angle							
	15 Hz scan rate							
	256 lines per scan							

NOTE 1 Only one operating condition per index.
NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB.
NOTE 3 Information need not be provided regarding TIC for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.
NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.
NOTE 6 Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.
NOTE 7 The depths z_{pii} and $z_{pii,a}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,a}$ apply to SCANNING MODES.

Table 2: Summary of Acoustic quantities: SR 7.5MHz Probe

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			1.04	0.30		0.30		0.25
Index component value				0.30	0.30	0.30	0.30	
Acoustic Parameters	pr,α at zMI	(MPa)	2.27					
	P	(mW)		17.65		17.65		17.65
	P1×1	(mW)		13.38		13.38		
	zs	(cm)			N/A			
	zb	(cm)					N/A	
	zMI	(cm)	1.30					
	zpii,α	(cm)	1.30					
	fawf	(MHz)	4.75	4.75		4.75		4.75
Other Information	prr	(Hz)	4608.0					
	srr	(Hz)	18.0					
	npps		1					
	Ipa,α at zpii,α	(W/cm2)	360					
	Ispta,α at zpii,α or zsii,α	(mW/cm2)	36.15					
	Ispta at zpii or zsii	(mW/cm2)	55.36					
	pr at zpii	(MPa)	2.80					
Operating control conditions	60 degree scan angle							
	18 Hz scan rate							
	256 lines per scan							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB. NOTE 3 Information need not be provided regarding TIC for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths zpii and zpii,α apply to NON-SCANNING MODES, while the depths zsii and zsii,α apply to SCANNING MODES.

Table 3: Summary of Acoustic quantities: ER 12 MHz Probe

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.46	9.45E-03		9.45E-03		3.31E-02
Index component value				9.45E-03	9.45E-03	9.45E-03	9.45E-03	
Acoustic Parameters	pr,α at zMI	(MPa)	1.44					
	P	(mW)		1.25		1.25		1.25
	P1×1	(mW)		0.19		0.19		
	zs	(cm)			N/A			
	zb	(cm)					N/A	
	zMI	(cm)	1.30					
	zpii,α	(cm)	1.30					
	fawf	(MHz)	9.70	9.70		9.70		9.70
Other Information	prr	(Hz)	5120.0					
	srr	(Hz)	10.0					
	npps		1					
	Ipa,α at zpii,α	(W/cm2)	1.1E+02					
	Ispta,α at zpii,α or zsii,α	(mW/cm2)	0.59					
	Ispta at zpii or zsii	(mW/cm2)	1.40					
	pr at zpii	(MPa)	2.22					
Operating control conditions	360 degree scan angle							
	10 Hz scan rate							
	512 lines per scan							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB. NOTE 3 Information need not be provided regarding TIC for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths zpii and zpii,α apply to NON-SCANNING MODES, while the depths zsii and zsii,α apply to SCANNING MODES.

Appendix F - Interson SeeMore Probes - Indications for Use

Interson probes are intended for transcutaneous imaging to aid in the detection and assessment of physical and functional abnormalities using established diagnostic criteria, as follows:

SeeMore USB Probes **Clinical Application**	GP 3.5 MHz	ER 12.0 MHz	SR 7.5 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)			

See Appendix D for descriptions of each probe.

Appendix G – EMC Information

Guidance and manufacturer's declaration – electromagnetic emissions		
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.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	Interson's USB Ultrasound Probes use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 6100-3-2	N/A	N/A
Voltage fluctuations / flicker emissions IEC 6100-3-3	N/A	

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.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2kV ±4kV ±6kV contact discharge ±2kV ±4kV ±8kV air discharge	±2kV ±4kV ±6kV contact discharge ±2kV ±4kV ±8kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 1 kV I/O Lines 5/50 5 kHz	± 1 kV I/O Lines 5/50 5 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	N/A	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	N/A	N/A	N/A

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.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz 3 V_{rms} 1 kHz	150 kHz to 80 MHz 3 V_{rms} 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level b in each frequency range Interference may occur in the vicinity of equipment marked with this symbol. 
Radiated RF IEC 61000-4-3	80 MHz to 2.5 GHz 3 V/m, 80% @ 1 kHz	80 MHz to 2.5 GHz 3 V/m, 80% @ 1 kHz	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 66.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, 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 USB Ultrasound Probe is used exceeds the applicable RF compliance level above, the USB Ultrasound Probe should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the USB Ultrasound Probe.

d. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m

Appendix H - 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.

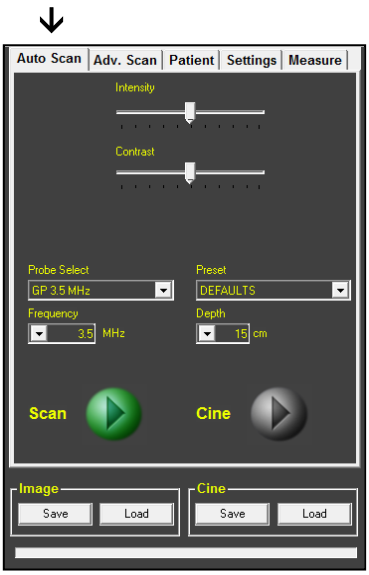
Note: Interson software does not include electronic signature control and is not meant to substitute for an electronic medical record.

Appendix I - SeeMore User Controls, Version 2 User Interface

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**.

I.1. Auto Scan Tab, version 2 user interface

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.

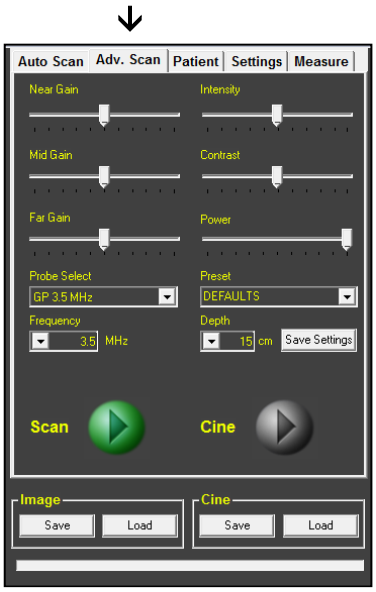
SeeMore automatically saves the most recent frames. After stopping a scan the most recent frames can be replayed by pressing the **Cine** play button. The number of frames that are automatically saved in the cine frames buffer is selected in the **Settings** tab.

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.

I.2. Advanced Scan Tab, version 2 user interface

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.

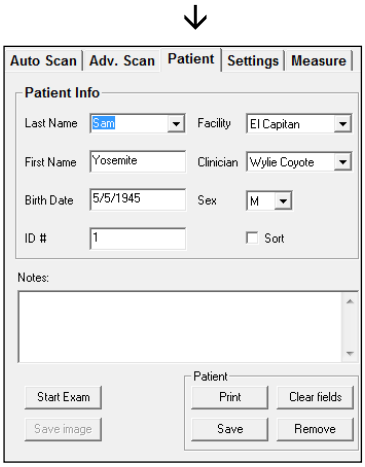
SeeMore automatically saves the most recent frames. After stopping a scan the most recent frames can be replayed by pressing the **Cine** play button. The number of frames that are automatically saved in the Cine frames buffer can be set in the **Settings** tab.

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.

I.3. Patient Tab, version 2 user interface

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.

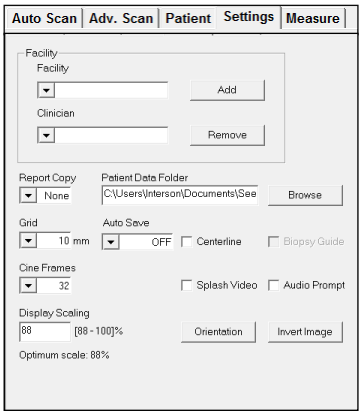
Start Exam posts the current patient information to the Status Window and makes a patient folder in the Documents/SeeMore Data/Patient Data directory. Images and calculations are stored to this folder. Start and then stop/freeze a scan. You may use either the **Scan** button on the screen, the button 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.

I.4. Settings Tab, version 2 user interface

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.

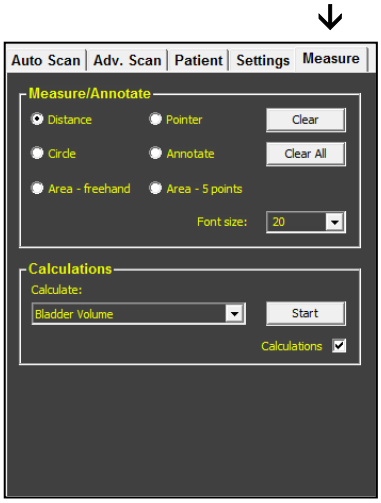
Display Scaling controls the size of the SeeMore application window. Setting display scaling larger than optimal, will cause Windows to add pixels to the image data. Enter a value, press return, close and reopen SeeMore to change the display scaling.

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.

I.5. Measure Tab, version 2 user interface

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. **Angle** is invoked by placing three points on the image window. The second point is the angle's vertex.

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 ± 5 % ± 5 mm.

Appendix J – Calculations

Industry standard calculations* are available from the Measure Tab. Specific calculations may or may not be available depending on the version and date of your SeeMore application software. Contact Interson about enabling specific calculations that may not be available in your SeeMore application software.

Available Calculations:

Abdominal Circumference
Hadlock 1984
8.14 + 0.753 * [cm] + 0.0036 * [cm]) ^ 2

Bi-Parietal Diameter
Hadlock 1984
9.54 + 1.482 * [cm] + 0.1676 * [cm] ^ 2

Bladder Volume
$= 0.0285x^2 – 3.6624x + 129.65$, where x = H + W

Bladder Volume 3D
Poston et al, 1983
= 0.7 x H x W x T

Crown Rump Length
Hadlock 1992
1.684969 + 0.315646 * [cm] - 0.049306 * [cm] ^ 2 + 0.004057 * [cm] ^ 3
- 0.000120456 * [cm] ^ 4

Femur Length
Hadlock 1984
10.35 + 2.46 * [cm] + 0.17 * [cm] ^ 2

Gestational Sac
Nyberg 1992
([mm])/10) + 4.28

Gestational Sac 2-plane
Nyberg 1992
([mm])/10) + 4.28

Head Circumference
Hadlock 1984
8.96 + 0.54 * [cm] + 0.0003 * [cm]^ 3

Prostate Volume
= 0.5 x H x W x T

* http://dicom.nema.org/MEDICAL/Dicom/2014a/output/chtml/part16/sect_CID_12013.html

Appendix K – Interson Customer Warranty

Interson (“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
7150 Koll Center Parkway
Pleasanton, CA 94566 USA
Phone: 925.462.4948
Fax: 925.462.4833
Email: support@interson.com
Website: www.interson.com

Appendix L - 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
7150 Koll Center Parkway
Pleasanton CA 94566
Tel: 925.462.4948
Fax: 925.462.4833
Email: support@interson.com
www.interson.com