



Instructions For Use

# Simpli Series

Ultrasound Imaging System

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Information in this document is subject to change without notice.

These Instructions For Use are applicable to the following Simpli™ Series probes:

GP-C01  
SP-L01

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# Overview

## Introduction

Congratulations on your purchase of the Interson Simpli Series™ Ultrasound Probe System. Please review this user manual before you begin imaging. Contact Interson or your sales representative if you have any question.

**Note: The sale of this item is subjected to regulation by the U.S. Food and Drug Administration (FDA) and state and local regulatory agencies.**

## **Y**CAUTION

*U.S. federal law restricts this device to sale by or on the order of a physician.*

## Warnings and Safety Information

### Meaning of Signal Words and Symbols

In this user manual, the signal words such as **WARNING** and **CAUTION** are used regarding safety and important instructions. All users of the Interson Ultrasound Probe System must understand the meaning of these signal words. These signal words and symbols and their meaning are as follows.

Signal Word	Meaning
<b>Y</b> WARNING	Indicates a potentially hazardous situation which, if not avoided, could cause injury or harm to the operator or patient.
<b>Y</b> 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
<b>Y</b>	<b>ATTENTION</b> , refer to user manual

### General Cautions and Warnings

## **Y**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.*

## **Y**WARNING

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

## **Y**WARNING

*Interson probes will not exhibit excessive surface temperatures under normal use. Disconnect the equipment if unsafe temperatures are observed. Refer to **Appendix I** for temperature safety information.*

## **Y**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 in such cases.*

## **Y**WARNING

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

## **Y**WARNING

*The use of 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.*

## **Y**WARNING

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

## **Y**WARNING

*USB Probe System is not to be used with HF (high frequency) surgical equipment.*

## **Y**WARNING

*The use of non-ISO 10993-compliant Ultrasound Transmission Gel could potentially cause harm to the probe, operator and/or the patient.*

## **Y**WARNING

*Do not submerge the USB probe in water.*

## **Y**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.*

## **Y**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.*

## Symbology

The following symbols may be used on Interson labeling:

	Symbol for “Serial Number”
<b>REF</b>	Symbol for “Part Number”
	Symbol indicating the “date of manufacture”
<b>CE</b>	Indicates conformance with European Council Directive 93/42/EEC and 2017/745
<b>M</b>	Equipment manufacturer
<b>P</b>	EC representative
	TUV Rheinland of North America, Inc, cTUVus Certification
	Medical Device

## Ultrasound Probes

### Device Description

The Interson USB Ultrasound Probe System is a self-contained, portable, multiple-mode, and multiple-application diagnostic ultrasound 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 of probes offered with the system permits a wide range of clinical applications including fetal, abdominal, OB/GYN, pediatric, small organ (Scrotum, prostate, lymph nodes, thyroid, breast), muscular-skeletal, pelvic floor, neuromuscular, urology, cardiac and Peripheral vessel. With these general areas of intended use, the various probes adapt the system for the specific imaging tasks.

Different models of the USB Ultrasound Probe System are available. 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 supports B-Mode mode scanning, M-Mode scanning, providing high resolution and high penetration performance. The probes can be used in applications such as fetal heart, abdomen, OB/GYN, pediatric, small organ, Musculo-skeletal, neuro-muscular, pelvic floor, cardiac, peripheral vessel and urology. The Interson USB Ultrasound Probe System can measure distances and calculate areas, circumferences and volumes. A Color Flow Mapping (CFM) mode provides a qualitative indication of fluid flow and direction. 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.

The expected service life of Interson probes is at least five (5) years.

Refer to **Appendix B** for more information on the Interson Probe System. Refer to **Appendix D** for more information on Interson probes.

## **Indications for Use**

Please refer to **Appendix G**.

## **Intended Purpose**

The Interson USB Ultrasound Array Probe System is intended for diagnostic ultrasound imaging.

## **Intended User**

The system is intended for use by trained healthcare professionals who have a general knowledge of the use of ultrasound imaging devices and imaging protocols in environments where healthcare is provided by healthcare professionals.

## **Target Patient Population**

The Interson USB ultrasound probes are intended to be used on patients, including pediatric patients, where diagnostic ultrasound is indicated. (Appendix G)

## **Contraindications**

The Interson Simpli Series GP-C01 and SP-L01 ultrasound probes are not indicated for ophthalmic use or any application that causes the acoustic beam to pass through the eye.

## Clinical Benefit

The expected clinical benefits of Interson USB ultrasound probe System is to Aid in the diagnosis of diseases via imaging visualization of target tissue.

## Acoustic Energy and Surface Temperatures

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 and **Appendix F** for guidance on how to best implement ALARA.

## Electromagnetic Compatibility (EMC)

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

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 H** of this manual for EMC test details.

### **Y** CAUTION

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

### **Y** 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.*

## 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.

## 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 probe housing and transducer lens for cracks. Regularly check the cable for cuts, cracks, and kinks. This could also impair the performance of the probe.

## Maintenance

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

## **Y** 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.*

## Cleaning and Disinfection

### **Y** WARNING

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

### **Y** WARNING

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

### **Y** WARNING

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

## 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.

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.

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

### Probe Disinfecting

A 10<sup>6</sup> 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	Phenol	K904581
Revital- Ox™ Resert® HLD	USA	Liquid	Hydrogen Peroxide	K080420

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

### **Y** 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).*

### **Y** 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 L**.*

### **Y** WARNING

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

- Examine the probe for damage such as cracks, splitting, sharp edges or projections. If damage is evident, abandon disinfection, discontinue use of the probe, and contact a customer service representative.
- 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.
- Immerse the probe up to the cable in the disinfecting solution for the recommended length of time per the manufacturer. 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 strain relief, and then air dry or towel dry with a clean cloth.

## Training

This USB probe system should be used by trained healthcare professionals only.

The specific probe functions are described in this manual and are also available through the SimpliVue system software Help Menu.

## Storage

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

## **Y** CAUTION

*Disinfect the probe before use to avoid it becoming a source of infection.*

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

- Excessive vibration
- Excessive dust and 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

## 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 a Return Material Authorization (RMA) 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.

## Disposal

1. Contact Interson Corporation before disposing of the probe(s).
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.

## Troubleshooting

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

### No image:

1. Disconnect the probe, exit the program and turn off the computer.
2. Turn on the computer, reconnect the probe and restart the program.

### Image not clear:

1. Adjust the image controls in the system controls area of the imaging display by changing gain and/or contrast.

### Error messages:

1. Repeat all steps listed in “No image.”

## Customer Service

If you are not able to find the solution by using this manual, 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 emailing **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 to a service partner:

If advised to take the USB probe to your service partner, be sure to provide the service partner with the information listed in “Prepare to call customer service.”

## 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.

## Probe Preparation

### **Y** 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.

## **General Use**

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

## **Invasive or Surgical Use**

### **Y 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.*

## **Installing Sheaths**

Interson recommends the use of market-cleared, transducer sheaths for intra-cavity 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 transducer's face and the sheath, the ultrasound image may be affected.
6. Inspect the sheath to ensure there are no holes or tears.

## **Getting Started**

### **Minimum System Requirements**

Interson cannot guarantee that SimpliVue will work on your device without issue, but your device must meet or exceed the following specifications:

- Operating System: Windows 7 & 10
- Processor: 2.5 GHz
- Memory: 4 GB
- Storage: 75 MB

- USB 2.0 port

## **System Components**

The system consists of the following:

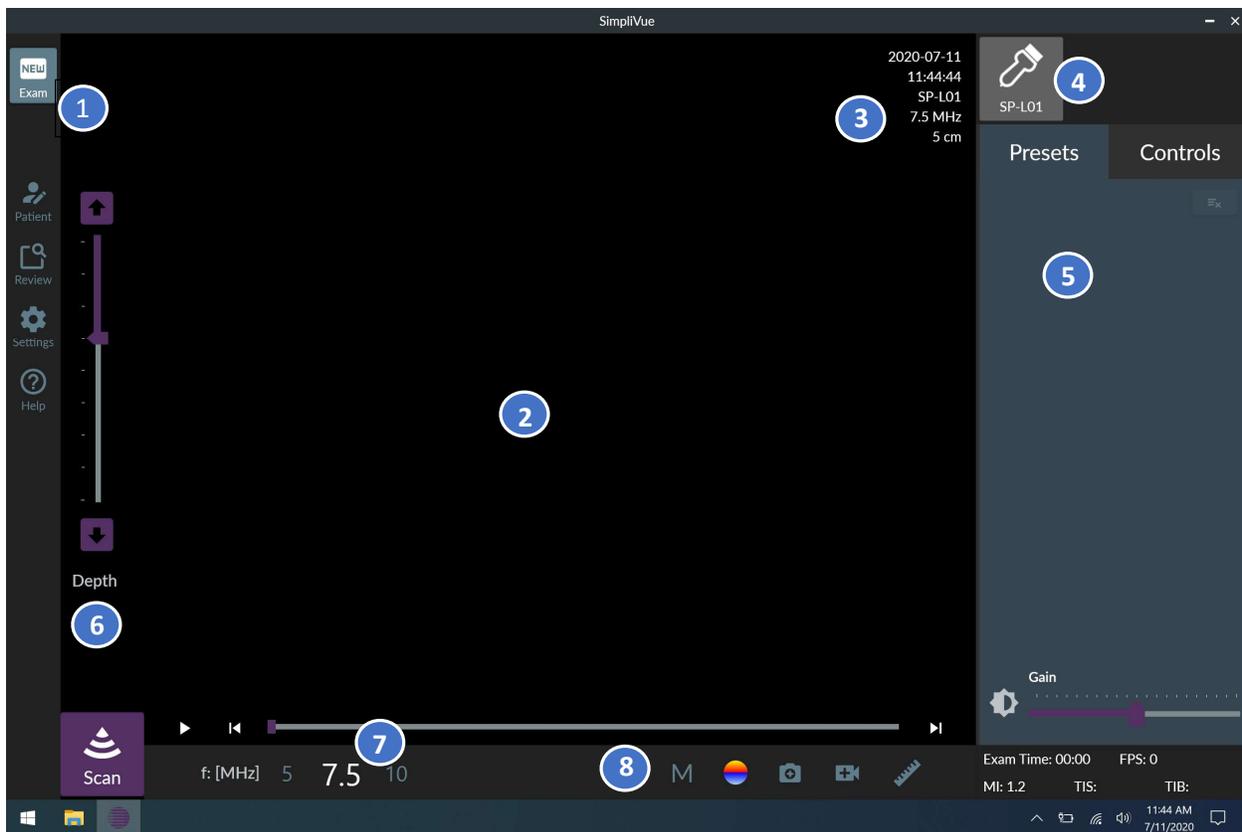
- A commercial off-the-shelf (COTS) Windows tablet, laptop, or PC
- SimpliVue running as a software on the COTS device
- The SP-L01 linear array probe and/or the GP-C01 curved array probe
- USB cable

## **Installing SimpliVue**

Please refer to **Appendix A**.

## **Imaging Display**

The imaging display contains an ultrasound image, exam and image information, depth and frequency indicators, and system controls.



## Imaging Display

- 1 Navigation menu (new exam, enter patient information, review exam, settings, help)
- 2 Image area
- 3 Image information
- 4 Probe selection
- 5 System controls area
- 6 Depth selection
- 7 Frequency selection
- 8 Imaging controls area (M-Mode, CFM, save image, save cine, measurement & annotation)

## Using SimpliVue

This section describes the common procedures that may be used in performing patient exams with the system.

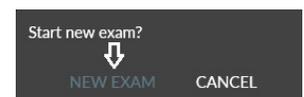
**Note: The software should be used in landscape orientation only.**

### Starting a New Exam

1. Touch **New Exam**



. On the **New Exam** dialogue box, touch **New Exam**.

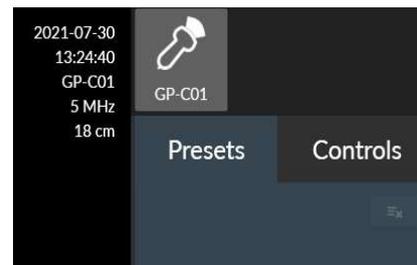


## Changing Presets

1. Touch **Presets** in the system controls area.
2. Touch a preset.
  
3. To edit a preset, select the preset you want to edit and touch **Controls**. Adjust the controls as desired and save the changes.

Refer to **Optimizing the Image**.

**Note:**



4. To delete a preset, select the preset you want to delete and touch **Delete Preset**  .

**Note:**

**You can uncheck any selected preset by clicking it again and revert to the predetermined Control settings provided with the software.**

## Editing Patient Information

1. Touch **Patient Information**  .
2. The **Patient Information Window** will appear.  
Touch the field you want to edit and use the keyboard to replace, insert, or delete text. Touch **Save**.
3. To close the **Patient Information** window, touch the **X** at the top right corner of the open window.
4. The Last Name, First Name, Patient ID, Date of Birth, and Sex fields must be completed to save a new patient profile.

A screenshot of the 'Patient Information' window. The window has a title bar with 'Patient Information' and a close 'X' button. Below the title bar are several input fields: 'Last Name', 'First Name', 'Patient ID', and 'Date of Birth'. Below these fields are two radio buttons for 'Female' and 'Male'. Below the radio buttons is a 'Notes' field with a text input area. At the bottom of the window are three buttons: 'Clear', 'Save', and 'Remove'.

5. To select an existing patient profile, expand the drop-down arrow in the Last Name field and touch a patient name. After choosing the patient profile, touch the **X** at the top right corner of the open window.
6. To delete an existing patient profile, expand the drop-down arrow in the Last Name field and touch the name of the patient. Touch **Remove**.

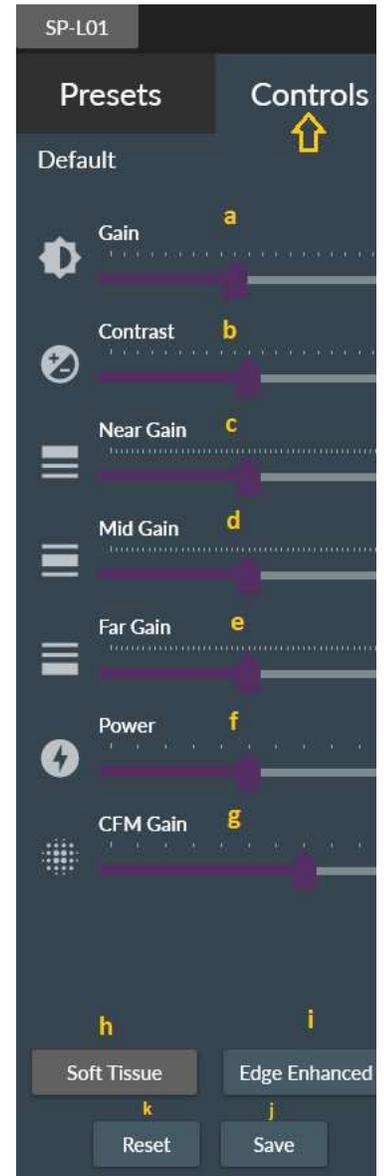
## Optimizing the Image

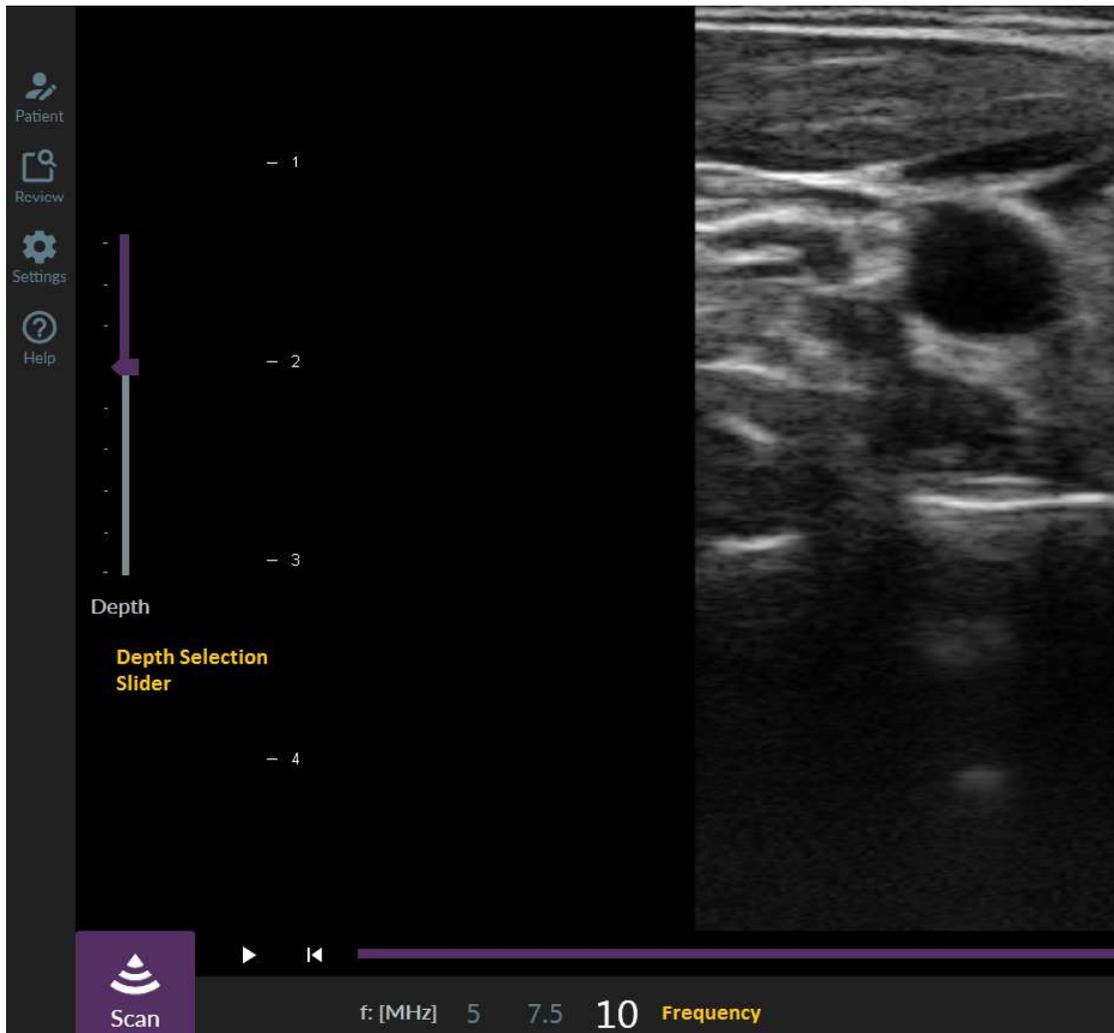
1. Touch **Controls** tab in the systems control area.
 

**Note: The controls are not all visible at the same time.**

**Use the scroll bar to scroll up or down to access all the controls.**

  - a. To control the image gain, adjust the **Gain** slider.
  - b. To control the image contrast, adjust the **Contrast** slider.
  - c. To control the gain to the part of the image closest to the probe, adjust the **Near Gain** slider.
  - d. To control the gain to the middle part of the image, adjust the **Mid Gain** slider.
  - e. To control the gain to the part of the image farthest from the probe, adjust the **Far Gain** slider.
  - f. To control the power output, adjust the **Power** slider.
  - g. To control the image gain during CFM mode, adjust the **CFM Gain** slider. High gain suppresses color information and a low setting highlights color information.
  - h. To turn soft tissue image processing filter on and off, touch **Soft Tissue**.
  - i. To turn edge enhancement image processing filter on and off, touch **Edge Enhanced**.
  - j. To save changes to image control adjustments, touch **Save**. Enter a new name in the **Save** dialogue box if you wish to create a new preset.
  - k. To reset any image control adjustments to the last saved settings, touch **Reset**.
2. To increase or decrease the image depth, adjust the **Depth** selection slider.
3. To increase or decrease the probe operating frequency, touch a frequency you want from the **frequency** selection.





## Imaging Modes

This system supports two imaging modes: B-Mode and Color Flow Mapping (CFM).

### Using B-Mode

1. The software initializes in B-Mode.
2. Touch a preset from the preset list displayed in the system controls area. To adjust the image, touch **Controls tab** and adjust the image using the controls available. Refer to **Optimizing the Image**.
3. Touch **Scan**  or push the button located on the probe. You can now begin B-mode imaging.
4. Touch **Freeze**  or push the button located on the probe to pause imaging.

### Using CFM Mode

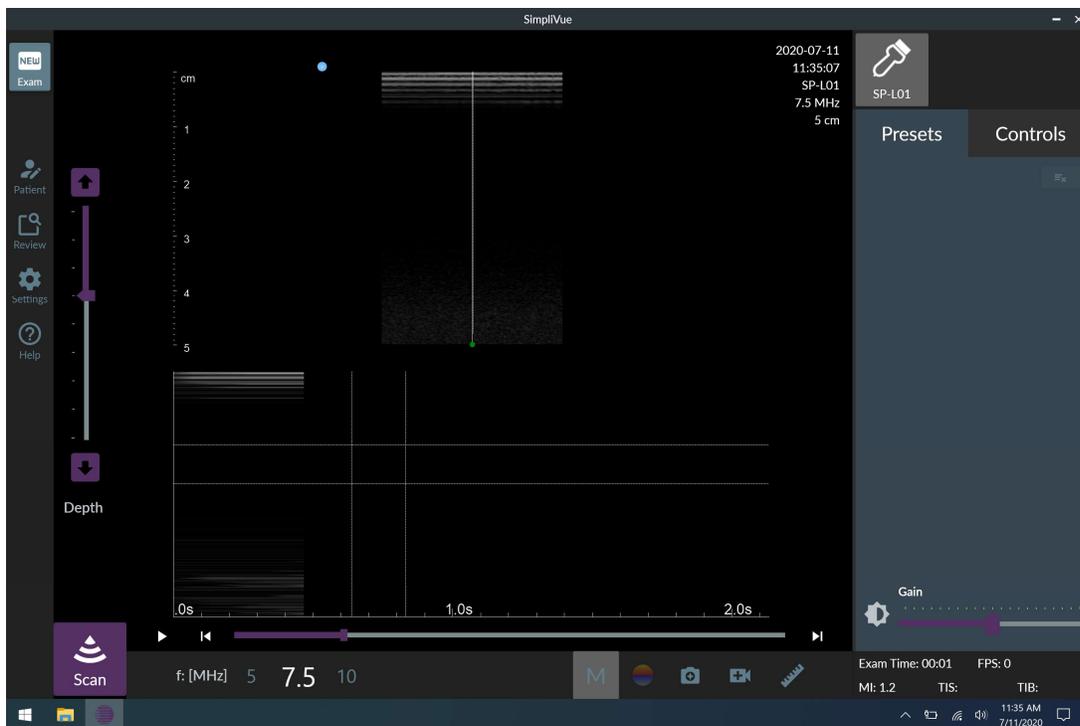
1. You must start B-mode imaging before using CFM mode. Touch **Scan**  or push the button located on the probe. You can now begin B-mode imaging.

2. Touch **CFM**  to start CFM mode. A color box is overlaid on the B-mode image. The direction and velocity of flow in the color box are represented with different colors for direction and different shades for velocity. A color key is shown to the right of the image area.
3. Touch **CFM**  again to stop CFM mode.

### Using M-Mode

1. While in B-Mode, Touch **M**  to start Motion Mode.
2. Touch **Scan**  or push the button located on the probe to start M-Mode imaging.
3. Touch **Scan**  or push the button located on the probe to stop M-Mode imaging.
4. Touch **M**  to stop Motion Mode to go back to B-Mode.

See M-Mode screen below



## Saving Images

The software automatically saves an image every time you freeze imaging. The acquired image is saved in the \_Stat Images folder by default and a thumbnail of it is available in the **Review** window.

To manually save an image, touch **Save Image** . In the **Save As** dialogue box, enter a name for the image file and touch **Save**. If no patient profile has been selected, the saved image is saved in the \_Stat Images folder by default.

NOTE: The software automatically saves up to 10 images in the \_Stat Images folder by default and these are purged upon exiting the application if no patient profile is selected. There is no limitation however while saving images in the \_Patient Data Folder.

## Saving Cines

Touch **Save Cine** . In the **Save As** dialogue box, enter a name for the cine file and touch **Save**. If no patient profile has been selected, the acquired cine is saved in the \_Stat Images folder by default.

## Imaging Tools

Touch **Additional Tools**  to display a pop-up menu of annotation, pointer, measurement, calculation tools on the screen.

Measurement tools are available when you pause imaging or when reviewing a saved image. Touch  to hide the pop-up menu.

To retain annotation, pointer, measurement, and calculation on an image, acquire it. Refer to **Saving Images**.

### Annotation

1. Touch **Annotate** .

2. Touch the image area. Use the keyboard to type your text.

**Note: You must press Enter after typing your text to complete annotation.**

3. Touch **Annotate**  to stop annotation.

### Adding pointers

1. Touch **Pointer** .

2. Touch the image area at the location you want to place a pointer.

3. Touch **Pointer**  to stop pointers.

## Measurements and Calculations

### *Performing Distance Measurements*

1. Distance measurement uses two calipers to measure the length of a straight line between two

points. Touch **Distance**  to begin distance measurements.

2. Touch the image area to place the first caliper and drag to position the second caliper. The distance measurement result is displayed next to the second caliper.

3. Touch **Distance**  to stop distance measurements.

4. To remove the last measurement, touch **Undo** .

5. To remove all measurements, touch **Clear All** .

#### *Performing Area and Circumference Measurements*

1. There are three shape tools available to measure area and circumference: **Circle** ,

**Freehand** , and **5-points** .

a. Use **Circle** measurement to define the area and circumference of a circle.

i. Touch **Circle**  to begin circle measurements.

ii. Touch the image area and drag until the circle is of the desired size. The area and circumference result are displayed next to the circle.

iii. Touch **Circle**  to stop circle measurements.

b. Use **Freehand** measurement to define the area and circumference of a custom shape.

i. Touch **Freehand**  to begin freehand measurements.

ii. Draw the desired shape in the image area. The area and circumference result are displayed next to the shape.

iii. Touch **Freehand**  to stop freehand measurements.

c. Use **5-points** measurement to define the area and circumference of a shape of best fit generated from five points placed on an image.



- i. Touch **5-points** to begin 5-points measurements.
- ii. Touch the image area five times. The area and circumference result are displayed next to the shape.

- iii. Touch **5-points**  to stop 5-points measurements.

- 2. To remove the last measurement, touch **Undo** .

- 3. To remove all measurements, touch **Clear All** .

#### *Performing Angular Measurements*

- 1. Angular measurement uses three calipers to measure an angle. The second caliper is the vertex of the angle. Touch **Angle**  to begin angular measurements.

- 2. Touch the image area to place the three calipers. The angular measurement result is displayed next to the second caliper.

- 3. Touch **Angle**  to stop angular measurements.

- 4. To remove the last measurement, touch **Undo** .

- 5. To remove all measurements, touch **Clear All** .

#### *Performing Calculations*

- 1. There are a number of calculation modes available in the software. To select a calculation to

perform, touch **Settings**  on the navigation menu. Expand the **Calculation Mode** dropdown list and touch a calculation mode. Calculation results will be displayed in the top-left area of the image area.

- 2. Touch **Calculate**  to start the calculation. Follow the instructions provided in the message appearing on top of the image area.

- 3. Touch **Stop**  or touch **Cancel** on the message to stop the calculation.

- 4. To remove the last calculation, touch **Undo** .

- 5. To remove all calculations, touch **Clear All** .

## Statement of Accuracy

Distance Measurements: Accuracy of distance measurements is the greater of  $\pm 2\%$  or  $\pm 2$  mm. All measurements made by the USB ultrasound system assume an average sound velocity of 1540 m/s in soft tissue. As the USB ultrasound system can only measure what is displayed on the screen, the operator must be diligent in obtaining a good image. Measurements should not be used as the sole determinant of diagnosis and treatment but should always be combined with other clinical data. Various factors including the scanning technique, familiarity with placement of the calipers, and the tissues being imaged, affect the image quality and thus the measurement accuracy.

Color Doppler Display: By selecting the CFM mode, the image display will show different colors to indicate fluid flow toward or away from the probe, and different shades to indicate velocity. The color information displayed is a qualitative indication of fluid flow and direction. The SP-L01 and GP-C01 probes are able to discriminate between positive and negative low flow rates of 5.5 cm/sec and 3.7 cm/sec respectively at the center of the scale, and show representative lightening of the color displayed as the flow rates increase, to a maximum scale value of  $\pm 28.0$  cm/sec.

## WARNING

*The experience and diligence of the operator in achieving a quality image are major factors in the accuracy of distance measurements. The operator must ensure that measurements are made only on suitable images to achieve accurate measurements.*

## General Settings

To configure miscellaneous settings on your software, touch **Settings**



on the navigation

### Configuring Export Destination

Touch **Browse** to the right of the **Export Destination** field. Select the folder in your local or network directory in which you want to store exam images, cines, and reports. The path to the folder you selected will appear in the **Export Destination** field.

### Editing Clinician and Facility Information

1. Touch the field you want to edit and use the keyboard to replace, insert, or delete text. Touch **Save**.
2. To select an existing user profile, expand the drop-down arrow in the Clinician field and touch a name.
3. To delete an existing user profile, expand the drop-down arrow in the Clinician field and touch a name. Touch **Remove**.

### Changing Left-Right Orientation of Image

To flip the left-right orientation of the image, touch **Orientation**

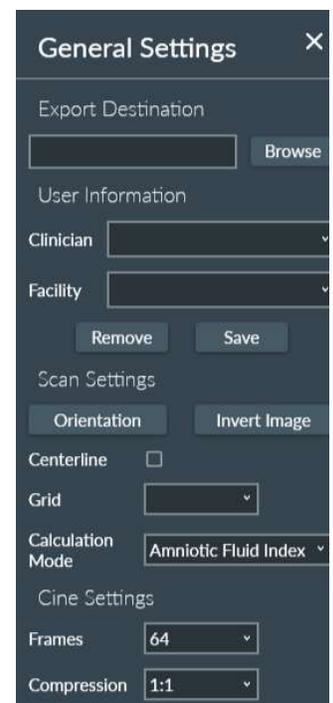
**Orientation**

**Note: The change will only take effect during live imaging or when image is unfrozen.**

### Inverting Image

To invert the image, touch **Invert Image**

**Invert Image**



**Note: The change will only take effect during live imaging or when image is unfrozen.**

## Displaying a Centerline

To display a centerline on the image, check the **Centerline** checkbox.

## Grid

Expand the **Grid** drop-down list and select the number of minor and major graduations of the depth indicator.

**Note: The change will only take effect during live imaging or when image is unfrozen.**

## Configuring Cine Duration

Expand the **Frames** drop-down list. To increase cine duration, select higher number of frames. To decrease cine duration, select lower number of frames.

**Note: The change will only take effect during live imaging or when image is unfrozen.**

## Configuring Cine Compression Setting

Expand the **Compression** drop-down list. For more compression (reduce the cine file size), select a higher compression ratio. For less compression (increase the cine file size), select a lower compression ratio.

## Review

In the **Review** window, you can view and delete automatically acquired images, load manually acquired images and cines, save changes made to an image (i.e. annotations or measurements), and generate a report.

Controls for optimizing the image are available during **Review**. Adjustments made to the controls during review will revert to its previous settings when you exit **Review** and return to imaging. Refer to **Optimizing the Image**.

To start **Review**, touch **Review**  in the navigation menu.

To exit **Review** and return to imaging, close the **Review** window and touch **Scan** .

## Reviewing Images

Thumbnails of images automatically acquired when you paused imaging appear in the **Review** window. Touch a thumbnail to view a full-sized image in the image area.

To review images not shown as a thumbnail, touch **Load Images**  and select the image file you want to review. The image will appear in the image area.

Imaging tools (annotations, pointers, measurements, and calculations) are available during review of images. To save annotation, pointers, measurements or calculations added to an image, save the image after the changes have been made. Refer to **Saving Images**.

## Reviewing Cines

1. Touch **Load Cine**  and select the cine file you want to review. The cine will appear in the image area.

2. Use the cine controls beneath the cine.



#### Cine Controls

- 1 Play and pause the cine.
- 2 Navigate backwards one frame.
- 3 Drag thumb to cycle through cine to a specific frame.
- 4 Navigate forward one frame.

### Generating Reports

1. You must enter patient information and have saved images to the patient exam before you are able to print a report. Refer to **Editing Patient Information** and **Saving Images**.
2. Touch **Save to Report** .
3. Touch **Print** . An html report is saved in the patient exam folder and automatically opened in a web browser for review.

### Deleting Images, Cines, and Reports

1. Touch a thumbnail image and touch **Delete** .
2. For everything else (reports, cines or images not shown as a thumbnail), navigate to the patient exam folder in File Explorer and delete the files. Empty the Recycle Bin to permanently delete the files.

### Exporting Images, Cines, and Reports

All images, cines, and reports are accessible by navigating to the patient exam folder in Files Explorer. These files could be sent as an attachment in an e-mail through the e-mail application of your choice.

## Remote Viewing

Before you can use SimpliVue with any third-party telecommunications application for the first time, you must be connected to the internet and set up an account in the telecommunications application.

### Configuring for Remote Viewing of Ultrasound Imaging

The telecommunications application must be installed on the device running SimpliVue and on the remote user's device that you wish to share live imaging with.

To begin configuring the application for remote viewing:

1. Open the application and log in to your account on the device running SimpliVue.
2. On the left-hand navigation menu, click **Settings**.
3. With **Settings** displayed, click **Video**.
4. Click the drop-down list and select **Ultrasound Stream**.

Your device is now configured to share live imaging on the application .

## Add Contacts

With the telecommunications application installed on the device running SimpliVue and on the remote user's device that you wish to share live ultrasound image with, you will want to add each other to your contact list.

To add a contact,

<p>On a Windows PC workstation or tablet:</p> <ol style="list-style-type: none"><li>1. On the left-hand navigation menu, click <b>Contacts</b>.</li><li>2. Search for the contact you want to add in the search bar by entering their email address and select <b>Find this Person</b>.</li><li>3. Click <b>Add</b> to add to your contacts list.</li></ol>	<p>On an Android or iOS mobile device:</p> <ol style="list-style-type: none"><li>1. Select the <b>Contacts</b> tab.</li><li>2. Select the <b>+</b> icon in the top-right corner of the app.</li><li>3. Select <b>Add Contact</b>.</li><li>4. Enter the email address of the contact you want to add and select <b>ADD CONTACT</b>.</li></ol>
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## Initiating a Call Session

Either the remote user or the user running SimpliVue can initiate a call.

To initiate a call,

<p>On a Windows PC workstation or tablet:</p> <ol style="list-style-type: none"><li>1. On the left-hand navigation menu, click <b>Contacts</b>.</li><li>2. If you have a mouse, hover mouse over the contact you want to call and click the video icon next to your contact to immediately start a videocall.</li><li>3. If you do not have a mouse, click the contact you want to call. <b>Chat</b> will appear. Click the video icon at the upper-right corner of the chat window.</li></ol>	<p>On an Android or iOS mobile device:</p> <ol style="list-style-type: none"><li>1. Select the <b>Calls</b> tab.</li><li>2. Select <b>Start new call</b>.</li><li>3. Select the contact you want to call to immediately start a videocall.</li></ol>
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Once both users connect to the call, the video call will initiate with the device running SimpliVue sharing the ultrasound image with the remote user.

## Appendix A – SimpliVue Software Installation

Do **NOT** plug in the USB ultrasound probe(s) until the software has been installed.

### Software Installation:

1. Insert the flash drive into one of the device's USB ports.
2. Locate the installation file **SimpliVueArraySetup\_v.X.Y.Z.exe\*** on the flash drive.
3. Copy the installation file to your desktop or other location of your choice.
4. Remove the flash drive and store it in a safe place.
5. Go to the location where you saved **SimpliVueArraySetup\_v.X.Y.Z.exe**.
6. Double click on **SimpliVueArraySetup\_v.X.Y.Z.exe**.
7. Go through the installation steps, clicking yes and next when prompted.
8. Launch the SimpliVue software using the desktop shortcut.
9. The SimpliVue software will now launch and you are ready to begin imaging.

\*The name of the installation file may differ depending on the version of the SimpliVue software.

## Appendix B – Interson Probe System Specifications

Imaging Mode	B Scan
Functions	<ul style="list-style-type: none"> <li>• Standard USB port (2.0) connectivity</li> <li>• Multiple freeze methods: button on probe, keyboard, or button on screen</li> <li>• Auto image save on Freeze</li> </ul>
Image Resolution	<ul style="list-style-type: none"> <li>• 0.1 to 2.0 mm resolution*</li> </ul>
Gray Shades	<ul style="list-style-type: none"> <li>• True 256 (8 bits) shades of gray</li> </ul>
Sector Size	<ul style="list-style-type: none"> <li>• Rectangular* or 60° sector*</li> </ul>
Transducers	<ul style="list-style-type: none"> <li>• High bandwidth, multiple elements: 5.0 MHz and 7.5 MHz nominal frequencies*</li> </ul>
Depth Selections	<ul style="list-style-type: none"> <li>• 2 cm through 24 cm depths*</li> </ul>
Measurements	<ul style="list-style-type: none"> <li>• Distance, angle, area, circumference, and volume measurements</li> </ul>
Signal Processing	<ul style="list-style-type: none"> <li>• TGC controls: near, mid, and far</li> <li>• Contrast and image intensity controls</li> <li>• Frame averaging</li> <li>• Interpolation</li> </ul>
Archives Functions	<ul style="list-style-type: none"> <li>• Exam data</li> <li>• Cine buffer range 32-1024 frames</li> <li>• Open system architecture</li> </ul>
Power Supply Requirements	<ul style="list-style-type: none"> <li>• DC 5.0 VDC, ±5% at 500 mA (max) 2.5 watts (max) obtained from the USB 2.0 port.</li> </ul>
Environmental	<ul style="list-style-type: none"> <li>• Max operating temperature: 50°C (122°F)</li> <li>• Min operating temperature: -10°C (14°F)</li> <li>• Operating humidity range: 20-80% Non-condensing</li> </ul>
Storage Temperature	<ul style="list-style-type: none"> <li>• -10°C to 50°C (14°F to 122°F)</li> </ul>

\*Probe dependent

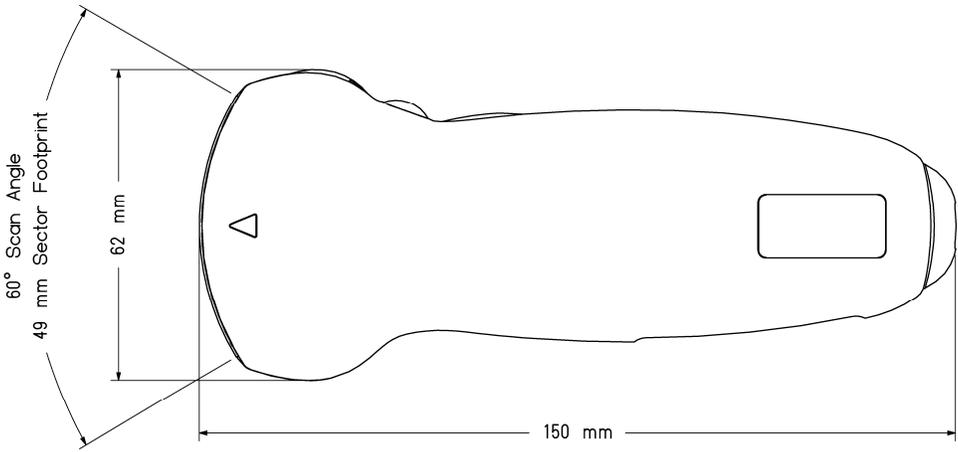
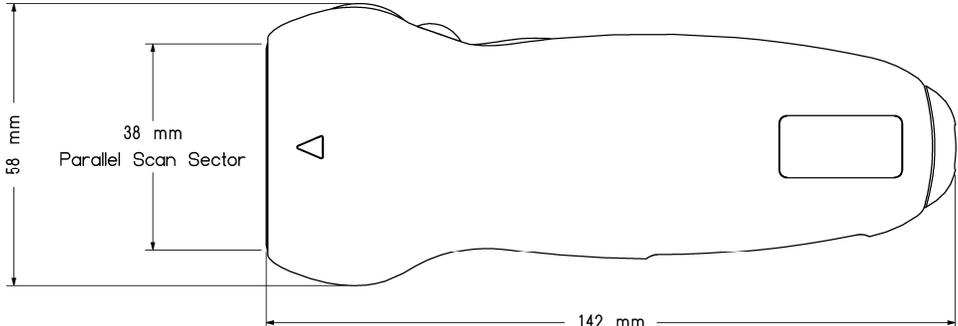
## Appendix C – Computer System Specifications

Open System Architecture	System specification requirements for PC, laptop, or tablet
Processor	2.5 GHz or higher
Memory	4 GB or greater
Video chipset	Intel 815EM or higher performance equivalent
Video memory	16 MB SDR or greater
Display	12.1" TFT XGA 1366x768 or greater
Digital ports	USB 2.0 port(s)
Keyboard	83 keys or equivalent
Mouse	Touchpad, USB mouse, or equivalent
AC Adapter	Medical grade
Battery Type	PCGA-BP2R or equivalent
Operating System	Windows 7, 8, 10
Software	Interson Corporation – SimpliVue

### **Y** 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	Design
<p style="text-align: center;"><b>USB PROBE GP-C01</b></p>	 <p>The diagram shows a hand-held, curved linear array solid-state sector probe. A 60° Scan Angle is indicated by a curved arrow. The footprint of this angle is 49 mm. The total length of the probe is 150 mm. A small triangle on the probe face indicates the scan direction.</p>
<p style="text-align: center;"><b>USB PROBE SP-L01</b></p>	 <p>The diagram shows a hand-held, flat linear array solid-state probe. The parallel scan sector is 58 mm wide. A smaller section of 38 mm is also indicated. The total length of the probe is 142 mm. A small triangle on the probe face indicates the scan direction.</p>

### Transducer Model GP-C01

This device is a hand-held, curved linear array solid-state sector probe for transcutaneous use with the Interson USB Ultrasound Probe System. The nominal operating frequency is 5.0 MHz with upper and lower range ends of 7.5 MHz and 3.5 MHz respectively. The operating modes are B, M, color doppler and combined B + color Doppler modes.

### Transducer Model SP-L01

This device is a hand-held, flat linear array solid-state probe for transcutaneous use with the Interson USB Ultrasound System. The nominal operating frequency is 7.5 MHz with upper and lower range ends of 15.0 MHz and 4.0 MHz respectively. The operating modes are B, M, color doppler and combined B + color Doppler modes.

See Appendix G for the Indications for Use for Interson Ultrasound Probes.

## Appendix E – Summary of the Acoustic Quantities

The acoustic output data is shown for each probe in each operating mode.

Summary of the acoustic quantities: GP-C01 Probe Mode: B-Mode									
Index				MI	TIS		TIB		TIC
					At Surface	Below Surface	At Surface	Below Surface	
Maximum index value				1.02	0.115		0.322		(3)
Index Component Value					0.115	0.115	0.322	0.115	-
	IEC	FDA	Units						
Associated acoustic parameter	$p_{r,a}$ at $Z_{MI}$	$p_{r,3}$	(MPa)	1.96					
	P	$W_0$	(mW)		32.9		32.9		-
	$P_{1x1}$		(mW)		6.62		6.62		-
	$Z_s$	$Z_1$	(cm)			1.63			
	$Z_b$	$Z_{sp}$	(cm)				-	1.63	
	$Z_{MI}$	$Z_{MI}$	(cm)	1.63					
	$Z_{pi,\alpha}$	$Z_{pi,\alpha}$	(cm)	1.63			-		
	$f_{awf}$	$F_c$	(MHz)	3.65	3.65		3.65		-
Other Information	pr		(Hz)	5120					
	srr		(Hz)	40					
	$n_{pps}$			1					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$		(W/cm <sup>2</sup> )	180			-		
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ OR $Z_{sii,\alpha}$		(mW/cm <sup>2</sup> )	10.3					
	$I_{spta}$ at $Z_{pii}$ OR $Z_{sii}$		(mW/cm <sup>2</sup> )	15.5					
	$p_r$ at $Z_{pii}$		(MPa)	2.4					
Operating Control Conditions	Scan rate			40 Hz					
	Lines per scan			128					
	Scan angle			60°					
	Transmit focus			2.0 cm					

Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any Transducer Assembly not intended for transcranial or neonatal cephalic uses.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Indication does not include cephalic so TIC is not computed.

Summary of the acoustic quantities: GP-C01 Probe Mode: Color Flow Doppler (Combined Mode)									
Index				MI	TIS		TIB		TIC
					At Surface	Below Surface	At Surface	Below Surface	
Maximum index value				1.02	1.84		2.69		(3)
Index Component Value					1.84	1.84	2.69	1.84	-
	IEC	FDA	Units						
Associated acoustic parameter	$p_{r,\alpha}$ at $Z_{MI}$	$p_{r,3}$	(MPa)	1.96					
	P	$W_0$	(mW)		275		32.9		-
	$P_{1 \times 1}$		(mW)		110		110		-
	$Z_s$	$Z_1$	(cm)			1.63			
	$Z_b$	$Z_{sp}$	(cm)				-	1.63	
	$Z_{MI}$	$Z_{MI}$	(cm)	1.63					
	$Z_{pi,\alpha}$	$Z_{pi,\alpha}$	(cm)	1.63			-		
	$f_{awf}$	$F_c$	(MHz)	3.65	3.49		3.49		-
Other Information	pr		(Hz)	2560					
	srr		(Hz)	20					
	$n_{pps}$			1					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$		(W/cm <sup>2</sup> )	180			-		
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ OR $Z_{sii,\alpha}$		(mW/cm <sup>2</sup> )	10.3					
	$I_{spta}$ at $Z_{pii}$ OR $Z_{sii}$		(mW/cm <sup>2</sup> )	7.73					
	$p_r$ at $Z_{pii}$		(MPa)	5.13					
Operating Control Conditions	Scan rate			20 Hz					
	B-Mode Scan Angle			60°					
	B-Mode Scan Lines			128					
	CFM Scan Angle			30°					
	CFM Scan Lines			32					
	CFM Pulses Per Line			14					
	Transmit Focus			2.0 cm					
<p>Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.</p> <p>Note 2: Information need not be provided regarding TIC for any Transducer Assembly not intended for transcranial or neonatal cephalic uses.</p> <p>Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).</p> <p>(a) Indication does not include cephalic so TIC is not computed.</p>									

Summary of the acoustic quantities: SP-L01 Probe					Mode: B-Mode					
Index				MI	TIS		TIB		TIC	
					At Surface	Below Surface	At Surface	Below Surface		
Maximum index value				1.15	0.084		0.197		(3)	
Index Component Value					0.084	0.084	0.197	0.084	-	
	IEC	FDA	Units							
Associated acoustic parameter	$p_{r,a}$ at $Z_{MI}$	$p_{r,3}$	(MPa)	2.66						
	P	$W_0$	(mW)		12.3		12.3		-	
	$P_{1x1}$			(mW)		3.31		3.31		-
	$Z_s$	$Z_1$		(cm)		0.8				
	$Z_b$	$Z_{sp}$		(cm)			-	0.8		
	$Z_{MI}$	$Z_{MI}$		(cm)	0.8					
	$Z_{pi,\alpha}$	$Z_{pi,\alpha}$		(cm)	0.8			-		
	$f_{awf}$	$F_c$	(MHz)	5.32	5.32		5.32		-	
Other Information	pr		(Hz)	5120						
	srr		(Hz)	40						
	$n_{pps}$			1						
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$			(W/cm <sup>2</sup> )	346			-		
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ OR $Z_{sii,\alpha}$			(mW/cm <sup>2</sup> )	13.9					
	$I_{spta}$ at $Z_{pii}$ OR $Z_{sii}$			(mW/cm <sup>2</sup> )	18.6					
	$p_r$ at $Z_{pii}$			(MPa)	3.08					
Operating Control Conditions	Scan rate			40 Hz						
	Lines per scan			128						
	Scan angle			3.84 cm						
	Transmit focus			2.0 cm						
<p>Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.</p> <p>Note 2: Information need not be provided regarding TIC for any Transducer Assembly not intended for transcranial or neonatal cephalic uses.</p> <p>Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).</p> <p>(a) Indication does not include cephalic so TIC is not computed.</p>										

Summary of the acoustic quantities: SP-L01 Probe Mode: Color Flow Doppler (Combined Mode)									
Index				MI	TIS		TIB		TIC
					At Surface	Below Surface	At Surface	Below Surface	
Maximum index value				1.35	2.54		3.14		(3)
Index Component Value					2.54	2.54	3.14	2.54	-
	IEC	FDA	Units						
Associated acoustic parameter	$p_{r,a}$ at $Z_{MI}$	$p_{r,3}$	(MPa)	3.03					
	P	$W_0$	(mW)		196.3		32.9		-
	$P_{1x1}$		(mW)		106.5		106.5		-
	$Z_s$	$Z_1$	(cm)			0.8			
	$Z_b$	$Z_{sp}$	(cm)				-	0.8	
	$Z_{MI}$	$Z_{MI}$	(cm)	0.8					
	$Z_{pi,\alpha}$	$Z_{pi,\alpha}$	(cm)	0.8			-		
	$f_{awf}$	$F_c$	(MHz)	5.01	5.01		5.01		-
Other Information	pr		(Hz)	8960					
	srr		(Hz)	20					
	$n_{pps}$			1					
	$I_{pa,\alpha}$ at $Z_{pii,\alpha}$		(W/cm <sup>2</sup> )	606			-		
	$I_{spta,\alpha}$ at $Z_{pii,\alpha}$ OR $Z_{sii,\alpha}$		(mW/cm <sup>2</sup> )	387.2					
	$I_{spta}$ at $Z_{pii}$ OR $Z_{sii}$		(mW/cm <sup>2</sup> )	510.5					
	$p_r$ at $Z_{pii}$		(MPa)	3.48					
Operating Control Conditions	Scan rate			20 Hz					
	B-Mode Scan Angle			3.84 cm					
	B-Mode Scan Lines			128					
	CFM Scan Angle			1.92 cm					
	CFM Scan Lines			32					
	CFM Pulses Per Line			14					
	Transmit Focus			2.0 cm					
<p>Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.</p> <p>Note 2: Information need not be provided regarding TIC for any Transducer Assembly not intended for transcranial or neonatal cephalic uses.</p> <p>Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).</p> <p>(a) Indication does not include cephalic so TIC is not computed.</p>									

## Appendix F – Achieving ALARA

The acoustic power of diagnostic ultrasound and its possible effects on human tissue has been studied for many years. The acoustic power of ultrasound imaging transducers must be below specific limits that are established by international standards bodies as well as required by governmental regulatory controls. While modern ultrasound imaging transducers are well below the allowable limits, it is standard practice to abide by the principle to set the power and limit the use to "As Low As Reasonably Achievable" (ALARA). The concept is quite simple: keep the acoustic exposure at the lowest possible levels and use the shortest amount of time that is necessary to obtain the desired diagnostic image. As the acoustic power can only be set lower than the allowed limit, the combination of lowering the transmit power and reducing the exposure time will minimize any possible biological effects.

There are two output display indices (Thermal Index and Mechanical Index) that notify the user of the amount of energy that is being transmitted. The output display indices are updated based on the settings that the operator of the ultrasound system uses to optimize the image. By providing the indices, operators are informed of the values and can therefore adapt their procedure to better abide by ALARA.

### ALARA Guidelines

ALARA puts responsibility to lower the power from the maximum level on the operator. As was mentioned above, acoustic power can only be lowered from its maximum and the maximum is well below the allowable limit. How does the operator determine what power level to set? ALARA directs the operator to use the lowest possible acoustic power that still allows a diagnostic quality image to be obtained. Using a higher transmit frequency results in lower biological effects. Therefore, using the highest possible frequency that still allows the operator to see to the required depth would be applying ALARA correctly. The quality of the image is also determined by the receiver controls such as gain, intensity, and contrast. As receiver controls do not affect acoustic transmit power, it is always good practice to adjust the receiver controls before considering an increase in acoustic transmit power. ALARA also directs the operator to use the transducer for the minimum amount of time that is necessary to obtain the desired diagnostic-quality image.

### Applying the ALARA Principle

Prior to starting the ultrasound scan, be sure to select the proper transducer for your application. The linear array transducer is used for small parts, close to the surface scanning, down to about 6 cm. The curved array transducer is generally used for abdominal scanning at depths greater than 10 cm.

The SimpliVue software opens with power set to a specific value and the pulse frequency set to the center value. However, as a higher pulse frequency creates less of a biological effect, increase the pulse frequency as high as possible while still allowing you to reach your target depth. Although this acoustic power setting is well below the allowable limits, the ALARA principal directs you to use the lowest possible power. Use the highest pulse frequency and lowest acoustic power while still enabling you to acquire the image that you need.

Scanning time should be kept to a minimum. However, do not shorten the session so much that a follow-up exam is necessary as this would only increase the overall exposure for the patient.

## **Display of Indices**

The calculated Mechanical Index and Thermal Index can be viewed on the main display screen and can be monitored by the operator. By monitoring these displayed values as the acoustic power, depth, and frequency are adjusted, the operator can achieve the lowest possible values of the indices that still enables them to acquire the desired image. Proper ALARA principles direct you to move through the exam quickly and ensure that the indices are kept to a minimum. The resolution of displayed Mechanical and Thermal Indices is 0.1. Displayed values are relative values based on acoustic power testing and change in frequency, transmit power, and focal depth. Mechanical and Thermal indices are calculated values. They cannot be measured and as such should be only used as input to properly practice the ALARA principles of keeping the acoustic power exposure to a minimum.

## **Thermal Index Display**

There are three thermal indices. The TIB informs the user of potential heating near the focus after the ultrasound has transitioned through fluid or soft tissue. TIC informs the user of potential heating of bone at or near the surface. TIS is used to indicate any heating effect in soft homogenous tissue. If the ultrasound device is not capable of exceeding a thermal index of 1.0 in any mode, then the thermal index is not displayed.

## **Adjusting Image Controls to Minimize the Indices**

As acoustic power is minimized you will see the Mechanical and Thermal indices values changing. When using color mode with standard 2D mode, the system will display the Indices for the color or 2D, whichever is greater. Biological effects are also dependent on pulse frequency. Higher pulse frequencies have lower biological effects. Therefore, use the highest pulse frequency that still allows you to obtain the desired image.

As displayed depth is changed the transmit focal point and frame rate are adjusted automatically for the user. If the new depth and focal point affect the indices, the user will see the displayed indices change.

## **ALARA Resources**

Medical Ultrasound Safety, Third Edition, AIUM 2014

American Institute of Ultrasound in Medicine Bioeffects Consensus Report Vol. 27, Issue 4, April 2008

AIUM Consensus Report on Potential Bioeffects and Safety of Diagnostic Ultrasound." January 1993

# Appendix G – Interson Ultrasound Probes – Indications for Use

## Indications for Use

It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications::

- Abdominal
- Fetal/ Obstetric
- Pediatric
- Small Organ
- Peripheral Vascular
- Carotid
- Musculoskeletal (Conventional)
- Musculoskeletal (Superficial)
- Urology
- Gynecology

Diagnostic Ultrasound Indications for Use  
 Interson USB Ultrasound System  
 Mode: B, M, B + color Doppler

The probes can be used in the following applications:

	<b>GP-C01</b>	<b>SP-L01</b>
Ophthalmic		
Fetal/Obstetric	✓	
Abdominal	✓	✓
Intra-Operative (Specify)		
Intra-Operative Neurological		
Laparoscopic		
Pediatric (excluding transcranial & neonatal)	✓	✓
Small Organ (Scrotum, prostate, lymph nodes, thyroid, breast)		✓
Neonatal Cephalic		
Adult Cephalic		
Trans-rectal		
Trans-vaginal		
Trans-urethral		
Trans-esoph. (non-card.)		
Muscular-Skeletal (Conventional)		✓
Muscular-Skeletal (Superficial)		✓
Intravascular		
Other (Urology)	✓	
Other (Gynecology)	✓	
Other (Pelvic Floor)		
Other (Neuromuscular)		
Cardiac Adult		
Cardiac Pediatric		
Intravascular (Cardiac)		
Trans-esoph. (Cardiac)		
Intra-cardiac		
Peripheral vessel		✓
Carotid		✓
Other (Specify)		

## Appendix H – EMC Information

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>			
Interson's USB Ultrasound Probes are 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.			
<b>Emissions test</b>	<b>Test Level</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
Conducted Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	Class B 150 kHz to 30 MHz	Class B 150 kHz to 30 MHz	The USB Ultrasound Array System uses RF energy for its internal function. Nearby electronic equipment may be affected.
Radiated Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	Class B 30 MHz to 1 GHz	Class B 30 MHz to 1 GHz	
Harmonics IEC/EN 61000-3-2:2006/A2:2009	Class A Device	Per Clause 5 of the Standard	
Flicker IEC/EN 61000-3-3:2013	Per Clause 5 of the Standard	Per Clause 5 of the Standard	

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
Interson's USB Ultrasound Probes are 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.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic Discharge IEC/EN 61000-4-2	± 8 kV contact discharge ± 2, 4, 8 & 15kV air discharge	± 8 kV contact discharge ± 2, 4, 8 & 15kV 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 %.
Radiated Immunity IEC/EN 61000-4-3	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	
Proximity field from RF wireless communications equipment IEC 61000-4-3	Table 9 of the Standard	Table 9 of the Standard	Mains power quality should be that of a typical commercial or hospital environment.
Conducted Immunity (AC Power) (I/O Lines) IEC/EN 61000-4-6	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	
Electrical Fast Transients (AC Power) IEC/EN 61000-4-4	±2 kV AC Mains ±1 kV I/O Lines 5/50 5kHz & 100 kHz	±2 kV AC Mains ±1 kV I/O Lines 5/50 5kHz & 100 kHz	
Surge Line to Line (AC Power) IEC/EN 61000-4-5	±1 kV Line to Line ±2 kV Line to Ground	±1 kV Line to Line ±2 kV Line to Ground	
Magnetic Immunity IEC/EN-61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Voltage Dips & Interruptions IEC/EN 61000-4-11	0% $U_T$ .5 cycle 0% $U_T$ 1 cycle 70% $U_T$ 25 cycles 0% $U_T$ 5 Sec	0% $U_T$ .5 cycle 0% $U_T$ 1 cycle 70% $U_T$ 25 cycles 0% $U_T$ 5 Sec	If the user requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery
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<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
Interson's USB Ultrasound Probes are 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.			
<b>IMMUNITY test</b>	<b>IEC 60601 TEST LEVEL</b>	<b>Compliance Level</b>	<b>Electromagnetic environment – guidance</b>
			<p>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.</p> <p>Recommended separation distance:  <math>d = 1.2\sqrt{P}</math>  <math>d = 1.2\sqrt{P}</math> for 80 MHz to 800 MHz  <math>d = 2.3\sqrt{P}</math> for 800 MHz to 2.5 GHz</p> <p>Where <math>P</math> is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with this symbol.</p> 
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 I – Maximum Probe Temperature

Interson probes will not exhibit excessive surface temperatures under normal use. Disconnect the equipment if unsafe temperatures are observed. Interson probes have been tested to conform with IEC 60601-2-37.

<b>Probe</b>	<b>Max. Temp. (Simulated use)</b>	<b>Max. Temp. (Still air)</b>
GP-C01	23.6°C (74.5°C)	24.3°C (75.7°F)
SP-L01	25.9°C (78.6°F)	24.5°C (76.1°F)

## Appendix J – 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. Always control the computer and storage devices. They should be locked up when not under direct control of user.
2. Limit access to the computer to authorized users.
3. Passwords protect computer – require login.
4. Passwords 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 it 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 K – 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 SimpliVue software. Contact Interson about enabling specific calculations that are not available in your version of SimpliVue software.

### Available Calculations:

<b>Abdominal Circumference</b> Hadlock 1984	$8.14 + 0.753 * [\text{cm}] + 0.0036 * [\text{cm}]^2$
<b>Bi-Parietal Diameter</b> Hadlock 1984	$9.54 + 1.482 * [\text{cm}] + 0.1676 * [\text{cm}]^2$
<b>Bladder Volume</b>	$= 0.0285x^2 - 3.6624x + 129.65$ , where $x = H + W$
<b>Bladder Volume 3D</b> Poston et al, 1983	$= 0.7 \times H \times W \times T$
<b>Crown Rump Length</b> Hadlock 1992	$1.684969 + 0.315646 * [\text{cm}] - 0.049306 * [\text{cm}]^2 + 0.004057 * [\text{cm}]^3 - 0.000120456 * [\text{cm}]^4$
<b>Femur Length</b> Hadlock 1984	$10.35 + 2.46 * [\text{cm}] + 0.17 * [\text{cm}]^2$
<b>Gestational Sac</b> Nyberg 1992	$([\text{mm}]) * 0.132 + 4.299$
<b>Gestational Sac 2-plane</b> Nyberg 1992	$([\text{mm}]) * 0.132 + 4.299$
<b>Head Circumference</b> Hadlock 1984	$8.96 + 0.54 * [\text{cm}] + 0.0003 * [\text{cm}]^3$
<b>Prostate Volume</b>	$= 0.5 \times H \times W \times T$

\*[http://dicom.nema.org/MEDICAL/Dicom/2014a/output/chtml/part16/sect\\_CID\\_12013.html](http://dicom.nema.org/MEDICAL/Dicom/2014a/output/chtml/part16/sect_CID_12013.html)

## Appendix L – Interson Customer Warranty

Interson (“Company”) warrants that the 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 two years 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 any 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 **M**

Interson Corporation  
7150 Koll Center Parkway  
Pleasanton, CA 94566 USA  
Phone: 925.462.4948  
Fax: 925.462.4833  
Email: [support@interson.com](mailto:support@interson.com)  
Website: [www.interson.com](http://www.interson.com)

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# Appendix M – Warranty and Extended Warranty Registration

Interson probes come with a standard two-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 it to Interson with payment.

Customer \_\_\_\_\_

Address \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_ Zip \_\_\_\_\_

Phone \_\_\_\_\_ E-mail \_\_\_\_\_

Purchase Date \_\_\_\_\_

Additional one year coverage: \$900 USD per probe

Additional two-year coverage: \$1800 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
		1 Year	2 Years

Interson Corporation  
 7150 Koll Center Parkway  
 Pleasanton, CA 94566 USA  
 Phone: 925.462.4948  
 Fax: 925.462.4833

Amount enclosed: \_\_\_\_\_

Email: [support@interson.com](mailto:support@interson.com)  
Website: [www.interson.com](http://www.interson.com)