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Instructions For Use

Ultrasound Imaging System Exclusively for the ARROW® VPS Rhythm® DLX Device

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CE **2797**

Information in this document is subject to change without notice.

These Instructions For Use are applicable to the following Interson ultrasound probe:

SP-L01

Contents

Introduction

Congratulations on your purchase of the Interson Simpli Series™ Ultrasound Probe System exclusively for use with the Arrow® VPS Rhythm® DLX Device. The VPS Rhythm® DLX Device ultrasound module consists of a plug-in ultrasound probe optimized for vascular access use. The ultrasound module can be used alone for a variety of patient assessments, or in conjunction with ECG technology to assess a patient's vasculature prior to CVAD tip placement allowing ultrasound imaging of the vasculature and other tissue. The primary use of ultrasound is for facilitation of vessel puncture to avoid complications while gaining vessel access.

Please review this user manual before you begin imaging. Contact Interson or your sales representative if you have any questions.

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.

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, 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
WARNING	Indicates a potentially hazardous situation which, if not avoided, could cause injury or harm to the operator or patient.
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 manual

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 cables.

WARNING

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

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.

WARNING

Do not attempt to connect the probe to anything other than the VPS Rhythm® DLX system.

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. 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 probe System's cable connector and the patient simultaneously.

WARNING

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

WARNING

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

WARNING

Do not submerse the probe 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.

Symbology

The following symbols may be used on Interson labeling:

	Symbol for “Serial Number”
REF	Symbol for “Part Number”
	Symbol indicating the “date of manufacture”
	Indicates conformance with European Council Directive 93/42/EEC
	Equipment manufacturer
	EC representative
	TUV Rheinland of North America, Inc, cTUVus Certification
	Medical Device
	Consult instructions for use
	Keep away from sunlight
	Keep dry
	Not made with natural rubber latex
	Waste Electrical and Electronic Equipment

Ultrasound Probes

Device Description

The Interson 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, 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 abdomen, vascular, extremity, pediatric, urology. With these general areas of intended use, the various probes adapt the system for the specific imaging tasks.

The Interson Ultrasound Probe System supports B-Mode mode scanning, providing high resolution and high penetration performance. The probes can be used in applications such as abdomen, vascular, extremity, pediatric, and urology. A Color Flow Mapping (CFM) mode provides a qualitative indication of fluid flow and direction.

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

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

Indications for Use
Please refer to **Appendix E**.

The system is intended for use by healthcare professionals.

Contraindications
The Interson Simpli Series SP-L01 ultrasound probe is not indicated for ophthalmic use or any application that causes the acoustic beam to pass through the eye.

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 C** of this manual for Acoustic measurements and **Appendix D** for guidance on how to best implement ALARA.

Electromagnetic Compatibility (EMC)

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

Like other medical equipment, Interson Ultrasound Probes require special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), Interson Ultrasound Probes must be installed and operated according to the EMC information provided in this manual.

The Interson Ultrasound Probes have been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.

See **Appendix F** of this manual for EMC test details.

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

⚠ **CAUTION**

Do not use cables or accessories other than those provided with the Interson 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. 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 probe. If the probe is dropped on a hard surface, it can be damaged.

DO NOT DISCONNECT OR REMOVE CABLE FROM THE PROBE

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

Maintenance

The probe should be cleaned after every use.

After every use check the probe housing and transducer lens for cracks, splitting, sharp edges or projections. If damage is evident discontinue use of the probe and contact VPS Technical Support or your local Teleflex representative.

After every use check the cable for cuts, cracks, and kinks. This could also impair the performance of the probe. If damage is evident discontinue use of the probe and contact VPS Technical Support or your local Teleflex representative.

⚠ **WARNING**

Users of this 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

⚠ **WARNING**

Always disconnect the ultrasound probe system from the host system 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. Even the use of soft brushes can damage the probe.

⚠ **WARNING**

Do not immerse the probe in solution during cleaning and disinfection.

Probe Cleaning

The 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. Using a Bleach Wipe
    a. Wipe the probe and cable using a PDI® Sani-Cloth bleach wipe to remove gross soil avoiding the connectors if possible.
        i. Wipe all seams, creases, recessed areas, and mated surfaces.
    b. Using a fresh PDI® Sani-Cloth bleach wipe, wipe all surfaces of the probe and cable, allowing the devices to remain visibly wet for 4 minutes, per the manufacturer's recommendation.
        i. Use additional wipes as needed to achieve desired contact time.
6. Allow the probe and cable to air dry.
7. If visible soil remains on the probe and/or cable the cleaning steps may be repeated.

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 though the FDA 510(k) process) and their compatibility with Interson ultrasound product materials.

1. Wear protective gloves when performing the disinfecting procedure.
2. Check the expiration date on the solution that is being used.
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**.*

⚠ 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.

1. 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 VPS Technical Support or your local Teleflex representative.
2. After cleaning, disinfect the probe using a bleach wipe
3. Using a Bleach Wipe
    a. Wipe all visible surfaces of the probe and cable using a PDI® Sani-Cloth bleach wipe to pre-wet the device, avoiding the connector if possible.
        i. Wipe all seams, creases, recessed areas, and mating surfaces.
    b. Using a fresh PDI® Sani-Cloth bleach wipe, wipe all surfaces of the probe and cable, allowing the devices to remain visibly wet for 4 minutes, per the manufacturer's recommendation.
        i. Use additional wipes as needed to achieve desired contact time.
        ii. Rinse using a lint free cloth moistened with USP water for irrigation.
4. Allow the probe and cable to air dry.

Training
This probe system is intended to be used by trained medical professionals only.

The specific probe functions are described in this manual.

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 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 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 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, make sure the probe is properly protected from dropping or damage.
- Call VPS Technical Support or your local Teleflex representative 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 VPS Technical Support or your local Teleflex representative 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 probe, try the suggestions listed below:

No image:

1. Disconnect the probe and turn off the system.
2. Reconnect the probe and turn on the system.

Image not clear:

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

Error messages:

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

Technical Support

If you are not able to find the solution by using this manual, contact Teleflex VPS Tech Support or your local Teleflex representative.

Prepare to contact Technical Support:

To receive the fastest possible resolution of a problem, have the following information available when contacting Teleflex VPS Tech Support (North America) (VPSTechSupport@teleflex.com, +1.877.236.6869) or your local Teleflex representative:

- Serial number
- Conditions under which the problem occurred.
- Error messages that have been displayed.

Probe 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.

General Use

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

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.

Installing Sheaths

Interson recommends the use of market-cleared, transducer sheaths for intracavity 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.

Getting Started

System Components

The system consists of the following:

- The VPS Rhythm® DLX system
- The SP-L01 linear array probe and cable

See the VPS Rhythm® DLX Operator's Manual for operating instructions and for connection of the ultrasound probe to the VPS Rhythm® DLX Device.

Statement of Accuracy

Distance Measurements: Accuracy of distance measurements is the greater of ± 2% or ± 2 mm. All measurements made by the ultrasound system assume an average sound velocity of 1540 m/s in soft tissue. As the 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 probe is able to discriminate between positive and negative low flow rates of 5.5 cm/sec 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 ± 28.0 cm/sec.

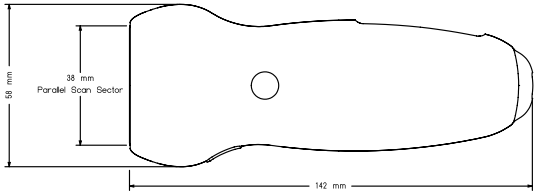
⚠WARNING

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.

Appendix A – Interson Probe System Specifications

Imaging Mode	B Scan
Functions	• Multiple freeze methods: button on probe or button on screen
Image Resolution	• 0.1 to 2.0 mm resolution*
Gray Shades	• True 256 (8 bits) shades of gray
Sector Size	• Rectangular*
Transducers	• High bandwidth, multiple elements: 7.5 MHz nominal frequencies*
Power Supply Requirements	• DC 5.0 VDC ±5%, 3.0 watts (max).
Environmental	• Max operating temperature: 31°C (88°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)

Appendix B – Interson Probes and Their Applications

Description	Design
PROBE **SP-L01**	

Transducer Model SP-L01

This device is a hand-held, flat linear array solid-state probe intended for transcutaneous use with the Interson 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 and combined B + color Doppler modes.

See **Appendix E** for the Indications for Use for Interson Ultrasound Probes.

Appendix C – Summary of the Acoustic Quantities

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

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	prr		(Hz)	5120					
	srr		(Hz)	40					
	n_{pps}			1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$		(W/cm^2)	346			-		
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$		(mW/cm^2)	13.9					
	I_{spta} at z_{pii} or z_{sii}		(mW/cm^2)	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					

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) Intended use does not include cephalic so TIC is not computed.

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	prr		(Hz)	8960					
	srr		(Hz)	20					
	n_{pps}			1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$		(W/cm^2)	606			-		
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$		(mW/cm^2)	387.2					
	I_{spta} at z_{pii} or z_{sii}		(mW/cm^2)	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					

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) Intended use does not include cephalic so TIC is not computed.

Appendix D – 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 places 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 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 principle 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 E – Interson Ultrasound Probes – Indications for Use

The Interson Ultrasound System is intended for diagnostic ultrasound imaging in B or Combined (B + Color) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

- Abdominal
- Pediatric
- Small Organ
- Musculo-skeletal (conventional)
- Musculo-skeletal (superficial)
- Urology
- Gynecology
- Pelvic Floor
- Neuro-muscular
- Peripheral Vessel

The system is only intended for use by healthcare professionals.

Diagnostic Ultrasound Indications for Use
Interson Ultrasound System
Mode: B, B + color Doppler
Intended Use: Diagnostic ultrasound imaging and fluid flow analysis of the human body as follows:

	SP-L01
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	✓
Other (Specify)	

Appendix F – EMC Information

Guidance and manufacturer's declaration – electromagnetic emissions		
Interson's Ultrasound Probes are intended for use in the electromagnetic environment specified below. The customer or the user of the Interson Ultrasound Probe should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group1	Interson's 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 61000-3-2	Class A	The system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
Interson's Ultrasound Probes are intended for use in the electromagnetic environment specified below. The customer or the user of the Interson 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	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air	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	±2 kV AC Mains ±1 kV I/O Lines 5/50 5 kHz & 100 kHz	±2 kV AC Mains ±1 kV I/O Lines 5/50 5 kHz & 100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
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	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 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	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or battery.
Power frequency magnetic immunity (50/60 Hz) IEC 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.

Guidance and manufacturer's declaration – electromagnetic immunity

Interson's Ultrasound Probes are intended for use in the electromagnetic environment specified below. The customer or the user of the Interson 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	0.15 – 80 MHz 3 V_{rms} & 6 V_{rms} 1 kHz	0.15 – 80 MHz 3 V_{rms} & 6 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 6 GHz 3 V/m & 10 V/m 80% @ 1 kHz Spot Frequencies 385 MHz to 5.750 GHz Pulse Modulation	80 MHz to 6 GHz 3 V/m & 10 V/m 80% @ 1 kHz Spot Frequencies 385 MHz to 5.750 GHz Pulse Modulation	

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 Ultrasound Probe is used exceeds the applicable RF compliance level above, the 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 Ultrasound Probe.

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

Appendix G – 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.

Probe	Max. Temp. (Simulated use)	Max. Temp. (Still air)
SP-L01	25.9°C (78.6°F)	24.5°C (76.1°F)

Appendix H – Interson Customer Warranty

Interson (“Company”) warrants that the 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 in accordance with Teleflex’s Manufacturer’s Warranty Period (see Operator’s Manual for Arrow® VPS Rhythm® DLX Device. 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.

To receive the fastest possible resolution of a problem under warranty, have the following information available when contacting Teleflex VPS Tech Support (North America) (VPSTechSupport@teleflex.com, +1.877.236.6869) or your local Teleflex representative:

- Serial number
- Conditions under which the problem occurred.
- Error messages that have been displayed.

Equipment Manufacturer

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