# UltraVision-XR

# UltraVision-XC

# and

# UltraVision-XS

# Diagnostic Ultrasound System

# User Manual

## Revision 6.1

Manufactured by:
**UltraVision Corporation**
11911 US Highway 1, Suite 204
North Palm Beach,
Florida, 33408, USA
Tel: (561) 626 4055
email info@ultravisionusa.com
© Copyright UltraVision Corporation 2024

# STATEMENT

This manual is designed to guide the user of the UltraVision System in its correct and safe operation and the system should be used by personnel who have read, understand, and can comply with the directions given in this document. This manual is designed to supply fundamental concepts on safety precautions. Failing to comply with the directions herein may result in accident or malfunction for which UltraVision Corporation cannot be held liable.

The UltraVision Corporation is responsible for the performance, reliability, and safety of this system only if repairs, adjustments, and modifications are carried out by UltraVision Corporation authorized personnel, and electrical installation complies with international standards, and the system is used in accordance with this user manual.

There are no user serviceable parts inside the system console, computer, or transducers. Please contact UltraVision or its distributor for any service requirements. All repairs must be performed by a qualified UltraVision Service Engineer.

# NOMENCLATURE

## WARNING

A **WARNING** label or indication in this manual advises against certain actions or situations that could result in personal injury or death.

## CAUTION

A **CAUTION** label or indication in this manual advises against actions or situations that could damage the equipment, produce inaccurate data, or invalidate a procedure.

## INFORMATION NOTES

A **NOTE** provides useful information regarding a function or a procedure.

# MANUAL VERSION

This is a complete version of the UltraVision's Operators Manual. All pages carry the same version number:
820.120.0005 Rev 6.1

. This is installed as a .pdf and may be reviewed or printed from the help tab of the systems User Interface.

# Contents

STATEMENT ..... 2
NOMENCLATURE ..... 2
WARNING ..... 2
CAUTION ..... 2
INFORMATION NOTES ..... 2
MANUAL VERSION ..... 2
Chapter 1 Safety Guidance ..... 6
1.1 Warnings and Cautions ..... 6
1.2 Safety Warnings ..... 6
1.3 General Cautions ..... 10
1.4 Labeling symbols ..... 12
Chapter 2 Introduction ..... 15
2.1. Overview ..... 15
2.2. Features ..... 15
2.3. Intended Use ..... 15
2.4. Model ..... 15
2.5. Contraindications ..... 15
Chapter 3 System Overview ..... 16
3.1. Appearance ..... 16
3.1.1. Front View ..... 16
3.1.2. Right Front Side View ..... 17
3.1.3 Left Side View ..... 18
3.1.4 Configuration ..... 19
1.1.5 Options ..... 19
Chapter 4 Installation Instructions ..... 20
4.1. Environmental Requirements ..... 20
4.2. Unpacking Inspection ..... 20
4.3 Transporting the system ..... 20
4.4. Connecting Procedure ..... 20
4.5. Connecting and Disconnecting Probes ..... 21
4.6. Peripheral Connections ..... 22
4.7. Equipotential Bonding ..... 23
4.8 Printer Installation ..... 23
Chapter 5 System Control ..... 24

5.1. Powering On/Off SYSTEM....24
5.2 Starting the System....25
5.3 The Patient Information Screen....25
5.4 Patient Information Screen Buttons....26
5.5 Image Acquisition Screen....27
5.5.0 Start/Scan....27
5.5.1 Scan Settings Panel....28
5.5.2 The Image Display Panel....30
5.5.3 The Time Gain Control Panel / Gallery Panel /Accessories Panel....31
5.5.4 Gallery....31
5.5.5 ADC....32
5.5.6 Archive Import / Export....34
5.5.7 System Settings....35
5.8 Modes....44
Chapter 8 B-Mode....46
Chapter 9 Color Flow Doppler Mode....49
Chapter 10 A Mode....50
Chapter 11 M Mode....51
Chapter 11A Biopsy Mode....51
Chapter 12 Elastography Mode....52
Chapter 14 PWD (Spectral Doppler) Mode....53
Chapter 15 3D Mode....54
Chapter 16 Photoacoustic Mode....57
Chapter 17 Acoustic Output Testing....59
Chapter 18 Inspection and Maintenance....67
Chapter 19 Transportation and Storage....71
Appendix 1 UltraVision Definition of Image and Data Formats....72
Appendix 2 Loading Updated User Code....74
Appendix 3 Reprogramming the FPGA for 40 or 60 MHz clock....75
Appendix 4 EMC Information Guidance and Manufacturer's Declaration....76
Appendix 5 Body Markers....80
Appendix 6 Research Platform....82
TRADEMARKS....84
CAUTION!....84
LICENSE AGREEMENT....84

# Chapter 1 Safety Guidance

## 1.1 Warnings and Cautions

In order to use the equipment safely and effectively, and avoid possible dangers caused by improper operation, please read through the user manual and be sure to be familiar with all functions of the equipment and proper operation procedures before use. This user manual is installed as a .pdf on the system and may be reviewed or printed from the help tab of the systems User Interface.

Please pay attention to the following warning and caution information.

## 1.2 Safety Warnings

**NOTE**:

The reliability of the device and the safety of operators and patients are considered during product design and production.

The following safety and preventive measures should be carried out by the user:

**WARNINGS**

1. This equipment is not intended for treatment.
2. This equipment is not intended for home use.
3. The diagnosis and examination function of the ultrasonic imaging management system should be integrated with clinical situation of patients, and the diagnostic results are only for a physician's reference.
4. EXPLOSION HAZARD-Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
5. The device should be operated by qualified operators or under their instructions.
6. The device should be operated appropriately to avoid mechanical damage to the transducer.
7. The device is not waterproof. Do not use it in locations where water or any liquid leakage may occur.
8. Do not pour any fluid onto the system surface, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.
9. Do not spray cleansers on the system, as this may force cleaning fluid into the system and damage electronic components. It is also possible for the solvent fumes to build up and form flammable gases or damage internal components.
10. The parameters of the device are not recommended to be altered at will. If it is necessary, please consult UltraVision Corporation or an authorized representative for service.
11. The device has already been adjusted to its optimum performance. There are no presetting controls or switches.
12. If the device breaks down, please shut down the machine immediately and contact UltraVision Corporation or its authorized representatives.

**WARNINGS CONTINUED**

13 Only accessories supplied or recommended by UltraVision Corporation can be used, the battery, desk top power supply and probes of UltraVision Corporation can be only used on UltraVision Corporation's systems. Otherwise, the performance and electric shock protection cannot be guaranteed. If electrical or mechanical equipment from other companies need to be connected to the device, please contact UltraVision Corporation or authorized representatives before connection. Any person who creates a system by connecting this equipment to other equipment (both medical and non-medical) should confirm the system as being in compliance with Clause 16 of IEC 60601-1:2005 (ME SYSTEMS). Only items specified by UltraVision should be connected to the phono or USB ports. During scanning the ports should be covered by the supplied plugs to prevent ESD interruption of the computer. When inserting a USB Stick the user should touch the case first to discharge any static electricity prior to inserting a USB stick.

14. The equipment should be serviced by a qualified service engineer. Do not try to access the interior of the unit. Only authorized service personnel should remove any cover.

15. Equipment connected to the UltraVision and located in the patient zone must be powered from a medically isolated power source or must be a medically-isolated device. Equipment powered from a non-isolated source can cause your system to exceed leakage current limits. Enclosure leakage current created by an accessory or device connected to a non-isolated outlet may add to the enclosure leakage current of the imaging system.

16. When more than one medical device is connected to the patient, leakage current of the devices is summed together. Take appropriate caution.

17. SHOCK HAZARD - Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.

18. SHOCK HAZARD - Don't connect non-medical electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.

19. SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlets supplying the system.
20. Multiple portable socket-outlets shall not be placed on the floor.

21. Do not exceed the maximum permitted load when using multiple portable socket-outlets to supply the system.

22. Do not use the additional multiple portable socket-outlet or extension cord in the medical electrical system, unless it's specified as part of the system by manufacturer and the multiple portable socket-outlets provided with the system shall only be used for supplying power to equipment which is intended to form part of the system.

23. Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously.

24. A damaged probe can also increase the risk of electric shock if conductive liquids come in contact with

internal live parts. Inspect probes often for cracks or openings in the enclosure and holes in and around the acoustic window or other damage that could allow liquid entry.

25. To avoid electrical shock, never modify the ultrasound system's AC power circuit.

26. To avoid electrical shock and damage to the system, turn off and disconnect the device from the AC power source before cleaning and disinfecting.

27. Don't touch any signal input or output connector and the patient simultaneously.

28. To avoid the possibility of electrostatic shock and damage to the system, avoid using aerosol spray cleansers on the monitor screens.

29. Any non-medical equipment (such as an external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).

30. Periodically have the integrity of the system ground checked by a qualified service engineer.

31. This device is not suitable for intra-cardiac use or direct cardiac contact.

32. UltraVision Corporation makes every effort to manufacture safe and effective probes. You must take all necessary precautions to eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials. These precautions should be considered in the use of any application that may indicate the need for such care, and during endo-cavity scanning.

33. If the liquid crystal material leaks from the display panel, it should be kept away from the eye or mouth. In case of contact with hands, skin or clothes, it has to be washed away thoroughly with soap.

34. Ultrasound may be harmful to human body. This device should be used for valid reasons, for the shortest period, and at the lowest mechanical and thermal indices necessary to produce clinically acceptable images. According to the ALARA (As Low As Reasonably Achievable) principles, acoustic output should be set to the lowest level required to satisfactorily perform the examination. Long time exposure should be avoided. For the parameters of sound output, please refer to Chapter 6. The UltraVision complies with the requirements of applicable International Electrotechnical Commission (IEC) standards in terms of safety and acoustic output levels.

35. Contact with natural rubber latex may lead to a severe anaphylactic reaction in persons sensitive to the natural latex protein. Sensitive users and patients must avoid contact with these items. UltraVision Corporation strongly recommends that health-care professionals identify their latex-sensitive patients, and refer to the FDA's March 29, 1991 Medical Alert on Latex products. Be prepared to treat allergic reactions immediately.

**NOTE:**

The probe stops transmission when the image is frozen, disconnecting the probe, or entering sleeping mode. Main control software checks the probe connection all the time, once probe disconnects from the probe socket, the system stops transmitting.

The system should be frozen before disconnecting the probe.

**Electromagnetic Compatibility (EMC)**

Operating the UltraVision near sources of strong electromagnetic fields, such as radio transmitter stations or similar installations may lead to interference visible on the monitor screen. However, the device has been designed and tested to withstand such interference and will not be permanently damaged.

**EMI Limitations**

Ultrasound machines are susceptible to Electromagnetic Interference (EMI) from radio frequencies, magnetic fields, and transients in the air. Ultrasound machines also generate EMI. The UltraVision complies with limits as stated on the EMC label. However, there is no guarantee that interference will not occur in a particular installation.

Possible EMI sources should be identified before the unit is installed. The presence of a broadcast station or broadcast van may also cause interference. If you find evidence of EMI in the form of noise on a B-Mode image, please check for a source.

Electrical and electronic equipment may produce EMI unintentionally due to one of the following defects: high frequency electro-tome, transformer, defibrillator, wireless LAN equipment, medical lasers, scanners, cauterizing guns, computers, monitors, fans, gel warmers, microwave ovens, light dimmers, portable phones.

## 1.3 General Cautions

**CAUTION**

1. No user serviceable parts are inside the system. All repairs on the system must be performed by an UltraVision Corporation certified service personnel.

2. If the power cord of the system is missing, damaged or not provided, please replace the power cord meeting the specification requirements for the original one and complying with the local regulations. Contact UltraVision for a replacement or approval of a replacement cord.

3. It is necessary to take the probe out of the probe holder during moving and transporting; otherwise, the probe may be broken.

4. Please use the standard power cord as the input line of the network power supply for the adapter to reduce electrical risk.

5. To ensure proper grounding and leakage current levels, it is the policy of UltraVision Corporation to have an authorized UltraVision Corporation representative, or an UltraVision Corporation approved third party to perform all on-board connections of documentation and image storage devices to the UltraVision.

6. The device and accessories are to be disposed of according to local regulations. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do not dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the dealer where you purchased the product.

7. The normal ultrasonic examination is recognized as being safe. To avoid burns, do not scan in the same area for a long period of time. Always minimize the exposure time while acquiring necessary clinical information.

8. Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

9. To avoid misdiagnosis from inaccurate measurement values, ensure that the target area of interest and image are correct, and the measurement area is valid.

10. Before using the system, you must make sure that there is no visible evidence of damage on the equipment, cables and probes, which may affect patient safety or diagnostic capability. The recommended inspection interval is once per week or less. If damage is evident, replacement is recommended before use.

11. Before cleaning the scanner, switch the scanner off and disconnect the power cable to the scanner. Cleaning the scanner is done by gently wiping the scanner using a new tissue or dry cloth. Cleaning the transducer is done by first removing the ultrasound coupling gel with a soft tissue and then gently wiping the transducer dry using a new tissue or dry cloth. When more cleaning is required only a mild detergent or hand-soap may be used together with some water and a soft tissue cloth. For disinfecting refer to the transducer disinfecting section of this manual.

12. To avoid possible damage, the transducer cable must not be coiled to a diameter of less than 4 inches (100 mm).

**CAUTION CONTINUED**

13. A transducer may only be connected to, or disconnected from the scanner while the UltraVision is powered off or is in Freeze Mode. Ignoring this may cause severe damage to your scanner and/or transducer.

14. The use of non-UltraVison Corporation components with this scanner may result in damage to the scanner.

15. Do not subject the equipment to excessive mechanical shock, for example, when moving the equipment. If the equipment is repeatedly subjected to excessive shock, mechanical parts may be damaged.

16. Do not use the equipment in locations subject to intense electric or magnetic fields (near transformers, for example).

17. Do not use the equipment near devices generating high frequencies (such as medical telemeters and cordless telephones). If used near such devices, the equipment may malfunction or adversely affect such devices.

18. To guarantee proper unit operation do not operate the scanner in an environment with a temperature in excess of 40 degrees centigrade. If the equipment is used in a small room, the room temperature may rise. Proper ventilation must be provided.

19. Avoid installation near a heater or in direct sunlight.

20. The scanner draws air in the front grill and expels it out the back grill. Do not obstruct either grill as it may cause the scanner to overheat.

21. The scanner contains components which should not be frozen or exposed to excessive heat. Store and operate the scanner above 4 degrees centigrade and below 40 degrees centigrade.

22. Equipment not rated for use in elevations above 2000 m.

**NOTE:**

To avoid damaging the system, DO NOT use it in any environment described below:

1. Locations exposed to direct sunlight.

2. Locations subject to sudden changes in ambient temperature.

3. Dusty locations.

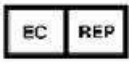
4. Locations subject to vibration.

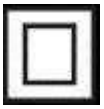
5. Locations near heat sources.

6. Locations with high humidity.

## 1.4 Labeling symbols

Descriptions of symbols of the device labeling and the device manuals are shown in Table 1.

| Symbol | Title and Description | Reference number and applicable standard |
|---|---|---|
| SN | **Serial number**<br>Indicates the manufacturer's serial number so that a specific medical device can be identified | 5.1.7<br>ISO 15223-1:2012 |
|  | **Date of manufacture**<br>Indicates the date when the medical device was manufactured | 5.1.3<br>ISO 15223-1:2012 |
|  | **Manufacturer**<br>Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC | 5.1.1<br>ISO 15223-1:2012 |
|  | **Consult instructions for use**<br>Indicates the need for the user to consult the instructions for use. | 5.4.3<br>ISO 15223-1:2012 |
|  | **Caution**<br>Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself | 5.4.4<br>ISO 15223-1:2012 |
| Rx only (U.S.) | Federal (U.S.) law restricts this device to sale by or on the order of a physician | Federal Register Volume 81, number 115 rules and regulations pages 38911-38931, "Use of Symbols in Labeling" FDA, HHS final rule comment 19 |
|  | **Authorized representative in the European Community**<br>Indicates the authorized representative in the European community | 5.1.2<br>ISO 15223-1:2012 |

| | | |
|---|---|---|
|  | **Type BF applied part**<br>Indicates a type of BF applied part | 5333<br>IEC 60417:2002 DB |
|  | **Alternating current**<br>Indicates alternating current | 5032<br>IEC 60417:2002 DB |
|  | On (AC power supply) | 5007<br>IEC 60417:2002 DB |
|  | Off (AC power supply) | 5008<br>IEC 60417:2002 DB |
|  | Equipotentiality | 5021<br>IEC 60417:2002 DB |
|  | VGA output, external monitor | 5051<br>IEC 60417:2002 DB |
|  | Class II double insulated electrical appliance which has been designed that it does not require a safety connection to electrical earth. (US: ground) | 5172<br>IEC 60417:2002 DB |
|  | Fuse | 5016<br>IEC 60417:2002 DB |
|  | Footswitch | 5114<br>IEC 60417:2002 DB |
|  | Protective earth | 5019<br>IEC 60417:2002 DB |
|  | Recording on an information carrier | 5163<br>IEC 60417:2002 DB |
|  | Dangerous voltage | 5036<br>IEC 60417:2002 DB |

| | | |
|---|---|---|
|  | **Variability**<br><br>Rotate clockwise to increase value and counterclockwise to decrease | 5004<br><br>IEC 60417:2002 DB |
|  | Brightness | 5056<br><br>IEC 60417:2002 DB |
|  | Sound muting | 5436<br><br>IEC 60417:2002 DB |
|  | Loudspeaker to adjust volume | 5080<br><br>IEC 60417:2002 DB |

Table 1

# Chapter 2 Introduction

## 2.1. Overview

The UltraVision is a portable Diagnostic Ultrasound System, which applies the latest technologies to produce optimal images. Various image parameter adjustments, a, high resolution display, touch screen and custom probes are configured to provide clear and stable images.

## 2.2. Features

Gray Scales: 256
Display Modes: B, M, CF, PW, Elastography and Research Modes
Measurements: Multiple Distances

## 2.3. Intended Use

This diagnostic ultrasound system (UltraVision) and its transducers are intended for use in clinical examinations to evaluate differences in the echogenicity of soft tissue of small parts in adult patients, (thyroid, breast, and testicles) and for abdominal, peripheral vessel and superficial muscular skeletal diagnosis.

The system is for prescription use only by a trained sonographer under the direction of a qualified physician or directly by a qualified physician.

## 2.4. Model

This manual is applicable to the following three models: UltraVision-XR, -XC, or -XC

## 2.5. Contraindications

1. The equipment is not applicable to the diagnosis of the pneumatic organs that contain gas such as lung, stomach, intestines, etc.
2. It is recommended not to examine the parts with wounds or acute inflammation to avoid cross infection.
3. Patients in the following situations are not allowed to be examined with the UltraVision's probe: vaginal infection (such as trichomonal vaginitis, colpomycosis, venereal disease etc.), vagina deformity, menstrual period, postmenopausal vagina atrophy, difficulty in per vagina ultrasonic examination, colporrhagia, Pyrilamine placenta previa, etc. The UltraVision is unsuitable for ophthalmic, transcranial, transesophageal, interoperative, transrectal or transvaginal examinations.
4. Patients with known or suspected Creutzfeldt-Jakob disease (CJD) should not be scanned with the UltraVision. Any probe sheath cannot be relied upon to prevent contamination of the probe. A transducer exposed to central nervous system tissue from a known CJD or a vCJD should be destroyed since it may not be possible to sterilize it.

# Chapter 3 System Overview

## 3.1. Appearance

### 3.1.1. Front View

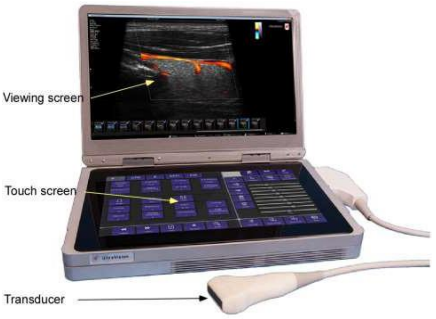
THE ULTRAVISION XR, XC and XS



UltraVision-XR



UltraVision-XC




UltraVision-XS

This manua

l will default to the UltraVision-XR but the software is identical for all three devices.

**NOTE:**

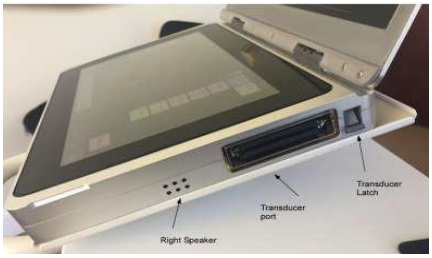
The pictures and interfaces in this manual are for reference only.

**CAUTION**

To have good aeration performance and be able to operate normally, please don't cover or obstruct the air inlet or outlet partly or wholly with any object. The system is designed to operate in a clean, dust free, and dry environment. The system is not suitable for operation in the presence of any flammable anesthetic liquids or gasses.

### 3.1.2. Right Front Side View



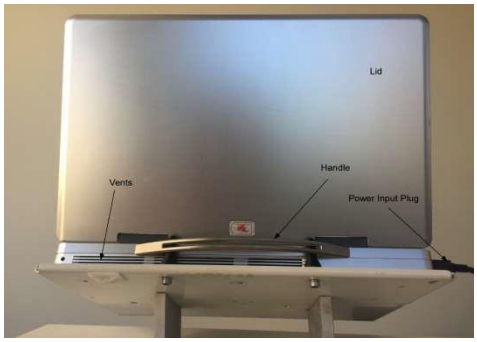

View of Transducer Port





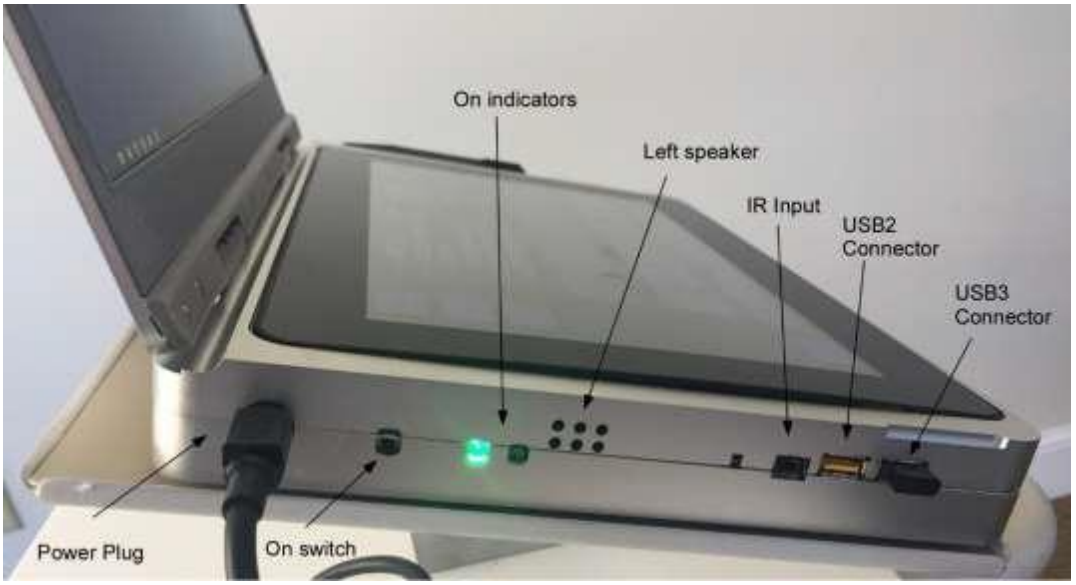

Transducer Inserted






To have good aeration performance and be able to operate normally, please don't cover or plug air inlet partly or wholly by using any object.

### 3.1.3 Left Side View




Left side showing handle and USB2 connections on XS.

**CAUTION**

For easy control, please don't cover the power switch. Connect the power supply input to a suitable 90-264 VAC power source. The system is supplied with a power cord for the source of the region that the system is shipped to, do not change this power cable. UltraVision will supply other suitable power cables if the region is changed. If the system consumes excessive power, the power supply will shut down until the excessive power drain is removed. The system does contain non operator accessible fuses and if these are suspected to have failed UltraVision authorized personnel will be required to diagnose the fault and change the internal fuses.



Class 2 IEC60101-1 18 volt power supply

### 3.1.4 Configuration

1. 1 UltraVision main unit
2. 1 linear array probe: L14-4
3. 1 power cord and UL60601-1 Power supply.
4. 1 user manual
5. 1 packing list

### 1.1.5 Options

#### 1.1.5.1 Cart

#### 1.1.5.2 Mouse

# Chapter 4 Installation Instructions

## 4.1. Environmental Requirements

Keep the device away from equipment with strong electric field, strong magnetic and high voltage field, and protect the display screen from direct exposure to strong sunlight. Keep good clean dust free ventilation. Do not use or store the device in a location subject to vibration. Do not operate with obstructions over the air vents.

## 4.2. Unpacking Inspection

Visually examine the package prior to unpacking. If any signs of mishandling or damage are detected, contact the carrier to claim for damage. After unpacking the device, you should follow the packing list to check the product carefully and to make sure that no damage has occurred during transportation. Then, install the device according to the installation requirements and methods.

**WARNING**

1. Do not use the device if it is found to be damaged or defective.
2. Do not drop or impact the probe with any hard surface.

## 4.3 Transporting the system

The System should be transported in its carrying case with the transducer disconnected and placed in its own transducer case in the carrying case with the desk top power supply. The system should not be subjected to vibration or excessive temperatures or a dirty environment while being transported.

## 4.4. Connecting Procedure

1. Take the main unit and accessories out from the packaging.
2. Connect the probe to the main unit correctly.
3. Plug one end of the power cable to the power socket of the system, and the other end into the power output socket of the hospital. Note the green power present light is lit.
4. (If optional printer was purchased). Connect the printer and load the recording paper.
5. Switch on the power switch on the left side (handle) of the system. Note the power on light is lit. You can operate the main unit after the main interface appears on the screen.

**NOTE**

Ensure that the system is shut down, or the image is frozen, before connecting and disconnecting the probe.

## 4.5. Connecting and Disconnecting Probes

The scan direction mark located at the side of probe indicates the beginning direction of scanning.

The scan direction mark is shown below.




Figure 4-5 Probe Scan Direction Mark

1. Marks indicate left side of screen.

There is information about Model and SN on the probe connector (see Figure 3.2)

**To connect a probe:**

1. Place the system in FREEZE (this switches off and transmit voltages).
2. Place the probe's carrying case on a stable surface and open the case.
3. Carefully remove the probe and unwrap the probe cable.
4. Do not allow the probe head to hang free. Impact to the probe head could result in irreparable damage.
5. Place the probe locking leaver in the down position.
6. Align the connector with the probe cable port towards the front of the system and carefully push into place.
7. Pull the probe locking connector to the up position.
7. Place the probe in the probe holder.

**To disconnect a probe:**

1. Place the system in FREEZE (this switches off and transmit voltages).
2. Place the probe locking connector in the down position and remove the probe cable housing from the UltraVision.
3. Store each probe in its protective carrying case.

**CAUTION**

Do not touch or allow to be touched the pin of probe connector in the system. It has pins which must not be bent (See Figure 3.2)

When the probe is inserted or removed the system should be FROZEN (this switches off and transmit voltages).

When the probe is not plugged in the system is automatically FROZEN.

**NOTE:**

Once the probe is connected to the main unit, please do not reinstall it frequently. This is to avoid poor contact between the probe and the main unit.

## 4.6. Peripheral Connections

Video connections (USB) are located on the left edge of the UltraVision.

**WARNING**

1. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore, anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local UltraVision distributor.

2. Parts and accessories used must meet the requirements of the applicable IEC/EN 60601 series safety standards, and/or the system configuration must meet the requirements of the IEC/EN 60601-1 medical electrical systems standard.

3. Connecting any accessory (such as external printer) or other device to this equipment makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:

    a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1.

    b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.

4. Parts and accessories must be connected to the I/O ports designated. For example, only the supplied or recommended USB device can be connected to the USB ports; DO NOT connect telephone line to the network port; DO NOT connect earphone to the footswitch port or remote port.

**CAUTION**

To ensure proper grounding and leakage current levels, it is the policy of UltraVision Corporation to have an authorized UltraVision Corporation representative or UltraVision Corporation approved third party perform all on-board connections of documentation and storage devices to the UltraVision.

## 4.7. Equipotential Bonding

An equipotential bonding ¼ 20 screw hole is available on the bottom (XS) or back (XR) of the system.

Any use of other devices with the system is at the user's risk and may void the system warranty. In order to fulfill IEC/EN 60601-1 requirements, connections of peripheral equipment to the UltraVision must adhere to one of the following conditions:

1. The peripheral equipment itself is a medical device approved according to IEC/EN 60601-1
2. Non-medical peripheral equipment approved according to any other EN or IEC standard must use the following setup for connection:
3. Connect the equipotential connector of UltraVision to an independent protective earth terminal with a potential equalization conductor.
4. The peripheral equipment is located at least 1.5 meters (1.8 meters in Canada and the U.S.A) outside the patient environment. A patient environment is defined as the area in which medical examination, monitoring, or treatment of the patient takes place.
5. The peripheral equipment is connected to a main outlet outside the patient environment but still within the same room as the ultrasound system.

**WARNING**

1. Equipotential bonding: when the device is running with other instruments jointly, consideration should be given to equipotentiality.
2. Doctors and patients might be exposed to the hazardous and uncontrollable effects of compensating current caused by unbalanced equipotentiality between indoor medical device and touchable conductive parts. The safest solution is to build a unified equipotential network, to which the medical device is connected, using an angular plug.

## 4.8 Printer Installation

The only accessory that the UltraVision System supports is a USB2 color video printer type Sony UPD25MD. To install a video printer: Connect the USB2 port to the printer.

**NOTE:**

1. The video printers should not be used in patient vicinity. (1.5 meters)
2. Chromatic aberration, unfriendly brightness, contrast, or overall appearance may occur if you print images with default presetting of video printer. To obtain good printings, please adjust video printer parameters according to the images.
3. If you want to use a multiple portable socket-outlet to supply power to the whole UltraVision system, you are suggested to calculate the system power consumption when building an UltraVision system so as to match the system power consumption with the power sustained by a multiple portable socket-outlet.

# Chapter 5 System Control

## 5.1. Powering On/Off SYSTEM

Before powering on this device, check as below:

1. Check the potential equalization conductor and make sure it is connected properly if needed.
2. Check all the cables and make sure there are no scrapes or cracks.
3. Check the control panel and the monitor and make sure there are no cracks.
4. Check the probe and the connection and make sure there are no scrapes or cracks.
5. Check the power socket and the switch and make sure there is no damage.

To power on the UltraVision:

1. Connect the power supply to a standard three-pin power supply socket via the power cable supplied with the system, connect the power supply to the barrel 12-volt connector (or for the -XS use the 19 volt input 4pin connector on the side of the system. When system is plugged in the battery packs will automatically charge if this option is fitted. Each battery is capable of 50 minutes of continuous scanning allowing the user up to 100 minutes of continuous scanning when power supply is not plugged in.

2. Toggle up the switch on the right side of the -XR system and the green light next to this power switch will turn on. When the connection to the PC is established, the blue light will also turn on.
   (Or for the -XS pressing and holding the power switch on the left side of the system for approximately 1 second will turn on the power indicated by the the green light followed by the blue light indicating the PC is powered up.

3. The user may then be challenged for a password which is "probe" by default which may be entered by pressing in the white box and entering the password with the keyboard that appears.

   **Note:** The sequencing of the powers supplies is handled by the system which presents the user with the **Exam Info** screen. This can be filled out or the **Begin Exam** button pressed to get to the imaging screen. The Patient Information, institution, etc. may be entered at any time later by returning to the **Exam Info** screen. The fans in the system will run quieter once the system is fully powered up.

To shut down the UltraVision

Toggle down the power switch.

(Or in the case of the-XS press the power switch and the system will automatically shut itself down.

**NOTE**

By default, if the system is left on and live without an operator, it will move into Freeze mode. Depressing any key, mouse click, or gesture will reset this timer. When Freeze mode is entered by this path the Freeze Button will be orange. Depressing the Freeze Button will re-enter the live scanning mode (as normal). When the Freeze Button is orange, a right click on the mouse (or Control Shift) on the User Interface Keyboard will enter a mode where the interval of time for this time out can be set to any value.

By default if the system is left in Time Out Mode for greater that 5 minutes the Freeze Button will turn Red and the system will be Hibernated for a further 30 seconds. Return from Hibernate will show a Red Freeze button from where the system can be returned to live scanning by activating the Freeze Button.

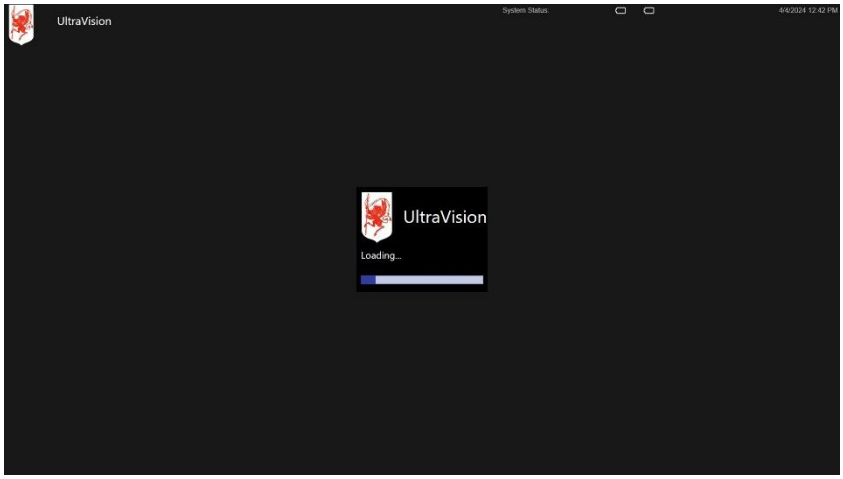
**CAUTION**

Do not unplug the power to the system before it has fully shut down and turned off the fans. The PC and Windows does certain housekeeping which may take up to 1 minute before it shuts itself down.

## 5.2 Starting the System.

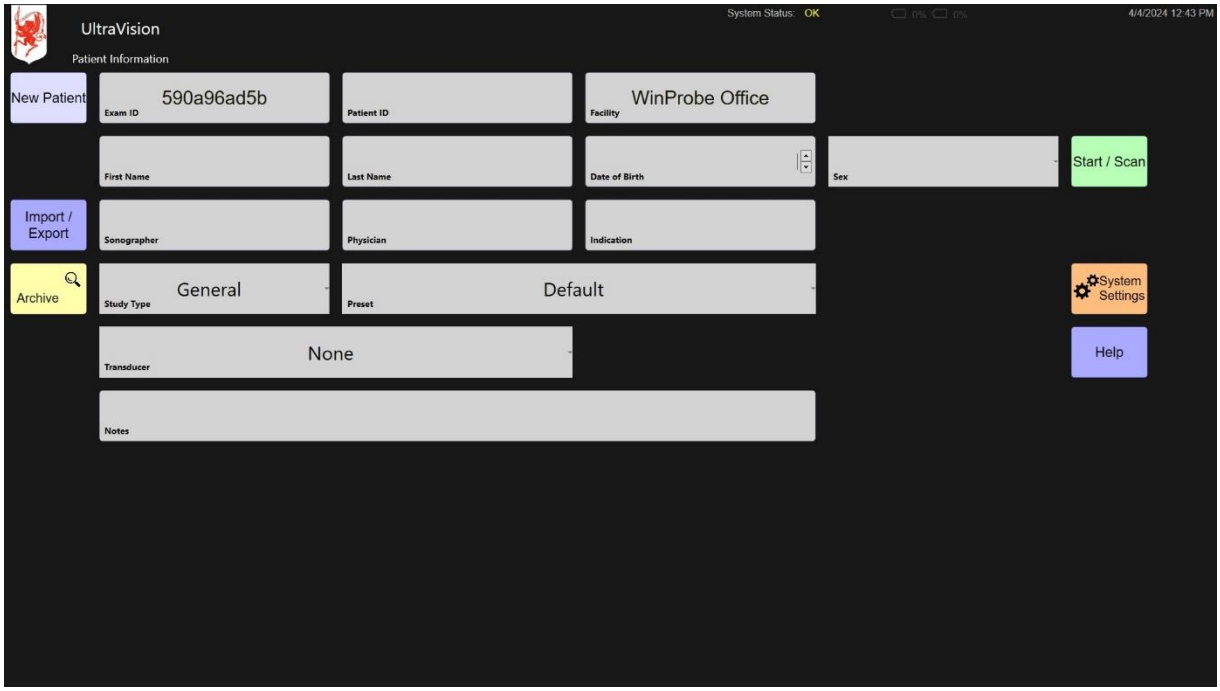
The desktop displays windows programs among which is the UltraVision Icon. Double left click the UltraVision Icon and the system will start.

Depending on the speed of the attached PC this screen can be displayed with the progress bar from 20 to 60 seconds.




## 5.3 The Patient Information Screen

The Patient Information Screen is populated with a default EXAM ID so any images stored will be saved to this folder, but you may overwrite this Exam ID with a more useful folder name that will be the stored in the Archive.




If a transducer is plugged into the system, its ID will be automatically populated or if the transducer is later plugged in it will automatically populate this field. This field may be populated from its dropdown selection if the transducer does not have an ID programmed of if the user wishes to select another set of transducer parameters in research mode.

## 5.4 Patient Information Screen Buttons.

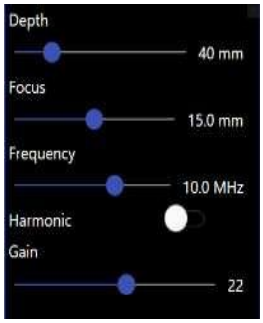
| | |
|---|---|
| Exam ID | Automatically populated but can be overwritten by user |
| Patient ID | To be populated by the sonographer. |
| Facility | May be populated by the sonographer or preprogrammed by UltraVision personal |
| First name | Populated by the sonographer. |
| Last Name | Populated by the sonographer. |
| Date of Birth | Populated by the sonographer. |
| Sex | Populated by the sonographer. |
| Sonographer | Populated by the sonographer. |
| Physician | Populated by the sonographer. |
| Indication | Populated by the sonographer. |
| Study Type | Drop-down menu presets depending on attached transducer. |
| Preset | Drop-down menu presets depending on attached transducer. |
| Transducer | Automatically populated form transducer ID |
| Notes | Populated by the sonographer. |

| | |
|---|---|
| New Patient | Overwrites all the above boxes except study type, transducer and preset. |
| Import/Export | Allows the user to import an UltraVision Exam or Preset. |
| Archive | Opens an archive of previous exams saved on this system. |
| Start Scan | Begins a new exam. |
| System Settings | Shows system setting where some may be edited. |
| Help | Launches Quick Reference guide and User Manual |

All buttons when the focus is hovered over them will indicate their use.



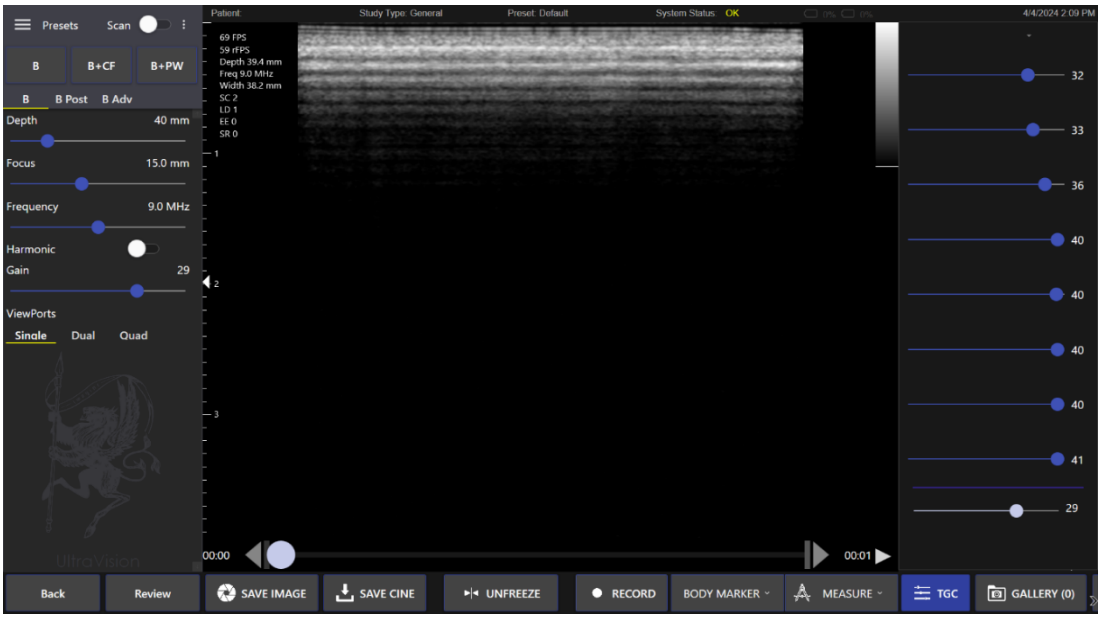
1. **Sliders or horizontal potentiometers** are used to adjust values by tapping either side of the ball along the horizontal line. Slider button are also available for functions that are either on or off.



## 5.5 Image Acquisition Screen

### 5.5.0 Start/Scan

Start/Scan takes the user to the control panel as shown in Figure 5.2.1 to begin scanning. “Return to exam” is present only if the user has begun an exam and pressed “Exam Info” to change some demographic data.




This screen comprises of three panels.

| | |
|---|---|
| Scan Settings Panel | Sets image acquisition modes, settings and display options. |
| Image Panel | Displays images and videos and has controls. |
| TGC/Gallery Pannel | Control for Time Gain Controls and images and cines save during this session. |

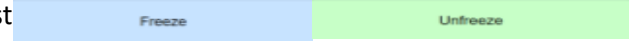
The UltraVision System is via Control Panel which appears on the Touch Screen (Monitor). The Control Panel contains virtual buttons, potentiometers and controls and they govern the operation of the system. Controls can change appearance to indicate their status or even appear or disappear as their relevance becomes useful or not in the instance.

In this manual controls which appear on the Control Panel are referred to as buttons. Buttons take several forms;

2. **Push Button** which performs an operation each time it is pressed. For example, the **Save Image** button takes the current image on the screen and saves it to system memory and creates or updates a thumbnail of the image in the image gallery. Each time it is pressed a the current image will be saved.




3.
4. **Toggle Button** which changes a state until it is pushed again when it returns the system to it previous state. Some Toggle Buttons change color to indicate the state. For example Freeze and Unfreeze are toggle st

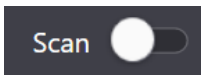



5. **Tab Button** is attached to a panel where other controls reside. For example the **TGC and Gallery** are Tab Buttons. Pressing the Tab Button **TGC** will fill the panel with nine potentiometers for adjusting the gain with respect to depth.

### 5.5.1 Scan Settings Panel



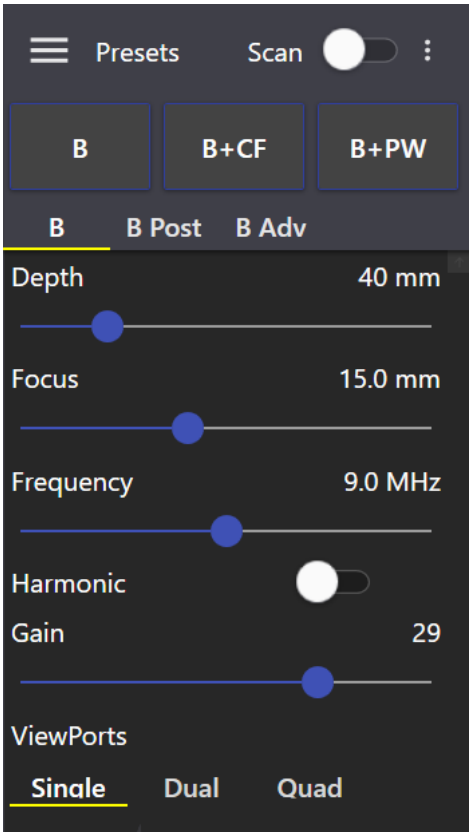

This button selects several system image tests that are detailed in Appendix A.




This slide switch selects between a selection of controls for scanning mode and a selection of controls that are used in **Review** mode. **Review** mode shows only the controls that are functional for post scanning on a frozen image. These are Brightness, Contrast, Gamma, B-Map, Speckle Reduction, Edge enhancement and a rectangular or trapezoidal image. The review allows editing of Cine images to be reduced in time from a selection of their start and stop frames and the speed that the frames are displayed at.



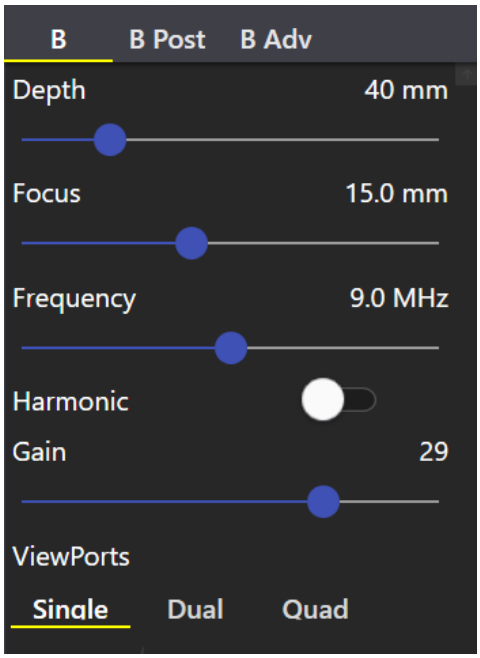
This Button edits what controls are visible in the Scan Settings panel for each mode that the scanner operates in. This enables quick access to multiple functions from the Scan Settings Panel and are detailed in Appendix B.




The next line down of buttons displays **B, B+CF, and B+PW**. Each button will set up the Image panel for acquitting just **B-mode** images or **B-Mode and Color Flow image**s or **B-Mode and Pulse Wave images**. All of these combination modes allow live acquisition of the mode or multiple modes.

The next line down of buttons displays **B, B Post** and **B Adv.** Each of these functions changes the panel below to provide the controls for the selection needed for the functionality.

**B**-mode




**Depth** is a slider control that allows the user to select the depth of the Field of View from 10 to 17 cm.

**Focus** is a slider control that allows the user to select the depth of the primary focus of the transmit function. The primary focus may be surrounded by three other focus depths depending on the mode.

**Frequency** is a slider control that allows the user to select the transmit frequency. The higher the frequency the better the resolution and the lesser the penetration. Frequency only controls the transmit frequency as the receive frequency is wide open.

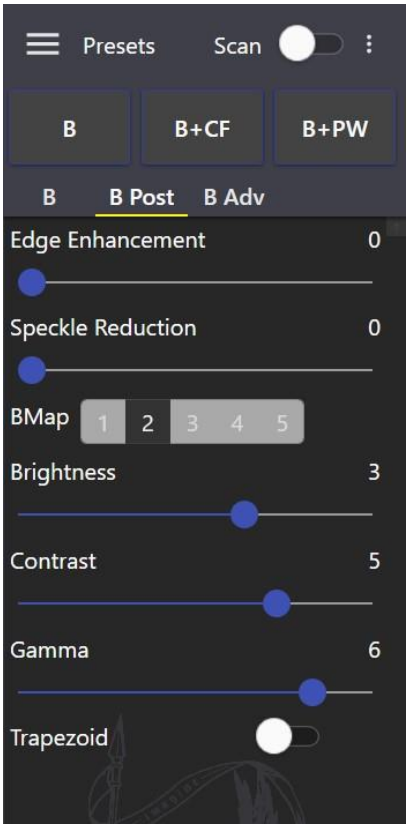
**Harmonic** is a mode where the system takes one of the nearest specific harmonic frequencies which is limited by the band width of the transducer. This first transmits a positive then a negative pulse at half the selected frequency and on the next transmission in the same spatial space transmits a negative then a positive pulse at half the selected frequency and then the two acoustic lines are added which removes the fundamental frequency content leaving just the harmonic frequency which is at the fundamental frequency selected. This is called Pulse Inversion Harmonic Imaging. As the transmit frequencies are one half the selected frequencies and the lobes of energy are narrower.

**Gain is** a slider control that increases the gain of the receive amplifiers but this is shared with the 40 dB of the TGC controls.

**View Ports** controls the image panel to display one, two or four images simultaneously but only one image may be live.

**B Post**

This panel displays the post scan processing which does not effect the image data but does effect how it is displayed. These settings will apply to the scanners live and frozen image quality.




**Edge Enhancement** is a slider control between 0 and 5 that enhances the edges in the image. This should be selected from the available settings to the viewers preference.

**Speckle Reduction** is a slider control between 0 and 5 that reduces the speckle in the image. This should be selected from tha available settings to the viewers preference

**B-Map** adjusts the compression from 64 thousand values to the 256 values that are available in a greyscale image. For example 3 is a log compression and 2 is an exponential compression. Again this should be selected from the available settings to the viewers preference.

**Brightness** refers to the absolute value of the greyscales brightness or darkness. This moves the image intensity gain of all of the image so drk areas will become white.

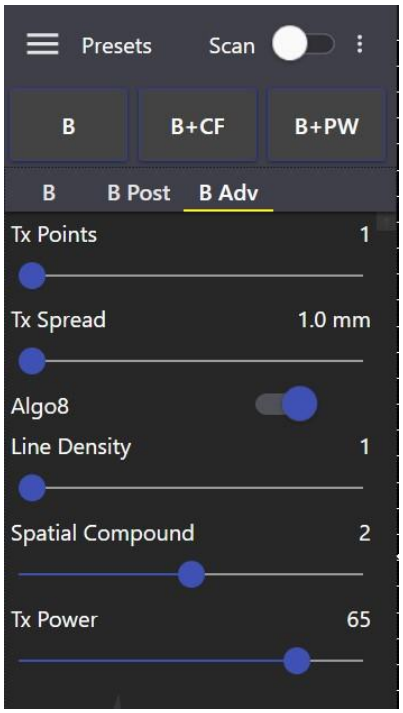
**Contrast** refers to the distinction between lighter and darker areas of an image. Decreasing the contrast makes the image appear more flat.

**Gamma** is a non linear adjustment that compensates for the displays non linear response to brightness levels.

**Trapezoid** selects a rectangular image cutting out acoustic lines that fall outside the rectangular space defined by the width of the transducer. Trapezoid displays all the acoustic lines that are generated by angular acoustic lines in the image generation.

**B Adv**anced

This Panel contains the controls for advanced but often used image processing. These settings will apply to the scanners live and frozen image quality.




**Tx Points** is a slider control between 0 and 4 that selects the number of depths down the image that the transmit pulse is focused at. Each depth requires a new transmission.

**Tx Spread** defines the distance in mm between the focus points.

**Algo8** is a minimum variance beamforming technique that improves the image quality.

**Spatial Compounding** transmits acoustic lines at small angles from the perpendicular to the transducer which sample the same volume of tissue at these different angles which are then summed and normalized. This is perhaps the greatest improvement inn image quality.

**Tx Power** is the amplitude of the transmit pulse in volts which may be adjusted between 40 and 70 volts. This voltage applies the the positive and negative pulses, so the voltage is actually twice the displayed voltage. Some transducers are limited in the voltage that can be applied to them.

## 5.5.2 The Image Display Panel




This is the image display output of the ultrasonic data. This panel is largely controlled by the buttons at the bottom of the screen.

**Back** returns the system control to the previous state.

**Review** allows viewing of the saved images, cines and recordings currently in the Archive for the current patient.

**Save Image** places the current image in the patient **Archive.**

**Cine** the UltraVision saves the running last 8 seconds of images in a memory for **Cines.** Progress through these images is displayed when the screen is **Frozen,** either by pressing an arrow at the bottom of the screen or by placing the mouse (touchscreen) curser on the **Round Button** and moving the left and right to view the desired image. The operator may click the Arrows to change the speed of the **Cine** presentation. **Save Cine** places the short video in the current patient **Archive**

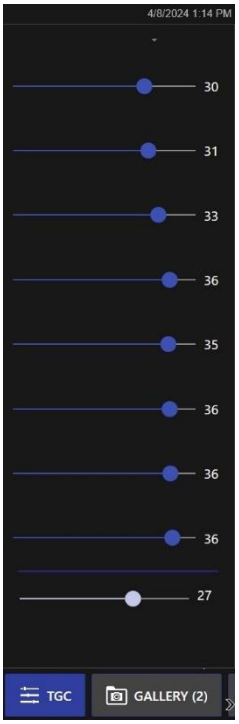
**Freeze / Unfreeze** freezes and Unfreezes the current image for viewing. This toggling switch also suspends transmitting pulses to provide a safe method of changing transducers.

**Record**. Records the current image frame to the hard drive and places it in the patient archive. This consumes a lot of hard drive space and so should be used judiciously.

**Body Marker** places an icon from a selection of icons that indicate where on the body that the current image has been taken. This is detailed in Appendix C.

**Measure** places a caliper on the screen. Multiple calipers may be used which are color coded in pairs for clarity.

### 5.5.3 The Time Gain Control Panel / Gallery Panel /Accessories Panel




**TGC panel** is the default panel and shows eight (8) liner slider potentiometers equally spread down the image controlling the gain from 0 to 40 dB at approximately the position of the potentiometer. It is approximately as this gain is dependent on the previous (above) gain settings as the slew rate is controlled to not cause oscillations in the amplifiers controlling the gains.

**Overall Gain** is the ninth (9) potentiometer at the bottom of the panel and it is used to control all the gains together to brighten or darken the image. There is only 40 dB available, so its functionality is limited if the other potentiometers are near their extremes.

### 5.5.4 Gallery




Save image or save Cine places the image or Cine in the Gallery or Record.

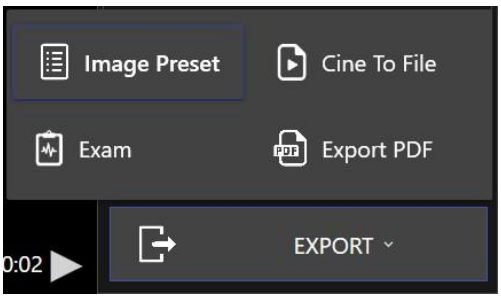
**Image Preset** (all the image settings) to an XML file and a File Browser where the user can select where to save the presets. The Export/Import Buttons in the Patient Information Screen allow these settings to be used in other patient studies.

**Cine to File** save the selected Cine to the location selected in the **File Browser** as an MP4.

**Export EXAM** exports all the **Cines, and Images** from this **Exam** in a zip file in the selected **File Browser** location.

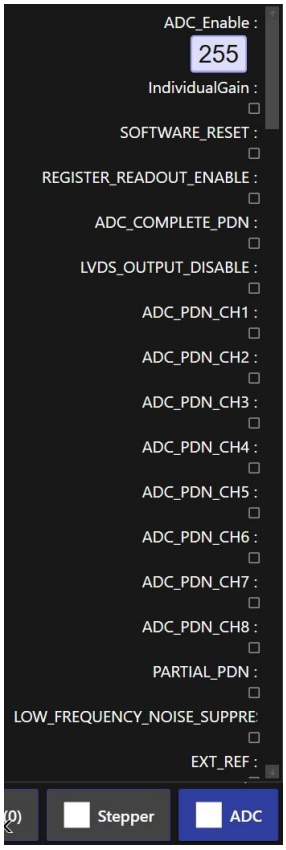
**Export PDF** exports the selected imaged (selected with the check box in the upper left corner) to the Captures folder for this exam. The Captures Folder is under Documents/UltraVision/Captures/"GUID"/…. This also opens the PDF in the default PDF viewer for printing or saving to a new location.

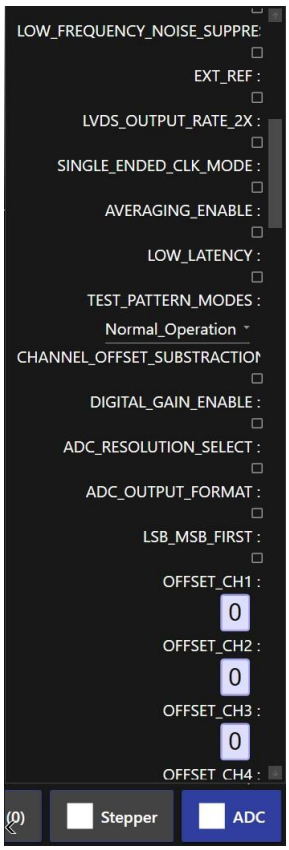
**Export to DICOM** saves one image with the check box selected to the File Browser location.

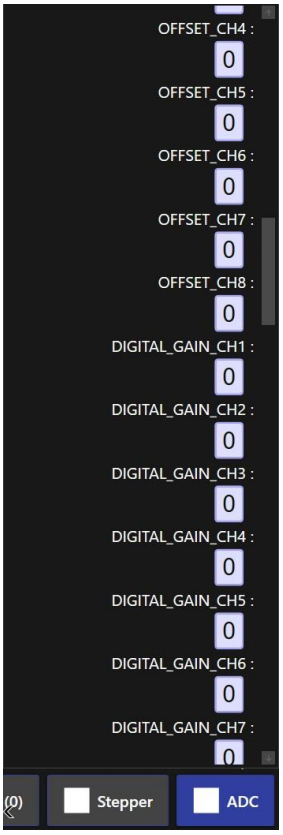


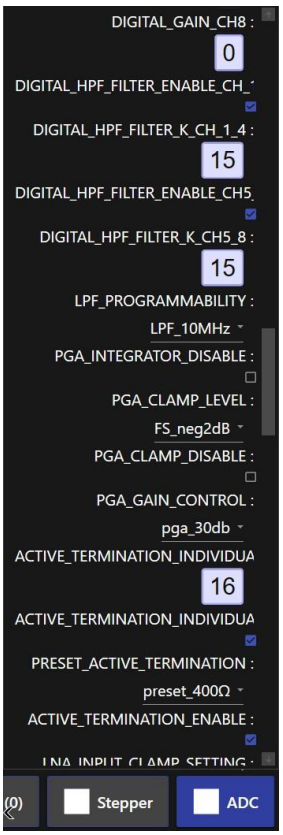
### 5.5.5 ADC

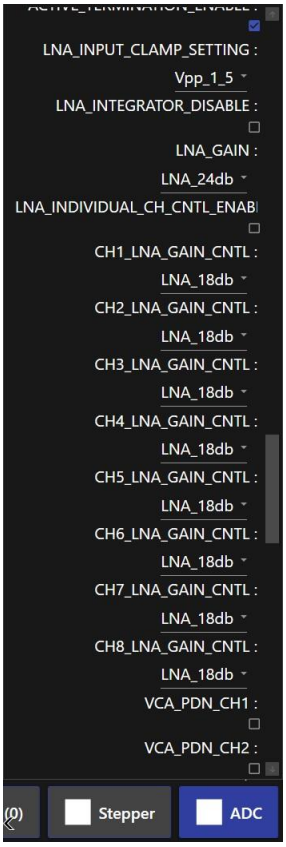
(Available in Research mode Only) allows access to eight panels of settings and we refer the user to the research Scanner Manual, or you may be instructed to change a parameter by an UltraVision engineer.

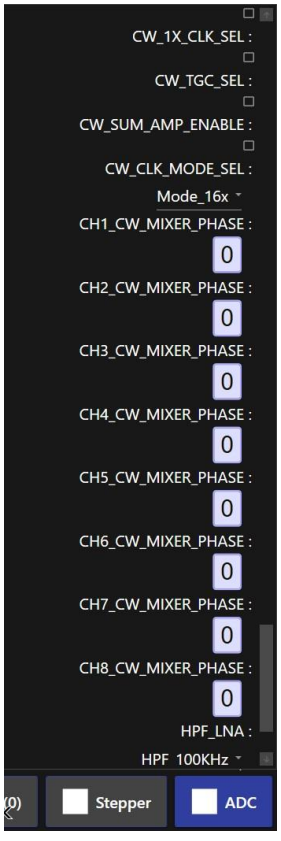


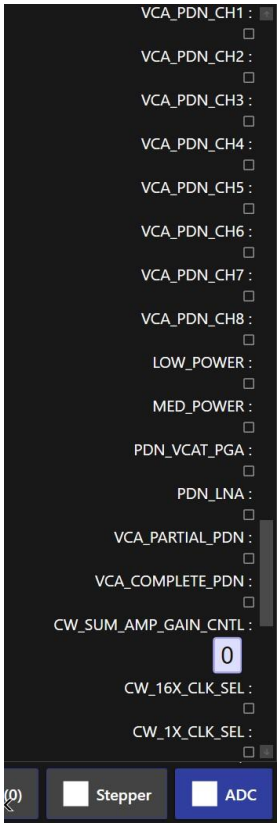



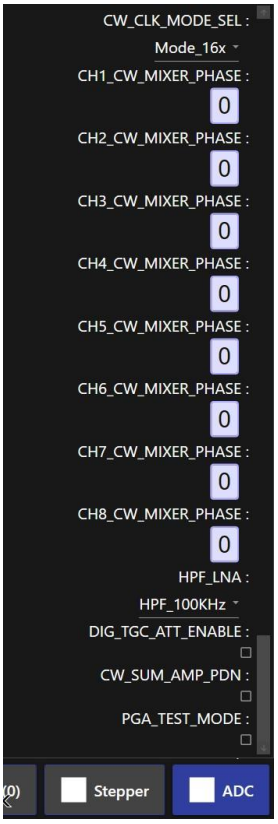



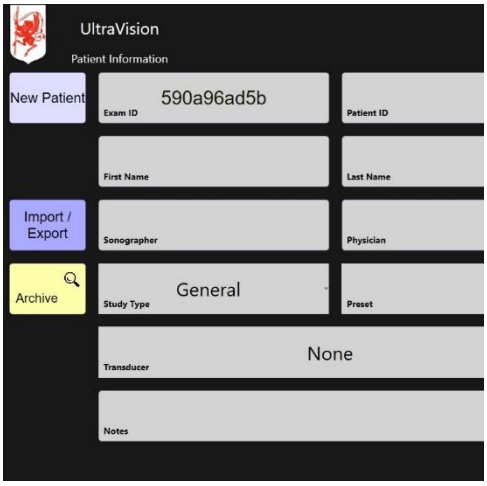






Import/Export gives the user the options to import an exam from a file, import a preset, and to export a preset as shown in Figure 5.3.1.2. Import is used to recall a study that was saved to a file on the system or a peripheral. Import Exam will bring up a Windows Explorer Type screen so the user may select the location and name of the file to import. Only files that have been previously exported will be shown as in Figure 5

**Figure 5.3.1.2 Import/Export Screen**

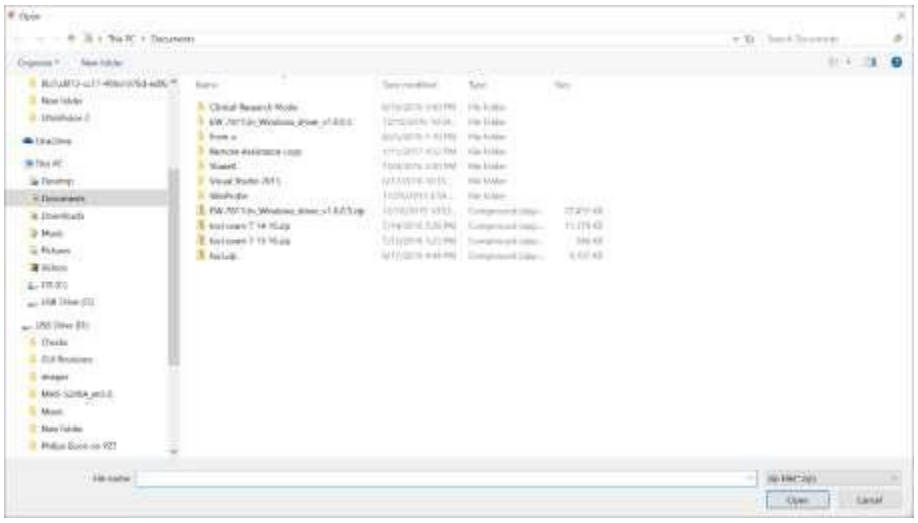


**Figure 5.3.1.3 Importing an Exam**

### 5.5.6 Archive Import / Export

Archive is the third button on the left and allows the user to select a previous exam. When anexam is selected, the images from the exam are displayed on the monitor as shown in figure 5.3.1.4. The user has the option to page through the images on the monitor with the “Page Images Left” and “Page Images Right” buttons as shown in figure 5.3.1.5. This allows the user to review the exam before selecting it for any modifications by pressing “Select”.



**Figure 5.6 Monitor view in Archive**

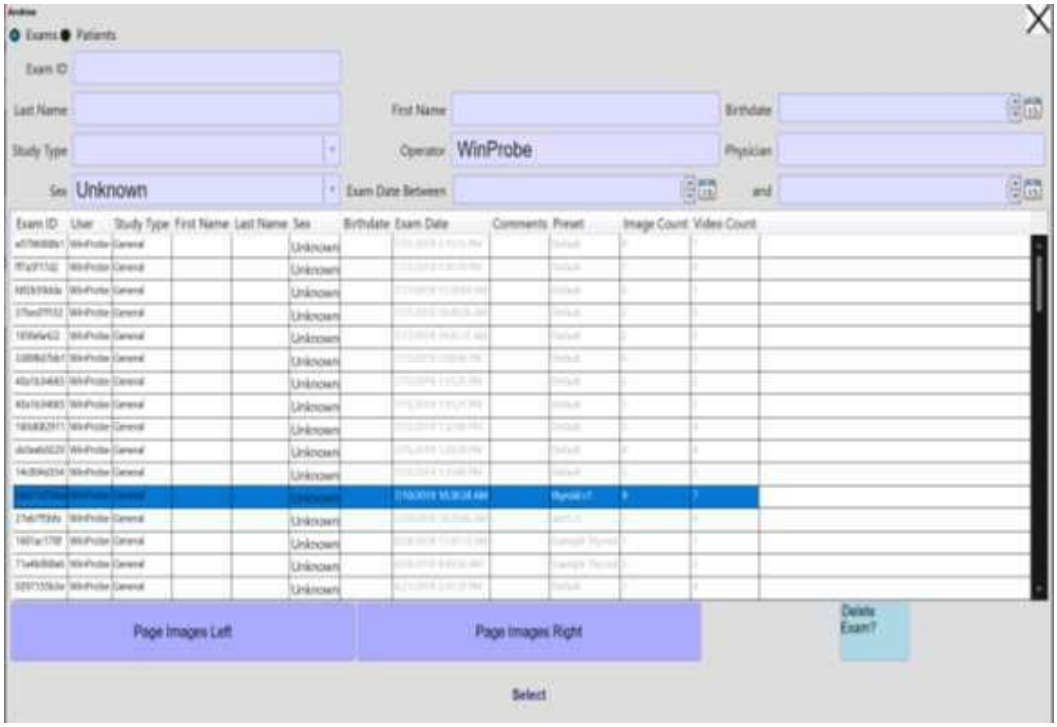



**Figure 5.3.1.5 Touchscreen view in Archive**5.5.3 System Settings

## 5.5.7 System Settings

The "System Settings" control brings a user to a screen with options based on their log-in credentials as shown in Figure 5.3.2.1. This screen contains a list of the software modules and their revision levels in the system which may be used to establish the levels of upgrades in the system.




**Figure 5.3.2.1 Set Up Options**

The set up options are shown in Figure 5.3.2. 1. The available options on the set up screen are contingent upon user credentials.

### Body Markers

The UltraVision predefined body markers are in the Appendix section. They may be added is a new marker is drawn with a graphics program and saved as a .png file.

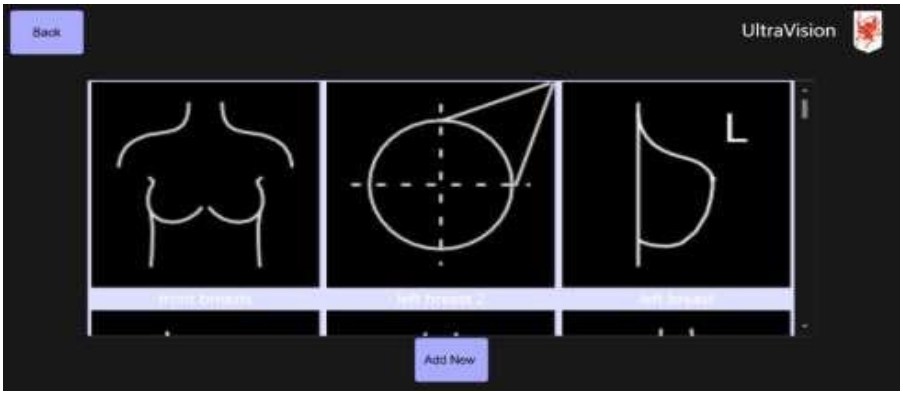



**Figure 5.3.2.2 Body Markers**

## Presets

The “Presets” button provides a list of the presets for exams. The default presets for the UltraVision are Thyroid, Breast, General, Musculoskeletal, Peripheral Vascular, and Testicle as shown in Figure 5.3.2.3. These presets can be edited by the user.

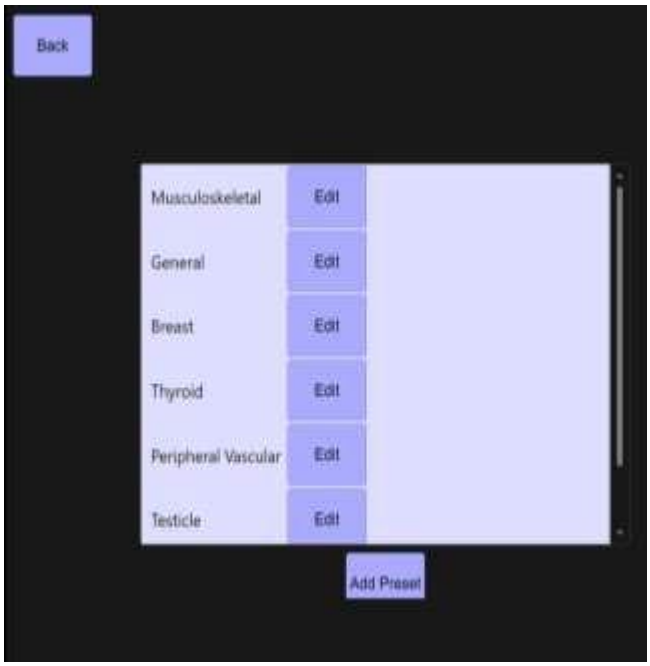



**Figure 5.3.2.3 Presets**

## Patients

This displays patients that have been entered into the system and allows new patients to be entered and saved.




**Figure 5.3.2.4**

## Diagnostics

The top page displays the voltages, temperatures and fan speeds currently of the system.




**Figure 5.3.2.5 Diagnostics**

### FLASH FPGA (Restricted to Administrators)

The code for the Field Programmable Gate Array may be changed by the user to repurpose the system as in changing the master clock between 40 and 60 MHz or updating the system with new features or possible bug fixes. Descriptions of its use are in the Appendices and the files this feature loos for are of the type .MCS.

### RF CAPTURE ENABLED (Restricted to Administrators)

This is a research mode which writes the results of every digitization of every (64) analog to digital converter to a file in the PC. This is the raw RF data that some researchers find useful.

CHANNEL SCOPE

(Restricted to Administrators) This is an acquisition mode which runs with the other modes in its own window. It displays every digitization (defaults to 4098) of every channel in a 64 channel oscilloscope mode. A line number must be chosen, the system must be live (not frozen) and the user presses Update to activate.

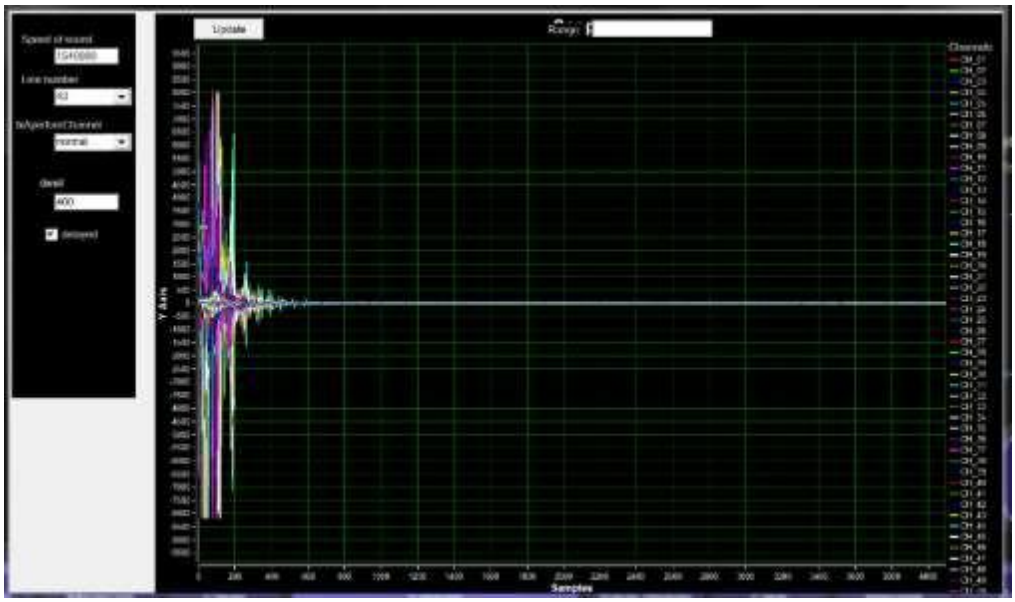


**Figure 5.3.2.5.1**

This feature is useful for viewing the individual elements response of a transducer for quality control of the transducer and checking that the correct delays are used in acquiring an image. This second use requires checking the delayed box or the channels will be accessed prior to the beamformer delay. We refer the reader to the Research Platform Manual for details. The scope can be maginified to show individual digitizations from 16K to individual clocks 16.6-25 ns.

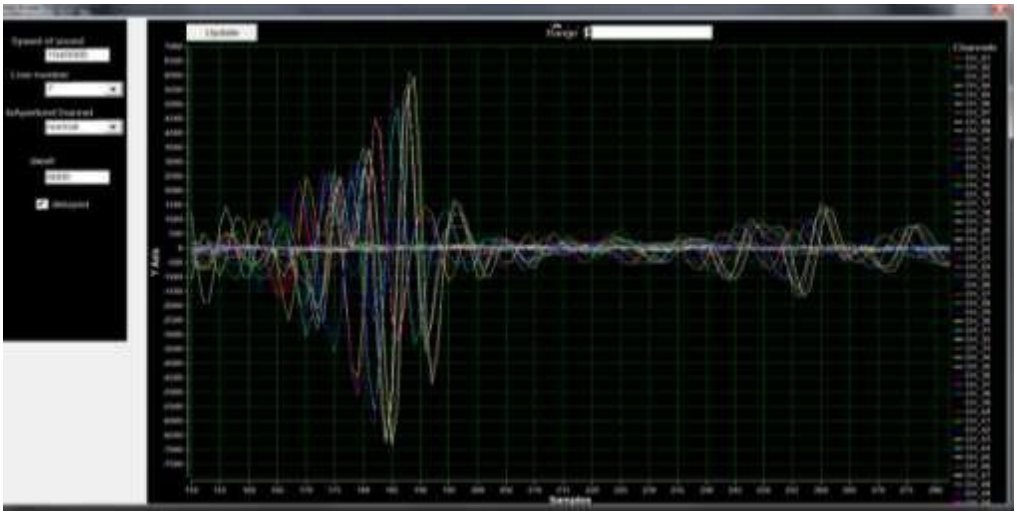


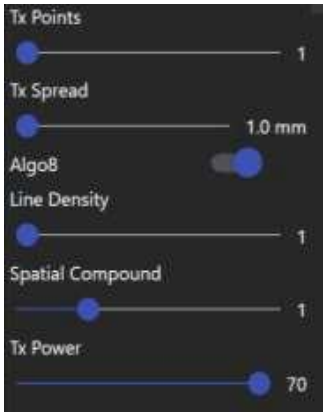
**Figure 5.3.2.5.2**Major Buttons

When entering from Start/Scan the system displays the Operating Screen and a live image for ½ a second just to establish that the system is functioning correctly and then Freezes the image. The operating screen appears as shown in Figure 5.2.1. All image settings are grouped in the left panel. Descriptions of those controls are the following:

### B mode settings

**Depth** (from 10 to 300 mm depending on the transducer attached)
**Focus** is the point or start of points for the transmit aperature.
**Frequency** is a set of available frequencies for the attached transducer. The higher the frequency the finer the resolution but shorter the penetration.
**Harmonic** turns on pulse inversion harmonic imaging
**Gain** displays and allows the user to adjust overall gain. Gain can also be adjusted by moving the potentiometers in the TGC panel

**B Post Settings, Edge Enhancement** emphasizes the edges or derivatives of the image. It is usually used with Speckle Reduction
**Speckle Reduction** reduces speckle on the image
**BMap** adjusts the brightness intensity mapping. The recommended setting is 2.
**Gamma** adjusts the log scale of the conversion of 16 bits of data to the 8 bits of grayscale that can be displayed on the screen. This is the equivalent of adjusting the dynamic range of the image.
**Brightness** is the brightness control for the image on the screen.
**Contrast** is the contrast control for the image on the screen.
**Trapezoid** visualizes all the acoustic lines from a spatial compound which makes a trapezoid shape. The outer lines will not have as much spatial compounding and so will be of inferior resolution but they will show the anatomy that would not usually be visualized.
**Line Density** adjusts the number of lines in a frame from 128 to 2048. The higher the line density the lower the frame rate and at some point (usually 256) increasing the line density does not improve the lateral resolution
**Spatial Compound** When using a linear or curved array the system may take additional images at offset angles which are used to visualize the vertical sides of structures and reduce speckle in the image. A setting of OFF is the equivalent to no spatial compounding, 2 uses 3 images with 2 offset by the SC angle, 3 means 5 images etc. This reduces the frame rate but may visualize structures better.
**Tx Points** adjusts the number of focus points up to 4




**5.1.1 B Adv setting**

## Annotations

The annotations allow the user to measure and mark features on the screen and save the annotated screen.




**Figure 5.4.4 Annotations Menu**

## Measure

allows the user to measure the size of objects. Up to 16 objects can be measured on the one screen each is depicted in a different color. This control allows the user to make distance measurements on an image as shown in Figure 5.3.3.3. Selecting this control changes the cursor to an x which can be placed anywhere on the image. Dragging the touch or pressing the mouse will lock the x in place and a second x in the same color can be drawn away while the distance (of the same color) between the two x's is displayed.. To correct a caliper measurement the user can place their finger to make the cursor on the measurement's location and adjust either end of the measurement. The measurements made with calipers are displayed in the lower right corner of the image area.

**CAUTION**

To avoid misdiagnosis from inaccurate measurement values, ensure that the target area of interest and image are correct and the measurement is valid.

## Body Marker

displays a selection of available body markers for the exam. The available body markers are determined by the preset for the exam. The presets can be edited by the user in the "presets" section of the "system settings" menu. A complete list of available body markers is in this manual as Appendix 5.

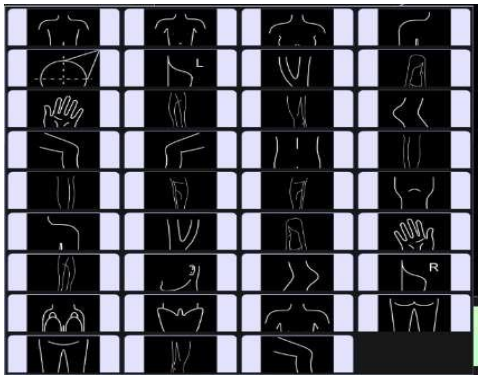


**Figure 5.4.6 Body Markers**

Text

allows the user to place a text annotation anywhere on the image area. The user can press or click anywhere in the image area and a cursor will appear allowing the user to enter text.

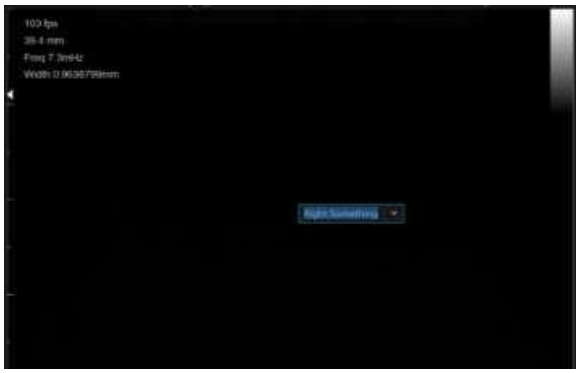


**Figure 5.4.7 Text Button allows the user to enter text**

Arrow

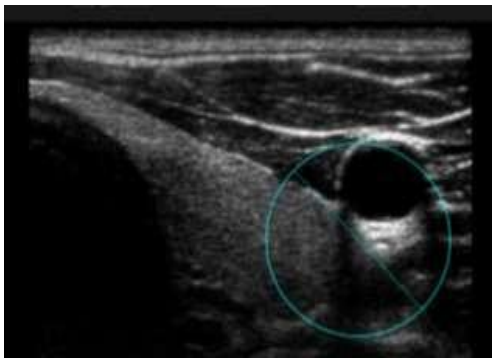
allows user to place an arrow on the screen which can then be moved and rotated by touching the screen



**Figure 5.4.8 Arrow in image area**

Circle

allows user to place a circle on the image area.



**5.4.9 Circle annotation on image area**

Delete This control removes the measurements and/or annotations on the selected image. The user has the option to delete all annotations or the last annotation added to the image.

**Note:**

Saved images can be found along the following directory pathway:

**C:\Users\UltraVision\Documents\UltraVision\Captures**

In the Captures fold y look like cd934998-f87e-4b5d-969d-95ceb3e33b11. These identifiers are present to protect patient's information. The exams will be in order of date and time so the user can find the appropriate exam. The folder will contain the .bmp files of the saved images.er, the exams will be labeled with a unique 32-digit Global Unique Identifier (GUID). For example, it ma

### Save Cine

This control saves the last 10 seconds of live scanning as a video in the gallery. For longer recordings the user can use the record control.

### Record

This control begins recording the live image to the hard drive which offers several giga-bytes of storage. The recording stops when the user presses the button a second time. When pressed, the record button will turn red and display of the length of the recording in seconds.

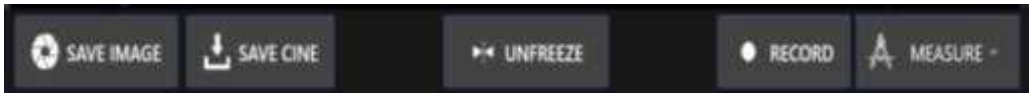



**Figure 5.4.10 Bottom row buttons**

### Review

This control brings the user to the review screen where the user has the options to modify an exam, generate a report, or export the exam. Post processing controls are available in review to annotate or modify the images. Exams or individual files within an exam can be exported onto a USB drive. When an exam is selected from the archive, it will open in review.

### TGC

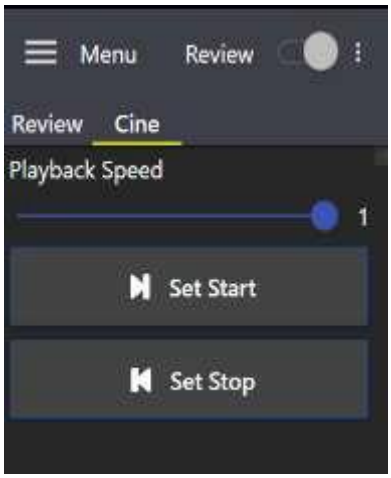
(Time Gain Control) consists of 9 potentiometers. Eight control the receive gain over the vertical segment of the image and the bottom controls the **Over All Gain.** Each may be adjusted by touch or pointing device. Swiping across the B mode image will adjust the TGC potentiometer corresponding to where the user touched.

The **Over All Gain** adjusts all the potentiometers together but adds no additional gain or dynamic range to the system.

### Cine

When the gallery menu is open, the user also has access to the **Cine** options.The system is always recording the last 200 Mbytes of images. Cine allows the user to review this video log and, select contiguous blocks of images and save

the entire 200 MByte or sections of it as .avi videos. The 200 MB is not a specific time as the various modes and methods of compounding or number of lines per frame all impact this storage limit.
On pressing the **Cine** button, the panel will change to the Cine functions, the freeze state will be entered and a time strip appears at the bottom of the image screen with a green, orange and red marker each indicating the start location, current image location, and stop location, respectively, for a cine loop.
Pressing the **Play** button next to the time strip will loop video between the start and stop markers. All three markers can be moved, to select a section of the last 200Mbytes of images to loop through by either dragging them or pressing the **Set Start** and **Set Stop** buttons which will be set at the current location of the orange marker.
The **Playback Speed** can be adjusted between real time and 1/8 real time.
The **Save Video** records from the green (start) to the red (stop) locations. The thumbnail of the new saved video will appear in the thumbnail strip at the bottom of the image and the user can play/pause or delete the video or the source video. The recording will be saved and exported as part of the exam or can be exported on its own with the **Export Cine to File** option for presentations.
When **Export Cine to File** is pressed and a window will open allowing the user to name the folder and file in which the cine will be placed. Not selecting a folder will place the video in the default folder for the session. The compression to an .avi will require some time.
Multiple cine loops may be saved from the same cine's most recent 200 Mbytes of storage.
Frames are recorded as acoustic line data with 512 samples of 2 bytes per line. The simplest Frames contain 128 acoustic lines which are 128 kilobytes. Spatial compounding can increase the size of a frame up to nine times (1.28 Mbytes) and color flow, and elastography will also increase a frames size reducing the number of frames that can be stored in the 200Mbytes allocated for this feature.
**Export Image Preset** allows the user to export the image settings for a selected image as a preset to use on future exams.




**5.4.13 Cine Menu**

## The Left Panel Forward, Backward, Modes and Views

The system may be operated in Clinical or Research mode under a user with Administrator rights. In research mode all images will have a designation of "Research Mode" placed in a watermark on them. Research Mode will be made available only to Institutions conducting Research and have agreed to UltraVision Corporation's Research EULA.
Currently the modes available for Clinical are B-Mode, M-Mode, Color Flow Doppler Mode, E-Mode, and PW Mode. The UltraVision program may have several Modes enabled depending on options and may have several Modes operational at a time.

## 5.8 Modes

Pressing the button brings up a set of Buttons that are available in the system

**B-Mode**.

This is the classical grayscale two-dimensional slice of tissue under the transducer showing the morphology in the field of view of the transducer. The full description is given in Chapter 7.

**Color Flow Mode.**

This mode displays the Doppler Shifted acoustic waves in an overlay of the B-Mode image that indicates the flow or movement of blood or tissue. The system computer converts the Doppler sounds into colors that are overlaid onto the image of the blood vessel and the colors represent the speed and direction of the blood flow of the vessel. This is a display of the blood flow with blood with a vector component moving towards the transducer as blue and away from the transducer in red. It has many settings that appear in the right side panel that require setting for an optimal display. The full description is given in Chapter 8.

**A-Mode**.

This is a graphical representation of the amplitude of the beamformed compressed acoustic line versus the time or depth of the digitization. Normally 4096 digitizations are made in a line over the chosen field of view and digitizations occur every 25 nanoseconds. For fields of view greater than 16 cm 8196 digitizations may be made. (Alternative A-Mode options are a graphic representation of the amplitude of the 64 individual channels that may be displayed either pre or post beamformed may be viewed under the diagnostic Menu\Channel Scope). This mode may be used to perform quality assessment of the transducer. The full description is given in Chapter 9.

**M-Mode**.

This is the classical M-Mode where the vertical axis of the image is the grayscale representation of the amplitude of the echoes received in the vertical direction and the time of the acoustic lines reception in the horizontal direction. The full description is given in Chapter 10.

**Elastography Mode.**

This is a manual compression mode that displays the derivative of the tissues displacement after a small depression is made on the skin by the transducer. It dispalys the strain or relative hardness of the tissue in the Field of View of the transducer. Elastography mode (E Mode) allows the qualitative images of the mechanical properties of tissue. Ultrasound elastography provides information on the hardness of tissue, which complements the acoustic impedance and vascular flow information provided by B mode and Doppler modes respectively. Elastography operates on the general principal that stress applied to tissue causes changes within the tissue depending on the elasticity of the tissue. Strain (or compression) ultrasound elastography is the most common technique that allows real-time imaging of tissueand can be used to detect and characterize lesions in a variety of tissues. E mode places live elastography images on the screen that are the result of cross-correlating sequential frames of B Mode data to display the relative hardness of the tissue based on displacement values. UltraVision makes no claims to their efficacy and leaves any determinations of their use to the physician. The full description is given in Chapter 11.

**PA-Mode** or **Photoacoustics Mode.**

**(Research Platform Only This mode is not approved for clinical use by the FDA and is only supplied in research systems to academic or qualified research institutions.)** This mode places pseudo live images on the screen that are the result of acquiring data received by acoustic waves induced by a laser flash. A trigger from the laser flash is used to synchronize the acquisition. As the normal laser requires 100 milliseconds to recharge this time can be used to acquire B-Mode images. (See Research Platform User Manual)

**PW Doppler Mode (Spectral Doppler Mode).**

This mode displays a vector on the B-Mode image upon which the user may select a position and a region on the vector. The area defined will be used to select sample Doppler information and display a spectrum of the backscatter motion in the region. The full description is given in Chapter 13.Chapter 6 Examining the Patient

**CAUTION**

The System should be used for valid reasons, for the shortest amount of time and at the lowest mechanical and thermal indices necessary to produce clinically acceptable images. The ALARA (As Low as Reasonably Achievable) principal should be used in accordance with the American Society of Ultrasound in Medicine (AIUM) guidelines. Long term exposure should be avoided.

1. Please be gentle when contacting the target area with a probe. This is to avoid probe damage or disturbing the patient.

2. Please choose a proper probe for the target area with an appropriate frequency to begin the diagnostic operation.

3. Adjust the gain control slowly to allow for visual feedback of results. The user can quickly ascertain the appropriate speed from the live image results.

# Chapter 8 B-Mode

**B-Mode**

Apply an appropriate amount of coupling gel (medical ultrasound coupling agent) to the body area to be examined, and then contact the area with the acoustic window of the probe.

Controls Used in B-Mode are:

In the Bottom Pannel, press the Freeze / Execute button and a live cross-sectional image of tissues will be displayed on the screen.

In the Left Panel, the Time Gain Compensation (TGC) eight slider potentiometers can be adjusted to increase or decrease the gain over the section of the image immediately to the right of the potentiometer. An Overall Gain Potentiometer

The Transmit Focus can be adjusted by placing the focus of the mouse over the white chevron on the depth scale on the left edge of the image and dragging it to the desired depth for optimal focus.

In the Right Panel:

The Depth (mm) when pressed brings up a selection of depths suitable for the transducer from which the user may make a selection. The depth of field may be selected in 10 millimeter increments from 20 to 170 mm but the selection may be reduced because of the transducers limitations and for simplifying the user interface. Adjust the FIELD of View to envelop the structure to envelop the feature of interest.

The FOCUS button when pressed displays a menu of

1. the Focus Depth which may be adjusted in mm by a potentiometer at the bottom of the panel,
2. the Number of Focus Points from 1 to 4. ( The frame rat will be slowed by the selection of more Focus points).
3. The Spread of the focus poits may be adjusted by the potentiometer at the bottom of this panel.

The Frequency button first brings up an option of TX Frequency or RX Frequency.

Pressing Tx Frequency brings up a selection of buttons on the right edge that the transmit frequency can be set to. There is an optimal frequency for each transducer where the maximum power of the porbe is available and moving off this frequency will reduce the power but will emphasize the characteristics of a higher frequency (finer resolution) or lower frequency (lower resolution) but a loss of power is to be expected the fartre from the base frequency that is selscted. As an example with the * Mhz transducer finer structure can be visualized at 11.4 MHz.

Pressing RX Frequency brings up a selection of eight frequency bands that filter the returning backscatter. The widest bandwith (1) will return the highest resolution but other frequencies may be chosen to bring out features like Harmonics or Sub Harmonics.

The Compound button brings up a selection of Spatial Compound, SC Angle, Frequency Compound and Trapezoid.

Spatial Compound is by default selected and it shows a further selection of Off, 1, 2, 3, and 4.
(Spatial compounding is where the image is formed by the addition of vectors fired at different angles from the transducer, so the ultrasonic pulse has taken a different paths to any point on the image. The different path decorrelates the data that was accumulated on the paths, so the speckle is different between each vector. This makes a clearer image and displays features like the vertical edge of an anechoic vessel visible. The ultrasound pulse can be reflected spatially where at an oblique angle the backscatter is not directed back to the transducer. Spatial compounding reduces this effect on the walls of cystic structures.)

Off turns off Spatial compounding and the image will appear as a traditional B-Mode image. This is not recommended for visual presentation reasons but may be used for certain circumstances.

1- means as well as the vector that is fired at 90 degrees to the probe two extra vectors will be fired at 90 degrees plus and minus the angle specified in SC angle below.
2- means as well as the vector that is fired at 90 degrees to the probe four extra vectors will be fired at 90 degrees plus and minus the angle and twice the angle specified in SC angle below.
3- means as well as the vector that is fired at 90 degrees to the probe six extra vectors will be fired at 90 degrees plus and minus the angle and twice the angle and thrice the angle specified in SC angle below.
4- means as well as the vector that is fired at 90 degrees to the probe 8 extra vectors will be fired at 90 degrees plus and minus the angle and twice, thrice and four times the angle specified in SC angle below.
(Adding vectors to the image will reduce the frame rate by 3,5,7,and 9 times but the resolution improvements are useful for static structures).

SC Angle brings up a menus of 1 to 9 which are equivalent to the spread of the vectors described above in Spatial Compounding. The use of excessive angle will degrade the image by bring the side lobes of the transducer into the scan conversion process. This is a limit derived from the pitch and characteristics of the transducer. An angle of 4 or 5 is optimal for a setting of 3 vector and an angle of 6 or seven is optimal for 1 or 2 above.

Frequency Compounding brings up a menu of 1 to 4. I is off and 2 to 4 are the number of different frequency filters that can be applied to a vector's backscatter to provide different speckle characteristics. Applying a frequency filter to the backscatter will affect the speckle content so adding the results of multiple frequency filters can reduce the speckle content. The UltraVision has multiple simultaneous frequency filters built in so this has no effect on the frame rate.

Trapezoid brings up a selection of False (off) or True (On). False presents the normal rectangular box of a linear array. True views the vectors at the edge of the image that extend beyond the rectangular area giving a trapezoidal presentation of a larger field of view. These edge areas provide visualization of the the wider area and will consist of content from only the vectors that cross the areas so may be of slightly less image quality.

The Power button when pressed brings up as selection of voltages between plus and minus 40 and 70 volts with 10 volts increments with the 70 volts giving the maximum gain. This 70 volts is the voltage that the output power was measured at for the Acoustic Output testing in Chapter 14. Usually 40 volts is adequate for B-Mode imaging and should be used if possible in accordance with ALARA ( As Low As Reasonably Achievable) but the power output

of the UltraVision is low and the user should not avoid the higher voltages at the sacrifice of patient diagnosis.

The Image Settings button when pressed brings up a selection of Brightness, Contrast, Gamma, Speckle Reduction, Line Density and Edge Enhancement each of which brings up a further selection.

Brightness brings up a selection of -10 to +10. This is a post acquisition feature that effects the display settings.

-10 reduces the lower grayscales and makes a darker image.
+10 emphasizes the lower grayscales and makes a brighter image.
The 18 values between -10 and +10 are available for the users choice.

Contrast brings up a selection of -10 to +10. This is a post acquisition feature that effects the display settings.

-10 reduces the slope of the grayscales and makes a flatter and overall brighter image.
+10 increases the slope of the grayscales and makes a sharper or contrasted image.
The 18 values between -10 and +10 are available for the users choice.

Gamma brings up a selection of 0 to +10. This is a post acquisition feature that effects the display settings. As the ultrasound data is sent to the scan conversion process as 16 bit (4096 levels) and the display is capable of displaying only 8 bit (256 levels) the translation of the 4096 to 256 is not necessarily linear allowing for emphases on the smaller or larger echoes. This feature may be used to increase the visualization of small echoes and visually increase the gain when penetration is needed.

0 increases the emphasis of the larger echoes and makes a sharper and darker image.
+10 increases the emphasis on smaller echoes and makes a flatter and brighter image.
The 9 values between -0 and +10 are available for the users choice.

Speckle Reduction brings up a selection of 0 to 5. This is a pre acquisition feature that works on live images either form the transducer or from a cine or video recording. Speclke reduction is a non isotropic blur that takes into account the axial and lateral resolutions of the image. O is off and 5 is a visible blur with a value of 2 being recommended value in most cases.

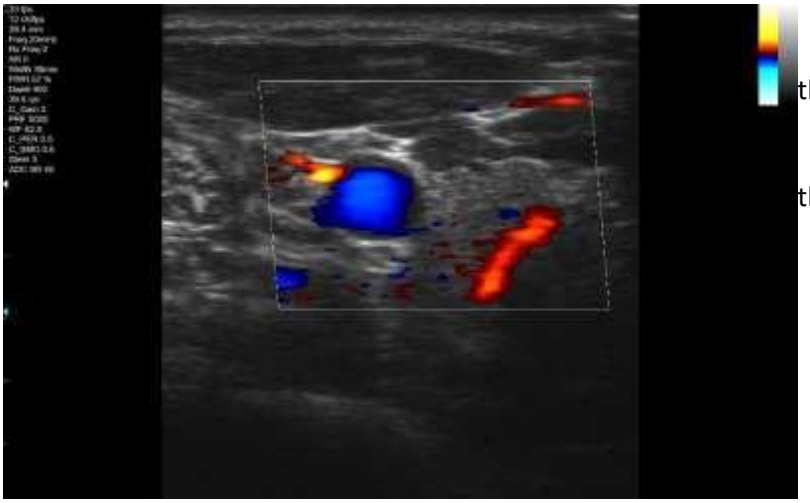
Line Density brings up a selection of 1, 2, 4 and 8. A high speed image is usually made fro 128 acoustic lines. If more resolution is required a hier resolurion can be attained at the expense of frame rate new vectors will be constructed transmitted from the transducer to form images of 256, 512 or 1024 vectors. The point spread function of the transducer will reduce the value of creating more acoustic lines.

Edge Enhancement brings up a selection of 0, 1, 2, 3, 4,and 5. This is a pre aquisiotion feature that works on live images either form the transducer or from a cine or video recording. It is a two dimensional laplace transform that enhances edges. A setting of 2 is recommended (with a setting of 3 in Speckle Reduction).

The buttons of the bottom panel are used with B-Mode and their features are described in Chapter 5 Above.

# Chapter 9 Color Flow Doppler Mode

The process usually starts with a live B-Mode image showing the morphology to locate the area of interest and ten the Mode button is pressed followed by selecting the CFD button.
A box will appear which delineates the are that the Color Flow will appear. The user should then place each of the corners of this box in the focus of the pointing device and drag the corners to the area desired to attain a CFD Image. The wider the image the lower the frame rates will be.



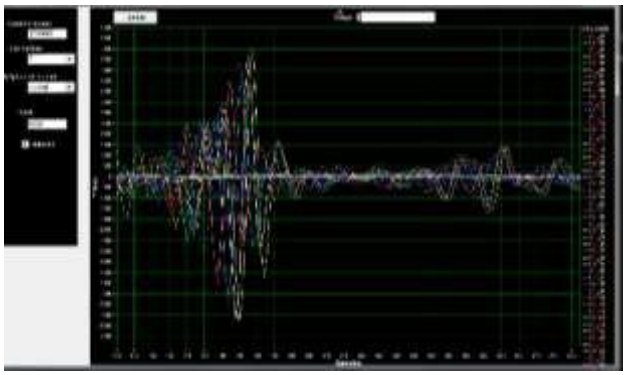
Example of flow in the neck

A CFD Settings Button will appear in the right panel. The selections are Angle, Gain, CFD/B, PRF,Tx Focus Depth, CFD TX Frequency, and Wall Filter
Angle brings up a selection of -15, -10, -5, 0, 5, 10, and 15 . These are the offset angle in degrees that the CFD box and the CFD vectors are drawn at with respect to the face of the transducer. The angle of the transducer and the vessel dictate which angle is appropriate. The user should try to maximize the direction of the offset to maximize the component of the bloods flow to the transducer. This component is proportional to the cosine of the angle of the blood to the box. If the blood flowed directly towards or away from the vertical direction of the box the signal would be maximum. If the blood flow os perpendicular to the orientation of the box the signal is zero.
Gain brings up a choice of the CFD gain form 1 to 10. A gain of 10 will bring in very small tissue movements while a gain of 1 will require a large directed flow to or from the transducer.
CFD/B brings up a set of numbers that span 1 to 128 and this allocates the amount of time the UltraVision devotes to creating B-Mode image to a CFD image. 128 indicates that 128 B-Mode acoustic lines will be acquired for every CFD line. The FPs and CFDFPS readings at the top left of the image are will indicate the results of this setting.
PRF (Pulse Repetition Frequency) is the rate at which CFD lines are made and selection buttons are available for 500 to 10,000. The PRF should be selected based on the speed of the flow expected in the vessel being observed. For Carotid arteries where the flow is very pulsatile and peak velocities of 1000 mm/second may be observed a setting of 8000 is recommended. For Deep veins in the legs where the flow is very slow or stationary a setting of 500 is recommended.
TX Focus Depth is the depth don the image that the optimal focus is made for the Color Flow Transmissions. It is depicted on the left of the image on the scale as a Blue cheveron. Initially it is the same as the B-Mode focus depth but the chevrons my be separated by depressing the TX Focus Depth button and dragging the blue chevron with the pointing device.

CFD Tx Frequency is the frequency that the CFD transmit is made at. The higher the frequency the less the penetration but higher the resolution of the CFD image. The further away from the transducers stated frequency the lower the power.
Wall Filter sets the lowest frequency the UltraVisions frequency filters will allow to create the CFD image. It has selection values of 1/20, 1/40, 1/80 and 1/160 which when expressed as a fraction of the PRF is the frequency edge of their high pass filter.

# Chapter 10 A Mode

A Mode is not supported in the UltraVision but in Administrative Mode there is a Channel scope and an acoustic line scope which can be used for a quality control. feature where all the elements of a transducer can be viewed to verify their connection and contribution to an image.



The Administrative mode is entered with appropriate password and the Channel scope is selected and a window with the Cannel Scope will appear like an oscilloscope output with selections to the left side of the image.

The image should be live, and the Update button pressed and the A-Modes will appear on the screen.

The Channels may be selected or deselected by clicking on the Chanel number and color on the right panel. The

Data Scope selections are Speed of sound, Line Number, Tx Aperture Channel, Dwell and delayed.

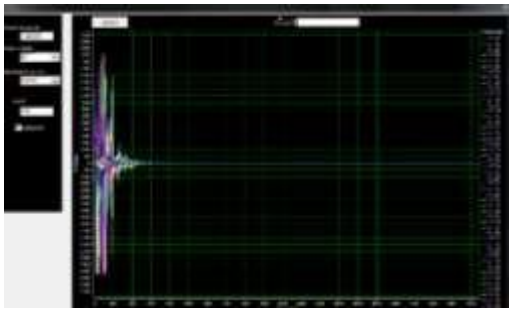
Speed of sound may be adjusted with this control as for tests in a water bath may require setting the speed of sound to the speed of sound in water of 1482 m/s from the default speed of sound in tissue of 1540 m/s.

Line Number collects all the channels from a specific acoustic line number for 1 to 128.

Tx Aperture Channel manually over rides the transmit aperture. Normally set to an F –number of 2 this allow looking at a specific channel, group of channels or all channels.

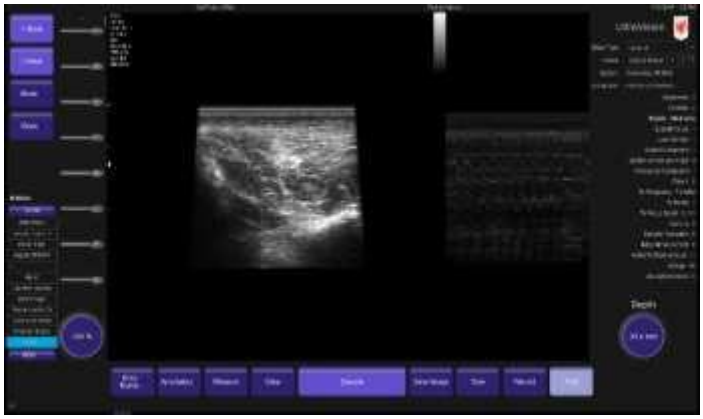
Dwell places the system in a dwell period measured in clocks (40 MHz or 25 ns intervals or 60 MHz or 16.6 ns intervals). This is typically used in water bath to allow dissipation of echoes from reflections in a nonattenuation media. Usually set to 40,000 for a typical fish tank.

Delayed shows the channels after they have been delayed by the delay section of the beamformer to illustrate that they would normally line up if the correct speed of sound is chosen.



There are controls in the top right and bottom left to magnify and offset the scope traces so a single digitation value to 16K (14 bits) value may be viewed vertically or a single clock to 8196 digitizations can be viewed horizontally.

# Chapter 11 M Mode



Selecting M from the mode's menu brings up a dual image with the B-Mode image on the left and the M Ome image on the right.

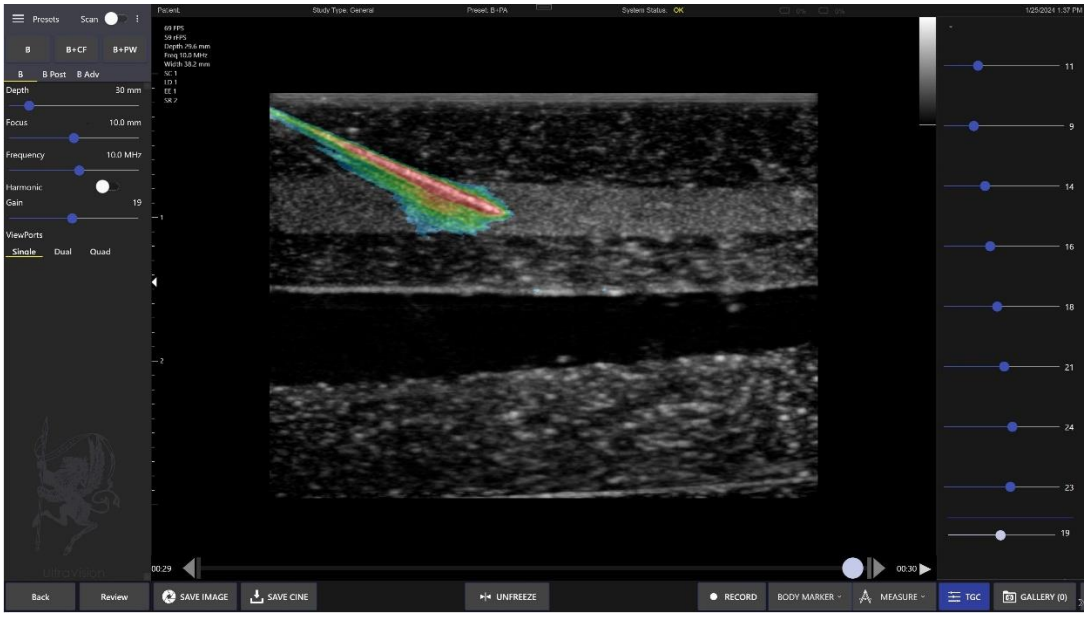
A green line in the B-Mode may be dragged to the acoustic line of interest in the B-Mode view.

An M-Mode image will appear on the right which be of the same scale and scale with the B-Mode image.

Calipers when placed on the M-Mode will measure distance vertically and time horizontally. The horizontal scale of the M-Mode may be varied by the wheel of the mouse.

## Chapter 11A Biopsy Mode

There is a Biopsy mode where a combination of the modes mentioned in this manual combine to get the best signal from fine needles

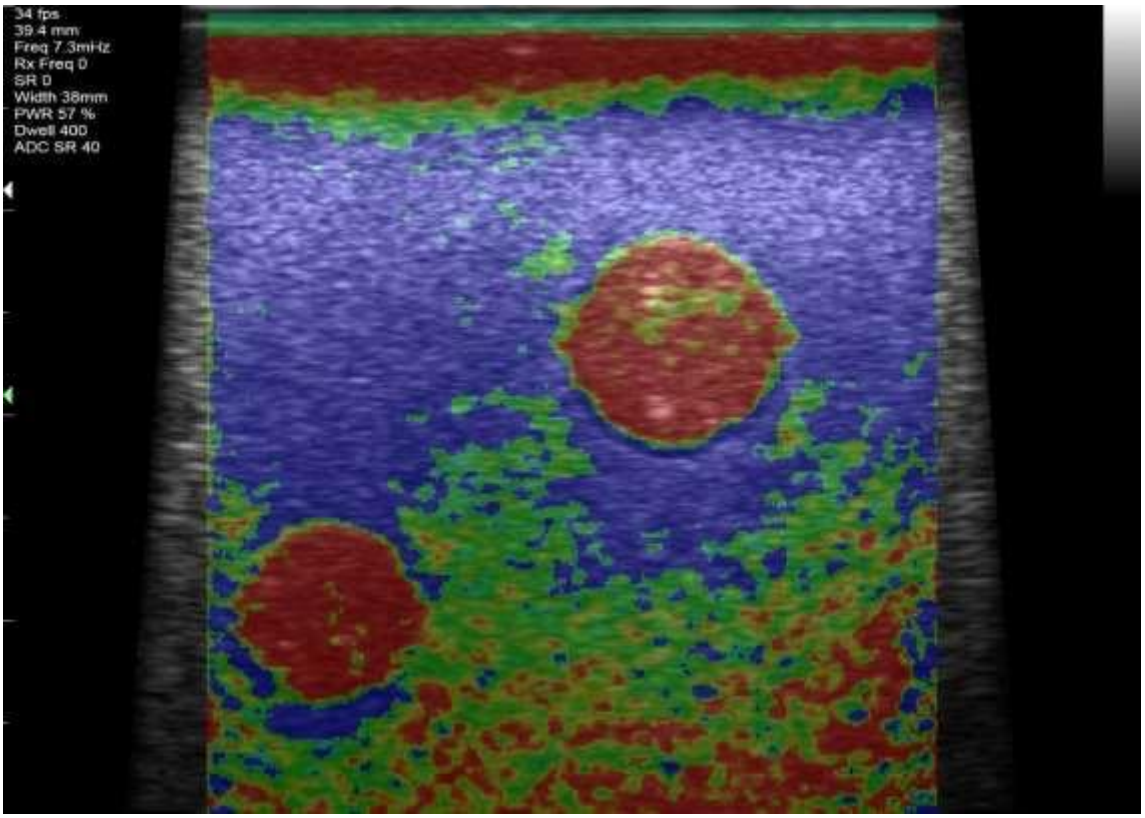


# Chapter 12 Elastography Mode

The compression elastography mode is superimposed over the B-Mode single image display and requires the user to apply very small displacements to the skin with the transducer. In many case the heart beat or breathing of the patient will supply sufficient displacements.

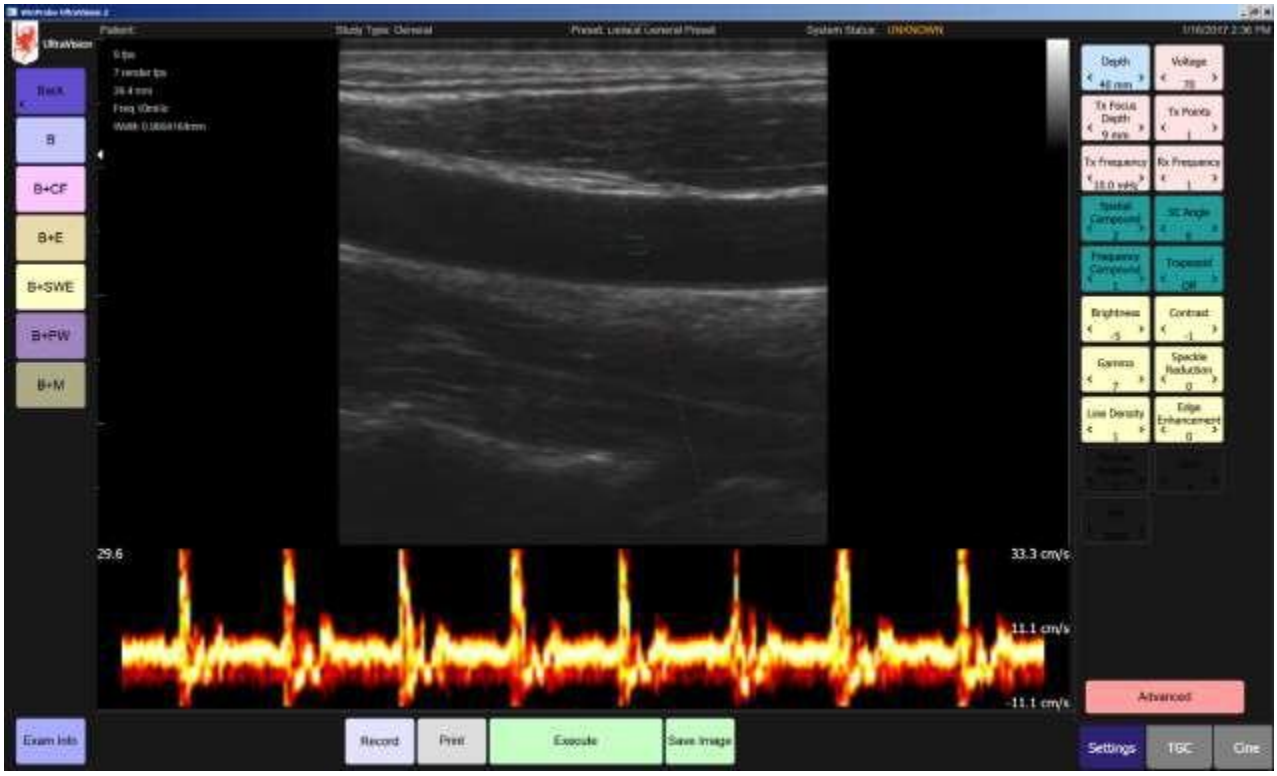
We recommend the user purchase a Breast Elastography Phantom Model 059 from CIRS (cirsinc.com) and develop this skill. When the user can differentiate a hard lesion without any surrounding artifacts on this phantom the skill is becoming developed.

The elastography mode is a non-quantifiable image that shows regions of higher strain that is used to direct the users attention to these regions for closer examination.




Successful execution of elastography push.

# Chapter 14 PWD (Spectral Doppler) Mode




From the **Mode Button** in the left panel the **PW Button** enters this mode. In this mode the screen changes to include a purple dotted line emanating from the center of the transducer with a green widow in the line and a blue line indicating the angle of the flow in the vessel between the green cursers. These features are to position the sampling area for the Spectral Doppler acquisition.

The purple line is controlled by the **Angle Button** form -45 to +45 degrees from the vertical (or placed when held in *focus* by a pointing device and may be moved across the transducer face by pressing the left button and dragging and may be swept through an angle by rotating the mouse wheel).

The sampling depth is the distance form the transducer face and the mean of the two green lines is controlled by the **Depth Button** (or may be positioned by placing the top green line in focus and dragging to the top of a vessel and sampling depth may be changed by placing the focus on the bottom green and dragging it to the distal wall of the vessel.

The sample widow width (the distance between the two green lines) is controlled by the **Width Button** and incremented in mm.

The angle of the flow may be controlled by the Angle Botton from -45 degrees to + 45 degreees from the horizontal which is aslo be indicated by the angle of the blue line ( or by placing the focus in the center of the two blue lines and the caliper indicator changes and it anle may be changed by the mouse wheel.

The bottom of the screen will now be showing the spectral Doppler display. The Text will show an estimate of the flow through the green gate.

# Chapter 15 3D Mode

3D Mode requires the NDI option. An example is give here of a volume breast volume but vascular and other organs are equally applicable.

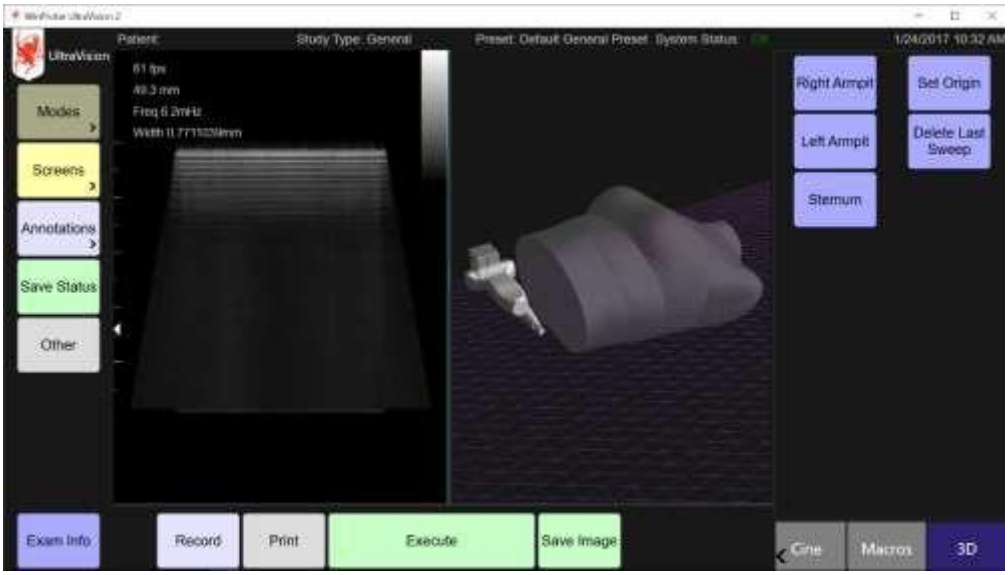
This Option allows the user to create a cine while sweeping the transducer across the skin and a 3D visualization will be created from the areas scanned in each frame and the six degrees of positional and angulation information attained from an attached NDI sensor. The UltraVision will place the areas of each frame relative to each other, to form the visualization of the transducers path to indicate to the user that the volume has been surveyed.

As a quality check of the continuity of the volume, the vertices of each frame will be checked to be within a threshold distance of the corresponding vertices of the previous frame. If the verticies are beyond the threshold distance the frame edges of the vertex qualifying as beyond the threshold will be colored red. Two thresholds will be supported so a warning and an error indication can be made. The user should recreate the last sweep if any red lines are visible in the normally blue lines that indicate the sweep volume.

A second sweep adjacent to a previous sweep volume may have a colored indicator to show that the overlap of the current frame to the previously swept volume is not at least 10% of the area of a frame. The User should recreate the last sweep if any red lines are visible in the normally blue lines that indicate the sweeps volume.

The thresholds for the indication of distance between adjacent verticies of frames is blue for under 0.5 mm, yellow for between 0.5 mm and 1 mm, and red for over 1 mm.

An NDI DriveBAY option is required. The NDI Transmitter should be placed in a stable location near the patient so its field encompases the volume to be scanned. The user should scroll the Settings Tab to 3D where the following screen will appear.




**Model Orientation**

The right side image is used for navigation. The user should orientate the model for best viewing of the area to be scanned by:

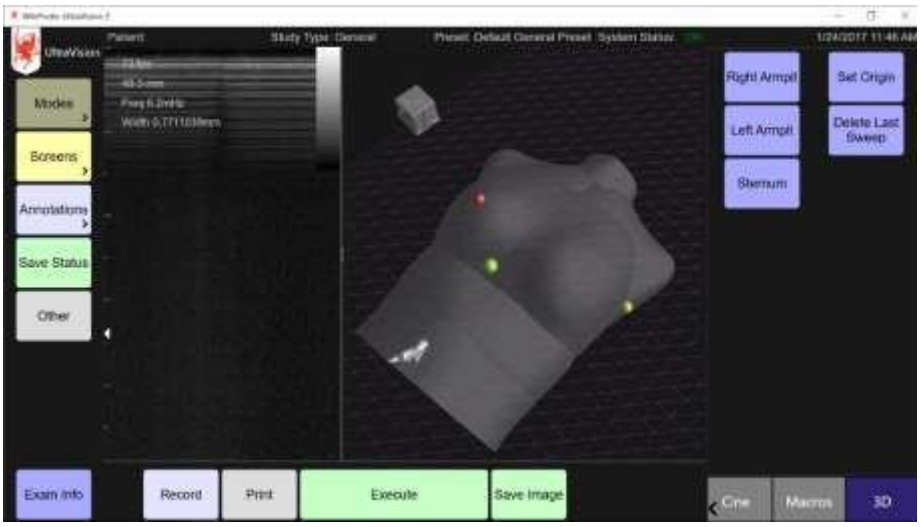
**One finger** over this screen moves the center of the model relative to the window (Equivalent to Right Mouse button).

**Two Fingers** over the screen, when rotated together, rotate the model about a point just behind the left sholder of the model (Equivalent of the Mouse Left Button).

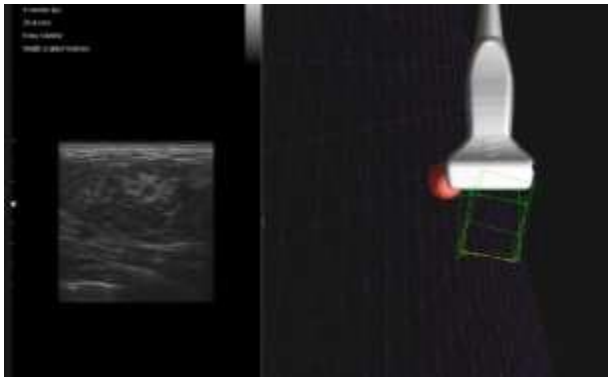
**Two Fingers** when moved appart or together zoom out or in on the model (Equivalent of the Scroll wheel).

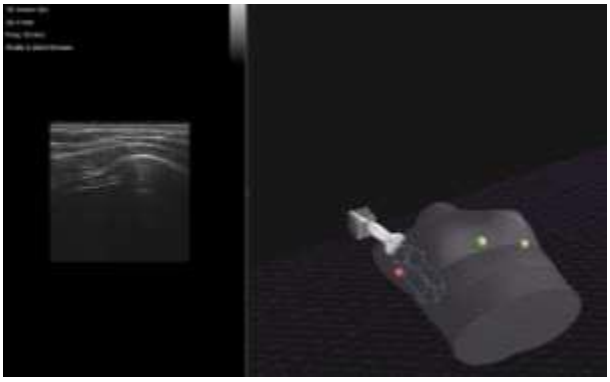
**Patient Orientation**

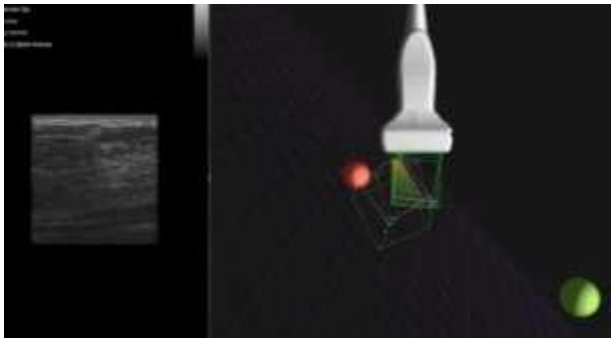
In order to orient the model with the patient 3 points are taken with the transducer which contains a six degrees of freedom position sensor. The transducer is moved to these points. For the breast they are the Right Armpit (Red Dot), the Left Armpit (Yellow Dot) and the Sternum (Green Dot).



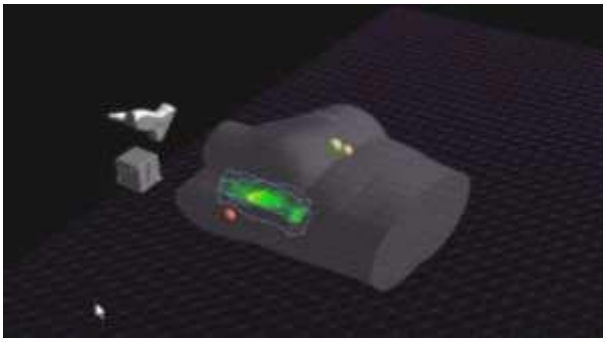

Once the patient and the 3D Model are orientated the transducer should be taken to the location of the beginning of the first sweep on the patient and the Execute Button should be pressed. The Body model will disappear but the plane and the three marker points will remain.







During the first track a cuboid will be visualized

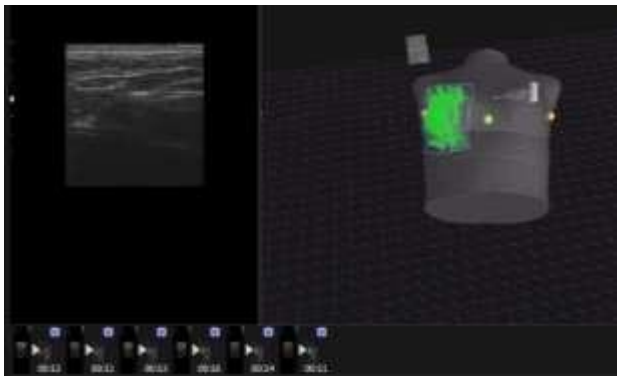


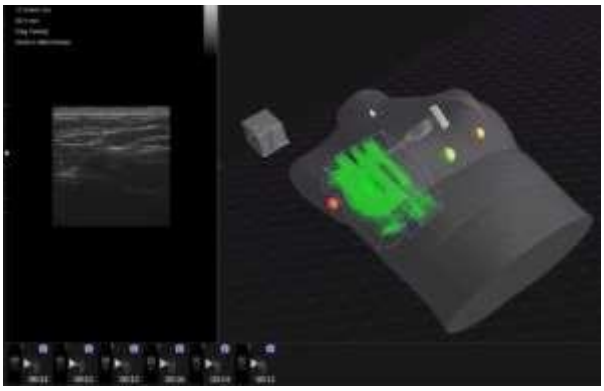
Freezing will then show the volume traced on the mode

During the second trace the previous trace is visible. During Freeze the model may be orientated for visibility.

As an area of non overlap was detected the 2nd Trace should be deleted and repeated with the **Delete Last Sweep Button**.

Multiple overlapping Cines are thus collected. They are shown in the Thumbnails strip at the bottom of the image area and can be selected for review at any time after collection. The thumbnail indicates its length in seconds. The model can be reorientated for better visualization at any time during Freeze. For training the user is referred to the WinProbe.com website for recorded videos of the process.





# Chapter 16 Photoacoustic Mode

This is for research only. No FDA approval is available at this time.

The mode is entered by pressing the B+PA mode button under Modes. The system now uses the one way speed of sound automatically in forming images. The UltraVision will fuse the photoacoustic image over the ultrasound image that the UltraVision will acquire while the laser is recharging (assuming a 10-20 repetition rate on a NdYag deriver laser pulse). In dual Image mode the images will be separate with the co-located ultrasound image on the left and the photoacoustic image on the right. If insufficient time is available between flashes (<15 milliseconds) no ultrasound image will be acquired. Normal recording functions are available.

The UltraVision has four Modes of gathering photoacoustic images.

a) 64 Channel Mode: From an aperture in the center of the transducer 64 sets of channel data is acquired from a flash into the Flash memory. As defined by the other settings, images are created with 64 to several hundred photoacoustic lines by spatially compounding data from the flash memory.
b) The 128 Channel Mode: From an aperture on the left of the transducer 64 sets of channel data is acquired from a flash into flash memory and the system moves the aperture to the right side of the transducer and waits for a second flash which is then acquired into flash memory. As above images are then created with 128 to several hundred photoacoustic tracks. The image quality will be better in the peripheries of the image but the image will be subject to motion blurring.
c) RF Data: The user may choose to read the Flash memory and process the RF data into an image. This is done by the Other Menu and results in the Capture Folder (C:\Users\computer name\Documents\UltraVision\Captures\RFCaptureSession_3_4_2017 9_41_14 PM\0 ) having RFCapture folders with dates and times of acquisitions. The system acquires data at approximately 1000 RF data channels per second so acquisition may slow while this data is uploaded and written to files.
d) LED mode: Due to the lower illumination (100s of microwatts vs. 10s of milliwatts) but faster repetition rate (100 milliseconds vs. ~1 millisecond) the UltraVision will accumulate multiple LED flashes which are averaged above the noise to form an image.



Photoacoustics Settings panel




The following controls in the SETTINGS window are operational in PA Mode:

a. **PA delay**: This inserts a positive or negative delay to align the image if there is a difference in the actual laser pulse and the trigger pulse.
b. **Trigger Out**: If ON places pulses on the red RCA cable to trigger the laser if OFF looks for a trigger on the Black RCA connector.
c. **Flash Color**: Changes the color of the photoacoustic overlay from red to green to blue.
d. **Power Averaging**: Number of times it will add the photoacoustic data.
e. **Power Multiplier:** Multiplier to bring up the photoacoustic gain.

f. **PRF:** Setting for output trigger.

g. **Threshold:** Hard threshold that the image must be above from photoacoustic image to reduce noise.

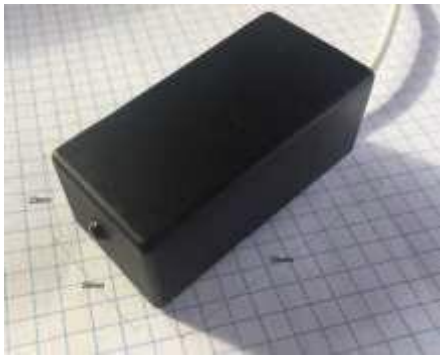
The UltraVision if purchased as a photoacoustic system will have an audio jack on the back of the system and will be supplied with a cable with the audio jack to two RCA connectors. The red RCA pin supplies synchronization pulses for triggering the laser when the UltraVision is the master.





The UltraVision waits for a TTL pulse (Trigger In) from the laser to trigger an acquisition (0 to 3.3 volt), and the black is for the ultrasound system being the master triggering the laser to pulse.

There is also an optional optical trigger available that when shared a small amount of the laser flash that can be used to trigger the system.



**WARNING**

Do not connect voltages above TTL levels (0-5 volts) to the trigger input.

# Chapter 17 Acoustic Output Testing

The UltraVision System has been tested for ultrasonic power output in its worst case scenario of 11700 transmissions per second (PRF) at full transmit voltage and it was found to be sufficiently low to facilitate the Track 1 Output Display Standard.

The UltraVision System uses a method of cross–correlation to attain Doppler and Elastography information and thus is able to use the same transmit pulse for all modes. Thus the acoustic output reporting tables for B-Mode, M-Mode, CFD-Mode, PW-Mode, E-Mode and SWA –Mode are all identical. The pulse shape or power does not change but may be less due to the mode not fully utilizing the full pulse repetition frequency of B-Mode.

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning Mode

T1: Transducer Model: UltraVision Linear Array 7.5 MHz HL5-10EPN

Operating Mode: B-Mode

Application(s):

| Acoustic Output | | | MI | ISPTA.3 (mW/cm2) | ISPPA.3 (W/cm2) |
|---|---|---|---|---|---|
| Global Maximum Value | | | 0.164 | 8.30 | 120 |
| | Pr.3 (MPa) | | 0.45 | | |
| | $W_0$ (mW) | | | 0.35 | 0.35 |
| | fc (MHz) | | 7.64 | 7.64 | 7.64 |
| | Zsp (cm) | | 1.95 | 1.95 | 1.95 |
| | Beam Dimensions | x-6 (cm) | | 0.111 | 0.111 |
| | | y-6 (cm) | | 0.15 | 0.15 |
| | Period (µS) | | 0.36 | | 0.16 |
| | PRF (Hz) | | 11700 | | 11700 |
| | EBD | Az. (cm) | | | |
| | | Ele. (cm) | | | |
| Operating Control Conditions | Max Power | | | | |

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning Mode

Transducer Model: HL5-10EPN

Operating Mode: B Mode, B+M Mode

Application(s): Small Organ, Superficial Musculoskeletal, Abdominal, Peripheral Vessel

| Acoustic Output | | | MI | $I_{SPTA.3}$ (mW/cm²) | $I_{SPPA.3}$ (W/cm²) |
|---|---|---|---|---|---|
| Global Maximum Value | | | 0.887 | 18.07 | 106.9 |
| Associated Acoustic Parameter | $p_{r.3}$ | (MPa) | 1.96 | | |
| | $W_o$ | (mW) | | 2.682 | 2.682 |
| | $f_c$ | (MHz) | 4.88 | 4.88 | 4.88 |
| | $z_{sp}$ | (cm) | 3.01 | | 3.01 |
| | Beam dimensions | $x_{-6}$ (cm) | | | 1.15E-03 |
| | | $y_{-6}$ (cm) | | | 1.86E-03 |
| | PD | (µsec) | 0.225 | | 0.225 |
| | PRF | (Hz) | 12480 | | 12480 |
| | EDS | Az. (cm) | | 1.9 | |
| | | Ele. (cm) | | 0.5 | |
| Operating Control Conditions | Transmit Freq. | MHz | 5.0 | | |
| | Transmit Depth | cm | 3.27 | | |
| | Transmit Power | V | 70 | | |
| | Depth of Field | cm | 4.0 | | |

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning Mode

Transducer Model: HL5-10EPN

Operating Mode: B+PW Mode

Application(s): Small Organ, Superficial Musculoskeletal, Abdominal, Peripheral Vessel

| Acoustic Output | | | MI | $I_{SPTA.3}$ (mW/cm²) | $I_{SPPA.3}$ (W/cm²) |
|---|---|---|---|---|---|
| Global Maximum Value | | | 0.887 | 12.05 | 106.9 |
| Associated Acoustic Parameter | $p_{r.3}$ | (MPa) | 1.96 | | |
| | $W_o$ | (mW) | | 2.682 | 2.682 |
| | $f_c$ | (MHz) | 4.88 | 4.88 | 4.88 |
| | $z_{sp}$ | (cm) | 3.01 | | 3.01 |
| | Beam dimensions | $x_{-6}$ (cm) | | | 1.15E-03 |
| | | $y_{-6}$ (cm) | | | 1.86E-03 |
| | PD | (µsec) | 0.225 | | 0.225 |
| | PRF | (Hz) | 8320 | | 8320 |
| | EDS | Az. (cm) | | 1.9 | |
| | | Ele. (cm) | | 0.5 | |
| | Transmit Freq. | MHz | 5.0 | | |
| Operating Control Conditions | Transmit Depth | cm | 3.27 | | |
| | Transmit Power | V | 70 | | |
| | Depth of Field | cm | 4.0 | | |
| | PW PRF | Hz | 2500 | | |

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning Mode

Transducer Model: HL5-10EPN

Operating Mode: B+CFD Mode

Application(s): Small Organ, Superficial Musculoskeletal, Abdominal, Peripheral Vessel

| Acoustic Output | | | MI | $I_{SPTA.3}$ ($mW/cm^2$) | $I_{SPPA.3}$ ($W/cm^2$) |
|---|---|---|---|---|---|
| Global Maximum Value | | | 0.887 | 2.835 | 39.37 |
| Associated Acoustic Parameter | $p_{r.3}$ | (MPa) | 1.96 | | |
| | $W_o$ | (mW) | | 1.314 | 0.653 |
| | $f_c$ | (MHz) | 4.88 | 4.88 | 4.88 |
| | $z_{sp}$ | (cm) | 3.01 | | 3.01 |
| | Beam dimensions | $x_{-6}$ (cm) | | | 1.15E-03 |
| | | $y_{-6}$ (cm) | | | 1.86E-03 |
| | PD | (µsec) | 0.239 | | 0.239 |
| | PRF | (Hz) | 5000 | | 5000 |
| | EDS | Az. (cm) | | 1.28 | |
| | | Ele. (cm) | | 0.6 | |
| Operating Control Conditions | Transmit Freq. | MHz | 7.3 | | |
| | Transmit Depth | cm | 2.64 | | |
| | Transmit Power | V | 70 | | |
| | Depth of Field | cm | 4.0 | | |
| | CFD PRF | Hz | 5000 | | |
| | B Mode FPS | | 6 | | |

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning Mode

Transducer Model: HL5-10EPN

Operating Mode: B+E Mode

Application(s): Small Organ, Superficial Musculoskeletal, Abdominal, Peripheral Vessel

| Acoustic Output | | | MI | $I_{SPTA.3}$ ($mW/cm^2$) | $I_{SPPA.3}$ ($W/cm^2$) |
|---|---|---|---|---|---|
| Global Maximum Value | | | 0.887 | 16.88 | 106.9 |
| Associated Acoustic Parameter | $p_{r.3}$ | (MPa) | 1.96 | | |
| | $W_o$ | (mW) | | 2.682 | 2.682 |
| | $f_c$ | (MHz) | 4.88 | 4.88 | 4.88 |
| | $z_{sp}$ | (cm) | 3.01 | | 3.01 |
| | Beam dimensions | $x_{-6}$ (cm) | | | 1.15E-03 |
| | | $y_{-6}$ (cm) | | | 1.86E-03 |

| | | | | | |
|---|---|---|---|---|---|
| | PD | (µsec) | 0.225 | | 0.225 |
| | PRF | (Hz) | 9990 | | 9990 |
| | EDS | Az. (cm) | | 1.9 | |
| | | Ele. (cm) | | 0.5 | |
| Operating Control Conditions | Transmit Freq. | MHz | 5.0 | | |
| | Transmit Depth | cm | 3.27 | | |
| | Transmit Power | V | 70 | | |
| | Depth of Field | cm | 4.0 | | |

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning Mode

Transducer Model: HL5-10EPN

Operating Mode: B+SWE Mode

Application(s): Small Organ, Superficial Musculoskeletal, Abdominal, Peripheral Vessel

| Acoustic Output | | | MI | $I_{SPTA.3}$ (mW/cm²) | $I_{SPPA.3}$ (W/cm²) |
|---|---|---|---|---|---|
| Global Maximum Value | | | 0.887 | 18.07 | 106.9 |
| Associated Acoustic Parameter | $p_{r.3}$ | (MPa) | 1.96 | | |
| | $W_o$ | (mW) | | 2.682 | 2.682 |
| | $f_c$ | (MHz) | 4.88 | 4.88 | 4.88 |
| | $z_{sp}$ | (cm) | 3.01 | | 3.01 |
| | Beam dimensions | $x_{-6}$ (cm) | | | 1.15E-03 |
| | | $y_{-6}$ (cm) | | | 1.86E-03 |
| | PD | (µsec) | 0.225 | | 0.225 |
| | PRF | (Hz) | 12480 | | 12480 |
| | EDS | Az. (cm) | | 1.9 | |
| | | Ele. (cm) | | 0.5 | |
| Operating Control Conditions | Transmit Freq. | MHz | 5.0 | | |
| | Transmit Depth | cm | 3.27 | | |
| | Transmit Power | V | 70 | | |
| | Depth of Field | cm | 4.0 | | |

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning ModeT3 Transducer Model: UltraVision Linear Array L14-4 Operating Mode: B-Mode
All Application(s):

| Acoustic Output | | | $MI$ | $I_{SPTA.3}$ (mW/cm$^2$) | $I_{SPPA.3}$ (W/cm$^2$) |
|---|---|---|---|---|---|
| Global Maximum Value | | | 0.82 | 75 | 28 |
| | $P_{r.3}$ (MPa) | | 2.142 | | |
| | $W_o$ (W) | | 15.343 | | |
| | $f_c$ (MHz) | | 7.55 | | |
| | $z_{sp}$ (cm) | | 2.3 | | |
| | Beam Dimensions | $x_{-6}$ (cm) | 0.0325 | | |
| | | $y_{-6}$ (cm) | 0.0585 | | |
| | $PD$ (µs) | | 0.270 | | |
| | $PRF$ (Hz) | | 9803 | | |
| | $EBD$ | Az. (cm) | 1.4 | | |
| | | Elev. (cm) | 0.5 | | |
| Operating Control Conditions | Max Power | | | | |

Operating Mode: B Mode, B+M Mode

Application(s): Small Organ, Superficial Musculoskeletal, Abdominal, Peripheral Vessel

| Acoustic Output | | | MI | $I_{SPTA.3}$ (mW/cm²) | $I_{SPPA.3}$ (W/cm²) |
|---|---|---|---|---|---|
| Global Maximum Value | | | 0.598 | 19.66 | 167.2 |
| Associated Acoustic Parameter | $p_{r.3}$ | (MPa) | 1.564 | | |
| | $W_o$ | (mW) | | 0.473 | 0.473 |
| | $f_c$ | (MHz) | 6.84 | 6.84 | 6.84 |
| | $z_{sp}$ | (cm) | 2.43 | | 2.43 |
| | Beam dimensions | $x_{-6}$ (cm) | | | 8.50E-04 |
| | | $y_{-6}$ (cm) | | | 1.25E-03 |
| | PD | (µsec) | 0.157 | | 0.157 |
| | PRF | (Hz) | 13284 | | 13284 |
| | EDS | Az. (cm) | | 1.28 | |
| | | Ele. (cm) | | 0.6 | |
| Operating Control Conditions | Transmit Freq. | MHz | 7.3 | | |
| | Transmit Depth | cm | 2.64 | | |
| | Transmit Power | V | 70 | | |
| | Depth of Field | cm | 4.0 | | |

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning Mode

Transducer Model: L14-4

Operating Mode: B+PW Mode

Application(s): Small Organ, Superficial Musculoskeletal, Abdominal, Peripheral Vessel

| Acoustic Output | | | MI | $I_{SPTA.3}$ (mW/cm²) | $I_{SPPA.3}$ (W/cm²) |
|---|---|---|---|---|---|
| Global Maximum Value | | | 0.598 | 13.15 | 167.2 |
| Associated Acoustic Parameter | $p_{r.3}$ | (MPa) | 1.564 | | |
| | $W_o$ | (mW) | | 0.473 | 0.473 |
| | $f_c$ | (MHz) | 6.84 | 6.84 | 6.84 |
| | $z_{sp}$ | (cm) | 2.43 | | 2.43 |
| | Beam dimensions | $x_{-6}$ (cm) | | | 8.50E-04 |
| | | $y_{-6}$ (cm) | | | 1.25E-03 |
| | PD | (µsec) | 0.157 | | 0.157 |
| | PRF | (Hz) | 8856 | | 8856 |
| | EDS | Az. (cm) | | 1.28 | |
| | | Ele. (cm) | | 0.6 | |
| Operating Control Conditions | Transmit Freq. | MHz | 7.3 | | |
| | Transmit Depth | cm | 2.64 | | |
| | Transmit Power | V | 70 | | |
| | Depth of Field | cm | 4.0 | | |
| | PW PRF | Hz | 2500 | | |

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning Mode

Transducer Model: L14-4

Operating Mode: B+CFD Mode

Application(s): Small Organ, Superficial Musculoskeletal, Abdominal, Peripheral Vessel

| Acoustic Output | | | MI | $I_{SPTA.3}$ (mW/cm$^2$) | $I_{SPPA.3}$ (W/cm$^2$) |
|---|---|---|---|---|---|
| Global Maximum Value | | | 0.598 | 2.242 | 41.65 |
| Associated Acoustic Parameter | $p_{r.3}$ | (MPa) | 1.564 | | |
| | $W_o$ | (mW) | | 0.174 | 0.174 |
| | $f_c$ | (MHz) | 6.84 | 6.84 | 6.84 |
| | $z_{sp}$ | (cm) | 2.43 | | 2.43 |
| | Beam dimensions | $x_{-6}$ (cm) | | | 8.50E-04 |
| | | $y_{-6}$ (cm) | | | 1.25E-03 |
| | PD | (µsec) | 0.191 | | 0.191 |
| | PRF | (Hz) | 5000 | | 5000 |
| | EDS | Az. (cm) | | 1.28 | |
| | | Ele. (cm) | | 0.6 | |
| Operating Control Conditions | Transmit Freq. | MHz | 7.3 | | |
| | Transmit Depth | cm | 2.64 | | |
| | Transmit Power | V | 70 | | |
| | Depth of Field | cm | 4.0 | | |
| | CFD PRF | Hz | 5000 | | |
| | B Mode FPS | | 6 | | |

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning Mode

Transducer Model: L14-4

Operating Mode: B+E Mode

Application(s): Small Organ, Superficial Musculoskeletal, Abdominal, Peripheral Vessel

| | | | | | |
|---|---|---|---|---|---|
| Operating Control Conditions | Transmit Power | V | 70 | | |
| | Depth of Field | cm | 4.0 | | |
| Acoustic Output | | | MI | $I_{SPTA.3}$ (mW/cm²) | $I_{SPPA.3}$ (W/cm²) |
| Global Maximum Value | | | 0.598 | 17.05 | 167.2 |
| Associated Acoustic Parameter | $p_{r.3}$ | (MPa) | 1.564 | | |
| | $W_o$ | (mW) | | 0.473 | 0.473 |
| | $f_c$ | (MHz) | 6.84 | 6.84 | 6.84 |
| | $z_{sp}$ | (cm) | 2.43 | | 2.43 |
| | Beam dimensions | $x_{-6}$ (cm) | | | 8.50E-04 |
| | | $y_{-6}$ (cm) | | | 1.25E-03 |
| | PD | (µsec) | 0.157 | | 0.157 |
| | PRF | (Hz) | 11520 | | 11520 |
| | EDS | Az. (cm) | | 1.28 | |
| | | Ele. (cm) | | 0.6 | |
| | Transmit Freq. | MHz | 7.3 | | |
| | Transmit Depth | cm | 2.64 | | |

ACOUSTIC OUTPUT REPORTING TABLE FOR TRACK 1

Auto-Scanning Mode

Transducer Model: L14-4

Operating Mode: B+SWE Mode

Application(s): Small Organ, Superficial Musculoskeletal, Abdominal, Peripheral Vessel

| | | | | | |
|---|---|---|---|---|---|
| Acoustic Output | | | MI | $I_{SPTA.3}$ (mW/cm²) | $I_{SPPA.3}$ (W/cm²) |
| Global Maximum Value | | | 0.598 | 18.47 | 167.2 |
| Associated Acoustic Parameter | $p_{r.3}$ | (MPa) | 1.564 | | |
| | $W_o$ | (mW) | | 0.473 | 0.473 |
| | $f_c$ | (MHz) | 6.84 | 6.84 | 6.84 |
| | $z_{sp}$ | (cm) | 2.43 | | 2.43 |
| | Beam dimensions | $x_{-6}$ (cm) | | | 8.50E-04 |
| | | $y_{-6}$ (cm) | | | 1.25E-03 |
| | PD | (µsec) | 0.157 | | 0.157 |
| | PRF | (Hz) | 12480 | | 12480 |
| | EDS | Az. (cm) | | 1.28 | |
| | | Ele. (cm) | | 0.6 | |
| Operating Control Conditions | Transmit Freq. | MHz | 7.3 | | |
| | Transmit Depth | cm | 2.64 | | |
| | Transmit Power | V | 70 | | |
| | Depth of Field | cm | 4.0 | | |

# Chapter 18 Inspection and Maintenance

## 18.1 Daily Checklist

Check before the system is switched on, if any system malfunction is experienced, eliminate the malfunction before use, or contact UltraVision or authorized UltraVision Distributer for service if needed.

- Visually inspect all the probes. Do not use a damaged probe.Visually inspect all the probe assembly cables and associated connectors.
- Visually inspect the power cord. Do not turn on the power if a cord is frayed or split or shows signs of wear.
- Verify that the console and display are clean and free from gel or contaminants.

Check after the system is switched on:

- Visually check the display and indicator lights. Verify that the monitor displays the current date and time and there are not any error messages.
- Verify that the probe identification and indicated frequency on the screen are correct for the activated probe.
- Verify that there is not any abnormal noise, noise from the speakers, noise from a fan, discontinuous image, or dark area.
- Verify that there is no burning smell or that any part of the system is hot.
- Verify the face of the transducer is not too hot by feeling with your hand.

**Note**

System should be turned on every 6 months and run for 30 minutes.

## 18.2 Cleaning and Disinfection

All exterior parts of the system, including the control panel, transducers and any accessories should be cleaned and/or disinfected as necessary or between uses with a recommended cleanser or disinfectant. Clean each part to remove any surface particles. Disinfect each part to kill vegetative organisms and viruses.

You must take all necessary precautions to eliminate the possibility of exposing patients, operators or third parties to hazardous or infectious materials. Use universal precautions during cleaning and disinfection. You should treat all parts of the system that come in contact with human blood or other body fluids as if they were known to be infectious.

After use, clean all exposed surfaces of the system with a soft dry cloth gently.

The cleaning of internal components of the system should be performed by authorized and qualified personnel. An annual service should be scheduled with a qualified UltraVision service engineer.

**WARNING**

1. To avoid electrical shock and damage to the system, always shut down the system and disconnect the system from the AC power source before cleaning and disinfection.
2. To avoid infection, always use protective gloves when performing cleaning and disinfection procedures.
3. To avoid infection, ensure that the solution expiration date has not passed.

**CAUTION**

1. Be careful when cleaning the display screen. Since the display screen is easily scratched or damaged use a soft dry cloth and wipe carefully.To avoid the possibility of electrostatic shock and damage to the system, avoid the use of aerosol spray cleaners on the monitor.
2. Do not use spray detergents on the system as it may force cleaning fluid into the system that could damage internal electronic parts. Sprays may build up solvent fumes and form a flammable gas mixture.
4 Do not pour any liquid onto the system surface, as fluid seepage into electrical circuitry may cause leakage current or system failure.
5 Do not leave residual detergent on the surface of the system.

## 18.3 System Surface Cleaning

To clean the system surface:

1. Power off the system and disconnect the power supply.
2. Use a clean gauze or lint-free cloth, moistened lightly with a mild detergent and Javel water (an aqueous solution of potassium or sodium hypochlorite) to wipe the surface.
3. After cleaning reconnect the power source.

**CAUTION**

Make sure the cleaning solution does not seep into the system openings.

## 18.4 Probe and Probe Holder Cleaning and Disinfection

To clean probe holder:

1. Disassemble the probe holder by uninstalling the two screws.
2. Wash the holder with flowing water, using a mild detergent (Javel water).
3. After cleaning and drying, assemble the probe holder to the main unit.

Every time before use, layer of medical ultrasound coupling gel should be applied evenly on the area of the acoustical window of the probe. Be careful not to generate any air bubbles.

To clean the probes:

1. Disconnect the probe from the system.
2. Wipe off all the gel gently with a soft cloth.
3. Rinse the probe with enough distilled water to remove all visible residues.
4. Air dry or dry with a soft cloth.

To disinfect the probe:

Disinfection should be performed each time after use.

1. Prepare the disinfectant (2.4% Glutaraldehyde or 0.55% Ortho-Phthalaldehyde).
2. Place the cleaned and dried probe in contact with the disinfectant up to the nose cone line for the time specified by the disinfectant manufacturer.

**WARNING**

1. Do not immerse the probe connector. If the cable connector is immersed, do not plug the connector into

the system. Rinse the connector under running water and dry it thoroughly. If necessary, contact UltraVision for service.

2. Prohibit infiltration of any type of liquid into the device or the probe.
3. Do not sterilize the probe using techniques such as autoclave, ultraviolet, gamma radiation, gas, steam, or heat. Otherwise, severe damage will result.
4. The coupling gel applied to the probe is a medical ultrasound coupling gel. Use the ultrasound coupling gel that complies with the local regulations.
5. Do not immerse the power cord and connector of the probe into solutions. Probes can be submerged to, but not including, the strain relief of the probe array. Do not immerse or soak any part of a probe in any cleaning material not listed in the recommended list of disinfectants.

## 18.5 Proper Use of Probes

In order to extend the service life and to obtain optimum performance of the probe, please operate as follows:

1. Inspect power cord, socket and acoustical window of the probe periodically.
2. Freeze the system before connecting or disconnecting the probe.
3. Do not drop the probe onto the floor or collide with hard objects. Otherwise it will be damaged easily.
4. When the probe is not used, put it in the probe holder.
5. Heating the probe is strictly forbidden.
6. Pulling or bending the cord of the probe is strictly forbidden; otherwise internal connecting lines of the power cord may rupture.
7. Coupling gel can only be used on the head of the probe, and it should be wiped off after use.
8. Each time after use, clean and disinfect the probe.
9. The acoustical window and the shell of the probe should be examined frequently.

**WARNING**

The UltraVision cannot be used together with high-frequency surgical equipment.

**CAUTION**

1. Do not disinfect or clean probes under high temperature, and the temperature should be below 45°C.
2. In order to avoid damaging the device, the disinfection method is limited to regular maintenance of devices in hospitals. Disinfecting instruments should be cleaned first.

## 18.6 Disinfectants

| | Disinfectants' chemical name | Disinfectants' Trade Name |
|---|---|---|
| | Glutaraledhyde (2.4%) | Cidex Activated Dialdehyde Solution (2.4%) |
| Probe | Ortho-Phthaladehyde (0.55%) | Cidex OPA (0.55%) |
| | | |
| System | 75% medical alcohol | / |
| | Glutaraldehyde (2.4%) | Cidex Activated Diadehyde Solution (2.4%) |
| | | |

## 18.7 Maintenance Periods

The recommended routine maintenance is annually and this is essentially made for cleaning of filters and fans. If the user experiences shutdowns due to overheating due to a polluted environment then the system should immediately undergo a cleaning maintenance. This recommended period should be adjusted to the environment.

The UltraVision is entirely digital and no routine calibrations are necessary.

UltraVision may from time to time offer upgrades to improve a digital feature and this may be performed form a USB stick or with special UltraVision supervised actions over the internet.

Maintenance or Service can be coordinate by contacting UltraVision Corporation at:

Service
UltraVision Corporation
11911 US Highway 1, Suite 204,
North Palm Beach
Florida 33408
Tel: 561 626 4055
Fax:561 624 0914
info@winprobe.com

# Chapter 19 Transportation and Storage

## 19.1 Moving the System

The system is designed to be hand carried and easily transported. Power off the system and secure all accessories before moving it to another location.

**CAUTION**

1 Switch off the ultrasound system. Unplug the power cord from the power source and secure the power cable and the system in the carrying case.

2 Put the probes in their protective carrying cases.

3 Secure the system and complete the system setup, and then perform all the daily checks before using it upon unpacking.

## 19.2 Storage

1. Do not place the device near the ground, walls, or the roof.
2. Keep dry good indoor ventilation. Avoid strong and direct sunlight.

## 19.3 Transportation

To prepare the system for shipment over long distances or rough terrain, repack the system in the factory packing

Prevent sudden jarring of the system during transport, provide anti-shock cushions beneath the system.

It is suitable for transportation by air, railway, highway, and ship. Protect the system from inversion, collision, and splashing with rain and snow.

# Appendix 1 UltraVision Definition of Image and Data Formats

**Acoustic Line**

Acoustic line refers to a a data set acquired when a vector is fired into the patient from an apeture on the transducer at a specific angle. The magnitude of the backscattered echo intensity is collected by the analog to digital converters and beamformed into a collection of amplitidue estimates of 16-bits depth every 25 nanoseconds (19 microns at 40 MHz or 512 samples per 10 mm).

**Sample Data**

Acoustic lines are stored in the console and transferred to the PC in image frames. The mimimum image frame consists of 128 vectors but the number of vectors in a FRAME increases by:

a) a factor of 2, 4, or 8 if a LINE DENSITY of 2, 4 or 8 is selected respectively or

b) a factor of 3, 5, 7 or 9 if SPATIAL COMPOUNDING of 1, 2, 3 or 4 is selected respectively

These factors are commutative and as the acquisition time for an acoustic line particular depth of view is a constant the FRAME RATE drops as the number of vectors increases. In an extreme case a FRAME may consist of 9216 acoustic lines.

**Save Image**

Save image saves the **Sample Data** to an SQL database, while the visible image on the screen (View Port) saves the image in a .jpg format to the capture folder in the patient or session folder with a GUID (global unique identification) for the path. This .jpg image is used for display in the Thumbnail Strip and may be used to later select the image for loading back the Sample Data from the SQL data into the View Port.

Thus all of the image processing functions that do not require changes to the incoming data stream are available.

**Cine Mode**

The application is continuously saving the last 200 MBytes of Sample Data images. This is a variable amount of FRAMES as the size of the FRAMES can vary significantly. Typically, an 80 mm field of view with no SPATIAL COMPOUNDING and a LINE DENSITY of 1 (128 vectors) will comprise of one megabyte of data so 200 FRAMES are saved in the CINE MODE buffer. The maxim FRAME RATE for third field of view where each vector is created in 150 microseconds or 6666 per second is 52 so in this case the CINE buffer will store the last 4 seconds.

A progress bar is added to an area below the image area. The progress bar has a Green dot (start), an Orange Dot (current pointer), and a Red dot (end). Pressing PLAY CINE will cycle through the Cine Buffer between the Green Dot and the Red Dot. The Locations of the Red and Green Dots may be moved directly or by pressing the Cine Start and Cine Stop buttons at the location of the Orange Dot. In this way it is possible to save shorter AVI clips to the Patient file.

SAVE CINE

The CINE BUFFER stores images as sample data which is proprietary to UltraVision but SAVE CINE converts the sample data frames to the common video standard of .AVI (Audio Video Interleaved Format).
This conversion can take some time.

RECORD

Record saves the forward going Series of SAMPLE DATA images to an XML file on the SSD or hard drive while the patient data base keeps only a reference to the file. This allows the recording to be of any length within the available space of the hard drive.

Record also places a Thumbnail on the strip at the bottom of the Image field which when clicked upon returns the Recorded Sample Data Images through the scan conversion processes to the View Port in a similar fashon as CINE MODE.

REPORT

The REPORT button during a session will export the saved images (from the .jpg files) into a PDF report, which includes the patient information.

DICOM

The DICOM button will export the current image, along with the patient information to a .DCM file which may be saved on a USB stick (preferred method) or user selected location from where it may be imported to a DICOM data base.

# Appendix 2 Loading Updated User Code.

From time to time updates to the UltraVision's code will become available and will appear on the winprobe.com/ support website. If important updates become available you will be alerted as either you have registered for updates with your installation package or your institution will have enrolled you as a sight administrator.

The site will contain a description of the update and the date after which systems shipped will already have had the update installed. You have to read the updates from your systems installation or latest update to be informed about all the updates. Some updates are for performance improvements, some for new features and some for fixes.

If you are an administrator for the system and you wish to update your system please follow the following procedure.

1. Either use another computer that is connected to the internet.

Or if the UltraVision can be connected to the internet log on as an administrator and navigate to the windows desktop,

2. and plug in the UltraVision Back.UP USB drive shipped with the system and down load the update to the USB_DRIVE: WinProbe/support folder.
   a. Files that run code in the windows operating system are xxxx.msi flies and by ckicking on the file name in the windows explorer will install itself in a procedure where you will be asked to proceed several times. The installation will also remove old versions of the software and the system arfter rebooting will run the new version.

   b. Files that run in the FPGA hardware are xxxx.msc files which are installed from the UltraVision code by navigating to SETUP, DIAGNOSTICS, PROGRAM FPGA buttons.

   c. Files that update other various forms of hardware are xxxx.bat files. That are run by double clicking them in the windows/explorer window.

3. Checksums and various security features secure the transmission over the internet and the internet facility will be terminated once the system is rebooted at the end of any of these update procedures.

**WARNING**

4. As an administrator you are instructed to not attempt to turn on any widows update procedures or to borws the internet while this facility is available under administrator mode. Any violation of this will jepodize the systems stability and may require major cost in reprogramming at the factory.

## Appendix 3 Reprogramming the FPGA for 40 or 60 MHz clock.

The UltraVision software displays the frequency that the system is running at in the top left set of parameters on the image screen.

The UltraVision system can be set up to run at one of two frequencies, 40MHz and 60MHz. For fifteen MHz transducers and above the 60 MHz is recommended and for all other transducers the 40 MHz is recommended.

There is a procedure where the user can change the master clock frequency from one frequency to the other. The process requires loading new code into the systems Field Programmable Gate array.

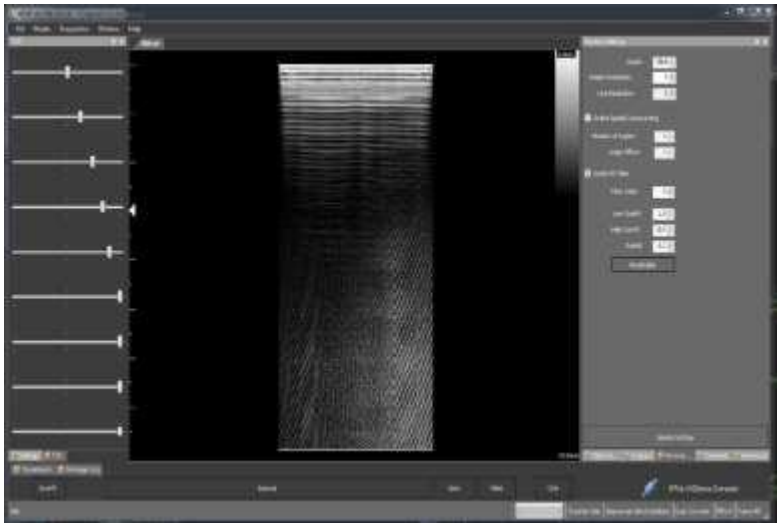
First the user should check the winprobe.com/support web site to assure he or she has the latest code. The code on the web site will have performance changes or fixes that the user may want specifically or that have become available since the system shipped. The user is requested to check the revision levels against the code in the revision levels on the UltraVision Backup USB Stick* that was shipped with the system, and unly down load new code if needed. This process will require a separate computer with access to the internet and see Appendix 2 for instructions for this procedure.

1. Load the USB stick into the system.
2. Log pn as an administrator and go to the windows desktop.
3. Navigate to the usb drive: WinProbe/support/frequency.
4. Run the desired batch file from the “Freq Change” folder, by double clicking either the 40MHz file or the 60MHz file.
5. Run the UltraVision software, click Set Up, then Diagnostics, then Flash FPGA.
6. Select the 40Mhz or 60 Mhz MCS file.
7. Click Flash FPGA. A progress bar will appear while it updates, and will disappear when the process is finished.
8. Cycle power. Power down the system, wait 20 seconds then power the system back up.
9. The system should now be running at the new frequency.

## Appendix 4 EMC Information Guidance and Manufacturer's Declaration

**NOTE:** To protect from EMI, Please keep the UltraVision 2 system away from the EMI sources. For technical reasons, electromagnetic immunity is limited to 1 V rms, otherwise, the interfaced images may affect the diagnosis and measurements.

When the transducer or system is in the presence of a strong RF Field the image area could appear as simulated as in the image below. This level of interference is UltraVision's recommended limit and should not be exceeded. If this occurs the UltraVision 2 should be reoriented or relocated to an area of lesser interference.



| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The UltraVision 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the UltraVision 2 system should assure that it is used in such an environment. | | |
| Emission Test | Compliance | Electromagnetic environment - guidance |
| RF emissions<br><br>CISPR 11 | Group 1 | The UltraVision 2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br><br>CISPR 11 | Class B | The UltraVision 2 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. |
| Harmonic emissions<br>IEC 61000-3-2 | Class B | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Complies | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** |
|---|

| The UltraVision 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the UltraVision 2 system should assure 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 | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 8 kV air | Floors should be wood, concrete, or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines | ± 2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br><br>IEC 61000-4-5 | ± 1 kV line to line<br><br>± 2 kV line to ground | ± .5 kV line to line<br><br>± 1 kV line to ground | Mains power quality should be that of a typical commercial or hospital environment. If the user of the UltraVision 2 requires continued operation during power mains interruptions, it is recommended that the UltraVision 2 be powered from uninterruptible power supply or battery |
| Voltage dips, short interruptions, and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | <5 % $U_T$ (>95 % dip in $U_T$) for 0.5 cycle<br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br><5 % $U_T$ (>95 % dip in $U_T$) for 5 s | <5 % $U_T$ (>95 % dip in $U_T$) for 0.5 cycle<br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br><5 % $U_T$ (>95 % dip in $U_T$) for 5 s | Mains power quality should be that of typical commercial or hospital environment. If the user of the UltraVision 2 requires continued operation during power mains interruptions, it is recommended that the UltraVision 2 be powered from uninterruptible power supply or battery. |
| Power frequency (50/60 Hz) magnetic field | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The UltraVision 2 is intended for use in the electromagnetic environment specified below. The customer or the user of the UltraVision 2 system should assure 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<br><br>Radiated RF IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br><br>3 V/m<br>80 MHz to 2.5 GHz | 1 Vrms<br><br>1 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the UltraVision 2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br><br>$d = [3.5/V_1]\sqrt{P}$<br><br>$d = [3.5/E_1]\sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = [7/E_1]\sqrt{P}$ 800 MHz to 2.3 GHz<br><br>Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br> |
| NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. | | | |

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Ultravision 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the UltraVision 2.

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

**Recommended separation distances between portable and mobile RF communications equipment and the UltraVision 2**

The UltraVision 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the UltraVision 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UltraVision 2 as recommended below, according to the maximum output power of the communications equipment.

| **Rated Maximum output power of transmitter**<br><br>**W** | **Separation distance according to frequency of transmitter**<br><br>**m** | | |
|---|---|---|---|
| | **150 kHz to 80 MHz**<br><br>$d = [3.5/V_1]\sqrt{P}$ | **80 MHz to 800 MHz**<br><br>$d = [3.5/E_1]\sqrt{P}$ | **800 MHz to 2.5 GHz**<br><br>$d = [7/E_1]\sqrt{P}$ |
| 0.01 | 0.35 | 0.35 | 0.7 |
| 0.1 | 1.1 | 1.1 | 2.2 |
| 1 | 3.5 | 3.5 | 7 |
| 10 | 11 | 11 | 22 |
| 100 | 35 | 35 | 70 |

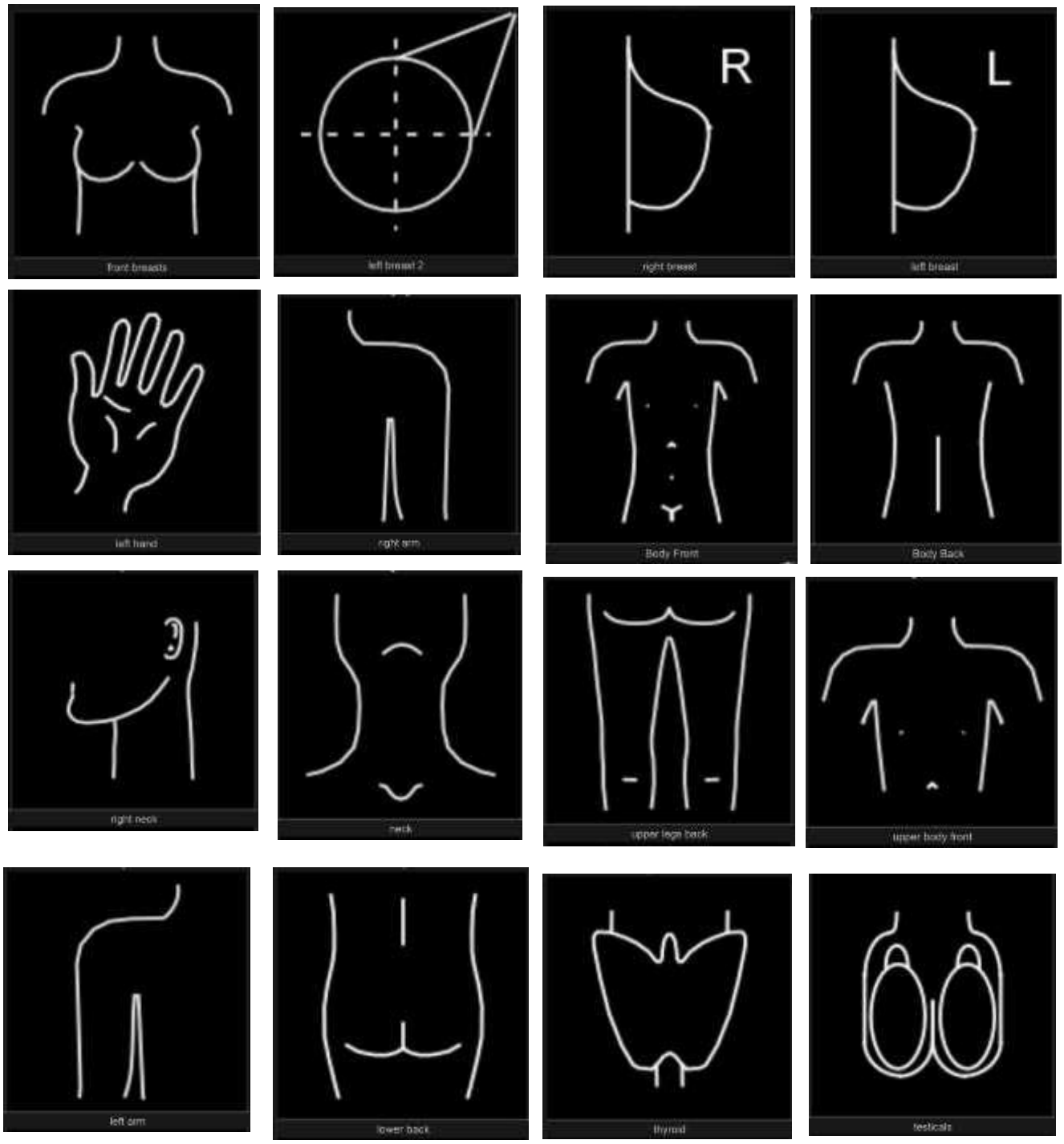
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

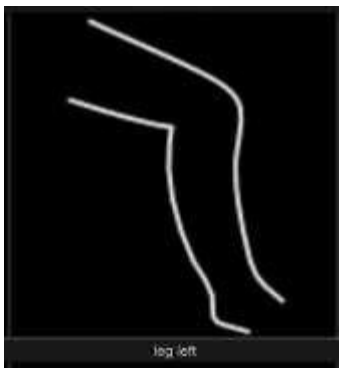
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

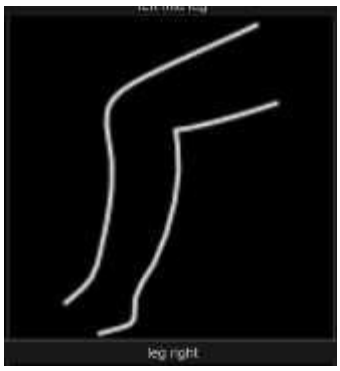
## Appendix 5 Body Markers

The “Body Markers” shows all available body markers which can be selected and named by the user.The available body marker options are as follows:




Body Markers



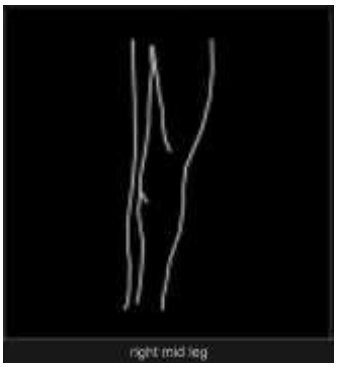


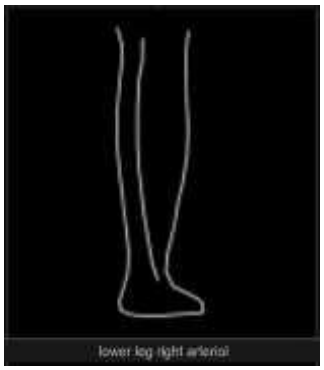


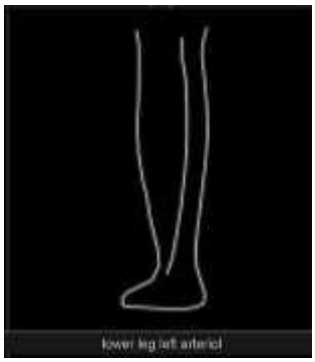








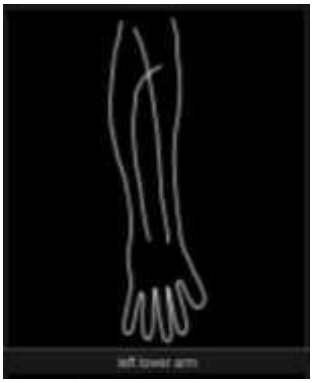

























Body Markers Continued

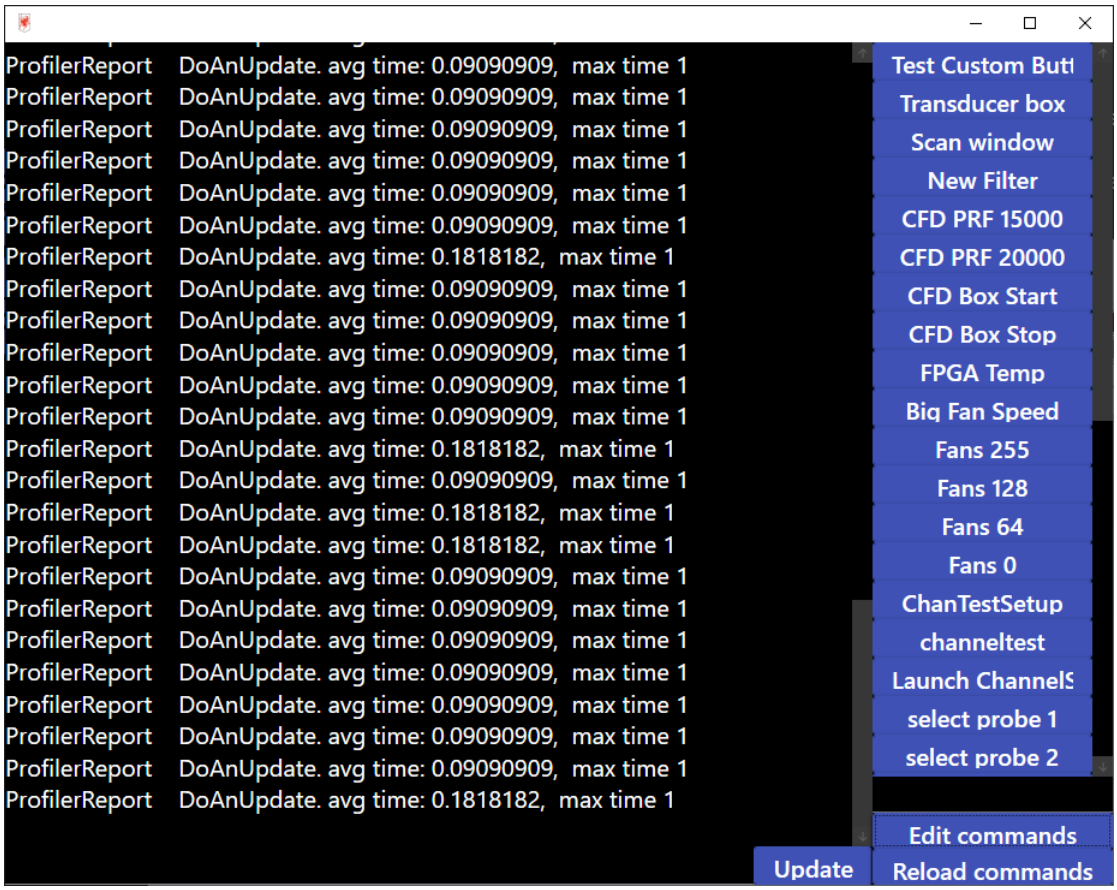
## Appendix 6 Research Platform

The Developer Console can be opened by pressing the Backslash key ("\") on the keyboard while the UltraVision software is running.
Commands can be typed into the text box at the bottom of the console, or the Macro Buttons in the Right side panel of the console can be used.
To add console macro buttons, click on the "Edit Commands" button. This will open a Notepad where commands can be entered.
After editing the commands, clicking on "Reload commands" will update the list of macro buttons in the right side panel.
Each command gets a name (which appears on the macro button), and must be formatted correctly to work.

An example of some commands are as follows:

```
Test Custom Button:help
[OnStartup]:set NewExam.IsTransducerBoxVisible true;
Transducer box:set NewExam.IsTransducerBoxVisible true
Scan window:exec ScanViewModel.LaunchSecondScanWindowCommand
New Filter:exec ScanViewModel.ImportFilterCommand
CFD PRF 15000:set CFDMode.ColorFlowSettings.PRF 15000
CFD PRF 20000:set CFDMode.ColorFlowSettings.PRF 20000
CFD Box Start:set CFDMode.ColorFlowSettings.StartLine 1;
CFD Box Stop:set CFDMode.ColorFlowSettings.StopLine 192;
FPGA Temp:get SystemViewModel.CurrentDevice.Readings2.FPGADieTemperature
Big Fan Speed:set SystemViewModel.CurrentDevice.Readings2.FanSpeed0 255
Fans 255:set SystemViewModel.CurrentDevice.Readings2.FanSpeed0 255;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed1 255;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed2 255;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed3 255
Fans 128:set SystemViewModel.CurrentDevice.Readings2.FanSpeed0 128;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed1 128;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed2 128;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed3 128
Fans 64:set SystemViewModel.CurrentDevice.Readings2.FanSpeed0 64;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed1 64;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed2 64;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed3 64
Fans 0:set SystemViewModel.CurrentDevice.Readings2.FanSpeed0 0;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed1 0;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed2 0;set
    SystemViewModel.CurrentDevice.Readings2.FanSpeed3 0
ChanTestSetup:set Session.CurrentViewPortSession.BMode.ApodizationViewModel.FNumber 100000;set
    Session.CurrentViewPortSession.BMode.TransmitViewModel.TxFNumber 100000;set
    Session.PendingRecreateTables true
channeltest:set DxDeviceContainer.FirstBScene.Channeltest true
Launch ChannelScope:exec ScanViewModel.ChannelScopeCommand
Samples Per Kernel 2:set Session.CurrentViewPortSession.CFDMode.ColorFlowSettings.SamplesPerKernel 2
```

Samples Per Kernel 4:set Session.CurrentViewPortSession.CFDMode.ColorFlowSettings.SamplesPerKernel 4
Samples Per Kernel 8:set Session.CurrentViewPortSession.CFDMode.ColorFlowSettings.SamplesPerKernel 8
Samples Per Kernel 12:set Session.CurrentViewPortSession.CFDMode.ColorFlowSettings.SamplesPerKernel 12
Samples Per Kernel 16:set Session.CurrentViewPortSession.CFDMode.ColorFlowSettings.SamplesPerKernel 16
Stop Sample 128:set Session.CurrentViewPortSession.CFDMode.ColorFlowSettings.StopSample 128
Stop Sample 256:set Session.CurrentViewPortSession.CFDMode.ColorFlowSettings.StopSample 256
Stop Sample 512:set Session.CurrentViewPortSession.CFDMode.ColorFlowSettings.StopSample 512
Stop Sample 1024:set Session.CurrentViewPortSession.CFDMode.ColorFlowSettings.StopSample 1024
SetBlock 4:set BMode.BufferCount 4;set Session.PendingRecreateTables true
SetBlock 16:set BMode.BufferCount 16;set Session.PendingRecreateTables true
SetBlock 256:set BMode.BufferCount 256;set Session.PendingRecreateTables true
RedoStuff :set Session.PendingRecreateTables true
Set 0 Volt:set Session.Voltage 0
CFD Samples per kernal 2:set CFDMode.ColorFlowSettings.SamplesPerKernel 2;set Session.PendingRecreateTables true
CFD Samples per kernal 4:set CFDMode.ColorFlowSettings.SamplesPerKernel 4;set Session.PendingRecreateTables true
CFD Samples per kernal 8:set CFDMode.ColorFlowSettings.SamplesPerKernel 8;set Session.PendingRecreateTables true
Save Video:exec ScanViewModel.CineViewModel.SaveVideoCommand



Developer Console

## COPYRIGHT

Copyright © 2015 by UltraVision Corporation. All rights reserved. No part of this publication may be reproduced, transcribed, transmitted, stored in retrieval systems, or translated into any language or computer language, in any form or by any means, electronic, or otherwise, without the prior written permission of UltraVision Corporation.

UltraVision Corporation reserves the right to change its products and services at any time. In addition, this manual is subject to change without notice. UltraVision Corporation welcomes customer input on corrections and suggestions for improvements to this manual.

Although UltraVision Corporation attempts to ensure accuracy throughout this manual, UltraVision Corporation assumes no liability for any errors or omissions, nor for any damages resulting from the application or use of this information.

## TRADEMARKS

Windows, Vista and XP are registered trademarks of Microsoft Corporation, Cidex. Cidex Plus, and Cidex 7 are registered trademarks of Surgikos, Inc. K-Y Lubricating Gel is a trademark of Johnson & Johnson Products, Inc. IBM is a registered trademark of International Business Machines Corporation. Metricide is a trademark of Metrex Research Corporation. Omnicide is a trademark of Cottrell. Ltd. Panasonic is a trademark of Matsushita Electric Industrial Co. Ltd. Polaroid is a registered trademark of Polaroid Corporation. 3M is a registered trademark of Minnesota Mining and Manufacturing. Apple, AppleTalk, EtherTalk, LocalTalk, Macintosh, MultiFinder. and LaserWriter are trademarks of Apple Computer, Inc. DOT is a registered trademark of Digital Optical Technologies. Pinnacle Micro Inc.. Kodak, and Ektascan are registered trademarks of Eastman Kodak Company. PostScript is a registered trademark of Adobe Systems. Incorporated. Ricoh is a trademark of Ricoh Company, Ltd. Sony is a registered trademark of Sony Corporation of America. Verbatim is a registered trademark of Verbatim Corporation. Tosoh is a trademark of Tosoh Corporation. Multi-Imager is a trademark of International Imaging Electronics. All other product names are trademarks of their respective companies.

## CAUTION!

Federal Law restricts clinical use of this device to or on the order of a physician.

## LICENSE AGREEMENT

All computer programs rare copyright 2005-2013 by UltraVision Corporation or its suppliers. Such programs are licensed under the following software license agreement:

UltraVision Corporation or its suppliers retain ownership of and title to any computer program supplied with the equipment and to the trade secrets embodied in such computer programs. Subject to the Buyer s acceptance and fulfillment of the obligations in this paragraph, UltraVision Corporation grants the Buyer a personal, non-transferable, perpetual, non-exclusive license to use any computer program supplied with the Equipment that is necessary to operate the Equipment solely on the medium in which such program is delivered for the purpose of operating the equipment in accordance with the instructions set forth in the operator s manuals supplied with the Equipment and for no other purpose whatsoever. Buyer may not reverse-assemble, reverse-compile or otherwise reverse-engineer such computer programs nor may Buyer make a copy of such program or apply any techniques to derive the trade secrets embodied therein. In the event of a failure by Buyer to comply with the terms of this license, the license granted by this paragraph shall terminate. Further, because unauthorized use of such computer programs will leave UltraVision Corporation without an adequate remedy at law. Buyer agrees that injunctive or other equitable relief will be appropriate to restrain such use, threatened or actual. Buyer further agrees that (i) any of UltraVision Corporation’s suppliers of software is a direct and intended beneficiary of this end-user sublicense and may enforce it directly against Buyer with respect to software supplied by such supplier, and (ii) no supplier of UltraVision Corporation shall be liable to buyer for any general, special, direct, indirect, consequential, incidental or other damages arising out of the sublicense of the computer programs supplied with the equipment.