

# Piloter Color Diagnostic Ultrasound System

## User manual



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# Statement

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The content of this Manual is subject to change without prior notice.

Only if the following requirements are met, Wisonic will be responsible for the safety, reliability and performance of the product, i.e.:

- Assembly, expansion, re-adjustment, improvement and repair should only be performed by qualified personnel approved by Wisonic;
- All the replaced parts and supported accessories and consumables relate to the maintenance shall be originally from Wisonic or others approved by Wisonic;
- DO NOT make changes or modifications to the software or hardware of this system
- The electrical equipment complies with relevant standards and the requirements of this Manual;
- The product is operated in accordance with this Manual.

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# Preface

## Notice

This User Manual is the necessary instructions for the safe use of this product. This Manual introduces the use, properties, method of operation, safety information and intended use of the Piloter series ultrasound system in details. Before using the product, please carefully read and understand the contents of this Manual, and abide by the method of operation stated in this Manual in order to ensure the safety of patients and operators.

This User Manual is a major component of the product, and should always be placed near the product for easy reference.

## Object of Application

This User Manual is intended for professional clinical staff or personnel with experience in the use of ultrasound diagnostic equipment. The readers should have knowledge and work experience in medical procedures, practices and terminology of ultrasound diagnosis.

## Illustration

All the illustrations in this user Manual are for reference only. The menus, settings and parameters of the illustrations may be different from your actual currently use system. The content varies depending on the software version, preset settings and optional configuration.

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# 1 Introduction

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## Attention

Contents of this manual are subject to change without prior notice.

This manual contains necessary and sufficient information to operate the system safely. Advanced equipment training may be provided by a factory trained Applications Specialist for the agreed-upon time period.

Read and understand all instructions in this manual before attempting to use the system. Keep this manual with the equipment at all times. Periodically review the procedures for operation and safety precautions.

Disregarding information on safety is considered abnormal use.

Not all features or products described in this document may be available or cleared for sale in all markets. Please contact your local Wisonic Ultrasound representative to get the latest information.

**NOTE:** *Please note that orders are based on the individually agreed specifications and may not contain all features listed in this manual.*

**NOTE:** *All references to standards / regulations and their revisions are valid for the time of publication of the user manual.*

## 1.1 Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

### Exemptions

Wisonic's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Wisonic or repairs by people other than Wisonic authorized personnel.

**This warranty shall not extend to:**

**Malfunction or damage caused by improper use or man-made failure.**  
**Malfunction or damage caused by unstable or out-of-range power input.**  
**Malfunction or damage caused by force majeure such as fire and earthquake.**  
**Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.**  
**Malfunction of the instrument or part whose serial number is not legible enough.**  
**Others not caused by instrument or part itself.**

## **1.2 Company Contact**

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## 1.3 Important Information

1. Medical ultrasound images are created by computer and digital memory from the transmission and reception of mechanical high-frequency waves applied through a transducer. The mechanical ultrasound waves spread through the body, producing an echo where density changes occur. For example, in the case of human tissue, an echo is created where a signal passes from an adipose tissue (fat) region to the liver. The echoes return to the transducer where they are converted back into electrical signals.
2. These echo signals are highly amplified and processed by several analog and digital circuits having filters with many frequency and time response options, transforming the high-frequency electrical signals into a series of digital image signals which are stored in memory. Once in memory, the image can be displayed in real-time on the image monitor. All signal transmission, reception and processing characteristics are controlled by the main computer. By selection from the system control panel, the user can alter the characteristics and features of the system, allowing a wide range of uses, from obstetrics to peripheral vascular examinations.
3. Transducers are accurate, solid-state devices, providing multiple image formats. The digital design and use of solid-state components provides highly stable and consistent imaging performance with minimal required maintenance. Sophisticated design with computer control offers a system with extensive features and functions which is user-friendly and easy to use.

## 1.4 About This Manual

<b>⚠CAUTION:</b> The safety instruction must be reviewed before operation of the unit.
--

**Piloter series documentation consists of various manuals:**

- The user manual provides information needed by the user to operate the system safely. It describes the basic functions of the system, safety features, operating modes, measurements/calculations, probes, OB tables, and user care and maintenance. The Piloter series include Piloter Exp/T/PE/P/S/B/D/F/R/RE/V/U/SE/i/X and Piloter totally sixteen model systems.

**NOTE:** *Probe information displayed on screen examples does not necessarily reflect the probes available on your ultrasound system. Please refer to the Probes chapter for a listing of available probes and features.*

- The Acoustic Power Reference Manual contains Acoustic Output tables. The Piloter series manuals are written for users who are familiar with basic ultrasound principles and techniques. They do not include sonographic training or detailed clinical procedures.

**NOTE:** *The system cover color varies.*

**NOTE:** *The screen graphics in this manual are only for illustrational purpose.*

# 2 Safety Precautions

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## 2.1 Precaution Levels

### Icon Description

Various levels of safety precautions may be found on the equipment and different levels of concern are identified by one of the following flag words and icons which precede the precautionary statement.

Symbol	Meaning
 <b>DANGER</b>	Indicates that a specific hazard is known to exist which through inappropriate conditions or actions will cause serious personal injury or death.
 <b>WARNING</b>	Indicates that a specific hazard is known to exist which through inappropriate conditions or actions may cause series personal injury or death
 <b>CAUTION</b>	Indicates that a potential hazard may exist which through inappropriate conditions or actions may cause minor personal injury, product damage, or property damage.
NOTE	Indicates a potentially hazardous situation that, if not avoided, may result in property damage.
Tips	Important information that helps you to operate the system more effectively.

## 2.2 Safety Classification

The type of protection against electric shock:

CLASS I Equipment

The degree of protection against electric shock:

Type BF Applied Part

The degree of protection against harmful ingress of water:

The System is ordinary Equipment (IPX0), the probes belong to IPX7, and the Transducer extender belongs to IPX0.

According to the degree of safety of application in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE:

EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE

The mode of operation:

Continuous operation

The installation and use:

Portable Equipment

Mobile Equipment (installed on the trolley)

## 2.3 Important Safety Considerations

The following topic headings (Patient Safety, and Equipment and Personnel Safety) are intended to make the equipment user aware of particular hazards associated with the use of this equipment and the extent to which injury can occur if precautions are not observed.

Additional precautions may be provided throughout the manual.

### **⚠CAUTION:**

Improper use can result in serious injury. The user must be thoroughly familiar with the instructions and potential hazards involving ultrasound examination before attempting to use the device. Training assistance is available from Wisonic Medical Systems if needed.

The equipment user is obligated to be familiar with these concerns and avoid conditions that could result in injury.

## 2.4 Patient Safety

### **⚠WARNING:**

The concerns listed can seriously affect the safety of patients undergoing a diagnostic ultrasound examination.

#### **Patient identification**

Always include proper identification with all patient data and verify the accuracy of the patient's name and ID numbers when entering such data. Make sure correct patient ID is provided on all recorded data and hard copy prints. Identification errors could result in an incorrect diagnosis.

The ultrasound system is not meant to be used for long term storage of patient data or images. The user is responsible for the data on the system and a regular backup is highly recommended.

If the system is sent for repair, please ensure that any patient information is backed up and

erased from the system before shipping. It is always possible during system failure and repair to lose patient data. Wisonic is not responsible for the loss of this data.

### **Diagnostic information**

Equipment malfunction or incorrect settings can result in measurement errors or failure to detect details within the image.

The equipment user must become thoroughly familiar with the equipment operation in order to optimize its performance and recognize possible malfunctions. Applications training are available through the local Wisonic representative. Added confidence in the equipment operation can be gained by establishing a quality assurance program.

### **Mechanical hazards**

The use of damaged probes can result in injury or increased risk of infection. Inspect probes often for sharp, pointed, or rough surface damage that could cause injury or tear protective barriers. Become familiar with all instructions and precautions provided with special purpose probes.



### **Electrical**

#### **Hazard:**

A damaged probe can also increase the risk of electric shock if conductive solutions come in contact with internal live parts. Inspect probes often for cracks or openings in the housing and holes in and around the acoustic lens or other damage that could allow liquid entry. Become familiar with the probe's use and care precautions outlined in *Probes and Biopsy*.

### **⚠Caution:**

Ultrasound transducers are sensitive instruments which can easily be damaged by rough handling. Take extra care not to drop transducers and avoid contact with sharp or abrasive surfaces. A damaged housing, lens or cable can result in patient injury or serious impairment or operation.

**⚠Caution:**

Ultrasound can produce harmful effects in tissue and potentially result in patient injury. Always minimize exposure time and keep ultrasound levels low when there is no medical benefit. Use the principle of ALARA (As Low As Reasonably Achievable), increasing output only when needed to obtain diagnostic image quality. Observe the acoustic output display and be familiar with all controls affecting the output level. See the Bioeffects section of the Acoustic Output chapter in the Advanced Reference Manual for more information.  
The basket of trolley is 5 Kg.

## 2.5 Personnel Safety

**⚠DANGER:**

The concerns listed below can seriously affect the safety of equipment and personnel during a diagnostic ultrasound examination.



**Electrical**

**Hazard:**

To avoid injury:

- Do not remove protective covers. No user serviceable parts are inside. Refer servicing to qualified service personnel.
- Never use any adaptor or converter of a three-prong-to-two-prong type to connect with a mains power plug. The protective earth connection will loosen.
- Do not place liquids on or above the console. Spilled liquid may contact live parts and increase the risk of shock.
- The operator shall not touch adaptor DC output and the patient simultaneously.
- The user must check that the equipment functions safely and see that it is in proper working condition before being use
- The operator shall not touch DC output of adapter and the patient simultaneously.



**Smoke & Fire**

**Hazard**

The system must be supplied from an adequately rated electrical circuit. The capacity of the supply circuit must be as specified.



## Biological

### Hazard

For patient and personnel safety, be aware of biological hazards while performing invasive procedures. To avoid the risk of disease transmission:

- Use protective barriers (gloves and probe sheaths) whenever possible. Follow sterile procedures when appropriate.
- Thoroughly clean probes and reusable accessories after each patient examination and disinfect or sterilize as needed. Refer to *Probes and Biopsy* for probe use and care instructions.
- Follow all infection control policies established by your office, department or institution as they apply to personnel and equipment.

### WARNING:

- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth
- This equipment contains dangerous voltages that are capable of serious injury or death.
- If any defects are observed or malfunctions occur, stop operating the equipment and perform the proper action for the patient. Inform a qualified service person and contact a Service Representative for information.
- There are no user serviceable components inside the console. Refer all servicing to qualified service personnel only.
- The system provides calculations (e.g. estimated fetal weight) and charts based on published scientific literature. The selection of the appropriate chart and clinical interpretation of calculations and charts are the sole responsibility of the user. The user must consider contraindications for the use of a calculation or chart as described in the scientific literature. The diagnosis, decision for further examinations and medical treatment must be performed by qualified personnel following good clinical practice.

### WARNING:

- Only approved and recommended peripherals and accessories should be used.
- All peripherals and accessories must be securely mounted to the system

**⚠CAUTION:**

- Do not use this equipment if a safety problem is known to exist. Have the unit repaired and performance verified by qualified service personnel before returning to use.
- Contact with natural rubber latex may cause a severe anaphylactic reaction in persons sensitive to the natural latex protein. Sensitive users and patients must avoid contact with these items. Refer to package labeling to determine latex content and FDA's March 29, 1991 Medical Alert on latex products.
- Archived data is managed at the individual sites. Performing data backup (to any device) is recommended.
- DO NOT use high-frequency surgical equipment with the system.
- Do not position the equipment so that it is difficult to operate the disconnection device.

**Note:**

Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact your local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.



The WEEE label applies to EU member states only and may be attached to main unit for system products.

## 2.6 General Caution

### CAUTION:

- Standard maintenance must be performed by authorized service personnel for the lifetime of the product (5 years).
- Proceed cautiously when crossing door or elevator thresholds with the Docking Cart or Isolation Cart. Use the handle to push/ pull the system, e.g., do not use the Docking Cart external LCD. Failure to do so may cause serious injury or system damage.
- The device requires no calibration.
- Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.
- Magnetic and electrical fields are capable of interfering with the proper performance of the system. For this reason make sure that all external devices operated in the vicinity of the system comply with the relevant EMC requirements. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

## 2.7 Symbols

This system uses the symbols listed in the following table, and their meanings are explained as well.

No.	symbol	Description
1		Type-BF applied part
2		Caution!
3		General warning sign (Background color: yellow).
4		Danger, high voltage

No.	symbol	Description
5		Power switch
6		Transducer port
7		Ethernet port
8		USB port
9		HDMI Connects
10		DC(Direct current)
12		Please refer to the instruction manual
13		Non-ionizing radiation
14		Do not place the system with the mobile trolley on a sloped surface. Otherwise the system may slide, resulting in personal injury or the system malfunction. Two persons are required to move the system over a sloped surface.
15		DO NOT push the system when the casters are locked.
16		Do not sit on the system

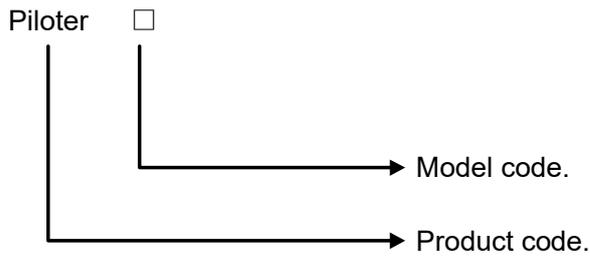
No.	symbol	Description
17		Serial Number
18		Manufacture date
19		Manufacture information
20		Authorized representative in the European Community
21		This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93 / 42 / EEC concerning Medical Devices. The number adjacent to the CE marking (0123) is the number of the EU-notified body certified for meeting the requirements of the Directive.



# 3 System Overview

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## 3.1 Product and Model Code



NOTE: The functions described in the basic user manual may vary depending upon the specific system you purchased.

## 3.2 Intended Use

The ultrasonic diagnostic system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in the abdomen (liver, spleen, gallbladder, pancreas, kidney), obstetrics and Gynecology, small organs (thyroid and parathyroid gland, testis, prostate, breast, salivary gland, superficial lymph), and peripheral blood vessels, heart and vaginal.

## 3.3 Contraindication

The ultrasonic diagnostic system is not intended for ophthalmic use or any possible ways that cause the acoustic beam to pass through the eye.

## 3.4 Product Specifications

### 3.4.1 External Dimensions and Weight

**Main unit external dimensions:** 234 mm (H) ×340 mm (L) ×36 mm (W)

**System weight:** 1.9 Kg (including cart)

### 3.4.2 Imaging Modes

<b>B Mode</b>	B
<b>M Mode</b>	M
<b>C Mode</b>	Color  Power (Dirpower)
<b>D Mode</b>	PW Doppler  CW Doppler
<b>Advanced Imaging</b>	Support for Wisonic's unique Holo (flat wave PW) imaging

### 3.4.3 Power supply

<b>Power Adapter</b>	MANGO60-19AB-WIS
<b>Voltage</b>	100-240V~ (AC adapter)
<b>Frequency</b>	50/60Hz (AC adapter)
<b>Input Power</b>	1.5-0.7A (AC adapter)
<b>Battery</b>	LI14I03A
<b>Battery Spec</b>	Lithion, 14.4V,2900mAh
<b>Power cord</b>	H05VV-F 3G 1.0mm <sup>2</sup> /SJT VW-1 300V 1.31mm <sup>2</sup> /SJT VW-1 300V 0.824mm <sup>2</sup>

- NOTE:**
1. The CE region applied voltage is 220-240V~.
  2. Power supply set meet the requirements with local regulations and has a reliable ground connection.
  3. The power cord diameter is at least 0.75 square millimeters.

### 3.4.4 Environmental Conditions

	Operating conditions	Storage and transportation conditions
<b>Ambient temperature</b>	0°C~40°C	-20°C~55°C
<b>Relative humidity</b>	30%~85% (no condensation)	30%~95% (no condensation)
<b>Atmospheric pressure</b>	700hPa~1060hPa	700hPa~1060hPa

**⚠ WARNING:** Do not use this system in the conditions other than those specified.

## 3.5 System Configuration

### 3.5.1 Standard Configuration

**Main unit**

**Accessories**

- User manuals
- Power adapter and connecting cable

## 3.5.2 Options

### 3.5.2.1 Probes and Needle-guided Brackets Available

Probe model	Type	Intended Use	Region Applied
C5-2	Convex	Abdomen, Gynecologic, Obstetric, Nerve block	Body surface
C5-2B	Convex	Abdomen, Gynecologic, Obstetric, Nerve block	Body surface
C8-3	Convex	Abdomen, Gynecologic, Obstetric, Nerve block	Body surface
L15-4NB	Linear	Small parts, Vascular, Nerve block, Muscular-Skeletal	Body surface
L10-5	Linear	Small parts, Vascular, Nerve block, Muscular-Skeletal	Body surface
LH15-6	Linear	Superficial, Vascular, Nerve block, Muscular-Skeletal, Small parts	Body surface
P4-1	Phased	Cardiology, Transcranial, Nerve block, abdominal	Body surface
P7-3	Phased	Cardiology, Transcranial, Nerve block, Abdominal	Body surface
EV10-4	Transvaginal	Gynecology, Obstetrics, Urology	Transvaginal

### 3.5.2.2

### 3.5.2.3 Options

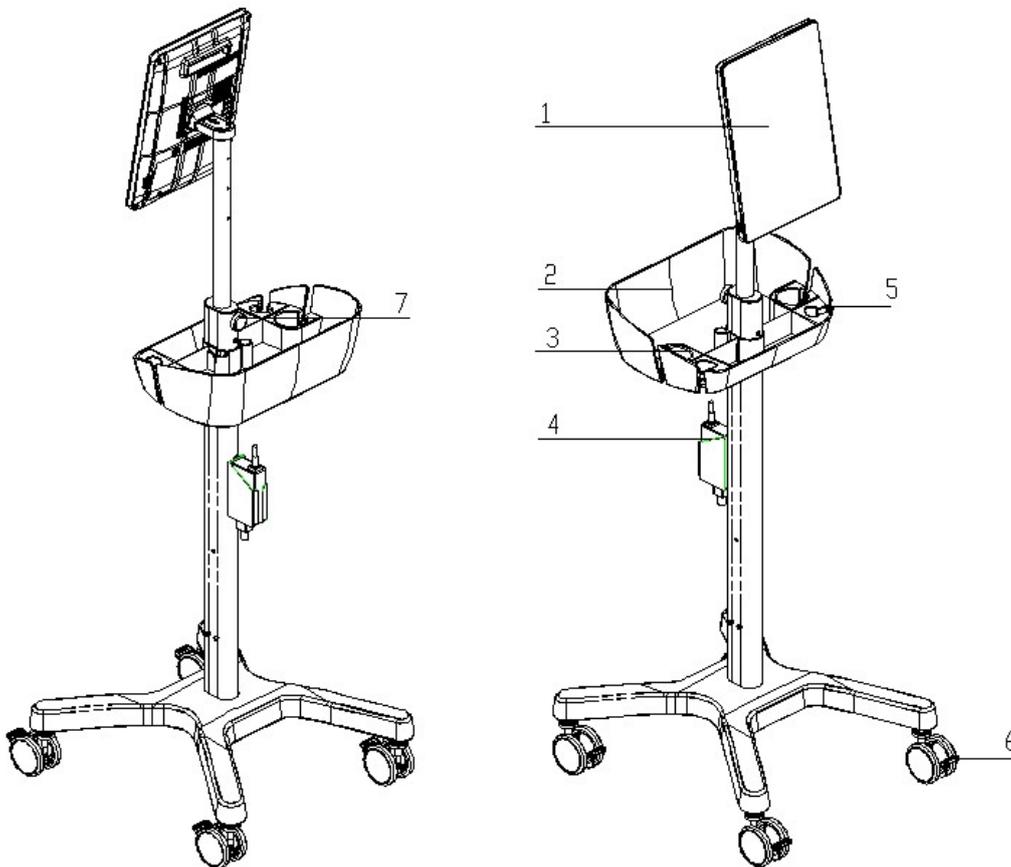
No.	Item
1	CW module (requires to be configured in factory)
2	PW module
3	Trolley
4	Desktop stand
5	Probe extender
6	DICOM Basic
7	DICOM Worklist
8	DICOM MPPS
9	DICOM QR
10	4G Driver module (requires to be configured in factory)
11	wiNeedle
12	wiLearn
13	General application package
14	Anesthesia application package
15	Pain management package

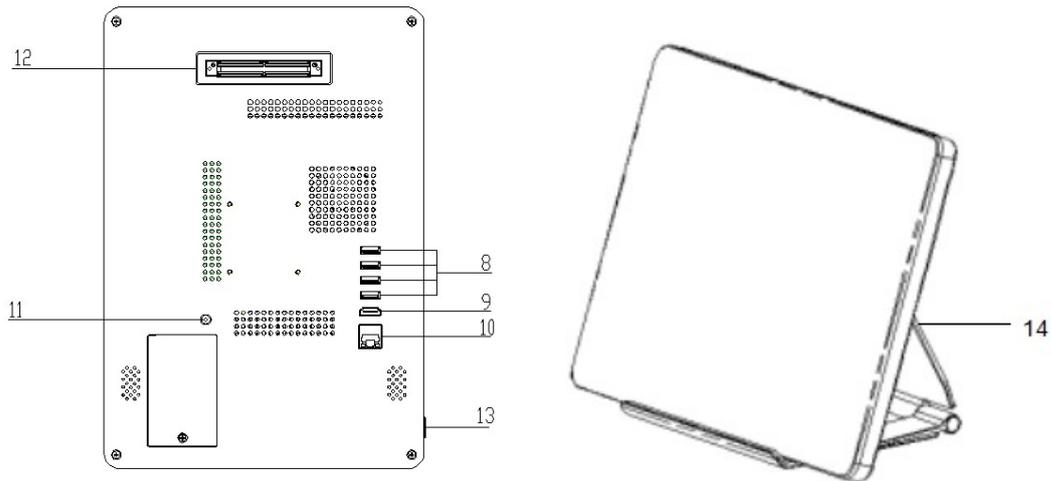
Note: Options listed here may vary country to country, please contact your local distributor for more detailed info.

**⚠ WARNING:**

Piloter Series complies with IEC60601-1-2:2007, and its RF emission meets the requirements of CISPR11 Class B. In a domestic environment, the customer or the user should guarantee to connect the system with Class B peripheral devices; otherwise RF interference may result and the customer or the user must take adequate measures accordingly.

### 3.6 Introduction of Each Unit





NO.	Name	Function
1	Touch screen monitor	Image display, operator-system interface or control.
2	Storage basket	Used to store any small accessories.
3	Holder of Gel	Used to store gel.
4	Adapter	Used to supply power to the host
5	Cup sleeve of probe	Used to store temporary probe
6	Wheel	Support and move the system.
7	USB 	USB port
8		For extended high definition display
9	Ethernet port 	Connect internet
10	Power input 19V  3.15A {max. }	Main system power input.

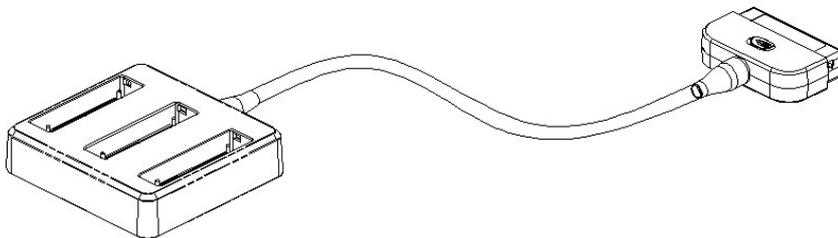
NO.	Name	Function
11	Probe port 	Connects a probe to the main unit; or connects a probe extend module.
12	Power 	Power on/off the system.
13	AC power input	System AC input
14	Desktop stand	Support the main unit

## 3.7 Extension Module

### 3.7.1 Probe Extender

**Be careful:**

- For the probe expansion module of the plug, please try to operate in the system after the freeze, so as to reduce the loss of the probe extension module life.
- The probe expansion module is connected with the probe, because the probe cable becomes longer, and the image quality can be reduced.
- Introduction of components:



The probe is connected with the probe extender ports: it can connect 3 probes.

# 4 Preparing the System

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## 4.1 Site Requirement

This medical equipment is approved, in terms of the prevention of radio wave interference, to be used in hospitals, clinics and other institutions which are environmentally qualified. The use of this equipment in an inappropriate environment may cause some electronic interference to radios and televisions around the equipment.

Take precautions to ensure that the console is protected from electromagnetic interference.

Precautions include:

- Operate the console at least 15 feet away from motors, typewriters, elevators, and other sources of strong electromagnetic radiation.
- Operation in an enclosed area (wood, plaster or concrete walls, floors and ceilings) helps prevent electromagnetic interference.
- Special shielding may be required if the console is to be operated in the vicinity of radio broadcast equipment.

### **Notice:**

Perform regular preventive maintenance.

Maintain a clean environment. Turn off, and if possible, disconnect the system before cleaning the unit.

Never set liquids on the unit to ensure that liquid does not drip into the control panel or unit.

## 4.2 Move/Posit System

When moving or transporting the system, follow the precautions below to ensure the maximum safety for personnel, the system, and other equipment.

### **Before moving the system**

1. Shut down the system.
2. Unplug the power cord (if the system is plugged in).
3. Disconnect all cables from off-board peripheral devices (external printer, etc.) from the console. To prevent damage to the Power Cord, DO NOT pull excessively on the cord or make sharp bends while wrapping.
4. Store all probes in their original cases or in soft cloth or foam to prevent damage.

5. Store sufficient gel and other essential accessories in the special storage case..

**⚠ CAUTION:**

The system weighs approximately 1.9kg. To avoid possible injury and equipment damage:

- Do not let the system strike walls or door frame.
- Limit movement to a slow careful walk.

### Transporting the System

Use extra care when transporting the system using vehicles. In addition to the instructions used when moving the system, also perform the following:

1. Before transporting, place the system in its special storage case.
2. Ensure that the system is firmly secured while inside the vehicle.
3. Secure system with straps or as directed otherwise to prevent motion during transport.

## 4.3 Power Supply

This system can work normally only when it is connected to the external power supply or the battery capacity is sufficient.

### 4.3.1 Connecting the External Power Supply

1. Connect the connector of the power adapter to the adapter port in the system.
2. Use a three-wire cable to connect the adapter with the external power supply.
3. The external power supply system must meet the following requirements:
  - Power supply voltage: 100-240V~
  - Power supply frequency: 50/60Hz
  - Input current: 1.5- 0.7 A
  - The model of the power adapter: MANGO60-19AB-WIS

If you have any question about the power adapter, please contact your sales representative.

- NOTE:**
1. You must use the specified power adapter.
  2. Do not use this power adapter in the conditions other than those specified.
  3. The plug (or appliance separable) is used as disconnect to the mains supply, do not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.

## 4.3.2 Powered by Batteries

The lithium ion battery provides power when an AC power source is not available. A battery in the battery bay is standard with the system. Lithium ion batteries last longer than conventional batteries and do not require replacement as often.

**NOTE:** *The battery is designed to work with Piloter series systems only.*  
*Only use the batteries authorized by Wisonic.*

## 4.4 Powering the System

### 4.4.1 Power ON

#### Connecting and Using the System

To connect the system to the electrical supply:

1. Ensure that the wall outlet is of the appropriate type.
2. Plug the AC adapter connector on the system.
3. Push the power plug securely into the wall outlet.

**⚠CAUTION:** Use caution to ensure that the power cable does not disconnect during system use.  
If the system is accidentally unplugged, data may be lost.

**⚠WARNING:** DO NOT use the system on plastic foam, paper or similar type surfaces. The system could overheat and slow down.  
Ensure that the system is on a sturdy, heat resistant surface.  
To avoid risk of fire, the system power must be supplied from a separate, properly rated outlet.  
Under no circumstances should the AC power plug be altered, changed, or adapted to a configuration rated less than specified. Never use an extension cord or adapter plug.  
To help assure grounding reliability, connect to a “hospital grade” or “hospital only” grounded power outlet.

#### Turning on Power

1. Press the power button in the upper right side on the touch panel.
2. The system enters the work status.
3. The indicator lights on and becomes green.

## 4.4.2 Power OFF

You need to follow the correct procedures to power off the system. In addition, after you upgrade the software or when the system is down, you need to power off and restart it.

**If you will not use the system for a long period of time, you shall:**

1. Disconnect the power adapter.
2. Disconnect the mains power.
3. Turn off powers of all peripherals connected to the system.

**To power off your system normally:**

1. When you shut down the system, enter the scan screen and lightly press the **Power On/Off** switch at right bottom side of the system for more than 1 sec. The System-Exit window is displayed.
2. Touch **Power Off**. The shutdown process takes a few seconds and is completed when the LED turns from green to off.

- NOTE:**
1. DO NOT rush shutdown of the system in a direct way. It may destroy the data.
  2. If the system has not fully shut down in 60 seconds, press and hold down the On/Off switch until the system shuts down.

## 4.4.3 Standby

Standby definition: in a normal temperature and humidity environment, the system is connected to the probe and without additional equipment or modules. After a period of time, the system will freeze, screen dimmed.

To enter standby mode:

1. Lightly press the **Power On/Off** switch for more than 1 sec. The System-Exit window is displayed.
2. Touch **Standby**. The shutdown process takes a few seconds and is completed when the LED will turn orange.

To quit standby:

Please press the power switch.

When the system is in standby mode and you need to power off, please:

Press the power switch to quit standby first. Press the **Power On/Off** switch for more than 1 sec and then touch **Power Off**.

- NOTE:**
1. If you do not use the system for a long time (including storage and transportation), please turn off the system, otherwise it will cause battery exhaustion and permanent damage.
  
  2. If you do not use the system for a long time, please do not enter the standby. You should turn off the system, unplug the power and shut down all connected devices.

## 4.5 Battery

The lithium ion battery provides power when an AC power source is not available. A battery in the battery bay is standard with the system.

The lithium ion technology used in your system's battery is significantly less hazardous to the environment than the lithium metal technology used in some other batteries (such as watch batteries). Used batteries should not be placed with common household waste products. Contact local authorities for the location of a chemical waste collection program nearest you.

*The battery is designed to work with systems only.*

**NOTE:** *Only use the batteries authorized by Wisonic.*

**⚠ WARNING:**

- The battery has a safety device. Do not disassemble or alter the battery.
- Charge the batteries only when the ambient temperature is between 0 and 40 degrees C (32 and 104 degrees F) and discharge the batteries between 0 and 40 degrees C (32 and 104 degrees F).
- Do not short-circuit the battery by directly connecting the negative terminals with metal objects.
- Do not heat the battery or discard it in a fire.
- Do not expose the battery to temperature over 50 degrees C (122 degrees F). Keep it away from fire and other heat sources.
- Do not charge the battery near a heat source, such as a fire or heater.
- Do not leave the battery in direct sunlight.
- Do not pierce the battery with a sharp object, hit it, or step on it.
- Do not use a damaged battery.
- Do not solder a battery.
- Do not connect the battery to an electrical power outlet.
- If the system is not being used on a monthly basis, the battery needs to be removed during the lengthy non-use period.

## 4.5.1 Battery Status

The battery status indicator is located on the main screen, indicating the battery capacity.

When the power capacity is not enough, the icon will flash in order to let the user charge the system or shut down the system.

## 4.5.2 Checking Battery Performance

The battery performance may be degraded over time, so you need to check the battery performance periodically. The checking procedures are shown as follows:

1. Stop the ultrasound exam.
2. Connect the system to the AC power supply to charge the battery until current capacity is full.
3. Disconnect the system from the AC power supply to power the system by the battery until the system automatically shuts down.
4. The powering time of the battery indicates the battery performance.

If the powering time of the battery is much shorter than that specified, you may replace the battery or contact the service personnel.

**NOTE:** The usage life of the battery is 300 charge / discharge cycles. If the battery is improperly used, its life may be shortened.

### 4.5.3 Battery Disposal

You need to dispose of the battery when it damages or severely degraded.

**NOTE:** Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

### 4.5.4 Recycling Battery

When the battery no longer holds a charge, it should be replaced. The batteries are recyclable. Remove the old battery from the system and follow your local recycling guidelines.

## 4.6 Connecting /Disconnecting a Probe

### 4.6.1 Connecting a Probe

1. Place the probe's carrying case on a stable surface and open the case.
2. Carefully remove the probe and unwrap the probe cord.

**Note:**

**DO NOT allow the probe head to hang free. Impact to the probe head could result in irreparable damage.**

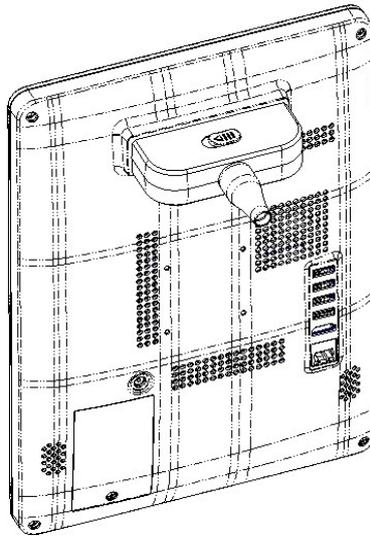
**Use the integrated cable management hook to wrap the cord.**

**Inspect the probe before and after each use for damage or degradation to the housing, strain relief, lens, seal and connector.**

**DO NOT use a transducer which appears damaged until functional and safe performance is verified.**

**Inspection should be conducted during the cleaning process.**

3. Align the connector with the probe port and carefully push into place with the cable facing downward of the system.
4. Carefully position the probe cord so it is free to move and is not resting on the floor.
5. When the probe is connected, it is automatically be known by the system.



**⚠WARNING:**

The probes, cables and connectors are in proper operating order and free from surface defects, cracks and peeling. Using a defective probe may cause electric shock.

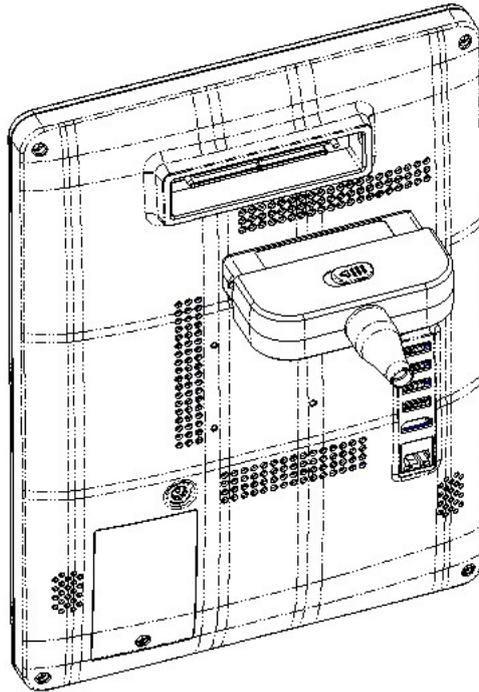
**⚠CAUTION:**

Fault conditions can result in electric shock hazard. Do not touch the surface of probe connectors which are exposed when the probe is removed. Do not touch the patient when connecting or disconnecting a probe.

## 4.6.2 Disconnecting a Probe

Probes can be disconnected at any time. However, make sure image is frozen when disconnecting the probe.

1. Slide the connector button.
2. Pull the probe and connector straight out of the probe port.
3. Carefully slide the probe and connector away from the probe port.
4. Ensure the cable is free.
5. Be sure that the probe head is clean before placing the probe in its storage box or a wall hanging unit.

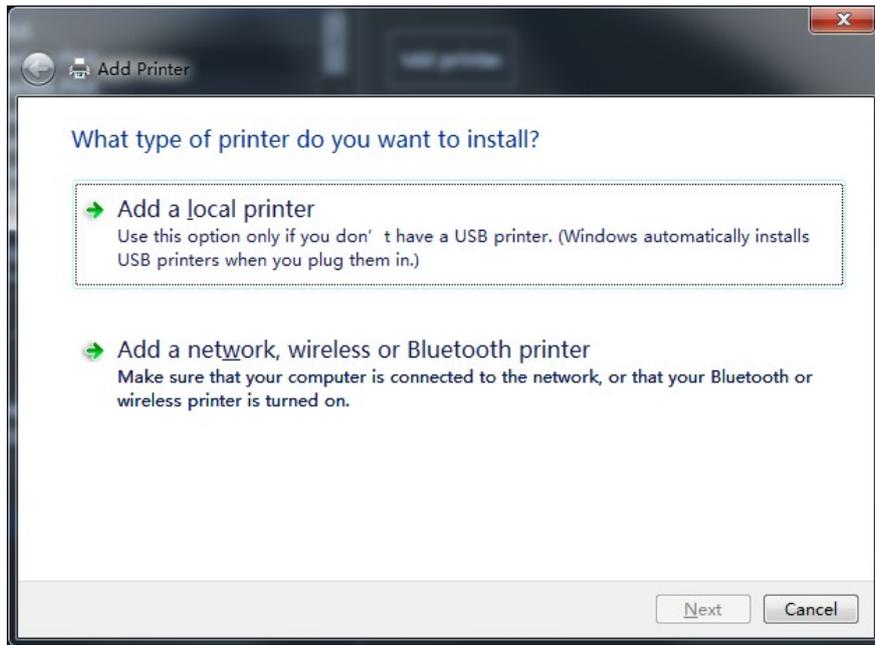


## 4.7 Graph /Text printer

### Connecting a local printer

As shown in the figure below, a graph /text printer has a power cord and data cable. The power cord shall be directly connected to a protective grounding wall receptacle as required.

1. Connect the two USB ports of the printer and the system with the USB cable of the printer.
2. Power on the system and the printer.
3. Install the printer driver: "Setup→ Peripheral" and touch "Add Printer", as shown in the figure:



1. Select "Add Local Printer" and touch "Next" to enter the screen of browsing driver; select the desired driver and touch "OK" to install the driver.

- Printers listed have drivers installed already.
- Touch "Property" to see the printer attribute.

2. Touch "OK" to finish the installation.

#### ■ Add Network Printer

After the system is connected into a LAN, enter the "Setup" → "Peripheral" screen.

1. Touch [Add Printer] and select the types of adding network printer

- Search Network Printer

Select "Search Network Printer" and touch "Next" to search for the printer; select the domain and server in the screen to find the printer.

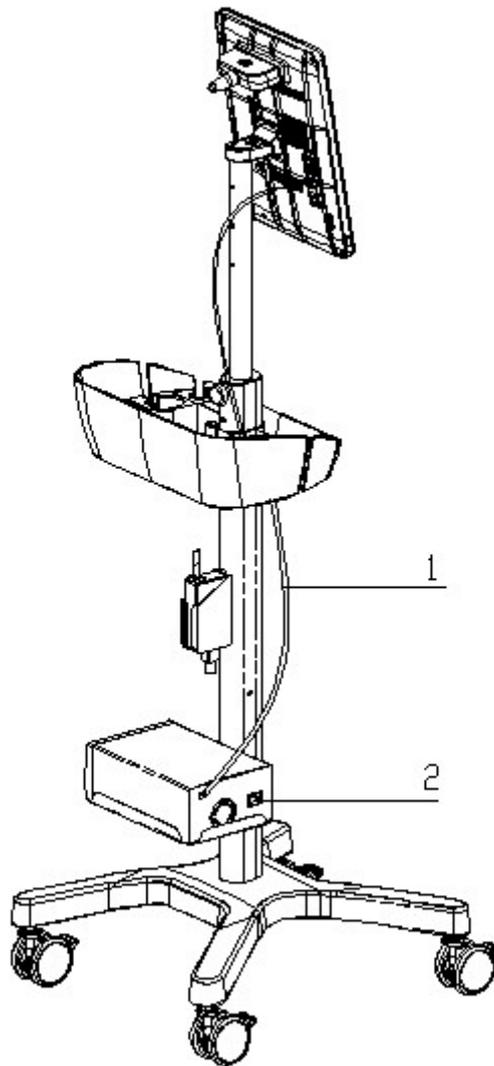
2. When the network printer is successfully connected, you can see the printer in the list.

Tips: the network printer functions depending on the configured network environment in the hospital, please consult the network configuration manager in case of failure.

**NOTE:** When you install the printer's driver, you must specify the specific path for installation; otherwise, vague path may result in longer time for searching.

## 4.8 Video Printer

The system support digital video printers, including B/W printers and color printers.



1. USB Cable

2. Power cable

■ Connecting a local printer (Sony UP-D897 as an example)

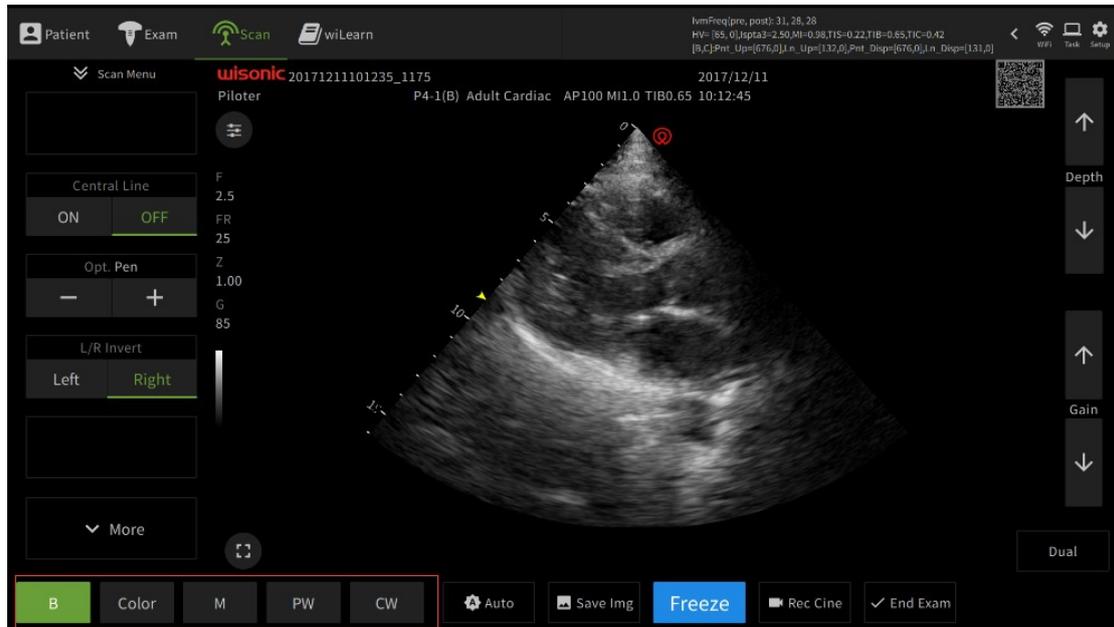
1. Place the printer in the proper position.
2. Connect the power cord of the printer to a receptacle. Use a USB cable to connect the USB port of the system with the USB port of the printer.
3. Load a paper roll, and turn on the system and printer.
4. Install the printer driver (steps are the same as of graph/text printers; please refer to relevant chapters for details).

Please refer to the accompanying manuals of the printers for more details.

## 4.9 Monitor Display

### 4.9.1 Basic Screen

The following diagram maps out the different areas in the screen:



#### Information Area

The information area displays manufacturer logo, hospital name, exam date & time, acoustic power & MI/TI, patient information, probe, current exam mode, and Operator, etc.

To preset whether gender, age or operator is displayed: Enter "Setup→System→General" and check "Name", "Patient ID" or "Operator" in the "Patient Info" box in the upper left corner of the screen.

- Logo  
Manufacture logo, displayed in the upper left of the screen.
- Hospital name  
Display the hospital name. Hospital name can be set via "Setup→System→Hospital name".
- Exam time  
Displays the exam time, including date and time.
- Acoustic power & MI/TI

Display the acoustic power, including the acoustic power, MI (Mechanical Index) and TI (Thermal Index).

- Patient Information

Displays patient name, ID, etc. Enter the patient information through the "Patient Info" screen.

- Probe

Display the currently-used probe model, or the default model.

- Exam Mode

Displays the currently used exam type, e.g. Abdomen, is displayed.

- Operator

Displays the operator's name on the screen. This information is entered through the "Patient Info" screen.

### Imaging Area

The image area displays the ultrasound images, probe mark (or activating window mark), time line (in M or PW mode), coordinate axis (including depth, time, velocity/frequency), focal position (located at depth axis in the form of ) , besides, the annotation, body mark, measurement calipers, color bar/grayscale bar are also displayed here.

### Workflow and Imaging Menu Area

- Workflow

Includes Patient, Exam, Scan, Review.

To active a specific workflow point, you need only to touch the icon of desired function.

- Patient

Where you either input the basic patient information, or record detailed info via extend the dialog with touch of "Advanced". After confirmation of patient, system directly go to the menu of "Scan".

- Exam

Where you select which probe to perform, and then choose a specific exam according to your requirement.

- Scan

At unfrozen mode, "Scan" shows the imaging parameter menu for user to adjust. At frozen mode, "Scan" goes to menu of post application such as "Measure", "Comment", "Bodymark".

- Review

Where you review the history of patient who was examined or under scanning.  
And you can also backup or export patient images.

# 5 Preparing for an Exam

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## 5.1 Begin an Exam

Begin an exam by entering new patient information.

The operator should enter as much information as possible, such as:

1. Patient ID
2. Patient name
3. Exam category
4. Exam Information

The patient's name and ID number is retained with each patient's image and transferred with each image during archiving or hard copy printing.

### CAUTION:

To avoid patient identification errors, always verify the identification with the patient. Make sure the correct patient identification appears on all screens and hard copy prints.

## 5.2 Begin a New Patient

Touch the **"Patient"** on screen.

New Patient should be selected at the beginning of each new patient exam.

End Exam should be used at the end of each exam.

Touch **"End Exam"**, system automatically stores all patient data, annotations, measurements, calculations and worksheets of the last exam.

Create a patient

- After enter the patient id and other information, touch **"Confirm"** on the **"Patient"** screen to create a new patient.

Quickly create a patient

- Directly touch **"AUTO"** on the **"Patient"** screen, you can quickly generate a new patient data.

### 5.2.1 New Patient information

- Touch on each patient information fields will pop up soft keyboard, you can enter information or select options at this time; After enter the patient information, close the soft keyboard to finish the input; For the drop-down list, select on options.

## Detailed information is described as follows:

### 1. General information

- Patient ID

Once you Input the ID and confirm it, you are only permitted to change it within 24 hours. There are 2 ways to generate the patient ID.

- Temporary ID

Touch **"AUTO"** on the **"Patient Info"** screen, will jump to **"Scan"** interface. Then, the patient ID can't be edited

- Enter the ID

If you don't apply auto ID, you need to enter an ID. If you touch OK to confirm patient ID, it could not be edit again

#### **Attention:**

If an ID that is already existed in the system is entered, the system prompts **"Patient exists. Are you sure to load?"** you can import the data.

- Name

Input the patient name directly through the pop-up keyboard. Characters of A to Z and 0 to 9 and "." are available "\", "^", "=" and "," are not permitted.

- Gender

Select Male or Female

- DOB (Date of birth):

Not allow to input the birth date of a patient manually. Touch **"DOB"** to select the birthday of patient. You can select the desired year, month and day, then touch **"OK"** to finish it. The default date is today.

- Age:

- Auto generated age: once the DOB is done, the system can display an auto-generated age in the field box, the unit can be **"Years"**, or **"Days"**. If the age is less than one year, the system will automatically show the age in days.
- Also, you can manually input the age.

#### **Attention**

When you manually input the age, it won't convert to DOB. DOB is still empty at this time.

- MRN

Submitted to the insurance with a social security number. The combination of Numbers and letters, or pure Numbers.

- Object:

You can manually input the Object.

- Operator

People who is responsible for images acquisition and scanning. "\", "^", "=", and ", "are not allowed.

- Study description:

Allow users to input check explanation and annotation manually.

## 2. Application Type

- Application type

You can select among 10 types: ABD (Abdomen), OB (Obstetrics), GYN (Gynecology), CARD (Cardiac), VAS (Vascular), URO (Urology), SMP (Small Part), and PED (Pediatrics), ICU, NERVE.

Select the type tab to input the exam-specific information.

- Exam specified information:

Application Type	Contents	Meaning/Purpose
ABD (Abdomen)	Height	Unit can be modified in < preset >- < measurement tools > "unit && formula", choose metric or inch;
	Weight	Unit can be modified in < preset >- < measurement tools > "unit && formula", choose metric or inch;
	BSA (body surface area)	After the height and weight are inputted, the system will automatically calculate the BSA based on the formula which is set via " <b>Setup</b> → <b>Meas tools</b> ".
OB (Obstetric)	Origin	<p>LMP (last menstrual period), IVF (in vitro fertilization), BBT (basic body temperature), DOC (Date of Conception), EDD (estimated delivery date), the system can automatically calculate GA and EDD (estimated delivery date); or, calculates GA and LMP according to the EDD and entered date.</p> <ul style="list-style-type: none"> <li>● LMP: After you enter LMP, the system will calculate and display GA and EDD.</li> <li>● IVF: After you enter IVF, the system will calculate GA and EDD.</li> <li>● BBT: input BBT, the system will calculate the GA and EDD.</li> <li>● DOC: input DOC, the system will calculate the GA and EDD.</li> <li>● EDD: input EDD, the system will calculate the GA and EDD.</li> </ul>
	Gravida	Num of pregnancy.
	Ectopic	Num of abnormal pregnancy. e.g. extra uterine pregnancy
	Gestations	Number of embryos (1, 2, 3; 1 is default)
	Para	Num of delivery
	Aborta	Num of abortion
	LMP	Last menstrual period

Application Type	Contents	Meaning/Purpose
(Gynecology)	Gravida	Num of pregnancy.
	Para	Num of delivery
	Ectopic	Num of abnormal pregnancy. e.g. extra uterine pregnancy
	Aborta	Num of abortion
Cardiology	Height	Unit can be modified in < preset >- < measurement tools > "unit && formula", choose metric or inch;
	Weight	Unit can be modified in < preset >- < measurement tools > "unit && formula", choose metric or inch;
	BSA (body surface area)	After the height and weight are inputted, the system will automatically calculate the BSA based on the formula which is set via " <b>Setup</b> → <b>System Preset</b> → <b>General</b> ".
	BP	Blood pressure.
	HR	Heart rate
	RAP	Right Atrium Pressure
VAS (Vascular)	BP(L)	Input left arm blood pressure.
	BP(R)	Input right arm blood pressure.
URO (Urology)	Serum PSA	/
	PPSA coefficient	/
SMP (Small Parts)	None	/
PED (Pediatrics)	None	/
ICU	Same as cardiology	/
Nerve	None	/

### 3. Operating Information

- Accession #: exam number used in DICOM. It should be entered within 16 letters or characters; "\" is not permitted.
- Perf. Physician: people who is responsible for the exam. "\", "^", "=", "and", "," are not allowed.
- Ref. Physician: the people who requires the ultrasound exam. "\", "^", "=", "and", "," are not allowed.
- Comment: exam-specific explanation or remarks.

### 5-4 Preparing for an Exam

#### 4. Functional key

- **“Confirm /Update”**: touch **“Confirm”** to save the patient data entered and jump to **“Scan”**. **“Confirm”** change to **“Update”**, when users return to the patient dialog to edit the information. Touch **“Update”** to save the modified patient data, it will not jump to **“Scan”** at this time.
- **“New Patient”**: touch to clear the current patient information in the patient information screen in order to input information of a new patient.
- **“Auto” ID**: according current status, when there is no patient on board, the button can be use, if not, it would not be in use .Touch this button to automatically create a new patient and jump to **“Scan”**.
- **Clear All**: touch this button will remove all patient information except ID.
- **Worklist**: After touching **“Worklist”**, **“Worklist”** change to **“Patient”**. Patient information change into the Worklist list, you can input some patients information to search the patient on the server.

## 5.2.2 Retrieve Patient information

The patient data can be obtained in Review from the system SSD or USB memory device.

### 1. Directly browse

Touch **“Review”** to enter the Review interface, you can browse directly for patient information and movie.

### 2. Set the searching condition

- Directly input key word to search exam you want.
- Touch **“Clear”**, the system will clear the information you entered, and all the recorded patient information of the system will be listed out.

### 3. Select the desired patient information from the list.

- **New Exam**: click to enter **“Patient”** screen, meanwhile, the corresponding patient information is also imported to the new exam. After you edit the patient information in the Patient Info screen, select **OK** to start a new exam.
- **Patient Info**: click to enter **“Patient Info”** screen, browse the information of patient.
- **Pause Exam**: click to stop the activated exam.
- **Continue Exam**: click to continue an unfinished exam that is carried out within 24 hours.
- **Activate Exam**: click to continue an exam that is finished within 24 hours.
- **Modify**: click to enter **“Patient Info”** screen and continue an exam within 24 hours.
- **QR Code**: click to show the QR code of patient.

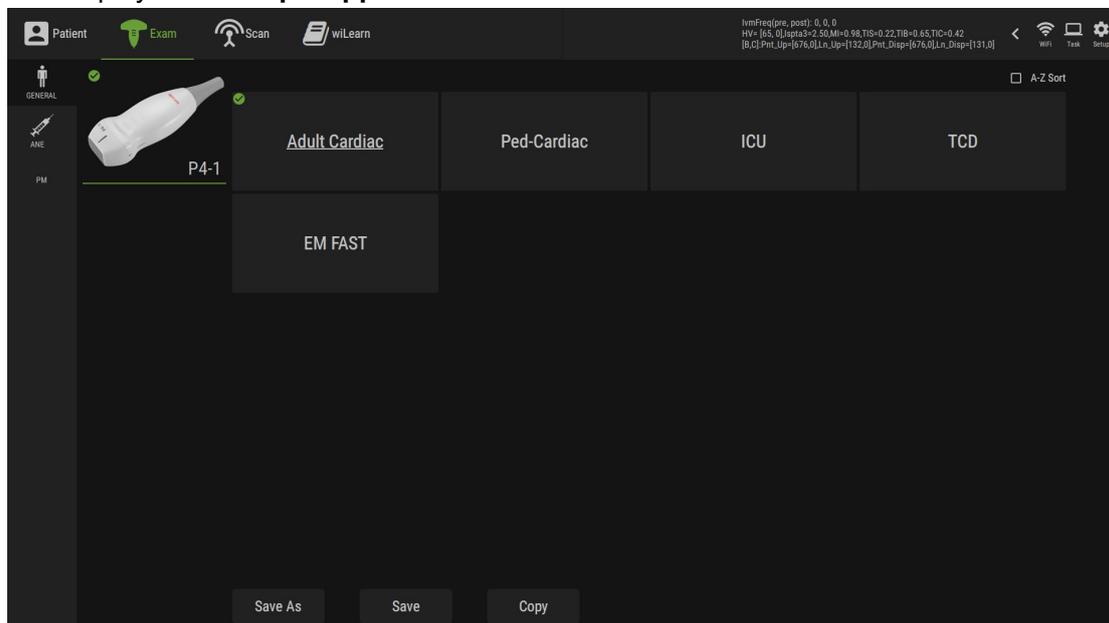
## 5.3 Select an Exam and Probe

### ⚠CAUTION:

If the exam mode is changed during a measurement, all measurement calipers on the image will be cleared. The data of general measurements will be lost, but the data of application measurements will be stored in the reports.

### 5.3.1 Selecting an Exam

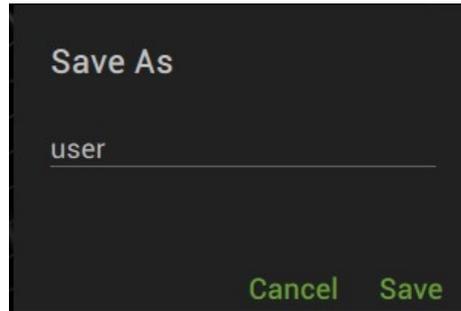
1. Press the “**Exam**” icon.
2. The exam category preset that best describes the desired exam to be performed is chosen after the exam category is selected. The factory default preset selections are displayed in **Setup->Application** Screen.



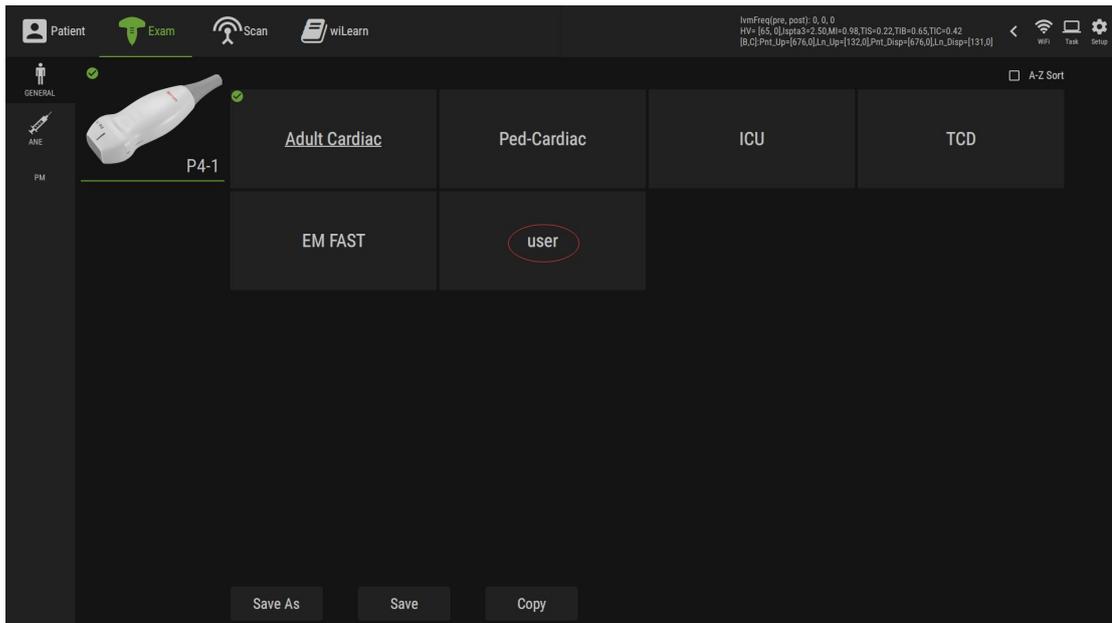
### 5.3.2 User-Defined Exam

To set up User-Defined Application Presets,

1. Touch the “**Exam**” key. The Probe screen appears.
2. Click “**Save as**” button. A pop-up menu appears:

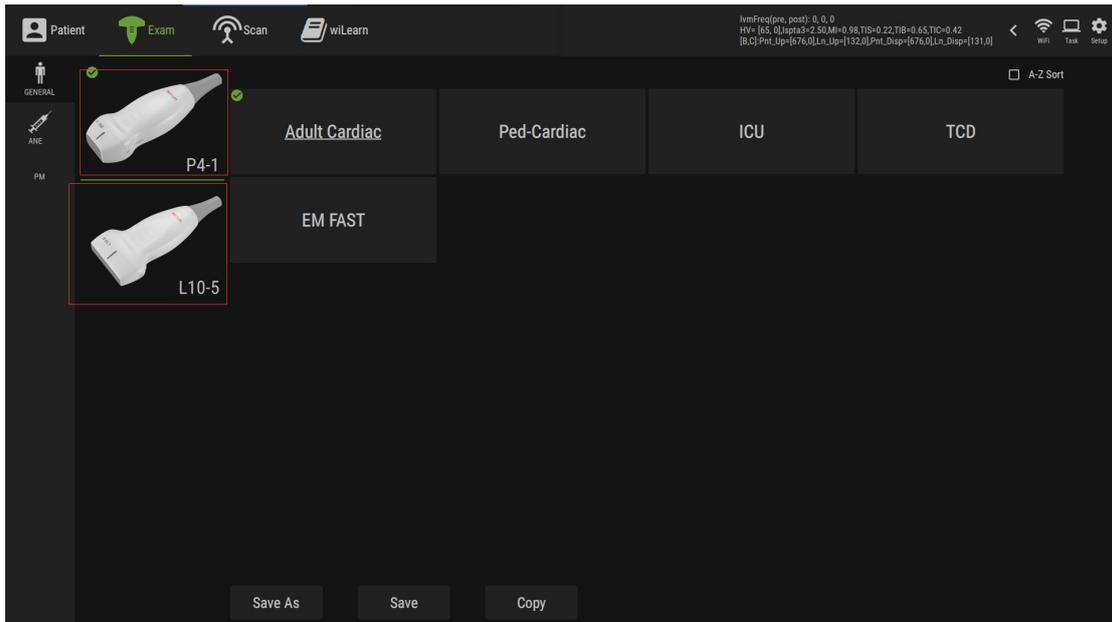


3. Type the name of the new application. The new application now appears on the probe preset screen.



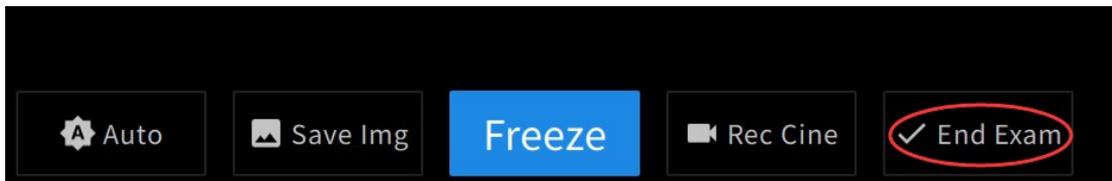
### 5.3.3 Selecting a Probe

1. Touch the "Exam" key.
2. Select a probe from images listed.



### 5.3.4 Ending a Patient Exam

When you have completed the study, touch “**End Exam**” key, the system automatically archives the information, clears all patient data and jump to “**Patient**” interface.



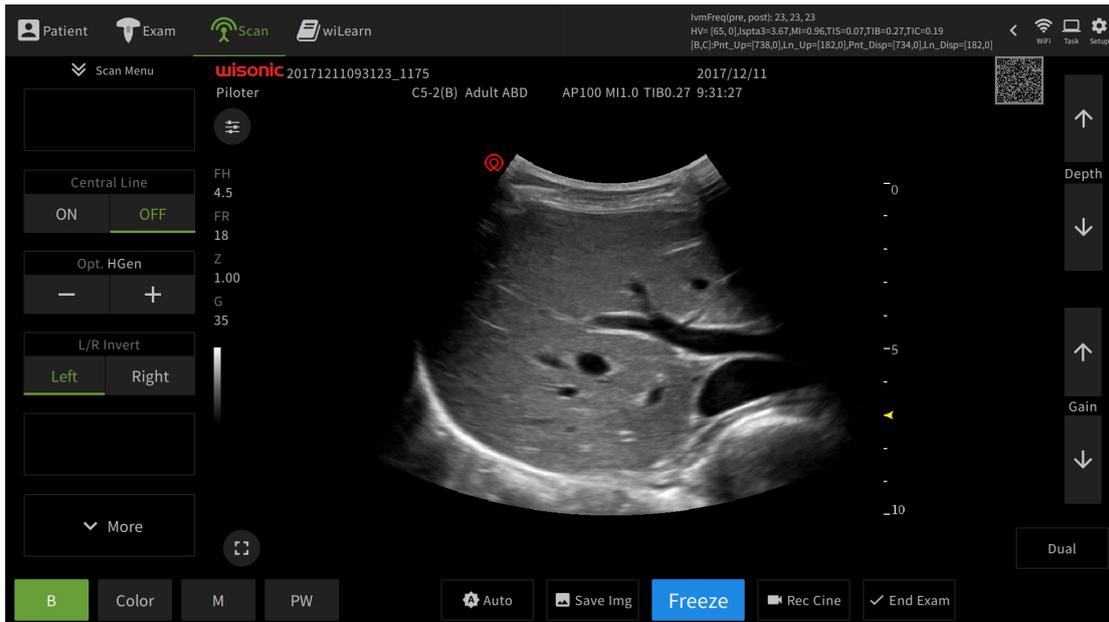
# 6 Optimizing Image

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- ⚠ WARNING:**
1. Images are displayed on system only for reference. Wisonic is not responsible for the diagnostic results. Who performs the exam, is responsible for the diagnostic results.
  2. In Dual-B imaging mode, the measurement results of the merged image may be inaccurate. Therefore, the results are provided for reference only, not for confirming a diagnosis.

## 6.1 Imaging Modes Controls

Key	Description
B Button	B Mode key: press to enter B Mode.
M Button	M Mode key: press to enter M Mode.
PW Button	PW Mode key: press to enter PW Mode.
CW Button	CW Mode key: press to enter CW Mode.
COLOR Button	Color Mode key: press to enter Color Mode.
Update Button	Press to change the currently active window.



## 6.2 Image Adjustment

Before optimizing the image by adjusting image parameters, adjust the brightness and contrast of the monitor to the best.

Intension	Action
To modify the brightness	<ul style="list-style-type: none"> <li>Adjust gain</li> <li>Adjust TGC</li> <li>Adjust AP (do try to adjust gain first before increasing the acoustic power)</li> </ul>
To modify gray scale image effect	<ul style="list-style-type: none"> <li>Adjust DR</li> <li>Adjust Gray Map</li> <li>Adjust Persistence</li> <li>Adjust SSI</li> </ul>

Intension	Action
To increase frame rate of gray scale imaging	Decrease depth Decrease the Focus Num in B mode Decrease the FOV in B mode Decrease Line Density
To increase frame rate of color imaging	Decrease ROI in Color/Power mode Decrease Line Density
To modify flow images effect (Resolution and sensitivity)	Adjust Opt Adjust Scale Adjust Sensitivity Adjust Line Density Adjust Smooth

## 6.3 Optimizing B Mode Image

B-Mode is intended to provide two-dimensional images and measurement capabilities concerning the anatomical structure of soft tissue.

### 6.3.1 Typical B Mode Exam Protocol

A typical examination using B-Mode might proceed

1. Record exam-related patient information. Verify system setup (probes and presets).
2. Position the patient and the console for optimum operator and patient comfort. Perform the scan.
3. Complete the study by collecting all the data.

## 6.3.2 B Mode Parameters

- In B Mode scanning, the image parameter area in the upper left corner of the screen will display the real-time parameter values as follows:



Display	FH 10	40mm	FR 25	Z1.00
Parameter	Frequency	Depth	Frame Rate	Zoom Rate

- Parameters that can be adjusted to optimize the B Mode image are indicated in the following.

Adjustment	Items
Adjust on the main Screen	Gain, Depth, TGC, Focus Positon, Auto
Menu	wiNeedle, Needle E. Dual, SCI , ExFOV ,Mid Line, Focus Number, Opt, Dynamic Range, SSI , Chroma, Gray Map, LGC, L/R Invert, U/D Invert, Line Density, Persistence, AP, B Steer, Smooth, Thermal Idx, FOV

## 6.3.3 Controls

### Gain

**Description** B-Mode Gain increases or decreases the amount of echo information displayed in an image. It may have the effect of brightening or darkening the image if sufficient echo information is generated.

**Adjusting** Slide the slider below the image, Sliding to the right to increase the gain, and sliding to the right to decrease.

The adjusting range is 0-100.

**Benefits** Gain allows you to balance echo contrast so that cystic structures appear echo-free and reflecting tissue fills in.

## Depth

<b>Description</b>	Depth controls the distance over which the B-Mode images anatomy. To visualize deeper structures, increase the depth. If there is a large part of the display which is unused at the bottom, decrease the depth.
<b>Adjusting</b>	To change depth, use your finger click button on the right of image screen, touch up one to decrease the depth; touch down one to increase the depth.  The adjustable depth values vary depending upon the probe types.
<b>Benefits</b>	Depth adjusts your field of view. It increases your field of view to look at larger or deeper structures; it decreases your field of view to look at structures near the skin line.
<b>Impacts</b>	Depth increase will cause a decrease in the frame rate.

## TGC

<b>Description</b>	TGC amplifies returning signals to correct for the attenuation caused by tissues at increasing depths. TGC slide pots are spaced proportionately to the depth. The area each pot amplifies varies as well. A TGC curve may appear on the display, matching the controls that you have set (except during zoom).
<b>Adjusting</b>	To increase the gain compensation at an area of interest, slide the TGC slider to the right.  To decrease the gain compensation at an area of interest, slide the TGC slider to the left.  About 2s after the adjustment is finished, the TGC curve disappears.
<b>Benefits</b>	TGC balances the image so that the density of echoes is the same throughout the image

## Opt. (Frequency)

<b>Description</b>	Frequency mode lets you downshift to the probe's next lower frequency or shift up to a higher frequency.
<b>Adjusting</b>	You can select a harmonic frequency or a B mode frequency.  Adjust the frequency value through the “ <b>Opt</b> ” item in the Menu, “THI” indicates harmonic frequency.  Values of frequency vary depending upon the probe types.  Select the frequency according to the detection depth and current tissue characteristics.

**Benefits** This optimizes the probe's wide band imaging capabilities at multiple frequencies to image at greater depths.

### **Acoustic Power**

**Description** Refers to the power of ultrasonic wave transmitted by the probe, the real-time value of which is displayed in the patient header area in the upper of the screen.

**Adjusting** Adjust through the AP item in the Menu

The adjusting range is 10%-100% in increments of 3%.

**Benefits** Generally, increasing the acoustic power will increase the brightness and contrast of the image as well as the force of penetration.

**Impacts** You should perform exams according to actual situation and follow the ALARA Principle.

### **Focus**

**Description** Increases the number of focal zones or moves the focal zone(s) so that you can tighten up the beam for a specific area. A graphic caret corresponding to the focal zone position(s) appears on the right edge of the image.

**Adjusting** Adjust the focus number through the Focus Num in the Menu.

Adjust the focus position through the Focus Pos on The main Screen

Focal zones adjust automatically when you adjust the depth.

**Benefits** Focus optimizes the image by increasing the resolution for a specific area. Increasing the number of focal zones improves image quality.

**Impacts** Changing the focal number affects the frame rate. The greater number of focal zones, the slower the frame rate.

### **Imaging Display Adjustment**

**Description** More information can be obtained without moving the probe or changing the sampling position.

**FOV (Field of View)** You can widen or narrow the size of the sector angle to maximize the image's region of interest (ROI).

The system provides four levels of scan range: 50%, 70%, 90%, and 100%.

You can get a much larger field of view when selecting a larger FOV, but the frame rate will decrease.

**B Steer** You can slant the B-Mode linear image to the left or the right without moving the probe. This steering function only applies to linear probe

**ExFOV** On Linear and convex probes, ExFOV provides a larger field of view in the far field.

**Impacts** The FOV position is available only for the convex and phased probes.

The ExFOV function is available only for linear probes and convex.

### **Line Density**

**Description** Optimizes B-Mode frame rate or spatial resolution for the best possible image.

**Adjusting** Adjust through the Line Density item in the Menu.

There are three levels of line density available: L, M, H, UH.

**Benefits** The higher the line density, the higher the resolution, and the lower the frame rate.

### **Dynamic Range**

**Description** Dynamic Range controls how echo intensities are converted to shades of gray, thereby increasing the adjustable range of contrast.

**Adjusting** Adjust through the DR item in the Menu

The adjusting range is 30-180 dB in increments of 4 dB.

**Benefits** Dynamic Range is useful for optimizing tissue texture for different anatomy. Dynamic Range should be adjusted so that the highest amplitude edges appear as white while lowest levels (such as blood) are just visible

## SSI

**Description** SSI is an adaptive algorithm to reduce the unwanted effects of speckle (noise) in the ultrasound image. Image speckle usually appears as a grainy texture in otherwise uniform areas of tissue. Its appearance is related to image system characteristics, rather than tissue characteristics, so that changes in system settings, such as probe type, frequency, depth, and others, can change the appearance of the speckle. Too much speckle can impair image quality and make it difficult to see the desired detail in the image. Likewise, too much filtering of speckle can mask or obscure desired image detail. Extra care must be taken to select the optimal SSI level.

**Adjusting** Adjust through the SSI item in the Menu.

The system provides 5 levels of SSI effects adjustment, off represents no SSI is turned on, and the bigger the value the stronger the effect.

**Benefits** The bigger the value the more clearly the profile of the image.

## Persistence

**Description** Temporal filter that averages frames together, thereby using more pixels to make up one image. This has the effect of presenting a smoother, softer image.

**Adjusting** Adjust through the Persistence item in the Menu.

**Benefits** Smooths the image.

**Impacts** Persistence increase may lead to signal missing.

## Invert

**Description** This function provides a better observation for image display.

**Invert(U/D** To invert the image horizontally or vertically.

**Invert and L/R Invert)** Click L/R Invert or U/D Invert in the Menu to invert the image.

When you invert or rotate an image, the “” mark will change its position correspondingly on the screen; the M mark is located in the upper left corner of the imaging area by default.

**Impacts** The function is available in real-time imaging, freeze or cine review status.

## **SCI**

**Description** SCI is available on all linear and convex probes. Multiple focal zones are supported. Steering is optimized by probe. The displayed compound image depth is equal to the image depth of the non-steered frame.

**Adjusting** Adjust through the SCI item in the Menu

**Benefits** The combined single image has the benefits of reduced speckle (noise), reduced clutter and continuity of specular reflectors and borders. Therefore, this technique can improve contrast resolution with increased visualization of low contrast lesions, better detection of calcifications, biopsy needle visualization, and cystic boundary definition.

**Impacts** When linear probe is being used, SCI function is not available when ExFOV function is turned on or B steer is adopted.

## **Gray Map**

**Description** This function applies the gray correction to obtain the optimum images.

**Adjusting** Select among the maps through the Gray Map item in the Menu.

**Impacts** The function is available in real-time imaging, freeze or cine review status.

## **Chroma**

**Description** Chroma is the colorization of a conventional B-Mode image or Doppler Spectrum to enhance the user's ability to discern B, M, and Doppler Mode intensity valuations. Colorize is NOT a Doppler Mode.

**Adjusting** Turn on or off the function through the Chroma item in the Menu.

Select the Chroma through the Chroma item in the Menu.

The system provides 10 Chroma maps to be selected among.

**Impacts** The function is available in real-time imaging, freeze or cine review status.

## **Auto**

**Description** To optimize image parameters as per the current tissue characteristics for a better image effect.

**Adjusting** Press “**Auto**” button below the main image screen to turn on the function, the symbol of which will be displayed in the image parameter area of the screen.

## 6.4 Optimizing M Mode Image

### 6.4.1 Typical M Mode Exam Protocol

A typical examination using M-Mode might proceed as follows:

1. Get a good B-Mode image. Survey the anatomy and place the area of interest near the center of the B-Mode image.
2. Press **M Button**.
3. Trackball to position the mode cursor over the area that you want to display in M-Mode.
4. Press **M Button**.
5. Adjust the Sweep Speed, TGC, Gain, Power Output, and Focus Position, as needed.
6. Press **Freeze** to stop the M trace.
7. Perform desired measurements.
8. Record the trace and calculations to hard disk and/or hard copy device.
9. Press Freeze to continue imaging.
10. To exit, press M Button.

### 6.4.2 M Mode Parameters

In M mode scanning, the image parameter area in the upper left corner of the screen displays the real-time parameter values as follows:

**40mm**

Display	40mm
Parameter	Depth

Parameters that can be adjusted to optimize the M mode image are indicated in the following.

Adjustment	Items
Adjust on the main Screen	Gain, TGC, Depth, Focus Position

Adjustment	Items
Menu	Time Mark, Speed, Chroma, Edge Enhance, Dynamic Range, Display Format ,Gray map,

During M mode imaging, B mode parameters can't be adjusted.

During M mode scanning, frequency and acoustic power of the probe are synchronous with that of B mode.

Adjustment of the depth, focus position or TGC to the B mode image will lead to corresponding changes in M mode image.

## 6.4.3 Controls

### Time Mark

**Description** To show the time mark in M mode image.

**Adjusting** Turn on or off the function through Time Mark item in the Menu.

**Benefits** When time mark is displayed on the M mode image, it's much easier to identify the cardiac cycles and detect more details.

**Impacts** The function is available in real-time imaging, freeze or cine review status.

### Display Format

**Description** To set the display format of M mode image with B mode image.

**Adjusting** Adjust through the Display Format item in the Menu.

There are 3 formats available for image display: L/R, V1:1, V1:2.

**Benefits** Adjust according to the actual situation and obtain a desired analysis through comparison.

**Impacts** The function is available in real-time imaging, freeze or cine review status.

### Speed

**Description** Changes the speed at which the timeline is swept.

**Adjusting** Change the speed through the Speed item in the Menu.

**Benefits** You can speed up or slow down the timeline to see more or fewer occurrences over time.

## Edge Enhance

**Description** This function is used to increase image profile, so as to distinguish the image boundary.

**Adjusting** Adjust through the Edge Enhance item in the Menu.

**Impacts** Larger edge enhance may lead to noise increasing.

## 6.5 Color Mode Image

Color Flow Mode is a Doppler Mode intended to add color-coded qualitative information concerning the relative velocity and direction of fluid motion within the B-Mode image.

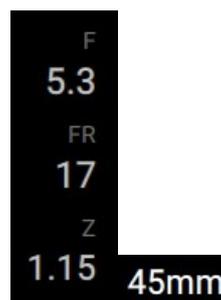
### 6.5.1 Typical Color Mode Exam Protocol

A typical examination using Color Flow Mode,

1. Follow the same procedure as described under B-Mode to locate the anatomical area of interest.
2. After optimizing the B-Mode image, add Color Flow.
3. Move the color flow area of interest as close to the center of the image as possible.
4. Optimize the color flow parameters so that a high frame rate can be achieved and appropriate flow velocities are visualized.
5. Touch "**Freeze**" to hold the image in memory.
6. Record color flow images as necessary.
7. If more definitive information is needed about flow, utilize the procedures described under Doppler Mode.

### 6.5.2 Color Mode Parameters

In Color mode scanning, the image parameter area in the upper left corner of the screen displays the real-time parameter values as follows:



Display	F 5.3	45mm	FR 17	Z1.15
Parameter	Frequency	Depth	Frame Rate	Zoom Rate

Parameters that can be adjusted to optimize the Color mode image are indicated in the following.

Adjustment	Items
Adjust on the main Screen	Gain, Depth, TGC, Auto
Menu	Opt. , Priority, Baseline, Sensitivity, Dual Live, Map, AP, Scale, WF, Invert, Line Density, Smooth, Persistence, Steer

In Color mode, acoustic power is synchronous with that of B mode. Adjustment of the depth or zoom to the B mode image will lead to corresponding changes in Color mode image.

## 6.5.3 Controls

### Color Gain

#### Description

Gain amplifies the overall strength of echoes processed in the Color Flow window or spectral Doppler timeline

#### Adjusting

Slide the slider below the image, Sliding to the right to increase the gain, and sliding to the left to decrease.

#### Benefits

Allows you to control the amount of color within a vessel

### ROI Adjustment

#### Description

To adjust the width and position of ROI in Color mode.

#### Adjusting

Put two finger on the ROI and zoom the ROI.

Put one finger on the ROI and move on the screen to change the position.

#### Impacts

The larger the ROI box, the lower the frame rate, and the lower the resolution and color sensitivity.

## **Opt. (Frequency)**

**Description** Frequency mode lets you downshift to the probe's next lower frequency or shift up to a higher frequency.

**Adjusting** Select the frequency value through the Opt item in the Menu.

Values of frequency vary by probes. Select the frequency value according to the need of the detection depth and the current tissue characteristics.

**Benefits** The Lower the frequency, the worse the axial resolution, and the better the force of penetration.

## **Dual Live**

**Description** This function is used to display B image and Color image simultaneously at dual images.

**Adjusting** Click Dual Live in the Menu to turn on or off the function. When the function is turned on, the window will be automatically switched to the dual windows (one for B image, and the other for Color image).

**Impacts** The function is available in real-time imaging, freeze or cine review status.

## **Steer**

**Description** You can slant the ROI of the Color Flow linear image left or right to get more information without moving the probe. The Angle Steer function only applies to linear probes.

**Adjusting** Adjust through the Steer item in the Menu, rotate to get 1° per increment

**Benefits** Provide a Color Doppler angle suitable for linear probe orientation. Beneficial in Peripheral Vascular to image carotid arteries and the arteries and veins of extremities.

**Impacts** Steer is available only for linear probes.

## **Line Density**

**Description** Optimizes the Color Flow frame rate or spatial resolution for the best possible color image

**Adjusting** Adjust through the Line Density item in the Menu.

**Benefits** The higher the line density, the higher the resolution.

**Impacts** Line density changes the vector density and frame rate

### **Sensitivity**

**Description** This function is an indication of the ability to detect flow, which is used to adjust the accuracy of color flow.

**Adjusting** Adjust through the Sensitivity item in the Menu.

**Benefits** The higher the packet size, the more sensitive indication for low-velocity flow.

**Impacts** Increasing the packet size will lead to frame rate decrease.

### **Persistence**

**Description** Averages color frames.

**Adjusting** Adjust through the Persistence item in the menu or the Menu.

### **Smooth**

**Description** This feature is used to reject noise and smooth the image.

**Adjusting** Adjust through the Smooth item in the Menu.

The system provides 4 levels of smooth function, the bigger the value the higher the smooth.

### **Scale**

**Description** Increases/decreases the PRF on the color bar.

**Adjusting** To raise/lower the velocity scale, press PRF/Wall Filter until you reach PRF, then adjust PRF up/down.

**Benefits** Aligns the velocity scale to different blood flow velocities. Imaging of higher velocity flow requires increased scale values to avoid aliasing. Imaging of lower velocity flow requires decreased PRF.

**Impacts** Low velocities may not be identified when a high velocity scale is used.

## **Baseline**

**Description** Changes the Color Flow or Doppler spectrum baseline to accommodate higher velocity blood flow. Minimizes aliasing by displaying a greater range of forward flow with respect to reverse flow, or vice versa.

**Adjusting** To adjust the baseline, adjust **Baseline** up/down, as necessary.

**Impacts** The function is available in real-time imaging, freeze or cine review status.

## **Invert**

**Description** Let's you view blood flow from a different perspective, e.g., red away (negative velocities) and blue toward (positive velocities). You can invert a real-time or frozen image.

**Adjusting** Turn on or off the function through the Invert item in the Menu.

**Impacts** The function is available in real-time imaging, freeze or cine review status.

## **Map**

**Description** Allows you to select a specific color map. After you have made your selection, the color bar displays the resultant map.

**Adjusting** Select among the maps through the Map item in the Menu.

**Benefits** Shows the direction of the flow and highlights the higher velocity flows.

## **WF (Wall Filter)**

**Description** Filters out low flow velocity signals. It helps get rid of motion artifacts caused from breathing and other patient motion.

**Adjusting** Select through the WF item in the Menu.

**Benefits** Gets rid of excess, unnecessary low frequency signals caused by motion.

## **Priority**

**Description** This function is used to set levels of the flow display, to display the grayscale signal or color signal.

**Adjusting** Select the value through the Priority item in the Menu.

**Effects**      The higher the value, color signals are prior to be displayed; while the lower the value, grayscale signals are prior to be displayed.

## 6.6 Optimizing Power Mode Image

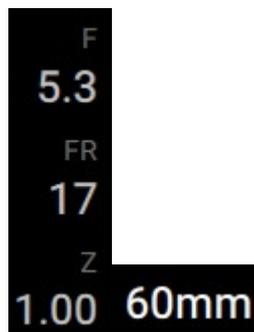
Power Doppler Imaging (PDI) is a color flow mapping technique used to map the strength of the Doppler signal coming from the flow rather than the frequency shift of the signal. Using this technique, the ultrasound system plots color flow based on the number of reflectors that are moving, regardless of their velocity. PDI does not map velocity, therefore it is not subject to aliasing.

### 6.6.1 Typical Power Mode Exam Protocol

1. Select a high-quality image during B mode or B+ Color scanning, and adjust to place the area of interest in the center of the image.
2. In Color Menu, click the Power button to enter B+Power mode. Use the finger to change position and size of the Region of Interest (ROI).
3. Adjust the image parameters to obtain optimized images.
4. Perform other operations (e.g. measurement and calculation) if necessary.

### 6.6.2 Power Mode Parameters

- In Power mode scanning, the image parameter area in the upper left corner of the screen displays the real-time parameter values as follows:



Display	F 5.3	60mm	FR 17	Z1.00
Parameter	Frequency	Depth	Frame Rate	Zoom Rate

Parameters that can be adjusted to optimize the Power mode image are indicated in the following.

Type	Parameter
Adjust on the main Screen	Gain, TGC, Depth, Auto
Menu	Opt. , Priority, Dual Live, Map, Acoustic Power, Scale, Wall Filter, Invert, Line Density, Smooth, Persistence, Steer

In Power mode, acoustic power is synchronous with that of B mode. Adjustment of the depth or zoom to the B mode image will lead to corresponding changes in Power mode image.

Parameters consistent with those in Color mode and B mode are not to be introduced, please refer to relevant section of the Color mode and B mode, while special items of the Power mode are introduced in the following.

### 6.6.3 Power Mode Image Optimization

#### Map

**Description** This feature indicates the display effect of power image. The maps in Power mode image are grouped into two categories: Power maps and Directional Power maps.

**Adjusting** Select the map through the Map item in the Menu.

The Directional Power maps provide information of flow direction.

**Impacts** The function is available in real-time imaging, freeze or cine review status.

## 6.7 Optimizing PW/CW Doppler Mode

Doppler is intended to provide measurement data concerning the velocity of moving tissues and fluids. PW Doppler lets you examine blood flow data selectively from a small region called the sample volume.

## 6.7.1 Typical PW / CW Mode Exam Protocol

1. Scan B and Color image first, then adjust to place the ROI in vessels interested.
2. Touch “PW”/ “CW” button to enter the sampling state,
  - The sampling parameters will be displayed in the image parameter area on the left part of the screen as follows:

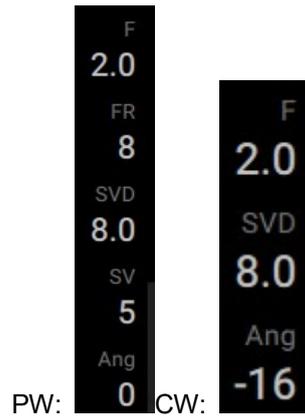
PW Sampling Line Adjustment 	Frequency (of B or COLOR)	FH10
	Frame Rate	FR25
	Angle	Correction Angle 0°
	SV Size	SV 1mm
	SVD	SVD 1.4 cm
CW Sampling Line Adjustment 	Frequency (of B or COLOR)	FH3.4
	Frame Rate	FR62
	Angle	Angle 0°
	CW Focus Depth	SVD 8.0 cm

3. Set the SVD in the middle of vessels cavity; adjust the angle and SV size according to the actual situation.
4. Touch “PW”/ “CW” button again or “Update” button to enter PW/CW Mode and perform the examination. You can also adjust the SV size, angle and depth in the real-time scanning.

5. Adjust the image parameters during PW/CW mode scanning to obtain optimized images.
6. Perform other operations (e.g. measurement and calculation) if necessary.

## 6.7.2 PW/CW Mode Parameters

In PW/ CW mode scanning, the image parameter area in the upper left corner of the screen displays the real-time parameter values as follows:



PW	Display	F 2.0	SV 5	SVD8.0cm	Angle 0	FR8
	Parameters	Frequency	SV size	SV Position	Angle 60°	Duplex or triplex Frame Rate
CW	Display	F 2.0		SVD 8.0cm	Angle -16°	
	Parameters	Frequency		SV Position	Angle -16°	

Parameters that can be adjusted to optimize the PW/ CW mode image are indicated in the following.

Adjustment		Items
Adjust on the main Screen		Gain, TGC, Depth, Focus Position, Auto
Menu	PW	Invert, SV, WF, Frequency, Duplex/Triplex, Trace Line, Volume, Chroma, Speed, Acoustic Power , T/F Res, Gray Map, Dynamic Range, Scale, Baseline, Quick Angle, Angle, Time Mark, PW Steer

Adjustment	Items
	WF, Invert, Chroma, Frequency, Speed, Dynamic Range, Audio, Trace Sensitivity, Gray Map, Scale, Baseline, Quick Angle, Angle, Acoustic Power, Time Mark, T/F Res,

### 6.7.3 Controls

#### Scale

**Description** Adjusts the velocity scale to accommodate faster/slower blood flow velocities. Higher PRF is generally used for higher velocity blood flow and lower PRF is generally used for lower velocity blood flow. Velocity scale determines pulse repetition frequency.

**Adjusting** To raise/lower, adjust the PRF on the Menu. The display updates velocity scale parameters after you adjust the velocity scale

**Benefits** Blood flow information is not cut off due to the effect of aliasing.

**Impacts** Velocity Scale values vary by probe and application. In Triplex, when you change the velocity scale in Color Flow, the Doppler Mode velocity scale is also updated if Triplex is on.

#### Auto Trace and Parameter

**Description** This function is used to trace the spectrum and calculate parameters of PW mode image, and the results of which are displayed in the result window.

**Adjusting** Click Auto Trace in the Menu, to turn on or off the function.

Select parameters in the dialogue box prompted by clicking Auto Trace Para.

In real-time scanning, the results displayed are derived from the calculation of latest cardiac cycle.

In the freezing and cine status, the results displayed are calculated from the current selected area.

**Impact** Note: heart rate value obtained by auto calculation may be of deviation, please adopt manual measurement to get the precise value.

## **Invert**

**Description** Used to set the display scale of spectrum.

**Adjusting** Turn on or off the function through the Invert item in the Menu.

**Impacts** Available in real-time imaging, freeze or cine review status.

## **T/F Res**

**Description** Adjusts image appearance so that if you select a lower setting, the image appears smoother; if you select a higher setting, the image appears sharper.

**Adjusting** Adjust through the T/F Res item in the Menu.

## **WF (Wall Filter)**

**Description** Insulates the Doppler signal from excessive noise caused from vessel movement.

**Adjusting** Select through the WF item in the Menu.

**Impacts** Wall filter may be changed by changes to the velocity scale.

## **Trace**

**VMax&VMean&Both** To display maximum speed or average speed, or both in the spectrum.

**Adjusting** Click V Max or V Mean in the Menu, to turn on or off the function.

In the spectrum map, maximum speed is displayed in blue curve, while the average speed is displayed in yellow curve.

**Benefits** The function is available in real-time imaging, freeze or cine review status.

## **Display Format**

**Description** Changes the horizontal/vertical layout between B-Mode and M-Mode, or timeline only.

**Operation** Adjust through the Display Format item in the Menu.

There are 3 formats to display the images: V1:1, L/R, V1:2.

**Benefits** The function is available in real-time imaging, freeze or cine review status.

### **Duplex/ Triplex**

**Description** Duplex allows two modes to be active at the same time; Triplex allows three modes to be active at the same time.

**Adjusting** Turn on or off the function through the Duplex/ Triplex in the Menu.

**Benefits** Allows the user to have multiple modes active at the same time.

### **Baseline**

**Description** Adjusts the baseline to accommodate faster or slower blood flows to eliminate aliasing.

**Adjusting** Adjust through the Baseline item in the Menu.

**Benefits** Adjust baseline according to the actual situation to change the range of flow velocity to optimize the image.

Positive value means to enhance the signals above the baseline, and negative value means to enhance the signals below the baseline.

**Impacts** The function is available in real-time imaging, freeze or cine review status.

### **Angle**

**Description** Estimates the direction and velocity of flow at an angle to the Doppler vector by computing the angle between the Doppler vector and the flow to be measured.

**Adjusting** Adjust through the Angle item in the Menu.

The adjustable angle range is -89~89° in increments of 1°.

**Impacts** The function is available in real-time imaging, freeze or cine review status.

### **Quick Angle**

**Description** To adjust the angle faster in increments of 60°, and the real-time value of which is displayed on the right part of the spectrum map.

**Adjusting** Adjust through the Quick Angle item in the Menu.

There are 3 angles for quickly adjustment:  $-60^\circ$ ,  $0^\circ$ , and  $60^\circ$ .

**Benefits** Optimizes the accuracy of the flow velocity. This is especially useful in vascular applications where you need to measure velocity

### **Dynamic Range**

**Description** Dynamic range controls how echo intensities are converted to shades of gray, thereby increasing the range of contrast you can adjust.

**Adjusting** Adjust through the DR item in the Menu.

**Benefits** The more the dynamic range, the more specific the information, and the lower the contrast with more noise.

**Impacts** Available in real-time imaging, freeze or cine review status.

### **Audio**

**Description** Adjust the output volume of the spectrum.

**Adjusting** Adjust through the Audio item in the Menu.

**Benefits** Audio helps to identify the feature and status of flow.

### **PW Steer**

**Description** Adjust the scan angle of PW waves on linear probes

**Adjusting** Adjust through the PW Steer item in the Menu.

**Benefits** This feature is used to steer the direction of the beam so as to change the angle between the beam and flow direction with immobility of the linear probe.

**Impacts** Available in real-time imaging, freeze or cine review status.

## SV

**Description** To adjust the SV position and size of sampling in PW mode, the real-time value of SV and SVD are displayed in the image parameter area in the upper left corner of the screen.

**Adjusting** Adjust the SV size through the SV item in the Menu.

**Benefits** The smaller the SV size, the more accurate the result; and more information can be obtained when selected large SV size.

## 6.8 wiNeedle

In the image without deflection situation, you can activate wiNeedle parameter in order to show needle tip and make needle-path clearer.

### Attention

- **This is optional function. Linear array probe support this function.**
- **Some parts are mistaken for needle-path, because the location of the muscle fascia parallel needle-path. Maybe it will make a pseudo image, too.**
- **If the angle of needle is vertical to transmitting ultrasound beam, the effect of wiNeedle is better.**

entry and exit:

You can Click the wiNeedle button which in B menu to enter or exit out of wiNeedle interface.



# 7 wiGuide

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wiGuide is the special feature for improving needle visualization and placement. It is an option and only be available in the L15-4NB probe. This function need software license authorized. wiGuide can provide needle detection and orientation information for in-plane and out-of-plane approaches.

## **⚠ Caution:**

- **Probe Condition-check the condition of the probes package on delivery. If it is damaged, the probe must not be used and repacked. Please contact your representative.**

## **⚠ Warnings:**

- **The Magnetiser generates a magnetic field that can affect the WiGuide probe calibration. The Magnetiser must remain at least 1m from a wiGuide probe at all times.**
- **The Magnetiser produces a weak magnetic field. It should be kept away from any device that is sensitive to magnetic fields, for example pacemakers.**

## 7.1 Calibration

Calibration is a simple process but it is extremely important to hold the probe in the air making sure it is far away from any metal or magnetic objects. If there are any objects then the calibration will be poor.

Calibration is required when the Signal Strength Indicator is not at the top of the green scale as shown in the picture below. Before calibrating the probe hold it still for a couple of seconds. If the problems persist proceed with the calibration.



Press the calibration button to start the calibration process. While holding the probe in air press the button and wait for a few seconds until the system indicates the process has completed.

After this has been done, while keeping the probe in the air, quickly check the Signal Strength Indicator. It should now be back at the top of the green scale.

## 7.2 Setting

The display setup allows the user to choose the features from the WiGuide that will be displayed on and beside the ultrasound image.

Pressing the display SETTINGS button opens a menu from which elements of the display can be turned on or off.

The following display settings can be changed separately for in-plane injections or out-of-plane injections:

1. Press the Trajectory toggle button to turn the trajectory display on or off in-plane and/or out of plane.
2. Press the Position toggle button to turn the Position display on or off in-plane and/or out of plane.
3. Press the Target toggle button to turn the target display on or off in-plane and/or out of plane.

NEEDLE INDICATORS		
	In plane	Out of plane
TargetBox	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Position	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Trajectory	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

The following display settings can be changed only for both in-plane injections and out-of-plane injections:

1. Press the Alignment Image toggle button to turn the indicator display on or off.
2. Press the Tip Sound toggle button to turn the prompt sound on or off.



## 7.3 How to use

The WiGuide detects the position and orientation of magnetized needles in the presence of the probe and displays this information relative to the ultrasound image. Spatial positioning of the needle, with respect to the ultrasound image, is then updated in real time.

This guides the operator to better visualize the needle in the ultrasound image during ultrasound guided needling procedures.

In this case the user should only use Needle Guidance following the recommended procedure:

1. Scan the patient as normal to find the correct anatomy for needle insertion.
2. Hold the probe steady at this position with minimum motion.
3. Introduce the needle to the desired anatomic target without significant motion of the probe;  
i.e moving +/-1cm in any direction is permissible.

### WARNINGS:

- **Ensure the magnetiser is at least 1m from the WiGuide probe at all times.**
- **Ensure there is sufficient lighting to identify the magnetiser needle entry port when magnetising a needle.**
- **Verify that Signal Strength Indicator is green or orange at his location.**
- **The Magnetiser should be handled and disposed of following your institution's procedures for infectious/bio-hazardous materials, including any local laws and regulations on its disposal.**
- **Follow the proper shelf life handling, with special attention to the expiration dates.**
- **Risk of needle damage: It is essential that the needle be introduced carefully into the magnetiser. Failure to do so may result in needle damage.**

### 7.3.1 Indicator

- Depth Indicator

Once the wiGuide is activated and a connection to the needle has been made, the Depth Indicator is displayed.



The Depth Indicator shows the maximal depth the selected needle can reach during a procedure. If that depth is outreached the Needle Guidance will temporarily not be able to display the location of the needle tip, as it has moved out of the ultrasound image. The needle tip will be shown again when the needles position is corrected by the user.

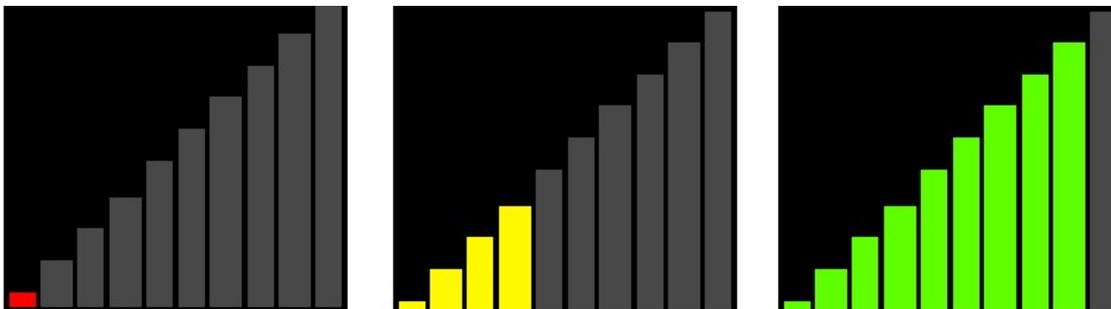
### **⚠ Warning:**

- **The number indicated by Depth indicator only shows the maximum depth for which needle guidance is supported. Please note that this number is NOT related to the needles length. The needle can be longer or shorter than the displayed mm.**

- Signal strength indicator

The Signal Strength Indicator estimates the level of stray fields in the environment of the probe. It is always present when WiGuide is activated.

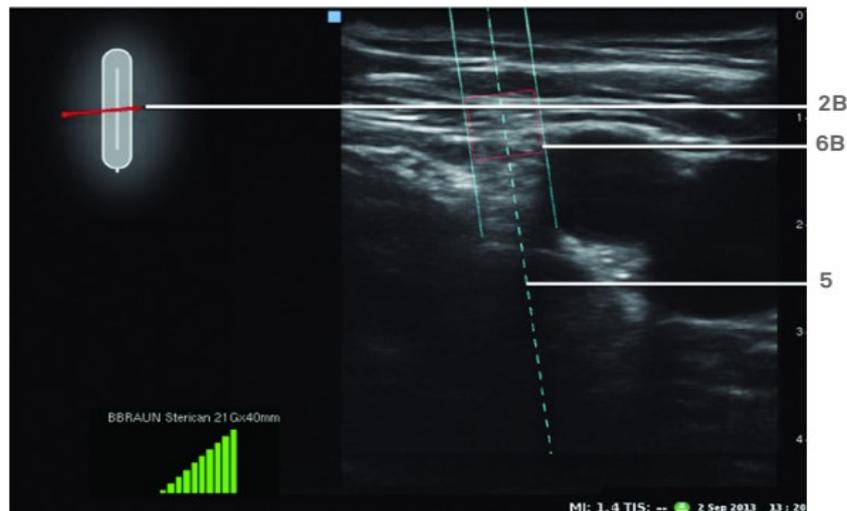
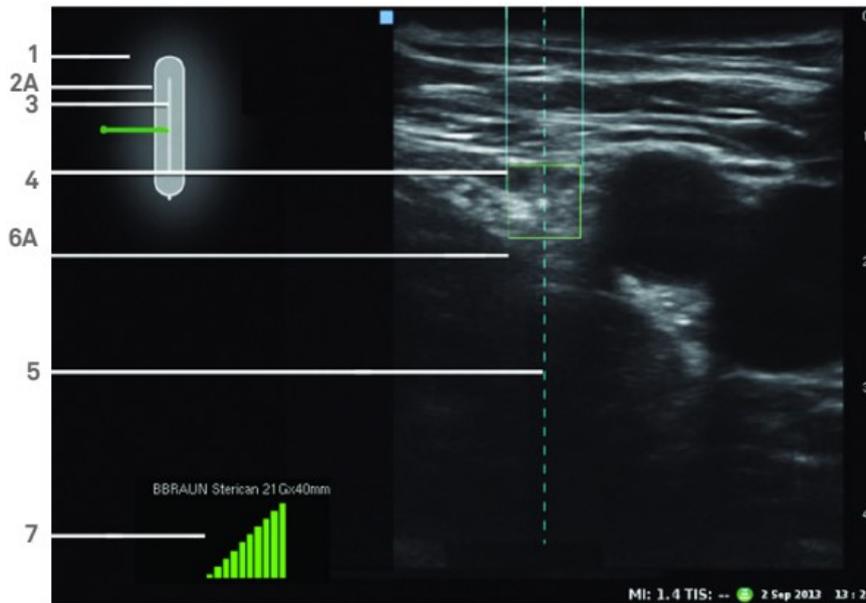
The bars indicate the level of stray fields on a color scale:



- 1) Green means low stray fields are present, and indicates optimal conditions for the WiGuide.
- 2) Orange means moderate stray fields, and indicates poor conditions for the WiGuide. When in this range extra care must be taken to hold the probe steady.
- 3) Red means strong stray fields are present which means unworkable conditions for the WiGuide. When the bar is in the range, the WiGuide will be automatically disabled. If this happens, move the needle away for a moment, waiting until the indicator changes to at least yellow, then try again, change location or environment or perform the procedure with normal ultrasound guided techniques.
- 4) Blinking: The Indicator blinks when the probe moves, and continues until the probe remains stable. If the blinking occurs while the indicator is between orange and green,

the connection to the needle is about to break. The probe must be held steady so the wiGuide can stabilize.

### 7.3.2 OUT-OF-PLANE Needle Guidance



Screen controls and display information related to OUT-OF-PLANE WiGuide.

NO.	NAME	FUNCTION/DESCRIPTION
1	Alignment image WiGuide display: active area	A plan view of the area surrounding the probe. In this area the system may be able to detect the presence of a needle.
2	Alignment image WiGuide display: needle	A plan view of the needle. Circle represents the hub end of the needle and

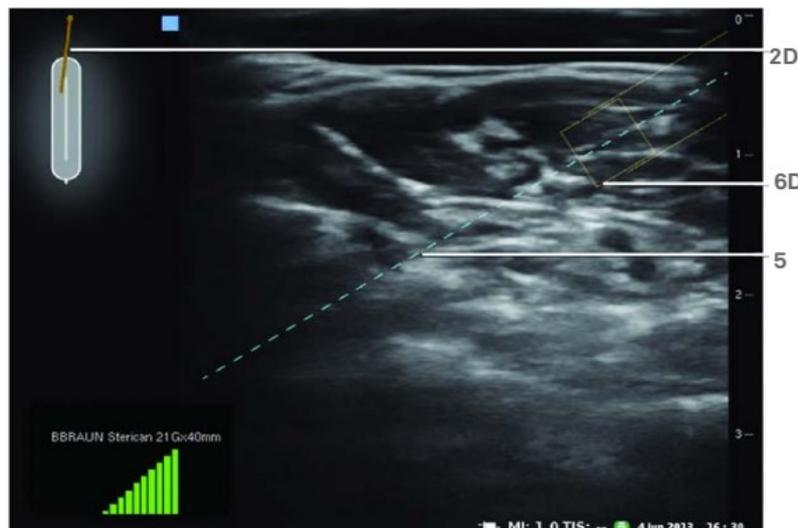
		<p>other end is needle tip.</p> <p>Out-of-plane injections 2A: When the tip of the needle is IN the ultrasound image plane then the needle is green.</p> <p>Out-of-plane injections 2B: When the tip of the needle is NOT in the ultrasound image plane then the needle is red.</p>
3	Alignment image WiGuide display: Probe	A plan view of probe, central white line represents ultrasound plane. Note the notch position is also indicated on the probe which coincides with the blue square on the top left hand side of the image.
4	On image display: Needle	Colored lines indicate the estimated projection of a detected needles position onto the ultrasound plane. Under optimal operating conditions and expert use there is a high likelihood that the needle will be positioned between the two colored lines relative to the ultrasound image.
5	On image display: Trajectory	Dashed line indicates the needle trajectory should the operator advance the needle forward from that position.
6	On image display: Target	<p>Box indicates the estimated position at which the needle tip will cross the ultrasound image plane for out-of-plane injections. Under optimal operating conditions and expert use there is a high likelihood that the needle tip will cross the ultrasound image plane within the box.</p> <p>OUT-of-plane injections 6A: When the tip of the needle is IN the ultrasound image plane then the trajectory is green.</p> <p>OUT-of-plane injections 6B: When the tip of the needle is NOT in the ultrasound image plane then the box is red.</p>
7	Signal Strength Indicator	Indicates stray field characteristics.
8	Depth indicator	A connection to the needle has been made. wiGuide can estimate the needle positions up to the depth displayed.

**NOTE:**

**Needles will only be detected and tracked well when approaches are made if there is a strong connection. To detect a needle the user must make a connection**

between the needle and the probe by moving the needle tip to within 5mm from the probe

### 7.3.3 In-Plane Needle Guidance



NO.	NAME	FUNCTION/DESCRIPTION
2	Off image WiGuide display: needle	<p>A plan view of the needle.</p> <p>Circle represents the hub end of the needle and other end is needle tip.</p> <p>In-plane injections 2C:</p> <p>When the needle is aligned with the ultrasound image plane then the needle is colored green.</p>

		<p>In-plane injections 2D:</p> <p>When the needle is NOT aligned with the ultrasound image plane then the needle is colored red.</p>
5	On image display: Trajectory	<p>Dashed line indicates the needle trajectory should the operator advance the needle forward from that position.</p>
6	On image display: Target	<p>Box indicates the estimated position at which the needle tip is. Under optimal operating conditions and expert use there is a high likelihood that the needle tip will be within the box.</p> <p>In-plane injections 6C:</p> <p>When the needle is aligned with the ultrasound image plane then box is green.</p> <p>In-plane injections 6D:</p> <p>When the needle is NOT aligned with the ultrasound image plane then the box is red.</p>
7	Signal Strength Indicator	<p>Indicates stray field characteristics.</p>
8	Depth indicator	<p>A connection to the needle has been made. wiGuide can estimate the needle positions up to the depth displayed.</p>

# 8 Scanning & Display

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## 8.1 Display

Zoom is used to magnify a zoom region of interest (ROI). The system adjusts all imaging parameters accordingly. You can also zoom frozen images. Zooming an image changes the frame rate which tends to change thermal indices. The position of the focal zones may also change which may cause the peak intensity to occur at a different location in the acoustic field. As a result, the MI (TI) may change.

### 8.1.1 ReadZoom

#### To Zoom

At real time scanning or freeze status, use two fingers pinch or spread on the screen and zoom it.

#### Zoom Adjustment

- To change the magnification factor (the maximum is 10 times).

Pinch two fingers close to decrease the magnification factor; Spread two fingers away to increase the magnification factor.

The magnification factor is displayed in Area of Image Parameters. For example, **Z1.6** indicates the current magnification factor is 1.6.

- Move the finger to change the zoom display position.

#### Exit Zoom

Pinch two fingers close until zoom rate to 1.0 to exit the zoom status.

### 8.1.2 Front Zoom

With Write Zoom, the ultrasound line density and/or sampling frequency increases, giving a better resolution.

**NOTE:** The difference between Read Zoom and Write Zoom can be described in relation to photography. With a photograph, Read Zoom manipulates the negative and enlarges the picture; whereas Write Zoom uses a telephoto lens to bring the image closer before taking the picture.

### To Zoom

At real time scanning, click “**Front Zoom**” in Menu, the system will display the ROI.

Then select the ROI position and the size by use two fingers, then click  to enter the zoom status.

### Exit Zoom

Click “**Front Zoom**” to exit the zoom status

## 8.1.3 Dual Display

The system supports dual-split display format. However, only one window is active at one time.

- Dual-split: press “**Dual**” button in the Menu of B mode to enter the dual-split mode, and click the probe tag  to activate between two windows; press “**B**” on the control panel to exit.

Imaging modes support splitting display: B mode, Color mode, Power mode

## 8.1.4 FZoom (Full-screen Zoom)

**Function: to magnify the image in full screen.**

1. Open the image (or the under scanning image), Click  to enter Full Screen zoom status. In FZoom status, only image area is shown. You can click anywhere in the image area, and then system will pop up "Save Img, Save Cine, Freeze, End Exam, depth" button. If you the image area again, these buttons will disappear.
2. Click  to return to normal status.

**In FZoom status:**

Cannot Measure or Comment the image.

It is not the currently zooming region that is used for video output, image saving and print functions.

## 8.1.5 Freezing an Image

Freezing a real-time image stops all movement and allows you to measure and print the image.

**Freeze an image:**

1. Manually enter the freeze: click “**Freeze**” on the screen.
2. Automatically enter the freeze: In the <Setup > - < system Settings > - < image>, set the “**Automatic freeze**” time, such as 5 minutes; 5 minutes later without any operation, the

machine automatically enter the freeze.

Unfreeze an image: click “UNFREEZE” on the screen to activate image.

**NOTE:** *While the image is frozen, all Power Output is suspended.*

*Selecting a new probe will unfreezes the image.*

## 8.2 Using Cine

CINE images are constantly being stored by the system and are available for playback or manual review via CINE.

Timeline data is continually stored at four times the display width of timeline data (and updates the corresponding B-Mode images).

You can view CINE as a continuous loop via CINE Loop or manually review CINE images frame by frame via the button controls.

Data in CINE is available until new data is acquired. CINE is stored on the system's memory and can be archived as well.

CINE is useful for focusing on images during a specific part of the heart cycle or to view short segments of a scan session.

### 8.2.1 Activating Cine Review

**To activate CINE:**

1. Click Freeze Button.
2. Slide the slider below the image region will replay the images.

### 8.2.2 Cine and Monitor Display

The CINE display (located on the bottom side of the image area) indicates which frame you are viewing of the whole loop.



#### ■ Auto Review

- **Review all**

In the manual cine review status, click  to activate auto cine review.

- **Setting Length of Auto Review**

You can set a length of cine loop which can be reviewed automatically. After the auto review region is set, the auto cine review can only be performed within this region;

- a) Move Start: Slide the blue button  upon the cine slider to set it as start point.
- b) Move End: Slide the blue button  below the cine slider to set it as end point.
- c) Click Save Cine in the Menu to save the cine of the selected length.

## 8.3 Annotating an Image

The comment function provides the capability to type the comments of free text and/or insert the pre-defined comments from the comment library. It also provides the user with arrow markers to point to parts of the image.

Press the “**Freeze**”–“**Scan**”–“**Comment**” button to enter comment state.

### 8.3.1 Adding Comments

1. To initiate comment:
  - Press the “**Freeze**” button, and go to “**Scan**”–“**Comment**” page, touch the pre-defined comments to add them.
  - Touch “**Keyboard**” menu, and type the characters on the soft keyboard.
  - Touch the “**Arrow**” menu to mark with the arrow comment.

Tips: when the system entered comment status, the default characters entered are capitalized. The  indicator is on.

2. Choose comment type at “**Scan**”–“**Comment**” page, and add the comments. Then modify, move or delete the comments added.
3. Exiting comment:
  - Exit “**Scan**”–“**Comment**” page.
  - Touch “**Unfreeze**” to exit comment and go to scan.

### 8.3.2 Comment Menu

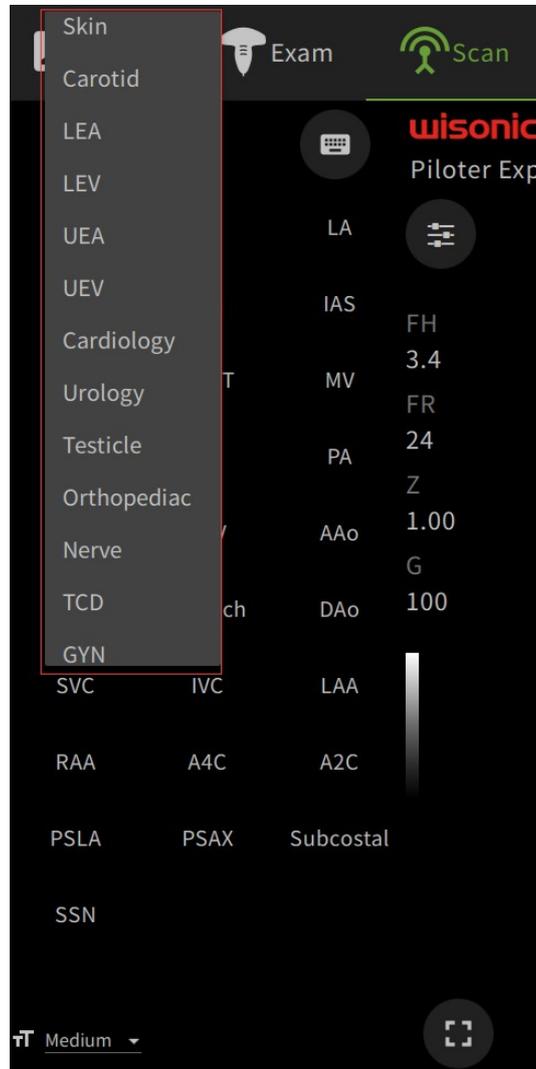
Use comment menu list to modify comment menu under comment state.

#### Home position

Move the cursor to the desired location and click Set Home. The current position will be saved as a home position for next comment. Clear all the comments, and add a new comment, the comment will be added at home position.

### Font Size/Arrow Size

- Under “**Comment**” Menu, Touch the font size list to choose different size: Small, Med, and Big.
- Under “**Arrow**” menu, touch Small, Mid, Big to change the arrow size.
- Under comment menu, select the comment menu list to change the comment library (the available ones are libraries for all the exams). See the screen below:



When Input the comment, the system displays the customized comment text library for the current exam.

### Set comment language

Under “**Comment**” menu, switch the language list between English and current system default language for comment menu.

If the current language is English, this function is not available, the list only contain English.

### 8.3.3 Moving Comments

Drag the comment to the place where you want, and loose up the finger. And the comment color is changed to high light green.

### 8.3.4 Deleting Comments

#### Deleting a character of a Comment

1. Under comment state, click the comment, and move the cursor after the character you want to delete.
2. Touch the  key on the soft keyboard to delete the character.

#### Deleting a Comment or an Arrow

1. Under comment mode, touch “**Clear**” button, the comments will be deleted according to the adding sequence.

#### Deleting all the Comments

1. Under comment mode, long press “**Clear**” button, all the comments will be deleted.

#### Auto deleting the Comments

1. Go to “**Setup**”– “**System Setup**”– “**Image**” page, and check the function “**Unfreeze Clear**”. All the comments will be deleted after a Freeze execution is performed. Otherwise the comments will be deleted through switch patient, probe or exam mode only.

- |   |
|---|
| <p><b>NOTE:</b></p> <ol style="list-style-type: none"><li>1. When no object is selected, Touching the “<b>Clear all</b>” key will clear all comments, Body marks and all measurements calipers.</li><li>2. After powering off, the system will clear all comments on the image.</li></ol> |
|---|

## 8.4 Body Marks

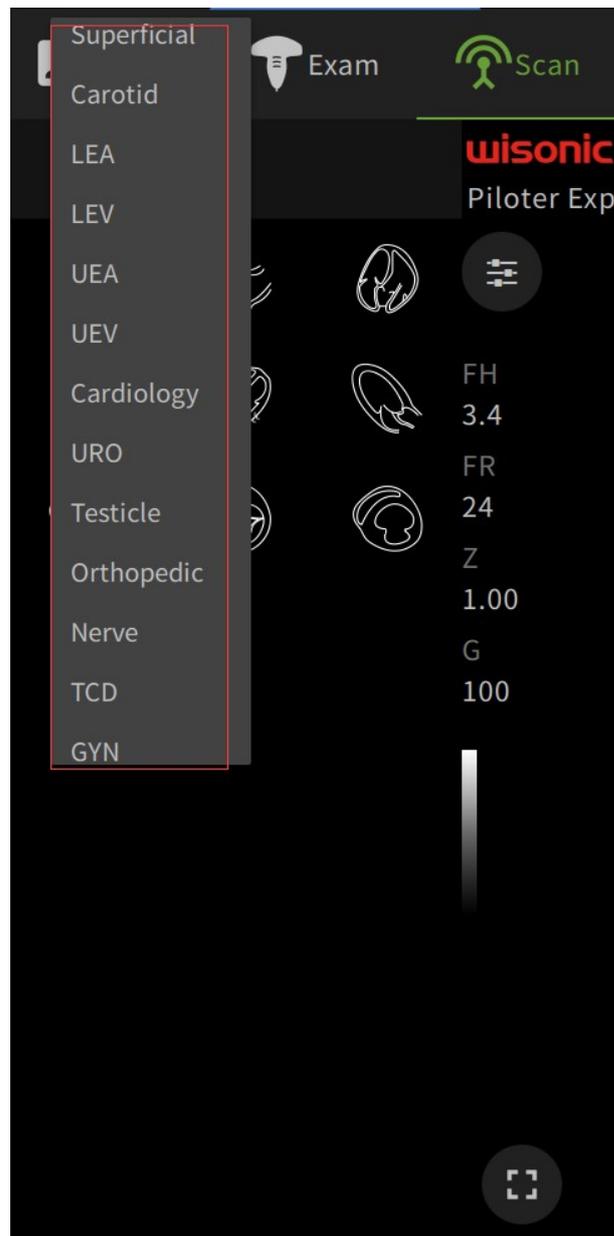
An additional way to annotate the image display is with body patterns. Body patterns are a simple graphic of a portion of the anatomy that is frequently scanned. The body pattern and probe marker can serve as a reference for a patient and probe positioning when images are archived or scanned. To activate body patterns, enter a frozen state, and touch “**Scan**”–“**BodyMark**” button.

## 8.4.1 Menu for Body Marks

The body mark Menu displays the settings for the current mode:

Switch body mark library list

1. Under body mark mode, switch body mark library lists, the page will display the body marks under the menu. See the screen below:

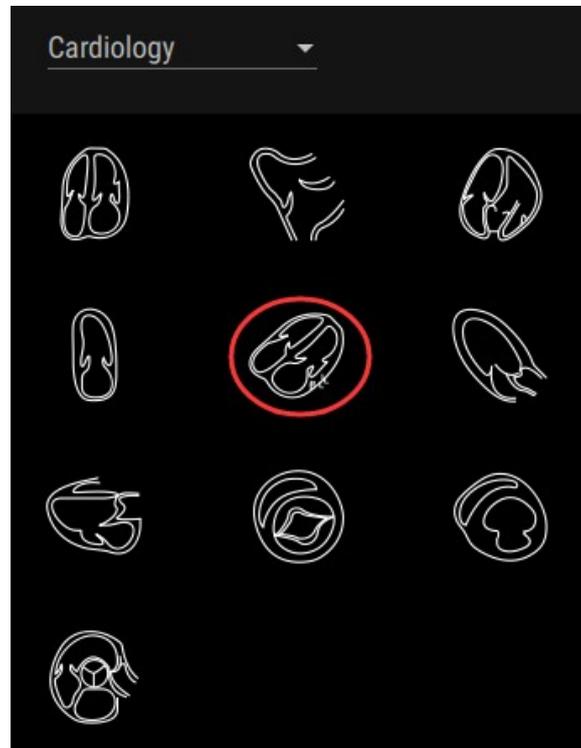


When Input the body mark, the system displays the customized body mark library for the current exam.

## 8.4.2 Adding Body Marks

To add the body mark:

1. Under frozen state, touch “**Scan**” –“**BodyMark**”, switch to the body mark library, and Touch the body mark you want to add.



To modify the body mark probe:

1. Touch “**Probe Mark**” Menu, and there are eight different direction probes displayed. See the picture below. Touch the probe needed to modify the direction of the probe.
2. Touch “**Probe Mark**” Menu, drag the probe mark to the place where you want to add, and loose finger to fix position of probe mark.



### 8.4.3 Moving Body Marks

You can move the body mark graphics to any desired position within the image area.

1. Drag the body mark to the new position, the back ground color of the body mark changes to grey.
2. Release finger, the movement finished.

**NOTE:** In Dual B Mode, a body mark cannot be moved between the separated image windows.

### 8.4.4 Deleting Body Marks

**To delete a body mark**

1. Under body mark mode, Touch **“Clear”** button to delete the body mark on the image.
2. Auto deleting the Body Marks

Go to **“Setup”– “System Setup”– “Image”** page, and check the function **“Unfreeze”** or **“Clear”**. All the Body Marks will be deleted after a Freeze execution is performed. Otherwise the Body Marks will be deleted through switch patient, probe or exam mode only.

**NOTE:** In the Body Mark mode, if no object is selected, long Touch the Clear key will clear all comments, body marks and general measurements from the screen.

Tips:

- Powering off, preset returning, switching the exam/ patient/ mode/ probe will clear the body marks.
- Switch the dual window will change to active the body mark of another window.

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# 9 Measurement

Measurements and calculations derived from ultrasound images are intended to supplement other clinical procedures available to the attending physician. The measurement could be performed in both Zoom In and cine play mode, and also in frozen mode.

## **⚠ WARNING:**

1. **Must make sure that the measure target and the image are right, the measurement area should be effective, otherwise will led a misdiagnosis.**
2. **When measure the Doppler blood, the probe must not be vertical to the blood direction, otherwise will led a wrong blood information. And the comment added must be correct, otherwise will led a misdiagnosis.**
3. **During the measurement, once unfreeze or changing the operation mode, all the measurement ruler will be deleted, and the ordinary measurement data will be lost (application measurement data will be saved in the report).**
4. **During the measurement, shutdown the machine or press the End Exam button will led t lost the data.**
5. **Under the Dual B mode, there is deviation for the measurement. The measurement could be only used for reference but can't diagnose.**

### Measurement Related

1. **Measure:** Under Freeze mode, go to “Scan” page, and press “Measure” button to start an ordinary measurement.
2. **Calc:** Under Freeze mode, go to “Scan” page, and press “Calc” button to start a application calculation measurement

## 9.1 Measurement Accuracy

Table 1 Precision of 2D Images

Parameter	Value Range	Error
Distance	Maximum $\geq 300$ mm	Within $\pm 3\%$ ; or when the measured value is less than 40 mm, the error is less than 1.5 mm.
Area (Trace)	Maximum $\geq 1126$ cm <sup>2</sup>	Within $\pm 7\%$ ; or when the measured value is less than 16 cm <sup>2</sup> , the error is less than 1.2 cm <sup>2</sup> .

Parameter	Value Range	Error
Area (ellipse, circle)	Maximum $\geq 884\text{cm}^2$	Within $\pm 7\%$ ; or when the measured value is less than $16\text{ cm}^2$ , the error is less than $1.2\text{ cm}^2$ .
Angle	0-180°	Within $\pm 3\%$ .

Table 2 Volume Measurements

Parameter	Value Range	Error
Volume	Maximum $> 999\text{cm}^3$	Within $\pm 10\%$ ; or when the measured value is less than $64\text{ cm}^3$ , the error is less than $6.4\text{ cm}^3$ .

Table 3 Time/Motion Measurements

Parameter	Value Range	Error
Distance	Maximum $\geq 300\text{ mm}$	Within $\pm 3\%$ ; or when the measured value is less than $40\text{ mm}$ , the error is less than $1.5\text{ mm}$ .
Time	Maximum $8\text{ s}$	Within $\pm 1\%$ .
Heart rate	15-999 beats per minute	Within $\pm 4\%$ .

Table 4 Doppler Velocity Measurement

Parameter	Value Range	Error
Velocity (PW mode)	Maximum $\geq 2.5\text{ m/s}$	When angle $\leq 60^\circ$ , $\leq 5\%$ .
Velocity (CW mode)	Maximum $\geq 2.5\text{ m/s}$	When angle $\leq 60^\circ$ , $\leq 5\%$ .

**NOTE:** *Within the selected field range, the measurement accuracy is ensured within the range mentioned above. The accuracy specifications are performance in the worst conditions, or based on the real test for the system, regardless of acoustic speed error.*

## 9.2 Measurement and Calculation Setup

*Measurements and studies are organized for typical work flows. If you want, you can change this setup. You can specify which studies are in each exam category, and which measurements and calculations are in each study. You can change the measurements that are available on the measurement window. The Clover allows you to quickly and easily set up your system so that you can work most efficiently.*

### 9.2.1 Measurement Menu Setup

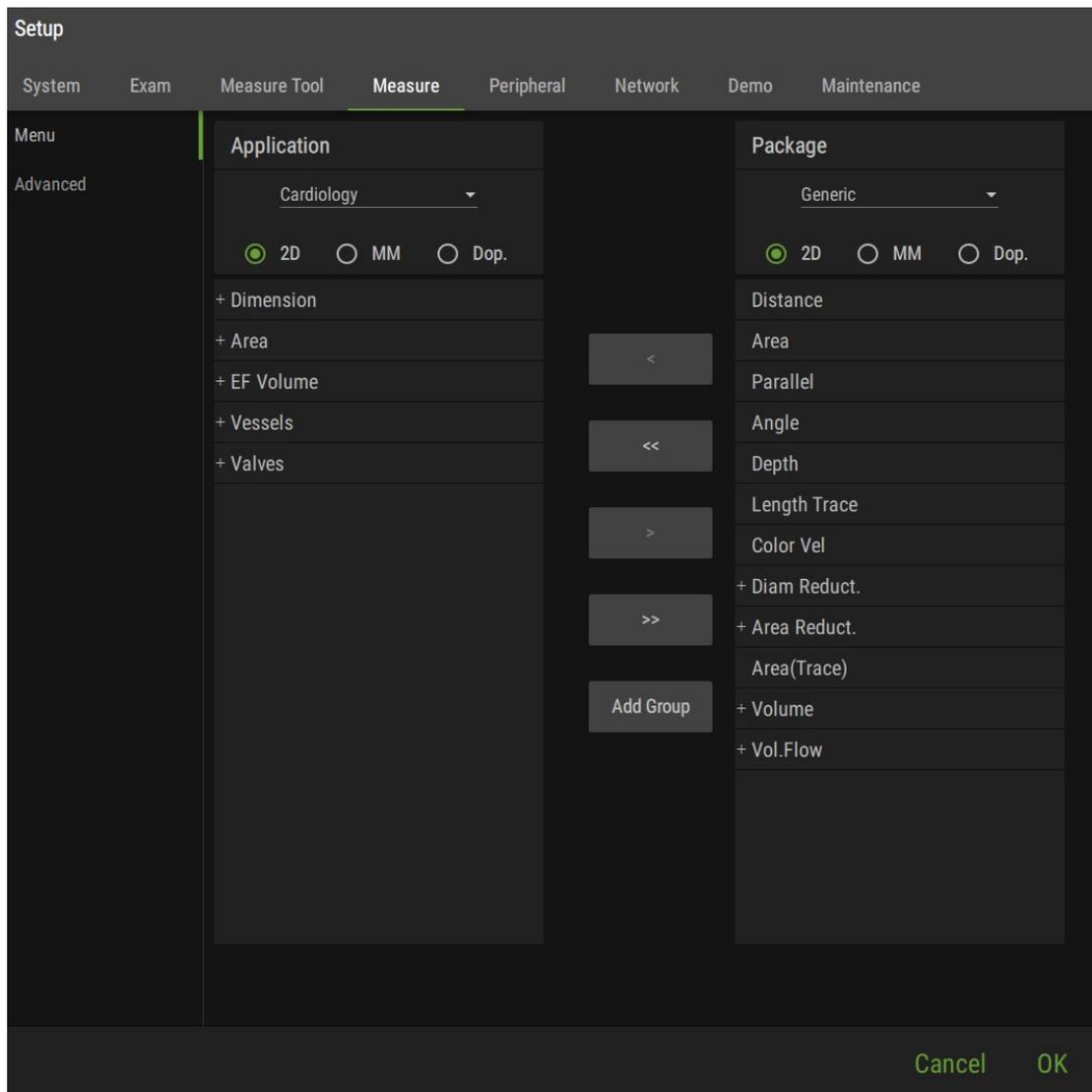
You can make changes to studies and measurements in the "**Meas & Calc**" screen. To open the screen:

1. Press **Setup**.

The system displays the **Setup** dialog on the monitor display.

2. Select "**Meas & Calc**" at the top of the screen

The system displays the App Package "**Menu**" screen.



## In Menu

The "In Menu" section lists studies and measurements for current use

### Selecting an Measure Package for "In Menu"

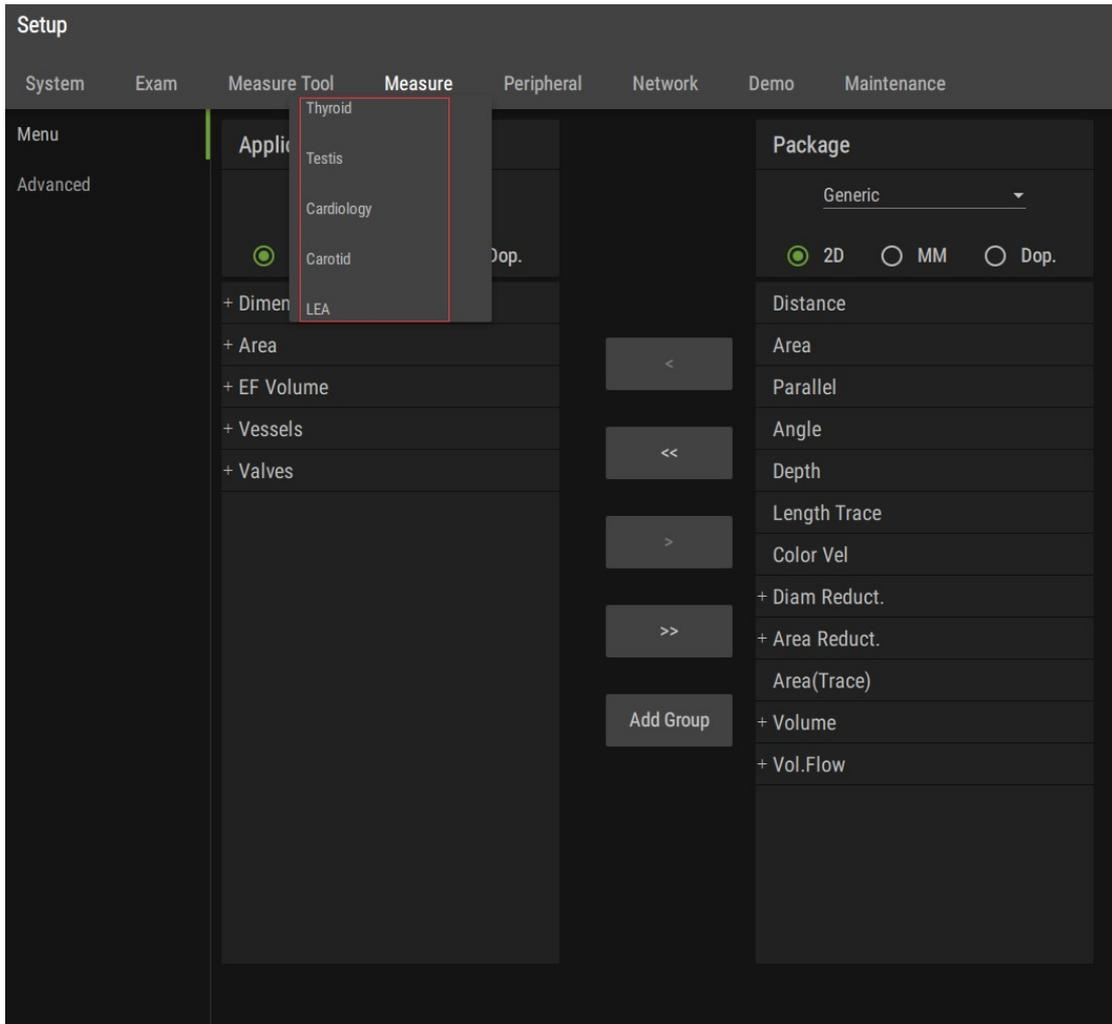
When you open the "**Meas & Calc**" screen, it displays the default Measurements Package of the current exam category. To select the Measure Package you want to work with:

1. Move to the "**Application**" drop-down menu.
2. Click it

The system displays a list of Measurements Package.

3. Choose the Measurements Package you want.

The **"In menu"** lists studies and measurements for the selected Measurements Package.



### Selecting the measurement mode for "In Menu"

In the **"Menu Mode"** section of the **"Menu"** screen, select one of the following:

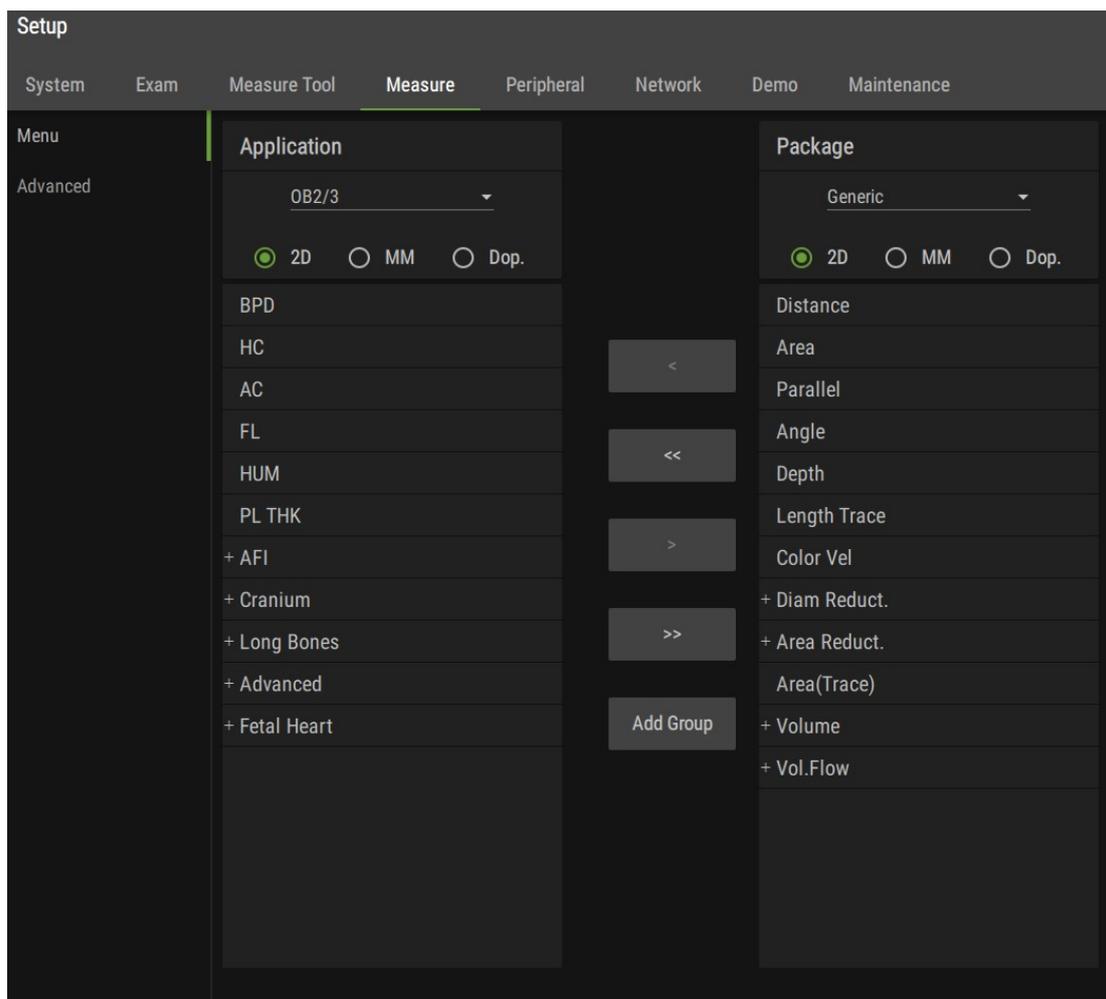
- 2D (B-Mode)
- MM (M-Mode)
- Dop. (Doppler Mode)

The **"In Menu"** lists studies and measurements for the selected mode.



## Selecting a study or measurement

To work with a study or measurement, you must first select it in the **"In Menu"**. The **"In Menu"** lists the studies and measurements for a Measurements package. The studies and measurements are organized in a hierarchy, in the same order that they are organized on the summary window while doing measurements. The following example shows the highest level of the OB2/3 Measurements Package. After you select the OB2/3 in **"Application"** drop-down menu, The **"In Menu"** shows all studies and measurements for the OB2/3.



### To select a study or measurement:

1. Move to the **"In Menu"** and highlight the study or measurement
2. Click a measurement.

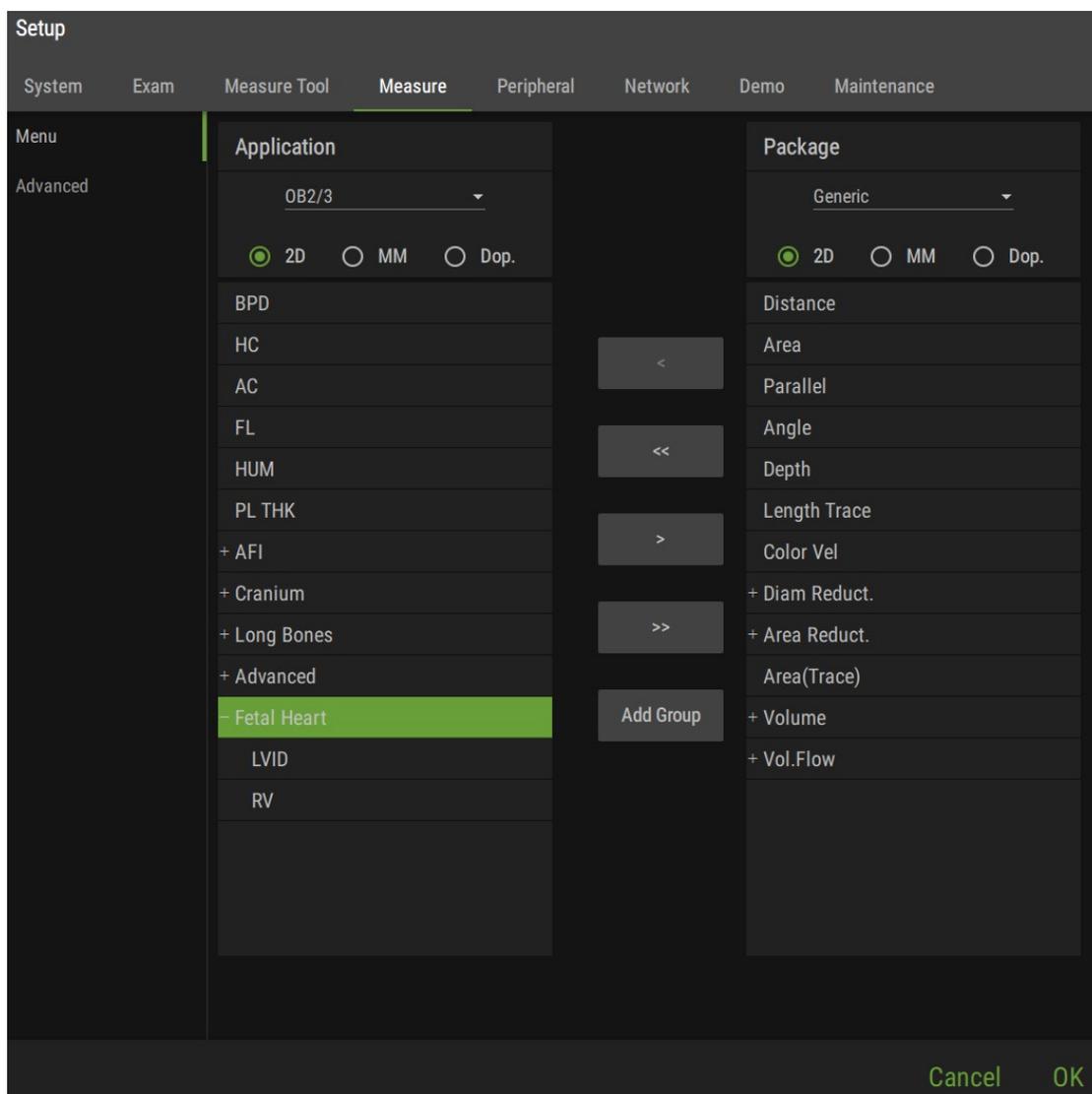
The following example shows the **"In Menu"** after the **"Fetal Heart"** measurement is expanded. The measurements in study **"Fetal Heart"** is now displayed.

### Expand a study:

1. Move to the **"In Menu"** and highlight the study **"Fetal Heart"**

2. Click it

The system displays the measurements in study "**Fetal Heart**"



## Specifying Which Measurements Go in Menu or Study

The "**Available Items**" section is where you specify which items go in a study.

### Selecting an Measure Package for Available Items

When you open the "**Meas & Calc**" screen, "**Available Items**" displays regular Package. To select the Available Package you want to work with:

1. Move the finger to the "**Package**" drop-down menu.
2. Click it

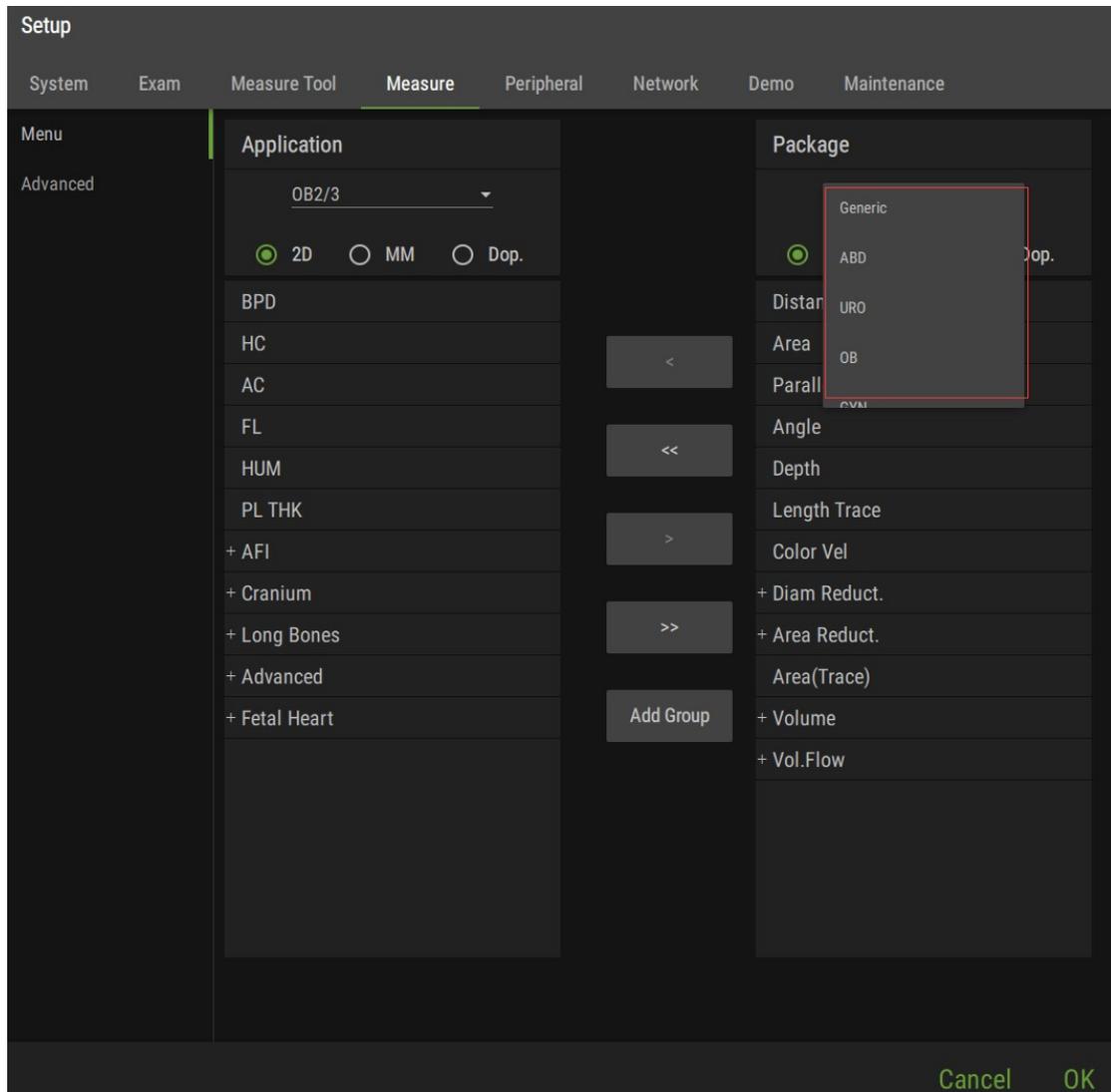
The system displays a list of Measurements Package.

3. Move the finger to highlight the Measurements Package you want.

Measurement9-7

4. Click it.

The **"Available Items"** lists studies and measurements for the Available Measurements Package.



### Selecting the measurement mode for Available Items

In the **"Package Mode"** section of the **"Menu"** screen, select one of the following:

- 2D (B-Mode)
- MM (M-Mode)
- Dop. (Doppler Mode)

The **"Available Items"** lists studies and measurements for the selected mode.

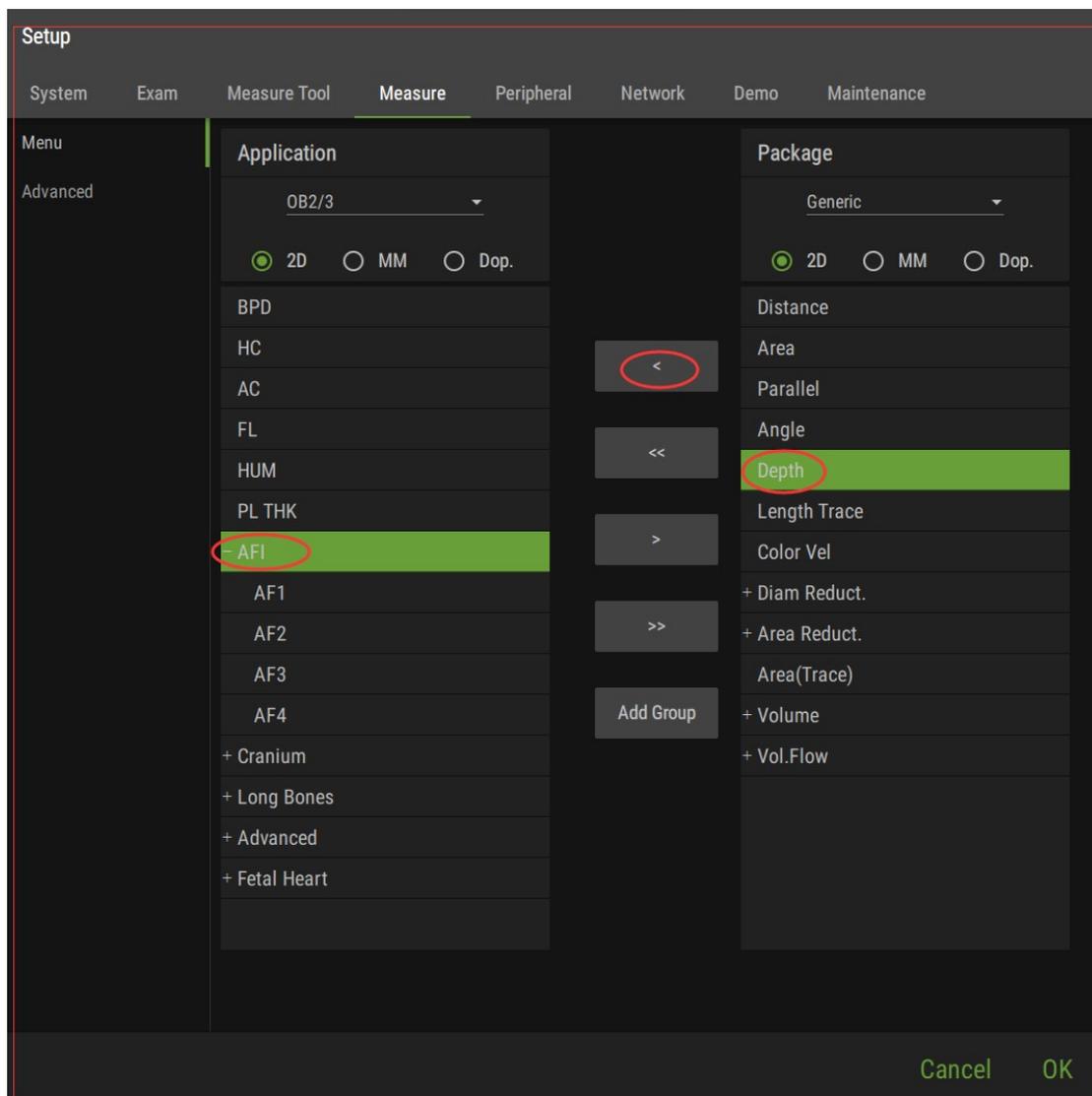


## Adding Measurements and Studies

### Adding a measurement or a study to "In Menu"

You can add a measurement in a system-defined folder or in a folder you created.

1. In the **"In Menu"** section, select the study where you want to add the measurement or study.
  - If you don't select any study, the measurement will be added to the top menu
2. In the **"Available Items"** section, select the measurement or study you want to be added
3. Click "<" between **"In Menu"** section and **"Available Items"** section

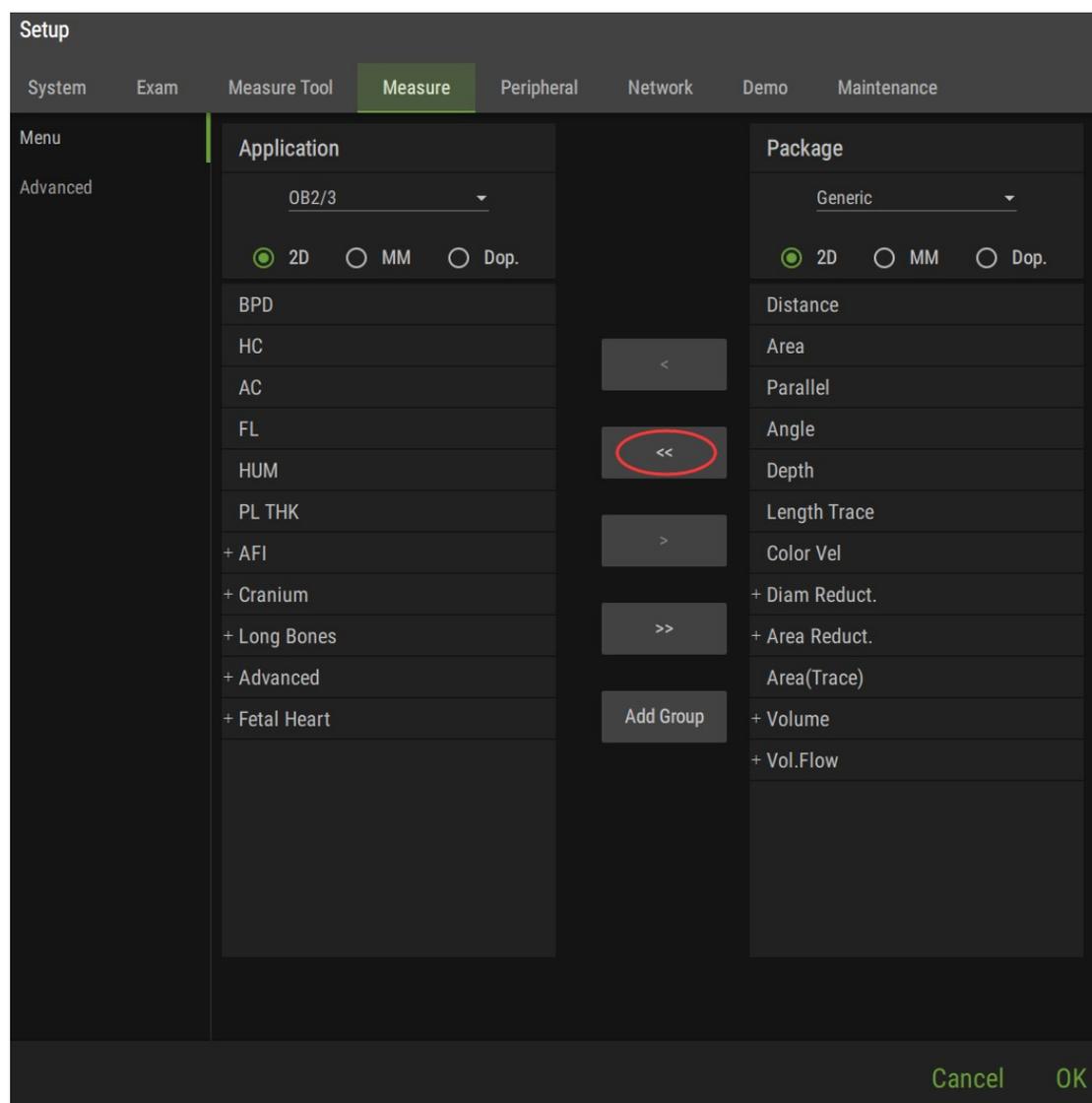


### Adding all measurements in "Available Items" to "In Menu"

You can add a measurement in a system-defined folder or in a folder you created.

*NOTE: If the Tool field is gray, it cannot be removed.*

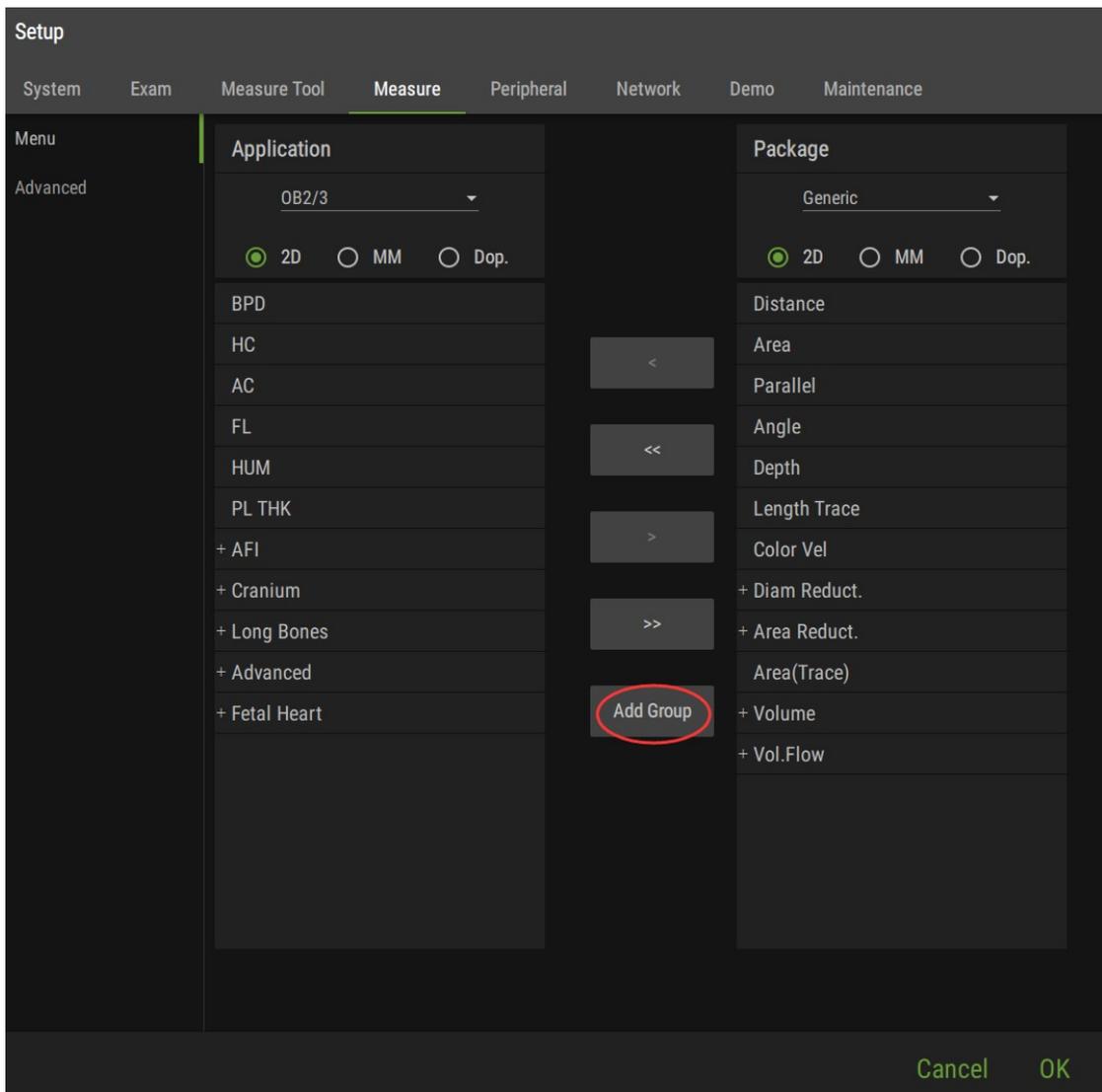
1. In the **"In Menu"** section, select the study where you want to add the measurement or study.
  - if you don't select any study, the measurement will be added to the top menu
2. In the **"Available Items"** section, select the "package" and "Package Mode" you want to add
3. Click "<<" between **"In Menu"** section and **"Available Items"** section



### **Adding a user-defined study**

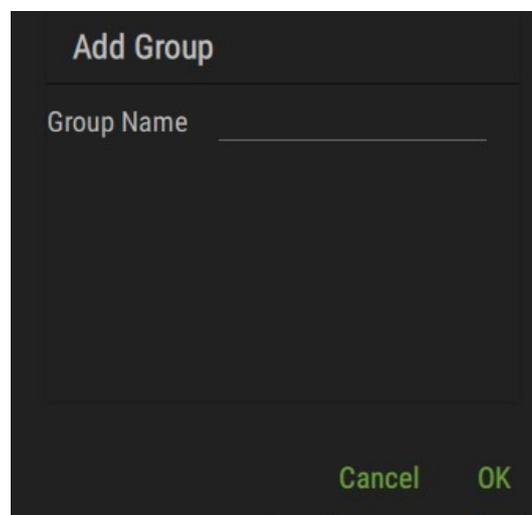
A measurement study is a Group that includes related measurements.

1. In the **"In Menu"**, in the top menu or select the study where you want to add the study.
2. In the **"In Menu"** section, Move the **finger** to the **"Add Group"**



3. Press **Set**

The system displays a dialog of inputting "Group Name".



4. Type the study name, then select **"OK"**

The study is added

5. To add measurements to the study, see 'Adding a measurement or a study to **"In Menu"**

### **Remove a Study or Measurement from "In Menu"**

*You can only remove the studies or measurement from **"In Menu"** which for displaying. You cannot delete default system studies or measurements in **"Available Items"**.*

*NOTE: If the Tool field is gray, it cannot be removed.*

1. Select the study or measurement in the **"In Menu"**.
2. Select **">"** to remove the measurement or study which for displaying.

### **Remove all Studies and Measurements from "In Menu"**

*You can only remove the studies or measurement from **"In Menu"** which for displaying. You cannot delete default system studies or measurements in **"Available Items"**.*

1. In the **"In Menu"** section, select the "App package" and "Menu Mode" you want to remove
2. Select **">>"** to remove all the measurements and studies.

## **9.2.2 Measurement Advanced Setup**

The system allows you to specify application-specific values for certain parameters. You specify the parameter values on the advanced tab of the Meas&Calc screen.

### **Enter Advanced Preset**

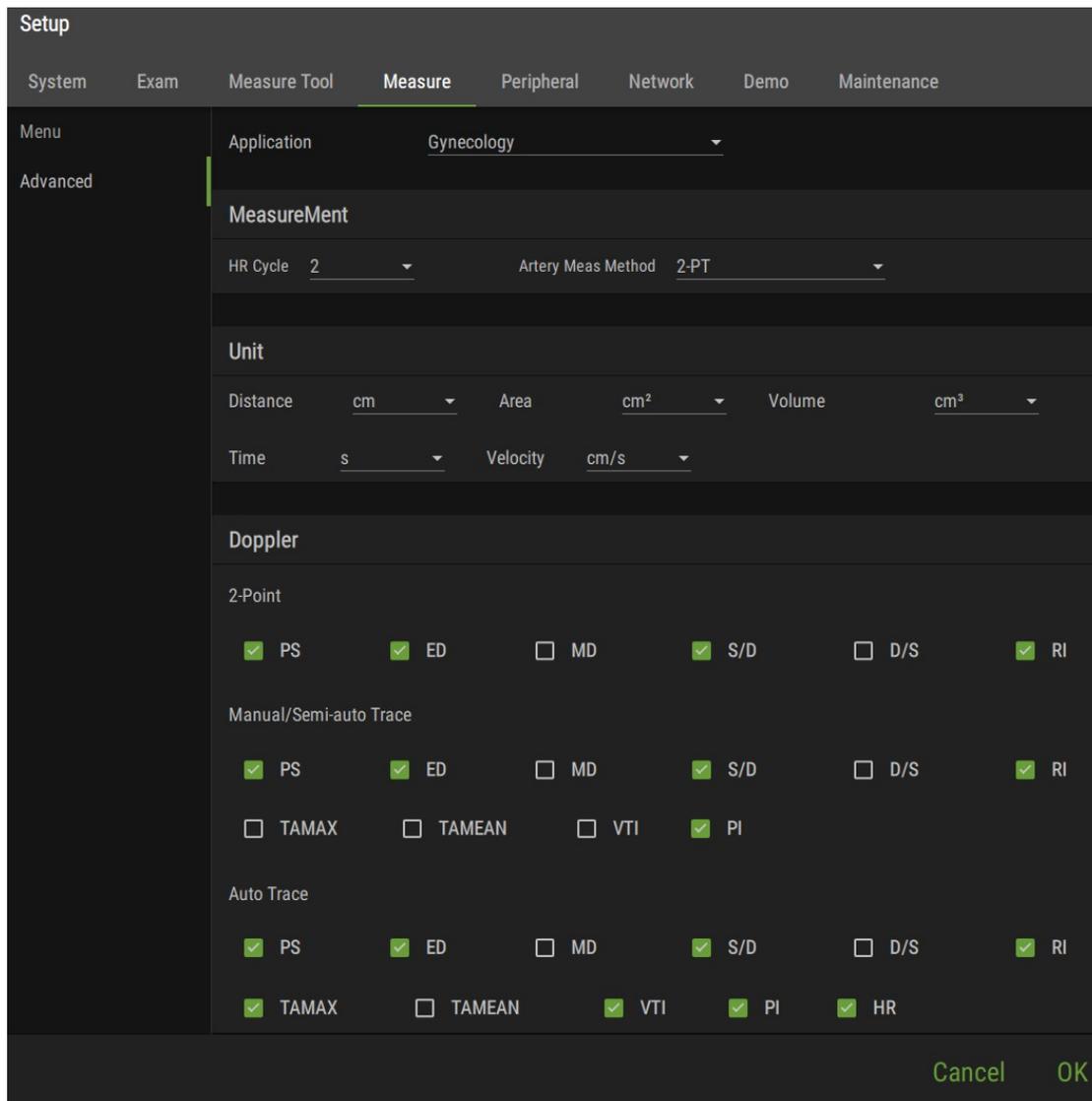
You can make changes to studies and measurements in the Meas&Calc screen. To open the screen:

1. Press **Setup**.

The system displays the Setup screen on the monitor display.

2. Select **"Meas & Calc"** at the top of the screen and click it, select **"Advanced"** on the monitor display

The system displays the App Package **"Advanced"** screen.



## Selecting an App Package

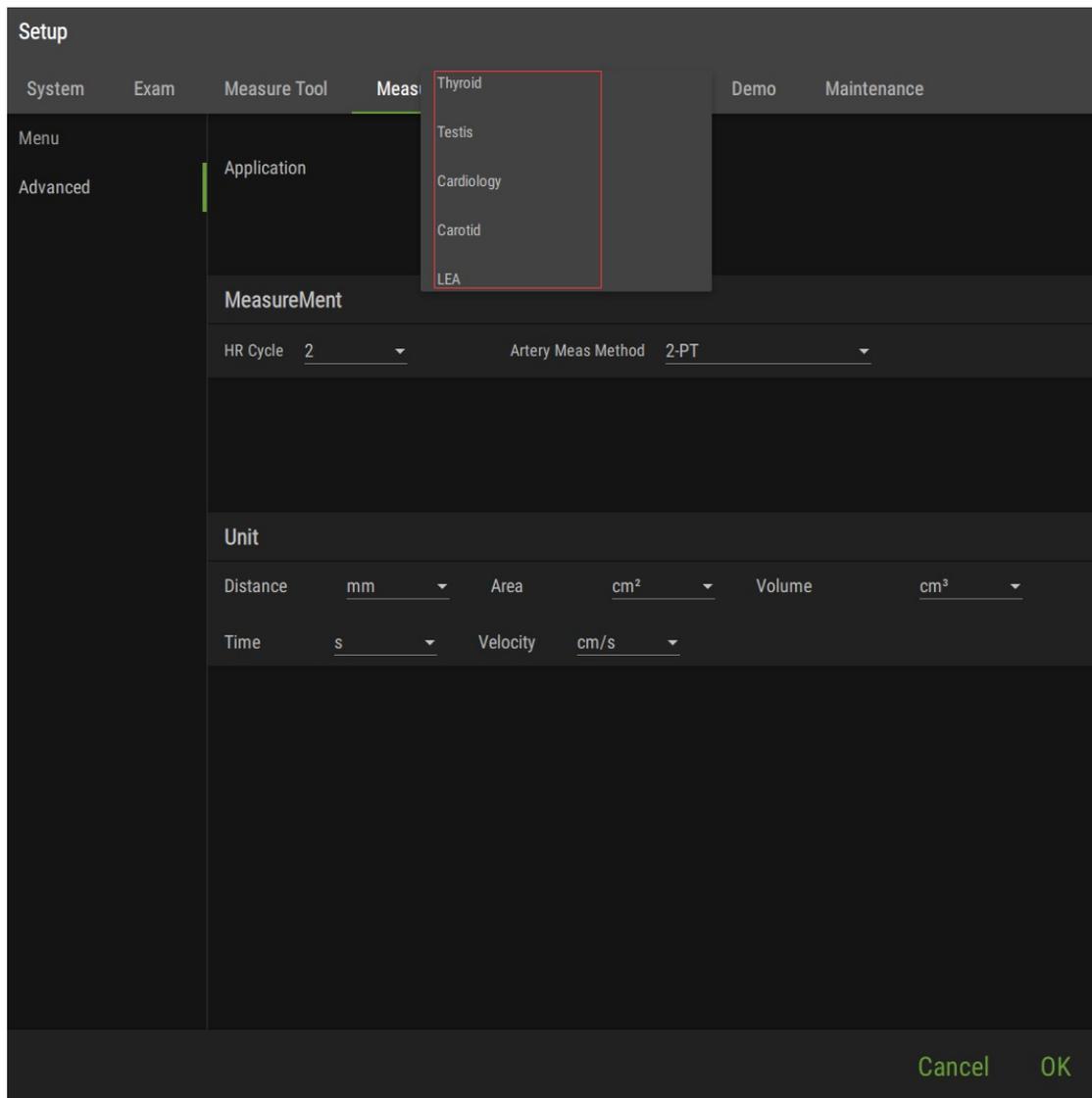
When you open the **Advanced Menu** of the **"Measure"** screen, it displays the default Measurements Package of the current exam category. To select the Measure Package you want to work with:

1. Move the finger to the "Application" drop-down menu.
2. Click it.

The system displays a list of Measurements Package.

3. Move the finger to choose the Measurements Package you want.

The **"In menu"** lists studies and measurements for the selected Measurements Package.



### Set the Heart Cycle for the Measure Package

To select a value for a **Heart Cycle** parameter, select it from the Value list.

Heart Cycle: 1, 2, 3, 4 or 5

### Set the Artery Measure for the Measure Package

To select a value for an **Artery Measure** parameter, select it from the Value list.

Artery Measure: 2PT, Trace or S-Auto

## Set the Units for the Measure Package

To select a value for the **Units**, select it from the Value list.

You can set units as follows.

<b>Unit</b>		<b>Conversion (coefficient value)</b>
Distance	mm	x10
	cm	x1
Area	mm <sup>2</sup>	x100
	cm <sup>2</sup>	x1
Volume	mm <sup>3</sup>	x1000
	cm <sup>3</sup>	x1
Time	ms	x1000
	s	x1
Velocity	mm/s	x100
	cm/s	x10
	m/s	x1

## Set the Result Items of Doppler for the Measure Package

The system allows you to preset the parameters for manual calculations. You specify the parameter values in the Doppler frame of the advanced screen.

## Doppler

**2-Point**

PS   
 ED   
 MD   
 S/D   
 D/S   
 RI

**Manual/Semi-auto Trace**

PS   
 ED   
 MD   
 S/D   
 D/S   
 RI

TAMAX   
 TAMEAN   
 VTI   
 PI

**Auto Trace**

PS   
 ED   
 MD   
 S/D   
 D/S   
 RI

TAMAX   
 TAMEAN   
 VTI   
 PI   
 HR

---

**Abbreviations**

Peak Systolic Velocity (PS)

End-Diastolic Velocity(ED)

Min Diastolic Velocity(MD)

Systolic/End-Diastolic Ratio(S/D)

End-Diastolic/Systolic Ratio(D/S)

Time Avg Max Velocity(TAMAX)

Time Avg Mean Velocity(TAMEAN)

Velocity Time Integral(VTI)

Resistive Index(RI)

Pulsatility Index(PI)

Heart Rate(HR)

- **2-Point**

In the 2-Point frame, select the measurements that you want to the system to show for 2-Point Doppler measurements for the selected study.

The Result Items of 2-Point includes PS, ED, MD, S/D, D/S and RI, of which ED and MD are mutual exclusive.

- **Manual/Semi-Auto Trace**

In the Manual/Semi-Auto frame, select the measurements that you want to the system to show for Manual and Semi-Auto Doppler measurements for the selected study.

The Result Items of Manual/Semi-Auto includes PS, ED, MD, S/D, D/S TAMAX,

VTI, RI and PI, of which ED and MD are mutual exclusive.

- **Auto Trace**

In the Auto Trace frame, select the measurements that you want to the system to show for Auto Trace Doppler measurements for the selected study.

The Result Items of Auto Trace conclude PS, ED, MD, S/D, D/S TAMAX, TAMEAN, VTI, RI, PI and HR, of which ED and MD are mutual exclusive.

## 9.2.3 Mode Measurements

### B-Mode Measurements

Some basic measurements can be made in B-Mode

- Distance
- Area
- Volume
- Angle
- Depth
- Four Points And Three Lines

*Attention: Only Piloter Exp/T/P/S/F/RE/U/i support depth measurement.*

*Only Piloter, Piloter Exp/T/D/V/U/SE/i support Color Vel measurement.*

*Only Piloter Exp/S/B/D/R/RE/V/U support CIA Diam measurement.*

*Only Piloter, Piloter Exp/T/F/R/RE/V/X support Interlobar A measurement.*

### Distance

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Distance**> button.
2. There is a high light green dotted line with two active ring on each end point on the screen.
3. To measure the distance, there are two methods:
  - a. Press any point P on the image, the end which is closed to P will be moved to position P.
  - b. Drag any end point to position P in the image, and loose up, the end point will be moved to position P.
4. To complete the measurement, exit measurement mode or start another measurement.

The system displays the distance value in the Results Window.

**NOTE:**

*Before you complete a measurement:*

- *The measure ruler is in active mode, touch “Delete” button, the measure ruler will be deleted, and the value in result window also will be deleted.*

**Circumference and area (Ellipse)**

1. Under Freeze mode, go to “Scan” page, and press “Measure” button, and press <Area> button, click method list and choose <Ellipse>.
2. There is a high light green circle on the screen, there are two vertical intersection lines inside the circle, and on each end point of the line, and there is an active ring.
3. To measure circumference and area, drag two end point ring of vertical line, these end point rings could only be moved on the vertical direction.
4. Drag the end point ring on the horizon line, there end point rings could be moved in any direction.
5. To complete the measurement, exit measurement mode or start another measurement.

The system displays the distance value in the Results Window.

**NOTE:**

*Before you complete the ellipse measurement:*

- *To erase the ellipse and the current data measured, touch “Delete” button, the measure ruler will be deleted, and the value in result window also will be deleted.*

**Circumference and area (Trace)**

1. Under Freeze mode, go to “Scan” page, and press “Measure” button, and press <Area> button, click method list and choose <Trace>.
2. There is a high light green cross point on the screen.
3. To posit the first point, drag the cross point to the start position of the trace, and loose up. There will be the second active cross point on the screen.
4. To trace the area, drag the second active cross point along the trace image, and loose up when finished the trace.
5. The measurement is finished automatically.
6. The trace area is rounded with dotted line, and the circumference and area value are displayed in the result widow.

## NOTE

Before you complete the trace measurement:

- To erase measurement rule and measurement data, press “**Delete**” button.

### Volume (Three Dist)

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Volume**> button to enter measurement item page.
2. Press <**Diam 1**> button, the first diam is displayed with two active ring on each end point. Posit the first diam through drag these two active rings.
3. Press <**Diam 2**> button, the second diam is displayed with two active ring on each end point. Posit the second diam through drag these two active rings.
4. Press <**Diam 3**> button, the third diam is displayed with two active ring on each end point. Posit the third diam through drag these two active rings.
5. The diam values and volume value will be displayed in the result window.

#### NOTE:

- Press “**Delete**” button to delete the added measurement.

### Angle

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Angle**> button.
2. There are two crossed line on the screen. Through drag or press the end point of the line to measure the angle.
  - a. Press the end point of the line  
Press any point P on the image, the end point closed to P will be moved to P.
  - b. Drag the end point of the line  
Drag the end point to position P, loose up, the movement is finished.
3. To complete the measurement, exit measurement mode or start another measurement. And the angle value will be displayed in the result window.

### Depth

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Depth**> button.
2. There is a high light green cross point on the screen.
3. To measure the depth, there are two methods:
  - a. Press any point P on the image, the cross point is moved to P, the depth of position

P is measured.

- b. Drag the cross point to P, and loose up, the depth of position P is measured.
4. To complete the measurement, exit measurement mode or start another measurement. And the depth value will be displayed in the result window.

## **Four Points and three lines**

*The measurement ruler is in cardiac measure library under the directory EF Volume - Cube/Teicholz*

1. Under Freeze mode, go to "Scan" page, and press "**Calc**" button, and click the measurement library list, choose Cardiac library. Go to **<EF Volume> -<Cube/Teich>** page, and press **<Diastole>** button.
2. There are three mutual vertical lines displayed on the screen, and there are four active rings at the end point of the lines, the distance of each line is measurement value of the Four Points And Three Lines.
3. To measure Four Points And Three Lines, drag the active rings to confirm the position.
4. To complete the measurement, exit measurement mode or start another measurement. And the Four Points and Three Lines value will be displayed in the result window.

## **M-Mode Measurements**

Basic measurements that can be taken in the M-Mode portion of the display are:

- Distance
- Time
- Heart Rate
- Slope
- Four Points And Three Lines

*NOTE:*

*To perform any of these measurements, perform the following steps:*

1. *In the B-Mode part of the display, scan the anatomy you want to measure.*
2. *Go to the M-Mode part of the display.*
3. *Adjust the M-Mode gate*
4. *Press "**Freeze**".*

## Distance

Distance measurement in M-Mode functions the same assistance measurement in B-Mode. It measures the vertical distance between calipers.

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Distance**> button.
2. There are vertical lines with one horizon line connected on the screen, and there are two active rings at the junctions. The distance between the two rings is the distance.
3. To measure M distance, drag the two rings to confirm the position.
4. To complete the measurement, exit measurement mode or start another measurement. And distance value will be displayed in the result window.

## Time

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Time**> button.
2. There are vertical lines with one horizon line connected on the screen, and there are two active rings at the junctions.
3. To measure M time, drag the two rings to confirm the position.
4. To complete the measurement, exit measurement mode or start another measurement. And time value will be displayed in the result window.

## Heart Rate

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Heart Rate**> button.
2. There are vertical lines with one horizon line connected on the screen, and there are two active rings at the junctions..
3. To measure M heart rate, drag the two rings to confirm the position.
4. To complete the measurement, exit measurement mode or start another measurement. And heart rate value will be displayed in the result window.

## Slope

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Slope**> button.

2. There are vertical lines with one horizon line connected on the screen, and there is one active ring at the junctions of the vertical line and horizon line. And there is a active ring on another vertical. The slope of the two rings is M slope.
3. To measure M slope, drag the two rings to confirm the position.
4. To complete the measurement, exit measurement mode or start another measurement. And slope value will be displayed in the result window.

### **Four Points and Three Lines**

*The measurement ruler is in cardiac measure library under the directory EF Volume - Cube/Teicholz under M mode.*

1. Under Freeze mode, go to “**Scan**” page, and press “**Calc**” button, and click the measurement library list, choose Cardiac library. Go to <**EF Volume**> -<**Cube/Teich**> page, and press <**Diastole**> button.
2. There is a line with four active rings displayed on the screen, and confirm three lines, the distance of the line is the measurement value of Four Points and Three Lines.
3. To measure Four Points and Three Lines, drag these active rings to confirm the position.
4. To complete the measurement, exit measurement mode or start another measurement. And Four Points and Three Lines value will be displayed in the result window.

### **Doppler Mode Measurements**

Some basic measurements can be made in Doppler-Mode

- Velocity
- Time
- Heart Rate
- Acceleration
- Spectrum
- Cardiac Trace

### **Note**

*To perform any of these measurements, perform the following steps:*

1. In the B-Mode part of the display, scan the anatomy you want to measure.

2. Go to the Doppler Mode part of the display.
3. Adjust the Doppler gate.
4. Press **Freeze**.

### **Velocity**

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Vel**> button.
2. There is a cross point on the screen, the velocity of the cross position is the doppler velocity.
3. To measure the velocity, there are two methods:
  - a. Press any position P of the image, the cross point will be moved to P to measure the velocity.
  - b. Drag the cross point to position P, and loose up to.
4. To complete the measurement, exit measurement mode or start another measurement. And Four Points and Three Lines value will be displayed in the result window.

### **Time**

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Time**> button.
2. There are vertical lines with one horizon line connected on the screen, and there are two active rings at the junctions.
3. To measure M time, drag the two rings to confirm the position.
4. To complete the measurement, exit measurement mode or start another measurement. And time value will be displayed in the result window.

### **Heart Rate**

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Heart Rate**> button.
2. There are vertical lines with one horizon line connected on the screen, and there are two active rings at the junctions.
3. To measure M heart rate, drag the two rings to confirm the position.
4. To complete the measurement, exit measurement mode or start another

measurement. And heart rate value will be displayed in the result window.

### **Acceleration**

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Accel**> button.
2. There are vertical lines with one horizon line connected on the screen, and there is one active ring at the junctions of the vertical line and horizon line. And there is an active ring on another vertical. The slope of the two rings is Doppler acceleration.
3. To measure Doppler acceleration, drag the two rings to confirm the position.
4. To complete the measurement, exit measurement mode or start another measurement. And acceleration value will be displayed in the result window.

### **Spectrum (Two Point)**

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Two Point(RI)**> button.
2. There are two vertical lines and a horizon line on the screen, and there is one active ring at the junctions of the vertical line and horizon line. And there is an active ring on another vertical.
3. To measure Doppler Two Points (RI), drag the two rings to confirm the position.
4. To complete the measurement, exit measurement mode or start another measurement. And two points (RI) value will be displayed in the result window.

### **Spectrum (Manual Trace)**

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Spectrum**> button, and choose <**Manual**> measure method.
2. There are one vertical line and one horizon line crossed, and there is a cross point at the junction.
3. To confirm the start point, drag the cross point and loose up. The horizon line disappeared.
4. To trace the spectrum, drag the cross point.  
Note: To erase the trace line, drag the cross point to the left direction.
5. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

### Spectrum (Semi-Auto Trace)

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button, and press <**Spectrum**> button, and choose <**semi-auto**> measure method.
2. There are two vertical lines and one horizon line displayed on the screen.
3. To trace the semi-auto spectrum, move the two vertical lines to confirm the position.
4. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

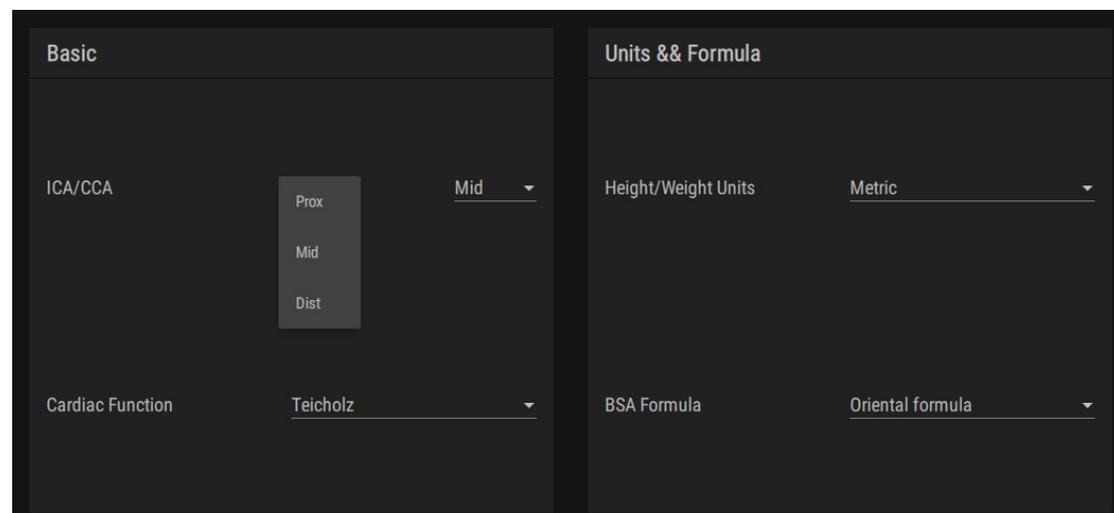
## 9.3 Measure Tools

*Measures tool consists of two parts function. Including the basic functions and unit formula switching function. You can switch different formula according to your need.*

### ICA/CCA

ICA/CCA is used to preset the calculation method of flow velocity ratio of ICA (Internal Carotid Artery) and CCA (Common Carotid Artery). Select one of following in each down-drop lists:

- Prox
- Mid
- Dist

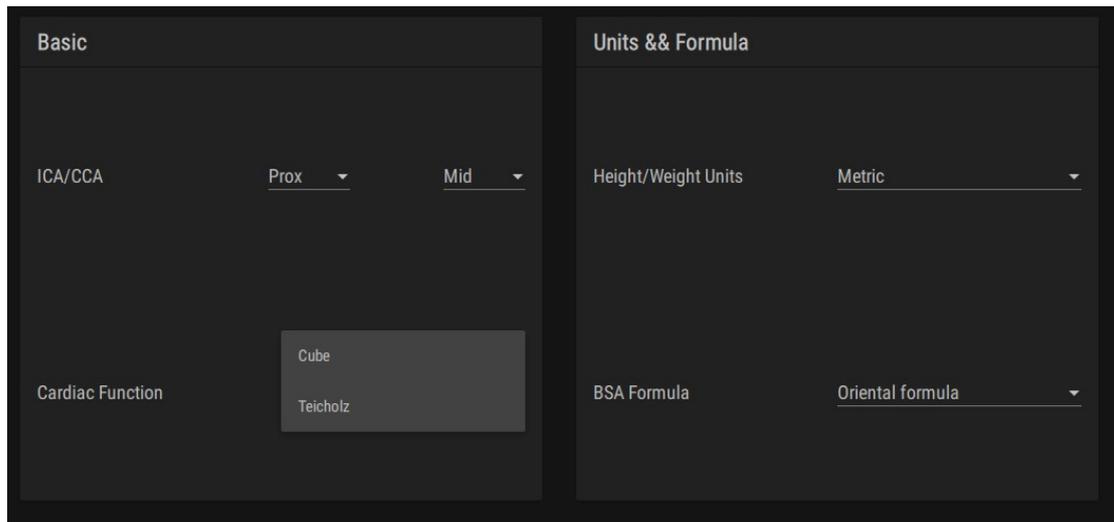


### Cardiac Function

Cardiac Function is used to preset the calculation method of EDV and ESV in package "Cardiology", select on of following:

- Cube:

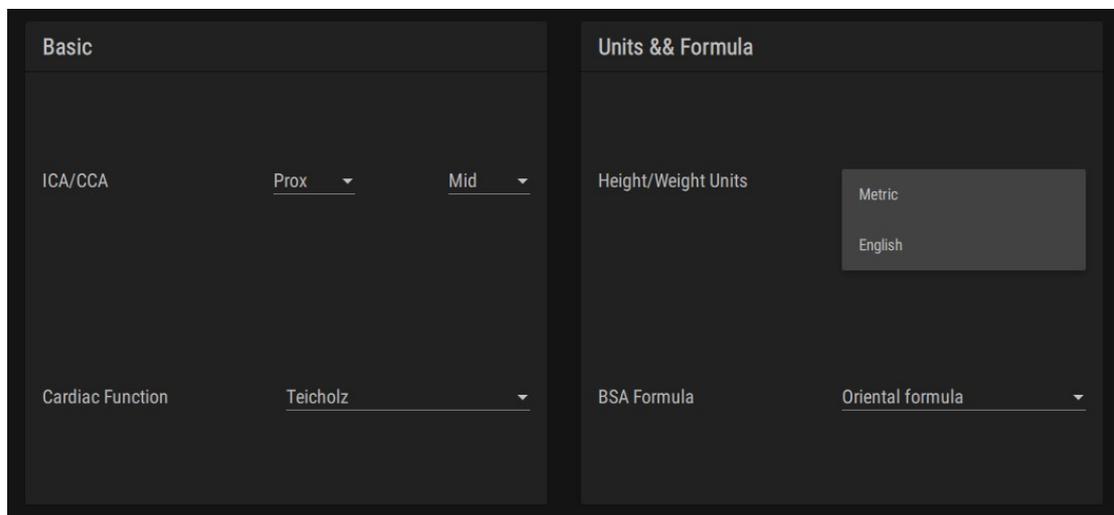
- Teicholz:



## Height/Weight Unit

Height/Weight unit affects the unit of height and weight in Patient information, select one of following:

- Metric
- English



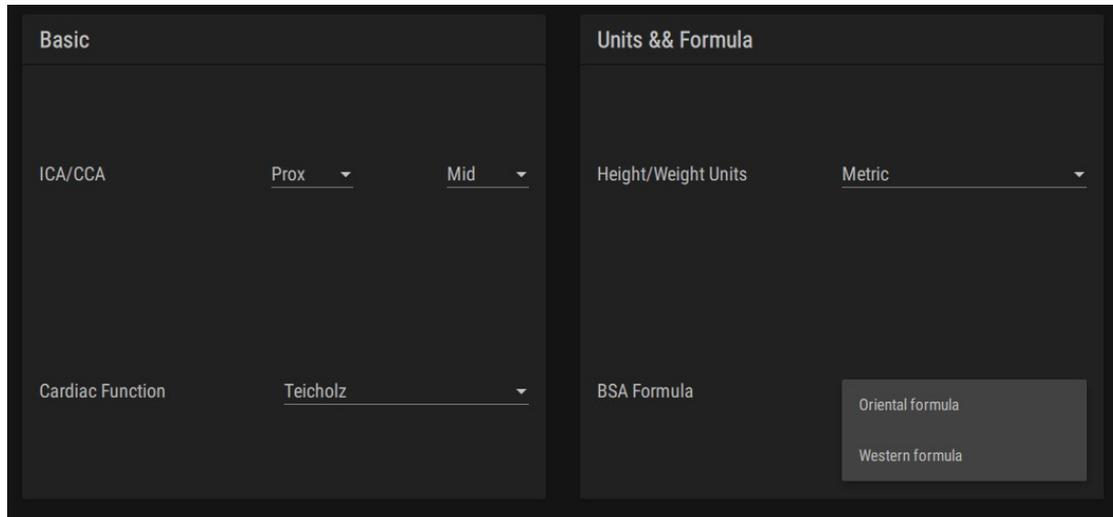
## BSA Formula (Body Surface Are)

*BSA is calculated by entering the patient's weight and height by using the "Patient" window, it will be involved in the calculation of CO (Cardiac Output) in package "Cardiology"*

BSA Formula can be set to Oriental formula or Western formula, and the following shows the contents of calculation formula:

Oriental:

Western:

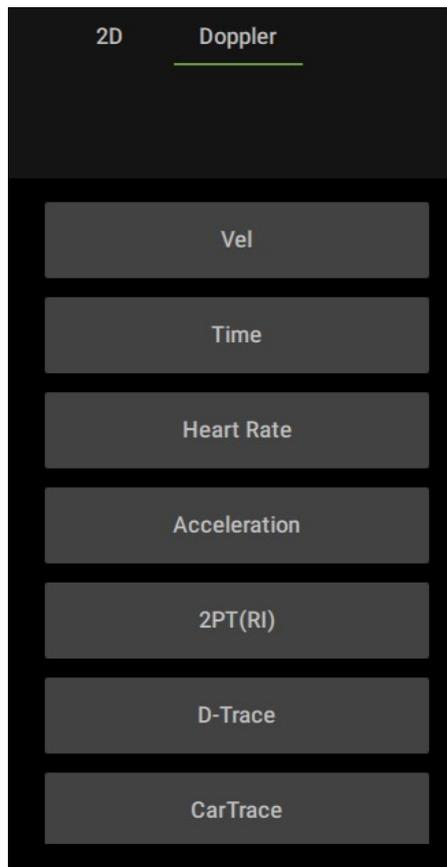
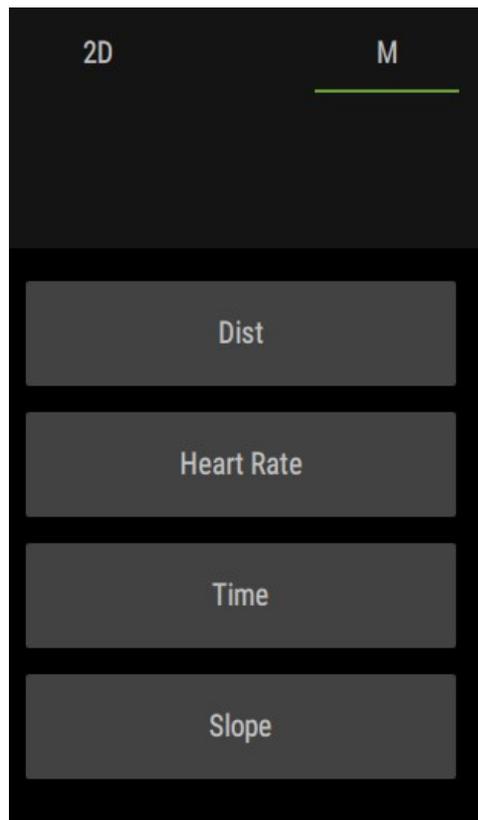
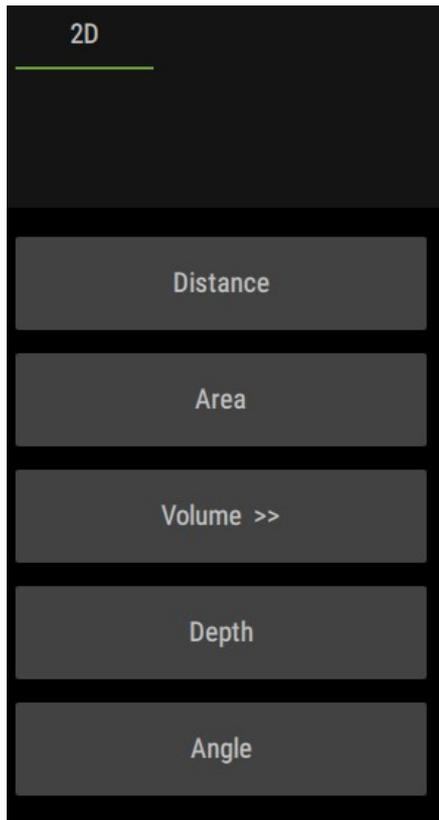


## 9.4 Generic Measurements

*The Generic studies provide you quick access to measurements such as volume, angle. This section describes generic measurements, organized by mode.*

### Introduction

1. Under Freeze mode, go to “**Scan**” page, and press “**Measure**” button.
2. Click the measurement ruler.



## B-Mode Measurements

In B-Mode, the Generic study includes the following measurements:

Type	Item	Description	Method
Measurement	Distance	/	2D Distance
	Area	/	Ellipse,Trace2D,Spline,CrossLine
	Volume	/	ThreeDist,EllipseDist
	Angle	/	Angle
	Depth	/	Depth

*Note: Piloter PE/P/S/B/F/R/RE/X do not support Color vel; Piloter PE/P/S/B/D/U/SE/i do not support Depth.*

## M-Mode Measurements

In M-Mode, the Generic study includes the following measurements:

Type	Item	Description	Method
Measurement	Distance	/	M Distance
	Heart Rate	/	M Heart Rate
	Time	/	M Time
	Slope	/	M Slope

## Doppler Mode Measurements

In D-Mode, the Generic study includes the following measurements:

Type	Item	Description	Method
------	------	-------------	--------

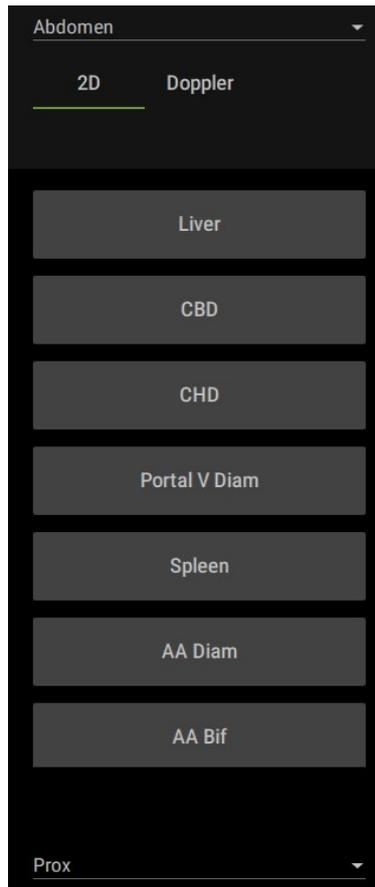
Type	Item	Description	Method
Measurement	Vel	Velocity	M Distance
	Time	/	M Heart Rate
	Heart Rate	/	M Time
	Acceleration	/	M Slope
	2PT(RI)	2 Point(Resistive Index)	2 Point
	D-Trace	Doppler Trace	Manual Trace, Semi-Auto Trace
	Car Trace	Cardiac Trace	Manual Trace, Semi-Auto Trace

## 9.5 Abdomen

*Describes how to perform Abdomen measurements and calculations.*

### Introduction

1. Under Freeze mode, go to “**Scan**” page, and press “**Calc**” button to start an application measurement.
2. Switch to <**Abdomen**> measurement library, and press the measurement item.



### **B-Mode Measurements**

The following measurements are located in the Exam Calcs for the Abdomen exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements (Liver, CBD, CHD, Portal V Diam, Gall Bladder study, Renal study, Pancreas study, Bladder study, Spleen, AA Diam, AA Bif, and CIA Diam) are listed on the following pages.

#### **Example:**

##### **Liver**

1. Select "**Liver**"; there is a high light green dotted line on the screen with two active rings on the end point of the line.
2. To measure the distance, there are two methods:
  - a. Press any point P on the image, the end which is closed to P will be moved to position P.
  - b. Drag any end point to position P in the image, and loose up, the end point will be moved to position P.
3. To complete the measurement, exit measurement mode or start another measurement.
4. The system displays the Liver value in the Results Window.

Type	Item	Description	Method
Measurement	Liver	Liver	2D Distance
	CBD	Common Bile Duct	
	CHD	Common Hepatic Duct	
	Portal V Diam	Portal Vein Diameter	
	GB L	Gall Bladder Length	
	GB H	Gall Bladder Height	
	GB W THK	Gall Bladder Wall Thickness	
	Renal L	Renal Length	
	Renal H	Renal Height	
	Renal W	Renal Width	
	Cortex	Cortex	
	Panc Duct	Pancreas Duct	
	Panc Head	Pancreas Head	
	Panc Body	Pancreas Body	
	Panc Tail	Pancreas Tail	
	Spleen	Spleen	
	Pre-V BL L	Pre-Void Bladder Length	
	Pre-V BL W	Pre-Void Bladder Width	
Pre-V BL H	Pre-Void Bladder Height		

Type	Item	Description	Method
	Post-V BL L	Post-Void Bladder Length	
	Post-V BL W	Post-Void Bladder Width	
	Post-V BL H	Post-Void Bladder Height	
	AA Diam	Abdomen Aorta Diameter	
	AA Bif	Abdomen Aorta Bif	
	CIA Diam	Common Iliac Artery Diameter	

*Note: Only Piloter Exp/S/B/D/R/RE/V/U support CIA Diam measurement.*

### **Doppler Mode Measurements**

The following measurements are located in the Exam Calcs for the Abdomen exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements (Abd Aorta, Celiac Trunk, SMA, Hepatic A, CBA, Splenic A, Main Renal A, Arcuate A, Segmental A, Interlobar A, SMV, Renal V, IVC, Portal V, Hepatic V, M Hepatic V, Splenic V) are listed on the following pages.

### **Artery Example:**

#### **Abd Aorta**

1. Select "**Abd Aorta**";
2. Click measure methods at measure method list: Two Point, Manual, and Semi-Auto.

#### **2PT (2 Point)**

- a. Choose "**Two Point**".
- b. There are two vertical lines and a horizon line on the screen, and there is one active ring at the junctions of the vertical line and horizon line. And there is an active ring on another vertical.
- c. To measure Doppler Tow Point (RI), drag the two rings to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement.

#### **Manual (Manual Trace)**

- a. Choose "**Manual**"
- b. There are one vertical line and one horizon line crossed, and there is a cross point at the junction.
- c. To confirm the start point, drag the cross point and loose up. The horizon line disappeared.
- d. To trace the spectrum, drag the cross point.  
Note: To erase the trace line, drag the cross point to the left direction.
- e. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

### **S-Auto (Semi-Auto Trace)**

- a. Choose "**Semi-Auto**"
- b. There are two vertical lines and one horizon line displayed on the screen.
- c. To trace the semi-auto spectrum, move the two vertical lines to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

Type	Item	Description	Method
Measurement	Abd Aorta	Abdomen Aorta	2 Point, Manual Trace, Semi-Auto Trace
	Celiac Trunk	Celiac Trunk	
	SMA	Superior Mesenteric Artery	
	Hepatic A	Hepatic Artery	
	CBA	Common Bile Artery	
	Splenic A	Splenic Artery	
	Main Renal A	Main Renal Artery	
	Arcuate A	Arcuate Artery	
	Segmental A	Segmental Artery	
	Interlobar A	Interlobar Artery	

Type	Item	Description	Method
	SMV	Superior Mesenteric Vein	Peak Velocity
	Renal V	Renal Vein	
	IVC	Inferior Vena Cava	
	Portal V	Portal Vein	
	Hepatic V	Hepatic Vein	
	M Hepatic V	Middle Hepatic Vein	
	Splenic V	Splenic Vein	

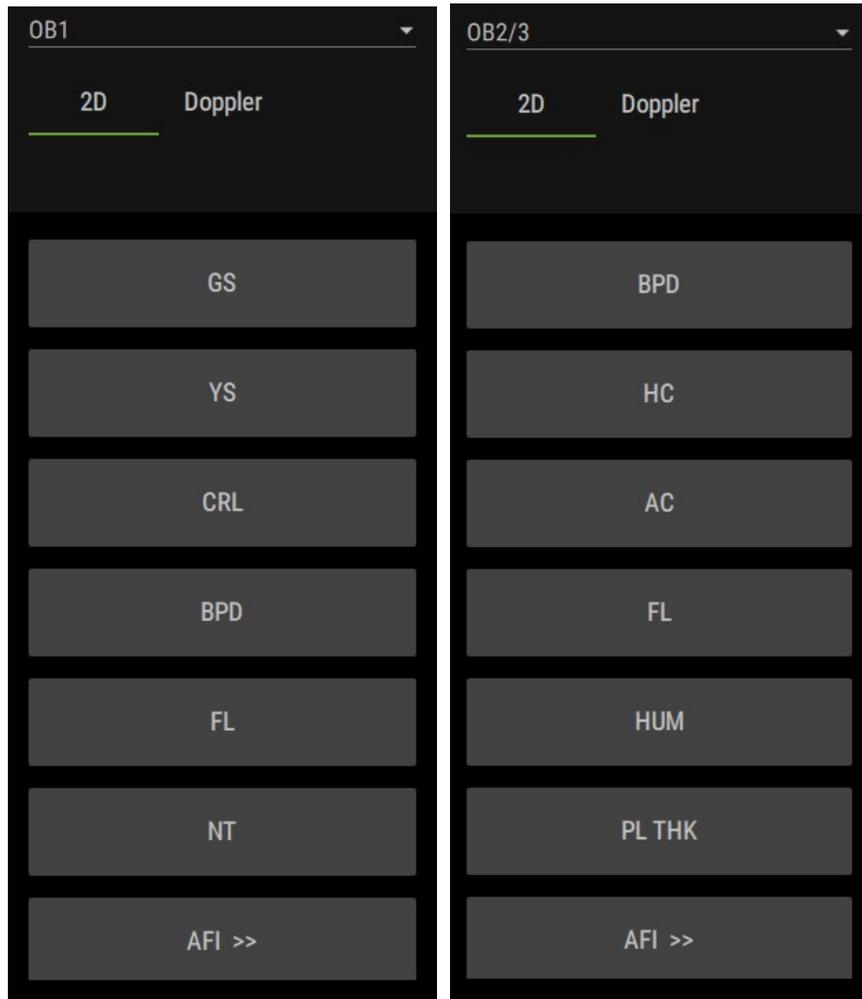
## 9.6 OB

*Describes how to perform OB measurements and calculations.*

*OB calculation package includes OB1, OB2/3.*

### Introduction

1. Under Freeze mode, go to “**Scan**” page, and press “**Calc**” button to start an application measurement.
2. Switch to <**OB1**> or <**OB2/3**> measurement library, and press the measurement item.



## B-Mode Measurements

The following measurements are located in the Exam Calcs for the OB exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements are listed on the following pages.

### Example:

#### BPD

To measure **BPD**, make one distance measurement:

1. Press "**BPD**"; an active caliper displays.
2. To measure the distance, there are two methods:
  - a. Press any point P on the image, the end which is closed to P will be moved to position P.
  - b. Drag any end point to position P in the image, and loose up, the end point will be moved to position P.
3. To complete the measurement, exit measurement mode or start another

measurement.

- The system displays the BPD value in the Results Window.

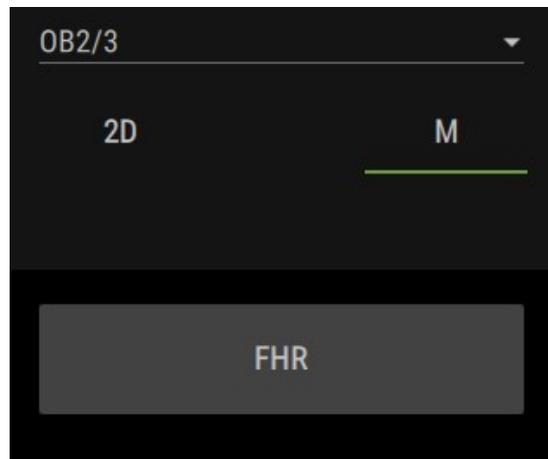
Type	Item	Description	Method
Measurement	GS	Gestational Sac Diameter	2D Distance
	YS	Yolk Sac	
	CRL	Crown Rump Length	
	NT	Nuchal Translucency	
	PL THK	Placental Thickness	
	BPD	Biparietal Diameter	
	OFD	Head Circumference	
	FL	Femur Length	
	AF1	Amniotic Fluid 1	
	AF2	Amniotic Fluid 2	
	AF3	Amniotic Fluid 3	
	AF4	Amniotic Fluid 4	
	TAD	Abdominal Transversal Diameter	
	APAD	Anteroposterior Abdominal Diameter	
	CEREB	Cerebral	
Cist Magna	Cist Magna		
LVW	Lateral Ventricle Width		

Type	Item	Description	Method	
	HEM	Hemisphere Width		
	EOD	External Orbital Diameter		
	IOD	Inter Orbital Diameter		
	HUM	Humerus Length		
	Ulna	Ulna Length		
	RAD	Radius Length		
	TIB	Tibia Length		
	FIB	Fibula Length		
	CLAV	Clavicle Length		
	Vertebra	Length of Vertebrae		
	Foot	Foot Length		
	Ear	Ear Length		
	APTD	Anteroposterior trunk diameter		
	TTD	Transverse trunk diameter		
	LVID	Left Ventricular Internal Diameter		
	RV	Right Ventricle		
	HC	Head Circumference		2D Area
	AC	Abdominal Circumference		

Type	Item	Description	Method
	FTA	Fetal Trunk Cross-sectional Area	
Study	AFI	/	
	Fetal Heart	/	
Calculation	AFI	Amniotic Fluid	$AFI = AF1 + AF2 + AF3 + AF4$
	FTA	Fetal Trunk Area	$FTA = \pi/4 * APTD * TTD$

### M-Mode Measurements

The following measurements are located in the Exam Calcs for the OB exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements are listed on the following pages.



Type	Item	Description	Method
Measurement	FHR	Fetal heart rate	M Heart Rate

### Doppler Measurements

The following measurements are located in the Exam Calcs for the OB exam category. Some measurements are only available in certain Exam Calcs. Those specific

measurements are listed on the following pages.

Type	Item	Description	Method
Measurement	FHR	Fetal Heart Rate	M Heart Rate
	Umb A	Umbilical Artery	2 Point, Manual Trace, Semi-Auto Trace
	Ductus V	Ductus Venous	
	Placenta A	Placenta Artery	
	MCA	Middle Cerebral Artery	
	Fetal Aorta	Fetal Aorta	
	Desc Aorta	Descending Aorta	
	Uterus A	Uterus Artery	
	Ovary A	Ovary Artery	

### Artery Example:

#### Umbilical Aorta

1. Select "Umb **Aorta**";
2. Click measure methods at measure method list: Two Point, Manual, and Semi-Auto.

#### 2PT (2 Point)

- a. Choose "**Two Point**".
- b. There are two vertical lines and a horizon line on the screen, and there is one active ring at the junctions of the vertical line and horizon line. And there is an active ring on another vertical.
- c. To measure Doppler Tow Point (RI), drag the two rings to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement.

#### Manual (Manual Trace)

- a. Choose "**Manual**".
- b. There are one vertical line and one horizon line crossed, and there is a cross point at the junction.
- c. To confirm the start point, drag the cross point and loose up. The horizon line

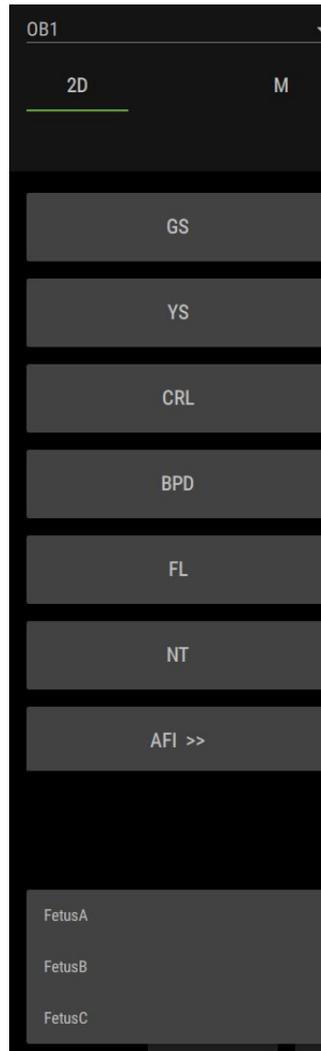
- disappeared.
- d. To trace the spectrum, drag the cross point.  
Note: To erase the trace line, drag the cross point to the left direction.
  - e. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

### **S-Auto (Semi-Auto Trace)**

- a. Choose "**Semi-Auto**"
- b. There are two vertical lines and one horizon line displayed on the screen.
- c. To trace the semi-auto spectrum, move the two vertical lines to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

### **More than one fetus**

The System will mark each fetus during process of measurement and calculations. For example, fetus A marks the first tile, fetus B marks the second tile, and fetus C marks the third tile.



### **To identify a fetus**

For measurements, calculations, to switch the fetus, please do the following operations:

1. Select a measurement of OB mode, press fetus list, and choose the corresponding fetus.

### **Ultrasound GA**

Ultrasound GA and ultrasound EDD are calculated according to the parameters obtained in measurements.

- GA in OB Items
- AUA (Average Ultrasound Age)

### **Estimated Fetal Weight Calculation (EFW)**

EFW is a calculation item. If all tools required for EFW formula have been performed, EFW will be obtained automatically. The system will recalculate the EFW after new measurements are completed.

The Fetal Weight formulas are shown in the following table:

Formulas	Descriptions	Units	
		EFW	item
Hadlock	$FW = 10^{(1.1134 + 0.05845 \times AC - 0.000604 \times AC^2 - 0.007365 \times BPD^2 + 0.000595 \times BPD \times AC + 0.1694 \times BPD)}$	g	cm
Merz	$FW = -3200.40479 + 157.07186 \times AC + 15.90391 \times BPD^2$	g	cm
Shepard	$FW = 10^{(-1.7492 + 0.166 \times BPD + 0.046 \times AC - 0.002646 \times AC \times BPD)} \times 1000$	g	cm
	SD=0.2120*EFW		
Campbell	$FW = e^{(-4.564 + 0.282 \times AC - 0.00331 \times AC^2)} \times 1000$	g	cm
	SD=0.146*EFW      SD Type= ± 2SD		
Hadlock4	$FW = 10^{(1.3596 - 0.00386 \times AC \times FL + 0.0064 \times HC + 0.00061 \times BPD \times AC + 0.0424 \times AC + 0.174 \times FL)}$	g	cm
	SD=0.146*EFW      SD Type= ± 2SD		
Hadlock3	$FW = 10^{(1.326 - 0.00326 \times AC \times FL + 0.0107 \times HC + 0.0438 \times AC + 0.158 \times FL)}$	g	cm
	SD=0.148*EFW      SD Type= ± 2SD		
Hadlock2	$FW = 10^{(1.335 - 0.0034 \times AC \times FL + 0.0316 \times BPD + 0.0457 \times AC + 0.1623 \times FL)}$	g	cm
	SD=0.146*EFW      SD Type= ± 2SD		
Hadlock1	$FW = 10^{(1.304 + 0.05281 \times AC + 0.1938 \times FL - 0.004 \times AC \times FL)}$	g	cm
	SD=0.154*EFW      SD Type= ± 2SD		

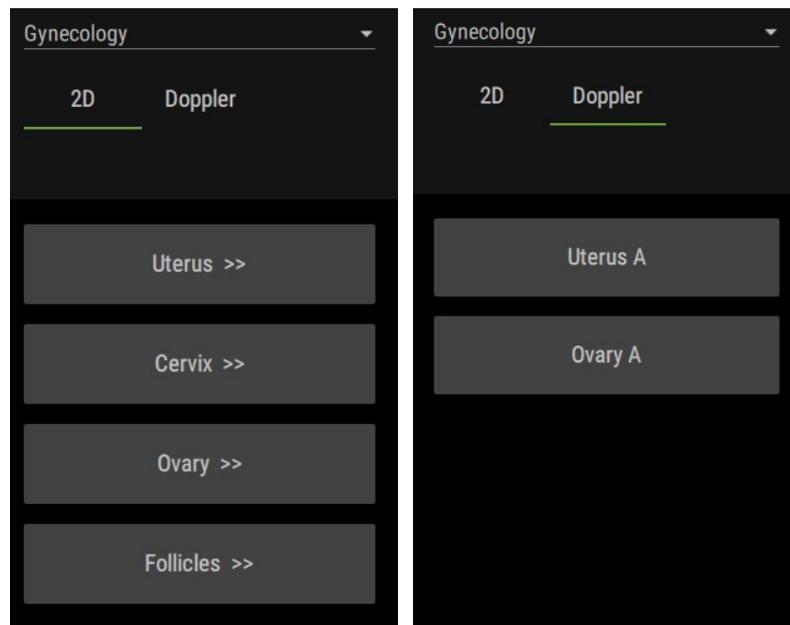
Tokyo	$FW = 1.07 \times BPD^3 + 3.42 \times APTD \times TTD \times FL$	g	cm
Osaka	$FW = 6.3 + 1.25647 \times BPD^3 + 3.50665 \times FTA \times FL$	g	cm
Hansmann	$FW = (-1.05775 \times BPD + 0.649145 \times TTD + 0.0930707 \times BPD^2 - 0.020562 \times TTD^2 + 0.515263) \times 1000$	g	cm

## 9.7 Gynecology

*Describes how to perform Gynecology measurements and calculations.*

### Introduction

1. Under Freeze mode, go to “**Scan**” page, and press “**Calc**” button to start an application measurement.
2. Switch to <**Gynecology**> measurement library, and press the measurement item.



### B-Mode Measurements

The following measurements are located in the Exam Calcs for the Gynecology exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements are listed on the following pages.

### Example:

9-44Measurement

## Uterus length, width, and height

Each of these is a standard distance measurement. Typically, length and height are measured on the sagittal plane while the width is measured on the transverse plane.

To measure uterus length, width, or height:

1. Scan the patient in the appropriate scan plane.
2. Select the **Uterus** study, then select **UT L**, **UTW**, or **UT H**.

An active caliper displays.

3. To measure the distance, there are two methods:
  - a. Press any point P on the image, the end which is closed to P will be moved to position P.
  - b. Drag any end point to position P in the image, and loose up, the end point will be moved to position P.
4. To complete the measurement, exit measurement mode or start another measurement. The system displays the UTL value in the Results Window.
5. To measure the second and the third measurement, please repeat step 2~4. After finishing the three measurement, there will be Uterus Volume calculated in the result window.

Type	Item	Description	Method
Measurement	UT L	Uterine Length	2D Distance
	UT W	Uterine Width	
	UT H	Uterine Height	
	Endo	Endometrium Thickness	
	Ovary L	Ovary Length	
	Ovary W	Ovary Width	
	Ovary H	Ovary Height	
	Cervix L	Uterine Cervix Length	
	Cervix W	Uterine Cervix Width	

Type	Item	Description	Method
	Cervix H	Uterine Cervix Height	
	Follicle1	Follicle1	Follicle
	Follicle2	Follicle2	
	Follicle3	Follicle3	
	Follicle4	Follicle4	
	Follicle5	Follicle5	
	Follicle6	Follicle6	
	Follicle7	Follicle7	
	Follicle8	Follicle8	
	Follicle9	Follicle9	
	Follicle10	Follicle10	
	Follicle11	Follicle11	
	Follicle12	Follicle12	
	Follicle13	Follicle13	
	Follicle14	Follicle14	
	Follicle15	Follicle15	
	Follicle16	Follicle16	

### Doppler Mode Measurements

The following measurements are located in the Exam Calcs for the Gynecology exam

9-46Measurement

category. Some measurements are only available in certain Exam Calcs.

Type	Item	Description	Method
Measurement	Uterus A		2 Point, Manual Trace, Semi-Auto Trace
	Ovary A		

## Artery Example:

### Uterus Aorta

1. Select "**Uterus Aorta**";
2. Click measure methods at measure method list: Two Point, Manual, and Semi-Auto.

### 2PT (2 Point)

- a. Choose "**Two Point**".
- b. There are two vertical lines and a horizon line on the screen, and there is one active ring at the junctions of the vertical line and horizon line. And there is an active ring on another vertical.
- c. To measure Doppler Tow Point (RI), drag the two rings to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement.

### Manual (Manual Trace)

- a. Choose "**Manual**".
- b. There are one vertical line and one horizon line crossed, and there is a cross point at the junction.
- c. To confirm the start point, drag the cross point and loose up. The horizon line disappeared.
- d. To trace the spectrum, drag the cross point.  
Note: To erase the trace line, drag the cross point to the left direction.
- e. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

### S-Auto (Semi-Auto Trace)

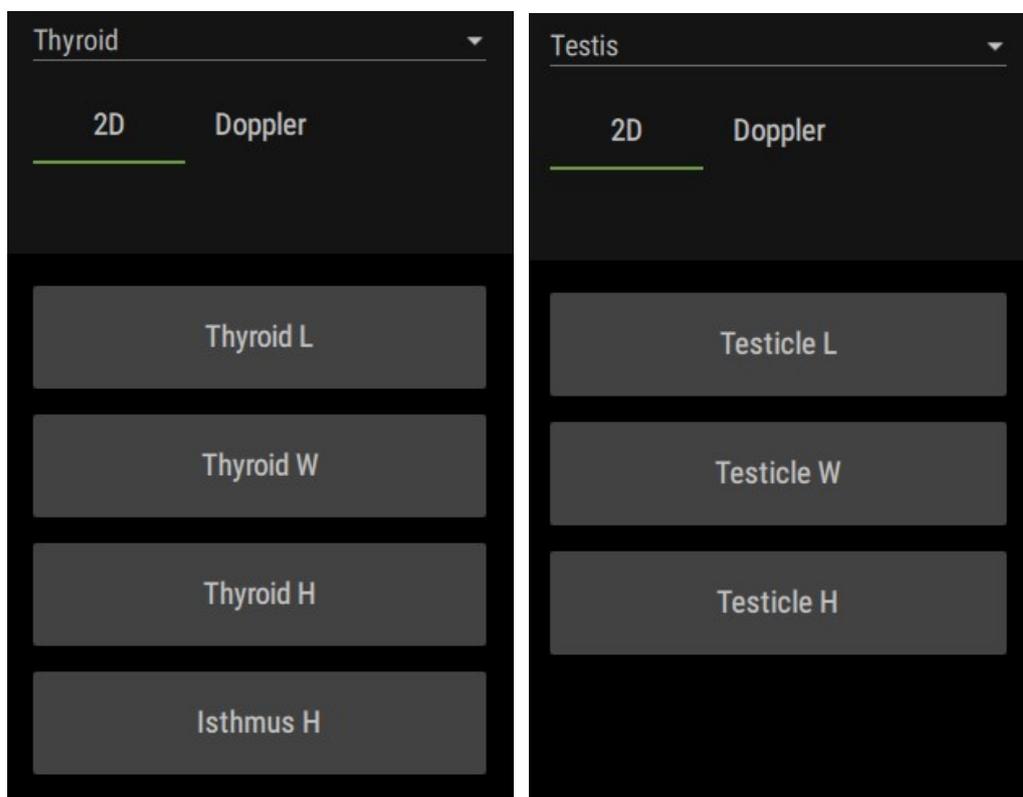
- a. Choose "**Semi-Auto**".
- b. There are two vertical lines and one horizon line displayed on the screen.
- c. To trace the semi-auto spectrum, move the two vertical lines to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

## 9.8 Small Parts

*Describes how to perform Small Parts measurements and calculations.*

### Introduction

1. Under Freeze mode, go to “**Scan**” page, and press “**Calc**” button to start an application measurement.
2. Switch to <**Thyroid**> or <**Testis**> measurement library, and press the measurement item.



### B-Mode Measurements

The following measurements are located in the Exam Calcs for the Small Parts exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements (Thyroid study, Testis study) are listed on the following pages.

#### Example:

##### Thyroid length, width, and height

Each of these is a standard distance measurement. Length and height are typically measured in the sagittal plane. Width is measured in the transverse plane.

1. Select the appropriate orientation (side): **"Right"** or **"Left"**.
2. Select **"Thyroid L, Thyroid W, or Thyroid H"**. An active caliper displays.
3. To measure the distance, there are two methods:
  - a. Press any point P on the image, the end which is closed to P will be moved to position P.
  - b. Drag any end point to position P in the image, and loose up, the end point will be moved to position P.
4. To complete the measurement, exit measurement mode or start another measurement. The system displays the Thyroid L value in the Results Window.
5. To measure the second and the third measurement, please repeat step 2~4. After finishing the three measurement, there will be Thyroid Volume calculated in the result window.

Type	Item	Description	Method
Measurement	Thyroid L	Thyroid Length	2D Distance
	Thyroid H	Thyroid Height	
	Thyroid W	Thyroid Width	
	Isthmus H	Isthmus H	
	Testicle L	Testicle Length	
	Testicle H	Testicle Height	
	Testicle W	Testicle Width	

### Doppler Mode Measurements

The following measurements are located in the Exam Calcs for the Abdomen exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements (STA, ITA) are listed on the following pages.

### Artery Example:

#### STA

1. Select **"STA"**; an active caliper displays.
2. Click measure methods at measure method list: Two Point, Manual, and Semi-Auto.

#### 2PT (2 Point)

- a. Choose **"Two Point"**.
- b. There are two vertical lines and a horizon line on the screen, and there is one active Measurement9-49

- ring at the junctions of the vertical line and horizon line. And there is a active ring on another vertical.
- c. To measure Doppler Tow Point (RI), drag the two rings to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement.

**Manual (Manual Trace)**

- a. Choose “**Manual**”
- b. There are one vertical line and one horizon line crossed, and there is a cross point at the junction.
- c. To confirm the start point, drag the cross point and loose up. The horizon line disappeared.
- d. To trace the spectrum, drag the cross point.  
Note: To erase the trace line, drag the cross point to the left direction.
- e. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

**S-Auto (Semi-Auto Trace)**

- a. Choose “**Semi-Auto**”
- b. There are two vertical lines and one horizon line displayed on the screen.
- c. To trace the semi-auto spectrum, move the two vertical lines to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

Type	Item	Description	Method
Measurement	STA	Superior Thyroid Artery	2 Point, Manual Trace, Semi-Auto Trace
	ITA	Inferior Thyroid Artery	

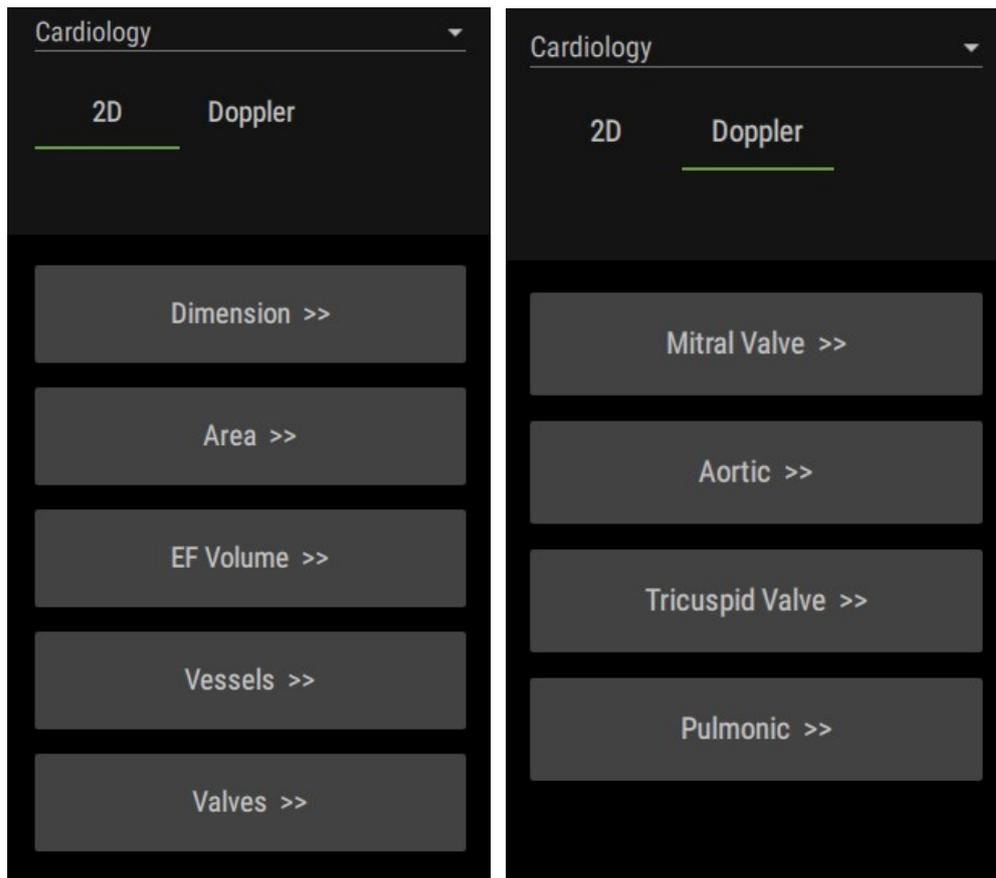
## 9.9 Cardiology

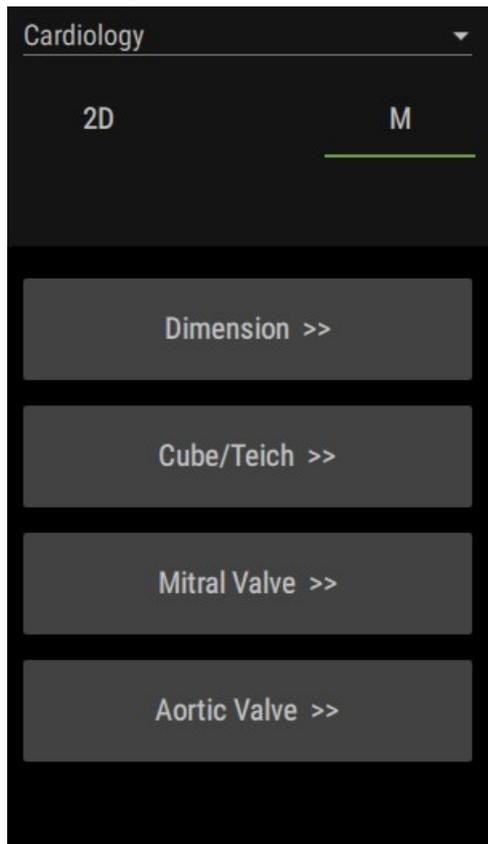
*Describes how to perform Cardiac measurements and calculations.*

**Introduction**

- 1. Under Freeze mode, go to “**Scan**” page, and press “**Calc**” button to start an application measurement.

2. Switch to <Cardiology> measurement library, and press the measurement item.





### B-Mode Measurements

The following measurements are located in the Exam Calcs for the Cardiology exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements are listed on the following pages.

#### Example:

##### LA Diam

1. Select "**LA Diam**"; an active caliper displays.
2. To measure the distance, there are two methods:
  - a. Press any point P on the image, the end which is closed to P will be moved to position P.
  - b. Drag any end point to position P in the image, and loose up, the end point will be moved to position P.
3. To complete the measurement, exit measurement mode or start another measurement.
4. The system displays the LA Diam value in the Results Window.

Type	Item	Description	Method
Measurement	RVAWd	Right Ventricle Anterior Wall	2D Distance

Type	Item	Description	Method
		end-diastole	
	RVIDd	Right Ventricle Anterior Wall end-systole	
	IVSd	Interventricular Septal Thickness at end-diastole	
	LVIDd	Left Ventricular Internal Diameter at end-diastole	
	LVPWd	Left Ventricular Posterior wall thickness at end-diastole	
	IVSs	Interventricular Septal Thickness at end-systole	
	LVIDs	Left Ventricular Internal Diameter at end- systole	
	LVPWs	Left Ventricular Posterior wall thickness at end- systole	
	LA Diam	Left Atrium Diameter	
	Ao Root Diam	Aorta Root Diameter	
	LVOT Diam	Left Ventricular Outflow Tract Diameter	
	RVOT Diam	Right Ventricular Outflow Tract Diameter	
	Ao st junct	Aorta ST junct Diameter	
	Asc Ao Diam	Ascending Aorta Diameter	

Type	Item	Description	Method
	Ao Arch Diam	Aorta arch Diameter	
	Desc Ao Diam	Descending Aorta Diameter	
	MPA Diam	Main pulmonary Artery Diameter	
	LPA Diam	Left pulmonary Artery Diameter	
	RPA Diam	Right pulmonary Artery Diameter	
	LCA Diam	Left Coronary Artery Diameter	
	RCA Diam	Right Coronary Artery Diameter	
	IVC Diam	Inferior Vena Cava Diameter	
Measurement	IVC Ins Diam	Inferior vena cava inspiration Diameter	2D Distance
	IVC Exp Diam	Inferior vena cava expiration Diameter	
	MV Diam	Mitral Valve Diameter	
	EPSS	Distance between point E and Interventricular Septum when mitral valve is fully open	
	AV Diam	Aortic Valve Diameter	
	AV Cusp Sep	Aortic Valve Cusp Separation	

Type	Item	Description	Method
	TV Diam	Tricuspid Valve Diameter	
	PV Diam	Pulmonic Valve Diameter	
	EDA	End-Diastole Area	2D Area
	ESA	End-Systole Area	
	MVA	Mitral Valve Area	
	AVA	Aortic Valve Area	
	TVA	Tricuspid Valve Area	
	PVA	Pulmonic Valve Area	
	LA Area	Left Atrium Area	
	RA Area	Right Atrium Area	
Study	Simpson	/	/
	Mod. Simpson	/	
	Cube/Teich	/	

### M-Mode Measurements

The following measurements are located in the Exam Calcs for the Abdomen exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements are listed on the following pages.

Type	Item	Description	Method
Measurement	RVAWd	Right Ventricle Anterior Wall end-diastole	M Distance
	RVIDd	Right Ventricle Anterior Wall	

Type	Item	Description	Method
		end-systole	
	IVSd	Interventricular Septal Thickness at end-diastole	
	LVIDd	Left Ventricular Internal Diameter at end-diastole	
	LVPWd	Left Ventricular Posterior wall thickness at end-diastole	
	IVSs	Interventricular Septal Thickness at end-systole	
	LVIDs	Left Ventricular Internal Diameter at end- systole	
	LVPWs	Left Ventricular Posterior wall thickness at end- systole	
	LA Diam	Left Atrium Diameter	
	Ao Root Diam	Aorta Root Diameter	
	EPSS	Distance between point E and Interventricular Septum when mitral valve is fully open	
	MV Cusp Sep	Mitral Valve Cusp Separation	
	AV Cusp Sep	Aortic Valve Cusp Separation	
	LVET	Left Ventricle Ejection Time	
	LVPEP	Left Ventricle Pre-Ejection Period	
			M Distance
			M Time

Type	Item	Description	Method
	MV D-E Exc	Mitral valve D-E excursion	M Slope
	MV C-O Dur	Mitral valve C-O Duration	
	MV D-E Slope	Mitral valve D-E Slope	
	MV E-F Slope	Mitral valve E-F Slope	
Study	Cube/Teich	/	

### Doppler Measurements

The following measurements are located in the Exam Calcs for the Cardiology exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements are listed on the following pages.

Type	Item	Description	Method
Measurement	MV VTI	/	Trace
	MR VTI	/	
	LVOT VTI	/	
	AV VTI	/	
	AR VTI	/	
	TV VTI	/	
	RVOT VTI	/	
	PV VTI	/	
Measurement	MV PHT	/	PHT

Type	Item	Description	Method
	AV(PHT)	/	
	AR PHT	/	
	PVA(PHT)	/	
	MR Vmax	/	Single Point Velocity
	LVOT Vmax	/	
	AV Vmax	/	
	AAo Vmax	/	
	DAo Vmax	/	
	TV Vmax	/	
	PV Vmax	/	
	MPA Vmax	/	
	RPA Vmax	/	
	LPA Vmax	/	
	MV Dec Time	/	
	AV Acc Time	/	
	AV Dec Time	/	
	PV Acc Time	/	

**Study Operations**  
**Left Ventricular Function**

A group of measurements is to estimate LV Function at diastole and systole phase under B and M mode, with calculations list as following:

Calc Item	Description	Formulas
SV	Stroke Volume	$SV(ml) = EDV(ml) - ESV(ml)$
CO	Cardiac Output	$CO(l/min) = SV(ml) \times HR(bpm) / 1000$
EF	Ejection Fraction	$EF(\%) = SV(ml) / EDV(ml)$
SI	SV Index	$SI(\text{No unit}) = SV(ml) / \text{Body Surface Area (m}^2)$
CI	CO Index	$CI(\text{No unit}) = CO(l/min) / \text{Body Surface Area (m}^2)$
FS	Fractional Shortening	$FS(\text{No unit}) = (LVIDd(\text{mm}) - LVIDs[\text{mm}]) / LVIDd(\text{mm})$
MVCF	Mean Velocity of Circ Fiber Shortening	$MVCF = (LVIDd(\text{mm}) - LVIDs(\text{mm})) / (LVIDd(\text{mm}) \times LVET(\text{ms}) / 1000)$

### Cube

- Study Items

Measure Items	Description	Method
Diastole	Diastole Measurement	3 Consecutive Line
Systole	Systole Measurement	3 Consecutive Line
LVIDd	Left Ventricular Internal Diameter at end- diastole	2D Distance

LVIDs	Left Ventricular Internal Diameter at end- systole	2D Distance
-------	--	-------------

● Study Result

Result	Description	Formulae
IVSd	Interventricular Septal Thickness at end-diastole	/
LVIDd	Left Ventricular Internal Diameter at end-diastole	/
LVPWd	Left Ventricular Posterior wall thickness at end-diastole	/
IVSs	Interventricular Septal Thickness at end-systole	/
LVIDs	Left Ventricular Internal Diameter at end- systole	/
LVPWs	Left Ventricular Posterior wall thickness at end- systole	/
EDV(Cube)	End-diastolic Left Ventricular Volume	$EDV(ml) = LVIDd(cm)^3$
ESV(Cube)	End-systolic Left Ventricular Volume	$ESV(ml) = LVIDs(cm)^3$
SV(Cube)	Stroke Volume	See LV Function part
CO(Cube)	Cardiac Output	
EF(Cube)	Ejection Fraction	

FS(Cube)	Fractional Shortening	
MVCF(Cube)	Mean Velocity of Circumferential Fiber Shortening	
SI(Cube)	SV Index	
CI(Cube)	CO Index	
LV Mass(Cube)	Left Ventricular Mass	$\text{LV Mass (g)} = 1.04 \times ((\text{LVPWd(cm)} + \text{IVSd(cm)} + \text{LVIDd(cm)})^3 - \text{LVIDd(cm)}^3) - 13.6$

### Mod. Simpson

- Study Items

Measure Items	Description	Method
LVLd apical	Left Ventricular Long-axis Length at End-diastole in apical view	2D Distance
LVLs apical	Left Ventricular Long-axis Length at End-systole in apical view	2D Distance
LVA <sub>d</sub> sax MV	Left Ventricular Area at Mitral Valve level at End-diastole in Short-axis view	2D Area
LVA <sub>s</sub> sax MV	Left Ventricular Area at Mitral Valve level at End-systole in Short-axis view	2D Area
LVA <sub>d</sub> sax PM	Left Ventricular Area at Papillary Muscle level at end-diastole in short axis view	2D Area
LVA <sub>s</sub> sax PM	Left Ventricular Area at Papillary Muscle level at end-systole in short axis view	2D Area

- Study Result

Result	Description	Formulae
EDV	End-diastolic Left Ventricular Volume	A*
ESV	End-systolic Left Ventricular Volume	B*
SV	Stroke Volume	LV Function part See LV Function part
CO	Cardiac Output	
EF	Ejection Fraction	
SI	SV Index	
CI	CO Index	

A\* stands for:

B\* stands for:

#### Operating Procedures

1. In **Calc Menu**->“**EF Volume**”->“**Mod. Simpson**”

2. At view of Apical Long-Aixs, measure

LVLd Apical

LVLs Apical

3. At short-axis view at mitral valve level, measure

LVA<sub>d</sub> sax MV

LVA<sub>s</sub> sax MV

4. At short-axis view at papillary muscle level, measure

LVA<sub>d</sub> sax PM

LVA's sax PM

5. Finally, all results in above table will show up

### **Mitral Valve Area (MVA)**

- Study Items

Measure Items	Description	Method
LVOT Diam	Left Ventricular Outflow Tract Diameter	2D Distance
LVOT VTI	Left Ventricular Outflow Tract Velocity-Time Integral	D Trace
MV VTI	Mitral Valve Velocity-Time Integral	D Trace

- Study Result

Except above measurement result, also the calc result are shown as follow:

Result	Description	Formulae
MVA	Mitral Valve Area	

### **Aortic Valve Area (AVA)**

- Study Items

Measure Items	Description	Method
LVOT Diam	Left Ventricular Outflow Tract Diameter	2D Distance
LVOT VTI	Left Ventricular Outflow Tract Velocity-Time Integral	D Trace
AV VTI	Aortic Valve Velocity-Time Integral	D Trace

- Study Result

Except above measurement result, also the calc result are shown as follow:

Result	Description	Formulae
AVA	Aortic Valve Area	

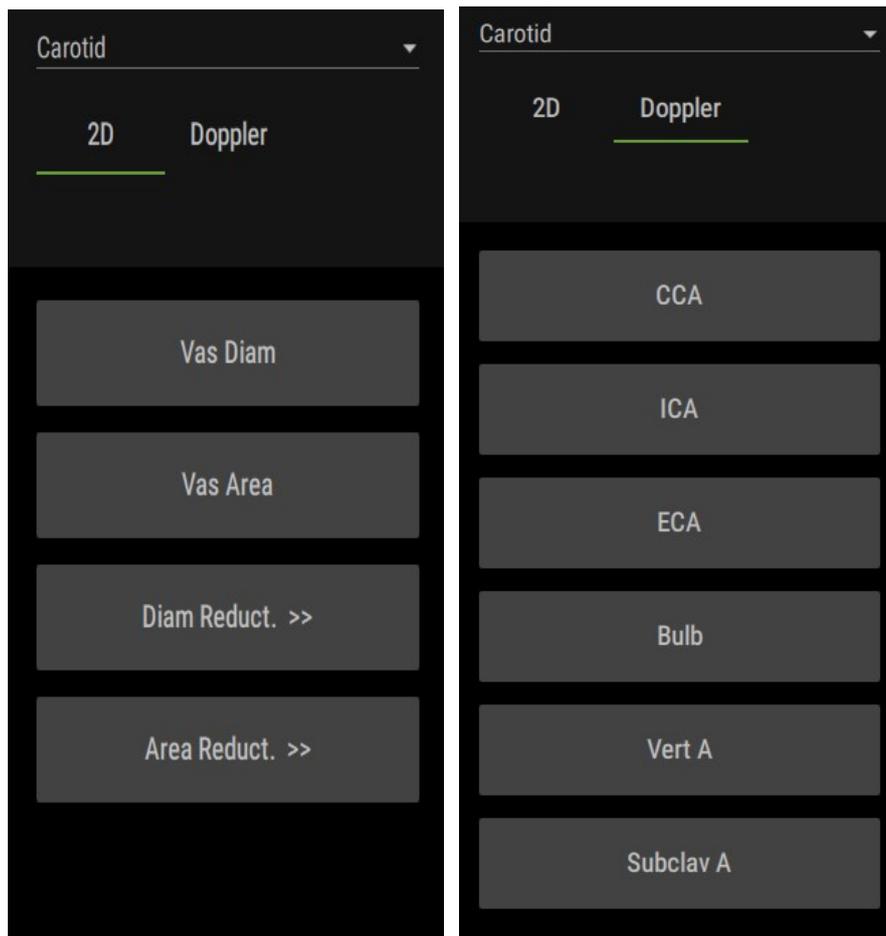
## 9.10 Vascular

*Describes how to perform vascular measurements and calculations.*

*Vascular calculation package includes Carotid, LEA, LEV, UEA, UEV, and TCD.*

### Introduction

1. Under Freeze mode, go to “**Scan**” page, and press “**Calc**” button to start an application measurement.
2. Switch to <**Vascular**> measurement library, and press the measurement item.



### B-Mode Measurements

9-64Measurement

The following measurements are located in the Exam Calcs for the Abdomen exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements (Vas Diam, Vas Area, Diam Reduction, and Area Reduction) are listed on the following pages.

### Example:

#### Vas Diam

1. Select "**Vas Diam**"; an active caliper displays.
2. To measure the distance, there are two methods:
  - a. Press any point P on the image, the end which is closed to P will be moved to position P.
  - b. Drag any end point to position P in the image, and loose up, the end point will be moved to position P.
3. To complete the measurement, exit measurement mode or start another measurement.
4. The system displays the Vas Diam value in the Results Window.

Type	Item	Description	Method
Measurement	Vas Diam	Vascular Diameter	2D Distance
	Diam Resid	Diameter Residue	
	Diam True	Diameter True	
	Vas Area	Vascular Area	2D Area
	Area Resid	Area Residue	
	Area True	Area True	
Calculation	Diam Reduct.	Diameter Reduction	$\text{Diam Reduct} = (\text{Diam True} - \text{Diam Resid}) / \text{Diam True}$
	Area Reduct.	Area Reduction	$\text{Area Reduct} = (\text{Area True} - \text{Area Resid}) / \text{Area True}$

#### Doppler Mode Measurements

The following measurements are located in the Exam Calcs for the Abdomen exam

category. Some measurements are only available in certain Exam Calcs. Those specific measurements are listed on the following pages.

### Artery Example:

#### STA

1. Select "**CCA**"; an active caliper displays.
2. Click measure methods at measure method list: Two Point, Manual, and Semi-Auto.

#### 2PT (2 Point)

- a. Choose "**Two Point**".
- b. There are two vertical lines and a horizon line on the screen, and there is one active ring at the junctions of the vertical line and horizon line. And there is a active ring on another vertical.
- c. To measure Doppler Tow Point(RI), drag the two rings to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement.

#### Manual (Manual Trace)

- a. Choose "**Manual**".
- b. There are one vertical line and one horizon line crossed, and there is a cross point at the junction.
- c. To confirm the start point, drag the cross point and loose up. The horizon line disappeared.
- d. To trace the spectrum, drag the cross point.  
Note: To erase the trace line, drag the cross point to the left direction.
- e. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

#### S-Auto (Semi-Auto Trace)

- a. Choose "**Semi-Auto**".
- b. There are two vertical lines and one horizon line displayed on the screen.
- c. To trace the semi-auto spectrum, move the two vertical lines to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

Type	Item	Description	Method
Measurement	CCA	Common Carotid Artery	2 Point, Manual Trace, Semi-Auto Trace
	ICA	Internal Carotid Artery	

Type	Item	Description	Method
	ECA	External Carotid Artery	
	Bulb	Bulb	
	Vert A	Vertebral Artery	
	Subclav A	Subclavian Artery	
	Axill A	Axillary Artery	
	Brachial A	Brachial Artery	
	Ulnar A	Ulnar Artery	
	Radial A	Radial Artery	
	Innomi A	Innominate Artery	
	C.Iliac A	Common Iliac Artery	
	IIA	Internal Iliac Artery	
	Ex.Iliac A	External Iliac Artery	
	CFA	Common Femoral Artery	
	PFA	Profound Femoral Artery	
	SFA	Superficial Femoral Artery	
	Pop A	Popliteal Artery	
	TP Trunk A	Tibioperoneal Trunk Artery	
	Peroneal A	Peroneal Artery	
	P. Tib A	Posterior Tibial Artery	

Type	Item	Description	Method
	A. Tib A	Anterior Tibial Artery	
	Dors. Ped A	Dorsalis Pedis Artery	
Measurement	Subclav V	Subclavian Vein	Peak Velocity
	Axill V	Axillary Vein	
	Cephalic V	Cephalic Vein	
	Basilic V	Basilic Vein	
	Brachial V	Brachial Vein	
	Ulnar V	Ulnar Vein	
	Radial V	Radial Vein	
	C.Iliac V	Common Iliac Vein	
	IIV	Internal Iliac Vein	
	Ex.Iliac V	External Iliac Vein	
	Femoral V	Femoral Vein	
	CFV	Common Femoral Vein	
Measurement	SFV	Superficial Femoral Vein	Peak Velocity
	PFV	Profound Femoral Vein	
	Saph V	Saphenous Vein	
	SSV	Small Saphenous Vein	
	Pop V	Popliteal Vein	

## **Operation procedures:**

### **Artery**

1. Select desired Artery in Calc Menu
2. Adjust method used for measurement
3. Finish measurement, then related measurement results will appear.

### **Vein**

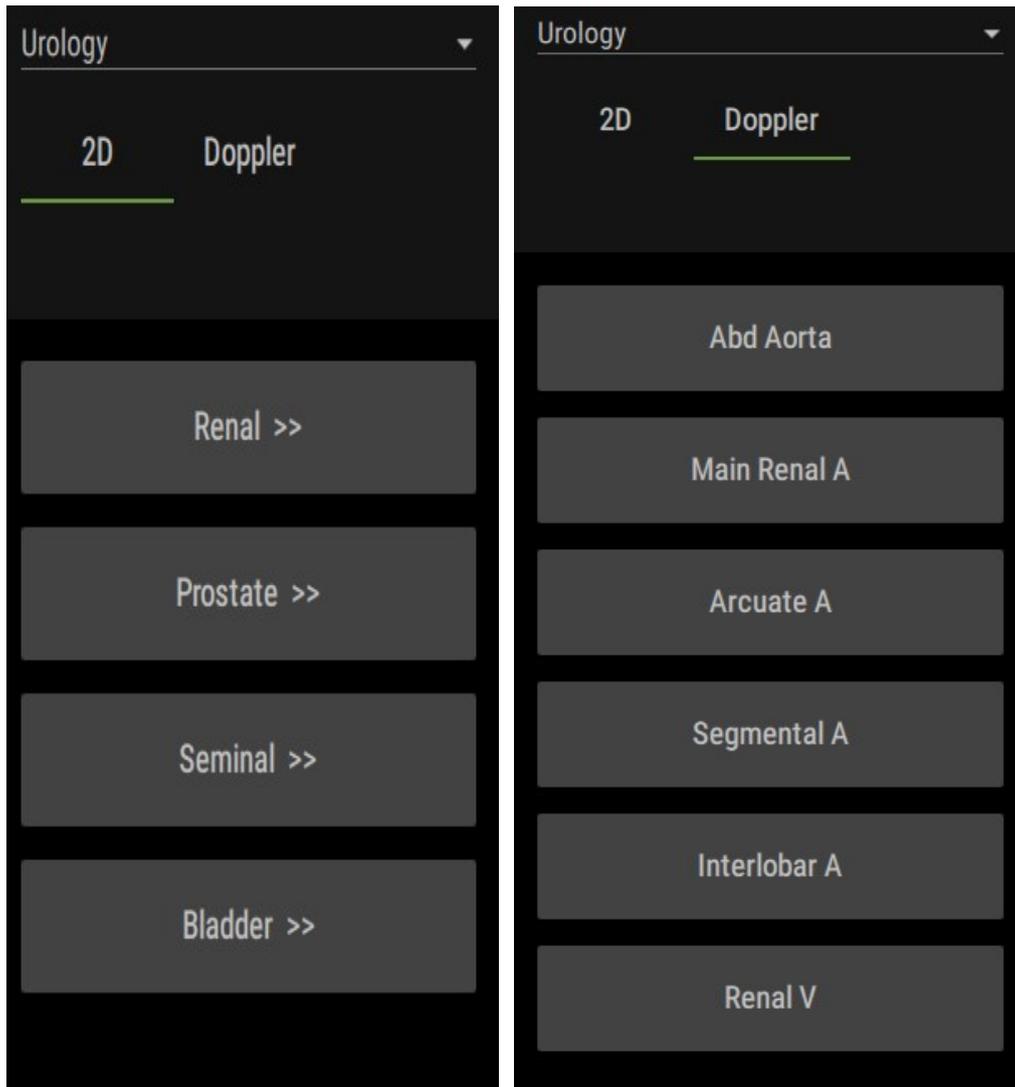
1. Select desired Vein in Calc Menu
2. Finish measurement, then related measurement results will appear.

## **9.11 Urology**

*Describes how to perform Urology measurements and calculations.*

### **Introduction**

1. Under Freeze mode, go to “**Scan**” page, and press “**Calc**” button to start an application measurement.
2. Switch to <**Urology**> measurement library, and press the measurement item.



### **B-Mode Measurements**

The following measurements are located in the Exam Calcs for the Urology exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements (Renal study, Prostate study, Adrenal study, Seminal study, Bladder study) are listed on the following pages.

#### **Example:**

##### **Renal length, width, and height**

Each of these is a standard distance measurement. Length and height are typically measured in the sagittal plane. Width is measured in the transverse plane.

1. Select the appropriate orientation (side): "**Right**" or "**Left**".
2. Select "**Renal L**, **Renal W**, or **Renal H**". An active caliper displays.
3. To measure the distance, there are two methods:
  - a. Press any point P on the image, the end which is closed to P will be moved to position

- b. Drag any end point to position P in the image, and loose up, the end point will be moved to position P.
4. To complete the measurement, exit measurement mode or start another measurement. The system displays the Renal L value in the Results Window.
  5. To measure the second and the third measurement, please repeat step 2~4. After finishing the three measurement, there will be Renal Volume calculated in the result window.

Type	Item	Description	Method
Measurement	Renal L	Renal Length	2D Distance
	Renal H	Renal Height	
	Renal W	Renal Width	
	Prostate L	Prostate Length	
	Prostate H	Prostate Height	
	Prostate W	Prostate Width	
	Seminal L	Seminal Length	
	Seminal H	Seminal Height	
	Seminal W	Seminal Width	
	Pre-V BL L	Pre-Void Bladder Length	
	Pre-V BL H	Pre-Void Bladder Height	
	Pre-V BL W	Pre-Void Bladder Width	
	Post-V BL L	Post-Void Bladder Length	
	Post-V BL H	Post-Void Bladder Height	
Post-V BL W	Post-Void Bladder Width		

Type	Item	Description	Method
	Adrenal L	Adrenal Length	
	Adrenal H	Adrenal Height	
	Adrenal W	Adrenal Width	

### Doppler Mode Measurements

The following measurements are located in the Exam Calcs for the Urology exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements (Abd Aorta, Main Renal A, Arcuate A, Segmental A, Interlobar A, Renal V) are listed on the following pages.

### Artery Example:

#### Main Renal A

1. Select "**Main Renal A**"; an active caliper displays.
2. Click measure methods at measure method list: Two Point, Manual, and Semi-Auto.

#### 2PT (2 Point)

- a. Choose "**Two Point**".
- b. There are two vertical lines and a horizon line on the screen, and there is one active ring at the junctions of the vertical line and horizon line. And there is an active ring on another vertical.
- c. To measure Doppler Tow Point (RI), drag the two rings to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement.

#### Manual (Manual Trace)

- a. Choose "**Manual**".
- b. There are one vertical line and one horizon line crossed, and there is a cross point at the junction.
- c. To confirm the start point, drag the cross point and loose up. The horizon line disappeared.
- d. To trace the spectrum, drag the cross point.  
Note: To erase the trace line, drag the cross point to the left direction.
- e. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

#### S-Auto (Semi-Auto Trace)

9-72Measurement

- a. Choose "**Semi-Auto**"
- b. There are two vertical lines and one horizon line displayed on the screen.
- c. To trace the semi-auto spectrum, move the two vertical lines to confirm the position.
- d. To complete the measurement, exit measurement mode or start another measurement. And spectrum value will be displayed in the result window.

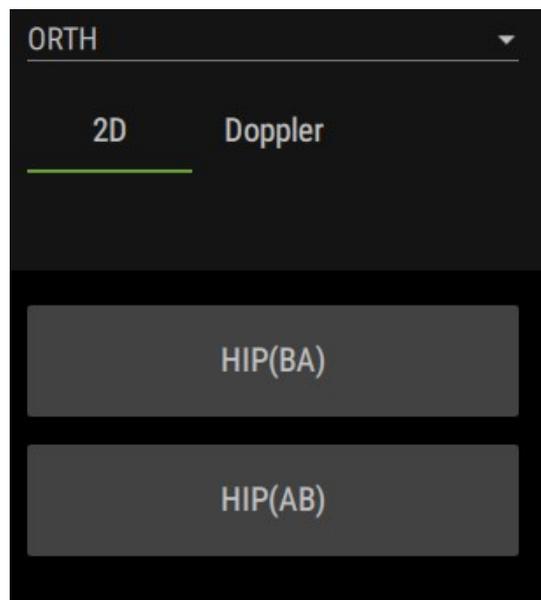
Type	Item	Description	Method
Measurement	Abd Aorta	Abdomen Aorta	2 Point, Manual Trace, Semi-Auto Trace
	Main Renal A		
	Arcuate A		
	Segmental A		
	Interlobar A		
	Renal V		Peak Velocity

## 9.12 Pediatrics

*Describes how to perform Pediatrics measurements and calculations.*

### Introduction

1. Under Freeze mode, go to “**Scan**” page, and press “**Calc**” button to start an application measurement.
2. Switch to <ORTH> measurement library, and press the measurement item.



### B-Mode Measurements

The following measurements are located in the Exam Calcs for the Pediatrics exam category. Some measurements are only available in certain Exam Calcs. Those specific measurements (HIP (BA), HIP (AB)) are listed on the following pages.

### Example:

Each of these is an angle measurement with two angles calculated.

#### HIP (BA), HIP (AB)

1. Select the appropriate orientation (side): “**Right**” or “**Left**”.
2. Select “**HIP (BA)**” or “**HIP (AB)**”. An active line displays, and there is a fulcrum on the line.
3. There are two crossed line on the screen. Through drag or press the end point of the line to measure the angle.
  - a. Press the end point of the line  
Press any point P on the image, the end point closed to P will be moved to P.
  - b. Drag the end point of the line

Drag the end point to position P, loose up, the movement is finished.

4. To complete the measurement, exit measurement mode or start another measurement. And the angle value will be displayed in the result window.

Type	Item	Description	Method
Measurement	HIP(BA)	HIP beta to alpha angle	2D Angle
	HIP(AB)	HIP alpha to beta angle	

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# 10 Patient Data Management

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An exam record consists of all information and data of one exam.

An exam record consists of the following information:

- Patient basic information and exam data
- Image files
- Reports

**NOTE:**

1. DO NOT use the internal hard drive for long-term image storage. Daily backup is recommended. External storage media is recommended for image archive.
2. The system patient database space is limited, please back up or clear patient data in time.
3. Wisonic is not responsible for lost data if you DO NOT follow suggested backup procedures.

## 10.1 Patient Information Management

### 10.1.1 Enter Patient Information

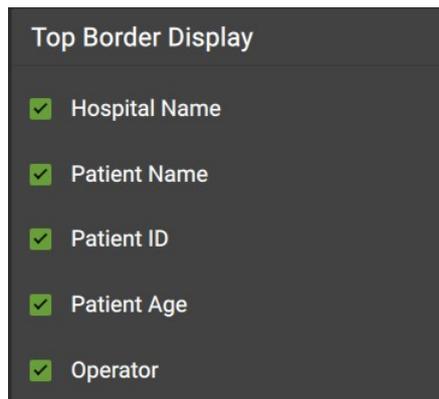
The general patient information and exam information are entered through the Patient Info screen

After completion of patient information entry, click "**Confirm**" to save the patient information to the patient data.

### 10.1.2 Patient Information Setting

Open "**Setup**→**System**→**General**", and then set the following in the Patient Info area. Here, you can select if to display patient ID, name, hospital, age or operator in the screen.

- Setting patient information display



## 10.2 Image File Management

You can store the image files either in the patient database in the system, or to external memory devices. For a saved image, you can perform operations like image reviewing, analyzing and demonstration (Demo).

### 10.2.1 Memory Media

System supported memory media including:

- System hard disk
- USB memory devices: USB flash drive, removable USB hard disk

### 10.2.2 Image File Formats

The system supports two types of image file formats: system-relevant and PC-compatible.

#### **System-relevant formats:**

- Single-frame image file (SFR)  
Refers to single-frame static image files not to be compressed; you can perform measurements and comments adding on this type of files.
- Cine file (Loop)  
System-defined multi-frame file format; you can perform manual or auto cine review, and perform measurements or add comments for the reviewed images. After you open a stored cine in file, the system automatically enters cine review status.

The system can save SFR files as well as BMP, JPG, PNG or DCM files, or save loop cine files as AVI, DCM files. The system can also open SFR, JPG, BMP and Loop files.

### PC-compatible formats:

- Screen file (BMP)  
Single-frame file format, used to save the current screen, non-compressed format.
- Screen file (JPG)  
Single-frame file format, used to save the current screen in the compressed format; you can set the compression ratio.
- PNG: Portable Network Graphic  
Single-frame file format, used to save the current screen, non-compressed format.
- Multi-media files (AVI)  
Multi-frame file format, general cine file format.
- Multi-media files (MP4)  
Multi-frame file format, general cine file format.
- DICOM files (DCM)  
DICOM standard files format, single-frame or multi-frame format, used to record patient information and images.

## 10.2.3 Image Storage Preset

### Set single frame export format

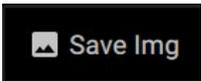
- Format  
You can select the image export format in the “**Send To**” dialogue box.

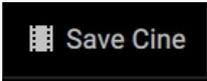
### Set cine saving length

Open “**Setup**→**System**→**Imaging**”, set the cine saving length in the “Cineloop capture”.

## 10.2.4 Saving Images to the System

To save a single-frame image or a cine in the system:

- (1) Touch  on the screen, and a single frame image will be saved

- (2) Touch  on the main interface directly, and a cine will be saved.

- (3) Touch  on the main interface directly, and a cine will be saved.

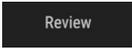
## 10.2.5 Image Review and Analysis

You can review and analyze the stored images (only refer to the images stored in the system default path).

### 10.2.5.1 Review an Image

You can review all images stored in an exam, and send, delete or analyze the stored images.

#### To enter Review:

- Touch  to enter Review screen. The system displays the images stored in this exam of the current patient (if there is no current patient information, you can review the images of the latest exam).

#### To exit Review:

Directly click on other pages, such as "Scan".

#### Basic operations

1. Click on an exam record in the Exam History area. The selected item is highlighted.
2. Open a cine and then you can click Patient to view patient information.
3. Click a thumbnail to view and analyze an image.

The function buttons are described as follows:

- Exam History:
  - You can select one certain exam from the exam directory to review the images.
    - the Review screen default displays the images of the current exam
    - If previously examined image is opened, it displays this specific patient's images.
- Patient Info:
  - Click to enter the Patient Info screen, you can review or edit the currently-selected patient information.
- Image operations:
  - Select: Select multiple images or multiple exams.
  - Cancel: After clicking the Cancel, the button changes into Select, you can cancel all the selections by clicking Cancel.

Send To: Click to send the selected image to other location, DICOM server, printer and etc.

Delete: Click to delete the selected image.

Backup: Click to backup exam.

### 10.2.5.2 Image Analysis

For the image analysis, you can view, zoom, perform post processing and measurements, add comments and perform cine (multi-frame) review for a stored image. The operation steps are the same as those for real-time scanning; please refer to relevant sections for details.

#### To enter image analysis:

- In the image scanning status, click **“Freeze”** to enter the Frozen status; or
- In the Review status, select a thumbnail and click Open or directly click the selected thumbnail to open the image. Click **“Scan”** to enter image analysis.

#### To exit the image analysis:

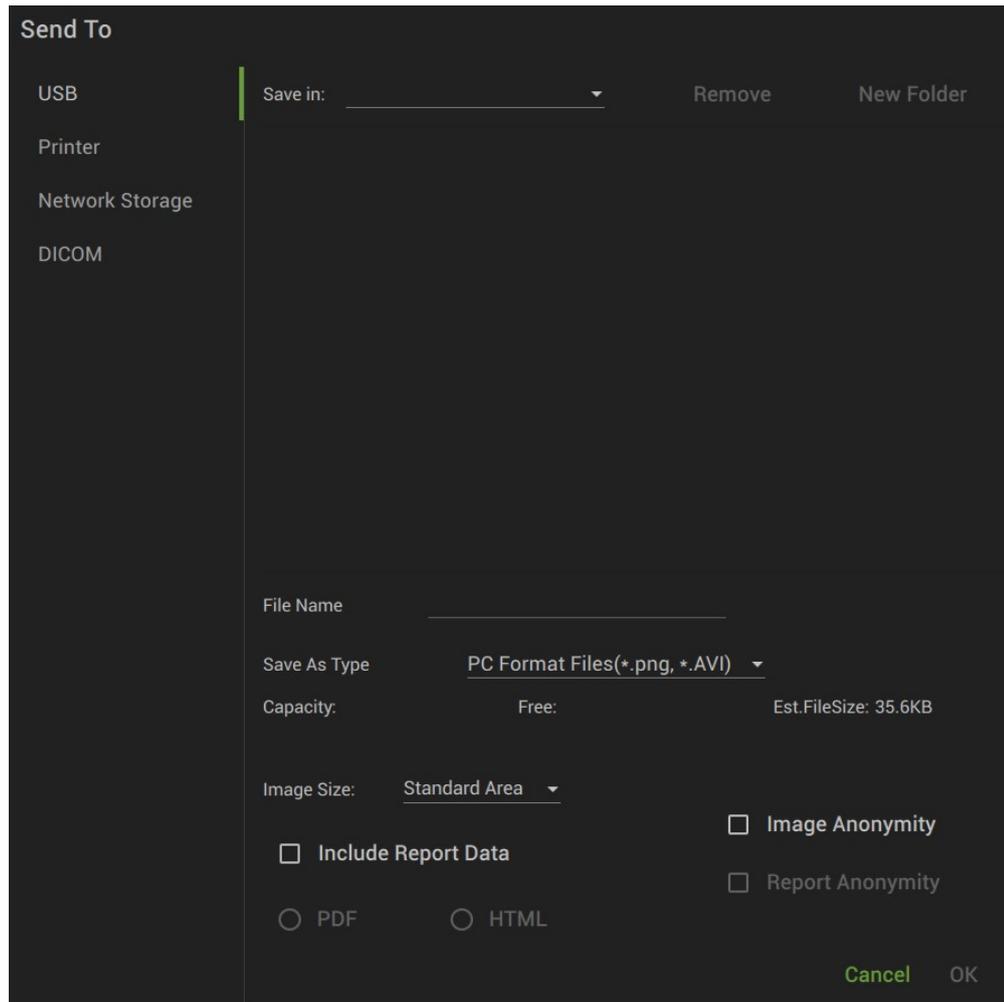
- Touch **“UnFreeze”** to exit and enter the real-time scanning status.
- Touch **“Review”** to exit from the image analysis to the Review status.

### 10.2.6 Sending Image File

On the image screen, select a stored image thumbnail (Click on the different image to select more than one at the same time), click **“Send”** button, the image can be sent to the external devices.

In the Review screen, click **“Send”** to send the selected image to the external devices.

See the figure below.



- For external memory devices (e.g. USB memory devices, or network storage server):
  - a) PC format transfer: JPG/ AVI, BMP/ AVI, PNG/ AVI. Where a single-frame image is exported as JPG, PNG or BMP, and the cine file exported as AVI.
  - b) DCM format transfer: DCM (including single-frame DCM and multi-frame DCM).
  - c) You can also select to export report in PDF format.
- For a video printer, send images to the video printer connected with the system. For a graph/ text printer, send the images to the default graph/ text printer.

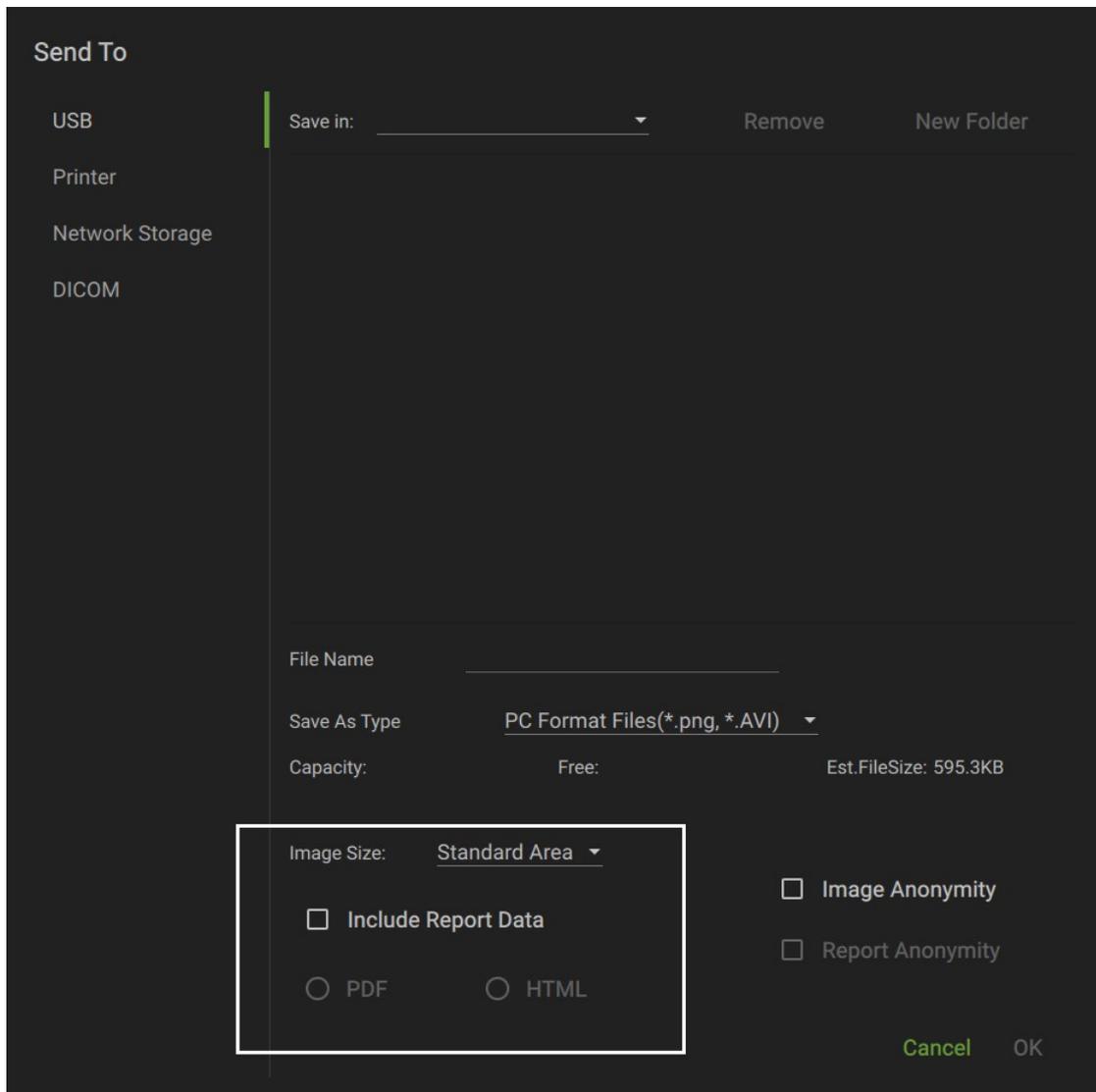
## 10.3 Report Management

### Report storage:

The exam reports are stored under the directory of the exam of the patient.

## Exporting and sending a report

In the Review screen, click "Send" to send patient data to an external memory device, you can choose if reports are exported with images. See the figure below.



To export the report:

- (1) Check **"Include report data"** on the screen.

## Printing report

Use a connected graph/text printer to print a report. Please refer to "Peripheral PresePeripheral Preset" for details about default report printer setting.

## 10.4 Patient Data Management (Review)

### 10.4.1 Viewing Patient Information

#### Dataflow

Select the data source of patient data, the system patient database is default.

#### Patient list

Display patient information, image and cine.

#### Patient Info

Select an exam of a patient, open an image and click Patient to display the patient information of this exam.

### 10.4.2 Searching a Patient

- (1) Select the data source.
- (2) Enter the keyword in accordance with what you want, and the system searches and displays the results in the patient list.
- (3) When you select a patient in the patient list, the images of this patient will be displayed on the right side of the screen.

### 10.4.3 Patient Data Management

#### Send To

The system supports to send data to external memory, or DICOM server or send images or reports to printers to print.

- Select multiple exams, the "**Send**" button is used to send exam data or images of the selected exam.
- Select multiple images, the "**Send**" button is used for sending selected images.
  - Send patient exam data to USB devices, network storage.
  - Send images to USB devices, disc, DICOM storage server, DICOM printer, video printer, text/ graph printer, network storage.
  - Send images with report to USB devices, and network storage.
  - Format transfer is available when sending images to USB devices, network storage.

## **Delete**

To delete the selected patient or exam data, click the **"Delete"** button on the right side of the patient list. However, you cannot delete patient data being printed, exported or sent, or delete the current exam.

- Select exams, click **"Delete"** button to delete the selected exam.
- Select image, click **"Delete"** button to delete the selected images.

## **Backup/ Restore**

You can back up the selected patient data to the system-supported media in order to view it on computers, or restore the patient data to the system from an external media.

Backup: click to export the selected patient data to the system-supported media.

Restore: click to import the patient data from an external media. If no external data source is connected, then the button is unavailable.

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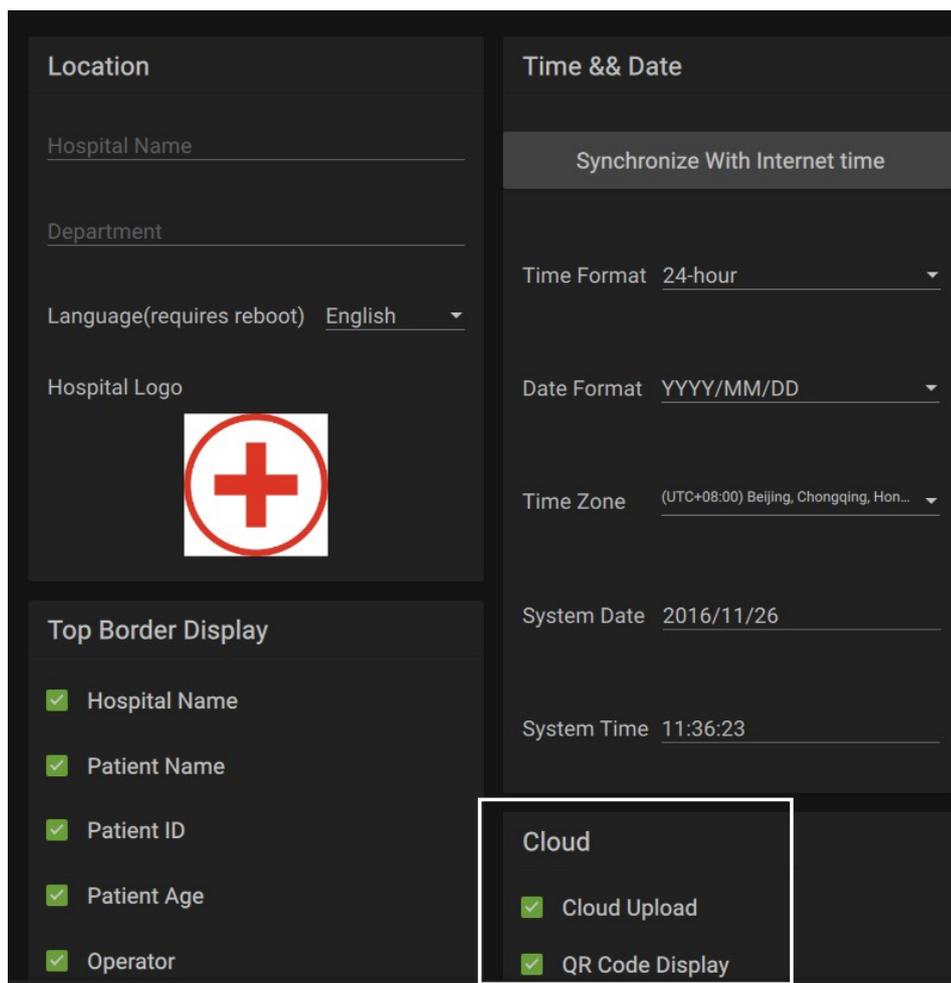
# 11 Cloud Share

**Warning:** this system provides the image of cloud sharing services for clinical reference only, do not for diagnosis, do not responsible for the correctness of the results of the diagnosis.

This chapter describes how to use the cloud share function, please ensure that the network can be connected to the internet.

## 11.1 Turn ON or OFF the Cloud

Click Setup to enter “**System-General**”, while the Cloud settings is on the bottom right of corner, check mark the “**Cloud Upload**” will upload exam data to the internet(details are shown in Preset chapter)



## 11.2 QR code for Exam share

Exam share is upload to cloud, what can be share are:

- Basic Information of patient (includes: Name, Age, Sex)
- Exam Information of patient
- Pictures during the examination
- Measured data, comments, bodymarks in the pictures.

Followings are not support in cloud:

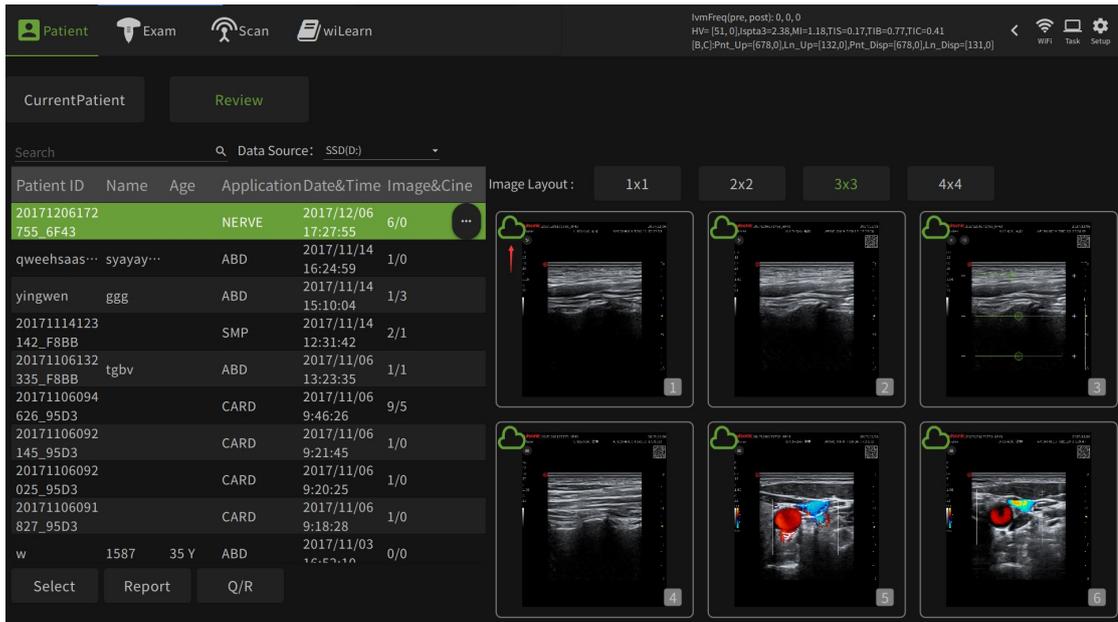
- Full screen picture
- Cine files

After turn On the Cloud Upload and QR Code Display, back to main screen:

1. Create a new patient, scan on body.
2. Click Save Img, and picture will be uploaded to cloud server, then QR Code is generated at the top right of screen.



3. Review page will show the uploaded image:



A green cloud shown at the top left corner of the thumbnail indicating the picture uploaded already.

Note:

1) Only Single Frame image can uploaded.

2) Click  can show more function of an exam, Click QR Code can show the QC code of this exam.

## 11.3 View share data with mobile phone

After get a QR code:

1. Scan the QC code with mobile phone by the internet browser apps, then can view the images without any patient information as below:

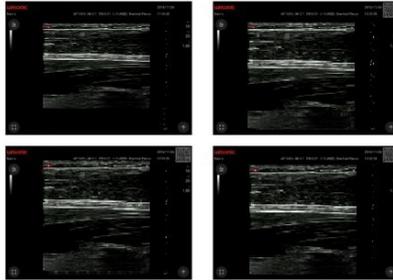
wisonic

Expired date: 2017-02-24

Patient ID: 20161126115443\_9E19

Exam Time: 2016-11-26 11:54:43

Patient Name: Just,for,test



Load more

2. User can click the thumbnail to enlarge the pictures
3. After zoom in the picture, if want to review more information and report, it need to login in. Click the log in button:

A login form for Wisonic. The background is light blue with white clouds. At the top right, there are two language options: '中文' and 'English'. The 'wisonic' logo is in the center. Below the logo are two input fields: the first is labeled 'Name' and the second is labeled '20150101(format)'. Below the input fields is an orange 'Login' button.

4. Input correct name and exam date (format 20150101),and the login in click, can review the report of this exam.

This page was intentionally left blank.

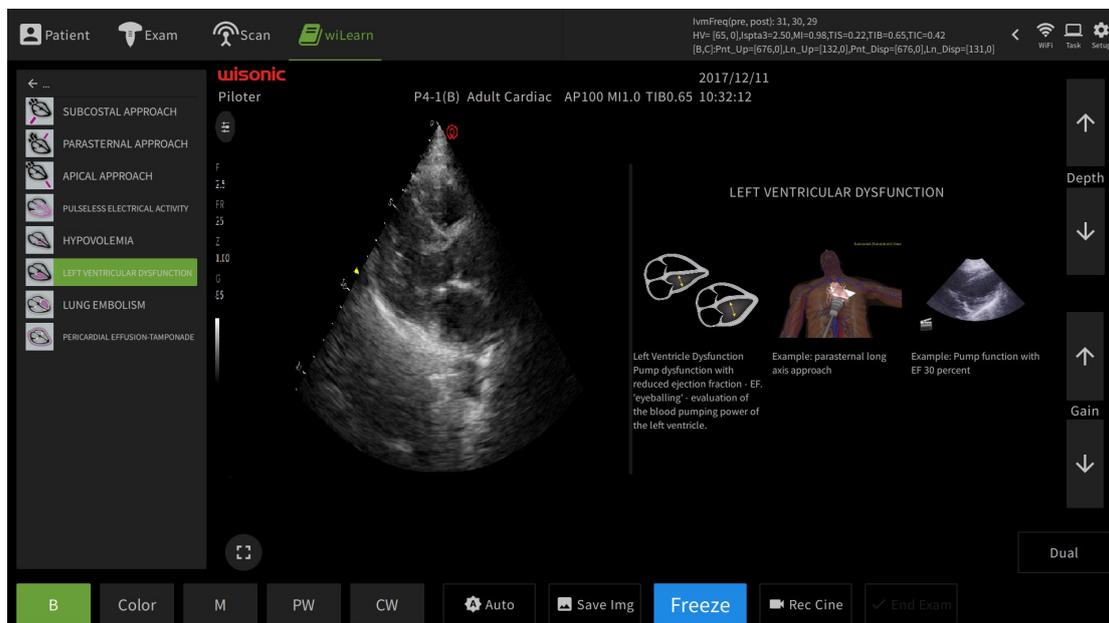


# 12 wiLearn Education Center

## 12.1 wiLearn Education Center

The function of wiLearn provide varied education resources, to help the users to study how to scan different objects and operate a biopsy.

Click wiLearn to enter wiLearn page:



The content of wiLearn function are as following:

Categories	Contents
EMERGENCY	ABDOMINAL AORTIC ANEURYSM, FAST, FEEL, PLEURAL EXAMINATION, PREP
EPIDURAL AND SPINAL	EPIDURAL AND SPINAL
MSK	CARPAL TUNNEL, INTERCARPAL SCAPHOLUNATE, KNEE INJECTION, SHOULDER1: SHOULDER SCANNING, SHOULDER 2: BURSITIS, SHOULDER 3: TENDINOSIS, SHOULDER 4: IMPINGEMENT, SHOULDER 6: INJECTION.
PAIN TREATMENT	GREATER OCCIPITAL NERVE BLOCK, ILIOINGUINAL BLOCK, INTERCOSTAL BLOCK, SAPHENOUS NERVE BLOCK, STELLATE GANGLION BLOCK, SUPRASCAPULAR BLOCK, TAP BLOCK.
REGIONAL ANESTHESIA	AXILLARY PL. BR., DISTAL N. ISCHIADICUS, INTERSCALENE PL. BR., N. FEMORALIS, PROXIMAL N. ISCHIADICUS, SAPHENOUS NERVE BLOCK, SUPRACLAVICULAR PL. BR., TAP.
RESCUE BLOCKS	AXILLARY BLOCK, MEDIANUS NERVE, RADIALIS NERVE, ULNARIS NERVE.
VASCULAR ACCESS	1.A CENTRAL VEINS EVALUATION, 1.B CENTRAL VEINS, 2.A PVA ARM EVALUATION, 2.B PVA ARM, 3.A PVA FEMORAL EVALUATION, 3.B PVA FEMORAL VEIN, V. AXILLARIS, V.FEMORALIS, V.JUGULARIS INTERNA

Double click each content to enter detail operation page, follows each step in the page to scan or biopsy. Single click the picture or movie will zoom out them, and single click them again, the picture or movie will be in normal size.

← ...

EXAMINATION CVC

1 CRITERIA: VEIN LOCATION

2 CRITERIA: LUMEN

3 CRITERIA: PATHWAY

EXAMINATION CVC



Patient in supine position. Scan start: neck area (IJV).

Scan the different veins in the neck and shoulder area.

Evaluate the veins and find the best puncture point.

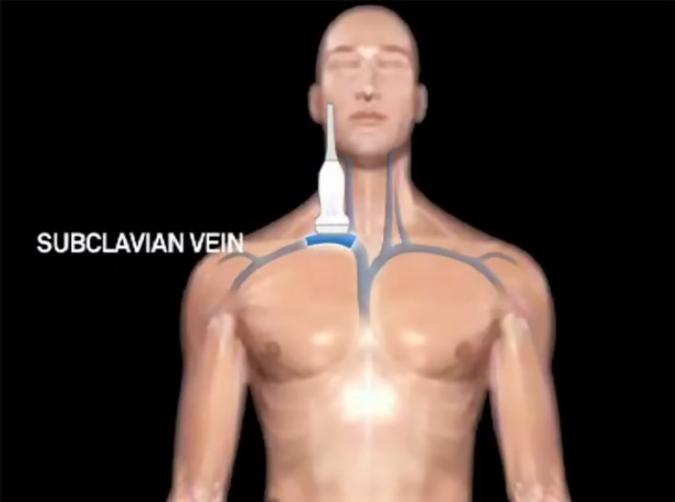
← ...

EXAMINATION CVC

1 CRITERIA: VEIN LOCATION

2 CRITERIA: LUMEN

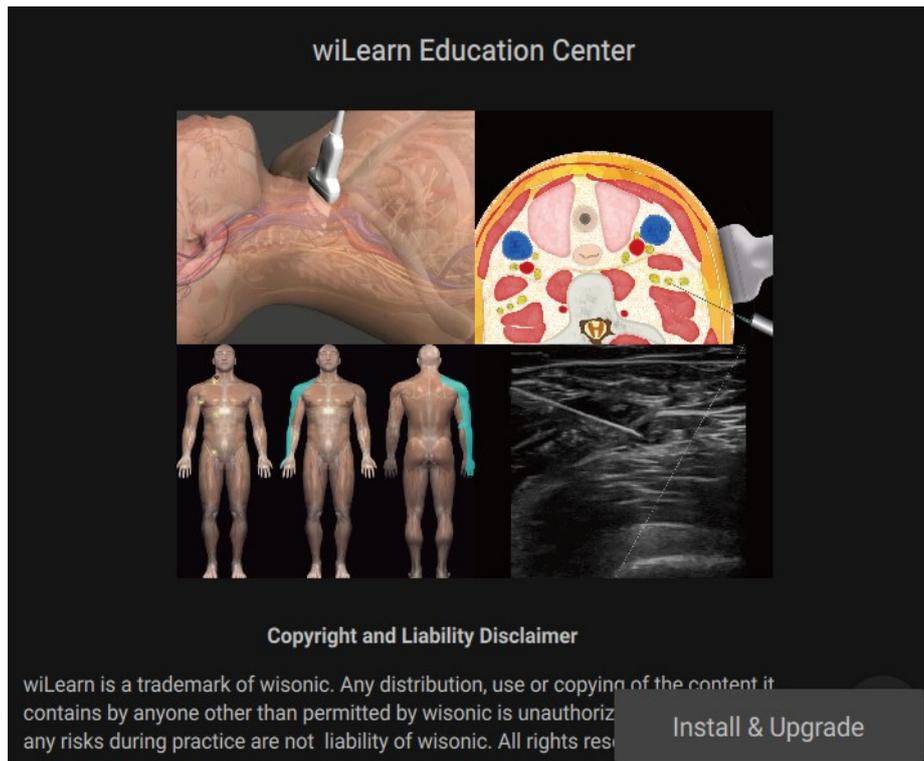
3 CRITERIA: PATHWAY



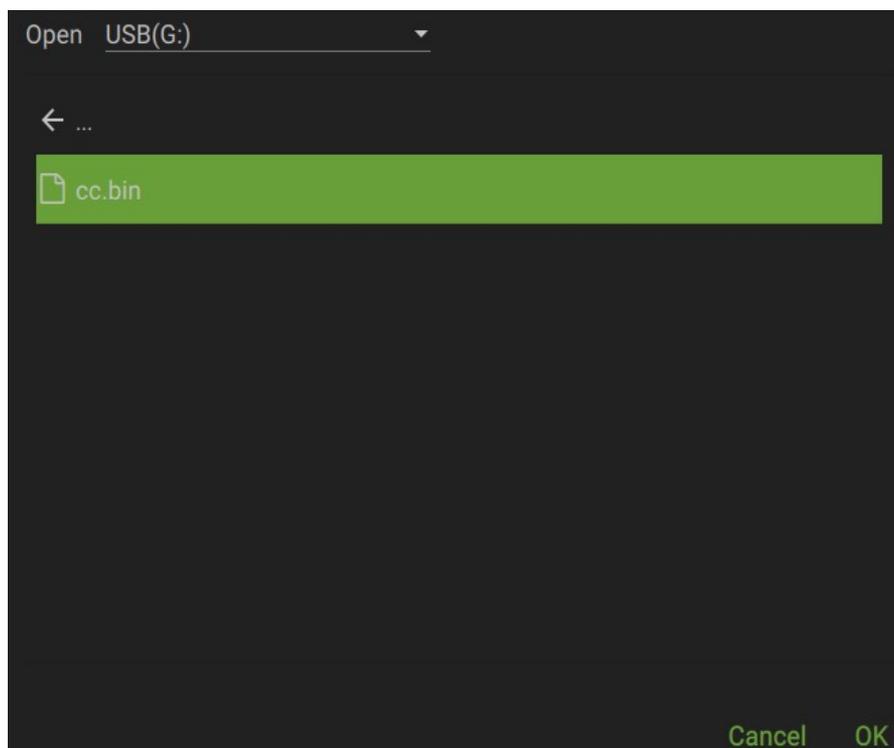
Scan the different veins in the neck and shoulder area.

## 12.2 Install & upgrade

Click  icon, and pop up install & upgrade button:



Click install & upgrade button, choose the installing document:



Click OK button to install and upgrade, and pop up the following page:

12-4wiLearn Education Center

wiLearn data has been loaded, system will  
reboot, are you sure to reboot system?

Cancel OK

After restarting, we finished the install and upgrade function.



Click  icon to enter "setup-maintenance" page, check the version and date of wiLearn.

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# 13 Setup

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Preset Menu provides the following functionality:

- **System.** View and update general system configuration settings, and video settings, and key settings, and authority management.
- **Exam.** Configure exams under each probe and specific application and user-specific settings.
- **Measure Tool.** Set measure related tools and formula.
- **Peripheral.** Provide settings to printer
- **Network.** Define connection and communication setup, including exam dataflow information.
- **Demo:** Play Demo.
- **Maintenance.** Customize preset data, look up system info, and provide service related functions.

To access these functions, Click the setup Icon on the screen then select the appropriate tab menu to configure.

## 13.1 System Preset

System setup, support setting page:

Page	Meaning/Purpose
General	To set the hospital name, language, time zone, time format, system date/time, logo and so on.
	To set patient information and cloud.
Imaging	To set some general parameters in imaging modes.
Security	To set the user account control relevant information.

### 13.1.1 General

General page via "**Setup**→ **System** →**General**", items are listed as follows:

### Location

Hospital Name shenzhen

Department \_\_\_\_\_

Language(requires reboot) English ▾

Hospital Logo



### Time & Date

Synchronize With Internet time

Time Format 24-hour ▾

Date Format YYYY/MM/DD ▾

Time Zone (UTC+08:00) Beijing, Chongqing, Hong... ▾

System Date 2017/05/18

System Time 14:08:28

### Top Border Display

- Hospital Name
- Patient Name
- Patient ID
- Patient Age
- Operator

### Review Window

- Thumbnail
- Table

### Cloud

- Cloud Upload
- QR Code Display

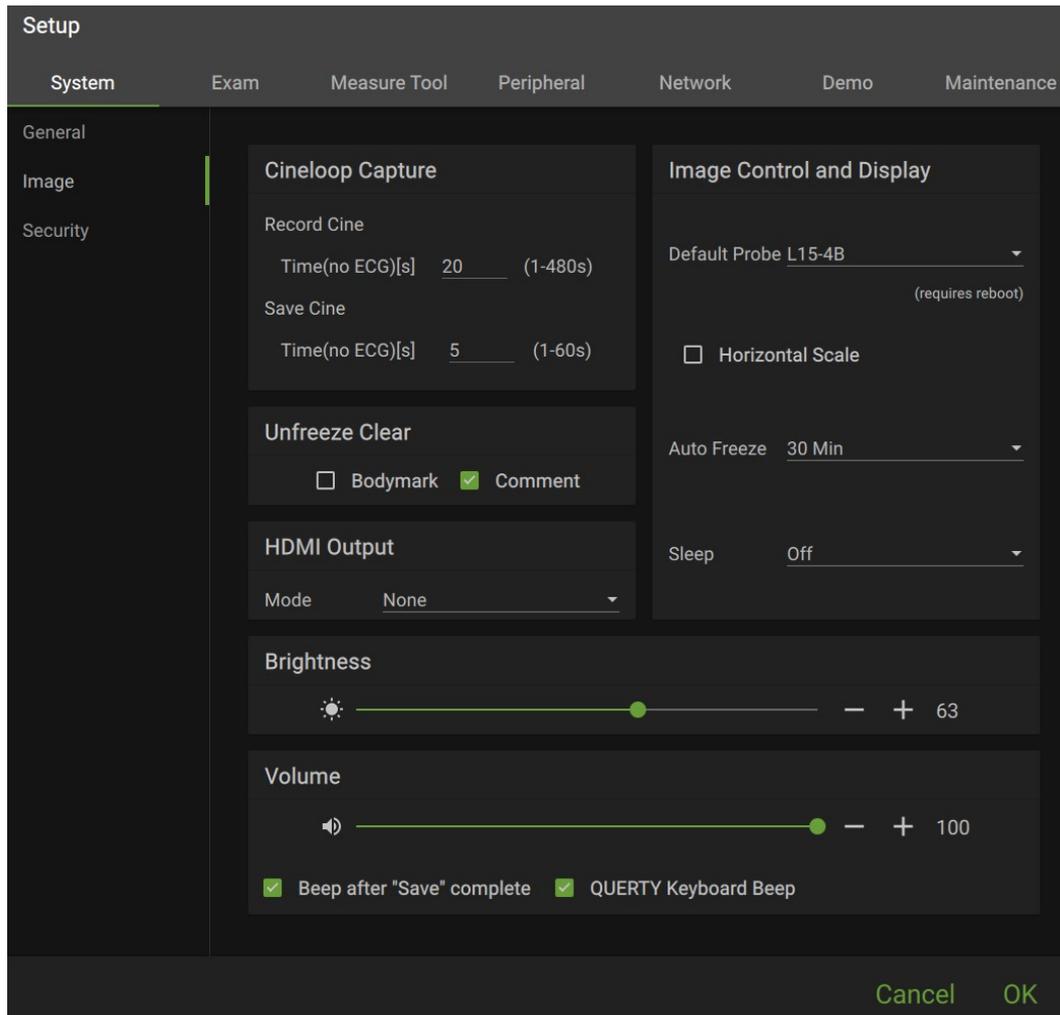
Cancel   OK

Region	Items	Meaning/Purpose
Location	Hospital Name	Set hospital name
	Hospital Logo	Load hospital Logo
	Department	Set department
	Language	Select display language

Region	Items	Meaning/Purpose
Time&Date	Time format	Select time format
	Date format	Select date format
	Time zone	Select time zone
	System date	Adjust system date
	System time	Adjust system time
Patient Information	Hospital name	Whether display in the main interface
	Patient name	Whether display in the main interface
	Patient ID	Whether display in the main interface
	Patient age	Whether display in the main interface
	Operator	Whether display in the main interface
Cloud	Sync Cloud	Set cloud sync cloud active
	QR code display	Display QR code on screen
Review	Thumbnail	Set Review display Thumbnail
	Table	Set Review display exams list

## 13.1.2 Image

Image page via “**Setup**→**System**→**Image**”.



Region	Items	Description
Cineloop Capture	Prospective time	Input time
	Retrospective	Input time
Image Control & Display	Default probe	When no probe connects, system assign default probe on screen
	Horizontal Scale	Horizontal scale on screen
	Unfreeze clear	Bodymark, Comment
	Auto freeze	Set a time to enter freeze

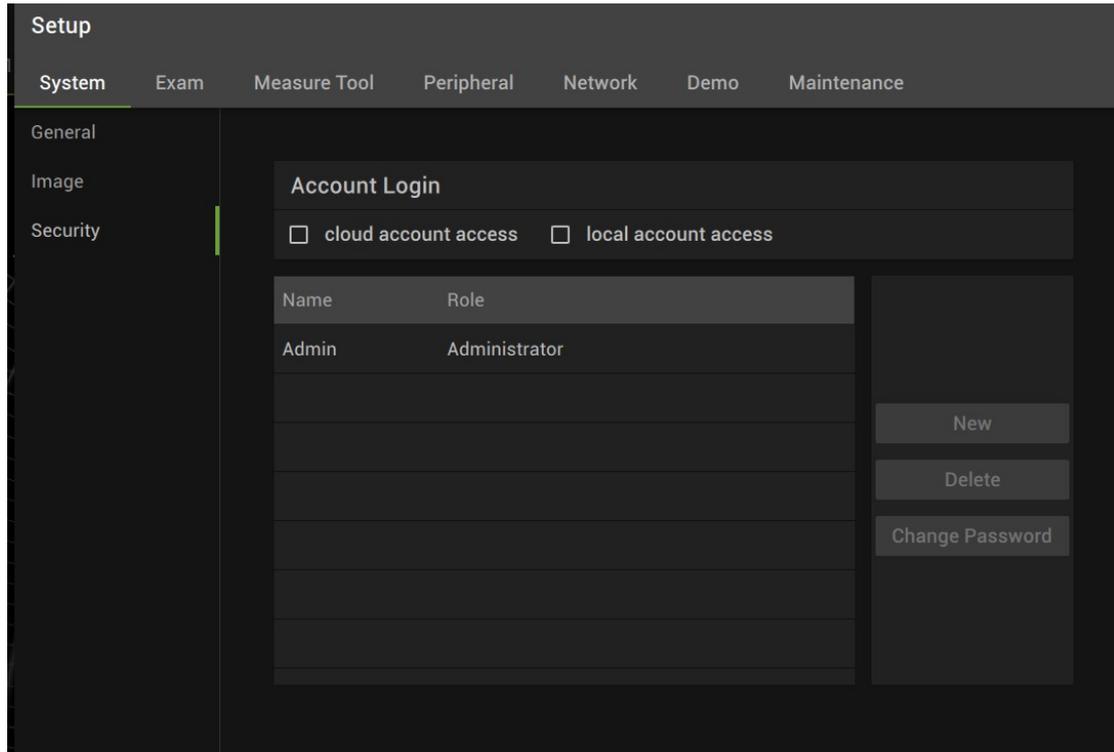
Region	Items	Description
	Sleep	Set a time to enter sleep mode
Others	HDMI output mode	Set the output area size
	Brightness	Can set the screen brightness
	Volume	Can set the sound, Beep after "Save" complete, QUERTY Keyboard Beep
	Beep after "Save" complete	There will be a Beep when Save Img is finished
	QUERTY Keyboard Beep	There is a sound when pressing the keyboard

### 13.1.3 Security

Open the Security page via "**Setup**→**System**→ **Security**".

Security page provides user to admin the system if in need.

- **local account access:** to open the local account login page
- **cloud account access:** to open the cloud account login page
- **New:** to create a new user
- **Delete:** to delete a user
- **Change password:** to change password to a new one



### 13.1.3.1 System Login

If access control has been set by the system administrator, you can access the data in the system only after you log on the system.

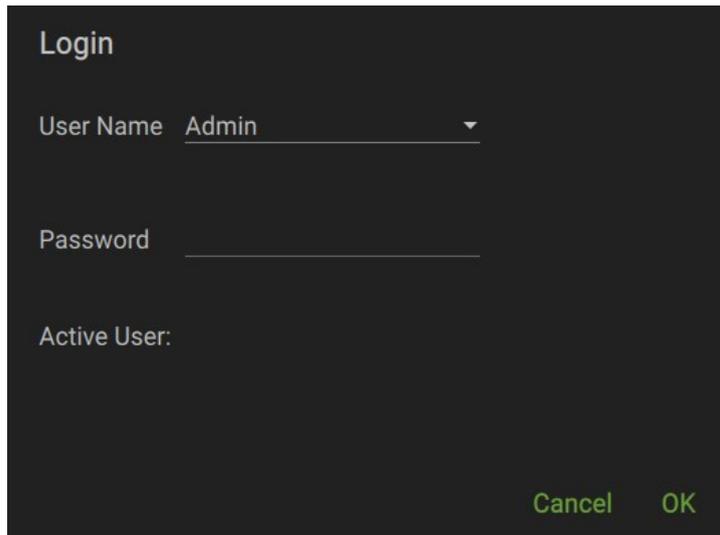
You need to enter user name and password in the following cases:

- Before entering the system
- Changing user

As long as the system is in the working status, you can enter the above screens without entering user name and password repeatedly.

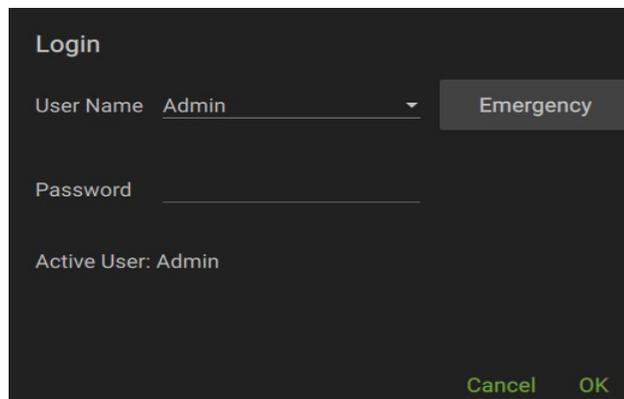
■ Log on the system:

- (1) If the system requires you to log on the system before you access the data, you can see the following dialogue box.



- (2) Select the user name in the drop-down list of User Name.
  - (3) Enter password and click Login.
2. Log out the system:

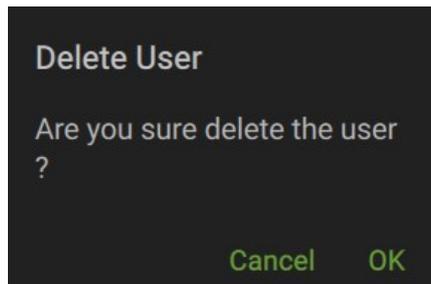
- (1) To log out the current user and change to another user, click  at the upper right corner of the screen to pop up the following dialogue box:



- (2) Click Change User to pop up the Login dialogue box.
- (3) Enter the user name and password in the field box.

### 13.1.3.2 Add/ Delete a User

The system administrator can add and delete a user, while the operator can't.

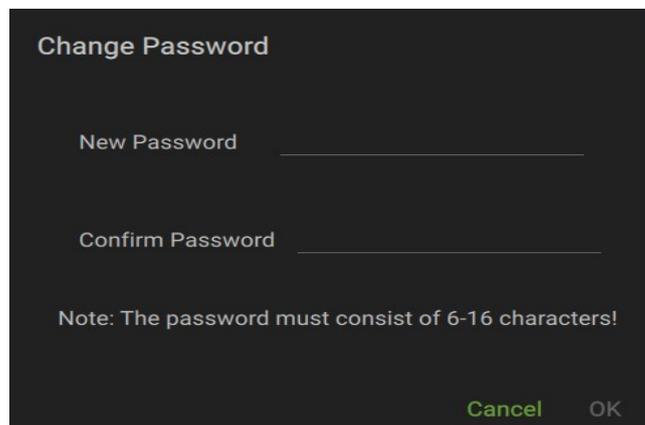


### 13.1.3.3 Change Password

The system administrator can modify password of all users.

The operator can only modify his/her own password.

There are two ways to modify password: modify it on "Admin" page or on "Session Manage" dialogue box.



## 13.2 Exam

Open "Setup-Exam" selection screen to enter Exam Preset screen.

### 13.2.1 Exam Preset

Preset page via "Setup→Exam→ preset".

Probe	Exam	
P4-1	Brachial Plexus	
L15-4B	Femoral N	
L10-5	Sciatic N	
LH15-6	Obturatorius N	
EV10-4	<u>General N</u>	Move Up
C7-3B	CVC	Move Down
C5-1B	PICC	Delete
	Lung	
	MSK	Default
	ICU	
	Epidural & Spinal	
	TAP	
	Radial A.	
	custom_Thyriod_1	

- **Set the default exam mode**

Selected a probe, and then select an exam mode, click the default button to set the exam for the default mode of the probe.

- **Delete exam mode**

Click the Delete button to delete a customized exam.

- **Up/Down**

Select an exam mode, click move up or down, this place of exam in the list move up or down.

## 13.2.2 Application configuration

Application page via “**Setup**→**Exam**→**Application**”.

Exam	Application	Measure	Comment	Bodymark
Adult ABD	ABD	Abdomen	Abdomen	Abdomen
Adult Cardiac	Cardiology	Cardiology	Cardiology	Cardiology
GYN	GYN	Gynecology	GYN	GYN
OB1	OB	OB1	OB	OB
OB2/3	OB	OB2/3	OB	OB
Fetal Cardiac	OB	OB2/3	OB	OB
Kidney	Urology	Urology	Kidney	Kidney
Prostate	Urology	Prostate	Prostate	Prostate
Thyroid	SMP	Thyroid	Thyroid	Thyroid
Breast	SMP	Generic	Breast	Breast
Superficial	SMP	Generic	Superficial	Superficial
Skin	SMP	Generic	Skin	Superficial
Carotid	Vascular	Carotid	Carotid	Carotid
LEA	Vascular	LEA	LEA	LEA

Cancel OK

After an exam mode is selected,

Click a selection in Application list, you can select a new application for the exam mode in the popped up drop-down list.

Selected a line, click export, this exam mode of data can be send to the U disk.

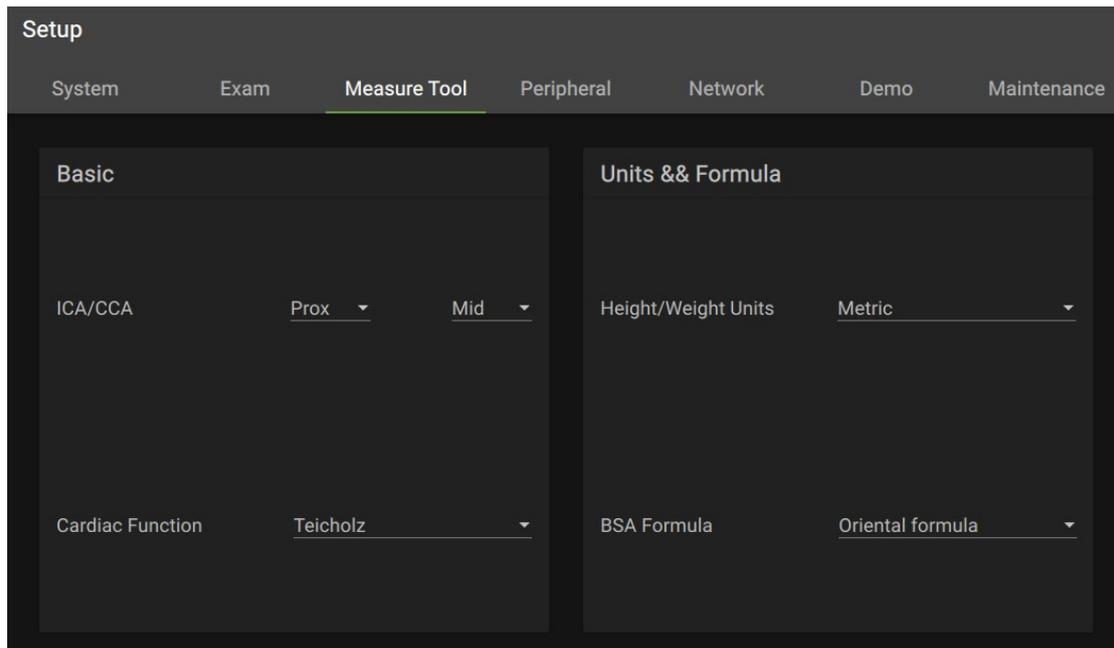
Click export all, all exams can be exported to the U disk.

Click import, the exam data of the U disk can be import to the machine.

Tips: loading or pasting exam setup data will overwrite previous presets and can't be reverted.

## 13.3 Measure Tool

The Measure Tool Config screen is used to set measure related tools and formula.

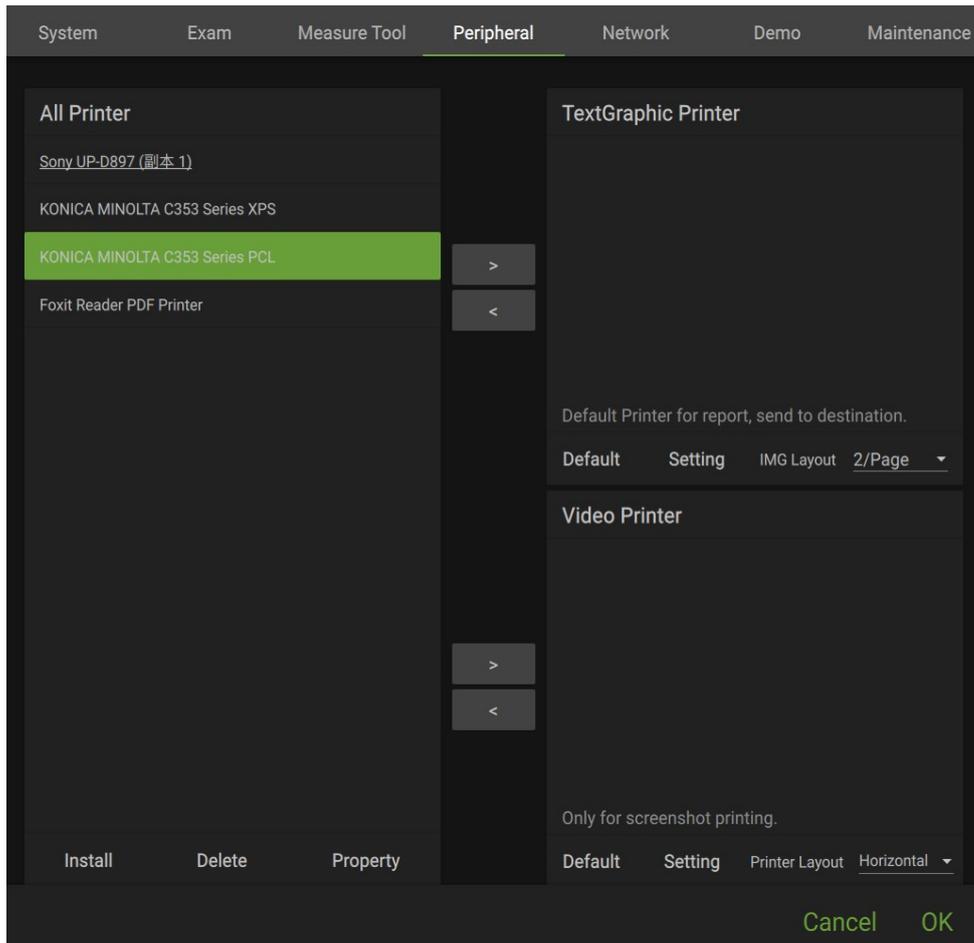


Region	Items	Description
Basic	ICA/CCA	Config different measure direction.
	Cardiac Function	Config different calculate formula.
Units && Formula	Height/Weight Units	Config measure unit
	BSA Formula	Config BSA formula

## 13.4 Peripheral Preset

The Peripheral Config screen is used to set up printer and Input& Display.

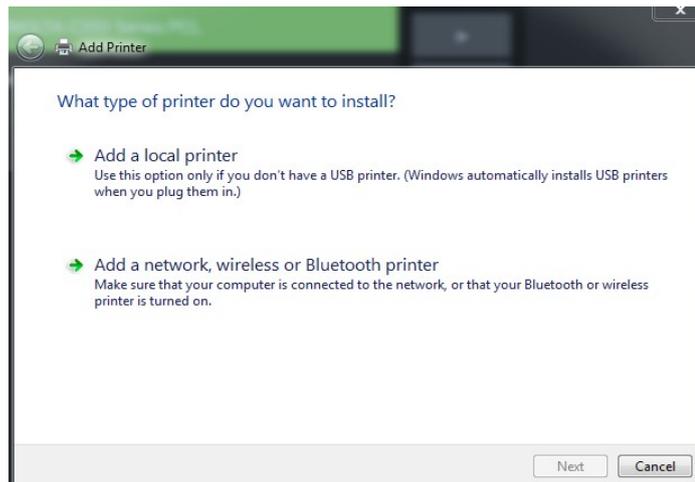
## Printer setting



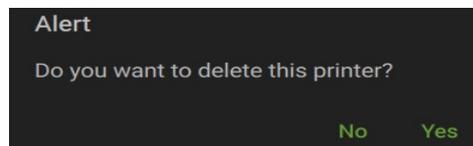
The settings of a printer include print service and print driver.

**NOTE:** If you use the user-defined key to print, the user-defined printer type shall be consistent with that of the default printer.

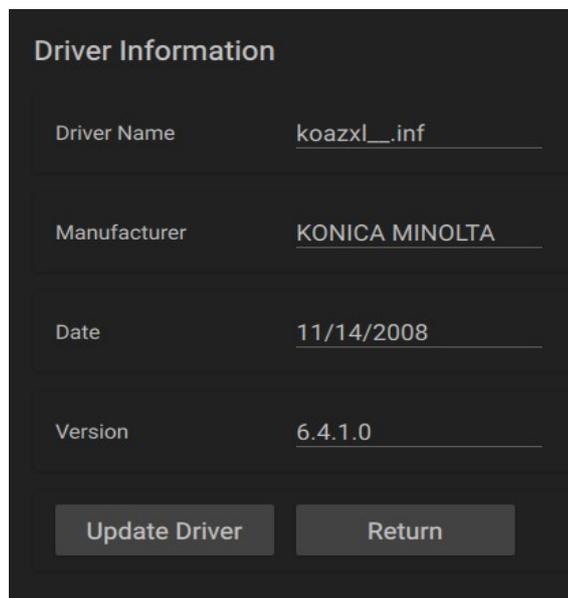
- All Printer
  - **Install:** click to start install a new printer.



- Delete: Delete printer from the list.



- Property: Detailed info about printer



- Text & Graphic Printer
  - **Default:** Make the selected printer as a default printer
  - **Setting:** Pop up the paper printer setting window
  - **Img Print Layout:** Layout for image print setting
- Video Printer

- **Default:** Make the selected printer as a default printer
- **Setting:** Pop up the paper printer setting window
- **Print Layout:** Horizontal or Vertical

## 13.5 Network

### 13.5.1 TCP/IP

Open the TCP/IP page via “**Setup** → **Network** → **TCP/IP**”.

Set the items as followed:

#### TCP/IP

Name	Illustrations
System Name	The name of operation system, can only be reviewed but not be modified
Network Adapter	The name of network adapter, including wireless network and local network.

Physical Address	The physical address of the network adapter. There is adapter name before physical address.
IP address	The IP address of the adapter, including DHCP and Static.
DNS address	The DNS address of the adapter, including DHCP and Static.
OK	Save the modifications.
Cancel	Cancel the modifications

### Wireless Networks

Name	Illustrations
SSID	The SSID list including all the wireless networks connected successfully.
Security Type	The Security Type of the wireless networks, including Open system, Shared key, WPA-Personal, and WPA2-Personal.
Encryption Type	The Encryption Type of the wireless networks, including TKIP and AES.
Security key	The Security key of the wireless networks.
Connect automatically	Check "Connect automatically", the wireless network will be connected automatically the next time start up the system.
Remove	Click Remove button, there is a confirm page pop out, if choose Yes button, the password is needed the next time connect the wireless network.

## 13.5.2 Network Storage.

Open the Network Storage page via "**Setup** → **Network** → **NetworkStorage**".

The screenshot displays a 'Network Storage Config' interface. At the top, there are three input fields: 'Service Name', 'Device/IP', and 'Shared Dir'. Below these is a 'Ping' button. Further down are 'User Name' and 'Password' input fields. A row of four buttons follows: 'Create', 'Verify', 'Reset', and 'Update'. Below this is a table titled 'Network Storage' with columns for 'Service Name', 'Device/IP', 'Shared Dir', and 'Default'. At the bottom of the table area are three buttons: 'Browse', 'Delete', and 'Set as Default'.

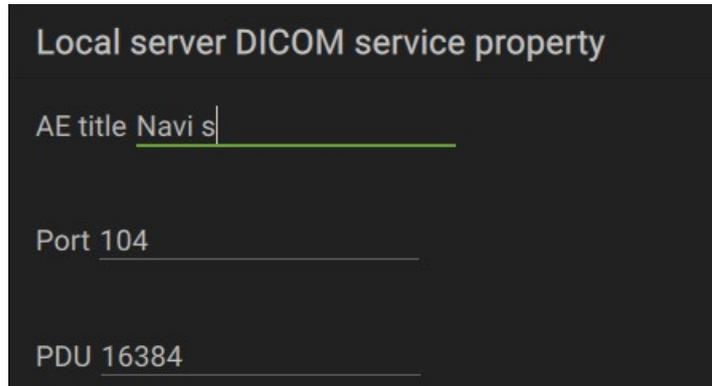
The items as followed:

Name	Illustrations
Servie Name	The name of a network storage.
Device/IP	IP address or device name of the network storage server.
Shared Dir	The name of shared dir.
User Name	User name of the network storage server.
Password	Password of the network storage server.

- **Create:** To create a network storage service.
- **Verify:** To verify whether the service is available.
- **Reset:** Clear all the content filled.
- **Update:** Modify the service content.
- **Browse:** View the network storage server.
- **Delete:** Delete a service.
- **Set as Default:** Set a service to be default service.
- **Ping:** Test the network to storage server status.

### 13.5.3 DICOM Local

Open the DECOM Local page via “**Setup** → **Network** → **DICOM Local**”.



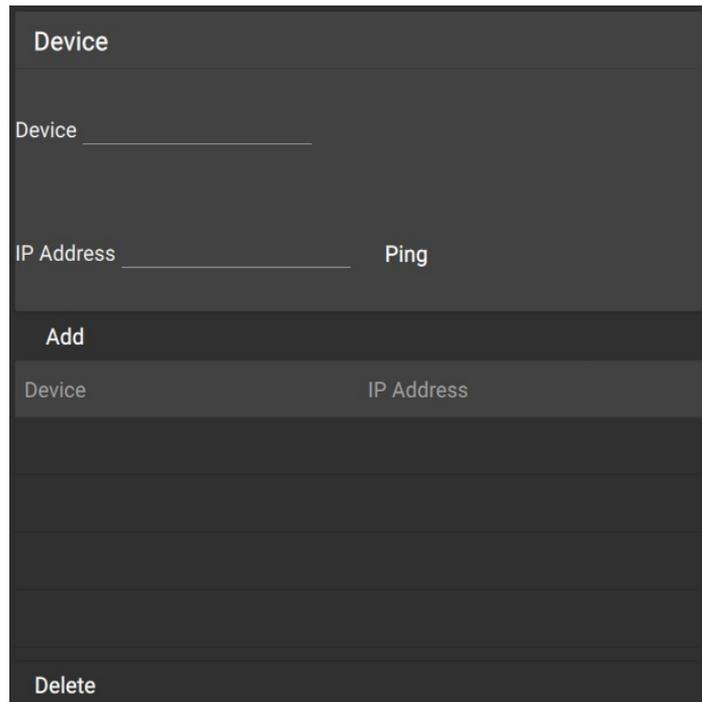
DICOM Local Setting items are described as follows:

Name	Description
AETitle	Application entity title of the ultrasound system. The AE title here should be the same with the one of the acceptable SCU set in the server.
Port	DICOM communication port, which should be the same with the one in the server.
PDU	Maximum PDU data package.
OK	Click to save parameter setting.
Cancel	Click to cancel parameter setting.

### 13.5.4 DICOM Server

To add or delete DICOM servers, or set IP address and name for the DICOM server.

- a) Touch  to enter the Setup menu.
- b) Select “**Network**”; select “DICOM Server” to open the screen, as shown in the figure below.



c) DICOM server setting items are described as follows:

Name	Description
Device	Name of the device supporting DICOM services The device name is empty or has the same name, does not support the increase.
IP Address	IP address of the server. IP address where there is an empty, no support for the increase.
Ping	You can ping other machines to verify connection after entering the correct IP address. Also you can check the connection of the already added server in the list.
Add	Click to add servers to the device list.
Delete	Click to delete the selected server(s) in the device list.
OK	Click to save parameter setting.
Cancel	Click to cancel parameter setting.

## 13.5.5 DICOM Storage

- a) Touch **“Setup”** to enter the Setup menu.
- b) Select **“Network”**; select **“DICOM Storage”** to open the screen, as shown in the figure below.

### Connection Config

Device  Service Name  AE title  Port 104

Maximum Retries 3 Interval Times(s) 15 Timeout(s) 15

---

### Service Config

Cine Zoom Mode Standard Area

Compression Mode Uncompressed Compression Ratio Lossless

Color Mode Color  Allow Multiframe Max Framerate 35

Add
Cancel
Update

---

### Service List

Device	Service Name	AE Title	Port	Default

Delete
Default
Verify

c) DICOM server setting items are described as follows:

Name	Description
Device	After you set the server(s) in DICOM Server Setting, the name(s) will appear in the drop-down list, select the name of the storage server.
Service Name	The service name is set up here, as the storage service name for the Station interface.
AETitle	Application Entity title, here, it should be consistent with that of the storage server.
Port	Here, the port should be consistent with that of the storage server port.
Maximum Retries	Optional range 1-10
Interval Time(s)	Reserved feature.
Timeout (s)	Refers to time after which the system will stop trying to establish a connection to the service. Value: 5—SD. The step size is 5, and the default is 15.
Cine Region	Option: Original、640*480
Compression Mode	Option: uncompressed、RLE、JPEG.
Compression	When JPG is selected, the setting is allowed.

Ratio	Option: Lossless、Low、Medium、High。
Color Mode	Option: Color、Mixed、Gray。
Allow Multi-frame	If SCP supports this function, then select it.
Max Frame-rate	When Allow Multi-frame is selected, the setting is allowed. Option: 25、30、35、All。
Add	Click to add servers to the Service List.
Cancel (Up)	Empty this time to modify the data set.
Update	Select an item in the service list, change the parameters in the above area, and click [Update] to update the item in the service list.
Delete	Click to delete the selected service in the service list.
Default	Select one item from the service list, and click the default, which is called a hook. Only one item is set to the default service.
Verify	Click to verify if the two DICOM application entities are normally connected.
OK	Click to save parameter setting.
Cancel	Click to cancel parameter setting.

### 13.5.6 DICOM Worklist

- a) Touch “**Setup**” to enter the Setup menu.
- b) Select “**Network**”; select “**DICOM Worklist**” to open the screen, as shown in the figure below.

### Connection Config

Device  Service Name  AE title  Port

Maximum Retries  Interval Times(s)  Timeout(s)

MaxSearchNum

Add
Cancel
Update

#### Service List

Device	Service Name	AE Title	Port	Default

Delete
Default
Verify

c) DICOM server setting items are described as follows:

Name	Description
Device	After you set the server(s) in DICOM Server Setting, the name(s) will appear in the drop-down list, select the name of the storage server.
Service Name	The service name is set up here, as the worklist service name for the Station interface.
AETitle	Application Entity title, here, it should be consistent with that of the worklist server.
Port	Here, the port should be consistent with that of the storage server port.
Maximum Retries	Optional range 1-10
Interval Time(s)	Reserved feature.
Timeout (s)	Refers to time after which the system will stop trying to establish a connection to the service. Value: 5–SD. The step size is 5, and the default is 15.
MaxSearchNum	The Maximum exam number to search
Add	To create a new Dicom Storage service.
Delete	To delete a Dicom Storage service.
Cancel	To set all the content to default value.
Update:	To modify a Dicom Storage service.
Default:	To set a Dicom Storage service to default.
Verify	To test the network to a Dicom Storage server.

## 13.5.7 DICOM MPPS

- a) Touch “**Setup**” to enter the Setup menu.
- B) Select “**Network**”; select “**DICOM MPPS**” to open the screen, as shown in the figure below.

- c) DICOM MPPS setting items are described as follows:

Name	Description
Device	After you set the server(s) in DICOM Server Setting, the name(s) will appear in the drop-down list, select the name of the storage server.
Service Name	The service name is set up here, as the MPPS service name for the Station interface.
AETitle	Application Entity title, here, it should be consistent with that of the MPPS server.
Port	Here, the port should be consistent with that of the storage server port.
Maximum Retries	The step size is 1,Optional range 1-10.
Interval Time(s)	Value: 5—65.The step size is 5, and the default is 15.
Timeout (s)	Refers to time after which the system will stop trying to

	establish a connection to the service. Value: 5—65. The step size is 5, and the default is 15.
Add	Click to add servers to the Service List.
Cancel	Empty this time to modify the data set.
Update	Select an item in the service list, change the parameters in the above area, and click [Update] to update the item in the service list.
Delete	Click to delete the selected service in the service list.
Default	Select one item from the service list, and click the default, which is called a hook. Only one item is set to the default service.
Verify	Click to verify if the two DICOM application entities are normally connected.
OK	Click to save parameter setting.
Cancel	Click to cancel parameter setting.

### 13.5.8 DICOM QR

- a) Touch **“Setup”** to enter the Setup menu.
- b) Select **“Network”**; select **“DICOM QR”** to open the screen, as shown in the figure below.

**Connection Config**

Device  Service Name  AE title  Port

Maximum Retries  Interval Times(s)  Timeout(s)

**Service List**

Device	Service Name	AE Title	Port	Default

- c) DICOM QR setting items are described as follows:

<b>Name</b>	<b>Description</b>
Device	After you set the server(s) in DICOM Server Setting, the name(s) will appear in the drop-down list, select the name of the storage server.
Service Name	The service name is set up here, as the QR service name for the Station interface.
AETitle	Application Entity title, here, it should be consistent with that of the QR server.
Port	Here, the port should be consistent with that of the storage server port.
Maximum Retries	The step size is 1,Optional range 1-10.
Interval Time(s)	Value: 5—65.The step size is 5, and the default is 15.
Timeout (s)	Refers to time after which the system will stop trying to establish a connection to the service. Value: 5—65. The step size is 5, and the default is 15.
Add	Click to add servers to the Service List.
Cancel	Empty this time to modify the data set.
Update	Select an item in the service list, change the parameters in the above area, and click [Update] to update the item in the service list.
Delete	Click to delete the selected service in the service list.
Default	Select one item from the service list, and click the default, which is called a hook. Only one item is set to the default service.
Verify	Click to verify if the two DICOM application entities are normally connected.
OK	Click to save parameter setting.
Cancel	Click to cancel parameter setting.

### 13.5.9 Storage Commitment

- c) a) Touch **“Setup”** to enter the Setup menu.
- d) b) Select **“Network”**; select **“Storage Commitment”** to open the screen, as shown in the figure below.

**Connection Config**

Device  Service Name  AE title  Port

Maximum Retries  Interval Times(s)  Timeout(s)

Associated Storage Service

**Service List**

Device	Service Name	AE Title	Port	Default

c) Storage Commitment setting items are described as follows:

Name	Description
Device	After you set the server(s) in DICOM Server Setting, the name(s) will appear in the drop-down list, select the name of the storage server.
Service Name	The service name is set up here, as the storage commitment service name for the Station interface.
AETitle	Application Entity title, here, it should be consistent with that of the storage commitment server.
Port	Here, the port should be consistent with that of the storage server port.
Maximum Retries	The step size is 1,Optional range 1-10.
Interval Time(s)	Value: 5—65.The step size is 5, and the default is 15.
Timeout (s)	Refers to time after which the system will stop trying to establish a connection to the service. Value: 5—65. The step size is 5, and the default is 15.
Associated Storage Service	Associated with the DICOM storage service.
Add	Click to add servers to the Service List.
Cancel	Empty this time to modify the data set.

Update	Select an item in the service list, change the parameters in the above area, and click [Update] to update the item in the service list.
Delete	Click to delete the selected service in the service list.
Default	Select one item from the service list, and click the default, which is called a hook. Only one item is set to the default service.
Verify	Click to verify if the two DICOM application entities are normally connected.
OK	Click to save parameter setting.
Cancel	Click to cancel parameter setting.

### 13.5.10 Dicom Print

- e) a) Touch "**Setup**" to enter the Setup menu.
- f) b) Select "**Network**"; select "**Dicom Print**" to open the screen, as shown in the figure below.

### Connection Config

Device  Service Name  AE title  Port

Maximum Retries  Interval Times(s)  Timeout(s)

---

### Service Config

Copies  Settings  filmOrientation

Priority  Film Size  Display Format

Min Density  Medium Type  Destination

Max Density  Trim  Magnification Type

Configuration Info

---

### Service List

Device	Service Name	AE Title	Port	Default

c) Dicom Print setting items are described as follows:

Name	Description
Device	After you set the server(s) in DICOM Server Setting, the name(s) will appear in the drop-down list, select the name of the storage server.
Service Name	The service name is set up here, as the dicom print service name for the Station interface.
AETitle	Application Entity title, here, it should be consistent with that of the dicom print server.
Port	Here, the port should be consistent with that of the storage server port.

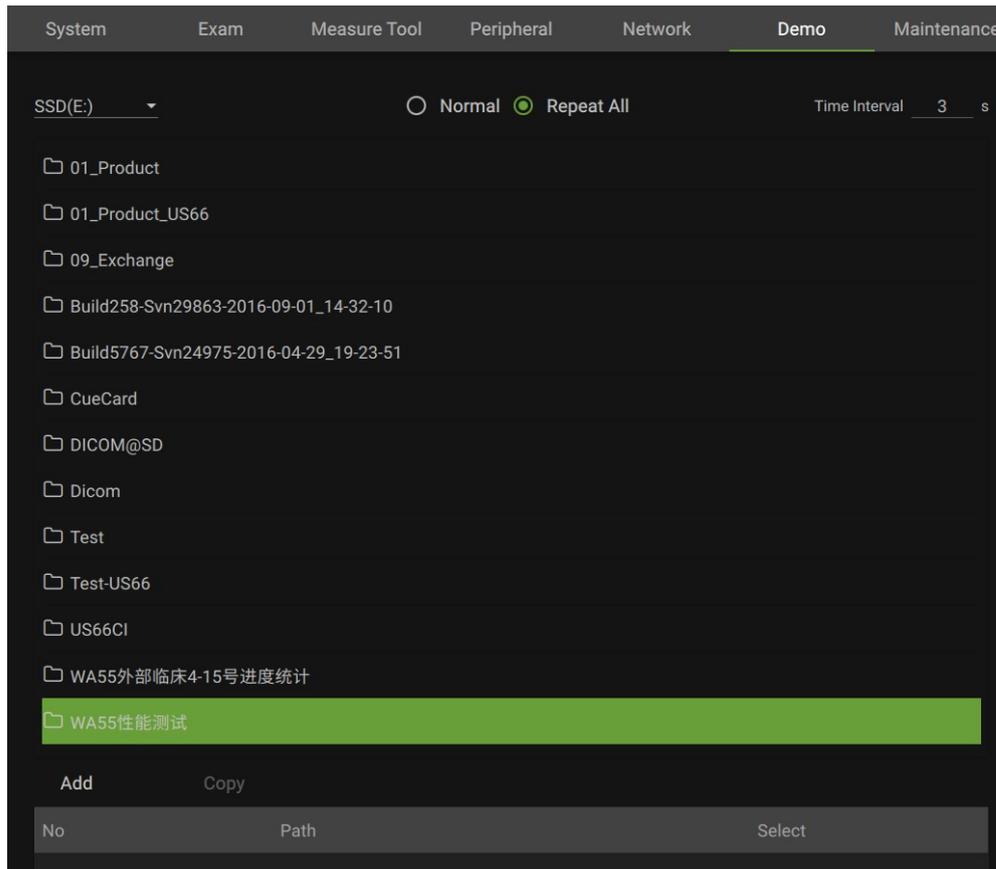
Maximum Retries	The step size is 1,Optional range 1-10.
Interval Time(s)	Value: 5—65.The step size is 5, and the default is 15.
Timeout (s)	Refers to time after which the system will stop trying to establish a connection to the service. Value: 5—65. The step size is 5, and the default is 15.
Copies	Optional range 1-5.
Setings	Option: RGB、MONOCHROME2.
filmOrientation	Option: LANDSCAPE、PORTRAIT.
Priority	Option: High、Middle、Low.
Film Size	Option: 8IN×10IN、8_5IN×11IN、10IN×12IN、10IN×14IN、11IN×14IN、11IN×17IN、14IN×14IN、14IN×17IN、24IN×24IN、24IN×30IN、A3、A4.
Display Format	Option: STANDARD\1,1、STANDARD\1,1、STANDARD\1,1、STANDARD\1,1、STANDARD\1,2、STANDARD\1,3、STANDARD\2,1、STANDARD\2,2、STANDARD\2,3、STANDARD\2,4、STANDARD\3,3、STANDARD\3,4、STANDARD\3,5、STANDARD\3,6、STANDARD\4,4、STANDARD\4,5、STANDARD\4,7、STANDARD\4,8、STANDARD\5,5、STANDARD\5,6、STANDARD\5,7、STANDARD\5,8、STANDARD\6,6、STANDARD\6,7、STANDARD\6,8、STANDARD\6,9、STANDARD\6,10、STANDARD\7,7、STANDARD\7,8、STANDARD\7,9、STANDARD\7,10、STANDARD\8,8、STANDARD\8,9、STANDARD\8,10.
Min Density	Set the minimum density to print here.
Medium Type	Option: PAPER、CLEAR FILM、BLUE FILM.
Destination	Option: MAGAZINE、PROCESSOR.
Max Density	Set the maximum density to print here
Trim	Option: NO、YES.
Magnification Type	Option: NONE、BILINEAR、CUBIC、REPLICATE.
Configuration Info	Set the printed properties here.
Add	Click to add servers to the Service List.
Cancel	Empty this time to modify the data set.
Update	Select an item in the service list, change the parameters in the above area, and click [Update] to update the item in the service list.
Delete	Click to delete the selected service in the service list.
Default	Select one item from the service list, and click the default, which is called a hook. Only one item is set to the default service.
Verify	Click to verify if the two DICOM application entities are normally connected.
OK	Click to save parameter setting.
Cancel	Click to cancel parameter setting.

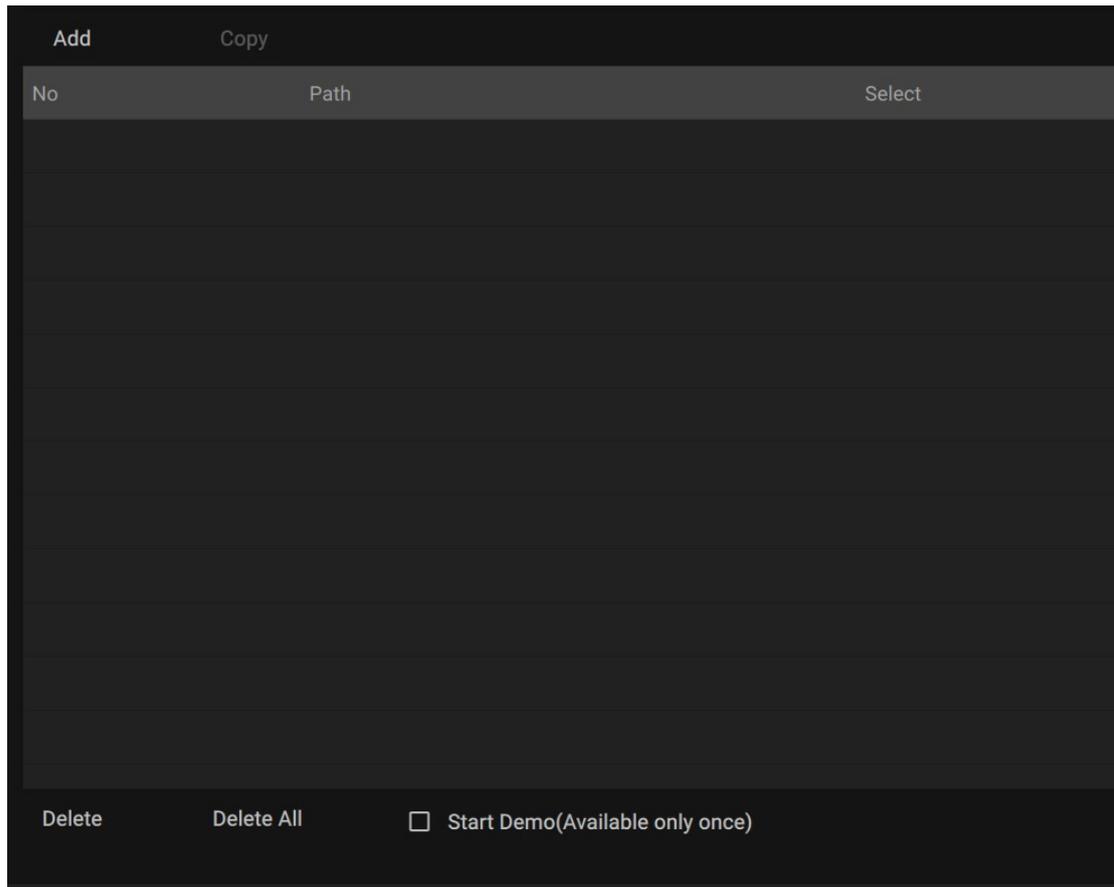
# 13.6 Demo

The Demo function is designed for you to play a demo.

## 13.6.1 Demo Page

Demo page via “Setup→ Demo”, screen is as follows:

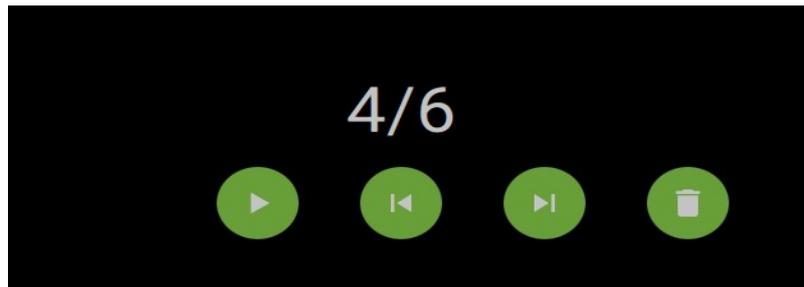




- **Normal:** Only play all the demo documents one time, and quit demo mode, enter to scan mode.
- **Repeat All:** play all demo document by recycling. Until quit demo mode manually.
- **Time interval:** Could be set from 1-500 minutes, default value is 3 minutes. To control the play speed.
- **Add:** to add a demo document to the play list.
- **Copy:** to add a demo document to the play list, and at the same time copy the document to E disk.
- **Delete:** to delete the selected document in the list.
- **Delete All:** to delete all the document in the list.
- **Start Demo:** check the item, and press OK button to start playing a demo.

## 13.6.2 Demo Play Page

Play a Demo, the controls are as followed:



- : to continue playing.
- : to pause playing.
- : to go to previous picture.
- : to go to next picture.
- : to delete current picture.
- : to quit demo mode.

## 13.7 Maintenance

The Maintenance function is designed for you to update the system software or other special functions. If you require these functions, please contact Wisonic Customer Service Department or sales representative.

Through the menu, you can perform net update, remote desktop, system test, log operation, etc.

### 13.7.1 About

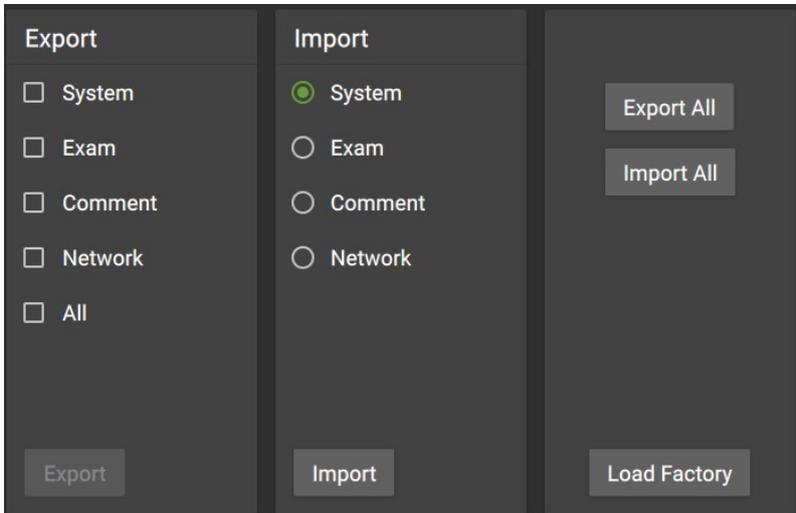
In the Setup menu to enter the system information screen via “**System->Maintenance->About**”.

```
CRC: 9426
OS Version: 0
Build Config: WA55-HUMAN
Software Version: 1.0.0
Build No: 258
SVN Revision: 29863
Date Time: 2016-09-01_14-32-10
Purpose: Human
DSP FPGA: 0x0
TR32A FPGA: 0x0
TR32B FPGA: 0x0
PCIe Driver: 0x0
EC Firmware: 0x0
PHV Firmware: 0x0
SM Firmware: 0x0
MainBoard: 0x0
CW Board: Installed
TR32B Board: 0x0
PHV Board: 0x0
ECG Plugged: Installed
Module 3G: Not Available
Screen serial: Unknown
```

This screen displays the system software version and versions of other devices. You cannot edit the information but only view them. The information varies depending upon the system configurations and version.

### 13.7.2 Data Manage

In the Setup menu to enter the Data Manage screen via “**System->Maintenance->Data Manage**”.

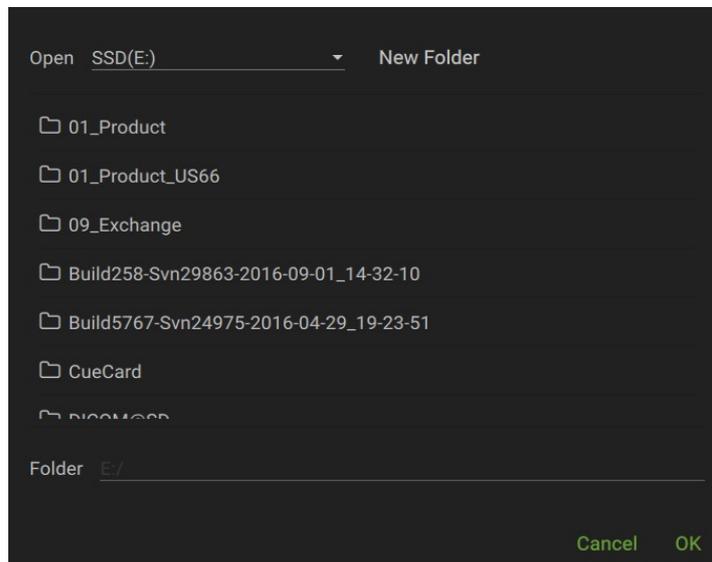


### 13.7.2.1 Export

This function is used to write the selected setup data into a disk for backup. The format of the data file is .zip.

Procedures:

1. Select some or all items in the “**Export**” field on the left side of the “**Data Manage**” screen.
2. Click “**Export**” to open the Export Data screen.
3. Select the path to save the data.



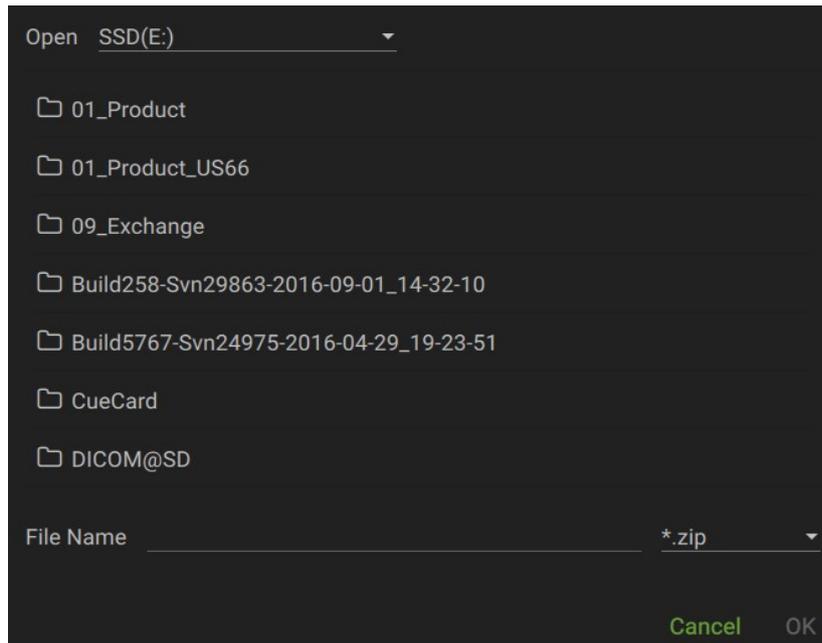
4. Select the exported file and type as DTA and click OK.

### 13.7.2.2 Import

This function is used to import the existing setup data to the setup data memory of the system. The system will reset and operate according to the setup preferences that were imported.

Procedures:

1. Select an item in the Import field on the right side of the Manage Settings screen.
2. Click Import to open the Load Data screen.
3. Select the imported file and type as DTA.



4. Click OK, a progress bar will appear and the setup data in DTA format is imported to the specified path.

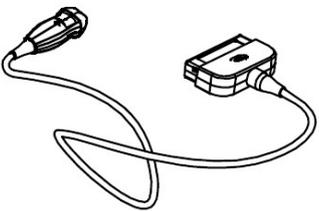
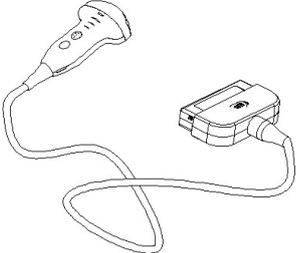
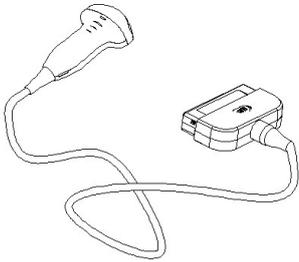
5. To restore the factory setup data, click Restore Factory on the right side of the screen.

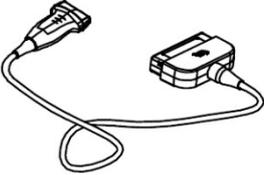
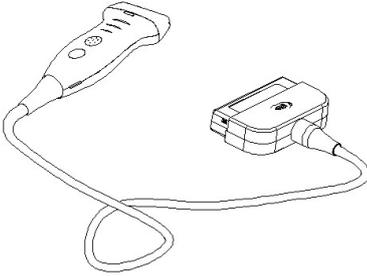
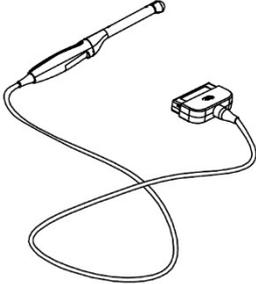
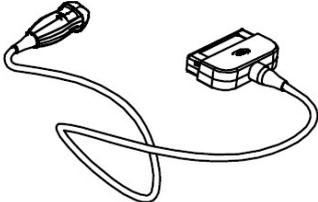
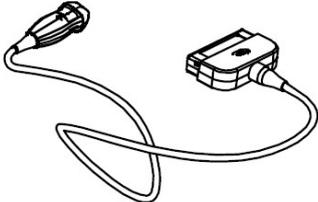
You can use Export All, Import All, or Load Factory at the bottom of the screen to export/import all setup data of the system or restore all factory setup data of the system. The operating methods are the same as those mentioned above.

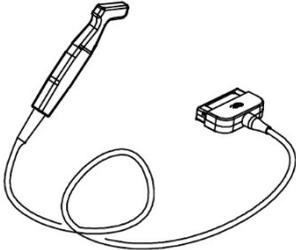
# 14 Probes and Biopsy

## 14.1 Probe

The system supports the following probes:

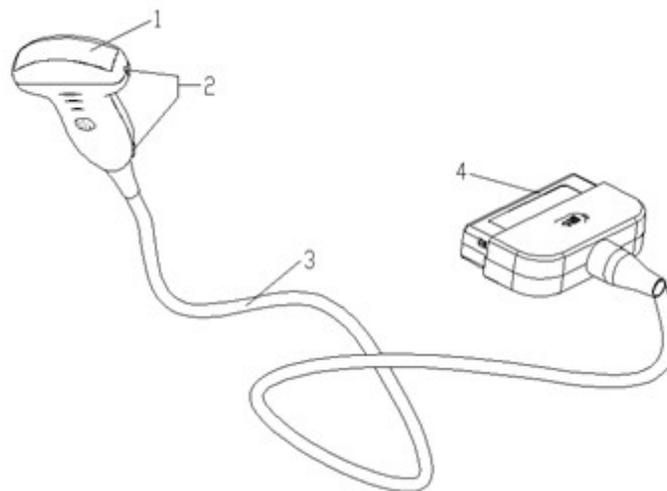
No.	Probe Model	Illustration
1.	C8-3	
2.	C5-2B	
3.	C5-2	

No.	Probe Model	Illustration
4.	L10-5	
5.	L15-4NB	
6.	EV10-4	
7.	P4-1	
8.	P7-3	

No.	Probe Model	Illustration
9.	LH15-6	

### 14.1.1 Name and Function of Each Part of the Probe

The basic structures and corresponding functions of probes are basically the same. The following will take probe C5-2B as an example to illustrate.



No.	Name	Function
<1>	Probe head	<p>It converts the electrical signal into ultrasound signal, making the sound beams focus in the given direction; meanwhile, it will receive the ultrasound signal and then convert the received signal into electrical signal.</p> <p>The lens on the surface is the acoustic lens. Apply ultrasound gel on the acoustic lens.</p>

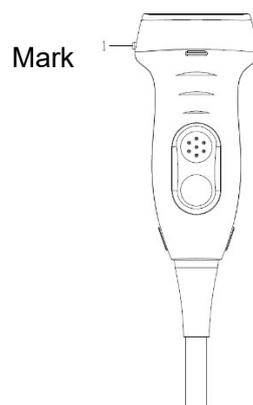
No.	Name	Function
<2>	Needle-guided bracket fix tabs and grooves	Used to mount the needle-guided bracket.
<3>	Probe cable	Used to transmit electrical signals between the probe body and connector.
<4>	Probe connector	Used to connect the probe to the ultrasonic diagnostic system.

Tips:

The probes' structure marked <2> in the figure above may vary with the matched needle-guided brackets.

## 14.1.2 Orientation of the Ultrasound Image and the Probe Head

The orientation of the ultrasound image and the probe are shown as below. The "Mark" side of the ultrasound image on the monitor corresponds to the mark side of the probe. Check the orientation before the examination (Here takes linear probe as an example).



## 14.1.3 Procedures for Operating

### 14.1.3.1 Inspecting probes

Perform After Each Use

Inspect the probe's lens, cable, casing, and connector. Look for any damage that would allow liquid to enter the probe. If any damage is found, do not use the probe until it has been inspected and repaired/replaced by a Wisonic Service Representative.

*NOTE: Keep a log of all probe maintenance, along with a picture of any probe malfunction.*

### 14.1.3.2 Environmental Requirements

Probes should be operated, stored, or transported within the parameters outlined below.

	Operational	Storage and transport
Temperature	0-40 ° C	-20-55 ° C
Humidity	30%-85% (non-condensing)	30%-95% (non-condensing)
pressure	700hPa-1060hPa	700hPa-1060hPa

**⚠Caution:** 1. Ensure that the probe face temperature does not exceed the normal operation temperature range

### 14.1.3.3 Probe Safety

#### Handling precautions

**⚠Warning** 1. Ultrasound probes are highly sensitive medical instruments that can easily be damaged by improper handling. Use care when handling and protect from damage when not in use. DO NOT use a damaged or defective probe. Failure to follow these precautions can result in serious injury and equipment damage.

The probe is driven with electrical energy that can injure the patient or user if live internal parts are contacted by conductive solution:

## **⚠Warning**

:

**DO NOT** immerse the probe into any liquid beyond the level indicated by the immersion level diagram. Refer to the immersion illustration in the Probe Cleaning Process section. Never immerse the probe connector or probe adaptors into any liquid.

**DO NOT** drop the probes or subject them to other types of mechanical shock or impact. Degraded performance or damage such as cracks or chips in the housing may result.

Prior to each use, visually inspect the probe lens and case area for cracks, cuts, tears, and other signs of physical damage. **DO NOT** use a probe which appears to be damaged until you verify functional and safe performance.

You must perform a more thorough inspection, including the cable, strain relief, and connector, each time you clean the probe.

Before inserting the connector into the probe port, inspect the probe connector pins. If a pin is bent, do not use the probe until it has been inspected and repaired/replaced by a Wisonic Service Representative.

**DO NOT** kink, tightly coil, or apply excessive force on the probe cable. Insulation failure may result.

### **Mechanical hazards**

#### **⚠Caution:** 1.

A defective probe or excessive force can cause patient injury or probe damage:

Observe depth markings and do not apply excessive force when inserting or manipulating intercavitary probes.

Inspect probes for sharp edges or rough surfaces that could injure sensitive tissue.

**DO NOT** apply excessive force to the probe connector when inserting into the probe port. The pin of a probe connector may bend.

### **Special handling instructions**

#### **⚠Caution:** 1.

Protective barriers may be required to minimize disease transmission.

Probe sheaths are available for use with all clinical situations where infection is a concern. Use of legally marketed, sterile probe sheaths is mandatory for intra-cavitary and intra-operative procedures. Use of legally marketed, sterile, pyrogen free probe sheaths is **REQUIRED** for neurological intra-operative procedures.

**Instructions.** Custom made sheaths are available for each probe. Each probe sheath kit consists of a flexible sheath used to cover the probe and cable and elastic bands used to secure the sheath.

Sterile probe sheaths are supplied as part of biopsy kits for those probes intended for use in biopsy procedures. In addition to the sheath and elastic bands, there are associated accessories for performing a biopsy procedure which are included in the kit. Refer to the

biopsy instructions for the specific probes in the Discussion section of this chapter for further information.

**Reordering.** To reorder sheaths, please contact your local distributor or the appropriate support resource.

**⚠Caution:** 1. Devices containing latex may cause severe allergic reaction in latex sensitive individuals

Do not use pre-lubricated condoms as a sheath. In some cases, they may damage the probe. Lubricants in these condoms may not be compatible with probe construction.

DO NOT use an expired probe sheath. Before using probe sheaths, verify whether the term of validity has expired.

#### **Endocavitary Probe Handling Precautions**

If the sterilization solution comes out of the endocavitary probe, please follow the cautions below.

**⚠Caution:** 1. Sterile/sanitary sheaths are to be used on the probe during its actual use with patients. Wearing gloves protects the patient and operator.

**Sterilant Exposure to Patient (e.g., Cidex)**—Contact with a sterilant to the patient’s skin or mucous membrane may cause an inflammation. If this happens, refer to the sterilant’s instruction manual.

**Sterilant Exposure from Probe Handle/Connector to Patient (e.g., Cidex)**—DO NOT allow the sterilant to contact the patient. Only immerse the probe to its specified level. Ensure that no solution has entered the probe’s handle before scanning the patient. If sterilant comes into contact with the patient, refer to the sterilant’s instruction manual.

**Endocavitary Probe Point of Contact**—Refer to the sterilant’s instruction manual.

#### **14.1.3.4 Probe handling and infection control**

This information is intended to increase user awareness of the risks of disease transmission associated with using this equipment and provide guidance in making decisions directly affecting the safety of the patient as well as the equipment user. Diagnostic ultrasound systems utilize ultrasound energy that must be coupled to the patient by direct physical contact. Depending on the type of examination, this contact occurs with a variety of tissues ranging from intact skin in a routine exam to recirculating blood in a surgical procedure. The level of risk of infection varies greatly with the type of contact.

One of the most effective ways to prevent transmission between patients is with single use or disposable devices. However, ultrasound transducers are complex and expensive devices that must be reused between patients. It is very important, therefore, to minimize

the risk of disease transmission by using barriers and through proper processing between patients.

**⚠ Caution:** 1. Risk of Infection. ALWAYS clean and disinfect the probe between patients to the level appropriate for the type of examination and use FDA-cleared probe sheaths where appropriate. Adequate cleaning and disinfection are necessary to prevent disease transmission. It is the responsibility of the equipment user to verify and maintain the effectiveness of the infection control procedures in use. Always use sterile, legally marketed probe sheaths for intra-cavitary and intra-operative procedures.

**⚠ WARNING:** Disinfect the probe and sterilize the needle-guided bracket before and after an ultrasound-guided biopsy procedure is performed. Failure to do so may cause the probe and the needle-guided bracket become source of infection.

#### 14.1.4 Wearing the Probe Sheath

A legally marketed probe sheath must be installed over the probe before performing intra-cavitary and intra-operative examination. Protective barriers may be required to minimize disease transmission. Probe sheaths are available for use with all clinical situations where infection is a concern.

To order probe sheath, contact:

CIVCO Medical Instruments Co.

102 First Street South, Kalona, IA 52247-9589 USA Tel: 1-319-656-4447

E-mail: [info@civco.com](mailto:info@civco.com)

<http://www.civco.com>

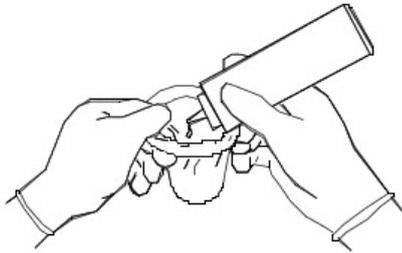
**⚠ CAUTION:** 1. Be sure to cover the probe with a new (unused) probe sheath to prevent infection during examination. If the package of a probe sheath is open or broken, the sterilization of the probe sheath may not be sufficient. DO NOT use such a probe sheath.

**2. The cover contains natural rubber latex and talc that can cause allergic reactions in some individuals.**

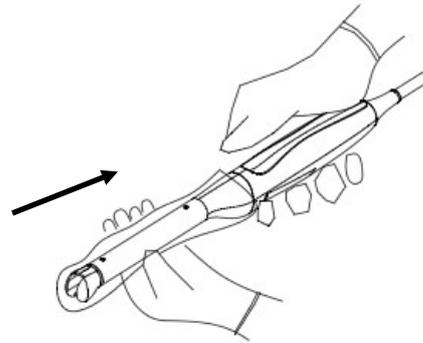
**3. DO NOT use an expired probe sheath. Before using probe sheaths, verify whether the term of validity has expired.**

Method (for reference only):

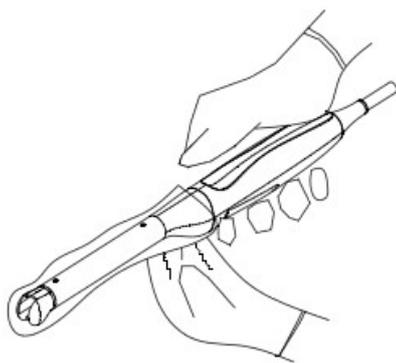
1. Place an appropriate amount of gel inside the sheath or on probe face. Poor imaging may result if no gel is used.



2. Insert the probe into the sheath; make sure to use proper sterile technique. Pull cover tightly over probe face to remove wrinkles and air bubbles, taking care to avoid puncturing cover.



3. Secure the sheath with enclosed elastic bands.



4. Inspect the sheath to ensure there are no holes or tears.

## 14.1.5 Probes Cleaning and Disinfection

### 14.1.5.1 14.1.5.1 Cleaning

After completing each examination, clean and disinfect the probes as required. Please refer to the follow instructions for cleaning.

#### **WARNING**

- **Disconnect the probes from the main unit.**
- **DO NOT immerse the probe connector into liquid such as water or disinfectant, which may cause electrical shock or system malfunction.**

#### **CAUTION**

- Wipe off the gel thoroughly after examination.
- Avoid collision the probe head with hard object in probe cleaning process.



- **When performing cleaning of probe to prevent infection, please wear sterile gloves.**

Please refer to the following instruction and your hospital policy for probe cleaning.

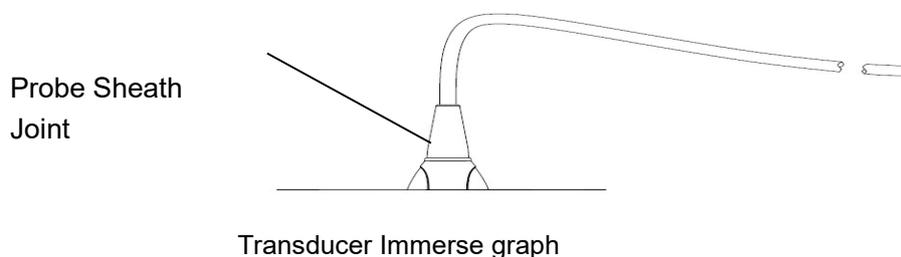
1. Disconnect the probe with the main unit
2. Wear the sterile gloves to prevent infection.
3. Wipe off the ultrasound gel and other foreign matter thoroughly with soft cotton ball or medical gauze,
4. Wash the probe head with clean water of soapy water(about 3 gallon.) to remove all remaining foreign matter.
5. After rinsing the probe head clean, dry the probe using a sterile cloth or gauze. Never dry the probe by heating.

### 14.1.5.2 Disinfection

The probe of ultrasonic diagnostic system is direct contact with patient. Different type examination leads to contact with different body part. The risk of infection depends on the contact body with the probe. The FDA guidance has indicates that ultrasound probes that are non-critical devices only need to be cleaned and low-level disinfected between patient uses. The probes used in semi-critical applications should be cleaned and sterilized or at least receive high level disinfection after use even if a sheath was used.

#### **⚠️ ⚠️WARNING**

- **Must follow local regulations when using the disinfectant.**
- **Please refer to the instruction concerning concentration of the disinfectant solution provided by the disinfectant manufacturer, and comply with the method of disinfection and dilution and caution during use, otherwise it may damage the probe.**
- **Only immerse part of the probe below the sheath joint when immerse the probe in the solution, observe the graph below carefully to immerse the probe.**



- **Do not immerse the part of probe connector or the cable near it into water or disinfectant, otherwise it may cause electric shock or probe damage.**
- **Please mind the expiry date of the disinfectant before performing probe disinfection. Do not use the expired disinfectant.**

#### **⚠️ ⚠️CAUTION**

- **Do rinsing the probe with plenty of sterile water to remove residual chemical on it. Because the chemical may be harmful to human body.**

- **Do not using the high-pressure steam/immersion for probe sterilization.**
- **Be sure to use sterile probe, the unsterile probe may become a source infection.**

**NOTE**

- Clean the probe before performing sterilization. Please use the disinfection or sterilization solution that recommended in this manual, because the disinfection have be accomplished chemical and biometric compatibility verification.
- If not use the manual recommended disinfectant, please refer to the instructions provided by the chemical manufacturer concerning concentration of the sterilization solution, method of sterilization and dilution and cautions during use.
- Wipe off the ultrasound gel thoroughly from the probe head after completing the examination, otherwise the residual ultrasound gel may solidify and degrade the image quality.
- Do not make the probe to become overheat (more than 55°C) during cleaning and disinfections. High temperature may cause the probe damaged.



- When performing cleaning and disinfection of the probe to prevent infection, wear the sterile gloves and protective eyewear.

**14.1.5.2.1 Disinfection for Surface probe**

Be sure to perform disinfection after use of the surface probe, process as follows,

1. Cleaning the probe before disinfection. Please refer to the “1.5 probe cleaning”
2. WISONIC recommends the following solution to disinfect the probe with low level disinfection.

Chemical Name	Solution Name	Manufacturer	Type	Time of duration
---------------	---------------	--------------	------	------------------

Chemical Name	Solution Name	Manufacturer	Type	Time of duration
Iso-Propyl alcohol (70%)	IPA	All	Spray /sponge	10 minutes

3. Rinse the transducer with plenty of sterile water (about 2 gallons) for at least 1 minute to remove all residues chemical on it, or follow the rinsing method recommended by the disinfectant manufacturer.

4. Wipe off the water on the transducer with sterile cloth or gauze after rinsing it. Do not dry the transducer by heating.

#### 14.1.5.2.2 Disinfection for intracavitary probe

Be sure to perform disinfection after use of the intracavitary probe, process as follows,

1. Cleaning the probe before disinfection. Please refer to the “1.5 probe cleaning”
2. WISONIC recommends the following solution to disinfect the probe with high level disinfection.

Chemical Name	Solution Name	Manufacturer	Type	Time of duration
Ortho-phthal aldehyde (0.55%)	Cidex OPA	J&J	Solution	12 minutes(25°C)

1. Rinse the transducer with plenty of sterile water (about 2 gallons) for at least 1 minute to remove all residues chemical on it, or follow the rinsing method recommended by the disinfectant manufacturer.

3. Wipe off the water on the transducer with sterile cloth or gauze after rinsing it. Do not dry the transducer by heating

#### NOTE

1. It is normal phenomenon that the acoustic lens change color after being repeatedly disinfected.
2. Repeated disinfection may degrade the performance and safety of the probe. Before examination is performed and after disinfected of the probe, confirm that the probe is normal. Manually confirm that the appearance of the probe do not has surface defects, cracks and peeling. If an abnormality is found on the probe,

immediately stop using it and contact WISONIC customer service department or sales representative.

## 14.1.6 Storage and transportation

After the examinations are accomplished, please confirm that the probe is normal. The disinfected probe should be stored in a suitable place so that the next examination can be conducted smoothly.

1. To prevent the probe from being damage, Do Not store it in location where it may be exposed to:
  - Direct sunlight and X-ray
  - Temperature extreme changes
  - Dust
  - Excessive vibration
  - Heat generators
2. Store and transport the probe under the following ambient condition:
  - Ambient temperature : -20°C ~ 55°C
  - Relative humidity : 30% ~ 95% (no condensation)
  - Atmosphere : 700hPa ~ 1060hPa
3. Be sure to disinfect the probe and keep it in the case to prevent infection when sent it to WISONIC customer service department or sales representative for repair.
4. Please disinfect the probe case as necessary.

## 14.2 Biopsy

Please refer to the corresponding biopsy bracket guide operation manual.

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# 15 System Maintenance

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Routine system maintenance shall be carried out by the user. Service maintenance will be provided by Wisonic service engineers while the system is under warranty. System maintenance after the warranty has expired is the full responsibility of the owner /operator.

- |                  |   |
|------------------|---|
| <b>⚠️ WARNIN</b> | 1. Only an authorized Wisonic service engineer can perform maintenance not specified in this basic user manual. |
| <b>G:</b>        | 2. For the sake of the system performance and safety, you should perform periodical checks for the system.      |

## 15.1 Daily Maintenance

You are responsible for daily maintenance.

### 15.1.1 Cleaning the System

- |                  |  |
|------------------|--|
| <b>⚠️ WARNIN</b> | Before cleaning the system, be sure to turn off the power and disconnect the power cord from the outlet. If you clean the system while the power is “On”, it may result in electric shock. |
| <b>G:</b>        |  |

#### ■ Cleaning the probe

Please refer to the basic user manual of the corresponding transducer or “12 Probe and Biopsy” chapter to perform cleaning and disinfection.

#### ■ Cleaning the probe cable

- a) Use soft dry cloth to wipe off stains from the probe cable.
- b) If it is difficult to clean the stains thoroughly, use soft cloth dipped with mild detergent, and then let the cable air dry.

#### ■ Cleaning the monitor

Use a soft cloth, apply a glass cleaner directly to the cloth and wipe down the monitor to remove finger marks, dust and smudges. Then allow the monitor to air-dry.

- NOTE:**
1. Do not use hydrocarbon glass cleaner or cleaner for OA (Office Automation) equipment to clean the monitor. These substances may cause deterioration of the monitor.
  2. Please clean the control panel periodically, otherwise the button may be blocked by dirt and the system will be buzzing while the button makes no response.

■ **Cleaning the control panel, cover and bracket**

Use dry soft cloth to clean the surface of the system. If the system is dirty, moisten the soft cloth with a mild or neutral detergent and wipe off any stains. Use dry soft cloth to remove any moisture and allow all hard surfaces to completely air-dry.

### 15.1.2 Checking the Probe

Check the probe connector for crack each time before use. DO NOT use the probe if a crack is inspected. A thorough inspection to the probe including cable and connector is required each time when you clean the probe.

### 15.1.3 Backup of the System Hard Drive

To prevent deterioration or loss of data stored in the system hard drive, create a backup copy of the hard drive at regular intervals.

## 15.2 Maintenance Checks by Service Engineer

The following checks must be performed to ensure and maintain system safety and performance. Please contact Wisonic Customer Service Department or sales representative to schedule and carry out these checks.

Check Category	Check Item
Cleaning	Interior of the system Peripherals
Electric safety	Ground leakage current Enclosure leakage current Patient leakage current Patient leakage current (110% supply voltage on applied part) Patient auxiliary leakage current

Check Category	Check Item
Mechanical safety	Monitor mounting mechanism Control panel Mounting mechanism for the peripheral devices Check other mechanical structures Check the probe appearance
Image recording	Images in each mode Image recording by using the standard probe

## 15.3 Consumables and Periodic Part Replacement

This system contains some consumables and parts requiring periodic replacement. Before replacing them, please contact Wisonic Customer Service Department or sales representative for instructions.

## 15.4 Troubleshooting

To ensure proper system operation and function, it is recommended that a maintenance and inspection plan be established to periodically check the safety of the system. If any system malfunction is experienced, contact Wisonic Customer Service Department or sales representative.

If any persistent system malfunction is experienced, e.g. an onscreen error message, blank imaging screen, absent menus, please refer to the following table below. If the failure cannot be eliminated, please contact Wisonic Customer Service Department or sales representative.

### **⚠CAUTION:**

- 1 Do not spill water or other liquid into the system while you perform the cleaning. Otherwise it may result in malfunction or electric shock.**
- 2 When you want to clean probe connectors and TGC sliders, contact Wisonic Customer Service Department or sales representative. Cleaning it yourself may result in malfunction or degradation of the performance.**

Troubleshooting Table

No.	Failure	Cause	Measure
1	After the power supply is turned on, the power indicator does not light on.	Abnormal power system or incorrect connection of the power cord.	Verify that the plug has not become loosened or dislodged from the back of the system.
2	When the power indicator of the monitor is on and image is blank.	<ul style="list-style-type: none"> <li>■ The interval between turnoff and restart is too short – wait a minimum time of 20 seconds.</li> <li>■ The monitor brightness or contrast may be improperly set.</li> </ul>	<ul style="list-style-type: none"> <li>■ Turn off the system and wait a minimum time of 1 minute, and then restart the system.</li> <li>■ Adjust the monitor brightness and contrast back to factory defaults.</li> </ul>
3	The monitor displays the characters but no images.	<ul style="list-style-type: none"> <li>■ The transmission power, overall gain or TGC controls are improperly set.</li> <li>■ Verify that a probe is connected and / or fully connected.</li> <li>■ The system is in the frozen status.</li> </ul>	<ul style="list-style-type: none"> <li>■ Adjust the transmission power, gain or TGC control.</li> <li>■ Ensure proper probe connection.</li> <li>■ Unfreeze the image.</li> </ul>
4	The image quality is degraded	<ul style="list-style-type: none"> <li>■ The exam mode is not correct.</li> <li>■ The settings of the image post processing are not correct.</li> <li>■ The image presets are inappropriate</li> </ul>	<ul style="list-style-type: none"> <li>■ Select an appropriate exam mode.</li> <li>■ Adjust the settings of the image via post processing or reset the post processing to the default values.</li> <li>■ Reset the factory default setups.</li> </ul>
5	The button is response less with the system buzzing	<ul style="list-style-type: none"> <li>■ There is too much dirt blocking the button</li> </ul>	<ul style="list-style-type: none"> <li>■ Check the control panel for the button being blocked and press it several times to release it.</li> <li>■ Clean the button.</li> </ul>

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# 16 Acoustic Output

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This section of the basic user manual applies to the overall system including the main unit, probes, accessories and peripherals. This section contains important safety information for operators of the device, pertaining to acoustic output and how to control patient exposure through use of the ALARA (as low as reasonably achievable) principle. Also this section contains information regarding the acoustic output testing and the real-time output display.

Read this information carefully before using the system.

## 16.1 Concerns with Bioeffects

Diagnostic ultrasound is recognized as being safe. In fact, there have been no reports of injuries to patients caused by diagnostic ultrasound.

It cannot be stated categorically that ultrasound is 100% safe. Studies have revealed that ultrasound with extremely high intensity is harmful to body tissues.

Diagnostic ultrasound technology has made a great leap forward during the last several years. This rapid advance has generated concerns about the potential risk of bioeffects when new applications or diagnostic technologies become available.

## 16.2 Prudent Use Statement

Although there are no confirmed biological effects on patients caused by exposures from present diagnostic ultrasound instruments, the possibility exists that such biological effects may be identified in the future. Thus ultrasound should be used in a prudent manner to provide medical benefit to the patient. High exposure levels and long exposure times should be avoided while acquiring necessary clinical information.

## 16.3 ALARA Principle (As Low As Reasonably Achievable)

It is required to practice ALARA when using ultrasound energy. Practicing ALARA ensures that the total energy level is controlled below a low enough level at which bioeffects are not generated while diagnostic information is being accumulated. The total energy is

controlled by output intensity and total radiation time. The output intensity necessary for examinations differs depending on the patient and the clinical case.

Not all examinations can be performed with an extremely low level of acoustic energy. Controlling the acoustic level at an extremely low level leads to low-quality images or insufficient Doppler signals, adversely affecting the reliability of the diagnosis. However, increasing the acoustic power more than necessary does not always contribute to an increase in quality of information required for diagnosis, rather increasing the risk of generating bioeffects.

Users must take responsibility for the safety of patients and utilize ultrasound deliberately. Deliberate use of ultrasound means that output power of ultrasound must be selected based on ALARA.

Additional information regarding the concept of ALARA and the possible bioeffects of Ultrasound is available in a document from the AIUM (American Institute of Ultrasound Medicine) title "*Medical Ultrasound Safety*".

## **16.4 MI/TI Explanation**

### **16.4.1 Basic Knowledge of MI and TI**

The relationship of various ultrasound output parameters (frequency, acoustic pressure and intensity, etc.) to bioeffects is not fully understood presently. It is recognized that two fundamental mechanisms may induce bioeffects. One is a thermal bioeffect with tissue absorption of ultrasound, and another one is a mechanical bioeffect based on cavitations. Thermal Index (TI) gives the relative index of temperature increase by thermal bioeffect, and Mechanical Index (MI) gives the relative index of mechanical bioeffect. TI and MI indices reflect instantaneous output conditions, so they DO NOT consider the cumulative effects of the total examination time. TI and MI models contain practical simplifications to complex bioeffects interaction. Then the operator should be aware that the actual worst case temperature rise may be up to several times higher than the displayed TI value.

#### ■ MI (Mechanical Index):

The mechanical bioeffects are the result of compression and decompression of insonated tissues with the formation of micro bubbles that may be referred to as cavitations.

MI is an index that shows the possibility of the cavitations generation based on acoustic pressure, and the value in which the peak-rarefactional acoustic pressure is divided by the square root of the frequency. Therefore MI value becomes smaller when the frequency is higher or the peak-rarefactional acoustic pressure is lower, it becomes difficult to generate the cavitations.

$$MI = \frac{P_{r, \alpha}}{\dots} \times C_{MI}$$

$$C_{MI} = 1 \text{ (MPa/...)}$$

For the frequency 1 MHz and the peak-rarefactional acoustic pressure 1 MPa, MI becomes 1. It is possible to think MI to be one threshold of the cavitations generation. Especially, it is important to keep MI value to be low when both gases and the soft tissues exist together, for such as lung exposure in cardiac scanning and bowel gas in abdominal scanning.

■ TI (Thermal Index):

TI is determined by the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1 degree C. In addition, because the temperature rises is greatly different according to tissue structures, TI is divided three kinds: TIS (Soft-tissue Thermal Index), TIB (Bone Thermal Index) and TIC (Cranial-bone Thermal Index).

- TIS: Thermal index related to soft tissues, such as abdominal and cardiac applications.
- TIB: Thermal index for applications, such as fetal (second and third trimester) or neonatal cephalic (through the fontanel), in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.
- TIC: Thermal index for applications, such as pediatric and adult cranial applications, in which the ultrasound beam passes through bone near the beam entrance into the body.

Although the output power is automatically controlled for the selected applications, high TI values should be kept to a minimum or avoided in obstetric applications. WFUMB (World Federation for Ultrasound in Medicine and Biology) guidelines: state that temperature increase of 4 degree C for 5 min or more should be considered as potentially hazardous to embryonic and fetal tissue.

The smaller the MI/TI values, the lower the bioeffects.

## 16.4.2 MI/TI Display

TI and MI values are displayed in real time in the upper part of the screen. The operator should monitor these index values during examinations and ensure that exposure time and output values are maintained at the minimum amounts needed for effective diagnosis.

Under different operating conditions, once there is a situation that a MI value is greater than 1.0; the start point of displaying MI values is 0.4.

In the same way, once there is a situation that a TI value is greater than 1.0, the TI value will be displayed and the start point is 0.4. You can set which TI item is to be displayed in the setup.

**NOTE:** If there is a value of MI or TI exceeds 1.0, you must be careful to practice the ALARA principle.

The display precision is 0.1.

## 16.5 Acoustic Power Setting

### ■ Acoustic power adjustment

Touch AP in the Menu to adjust the acoustic power percentage, and its value is displayed on the corresponding item. The greater the acoustic power percentage, the greater the current acoustic output.

When the image is frozen, the system stops transmitting acoustic power.

### ■ Default setting of acoustic power

Selection of diagnostic applications is the most important factor for controlling ultrasound output.

The permissible level of intensity of ultrasound differs depending on the region of interest. For fetal examinations, in particular, much care must be exercised.

In this system, imaging setups can be created using the ultrasound output set by you. At this time, the default function is disabled. It is the user's responsibility for any change to the default settings.

Default choices

Initial power	10% to 100%*
---------------	--------------

\* Definition of 100%: The maximum acoustic power of a transducer determined by the increase in transducer surface temperature in the selected mode and the acoustic power restrictions specified by the FDA.

**NOTE:** This system automatically returns to the settings whenever changes are made to the values (when you turn on the power, switch between probes, press <End Exam>, or select Return in the Setup menu). In the factory default settings, the Acoustic Output is limited below settings. Following the ALARA restriction, you are allowed to increase the acoustic power under FDA 510(k) Guidance-Track3 limits and to set it in the image preset screen.

The acoustic output of the system has been measured and calculated in accordance with IEC60601-2-37: 2005, FDA 510(K) GUIDANCE, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (NEMA UD-2 2004) and the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (AIUM and NEMA UD-3 2004).

## 16.6 Acoustic Power Control

The qualified operator may use the system controls to limit the ultrasound output and to adjust the quality of the images. There are three categories of system controls relative to output. They are controls that have direct effect on the output, controls that indirectly control output and controls that are receiver controls.

### ■ Direct Controls

It is possible to control, if necessary, the acoustic output with the Menu control on the control panel. In this case, the maximum value of the acoustic output never exceeds an MI of 1.9, TI of 6 and an  $I_{SPTA,3}$  of 720 mW/cm<sup>2</sup> in any mode of operation.

### ■ Indirect Controls

The controls that indirectly affect output are many imaging parameters. These are operating modes, frequency, focal point positions, image depth and pulse repetition frequency (PRF).

The operating mode determines whether the ultrasound beam is scanning or non-scanning. Thermal bioeffect is closely connected to M mode, Doppler and Color mode.

Acoustic attenuation of tissue is directly related to transducer frequency.

The focal point is related to active aperture of transducer and beam width.

For the higher PRF (pulse repetition frequency), the more output pulses occur over a period of time.

### ■ Receiver Controls

The receiver controls (for example, gain, dynamic range, and image post-processing, etc.) do not affect output. These controls should be used, when possible, to improve the image quality before using controls that directly or indirectly affect output.

# 16.7 Acoustic Output

## 16.7.1 Derated Ultrasonic Output Parameters

In order to determine the relevant Ultrasonic Output Parameters, a method is used which allows for the comparison of ultrasound systems which operate at different frequencies and are focused at different depths. This approach, called "derating" or "attenuating", adjusts the acoustic output as measured in a water tank to account for the effect of ultrasound propagation through tissue. By convention, a specific average intensity attenuation value is used, which corresponds to a loss of 0.3 dB/cm/MHz. That is, the intensity of ultrasound will be reduced by 0.3 dB/MHz for every centimeter of travel from the transducer. This can be expressed by the following equation:

$$I_{\text{atten}} = I_{\text{water}} \times 10^{(-0.3/10 \times f_c \times z)}$$

Where  $I_{\text{atten}}$  is the attenuated intensity,  $I_{\text{water}}$  is the intensity measured in a water tank (at distance  $z$ ),  $f_c$  is the center frequency of the ultrasound wave (as measured in water), and  $z$  is the distance from the transducer. The equation for attenuating pressure values is similar except that the attenuation coefficient is 0.15 dB/cm/MHz, or one-half the intensity coefficient. The intensity coefficient is double the pressure coefficient because intensity is proportional to the square of pressure.

Although the attenuation coefficient chosen, 0.3 dB/cm/MHz, is significantly lower than any specific solid tissue in the body, this value was chosen to account for fetal examinations. In early trimester ultrasound fetal examinations, there may be a significant fluid path between the transducer and the fetus, and the attenuation of fluid is very small. Therefore the attenuation coefficient was lowered to account for this case.

## 16.7.2 Limits of Acoustic Output

In accordance with the FDA Track 3 requirements, the derating (or attenuated) approach was incorporated into the FDA Acoustic Output Limits, as listed below. The maximum acoustic output level from any transducer in any operating mode is expected to fall below these limits.

FDA Maximum Acoustic Output Limits for Track 3 (Attenuated Values)

Application	$I_{\text{spta.3}}$ (mW/cm <sup>2</sup> )	$I_{\text{sppa.3}}$ (W/cm <sup>2</sup> )	MI
Regions (except eyes)	720	≤ 190	≤ 1.9

### **16.7.3 Differences between Actual and Displayed MI and TI**

In operation, the system will display to the operator the Acoustic Output Parameters Thermal Index, TI, or Mechanical Index, MI (or sometimes both parameters simultaneously). These parameters were developed as general indicators of risk from either thermal or mechanical action of the ultrasound wave. They serve to indicate to the operator whether a particular setting of the system increases or decreases the possibility of Thermal or Mechanical effect. More specifically, they were designed to assist in the implementation of the ALARA principle. As an operator changes a given system control, the potential effect of the change in output will be indicated. However, the Thermal Index is not the same as temperature rise in the body, for several reasons. First of all, in order to provide a single display index to you, a number of simplifying assumptions had to be made. The biggest assumption was the use of the attenuating formula described above, which is much lower than the actual value for most tissues within the body. Scanning through muscle or organ tissue, for example, will produce much higher attenuation than 0.3 dB/cm/MHz. There were also significant simplifications made for the thermal properties of tissue. Therefore, scanning through highly perfused tissue, such as the heart or vasculature, will produce significantly less thermal effect than that suggested by the Thermal Index.

Similarly, the Mechanical Index was derived to indicate the relative possibility of mechanical (cavitation) effects. The MI is based on the derated peak-rarefactional pressure and the center frequency of the ultrasound wave. The actual peak-rarefactional pressure is affected by the actual attenuation caused by tissue in the path between the transducer and the focal point. Again, all solid tissues within the body have higher attenuation than the proscribed 0.3 dB/cm/MHz value, and therefore, the actual peak-rarefactional pressure will be lower. Further, the actual peak-rarefactional pressure will change depending upon the region of the body being scanned.

For these reasons, the TI and MI displays should only be used to assist the operator in implementing ALARA at the time of the patient examination.

## **16.8 References for Acoustic Power and Safety**

1. "Bioeffects and Safety of Diagnostic Ultrasound" issued by AIUM in 1993
2. "Medical Ultrasound Safety" issued by AIUM in 1994

3. "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3" issued by AIUM/NEMA in 2004
4. "Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment, Revision 2" issued by AIUM/NEMA in 2004
5. "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued by FDA in 2008.
6. "Medical electrical equipment – Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment" issued by IEC in 2005.

# 17 Guidance and Manufacturer's Declaration

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The system complies with the EMC standard IEC60601-1-2: 2007.

**⚠️ WARNIN** The use of unapproved accessories may diminish system performance.

**G:**

- NOTE:**
- 1 Use of accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of system.
  - 2 The system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, system should be observed to verify normal operation in the configuration in which it will be used.
  - 3 The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
  - 4 Preventing conducted RF immunity. Due to technological limitations, the conducted RF immunity level are limited to 1Vrms level, conducted RF interference above 1Vrms may cause wrong diagnosis and measurements. We suggest that you position system further from sources of conducted RF noise.
  - 5 Operation of system, in the case that the patient physiological signal is lower than the minimum amplitude or value specified in the product specifications, may cause inaccurate results.
  - 6 Portable and mobile RF communications equipment can affects system. See tables 1, 2, 3, and 4 below.

TABLE 1

<b>GUIDANCE AND WISONIC DECLARATION—ELECTROMAGNETIC EMISSIONS</b>		
The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.		
<b>EMISSIONS TEST</b>	<b>COMPLIANCE</b>	<b>ELECTROMAGNETIC ENVIRONMENT — GUIDANCE</b>
RF emissions CISPR 11	Group 1	The system 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 CISPR 11	Class B	The system is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Compliance	

TABLE 2

<b>GUIDANCE AND WISONIC DECLARATION—ELECTROMAGNETIC IMMUNITY</b>			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.			
<b>IMMUNITY TEST</b>	<b>IEC 60601 TEST LEVEL</b>	<b>COMPLIANCE LEVEL</b>	<b>ELECTROMAGNETIC ENVIRONMENT-GUIDANCE</b>
Electrostatic Discharge(ESD) IEC 61000-4-2	±6 kV contact; ±8 kV air	±6 kV contact; ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient / burst IEC 61000-4-4	±2 kV for power supply voltage; ±1 kV for input/output voltage	±2 kV for power supply voltage;	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV voltage(s) to voltage(s); ±2 kV voltage(s) to earth	±1 kV voltage(s) to voltage(s); ±2 kV voltage(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variation on power supply input voltage IEC 61000-4-11	<5% UT (>95% dip in UT ) for 0.5 cycle 40% UT (60% dip in UT ) for 5 cycle 70% UT (30% dip in UT ) for 25 cycle <5% UT (>95% dip in UT ) for 5 sec	<5% UT for 0.5 cycle 40% UT for 5 cycles 70% UT for 25 cycles <5% UT for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/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.			

TABLE 3

<b>GUIDANCE AND WISONIC DECLARATION—ELECTROMAGNETIC IMMUNITY</b>			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.			
<b>IMMUNITY TEST</b>	<b>IEC 60601 TEST LEVEL</b>	<b>COMPLIANCE LEVEL</b>	<b>ELECTROMAGNETIC ENVIRONMENT-GUIDANCE</b>
Conduced RF IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-3	3V/m 80MHz - 2.5GHz	3V/m	$d = 1.2 \times \sqrt{P}$ $d = 1.2 \times \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \times \sqrt{P} \quad 800 \text{ MHz to } 2.5\text{GHz}$ <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

TABLE 4

<b>RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND THE SYSTEM</b>			
The system is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and system as recommended below, according to the maximum output power of the communication equipment.			
<b>Rated Maximum Output power of Transmitter (W)</b>	<b>Separation Distance According to Frequency of Transmitter (m)</b>		
	150kHz -80MHz $d = 1.2\sqrt{P}$	80MHz-800MHz $d = 1.2\sqrt{P}$	800MHz-2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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.			

Table 5

<b>Main technical parameters of 4G/WIFI</b>				
The device includes RF transmitter, each transmitter frequency, modulation type, frequency characteristic and effective radiated power parameters are provided as follow to refer				
RF	<b>technical parameters</b>			
	frequency/frequency band	modulation type	frequency tolerance	transmit power

3G	885-915MHz 1710-1755MHz 1920~1980MHz	GMSK/8PSK BPSK	$\leq 0.1 \text{ ppm}$	33/30dBm $\pm$ 2dB $\leq$ 24dBm+1
WIFI	2.412GHz~2.483 5GHz	802.11b :CCK,QPSK,BPSK, 802.11 g/n:OFDM	/	11b:17 $\pm$ 1.0dBm@11 Mbps;  11g:14 $\pm$ 1dBm@54M bps  802.11n(HT 20),12+/-1d Bm,  802.11n(HT 40),12+/-1d Bm



# 18 Appendix

## 18.1 OB Reference

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