# TE Air

## Diagnostic Ultrasound System

## Operator's Manual

For this Operator's Manual, the issue date is 2024-01.

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The electrical installation of the relevant room complies with the applicable national and local requirements; and the product is used in accordance with the instructions for use.

## NOTE

This equipment must be operated by skilled/trained clinical professionals.

## ⚠ WARNING

**It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.**

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This warranty shall not extend to:

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- 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.

# Customer Service Department

| | |
|---|---|
| Manufacturer: | Shenzhen Mindray Bio-Medical Electronics Co., Ltd. |
| Address: | Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China |
| Website: | www.mindray.com |
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| | |
|---|---|
| Manufacturer: | Mindray DS USA, Inc. |
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| Toll Free: | +1 (800) 288-2121 |
| Fax: | +1 (800) 926-4275 |

# Important Information

- It is the customer's responsibility to maintain and manage the system after delivery.
- The warranty does not cover the following items, even during the warranty period:
  - Damage or loss due to misuse or abuse.
  - Damage or loss caused by Acts of God such as fires, earthquakes, floods, lightning, etc.
  - Damage or loss caused by failure to meet the specified conditions for this system, such as inadequate power supply, improper installation or environmental conditions.
  - Damage or loss due to use of the system outside the region where the system was originally sold.
  - Damage or loss involving the system purchased from a source other than Mindray or its authorized agents.
- This system shall not be used by persons other than fully qualified and certified medical personnel.
- DO NOT make changes or modifications to the software or hardware of this system.

- In no event shall Mindray be liable for problems, damage, or loss caused by relocation, modification, or repair performed by personnel other than those designated by Mindray.
- The purpose of this system is to provide physicians with data for clinical diagnosis. The physician is responsible for the results of diagnostic procedures. Mindray shall not be liable for the results of diagnostic procedures.
- Important data must be backed up on external memory media.
- Mindray shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents.
- This manual contains warnings regarding foreseeable potential dangers, but you shall also be continuously alert to dangers other than those indicated. Mindray shall not be liable for damage or loss resulting from negligence or ignorance of the precautions and operating instructions described in this operator's manual.
- If a new manager takes over this system, be sure to hand over this operator's manual to the new manager.

# About This Manual

This operator's manual describes the operating procedures for this diagnostic ultrasound system and the compatible probes. To ensure safe and correct operation, carefully read and understand the manual before operating the system.

# Meaning of Signal Words

In this manual, the signal words **DANGER**, **WARNING**, **CAUTION**, **NOTE** and **Tip** are used regarding safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

| Signal word | Meaning |
|---|---|
| **DANGER** | Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury. |
| **WARNING** | Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury. |
| **CAUTION** | Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. |
| **NOTE** | Indicates a potentially hazardous situation that, if not avoided, may result in property damage. |
| **TIP** | Important information that helps you to use the system more effectively. |

# Manuals

- Operator's Manual
  - Describes the basic functions and operations of the system, safety precautions, exam modes, imaging modes, preset, measure, maintenance and acoustic output, etc.
  - Contains data tables of acoustic output for transducers.
- Quick Reference Guide
  - Contains a quick reference guide for basic system operations.

## NOTE

- The accompanying manuals may vary depending on the specific system you purchased. Please refer to the packing list.

## Software Interfaces in this Manual

Depending on the software version, preset settings and optional configuration, the actual interfaces may be different from those in this manual.

## Conventions

In this manual, the following conventions are used to describe the buttons on the control panel, items in the menus, buttons in the dialog boxes and some basic operations:

- [**Items in menu or buttons in dialog box**]: square brackets indicate items in menus, on the soft menu or buttons in dialog boxes.
- Tap [**Items or Buttons**]: tap the corresponding item on the screen.
- [**Items in menu**] > [**Items in submenu**]: select a submenu item following the path.

## Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and possibly to the competent authority of the Member state in which the user and / or patient is established.

These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

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# 1 Important Information

## 1.1 Safety Precautions

Please observe the following precautions to ensure patient and operator's safety when using this system.

### ⚠ DANGER

**Do not operate this system and probes in an atmosphere containing flammable gases or liquids such as anesthetic gases, hydrogen, and ethanol, because there is danger of explosion.**

### ⚠ WARNING

- **The ultrasound probe is only for use with the specified ultrasound diagnostic system.**
- **The ultrasound probe must be used only by qualified professionals.**
- **Confirm that the transducer and probe cable are normal before and after each examination. A defective probe may cause electric shock to the patient.**
- **Do not subject the probe to shock. A defective probe may cause electric shock to the patient.**
- **Do not disassemble the probe to avoid the possibility of electric shock.**
- **When using a probe, pay attention to the status of the ultrasound image. Do not use the probe to perform image acquisition when the image is frozen.**
- **Do not use this system when any digital device such as a high-frequency electrotome, high-frequency therapeutic device or defibrillator is applied already. Otherwise, there is a risk of electric shock to the user or patient.**
- **Additional equipment (analog or digital) connected to the ultrasound system must comply with the relevant IEC standards (e.g., IEC 60950 information technology equipment safety standard and IEC 60601-1 medical equipment standard). Furthermore, all configurations must comply with the standard IEC 60601-1. It is the responsibility of the person who connects the additional equipment to the signal input or output ports and configures a medical system to verify that the system complies with the requirements of IEC 60601-1. If you have any questions regarding these requirements, consult your vendor.**
- **Do not use an aftermarket probe other than those specified by Mindray. The probes may damage the system causing a profound failure, e.g. a fire in the worst case.**

### ⚠ CAUTION

- **Do not use the system to examine the same part for a long period of time.**
- **When using the probe, wear sterile gloves to prevent infection.**
- **Please use the ultrasound gel compliant with the relevant local regulations. And manage the ultrasound gel properly to ensure that it does not become a source of infection.**
- **In normal diagnostic ultrasound mode, there is no danger of a normal-temperature burn; however, do not keep the probe on the same region of the patient for more than 10 minutes to avoid risk of burn.**
- **Do not use the carrying case for storing the transducer. If the carrying case is used for storage, it may become a source of infection.**
- **It is required to practice ALARA when operating ultrasound system. Minimize the acoustic power without compromising the quality of images.**

- **The probe and accessories supplied with it are not delivered disinfected.**
- **Disposable components should be packaged sterile and for single-use only. Do not use if integrity of packaging violated or if expiration date has passed. Please use the disposable components compliant with the relevant local regulations.**
- **Please use the disinfection solution recommended in this operator's manual; otherwise Mindray will not be liable for damage caused by other solutions. If you have any questions, please contact Mindray Customer Service Department or sales representative.**
- **Do not use pre-lubricated condoms as a sheath. Lubricant may not be compatible with the probe material and damage may result.**
- **The damage of the transducer may be caused by the contact of improper gel or cleaner:**
  - **DO NOT dip the transducer in the strong polar solution of ethanol, chloride of lime, ammonium chloride, acetone and formaldehyde.**
  - **DO NOT contact the transducer with solution or ultrasound gel containing oily medium such as mineral oil or lanoline.**
- **Malfunctions due to radio wave:**
  - **If a radio wave emitting device is used in the proximity of this system, it may interfere with operations. Do not use or take any devices transmitting RF signals (such as cellular phones, transceivers and radio controlled products) in the room placing the system.**
  - **If a person brings a device that generates radio waves near the system, ask him/her to immediately turn OFF the device.**
- **If the system is powered off improperly during operation, it may result in data damage of the system's hard disk or system failure.**

## NOTE

- DO NOT use the system in the vicinity of strong electromagnetic field (such as a transformer), which may affect the performance of the system.
- Do not use the system in the vicinity of high-frequency radiation source (e.g. cellular phones), which may affect the performance of the system or even lead to failure.
- Read the following precautions to prevent the probe from malfunction:
- Before connecting or disconnecting the probe, freeze or turn off the system.
- Clean and disinfect the probe before and after each examination.
- After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and the image quality would be degraded.
- Repeated disinfection will eventually damage the probe, please check the probe performance periodically.
- To dispose of the system or any part, contact Mindray Customer Service Department or sales representative. Mindray is not responsible for any system content or accessories that have been discarded improperly.
- The system should not be connected to an unsecured network.
- Ensure that probe software and the TE Air software versions are latest and compatible with each other. Otherwise, it could cause issues in the basic functionality of the TE Air and could also cause issues in pairing the probe with the app.
- The operating system should not be rooted or jail-broken. Otherwise, the security of the operating system will be degraded.
- The operating system of the device is a safe system. Follow the security suggestions of the operating system for use.

- Please download the application through the recommended channel of the device to prevent the security of the operating system from being degraded by third-party software or malicious software attacks.
- The probe has an over-temperature protection mechanism. When the probe temperature exceeds the upper limit, the probe will be shut down forcibly.

## 1.2 Latex Alert

When choosing a probe sheath, it is recommended that you directly contact CIVCO for obtaining information regarding probe sheaths, pricing, samples and local distribution.

For CIVCO information, please contact the following:

CIVCO Medical Instruments

Tel: 1-800-445-6741

www.civco.com

Allergic reactions in patients sensitive to latex (natural rubber) may range from mild skin reactions (irritation) to fatal anaphylactic shock, and may include difficulty breathing (wheezing), dizziness, shock, swelling of the face, hives, sneezing, or itching of the eyes (FDA Medical Alert on latex products, “Allergic Reactions to Latex-containing Medical Devices”, issued on March 29, 1991).

## 1.3 Parts That Can be Used Within Patient Environment

The ultrasound system

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# 2 System Overview

## 2.1 Intended Use

TE Air Diagnostic Ultrasound System  is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in abdominal, pediatric , thoracic/pleural (For detection of fluid and pleural motion/sliding.), adult and pediatric cardiac, neonatal and adult cephalic, and urology exams.

This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.

Modes of operation include: B, M, PWD, Color Doppler, Amplitude Doppler, Combined mode(Color+B, Power+B), Tissue Harmonic Imaging, and TDI.

### NOTE

The system is not intended for central cardiovascular or central nervous system use.

## 2.2 Safety Classifications

- According to the type of protection against electric shock: internally powered equipment
- According to the degree of protection against electric shock: Type-BF applied part
- According to the degree of protection against harmful ingress of water: IP68
- According to the disinfection and sterilization method(s) recommended by manufacturer: Equipment with disinfection and sterilization method(s) recommended by manufacturer.
- 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
- According to the mode of operation: Continuous operation
- Does the equipment has any defibrillation-proof applied parts: Non-defibrillation-proof applied part
- Does the equipment has any signal input and output parts: With signal input and output parts
- Permanently installed equipment or non-permanently installed equipment: Non-permanently installed equipment
- According to the mode of movement: Handheld

### NOTE

**Please refer to the safety classification information in the related operator's manual for the ultrasonic diagnostic system when the probe is used with the matched ultrasonic diagnostic system.**

## 2.3 Security

The following measures are taken by Mindray to ensure information security and network security:

- Role-based access control
- The patient database is encrypted locally, and the patient data is encrypted during transmission.
- Support wireless encryption standard WPA2 (PSK)
- Use the latest commercial vulnerability scanning tool to evaluate potential system vulnerabilities.

# 2.4 Operating Environment

The operating condition is the minimum configuration.

## 2.4.1 Hardware Configuration

### For iOS Platform

- Processor: Apple A10 processor
- Hard disk: 128 GB
- Storage space: 2 GB
- Display size: 4.7 inches (Diagonal)
- Display resolution: 1334 × 750
- Display brightness: 400 nit

### For Android Platform

- Processor: Qualcomm Cellulon 855
- Hard disk: 256 GB
- Storage space: 8 GB
- Display size: 6.41 inches (Diagonal)
- Display resolution: 2340 × 1080
- Display brightness: 400 nit

## 2.4.2 Software Environment

Apple platform required 13.0 version or above, with the function of automatically optimizing the screen brightness according to the ambient light.

Android platform required 9.0 version or above.

## 2.4.3 Network Conditions

- Wireless network: The protocol is compatible with IEEE 802.11 a/b/g/n/ac standard
- Operating frequency: 2.4G/5G
- Data security/encryption: WEP, WPA, and WPA2
- Operating band: 5.18-5.85 GHz
- Modulation technique: DSSS (DBPSK, DQPSK, CCK), OFDM (BPSK, QPSK, 16QAM, 64QAM) OFDM (BPSK, QPSK, 16QAM, 64QAM, 256QAM)
- Transmission power: <20.5 dBm

# 2.5 Probe Specifications

The probe adopts the standard Wi-Fi transmission protocol for wireless data transmission. The frequency band used for wireless probe transmission is 5 GHz, and the communication protocol is IEEE 802.11a/b/g/n/ac.

## 2.5.1 Power Supply

- Input voltage: 5V or 9V
- Input current: 3A max
- Battery: 3.85V DC, 1650 mAh
- Adapter:

  - IEC 62368-1, IEC 60601-1
  - Certification: FCC, CE
  - Output interface: USB TypeA
  - Output voltage: 5V DC
  - Output current: ≥3A
  - Model: MDY-11-EX
- Wireless Charging Dock
  - Model: CP61
  - Certification: FCC, CE
  - Input voltage: 5V-10V
  - Input current: 4A Max

**NOTE:**

The power adapters and wireless charging docks are not configured or sold by Mindray. The user can purchase them based on the specific needs. It is recommended to purchase via www.ebay.com or www.amazon.com.

### 2.5.2 Probe Environmental Conditions

**⚠ WARNING**

**Do not use the probe in the conditions other than those specified.**

#### Operational conditions

- Ambient temperature: 0°C ~ 35°C
- Relative humidity: 20% ~ 85% (no condensation)
- Atmospheric pressure: 700 hPa ~ 1060 hPa

#### Storage and transportation conditions

- Ambient temperature: -20°C ~ 45°C
- Relative humidity: 20% ~ 85% (no condensation)
- Atmospheric pressure: 700 hPa ~ 1060 hPa

### 2.5.3 Dimensions and Weight

- Dimensions: 46.5×33×170 mm
- Weight (weight of the probe end) : 199±3 g

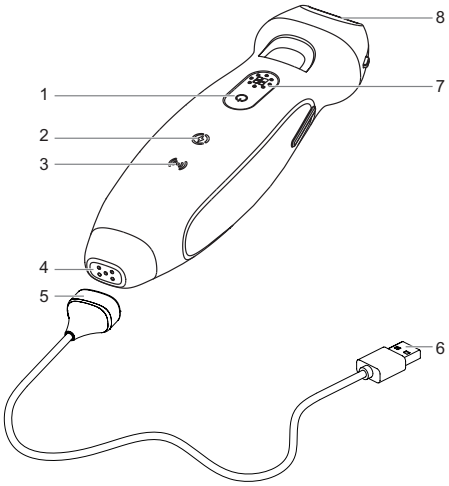
## 2.6 System Configuration

| | |
|---|---|
| Standard Configuration | Probe (Including charging cable) |
| Optional Configuration | Air Capsule (Including charging cable) |
| | TDI |
| | Extended Connection |
| | AutoEF |

## 2.7 Probes Available

Please see “10 Probes”.

## 2.8 Introduction of Each Unit

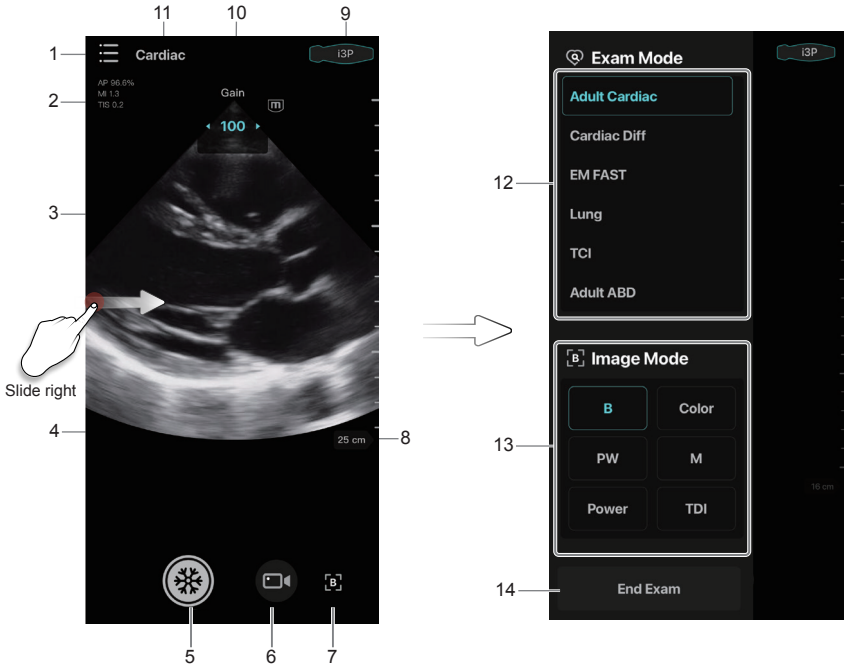



| No. | Name | Function |
|---|---|---|
| 1 | Power key | Long press to power on or power off the probe.<br>Press to display the battery capacity. |
| 2 | Battery status indicator | It indicates the charging status of the built-in battery of the probe.<br>It illumines in white when fully charged and blinks in orange in low battery. |
| 3 | Wi-Fi connection indicator | It indicates the connection status of the probe.<br>The indicator is blinking when the probe is not connected. The indicator is white when the probe is connected successfully. |
| 4 | Charging port | Charges the built-in battery of the probe. |
| 5 | Charging cable plug | Connects with the charging port of the probe. |
| 6 | Charging cable USB interface | Connects with the external USB power adapter. |
| 7 | Multifunction button | Presets the function of the key. For details, see “4.3 Probe Preset”. |
| 8 | Ultrasonic transmitting head | 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. The lens on the surface is the acoustic lens. Apply ultrasound gel on the acoustic lens. |

# 2.9 Screen Display

## 2.9.1 Main Screen

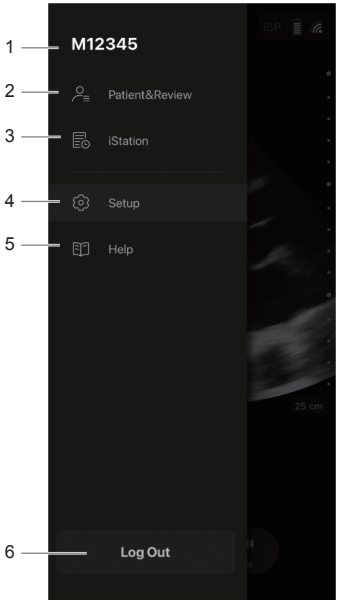
The imaging screen contains ultrasound image, exam and image information and system controls.




| No. | Name | Function |
|---|---|---|
| 1 | System Tools button | Selects Patient Information and Review, iStation, Setup, etc.<br>Reviews the stored images and cines in the “Patient Info.&Review” menu. |
| 2 | Image parameters | Displays the parameter values of the current image. |
| 3 | Imaging area | In B mode, slide up or down in the imaging area to adjust the imaging depth. |
| 4 | iTouch | Taps to enter iTouch mode. |
| 5 | Freeze button | Taps to freeze a scanning image. |
| 6 | Cine button | Taps to save a cine automatically. |
| 7 | Return to B mode | Tap to return to B mode. |
| 8 | Depth scale | Slides up or down in the imaging area to adjust the imaging depth. The real-time depth value is displayed above the imaging area. |
| 9 | Probe settings | Taps to enter Probe Settings, which displays battery level and configuration of the probe. |
| 10 | Gain | Slides left or right in the imaging area to adjust the imaging gain. The real-time gain value is displayed above the imaging area. |

| No. | Name | Function |
|---|---|---|
| 11 | Exam Mode | Displays the current exam mode. |
| 12 | Exam Mode area | Displays exam modes. Tap to enter the corresponding mode. |
| 13 | Imaging Mode area | Displays the current image modes. Tap to enter the corresponding mode. |
| 14 | End Exam button | Taps to end the current exam and start a new one. |

## 2.9.2 System Tools




| No. | Name | Function |
|---|---|---|
| 1 | User name | Displays user name. |
| 2 | Patient & Review | Taps to enter Patient Info and Review page. |
| 3 | iStation | Taps to enter iStation and manage patient data. |
| 4 | Setup | Sets system parameter. |
| 5 | Help | Views Quick Guide and User Manual. In Submit Log page, select logs and send to a desired destination. |
| 6 | Log Out | Taps to log out the system. |

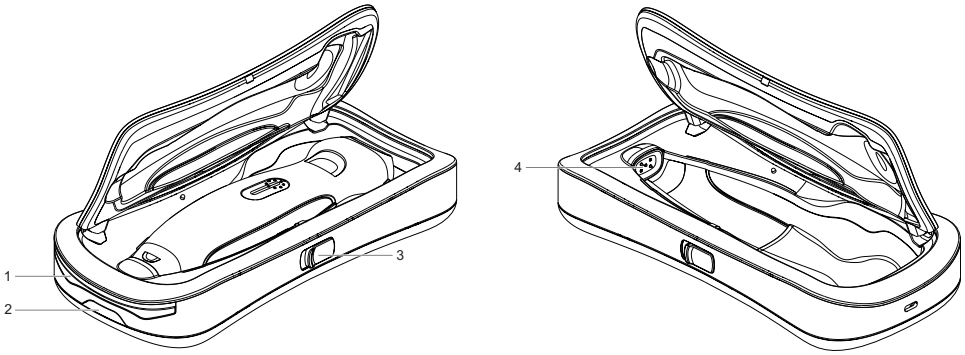
### 2.9.3 Measurement, Annotations and Body Marks Menu


| No. | Name | Function |
|---|---|---|
| 1 | Measurement tab | Taps to enter measurement status. |
| 2 | Annotation tab | Taps to enter annotation status. |
| 3 | End Exam button | Taps to end the current exam and start a new one. |
| 4 | Body Mark tab | Taps to enter body mark status. |

## 2.10 The Air Capsule

### 2.10.1 Charging the Wireless Probe

The Air Capsule is a probe storage device with a battery. An external Type-C charging cable is supplied to charge the Air Capsule. When the wireless probe is placed in the Air Capsule, the Air Capsule can charge the wireless probe through the magnetic contact output interface (pogo-pins).



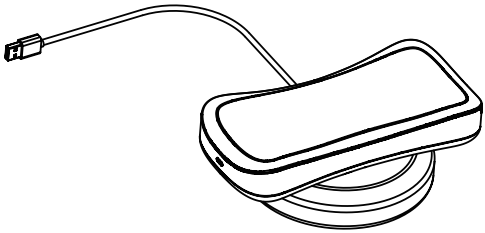

| No. | Name | Function |
|---|---|---|
| 1 | Battery capacity indicator | 95% < battery capacity: the indicator is in green.<br>30% < battery capacity ≤ 95%: the indicator is in white.<br>0% ≤ battery capacity ≤ 30%: the indicator is in orange.<br>Error: the indicator is in purple. |
| 2 | Battery capacity indicator button | Press to turn on the battery capacity indicator. |
| 3 | Switch button | Slide and press to open the Air Capsule. |
| 4 | Pogo-pins | Provide a power interface for the wireless probe. |

Perform the following procedure:

1. Check whether the Air Capsule is fully charged. If not, connect the Type-C charging cable and adapter to charge the Air Capsule.
2. The Air Capsule is fully charged. Open the Air Capsule and put the wireless probe in. The Air Capsule charges the wireless probe.

### 2.10.2 Charging the Air Capsule

The Air Capsule can be charged by an external Type-C charging cable and wireless charging dock.



When you charge the Air Capsule, place it into the charging area of the wireless charging dock. The battery capacity indicator turns on when the Air Capsule is charged.

## 2.11 Warning Labels

The warning labels are attached to this system in order to call your attention to potential hazards.

The warning labels use the same signal words as those used in the operator's manual. Read operator's manual carefully before using the system.

The name, pattern and meaning of each warning label are described as follows:

| Symbol | Description |
|---|---|
|  | Caution! |
|  | General warning sign |
|  | Read this information carefully before using the system. |
|  | Non-ionizing electromagnetic radiation |

The general meaning assigned to geometric shapes, safety colors and contrast colors for safety signs are as follows:

| Geometric shape | Meaning | Safety color | Contrast color | Graphical symbol color |
|---|---|---|---|---|
|  | Prohibition | Red | White | Black |
|  | Mandatory action | Blue | White | White |
|  | Warning | Yellow | Black | Black |

## 2.12 Symbols

This system uses the symbols listed in the following table. Their meanings are explained as follows:

| Symbol | Description |
|---|---|
|  | Type-BF applied part<br>The ultrasound probes connected to this system are type-BF applied parts. |
|  | Product serial number |
|  | Manufacture date |

| Symbol | Description |
|---|---|
|  | Manufacture |
|  | Temperature limit |
|  | Humidity limit |
|  | Atmospheric pressure limitation |
|   | Non-ionizing electromagnetic radiation |
|   | CONFORMS TO AAMI Std. ES 60601-1, IEC Std. 60601-2-37, IEC Std. 60601-2-18;<br>CERTIFIED TO CSA Std. C22.2 NO. 60601-1, 60601-2-37, 60601-2-18 |
|  | This way up |
|  | Fragile, handle with care |
|  | Keep dry |
|  | Do not roll |
|   | Stack height limit |
|  | Electromagnetic Compatibility Certification |

| Symbol | Description |
|---|---|
|  | MR Unsafe – the system is not intended to be used within magnetic resonance (MR) environment. |
|  | Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner (USA). |
|  | The following definition of the WEEE label applies to EU member states only: The use of this symbol indicates that this system should not be treated as household waste. By ensuring that this system is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this system, please consult the distributor from whom you purchased the system. |

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# 3 System Preparation

## 3.1 Probe Preparation

### 3.1.1 Check before Using

**⚠ CAUTION**

**To ensure safe and effective system operation, you must perform daily maintenance and checks. If the system begins to function improperly, immediately stop scanning. If the system continues to function improperly, fully shut down the system and contact the Mindray Customer Service Department or a sales representative. If you use the system in a persistent improperly functioning state, you may harm the patient or damage the equipment.**

Check before using the system :

- The temperature, relative humidity and atmospheric pressure meet the requirements of the operating conditions.
- There is no condensation.
- There is no distortion, damage or dirt on the system and peripheral devices.
- The wireless probes shall be free of damage or stains. If any dirt is found, perform cleaning and disinfection as required.
- Wireless probe cleaning and disinfection.
- The entire scanning environment and field must be clean.

### 3.1.2 Power Supply

This system can work normally only when the battery capacity is sufficient.

It is recommended to fully charge the device and the probe before imaging. To avoid accidental discharge of the battery, please charge the device periodically or charge the device when a low battery warning is displayed.

**⚠ WARNING**

- **The battery is inside the probe. Only Mindray technical professionals or engineers authorized by Mindray following training can perform battery installation and uninstallation.**
- **Use the accompanying power cord for charging when you charge the probe. When connecting the power cord, gently push the charging cable plug to ensure that the charging cable plug is fully connected to the charging port of the probe.**
- **Do not use this power adapter in the conditions other than those specified.**
- **If the probe is powered off during firmware upgrade, the probe may not be restarted.**
- **For problems related to the device battery, please refer to the accompanying manual of the device.**
- **The lithium-ion battery has a service life of five years. Replace your battery when it reaches the end of its service life.**

### Probe Battery

- When a charging cable is used for charging, the battery charging time from capacity 0 to 100% takes no more than 45 minutes with the adapter whose output voltage is 5V and output current is 3A;
- When charged by the Air Capsule, the battery charging time from capacity 0 to 100% takes no more than 45 minutes.

### Air Capsule

- When the Air Capsule charged by Type-C cable, the battery charging time from capacity 0 to 100% takes no more than 4 hours;
- When charged by the wireless dock, the battery charging time from capacity 0 to 100% takes no more than 8 hours.
- The continuous normal working time lasts more than 80 minutes under full battery power supply.

#### NOTE

**Power off the system if you will not use the system for a long period of time (including storage/ transportation condition). Do not leave the system in standby status, otherwise the batteries will be discharged and permanently damaged.**

### 3.1.3 Power ON/OFF

Long press the power button of the probe to power on or power off the probe.

## 3.2 Installing Applications

The device can download the **TE Air** application from the App Store or Google Play. Before installing the application, make sure that your device meets the minimum configuration requirements. For details, please refer to “2.4.1 Hardware Configuration”.

## 3.3 System Login

Access control has been set by the system administrator, you can access data in the system only after logging onto the system.

You must log in again after system restart or dormancy unless the [**Remember me**] is selected.

### 3.3.1 Signing up an Account

To create a new account, perform the following procedure:

1. Tap **TE Air** application icon.
2. Specify the user name and password at the Sign Up page.

   The user name and password length should be between 8 and 16 and include at least one letter. Password can only be letters and numbers.
3. Select [**Sign up**] to create a new account and login onto the system.

### 3.3.2 Logging onto the System

#### Using Local Account/LDAP Account

Perform the following procedure:

1. Select the login type (Local or LDAP).
2. Enter the user name and password, and tap [**Login**].

### Using Emergency Account

The system can be accessed through emergency account without logging in when users need to use the system in an emergency and he forgot his user ID.

When using the Emergency account, the patient data of other accounts (Local and LADP) in the iStation cannot be accessed.

#### NOTE

Do not use this function frequently.

### 3.3.3 Logging out the System

Perform the following procedure:

1. Tap System tools button.
2. Tap [**Log out**].

## 3.4 Creating Connection

The working range between the probe and the device is 3 meters. Connect and perform operation within the wireless network working range of the probe.

#### NOTE

If the probe is not operated in 10 minutes after it is disconnected from the system, the probe will be shut down automatically.

### 3.4.1 Connecting a Probe for the First Time

Perform the following procedure:

1. After login in, the “**Connect probe**” window pops up, and tap [**Connect**].
2. Long press the power key of the probe until the  indicator of the probe starts flashing. Tap [**Next**].
3. Tap [**Next**] when the  indicator of the probe blinks.
4. Connect the probe by the following 2 methods, and select [**Join**] in the system prompt.
   - Tap [**Scan**] to scan the QR code on the probe.
   - Tap [**Manually Enter SN Code**] to enter the SN code, and tap [**Connect**].

   After successful connection, the  indicator of the probe is on.

### 3.4.2 Connecting a Probe after the First Time

Perform the following procedure:

1. After login in, the “Connect the latest probe” window pops up.
2. Follow anyone of the method below.
   - Tap [**Connect**]. And then tap [**Join**] in the prompt box.
   - Tap [**Connect to another probe**] > [**Add new probe**], or connect an existing probe in the list.

   After successful connection, the  indicator of the probe is on.

### 3.4.3 Activating the Probe

After connecting a probe for the first time, activate the probe by activation code.

Perform the following procedure:

1. Click [**Start**] in the "Activate the probe" window.
   If there is an activation code, tap [**Enter Activation Code**].
   Make sure your device is connected to a wireless or cellular network.
2. Fill in the form in the "Activate the Probe" page.

3. Tap [**Next**], the system sends the activation code to the verification email.
   When there is no cellular network, tap [**Setup**] in the popup window and connect a Wi-Fi in the system "Setup" page.
4. Input the activation code in the "Verify Code" page and tap [**Next**] to activate the probe.
   Reconnect the probe according to the prompt when there is no cellular network.
5. Activate the probe successfully.
   The activation time can be viewed in the "Probe information" page. See “4.3 Probe Preset”.

## 3.5 Display Adjustment

When the probe is used with the application, make sure the device in which the application is installed has enabled the ambient light function. For details, please refer to the accompanying manual of the device. When the probe is used with the ultrasound diagnostic device, please refer to the accompanying manual of the ultrasound diagnostic device for adjustment.

# 4 System Setup

The Setup function is designed to set the configuration parameters of operating the system and maintaining user workflow setup data.

To enter Setup: Tap [**Setup**] in System Tools to enter setup menu.

## 4.1 Font Preset

| Item | Description |
|---|---|
| Larger Text | To set whether to enable Larger Test.<br>Enable Larger Test to improve legibility. |

## 4.2 Image Preset

To preset some general parameters in imaging modes.

| Item | Description |
|---|---|
| A.Power | To adjust the acoustic power by dragging the slider.<br>The greater the acoustic power percentage, the greater the current acoustic output. When the image is frozen, the system stops transmitting acoustic power. |
| Scale Level | Selects scale level. |
| Thermal Index | To set whether the displayed thermal index is TIB/TIC/TIS. |
| IQ Image Quality | To adjust different frequency levels. |
| PW Mode Settings | To set the scanning speed of PW mode imaging. Changing the speed makes it easier to identify the cardiac cycles and to detect more details. |
| iClear | To set whether to turn on iClear. iClear is used to enhance the image profile so as to distinguish the image boundary for optimization. |
| TGC | To set whether to turn on TGC. The system compensates the signals from deeper tissue by segments to optimize the image. |
| Auto Brightness | To set whether to turn on Automatic Brightness. |
| Movie Time(s) | To set the cine length. |
| Dynamic Range | Adjusts contrast resolution of an image, compresses or expands gray display range.<br>The more the dynamic range, the more specified the information, and the lower the contrast with more noise. |

## 4.3 Probe Preset

To preset functions of the probe.

| Item | Description |
|---|---|
| Firmware Update | Taps to upgrade probe firmware. |
| Auto Freeze | Sets auto freezing time after the probe is scanned into idle state. |
| Probe Key Functions | Sets functions of probe keys K1 and K2 in short press or long press. |
| Configuration | Configures wireless network. |
| Probe Information | Displays information such as probe model and serial number.<br>The system information is consistent with the probe information. |
| Self-test | Perform sensor self-check regularly. The self-check records are displayed in the list and can be shared to the specified destination. |
| Channel Setting | After selecting the region, configure the appropriate Wi-Fi channel for the connected probe. |
| QR Code | Taps to view the QR code of the probe. Taps [**Save to Local Album**] to save the QR code. |

### 4.3.1 Probe Check

This function is used to check the condition of transducer elements to evaluate the probe performance.

Before performing the probe check, ensure the probe head must be clean and the probe is in non-scanning state.

Tap [**Probe Check**] to enter the Probe Check screen:

- If a transducer element is in malfunction, it is displayed as a red spot.
- If a transducer element functions well, it is displayed as a green spot. You can export the result image to the external device.

## 4.4 WorkList Settings

Set related items of WorkList setting.

| Item | | Description |
|---|---|---|
| Server Settings | Client AE Title | Local Application Entity title. |
| | Server AE title | Application Entity title of the server. |
| | Server Address | Sets the IP address of the server. |
| | Port | DICOM communication port, 104 by default. Here, the port should be consistent with that of the WorkList server port. |
| | Import Certificate | Imports the encryption key/certificate. |
| Advanced Settings | Maximum | To set the maximum storage quantity of the buffer. The default value is 200. |
| | Modality | To set the device to be used. The default device is US-Ultrasound. |
| | Exam Date | Sets the exam date. The default date is Today. |
| Clear Worklist Cache | Tap to clear cache of Worklist. | |

## 4.5 DICOM Server Settings

DICOM server preset items are described as follows:

| Item | Description |
|---|---|
| Client AE Title | Local Application Entity title. |
| Server AE title | Application Entity title of the server. |
| Server Address | To set the IP address of the server. |
| Port | To set the server port. |
| TLS | Transport Layer Security. Select whether to encrypt the data during network transportation. |
| Import Certificate | Imports the encryption key/certificate. |

### Add a Server

Perform the following procedure:

1. Tap [**+**]. Enter the correct AE Title, port, etc.
2. Tap [**Test**] to check the connection.
3. Tap [**Add**] to add the server to the device list, and its name and address are displayed in the list.

### Delete a Server

Select a server in the device list, slide left and then tap [**Delete**].

## 4.6 My Account

Setting up registered accounts.

### 4.6.1 Change Password of Local Account

1. Select [**Change Password**], and enter device password for **TE Air**.
2. Input new password and confirm password. Select [**Save**].
   Return to the login interface and use the new password to log in the account.

### 4.6.2 Set Keep Password Days

Drag to set the Keep Password Days of LDAP account.

## 4.7 Network Settings

Add a network in the current environment for the system.

| Item | Description |
|---|---|
| Add New Wi-Fi | Taps to setup a new Wi-Fi. |
| Wi-Fi1 | The Wi-Fi name can be automatically created by the system or defined by user. |
| Wi-Fi Name | Enters Wi-Fi name existing in the current environment. |
| Password | Enters Wi-Fi password existed in the current environment. |
| Save | Taps to save the settings. |
| Join | Taps to join in the Wi-Fi. |

### NOTE

- Before setting, please enable Wi-Fi function of the device.
- Please ensure that the entered Wi-Fi name and password are correct.

# 4.8 Measurement Preset

"Exam Mode XX" on the upper left side refers to the currently configured exam mode. The configured general/application menus are only related to the current exam mode.

## 4.8.1 Measurement Menu Preset

Perform the following procedure:

1. Tap [**Measure**] on the measurement preset screen.
2. Select [**Exam Mode**] and [**Image Mode**].
3. Tap [**+**] or  to add or remove measurement items.
4. Tap  and drag the measurement item to the expected position.

## 4.8.2 Obstetrics Measurement Preset

Perform the following procedure:

1. Tap [**OB**] in the measurement preset screen to enter the OB preset screen.
2. Preset the formula of Gestational Age and Fetal Calc.
   For more details, see "GA Formulae" and "Fetal Weight Formulae".

### GA Formulae

The GA formulae are shown in the table below:

Note: "/" means no formula provided for the item.

| Tools | GA formulae |
|---|---|
| BPD | Hadlock<br>Tokyo<br>Jeanty<br>Kurtz<br>Hansmann<br>Merz<br>Rempen<br>ChittyOI<br>Osaka<br>China<br>Nicolaides<br>ASUM<br>Verburg(O-O) |
| HC | Hadlock<br>Jeanty<br>Hansmann<br>ChittyPL<br>ChittyDer<br>Nicolaides<br>ASUM |

| Tools | GA formulae |
|---|---|
| AC | Hadlock<br>Jeanty<br>Merz<br>Nicolaides<br>ASUM<br>CFEF<br>Hansmann<br>Chitty |
| FL | Hadlock<br>Tokyo<br>Jeanty<br>Hohler<br>Merz<br>Hansmann<br>Warda<br>Chitty<br>Osaka<br>China<br>Nicolaides<br>ASUM |

## Fetal Weight Formulae

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

The Fetal Weight formulae are shown in the following table:

| Formulae | Descriptions | Units | |
|---|---|---|---|
| | | EFW | Item |
| Hadlock (AC, FL) | EFW= 10^(1.304+ (0.05281*AC)+ (0.1938*FL)- (0.004*AC*FL)) | g | cm |
| | SD=0.154*EFW SD Type=±2SD | g | g |
| Hadlock (AC, FL, BPD) | EFW= 10^(1.335 -(0.0034*AC*FL) + (0.0316*BPD) + (0.0457*AC) + (0.1623*FL)) | g | cm |
| | SD=0.146*EFW SD Type=±2SD | g | g |
| Hadlock (AC, FL, HC) | EFW= 10^(1.326-(0.00326*AC*FL)+ (0.0107*HC)+ (0.0438*AC)+ (0.158*FL)) | g | cm |
| | SD=0.148*EFW SD Type=±2SD | g | g |
| Hadlock (AC, FL, HC, BPD) | EFW= 10^(1.3596- (0.00386*AC*FL)+ (0.0064*HC)+ (0.00061*BPD*AC)+ (0.0424*AC)+ (0.174*FL)) | g | cm |
| | SD=0.146*EFW SD Type=±2SD | g | g |
| Shepard(AC, BPD) | EFW (kg) = 10^(-1.7492+ (0.166*BPD)+ (0.046*AC)- (2.646*AC*BPD/1000)) | kg | cm |
| | SD=0.202*EFW SD Type=±2SD | g | g |
| Merz1 (AC, BPD) | EFW=-3200.40479+(157.07186*AC)+(15.90391*(BPD^2)) | g | cm |
| Merz2 (AC) | EFW=0.1*(AC^3) | g | cm |

| Formulae | Descriptions | Units | |
|---|---|---|---|
| | | EFW | Item |
| Campbell (AC) | EFW (kg) = EXP (-4.564+(0.282*AC)-(0.00331* (AC^2))) | kg | cm |
| Schild(HC, AC, FL) | EFW = 5381.193 + 150.324*HC + 2.069*FL^3 + 0.0232*AC^3 -6235.478*log(HC) | g | cm |

## 4.9 Scan Code Settings

Scan code preset items are described as follows:

| Item | Description |
|---|---|
| Scan Barcode Example | Input a barcode example, barcode example is separated by separators (the separator is used to set the start and end position of each item), and the barcode data is displayed in the following items in turn. |
| Regular Expression | Tap  to set the regular expression according to the bar code format. |
| Scan Item | After scanning 1D bar code, the regular expression is matched in the priority order: “Patient ID > Other ID > First name > Last name > Middle name > Accession# > Operator > Diagnostician”. If the regular expression is matched successfully, the data of 1D bar code will be displayed in this item in Patient page automatically.<br>Example: The data of the bar code is 123 after scanning 1D bar code. The regular expression is matched in the priority order: “Patient ID > Other ID > First name > Last name > Middle name > Accession# > Operator > Diagnostician”. If the regular expression of “Other ID” is matched successfully, “123” will be displayed in “Other ID” item in Patient page automatically. |

## 4.10 Option Settings

Set to trial or activate the optional function.

| Item | Description |
|---|---|
| Scan to Activate | Scan the QR code of the optional function in the Wireless Probe Operate Guide to activate this function.<br>**Note:**<br>The App's access to the camera of the mobile device must be enabled before scanning. |
| Trail | After selecting and confirming, you can try the selected function. |

## 4.11 System Information

Tap [**About**] in the Setup menu to enter the system information screen.

# 5 Exam Preparation

You can start a patient exam in the following situations:

- New patient information: to start a new patient exam, patient information must first be entered.
- New exam: to start a new exam for patient who is already registered, the recorded information can be obtained through either iStation or WorkList.

## 5.1 Patient Information

### 5.1.1 New Patient Information

#### ⚠ CAUTION

**Before examining a new patient, tap the [End Exam] to end the exam of the previous patient, update the patient ID and information, to avoid mixing data of the next new patient.**

To start a new patient exam, it is better to type the detailed patient information. The system will set up a unique information database for each patient based on the patient information entered, so that the information of one patient will not be confused with that of another patient.

1. Tap [**Exam Mode**] to select an exam mode.
2. Tap > [**Patient&Review**] to enter the patient information page.
   Place the cursor onto the targeted box. The field box is highlighted and a flashing cursor appears. Information can be entered or selected from the options.

#### NOTE

- Patient ID is generated automatically by the system after starting a new patient, and can be modified manually. The characters "\", "\", "*", "?" are not permitted.
- The system supports logging data as patient ID by scanning code.
- You can either enter the patient's date of birth manually, or click to select the date.

3. Functional keys
   - [**WorkList**]: imports patient data from history exam list or WorkList.
   - [**Scan**]: saves the patient data entered and start scanning.
   - [**End Exam**]: end current exam and start a new one.

### 5.1.2 Retrieve Patient Information

#### Retrieve from WorkList

Tap [**WorkList**] in the Patient Info screen to query or import the patient data. Before retrieving patient information from WorkList, Wi-Fi settings should be set, for details, see "4.7 Network Settings".

## 5.2 End an Exam

Be sure to avoid mixing data between patients.

Before examining a new patient, tap [**End Exam**] to end the exam of the previous patient.

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# 6 Image Acquisition

The images displayed in this system are only reference for diagnosis. Mindray is not responsible for the correctness of diagnostic results.

Operations for switching between different image modes and optimizing images, see the System Overview chapter.

## 6.1 B Mode

B mode is the basic imaging mode that displays real-time views of anatomical tissues and organs.

### 6.1.1 B Mode Image Scanning

The system enters B mode by default after selecting the probe and exam mode.

If the system is in another imaging mode, tap [**B**] to enter B mode.

Adjust the image parameters during scanning to optimize the image.

### 6.1.2 B Mode Image Parameters

#### Image Quality

To switch between the fundamental frequency and harmonic frequency as well as select the corresponding frequency type. The real-time frequency value is displayed in the image parameter area of the screen.

The system provides an imaging mode using harmonics of echoes to optimize the image. Harmonic imaging enhances near-field resolution and reduces low-frequency and large amplitude noise, so as to improve small parts imaging. If harmonic frequency is used, “H” is displayed as harmonic frequency value.

Please select the frequency according to the detection depth and current tissue features.

#### Gain

To adjust the gain of the whole receiving information in B mode. Increasing the gain will brighten the image and you will see more received signals. However, noise may also be increased.

#### Depth

This function is used to adjust the sampling depth, the real-time value of which is displayed in the image parameter area of the screen. Increase the depth to see tissue in deeper locations, or decrease the depth to see tissue in shallower locations. Depth increase will cause a decrease in the frame rate.

#### TGC

The system compensates the signals from deeper tissue by segments to optimize the image and get a balanced image.

There are 5-segment TGC sliders corresponding to the areas in the image.

After the adjustment is finished, the TGC curve disappears.

#### Acoustic power

Refers to the power of ultrasonic wave transmitted by the probe, the real-time value of which is displayed in the image parameter area in the upper left corner of the screen. Generally, increasing the acoustic power will increase the brightness and contrast of the image as well as the force of penetration.

### TIP

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

#### iClear Image Enhance

The function is used to enhance the image profile so as to distinguish the image boundary for optimization.

#### Rotation/Invert (L/R Flip)

This function provides a better observation for image display.

#### Gray map

Adjusting grayscale contras to optimize the image.

## 6.2 M Mode

### 6.2.1 M Mode Image Scanning

In M mode, the tissue motion can be observed along with anatomical images of B mode. During the scanning process, the sampling line can be adjusted accordingly when necessary.

Perform the following procedure:

1. Select a high-quality image during B mode scanning, and adjust to place the area of interest in the center of the B mode image.
2. Tap [**M**] to enter M sampling line status.
3. Drag the sampling line to position it on the target area.
4. Tap [**M**] again or tap [Update] to enter M mode.

   You can then observe the tissue motion along with the anatomical images of B mode. During the scanning process, you can also adjust the sampling line accordingly when necessary.
5. Adjust the image parameters during scanning to optimize the image.

### 6.2.2 M Mode Image Parameter

#### Gain

To adjust the gain of M mode image, the real-time gain value is displayed in the image parameter area. Increasing the gain will brighten the image and you will see more received signals. However, noise may also be increased.

#### Depth

This function is used to adjust the sampling depth, the real-time value of which is displayed in the image parameter area of the screen. Increase the depth to see tissue in deeper locations, or decrease the depth to see tissue in shallower locations.

#### Speed

This function is used to set the scan speed of M mode imaging, and the real-time speed value is displayed in the image parameter area.

## 6.3 Color Mode

The Color mode is used to detect color flow information, and the color is designed to judge the direction and speed of blood flow. Generally, the color above the color bar indicates the flow towards the probe, while the color below the color bar indicates the flow away from the probe. The brighter the color, the faster the flow speed, while the darker the color, the slower the flow speed.

### TIP

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.

## 6.3.1 Color Mode Image Scanning

Perform the following procedure:

1. Select a high-quality image during B mode scanning, and adjust to place the area of interest in the center of the image.
2. Tap [**Color**] to enter B+Color mode.
3. Drag the Region of Interest (ROI) locating at the target area, and change the position and size of the ROI.
4. Adjust the image parameters during scanning to optimize the image.

## 6.3.2 Color Mode Image Parameter

### Color Gain

Refers to the overall sensitivity to flow signals. The real-time gain value is displayed in the image parameter area.

Increasing the gain will increase the flow signal presented as well as noise, while the signals may be missing when the gain is adjusted too low.

### ROI Adjustment

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

The larger the ROI box is, the lower the frame rate becomes, and the lower the resolution and color sensitivity will be.

### Image Quality

Select the frequency according to the needs of the detection depth and the current tissue characteristics.

### Acoustic power

Refers to the power of ultrasonic wave transmitted by the probe, the real-time value of which is displayed in the image parameter area in the upper left corner of the screen. Generally, increasing the acoustic power will increase the brightness and contrast of the image as well as the force of penetration.

### TIP

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

### iTouch

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

The iTouch function automatically adjusts and optimizes the image effect based on the tissue characteristics of the current scanning area.

# 6.4 Power Mode

Power mode provides a non-directionally display of blood flow in the form of intensity as opposed to flow velocity.

### TIP

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.

### 6.4.1 Power Mode Image Scanning

Perform the following procedure:

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. Tap [**Power**] to enter B+Power mode.
3. Locate the ROI at the target area, and change the position and size of the ROI when necessary.
4. Adjust the image parameters during scanning to optimize the image.

### 6.4.2 Power Mode Image Parameter

Because both are based on Doppler color imaging, the adjustments of Power mode are same with these of Color mode's. Hence, only the adjustments of Power mode are introduced.

#### Power Gain

Refers to the overall sensitivity to flow signals, and this function is used to adjust the gain in Power mode. The real-time gain value is displayed in the image parameter area on the top of the screen.

## 6.5 PW Mode

PW (Pulsed Wave Doppler) mode is used to provide blood flow velocity and direction utilizing a real-time spectrum display. The horizontal axis represents time, while the vertical axis represents Doppler frequency shift.

PW mode provides a function for examining flow at one specific site for its velocity, direction and features.

### 6.5.1 PW Mode Image Scanning

Perform the following procedure:

1. Select a high-quality image during B mode or B+ Color (Power) scanning, and adjust to place the area of interest in the center of the image.
2. Tap [**PW**] to enter PW sampling line adjustment status.
3. Set the position of the sample line by dragging the sampling line; drag the SV gate to place the SV on the target.
4. Adjust the angle and SV size according to the actual situation: drag the PW angle line to change the angle, pinch on the image area to adjust SV size.
5. Tap [**PW**] again or [**Update**] to enter PW Mode and perform observation and calculation with B mode or Color mode image. You can also adjust the SV size, angle and depth in the real-time scanning.
6. Adjust the image parameters during PW mode scanning to optimize the image.

### 6.5.2 PW Mode Image Parameter

#### Gain

This function is intended to adjust the gain of spectrum map. The real-time gain value is displayed in the image parameter area.

Increasing the gain will brighten the image and you will see more received signals. However, noise may also be increased.

#### PW Sampling Gate

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 of the screen, in which SV represents the size of the sampling gate, and SVD represents the sampling depth.

The smaller the SV size becomes, the more accurate the result is; and more information can be obtained when selecting large SV size.

### Image Quality

Refers to the transmitting frequency in Doppler mode of the probe, the real-time value of which is displayed in the image parameter area.

The higher the frequency and the better the force of penetration is, the poorer the axial resolution becomes. Please select the frequency according to the detection depth and current tissue features.

### Scale

This function is used to adjust the speed range of color flow. To provide a much clearer color flow image.

Aliasing may occur if low velocity scale is used and high velocities are encountered.

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

### iTouch

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

### Speed

This function is used to set the scan speed of PW mode imaging.

Changing the speed makes it easier to identify the cardiac cycles and to detect more details.

### Baseline

Refers to the area where the velocity in zero in the spectrum. The map changes after being edited.

To optimize the image, adjust baseline according to the actual situation to change the range of flow velocity.

### Angle

This function is used to adjust the angle between Doppler vector and flow to make the velocity more accurate.

The real-time adjusting angle value is displayed in the image parameter area.

### Acoustic power

Refers to the power of ultrasonic waves transmitted by the probe, the real-time value of which is displayed in the top-left part of the screen. Generally, increasing the acoustic power will increase the brightness and contrast of the image as well as the force of penetration.

### Auto Calculation

This function is used to trace the spectrum and calculate the PW/CW mode image parameters. The results are displayed in the results window.

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

- Auto Calculation Cycle: To set the heart cycle number for auto-calculation.
- Trace Area: To set the trace area of the Doppler wave in the spectrum map.
- Smooth: To set the smooth level when tracing.
- Sensitivity: This function is used to set the sensitivity of tracing in the spectrum.

## 6.6 TDI

TDI mode is intended to provide information of low-velocity and high-amplitude tissue motion, specifically for cardiac movement.

There are the following types of TDI mode available:

- Tissue Velocity Imaging (TVI): This imaging mode is used to detect tissue movement with direction and speed information. Generally the warm color indicates the movement towards the transducer, while the cool color indicates the movement away from the transducer.
- Tissue Energy Imaging (TEI): This imaging mode reflects the status of cardiac movement by providing the energy information, the larger the energy is, the brighter the color becomes.
- Tissue Velocity Doppler Mode (TVD): This imaging mode provides direction and speed information of the tissue.

## 6.6.1 TDI Mode Image Scanning

Perform the following procedure:

1. Select [**TDI**] button to enter the TDI mode.
   - In B or B+Color mode: to enter TVI Mode.
   - In Power mode: to enter TEI Mode.
   - PW mode: select [**TDI**] button and then select the PW mode button or [**Update**] button to enter TVD.
2. In TDI mode, press the corresponding imaging mode button to switch among the modes.
3. Adjust the image parameters to obtain optimized images.
4. Select [**TDI**] button to exit from TDI mode and enter general imaging modes. Or, select the B mode button to return to B mode.

## 6.6.2 TDI Mode Image Parameters

In each TDI mode, the parameters that can be adjusted are similar to those in the color flow modes (Color, PW, and Power). See the relevant sections for details. The following introduces the specific items in TDI mode.

### Tissue State

This function is used for fast image optimization.

# 7 Display & Cine Review

## 7.1 Image Magnification

### NOTE

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 filed. As a result, the MI may change.

Use two fingers to pinch on the image area to zoom in/out the image so as to view more subtle lesions.

## 7.2 Freeze/Unfreeze the Image

Tap [**Freeze**] to freeze a scanning image. In freeze mode, the probe stops transmitting acoustic power, and all images and parameters are frozen.

Tap [**Freeze**] in freeze mode to unfreeze the image, and the system continues image scanning.

### 7.2.1 Imaging Mode Switching When Frozen

Imaging mode switching in freeze mode follows these principles:

- In splitting display B mode, tap each image window to switch between the windows.
- In freeze mode, the system supports imaging mode switching between the sub-modes (only for the activated window). For example, if the frozen image is in B+Color+PW mode, the system supports imaging mode switching between B+Color+PW, B+Color, B+PW and B by tapping [**Color**] or [**PW**].

The imaging mode and parameters of an unfrozen image is the same as the corresponding one that before frozen; but the display format is the same as the one before unfrozen.

## 7.3 Cine Review

The system allows you to review and edit the images prior to the image frozen. This function is called as cine review. The magnified images can also be reviewed after [**Freeze**] is pressed, and the operating method is the same.

### ⚠ CAUTION

- **The cine memory must be cleared at the end of the current patient and the onset of the next new patient by selecting the [End Exam].**
- **Cine files stored in the system shall contain patient information, to avoid the selection of an incorrect image file and potential misdiagnosis.**

### 7.3.1 Entering/Exiting Cine Review

#### To Enter Cine Review

In real-time image scanning mode, the system enters manual cine review status once [**Freeze**] is tapped.

#### To Exit Cine Review

Tap [**Freeze**] and the system will return to image scanning and exit cine review.

### 7.3.2 Manual Cine Review

After entering cine review in 2D mode, drag playback mark to review the cine images on the screen one by one.

If you roll the playback mark to the left, the review sequence is reversed to the image-storing sequence, thus the images are displayed in descending order. Whereas, if you roll the playback mark to the right, the review sequence is the same as the image-storing sequence, thus the images are displayed in ascending order.

When you review images until the first or the last frame, further rolling the playback mark will display the last or first frame.

## 7.4 Cine Saving

### 7.4.1 Live Capture

Live capture refers to saving the images or cines in image scanning status; after the storage, the system continues image scanning.

Tap the save button again or [**Freeze**] to stop saving.

When a saving is completed, the progress bar disappear.

### 7.4.2 Frozen Image Storage

When the image is frozen, select the cine button to save the cine.

# 8 Measurement, Annotations and Body Mark

## 8.1 Measurement

There are general measurement and application measurement.

There are three types of General Measurement menus available: 2D (B / Color / Power Mode), M Mode, and Doppler (PW) Mode.

You can perform measurements on a zoomed image, cine reviewing image, real-time image, or frozen image.

### ⚠ WARNING

- **Be sure to measure areas of interest from the most optimal image plane to avoid misdiagnosis from inaccurate measurement values.**
- **To obtain accurate Doppler flow measurement values, make sure the transmitting beam is not perpendicular to the flow, otherwise false readings and potential misdiagnosis may result.**

### ⚠ CAUTION

- **If an image is unfrozen or the mode is changed during a measurement, the calipers and measurement data will be cleared from the screen, but the measurement data will be stored in the report.**
- **If the system is turned off or the [End Exam] button is selected during a measurement, the data not saved will be lost.**

### Measurement Accuracy

**Table 8-1 Error of 2D Images**

| Parameter | Range | Error |
|---|---|---|
| Distance | Full Screen | Within ±4% |
| Area | Full Screen | Within ±10% |
| Circle | Full Screen | Within ±10% |
| Angle | Full Screen | Within ±3% |
| Volume | Full Screen | Within ±10% |

**Table 8-2 Time/Motion Measurements**

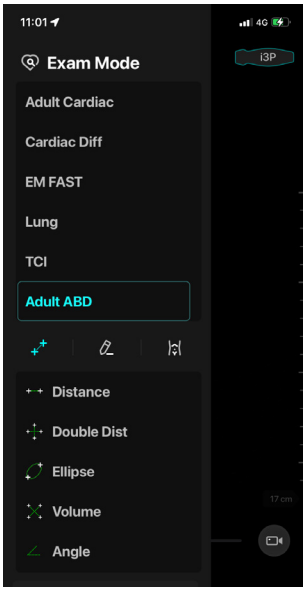
| Parameter | Range | Error |
|---|---|---|
| Distance | Full Screen | Within ±4% |
| Time | Timeline Display | Within ≤ 2% |
| Heart Rate | Timeline Display | Within ±4% |
| Velocity (PW mode) | 10-200 cm/s (for non-transcranial application)<br>10-300 cm/s (for transcranial application) | Within ±20% (for transcranial application)<br>When angle ≤ 60°, within ±5% (for non-transcranial application) |

**Table 8-3 Auto Measurements**

| Parameter | Error |
|---|---|
| AutoEF | Within ±10% |
| Smart Bladder | Within ±10% |

## 8.1.1 Measurement Menu

Freeze and select [**Exam Mode**]. The measurement menu is displayed on the left tab.




## 8.1.2 General Measurements

### Distance

Function: Measure the distance between two points on 2D and M image.

Perform the following procedure:

1. Tap [**Distance**] in the menu, and the cursor appears on the screen.
2. Select the left cross cursor and drag it to the measurement starting point.
3. Select the right cross cursor and drag it to the measurement end point.
4. The result window shows result.

### Angle

Function: Measures the angle of two crossing planes on the image and the range is: 0°-180°.

Perform the following procedure:

1. Tap [**Angle**] in the menu, and the cursor appears on the screen.
2. Set two line segments, and refer to “Distance” for detailed operation.
3. The angle will be displayed in the result window after setting two line segments.

## Double Dist

Function: Measure the distance between two points of two vertical line segments on B image.

Perform the following procedure:

1. Tap [**Double Dist**] in the menu, and two vertical cursor appears on the screen.
2. Set two line segments, and refer to “Distance” for detailed operation.
3. The distance will be displayed in the result window after setting two line segments.

## Volume

Function: Measure the target object with the three-distance method and calculate the volume on B image.

To calculate the object’s volume with 3 axes of two images scanned in the plane perpendicular to each other in B mode.

Calculation formulas are as follow:

Volume (cm^3) = π/6×D1 (cm) ×D2 (cm) ×D3 (cm)

Here, D1, D2, D3 are length of three axes of the target object.

Perform the following procedure:

1. Tap [**Volume**] in the measurement menu, and the cursor appears on the screen.
2. Here, D1, D2, D3 are length of 3 axes of the target object, see “Distance” for details.
3. Generally, D1, D2, D3 should belong to different scanning plane.

## Velocity

Function: Measure the velocity of a point on the Doppler spectrum.

Perform the following procedure:

1. Tap [**Vel**] in the measurement menu.
2. Move the cursor to the point to be measured for velocity and the measurement result is displayed in the result window.

## Time

Function: Measure the time interval of two points on M and Doppler images.

Perform the following procedure:

1. Tap [**Time**] in the measurement menu, and two parallel cursors should be in the middle of the screen.
2. Move the left cursor to the measurement starting point.
3. Move the right cursor on the measurement end point, and the measurement result is displayed in the result window.

## Slope

Function: Measure the distance and time between two points on the M image and calculate the slope between the two points.

Perform the following procedure:

1. Tap [**Slope**] in the measurement menu, and the cursor should be in the middle of the screen.
2. Move the cursor to the measurement starting point.
3. Move the cursor to the measurement end point. At this time, there is always a dotted line between the cursor and the measurement starting point.

## Area & Circumference

Function: On 2D image, measures the area and circumference of a closed region on the image. Two measurement methods are available:

- Ellipse: fix an ellipse region by two equal-cut perpendicular axes. Perform the following procedure:

a. Tap [**Area**] in the measurement menu and select [**Ellipse**]. Then the cursor appears on the screen.

b. Drag the cursor to an area of interest.

c. Select and drag any measurement cursor to confirm the ellipse area, and the measure result will be displayed in the results window.

- Trace: fix a closed region by free tracing. Perform the following procedure:

  a. Tap [**Area**] in the measurement menu and select [**Trace**]. Then the cursor appears on the screen.

  b. Move the cursor to an area of interest.

  c. Tap the cursor to fix the starting point.

  d. Move the cursor along the target to trace the outline of the target.

  To modify the line, you can drag the hand icon to move the cursor backward along the trace line.

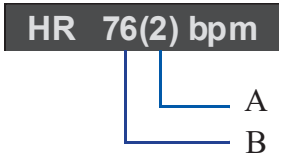
  e. Tap the hand icon and the trace line will be closed with a straight line connecting the start and end points. The trace will also be closed when the cursor is very near to the starting point.

## Heart Rate (HR)

Function: Measure the time interval between two cardiac cycles on M and Doppler images and calculate the heart rate.

Perform the following procedure:

1. Click [**HR**] in the measurement menu, and the cursor should be in the middle of the screen.
2. Select 2 cardiac cycles.
3. The HR result in the result window, as shown in the figure below, displays the measured heart rate value and the preset number of cardiac cycles. See the following figure.




| | |
|---|---|
| A | Number of cardiac cycle |
| B | HR numeric |

## PS/ED

Function: Measure the Peak Systolic (PS) velocity and End Diastolic (ED) velocity on the Doppler spectrum, and calculate their resistance index (RI), S/D and correction angle θ.

Perform the following procedure:

1. Tap [**PS/ED**] in the measurement menu, and the cursor and measurement result appear on the screen.
2. Move the cursor to the Systolic Peak and finish the measurement of Systolic Peak.
3. Move the cursor to the End-Diastolic and finish the measurement of End-Diastolic.

## Simpson

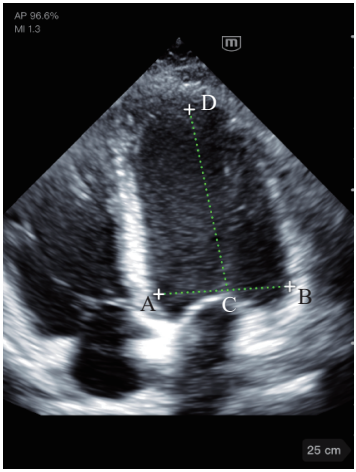
Function: Measure the left ventricular volume in apical view.

Perform the following procedure:

1. Tap [**Simpson**] in the measurement menu in cardiac mode, and the cursor appears on the screen.
2. Move the cursor to set control points A and B.

- A: Left ventricular interventricular septal and mitral valve junction;
- B: Left ventricular wall and mitral valve junction;

3. After setting A and B, the cursor positions automatically at point D where considered as the apical part by system detecting, also the long axis (line segment CD) and the line that traces the endocardium are displayed at the same time. Where,
   - C: Midpoint of A and B.
   - D: Apical part of left ventricle.
4. You can perform the following operations:
5. Adjust the long axis: Move the cursor to adjust the position of D (C remains unchanged).
6. Adjust the trace line: drag the cursor and adjust the trace line according to the target area (with ABD points unchanged).




7. After adjustment, tap the screen again to confirm the adjustment.
   The result window shows result.
   - Tap to delete all results.
   - Tap a result and select [**X**] to delete it.

## VTI

Function: On Doppler image, measures clinical indices using spectral Doppler tracing. Measurement methods available are Trace and Auto.

Perform the following procedure:

1. Freeze in PW/CW mode. Tap [**VTI**] in the measurement menu and select [**Manual**].
2. Move the cursor to the starting point to be measured and tap the cursor to fix the point.
3. Drag and move the cursor around the object.
   - Move the cursor right: draw a trace line overlapping the spectrum as much as possible.
   - Move the cursor left to correct the trace line already drawn.
4. The result is displayed in the result window.

Perform the following procedure:

1. Freeze in PW/CW mode. Tap [**VTI**] in the measurement menu and select [**Auto**].
2. Move the cursor to the starting point to be traced and tap the cursor to fix the point.
3. Move the cursor to the end point of the spectrum to be traced.

4. The system traces the spectrum between the starting and the end point.
5. The result is displayed in the result window.

## LVOT Diam

Perform the following procedure:

1. Tap [**LVOT Diam**] in the measurement menu, and the cursor appears on the screen.
2. Select the left cross cursor and drag it to the measurement starting point.
3. Select the right cross cursor and drag it to the measurement end point.
4. The result window shows result.

## LVOT VTI

Function: On Doppler image, measures clinical indices using spectral Doppler tracing. Measurement methods available are Trace and Auto.

Perform the following procedure:

1. Freeze in PW/CW mode. Tap [**LVOT VTI**] in the measurement menu and select [**Manual**].
2. Move the cursor to the starting point to be measured and tap the cursor to fix the point.
3. Drag and move the cursor around the object.
   - Move the cursor right: draw a trace line overlapping the spectrum as much as possible.
   - Move the cursor left to correct the trace line already drawn.
4. The result is displayed in the result window.

Perform the following procedure:

1. Freeze in PW/CW mode. Tap [**LVOT VTI**] in the measurement menu and select [**Auto**].
2. Move the cursor to the starting point to be traced and tap the cursor to fix the point.
3. Move the cursor to the end point of the spectrum to be traced.
4. The system traces the spectrum between the starting and the end point.
5. The result is displayed in the result window.

The result LVOT SV is displayed after the LVOT Diam is measured.

The result LVOT CO is displayed after the Heart Rate is measured.

## LVIDd&LVIDs

Perform the following procedure:

1. Freeze in M mode. Tap [**LVIDd**] in the measurement menu, and the cursor appears on the screen.
2. Move the cursor to measure LVIDd.
   The LVIDd and EDV value are obtained.
3. Tap [**LVIDs**] in the measurement menu, and the cursor appears on the screen.
4. Move the cursor to measure LVIDs
   The LVIDs and ESV value are obtained.
   The system calculates the SV and EF.

## MV E Vel

Perform the following procedure:

1. Tap [**MV E Vel**] in the measurement menu.
2. Move the cursor to the point to be measured for velocity and the measurement result is displayed in the result window.

## MV A Vel

Perform the following procedure:

1. Tap [**MV A Vel**] in the measurement menu.

2. Move the cursor to the point to be measured for velocity and the measurement result is displayed in the result window.

### MV Ea (medial)

Perform the following procedure:

1. Tap [**MV Ea (medial)**] in the measurement menu.
2. Move the cursor to the point to be measured for velocity and the measurement result is displayed in the result window.
3. After the results are saved, measure MV E Vel item to get E/Ea result.

### MV Ea (lateral)

Perform the following procedure:

1. Tap [**MV Ea (lateral)**] in the measurement menu.
2. Move the cursor to the point to be measured for velocity and the measurement result is displayed in the result window.
3. After the results are saved, measure MV E Vel item to get E/Ea result.

### Stenosis(A)

Function: measures the Normal Area and Resid. Area, calculates the Stenosis A.

Formulae: Stenosis A (No unit) = | (A1-A2) / MAX (A1, A2) |*100%

Where A1 and A2 refer to the measured vascular area, and MAX (A1, A2) represents the larger value of the two.

Perform the following procedure:

1. Tap [**Stenosis(A)**] in the measurement menu.
2. Use the Area measurement method to measure the Normal(A) and Resid(A).
   The Stenosis A is calculated automatically.

### Stenosis(D)

Function: measures the Normal Diam. and Resid. Diam., calculates the Stenosis D.

Formulae: Stenosis D (No unit) = (Normal Diam. (cm) – Resid Diam. (cm)) / Normal Diam. (cm) × 100%

Stenosis D (No unit) = | (D1-D2) / MAX

(D1, D2)|*100%

Where D1 and D2 refer to the measured vascular diameter, and MAX (D1, D2) represents the larger value of the two.

Perform the following procedure:

1. Tap [**Stenosis(D)**] in the measurement menu.
2. Use the Distance measurement method to measure the Normal(D) and Resid(D).
   The Stenosis D is calculated automatically.

### Volume Flow

Function: measures blood flow through a vascular cross section per unit time.

Perform the following procedure:

1. Freeze in PW/CW mode. Tap [**Volume Flow**] in the measurement menu. Tap [**Vas Area**] to select the method for calculating the area: dist. or trace.
2. Measure the vascular area.
3. Tap [**TAMEAN**] or [**TAMAX**] to calculate the volume flow.

| Item | | Description | Method or formula |
|---|---|---|---|
| Vas Area | Dist. | Obtain the area by measuring the vascular diameter. | Vas. Area = π × Vas Diam (cm)2/ 4 |
| | Trace | Obtain the area using the trace method. | Area in 2D General Measurements |
| TAMEAN | | Vol Flow(Area) - TAMEAN | Vol Flow(A) (ml/min) = \|Vas TAMEAN (cm/s)\| × Vas. Area (cm2) × 60 (s)<br>Vas. TAMEAN - Time Averaged Mean Velocity, obtained from the Vas. Trace measurement. |
| TAMAX | | Vol Flow(Area) - TAMAX | Vol Flow(A) (ml/min) = \|Vas TAMAX (cm/s)\| × Vas Area (cm2) × 60 (s)<br>Vas. TAMAX - Time Averaged Maximum Velocity, obtained from the Vas. Trace measurement. |

## BPD

Function: Measure the distance between the widest two sides of the fetal head bone.

Perform the following procedure:

1. Tap [**BPD**] in the menu, and the cursor appears on the screen.
2. Select the left cross cursor and drag it to the measurement starting point.
3. Select the right cross cursor and drag it to the measurement end point.
4. The result window shows result.

## HC

Function: Measure the circumference of the widest part of the Fetal Head. In the HC measurement, if the measurement cursor of BPD appears on the screen, then the measurement starting point will be automatically positioned at the measurement cursor starting point of the last BPD. If you use “Ellipse” to measure the HC, the measurement cursor of the last BPD will be the first axis of the ellipse in the default status.

Perform the following procedure:

1. Tap [**HC**] in the measurement menu, and the cursor appears on the screen.
2. Drag the cursor to an area of interest.
3. Select and drag any measurement cursor to confirm the ellipse area, and the measure result will be displayed in the results window.

## AC

Function: Measure the maximum fetal abdominal circumference.

Perform the following procedure:

1. Tap [**AC**] in the measurement menu, and the cursor appears on the screen.
2. Drag the cursor to an area of interest.
3. Select and drag any measurement cursor to confirm the ellipse area, and the measure result will be displayed in the results window.

## FL

Function: Measure the length of the fetal femoral epiphysis.

Perform the following procedure:

1. Tap [**FL**] in the menu, and the cursor appears on the screen.
2. Select the left cross cursor and drag it to the measurement starting point.
3. Select the right cross cursor and drag it to the measurement end point.

4. The result window shows result.

### AFI

Function: To evaluate whether the amniotic fluid volume is within the normal range.

Formulae: Measure AF1, AF2, AF3, and AF4 respectively, and AFI =AF1+AF2+AF3+AF4.

Perform the following procedure:

1. Tap [**AFI**] in the measurement menu. Enter the submenu.
2. Measure the maximum AFs of the four amniotic fluid pockets of a pregnant woman. The AFI is calculated automatically.

### Umb A

Function: The method of measurement of Umbilical Artery includes 2 PT, Trace and Auto.

Perform the following procedure:

1. Freeze in PW/CW mode. Tap [**Umb A**] in the measurement menu and select [**2 PT**].
2. Select the left cross cursor and drag it to the measurement starting point.
3. Select the right cross cursor and drag it to the measurement end point.
4. The result window shows result.

Perform the following procedure:

1. Freeze in PW/CW mode. Tap [**Umb A**] in the measurement menu and select [**Manual**].
2. Move the cursor to the starting point to be measured and tap the cursor to fix the point.
3. Drag and move the cursor around the object.
   - Move the cursor right: draw a trace line overlapping the spectrum as much as possible.
   - Move the cursor left to correct the trace line already drawn.
4. The result is displayed in the result window.

Perform the following procedure:

1. Freeze in PW/CW mode. Tap [**Umb A**] in the measurement menu and select [**Auto**].
2. Move the cursor to the starting point to be traced and tap the cursor to fix the point.
3. Move the cursor to the end point of the spectrum to be traced.
4. The system traces the spectrum between the starting and the end point.
5. The result is displayed in the result window.

## 8.1.3 AutoEF

Function: Automatic measuring of the diastolic and systolic sectional planes.

Measure Result:

| Item | Description |
|---|---|
| EDV (A2C/A4C/BP) | End-diastolic Left Ventricular Volume (apical 2-chamber / 4-chamber / bi-planar) |
| ESV (A2C/A4C/BP) | End-systolic Left Ventricular Volume (apical 2-chamber / 4-chamber / bi-planar) |
| SV (A2C/A4C/BP) | Stroke volume (apical 2-chamber / 4-chamber / bi-planar) |
| EF (A2C/A4C/BP) | Ejection fraction (apical 2-chamber / 4-chamber / bi-planar) |

Perform the following procedure:

1. Tap [**AutoEF**] in the measurement menu in cardiac mode, and the auto drawn trace line appears on the screen. Here,
2. In the section ED, move the cursor on the trace line to adjust the trace line.
3. Tap [**ES**] to switch to the section ES, move the cursor on the trace line to adjust the trace line.

4. The result is displayed in the result window. Tap [**Done**] to confirm the result.

## 8.1.4 Smart Bladder

Function: Automatically measuring the urine volume in the bladder.

Perform the following procedure:

1. Scan the cross section image of bladder, select and freeze it.
2. Tap [**Smart Bladder**] in the measurement menu.
3. The system automatically traces the trace line in the cross section of bladder and identifies two perpendicular lines d1 and d2. Tap the end point of the line to change its length.
4. Tap [**Accept**] to confirm measurements of d1 and d2.
5. Scan the cross section image of bladder, select and freeze it.
6. Tap [**Smart Bladder**] in the measurement menu.
7. The system automatically traces the trace line in the cross section of bladder and identifies line d3. Here,
8. Tap the end point of the line to change its length.
9. Tap [**Done**] to confirm measurements of d3.
10. The bladder volume is calculated automatically.

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### Stroke Volume (SV):

Gorge, G., et al., "High Resolution Two-dimensional Echocardiography Improves the Quantification of Left Ventricular Function," Journal of the American Society of Echocardiography, 1992, 5: 125-34.

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Pombo, J.F., "Left Ventricular Volumes and Ejection by Echocardiography," Circulation, 1971, Vol. 43, pp. 480-490.

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Maron, Barry J., et al., "Noninvasive Assessment of Left Ventricular Diastolic Function by Pulsed Doppler Echocardiography in Patients with Hypertrophic Cardiomyopathy," Journal of the American College of Cardiology, 1987, Vol. 10, pp. 733-742.

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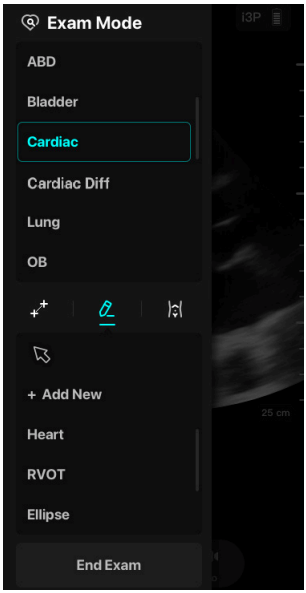
## 8.2 Annotation

Annotations can be added to an ultrasound image to bring attention, notate or communicate information observed during the examination. You can add annotations to frozen images.

In annotation status, you can enter annotation to the image through the touch screen.




## ⚠ WARNING

**Ensure that the entered annotations are correct. Incorrect annotations may lead to misdiagnosis!**

## 8.2.1 Adding Annotations

### Adding a Comments Text

Perform the following procedure:

1. After the image is frozen, tap [**Exam Mode**] and select in the menus to enter the comment interface.
2. Tap and drag to move the cursor to the desired location for comments.
3. Do one of the following to add a comment:
   - Tap to select the desired annotation text on the annotation menu.
   - Type the alphanumeric characters through the keyboard.
4. In edit status, tap [**return**] on the keyboard to confirm the added comments text and exit the edit status.

### Adding a User Defined Annotation

Perform the following procedure:

1. Tap [**+ Add New**].
2. Type the alphanumeric characters through the keyboard.
3. Tap [**return**] on the keyboard to confirm the added comments text.

### Adding an Arrow

You can add an arrow to a location where you want to pay attention.

Perform the following procedure:

1. In annotation status, tap the desired place to set the annotation location in the image area.

2. Tap the arrow icon in the comment function menu.
3. Repeat the above steps to add more arrows when necessary.

### 8.2.2 Modifying (Editing) Annotations

#### Modifying (Editing) a Character

Perform the following procedure:

1. In annotation status, move the cursor onto the annotations to be modified:
   Tap alphabetic keys to enter the character to the cursor position directly.
2. Tap [**Back**] to delete the annotation character or text on the left side of the cursor.

#### Modifying (Editing) an Arrow

Perform the following procedure:

1. Tap to select the added arrow and a frame line appears around the selected arrow, indicating that the arrow is editable.
2. Drag the arrow to the target position and change the arrow position.

### 8.2.3 Deleting Annotations

#### Deleting Annotation Characters, Texts or Arrows

Perform the following procedure:

1. Tap to select the annotation to be deleted.
2. Tap [**X**] to delete the annotation.

#### Delete all Annotations

**NOTE**

- After powering off, the system will clear all comments on the image.
- In the preset, you can set whether to clear comments when unfreezing the image, changing probe or changing the exam mode.

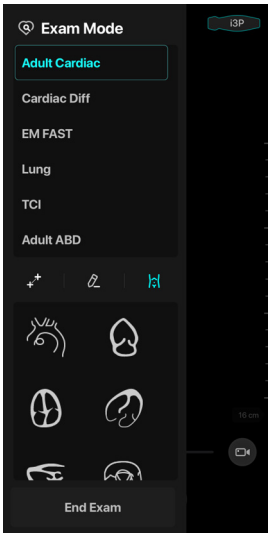
Tap  to delete all the comment items on the screen.

## 8.3 Body Mark

**NOTE**

- After powering off, the system will clear body marks.
- The body mark feature is used for indicating the exam position of the patient and transducer position and orientation.
- The body marks are different in different exam modes. The system supports user-defined body marks.

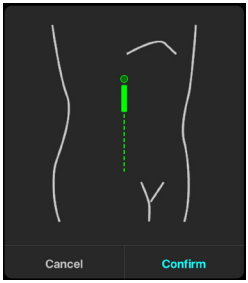
In the main screen, tap [**Exam Mode**] and select  tab to enter body mark status.




## 8.3.1 Adding Body Marks

Perform the following procedure:

1. Select body mark to be added in the body mark list.
2. Adjust the probe marker:
   - Tap and drag the probe marker to identify the location.
   - Drag and rotate the probe marker extension cable to adjust the probe marker orientation.




3. Tap [**Confirm**] to add the body mark.

## 8.3.2 Moving Body Marks

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

Perform the following procedure:

1. Tap to select the added body mark, and the body mark is covered by a frame.
2. Tap the desired position to place the body mark.

### 8.3.3 Deleting Body Marks

#### NOTE

Preset returning, switching the exam mode/patient/ probe will clear the body marks.

Perform the following procedure:

- Select the body mark to be deleted, and tap [**X**] to delete body mark.
- In editing status, tap  to delete all added body marks.

# 9 Patient Data Management

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
- Report

### NOTE

- DO NOT use the internal hard drive for long-term image storage. Daily backup is recommended. The system patient database space is limited, please back up or clear patient data in time.
- Exporting image in a compression format may result in image distortion.
- Mindray is not responsible for lost data if you DO NOT follow suggested backup procedures.
- When not operating for a long time, please lock the device screen in time to prevent patient information leakage or modifying.
- The system support sharing patient information via the DICOM on the TE Air application and data shared is secured.

## 9.1 Image File Management

You can store the image files in the patient database in the system. For a save image, you can perform operations like image reviewing and demonstration.

### 9.1.1 Storage Media

The image is saved to the default path with the default name.

### 9.1.2 Image File Formats

The system supports file formats which belong to the system and file formats which are PC-compatible.

#### System-relevant Formats

- Single-frame image file (JPG)

  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 (MP4)

  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 MP4 file, the system automatically enters cine review status.

### 9.1.3 Image Review

You can review all images stored in an exam, and send or delete the stored images.

Tap > [**Patient&Review**] to enter the review page or select the exam in iStation screen. Images of the current exam and the current patient are displayed.

### 9.1.4 Sending Image File

#### NOTE

Data saved this way can only be reviewed on the PC and cannot be restored to the ultrasound system.

Perform the following procedure:

1. Tap > [**Patient&Review**] to enter the Review page or select the exam in iStation screen.
2. In the Review screen, tap [**Select**] and select a stored image thumbnail.
3. Tap [**Send To**]. Select a desired destination.

## 9.2 Patient Data Management (iStation)

The patient data include basic patient information, exam information, image files. You can view, send, delete patient data in iStation.

Select the desired patient information in the list.

| Item | Description |
|---|---|
| Review an image | Selects an exam of a patient, tap [**Review**] to enter Review screen. |
| Patient Information | Selects an exam of a patient, tap [**Patient Info**] to check the patient information of this exam. |
| Delete Exam | Taps [**Select**] and select the patient record. Tap [**Delete**] to delete the exam. Or select the patient record and tap X on the right side. |
| Send Exam | You can use this function to export the exam data to DICOM (in DICOMDIR data format) and then import to PC to review the data.<br>1. Taps to send a patient record or taps [**Select**] to select patient records and then taps [**Send To**] in the menu to send exam data.<br>2. Selects from the destination, and set related settings.<br>3. Taps to enter Export Queue page and check the status of the tasks. When the task have failed, you can select [**Retry**] or [**Cancel**]. |

## 9.3 Q-Path

You can use the ultrasound system to sent data (exam images and report) to the Q-Path after setting the DICOM server.

## 9.4 DICOM

#### NOTE

Before using DICOM, please read the electronic file DICOM CONFORMANCE STATEMENT along with the device.

This section is confined to introduce the application and DICOM for DICOM-configured ultrasound machine, not including SCP configurations like PACS/ RIS/ HIS.

This system supports the following DICOM functions:

- DICOM Storage
- DICOM WorkList

If the system is configured with DICOM modules, and connected to the relevant DICOM servers, after verifying connection, you can perform storage and WorkList.

For detailed information about DICOM presets, see “2.4.1 Hardware Configuration”.

## 9.5 WorkList

When the DICOM basic package is configured and the WorkList server has been set, tap [**WorkList**] in the “Patient Info” screen to query or import the patient data.

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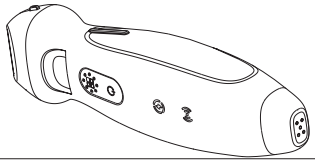
# 10 Probes

## 10.1 Probes

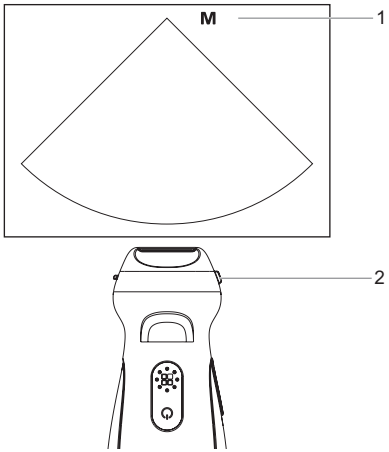
| Probe Mode | Probe Figure |
|---|---|
| i3P, i3PA |  |

### NOTE

For disinfected probes, refer to your hospital policy and procedures for details of storage times and conditions.

## 10.2 Orientation of the Ultrasound Image and the Prober Head

The orientation of the ultrasound image and the transducer are shown below. The “M” side of the ultrasound image on the monitor corresponds to the mark side of the probe. Check the orientation before the examination.




| | |
|---|---|
| 1 | Orientation mark |
| 2 | Mark |

## 10.3 Procedures for Operating

The proper clinical technique to be used for operating the transducer should be selected on the basis of specialized training and clinical experience.

1. Inspection before examination
2. Connection to the system
3. Examination
4. Power off the probe
5. Wiping off the ultrasound gel
6. Thoroughly cleaning the probe
7. Drying the probe
8. Disinfecting the probe
9. Rinsing the probe
10. Drying the probe
11. Inspection after use
12. Storage

## 10.4 Probes Cleaning and Disinfection

Before and after completing each examination, clean and disinfect the probes as required. Fail to do so may result in the probe to becoming a source of infection.

Refer to Technical Specifications for Disinfection in Medical Institution to select proper disinfection level:

| Disinfection Level | Probe Application |
|---|---|
| Low level disinfection | Contact with intact skin rather than mucous membranes. |
| High level disinfection | Contact with intact mucous membranes without entering the sterile tissues, organs and blood stream of the human body, and without contacting the damaged skin and mucous membranes. |

### ⚠ CAUTION

- **Before and after completing each examination, clean and disinfect the probes as required.**
- **Before performing cleaning and disinfection of the probe, disconnect all cables of the probe.**
- **When performing cleaning and disinfection of the probe, wear sterile gloves to prevent from Infection.**
- **Use protective eyewear when disinfecting using sprays or wipes disinfectant.**
- **Check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill after cleaning and disinfection. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department or a sales representative.**
- **Rinse the probe thoroughly by using a large amount of sterile distilled or softened water to remove chemical residues. Chemical residues on the probe may be harmful to the human body.**
- **The efficacy of disinfectants solutions is not guaranteed by MINDRAY. Contact the manufacturers for information on the activity of the products.**
- **No cleaning and disinfecting may result in the probe becoming a source of infection.**

### NOTE

- After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and degrade the image quality of the probe.

- Do not permit the transducer to become overheated (more than 55°C) during cleaning and disinfections. High temperature may cause the probe to become deformed or damaged.
- Repeated disinfection will eventually damage the probe, please check the probe performance periodically.
- Never immerse the probe USB connector into liquid such as water or disinfectant. Immersion may cause electrical shock or malfunction.

### 10.4.1 Cleaning

Perform the following procedure:

1. Wear a pair of gloves to prevent infection.
2. Power off the probe. If the sheath is used, take off the sheath and discard it.
3. Wipe off the ultrasound gel or other visible dirt on the surface of the probe by using a damp piece of disposable lint-free soft cloth or tissue.
4. Choose an appropriate cleaning agent including sprays, wipes disinfectant, neutral detergents, enzymatic cleaners and specially designed enzymatic sponges.
5. Immerse the probe fully in the cleaning fluid for at least 1 minute or according to manufacturer's instructions. Lightly mechanical clean the probe with a piece of lint-free soft cloth or soft sponge until no dirt is visible. Avoid using a brush, because it may damage the probe.
6. Rinse the probe thoroughly by using a large amount of clean water (about 7.5 L/2 gallons) at room temperature for about 30 s to remove the residual dirt and cleaning solvent. Repeat the rinsing operation twice.
7. Dry the probe by wiping with a piece of disposable lint-free soft cloth or tissue.
8. Do not dry the probe by heating.
9. Inspect the probe. If visible dirt still exists, repeat the preceding steps to wash the probe until it is all clean.

### 10.4.2 Low Level Disinfection

Perform the following procedure:

1. Wear a pair of gloves to prevent infection.
2. Clean the probe thoroughly in accordance with the cleaning procedure before disinfection.
3. Disinfect the probe by using an appropriate low-level disinfectant. Follow the disinfection agent manufacturer's instructions for preparation and use of the disinfectant.
   - Wipes: Wipe all the surface of the probe according to the wiping duration specified in the operator's manual provided by the manufacturer.
   - Spray: Spray the disinfectant directly on the surface of the probe or spray the disinfectant on a piece of disposable lint-free soft cloth and wipe the probe according to the wiping duration in the operator's manual provided by the manufacturer.
4. Wipe away the residual disinfectant on the probe by using a piece of lint-free soft cloth soaked with distilled water. Wipe three times. Or rinse the probe thoroughly by using a large amount of clean water (about 7.5 L/2 gallons) at room temperature.
5. Dry the probe by wiping with a piece of disposable lint-free soft cloth.
6. Do not dry the probe by heating.
7. Store the probe in a cool, clean and dry environment.

### 10.4.3 High Level Disinfection

Perform the following procedure:

1. Wear a pair of gloves to prevent infection.
2. Clean the probe thoroughly in accordance with the cleaning procedure before disinfection.

3. Disinfect the probe by using an appropriate high-level disinfectant or system. For how to use a high-level disinfectant or system, see the operator's manual provided by the manufacturer. Prepare a disinfectant by using sterile distilled or softened water when necessary.
4. Immerse the probe fully in the disinfectant and shake the probe appropriately to remove any bubbles on the probe surface. For details about the probe immersion duration, see the operator's manual provided by the manufacturer.
5. Rinse the probe thoroughly by using a large amount of clean water (about 7.5 L/2 gallons) at room temperature for about 30 s to remove the residual disinfectant. Repeat the operation twice. Or follow the disinfectant manufacturer's instructions regarding rinsing.
6. Dry the probe by wiping with a piece of clean disposable lint-free soft cloth.
7. Do not dry the probe by heating.
8. Store the probe in a cool, clean and dry environment.

### 10.4.4 Compatible Cleaner, Disinfectants

For the cleaner, disinfectants information, please refer to Quick Reference Guide.

## 10.5 Storage and Transportation

When all examinations for the day have been completed, confirm that the probe is in good condition. After disinfecting the probe, confirm that the probe is in good condition and stored in a suitable place.

To prevent the probe from being damaged, DO NOT store it in locations where it may be exposed to:

- Direct sunlight
- Sudden changes in temperature
- Dust
- Excessive vibration
- Heat generators

When the probe is sent to MINDRAY Customer Service Department or sales representative for repair, be sure to disinfect it and keep it in the carrying case to prevent infection.

Disinfection the carrying case as necessary.

# 11 System Maintenance

Routine system maintenance shall be carried out by the user. System maintenance after the warranty has expired is the full responsibility of the owner/operator.

The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product.

If you have any questions, please contact Mindray Customer Service Department or sales representative.

**⚠ WARNING**

- **Only an authorized Mindray service engineer can perform maintenance not specified in this operator's manual.**
- **The system shall not be serviced or maintained while in use with a patient.**
- **For the sake of the system performance and safety, you should perform periodical checks for the system.**
- **Before cleaning the probes, be sure to turn off the power and disconnect the power cord from the outlet. Cleaning the probe while the power is "On" may result in electric shock.**

## 11.1 Daily Maintenance

You are responsible for daily maintenance.

### 11.1.1 Cleaning Probes

For details, see "10.4.1 Cleaning".

### 11.1.2 Cleaning the Air Capsule

Tools: mild soapy water, dry soft cloth, soft brush

Method:

1. Wipe out the dust attached to surface of Air Capsule.
2. Use soft brush to clean the pogo-pins inside the Air Capsule gently.
3. Remained stain or dust attached to the inner and outer surfaces of the Air Capsule should be washed out by cloth with little soapy water, and then air-dry.

**NOTE**

Don't use cloth with water to clean the pogo-pins inside the Air Capsule.

### 11.1.3 Checking the Probe

- Visually check to confirm that there are no cracks or expansion of the probe head.
- Visually check to confirm that there is no deterioration or erosion of the probe cable.

### 11.1.4 Checking the Power Cable

Visually check to confirm that there are no wrinkles, cracks or deterioration, and no cracks or expansion on the surface of the adapter.

Manually check to confirm that there is no looseness or rupture. The connection of the plug is reliable.

### 11.1.5 Checking the Air Capsule

- Visually check to confirm that there are no cracks, expansion or obvious stacking of glue on the surfaces of the Air Capsule
- Manually check to confirm that the both ways to charge the Air Capsule function well, USB Type-C and Wireless charging included.
- Manually check to confirm that the moving mechanical parts won't get stuck under normal use.
- Manually check to confirm that the probe can get well charged in the Air Capsule under normal use.

## 11.2 Troubleshooting

If any persistent system malfunction is experienced, e.g., an on-screen error message, blank imaging screen, absent menus, see the table below. If the failure cannot be resolved, contact the Mindray Customer Service Department or a sales representative.

| No. | Failure | Cause | Measure |
|---|---|---|---|
| 1 | The display has no output. | The interval between turning off and restarting the system is too short - wait at least 20 seconds. | Turn off the system and wait at least 1 minute, then restart the system. |
| | | The display brightness or contrast may be improperly set. | Adjust the display brightness and contrast. |
| 2 | The touch screen displays the characters and menus but no images. | Check that a probe is connected. | Check probe connection. |
| | | The system is in frozen status. | Unfreeze the image. |
| 3 | The image quality is degraded | The exam mode is incorrect. | Select an appropriate exam mode. |
| | | The image parameter settings are incorrect. | Adjust the image parameters. |
| 4 | The APP cannot start | / | Delete and reinstall the APP. |
| 5 | The APP crashes | / | Close and restart the APP. |

# 12 Acoustic Output

This section of the operator's 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.

## 12.1 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.

## 12.2 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.

## 12.3 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”.

# 12.4 MI/TI Explanation

## 12.4.1 Basic Knowledge of MI and TI

### Mechanical Bioeffect and Thermal Bioeffect

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.

### 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.

$$MI = \frac{P_{r,\alpha}}{\sqrt{f_{awf}} \times C_{MI}}$$

$C_{MI} = 1\ (MPa / \sqrt{MHz})$

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.
- 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.

## 12.4.2 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.

Here you can set the level of acoustic power.

### 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.

Real-time Display accuracy: MI within ± 28.5%, TI within ± 38.7%.

## 12.5 Acoustic Power Setting

### Acoustic Power Adjustment

Use the [**A.power**] to adjust the acoustic power percentage, and its value is displayed at the top of the screen. 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.

### Adjusting Range

Initial power: 0.13% 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.

Default settings of acoustic power value refer to the best image quality of the probe. The larger the acoustic power value, the better the image quality.

In this product, to obtain optimum images for applications under the requirements of safety and ALARA principle, we set acoustic power default values in factory to be maximum 93.33% in all exam modes for a better image quality. The user can make adjustments according to the imaging effect in practical use.

### NOTE

This system automatically returns to the settings whenever changes are made to the values (when you turn on the power, switch between probes, tap [**End Exam**], or select Return in the Setup menu). In the factory default settings, the Acoustic Output is limited below 100%. Following the ALARA restriction, you are allowed to increase the acoustic power under FDA 510 (k) Guidance-Track 3 limits and to set it in the image preset screen.

The acoustic output of the system has been measured and calculated in accordance with GB9706.9-2008, FDA 510(K) GUIDANCE, "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (NEMA UD 2 2004)", the "Standard for Real-Time Display of Thermal and Mechanical Indices on Diagnostic Ultrasound Equipment (AIUM and NEMA UD-3 2004) and "Requirement for the Declaration of the Acoustic Output of Medical Diagnosis Ultrasonic Equipment (GB/T 16846-2008)".

## 12.6 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
- Controls that indirectly control output.

### 12.6.1 Direct Controls

It is possible to control, if necessary, the acoustic output with the “A.power” item. In this case, the maximum value of the acoustic output never exceeds an MI of 1.9, TI of 6 and an ISPTA.3 of 720 mW/cm2 in any mode of operation.

### 12.6.2 Indirect Controls

The controls that indirectly affect output are the 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, PW 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.

### 12.6.3 Receiver Controls

The receiver controls (for example, gain, dynamic range, and image post-processing, etc.) won’t affect output. These controls should be used, when possible, to improve the image quality before using controls that directly or indirectly affect output.

## 12.7 Acoustic Output

### 12.7.1 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:

$$I_{atten} = I_{water} \times 10^{((-0.3)/10 \times f_c \times z)}$$

Where $I_{atten}$ is the attenuated intensity, $I_{water}$ is the intensity measured in a water tank (at distance z), fc 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 of 0.3 dB/cm/MHz is much lower than the actual attenuation coefficient.

### 12.7.2 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 | $I_{spta.3}$(mW/cm$^2$) | $I_{sppa.3}$(W/cm$^2$) | Or | MI |
|---|---|---|---|---|
| Regions (except eyes) | ≤720 | ≤190 | | ≤ 1.9 |

### 12.7.3 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 prescribed 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.

## 12.8 Measurement Uncertainty

The total estimated measurement uncertainty (where the total uncertainty includes the uncertainties in hydrophone response, measurement, calculation, and positioning) are:

| | |
|---|---|
| Ispta | 26.48% for non-scan modes; 26.93% for scan modes. |
| Isppa | 26.5% |
| Center frequency(fc) | 0.22% |
| Total power (W) | 26.48% for non-scan modes; 6.03% for scan modes. |
| Peak-rarefactional pressure (pr) | 13.01% |

## 12.9 References for Acoustic Power and Safety

- “Bioeffects and Safety of Diagnostic Ultrasound” issued by AIUM in 1993
- “Medical Ultrasound Safety” issued by AIUM in 1994
- Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, June 27, 2019. Center for Devices and Radiological Health.
- Medical electrical equipment-Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment issued by IEC in 2015
- IEC 62359, Ultrasonics-Field characterization-Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017.

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# 13 EMC Guidance and Manufacturer's Declaration

TE Air complies with the EMC standard IEC 60601-1-2: 2014+A1:2020.

Intended Environments: Professional healthcare facility environment (except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging).

## ⚠ WARNING

- **The use of unapproved accessories may diminish system performance.**
- **Use of components, accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of system.**
- **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of TE Air,including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
- **TE Air needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Other devices may interfere with this equipment even though they meet the requirements of CISPR.**
- **Portable and mobile RF communications equipment could affect system. See below tables.**
- **The EMC test is based on iPhone XR, and the probe itself is complies with IEC 60601-1-2 and its RF emission meets the requirements of CISPR11 Class B. In a HOME HEALTHCARE ENVIRONMENT, the customer or the user should guarantee to connect the system with Class B Terminal devices; otherwise RF interference may result and the customer or the user must take adequate measures accordingly. It is recommended that users select devices for sale through formal channels when selecting terminals that have FCC certification and RF emissions meets ClassB.**
- **TE Air should be away from RFID, MRI, diathermy, and electrocautery testing, wireless power transfer, 5G cellular and security equipment (such as electromagnetic anti-theft system and metal detector). If the devices are near and are interfered by the concealed and undiscovered RF transmitter (for example, scanning mode changes or image disturbances affecting diagnosis), the user should immediately take mitigation measures, such as redirecting, repositioning or shielding the RF transmitter.**
- **This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.**

- **This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:**
  - **Reorient or relocate the receiving antenna.**
  - **Increase the separation between the equipment and receiver.**
  - **Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.**
  - **Consult the dealer or an experienced radio/TV technician for help.**

  **Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.**

  **The device has been evaluated to meet general RF exposure requirement.**

If TE Air is operated within the electromagnetic environment listed in see "Table 13-1", and see "Table 13-2", TE Air will remain safe and will provide the following basic performances:

- Imaging;
- Doppler acoustic spectral displaying;
- Taking measurements;
- Patient information;
- Date/time information.

If the basic performance of TE Air is lost or degraded, adjust the operating environment based on the ELECTROMAGNETIC ENVIRONMENT-GUIDANCE from "Table13-1" to "Table 13-6".

**Table 13-1**

| GUIDANCE AND MINDRAY DECLARATION-ELECTROMAGNETIC EMISSION | | |
|---|---|---|
| The Probe which integrated in TE Air 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. | | |
| EMISSIONS TEST | COMPLIANCE | ELECTROMAGNETIC ENVIRONMENT - GUIDANCE |
| RF emissions<br>CISPR 11 | Group 1 | TE Air 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 | TE Air is suitable for use in all establishments including domestic establishments and those directly connected to the public lowvoltage 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 13-2**

| GUIDANCE AND MINDRAY DECLARATION-ELECTROMAGNETIC EMISSIONS | | | |
|---|---|---|---|
| TE Air 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. | | | |
| IMMUNITY TEST | IEC 60601 TEST LEVEL | COMPLIANCE LEVEL | ELECTROMAGNETIC ENVIRONMENT-GUIDANCE |
| Electrostatic Discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact;<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±8 kV contact;<br>±2 kV, ±4 kV, ±8 kV, ±15kV 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<br>IEC 61000-4-4 | ±2 kV for power supply lines;<br>±1 kV for input/ output lines | ±2 kV for power supply lines;<br>±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±0,5 kV, ±1 kV line(s) to line(s);<br>±0,5 kV, ±1 kV, ±2 kV line(s) to earth | ±0,5 kV, ±1 kV line(s) to line(s);<br>±0,5 kV, ±1 kV, ±2 kV line(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<br>IEC 61000-4-11 | 0 % UT; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % UT; 1 cycle<br>70% UT for 25/30 cycle at 0°<br><br>0 % UT; 250/300 cycle | 0 % UT; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % UT; 1 cycle<br>70% UT for 25/30 cycle at 0°<br><br>0 % UT; 250/300 cycle | 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<br>IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE: UT is the A.C. mains voltage prior to application of the test level. | | | |

**Table 13-3**

| GUIDANCE AND MINDRAY DECLARATION-ELECTROMAGNETIC IMMUNITY | | | |
|---|---|---|---|
| TE Air 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. | | | |
| IMMUNITY TEST | IEC 60601 TEST LEVEL | COMPLIANCE LEVEL | ELECTROMAGNETIC ENVIRONMENT-GUIDANCE |
| Conduced RF IEC 61000-4-6 | 3 Vrms<br>0,15 MHz – 80 MHz<br><br>6 Vrms in ISM[a] and amateur radio bands between<br>0,15 MH and 80 MHz | 3 Vrms<br>0,15 MHz – 80 MHz<br><br>6 Vrms in ISM[a] and amateur radio bands between<br>0,15 MH and 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:<br>$d = 1.2 \times \sqrt{P}$<br>$d = 2\times \sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 10 V/m<br>80MHz - 2.7GHz | 10 V/m<br>80MHz - 2.7GHz | $d = 1.2 \times \sqrt{P}$ 80 MHz ~ 800 MHz<br>$d = 2.3 \times \sqrt{P}$ 800 MHz ~ 2.7GHz<br>Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[b], should be less than the compliance level in each frequency range[c].<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

| GUIDANCE AND MINDRAY DECLARATION-ELECTROMAGNETIC IMMUNITY |
|---|
| a: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz. |
| b: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. |
| c: Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m. |

**Table 13-4**

| GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY | | | |
|---|---|---|---|
| TE Air 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. | | | |
| **IMMUNITY TEST** | **IEC 60601 TEST LEVEL** | **COMPLIANCE LEVEL** | **ELECTRO-MAGNET-IC ENVI-RONMENT – GUID-ANCE** |
| Proximity magnetic fields<br>IEC 61000-4-39 | 8 A/m<br>30 kHz<br>CW | 8 A/m<br>30 kHz<br>CW | / |
| | 65 A/m<br>134,2 kHz<br>Pulse modulation<br>2,1 kHz | 65 A/m<br>134,2 kHz<br>Pulse modulation<br>2,1 kHz | |
| | 7,5 A/m<br>13,56 MHz<br>Pulse modulation<br>50 kHz | 7,5 A/m<br>13,56 MHz<br>Pulse modulation<br>50 kHz | |

**Table 13-5**

| Recommended separation distances between portable and mobile RF communications equipment and system | | | | | | |
|---|---|---|---|---|---|---|
| TE Air is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and TE Air as recommended below, according to the maximum output power of the communications equipment. Portable and mobile radio communications equipment (e.g. two-way radio, cellular/ cordless telephones and similar equipment) should be used no closer to any part of this system, including cables, than determined according to the following method: | | | | | | |
| **Test frequency (MHz)** | **Band(MHz)** | **Service** | **Modulation** | **Maximum power (W)** | **Distance (m)** | **Immunity test level (V/m)** |
| 385 | 380 - 390 | TETRA 400 | Pulse modulation 18Hz | 1.8 | 0.3 | 27 |
| 450 | 430 -470 | GMRS 460<br>FRS 460 | FM ±5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710 | 704 - 787 | LTE Band 13,17 | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| 745 | | | | | | |
| 780 | | | | | | |
| 810 | 800 - 960 | GSM 800/900,<br>tetra 800,<br>iDEN 820,<br>CDMA 850,<br>LTE Band 5 | Pulse modulation 18 Hz | 2 | 0.3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |
| 1720 | 1700 -1990 | GSM 1800,<br>CDMA 1900,<br>GSM 1900,<br>DECT,<br>LTE Band 1, 3,4,25,UMTS | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400 -2570 | Bluetooth,<br>WLAN,<br>802.11 b/g/n,<br>RFID 2450, LTE Band 7 | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 5240 | 5100 -5800 | WLAN,<br>802.11 a/n | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |

**Table 13-6**

| RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND THE SYSTEM | | | | |
|---|---|---|---|---|
| TE Air 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. | | | | |
| Rated Maximum Output power of Transmitter (W) | Separation Distance According to Frequency of Transmitter (m) | | | |
| | 150kHz -80MHz Out ISM and amateur radio bands $d=1.2\sqrt{P}$ | 150kHz -80MHz in ISM and amateur radio bands $d=2\sqrt{P}$ | 80MHz-800MHz $d=1.2\sqrt{P}$ | 800MHz-2.7GHz $d=2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.2 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.64 | 0.38 | 0.73 |
| 1 | 1.2 | 2 | 1.2 | 2.3 |
| 10 | 3.8 | 6.4 | 3.8 | 7.3 |
| 100 | 12 | 20 | 12 | 23 |
| For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined 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.<br>If system image distortion occurs, it may be necessary to position system further from sources of conducted RF noise or to install external power source filter to minimize RF noise to an acceptable level.<br>Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | | |

## Sample Cable

| Name | Cable length (m) | Shield or not | Remarks |
|---|---|---|---|
| Probe Cable | 1 | Shielded | / |

## Electromagnetic Radiation Exposure

TE Air has passed the test and met the FCC and CE safety restrictions on electromagnetic radiation exposure. However, the use of accessories not included in the claimed product may cause electromagnetic radiation exposure to exceed expectations.

# 14 Wireless LAN

## NOTE

- Other non-medical devices in the same frequency band may cause interference, please be cautious.
- Wireless network designing, deploying, debugging, and maintenance should be executed by Mindray service personnel or authorized technicians.
- Always set the wireless network according to local wireless regulations.
- Keep network authentication information, for example password, safe, protecting the network from being accessed by unauthorized users.
- If the wireless signal is poor, the ultrasound machine may fail to send data to the server.
- RF interference may result in wireless network disconnection.
- Disconnecting from the network may result in send data to server failure. Solve the network problem as soon as possible.
- Ensure that the ultrasound device IP address setting is correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on setting the IP address.
- To make sure that the ultrasound system works well, the ultrasound system can coexist with Wi-Fi as the interfering network operating at maxmum throughput and maxmum transmit power when a separation distance of 1m is maintained.
- Wi-Fi function is not affected when the system is imposed with radiation interference complied with IEC 60601-1-2: 2014 standard.

The quality of service information is shown as follow:

| No. | Item | Specifications |
|---|---|---|
| 1 | Data rate | 802.11a: up to 54 Mbps @ 5 GHz<br>802.11n: up to 300 Mbps @ 5 GHz<br>802.11ac: up to MCS9 @ 5 GHz |
| 2 | Data security | WPA/WPA2 |
| 3 | Vision Distance Communications | The ultrasound diagnostic system can be connected within 3 meters of the wireless network, and the system can perform the following operations and realize its intended use:<br>• Support DICOM transferring patient data through the wireless network (Wi-Fi).<br>• Support the remote network storage of patient data to the PC server (iStorage). |
| 4 | Application-layer delay | ≤10 seconds |
| 5 | Application-layer reliability | If the connection fails, the user will be prompted by the Wi-Fi icon. |
| 6 | System capacity | When the ultrasound system is used as the hotspot AP, no more than 1 access device is allowed. |
| 7 | System anti-interference | It is allowed to coexist with multiple Wi-Fi devices. |

| No. | Item | Specifications |
|---|---|---|
| 8 | Network interruption alarm |  : Wireless signal not connected<br>: Strong wireless signal<br>: Normal wireless signal<br>: Weak wireless signal<br>If DICOM or other data transfer fails, a window will pop up for alarm and LOG recording. |
| 9 | Coexist & EMC test process | Wi-Fi function is not affected when the system is imposed with radiation interference complied with AAMI TIR69:2017 &IEC60601-1-2:2014 standard. |

RF parameter:

| Standard | Modulation | Data Rates | 5 GHZ TX Power with IEEE 802.11 EVM and Spectral Mask at +25°C | | | | |
|---|---|---|---|---|---|---|---|
| | | Index | 802.11a | 802.11n/ac 20 MHz | 802.11n/ac 40 MHz | 802.11n/ac 80 MHz | Units |
| | | | Typical | Typical | Typical | Typical | |
| 802.11a | BPSK | 6 Mbps | 13.5 | - | - | - | dBm |
| | BPSK | 9 Mbps | 13.5 | - | - | - | dBm |
| | QPSK | 12 Mbps | 13.5 | - | - | - | dBm |
| | QPSK | 18 Mbps | 13.5 | - | - | - | dBm |
| | 16 QAM | 24 Mbps | 13.0 | - | - | - | dBm |
| | 16 QAM | 36 Mbps | 12.0 | - | - | - | dBm |
| | 64 QAM | 48 Mbps | 11.5 | - | - | - | dBm |
| | 64 QAM | 54 Mbps | 10.5 | - | - | - | dBm |
| 802.11n/ac | BPSK | MCS0 | - | 13.0 | 12.0 | 11.5 | dBm |
| | QPSK | MCS1 | - | 13.0 | 12.0 | 11.5 | dBm |
| | QPSK | MCS2 | - | 13.0 | 12.0 | 11.5 | dBm |
| | 16 QAM | MCS3 | - | 13.0 | 12.0 | 11.5 | dBm |
| | 16 QAM | MCS4 | - | 12.0 | 12.0 | 11.5 | dBm |
| | 64 QAM | MCS5 | - | 11.5 | 10.5 | 11.5 | dBm |
| | 64 QAM | MCS6 | - | 10.0 | 10.5 | 9.5 | dBm |
| | 64 QAM | MCS7 | - | 9.5 | 10.0 | 9.5 | dBm |
| 802.11ac | 256 QAM | MCS8 | - | 9.0 | 9.0 | 9.0 | dBm |
| | 256 QAM | MCS9 | - | - | 7.0 | 8.5 | dBm |

# 15 Acoustic Power Data and Surface Temperature Data

This manual gives all the transducers Acoustic Output Power data and Surface Temperature Data for this Diagnostic Ultrasound System. Please refer to correlative tables in use.

# 15.1 Description of Symbols Used in Acoustic Output Tables

| Symbol | Description |
|---|---|
| Zmin | Minimum measurement depth in cm |
| pr | Peak-rarefactional acoustic pressure in MPa |
| pr, α(z) | Attenuated peak-rarefactional acoustic pressure |
| P | Time-average power in mW |
| P1×1 | Bounded-square output power |
| Pα(z) | Output power after attenuation |
| zbp | Break-point depth in centimeter |
| zs,ns | Depth for soft-tissue thermal index for non-scanning modes in centimeter |
| zb,ns | Depth for bone thermal index for non-scanning modes in centimeter |
| pii(z) | Pulse-intensity integral in mJ/cm2 |
| piiα(z) | Attenuated pulse-intensity integral in mJ/cm2 |
| sii(z) | Scan intensity integral in mJ/cm2 |
| siiα(z) | Attenuated scan intensity integral in mJ/cm2 |
| zpii | Depth for peak pulse-intensity integral |
| zpii,α | Depth for peak attenuated pulse-intensity integral |
| zMI | Depth for mechanical index |
| zsii | Depth for peak scan intensity integral |
| zsii,α | Depth for peak attenuated scan intensity integral |
| fawf | Acoustic working frequency in MHz |
| prr | Pulse repetition rate in Hz |
| srr | Scan repetition rate in Hz |
| npps | Number of pulses per ultrasonic scan line |
| Ita(z) | Time-average of the instantaneous intensity |
| Ita,α(z) | Value of the temporal-average intensity after attenuation |
| Ispta | Spatial-peak temporal-average intensity |
| Ispta,α(z) | Attenuated spatial-peak temporal-average intensity |
| Aeq(z) | Equivalent beam area |
| deq(z) | Equivalent beam diameter in centimeter |
| td | Pulse duration in second |
| Ipa(z) | Pulse-average intensity in W/cm2 |
| Ipa,α(z) | Attenuated pulse-average intensity in W/cm2 |
| MI | Mechanical Index |
| TIS | Soft tissue thermal index |

| Symbol | Description |
|---|---|
| TISas,ns | Soft tissue thermal index at-surface for non-scanning modes |
| TISbs,ns | Soft tissue thermal index below-surface for non-scanning modes |
| TISas,sc | Soft tissue thermal index at-surface for scanning modes |
| TISbs,sc | Soft tissue thermal index below-surface for scanning modes |
| TIB | Bone thermal index |
| TIBbs,ns | Bone thermal index below-surface for non-scanning modes |
| TIBbs,sc | Bone thermal index below-surface for scanning modes |
| TIC | Cranial-bone thermal index |
| TICas,ns | Cranial-bone thermal index at-surface for non-scanning modes |
| TICas,sc | Determination of the cranial-bone thermal index at-surface for scanning modes |

## 15.2 Transducer Maximum Surface Temperature

According to the requirements of the section 201.11 in the standard IEC 60601-2-37: 2015, the transducer surface temperature has been tested in two kinds of conditions: the transducer suspended in still air or transducer contacting human-tissue mimicking material.

The measurement data were obtained under the test conditions employed at Mindray.

| Transducer model | Maximum surface temperature(°C) Contacting TMM | Maximum surface temperature (°C) Suspending in air |
|---|---|---|
| i3P | 41.0 | 33.2 |
| i3PA | 41.2 | 33.6 |

# 15.3 Acoustic Output Reporting Table (IEC 60601-2-37: 2015)

## 15.3.1 i3P

Transducer Model: i3P

Imaging Mode: M-mode

| Index label | | MI | TIS | | TIB | | TIC |
|---|---|---|---|---|---|---|---|
| | | | At surface | Below surface | At surface | Below surface | |
| Maximum index value | | 1.44 | 0.07 | | 0.35 | | 0.23 |
| Index component value | | | 0.02 | 0.07 | 0.12 | 0.35 | |
| Acoustic Parameters | $p_{r,\alpha}$ at $z_{MI}$ (MPa) | 1.94 | | | | | |
| | P (mW) | | 22.00 | | 22.00 | | 11.17 |
| | $P_{1\times1}$ (mW) | | 1.32 | | 1.32 | | |
| | $z_s$ (cm) | | | 7.00 | | | |
| | $z_b$ (cm) | | | | | 7.04 | |
| | $z_{MI}$ (cm) | 3.76 | | | | | |
| | $z_{pii,\alpha}$ (cm) | 3.76 | | | | | |
| | $f_{awf}$ (MHz) | 1.81 | 3.12 | | 1.27 | | 2.20 |
| Other Information | prr (Hz) | 1,000.00 | | | | | |
| | srr (Hz) | / | | | | | |
| | $n_{pps}$ | / | | | | | |
| | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm$^2$) | 64.24 | | | | | |
| | $I_{spta,\alpha}$ at $_{zpii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm$^2$) | 46.74 | | | | | |
| | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ (mW/cm$^2$) | 76.91 | | | | | |
| | $p_r$ at $z_{pii}$ (MPa) | 2.32 | | | | | |
| Operating control conditions | Acoustic power | 100% | 100% | | 100% | | 100% |
| | Display depth | 16cm | 16cm | | 16cm | | 16cm |
| | Focus position | 8.0cm | 8.0cm | | 8.0cm | | 8.0cm |
| | Working Frequency | Pen | Res | | HPen | | Gen |
| | PRF | 1000 | 1000 | | 1000 | | 1000 |

Transducer Model: i3P

Imaging Mode: B-mode/Tissue Harmonic Imaging

| Index label | | MI | TIS | | TIB | | TIC |
|---|---|---|---|---|---|---|---|
| | | | At surface | Below surface | At surface | Below surface | |
| Maximum index value | | 1.40 | 0.02 | | 0.13 | | 0.12 |
| Index component value | | | 0.02 | 0.02 | 0.13 | 0.02 | |
| Acoustic Parameters | pr,α at $z_{MI}$ (MPa) | 1.90 | | | | | |
| | P (mW) | | 22.00 | | 22.00 | | 11.17 |
| | $P_{1\times1}$ (mW) | | 1.32 | | 1.44 | | |
| | $z_s$ (cm) | | | / | | | |
| | $z_b$ (cm) | | | | | / | |
| | $z_{MI}$ (cm) | 4.19 | | | | | |
| | $z_{pii,\alpha}$ (cm) | 4.19 | | | | | |
| | $f_{awf}$ (MHz) | 1.83 | 3.14 | | 3.14 | | 2.22 |
| Other Information | prr (Hz) | 1,887.00 | | | | | |
| | srr (Hz) | 26.57 | | | | | |
| | $n_{pps}$ | 0.00 | | | | | |
| | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ ($W/cm^2$) | 68.58 | | | | | |
| | $I_{spta,\alpha}$ at $_{zpii,\alpha}$ or $z_{sii,\alpha}$ ($mW/cm^2$) | 3.85 | | | | | |
| | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ ($mW/cm^2$) | 6.61 | | | | | |
| | $p_r$ at $z_{pii}$ (MPa) | 2.34 | | | | | |
| Operating control conditions | Acoustic power | 100% | 100% | | 100% | | 100% |
| | Display depth | 16cm | 16cm | | 16cm | | 16cm |
| | Focus position | 8.0cm | 8.0cm | | 8.0cm | | 8.0cm |
| | Working Frequency | Pen | Res | | Res | | Gen |
| | PRF | 1887 | 1942 | | 1942 | | 1887 |

Transducer Model: i3P

Imaging Mode: PW-mode/TVD-mode

| Index label | | MI | TIS | | TIB | | TIC |
|---|---|---|---|---|---|---|---|
| | | | At surface | Below surface | At surface | Below surface | |
| Maximum index value | | 0.84 | 0.13 | | 0.98 | | 0.18 |
| Index component value | | | 0.02 | 0.13 | 0.19 | 0.98 | |
| Acoustic Parameters | pr,α at $z_{MI}$ (MPa) | 1.13 | | | | | |
| | P (mW) | | 30.00 | | 28.00 | | 28.00 |
| | $P_{1\times1}$ (mW) | | 2.83 | | 2.65 | | |
| | $z_s$ (cm) | | | 5.65 | | | |
| | $z_b$ (cm) | | | | | 5.65 | |
| | $z_{MI}$ (cm) | 0.59 | | | | | |
| | $z_{pii,\alpha}$ (cm) | 0.59 | | | | | |
| | $f_{awf}$ (MHz) | 1.79 | 1.82 | | 1.82 | | 1.82 |
| Other Information | prr (Hz) | 5,263.00 | | | | | |
| | srr (Hz) | / | | | | | |
| | $n_{pps}$ | / | | | | | |
| | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm$^2$) | 35.52 | | | | | |
| | $I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm$^2$) | 385.91 | | | | | |
| | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ (mW/cm$^2$) | 414.95 | | | | | |
| | $p_r$ at $z_{pii}$ (MPa) | 1.17 | | | | | |
| Operating control conditions | Acoustic power | 100% | 100% | | 100% | | 100% |
| | Display depth | 16cm | 16cm | | 16cm | | 16cm |
| | Focus position | 8.0cm | 8.0cm | | 8.0cm | | 8.0cm |
| | Working Frequency | Pen | Res | | Res | | Gen |
| | PRF | 1887 | 1942 | | 1942 | | 1887 |
| | SV | 0.5mm | 0.5mm | | 0.5mm | | 0.5mm |

Transducer Model: i3P

Imaging Mode: Color+B-Mode / Power+B-Mode /TVI+B/TEI+B

| Index label | | MI | TIS | | TIB | | TIC |
|---|---|---|---|---|---|---|---|
| | | | At surface | Below surface | At surface | Below surface | |
| Maximum index value | | 1.40 | 0.03 | | 0.03 | | 0.27 |
| Index component value | | | 0.03 | 0.03 | 0.03 | 0.03 | |
| Acoustic Parameters | pr,α at $z_{MI}$ (MPa) | 1.98 | | | | | |
| | P (mW) | | 44.00 | | 48.00 | | 44.00 |
| | $P_{1\times1}$ (mW) | | 3.56 | | 3.89 | | |
| | $z_s$ (cm) | | | / | | | |
| | $z_b$ (cm) | | | | | / | |
| | $z_{MI}$ (cm) | 0.50 | | | | | |
| | $z_{pii,\alpha}$ (cm) | 0.50 | | | | | |
| | $f_{awf}$ (MHz) | 1.99 | 1.75 | | 1.75 | | 1.75 |
| Other Information | prr (Hz) | 2,640.00 | | | | | |
| | srr (Hz) | 16.29 | | | | | |
| | $n_{pps}$ | / | | | | | |
| | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm$^2$) | 33.31 | | | | | |
| | $I_{spta,\alpha}$ at $_{zpii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm$^2$) | 5.00 | | | | | |
| | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ (mW/cm$^2$) | 5.35 | | | | | |
| | $p_r$ at $z_{pii}$ (MPa) | 2.05 | | | | | |
| Operating control conditions | Acoustic power | 100% | 100% | | 100% | | 100% |
| | Display depth | 16cm | 16cm | | 16cm | | 16cm |
| | B Focus Position | 8.0cm | 8.0cm | | 8.0cm | | 8.0cm |
| | Color Sampling Gate Position | 2.0cm | 2.0cm | | 2.0cm | | 2.0cm |
| | B Working Frequency | Pen | HGen | | HGen | | HGen |
| | C Working Frequency | Gen | Pen | | Pen | | Pen |
| | B PRF | 1157 | 1361 | | 1361 | | 1361 |
| | Color PRF | 2640 | 3843 | | 3843 | | 3843 |

## 15.3.2 i3PA

Transducer Model: i3PA

Imaging Mode: M-mode

| Index label | | MI | TIS | | TIB | | TIC |
|---|---|---|---|---|---|---|---|
| | | | At surface | Below surface | At surface | Below surface | |
| Maximum index value | | 1.41 | 0.07 | | 0.35 | | 0.12 |
| Index component value | | | 0.02 | 0.07 | 0.12 | 0.35 | |
| Acoustic Parameters | pr,α at $z_{MI}$ (MPa) | 1.87 | | | | | |
| | P (mW) | | 22.00 | | 22.00 | | 22.00 |
| | $P_{1\times1}$ (mW) | | 1.32 | | 1.32 | | |
| | $z_s$ (cm) | | | 7.00 | | | |
| | $z_b$ (cm) | | | | | 7.04 | |
| | $z_{MI}$ (cm) | 3.76 | | | | | |
| | $z_{pii,\alpha}$ (cm) | 3.76 | | | | | |
| | $f_{awf}$ (MHz) | 1.75 | 3.03 | | 1.23 | | 2.14 |
| Other Information | prr (Hz) | 1,000.00 | | | | | |
| | srr (Hz) | / | | | | | |
| | $n_{pps}$ | / | | | | | |
| | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm$^2$) | 61.89 | | | | | |
| | $I_{spta,\alpha}$ at $_{zpii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm$^2$) | 45.03 | | | | | |
| | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ (mW/cm$^2$) | 73.06 | | | | | |
| | $p_r$ at $z_{pii}$ (MPa) | 2.22 | | | | | |
| Operating control conditions | Acoustic power | 100% | 100% | | 100% | | 100% |
| | Display depth | 16cm | 16cm | | 16cm | | 16cm |
| | Focus position | 8.0cm | 8.0cm | | 8.0cm | | 8.0cm |
| | Working Frequency | Pen | Res | | HPen | | Gen |
| | PRF | 1000 | 1000 | | 1000 | | 1000 |

Transducer Model: i3PA

Imaging Mode: B-mode/Tissue Harmonic Imaging

| Index label | | MI | TIS | | TIB | | TIC |
|---|---|---|---|---|---|---|---|
| | | | At surface | Below surface | At surface | Below surface | |
| Maximum index value | | 1.38 | 0.02 | | 0.13 | | 0.12 |
| Index component value | | | 0.02 | 0.02 | 0.13 | 0.02 | |
| Acoustic Parameters | pr,α at $z_{MI}$ (MPa) | 1.83 | | | | | |
| | P (mW) | | 22.00 | | 24.00 | | 22.00 |
| | $P_{1\times1}$ (mW) | | 1.32 | | 1.44 | | |
| | $z_s$ (cm) | | | / | | | |
| | $z_b$ (cm) | | | | | / | |
| | $z_{MI}$ (cm) | 4.19 | | | | | |
| | $z_{pii,\alpha}$ (cm) | 4.19 | | | | | |
| | $f_{awf}$ (MHz) | 1.77 | 3.05 | | 3.05 | | 2.15 |
| Other Information | prr (Hz) | 1,887.00 | | | | | |
| | srr (Hz) | 26.57 | | | | | |
| | $n_{pps}$ | 0.00 | | | | | |
| | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm$^2$) | 66.20 | | | | | |
| | $I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm$^2$) | 3.71 | | | | | |
| | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ (mW/cm$^2$) | 6.28 | | | | | |
| | $p_r$ at $z_{pii}$ (MPa) | 2.24 | | | | | |
| Operating control conditions | Acoustic power | 100% | 100% | | 100% | | 100% |
| | Display depth | 16cm | 16cm | | 16cm | | 16cm |
| | Focus position | 8.0cm | 8.0cm | | 8.0cm | | 8.0cm |
| | Working Frequency | Pen | Res | | Res | | Gen |
| | PRF | 1887 | 1942 | | 1942 | | 1887 |

Transducer Model: i3PA

Imaging Mode: PW-mode/TVD-mode

| Index label | | MI | TIS | | TIB | | TIC |
|---|---|---|---|---|---|---|---|
| | | | At surface | Below surface | At surface | Below surface | |
| Maximum index value | | 0.82 | 0.13 | | 0.98 | | 0.18 |
| Index component value | | | 0.02 | 0.13 | 0.19 | 0.98 | |
| Acoustic Parameters | pr,α at $z_{MI}$ (MPa) | 1.09 | | | | | |
| | P (mW) | | 30.00 | | 28.00 | | 28.00 |
| | $P_{1\times1}$ (mW) | | 2.83 | | 2.65 | | |
| | $z_s$ (cm) | | | 5.65 | | | |
| | $z_b$ (cm) | | | | | 5.65 | |
| | $z_{MI}$ (cm) | 0.59 | | | | | |
| | $z_{pii,\alpha}$ (cm) | 0.59 | | | | | |
| | $f_{awf}$ (MHz) | 1.74 | 1.76 | | 1.76 | | 1.76 |
| Other Information | prr (Hz) | 5,263.00 | | | | | |
| | srr (Hz) | / | | | | | |
| | $n_{pps}$ | / | | | | | |
| | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm$^2$) | 33.82 | | | | | |
| | $I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm$^2$) | 367.41 | | | | | |
| | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ (mW/cm$^2$) | 394.20 | | | | | |
| | $p_r$ at $z_{pii}$ (MPa) | 1.12 | | | | | |
| Operating control conditions | Acoustic power | 100% | 100% | | 100% | | 100% |
| | Display depth | 16cm | 16cm | | 16cm | | 16cm |
| | SV Position | 2.0cm | 3.0cm | | 3.0cm | | 5.0cm |
| | Working Frequency | Gen | Res | | Res | | Gen |
| | PRF | 5263 | 5263 | | 5263 | | 4348 |
| | SV | 0.5mm | 0.5mm | | 0.5mm | | 0.5mm |

Transducer Model: i3PA

Imaging Mode: Color+B-Mode / Power+B-Mode /TVI+B/TEI+B

| Index label | | MI | TIS | | TIB | | TIC |
|---|---|---|---|---|---|---|---|
| | | | At surface | Below surface | At surface | Below surface | |
| Maximum index value | | 1.40 | 0.03 | | 0.03 | | 0.27 |
| Index component value | | | 0.03 | 0.03 | 0.03 | 0.03 | |
| Acoustic Parameters | pr,α at $z_{MI}$ (MPa) | 1.98 | | | | | |
| | P (mW) | | 44.00 | | 48.00 | | 44.00 |
| | $P_{1\times1}$ (mW) | | 3.56 | | 3.89 | | |
| | $z_s$ (cm) | | | / | | | |
| | $z_b$ (cm) | | | | | / | |
| | $z_{MI}$ (cm) | 0.50 | | | | | |
| | $z_{pii,\alpha}$ (cm) | 0.50 | | | | | |
| | $f_{awf}$ (MHz) | 1.99 | 1.75 | | 1.75 | | 1.75 |
| Other Information | prr (Hz) | 2,640.00 | | | | | |
| | srr (Hz) | 16.29 | | | | | |
| | $n_{pps}$ | / | | | | | |
| | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm$^2$) | 33.31 | | | | | |
| | $I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm$^2$) | 5.00 | | | | | |
| | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ (mW/cm$^2$) | 5.35 | | | | | |
| | $p_r$ at $z_{pii}$ (MPa) | 2.05 | | | | | |
| Operating control conditions | Acoustic power | 100% | 100% | | 100% | | 100% |
| | Display depth | 16cm | 16cm | | 16cm | | 16cm |
| | B Focus Position | 8.0cm | 8.0cm | | 8.0cm | | 8.0cm |
| | Color Sampling Gate Position | 2.0cm | 2.0cm | | 2.0cm | | 2.0cm |
| | B Working Frequency | Pen | HGen | | HGen | | HGen |
| | C Working Frequency | Gen | Pen | | Pen | | Pen |
| | B PRF | 1157 | 1361 | | 1361 | | 1361 |
| | Color PRF | 2640 | 3843 | | 3843 | | 3843 |

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# 16 Indications for use

| Intended Use: | Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Clinical Application | | Mode of Operation | | | | | | | |
| General(Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (Specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | N | N | N | | N | N | N | Note 1 |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | N | N | N | | N | N | N | Note 1 |
| | Small Organ (Specify**) | | | | | | | | |
| | Neonatal Cephalic | N | N | N | | N | N | N | Note 1 |
| | Adult Cephalic | N | N | N | | N | N | N | Note 1 |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Thoracic/Pleural (Specify****) | N | N | N | | N | N | N | Note 1 |
| Cardiac | Cardiac Adult | N | N | N | | N | N | N | Note 1,2 |
| | Cardiac Pediatric | N | N | N | | N | N | N | Note 1,2 |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | | | | | | | | |
| | Other (Specify***) | N | N | N | | N | N | N | Note 1 |

N=new indication; P=previously cleared by FDA;

Additional comments: Combined modes--Color + B, Power+B;

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

****For detection of fluid and pleural motion/sliding.

Note 1: Tissue Harmonic Imaging.

Note 2: TDI

| Transducer: | i3P | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Intended Use: | Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: | | | | | | | | |
| Clinical Application | | Mode of Operation | | | | | | | |
| General(Track1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (Specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | N | N | N | | N | N | N | Note 1 |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | N | N | N | | N | N | N | Note 1 |
| | Small Organ (Specify**) | | | | | | | | |
| | Neonatal Cephalic | N | N | N | | N | N | N | Note 1 |
| | Adult Cephalic | N | N | N | | N | N | N | Note 1 |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Thoracic/Pleural (Specify****) | N | N | N | | N | N | N | Note 1 |
| Cardiac | Cardiac Adult | N | N | N | | N | N | N | Note 1,2 |
| | Cardiac Pediatric | N | N | N | | N | N | N | Note 1,2 |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | | | | | | | | |
| | Other (Specify***) | N | N | N | | N | N | N | Note 1 |
| N=new indication; P=previously cleared by FDA; | | | | | | | | | |
| Additional comments; Combined modes--Color + B, Power+B; | | | | | | | | | |
| *Intraoperative includes abdominal, thoracic, and vascular. | | | | | | | | | |
| **Small organ-breast, thyroid, testes. | | | | | | | | | |
| ***Other use includes Urology. | | | | | | | | | |
| ****For detection of fluid and pleural motion/sliding. | | | | | | | | | |
| Note 1: Tissue Harmonic Imaging. | | | | | | | | | |
| Note 2: TDI | | | | | | | | | |

| Transducer: | i3PA | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Intended Use: | Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: | | | | | | | | |
| Clinical Application | | Mode of Operation | | | | | | | |
| General(Track1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (Specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | N | N | N | | N | N | N | Note 1 |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | N | N | N | | N | N | N | Note 1 |
| | Small Organ (Specify**) | | | | | | | | |
| | Neonatal Cephalic | N | N | N | | N | N | N | Note 1 |
| | Adult Cephalic | N | N | N | | N | N | N | Note 1 |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Thoracic/Pleural (Specify****) | N | N | N | | N | N | N | Note 1 |
| Cardiac | Cardiac Adult | N | N | N | | N | N | N | Note 1,2 |
| | Cardiac Pediatric | N | N | N | | N | N | N | Note 1,2 |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | | | | | | | | |
| | Other (Specify***) | N | N | N | | N | N | N | Note 1 |
| N=new indication; P=previously cleared by FDA; | | | | | | | | | |
| Additional comments; Combined modes--Color + B, Power+B; | | | | | | | | | |
| *Intraoperative includes abdominal, thoracic, and vascular. | | | | | | | | | |
| **Small organ-breast, thyroid, testes. | | | | | | | | | |
| ***Other use includes Urology. | | | | | | | | | |
| ****For detection of fluid and pleural motion/sliding. | | | | | | | | | |
| Note 1: Tissue Harmonic Imaging. | | | | | | | | | |
| Note 2: TDI | | | | | | | | | |

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