Nano Series

Diagnostic Ultrasound System

Version 1.002

User Manual

CE 0123

EDAN

About This Manual

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This User Manual applies to 1.0X releases for Nano Series Diagnostic Ultrasound Systems including Nano C5 EXP and Nano L12 EXP.

This User Manual contains necessary and sufficient information to use the Nano Series Diagnostic Ultrasound Systems safely for the intended purposes and approved clinical applications.

Please read and make sure you understand all of the instructions in this manual prior to using the system. Disregarding instructions, particularly warnings and cautions, is considered abnormal use.

Not all measurements and features are available for all system models and configurations. This manual is based on the complete set of probes and features available. Therefore, some of the contents may not apply to your product. If you have any questions, please contact your local EDAN representative. The pictures and interfaces in this manual are for reference only.

Conventions

In this manual, the following conventions are used to describe the system for better understanding:

- **Bold**: bold texts indicate keys or items on main screen or touch screen.
- <**Bold**>: bold texts in angular brackets indicate buttons, knobs and other controls or on the keyboard.

- ->: Arrow indicates operations following the path.

Contact Information:

EDAN will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of the equipment that are designated by EDAN as repairable by service personnel.

For sales or service information, please contact your local distributor or the EDAN service department at support@edan.com

Contents

1 Introduction

1.1 Intended Use/ Indications for Use

The Nano Series Diagnostic Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluation in hospitals, clinics, road ambulances or at home. Nano Series Diagnostic Ultrasound System clinical applications include Abdominal, Gynecology, Obstetric, Small parts, Musculoskeletal, Urology, Peripheral vascular, Pediatric, Pleural/Thoracic and Cardiac.

The Modes of Operation for Nano Series include B mode, M mode, Doppler mode, Harmonic Imaging and their combination modes.

1.2 Patient Population

There is no restriction on patient population.

1.3 Contra-indications

The Nano Series Diagnostic Ultrasound System is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

1.4 Device Description

The Nano Series Diagnostic Ultrasound System circuitry generates an electronic voltage pulse, which is transmitted to the probe. In the probe, a piezoelectric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The waves are then reflected within the body and detected by the probe, which then converts the waves back to an electrical signal. The system then analyzes the returned signals and generates an ultrasound image or spectral Doppler display.

The Diagnostic Ultrasound System provides the operator the ability to measure anatomical structures, and offers analysis packages that provide information used by competent health care professionals to make a diagnosis.

All operations of the Nano system can be realized with a flat touch.

2 Safety

Throughout this document, the following terms are used:

- **Warning**: Advises against certain actions or situations that could result in personal injury or death.
- **Caution**: Advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.
- **Note**: Provides useful information regarding a function or a procedure.

Please read all warnings and cautions prior to using the system. For your convenience, all warnings and cautions are provided in this section, but may be duplicated elsewhere in this document in the context of the instructions for use.

2.1 Warnings

- Only use Edan supplied power adapter.Do not use adapter in transportation and emergency environments.
- Only use Edan supplied probe. Use of other probes may result in electric shock or system malfunction.
- The battery is non-removable.
- Nano is an IP67 waterproof product. It is highly resistant to dust and can withstand temporary immersion in water without being damaged. Do not immerse or expose any of the parts to extended moisture. Splash resistance does not extend to probe connectors. Please keep connectors dry.
- Do not use or charge in a wet environment or when the relative humidity exceeds 95%.
- To prevent unnecessary power consumption and potential hazards, always unplug the charger when it is not actively charging the device. Leaving the charger connected to an outlet without purpose may result in energy wastage and increase the risk of electrical incidents.
- Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.

- Avoid excessive temperatures, sunshine, humidity or dirt.
- Do not use the probe near heat sources or when the ambient temperature is over 40°C. Do not heat or dispose of in fire.
- Parts and accessories used must meet the requirements of the applicable IEC/EN60601 series safety standards, and/or the system configuration must meet the requirements of the IEC/EN60601-1.
- Use protective barriers (FDA cleared/ legally marketed gloves and probe sheaths) whenever possible. Follow sterile procedures when appropriate. Thoroughly clean probes and reusable accessories after each patient examination and disinfect or sterilize as needed. Refer to probe use and care instructions. Follow all infection control policies established by your office, department or institution as they apply to personnel and equipment.
- If a sterile probe cover becomes compromised during an intra-operative application involving a patient with transmissible spongiform encephalopathy, such as Creutzfeldt-Jakob disease, follow the guidelines of the U.S. Disease Control Center and this document from the World Health Organization: WHO/CDS/APH/2000/3, WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. The probes for your system cannot be decontaminated using a heat process.
- Some probe sheaths may contain natural rubber latex, which can lead to a severe anaphylactic reaction in persons sensitive to the natural latex protein. Sensitive users and patients must avoid contact with these items. EDAN strongly recommends that health-care professionals identify their latex-sensitive patients, and refer to the March 29, 1991 Medical Alert on Latex products. Be prepared to treat allergic reactions immediately.
- Improper operation may cause the internal lithium battery (hereinafter-called battery) to become hot, ignited or possibly explode, and it may lead to decreased battery capacity. It is necessary to read the user manual instructions and warning messages carefully.
- Do not touch accessible contacts of electrical equipment and the patient simultaneously.
- This device is not suitable for intra-cardiac use or direct cardiac contact.
- The system shall not be serviced or maintained while in use with a patient.

- Install the system according the EMC guidance provided in Appendix D
- Do not stack the system on other electronic equipment.
- The use of accessories and connecting cable not supplied by EDAN may result in increased emissions or decreased immunity of the equipment.
- Refer to Appendix D for recommended separation distances from other equipment, including portable and RF communication devices.
- The mains plug is used to isolate the system from main power. Position the system so that it is easy to disconnect it from the power supply.
- Interference may occur when multiple devices are in operation in the emergency vehicle. To ensure proper functionality, please maintain a minimum separation distance between these devices to prevent interference.
- No modification of this equipment is allowed.
- The system should be maintained regularly, at least annually, by a qualified technician who has adequate training, knowledge and experience. That person should be familiar with the Service Manual, available from your Edan representative.
- Keep non-medical equipment out of the vicinity of the patient. (1.5m/6ft.)
- Always use sterile technique during a biopsy procedure. Sterilize the needle guide assembly between uses.
- Use a sterile needle with each use.
- The system may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.
- The system cannot be used together with high-frequency surgical equipment.
- Not intended for Ophthalmic use or any use causing the acoustic beam to pass through the eye.
- To avoid infection, always use protective gloves when cleaning or disinfecting
- Read and follow all manufacturer instructions for disinfection agents.
- To avoid infection, ensure that expiration date of the disinfecting solution has not passed.

- The Nano is not intended to come into contact with the central nervous system and central cardiovascular system.
- Disconnect the probe from the compatible electronic device prior to cleaning or disinfecting.
- Do not immerse the probe beyond the point indicated in Figure 6-3.
- Do not allow the probe connector to get wet.
- If the probe is stored alone and not used for a long time, we recommend that the probe should be charged at least once every 3 months to prevent overdischarge.

2.2 Cautions

- Excessive dust and dirt could clog internal airflow and cause overheating. Do not use in a dusty environment.
- Inspect the system regularly, at least weekly. Before use ensure there is no visible evidence of damage to the equipment, USB cables, and probes. If a component is damaged, replace it before use.
- Do not use in locations subject to vibration.
- Read and understand the *Appendix B.2 Ultrasound Safety and the ALARA Principle* before using the system. Do not expose a patient to ultrasound energy longer than clinically reasonable.
- Practice ALARA principle when operating ultrasound system. Minimize the acoustic power without compromising the image quality.
- Do not use in the presence of a flammable anesthetic.
- The system generates radio frequency energy, which may cause interference with other devices in the vicinity. If interference is suspected, try re-orienting or relocating the equipment.
- The use of electrosurgical units or other devices that generate radio frequency interference may cause image distortion or other malfunctions.
- The system should only be used by a qualified physician or allied health professional for ultrasound evaluations.
- Use only Edan supplied or recommended parts and accessories.

- Verify measurement results prior to entering them into a report.
- Please read and understand cleaning instructions prior to use.
- Please read and understand maintenance instructions prior to use.
- Please read and understand instructions for system operation prior to use.
- Studies stored on the compatible electronic device should be archived regularly. The system is not intended for long term storage of patient information. Confirm successful archiving before deleting a study from the compatible electronic device.
- Confirm patient identification information prior to storing or printing any exam information.
- If you have any question about maintenance, technical specifications, or system functionality, please contact your local distributor or Edan Service at: support@edan.com
- Ultrasound images occasionally have artifacts, and should only be used as one part of an overall clinical assessment.
- To avoid electrical shock, turn off and disconnect the device from the AC power source before cleaning and disinfecting.
- No user serviceable parts are inside the system. All repairs on the system must be performed by EDAN certified service personnel.
- The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.
- The packaging is to be disposed of according to local or hospital’ s regulations; otherwise, it may cause environmental contamination. Place the packaging at the location that is inaccessible to children.
- Properly dispose of used cleaning agents or disinfectants according to your hospital's regulation.
- The system does not need calibration as part of routine maintenance.

- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- Automated cleaning/disinfection is prohibited for ultrasound system and its accessories
- Nano is not suitable for intracardiac use or direct cardiac contact.
- Do not uninstall Nano application at will.
- Do not switch the Nano interface during image scanning.
- In order to prevent local data from being lost and irrecoverable, please do not delete the original APP during the APP update process
- To prevent the loss of patient data caused by uninstalling the Nano software, please backup the data before uninstalling.

Probe Cautions

- Do not use disinfection agents beyond their expiration date.
- Do not use sterile sheaths beyond their expiration date.
- Inspect the type-C cable, and head periodically. Do not use if there is evidence of excessive wear or damage.
- Do not operate the probe to temperatures in excess of 40°C or store the probe in temperatures in excess of 55°C.
- Do not use a probe giving off excessive heat or anything not functioning properly, otherwise it may do harm to the patient such as tissue damage or coagulation.
- Do not kink or pull on the USB cable.
- When using the probe in a home environment, please ensure proper placement of the connecting cables to prevent accidental strangulation.
- When using the probe in a home environment, the probe should be stored away to prevent potential harm from or to pets, pests, or children.

Network Security Cautions

- Keep your ultrasound system safe to protect the patient information and data from being modified, damaged or disclosed caused by unauthorized disassembly.
- Always ensure the privacy of patient information and data displayed/stored in the

ultrasound system or exported to external storage devices.

- Make sure the ultrasound system is used under secure network environment, and all the approved devices connecting with the ultrasound system are physically secure.
- When the ultrasound system is returned for maintenance, disposed of, or removed from the medical institution for other reasons, ensure all patient data are removed from the ultrasound system.
- Uninstalling the software will result in the loss of patient data. Please backup the data before stalling.
- Make sure the AC power supply complies with the following specifications: 100V-240V~,50Hz/60Hz.

Federal Communications Commission (FCC) Statement:

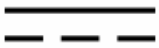
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- 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.

2.3 Labeling Symbols

The following labels are used on the system:

No.	Symbol	Definition
1.		Serial Number
2.	P/N	Part Number
3.		Date of Manufacture
4.		Manufacturer
5.		Operating instructions
6.		Warning (Background: Yellow; Symbol & outline: Black)
7.		Refer to instruction manual/ booklet (Background: Blue; Symbol: White)
8.		Caution
9.		Biological Risks
10.	CE 0123	CE Marking
11.	EC REP	Authorized Representative in the European Community

12.		The products marked with this symbol apply to the European WEEE directive. This symbol indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste, but collected separately. Contact an authorized representative of the manufacturer for information for the decommissioning.
13.		General Symbol for Recovery / Recyclable
14.	Rx only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
15.	IP67	Highly resistant to dust and can withstand temporary immersion in water without being damaged
16.		Type BF Applied Part
17.	EDAN	Trademark
18.		Direct current
19.		Non-ionizing electromagnetic radiation
20.		Type CF Applied Part with Defibrillation-proof protection
21.		Non-sterile. Indicates a medical that has not been subjected to a sterilization process.
22.	UDI	Unique Device Identifier
23.	MD	Medical Device

24.		MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment
25.		Power switch: The white light is on after startup, and the indicator is off after shutdown.

The following labels are used on the packaging:

No.	Symbol	Definition
1		THIS WAY UP
2		Fragile, handle with care
3		Keep dry
4		General Symbol for recovery / recyclable
5		STACKING LIMIT BY NUMBER
6		DO NOT STEP ON
7		HANDLE WITH CARE

NOTE:

The user manual is printed in black and white.

3 System Description

This chapter serves as an introductory guide to Nano, providing essential information about its features, system components, system requirements for downloading, installing, and using the Nano App, as well as a brief overview of the user interface.

3.1 Overview

Nano is a hand-held general purpose diagnostic ultrasound imaging device. Nano comprises three key components:

- Compatible Android Electronic Devices: This includes smartphones and tablets, commonly referred to as the "mobile device."
- The Nano Application (App): The Nano App is a software component that needs to be downloaded and installed on the compatible mobile device.
- Nano C5 EXP and Nano L12 EXP Probes: These probes connect to the mobile device to generate and receive ultrasound signals, facilitating diagnostic imaging.

3.2 System Components

3.2.1. APP

The Nano App's primary function is to support general-purpose diagnostic imaging. It is intended for use by a qualified physician or allied health professional for ultrasound evaluation in hospitals, clinics, ambulance or at home. Nano enables professionals to visualize and measure anatomical structures within the human body accurately.

3.2.2. Probe

- **Probe Model**

Model	Type	Center Frequency	Application	Applied Region
Nano C5 EXP	Convex	3.5MHz	Abdominal Gynecology	Body Surface

			Obstetric Pleural/Thoracic Urology Cardiac	
Nano L12 EXP	Linear	7.7MHz	Peripheral vascular Small parts Musculoskeletal Pediatric	Body Surface

● Needle Guide Bracket Kit

Model	Type	Angle/Depth	Description
BGK-017	In-plane	20°, 30°, 40°	For use with the Nano C5 EXP, Supports: 14G-23G

● System overview

The Nano C5 EXP/Nano L12 EXP probe is only for use with the Nano App. Do not attempt to connect the probe to other ultrasound systems. The illustration takes Nano C5 EXP as an example.

Figure 3-1 Front View

Figure 3-2 Rear View

Image Orientation Mark

The image orientation marks on the display screen and on the probe are shown as below. The side of orientation mark on the probe corresponds to the side of orientation mark on the display screen. Ensure orientation marks on the display screen and probe are on the same side prior to scanning.

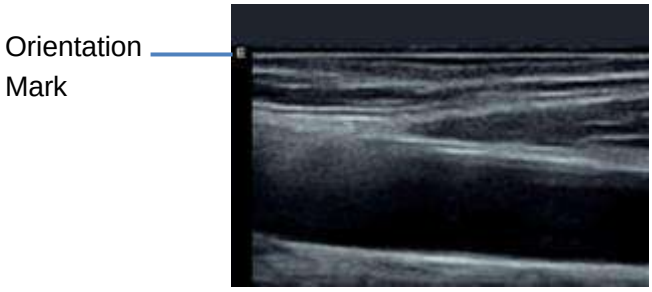


Figure 3-3 Image Orientation Mark

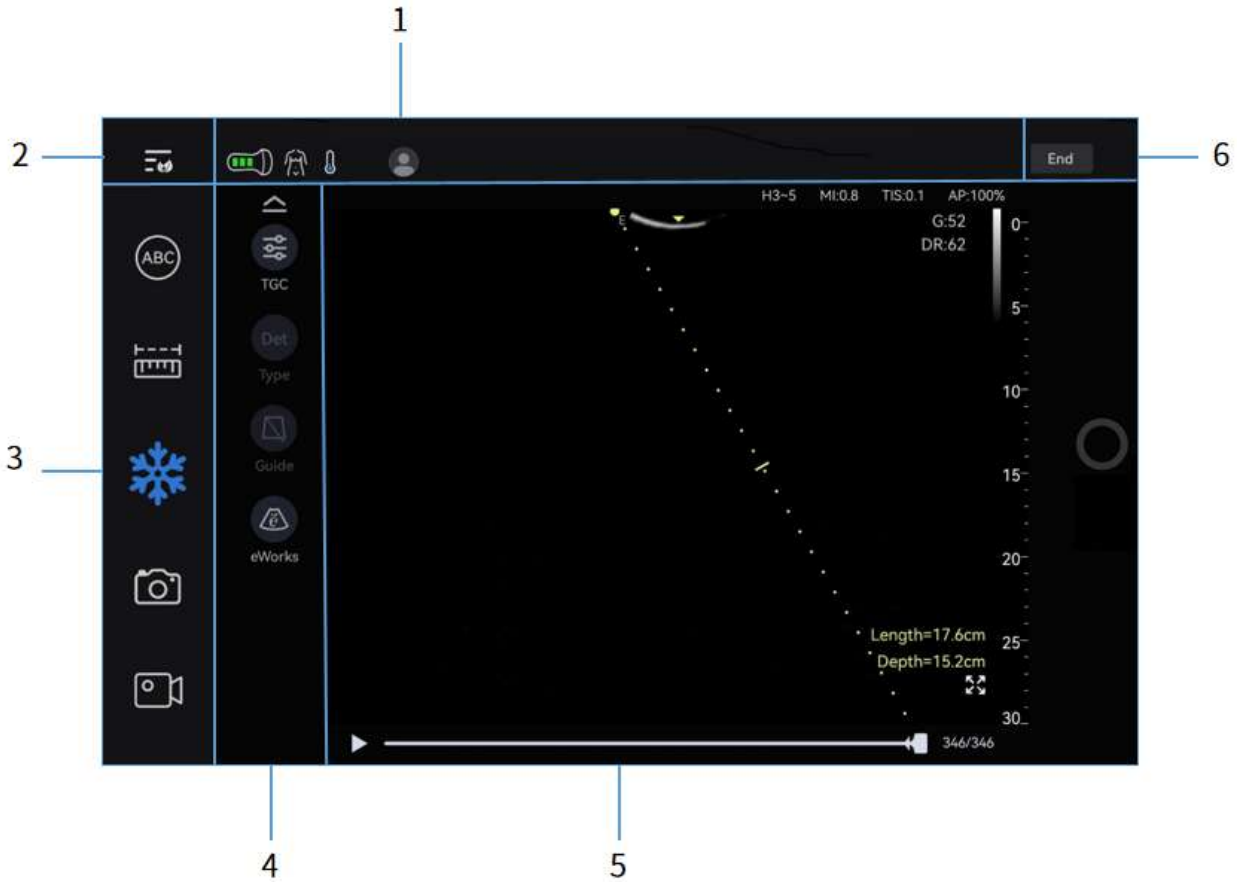
- **Proper Use of Probes**

To extend the service life and maintain optimum probe performance, please operate as follows:

- Inspect probe cable and acoustical window of the probe periodically.
- Shut down the probe before connecting or disconnecting the probe.
- Do not drop the probe onto the floor or collide with hard objects. Otherwise it will be damaged easily.
- Do not heat the probe.
- Do not pull or bend the USB cable.
- Coupling gel can only be used on the head of the probe, and it should be wiped off after use.
- Clean and disinfect the probe after every use.
- The acoustical window and the shell of the probe should be examined frequently.

CAUTION

1. Do not disinfect or clean probes under high temperature. The temperature should be below 45°C.
2. To avoid damaging the device, the disinfection method is limited to regular maintenance of devices in hospitals. Disinfecting instruments should be cleaned first.
3. The coupling gel adapted to the probe is a medical ultrasound coupling gel. Use only ultrasound coupling gel that complies with local regulations. When using ultrasound coupling gel, please follow the instructions given by the coupling gel manufacturer.



3.2.3.Screen Layout

Figure 3-4 Main Screen Display

1. Information Field

No.	Icons		Description
1.1.		probe &Preset	Switch probe or exam presets. Through icon  , users can determine the remaining battery level of the probe by the number of battery bars in it and judge the connection status between the probe and the portable device by its color. – Four bars: Indicates a battery level of

			75%-100%. – Three bars: Indicates a battery level of 50%-75%. – Two bars: Indicates a battery level of 25%-50%. – One bar: Indicates a battery level of 5%-25%. – Zero bars with a red icon: Indicates a battery level of 0%-5%. – Grey icon: Indicates that the probe is not connected.
1.2.		Probe Temperature	Real-time display of the temperature status of the probe. The color of the thermometer icon changes following the temperature of the probe: – Temperature level 1: The icon is blue. – Temperature level 2: The icon is yellow. – Temperature level 3: The icon is red.
1.3.		Patient	Entering the patient information screen allows you to edit the patient information

2. Menu

Tap  button to navigate through the application's menus, where you can make more Nano related settings and obtain additional information about the Nano.

3. Shortcut Field

The image mode and whether it is currently frozen or not will affect the display of the keys in the shortcut button field.

No.	Icons		Description
3.1.		Annotation	You can add annotations to the image, including comments and body marks.
3.2.		Measurement	Invokes measurements
3.3.		Freeze	Press to switch between the frozen and real-time states.The button is highlighted when the image is frozen.
3.4.		Store Image	Press to store static images.
3.5.		Store Clip	Press to store clips.
3.6.		Auto	Each single press of the button renews the automatic optimization.
3.7.		Image Modes	Indicating the Current Image Mode.
			
			
			
3.8.		Update	In Pre-Doppler mode, pressing <**Update**> invokes Spectral Doppler mode. When Spectral Doppler strip is displayed, pressing <**Update**> allows switching between live

			acquisition of the Doppler strip or the reference image.

4. Image Functional Field

The Image Functional Field displays the adjustable parameters for the current image mode, allowing you to make simple adjustments to the image. Once you have entered the measurement, this column also shows the specific measurement

5. Image Field

The ultrasound image appears in the Image field, under the Information field. The Image field also contains the following information:

- Information typically associated with the image such as depth, TGC, maps, image parameters.
- MI and TI

No.	Icons		Description
5.1.		Zoom	Full Screen Zoom.
5.2.		B-mode shortcut key	Return to B-mode in one key.

6. END

The END button is located at the top right of the screen and can be clicked to terminate the current check in progress.

3.3 System Preparation

3.3.1. Getting the App

Install the Nano App:

1. Switch on your display device and download the Nano App for free from the EDAN website<www.edan.com> or Google Play Store.
2. Install the Nano App on the device.
3. Set the Allow Nano permission on the display device to allow the Nano App to access photos, media and files on the portable device.

3.3.2. Probe Connection

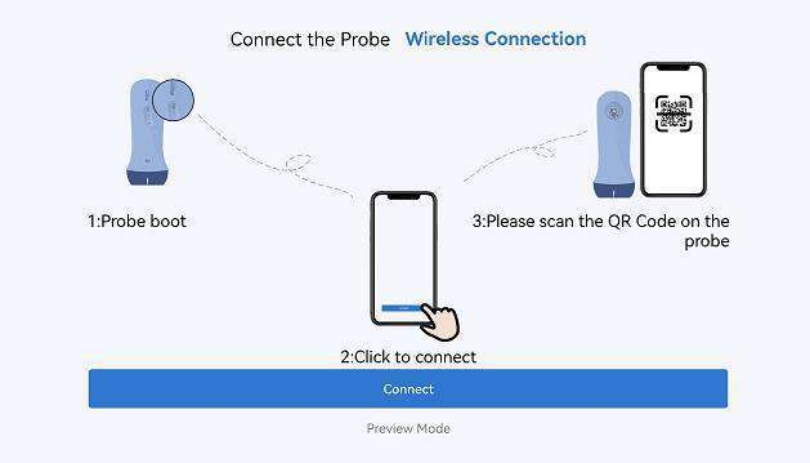
The first time you access the App, you will need to select a clinical application for the Nano. The system will adjust the presets according to the clinical application selected by the user.

The Nano system supports both wired and wireless connections. EDAN recommends wireless connection.

Wired connection: Connect the ultrasound main unit with the portable display device via Type-C cable, and the system will work normally after switching on.

Wireless connection:

1. Turn on the Wi-Fi function of the portable device.
2. Long press the power on function button to switch the probe on.
3. Enter the app, click New Connect, scan the QR code on the body of the probe and connect it after successful recognition.
   Users can also click the manual input button in the code scanning interface and type in the SSID of the probe body to connect.

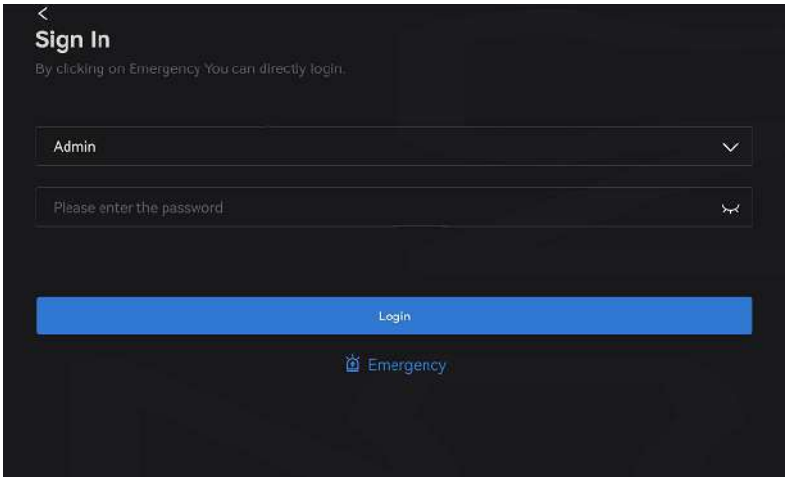


3.3.3. System Login

Login

- When logging into Nano for the first time, the system will automatically generate an Admin account with a default password of 123456. After successfully logging in, you need to set a new password for the account, and the new password must not be duplicated with the initial password.

- In case of emergency, users can click Emergency to enter the system directly without entering the user name and password.



Attention:

1. It is not recommended to use "Emergency" user login in case of emergency. Before image scanning, please use your own account to log in the ultrasound system, or switch to your own account through the "Switch User" function.
2. Be careful to protect the privacy of patient information and patient data for examinations performed through the emergency account login. In case of emergency, remove all patient data from the ultrasound system after image scanning to avoid unauthorised access.

3.3.4. Power Connection

After confirming that the AC power supply in your environment is normal, plug one end of the power adapter into the charging port of the device and plug the other end into an AC outlet. The power indicator light will blink while charging is in progress.Once all indicator lights are steadily lit without any flickering, it signifies that the battery is fully charged.

NOTE:

- Only use the charger supplied with the probe.
- Do not use the probe while charging.
- When the battery charge is too low, you may not be able to perform a study until the battery is recharged. Keep the battery fully charged whenever possible.

3.3.5. Powering on/ off

Please review and follow the steps described in the Section *13.1.Daily Checklist* prior to powering on the system.

- **To power on**

Press and hold the power button for three seconds and the power indicator light will be on, which means the probe has been successfully switched on.

- **To power off**

In the power on state, long press the power button, after three seconds, the power indicator light will be off, it means the probe has been switched off.

4 Exam Operation

4.1 Start/End an Exam

- To start an exam:

After entering the system, a new exam is started by default, users can directly carry out the ultrasound scanning.

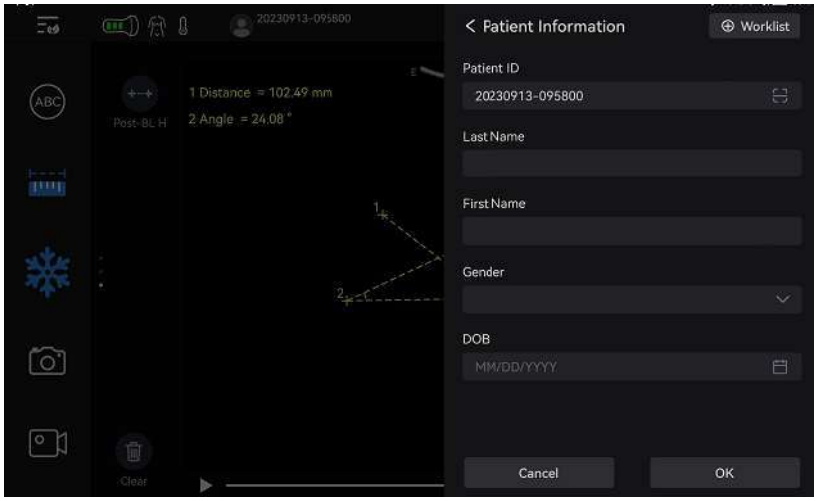
- To end an exam:

Click the END button on the upper right corner of the screen to end the current examination, and enter the new examination by default.

4.2 Edit Patient Information

After entering a new examination, click the Patient Information button, the system will automatically generate a patient ID for the current patient and enter the Patient Information screen.

The Patient Information Page is used to enter or modify patient demographic data. The following figure is an example.

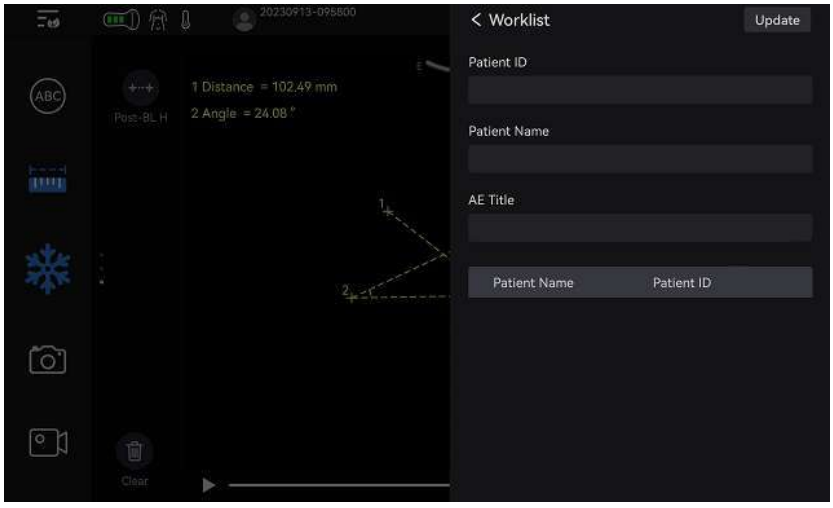


In the Patient Information Page, you can edit the Patient ID, Last Name, First Name, Gender, and Date of Birth.

4.3 Modality Worklist

Modality worklist provides a list of scheduled patients derived from a DICOM server. It is available only when a DICOM server is configured and worklist is enabled.

When the modality worklist function is enabled and configured in DICOM Connectivity screen. You can press Worklist button in the upper right of patient information corner to enter the worklist page , as shown below.



The worklist is displayed at the right side of the current page, and labeled two columns patient name and patient ID. Clicking on the header of each column will sort the list for the corresponding column.

The worklist shows all scheduled ultrasound exams within the date-range specified in the

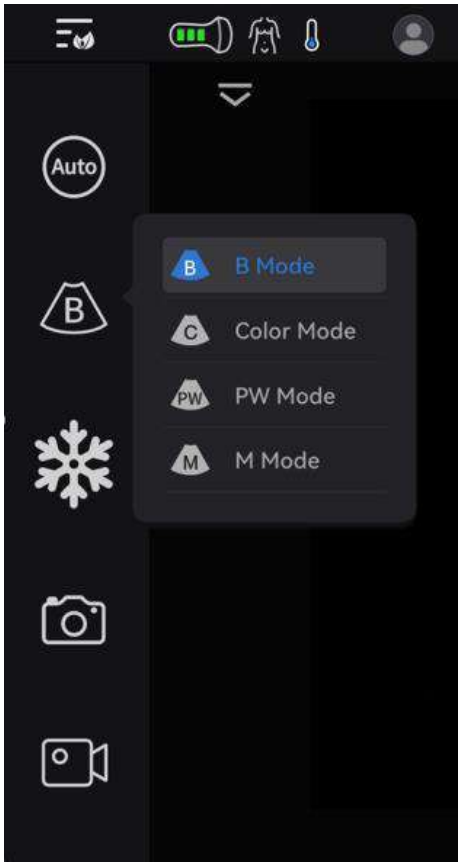
Connectivity Utility (See 10.6). Typing any text in the Patient Name, ID or AE title fields will filter the list to exams that contain the entered text.

Update: Press to query the patient data and update the list manually.

Select one patient from the list and the detailed patient information is entered into the associated fields on the patient information page, with the option to edit or complete. Then you can back to start an exam.

5 Imaging

The image modes supported by this system are B mode, C mode, M mode and PW mode. B mode is the default image mode, you can click the image mode button to switch the image mode.



5.1 B-mode

B-mode ultrasound is a common imaging mode in clinical ultrasound diagnosis, which can display the internal structure of the target tissue.

5.1.1. Using B mode

1. Click the image mode button and select the B mode icon to enter B mode
2. Perform image scan.
3. Adjust the image parameters to optimize the image.

5.1.2. B Image Optimization

The following controls can be used to optimize the B-mode image.

- Depth: Swipe your finger up and down on the image area to increase or decrease Depth.
- Gain: Swipe your finger left or right in the image area to increase or decrease Gain.
- TGC: The Time Gain Compensation control (TGC) adjusts the gain of the image at different depths. Each slider can be adjusted separately.
  Glide the slide controls to adjust the TGC. Glide the upper segments to adjust the near field gain, and the lower segments to adjust the far field gain; glide rightward to increase TGC, and glide leftward to decrease.
- Image Type: B-mode supports presets for Detail, General, and Penetration.

5.2 Color Mode

Color (Color Doppler): This is velocity Color Doppler that shows direction and velocity of flow. Different colors represent different velocities and positive flow has different colors than negative flow.

5.2.1. Using Color Mode

1. Click the Image Mode button and select the C mode icon to enter Color mode. The image area is labeled with the ROI box;
2. Move one finger inside the ROI box to adjust the position of the ROI box; drag and drop any corner of the ROI box to adjust the size of the ROI box.
3. Adjust the image parameters to optimize the image.

5.2.2. Color Image Optimization

The following touch controls can be used to optimize the Color image.

- Depth: Swipe your finger up and down on the image area to increase or decrease Depth.
- Gain: Swipe your finger left or right in the image area to increase or decrease Gain.
- Image Type: Color Doppler supports image presets for Low Flow, Medium Flow, and High Flow.

5.3 M Mode

5.3.1. Using M Mode

1. Click the Image Mode button, select the M-mode icon, and the M-mode sampling line will be displayed in the image area.

2. Click Update button to display the M spectrum.
3. Select the sampling line and stroke the left stone to adjust the position of the sampling line. Every time the position of the sampling line changes, the spectrum will be updated automatically.
4. Adjust the image parameters to optimize the image.

5.3.2. M-mode Image Optimization

The following touch controls can be used to optimize the M-mode image.

- Depth: Swipe your finger up and down on the image area to increase or decrease Depth.
- Gain: Swipe your finger left or right in the image area to increase or decrease Gain.
- TGC: The Time Gain Compensation control (TGC) adjusts the gain of the image at different depths. Each slider can be adjusted separately.
  Glide the slide controls to adjust the TGC. Glide the upper segments to adjust the near field gain, and the lower segments to adjust the far field gain; glide rightward to increase TGC, and glide leftward to decrease.
- Image Type: B-mode supports presets for Detail, General, and Penetration.

5.4 PW Mode

5.4.1. Using PW Mode

1. Click the Image Mode button and select the PW Mode icon, the image area will show the sampling line.
2. Click Sampling Gate and swipe left and right to adjust the angle of the sampling gate, swipe up and down to adjust the position of the sampling gate, and select Sampling Gate Pinch to adjust the size of the sampling gate.
3. Click Update button to display PW spectrum.
4. Adjust the image parameters to optimize the image.

5.4.2. PW Image Optimization

The following touch controls can be used to optimize the PW image.

- Quick-Angle: Adjusts the angle correct quickly to one of 30/60/0/-60/-30.
- Depth: Swipe your finger up and down on the image area to increase or decrease Depth.
- Gain: Swipe your finger left or right in the image area to increase or decrease Gain.

- Image Type: Spectral Doppler supports image presets for Low Flow, Medium Flow and High Flow.
- Invert: Normally, signals above the baseline are positive velocities (moving toward the probes). However, when Invert is pressed, the negative velocities are displayed above the baseline. Invert does not affect the baseline position.
- Sweep Speed: Sweep adjusts the sweep speed of the Doppler strip. Options of Slow, Low, Med, High and Fast are available. Upward presses increase sweep speed. Downward presses decrease sweep speed.
- Auto Trace: Press to activate the Auto Trace function on a real-time or frozen PW Doppler strip. The Auto Trace function automatically traces the spectral Doppler waveform and records several measurements on selected waveforms.

5.5 ECG

The Nano ultrasound system can be configured with an optional ECG module. The ECG module obtains ECG signals via ECG patient cable to display ECG waveform synchronously with the ultrasound image. The ECG signals can be used as time reference in cardiac exam for marking the systolic and end diastolic moments.

WARNING

1. The ECG waveforms displayed on the main screen are not intended for ECG diagnosis and monitoring.
2. The ECG module and electrodes are not intended for intra-cardiac use or direct cardiac contact.
3. Do not use the ECG function on the patient with pacemaker.
4. Only the ECG module, patient cable and electrodes supplied by EDAN can be used.
5. Only authorized service personnel can service the ECG module.
6. The conductive parts of electrodes and associated connectors, including the neutral electrode, should not contact any other conductive parts including earth.
7. The electrodes must be removed from the patient before a high-frequency surgical equipment is used on the patient.
8. The quality of the ECG waveform depends on the stability and conductivity of the electrodes because patient's movements can cause artifacts.
9. Only the ECG applied part is defibrillation-proof. Please remove transducer and other accessories from patient before defibrillation. Always refer to the defibrillator's user manual when performing defibrillation.
10. After defibrillation, the ECG waveform recovers within 10 seconds if the correct electrodes are used and applied according to the manufacturer's instructions.
11. Always do the follows prior to operation:

    Check the patient cable for visible evidence of any damage. If any damage is found, a new

patient cable should be used.

Connect the electrodes to patient correctly following the manufacturer's instruction. If a ECG lead is off, the ultrasound system will display " ECG Lead Off " message..

12. The disposable electrodes can only be used for one time. Do not use the electrodes passing its expiry date.
13. The disposable electrodes should be disposed of according to the local regulations.
14. Regularly check, clean and maintain the patient cable and electrodes following the manufacturer's instruction.

5.5.1. ECG Basic Operations

1. Invoke ECG function.

   Invoke a phased array transducer as the currently active transducer, and select the Cardiac exam preset. Press **ECG** on the touch screen to invoke the ECG function and display ECG controls on the screen.

2. Connect patient cable and electrodes.

   Connect the patient cable to the ECG connector on the ultrasound system first.

   Place electrodes on the patient's body as the figure below (Take 3-lead placement of AHA standard as an example).

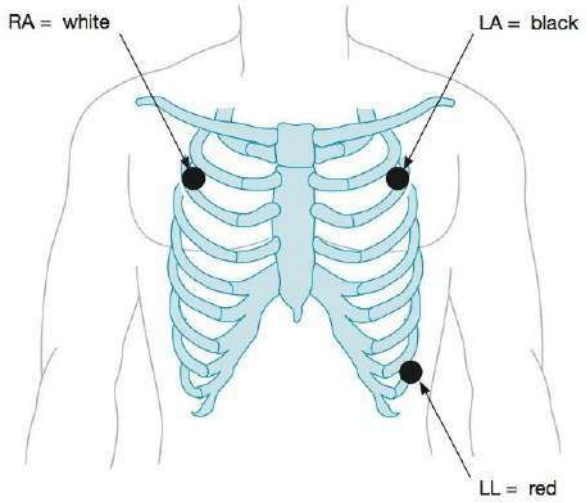


Figure 5-9 3-lead Placement of AHA Standard

3. The image area displays real-time ECG waveform and heart rate value. There is a red mark

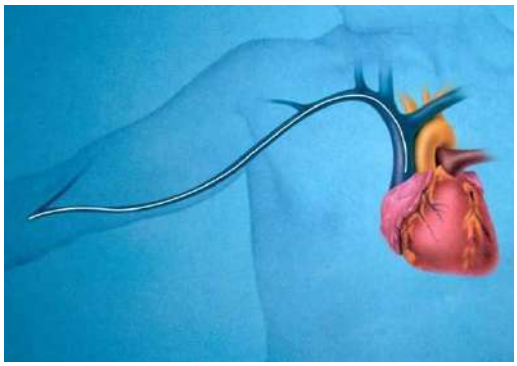
on the ECG waveform indicating the temporal position of ultrasound image in relation to the ECG waveform.

4. Switch imaging modes and adjust relevant parameters to optimize the image.
5. Adjust ECG Gain and select ECG lead if necessary.
6. Freeze the image and review.
7. Exit ECG mode.

Remove electrodes from patient's body and disconnect ECG module from the ultrasound system.

5.6 PICC

PICC catheter placement involves the insertion of a central venous catheter through peripheral veins, as shown in the diagram below:



During catheter placement, the use of intracardiac ECG positioning in the right atrium can assist in determining the location of the catheter tip within the superior vena cava. This procedure is real-time and intuitive, improving the success rate and efficiency of catheter placement. Before PICC catheterization, the ultrasound diagnostic system can provide a visual image of the blood vessels to help doctors understand vessel size and provide guidance during the puncture.

This section primarily focuses on the application of the ultrasound system before PICC catheterization and the operation of intracardiac ECG positioning. For the specific procedure of PICC catheter placement, please refer to clinical operation guidelines.

5.6.1. Vessel Scanning

Before PICC catheterization, you can use the ultrasound diagnostic system to scan images of the blood vessels, confirming the diameter of the blood vessels and aiding in the selection of an

appropriate catheter size. The specific steps are as follows:

1. Activate the linear array transducer and select the PICC examination preset.

2. Enter B-mode and scan transverse sections of the blood vessels to obtain the best frame image, then freeze the ultrasound system.

3. Choose an appropriate catheter size based on the diameter of the blood vessels. You can do this in two ways:

a. Refer to the catheter size diagram displayed on the ultrasound system's interface and select the suitable catheter size.

b. Note: If you are using a non-PICC examination preset for vessel scanning, you can enable the catheter size diagram in the system settings -> POC settings, which will display the catheter size diagram on the interface.

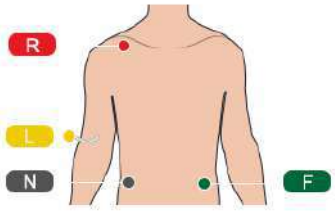
4. Measure the diameter of the blood vessels to confirm the catheter size. Activate the measurement function, click on the blood vessel diameter measurement item, manually measure the vessel's diameter using the distance tool or use the automatic tool to measure it. Then choose the appropriate catheter size based on the vessel's diameter. You can click the catheter size button on the touchscreen to select the catheter size.

Connecting the ECG Module and Leads

1. Connect the external ECG module to the ultrasound diagnostic system's USB port using a USB cable.

2. Connect the ECG leads to the ECG module.

3. Attach the ECG leads and electrodes to the patient's body, following the specific diagram. The L electrode should be connected to the catheter.



Note: To ensure aseptic operation throughout the procedure, it is recommended to connect the ECG module and surface electrodes before the puncture.

5.6.2. PICC Electrocardiogram Localization

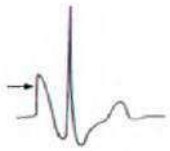
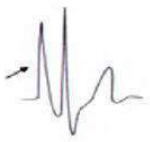
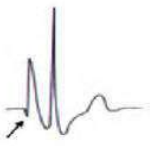
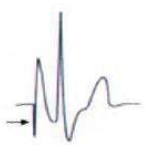
After confirming that the catheter has entered the superior vena cava correctly, you can use intracardiac ECG to locate the position of the catheter tip, ensuring that the catheter is in the most suitable position within the superior vena cava. This involves several aspects:

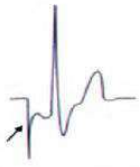
Real-time display of internal waveform.

A display area for stored waveforms, including waveform name, storage time, and catheter length record.

Observing P-Wave Changes:

As the catheter tip gradually advances, the P-wave of the intracardiac electrocardiogram will change accordingly. There are several stages of P-wave changes (Source: "Application of Specific P-Wave Morphology Changes in Intracardiac Electrocardiography in Valve-type PICC Tip Positioning," Chinese Nursing Journal, November 2015, Vol. 50, No. 11). The optimal position for the catheter tip should be at the junction of the superior vena cava and the right atrium. When observing a negative P-wave, gently withdraw the catheter outward by 1-2 cm.

Catheter Tip Position	P-Wave Change	Explanation
		After entering the superior vena cava: P-wave amplitude gradually increases.
		At the junction of the superior vena cava and the right atrium: High-amplitude positive P-wave.
		At the junction of the superior vena cava and the right atrium: High-amplitude positive P-wave.
		Mid-section of the right atrium: Biphasic P-wave.

		Approaching the right ventricle: Inverted P-wave.

Storing Waveforms

You can store waveforms during the electrocardiogram localization procedure for printing and output. The electrocardiogram localization interface supports two layout options for displaying stored waveforms: 3-window or 4+1-window, which can be switched by touching the storage window button on the touchscreen.

3-Window (default): In addition to the real-time display of surface and intracardiac waveforms, it displays three waveform channels for recording surface waveforms, internal bidirectional waveforms, and the best internal waveform. You can click the buttons on the touchscreen labeled "Surface," "Internal Bidirectional," and "Best Internal" to store the corresponding waveforms.

4+1-Window: In addition to the real-time display of internal waveforms, it also displays four waveform channels for recording internal waveforms 1/2/3/4. Click the touchscreen buttons labeled "Internal 1," "Internal 2," "Internal 3," and "Internal 4" to store the corresponding waveforms. To store a surface waveform, click the "Surface" storage button on the touchscreen, and the stored waveform will be displayed in the area where the surface waveform is real-time. To view the real-time surface waveform again, click the "Refresh Surface" button on the touchscreen to switch.

Recording Catheter Length

If you need to record the catheter's length, ensure that "Record Catheter Length" is selected in the system settings -> POC settings. Press the depth knob on the control panel to select the stored waveform in the main interface. Then, turn the depth knob to switch between "Catheter Inserted Length" or "External Scale." You can click the "External Scale" button on the touchscreen to switch between the two length recording modes.

Printing Reports

After storing waveforms, the system generates PICC electrocardiogram waveform reports. These reports can be previewed, printed, and exported in PDF format.

Other Settings

- Click the "Gain" button on the touchscreen to adjust the gain of the electrocardiogram waveform.

- Click the "Speed" button on the touchscreen to adjust the scanning speed of the electrocardiogram waveform.

- Click the "Mode" button on the touchscreen to switch the filtering mode.

- Click the "End Exam" button on the touchscreen to clear the patient information and stored waveform signals on the current interface. You can view historical data in the examination database.

- Set the layout of PICC electrocardiogram waveform reports: Enter the system settings -> POC settings and set the report layout to landscape or portrait.

- Set AC filtering: Enter the system settings -> POC settings and set AC filtering to 50Hz.

5.6.3. Viewing Historical Data

In the ultrasound system, you can browse historical data. Press the "Browse" button on the control panel to enter the examination database, select historical data, and click the "View PICC Waveforms" button on the touchscreen to view stored electrocardiogram waveform reports, print them, and export them.

5.7 eWorks

The eWorks automatic workflow feature provides workflow template protocols for each application site to efficiently screen and store exam sections. This function simplifies the operation and provides reference for image scanning and retrieval.

Each exam protocol contains a complete template section, and is set up with corresponding image mode, Comment and Body Mark, which is easy to operate more quickly.

To use eWorks function:

1. Connect the probe and select either Emergency or GI Clinical Preset.
2. Tap the eWorks icon on the screen to access the eWorks function.
3. The bottom left corner of the image area will display the workflow indicator box. eWorks includes FAST and Lung protocols, each containing FAST & eFAST schemes, and the BLUE scheme. Under the Lung protocol, you can also choose lung views of 3*2, 4*2, or 6*2.
4. Click the image save button to automatically move to the next view.The names of saved views will appear in blue in the indicator box with a completed icon.
5. Repeat step four until all views are acquired.
6. Click 'X' to close the indicator box, your data will be saved. Clicking the eWorks icon again allows you to continue collecting views.

6 Probes and Biopsy

6.1 Probe Cleaning and Disinfecting

Probes should be cleaned and/or disinfected as necessary or between use with a recommended cleanser or disinfectant. Disconnect the probe from the system prior to cleaning and disinfecting.

6.1.1. Cleaning

The validated cleaning agents for cleaning the probes are:

- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, sterile, non-abrasive cloth or paper towel.

To clean the probes:

1. Disconnect the probe from the system.
2. Wear sterile protective gloves to prevent infection.
3. Remove all residual foreign matters from the probe using sterile cloth or paper towel immediately after examination. For the situation where a protective sheath is used, the protective sheath should be removed first and discarded.
4. Wipe the surface of probe and cable with a sterile cloth dampened with the cleaning solution until no visible contaminants remain.
5. After cleaning, wipe off the cleaning solution with a new sterile cloth dampened with tap water until no visible cleaning agent remains.
6. Wipe off with a dry sterile cloth to remove residual moisture.
7. Leave the probe to air dry.
8. If the probe is not visually clean at the end of the cleaning steps, please repeat the cleaning steps through step 4 to step 7.

9. Inspect the probe to ensure that there is no damage. The probe should be disposed of properly when any damage is found.

WARNING

1. Disconnect the probe from the system prior to cleaning or disinfecting.
2. To avoid infection, always use protective gloves when performing cleaning and disinfecting procedures.
3. Prohibit infiltration of any type of liquid into the device or the probe.

6.1.2. Disinfection

Selecting a proper way to disinfect your probes based on your probe applied region:

Probe Applied Region	Disinfecting Intensity	Disinfecting Method
Contact intact body surface	LLD	Spraying or wiping
Note:LLD=Low-level Disinfection		

The validated disinfectants for probe are:

Disinfectants	Disinfecting Intensity	Disinfecting Method
Ethanol (75%)	LLD	Spraying or wiping
Isopropanol (70%)	LLD	Spraying or wiping

WARNING

1. Disconnect the probe from the system prior to cleaning or disinfecting.
2. To avoid infection, always use protective gloves when performing cleaning and disinfecting procedures.
3. To avoid infection, ensure that expiration date of the disinfecting solution has not passed.
4. Please clean the probe prior to disinfection.

Disinfecting by spraying or wiping:

1. Disconnect the probe from the system.
2. Wear protective gloves to prevent infection.
3. Clean and dry the probe according to the methods in section *6.3.1 Cleaning*.
4. Prepare the disinfectant solution (75% ethanol or 70% isopropanol).
5. Spray the solution to the probe interface or wipe it with a sterile cloth dampened with the disinfectant solution. Follow the disinfectant manufacturer's recommended contact time and mode.
6. Rinse the probe according to the disinfectant instructions. Wipe the probe with a dry sterile cloth or leave the probe to air dry.
7. Inspect the probe to ensure that there is no damage.

Note: If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new sterile cloth is required for the disinfection step.

WARNING

1. Do not immerse the probe connector. If the cable connector is immersed, do not plug the connector into the portable device. Rinse the connector under running water and dry it thoroughly. If necessary, contact EDAN for service.
2. Prohibit infiltration of any type of liquid into the device or the probe.
3. Do not immerse the cable and connector of the probe into solutions. Probes can be submerged to, but not including, the strain relief of the probe array. Do not immerse or soak any part of a probe in any cleaning material not listed in the recommended list of disinfectant.
4. Only non-immersion method can be used with solution of ethanol or isopropanol.
5. The immersion time should not exceed the time that is specified by the disinfectant manufacturer.

6.1.3. Storage

WARNING

1. Do not use the carrying case for storing the probe, because the carrying case may become a source of infection.

1. Ensure the probe is cleaned, disinfected, sterilized and completely dried before storage.
2. Store the probe in a sterile environment or in a disposable sterile package.
3. Store the probe under the following conditions:
   a) Atmospheric Temp.: -20℃～+45℃
   b) Relative Humidity: 15%~95% (Non-condensing)
   c) Atmospheric Pressure: 62kPa ~ 106kPa.

6.2 Needle Biopsy Guide

NOTE:

Use proper sterile technique at all times when performing a biopsy.

Always follow these basic precautions:

WARNING

1. Sterilize the needle guide kit before the first use and after each subsequent use.
2. When performing biopsy procedures, use only sterile ultrasound gel that is certified to be safe. Manage the ultrasound gel properly to ensure that it does not become a source of infection.
3. Calibrate the needle guide kit (see section6.4.3) under any of the following conditions:
   a) The first time that each bracket/probe combination is used.
   b) If the bracket or probe head is dropped or struck, or has evidence of wear.
   c) If previous use has shown some drift of the needle from the center of the guidelines.
4. The displayed needle guide pathway on the display monitor is intended for reference during biopsy procedures. A variety of factors outside EDAN’ s control, such as changing tissue

density, bending of the needle, off-axis pressure by the person holding the probe, etc., may cause deflection of a needle outside of the displayed video pathway even when the probe, needle guide, and the system software are all performing as intended and within manufacturing specification. The specialist performing a biopsy procedure must be aware of potential external factors when performing an invasive procedure.

5. Do not freeze the system when performing a biopsy.
6. EDAN needle guides are designed and manufactured to attach firmly to designated probes and should not require excessive force to assemble or disassemble. Do not use a needle guide that requires excessive force or manipulation to assemble or disassemble.
7. A single-use sheath should be used on probe when performing a biopsy.
8. Use the needle guide kit that meets the standard sterile technique requirement.

6.2.1. Installing Needle Guide Bracket

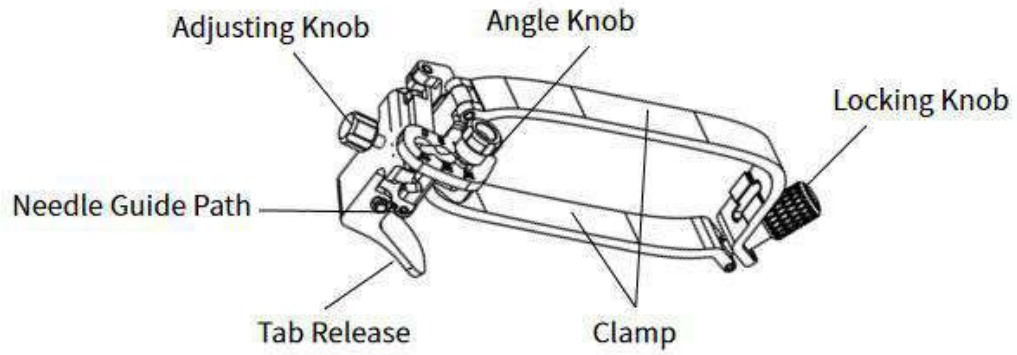
WARNING

1. For illustration purpose only, probe and bracket may be shown without a protective sheath. Always place a protective sheath on probe and bracket to protect cross infection.

■ BGK-017

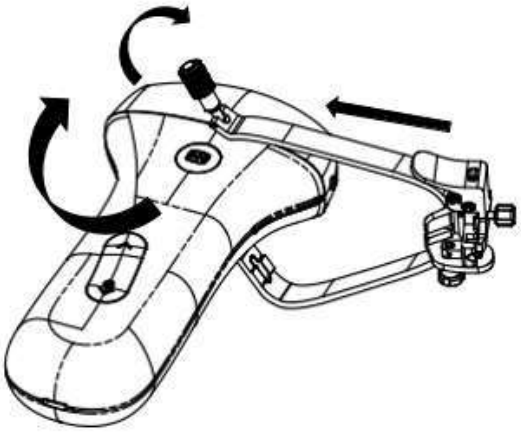
The installation steps for these brackets are the same. Here we take one bracket for illustration.

Structures:

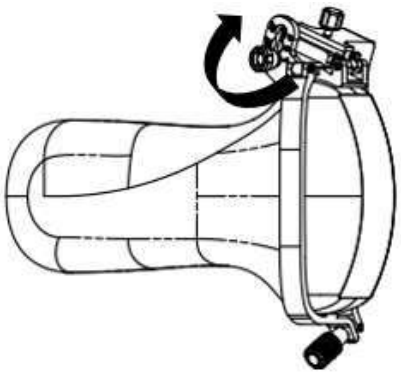


Installation and Use Steps:

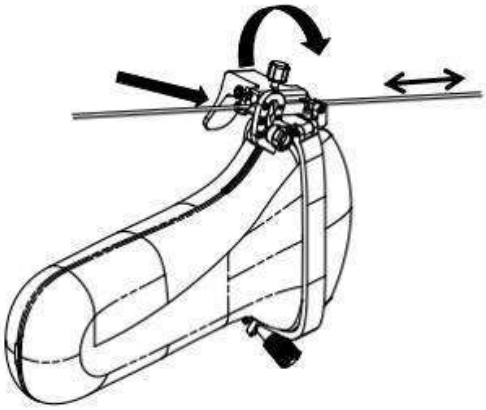
1. Place an appropriate amount of gel on probe surface, and insert probe into the sheath.
2. Loosen the locking knob to open the clamp of bracket. Attach the bracket to the probe by aligning the locating markers on the bracket and the probe. Properly secure the clamp of bracket with the locking knob. Ensure the backet is firmly attached.



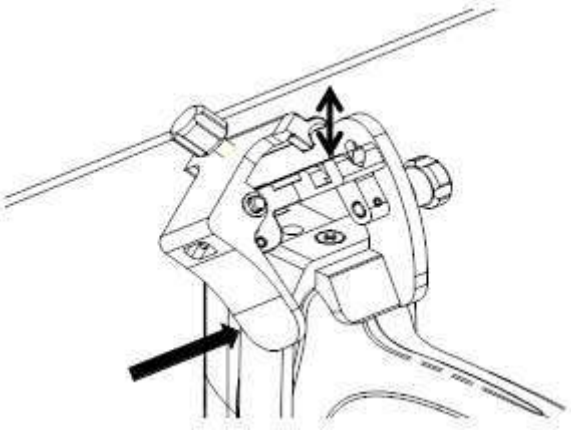
3. Loosen the angle knob to select a needle guide angle, and secure the angle knob.



4. Press the tab release and place the biopsy needle into the needle guide path. Use the adjusting knob to properly secure the needle.



5. After biopsy, press the tab release to remove the needle, and loosen the locking knob to remove the bracket from the probe.



6.2.2. Activating Needle Guide Function

To enable the needle guide function:

1. In the B mode imaging, press **Needle Guide** icon on touch screen to active the Needle Guide function.
2. Press **Double Line** button to switch double line and single line as the Needle guide Line graphics.
3. Some needle guide brackets support multiple angles. If the current probe supports such a guide then the **Line** key appears. Pressing it selects guide lines of different angles. Each line represents a corresponding angle marked on the needle guide bracket.
4. If you wish to edit the guide line again, long press the icon and activate editing.

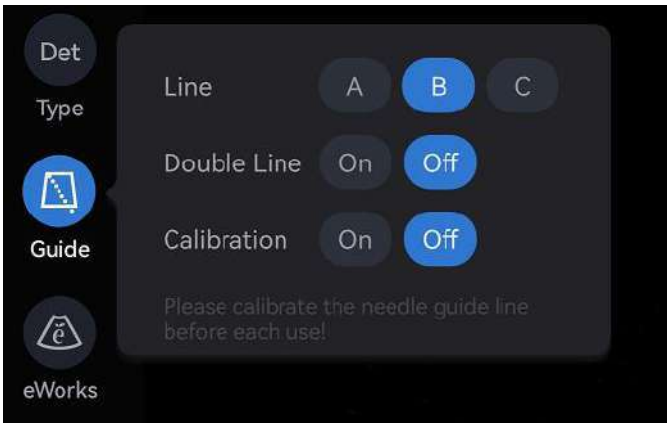


Figure 6-4 Needle Guide Touch Screen

WARNING

1. To avoid patient injury when using a multi-angle bracket, make sure that the same angle (A, B or C) is selected on both the bracket and the ultrasound system.

NOTE:

The distance between each dot of the needle guide line indicates 0.5 cm.

6.2.3. To Adjust the Needle Guide Line

WARNING

1. Calibrate the needle guide under any of the following conditions:
   a) The first time a needle guide is used with a given probe.
   b) Any time the needle guide or probe has been dropped or struck against a hard surface.
   c) After repeated use.
2. Do not use the needle guide bracket if the needle does not track with the guide during calibration.

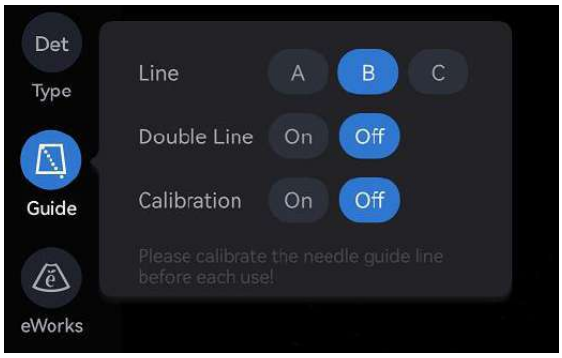


Figure 6-5 Needle Guide Calibration Touch Screen

To calibrate the guide line

1. Assemble the needle guide bracket on the probe, and use the probe to image a water bath or needle guide phantom.
2. Press the **Line** key to select a guide line.
3. Press the **Calibration** button on the touch screen to display the **Angle** and **Position** paddle button.
   - Tap the blue point of the guide line to adjust the line horizontally until the origin aligns with the actual needle.
   - Tap the body of the guide line to adjust the angle of the line until the entire line aligns with the actual needle.
4. Any changes will be saved as the default value automatically.

5. If you wish to edit the guide line again, long press the icon  and activate editing.

6.3 Center Line

The Center Line is a vertical dotted line displayed at the middle of the image field, representing the middle of ultrasound beam. The Center Line helps to locate the position and depth of a target disease focus for out-of-plane biopsy, lithotripsy and etc..

To use Center Line:

1. In the image settings interface, you can enable the display of the Center Line, which will be shown on the B-mode image. See section 11.2 for details on how to configure these.
2. A dotted center line is displayed vertically at the middle of the image field. The position and direction of the center line cannot be changed.
3. Move the probe to locate the target.
4. Use distance measurement to obtain the depth of the target.

6.4 Needle Guide Bracket Cleaning and Sterilization

NOTE:

1. Use proper sterilization technique at all times when performing a biopsy.
2. Ensure that protective gloves are worn.

WARNING

1. The needle guide bracket kits are not disinfected or sterilized before delivery. The operator should sterilize the needle guide kit before the first use and after each subsequent use.
2. Inspect the bracket for damage such as cracks or breakage. If damage is evident, discontinue use of bracket and contact your Edan representative for disposal guidance.
3. Sterilize the bracket before disposal or sending back to manufacturer for repair.

6.4.1. Cleaning

1. Wear sterile protective gloves to prevent infection.
2. Disconnect the needle guide bracket from the probe after each use, and remove all visible residues from the needle guide bracket using a small and soft-bristled brush or other similar devices. Do the cleaning quickly before the needle guide bracket dries out.
3. Soak the needle guide bracket in the cleaning solution (Ethanol 75% or Isopropanol 70%) for at least five minutes. Use a soft-bristled brush to clean the needle guide bracket during the soaking.
4. Take out the needle guide bracket from the cleanser and wipe all residues with a sterile cloth.
5. Let the bracket air dry, or dry the bracket with a sterile cloth.
6. If the bracket is not visually clean at the end of the cleaning steps, please repeat the cleaning steps through step 3 to step 5.
7. Inspect the bracket to ensure that there is no damage. The bracket should be disposed of properly when any damage is found.

6.4.2. Sterilization

1. Wear sterile protective gloves to prevent infection.
2. Disconnect the bracket from the probe, and remove all visible residues from the bracket using sterile cloth.
3. Clean and dry the bracket according to the methods in section *6.7.1 Cleaning*.
4. Sterilize the bracket assembly by dynamic air removal steam sterilizer for at least four minutes at 132℃.Dry the bracket for at least 30 min after sterilization.
5. Inspect the bracket to ensure that there is no damage.

6.4.3. Storage

WARNING

1. Dry the bracket after sterilization and store it in sterile environment.
2. Do not use the carrying case for storing the bracket, because the carrying case may become a source of infection.

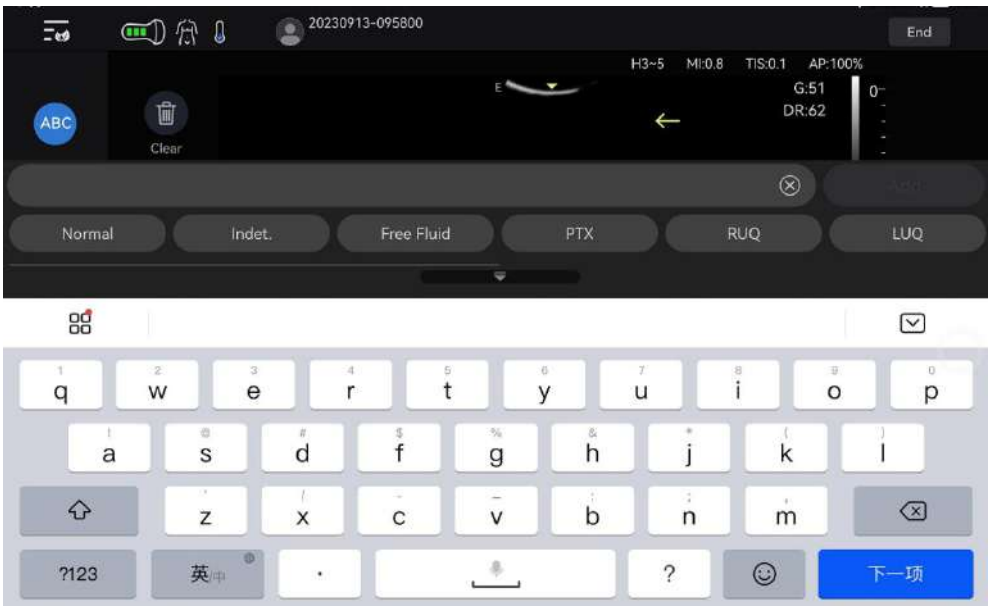
1. Ensure the bracket is cleaned, sterilized and completely dried before storage.
2. Store the bracket in a sterile environment or in a disposable sterile package.
3. Store the bracket under the following conditions:
   a) Atmospheric Temp.: -25℃～+45℃
   b) Relative Humidity: 15%~95% (Non-condensing)
   c) Atmospheric Pressure: 62kPa ~ 106kPa.

7 Features

7.1 Annotations

7.1.1. Comments

Nano allows users to add clinical comments to ultrasound images to record their observations, interpretations, or findings during a patient's examination. These comments can be useful for reference and communication with colleagues.



Adding Comments:

1. Freeze the image when you want to add annotations.
2. Click the Annotation button ABC and select Comment.
3. The system will display a keyboard, allowing you to type your comment. Above the keyboard are preset comments provided by the system. By tapping on ⬇ you can expand to view all comments. Click on the comment you want to add, and it will automatically populate the input field.
4. Click Add to confirm the Comment.

Deleting **Comments:**

Click on the Comment you want to delete, then press the Delete button to remove it.

7.1.2. Body Mark

Body Mark allows you add a body mark graph into an image and indicate the location of the probe using a probe icon on that graphic.

Adding Body Marks:

1. Freeze the image when you want to add body marks.
2. Click the Annotation button 

and select Body Mark.
3. At the bottom of the screen, preset body marks will be provided based on your current clinical application. Swipe left to view more body marks.
4. Click on the body mark you want to add, and it will automatically appear in the bottom left corner of the image.
5. The **!** mark indicates the probe's position, and the dot represents the direction indicator.
   You can control the position of the **!** mark by tapping the circle where the **!** mark appears and dragging it to the desired probe location.
   Click on the dot, and by following the dotted circle path with your finger, you can adjust the orientation of the probe direction indicator.

Deleting Body Marks:

Click on the Body Mark you want to delete, then press the Delete button to remove it.

7.1.3. Arrow

Adding Arrows:

1. Freeze the image when you want to add arrows.
2. Click the Annotation button 

and tap the arrow button to add an arrow.
3. You can control the arrow by clicking in the center area and dragging it to your desired location.
   To adjust the arrow's direction, place a single finger in the gray circle area at the front of the arrow, and rotate your finger to control the arrow's orientation.
4. Click the arrow again to complete the operation.
5. If you wish to edit the arrow again, tap the arrow you want to edit to activate editing.

Deleting Arrows:

Click on the arrow you want to delete, then press the Delete button to remove it.

7.2 Zoom

The system supports two types of zoom: Spot Zoom and Full Screen Zoom.

7.2.1. Spot Zoom

Spot Zoom focuses on processing the image of the selected area and enlarges the image with higher resolution. In the image area, use two fingers to pinch and zoom in on the desired area to zoom in or out.

Note:

1. In Spot Zoom mode, the thumbnail image is not updated. It is the last image before Spot Zoom mode was activated.
2. In Color mode, the Spot Zoom mode is activated when you first press the Zoom knob, and the position of the zoom box is the same as the Color ROI box, but 10% bigger in size. When the box size or box position is changed, the Color box and zoom box are adjusted so that above relation remains constant.

7.2.2. Full Screen Zoom

Full screen zoom function can zoom in the image to full screen display. In the image area, click the magnifying glass icon  in the lower right corner to go full screen.

8 eVocal

The eVocal function enables the user to operate the system by inputting voice commands through a microphone device.

To use eVocal Function:

1. Connect the microphone device to the microphone port on the back of the device.
2. To activate voice control, enter the settings interface, then click the eVocal button and select to enable voice control. A microphone icon will appear in the upper right corner of the main screen, indicating that the eVocal feature is activated.
3. Speak to the microphone to input a voice command. After the system recognizes the voice command, it will automatically perform the corresponding operations. The microphone icon displays the voice volume in real time when you input voice commands.

The default voice commands supported by the system are listed in the table below. You can view them on the main screen by clicking the microphone icon or inputting "Help" voice commands.

Command (English)	Function
B mode	Back to B mode
Color mode	Enter/Exit Color mode
PW mode	Enter/Exit Pre-PW mode
M mode	Enter/Exit Pre-M mode
Update	Update PW mode
Gain increase	Gain increase by 1 step
Gain decrease	Gain decrease by 1 step
Depth increase	Depth increase by 1 step
Depth decrease	Depth decrease by 1 step
Freeze	Freeze the system
Unfreeze	Unfreeze the system

Store image	Store Image
Store Clip	Store Clip

Note: The system only supports Chinese and English command in this version.

9 Measurements

The Measurement function lets you perform measurements on a live or frozen image.

9.1 Generic Measurements

Each imaging mode supports different types of generic measurements. This chapter describes all the generic measurements supported in each imaging mode.

9.1.1. B-mode Generic Measurements

9.1.1.1.Distance

The distance measurement measures the distance between two points.

1. Freeze the image and click the measurement function button.

2. Select Distance Measurement; a virtual caliper will appear in the image area.

3. Click on the caliper to activate measurement line editing. Select either end of the ruler, then drag to adjust the desired measurement range.

4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.

5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.1.2.Circumference/Area

Circumference/Area measurement can measure the circumference and area of a closed region.

1. Freeze the image and click the measurement function button.

2. Select Area Measurement; a virtual caliper will appear in the image area.

3. Click on the caliper to activate measurement line editing. Select any point on the ruler, then drag to adjust the desired measurement range.

4. Click anywhere else in the image area to fix the endpoint and complete the area measurement. The measurement result will display in the upper left corner of the image area.

5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.1.3.Angle

The Angle measurement is always done with an angle tool. To measure Angle:

1. Freeze the image and click the measurement function button.

2. Select Angle Measurement; a virtual caliper will appear in the image area, consisting of two intersecting lines.

3. Click on the caliper to activate measurement line editing. Select any point on the ruler, then drag to adjust the desired measurement range.

4. Click anywhere else in the image area to complete the angle measurement. The measurement result will display in the upper left corner of the image area.

5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.1.4.Volume

Volume can be measured with 3 Distances or Ellipse1 distance method.

1. Freeze the image and click the measurement function button.

2. Select Volume Measurement; a virtual caliper will appear in the image area.

3. Click on the caliper to activate measurement line editing.

4. Select any point on the ruler, then drag to adjust the desired measurement range.

5. Click anywhere else in the image area to complete the first set of distance measurements. The system will automatically display the next active endpoint.

6. Repeat steps 5-6 to complete the second and third sets of distance measurements. The measurement results will display in the upper left corner of the image area.

7. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.2. M-mode Generic Measurements

9.1.2.1.Distance

The distance measurement measures the distance between two points.

1. Freeze the image and click the measurement function button.

2. Select Distance Measurement; a virtual caliper will appear in the image area.

3. Click on the caliper to activate measurement line editing. Select either end of the ruler, then drag to adjust the desired measurement range.

4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.

5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.2.2.Slope

The Slope measurement measures the distance and time between two points, and calculates the slope. To measure Slope:

1. Freeze the image and click the measurement function button.

2. Select Slope Measurement; a virtual caliper will appear in the image area.

3. Click on the caliper to activate measurement line editing. Select either end of the ruler, then drag to adjust the desired measurement range.

4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.

5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.2.3.Time

The Time measurement measures the time interval between two points. To measure Time:

1. Freeze the image and click the measurement function button.

2. Select Time Measurement; a virtual caliper will appear in the image area.

3. Click on the caliper to activate measurement line editing. Select either end of the ruler, then drag to adjust the desired measurement range.

4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.

5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.2.4.HR

The HR measurement measures the time interval between two points, and calculates the heart rate. To measure HR:

1. Freeze the image and click the measurement function button.

2. Select HR Measurement; a virtual caliper will appear in the image area.

3. Click on the caliper to activate measurement line editing. Select either end of the ruler, then drag to adjust the desired measurement range.

4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.

5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.3. PW-mode Generic Measurements

9.1.3.1.Velocity

Multiple types of velocity measurements are supported on Doppler Strip, for example velocity at any point, at PS or ED.

PS/ED: measures the velocity at PS and ED points.

1. Freeze the image and click the measurement function button.

2. Select **PS , ED or PS/ED** Measurement; a virtual caliper will appear in the image area.

3. Move the caliper to the PS or **ED** point on the strip.

4. Click anywhere else in the image area to fix the endpoint and complete the distance measurement. The measurement result will display in the upper left corner of the image area.

5. To revise the measurement result, click on the ruler to activate measurement line editing.

9.1.3.2.Auto Trace

The Auto Trace measurement can provide a wide range of results, as shown below.

- PS
- ED
- MD
- TAMax
- PGmax
- PGmean
- PI
- RI
- S/D
- VTI
- Time
- AT
- DT
- HR

Trace measurement is only available on a frozen strip.

Auto Trace Method:

1. Freeze the image and click the measurement function button.

2. Select Auto Trace Measurement

3. The trace waveform(s) automatically appear, and measurement result displays.

NOTE:

1. Auto trace measurement can only be activated on a frozen Doppler strip.
2. Live Auto Trace is available as a separate feature on the Doppler touch screen. To activate Auto Trace in real time mode, press **Auto Trace** button on PW touch screen.

9.1.3.3.Time

The steps of time measurement are the same as those of time measurement in M mode. Please refer to *section 9.1.2.3* for details.

9.1.3.4.HR

The steps of HR measurement are the same as those of HR measurement in M mode. Please refer to *section 9.1.2.4* for details.

9.2 Application Measurements

Application Measurements have a pre-defined meaning and can be entered into a report. The system supports the following application measurement packages, each with its own set of measurements, calculations and report:

- ABD
- OB
- GYN
- Cardiac
- Vascular
- PICC

When you select an application measurement from the touchscreen it will automatically invoke the type of measurement it needs. For example, if you select ‘‘BPD’’ from the OB application it will automatically invoke a distance measurement. These measurements generally behave as described above for generic measurements.

Some application measurements can have multiple variations. For example, in a twin OB exam the OB measurements can be done on either fetus. As another example, in Vascular exams several measurements can be done in a Proximal, Mid, or Distal location. When a measurement has multiple variations you will see keys on the touchscreen that let you pick which variation you are measuring.

9.2.1. Abdomen Measurements

No.	Measurement Item	Description	Method
Section 1: B-mode Measurements			
1.1	Pre-BL L	Pre-void Bladder Length	Distance in B-mode generic measurements
1.2	Pre-BL W	Pre-void Bladder Width	
1.3	Pre-BL H	Pre-void Bladder Height	
1.4	Post-BL L	Post-void Bladder Length	
1.5	Post-BL W	Post-void Bladder Width	
1.6	Post-BL H	Post-void Bladder Height	

9.2.1.1.Auto-B Line

Auto B-Line measurement can assist the orthopedic clinician to quickly complete the corresponding vital sign measurement and automatically complete the relevant measurement in the severe clinical environment where the patient's condition is complex and the vital signs are unstable.

NOTE:

1. Auto B-Line is optional and requires a license to activate it.

2. When the number of B lines is more than or equal to five, the system does not display the number of B lines.

WARNING

1. The lung image for Auto B-Line measurement should be standard section, otherwise the measurement accuracy may be affected. When no valid lung image is recognized, the system will prompt you with "No valid measurement results."
2. Auto B-Line measurement is only available on a real-time image.
3. The measurement result of Auto B-Line is for reference only. The measurement accuracy can be affected by image quality, fetal image section, the position of ROI box, etc. Always confirm the detection of NT structure by visual inspection before storing the results in the worksheet and report. If the result is in doubt, manual or other effective methods should be applied to verify the correctness.

To use Auto B-Line measurement:

1. Connect the probe and select either Lung exam preset.
2. Scan lung images, then click the Auto B-Line icon to access the Auto B-Line function.
3. Automatic measurement will begin. The system will automatically scan lung images and calculate the number and spacing of B-Lines in the lung. Measurement results will automatically display on the main screen.

Evaluation criteria:

Scoring criteria and expression	
(0) N	Displays a lung sliding sign and A line, or isolated B lines (<3)
(1) B1	Displays multiple clearly-distributed B lines
(2) B2	Displays intensively fused B lines
(3) C	Displays the image similar to the liver lesion structure and air bronchogram
(3) C/P	The lung consolidation and pleural effusion occur at the same time

9.2.2. Obstetrics Measurements

Obstetric measurements are used to calculate the GA (Gestation Age), EDD (Estimated Delivery Date) and EFW (Estimated Fetus Weight).

The Obstetric package supports measurements on up to four fetuses. If you know the number of fetuses at the start of the exam then you can enter this in the Patient page (see section 4.4). When the number of fetuses is known, the system adjusts the user interface to optimize for that number. If no information is entered about the number of fetuses, the system will assume there is one.

No.	Measurement Item	Description	Method
Section 1: B-mode Measurements			
1.7	BPD	Biparietal Diameter	B-mode generic

No.	Measurement Item	Description	Method
1.8	HC	Head Circumference	measurements
1.9	AC	Abdominal Circumference	
1.10	FL	Femur Length	
1.11	CRL	Crown Rump Length	
1.12	GS	Gestational Sac	
1.13	Q1	Amniotic Fluid Index	
1.14	Q2		
1.15	Q3		
1.16	Q3		
Section 1: PW-mode Measurement			
2.1	Umb. A	Umbilical Artery	Doppler generic measurement

* The measurement method including 1 Distance, 2 Distances and 3 Distances can be switched by the Tool Options key.

9.2.3. Cardiac Measurements

No.	Measurement Item	Description	Method
Section 1: B-mode Measurements			
1.1	LA	Left atrial diameter	B-mode generic measurements
1.2	Ao	Aortic root diameter	
1.3	IVCmax	Abdominal Circumference	
1.4	IVCmin	Femur Length	
Section 2: M-mode Measurements			
2.1	IVSTd	Interventricular Septal Thickness at End-diastole	M-mode generic measurements
2.2	LVIDd	Left Ventricular Internal Diameter at End-diastole	
2.3	LVPWd	Left Ventricular Posterior Wall Thickness at End-diastole	
2.4	IVSTs	Interventricular Septal Thickness at End-systole	
2.5	LVIDs	Left Ventricular Internal Diameter at End-systole	
2.6	LVPWs	Left Ventricular Posterior Wall Thickness at End-systole	
2.7	LA	Left atrial diameter	
2.8	Ao	Aortic root diameter	
2.9	IVCmax		
2.10	IVCmin		

No.	Measurement Item	Description	Method
2.11	E-F Slope	Mitral Valve E-F slope	
Section 2: PW-mode Measurements			
3.1	E Vel		Doppler generic measurements
3.2	A Vel		
3.3	E Dur		
3.4	A Dur		
3.5	AccT		
3.6	DecT		
3.7	PHT		

9.2.4. Vascular Measurements

No.	Measurement Item	Description	Method
Section 1: B-mode Measurements			
1.1	Auto Diam	Left atrial diameter	B-mode generic measurements
1.2	eSten%	Aortic root diameter	
1.3	IMT Far	Abdominal Circumference	
1.4	IMT Near	Femur Length	

9.2.4.1.Auto Diam

1. Connect the probe and set the clinical application to Renal or PICC.

2. In B-Mode, scan vascular images, then click the freeze button.

3. Click the measurement icon, select Auto Diam. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.

4. Click elsewhere in the image area to fix the endpoint.

5. The system will automatically recognize and trace the area to be measured. The measurement

result will display in the upper right corner of the image area.

9.2.4.2.eSten%

1. In B-Mode, scan vascular images, then click the freeze button.

2. Click the measurement icon, select eSten%. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.

3. Click elsewhere in the image area to fix the endpoint.

4. The system will automatically recognize the area to be measured, and the measurement result will display in the upper left corner of the image area.

9.2.4.3.IMT Far

1. Connect the probe and set the clinical application to Renal.

2. In B-Mode, scan vascular images, then click the freeze button.

3. Click the measurement icon, select IMT Far.

4. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.

5. Click elsewhere in the image area to fix the endpoint.

6. The system will automatically recognize the area to be measured, and the measurement result will display in the upper left corner of the image area.

9.2.4.4.IMT Near

1. Connect the probe and set the clinical application to Renal.

2. In B-Mode, scan vascular images, then click the freeze button.

3. Click the measurement icon, select IMT Near.

4. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.

5. Click elsewhere in the image area to fix the endpoint.

6. The system will automatically recognize the area to be measured, and the measurement result will display in the upper left corner of the image area.

9.2.4.5.Live VF

1. Connect the probe and set the clinical application to Renal.

2. In PW-Mode, scan vascular images, then click the freeze button.

3. Click the measurement icon, select Live VF.

4. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.

5. Click elsewhere in the image area to fix the endpoint.

6. The system will automatically recognize the area to be measured, and the measurement result will display in the upper left corner of the image area.

9.2.4.6.eVol.Flow

1. Connect the probe and set the clinical application to Renal.

2. In PW-Mode, scan vascular images, then click the freeze button.

3. Click the measurement icon, select eVol.Flow.

4. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.

5. Click elsewhere in the image area to fix the endpoint.

6. The system will automatically recognize the area to be measured, and the measurement result will display in the upper left corner of the image area.

NOTE:

1.All these automatic measurements above are optional and require a license to activate them.

9.2.5. PICC Measurements

No.	Measurement Item	Description	Method
Section 1: B-mode Measurements			
1.5	Auto Diam	Left atrial diameter	/

9.2.5.1.Auto Diam

1. Connect the probe and set the clinical application to Renal or PICC.

2. In B-Mode, scan vascular images, then click the freeze button.

3. Click the measurement icon, select Auto Diam. A caliper will appear in the image area. Click and move the ruler to the area you want to measure.

4. Click elsewhere in the image area to fix the endpoint.

5. The system will automatically recognize and trace the area to be measured. The measurement result will display in the upper right corner of the image area.

9.3 Measurement Accuracy

Table 1 Measurement accuracy

Parameter	Range	Accuracy
1.B Mode Measurement		
Distance	Full Screen	< ±5%
Circumference (Ellipse)	Full Screen	< ±5%
Area (Ellipse)	Full Screen	< ±8%
Angle	Full Screen	< ±3%
2. M Mode Measurement		
Distance	Full Screen	< ± 5%
Time	Timeline display	< ±3%
HR	Timeline display	< ±5%
3.Doppler Mode Measurement		
Velocity(PW mode)	10-200cm/s	When angle ≤60°, < ± 10%
Time	Timeline display	< ±3%
HR	Timeline display	< ±3%

Table 2 Accuracy of Auto measurements

Auto Measurements	Error
Auto B-Line	≤±15%

Live VF	⩽±10%
eVol Flow	⩽±15%
Auto Diam	⩽±10%
eStenos%	⩽±10%
Auto IMT	⩽±10%

Note: The performance specification listed above was verified on the Elasticity QA phantom, and the accuracy of strain ratio measurement were verified within the range mentioned above on the Elasticity QA phantom.

10 Exam Data Management

10.1 Storing Images

The system supports storing static images and cine clips. What is displayed in Information area, Image area and Image parameter area on the main screen will be stored.

Nano has two store keys, as shown below:

No.	Key	Name	Function
1		Store Image	Stores static images.
2		Store Clip	Stores cine clips.

Storing an image:

Pressing a Store key will always capture what is on the image area of the screen. This includes live, frozen, or Cine images. It also includes reports or other GUI screens and review.

Storing a clip:

Pressing a Store key will capture the moving images in scanning or cine review status. If the image is frozen or a non-image screen is displayed then a static image is stored.

The store starts with the press of a Store key and continues for the configured length of the clip or until the clip store is interrupted. The length of the clip can be configured on the **Store** page (See section 10.1.3 for details).

The following events can cause the clip store to stop:

- A second press of the store key
- Display of a GUI screen or dialog
- Mode change
- Image parameters change

- Cine play pause

  NOTE:

  1. If the image is frozen or a non-image screen is displayed, a static image is always stored when pressing a store key.
  2. In panorama mode, a static image is always stored when pressing a store key.

10.2 Reviewing Images

If Static or Clip images have been stored for the current exam then they can be reviewed by pressing the <**Review**> key .

NOTE: If nothing has been stored in the current exam then the <**Review**>key will invoke the Patient Database function .

10.3 Exam Database

The Exam Database provides a list of recently performed studies. It can be accessed by pressing the <**Review**> key when there is no active exam.

The main part of the display shows a list of studies. Clicking on the header of a field will sort the list by that field. Fields can be displayed or hidden. If Password Protection is enabled, admin can view and operate all the studies, operators can only view and operate the studies they created.

Filter: The database filter field at the top-left of the screen provides a powerful tool to find the study of interest. It filters the list based on whatever text is typed in this field. The filter applies to all fields. For example, typing ‘ ‘Ab’ ’ into the filter will show exams that either have that text in either the patient name or in the Exam preset. By default the filter is set to blank, so the default list shows all exams.

Storage Area: There is a database storage area field at the top-right of the screen. User can select to review the studies in local or USB storage, and also can send the studies from local to USB or from USB to local. Select the required studies and click Send to complete. When sending the studies from USB to local, only images in DCOM format can be sent.

Storage Size: There is a box displaying current disk usage. It contains text with the current usage and is filled with a solid color to the extent that the current capacity is used. The text shows

‘‘<current usage> of <total capacity>’’. The units are ‘‘Mb’’ for values less than 1 Gb, and ‘‘Gb’’ for anything larger. The solid color fill is green when usage is less than 75% of capacity, yellow for usage between 75% and 95%, and red when disk usage is above 95%.

Destination: The location where the highlighted exam(s) shall be exported, including:

- Available DICOM server location(s).
- Available FTP server location(s).
- Any inserted USB disk or DVD drive.

Export Format: This location displays export format for static images and clips. BMP, JEPG, TIF and DICOM formats are available for static images. AVI, WMV and DICOM formats are available for clips.

Send/Burn: Pressing this will send/burn the highlighted exam(s) to the destination. This button is available when one or more exams are selected.

- **Working with one study:**

  A study is selected by clicking on it. When a study is selected thumbnail images from that study are shown on the right side of the screen. Operations such as editing report, reviewing, deleting and restarting of the selected study can be accessed on the touch screen.

  A study can also be send to a network server, saved to a USB device or DVD drive, or deleted. If the study has been copied to either a server or to a USB device or DVD drive a small disk icon appears next to it, indicating that it has been saved.

  CAUTION:

  - Studies stored on the system hard drive should be archived regularly. The system is not intended for long term storage of patient information. Confirm successful archiving before deleting a study from the hard drive.

- **Working with multiple studies:**

  Multiple studies can be selected by clicking the small box at the left of each listed study. Multiple studies can be stored to a network server, saved to a USB device or DVD drive, or deleted. Only one study can be reviewed at a time.

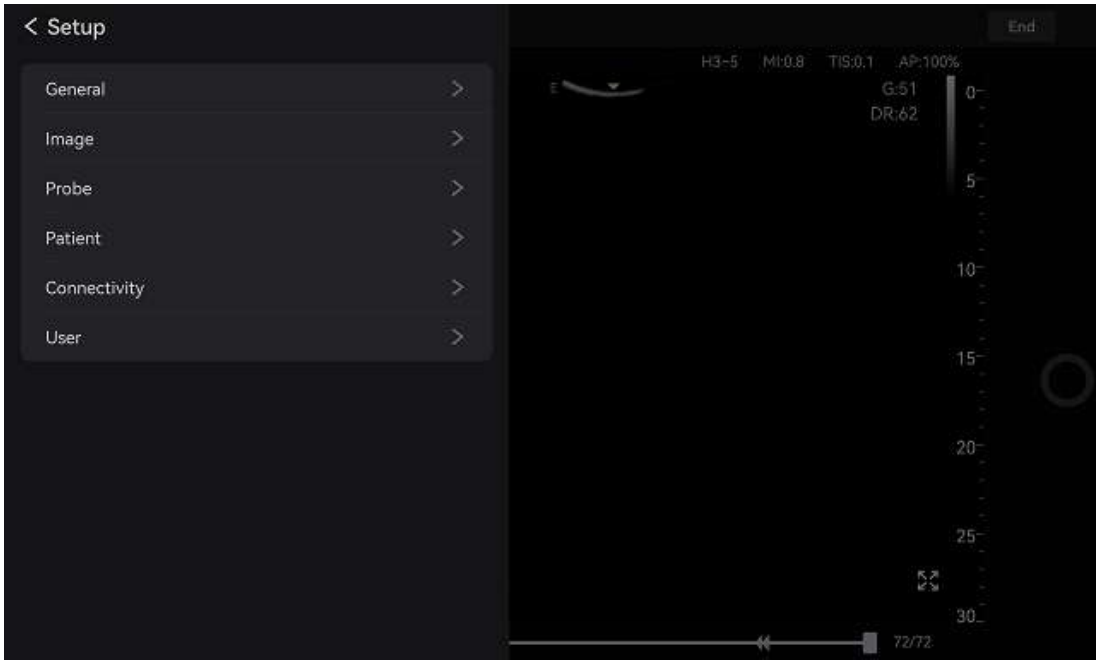
Query/Retrieve:

Pressing this will open the Query/Retrieve page, as shown below, where you can enter key words and query prior exams from the configured DICOM Server. How to configure the DICOM server, please see section 10.6.2.1.

- **Patient ID, Patient Name, Accession**: enter the key words for query.
- **Exam Date**: enter the date range.
- **Query**: press to start the query, and all the queried exams will be displayed in the box below.
- **Retrieve**: select one queried exam and press **Retrieve** to download it from the DICOM server to the **Retrieve result** box.
- **Clear**: clear all the queried and retrieved results.

11 System Set-up

Tap Menu button and then click Setup to enter the system setting interface. In this page, you can make settings for Image, Probe, Patient, Connectivity and so on. Each of these is described in the following subsections.



11.1 General Set-up

Item	Options	Description
Auto-Brightness	ON/OFF	Set whether the interface brightness of Nano application is automatically adjusted.
Language	Chinese English …	Set the language of Nano system, the new set language needs to restart the system to take effect.
Clinical	GI Emergency Anesthesiology	Set the clinical application of Nano, the system will adjust the parameters and presets according to different

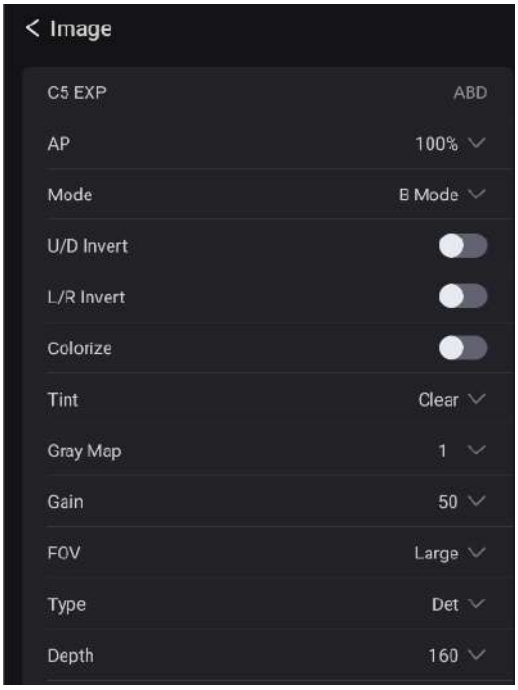
	Pain Nephrology PICC	clinical applications.

11.2 Image Set-up

Item	Options	Description
Center Line	ON/OFF	Set whether to display the centerline in the image.
Auto Freeze	10s, 20s, 30s, 60s, 120s	Set the time the system waits to enter image freeze when there is user operation.
Clip Duration	1s, 2s, 5s, 15s, 30s, 60s, 90s, 120s	Set the time for the system to store forward/backward in the real-time state.

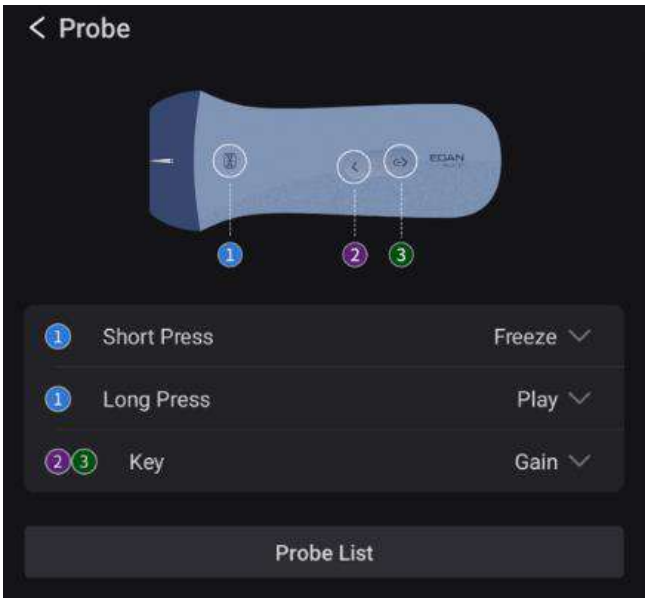
Image Preset:

The Figure below shows an example set-up screen for Image Preset, where you can configure the imaging parameters for an exam preset. This example shows the screen for editing the B-mode settings for the Nano C5 EXP ABD exam preset.



11.3 Probe Set-up

Probe Key Customization:

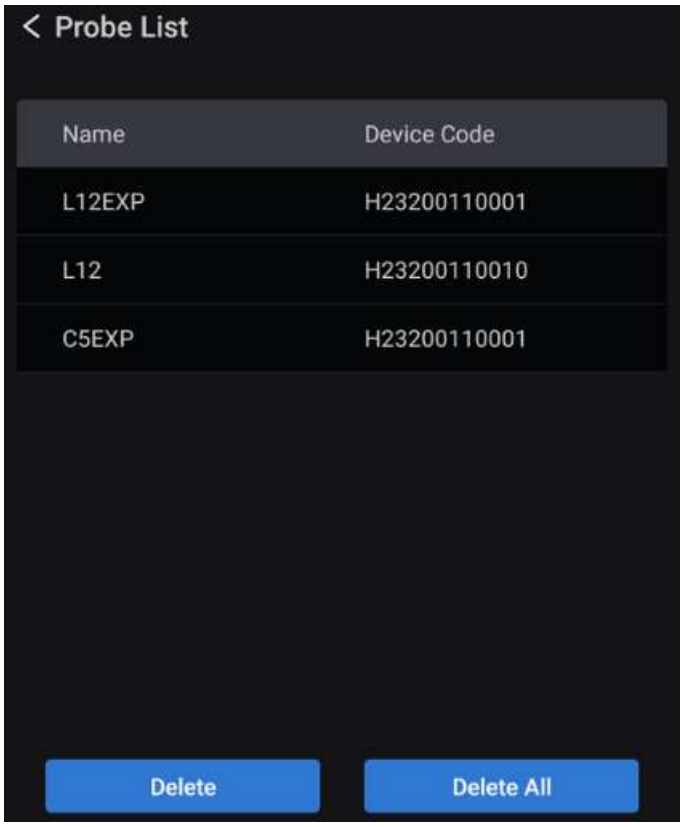


There are three buttons on the body of the Nano Probe, namely buttons ①, ② and ③. User can define the functions of the three buttons for quick operation according to their needs.

Item	Options	Description
①Short Press	Freeze, Play, eVocal,	Set the function of short press probe button ①. You can set the function to

	None	freeze image, play video, enable eVocal function, or not to set the function.
①Long Press		Set the function of long press probe button ①. You can set the function to freeze image, play video, enable eVocal function, or not to set the function.
②③Key	Depth, Gain, None	Set the function of pressing button ② and button ③. You can set the function to increase the depth, adjust the gain, or not to set the function.

Probe List:



All the probes that have been connected will be shown in this list, you can delete the connected probes one by one, or press **Delete All** button to delete all the connected probes with one click.

11.4 Patient Set-up

Item	Options	Description
Auto Patient ID	ON/OFF	When you enter a new exam, tap the patient information image, and the system automatically generates a patient ID for the current exam with a time letter urgency.
Pop up patient info window when End Exam	ON/OFF	Set whether or not to bring up the patient information screen when the END button is pressed to end the exam.
Restart Time Limit	24h/48h/72h/unlimited	You can define the time limit for restarting exam. Only exams within the time limit can be restart. If 0 is selected, no exam can be restart.
Patient Name Display	One field/Two fields	You can define the patient name display format. The patient information page displays ‘ ‘Patient Name’ ’ for one field and displays ‘ ‘Last Name’ ’ and ‘ ‘First Name’ ’ for two fields.
Clinical GA	LMP,BBT	Select one item as the beginning date of clinical GA. The selected item will be displayed on the Patient Information Page by default.
Clinical EDD	40W,41W	Select one item as the default time period of pregnancy. This will affect the calculation of clinical EDD.

11.5 Connectivity Set-up

Device Configuration:

Local AE Title: Any 16 characters that uniquely identify this system on your DICOM network. The default ‘‘EDAN_STR_SCU’’ will work unless you have multiple Edan systems on your network.

Time Out: This determines the time after which this system will stop trying to establish a connection to the DICOM server.

IP Address: Nano uses its IP address to find the right destination and make sure the data reaches the correct place.

Server Settings:

The server list displays all the configured servers. It starts off as an empty list, and grows as servers are added. Most sites will only use one server, but if the system is moved between locations then multiple servers may be entered. Clicking in any field in this list will select that server. Depending on the exact level of software a second click may be needed to edit that field. The fields are:

- **Name**: The name of the server that appears in the drop-down list of the exam database.
- **AE Title, IP Address, Port:** These are the settings of the destination DICOM server; it’s how the system finds the DICOM server on your network. The AE title and IP Address are unique to your network; contact your network IT manager for these settings. The most common setting of Remote Port for DICOM servers is 104, although your server may be different.
- **Storage-TLS**: Sets whether to use the TLS protocol to encrypt DICOM store process.

  Note:

  The precondition of using TLS protocol to encrypt DICOM store process is that the DICOM server should support TLS protocol.
- **Testing the server:** There are two tests to ensure that the server information is entered correctly. Click on any field for a given server to make that server selected, then:

➢ **Ping**: A successful Ping means that the system can communicate with the server at a

low-level; basically that the two computers 'see' each other. As a security measure, some servers on the Internet may be configured to not respond to a Ping even if the connection is successful.

- **Verify**: A successful Verify means that the system can communicate with the server at a DICOM level; basically that the DICOM on both computers understand each other. A successful Verify will typically mean that your DICOM configuration is correct.

- **Other controls:**

- **Add**: Adds another line in the list of servers.
- **Delete**: Deletes the selected server.

11.6 User Set-up

Item	Options	Description
Enable Password Protection	√/×	Show or hide the login dialog when booting up the system. Password is required to enable password protection function.
User List	/	Show all users displaying user name and user type. Click the dialog before the user to select this user for edit operation

User type includes Administrator and Operator.

- Administrator users have authority to enable/disable password protection, add/delete/edit users and can view all exams in the patient database. There is one pre-defined administrator user called Admin.
- Operator users can only edit their own user information, change their own password, and view exams that they created.
- There's one pre-defined operator user called Emergency for Emergency login without entering password. The exams created by Administrator and Operator cannot be viewed through Emergency login.

There's a couple of buttons for different user edit operation. It includes Add User, Delete User,

Edit User, and Change Password.

- **Add User**: Click it to add user in the user list.
- **To Switch Users**

If Password Protection is enabled, switching users is allowed without restarting the system.

- Press Power on/off key, and the system will display a confirmation dialog box.
- Select **User** from the confirmation dialog box. A login information dialog box will be displayed providing access to change user.
- Select **Change User** and this brings up the system login dialog box.
- Select another user from the User Name drop-down list and then enter password to login.

- **Edit User**: Click it to modify the user information.
- **Delete User**: Click it to delete the highlighted user in user list.

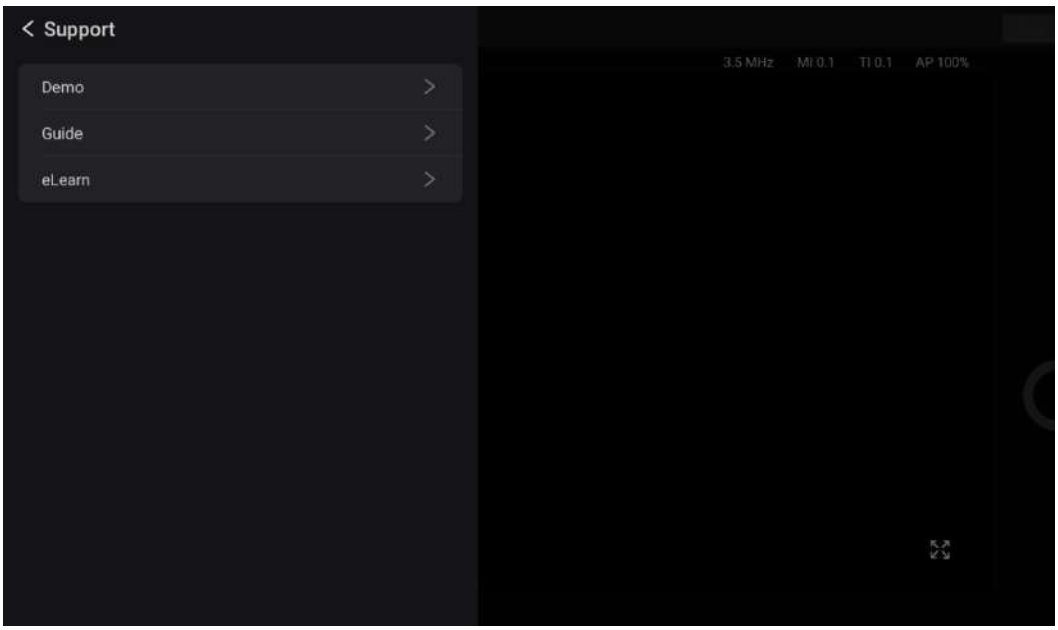
Note: Only the administrator has the permission to add users and change passwords of other users. Operators do not have the permission to add users and can only change their own passwords.

Caution

1. For security consideration, a password with high secure intensity is suggested for each user account, and the password should be changed periodically.
2. Please keep your user name and password safe.
3. Change the password of the pre-defined administrator user "Admin" immediately when you get the ultrasound system, and set a new password with high security.
4. Always enable the function of user login with password protection.
5. When the password of the pre-defined administrator user "Admin" is forgotten, please contact the serviceman for the system password reset.

12 Getting Support

Tap Menu button and then click Support to enter the system support interface. In this page, you can get help and support on the use of Nano .



12.1 Demo

The Demo screen provides access for you to show a set of images you collected for demonstration purpose.

These images and videos will play automatically, or you can use one finger to swipe left or right on the screen to control the playback of the slides.

12.2 Guide

User operation animation guide for products is a visual aid tool designed to help you easily understand and learn how to use a certain product. It utilize animations and graphics to present operational steps and functions in a concise and clear manner, enabling users to quickly get started.

12.3 eLearn

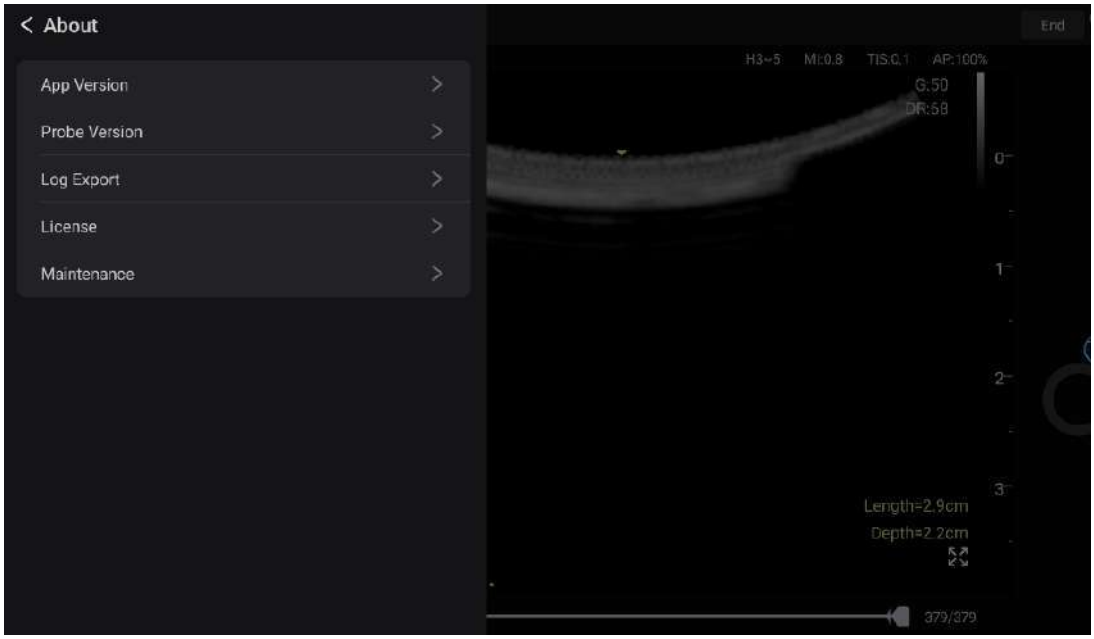
Press to access the instruction guide for basic scanning and for nerve block.

eLearn specifically designed to assist healthcare professionals in performing ultrasound scans or exams.

13 Maintenance

Entering Maintenance Screen:

Press **Utilities**-> **Maintenance** touch screen buttons to access **Maintenance** screens.



13.1 App Version

The App Version refers to the specific release or edition of the software application you are currently using. Regularly checking and keeping your app up-to-date ensures that you have access to the latest features and improvements.You can typically find the app version information in the application's settings. It helps in troubleshooting and ensures you're using the most current and reliable version of the application.

13.2 Probe Version

The Probe Version serves as an essential identifier for the particular iteration of the probe, and any updates or modifications that may have been made to it.

Regularly checking the probe version is important to ensure that you are using the most up-to-date and accurate equipment. This version information is typically found in the system settings. Staying informed about the probe version is crucial for maintaining the reliability and precision of your diagnostic procedures.

13.3 Log Export

The system supports export of user-configured presets and settings to an external storage device. This same UI supports the export of system log files.It allows you to retrieve and save records of activities, events, or diagnostic data generated by the device.

To export user data:

- Press **Menu** , select **About→ Log Export→Export.**

13.4 License

The **License** page displays which features are currently licensed for use on the system. At the top of the screen is displayed the current license key. Below that is a list of all licensable features, along with its current status.

To activate a license:

1. Send the probe SSID to EDAN customer service, and will receive the QR code from EDAN.

2. Press Scan to activate ,and then scan the QR code.

3. If successfully identificated, the advanced function would be enabled.

13.5 Maintenance

13.5.1. Probe Element Check

Proper performance of the probe is the prerequisites for acquiring images or signals that provide the intended information for the users. To ensure the proper performance of a probe, it is suggested to implement the probe element check each time a probe is activated for use or at regular probe performance check.

To perform probe element check:

- Press **Menu** , select **About→ Maintenance→Probe Check→Start Check.**

1.Connect a probe, enter the Menu screen.

2.Select **About→ Maintenance→Probe Check** to open the page for probe element check.

3.Ensure the probe is unloaded in the still air and the residual coupling gel has been removed. Press **Start check** to initiate the process of element check.

4.Wait until the test report is displayed.

The test report includes two parts:

a.Elements graphic, showing element number and element performance. Red color indicates the performance of the elements have been compromised. Green color indicates the elements are in normal performance. For the linear and convex probes, the image at the regions under or near the compromised elements may be compromised; for the phased array probes, the whole image regions may be compromised.

b.Test result text.

For each possible message in the test result report, a workaround is provided in the table below:

No.	Message	Workaround
1	Probe is in normal performance.	The performance of the probe is normal. You can use it normally.
2	Probe performance is degraded severely. Compromised image quality will result.	Continuous use of the probe will result in compromised image quality. Please stop using the probe and contact the Serviceman for repair.
3	The performance of probe elements [n1,n2,...] are degraded severely. Compromised image quality will result.	This may be caused by compromised elements or broken probe socket. Try a probe of normal performance at the same probe socket for element check. If the test result is the same, it indicates the probe socket has been broken; otherwise, it indicates the performance of the elements have been compromised.

		Please contact the Serviceman for repair.
4	Ultrasound module malfunction.	The ultrasound module is in malfunction. Continuous use of the system will result in compromised image quality. Please contact the Serviceman for repair of the ultrasound module. Redo the element check after the ultrasound module is repaired to ensure the performance of the probe is normal.

14 In Between Exams

14.1 Unpacking

Visually examine the package prior to unpacking. If any signs of mishandling or damage are detected, contact the carrier to claim for damage. After unpacking the device, you should follow the packing list to check the product carefully and to make sure that no damage has occurred during transportation. For installation, please contact your local distributor or the EDAN service department at: support@edan.com.

WARNING

1. Do not use the device if it is found to be damaged or defective.
2. Do not drop or collide with the probe. Otherwise you shall give up using it.

14.2 Transport

Power off the system and secure all accessories before moving it to another location.

CAUTION

1 Switch off the ultrasound system. Disconnect the charger from the power source and secure the USB cable.

2 Remove the probe and place them in a safe place.

3 Disconnect and secure the connecting cable.

4 Connect optional system accessories.

5 Secure the system and complete the system setup, and then perform all the daily checking before using it.

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

To prepare the system for transport over distances: load the system into a vehicle using a lift gate.

To prevent lateral movement of the system, secure the system with cargo straps. To prevent sudden jarring of the system during transport, provide anti-shock cushions beneath the system.

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

14.3 Storage

- Do not place the device near the ground, walls or the roof.
- Keep good indoor ventilation. Avoid strong and direct sunlight, and erosive gas.

15 Troubleshooting and Maintenance

In order to ensure proper system operation and function, a maintenance and inspection plan should be established to periodically check the safety of the system. If any system malfunction is experienced, contact EDAN or authorized representatives.

15.1 Daily Checklist

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

- Visually inspect all the probes. Do not use any damaged probe.
- Visually inspect all the probe USB cable and associated connector. Do not turn on the power if a USB cable is frayed or split, or shows signs of wear.
- Verify that the controls are clean and free from gel or contaminants.

Check after the system is switched on:

- Visually check the on-screen display and lighting. Verify that the compatible mobile device displays the current date and time and there isn't any error message.
- Verify that the probe identification and indicated frequency on the screen are correct for the activated probe.
- Ensure that there isn't obvious abnormal noise, discontinuous image or dark area.
- Ensure that it isn't smelly or too hot.
- Ensure that the ultrasound window isn't too hot, checking with your hand.
- Verify that the buttons of probe are good to operate.

15.2 Troubleshooting

If any persistent system malfunction is experienced, e.g. an onscreen error message, blank imaging screen, absent menus, please refer to the following table below. If the failure cannot be eliminated, please contact EDAN or authorized representatives.

Item	Problem	Solution
1	When the power switch is on, there isn't any image displayed.	1. Check power supply. 2. Check wires and plugs.
2	Strip-shape or snowflake-shape disturbance occurs on the display screen.	1. Inspect the power supply. 2. Check whether it is disturbed by the ignition action of any other device. 3. Check the disturbance of electric or magnetic field in the surrounding environment.
3	Image is not displayed clearly on the screen.	1. Adjust overall gain (Gain). Adjust eight TGC slide controls.
4	Image window is dark.	1. Adjust the brightness and slide the TGC controls on the touch screen. 2. Check whether the probe is connected well.

15.3 Cleaning and Disinfecting the System

Use only the EDAN-approved substances and methods listed in this chapter to clean the system. The warranty does not cover damage caused by using unapproved substances or methods.

Edan Instruments has validated the cleaning and disinfection instructions included in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

General Points:

Keep your device, USB cable and accessories free of dust and dirt. To prevent the device from damage, please follow the procedure:

- Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute according to the manufacturer's instructions.

- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the system.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the monitor and reusable accessories after they are cleaned and disinfected.

WARNING

1. The connector of Nano is not waterproof. Do not immerse or expose to extended moisture. Splash resistance does not extend to probe connectors. Keep connectors dry.
2. If the probe is stored alone and not used for a long time, we recommend that the probe should be charged at least once every 3 months to prevent overdischarge.

15.3.1. Cleaning and Disinfecting the System Surface

System Surface Cleaning

The validated cleaning agents for cleaning the system are:

- Ethanol (75%)
- Isopropanol (70%)

To clean the probe surface:

1. Switch off the system and unplug it.
2. Wear sterile protective gloves to prevent infection.
3. Remove all residual foreign matters from the system surface using sterile cloth or paper towel immediately after examination.
4. Use a sterile cloth dampened with cleaning agent to gently wipe the entire exterior surface, including the screen, of the equipment thoroughly until no visible contaminants remain.
5. After cleaning, wipe off the cleaning agent with a sterile cloth dampened with tap water until no visible cleaning agent remains.
6. Wipe off with a dry sterile cloth to remove residual moisture.
7. Leave the system to air dry.

8. If the system is not visually clean at the end of the cleaning steps, please repeat the cleaning steps through step 4 to step 7.
9. Inspect the system to ensure that there is no damage.

NOTE:

1. Make sure the system is free of gel and any other visible residue.
2. Use a soft dry cloth without chemicals for cleaning. The monitor surface is easily scratched.

System Surface Disinfection

The validated disinfecting agents for disinfecting the system are:

- Ethanol (75%)
- Isopropanol (70%)

To disinfect the system surface:

1. Switch off the system and unplug it.
2. Wear protective gloves to prevent infection.
3. Clean the system prior to disinfection.
4. Prepare the disinfectant solution.
5. Wipe the entire exterior surface of the equipment thoroughly with a soft sterile cloth dampened with the disinfectant solution. Follow the disinfectant manufacturer's recommended contact time and mode.
6. After disinfection, wipe off the disinfecting agent with a new sterile cloth dampened with sterile water.
7. Wipe the system with a dry sterile cloth or leave the system to air dry.
8. Inspect the system to ensure that there is no damage.

15.3.2. Cleaning and Disinfecting the ECG Module and Cable

ECG module and cable cleaning

The validated cleaning agents for cleaning the ECG module and cable are:

- Ethanol (75%)

- Isopropanol (70%)

To clean the ECG cable:

1. Disconnect ECG cable from the patient and disconnect the ECG module from the ultrasound system.
2. Wear sterile protective gloves to prevent infection.
3. Remove all residual foreign matters from the ECG module and cable using sterile cloth or paper towel immediately after examination.
4. Use a sterile cloth dampened with cleaning agent to wipe the entire exterior surface of the ECG module and cable thoroughly until no visible contaminants remain.
5. After cleaning, wipe off the cleaning agent with a sterile cloth dampened with tap water until no visible cleaning agent remains.
6. Wipe off with a dry sterile cloth to remove residual moisture.
7. Leave the ECG module and cable to air dry.
8. If the ECG module and cable is not visually clean at the end of the cleaning steps, please repeat the cleaning steps through step 4 to step 7.
9. Inspect the ECG module and cable to ensure that there is no damage.

ECG module and cable disinfection

The validated disinfecting agents for disinfecting the ECG module and cable are:

- Ethanol (75%)
- Isopropanol (70%)

To disinfect the ECG module and cable:

1. Disconnect ECG cable from the patient and disconnect the ECG module from the ultrasound system.
2. Wear protective gloves to prevent infection.
3. Clean the ECG module and cable prior to disinfection.
4. Prepare the disinfectant solution.

5. Wipe the entire exterior surface of ECG module and cable thoroughly with a soft sterile cloth dampened with the disinfectant solution. Follow the disinfectant manufacturer's recommended contact time and mode.
6. After disinfection, wipe off the disinfecting agent with a new sterile cloth dampened with sterile water.
7. Wipe the ECG module and cable with a dry sterile cloth or leave the system to air dry.
8. Inspect the system to ensure that there is no damage.

15.4 Maintenance

Please check the label for the date of manufacture. If properly maintained, the expected service life of Nano is 3 years(The service life is limited to the unit, not including the replaceable accessories).

The expected service life of ECG cables is also 3 years. Please replace the adapter and other accessories according to the actual use. If an accessory is found to be damaged, please refer to the appendix C Order List to order a new accessory and directly replace the damaged one .

The system should be maintained regularly, at least annually, by a qualified technician who has adequate training, knowledge and experience. That person should be familiar with the Service Manual, available from your Edan representative.

16 Warranty and Service

16.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

a) damage caused by mishandling during shipping.

b) subsequent damage caused by improper use or maintenance.

c) damage caused by alteration or repair by anyone not authorized by EDAN.

d) damage caused by accidents.

e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

NOTE:

The products marked with this symbol apply to the European WEEE directive. This symbol indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste, but collected separately. Contact an authorized representative of the manufacturer for information for the decommissioning.

16.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.

Appendix A Specifications

A.1 Electrical Safety Classifications

According to the type of protection against electric shock	Internally powered equipment (for working) Class II equipment(for charging)
According to the degree of protection against electric shock	Type BF(Probe) Type CF(ECG module)
According to the degree of protection against harmful ingress of liquid	Whole device: IP67
According to the degree of safety of application in the presence of a flammable gas	Equipment not suitable for use in the presence of a flammable gas
According to the mode of operation	Continuous operation
According to the grade of EMC	CISPR 11 Group 1, Class B
Standards Compliance	EN 60601-1:2006/A2:2021 idt IEC60601-1:2005/A2:2020 EN 60601-1-2:2015/A1:2021 idt IEC60601-1-2:2014/A2:2020 EN 60601-2-37:2018/A1:2015 idt IEC 60601-2-37:2007/A1:2015

A.2 Power Supply

Operating Voltage	100 -240 V~
Operating Frequency	50 Hz/60 Hz

DC Input Current	5V⎓3A

A.3 Battery

Capacity	3800 mAh
Voltage	3.8V
Average working time	About 5 Hours (Work condition: 50% scanning, 50% frozen status)
Charging time	About 2.5 hours
Cycle life	About 500

A.4 Machine Specifications

Main unit dimensions	Nano C5 EXP: 158±1mm ×80±1mm×28±1mm Nano L12 EXP: 158±1mm×63±1mm×25±3mm
Net weight	Nano C5 EXP:245g Nano L12 EXP:205g

A.5 Technical Specifications

General Specifications	
Display Modes	B Mode/C Mode/PW Mode/M Mode
Measurement Packages	Abdomen, Obstetrics, Vascular, Cardiac,PICC
Wi-Fi Specifications	
Standard Conformance	802.11a,802.11n
Frequency Band	5GHz band
Modulation Technique	OFDM(BPSK,QPSK,16QAM,64QAM)

Typical Transmit Power(±2dBm)	5G Transmit 11a 54M: 13.0dBm 11n HT20 MCS7: 12.0dBm 11n HT40 MCS7: 12.0dBm
Wi-Fi Quality of Service	
Data rate	802.11a: up to 54 Mbps @ 5 Ghz 802.11n: up to 135 Mbps @ 5 Ghz
Data security	WPA2 encryption
Application-layer delay	No requirement. It's not used in real time.
Application-layer reliability	No requirement. Application failure will be notified to the user immediately.
System capacity	No more than one device will be allowed to connect with the ultrasound system.
System anti-interference	Can be coexistent with other Wi-Fi devices.
Network interruption alarm	Network interruption is notified by disconnection icon and failure in transmission is notified in Transfer Status window.
EMC test process	Wi-Fi function is not affected when the system is imposed with radiation interference complied with IEC60601-1-2:2014/A2:2020 standard.
ECG Specifications	
Patient Cable	AHA
Lead Mode	5-Lead: I, II, III, IV, V
AC Filter	50 Hz, 60 Hz
HR Range and Accuracy	Adult: 15 bpm to 300 bpm Pediatric: 15 bpm to 350 bpm

	Resolution: 1 bpm Accuracy: ±1% or 1 bpm, whichever is greater.
QRS Detection	Range: 40 ms~120 ms
	Amplitude:0.5 mV~5 mV
Patient Leakage Current	< 10 μA
Supply Voltage	USB-supply (5V, 300mA)

A.6 Operating, Storage and Transportation Environment

Operating Environment

Temperature	0 °C ~ +40 °C(+32 °F~+104 °F)
Relative humidity range	15% RH ~ 95% RH(non-condensing)
Atmospheric pressure range	62kPa ~ 106kPa

Storage and Transportation Environment

Temperature	-20 °C ~ +45 °C(-68 °F~+113 °F)
Relative humidity range	15% RH ~ 95% RH(non-condensing)
Atmospheric pressure range	62kPa ~ 106kPa

Environmental conditions of transport and storage between uses

Temperature	-40 °C ~ +70 °C(-104 °F~+158 °F)
Relative humidity range	≤90% RH(non-condensing)
Atmospheric pressure range	62kPa ~ 106kPa

The time required for the probe to warm from the minimum storage temperature between uses until it is ready for intended use is at least 30 minutes; the time required for the probe to cool from the maximum storage temperature between uses until it is ready for intended use is at least 30 minutes.

Permissible transient environmental operating conditions:

- Temperature range: -20 °C ~ +50 °C

- Device will function for a minimum of 20 minutes when placed in an environment with temperatures ranging from -20°C to 50°C after storage at room temperature (20 ± 2°C)
- Following storage at temperatures ranging from -20°C to +50°C, start the device within 10 minutes after being returned to room temperature (20 ± 2°C), function for a minimum of 20 minutes.

A.7 Probe Specifications

No.	Probe	Center Frequency
1	Nano C5 EXP	3.2MHz
3	Nano L12 EXP	7.7MHz

Appendix B Ultrasound Intensity and Safety

B.1 Ultrasound in Medicine

The use of diagnostic ultrasound has proved to be a valuable tool in medical practice. Given its known benefits for non-invasive investigations and medical diagnosis, including investigation of the human fetus, the question of clinical safety with regards to ultrasound intensity arises.

There is no easy answer to the question of safety surrounding the use of diagnostic ultrasound equipment. Application of the ALARA (As Low As Reasonably Achievable) principle serves as a rule-of-thumb that will help you to get reasonable results with the lowest possible ultrasonic output.

The American Institute of Ultrasound in Medicine (AIUM) states that given its track record of over 25 years of use and no confirmed biological effects on patients or instrument operators, the benefits of the prudent use of diagnostic ultrasound clearly outweigh any risks.

B.2 Ultrasound Safety and the ALARA Principle

Ultrasound waves dissipate energy in the form of heat and can therefore cause tissue warming. Although this effect is extremely low with Transcranial Doppler, it is important to know how to control and limit patient exposure. Major governing bodies in ultrasound have issued statements to the effect that there are no known adverse effects from the use of diagnostic ultrasound, however, exposure levels should always be limited to As Low As Reasonably Achievable (the ALARA principle).

Imaging Functions Affecting Acoustic Output

In addition to the level of voltage transmitted, adjustment of the following imaging functions and /or controls may affect the acoustic output.

Item	Affection
Probe	Acoustic output will be changed with the change of probe.
Imaging mode	There are different parameters applied in B mode, Color mode, M

	mode, and PW mode, so acoustic output will be changed with the change of among B mode, Color mode, M mode, and PW mode.
Field of view (scan angle or scan width)	Frame rate may be changed with the change of the scan angle or the scan width, and the acoustic output will also be changed.
Image depth	Pulse repeated frequency will be changed with the change of the image depth, and the acoustic output will be changed.
Focus number	Frame rate and focus position will be changed with the change of the focus number, and acoustic output will also be changed.
Focus position	Beam power level and the beam aperture will be changed with the change of the focus position, and acoustic output will also be changed.
Freeze	When freezing the system, it will stop transmitting ultrasonic wave.
Transmission power	The output of probe will be changed with the change of the transmission power, and acoustic output will be changed.
Multi-frequency	The character of the wave focus will be changed with the change of the frequency, and acoustic output will be changed.
Line density	The acoustic output will be changed with the change of the number of the scanning line (line density).
PRF	The acoustic power will be changed with the change of PRF.
Sample volume	The pulsed wave and the power will be changed with the change of the sample volume, and acoustic output will be changed.
Presets	Presets contain all the parameters above, so any change of the presetting will change acoustic output.
Power on/off	System will return to the default setting when powering on/off, and acoustic output will be changed.

B.3Explanation of MI/TI

B.3.1 MI (Mechanical Index)

Cavitations will be generated when ultrasound wave passes through and contacts tissues, resulting in instantaneous local overheating. This phenomenon is determined by acoustic pressure, spectrum, focus, transmission mode, and factors such as states and properties of the tissue and boundary. This mechanical bio effect is a threshold phenomenon that occurs when a certain level of ultrasound output is exceeded. The threshold is related to the type of tissue. Although no confirmed adverse mechanical effects on patients or mammals caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported, the threshold for cavitation is still undetermined. Generally speaking, the higher the acoustic pressure, the greater the potential for mechanical bio effects; the lower the acoustic frequency, the greater the potential for mechanical bio effects.

The AIUM and NEMA formulate mechanical index (MI) in order to indicate the potential for mechanical effects. The MI is defined as the ratio of the peak-rare factional acoustic pressure (should be calculated by tissue acoustic attenuation coefficient 0.3dB/cm-MHz) to the square root of acoustic frequency.

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

Where, $C_{MI} = 1\ \text{Mpa.MHz}^{-1/2}$, $P_{r,a}$ is theAttenuated Peak-rare-factional Acoustic Pressure and f_{awf} is Acoustic Working Frequency.

B.3.2 TI (Thermal Index)

Heating of tissues is caused by absorption of ultrasound when the ultrasound energy is applied. The temperature rise is determined by the acoustic intensity, exposed area and thermophysical properties of the tissue.

In order to indicate the potential for temperature rise caused by thermal effects, the AIUM and NEMA formulate thermal index (TI). It is defined as the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1°C.

According to different thermophysical properties of the tissue, TI is divided into three kinds: TIS,

TIB and TIC.

TIS (Soft **T**issue **T**hermal Index): It provides an estimate of potential temperature rise in soft or similar tissues.

TIB (Bone Thermal **I**ndex): **I**t provides an estimate of potential temperature rise when the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.

TIC (Cranial Bone Thermal **I**ndex): It provides an estimate of potential temperature rise in the cranial bones or superficial bones.

B.3.3 Display of MI/TI

The system provides real-time display of MI/TI values in the upper right part of the screen. The start point of MI value is 0.01, and the start point of TI value is 0.1.

The operator should monitor these values during examinations and keep the exposure time and output level at the minimum amounts needed for effective diagnosis.

The display precision is 0.1.

MI display error:

When measured MI≤0.5, the absolute display error≤0.25;

When measured MI > 0.5, the relative display error ≤±50%.

TI display error:

When measured TI ≤2.0, the absolute display error ≤1.0;

When measured TI > 2.0, the relative display error ≤±50%.

B.4Acoustic Output

B.4.1 Factors that Contribute to Uncertainty in the Output Display

A number of factors should be considered in display accuracy determination methods, such as:

- Probe variability
- System variability
- Measurement variability and accuracy

- The number of operating conditions of which the system is capable and the number tested in obtaining display accuracy results
- Whether display accuracy will be determined by specific combinations of system, mode, probe assembly and transmit patterns, or all allowed combinations of them
- Accuracy of system software MI and TI calculation algorithms.
- Engineering approximations for real-time calculations

B.4.2 Differences between Actual and Displayed MI/TI

Actually, many assumptions adopted in the process of measurement and calculations are relatively conservative. Over-estimation of actual in situ intensity exposure, for the majority of tissue paths, is made to the measurement and calculation process. For example, attenuation coefficient of 0.3 dB/cm-MHz, which is much lower than the actual value for most tissues of the body, is adopted. And conservative values of tissue characteristics are selected for use in TI models. Therefore, the display of MI and TI should be used as relative information to assist operator in prudent use of ultrasound system and implementation of ALARA principle, and the values should not be interpreted as the actual physical values in tissues or organs examined.

B.4.3 Measurement Uncertainty

Measurement uncertainties table

	Intensity	Pressure	Power	Center frequency	MI
Uncertainty(K=2)	±29.06%	±14.53%	±29.06%	±0.20%	±14.53%

B.4.4 Acoustic Power Default Settings

The ultrasound system allows direct control of acoustic power by the Power key on the touch screen. The range can be adjusted is 10% to 100%. The higher the acoustic power number, the greater the acoustic output.

The factory default settings of acoustic power is 100%. The default settings can be reconfigured by the operator through the Acoustic Power item on <**Utilities**>->**Set up**->**Preset** page. The ultrasound system switch to default settings upon power up, new patient, new exam or new probe.

B.4.5 Limits of Acoustic Output

In accordance with the FDA Track 3 requirements, the maximum acoustic output level from any probe in any operating mode is expected to fall below the limits as listed below.

FDA Maximum Acoustic Output Limits for Track 3(Attenuated Values)

Application	$I_{spta.3}$(mW/cm²)	MI	TIS/TIB/TIC
Regions(except eyes)	⩽720	⩽1.9	⩽6.0

B.5Operator Control Features

The possibility of producing mechanical/thermal biological effects can be influenced by three kinds of controls: Direct Controls, Indirect Controls, and Receiver Controls. The qualified operator may use the system controls to minimize the ultrasound output while acquiring necessary clinical information.

◆ Direct Controls

The acoustic output of the system can be controlled directly through the level of voltage transmitted. In this case, the maximum acoustic output never exceeds the limits in any mode of operation.

◆ Indirect Controls

The acoustic output of the system can be controlled indirectly through many imaging parameters, including imaging modes, field of view, line density, probe frequency, focus number/position, depth and pulse repetition frequency (PRF).

The imaging mode determines whether the ultrasound beam is scanning or non-scanning. Thermal bio effect is closely associated with B, M, PW and Color mode.

Acoustic attenuation of tissue is directly connected to probe frequency.

The focus number/position is related to active aperture of probe, beam width and frame rate.

The higher PRF (pulse repetition frequency), the more output pulses occur over a period of time.

◆ Receiver Controls

The receiver controls (such as gain, TGC, dynamic range and image processing), which are used

to improve image quality, have no effect on acoustic output. Thus these controls should be optimized before increasing acoustic output.

B.6Prudent Use Statement

Although no confirmed bio effects on patients caused by exposure from present diagnostic ultrasound equipment have ever been reported, the potential exists that such bio effects may be identified in the future. Therefore, the ultrasound should be used prudently. High levels of acoustic output and long exposure time should be avoided while acquiring necessary clinical information.

B.7References for Acoustic Output and Safety

1. ‘‘Bioeffects and Safety of Diagnostic Ultrasound’’ issued by AIUM in 1993
2. ‘‘Medical Ultrasound Safety’’ issued by AIUM in 1994
3. IEC 62359:2017, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.
4. "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Probes" issued in 2008.
5. IEC60601-2-37, Medical electrical equipment - Part 2-37:2007+AMD1:2015 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, International Electro technical Commission.
6. Roy C. Preston, David R. Bacon, and Robert A. Smith, Calibration of Medical Ultrasonic Equipment - Procedures and Accuracy Assessment, IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. 35, No. 2, page110, March 1988.

B.8Probe Acoustic Output Data

B.8.1 Acoustic Output Table for Nano C5 EXP

Acoustic Output Reporting Table for IEC60601-2-37

Transducer Model: Nano C5 EXP

Operating Mode: B

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximun Index Value		0.80	0.08		0.08		0.27
Index Component Value			0.08	0.08	0.08	0.08	
Acoustic Parameters	Pr,α at zMI /MPa	1.29					
	P /mW		11.13		11.13		11.13
	P_{1x1} /mW		8.90		8.90		
	Zs /cm			-			
	Zb /cm					-	
	zMI /cm	4.72					
	zpii,α /cm	4.72					
	fawf /MHz	2.64	1.95	1.95	1.95	1.95	1.95
Other Information	prr /Hz	424.00					
	srr /Hz	8.00					
	npps	1.00					
	Ipa, α at zpii, α /(W/cm²)	86.30					
	Ispta,α at zpii,α or	1.06					

	zsii,α/(mW/cm²)						
	Ispta at zpii or zsii /(mW/cm²)	1.11					
	Pr at zpii /MPa	1.63					
Operating control conditions	Probe Application	ABD	ABD		ABD		ABD
	B Frequency	2~4	H2~4		H2~4		H2~4
	B Depth Pos /mm	140.00	60.00		60.00		60.00
	B FOV	Full	Full		Full		Full
	B LineDensity	-	-		-		-

Acoustic Output Reporting Table for IEC60601-2-37

Transducer Model: Nano C5 EXP

Operating Mode:B+C

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximun Index Value		0.76	0.09		0.20		0.19
Index Component Value			0.04	0.09	0.04	0.20	
Acoustic Parameters	Pr,α at zMI /MPa	1.05					
	P /mW		16.44		16.44		16.44
	P1x1 /mW		4.42		4.42		
	Zs /cm			3.76			
	Zb /cm					3.76	
	zMI /cm	4.37					

	zpii,α /cm	4.37					
	fawf /MHz	1.92	1.92	1.92	1.92	1.92	1.92
Other Information	prr /Hz	125.00					
	srr /Hz	-					
	npps	1.00					
	Ipa, α at zpii, α /(W/cm2)	66.85					
	Ispta,α at zpii,α or zsii,α/(mW/cm2)	12.02					
	Ispta at zpii or zsii /(mW/cm2)	23.05					
	Pr at zpii /MPa	1.43					
Operating control conditions	Probe Application	ABD	ABD		ABD		ABD
	B Frequency	H2~4	H2~4		H2~4		H2~4
	B Depth Pos /mm	300.00	300.00		300.00		300.00
	B FOV	Full	Full		Full		Full
	B LineDensity	-	-		-		-
	M Speed	Med.	Med.		Med.		Med.

Acoustic Output Reporting Table for IEC60601-2-37

Transducer Model: Nano C5 EXP

Operating Mode:B+C

Index Label	MI	TIS		TIB		TIC
		At	Below	At	Below	

			Surface	Surface	Surface	Surface	
Maximun Index Value		0.77	0.11		0.11		0.32
Index Component Value			0.11	0.11	0.11	0.11	
Acoustic Parameters	Pr,α at zMI /MPa	1.23					
	P /mW		21.30		21.30		21.30
	P1x1 /mW		9.86		9.86		
	Zs /cm			-			
	Zb /cm					-	
	zMI /cm	1.25					
	zpii,α /cm	1.25					
	fawf /MHz	2.19	2.19	2.19	2.19	2.19	2.19
Other Information	prr /Hz	102.00					
	srr /Hz	6.00					
	npps	1.00					
	Ipa, α at zpii, α /(W/cm2)	102.51					
	Ispta,α at zpii,α or zsii,α/(mW/cm2)	2.38					
	Ispta at zpii or zsii /(mW/cm2)	1.94					
	Pr at zpii /MPa	1.77					
Operating control	Probe Application	ABD	ABD		ABD		ABD
	B Frequency	2~4	2~4		2~4		2~4
	B Depth Pos /mm	300.00	300.00		300.00		300.00

conditions	B FOV	Full	Full	Full	Full
	B LineDensity	-	-	-	-
	C Frequency	2.2MHz	2.2MHz	2.2MHz	2.2MHz
	C LineDensity	Low	Low	Low	Low
	C Prf /kHz	0.80	0.80	0.80	0.80

Acoustic Output Reporting Table for IEC60601-2-37

Transducer Model: Nano C5 EXP

Operating Mode:PW

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximun Index Value		0.67	0.40		1.71		1.35
Index Component Value			0.37	0.40	0.37	1.71	
Acoustic Parameters	Pr,α at zMI /MPa	0.95					
	P /mW		48.18		48.18		47.12
	P1x1 /mW		38.54		38.54		
	Zs /cm			1.00			
	Zb /cm					1.45	
	zMI /cm	1.50					
	zpii,α /cm	1.50					
	fawf /MHz	2.02	2.02	2.02	2.02	2.02	2.02
Other Information	prr /Hz	1800.00					
	srr /Hz	-					
	npps	1.00					

	Ipa, α at zpii, α /(W/cm2)	32.58					
	Ispta,α at zpii,α or zsii,α/(mW/cm2)	195.60					
	Ispta at zpii or zsii /(mW/cm2)	264.22					
	Pr at zpii /MPa	0.99					
Operating control conditions	Probe Application	ABD	ABD		ABD		ABD
	B Frequency	2~4	2~4		2~4		2~4
	B Depth Pos /mm	290.00	290.00		290.00		290.00
	B FOV	Full	Full		Full		Full
	B LineDensity	-	-		-		-
	PW Frequency	2.0MHz	2.0MHz		2.0MHz		2.0MHz
	PW svDepth /mm	40.00	40.00		40.00		35.00
	PW Prf /kHz	1.80	1.80		1.80		1.80

B.8.2 Acoustic Output Table for Nano L12EXP

Acoustic Output Reporting Table for IEC60601-2-37

Transducer Model: Nano L12EXP

Operating Mode: B

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximun Index Value		1.47	0.12		0.12		0.19
Index Component Value			0.12	0.12	0.12	0.12	
Acoustic Parameters	Pr,α at zMI /MPa	3.68					
	P /mW		3.93		3.93		4.29
	P1x1 /mW		3.93		3.93		
	Zs /cm			-			
	Zb /cm					-	
	zMI /cm	1.61					
	zpii,α /cm	1.61					
	fawf /MHz	6.25	6.25	6.25	6.25	6.25	5.10
Other Information	prr /Hz	1090.00					
	srr /Hz	10.00					
	npps	1.00					
	Ipa, α at zpii, α /(W/cm2)	529.82					
	Ispta,α at zpii,α or zsii,α/(mW/cm2)	3.38					

	Ispta at zpii or zsii /(mW/cm2)	2.82					
	Pr at zpii /MPa	5.06					
Operating control conditions	Probe Application	SMP	SMP		SMP		SMP
	B Frequency	5~8	5~8		5~8		H6~10
	B Depth Pos /mm	35.00	35.00		35.00		30.00
	B FOV	Full	Full		Full		Full
	B LineDensity	High	High		High		High

Acoustic Output Reporting Table for IEC60601-2-37

Transducer Model: Nano L12EXP

Operating Mode: M

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximun Index Value		0.89	0.04		0.06		0.06
Index Component Value			0.04	0.04	0.04	0.06	
Acoustic Parameters	Pr,α at zMI /MPa	1.98					
	P /mW		2.09		2.09		2.09
	P1x1 /mW		1.64		1.64		
	Zs /cm			0.55			
	Zb /cm					1.36	
	zMI /cm	1.36					
	zpii,α /cm	1.36					

	fawf /MHz	4.95	4.95	4.95	4.95	4.95	4.95
Other Information	prr /Hz	125.00					
	srr /Hz	-					
	npps	1.00					
	Ipa, α at zpii, α /(W/cm2)	169.32					
	Ispta,α at zpii,α or zsii,α/(mW/cm2)	11.07					
	Ispta at zpii or zsii /(mW/cm2)	14.40					
	Pr at zpii /MPa	2.02					
Operating control conditions	Probe Application	SMP	SMP		SMP		SMP
	B Frequency	H6~10	H6~10		H6~10		H6~10
	B Depth Pos /mm	100.00	100.00		100.00		100.00
	B FOV	Full	Full		Full		Full
	B LineDensity	High	High		High		High
	M Speed	Med.	Med.		Med.		Med.

Acoustic Output Reporting Table for IEC60601-2-37

Transducer Model: Nano L12EXP

Operating Mode: B+C

Index Label	MI	TIS		TIB		TIC
		At Surface	Below Surface	At Surface	Below Surface	

Maximun Index Value		0.95	0.09		0.09		0.12
Index Component Value			0.09	0.09	0.09	0.09	
Acoustic Parameters	Pr,α at zMI /MPa	2.29					
	P /mW		4.02		4.02		4.02
	P1x1 /mW		3.16		3.16		
	Zs /cm			-			
	Zb /cm					-	
	zMI /cm	1.34					
	zpii,α /cm	1.34					
	fawf /MHz	5.82	5.82	5.82	5.82	5.82	5.82
Other Information	prr /Hz	136.00					
	srr /Hz	8.00					
	npps	1.00					
	Ipa, α at zpii, α /(W/cm2)	366.15					
	Ispta,α at zpii,α or zsii,α/(mW/cm2)	4.38					
	Ispta at zpii or zsii /(mW/cm2)	1.50					
	Pr at zpii /MPa	2.94					
Operating control condition	Probe Application	SMP	SMP		SMP		SMP
	B Frequency	5~8	5~8		5~8		5~8
	B Depth Pos /mm	100.00	100.00		100.00		100.00
	B FOV	Full	Full		Full		Full

s	B LineDensity	High	High	High	High
	C Frequency	5.2MHz	5.2MHz	5.2MHz	5.2MHz
	C LineDensity	Low	Low	Low	Low
	C Prf /kHz	0.80	0.80	0.80	0.80

Acoustic Output Reporting Table for IEC60601-2-37

Transducer Model: Nano L12EXP

Operating Mode: PW

Index Label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximun Index Value		0.64	0.07		0.28		0.16
Index Component Value			0.07	0.06	0.07	0.28	
Acoustic Parameters	Pr,α at zMI /MPa	1.39					
	P /mW		2.88		2.88		2.83
	P1x1 /mW		2.88		2.88		
	Zs /cm			0.50			
	Zb /cm					1.36	
	zMI /cm	1.31					
	zpii,α /cm	1.31					
	fawf /MHz	4.81	4.81	4.81	4.81	4.81	4.81
Other Information	prr /Hz	1800.00					
	srr /Hz	-					
	npps	1.00					
	Ipa, α at zpii, α	76.73					

	/(W/cm2)						
	Ispta,α at zpii,α or zsii,α/(mW/cm2)	109.41					
	Ispta at zpii or zsii /(mW/cm2)	168.49					
	Pr at zpii /MPa	1.71					
Operating control conditions	Probe Application	SMP	SMP		SMP		SMP
	B Frequency	5~8	5~8		5~8		5~8
	B Depth Pos /mm	100.00	100.00		100.00		100.00
	B FOV	Full	Full		Full		Full
	B LineDensity	High	High		High		High
	PW Frequency	4.7MHz	4.7MHz		4.7MHz		4.7MHz
	PW svDepth /mm	22.50	25.00		25.00		22.50
	PW Prf /kHz	1.80	1.80		1.80		1.80

B.9Maximum Transducer Surface Temperature

Transducer Model	Surface Temperature of Transducer Contacting with TMM	Surface Temperature of Transducer Suspending in Still Air
Nano C5 EXP	42.51	41.10
Nano L12EXP	40.71	37.81

Uncertainty of temperature rise test:

Uncertainty of temperature rise test in simulate use: $\bar{X}$=7.73°C, U=0.26°C, K=2.

Uncertainty of temperature rise test in still air: $\bar{X}$=14.06°C, U=0.24°C, K=2.

The system limits patient contact temperature to 43°C, and the acoustic output below the maximum acoustic output limits for track 3. A power-protection circuit is used to prevent over-current conditions. If the power monitor protection circuit detects an over-current condition, then the drive current to the transducer is cut off promptly, preventing overheating of the transducer surface and limiting acoustic output. Validation of the power protection circuit is performed during normal operation. In single fault condition, when an abnormally large current or voltage is detected the system will automatically limit the current or voltage

Appendix C Order List

The following accessories are recommended for use on the system.

WARNING

Only accessories supplied or recommended by EDAN can be used, the probes of EDAN can be only used on EDAN's systems. Otherwise, the performance and electric shock protection cannot be guaranteed. If electrical or mechanical equipment from other companies need to be connected to the device, please contact EDAN or authorized representatives before connection.

Part Name	Part Number
BGK-017	01.52.434971
Adapter	01.21.064414
Power Plug, European Standard	01.12.032796
Power Plug, American Standard	01.12.032797
Power Plug, UK Standard	01.12.032798
Power Plug, Australian Standard	01.12.032799
Ultrasound Gel	01.57.078170
Trolley MT-320	83.63.560683
Portable Case	01.56.467664
ECG Module, European Standard	02.01.219671
ECG Module, American Standard	02.01.219672
ECG USB signal cable	01.13.038210
ECG cable, 5-lead, AHA, Defib, Snap	01.57.472509
ECG electrodes, disposable	01.57.471858

NOTE: The part name may vary depending on context, but the part number is constant.

Appendix D EMC Information

Electromagnetic Compatibility (EMC)

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

EMI Limitations

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

Possible EMI sources should be identified before the unit is installed.

Electrical and electronic equipment may produce EMI unintentionally due to one of the following defects:

- High frequency electrotome
- Transformer
- Defibrillator
- Wireless LAN equipment
- Medical lasers
- Scanners
- Cauterizing guns
- Computers
- Monitors
- Fans
- Gel warmers
- Microwave ovens
- Light dimmers

- Portable phones

The presence of a broadcast station or broadcast van may also cause interference.

If you find strong interference shows on the screen, please check the sources.

Electromagnetic emissions

Guidance and manufacture' s declaration – electromagnetic emission		
The system is intended for use in the electromagnetic environment specified below; The customer or the user of the system should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

NOTE:

The EMISSIONS characteristics of the system make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) the system might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic immunity

Guidance and manufacture' s declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that they are used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV for line to line ±2 kV for line to ground	±1 kV for line to line ±2 kV for line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity

Guidance and manufacture' s declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that they are used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 6Vrms[c] in ISM bands between 0.15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz See table 1	3 V_{rms} 150 kHz to 80 MHz 6Vrms[c] in ISM bands between 0.15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz Comply with table 1	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150KHz to 80MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P}/\mathrm{E}$ at RF wireless communications equipment bands (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 the system, including cables specified by the manufacturer).

			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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

[a] 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 system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

c The ISM (industrial, scientific and medical) bands between 0.15 MHz 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.

Table 1 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900;	Pulse modulation [b]	2	0.3	28
1845						

1970		DECT; LTE Band 1, 3, 4, 25; UMTS	217 Hz			
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended Separation Distances

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

output power of transmitter (W)	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be 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.

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

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

Appendix E Obstetrical References

Rempen:

Rempen A.‘‘Biometrie in der Frühgravidität’’(I. Trimenon) (Biometry in Early Pregnancy (1st Trimester)).’’ Der Frauenarzt 32:425，1991

表格 GS，**Rempen**

GS mm	MA	+/- 2SD	GS mm	MA	+/- 2SD	GS mm	MA	+/- 2SD	GS mm	MA	+/- 2SD
02.0	4w6d	12	20.0	6w6d	12	38.0	9w1d	12	56.0	11w4d	12
03.0	5w0d	12	21.0	7w0d	12	39.0	9w2d	12	57.0	11w5d	12
04.0	5w1d	12	22.0	7w1d	12	40.0	9w3d	12	58.0	11w6d	12
05.0	5w1d	12	23.0	7w2d	12	41.0	9w4d	12	59.0	12w0d	12
06.0	5w2d	12	24.0	7w3d	12	42.0	9w5d	12	60.0	12w1d	12
07.0	5w3d	12	25.0	7w4d	12	43.0	9w6d	12	61.0	12w2d	12
08.0	5w4d	12	26.0	7w4d	12	44.0	9w6d	12	62.0	12w3d	12
09.0	5w5d	12	27.0	7w5d	12	45.0	10w0d	12	63.0	12w4d	12
10.0	5w5d	12	28.0	7w6d	12	46.0	10w1d	12	64.0	12w5d	12
11.0	5w6d	12	29.0	8w0d	12	47.0	10w2d	12	65.0	12w6d	12
12.0	6w0d	12	30.0	8w1d	12	48.0	10w3d	12	66.0	13w0d	12
13.0	6w1d	12	31.0	8w2d	12	49.0	10w4d	12	67.0	13w1d	12
14.0	6w2d	12	32.0	8w3d	12	50.0	10w5d	12	68.0	13w2d	12
15.0	6w2d	12	33.0	8w3d	12	51.0	10w6d	12	69.0	13w3d	12
16.0	6w3d	12	34.0	8w4d	12	52.0	11w0d	12	70.0	13w4d	12
17.0	6w4d	12	35.0	8w5d	12	53.0	11w1d	12	71.0	13w5d	12
18.0	6w5d	12	36.0	8w6d	12	54.0	11w2d	12	72.0	14w0d	12
19.0	6w6d	12	37.0	9w0d	12	55.0	11w3d	12	73.0	14w1d	12

P/N: 01.54.459796
MPN: 01.54.45979601002

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FCC Statement

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.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

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.

Specific Absorption Rate (SAR) information:
This Nano Series Diagnostic Ultrasound Systen meets the government's requirements for exposure to radio waves. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health. FCC RF Exposure Information and Statement the SAR limit of USA (FCC) is 1.6 W/kg averaged over one gram of tissue. Device types: Nano Series Diagnostic Ultrasound Systen has also been tested against this SAR limit. This device was tested for typical body-worn operations with the back of the Nano Series Diagnostic Ultrasound Systen kept 0mm from the body. To maintain compliance with FCC RF exposure requirements, use accessories that maintain an 0mm separation distance between the user's body and the back of the Nano Series Diagnostic Ultrasound Systen. The use of belt clips, holsters and similar accessories should not contain metallic components in its assembly. The use of accessories that do not satisfy these requirements may not comply with FCC RF exposure requirements, and should be avoided.