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.

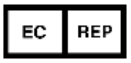
Federal Communications Commission (FCC) Statement:

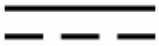
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 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 Marking
11.		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.

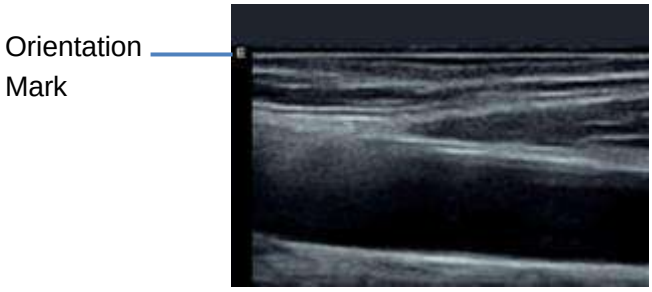


Figure 3-3 Image Orientation Mark

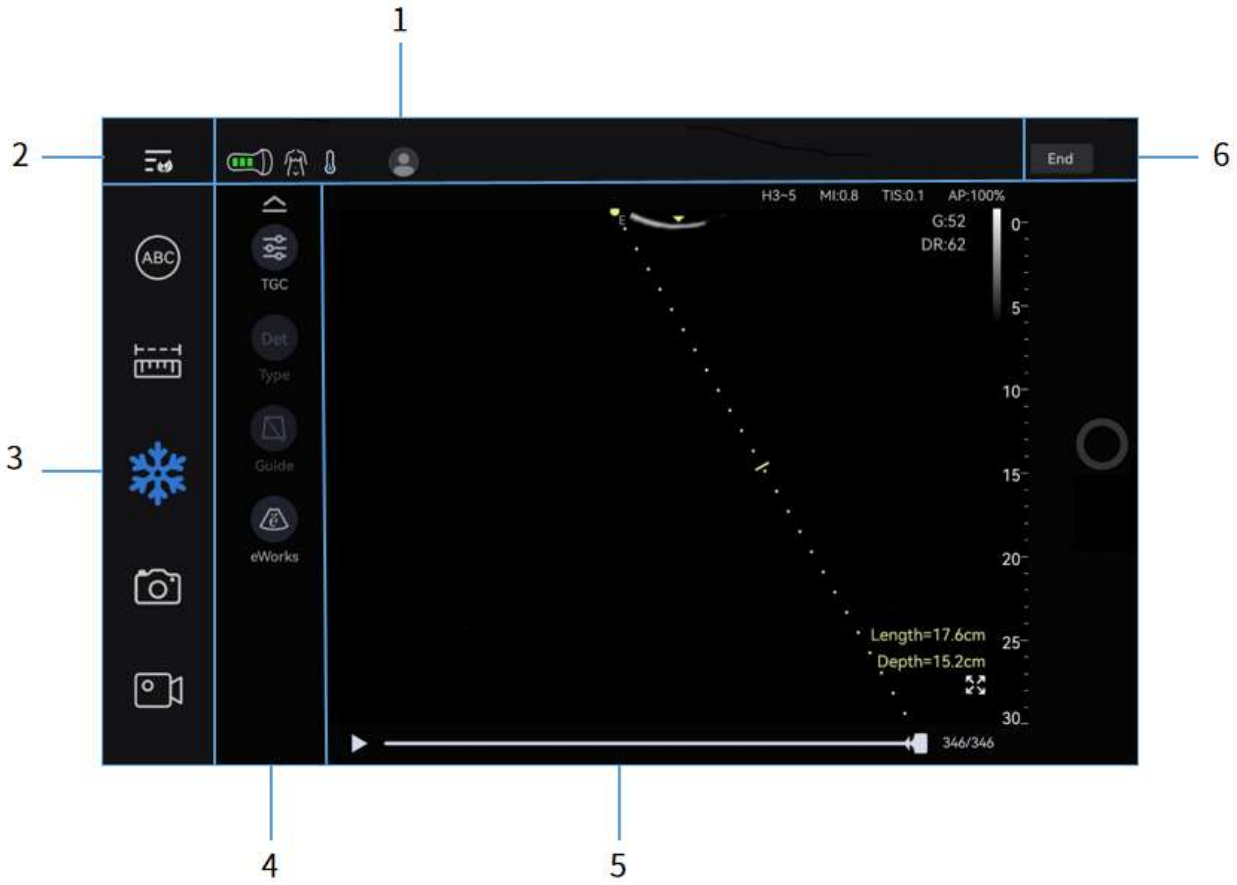
- **Proper Use of Probes**

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:

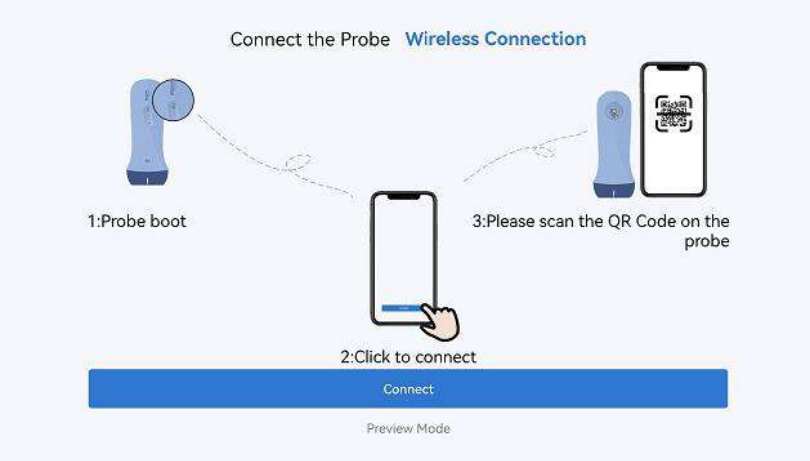
1. Switch on your display device and download the Nano App for free from the EDAN website<www.edan.com> or Google Play Store.
2. Install the Nano App on the device.
3. Set the Allow Nano permission on the display device to allow the Nano App to access photos, media and files on the portable device.

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.

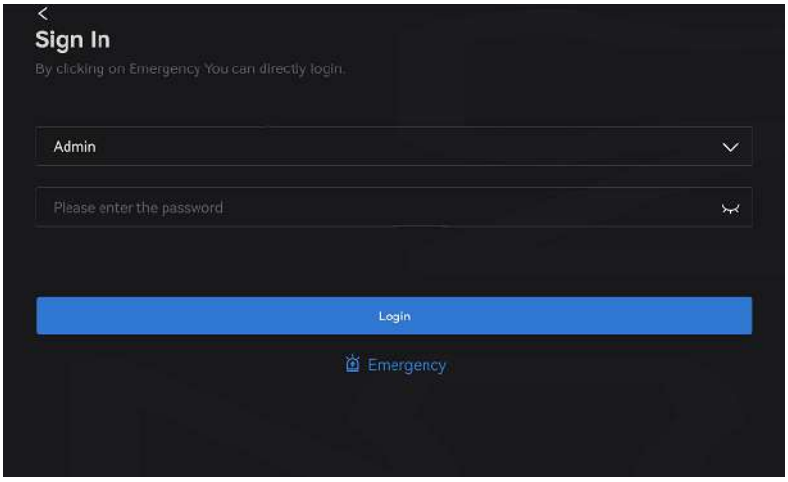


3.3.3. System Login

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.

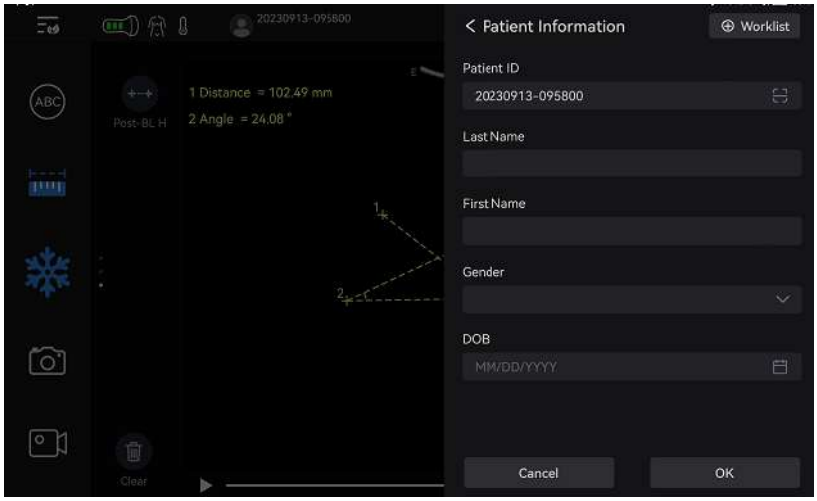
- To end an exam:

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.

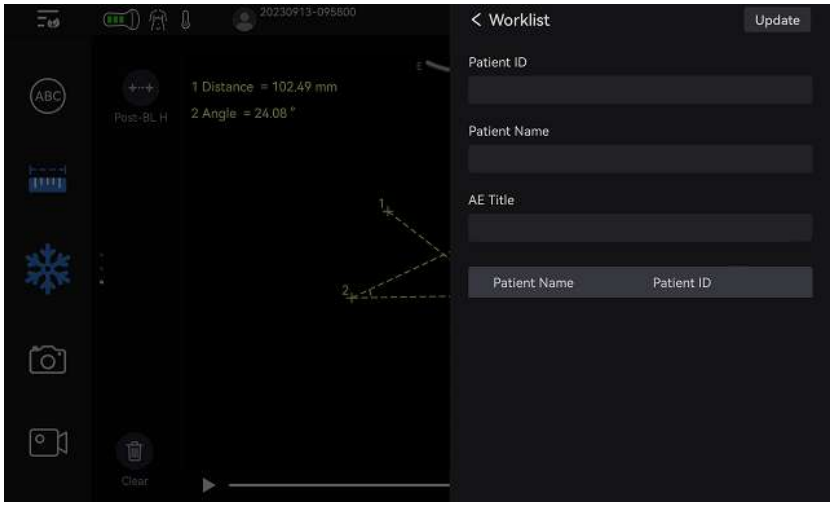


In the Patient Information Page, you can edit the Patient ID, Last Name, First Name, Gender, and Date of Birth.

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

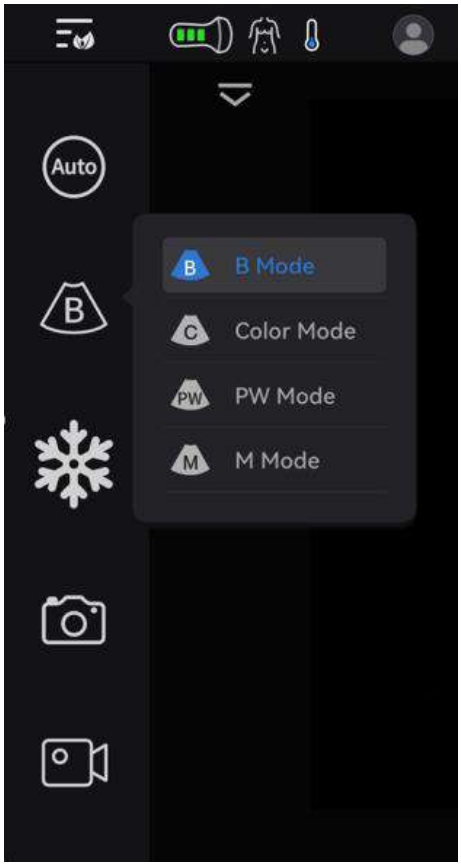
Connectivity Utility (See 10.6). Typing any text in the Patient Name, ID or AE title fields will filter the list to exams that contain the entered text.

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).

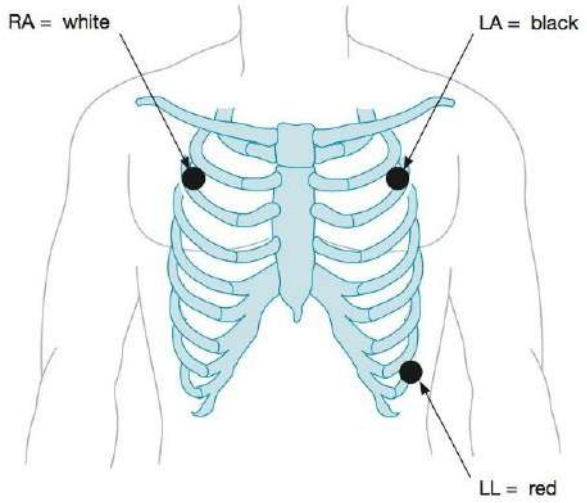


Figure 5-9 3-lead Placement of AHA Standard

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

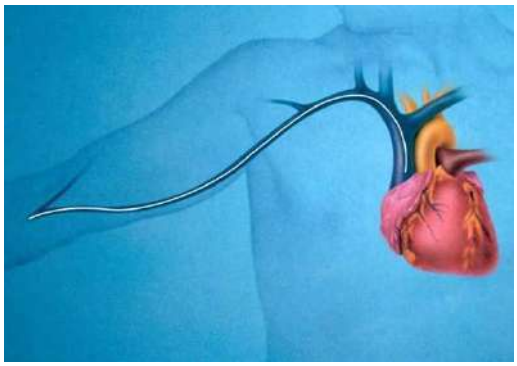
on the ECG waveform indicating the temporal position of ultrasound image in relation to the ECG waveform.

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.

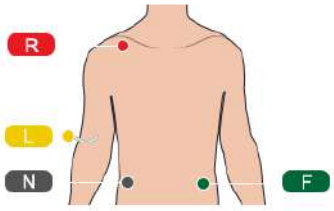
4. Measure the diameter of the blood vessels to confirm the catheter size. Activate the measurement function, click on the blood vessel diameter measurement item, manually measure the vessel's diameter using the distance tool or use the automatic tool to measure it. Then choose the appropriate catheter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