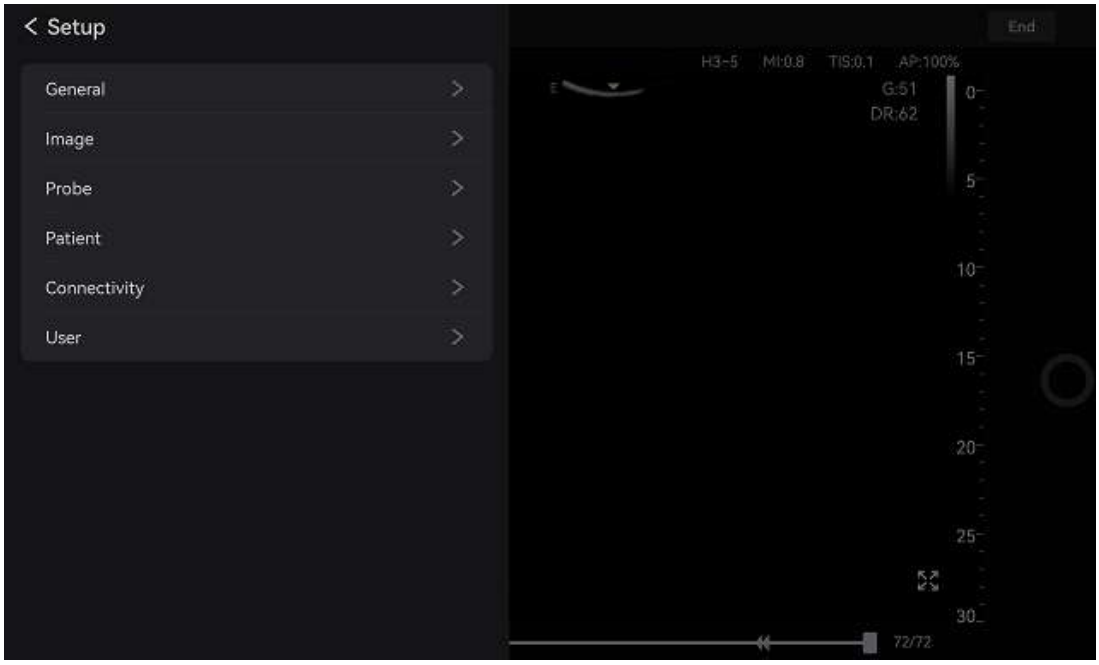
Query/Retrieve:

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

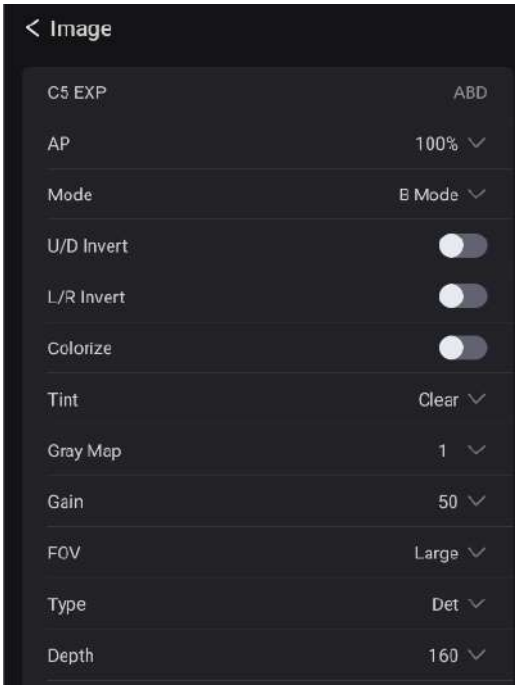
	Pain Nephrology PICC	clinical applications.

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.

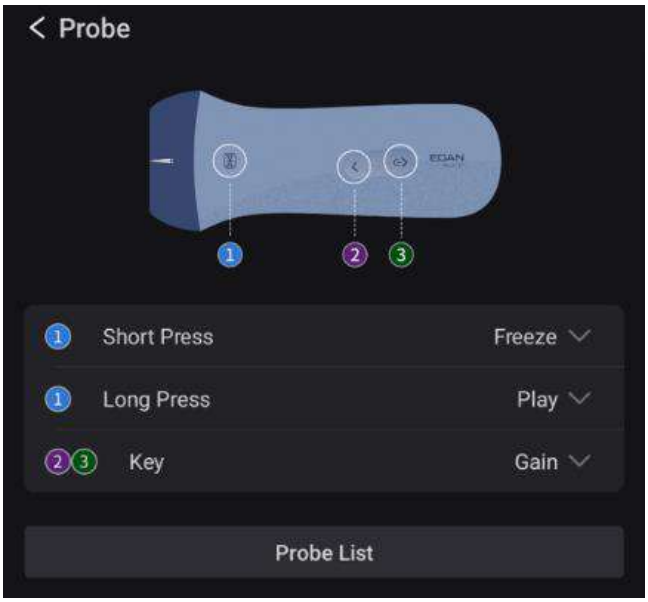
Image Preset:

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:

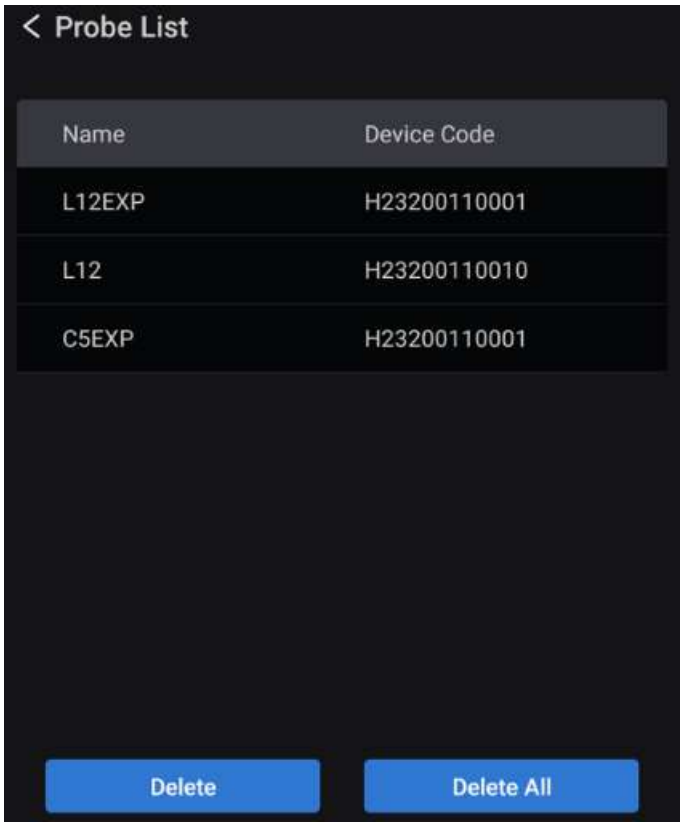


There are three buttons on the body of the Nano Probe, namely buttons ①, ② and ③. User can define the functions of the three buttons for quick operation according to their needs.

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.

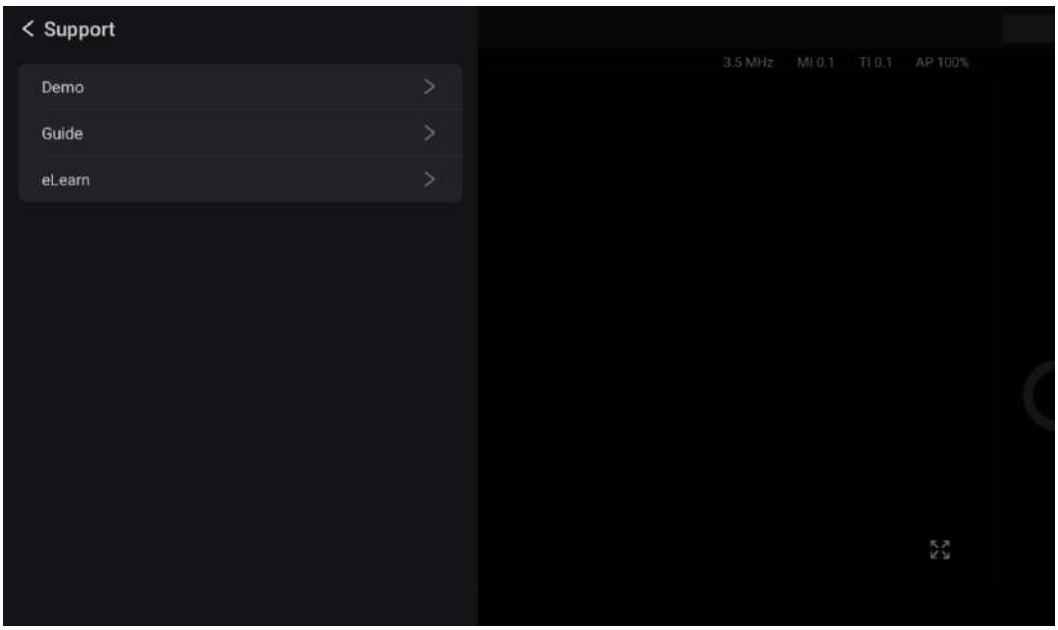
Note: Only the administrator has the permission to add users and change passwords of other users. Operators do not have the permission to add users and can only change their own passwords.

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

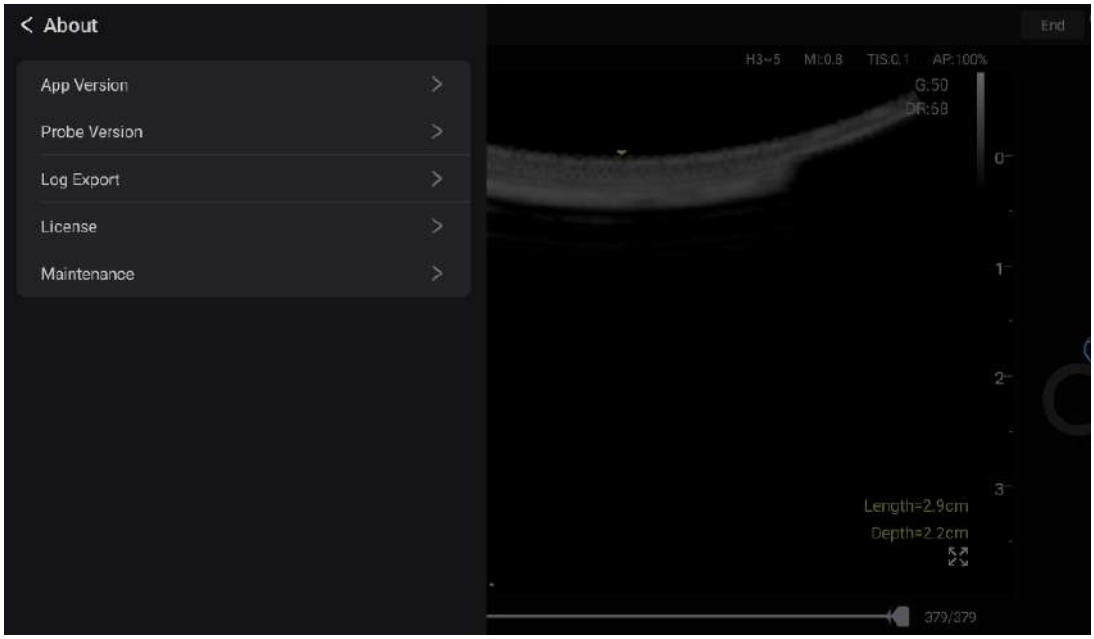
Press to access the instruction guide for basic scanning and for nerve block.

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, $C_{MI} = 1\ \mathrm{Mpa.MHz}^{-1/2}$, $P_{r,a}$ 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 Tissue Thermal Index): It provides an estimate of potential temperature rise in soft or similar tissues.

TIB (Bone Thermal Index): It 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 Index): 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/cm^2)	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.6 Prudent 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.7 References 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/cm^2)	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.