NUSONO

Handheld Ultrasound Scanner

User Manual

English Version B

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NuroData

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1. About the Device

“NUSONO” Handheld Ultrasound Scanner

1.1 Pre-use Information

Before applying the following information, you must thoroughly read the user manual and follow the instructions. The operator must obtain operational qualifications in compliance with local regulations, review, and clinical audit procedures, and strictly follow the warnings and prohibitions to ensure safe operation. Users should be familiar with the functions, settings, and accessories of this product as much as possible. Some specific functions of this product may not be executable. This product can only be obtained in countries where it is allowed to be on the market. Please contact your local Nurodata representative.

The NUSONO Handheld Ultrasound Scanner C35 series (hereinafter referred to as the NUSONO ultrasound system or system), in addition to the ultrasound transducer probe device (hereinafter referred to as ‘NUSONO Ultrasound Device’, the ultrasound device or device), also needs to be paired with a supported mobile device, which can be used after establishing a connection and registering an account on NURODATA Cloud. The connection method can be through the built-in Wi-Fi connection of the mobile device. The detailed operations will be explained in the following chapters. This product may not be able to perform some specific functions due to the difference of mobile devices.

This manual does not contain the training and clinical procedures of ultrasound scanning. This manual is applicable to medical professionals who operate and maintain the NUSONO Handheld Ultrasound Scanner. This product involves the collection, processing, and use of personal data, and should comply with the relevant regulations related to the management of personal health information (such as HIPAA in the United States) and be regulated by the personal data protection laws.

1.1.1 Product Models

The models of the NUSONO Ultrasound Device are: NUSONO-C35 (Convex), NUSONO-L75 (Linear) , NUSONO-P25 (Phased array).

1.1.2 Product Components

Ultrasound Device Model	Components
NUSONO-C35	Scanner Model: C35, USB Type-C Charging Cable, Adaptor, Charging Dock. Download the operating software for this product through an Android or iOS mobile device.
NUSONO-L75	Scanner Model: L75, USB Type-C Charging Cable, Adaptor, Charging Dock. Download the operating software for this product through an Android or iOS mobile device.
NUSONO-P25	Scanner Model: P25, USB Type-C Charging Cable, Adaptor, Charging Dock. Download the operating software for this product through an Android or iOS mobile device.

*Adaptor Model: QH-Z21-C15W-01

1.1.3 Product Specifications

Types of Ultrasound Device	Convex Ultrasound Device NUSONO-C35	Center Frequency	Nom. 3.5 ± 0.5 MHz
		Operating Frequency	3.0 - 4.0 MHz
		Curvature Radius	60 mm
		Field of View	54.57 Degree
		Depth	4.0 - 18.5 cm
		Imaging Modes	B mode, M mode, Color Doppler mode, Power Doppler mode
		Total Weight	235.0 g
		Dimensions	154.2 X 72.5 X 37.6 mm (L X W X H)
	Linear Ultrasound Device NUSONO-L75	Center Frequency	Nom . 7.5 ± 0.5 MHz
		Operating Frequency	6.0 - 7.5 MHz
		Field of View	N/A
		Depth	1.0 - 8.0 cm
		Imaging Modes	B mode, M mode, Color Doppler mode,Power Doppler mode

		Total Weight	222.0 g
		Dimensions	154.5 X 72.5 X 37.6 mm (L X W X H)
	Phased Array Ultrasound Device NUSONO-P25	Center Frequency	Nom. 3.0 ± 0.5 MHz
		Operating Frequency	2.5 - 3.5 MHz
		Field of View	N/A
		Depth	4.0 - 18.5 cm
		Imaging Modes	B mode, M mode, Color Doppler mode, Power Doppler mode
		Total Weight	223.5 g
		Dimensions	154.2 X 72.5 X 37.6 mm (L X W X H)
Biometric Measurement		Ellipse Measurement Tool (Unit: mm): Under the same conditions of measuring the circumference, the measurement error is less than 10%. Distance Measurement Tool (Unit: mm): Under the same conditions of measuring the linear distance, the measurement error is less than 5%.	
Transmission method		Wi-Fi : IEEE 802.11ac	
Battery capacity		3.7V, 2200mAh	
Image files		JPG, DICOM	
IP Ratings（Ingress Protection Ratings）		IP67	
Operating environment		Temperature: 0℃ ~ 35℃ Humidity: 30%~80% Atmospheric pressure: 700hPa-1060hPa	
Transportation and Storage environment		Temperature: -5℃ ~ 50℃ Humidity: 10% ~ 90% Atmospheric pressure: 700hPa-1060hPa	
Minimum specifications for mobile devices		Android	Android OS 12 ROM : 16GB CPU : 1.5GHz, dual-core RAM : 2G Remaining device storage capacity greater than 5GB Supports Wi-Fi 802.11 ac Minimum mobile device/tablet screen resolution is 1024 X 800 pixels

	iOS	iOS 14 Remaining device storage capacity greater than 5GB Supports Wi-Fi 802.11ac Minimum mobile device/tablet screen resolution is 1280 X 800 pixels

⚠	CAUTION: Using devices with screens that are too small may not provide the resolution required to inspect image details.

1.1.4 Supply and Accessories

The accessories of NUSONO Handheld Ultrasound Scanner includes:

1. One carrying bag
2. One gel dispenser with cap
3. One probe protecting cap of the corresponding probe

If you need to order this product and its accessories, please visit the Nurodata website (www.nurodata.com) or contact the manufacturer. The manufacturer's name/address is as follows:

NURODATA INC. (Address: **5 F.-3, No. 6-2, Sec. 2, Shengyi Rd., Hsinchu Science Park, Zhubei City, Hsinchu County 302058, Taiwan, R.O.C.**)
entrusted:
ACME PORTABLE CORP. (Address: **5 F., No. 25, Wuquan 3rd Rd., Wugu Dist., New Taipei City 24891, Taiwan**) to manufacture

Adaptor manufacturer: Shenzhen Qihang Chuangshi Technology co., Ltd

Medical Device US Sales Representative: ()
Medical Device US Sales Representative Address:: ()
Medical Device US Sales Representative Telephone:

NURODATA INC.
Telephone: +886-3– 6588- 233 (Hsinchu County, Taiwan)
Fax : +886-3– 6588- 232 (Hsinchu County, Taiwan)
e-mail: service@nurodata.com
Website: www.nurodata.com

1.1.5 Operational Principle

The device uses a transducer to generate high-frequency sound waves that are emitted into the body tissues. As the sound waves pass through the body and

encounter boundaries between different tissues (such as between muscles and bones), some of the sound waves are reflected back to the transducer. Sensors detect the returning reflected sound waves (echoes), and create an image of the internal body structure by using the time of return and the strength of the echo. The ultrasound images are then transmitted in real-time via Wi-Fi to a mobile device and displayed on the screen of the mobile device, allowing healthcare professionals to interpret these images for diagnosing various medical conditions.

1.1.6 Updates and Upgrades

Nurodata is committed to product innovation and continuous improvement. When there are hardware or software improvement and optimization contents, Nurodata will release upgrade information and the product models, software versions and other related information that need to be upgraded. When the NOSONO APP automatically releases software optimization or major updates, users please refer to **[2.3.2 Software Updates and Ultrasound Device Firmware Updates]** to perform version updates. Failure to update may result in some new functions or problem fixes not being performed. Please confirm that the NUSONO APP and the NUSONO ultrasound device are the latest versions.

1.1.7 Warranty

The lifecycle of this ultrasound device is 5 years, with a warranty service period of 2 years. Please contact your local authorized representative or email:

service@nurodata.com in case of any malfunction or repair needs.

1.2 Indications For Use

The NUSONO Handheld Ultrasound Scanner is a portable and software-based ultrasound imaging system, indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:
NUSONO-C35
Fetal, Abdominal, Pediatric, Urology, Gynecology, Lung.
NUSONO-L75
Pediatric, Small Organ (Thyroid, Prostate, Scrotum, Breast), Musculoskeletal (Superficial and Conventional), Peripheral Vessel, Others (Carotid), Lung
NUSONO-P25
Fetal, Abdominal, Pediatric, Urology, Gynecology, Cardiac (adult and pediatric), Lung

The system provides diagnostic ultrasound imaging in B mode, M mode, Color Doppler mode, Power Doppler mode and combine mode (B+M, B+CD, B+PD), intended for use in environments where healthcare is provided by trained healthcare professionals. The environments where the system can be used include physician offices, clinics, hospitals, and clinical point of care for diagnosis of patients except environments where intensity of electromagnetic disturbances is high.

Indications For Use Table (FDA)
DEVICE NAME: NUSONO-C35/ NUSONO-L75/NUSONO-P25
INDICATIONS FOR USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

NUSONO Handheld Ultrasound Scanner - C35

Clinical Application		**Mode of Operation**					
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**Combined(Specify)**	**Other***
Ophthalmic	Ophthalmic						

Fetal Imaging & Other	Fetal	N	N	N	N	B+M; B+CD; B+PD;	
	Abdominal	N	N	N	N	B+M; B+CD; B+PD;	
	Intra-operative (Abdominal organs & vascular)						
	Laparoscopic						
	Pediatric	N	N	N	N	B+M; B+CD; B+PD;	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esophageal (non-Cardiac)						
	Musculo-skeletal (Conventional)						
	Musculo-skeletal (Superficial)						
	Intravascular						
	Other (Urology, Gynecology)	N	N	N	N	B+M; B+CD; B+PD;	
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Intravascular (Cardiac)						
	Trans-esophageal (Cardiac)						
	Intra-cardiac						
	Other (specify)						
Peripheral Vessel	Peripheral Vessel						
	Other (Carotid)						
N = new indication							

Clinical Application		Mode of Operation					
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**Combined(Specify)**	**Other***
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Abdominal organs & vascular)						
	Laparoscopic						
	Pediatric	N	N	N	N	B+M; B+CD; B+PD;	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	N	N	N	N	B+M; B+CD; B+PD;	
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esophageal (non-Cardiac)						
	Musculo-skeletal (Conventional)	N	N	N	N	B+M; B+CD; B+PD;	
	Musculo-skeletal (Superficial)	N	N	N	N	B+M; B+CD; B+PD;	
	Intravascular						
	Other (Urology, Gynecology)						
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Intravascular (Cardiac)						
	Trans-esophageal (Cardiac)						
	Intra-cardiac						
	Other (specify)						
Peripheral Vessel	Peripheral Vessel	N	N	N	N	B+M; B+CD; B+PD;	

	Other (Carotid)	N	N	N	N	B+M; B+CD; B+PD;	
N = new indication							

NUSONO Handheld Ultrasound Scanner - P25

Clinical Application		**Mode of Operation**					
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**Color Doppler**	**Power Doppler**	**Combined(Specify)**	**Other***
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal	N	N	N	N	B+M; B+CD; B+PD;	
	Abdominal	N	N	N	N	B+M; B+CD; B+PD;	
	Intra-operative (Abdominal organs & vascular)						
	Laparoscopic						
	Pediatric	N	N	N	N	B+M; B+CD; B+PD;	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esophageal (non-Cardiac)						
	Musculo-skeletal (Conventional)						
	Musculo-skeletal (Superficial)						
	Intravascular						
	Other (Urology, Gynecology)	N	N	N	N	B+M; B+CD; B+PD;	
Cardiac	Cardiac Adult	N	N	N	N	B+M; B+CD; B+PD;	
	Cardiac Pediatric	N	N	N	N	B+M; B+CD; B+PD;	
	Intravascular (Cardiac)						

	Trans-esophageal (Cardiac)						
	Intra-cardiac						
	Other (specify)						
Peripheral Vessel	Peripheral Vessel						
	Other (Carotid)						
N = new indication							

⚠	WARNING: Please ensure that you have received sufficient and appropriate safety and effective operation training before using this system for any application. If you are unsure of your ability to operate the system safely and effectively, do not use the system. Operating the system without proper and sufficient training may lead to fatal or other serious injuries to personnel.
⚠	WARNING: Image quality and diagnosis are the responsibility of the user. Before conducting clinical assessments and analyses, please review the relevant data generated by the NUSONO ultrasound system. When performing measurements, ensure an adequate amount of data is concurrently confirmed.
⚠	WARNING: The United States federal law strictly stipulates that this product can only be ordered by physicians.

1.2.1 Contraindication

DO NOT use this product in the following situations, as the resulting images may be inaccurate:

- When a patient has undergone surgery, the cellular composition of the test may have changed, and the measurement of density may deviate or change.
- Patients with implants or other foreign objects that may produce artifacts.
- Use during surgery, including use in invasive surgical incisions or drilling.
- Use in ophthalmology or any application. This will cause ultrasound penetration through the eye and will pose a serious risk.
- Use in body cavities, such as placing the ultrasound device into a patient's body organs or cavities.
- Use in performing scans on open wounds.
- Emergency situations outside of professional medical care settings, such as

transporting a patient to a professional medical care facility or during transit from one professional medical care facility to another.

Except for the above contraindications, there is no restriction on the patient.

1.2.2 Intended Patient Population

The NUSONO Ultrasound System is intended for use for diagnostic ultrasound imaging and fluid flow analysis of anatomical structures and fluids of adult and pediatric patients.

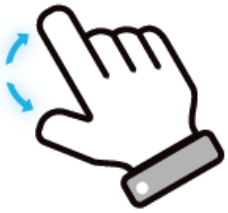
1.3 Document Definitions

1.3.1 Document Terminology

- System, ultrasound system or NUSONO Ultrasound System: The combination of the NUSONO Ultrasound Device, NUSONO APP, and NURODATA Cloud platform, which is collectively referred to as the ultrasound system.
- Device, ultrasound device or NUSONO Ultrasound Device: Refers to the ultrasound transducer probe device that comes with the NUSONO Handheld Ultrasound Scanner.
- Mobile Device: Refers to a device with Wi-Fi and internet communication capabilities, commonly known as a handheld device, mobile terminal, or mobile communication terminal.

1.3.2 Touch Gestures

Gesture	Name	Description
	Tap	Touch the control item with your finger.
	Swipe	Touch the screen with your finger to quickly move left, right, up, and down.

	Drag	Touch and move your finger on the screen without lifting your finger.
	Pinch	Touch the screen with two fingers and then move your fingers closer together.
	Spread	Touch the screen with two fingers and then move them apart.

1.3.3 Icons

Icon	Description
⚠	Warning or Precaution

1.3.4 Labels

The following symbols apply to NUSONO Ultrasound System , all in accordance with the latest standards: ISO 7000, ISO 7010, IEC 60417, (EN) ISO 15223-1, and EN 15986

Label Icons	Description
Rx Only	This medical device is restricted by the U.S. Federal law to sell by or on the order of a licensed physician.

	UL — Component recognition mark of Underwriters Laboratories of Canada and the United States
	FCC — Tested in accordance with the requirements of the Federal Communications Commission.
	CE mark indicating that the product complies with the relevant European Union directives.
	Isolated Patient Connection (Compliant with IEC 60601-1/GB 9706.1 for BF Type Applied Parts)
	Refer to User Manual - Indicates that the user needs to read the user manual
	Read Instruction Manual Before Operation - Advises users to review the instruction manual before starting operations
	Complies with EU Directives 90/385/EEC, 93/42/EEC, and 98/79/EC for Medical Device Manufacturers
	Manufacturing Date of Medical Equipment
	Do Not Dispose of Indiscriminately. Follow Local Regulations for Recycling.
	WEEE Directive - Waste Electrical and Electronic Equipment If marked, it indicates components of this equipment may contain lead or mercury, and these substances must be recycled or disposed of in accordance with local, state, or federal laws. |
REF	Manufacturer's Catalog Number for Identifying Medical Equipment

SN	Manufacturer's Serial Number for Identifying Specific Medical Equipment
MD	Medical Device
LOT	Batch Code Used by the Manufacturer to Identify Batches or Lot
NON STERILE	Medical Equipment Not Sterilized
	Do Not Use If Damaged or Opened.
	Keep Dry - Avoid Moisture Exposure
	Fragile.
UP	This Side Up
	Handle with Care

1.4 Safety

Before using the NUSONO ultrasound system, be sure to read the user manual carefully. The user manual applies to the ultrasound device and the NUSONO APP, and NURODATA Cloud website.

The combination of the ultrasound device, NUSONO APP, and mobile device is considered a medical device. This device is only provided for use by fully trained medical professionals in a healthcare environment.

The NUSONO ultrasound system can perform non-invasive scans of the patient's physiological structures, providing ultrasound imaging and measurement data. However, this imaging and data content will not reduce your clinical judgment and procedural responsibilities. The installation, use and operation of this system must fully comply with the intended use of this system, and must also fully follow the procedures and operations in the user manual attached to this product.

Nurodata shall not be liable in whole or in part for any damage or injury caused by the use of the NUSONO ultrasound device and related systems for purposes other than those for which Nurodata is intended or for purposes other than those declared by Nurodata, or for failure to fully comply with the procedures and operations in the instruction manual of this product.

Please read the following warnings and precautions carefully. For any serious safety incidents related to the ultrasound system, please report to Nurodata and the competent authorities of the country where the user and the patient are located.

This section only contains general safety information. Other safety information applicable to specific tasks will be explained in the task procedures.

⚠	"WARNING" emphasizes critical information to ensure the operator's, and the patient's safety.
⚠	"CAUTION" emphasizes ways in which the product may be damaged and thus void the warranty or service contract, or may result in the loss of patient or system data.
⚠	WARNING: Before using the system for any application, you must thoroughly read, understand and familiarize yourself with all the safety information, safety procedures, and emergency steps contained in 1.4 "Safety" section. Operating the system without the correct concept of safe use can result in fatal or other serious personal injury.
⚠	WARNING: If there is a known or suspected defect, or improper calibration of ANY part of the system, DO NOT use the system until repairs are completed. Operating a system with defective or improperly functioning components may pose risks to you and the patients.

⚠	WARNING: If the ultrasound device casing is found to be damaged, it is recommended to stop using the device. A damaged casing indicates that the device may be vulnerable to physical security breaches, potentially allowing attackers to exploit system vulnerabilities. This could pose a risk to your data and the security of your workplace network.
⚠	WARNING: DO NOT use the system for any purpose other than those for which it is intended or for purposes other than those stated by NUSONO. Nurodata or its agents may be exempted from all or part of any damage, harm, or injury.
⚠	WARNING: No modification of this equipment is allowed.
⚠	CAUTION: This ultrasound device is non-sterile and should be disinfected and cleaned according to the maintenance and cleaning methods in Section 5 before use.

1.4.1 Basic Safety

The ultrasound device is an energy conversion device that heats up at different rates depending on the time and environmental conditions of use. Please note the following when operating this device:

- Ensure that the ultrasound device is adequately cooled after any scanning session.
- If you take the ultrasound device out of a 25°C (77°F) environment, you can scan continuously for 15 minutes.
- It is recommended to limit the use of this device for a continuous scanning session of 15 minutes. If the scanning time is too long, the ultrasound device may overheat and cause operation interruption. The cooling time after powering off the device is approximately 30 minutes, depending on the temperature of the ultrasound device in the previous ultrasound scan session and the ambient temperature.
- If you place the ultrasound device in an environment above 35°C (95°F), please cool it down to the operating temperature before turning on the power.
- According to international standard IEC 60601-2-37, the temperature of the radiating surface of the transducer assembly shall not exceed 43 °C (109°F) during the test. If the temperature of the ultrasound device is higher than 43°C (109°F), the operation of the device will be temporarily suspended. Please wait for it to cool down to the operating temperature before turning on the power again.

- If the ultrasound device detects that the internal temperature is too high, the device will automatically cut off the power and can only be operated after 12 minutes.
- If the temperature of the ultrasound device is lower than 0°C (32°F), it may cause damage due to internal condensation. Please wait for the ultrasound device to warm up to the operating temperature. The time required for the device to warm up to the operating temperature depends on the exposure time of the ultrasound device to the ambient.
- It is required to wait for the ultrasound device to return to the operating temperature from a storage environment temperature of -5°C (23°F) or 50°C (122°F) to an operating temperature of 25°C (77°F). The time required for the device to return to the operating temperature depends on the exposure time of the device to the ambient.
- The operating temperature of the metal heat sink on the case may be higher than 56°C (132°F). Please DO NOT touch them during the use of the ultrasound device.
- The maximum temperature of the charging dock and charger may be higher than 43°C (109°F). Please DO NOT touch them for an extended period of time when the ultrasound device is charging.

⚠	WARNING: Do not directly use this ultrasound device in an environment above 35°C or below 0°C.
⚠	WARNING: When the temperature of this ultrasound device exceeds 43°C (109°F), the operation of the device will be temporarily suspended. Do not use it or touch the patient.

1.4.2 Electrical Appliance Safety

- To avoid the risk of electric shock, make sure to check the ultrasound device (including the front-end transducer) before use. Check the contact surface, case, and charging cable. If the contact surface is broken, has gaps or cracks, the case is damaged, or the charging cable is worn, do not use it.

- The ultrasound device is an Applied Part (AP) and complies with the IEC 60601-1 standard.

- When using, keep the ultrasound device and charging dock away from fire sources. Do not use or damage the ultrasound device and charging dock in flammable gas or anesthetic environments. Please do not use or damage the ultrasound device and the charging dock in any improper manner.

- Electrostatic discharge (ESD) may occur in dry or low-humidity environments,

such as spaces with heating or air conditioning units. In certain low-humidity conditions, ESD may accumulate on your body or an object, such as a peripheral device, and then discharge onto another object. Please use anti-static mats and workbench mats as much as possible. Touch metal grounded objects regularly to remove the static electricity that may accumulate on you.

- When operating the ultrasound device, pay attention to ESD prevention measures. Common ESD prevention measures include using anti-static mats, using electrostatic eliminators, and using anti-static mats on workbenches.

⚠	WARNING: Only the ultrasound device is waterproof. Unless specific cleaning instructions indicate otherwise, do not immerse other accessories in any liquid.
⚠	WARNING: DO NOT use corrosive cleaners, acetone, butanone, paint thinners, or strong solvents to wipe the ultrasound device and accessories.

1.4.3 Battery Safety

- DO NOT use this device while it is being charged in order to prevent the risk of burns due to overheating of the battery or device.

- This device is only allowed to charge with the originally-equipped charging cable, adaptor and charging dock provided by Nurodata. DO NOT use accessories and methods which are not supplied or recommended by Nurodata, such as connecting the ultrasound device with a USB Type-C cable to an unsupported device like laptops for charging. Other accessories may adversely affect electromagnetic compatibility (EMC).

- The battery is located inside the device. If the battery cannot be charged, has leakage, is deformed or emits an unusual odor, or if there are any abnormalities during use or storage, please stop using and immediately contact your sales representative.

⚠	WARNING: DO NOT charge the battery on a vehicle such as an airplane or an ambulance. When charging a battery in an emergency machine or an ambulance, the battery charger power supply may interfere with the electronic system of an aircraft or car, causing them to malfunction and cause control,

	instrumentation, and communication system failures.

1.4.4 Equipment Safety

- When this device is connected to additional peripheral mobile devices, it must be considered as a medical electrical system. The user must follow the provisions of IEC 60601-1 and test the system for compliance. For any questions, please contact your local sales representative.

- Before each use, please carefully check all parts of the ultrasound device (including the transducer) for any cracks or damage and any gaps or other damage that compromise the integrity of the ultrasound device. If there is obvious and unacceptable corrosion, discoloration, pitting, or seal rupture, please inform the Nurodata local sales representative and stop using it immediately.

⚠	WARNING: The ultrasound device accessories have small, detachable parts that pose a choking hazard, and the ultrasound device charging cable poses a strangulation hazard. DO NOT leave children unattended near the system.
⚠	WARNING: Artifacts caused by reflection or other reasons may result in a puncture location different from the actual one, so please make sure the image is correct when performing a puncture examination.
⚠	WARNING: In puncture-related examinations, the fine needle may bend. The actual positioning needs to be verified through echoes. Do not perform a puncture examination if you cannot see the puncture needle.
⚠	CAUTION: This device does not require a periodic calibration, but it is still recommended to test your device weekly or monthly. If you suspect abnormal test results, please stop using and contact the authorized sales representative.
⚠	WARNING: Repeated ultrasound scans may cause Carpal Tunnel Syndrome and related symptoms in the user. When performing scans, please keep joints in a stable position with balanced posture and avoid gripping the device excessively hard. It is recommended to take breaks during continuous scanning, so that the relevant body parts can recover from repetitive movements and incorrect postures.

1.4.5 Electromagnetic safety

- DO NOT expose the device to strong electrostatic fields or magnetic fields, as this may result in inaccurate results.

- DO NOT place the device near other devices or stack the device with other devices as this may cause abnormal operation.

- Electrosurgical Unit (ESU) and other high-frequency surgical devices generate electromagnetic fields or currents with radiation frequencies that affect the patient. The ultrasound imaging frequency happens to be within this frequency range. Because its radio frequency is in the same range as the ultrasound system image, the ultrasound circuit is subject to be interfered by other radiation waves, and the image may be subject to severe noise interference.

- To avoid burn risk, DO NOT use this device with Electrosurgical Unit (ESU) and high-frequency devices. If the neutral electrode connection of the electrosurgical unit and high-frequency surgical equipment is defective, there may be a risk of burns.

- If other medical electronic diagnostic devices, such as pacemakers emitting high-frequency electronic signals, are used at the same time as the normal use of the ultrasound device, there is a possibility of interference with the operation of that device. Even if the probability of interference is low, it is essential to be aware of this potential risk. If such interference is found, please stop using the device immediately.

- If this product is used in an electromagnetic field environment, it may cause temporary degradation of the ultrasound image quality. When the electromagnetic interference factors are present or intermittent, you must pay extra attention when using this product continuously. If electromagnetic interference (EMI) is caused, you may need to find another place to place the product. If interference occurs frequently, re-examine the operating environment of the product and identify the possible sources of radiation. The radiation waves may come from electronic devices in the same room or adjacent rooms, such as mobile phones and pagers, which can also generate these radiation waves. Nearby radios, televisions, or microwave emitting devices may also generate radiation waves.

- Any part of this device should be kept at least 30 cm (12 inches) away from wireless communication devices, such as networking devices, mobile phones, and walkie-talkies, otherwise it may cause erroneous display or inaccurate results.

- The possible factors of electromagnetic interference with this system include: the operating mode of the device, the image control settings, the type and intensity of the electromagnetic waves, etc. If electromagnetic interference

occurs or happens intermittently, please use this system with caution.

- Household electronic devices such as humidifiers, heaters or microwaves, etc. may interfere with the device. Please ensure that the operating environment meets the conditions described in the detailed information on electromagnetic radiation in this user manual. Operating the system in an environment that does not meet these conditions may reduce system performance.

⚠	WARNING: This device is not intended for use in residential environments where it may not provide adequate protection against radio reception in such environments.
⚠	WARNING: Do not bring this device into a Magnetic Resonance Imaging (MRI) room or place it in an environment with a magnetic resonance imaging scanner, as this device is not a safe device compatible with the principles of nuclear magnetic resonance and should avoid the risks associated with magnetic attraction.

1.4.6 Wi-Fi Safety

Malfunction or degradation in function may occur due to interference of Wi-Fi function, reducing Wi-Fi signal strength and further contributing to delayed or blocked transmission.

※ *Due to the fact that medical products are non implantable medical devices, according to the FDA Electromagnetic Compatibility (EMC) of Medical Devices Guidance, electromagnetic interference testing is required to test the basic safety of IEC 60601-1-2 and IEC /TS 60601-4-2. After confirm the consensus standards related to EMC according to the FDA consensus standard database（http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm), it was found that the following items need to be tested.*

EMC testing type	Wireless coexistence
Phenomena	Wireless coexistence
Test item	Wireless coexistence
Reference Standard(s)	IEEE ANSI USEMCSC C63.27-2021
Is it applicable	Applicable
Testing requirements	Category C Tier2 Interference source：

	WIFI LTE Separation distance： 1M 0.1M 0.01M
Recognized Consensus Standards: Medical Devices?	Yes (IEEE ANSI USEMCSC C63.27-2021)

Wireless pass/fail criteria:
1. Bit/packet error rate < 1%
2. Throughput ≥ 44.3Mbps
3. Latency ≤ 80ms (average 22.13ms)

Possible interference:
1. Other 5GHz equipment: such as wireless router, wireless TV, wireless camera, etc. These devices also use the 5GHz frequency, which may cause signal conflicts with your wireless network.
2. Electronic equipment: such as microwave oven, TV, mobile phone, computer, etc. These everyday electronic devices may also emit 5GHz signals, which can cause interference with wireless networks.
3. Metal obstacles: metal objects such as metal walls, metal furniture, metal doors, etc. These objects can block the transmission of 5GHz signals and affect the stability of wireless networks.
4. Buildings: such as buildings, walls, cement floors, etc. These buildings may block or reflect 5GHz signals, resulting in reduced signal strength or blocked transmission.
5. Other factors: Adjacent wireless networks, interference sources and weather conditions may also interfere with 5GHz wireless networks.

1.4.7 Biological Safety

Biological effects refer to the biological changes caused by the interaction between ultrasound waves and the scanned tissues. The Thermal Index (TI) and Mechanical Index (MI) are usually controlled according to safety standards to ensure the safety of imaging and examination processes.

Depending on the characteristics and the sensitivity of scanned tissues, ultrasound waves have the potential to cause significant biological effects. To date, human ultrasound examinations have been performed on a large number of patients, including those with sensitive tissues such as growing fetuses, and there has been no record of serious adverse reactions. Operators of ultrasound devices must also take these potential biological effects into account when examining overall device operational safety. There are two basic indices on the

output display of the ultrasound device: the Mechanical Index (MI) and Thermal Index (TI) of the ultrasound device system.

Thermal Index (TI) :
When ultrasound waves pass through tissues, its energy is absorbed and converted into heat, which heats up the tissue, and it is also the main cause of ultrasound energy attenuation. TI is used to assess the extent to which ultrasound affects the thermal effects of tissues. A higher TI indicates more energy in the ultrasound pulse, potentially causing a more pronounced thermal effect on tissues. A higher TI value may cause tissue heating, and TI should follow the ALARA principle

- Soft Tissue Thermal Index (TIS): TIS shows how much the temperature is likely to rise within the homogeneous soft tissues at or near focal point as the ultrasound beam passes through the soft tissue or body fluid.
- Bone Thermal Index (TIB): TIB shows how much the bone in or near the focal point is likely to heat up as the ultrasound beam passes through the bone.
- Cranial Bone Thermal Index (TIC): TIC shows how much the skull in or near the focal point is likely to heat up as the ultrasound beam passes through the skull.

Mechanical Index (MI) :
MI is a parameter that describes the mechanical effects of ultrasound waves on tissues. The main focus is on other biological effects such as cavitation erosion, which are caused by the mechanical properties of ultrasound. MI values are usually positive, and higher MI values may have a greater impact on the mechanical effects of the tissue, so MI should follow the ALARA principle.

Ultrasound Spatial Peak Temporal Average Intensity (ISPTA)
ISPTA refers to the time-averaged intensity at the spatial peak of the ultrasound beam and is related to the amplitude of the excitation signal, the number of excitation cycles, and the pulse repetition frequency (PRF). In general, as the signal amplitude increases, the number of excitation cycles rises, and the pulse repetition frequency becomes higher, the ISPTA will be larger. Taking into account the attenuation effect of tissues on sound pressure, correction is made using an attenuation coefficient of 0.3 dB/cm-MHz and is represented by the symbol Ispta.3. This device regulates the settings of amplitude and excitation cycles of the excitation signal to ensure compliance with IEC 62359 (Ispta.3 ≤ 720 mW/cm^2), but it is not displayed on the screen.

Acoustic Output Limitations: (Limitations for non-ophthalmic applications)

- Ispta.3 ≤ 720 mW/cm^2
- MI ≤ 1.9

- TI ≤ 6.0

For more information, please refer to the Acoustic Output Report for NUSONO Handheld Ultrasound Scanner.

1.4.8 As Low As Reasonably Achievable Principle (ALARA)

- This product complies with the principle of "As Low as Reasonably Achievable" (ALARA) for radiation exposure. The indicators displayed on the ultrasound device provide essential information, offering users guidance on adhering to the ALARA principle.
- Use with caution when performing scans and follow the ALARA (As Low As Reasonably Achievable) principle. Select the correct part of the application for the required examination procedures, and use the human body parts with lower limits of acoustic power output for some applications, and ensure that it is maintained during the entire examination procedure.
- The ALARA principle defines the guidelines for the use of ultrasound examination. Decisions on the reasonability should be made by qualified personnel, and it should be noted that any standardized rules cannot fully explain the correct response for each situation. When capturing images, users should pay attention to reducing the ultrasound exposure to minimize the biological effects of ultrasound. Since the threshold of the biological effects of ultrasound examination has not been determined, the total energy transmitted to the patient must be controlled by the ultrasound device operator, and a balance must be achieved between the exposure time and image quality while ensuring the image quality and limiting the exposure time.
- The ultrasound device operators should understand the characteristics of the imaging modes used, decide the imaging mode to be used according to the required information, and follow the ALARA principle. The ultrasound device frequency, system settings, scanning techniques and operational experience enable ultrasound device operators to meet the standards defined by the ALARA principle. The acoustic power output in the final analysis will be determined by the operator.
- The numerical values depend on the following factors: patient type, examination type, medical record, difficulty in obtaining applicable diagnostic information and the effect of the scanning surface temperature on the local temperature of the patient's body. Users should limit the scanning of patients with the lowest index in the shortest time to obtain acceptable examination results.
- When the index is high, be sure to reduce the effect as much as possible, such as: limit the exposure time. Although a higher index does not mean that biological effects will definitely occur, caution is still required.
- No specific criteria can inform the ultrasound operators how to make the correct response for each environment. Qualified operators can improve the image quality and minimize output intensity. The following variables can

affect the output display index used to implement the ALARA principle:
    - Index value
    - Body size
    - Bone position relative to the focal point
    - Ultrasound attenuation in the body
    - Ultrasound exposure time. This is a means directly controlled by the user.
- This ultrasound device does not have direct control over the output, so the ultrasound operator must control the exposure time and utilize the scanning technique to implement the ALARA principle.

1.4.9 Fire and Electrical Safety

- Using the product in an unintended environment may cause fire or explosion. Fire regulations for this type of medical area should be fully complied with when using this product.
- In the event of an electrical or chemical fire, only use the fire extinguishers designated for such purposes. Using water or other liquids in an electrical fire can be fatal or cause other serious injuries. Before attempting to extinguish a fire, try to isolate the product from other electrical devices under safe circumstances to reduce the risk of electric shock.

⚠	WARNING: In the event of an electrical or chemical fire, only use the fire extinguishers designated for such purposes.

1.4.10 Recycle & Disposal

If you no longer wish to use the NUSONO APP, please follow the procedures outlined in **[2.3.3 Delete User Account]** and **[2.3.4 Uninstall NUSONO Application]** to remove the personal account and related diagnostic records. Ensure that you are aware of and adhere to local regulations before disposing of these records, exercising caution in handling the management and protection requirements of patient health information carefully, as once the records are deleted, they cannot be recovered.

Nurodata is committed to protecting the natural environment through appropriate support, maintenance, and training, assisting in ensuring the continued safe and effective use of this system. The design and manufacture of the NUSONO ultrasound device comply with relevant environmental protection guidelines. When users follow the correct procedures for operating and maintaining the device, the NUSONO ultrasound device poses no harm to the environment. However, if proper disposal procedures are not followed, the NUSONO ultrasound device and the materials inside the battery may pose risks

to the environment. When the lifespan of the NUSONO ultrasound device ends, users should dispose of the device and accessories in compliance with local, state, provincial, and/or national regulations. Before its disposal, the ultrasound device should undergo cleaning and disinfection procedures to ensure no contaminants are present (please refer to **Section 5. Maintenance and Cleaning**).

Waste Electrical and Electronic Equipment Directive (WEEE)

This symbol indicates that the device falls within the scope of the Waste Electrical and Electronic Equipment Directive (WEEE) 2002/96/EEC and corresponding national regulations implementing such directives. At the end of the device's lifespan, it must not be disposed of as unclassified waste and must be separately collected at authorized disposal facilities. For assistance with recycling, please contact local authorized representatives and authorized disposal companies.

⚠	WARNING: This device (including the adaptor, charging cable and charging dock) contains materials that may cause environmental pollution, such as lead or other potentially harmful substances.
⚠	WARNING: DO NOT dispose of this device (including the adaptor, charging cable and charging dock) and any parts with industrial or household waste.
⚠	WARNING: This device is a medical electrical product that contains internal batteries. It should be disposed of or recycled according to environmental and medical waste disposal methods, following local regulations for handling discarded devices.
⚠	WARNING: DO NOT disassemble, puncture, or incinerate the battery.
⚠	WARNING: To prevent fire hazards, do not short-circuit the battery terminals.

2. Product Use

This section provides a brief explanation and introduction to the NUSONO Handheld Ultrasound Scanner.

2.1 Mobile Device Requirements

Nurodata cannot guarantee that the NUSONO APP will operate on all mobile devices, as there are required minimum device specifications. Please make sure that the device you are operating meets the following conditions:

- Storage space of 512MB and above (additional space is required for patient data storage)
- Color display
- Touchscreen
- Operating system versions: iOS 14, iOS 15 / Android OS 12
- Minimum resolution: 1280 x 800 Pixels/ 1024 x 800 Pixels
- Equipped with audio broadcasting/receiving functionality (speaker/microphone)
- Equipped with front and rear cameras
- Wi-Fi and mobile network connectivity (Wi-Fi 802.11ac, LTE, or 5G Data Transmission)

2.2 Precautions

⚠	WARNING: Installing the NUSONO APP on mobile devices that do not meet the required minimum specifications may result in unexpected image quality or possible misdiagnosis.
⚠	CAUTION: Disclosure of protected information on this system to anyone other than the patient and authority without the consent of the patient and the patient's authorized representative on this system is prohibited. However, it does not prohibit the patient from voluntarily sharing health information.

⚠	CAUTION: NURODATA Cloud, in compliance with the requirements of the United States federal government's Health Insurance Portability and Accountability Act (HIPAA), will retain patient information files for six years.
⚠	WARNING: The responsibility for diagnosing after interpreting the quality image lies with the user of this ultrasound system. Please confirm the data used for analysis and diagnosis when using and ensure sufficient space, time, and data for measurement methods to use.
⚠	WARNING: Users must comply with the security policy of the medical institution to set up this device and network service system. Notifications and alerts from third-party applications may interfere with the examinations during operation.
⚠	CAUTION: Users should follow the relevant security regulations for mobile devices to prevent unauthorized access to unencrypted patient data.

2.3 System Settings

2.3.1 NUSONO APP Download & Installation

To operate the NUSONO ultrasound device, the NUSONO APP must be used. Depending on your mobile device's operating system, you can download the latest certified version of the application from the respective service platform.

- **For Android Users**:
  Download the NUSONO APP from the Google Play Store and install it on your Android device. Users must grant permissions for location access, camera, microphone, folders, and screen recording to ensure the application functions properly.
- **For iOS Users**:
  Download the NUSONO APP from the App Store and install it on your iOS device. Users must grant permissions for location access, camera, microphone, folders, and screen recording to ensure the application functions properly.

⚠	WARNING: The NUSONO Ultrasound Device can only be connected to the NUSONO APP via Wi-Fi and this ultrasound device can only be operated through the NUSONO APP for scanning. If the ultrasound device is connected in other ways, it may cause damage to the device or make it impossible to scan.

2.3.2 Software Updates and Ultrasound Device Firmware Updates

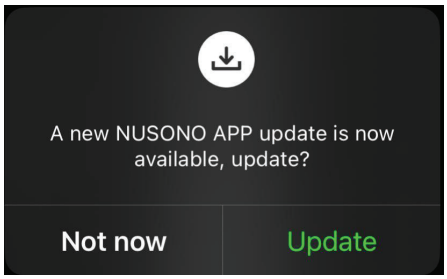
Nurodata continuously develops new technologies and features to enhance service quality. This process may involve adding or removing functionalities, adjusting service limitations, and introducing new services or retiring old ones. Below is an explanation of the update management and notification mechanisms for the NUSONO APP and ultrasound device firmware:

- When a new version of the NUSONO APP is available, updates can only be downloaded through the supported mobile platform stores (App Store or Google Play Store). If your device is set to auto-update apps, the NUSONO APP will automatically update when a new version is available.
- In addition to platform store notifications, Nurodata will provide update information through the official website and via email notifications from **no-reply@nurodata.com**.
- When the NUSONO APP is connected to the ultrasound device, it will automatically check if a firmware update is required. If an update is needed, the app will initiate the firmware update process.
- Ensure that the NUSONO APP is launched with active mobile data or an external network connection. The app will automatically check for updates and display a pop-up window to guide users to update through the platform store.
- If Nurodata determines that an update addresses significant security vulnerabilities or improves malware detection and prevention, users will receive notifications about the new version or feature release.
- Users requesting the SBOM can contact **service@nurodata.com**. After identity verification, the SBOM will be provided to authorized users. The SBOM includes the following details: Vendor Name, Software Package Name, Package Version, End-of-Support Date, Known Vulnerabilities.
- Download and Update Information:
    - iOS:

      Open the App Store, use

      to search for "NUSONO," and check the NUSONO APP page for the latest official version information under "What’s New ".

When opening the NUSONO APP, an update prompt will appear. Clicking the "Update" button will redirect you to the App Store to install the latest version.

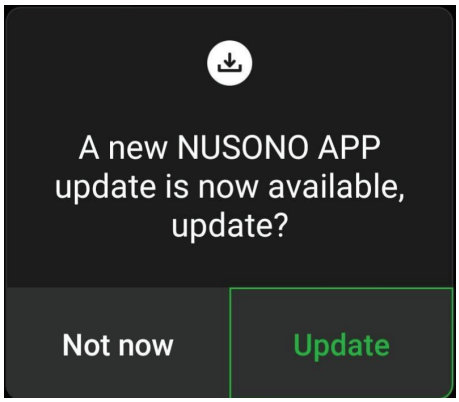


- Android OS:

  Open the Google Play Store, use

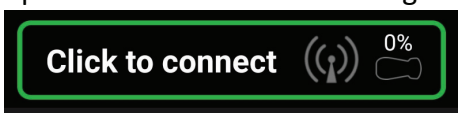
to search for "NUSONO,"and click the arrow (→) next to "What's new" on the app page to view the official latest version information.

When opening the NUSONO APP, an update prompt will appear. Clicking the "Update" button will redirect you to the Google Play Store to install the latest version.

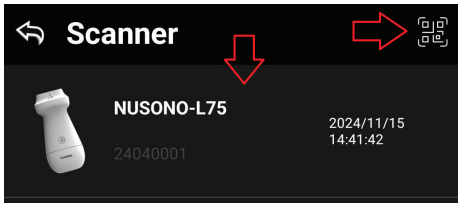


- Ultrasound Device Firmware Updates
  After updating the NUSONO APP, reconnect the app to the ultrasound device to check for firmware updates.

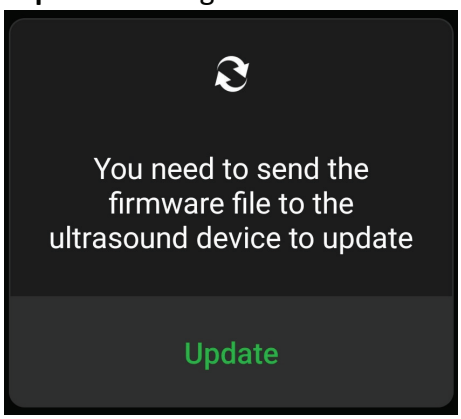
  - Open the **Information Bar** and go to the ultrasound device list page.



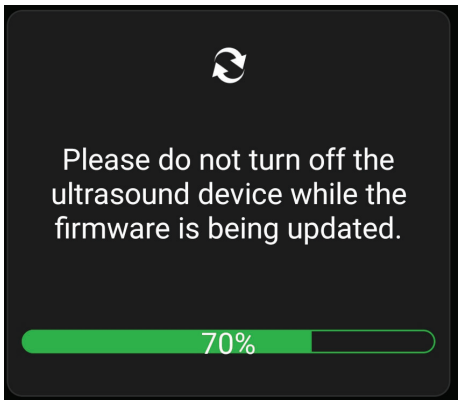
- Scan the QR code on the back of the ultrasound device or click the serial number in the connection list to connect.



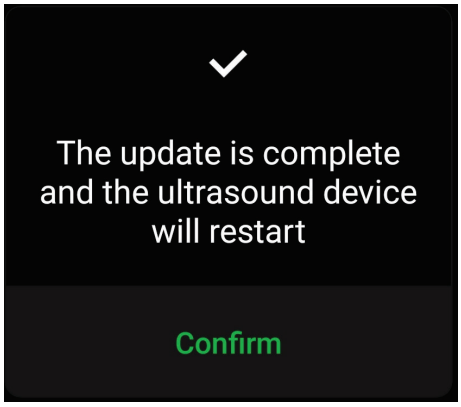
- If a firmware update is needed, the system will display a prompt. Click **"Update"** to begin.



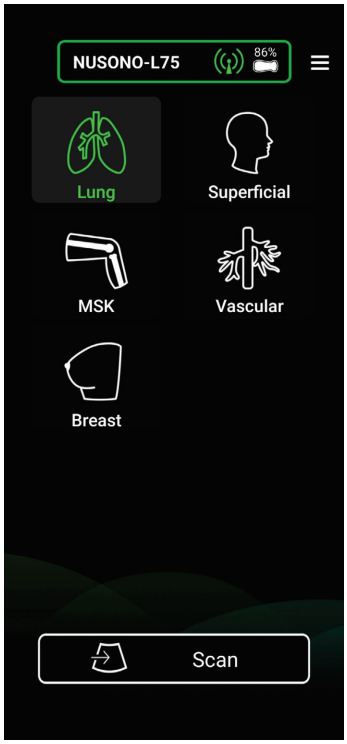
- During the firmware update process, the app will prompt users not to turn off the ultrasound device and will display the update progress (indicated by the ultrasound device flashing a purple light).



- Once the firmware update is complete, the NUSONO APP will display a notification window, and the ultrasound device will restart automatically. After clicking **"Confirm"**, users will need to reconnect to the ultrasound device.



- Once the connection is successfully re-established, the app will return to the **Home Page**, allowing users to begin diagnostic tasks.



⚠	CAUTION: Failure to update the NUSONO APP may lead to information security risks caused by major vulnerabilities, and the inability to provide software optimization or partial update functions.
⚠	CAUTION: The ultrasound device cannot perform firmware updates when the battery is low.

⚠	CAUTION: Do not interrupt the Wi-Fi connection or turn off the power during firmware updates of the ultrasound device.
⚠	CAUTION: If you do not update the ultrasound device firmware, a mismatch of the NUSONO APP version and the connected ultrasound firmware version may result in the inability to continue using the ultrasound device.
⚠	WARNING: When the ultrasound device is powered on, it automatically checks the integrity and confidentiality of the firmware. If the ultrasound device indicator light is steadily red, it indicates that the integrity and confidentiality of the device have been compromised. Please immediately power off the device and contact your local sales representative for technical support.

2.3.3 Delete User Account

NUSONO ultrasound devices require an account with NURODATA Cloud for user operation. Users may store patient information and diagnostic records in both the NUSONO APP and NURODATA Cloud. Please carefully confirm whether to delete your account and diagnostic data, and formally submit an account deletion request to Nurodata via service@nurodata.com. We will delete your account identity and patient information in NURODATA Cloud as requested, as well as any related diagnostic content, including images and videos.

2.3.4 Uninstall NUSONO APP

When uninstalling the NUSONO APP on Android or iOS devices, all files and folders under the app installation path will be deleted, including:

- Connection information for the ultrasound device.
- Account information stored on the mobile device (e.g., login credentials, personal avatar).
- Diagnostic records.
- DICOM Server settings.
- Worklist Server settings.
- App operation logs.

Uninstalling the app will permanently delete all diagnostic records stored on the mobile device. Users are advised to handle this process carefully and ensure diagnostic records are saved separately according to local regulations before uninstalling.

Users can uninstall the NUSONO APP using the standard uninstallation methods

available on their mobile device's operating system. Please note that the account information and diagnostic records stored in the cloud will not be deleted.

⚠	CAUTION: Before the uninstallation of NUSONO APP, deletion of any confidential personal privacy information should be in compliance with requirements from local regulation or your medical institution.

2.3.5 Software of Unknown Provenance (SOUP) update

NURODATA regularly verifies the software referenced in the NUSONO APP, tracking messages released by the software's respective suppliers regarding updates, security vulnerabilities, and other legal or cybersecurity notifications. Security checks, vulnerability scanning, and risk management will be conducted. When necessary, software updates will be released on the APP store, listing the latest applicable operating system versions, and ensuring that the Software of Unknown or Proprietary Origin (SOUP) complies with relevant regulations and compliance requirements.

⚠	CAUTION : When releasing the NUSONO APP versions, we will assess the most suitable operating system environment. After confirming the operating system, users are advised not to arbitrarily update the operating system environment to avoid rendering the device unusable. If there are newer versions of the operating system, Nurodata will continually monitor to confirm whether there are cybersecurity vulnerabilities or other issues and assess whether updates should be released in the future.

2.4 Network and Firewall Connection Settings

2.4.1 Network

Certain features of the NUSONO APP and NURODATA Cloud services require an active internet connection. Before using these features, ensure proper network and firewall configurations are in place:

- **NURODATA Cloud**

  Domain: cloud.nurodata.com
  IP Address: 50.18.223.110
  Port: 443
  Functionality: Registration, identity authentication, diagnostic record upload, and storage.

  ❖ For Mobile Devices - NUSONO APP

Before using registration and authentication functions in the NUSONO APP, check the firewall configuration on the mobile device to ensure the app is not blocked in the service denial list.

❖ For Desktop or Laptop Computers

Before using NURODATA Cloud web services, verify that the client device's network connection and firewall settings allow outgoing traffic to the NURODATA Cloud address and port.

Note:
If the client device is part of an internal LAN, ensure the network equipment or devices facilitating external connections have the appropriate firewall settings. For further assistance, consult your organization's IT department.

- **STUN/TURN Server**

Domain: tm.nurodata.com
IP Address: 52.9.236.138
Port: 3478(STUN-TCP/UDP)、5349(TURNS-TCP)
Function: Remote Image Transmission

Before using the telemedicine feature in the NUSONO APP, verify the network connection and firewall configuration of the client device. Ensure the STUN/TURN server's address and port are set as allowed in the outbound rules.

Note*:*
If the client device (both local and the communication partner's device) operates within an internal LAN, also confirm the firewall settings of devices facilitating external connections. For further details, consult your organization's IT department.

- **DICOM/Worklist Server**

Address: Provided by the service.
Port: Provided by the service.
Functionality: Upload DICOM image files and download Worklist entries.

Before using the DICOM/Worklist feature in the NUSONO APP:

1. Check the firewall configuration to ensure the NUSONO APP is not blocked.
2. Verify that the target server’s firewall has the necessary ports open.

Note:

1. *If the client device operates within an internal LAN, ensure the firewall settings of the device handling external connections are appropriately configured. For further details, consult your*

organization's IT department.

2. *When connecting to a medical institution's system, consider the following security measures to mitigate risks:*
    1) *Enable the firewall on the client device and keep its open state to the minimum necessary.*
    2) *Ensure the client device's operating system is up to date with the latest security updates.*
    3) *Install appropriate tools to prevent malware (e.g., viruses, trojans).*
    4) *Use the client device exclusively for work-related purposes and avoid non-work-related downloads or browsing.*
    5) *For connections to medical systems, implement an IP whitelist on the system's firewall for devices using this service to enhance security.*

2.4.2 Ultrasound Device Connection

The NUSONO APP connects to the ultrasound device through the device's Wi-Fi AP, establishing a one-to-one local network connection. Before connecting, ensure the firewall configuration of the client device is properly set:

- NUSONO Handheld Ultrasound Scanner

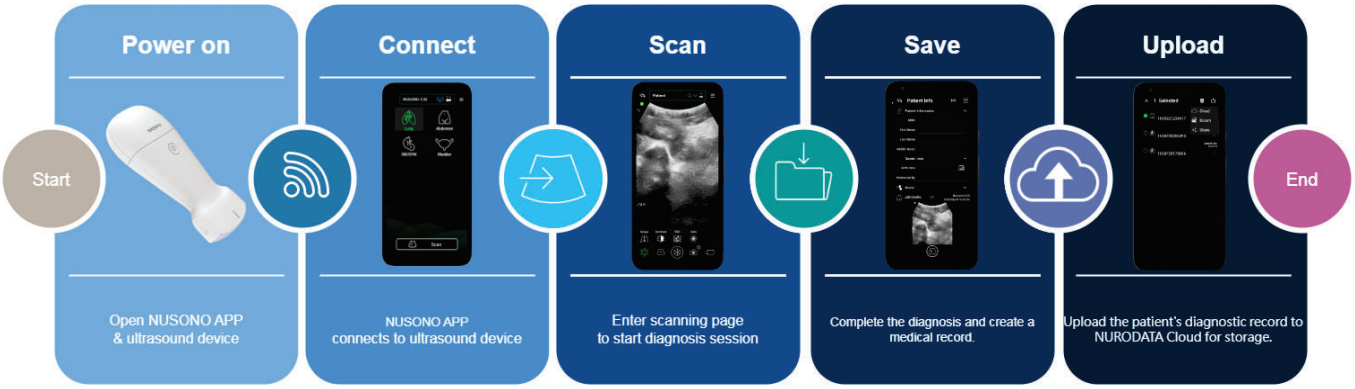
  Address: 192.168.1.10
  Port: 8080(TCP)、8082(UDP)
  Functions: Ultrasound device command communication and image data transmission.

  Pre-connection Checklist
  1. Verify that the client device's Wi-Fi is active and functional.
  2. Ensure the NUSONO APP is not blocked in the service denial list.
  3. Confirm the following permissions are enabled for the NUSONO APP:
     - Camera
     - Microphone
     - Screen Recording
     - Storage Access
     - GPS Location

⚠	WARNING: When connecting a device with the NUSONO APP installed to a medical institution's system, the device is used exclusively for work-related purposes. Non-work-related activities are strictly prohibited to ensure the security of the overall system and network environment.

⚠	WARNING: Ensure that the operating system is updated to the latest security version when connecting a device with the NUSONO APP installed to a medical institution's system. This is critical to maintaining the security of the overall system and network environment.

2.5 System Process



You can operate the ultrasound device through Wi-Fi Direct.

Step 1	Power On	Activate the NUSONO APP and the ultrasound device.
Step 2	Connect	Connect the NUSONO APP to the ultrasound device.
Step 3	Scan	Enter the scanning page to start the diagnosis session.
Step 4	Save	After the diagnosis is completed, enter patient information and save the medical record.
Step 5	Upload	Upload the patient's diagnostic record to the cloud for storage.

2.6 NUSONO Ultrasound Device Basic Guide

This section primarily introduces the basic operations of using the NUSONO Ultrasound Device, providing you with a quick understanding of the operation of this ultrasound system.

2.6.1 Connect NUSONO APP to the Ultrasound Device via Wi-Fi.

Place your newly purchased ultrasound device on the charging dock and wait for the device's battery to be fully charged. When the battery is full, the indicator light of the ultrasound device will transition from a breathing green state to a steady white light. Please remove the

ultrasound device from the charging dock and start the first device connection setup operation.

Initial Connection

Step 1 Power on the Ultrasound Device

Press and hold the ultrasound device's power button for 2 seconds until the green light on the ultrasound device exhibits a gradual breathing pattern. (Note : If the ultrasound device is not connected to a mobile device via Wi-Fi within 3 minutes after startup, the device will automatically shut down.)

Step 2 Log in to the NUSONO APP

Open the NUSONO APP and log in to your account. If you don't have an account, please register first. (for login/registration procedures, see sections 4.1.3 and 4.1.4)。

Step 3 Ultrasound Connection Setup - Select the Ultrasound Device to Connect

- Log in to the NUSONO APP and click on the green breathing box at the top of the main screen to enter the connection list.
- In the connection list, a prompt box will appear. Please enable the location and Wi-Fi services on your mobile device. (please ensure that both location and Wi-Fi functions are turned on before proceeding to the next connection step.)
- For the initial connection, click on the scan icon in the upper right corner, scan the 2-dimensional barcode on the ultrasound device, and then select this ultrasound device in the connection list. If you have previously connected to an ultrasound device, simply click on the desired ultrasound device in the list.

Step 4 Successful Connection

Once connected to the ultrasound device, the indicator lights on the device will stop flashing and turn into a steady green light. Return to the main screen where you can see the model and serial number of the ultrasound device displayed in the green box in the top, along with an icon in green.

Body Part Not-In-Contact Detection Mode

If no body part is contacted during the ultrasound device scanning session, the ultrasound device will freeze due to the Body Part Not-in-Contact Detection mode. The ultrasound device's blue breathing light will be illuminated until it shuts down after reaching the set time in the Keep Awake mode.

Shutdown

If the ultrasound device is active, press and hold the power button for 2 seconds to turn off your ultrasound device.

2.6.2 Introduction to NUSONO Ultrasound Device Indicator Lights

When using the NUSONO Ultrasound Device, the indicator lights on the ultrasound device can clearly inform you of the status of current connection and power.

The following list explains the status of the device indicator lights:

Power On	The System is booting up		Steady Blue Light	The system is starting up
Wi-Fi Direct	The ultrasound device is waiting for the NUSONO APP to connect		Breathing Green Light	The ultrasound device is waiting for NUSONO APP to pair and establish a connection
	The ultrasound device & the NUSONO APP are successfully		Steady Green Light	The NUSONO APP has correctly paired with the ultrasound device and connected to its Wi-Fi.

	connected			
	The ultrasound device is in a freeze state		Breathing Blue Light	The ultrasound device is in a freeze state
Charging Status	The ultrasound device is connected to the charging cable and adaptor/ charging dock		Breathing Yellow Light	The ultrasound device is connected to the charging cable or placed on the charging dock
			Steady White Light	Battery on the ultrasound device is fully charged
Low Battery Status	Low battery		Steady Yellow Light	The power of the ultrasound device is below 30%, a power depletion message will be prompted
Update	The update and installation of the ultrasound device firmware		Flashing Purple Light	The ultrasound device is undergoing firmware update. DO NOT turn it off arbitrarily.
Overheated	The ultrasound device is overheated, protection mechanism activated		Steady Purple Light	Surface temperature of the ultrasound device exceeds 43°C, and operation is temporarily suspended. (At the time being, the ultrasound power-off button is invalid.)

2.6.3 Introduction to NUSONO Ultrasound Device Vibration Feedback

When you connect a mobile device with a NUSONO Ultrasound Device, a vibration feedback mechanism is set up to let you know more quickly that the status of the ultrasound device has changed.

Successfully connected to the ultrasound device	The mobile device vibrates once
During scanning status, no body part is contacted for over 20 seconds. The ultrasound device enters freeze mode	The mobile device vibrates once, and the screen enters freeze mode
The battery level of the ultrasound device is less than 30%	The mobile device vibrates once
During scanning status, the ultrasound device shuts down due to the activation of the overheat protection mechanism	The mobile device vibrates once and enters freeze screen

2.6.4 Introduction to NUSONO Ultrasound Device Audible Notification

Sound	Meaning
1 beep	Power on
1 beep	Power off

2.7 NUSONO Ultrasound Device Troubleshooting

If the ultrasound device encounters the following malfunctions, please troubleshoot according to the corresponding methods：

Unable to start up the ultrasound device	1. Check if the ultrasound device is properly powered on and the battery has been charged. 2. Restart the ultrasound device. 3. If the issue persists, immediately stop using the device. Contact your local technical support or sales representative for further assistance.
The ultrasound device fails to enter the operating interface after startup	1. Restart the ultrasound device. 2. Ensure that the NUSONO APP installed on your mobile devices is the latest version. 3. If the issue persists, immediately stop using the device and power it off. Contact your local technical support or sales representative for further assistance.
When powered on, the ultrasound device is unable to connect to the mobile device via Wi-Fi.	1. Restart the ultrasound device. 2. Disable the Wi-Fi on your mobile device and then enable it. 3. Reestablish Wi-Fi pairing process. 4. If the issue persists, immediately stop using the device and power it off. Contact your local technical support or sales representative for further assistance.
The indicator light of the ultrasound device is abnormal while connected to the charging devices and the fast charging function is not working	1. Restart the ultrasound device. 2. Please re-plug the charging cable to the charging dock and ensure that the charging cable, adaptor and/or charging dock provided by the original manufacturer are used. 3. When being disturbed, the charging of the device is interrupted and the charging indicator light may go out. After the interference ends, it automatically resumes operation and functions normally. 4. If the issue persists, immediately stop using the device and power it off. Contact your local technical support or sales representative for further assistance.
No battery level of the ultrasound device is displayed on NUSONO APP	1. Restart the ultrasound device. 2. Reconnect to the mobile device. 3. If the issue persists, immediately stop using the device and power it off. Contact your local technical support or sales representative for further assistance.
NUSONO APP is unable to display ultrasound imaging in real-time	1. Restart the ultrasound device. 2. Reconnection to the mobile device. 3. Ensure that the NUSONO APP installed on your mobile devices is the latest version. 4. If the issue persists, immediately stop using the device and power it off. Contact your local technical support or sales representative for further assistance
Interference occurred on the display of the NUSONO APP	1. Re-examine the environment in which the ultrasound device is used to identify possible sources of radiation. The radiation waves may come from electronic devices in the

	same room or neighboring rooms. 2. In the event of EMI (Electromagnetic Interference) is caused, it may be necessary to remove related devices or relocate this device.
Device freeze mode or shut down mechanism failure	1. Restart the ultrasound device. 2. Reconnect to the mobile device. 3. If the issue persists, immediately stop using the device and power it off. Contact your local technical support or sales representative for further assistance.
The indicator light on the ultrasound device is abnormal	1. Please check whether the ultrasound device is out of power. 2. If the ultrasound device has power and experiences abnormal lights, please reboot. 3. Reconnect to the mobile device. 4. If the issue persists, immediately stop using the device and power it off. Contact your local technical support or sales representative for further assistance.
While logging in to NUSONO APP or NURODATA Cloud, a prompt is displayed and an error message shows 'account or password entered is incorrect.'	1. Please verify whether the entries of account and password are correct. Alternatively, ask the organizational administrator to confirm whether the user has been granted network access rights. 2. Please confirm whether the mobile device is connected to a valid Wi-Fi or the mobile network is enabled.
The storage space on the mobile device is full.	Check scan storage, and avoid unnecessary storage space usage. Please free up storage space for the scan to function properly.
If your iPad cannot scan 2-dimensional barcodes after updating to iPadOS 17.4.	If your iPad is unable to scan 2-dimensional barcodes using the Camera app after updating to iPadOS 17.4, please update your iPad to iPadOS 17.4.1. Refer to the official iOS documentation: https://support.apple.com/en-lamr/118614

If you encounter an issue that cannot be fixed by troubleshooting, please contact the sales representative in your region.

2.8 Information Security

2.8.1 Mobile Device

- To prevent the mobile device used to connect the ultrasound device from being stolen or used without authorization, resulting in improper disclosure or unauthorized acquisition of patient information, users must properly secure the mobile device, and are advised to set up an identity authentication method with strong security and screen locking.

2.8.2 Account

- To prevent unauthorized use of account functions, users are responsible for protecting account passwords and setting strong passwords.
- Users who are authorized to access and obtain patient information and images shall be responsible for protecting patient data and information from unauthorized disclosure.
- If the NUSONO APP is not running on a dedicated device or is used in an untrusted network environment, it is recommended to log out of the account after completing the diagnosis and stopping the use of the NUSONO APP to protect patient data security and reduce the risk of information leakage.
- Users are responsible for ensuring the protection of patient health information when using NUSONO APP features that may disclose identifiable information to other viewers (e.g., Telemedicine).
- If the account password does not match during login attempts and exceeds a certain number of consecutive attempts, the system will lock the account for a specified time to ensure account security.

2.8.3 NUSONO APP

- To avoid information security risks caused by major vulnerabilities, users are advised to ensure that the version of the NUSONO APP software is the latest.
- If Nurodata detects abnormal security behavior (including potential actions related to network security vulnerabilities), users will be notified via the official email address (**no-reply@nurodata.com**), and information regarding the abnormal behavior of the NUSONO APP and ultrasound device will be sent to the email address registered with your account.
- When operating the NUSONO APP, log records are created by date and stored in a controlled folder on the mobile device, documenting user actions.

- When connecting the ultrasound device through the NUSONO APP, the ultrasound device events are also recorded in the NUSONO APP's log.

2.8.4 NURODATA Cloud

- NURODATA Cloud is built on the AWS cloud platform, utilizing AWS EC2, AWS RDS, and AWS S3, with AWS GuardDuty and AWS WAF services enabled to ensure network security for cloud services.
- NURODATA Cloud enables and configures IP connection whitelists through a firewall to ensure connection security for cloud services.
- NURODATA Cloud ensures communication security through SSL/TLS encryption.
- NURODATA Cloud logs important user actions.

2.8.5 Malware

- The use of the NUSONO APP and NURODATA Cloud website involves not only the security of user credentials but may also include patient personal privacy. Malware could potentially lead to the leakage of such information or directly/indirectly cause system malfunctions. To ensure credential security and protect patient privacy, ensure the system environment of the platform device is secure:
    - Enable a firewall and, unless necessary, ensure that it is minimally open to external traffic.
    - Keep the operating system updated with the latest security patches.
    - Install appropriate anti-malware tools (e.g., antivirus, anti-trojan software).
    - Avoid downloading or browsing non-work-related online resources on the platform device used for working purposes.

⚠	WARNING: Certain actions may expose mobile devices running the NUSONO APP to virus attacks, such as installing non-product software, connecting unauthorized USB drives, or accessing insecure networks. If you perform these actions or engage in any other behavior that might expose the NUSONO APP to virus attacks, Nurodata strongly recommends enabling mobile device security protections (e.g., Google Play Protect) or installing effective antivirus software.
⚠	WARNING: Malware or insecure software could steal personal information or harm user devices. If you notice sudden significant reductions in storage space, noticeably slower device performance, unexpected app crashes, browsers redirecting to unfamiliar pages or ads, or persistent unauthorized changes to the browser homepage, it is

	recommended to replace your mobile device immediately. This will help ensure the security of patient medical information and the functionality of the ultrasound device.

2.8.6 Network Connection

- When connecting to the ultrasound device, ensure that your mobile device connects via a network supporting Wi-Fi 802.11ac.

- For security purposes, it is recommended to use the latest version of the NUSONO APP and the NUSONO firmware for secure network connections and security protocols to protect your mobile device.

  ※ *Note*：*The following operations may pose new risks to patients, operators, and third parties*：
  1. *Change network configurations*
  2. *Disconnect from the existing network and connect to other networks*
  3. *Upgrade and update software and devices*

  Your organization is responsible for identifying, analyzing, evaluating, and controlling relevant risks.

2.8.7 Wi-Fi Connection

- When connecting the mobile device to a local network or NURODATA Cloud, it is recommended to use WPA2 (Wi-Fi Protected Access II) as the security protocol to protect the network.
  ※ *For wireless network equipment security settings, refer to the operation manual of your network device.*
- Using an untrusted wireless access point may allow malicious actors to view your Wi-Fi signals, perform harmful actions, and intercept communications between smart devices. If no secure access points are available, discontinue the mobile device connection.

2.8.8 Confidentiality

- The ultrasound device does not process or retain any identifiable patient information or records during operation.
- The ultrasound device connects via Wi-Fi/WPA2 with a one-to-one encrypted network to send image information to the NUSONO App for further display and processing.
- The image files in patient exam records do not save any information associated with the identification of the patient or user account.
- The NUSONO APP encrypts and stores patient diagnostic records on the mobile device until the user removes the app or deletes the records.
- Sensitive user information for the NURODATA Cloud web service is encrypted and stored within the browser.

- The patient diagnostic records information can be uploaded to NURODATA Cloud for storage via SSL/TLS encrypted transmission.
- The patient diagnostic records can be uploaded to a DICOM server for storage through the connection settings. If you wish to set the configurations, please consult with the information system technicians at your organization to obtain more information. Ensure the reliability of the related connections and transmissions, and comply with local security policies and regulatory requirements.

2.8.9 Integrity

- The ultrasound device and NUSONO APP transmit images and commands via TCP and UDP.
- When updating firmware, the ultrasound device verifies the integrity and validity of the received data. If any data is incomplete or invalid, the update will not proceed.
- When uploading the patient's diagnostic record information to NURODATA Cloud for storage, SSL/TLS encrypted transmission and content encryption and verification methods are used to prevent abnormal tampering of related information and ensure the integrity of transmitted data.

2.8.10 Availability

- After a disconnection, the ultrasound device continues self-monitoring and disables acoustic energy transmission. It will automatically power off after a period of inactivity to reduce battery usage.
- The ultrasound device does not retain any user profiles or information. Following a disconnection, all ultrasound device settings are stored on the mobile device via the NUSONO APP. Users can upload medical records to the NURODATA Cloud for backup and storage as needed.
- Upon restarting, the ultrasound device resets to factory default settings.
- Each time the ultrasound device pairs with the NUSONO APP, the device is configured based on the parameters provided by the app.
- The ultrasound device only allows one user connection at a time. Once a user connects to the device using the NUSONO APP, other users cannot connect to the device. All data transmitted between the ultrasound device and the NUSONO APP belongs exclusively to the connected user.

3. Ultrasound Device Connection

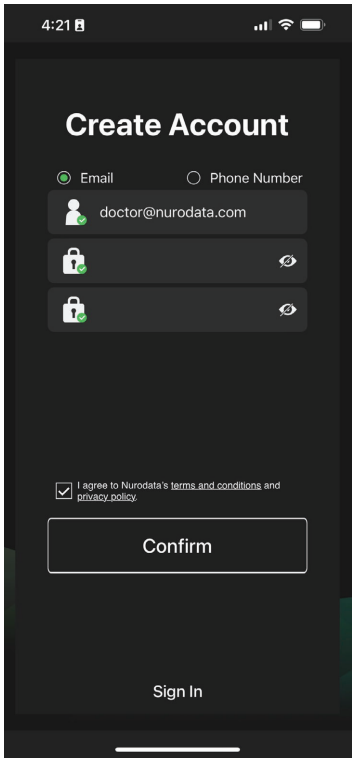
3.1 Connection Guide

Please follow these steps to connect the application to the ultrasound device.

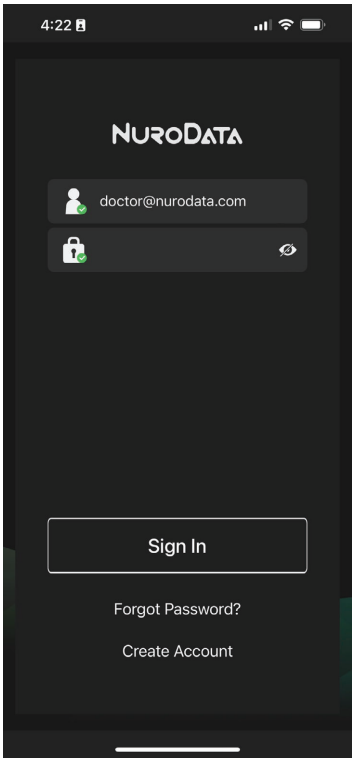
→ Register/Login on the NUSONO APP.
→ Power on the ultrasound device (device breathing green light).
→ Scan the 2-dimensional barcode on the back cover.
→ Successfully connect the ultrasound device to the NUSONO APP (device steadily green light).

(a) If you do not have a NUSONO APP account, please create an account and log in to the NUSONO application first. (For detailed instructions, please refer to sections 4.3 and 4.4)

Register



Login



(b) Press and hold the ultrasound device power button until the blue indicator light is on in order to activate your ultrasound device. When the indicator

light on the ultrasound device turns into a green breathing light, it indicates that you can proceed with the connection.

(c) With the **Location** and **Wi-Fi** functions of mobile device enabled, click the "**Click to connect" in the information bar** in the top of the NUSONO APP to open the ultrasound device list or connect via the mobile device camera, as shown in the figure:

Information Bar at the Top

※ *If you have not connected to the NUSONO ultrasound device before, please allow the NUSONO APP to access your mobile device's camera.*

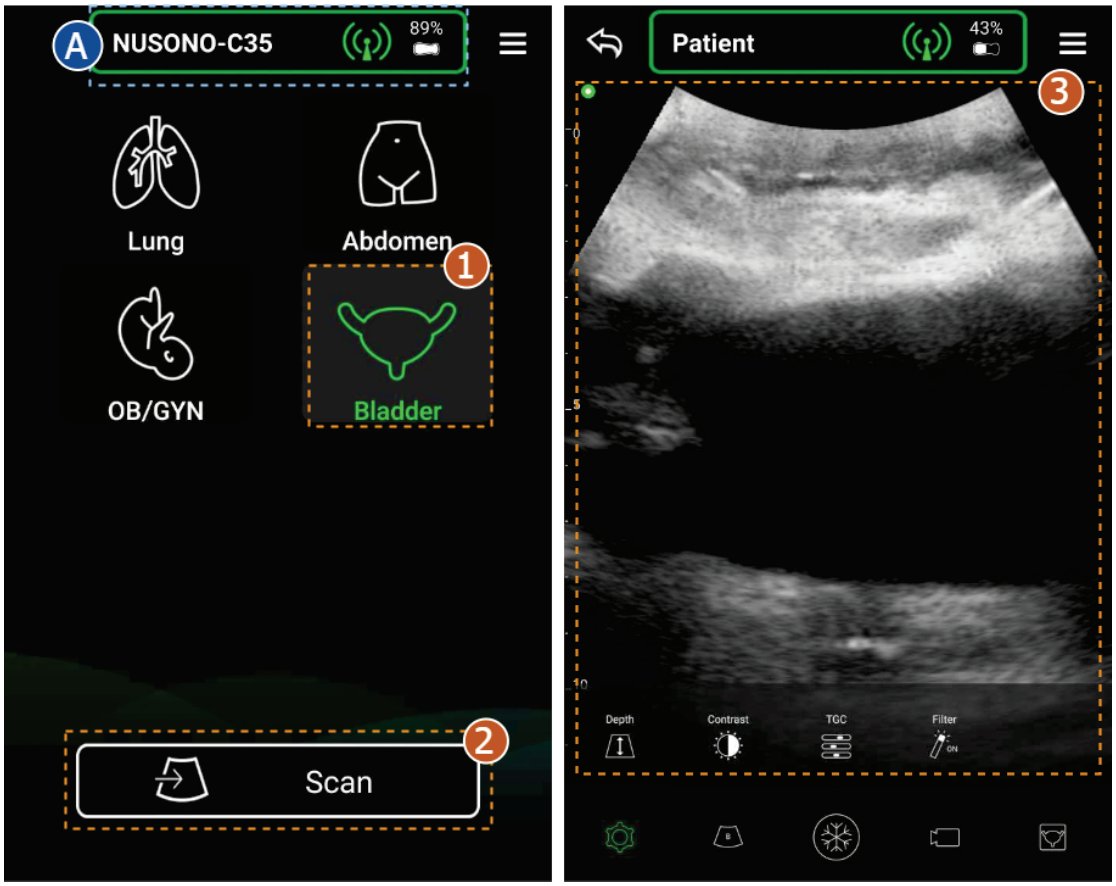
(d) Click on the device option you want to connect to in the ultrasound device list or scan the 2-dimensional barcode on the ultrasound device using the mobile device camera to establish a connection.

(01)04719884780033
(21)23020001

(e) When you successfully connect to the ultrasound device's Wi-Fi through the NUSONO APP, the green light on the ultrasound device will turn into a ***steady*** state. In the upper information bar of the NUSONO APP (as shown in the figure A below), the model, connection status, and battery level of the ultrasound device will be correctly displayed.

(f) To start a scan session, please go to the【**Home**】page and choose the examination category by default or from other examination icons on the screen. Click the **Scan** button to perform the scanning imaging task.

1) Select the part to be examined.
2) Click **Scan**
3) Start scanning



3.2 Meaning of the Top Information Bar

When you use the NUSONO APP, the icons in the top information bar will guide you to understand the current connection status with the ultrasound device.

The following list explains the meaning of the icons in the top information bar on the **Home** and **Scan/Freeze** pages.

Home

Scan/Freeze Page

≡	Main Menu		Open or close the menu
	Ultrasound Device Indicator Light		Not connected to the ultrasound device
			Connected to the ultrasound device

	Ultrasound Device Battery Status		The ultrasound device not connected display the actual battery level in %
	Return to the previous page		No ultrasound image for this examination, and this record will not be saved
NUSONO-C35	Ultrasound Device Model		Display the currently connected device
Dorothy 5688644	Patient Name Medical Record Number		Displayed according to the actual input

4. Instructions for Use of the NUSONO APP

This section will guide you through the operation of the NUSONO APP, helping you familiarize yourself with its various functions.

4.1 Download and Install

To obtain the NUSONO APP：

- Android users can download and install it directly from Google Play Store.
- iOS users can download and install it directly from the App Store.

4.2 Activate

After the installation of the NUSONO APP is complete, return to your mobile device's desktop screen, and click on the NUSONO APP icon to activate it.

4.3 Account Registration

Before using the NUSONO APP, you need to have a NURODATA Cloud account. Please proceed with online registration.

Step 1 Access the Registration Page

Open the NUSONO APP, click on【**Create Account**】and access the registration page.

Step 2 Registering Account Information

You can choose to use an email address or a mobile phone number as your account name. The system will provide a verification code based on your choice to confirm your account application and creation.

Account	Verification Method
Apply with Email	Server sends a verification code to the applied email address.
Apply with Mobile Phone Number	Server sends an SMS text message verification code to the applied phone number.

1 Enter a valid email address.

2 Enter a password, with the following restrictions:

	• Password Length: 6 to 16 characters • Must contain at least one English letter (a-z A-Z) • Must contain at least one number (0-9) • Only English letters (both upper and lower case) and numbers are allowed, no other symbols.
3	Confirm password.
4	Agree to Nurodata's terms and privacy policy.
5	Create an account.

※ *Enter the relevant registration information. If the icon is shown in red, it means the entry does not comply with the rules, indicating an invalid email or password. When the icon turns green, you can click the button to create the account.*

Step 3 Fill in the verification code

Nurodata will send a verification code to your email or mobile device. Please fill in the verification code within the specified period.

※ *If you do not received the verification code within a certain period of time, you can click on **Resend**.*

Step 4 Set password

Please continue to set the password for your account on the NUSONO APP and confirm the password. Click **Confirm** to complete the account creation.

4.4 Sign in to Your Account

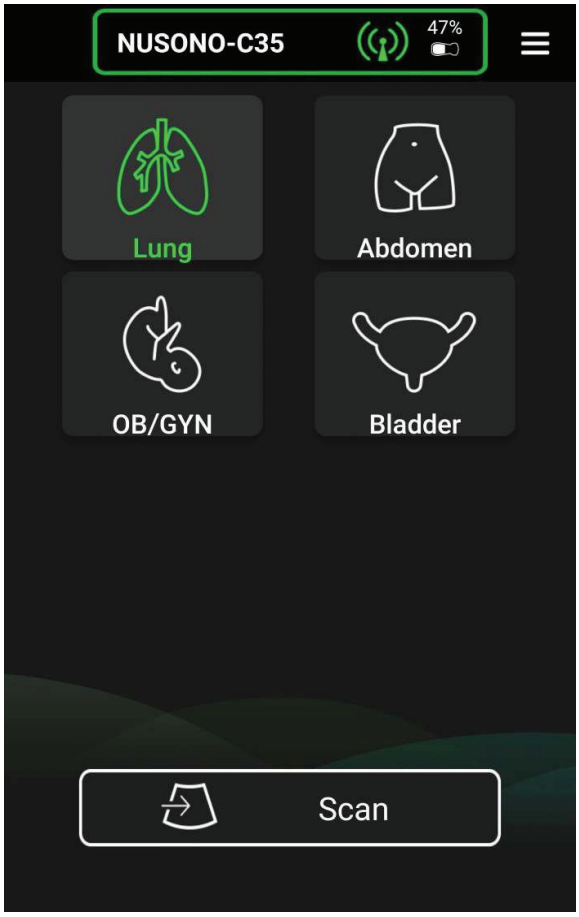
Please proceed with the account sign-in process in the NUSONO APP.

Step 1 Access the sign in page

Please enter the account and password you created on NURODATA Cloud to sign in.

Step 2 Sign-in successful

Upon a successful sign-in, you will enter the application's homepage.



4.5 Forgot Password

When you forgot your password, please follow the steps below to reset it.

Step 1 Click on【Forgot Password?】
On the sign-in page, enter your account and click the【**Forgot Password?**】button.

Step 2 Nurodata will send a verification code
Nurodata will send a verification code to your email or mobile device. Please fill in the verification code within the specified period of time.
※ *If you haven't received the verification code within a certain period of time, you can click on* ***Resend****.*

Step 3 Reset Password
After the identity authentication is confirmed, proceed to the password reset page and enter your new password. Confirm the new password again to complete the password reset.

4.6 Scanning

※ Before performing the scanning function, please ensure that NUSONO APP has already connected to the NUSONO Ultrasound Device (refer to Section 3.1)。

When using the ultrasound device for scanning, you can operate B-Mode, M-Mode, Color Doppler Mode, and Power Doppler Mode. In order to obtain an optimal ultrasound image, the NUSONO APP provides you with various adjustment tools.

- **Probe and preset organs**
  To ensure optimal image quality, the NUSONO Handheld Ultrasound Scanner has predefined scanning settings optimized for different applications. Refer to the table below to select the correct transducer and preset combination before scanning.

Transducer	Preset Organ		Application
Convex NUSONO-C35		Lung	A-line/B-line Pleura Lung tissue
		Abdomen	Liver Spleen Kidneys
		OB/GYN	Ovaries Fetus
		Bladder	Urinary bladder Prostate
Linear NUSONO-L75		Lung	A-line/B-line Pleura Lung tissue
		Superficial	Joints Long bones Muscles Tendons Ligaments
		MSK	
		Vascular	Veins Arteries

		Breast	Breast
Phased Array NUSONO-P25		Lung	A-line/b-line Pleura Lung tissue
		Abdomen	Liver Spleen Kidneys
		OB/GYN	Ovaries Fetus
		Cardiac	Heart

※ For more detailed **lung preset** information, please refer to **Appendix 1**.

- **Control Effect**
  The system automatically adjusts acoustic output values based on the selected application. Factory default settings vary depending on the probe type. All default values are set below FDA limits for their intended use.

  Each probe has unique specifications, including contact area, beam shape, and center frequency. When a probe is selected, the system automatically applies its corresponding default settings, with each probe operating at a fixed frequency. All default values remain within FDA safety limits.

  For detailed parameters of each probe, imaging mode, and application, please refer to the next section.

- **Preset Parameters**

NUSONO-C35【Frequency : 3MHz】
Preset table
(BMode , MMode)

Organ	Depth 4cm ~ 18.5cm	Contrast 0~100	TGC1 0~511	TGC2 0~511	TGC3 0~511	Filter on/off
Lung	10	10	100	220	300	off
Abdomen	15	10	100	220	300	on
OB/GYN	12	10	350	430	480	on
Bladder	12	10	380	430	500	on

NUSONO-C35【Frequency : 3MHz】
Preset table
(Color Doppler , Power Doppler)

Organ	Depth 4cm ~ 18.5cm	Contrast 0~100	TGC1 0~511	TGC2 0~511	TGC3 0~511	Filter on/off
Lung	10	10	440	480	490	off
Abdomen	15	10	440	480	490	on
OB/GYN	12	10	440	480	490	on
Bladder	12	10	440	480	490	on

NUSONO-C35:

- The probe frequency is preset and fixed at 3 MHz, regardless of the imaging mode or selected organ.
- In B-Mode and M-Mode, the TGC values change according to the preset organ.
- In Doppler mode, the TGC values remain fixed and do not change based on the preset organ. Only one set of parameters is assigned.
- The contrast setting is fixed at 10 by default, regardless of the imaging mode or selected organ.

NUSONO-L75【Frequency : 6MHz】
Preset table
(BMode , MMode , Color Doppler , Power Doppler)

Organ	Depth 1cm ~ 8cm	Contrast 0~100	TGC1 0~255	TGC2 0~255	TGC3 0~255	Filter on/off
Lung	6	10	50	80	150	off
Superficial	4	10	70	90	150	on
MSK	3	10	50	150	200	on
Vascular	3	10	100	130	210	on
Breast	4	10	110	150	200	on

NUSONO-L75:

- The probe frequency is preset and fixed at 6 MHz, regardless of the imaging mode or selected organ.
- The TGC values are adjusted based on the organ rather than the imaging mode.
- The contrast setting is fixed at 10 by default, regardless of the imaging mode or selected organ.

NUSONO-P25【Frequency : 3MHz】
Preset table
(BMode , MMode)

Organ	Depth 4cm ~ 18.5cm	Contrast 0~100	TGC1 0~511	TGC2 0~511	TGC3 0~511	Filter on/off
Lung	10	10	90	210	360	off
Abdomen	15	10	270	360	430	on
OB/GYN	12	10	350	430	480	on
Cardiac	15	10	270	380	450	on

NUSONO-P25【Frequency : 3MHz】
Preset table
(Color Doppler , Power Doppler)

Organ	Depth 4cm ~ 18.5cm	Contrast 0~100	TGC1 0~511	TGC2 0~511	TGC3 0~511	Filter on/off
Lung	10	10	440	480	490	off
Abdomen	15	10	440	480	490	on
OB/GYN	12	10	440	480	490	on
Cardiac	15	10	440	480	490	on

NUSONO-P25:

- The probe frequency is preset and fixed at 3 MHz, regardless of the imaging mode or selected organ.
- In B-Mode and M-Mode, the TGC values change according to the preset organ.
- In Doppler mode, the TGC values remain fixed and do not change based on the preset organ. Only one set of parameters is assigned.
- The contrast setting is fixed at 10 by default, regardless of the imaging mode or selected organ.

- **Image Adjustment Settings**:

You can click on to open/close the image adjustment toolbar,

1)

Adjust Depth : Zoom in or out to modify the image depth.

2)

Adjust Image Contrast：Enhance or weaken the contrast of the image.

3)

Time Gain Compensation (TGC) Settings：To adjust TGC based on three depth ranges.

4)

Image Optimization Settings：Enable/disable image optimization based on the medical category of the part for the examination.

- **Switching Scan Modes**：

When you begin an ultrasound scan session, the system will begin in B-Mode by default . If you need to examine in different modes, you can click to open the image mode submenu.

Mode	Description
B-Mode	Imaging in grayscale 2D mode, the default mode.
M-Mode	By altering the vertical reference axis of the upper (left) half of the B-Mode image, the ultrasound system will create a continuous dynamic image in the lower (right) half. Over time, different temporal images are generated along the horizontal axis to capture the motion status of this part.
Color Doppler	By means of the Doppler phenomenon, moving the color box to the target area can detect blood flow velocity and direction. Clicking the bottom right corner of the color box can change the box size, and clicking the center of the color box can move the box's position.
Power Doppler	By means of the Doppler phenomenon, the display of blood flow details is enhanced in a gain approach. Click the bottom right corner of the color box to change its size, and click the center of the color box to move the box.

On the ultrasound screen, using finger operations (pinch) or (spread) can change the magnification of the image, (drag) or (slide) can change the position of the ultrasound image or move measurement objects.

- **Switch to the freeze page**：

Click on to freeze the image and the ultrasound device will stop sending ultrasound waves, and enter the measurement tool page for ultrasound image measurement. The ultrasound device stops sending sound waves when it freezes, and the indicator light changes to a blue breathing light.

- **Recording**：

With this function, you can obtain a dynamic video. When you click on to

record, the icon will change to , indicating recording the video on your mobile device, and stopping the recording when the timer ends or clicking to click on this button at any time to stop your recording. After the recording ends, the number of your files will increase and be displayed on the button.

- **Organ Toggle**:

Click to switch between organs and default values.

- **Centerline Switch**:

You can click to open/close the central reference line.

4.7 Freeze

- **Measurement Function**

When the ultrasound image is frozen, you can proceed with measurements for the images. Click on button to open a series of measurement tools. We have prepared general measurement tools for you, as well as special measurement tools according to the selected diagnostic category, such as the HC, AC, FL, BDP tools for obstetrics and gynecology, and the RU tool for examining residual urine in the bladder. In addition, if the screen is frozen in M Mode, you will have access to the V Distance, Velocity, and Time measurement tools exclusive to the M Mode.

Tool Category	Item	Description
General Measurement Tools	**Distance Measurement**	You can drag either end to determine the two endpoints of the measurement, and the system will dynamically calculate the measurement result in the top-left corner. To delete a measurement line segment on the screen, click on the segment to be deleted and click the icon to remove the currently selected measurement line segment and its calculated value.
	Measuring the Area and Perimeter of an Ellipse	You can drag either end to rotate the ellipse or scale its size, and the system will dynamically calculate the measurement results in the upper left corner. To delete a measurement object on the screen, click on the

		object to be deleted and click the icon to remove the currently selected measurement object and its calculated value.
	Delete All Measurement Objects and Values	Clicking will delete all measurement values and objects on the ultrasound image.
Obstetrics and Gynecology Tools 【OB/GYN】	**HC Measurement**	You can measure the fetal head circumference and obtain an estimated gestational age. To delete a measurement object on the screen, click on the object to be deleted and click the icon to remove the currently selected measurement object and its calculated value.
	AC Measurement	You can measure the fetal abdominal circumference and obtain an estimated gestational age. To delete a measurement object on the screen, click on the object to be deleted and click the icon to remove the currently selected measurement object and its calculated value.
	FL Measurement	You can measure the length of the fetal femur and obtain an estimated gestational age. To delete a measurement line segment on the screen, click on the segment to be deleted and click the icon to remove the currently selected measurement line segment and its calculated value.
	BPD Measurement	You can measure the length of the fetal biparietal diameter and obtain an estimated gestational age. To delete a measurement line segment on the screen, click on the segment to be deleted and click the icon to remove the currently selected

		measurement line segment and its calculated value.
Bladder Examination Tool 【Bladder】	**RU Measurement**	After freezing, select the measurement tool: 1. Use the drag-and-drop line segment tool to measure the length and height values of the bladder. Capture the first image to obtain the length and height values of the bladder. 2. Return to the scan page to capture an image of the bladder width and freeze the screen. 3. Use the drag-and-drop line segment tool to measure the width, capture the second image, and measure the width and residual urine estimate.
Click Freeze in M Mode		
【M MODE】 Measurement Tools	**V Distance**	Measure the distance in the M Mode images.
	Velocity	Measure the movement rate in the M Mode images.
	Time	Measure the time it takes for the motion process in M Mode images.

- **Measurement Accuracy**

This section provides guidance to users in assessing potential variations or measurement errors when performing clinical measurements with this device. Measurement errors may result from both equipment limitations and improper user techniques. To minimize user-related errors, always follow the provided measurement instructions and ensure consistency in measurement techniques among all operators. To identify any potential equipment malfunctions that could impact measurement accuracy, it is recommended to implement routine accuracy checks using tissue-mimicking phantoms to verify the device's performance.

Please note that all distance-related measurements through tissue depend on the speed at which sound propagates within the tissue. Since this velocity

varies depending on the tissue type, an average propagation velocity for soft tissue is assumed. This device is designed based on, and its accuracy specifications are derived from, an assumed average sound velocity of 1540 m/s.

The following two tables present the measurement accuracy and error analysis of the NUSONO Handheld Ultrasound Scanner.

B-Mode Measurement Accuracy

Measurement	NOSONO-C35	NOSONO-L75	NOSONO-P25	Range
Axial	±2.5%	±5%	±2.5%	0-18.5cm
Lateral	±4.5%	±2%	±3.5%	0-25.47cm
Perimeter	±3.5%	±3.5%	±3%	0-144.12cm
Area	±5.5%	±5.5%	±4.5%	0-1480.3cm^2
Volume	±7%	±7.5%	±5.5%	0-8640.96cm^3

M-Mode Measurement Accuracy

Measurement	NOSONO-C35	NOSONO-L75	NOSONO-P25	Range
Time	±2%	±2%	±2%	0-6.4Sec
Distance	±2.5%	±5%	±2.5%	0-18.5cm
Velocity	±3.5%	±5.5%	±3.5%	0-$Note^1$

$Note^1$: The range depends on the viewing device used and the amount of M-spectrum that can be displayed on the device's screen.

- **Annotation Function**

Click to open the annotation sub-toolbar, which includes tools such as the【Arrow Indicator】and【Text Description】.

Annotation Tools	Description
Arrow Indicator	Creating an arrow indicator on the ultrasound image allows you to freely drag the front or the tail of the arrow, changing the position you want to indicate and moving the arrow to the appropriate location. To delete annotation objects on the screen, click on the object to be deleted and click on the icon to remove the currently selected annotation object.

Text Description	Creating text content on the ultrasound image enables you to input any text at the cursor position and click the text to freely drag it to the desired location. To delete annotated objects on the screen, click the object to be deleted and click the icon to remove the currently selected annotation object.

- **Switch to Scan Page**

Click on to return to the scanning task.

- **Take a Snapshot**

Adjust the ultrasound image to the optimal condition, click to take a snapshot to capture a screenshot of the current ultrasound image. After the screenshot is captured, the number of your files will increase and be displayed on the button.

- **Organ Switching**

Click to switch between organs and default values.

- **Play / Pause**

The system retains the most recent segment of the dynamic video, and you can use this segment to capture the required ultrasound images. (Cineloop can playback for 10 seconds)

Click the icon to play the video and click icon to pause the video, or you can move the image clip by dragging the dot on , you can capture the required image from this dynamic video, and after annotating or measuring the image, combined with the function of taking snapshots icon (when pressing this shutter, this icon will accumulate the number of files of your medical record images), you can save the created ultrasound image at the end of your examination.

※ If you click freeze before the scanned images in the NUSONO app fill up the buffer, the play button may not appear, and there will not be sufficient images to provide playback. Please continue scanning.

4.8 Saving Ultrasound Diagnosis

After completing the examination, please click the icon in the upper left

corner to exit the ultrasound scan session. If no photos or videos were taken, clicking will directly return to the previous page. However, if ultrasound images or videos were captured during the scanning process, upon finishing the diagnosis and exiting the ultrasound scan, the system will open the **Patient Information Page**, providing patient details and medical history.

Patient Information Page is categorized into 4 sections：

1) **Patient Information**

This section assists you in creating patient information. There are 3 ways to create patient data：

- **Manual Input**

You can touch any field in patient information to edit the data. The medical record number (MRN) and name fields in patient data are important reference content for saving the diagnosis.

※ *The Medical Record Number (MRN) and the Name (First Name, Middle Name, Last Name) fields in patient data are important reference details for saving the diagnosis. Please remember to fill them out. If the MRN or name is not filled in, the NUSONO APP will use a timestamp as the MRN to save the diagnosis record.*

- **Scan 2-Dimensional Barcode**

On the【Patient Information】page, click the icon in the upper right corner to open the submenu. Choose the 2-dimensional barcode icon, scan the 2-dimensional barcode on the medical record. Fill in the patient data according to the instructions. After clicking on【Confirm】, the system will automatically populate the patient data into the form.

※ *To use your mobile device's camera as a "2-dimensional barcode scanner," you need to grant permission for the NUSONO APP to use the camera function.*

- **Worklist**

On the【Patient Information】page, click on the icon in the upper right corner to open sub-functions, select the Worklist icon to open the **Worklist Server** from the hospital, and search for patient data. After selecting the desired patient data, the system will automatically fill in the patient information in the form.

※ *Worklist Server information setup (please refer to section 4.1.10 Worklist Server).*

2) **Notes**

Here, you can manually input records of the patient's medical condition

and important information.

3) Report

When you perform measurements during scanning and capture ultrasound images by taking snapshots, the NUSONO APP will compile measurement information here.

4) Ultrasound Image Compilation

Ultrasound images and videos you captured during the scanning process will be compiled and displayed here.

After final confirmation, click the button to save the diagnosis results. The system will automatically save this diagnosis record and display it on the【Diagnosis List】page.

4.9 Diagnosis Records

Diagnosis records are linked to the account and can be viewed after signing into the account.

Each diagnosis record reveals the organ, medical record number, username, diagnosis date, and whether the record is saved in NURODATA Cloud or the hospital's DICOM server. The following will explain the function and indicator：

Indicator			
	Status of Uploading to the NURODATA Cloud		Diagnosis records have not yet been uploaded to the NURODATA Cloud. Failed to upload diagnosis record to the NURODATA Cloud.
			Diagnosis records uploaded to NURODATA Cloud successfully
	Status of Uploading to DICOM Server Status		Diagnosis records have not yet been uploaded to DICOM Server Failed to upload diagnosis record to DICOM Server
			Diagnosis records uploaded to DICOM Server successfully
Functions			
	Function Menu Buttons		Use the search function to locate the diagnosis record Use the sorting function to rearrange diagnosis records Select a diagnosis record for additional operations, such as deletion or sharing

In the function menu, three features can be used：

- **Search Function**：Search for records according to the medical

record number or patient name.

- **Sorting Function**：Click on the icon to select the category for sorting. The records will be displayed in the order of the selected category. Options for categories include date, medical record number, name, and organ.
- **Selection Function**：Select a diagnosis record for additional operations, such as 【delete】, 【sharing to NURODATA Cloud, DICOM server, or other applications】.

When clicking on a diagnosis record to open the【View】page, the content is divided into four sections：

1. **Patient Information**
2. **Notes**
3. **Report**
4. **Ultrasound Image Compilation**

Click on , you can edit the patient's information, notes and report again.

Additionally, you can choose to share it via the icon in the upper right corner of the page, which enables you to【Share with NURODATA Cloud, DICOM server, or other applications】.

4.10 PACS Connection Settings

- **DICOM Server**

Enter the following as indicated in the fields, including Client AE Title, Server AE Title, IP or server name, server port, institution name, and the name and password of your default Wi-Fi device. After completion, click【Save】to store the information, and the system will connect to the DICOM server. This allows you to directly upload ultrasound diagnostic results to the DICOM server through the NUSONO APP.

※ *Please contact the IT department at your institution or hospital before using this feature.*
※ *When performing DICOM server functions, it is the user's responsibility to protect patient privacy and scan data security. Therefore, when performing this function, it is recommended to ensure a secure and reliable network connection.*

- **Worklist Server**

After the setting is completed, click【Save】to store the settings. The system will automatically connect to the server, allowing you to search for patient data from the Worklist Server of your hospital or institution.

Enter the following in the fields as indicated, including Client AE Title, Server AE Title, IP or server name, server port, institution name, and the name and password of your default Wi-Fi device. After configuration,

click【Save】to store the information, and the system will connect to the Worklist server. You will be able to search for patient data from the Worklist Server at your hospital or institution.

※ *Please contact the IT department at your institution or hospital before using this feature.*
※ *When performing Worklist server functions, it is the user's responsibility to protect patient privacy and scan data security. Therefore, when performing this function, it is recommended to ensure a secure and reliable network connection.*

- **NURODATA Cloud**

NURODATA Cloud is the service platform where your diagnostic records are stored. You can choose whether to automatically upload diagnostic records to NURODATA Cloud or not.

※ *When validly logged in, you will be able to get the information on the cloud capacity usage of the last connected device.*

4.11 Telemedicine [iOS Only Feature]

You can synchronously transmit images to a remote location while performing a scan. For iOS device users, please make sure you can access both Wi-Fi and mobile data services at the same time.

1) On the scanning page, open the main menu, and select the【Telemedicine】feature.
2) Read and agree to the disclaimer for using telemedicine, and choose the way to share the video link.
3) In【Email】, please fill in the email address of your invitee or use【Sharing】to send the link via a third-party communication app to your invitee. Click【Create Video】to wait for the invitee to accept your call.
   ※ *Please allow the NUSONO APP to access your camera and microphone.*
4) When the invitee opens the link, you can start audio and video communication.
5) Your invitee will see the same screen and camera images as you do through the NUSONO APP.

※ ***Execute the function of telemedicine service while protecting patient privacy and diagnosis security is the user's responsibility. Therefore, when performing this function, it is recommended to ensure a secure and reliable network connection, such as VPN.***

※ ***When using telemedicine on iOS 14 and iOS 15, the NUSONO APP may crash during the process of sharing to third-party communication software via the share function. It is recommended to upgrade to the latest version of iOS.***

4.12 Settings Page

- **Keep Awake**

After your ultrasound device is connected, if no scanning operation is performed, the ultrasound device will automatically shut down after three minutes. If a scanning session is started and enters the freeze mode, the ultrasound device will be in **Keep Awake** standby mode. When it reaches the standby time setting value, the ultrasound device will automatically shut down to save power and protect the device.

- **Language**

You can switch between four language options to change the text display of your user interface. Some texts are kept in English depending on the professional terms.

- **Audit Log**

The audit log records the actions and information related to your use of the NUSONO APP and is saved by date.

- **Scanner Information**

After successfully connecting with the ultrasound device, click here to obtain the device's model and serial number, firmware information, and NUSONO APP version.

4.13 About

- **Privacy Policy**

Discloses Nurodata's protection and policies for privacy.

- **Acknowledgment**

Discloses the third-party packages used by the NUSONO APP software

- **About Us**

Opens the Nurodata official website in a browser.

4.14 Sign out

Exit the NUSONO APP.

※ *If the NUSONO APP is not running on a dedicated device or is used in an untrusted network environment, it is advised to log out of the account after completing the diagnosis or stopping the use of the NUSONO APP to protect patient data security and reduce the risk of information leakage.*

4.15 Back up

To avoid data loss and facilitate case review, relevant cases can be uploaded to the cloud platform for further analysis. Backups can be performed via two methods: automatic and manual uploads.

- **Automatic Backup**: When automatic case upload (backup to the cloud) is enabled, after completing each scan and diagnosis, case information is automatically saved to the mobile device and uploaded to the cloud.
- **Manual Backup**: Access the scan list page, select specific cases, and manually upload the data to the cloud for backup.

5. Maintenance and Cleaning

Thorough cleaning and disinfection of the device between patient cases are essential steps in preventing the spread of diseases. All ultrasound devices must be thoroughly cleaned before disinfection. Please refer to section 5.2 for instructions to determine the appropriate disinfection level and perform maintenance and cleaning regularly as needed. In the following sections, the term "ultrasound device" refers to the main body of the ultrasound device, and the transducer refers to the part responsible for the mutual conversion of acoustic energy at the front.

As the NUSONO ultrasound device is considered a medical device, it is recommended that maintenance and cleaning be carried out by trained personnel. Proper care, including inspection, cleaning, and disinfection, is required for all NUSONO Ultrasound Devices. After each use, the ultrasound device must be cleaned and disinfected. Before each use, carefully inspect all parts of the ultrasound device for any gaps or damage that may compromise its integrity. If any damage is identified, please inform the Nurodata sales representative and stop using it immediately.

⚠	WARNING: Immediately stop using if users or patients experience redness, swelling, allergies, or other adverse reactions on the skin.
⚠	WARNING: The ultrasound device protective cover may contain natural rubber latex; be aware of latex allergy-related symptoms. Refer to "FDA Medical Alert for Latex." Note：The ultrasound device does not contain natural rubber latex that may come into contact with the human body.
⚠	WARNING: If the internal components or accessories of this device are contaminated with pathogens, as the internal components of the device and accessories cannot be disinfected, notify the Nurodata sales representative immediately. The contaminated device and accessories must be treated as biomedical hazardous waste in accordance with local laws.

⚠	WARNING: Users and patients may be affected by infection control-related factors. Please follow infection control procedures established to protect employees and patients in the institution.
⚠	WARNING: This device is intended for use on intact skin only.

5.1 Precautions

- Be advised to wear goggles and gloves when cleaning or disinfecting the device.
- Use a cleaning agent (70% isopropyl-Alcohol, chemical formula C_3H_8O) or a disinfectant (0.55% o-Phthalaldehyde, chemical formula $C_8H_60_2$).
- Do not use corrosive cleaning agents, acetone, butanone, paint thinners, or strong solvents to wipe the ultrasound device and other accessories. It is not recommended to use alcohol to disinfect the ultrasound device, as it may accelerate the aging of the transducer surface.
- Please refer to the instructions, recommendations, specifications, and local regulations provided by the cleaning agent and disinfectant manufacturers.
- Follow all accompanying instructions for maintenance and cleaning to avoid damage to the ultrasound device. Failure to follow instructions may result in warranty being voided.
- Disinfectants or cleaning chemicals must be disposed of according to waste disposal regulations. Products must be disposed of according to national regulations or introduced into a designated recycling system. The discharge of waste must comply with national and local regulations. Dispose of waste chemicals in their original containers, and do not mix them with other waste. Dispose of contaminated containers following the same standards as for the product being handled.

5.2 Cleaning & Disinfection Procedure

After each use of the NUSONO ultrasound device, make sure to clean and disinfect it to ensure the cleanliness of the device. Please follow the steps below:

※ *Turn off the ultrasound device and remove the charging cable/charging dock.Inspect the ultrasound device and the appearance of the product for any damage, such as fractures, corrosion, or dents. If there is obvious damage, do not use it and contact the Nurodata sales representative.*

5.2.1 Cleaning the Ultrasound Device

STEP-1: Cleaning: Wipe clean the gel, scales and other residual substances with clean paper towels first. After having wiped the surface of the ultrasound device with soft cloth moistened with detergent, dry the ultrasound device with clean soft cloth or wiper.
STEP-2: Take out the soft cloth or wiper and moisten with an appropriate amount (approximately 3~5 c.c.) of disinfectant (according to the user instruction of disinfectant).
STEP-3: Hold the NUSONO Ultrasound Device while the opposite side of the transducer is facing towards your body.
STEP-4: Softly wipe along the surface of the NUSONO Ultrasound Device with soft cloth or wiper, from your body side towards the transducer side.
STEP-5: Rotate the NUSONO Ultrasound Device and continue wiping softly with the same gesture in 3.3. When the soft cloth or wiper is fully stained, please replace it with another clean soft cloth or wiper and continue the cleaning process until the whole surface of the NUSONO Ultrasound Device is fully cleaned.
STEP-6: Use a clean, soft cloth or wiper to thoroughly dry all surfaces of the NUSONO Ultrasound Device.
STEP-7: Visual inspect the NUSONO Ultrasound Device for any residual substances (especially attend to the transducer, edge and groove). If necessary, please repeat the process STEP-1 to STEP-5 until the NUSONO Ultrasound Device is visibly clean.

5.2.2 Disinfecting the Ultrasound Device

STEP-1: Soak the NUSONO Ultrasound Device in a disinfectant solution. (The whole device can be rinsed, washed, dipped or soaked.)
STEP-2: When applying the NUSONO Ultrasound Device to intact skin, disinfection of the device is required. Please clean the NUSONO Ultrasound Device (referring to the **cleaning procedure in 5.2.1**) before the disinfection procedure to ensure all visible residual substances are removed in the cleaning procedure.
STEP-3: Please do not exceed the maximum time cycle regulated by the disinfectant while soaking the ultrasound device in the disinfectant solution. Soaking the ultrasound device overtime will cause its damage and early failure of the case of the device, which leads to potential hazard of electric shock.
STEP-4: Prepare a container and add disinfectant according to the manufacturer's instructions. Submerge the cleaned and dried ultrasound device into the disinfectant solution.
STEP-5: Please follow all the precautions for storage, use and treatment for the disinfectant. Ensure that the NUSONO Ultrasound Device is not covered by any blister while soaking in the disinfectant solution and observe the time cycle appointed by the manufacturer.

STEP-6: Thoroughly rinse the ultrasound device with critical water to remove any residual disinfectant. Use a sterile cleaning cloth to completely wipe and dry all surfaces of the NUSONO Ultrasound Device (this procedure follows the same steps as the Cleaning Procedure in 5.2.1, STEP-1 to STEP-5).

※ *For the definition of critical water, please refer to the AAMI ANSI ST108:2023 standard, which outline the three categories of water quality.*

5.3 Maintenance

5.3.1 Device Maintenance

Users must adhere to the regulations of medical institutions and the instructions in section 5.2, as well as local government policies for cleaning and disinfecting medical devices. It is the user's responsibility to properly clean and disinfect the NUSONO Ultrasound Device and mobile device. If the NUSONO Ultrasound Device and mobile device are contaminated with bodily fluids containing pathogens, you must immediately notify the local Nurodata sales representative. Parts inside the NUSONO Ultrasound Device cannot be disinfected and must be disposed of as biohazardous waste according to local or federal laws.

5.3.2 Ultrasound Device Maintenance

Before each use of the ultrasound device, please check for any gaps or other damages. After checking, clean the device following the steps in section 5.2 for cleaning and disinfection. Carefully inspect all parts of the ultrasound device before each use, checking for any breakage or damage that could compromise the integrity of the device. If there is noticeable and unacceptable corrosion, discoloration, pitting, or seal rupture, please stop using the device and contact the local Nurodata sales representative. The ultrasound devices do not require regular calibration, but Nurodata recommends periodic inspections. If there is any damage, please report it to the Nurodata sales representative and stop using the ultrasound device.

⚠	WARNING: Before using cleaning and disinfection solutions, please refer to section 5.2 for cleaning and disinfection and follow all steps for cleaning and disinfection.
⚠	WARNING: Using non-recommended or inappropriate disinfectants for the NUSONO Ultrasound Device, or soaking the ultrasound device for too long may damage the device and result in the termination of the NUSONO Ultrasound Device warranty.

⚠	WARNING: Cleaning and disinfection are mandatory after using the NUSONO Ultrasound Device to avoid cross-contamination.
⚠	WARNING: Some ultrasound transmission gels and certain solutions designed for pre-cleaning, disinfection, and sterilization may damage the transducer. Before using gels or solutions on the transducer, please read all information provided with the cleaning and disinfection agents, including information on the compatibility of the content ingredients of the disinfectant.

5.3.3 Ultrasound Device Cover

If the medical institution's regulations or local laws or the execution of needle puncture guidance procedures require the use of an ultrasound device protective cover, a qualified sterile ultrasound device protective cover must be used to prevent bloodborne infectious pathogen contamination. For detailed information on using the ultrasound device protective cover, please refer to the instructions provided with the ultrasound device cover.

⚠	WARNING: Please use the ultrasound cover only when the needle puncture procedure begins.
⚠	WARNING: Do not reuse disposable sterile ultrasound device covers.
⚠	WARNING: Check the ultrasound device protective cover for damage before and after diagnosis.
⚠	WARNING: Some protective covers on the market may contain latex and talcum to control infection during tissue sectioning. Please read the packaging to confirm whether the latex and talc are present. Some patients may be allergic to natural rubber latex. Please refer to FDA Medical Alert, dated March 29, 1991, Allergic Reactions to Latex-Containing Medical Devices. MDA91-1.

5.3.4 Ultrasound Device Storage and Transportation

Please follow the instructions to properly protect the ultrasound device.

For storage or transportation:

- When transporting or storing the ultrasound device, it is recommended to use the provided carrying bag for device protection.
- Do not store items other than the ultrasound device in the carrying bag to avoid collision damage to the ultrasound device.
- Ensure that the ultrasound device has been cleaned and disinfected before it is placed into the carrying bag to avoid contaminating the bag.
- Place the ultrasound device separately in the carrying bag to avoid tangling with the charging cable.

For Daily and Long-Term Storage:

- Avoid storing in direct sunlight and environments with excessively high or low temperatures; refer to section **1.1.3 Product Specifications** for transportation and storage conditions.
- Please wipe the ultrasound device dry before placing it in the packaging bag for storage.
- Before storing the ultrasound device, ensure that it has been cleaned, disinfected, and thoroughly dried.
- Store the ultrasound device separately from other equipment to prevent accidental damage to the ultrasound device.

5.3.5 Ultrasound Conductive Gel

Ultrasound gel serves as a conducting medium, facilitating a tight bond between the skin and the transducer, allowing the sound waves to be transmitted directly to the subcutaneous tissues and the area requiring imaging. Ultrasound gel reduces static electricity and serves as a coupling agent. To ensure proper ultrasound transmission to the human body during scanning, it is recommended to use the suggested gel. Apply the gel to the contact surface of the transducer and the body before initiating the examination, and avoid immersing the transducer in the gel. After use, clean the gel with a sterile wiping cloth.

Ultrasound gel should not contain the following ingredients ingredients that may damage the transducer, such as:

- Olive oil
- Methyl or hydroxybenzoate esters (hydroxybenzoic acid)
- Dimethylpolysiloxane
- Iodine
- Emulsions
- Lanolin
- Aloe vera
- Mineral oil

- Methanol, ethanol, or other alcohol-containing gels.

⚠	WARNING: It is prohibited to use gels containing ingredients that may damage the transducer, as it poses a risk of transducer damage and will also void the warranty.

5.3.6 Ultrasound Artifacts

Ultrasound imaging technology relies on the transducer on the ultrasound device receiving sound wave reflections, and different angles of irradiation may result in different images, and artifacts may occur during ultrasound scanning, depending on factors such as frequency, ultrasound beam, axial resolution, signal processing, limitations of physiological tissues, and operator control gestures. Common artifacts include：

- Reverberation
- Mirror image
- Speckle
- Edge shadow side lobe
- Ring Down
- Side lobes and grating lobes will cause targets not directly in front of the transducer to be mistakenly displayed on the sides.

⚠	WARNING: Ensure that you have received sufficient and appropriate safety and effective operation training before using this system for any application. If you’re unsure of your ability to operate the system safely and effectively, do not use the system. Operating the system without proper and adequate training may result in injuries or other harm to personnel.
⚠	WARNING: Evaluation of image quality and results of diagnosis are the user's responsibility. Before making clinical judgments and analyses, check the relevant data generated by the system. Ensure sufficient data during measurements.

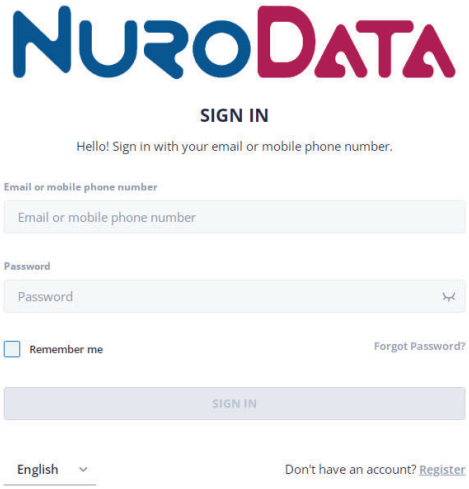
6. Introduction to NURODATA Cloud

NURODATA Cloud is a web-based application that provides account management for the NUSONO APP and allows editing and management of diagnostic case-related information uploaded to the cloud.

This section will introduce the operation of the NURODATA Cloud system, assisting you in understanding the various functions of this cloud system.

※ *NURODATA Cloud does not support the ultrasound-related data transmitted from third-party devices.*

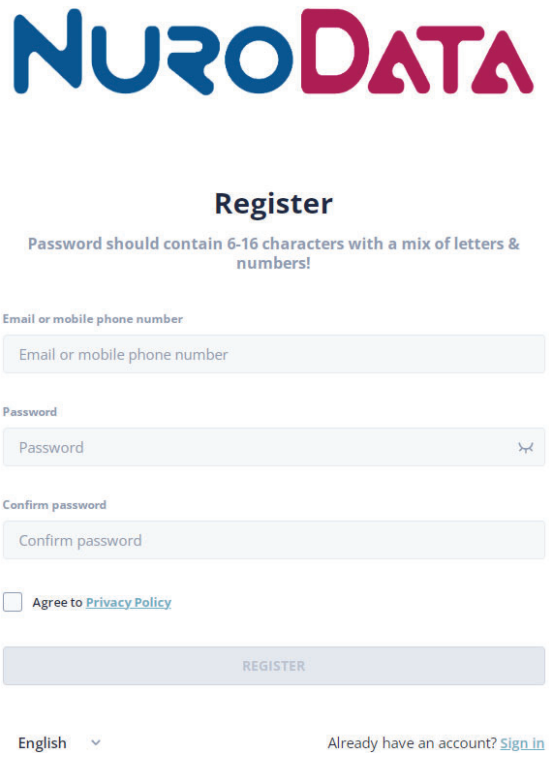
6.1 Sign In



1) Enter your email or phone number and password, and after verifying the account and password, click the "SIGN IN" button to proceed with the login operation. Following the account authentication, successful authentication completes the login process and access to the system will be granted. In case of authentication failure, a prompt message will appear：”Error! Email, mobile phone number or password does not match.
2) When entering the password, you can click to confirm whether the input is correct.

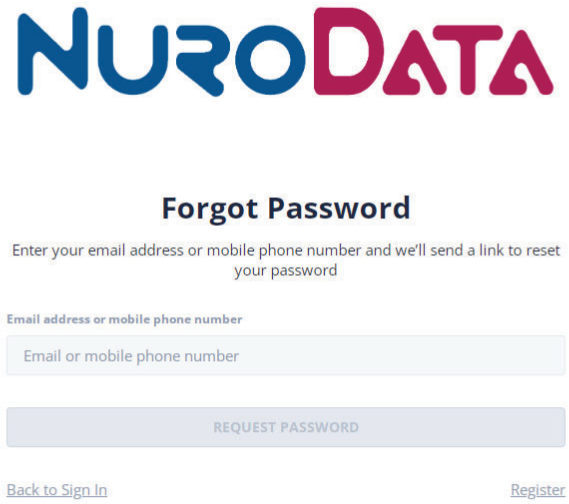
3) Select ”Remember me”to store the login information on this successful login.
4) Click on "English" in the language menu in the bottom left to select the display language.
5) Click on "Register" in the bottom right to navigate to the registration screen.
6) Click on "Forgot Password?" on the right side to navigate to the forgot password screen.

6.2 Registration



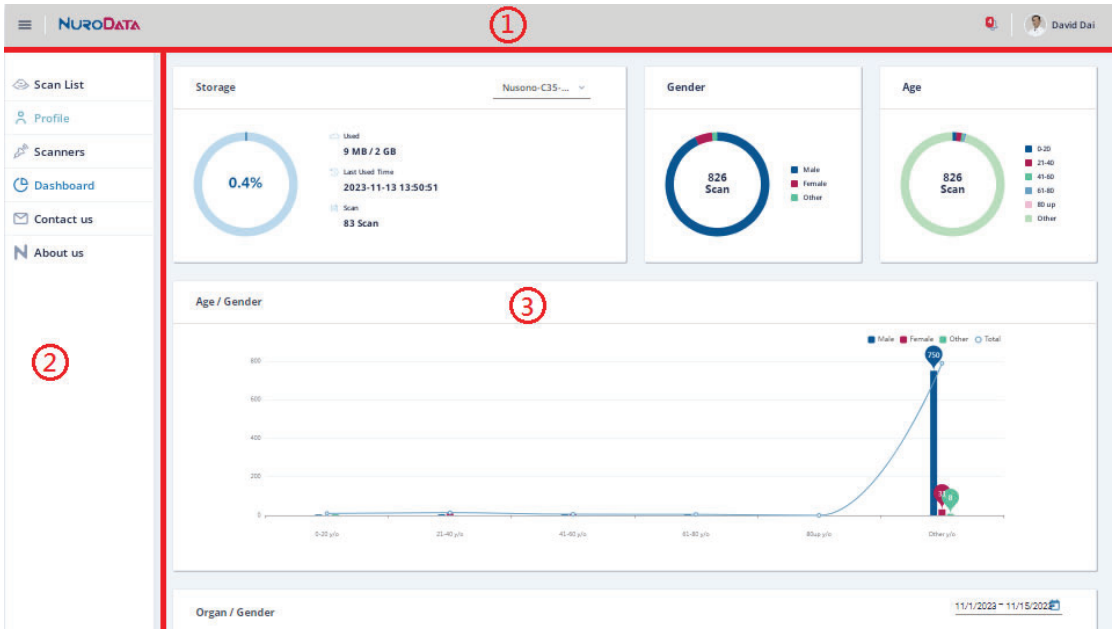
1) Enter your email or phone number, and password and after passing the account and password verification, enter the confirmation password, and agree to “Agree to Privacy Policy”, then click the “REGISTER” button, the system will send an authentication email or text message to the registered email or phone number, and open the input verification code message box.
2) When the authentication countdown reaches zero, click on "Resend" to resend the authentication email or SMS.。
3) Complete the input of the authentication code within the time limit and press "CONFIRM." When the authentication is successful, a prompt message will appear：”Register successfully! After 10 seconds, jump to the sign in page.” Afterwards, the system automatically returns to the login screen.
4) When entering the password, click to confirm whether the input is correct.
5) Click “Agree to Privacy Policy” to open the privacy policy message box.
6) Click on "English" in the language menu in the bottom left to select the display language.
7) Click “Sign In” at the bottom right to navigate to the sign-in screen.

6.3 Forgot Password?



1) Enter your email or phone number, and after verifying the account, click the "REQUEST PASSWORD" button to initiate the password reset request operation. The system will send an authentication email or SMS to the provided email or phone number, and open the input authentication code message box.
2) When the authentication countdown reaches zero, click "Resend" to resend the authentication email or SMS.
3) Complete the input of the authentication code within the time limit and press "CONFIRM." When the authentication code is valid, the modification screen will be opened.
4) Within the valid time, complete the input and confirmation of the new password. Click the "MODIFY PASSWORD" button. Upon successful modification, a prompt message will appear: "Success! Please sign in with your new password, thank you. After 10 seconds, the system will forward to the sign-in page." and then the system automatically returns to the login screen. In case of modification failure, a corresponding message will be displayed.
5) Click on "Back to Sign in" in the bottom left to return to the login screen.
6) Click on "Register" in the bottom right to navigate to the registration screen.

6.4 Main Structure Screen



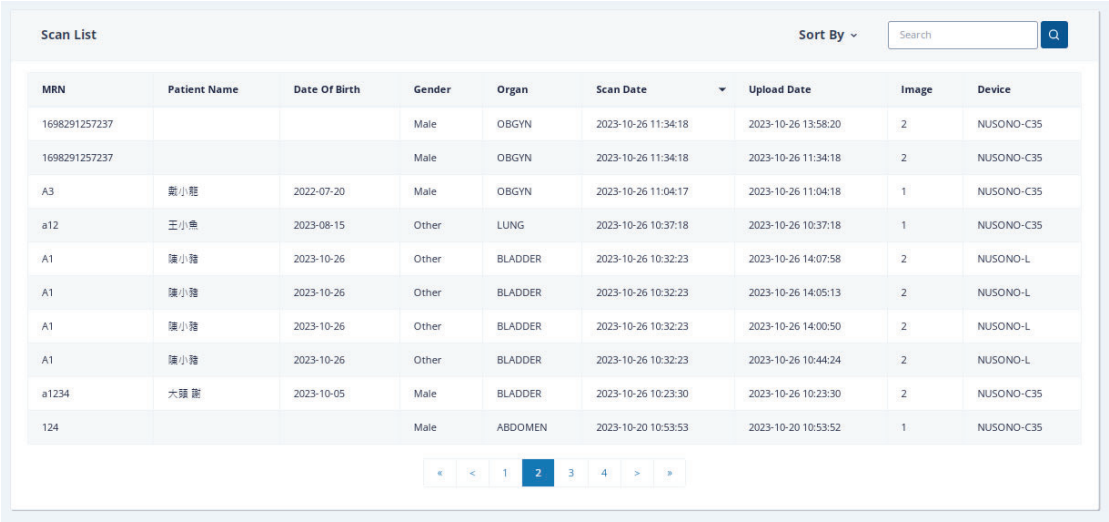
1) Block 1 : The upper left is the main menu button. Clicking on upper left to switch between showing and hiding the display; the upper right is the prompt messages and the account image :
   - displays the number of unread messages based on the received messages.
   - Clicking on the prompt messages opens the prompt message list.
   - Clicking on the account image block opens the function menu: Profile, Language, Sign Out.
   - Clicking on the function menu item "Profile" switches the display area to the profile screen.
   - Clicking on the function menu item “Language”, allows the user to choose the language of the interface.
   - Clicking on the function menu item "Sign out", the sign-out process will be executed and the sign-in screen will be displayed.
2) Block 2 : Main menu list
   - Scan List : Query and edit the management of uploaded medical records.
   - Profile : Manage personal information of the account.
   - Scanners : Record the ultrasound device information.
   - Dashboard : Organize statistical record compilation of uploaded medical records.
   - Contact Us : Fill out a message if you have any questions to notify us.

- About Us : NURODATA official website.

3) Block 3 : Display area for functional screens.

6.5 Medical Record Data

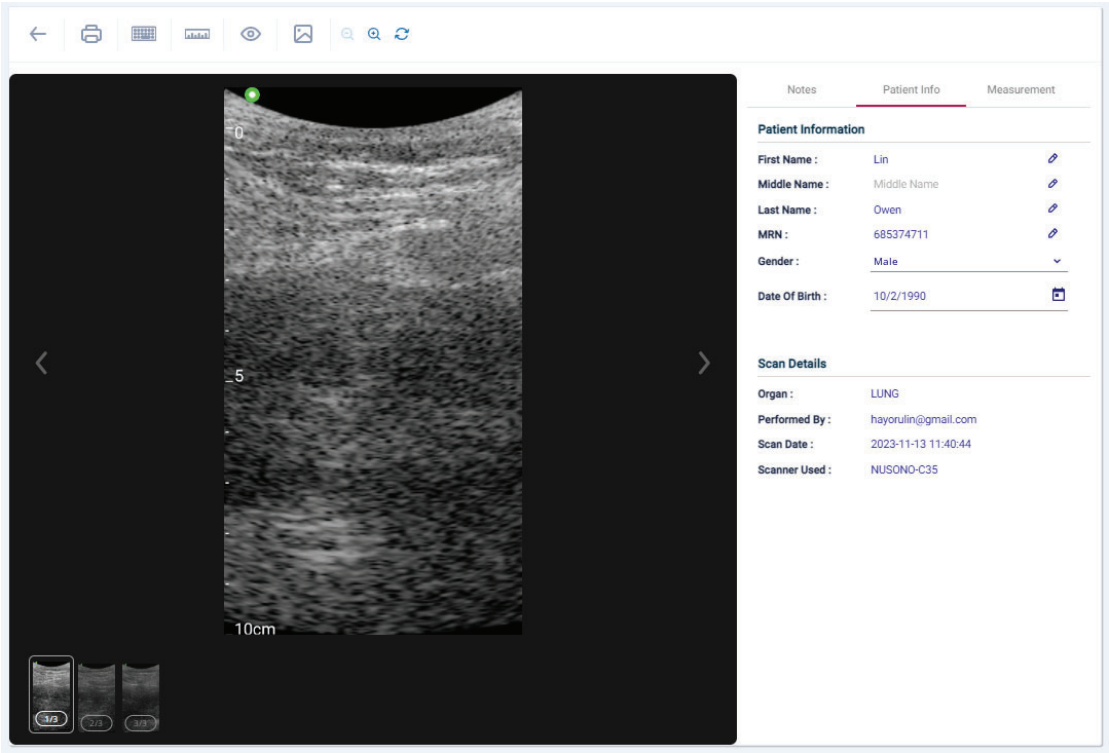
- Scan list



MRN	Patient Name	Date Of Birth	Gender	Organ	Scan Date	Upload Date	Image	Device
1698291257237			Male	OBGYN	2023-10-26 11:34:18	2023-10-26 13:58:20	2	NUSONO-C35
1698291257237			Male	OBGYN	2023-10-26 11:34:18	2023-10-26 11:34:18	2	NUSONO-C35
A3	戴小熊	2022-07-20	Male	OBGYN	2023-10-26 11:04:17	2023-10-26 11:04:18	1	NUSONO-C35
a12	王小魚	2023-08-15	Other	LUNG	2023-10-26 10:37:18	2023-10-26 10:37:18	1	NUSONO-C35
A1	陳小豬	2023-10-26	Other	BLADDER	2023-10-26 10:32:23	2023-10-26 14:07:58	2	NUSONO-L
A1	陳小豬	2023-10-26	Other	BLADDER	2023-10-26 10:32:23	2023-10-26 14:05:13	2	NUSONO-L
A1	陳小豬	2023-10-26	Other	BLADDER	2023-10-26 10:32:23	2023-10-26 14:00:50	2	NUSONO-L
A1	陳小豬	2023-10-26	Other	BLADDER	2023-10-26 10:32:23	2023-10-26 10:44:24	2	NUSONO-L
a1234	大頭 龍	2023-10-05	Male	BLADDER	2023-10-26 10:23:30	2023-10-26 10:23:30	2	NUSONO-C35
124			Male	ABDOMEN	2023-10-20 10:53:53	2023-10-20 10:53:52	1	NUSONO-C35

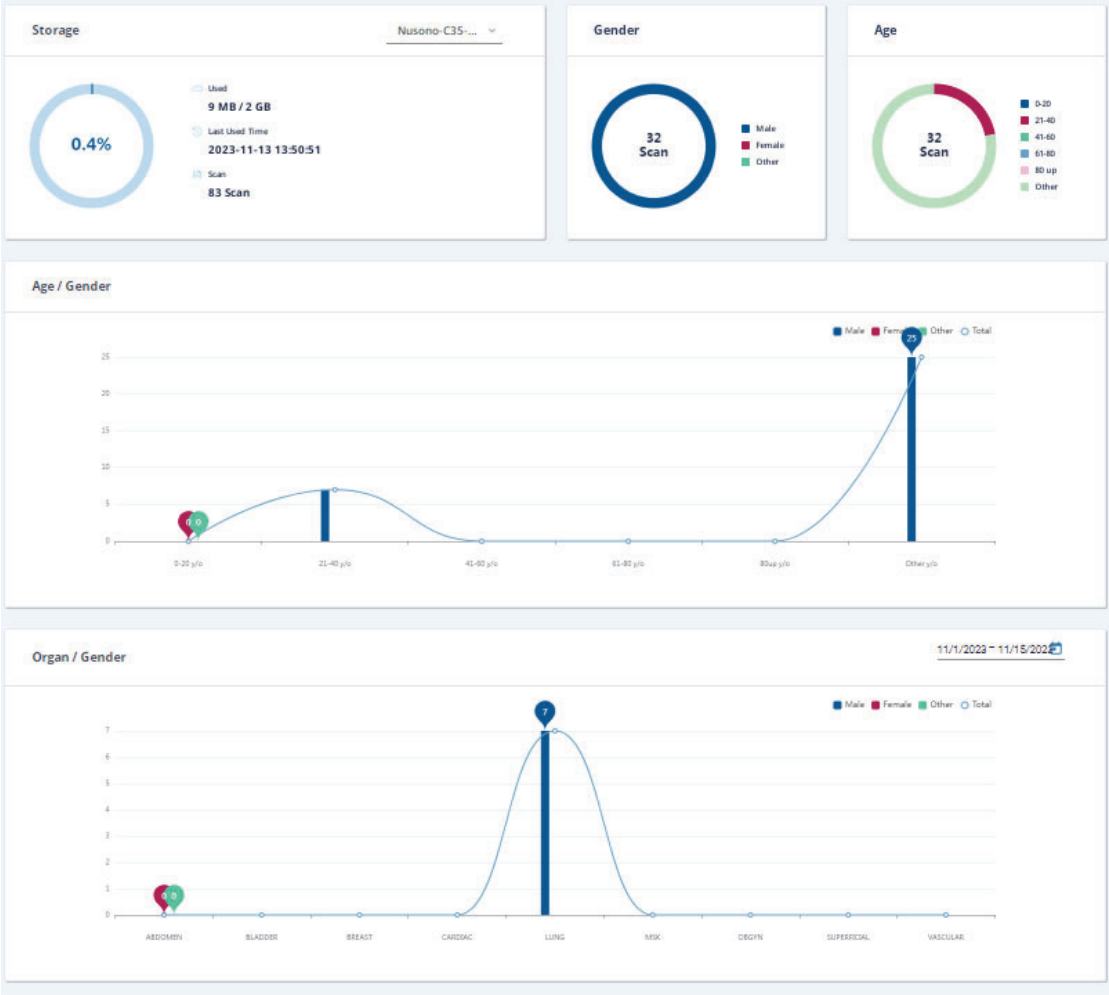
1) Click on a medical record item to open detailed information.
2) Click on the item title or "Sort By" above to change the sorting order.
3) In the upper right input box, click on to filter the content of medical record data.
4) Use the pagination or page-turning tools in the bottom to switch pages in the medical record list.

- Detailed Medical Record Information



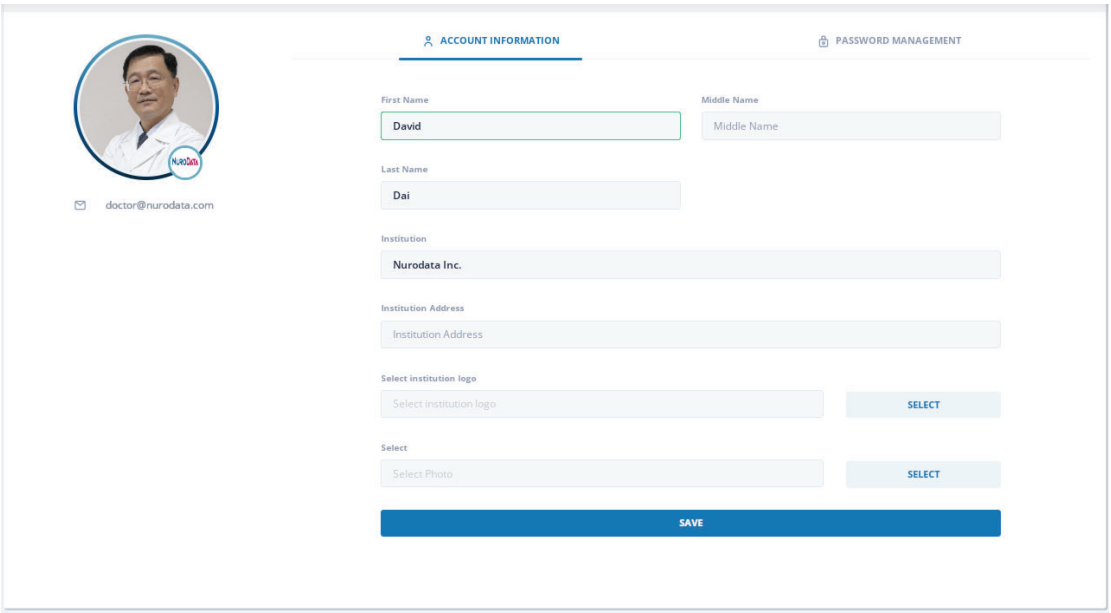
1) Click on the button in the top to return to the medical record list.
2) Click on the button in the top for a preview of printing/exporting reports.
3) Click on the button in the top to open annotation tools for editing.
4) Click on the button in the top to open measurement tools for editing.
5) Click on button in the top to switch the hidden/displayed annotations and measurements.
6) Click on the button in the top to export videos and images.
7) Click on the image display zoom tool at the top to adjust the display size: zoom in, zoom out, restore size.
8) Click on the small icons below or click on the sides of the display area to switch between displayed files.
9) Click on the "Notes" tab, enter diagnostic descriptive text in the input box below, and then click to add a diagnostic description.
10) Click on the "Patient Info" tab to view detailed diagnostic information or edit the patient's basic information.
11) Click on the"Measurement" tab to view measurement data from relevant measurement tools.

6.6 Statistical Information



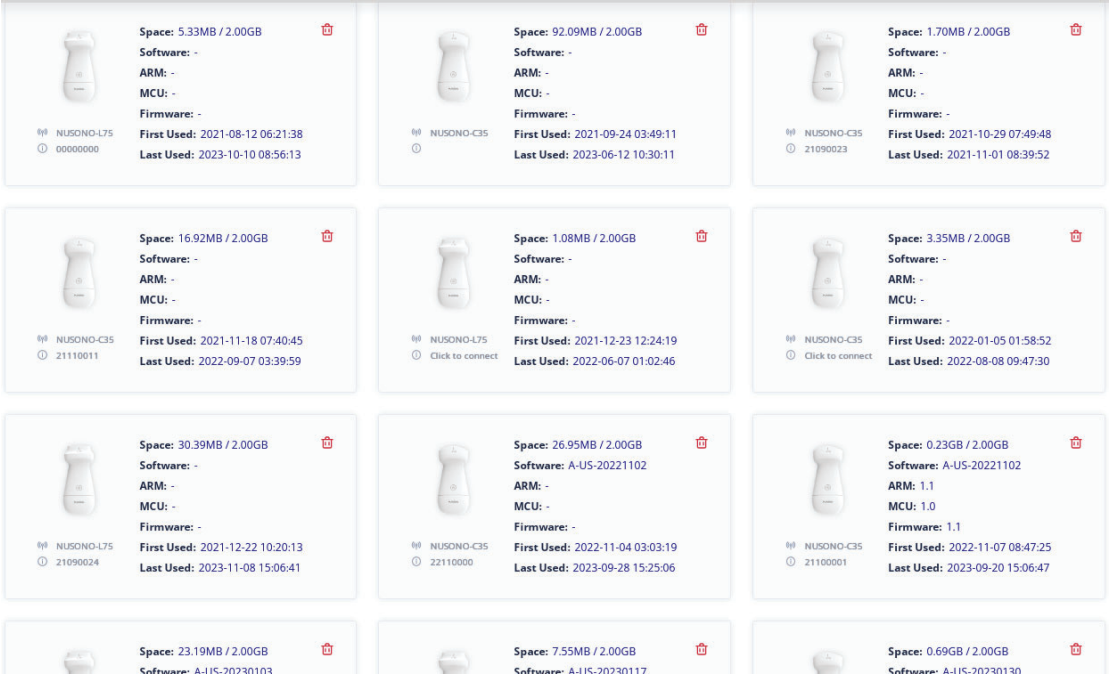
View various statistical information about the uploaded medical records.

6.7 Account Information



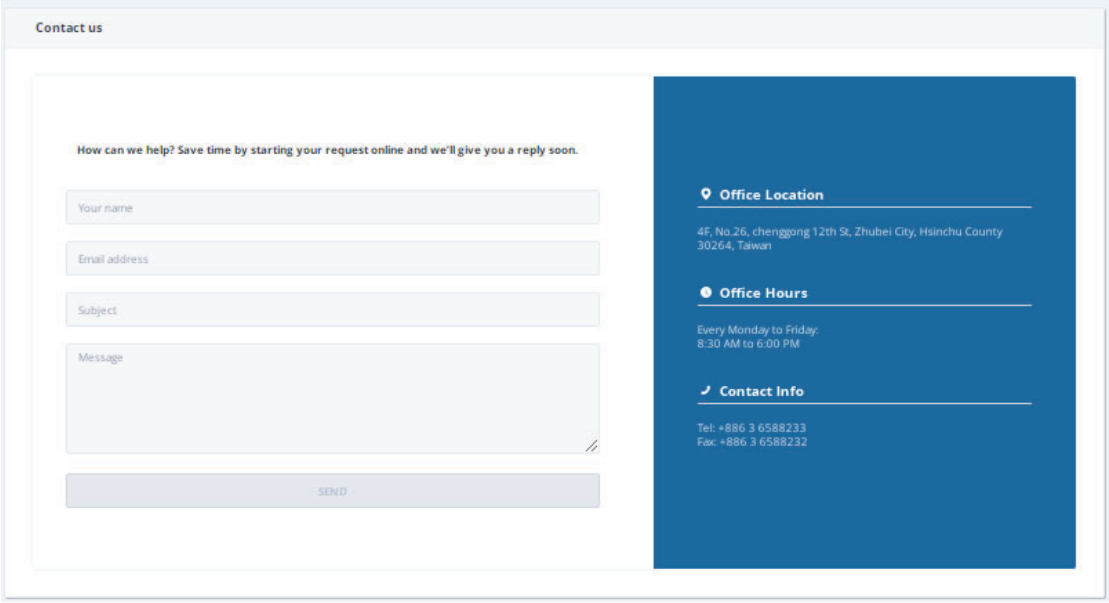
1) Click the "ACCOUNT INFORMATION" tab to switch and display account information, and proceed with the editing and modification of related information.
2) Click the "PASSWORD MANAGEMENT" tab to switch to the password modification screen and perform password modification operation.

6.8 Device Information



1) View all the device-related information used for uploading medical records.
2) Click on the upper right to delete the display of that device information.

6.9 Contact Us



Enter your name, email, subject, and problem description. After email format verification, click the "SEND" button. The system will send a notification email to the service mailbox.

6.10 About Us

Click to open a browser page, linking to https://www.nurodata.com/web/

7. Safety Regulatory Requirements

This device and system comply with relevant international and domestic standards and laws. Users are responsible for choosing mobile devices and ultrasound devices that comply with the laws of the region where the product is used. This device complies with all the standards listed in this section.

- **Product classification**
  - Device with transducer probes: Class B/Internally-powered medical electrical equipment
  - Type BF applied parts, Ingress Protection Rating IP67
  - Ordinary equipment/continuous operation
  - Non-AP (Anesthetic Proof)/APG equipment
  - US FDA: Class II

- **Biocompatibility**
  - ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
  - ISO 10993-5:2009 - Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity
  - ISO 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for skin sensitization
  - ISO 10993-23:2021 - Biological evaluation of medical devices - Part 23: Tests for irritation

- **Product Specifications, Design Overview, Verification / Confirmation, and Risks**
  - IEC 62304 2006 + A1:2015 - Medical device software - Software life cycle processes / Amendment 1
  - IEC 62366-1: 2015 + A1:2020 - Medical devices - Part 1: Application of usability engineering to medical devices
  - IEC 60601-1-6:2010 + A2:2020 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
  - ISO 13485 2016 Medical devices - Quality management systems
  - ISO 14971:2019 Medical devices - Application of risk management to medical devices
  - ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
  - ISO 10993-5:2009 - Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021 - Biological evaluation of medical devices - Part 23: Tests for irritation

- **Performance**
  - IEC 60601-1:2005 + A2:2020; EN 60601-1:2006 + A2:2021 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance / Amendment 2
  - IEC 60601-1-2:2014 + A1:2020; EN 60601-1-2:2015 + A1:2021; EN 301489-1:V2.2.3 (2019-11); EN 301489-17V2.2.1 (2012-09) - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
  - IEC 60601-2-37:2007 + A1:2015; EN 60601-2-37:2008 + A1:2015 - Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
  - IEC TR 60601-4-2 Edition 1.0 2016-05 - Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
  - AAMI TIR69:2017/(R2020) - Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems
  - IEEE ANSI USEMCSC C63.27-2021 - American National Standard for Evaluation of Wireless Coexistence

- **Built-in Lithium Battery**
  - IEC 62133-2:2017 + A1: 2021 - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

- **FCC**

  15.19
  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.

  "Federal Communications Commission (FCC) Statement

  15.105(a)
  This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are

designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense."

15.21
You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

FCC RF Radiation Exposure Statement:
1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. For portable operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

7.1 Manufacturer's declaration-electromagnetic emissions

Manufacturer's declaration-electromagnetic emissions		
The NUSONO-C35, NUSONO-L75, NUSONO-P25 is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the NUSONO-C35, NUSONO-L75, NUSONO-P25 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance** **(for professional healthcare environment)**
RF emissions CISPR 11	Group 1	The NUSONO-C35, NUSONO-L75, NUSONO-P25 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 A	The NUSONO-C35, NUSONO-L75, NUSONO-P25 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	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration-electromagnetic immunity

The NUSONO-C35, NUSONO-L75, NUSONO-P25 is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the NUSONO-C35, NUSONO-L75, NUSONO-P25 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for professional healthcare environment)
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ± 8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical professional healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV, ± 2kV line(s) to earth	± 0.5kV, ±1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical professional healthcare environment.

Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 25/30 cycles Voltage interruptions: 0 % *U*T; 250/300 cycle	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 30 cycles Voltage interruptions: 0 % *U*T; 300 cycle	Mains power quality should be that of a typical professional healthcare environment. If the user of the NUSONO-C35, NUSONO-L75, NUSONO-P25 requires continued operation during power mains interruptions, it is recommended that the NUSONO-C35, NUSONO-L75, NUSONO-P25 be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 60 Hz	The NUSONO-C35, NUSONO-L75, NUSONO-P25 power frequency magnetic fields should be at levels characteristic of a typical location in a typical professional healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The NUSONO-C35, NUSONO-L75, NUSONO-P25 is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the NUSONO-C35, NUSONO-L75, NUSONO-P25 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for professional healthcare environment)
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the NUSONO-C35, NUSONO-L75, NUSONO-P25 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Recommended separation distance: $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80MHz to 800 MHz $d = 2{,}\sqrt{P}3$ 800MHz to 2,7 GHz 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). Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distance between

portable and mobile RF communications equipment and the NUSONO-C35, NUSONO-L75, NUSONO-P25

The NUSONO-C35, NUSONO-L75, NUSONO-P25 is intended for use in an electromagnetic environment (for professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the NUSONO-C35, NUSONO-L75, NUSONO-P25 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NUSONO-C35, NUSONO-L75, NUSONO-P25 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d =1,2	80 MHz to 800 MHz d =1,2	800 MHz to 2,7 GHz d =2,3
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The NUSONO-C35, NUSONO-L75, NUSONO-P25 is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the NUSONO-C35, NUSONO-L75, NUSONO-P25 should assure that it is used in such an environment.

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for professional healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	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	28
870							
930							
1 720	1,700 –	GSM 1800;	Pulse	2	0,3	28	28

1 845 1 970	1,990	CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	modulation b) 217 Hz				
2 450	2,400 – 2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240 5 500 5 785	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9

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.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

The NUSONO-C35, NUSONO-L75, NUSONO-P25 is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the NUSONO-C35, NUSONO-L75, NUSONO-P25 should assure that it is used in such an environment.

Frequencies	Test Level [A/m]	Modulation	Dwell time [s]	Compliance LEVEL [A/m] (for professional healthcare)
30 kHz (a)	8	CW	3	8
134,2 kHz	65	Pulse modulation (b) 2,1 kHz	3	65 (c)
13,56 MHz	7,5	Pulse modulation (b) 50 kHz	3	7,5 (c)

Note:

(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the PROFESSIONAL HEALTHCARE ENVIRONMENT.

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

(c) r.m.s., before modulation is applied.

8. Appendix

8.1 Appendix 1: Lung Preset Details

8.1.1 Lung Presets Characteristics

- Lung ultrasound emphasizes artifacts (A-line, B-line) rather than echo structure resolution.
- Other imaging modes may excessively reduce artifacts, potentially affecting the accuracy of lung diagnostics.

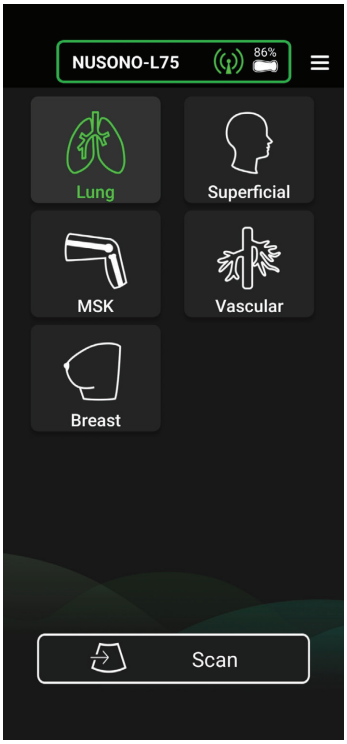
8.1.2 Types of Probes

The following probes are suitable for lung ultrasound:

- NUSONO-C35 (3MHz): Optimized for deep lung scanning.
- NUSONO-L75 (6MHz): Designed for shallow lung scanning.
- NUSONO-P25 (3MHz): Suitable for deep lung scanning, with a narrower transducer width, allowing easier scanning between the ribs during diagnostics.

8.1.3 Lung Preset Selection, Mode, and Adjustments

- After completing the connection setup for the ultrasound device with the NUSONO APP, go to the **Home Page** screen of the NUSONO APP and select the icon , which will turn green.



- **Presets available for Lung as Image Adjustment Settings and Switching Scan Modes**:

to open/close the image adjustment toolbar,

Adjust Depth: to modify the image depth.

Adjust Image Contrast: Enhance or weaken the image contrast.

Time Gain Compensation (TGC) Settings: To adjust TGC

.

The system will begin in B-Mode by default, to switch to different modes, users can click to open the image mode submenu. (Default B-mode settings: Please refer to Section 4.6 for the preset parameter table for each probe)

B/M Mode	Doppler*
B-Mode	**Color Doppler**
M-Mode	**Power Doppler**
*No quantitative claims regarding the Doppler sensitivity are made for the NUSONO-C35 series,thus a minimum performance specification of the Doppler sensitivity is not available.	

8.1.4 Clinical Applications : General Use and Image Interpretation

Normal Lung:

- A-line: Horizontally aligned artifacts, indicating air-filled lungs, a characteristic of normal lung imaging.
- Lung Sliding: In M-mode, appears as a "seashore sign," representing lung movement with respiration.

Abnormal Lung Findings:

- B-line: High-echo vertical streaks extending downward from the pleural line.

8.1.5 Image Optimization Techniques

For clear A-line and B-line visualization, adjust the following settings:

1. Depth: Increase for deeper lung assessment, decrease for pleural assessment.
2. TGC: Increase if B-lines are weak, decrease if A-lines are obscured by excessive brightness.
3. Probe Angle & Position: Adjust to align with the pleura, use intercostal approach to avoid rib shadowing.
4. M-Mode: Enable for lung sliding assessment (e.g., seashore sign = normal, barcode sign = pneumothorax).
5. Minimize Motion Artifacts: Keep the probe steady; ask the patient to briefly hold their breath if needed.

Proper depth, TGC, probe alignment, and mode selection ensure accurate pulmonary imaging and enhance diagnostic confidence.

8.1.6 Safety and Limitations of Lung Ultrasound

Lung Ultrasound Safety:

Lung ultrasound is a non-invasive, radiation-free imaging technique, making it a safe and effective tool for pulmonary evaluation. However, users must follow best practices to ensure accurate interpretation and minimize diagnostic errors.

- Proper Probe Handling: Ensure correct probe placement and angling to avoid misinterpretation of artifacts.
- Avoiding Over-Reliance on Ultrasound Alone: While highly useful for point-of-care assessment, lung ultrasound should be correlated with clinical symptoms and, when necessary, supplemented with additional imaging (e.g., X-ray or CT) to confirm findings.
- Refer to Section 1.4 Safety

Limitations of Lung Ultrasound:

While lung ultrasound is a valuable diagnostic tool, it has inherent limitations due to ultrasound wave properties and lung anatomy:

- Subcutaneous Gas (Subcutaneous Emphysema): Excessive trapped gas can obstruct ultrasound penetration, reducing image quality and pleural visibility. X-ray or CT may be needed for further assessment.
- Limited Deep Lung Resolution: Ultrasound effectively visualizes superficial lung structures (pleura, lung sliding, A-line, B-line) but cannot image deep lung parenchyma, alveoli, or hilar regions due to air-tissue impedance mismatch. CT or MRI may be required for deeper evaluations.
- Patient Positioning & Breathing Motion: Image quality can vary with patient positioning and respiratory cycle, requiring real-time adjustments to optimize lung sliding and artifact detection.
- Operator Dependency: Proper training and experience are essential to avoid misinterpretation of A-lines, B-lines, and lung sliding, ensuring accurate diagnosis through comparison with clinical criteria and predicate imaging.