2020/12/03 (English)

SONON

Ultrasound Imaging System

User Manual Rev. 6.0

Model name: SONON 300C, 300L

CE
0123

Keep this manual with the device for future reference.

HEALCERION

The SONON ultrasound devices are:

- Diagnostic ultrasound equipment which transmit ultrasound waves into the human body and generate images using the received echoes.
- Categorized as Class II Active Diagnostic Medical Products, according to MDD 93/42/EEC regulations for use on human patients.

Contact the manufacturer or visit the homepage for detailed information.

Manufacturer

HEALCERION

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Tel: +(82) 70-7582-6326 / E-mail: info@healcerion.com

EC Representative

Obelis S.A.

Bd. Général Wahis 53

1030 Brussels, BELGIUM

Tel: +(32) 2-732-59-54 / Fax: +(32) 2-732-60-03 / E-Mail: mail@obelis.net

⚠ CAUTION

This device should be used in compliance with all applicable laws.

⚠ ATTENTION

L’appareil doit être utilisé conformément à la législation applicable.

For USA only:

⚠ CAUTION

Federal law restricts this device to use by, or on the orders of, a physician.

Table of contents

About this user manual

This manual is intended to assist you with the safe operation of your SONON ultrasound device. Read this manual thoroughly before operating the product and observe all safety instructions.

HEALCERION has prepared this manual carefully in order to ensure that the information it contains is accurate. However, HEALCERION will not be liable for any possible errors or omissions of information in this manual.

HEALCERION reserves the right to make changes to the products or the associated software apps described in this manual without further notice, to improve product reliability, function, or design.

NOTE

- All references to standards and regulations and their revisions are valid as of the date of publication of this user manual.
- Some optional parts or functions described in this user manual may not be available in some countries. For information specific to your region, contact your local representative.
- The screenshots and illustrations in this manual are for illustrative purposes only. They may differ from the actual images on the display.

Intended audience

This user manual is intended for healthcare professionals who operate and maintain the SONON ultrasound device. The user must be properly trained in sonography and familiar with ultrasound techniques and clinical procedures. See the flowing table for the profile of intended users of the SONON ultrasound device.

Training	Trained professionals who have completed related coursework, such as doctors, nurses, emergency medical technicians, and medical students
Knowledge level	Qualifications: • Basic knowledge of sonography • Understanding of the physiological effects of ultrasound exposure • Ability to recognize, understand, operate, and update the mobile device that is linked to the SONON ultrasound device • Intuitive understanding of the software and hardware user interface and ability to update the software app • Understanding of the terms in the user manual, which are necessary for the operation of the device
Linguistic capability	Understanding of the instructions and procedures provided in this manual
Experience	Experience in the field of sonography
Vision	Corrected visual acuity of 1.0 or better
Memory	Ability to read through this user manual and remember the safety instructions and functions of the device

Document conventions

Safety messages used in this manual

The following safety messages are provided in this user manual to warn users against potentially hazardous situations that may result in death, injury, or property damage.

⚠ WARNING

Provides important information required for the safety of the operator and the patient.

⚠ AVERTISSEMENT

Fournit les renseignements importants qui sont nécessaires pour la sécurité de l'opérateur et du patient.

⚠ CAUTION

Provides information required to avoid damaging the device or losing patient data.

⚠ ATTENTION

Fournit les renseignements qui sont nécessaires pour éviter d'endommager l'appareil ou de perdre des données patient.

NOTE

Provides useful information that will help you operate the product more efficiently.

Symbols used in this manual

The following table lists symbols for use with electrical medical equipment, which are agreed upon as the international standard by the IEC. These symbols are used to provide information about safety, as well as additional information about the product and the use of the product.

Symbol	Definition
	Electrical protection: Insulated patient application (Type BF)
	Warning: This symbol indicates hazards related to operating conditions.
	Consult accompanying documents: This symbol advises the reader to consult the accompanying documents.
	Freeze mode: This symbol is used for the Freeze button on the device, which is used to freeze the scan screen.
	Stand-by: This symbol is used for the power button on the device, which is used to turn the device on or off or to put the device in standby mode.
	Wi-Fi: This symbol indicates wireless communication.
	Manufacturer information: This symbol is followed by the name and address of the device manufacturer.
	Manufacture date: This symbol is followed by the device manufacture date in the form YYYY-MM.
	Serial number: This symbol is followed by the device serial number.
	Model name: This symbol is followed by the model name of the product.
	Representative information: This symbol is followed by the information about manufacturer's EU representative.
	This way up: This symbol indicates the correct upright position of the transport package.
	Fragile; handle with care
	Keep dry
	Indicates the need for separate collection of electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive.

Symbol	Definition
	For more information, see “Disposal of the device” on page 24.
	USA federal law restricts this device to sale by or on the order of a physician.
	RF Equipment for non-ionizing radiation
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation

Safety information

Before you start operating your device you must thoroughly read and understand the safety information in this section and follow it strictly while operating the device.

General safety

The following safety instructions are intended to provide guidelines for using the SONON ultrasound device.

⚠ WARNING

- Do not use a damaged or defective device. Failure to follow can result in serious injury and equipment damage.
- In case of device failure, ensure that the device is repaired only by an authorized technician.
- If the device has been dropped on the floor or on any other hard surface, refrain from using the device. Using a dropped device may increase the risk of electric shock due to damaged electrical insulation.
- Do not attempt to open the device. The warranty may be voided if such an attempt is detected.
- The device is not delivered sterile. Before the first use, you must clean the device to avoid infection or disease transmission.
- The device must be cleaned before it is replaced or disposed of.
- Inspect the device prior to each use for damage to or degeneration of the housing, strain relief, lens, or seal. A thorough inspection should be conducted during the cleaning process.
- Do not modify this device without prior authorization by HEALCERION.
- Do not use the device with high-frequency surgical equipment. Doing so may damage the equipment.
- Do not touch the patient while using a mobile device.
- Do not touch the patient and the charging connectors simultaneously.
- Operate this device prudently in compliance with the ALARA (as low as reasonably achievable) principle. It is strongly recommended that you consider ALARA whenever you conduct ultrasound scans. See “Bioeffects and safety of ultrasound scans” on page 21 for additional information.
- Features that facilitate observation and measurement of ultrasound images must be configured with extreme care. Some default configurations are recommended by the device. If in doubt, verify the images by comparing them with manual measurements. Diagnostic interpretations of measurements shall be carried out at your discretion.

⚠ AVERTISSEMENT

- Ne pas utiliser un appareil endommagé ou défectueux. Le non-respect de cette consigne peut entraîner des blessures et des dommages matériels graves.

- En cas de panne de l’appareil, veiller à ce que celui-ci ne soit réparé que par un technicien agréé.
- Si l’appareil est tombé au sol ou sur une autre surface dure, s’abstenir d’utiliser l’appareil. L’utilisation d’un appareil ayant subi un choc peut augmenter le risque d’électrisation dû à un défaut d’isolement électrique.
- Ne pas essayer d’ouvrir l’appareil. La garantie est susceptible d’être annulée en cas de tentative d’ouverture.
- L’appareil n’est pas livré stérile. Avant la première utilisation, il convient de nettoyer l’appareil pour éviter tout risque d’infection ou de transmission d’une maladie.
- L’appareil doit être nettoyé avant d’être rangé ou mis au rebut.
- Inspecter l’appareil avant chaque utilisation pour détecter d’éventuels dommages ou détériorations sur le boîtier, le manchon anti-traction, la lentille ou le joint. Une inspection méticuleuse doit être effectuée durant le nettoyage.
- Ne pas modifier l’appareil sans autorisation préalable de HEALCERION.
- Ne pas utiliser l’appareil avec un équipement chirurgical à haute fréquence. Dans le cas contraire, cela pourrait endommager l’équipement.
- Ne pas toucher le patient en utilisant un appareil mobile.
- Ne pas toucher simultanément le patient et les connecteurs de charge.
- Utiliser l’appareil avec prudence, conformément au principe ALARA (aussi bas que raisonnablement possible). Il est vivement recommandé d’appliquer le principe ALARA lors de toute échographie. Consulter le chapitre « Effets biologiques et sécurité de l’échographie » à la page 22 pour des renseignements complémentaires.
- Les fonctionnalités permettant d’observer et de mesurer facilement des images échographiques doivent être configurées avec une extrême prudence. Certaines configurations par défaut sont recommandées par l’appareil. En cas de doute, vérifier les images en les comparant avec des mesures manuelles. ’interprétation des mesures à des fins de diagnostic est laissée à discrétion.

⚠ CAUTION

- This device should be used in compliance with applicable laws. Some jurisdictions restrict certain uses, such as gender determination.
- Allow the device to rest for 10 minutes after 10 minutes of scanning.
- Data stored in a mobile device cannot be recovered if you lose your mobile device.
- Changing the display settings can affect image quality and compromise diagnostic accuracy. It is your responsibility to adjust the display settings appropriately to obtain desirable image quality.
- Because this device is composed of highly sensitive electronic components, it can be easily damaged by improper handling. Use care when handling this device, and protect the device from damage when not in use.
- Using unapproved coupling gels or inappropriate cleaning agents may result in transducer damage.
- Do not soak or saturate the transducer (device head) with solutions containing alcohol, bleach, ammonium chloride compounds, hydrogen peroxide, or any incompatible solutions.

⚠ ATTENTION

- L’appareil doit être utilisé conformément à la législation applicable. Certaines juridictions restreignent des usages spécifiques, comme la détermination du sexe.
- Ne pas utiliser l’appareil pendant 10 minutes après 10 minutes du balayage.
- Les données conservées sur un appareil mobile ne peuvent pas être récupérées en cas de perte de ce dernier.
- La modification des paramètres d’affichage peut affecter la qualité d’image et compromettre la précision du diagnostic. Il est de la responsabilité de l’opérateur de régler les paramètres d’affichage de manière appropriée afin d’obtenir la qualité d’image recherchée.
- L’appareil étant constitué de composants électroniques hautement sensibles, il peut être facilement endommagé en cas de manipulation incorrecte. Manipuler l’appareil avec soin et le protéger contre les dommages lorsqu’il n’est pas utilisé.
- L’utilisation de gels d’échographie non homologués ou de produits de nettoyage inappropriés peut endommager le transducteur.
- Ne pas tremper ou imprégner le transducteur (tête de l’appareil) avec des solutions contenant de l’alcool, de l’eau de Javel, des composés à base de chlorure d’ammonium, du peroxyde d’hydrogène ou toute autre solution non compatible.

Electrical safety

The device is operated using electrical energy that can harm patients or users if live internal parts come into contact with conductive solutions.

⚠ WARNING

- Do not immerse the device in any liquid beyond the immersion level. Never immerse the device connector in any liquid.
- Do not drop the device or subject it to other types of mechanical shock or impact. Degraded performance or damage such as cracks or chips in the housing may result.
- Electrical leakage checks should be performed on a routine basis by qualified hospital personnel.

⚠ AVERTISSEMENT

- Ne pas plonger l’appareil dans un liquide au-delà de la limite d’immersion. Ne pas plonger le connecteur de l’appareil dans du liquide, quel que soit son type.
- Ne pas faire tomber l’appareil ou le soumettre à un autre type de choc ou d’impact mécanique. Dans le cas contraire, les performances de l’appareil peuvent être réduites ou des dommages peuvent apparaître sur le boîtier, comme des fissures ou des éclats.
- Un contrôle des fuites de courant doit être effectué régulièrement par du personnel hospitalier qualifié.

Battery-related safety information

⚠ CAUTION

- Do not disassemble or puncture the battery, or expose the battery to excessive impact.
- Do not place the battery near a heat source or expose it to open flame. Such exposure may lead to leakage of corrosive liquid, electric shock, or fire.
- If any liquid from the battery should come into contact with the eye, immediately wash the eye with plenty of water and seek medical assistance as soon as possible.
- Do not immerse the battery or expose the battery to water.
- The AC adapter must be kept outside the patient environment (refer to IEC 60601-1).

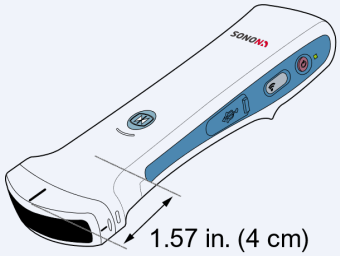
⚠ ATTENTION

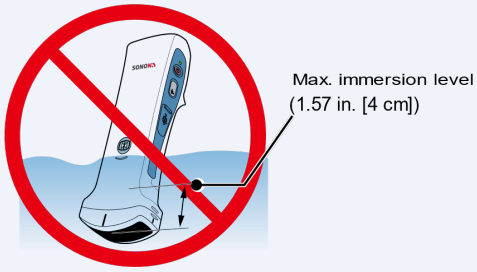
- Ne pas démonter ou percer la batterie, ni l’exposer à un choc excessif.
- Ne pas placer la batterie à proximité d’une source de chaleur, ni l’exposer à une flamme ouverte. Une telle exposition pourrait entraîner une fuite de liquide corrosif, une électrisation ou un incendie.
- Si du liquide s’écoulant de la batterie entre en contact avec les yeux, rincer immédiatement et abondamment à l’eau claire et demander un avis médical dès que possible.
- Ne pas immerger la batterie; ne pas exposer la batterie à l’eau.
- L’adaptateur CA doit être tenu en dehors de l’environnement du patient (voir norme IEC 60601-1).

Immersion level

⚠ CAUTION

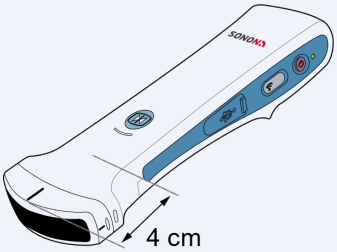
The SONON ultrasound device satisfies IPX7 requirements for being watertight up to a maximum of 1.57 in. (4 cm) from the head (transducer side). Do not immerge the device in any liquid over the maximum immersion level.





⚠ ATTENTION

L'échographe SONON est conforme aux exigences IPX7, car il est imperméable jusqu'à un maximum de 4 cm de la tête (côté transducteur). Ne pas plonger l'appareil dans du liquide, quelle que soit sa nature, au-delà de la limite maximale d'immersion.



Electromagnetic compatibility

- The SONON ultrasound device has been tested and found to comply with IEC 60601-1-2 electromagnetic compatibility (EMC) limits.
- This device is intended for use in the electromagnetic environment specified in “10.2 Guidance and manufacturer’s declarations” on page 165 of this manual.

Coupling gels

⚠ CAUTION

Do not use non-approved gels (lubricants). They may damage the device and void the warranty.

⚠ ATTENTION

Ne pas utiliser de gels (lubrifiants) non homologués. Ils peuvent endommager l’appareil et annuler la garantie.

Application

In order to ensure optimal transmission of energy between the patient and the SONON ultrasound device, a conductive gel or couplant must be applied liberally to the area of the patient’s body where scanning will be performed.

Precautions

Coupling gels should NOT contain any of the following ingredients, as they are known to cause damage to the ultrasound scanning device.

- Methanol, ethanol, isopropanol alcohol, or any other alcohol-based products
- Mineral oils
- Iodine
- Lotions
- Lanolin
- Aloe vera
- Olive oil
- Methyl or ethyl parabens (para hydroxybenzoic acid)
- Dimethylsilicone

Approved coupling gels

The coupling gels approved by the manufacturer are as follows.

Product name	Manufacturer
Aquasonics 100	Parker Laboratory Inc.
Clear Image	Sonotech Inc.
Scan	Parker Laboratory Inc.
Sonogel	Sonogel Vertriebs

Bioeffects and safety of ultrasound scans

Thermal safety

Maintaining a safe thermal environment for the patient has always been a design priority at HEALCERION. When contacting the ultrasound device on the skin, the maximum allowed temperature must remain below 109.4°F (43 °C).

Whenever ultrasound waves travel through tissues, there is always a certain risk of damage. There has been a great deal of research on the impact that high-frequency waves can have on different kinds of tissues under defined conditions, and “there is, to date, no evidence that diagnostic ultrasound has produced any harm to humans – including the developing fetus” (*Guidelines for the Safe Use of Diagnostic Ultrasound Equipment*, Safety Group of the British Medical Ultrasound Society 2010).

In contrast to the results of exposure to ionizing radiation, the physiological effects of exposure to ultrasound are generally assumed to be deterministic and only occur above a certain threshold, where the effects are only accidental. Ultrasound examinations can be conducted very safely if certain procedures are followed. Therefore, it is recommended that operators read the following sections and study the cited literature.

Prudent use

Despite the relatively low risk of ultrasound scans, as compared to other imaging techniques, the operator must choose exposure levels with caution to minimize the risks of bio-effects.

“A fundamental approach to the safe use of diagnostic ultrasound is to use the lowest output power and the shortest scan time consistent with acquiring the required diagnostic information. This is the ALARA (as low as reasonably achievable) principle. It is acknowledged that in some situations it is reasonable to use higher output or longer examination times than in others: for example, the risk of missing a fetal anomaly must be weighed against the risk of harm from potential bio-effects. Consequently, it is essential for operators of ultrasound scanners to be properly trained and fully informed when making decisions of this nature” *(Guidelines for the Safe Use of Diagnostic Ultrasound Equipment*, Safety Group of the British Medical Ultrasound Society 2010).

Special care regarding ALARA should be taken with obstetric examinations, as any potential bio-effects are likely to be of greatest significance in the embryo or fetus.

It is strongly recommended that operators consider ALARA when conducting ultrasound scans (See “Appendix B Medical Ultrasound Safety” on page 195).

SONON ultrasound devices provide the following frequency outputs and operating modes:

Model name	Frequency	Operating mode	Reference
SONON 300C	3.5 MHz	B, CF, PW, M modes	Low ultrasonic powered
300L	5MHz/7.5MHz/10MHz	B, CF modes	

When using the SONON ultrasound device you can control the following factors (TI/MI output value is less than 1).

- TGC (Time Gain Compensation)
- DR (Dynamic Range)
- FL (Focal Length)
- Depth
- Image filters

The SONON ultrasound device is safe to use in B, CF, PW and M modes, because the ultrasound waves applied to the human body are dispersed rather than concentrated at one point.

To further ensure safe operation of the SONON ultrasound device, HEALCERION provides an educational publication by the American Institute of Ultrasound in Medicine, *Medical Ultrasound Safety* (AIUM 2014), as an appendix to this document.

These educational materials are provided to prevent the improper use or abuse of the SONON ultrasound device.

Bioeffects

Thermal effects related to the heating of soft tissue and bone

The thermal indices “TIs” (for soft tissue), “TIb” (for bone near the focus), and “TIc” (for bone near the surface) were introduced to provide the operator with relative potentials of tissue temperature rise. The *Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (2004) stipulates that these thermal indices shall be displayed by ultrasound consoles. It should be noted that a TI of 1 does not necessarily mean that tissues being scanned will increase in temperature by 33.8°F(1˚C). Almost every scanning situation departs from the assumed model conditions, such as tissue types, blood perfusions, mode of operation and actual exposure time of the scanned area. However, by suggesting information regarding possible increase in risk from potential thermal bioeffects, thermal indices provide a relative magnitude that can be used to implement ALARA. In addition to tissue heating due to the generated ultrasound field, the temperature of the probe head itself can also increase during the examination. The operator should be aware that superposition of heat may result at the tissue regions near the ultrasonic transducer due to the ultrasound field, which is not considered in the TI values.

Non-thermal effects related to mechanical phenomena such as cavitation

Non-thermal bio-effects are caused by the interaction of ultrasound fields with very small pockets of gas (stabilized gas bodies), i.e., the generation, growth, vibration and possible collapse of microbubbles within the tissue. This behavior is referred to as cavitation (Medical Ultrasound Safety, 2nd Edition, AIUM 2009 / American Institute of Ultrasound in Medicine Consensus Report on Potential Bio-effects of Diagnostic Ultrasound, AIUM 2008 / Guidelines for the safe use of diagnostic ultrasound equipment, Safety Group of the British Medical Ultrasound Society 2010). The potential of cavitation increases with rarefactional peak pressure and decreases with pulse frequency. For these reasons, the “MI (Mechanical Index)” was introduced to take account of both pressure and frequency. Higher MI indicates greater risk of non-thermal bio-effects.

Other considerations

Operating temperature

Like most high-frequency computing devices, the electronic components of the SONON ultrasound device generate heat during normal operation. The device is equipped with safety mechanisms to automatically reduce computing speed (frame rate) and ultimately shut down the device before any risk of overheating occurs. The device has been verified to comply with harmonized safety standards under all operating conditions described in this manual.

> **NOTE**
>
> When you hold the SONON ultrasound device for operation, be careful not to block the air vent. The air vent keeps the device operating at an optimal temperature and ensures longer scanning times with the maximum frame rate.

Operating and storage conditions

Refer to the following table for the operating, storage, and transportation conditions of the SONON ultrasound device.

	Operating conditions	Storage/Transportation conditions
Temperature	+64.4°F to +86°F (+18°C to +35°C)	+14°F to +122°F (-10°C to +50°C)
Humidity	30% to 75% noncondensing	10% to 85% noncondensing
Pressure	700hPa (3000m) to 1060hPa	700hPa (3000m) to 1060hPa

Image display quality

The image display quality of your mobile device may vary depending on ambient light conditions. Avoid direct sunlight on the display when scanning and reviewing images.

Disposal of the device

This symbol indicates that electrical and electronic equipment waste must not be disposed of as unsorted municipal waste, and must be collected separately. Please contact the manufacturer or an authorized disposal company to decommission your equipment according to local regulations.

Battery disposal

⚠ CAUTION

Lithium batteries are included with this device. Do not puncture, mutilate or dispose of batteries in fire. Replace only with batteries of the same type, as recommended by the manufacturer. Dispose of used batteries in accordance with the manufacturer's instructions and in accordance with your local regulations.

⚠ ATTENTION

L'appareil contient des batteries au lithium. Ne pas percer, endommager, ou jeter au feu les batteries. Remplacer les batteries uniquement avec des batteries du même type, conformément aux recommandations du fabricant. Mettre au rebut les batteries usagées conformément aux instructions du fabricant et à la règlementation locale.

This separate collection symbol is affixed to a battery, or its packaging, to advise you that it must be recycled or disposed of in accordance with local and national laws. To minimize potential impact to the environment and human health, it is important that all marked batteries removed from the product be properly recycled or disposed of. For information on how batteries can be safely removed from the device, please consult the equipment instructions or your local authorities.

1 Device overview

Intended use

The SONON ultrasound device is a portable ultrasound scanner intended for use in professional healthcare environments, to obtain ultrasound echo images that can be used for clinical diagnostic purposes.

⚠ CAUTION

Appropriate data safety measures must be taken for patient data because the SONON ultrasound device stores diagnostic data on a personal mobile device. It is your responsibility to keep patient data safe and secure.

⚠ ATTENTION

Des mesures appropriées de protection des données doivent être prises eu égard aux données patient, car l'échographe SONON conserve les données de diagnostic sur un appareil mobile personnel. Il est de la responsabilité de l'utilisateur d'assurer la protection et la sécurité des données patient.

The SONON ultrasound device must be used only for the purposes for which the device was designed. The device is intended to be handled and operated in accordance with all the safety procedures and operating instructions in this user manual.

Indications for use

The SONON ultrasound device is indicated for ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications. Indications for use by model are as follows.

Model name	Applications
SONON 300C	• Obstetrics (OB) • Gynecology (GY) • General (abdominal)
300L	• Musculoskeletal (MSK) • Vascular • Small parts (breast, thyroid) • Thorax

Contraindications

⚠ WARNING

The SONON ultrasound device is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

⚠ AVERTISSEMENT

L'échographe SONON n'est pas destiné à un usage ophtalmique, ni à tout autre usage impliquant que le faisceau acoustique traverse l'œil.

Intended patient profile

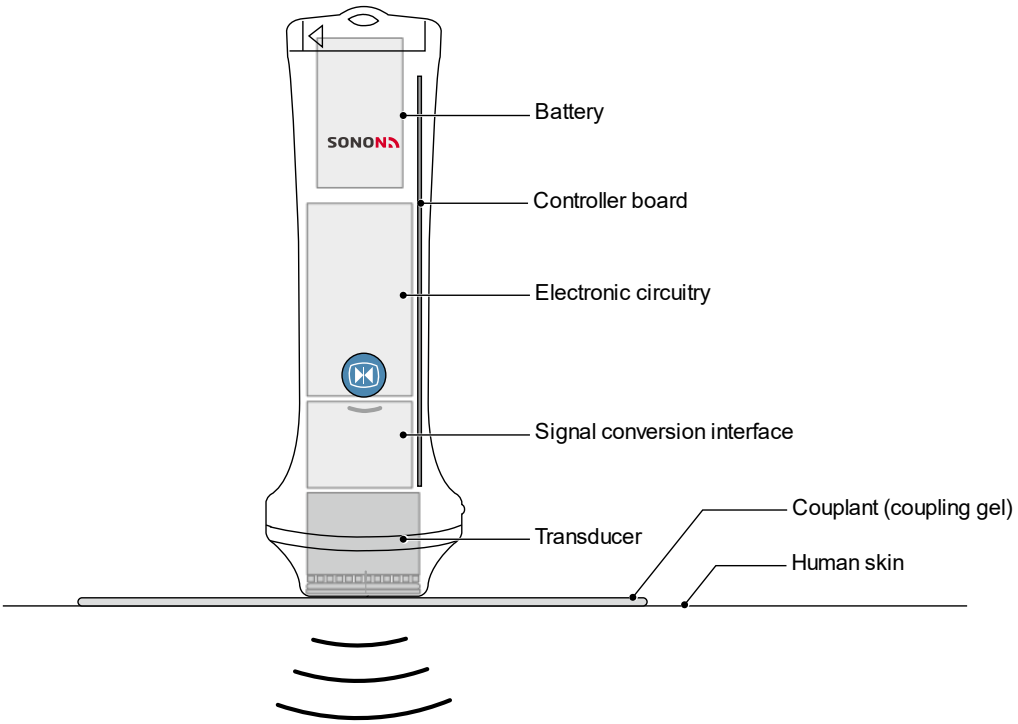
See the following table for the intended patient profile for the SONON ultrasound device.

Age	Any
Weight	Any
Health condition	Stable condition. Do not use this device to examine patients who may be harmed by exposure to ultrasound (e.g., patients with implanted pace-makers).
Use conditions	To be used by trained professionals only. Not to be used by patients.

Principles of operation

The SONON ultrasound device utilizes pulsed-echo technology to determine the depth and location of tissue interfaces.

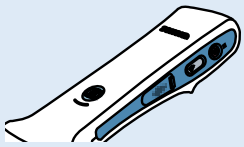
Ultrasound imaging requires mechanical oscillation of crystals excited by electrical pulses, generating a piezoelectric effect. A number of these crystals make up a transducer, which converts one type of energy into another. Using pulse-echo transformation by the piezoelectric crystals, an ultrasound transducer converts electricity into sound.



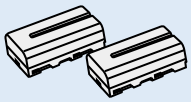
The SONON ultrasound device measures the duration of an acoustic pulse travelling from the transmitter to the tissue interface and back to the receiver. Ultrasound waves emitted from the transducer propagate through various tissues and return to the transducer as reflected echoes. These echoes are then converted into high-frequency electrical signals by the crystals in the transducer. Next, the signals are amplified and further processed by several analog and digital circuits and software filters to adjust the frequency and time response, in order to finally generate a series of digital images.

1.1 Package contents

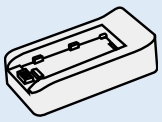
When you open the package, you will find the following items. Make sure that you have all of the items before using the device.



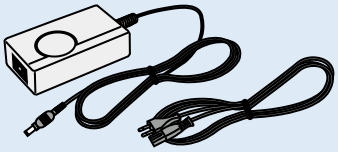
SONON ultrasound device*



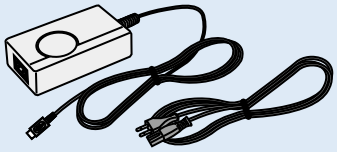
Batteries (2EA)



Battery charger



Power adapter / power cable (for battery charger)



Power adapter / power cable (micro USB for device)

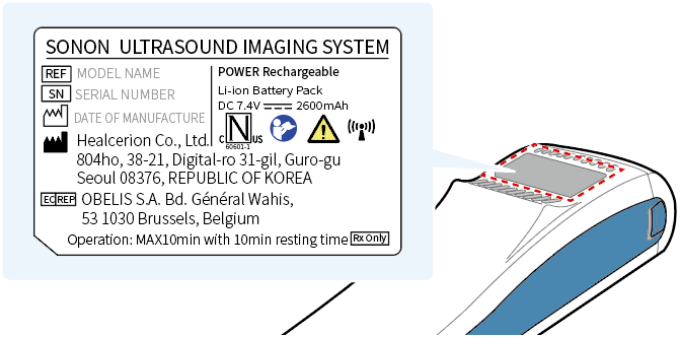
Quick start guide

* Check the ID label and ensure that the device name and model name are correct.

ID label

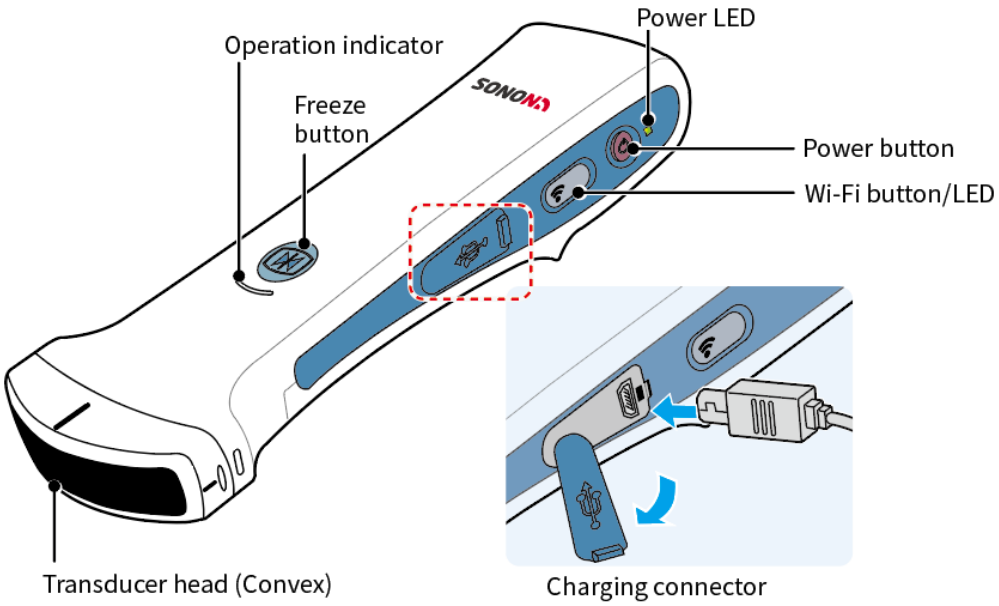
The ID label is attached to the back of the device. You can acquire the following product-related information from the ID label.

- Device name
- Model name
- Serial number
- Date of manufacture
- Power/battery information
- Certification marks and safety symbols
- Manufacturer/representative names and addresses



Part names

SONON 300C



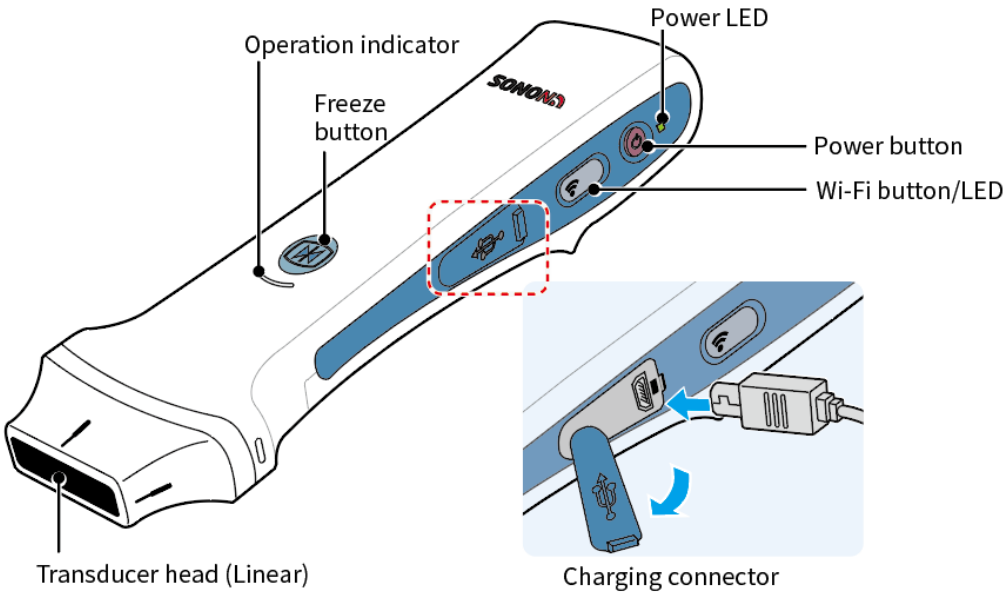
NOTE

For safety reasons, the device automatically turns off when directly charged with the micro USB connector.

Refer to the following table for buttons and operation status indicators.

Buttons/Indicators	Description
Power button	Press and hold power button for about 2 seconds to turn device on or off.
Power LED	When device is on: white When device is turned off: green (2 sec), then off While charging (micro USB): green
Freeze button (operation mode LED)	Press the Freeze button to switch between Freeze and Unfreeze modes. (Freeze mode: flashing blue / Unfreeze mode: blue)
Wi-Fi button	Press and hold to turn the Wi-Fi function of the device on or off. Device is ready: green Wi-Fi is on: blue (2.4 GHz) / green (5 GHz) (You can Press and hold the Wi-Fi button for about 5 seconds to switch between the frequencies.) Wi-Fi is off: off

300L



> **NOTE**
>
> For safety reasons, the device automatically turns off when directly charged with the micro USB connector.

Refer to the following table for buttons and operation status indicators.

Buttons/Indicators	Description
Power button	Press and hold power button for about 2 seconds to turn device on or off.
Power LED	When device is on: white When device is turned off: green (2 sec), then off While charging (micro USB): green
Freeze button (operation mode LED)	Press the Freeze button to switch between Freeze and Unfreeze modes. (Freeze mode: flashing blue / Unfreeze mode: blue)
Wi-Fi button	Press and hold to turn the Wi-Fi function of the device on or off. Device is ready: green Wi-Fi is on: blue (2.4 GHz) / green (5 GHz) (You can Press and hold the Wi-Fi button for about 5 seconds to switch between the frequencies.) Wi-Fi is off: off

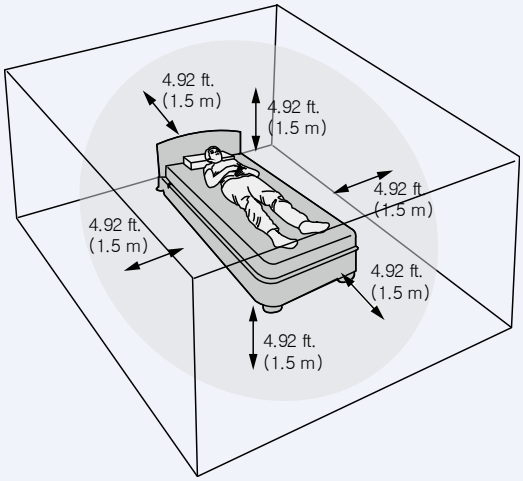
1.2 Charging and replacing battery

Your SONON ultrasound device is powered by a lithium-ion (Li-ion) battery. The battery is not fully charged prior to shipment. To maximize battery life, it is recommended that you fully charge the battery before initial use.

Battery-related safety information

⚠ CAUTION

- Do not disassemble or puncture the battery, or expose the battery to excessive impact.
- Do not place the battery near a heat source or expose it to open flame. Such exposure may lead to leakage of corrosive liquid, electric shock, or fire.
- If any liquid from the battery should come into contact with the eye, immediately wash the eye with plenty of water and seek medical assistance as soon as possible.
- Do not immerse the battery or expose the battery to water.
- The AC adapter must be kept outside the patient environment (refer to IEC 60601-1).

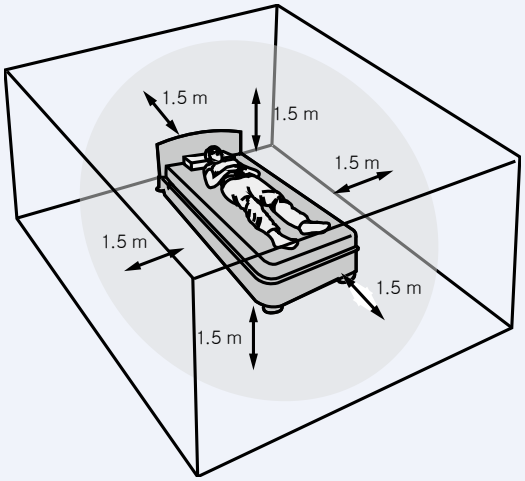


[Patient environment]

⚠ ATTENTION

- Ne pas démonter ou percer la batterie, ni l'exposer à un choc excessif.
- Ne pas placer la batterie à proximité d'une source de chaleur, ni l'exposer à une flamme ouverte. Une telle exposition pourrait entraîner une fuite de liquide corrosif, une électrisation ou un incendie.
- Si du liquide s'écoulant de la batterie entre en contact avec les yeux, rincer immédiatement et abondamment à l'eau claire et demander un avis médical dès que possible.
- Ne pas immerger la batterie; ne pas exposer la batterie à l'eau.

- L’adaptateur CA doit être tenu en dehors de l’environnement du patient (voir norme IEC 60601-1).



[L’environnement du patient]

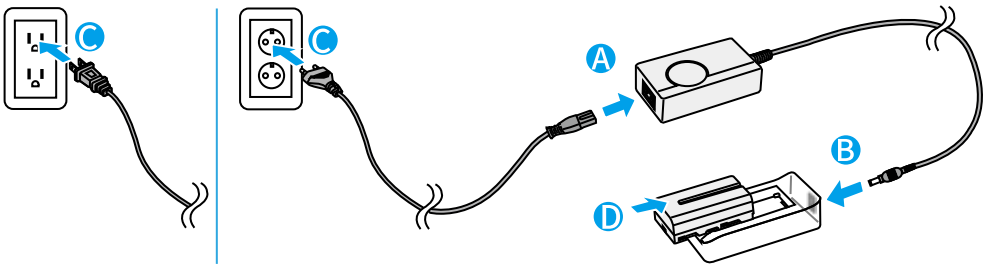
NOTE

If you travel by plane, pack your spare batteries in a carry-on bag whenever possible. In many countries including the USA, shipping spare Li-ion batteries (uninstalled) in checked bags is not allowed.

You can charge the internal battery of the SONON ultrasound device either by using the battery charger or by connecting the USB cable to the charging connector on the SONON ultrasound device.

Charging battery with battery charger

Connect the power cable to the AC adapter (A), connect the AC adapter to the battery charger (B), plug the power cable into the wall outlet (C), then attach the battery to the battery charger (D).



⚠ CAUTION

Use only the battery charger and AC adapter packaged with the device.

⚠ ATTENTION

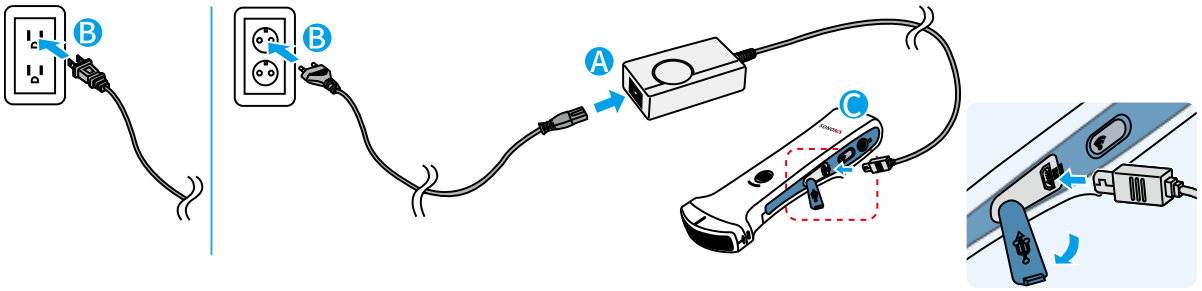
Utiliser uniquement le chargeur de batterie et l'adaptateur CA fournis avec l'appareil.

Battery charger indications during charging

LED status	Description
Green	Fully charged, or not charging / battery is not attached
Red	Charging

Directly charging device

Connect the power cable to the AC adapter (A), plug the power cable into the wall outlet (B), then plug the micro USB connector into the SONON ultrasound device (C).



> **NOTE**
>
> For safety reasons, the device automatically turns off when directly charged with the micro USB connector.

Power LED indications during a charge

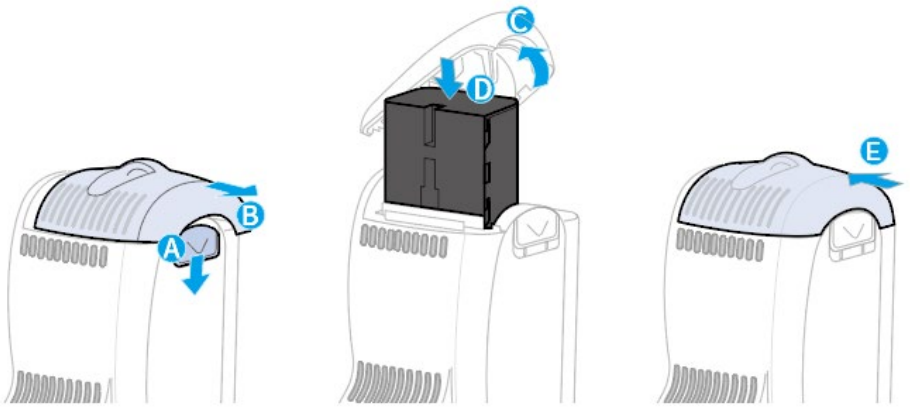
Power LED status	Description
Flashing green	Charging error / not charging
Steady green	Charging
OFF	Fully charged
White	Low battery

Installing and removing battery

Refer to the following instructions to install and replace a battery.

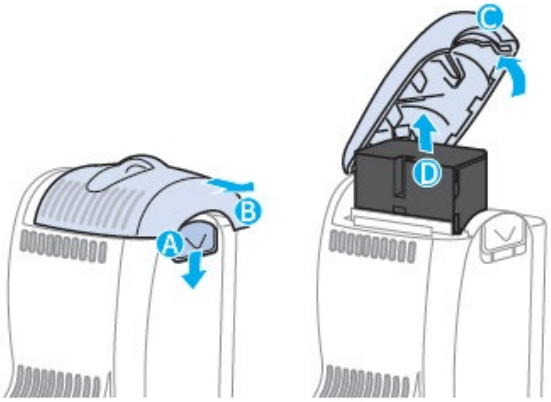
Installing the battery

1. Slide and hold down the lock lever (A), then slide the battery cover in the direction indicated by the arrow (B).
2. Lift the battery cover (C) and insert a charged battery into the battery chamber (D).
3. Close the battery cover and slide the battery cover in the direction indicated by the arrow until the cover locks into position (E).



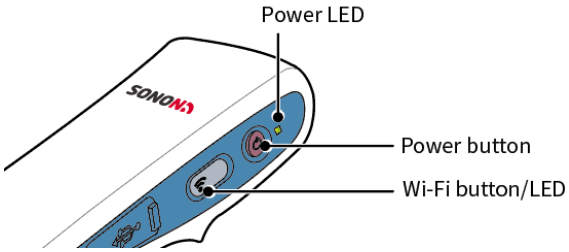
Removing the battery

1. Slide and hold down the lock lever (A) and slide the battery cover in the direction indicated by the arrow (B).
2. Lift the battery cover (C) and remove the battery (D).



1.3 Turning on or off the device

Refer to the following illustration for location of the power button and power indicator. Follow the instructions to turn your SONON ultrasound device on or off.



Turning on the device

Press and hold the power button for longer than 2 seconds. The Power LED will turn on white, then the Wi-Fi LED will turn on after a few seconds.

Turning off the device

Press and hold the power button for longer than 2 seconds. The power LED will change to green for a few seconds, then turn off.

NOTE

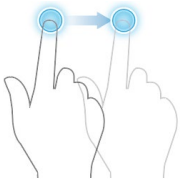
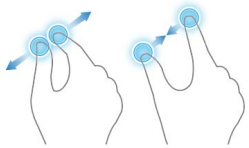
- The Wi-Fi connection will become available a few seconds after the device is turned on. Wait until the Wi-Fi LED turns on before attempting to connect the SONON ultrasound device to your mobile device.
- The SONON ultrasound device must be connected to your mobile device before you can start scanning.

2 Installing and registering the software

You must install the HEALCERION app (SONON X ultrasound app) on your mobile device and complete registration before you can connect the SONON ultrasound device to your mobile device and begin scanning.

Touchscreen gestures

The following touchscreen gestures are used in this manual to describe user interactions on the screen.

Interaction	Gesture	Action	Description	Function
Tap		• Select • Run	Briefly touch screen and remove finger	Launch an app, select an item, or run a function.
Drag		• Move items • Scroll up/down/across	Move finger while touching screen	Move an item or scroll through a list
Pinch out / Pinch in		• Zoom in • Zoom out	Move two fingers apart or together while touching screen with both fingers	Enlarge or minimize a part of an image

System requirements for mobile devices

The following tables list mobile device system requirements for installing and using the HEALCERION app (SONON X ultrasound app).

Operating system versions

Operating system	Requirement
iOS	iOS 11.0 or later
Android	Android 5.0 (Lollipop) or later
Windows (UWP)	Windows 10 (64-bit) or later

Compatible mobile devices

The following table lists mobile devices that have been tested and proved to be compatible for use with the SONON ultrasound device by the manufacturer.

Operating system	Compatible devices
iOS	• iPhone 6S and newer • iPad 5 and newer • iPad Air 2 and newer • iPad Mini 4 and newer • iPad Pro and newer
Android	• Samsung Galaxy S6 and newer • Samsung Galaxy Note 5 and newer • Samsung Galaxy Tab S3 and newer
Windows (UWP)	• Microsoft Surface Pro 3 and newer

NOTE

HEALCERION does not guarantee normal operation of the SONON ultrasound device or the HEALCERION app (SONON X ultrasound app) when they are used with other mobile devices that have not been tested for compatibility.

2.1 Installing the HEALCERION app (SONON X ultrasound app)

Follow the instructions below to install the HEALCERION app (SONON X ultrasound app) on your mobile device.

⚠ CAUTION

- Appropriate data safety measures must be taken with patient data because the SONON ultrasound device stores diagnostic data on a personal mobile device. It is your responsibility to keep patient data safe and secure.
- All stored data will be lost if you uninstall the HEALCERION app (SONON X ultrasound app). Back up all important data and store the backup files on a separate storage device before uninstalling the app or replacing your mobile device.
- The data stored on a mobile device cannot be recovered if the mobile device is lost. To prevent such data loss, back up your data on a regular basis.

⚠ ATTENTION

- Des mesures appropriées de protection des données doivent être prises eu égard aux données patient, car l'échographe SONON conserve les données de diagnostic sur un appareil mobile personnel. Il est de la responsabilité de l'utilisateur d'assurer la protection et la sécurité des données patient.
- Toutes les données conservées seront perdues si l'application HEALCERION (application de l'échographe SONON) est désinstallée. Sauvegarder toutes les données importantes et conserver les fichiers de sauvegarde sur un dispositif de stockage séparé avant de désinstaller l'application ou de remplacer l'appareil mobile.
- Les données conservées sur un appareil mobile ne peuvent pas être récupérées en cas de perte de ce dernier. Pour éviter la perte des données, sauvegarder les données régulièrement.

For Apple (iOS) smart devices

1. On your Apple smart device, tap  to launch the App Store.
2. Tap  , type "HEALCERION" or "SONON" in the search window, and tap Search.
3. From the search results, select the SONON X Ultrasound app and tap **INSTALL**.
4. Enter your Apple iTunes password.

For Android smart devices

1 On your Android smart device, tap  to launch the Play Store.

2 Type “HEALCERION” or “SONON” in the search window and tap  .

3 From the search results, select the SONON X Ultrasound app and tap **INSTALL**.

4 When the installation is completed, tap **OPEN** to launch the app.

For Universal Windows Platform (UWP) smart devices

1 On your UWP smart device, tap  to launch the Windows Store.

2 Type “HEALCERION” or “SONON” in the search window and tap  .

3 From the search results, select the SONON X Ultrasound app and tap **INSTALL**.

4 When the installation is completed, tap **OPEN** to launch the app.

2.2 Registering user information

Registration of your user information is required to launch the HEALCERION app (SONON X ultrasound app) for the first time. Follow the instructions below to register your information within the app or server.

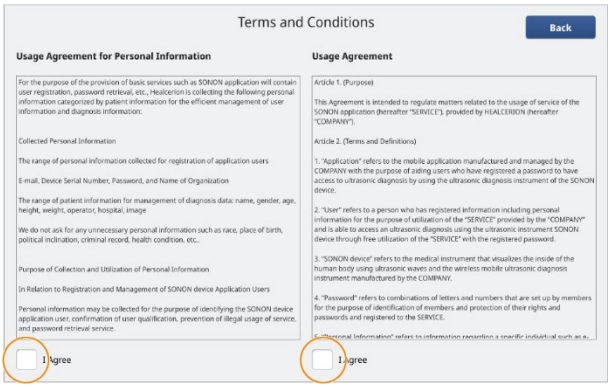
> **NOTE**
> In some countries, user information can only be registered through the app. In this case, registering through the server is not supported.

How to register user information in the app storage

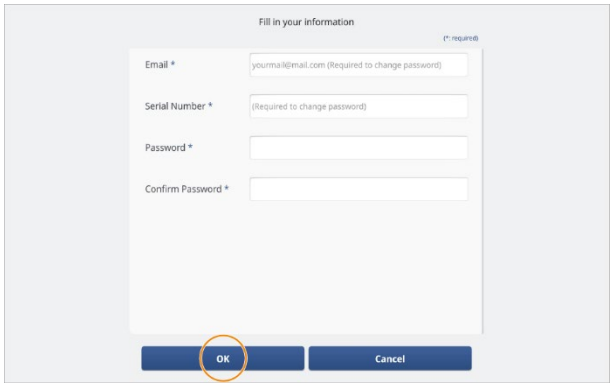
1 On your mobile device, tap to launch the HEALCERION app (SONON X ultrasound app), then tap **Store in app storage**.

> **NOTE**
> If the current version only supports registration through the app, tap the "**Store in app storage**" button to register

2 Read the terms and conditions and tap the **"I Agree"** checkboxes to proceed.

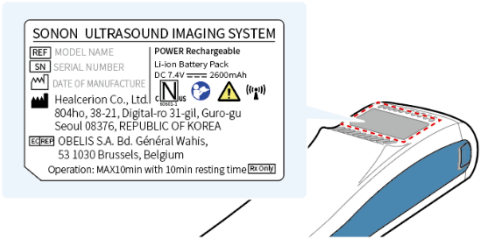


3 Enter your email address, device serial number, and password, then tap **OK**.



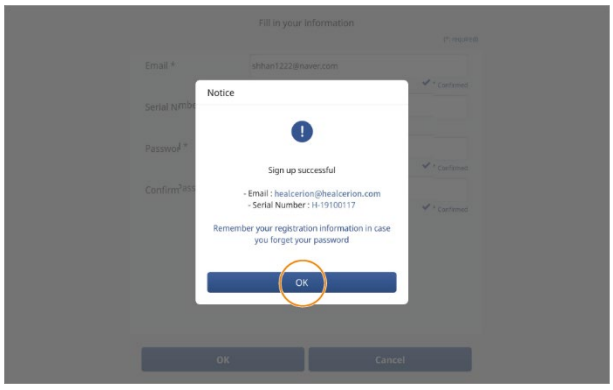
NOTE

- The serial number is provided on the marking plate, which is located on the back of the device.



- Write down your password and keep it in a secure place. You cannot start the app if you forget your password. See “Finding a forgotten password” on page 129 to reset a password.

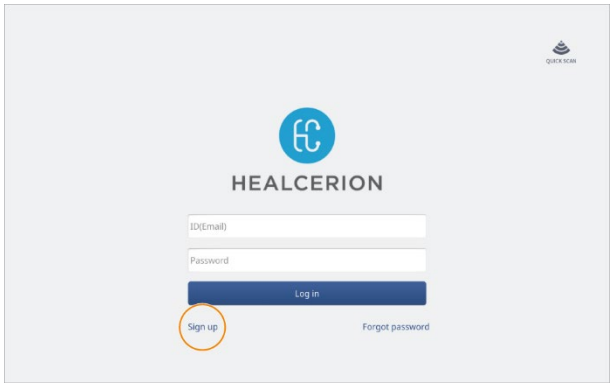
4 Review your registration information and tap **OK** to close the confirmation popup window.



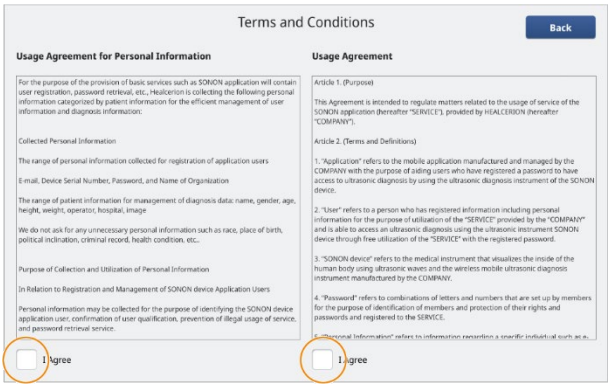
How to register user information through the server

1 On your mobile device, tap to launch the HEALCERION app (SONON X ultrasound app), then tap **Yes**.

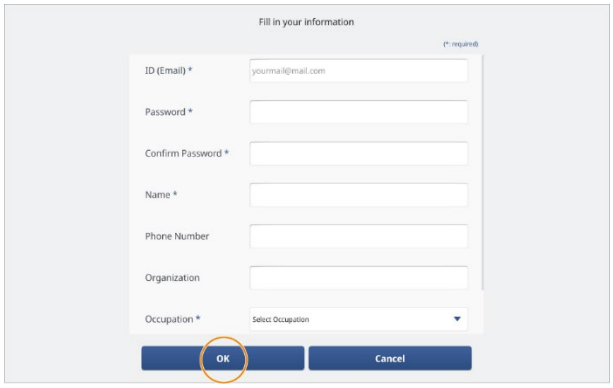
2 On the Log in screen, tap **Sign up**.



3 Read the terms and conditions and tap the **"I Agree"** checkboxes to proceed.



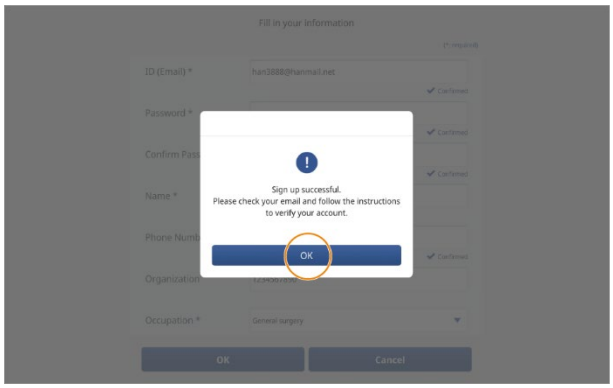
4 Enter your ID(email address), password, your name, phone number, organization, occupation, and country then tap **OK**.



NOTE

- Write down your password and keep it in a secure place. You cannot start the app if you forget your password. See “Finding a forgotten password (When user information is stored on the server)”on page 130 to reset a password.

5 Tap **OK** to close the pop-up window, then refer to the email to complete registration.



2.3 Starting an exam for the first time

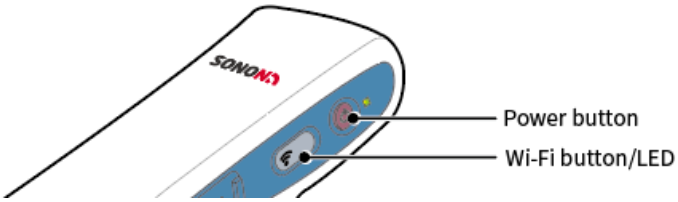
Follow the instructions below to perform an exam for the first time.

Connecting the device with Wi-Fi

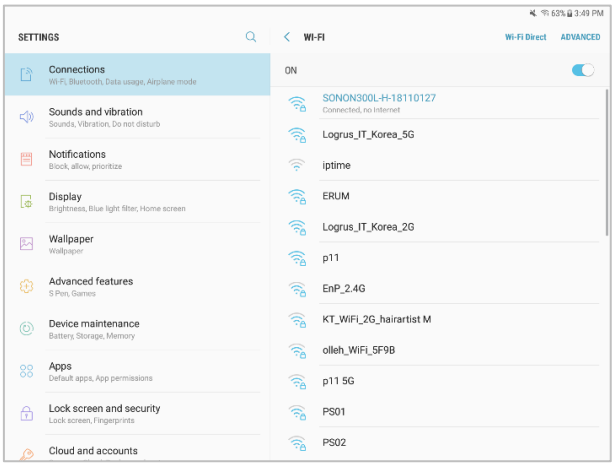
The SONON ultrasound device must be connected to your mobile device before you can start scanning.

> **NOTE**
> Disable “Power Saving (Low Battery)” features on your mobile device before attempting to connect your mobile device to the SONON ultrasound device. On some mobile devices, network connection to the SONON ultrasound device fails if the mobile device is running in power saving mode.

1 Turn on the SONON ultrasound device by pressing and holding the power button for at least 2 seconds, and wait until the Wi-Fi LED turns on.



2 Go to the Wi-Fi settings menu on your mobile device and search for the SSID of your SONON device (SSID: SONONXXXX-YYYYYYYY. X=model name, and Y=serial number).



3 Select your device from the SSID list and enter the default password (“1234567890”).

Starting a scan

⚠ WARNING

- Do not use the SONON ultrasound device for ophthalmic use.
- Do not allow the acoustic beam to pass through the eye.

⚠ AVERTISSEMENT

- Ne pas utiliser l'échographe SONON pour un usage ophtalmique.
- Ne pas laisser le faisceau acoustique traverser l'œil.

⚠ CAUTION

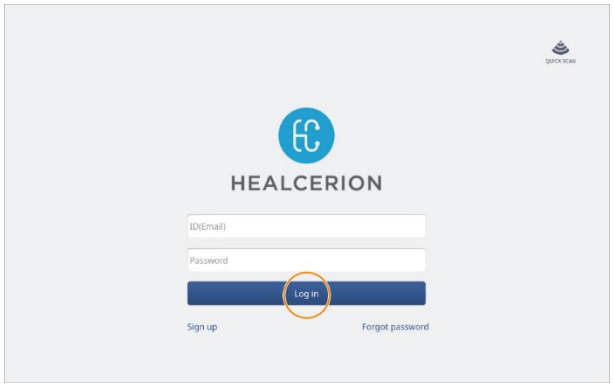
- This device should be used in compliance with applicable laws. Some jurisdictions restrict certain uses, such as gender determination.
- Allow the device to rest for 10 minutes after 10 minutes of scanning.
- Do not use gels (lubricants) that are not approved by HEALCERION. They may damage the probe and void the warranty.

⚠ ATTENTION

- L'appareil doit être utilisé conformément à la législation applicable. Certaines juridictions restreignent des usages spécifiques, comme la détermination du sexe.
- Ne pas utiliser l'appareil pendant 10 minutes après 10 minutes du balayage.
- Ne pas utiliser de gels (lubrifiants) qui ne sont pas homologués par HEALCERION. Ils peuvent endommager la sonde et annuler la garantie.

1 On your mobile device, tap to launch the HEALCERION app (SONON X ultrasound app).

2 Enter your ID(Email address) and password and tap **Log in**.

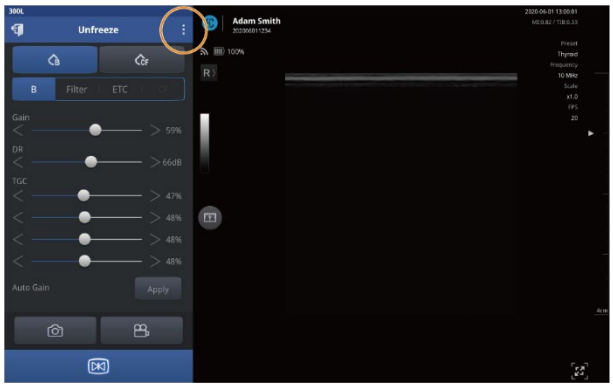


NOTE

When user information is registered in the app storage, you can log in to the HEALCERION app (SONON X ultrasound app) by entering the password.

3 On the home screen, tap **Start Scan**.

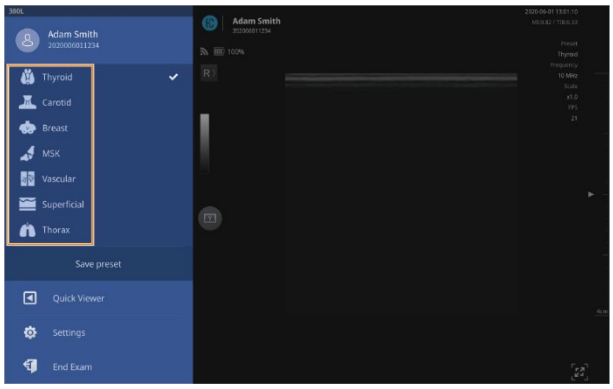
4 Tap ⋮ in the menu area. A list of presets will be displayed.



NOTE

Default display mode may vary depending on the type and screen size of your mobile device. You can tap ⛶ to show the menu area if the scan begins in full screen mode.

5 From the list, select an appropriate preset for your exam.



⚠ CAUTION

An appropriate preset for your application must be selected before you begin a scan. The accuracy of your diagnostics will be affected if you proceed with your scan without selecting an appropriate preset.

⚠ ATTENTION

Dans l'application, sélectionner un préréglage approprié avant de procéder à l'échographie. La précision du diagnostic sera affectée si l'échographie est réalisée sans avoir sélectionné au préalable un préréglage.

NOTE

- Scan begins in B mode by default. Select an appropriate mode for your examination needs.
- See "4.1 Utilizing presets" on page 70 for detailed information about using the default presets, making changes to them, and creating new presets.

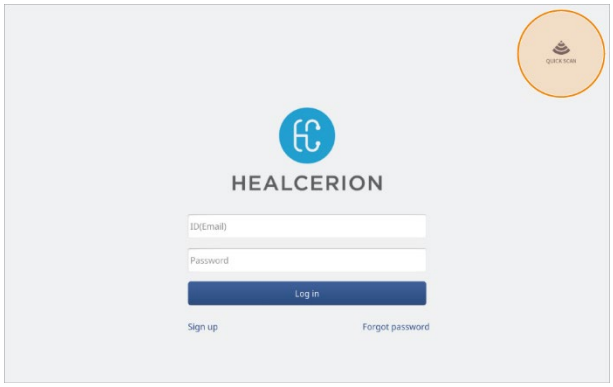
Quick scan in QUICK SCAN mode

If it's urgent, you can initiate a quick scan without logging in.

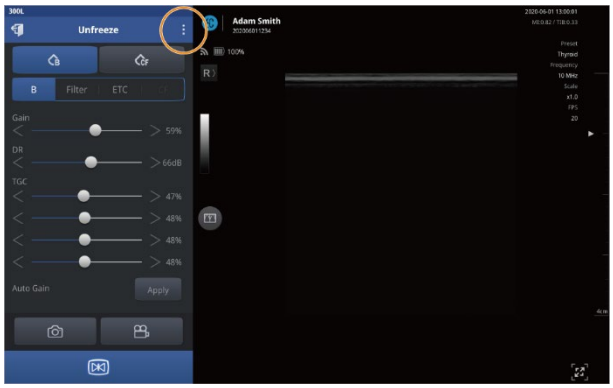
NOTE

- You must log in at least once with your registered user information to enable QUICK SCAN mode.
- Videos scanned with QUICK SCAN are for viewing only and will not be saved.
- Quick scan is used to see the corresponding image upon an emergency. However, some features are not provided as shown below.
  - Capturing images, Recording videos, Patient information, Saving presets, Quick Viewer, Dual screen
- Quick scan provides only the measure function to acquire the value in Freeze mode.

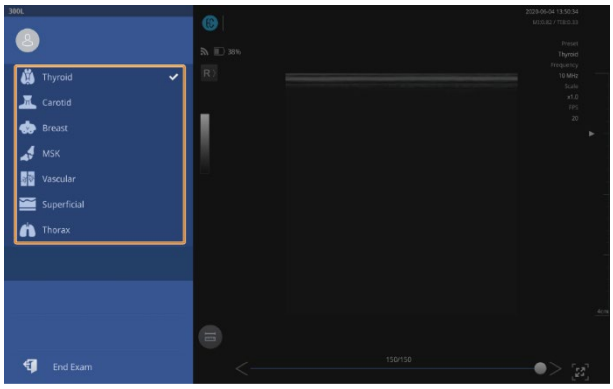
1 On the Log in screen, tap **QUICK SCAN**.



2 Tap ⋮ in the menu area. A list of presets will be displayed.



3 From the list, select an appropriate preset for your exam.

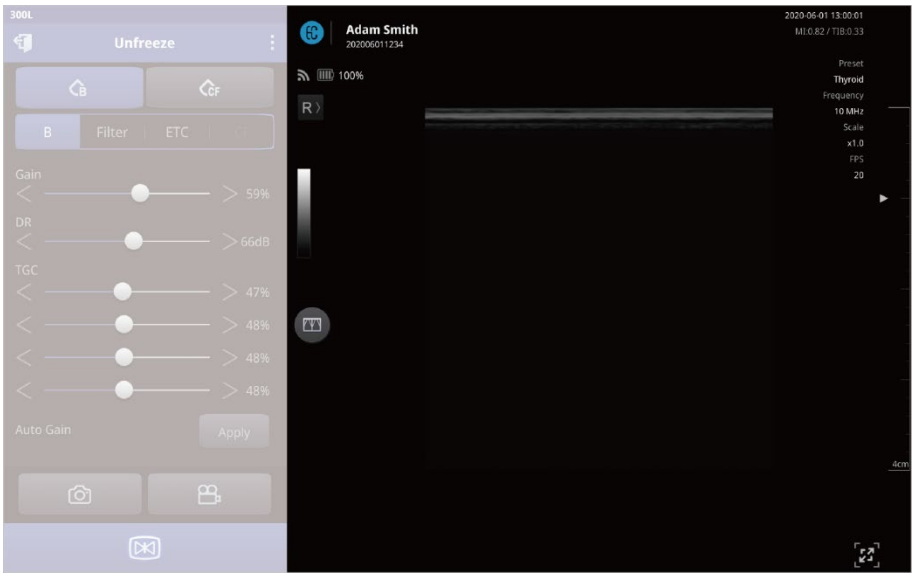


3 User interface and scan modes

3.1 User interface and screen settings

When you tap **Start Scan** on the home screen, the scan screen will be displayed on your mobile device. The following are features available in each section of the scan screen.

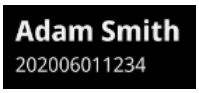
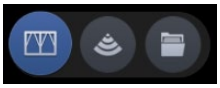
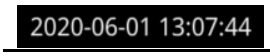
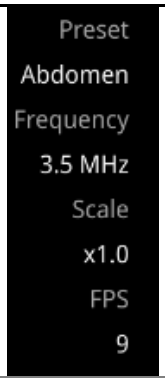
Scan screen interfaces



NOTE

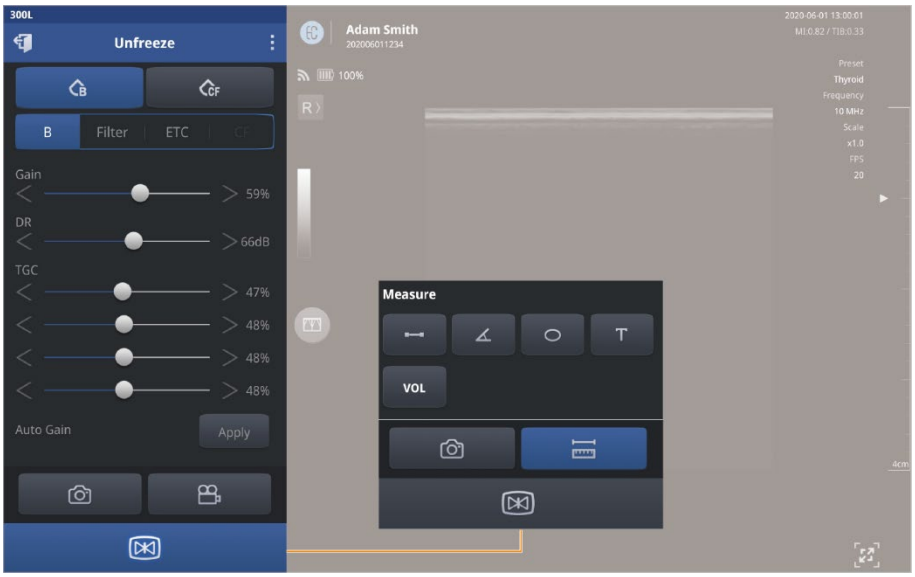
Default display mode may vary depending on the type and screen size of your mobile device. You can tap  to show the menu area if the scan begins in full screen mode.

The following user interfaces are available on the scan screen.

Display/Icons	Name	Description
	Patient name and ID (Exam date and time if ID is not assigned)	Indicates the currently selected patient, and the date and time of the exam. All recorded exams will be saved under the patient's account.
	Network and battery status	Displays the status of the network connection between your mobile device and the SONON ultrasound device, and the remaining battery charge for the SONON ultrasound device.
	Marker position / Reverse screen	Displays the marker position. You can tap the icon to reverse the screen (L-R/R-L). Reverse function is only available in Unfreeze mode.
	Gray scale bar (B mode) / Color scale bar (CF mode)	Displays the gray scale of the selected grayscale preset in B mode. Displays the color scale based on the CF mode parameter settings, such as flow speed, in CF mode.
	Dual Screen Mode	Displays the live-scanned or recorded videos in dual screen mode. Dual screen mode will allow you to check reference videos more easily.
	Date and time	Displays the date and time.
	Organization information | Physician name	Displays the organization information and Physician name.
	Acoustic output power indicator	Displays MI and TI values.
	Scan properties	Displays the following scan parameters. • Selected preset • Scan frequency • Magnification of image • Current frame rate of the scan

Display/Icons	Name	Description
	Focus and depth control bar	Tap on the control bar to set a focus. Drag on the control bar to set a scan depth.
	Full screen / partial screen button	Tap  to hide the menu area and expand the scan screen into full screen mode. Tap  to show the menu area and shrink the scan screen into partial screen mode.

Menu area interfaces

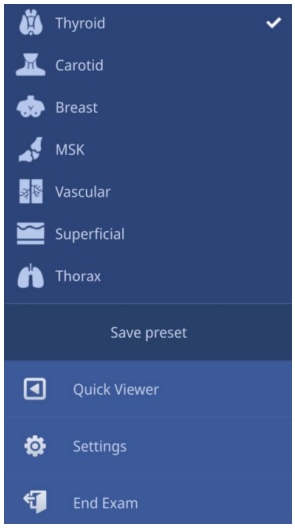


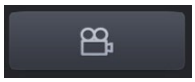
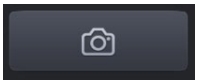
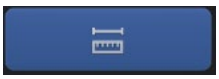
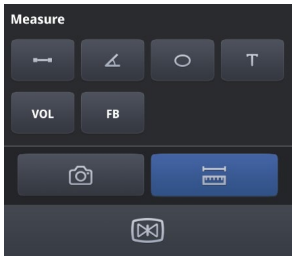
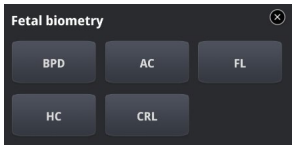
NOTE

Default display mode may vary depending on the type and screen size of your mobile device.

You can tap  to show the menu area if the scan begins in full screen mode.

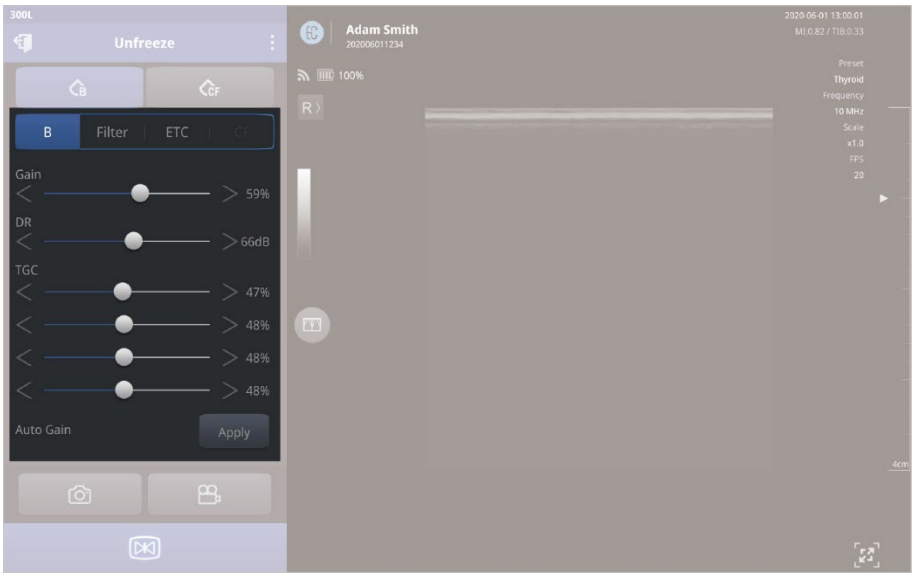
The following user interfaces are available in the menu area.

Display/Icons	Name/Sub menu	Description
	Expanded menu 	The expanded menu provides the following menu options. • Preset list: Select an optimized configuration that suits the type of the exam. • Save preset: Save the changes by overwriting the existing preset, or by creating a new preset. • Quick Viewer: Quickly review recorded exams from the scan screen. • Settings: Configure hardware and software settings including network options, set preferences, and check the firmware version. • End Exam: Exit the scan screen and return to the home screen. You can tap the patient's name to open the Patient List.
	Scan screen mode indicator: Unfreeze mode / Freeze mode	Displays the current scan screen mode. Unfreeze mode screen displays animated images to show the real time changes. Freeze mode provides a still image to allow measuring of on-screen objects and addition of comments.
	Device type	Displays the SONON ultrasound device model name.
	Exit	Tap this button to exit the scan screen and return to the previous screen.
	Scan mode selector	Tap to select a scan mode. • B (brightness) mode provides grayscale images. • CF (color flow) mode shows the direction and velocity of flow in red and blue. • PW (pulsed wave) mode displays different wave velocities and directions in a spectrum. (SONON 300C Only) • M (motion) mode displays the changes over time on a single line graph in a spectrum. (SONON 300C Only)

Display/Icons	Name/Sub menu	Description
	Screen parameter settings	In this section of the menu, you can configure various scan screen parameters to achieve optimal images. See “Configuring screen parameters“ on page 59 for detailed information about configuring screen parameters.
	Record	Tap this button to record a video file. Recorded videos can be converted into .mp4 or DICOM video files (See “Sharing, uploading, or deleting recorded exams” on page 118).
	Snap shot	Tap this button to capture the screen as a still image file. Captured images can be converted into .jpg or DICOM image files (See “Sharing, uploading, or deleting recorded exams” on page 118).
	Freeze	Tap this button to Freeze or Unfreeze the scan screen. You can also Freeze/Unfreeze the screen by using the Freeze button on the device.
	Measure  	This button is displayed on the freeze mode menu screen only. Tap this button to measure the length, angle, circumference, and volume of the objects on the scan screen and add text notes. • : Used to measure the length of an object on the screen. • : Used to measure the angle of an object on the screen. • : Used to measure the circumference and area of an object on the screen. • : Used to add a comment. • : Used to measure the volume of an object based on its dimensions. • (SONON 300C only): Used to measure fetal biometry parameters on the screen. See “Assessing fetal biometry ” on page 97 for detailed information.

Display/Icons	Name/Sub menu	Description
	Full screen / Partial screen	Tap  to hide the menu area and expand the scan screen into full screen mode. Tap  to show the menu area and shrink the scan screen into partial screen mode.

Configuring screen parameters



NOTE

Default display mode may vary depending on the type and screen size of your mobile device.

You can tap  to show the menu area if the scan begins in full screen mode.

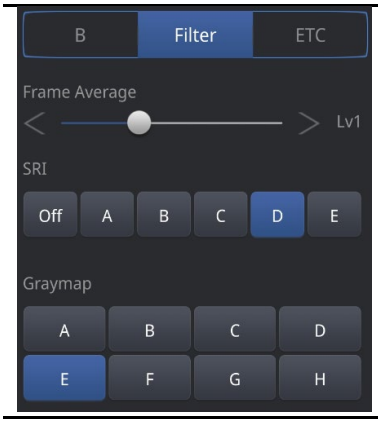
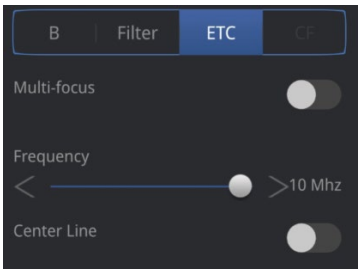
The following user interfaces are available in the menu area.

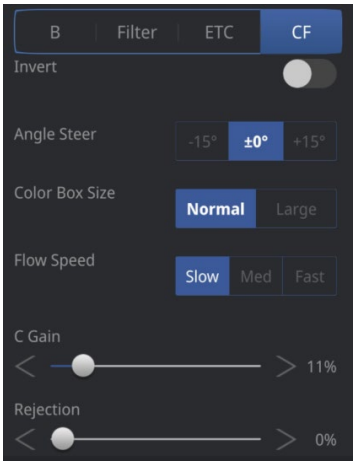
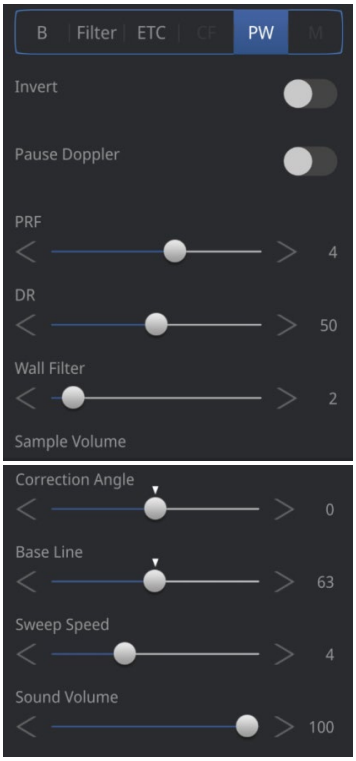
CAUTION

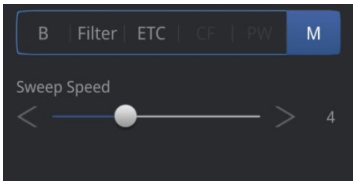
Changing the screen parameter settings can affect image quality and compromise diagnostic accuracy. It is your responsibility to adjust the display settings appropriately to obtain desirable image quality.

ATTENTION

La modification des paramètres de l'écran peut affecter la qualité d'image et compromettre la précision du diagnostic. Il est de la responsabilité de l'opérateur de régler les paramètres d'affichage de manière appropriée afin d'obtenir la qualité d'image recherchée.

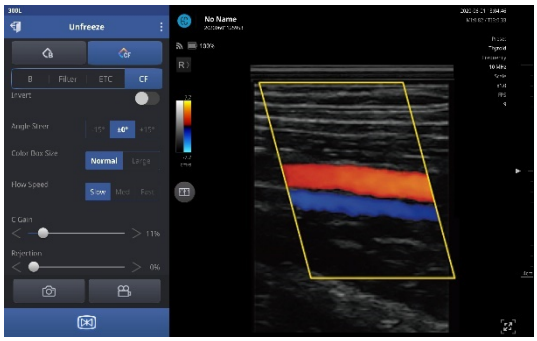
Menu screen	Name	Description/Default
	B Mode Image Parameters	• Gain: Adjust the intensity of the signal on the screen. Raising gain increases the brightness of the images. • DR (Dynamic Range): Set the amplitude range in which the device operates. Higher dynamic range results in softer images with reduced contrast. • TGC (Time Gain Compensation): Adjust the sensitivity of the ultrasound waves according to depth of body area. You can adjust the brightness separately for the 4 screen areas. • Auto Gain: Initialize Gain and TGC settings to preset values (Default: on).
	Filter Image Parameters	• Frame Average: Set the frame average (Off, level 1, 2, 3). Higher levels produce smoother images with lower resolution. • SRI (Speckle Reduction Imaging): SRI improves the image quality of a B mode scan. • Graymap: Determine how the scan is expressed on the screen based on signal strength. Select the preset which best fits your needs.
	Others Image Parameters	• Multi-focus: Enable or disable multi-focusing. Multiple focus increases resolution with low frame rates (Default: OFF). Multi focusing is only available on the SONON 300L, in B mode. • Frequency: Set the ultrasound wave frequency according to the area of the exam. Frequency is only available on the SONON 300L, in B mode. [Example] • 3.5 MHz: abdomen, deeper organs • 10 MHz: thyroid, shallower organs • Center Line: Display a vertical center line on the scan screen.

Menu screen	Name	Description/Default
	CF mode parameters	• Invert: Inverts colors of vessel flow. • Angle Steer: Adjust angle steer of the ROI (region of interest) box. • Color Box Size: Resize ROI (Region of interest) Box. Large ROI Box can only be used when Depth is more than 1.96 in. (5 cm). • Flow Speed: Control PRF (Pulse Repetition Frequency) to adjust velocity scale. • C Gain (Color Doppler Gain Control): Adjusts the intensity of the signal on the screen in CF mode. Raising gain increases the color sensitivity of the image. • Rejection: Suppress low signal and reduce noise in the signal.
	PW mode parameters (available with SONON 300C, in PW mode only)	• Invert: Inverts speed range. • Pause Doppler: Pauses to display the Doppler spectrum in real time. • PRF(Pulse Repetition Frequency): Adjusts the PRF. As the PRF increases, the velocity range displayed in a spectrum becomes wider. By increasing its depth, the maximum PRF can be decreased. • DR: Sets the amplitude range in which the device operates. Higher dynamic range results in softer images with reduced contrast. • Wall Filter: Adjusts the wall filter. By increasing the wall filter, the velocity components that are not concerned are removed. • Sample Volume: Adjusts the sample volume area. By increasing this sample volume, various velocity components can be detected. • Correction Angle: Adjusts the correction angle. Adjust the correction angle to detect correct velocity components. • Base Line: Adjusts the baseline to represent the Doppler spectrum as a single continuous signal.

Menu screen	Name	Description/Default
		• Sweep Speed: Adjusts the sweep speed. By increasing the sweep speed, the time range displayed in a spectrum can be increased. • Sound Volume: Adjusts the sound volume for the pulsed Doppler signal in PW mode.
	M mode parameters (available with SONON 300C, in M mode only)	• Sweep Speed: Adjusts the sweep speed. By increasing the sweep speed, the time range displayed in a spectrum can be increased.

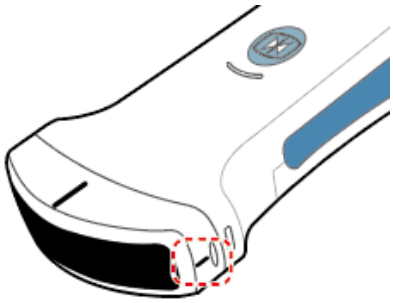
NOTE

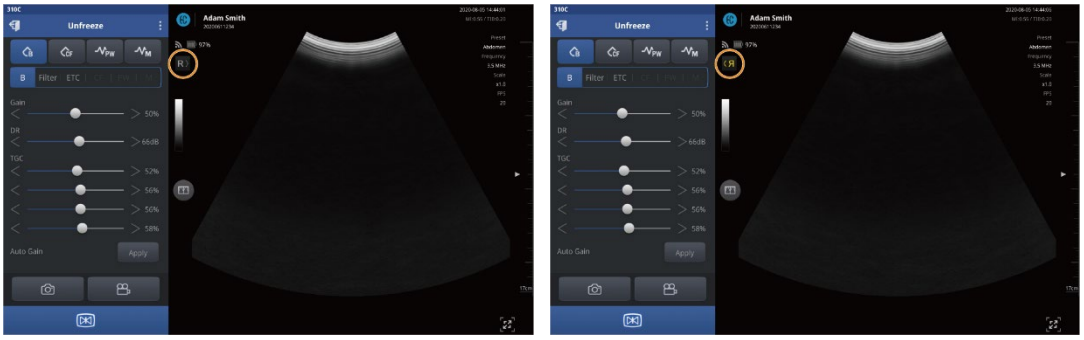
- In CF mode, a yellow ROI box is displayed on the screen to specify the region to be observed.



Device orientation

Your SONON device has a notch on one side of the head to help you determine the orientation of the transducer on the scan screen. This notch is used to identify the side of the device corresponding to the left side of the image on the scanning screen which has an orientation mark.





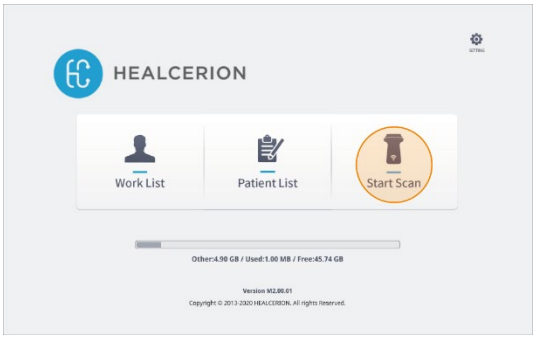
3.2 Selecting operating modes

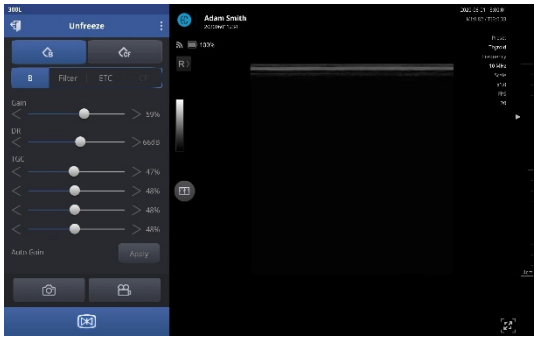
Refer to the following information about the operating modes available on your SONON ultrasound device. Some operating modes explained in this manual may not be supported in certain SONON ultrasound devices.

B mode operation (brightness mode, or 2D mode)

In B mode, images are displayed in grayscale.

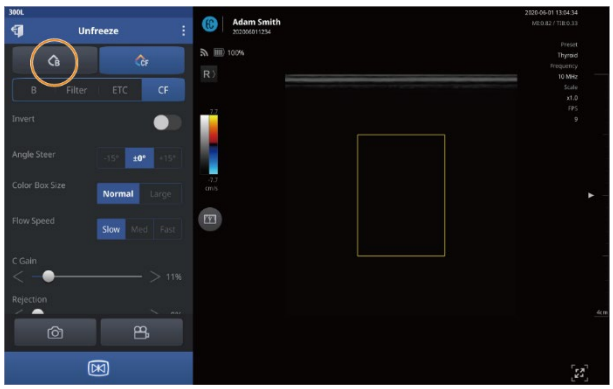
After you tap **Start Scan** on the home screen, scan begins in B mode by default.





NOTE

If you are in CF mode, tap  on the menu to switch to B mode.



B mode specific settings

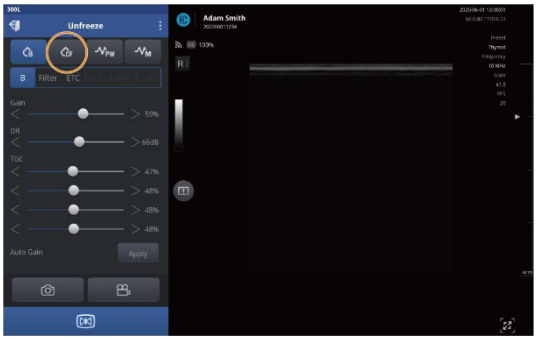
You can adjust the following settings in B mode.

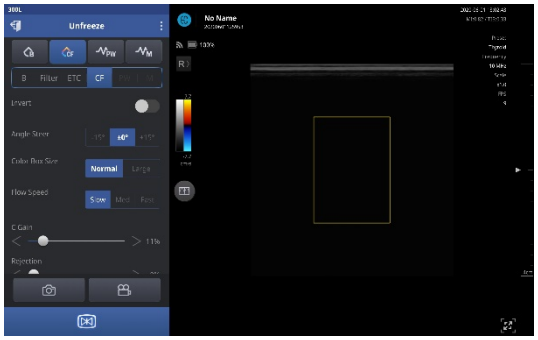
Menu screen	Name	Description/Default
	Other image parameters	Multi-focus: Enable or disable multi-focusing. Multiple focus increases resolution by lowering the frame rate (default: off). Multi focusing is available on the 300L only.

CF mode operation (color flow mode)

In CF mode (also known as “color doppler mode”), different velocity and direction of flow is displayed in different colors.

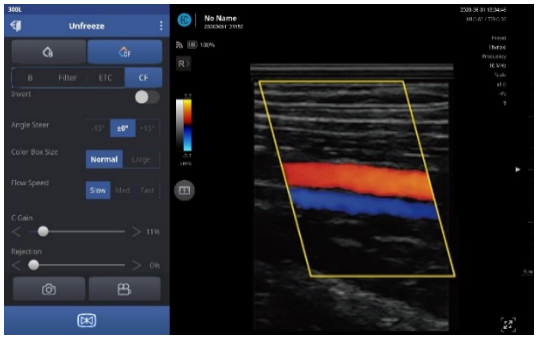
After you tap **Start Scan** on the home screen, scanning begins in B mode by default. Tap  on the mode select menu to switch to CF mode.





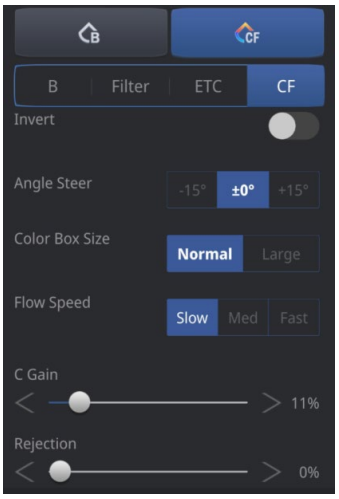
NOTE

- In CF mode, a yellow ROI box is displayed on the screen to specify the region to be observed.



CF mode specific settings

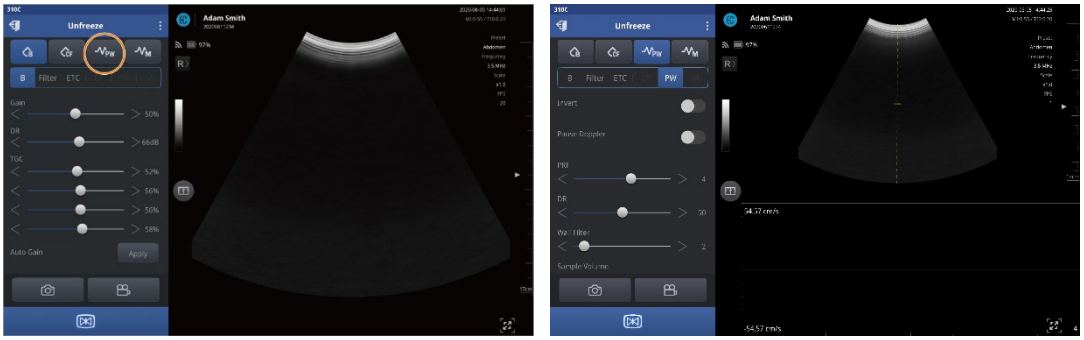
You can adjust the following settings in CF mode.

Menu screen	Name	Description/Default
	CF mode settings	• Invert: Inverts colors representing vessel flow. • Angle Steer: Adjusts the Angle Steer of the ROI (region of interest) box. • Color Box Size: Resizes ROI (region of interest) box. Large ROI Box can only be used when Depth is more than 1.96 in. (5 cm). • Flow Speed: Controls PRF (Pulse Repetition Frequency) to adjust velocity scale. • C Gain (Color Doppler Gain Control): Adjusts the intensity of the signal on the screen in CF mode. Raising gain increases the color sensitivity of the screen. • Rejection: Suppresses low signal and reduces signal noise.

PW mode operation (pulsed wave mode / SONON 300C Only)

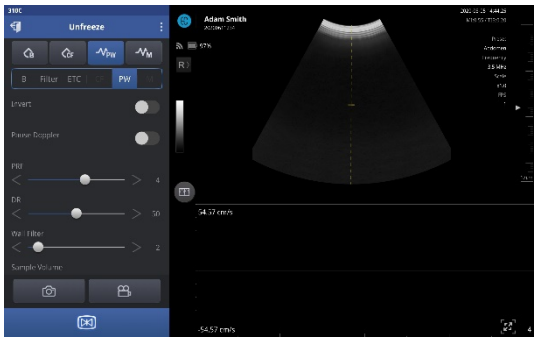
In PW mode (also known as “pulsed wave mode”), different velocity and direction of flow is displayed in spectrum.

After you tap **Start Scan** on the home screen, scanning begins in B mode by default. Tap PW on the mode select menu to switch to PW mode.



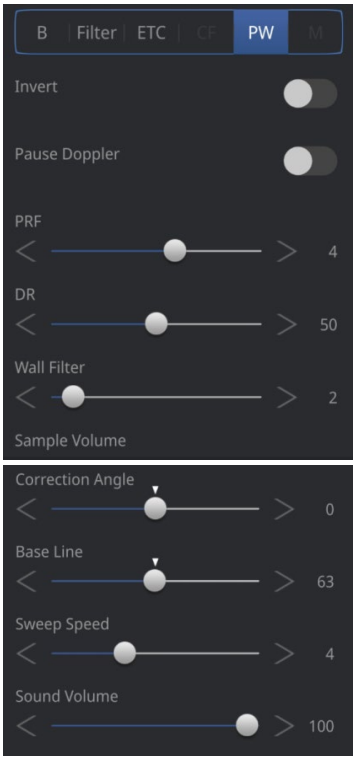
NOTE

- The 300L device does not support PW mode operation. PW mode operation is available on the SONON 300C device only.
- In PW mode, a yellow line is displayed on the screen to specify the region to be observed.
- Select the region of observe as a touch event.



PW mode specific settings

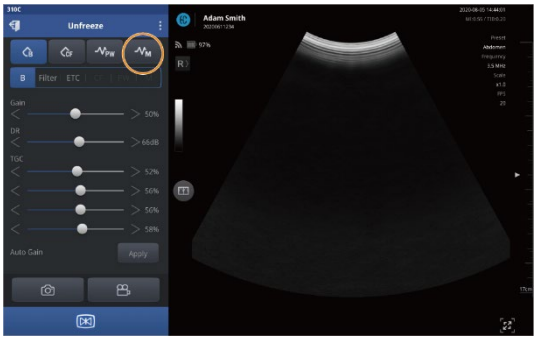
You can adjust the following settings in PW mode.

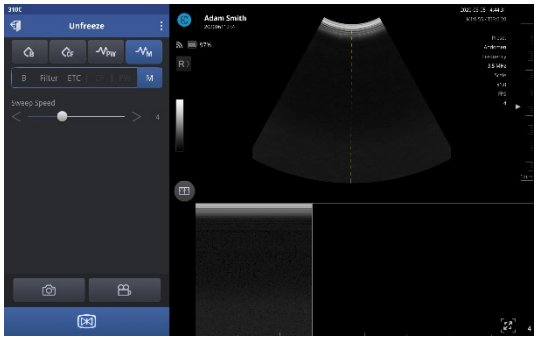
Menu screen	Name	Description/Default
	PW mode parameters (available with SONON 300C, in PW mode only)	• Invert: Inverts speed range. • Pause Doppler: Pauses to display the Doppler spectrum in real time. • PRF(Pulse Repetition Frequency): Adjusts the PRF. As the PRF increases, the velocity range displayed in a spectrum becomes wider. By increasing its depth, the maximum PRF can be decreased. • DR: Sets the amplitude range in which the device operates. Higher dynamic range results in softer images with reduced contrast. • Wall Filter: Adjusts the wall filter. By increasing the wall filter, the velocity components that are not concerned are removed. • Sample Volume: Adjusts the sample volume area. By increasing this sample volume, various velocity components can be detected. • Correction Angle: Adjusts the correction angle. Adjust the correction angle to detect correct velocity components. • Base Line: Adjusts the baseline to represent the Doppler spectrum as a single continuous signal. • Sweep Speed: Adjusts the sweep speed. By increasing the sweep speed, the time range displayed in a spectrum can be increased. • Sound Volume: Adjusts the sound volume for the pulsed Doppler signal in PW mode.

M mode operation (motion mode / SONON 300C Only)

In M mode (also known as “motion mode”), the changes over time on a line graph appears in a spectrum.

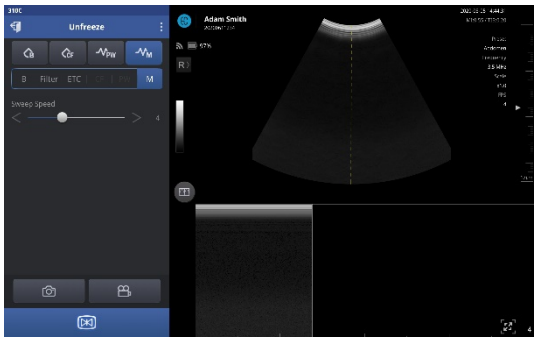
After you tap Start Scan on the home screen, scanning begins in B mode by default. Tap  on the mode select menu to switch to M mode.





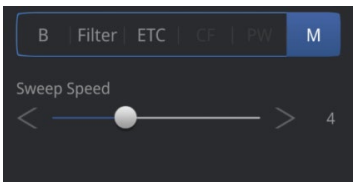
NOTE

- The 300L device does not support M mode operation. M mode operation is available on the SONON 300C device only.
- In M mode, a yellow line is displayed on the screen to specify the region to be observed.
- Select the region of observe as a touch event.



M mode specific settings

You can adjust the following settings in M mode.

Menu screen	Name	Description/Default
	M mode parameters (available with SONON 300C, in M mode only)	• Sweep Speed: Adjusts the sweep speed. By increasing the sweep speed, the time range displayed in a spectrum can be increased.

4 Utilizing scan screen features

The SONON ultrasound device provides various scan screen features, such as dual screen review, zooming, focus and depth adjustment, recording, preset selection, and measurement of on-screen objects.

> **NOTE**
> Measuring features are available in Freeze mode only.

Unfreeze/Freeze mode screens

By default, the scan screen is presented in Unfreeze mode, allowing all changes to be observed in real time.
You can press the Freeze button () on the device or on the app screen to switch to Freeze mode. On the Freeze mode screen, you can observe and analyze a still image of a scan and measure the on-screen objects according to your diagnostic needs.

4.1 Utilizing presets

Presets allow you to conveniently apply the appropriate settings for different applications. The SONON X Ultrasound app provides the following default presets with typical settings optimized for different types of exams.

> **NOTE**
> Available number and types of presets vary depending on the model of your SONON device.

Presets for the SONON 300C

- Abdomen
- Bladder
- FAST
- Early OB
- Late OB
- GYN

Presets for the 300L

- Thyroid
- Carotid
- Breast
- MSK
- Vascular
- Superficial
- Thorax

You can select one of the presets to immediately apply multiple setting parameters optimized for each application. After selecting a preset, you can make changes to the detailed screen or exam settings and save the changes by overwriting the existing preset, or by creating a new preset.

⚠ CAUTION

Changing the display settings can affect image quality and compromise diagnostic accuracy. It is your responsibility to adjust the display settings appropriately to obtain desirable image quality.

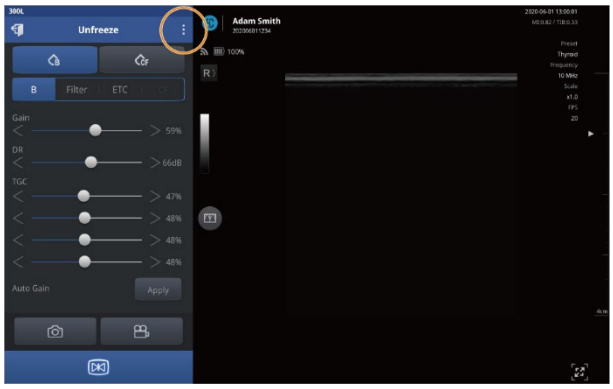
⚠ ATTENTION

La modification des paramètres d'affichage peut affecter la qualité d'image et compromettre la précision du diagnostic. Il est de la responsabilité de l'opérateur de régler les paramètres d'affichage de manière appropriée afin d'obtenir la qualité d'image recherchée.

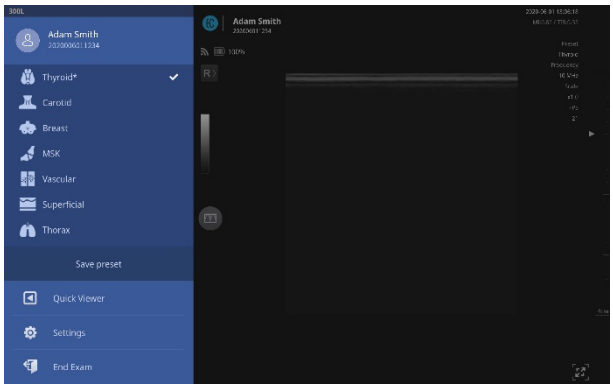
Selecting a preset

Follow the instructions below to select a preset for your application.

1 Tap ⋮ in the menu area to see the expanded menu. A list of presets is displayed.



2 Select a preset from the list.



NOTE

On the Unfreeze mode screen (default), you can instantly see the results of selecting different presets.

Saving a preset after making parameter changes

After selecting a preset, if you have made changes to the screen or exam parameters to suit your specific needs, you can save the changes to the currently selected preset, or create a new preset to save your settings.

See “Configuring screen parameters” on page 59 for detailed information about setting screen and exam parameters.

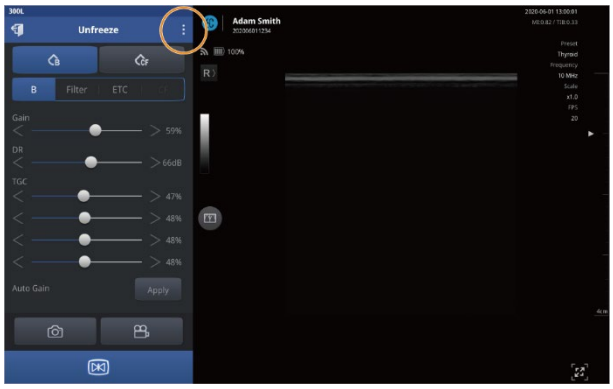
NOTE

On the Unfreeze mode screen (default), you can instantly see the results of screen parameter changes.

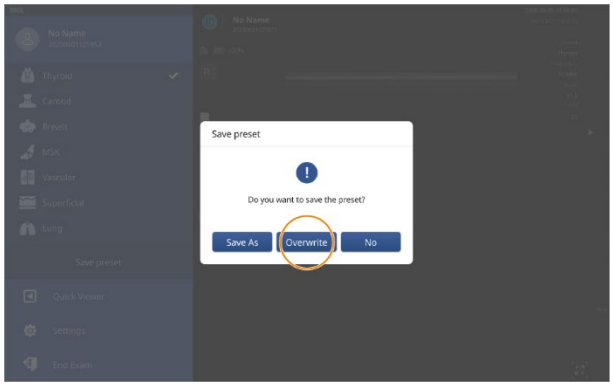
Saving changes to an existing preset

Follow the instructions below to save changes to a currently selected preset.

1 Tap ⋮ in the menu area to open the expanded menu.

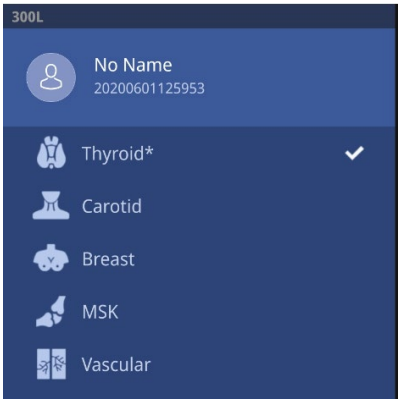


2 Tap **Save Preset** > **Overwrite**. Changes will be saved to the current preset.



NOTE

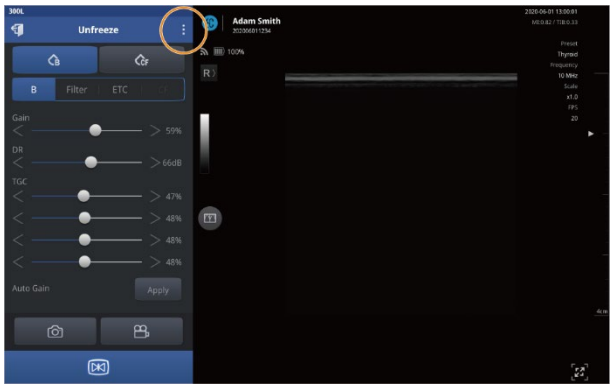
An asterisk (“*”) will be displayed at the end of the preset name if you overwrite a default preset after making changes.



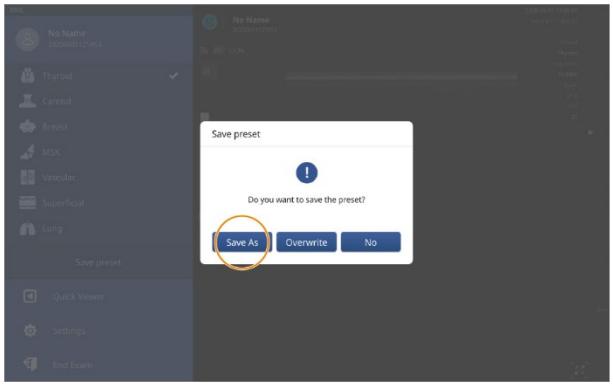
Creating a new preset after making changes

Follow the instructions below to save your changes as a new preset.

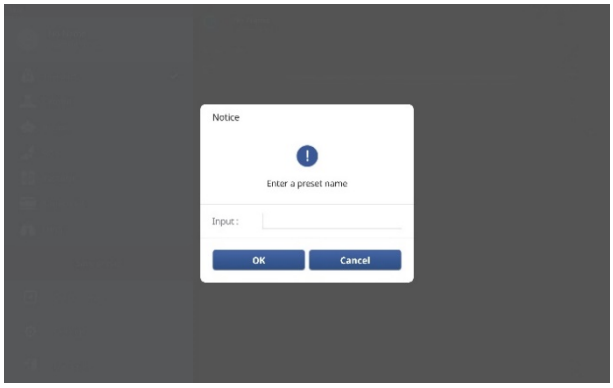
1 Tap ⋮ in the menu area to open the expanded menu.



2 Tap **Save Preset** > **Save As**.



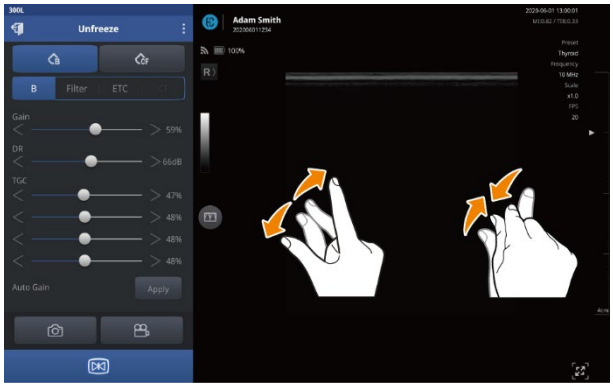
3 Enter a new preset name and tap **OK**. A new preset will be created in the list of presets.



4.2 Utilizing imaging features

Zooming in and zooming out

Whenever a closer look at the scan screen is needed during a scan, you can zoom in or zoom out on any section of the screen by pinching out or pinching in on the screen with your fingers.

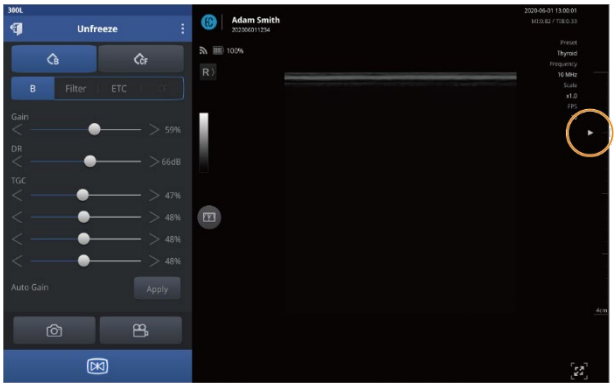


> **NOTE**
>
> Up to 400% magnification is available when you zoom in.

Adjusting scan focus (FL: Focal Length)

You can adjust focal length (FL) to set the focus of a scan to a desired depth.

Tap on the side bar on the right edge of the screen to set a focal length.



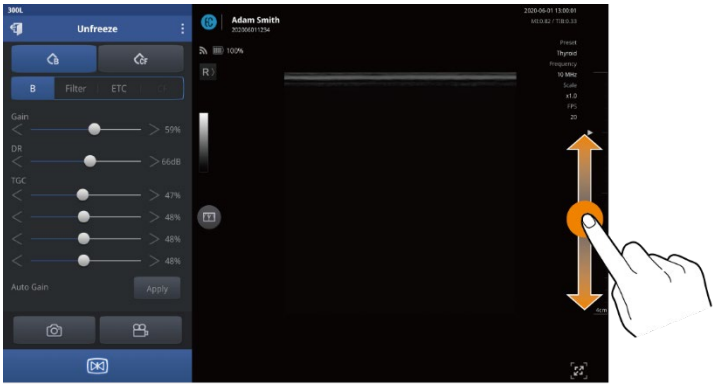
NOTE

- Available range of focal length (FL) varies by model.
  - SONON 300C: 0.78-6.29 in. (2-16 cm)
  - 300L: 0.19-2.36 in. (0.5-6 cm)
- MI (mechanical index) and TI (thermal index) values will change in accordance with the focus change. See “Acoustic output parameters” on page 172 for detailed information about the mechanical and thermal index parameters.
- FL cannot be set beyond Depth (scan depth). If you try to set FL beyond the available Depth, it will be automatically adjusted to 0.39 in. (1 cm) less than Depth (Depth – 0.39 in. [1 cm]).

Adjusting scan depth (Depth)

You can adjust scan depth (Depth) to set the distance the ultrasound waves travel into the patient’s body.

Drag your finger up and down on the side bar on the right edge of the screen until the desired scan depth is achieved.



NOTE

- Available range of depth (Depth) varies by model.
  - SONON 300C: 1.57-7.87 in. (4-20 cm)
  - 300L: 1.18-3.93 in. (3-10 cm)
- Depth cannot be set shallower than FL (Focal Length). If you set Depth to a length shorter than FL, FL will be automatically adjusted to 0.39 in. (1 cm) less than Depth (Depth – 0.39 in. [1 cm]).

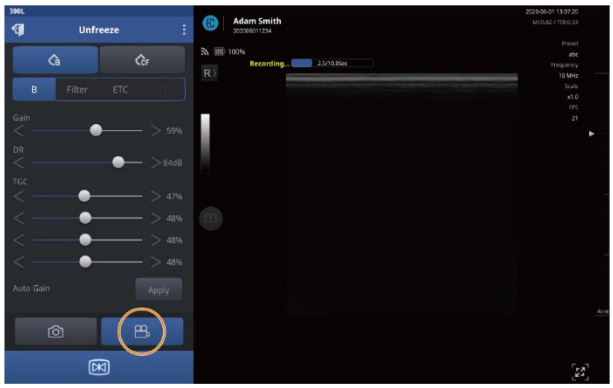
4.3 Recording and reviewing exams

You can record your exams as video or image files, and quickly review them in the Quick Viewer or Snapshot Slider. You can also review for your exams using the dual screen.

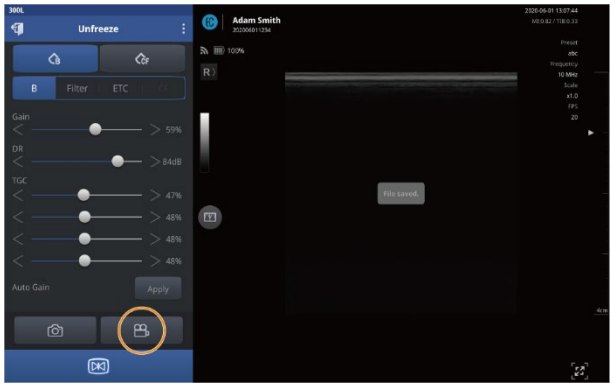
Recording exam videos

Follow the instructions below to record exams as video files.

1 Tap  in the menu area to begin recording. A status message (“Recording…”) will be displayed on the screen to indicate that the exam is being recorded.

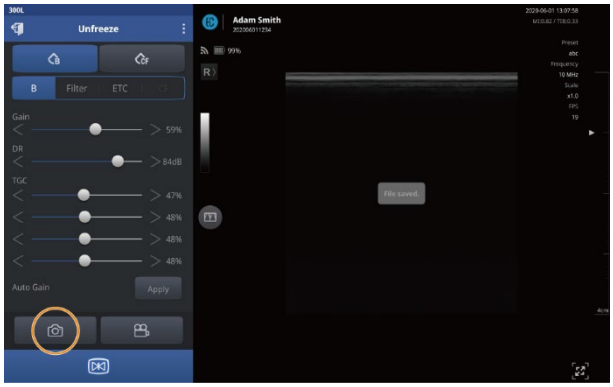


2 To stop recording, tap  in the menu area again. A status message (“File saved”) will be displayed on the screen to indicate that the recorded video has been saved.



Capturing images

Tap  in the menu area during an exam to capture a screen as an image file. A status message ("File saved") will be displayed to indicate that the captured image has been saved.

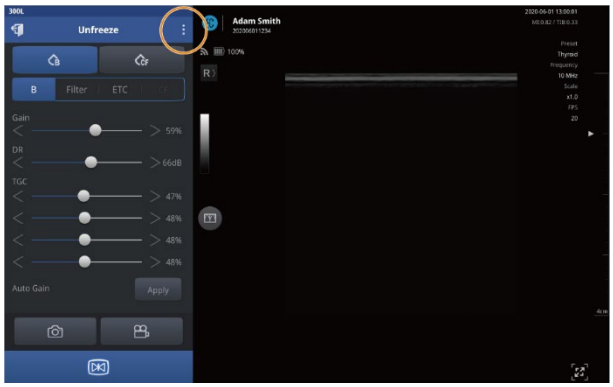


Playing back recorded exams with Quick Viewer

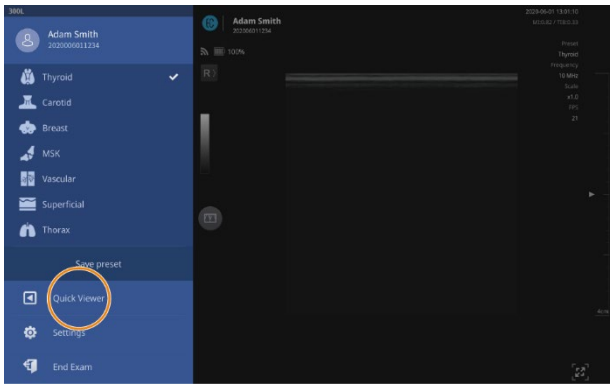
Follow the instructions below to quickly review recorded videos and images.

> **NOTE**
>
> You can also play back recorded videos and captured images in the Patient List. See "5.2 Reviewing and handling exam records" on page 108 for detailed information.

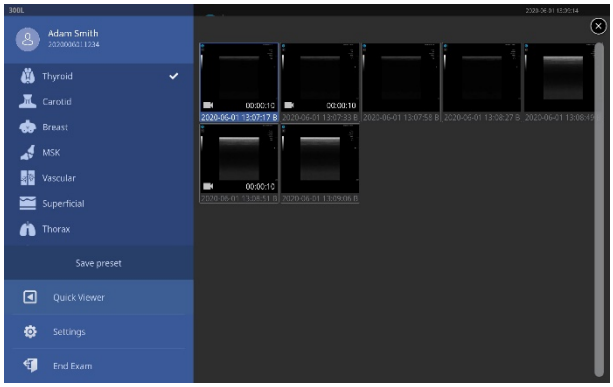
1 Tap  to open the expanded menu.



2 Tap **Quick Viewer** to open the playlist.



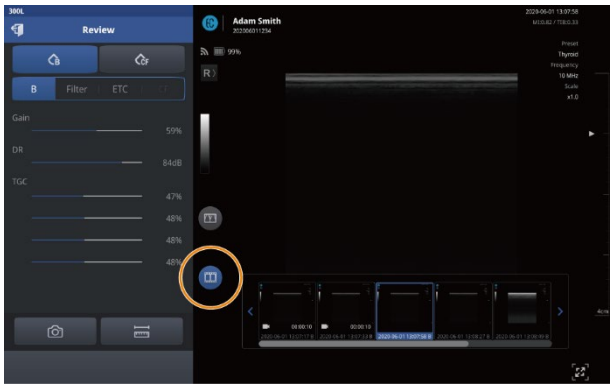
3 Select a video or image to play back.



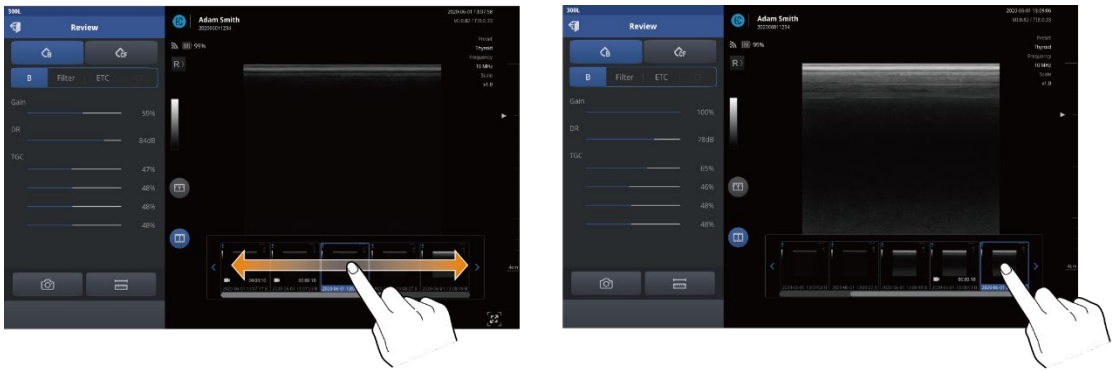
Playing back recorded exams with Snapshot Slider

1 Enter review mode after selecting a video or image.

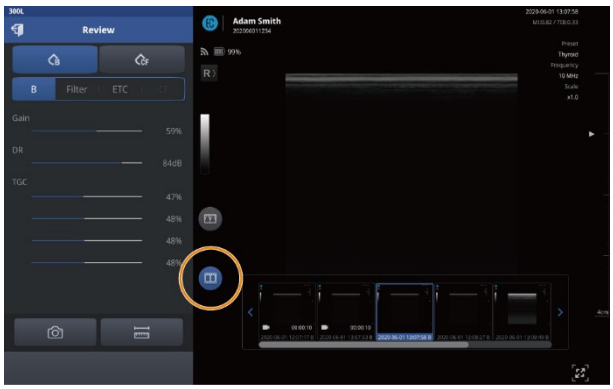
2 Tap  to open Snapshot slide.



3 Drag the Snapshot slide to the left or right, then tap the image or video you want.



4 Tap  to close Snapshot slider.

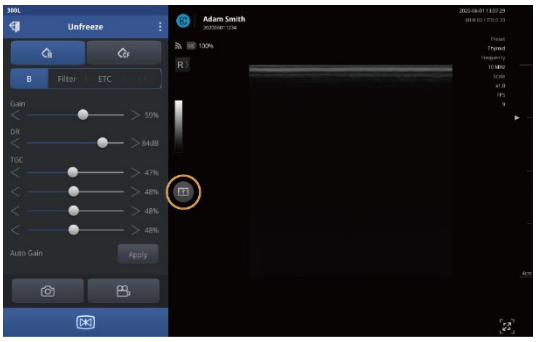


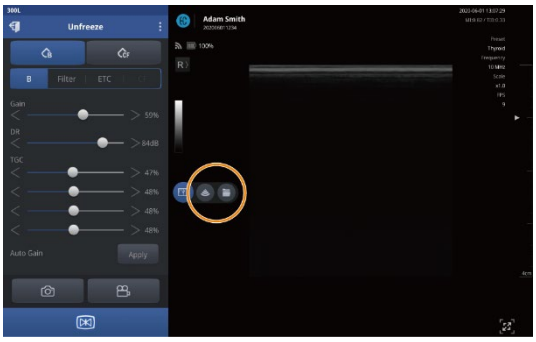
Reviewing exams in Dual screen

Dual screen's various review modes will allow you to much more conveniently and easily review for your exams.

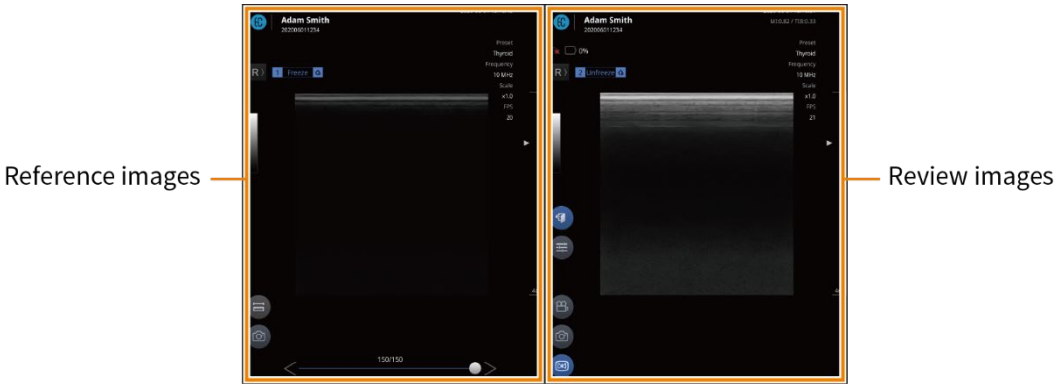
Starting Dual screen mode

1 Tap  in scan mode, then tap  or  to start dual screen mode.

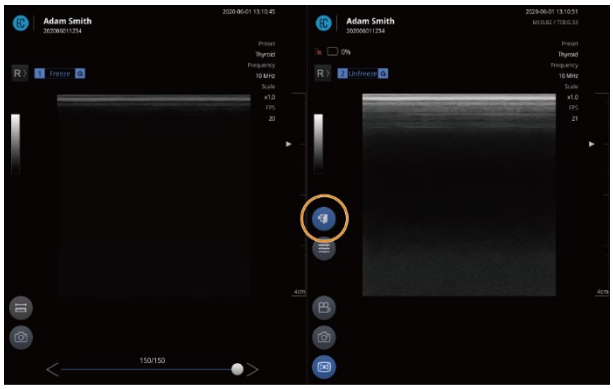




The reference sources for comparison, such as recorded images, videos, or freeze mode will be displayed on the left screen while in dual screen.
Images to review will be displayed on the right screen while in dual screen.



2 Tap  to close Dual screen mode.



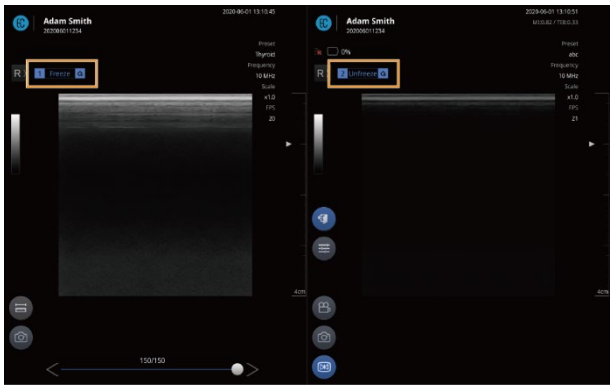
Utilizing Dual screen mode

Scan mode supports the following dual screen modes:

Live freeze + Live scan

Tap  >  while scanning.

You can review the live-scan image while referring to a freeze image.



NOTE

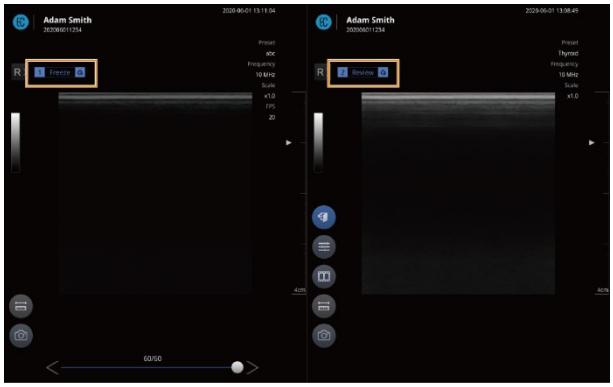
The control options available in dual screen mode are below. For more info, please check the corresponding page.

- Tap  to measure objects on the screen. (“4.4 Measuring on-screen objects” on page 86)
- Tap  to capture image. (“Capturing images” on page 78)
- Tap  to change screen parameter settings. (“Configuring screen parameters” on page 59)
- Tap  to record video. (“Recording exam videos” on page 77)
- Tap  to freeze the scan screen. (“Starting Freeze mode” on page 86)

Live freeze + Review

Tap  >  while scanning, then select the scanned image.

You can review scanned images while referring to a freeze image.



NOTE

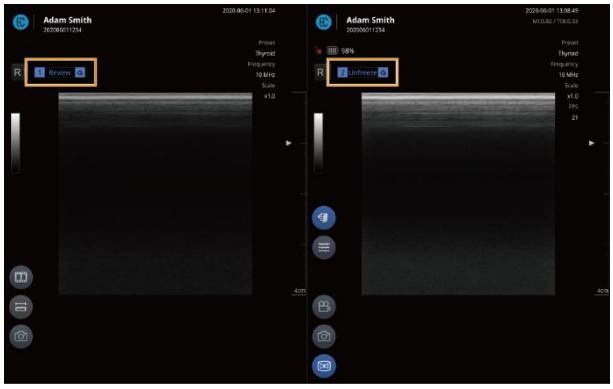
The control options available in dual screen mode are below. For more info, please check the corresponding page.

- Tap  to measure objects on the screen. (“4.4 Measuring on-screen objects” on page 86)
- Tap  to capture image. (“Capturing images” on page 78)
- Tap  to change screen parameter settings. (“Configuring screen parameters” on page 59)
- Tap  to open Snapshot Slider (“Playing back recorded exams with Snapshot Slider” on page 79)
- Tap  to play back a video. (“Playing recorded videos” on page 108)

Review + Live scan

Select the scanned image and tap > .

You can review the live-scan image while referring to a scanned image.



NOTE

The control options available in dual screen mode are below. For more info, please check the corresponding page.

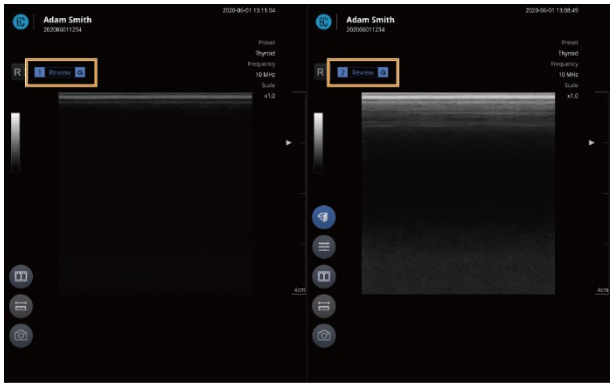
- Tap to open Snapshot Slider (“Playing back recorded exams with Snapshot Slider” on page 79)
- Tap to measure objects on the screen. (“4.4 Measuring on-screen objects” on page 86)
- Tap to capture image. (“Capturing images” on page 78)
- Tap to play back a video. (“Playing recorded videos” on page 108)
- Tap to change screen parameter settings. (“Configuring screen parameters” on page 59)
- Tap to record video. (“Recording exam videos” on page 77)
- Tap to freeze the scan screen. (“Starting Freeze mode” on page 86)

Review + Review

You can compare and review scanned images.

1 Select the scanned image and tap  >  .

2 Select the image to review.



NOTE

The control options available in dual screen mode are below. For more info, please check the corresponding page.

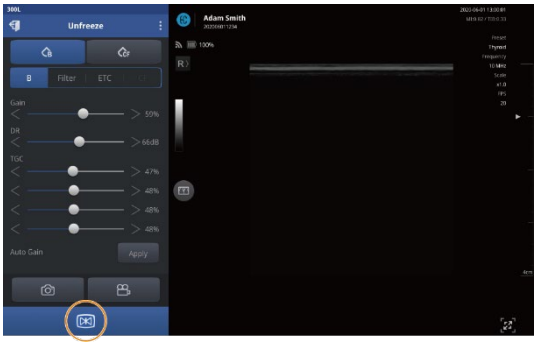
- Tap  to open Snapshot Slider (“Playing back recorded exams with Snapshot Slider” on page 79)
- Tap  to measure objects on the screen. (“4.4 Measuring on-screen objects” on page 86)
- Tap  to capture image. (“Capturing images” on page 78)
- Tap  to play back a video. (“Playing recorded videos” on page 108)
- Tap  to change screen parameter settings. (“Configuring screen parameters” on page 59)

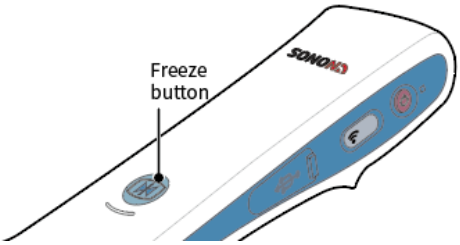
4.4 Measuring on-screen objects

In Freeze mode, you can measure objects on the screen and leave comments on the scan images.

Starting Freeze mode

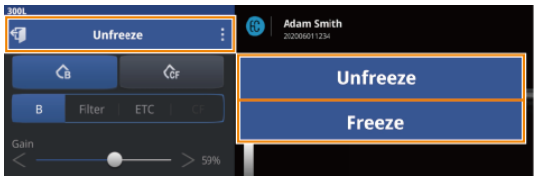
Tap  on the scan screen, or press the Freeze button () on your SONON device, to start Freeze mode.



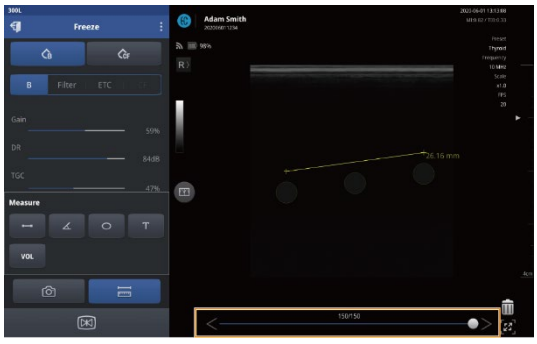


NOTE

- The scan status indicator in the menu area displays the current scan mode as you switch between Unfreeze and Freeze modes.



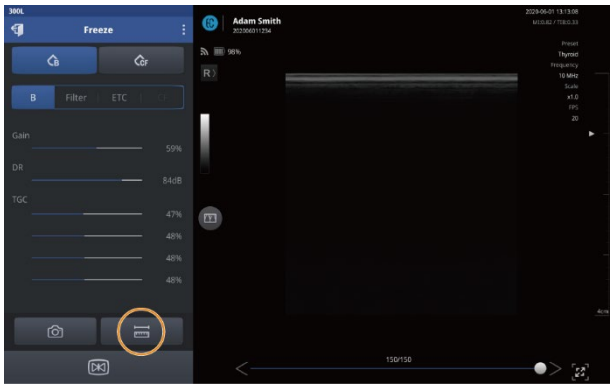
- During a measurement, a rewind bar is displayed at the bottom of the scan screen. You can drag the handle of the rewind bar to review saved images in the buffer (The buffer temporarily stores up to 150 frames).



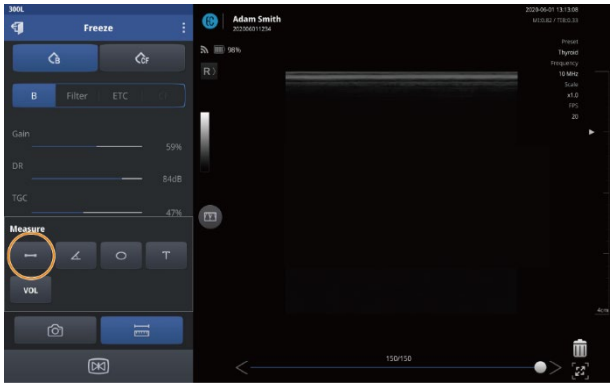
Measuring lengths

After switching to Freeze mode, follow the instructions below to measure the length of an object.

1 Tap  to open the Measure menu.

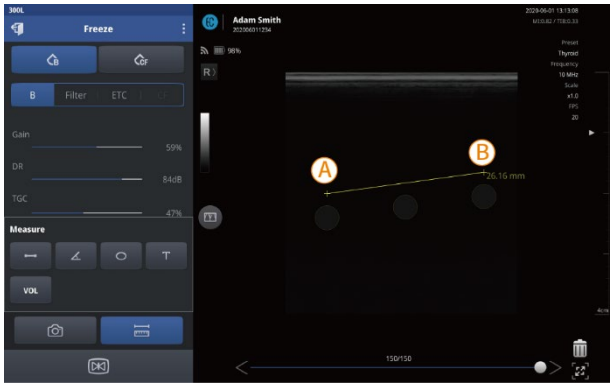


2 Tap  to start measuring.



3 Tap a starting point (A), then tap an ending point (B).

A yellow line will be displayed connecting the two points, and the distance between (A) and (B) will be displayed in yellow (in mm).



4 Tap  to capture measurements on the screen. A message (“File Saved”) will be displayed to indicate that the captured image has been saved.

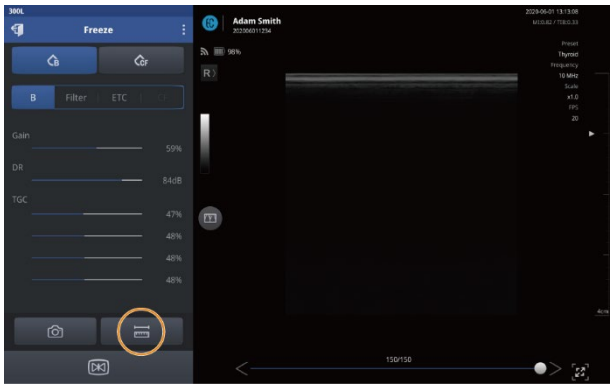
NOTE

- When there are multiple measurements on the screen, the currently selected measurement is displayed in yellow and others are displayed in green.
- You can move a measurement around the screen by dragging its center point.
- To save measurements, capture the screen before switching to Unfreeze mode. All measurements on screen will be deleted when you leave Freeze mode.

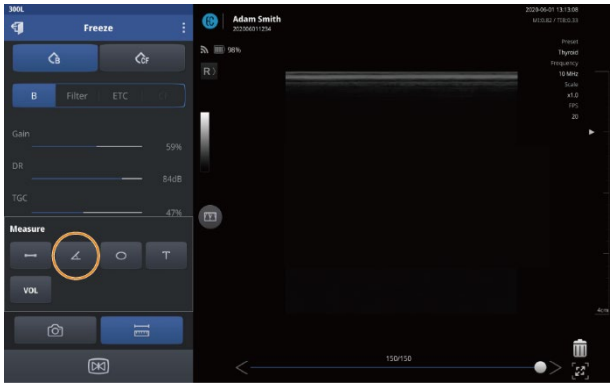
Measuring angles

After switching to Freeze mode, follow the instructions below to measure the angle of an object.

1 Tap  to open the Measure menu.

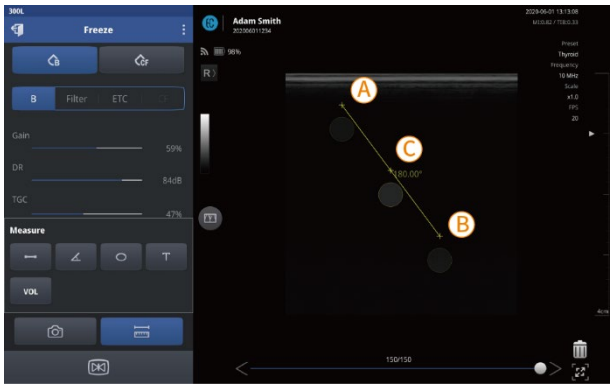


2 Tap  to start measuring.

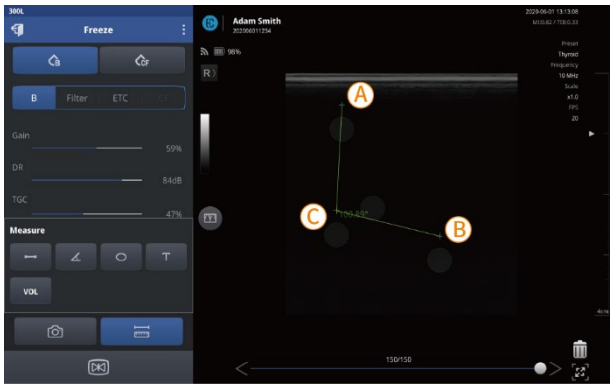


3 Tap a starting point (A), then tap an ending point (B).

A yellow line will be displayed connecting the two points. A center point (C) will be automatically generated and the angle of the section (A)-(C) against section (C)-(B) will be displayed in yellow (in °).



4 You can drag the three points freely to create an angle (in °).



5 Tap  to capture measurements on the screen. A message (“File Saved”) will be displayed to indicate that the captured image has been saved.

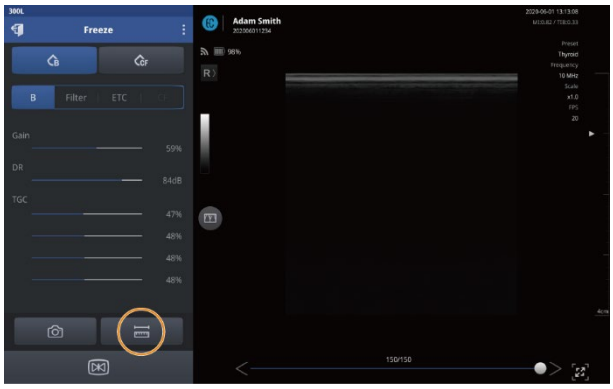
NOTE

- When there are multiple measurements on the screen, the currently selected measurement is displayed in yellow and others are displayed in green.
- You can move a measurement around the screen by dragging its center point.
- To save measurements, capture the screen before switching to Unfreeze mode. All measurements on screen will be deleted when you leave Freeze mode.

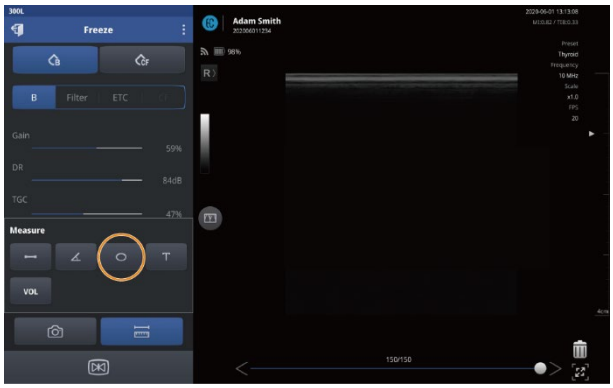
Measuring circumferences and areas

After switching to Freeze mode, follow the instructions below to measure the circumference and area of an object.

1 Tap  to open the Measure menu.

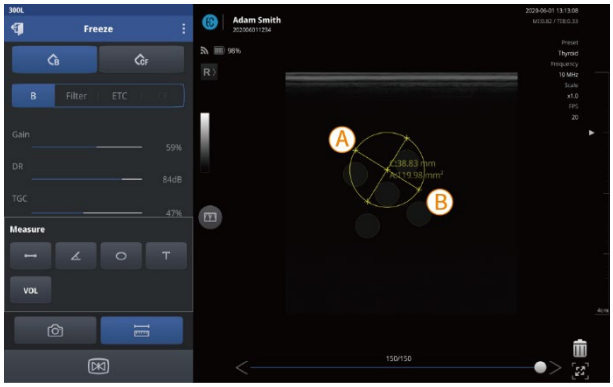


2 Tap  to start measuring.



3 Tap a starting point (A) and an ending point (B).

- A yellow axis connecting the two points, and an ellipse passing through the two points, will be displayed.
- Two more points on the perpendicular axis, as well as the center point, will be automatically generated.
- The circumference and area of the ellipse will be displayed in yellow numbers (in mm/mm^2).



4 Modify the shape by freely dragging the four points on the ellipse, or move the ellipse by dragging the center point, to measure the exact area.

5 Tap  to capture measurements on the screen. A message (“File Saved”) will be displayed to indicate that the captured image has been saved.

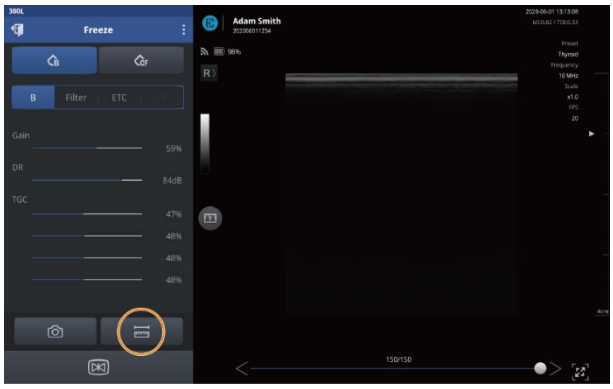
NOTE

- When there are multiple measurements on the screen, the currently selected measurement is displayed in yellow and others are displayed in green.
- You can move a measurement around the screen by dragging its center point.
- To save measurements, capture the screen before switching to Unfreeze mode. All measurements on screen will be deleted when you leave Freeze mode.

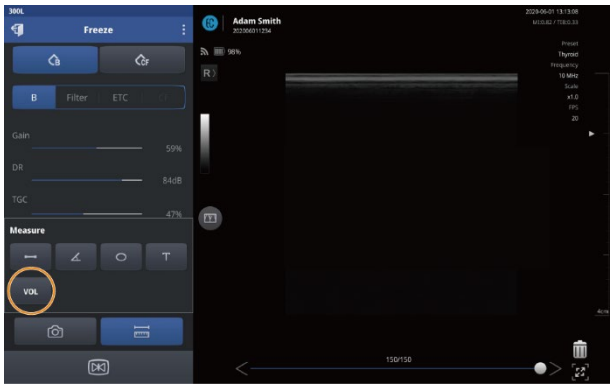
Measuring volumes

After switching to Freeze mode, follow the instructions below to measure the volume of an object.

1 Tap  to open the Measure menu.

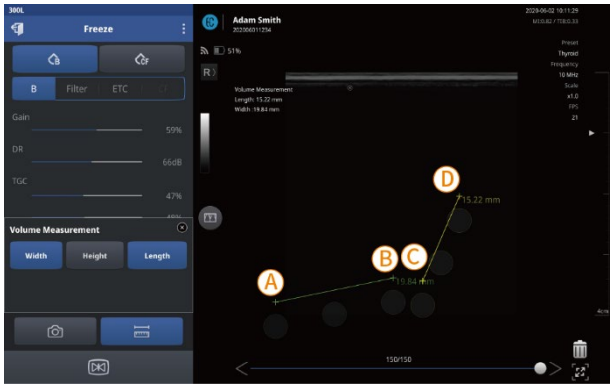


2 Tap  to start measuring.



3 Measure the length and width of the object.

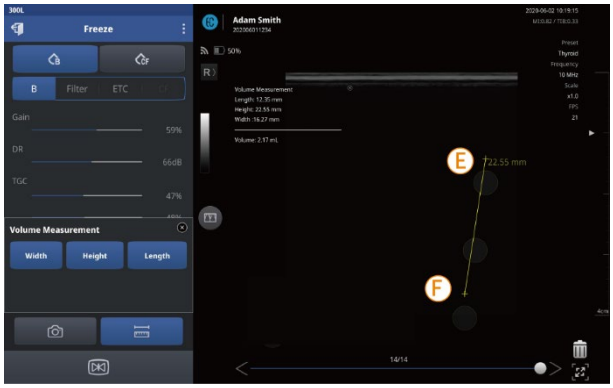
- Tap **Width**, then tap a starting point (A) and an ending point (B).
  A yellow line will be displayed connecting the two points, and the distance between A and B will be displayed (in mm).
- Tap **Length**, then tap a starting point (C) and an ending point (D).
  A yellow line will be displayed connecting the two points, and the distance between (C) and (D) will be displayed (in mm).



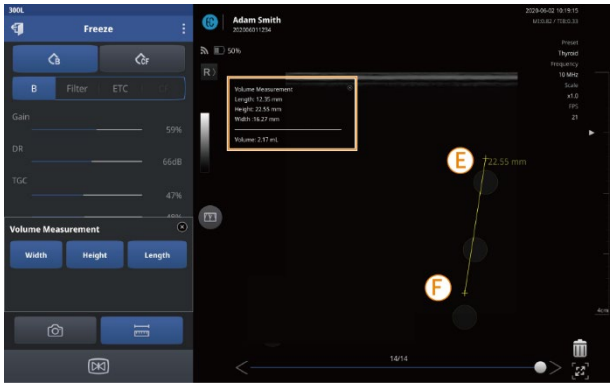
4 Tap  to switch back to Unfreeze mode, and scan from a different angle to measure the height of the object.

5 After locating the object on the scan screen, tap  to restart Freeze mode and tap  to open the Measure menu.

6 Tap **Height**, then tap a starting point (E) and an ending point (F).
A yellow line will be displayed connecting the two points, and the distance between (E) and (F) will be displayed (in mm).



- The dimensions and calculated volume are displayed on the screen (in mm and mL).



7 Tap  to capture the measurements on the screen. A message (“File Saved”) will be displayed to indicate that the captured image has been saved.

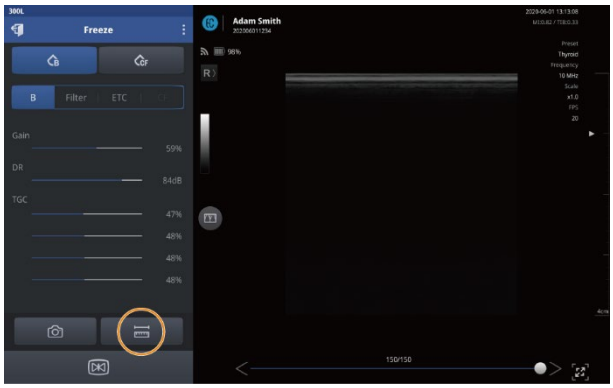
NOTE

- When there are multiple measurements on the screen, the currently selected measurement is displayed in yellow and others are displayed in green.
- You can move a measurement around the screen by dragging its center point.
- To save measurements, capture the screen before switching to Unfreeze mode. All measurements on screen will be deleted when you leave Freeze mode.

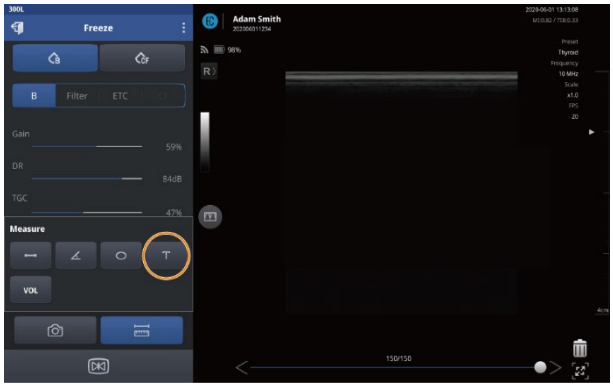
Leaving comments

After switching to Freeze mode, follow the instructions below to leave a comment on the screen.

1 Tap  to open the Measure menu.



2 Tap  , then tap the scan screen to add a comment.



3 Type your comment, the tap **OK** on the keypad.

4 Tap  to capture the comment on the screen. A message (“File Saved”) will be displayed to indicate that the captured image has been saved.

NOTE

- You can drag a comment to move it on the screen.
- To save comments, capture the screen before switching to Unfreeze mode. Any comments on the screen will be deleted when you leave Freeze mode.

Assessing fetal biometry (for SONON 300C only)

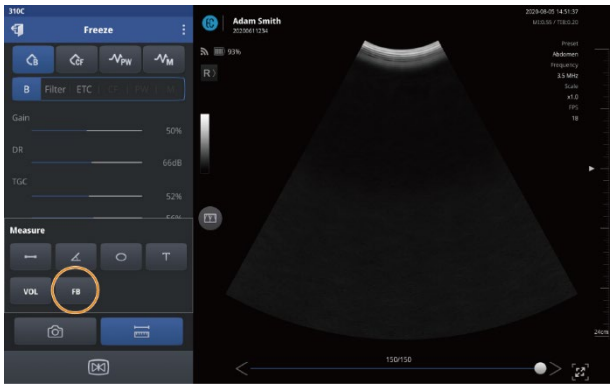
The SONON 300C ultrasound device provides a measuring mode specially designed for assessing fetal biometry.

After switching to Freeze mode, you can measure the following fetal biometry parameters on the measuring screen.

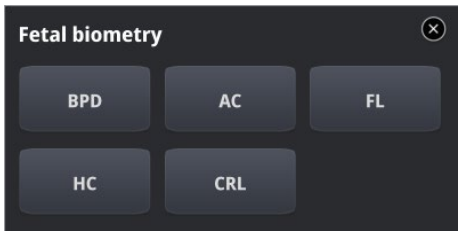
- BPD: Biparietal Diameter
- AC: Abdomenal Circumference
- FL: Femur Length
- HC: Head Circumference
- CRL: Crown Rump Length

1 Tap  to open the Measure menu.

2 Tap  to open the fetal biometry measuring tools.



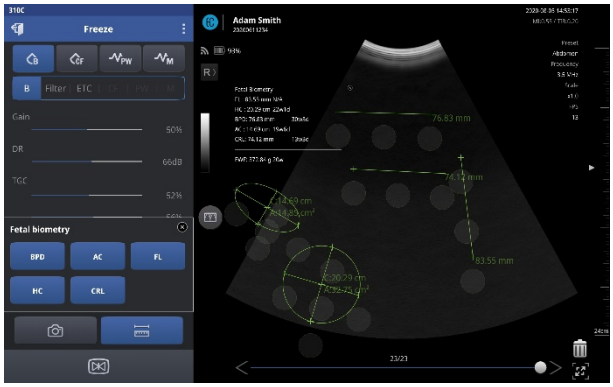
3 Tap to select each parameter and complete measuring.



NOTE

See “Measuring lengths” on page 87 and “Measuring circumferences and areas” on page 91 for detailed procedures for measuring length and circumference.

When you have finished measuring parameters, an estimated fetal weight (EFW) will be automatically calculated and displayed on the screen.



NOTE

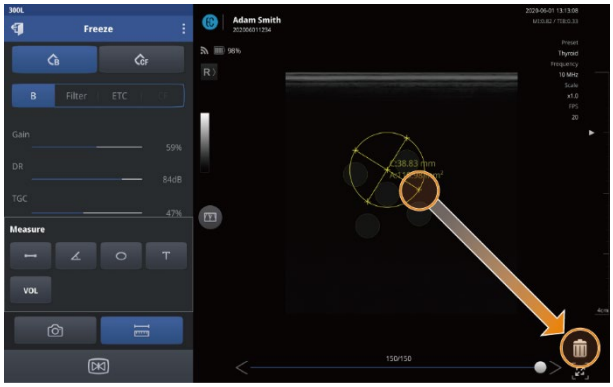
- When there are multiple measurements on the screen, the currently selected measurement is displayed in yellow and others are displayed in green.
- You can move a measurement around the screen by dragging its center point.
- To save measurements, capture the screen before switching to Unfreeze mode. All measurements on screen will be deleted when you leave Freeze mode.

Deleting measurements

Measurements on the screen can be deleted individually or all at once.

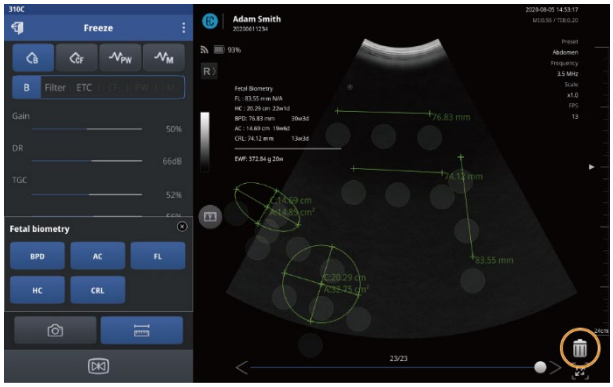
Deleting an individual measurement

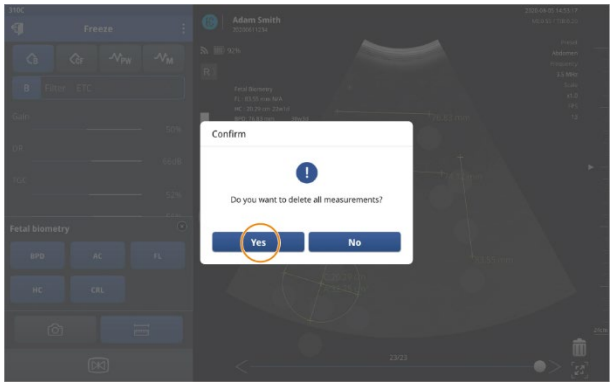
On the measurement screen, drag a measurement into the trash can to delete it.



Deleting all measurements

On the measurement screen, tap  then tap **Yes** to delete all measurements on the screen.





5 Managing patient data

The Patient List provides management features which allow you to register, edit, delete, move, share, and upload patient data entries.

5.1 Handling patient information

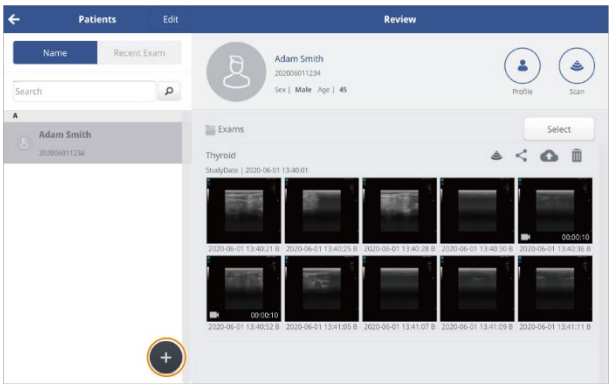
After performing and recording an exam, you can check recorded videos and images, and register them as patient information entries, in the Patient List.

Registering a patient

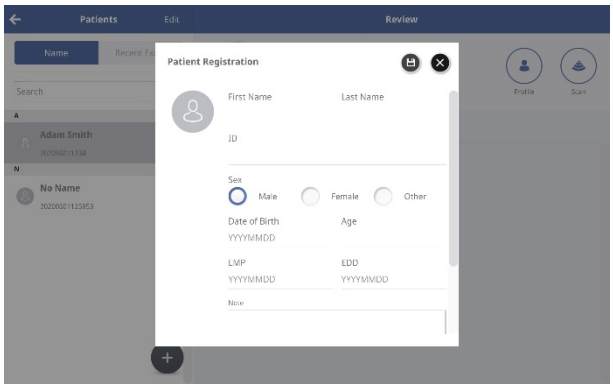
Follow the instructions below to add information for a new patient.

1 Tap **Patient List** on the home screen to open the Patient List.

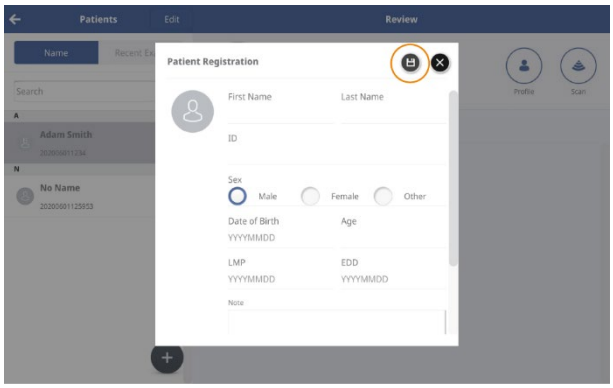
2 Tap ⊕ to register a new patient to the Patient List.



3 Enter patient information such as the patient's name, ID number, sex, and DOB.



4 Tap  to save the patient data.



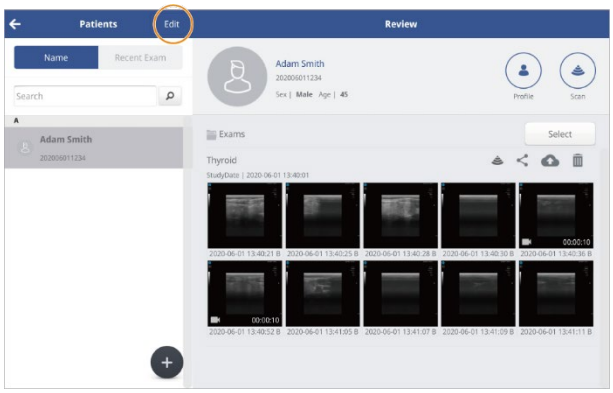
NOTE

You can start scanning from the Review screen by tapping  (**Scan**) at the top right corner. All recorded videos and images will be directly added to the currently selected patient's exam record.

Deleting patient entries

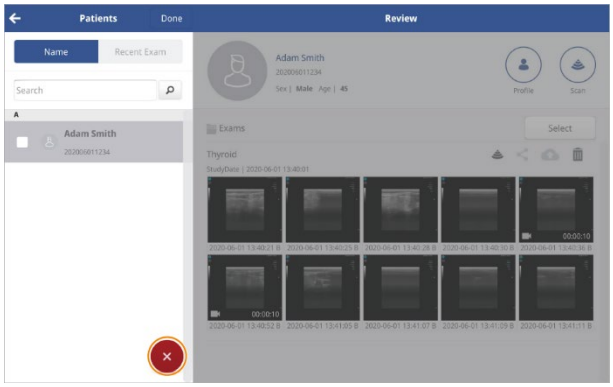
Follow the instructions below to delete patient entries from the Patient List. You can delete a single entry, or delete multiple entries at one time.

1 Tap **Edit** to begin editing.

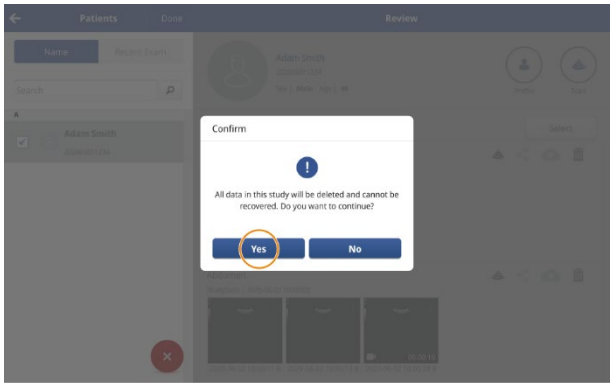


2 Tap on the Patient List to select a patient entry, or multiple entries.

3 Tap  to delete the selected entries.



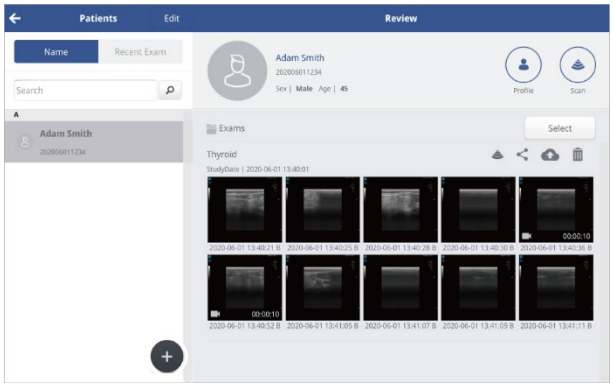
4 In the popup window, tap **Yes**.



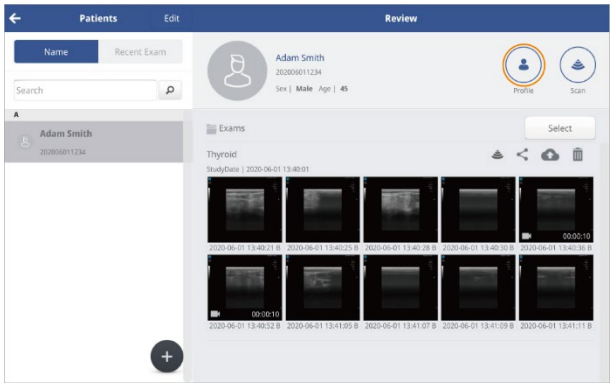
Editing patient information

Follow the instructions below to modify patient information.

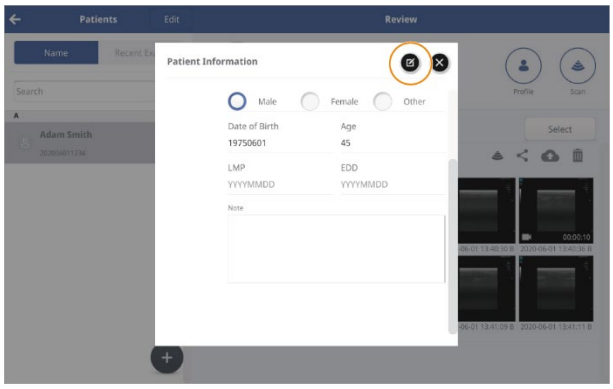
1 Tap a patient entry in the Patient List. The Review window will open, showing the patient's recorded exams as thumbnails.



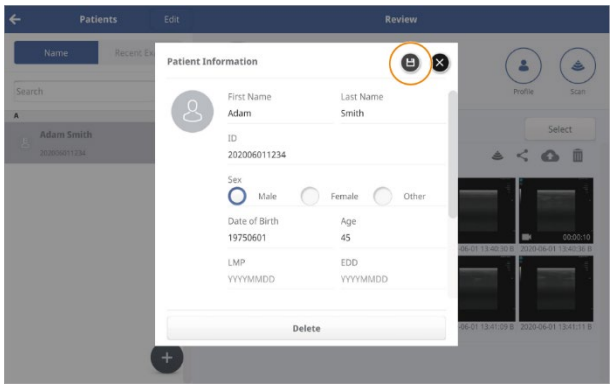
2 Tap (**Profile**) to open the patient information window.



3 Tap to make changes to the patient information or add a note.



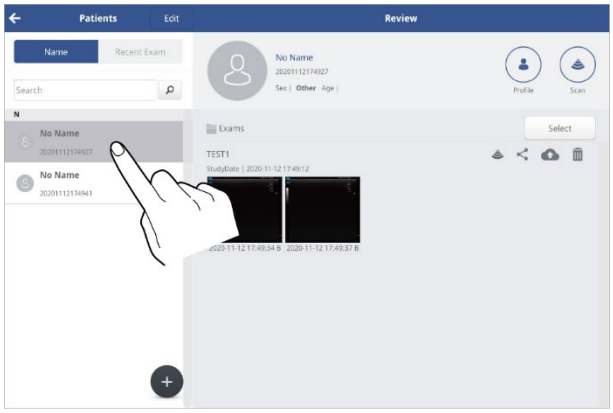
4 Tap  to save the data when you are done editing. A message (“Patient information saved”) will be displayed to indicate that the edited information has been saved.



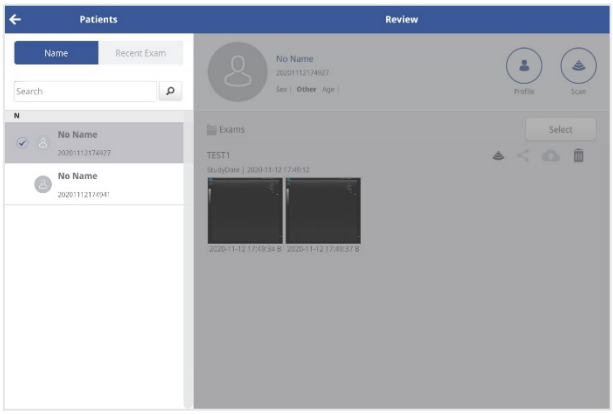
Moving patient diagnostic data

You can move a patient diagnostic data to other patient entries.

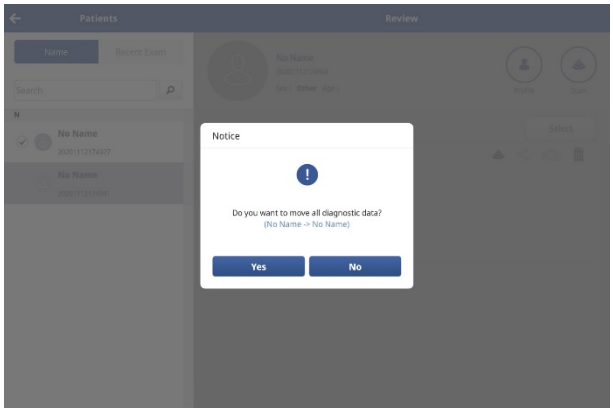
1 In the patient list, press and hold the patient entry for which you want to move diagnostic data for at least 3 seconds.



2 Tap **OK** in the pop-up window. A check box will be shown in the patient entry to which the diagnostic data will be moved.



3 Press and hold the patient entry to which the diagnostic data will be moved for at least 3 seconds. A pop-up window notifying that the diagnostic data will be moved from the name of the patient to be moved to the name of the patient being moved, will be shown.



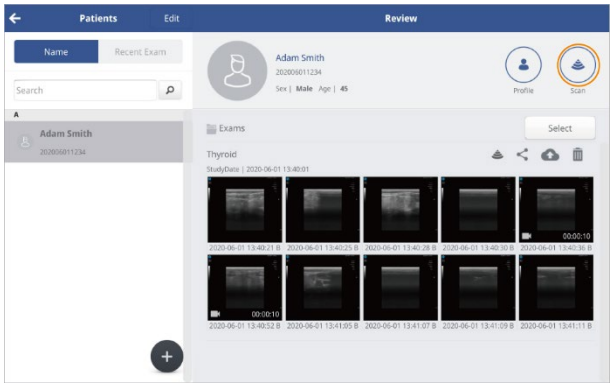
4 Tap Yes to move the patient's diagnostic data. The information about the patient to which the diagnostic data was moved is retained, but the diagnostic data will be deleted.

5.2 Reviewing and handling exam records

In the Review window, you can begin a scan for the selected patient, view previously recorded exams, and share, upload, or delete previously recorded exams.

NOTE

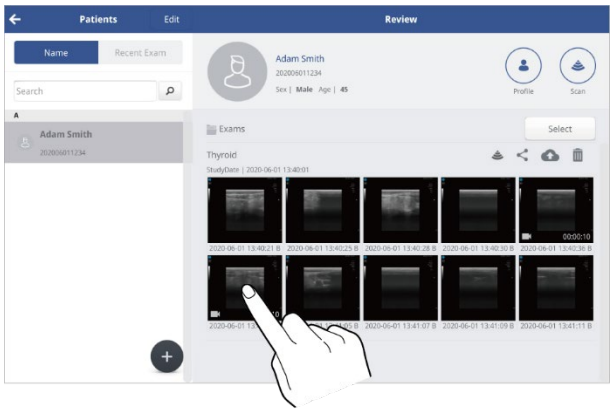
You can begin a scan from the Review window by tapping . All recorded videos and captured images will be directly added to the currently selected patient's exam record.

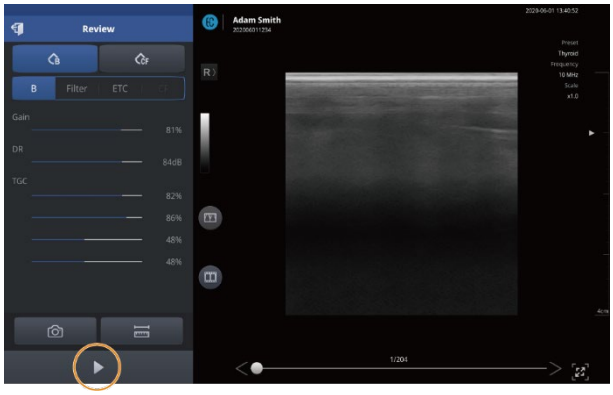


Playing recorded videos

You can play back recorded video files in the Patient List. While playing back recorded video files, you can stop a video to examine it, zoom in, measure objects on the screen and save files.

Tap a thumbnail to open a video file.

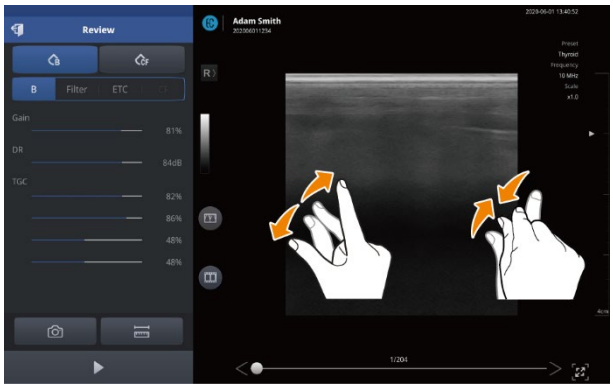




- Tap ⏸ to pause a video.
- Tap ▶ to play a video again from where it was paused.

> **NOTE**
>
> See “3.1 User interface and screen settings” on page 52 for detailed information about setting the imaging parameters.

Zooming in and out on the video



To look more closely at a section of the scan screen, you can zoom in or zoom out on any section of the screen by pinching out or pinching in on the screen with your fingers.

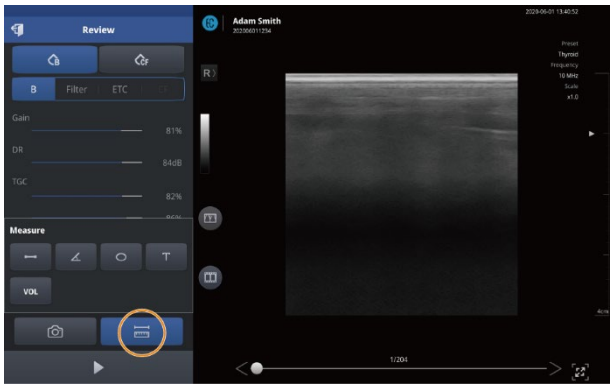
> **NOTE**
>
> Up to 400% magnification is available when you zoom in.

Measuring objects in a video

On a paused screen, you can measure the objects on the screen.

> **NOTE**
>
> See “4.4 Measuring on-screen objects” on page 86 for detailed information about measuring on-screen objects.

1 Tap  to open measuring tools, and select an appropriate tool for your measurement.



- Tap  to measure lengths.
- Tap  to measure angles.
- Tap  to measure circumferences and areas.
- Tap  to leave text comments.
- Tap  to measure volumes.
- Tap  to measure fetal biometry parameters (for SONON 300C only).

NOTE

Measurement of fetal biometry parameters is only available on the SONON 300C ultrasound device. Even when viewing videos taken with a SONON 300C device, measurement of fetal parameters will not be available if a 300L is currently connected to your mobile device, or if the last SONON ultrasound device connected to your mobile device was a 300L. Fetal biometry parameters available for measurement are as follows.

- BPD: Biparietal Diameter
- AC: Abdominal Circumference
- FL: Femur Length
- HC: Head Circumference
- CRL: Crown Rump Length

2 Tap  to capture measurements on the screen. A message (“File Saved”) will be displayed to indicate that the captured image has been saved.

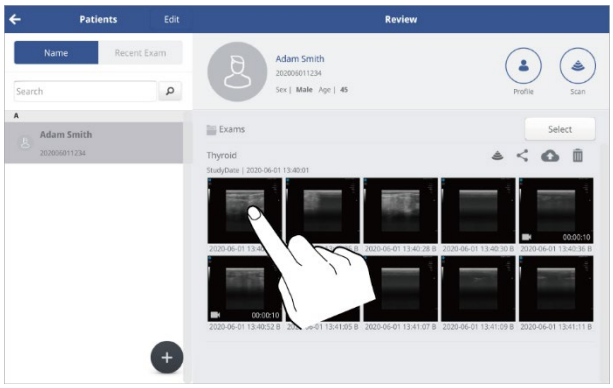
NOTE

When you leave the playback screen, all measurement data will be deleted. If you want to record measurement data, capture the screen.

Playing back captured images

You can review captured image files in the Patient List.

Tap a thumbnail to open an image file.

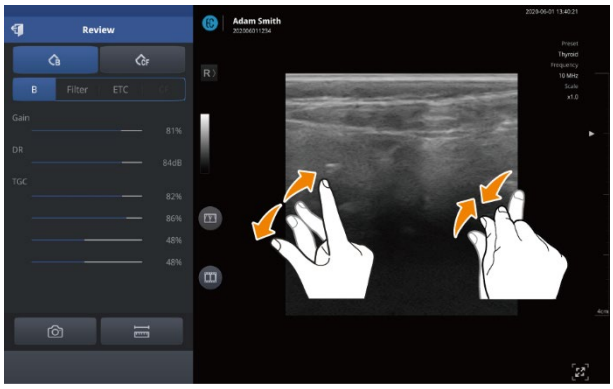


NOTE

- You can tap  to show full screen view. Full screen view allows you to examine images on a larger screen.

- See “Configuring screen parameters” on page 59 for detailed information about setting imaging parameters.

Zooming in and zooming out on an image

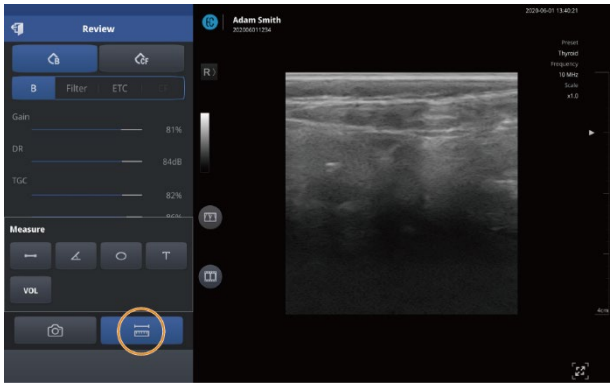


Whenever a closer look at the scan screen is needed, you can zoom in or zoom out on any section of the screen by pinching out or pinching in on the screen with your fingers.

> **NOTE**
>
> Up to 400% magnification is available when you zoom in.

Measuring objects

1 Tap to open the measuring tools, and select an appropriate tool for your measurement.



- Tap to measure lengths.
- Tap to measure angles.
- Tap to measure circumferences and areas.
- Tap to leave text comments.
- Tap to measure volumes.
- Tap to measure fetal biometry parameters (for SONON 300C only).

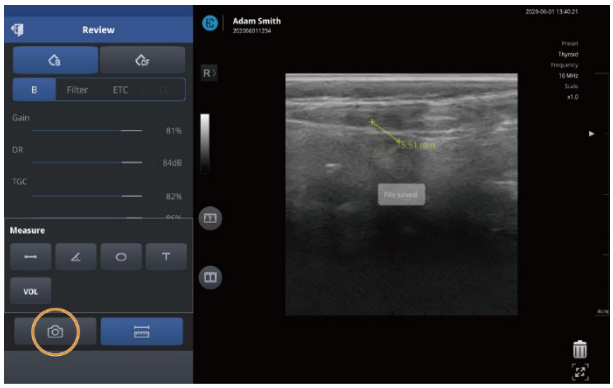
> **NOTE**
>
> See “4.4 Measuring on-screen objects” on page 86 for detailed information about measuring on-screen objects.

NOTE

Measurement of fetal biometry parameters is only available on the SONON 300C ultrasound device. Even when viewing videos taken with the SONON 300C devices, measurement of fetal parameters will not be available if a 300L is currently connected to your mobile device, or if the last device connected to your mobile device was a 300L. Fetal biometry parameters available for measurement are as follows.

- BPD: Biparietal Diameter
- AC: Abdominal Circumference
- FL: Femur Length
- HC: Head Circumference
- CRL: Crown Rump Length

2 Tap  to capture measurements on the screen. A “File Saved” message will be displayed to indicate that the captured image has been saved.



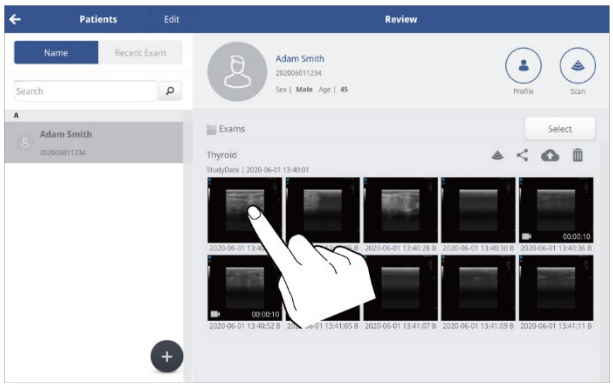
NOTE

When you leave the playback screen, all measurement data will be deleted. If you want to record measurement data, capture the screen.

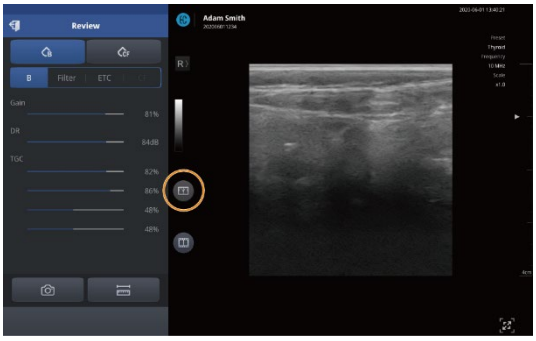
Reviewing exam records in Dual screen

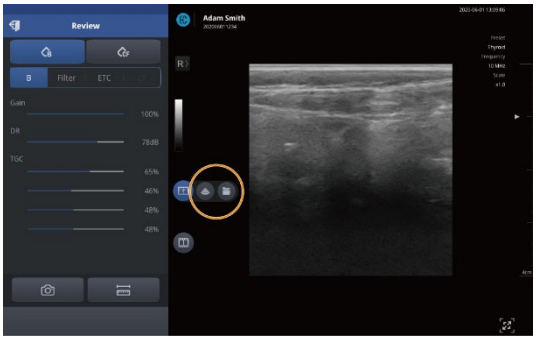
You can easily review exam records in the Patient List in dual screen mode.

1 Select an image or video from the Patient List.



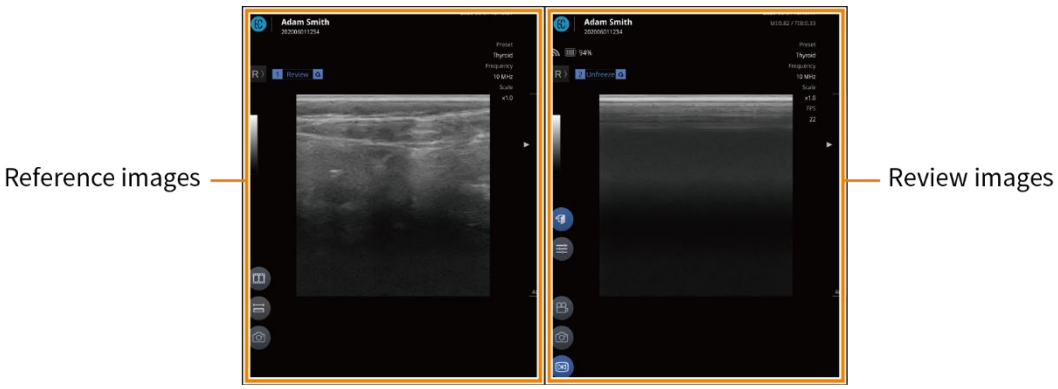
2 Tap , then tap or to start dual screen mode.



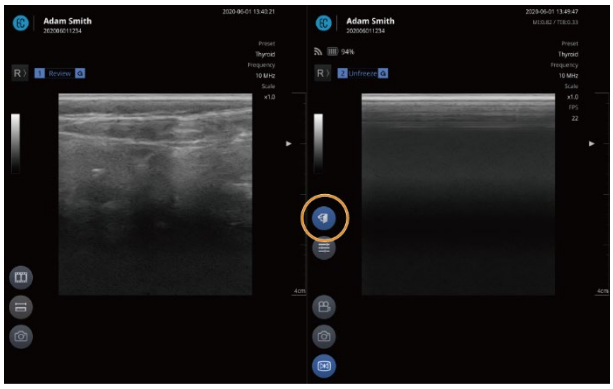


The images or videos selected from the Patient List will be displayed on the left screen while in dual screen.

The live scan image or the image or video to review will be displayed on the right screen while in dual screen.



3 Tap  to close Dual screen mode.



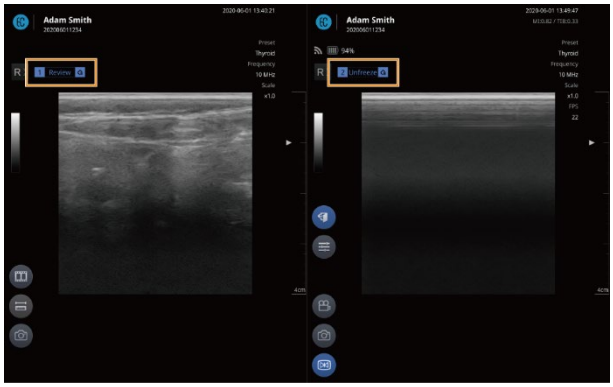
Utilizing Dual screen mode

The Patient List supports the following dual screen modes:

Review + Live scan

Select the image or video from the Patient List and tap  >  .

You can review the live-scan image while consulting the image.



NOTE

The control options available in dual screen mode are below. For more info, please check the corresponding page.

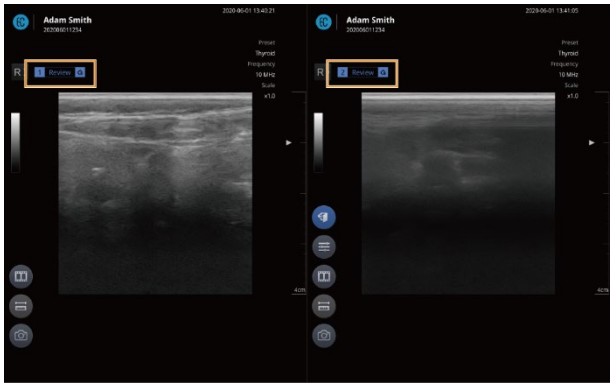
- Tap  to open Snapshot Slider (“Playing back recorded exams with Snapshot Slider” on page 79)
- Tap  to measure objects on the screen. (“4.4 Measuring on-screen objects” on page 86)
- Tap  to capture image. (“Capturing images” on page 78)
- Tap  to play back a video. (“Playing recorded videos” on page 108)
- Tap  to change screen parameter settings. (“Configuring screen parameters” on page 59)
- Tap  to record video. (“Recording exam videos” on page 77)
- Tap  to freeze the scan screen. (“Starting Freeze mode” on page 86)

Review + Review

You can compare and review recorded images or videos.

1 Select the image or video from the Patient List and tap > .

2 Select the image to review.



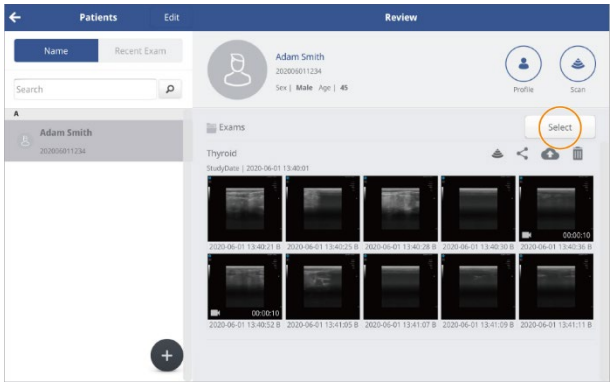
NOTE

The control options available in dual screen mode are below. For more info, please check the corresponding page.

- Tap to open Snapshot Slider (“Playing back recorded exams with Snapshot Slider” on page 79)
- Tap to measure objects on the screen. (“4.4 Measuring on-screen objects” on page 86)
- Tap to capture image. (“Capturing images” on page 78)
- Tap to play back a video. (“Playing recorded videos” on page 108)
- Tap to change screen parameter settings. (“Configuring screen parameters” on page 59)

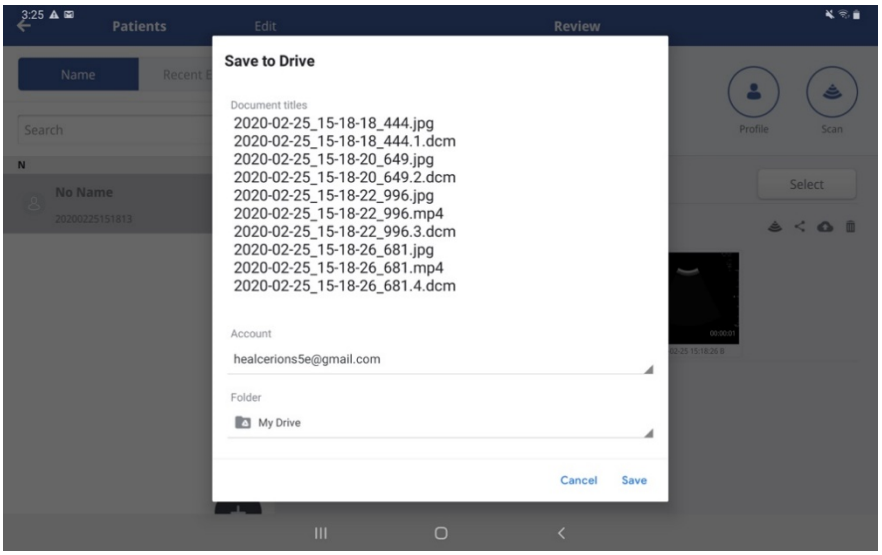
Sharing, uploading, or deleting recorded exams

1 Go to the Review window of the Patient List, and tap Select.

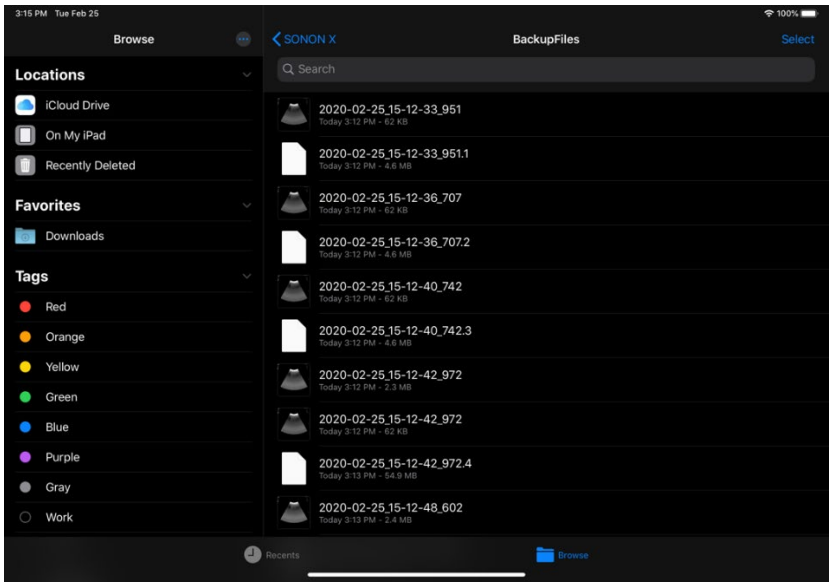


2 Tap the thumbnails to select a file or multiple files, then do the followings.

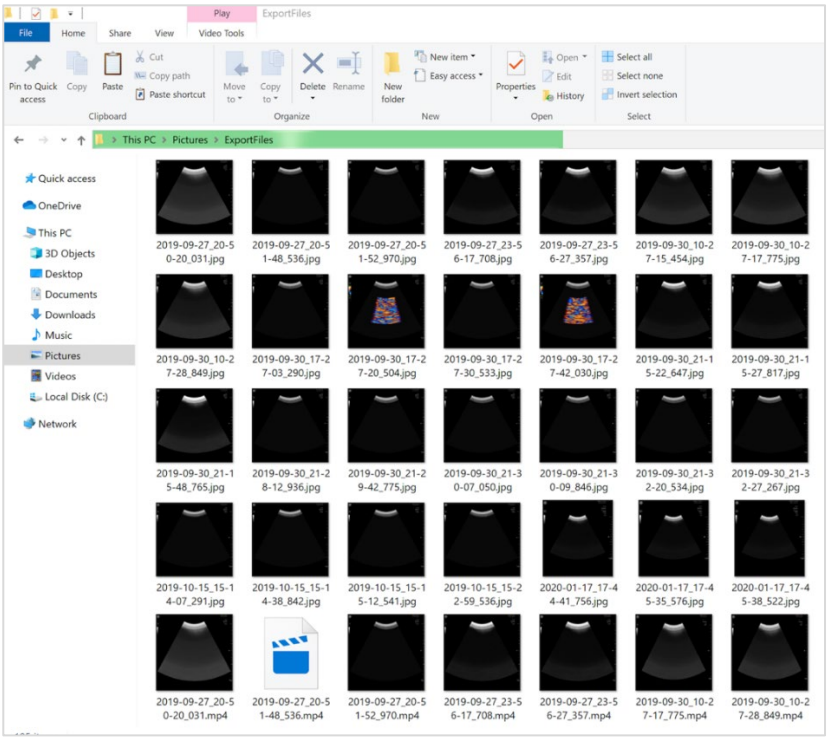
- Tap **Share** to share the exam records.
- Andorid : The data is stored in local folders or via e-mail or messenger applications.



- iOS : The data is stored in local folders or via e-mail or messenger applications.



- UWP : The data is stored in the picture folder.

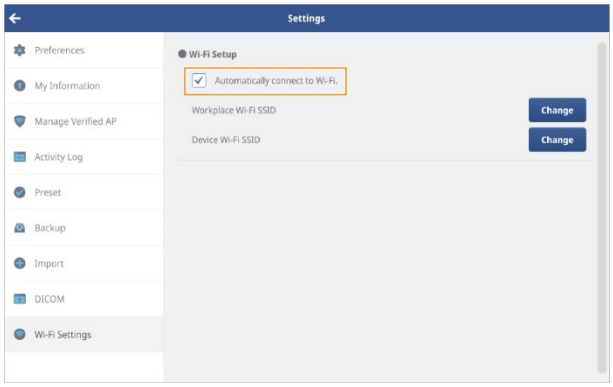


✧ Shared file names do not contain patient information.

- Tap  to upload the exam records to the PACS (See NOTE).
- Tap  to Delete the recorded exam files. All the records saved during the same exam will be deleted.

NOTE

- You must complete the DICOM network settings before you can start uploading exams to the PACS. See “7 DICOM” on page 144 for detailed information.
- You must disconnect your mobile device from the SONON ultrasound device and connect to your Workplace Wi-Fi before you can start uploading exams.
- On Android mobile devices, you can enable the “Automatically connect to Wi-Fi” option in the Wi-Fi Setting menu to automatically switch network connections when you upload exams to PACS.



6 Settings

In the Settings menu, you can adjust hardware and software settings, configure preferences, and check the firmware version.

6.1 Device settings

In the Device Settings menu, you can manage your Wi-Fi password and check the firmware version.

NOTE

On the home screen, tap **Start Scan >**  **> Settings** to access the Device Settings menu.
If you access the settings menu by directly tapping **SETTING** on the home screen, the Device Settings menu will be disabled in the Settings screen.

Changing Wi-Fi password

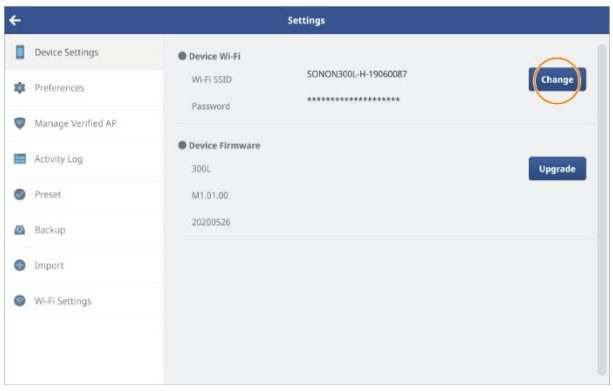
Follow the instructions below to change your Wi-Fi password.

NOTE

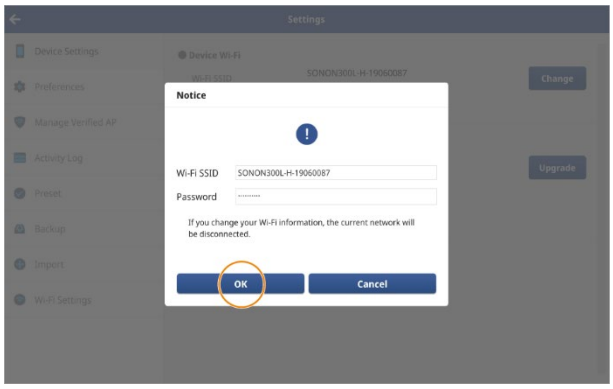
- The factory default Wi-Fi password is “1234567890”.
- Your new password must be 8–16 characters long.
- After changing the Wi-Fi password, you must reconnect the device to your mobile device with Wi-Fi before you can begin scanning.

1 On the home screen, tap **Start Scan** >  > **Settings** > **Device Settings**.

2 Tap **Change** to reset the Wi-Fi password.

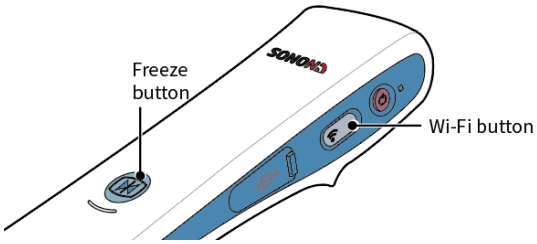


3 Enter a new Wi-Fi password and tap **OK**.



Resetting Wi-Fi password

In case you cannot remember the Wi-Fi password after changing it, press the Freeze button and the Wi-Fi button on your SONON ultrasound device simultaneously for about five seconds.



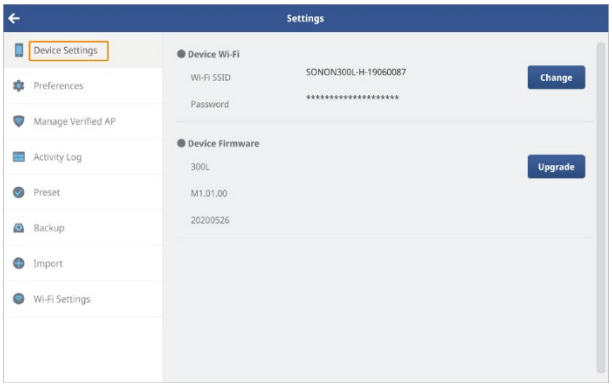
The Wi-Fi indicator will turn off, then turn on green again, and the SSID and the Wi-Fi password will be reset to the factory default.

NOTE

- Default SSID: SONONXXXX-YYYYYYYY (X=model name, and Y=serial number)
- Default password: 1234567890

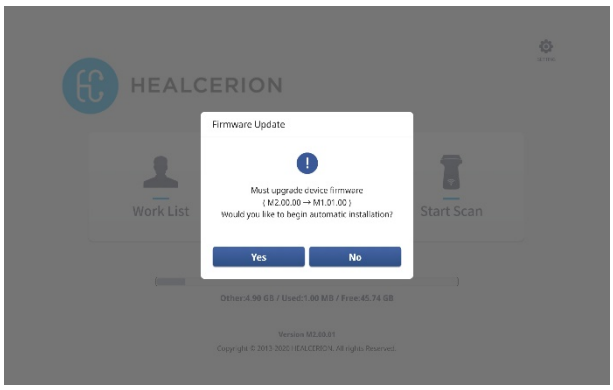
Checking device firmware version

You can tap **Start Scan >**  **> Settings > Device Settings** to view the current firmware version installed on the device.



NOTE

When you connect a SONON device with outdated firmware to your mobile device, a popup message will be displayed requesting an automatic update.

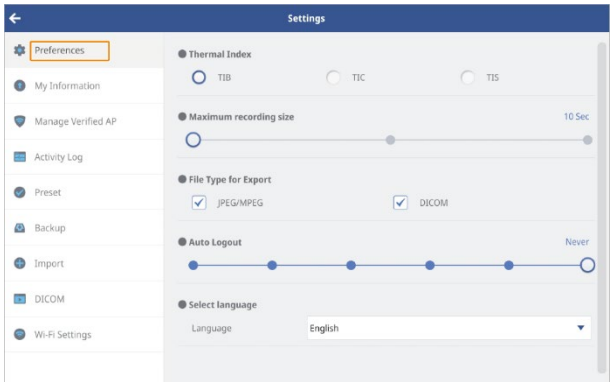


6.2 Setting preferences

You can select or configure thermal index (TI) type, choose the size of recorded video files, export file formats, and select an automatic logout time in the Preferences menu.

On the home screen, tap **SETTING > Preference** to access these options.

> **NOTE**
>
> You can also access the Settings menu from the scan screen by tapping **> Settings**.



- Thermal Index: Select type of thermal index (TI)
  - TIB: Bone thermal index. Used for fetal applications.
  - TIC: Cranial bone thermal index. Used for transcranial applications.
  - TIS: Soft tissue thermal index. Used for applications that do not image bones.

> **NOTE**
>
> For the mechanical index (MI), a fixed value is used. See “10.4 Acoustic output” on page 172 for detailed information.

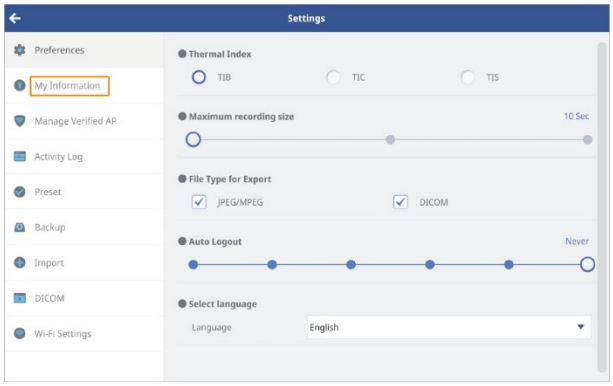
- Maximum Recording Size: Set the recording time for recorded video files.
- File Type for Export: Select the file formats used for exporting files.
- Auto Logout: Select the time until the user will be automatically logged out when no user activities are detected.
- Select Language: Select a language.

6.3 Changing login password

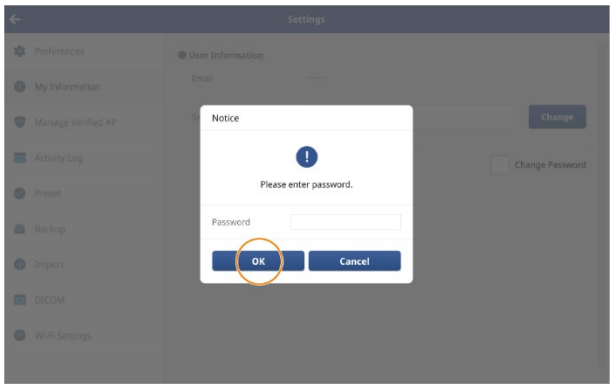
Follow the Instructions below to change the login password for the HEALCERION app (SONON X ultrasound app).

Changing login password (When user information is stored in app storage)

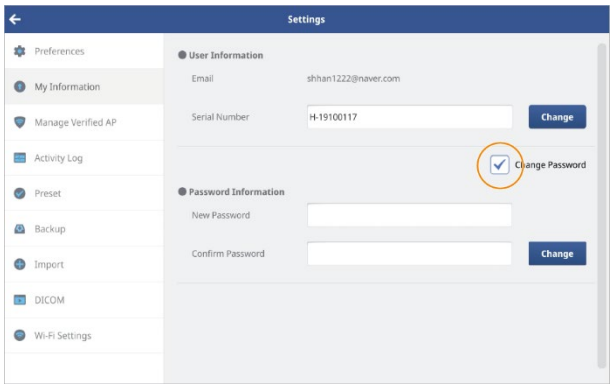
1 On the home screen, tap **SETTING** > **My Information**.



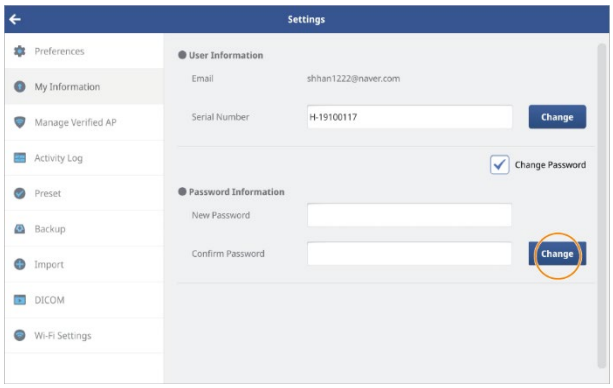
2 Enter your current password and tap **OK**.



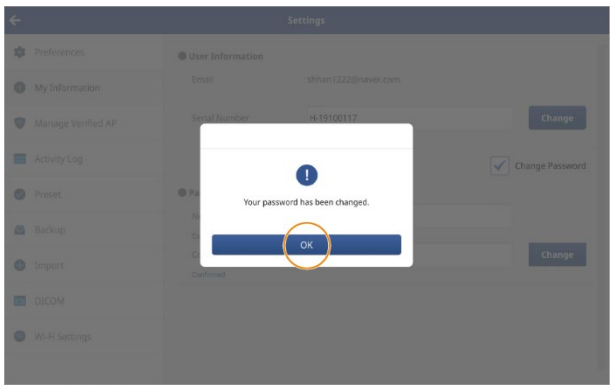
3 Tap the change password checkbox to change the password.



4 Enter your new password and tap **Change**. A popup will be displayed to inform you that your password has been changed.

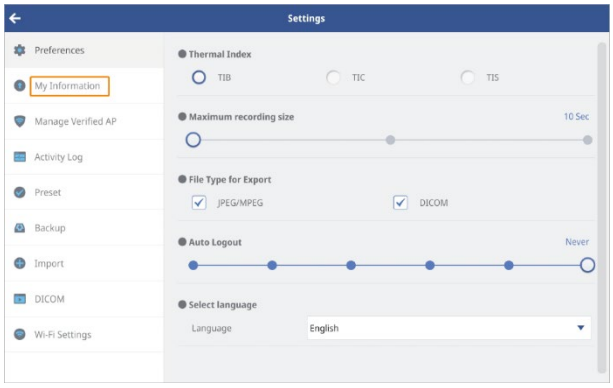


5 Tap **OK** to close the popup window, and log in with the new password.

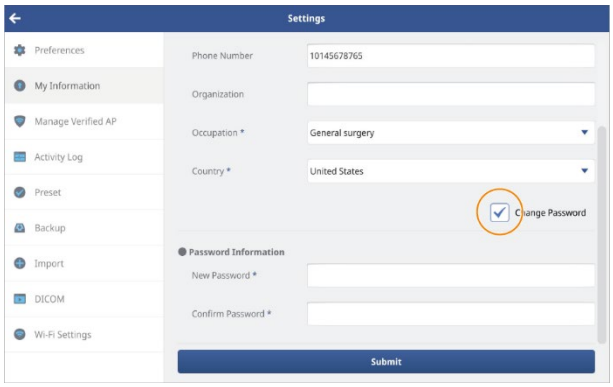


Changing login password (When user information is stored on the server)

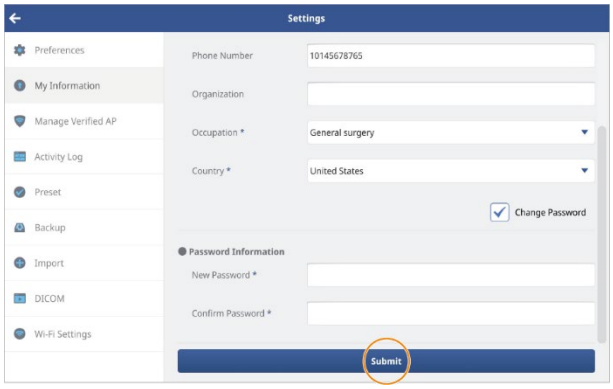
1 On the home screen, tap **SETTING** > **My Information**.



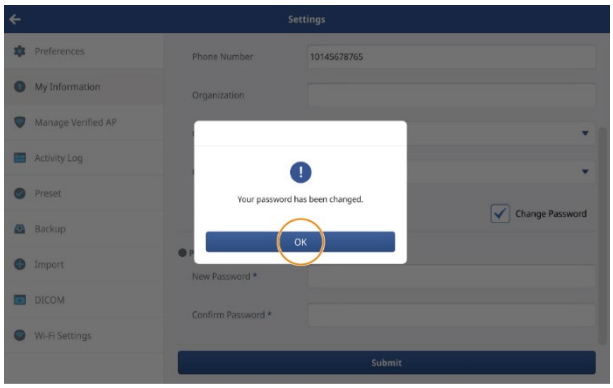
2 Tap the change password checkbox to change the password.



3 Enter your new password and tap **Submit**. A popup will be displayed to inform you that your password has been changed.



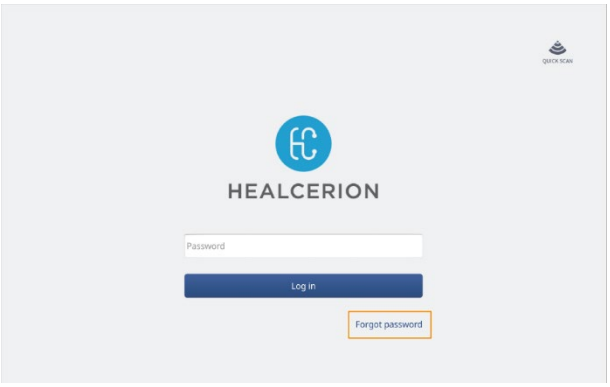
4 Tap **OK** to close the popup window, and log in with the new password.



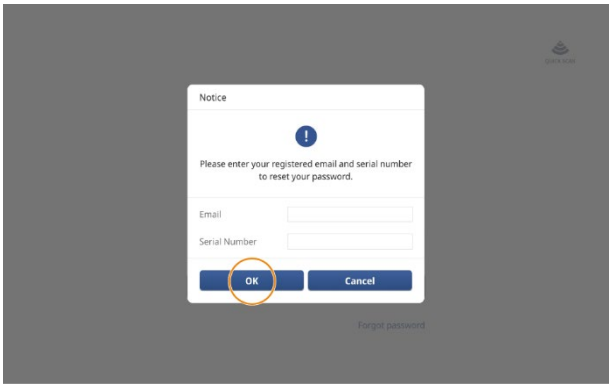
Finding a forgotten password (When user information is stored in app storage)

In case you cannot remember your login password, follow the instructions below to reset your password.

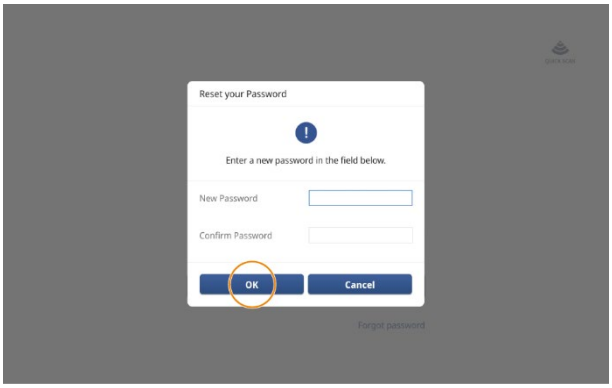
1 On the login screen, tap **Forgot password**.



2 Enter the email address and the device serial number registered in the HEALCERION app (SONON X ultrasound app), then tap **OK**.



3 In the popup window, enter a new password and tap **OK.** A popup will be displayed to inform you that your password has been changed.

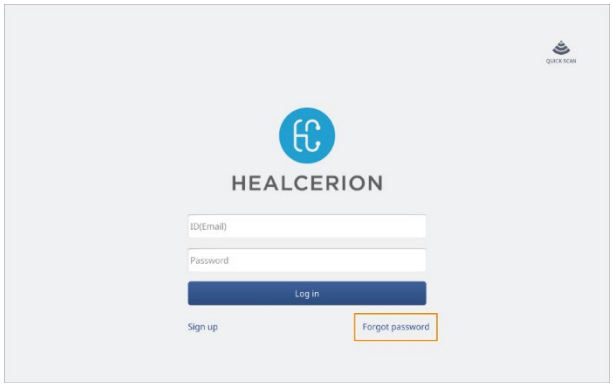


4 Tap **OK** to close the popup window, and log in with the new password.

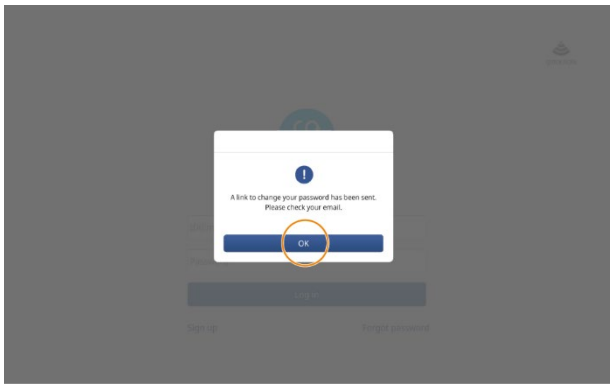
Finding a forgotten password (When user information is stored on the server)

In case you cannot remember your login password, follow the instructions below to reset your password. If you have registered user information on the server, you can reset your password through your registered email account.

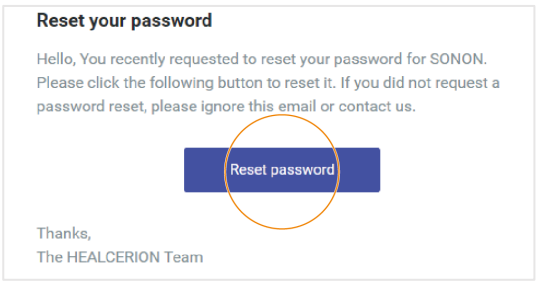
1 On the login screen, tap **Forgot password**.

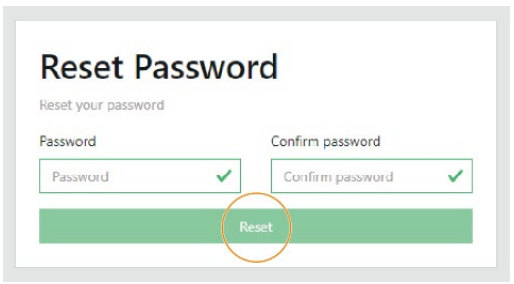


2 Tap **OK** in the pop-up window, then check your email to change your password.



3 Tap **Reset password,** then enter a new password and tap **Reset**. A message will be displayed to inform you that your password has been changed.

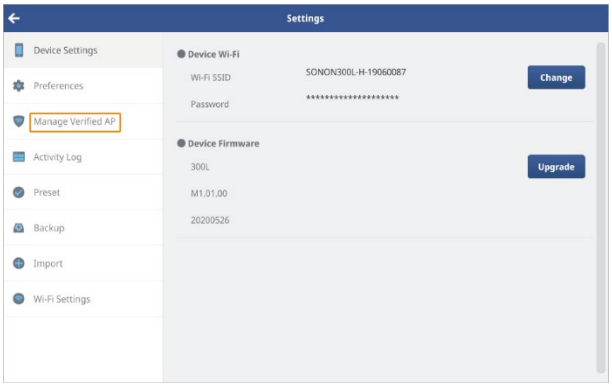




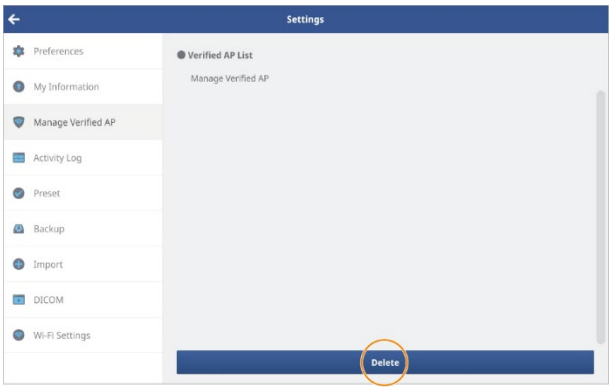
6.4 Managing verified AP list

A network connection to an AP (access point) is required to upload exam files to PACS. In the Settings menu, you can view the list of verified APs and delete APs that are no longer valid.

1 On the home screen, tap **SETTING** > **Manage Verified AP**.

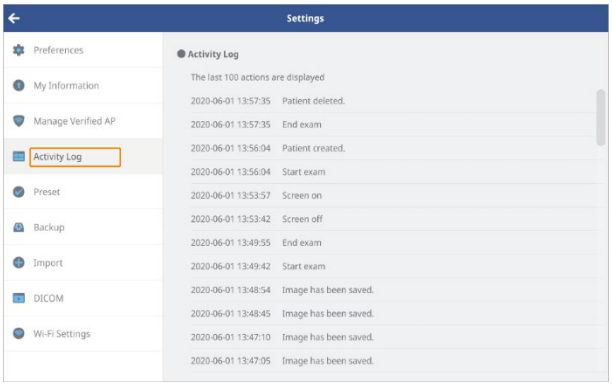


2 Select APs that are no longer in use and tap **Delete**.



6.5 Checking activity logs

You can check the activity logs to track the operation history of your SONON ultrasound device. On the home screen, tap **SETTING > Activity Log** to access the activity logs.



6.6 Managing preset

Any presets you have changed can be initialized back to the default settings, and you can delete custom presets you have created.

You can also export custom presets you have created to a file, or import exported presets into the HEALCERION app (SONON X Ultrasound App).

NOTE

Initializing, deleting, exporting and importing presets can only be performed from the Settings menu. See “4.1 Utilizing presets” on page 70 for detailed information about making changes to presets and creating new presets.

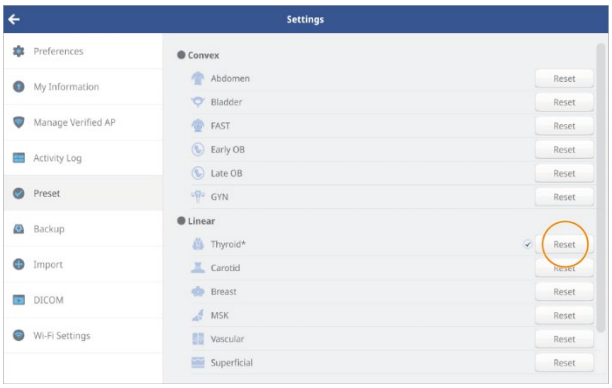
Initializing Presets

Follow the instructions below to initialize presets back to the default settings.

> **NOTE**
>
> An asterisk (“*”) at the end of a preset name indicates that the preset has been changed by the user.

1 On the home screen, tap **SETTING** > **Preset**.

2 Tap **Reset** on the right side of the preset to initialize.



3 In the popup window, tap **Reset** to confirm.

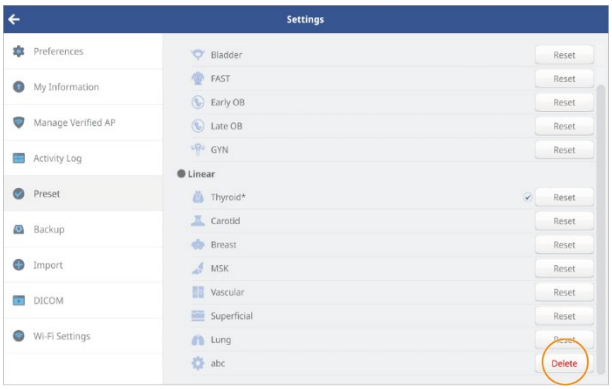
Deleting presets

Follow the instructions below to delete custom presets you have created.

> **NOTE**
>
> Only custom presets created by the user can be deleted.

1 On the home screen, tap **SETTING** > **Preset**.

2 Tap **Delete** on the right side of a preset to delete.



3 In the popup window, tap **Delete** to confirm.

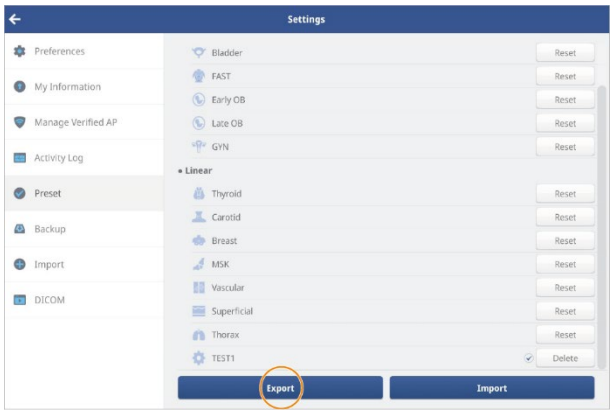
Exporting presets

You can export custom presets you have created to a file.

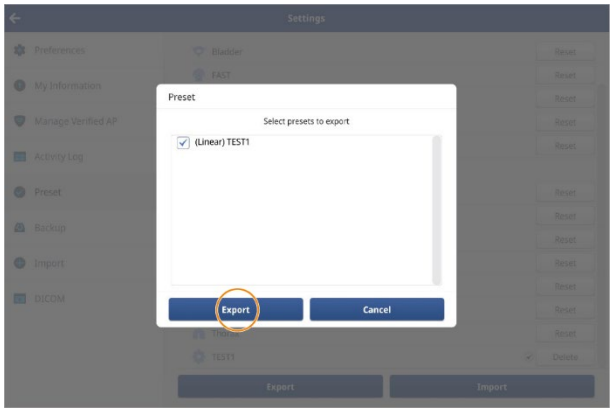
> **NOTE**
>
> Only custom presets you have created can be exported.

1 On the home screen, tap **SETTING** > **Preset**.

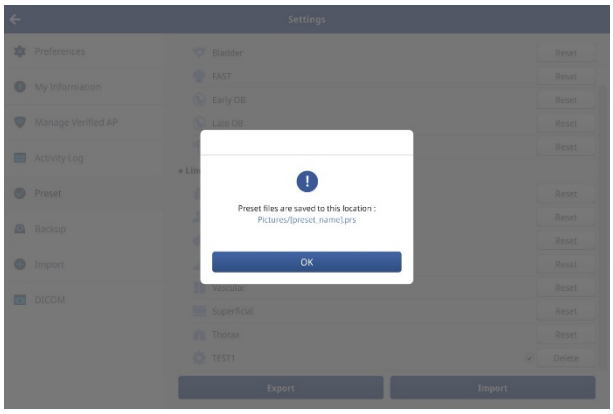
2 Tap **Export** at the bottom of the screen.



3 Select the preset item you want to export, then tap **Export**.



4 Tap **OK** in the pop-up window.



NOTE

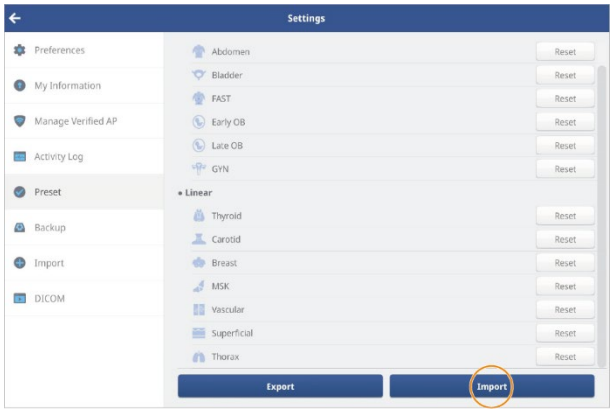
- On Android and iOS devices, exported files are saved in the Documents folder.
- On Windows (UWP) devices, exported files are saved in the Photo folder.

Importing presets

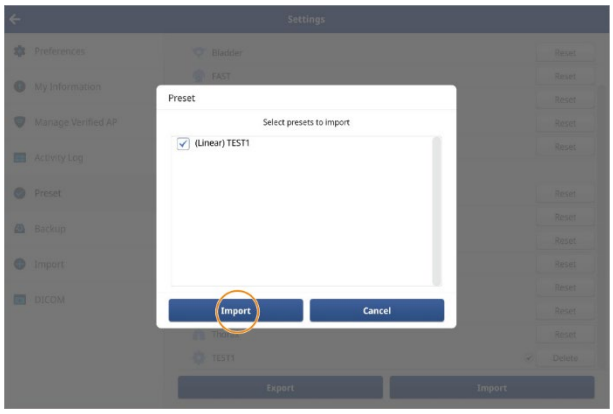
After exporting the custom preset you created, you can import it back into the HEALCERION app (SONON X Ultrasound app).

1 On the home screen, tap **SETTING** > **Preset**.

2 Tap **Import** at the bottom of the screen.



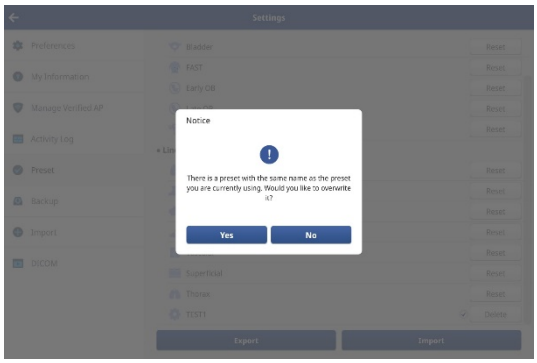
3 Select the preset item you want to import, then tap **Import**.



4 Tap **OK** in the pop-up window.

NOTE

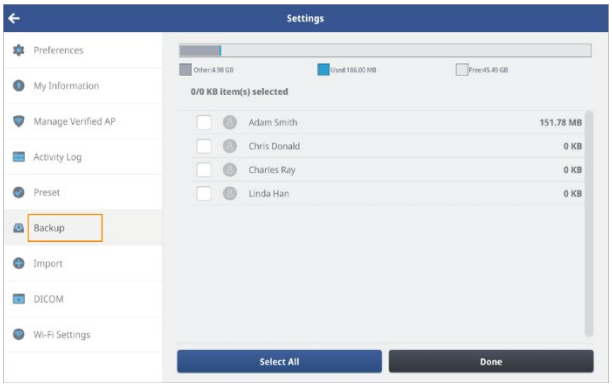
When importing a preset, if there is a preset with the same name, a pop-up window as shown below will appear. If you want to overwrite the preset to be imported, select **Yes**.



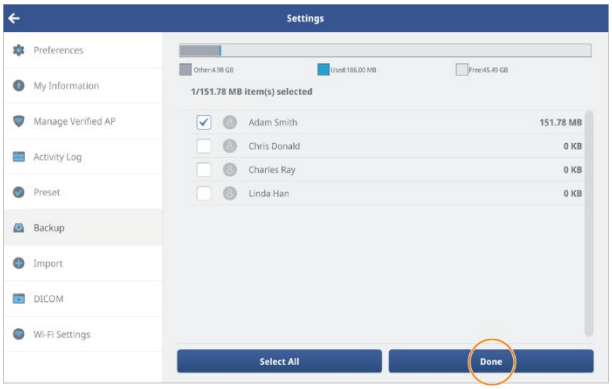
6.7 Backing up patient data

To prevent data loss, you can back up files in the Settings menu. Follow the instructions below to back up patient data.

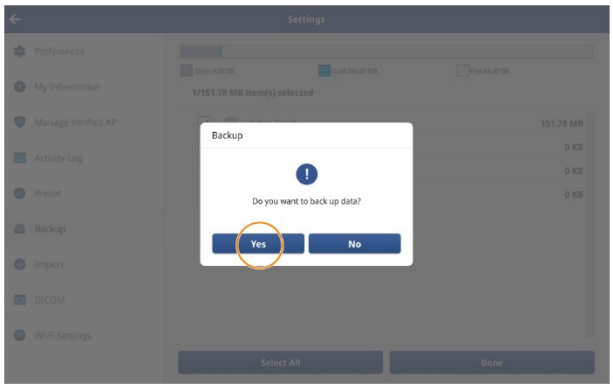
1 On the home screen, tap **SETTING** > **Backup**.



2 Tap the checkboxes to select patients to back up, then tap **Done**.



3 In the popup window, tap **Yes**.



NOTE

- On Android devices, files backed up are saved to the “BackupFiles” folder of the Documents.
- On iOS devices, files backed up are saved to the “BackupFiles” folder of the SONON.
- On Windows(UWP) devices, files backed up are saved to the “BackupFiles” folder of the Pictures.

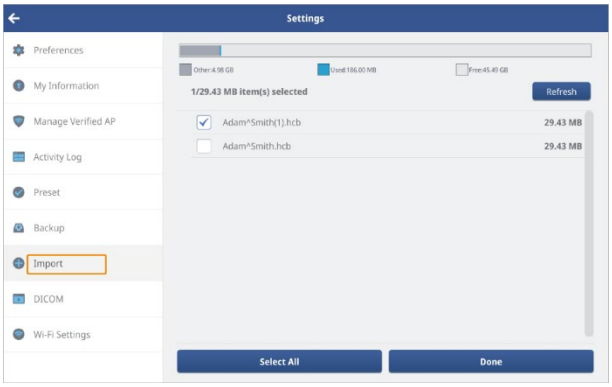
6.8 Importing backup files

You can import files that were previously backed up. Follow the instructions below to import backup files.

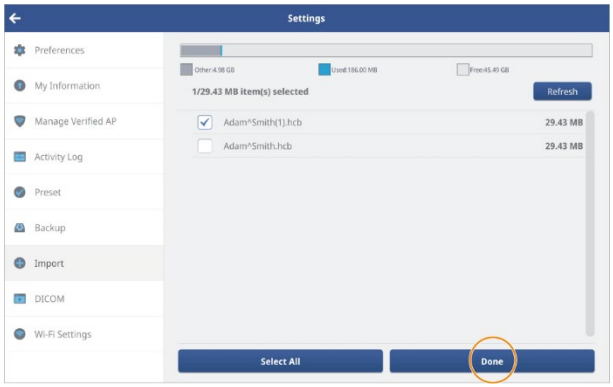
NOTE

- To import backup files from former versions of the HEALCERION app (SONON ultrasound app), you must first update the SONON app to the latest version, then proceed with backing up.
- Displayed measurement data will not be supported for imported backup files from former versions of the HEALCERION app (SONON ultrasound app).

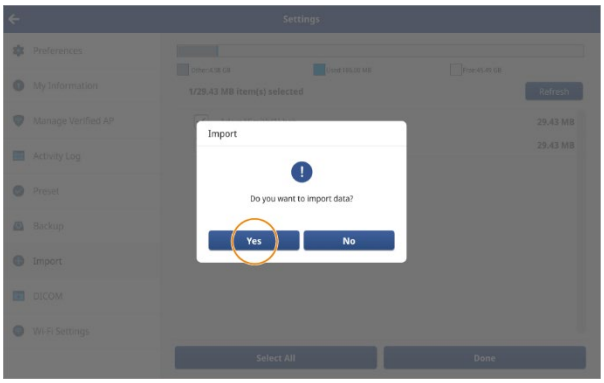
1 On the home screen, tap SETTING > **Import**.



2 Select the files(s) you would like to import, then tap **Done**.



3 In the popup window, tap **Yes**.



6.9 Changing Wi-Fi settings

Follow the instructions below to register SSIDs for your workplace network (Workplace Wi-Fi) and SONON ultrasound device (Device Wi-Fi).

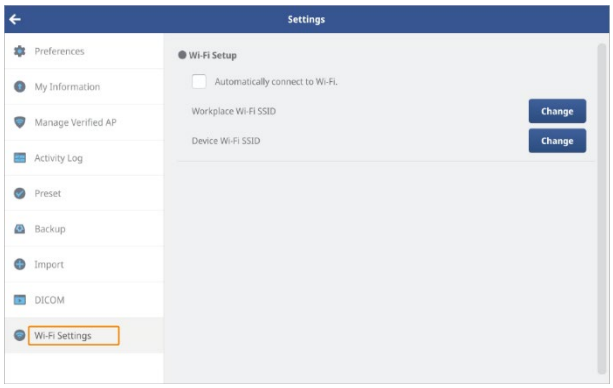
NOTE

Refer to the following regarding the difference between “Workplace Wi-Fi” and “Device Wi-Fi” connections.

- Workplace Wi-Fi: A local Wi-Fi network used to connect to PACS (mostly available at hospitals).
- Device Wi-Fi: A Wi-Fi network used to connect the SONON device to a personal mobile device.

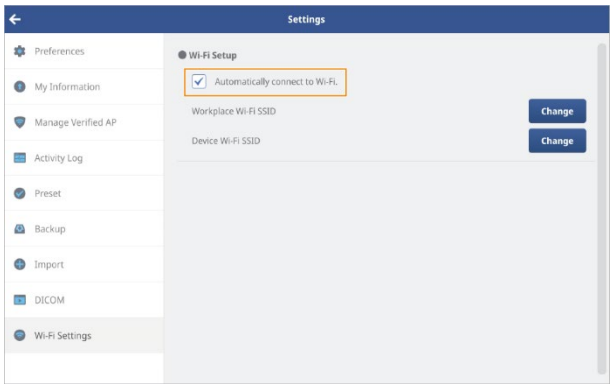
Changing Wi-Fi settings on Android mobile devices

1 On the home screen, tap **SETTING > Wi-Fi Setting**.

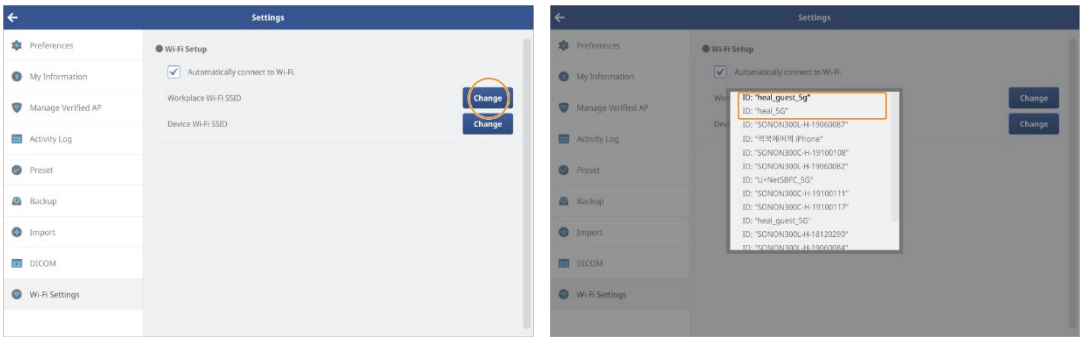


NOTE

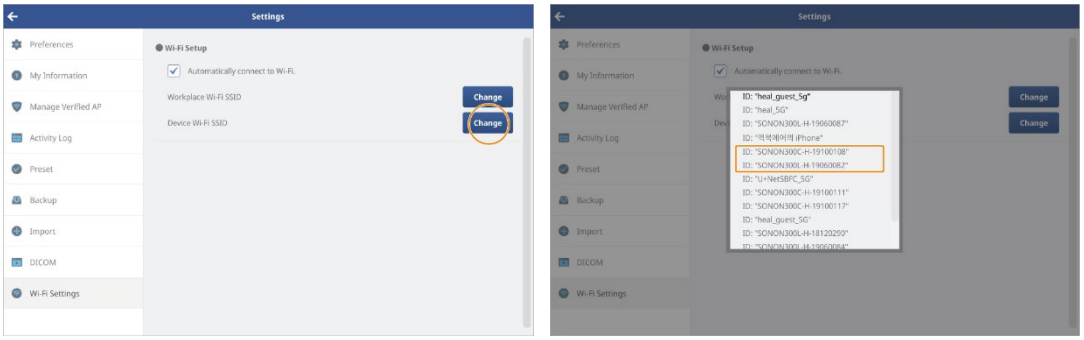
Enable the “Automatically connect to Wi-Fi.” option in the Wi-Fi Setting menu to automatically switch network connections when you upload exams to PACS.



2 Tap **Change** beside “Workplace Wi-Fi SSID” and select your workplace Wi-Fi SSID from the list.



3 Tap **Change** beside “Device Wi-Fi SSID” and select the Wi-Fi SSID for your device from the list.



> **NOTE**
>
> It usually takes a while until the Wi-Fi network connection changes take effect.

Changing Wi-Fi settings on iOS mobile devices

Apple iOS does not allow Wi-Fi setting changes inside the HEALCERION app (SONON X ultrasound app).

In order to register both the workplace and SONON ultrasound device Wi-Fi connections with an iOS device, the workplace network connection must be made in the Wi-Fi settings menu of the iOS mobile device before you attempt to register the SONON ultrasound device.

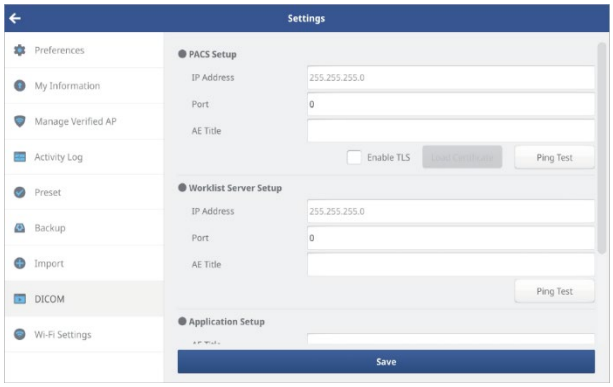
7 DICOM settings

You must configure all DICOM settings before you can convert videos and images from the HEALCERION app (SONON X ultrasound app) to DICOM standard and upload them to the PACS server.

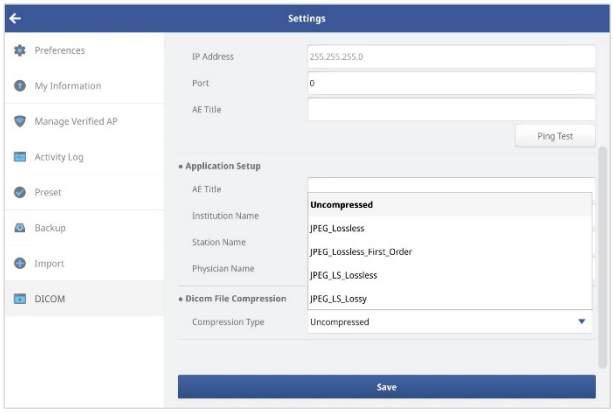
7.1 Configuring DICOM settings

1 On the home screen, tap **SETTING > DICOM**.

2 Fill in PACS Setup, Worklist Serve Setup, and Application Setup.



3 When sharing diagnostic data, or sending it to PACS, select the compression format for DICOM files.



4 Tap **Save** to save all information.

NOTE

- You can tap **Ping test** to ensure that the PACS connection is working.
- PACS must be set up before you can upload DICOM files or update the Work List.

7.2 Configuring DICOM TLS settings

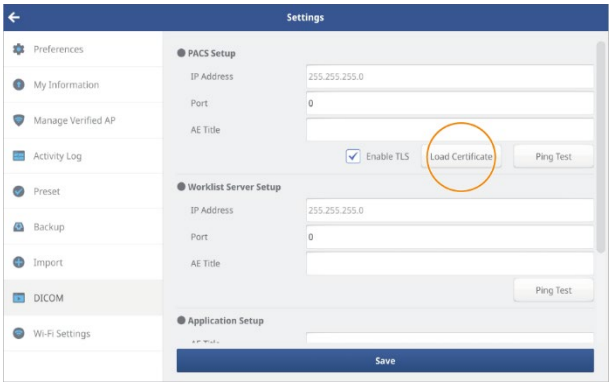
To set up TLS Security settings, you need a public certificate from SCP (server).
Copy the certificate and upload it into the HEALCERION app (SONON X ultrasound app).

> **NOTE**
>
> The storage location and name of the public certificate file is as follows.
>
> - Android: Documents/pacs.pem(or .cer)
> - iOS: [SONON X]/pacs.pem(or .cer)
> - Windows(UWP): Pictures/pacs.pem(or .cer)

1 On the home screen, tap **SETTING > DICOM**.

2 Tap **"Enable TLS"** checkboxes.

3 Tap **Load Certificate** to load the public certificate file.



4 Tap **Save** to complete the TLS security settings.

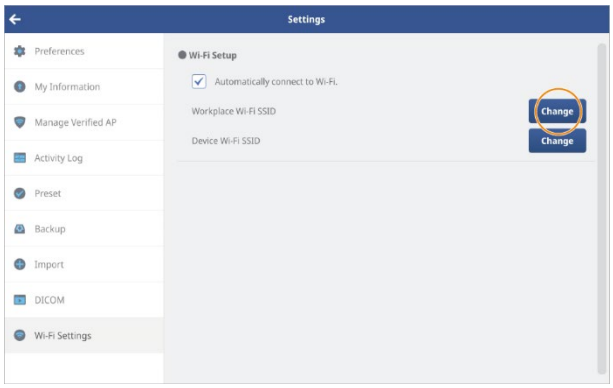
7.3 DICOM workflow

After configuring the DICOM settings, follow the instructions below to convert videos and images from the HEALCERION app (SONON X ultrasound app) to DICOM standard and upload them to the PACS server.

DICOM workflow for Android mobile devices

1 Launch the HEALCERION app (SONON X ultrasound app) and tap **SETTING > Wi-Fi setting**.

2 Enable the “Automatically connect to Wi-Fi” option, and tap **Change** to select an SSID for your workplace network (Workplace Wi-Fi SSID) and the SONON ultrasound device (Device Wi-Fi SSID).

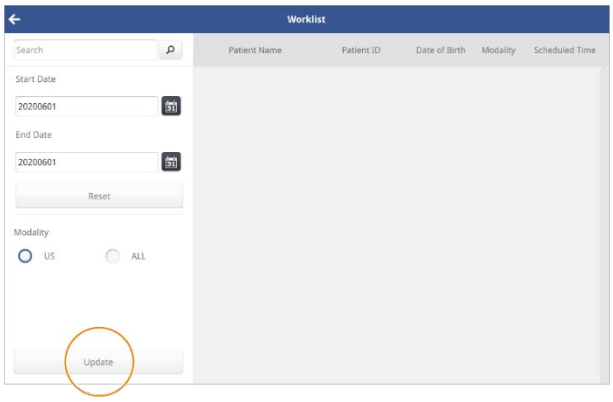


NOTE

Once you have enabled the “Automatically connect to Wi-Fi” option and selected (registered) the Workplace Wi-Fi SSID and Device Wi-Fi SSID, you can skip steps 1 and 2 when you upload exams to PACS via the same workplace network.

3 On the home screen, tap **Work List**.

4 Set a search condition and tap **Update**. The worklist will be loaded from the server and be saved to the device automatically.



5 Select a patient from the Work List. Scan screen will be displayed.

6 Perform an exam and save exam images or videos.

7 After the exam, tap **Patient List** on the home screen.

8 Select a patient from the list.

9 On the Review screen, select exam files and tap . Recorded exam files are automatically converted to DICOM format, then transmitted to the PACS server.

NOTE

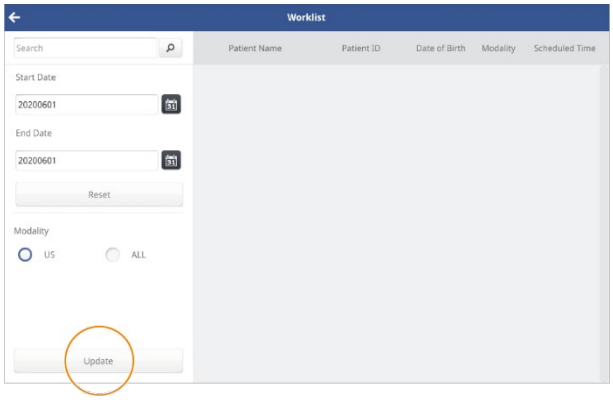
See “Sharing, uploading, or deleting recorded exams” on page 118 for detailed information about selecting exam files and uploading them to PACS.

DICOM workflow for iOS mobile devices

1 Access your mobile device's Wi-Fi settings (**Settings** > **Wi-Fi**) and connect to the Workplace Wi-Fi.

2 Launch the HEALCERION app (SONON X ultrasound app) and tap **Work List** on the home screen.

3 Set a search condition and tap **Update**. The worklist will be loaded from the server and be saved to the device automatically.



4 Minimize the HEALCERION app (SONON X ultrasound app), access your mobile device's Wi-Fi settings (**Settings** > **Wi-Fi**), and connect to the SONON device via Wi-Fi.

5 Switch back to the HEALCERION app (SONON X ultrasound app) and select a patient from the Work List. Scan screen will be displayed.

6 Perform an exam and save exam images or videos.

7 After the exam, tap **Patient List** on the home screen.

8 Select a patient from the list.

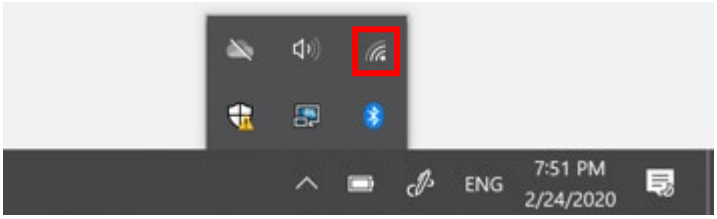
9 On the Review screen, select exam files and tap . Recorded exam files are automatically converted to DICOM format, then transmitted to the PACS server.

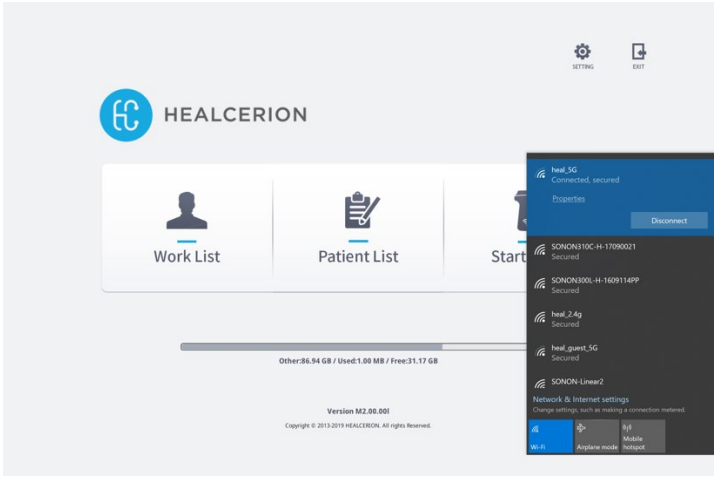
NOTE

See “Sharing, uploading, or deleting recorded exams” on page 118 for detailed information about selecting exam files and uploading them to PACS.

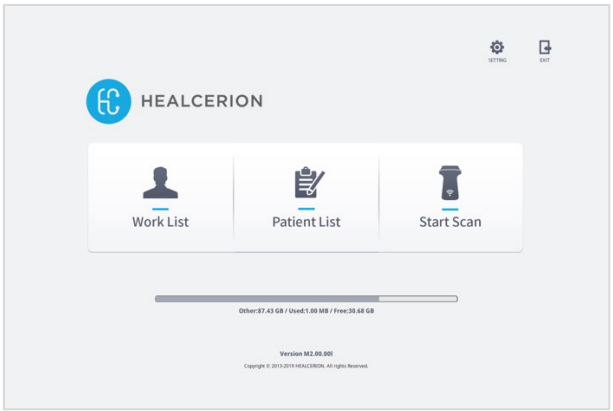
DICOM workflow for UWP mobile devices

1 Access your mobile device's Wi-Fi settings (**Network & Internet Setting** > **Wi-Fi**) and connect to the Workplace Wi-Fi.

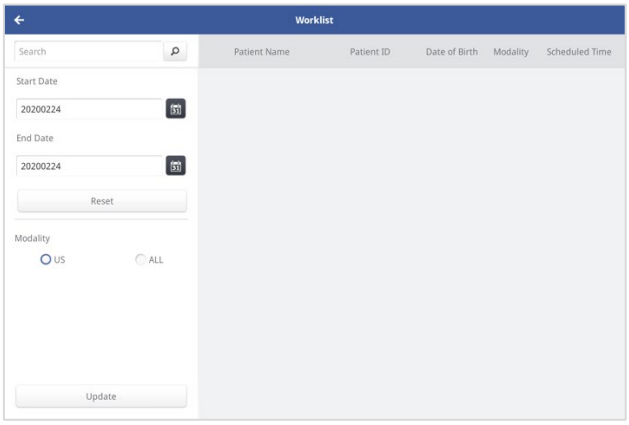




2 Launch the HEALCERION app (SONON X ultrasound app) and tap **Work List** on the home screen.



3 Set a search condition and tap **Update**. The worklist will be loaded from the server and be saved to the device automatically.



4 Minimize the HEALCERION app (SONON X ultrasound app), access your mobile device's Wi-Fi settings (**Network & Internet Setting** > **Wi-Fi**), and connect to the SONON device via Wi-Fi.

5 Switch back to the HEALCERION app (SONON X ultrasound app) and select a patient from the Work List. Scan screen will be displayed.

6 Perform an exam and save exam images or videos.

7 After the exam, tap **Patient List** on the home screen.

8 Select a patient from the list.

9 On the Review screen, select exam files and tap . Recorded exam files are automatically converted to DICOM format, then transmitted to the PACS server.

NOTE

See "Sharing, uploading, or deleting recorded exams" on page 118 for detailed information about selecting exam files and uploading them to PACS.

8 Maintenance

The SONON ultrasound device requires regular care and maintenance to function safely and properly. To ensure that the SONON ultrasound device operates continuously at maximum efficiency, observe the following procedures as part of your internal routine maintenance program.

⚠ CAUTION

- The user must ensure that safety inspections are performed at least every 12 months according to the requirements of patient safety standard IEC 60601-1 / UL60601-1.
- Only trained technicians are allowed to perform the safety inspections mentioned above.

⚠ ATTENTION

- L'utilisateur doit veiller à ce que les inspections de sécurité soient effectuées au moins tous les 12 mois, conformément aux exigences de la norme IEC 60601-1 / UL60601-1 sur la sécurité des patients.
- Seuls les techniciens dûment formés sont autorisés à effectuer les inspections de sécurité susmentionnées.

8.1 Inspecting the SONON ultrasound device

After each use, inspect the lens and casing of the device. Look for any damage that would allow liquid to enter the device.

Maintenance actions	Daily	Before/After each use	As necessary
Inspect transducer head	✓	✓	✓
Clean transducer head	✓	✓	✓

⚠ CAUTION

- If any damage is found, do not place the device into any liquid (e.g., for disinfection) and stop using it until it has been inspected and repaired/replaced by a HEALCERION service representative.
- The SONON ultrasound device satisfies IPX7 requirements for being watertight up to a maximum of 1.57 in. (4 cm) from the head (transducer side). Do not immerse the device into any liquid over the maximum immersion level.

⚠ ATTENTION

- Si un quelconque dommage est constaté, ne pas plonger l'appareil dans un liquide (par ex. pour sa désinfection) et ne pas l'utiliser jusqu'à ce qu'il ait été inspecté et réparé/remplacé par un représentant de service HEALCERION.
- L'échographe SONON est conforme aux exigences IPX7, car il est imperméable jusqu'à un maximum de 4 cm de la tête (côté transducteur). Ne pas plonger l'appareil dans du liquide, quelle que soit sa nature, au-delà de la limite maximale d'immersion.

8.2 Cleaning the SONON ultrasound device

Follow the instructions below when cleaning your SONON ultrasound device.

- Remove coupling gel and other visible substances from the device by wiping with a soft, dry cloth.
- When removing dried material attached to the surface, the cloth can be moistened with lukewarm water. Ensure that the cloth is not excessively wet to prevent water from entering the device.
- After each use, inspect the lens and casing. Look for any damage that would allow liquid to enter the device.

⚠ CAUTION

If any damage is found, do not place the device into any liquid (e.g., for disinfection) and stop using it until it has been inspected and repaired/replaced by a HEALCERION service representative.

⚠ ATTENTION

Si un quelconque dommage est constaté, ne pas plonger l'appareil dans un liquide (par ex. pour sa désinfection) et ne pas l'utiliser jusqu'à ce qu'il ait été inspecté et réparé/remplacé par un représentant de service HEALCERION.

Approved cleaning products

The cleaning products approved by the manufacturer are as follows.

Product name	Manufacturer
Tristel Duo ULT	Tristel
Bleach Germicidal Cleaner	Clorox
Transeptic Cleansing Sol.	Parker

⚠ CAUTION

- Do not use cleaning products containing abrasive substances.
- Do not soak or saturate the transducer (device head) with solutions containing alcohol, bleach, ammonium chloride compounds, hydrogen peroxide, or any incompatible solutions.
- Any damage to the SONON ultrasound device caused by non-approved cleaning products/substances will not be covered by the product warranty.

⚠ ATTENTION

- Ne pas utiliser de produits de nettoyage contenant des substances abrasives.
- Ne pas tremper ou imprégner le transducteur (tête de l'appareil) avec des solutions contenant de l'alcool, de l'eau de Javel, des composés à base de chlorure d'ammonium, du peroxyde d'hydrogène ou toute autre solution non compatible.
- Les éventuels dommages causés sur l'échographe SONON par des produits de nettoyage/substances non homologués ne seront pas couverts par la garantie du produit.

9 Troubleshooting

The sections 9.1-9.3 list system problems (messages), their causes, and suggestions for solving such problems.
The section 9.4 contains information about reporting security issues.

9.1 Device-related messages

Refer to the following table to find solutions to device-related problems that you may encounter while using your SONON ultrasound device.

Category	Message	Cause	Solution
Fan error	Fan control Failure. Please restart device.	Internal fan operation has failed.	Turn off the device then turn it back on.
Battery charging	Battery is Charging. Device will turn off automatically	The micro USB cable has been connected to the device and the device is being charged.	For safety reasons, the device cannot be operated while it is being charged. Disconnect the micro USB cable before trying to operate the device.
System temperature	Device overheated. Please cool the device before use.	Preliminary warning: the internal temperature has exceeded 149°F (65°C).	Stop operating the device and wait for 10 minutes before operating the device again.
	Device overheated. Device will turn off automatically.	Final warning: the internal temperature has exceeded 167°F (75°C). Device will automatically shut down.	
Low battery	Low battery. Please turn off and charge before use.	Preliminary warning: Low on battery.	Stop operating the device and charge the battery before operating the device again.
	Low battery. Device will turn off automatically.	Final warning: Very low on battery. Device will automatically shut down.	

If the messages persist even after taking the suggested solutions, contact HEALCERION and have the device, battery, battery charger, or AC power adapter serviced.

9.2 Device connection-related messages

Refer to the following table to find solutions to device connection-related problems that you may encounter while using the SONON ultrasound device.

> **NOTE**
> Disable “Power Saving” features on your mobile device before attempting to connect your mobile device to the SONON ultrasound device. In some mobile devices, network connection to the SONON ultrasound device fails if the mobile device is running in power saving mode.

Category	Message	Cause	Solution
Network connection failure	Network connection has failed. Please retry to connect with SONON.	Network connection could not be established.	Try again after resetting both the SONON device and the mobile device.
Connection terminated	Disconnected with the device. Please connect again.	Connection to the device has been lost.	
Duplicated network connection attempt	Already connected with other client.	The SONON device is already connected to another mobile device.	Find the mobile device that is currently connected to the device and terminate the connection before trying again.
Firmware upgrade failure	Firmware update failed	Firmware update could not be completed.	Try again after resetting both the SONON device and the mobile device.

If the messages persist even after taking the suggested actions, contact HEALCERION for solutions and have the device serviced if necessary.

9.3 DICOM network-related messages

Refer to the following table and find solutions to DICOM network-related problems that you may encounter while using the SONON ultrasound device.

Category	Message	Cause	Solution
Setting error 1	PACS information is not configured.	PACS has not been configured in Settings.	On the home screen, tap **SETTING** > **DICOM** to configure PACS, Work List, and Application information. If these fields are already filled in, verify that all the information is correct.
Setting error 2	Do you wish to set the PACS information?	Work List has not been configured in Settings.	
Setting error 3	Worklist server information is not set. Do you want to set the Worklist server information?	Institution has not been configured in Settings.	
Connection error 1	Workplace SSID information is not set. Do you want to set the SSID information?	Connection to PACS/Worklist failed.	Tap **Yes** and follow the on-screen instructions. Or, on the home screen, tap **SETTING** > **Wi-Fi Setting**. Tap **Change** beside “Workplace Wi-Fi SSID” and select the SSID for your workplace network.
Connection error 2	Cannot Connect to Server Please check network and server status.	Wi-Fi connection to server failed.	Check with your network administrator to ensure that the server network is up and running.
Connection error 3	Network connection failure. Please try to connect with the device.	Connection to PACS failed.	On the home screen, tap **SETTING** > **Wi-Fi Settings**. Tap **Change** beside “Device Wi-Fi SSID” and select the SSID for your device.
Connection error 4	PACS connection test failed.	Connection to worklist failed.	Try all the suggestions above.

If the messages persist even after taking the suggested solutions, contact HEALCERION for solutions and have the device serviced if necessary.

9.4 Reporting security issues

In the event of a threat related to the cybersecurity of the equipment and software, immediately stop the equipment or software from working and contact HEALCERION's service personnel to take the necessary action.

9.5 Security note

When using the SONON app, you should pay attention to the following security points.

- Do not install apps on rooted or jailbroken mobile devices. Otherwise, you may be exposed to multiple vulnerabilities.
- Do not download and install app files distributed outside Play Store (Android), App store (iOS) or Microsoft Store (Windows)
- If you are using Windows OS, we recommend using a personal PC firewall.
- Periodically perform OS updates on mobile devices and PCs to maintain the latest OS version. Otherwise, you may be exposed to multiple vulnerabilities.

10 Technical information

Safety conformance

The SONON ultrasound device conforms to the following safety standards.

- IEC 60601-1 *Electrical Medical Equipment*
- IEC 60601-1-2 *Electromagnetic Compatibility*
- IEC 60601-1-6 *Usability*
- IEC 62304 *Software Life Cycle Processes*
- IEC 60601-2-37 *Particular Requirements for the Safety of Ultrasound Medical Diagnostic and Monitoring Equipment*
- IEC 62359 *Ultrasonics – Field Characterization – Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields*
- ISO 10993 *Biological Evaluation of Medical Devices*

Essential performance

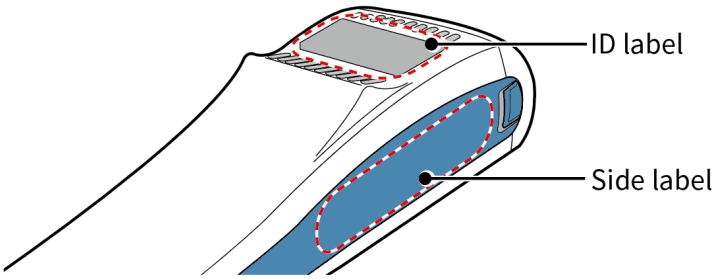
The following are the main purposes of using the SONON ultrasound device.

- Acquisition of ultrasound images
- Display of ultrasound images on main display
- Measurement of ultrasound images

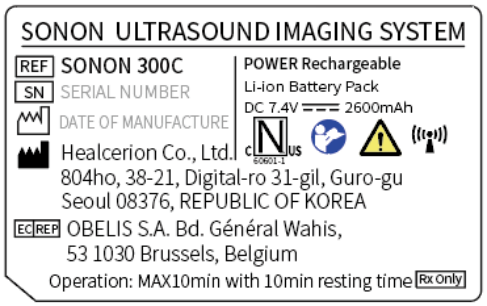
10.1 Marking labels

Marking labels are provided to inform users of safety information as well as device specifications.

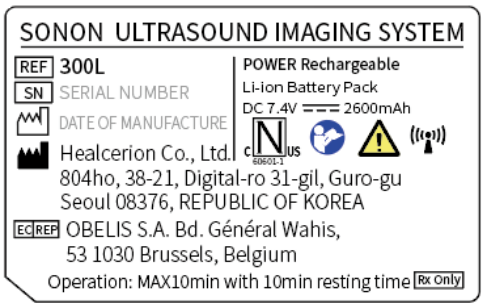
Marking labels on the device



ID label

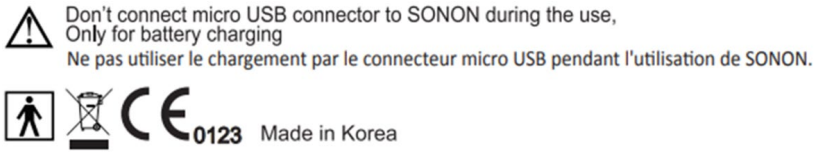


SONON 300C



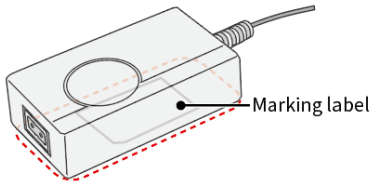
300L

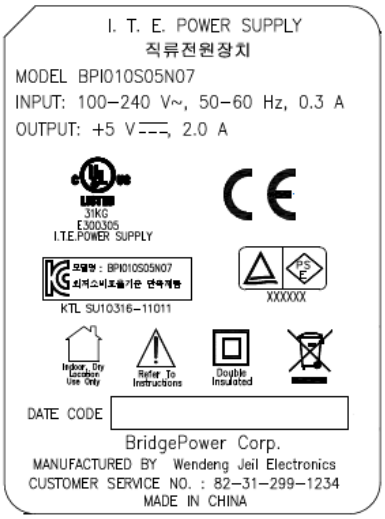
Side label



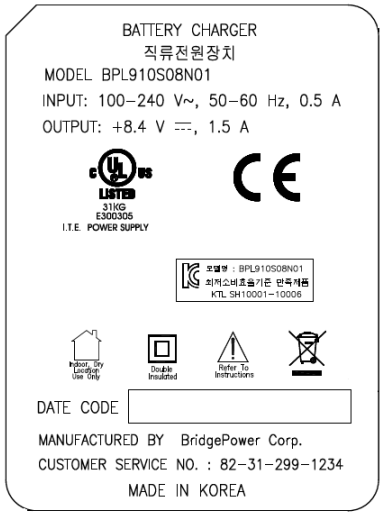
Marking labels on power supply accessories

AC adapter



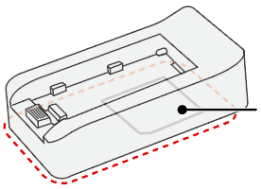


Device AC adapter



Battery charger AC adapter

Battery charger



⚠ WARNING

- Be careful of EMC-related problems when operating the SONON ultrasound device.
- Do not operate the SONON ultrasound device adjacent to or stacked with other equipment.
- Do not use any power adapters or cables other than those provided with the device. Using the wrong cables or accessories may adversely affect the devices' EMC performance.

⚠ AVERTISSEMENT

- Considérer les problèmes liés à la CEM lors de l'utilisation de l'échographe SONON.
- Ne pas utiliser l'échographe SONON s'il est placé à côté ou sur d'autres équipements.
- Ne pas utiliser d'adaptateurs ou de câbles d'alimentation autres que ceux fournis avec l'appareil. L'utilisation de câbles ou accessoires inappropriés peut nuire aux performances de CEM de l'appareil.

10.2 Guidance and manufacturer's declarations

Electromagnetic emissions

The SONON ultrasound device is intended for use in electromagnetic environments as specified below. It is your responsibility as the operator to ensure that it is operated in an environment conforming to the following conditions.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions – CISPR11	Group 1	The SONON ultrasound device uses RF energy only for its internal functions. The RF emissions are very low and not likely to cause any interference to nearby electronic equipment.
RF emissions - CISPR11	Class B	The SONON ultrasound device is suitable for use in all medical establishments (i.e., hospitals, clinics, etc.). This device is intended for professional use only.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC6100-3-3	Meets the requirements	

Electromagnetic immunity

The SONON ultrasound device is intended for use in electromagnetic environments as specified below. It is your responsibility as the operator to ensure that it is operated in an environment conforming to the following conditions.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast Transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV ± 1 kV	The main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV ± 2 kV	The main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Compliance for all test levels. Controlled shutdown with return to pre-disturbance condition after operator's intervention. (power-on switch)	The main power quality should be that of a typical commercial or hospital environment. If the user of the ME SYSTEM requires continuous operation, in which the main power is interrupted, it is recommended that the SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m 50 and 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
			Portable and mobile RF communications equipment should be used no closer to any part of the SONON ultrasound device, including

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 1.2\sqrt{P}$ 800MHz to 2,5 GHz $d = 2.3\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms [V1]	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m [E1]	

Notes:

- UT is the AC mains voltage prior to application of the test level.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection to and from structures, objects and people.

Separation from other RF communications equipment

The SONON ultrasound device is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. When you operate the SONON ultrasound device, you can help prevent electromagnetic interference by maintaining a minimum distance between your SONON ultrasound device and portable or mobile RF communications equipment (transmitters). The following table lists recommended separation distances depending on the maximum output power of the communications equipment.

Separation distance for SONON 300C

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (M)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.01	0.12
0.1	0.38	0.1	0.38
1	1.2	1	1.2
10	3.8	10	3.8
100	12	100	12

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.

Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection to or from structures, objects and people.

Separation distance for 300L

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (M)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection to or from structures, objects and people.

10.3 Applicable standards and test methods (IEC 60601-1-2 4th edition)

Test name	IEC 60601-1-2 4th edition	Ref. Standard	Ports to test	Tested voltage	Test level required	Notes
Mains terminal disturbance voltage	4th	CISRP 11:2009+A1:2010	AC Mains	100V–60Hz 230V–50Hz	Group1, Class B	
Radiated disturbance	4th	CISRP 11:2009+A1:2010	Enclosure	100V–60Hz 230V–50Hz d.c. 7.4V	Group1, Class B	
Harmonic Current Emissions	4th	IEC61000-3-2:2014	AC Mains	230V–50Hz	Class A	
Voltage Fluctuations and Flicker	4th	IEC61000-3-3:2013	AC Mains	230V–50Hz	Pst=1 Plt=0.65 Dmax=4% DC=3.3%	
Electrostatic Discharges (ESD)	4th	IEC61000-4-2:2008	Enclosure	230V–50Hz d.c. 7.4V	±8kV Contact ±2kV, ±4kV ±8kV, ±15kV Air	1pulse/1sec contact 8kV air 15kV
Radiated RF electromagnetic Fields	4th	IEC61000-4-3:2006+A1:2007+A2:2010	Enclosure	230V–50Hz d.c. 7.4V	3V/m 80MHz to 2.7GHz AM 80% at 1kHz, 2Hz RF Wireless Comm. (Refer to test report clause 1.15)	Dwell time is 3 sec.
Electric Fast Transfer and bursts	4th	IEC61000-4-4:2012	AC Mains	100V–60Hz 240V–50Hz	±2kV AC, 100kHz PRR	
Surges	4th	IEC61000-4-5:2014	AC Mains	100V–60Hz 240V–50Hz	±0.5kV, ±1Kv L1 to L2	5 pulses at 0°, 90°, 180°, 270°
Conducted Disturbances, induced by RF fields	4th	IEC61000-4-6:2013	AC Mains	230V–50Hz	150MHz to 80 MHz AM 80% at 1MHz, 2MHz 6 Vrms in ISM bands between 0.15 Mhz and 80MHz	Dwell time is 3sec.
Voltage Dips, Interruptions, and variations	4th	IEC61000-4-11:2004	AC Mains	100V–50Hz, 240V–50Hz	0% UT for 0.5 cycle	At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°

Test name	IEC 60601-1-2 4th edition	Ref. Standard	Ports to test	Tested voltage	Test level required	Notes
					0% UT for 1 cycle	At 0°, 180°
					50Hz: 70% UT for 25 cycles 60Hz: 70% UT for 30 cycles	At 0°, 180°
					50Hz: 0% UT for 250 cycles 60Hz: 0% UT for 300 cycles	At 0°, 180°
Power-frequency Magnetic Field	4th	IEC61000-4-8:2009	Enclosure	100V–60Hz 230V–50Hz d.c. 7.4V	30A/m	

10.4 Acoustic output

This section provides information about the acoustic output parameters, their definitions, and the test reports based on IEC and FDA standards.

Acoustic output parameters

Thermal Index (TI)

The term TI refers to an estimate of the temperature increase of soft tissue or bone. There are three thermal index categories:

- TIS: Soft tissue thermal index, the main TI category. Used for applications that do not image bones.
- TIB: Bone thermal index (for bone located in a focal region). Used for fetal applications.
- TIC: Cranial bone thermal index (for bone located close to the surface). Used for transcranial applications.

References on calculation of TI can be found in:

- NEMA Standards Publication UD 3: "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment", Revision 2
- IEC 60601-2-37. Medical Electrical Equipment. Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

Mechanical Index (MI)

The term MI refers to the estimated likelihood of tissue damage due to cavitation. The absolute maximum limit of the MI is 1.9, as set by the *U.S. Food and Drug Administration (FDA) 510(k) guidance on ultrasound systems* issued September 9, 2008 *("Guidance for Industry and FDA Staff, Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers").*

I_{spta}

The term I_{spta} stands for "Spatial Peak Temporal Average Intensity." The absolute maximum limit of I_{spta} is 720 mW/cm2 as set by the *FDA 510(k) guidance* of September 9, 2008.

Acoustic output reporting tables for SONON 300C

B mode (IEC 60601-2-37)

IEC 60601-2-37			
Clause	Requirement + Test	Result - Remark	Verdict

201.7.9.103	TABLE: Acoustic output reporting table							
Index label			MI	TIS			TIB	TIC
				Scan	Apart ≤ 1 cm²	Apart > 1 cm²	Nonscan	
Maximum index value			0.7861	0.2535			0.6403	0.3571
Associated acoustic parameters	$p_{r,\alpha z=}$ 6.3cm (Mpa)		1.4172					
	P (W)		0.01633				0.01633	
	Min of [Pα(zs), lta, α(zs)]							
	z_s			1.7144				
	Z_{bp}		1.7144					
	Zb (m)							
	z at max lpi α (m)		0.0375					
	deq (zb)		1.143					
	Fawf (MHz)		3.25					
	Dim of Aaprt	X	1.14					
		Y	0.9					
Other Information	td		1.46					
	Prr(PRF)		0.472ms					
	pr at max lpi(Pa) (Peak rarefactional)		1.417					
	deq at max lpi							
	lpi at max MI		0.16990					
	Focal Length	FLx	0.08					
		FLy	1.04					
Operating control conditions	Control 1		√		√		√	
	Control 2		√		√		√	
	Control 3		√		√		√	

B-mode (Track 3 for FDA)

Transducer	ISPTA.3	TIS	MI	IPA.3@MImax
Convex	0.0627 [W/cm2]	0.2535	0.7861	0.1699 [W/cm2]

B mode (with M mode) (IEC 60601-2-37)

IEC 60601-2-37			
Clause	Requirement + Test	Result - Remark	Verdict

201.7.9.103	TABLE: Acoustic output reporting table							
Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.664	0.0878		0.1135		n/a
Index component				0.0878	0.0878	0.1135	0.0878	
Acoustic parameters	$p_{r,\alpha}$ at Z_{MI}	(MPa)	1.236					
	p	(mW)		5.9		5.9		n/a
	p_{1x1}	(mW)		5.32		5.32		
	z_s	(cm)			n/a			
	Z_b	(cm)					n/a	
	Z_{MI}	(cm)	2.707					
	$Z_{pii,\ \alpha}$	(cm)	2.707					
	f_{awf}	(MHz)	3.46	3.46		3.46		n/a
Other Information	$p\gamma\gamma$	(Hz)	2000					
	$s\gamma\gamma$	(Hz)	10					
	n_{pps}		1					
	$I_{pa,\ \alpha}$ at z $_{pii,a}$	(W/cm^2)	43.8					
	$I_{spta,\ \alpha}$ at z $_{pii,a}$ or $z_{sii,\alpha}$	(mW/cm^2)	0.465					
	I_{spta} at z $_{pii}$ or z_{sii}	(mW/cm^2)	1.07					
	$p\gamma$ *at* z $_{pii,}$	(MPa)	1.58					

CF mode (with PW mode) (IEC 60601-2-37)

IEC 60601-2-37			
Clause	Requirement + Test	Result - Remark	Verdict

201.7.9.103	TABLE: Acoustic output reporting table							
Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.757	0.1136		0.1557		n/a
Index component				0.1136	0.1136	0.1557	0.1136	
Acoustic parameters	$p_{r,\alpha}$ at Z_{MI}	(MPa)	1.379					
	p	(mW)		8.09		8.09		n/a
	p_{1x1}	(mW)		7.2		7.2		
	z_s	(cm)			n/a			
	Z_b	(cm)					n/a	
	Z_{MI}	(cm)	2.774					
	$Z_{pii,\ \alpha}$	(cm)	2.774					
	f_{awf}	(MHz)	3.31	3.31		3.31		n/a
Other Information	$p\gamma\gamma$	(Hz)	2000					
	$s\gamma\gamma$	(Hz)	10					
	n_{pps}		1					
	$I_{pa,\ \alpha}$ at $z_{pii,a}$	(W/cm^2)	61.6					
	$I_{spta,\ \alpha}$ at $z_{pii,a}$ or $z_{sii,\alpha}$	(mW/cm^2)	0.65					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	1.495					
	$p\gamma$ *at* $z_{pii,}$	(MPa)	1.841					

B-mode (with M mode) (FDA)

201.7.9.3.101	TABLE: Acoustic output reporting table							
Index lable			MI	TIS		TIB		TIC
				At surfac	Belo w	At surfac	Below surfac	
Global Maximum index value			0.664	0.0927		0.1138		
Index component value								
Acoustic Parameters	$p_r.3$	(MPa)	1.236					
	$W0$	(mW)		5.9		5.9		
	P_{1x1}	(mW)						
	z_{sp}	(cm)						
	z_{bp}	(cm)						
	z_{MI}	(cm)						
	$Z@PII.3_{max}$	(cm)	2.707					
	f_c	(MHz)	3.46	3.46		3.46		
Other Information	PRF	(Hz)	2000					
	srr	(Hz)						
	n_{pps}							
	$I_{pa}.a3$ at MI_{max}	(W/cm^2)	43.8					
	$I_{spta}.3_{max}$	(mW/cm^2)	34.2					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)						
	$p_r@PII_{max}$	(MPa)	1.58					
Operating Control conditions	Control 1							
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	…							
	Control x							

CF-mode (with PW mode) (FDA)

201.7.9.3.101		TABLE: Acoustic output reporting table						
Index lable			MI	TIS		TIB		TIC
				At surfac	Belo w	At surfac	Below surfac	
Global Maximum index value			0.757	0.1213		0.1557		
Index component value								
Acoustic Parameters	$p_r.3$	(MPa)	1.379					
	W0	(mW)		8.09		8.09		
	P_{1x1}	(mW)						
	z_{sp}	(cm)						
	z_{bp}	(cm)						
	z_{MI}	(cm)						
	$Z@PII.3_{max}$	(cm)	2.774					
	f_c	(MHz)	3.31	3.31		3.31		
Other Information	*PRF*	(Hz)	2000					
	srr	(Hz)						
	n_{pps}							
	I_{pa}.a3 at MI_{max}	(W/cm^2)	61.6					
	$I_{spta}.3_{max}$	(mW/cm^2)	49.6					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)						
	$p_r@PII_{max}$	(MPa)	1.841					
Operating Control conditions	Control 1							
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	…							
	Control x							

Acoustic output reporting tables for 300L

B mode (IEC 60601-2-37)

201.7.9.3.101	TABLE: Acoustic output reporting table							
Index label			MI	TIS		TIB		TIC
Maximum index value			0.125	0.0196		0.0226		
Index component value								
Acoustic parameters	p at Z_{MI}	(MPa)	0.34					
	p	(mW)		0.55		0.55		
	p_{1x1}	(mW)						
	z_s	(cm)			1.06			
	Z_b	(cm)					1.054	
	Z_{MI}	(cm)						
	Z	(cm)	1.06					
	f_{awf}	(MHz)	7.5	7.5		7.5		
Other Information	prr	(Hz)	10000					
	srr	(Hz)						
	n_{pps}							
	Iat z	(W/cm^2)	0.53					
	Iat z or z	(mW/cm^2)	4.01					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)						
	P_r at z_{pii},	(MPa)	0.228					
Operating Control conditions	Control 1							
	Control 2							
	Control 3							
	Control x							

CF mode (IEC 60601-2-37)

201.7.9.3.101	TABLE: Acoustic output reporting table							
Index label			MI	TIS		TIB		TIC
Maximum index value			0.42	0.0275		0.041		
Index component value								
Acoustic parameters	p at Z_{MI}	(MPa)	0.95					
	p	(mW)		1.16		1.16		
	p_{1x1}	(mW)						
	z_s	(cm)			1.385			
	Z_b	(cm)					1.383	
	Z_{MI}	(cm)						
	Z	(cm)	1.39					
	f_{awf}	(MHz)	5	5		5		
Other Information	prr	(Hz)	5000					
	srr	(Hz)						
	n_{pps}							
	Iat z	(W/cm^2)	0.81					
	Iat z or z	(mW/cm^2)	5.83					
	I_{spta} at z $_{pii}$ or z_{sii}	(mW/cm^2)						
	P_r *at* z $_{pii,}$	(MPa)	0.204					
Operating Control conditions	Control 1							
	Control 2							
	Control 3							
	Control x							

B-mode (FDA)

201.7.9.3.101	TABLE: Acoustic output reporting table						
Index lable		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Global Maximum index value		0.125	0.0196		0.0226		
Index component value							
Acoustic Parameters	$p_{r.3}$ (MPa)	0.34					
	$W0$ (mW)		0.55		0.55		
	P_{1x1} (mW)						
	z_{sp} (cm)			1.06			
	z_{bp} (cm)					1.054	
	z_{MI} (cm)						
	$Z@PII.3_{max}$ (cm)	1.06					
	f_c (MHz)	7.5	7.5		7.5		
Other Information	PRF (Hz)	10000					
	srr (Hz)						
	n_{pps}						
	$I_{pa.}$a3 at MImax (W/cm^2)	0.53					
	$I_{spta.}$3 max (mW/cm^2)	4.01					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)						
	$p_r@PII_{max}$ (MPa)	0.228					
Operating Control conditions	Control 1						
	Control 2						
	Control 3						
	Control 4						
	Control 5						
	…						
	Control x						

CF-mode (FDA)

201.7.9.3.101	TABLE: Acoustic output reporting table						
Index lable		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Global Maximum index value		0.42	0.0275		0.041		
Index component value							
Acoustic Parameters	$p_{r.3}$ (MPa)	0.95					
	$W0$ (mW)		1.16		1.16		
	P_{1x1} (mW)						
	z_{sp} (cm)			1.385			
	z_{bp} (cm)					1.383	
	z_{MI} (cm)						
	$Z@PII.3_{max}$ (cm)	1.39					
	f_c (MHz)	5	5		5		
Other Information	PRF (Hz)	5000					
	srr (Hz)						
	n_{pps}						
	$I_{pa.}a3$ at MImax (W/cm^2)	0.81					
	$I_{spta.}3$ max (mW/cm^2)	5.83					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)						
	$p_r@PII_{max}$ (MPa)	0.204					
Operating Control conditions	Control 1						
	Control 2						
	Control 3						
	Control 4						
	Control 5						
	…						
	Control x						

10.5 Acoustic output and display accuracy

When you operate the SONON ultrasound device, the MI and TI values are displayed on the scan screen.
For all SONON ultrasound devices, TI stands for either the TIS or TIB values. Your SONON ultrasound device automatically selects an appropriate category based on its operation mode and the application you choose. Because your SONON ultrasound device will present only one TI, it is important that you choose the appropriate application for your diagnostic needs.

The maximum possible MI and I_{spta} when you operate the SONON ultrasound device are within the limits set in Track 3 in the *FDA 510(k)* guidance of September 9, 2008 (MI<1.9 / I_{spta} <720 mW/cm2).

Display accuracy and acoustic measurement uncertainty

The accuracy of the output display parameters depends on measurement system precision and the acoustic model used to calculate the parameters in the acoustic output of systems.
The measurement precision and overall accuracy of the measurements have been assessed by determining both random and systematic uncertainties, and are given in a percentage at a 95% confidence level.
Refer to the following table for the display accuracy and the measurement precision of the output display.

Display accuracy

Parameter	Uncertainty
Power	± 5.396%

Measurement accuracy

Parameter	Accuracy
Length	± 7%
Ellipse	± 10%

System controls affecting acoustic output

The operator controls which directly affect acoustic output are discussed in the “10.4 Acoustic output” on page 172. Because these tables show the highest possible acoustic intensity for given modes, which can be obtained only when the maximum combinations of control settings are selected, most settings will result in a much lower output than the figures presented in the tables.
Note the following information related to acoustic ultrasound intensity and ultrasound exposure.

- The duration of an ultrasound exam is as important as the acoustic output, since patient exposure to output is directly related to the exposure time.
- Better image quality yields faster clinical results, making it possible to complete the relevant ultrasound examination in a shorter period of time. Any control that improves the quality of the examination can help reduce patient exposure, even though it may not directly affect the acoustic output.

Choosing an appropriate clinical application

Choosing an appropriate application for a particular ultrasound exam ensures acoustic output within the limits which FDA guidelines provide for that application. Parameters will be automatically set in such a way as to optimize performance for the selected application, to help reduce patient exposure time.

10.6 Specifications

Model name: SONON 300C

	Specification
Dimensions (W x L x H)	3.07 x 8.62 x 1.49 in. (78 x 219 x 38 mm)
Weight (with battery)	13.75 oz (390 g)
Battery	Type: Rechargeable Li-ion Battery Pack Capacity: 2600 mAh
Wireless Communication	Type: Soft AP. Frequency: 2.4 and 5 GHz Dual band Wi-Fi
Mobile App	OS: iOS/Android/UWP
Application	General (abdomen)/OB/GY
IEC 60601-1	Type BF Applied Part Non-Continuous Operation (max 10 min with 10 min resting time) Internally Powered Equipment Probe head: IPX7
Ultrasound	Frequency: 3.5MHz Module: Convex Depth: Max. 7.87 in. (20 cm)
Software Version	Firmware version: M1.01.XX Software app version: M2.00.XX

Model name: 300L

	Specification
Dimensions (W x L x H)	3.07 x 8.62 x 1.49 (78 x 229 x 38 mm)
Weight (with battery)	13.05 oz (370g)
Battery	Type: Rechargeable Li-ion Battery Pack Capacity: 2600 mAh
Wireless Communication	Type: Soft AP. Frequency: 2.4 and 5 GHz Dual band Wi-Fi
Mobile App	OS: iOS/Android/UWP
Application	Musculoskeletal (MSK), Vascular, Small parts (breast, thyroid), Thorax
IEC 60601-1	Type BF Applied Part Non-Continuous Operation (Max 10 min with 10 min resting time)

	Specification
	Internally Powered Equipment Probe head: IPX7
Ultrasound	Frequency: 5MHz/7.5MHz/10MHz Module: Linear Depth: Max. 3.93 in. (10 cm)
Software Version	Firmware version: M1.01.XX Software app version: M2.00.XX

Battery (rechargeable Li-ion battery pack / all models)

	Specification
Capacity	2,600 mAh (7.4 V)
Guaranteed lifetime	6 months
Manufacturer	SAMSUNG SDI
Model name	MBP-2S1PSD26
Cell Type	ICR18650
Dimensions (W x L x H)	1.5 x 2.77 x 0.8 in. (38.3 x 70.49 x 20.5 mm)
Safety	PCM logic

NOTE

Contact the manufacturer or representative in your region for detailed information about purchasing extra batteries.

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Glossary - Abbreviations

IEC terms	Definitions
a	Acoustic Attenuation Coefficient
Aaprt	-12db Output Beam Area
CMI	Normalizing Coefficient
Deq	Equivalent Aperture Diameter
d-6	Pulse Beam Width
deq	Equivalent Beam Diameter
awf	Acoustic Working Frequency
lpa	Pulse-Average Intensity
lpa,a	Attenuated Pulse-Average Intensity
lpi	Pulse-Intensity Integral
lpi,a	Attenuated Pulse-Intensity Integral
lta(z)	Temporal-Average Intensity
lta,a(z)	Attenuated Temporal-Average Intensity
lzpta(z)	Spatial-Peak Temporal-Average Intensity
lzpta,a(z)	Attenuated Spatial-Peak Temporal-Average Intensity
MI	Mechanical Index
P	Output Power
Pa	Attenuated Output Power
P1	Bounded Output Power
pi	Pulse Pressure Squared Integral
pr	Peak-Rarefactional Acoustic Pressure
Pra	Attenuated Peak-Rarefactional Acoustic Pressure
prr	Pulse Repetition Rate
TI	Thermal Index
TIB	Bone Thermal Index
TIC	Cranial-Bone Thermal Index
TIS	Soft-Tissue Thermal Index
td	Pulse Duration / (same)
X, Y	-12 dB Output Beam Dimensions / (same)
z	Distance from the Source to a Specified Point / (same)
zbp	Depth for TIB / Depth at which the relevant index is maximum
zbp	Break-Point Depth / (same)
zs	Depth for TIS / Depth at which the relevant index is maximum

FDA terms	Definitions
MI	Mechanical Index
TISscan	Soft Tissue Thermal Index in auto-scanning mode
TISnon-scan	Soft Tissue Thermal Index in non-autoscanning mode
TIB	Bone Thermal Index
TIC	Cranial Thermal Index
Aaprt	Area of the active aperture (square centimeters)
pr.3	Derated peak rarefactional pressure associated with the transmit pattern giving rise to the value reported under MI (megapascals)
Wo	Ultrasonic power, except for TISscan, in which case it is the ultrasonic power passing through a one-centimeter window (milliwatts)
W.3(z1)	Derated ultrasonic power at axial distance z1 (milliwatts)
ITA.3(z1)	Derated spatial-peak temporal-average intensity at axial distance z1 (milliwatts per square centimeter)
z1	Axial distance corresponding to the location of max[min(W.3(z), ITA.3(z) x 1 cm2)], where z≥zbp (centimeters)
zbp	$1.69\sqrt{A_{aprt}}$ (centimeters)
zsp	The axial distance at which TIB is a global maximum (i.e., zsp = zB.3) (centimeters).
z@PII.3max	The axial distance corresponding to the maximum of the derated spatial-peak pulse intensity integral (megapascals).
deq(z)	the equivalent beam diameter as a function of axial distance z. It is equal to [(4/π)(Wo/ITA(z))]0.5 where ITA(z) is the temporal-average intensity as a function of z (centimeters).
fc	the center frequency (MHz). For MI, fc is the center frequency associated with the transmit pattern giving rise to the global maximum reported value of MI. For TI, for combined modes involving transmit patterns of unequal center frequency, fc is defined as the overall range of center frequencies of the respective transmit patterns.
Dim. of Aaprt	the active aperture dimensions for the azimuthal (x) and elevational (y) planes (centimeters).
PD	the pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.
PRF	the pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI (Hz).
pr@PIImax	the peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum (megapascals). See “Acoustic output parameters” on page 172, entitled “Measurement Methodology for Mechanical and Thermal Indices”.
deq@PIImax	the equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum (centimeters). See “Acoustic output parameters” on page 172, entitled “Measurement Methodology for Mechanical and Thermal Indices”.
FL	the focal length, or azimuthal (x) and elevational (y) lengths, if different (centimeters).

FDA terms	Definitions
IPA.3@MImax	the derated pulse-average intensity at the point of global maximum reported MI (watts per square centimeter).

Appendix A Usage Agreement

USAGE AGREEMENT FOR PERSONAL INFORMATION

For the purpose of provision of basic services such as the HEALCERION application user registration, password retrieval, etc., HEALCERION collects the following personal information, categorized into patient information for the efficient management of user information and diagnosis information:

1. Collected Personal Information
   - The range of personal information collected for registration of application users
     - E-mail, Device Serial Number, Password, Name of Organization
   - The range of patient information for management of diagnosis data:
     - Name, Gender, Age, Height, Weight, Operator, Hospital, Image
   - We do not ask for any sensitive personal information such as race, ideology, place of birth, political inclination, criminal record, health condition, etc.
2. Purpose of Collection and Utilization of Personal Information
   A. In Relation to Registration and Management of the HEALCERION Application, Users' Personal information may be collected for the purpose of identifying the HEALCERION application user, confirmation of user qualifications, prevention of illegal usage of service, and password retrieval service.
   B. In Relation to Registration and Management of Patient Information Regarding Ultrasonic Image Information Obtained by the HEALCERION device, Personal Information may be collected for the purpose of discerning target patients or diagnosed persons of corresponding ultrasonic image information and establishing reference data for future treatment.
   C. Entered information shall not be collected and utilized for any other purpose such as marketing and provision of product information, etc. The company, however, may contact users with service-related notifications, troubleshooting, etc.
3. Duration of Retention and Utilization of Collected Personal Information
   - The duration of retention and utilization of personal information is until the point of removal of the HEALCERION application.

- The collected personal information is saved on the mobile device through the HEALCERION application and deleted simultaneously with the removal of the HEALCERION application.

THE SONON ULTRASOUND DEVICE USAGE AGREEMENT

Article 1 (Purpose)

- This Agreement is intended to regulate matters related to the usage of service of the HEALCERION application, or the SONON X Ultrasound app (hereafter “SERVICE”), provided by HEALCERION (hereafter ”COMPANY”).

Article 2 (Terms and Definitions)

- “Application” refers to the mobile application manufactured and managed by the COMPANY with the purpose of aiding users who have registered a password to have access to ultrasonic diagnosis by using the HEALCERION ultrasonic diagnosis instrument.
- “User” refers to a person who has registered information including personal information for the purpose of utilization of the “SERVICE” provided by the “COMPANY” and is able to access an ultrasonic diagnosis using the HEALCERION ultrasonic instrument through free utilization of the “SERVICE” with the registered password.
- “HEALCERION ultrasonic diagnosis instrument” or “SONON ultrasound device” refers to the medical instrument that visualizes the inside of the human body using ultrasonic waves and the wireless mobile ultrasonic diagnosis instrument manufactured by the COMPANY.
- “Password” refers to combinations of letters and numbers that are set up by members for the purpose of identification of members and protection of their rights and passwords and registered to the SERVICE.
- “Personal Information” refers to information regarding a specific individual such as e-mail, name of organization, etc. (Also includes any information that has the potential to be combined with other information to make identification of a specific individual feasible).
- “Removal” refers to the action of removing the Application from the mobile device by the “User”.

Article 3 (Manifestation, Description and Amendment of the Agreement)

- This agreement is valid only by being posted for users on the service screen or otherwise notified.
- The COMPANY may amend contents of this agreement as long as there is no violation of laws or other related ordinances regarding regulation of the agreement and shall notify any changes through the procedure clarified in Article 1 above. However, significant

matters regarding rights and duties of the users shall be posted fifteen (15) days prior to implementation of amended content.

- The COMPANY bears no responsibility for any loss or damage to Users due to their ignorance of amended agreement.
- For matters not clarified in this agreement, all cases shall be considered according to the Act on the Promotion of Information and Communication Network Use and Protection of Information, other related laws and ordinances, or appropriate customs.

Article 4 (Content and Alteration of Service)

- The COMPANY may alter the contents of the SERVICE when it is unavoidable and shall issue notification of such altered contents and implementation date seven (7) days in advance.
- The COMPANY is not responsible for compensation for any loss to the users due to alteration of the SERVICE contents.
- However, it is NOT so if the COMPANY undertakes such alteration with bad intentions or significant errors.

Article 5 (Termination of SERVICE)

- The COMPANY may temporarily suspend provision of the SERVICE due to causes of force majeure such as repair, inspection, replacement or malfunction, interruption of communication, etc...
- The COMPANY is not responsible for compensation for any loss to the users or any third party caused by a temporary suspension of the SERVICE due to reasons clarified in Clause 1.
- However, it is NOT so if the COMPANY undertakes such alteration with bad intentions or significant errors.
- (Usage Registration and Removal)
- The user shall apply for registration of usage of the HEALCERION application by inputting personal information as required by the COMPANY and agreeing with this agreement.
- The user may at any time remove the HEALCERION application.
- However, upon removal of the HEALCERION application, all collected information is deleted and the COMPANY is not responsible for any loss to the user or any third party caused by the removal.

Article 6 (Personal Information Protection)

- The COMPANY conforms to all matters regulated by laws and ordinances such as the Act on the Promotion of Information and Communication Network Use and Protection of Information, etc...
- The COMPANY shall establish and post the “Privacy Policy” on the first SERVICE screen in order to protect personal information of the members.
- In addition, further details of the “Privacy Policy” shall be available in a separate section.

Article 7 (Limitation of Responsibility Regarding the SERVICE)

- The COMPANY shall make its best effort to maintain the best possible security by avoiding information leakage of diagnosis data of the users to any third party excluding doctors and those with rights to such diagnosis data.
- However, the COMPANY is not responsible when such diagnosis data is revealed, exposed or damaged due to the following reasons:
  - Leakage of password due to inattention of the user
  - When “deletion of diagnosis” function has been executed
  - When the HEALCERION application has been removed
  - Due to other force majeure causes such as natural disaster

Article 8 (Responsibility of the COMPANY)

- The COMPANY shall not conduct any actions that violate related laws, this agreement, or public morals and make its best effort to maintain its provision of stable and secure products conforming to this agreement.
- The COMPANY shall establish a proper security system for protection of the personal information (including credit information) of the members in order to allow them to safely utilize the SERVICE and post and conform to the”Privacy Policy”.
- The COMPANY shall immediately work to rectify any complaint or opinion of the members through appropriate procedures, when such complaint or opinion is considered objectively reasonable. When an immediate resolution is not likely, however, the COMPANY shall notify the member of the reason for such delay and the future settlement schedule.

Article 9 (Responsibility Regarding User ID and Password)

- All responsibility regarding user ID and password lies solely with the user and any civil/criminal responsibility due to negligent management of the ID and password also lies solely with the user.
- The user shall not allow any third party to have access to his or her user ID and password.
- When the user realizes that there has been a theft of his/her user ID and/or password or becomes aware that they are being used by a third party, he/she shall immediately notify the COMPANY and comply with any measures taken by the COMPANY.
- The user is fully responsible for any and all loss caused by nonfulfillment of the notification cited above in Clause 3 or noncompliance with the COMPANY‘s measures.

Article 10 (Responsibility of the User)

- The user shall conform to any and all related laws and ordinances, regulations set by this agreement, and usage guideline provided by the COMPANY and shall not conduct any behavior that may interrupt other operations of the COMPANY.

- The user shall be prohibited from the following behavior regarding utilization of the SERVICE:
  - Registration of false information at registration or alteration of the SERVICE
  - Illegal usage of others' information
  - Transmitting or posting other information (computer programs, etc.) than that determined by the COMPANY.
  - Violation of any intellectual property rights such as copyright of the COMPANY or any other third party.
  - Any behavior that defames the COMPANY or another third party and interferes with business operation.
  - Revealing or posting any obscene or violent message, video, audio or any other information that goes against public morals to the COMPANY.
  - Utilizing the SERVICE for business purposes without the consent of the COMPANY.
  - Any behavior that violates other related laws and ordinances or regulations of the COMPANY.

Article 11 (Copyright Ownership and Usage Limitation)

- All copyrights and intellectual property rights of the contents created by the COMPANY belong to the COMPANY.
- The user may not use information that belongs to the COMPANY due to intellectual property rights for business purposes or provide it to any third party through copying, transmitting, publishing, distributing, broadcasting, etc., without the prior consent of the COMPANY.
- When utilizing any copyright that belongs to the user, the COMPANY shall notify the corresponding user according to this agreement.

Article 12 (Arbitration)

- The COMPANY shall establish and manage a department for compensating for loss in order to reflect and apply reasonable opinions or complaints reported by the members and compensate for any loss.
- The COMPANY shall place priority on complaints and opinions of the members over other matters. When an immediate resolution is not likely, however, the COMPANY shall immediately notify the members of the reason for such delay and the future settlement schedule.

Article 13 (Jurisdiction and Governing Law)

- The Law of the Republic of Korea shall be the governing law over interpretation of this agreement and disputes between the COMPANY and its members.

- In case of any lawsuit arising from disputes between the COMPANY and its members regarding this agreement and the SERVICE, the court of jurisdiction shall be determined according to the Civil Procedure Code (CPC).

Appendix B Medical Ultrasound Safety

This document is only available in English.

To contact the AIUM concerning their publications:

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