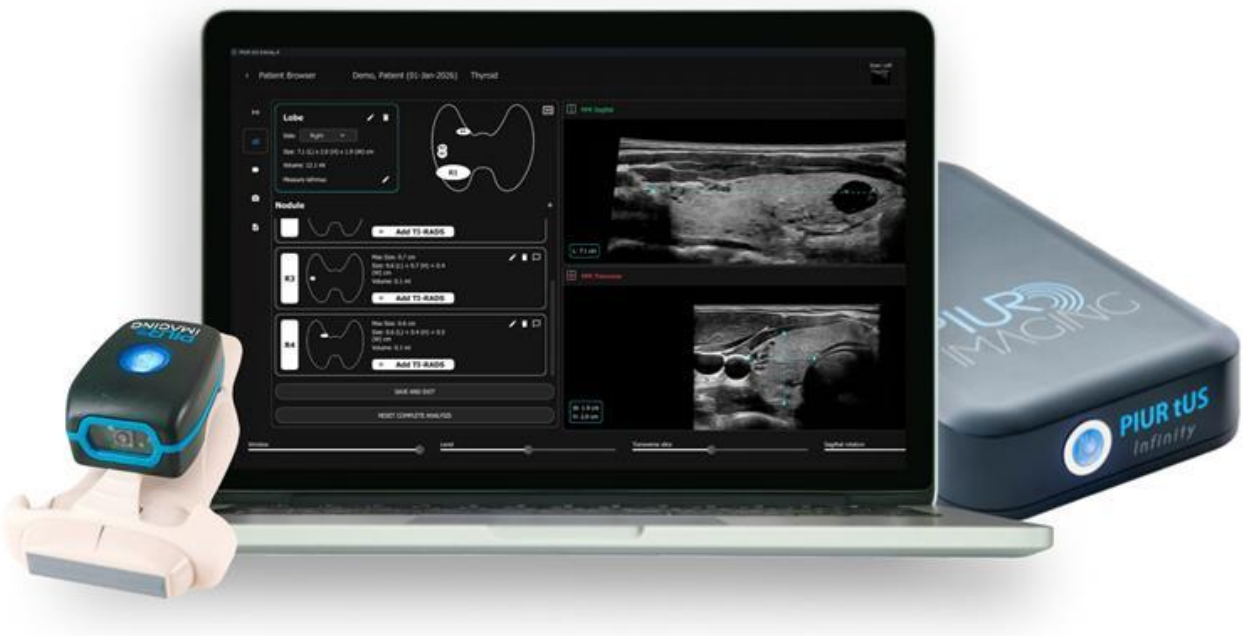
PIUR IMAGING

PIUR® tUS Infinity

User Manual



User Manual
PIUR® tUS Infinity

Document Revision 6.0

Software version: 4.4

Type: PIUR tUS Infinity

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1070 Vienna

Austria

Table of Contents

1 General Information

1.1 Abbreviations and Terms

Abbreviation / term	Description
US	Ultrasound
tUS	Tomographic ultrasound

1.2 Symbols in User Manual

Symbol	Description
	Helpful **information**, which simplifies daily work with the device.
	**Attention:** Important information that should be understood prior to operating the device.
	**Safety notice.** Situations in which misuse can lead to personal injury or damage to property.

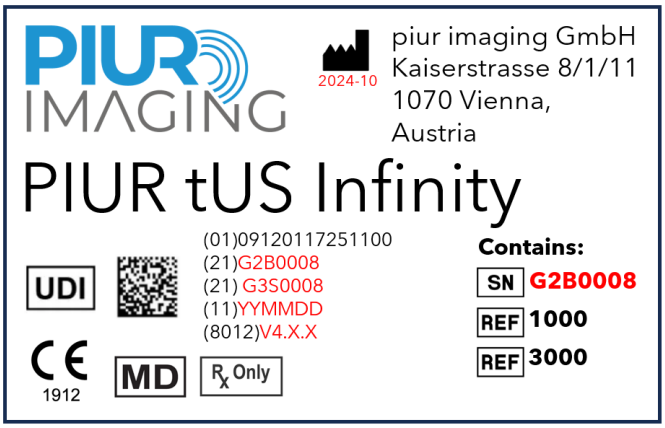
1.3 Symbols on Device

Symbol	Description
	Stand-by symbol
	Wireless charging symbol

1.3.1 Identification Labels

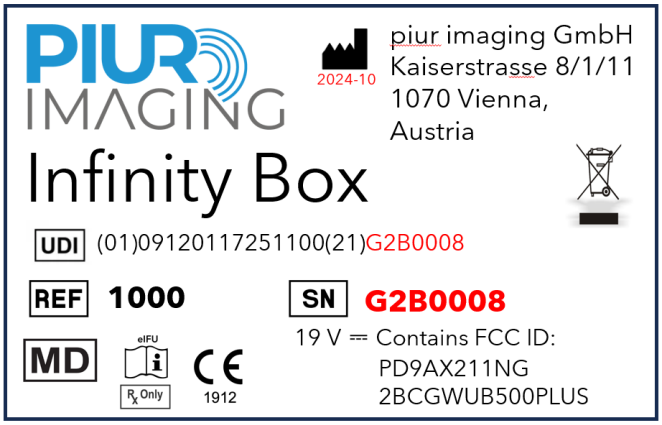
The identification label with the corresponding serial number can be used to identify the device. Please note down the serial number of the device before contacting the PIUR service.

System Label

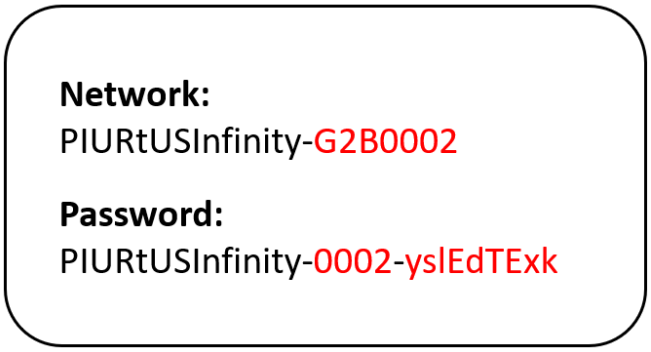


Infinity Box Label

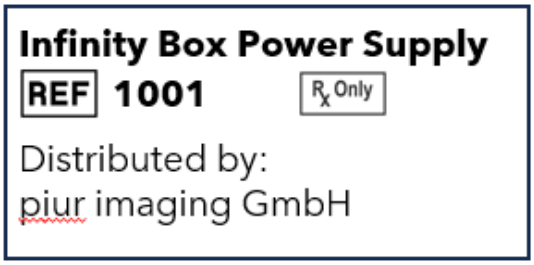
Affixed on device (component), size 60x40mm:



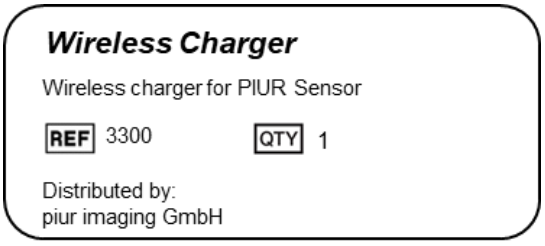
Wi-Fi label affixed on the device component:



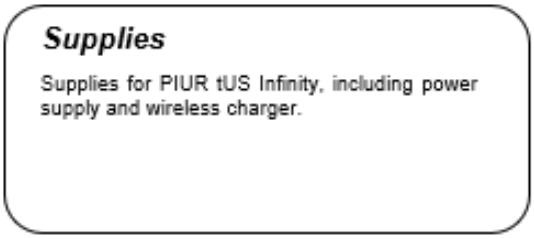
Infinity Box Power Supply Label



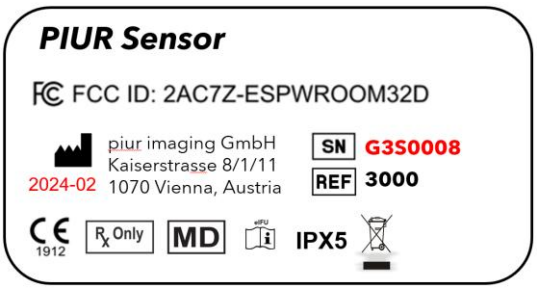
Wireless Charger Label



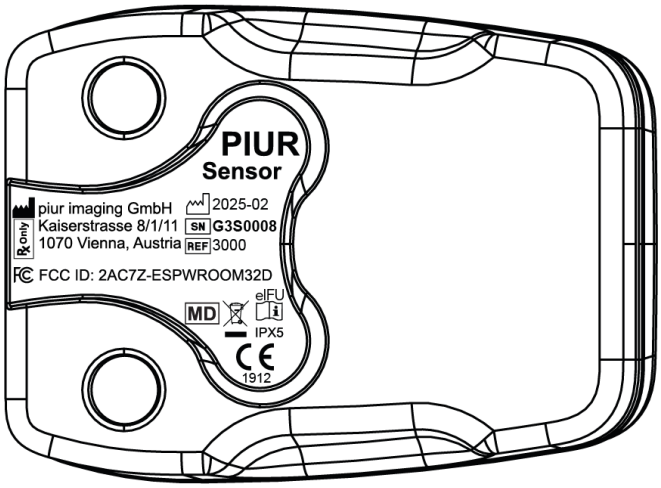
Infinity Box Supplies Label



PIUR Sensor Label



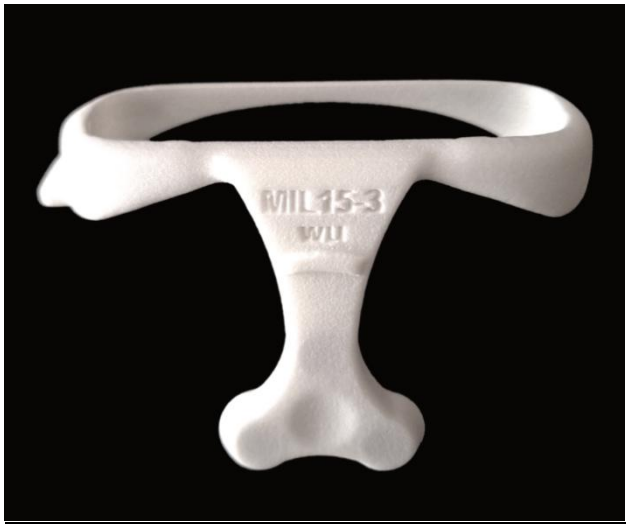
Markings on device (component) and 3D model overview:



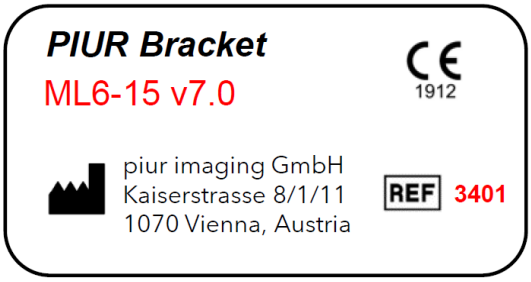
PIUR tUS Software Label

Remark: PIUR tUS Software Version will be the Software release version with respective Software Build Date.

PIUR Bracket



PIUR Bracket Label overview (specification):



The following additional symbols can be found on the identification label:

Symbol	Description
SN	Serial number
REF	Catalogue number
MD	The product is a Medical Device
UDI	Unique Device Identifier
	Manufacturer
CE 1912	CE mark with Notified Body number
eIFU Indicator	Consult Instruction for Use (electronic)
	Direct current (DC)
	Alternating current (AC)
	The system must not be disposed with normal waste (see Section 7.2).
Rx only	Rx Only means that the device is a prescription device. Caution: Federal law (USA) restricts this device to sale by or on the order of a physician
FC	FCC ID or Contains FCC ID

1.4 Function of this Document

This document provides a detailed description of the PIUR tUS Infinity system and its use within the scope of the application domain it was designed for. It provides instructions for use (IFU) to help the user in the safe and correct operation of the system.

1.5 Indication for Use

PIUR tUS Infinity is a computer-aided detection device intended to assist and support medical professionals in the diagnostic workflow of thyroid and thyroid nodules acquired from FDA-cleared ultrasound systems, including image documentation, analysis, and reporting. The device supports the physician with additional information during image review, including quantification and visualization of sonographic characteristics of thyroid nodules.

PIUR tUS Infinity may be used on any adult patient aged 22 and older, independent of gender, linguistic and cultural background, or health status, unless any of the contraindications apply.

The PIUR tUS Infinity acts as part of the diagnostic chain and must not be used as a sole source for treatment decisions, but as an add-on solution to regular 2D ultrasound imaging.

PIUR tUS Infinity device is not intended for body contact (including skin, mucosal membrane, breached or compromised surfaces, blood path indirect, tissues, bones, dentin, or circulation blood).

1.6 Disclaimer

The manufacturer is not responsible for improper use, failure to comply with the safety notes and non-observation of specifications due to negligence. piur imaging only assumes responsibility for the safety and reliability of the PIUR tUS Infinity system and components when all changes, enhancements, repairs and other work to the device and/or system have been performed by an authorized dealer of piur imaging and certified service person, or piur imaging directly and the User Manual has been observed before and during device operation.

Safety Notice: Do not modify this equipment without authorization of the manufacturer.

1.7 General Residual Risk Including Significant Risks

Considering possible sources of failure, foreseeable and unforeseeable errors of use and after risk mitigation residual risk of this medical product remain. Within the Risk Management process, a total of 101 residual risks have been identified. There following residual risks are considered as significant:

- Wrong but anatomical correct image

As a diagnostic system the most relevant output of the device is image information. This image information can influence medical decision in terms of therapy, treatment, prevention or further alternative diagnostic information. Caused by various factors the system may display incorrect image information after the image reconstruction. This wrong image information can be caused by erroneous input of image or tracking source or by software or user errors. The wrong image information can either appear as bad image quality or unrealistic image content in terms of anatomical appearance. In both cases the error is obvious to the user. In rare cases the wrong image information can display anatomically reasonable content that cannot be identified as obvious wrong image information and therefore may mislead the user and lead to undesired consequences- in the

worst case not getting necessary interventions or surgery or getting unnecessary intervention and surgery. This residual risk affects the patient.

- Incorrect measurement

Measurement features as part of the software can influence the diagnostic decision and therefore effect further therapy, treatment, prevention or further alternative diagnostic information of the patient. Due to various sequences of internal or external event, errors of use or inadequate image input measurement errors can occur. Especially out of plane (length) measurements depend on appropriate use and adequate image input with sufficient frame rate. The residual risk is a measurement deviation outside of the disclosed error range that may lead to wrong image information as the residual risk above "Wrong image information". The This residual risk affects the patient. For further details of measurement deviation and errors please see chapter 9.2.1 Measurement Function.

- Infection

Infection is a risk that can occur with any device that comes into contact with the human body, including sensors and brackets. However, it can be easily prevented with proper cleaning techniques. To reduce the risk of infection, it is important to regularly clean and disinfect the sensor and its brackets as recommended in the user manual (chapter 7.3). Failure to do so can lead to the accumulation of bacteria and other harmful microorganisms, which can cause infection and other health problems. By following the correct cleaning procedures, you can help ensure the safety and effectiveness of your device and protect yourself and others from potential health risks.

- Misdiagnosis due to wrong diagnostic output

Misdiagnosis due to wrong diagnosis output is a risk that include two possible situations of incorrect automatic suggestions. The first one is when the doctor accepts incorrect automatic Margin suggestions and the second when doctor accepts incorrect automatic Echogenic foci suggestions. A notification to the user by showing an exclamation mark in the UI for these TI-RADS parameters along with a warning for the user reminding her/him to check these parameters for accuracy, could easily avoid such risk and misdiagnosis.

- DICOM export orientation

When exporting a volume in multiplanar reconstruction (MPR), it is crucial to adhere to the established conventions for anatomical directions as defined in the 'Introduction to DICOM Coordinate Systems.' Failure to do so may result in incorrect interpretation of the volumetric images. This could lead to misidentification of the position of objects, lesions, or anatomical structures within the patient's body, such as confusing anterior-left with inferior positions

- Overheating of battery

The battery may overheat due to the lack of ventilation in the protective housing, which is necessary to meet IP rating requirements. Overheating can occur during charging or extended use and must be actively avoided to ensure safe operation.

- Disinfection agent

The use of unsuitable or aggressive disinfectants may damage the surfaces or materials of the device and its accessories. In some cases, device damage may result in incorrect system operation or inability to perform an examination

All residual risks are accepted and considered under scope of the Risk Management file.

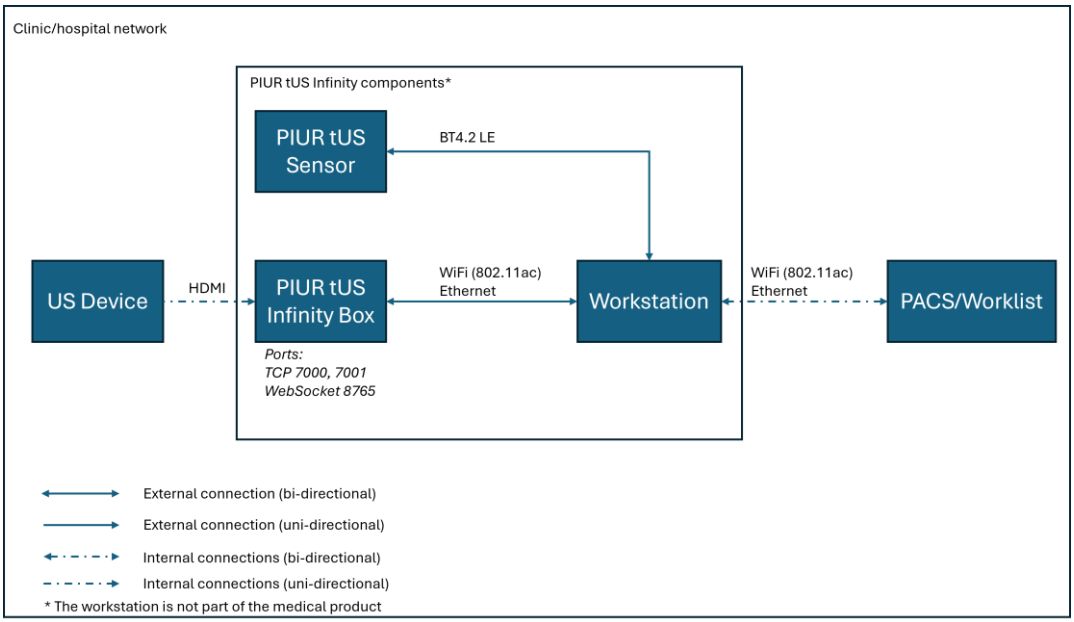
1.8 Recommendations Regarding Cybersecurity

The user of the PIUR tUS Infinity system is responsible for securing the computer that runs the PIUR software against data loss and access by non-authorized users. The database is encrypted to reduce the risk of non-authorized access. However, it is highly recommended to run regular backups of the patient database using the backup function provided by the software to avoid loss of data. It is also recommended to restrict access to the computer using password protection. If several users have access to the computer, it is recommended to restrict access to the PIUR software for selected users, for example through drive-partition or access restrictions to the installation folder. To protect the computer against non-authorized access, it is recommended to install an anti-virus application, a firewall and the latest Windows 10 Updates on a regular basis.

This section provides transparency on the cybersecurity features of the system and gives guidance to the user on device security to ensure proper handling in use and decommissioning.

1.8.1 System interfaces

The network scheme below is provided for clarity on the connection. The table provides details on all wired and wireless connections displayed in the scheme of the system with incoming and outgoing communication.



Name	Function	Details	Protocol for connection	Inbound connection	Outbound connection
HDMI / DVI / VGA	Connecting the video output from the ultrasound device to the PIUR tUS Infinity box	Cabled connection between two devices through the video out/in.	TMDS protocol DVI/VGA proprietary protocol	HDMI video port	None
Bluetooth 4.2 LE	Bluetooth connection established between the workstation (laptop) and the PIUR tUS PIUR Sensor	BT low energy, version 4.2 for bit transfer of the transducer movement	BT 4.2 LE proprietary protocol	None	BT 4.2 LE
Wi-Fi (2.4 GHz)	Connecting the PIUR tUS Infinity box with the workstation (laptop)	Wi-Fi data stream to send ultrasound live video (images) in two separate streams, compressed and uncompressed	TCP / IP, IEEE 802.11ac Wi-Fi standard WPA2 for password protection	Varying, established in 802.11ac protocol	TCP 7000, TCP 7001
Ethernet (OPTIONAL)	1)Connecting the workstation (laptop) with the hospital network. This connection not established by default, customer request only. 2)Connecting the workstation to the Infinity Box	Cabled connection for data exchange with the PACS and worklist server. Cabled connection for image transfer from ultrasound to workstation	Single-port integrated multi-gigabit (up to 2.5G) – standard IEEE 802.3 Ethernet interface for 2500BASE-T, 1000BASE-T, 100BASE-TX, 10BASE-TE connections (IEEE 802.3, 802.3u, 802.3bz, and 802.3ab)	Port 8765	Port 8765
DICOM SCP/SCU (OPTIONAL)	Communication with the PACS server and worklist. This connection not established by default, customer request only.	SCP SCU handshake protocol with PACS and worklist server to allow data exchange if AETitle, IP and port on both	TCP / IP, configurable IP and ports	Specifiable in PIUR tUS software settings, standard port 11112	Specifiable in PIUR tUS software settings

Name	Function	Details	Protocol for connection	Inbound connection	Outbound connection
		ends meet the required conditions. DICOM conformity for SOP UID required on the peer.			

Note on minimum ethernet connection speed:

The system does not require a minimum ethernet connection speed but any connection below 2Mbps will lead to significant increase in data transfer time. This might be noticed by a significant delay from initiating the Send to PACS until the data actually is received in full by the PACS.

1.8.2 Software updates and patches

The user will be informed via provided contact data once new software versions are available. The system does not provide means for downloading new software by the user or automatic updates, nor does the software display available updates.

Please contact PIUR Support (Section 8.2 Contact) for information on upcoming releases and scheduling of software updates.

Regarding the Windows operating system, please follow the manufacturer's (Microsoft) guidance on system updates:

- In Windows 11, you decide when and how to get the latest updates to keep your device running smoothly and securely. To manage your options and see available updates, select Check for Windows updates. Or select **Start** > **Settings** > **Windows Update** .
- In Windows 10, you decide when and how to get the latest updates to keep your device running smoothly and securely. To manage your options and see available updates, select Check for Windows updates. Or select the **Start** button and then go to **Settings** > **Update & Security** > **Windows Update**.

Please always keep your operating system up to date to ensure device security of the workstation, first and foremost with all updates labelled "**Security Update**", "**Service Pack**" and "**Security-only update**".

1.8.3 Device security features and anomaly detection

The system provides inbuild features for device security, especially for all used ports and network connections as follows:

- DICOM conform SCP/SCU protocol only allowing known AETs and ports for connection
- WAP2 secured Wi-Fi connection of Infinity box and computer
- Password protected user configuration for settings changes

The systems' connections can be compromised in very rare cases of a cyber-attack, if the inbuild measures are overcome or a to date unknown vulnerability is exploited.

The system will log all unauthorized access to the database, settings changes and will allow retrospective traceability.

If present functionality was working and suddenly stops working including,

- DICOM data cannot be send and/or is rejected from the PACS
- Ultrasound image data cannot be retrieved in acquisition mode
- The PIUR Sensor is not connecting but has more than 1% battery charge
- Patient browser stops displaying patients and patient data
- The antivirus program detected a virus or a malware

Please reach out immediately to PIUR Support (Section 8.2 Contact) if one of the above scenarios occurs and the user expects the system to be compromised. The scenarios above do not necessary indicate an attack but need to be analyzed in detail by the support team to exclude an attack as root cause.

1.8.4 Backup, retention and recovery of device configuration

The user of the PIUR tUS Infinity system is responsible for securing the computer that runs the PIUR software against data loss and access by non-authorized users. The database is encrypted to reduce the risk of non-authorized access.

The system performs automatic database backups for disaster recovery. It is highly recommended to setup a redundant array of independent disks (RAID), mirror the hard disk content on a cloud server or perform regular manual backups of the hard disk to not lose the data. The backup is described in Section 5.3.

For recovery of backed up data, please reach out to PIUR Support (Section 8.2 Contact).

To backup user configurations, please backup the folder C:\ProgramData\piur imaging\PIUR tUS into a secure location. If you decided to setup a RAID or cloud server backup of the complete hard disk, this step is not necessary for device configuration backup.

PIUR Service will backup the folder upon finished installation and secure it for the user for disaster recovery, but cannot back up any changes made by authorized users after installation.

1.8.5 User security configuration recommendation

The user of the PIUR tUS Infinity system is responsible for securing the computer that runs the PIUR software against data loss and access by non-authorized users. It is highly recommended to restrict access to the computer using password protection. If several users have access to the computer, it is recommended to restrict access to the PIUR software for selected users, for example through drive-partition or access restrictions to the installation folder. To protect the computer against non-authorized access, it is recommended to install an anti-virus application, a firewall.

The manufacturer suggests the most recent versions of the following anti-virus and malware detection programs:

- Norton 360 Antivirus
- TotalAV Pro Antivirus

The anti-virus program should allow the communication through the ports detailed in Section 1.9.1. Reach out to PIUR Support (Section 8.2 Contact) for assistance on setup and configuration.

A recommended total scan of the system should be performed at least each quarter, higher frequency leads to higher security of the operating system.

1.8.6 Security on end of support and end of life

There is currently no end of support nor end of life for this product planned.

1.8.7 Security recommendations on decommissioning

The PIUR tUS Infinity system including the PIUR Sensor and Infinity Box do not contain any sensitive data.
The system must be disposed in accordance with the national guidelines for electronic scrap. Alternatively, the device can be sent back to the manufacturer for disposal.

The sensitive data on the hard disk contains the patient database and user settings. To uninstall the PIUR software from the computer, use the built-in Windows function "Add or remove programs" to run the PIUR uninstaller. Please note that this removes the PIUR software only, acquired image and patient data will remain on the hard drive. To delete all image and patient data from the hard drive permanently, delete the folder "piur imaging" located in the installation drive. Make sure that the data does not remain in the Windows Recycle Bin. It is recommended to perform a full backup of the data beforehand, since this process cannot be undone.

For physical, non-recoverable disposal of the data, the hard disk of the computer needs to be physically destroyed.

1.9 Contact and Regulatory Information

PIUR tUS Infinity is a medical device of Regulatory Class II, in accordance with 21 CFR 892.2050.

Conformity of this product according to the general safety and performance requirements was proved with the Conformity Assessment Procedure.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. The manufacturer documents that with the Rx only symbol.

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2 Safety Regulations

The assembly of medical electrical systems and changes during the actual service life require a check with regard to the requirements set out in EN 60601-1 clause 16. Electrical installations in the room where PIUR tUS Infinity is used shall comply with the following:

	To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth
	Do not modify this equipment without authorization of the manufacturer.
	Connect only items that have been specified as part of the medical electrical system or that have been specified as being compatible with the medical electrical system. An additional multiple socket-outlet or extension cord must not be connected to the medical electrical system.
	The system is suitable for use in hospitals and professional healthcare environment except for near active HF surgical equipment and the RF shielded room for magnetic resonance imaging, where the intensity of EM disturbances is high.
	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
	Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PIUR tUS Infinity System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	If malfunctions and defects occur. **Occurrence of malfunctions and defects can lead to personal injury or damage to the device.** If malfunctions and defects occur, discontinue the use of the PIUR tUS system and inform our service team via the above contact details.

	The Sensor contains LED for skin illumination. During the acquisition, this LED should not face the eye.
	Do not exchange batteries without authorization of the manufacturer.
	The Ethernet cable used for the Infinity Box must be strictly limited to a maximum length of 1 meter.

Only the in chapter 4.1 specified power supply shall be used.

2.1 User Requirements for Use

- The user has been officially trained by an authorized person in using PIUR tUS Infinity and is issued with a corresponding certificate.
- The training is provided by authorized service personnel and follows the training protocol.
- The training includes system setup, patient management, image acquisition, image review, data export/import, typical errors of use, possible system errors and system shutdown.
- The clinical system integration must be performed by trained service personnel to ensure correct system operation and to avoid measurement errors.
- The assistants have carefully read and understood the User Manual.
- The user is required to observe the safety instructions and to adhere to the safety provisions.
- The user must be a physician skilled in ultrasonic diagnosis.
- Users have knowledge of human anatomy.
- Users have practical experience in the use of ultrasound for medical diagnostics and the fields of applications in which they use PIUR tUS Infinity.
- Patient should not move during the image acquisition as it could possibly lead to wrong image data.
- The acquisition should be performed with the recommended speed of 1 – 2 cm/s
- Users have sufficient knowledge of the English language.

3 Product Information

3.1 Functionality of the PIUR tUS Infinity

PIUR tUS Infinity is a computer-aided solution to aid in the diagnostic workflow of thyroid and thyroid nodules, including image documentation, analysis, and reporting. Computer vision and machine learning algorithms are applied to a sequence of ultrasound images of the thyroid that have been acquired by a compatible FDA-cleared ultrasound system. The solution identifies the thyroid lobe and proposes its margins to the user who then can make adjustments to the segmentation and approve the final result. Based on this, a lobe volume is being calculated. With additional user input, thyroid nodules can be marked, quantified, and visualized as multiplanar reconstructions or 3D volume renderings. The system provides a user interface for the user to select the five ACR TI-RADS parameters and calculates the ACR TI-RADS level from the user input for each nodule. All results must be verified, adjusted if necessary, and confirmed by the user before they can be added to an automatically generated clinical report.

The Infinity software runs on a stand-alone computer (Infinity Workstation – not part of the medical product) that fulfils the defined minimum requirements. It takes as an input a sequence of ultrasound images that are transmitted from the ultrasound to the Infinity Workstation wirelessly through the Infinity Box. The Infinity Box is a piece of hardware that connects to compatible standard ultrasound systems via digital video output such as HDMI or DVI. It grabs 2D ultrasound images through a video grabber and transfers the images to the Infinity Workstation via Wi-Fi in real-time. In addition, a small Infinity Sensor must be clipped onto the ultrasound transducer using individually designed attachments. An inertial measurement unit (IMU) tracks the orientation of the transducer during the scan and sends this information to the Infinity Workstation via Bluetooth. The Infinity Workstation combines information from the Infinity Box and Sensor to generate tomographic 3D ultrasound volumes on which the above-described image analysis can be performed.

The solution is intended to be used on patients aged 22 and older, independent of gender, linguistic and cultural background, or health status, unless any of the contraindications apply, in a non-sterile environment.

The solution is not intended to be used on patients with open wounds or irritated skin or during surgery.

3.2 Clinical Indications

Clinical Indication:

- Thyroid

Table 1 PIUR tUS Infinity apps and Respective Clinical Indications

App	Respective Clinical Indication
Thyroid App	Thyroid

3.3 Contraindications

The PIUR tUS Infinity system must not be used under the following conditions:

- On patients with open wounds or irritated skin
- During surgery

3.4 Clinical Benefits

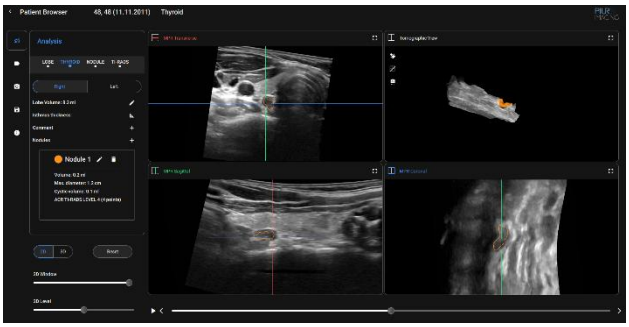
Key Features and clinical benefits of the PIUR tUS Infinity Thyroid application:

Key Features and benefits of the PIUR tUS Infinity Thyroid application:

- Multi-planar reconstructions
- Voxel-based volume measurements
- Semi-automatic lobe segmentation and volume measurements
- Semi-automatic nodule segmentation, nodule volume measurements
- Standardized reporting
- 3D Visualization of lobe and nodules
- Visual explanation of disease and treatment decisions to patient
- Full image documentation of lobe and nodules in one volume scan
- Side-by-side comparison of two datasets to monitor disease progression over time
- Reduced inter- and intra-observer variability compared to standard 2D ultrasound

4 Initial Use

4.1 Delivery Package



PIUR tUS Software
(installed)

PIUR tUS Infinity Quick Guide

PIUR Bracket
(depending on ultrasound system)

PIUR Sensor
REF 3000

Video cable HDMI-HDMI
REF 2130
(max. length 2 m)

Infinity Box
REF 1000
(HDMI input for video cable to connect with ultrasonic device)

Video adapter HDMI-DVI
REF 2133

Video adapter HDMI-Displayport
REF 2134

Infinity Box power supply cable
NEMA 5-15P to IEC 60320 C13 power cord (max. length 3 m)

Infinity Box power supply
REF 1001

LOGITECH control
REF 2140
Remote control to start, stop image acquisition, and take screenshots on PIUR tUS device

Anker Wireless charger
REF 3300

Suitable cables for the mains plug of the respective countries are supplied by the manufacturer and can be reordered if necessary.

4.2 Equipment of the Main Components

4.2.1 Requirements for the computer (laptop)

The PIUR tUS Infinity software is designed to run on a common computer (laptop) and all platforms basically that meet the following requirements:

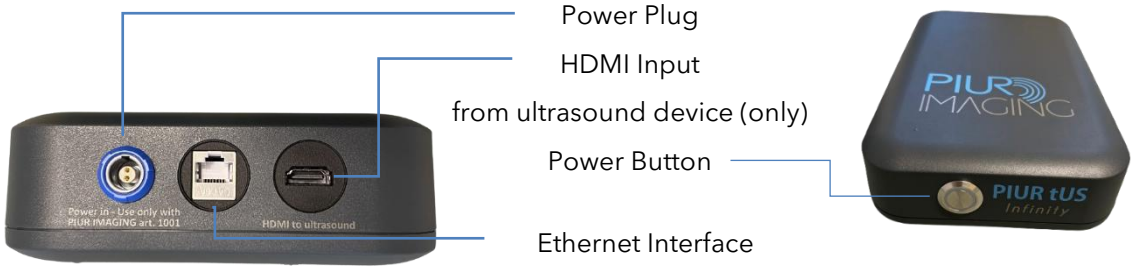
Minimum requirements:

- Windows operating system
  - Windows 10 64-bit, version 1803 or higher
  - Windows 11 24 H2 64-bit
- Full HD Display (1920x1080 pixels)
- NVIDIA Graphics Card with at least 4 GB GPU memory (e.g. NVIDIA GeForce GTX 1050 or similar)
- **Important:** Must be NVIDIA 16th series or newer (e.g. GTX16XX, RTX20XX, RTX30XX, RTX40XX) or equivalent NVIDIA workstation card.
- Quad-core processor (e.g. Intel i5 or AMD Ryzen 5)
- 8GB RAM
- Bluetooth 4.0 (supporting Bluetooth Low Energy)
- Wireless LAN (5 GHz Wi-Fi, supporting 802.11n standard)
  256GB SDD

Recommended requirements:

- Windows operating system
  - Windows 10 64-bit operating system, version 1803 or higher
  - Windows 11 64-bit operating system
- Full HD Display (1920x1080 pixels)
- NVIDIA Graphics Card with 8GB GPU memory (e.g. NVIDIA GeForce RTX 3050)
- **Important**: Must be NVIDIA 16*th* series or newer (e.g. GTX16XX, RTX20XX, RTX30XX, RTX40XX) or equivalent NVIDIA workstation card
- Hexa-core processor (e.g. Intel i7 or AMD Ryzen 7)
- 16GB RAM or more
- Bluetooth 4.0 or higher (supporting Bluetooth Low Energy)
- Wireless LAN (5 GHz Wi-Fi, supporting 802.11n standard)
- 1 TB SSD

4.2.2 Equipment of the Infinity Box



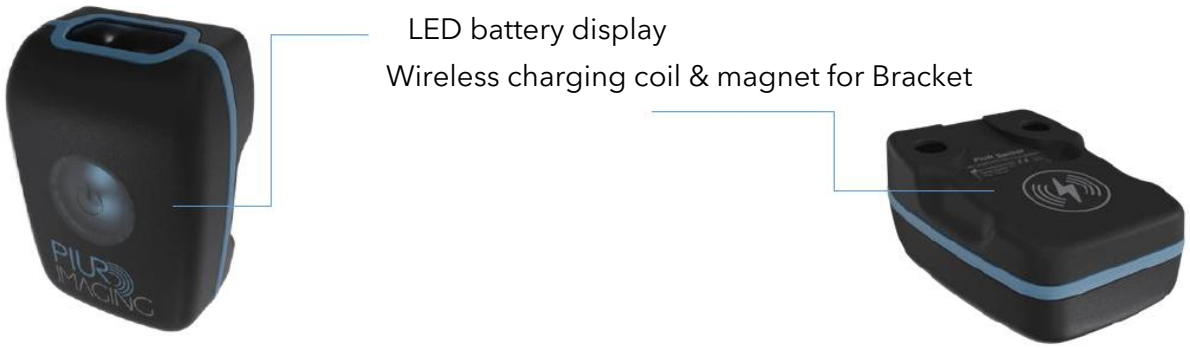
The video streaming box has an integrated frame grabber that continuously sends video signals to the computer. The box is automatically connected to the computer by internal Wi-Fi or through the

Ethernet interface. Ensure that the selected connection method is active and that the computer and the box are within range when using Wi-Fi.

In addition, the video box must be connected to the ultrasound device with a video cable, while its connection to the computer is established either wirelessly (Wi-Fi) or by Ethernet cable. The box can be attached to the ultrasound device using the included mount.

4.2.3 Equipment of the PIUR Sensor

Properties



The PIUR Sensor provides information about movement of an ultrasound transducer. It is embedded in a protective housing, which is fixed to the ultrasound transducer through a bracket. The PIUR Sensor can be charged using the provided wireless charger through the Qi 1.2 standard. The Sensor connects to other devices through a Bluetooth interface.

Information:

LED display provides information about the system status

The PIUR Sensor falls into sleep-mode if battery status is lower than 10% or if sensor has been disconnected for 10 minutes.

➔ Sensor can be re-started manually by pressing the start-button

The PIUR Sensor should be charged immediately after it shows battery status low and before the PIUR Sensor is not in use for a longer period.

Do not connect other Bluetooth devices like headsets or phones with the computer while using the PIUR Sensor

The damage of the sensor window from sharp tools or strong mechanical forces can result in harm to internal electronics, consequently, leading to the non-usable system.

Status	Color	Position
Sensor is charging	fading green	On the charging Dock
Sensor after turned on & searching for connection (Sensor <15%)	yellow	During use
Sensor after successful connection (Sensor <15%)	yellow	During use
Sensor after turned on & searching for connection (Sensor >=15%)	blinking blue	During use
Sensor after successful connection (Sensor >=15%)	static blue	During use
Sensor lost connection	blinking blue	During use
Sensor has error	blinking yellow	During use
Sensor startup	static white	During use

4.3 Connection with the Ultrasound Device

The computer on which the PIUR tUS software is used is connected to the Infinity Box via Wi-Fi. The Video Box connects to the ultrasound device through a video cable. Two cables suitable for the respective ultrasonic device (DVI and HDMI) are included. The PIUR Sensor provides the information of the Video Box to the computer, which processes the information using the software.

1. Connect the video cable to the ultrasound at the intended video output and connect it to the Infinity Box (HDMI)
2. Turn on the Video Box with the power button and then make sure the Box is connected to the computer via Wi-Fi or Ethernet.

Network: PIURtUSInfinity-*SerialNumber*

Password: *last 4 numbers of serialnumber*-*9 digits of randomized upper & lower case letters*

Exclusively ultrasound device(s) integrated by PIUR must be used. The use of an ultrasonic device of different type or manufacturer is prohibited.

4.3.1 Requirements for connected Ultrasound Devices

- The US Device has an HDMI, DisplayPort, or DVI video output
- The US Device has a minimum screen resolution of 1280 x 720 pixels

4.3.2 Compatibility

Compatible ultrasound transducers need to meet the following requirements:

- Type: Linear Array Transducer
- Frequency: between 7.5 and 15 MHz
- Depth: covering at least 3cm to 6cm

The transducers must be released for thyroid examinations by the third-party ultrasound manufacturer. It is recommended to select a thyroid preset at the ultrasound scanner before image acquisition.

The following probes can be used for PIUR tUS Thyroid acquisitions:

Manufacturer	Transducers
GE HealthCare	ML6-15, 9L, L3-12,
	ML4-20
Mindray	L12-4S, L13-3Ns
Philips	L12-5, L12-4, L12-3
Toshiba / Canon	11L3, 14L5,
Siemens	9L4, VF12-4, 14L5, 18L6
	10L4, L15-4
Hitachi / Fujifilm	L18-5
Supersonic	L18-5
Alpinion	L3-12H-WD, L3-12X
Vinno	F4-12L
ESAOTE	L4-15, L3-11

Please note that this list is not complete. If your thyroid transducer or ultrasound brand is not listed above, reach out to your local company representative or contact our service team at **service@piurimaging.com.**

4.4 Switching on PIUR tUS Software

1. Make sure the video cable is plugged between the Infinity Box and the ultrasonic device
2. Make sure that the ultrasonic device and computer are switched on and that the respective components are connected to each other
3. Turn on Infinity Box pressing the button
4. Open the PIUR tUS software by double clicking on the icon

It is recommended to close all other running applications before using PIUR tUS software to optimize performance.

The software checks the required resources when it starts to make sure enough memory is available.

Make sure there is a connection to all components. If one of the devices is not connected, no image will be transferred to your computer.

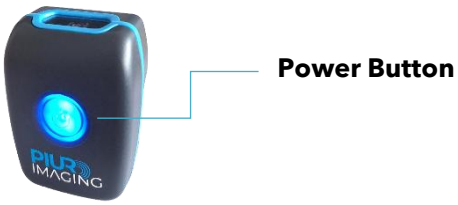
The device is properly installed and can operate safely and correctly if the following criteria are met:

- ☐ PIUR Sensor Illumination is blue
- ☐ Software is started
- ☐ Infinity Box is connected to ultrasound system with a video cable
- ☐ Infinity Box is connected to the computer wirelessly (Wi-Fi) or by Ethernet cable

The connection to the supply system can be separated by pulling the power plug or device plug. Make sure that the system is placed in a way that the power outlet or the device plug can be reached easily.

4.5 Switching the PIUR Sensor On and Off

1. Turn on the sensor by pressing the Power Button before scanning



2. A blinking blue LED light will signal that the sensor is operational
3. If not in use for several minutes, the sensor will automatically turn off
4. It can be turned off manually by pressing the Power Button
5. A static blue LED light on the sensor signal that it is connected and ready for scan acquisition.

- Make sure the PIUR Sensor is fully charged before operations.
- It is recommended to charge the PIUR Sensor after each use.
- When multiple sensors are configured in the software, only one sensor should be powered **on** at a time. All other sensors should remain ideally on the charging pad.

4.6 Charging and Storing PIUR Sensor

Charging of PIUR Sensor is done wirelessly.

1. Place PIUR Sensor on a charging pad.
2. A charging label printed on the bottom of PIUR Sensor must align with the center of the charging pad.

Figure 1: PIUR Sensor on a charging pad

LED feedback:

Illumination	Information about system status
▪ Fading green	On the charging pad, battery is charging

4.7 Securing the PIUR Bracket to the Probe

4.7.1 Identifying the correct PIUR Bracket

The PIUR Bracket matching your ultrasound transducer can be identified by its label. The Bracket label has the following format:

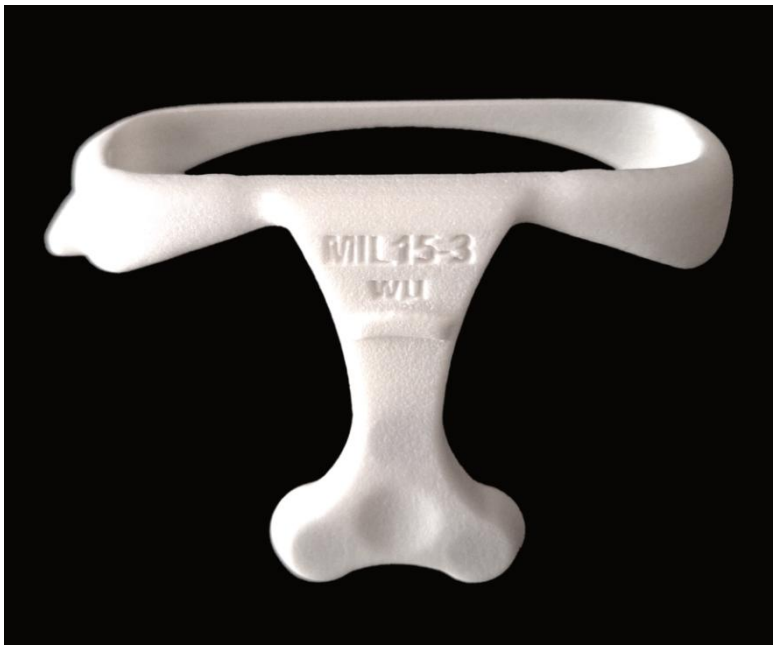


Figure 2: PIUR Bracket side and front view

The first two letters stand for the brand of the ultrasound transducer, following the coding scheme:

Letter on Bracket	Transducer Brand	Letter on Bracket	Transducer Brand
AP	Alpinion	SI	Siemens
ES	ESAOTE	SP	Sonoscape
FJ	Fujifilm Sonosite (Hitachi)	SU	Supersonic
GE	GE	TE	Telemed
MI	Mindray	TO	Toshiba (=CANON)
PH	Philips	TR	Terason
SA	Samsung	VS	Visualsonics

The part after the letter corresponds to the transducer's name. For example, bracket MIL15-3 fits the ultrasound transducer L15-3wu manufactured by Mindray. MI – transducer brand, L15-3wu – transducer name.

4.7.2 Front clip

Turn the probe as shown in the picture

Hook the PIUR Bracket to the right side of the probe and pull the clip on the Bracket plate over the sensor head until it locks into place with a click. Ensure the correct orientation of the probe.

The front clip must be correctly locked in and secure.

Information: Follow the User Manual in the reverse order to disassemble the clip.

Safety Notice: Use of not certified Brackets

- Only officially attachments delivered by piur imaging GmbH are allowed to be used with the device.
- The Bracket contains permanent magnets. To ensure correct system functioning, only use the supplied Brackets and mount them following the instructions in this User Manual.

4.7.3 Securing the sensor housing on the front part of the bracket

Place the sensors on the Bracket docking plate. The sensor should be attracted easily by the docking plate.

Make sure the sensor is snapped in properly before continuing with the acquisition workflow.

Information: Follow the User Manual in the reverse order to disassemble the attachment.

5 Using the PIUR tUS Software

5.1 PIUR tUS Start Screen

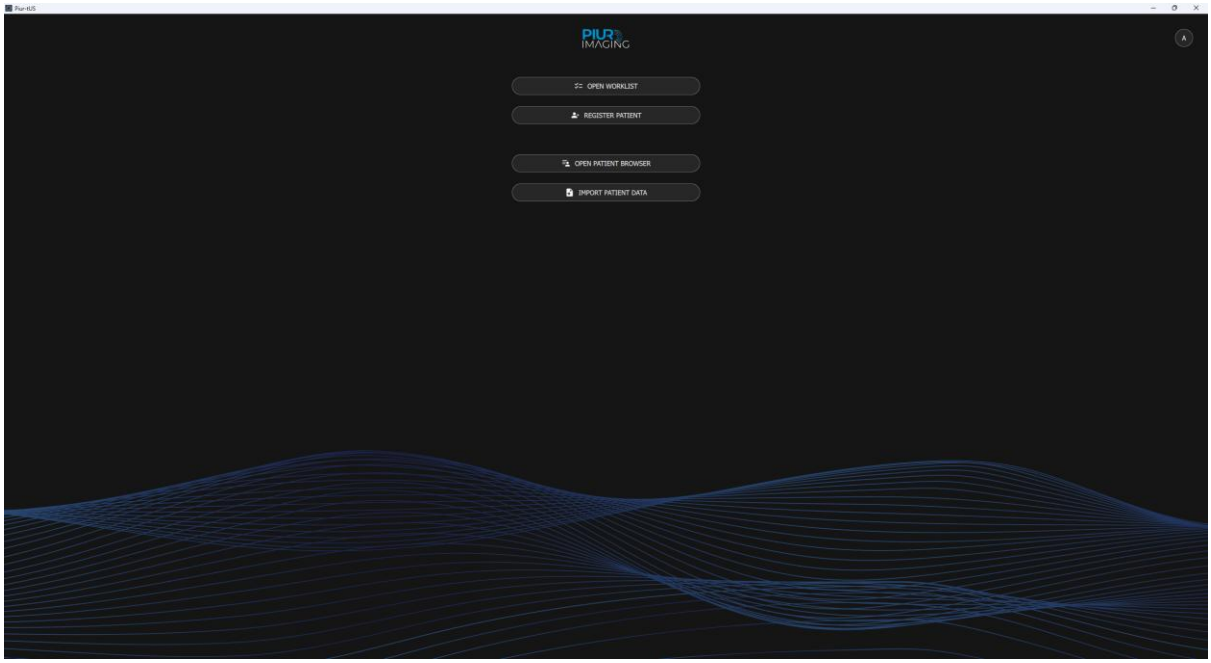


Figure 3: PIUR tUS starting screen

Explanation of the symbols and functions:

"Open Patient Browser"	Opens the patient database in which the files from the existing patients are located.
"Open Worklist"	Opens the worklist interface, to insert the patient information provided by the worklist server.
"Register Patient"	Opens a window to register a new patient.
"Import Patient Data"	Opens an explorer window to import patient data.

5.2 User Menu

Click on the User Icon in the top right corner

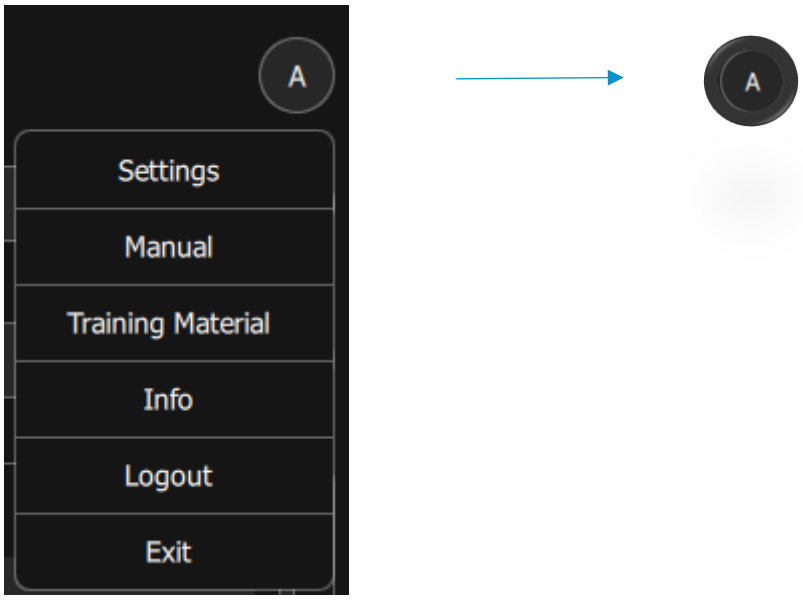


Figure 4: User Menu

Explanation of the symbols and functions:

"Settings"	Opens the screen where "User Settings", "General", "Infinity Box & Sensor", "PACS & Worklist" and "Licensing & Integration" can be modified.
"Manual"	Opens the digital user manual.
"Training Material"	Opens a window with a link and a QR code forwarding to Training Videos on the piur imaging website, and the keyboard shortcuts guide.
"Info"	Opens a window with current information about piur imaging GmbH, Software version, build date, supported Infinity Box Version, PIUR Sensor Version and certificates.
"Logout"	Logs out the User.
"Exit"	Closes the application.

5.3 Register New Patient

a) Click on "Register Patient"

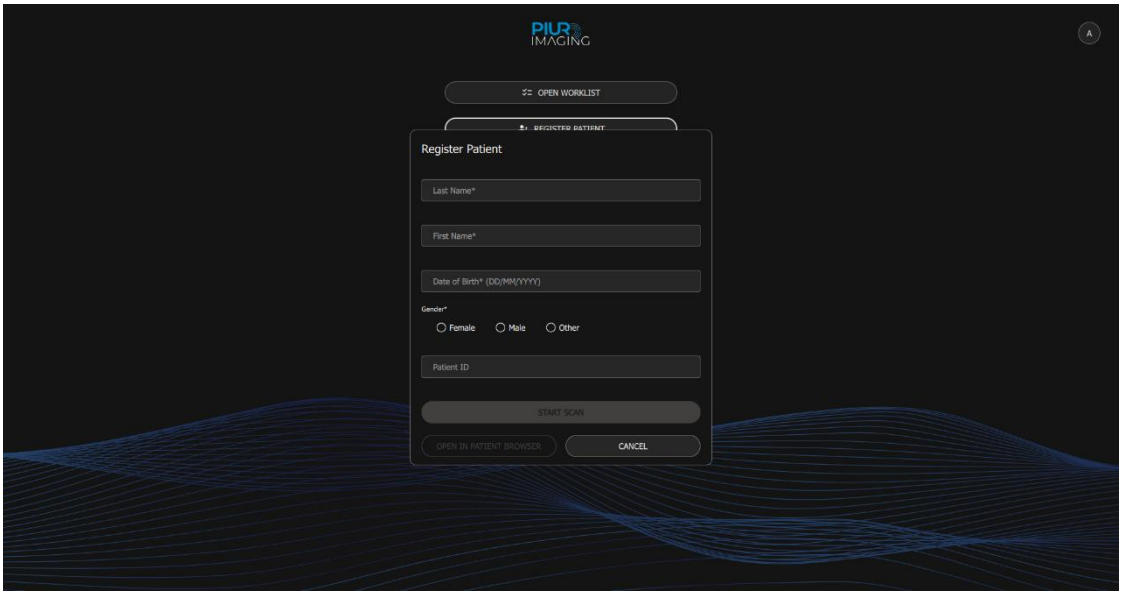


Figure 5: User interface "Register Patient"

b) Enter all the required data in the fields provided. Entries are mandatory for fields marked with *.

c) Confirm the entries with the button "Start Scan" or "Open in Patient Browser".

"Cancel"	Cancels the process, no new patient will be registered in the database.
"Start Scan"	Registers the patient after filling all fields and switches to "Acquisition mode".
"Open in Patient Browser"	Saves the new patient and automatically opens the patient browser.

5.4 Navigating in the “Patient Browser”

In the start screen, click on “Open Patient browser”

A list of the existing patients is displayed in the “Patient Browser”. By clicking on a patient, a further list opens with the scans previously taken for the selected patient. The free text search function and the sorting functions “Last name” / ”First name” / ”Patient ID” / ”Birth Date” / ”Last used” / ”Last study” / ”Status” can be used for a simplified patient search. Scans, Screenshots as thumbnails and reports are shown below the belonging study. Multiple patients can be selected by pressing and holding the “Ctrl” key and clicking on new patients from the list.

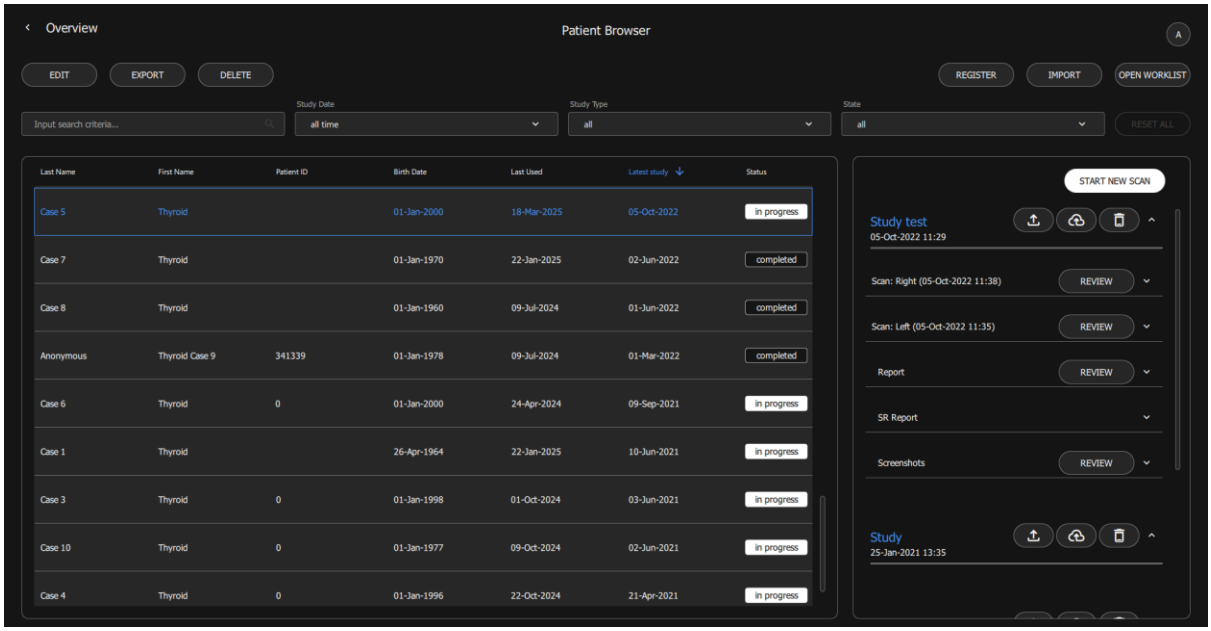


Figure 6: User interface "Patient Browser"

“Edit”	Opens patient registration window. All the patient information here can be edited and updated except the Patient ID.
“Export”	Opens the “Export” window for DICOM and PIUR Export. Single items from the patient can be selected.
“Delete”	Deletes the selected patient (incl. scans, screenshots, report) after confirmation.
“Register”	Opens “register” new patient window in the database.
“Import”	Opens the file explorer to import patient datasets from an external source (external hard disk or USB stick)
“Open Worklist”	Opens the worklist interface, to insert the patient information provided by the worklist server.

5.4.1 Patient menu

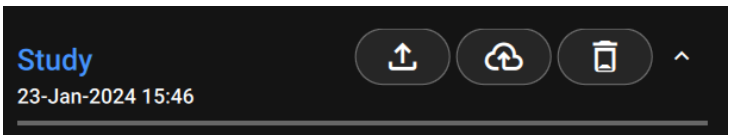


Figure 7: Options menu for exporting, sending to PACS or deleting a scan

Study	Double-click to change the name of the study
	Opens the "Export" window for DICOM and PIUR Export.
	Opens the „Send to PACS" window.
	Deletes the selected patient or scan / screenshot / report after confirmation.
	Scan/report/screenshots/all data of one patient was sent to PACS.
"Start new scan"	Switches to the acquisition mode to start a new scan for the selected patient. (Figure)
Scan "Review"	Opens the review screen with the acquired diagnoses and the possibility to start or redo the analysis (Figure)
Report "Review"	Opens report in Fullscreen. (Figure)
Screenshots "Review"	Opens screenshots in Fullscreen. (Figure)

Information: When a new scan is added to a patient or an existing report is updated, the corresponding "Sent to PACS" checkmarks in the Patient Menu are removed. This applies to each affected subsection, as well as the patient-level checkmark if all patient data had previously been sent to PACS. The checkmarks will remain absent until the new data is sent to PACS again.

5.4.2 Export

Studies can be exported either as DICOM or PIUR file. Click on the folder symbol to select the desired file path to store the entire study. Optionally, all files, image data (without labels) or just screenshots can be exported. In addition, by clicking on "Anonymize data" anonymized data can be exported for study purposes.

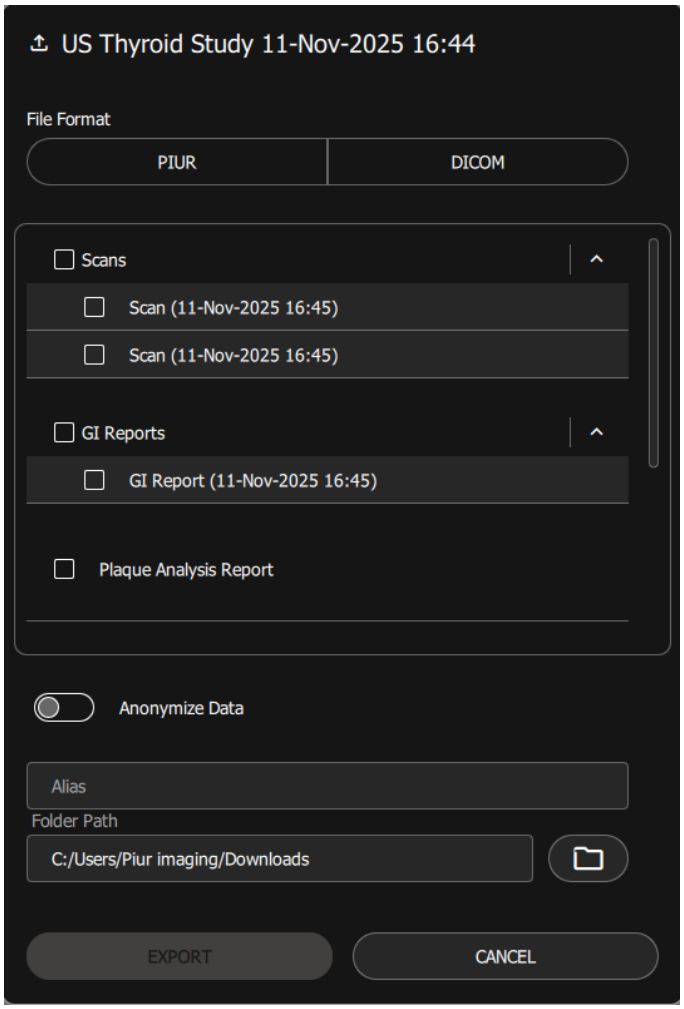


Figure 8: Export Study as DICOM or PIUR file

Anonymized data fields:

- Anonymized Patient name
- Anonymized date of birth, year remains
- Anonymized patient ID
- Anonymized hospital name

The DICOM section in User Settings provides options for configuring export settings. DICOM compression can be enabled to reduce file size and optimize storage, with a trade-off in scan quality. The volume memory limit can be adjusted within a range of 10 MB to 2000 MB, allowing customization based on system resources.

Within the Export DICOM Volume settings, there are three formats available:

- The MPR Sequences option can be enabled, and a desired Slice Thickness can be specified. After saving these settings and exporting a study as a DICOM file (as previously explained), additional files will be generated: sagittal and transversal MPRs. If the Export Coronal MPR option is activated, a coronal MPR file will also be included.
- The Secondary Capture option stores ultrasound frames as individual 2D images with real-world coordinates as additional DICOM data. Optionally, the export of full size, thyroid lobe, and thyroid nodule segmentations can be activated.
- When opening this volume in a DICOM viewer, if the viewer supports the reading of the additional spatial information for the Secondary Capture format, the volume can be reconstructed in 3D and the multiplanar reconstruction (MPR) can be displayed.
- The US Volume option stores the ultrasound sweep as a 3D dataset, maintaining the spatial relationships between the frames. This format allows for MPR, volume rendering, and the use of measurement tools.

During report export in DICOM format, it is possible to choose whether to export the DICOM Structured Report, the PDF embedded as DICOM, or both.

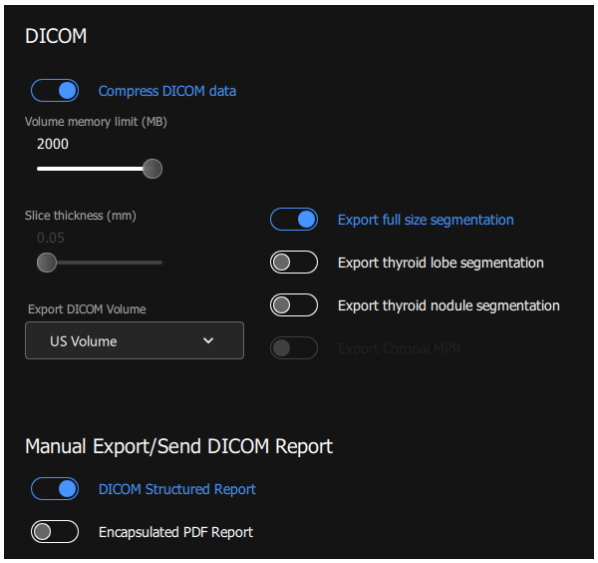


Figure 9: DICOM format options

5.4.3 PACS interface

The PACS is a digital system for processing, managing and archiving medical images and data. Image data of the modalities are sent to a central PACS server, stored there and in turn made available in diagnostic, viewing and post-processing locations. The merging of the individual modality takes place via DICOM format. Data can be sent to PACS from Patient Browser.

5.5 Acquisition Mode

After entering a new patient and selecting the function “Start New Scan” in the Patient Browser, the PIUR tUS Infinity automatically switches to the Acquisition mode.

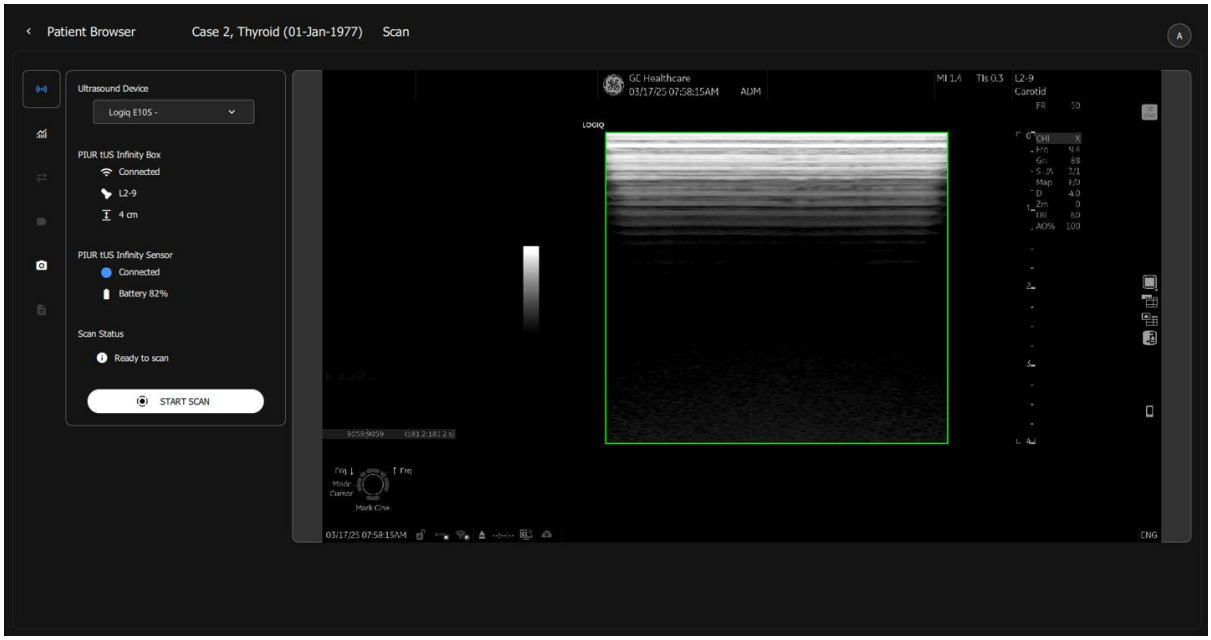
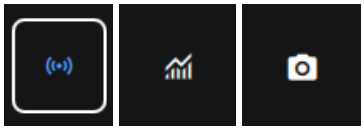


Figure 10: Acquisition mode

“Ultrasound Device”	If there is more than one ultrasound device configured with the PIUR tUS Infinity, the ultrasound device currently connected must be manually selected. If only one ultrasound device has been configured, this is automatically selected by the system.
“PIUR tUS Infinity Box”	Shows the status of the box connection. If there is no box connection, the user is informed to turn on the Wi-Fi on the PC in order to connect to the PIUR tUS Infinity Box. If the Box is connected and the correct US device configuration is selected, the transducer in use and the correct depth is displayed.
“PIUR Sensor”	Shows the status of the Sensor connection. If there is no connection, the user gets informed to turn on or charge the Sensor. If the Sensor is connected, it says “Connected” with a blue point. Below the battery level of the Sensor is displayed.

If the Scan Status is “not ready to scan”, the “Start” button is greyed out. The acquisition cannot be started.

If the Scan Status is “ready to scan” the “Start” button is active. An acquisition can be started. After starting, a "Stop" button is displayed in place of the "Start" button. Begin the probe movement after you heard the audio feedback. After acquisition, the system switches to the "Post-Acquisition Mode" user interface.



Side bar: when in the Acquisition screen, only two other buttons in the side bar will be available: switch to Review mode and take 2D Screenshots.

Information: It is possible to start and stop the scan with the optionally delivered remote control. The scan can be initiated and stopped by pressing the “right arrow” key of the remote control. The “left arrow” key allows to take a 2D screenshot when in the Acquisition mode, which will be automatically named “2D screenshot” and saved to the database as soon as an acquisition was performed right after the screenshot was taken.

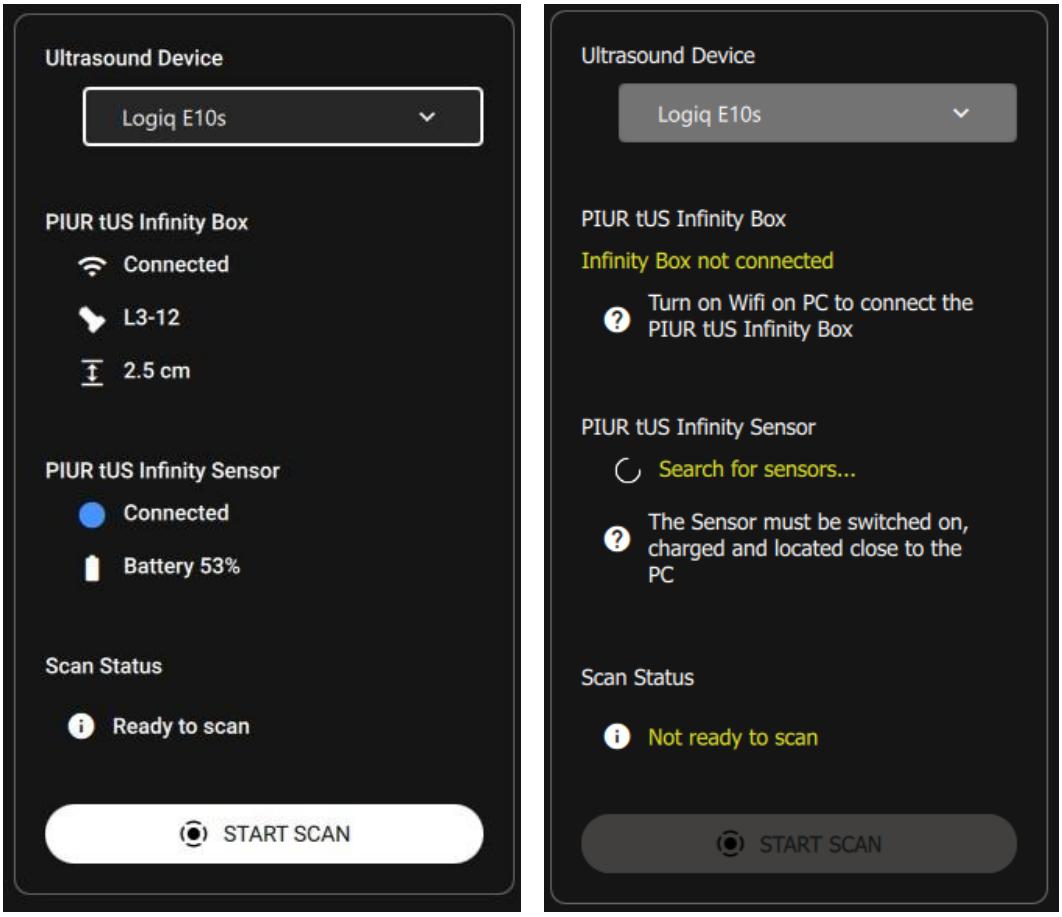
Important: Use of the delivered remote control may only be performed by the treating doctor/staff but **not** by the patient.

Safety Notice: Erroneous detection of parameters. In rare cases a system parameter can be wrongly identified. The Auto-detection symbol still lights green in this case.

- To avoid errors in the dataset, the parameters recognized by Auto-detection have to be checked visually before **every** acquisition.

5.5.1 Optical and acoustic signals in the “Acquisition Mode“

A series of optical and acoustic warning signals in the acquisition mode show application errors during the recording to ensure ideal handling and an optimal recording quality. The following table provides information on occurring warning signals:



Start/Stop beep	Starting and stopping an acquisition emits a significant two-tone beep.
Screenshot sound	Occurs when a screenshot is captured on the Acquisition screen.
Warning beep	Occurs if sensor and/or box are not connected, or wrong US device selected.

Information: Make sure the sound of the computer is turned on and the volume is high enough to hear all warning signals clearly.

5.5.2 "Post-Acquisition" mode

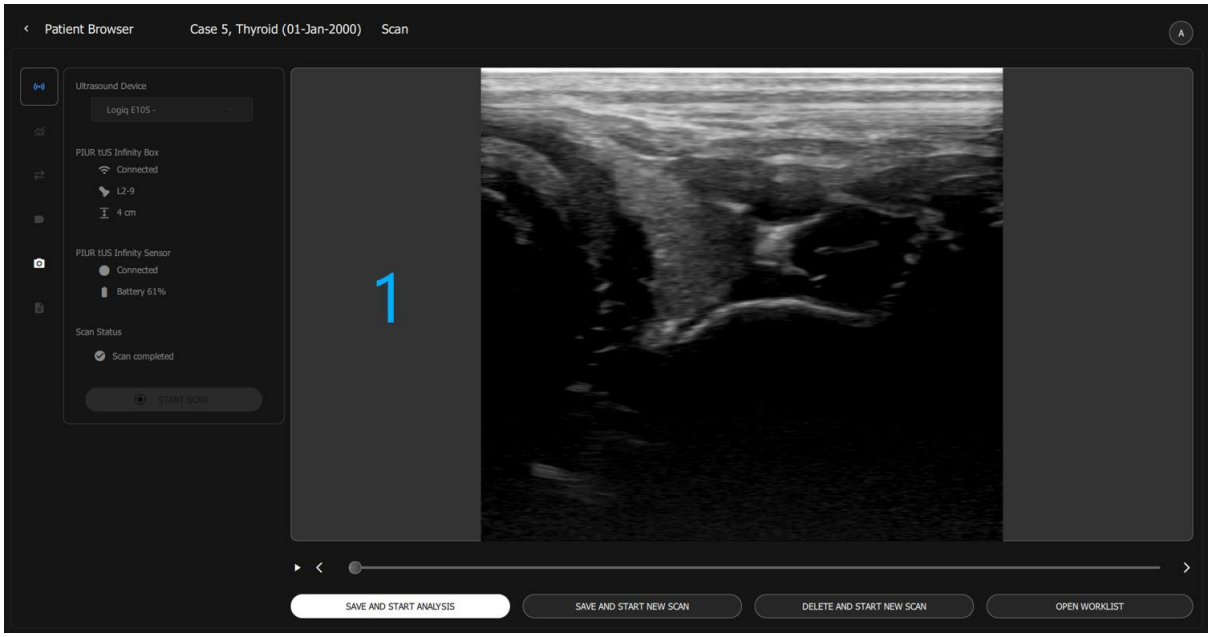


Figure 11: "Post Acquisition" user interface

1	"On-the-fly" transversal image display of the acquisition. The MPR slider can be used to scroll through the transversal planes of the acquisition.
"Save and start analysis"	Saves the acquisition and then switches to "Analysis" mode. (0)
"Save and start new scan"	Saves the acquisition and then switches back to the "Acquisition" mode to create a further scan.
"Delete and start new scan"	Deletes the acquisition and then switches back to the "Acquisition" mode to create a further scan.
"Open Worklist"	Opens the worklist interface, to insert the patient information provided by the worklist server.

5.6 "Review" Mode – Thyroid App

5.6.1 Display and operating Window in the "Review" mode

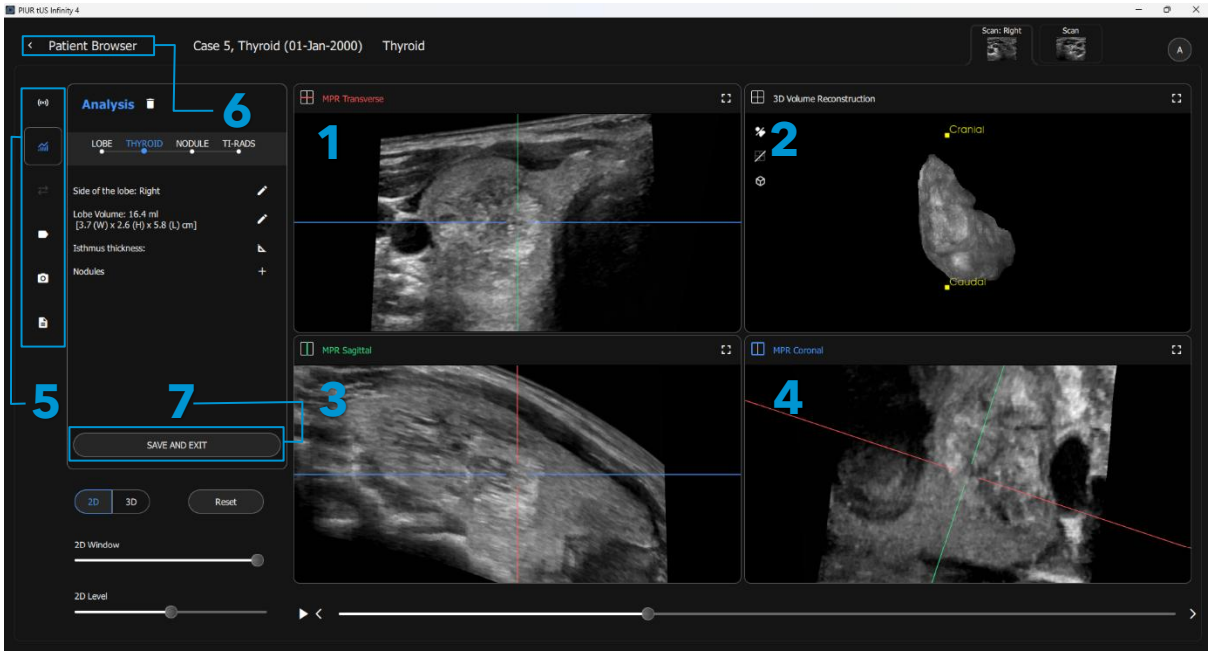


Figure 12: Operating window in the "Review" mode of Thyroid App

1	Multiplanar Transverse: Multiplanar reconstructions (MPR) of the transversal plane. Transversal section through the volume. With a left-click on the inner parts of the plane lines, both lines can be moved (green = sagittal and blue = coronal plane). By left-clicking on the outer parts of a plane line, the respective plane (transversal) can be rotated.
2	3D Volume Reconstruction: Represents the reconstructed ultrasound volume as a 3D reconstruction. Keep the left mouse button pressed to rotate the volume. The volume can be shifted with the middle mouse button pressed. The zoom factor can be set with the mouse wheel or moving the mouse vertically with the right mouse button pressed. The sectional planes (3, 4, 5) are represented in the 3D reconstruction as a box. which can be hidden and shown in the toolbar (see 5.6.2.2)
3	Multiplanar Sagittal: Multiplanar reconstructions (MPR) of the sagittal plane. Sagittal section through the volume. With a left-click on the inner parts of the plane lines, both lines can be moved (red = transversal and blue = coronal plane). By left-clicking on the

	outer parts of a plane line, the respective plane (sagittal) can be rotated.
4	Multiplanar reconstructions (MPR) of the coronal plane: Frontal section through the volume. With a left-click on the inner parts of the plane lines, both lines can be moved (green = sagittal and red = transversal plane). By left-clicking on the outer parts of a plane line, the respective plane (coronal) can be rotated.
5	Tool Selection: Provides different tools for scan acquisition, analysis, annotations, screenshots, and reports. (saving the changes in the report and sending to PACS if the Automatic Report and Autosend to PACS settings are activated).
6	Patient Browser button: Exits the scan.
7	When the Automatic Report setting is activated, the button "Save and Exit" saves all changes of all scans in the current study to the report.

Relevant for all 2D view windows:

Left click in the inner part of MPR-line	Moves both plane lines. Focus remains on same spot in image.
Left click in the outer part of MPR-line	Rotates the respective plane line. Focus remains on the same spot in image.
Left double click(in one 2D view)	Places the intersection point of the two planes at the point.
Left click hold and move up and down anywhere (in one 2D view) or scrolling the mouse wheel	Scrolling through the slices of the respective 2D view.
Right click hold and move up and down anywhere (in one 2D view)	Zooming in all three 2D views.
SHIFT + left click and move anywhere (in one 2D view):	Moves the image.
STRG + hold left click and move up and down anywhere (in one 2D view)	Up: increases window level Down: decreases window level
STRG + hold left click and move left and right anywhere (in one 2D view)	Right: increase level value Left: decrease level value
STRG + hold left click and move up/down and left/right at once	Combination of window and level value in-/decrease

5.6.2 Overview of the functions in the "Review" mode

5.6.2.1 Tool selection

	Go to Acquisition Screen
	Analyze Lobe and Nodules
	Annotations + Measurements, see Section 5.6.2.5
	Able to create 2D and 3D Screenshots
	See and update report

5.6.2.2 MPR view

The 2D and 3D view is controlled by (Hover symbol):

Icon	Function	Description
	Zoom	3D: zooms in and out 2D: zooms in and out in all 2D views
	Rotate	Rotates the MPR lines
	Move	Moves the MPR lines

The 3D View tools:

Icon	Function
	3D model of used transducer is visible in the 3D view.
	3D model of used transducer is **not** visible in the 3D view.
	MPR planes are visible in the 3D view.
	MPR planes are **not** visible in the 3D view.
	3D Volume Reconstruction is visible
	Original US frames are visible. The frame displayed is synchronized with the MPRs.

MPR slider:

The slider moves along the orientation of the Transversal MPR plane. The bar can be moved with the slider. Or a playback can be started/paused with the button. The left and right arrows can be also used for moving individual slices.

5.6.2.3 Window and level settings

The default Window and Level settings can be configured in the User Settings tab:

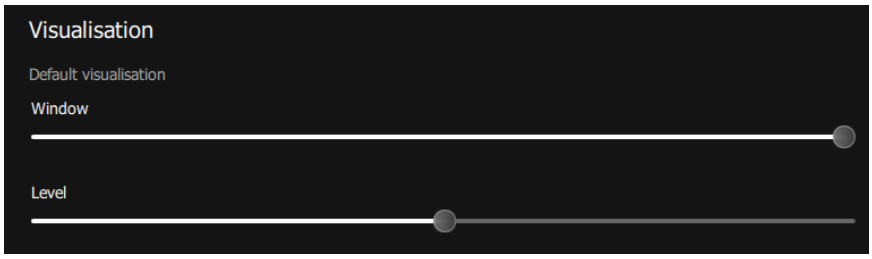
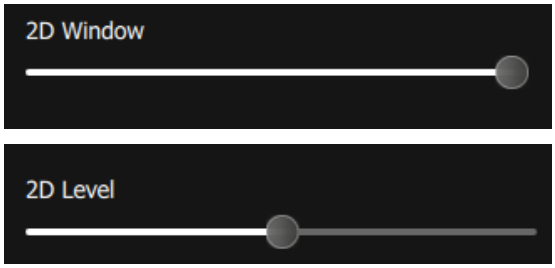
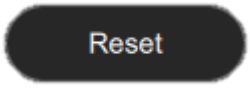


Figure 13: Default Window and Level in User Settings



The brightness and contrast can be changed with the slider. Switches to 3D when selected

Choose between 2D and 3D, to apply on the 2D MPR or 3D view.

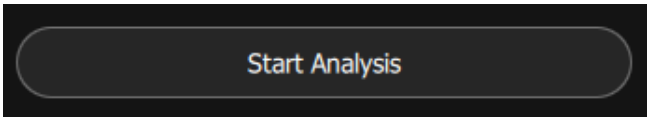


Reset the orientation of the MPR and 3D to default.

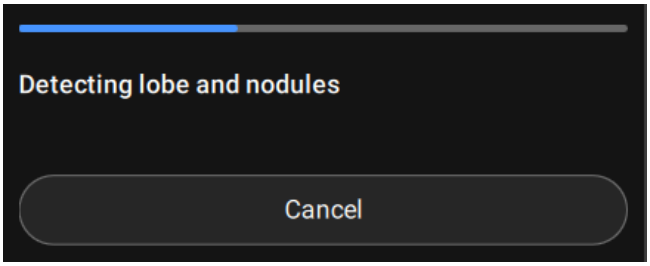
Reset the brightness of the image for 2D and 3D.

5.6.2.4 Image analysis

Menu Wizard

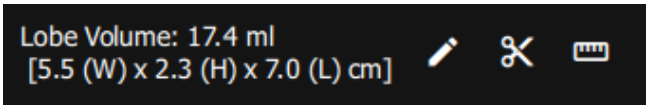


Press "Start Analysis" to trigger the prediction of the AI Network.



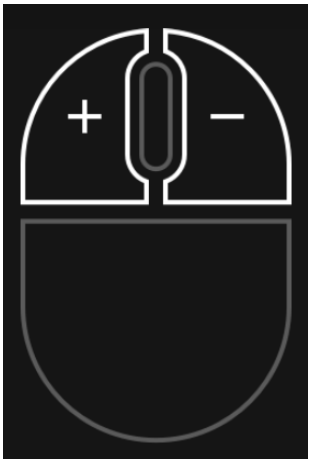
The progress bar gives indication regarding the process. There is also the option to cancel.

Auto-side selection. Side can be changed by clicking respective side button.



The automatic lobe volume is displayed. The options are "correction tool", "cut tool", "manual measurement tool".

Manual lobe segmentation correction tool.

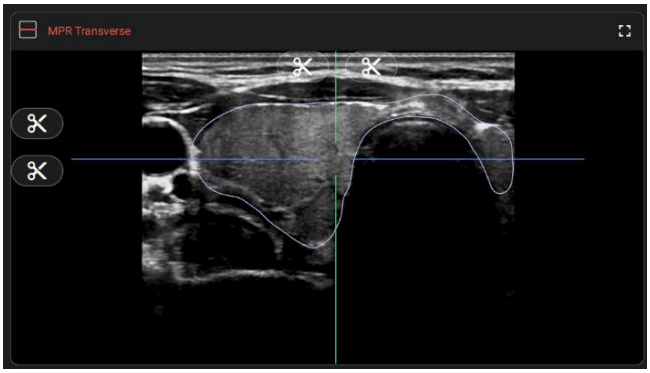
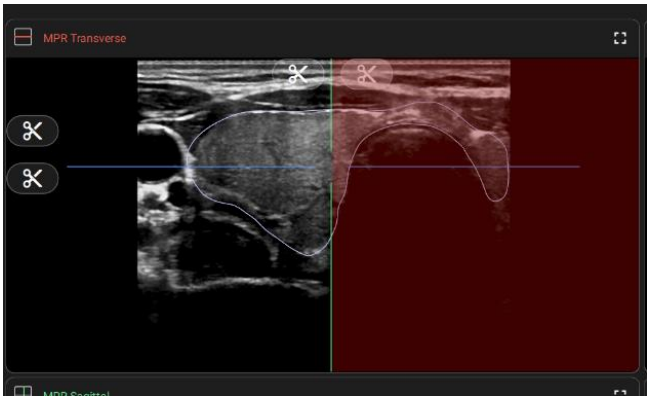
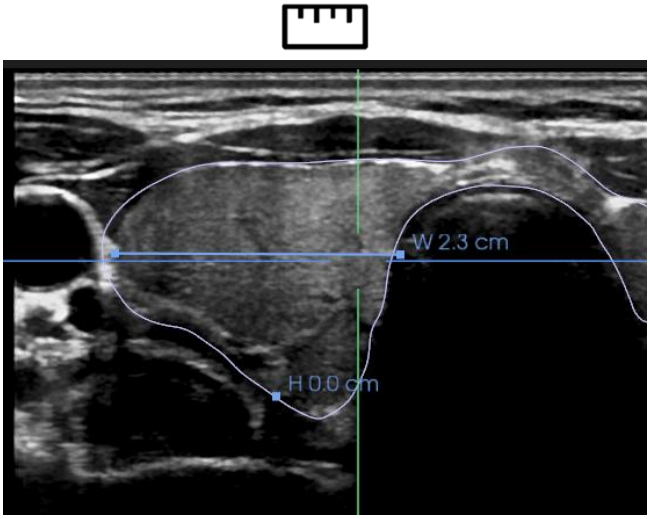
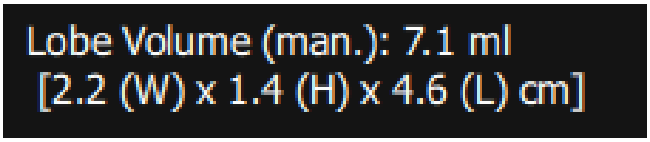


Here the user can adapt the automatic segmentation manually, by clicking the left and right mouse button as marked in the image.

"-" click and hold this button while moving over the parts of the segmentation which should be excluded from the volume segmentation

"+" click and hold this button while moving over the parts of the segmentation which should be included in the volume segmentation.

Press the scissor icon, to cut parts of the lobe volume.

	Cutting icons are displayed along the planes.
	Hover with the mouse over the icon gives a preview of the to cut area.
	3-line manual measurement tool (Width, Height and Length). Place the start and end point of each line by clicking in the 2D view. During the measurement, the respective letter is displayed next to the cursor.
	Lobe volume is adapted to the manually measured volume.
"Undo"	Jumps one step back, which was performed in the respective tool.
"Reset"	Resets all steps, which were performed in the respective tool.

	Accepts and saves the lobe including all editing steps to proceed with the analysis.

The thyroid analysis menu is illustrated below:

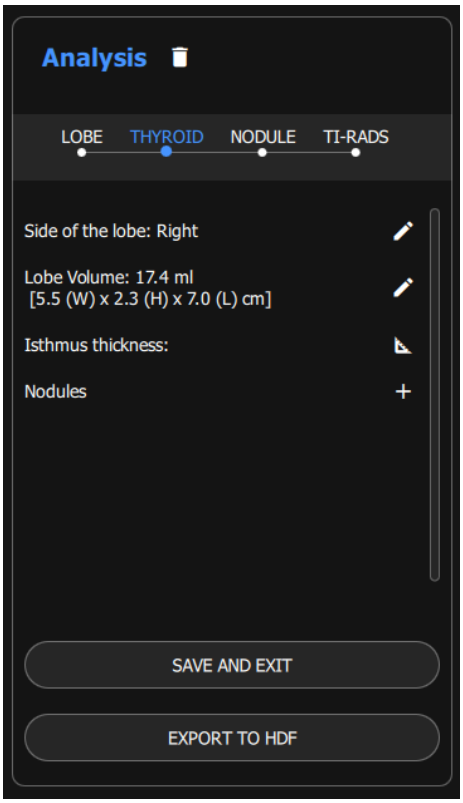
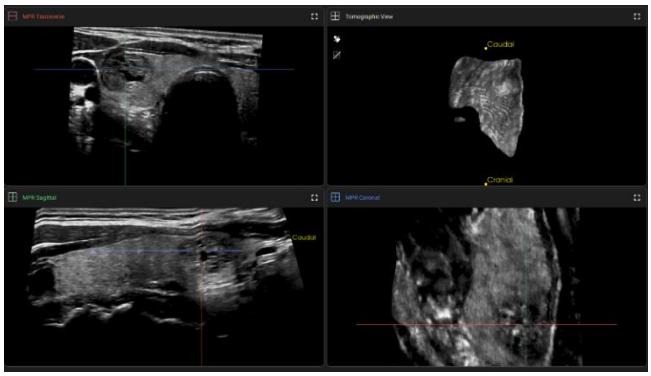
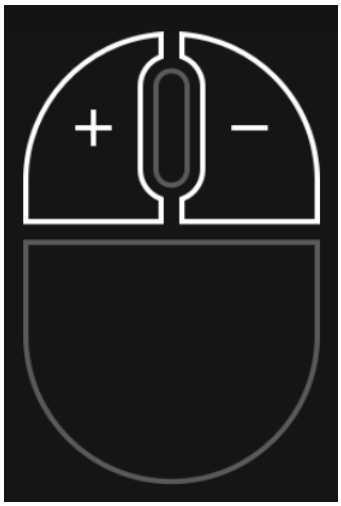
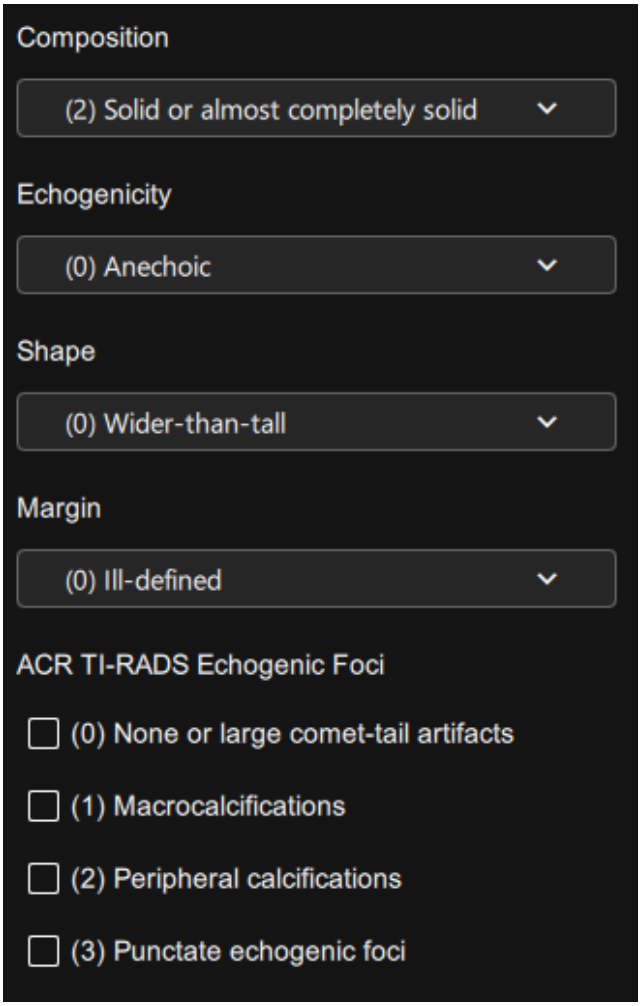


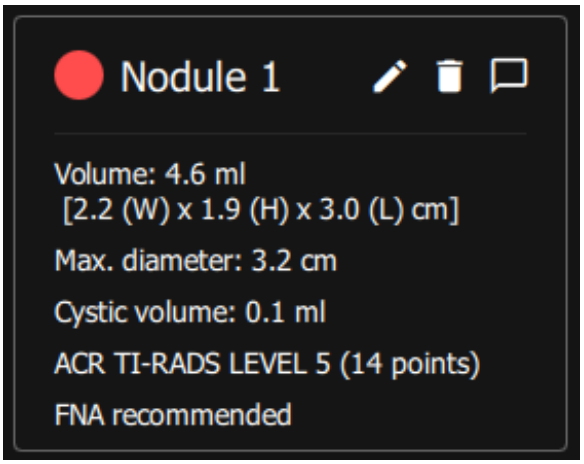
Figure 14: Thyroid Analysis Menu

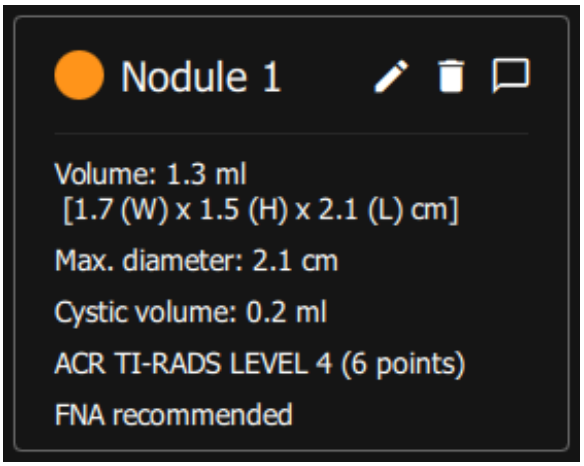
In thyroid analysis menu it is possible to proceed with the following options:

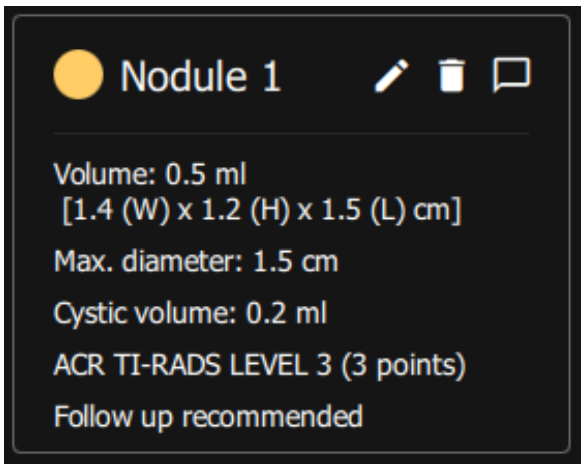
	Modify Side/ Volume of the lobe.
	Create a 2-point line measurement in the MPR to measure the Isthmus thickness.
	Add a nodule to the analysis by clicking on the "+" sign next to Nodules.

	Move the MPRs to the center of the targeted nodule. Click in the middle. The detected nodule is shown in the MPRs. This leads automatically to the manual nodule segmentation correction tool.
	Manual nodule segmentation correction tool. Here the user can adapt the automatic segmentation manually, by clicking the left and right mouse button as marked in the image. "-" click and hold this button while moving over the parts of the segmentation which should be excluded from the volume segmentation. "+" click and hold this button while moving over the parts of the segmentation which should be included into the volume segmentation. "H" click and hold disables the nodule segmentation mesh for better visualization during the analysis (also after finalizing one or several nodule analysis).
	Modify Volume of the nodule.
	3-line manual measurement tool (Width, Height and Length) as explained for the Lobe, but for the Nodule in this case.
	Discard the initial nodule segmentation mesh when automatic detection fails.
"Reset || Undo"	Click Undo to jump back one step in the nodule adjustment. Reset goes back to the initial view.

"Accept nodule"	Accepts nodule segmentation and jumps to ACR-TIRADs menu.
"Discard nodule"	Nodule is discarded and nodule menu is exited.
	Manually fill out the TI-RADS menu: Composition (0) Cystic or almost completely cystic (0) Spongiform (1) Mixed cystic and solid (2) Solid or almost completely solid Echogenicity (0) Anechoic (1) Hyperechoic or isoechoic c (2) Hypoechoic (3) Very hypoechoic Shape (0) Wider-than-tall (3) Taller-than-wide Margin (0) Ill-defined (0) Smooth (2) Lobulated or irregular (3) Extra-thyroidal extension ACR TI-RADS Echogenic Foci (0) None or large comet-tail artifacts (1) Macrocalcifications (2) Peripheral calcifications (3) Punctuate echogenic foci After reviewing and possibly adjusting, accept the selection.
"Accept"	Accepts the selected ACR-TIRADs points and the calculated TIRADs level.
"Skip"	Skips the ACR-TIRADs evaluation and shows only the nodule volume.







Overview of the nodule, including

- Volume
- Maximal diameter
- Cystic volume
- ACR TI-RADS Level
- FNA/ Follow-up recommendation

Three recommendations for Nodule are available:

- FNA recommended
- Follow up recommended
- No FNA, no follow up recommended

Add a comment, edit, or delete the shown nodule.

The arrow allows to jump between multiple nodules.

Saves patient analysis and exits the review screen back to the Patient Browser.

If **Automatic Report** generation and/or **Autosend to PACS** is turned on: sends all new changes since the last time.

In User Settings, it is possible to enable the following options:

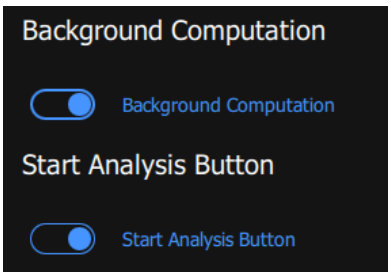
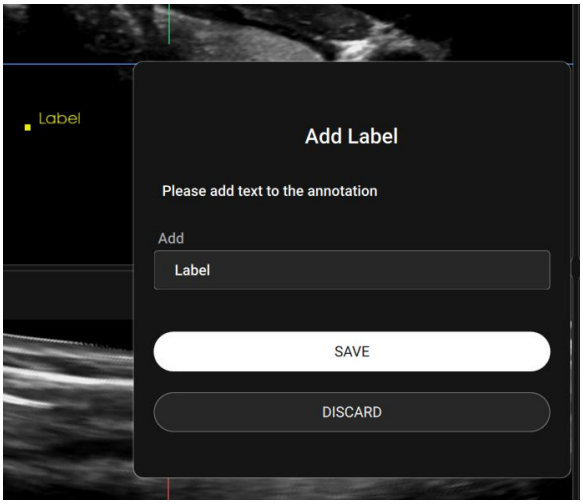


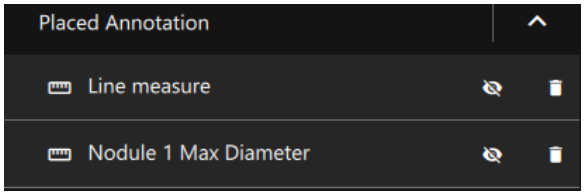
Figure 15: Analysis optimization User Settings

Below is the table describing each option in more detail:

"Background Computation"	The system starts the analysis for all yet non-analyzed scans within the last three weeks when the system is not being operated.
"Start Analysis Button"	When disabled, removes the "Start Analysis" button from the Review Mode and starts the analysis automatically.

5.6.2.5 Annotation menu

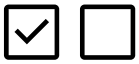
 **"Label"**	Choose between Label and Line Measurements.
	Target the marker in the MPR planes. Change Label name, discard or save.
"Line Measurement"	Target the first measurement point in the MPR plane.

	Click the second point to finish the measurement. The measured value is displayed next to the measurement line.
	Placed annotations are listed. Select each annotation by the checkbox.
	Disable / Enable selected annotations.
	Delete selected annotations.

Labels can be created in all MPR planes. A yellow point marks the current position of your mouse pointer. Likewise, the points you set in in the MPR planes are displayed in real-time in the MPRs and the 3D representation.

It is possible to draw annotations across several planes. During creation, the MPR planes can be switched with the mouse wheel or scrollbar for this purpose. In addition, points can be set in all three MPR planes.

5.6.2.6 Screenshot menu

"2D Screenshot"	2D Screenshot is taken (or with CTRL + S) and can be saved or discarded.
"3D Screenshot"	3D Screenshot is taken and can be saved or discarded.
	Select / unselect all checkboxes.
	Delete selected screenshots.

5.6.2.7 Report menu

In the "Generate Report" dialog (or "Update Report" if a report has already been created), the following options are available:

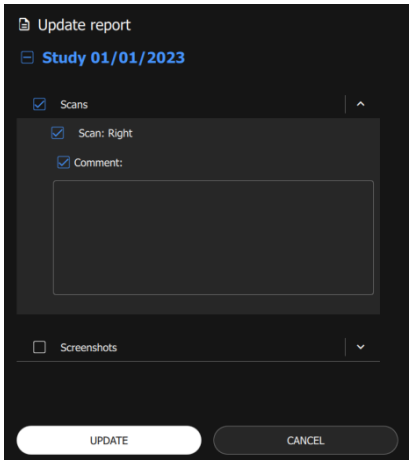
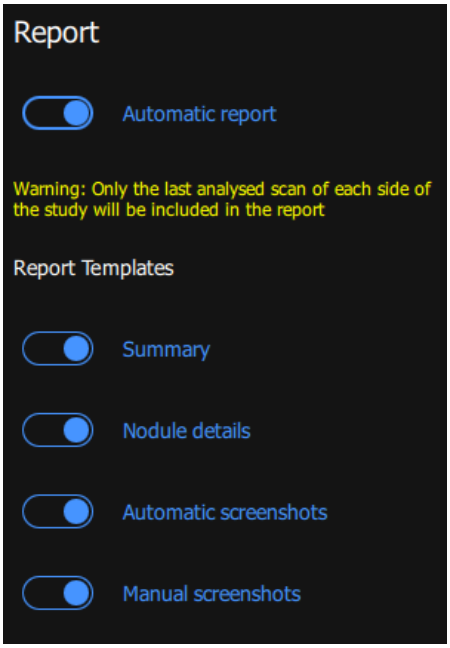


Figure 16: Dialogue "Update report"

Below is the table describing each option in more detail:

"Generate Report"	Opens pop-up window to select the content of the report. Max. 1 right and 1 left scan can be added to the report.
"Update Report"	Opens pop-up window to update the content of the report.
"Cancel"	Terminates the process without storage.



In the settings, the automatic report generation can be activated. Only the last performed scan of each side (left and right) of the study will be included in the report.

Every change in the Analysis will be saved automatically in the report after clicking "accept nodule" / "accept lobe" / "accept".

Different content sections of the report can be activated to be automatically included in every report generated.

Automatic report is generated as soon as using the "backward" button/ "exit" button.

Information: the report is study-based and accessible from the Patient Browser.

5.7 "Review" Mode – Thyroid App in Lite Mode

5.7.1 Display and operating window in the "review" mode

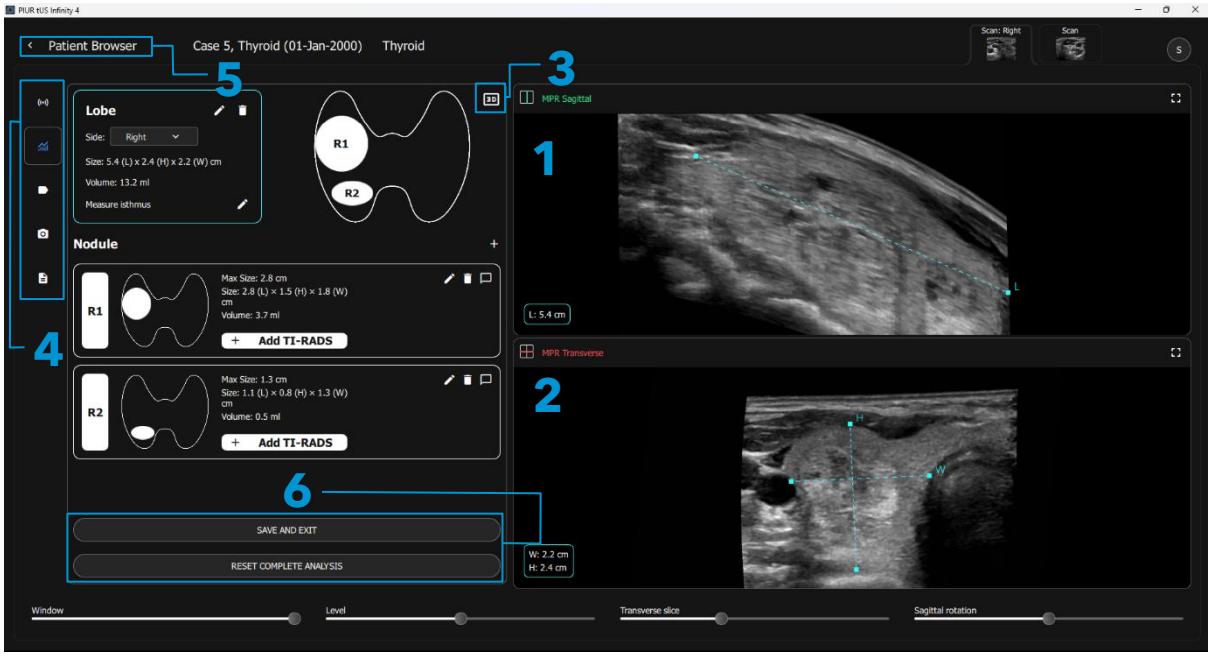


Figure 17: Operating window in the "Review" mode of Thyroid App in Lite Mode

1	Multiplanar reconstructions (MPR) of the sagittal plane. Sagittal section through the volume.
2	Multiplanar reconstructions (MPR) of the transversal plane. Transversal section through the volume.
3	3D Volume Reconstruction button: Represents the reconstructed ultrasound volume as a 3D reconstruction. Keep the left mouse button pressed to rotate the volume. The volume can be shifted with the middle mouse button pressed. The zoom factor can be set with the mouse wheel or moving the mouse vertically with the right mouse button pressed.
4	Tool Selection: Provides different tools for scan acquisition, analysis, annotations, screenshots, and reports. (saving the changes in the report and sending to PACS if the Automatic Report and Autosend to PACS settings are activated).
5	Patient Browser button: Exits the scan.

6	When the Automatic Report setting is activated, the button "Save and Exit" saves all changes of all scans in the current study to the report. Reset Complete Analysis button deletes the analysis and automatically restarts it.

Relevant for all 2D view windows:

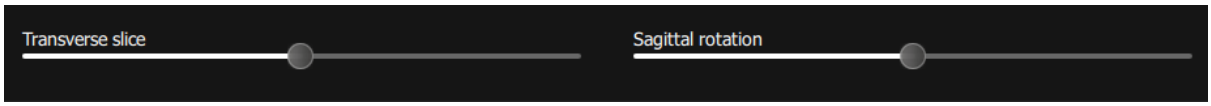
Left click in the inner part of MPR-line	Moves both plane lines. Focus remains on same spot in image.
Left click in the outer part of MPR-line	Rotates the respective plane line. Focus remains on the same spot in image.
Left double click(in one 2D view)	Places the intersection point of the two planes at the point.
Left click hold and move up and down anywhere (in one 2D view) or scrolling the mouse wheel	Scrolling through the slices of the respective 2D view.
Right click hold and move up and down anywhere (in one 2D view)	Zooming in all three 2D views.
SHIFT + left click and move anywhere (in one 2D view):	Moves the image.
CTRL + hold left click and move up and down anywhere (in one 2D view)	Up: increases window level Down: decreases window level
CTRL + hold left click and move left and right anywhere (in one 2D view)	Right: increase level value Left: decrease level value
CTRL + hold left click and move up/down and left/right at once	Combination of window and level value in-/decrease

5.7.2 Overview of the Functions in the "Review" mode

5.7.2.1 Tool selection

	Go to Acquisition Screen
	Analyze Lobe and Nodules
	Annotations + Measurements, see Section 5.7.2.5
	Able to create 2D and 3D Screenshots
	See and update report

5.7.2.2 MPR view



The Transverse Slice slider moves along the coupled transverse and sagittal MPR planes.

The Sagittal Rotation slider rotates the transverse and sagittal planes coupled to the respective coronal plane.

The 2D and 3D view is controlled by (Hover symbol):

Icon	Function	Description
	Zoom	3D: zooms in and out 2D: zooms in and out in all 2D views
	Rotate	Rotates the MPR lines
	Move	Moves the MPR lines

5.7.2.3 Window and level settings

The default Window and Level settings can be configured in the User Settings tab:

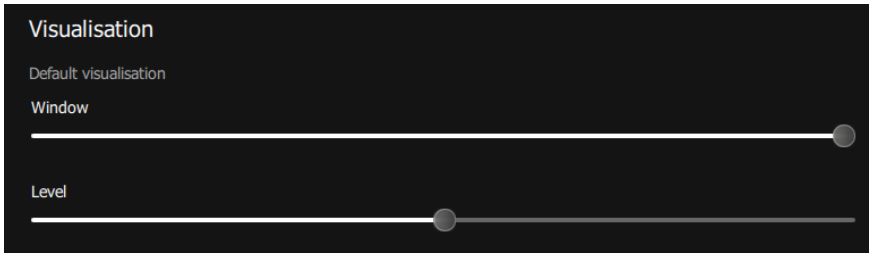
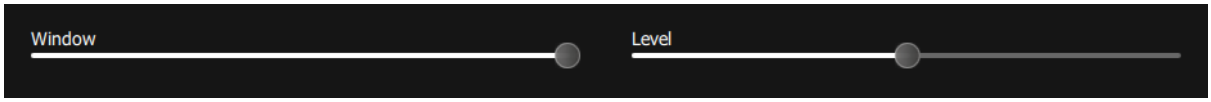
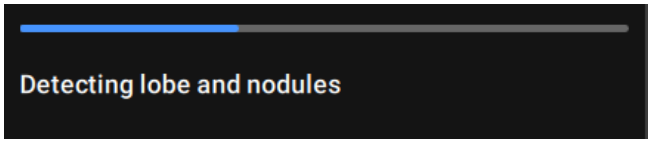


Figure 18: Default Window and Level in User Settings



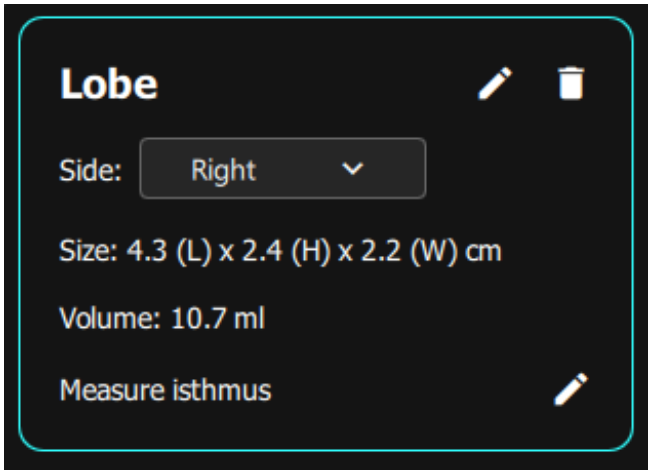
The brightness and contrast can be changed with the slider.

5.7.2.4 Image analysis



The progress bar indicates the status of the processing workflow.

Auto-side selection: The lobe side is automatically detected. The side can be changed by clicking the arrow next to the

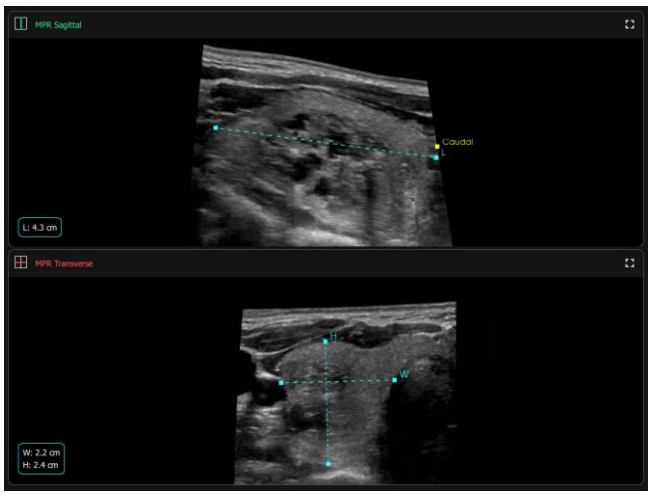


Side field and selecting the desired (Right or Left).

The **Size** field displays automatically calculated 3-line measurements of the detected lobe.

The **Volume** field displays the automatically calculated lobe volume in milliliters (ml).

The automatically generated three-line lobe measurements can be edited or deleted to allow them to be redrawn.

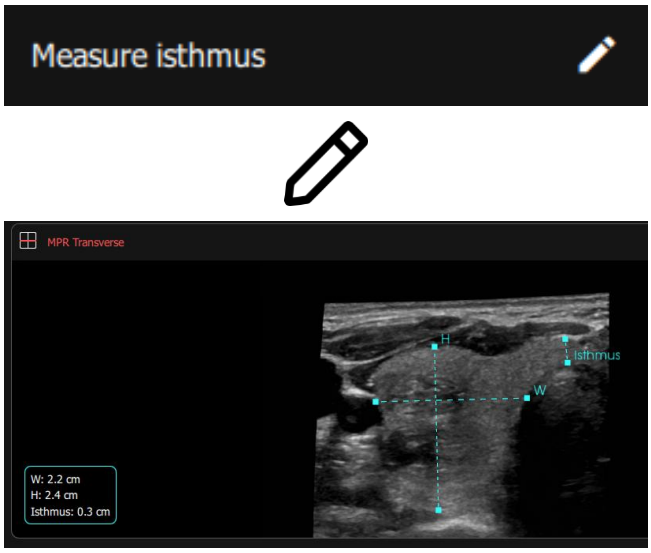


Manual Lobe Measurement Correction Tool

Click the Edit icon (or press Ctrl + E). Position the cursor over the endpoints of the 3-line measurements. Select an endpoint and drag it to the desired position. This adjustment can be performed for all endpoints.

Click the Accept icon (or press Enter), which replaces the Edit icon, to confirm the measurements.

Click the Delete icon to remove all three-line measurements and enable manual redrawing.



Isthmus Measurement

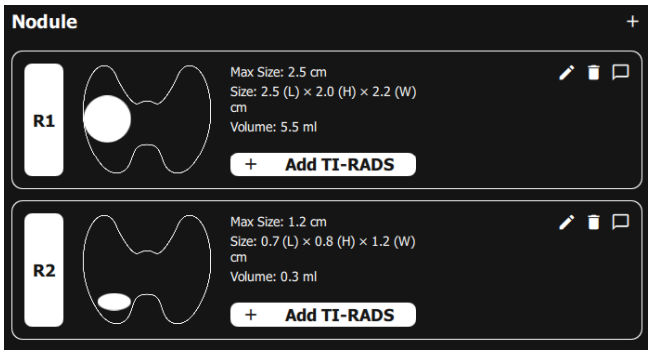
Click the Edit icon to enable manual drawing of the isthmus width.

Click once on the desired MPR view to set the first endpoint.

Click again to set the second endpoint.

After the second endpoint is placed, the tool automatically exits. The calculated isthmus thickness is displayed in the Lobe Summary.

The Edit icon is replaced by a Delete icon. If the isthmus measurement should be removed, click the Delete icon.



The summaries of automatically detected nodules include:

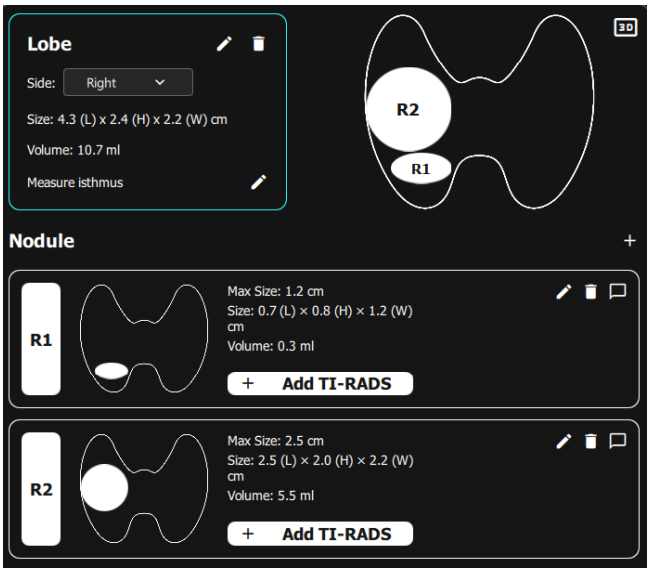
R/L/I + Nodule Number: The nodule index and the right (R), left (L) thyroid lobe, or the isthmus (I).

Pictogram: Provides a visual indication of the location and approximate size of the nodule within the thyroid.

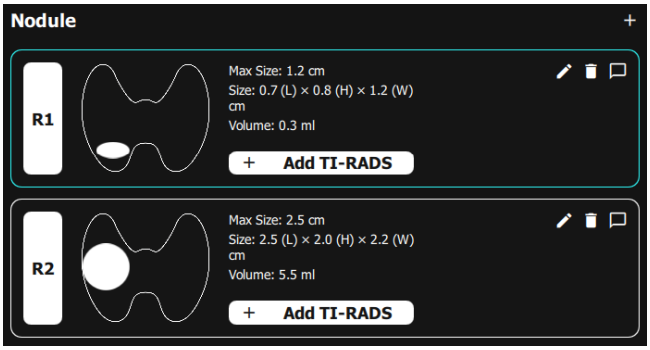
Max. Size: The longest dimension among the 3-line measurements.

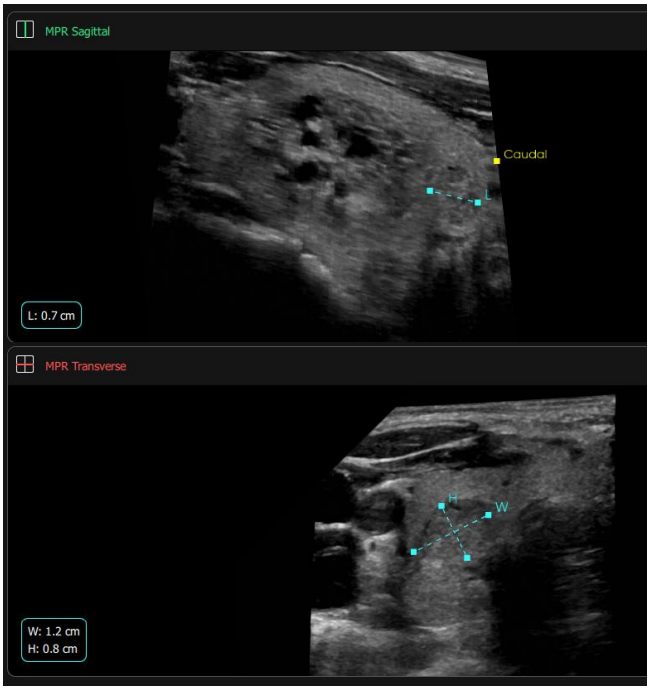
Size: The 3-line measurements of the nodule.

Volume: The calculated nodule volume in milliliters based on the 3-line measurements.

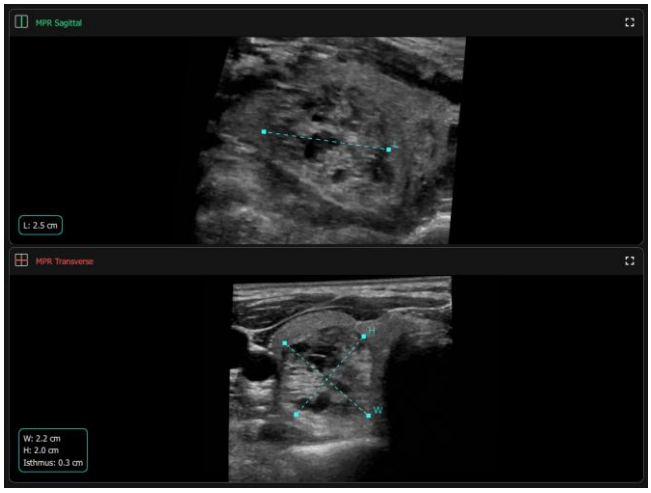


The nodules in the list can be reordered at any time (provided that Editing mode is not enabled). To change the order, drag and drop the desired nodule summary to the required position in the list.





Selecting any nodule summary (or the lobe summary) in the list automatically focuses the MPR views on the corresponding structure. The selected nodule or lobe is centered in the MPR views, and the associated 3-line measurements are displayed.



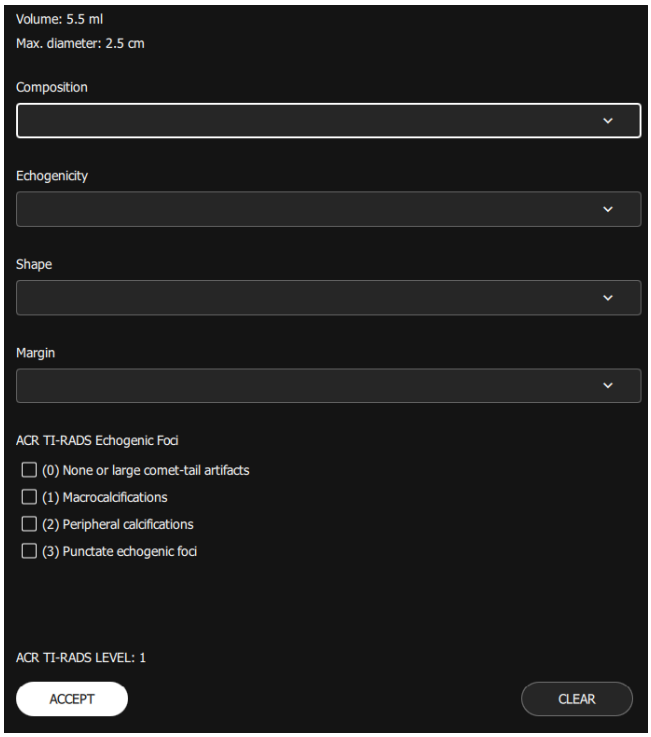
Manual Nodule Measurement Correction

Click the Edit icon. Move the cursor to the endpoints of the 3-line measurements. Select an endpoint and drag it to the desired position. This can be performed for any of the measurement endpoints.

Click the Accept icon (which replaces the Edit icon) to confirm the modifications.

Click the Delete icon to remove the nodule from the list.

Click the Comment icon to add additional text to the nodule summary.



Click the Add TI-RADS button to open the TI-RADS menu.

Manually fill out the TI-RADS menu:

Composition
(0) Cystic or almost completely cystic
(0) Spongiform
(1) Mixed cystic and solid
(2) Solid or almost completely solid

Echogenicity
(0) Anechoic
(1) Hyperechoic or isoechoic c
(2) Hypoechoic
(3) Very hypoechoic

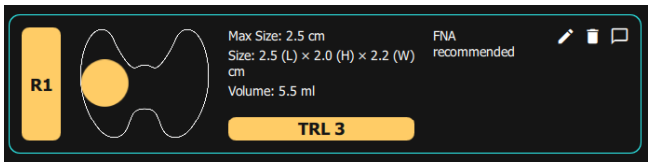
Shape
(0) Wider-than-tall
(3) Taller-than-wide

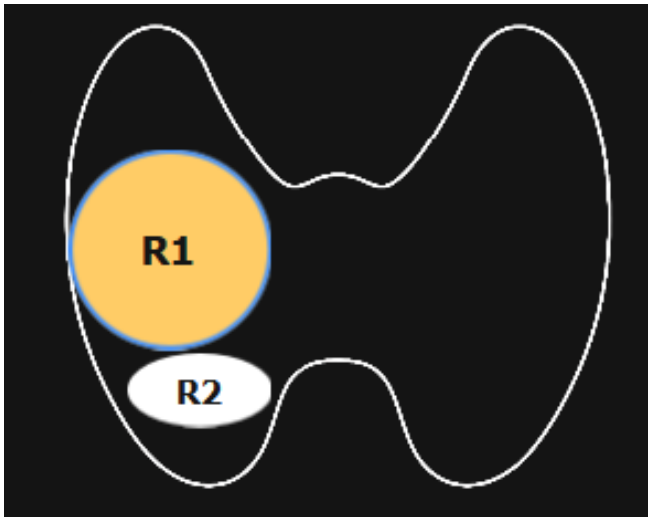
Margin
(0) Ill-defined
(0) Smooth
(2) Lobulated or irregular
(3) Extra-thyroidal extension

ACR TI-RADS Echogenic Foci
(0) None or large comet-tail artifacts
(1) Macrocalcifications
(2) Peripheral calcifications
(3) Punctuate echogenic foci

Click Accept to confirm the TI-RADS level.

Click Clear to return to the previous screen. With this action, **any previous TI-RADS analysis performed will be lost**.



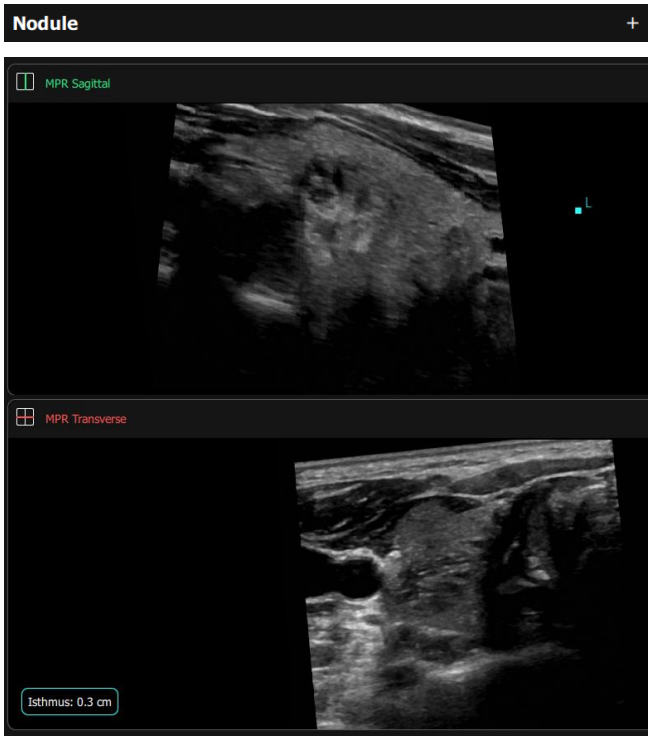


The TI-RADS level is automatically calculated based on the options previously selected in the menu.

The color of the nodule number, pictogram representation, TI-RADS menu button, and general scan pictogram are updated to reflect the corresponding TI-RADS level.

Three recommendations for the Nodule are available:

- FNA recommended
- Follow up recommended
- No FNA, no follow up recommended



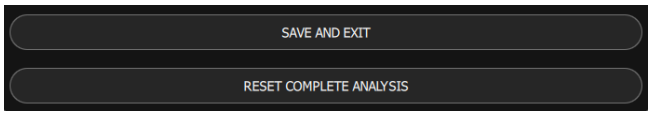
Add a nodule to the analysis by clicking the "+" icon next to Nodule.

Navigate through the MPR views and define the endpoints of the 3-line measurements by clicking on the desired locations.

The measurements are performed in the following order: Length (L), Height (H), and Width (W). During each measurement, the indicator (L, H, or W) is displayed next to the cursor to indicate the measurement currently being performed.

After the final endpoint is placed, the tool automatically exits. The calculated measurements and volume are then displayed in a new nodule summary added to the list.

All editing options previously described for automatically detected nodules are also available for manually added nodules.



Save and Exit: Saves patient analysis and exits the review screen back to the Patient Browser.

If **Automatic Report** generation and/or **Autosend to PACS** is turned on: sends all new changes since the last time.

Reset Complete Analysis: deletes and automatically restarts the lobe and nodules analysis.

In User Settings, it is possible to enable the following option:

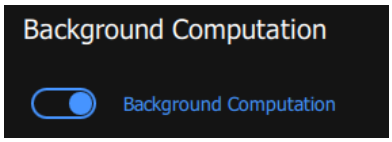


Figure 19: Analysis optimization User Settings

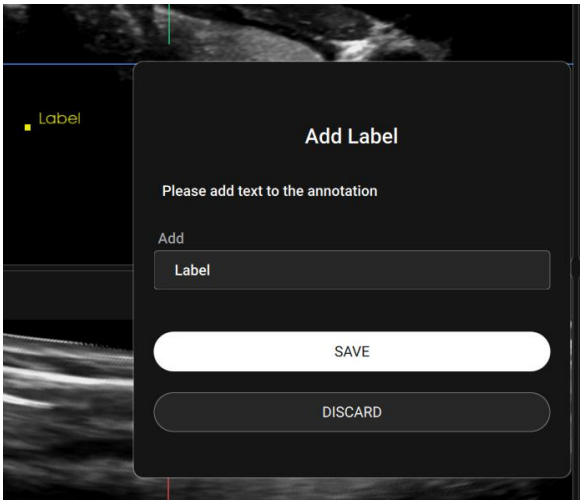
"Background Computation"

The system starts the analysis for all yet non-analyzed scans within the last three weeks when the system is not being operated.

5.7.2.5 Annotation menu

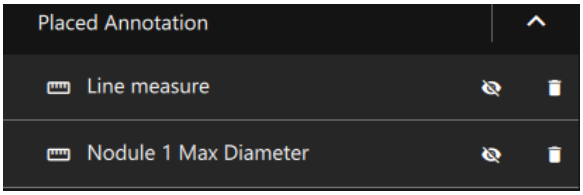
"Label"

Choose between Label and Line Measurements.



Target the marker in the MPR planes.

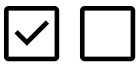
Change Label name, discard or save.

"Line Measurement"	Target the first measurement point in the MPR plane. Click the second point to finish the measurement. The measured value is displayed next to the measurement line.
	Placed annotations are listed. Select each annotation by the checkbox.
	Disable / Enable selected annotations.
	Delete selected annotations.

Labels can be created in all MPR planes. A yellow point marks the current position of your mouse pointer. Likewise, the points you set in in the MPR planes are displayed in real-time in the MPRs and the 3D representation.

It is possible to draw annotations across several planes. During creation, the MPR planes can be switched with the mouse wheel or scrollbar for this purpose. In addition, points can be set in all three MPR planes.

5.7.2.6 Screenshot menu

"2D Screenshot"	2D Screenshot is taken (or with CTRL + S) and can be saved or discarded.
"3D Screenshot"	3D Screenshot is taken and can be saved or discarded.
	Select / unselect all checkboxes.
	Delete selected screenshots.

In the Thyroid App in Lite Mode, screenshots of the lobe and nodules in 2D and 3D are automatically generated and saved in the Screenshots list.

All 2D screenshots are centered on the corresponding line measurements and include the patient's name, the visualized plane, and the associated measurements.

In addition, nodule screenshots include a pictogram indicating the location of the nodule within the thyroid. This allows the nodule position to be identified even when only the 2D screenshot is available and the 3D representation is not displayed.

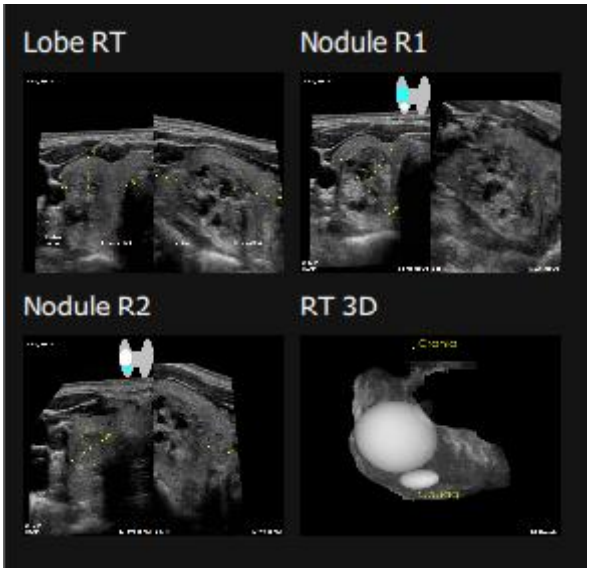


Figure 20: Automatic screenshots in Thyroid App in Lite Mode

5.7.2.7 Report menu

In the "Generate Report" dialog (or "Update Report" if a report has already been created), the following options are available:

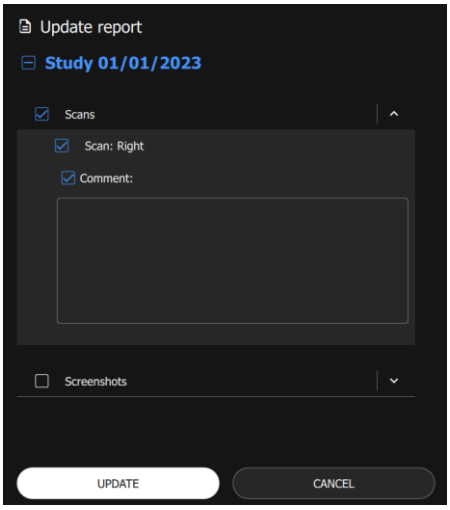
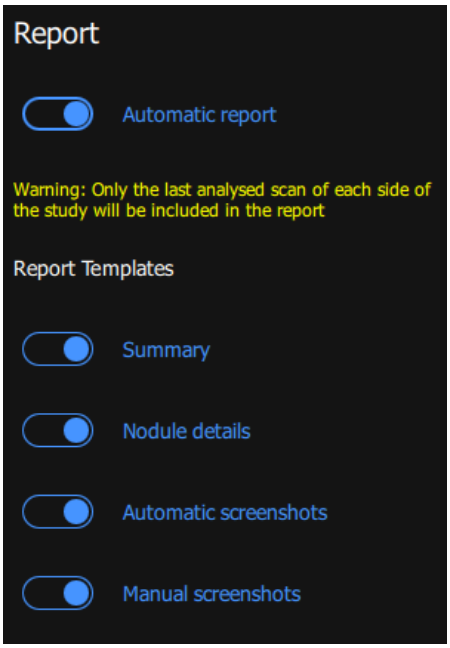


Figure 21: Dialogue "Update report"

Below is the table describing each option in more detail:

"Generate Report"	Opens pop-up window to select the content of the report. Max. 1 right and 1 left scan can be added to the report.
"Update Report"	Opens pop-up window to update the content of the report.

"Cancel"	Terminates the process without storage.



In the settings, the automatic report generation can be activated. Only the last performed scan of each side (left and right) of the study will be included in the report.

Every change in the Analysis will be saved automatically in the report after clicking "accept nodule" / "accept lobe" / "accept".

Different content sections of the report can be activated to be automatically included in every report generated.

Automatic report is generated as soon as using the "backward" button/ "exit" button.

Information: the report is study-based and accessible from the Patient Browser.

5.8 Telehealth Application

The Telehealth application is based on the PIUR tUS Infinity software and divides both temporally and physically the ultrasound scan acquisition (in the Acquisition Station) and the analysis and review of the acquired data (in the Review Station).

The user that performs the acquisition can be different from the user that perform the review, and the two users can be in different places, also very far from each other. The only requirement is that the workstations where the Acquisition Station and Review Station run are connected to the same PACS server (on-premises or cloud PACS)

The workstation where the Acquisition Station runs has no special requirement, while the workstation where the Review Station runs has the same requirements as the normal PIUR tUS Infinity software, particularly for the NVIDIA graphics card with at least 4 GB GPU memory, necessary for the volume compounding algorithm.

5.8.1 Acquisition station

It is activated by running the software with a special dedicated license.

The user can perform an acquisition as in the normal software, then the ultrasound sweeps are sent to the PACS server in DICOM format with all the necessary information for performing the reconstruction of the ultrasound volume added as private tags to the DICOM file.

The data can be sent to PACS automatically or manually.

In the Acquisition Station the ultrasound sweeps are not compounded and cannot be reviewed.

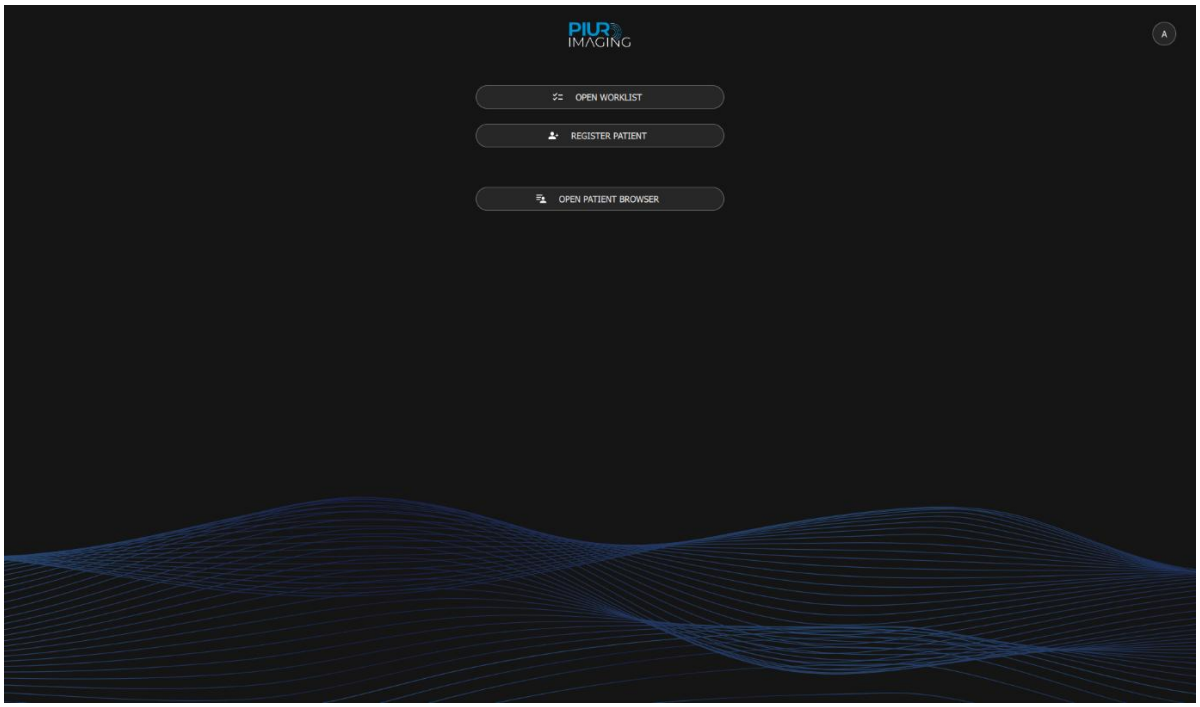


Figure 22: Acquisition Station - Overview Screen

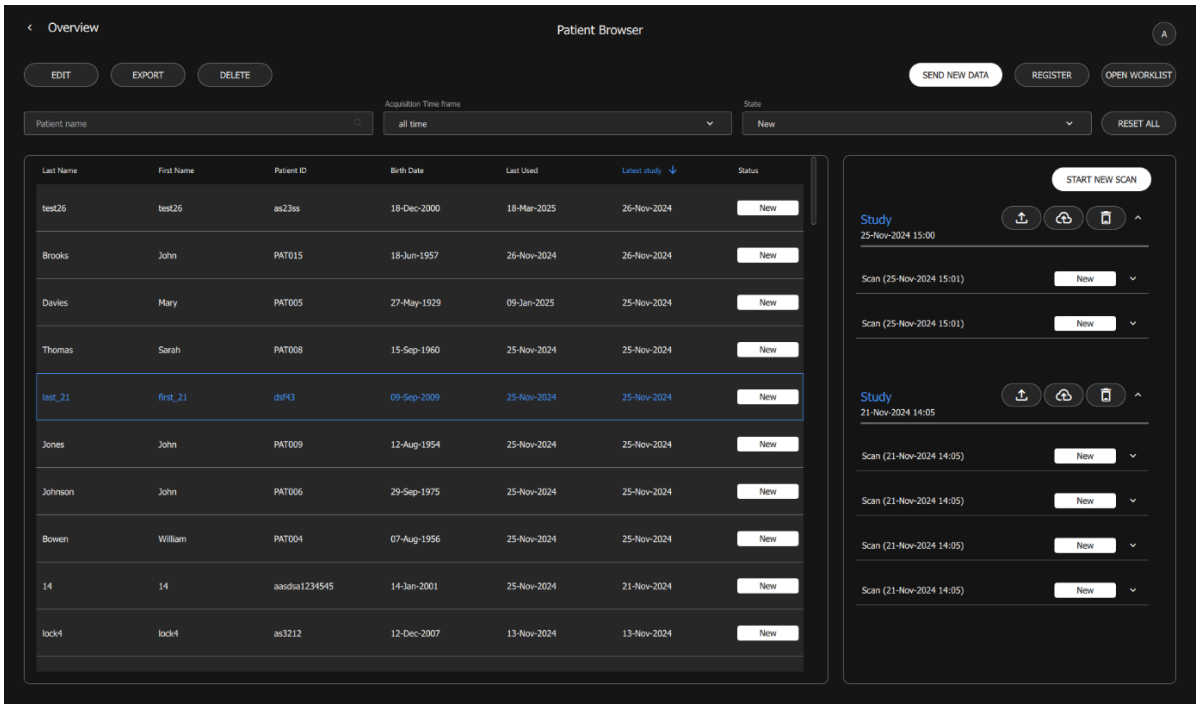
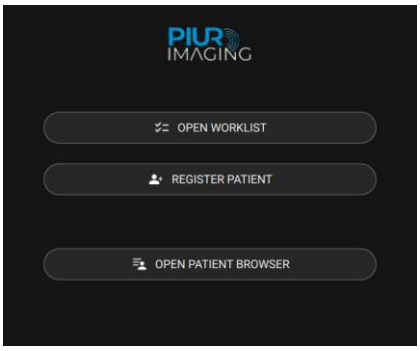
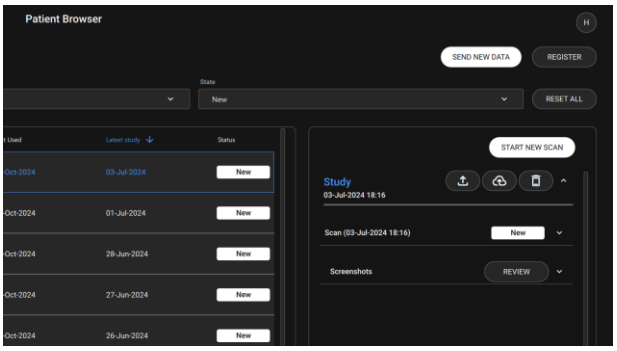


Figure 23: Acquisition Station - Patient Browser

The Acquisition Station is designed exclusively for scan acquisition and data transmission to PACS. In Acquisition Station, the functions Open Worklist, Register Patient, and Open Patient Browser, explained in Section 5., are the only available. In the Patient Browser, next to each scan, a label indicates its status as either New or Sent (transferred to PACS).





"Send New Data" Sends newly acquired scans to PACS.

Single data can also be sent via the usual Send to PACS button

See Section 5.4.1 "Patient Menu" for more details.

5.8.2 Analysis station

It is activated by running the software with a special dedicated license.

After the ultrasound sweeps are sent to the PACS server, they can be retrieved in the Review Station. Upon retrieval, the private tags are read, the volume is compounded, and the scan can be reviewed, analyzed and the report generated as in the normal PIUR tUS Infinity software.

In the Review Station is not possible to perform any scan acquisition.

Only the data that were sent by the Acquisition Station are retrieved from the PACS in the Review Station.

The data can be additionally filtered by:

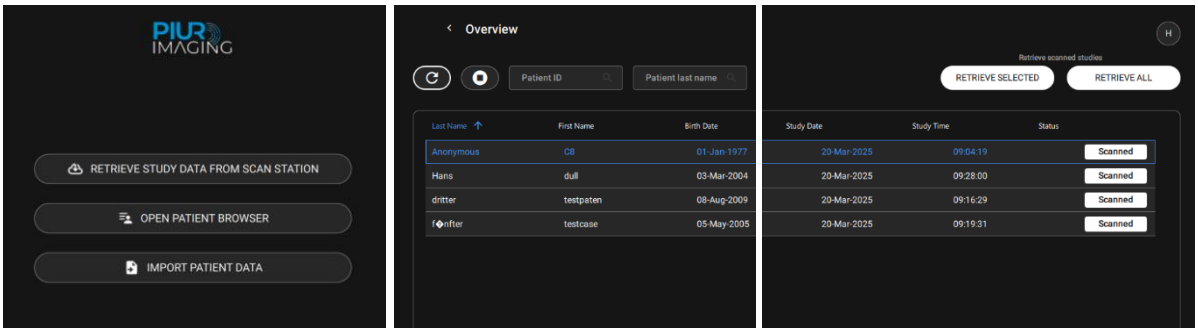
- Patient ID
- Patient last name
- Study date: today, last 7 days, not set
- Retrieval status: scanned, retrieved, not set

The data are retrieved by study and once imported, they are listed in the Patient Browser and can be reviewed and analyzed as usual.

It is possible to retrieve single study or all the studies that are displayed in the query screen.

Figure 24: Review Station - Overview screen

The interface of the Review Station does not include any functionality for acquiring new scans.



"Retrieve All"	Imports data from PACS that has not yet been retrieved to the current Analysis Station.
"Retrieve Selected"	Imports data of the patient, which is selected from PACS to the current Analysis Station.
	Stop Button: halts retrieve process.

6 PIUR tUS Infinity: Commencing Operation and Conducting the Examination

6.1 Moving the Ultrasound Probe with PIUR tUS Infinity

The ultrasound probe can also be used for regular ultrasound examinations with the PIUR Bracket mounted before and after 3D acquisition.

Requirements for performing a scan

Make sure the PIUR Sensor is active by pressing the switch button

The following movement patterns **are highly recommended** in order to receive an accurate image:

1. Move the probe with a scan speed of **1-2 cm/s**
2. Start the movement once you heard the audio feedback signal after pressing the start button to avoid missing data caused by a transmission delay. Make sure that the sound of the Laptop is turned on and the sound is enabled in the acquisition menu (1.1.1).

Certain movement patterns during acquisition have proven to be especially advantageous for optimal 3D reconstruction:

1. During acquisition, move the probe with as steadily and fluid movements as possible along the neck.
2. Move the probe linearly over the neck to be represented during acquisition. Avoid extreme sideward movements of the probe.
3. Avoid keeping the probe at one spot without any movement
4. Avoid side movements without any transversal movement along the thyroid
5. Avoid changing hands for holding the probe during acquisition

Information: The PIUR Sensor goes into sleep mode after 10 minutes without use and thus no longer transits any information.

If you start recording again more than five minutes, turn the sensor back on beforehand.

6.2 Parameter Settings of the Ultrasound Device

The image parameters on the ultrasound device can be set as normal as for classical 2D examinations on the thyroid.

7 Taking out of Operation

7.1 Switching Off and Storing the Device

The application is shut down by the Ultrasound environment.

Ensure you saved all relevant information.

7.2 Disinfecting and Cleaning

7.2.1 Removing and cleaning the PIUR Sensor

The PIUR Sensor must be cleaned before and after each use in accordance with the applicable disinfection and cleaning rules.

To ensure optimal hygiene and performance, the PIUR Sensor **must be cleaned after each use**. For added safety, **cleaning before use is also recommended.**

1. Remove the sensor housing from the attachment plate by levering it diagonally downwards with one hand.

2. Carefully remove all soiling and residues from the sensor housing, using a soft damp cloth if necessary.
3. Wipe the sensor surface with CaviWipesTM.
4. Let the sensor dry for about 2 minutes.

Safety Notice

Never submerge the PIUR sensor in disinfectant or any other liquid. Submerging of the component results in a loss of warranty and may cause damage to the system and endanger the patient. If these components are accidentally submerged into any substance, please contact the manufacturer.

7.2.2 Removing and cleaning the PIUR Bracket

Clean and disinfect the PIUR Bracket after every patient examination, as follows:

1. Release the Bracket from the anchoring by applying slight pressure to the Bracket plate and remove it from the ultrasound probe.

2. Wipe Bracket, with CaviWipesTM.
3. Let the Bracket dry for about 2 minutes.

Safety Notice

Never sterilize (e.g. autoclave) the components of the system. Sterilization of any of these components results in a loss of warranty and can cause damage to the system and endanger the patient. If these components are accidentally sterilized, please contact the manufacturer.

To ensure optimal hygiene, the PIUR Bracket **must be cleaned after each use**. For added safety, **cleaning before use is also recommended.**

Before starting cleaning and disinfection, please note the following:

- None of the (electrical) components shall have any visible damage; otherwise, water or cleaning/disinfection solution could penetrate. This could cause malfunctions or damage to the electrical components.
- Do not apply diving cleaning or disinfection.

Strictly follow the application instructions specified on the detergent used, disinfectant!

In accordance with the statutory hygiene regulations for the prevention of infections and the requirements for the treatment of medical devices, a careful and effective cleaning and disinfection must be carried out after each use.

If coarse impurities are visible, they must be removed with an appropriate cleaner (or disinfectant cleaner) before disinfection.

Appropriate means of disinfection must be used, the material compatibility of which has been demonstrated:

Cleaning Agents	CaviWipesTM (Disinfectant Wipes)
Active ingredient	Quaternary ammonium germicidal detergent solution
Dry time	2 Minutes

WARNING: Do not use any liquid or aerosol cleaner, only determined cleaning solution (agent) specified above.

7.2.3 Cleaning and Disinfecting of the remote control

The remote control must be disinfected with the wipes mentioned above.

7.3 Disposing of PIUR tUS Infinity Hardware

The system must be disposed in accordance with the local electronic waste regulations. Alternatively, the device can be sent back to the manufacturer for disposal.

7.4 Disposal of Software and Data

To uninstall the PIUR software from the computer, use the built-in Windows function "Add or remove programs" to run the PIUR uninstaller. Please note that this removes the PIUR software only, acquired image and patient data will remain on the hard drive. To delete all image and patient data from the hard drive permanently, delete the folder "piur imaging" located in the installation drive. Make sure that the data does not remain in the Windows Recycle Bin. It is recommended to perform a full backup of the data beforehand, since this process cannot be undone.

8 Service and Maintenance

8.1 Backup and Recovery of Patient Data

Under General Settings, a backup and restoration of the database and user data can be performed. The logs can also be exported to the chosen directory.

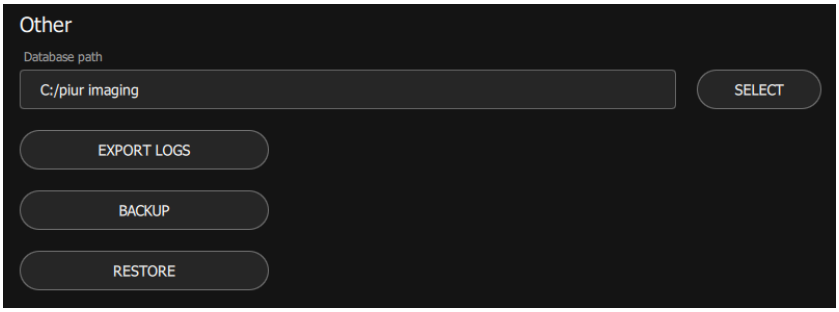


Figure 25: Export logs, Backup and Restore functions in General Settings

"Export Logs"	Opens the File Explorer to select a directory for exporting log files of the last 7 days as a compressed folder.
"Backup"	A menu allows to select "Database" and/or "System", and to define a path through the selection of a folder on the explorer. Confirm clicking on the "Backup" button of this new pop-up menu.
"Restore"	Initiates the restore of System and Database based on the specified files selected. It replaces forcefully all existing data in the specified locations.

8.2 Contact

service@piurimaging.com

Hotline: +43-12 650 16 8

Please write down the serial number of your system before contacting our service team. You can find the serial number on the identification label at bottom of the PIUR tUS Infinity system (see chapter 1.3.1).

8.3 Maintenance Interval

PIUR tUS Infinity does not require regular maintenance.

Information: Batteries Cycle Life at room temperature may drop to 80% of minimum capacity after 500 cycles or 2 years (depending on charging).

PIUR Sensor will anyway indicate when batteries are depleted.

8.4 Software Update

The user is not permitted to carry out software updates. Software updates are performed by trained service personnel.

8.5 Recurrent Testing

Recurrent testing according to EN 62353 must be done annually.

8.6 Procedure in Case of Faults and Defects

Safety Notice: If malfunctions and defects occur.

Occurrence of malfunctions and defects can lead to personal injury or damage to the device.

- If malfunctions and defects occur, discontinue the use of the PIUR tUS system and inform our service team via the above contact details.

9 Technical Data

9.1 General data

	Infinity Box	PIUR Sensor
Voltage	100-240 VAC, 50/60 Hz, 0.6-1.3 A	3,7 VDC (Lithium Polymer)
Dimensions	254x157x54 mm	41,7 x 56,2 x 25,3mm
Mass (without packaging)	1 kg power supply: 0.7 kg	40 g
Lifetime	5 years	2 years (due to Battery depletion) NOTE: Battery should be replaced after 2 years preventively, not to affect the lifetime of main product, i.e. to maintain safety and performance of the medical device!
Storage and transport condition	Temperature: -10 °C to +60 °C Relative humidity: 10 % – 90 % (no outside storage) Atmospheric pressure: 50 kPa to 106 kPa (EN 60601-1-2:2015 Annex A 7.9.3.1) Use or recharge PIUR Sensor within 3 months	
Recommended storage and transport conditions	Temperature: 0°C to +30°C Relative humidity: 10 % - 65% (no outside storage)	
Recommended operating conditions	Temperature: +10 °C to +30 °C Relative Humidity: 30 % to 75 % (EN 60601-1-2:2015 Annex A 7.9.3.1) Atmospheric pressure: 70kPa to 106 kPa (EN 60601-1-2:2015 Annex A 7.9.3.1	
Operating altitude	Maximal 2000 m	

9.2 Technical Characteristics and Performance Data

9.2.1 Measurement Function

Safety Notice: Accurate measurements can only be performed in the "Performance"-Domain of Tracking Sensor à same room

In case of leaving the "Performance"-Domain during a measurement a warning will appear.

Check if all parameters as Depth, Transducer and US Device are set correctly in the Acquisition-Mode (use autodetection if possible) before recording (Chapter 1.1.1).

PIUR tUS Infinity allows three-dimensional measurements within the reconstructed volume.

Measurement possibilities are:

- Line measurement
- Spline measurement
- Volume measurement

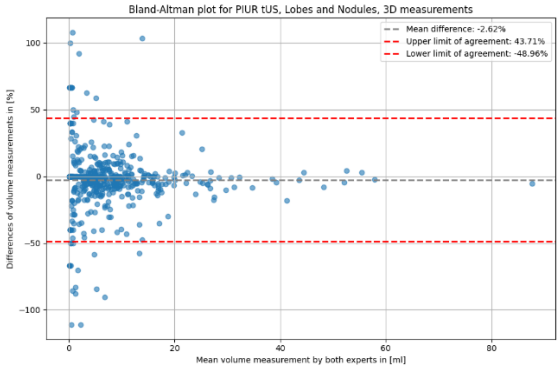
9.2.2 Performance assessment

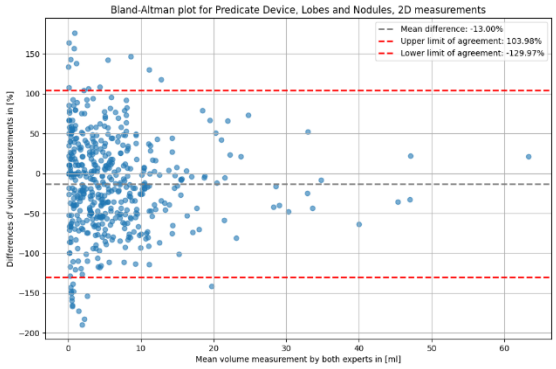
Within the performance assessment of PIUR tUS Infinity a comprehensive analysis of 196 patients from the USA, Brazil, and Europe has been conducted. The performance assessment was split into two parts:

1) Volume Validation: we assessed the variability in volume measurements among different observers using clinical 2D and 3D data. In addition, we assessed the accuracy of volume measurements by comparing 3D measurements against a known ground truth in a phantom.

The p-value from the Wilcoxon Signed-Rank Test, which compared the inter-observer variability between two health professionals (HPs) using the PIUR tUS Infinity and conventional 2D ultrasound was less than 0.01 (P-values = 1.23 * 10-51) which was well below the alpha level of 0.05. This result indicates that the inter-observer variability associated with the PIUR tUS Infinity is significantly smaller than that of conventional 2D ultrasound, suggesting superior consistency between observers when using the PIUR tUS Infinity.

The corresponding Bland-Altman plots can be found below (left: 3D; right: 2D):





Also, Lin's Concordance Correlation Coefficients of 0.9879 and 0.8252 for the total PIUR tUS Infinity and conventional 2D ultrasound respectively suggest, intraclass Lin's CCC obtained when using the PIUR tUS Infinity is greater than the Lin's CCC derived from the conventional protocol.

These results are underline by phantom data:

	Expert 1		***Expert 2***	
Phantom ID	*Squared Error (PIUR tUS Infinity vs Ground Truth)*	*Squared error (2D Ultrasound vs Ground Truth)*	*Squared Error (PIUR tUS Infinity vs Ground Truth)*	*Squared error (2D Ultrasound vs Ground Truth)*
1	0.03	0.41	0.68	0.79
2	0.79	0.92	0.06	0.04
3	0.40	0.00	0.02	0.00
4	0.11	0.74	0.00	0.01
5	0.02	0.09	0.15	1.57
6	0.02	3.36	0.02	0.00
Mean Squared Error (MSE) [ml²] ± SD	**0.23 ± 0.28**	**0.92 ± 1.13**	**0.15 ± 0.24**	**0.40 ± 0.59**

2) ACR TI-RADS Validation: we assessed the agreement between ACR TI-RADS classification of nodules based on 3D data and 2D data and compared the agreement against a threshold that has been derived from inter-observer agreement from two 2D reading.

The results are summarized in the following table:

Statistics	2D Rater vs 3D Rater	Threshold
Weighted Quadratic Cohen's Kappa Coefficient	0.4563	0.4748
95% Confidence Interval for Cohen's Kappa	[0.0775, 0.2516]	[0.1636, 0.4121]

Standard Error of Cohen's Kappa	0.0444	0.0634

The calculated z-statistic was 0.2390, with a p-value of 0.8110. This indicates no significant difference between the Cohen's Kappa coefficients of 2D vs. 3D and our threshold that is based on 2D vs. 2D.

Conclusion:

The assessment of both, volume measurements and ACR TI-RADS classification of nodules, demonstrated positive results. The PIUR tUS Infinity is therefore non-inferior to the conventional 2D ultrasound method for analyzing thyroid lobes and nodules.

9.2.3 Statement of Limitations and Uncertainties

It is important to understand the limitations and uncertainties of this Performance Test.

Different ultrasound equipment and different operator-skills might affect the outcome of tomographic 3D ultrasound examinations in the field. Although the study aimed to mitigate this by including a variety of ultrasound devices and a variety of healthcare professionals, it remains possible that outcomes in the clinical routine vary. However, this is true for tomographic 3D ultrasound as well es conventional 2D ultrasound, and therefore, both modalities are affected in a similar way.

Additional uncertainties might arise from the scanning speed during 3D acquisition. Scanning speeds below or above the recommended range might negatively influence measurement accuracy. Further sources of uncertainties that can affect performance include: side-shifts during acquisition, change of scanning direction, pauses during the scanning procedure.

We recommend that the user checks the original 2D ultrasound images directly on the ultrasound scanner if there is a concern about accuracy or image quality of the reconstructed images. If in doubt, the information obtained from 2D ultrasound prevails.

9.3 Classification

	Video Box	Sensor
Protection class	Power supply: Class I	Internally powered device
IP classification	IP2X requirements fulfilled	IPx5

9.4 Electromagnetic compatibility (EMC)

The Infinity Box and PIUR Sensor fulfil the requirements of the standards:

- EN 60601-1-2:2015 + A1:2021
- EN 60601-2-37:2016
- EN 301 489-1 V2.2.3 (2019-11)
- DRAFT EN 301 489-17 V3.2.5 (2022-08)
- FCC 47 CFR Part 15

These components are classified according to CISPR 11 as group 1, class B.

	Video Box	Sensor
Frequency band of reception	2.4 GHz (20/40 MHz channels) and 5 GHz (160 MHz channels)	2.4 GHz ISM frequency band
Bandwidth of the receiving section	max. 1.73 Gbit/s	max. 1 Mbit/s
Frequency band of transmission	2.4 GHz (20/40 MHz channels) and 5 GHz (160 MHz channels)	2.4 GHz ISM frequency band
Type and frequency characteristics of the modulation	IEEE 802.11a/b/g/n/ac	IEEE 802.15.1
Effective radiated power	max. 23dBm	19 dBm

Use Environment

The device is intended to be used in a standard clinical or hospital environment where diagnostic ultrasound examinations are being performed. This setup usually includes IT equipment, such as a PC, server, or laptop, monitors, an ultrasound system, and potentially additional medical equipment. The system is not intended to be used in operating rooms, or in rooms with heavy imaging devices that could cause strong EM disturbances, such as an MRI.

Do not operate device in an environment with known increased EM disturbances. Do not use devices which intentionally transmit RF Signals (cellular phones, transceivers, or radio-controlled products), other than those supplied by PIUR, in the vicinity of the equipment, as it may cause performance outside the published specifications. Keep the power to these type devices turned off when near this equipment.

Please also see operating conditions Section 9.1 General data.

NOTE: If this equipment is found to cause interference (which may be determined by turning the equipment on and off), the user (or qualified service personnel) should attempt to correct the problem by one or more of the following measure(s):

- reorient or relocate the affected device(s)
- increase the separation between the equipment and the affected device
- power the equipment from a source different from that of the affected device
- consult the point of purchase or service representative for further suggestions.

The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users' authority to operate the equipment.

Expected functions and performance

All types of electronic equipment may characteristically cause electromagnetic interference with other equipment, either transmitted through air or connecting cables. The term EMC (Electromagnetic Compatibility) indicates the capability of equipment to curb electromagnetic influence from other equipment and at the same time does not affect other equipment with similar electromagnetic radiation from itself.

Proper installation following the user manual is required in order to achieve the full EMC performance of the product. The product must be installed as stipulated in 4.3 Connection with the Ultrasound Device.

The Infinity box should be positioned on top of the ultrasound device to assure sufficient distance from other EM emitting devices.

When functioning as intended, the live ultrasound image from the connected ultrasound system should be streamed to and displayed by the PIUR Software without any changes in the image. The displayed image should be free from artefacts and should contain all information from the original ultrasound image as displayed on the ultrasound scanner.

The PIUR Sensor should connect to the workstation though a Bluetooth signal and should remain connected without interruptions.

In case of issues related to EMC, please call your service personnel.

Immunity and Emission Testing

The device has successfully passed the following emission measurements according to EMC Test Plan and EN 60601-1-2 and EN 60601-2-37:

- Norm Ref.: CISPR 11 - Radiated emissions 30 MHz to 1000 MHz
- Norm Ref.: CISPR 32 - Radiated emissions 1000 MHz to 6000 MHz

The device has successfully passed the following Immunity tests according to EMC Test Plan, EN 60601-1-2 and EN 60601-2-37:

- Norm Ref.: IEC 61000-4-2 - Electrostatic discharge immunity test
- Norm Ref.: IEC 61000-4-3 - Radio-frequency electromagnetic fields immunity test
- Norm Ref.: IEC 61000-4-3 - Proximity field from RF wireless communications equipment immunity test
- Norm Ref.: IEC 61000-4-8 - Power frequency magnetic fields immunity test
- Norm Ref.: IEC 61000-4-39 - Proximity magnetic fields immunity test

The device has successfully passed the following emission measurements according to EMC Test Plan and ETSI EN 301 489-1:

- Norm Ref.: EN 55032 class B - Radiated emissions 30 MHz to 1000 MHz
- Norm Ref.: EN 55032 class B - Radiated emissions from 1000 MHz to 6000 MHz

The device has successfully passed the following Immunity tests according to EMC Test Plan and ETSI EN 301 489-1:

- Norm Ref.: IEC 61000-4-3 - Radio-frequency electromagnetic fields immunity test
- Norm Ref.: IEC 61000-4-2 - Electrostatic discharge immunity test

The device has successfully passed the following emission measurements according to FCC 47 CFR Part 15 Subpart B - Unintentional Radiators:

- Norm Ref.: §15.109 ANSI C63.4-2014 - Radiated emission limits

Summary Table Electromagnetic Emissions and Immunity Declarations

Emissions Test	Compliance Level
RF Emissions, CISPR 11	Group 1, Class B Compliant Radiated emissions 30 MHz to 1000 MHz
IEC 61000-4-2 Electrostatic discharge immunity test	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge
IEC 61000-4-3 Radio-frequency electromagnetic fields immunity test	10 V/m; 80 MHz – 2,7 GHz; 1 kHz / 80 % AM
IEC 61000-4-3 Proximity field from RF wireless communications equipment immunity test	Compliant
IEC 61000-4-8 Power frequency magnetic fields immunity test	30 A/m, 50 Hz / 60 Hz
IEC 61000-4-39 - Proximity magnetic fields immunity test	30 kHz: 8 A/m; CW 134.2 kHz: 65 A/m; PM 2.1 kHz 13.56 MHz: 7.5 A/m; PM 50 kHz
§15.109 ANSI C63.4-2014 - Radiated emission limits	Compliant

Unexpected Disturbances and Malfunctions

EM disturbances as normally present in the defined use environment have no impact on the performance and functionality of the device. However, strong, unexpected EM disturbances at frequencies or intensities outside of the tested values might affect the performance of the device as follows:

- System malfunctions and does not turn on
- Image artefacts or unusual noise are visible in live stream of the transferred ultrasound image
- Live stream of the transferred ultrasound image might be blinking
- Large blocks of image information might be missing in the live stream of the transferred ultrasound image
- Live stream of the transferred ultrasound image might look corrupted in any other way
- Bluetooth connection of sensor or wireless connection of video box might not be possible