PIUR IMAGING

PIUR® tUS Infinity

User Manual

User Manual
PIUR® tUS Infinity

Document Revision 23.0

Software version: 4.4

Type: PIUR tUS Infinity

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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.

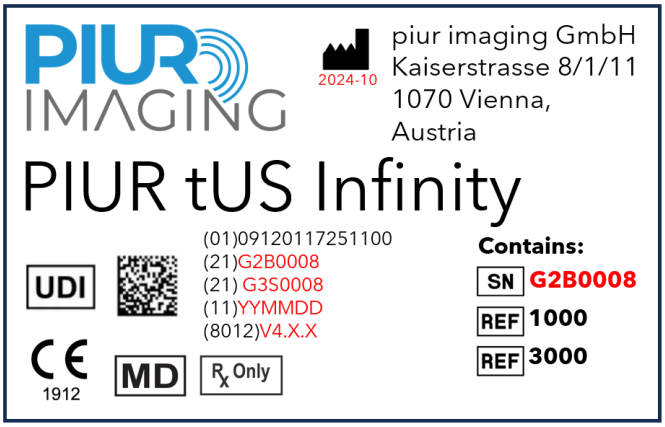
1.3 Symbols on Device

Symbol	Description
	Stand-by symbol
	Wireless charging symbol

1.3.1 Identification Label

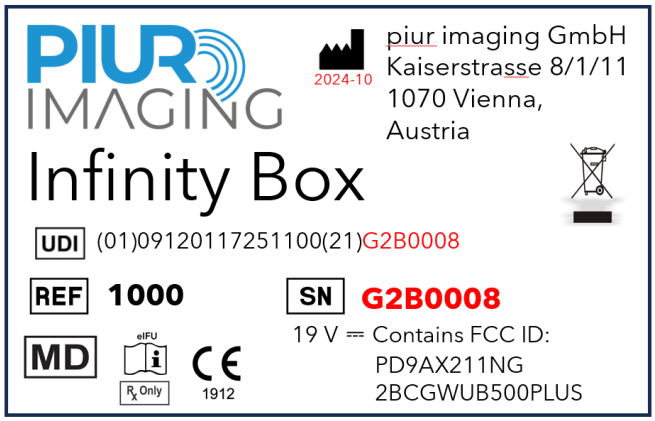
The identification label with the corresponding serial number can be used to identify the device. Please note down the serial number of the device before contacting the PIUR service.

System Label

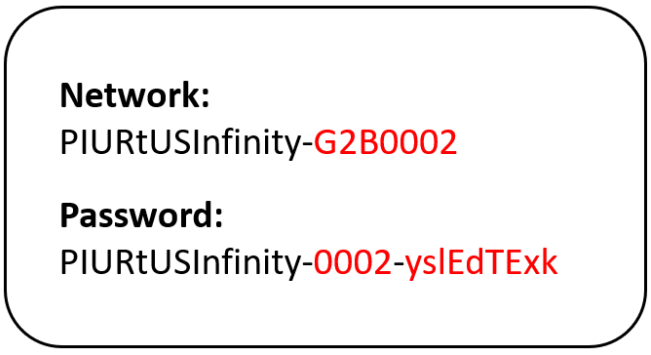


Infinity Box Label

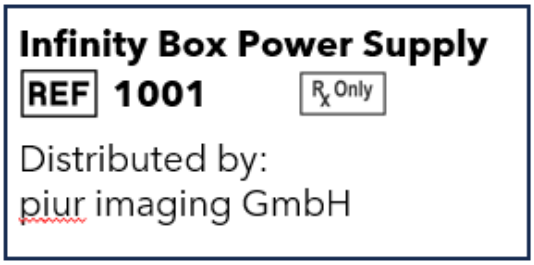
Affixed on device (component), size 60x40mm:



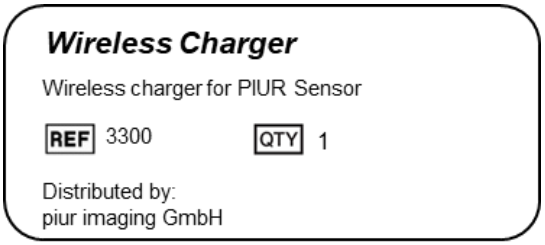
Wi-Fi label affixed on the device component:



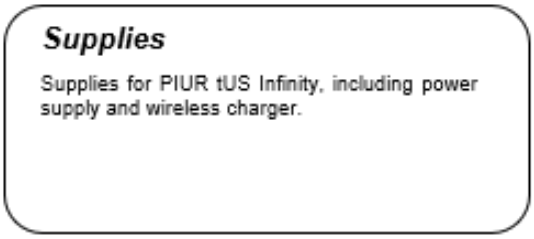
Infinity Box Power Supply Label



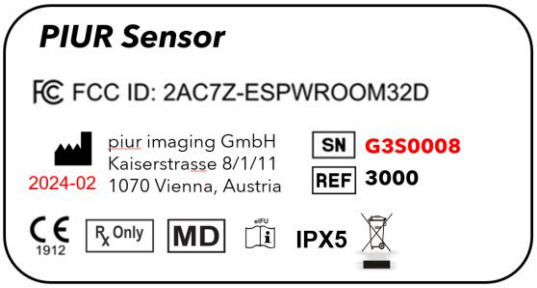
Wireless Charger Label



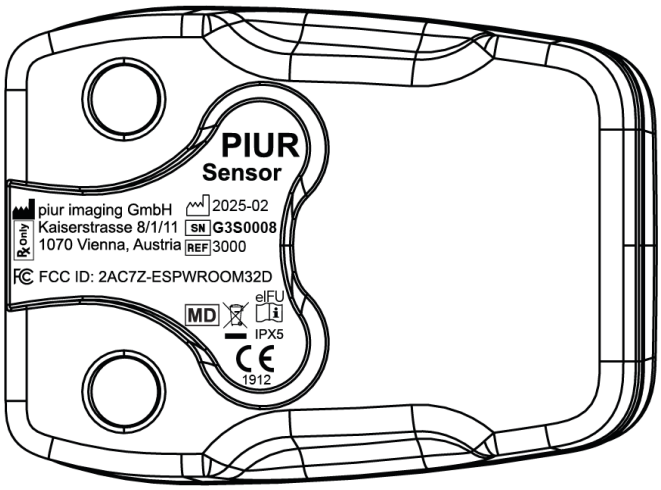
Infinity Box Supplies Label



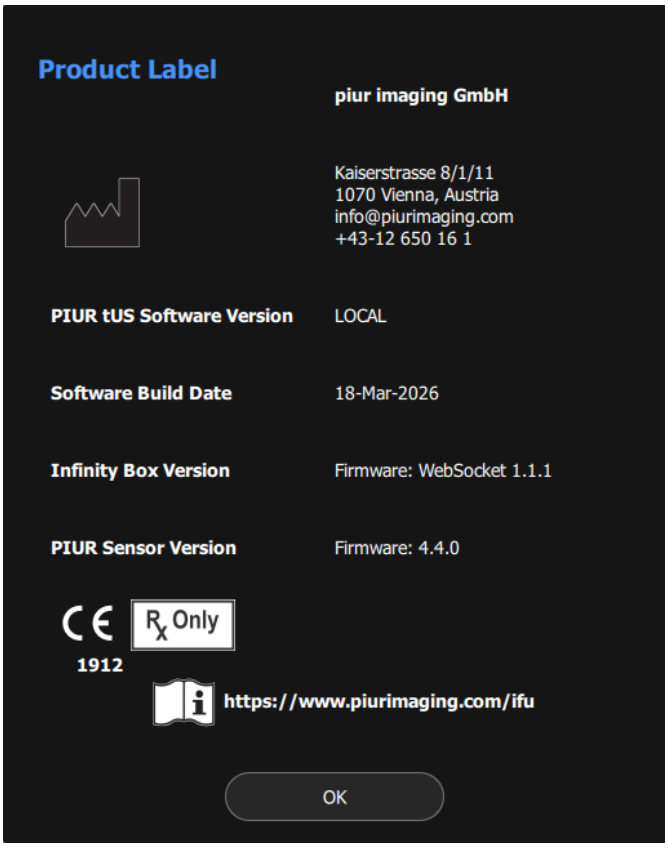
PIUR Sensor Label



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

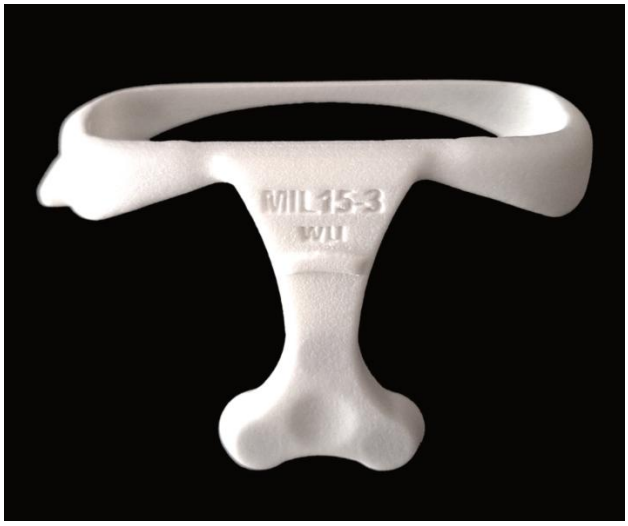


PIUR tUS Software Label

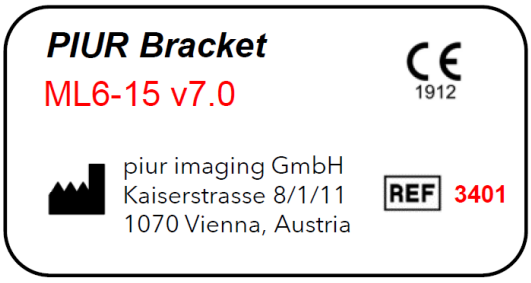


Remark: PIUR tUS Software Version will be the Software release version with respective Software Build Date.

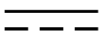
PIUR Bracket



PIUR Bracket Label overview (specification):



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

Symbol	Description
	Serial number
	Catalogue number
	The product is a Medical Device
	Unique Device Identifier
	Manufacturer
	CE mark with Notified Body number
	Consult Instruction for Use (electronic)
	Direct current (DC)
	Alternating current (AC)
	The system must not be disposed with normal waste (see Section 7).
	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
	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 to help the user in the safe and correct operation of the system.

1.5 Intended Use

The PIUR tUS Infinity system is a non-invasive, transient and active medical device which fulfills all MDR 2017/745 requirements for class IIa, intended to support the user with the examination on various clinical applications by providing 3D information generated from a sequence of external ultrasound images.

2D ultrasound images, acquired by a compatible third-party ultrasound device, and position data, generated by the system-integrated PIUR Sensor, are the basis for 3D image reconstruction. The third-party ultrasound device must be a medical device according to MDR 2017/745 with a valid CE-Label.

The PIUR tUS Infinity acts as part of the diagnostic chain only and must not be used as a sole source for treatment decisions.

PIUR tUS Infinity device is not intended for body contact (including skin, mucosal membranes, breached or compromised surfaces, blood-path indirect locations, internal tissues, bone, dentin, or circulating 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 GmbH 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 risks mitigation, residual risk of this medical product remain. Within the Risk Management process, a total of 125 residual risks have been identified. There following residual risks are considered as significant:

- Wrong but anatomically correct image

As a diagnostic system, the most relevant output of the device is image information. This image information can influence medical decisions in terms of therapy, treatment, prevention or further alternative diagnostic information. Caused by various factors, the system may display incorrect image information after image reconstruction. Such inaccuracies can result from erroneous image or tracking inputs, software issues, or user errors. The incorrect 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 missing necessary interventions or surgeries or performing unnecessary ones. This residual risk affects the patient.

- Incorrect measurement

Measurement features within the software may influence diagnostic decisions and, consequently, subsequent therapy, treatment, prevention, or alternative diagnostic actions. Due to various internal or external factors - including user errors, inadequate image input, or unintended event sequences - measurement inaccuracies may occur. Out-of-plane (length) measurements are particularly sensitive and require appropriate use and sufficient image quality with an adequate frame rate. The residual risk is a measurement deviation outside of the disclosed error range that may lead to wrong image information, similarly to the residual risk described under “Wrong image information”. This residual risk affects the patient. For further details of measurement deviation and errors please see Section 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. Failure to do so can lead to the accumulation of bacteria and other harmful microorganisms, which can cause infection and other health problems. Adherence to the recommended cleaning procedures helps maintain device safety, effectiveness, and reduces the potential health risks for both users and patients.

- Misdiagnosis due to wrong diagnostic output

Misdiagnosis may occur if incorrect automatic diagnostic suggestions are accepted without verification. This includes situations in which the user accepts inaccurate automatic Margin suggestions or incorrect automatic Echogenic Foci suggestions. To mitigate this risk, the software displays an exclamation mark in the UI for these TI-RADS parameters, accompanied by a warning reminding the user to verify their accuracy, to easily prevent incorrect assessments and reduce the likelihood of misdiagnosis.

- 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.

- DICOM export orientation

When exporting images or volumes in MPR format, the system uses the standard medical body directions (left–right, front–back, top–bottom).

This ensures that the exported images always show the correct anatomical orientation. The user can clearly see where a structure or lesion is located within the patient's body, for example from the front left towards the lower side.

- Disinfection agent

Disinfection agents used for disinfection can possibly damage sensitive components of medical equipment, such as probe, attachments, screen or cart. Disinfection agents may also harm the device's electronics if not used according to the manufacturer's guidelines.

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

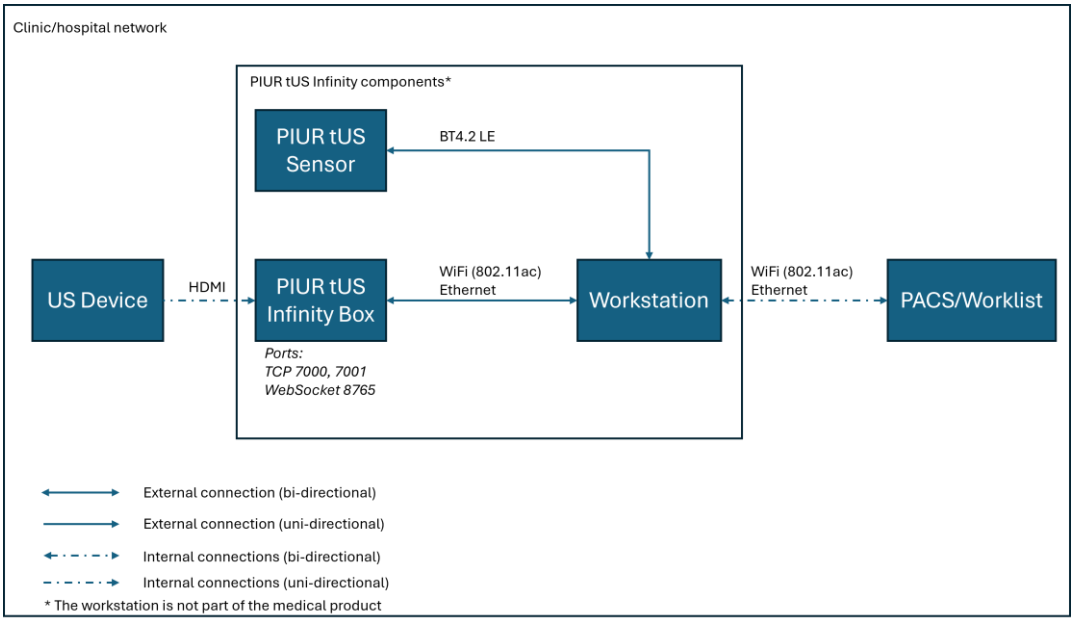
1.8 Recommendations regarding Cybersecurity

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 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 (5 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	Cabled connection for data exchange with the PACS and worklist server.	Single-port integrated multi-gigabit (up to 2.5G) – standard IEEE 802.3 Ethernet	Port 8765	Port 8765

Name	Function	Details	Protocol for connection	Inbound connection	Outbound connection
	not established by default, customer request only. 2)Connecting the workstation to the Infinity Box	Cabled connection for image transfer from ultrasound to workstation	interface for 2500BASE-T, 1000BASE-T, 100BASE-TX, 10BASE-TE connections (IEEE 802.3, 802.3u, 802.3bz, and 802.3ab)		
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 ends meet the required conditions. DICOM conformity for SOP UID required on the peer.	TCP / IP, configurable IP and ports	Specifiable in PIUR tUS software settings, standard port 11112	Specifiable in PIUR tUS software settings

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 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 Class IIa in accordance with the Medical Device Regulation 2017/745, Annex VIII.

The conformity of this product according to the general safety and performance requirements of MDR 2017/745 was proved with the Conformity Assessment Procedure as per Annex IX.

The manufacturer documents so with the CE-Label.

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Authorized Representative in UK:

Qserve Group UK, Ltd.

282 Farnborough Road, Farnborough, Hampshire GU14 7NA, England, United Kingdom

GMDN code: 40873 - Ultrasound imaging system application software

2 Safety Regulations

The assembly of medical electrical systems and changes during the actual service life require a check regarding 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 Infinity and inform the PIUR 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 power supply specified in Section 4.1 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 authorised service personal 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 a 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 supplements commercially available ultrasonic devices with tomographic image representation and thus allows 3D analysis of ultrasound data, comparable with CT or MRI image representation. Examining doctors can call upon both 2D as well as 3D ultrasound data to make their diagnosis, which can simplify daily work and improve diagnostic quality.

The high-resolution three-dimensional datasets are generated by an IMU (Internal Measurement Unit) sensor tracking on the ultrasonic probe during a free hand scan. The data is transmitted to a control unit via Bluetooth. The ultrasound images are continuously sent to the PIUR tUS Infinity Box via the video output of the ultrasonic device and transmitted wirelessly to the control unit via Wi-Fi or through the Ethernet interface. From this two information, the system then calculates the three-dimensional volume. From the video signal, all system parameters required for data generation, such as frame rate, depth, and US probe, are automatically detected, processed and transmitted to the computer via Wi-Fi or through the Ethernet interface.

In order to generate three-dimensional datasets, PIUR tUS Infinity requires the following components (see Figure 1):

- Computer with pre-installed PIUR tUS software
- Wireless tracking sensor installed in a compact sensor box
- A volume attachment or front clip to fix the sensors on different probe models
- A compatible ultrasound device including a probe to generate sonography images
- Infinity Box connected to the ultrasonic device

The Infinity system has no applied parts according to the standard EN 60601-1. The medical electrical system consists of the parts given in Section 4.1, the diagnostic ultrasound device and the computer. The computer is the only non-medical equipment that has to be placed outside the patient environment. The patient environment is shown in Figure 3. The PIUR Sensor is not an applied part according to the standard EN 60601-1 but fulfils all requirements for applied parts with exception of the marking.

Figure 1: PIUR tUS Infinity system set-up

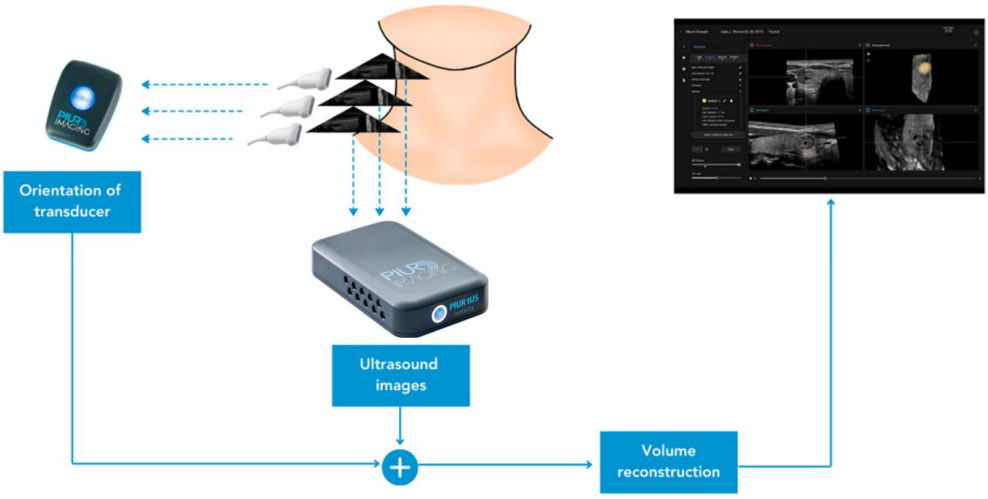


Figure 2 Generation of a 3D dataset

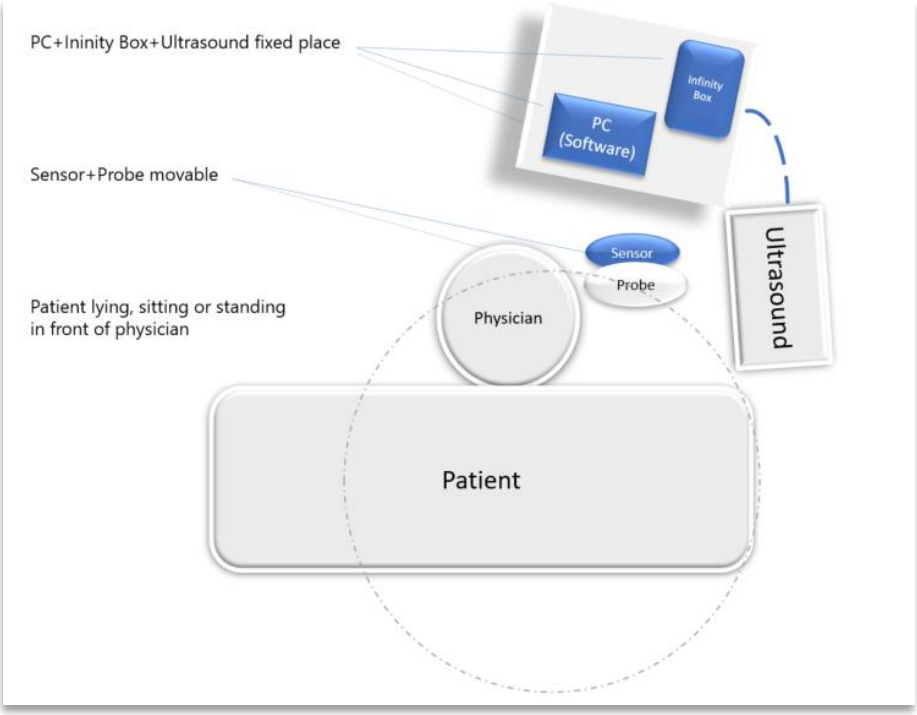


Figure 3 Patient environment as defined in EN 60601-1

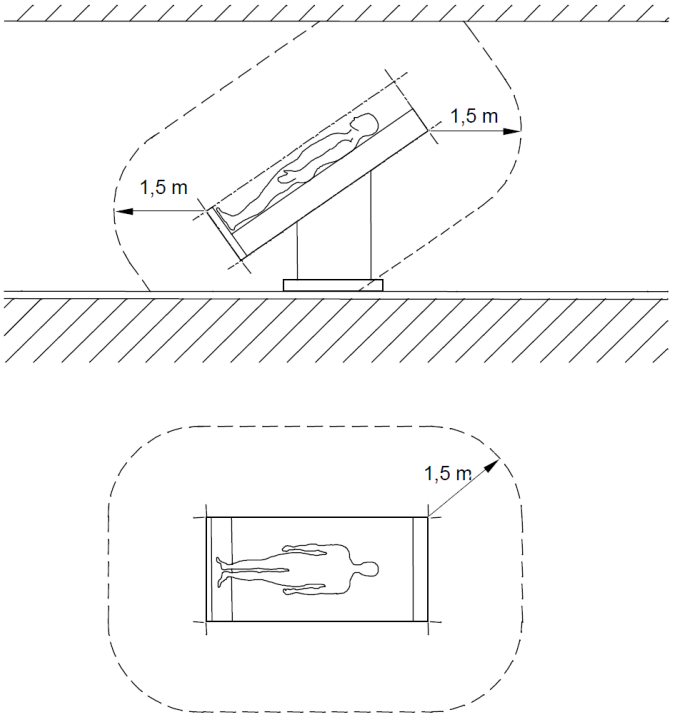


Figure 4 Clinical Setup

3.2 Clinical Indications

- Thyroid
- Cerebrovascular
- Vascular mapping
- Peripheral neuronal
- Abdominal

Table 1 PIUR tUS Infinity apps and Respective Clinical Indications

App	Respective Clinical Indication
Thyroid App	Thyroid
Plaque Analysis App	Cerebrovascular
General Imaging App	Vascular mapping
	Peripheral neuronal
	Abdominal

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

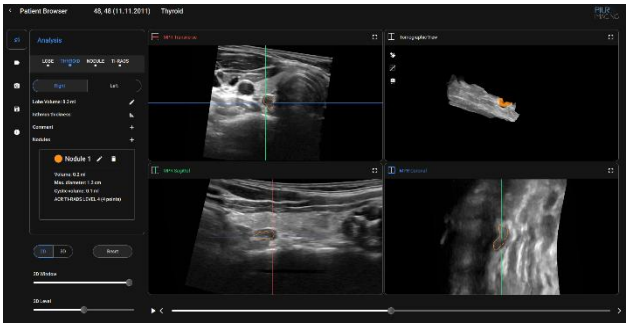
The clinical benefits of PIUR tUS Infinity are presented below:

Table 2 Benefits of the different Applications

Clinical Indication	Benefit
Thyroid	Accurate 3D volume measurements of thyroid nodules reducing the user dependency of volumetry from 2D US protocols
	Improved monitoring of disease progression over time
	Improved planning of thyroid ablations
	Simplified explanation of disease and treatment decisions to patient through 3D visualizations
	Standardized classification of thyroid nodules
Cerebrovascular	Fast scanning
	Less operator dependency
	Quantification of atherosclerotic burden
	Efficient monitoring of disease
	Reduced exposure to ionising radiation
Vascular mapping	Reduction in scanning time and higher patient-throughput
	The ability to retrospectively access the volumetric scans
	Easier illustration to surgeon/enhancement of the doctor's confidence in surgical decision-making
Abdominal	Fast scanning
	Improved accuracy
	Less operator dependency
	Enabling volumetric aneurysm measurement
	Reduced exposure to ionising radiation and nephrotoxic contrasts
Peripheral neuronal	Quantification of nerve compression

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
H05VV-F 3G0.75 C13 (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 to the Computer (laptop)

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

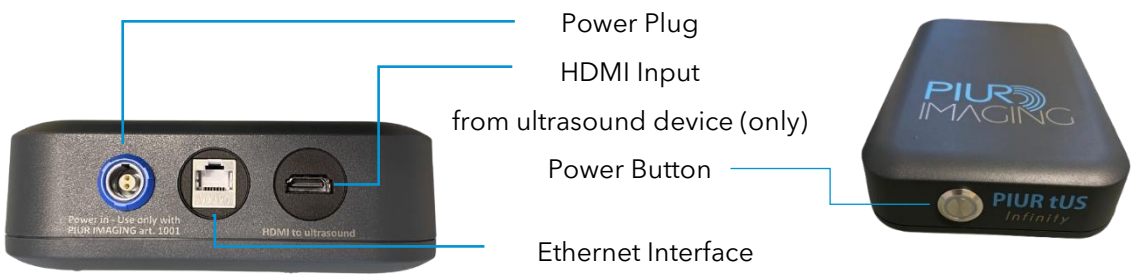
Minimum requirements:

- 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

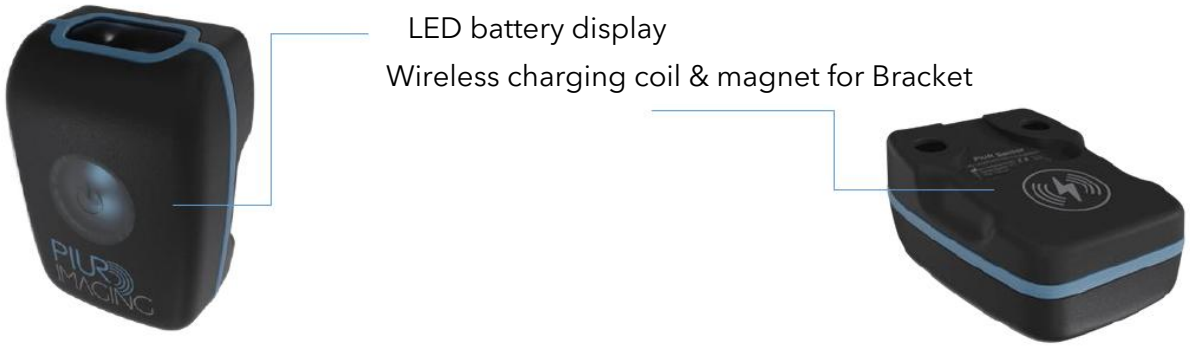


The video streaming box has an integrated frame grabber that continuously sends video signals to the computer. The box is automatically connected to the computer by internal Wi-Fi or through the Ethernet interface. Ensure that the selected connection method is active and that the computer and the box 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. 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 as headsets or phones with the computer while using the PIUR Sensor

The optical flow sensor (PAA5100JE-Q) does not use any lasers. The time of flight sensor does use a class 1 laser in compliance with IEC 60825-1:2007.
Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No.50, dated June 24, 2007.

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

Status	Colour	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 or Ethernet. The Video Box connects to the ultrasound device through a video cable. A HDMI cable including two adapters (DVI and Display Port) 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

The list of compatible ultrasound devices can be obtained from the manufacturer. Please contact **service@piurimaging.com**

4.4 Switching on PIUR tUS software

1. Make sure the video cable is connected to both 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 is starting 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.

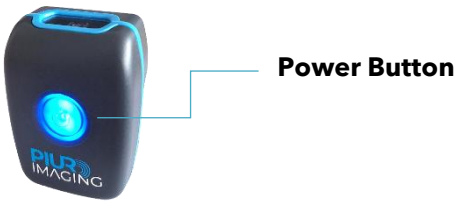
The device is properly installed and can operate safely and correctly if the following criteria are met:

- ☐ 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 5: 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 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 use 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.

4.7.2 Securing the PIUR 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

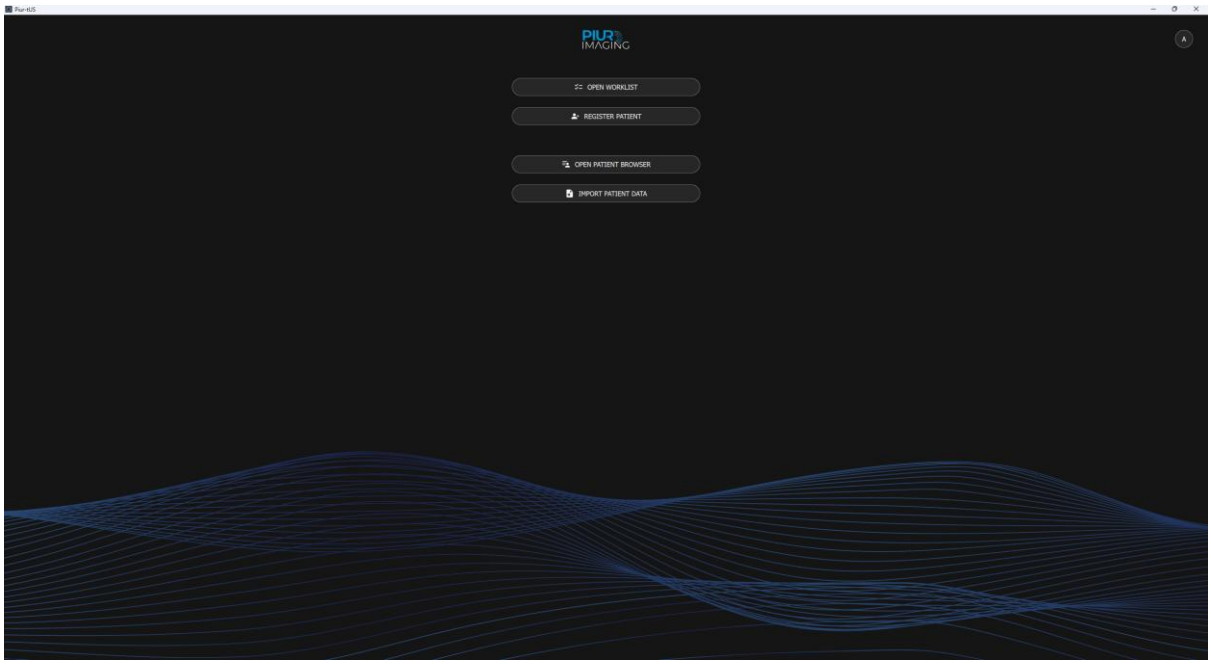


Figure 6: PIUR tUS starting screen

Explanation of the symbols and functions:

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

5.2 User Menu

Click on the User Icon in the top right corner

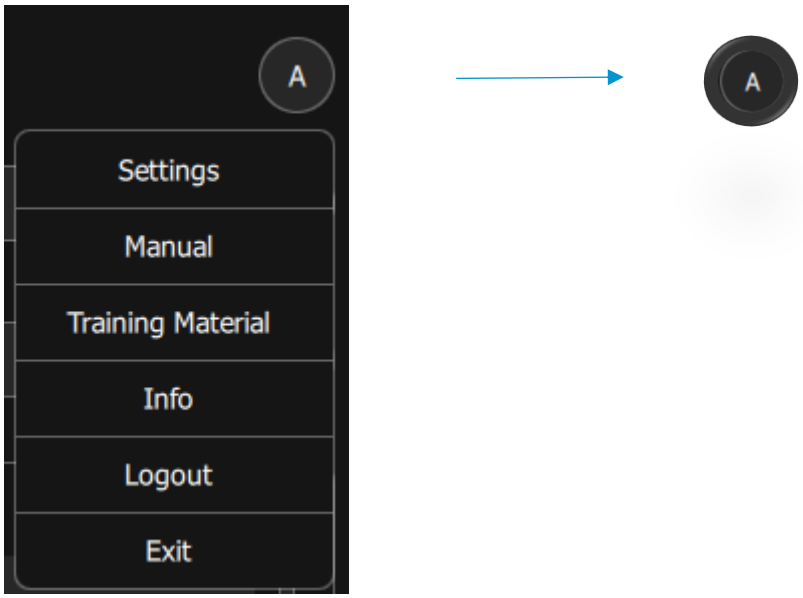


Figure 7: User Menu

Explanation of the symbols and functions:

"Settings"	Opens the settings 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"

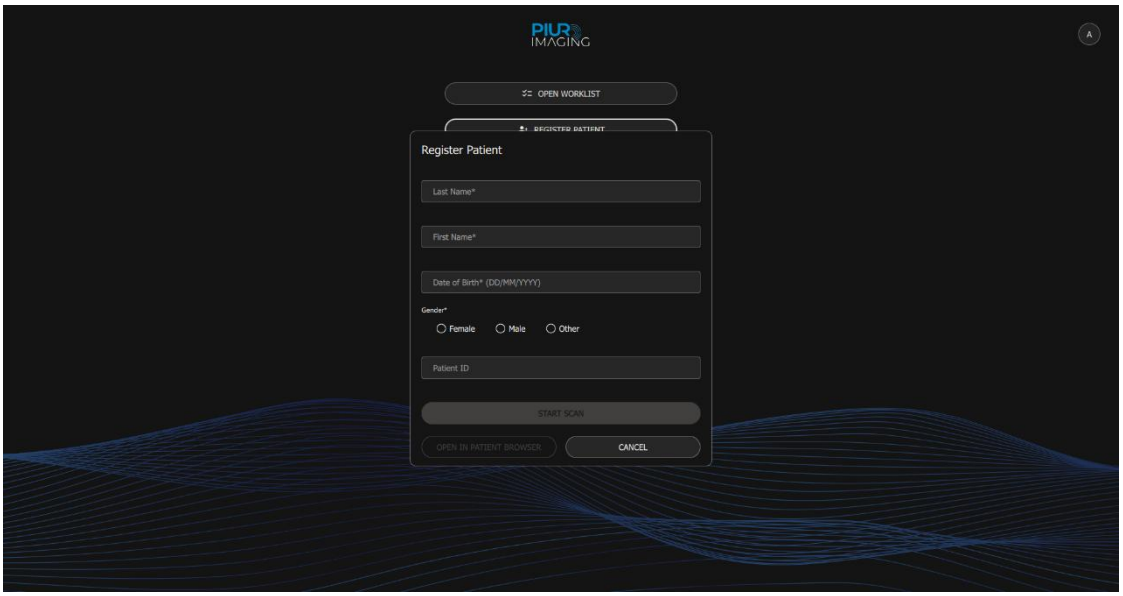


Figure 8: User interface "Register Patient"

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 patients previously entered 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 “strg” key and clicking on new patients from the list.

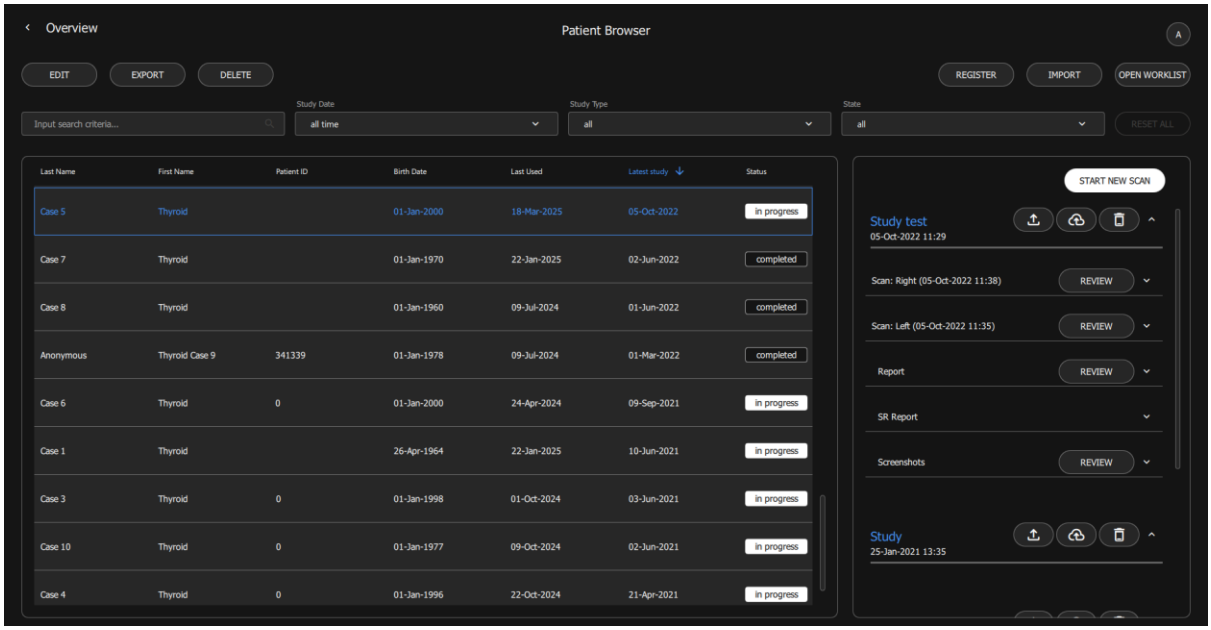


Figure 9: User interface "Patient Browser"

“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

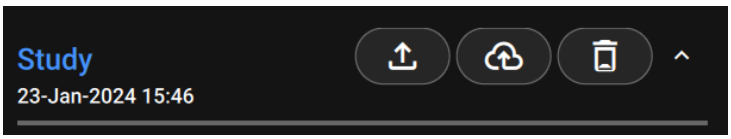


Figure 10: Options menu for exporting, sending to PACS or deleting a scan

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 9)
Scan "Review"	Opens the review screen with the acquired diagnoses and the possibility to start or redo the analysis (Figure 9)
Report "Review"	Opens report in Fullscreen. (Figure 9)
Screenshots "Review"	Opens screenshots in Fullscreen. (Figure 9)

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 11).

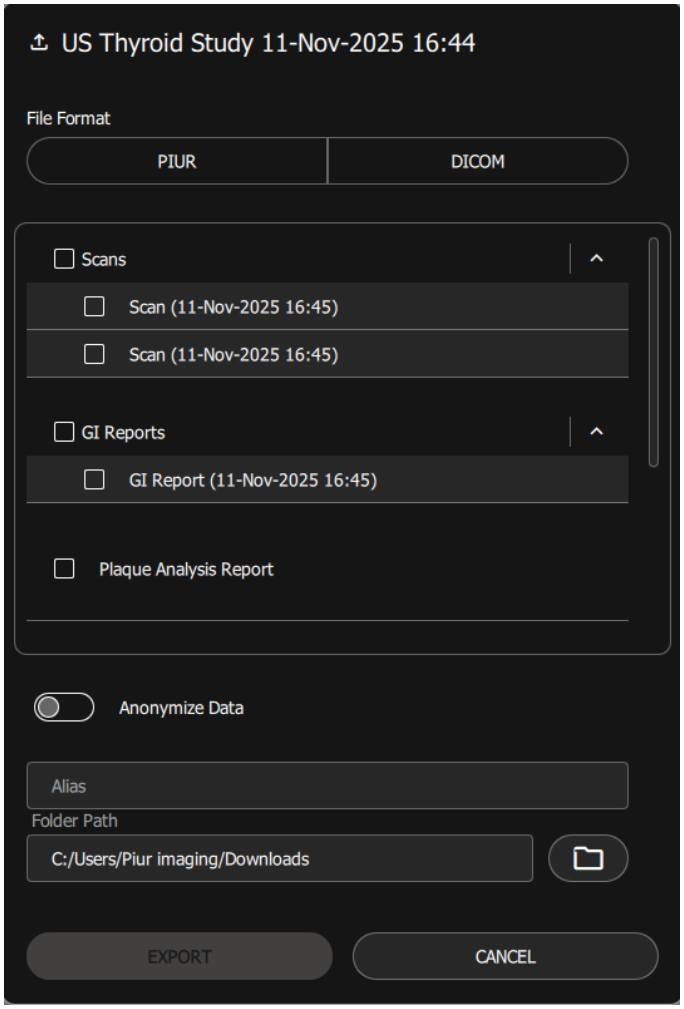


Figure 11: Export Study as DICOM or PIUR file

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.

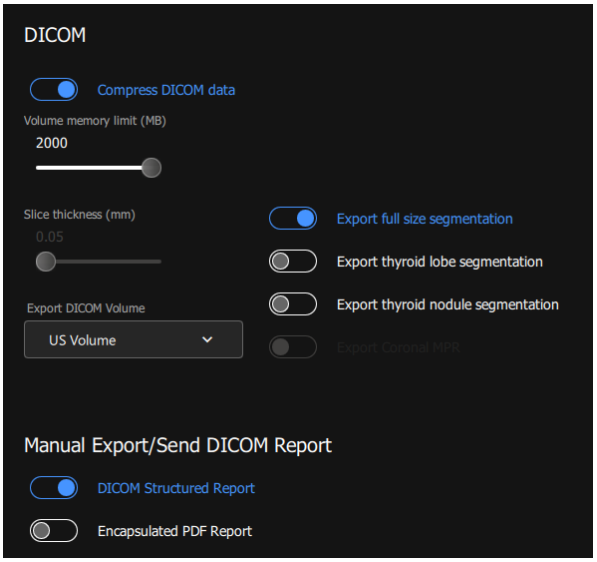


Figure 12: DICOM format options

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.

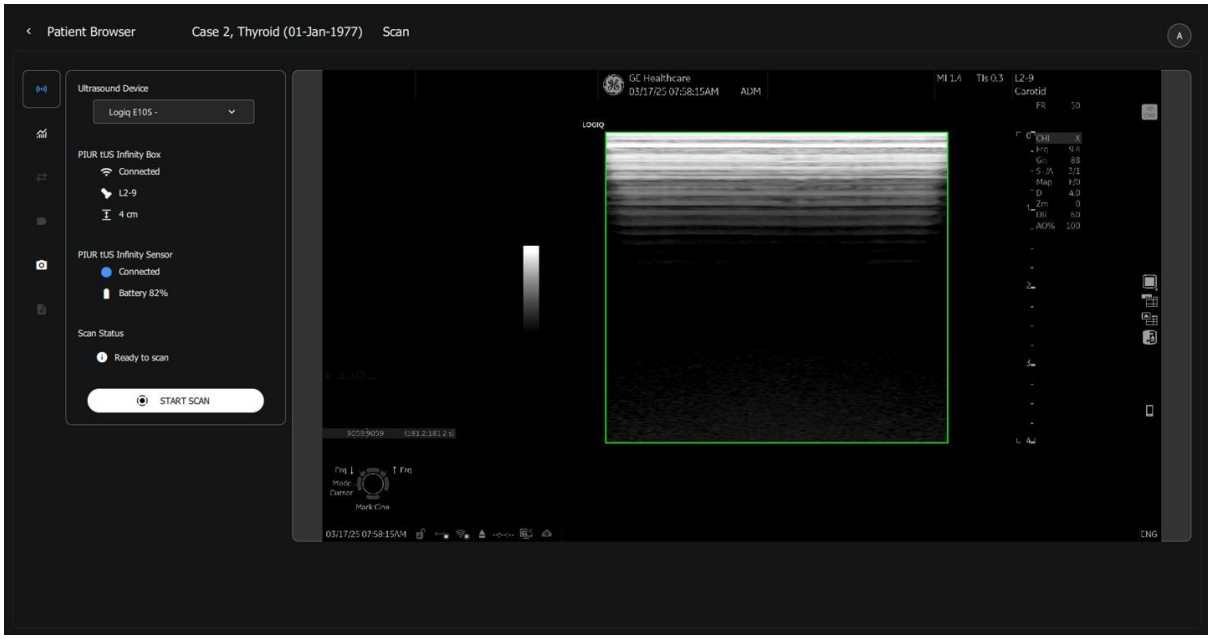
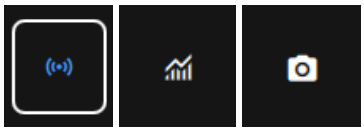


Figure 13: Acquisition mode

"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.

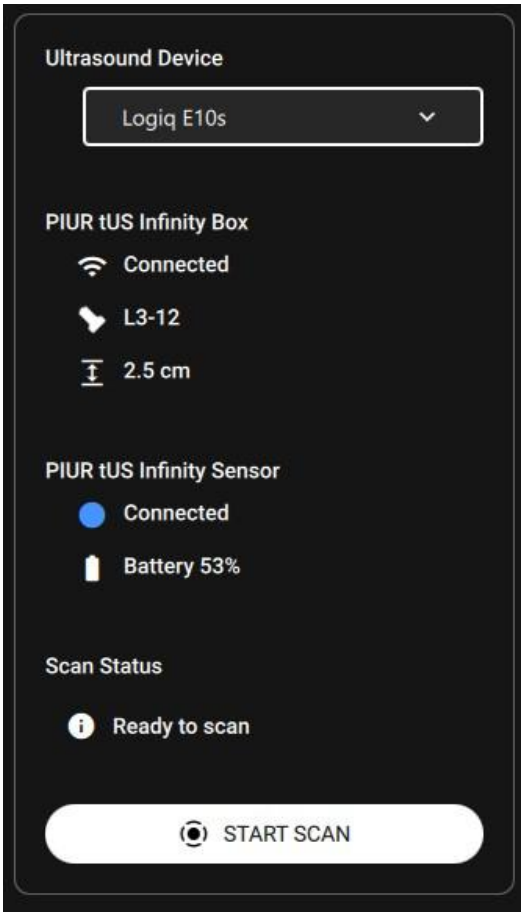
Important: Use of the delivered remote control may only be performed by the treating doctor/staff but **not** by the patient.

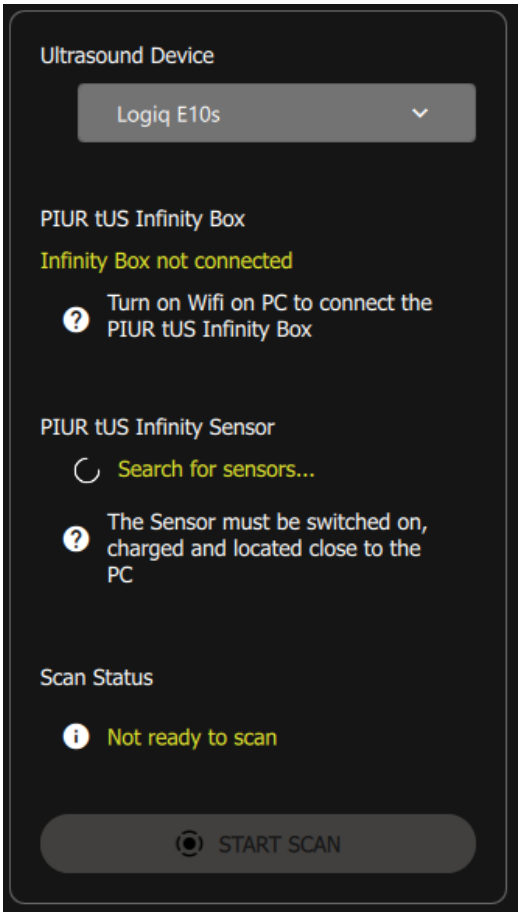
Safety Notice: Erroneous detection of parameters. In rare cases a system parameter can be wrongly identified. The Auto-detection symbol still lights green in this case.

- To avoid errors in the dataset, the parameters recognised 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

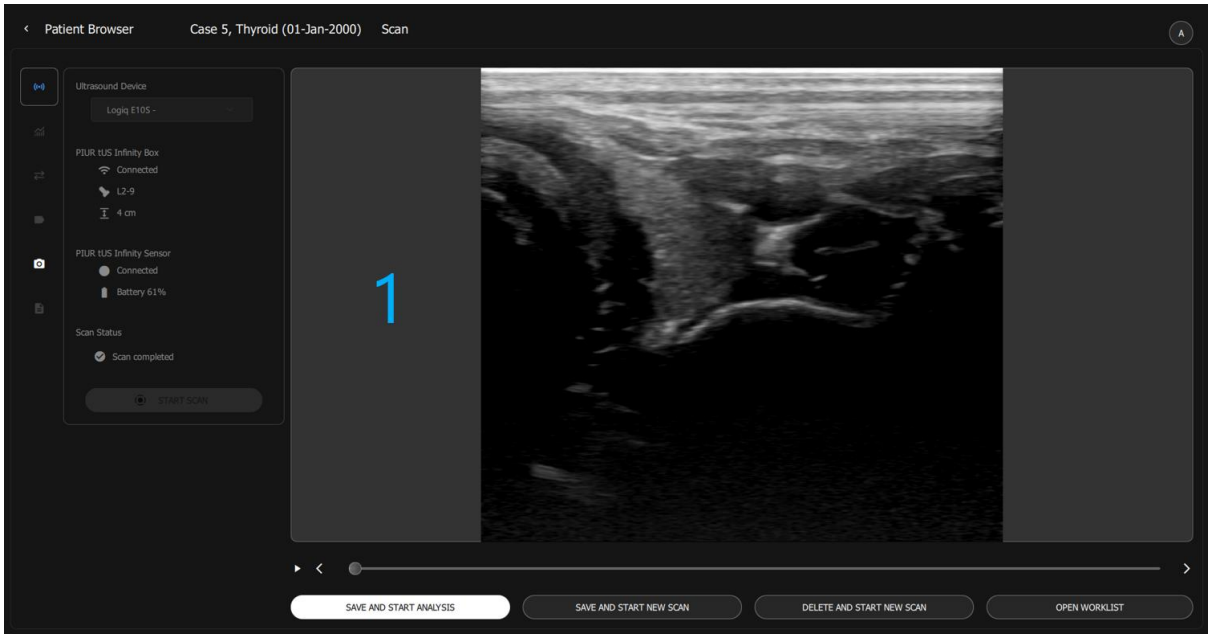


Figure 14: "Post Acquisition" user interface

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. (5.6.2.4)
"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

5.6.1 Display and Operating Window in the "Review" mode

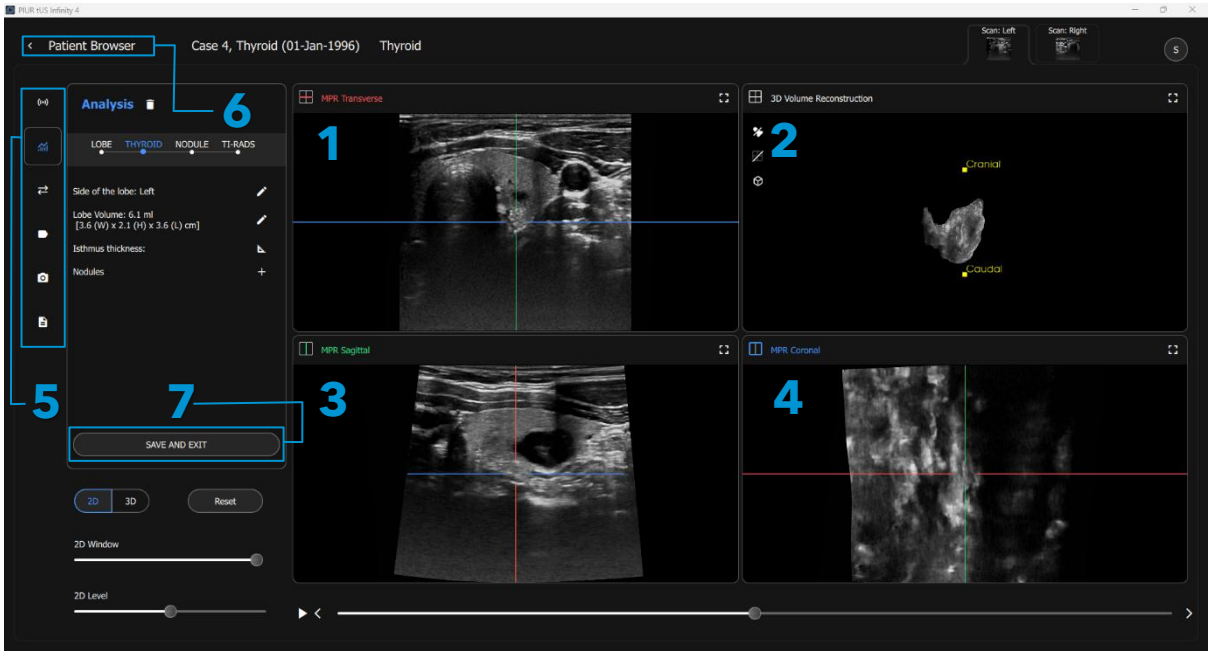


Figure 15: Operating window in the "Review" mode

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, app change, 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
	Analyse Lobe and Nodules
	Change between Thyroid App and General Imaging App
	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 level settings

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

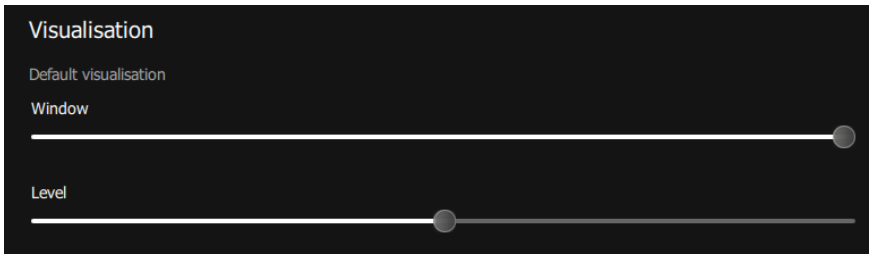
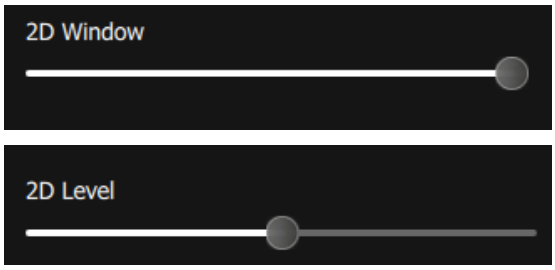
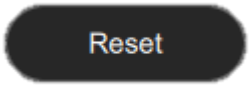


Figure 16 Default Window and Level in User Settings



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

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



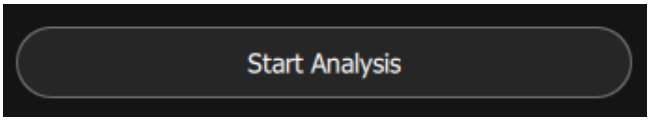
Reset the orientation of the MPR and 3D to default.

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

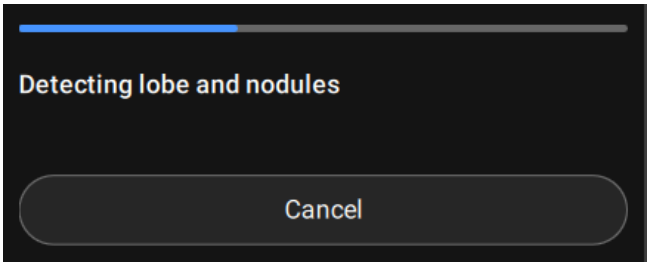
5.6.2.4 Image Analysis

Thyroid App

Menu Wizard

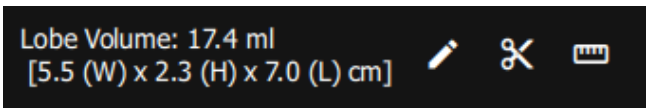


Press “Start Analysis” to trigger the prediction of the AI Network.



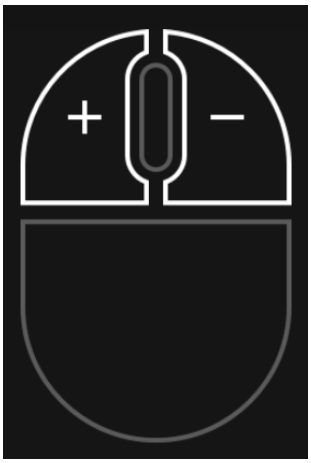
The progress bar gives indication regarding the process. There is also the option to cancel.

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.

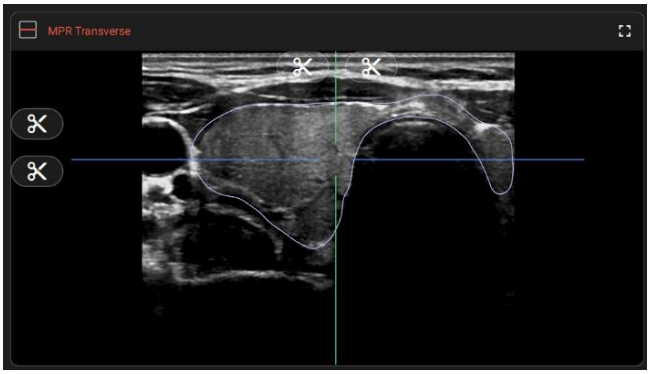


Here the user can adapt the automatic segmentation manually, by clicking the left and right mouse button as marked in the image.

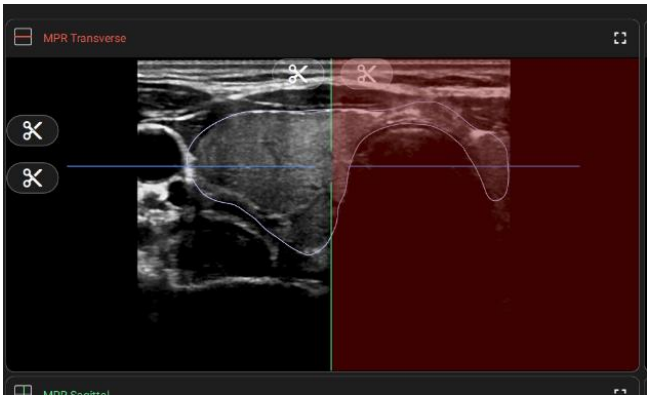
“-” click and hold this button while moving over the parts of the segmentation which should be excluded from the volume segmentation

“+” click and hold this button while moving over the parts of the segmentation which should be included into the volume segmentation.

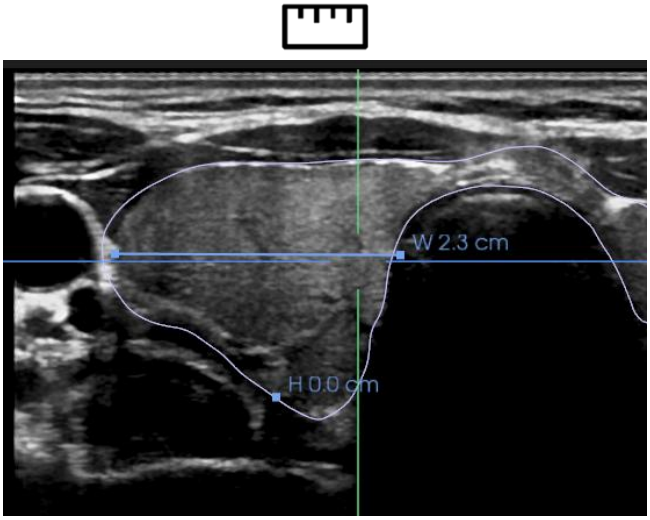
Press the scissor icon, to cut parts of the lobe volume.



Cutting icons are displayed along the planes.

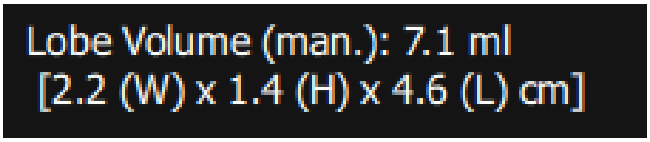


Hover with the mouse over the icon gives a preview of the to cut area.



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:

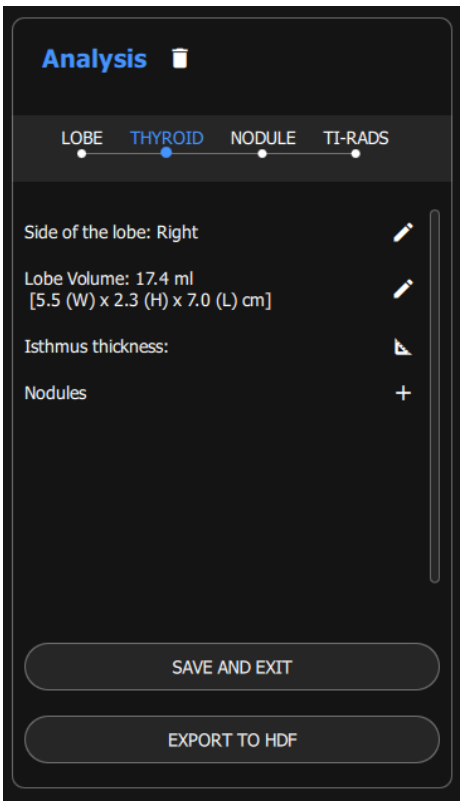
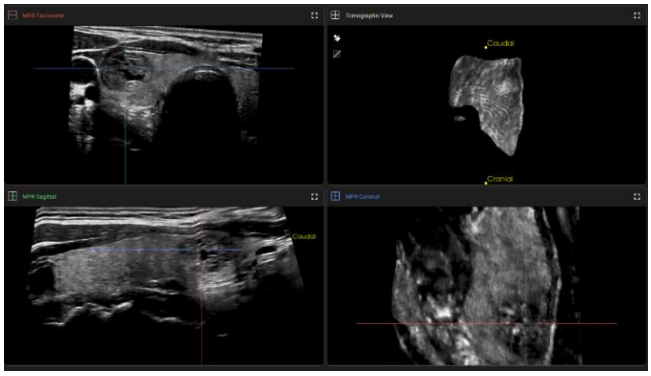
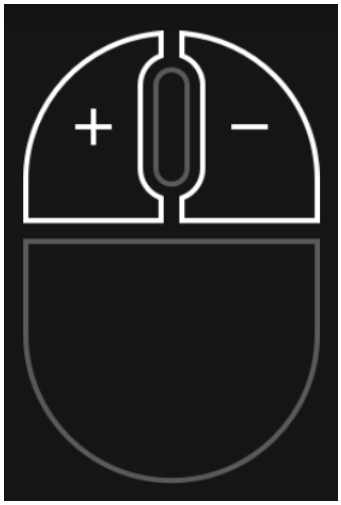
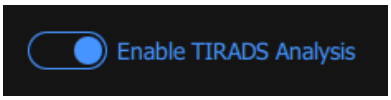
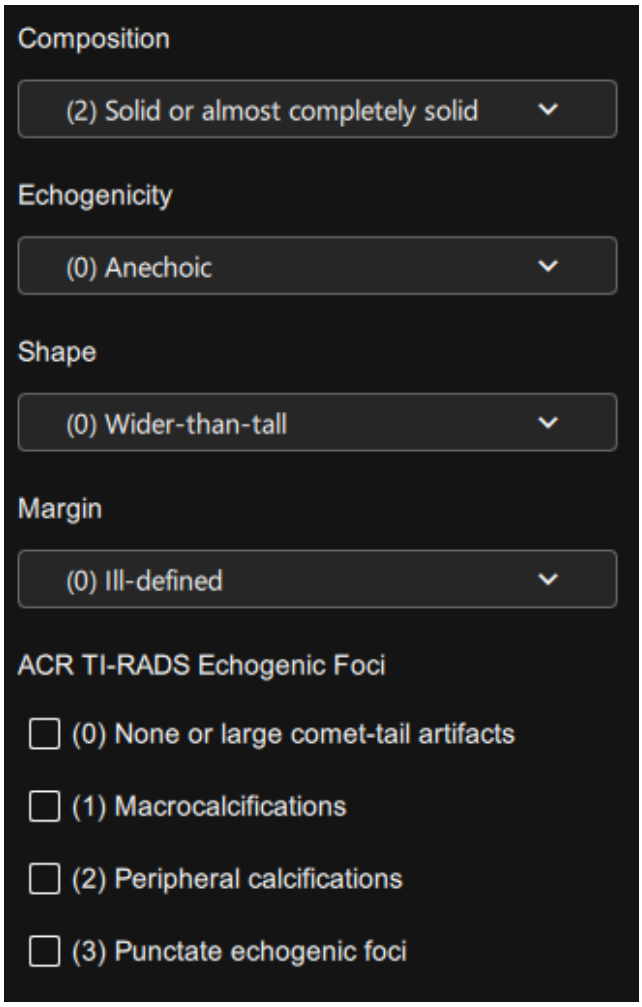


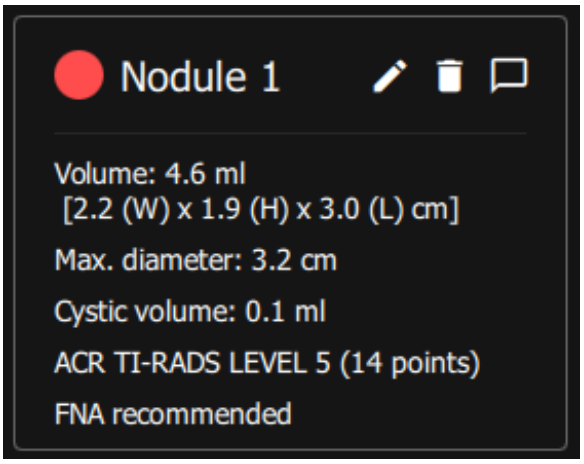
Figure 17: Thyroid Analysis Menu

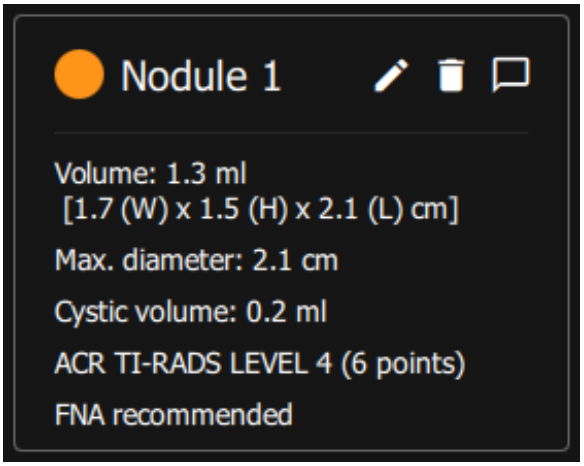
In thyroid analysis menu it is possible to proceed with the following options:

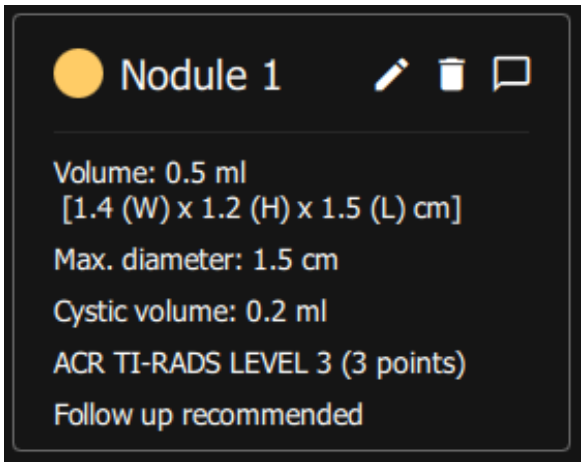
	Modify Side/ Volume of the lobe.
	Create a 2-point line measurement in the MPR to measure the Isthmus thickness.
	Add a nodule to the analysis by clicking on the plus.

	Move the MPRs to the centre 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 TI-RADS menu.

"Discard nodule"	Nodule is discarded and nodule menu is exited.
In General Settings: 	On: Enables software-generated TI-RADS suggestions Off: displays an empty TI-RADS analysis menu for manual entry of the user
	The software suggests: 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 maybe adjusting, accept the selection.
"Accept"	Accepts the selected ACR TI-RADS points and the calculated TI-RADS level.
"Skip"	Skips the ACR TI-RADS 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 let you 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:

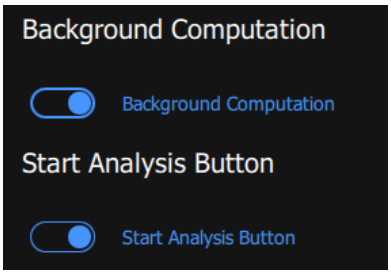
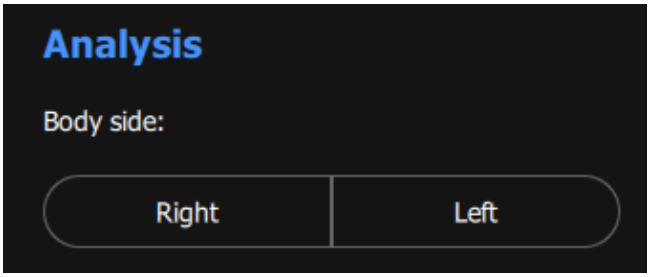
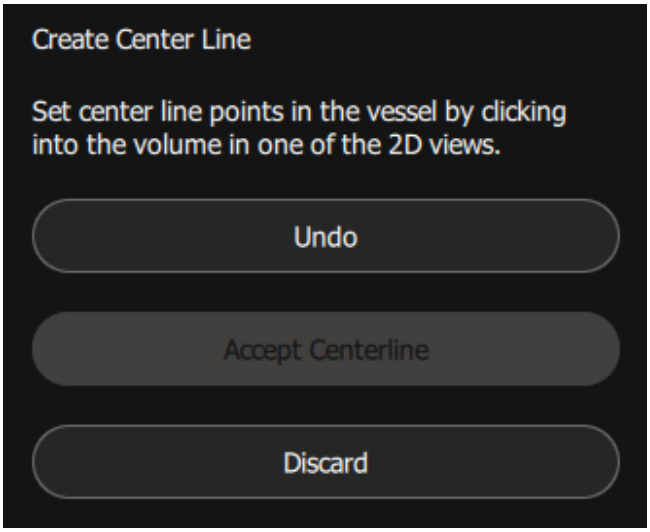


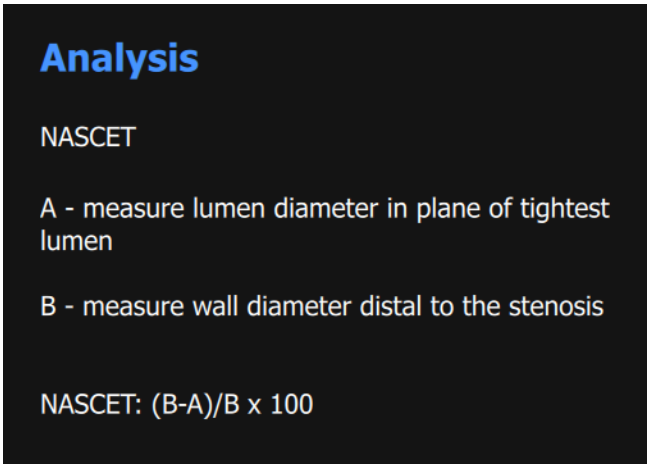
Figure 18: Analysis optimization User Settings

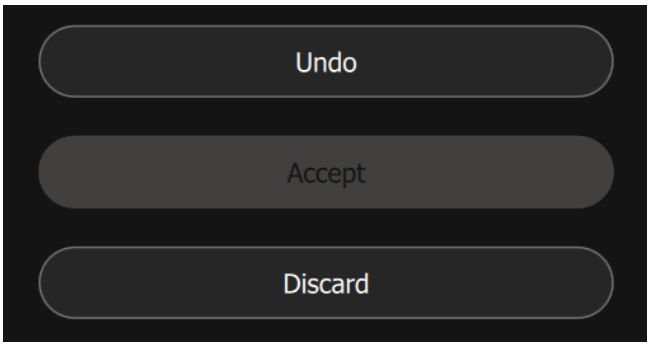
Below is the table describing each option in more detail:

"Background Computation"	The system starts the analysis for all yet non-analysed 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.

Plaque Analysis App

	Side can be selected by clicking the respective side button.
	Add the centerline of the vessel by clicking on the plus.
	Position the cursor in any of the 2D views and click to place a centerline point at the vessel's center. Scroll through the frames and place additional points as needed along the vessel path. After defining all desired points, select **"Accept Centerline"**.

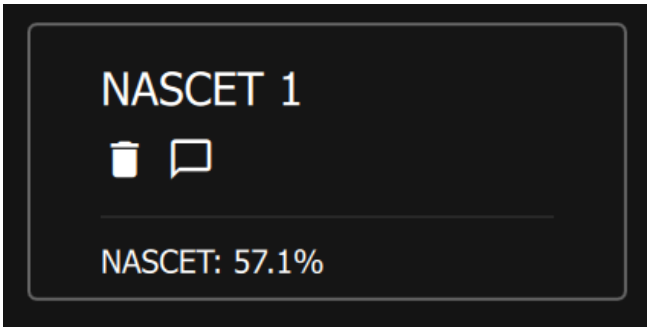




Click on the desired points in the 2D views to place the endpoints of lines A and B. Each endpoint is set with a mouse left-click.

Once both lines are defined, select **"Accept"** to perform the calculation.

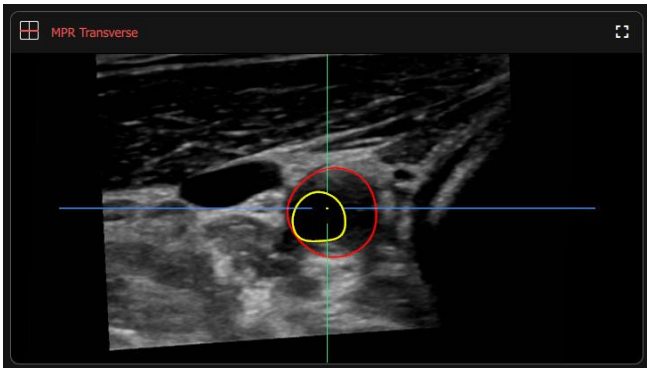
"Undo"	Jumps one step back, which was performed in the respective tool.
"Discard"	NASCET is discarded.

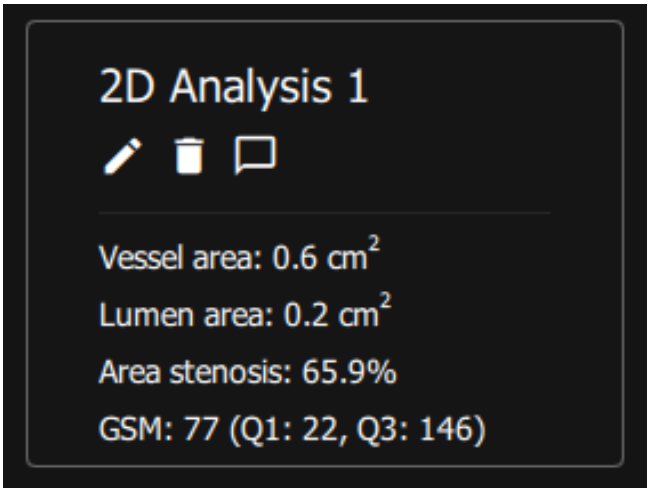


NASCET Summary:

- Rename: double-click on the name, make changes and press the Enter key
- Comment
- Delete

Create an area reduction measurement of the vessel by clicking on the plus.





Select a 2D plane to draw the vessel wall and lumen.

The vessel wall is outlined by placing points along its boundary using left-clicks (red). Once the contour is complete, it is confirmed by selecting **"Accept Wall"** or by right-clicking.

The lumen is outlined in the same manner and confirmed with **"Accept Lumen"** or a right-click.

The vessel area, lumen area, stenosis area, and GSM are automatically computed.

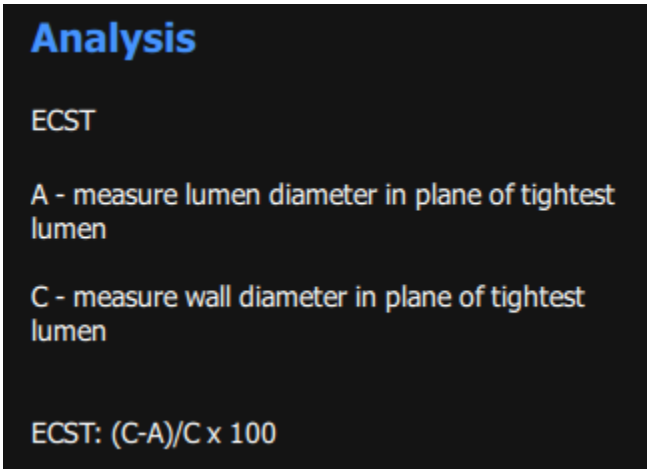
Add a comment, edit, or delete the analysis.

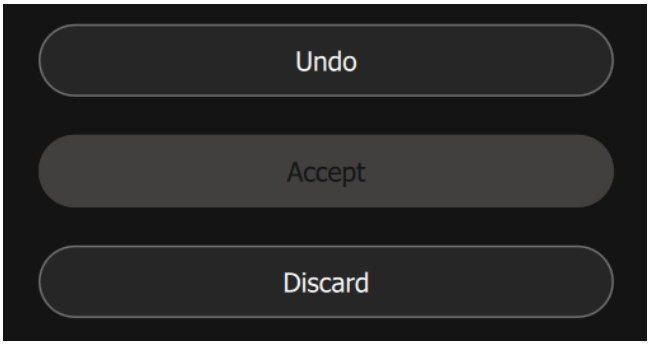
Edit Area Reduction tool

- Move points: press and hold left mouse button on existing points
- Delete points: click on existing point with right mouse button
- Add points: click and hold left mouse button on the spline, drag to the desired position, and release to place a point.

Area Reduction analysis is discarded.

Create a ECST measurement of the vessel by clicking on the plus.

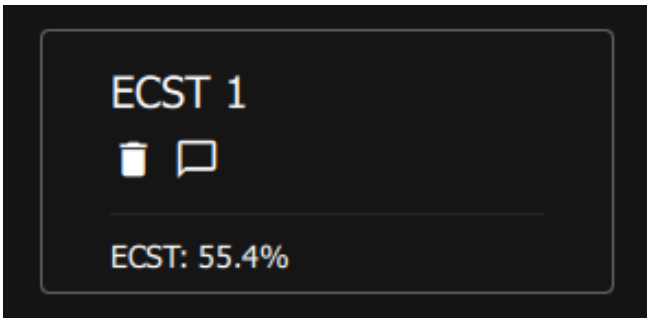




Select a 2D plane to draw the lines for the measurement. Click on the desired points in the chosen 2D view to place the endpoints of lines A and C. Each endpoint is set with a mouse left-click.

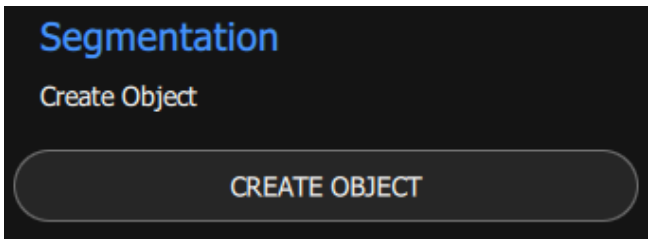
Once both lines are defined, select **"Accept"** to perform the calculation.

"Undo"	Jumps one step back, which was performed in the respective tool.
"Discard"	ECST is discarded.



ECST Summary:

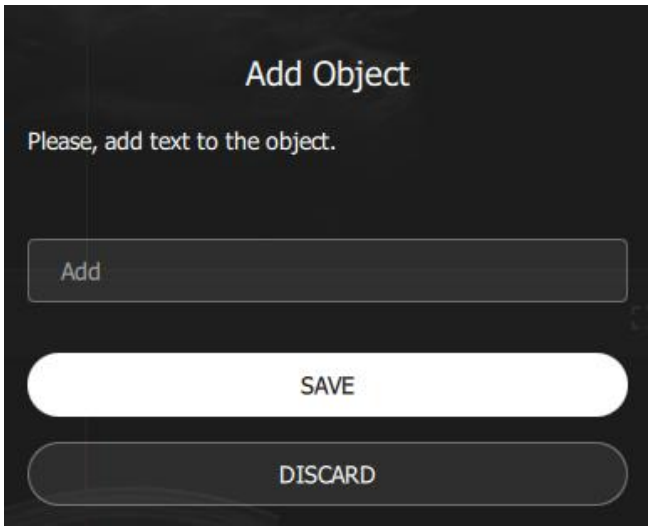
- Rename: double-click on the name, make changes and press the Enter key
- Comment
- Delete



Press “Create Object” to start the segmentation.

For details on the segmentation process, refer to the “Manual nodule segmentation correction tool” description in the Thyroid App Section.

“Reset || Undo”	Click Undo to jump back one step in the object adjustment. Reset goes back to the initial view.
“Accept object”	Accepts object segmentation.
“Discard object”	Object is discarded.

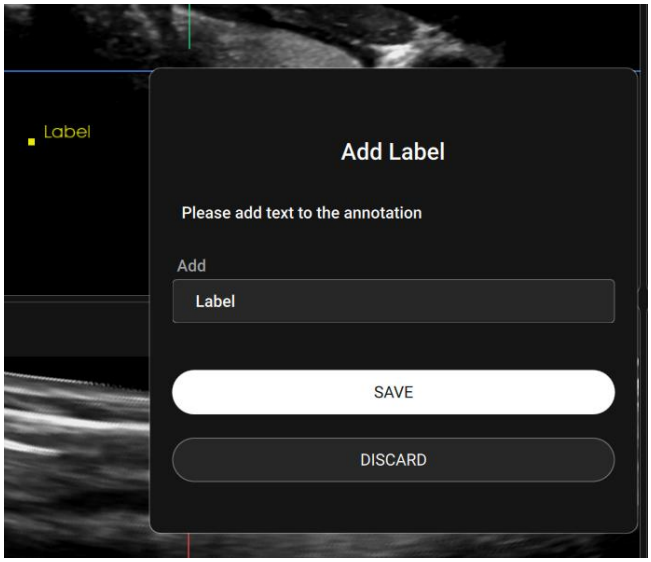


Change Object name, discard or save.

5.6.2.5 Annotation menu

“Label”

Choose between Label and Line Measurements.



Target the marker in the MPR planes.

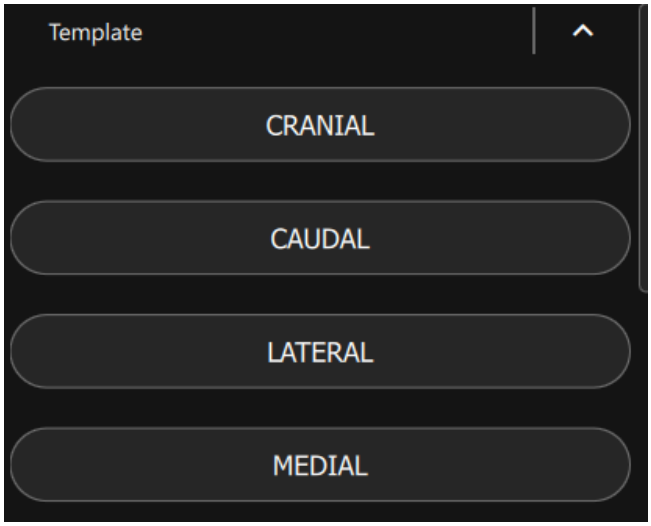
Change Label name, discard or save.

“Line Measurement”

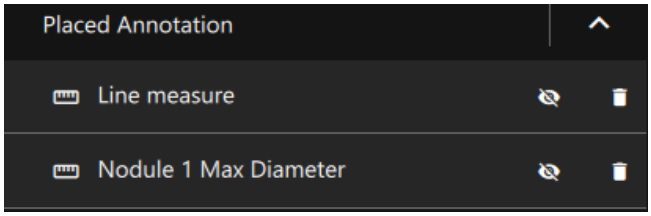
Target the first measurement pint in the MPR plane.

Click the second point to finish the measurement.

The measured value is displayed next to the measurement line.



Select a predefined Label and place it in the MPR plane.



Placed annotations are listed.

Select each annotation by the checkbox.

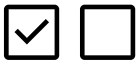
	Disable / Enable selected annotations.
	Delete selected annotations.

Labels can be created in the transversal, sagittal and frontal MPR plane. A yellow point in the 3D representation marks the current position of your mouse pointer within the 3D volume. Similarly, the points you set in in the MPR planes are displayed in real-time in 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.

It is possible to translate the three MPR images during the annotation creation process without ending it.

5.6.2.6 Screenshot menu

"2D Screenshot"	2D Screenshot is taken (or with STRG + S) and can be saved or discarded.
"3D Screenshot"	3D Screenshot is taken and can be saved or discarded.
"Virtual Endoscopy"	Create a fly-through video along the center line created for a virtual endoscopy video (Plaque Analysis App only)
	Select / unselect all checkboxes.
	Delete selected screenshots.

5.6.2.7 Report menu

In dialogue "Update Report" it is possible to proceed with the following options:

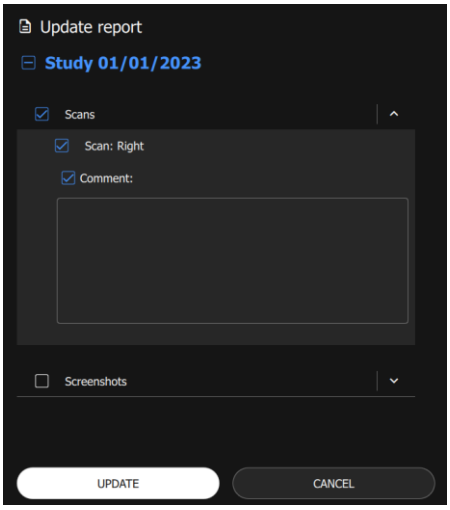
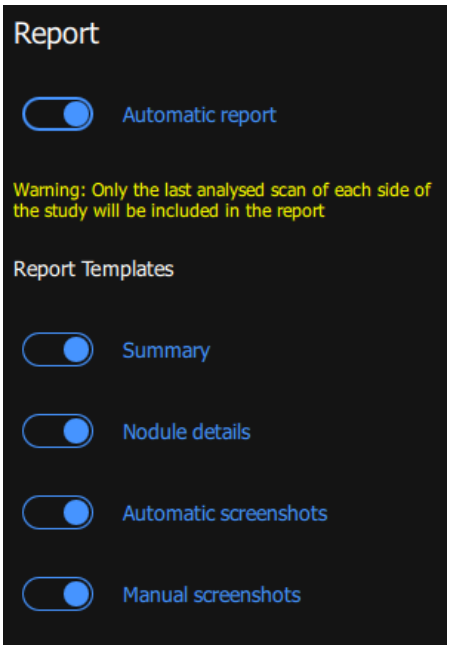


Figure 19: Dialogue "Update report"

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 Thyroid report is study-based and accessible from the Patient Browser, whilst the General Imaging report is scan-based and can only be reviewed in the Report Menu.

5.7 "Review" Mode – Thyroid App in Lite Mode

5.7.1 Display and operating window in the "review" mode

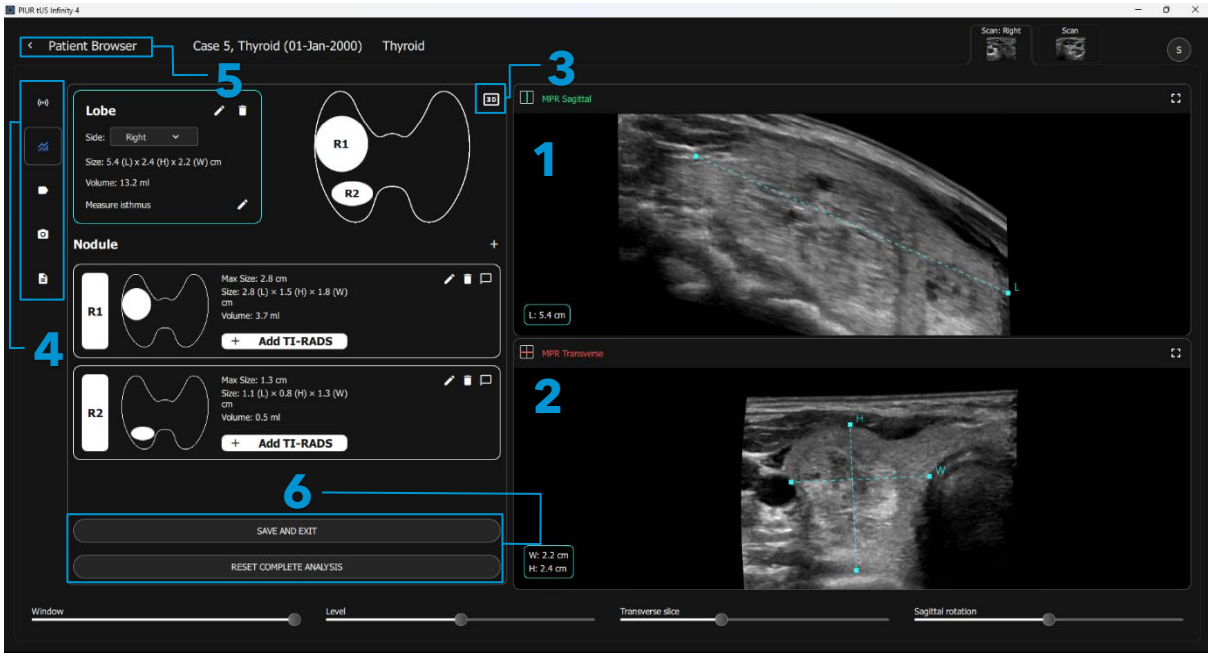


Figure 17: Operating window in the "Review" mode of Thyroid App in Lite Mode

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:

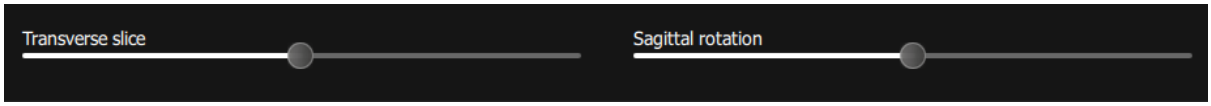
Left click in the inner part of MPR-line	Moves both plane lines. Focus remains on same spot in image.
Left click in the outer part of MPR-line	Rotates the respective plane line. Focus remains on the same spot in image.
Left double click(in one 2D view)	Places the intersection point of the two planes 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:

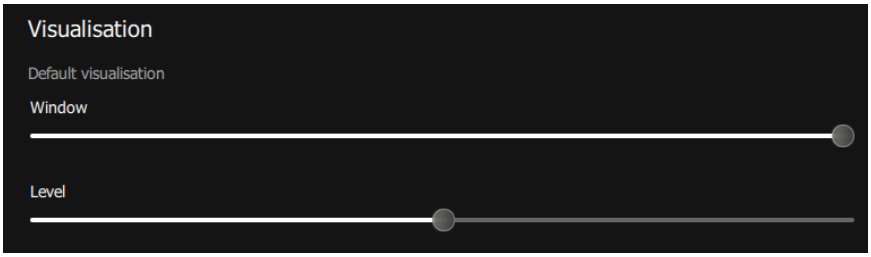
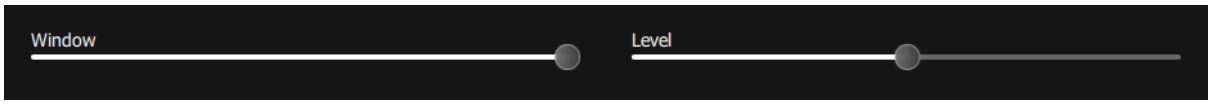
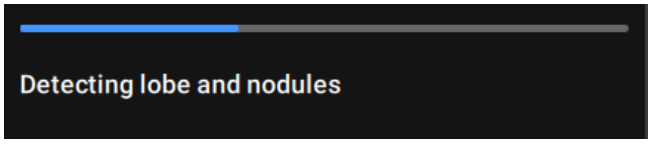


Figure 18: Default Window and Level in User Settings

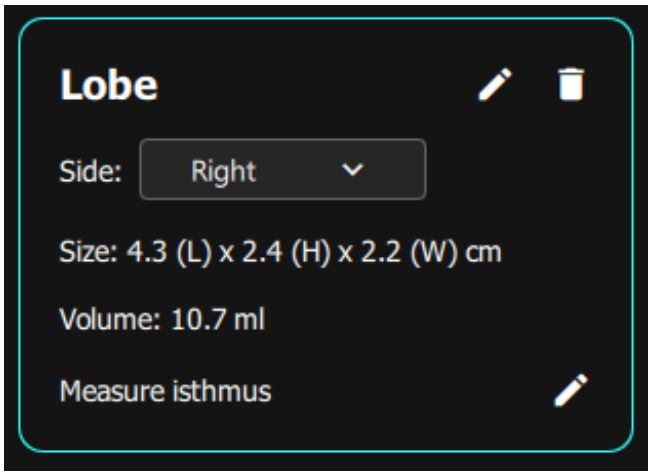


The brightness and contrast can be changed with the slider.

5.7.2.4 Image analysis



The progress bar indicates the status of the processing workflow.

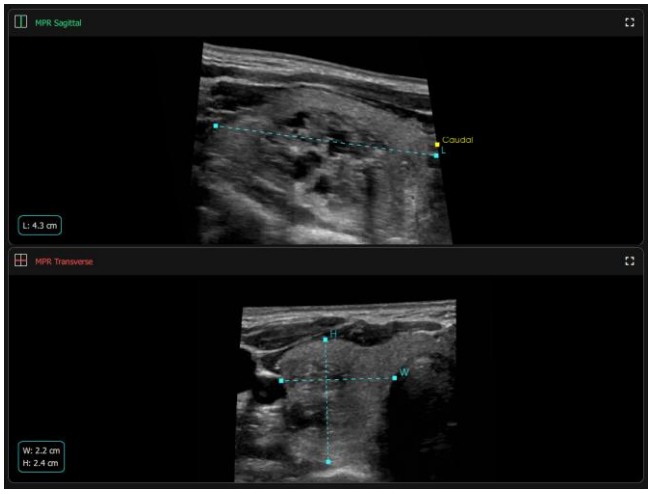


Auto-side selection: The lobe side is automatically detected. The side can be changed by clicking the arrow next to the Side field and selecting the desired (Right or Left).

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.

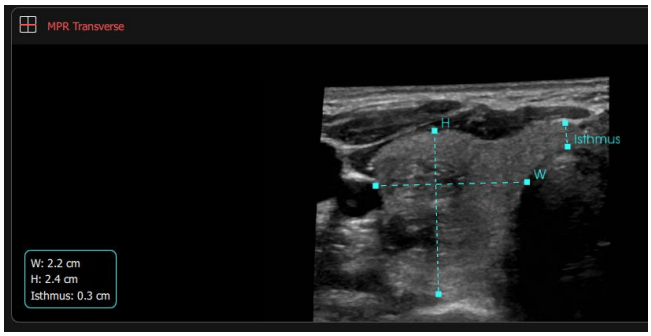


Manual Lobe Measurement Correction Tool

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

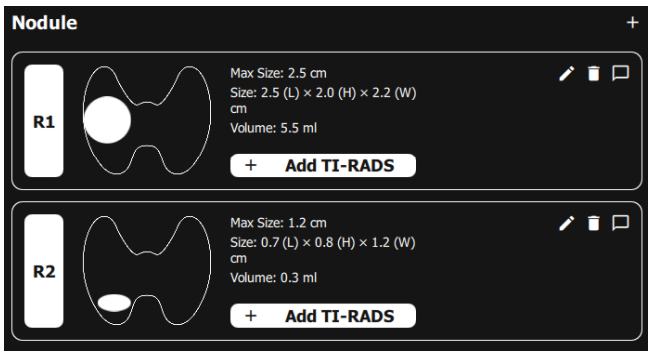
Click the Edit icon to enable manual drawing of the isthmus width.

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:

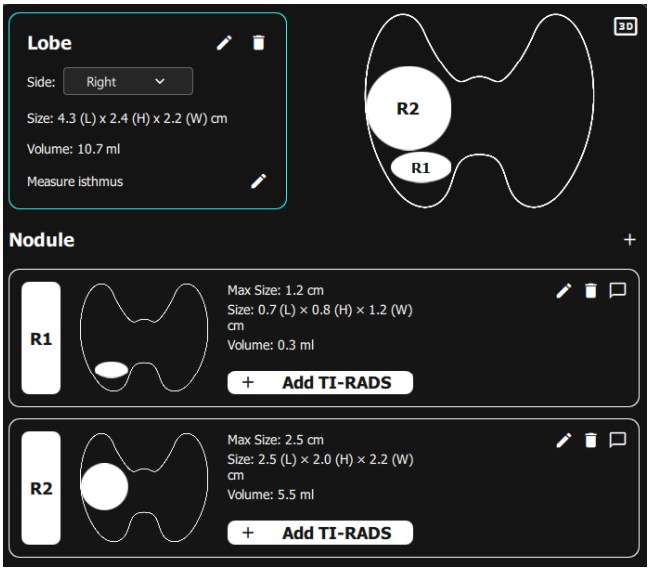
R/L/I + Nodule Number: The nodule index and the right (R), left (L) thyroid lobe, or the isthmus (I).

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

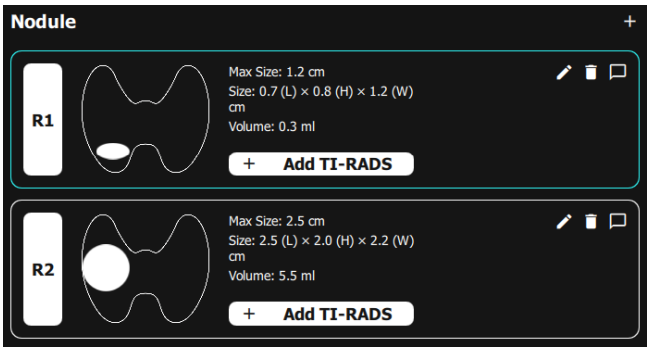
Max. Size: The longest dimension among the 3-line measurements.

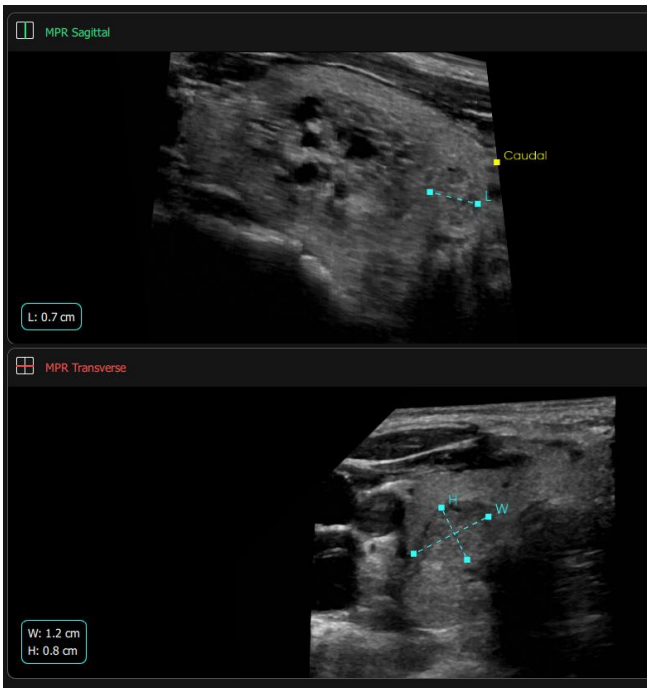
Size: The 3-line measurements of the nodule.

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

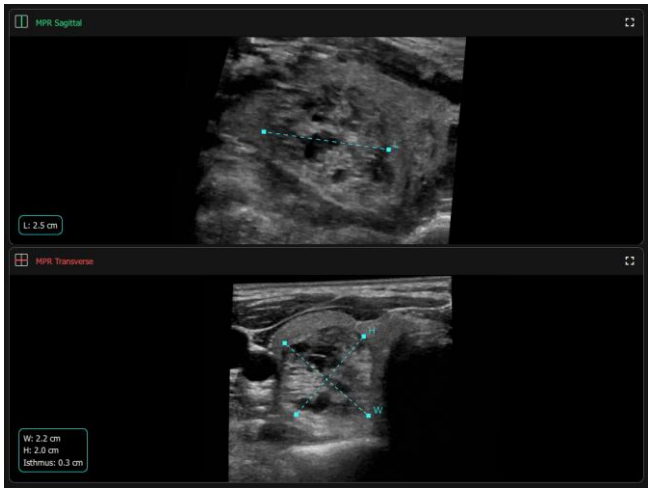


The nodules in the list can be reordered at any time (provided that Editing mode is not enabled). To change the order, drag and drop the desired nodule summary to the required position in the list.





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

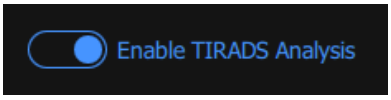
Click the Edit icon. Move the cursor to the endpoints of the 3-line measurements. Select an endpoint and drag it to the desired position. This can be performed for any of the measurement endpoints.

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

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

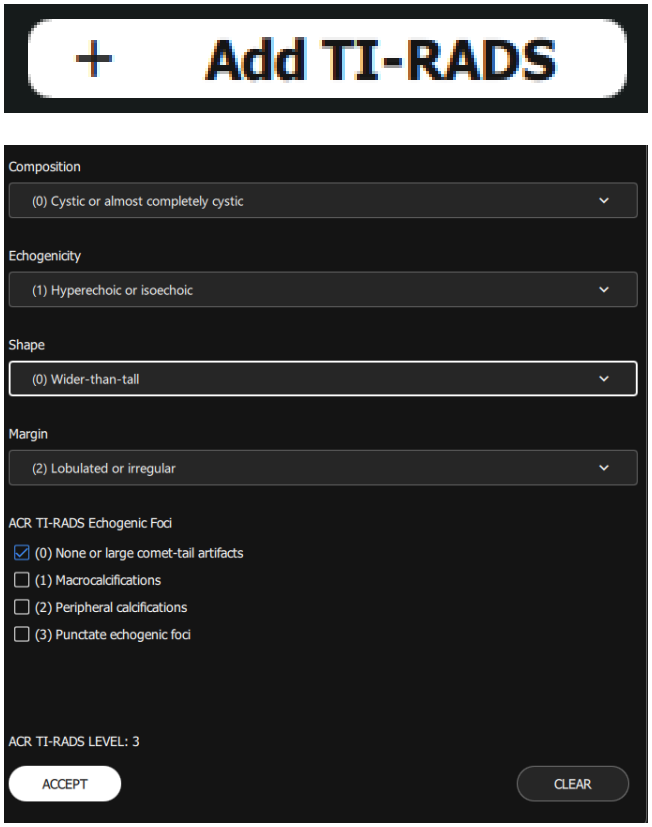
Click the Comment icon to add additional text to the nodule summary.

In General Settings:



On: Enables software-generated TI-RADS suggestions

Off: displays an empty TI-RADS analysis menu for manual entry of the user



The software suggests:

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

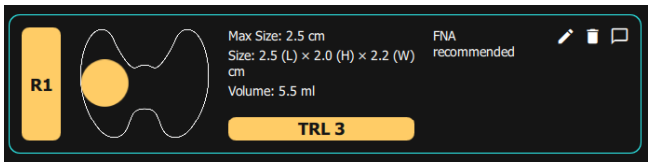
Shape
(0) Wider-than-tall
(3) Taller-than-wide

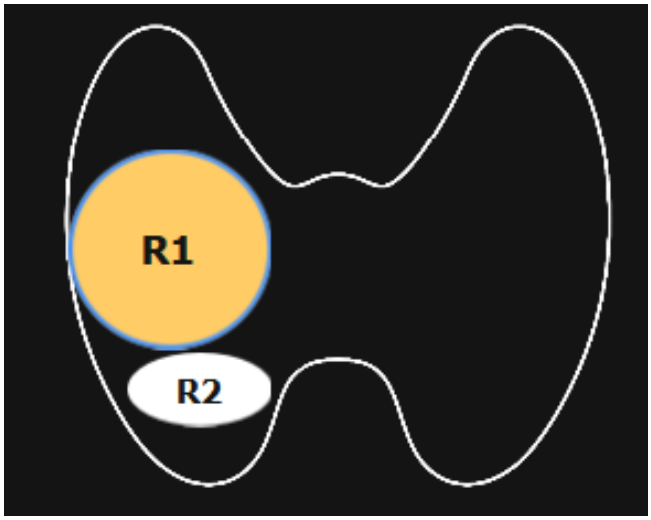
Margin
(0) Ill-defined
(0) Smooth
(2) Lobulated or irregular
(3) Extra-thyroidal extension

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**.
It is possible to manually edit the TI-RADS selection.



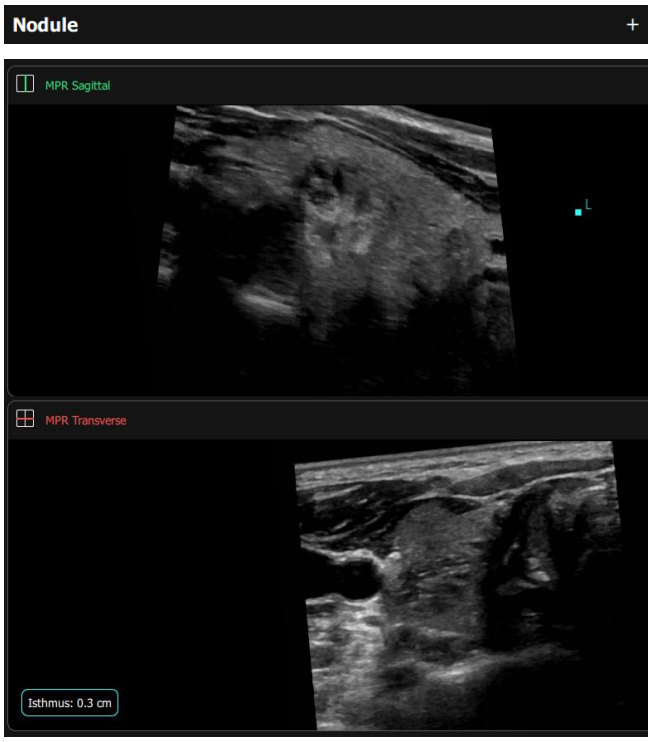


The TI-RADS level is automatically calculated based on the options previously selected in the menu.

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



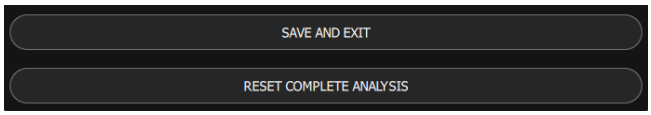
Add a nodule to the analysis by clicking the "+" icon next to Nodule.

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:

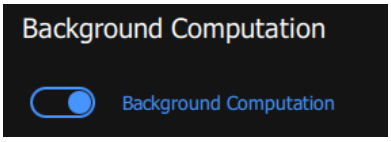


Figure 19: Analysis optimization User Settings

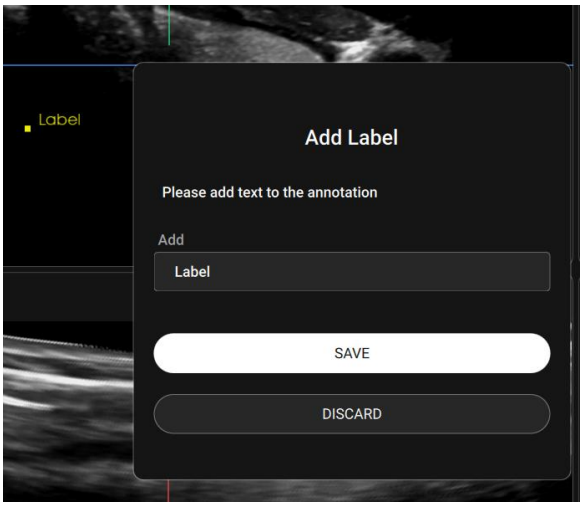
"Background Computation"

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

Choose between Label and Line Measurements.

"Label"

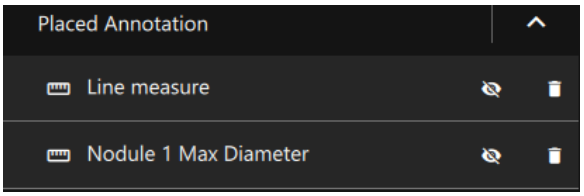


Target the marker in the MPR planes.

Change Label name, discard or save.

"Line Measurement"

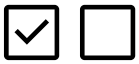
Target the first measurement point in the MPR plane.

	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.

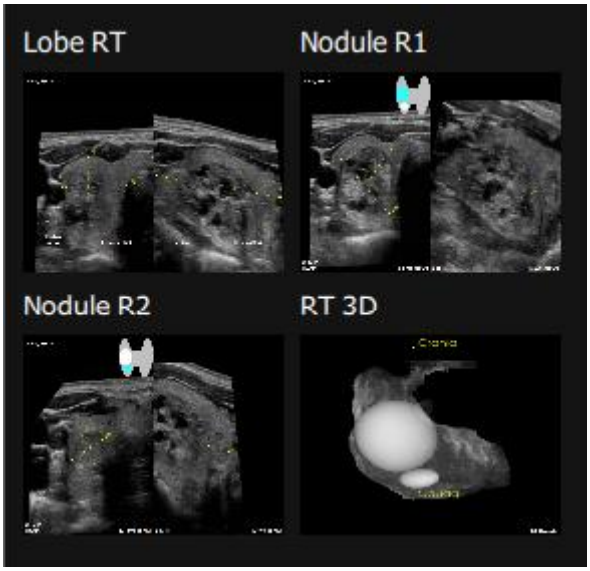


Figure 20: Automatic screenshots in Thyroid App in Lite Mode

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:

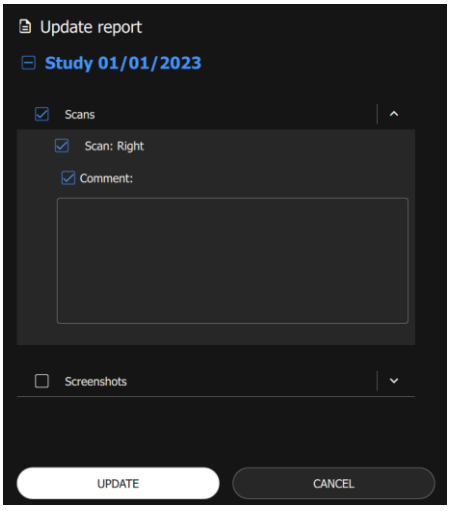
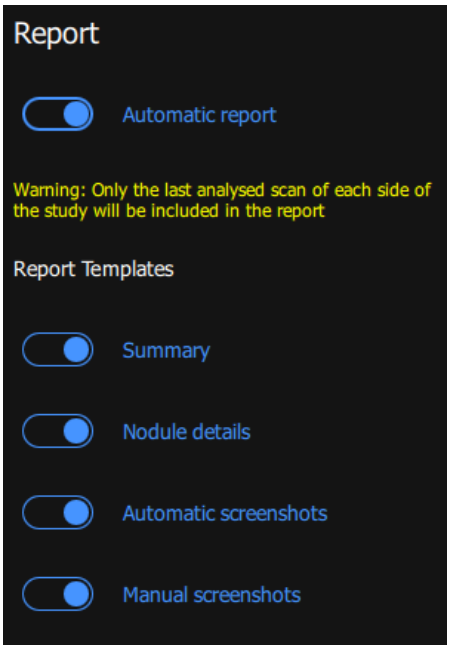


Figure 21: Dialogue "Update report"

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.

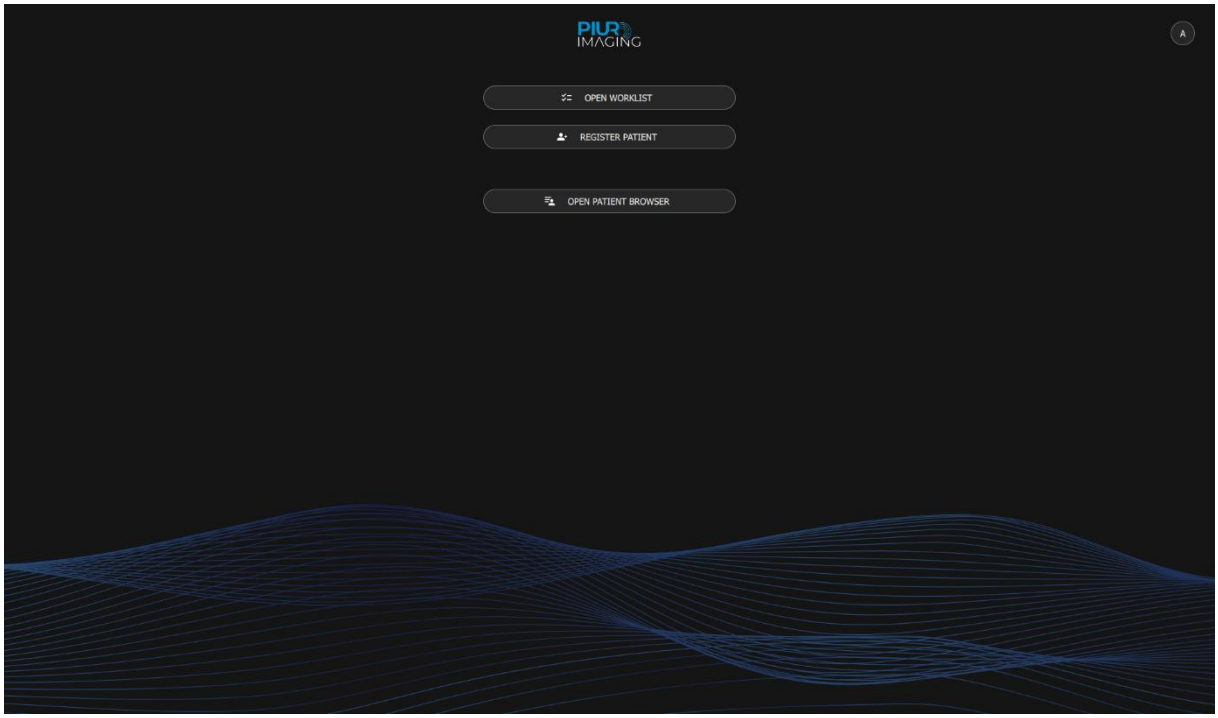


Figure 20: Acquisition Station - Overview Screen

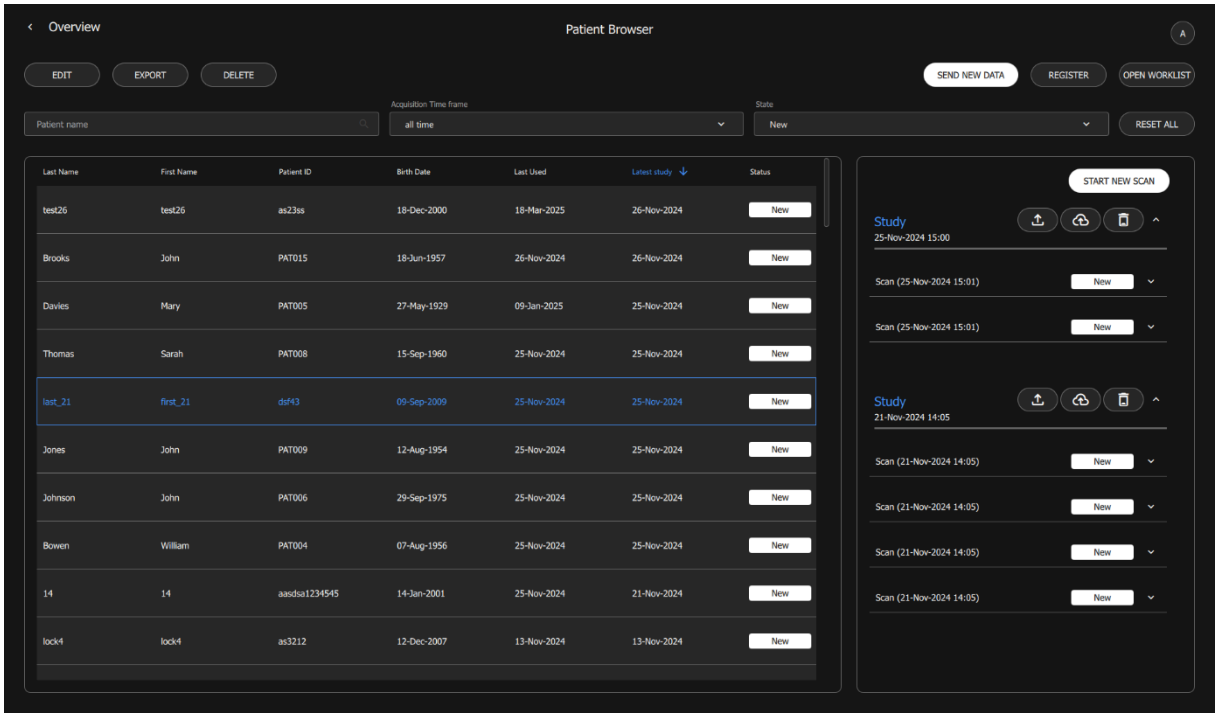
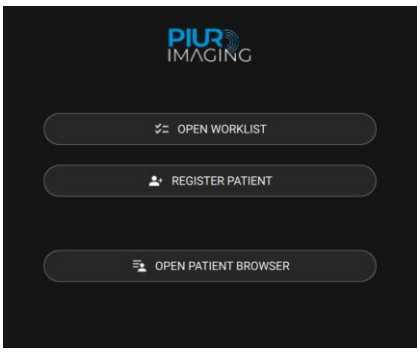
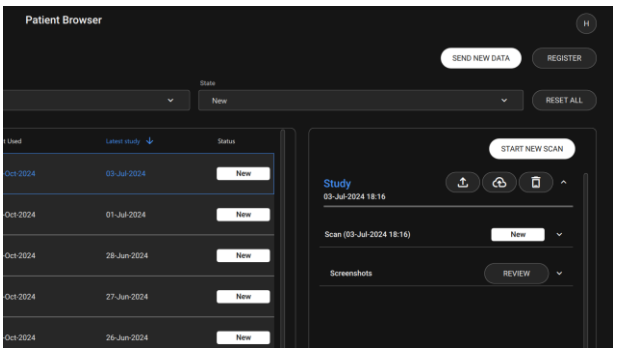


Figure 21: Acquisition Station - Patient Browser

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, analysed 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 analysed as usual.

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

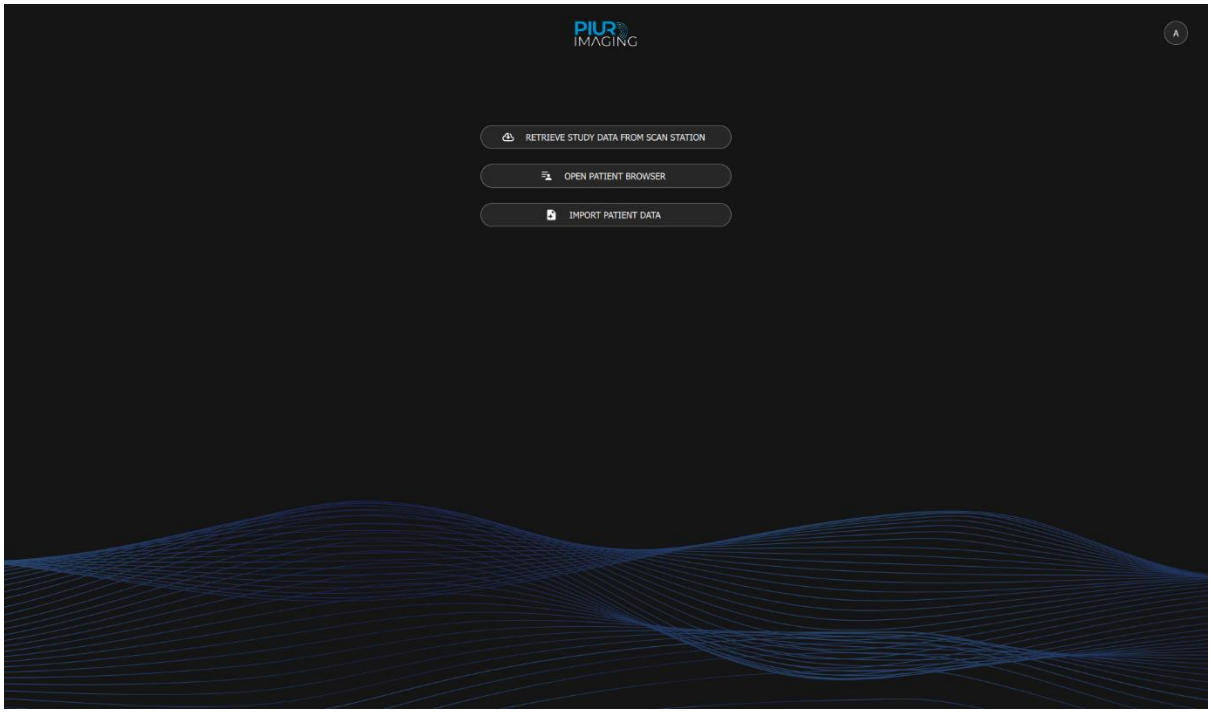
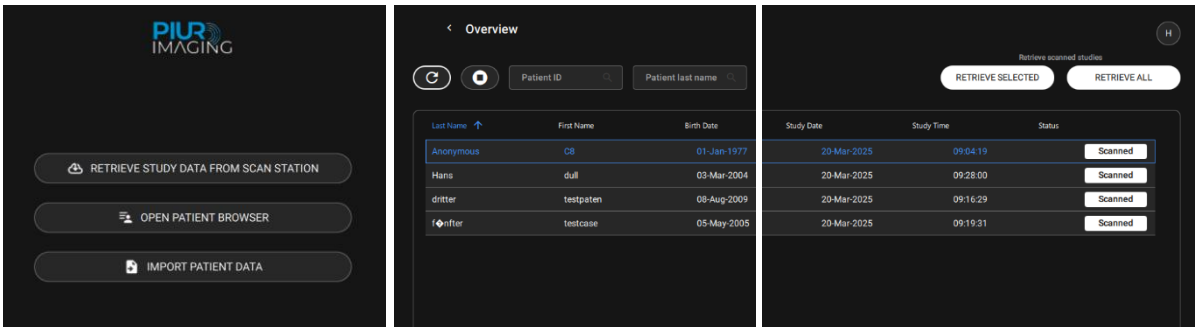


Figure 22: Review Station - Overview screen

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 (5.5).

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.

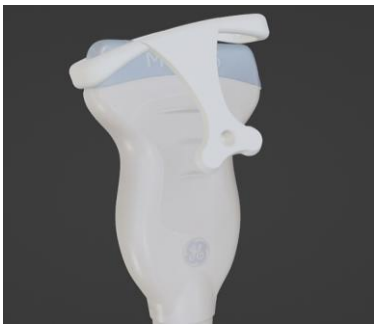
Safety Notice

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 Bracket

Clean and disinfect the 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 national guidelines for electronic scrap. 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.

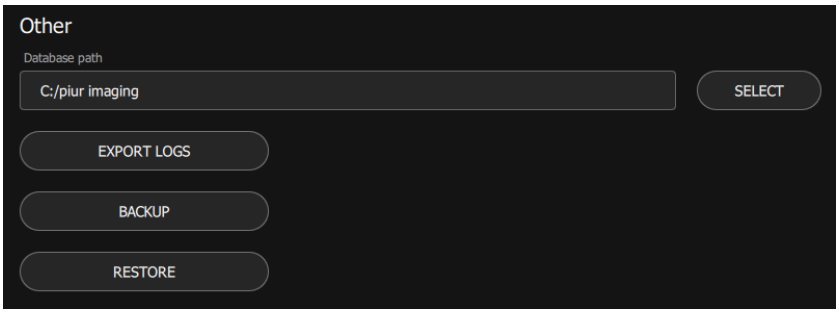


Figure 23: Export logs, Backup and Restore functions in General Settings

"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

E-mail: 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 Section 1.3.1 Identification Label).

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).

8.4 Software Update

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

8.5 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 Infinity 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 % Atmospheric pressure: 70kPa to 106 kPa	
Operating altitude	Maximal 2000 m	

9.2 Measurement Function

Safety Notice: Accurate measurements can only be performed in the "Performance"-Domain of Tracking Sensor (i.e. in the same room as the system)

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

Summary:
The accuracy of PIUR tUS Infinity:

The PIUR tUS Infinity, G3 sensor showed a smaller relative volumetric range of error (–21.24% to +10.38%) compared to 2D ultrasound, B-mode (–34.72% to +25.79%), where the range of error corresponds to the region containing 95% of measurements.

Aim:

The objective of this bench study was to compare the volumetric accuracy of PIUR tUS Infinity (G3 sensor) with 2D B-Mode ultrasound using phantoms with known ground-truth volumes.

Methods:

The study was conducted using 6 agar phantoms representing thyroid nodules, mounted on trachea-shaped pedestals. The phantoms had volumes of 4.14 mL, 4.44 mL, 5.62 mL, 4.35 mL, 4.73 mL, and 6.70 mL. Ground truth (GT) volumes were established by the water-displacement method and verified by 3D scan, CT, and a 31-day repeat, confirming stability. Each of the six phantoms was measured using multiple imaging modalities, including the investigational method PIUR tUS (G3 sensor) and the reference standard 2D ultrasound. Measurements were performed independently by two experts, resulting in a total of 12 measurements per modality.

The primary endpoint was to measure the relative volumetric error (%). The results were summarized as the 95% relative interval error.

Since the sample size is small (2 readers x 6 phantoms), normality cannot be assumed. Therefore, the non-parametric Wilcoxon signed-rank test was applied for significance testing at a significance level of 0.05. The following hypotheses were evaluated:

Whether there is a significant difference between PIUR tUS (G3 sensor) and the ground truth. This test assessed whether the median of relative volumetric error calculated between PIUR tUS (G3 sensor) and ground truth differs from 0.

Whether there is a significant difference between 2D B-Mode ultrasound and the ground truth. This test assessed whether the median of relative volumetric error calculated between 2D B-Mode Ultrasound and ground truth differs from 0.

Whether the median difference between PIUR tUS (G3 sensor) and the ground truth differs significantly from the median difference between 2D B-Mode ultrasound and the ground truth.

Results:

For PIUR tUS Infinity, the 95% of relative errors lay within interval of -21.24% to +10.38%. For 2D B-mode ultrasound the interval was -34.72% to +25.79%. It was demonstrated that relative error interval for PIUR tUS Infinity is narrower than for 2D Ultrasound, indicating higher accuracy. The relative errors were shown on Bland-Altman plot, on Figure 5.

The median relative volumetric error between PIUR tUS (G3 sensor) and the ground truth was –3.37%. The Wilcoxon signed-rank test yielded a p-value greater than 0.05, indicating no statistically significant difference between the PIUR tUS (G3 sensor) and the ground truth.

For 2D B-Mode ultrasound, the median relative volumetric error was –3.73%. The Wilcoxon signed-rank test resulted in a p-value greater than 0.05, also indicating no statistically significant difference from the ground truth.

Finally, the median difference between PIUR tUS (G3 sensor) and the ground truth compared to the median difference between 2D B-Mode ultrasound and the ground truth was 0.275%. The Wilcoxon signed-rank test resulted in a p-value of 0.91. This result suggests that there was no significant difference between the two methods.

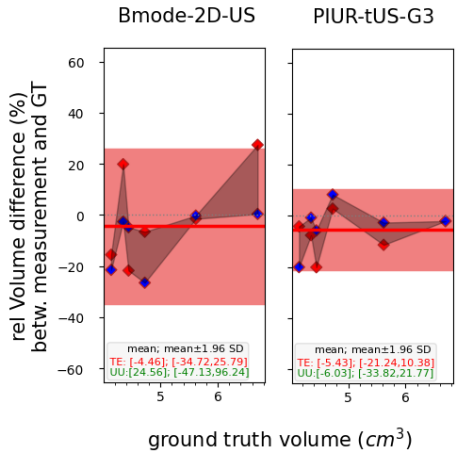


Figure 24: Relative volumetric error demonstrating difference between Ground Truth and two imaging modalities

Conclusion:

Across these phantoms, PIUR tUS Infinity (G3 sensor) showed a narrower error band than 2D B-mode, indicating better volumetric accuracy compared to the gold standard 2D ultrasound.

Note: This device has no essential performance according to EN 60601-1:2006+AMD2:2021.

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

	Video Box	Sensor
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.

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

10 Appendix

10.1 Usability and Safety-Related Design Requirements

The following requirements have been implemented to ensure safe and effective use of the device in accordance with ISO 24971:2020. These requirements address key human factors and usability considerations and are intended to support risk mitigation related to user interaction.

User Interface Design Minimizes Use Errors

The user interface is designed to reduce the likelihood of use errors. Particular attention has been paid to the layout of controls, indicators, and menus; the visibility of warnings; the audibility of alarms (IEC 60601-1-8); and ergonomic considerations. The design follows IEC 62366-1 guidelines to ensure intuitive and error-tolerant operation.

Consideration of Environmental Distractions

The design accounts for the possibility of use errors caused by environmental distractions, such as noise, interruptions, or repetitive tasks. The system remains operable and safe under realistic environmental conditions typically encountered in the intended use setting.

Clear and Accessible Display of Information

Displayed information is designed for clarity and visibility across all intended user populations and environments. Considerations include lighting conditions, display orientation, appropriate use of color and units, and emphasis on critical values to prevent misinterpretation.

Control Interface Minimizes Confusion and Errors

Control elements are structured to prevent slips, confusion, and operational mistakes. Design considerations include spacing, grouping, control labeling, visibility, feedback, directionality, and the ability to reverse actions where appropriate.

Provision of Information for Safe Use

All safety-relevant information is provided in a clear and accessible format. This includes instructions for installation, operation, and training requirements. Information may be directed at different user groups (e.g., end users, healthcare professionals, technicians) depending on the context of use.

Prevention of Incorrect Use of Connectors and Supplies

The design ensures that connectors and supplies cannot be incorrectly attached or confused with non-compatible components. Risks such as over- or under-tightening, incorrect fit due to similarity, or inadequate feedback during connection are minimized by mechanical and visual safeguards.