# PIUR® tUS inside

## User Manual





# User Manual

## *PIUR® tUS inside*

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Type: PIUR tUS inside

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# 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 the device

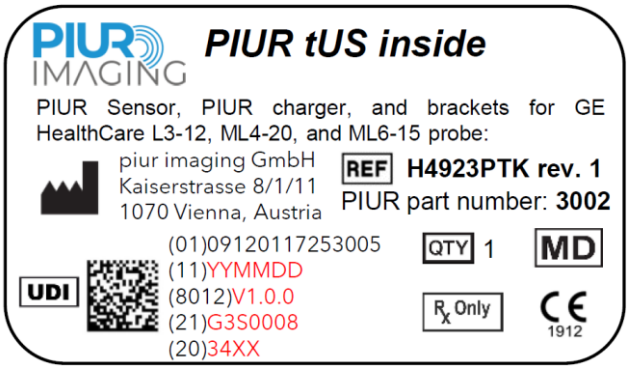
| Symbol | Description |
|---|---|
|  | Stand-by symbol |
|  | Charging |

## 1.3.1 Identification Labels

**PIUR tUS inside – System Label**

The system Label is affixed on Shipping box.

The label with the corresponding software version and UDI parameters (UDI-DI+UDI-PI), can be used to identify the device.



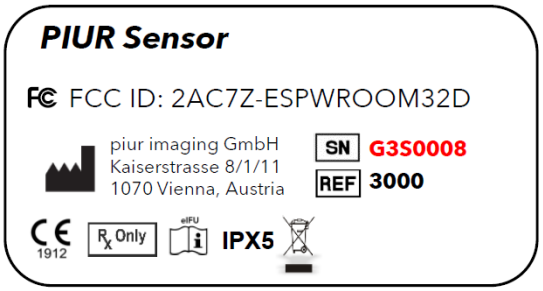

**PIUR tUS inside Software**

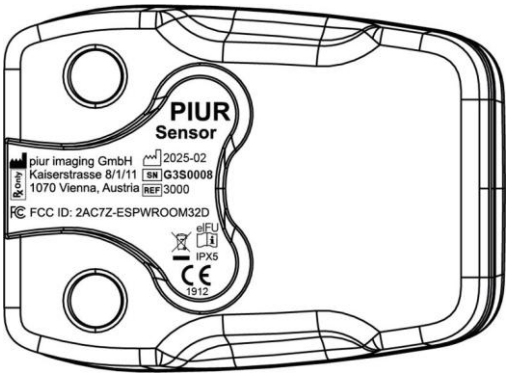
The identification label is displayed in the software itself (software user interface), in plain-text format.

Please note down the software version before contacting the PIUR service.



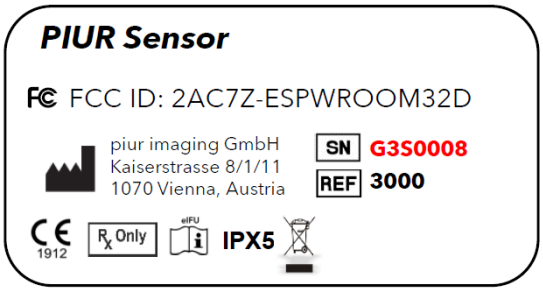
**PIUR Sensor**

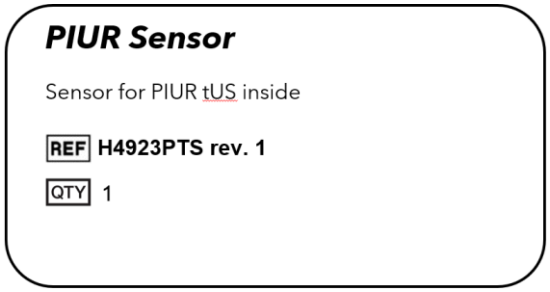



**PIUR Sensor Box**

Sensor packaging Label is affixed on the PIUR Sensor Box.

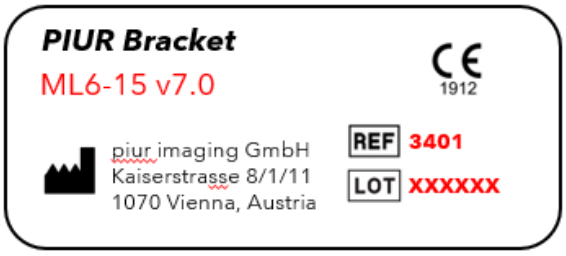


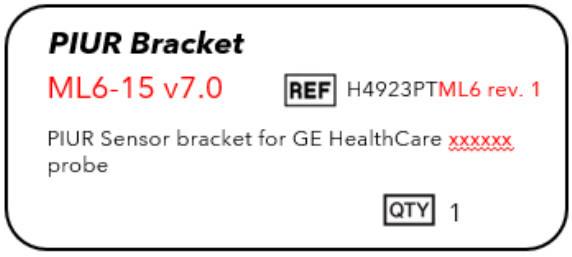




**PIUR Bracket**

Label specification for PIUR Bracket contains Model type, Version number and REF number (depending and based on the type).

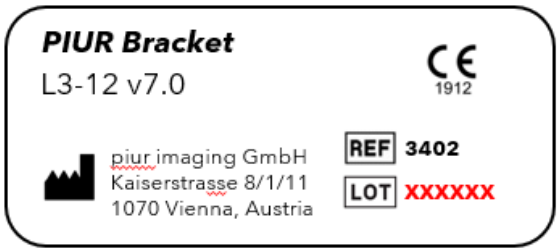
The Label is affixed on the PIUR Bracket packaging box.

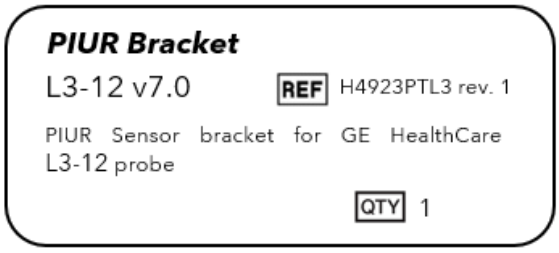


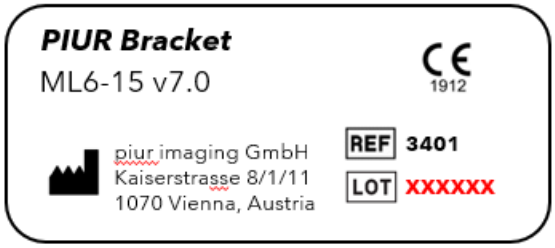
**Variants for the three probes:**

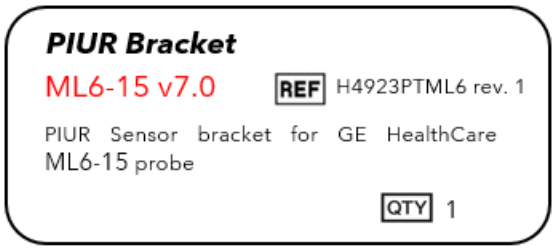
## L3-12 Probe



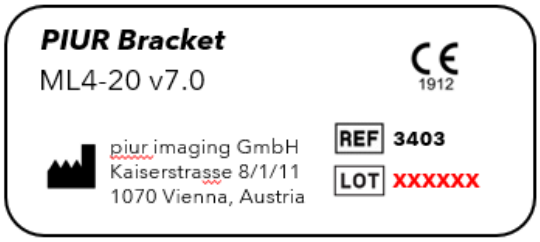



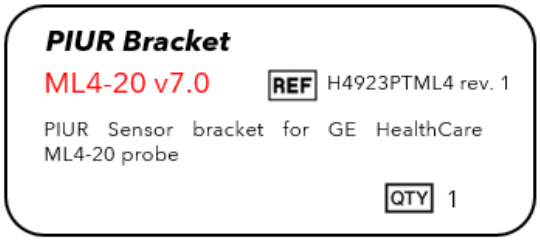

## ML6-15 Probe



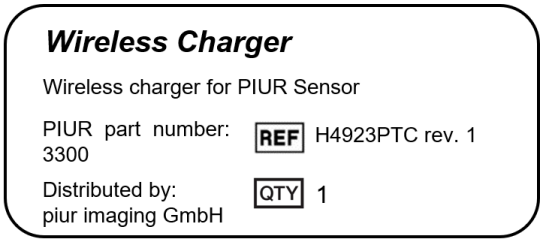

## ML4-20 Probe



**Wireless Charger**

The Label is affixed on the PIUR tUS inside shipping box.

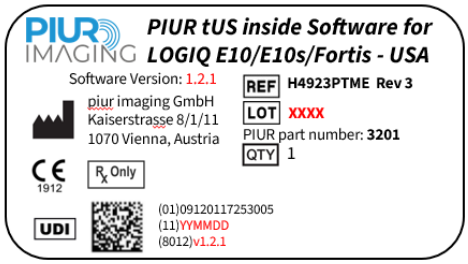



**USB Labels**

**PIUR tUS inside Software for LOGIQ E10/E10s/Fortis - USA**

**Software Version: 1.2.1**

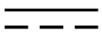
**GE HelathCare PN: H4923PTME Rev 3**




The labels shown in this manual are examples for illustrative purposes only. Refer to the labels supplied with your device for device-specific information.

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

| Symbol | Description |
|---|---|
| SN | Serial number |
| REF | Catalogue number |
| UDI | UDI Carrier label, containing UDI-DI + UDI-PI parameters, displayed in HRI (human readable interpretation). |
| | Manufacturer |
| CE 1912 | CE mark with Notified Body number (ID) |

| | |
|---|---|
|   | Operating instructions |
|  | Direct current |
|  | Alternating current (AC) |
|  | The system must not be disposed with normal waste. |
|   | Rx Only means that the device is a prescription device.<br><br>Caution: Federal law (USA) restricts this device to sale by or on the order of a physician |

## 1.4 Function of this Document

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

## 1.5 Indication for use

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

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

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

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

## 1.6 Disclaimer

The manufacturer is not responsible for improper use, failure to comply with the safety notes and non-observation of specifications due to negligence. piur imaging only assumes responsibility for the safety and reliability of the PIUR tUS inside system and accessories when all changes, enhancements, repairs and other work to the application 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 software application without authorization of the manufacturer.

## 1.7 General Residual Risk including significant Risks

Considering possible sources of failure, foreseeable and unforeseeable errors of use and after risk mitigation residual risk of this medical product remain. Within the Risk Management process, a total of 104 residual risks + 3 Cybersecurity risks have been identified. There following residual risks are considered as significant:

- Wrong but anatomical correct image

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

- Incorrect measurement

Measurement features 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 Measurement Function.

- Infection

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

- Misdiagnosis due to wrong diagnostic output

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

- Incorrect automatic Margin suggestions

Since margin predictions tend to have a lower accuracy with respect to very rare classes (lobulated / extra-thyroidal extension) the automatic suggestions of margin proposed to the user might be wrong. Although the system is considered semi-automatic, meaning that the user must accept the proposals or edit if needed, the wrong automatic suggestion could potentially mislead users, particularly those with less clinical experience.

- Incorrect automatic Echogenic foci suggestion

Since echogenic foci predictions tend to have a lower accuracy with respect to very rare classes (peripheral calcifications / punctate echogenic foci), the automatic suggestions of echogenic foci proposed to the user might be wrong. Although the system is considered semi-automatic, meaning that the user must accept the proposals or edit if needed, the wrong automatic suggestion could potentially mislead users, particularly those with less clinical experience.

- Overheating of battery

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

- Disinfection agent

Disinfection agent 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.

### 1.7.1 Potential Use Errors Related to User Interface Design and Safety Communication

As information to the user, here are presented the potential use errors (cases) with exact use interface and its characteristics related to safety.

| | |
|---|---|
|  | Please ensure that all dropdown fields in the ACR TI-RADS analysis form are fully completed before selecting “Accept”. If necessary, use the vertical scrollbar on the right side of the form to view and fill in all required options |
|  | When opening a scan, ensure that the desired scan is both selected and correctly opened from the patient list. Please verify that the correct scan (e.g. right vs. left lobe) is displayed before proceeding with the analysis |
|  | Please ensure that the correct patient file is selected before starting any analysis. |
|  | Please ensure to always pay attention to the screen when using it to not miss system warnings or notifications |
|  | Please ensure that the software is displayed in the correct language |

See Appendix for further information regarding User Interface Design and Safety Communication.

## 1.8 Recommendations regarding cybersecurity:

The PIUR tUS inside system is embedded in an existing Ultrasound device and therefore follows the cybersecurity recommendations from the ultrasound manufacturer.

The installation process is provided by the US manufacturers (GE Healthcare) e-delivery system and follows the cybersecurity recommendations from the ultrasound manufacturer.

Backup and restoring is controlled by the US environment and follows the cybersecurity recommendations from the ultrasound manufacturer.

Detection and reporting of cybersecurity vulnerability or incident is communicated to the responsible US manufacturer.

## 1.9 Contact and Regulatory Information

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

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

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

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# 2 Safety Regulations

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

| | |
|---|---|
|  | Do not modify this equipment without authorization of the manufacturer. |
|  | 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 components 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 Sensor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. |
|  | If malfunctions and defects occur.<br>**Occurrence of malfunctions and defects can lead to personal injury or damage to the device.**<br>If malfunctions and defects occur, discontinue the use of the PIUR tUS inside and inform our service team via the above contact details (also chapter 6). |
|  | 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 |

## 2.1 User Requirements for Use



- The user has been officially trained by an authorized person in using PIUR tUS inside 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, image review, application use, typical errors of use, possible system errors and app closing.
- The system includes turning the sensor on and off, charging, cleaning and an introduction to the LED signals.
- 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 has to 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 inside.
- 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 0.5-2 cm/s.

# 3 Product Information

## 3.1 Functionality of the PIUR tUS inside

*PIUR tUS inside* (Figure 1) is a medical device, which enhances standard ultrasound devices with a three-dimensional tomographic imaging method for a 3D analysis of ultrasound volumes. With PIUR tUS inside, examining physicians can make diagnostic decisions based on standard 2D as well as 3D image data integrated in an ultrasound device environment. This 3D data provides information which previously could have only been generated using other 3D imaging technologies like CT or MRI.



*Figure 1: PIUR tUS inside*

Three-dimensional ultrasound is already a common method in certain clinical areas. Ultrasound device manufacturers offer methods to create 3D image data. However, the technologies used for 3D image creation vary considerably and all of them have limitations for the imaging of anatomical structures. In order to visualize complete thyroid structures, the system needs to be able to perform non-linear scans measuring up to 20cm.

The PIUR tUS inside runs on a compatible GE Healthcare ultrasound system. The PIUR tUS inside takes as an input a sequence of 2D ultrasound images that are transmitted through a software interface from the ultrasound to the PIUR tUS inside. In addition, the PIUR Sensor must be clipped onto the ultrasound transducer using individually designed brackets. For image acquisition, the user moves the 2D ultrasound transducer perpendicular to the structure to be imaged over the region of interest of the patient's body. An inertial measurement unit (IMU), which is built into the PIUR Sensor, tracks the orientation of the transducer during the scan and sends this information to the ultrasound via Bluetooth (Figure 2). The PIUR tUS inside combines image information and sensor information to generate tomographic 3D ultrasound volumes on which image analysis can be performed.

One important property of this method is the unlimited length of the acquired volume. PIUR tUS inside therefore allows recording and analysing a complete thyroid lobe.

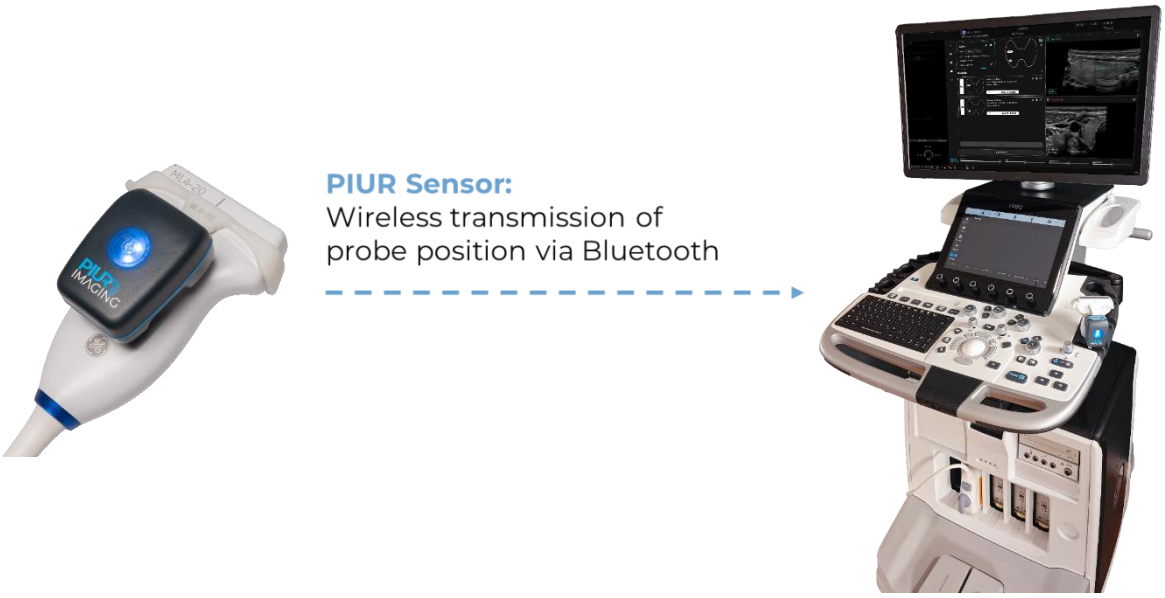



*Figure 2: Acquisition principle*

## 3.2 Clinical Indications

The PIUR tUS inside is used to examine thyroid and thyroid nodule.

## 3.3 Contraindications

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

## 3.4 Key Features and Clinical benefits

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

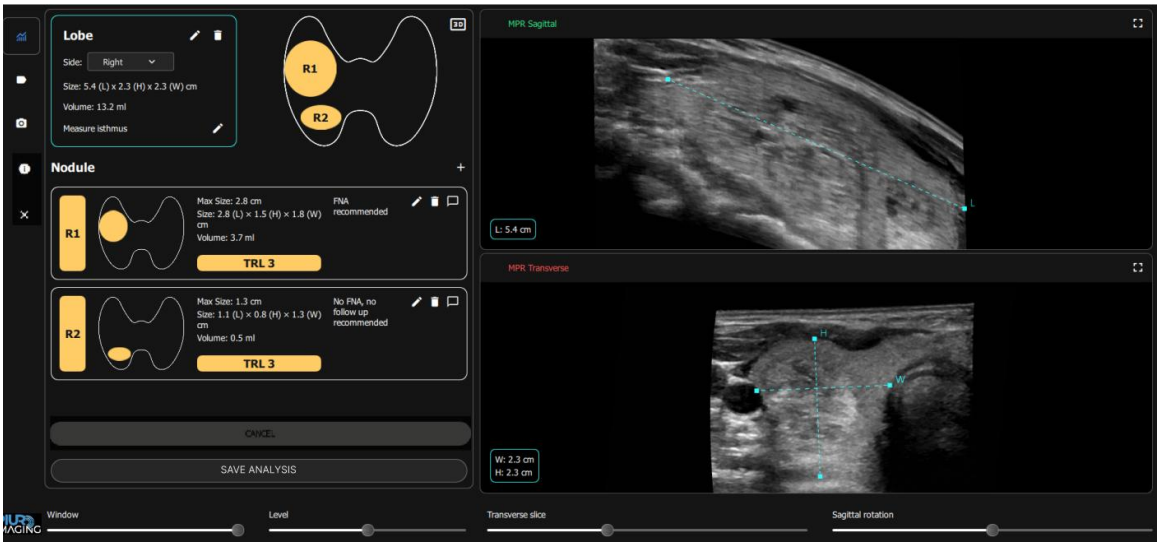
- Multi-planar reconstructions
- Voxel-based volume measurements
- Semi-automatic lobe segmentation and volume measurements
- Semi-automatic nodule segmentation, nodule volume measurements
- Standardized reporting
- 3D Visualization of lobe and nodules
- Visual explanation of disease and treatment decisions to patient
- Full image documentation of lobe and nodules in one volume scan
- Reduced inter- and intra-observer variability compared to standard 2D ultrasound
- Possibility of retrospective analysis of acquired image data

* The system's automated suggestions have to be accepted by a trained user, thus semi-automatic.

# 4 System components and Initial Use

## 4.1 Delivery Package

The deliver package consists of the e-delivered PIUR tUS inside software application installed or installable on the compatible GE Healthcare ultrasound device.




PIUR tUS inside Software

## 4.2 Components and Accessories (separate)

PIUR tUS inside requires the following components for acquiring tracked scans for 3D reconstruction.



PIUR Bracket
(depending on ultrasound transducer)
REF 34XX




PIUR Sensor
REF 3000



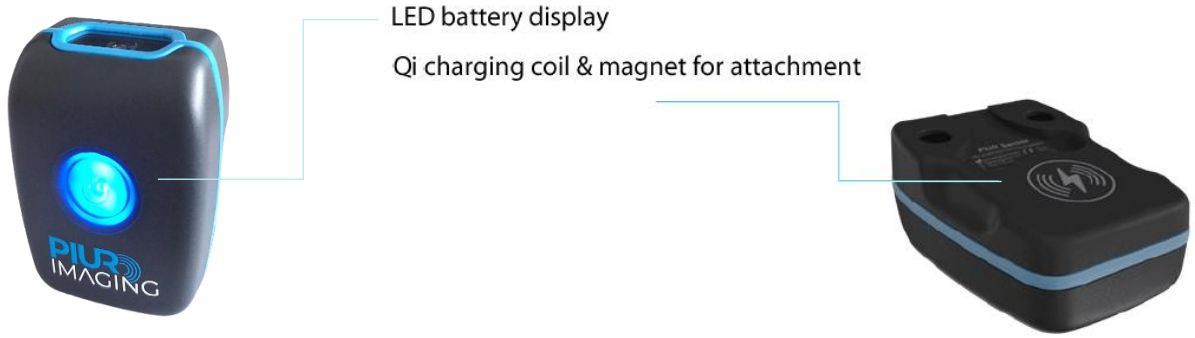
Wireless charger
REF 3300




PIUR Sensor Quick Guide

## 4.3 Equipment of the main components

**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 an bracket. The PIUR Sensor can be charged using the provided wireless charger through the Qi 1.2 standard. The Sensor connects to other devices through a Bluetooth interface.

**Information:**

LED display provides information about the system status.

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

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



The PIUR Sensor should be charged immediately after it shows battery status low and before it 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 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



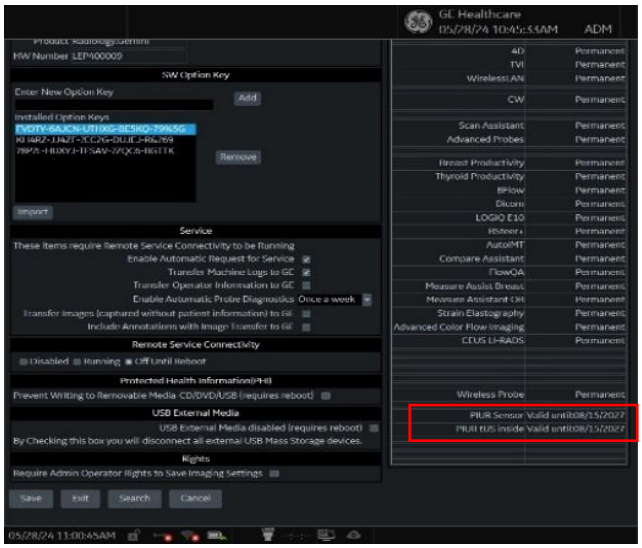
If the user has multiple sensors saved in the software settings, the user must ensure that only one sensor is turned on. The rest of the sensors recommended to be placed on the charging pads

| Status | Colour | Position |
|---|---|---|
| Sensor is charging | blinking green | On the charging Dock |
| Sensor fully charged =100% | static green | On the charging Dock |
| Sensor after turned on & searching for connection (Sensor <15%) | blinking orange | During use |
| Sensor after successful connection (Sensor <15%) | fast blinking orange | 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 |

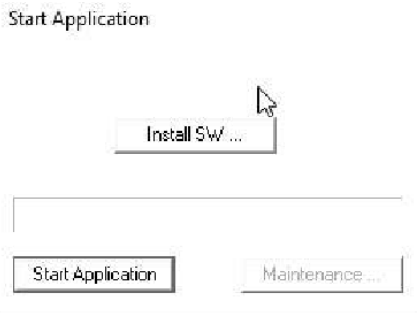
| | | |
|---|---|---|
| Sensor lost connection | blinking blue | During use |
| Sensor has error | fast blinking yellow | During use |
| Sensor startup | static white | During use |

## 4.4 Installation Process

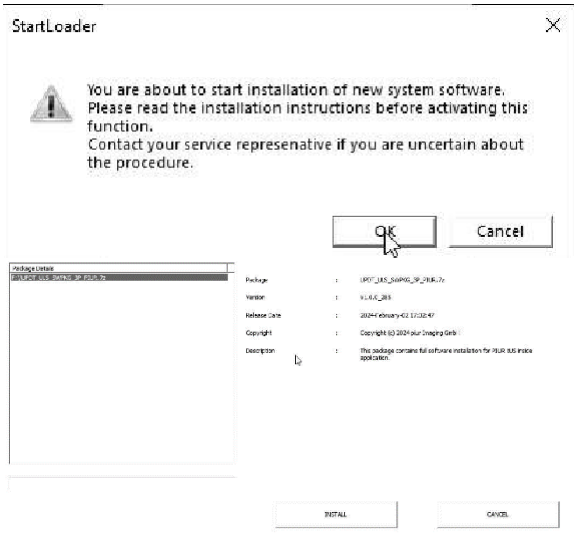
1. Check if there is an available option key for “PIUR tUS inside” on the option key sheet.
2. Enter the option key in the Utility+ -> Admin section.
3. Verify after restart, if the product keys were accepted by verifying the option keys “PIUR Sensor” and “PIUR tUS inside” appearing in the option key status list




4. Plug-in the USB which contains the software installation files to an available port on the machine.
5. Start the GE ultrasound machine.
6. Execute the installation setup file of software by performing following steps:



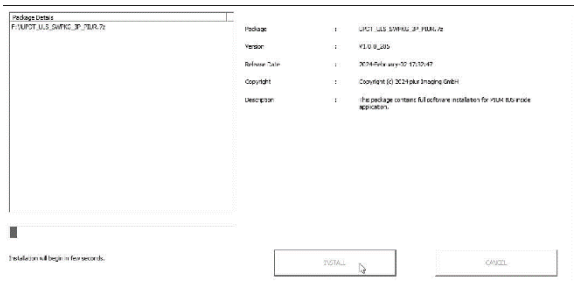

In the "Start Application" window, locate and click on the "Install SW" button to initiate the software installation process.




A dialog box labeled "StartLoader" will pop up. Click on "OK" to proceed.



Select the installation package by navigating to "F:\UPDT_ULS_SWPKG_3P_PIUR.7z"
Once the correct package is selected, click on the "Install" button to begin the installation process.



After clicking "Install", the GE System installation interface will appear, and the installation process will commence shortly.



GE System installation should appear and installation begins




During installation, a logo of Ultrasound model will display at the center of the screen.
Wait until the installation is finished
Once the installation process is finished, you are ready to start working with the software.

## 4.5 Switching the PIUR Sensor on and off and connect to GE Healthcare US device

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, the GE Healthcare device will display a blue and red bar (see the Acquisition Workflow), that the sensor is disconnected
5. Select "SCAN" on the GE device touch panel and swipe on the screen to the left
6. Select "PIUR Sensor" as position sensor type
7. A static blue LED light on the sensor as well as a green signal bar on the GE Healthcare device will (see the Acquisition Workflow) signal that the sensor is connected to the GE Healthcare US device.

Make sure the PIUR Sensor is fully charged before operations.

It is recommended to charge the PIUR Sensor after each use.

## 4.6 Securing the Sensor Bracket to the Probe

### 4.6.1 PIUR Bracket – front clip




1. Turn the probe as shown in the picture



2. 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.



3. The bracket must be correctly locked in and secured

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

**Safety Notice:** Use of not certified Brackets

- Only officially Brackets delivered by piur imaging GmbH are allowed to use with the device.

### 4.6.2 Securing the PIUR sensor housing on the front part of the bracket



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




2. 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 bracket.

# 5 Acquisition Workflow

After completing sections 4.4, 4.5, and 4.6, execute the following steps:

1. Ensure proper connection of the PIUR Sensor to the GE device. The connection will be indicated by:
   a. Green bar on the GE device screen
   b. Constant blue light on the PIUR sensor (described in chapter 4.3 and 7.7)
2. Position the probe, including the PIUR Sensor, on the patient's neck and locate a caudal/cranial position below/above the thyroid gland.
3. After positioning the probe, start the acquisition by pressing the "Mark Cine" button on the GE device.
4. Begin scanning by moving the probe from caudal to cranial / cranial to caudal along the entire side of thyroid. Continue the motion until the probe is positioned cranial above / caudal below the thyroid.
5. Press the "P1" button on the GE device to end the acquisition (see in Tips/Information for the acquisition, Button “P1”).
6. If you want to stop the ongoing scan, press the "Mark Cine" button again. This action will cancel the current acquisition (see in Tips/Information for the acquisition, Button “Mark Cine”).
7. Confirm the tracked loop with the blue cine icon appearing on the cine loop on the left panel (see in Tips/Information for the acquisition, Tracked and untracked loop).
8. Redo process for unscanned thyroid side.
9. After the acquisition was performed, make sure the cine loop marker next to the scan thumbnail on the left side appears in blue, confirming that the scan contains tracking information. If this appears grey, see the following tips/information.



**Attention:**

If the quality of the reconstructed images appears insufficient or unclear, review the original ultrasound images acquired directly from the ultrasound scanner.

**Tips/information for the acquisition:**

- Move the probe with constant speed, do not stop during sweep for diagnosis
- Make sure the whole thyroid gland is visible during the acquisition time of the probe movement. Change to a larger probe or turn on virtual convex if whole gland is not visible
- Make sure the acquisition includes the whole caudal and cranial end of the thyroid gland
- Be aware that dropping of the scan can occur by clicking the cine mark again, posing a risk of unintentionally discarding the scan.
- Be aware that only the scans with the blue cine loop marker contain the sensor tracking information. If the marker is grey, the sensor information is missing
- Sensor connection is confirmed by the green bar on the screen and the constant blue light on the sensor
- Sensor disconnection can happen due to:
- Entering sleep mode of the sensor (triggered 10 min after not using)
- Sensor battery level is too low
- Sensor is not selected on the GE device as tracking device
- Button Icons Table




**Button Mark Cine**

start the acquisition by pressing button

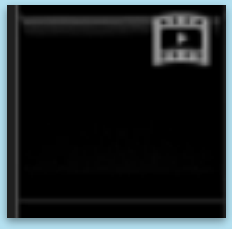



**Button P1**

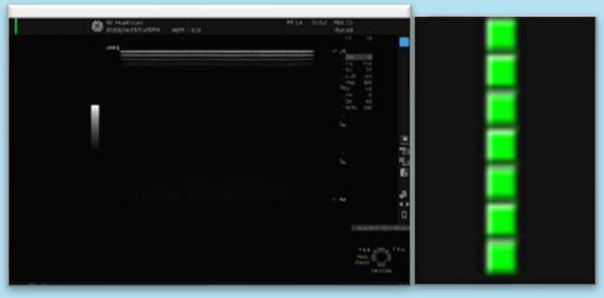
stop the acquisition by pressing button



**Tracked Loop**

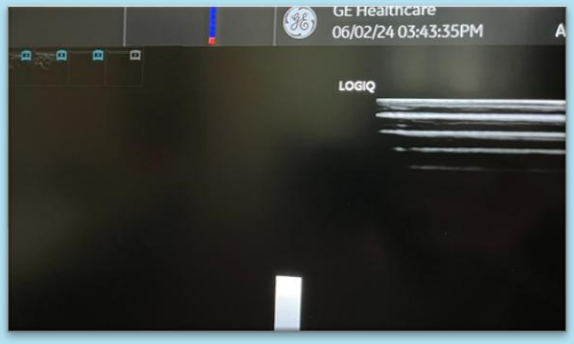


**Untracked Loop**



**Green Bar**

Confirmation of successful sensor connection




**Blue and Red Bar**

The sensor is disconnected

# 6 Review Workflow

## 6.1 Switching on PIUR tUS inside software

The software application is started by the user interface on the GE Healthcare US device.
From the GE Healthcare US device user interface move to “Utility+” menu. From there you can select the PIUR inside application via touch screen.

## 6.2 User interface overview

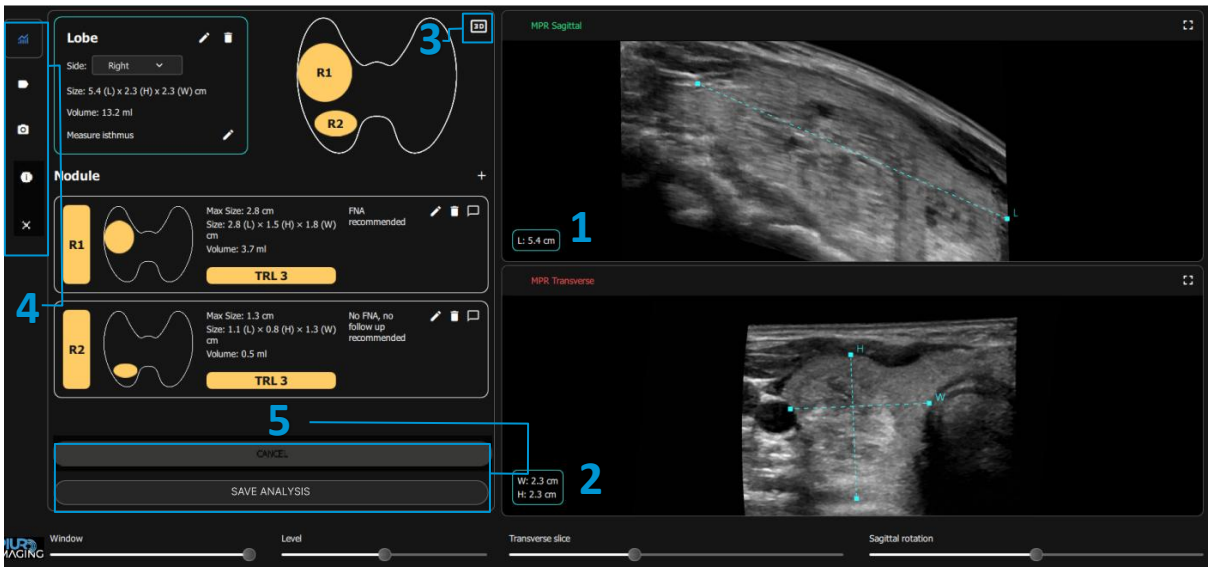



*Figure 3: Software main screen overview*

| | |
|---|---|
| **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, displaying the PIUR inside product label and closing the application. |

| | |
|---|---|
| 5 | “Cancel” button is active during editing tools and can be used to cancel the edit tool at any time.<br>“Save Analysis” saves all measurements and transfers them to the device. Warning: Once you saved the analysis, you cannot update or revert this action! |

## 6.3 Tool Selection

| | |
|---|---|
|  | Analyse Lobe and Nodules, see chapter 6.9 |
|  | Annotations + Measurements, see chapter 6.10 |
|  | Creates a Screenshot of the entire screen and stores it on the GE Healthcare US device. |
|  | View Information and Label |
|  | Close inside application |

## 6.4 3D view

The 3D view is controlled by:

| Icon | Function | Description |
|---|---|---|
|  | Zoom | Move the cursor to the 3D view. Right click and hold the click. The cursor indicates the current function. Move the trackball down to zoom out, move the trackball up to zoom in. |
|  | Rotate | Move the cursor to the 3D view. Left click and hold the click. The cursor indicates the current function. Move the trackball to rotate the 3D model. |

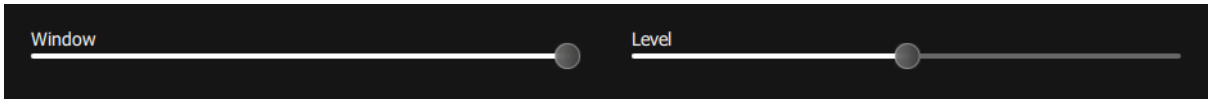
## 6.5 MPR view

MPR (2D) control units:

| Icon | Function | Description |
|---|---|---|
|  | Scroll | Scrolling function is selected by default. Left Click in in the picture in any MPR view. Hold the mouse click. The cursor indicates the function. |

| | | |
|---|---|---|
|  | Zoom | Right Click in the picture in any MPR view. Hold the mouse click. The cursor indicates the function. |
|  | Move | Activating “pan” functionality on the touch panel. Left click into one MPR view and hold to move the dataset. |

## 6.6 Window / Level settings




The brightness and contrast in the MPR views can be changed with the slider.

## 6.7 MPR slider




Moving the Transverse slice moves through the complete dataset.



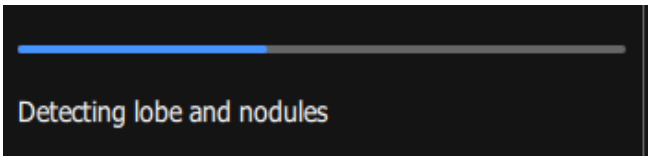

Moving the Sagittal rotation slider, rotates the sagittal view. During movement of the slider, the coronal view is displayed in the transverse MPR.

## 6.8 US device controls

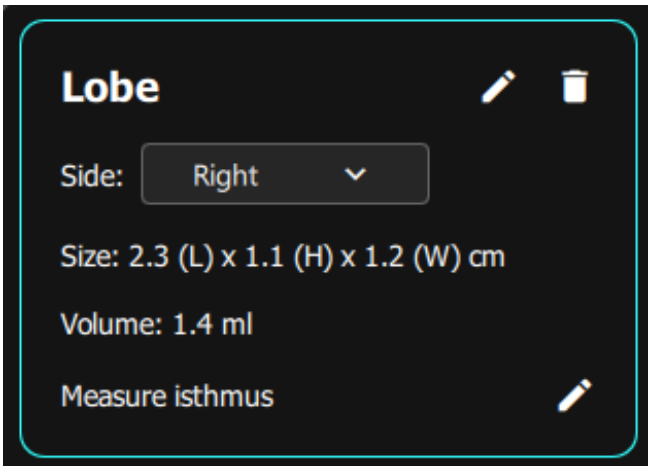
The US device provides embedded user interaction keys to interact with the application.

| | |
|---|---|
|  | Controls the scroll bar (refer to 6.7) |
|  | Moves transversal plane |
|  | Moves sagittal plane |
|  | Moves coronal plane |
| No symbol, labelled "Zoom" on touchpad | Controls Zoom |
|  | Controls window (2D) |
|  | Controls level (2D) |

## 6.9 Thyroid Analysis workflow




The progress bar gives indication regarding the process.




**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 millilitres (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 use functionality on the touch panel). 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, which replaces the Edit icon, to confirm the measurements.

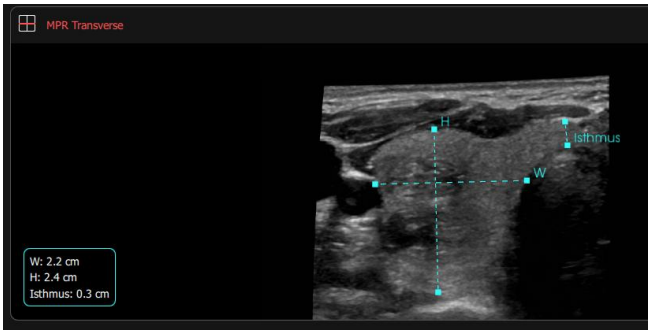


Click the Delete icon to remove all three-line measurements and enable manual redrawing. Confirmation pop-up opens before removal.

Click “cancel” to discard all changes and remove the lobe measurements.






**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.

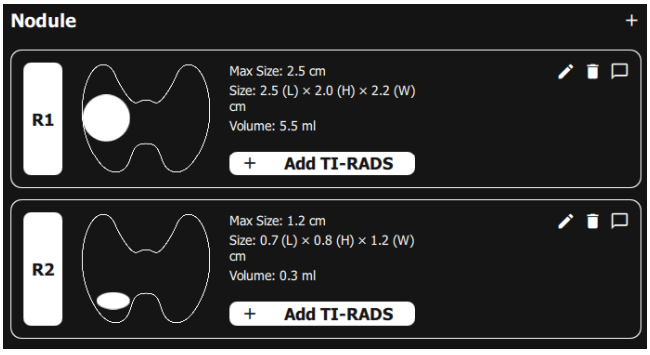
To exit the tool before finishing the line measurement, click the “cancel” button at the bottom of the menu. All changes are discarded.






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:

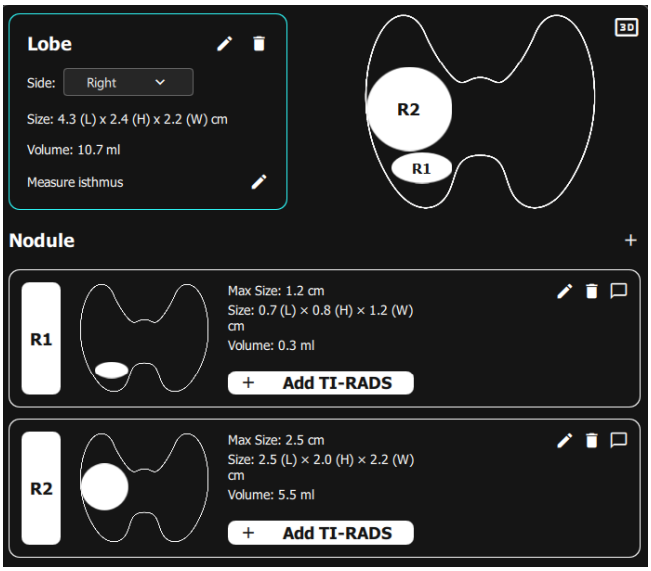
**R/L/I + Nodule Number:** The nodule index and the right (R), left (L) thyroid lobe, or the isthmus (I).

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

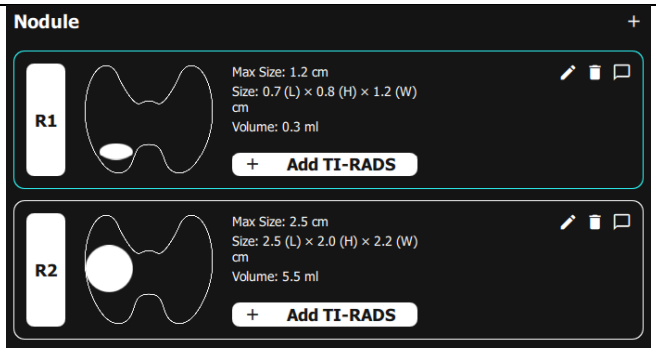
**Max. Size:** The longest dimension among the 3-line measurements.

**Size:** The 3-line measurements of the nodule.

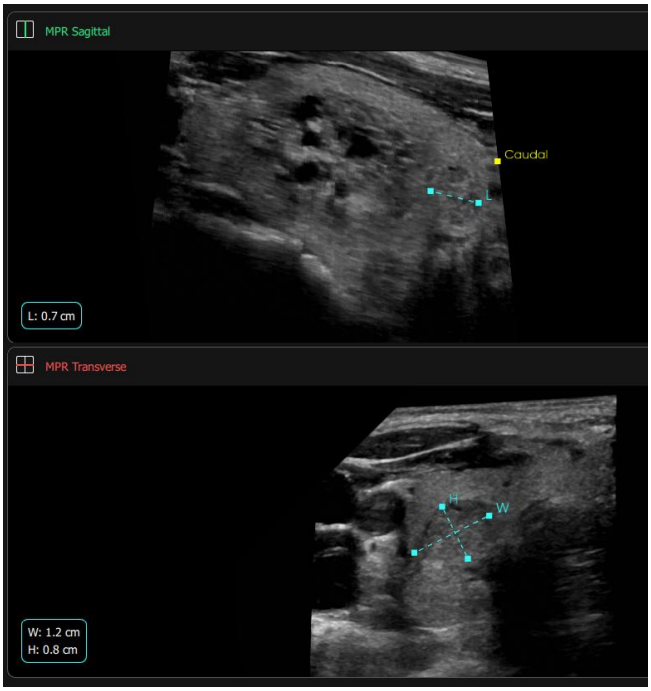
**Volume:** The calculated nodule volume in milliliters based on the 3-line measurements.




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.

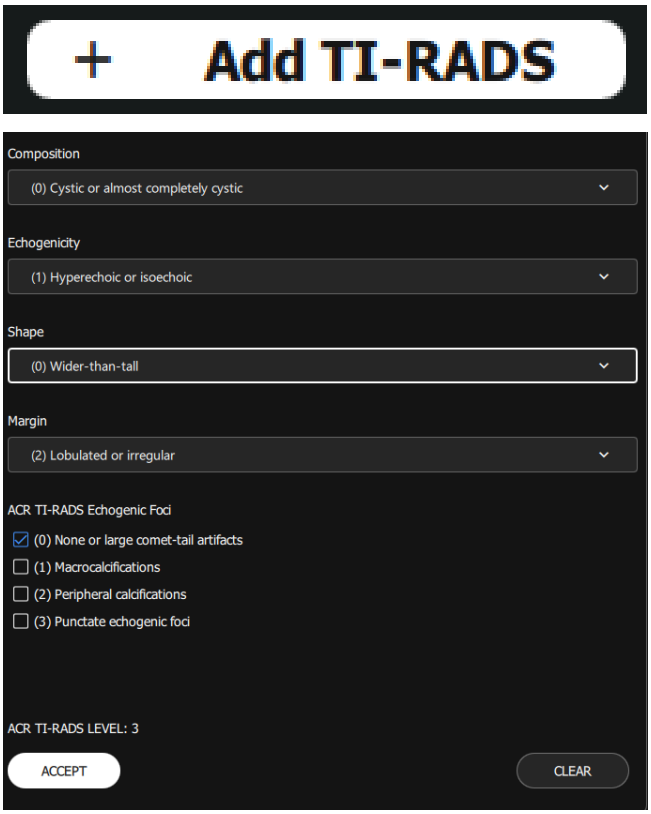
Click “Cancel” button for exiting the edit tool and discard all changes.

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

The edit functionality can also be enabled by clicking the “edit” button on the touch panel.

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

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




User should manually fill out the TI-RADS menu:

Composition

(0) Cystic or almost completely cystic

(0) Spongiform

(1) Mixed cystic and solid

(2) Solid or almost completely solid

Echogenicity

(0) Anechoic

(1) Hyperechoic or isoechoic c

(2) Hypoechoic

(3) Very hypoechoic

Shape

(0) Wider-than-tall

(3) Taller-than-wide

Margin

(0) Ill-defined

(0) Smooth

(2) Lobulated or irregular

(3) Extra-thyroidal extension

ACR TI-RADS Echogenic Foci

(0) None or large comet-tail artifacts

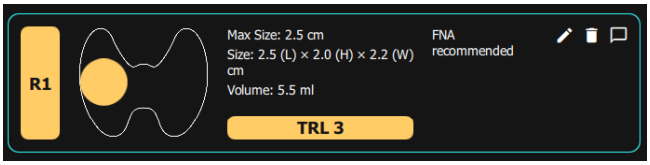
(1) Macrocalcifications

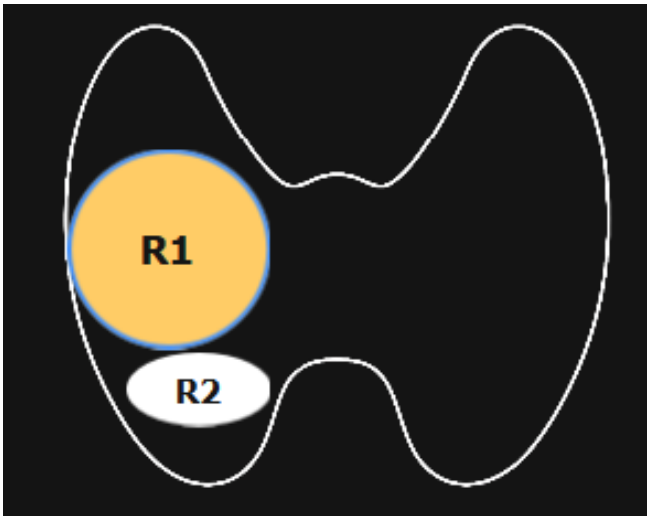
(2) Peripheral calcifications

(3) Punctuate echogenic foci

Click Accept to confirm the TI-RADS level.

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




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

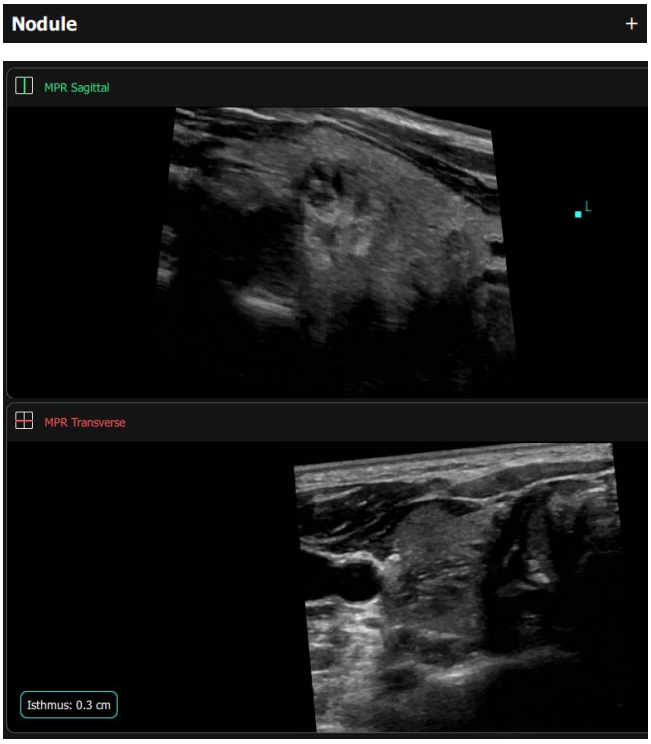
The color of the nodule number, pictogram representation, TI-RADS menu button, and general scan pictogram are updated to reflect the corresponding TI-RADS level.

Three recommendations for the Nodule are available:

FNA recommended

Follow up recommended

No FNA, no follow up recommended



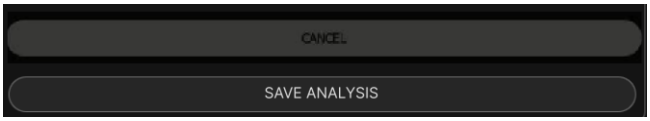

Add a nodule to the analysis by clicking the "+" icon next to Nodule.

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

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

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

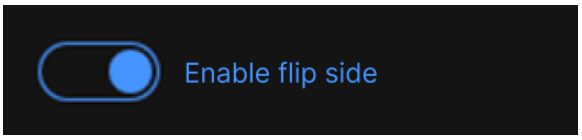
All editing options previously described for automatically detected nodules are also available for manually added nodules.




"Save Analysis" saves all measurements and transfers them to the device. Warning: Once you save the analysis, you cannot update or revert this action!

## 6.10Analysis Parameter Settings

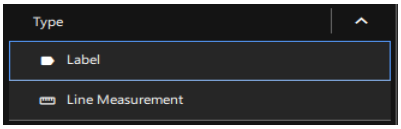
In the settings "utility", "scanner apps", "PIUR tUS inside", the following parameters can be changed for the analysis.



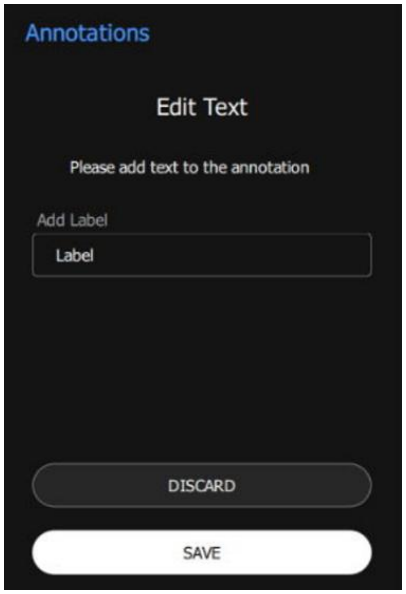

Active: The image is flipped to make a left scan a right scan.

| | |
|---|---|
| **"Minimum nodule volume (ml)" slider** | Move to slider to set the minimum size of a nodule to be detected automatically. The Current value of the slider is displayed below |
| **Generate and store 3D screenshot** | Select the checkbox to generate and store the 3D screenshot as soon as saving the analysis. |
| **Lobe/ Nodule measurement order** | Select in the drop-down menu which order shall be applied for measuring nodules/ lobe.<br>Options are:<br>• L,H,W<br>• L,W,H<br>• H,L,W<br>• H,W,L<br>• W,L,H<br>• W,H,L |

## 6.11Annotations



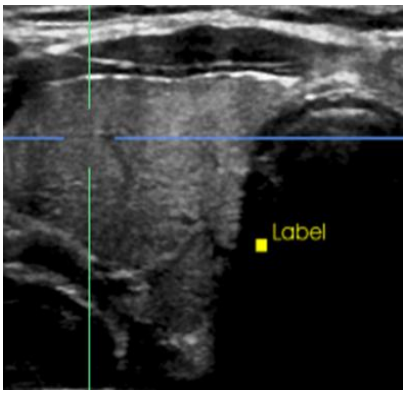

Choose between Label and Line Measurements or click on a template to create a label.

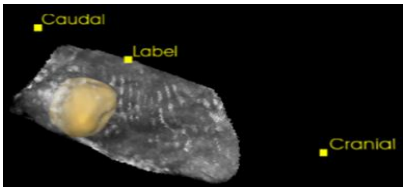



Target the label marker in the MPR planes.

Change Label name, discard or save.

Template text labels provide by default the template name in the text field.




Appearance of the Label in the MPRs and the 3D volume.

All placed annotation are listed in the “list of annotations”

Here the annotations can be made visible or can also be deleted.

# 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 Charging and Storing the Device

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 4: PIUR Sensor on a charging pad*

LED feedback:

| **Illumination** | **Information about system status** |
|---|---|
| ▪ Blinking green | On the charging pad, battery is charging |
| ▪ Static green | On the charging pad, battery is fully charged |
| ▪ Static blue | Off the charger, Sensor is connected and charged |
| ▪ Blinking blue | Off the charger, Sensor is not connected and charged |
| ▪ Static yellow | Off the charger, Sensor is connected and less than 15% charged |
| ▪ Blinking yellow | Off the charger, Sensor is not connected and less than 15% charged |

## 7.3 Disinfecting and Cleaning

### 7.3.1 Cleaning and Disinfecting 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 bracket 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.

### 7.3.2 Removing and Cleaning the Bracket

Clean and disinfect the  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 Agent | Active Ingredient | Dry time |
|---|---|---|
| **CapiWipes™ (Disinfectant Wipes)** | Quaternary ammonium germicidal detergent solution | 2 Minutes |

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

## 7.4 Disposing of PIUR tUS inside software

To uninstall the PIUR tUS inside software from the device please contact Service. Contact data can be found in section 8.1.

## 7.5 Disposing of PIUR Sensor

The PIUR Sensor must be disposed in accordance with the national guidelines for electronic scrap. Alternatively, the device can be sent back to the manufacturer for disposal.

# 8 Service and Maintenance

## 8.1 Contact

service@piurimaging.com

Hotline: +43-12 650 16 8

Please write down the software version before contacting our service team. You can find the software version number in the Info screen of PIUR tUS inside system on the information icon (see chapter 1.3.1).

## 8.2 Maintenance Interval

PIUR tUS inside does not require regular maintenance.



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

PIUR Sensor will anyway indicate when batteries are depleted.

## 8.3 Software Update

The user is not permitted to carry out software updates. Software updates are performed by trained service personnel or provided through the GE Healthcare app store.

## 8.4 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 inside system and inform our service team via the above contact details.

# 9 Technical Data

## 9.1 Compatibility

| US Manufacturer | US Model | PIUR inside Software version | GE device software version | Probe Model | Bracket Model | Display Resolution |
|---|---|---|---|---|---|---|
| GE | LOGIQ E10 | v1.2 | R5.1 | L3-12<br>ML6-15<br>ML4-20 | Standard G3 Bracket | 1552x970 |
| GE | LOGIQ E10s | v1.2 | R5.1 | L3-12<br>ML6-15<br>ML4-20 | Standard G3 Bracket | 1552x970 |
| GE | LOGIQ Fortis | v1.2 | R5.1 | L3-12<br>ML6-15 | Standard G3 Bracket | 1552x970 |

The minimum hardware requirements for PIUR tUS inside and criteria that must be met for compatibility:

- GE Ultrasound API environment
- Image framerate > 25 fps possible
- Windows 10 64-bit operating system
- Nvidia Graphics Card 4GB GPU memory (with CUDA)
- 16GB RAM
- Bluetooth 4.0 or higher

## 9.2 Technical Data

| Parameter | PIUR Sensor |
|---|---|
| **Voltage** | 3,7 VDC (Lithium Polymer) |
| **Power input** | ~ 0,15W |
| **Dimensions** | 41,8x56,2x25,3 mm |
| **Mass (without packaging)** | 40 g |
| **Lifetime** | 2 years (due to Battery depletion)<br><br>*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<br>• Relative humidity: 10 % – 90 % (no outside storage)<br>• Atmospheric pressure: 50 kPa to 106 kPa (EN 60601-1-2:2015 Annex A 7.9.3.1)<br>• Use or recharge within 3 months |
| Recommended Storage and transport conditions | • Temperature: 0°C to +30°C<br>• Relative humidity: 10 % - 65% (no outside storage) |

| | |
|---|---|
| **Recommended operating conditions** | • Temperature: +10 °C to +30 °C<br>• Relative Humidity: 30 % to 75 % (EN 60601-1-2:2015 Annex A 7.9.3.1)<br>• Atmospheric pressure: 70kPa to 106 kPa (EN 60601-1-2:2015 Annex A 7.9.3.1 |
| **Recommended operating altitude** | Maximal 2000 m |

## 9.3 Technical characteristics and performance data

### 9.3.1 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.

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

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

Measurement possibilities are:

- Line measurement
- Spline measurement
- Volume measurement

### 9.3.2 Performance assessment

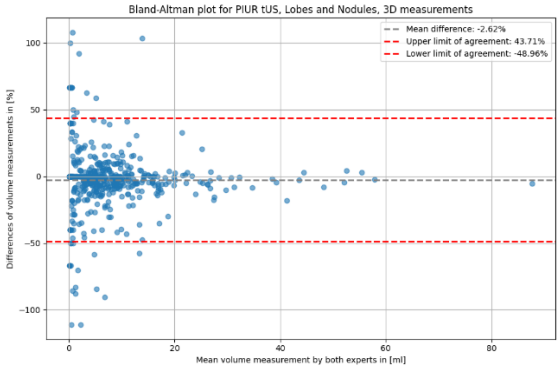
The performance of PIUR tUS inside is supported by clinical and phantom studies conducted with PIUR tUS Infinity. The applicability of these results to PIUR tUS inside is supported by the documented equivalence of the two devices with respect to the functions evaluated. These performance data were included in the submission supporting FDA clearance of PIUR tUS inside.

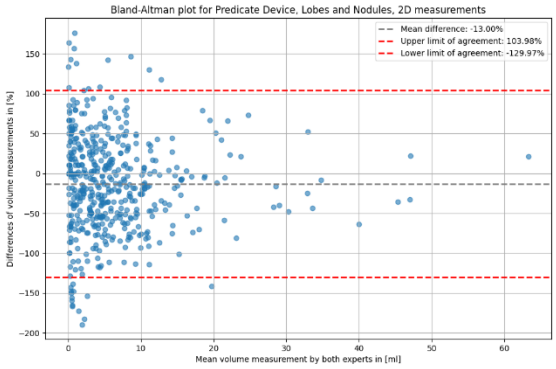
Within the performance assessment of PIUR tUS inside a comprehensive analysis of 196 patients from the USA, Brazil, and Europe has been conducted. The performance assessment was split into two parts:

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

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

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




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

These results are underline by phantom data:

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

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

The results are summarized in the following table:

| Statistics | 2D Rater vs 3D Rater | Threshold |
|---|---|---|
| Weighted Quadratic Cohen's Kappa Coefficient | 0.4563 | 0.4748 |
| 95% Confidence Interval for Cohen's Kappa | [0.3395, 0.5598] | [0.2969, 0.6277] |

| | | |
|---|---|---|
| Standard Error of Cohen's Kappa | 0.0444 | 0.0634 |

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

**Conclusion:**

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

### 9.3.3 Statement of Limitations and Uncertainties

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

Variations in operators' skills might affect the outcome of tomographic 3D ultrasound examinations in the field. Although the study aimed to mitigate this by including a variety of healthcare professionals, it remains possible that outcomes in the clinical routine vary. However, this is true for both PIUR tUS inside and the Predicate Device, and therefore, both products are affected in a similar way.

Additional uncertainties might arise from biases in the training dataset due to a bias towards certain nodule characteristics in the general patient population. The risks associated with this bias have been addressed as well as possible through mitigation measures in the software, however, a small risk remains. Further sources of uncertainty that can affect performance include side-shifts during acquisition.

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

We also remind the user to always verify any automatically calculated result before making diagnostic decisions.

## 9.4 Classification

| | **PIUR Sensor** |
|---|---|
| Protection class | Internally powered device |
| IP classification | IPx5 |

## 9.5 Electromagnetic compatibility (EMC)

The PIUR Sensor fulfils the requirements of the standards: EN 60601-1-2:2015,

- 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)

The PIUR Sensor is classified according to CISPR 11 as group 1, class B.

Under EN 60601-1-2, the DUT is classified into group 1, class B, according to CISPR 11 and into class B according to CISPR 32.

Under ETSI EN 301 489-1, the DUT is classified into class B according to CISPR 32.

| | PIUR Sensor |
|---|---|
| Frequency band of reception | 2,4 GHz ISM frequency band EN 60601-1-2:2015 5.2.2.3 |
| Bandwidth of the receiving section | max. 1 Mbit/s |
| Frequency band of transmission | 2,4 GHz ISM frequency band |
| Type and frequency characteristics of the modulation | IEEE 802.15.1 EN 60601-1-2:2015 5.2.2.4 |
| Effective radiated power | 19 dBm EN 60601-1-2:2015 5.2.2.4 |

**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 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 environmental conditions Chapter Technical Data.

**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 4.4, Connection with the Ultrasound Device.

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:

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

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

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

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

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

**Summary Table Electromagnetic Emissions and Immunity Declarations**

| Emissions Test | Compliance Level |
|---|---|
| RF Emissions, CISPR 11 | Group 1, Class B Compliant<br>Radiated emissions 30 MHz to 1000 MHz |
| IEC 61000-4-2 Electrostatic discharge immunity test | ± 8 kV contact discharge<br>± 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 |

**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:

- Sensor malfunctions and does not turn on
- Bluetooth connection of sensor might not be possible