

# PIUR IMAGING

## PIUR® tUS Infinity Instructions for use






## General Information



### Abbreviations and Terms

Abbreviation / term	Description
US	Ultrasound
tUS	Tomographic ultrasound

### Symbols

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

### Symbols on device

Symbol	Description
	Stand-by
	Indicator for scanning direction

## Identification Label

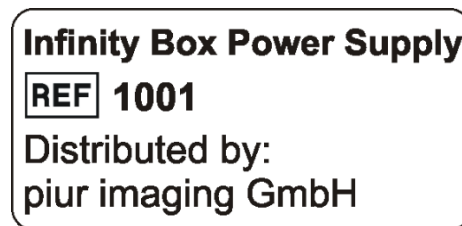
The identification label with the corresponding serial number can be used to identify the device. Please note down the serial number of the device before contacting the PIUR service.



*Label Infinity Box*











*Label Infinity Sensor*



*Label power supply*

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

Symbol	Description
	Serial number of the device
	Catalogue number
	Manufacturer
	CE mark

	Operating instructions
	Direct current
	Alternating current (AC)
	The system must not be disposed with normal waste (see chapter 7.3).

## Disclaimer

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

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

## 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 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.
- Users have sufficient knowledge of the English language.

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## Intended Use

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The PIUR tUS Infinity system serves as a non-invasive, transient and active medical device that is intended to support on issues concerning diagnosis of various diseases by providing 3D information generated from a sequence of external ultrasound images.

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

2D ultrasound images acquired by an ultrasound device that is not part of the product and position data of the system-integrated position tracking system are the basis for the 3D image reconstruction. This ultrasound device must be a medical device according to MDR 2017/745 with a valid CE-Label.

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## Operating Principle

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For image acquisition, the user moves the external 2D ultrasound transducer perpendicular to the structure to be imaged over the region of interest of the patient's body. The data acquired contains 2D image data from the ultrasound device that is an external product and not part of the PIUR tUS system, and position data acquired with the Infinity tracking sensor as part of the system. The respective ultrasound device must have a digital video output. The position of the ultrasound transducer is recorded using the tracking sensor mounted on the transducer through an attachment. Software merges the grabbed 2D image data from the ultrasound device with position information of the tracking sensor in order to compound a 3D volume and performs subsequent image processing.

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## Contact and Regulatory Information

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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 according to Annex IX.

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## Safety Regulations

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

	<p>To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.</p>
	<p>Do not modify this equipment without authorization of the manufacturer.</p>
	<p>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.</p>
	<p>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.</p>
	<p>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.</p>
	<p>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.</p>
	<p>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.</p>
	<p>If malfunctions and defects occur. <b>Occurrence of malfunctions and defects can lead to personal injury or damage to the device.</b> If malfunctions and defects occur, discontinue the use of the PIUR tUS system and inform our service team via the above contact details.</p>

## Product Information

### 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. 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.

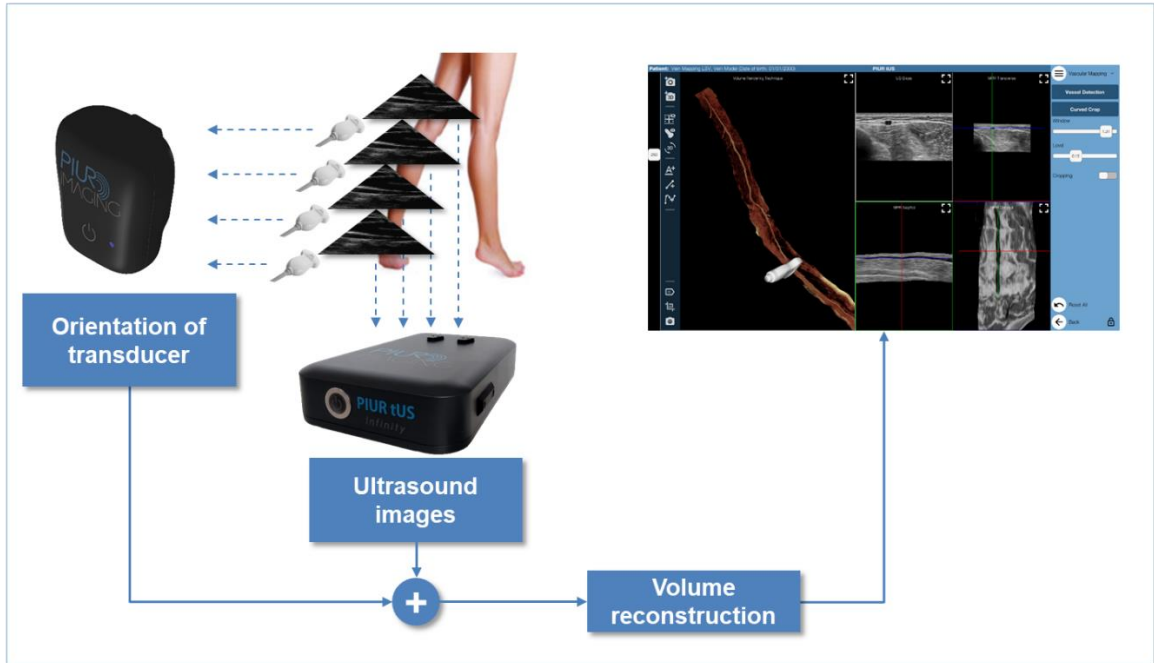
In order to generate three-dimensional datasets PIUR tUS Infinity requires the following components (see Figure 4):

- 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

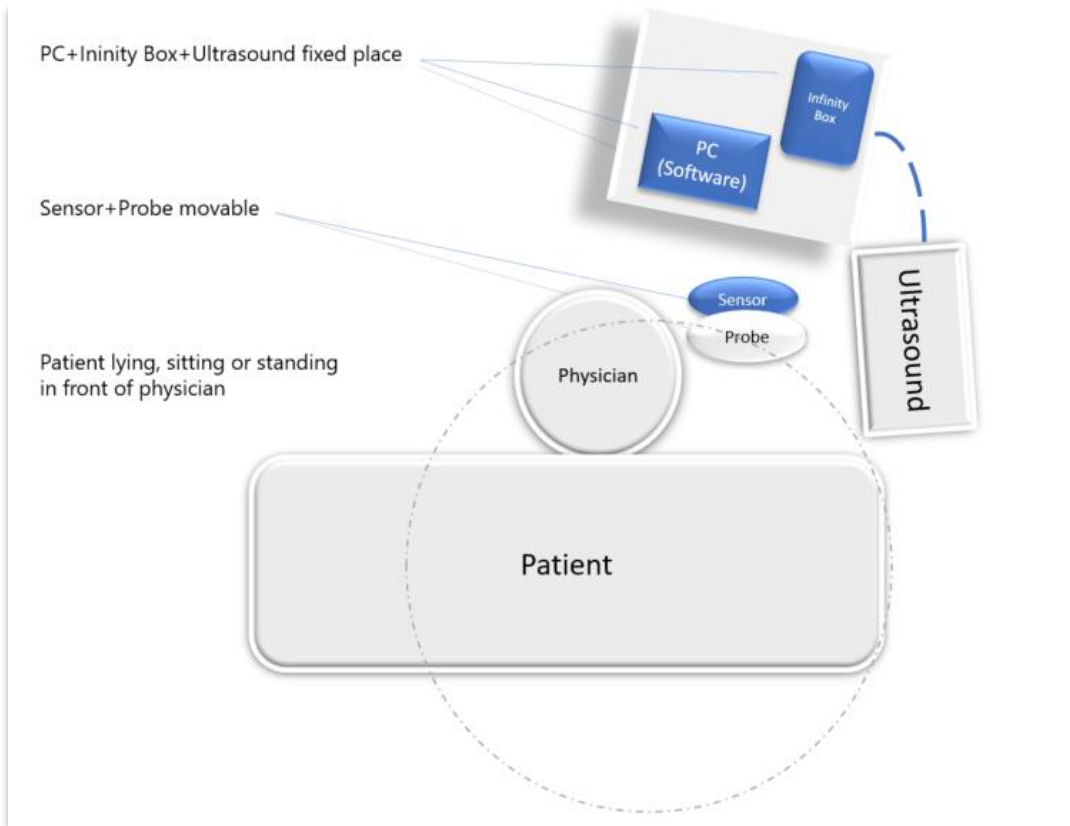
The Infinity system has no applied parts according to the standard EN 60601-1. The medical electrical system consists of the parts mentioned under chapter Components, the diagnostic ultrasound device and the computer. The computer is the only non-medical equipment that has to be placed outside the patient environment. The patient environment is shown on picture below. patient environment. The Infinity 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.



PIUR tUS Infinity system set-up

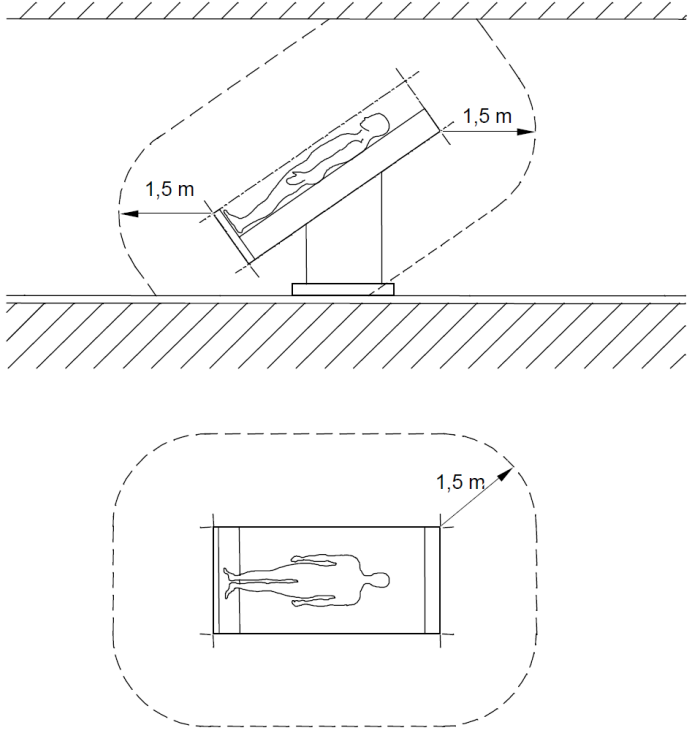


Generation of a 3D dataset



Clinical Setup





*Patient environment as defined in EN 60601-1*

## Clinical Indications

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- Cerebro-vascular
- Peripheral vascular
- Thyroid
- Peripheral neuronal
- Abdominal

## Contraindications

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

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

## Clinical Benefits

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There are many patient and system benefits relating to the use of tomographic ultrasound system.

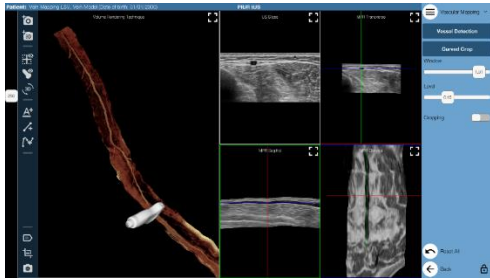
The manifold benefits often depend on the indication (see table 4). These include:

- Reduced exposure to ionising radiation (due to reduction of required CTA acquisitions);
- Reduce exposure to nephrotoxic contrast agents (due to reduction of required CTA/MRA acquisitions);
- Reduce waiting times (due to reduction of referrals to radiology for 3D imaging; 3D imaging can be performed in ultrasound lab with PIUR tUS Infinity);
- Reduced costs (due to reduction of required CTA / MRA acquisitions and radiologist reporting);
- Shorter hospital stays (due the reduction of side effects resulting from nephrotoxic contrast used by MRA);
- Freeing resources from CT / MR scanners
- Freeing up interventional vascular radiologists from reporting CT/MR scans meaning shorter intervention times.
- Shorter scan times (tUS scans are significantly quicker than 2D ultrasound) leading to increased departmental capacity.
- No maximal number of repeated exposure times, during the whole duration of product use.

Another great advantage of tomographic ultrasound with the aid of the PIUR tUS Infinity system is the communication between different treating physicians. Especially in the indication of arteriovenous fistulas, the doctor usually examines the artery with 2D ultrasound, but cannot provide the surgeon with an exact indication of position and shape. By storing three-dimensional images with which a localization can be easily determined, the patient can, for example, bring the data carrier to the assigned physician, as has long been standard in CT and MRI.

Application	Value Proposition				
<b>AV fistula planning</b>	Fast scanning and few operator-dependency	Easy treatment planning	Improved fistula management	Potentially earlier detection of complications	Longer-lasting fistulas
<b>Thyroid imaging and Volume Segmentation</b>	Complete documentation and archiving in PACS	Accurate and fast measurement of thyroid lobe and nodules	Separation of scanning and image analysis, increasing patient through-put	Enabling computer-aided diagnostic workflows	
<b>Vascular Mapping</b>	Reduction in scanning time by up to 85%	Higher patient-throughput can increase revenue	Documentation of complete volume data	Enabling separation of scanning and image analysis	Easier illustration to surgeon and patient

Components



PIUR tUS Software (installed)



PIUR tUS Infinity Quick Guide



Front clip  
(depending on ultrasound system)



Infinity Sensor



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



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



Video adapter HDMI-DVI



Video adapter HDMI-Displayport



Infinity Box power supply cable  
Ho5VV-F 3Go.75 C13 (max. length 3 m)



Infinity Box power supply

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## Requirements to the Computer (laptop)

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

### Minimum requirements:

Windows 10 64-bit operating system, version 1803 or higher  
Full HD Display (1920x1080 pixels)  
NVIDIA Graphics Card with at least 4GB GPU memory (e.g. NVIDIA GeForce GTX1050 or similar)  
**Important:** Must be NVIDIA  
Dual-core processor (e.g. Intel i5 or similar from AMD)  
8GB RAM or more  
Bluetooth 4.0 or higher  
Wireless LAN  
256 GB HDD

### Recommended requirements:

Windows 10 64-bit operating system, version 1803 or higher  
Full HD Display (1920x1080 pixels)  
Nvidia Graphics Card 4GB GPU memory (e.g. NVIDIA GeForce GTX 1050Ti)  
**Important:** Must be NVIDIA  
Quad-core processor (e.g. Intel i7 or similar from AMD)  
16GB RAM or more  
Bluetooth 4.0 or higher  
Wireless LAN  
512 GB SSD

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## Connection with the Ultrasound Device

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### 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

## Technical Data

### General data

	Infinity Box	Infinity Sensor
<b>Voltage</b>	19 VDC Power supply: 100-240 V 50/60 Hz	3,7 VDC (Lithium Polymer)
<b>Power input</b>	max. 90W	~ 0,15W
<b>Dimensions</b>	260x160x65 mm	48x40x26,5 mm
<b>Mass (without packaging)</b>	0,8 kg power supply: 0,7 kg	25 g
<b>Lifetime</b>	5 years	2 years
<b>Storage and transport condition</b>	Temperature: -10 °C to +60 °C Relative humidity: 10 % – 90 % (no outside storage) atmospheric pressure: 50 kPa to 106 kPa	
<b>Operating conditions</b>	Temperature: +10 °C to +30 °C Relative Humidity: 30 % to 75 % atmospheric pressure: 70kPa bis 106 kPa	
<b>Operating altitude</b>	Maximal 2000 m	

## Technical characteristics and performance data

### Measurement Function

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

Measurement possibilities are:

- Line measurement
- Spline measurement
- Volume measurement

The system accuracy is determined by a percental measurement error computed relative to the ground truth. The measurement error is the difference between the calculated measurement and the ground truth measurement relative to the ground truth measurement. Measurement errors are divided into the following categories:

- **In-plane measurement accuracy:** considered as measurements taken within the plane of recorded 2D slices, such as diameter measurement.
- **Out-of-plane measurement accuracy:** considered as measurements orthogonal to the plane of acquired 2D slices, such as lengths measurements.
- **Volumetric accuracy:** considered as volume measurement using all three dimensions of the dataset.

### Electromagnetic compatibility (EMC)

The Infinity Box and Infinity Sensor fulfil the requirements of the standards EN 60601-1-2:2015, EN 301 489-1 V2.2.0 (2017-03) and EN 301 489-3 V2.1.1 (2017-03).

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

	Video Box	Sensor
Frequency band of reception	2,4 GHz 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 and 5 GHz (160 MHz channels)	2,4 GHz ISM frequency band
Type and frequency characteristics of the modulation	IEEE 802.11a/b/g/n/ac	IEEE 802.15.1
Effective radiated power	max. 23dBm	5 dBm