

Aixplorer Ultimate

Fusion/Navigation User's Guide

Fusion/Navigation
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1 Introduction

Welcome!

The following documents are available for the Aixplorer® Ultimate Ultrasound System:

- **Quick Guide**
- **User's Guide**
- **Fusion/Navigation Guide**

The Quick Guide contains basic information regarding the use of the product.

It does not replace the User's Guide.

The User's Guide contains important information regarding the use and safety of the product. Please read this guide carefully and store it in a location where it can be easily accessed.

This Fusion/Navigation Guide contains important information regarding the use and safety of the Fusion/Navigation feature.

The Aixplorer® Ultimate system has been designed with the safety of the operator and patient in mind.

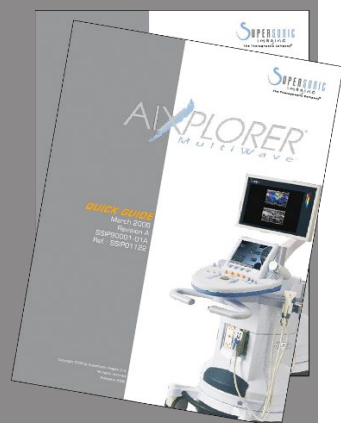
The Fusion/Navigation feature has been developed in collaboration with MedCom GmbH.

Please read the following chapters thoroughly before you start working with the system.

SuperSonic Imagine guarantees the system will perform as intended only when all cautions and warnings specified in this user's guide are observed.

Intended Use

Fusion/Navigation is a feature intended to support a clinical ultrasound exam and follow percutaneous procedures by means of providing additional real-time image information from a 2nd modality like CT, MR, PET or 3D US or their combination, with the possibility to plan ideal treatment procedure. The second modality is imported and then synchronized with the live US image, permitting the live correlation with the patient position.



The 2nd modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient probably not congruent with the current (real) patient situation and shall therefore always be seen as an **additional** source of information.



WARNING

The user must be a physician able to perform a biopsy, navigate into MRI or CT scanner volumes, and manipulate ultrasound devices.

3 packages are available for the Fusion/Navigation feature:

Package Name	Components
Fusion	<ul style="list-style-type: none"> -Full Data Import module -Target module with Risk Organs/Safety Margins -Registration module -Motion tracking (detection and correction) breathing detection with omniTRAX™
Volume Navigation and Needle Guidance	<ul style="list-style-type: none"> -Data Import* -Virtual Mode (eTRAX™, VirtuTRAX™ and US target definition) -Motion tracking (detection and correction) breathing detection with omniTRAX™ -Navigation module**
Fusion, Volume Navigation and Needle Guidance	<ul style="list-style-type: none"> -Full Data Import module -Target module with Risk Organs/ Safety Margins -Registration module -Navigation module -Virtual Mode module (eTRAX™, VirtuTRAX™ and US target definition) -Motion tracking (detection and correction) breathing detection with omniTRAX™

* does not allow import of external data, only 3D US scans.

** for 3D US scans only.

About This Fusion Guide

This Fusion/Navigation guide contains important information about the use and safety of the fusion feature of Aixplorer® Ultimate.

Please contact your local SuperSonic Imagine sales or service representative for further information.

Pictures are not contractual and are only displayed for general information purposes.

It also contains information about contacting SuperSonic Imagine for support.

This guide is intended for use by, or by the order of, and under direct supervision of a licensed physician qualified to direct the use of the ultrasound device.

This guide is intended for users who have been trained or are otherwise familiar with the use of medical ultrasound devices and the Fusion/Navigation feature.

Clinical guidance on how to perform an ultrasound examination is not provided in this manual.

This Fusion/Navigation guide complies with the following:

- 93/42/EEC European Directive modified by 2007/47/EEC European Directive
- FDA regulation, 21 CFR § 801

Training

In case further information is needed, trainings are advised and available upon request at SuperSonic Imagine. Please contact your local representative for more information.

Contact Us

Customer service representatives are available regionally to help answer your questions.

Please contact your local SuperSonic Imagine sales or service representative for assistance.

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Service

Call your SuperSonic Imagine local representative.

2 Safety

Safety Instructions



WARNING

a **WARNING** symbol describes precautions necessary to prevent injury or loss of life.



CAUTION

a **CAUTION** symbol describes precautions necessary to protect the equipment.



WARNING

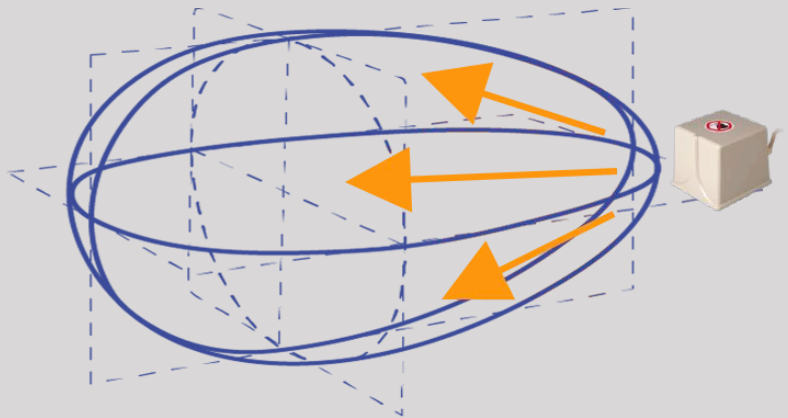
A diagnosis can not be only based on the results of the Fusion/Navigation feature. In particular the displayed image of the 2nd modality shall never be used as a standalone source for assessments since it represents computed and thus artificial information.

SuperSonic Imagine is not engaging any responsibility for indirect harm due to the use and evaluation of diagnosis data furnished by the Fusion/Navigation feature.



WARNING

The operational electromagnetic field (ovoid shape) is minimum 20cm, maximum 80 cm in front of the transmitter, 66cm for a good accuracy, +/-30cm above and below, +/- 28cm on the sides.



Avoid metallic objects that include steel or iron between the tracking transmitter and receiver since they may affect the accuracy of the tracking device. If in doubt, please contact your technical support.

Don't put the transmitter too close to walls containing metallic components, it could affect the accuracy of the tracking.

Patients with cardiac pacemakers shall not be treated with the Fusion/Navigation feature.

During and after the registration, do not move the transmitter nor the patient during the following session. For each session or in the event of a patient shift or transmitter movement, the registration procedure has to be repeated, unless “movement correction” is activated through the use of omniTRAX™ CT or MR.

When one of the the needle guidance tools (VirtuTRAX™ or eTRAX™) is enabled on the Ultrasound device while in Navigation or Virtual Mode, it displays a corresponding virtual biopsy line in the 2nd modality image. These guidelines are intended to be used as an additional orientation tool but must not be used without considering the real-time ultrasound biopsy line display. In particular it should not be considered during percutaneous procedures as it may not reflect the real-time situation.

The Virtual Needle length is defined by the distance between the sensor and the needle tip. Calibrate the needle to acquire the right length or enter it manually. The measure is considered in cm.

If the difference between the input and the measured distance is more than 5mm, the virtual needle may not be displayed properly and the procedure can be a risk for the patient.

The Virtual Needle displayed may not be congruent with the real needle position. Verify with Ultrasound or any other imaging modality useful to assess the real needle position. Do not perform any invasive procedure before the proper assessment of the needle tool.

When using the VirtuTRAX sensor the accuracy is sensitive to needle bending. Do not use needle with Gauge more than 16GA and only use rigid needle.

The accuracy of the system could be affected by tolerance existing in the VirtuTRAX plastic holder, or a slight shift of the needle tip during the calibration procedure. Before starting any procedure, always verify the reliability of your VirtuTRAX device by means of the dedicated accuracy verification procedure (See [Chapter 6, Settings \[97\]](#)).

The accuracy of the system could be affected by an incorrect assembling of the eTRAX needle or a damaged eTRAX device. Before starting any procedure, always verify the reliability of your eTRAX device by mean of the dedicated accuracy verification procedure (See [Chapter 6, Settings \[97\]](#)).

Use a sterilized sheath to cover the holder and the receiver before lock to the needle. Clean it with a dedicated product before and after use.

The accuracy of the breathing sensor depends on the position where it is attached to the patient.

Please verify the breathing in and breathing out positions after sensor calibration.

The omniTRAX™ needs to be placed on the patient skin before the CT scan or MR and patient movements after its placement can lead to a misalignment of the holder and consequently registration error.

When the breathing sensor is activated with the motion a constant time is needed to discern the movement due to the breathing to the one for the real patient movement. During this time (s) the accuracy could be degraded.

Do not base diagnosis on exported recorded clip or images only.







The interpolation process between the slices could modify the anatomical structure between them. Please verify the morphology before using it.

The Navigation accuracy in optimal condition can be affected by registration error, patient breathing and sensor support tolerance, EM interference ...

When loading 3D DICOM dataset please be aware that the Fusion/Navigation feature is not able to handle non equivalent distant acquisitions as well as 3D datasets that have been acquired while a gantry tilt was applied.

Symbols

The following symbols are used for the Fusion/Navigation feature only. Please refer to the Aixplorer® Ultimate User's Guide for all symbols regarding the Aixplorer® Ultimate .

Symbol	Meaning
	Type B
	Type CF
	Manufacturer
	Physician Only
	Unsafe for MR
	No Pacemaker

Symbol	Meaning
LOT	Batch Number
QTY	Quantity
REF	Reference
SN	Serial Number

Alarm System

The following alarms display pop-up windows:

Alarm condition	Message
Needle calibration (VirtuTRAX)	<ul style="list-style-type: none"> -Previous calibration detected -There is a previous needle calibration with length "xx" mm saved -Do you want to calibrate again? -Take the Needle and do a pivot movement and rotation -Keep needle tip in fixed position -Be aware that the error of the displayed needle position increases proportionally to the needle length!
Needle calibration failure (VirtuTRAX)	<ul style="list-style-type: none"> -Calibration failed! Needle Tip probably changed position during movement Keep needle tip in fixed position for calibration -Calibration failed! The needle is placed in the wrong direction -The needle needs to be inserted in the direction of the arrow

Alarm condition	Message
	(Look closely at the VirtuTRAX clamp)
Sensor position	-Please make sure the reference sensor is placed on the patient before starting the examination!
Sensor detection and correction	-Patient has moved! Please check if the registration is still accurate -From now on, do not move patient nor transmitter!
3D Ultrasound acquisition	-Please start an examination before US acquisition -Memory error: 3D acquisition requires more memory than is available. Please contact a SuperSonic Imagine representative. Try to change acquisition parameters.
Needle navigation with defined risk organs	-RISK organ in the way!
Import of secondary modality	-The patient name does not match the patient name of the current primary volume! The dataset will not be loaded

3 System Overview

General Description

The Fusion/Navigation feature is to be used with the following components:

- driveBAY (3D Guidance driveBAY Electronics Unit, sensor and mid-range transmitter)
- omniTRAX™ (optional)
- VirtuTRAX™ (optional)
- eTRAX™ (optional)
- Transmitter cart (optional) SSIP92922-A03

Only the following components may be connected to the driveBAY:

Component	Manufacturer	Reference
Transducer sensor	NDI	600786
General Purpose Electromagnetic Sensor	CIVCO	610-1066
eTRAX™	CIVCO	610-1055
3DG trackSTAR Mid-Range Transmitter	NDI	600222-H

Classification of the Devices Supported by the Fusion/Navigation Feature

This table compiles information related to the electrical protection of the devices used for the Fusion/Navigation feature.

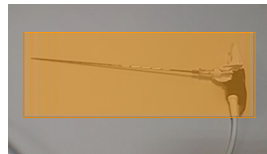
Component	Manufacturer	Classification	IP Code
eTRAX™	CIVCO	CF Applied Part	IPX 7
General purpose sensor for VirtuTRAX™ and omniTRAX™	CIVCO	B Applied Part	IPX0

Component	Manufacturer	Classification	IP Code
driveBAY	NDI	Class I	IPX0
Mid-range Transmitter	NDI	Class I	IPX0
Transducer Sensor	NDI	Class I, B Applied Part	IPX0

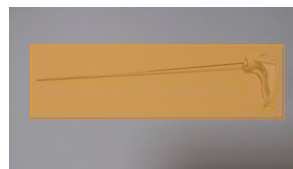
Applied Parts

This section describes which part of each device may be in contact with the patient during an exam or an interventional procedure (these parts are highlighted in orange on the pictures below).

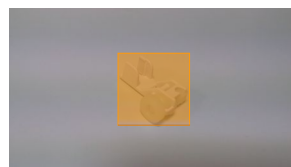
eTRAX™ Sheath



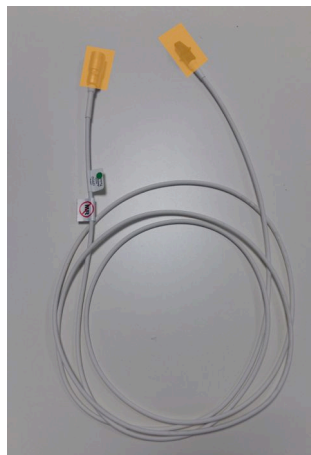
eTRAX™ Stylet



VirtuTRAX™



General Purpose Sensor



omniTRAX™ CT



omniTRAX™ MR



Component Description

Make sure all the following components are included in the package and not damaged.

driveBAY

driveBay is a high-accuracy electromagnetic tracker integrated to your Aixplorer® Ultimate . The device tracks the position and orientation (six degrees of freedom) of multiple sensors within the operating range of its transmitter. Tracking data is reported serially to your host computer via a USB interface.

Make sure you have the following components before using the driveBAY tracker:

- 3D Guidance driveBAY Electronics Unit



CAUTION

Check the driveBAY LED status before use.

LED Definition of the 3D Guidance Electronic Units:

LED State	Description of board status	Possible Error Conditions resulting in LED state:
OFF	Power applied to board.	PLD un-programmed PLD error LED faulty

LED State	Description of board status	Possible Error Conditions resulting in LED state:
		Board error Board un-powered
SOLID RED	PLD loaded and configured	Flash memory un-programmed POSERVER DSP error Board error
SOLID ORANGE	POSERVER DSP - boot loader successfully loaded and running. All preliminary tests completed.	Multi-Boot Loader test failed POSERVER main application not found Code corrupt DSP error Board error
SLOW BLINKING RED (<1Hz)	POSERVER DSP - application loaded, running and Command Handler executing	MDSP application not found in Flash Communications failure Failed starting MDSP
FAST BLINKING RED (>2Hz)	MDSP DSP - code downloaded by POSERVER	MDSP failed to respond to messages MDSP code corrupt MDSP error Board error
SLOW BLINKING ORANGE (<1Hz)	POSERVER successfully communicated with MDSP	SYSTEM EEPROM error PLD version error MDSP fails to respond after tests MDSP test failed
FAST BLINKING ORANGE (>2Hz)	All of POSERVER initialization and power on test is complete	Transmitter not present Transmitter EEPROM error Transmitter hardware failure
SLOW BLINKING GREEN (<1Hz)	System is fully functional. The transmitter is not being energized during acquisition. (ASLEEP)	System ASLEEP - normal ff auto-config issued then abnormal
SOLID GREEN	System is fully functional. The transmitter is being energized during the acquisition. (AWAKE)	System AWAKE normal If SLEEP command issued then abnormal.

LED State	Description of board status	Possible Error Conditions resulting in LED state:
FAST BLINKING RED/ORANGE (>2Hz)	Run-time Diagnostic Error	<p>One of the run-time diagnostics has failed.</p> <p>Primary suspect is a removed transmitter. (This shows up as a TX Temp Sense error)</p> <p>Secondary suspects might be TX Temp. Sense or EU Temp Sense (over-heating problem)</p>

- A Transducer sensor (Model 800)



NOTE



These clips are to be used to attach the sensor cable to the transducer cable. Twist the clip (as shown below) to firmly attach the cables.



- Mid-Range Transmitter



omniTRAX™ and omniTRAX™ MR

The omniTRAX™ provides clinicians automatic image registration of fused images for uninterrupted navigation when using real-time ultrasound with previously acquired CT volume data sets. This two-part system consists of omniTRAX™, a disposable locating device and a reusable general purpose electromagnetic sensor.



Compatible with imaging systems with navigation technology, this device allows physicians to quickly and accurately register patient anatomy eliminating a tedious manual image registration. When placed on the sternum or any solids parts of the body (such as ribs), omniTRAX™ can be used to synchronise images for viewing the needle path with a moving target. omniTRAX™ features multiple fixed reference points, visible under CT and ultrasound, in an accurate three-dimensional array which allows for connection of CIVCO's general purpose sensor. The active patient tracker offers an adhesive base for easy patient application and removal.

To ensure that the omniTRAX™ Patient Tracker is securely attached to the patient and won't move between the exams, you can use additional transparent film to cover and fix the device on the patient.



Skin marking zones allow for repositioning in both CT and ultrasound environments. The small active tracker may also be used as a reference sensor during image fusion, adjusting with small patient movements such as breathing. omniTRAX™ is designed for single-patient use and is sold non-sterile. The durable sensor is part of a Class B device. The device may be cleaned, high-level disinfected or sterilized according to instructions for use.



The omniTRAX device is also compatible with MR (the MR dedicated omniTRAX device is shown above).

VirtuTRAX™ (optional)

VirtuTRAX™ improves image guidance by tracking the instrument tip using electromagnetic technology and real-time navigation in the

interventional suite, allowing physician's safe and precise placement of instruments during each procedure. This two-part system consists of VirtuTRAX™, a sterile disposable hand-held device and a reusable general purpose electromagnetic sensor.



Compatible with imaging systems with navigation technology, this device allows physicians to more precisely track the tip of any rigid instrument such as biopsy needles as it is being directed to a targeted anatomical area. In the case of ultrasound, the instruments is inserted into the patient and the tip location is displayed in real time on the ultrasound screen.



WARNING

The Aixplorer® Ultimate is an imaging device. For interventional procedures, please refer to CIVCO appropriate documentation.



WARNING

VirtuTRAX™ sterile hand-held device is a single use device.

eTRAX™ (optional)

eTRAX™ needle tip tracking system improves image guidance by tracking the tip of a needle using electromagnetic technology and real-time navigation in the interventional suite. This system allows physicians safe and accurate placement of instruments during each procedure by monitoring the real-time trajectory of the needle as it advances through delicate anatomy to the center of a target such as a tumor, cyst or polyp. When integrated with visualization tools, eTRAX™ enables accurate percutaneous targeting of lesions without radiation or open surgery.

This two-part coaxial system consists of a reusable non-sterile needle handle with a 1.3mm sensor in the distal tip and a sterile disposable needle with a trocar tip. A sterile CIV-Flex cover is used to easily cover the reusable handle prior to insertion into the disposable needle and sheath. The cover ensured sterility once the needle handles are locked in position.



This device allows you to simultaneously track the tip of the needle and the scan plane. In order to visualize the patient anatomy as well as the position of the needle tip in real time.



The needle handle offers ergonomic positioning finger grips for easy in handling during complex procedures. The system offers a reinforced extended length cable of 2.5m (8.5') for expanded flexibility in positioning in the clinical environment. The durable sensor is part of a Class CF device. The device may be cleaned or disinfected according to instructions for use.

4 eTRAX™ models are compatible with the Aixplorer® Ultimate : 12GA, 14GA, 16GA and 18GA.

The list of compatible needles is available at: <http://www.civco.com>

Note that the maximum operational range of the eTRAX™ device is 35cm from the transmitter.

Cart

The cart is to be used to support the transmitter. It should be placed on the side of the bed and slightly above the patient during interventional procedures (See [the section called “Safety Instructions” \[12\]](#), for more information about the operational electromagnetic field of the transmitter).



You must mount the transmitter on the cart, for more information please refer to [the section called “Setting Up the Transmitter on the Cart” \[37\]](#).

Don't put the cart with the transmitter too close to walls containing metallic components, it could affect the accuracy of the tracking.



WARNING

Remove transmitter during cart transportation.

When using the 3D endo probe SEV12-3, the transmitter needs to be placed behind the probe handle to maximize the sensor detection.

Move the cart using the handle.

Use the braking system on two wheels to lock the system in position.

4 Preparation

Connecting to the driveBAY

The following sections explain how to connect the different devices to the driveBAY.

How to Connect the Transmitter to the driveBAY

1. Connect the mid-range transmitter cable to the connector marked 'Transmitter' on the front of the driveBAY
2. Align the slot on the top of the transmitter cable's plug with the connector
3. push the plug into the connector until it clicks into place



CAUTION

The transmitter weighs 2.6kg (5.73lbs). Grasp it firmly before moving it.

4. Set up the transmitter in a non-magnetic location (such as wood or plastic, but never on the floor), preferably on the optional transmitter cart

Try to keep at least a 61cm (24 inch) radius around the transmitter free from any magnetic object or electrical wiring (which means keeping the transmitter at least that distance away from the Aixplorer® Ultimate)



WARNING

Do not use the Fusion/Navigation feature if the transmitter fell down.

Do not use the Fusion/Navigation feature if the transmitter is damaged.

How to Connect the Sensors to the driveBAY

Connect the transducer sensor to the 'Sensors' connector marked with a '1'. Rotate the sensor plug until it aligns with the holes on the 'Sensor' connector, and then push until the plug clicks into place.

To connect the CIVCO devices, VirtuTRAX™, eTRAX™ and omniTRAX™, plug them as follows: VirtuTRAX™ to the connector marked '2', eTRAX™ to the connector marked '3', and omniTRAX to the connector marked '4'.



CAUTION

Do not put the transmitter or the sensor near metallic objects.



CAUTION

Always connect the sensors and the transmitter to the driveBAY when the Aixplorer® Ultimate is off.

Turning On the Aixplorer® Ultimate

Since the driveBAY is connected to the Aixplorer® Ultimate power supply, the driveBAY starts up when you turn on the Aixplorer® Ultimate.

The indicator light (on the front of the drive BAY) slowly blinks with a yellowish light while the driveBAY initializes. When complete, the indicator light turns to a slow blinking green. This takes about 10 seconds.



NOTE

If a slow blinking green light does not appear, then the driveBAY has not been properly initialized.

The slow blinking green light means that the transmitter is not being energized during the acquisition (this also happens if the Fusion/Navigation feature software is not active on the main screen), the solid green light means that the transmitter is being energized.

Shut down the Aixplorer® Ultimate and double check all the cable connections. Make sure all the cables are fully seated in their plugs. Then turn it back on.

Positioning the Transmitter

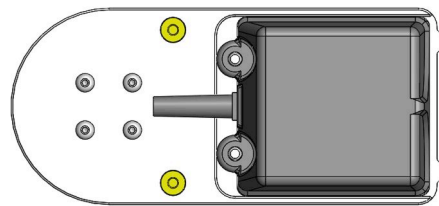
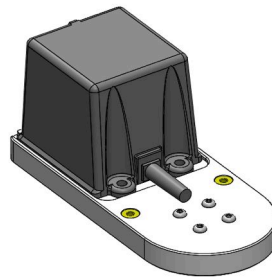
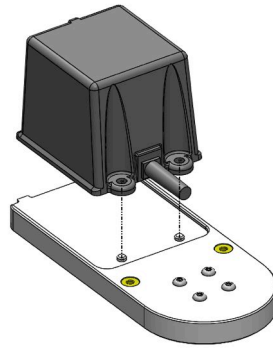
Once the patient is ready for the exam, position the transmitter on a stable non-magnetic support on the side and slightly over the patient so that the anatomy of interest is within the operational electromagnetic field.

Don't put the transmitter too close to walls containing metallic components, it could affect the accuracy of the tracking.

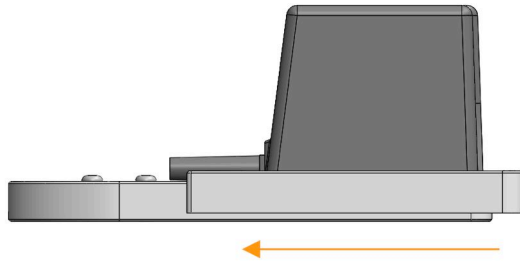
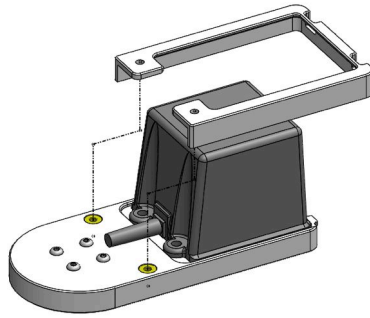
Setting Up the Transmitter on the Cart

This section explains how to set up the transmitter on the carrier of the cart.

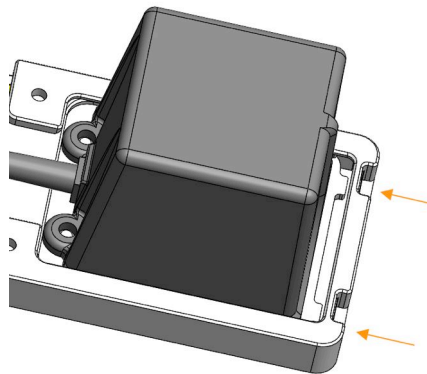
First of all, put the transmitter on the plate as shown below.

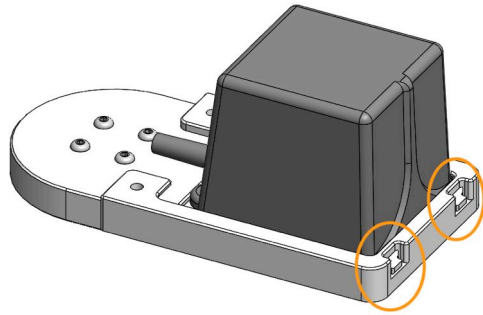


Then place the transmitter clamp on the plate as follows.

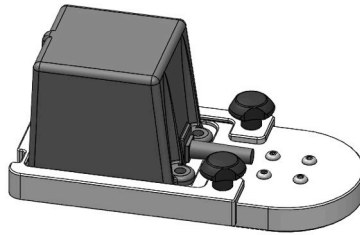
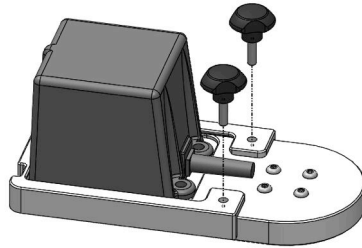


Make sure the clamp is well mounted on the plate, as shown below.





Finally, tighten the screws in the dedicated holes.



Preparing the Probe for the Exam

This section indicates the steps to follow to properly prepare the probe for the exams, as well as how to position the omniTRAX™, VirtuTRAX™ and eTRAX™ devices if needed.

Attaching the Bracket to the Transducer



WARNING

Make sure to clean, disinfect and sterilize the re-usable bracket before each use, according to the recommendations in the [Chapter 7, System Care & Maintenance \[101\]](#).

If the bracket does not fit properly, do not use it.

Once mounted, do not use the bracket if it is rotating or moving on the probe. Or if the sensor is rotating or moving on the bracket.

Please verify periodically that the bracket is not damaged and fits the probe properly without moving.

Place the bracket in the correct position on the probe as follows:

- For the XC6-1:



When mounting the bracket on the transducer, make sure the arrows on the side of both the bracket and the transducer are aligned (see picture below).



- For the SL10-2:



When mounting the bracket on the transducer, make sure the arrows on the side of both the bracket and the transducer are aligned (see picture below).



- For the SE12-3:



The clamp of the SE12-3 bracket has to be placed on the side of the thumb-dedicated area of the probe (see picture below).



- For the SEV12-3:



The clamp of the SEV12-3 bracket has to be placed on the side of the thumb-dedicated area of the probe (see picture below).



Attaching the Sensor to the Bracket



WARNING

Ensure the device is securely attached, failure to do so could result in inaccuracy.



WARNING

Do not use if the sensor fell down.

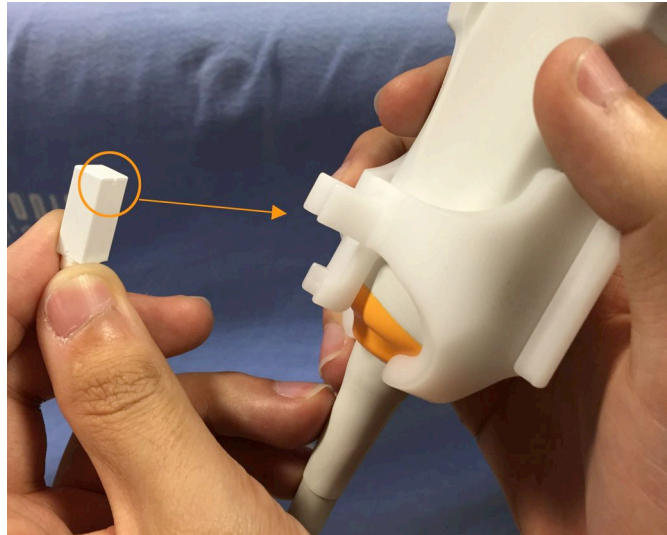
Attach the sensor to the bracket by putting the sensor side with the small notch (see picture below) on the sensor mount area of the bracket.





NOTE

When attaching the sensor, the side with the small notch has to be placed against the probe (see picture below). Make sure the sensor is firmly attached.



- For the XC6-1:



Mount the sensor on the dedicated area, as shown above.

- For the SL10-2:



Mount the sensor on the dedicated area, as shown above.

- For the SE12-3



The sensor mount area is located in the bracket, as shown above.

- For the SEV12-3



Mount the sensor on the dedicated area, as shown above.



NOTE

For the SE12-3, the sensor mount area is located in the bracket, therefore always put the sensor on the bracket before attaching the bracket to the transducer.



CAUTION

For the SE12-3, make sure to push the sensor so that it touches the bottom of the dedicated groove.



WARNING

Clean and disinfect/sterilize before usage and between each patient according the recommendations in the [Chapter 7, System Care & Maintenance \[101\]](#)

Covering the Transducer, Sensor and Bracket



WARNING

Use only recommended gels (see User's Guide). Petroleum or mineral oil based materials may harm the sheath.

Disposable components are packaged sterile and are single-use only. Do not use if the integrity of the packaging is violated or if the expiration date has passed.

For illustration purposes only, components may be shown without a sheath. Always place a sheath over the transducer, sensor and bracket to protect patients and user from cross-contamination.

Do not reuse, reprocess or resterilize single-use device. Reuse, reprocessing or resterilization may create a risk of contamination of the device, cause patient infection or cross-infection.

1. Place an appropriate amount of gel inside the sheath and/or the transducer face. Poor imaging may result if no gel is used.
2. Insert the transducer into the sheath making sure to use proper sterile technique. Pull the sheath tightly of the transducer face to remove the wrinkle and air bubble, taking care to avoid puncturing the sheath.
3. Secure the sheath with enclosed bands.
4. Inspect the sheath to ensure there are no holes or tears.

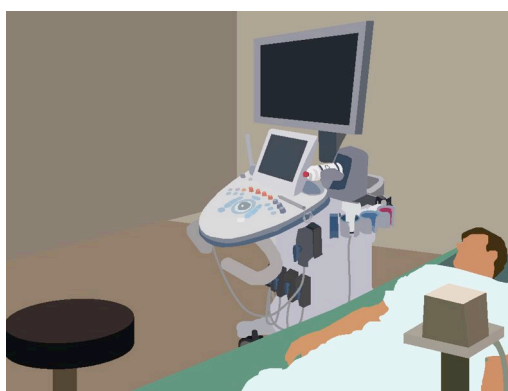
Positioning omniTRAX™, VirtuTRAX™ and eTRAX™ (optional)

To position and set up the CIVCO devices, please refer to the corresponding User's Guides.

5 Using The Fusion Feature

The Principle

The main purpose of the Fusion/Navigation feature is to provide additional image information from a 2nd modality during a therapeutic or diagnostic ultrasound session. This is accomplished by mounting a tracking device on the transducer, which provides its position and orientation in space while the standard ultrasound procedure takes place. The information from the tracking device and the 3D dataset of the 2nd modality (typically MRI or a CT scan) is combined to compute a virtual slice image that is spatially comparable to the currently displayed ultrasound scan.



WARNING

Fusion performance can be impacted by organ deformation due to application of excessive pressure of the transducer on the patient's body, patient's breathing or different patient position during the 2nd modality exam.

Before the system is able to compute the 2nd modality image correctly it is necessary to perform a "registration" procedure.



WARNING

Do not forget to register before any Fusion/Navigation exam.

After the registration, Fusion/Navigation displays the 2nd modality image and the current ultrasound image side by side, or overlaps the

2nd modality image directly on the live ultrasound information, or the opposite.

The dataset of the 2nd modality is transferred and loaded by using either DICOM data import from USB media, CD/DVD, DICOM Q/R or DICOM push mode. See the Aixplorer® Ultimate User's Guide.

For more details about how to use the Fusion/Navigation feature, please refer to the following sections in this chapter.

The Compatible Probes and Sheaths

The probes compatible with the Fusion/Navigation feature are the following:

- XC6-1
- SL10-2
- SE12-3
- SEV12-3



WARNING

Never re-use a sheath intended for invasive use.

The following list indicates the sheaths compatible with the probes:

XC6-1

Transducer width 7.89 cm (3.11 in.), cable length 2.1 m (82.7 in.)



Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
CIVCO	Sterile	Latex Free	CIV-Flex/ Telescopically Folded	610-637	8,9 x 91,5cm
CIVCO	Sterile	Latex Free	CIV-Flex/ Telescopically Folded	610-1000	10.2 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex/ Telescopically Folded (3D)	610-542	14 x 91.5cm
CIVCO	Non-Sterile	Latex Free	CIV- Flex/Flat Folded (3D)	610-362	14 x 61cm
Protek	Sterile	Latex Free	PullUp Probe Cover Kit	2097	14 x 121,9cm
Ecolab/ Microtek	Sterile	Latex Free	PullUp Probe Cover with gel	PC1292EU	15 x 244cm

SL10-2



Transducer width 5.92 cm (2.33 in.), cable length 2.1 m (82.7 in.)

Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
CIVCO	Sterile	Latex Free	CIV-Flex/ Flat Folded	610-323	6 x 91.5cm
CIVCO	Sterile	Latex Free	CIV-Flex/ Flat Folded	610-001	8,9 x 61cm
Ecolab/ Microtek	Sterile	Latex Free	PullUp Probe Cover with gel	PC1292EU	15 x 244cm

SE12-3

Transducer width at tip 2.42 cm (0.96 in.), transducer maximum width at handle 4 cm (1.58 in.), cable length 2.1 m (82.7 in.)

Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
CIVCO	Sterile	Latex Free	CIV-Flex/ Flat Folded	610-006	11.9 tapered to 3.8 x 61cm
CIVCO	Non-sterile	Latex Free	CIV-Flex/ Flat Folded/ No Gel	610-007	11.9 tapered to 3.8 x 61cm
CIVCO	Sterile	Latex Free	NeoGuard/ Rolled	610-844	4 x 30cm
CIVCO	Non-sterile	Latex Free	NeoGuard/ Rolled	610-838	4 x 30cm
CIVCO	Non Sterile	Latex Free	Eclipse/ Polyethylene cover with gel	610-1102	8.4 tapered to 4.3 x 24.1cm
CIVCO	Non Sterile	Latex Free	Eclipse/ Polyethylene cover with gel	610-792	6.1 tapered to 4.6 x 24.1cm
CG Medical	Sterile	Latex		PR- STC080316	8 x 30cm

SEV12-3

Transducer width at tip 2.47 cm (0.97 in.), transducer maximum width at handle 4 cm (1.58 in.), cable length 2.1 m (82.7 in.)

Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
CIVCO	Sterile	Latex Free	CIV-Flex/ Flat Folded	610-006	11.9 tapered to 3.8 x 61cm

Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
CIVCO	Non-sterile	Latex Free	CIV-Flex/ Flat Folded/ No Gel	610-007	11.9 tapered to 3.8 x 61cm
CIVCO	Sterile	Latex Free	NeoGuard/ Rolled	610-844	4 x 30cm
CIVCO	Non-sterile	Latex Free	NeoGuard/ Rolled	610-838	4 x 30cm
CIVCO	Non Sterile	Latex Free	Eclipse/ Polyethylene cover with gel	610-1102	8.4 tapered to 4.3 x 24.1cm
CIVCO	Non Sterile	Latex Free	Eclipse/ Polyethylene cover with gel	610-792	6.1 tapered to 4.6 x 24.1cm

Sheaths Compatible with the Fusion/Navigation Devices

Control Panel



Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
Vygon	Sterile	Latex Free		39.00.09	100 x 90 cm

Cart and Transmitter



Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
Vygon	Sterile	Latex Free		39.00.08	100 x 120 cm

eTRAX™

12GA



Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
CIVCO	Sterile	Latex Free	CIV-Flex	610-1207-10	12GA x 7cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1209-10	12GA x 9cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1211-10	12GA x 11cm with

Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
					7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1213-10	12GA x 13cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1217-10	12GA x 17cm with 7.6 tapered to 3.8 x 147cm

14GA

Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
CIVCO	Sterile	Latex Free	CIV-Flex	610-1407-10	14GA x 7cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1409-10	14GA x 9cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1411-10	14GA x 11cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1413-10	14GA x 13cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1417-10	14GA x 17cm with 7.6 tapered to 3.8 x 147cm

16GA

Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
CIVCO	Sterile	Latex Free	CIV-Flex	610-1606-10	16GA x 6cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1608-10	16GA x 8cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1610-10	16GA x 10cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1613-10	16GA x 13cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1615-10	16GA x 15cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1057	16GA x 17cm and 7.6 tapered to 3.8 x 147cm

18GA

Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
CIVCO	Sterile	Latex Free	CIV-Flex	610-1806-10	18GA x 6cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1808-10	18GA x 8cm with 7.6

Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
					tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1810-10	18GA x 10cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1813-10	18GA x 13cm with 7.6 tapered to 3.8x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1815-10	18GA x 15cm with 7.6 tapered to 3.8 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex	610-1818-10	18GA x 18cm with 7.6 tapered to 3.8 x 147cm

VirtuTRAX™



Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
CIVCO	Sterile	Latex Free	CIV-Flex/ Telescopically folded	610-1059	10-17GA with 8.9 tapered to 1.3 x 147cm

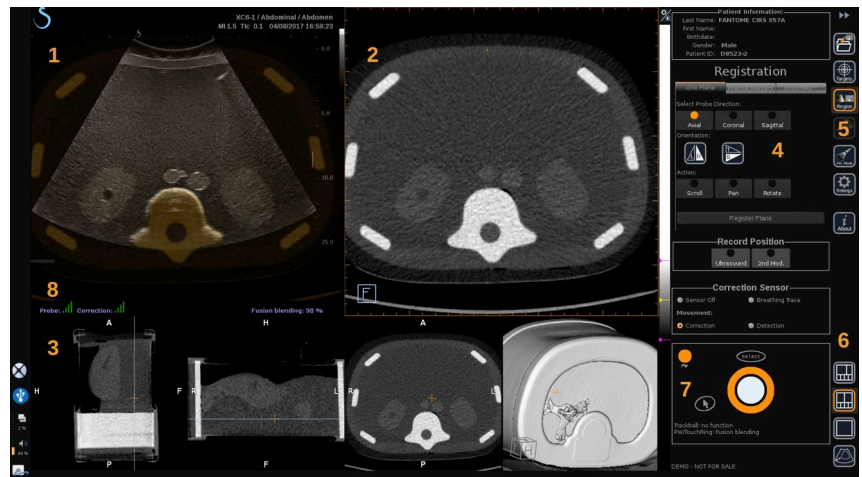
omniTRAX™ CT and MR Transparent Film



This transparent film is to be used to fix the omniTRAX™ Patient Tracker (CT and MR) on the patient so that it doesn't move between exams.

Manufacturer	Sterility	Latex/ Latex Free	Description	Product Number	Dimensions
3M	Sterile	Latex Free	Transparent Film Dressing Frame Style	1626W	10 x 12 cm

User Interface Description



1. Ultrasound image
2. 2nd modality volume
3. Thumbnails of 2nd modality views
4. Control interface
5. Menu with main modules
6. Layouts icons

Icons

In Fusion/Navigation, the following icons can be found. Please refer to the corresponding sections for more information.

About

Pressing this button displays general information about the software.



Settings

Settings allows you to configure the preferences of the navigation software.

See [Chapter 6, Settings \[97\]](#) for more details about the Settings.



Data Management

See [the section called “Data Import \(optional\)” \[72\]](#) for more details about Data Management.



Virtual Mode

See [the section called “Virtual Mode” \[68\]](#) for more details about Virtual Mode.



Targets

Allows to define targets or Risk Areas on the 2nd Modality dataset. A dedicated Target List menu is also available in the Virtual Mode to define targets on the ultrasound image.

See [the section called “Targets” \[90\]](#) for more details about Targets.



Navigation

See [the section called “Navigation” \[87\]](#) for more details about Navigation.





Registration

See [the section called “Registration” \[81\]](#) for more details about Registration.

Brightness Settings

Pressing this button allows you to load pre-defined profiles of window width and window level, depending on the modality visualized.

See [the section called “Importing 2nd Modality Data” \[72\]](#) for more details about the brightness settings.

Cropped

Cropped allows you to display part of the ultrasound image or the full Aixplorer ultrasound area.

Flip Left/Right

Pressing this button allows you to switch the selected plane from left to right or the opposite.

Flip Top/Bottom

Pressing this button allows you to switch the selected plane from top to bottom or the opposite.

Layouts

Pressing one of these buttons changes the display format of the on-screen information.

Full screen view

Click on this icon to enlarge the orange-highlighted modality (ultrasound image or second modality). Click on the modality you want to view in full screen before clicking on this icon.

Full screen view US only



Quad screen view



Live US Navigation and Fusion with Two Secondary Modalities
See [the section called “Live US Navigation and Fusion with Two Secondary Modalities” \[88\]](#) for more details about this layout.



Needle reference view

See [the section called “Needle Reference View” \[92\]](#) for more details about Needle reference view.



2/3 1/3 and 4 thumbnails



2/3 1/3



Side by side



Side by side and 4 thumbnails



6 view comparison layout between two imported modalities.

See [the section called “Comparing Two 2nd Modality Volumes” \[75\]](#) for more details about the 6 view comparison layout.



Collapse

Pressing this button allows to collapse and hide the user interface controls to maximize the image area.



Expand

When in Collapse mode, press this button to display back the user interface controls.



Matching View

Pressing this button allows to merge two modalities in one single view. You can then verify the matching between the two modalities when looking at a specific anatomical area. By moving the intersection cross you can adjust the display as needed.

See [the section called “Comparing Two 2nd Modality Volumes” \[75\]](#) for more details about Matching View.

Other Areas

Trackball and TouchRing Tooltip

This area shows you in real time the function of the **Trackball**, **TouchRing/PW** button and **Select**.

Depending on the context, you can use these buttons to modify settings. When you can use one of these buttons, it is highlighted in orange and its function is indicated. You can then change the settings by using the **Trackball** or **TouchRing**, by rotating the **PW** button or pressing **Select**.

Quality marker of the sensor signal

This area indicates in real time the sensor signal accuracy.

When close to the transmitter, the sensor signal appears green. When it moves away from the transmitter range, the sensor signal is displayed in yellow, then orange and finally red, meaning that the accuracy and quality of the tracking are not guaranteed.



TIP

Try to keep the distance between the sensor and the transmitter as close as possible to guarantee accurate results and ensure that the quality signal is green.

TissueTuner

The red TissueTuner marker appears when the TissueTuner currently used is not the same as the one used during the factory calibration. Always use the 1540 m/s TissueTuner value when in Fusion/Navigation.

Thumbnails

This area allows you to visualize in real-time the various planes of the 2nd modality.

Starting The Navigation/ Fusion Feature

Press **S-NAV** on the control panel.



The system is in Virtual Mode.



Virtual Mode

The Virtual mode allows you to display side by side the live ultrasound image with the 3D virtual probe representation in space.

Preparing an Interventional Procedure in Virtual Mode

This section describes how to prepare an interventional procedure.

Defining Ultrasound Targets

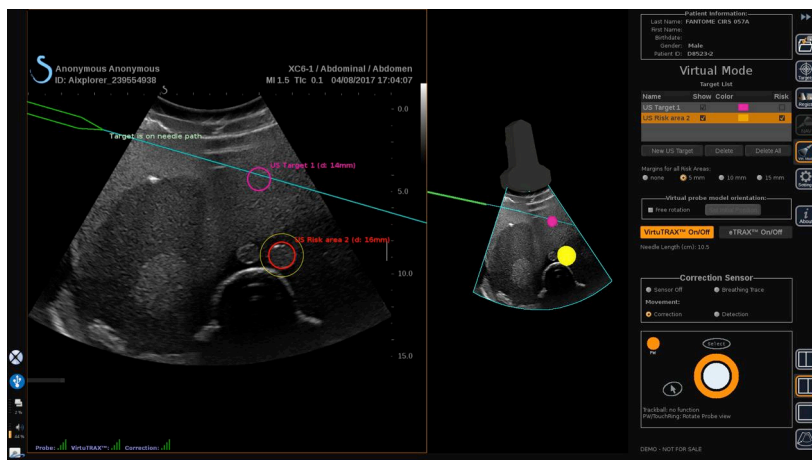
The Virtual mode allows you to define up to 7 biopsy targets or Risk Areas.

1. Click on **New US Target**

A virtual target is displayed on both sides.

2. Move the **Trackball** to position the target
3. Use the **TouchRing** or **PW** knob to resize the target (the diameter value is displayed in live)
4. Press **Select** to validate the target.

The target appears on the list.



NOTE

You may hide each target as needed.

Uncheck the "Show" checkbox to hide the target.

5. Click on the colored square on the right side to change the color of the target.
6. Check the Risk checkbox to change the target into a Risk area. You can define a security margin around this risk area from 5 mm to 15 mm.

When a risk area is defined, you will receive a warning message if the needle path crosses it.

Deleting Ultrasound Targets and Risk Areas

1. Select the target or risk area you want to delete
2. Click on **Delete**



NOTE

You may delete all targets or risk areas at once by clicking on **Delete All**.

Virtual probe model orientation

- **Free rotation** allows you to show the real orientation of the probe
- **Set initial position** allows you to set the initial position of the probe yourself
- **View from below** allows you to view the probe model from below and could be used to verify the position of either the VirtuTRAX™ or eTRAX™ devices

Selecting the Interventional Device

If they are correctly connected, click on either eTRAX™ **On/Off** or VirtuTRAX™ **On/Off** to activate one of the devices.



NOTE

There are 2 methods for the VirtuTRAX™ calibration in the Settings Menu, under Other Settings tab:

- Manual method

A popup window will appear asking you to manually enter the needle distance, which is the distance between the needle tip and the bottom part of the needle holder

- Pivot method

Do a pivot movement with the VirtuTRAX™ needle holder by putting the needle tip on a sterile and rigid plane surface.

Follow the on-screen instructions to perform the pivot calibration.

The progress bar will disappear when the calibration process is complete.

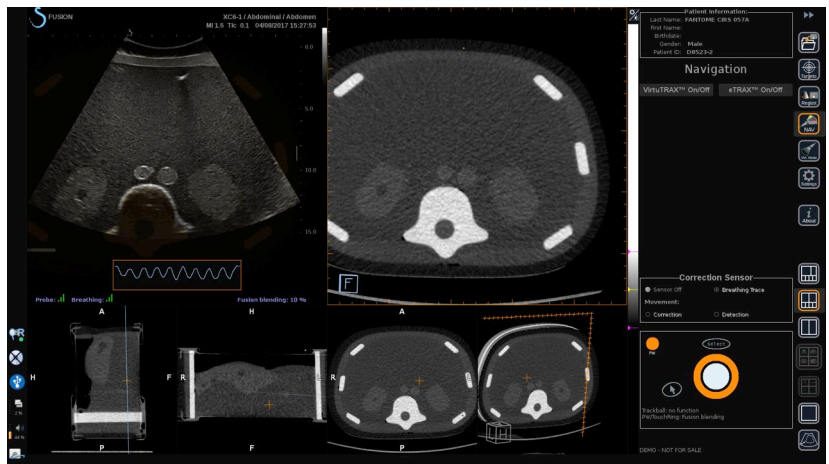
Using the Correction Sensor

The correction sensor option is intended to be used with the omniTRAX™ Patient Tracker.

You may use of the following options as needed:

- **Sensor Off** will not provide any corrections
- **Breathing Trace** will display the breathing curve of the patient after a detection period (if the omniTRAX™ is correctly connected, configured and well positioned on the patient)

It allows to monitor the patient breathing and ensure the breathing level is the same as the one used during the CT or MR acquisition.



- Movement **Correction** will automatically correct the referential as a function of patient's movement (if the omniTRAX™ is correctly connected, configured and well positioned on the patient)
- Movement **Detection** will display a pop-up message if a patient motion is detected (if the omniTRAX™ is correctly connected, configured and well positioned on the patient)

Performing the Interventional Procedure in Virtual Mode

Perform the interventional procedure with the virtual interventional procedure device, virtual path and target(s) displayed on the screen.

When the needle path is perfectly aligned with the scanning plane, the needle path is displayed as solid blue line.

When the needle path is not perfectly aligned with the scanning plane, but still parallel to it, the needle path is displayed as a solid grey line.

When the needle path is not parallel to the scanning plane, but crossing it, the needle path is displayed as a dotted blue line, with a circle showing the intersection between the needle path and the scanning plane, and the distance from the needle tip to the circle.

Data Import (optional)

Data Import

This section allows you to import 2nd modality data and to manage them.



WARNING

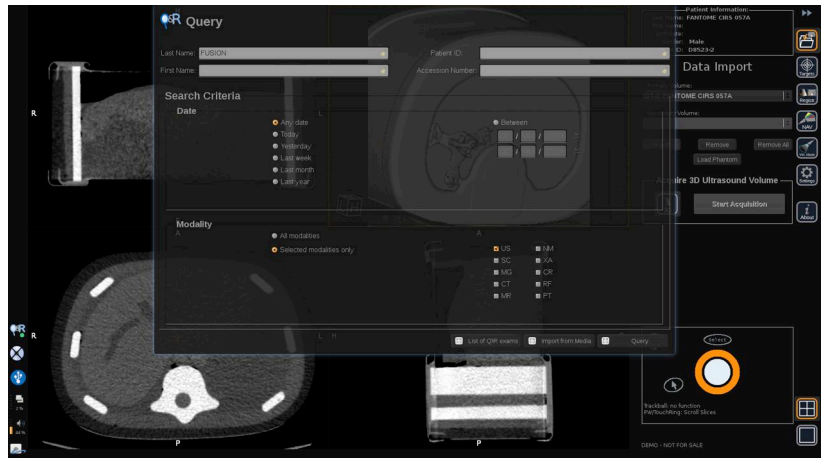
Always perform Registration after importing data.

Importing 2nd Modality Data

1. Press **Import**



The Q/R window is displayed.



2. Enter your patient information
3. Use search criteria as needed

Press **Query**.

4. Select the appropriate exam to retrieve

Press **Retrieve**

5. When Retrieved, Pushed or Imported (highlighted in green) appears, press **Send to fusion**



Alternatively, you can also press the **List of Q/R exams** to open the list of already retrieved or pushed or imported exams from a media.

To import DICOM data from a USB media or the CD/DVD, press **Import from Media**. A window will appear allowing you to import either a DICOM DIR file or a Folder containing the DICOM data to be imported.



6. Click on the black and white vertical bar to adjust the DICOM contrast and brightness



Use the **Trackball** horizontally to change the contrast, and vertically to change the brightness.

Press **Ok** when done.



NOTE

Click on the small **Settings icon** above the black and white vertical bar to select pre-defined brightness and contrast profiles for each modality.

Press **Remove** to remove a volume, or press **Remove All** to remove all the volumes.

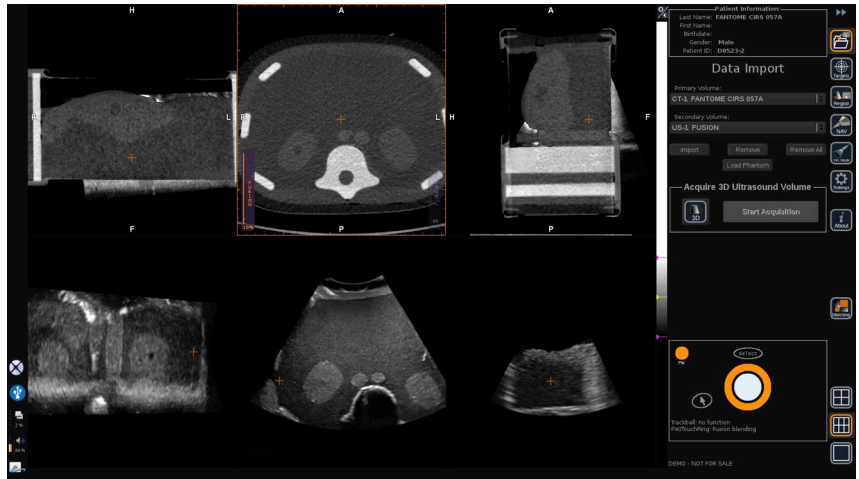
Comparing Two 2nd Modality Volumes

When at least two volumes have been imported, you can display the 2 modalities and compare them using the 6 view comparison layout icon.

The 3 MPR views of each volume will then be compared in a top/bottom display.

Select which modalities you want to compare under the primary volume and secondary volume dropdown lists.



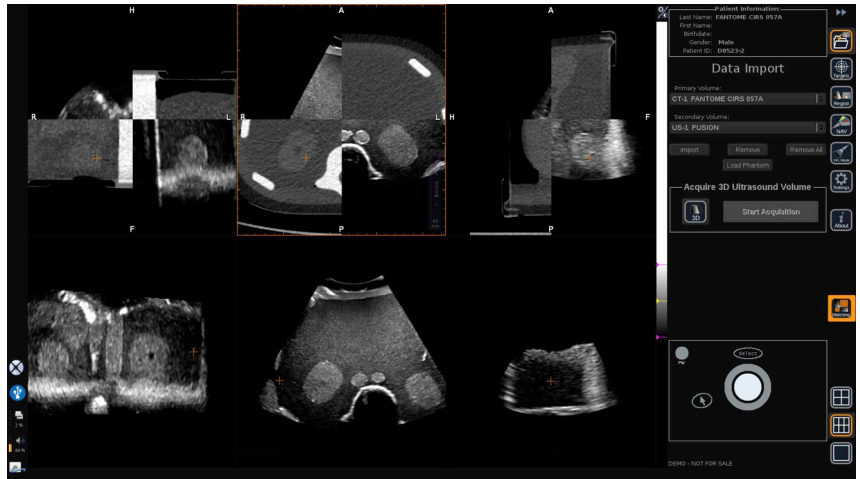


To fuse these two modalities, Select one of the 3 MPR views in the top part, and move the cursor on top of the vertical “Fusion” bar. You can then use either the **TouchRing** or **PW** to adjust the fusion blending control.



In addition, you can press the “Matching” icon to display in diagonal the 2 modalities and then use the **pointer** and **Select** button to focus on an area of interest to be displayed with the 2 modalities and see how they match.





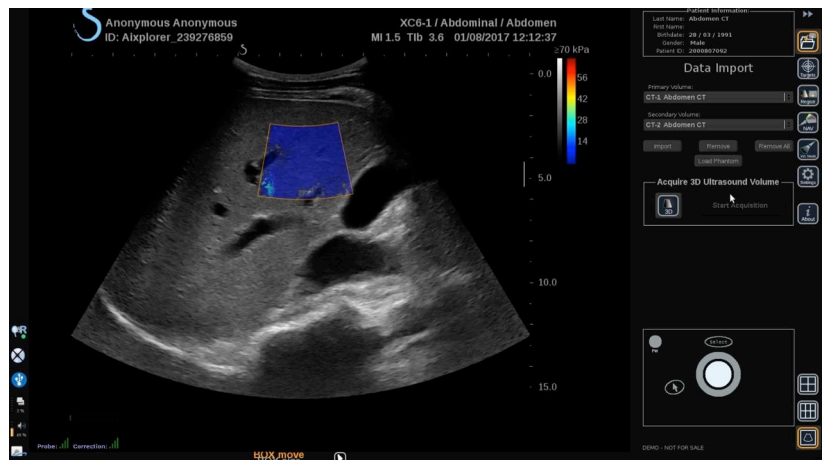
3D Acquisition

You may also acquire a 3D ultrasound volume as a 2nd modality.

This feature is available in B-mode, SWE™, CFI, CPI, dCPI, Angio PL.U.S. RT, CEUS and TriVu.



1. Click on the **3D** button

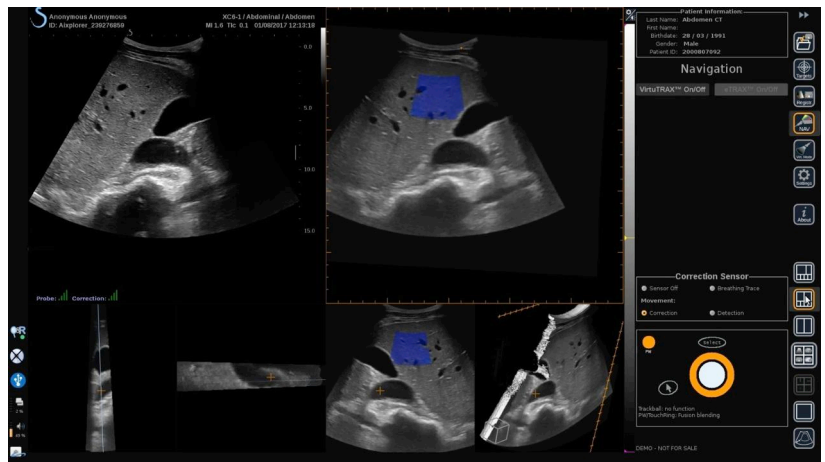


The system is in live ultrasound imaging.

2. Put the probe on the first plane of the volume you want to acquire
3. Click on **Start acquisition**



4. Sweep the probe to the last plane of the volume you want to acquire
5. Click on **Stop acquisition** or wait until the progress bar is complete



6. Once done, the system automatically switches to the Navigation mode with the 3D ultrasound acquisition on the right



NOTE

Please note that the 3D volume rendering is always displayed in black and white.

3D Motorized Acquisition Using the SEV12-3

When using the 3D endocavity Probe SEV12-3, you have an additional capability to use the motorized 3D acquisition. This feature is only available in B-mode.

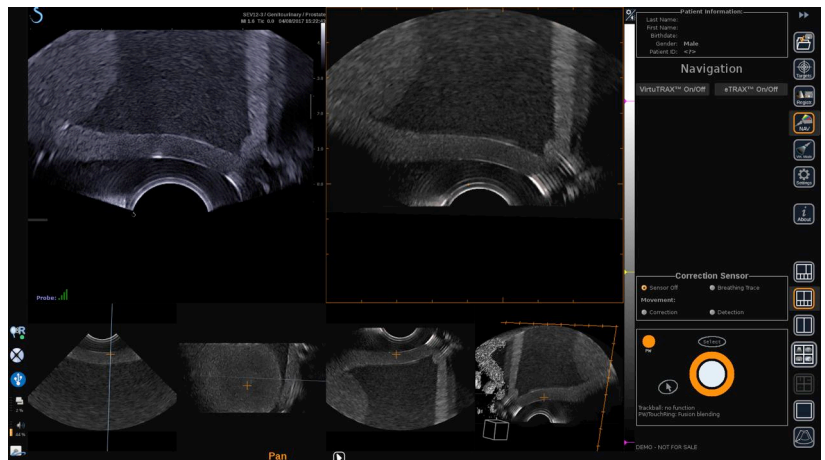
1. You can launch a 3D acquisition using the “3D Acquisition” button on the Touch screen.



2. This can be done either from the Data Import menu or from the Virtual Mode menu when SEV12-3 is used.



3. Unfreeze the image after the acquisition is completed and processed, in order to navigate within the 3D US volume acquired.



WARNING

When using the 3D endo probe SEV12-3, the transmitter needs to be placed behind the probe handle to maximize the sensor detection.

After a registration, the tilting of the transducer needs to be limited in order to minimize registration accuracy errors.



Registration

This menu allows you to synchronize the live ultrasound image with the 3D volume from the 2nd modality.



WARNING

Make sure to use the same patient data imported from other modalities.



WARNING

After performing one of the following registration methods, please make sure to redo the registration procedure if the transmitter has moved after the first registration has been done. Redo it especially if the omniTRAX™ patient tracker has not been used and the movement correction is not activated.

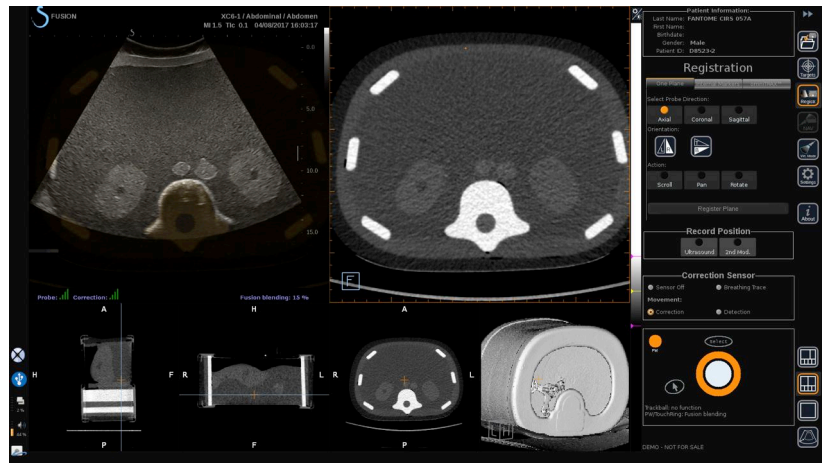
The registered slice of the 3D volume from the 2nd modality appears on the right side of the screen.

The live ultrasound image appears on the left side of the screen.

One Plane Registration

1. Click on the One Plane tab of the Registration module and select the plane of interest in the 2nd modality 3D volume:
 - Use the thumbnails at the bottom of the screen to select the appropriate MPR view to be used
 - Click on **Scroll** then use the **TouchRing** or **PW** to navigate through the 3D volume
2. Scan the patient with the ultrasound probe in order to find the same plane of interest

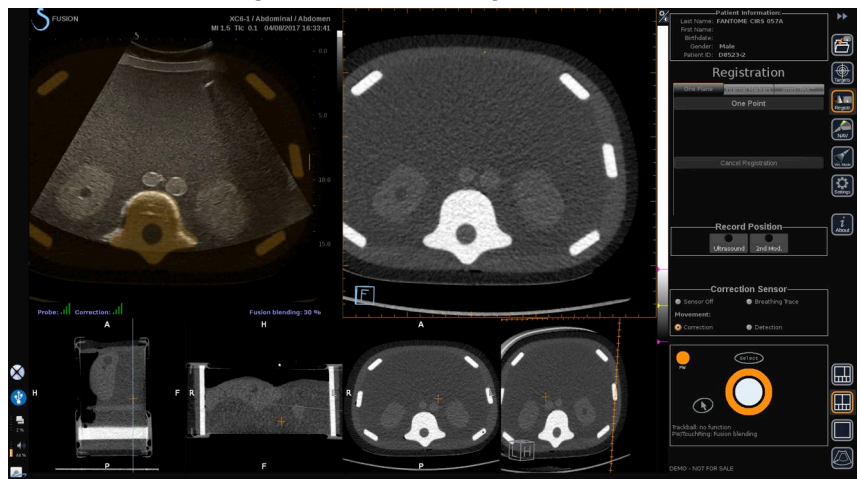
Use **Scroll**, **Pan** and **Rotate** as needed to better align the 2nd modality slice with the live ultrasound image.



3. When the same plane is displayed on both sides, click on **Register Plane**

When the registration has been performed, the transmitter will track the probe movement as well as the patient movement through the omniTRAX™ patient tracker if it has been used.

The system will display the ultrasound live image and the registered slice from the 2nd modality in a side-by-side manner including overlapping between the two images (Fusion Blending control).



Use the **TouchRing** or **PW** knob to change the priority on the overlapped images between live ultrasound and the registered slice of the 3D volume from the 2nd modality.

Fine Registration - With One Point

1. Click on **One Point** to better match the live ultrasound with the 2nd modality 3D volume.
2. Find an anatomical point on the live ultrasound (left side)
3. Click on **Ultrasound** under Record Position to freeze the ultrasound image
4. Click on the anatomical point to be registered on the ultrasound image
5. Move the probe to find the 2nd modality slice with the same anatomical point
6. Click on **2nd Modality** under Record Position to freeze the image
7. Click on the anatomical point to be registered on the 2nd modality

The live Ultrasound image is now perfectly synchronized with the 2nd Modality on a specific anatomical point.

When you want to register more than one internal marker, go to the Internal Markers Registration section.

Use the **TouchRing** or **PW** to change the priority between the ultrasound image and the 2nd modality (Fusion blending control).



WARNING

After registration and particularly before using the system for the current session, it is mandatory to check the system registration accuracy by performing a side-by-side comparison of the ultrasound live image and the registered 2nd modality image using the TouchRing or PW Overlap controls, to determine how well the two images match.

If the ultrasound live image and the corresponding 2nd modality image appear to be poorly registered, repeat the registration procedure.

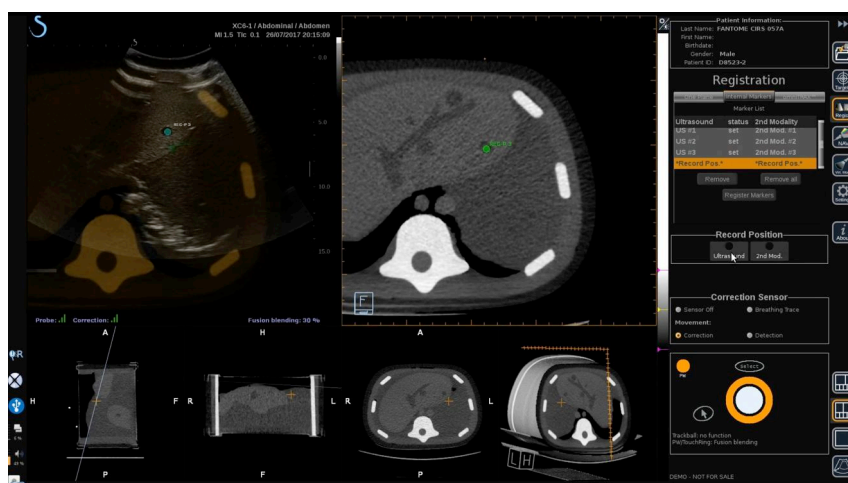
Internal Markers Registration

When you want to register more than one additional internal marker, Click on the **Internal Markers** tab to manage the additional points.

1. Find an anatomical point on the live ultrasound (left side)
2. Click on **Ultrasound** under Record Position to freeze the ultrasound image
3. Click on the anatomical point to be registered on the ultrasound image
4. Move the probe to find the 2nd modality slice with the same anatomical point
5. Click on **2nd Modality** under Record Position to freeze the image.
6. Click on the anatomical point to be registered on the 2nd Modality (Right side)
7. Repeat this procedure from step 1 on at least 3 different anatomical points
8. Click on **Register Markers**

The live Ultrasound image is now perfectly synchronized with the 2nd Modality based on the specific anatomical points recorded.

Use the **TouchRing** or **PW** to change the priority between the ultrasound image and the 2nd modality (Fusion blending control).





NOTE

Perform a One Plane registration before making an internal markers registration.

OmniTRAX™ Registration

This is the easiest method to automatically register the 2nd Modality, with the use of an omniTRAX™ patient tracker, CT or MR, see omniTRAX™ and omniTRAX™ MR sections for details.

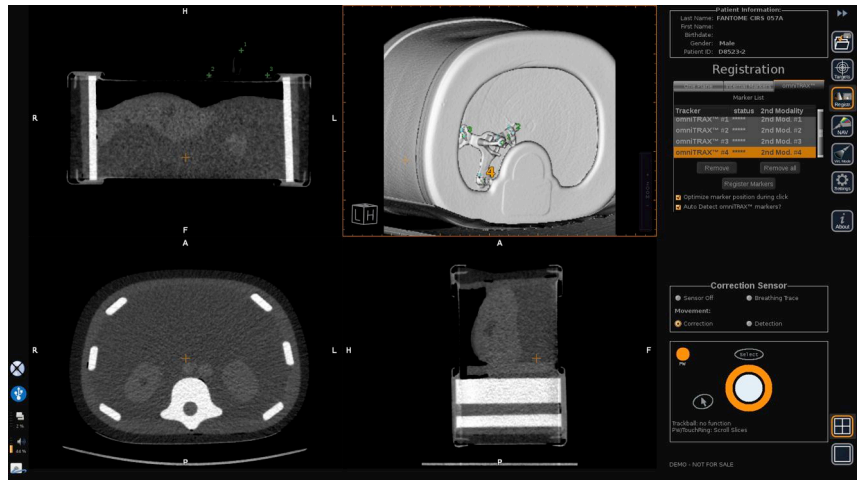
1. Click on the omniTRAX™ tab
2. Click on one of the four points of the omniTRAX™ markers seen on the 3D view (make sure the auto detection of the omniTRAX™ markers is enabled)
3. The 3 other points will be automatically detected and selected.

If the auto detection fails, you can select the markers manually, either on the 3D view or on one of the 3 MPR views, which can be scrolled using the **TouchRing** or **PW**.

The Settings option **Optimize marker position during click** allows you to ease the manual markers selection workflow.

4. Click on **Register Markers**

The 2 modalities are now registered.



NOTE

The patient tracker has to be placed on the patient before the CT or MR acquisition.

Make sure the correct omniTRAX™ model is used for the associated CT or MR acquisition.

If you do not use the omniTRAX™ auto detection, you can manually select the 4 omniTRAX™ markers on the 3D volume.

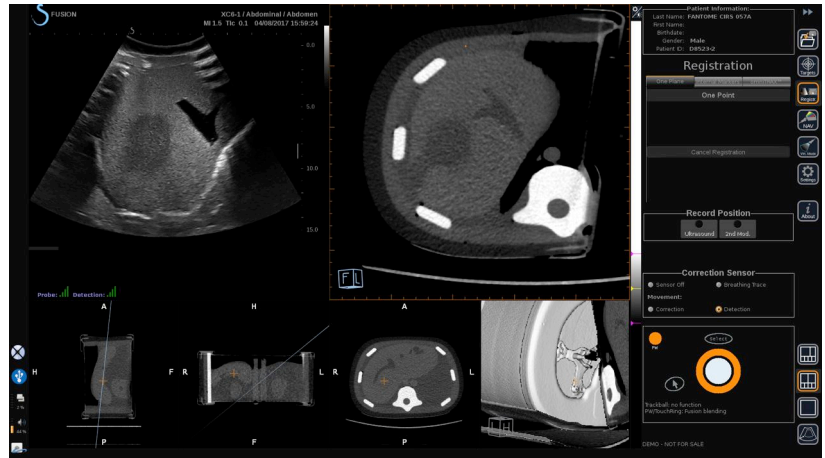
You can start by clicking on the marker located at the top of the omniTRAX.

Fine registration with One Point

You can improve the omniTRAX™ registration in order to compensate the differences of patient anatomical conditions and positions between the CT or MR exam and the ultrasound exam.

1. Click on the **One Plane registration** tab
2. Click on **One Point** to better match the live ultrasound with the 2nd modality 3D volume.

3. Find an anatomical point on the live ultrasound image (left side)
4. Click on **Ultrasound** under Record Position to freeze the ultrasound image
5. Click on the anatomical point to be registered on the ultrasound image



6. Move the probe to find the 2nd modality slice with the same anatomical point
7. Click on 2nd Modality under Record Position to freeze the image
8. Click on the anatomical point on the 2nd modality image

The live ultrasound image is now perfectly synchronized with the 2nd Modality on a specific anatomical point.

Navigation

The Navigation Mode is the main application of Fusion/Navigation: providing additional real-time image information from a 2nd modality side by side to the live ultrasound screen. Additionally, the virtually computed 2nd modality image might be overlapped on the current ultrasound situation.

Once the Registration is correctly performed, click on the **NAV** icon on the right side of the screen.

Use the **TouchRing** or **PW** to change the priority between the ultrasound image and the 2nd modality.





NOTE

Refer to the icon section for a description of the layout icons.

To get the focus on specific Aixplorer® Ultimate modes controls management and arbitration (such as color box size and position), place the **pointer** on top of the US image and press **Select**. To come back in the Navigation/Fusion UI controls environment, press **Pointer** again.

Click on VirtuTRAX™ **On/Off** or eTRAX™ **On/Off** as needed (see a precise description in section VirtualMode).



WARNING

During navigation, please check frequently the system registration accuracy by performing a side-by-side comparison of the ultrasound live image vs the registered 2nd modality image using the **PW** or **TouchRing** Overlap controls to determine how well the two images match.

Please repeat the registration procedure if the ultrasound live image and the corresponding 2nd modality image appear to be poorly registered.

Live US Navigation and Fusion with Two Secondary Modalities

After having successfully registered two different imported volume modalities with the live Ultrasound image (CT and MR for instance) or an imported volume modality and a 3D US acquisition, you can click on the Navigation icon. At that time clicking on this layout icon allows you to navigate between the live ultrasound and the two other modalities using a quad view layout.

The upper left image view corresponds to the live US mode.

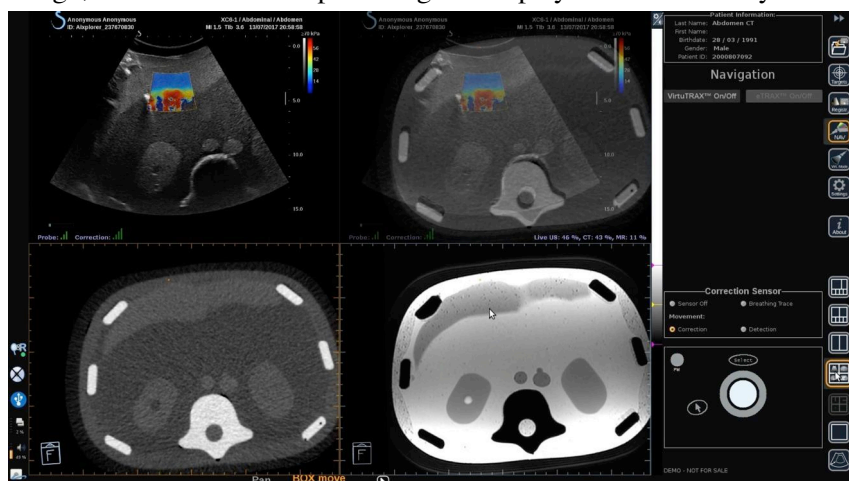


The bottom left image view corresponds to a cutting plane of the first modality selected as the "Primary Volume" within the Data Import Module.

The bottom right image view corresponds to a cutting plane of the second modality selected as the "Secondary Volume" within the Data Import Module.

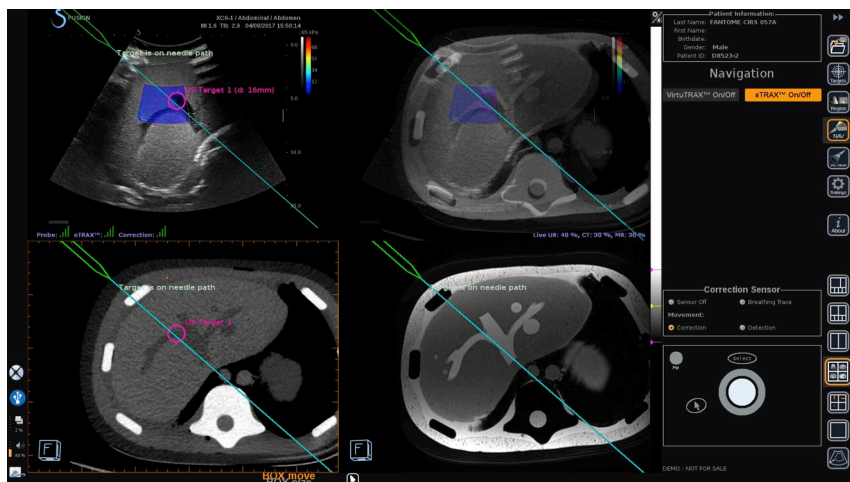
The upper right image view corresponds to a live Fusion of the 3 active modalities: Live US and the two other modalities.

Press the **Pointer** and place it on top of the main modality image you want to overlap over the two others, and use the **PW/TouchRing** as needed to adjust the overlapping. This will be reflected on the upper right image, with an associated percentage of display of each modality.



To get the focus on specific Aixplorer® Ultimate mode controls management and arbitration (such as color box size and position), place the **Pointer** on top of the US image and press **Select**. To come back in the Navigation/Fusion UI controls environment, press **Pointer** again.

Click on VirtuTRAX™ **On/Off** or eTRAX™ **On/Off** as needed (see [the section called "Virtual Mode" \[68\]](#) for a precise description)



WARNING

During navigation, please check frequently the system registration accuracy by performing a side-by-side comparison of the ultrasound live image vs the registered 2nd modality image using the **PW** or **TouchRing** Overlap controls to determine how well the two images match.

Please repeat the registration procedure if the ultrasound live image and one of the corresponding 2nd modality images appear to be poorly registered.

Targets

This section describes how to define targets for the 2nd modality only. 2 types of targets may be defined (see [the section called “Defining Ultrasound Targets” \[68\]](#))

- Interventional procedure targets
- Risk Areas

The Target mode allows you to define up to 7 biopsy targets or Risk Areas on the 2nd Modality.

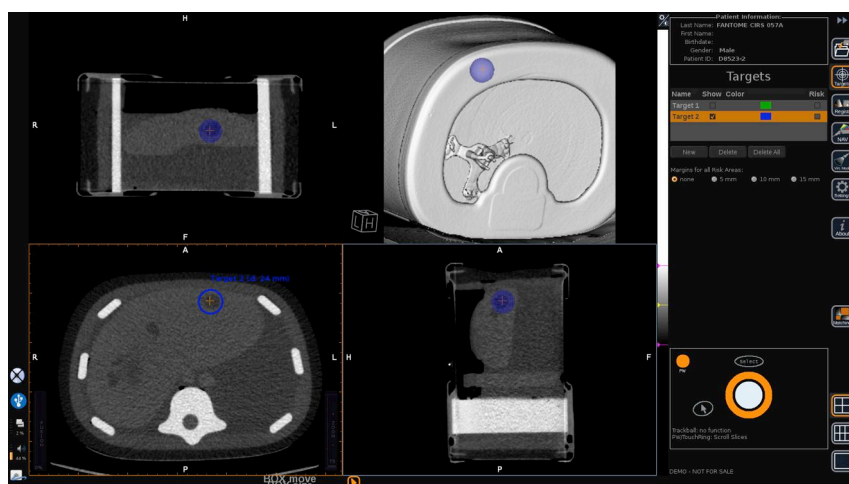


Click on the Targets icon, the 2nd modality is now displayed in 4 views layout: 3 MPR views and 3D view.

1. Select one of the 3 MPR views on which you want to add a target (to be highlighted in orange)

You may need to scroll within the MPR using the TouchRing/PW to find the area of interest

2. Click on **New**, a target is displayed on the 4 views.
3. Move the **Trackball** to position the target
4. Use the **TouchRing** or **PW** knob to resize the target (the diameter value is displayed in live)
5. Press **Select** to validate the target.
The target appears on the list.



NOTE

You may hide each target as needed. Uncheck the “Show” checkbox to hide the target.

Click on the colored square on the right menu to change the color of the target.

Check the Risk checkbox to change the target into a Risk area.

You can define a security margin around this risk area from 5 mm to 15 mm.

When a risk area is defined, you will receive a warning message if the needle path crosses it.

Deleting 2nd Modality Targets and Risk Areas

1. Select the target or risk area you want to delete
2. Click on **Delete**



NOTE

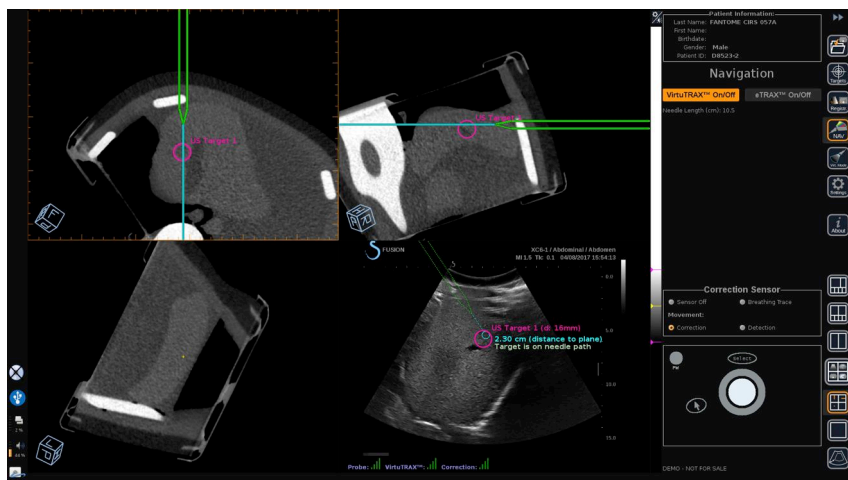
You may delete all targets or risk areas at once by clicking on **Delete All**.

Needle Reference View

This layout allows you, while in Navigation with a 2nd Modality, and with VirtuTRAX™ or eTRAX™ enabled, to display the needle as a fixed reference within the 3 MPR views of the 2nd Modality.

At that time, moving the needle or the treatment device will lead to a movement of the 3 MPR views, to better center the target on the 3 MPR views and better guide the needle into it. The live Ultrasound is also displayed in the bottom right view.





Saving Images and Clips

The Navigation/Fusion allows you to save images or prospective clips from any module or layout using the **Save Image** button or **Save Clip** button.

Only prospective clips are authorized, not retrospective clips.

The clip duration is defined in the Prospective Clip Save Time option settings from the main System Configuration menu of Aixplorer® Ultimate, which is managed by Ultrasound mode.



NOTE

Navigation/Fusion images or clips cannot be reviewed in Full screen from the Review mode, they can only be displayed in Review Image List as thumbnails.

All Navigation/Fusion images or clips can be exported in DICOM format through the Network or through USB media, or in JPEG and AVI files on USB media.

Accuracy

2nd Modality Image Display

The system accuracy concerning the matching between the ultrasound image and the 2nd modality image depends highly on the registration process and the condition of the patient compared to the situation when the 2nd modality (i.e. the CT scan) has been acquired. This also includes the breathing of the patient. Thus, please be aware that the current patient breath state should be comparable to the one during the 2nd modality acquisition.



WARNING

Minimize patient motion or use omniTRAX.

However, from the technical point of view an "overlapping" accuracy of at least 5mm can be achieved under the presumption that the registration has been done with an overall error better than 5mm.

Length Measurement

In the ultrasound image: 5% error, or better.

In the 2nd modality image: 5%-10%, or better. Please note that this value depends on the quality of the 2nd modality dataset.

6 Settings

This chapter describes how to configure the Fusion/Navigation feature.



Press the **Settings** icon in the icon menu bar on the right side of the screen to access the configuration menu.

The Settings menu is divided into 2 tabs:

- System Accuracy
- Other Settings



System Accuracy

The system accuracy tab (see picture above) allows you to configure the sensor port assignments.

It is divided in 3 sub-tabs:

- Needle Calibration Test
- Sensor Port Assignment
- Sensor Positions

Needle Calibration Test

Needle Calibration Test allows you to verify the calibration of the eTRAX™ and VirtuTRAX™ devices. The values obtained have to be as close as possible to 0. If it is not the case, redo the calibration and make sure that the device is within the electro-magnetic field and that there is no magnetic objects close to either the transmitter or the sensor of the device.



CAUTION

If after redoing the calibration the values are not close to 0, one of the devices may be damaged: if the transmitter is defective, please contact your SuperSonic Imagine representative, and if either the eTRAX™ or VirtuTRAX™ is defective, please contact CIVCO or the reseller.

To perform the Needle Calibration Test, please follow the instructions given on the screen in the 'Needle Calibration Test' menu.

Sensor Port Assignment

Sensor Port Assignment allows you to change the assignments of the sensor devices to the driveBAY ports.

Sensor Positions

Sensor Positions displays the position of the sensors (on the XYZ axes) according to the transmitter, as well as the quality (Q) of the tracking (the lower the values are, the better the quality is).



WARNING

Always press the 'Reset Tracker' button after re-assigning the devices.

Other Settings

The other settings tab is divided into 2 sub-tabs:

- Multiframe dataset options
- Miscellaneous



Multiframe dataset options

This option allows you to configure the way external data are imported: either by Acquisition Tag or Series Number. This option is available for each modality (CT, MR and PET).

Miscellaneous

This sub-tab allows you to define the criteria based on which the imported data and the US exam will be compared.

The criteria are the following:

- Patient Name
- Patient ID
- Date of Birth

If there is a mismatch, a pop-up will be displayed.

You can uncheck all the criteria if you don't want the modalities to be compared when external data is imported.

Miscellaneous also allows you to change the direction to which you should turn the PW/TouchRing to increase the fusion blending between the US and the 2nd modality:

- Clockwise
- Counter clockwise

Finally, you can change the calibration procedure of the VirtuTRAX:

- Manual - you must enter the length of the needle manually
- Pivot - you must keep the needle in a fixed position and do a pivot movement

7 System Care & Maintenance

Cleaning and Disinfecting the eTRAX™

1. After each use, remove needle sensor from needle, discarding single-use, disposable components. Remove visible contaminants from needle sensor surface.
2. Clean and disinfect all surfaces with common germicidal or antiseptic such as Sani-cloth® HB, CIDEX OPA® (Johnson & Johnson), ENZOL® (Johnson & Johnson), T-Spray™, Protex™ or alcohol.
3. Follow manufacturer's directions for all cleaning and disinfection.

Cleaning and Disinfecting the General Purpose Sensor for the omniTRAX™ CT and MR and VirtuTRAX™

This section explains how to clean, disinfect and sterilize the general purpose sensor used for the VirtuTRAX and omniTRAX devices. The other accessories used for these devices are single-use, and therefore disposable.



WARNING

Users of this product have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.

The recommended protocol for reprocessing the general purpose sensor has been evaluated for effectiveness and compatibility. If choosing to use a reprocessing protocol other than those listed, a validation must first be completed to ensure effectiveness and compatibility.

Do not gas sterilize or autoclave general purpose sensor.

Inspect general purpose sensor for damage such as cracks or breakage. If damage is evident, discontinue use of general purpose sensor and contact CIVCO.

Cleaning the General Purpose Sensor

1. After each use remove general purpose sensor, discarding single-use disposable components. Remove visible contaminants from general purpose sensor surface.
2. Soak general purpose sensor for minimum of 5 minutes in neutral pH, low foaming enzymatic detergent, such as ENZOL® Enzymatic Detergent (Johnson & Johnson). If visible contaminants cannot be easily removed, repeat soaking procedure for an additional five minutes. Remove general purpose sensor from cleaning solution and remove any remaining residue with dry wipe. Follow cleaning solution manufacturer's direction for use and recommendations for concentration.

Disinfecting and Sterilizing the General Purpose Sensor

- High-level disinfect general purpose sensor using CIDEX OPA® ortho-Phthaldehyde Solution (Johnson & Johnson) or equivalent .55% ortho-phthaldehyde-based solution. Follow manufacturer's instructions and recommendations for concentration, time of contact and post-process procedure.
- High-level disinfect or sterilize general purpose sensor using CIDEX® Activated Dialdehyde Solution (Johnson & Johnson) or equivalent 3.4% glutaraldehyde-based solution, or a hydrogen peroxide-base solution. Follow manufacturer's instructions and recommendations for concentration, time of contact and post-process procedure.

Cleaning, Disinfecting and Sterilizing the Bracket

Cleaning the Bracket

Reusable devices must be thoroughly cleaned before they are subjected to the sterilization or high-level disinfection. Brushes should be used to thoroughly clean all surfaces. Use enzymatic cleaners for removing proteins from reusable devices.

Remember, you cannot achieve sterilization or high-level disinfection unless the assembly is cleaned first.

When cleaning and sterilizing reusable devices, be sure to:

- Thoroughly clean all surfaces of reusable components with a brush while rinsing to loosen and remove materials.
- Thoroughly examine all surfaces, visually inspect the ENTIRE device is clean and no visible things remain.
- Flush with the high-level disinfectant to ensure that the disinfectant reaches all areas.
- Always use sterile water for rinsing or removing residual germicides from devices. Do not rinse reprocessed devices with tap water, which may recontaminate the device.
- Thoroughly dry the device after rinsing.
- Always use a probe cover to minimize any contaminants during the bracket usage.
- After sterilization or high-level disinfection, appropriately package and store the device to ensure that sterility is not compromised prior to reuse.

High-level Disinfecting and Sterilizing the Bracket

After cleaning by using the above recommendations, soak for a minimum of 5minutes in a neutral pH Enzol Enzymatic detergent such as made by Johnson & Johnson©.

High-level disinfect or sterilize with Cidex Activated Dialdehyde solution such as made by Johnson & Johnson®, or high-level disinfect with Cidex OPA, or ANSI/AAMI current standards, or any equivalent validated sterilization or high-level disinfection method adopted by the sterilization department for like devices.

Please refer to accompanying document of each Disinfectant or Sterilizing Agent to confirm appropriate usage and effect-efficacy.

Cleaning and Disinfecting the driveBAY

Periodically, clean the equipment (electronics unit, transmitter, sensor and cables) by wiping down with a cloth dampened in a cleaning solution such as mild soap and water, isopropyl alcohol or a similar acceptable cleaning solution. If the tracker's components come in contact with biological fluid or tissue, be sure to follow your organization's procedures for proper cleaning and disinfection.

The electronic units, transmitter and sensor are not designed to withstand autoclaving and gamma radiation. Sensors are ETO compatible. Do not submerge the electronic unit, transmitter, sensor or cables in liquids. Components are not waterproof.

8 Troubleshooting

If you encounter difficulty in the operation of the Fusion feature, use the information in this section to help correct the problem.

If the problem is not covered here, contact your Customer Support Representative.

See [the section called “driveBAY” \[22\]](#) for more details about LED status.

The troubleshooting table below contains a list of symptoms and the action to take to correct the problem.

Symptom	Possible Causes	Solution
No front panel LED illumination	No power	<ul style="list-style-type: none"> - Check AC connections to power supply - Reset hardware by cycling AC power
Front panel LED blinking red/yellow	No valid transmitter attached	<ul style="list-style-type: none"> - Attach transmitter - Reset transmitter connector
Demo Utility doesn't run	No serial communication	<ul style="list-style-type: none"> - Check the suggestions outlined in 'Not able to communicate' below
Power-up defaults did not change after configuring with the utility	Configuration download interrupted driveBAY did not reset (restart) after burning the Flash settings	<ul style="list-style-type: none"> - Re-start the driveBAY and the utility and set the defaults again. Be sure to click APPLY to send the setting to the Electronics - Cycle power to the driveBAY, and re-check the settings
Not able to communicate with the system using USB	Re-initialize USB	<ul style="list-style-type: none"> - MDSP failed to respond to messages - Cycle power on the driveBAY
Can communicate with the system, but data not changing	Sensor is saturated Transmitter is OFF and disconnected Component connections faulty	<ul style="list-style-type: none"> - Check the error codes for a sensor a saturation condition. Move the sensor farther away from the transmitter. - Check status of the transmitter. Turn on using SELECT_TRANSMITTER parameter (3D Guidance API)

Symptom	Possible Causes	Solution
		<ul style="list-style-type: none"> - Check that sensor/transmitter connectors are correctly installed. Inspect pins for wear or damage. - Contact technical support for assistance
Data is too noisy	<ul style="list-style-type: none"> Filters OFF Low signal External noise in environment Changing hemisphere Line frequency value set incorrectly 	<ul style="list-style-type: none"> - Check FILTER STATUS - Decrease distance from sensor to transmitter Be sure that the sensor is not located near the tracker's power supply or other electronic devices or cables. If the signs of the X, Y or Z position outputs suddenly change, you may have crossed a hemisphere boundary. Use the HEMISPHERE command to rectify Determine correct frequency (50 Hz in Europe, 60 Hz in North America) and set to correct value
Poor accuracy	<ul style="list-style-type: none"> Metal in tracking environment Damaged equipment Sensor or transmitter connector not properly inserted A software application error Board error 	<ul style="list-style-type: none"> Check all around the transmitter to the furthest distance from the centre of the transmitter to the maximum distance the sensor is used. Move or replace metal, or reposition the driveBAY system Check for damage Correctly by unplugging and plugging the components back into the board Verify formulas and scale factors Board error



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