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ADVANCED OPERATIONS

VIRTUAL NAVIGATOR OPTION

350022800

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Chapter 1

1. Introduction

Virtual Navigator Intended Use

Virtual Navigator[1] is a **MyLab** software option that is intended to support a radiological clinical ultrasound examination (first modality) and follow percutaneous procedures or surgical operations providing additional image information from a second imaging modality. As second imaging modality it is intended any image coming from CT, MR, US, PET, XA and NM.

The second modality provides additional security in assessing the morphology of the real time ultrasound image.

Virtual Navigator can be used in the following applications: Abdominal, Gynecological, Musculoskeletal, Obstetrics, Pediatric, Urologic, Small Organs, Intraoperative (Abdominal), Intraoperative (Neurological), Peripheral Vascular and Transcranial for radiological examinations only.

The second modality image is not intended to be used as a stand-alone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall, therefore, always be seen as an additional source of information.

WARNING

The Virtual Navigator tracking system is contraindicated for patients, operators, personnel and other people who use an electronic life support device (such as a cardiac pacemaker or defibrillator).

Virtual Navigator can be used with **MyLab** systems equipped with the following probes.

Table 1-1: Virtual Navigator probe list

Probe	Type
C 1-8	Convex Array
E 3-12	Convex Array
EC123	Convex Array

1. Virtual Navigator is based on NaviSuite software developed by MedCom GmbH (www.medcom-online.de)

Probe	Type
L 3-11	Linear Array
L 4-15	Linear Array
L 8-24	Linear Array
mC 3-11	Convex Array
P 1-5	Phased Array
SI2C41	Convex Array
TLC 3-13	Linear / Convex Array

WARNING

Do not base a diagnosis or any percutaneous procedure (such as biopsy, ablation treatments, etc.) on the results of Virtual Navigator only. In particular, the displayed image of the second modality shall never be used as a stand-alone diagnostic image.

ALL DIAGNOSTIC EVALUATIONS NOT FOLLOWING THIS WARNING SHALL FALL UNDER THE OPERATOR RESPONSIBILITY.

Virtual Navigator Main Features

Virtual Navigator improves the localization of pathologic targets using the spatial relationship between two diagnostic modalities (real time ultrasound + CT, real time ultrasound + MR, real time ultrasound + others).

The goal is to enhance the images produced by an Ultrasound Scanner by combining them with a second modality (like CT or MR). The system consists of an ultrasound real time scanner equipped with an electromagnetic tracking device enabling the image fusion based on the geometry data and the content of the second modality dataset.

The major benefit of medical ultrasound scanning lies in the real time characteristics of the image, in the ease of use, as compared to a CT/MRI scanner, and in the low costs per image. However, ultrasound images have a limited field of view and their quality can be affected by the physical and physiological conditions of the patient. Other methodologies, like computed tomography (CT) and magnetic resonance (MR) offer a wider field of view,

are rather patient-independent and often easier to interpret, but are inherently static in their presentation.

There is therefore an intrinsic difficulty in relating a target that has been identified in a CT or MR image to the corresponding ultrasound image that only encompasses a limited portion of the anatomy. The possibility of combining the ultrasound exam with a reference modality and to fuse this dataset with the ultrasound scan improves the understanding of the current scan situation, particularly in difficult cases. The result is a faster procedure and an increase in reliability. Also mini-invasive echo guided treatments can be performed in conditions otherwise almost impossible. The Virtual Navigator is a system that allows the real time visualization of the ultrasound scan side by side with the corresponding virtual slices obtained from other modalities.

Virtual Navigator option displays on the monitor both the real time ultrasound and the second modality image in the same dimension and cut plane. Virtual Navigator drives an electromagnetic tracking system in order to uniquely identify the ultrasound probe scan.

Functioning Principles

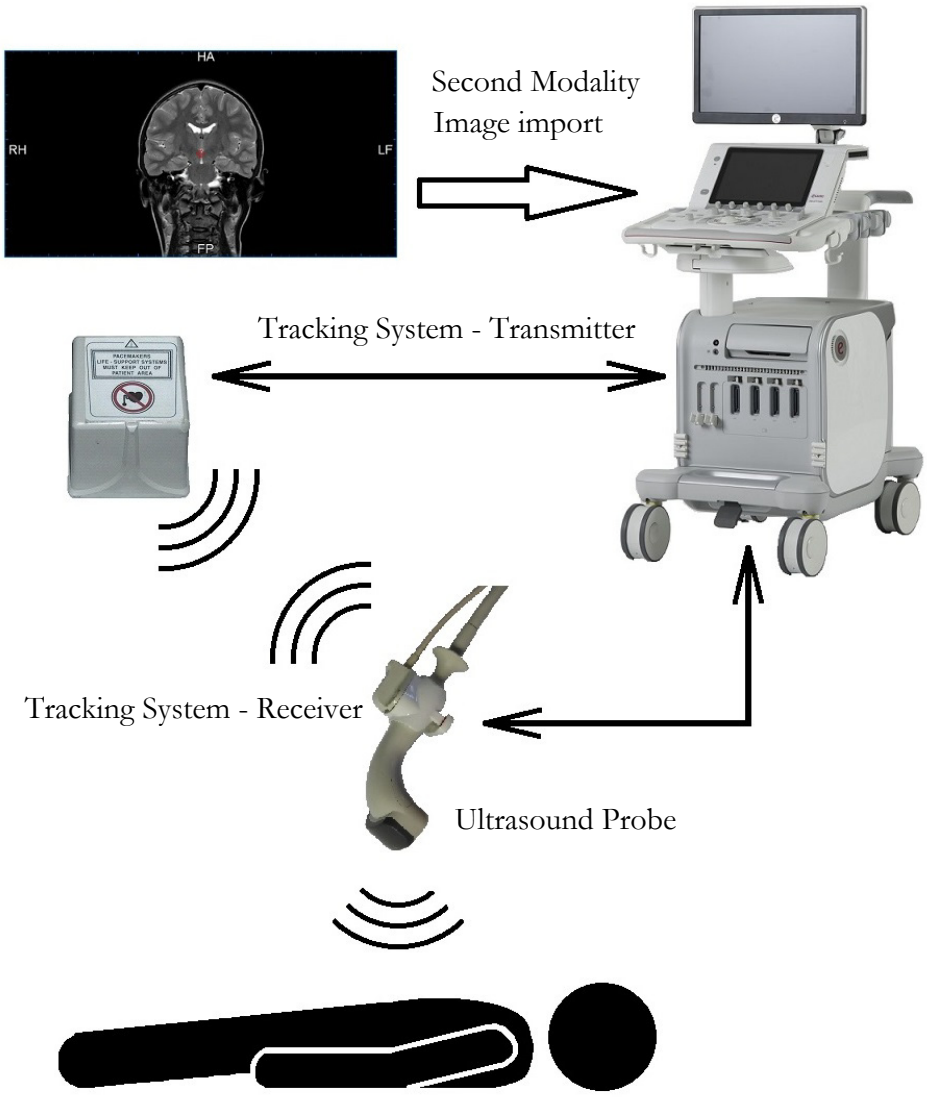
A tracking device is mounted on the transducer, which provides the position and orientation in space during a standard ultrasound scanning of the patient. The information from the tracking device and the 3D dataset of the second modality (typically a CT/MRI scan) is combined to compute a virtual slice image that is spatially consistent with the displayed real time ultrasound image.

Please refer to next chapters for further details.

Before the system is able to compute the second modality image correctly, it is necessary to perform an “alignment” procedure.

After the alignment, Virtual Navigator displays the second modality image on the side of the current real time ultrasound image, or overlaps the second modality image directly on the real time ultrasound information (fusion imaging).

Fig. 1-1: Virtual Navigator tracking system



WARNINGS

When loading 3D DICOM dataset from the second modality, please be aware that Virtual Navigator is not able to handle non equidistant (slice thickness must be constant for all slices) acquisition as well as 3D datasets that have been acquired while a gantry tilt was applied. Verify the anatomy and the morphology of the reconstructed 3D dataset before starting the exam.

When loading a study, a dataset, a volume or images, please be aware that your selection matches the patient. If you load historical data, the user is

responsible for confirming the appropriateness and accuracy of those images.

The registration, explained in detail in the next chapters, is a critical procedure for the correct use of Virtual Navigator: strictly follow the given instructions for the registration.

When the display of the biopsy line is enabled on the Ultrasound device, the Virtual Navigator displays a corresponding virtual biopsy line in the second modality image. This line is intended to be used as an additional orientation tool, but must not be used without considering the real time ultrasound biopsy line display.

Software Description

Please contact Esaote personnel for further details.

Virtual Navigator is available in different software configurations.

Licence	Features
Fusion Imaging 3D	Provides the basic functions to start with the navigation procedure including US to US fusion. (previously named Navisuite Basic)
Virtual Navigator	Provides complete alignment features including Marker Alignment and Marker Tuning, auto registration, 3D Target markers and the display of the biopsy line. Fusion Imaging 3D license required. (previously named Navisuite Advanced)
Virtual Biopsy	Includes Virtual Biopsy and Intelligent Positioning. (previously named IP & Virtual Biopsy)
Needle Tracking	Includes Needle Tracking and Procedures. Virtual Biopsy or Virtual Navigator license required
Fusion Imaging 2D - Body Map	Body Map, Realtime 2D Navigation. (previously named Body Map)

Chapter 2

2. Tracking System

The Tracking System provides tracking capabilities of the probe spatial position during the ultrasound scanning.

The Tracking System consists of:

- a Drive Bay,
- an Electromagnetic Transmitter,
- up to four Receivers:
  - Probe Receiver to track the probe spatial position during the ultrasound scanning. This receiver must be installed on the probe or on the Registration Pen for the Registration procedure.
  - Needle Receiver (both VTRAX and ETRAX) to track the needle spatial position.
  - Breathing Receiver to track the patient movement.

WARNING

The tracking system defines position and orientation by transmitting magnetic fields. The magnetic field is stronger at the transmitter and attenuates with distance from the transmitter. The magnetic field is lower than the Earth's magnetic field at 28cm (11 inches) from the transmitter. Before starting the exam, and during the exam, make sure that the proper operation of any life-supporting equipment (intended to actively keep alive or resuscitate patients) is not impaired by the transmitted magnetic field. Adjust the distance from the transmitter according to the susceptibility characteristics of the devices.

WARNING

Objects made of steel or iron may affect the accuracy of the tracking device. Do not place any object made of steel or iron between the tracking transmitter and the receiver.

WARNING

Other electrical and magnetic devices may share the immediate space with the tracking device. In many situations, electrical and magnetic devices near the system may influence tracking data.

Always verify the functionality of the Virtual Navigator option before each exam, following the System Accuracy test procedure described in this manual.

If in doubt, please contact Esaote personnel.

WARNING

Do not immerse the receiver/transmitter in liquids since it is not waterproof. Avoid contact of the sensor with the ultrasound gel on patient skin.

Virtual Navigator it is contraindicated for patients, operators, personnel and other people who use an electronic life support device (such as a cardiac pacemaker or defibrillator).

WARNING

Do not track instruments in an untested application environment, because an untested environment may contain elements that affect field generator functions. For example, electromagnetic field disturbances from other objects in the room and the proximity of metal and other field generators can adversely affect the system. Failure to test for such disturbances increases the possibility of inaccurate information and possible personal injury.

Drive Bay connections

Drive Bay is located on the back of MyLab and provides plugs for Electromagnetic Transmitter and Receivers.

Fig. 2-1: Drive Bay

Receivers must be connected in the correct sensor plug identified by a number ad a color as described in the table below.

Table 2-1: Drive Bar Sensors Connections

Number	Sensor	Color
1	Probe Receiver	Blue
2	VTRAX Receiver	Green
3	ETRAX Receiver	Orange
4	Motion Sensor	Yellow

Transmitter Positioning

Virtual Navigator offers a wide range of Transmitter supports also compatible with the most common surgery bed fixation systems. Supports are made in nonmagnetic material and easy cleanable.

During use, the Transmitter must be placed on its appropriate support with the transmitting face (opposite to the face in which the cable enters) oriented in the direction of the Receiver in order to maximize the electromagnetic field.

Fig. 2-2: Electromagnetic Transmitter

WARNING

Place the transmitter in the pegs present on the upper part of the removable part and secure it using the straps.

Completely insert the removable part inside the pillow, assuring that it is not possible to accidentally move it.

Use the straps to secure the pillow to the bed, ensuring that it cannot fall off.

Verify that the blocking system pivot of the height adjustment is properly inserted inside one of the available holes in the plastic part.

Do not lean against the transmitter support, it could cause disruption to the procedure and the recording.

Ensure that the fixing straps of the tracker support are properly locked. No tilting of the plane under the patient must be present.

Probe Receiver

The receiver installation is a two-step procedure. The first step consists in assembling the receiver, the second step in installing the receiver on the probe. The second step procedure is different depending on the probe type. A description of the different procedures is given below.

Assembling the Receiver

The receiver is composed of a sensor and a plastic support to be fixed on the probe.

Fig. 2-3: Disassembled Receiver

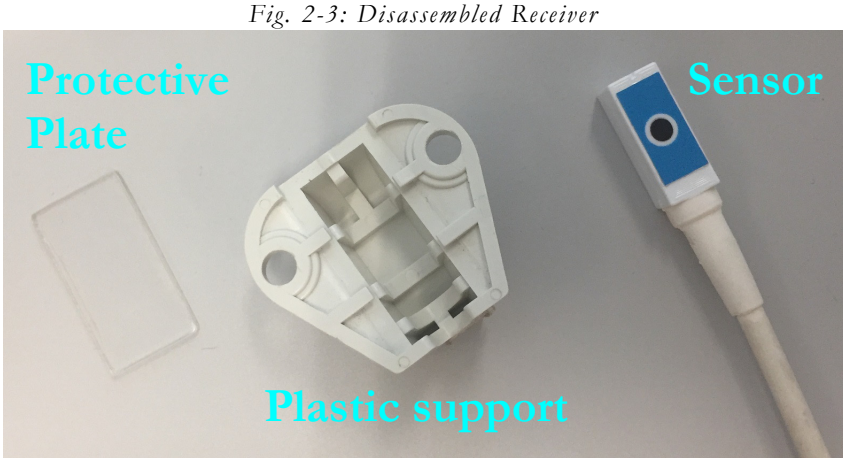
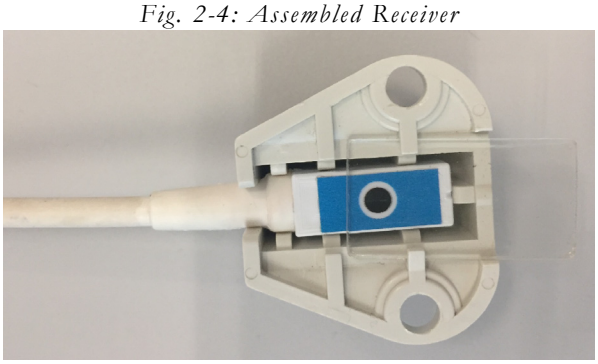


Fig. 2-4: Assembled Receiver



NOTE ***The receiver is already assembled and ready to use. The disassembly can be performed for cleaning purposes.***

Procedure

1. Insert the sensor in the cavity of the plastic support with the adhesive colored band towards the operator.
2. Slide the protective transparent plastic plate in the plastic support to close the sensor inside the support.

Installing the Receiver on C 1-8 Probe

The installation requires a special kit to be applied on the body of the probe. This kit enables the attachment of the receiver.

Fig. 2-5: C 1-8 probe and related kit

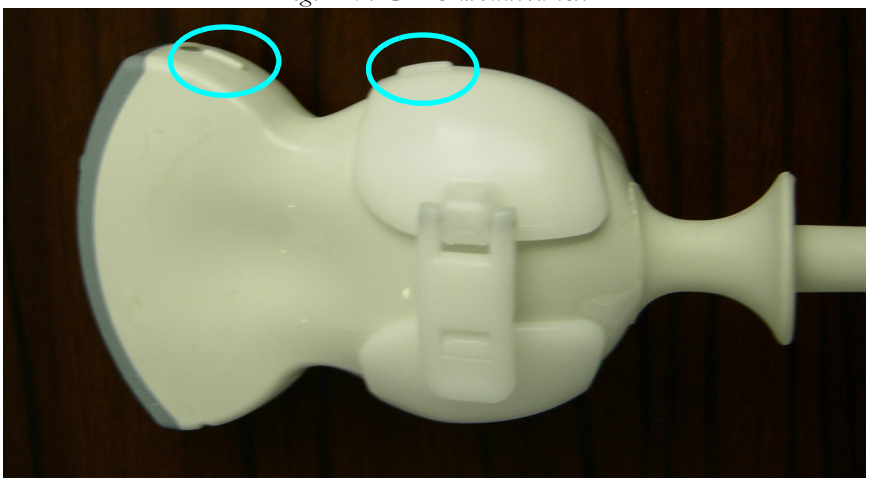
Procedure

1. Insert the probe in the kit as shown in the image below, then rotate the kit until it stops on the probe.

Fig. 2-6: C 1-8 mounting detail

2. Fix the kit using the suitable fastener. The plastic markers on the probe handle and on the kit must be on the same side after the probe holder has been applied.

Fig. 2-7: C 1-8 mounted kit

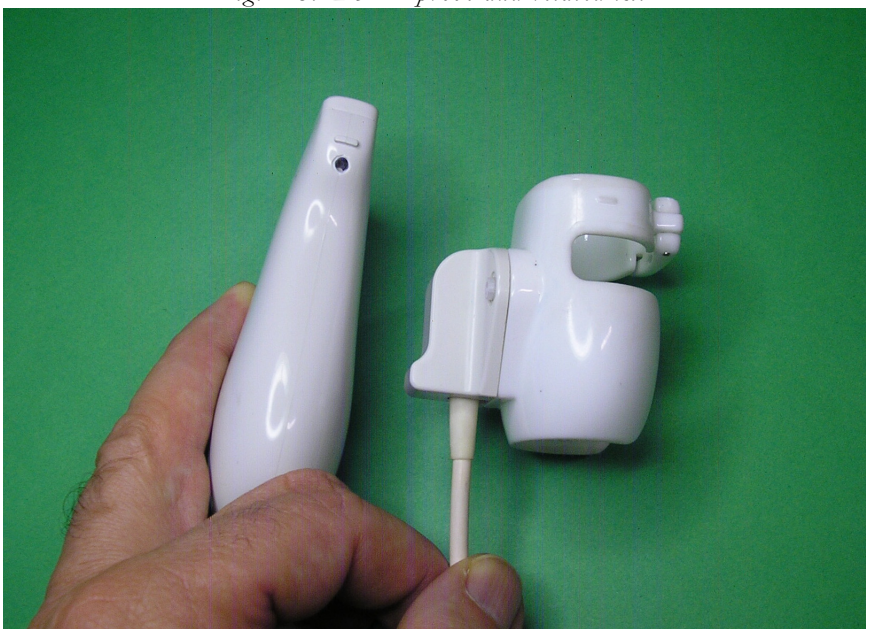


3. Fix the receiver to the kit pins on the opposite side of the fastener.

Installing the 3D Support on L 3-11 Probe

The installation procedure requires a special kit to be applied on the body of the probe. This kit enables the attachment of the receiver.

Fig. 2-8: L 3-11 probe and related kit



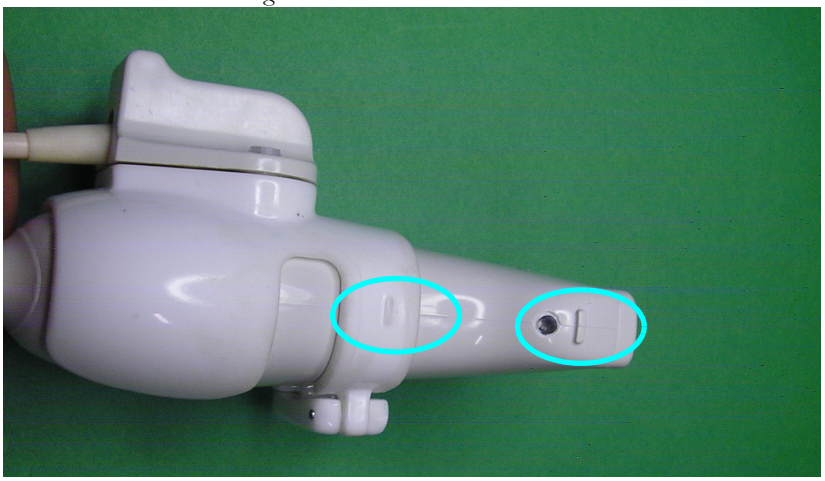
Procedure

1. Insert the probe on the kit as shown in the image below.

Fig. 2-9: L 3-11 mounting detail

2. Fix the kit using the suitable fastener. The plastic markers on the probe and on the kit must be on the same side after the probe holder has been applied.

Fig. 2-10: L 3-11 mounted kit



3. If necessary, protect the ensemble with a cover.

Fig. 2-11: L 3-11 mounted with cover

Installing the Receiver on L 4-15 and L 8-24 Probes

The installation procedure requires a special kit to be applied on the body of the probe. This kit enables the attachment of the receiver.

Fig. 2-12: L 4-15 probe and related kit

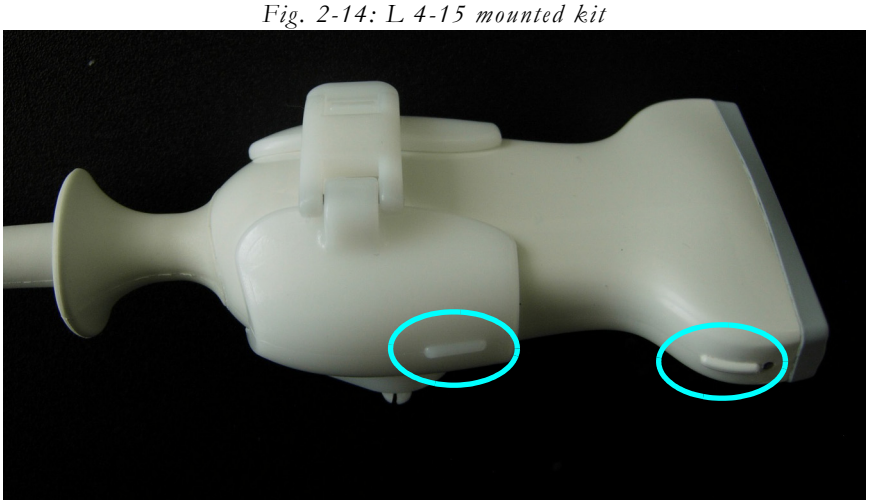
Procedure

1. Insert the probe on the kit as shown in the image below, then rotate the kit until it stops on the probe.

Fig. 2-13: L 4-15 mounting detail

2. Fix the kit using the suitable fastener. The plastic markers on the probe handle and on the kit must be on the same side after the probe holder has been applied.

Fig. 2-14: L 4-15 mounted kit



3. Fix the receiver to the kit pins on the opposite side of the fastener.

Installing the Receiver on P 1-5 Probe

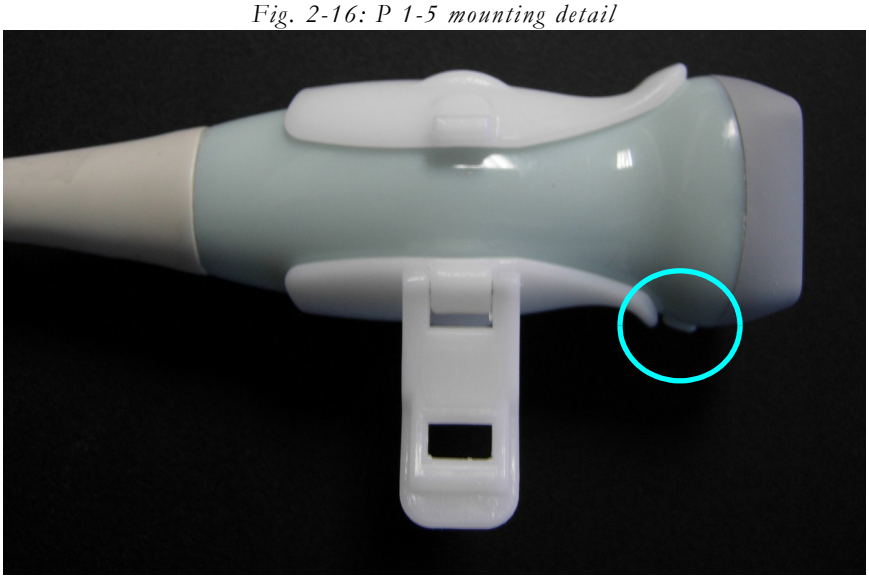
The installation requires a special kit to be applied on the body of the probe. This kit enables the attachment of the receiver.

Fig. 2-15: P 1-5 probe and related kit

Procedure

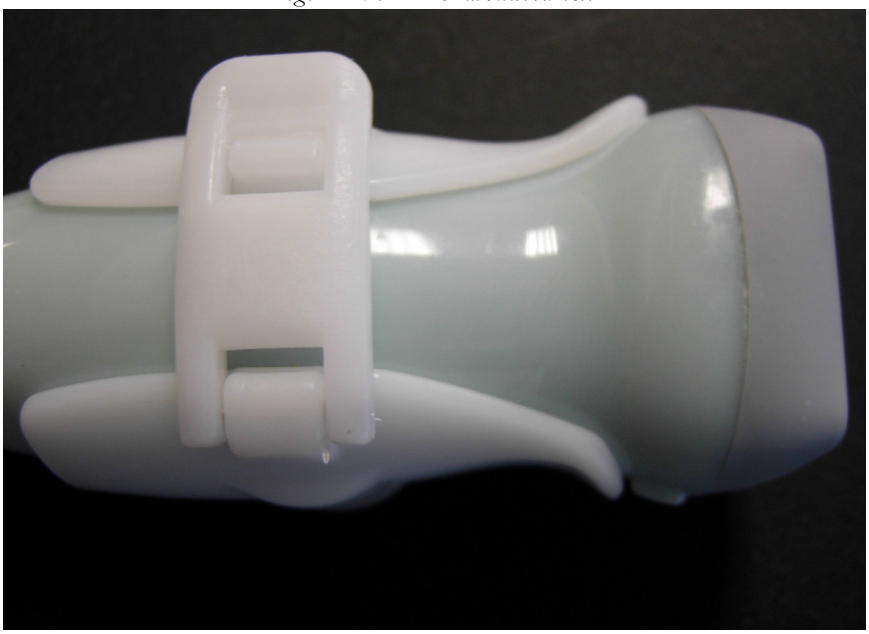
1. Insert the probe in the kit as shown in the image below, paying attention to the position of the shorter wing, which must be on the same side of the plastic markers of the probe handle.

Fig. 2-16: P 1-5 mounting detail



2. Fix the kit using the suitable fastener.

Fig. 2-17: P 1-5 mounted kit



3. Fix the receiver to the kit pins on the opposite side of the fastener.

Installing the Receiver on E 3-12 and EC123 Probes

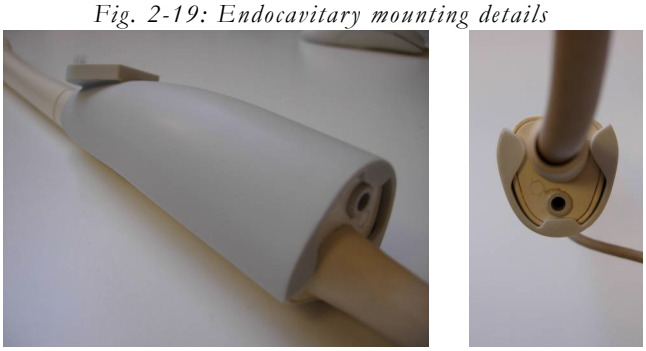
The installation requires a special kit to be applied on the body of the probe. This kit enables the attachment of the receiver.

Fig. 2-18: Endocavitary probe and related kit

Procedure

1. The kit must be fixed as shown in the following pictures by pressing the probe into the cavity of the kit until it is firmly fixed by the suitable fasteners.

Fig. 2-19: Endocavitary mounting details



2. The receiver must be fixed to the kit as shown in the picture.

Fig. 2-20: Endocavitary mounted kit

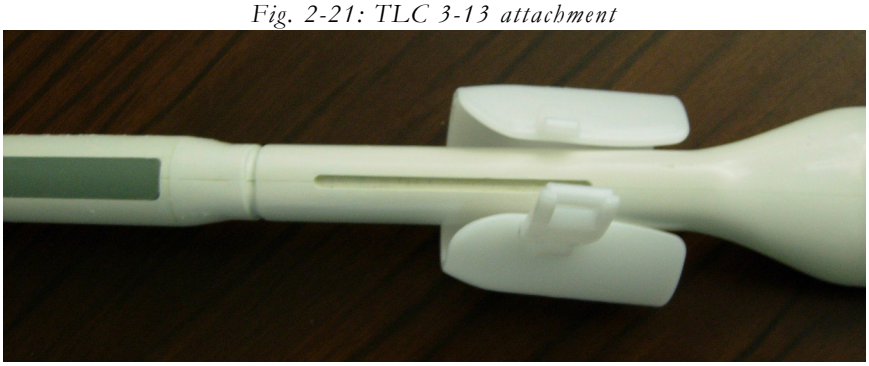
Installing the Receiver on TLC 3-13 Probe

The installation requires a special kit to be applied on the body of the probe. This kit enables the attachment of the receiver.

Procedure

1. The kit must be fixed on the handle of the probe as shown in the following pictures by sliding the probe into the kit until it is firmly fixed.

Fig. 2-21: TLC 3-13 attachment



2. Fix the kit using the suitable fastener as shown in the picture.

Fig. 2-22: TLC 3-13 linear closed

3. Fix the receiver to the kit pins on the opposite side of the fastener.

Installing the Receiver on SI2C41 Probe

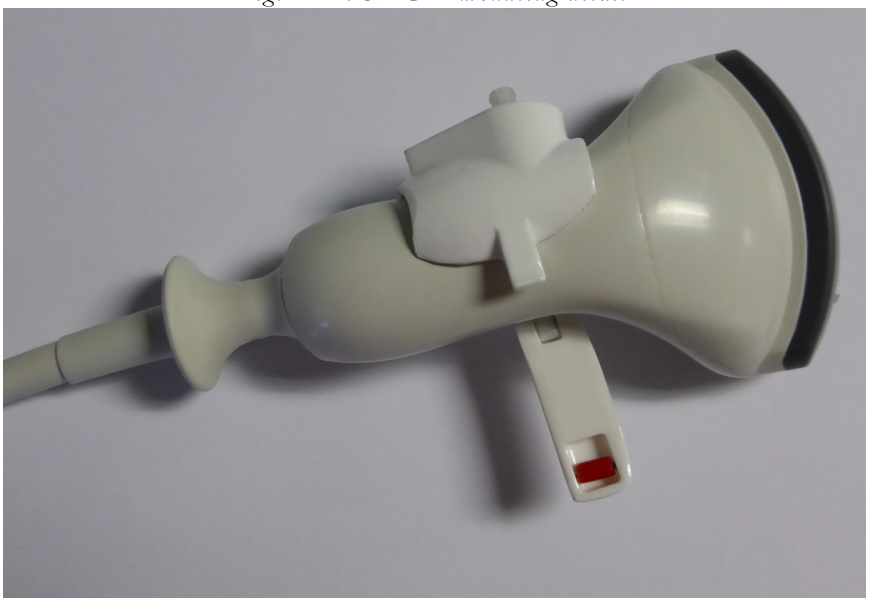
The installation requires a kit that must be applied on the body of the probe. The kit provides a place where the receiver can be attached.

Fig. 2-23: SI2C41 probe and related kit

Procedure

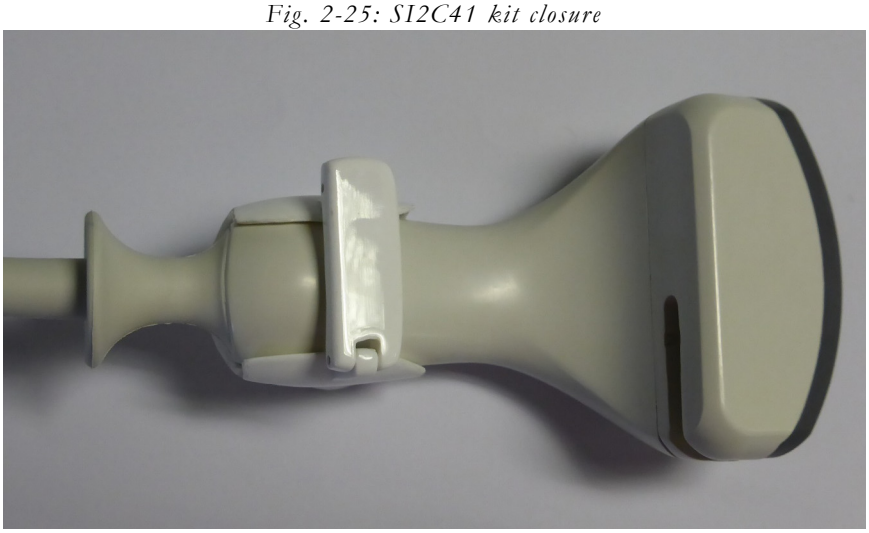
1. Insert the probe in the kit as shown in the image below, then rotate the kit until it stops on the probe.

Fig. 2-24: SI2C41 mounting detail



2. Fix the kit using the suitable fastener.

Fig. 2-25: SI2C41 kit closure

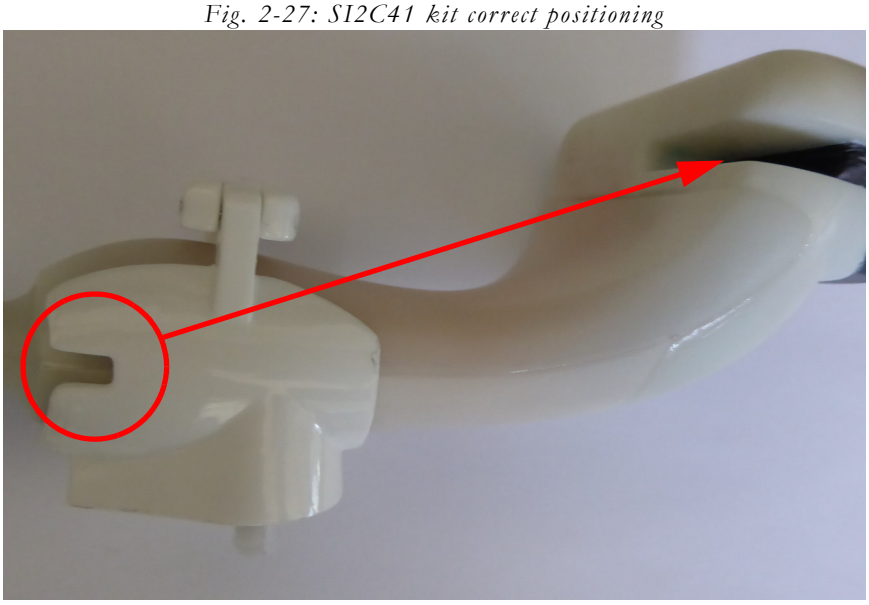


3. Fix the receiver to the kit pins on the opposite side of the fastener.

Fig. 2-26: SI2C41 mounted kit

4. Verify the cut side of the probe is on the same side of the cut part of the support.

Fig. 2-27: SI2C41 kit correct positioning



Installing the Receiver on mC 3-11 Probe

The installation requires a special kit to be applied on the body of the probe. This kit enables the attachment of the receiver.

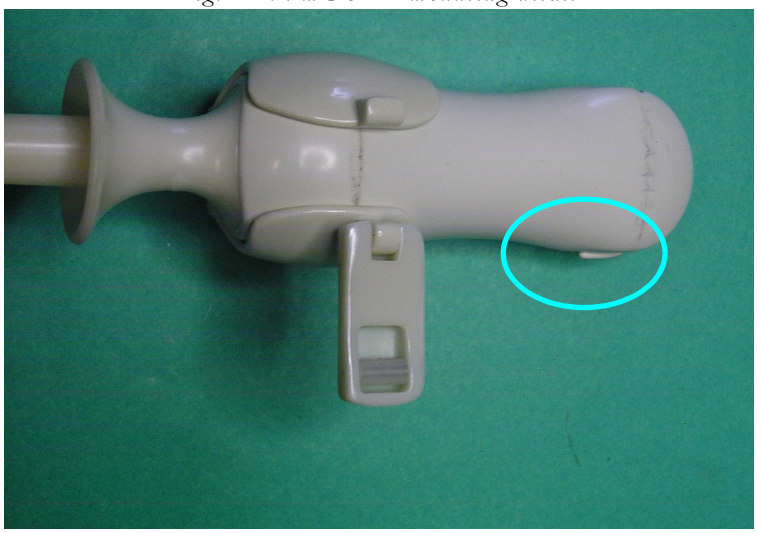
Fig. 2-28: mC 3-11 probe and related kit

Procedure

1. Insert the probe in the kit exactly as shown in the image below, paying attention to the position of the plastic marker

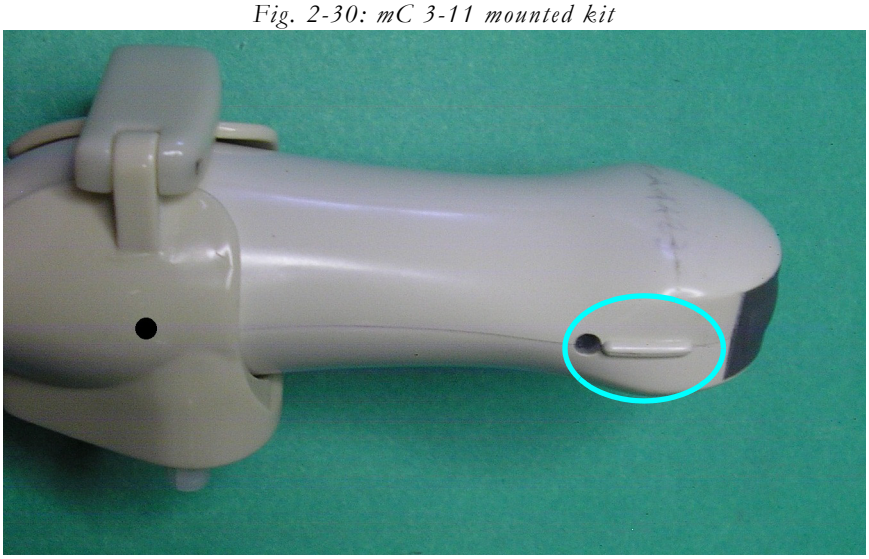
of the probe handle which must be on the same side of the opened fastener.

Fig. 2-29: mC 3-11 mounting detail



2. Fix the kit using the suitable fastener. The black dot on the kit must be on the same side of the plastic marker on the probe.

Fig. 2-30: mC 3-11 mounted kit

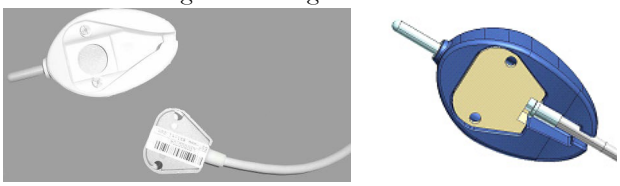


3. Fix the receiver to the kit pins on the opposite side of the fastener.

Tracking with the Registration Pen

The Registration Pen allows to register the skin markers. It is designed to host the electromagnetic receiver.

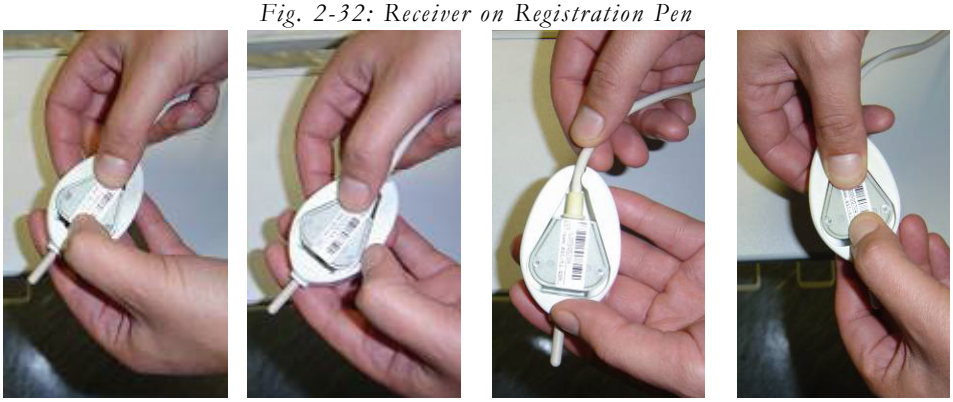
Fig. 2-31: Registration Pen



Installing the Receiver on the Registration Pen

The receiver must be attached as shown in the following pictures. Be sure to press the receiver into the cavity of the Registration Pen until it is firmly fixed by the suitable fasteners.

Fig. 2-32: Receiver on Registration Pen

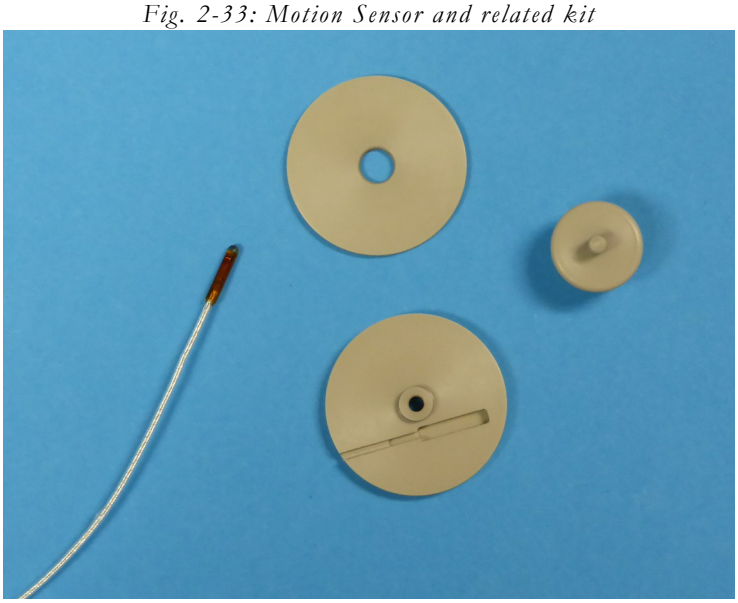


NOTE ***Always verify receiver registration pen functionality before starting a new procedure using the dedicated tool.***

Motion Sensor

The Motion Sensor is an additional sensor for patient movement tracing. The sensor can be lodged into a dedicate holder composed by a sandwich of two reusable plastic discs.

Fig. 2-33: Motion Sensor and related kit

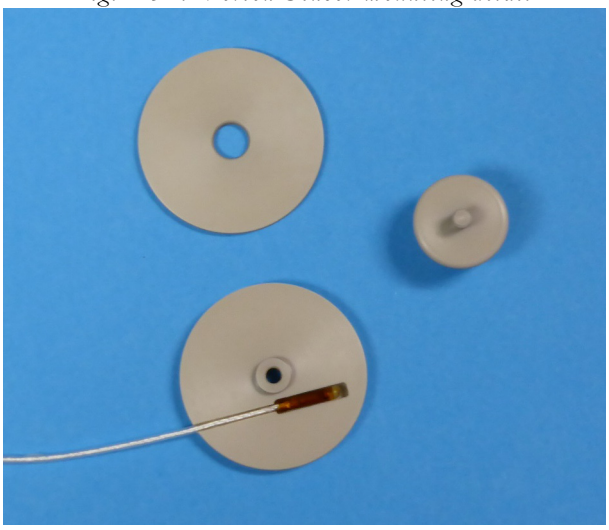


Assembly the motion sensor into the holder

Procedure

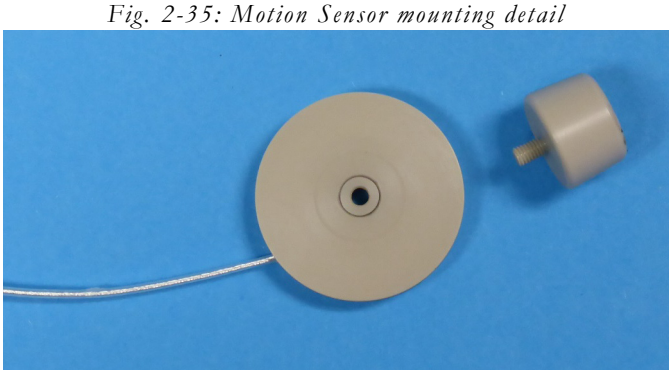
1. Insert the motion sensor in the cavity present in one of the two plastic discs.

Fig. 2-34: Morion Sensor mounting detail



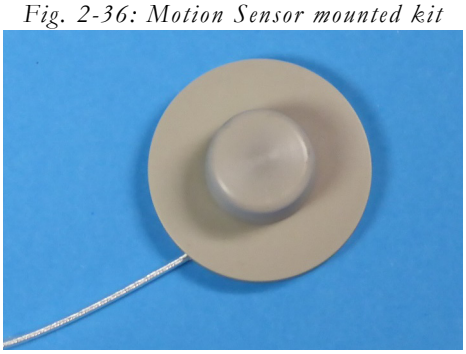
2. Close the sensor inside the holder using the second plastic disc.

Fig. 2-35: Motion Sensor mounting detail



3. Fix the assembly using the dedicated fixing screw.

Fig. 2-36: Motion Sensor mounted kit



The disc can be attached to the patient thanks to a dedicate disc tape (disposable) with a biocompatible layer (skin side). The plastic discs are in peek so a biocompatible and sterilizable material. The tape is not sterilizable so an use in surgeon field require the use of dedicate tape (not provided; Esaote suggests the use of Tegaderm-Film produced by 3M). Applying this sensor on a built-in region of the scan area it is possible to maintain the registration even after patient or transmitter movements.

The Motion Sensor connector has to be plugged on the port 4 and the sensor itself has to be attached to the patient using a standard tape.

The Motion Sensor is suitable for transcranic and musculoskeletal procedures.

Clean the motion sensor after each use. For further details on cleaning and disinfection agents suitable for the Motion Sensor refer to the manufacturer documentation (Ascension).

Needle Tracking

The needle tracking allows to see needle position during insertion.

The needle tracking requires a second receiver to be mounted.

Two different types of receiver kits can be mounted: eTRAX™ and VirtuTRAX™.

The eTRAX and VirtuTRAX will be named in the manual and software user interface as ETRAX and VTRAX respectively.

An ETRAX receiver kit consists of one reusable non-sterile needle sensor and a sterile disposable needle composed by a stylet and a sheath. The sterile disposable needle is manufactured by Civco (www.civco.com).

A complete set of lengths is now available.

Table 2-2: CIVCO eTRAX kit code list

PN	Description	Quantity
610-1057	Sterile eTRAX needle, 16GA x 17.7cm (7”) and 7.6 tapered to 3.8 x 147cm (3” tapered to 1.5” x 58”) CIV-Flex needle cover	10
610-1615	Sterile eTRAX needle, 16GA x 15cm (6”) and 7.6 tapered to 3.8 x 147cm (3” tapered to 1.5” x 58”) CIV-Flex needle cover	10
610-1613	Ssterile eTRAX needle, 16GA x 13cm (5.1”) and 7.6 tapered to 3.8 x 147cm (3” tapered to 1.5” x 58”) CIV-Flex needle cover	10
610-1610	Sterile eTRAX needle, 16GA x 10cm (3.9”) and 7.6 tapered to 3.8 x 147cm (3” tapered to 1.5” x 58”) CIV-Flex needle cover	10
610-1608	Sterile eTRAX needle, 16GA x 8cm (3.1”) and 7.6 tapered to 3.8 x 147cm (3” tapered to 1.5” x 58”) CIV-Flex needle cover	10
610-1606	Sterile eTRAX needle, 16GA x 6cm (2.4”) and 7.6 tapered to 3.8 x 147cm (3” tapered to 1.5” x 58”) CIV-Flex needle cover	10
610-1818	Sterile eTRAX needle, 18GA x 18cm (7”) and 7.6 tapered to 3.8 x 147cm (3” tapered to 1.5” x 58”) CIV-Flex needle cover	10
610-1815	Sterile eTRAX needle, 18GA x 15cm (6”) and 7.6 tapered to 3.8 x 147cm (3” tapered to 1.5” x 58”) CIV-Flex needle cover	10
610-1813	Sterile eTRAX needle, 18GA x 13cm (5.1”) and 7.6 tapered to 3.8 x 147cm (3” tapered to 1.5” x 58”) CIV-Flex needle cover	10
610-1810	Sterile eTRAX needle, 18GA x 10cm (3.9”) and 7.6 tapered to 3.8 x 147cm (3” tapered to 1.5” x 58”) CIV-Flex needle cover	10
610-1808	Sterile eTRAX needle, 18GA x 8cm (3.1”) and 7.6 tapered to 3.8 x 147cm (3” tapered to 1.5” x 58”) CIV-Flex needle cover	10

PN	Description	Quantity
610-1806	Sterile eTRAX needle, 18GA x 6cm (2.4") and 7.6 tapered to 3.8 x 147cm (3" tapered to 1.5" x 58") CIV-Flex needle cover	10

The ETRAX receiver is positioned on the sterile disposable needle tip. The operative range is 5÷35 cm of distance from the transmitter.

A VTRAX receiver kit consists of one reusable non-sterile general purpose sensor that can be attached to a sterile disposable item secured to a rigid needle. In this case several kinds of needles of different companies can be used. The sterile disposable item is manufactured by Civco (www.civco.com).

Table 2-3: CIVCO VirtuTRAX kit code list

PN	Description	Quantity
610-1059	VirtuTrax Instrument Navigator: Sterile navigator with (8.9 tapered 1.3 x 61 cm) telescopically-folded CIV-Flex sensor cover for use with 8.5FR-20GA instrument	5

The operative range is 5÷70 cm of distance from the transmitter.

In addition to the previous mentioned VTRAX a dedicate VTRAX holder is available to perform guided breast biopsy with Hologic ATEC vacuum biopsy system. The support is disposable. Refer to Civco manual for fixing the sensor to the holder and to the needle with the cover.

PC

The insertion of the needle can be driven using the optional adaptors for the biopsy needle guide. Please refer to the "Probe and Consumables" manual for further information on these kits.

AO

Refer to the "Advanced Operations" manual for a correct use of the needle guide.

WARNING

Follow the instructions provided by the manufacturer of ETRAX and VTRAX items to properly mount and use them and to clean, disinfect and sterilize them.

Medical Device Verification

The medical devices used in the vicinity of Virtual Navigator must be compatible with the Virtual Navigator electromagnetic field, i.e. must be specifically tested.

Compatibility of these devices with Virtual Navigator electromagnetic field systems guarantees that:

- no additional risk is generated for patient or operator;
- the quality of the additional information supplied by Virtual Navigator system is not altered by peripheral equipment;
- operation of medical devices is not altered by the one of the Virtual Navigator system.

Medical Devices Compatibility Test

The manufacturer of the medical device can assess the influence of the Virtual Navigator system on the relative device by assessing the proper functionality of the equipment by following this compatibility test:

- Place the peripheral equipment in proximity of the Virtual Navigator transmitter (in a range by 5 and 70 cm from the cube);
- Tap **VNAV** to activate Virtual Navigator;
- Tap **MENU**;
- In System Accuracy tab press **RECORD P1**.

The transmitter is now generating the magnetic filed and the manufacturer of the peripheral equipment can make the necessary assessments.

By closing the window, the magnetic field will be stopped.

Error Measurement

Ascension Drive Bay (tracking system) technical sheet indicates that the static accuracy is 1.4 mm RMS and the maximum RMS LOS (Line Of Sight) error is 0.5 degrees. Higher accuracies are achievable in smaller tracking volumes.

Notes on static accuracy. Accuracy is defined as the RMS position error of the magnetic center of a single sensor with respect to the magnetic center of a single transmitter over the translation range. Accuracy will be degraded if there are interfering electromagnetic noise sources or metal in the operating environment. Ferromagnetic objects and stray magnetic fields in the operation volume will degrade performance.

Chapter 3

3. Performing a Virtual Navigator Examination

In order to perform a Virtual Navigator examination based on a second modality, follow these steps:

1. Be sure the tracking system is correctly mounted and connected.
2. Import in **MyLab** archive DICOM data from a second modality like CT/MRI/PET. Refer to the Archive section of the Advanced Operations manual for further information on Archive management.

NOTE ***The image sequence should be divided in series, each one referred to a different phase. If a DICOM series contains images of different phases, the number of images belonging to different phases must be the same.***

3. Access to Start Exam screen.
4. Retrieve data from the imported second modality exam. Press exam list, then select the second modality exam. If necessary, select a different archive and/or insert a CD/USB.
5. Double click on a thumbnail, then **RETRIEVE PATIENT DATA**: this allows to automatically insert the patient information in the PATIENT ID screen.
6. Select the probe and application.
7. Press **START EXAM** to begin a new exam with retrieved DICOM data.
8. Press **VNAV** to activate Virtual Navigator as described further in this chapter.
9. If you want to perform a Virtual Navigator examination based on ultrasound as second modality, you need to acquire an ultrasound volume as described in Appendix B.
10. Check data in Series Management and Series Alignment (see chapter 4 and 5).

11. Perform the Registration (see chapter 6). This is not necessary if the second modality is an ultrasound volume acquired with Virtual Navigator.
12. Perform the Tuning, if necessary (see chapter 7).
13. Perform the exam navigating the images in Navigation (see chapter 8).

Virtual Navigator User Interface will help you correctly performing these steps.

Performing a Second Modality Scan

A Virtual Navigator exam requires a previously performed Second Modality Scan. The Second Modality Scan can be CT, MR, NM, PET, XA or US itself.

WARNING

Always base the diagnosis or perform a percutaneous procedure using the real time ultrasound image. Use the second modality display only to gain additional information.

To identify any deformation, patient movements or different breathing phases during the Second Modality acquisition, always use the 3D data workspace modality to detect such artifacts, where the 3D reconstructed volume and the coronal, axial and sagittal views are displayed.

When a Second Modality Scan is performed, it is suggested to use omniTRAX for CT/XA or the specific model for MR or External Markers to speed up the volume registration, as described in the following procedure.

Procedure

1. Place omniTRAX or External Markers on the patient skin. In case of External Markers, it is suggested to place at least 6 markers around the scanning area, if possible not on the same plane. It is suggested to verify that all markers are included in the scan making a scout. All the markers must be placed in a circle shape at the same distance (25-35 cm for best accuracy) to the transmitter.
2. Perform the Second Modality Scan acquiring the 3D dataset containing all these markers to be used with Virtual Navigator. All the acquired slices must be equidistant with distance less or equal than 5 mm.

NOTE

For MRI, 3D isotropic scans are suggested.
To perform multi phase acquisition, it is mandatory that:
• the slice thickness is equal between the two phases,

• *the acquisition starts and stops at the same location.*

3. Take note of the position and breathing phase of the patient during the Second Modality Scan because it is necessary to use the same condition during the ultrasound scan.
4. Do not remove the applied markers until the end of ultrasound scanning.

NOTE *You must verify that the 3D reconstruction is coherent.*

Virtual Navigator Activation

The Virtual Navigator tool can be activated at any time by pressing **VNAV** in the touchscreen tools section.

Press **SCAN** /**NAVIGATION** on touchscreen navigation bar to toggle between the Virtual Navigator environment and real time.

WARNING

Virtual Navigator (based on MedCom NaviSuite - Esaote edition) is a medical product intended to support a clinical ultrasound session by mean of providing additional real-time image information from second modality like CT or MR. By using the second modality image the user gains security in assessing the morphology of the ultrasound image. The second modality image is not intended to be used as a stand alone 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

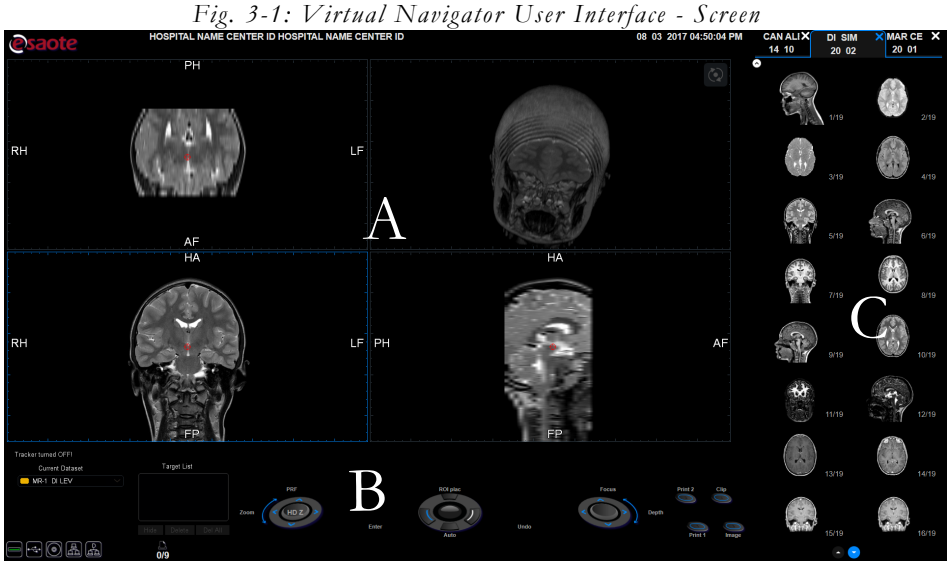
The ultrasound image has to be the reference. Never rely on the 2nd modality image only.

Virtual Navigator User Interface

After the activation, when in Virtual Navigator environment, the user interface is reconfigured to provide the Virtual Navigator controls.

The Virtual Navigator user interface is described in the following images:

Fig. 3-1: Virtual Navigator User Interface - Screen

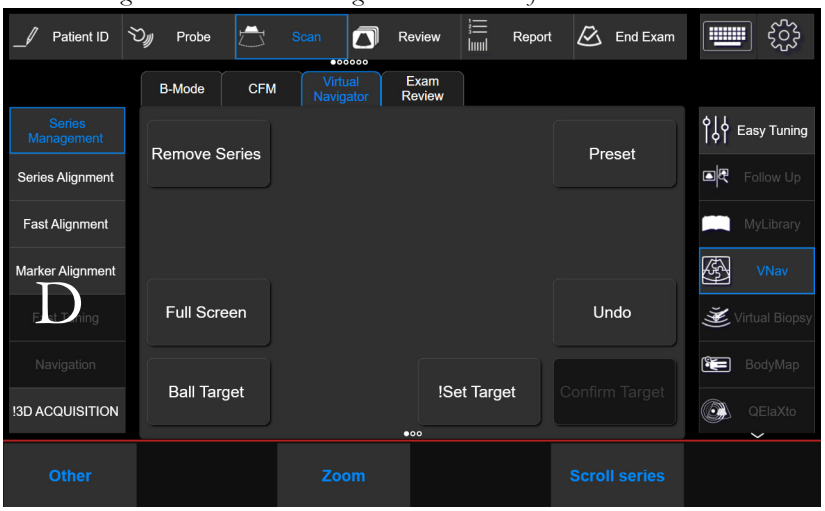


A. Image Views.

B. Bottom Bar Controls.

C. Thumbnail Views.

Fig. 3-2: Virtual Navigator User Interface - Touchscreen



D. Protocols Bar.

System Accuracy

2nd Modality Image Display

The system accuracy concerning the correlation between the real time 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) was acquired. This also includes the breathing of the patient. Thus, please be aware that the current patient breathing state should be comparable to the one during the 2nd modality acquisition.

Length Measurement (Ruler Function)

In the ultrasound image: refer to the "Measurements" section.

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

4. Series Management

Tap SERIES MANAGEMENT on the Protocols Bar to access this environment. Every time that a dataset is loaded from the database or acquired by the ultrasound, you can verify dataset, perform measures and define targets.

WARNING

Always base the diagnosis or follow a percutaneous procedure on the real time ultrasound image. Use the second modality display only to gain additional information.

To identify any deformation, patient movements or different breathing phases, always use the 3D data workspace modality, where the 3D reconstructed volume and the coronal, axial and sagittal views are displayed.

Description of available controls

This paragraph describes the controls available in this environment. For controls not described here refer to the previous chapter(s).

Touchscreen Controls

The touchscreen provides two menu levels: Basic Controls and Advanced Controls. Swipe left/right to switch from Basic to Advanced level.

Basic Level

SAVE CONFIGURATION

When data are loaded and visualized, it saves the current configuration into the Virtual Navigator internal database.

Current configuration is the ensemble of user settings: contrast, brightness, overlays, targets...

The configuration is stored to the location of the database tree, which the currently selected series belongs to.

Both registration and tuning, when good, can be saved for future use tapping **SAVE CONFIGURATION**.

An icon with a small volume is superimposed to the related thumbnail to identify a saved configuration.

When a saved configuration is loaded from the archive, Virtual Navigator automatically loads the volumes referenced by the configuration file as they were previously saved. In this way, you can select a configuration in the database and load it without having to load the corresponding volumes first.

BALL TARGET allows a direct placement of ball target.

CONFIRM TARGET Once the target is defined by **SET TARGET** or **BALL TARGET**, tap this button to confirm the target after placement and add it in Target List Window.

WARNING **Once a contour target is confirmed, verify that the segmented region properly covers the selected target by the slice regulator.**

FULL SCREEN This key allows to view in full screen one of the four images.

Select one of the views, then tap this key: the image is enlarged to full-screen mode. Tap again to go back to normal view.

Once an image is displayed in full screen, it is possible to apply other image controls.

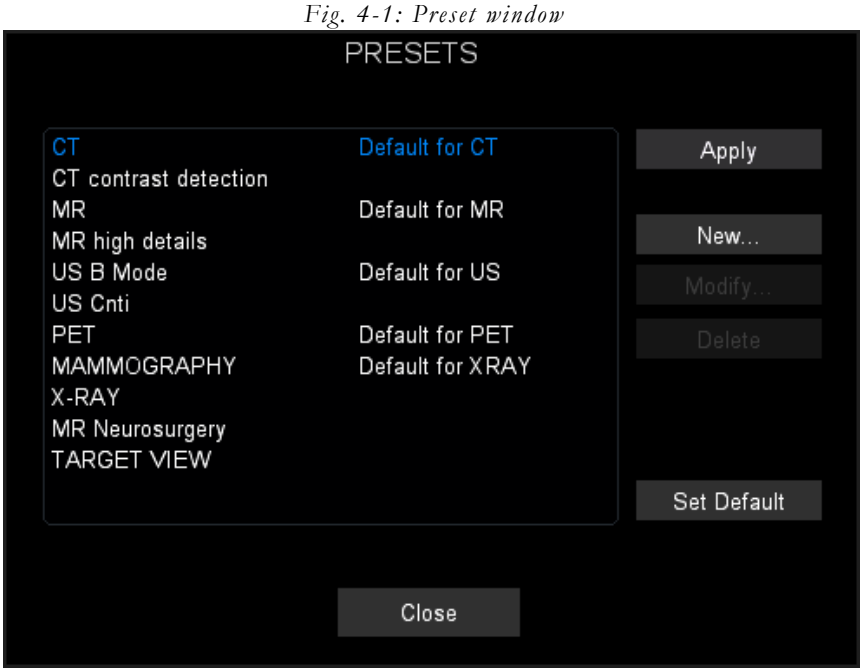
OVERLAP When more than one dataset is present, this key allows to superimpose the secondary dataset on the primary one.

To activate the function, tap it, then rotate it clockwise to overlap the secondary dataset image on the first dataset image.

NOTE ***It is recommended to use the overlapping mode to evaluate the degree of alignment.***

PRESET opens the Preset Parameters windows allowing to customize, edit, load and save presets in order to improve the quality of the second modality images.

Fig. 4-1: Preset window



PROTOCOL

Rotating the first knob located at bottom-left of the touchscreen changes the protocol related to the application in use. Protocol is a list of steps giving a help in the execution of a Virtual Navigator examination. Steps are shown top-down on the Protocols Bar on the left edge.

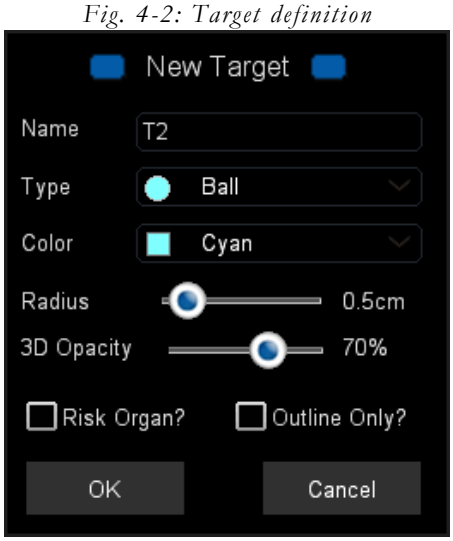
REMOVE SERIES

removes one series when it has been added.

SET TARGET

opens the New Target window allowing to define or draw one or more targets within the 3D dataset.

Fig. 4-2: Target definition



The NAME field allows to set the name of the target. As default 'T #' is available. Two or more targets can not have the same name.

The TYPE field allows to define the target type:

- BALL, to define a ball in the volume. This target can be used to facilitate its recognition on the ultrasound image.
  Once the target is defined, it is possible to place the ball in the 2D views: select one of the 2D views, place the cursor on the desired point and press ENTER to confirm the position.
  Press **CONFIRM TARGET** to confirm the position and add it into the Target List. Press **UNDO** to exit without adding the new target.

- CONTOUR, to draw a three-plane contour. This target can be used to give evidence of a pathological lesion. For this kind of target it is possible to set a margin around its volume.
  Once the target is defined it is possible to draw it in the 2D axial views. Place the cursor in the starting point and press ENTER to confirm. Repeat to set the next point. Press UNDO to remove the last point, press ENTER twice to close the contour. Move in the sagittal and coronal view to better define the contour.
  Press **CONFIRM TARGET** to confirm the contour and add it into the target list. Press **UNDO** to exit without adding the new target.

- SLICE CONTOUR, to draw a multi slice contour. This target can be used to give evidence of a pathological lesion with irregular shape. For this kind of target it is possible to set a

margin around its volume.
Once the target is defined, it is possible to draw it in different slices of the same 2D view. Place the cursor in the starting point and press ENTER to confirm, repeat to set the next point. Press UNDO to remove the last point, press ENTER twice to close the contour. The system will automatically draw the projection of the contour in the other two views. Repeat the procedure until the target is completely contoured. The system interpolate the contour among the slices in order to speed up the process. Press **CONFIRM TARGET** to confirm the contour and add it into the target list. Press **UNDO** to exit without adding the new target.

- AUTO CONTOUR, to quickly contour a region of interest without having to do multiple clicks on several slices.
  Once the target is defined place the cursor on the area of interest then press ENTER twice. After a short computational time, the lesion is segmented in 3D and a new entry is added to the targets list.
- VESSEL CONTOUR, to automatically contour a vessel tree. Once the target is defined, place the cursor on the vessel of interest (it has to be white because of the contrast agent in order to be segmented) then press ENTER twice. After a short computational time, the vessel tree is segmented in 3D and a new entry is added to the targets list.

NOTE ***Vessel contour works only with white vessels on the 2nd modality image.***

WARNING **Moving the slices, always verify the result of the segmentation. If the result is not satisfactory, segment the lesion in manual mode slice by slice.**

WARNING **Once a contour target is confirmed, verify that the segmented region properly covers the selected target by the slice regulator.**

The COLOR field allows to define the color of the target (contour or ball). Color can be defined also tapping **TARGET DIMENSIONS**.

The RADIUS field allows to define the radius of the ball (active only when a ball is selected). Radius can be defined also rotating **TARGET DIMENSIONS**.

The MARGIN field allows to define a margin around the 3D contour (active only when a 3D contour is selected). In literature this margin is commonly defined as safety halo, which is displayed in yellow.

NOTE ***The margin value will be applied to all 3D contour markers already defined and is the same for all.***

The 3D OPACITY field allows to define the transparency of the target on the 3D image (minimum value to 0%).

The option OUTLINE ONLY allows to display the target filled or no. The thick of the target contour can be set in **MENU** and accessing to **OTHER SETTINGS** tab, Miscellaneous area by acting on CONTOUR OUTLINE.

NOTE ***On the 3D view transparency affects ball and contour in the same way, while in the other views it does not.***

WARNING

On the 3D view, if two targets are intersected and the opacity is set to 0% on one of them, the second remains not visible. This means that making one target transparent, the intersection of the second target in common with the first one is transparent as well.

The intersection on 3D of two targets with different opacity level can become transparent.

Checking the option RISK ORGAN the target is transformed in a safety area. When the virtual needle or the biopsy line path intercepts the risk organ target, a caution message is displayed.

Press **OK** to define the new target; the target is displayed on the three 2D views with the tag "target not defined". Press **CANCEL** to close the window without setting a new target.

When a target is present, a compass is displayed above the image to indicate the user in which direction to move the probe in order to visualize the target on the screen. This function assumes that the user looks at the probe with the magnetic sensor facing on the back side. The compass indicator is shown on the left part close to the palette.

TARGET DIMENSIONS

Once a ball target is set on the image but not yet confirmed, tap it to change the target colors, rotate it to change the target radius.

UNDO

Closes the set target process without adding the new target.

VOLUME ROTATION

Once a 3D view is selected, this knob allows to rotate the volume clockwise/counterclockwise along its axis.

Tap it to change the rotation axis, an icon on the screen will show the selected axis.

Rotate it to rotate the volume along the selected axis.

Once a 3D view is selected, the volume can be also rotated pressing ENTER and moving the trackball directly on the volume dataset image.

ZOOM

Once one of the 2D views or the 3D view is selected, rotate clockwise/counterclockwise to enlarge/reduce the image respectively.

Advanced Level

AUTO SWITCH PLANE

When enabled, the system automatically selects the optimal dataset for the current probe position (axial or coronal).

CENTER IMAGE

When an image has been panned through **PAN IMAGES**, tap it to restore the original position.

CONTRAST & BRIGHT

This key allows to change the contrast and the intensity values of the image.

Select one of the 2D.

Once a window is highlighted, tap this key, then move the trackball:

- vertically to change the contrast,
- horizontally to change the intensity.

A lateral bar helps to optimize the values.

The results of the action performed are applied directly on the loaded dataset. In order to improve the understanding of the applied contrast/intensity values, a vertical bar, representing the obtained grey map, is shown.

FLIP H
FLIP V

When one of the 2D views is selected, this key allows to horizontally or vertically flip the image, so that the image is left/right or up/down mirrored and the other planes rotate consequently. The volume keeps the same position.

If the 3D view is selected, it is mirrored left/right up/down but the 2D views stay in the same position.

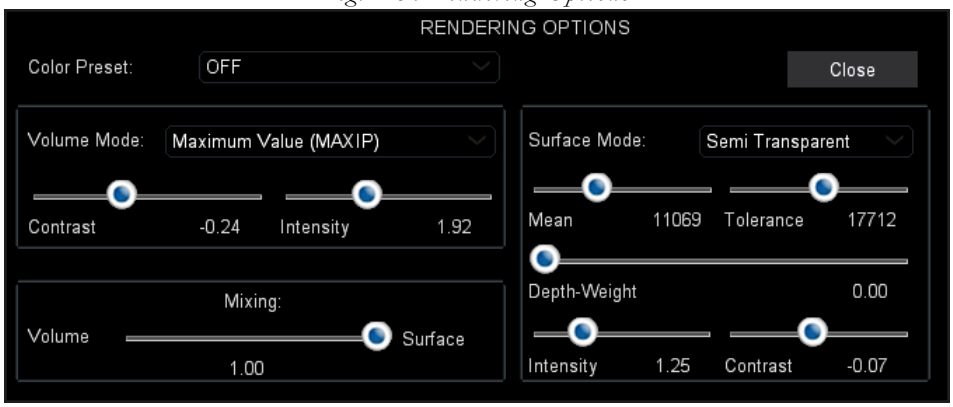
MENU

Opens a window with additional controls and options. Refer to "Menu Function" paragraph further in this chapter.

PALETTE & RENDERING

This option opens the Rendering Options panel allowing to define the parameters for the 3D image generation (rendering) and also to set the 2D images color palette.

Fig. 4-3: Rendering Options



COLOR PRESET allows to change the color of the original grey scale data. The curtain menu offers four different choices: OFF (grey-scale), orange, rainbow and inverse.

VOLUME MODE allows to set the transparent display of the volume that is the exact calculation of the pixel values as grey shade values. The curtain menu offers three different choices:

- OFF: no transparent visualization.
- Maximum Value (MAXIP): the maximum grey shade value is calculated along a virtual ray. This mode is useful to visualize the maximum grey shade value in the line of sight. In CT datasets, the bones are enhanced by this mode.
- Absorption (X-ray): X-ray pictures are simulated out of 3D ultrasound pictures. The calculation of the simulation is done on the basis of the absorption along a virtual ray. A simulated X-ray picture, by means of 3D ultrasound datasets, resembles a true X-ray picture. The simulated X-ray picture of CT datasets is similar to a true X-ray picture.

CONTRAST: sets contrast for the volume modes.

INTENSITY: sets light intensity for the volume modes.

SURFACE MODE allows to select the modes for calculating the reconstructed surfaces of the volume. The curtain menu offers four different choices:

- OFF: no surface reconstruction.
- ISO-VALUE: a smoothened surface is visualized by balancing.
  In the Iso-Value mode the influence of the setting of the mean value is decreased or increased by modifying the regulator Tolerance (see below). If the tolerance is set to 0 and the mean value, e.g., to 51 only the grey shade 51 is used for calculating the surface. The higher the tolerance is set, the more grey shades varying from the mean value are considered.
- GRADIENT: grey shade gradients and opaque structures are used for the calculation of the surface. Along a virtual ray, opaque structures are used as weighting factors.
  The Gradient mode is well suited for poorly defined surfaces, e.g. for ultrasound acquisition. As the grey shade modification tendency increases, the larger is the area which is included for the surface calculation.
- SEMI TRANSPARENT: grey shades along a virtual ray are summed up. Semi-transparent and opaque structures are visualized.
  For the Semi Transparent mode, all darker grey shades lying to the left of a selected mean value are discriminated when choosing Mean Value (see below) regulator. However, all lighter grey shades lying to the right of the mean value are included in the calculation.

MEAN and TOLERANCE regulators adjust the threshold value for the surface. The tolerance indicates how exact the threshold value influences the surface extraction. For very small tolerance values, Navigator calculates surfaces with the same shade (ISO surfaces).

Using the DEPTH WEIGHT regulator, objects closer to the observer can be displayed brighter than objects which are further away. This effect is switched off when set to 0.0.

CONTRAST: sets contrast for the surface modes.

INTENSITY: sets light intensity for the surface modes.

The regulator MIXING allows to mix Volume and Surface modes when both are active.

PAN IMAGES

Tap it to activate; when active, moving the trackball keeping ENTER pressed moves the image on the selected view. Tapping **CENTER IMAGE**, the original position is restored.

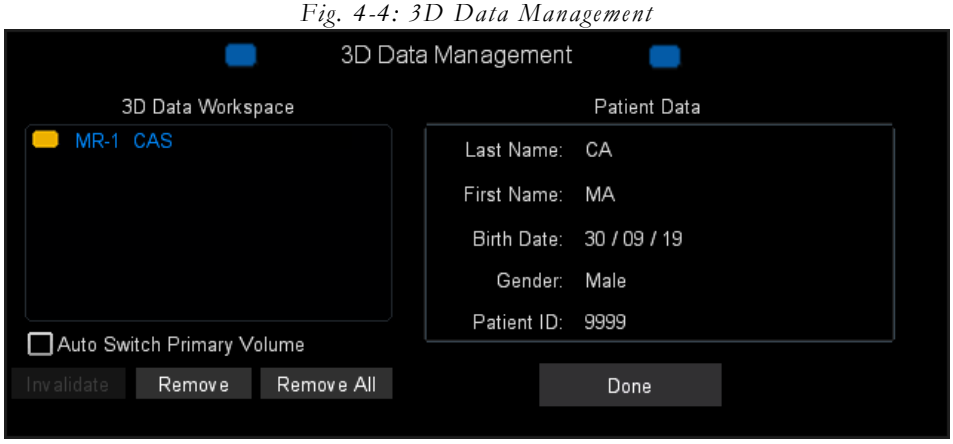
SCROLL SERIES

Tap the key to select a different view, rotate the knob to navigate among the slices of the selected view.

SERIES DETAILS

This option opens the 3D Data Management window that gives information of the loaded datasets and allows to add, to save, to remove or to invalidate datasets.

Fig. 4-4: 3D Data Management



The loaded volumes are listed in the 3D Data Workspace area where, for each volume, a line displays the status, the modality (US, CT, MRI or PET), a progressive number and the patient name.

The status is represented by an icon with the following characteristics:

- Shape: the icon is a cone for ultrasound volumes and a rectangle for CT/MRI/PET series.
- Filling: full when the volume has been saved into database, empty when it has not been saved into database.
- Colour: green for validated volumes, orange for not validated volumes (refer to chapter 5 for further information on volume validation).

To select a volume, place the cursor on the corresponding line and press ENTER.

Add allows to add one or more series belonging to the same patient to the already saved dataset, loading the series from the database.

If the volume does not belong to the same patient, the system will prompt the following message: "The patient name does not match the patient name of the current primary volume. The dataset will not be loaded".

Volumes acquired by the ultrasound scanner are automatically added to the 3D Data Workspace.

SAVE allows to store the selected volume in the database.

REMOVE allows to delete the current volume from the list (not from the database). If the volume is not stored in the database, it will be lost forever.

REMOVE ALL allows to delete all volumes from the list.

EXPORT allows to export in DICOM the acquired ultrasound volume on USB.

INVALIDATE allows to remove the spatial link activated between two or more datasets (refer to chapter 5 for further information).

The panel "Patient Data" shows the information regarding the patient. These data belong to each volume and are not common for every volume.

DONE closes the window.

SPLIT VIEW

When the option is active, each slice is divided in four squares: the first two squares belong to primary dataset and the other two to the secondary dataset in diagonal mode. Press again to deactivate the functionality.

Bottom Bar Controls

Current Dataset

The list displays only the datasets enabled for navigation. Once an item is selected, the corresponding volume is displayed on the screen.

Target List Window

The Target List Window displays both ball and well contour target when confirmed with the computation of the volume in milliliters (ml).

- **HIDE**: Hide/show the selected target (s).
- **DELETE**: Delete the selected target (s).
- **DEL ALL**: Delete all targets. A message will appear requiring to confirm the operation.

When the QElaXto is enabled during a Virtual Navigator examination, the elasticity values are displayed in this window.

NOTE ***When in Virtual Navigator environment, the maximum number of displayed values is 7 while in ultrasound environment is 10.***

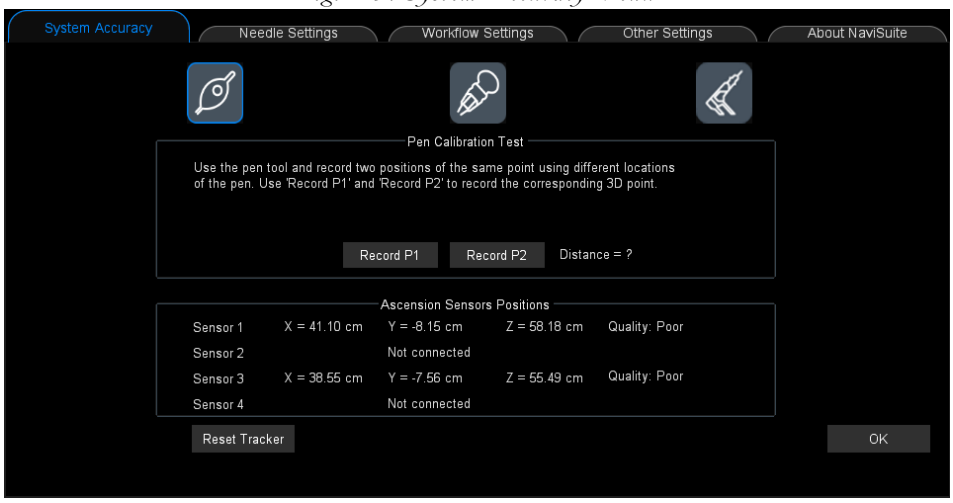
Menu Functions

This option allows to access the window for System Accuracy test, Needle Settings, DICOM Settings and Other Settings.

System Accuracy

From here you can start a System Accuracy Test to perform the calibration test for the pen, needle and probe. At any time, the accuracy and performance of the tracking devices (pen, needle and probe) can be verified using this function.

Fig. 4-5: System Accuracy Menu



Procedure

Choose **PEN TEST**, **NEEDLE TEST** or **PROBE TEST**, then follow the instructions displayed.

For each sensor it is possible to acquire two points and the system will calculate the distance between them.

Pen Calibration Test

Use the pen tool and record two positions of different points using different locations of the pen.

Use **RECORD P1** and **RECORD P2** to record the corresponding 3D point.

The test result distance must not be higher than 4 mm.

Probe Calibration Test

Use the ultrasound image to record a single point. Press **RECORD P1** to activate the ultrasound image and generate an image of the point. Mark the point using the trackball cursor and close the ultrasound image.

Record the second image in the same way using **RECORD P2**.

The test result distance must not be higher than 5 mm.

Needle Calibration Test

Depending on the needle type selected (either ETRAX, VTRAX, ATEC or V POINTER) in the drop down menu, two different test procedures are available:

Procedure for ETRAX

- when the ETRAX needle is selected, place the needle tip on a single position;
- record then two positions of different points by using different needle orientations.

Procedure for VTRAX

Since the VTRAX sensor can be attached to any needle at different distances from its tip, before starting any procedure it is necessary to perform the following check:

- when the VTRAX needle is selected, an accuracy window will be prompted;
- position the sensor coupler on the needle as described in the CIVCO user manual, taking into account the thickness of the biopsy kits that could be used;
- measure the distance between the needle tip and the sensor using a sterile ruler and insert the obtained value (in millimeters) in the INPUT DISTANCE field and then press Next.

WARNING

VTRAX sensor accuracy is affected by needle bending.

Do not use needles with diameter below 1.3mm (16G) and use only rigid needles.

Do not attach this sensor to a flexible needle. Always refer to the ultrasound image for needle recognition!

NOTE ***Place the sensor on the needle shaft from 20mm to 200mm of distance from the needle tip.***

- To check whether the distance input at the previous point is correct, keep the needle straight with the tip in a sterile point (could be the skin itself) and press **RECORD P1**. Tilt then the needle (of about 80°) without moving the tip and press **RECORD P2**. The resulting distance must differ of less than 5mm from the input distance;

Possible errors can be caused by the following conditions:

- the Start and End positions are too close;
- there is too much difference between the input distance and the measured one. This can be due either to a movement of the needle tip during the measurement or to the entering of a wrong distance;
- the needle bending gives an erroneous indication. Check that the needle stiffness is appropriate;
- the sensor is upside/down mounted.

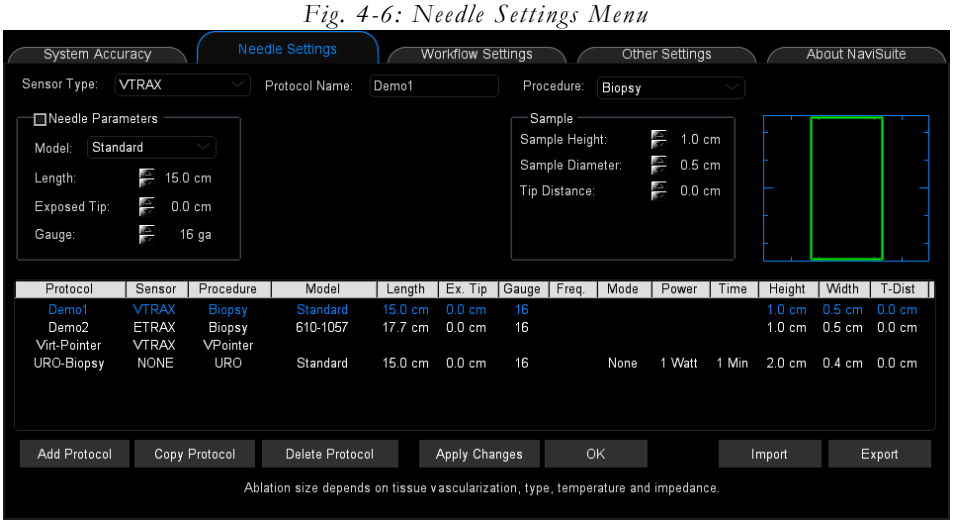
In all these cases it can be decided either to repeat the measure by pressing **BACK**, or to display the virtual needle by pressing **FINISH**. If the value between the input distance and the distance calculated by the system is lower than 5mm, the system displays the virtual needle. Nevertheless the distance used by the software is the one which has been entered, and not the one which has been calculated.

If the value between the input distance and the distance calculated by the system is higher than 5mm, the virtual needle can not be properly displayed since the procedure can include a risk for the patient. Repeat the procedure by pressing **ABORT**.

Needle Settings

From here you can define the needle specific parameters for creating/ modifying protocols.

Fig. 4-6: Needle Settings Menu



Press **ADD PROTOCOL** to create a new protocol.

To modify an existing protocol, select it from the list, edit the changes then press **APPLY CHANGES**.

When a protocol is created, it is mandatory to select the SENSOR TYPE (NONE, ATEC, ETRAX, or VTRAX), to give an unambiguous PROTOCOL NAME to it and to select the PROCEDURE type (General, Biopsy, Laser Ablation, RF Ablation, MW Ablation, Cryo Ablation or Virtual Pointer).

NOTE

For the ETRAX sensor type, only Biopsy and Laser procedures can be selected.

For Virtual Pointer the characteristics are fixed and not modifiable.

When NONE is selected, you can do the planning without sensor on the needle and the area of necrosis or biopsy sample can be manually moved or rotated at the needle displayed on the ultrasound image.

The needle must be coplanar with the ultrasound image (see the image below).

WARNING

When a necrotic image is acquired with one of the defined protocols, be sure that:

1. The needle is coplanar with the ultrasound probe;

2. Place the necrotic ellipse or biopsy sample, panning and rotating it, in the proper position referring to the needle stylet shown in the ultrasound image.

When GENERAL is selected as PROCEDURE, only the needle type must be defined as needle parameter.

When "RF,MW,LASER,CRYO is selected as PROCEDURE, it is necessary to fill, if required, also the System parameters and the Burning ellipse parameters to needle parameters.

When BIOPSY is selected as PROCEDURE, no system parameter is present but it is possible to customize the biopsy sample.

In addition, the system allows the user to input further parameters by selecting the corresponding check box displayed on its left and then by selecting the options listed below.

Needle Parameters

Always displayed.

Table 4-1: Needle Parameters

Field	Parameter
MODEL	Needle name or part number
LENGTH	Needle length
EXPOSED TIP	Emitting needle length
GAUGE	Needle diameter

NOTE ***For the ETRAX sensor type needle parameters cannot be modified.***

System Parameters

Displayed only when an ablation procedure has been selected.

Table 4-2: System Parameters

Field	Parameter
FREQ	Generator frequency
MODE	Type of emission (pulse, continuous...)

Field	Parameter
POWER	Operating emitting energy
TIME	Ablation time

Burning Ellipse

Burning Ellipse parameters allow to define the necrosis area.

Displayed only when an ablation procedure has been selected.

Table 4-3: Burning Ellipse

Field	Parameter
LONG DIAMETER	Necrotic ellipse long diameter
SHORT DIAMETER	Necrotic ellipse short diameter
TIP DISTANCE	Distance from needle tip to ellipse circumferences

When a value is modified the graphics is updated in real time to give an immediate feedback of the input changes.

WARNING

Ablation size depends on tissue vascularization, type, temperature and impedance.

Sample Parameters

Displayed only when a biopsy procedure has been selected.

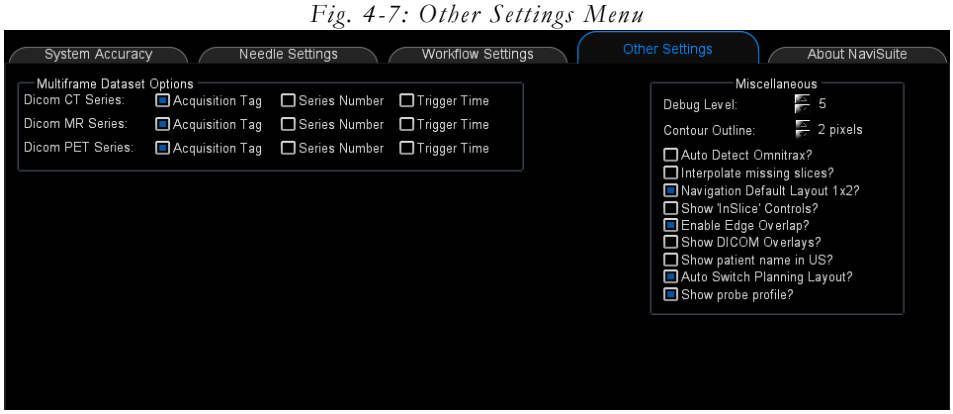
Table 4-4: Sample Parameters

Field	Parameter
SAMPLE HEIGHT	Lenght of the bioptic sample
SAMPLE DIAMETE R	Width of the bioptic sample
TIP DISTANCE	Distance from needle tip to bioptic sample

Other Settings

From here you can define additional settings.

Fig. 4-7: Other Settings Menu



When checked, INTERPOLATE MISSING SLICE will create artificial interpolated slices at the position where slices from the dataset are missing. The feature is useful for datasets which are acquired with different slice thickness.

Selecting SHOW PATIENT NAME IN US the Ultrasound patient name and current Study date are superimposed on the saved clip as it appears on the real time image.

Refer to next chapters for settings not described here.

About NaviSuite

Here you can find information about software version.

Fig. 4-8: About NaviSuite Menu

Chapter 5

5. Series Alignment

Tap **SERIES ALIGNMENT** on the Protocols Bar to access this environment. Here you can add new datasets and you can verify the morphological matching between two (or more) datasets when more than one dataset is loaded. If the two datasets spatially and morphologically match, you can use both for the navigation.

When the loaded dataset is multiphase, the Virtual Navigator automatically opens Series Alignment.

In order to have more than one dataset, you can:

- Load a multiphase dataset.
- Add a new dataset by accessing the **ARCHIVE** or double clicking on a thumbnail.
- Acquire one or more ultrasound volumes.

Once more than one dataset is displayed, in order to validate the dataset, it is necessary to follow one of the procedures described in the paragraphs below.

WARNING

Always base the diagnosis or follow a percutaneous procedure on the real time ultrasound image. Use the second modality display only to gain additional information.

To identify any deformation, patient movements or different breathing phases, always use the 3D data workspace modality, where the 3D reconstructed volume and the coronal, axial and sagittal views are displayed.

Description of available controls

This paragraph describes the controls available in this environment. Controls already described in previous chapters are not listed here.

Touchscreen Controls

The touchscreen provides two menu levels: Basic Controls and Advanced Controls. Swipe left/right to switch from Basic to Advanced level.

ADJUST SERIES

This option allows to pan and rotate the secondary dataset onto the primary one for a better matching. Press it to activate the function, then keep ENTER pressed and scroll the trackball to pan the image. Press it again to deactivate the function.

Once a view is selected, the image can be panned by pressing ENTER and moving the trackball accordingly.

AUTO ALIGNMENT

Automatically verifies the matching between the two defined areas of interest within the two datasets.

CONFIRM ALIGNMENT

Once the Alignment procedure has been performed, tap this key to confirm the Alignment.

SET ROI

Selects an area of interest in all views (axial, coronal and sagittal) and on both datasets.

SET TARGET

This key allows to define or to draw one or more targets within the 3D dataset. For additional detail refer to the previous chapter.

NOTE

The Target will belong to the primary dataset only. In order to define a target potentially correlated to an anatomical landmark present only in the secondary dataset, it is necessary to overlap the second one to the first one.

Verify the perfect alignment of the two datasets and draw the target in correspondence of the info coming from the overlap.

As soon as a new target is selected, the following warning will be displayed:

WARNING

Please verify that datasets are well aligned!

Bottom Bar Controls

Current Dataset (Primary Dataset)

This list allows to select the data to be visualized. If more than one dataset is available, it can be selected by the combo-list and visualized. These data can be selected during the navigation. If a multi-phase series is loaded, the first series will be added in the primary dataset and the following series (also more than one) in the secondary dataset. In order to select the primary dataset, scroll the menu to load the more suitable phase for the navigation.

Secondary Dataset

This curtain menu is filled every time that a second dataset is loaded. The first is in the current dataset list and the second will be placed in the secondary dataset list. The secondary dataset is always displayed in the second row.

Target List Window

When two datasets are loaded and at least one target has been defined on the primary dataset, in the Target List Window the button **DELETE ALL** is replaced by **COPY** allowing to copy the target from primary dataset to the secondary one.

Alignment Procedures

Manual Alignment Procedure

1. Select the main dataset in the primary dataset list (Current dataset) and the dataset to be validated in the secondary dataset list (Secondary dataset).
2. Select a view of the first row and select a slice containing anatomical landmarks that can be commonly visualized also in the secondary dataset.
3. Verify the matching between the two datasets by using **OVERLAP** and/or the split function and scrolling the slices.
4. If there are displacements between the two series, these can be reduced through **ADJUST SERIES**, allowing to pan and rotate (**IMAGE ROTATION**) the secondary dataset with respect to the primary.
5. If the two datasets do not present any mismatch during the overlap function (primary dataset liver with secondary dataset liver; primary dataset bone with secondary dataset bone; and so on) press **CONFIRM ALIGNMENT** in order to validate the

secondary dataset. The box beside the dataset name becomes green from yellow to indicate the dataset has been verified.

Automatic Alignment Procedure

The matching between two dataset can also be done automatically.

Automatic alignment is available for CT, MR and PET. The automatic alignment between two datasets is useful to best fit acquisition from different modalities like CT with PET or CT with MR. The function does not compensate any organ or patient deformation.

It is also available for ultrasound volumes with others ultrasound volumes but not between ultrasound volumes and the above modalities. This means that for ultrasound both datasets have to belong to ultrasound modality.

Once two or more datasets are loaded, it is necessary to follow the procedure below:

Procedure

1. Select the main dataset in the primary dataset list (Current dataset) and the dataset to be validated in the secondary dataset list (Secondary dataset).
2. Select a view of the first row and select a slice containing anatomical landmarks that can be commonly visualized also in the secondary dataset.
3. Verify the matching between the two datasets by using **OVERLAP** and/or the split function and scrolling the slices.
4. If there are displacements between the two series, these can be reduced through **ADJUST SERIES**, allowing to pan and rotate (**IMAGE ROTATION**) the secondary dataset with respect to the primary.
5. Tap **SET ROI** and using the trackball select an area of interest in all views (axial, coronal and sagittal) and on both datasets.
6. Press **AUTO ALIGNMENT** to automatically verify the matching between the two defined areas of interest within the two datasets.
7. Press **CONFIRM ALIGNMENT** in order to validate the secondary dataset. The box beside the dataset name becomes green from yellow to indicate the dataset has been verified.

6. Registration

The Registration procedure allows the virtual correlation between the second modality volume data and the patient body.

To best fit your needs you can perform the Registration by two different modalities:

1. Fast Registration,
2. Markers Registration.

WARNING

The distance between the tracking transmitter and the receiver must not be less than 5 cm and more than 70 cm.

After Registration and particularly before using the system for the current session, it is mandatory to verify the system accuracy by a side by side comparison of the ultrasound image and the second modality image.

After Registration, do not move the transmitter or the patient during the following session. For each session, or in the event of a patient shift or transmitter movement, the Registration procedure must be repeated.

If more than one series is validated, switching from the one registered to a new one (i.e. from portal to arterial or transversal phase) may cause a loss in accuracy due to different patient breathing. Please always verify the accuracy using the overlap function. Similarly, if the phase needs to be changed after registration, verify the accuracy with the overlap function and, if needed, perform the Tuning or a new Registration.

Preliminary Operations

These preliminary operations must be performed for both Fast and Marker Registration.

Ensure that the Receiver and Transmitter are correctly positioned. Ensure that the probe cables allow a comfortable scanning. Select the probe.

WARNING

Please verify that the Virtual 3D patient volume corresponds to the correct patient anatomy (no wrinkles and/or gaps).

Please verify in the 2D slice views that the loaded series is complete and correct and all slices will belong to the same phase.

WARNING

Using a multi-phase acquisition, the patient breathing or body movement among the phases can be different.

Verify the organ position in the phases before starting the Registration to evaluate possible shift during different phase utilization.

Select the suitable phase for the Registration and Navigation.

WARNING

All datasets need to be validated before the Registration otherwise they will not be placed in the correct position.

Fast Registration

Tap **FAST REGISTRATION** on the Protocols Bar to align the 3D Volume Data to the current ultrasound image, by means of placing the ultrasound probe in an Axial, Sagittal or Coronal direction and manually searching for a corresponding 3D Volume Slice and thus manually register both modalities. The current real time ultrasound image can either be adjusted to a selected 3D data slice or the current ultrasound image can be frozen and manually aligned to a selected 3D slice. It is possible either to adjust the current live ultrasound image to a selected 3D data slice or manually align a selected 3D slice to the frozen current ultrasound image.

WARNING

Perform all the Registration procedures taking into account that the patient must be maintained in the same position and breathing phase of the CT/ MRI scan.

WARNING

Verify that the transmitter is placed in the field of the operative range and no quality error is displayed.

Description of available controls

This paragraph describes the controls available in this environment. Controls already described in previous chapters are not listed here.

Touchscreen Controls

The touchscreen provides two menu levels: Basic Controls and Advanced Controls. Swipe left/right to switch from Basic to Advanced level.

OVERLAP

This key allows to superimpose the ultrasound image and the dataset image.

To activate the function, tap the key, then rotate the knob:

- clockwise to overlap the ultrasound image on the second modality image,
- counterclockwise to overlap the second modality image on the ultrasound image.

NOTE ***It is recommended to use the overlapping mode to estimate the degree of alignment.***

A new tap changes the overlap functionality to edge detection (if the ENABLE EDGE OVERLAP option has been checked in other settings menu). By rotating the knob, the detail level can be increased. Tap again to close the overlap option.

IMAGE ROTATION

Once the secondary dataset image is selected, this knob allows to rotate the secondary dataset volume clockwise/counterclockwise along its axis.

Tap it to change the rotation axis, an icon on the screen will show the selected axis.

Rotate it to rotate the volume along the selected axis.

FREEZE ULTRASOUND

Freezes/unfreezes the ultrasound image.

CONFIRM REGISTRATION

Once the Registration procedure has been performed, tap this key to confirm the Registration. It is disabled if the probe is too far (more than 70 cm.) from the transmitter or if the quality is too low.

MOTION DETECTION

Activates/deactivates the movement detection by the optional Motion Sensor during the ultrasound scan. At patient movement a message will ask to verify the Registration. You can manually tune the dataset in the new patient position.

Since the sensor cannot be placed in a built in area with the scan region (same organ) the sensor cannot provide a Registration correction but only a movement detection. (i.e. sensor in patient back during urological examination).

NOTE ***Both breathing trace and motion sensor have to be activated before the Registration.***

WARNING

Before starting the exam, check that the sensor is firmly fixed on the patient and within the operating range of the transmitter (for this sensor 50cm).

The motion sensor must be placed on the part of the body under exam taking into account to avoid any deformable part during the probe scan otherwise it will give a wrong information.

The sensor is integral with the body but not deformable during the scan. Place the Motion Sensor on a non-deformable rigid part of the body, otherwise the compensation given is wrong.

MOTION CORRECTION

Activates/deactivates the motion correction by the optional Motion Sensor with the purpose of correct movement of a rigid body in the space during the ultrasound scan. At patient movement the Registration is automatically corrected.

NOTE ***Both breathing trace and motion sensor have to be activated before the registration.***

BREATHING TRACE

Shows/hides a respiratory trace generated by the reading the Motion Sensor position when placed on patient abdomen.

If the breathing diagram is activated again after deactivation, a popup asks if the old calibration is OK or you want to repeat the procedure.

The trace background is dark transparent and the breathing trace blue. When the sensor is saturated (goes below the minimum or maximum value) the line color changes to red to indicate that there is a problem.

NOTE ***Both breathing trace and motion sensor have to be activated before the registration.***

The breathing trace is automatically reset at new patient loading. In this case you will be warned to place the sensor on the patient but not to use old data.

Tap **SET BREATHING LEVEL** to select the breathing phase that give the best match; a dot superimposed on the image will give information related to the correlation between the registration and the breathing phase:

- Green dot means the registration has been done in the same breathing phase currently displayed by the trace;

- Yellow dot means the registration has been done in a breathing phase slightly different from the current one;
- Red dot means the registration has been done in a different breathing phase.

WARNING

Please be aware that the sensor is properly:
- Placed on patient abdomen if used as respiratory gate,
- Placed in a built in area with the organ under scan if used as movement sensor.
In case to be used as 'both' please verify the consistency of registration during the patient breathing.

Fast Registration Procedure

1. Scan the patient in one of the main orientations (Axial, Sagittal, Coronal) to find an ultrasound image with distinctive characteristics.

WARNING

Hold the probe aligned (i.e. parallel) to the principal scanning direction (e.g. axial) when performing the manual registration.

2. Freeze the image pressing **FREEZE ULTRASOUND**.
3. Depending on the direction in which the ultrasound image was taken, press the corresponding direction 2D view (Axial, Sagittal or Coronal). This view will be the second modality reference image for the ultrasound.
4. Search for the slice which fits over the ultrasound image, by **SCROLL SERIES** and moving the trackball in second modality window.
5. Using touchscreen controls shift, rotate, flip the second modality image to find the best matching with the frozen ultrasound image.
6. When the overlapped images are identical, press **CONFIRM REGISTRATION**.
7. If the motion sensor has been activated, the message: "Please make sure that the reference sensor is placed on the patient before starting the exam" is shown.

8. The Fast Registration is done and the 3D volume is adjusted to the ultrasound live image.

NOTE ***During the registration it is important to select an ultrasound image in the same scan plane of the second modality reference image and as near as possible to it; the procedure with one point registration will adjust automatically any spatial error.***

NOTE ***The fast registration cannot guarantee that a registration applies to all principal scanning directions with the same quality. Usually, the registration becomes weaker when increasing the distance from the area where you performed the manual registration.***

NOTE ***Applying the registration, the acquired planning insertions will be deleted.***

Marker Registration

Tap **MARKER REGISTRATION** on the Protocols Bar to access this environment. Here markers can be aligned to adjust the second modality dataset geometry to the ultrasound device geometry. One marker aligns a point in the second modality volume and the appropriate point on the patient. With this information the second modality dataset is adjusted to the ultrasound image.

To register the second modality dataset with the ultrasound image, it is required to place markers on the patient skin (around the scanning area) and acquire the 3D dataset with these markers. From a minimum of 3 markers up to 9 markers can be registered; Esaote suggests using 6 skin markers or more.

For CT/MRI examinations, Esaote suggests using the following marker type (REF 9610056001), produced by Beekley Corp. (http://www.beekley.com/):

Fig. 6-1: Beekley marker

WARNING

Perform the registration procedure taking in account that the patient must be maintained in the same position and breathing phase of the CT/MRI scan.

NOTE

Do not remove the markers after the 3D acquisition dataset. These markers must be used for the external marker registration. Remove them only after the ultrasound examinations.

Description of available controls

This paragraph describes the controls available in this environment. For controls not described here refer to the previous chapter(s).

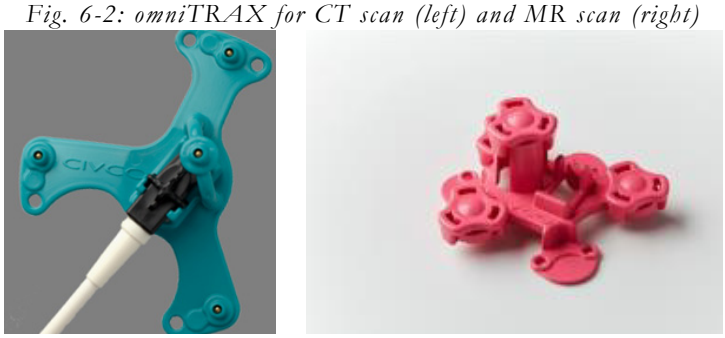
Touchscreen Controls

Controls already described in previous chapters are not listed here.

SET OMNITRAX

The omniTRAX is a tool providing four well defined external markers which do not have to be acquired with the registration pen one by one because a Sensor model 800 is already attached to the tool itself.

Fig. 6-2: omniTRAX for CT scan (left) and MR scan (right)



NOTE

The sensor model 800 has to be connected on the port 4 when the MyLab is switched off.

SET EXTERNAL MARKER

Tap this key to register the position of the external markers placed on the patient skin.

Manual Marker Registration Procedure

1. Move the cursor on the marker verifying that it is displayed on the three 2D views (sagittal, coronal, axial).
2. Double click on the image to set the point. The registered marker is displayed in green and added to the Marker List window.
3. Repeat this procedure with all markers visible in the 3D dataset.
4. Select the first marker in the marker list. Hold the Registration Pen on the corresponding marker position of the patients skin and press **SET EXTERNAL MARKER** to register this point. Ensure that, during the skin marker acquisition, the breathing phase must be equal as possible to the breathing phase during the CT/MRI acquisition.

Fig. 6-3: Points on patient surface

5. Repeat this procedure for all markers. Every point in the volume should be associated with a point on the surface of the patient.
6. When all markers have been registered, tap **CONFIRM REGISTRATION**. The system calculates the adjustment (Registration) of the 3D Dataset to the ultrasound geometry and generates an error value.

Below the Marker List window, **RESET ROW** deletes the registration for the selected marker while **RESET ALL** deletes all registration information of all markers.

WARNING

After registration and particularly before using the system for the current session, it is mandatory to verify the system accuracy by doing a side by side comparison of the ultrasound image and the second modality image.

WARNING

After registration, do not move the transmitter or the patient during the following session. For each session, or in the event of a patient shift or transmitter movement, the registration procedure must be repeated.

NOTE

During the registration, the acquired planning insertions will be deleted (see next chapters on the user manual).

omniTRAX Marker Registration Procedure

1. Fix omniTRAX on the patient skin near the scanning area, then perform a CT or MR scan. Follow the CIVCO user guide for proper fixing instructions.
2. Activate omniTRAX pressing **SET OMNITRAX**.
3. Move the cursor on the marker verifying that it is displayed on the three 2D views (sagittal, coronal, axial).
4. Double click on one of the omniTRAX points to set all the four points of omniTRAX. The registered markers are displayed in green and added to the Marker List window.
5. Fix the sensor to the omniTRAX.
6. Tap **CONFIRM REGISTRATION**. The system calculates the adjustment (Registration) of the 3D Dataset to the ultrasound geometry and generates an error value.

If the registration is not precise, the corresponding markers can be acquired manually with the trackball either in the 3D volume reconstruction window or on the slices. To enable manual acquisition with omniTRAX press **MENU**, access to **OTHER SETTINGS** tab, and deselect the box AUTO DETECT OMNITRAX in the Miscellaneous area.

NOTE

Do not cover the omniTRAX with any blancket during the CT acquisition.

Set the omniTRAX point by double clicking on the 2D slice and not on the 3D volume

WARNING

Please be aware to attach the sensor on the omniTRAX holder in proper position.

WARNING

Follow the CIVCO user guide for sensor cleaning and omniTRAX proper placement.

Measurement Error

In order to define the registration accuracy of the Virtual Navigator, the following parameters have been identified:

a. Tracker system accuracy;

b. Worst case of distance between the tracker receiver and the image plane;

c. Accuracy in the points acquisition in US (including pixel matrix, sound velocity estimation and probe resolution).

The maximum registration error committed by the Virtual Navigator is <5mm and so the technical system accuracy is always <5mm.

Error Values

At the end of the registration, an error value – that takes into account possible operator errors – will be calculated showing:

- The average registration error for global registration.
- The quality of the registration in comparison to the other markers for each marker.

The color codification is based exclusively on laboratory test and clinical evaluation in ex-vivo animal and in-vivo on human in abdominal application during the evaluation phase of the project.

After the registration of the two modalities using the dedicate tools for the accuracy verification the above color code has been introduced.

Based on the markers points, the system fits the virtual volume minimizing the distance between the identified point in the virtual volume and the acquired actual one. This implies that even if the points are not acquired well

(human error), the system is able to identify the best position of the virtual volume in the real space in order to minimize the error.

Error Values for Global Registration

After every registration with at least three markers, the software calculates the error based on the RMS (Root Mean Square) value between the acquired points and the points marked on the volume of the second modality (gold standard). The software assigns to the computed RMS value a color code: red, yellow or green.

Green means that the registration for the marker is successful; RMS value < 0.5cm; the operator error is less than the system accuracy.

When all markers are registered with a green result, the registration is complete, the second modality image is adjusted to the life ultrasound image and the exam with Virtual Navigator can start.

Yellow means that the registration for the marker is successful but not optimal 0.5<RMS value <1cm; an operator error, that can be reduced improving the procedure, has been introduced.

When some markers are registered with a yellow result, the registration is not optimal and reduces the system accuracy. The registration can be improved by deleting or registering again the yellow markers. To delete a marker select it and press RESET; when the markers are deleted, press ACQUIRE to update the registration again. If there are only a few yellow markers it is recommended to register this marker exactly again.

Red means that the registration for the marker is not optimal (reset and register again) RMS value >1cm: a non-acceptable operator error has been introduced.

When a red result is given, delete all registration information for all markers (Reset All button) and repeat the complete registration process again.

WARNING

Even after a successful registration (i.e. a "green light") you must check the registration accuracy by comparing the content of the ultrasound image with the currently generated second modality image.

WARNING

During and in particular after registration do not move the tracking transmitter or the patient. Even a little shift degrades the accuracy of the displayed image comparison immediately.

Error Values for Each Marker

If the registration is performed with more than 6 markers, the system is able to identify which markers are useful to improve the accuracy.

For External and Internal Markers registration, a Registration Result in the Marker List is displayed. This dialog informs about the average registration error. For each marker an error value is calculated, which shows the quality of the registration in comparison to the other markers.

- Error < 1.2 Green: means this marker makes the registration result better,
- 1.2<Error<1.5 Yellow: means that this point is within the average error state,
- Error >1.5 Red: means this marker makes the registration result worse.

7. Tuning

Tap **FAST TUNING** on the Protocols Bar to access Tuning environment. Here, if the adjustment of the second modality dataset appears to be insufficient, you can better adjust the Registration.

To best fit your needs, you can perform tuning by three different modalities:

1. One Point Tuning,
2. Manual Tuning,
3. Anatomical Markers Tuning,
4. Automatic Registration Tuning.

ANATOMICAL MARKERS

Allows Anatomical Markers Tuning. Refer to dedicated paragraph further in this chapter.

AUTOREG ACQUISITION

Allows Automatic Registrations Tuning. Refer to dedicated paragraph further in this chapter.

CONFIRM REGISTRATION

Applies the tuning between the displayed ultrasound image and the selected secondary dataset plane.

FREEZE 2ND MODALITY

Freezes the secondary dataset image.

FREEZE ULTRASOUND

Freezes the ultrasound image.

IMAGE ROTATION

Available when the secondary dataset image is frozen, allows to rotate the secondary dataset volume clockwise/counterclockwise along its axis. Tap it to change the rotation axis; an icon on the screen will show the selected axis.

Rotate it to rotate the volume along the selected axis.

OVERLAP

This key allows to superimpose one dataset on the other.

To activate the function, tap the key, then rotate the knob:

- clockwise to overlap the secondary dataset image on the first dataset image,
- counterclockwise to overlap the first dataset image on the secondary dataset image.

NOTE ***It is recommended to use the overlapping mode to evaluate the degree of alignment.***

A new tap changes the overlap functionality to edge detection (if the ENABLE EDGE OVERLAP option has been checked in other settings menu). By rotating the knob, the detail level can be increased. Tap again to close the overlap option.

PAN IMAGES Tap it to activate; when active, moving the trackball keeping ENTER pressed moves the image on the selected view.

SCROLL SERIES Tap the key to select a different view, rotate the knob to navigate among the slices of the selected view.

UNDO If the tuning is not satisfactory, tap **UNDO** to delete the tuning.

ZOOM Rotating the knob increases/reduces the enlargement factor of the second modality image.

One Point tuning

To improve the registration result, tune it by setting an internal marker to automatically correct any offset error in x, y, z directions.

Procedure

1. Set a reference point on the ultrasound view by double clicking on it;
2. Set the correspondent point on the second modality view, at this second double click the correction is applied.

At any new double click the point is overwritten and the registration updated.

NOTE ***Taking the point is necessary to use the pointer with the white cross, the active one. The secondary is just for indication.***

Manual Tuning

If the adjustment of the second modality dataset appears to be insufficient, you can manually tune the Registration. This is accomplished by recording a reference ultrasound image of a certain body region and afterwards manually adjusts the second modality image by moving the ultrasound probe in the same position. It is recommended to use the overlap to assess the grade of adjustment.

Procedure

1. Ask patient to stop breathing.
2. Acquire an ultrasound image containing well defined structures which can be used for tuning.
3. Stop moving the probe and tap **FREEZE ULTRASOUND**.
4. Let patient resume breathing.
5. Set an useful transparency value rotating **OVERLAP**.
6. Move the ultrasound probe (only the second modality will move) until the second modality image perfectly overlaps the ultrasound frozen image.
7. When the overlap is good, tap **FREEZE 2ND MODALITY**.
8. Verify the proper alignment and, if necessary, rotate and pan.
9. Tap **CONFIRM REGISTRATION**.

A new tuning can be performed at any time.

WARNING

Even if you achieve an acceptable fine-tuning, be aware that the grade of overlapping might be insufficient when holding the probe in a different position.

If the two images are placed on the same plane and a lateral, vertical or tilting adjustment is needed, follow this procedure:

Procedure

1. Tap **PAN IMAGES**, both ultrasound and second modality image are frozen.
2. Set an useful transparency value rotating **OVERLAP**.
3. Move the trackball keeping ENTER pressed to perform vertical and lateral adjustments on the second modality image until the two images perfectly match.
4. Rotate the image on the three axis by **IMAGE ROTATION**.
5. If necessary change the plane by **SCROLL SERIES**.

WARNING

After performing tuning, the recorded plans will not be reliable anymore (see next planning chapter).

Anatomical Markers Tuning

Anatomical Markers are anatomical structures that can be easily identified both in ultrasound image and in the second modality image.

For a more precise adjustment of the Registration, you can set Anatomical Markers in the ultrasound image and select also the appropriate point in the second modality volume.

NOTE ***Select Internal Marker within the organ under study.***

Procedure

1. Tap **ANATOMICAL MARKERS** to access Anatomical Markers environment.
2. Ask patient stop breathing.
3. Acquire an ultrasound image containing well defined structures which can be used for tuning.
4. Double click on an Anatomical Marker on the ultrasound image to set it.
5. Move the probe till the same anatomical structure point set in the ultrasound image is visualized on the second modality
6. Double click on the second modality image to set it.
7. Allow patient to resume breathing.
8. Repeat this procedure from point 2 to 7 at least for three markers.
9. When more than three markers are acquired, tap **CONFIRM REGISTRATION** to finish the tuning procedure. The software calculates the adjustment of the 3D Dataset to the ultrasound geometry.

NOTE ***It is strongly suggested to record at least 6 markers.***

If One Point Tuning has already been performed, the One Point is the first internal marker of the list.

Anatomical Markers are added to the Marker List window where **RESET ROW** deletes the registration for the selected marker while **RESET ALL** deletes all registration information of all markers.

WARNING **After performing tuning the recorded plans will not be reliable anymore.**

Automatic Registration Tuning

Once a dataset has been registered and a vessel target defined, automatic registration algorithm can be used by acquiring a 3D CFM/PWR dataset.

Procedure

1. Acquire a 3D ultrasound volume in CFM/PWR.

NOTE ***The 3D acquisition must be done in CFM/PWR, otherwise, with a 3D B-Mode acquisition the automatic registration won't be performed.***

NOTE ***It is important to perform a CFM/PWR 3D acquisition of the vessel tree.***

2. Tap AUTOREG ACQUISITION.
3. Automatic Registration extrapolates the vessel tree on the 2nd modality and on the ultrasound volume searching for the best matching of them.
4. The system automatically switches in tuning environment where the final result can be evaluated just applying the overlap.

If the ultrasound volume is not satisfying, the procedure can be repeated several time in a different organ vessel tree by applying the registration again and then performing a CFM/PWR 3D ultrasound volume acquisition.

Chapter 8

8. Navigation

Navigation is the main environment of Virtual Navigator providing the instruments to navigate the images, perform measures and define targets.

To access Navigation, once a dataset has been validated, tap **NAVIGATION** in the Protocols area on the touchscreen.

WARNING

The patient's breathing or body movement among the phases can be different. Verify the organ position in the phases before starting the navigation to evaluate possible shift during different phase utilization.

Touchscreen Controls

The touchscreen provides two menu levels: Basic Controls and Advanced Controls. Swipe left/right to switch from Basic to Advanced level.

Controls already described in previous chapters are not listed here.

PROTOCOL SELECTION

Tap it to open the protocol selection window where you can select the desired Instrument Protocol from the list, then press **OK** to confirm. Refer to "Needle Settings" paragraph on chapter 4.

When an Instrument Protocol has been selected, after **BIOPSY** pressure, the Needle Receiver and Virtual Needle are enabled.

The virtual needle is displayed computing its projection on the biopsy line. Any distortion on the real needle position is not considered and the information of the virtual needle can be different from the real needle position.

The needle is displayed in the second modality window. The red area at the end of it represents the exposed tip (see chapters 9 and 10 for further details).

LAYOUT

Tap the button or rotate the associated knob to change the current layout selecting it among several layouts:

- Ultrasound and second modality image plus 3D and perpendicular planes. The current orientation of the

ultrasound probe is indicated by a blue line within the slice views. This is the default layout.

- Ultrasound and second modality image only. The ultrasound image is live from the probe and the second modality image is calculated from the dataset. Rotating **ZOOM** increases or reduces the enlargement factor of the second modality image. This layout is not available when needle is on (interventional release only).

NOTE ***Pressing*** **MENU** ***and accessing to*** **OTHER SETTINGS** ***tab,*** MISCELLANEOUS ***area and selecting*** NAVIGATION DEFAULT LAYOUT 1X2 ***this layout is set as default layout.***

- Ultrasound and second modality image plus 3D and second modality image plane perpendicular to the ultrasound probe in a quad screen.
  - If the display of the biopsy line is activated, the perpendicular image is switched to an image representation that is perpendicular to the probe plane and lay on the biopsy line.
  - When the biopsy line is not activated but the needle is on, the perpendicular view window is substituted with a view along the needle axis. This view is independent from the probe position and it depends only on the position of the needle. The view will be orientated in such a way that the needle axis goes vertically from the top middle to the center point of the screen, thus allowing the user to see a region which is below the needle tip but in the same plane.
  - When biopsy line is off and needle is off, this perpendicular view window represents the perpendicular view to the probe plane centered in the middle of it.
- Second modality image only (available only without biopsy line). In this case the following warning is displayed: "The ultrasound image has to be the reference".
- An additional layout is present when two or more volumes are validated to each other and registered; in this way up to three modalities can be shown simultaneously. This layout is defined with 4 screens: upper left is the real-time US image, upper right is the primary volume oblique cut image, lower right is the secondary volume oblique cut and lower left is the

mixing window. In the mixing window the overlap function should be available in all possible combinations. When the layout is activated, the target list together with the buttons related to it are hidden and a mixing triangle is shown in the bottom-right side of the image. Moving the marker inside the triangle is possible to heavy the contribution of the three modalities in the fourth image.

Bottom Bar Controls

Current Dataset

The list displays only the datasets ready for validation. To validate a dataset refer to the paragraph "Series Alignment" in Chapter 5. Once an item is selected, the corresponding volume is displayed on the screen.

NOTE ***The dataset can change during the navigation. Always verify the new dataset accuracy using the overlap function.***

Performing Measurements

In Navigation environment, as well as in Series Management environment, you can perform distance and volume measurements.

Distance Measurements

When the image is frozen, press + ···+ to activate the ruler function to perform length measurements in the selected 2D view. The measurement is not available in the 3D view.

Place the cursor on the selected view on the point where the measurement has to be started and press ENTER, move the trackball to the final point of the measurement and press ENTER again. For each view it is possible to perform up to three length measurements.

Press UNDO to remove the measurements in the active plane.

Volume Measurements

When the image is frozen, press MEASURE to activate the ellipse function to perform volume measurements in the selected 2D view. The function is not available in the 3D view.

Place the cursor on the selected view and press ENTER: an ellipse with three markers is displayed. Position the cursor on the central marker, then move the trackball keeping ENTER pressed to move the ellipse. Position the cursor on one of the other markers, then move the trackball keeping ENTER pressed to change the axis length. Only one ellipse per view can be activated.

Press MEASURE to remove the ellipse in the active plane.

9. Procedures

Procedures provide:

- capability to track the needle position during the insertion. It requires the Needle Receiver.
- capability to plan and document the treatment of target volumes properly defined.

Tap **ENABLE PROCEDURE** on the Protocols Bar to access Procedures environment. The selection will be enabled when a 3D target is defined, biopsy has been activated and an Instrument Protocol has been selected.

Description of available controls

This paragraph describes the controls available in this environment. Controls already described in previous chapters are not listed here.

Touchscreen Controls

The touchscreen provides two menu levels: Basic Controls and Advanced Controls. Swipe left/right to switch from Basic to Advanced level.

RECORD PROCEDURE

Tap it to add the current real time multimodality image in the target coverage window (refer to the screen controls for further information). The necrotic ellipse is placed on the virtual needle tip. You can move the ellipse but you can not change the dimension and shape.

NOTE

RECORD PROCEDURE ***is only enabled when the needle is parallel to the image plan and displayed on it, otherwise it is disabled.***

SAMPLE ROTATION
SAMPLE STEPS

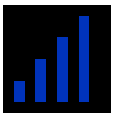
This option allows to visualize the insertion steps (available with some Instrument Protocols).

Tap **SAMPLE STEPS** to activate the function, the recorded steps are listed in the target coverage window.

By rotating **SAMPLE ROTATION** you can scroll among the images.

By pressing **SAMPLE** again the system shows the real time images also in the bottom corner. When changing the images, the 'Target coverage second list' is scrolled giving a link between the shown image and the treatment done with that insertion.

Bottom Bar Controls



This symbol gives a real time information about the quality of the signal both for probe receiver and needle receiver.

Target Coverage Window

Target Coverage Window is composed of two parts:

- Target curtain menu to select the target to be treated. The percentage (%) of the volume treated is computed after each insertion.
- Insertion list, to display the list of insertions done and the percentage (%) of the volume treated for each single insertion.
- **HIDE**: hides/shows the selected insertion (s).
- **DELETE**: deletes the selected insertion (s).
- **DELETE ALL**: deletes all insertion. A message will appear to confirm the deletion.

How to Treat a Target

Procedures environment allows to document the treatment of target volumes properly defined.

The green area represents the expected ablation size (burning area) of the selected needle (see below how to define the lesion size). The target area out of the green region shall probably not be treated. Any additional insertion shall be focused in the regions not covered by the green area.

WARNING

Ensure to keep the needle straight and verify its position during insertion and treatment.

During the percutaneous procedures the needle has to be followed on the real time ultrasound image for the whole procedure. Do not base the percutaneous procedure on the information displayed by the virtual needle visualized.

During needle tracking, the displayed "ablation-area" is an estimation of the physical result when applying RF ablation. Please be aware that the real shape of the burning area can be different. The user can define custom necrotic areas following his/her own personal studies.

During the needle insertion, the biopsy kit forces the needle parallel as much as possible to the probe plane.

Do not tilt/traverse/swing the probe with the needle inserted. Always visualize the needle in the probe plane.

Verify the quality of the signal before the protocol selection.

Before proceeding with the insertion, verify that the target is not farther than 70cm for VTRAX and 35cm for ETRAX.

Procedure

1. In Navigation environment, measure the maximum diameter of the target,
2. Tap **B-MODE** tab to switch to ultrasound,
3. Tap **BIOPSY** and activate biopsy procedure,

WARNING

When the biopsy line display is enabled on the ultrasound device, the navigator displays a corresponding virtual biopsy line in the second modality image. This line is intended to be used as an additional orientation tool, but must not be used without considering the real time ultrasound biopsy line display.

The ultrasound image has to be the reference. Do not rely on virtual biopsy display during percutaneous procedures.

4. Tap **VIRTUAL NAVIGATOR** tab to switch to Virtual Navigator,
5. Select the desired protocol from **PROTOCOL SELECTION**. Information on the selected protocol and on the related burning volume is displayed on the bottom left part of the screen.
   If the protocol uses the VTRAX sensor, go to next point; if the protocol uses the ETRAX sensor go to point 10.

NOTE

On ETRAX the Rx sensor is on the tip of the needle.

On VTRAX the Rx sensor is on the needle shaft.

It is strongly suggested to perform the procedure supporting the needle with biopsy kits. The use of these kits ensures that the needle plane is the same of the probe plane and a path preview is displayed on the ultrasound window.

6. Before starting the procedure it is necessary to verify the input data since the VTRAX sensor can be attached to any needle at any distance from the tip. When the VTRAX protocol is selected, a setting window will be prompted.
7. Position the sensor coupler on the needle as described in the CIVCO user manual taking into account the thickness of the biopsy kit that could be used.
8. Measure the distance between the needle tip and the sensor using a sterile ruler and insert the obtained value (in millimeters) in the INPUT DISTANCE field and then press **NEXT**.

WARNING

VTRAX sensor accuracy is affected by needle bending. Do not use needles with diameter below 1.3mm (16G) and use only rigid needles. Always refer to the ultrasound image for needle recognition!

NOTE

Place the sensor on the needle shaft at the distance of 20mm up to 200mm from the needle tip.

9. To check whether the distance input at the previous point is correct, keep the needle straight with the tip in a sterile point (could be the same skin) and press **RECORD P1**. Tilt then the needle (of about 80°) without moving the tip and press **RECORD P2**. The resulting measured distance must differ less than 5mm from the input distance.
   Possible errors can be caused by the following conditions:
   a The Start and End positions of sensor are too close.
   b The difference between the input distance and the measured distance is too large. This can be due either to a movement of the needle tip during the measurement or to entering a wrong distance.
   c The needle bending gives an erroneous indication. Check that the needle stiffness is appropriate.

In all these cases it can be decided either to repeat the measurement by pressing **BACK**, or to display the virtual needle by pressing **FINISH**. If

the value between the input distance and the distance calculated by the system is lower than 5mm, the system displays the virtual needle. Nevertheless the distance used by the software is the one which has been entered, and not the one which has been calculated.

If the value between the input distance and the distance calculated by the system is higher than 5mm, the virtual needle can not be properly displayed since the procedure can include a risk for the patient. Repeat the procedure by pressing **ABORT**.

10. Keep the needle on a plan parallel to the probe. To ensure this condition, the use of biopsy kits is recommended.
11. Verify that all the conditions listed below are respected:
    a the selected target is always visible in the real time image;
    b the virtual needle is displayed in green and yellow, represented with a continuous line (no dots, no gray). If not, adjust the needle trajectory till it becomes green;
    c check the correct needle position by performing an orthogonal scan.
12. Tap **ENABLE PROCEDURE**: the layout is changed in 1x2.

NOTE ***The virtual needle will be displayed in colored mode only when the probe plane is parallel to the needle axis. Increasing the discordance between the probe plane and the needle it will be gray until it completely disappears. Refer to chapter 10 for further details on graphic presentation of the needle position.***

WARNING

Do not perform any tuning after recording the first image. Before starting the ablation procedure verify the registration on different planes.

Keep the probe and the needle on the same plane during 'planning' image recording.

Hold the needle in position during 'planning' image recording. The needle tip must always be visualized in the ultrasound image.

13. Assure that the needle and the probe are parallel taking in consideration that the needle must be bent and pressed to the capture site to record the first insertion. The layout is now 2x2. The first row represents the real time image of ultrasound and its related second modality image; where the second row represents the acquired image.

14. In the recorded image the ellipse representing the expected ablation size is automatically placed on the top of the virtual needle. Since the position of the virtual needle could be different from the real position of the needle tip in ultrasound windows (due to ribs shift or organ tissue consistency), it is possible to better center or rotate the ellipse on the real needle tip visualized in ultrasound. If necessary, position the ellipse with the trackball.

WARNING

Adjust the automatic ellipse positioning manually until it corresponds with the visualized tip in ultrasound image.

15. After a plan image has been recorded and the ellipse is placed on the target, either manually, using the mouse, or by using the needle tracking, the treated target is computed and the ellipse will be colored in green. The statistics fields below will be updated, providing quantitative information on how much of the target volume has been covered with the recorded position(s).

TOTAL TARGET VOLUME: this value, expressed in ml, represents the volume of the contoured target. If the safety margin is applied, the Target tumor volume will take into account also the volume of the safety margin.

TOTAL TREATED TARGET VOLUME: this value, expressed in ml, represents the part of the Target (Tumor) volume treated by all contribution of the already performed insertions.

TREATED TARGET VOLUME BY INSERTION: this value, expressed in ml, represents the part of the Target (Tumor) volume treated by the contribution of the selected insertions.

WARNING

The above values are computed considering the expected necrotic area set for the chosen needle and intersection with the contoured target volume. The registration result and the system accuracy affect the above computation. For this reason, the computation and the color coding cannot be considered as reliable values. This indication must be considered only as a suggestion and does not reflect the real situation.

When the selected protocol is changed and the necrotic image is already acquired, for that target it is recommended to delete the previous necrotic image. Anyway, in these cases, the following message is displayed: "Plan images are already recorded with different protocol. It is suggested to remove the old plan images before acquiring new ones".

16. Now tapping **SAMPLE STEP** (o **RECORD PROCEDURE**) the layout changes in 1x2 and you can perform a new insertion repeating the previous procedure. The contribution of each insertion will be combined generating a large green area. Each insertion is displayed in the insertion list with the percentage value of the contribution of that insertion in respect to the total target volume. In order to visualize any recorded image, use the **SAMPLE STEP** (o **RECORD PROCEDURE**) control.

WARNING

Do not perform any tuning after recording the first image. Before starting the ablation procedure verify the registration on different plans. The images will be deleted automatically.

To treat a new target, load it from the target coverage curtain menu.

10.Virtual Biopsy

Virtual Biopsy provides:

- capability to define an ultrasound target in the real time ultrasound image and to recognize it with different probe position and orientation. The aim is to be able to recognize the target using different scan approach once it has been set over the anatomical reference.
- capability to follow percutaneous procedure by superimposing the needle tracking information on the real time ultrasound image when a sensorized needle is used.

Tap **VIRTUAL BIOPSY** in the touchscreen tools section to access Virtual Biopsy environment.

The main advantage is the one of getting evidence of needle path in order to choose the suitable trajectory and to assess the needle position once it is inside the patient body.

The Virtual Biopsy license helps the user in the needle path selection during percutaneous procedures.

WARNING

The ultrasound image MUST be the reference. Do not rely on virtual biopsy display alone during percutaneous procedures!

During the percutaneous procedures the needle has to be followed on the real time ultrasound image for the entire procedure. Do not base the percutaneous procedure on the information displayed by the virtual biopsy tool.

Description of available controls

This paragraph describes the controls available in this environment. Controls already described in previous chapters are not listed here.

Touchscreen Controls

The touchscreen provides two menu levels: Basic Controls and Advanced Controls. Swipe left/right to switch from Basic to Advanced level.

LAYOUT

Tap **LAYOUT** to change the current layout selecting one of the three options available:

- Default layout: single standard ultrasound real time image plus small image on the right of the 3D image of probe and needle.
- The ultrasound real time image on the left and on the right part is divided into: small image on the right lower part of the 3D image of the probe and needle and a radar system for a better target detection on the upper right part.
- Ultrasound real time image on the left and 3D image of probe and needle on the right.

Rotate **LAYOUT** knob to change the zoom factor of the 3D image of the probe.

PROBE VIEW

This option allows to display the relative position between the probe and the needle.

By rotating it, the view angle for the 3D probe and needle window are adjusted at 5 degrees steps. By pressing it, the 3D probe is displayed in horizontal view.

WARNING

From now on, DO NOT move the patient nor the transmitter.

How to Perform a Virtual Biopsy

Procedure

1. Press START/END to display the start exam page.
2. Insert the patient data.
3. Select probe, application and preset, then start a new exam.
4. Tap **BIOPSY** and activate biopsy procedure,
5. Tap **VIRTUAL BIOPSY** on the touchscreen tools section.

6. Select the desired protocol from **PROTOCOL SELECTION**. Information on the selected protocol and on the related burning volume is displayed on the bottom left part of the screen.
   If the protocol uses the VTRAX sensor, go to next point; if the protocol uses the ETRAX sensor, go to point 11.

NOTE ***On ETRAX the Rx sensor is on the tip of the needle.***

On VTRAX the Rx sensor is on the needle shaft.

NOTE ***It is strongly suggested to perform the procedure supporting the needle with biopsy kits. The use of these kits ensures that the needle plan is the same of the probe plan.***

7. Before starting the procedure it is necessary to verify the input data since the VTRAX sensor can be attached to any needle at any distance from the tip. When the VTRAX protocol is selected, a setting window will be prompted.
8. Position the sensor coupler on the needle as described in the CIVCO user manual taking into account the thickness of the biopsy kit that could be used.
9. Measure the distance between the needle tip and the sensor using a sterile ruler and insert the obtained value (in millimeters) in the INPUT DISTANCE field and then press **NEXT**.

WARNING **VTRAX sensor accuracy is affected by needle bending. Do not use needles with diameter below 1.3mm (16G) and use only rigid needles. Always refer to the ultrasound image for needle recognition!**

10. To check whether the distance input at the previous point is correct, keep the needle straight with the tip in a sterile point (it could be the same skin) and press **RECORD P1**. Tilt then the needle (of about 80°) without moving the tip and press **RECORD P2**. The resulting measured distance must differ less than 5mm from the input distance. Possible errors can be caused by the following conditions:
    a The Start and End positions are too close.
    b The difference between the input distance and the measured distance is too large. This can be due either to a

movement of the needle tip during the measurement or to entering a wrong distance.

c The needle bending gives an erroneous indication. Check that the needle stiffness is appropriate.

In all these cases it can be decided either to repeat the measurement by pressing **BACK**, or to display the virtual needle by pressing **FINISH**. If the value between the input distance and the distance calculated by the system is lower than 5mm, the system displays the virtual needle. Nevertheless the distance used by the software is the one which has been entered, and not the one which has been calculated.

If the value between the input distance and the distance calculated by the system is higher than 5mm, the virtual needle can not be properly displayed since the procedure can include a risk for the patient. Repeat the procedure by pressing Abort.

10. Keep the needle on a plan parallel to the probe. To ensure this condition, the use of biopsy kits is recommended.

11. Verify that all the conditions listed below are respected:

    a the selected target is always visible in the real time image;

    b the virtual needle is displayed in green and yellow, represented with a continuous line (no dots, no gray). If not, adjust the needle trajectory till it becomes green;

    c check the correct needle position by performing an orthogonal scan.

By pressing IMAGE or CLIP, images and clips are saved under the patient name.

Once the virtual needle is displayed, it is represented by two parallel lines whose graphic presentation depends on the needle position:

- The needle is parallel and close to ±3mm to probe plane. Continuous lines are displayed. The green part represents the needle itself while the yellow part displays the subsequent needle path. In proximity of the needle tip two orthogonal lines indicate its position.

- The needle is parallel and close to ±5mm to probe plane. Continuous lines are displayed. The needle itself and the needle path are both in grey to indicate that the needle is not belonging to the probe plane. In proximity of the needle tip two orthogonal lines indicate its position.

- Dotted lines are displayed to indicate that the needle is not parallel to the probe plan; a circle shows the intersection between the probe plan and the needle itself. The green dotted lines represent the needle itself while the yellow ones its path. The circle is green if the needle has already gone through the needle plan, yellow in the opposite case, as shown in the figures below.
- The needle is parallel to the probe plan but far more than ±5mm. No needle is displayed.
- The needle tip is far more than 60mm from the probe axis. No needle is displayed.
- The needle is tilted more by than 85° with respect the probe plan. No needle is displayed.

The distance and the relative angle with respect to the probe plan are reported in the info bar.

Radar Window

The "radar" window represents a view point from the needle tip. Its aim is to help the user to navigate the needle to the selected target. It should simulate a camera fixed to the needle tip which is pointing in the needle direction.

If the ultrasound plane does not intersect the currently selected target (or no target is defined), there is only a grey circle drawn inside the window indicating that it is disabled. Otherwise, both the currently selected target and the probe are displayed. Moreover, the grey circle becomes green and its size decreases as the needle tip approaches to the center of the active target. If the distance from the target exceeds of 12cm, the circle size does not change anymore. A green arrow points to the direction where the target is located when the target itself is not yet visible inside the "radar" window. The arrow disappears once the active targets center is indicated inside the green distance indicator circle.

Error Measurement

The maximum error committed when visualizing the virtual needles ETRAX and VTRAX is <5mm: the real needle is always properly visualized inside the virtual needle. A correct indication on the needle path and needle tip position is obtained.

Chapter 11

11 Breast Navigation

Breast Navigation provides capabilities:

- to navigate a breast model both 2D and 3D;
- to define ultrasound targets;
- to follow biopsies with tracked needles.

When in breast application and if both Virtual Navigator and Breast Navigation licences are enabled on your **MyLab**, you have to select which of the two functions you want to use. To make selection, press MENU then **NAVIGATOR CONFIGURATION** to choose, as APPLICATION FAMILY, between FUSION NAV for Fusion Imaging and Virtual Navigator, or BREAST NAV for Breast Navigation: the related key will be displayed on the tools section of the touchscreen.

Start a Breast examination with L 4-15 or L 8-24 probe. The Navigation hardware has to be correctly installed as described in the first chapters of this manual.

As soon as the exam starts, tap **BREAST NAV** in the tool section of the touchscreen: in the main screen is displayed a 3D model of a female body midsection while the touchscreen is reconfigured providing the controls for Breast Navigation environment in a dedicated tab.

The protocols bar on the left side of the touchscreen lists the different steps to be followed for a correct breast navigation:

1. Patient-Model Registration, to correlate the breast model and the patient body,
2. Model Scan,
3. Sweep Acquisition,
4. Sweep Review,
5. 3D Analysis,
6. US imaging comparison,
7. Biopsy (only if licence is present).

Description of available controls

This paragraph describes, for each step, the controls available on the touchscreen.

The tab **BREAST NAV** on the touchscreen provides two menu levels: Basic Controls and Advanced Controls. Swipe left/right to switch from Basic to Advanced level.

Patient-Model Registration

As first action for correct breast navigation, the Registration procedure is necessary to correlate the model and the patient body.

Selecting **PATIENT–MODEL REGISTRATION** it is possible to perform an horizontal and a vertical scan to record the patient breast shape and align with the model. For considerable breast it is suggested to acquire also points in order to better define the attachment of the breast with the thorax.

In this phase the target is shifted in the new coordinates defined by the registration between the model and the patient now in prone position.

Procedure

1. As soon as the breast model is loaded, six reference yellow points are displayed on it,
2. Select the preferred model: **2D MODEL** or **3D MODEL**,
3. Select the correct laterality tapping **LEFT BREAST** or **RIGHT BREAST**,
4. Select the right **PATIENT POSITION**,
5. Select the **REGISTRATION DEVICE** (probe or pen),
6. Select **HORIZONTAL STRIPE**, place the selected registration device on the patient breast and softly follow the breast profile intersecting the nipple with an horizontal scan,
7. Select **VERTICAL STRIPE**, place the selected registration device on the patient breast and softly follow the breast profile intersecting the nipple with a vertical scan,
8. If necessary, to improve the registration, you can acquire also six reference points (P1-P6). Every point in the model should be associated with the related point on the breast of the patient tapping **ACQUIRE POINT** to register this point,
9. Tap **CONFIRM REGISTRATION** to finalize the registration,

10. Wait for registering breast model,
11. When the registration is completed the points become green and the model adapts to the real situation, the ultrasound live image is displayed on the screen and the breast navigation begins.

If the registration is not satisfying, it can be invalidated tapping **RESET REGISTRATION**.

Touchscreen controls

PATIENT POSITION	defines the patient position under investigation (supine or lateral decubitus).
REGISTRATION DEVICE	defines the device (probe or pen) used for the registration.
MENU	opens a window with additional controls and options. Refer to "Menu Functions" paragraph further in this chapter.
SHOW QUADRANT	when the 2D model is selected, divides the view in four breast quadrants.
SIDE VIEW	changes the view from frontal to lateral.
PAN	when active, you can move the model with the trackball.
CENTER	when the model has been panned, tap it to restore the original position.
MODEL SURFACE	changes the 3D model representation.
ZOOM	changes the zoom factor of the model.
MODEL TRANSPARENCY	sets the value of transparency for the 3D Model.

Model Scan

After the registration you can access Model Scan environment where real-time ultrasound image is displayed side-by-side to the breast model. During the scan of the breast, every single sweep of the probe on the breast is showed on the model and it can be recorded for future investigations.

Touchscreen controls

RECORD MOVEMENT Tap it to start the recording of the probe movement and tap it again to stop.

RESET MOVEMENT deletes the trace of the scans.

SAVE CONFIG saves the current configuration (settings, targets,...) and scans into the archive.

Breast Navigation Icon When a configuration has been saved a breast icon is superimposed to the thumbnail to identify it.

FULL SCREEN enlarges the model ultrasound image at full screen.

BALL TARGET allows a direct placement of a ball target.

When the target is placed you can position it on the ultrasound image moving the trackball and double clicking to confirm. The ball target is automatically placed on the breast model.

You can also set the ball target radius rotating the knob **TARGET SIZE**. Tapping target size you can change the **TARGET COLOR**.

Sweep Acquisition

Basic touchscreen controls

AUTOMATIC RECORDING When selected the system automatically records each single sweep. The system automatically recognizes when the scan starts and when it stops.

Recorded sweeps are visualized in green on the breast model, labeled with S followed from an increasing number and listed in the box BREAST SWEEPS in the bottom bar.

Grey sweeps mean that plane-to-plane distance is greater than 5 mm.

WARNING

The images composing the acquired sweeps can be far each other more than 5 mm, due to a fast acquisition.

DELETE SWEEP deletes the selected sweep.

MANUAL RECORDING

Tap it to start the recording and tap it again to stop.

SELECT SWEEP

Rotate the knob to select a different sweep.

UNDO

Rotating the knob, you can go back step-by-step (and go forward) through the performed actions.

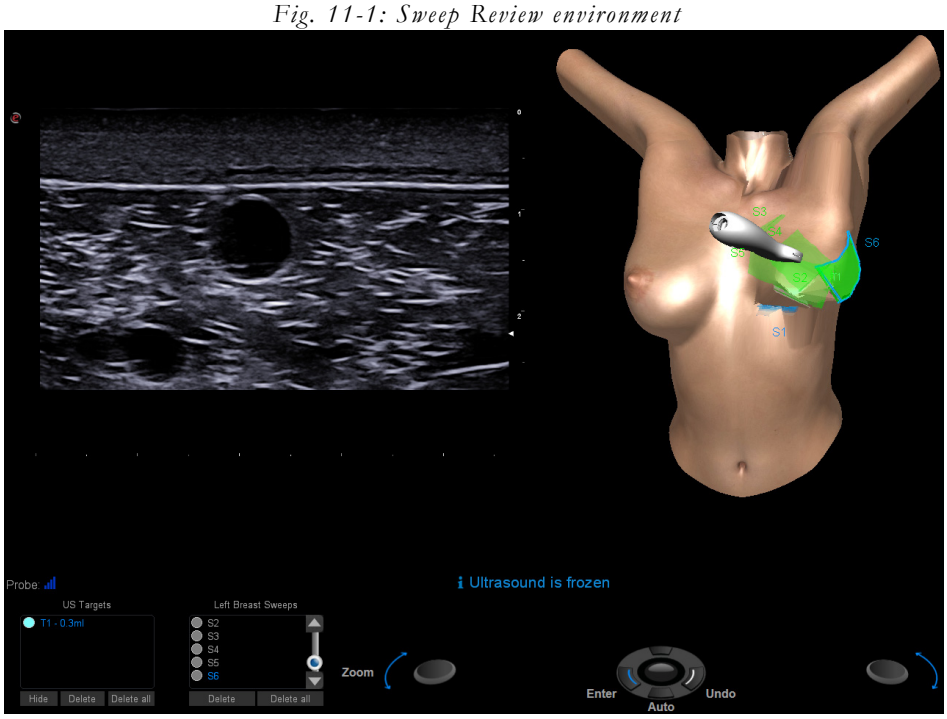
Sweep Review

When at least a sweep is present both in real-time or in a saved configuration, in Sweep Review environment you can review each single sweep.

WARNING

The sweeps are colored in blue when the loaded configuration does not belong to the current patient position.

Fig. 11-1: Sweep Review environment



Basic touchscreen controls

PERPENDICULAR FRAME

shows the frame perpendicular to the image currently displayed.

3D REGION To make a 3D analysis (refer to 3D Analysis paragraph further in this chapter).

PLAY/STOP plays and stops the reproduction of the clip related to the selected sweep.

SELECT SWEEP selects the recorded sweep.

SELECT IMAGE selects the ultrasound image frame-by-frame for the selected sweep.

Advanced touchscreen controls

SHOW ALL US FRAMES shows on the model all ultrasound frames.

SHOW CURRENT US FRAME shows on the model the current ultrasound frame.

PLAY SPEED changes the speed of reproduction.

Each line becomes green when the related sweeps (scan) has been reviewed. Beside there is the number of times it has been reviewed.

During review sweeps identifying the recorded scans are visualized in blue.

If you review a sweep with a target belonging to, the target is displayed.

3D Analysis

The 3D Analysis environment allows to investigate a sweep in three dimensions; the screen is divided in four parts: 3D image and single plane views.

Procedure

1. In Scan Review environment, select a sweep.
2. Select an image with a target to be analyzed in three dimensions.
3. Press **3D REGION**: a blue box is displayed.
4. Resize the blue box rotating **REGION SIZE** to include the lesion to be analyzed.
5. Move the trackball to position the cursor on the lesion, then click: the blue box is centered around the lesion.
6. Double click on the image inside the box: the 3D Analysis environment is displayed.

Because the reconstruction method is intrinsically affected by errors owing to the poor image quality and/or errors due to the movement of the part under examination, any type of diagnosis cannot be therefore performed basing on reconstruction results only.

WARNING

Diagnosis made only by assessing 3D reconstructed views are not permitted; every diagnostic findings have to be evaluated in 2D as well.

SCROLL SLICES

Scroll the slices belonging to the selected view; the other views are updated consequently.

CONTRAST & BRIGHT

This key allows to change the contrast and the intensity values of the image.

Select one of the 2D.

Once a window is highlighted, tap this key, then move the trackball:

- vertically to change the contrast,
- horizontally to change the intensity.

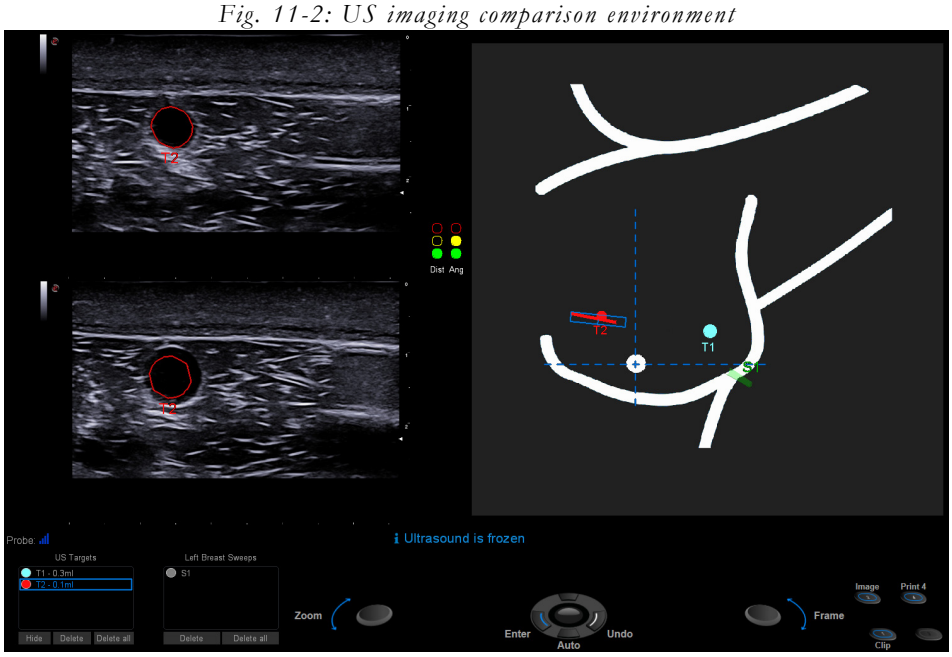
A lateral bar helps to optimize the values.

The results of the action performed are applied directly on the loaded dataset. In order to improve the understanding of the applied contrast/intensity values, a vertical bar, representing the obtained grey map, is shown.

US imaging comparison

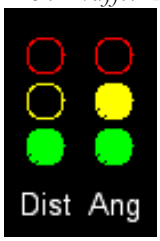
This environment allows to compare a real-time scan with a recorded sweep. The image is divided so that at top-left there is ultrasound live, at bottom-left the recorded sweep, to the right the breast model.

Fig. 11-2: US imaging comparison environment



A couple of traffic lights guide you to find in the real-time scan the same position of the recorded one. Lights tell how the distance (Dist) and the angle (Ang) of the probe are close to the position of the probe in the recorded one.

Fig. 11-3: Traffic Lights



Basic touchscreen controls

COMPARE FRAMES

Ultrasound real-time image and recorded sweep are displayed side-by-side while the breast model is not showed.

Biopsy

When a target has been defined, **BIOPSY** provides capability to follow percutaneous procedure by superimposing the needle tracking information on the real time ultrasound image when a sensorized needle is used.

Beside the ultrasound real-time image, the 3D model helps in the procedure.

Refer to Virtual Biopsy chapter for further explanations.

PROTOCOL SELECTION

selects the desired Instrument Protocol.

VIEW BREAST

After needle selection, it defines the point of view between standard and needle view.

Menu Functions

Press **MENU** to access the settings window where you can access to many options.

- System Accuracy, for probe and needle calibration test. Refer to chapter 4 for further information.
- Needle Settings, to set specific parameters for the needles to be used during biopsy. Refer to chapter 4 for further information.
- Other Settings, where you can define additional settings for breast navigation. Refer to paragraph below for further information.
- About NaviSuite, here you can find information about software version.

Other Settings

BreastNavi Options

From here you can define settings for breast Navigation.

When DO YOU WANT TO SHOW 2D BREAST QUADRANT AS DEFAULT? is checked, the quadrants are automatically added to the 2D model.

When DO YOU WANT TO USE 3D MODEL AS DEFAULT? is checked, the 3D model is displayed as default.

When DO YOU WANT TO SWITCH TO BREAST NAVIGATION AFTER REGISTRATION? is checked, the system automatically switches to breast navigation after the registration.

Selecting DO YOU WANT AUTOMATIC ACQUISITION TO BE ACTIVE BY DEFAULT? the acquisition automatically starts during the breast scan.

SHOW THE US PLANE IN 3D shows the Ultrasound image attached to the 3D probe model.

A. Cleaning and Disinfection

The following products can be used to clean and disinfect the Receiver, the kit, the Transmitter and the Registration Pen:

- Cidex OPA,
- Medister.

WARNING

Remove the Receiver from the Registration Pen and/or probe/needle receiver holder before any cleaning/disinfecting procedure.

Do not soak the Registration Pen and/or probe/needle receiver holder in the disinfection solution for periods longer than the time required to achieve a disinfection.

PC

Consult the "Probes and Consumables" manual for correct cleaning instructions for probe, support kit and registration pen.

To clean the receiver

1. Remove all residues of ultrasound gel from the receiver using a soft cloth.
2. Clean the receiver by rubbing it lightly with a soft cloth soaked in a solution of water and mild soap.
3. If necessary, spray a sterilizing cleaner onto a clean, soft cloth and then wipe the surface.

B. 3D Acquisition

Once the Virtual Navigator tool has been activated, ultrasound volumes can be acquired both in B-Mode and CFM with the aim of navigating them.

In case a CFM volume is acquired, pressing **MENU** and then **OTHER SETTINGS** tab, in COLOR FLOW VOLUME RESAMPLE area you can define the type of ultrasound volume loaded: CFM only, B-Mode only or CFM and B-Mode together. B+CFM is the default selection.

Thanks to the Virtual Navigator tracking system, the acquired volume is already available for the navigation without the needs to be aligned with the patient position.

WARNING

Do not move the patient or the transmitter after the ultrasound volume acquisition.

The ultrasound volume can be acquired alone or when other second modality dataset is already loaded and aligned in Virtual Navigator.

Procedure

1. Start a new exam taking in account that the receiver is correctly locked on the probe and the transmitter is correctly positioned.
2. Tap **3D ACQUISITION** in the Protocols area on the touchscreen.

NOTE

3D ACQUISITION ***is active in real time only when Virtual Navigator tool is active.***

3. Tap **START/STOP** to start the volume acquisition.
4. Move the probe slowly to acquire the volume.
5. Tap **START/STOP** again to stop the acquisition.
6. After a short computation time, the acquired volume is displayed. If the volume is the first dataset loaded, it is displayed as the current dataset, otherwise it is displayed in the secondary dataset volume list.

7. If the volume is an additional dataset, it is necessary to validate it for the navigation. Select it in the secondary dataset curtain menu and press the validate icon or **3D ACQUISITION**, the volume is then moved in the current dataset curtain menu.
8. Select the acquired volume as current dataset.
9. Tap **SHOW 3D** to show the acquired volume.
10. Go into the navigation environment to navigate the volume.
11. Several volumes can be acquired. When more than one volume is acquired the system will go into data matching for the dataset validation.
12. Tap **SAVE 3D** to save the acquired volume. An icon with a small volume is superimposed to the related thumbnail to identify a saved volume.

This procedure can be also applied when a second modality dataset is already loaded. It is strongly suggested to register it before acquiring the ultrasound volume in order to have a direct correlation of the ultrasound volume position on the second modality dataset.

C. Body Map

Body Map enables the navigation on the second modality image, on the graphic representation of a body structure or on a picture taken with an optional camera.

Tap **BODYMAP** in the touchscreen tools section to activate/deactivate the Body Map tool.

Procedure

1. Start a new exam taking into account that the receiver is correctly locked on the probe and the transmitter is correctly positioned.
2. When in real time, tap **BODYMAP**.
3. The layout will display on the left side the ultrasound image while in the right side you can load a second modality image, a graphic representation of the body anatomical structure under study or a picture taken with an optional camera.

To load the second modality image, access the database pressing ARCHIVE and select the image you desire. The second modality image can be any DICOM image like X-Ray mammography, CR (Computer Radiography), or whatever can be displayed close to the real-time ultrasound examination as reference.

To load the graphic representation of the body anatomical structure, rotate **LOAD BODYMARK** to change selection, then press **LOAD BODYMARK** to confirm the selection. The selected bodymark is displayed to the right side of the image.

To take a picture with the optional camera, be sure the camera is connected to the USB port of **MyLab**; a first tap on **ACTIVATE CAMERA IMAGE** activates the camera while a second tap on **ACTIVATE CAMERA IMAGE** takes the picture.

As soon as the second modality image, the bodymark or the picture is selected, the system displays the following warning:

WARNING

The ultrasound image has to be the reference. Never rely on the 2nd modality image only.

4. The second modality image, the bodymark and the picture require to be registered with the probe position by defining external reference markers. The relation between the ultrasound and the reference image (second modality, bodymark or picture) is not precise but it is only approximated since puts in relationship a 2D image with a 3D structure. Take also in consideration that patient position can be really different from the ultrasound scan and the 2D image (in case of mammography also a big deformation is applied).
5. Double click on the second modality image, on the bodymark or on the picture to set the point. The marker is displayed in blue while the previously fixed markers are displayed in yellow.
6. Repeat this procedure for at least 3 markers.

NOTE ***The more complex the area is, the greater must be the number of points.***

7. Move the probe to identify the corresponding marker position of the patient skin and press **SET EXTERNAL MARKER** to register this point. The point label changes from blue to green. Ensure that, during the skin marker acquisition, the breathing phase must be as equal as possible to the breathing phase during the CT/MRI acquisition.
8. Repeat this procedure for all markers. Every point should be associated with a point on the surface of the patient.
9. The software will internally generate a spline connecting the set points and defining the area where the probe can navigate and it will be visualized. The probe cannot navigate outside the defined area.
10. Navigate the second modality image, the bodymark or the picture.

RESET EXTERNAL MARKER removes the last point.

RESET ALL SKIN MARKERS removes all points.

HIDE ALL hides all points label.

Body Map in Breast Navigation

A dedicate Body Map is available for Breast Navigation allowing to navigate a 2D image coming from Dicom as well a bodymark or an image acquired by a dedicated camera.

Three main environments are available allowing to register, navigate and managing camera acquisition.

Body Map Registration

In this environment, after that a bodymark or an image is visualized, you can register it as usual.

Touchscreen Controls

FLIP H FLIP V	horizontally or vertically flips the image, so that the image is left/right or up/down mirrored and the other planes rotate consequently.
HIDE MARKER	hides registration markers.
ACQUIRE MARKERS	records the position of the markers on the patient.
POINTER SIZE	defines the diameter of the pointer.
POINTER POS	defines the position of the pointer.
ZOOM	Rotate clockwise/counterclockwise to enlarge/reduce the image respectively.

BodyMap Navigation

In this environment you can scan the patient having as reference of the probe position a pointer in the reference modality. More than one image/projection can be loaded simultaneously but each of them requires a dedicated registration.

Touchscreen Controls

LAYOUT	changes the current layout between still image, and live camera image.

BodyMap Camera

Optional camera supplied by Esaote is the Intel® RealSense™ Depth Camera D415, an USB-powered camera that includes depth sensors and a RGB sensor.

The bodymap camera contains a 850 nm semiconductor laser. The camera is classified as a Class 1 Laser product under EN/IEC 60825-1, Edition 3 (2014) internationally and IEC 610825-1, Edition 2 (2007) in the US.

The laser radiation emitted is invisible to the human eye.

The camera complies with US FDA performance standards under 21 CFR 1040.10 for laser products except for deviations pursuant to Laser Notice No. 50 dated June 24, 2007.

Fig. C-1: Body Map Camera

CAUTION

Use of controls or adjustments or performances of procedures other than those specified herein may result in hazardous radiation exposure.

WARNING

No magnifying optical elements, such as eye loupes and magnifiers, are allowed.

Do not power on the product if any external damage was observed.

Do not attempt to open any portion of this laser product. There are no user serviceable parts.

Invisible laser radiation when opened. Avoid direct exposure to beam.

Do not modify or service the product in any way. Modification or service of the hardware might cause the emissions to exceed the Class 1 level.

The camera can be used to acquire a reference picture as well to shoot an examination coupling the ultrasound real time image with the current live probe position

Touchscreen Controls

ACQUIRE IMAGE acquires a still image from the live video.

FULL SCREEN shows the live image in full screen.

ZOOM Rotate clockwise/counterclockwise to enlarge/reduce the camera image respectively.