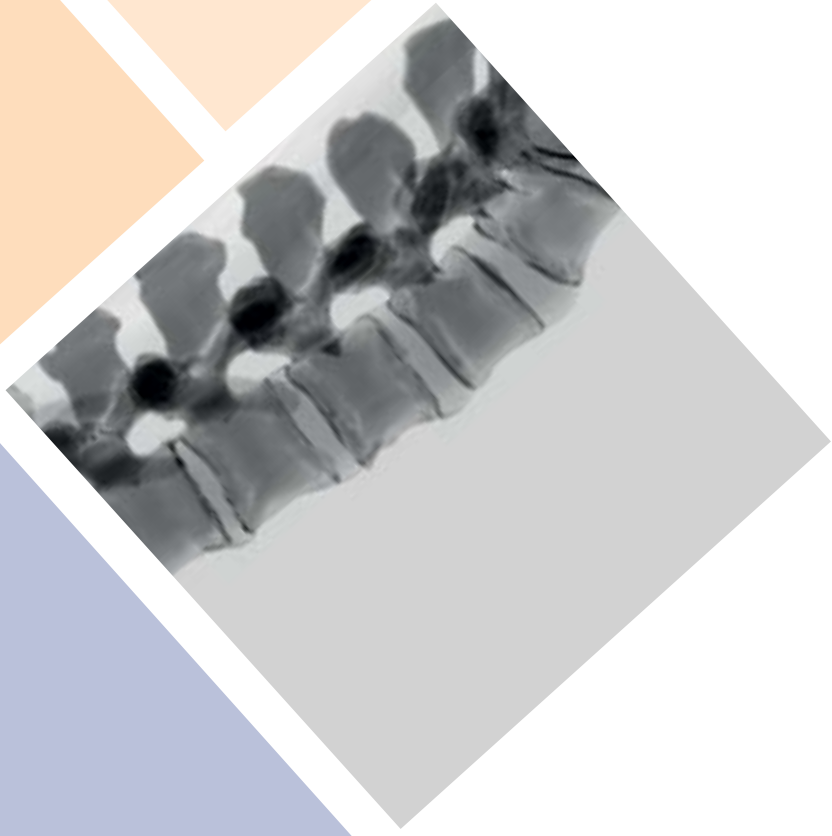
PHACON
3D LIFE MODELING & SIMULATION

USER MANUAL

PHACON LUMBAR SPINE TRAINER



DISCOVER THE INTRODUCTION
IN OUR PHACON TRAINER:

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IMPORTANT INFORMATION

The words **WARNING**, **CAUTION**, and **NOTE** have special meaning and should be reviewed.

WARNING:	Disregarding WARNING information may compromise the safety of the patient and/or healthcare staff and may result in injury.
CAUTION:	Disregarding CAUTION information may compromise product reliability and may result in damage.
NOTE:	NOTE information supplements and/or clarifies procedural information.
⚠	A triangle with an exclamation point alerts the healthcare professional to read and understand the accompanying instructions, especially the operating, maintenance and safety information.

INTENDED USE

The PHACON Trainer is intended to be used by healthcare professionals for education and training purposes only. The trainer allows surgical residents and other healthcare professionals to use actual surgical instruments on three dimensional (3-D) anatomical models in a simulated surgical setting.

The PHACON Trainer and PHACON Patient can only be used in the manner described in the manual, otherwise serious personal injury may result.

If you are not sure whether parts are damaged or faulty, or if you have any questions regarding the use, please contact PHACON Support (Phone: +49 (0)341 47 83 97 32 or support@phacon.de) in immediately.

USER SAFETY

⚠ WARNINGS:

• Only trained and experienced healthcare professionals should use this equipment. Before using any system component, or any component compatible with this trainer, read and understand the instructions. Pay special attention to WARNING information. Become familiar with the trainer components prior to use.
• Upon initial receipt and before each use, operate the equipment and inspect each component for damage. DO NOT use any component if damage is apparent. *See the Periodic Maintenance section.*
NOTE: If you need more information:
Phone: +49 (0)341 47 83 97 32
Mail: support@phacon.de

ACCESSORY INFORMATION

⚠ WARNINGS:

• Use only PHACON-approved components and accessories, unless otherwise specified. DO NOT modify any component or accessory.

DESCRIPTION	REF
• PHACON Lumbar Spine Trainer “Schumann”	[S-00080-C]
- 1 body	[RE-00077]
- 1 torso with skin an muscle	[SP-dc-flesh]
- 1 navigation camera	[RE-00019]
- 1 manual	[ZS-00013]
- 1 instrument tracker set for Spine surgery	[RE-00017]
- 1 notebook with PHACON simulation software	[RE-00011]
- 1 USB 3.0 hub	[RE-00013]
- 1 computer mouse	[RE-00012]
- 1 notebook carry case	[RE-00007]
- 1 USB foot switch	[RE-00034]
- 1 Lumbar spine patient “Schumann”	[SP-da]
- 1 Live-camera with ball-head	[RE-0005]
- 1 calibration tool - prone	[SP-do]
- 1 calibration tool - lateral left	[SP-dp]
- 1 calibration tool - lateral right	[SP-dq]

NOTE: If you need more information or a complete list of accessory information, contact your PHACON sales representative at +49 (0)341 47 83 97 32.

DESCRIPTION

The PHACON Lumbar Spine Trainer is a modular system.
This trainer consists of a body model connected to a laptop computer configured with special training system software. The body model is designed to receive a disposable lumbar spine insert and the suitable torso with skin and muscle. The inserts are intended to be used for a single surgical simulation and discarded after use. The trainer provides visual and tactile feedback through the laptop computer’s graphical user interface (GUI) and the use of real surgical instruments.

The body model is also equipped with a navigation camera. The camera used in combination with the navigation feature provides the capability to monitor the tip location of a pointer or surgical instrument.

Through the use of navigation the trainer is able to detect whether the surgical instrument has made contact with a critical anatomical risk structure or is in a critical area. Then a visual and audible signal is provided during the simulation.

The training system software will record the duration of the training simulation, the type of risk structure injured, and the number of risk structures injured. After the training simulation, this information may be viewed and statistically evaluated.

OTHER GENERAL WARNINGS

Please put the trainer and laptop on a firm surface that can not tilt.
Do not place the laptop with its power cable directly to the PHACON assistant with his skull and PHACON patient. Water injection risk!

If you find that the insulation on the cables is loose, please replace it and do not use any damaged parts.

Always use your surgical instruments according to the intended use of the manufacturer.

Cases and packaging

⚠ WARNINGS:

The suitcase and the packaging foils are not toys and not suitable for children. There is a risk of suffocation!
The packaging material is not suitable for eating.

Packaging waste is not to be disposed of via normal household waste. Please think about your environment.

There is a risk of tripping due to loose cables.
There is a risk of strangulation due to cables.

Please do not use any liquid food or drink during use.

BUTTONS

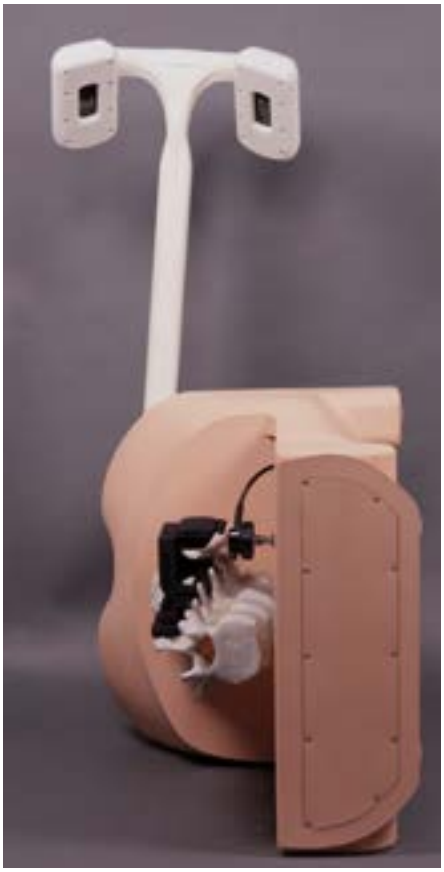
Button	Definition	Button	Definition
Main Menu	Access the MAIN MENU screen to view major menu options.	Exit	Close and exit the program.
Simulation	Access the SIMULATION screen to begin a training session.	End	End the SIMULATION or training session.
Results	Access the RESULTS screen to view and compare the training session data.	Help	Access the HELP dialog box to view instructions for use information.
About	Access the ABOUT dialog box to view hardware and software information.	View	Access the VIEW panel to select or modify a screen view or perspective.
OK	Accept inputs, changes or selections and return to the previous screen.	Status	Access the STATUS panel to view the number of injured risk structures during a training session.
Cancel	Reject inputs, changes or selections and return to the previous screen.	X	Access the coronal view of the CT data as a full screen display.
Create New User	Access the CREATE NEW USER dialog box to create a new user profile, user name and password.	Y	Access the coronal view of the CT data as a full screen display.
Setup	Access the SETUP panel to perform calibration of an instrument or patient.	Z	Access the transversal view of the CT data as a full screen display.
Recalibrate	Initiate the calibration of instruments or patient from the SETUP panel.	3D	Access the 3-D view of the Patient and as a full screen display.
Use default values	Select the factory default calibration set-tings programmed for the instrument or Patient.		Return to the default 4-windowpane screen view.
Start	Begin a SIMULATION or training session from the SETUP panel.	Classic	View a navigated instrument without the virtual camera option.
Resume	Continue a SIMULATION or training session from the SETUP panel.	Rotate Patient	Rotates/Flips the 3D model and X-Ray images of the patient by 180°
Graph	Access and view the training session results in a graphical format.	Navigation	Enables/Disables the navigation. If the X-Ray-View is enabled, enabling the navigation will switch the view to the default CT/3D view.
Table	Access and view the training session results in a tabular format.	X-Ray	Disables the navigation and switches the view to the X-Ray-View of the patient. Every click on X-Ray creates a new snapshot of the current position of the tool within the X-Ray images.
Extend Tool	Virtual extension of the instrument.		
Tutorial	Open a tutorial.		
Add Graph	Add a graph in the result screen.		
English	Select or toggle the language for the software (German/ English).		
Reset	Reset the default settings for brightness, contrast and slice position in the 4 windowpane in the simulation mode.		

OPERATE THE TRAINER

OPERATE THE TRAINER

SET UP THE OPERATION-AREA

- Place the torso in desired position.
- Mount the spine in the torso.
- Insert the navigation camera
- Position the live-camera.



SET UP THE NOTEBOOK

- Connect navigation cameras directly to the two left USB ports on the notebook.
- Connect the mouse and the live-camera via USB splitter to the notebook on the right side.

ENTER THE APPLICATION

- Double click on the “PHACON Trainer” icon located on the notebook desktop to log into the training program.

- Type in your user name and password.

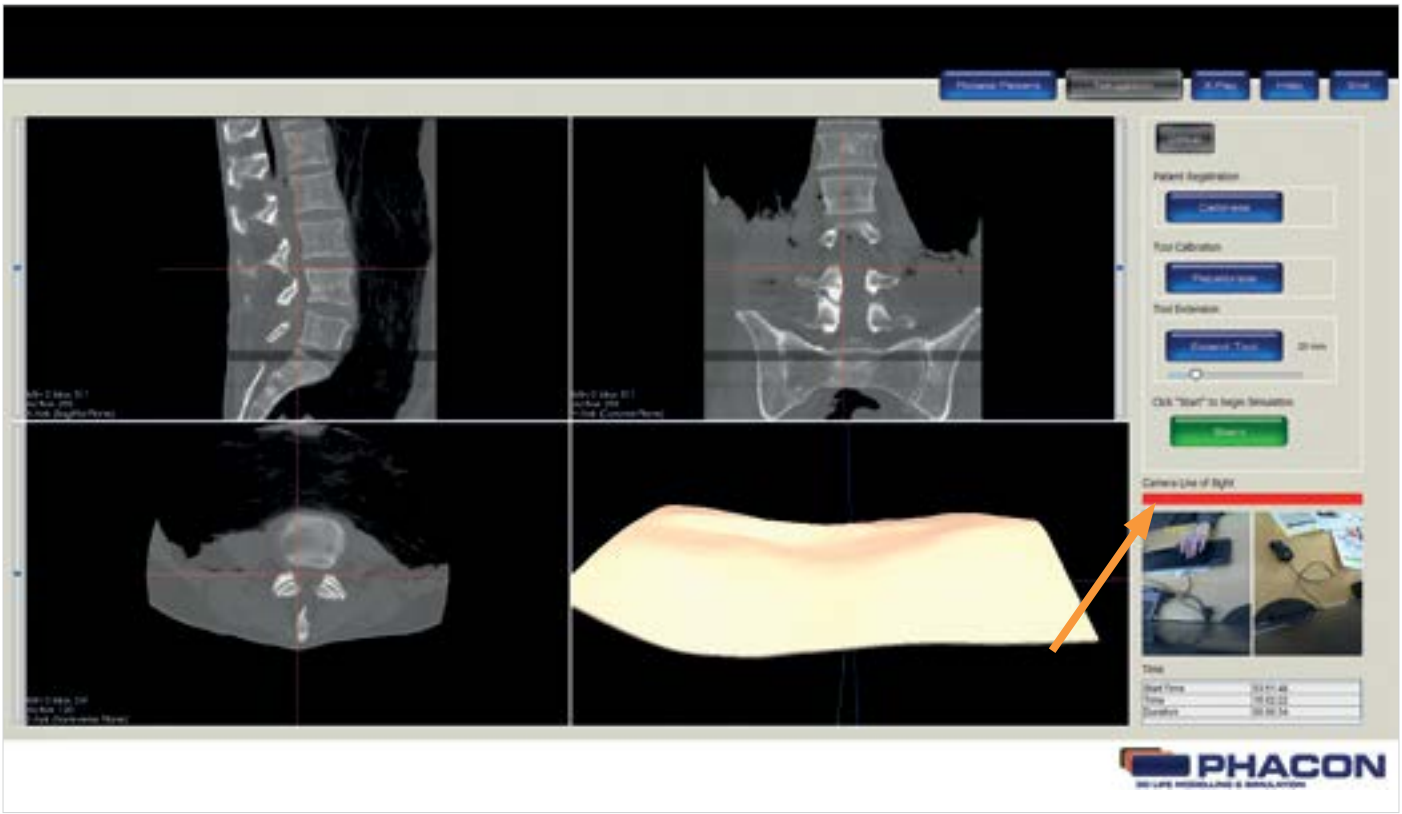
  If you do not have an account you can create one or log in as guest.

• To create a new user, fill in your first and last name. Define a username, type in a password and re-type your password. The other fields are optional.

• From the MAIN MENU screen, click the SIMULATION button.

PERFORM SETUP FOR NAVIGATION

- Click on the SETUP button to perform patient and instrument calibration for optimal navigation results.

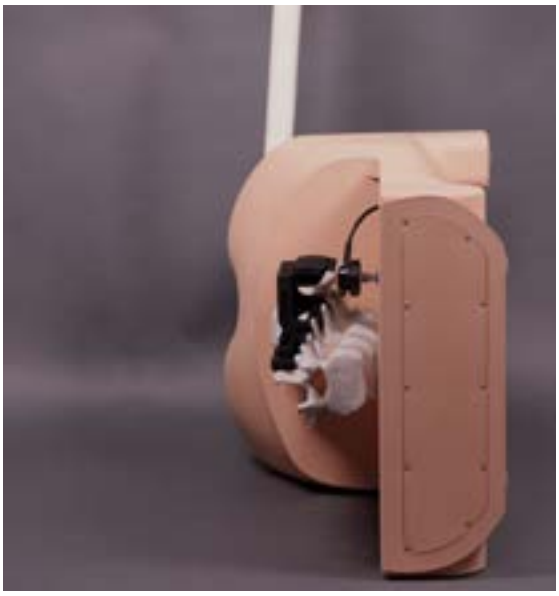


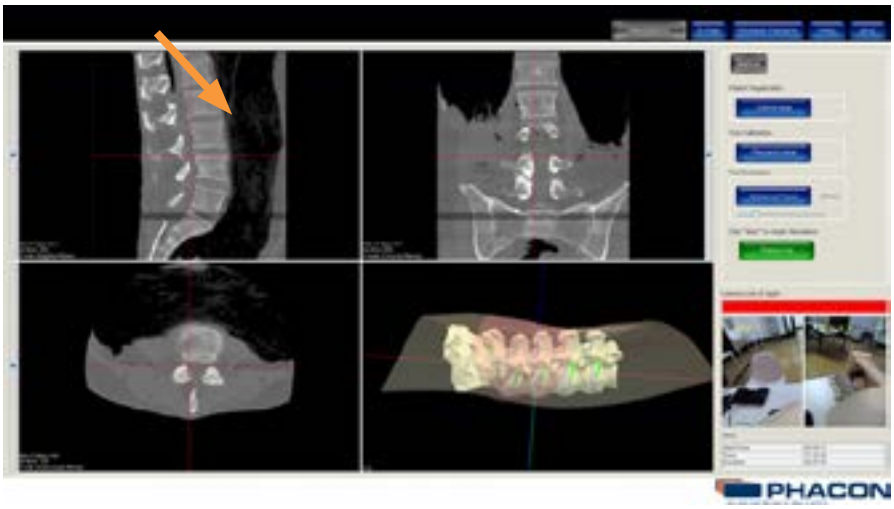
TOOL DETECTION INDICATOR

green = if an instrument is detected.
yellow = if multiple instruments are detected.
red = if no instrument is detected.

PERFORM PATIENT CALIBRATION / REGISTRATION

- Put the appropriate calibration aid on the spine (each calibration aid lies on the vertebrae 2, 3, 4 - on the facet joint and the dorsal process).
- Click the CALIBRATE button.





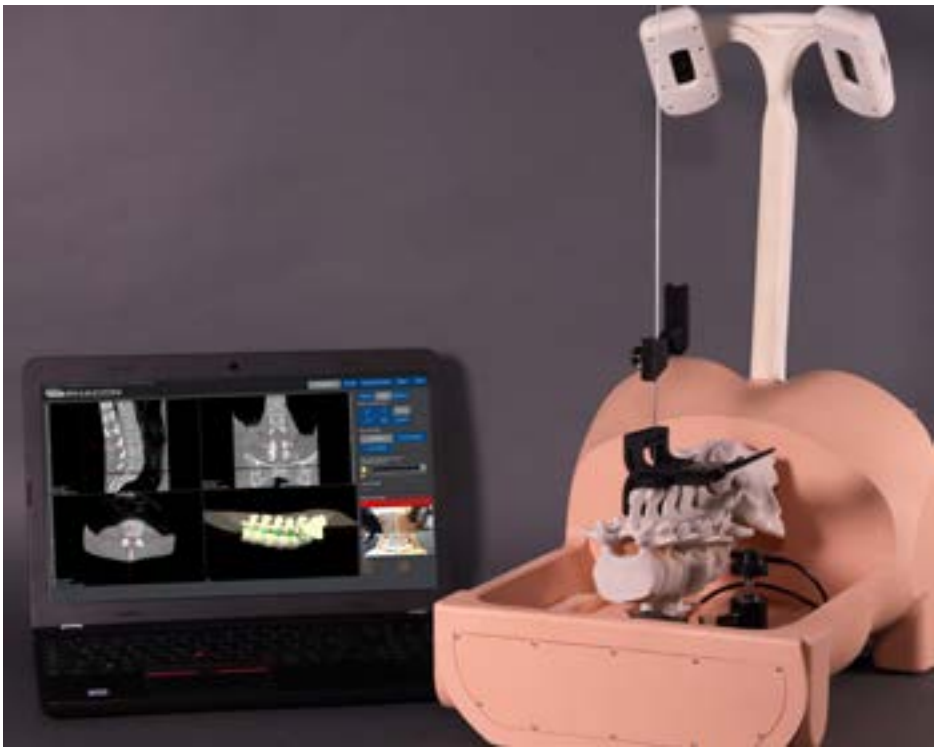
NOTE

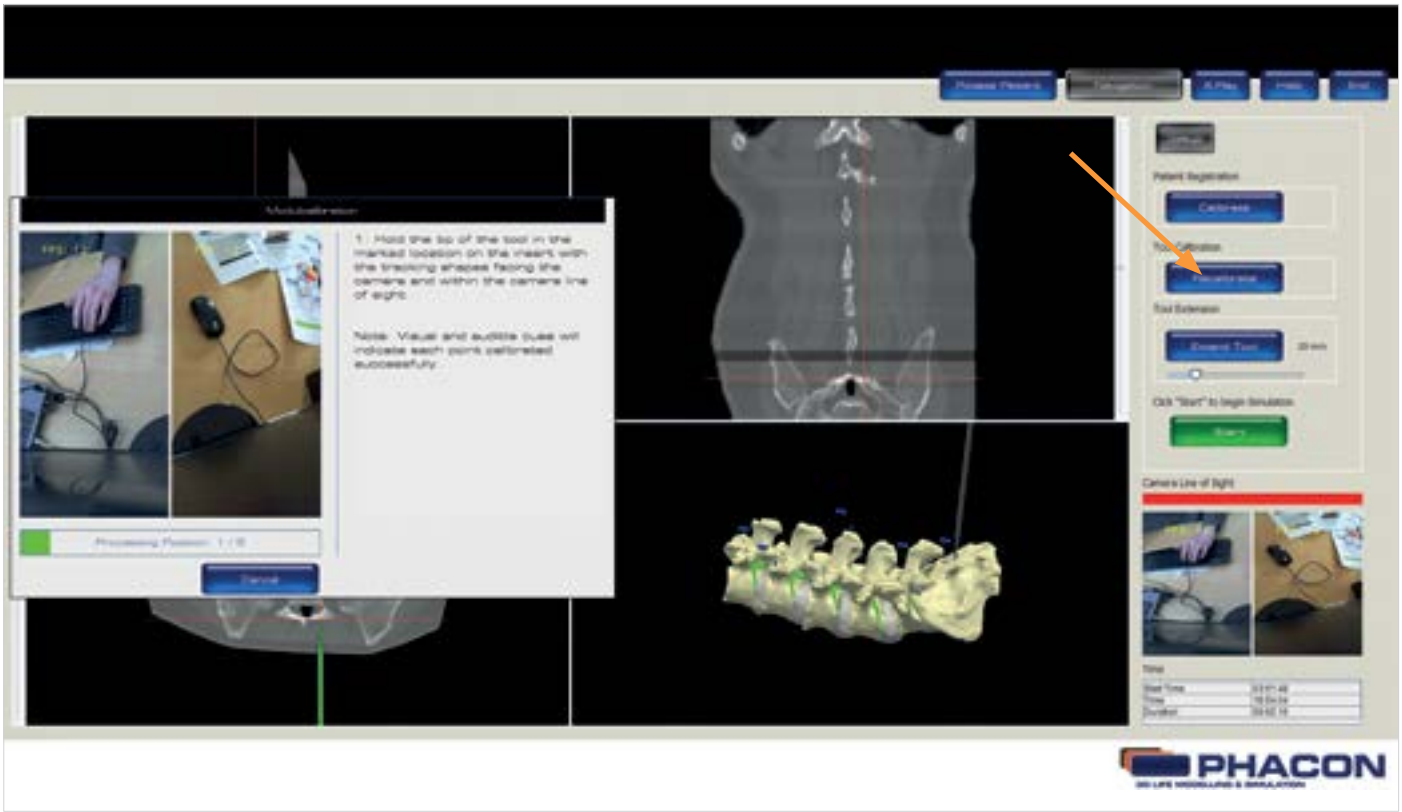
The spine patient calibration is performed to align the spine coordinate system with the coordinate system of the pointer or your tool.
The five calibration points are visible on the Spine Patient and within the 3-D windowpane during calibration. Progress bar provided in the Patient Calibration dialog window as visual feedback during the calibration process.

An INFORMATION MESSAGE pop-up will appear to indicate the successful completion of the calibration procedure. Click on the START/ RESUME button to begin or continue the simulation, respectively, if desired.

PERFORM TOOL CALIBRATION

- Attach the appropriate tracker firmly to the instrument.
- Put each instrument into the correct hole in the calibration aid.
- Click on the button “RECALIBRATE” under Tool Calibration.





NOTE

- Repeat the process for each instrument separately by putting it in the right hole (Pointer in “RE”, Working Tube in “WT”, Reamer in “RE”, Guiding Rod in “GR”, Needle in “NE”).
- Each instrument must be calibrated before the instrument may be used within the navigation.
- The pattern of the calibration aid must be covered while calibrating the instuments
- To apply navigation, make sure the appropriate tracker is installed on your tool.

ALWAYS make sure the round shapes of the pointer or instrument tracker are aligned and visible to the navigation camera’s line of sight during any calibration.

The dialog box is showing which instrument will be calibrated. To calibrate another instrument, the selected tool can be exchanged during the shown time in seconds. The software automatically detects the current instrument in use. The tracker must not be moved on the instrument after the calibration.

SELECT A VIEW DURING SIMULATION

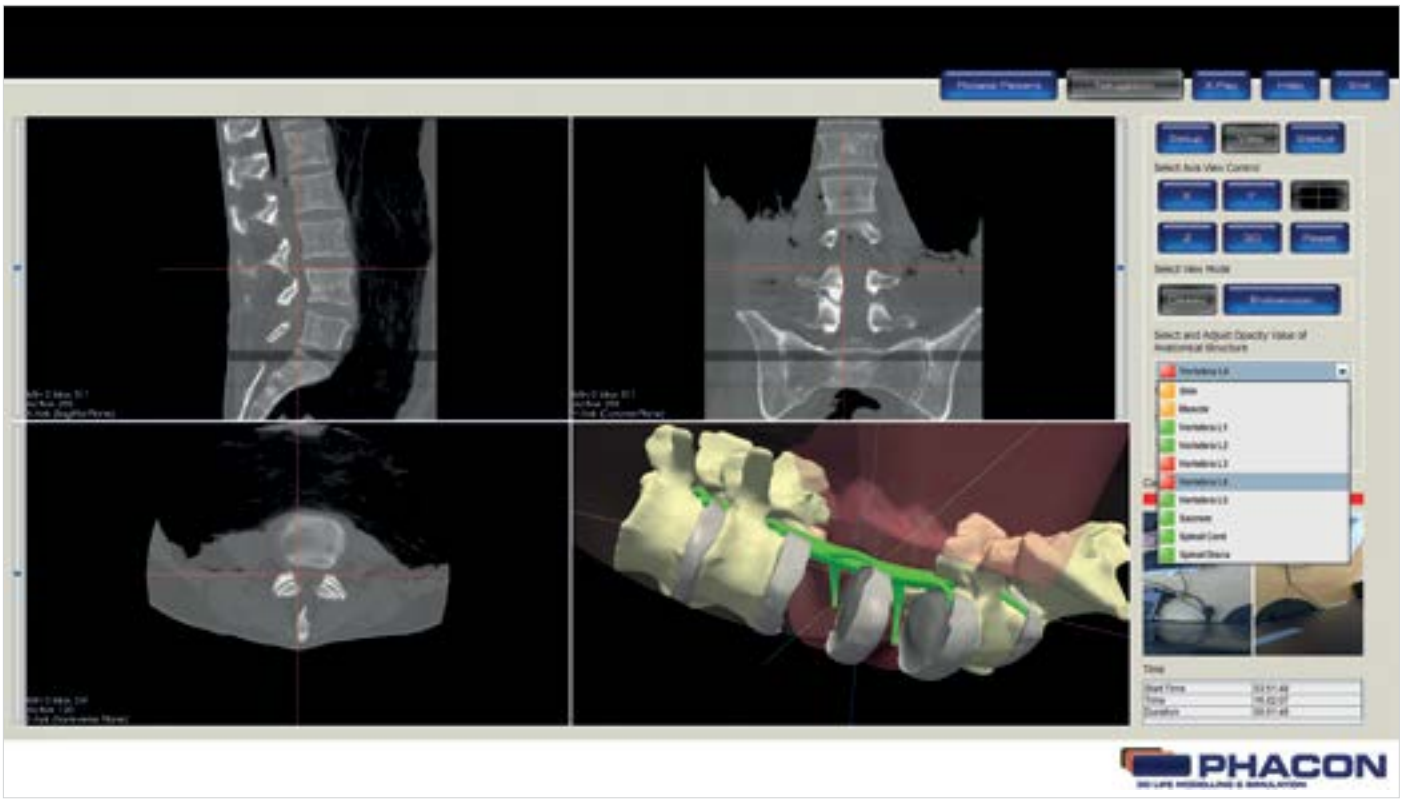
From the panel menu bar, click on the VIEW button to access the VIEW panel options including AXIS VIEW CONTROL, VIEW MODE, and the OPACITY VALUE of an ANATOMICAL STRUCTURE.

NOTE

The hair cross is visible within each windowpane represent the location of the pointer, or instrument tip when using the navigation.

SELECT THE AXIS VIEW

- Click on the X, Y, Z, or 3-D button to access the X, Y, Z, or 3-D surface windowpane in a full screen view.
- Click on the four-quadrant windowpane button to return to the default fourquadrant screen view.
- Click on the RESET button to return the X, Y, Z and 3-D view, if modified, to their original default settings.

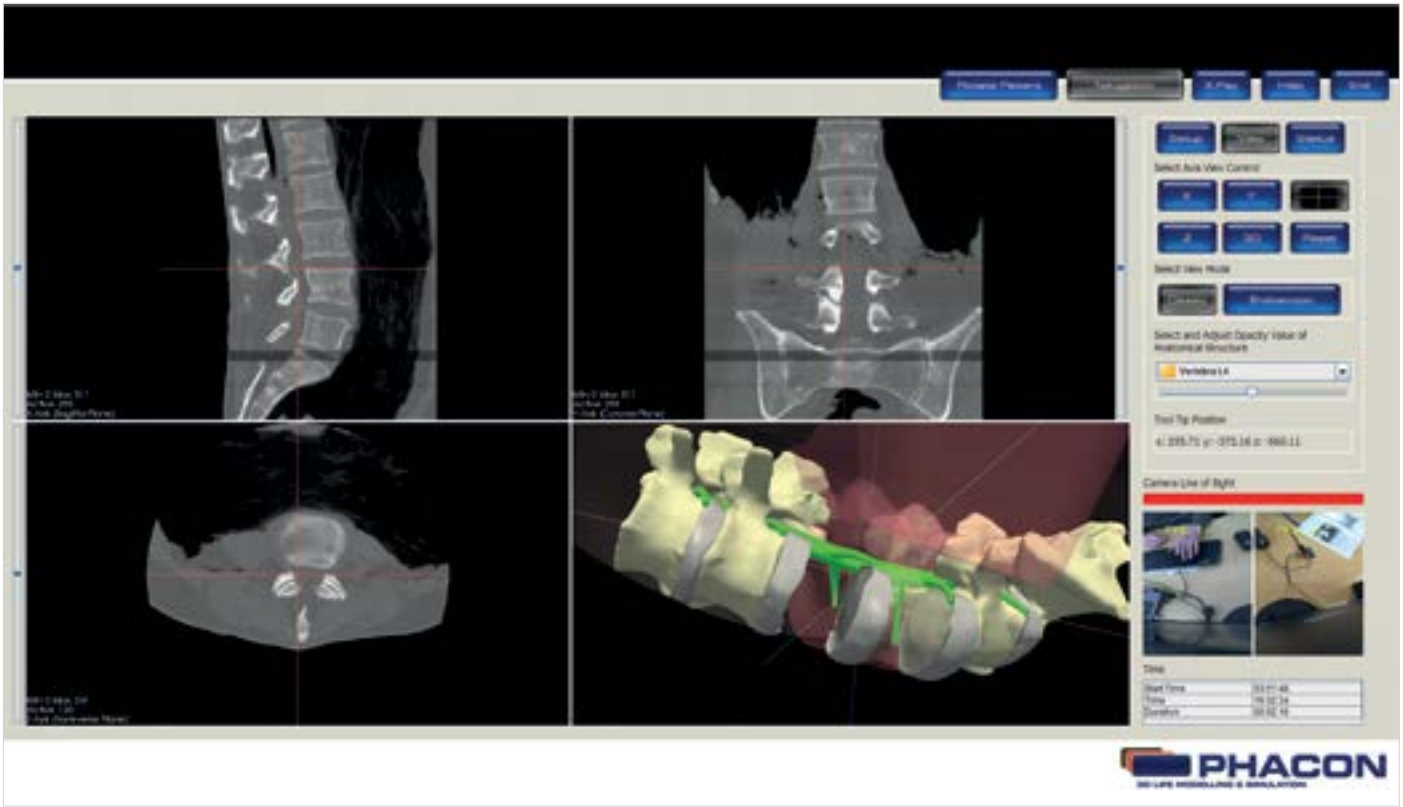


ADJUST THE QUALITY OR PERSPECTIVE OF THE X, Y, AND Z WINDOWPANE DISPLAY

- To adjust the brightness click into the desired windowpane, hold down the left mouse button and move the mouse up and down.
- To adjust the contrast click into the desired windowpane, hold down the left mouse button and move the mouse left and right. The middle mouse button may also be used.
- To pan, click on the desired windowpane, hold down the shift key and left mouse button, and move the mouse up and down or left and right. The middle mouse button may also be used.
- When using the navigation, the CT image slice is selected automatically based on the tip location of the pointer, or manual instrument. To view different slices of a specific X, Y, or Z perspective, move the slider of the appropriate windowpane.

ADJUST THE PERSPECTIVE OF THE 3-D WINDOWPANE DISPLAY

To rotate, click on the 3-D windowpane, hold down the left mouse button and move the mouse down. The mouse wheel may also be used.



NOTE

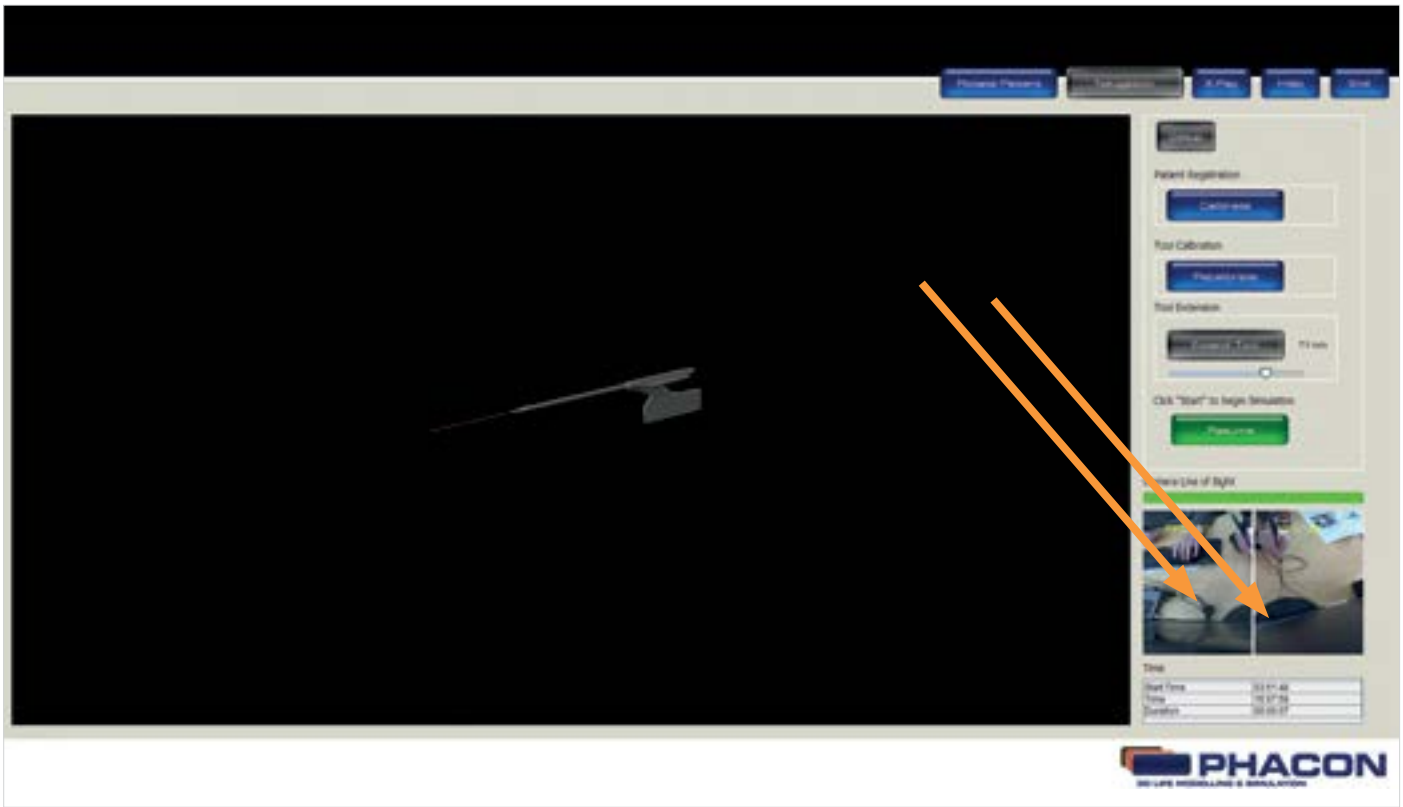
The ENDOSCOPIC view button allows you to use a navigated tool as a virtual endoscope.

VIRTUALLY EXTEND THE TOOL

NOTE

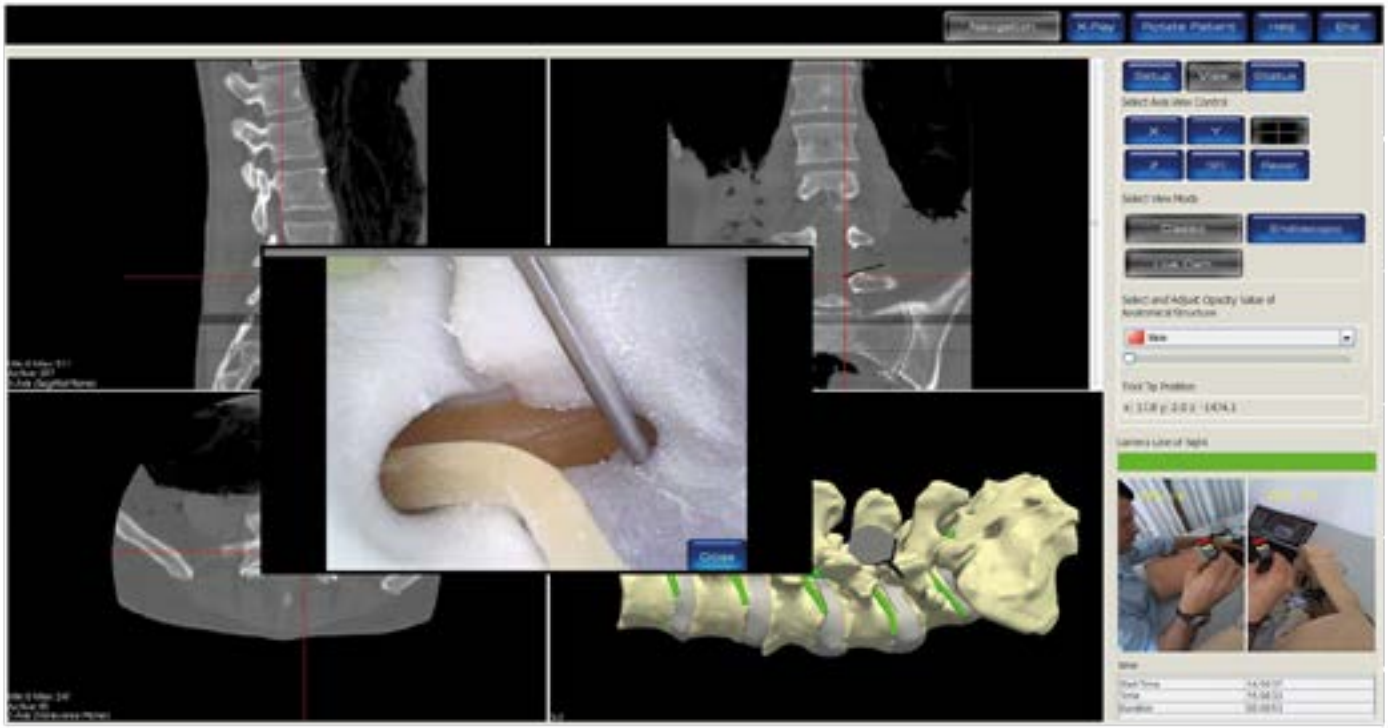
Tool extension can be performed to show the tool path during the simulation.

To virtually extend the tool in the 3-D windowpane, click on the EXTENDED TOOL button and move the slider to variable extend. The virtual tool extension is shown as a red line in the 3-D windowpane.



SELECT THE LIVE-CAM VIEW

By clicking the “Live-Cam” button, you will get into the live view mode. A separate and adjustable window occurs, which is showing the live view of your area of interest. Therefore you have to fix the camera in the desired position. The camera is freely positionble and inclinable by using the ball-head.



NOTE

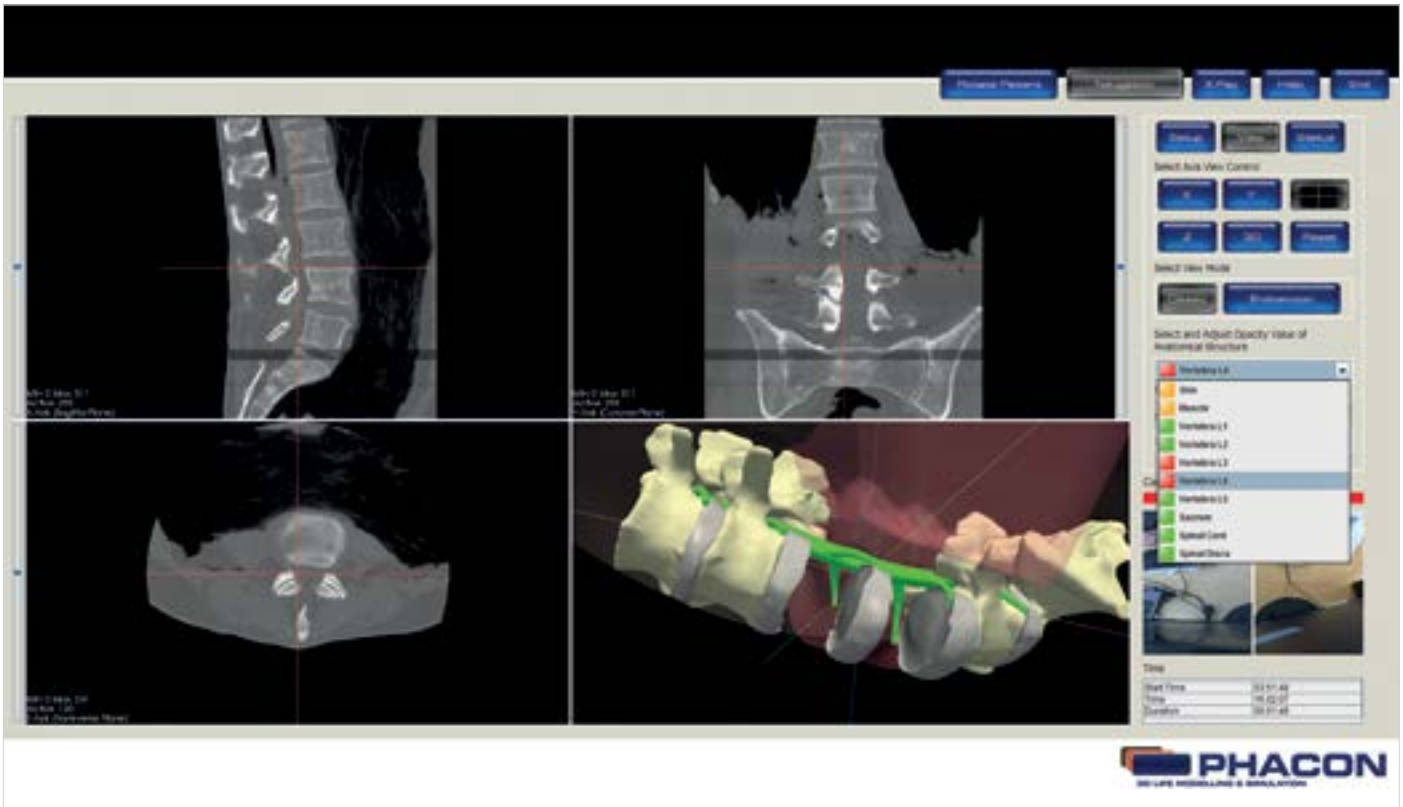
You can freely adjust the position and size of the “Live-View” window on your screen (including on a different monitor if you are running multiple monitors).

The window settings will be saved until the end of your session.

ADJUST THE OPACITY VALUE OF AN ANATOMICAL STRUCTURE

The opacity of a specific anatomical structure may be changed to provide better visualization within and behind the Patient.

- Click on the drop-down list and select the desired anatomical structure.
- Move the slider to change the opacity of the selected structure or click on the square button next to the selected structure to change opacity in steps „off“ (red), 25 % (orange), 75 % (yellow), „on“ (green).



NOTE

Transparencies will be saved and will be reloaded when restarted.
At the end of the list for anatomical structures there is a reset button that will put all structures back to full visible.

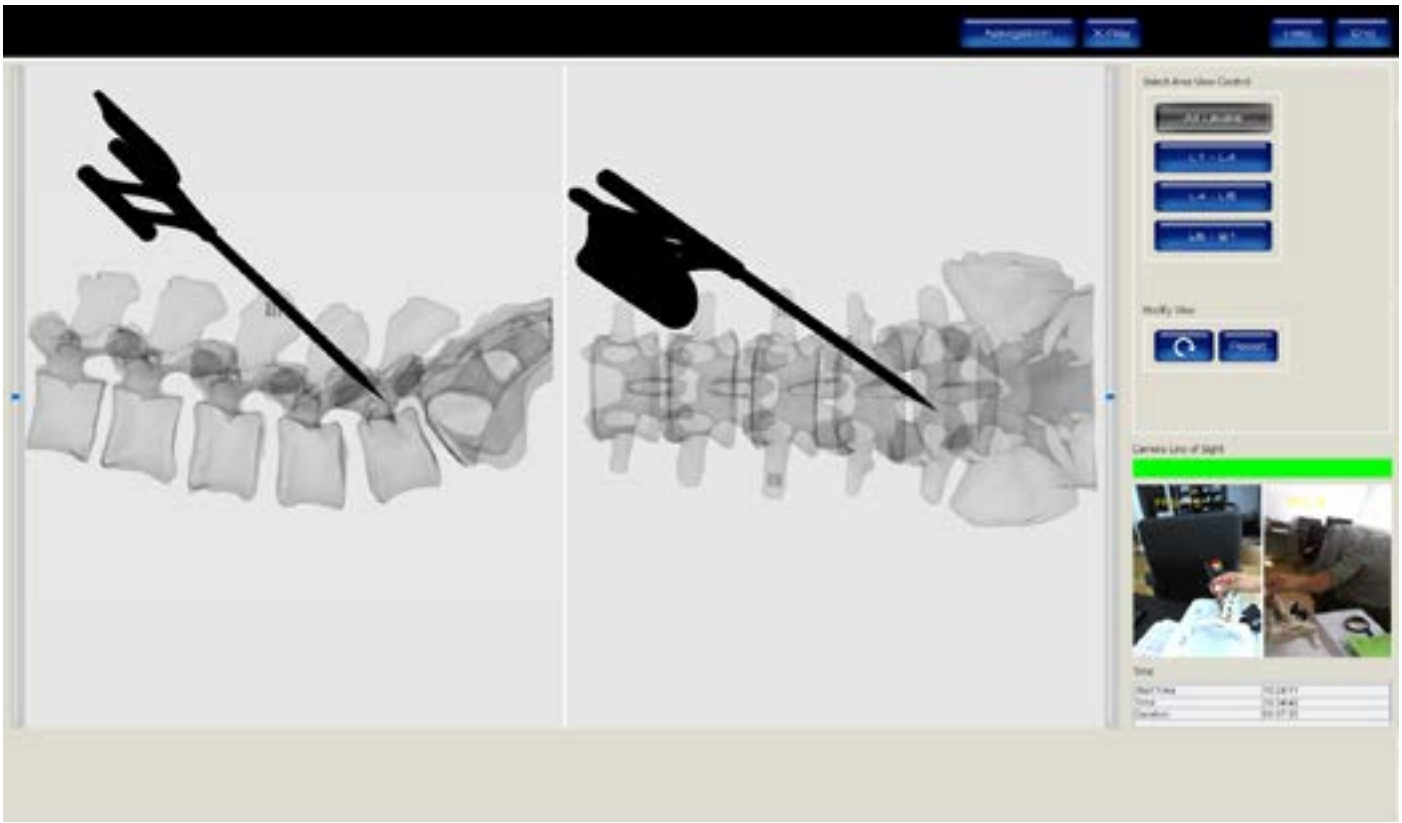
X-RAY FUNCTION

NOTE

The software has a virtual X-ray function that enables the user to create an X-ray image of the exact location of the instrument in relation to the spine structure.
To operate the X-ray function use the right foot-step. To get back to the regular view of the navigation use the left foot switch. If you press the right foot-step again in X-ray view a new shot is taken.

NOTE

You can create the X-ray image also by pressing the button F6 on your keyboard or by pressing the X-RAY button located within the software. To switch back to the navigation press F5 on your keyboard or click on the button NAVIGATION.



NOTE

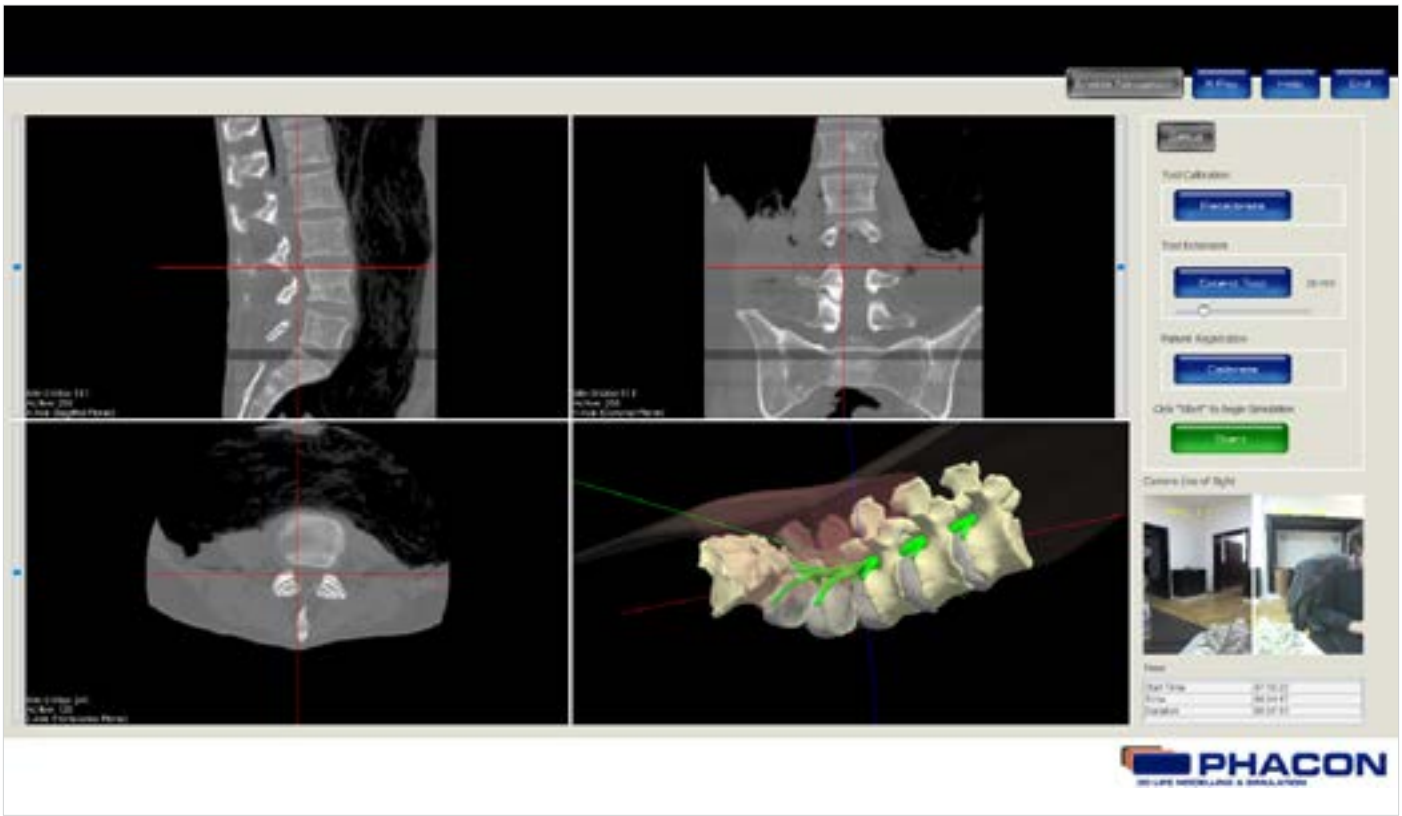
You can adjust the contrast of the X-ray image by holding the left mouse button and moving the mouse up and down on the image.

DETECTION OF THE SPINAL CORD

NOTE

The software works with a detection function. When the instrument gets close to the spinal cord an acoustic signal occurs. The closer you get to the spinal cord the more rapid the signal appears.

Besides the acoustic signal, the spinal cord changes color from green to red.



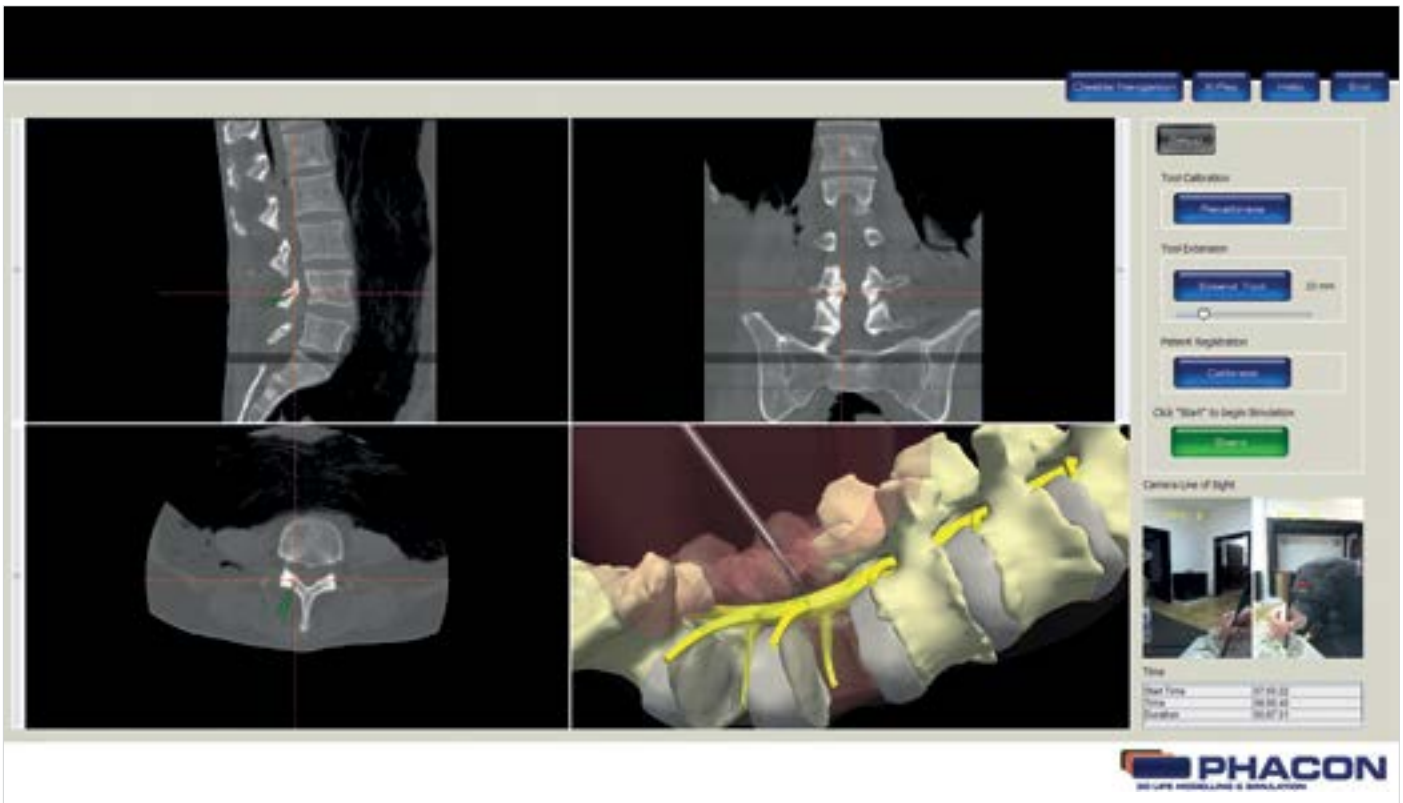
NOTE

The green color means there is a safe distance to the spinal cord.

DETECTION OF THE SPINAL CORD

NOTE

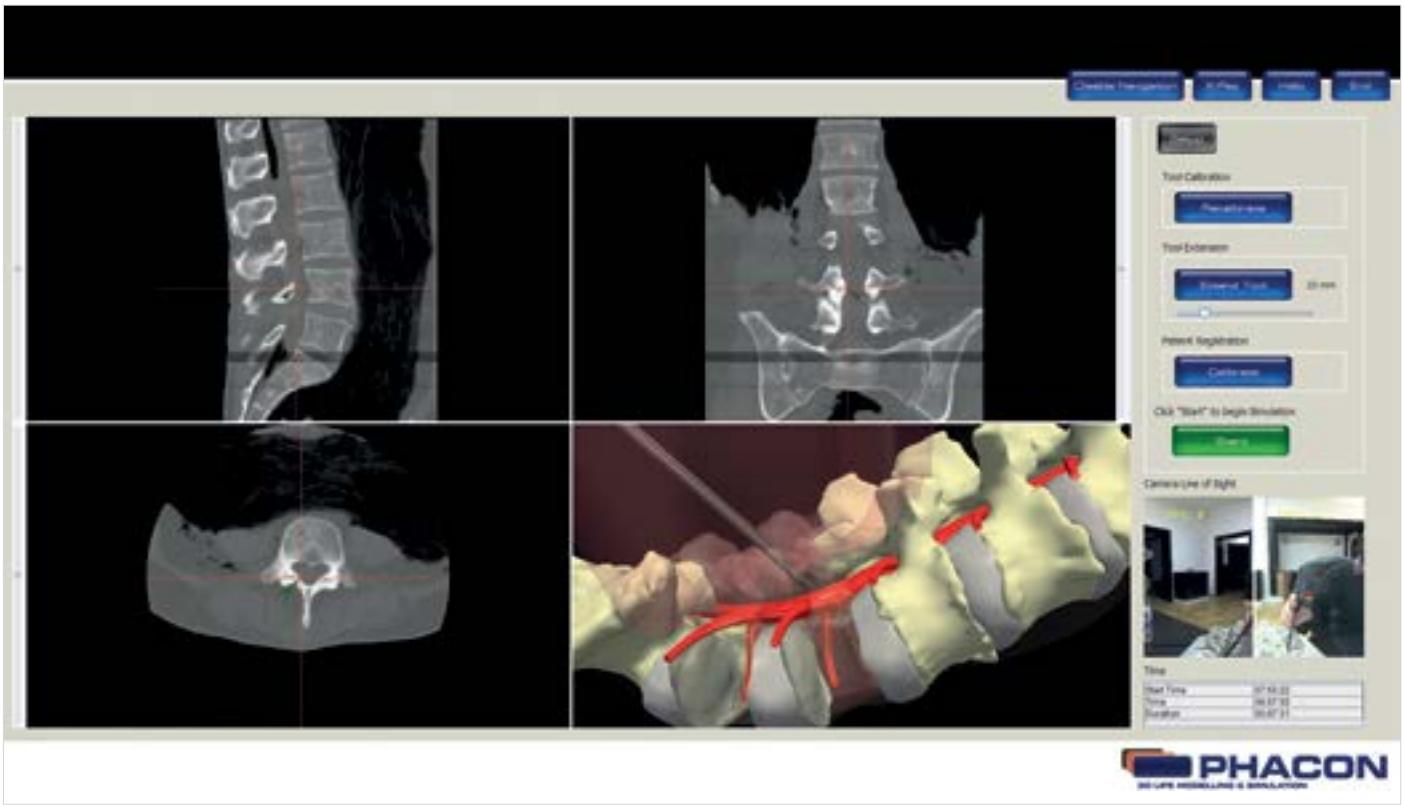
The yellow color signals the tip of the instrument is very close to the spinal cord.
This is a dangerous distance and an injury might occur.



DETECTION OF THE SPINAL CORD

NOTE

The red color signals an injury of the spinal cord.



TROUBLESHOOTING

PROBLEM	CAUSE	ACTION
The software application locks up.	The application is experiencing an internal malfunction.	Press the CTRL/ALT/Delete buttons simultaneously to perform a soft reboot. Press the ON/OFF button to perform a hard reboot.
The navigation system is not functioning or is not functioning properly.	The camera lens is covered with debris.	Clean the camera lens.
	An unobstructed line-of-sight does not exist between the navigation camera lens and the tracker.	Make sure the line-of-sight between the navigation camera lens and the tracker is unobstructed.
	An other additional tracker is in the line-of-sight of the camera.	Remove the additional tracker from the navigation camera line of sight.
The navigation system is not accurate based on visual indications.	The pointer, drill, or instrument is out of calibration.	Recalibrate the pointer, drill, or instrument. See the To Perform Tool Calibration section.
	The Patient is out of calibration.	Recalibrate the Patient.
The slice selection slider bar does not work.	A tracker is within the navigation camera line of sight.	Remove the tracker from the navigation camera line of sight.
The instrument does not appear in the software.	The pattern on the instrument tracker is not in the line-of-sight of the camera.	Hold the tracker on the instrument into the line-of-sight of the camera, while the pattern on top of the tracker is facing to the camera.
The camera does not detect the tracker on the instrument, although the pattern is facing to the camera.	The detection of the tracker can be disturbed by very bright light shining on the camera or on the pattern of the tracker.	Make sure the light shining on the tracker or camera is reduced.
The virtual 3-D model does not appear in the 3-D-view.	During the endoscopic mode: An other additional instrument tracker is in the line-of-sight of the camera.	Remove the additional instrument tracker from the line-of-sight of the camera.
	The Patient calibration is not correct.	Recalibrate the Patient in the Setup menu.
The virtual 3-D model can not be moved.	The endoscopic mode is enabled.	Change to the Classic mode in the view panel options.
The virtual 3-D model has a delayed reaction.	The notebook is accu driven. The power supply is not connected.	Connect the power supply.
During scrolling through the CT-images, always the same area is shown.	The view mode ENDOSCOPIC is enabled.	Change to the Classic mode in the view panel options.
	An instrument tracker is in the line-of-sight of the camera in the classic mode.	Remove the tracker from the line-of-sight of the camera.

TROUBLESHOOTING

PROBLEM	CAUSE	ACTION
Camera is not recognized by the software.		Check if camera is connected directly to the laptop. If connected to the USB-HUB problems might occur.
Camera arm can not be fixed.		Untight adjusting screw, repeatedly turn the hinged bracket counter clockwise several times. Fix again the adjusting screw.
If the navigation does not work.		Please check if the navigation button is displayed in “grey” (navigation is activated), “blue” mean navigation is deactivated.

ERROR MESSAGES

MESSAGE	CAUSE	ACTION
The entered group name already exists in the system. Please enter a unique group name.	The entered group name is already used.	Enter a new group name into the system (maximum of 150 characters).
The group name field was left empty. Please enter a unique group name.	The required field data was not provided.	CEnter a group name (maximum of 150 characters).
A maximum of 150 characters is allowed.	The entered group name consists of more than 150 characters.	Enter a group name with a maximum of 150 characters.
The LOGIN password or user name is/are incorrect. Please try again.	The LOGIN password or user name is/are incorrect.	Enter correct LOGIN password or user name. Pay attention to case sensitivity.
The calibration was not successful.	The instrument or patient calibration failed.	Recalibrate the instrument or patient or use the classic.
No camera found.	The camera is not connected to the notebook.	Make sure the camera is connected to the notebook and click on TEST CONNECTION.
In the setup menu: No camera found.	The camera is not connected to the notebook.	Make sure the camera is connected to the notebook and click on TEST CONNECTION.

STORAGE AND HANDLING

Store the equipment within the specified environmental condition value(s) throughout its useful life. See the Specifications section. To ensure the longevity, performance and safety of this equipment, use the original packaging materials when transporting this equipment.

RECYCLING

Follow the current local regulations governing environmental protection to recycle or dispose of electrical equipment at the end of its useful life.

SUPPORT

PHACON GmbH
Druckereistr. 11
04159 Leipzig
Germany

Tel.: + 49 (0)3 41 47 83 97 35
e-mail: support@phacon.de

www.phacon.de

PRODUCT WARRANTIES

PHACON END USER WARRANTIES

PHACON Surgical Training Hardware, Instruments and Disposables (collectively, the “Products”) are warranted to the original purchaser for a period of one year from the date of purchase. Products are warranted to be free from defects in material and workmanship. The foregoing warranty covers parts, labor, and travel if maintained and operated in accordance with manufacturer’s instructions for use. Abnormal wear and tear or damage caused by misuse or by failure to perform normal and routine maintenance as set out in the User Manual, or as demonstrated by an authorized PHACON or PHACON designee’s representative, is not covered by this warranty. In order to ensure safe operation of the Products, only PHACON accessories should be used. PHACON reserves the right to invalidate product warranties if Products are used with accessories not manufactured by PHACON or if repairs are performed by any party other than authorized PHACON repair personnel.

Except as set forth above, phacon makes no warranties with respect to the products or software, express or implied, including but not limited to, any warranties of merchantability or fitness for particular purpose.

The sole liability of PHACON in the event of a breach of the above warranties is the obligation to repair or replace the products as provided above.

In no event shall PHACON be liable for any damages resulting from or related to defects in the product or software, including, but not limited to, damages resulting from a loss of data or from a system or hardware non-compatibility or a system “crash” resulting from the use of the software.

In no event shall PHACON be liable for any indirect, special or consequential damages, lost profits or lost business information arising out of or related to the product or software even if PHACON has been advised of the possibility thereof.

Manufactureres declaration / Herstellererklärung

We declare that the following named device conforms with the requirements of the below marked EEC Directives. If the device is mounted in a machine the operation of that machine is forbidden until the machine itself conforms with the requirements of Safety of Machinery Directive 89/392/EEC with Appendix.

Hiermit erklären wir, dass das nachfolgend bezeichnete Gerät den Bestimmungen der unten markierten EG-Richtlinien entspricht. Wird es in eine andere Maschine eingebaut, so ist die Inbetriebnahme solange untersagt, bis festgestellt wurde, dass die Maschine in die das nachfolgend bezeichnete Gerät eingebaut werden soll, den Bestimmungen der EG-Maschinenrichtlinie 89/392/EWG mit Anlage entspricht.

Denomination:	Simulations system for lumbar spine surgery, Lumbar Spine Trainer
Bezeichnung:	Simulations-System für die Wirbelsäulenchirurgie, Lumbar Spine Trainer
Type:	Lumbar Spine
Typ:	Wirbelsäule

Identification number Produktnummer / Identification number: S-00082

Considered EEC-directives/ Berücksichtigte Richtlinien:	73/23/EEC Low voltage directive/ Niederspannungsrichtlinie

CE

PHACON GmbH
Druckereistr. 11

04159 Leipzig

Hendrik Möckel	Robert Haase
Geschäftsführer	Geschäftsführer

PHACON GmbH

Druckereistr. 11
04159 Leipzig, Germany

Tel. +49 (0) 3 41-47 83 97 32
Fax.+49 (0) 3 41-47 83 91 74

www.phacon.de