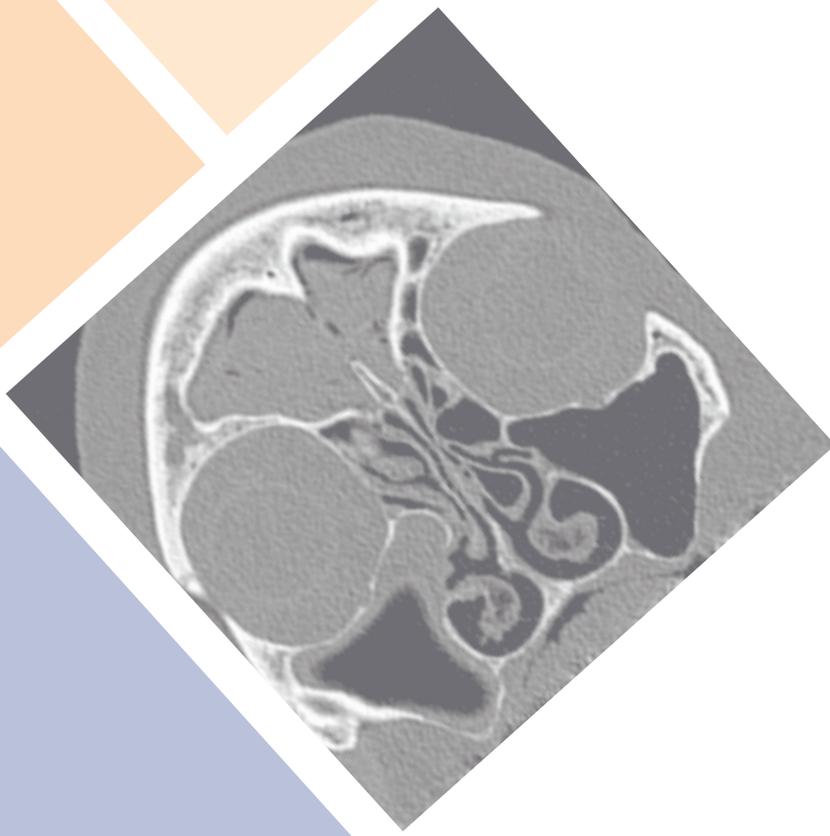
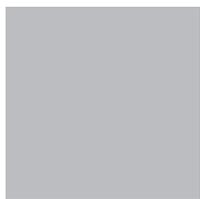
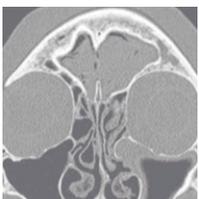
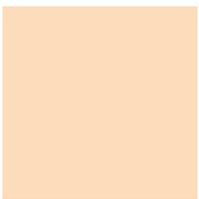
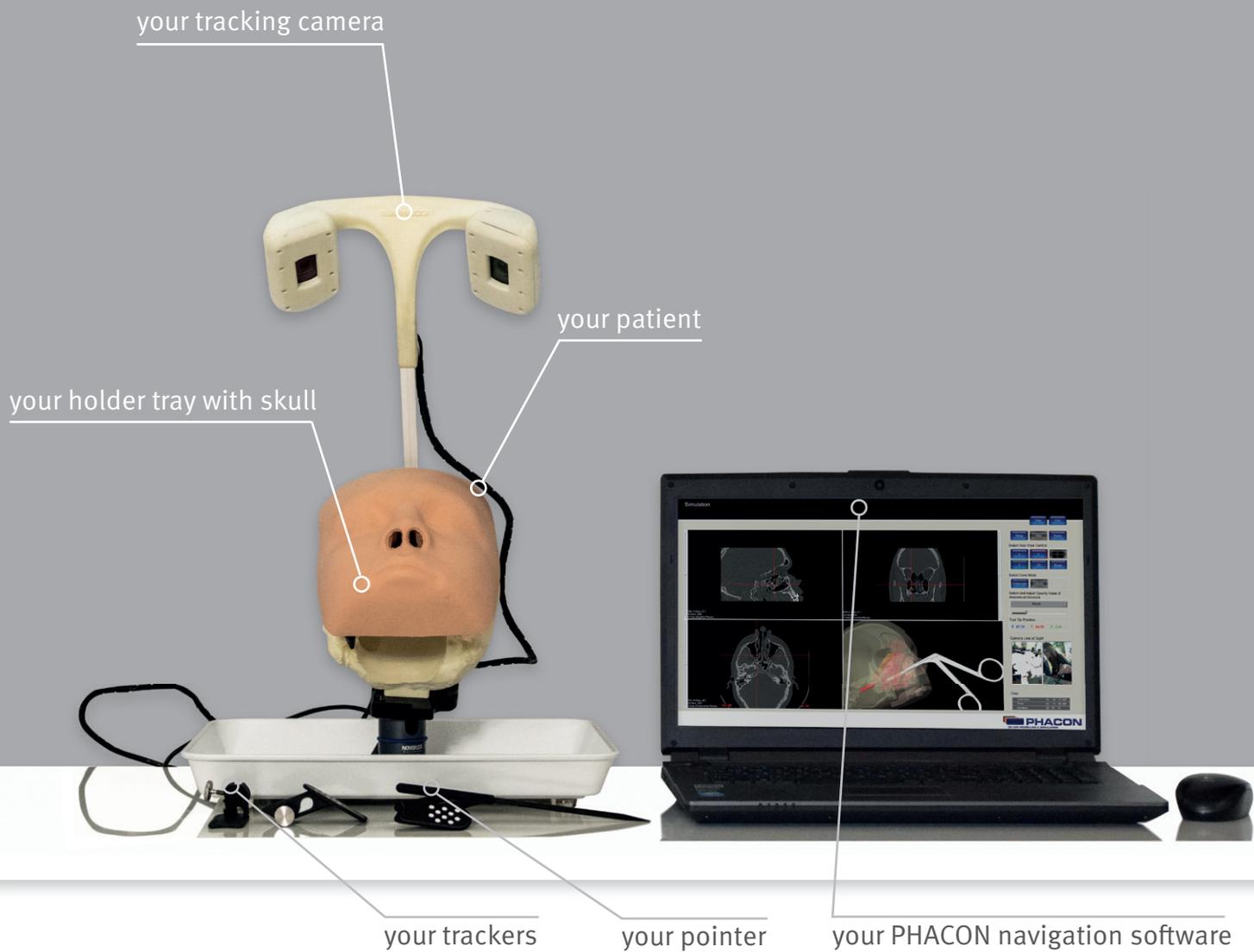


USER MANUAL

PHACON SINUS TRAINER







DISCOVER THE INTRODUCTION
IN OUR PHACON TRAINER:



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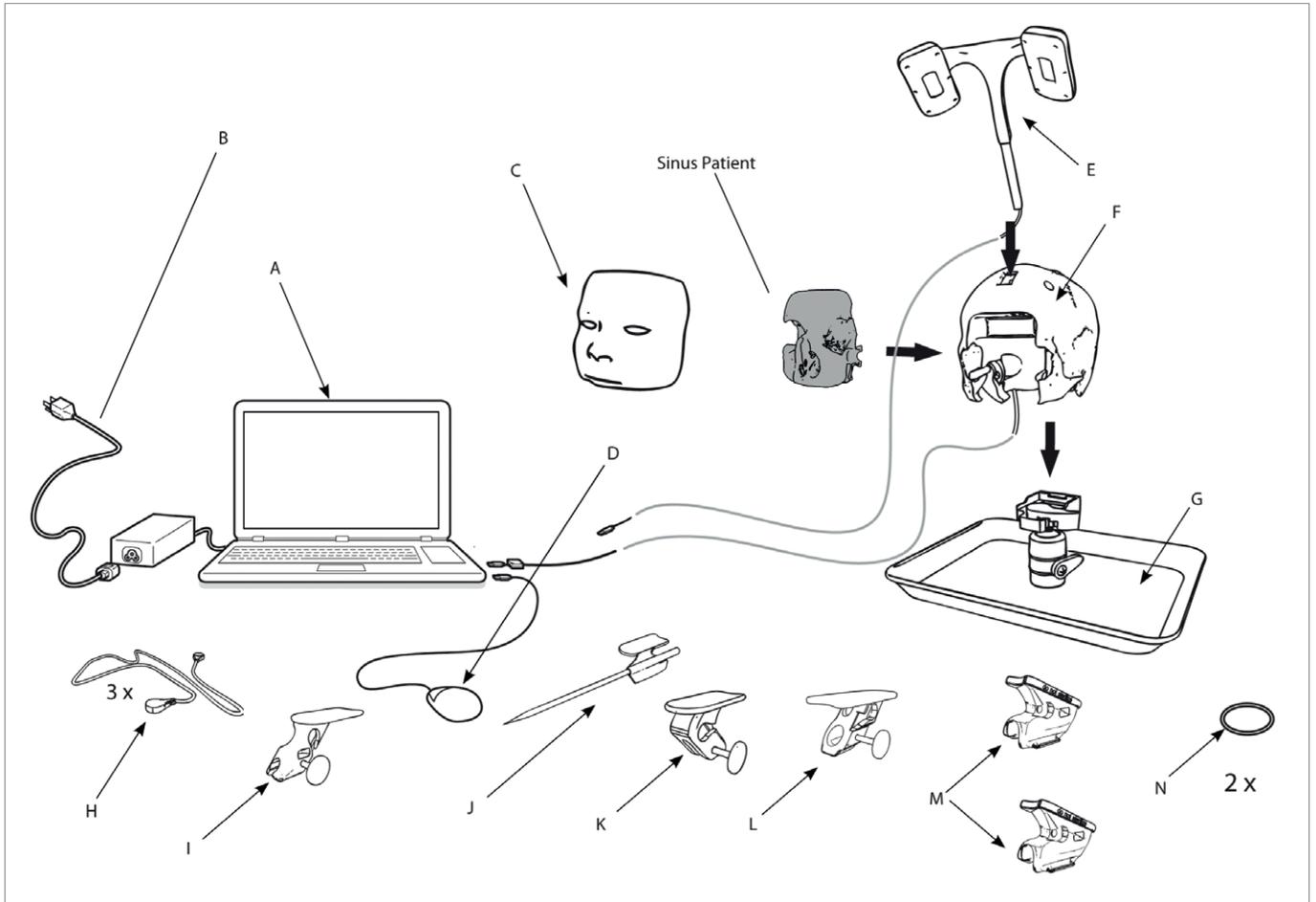
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TRAINER COMPONENTS



A Laptop with navigation software

B Power supply suitable for the voltage of the country

C Mask

D Mouse

E Navigation camera

F Sinus skull

G Holder Tray with adjustable skull fixation

H Ground cable (3x)

I Instrument tracker for ball probe

J Pointer

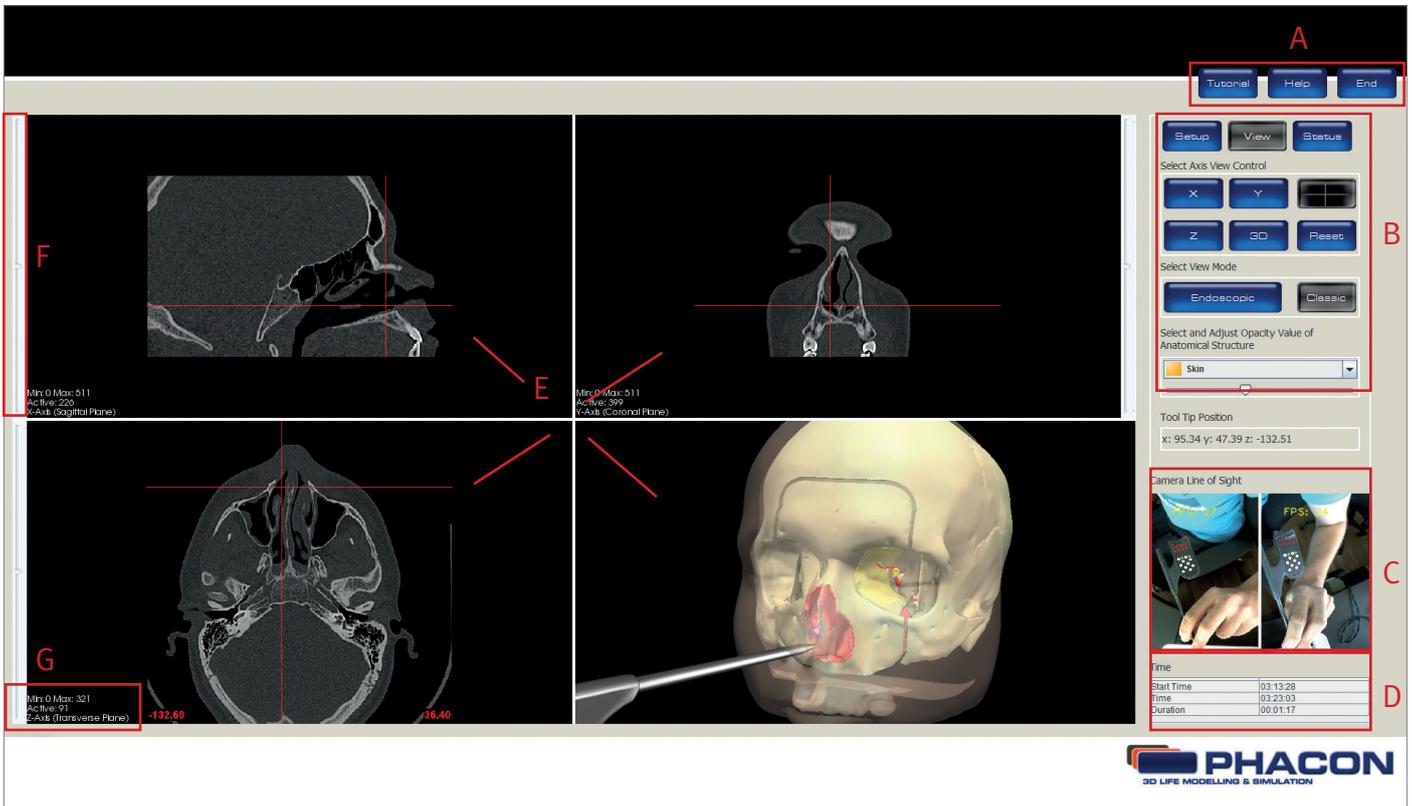
K Instrument tracker for suction

M 3 x Instrument tracker for different drills

L Instrument tracker for a blakesley or trucut

N O-Ring for fixation of the tracker drill

LAPTOP DISPLAY SCREEN



A Title Menu Bar – Used to access the title bar button options, including the HELP button, the TUTORIAL button and the END button to return to the MAIN MENU.

B Panel Menu Bar – Used to access the panel menu button options, including the SETUP button, the VIEW button, and the STATUS button. Each button provides access to a specific panel type.

C Camera Line of Sight – Used to display the image within the navigation camera's line of sight.

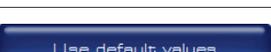
D Simulation Time – Used to display the start time of the simulation, the current time, and the duration of the simulation session.

E Windowpanes (4) – Used to display the three computed tomography (CT) scan image views and 3-D view of the skull and Patient.

F Slice Selection Slide Bar – Used to select the slice view of the CT scan image.

G Axis Identification – Used to identify the CT scan image axis, including the x-axis (sagittal plane), the y-axis (coronal plane), and the z-axis (transverse plane), the maximum number of slices and the current slice.

BUTTONS

Button	Definition	Button	Definition
	Access the MAIN MENU screen to view major menu options.		Close and exit the program.
	Access the SIMULATION screen to begin a training session.		End the SIMULATION or training session.
	Access the RESULTS screen to view and compare the training session data.		Access the HELP dialog box to view instructions for use information.
	Access the ABOUT dialog box to view hardware and software information.		Access the VIEW panel to select or modify a screen view or perspective.
	Accept inputs, changes or selections and return to the previous screen.		Access the STATUS panel to view the number of injured risk structures during a training session.
	Reject inputs, changes or selections and return to the previous screen.		Select the POINTER for recalibration and use.
	Access the CREATE NEW USER dialog box to create a new user profile, user name and password.		Select the angled drill for recalibration and use.
	Access the SETUP panel to perform calibration of an instrument or patient.		Select the ballprobe for recalibration and use.
	Initiate the calibration of instruments or patient from the SETUP panel.		Select the blakesley for recalibration and use.
	Select the factory default calibration settings programmed for the instrument or Patient.		Select the suction device for recalibration and use.
	Begin a SIMULATION or training session from the SETUP panel.		Access the sagittal view of the skull CT data as a full screen display.
	Continue a SIMULATION or training session from the SETUP panel.		Access the coronal view of the skull CT data as a full screen display.
	Access and view the training session results in a graphical format.		Access the transversal view of the skull CT data as a full screen display.
	Access and view the training session results in a tabular format.		Access the 3-D view of the Patient and skull as a full screen display.
	Virtual extension of the instrument.		Return to the default 4-windowpane screen view.
	Open a tutorial.		View a navigated instrument in the 3-D windowpane as if a virtual camera was mounted on the tip of the instrument.
	Add a graph in the result screen.		View a navigated instrument without the virtual camera option.
	Select or toggle the language for the software (German / English).		Access the camera view onto the transparent cochlea.
	Reset the default settings for brightness, contrast and slice position in the 4 windowpane in the simulation mode.		Record a video of the camera view of the cochlea.
	Login as guest.		Reload detected patient CT-data.

OPERATE THE TRAINER

ENTER THE APPLICATION

1. Double click on the „PHACON Trainer“ icon located on the laptop computer desktop to log into the training program (Fig. 2).

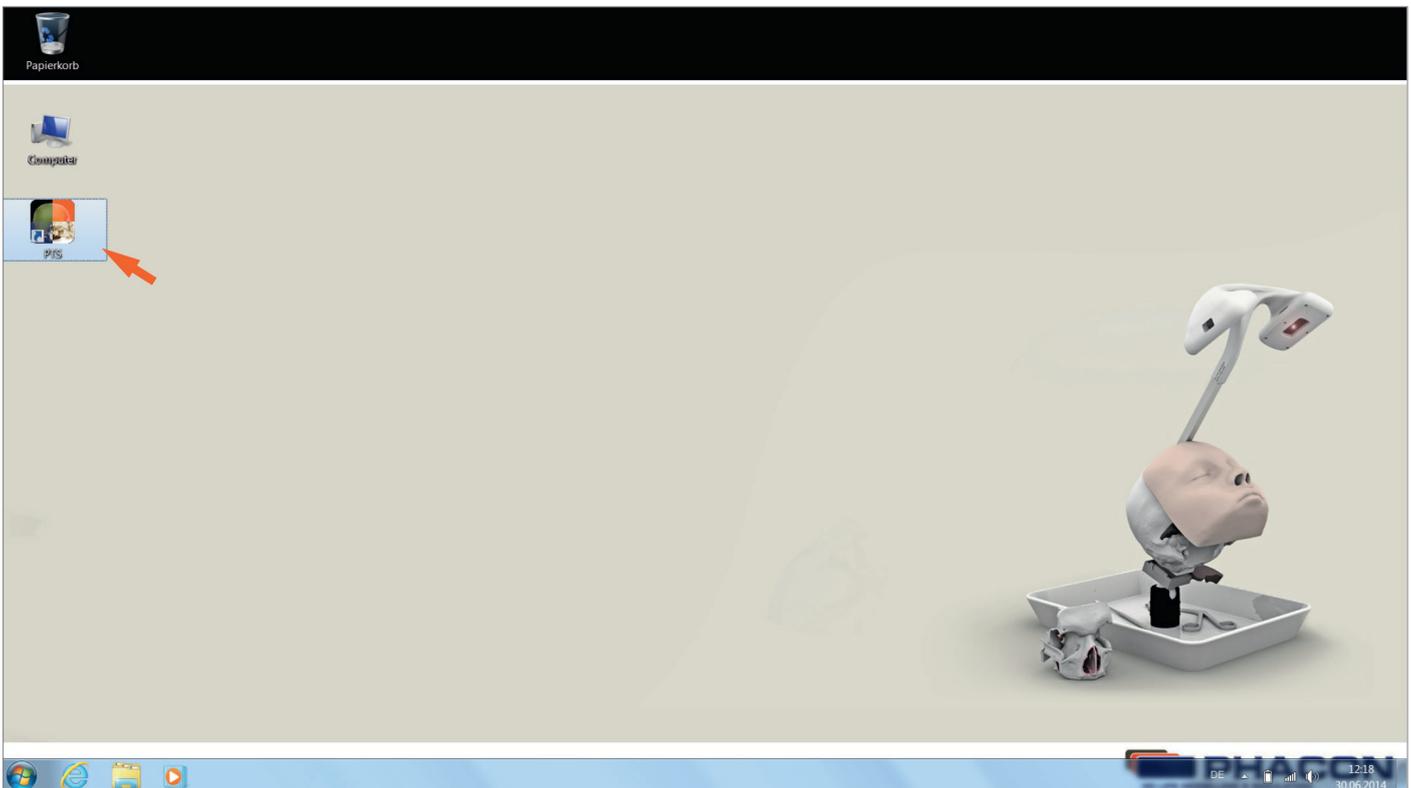


Fig.: 2

2. Enter your unique user name and password.

NOTE: If you are a new user, click on the CREATE NEW USER button. A CREATE NEW USER dialog box will appear. Enter the required information into each field, and then click OK.

3. After a successful LOGIN, an existing group can be selected in the GROUP drop-down list (Fig. 3 page 5). Select an existing group or enter a new group name into the NEW GROUP NAME field, then click OK.

4. From the MAIN MENU screen, click the SIMULATION button (Fig. 3 page 5).

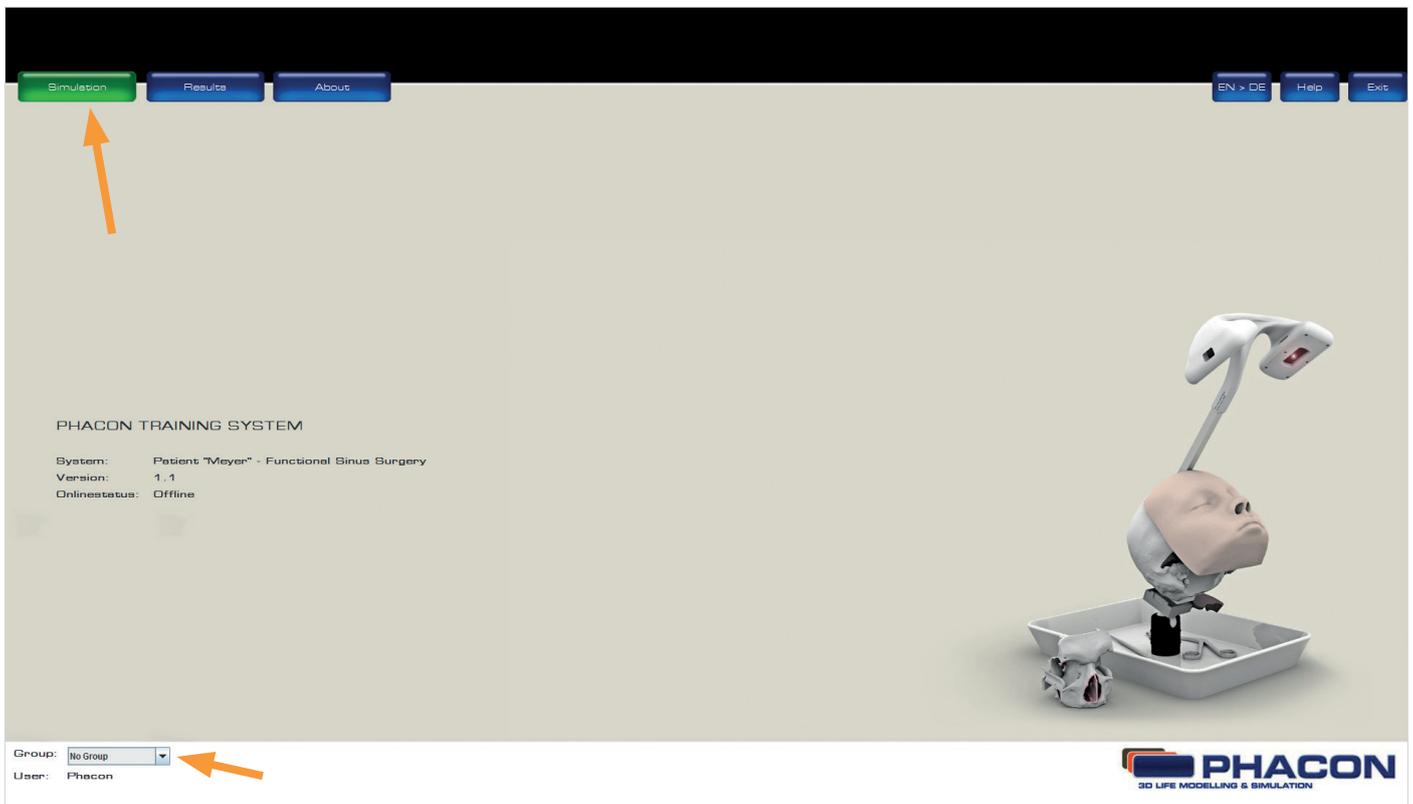


Fig.: 3

5. Click on the SETUP button to perform instrument and patient calibration for optimal navigation results.
6. See To Perform *Setup for Navigation* section.
7. Click on the START button to begin simulation without performing calibration (Fig. 4).

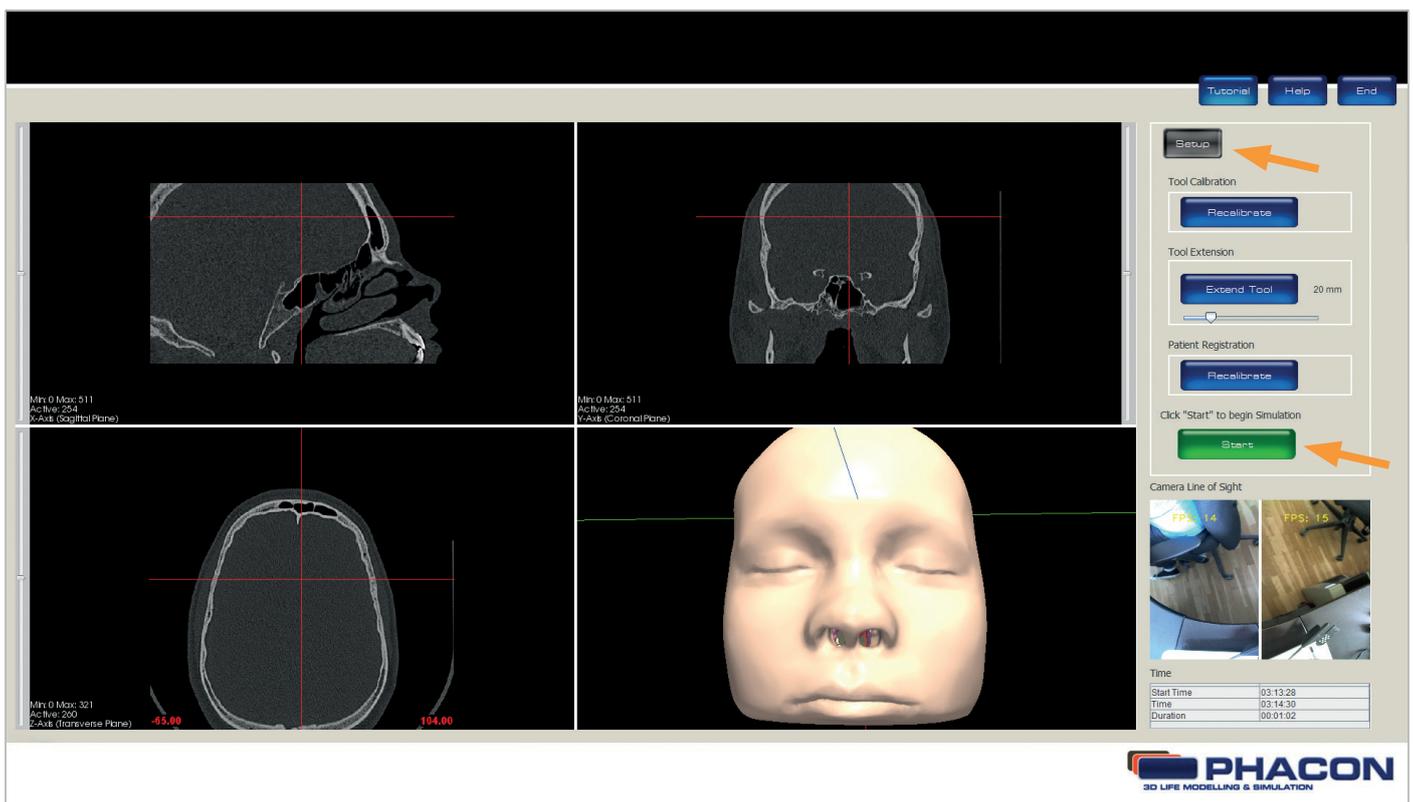


Fig.: 4

PERFORM SETUP FOR NAVIGATION

NOTES:

- Each instrument must be selected and calibrated before the instrument may be used in a navigated fashion.
- To apply navigation, make sure the appropriate tracker is installed on the drill or the manual instrument. The pointer is designed with a tracker and is already precalibrated.

To calibrate your instrument click on icon Tool calibration -> „RECALIBRATE“ (Fig. 5).

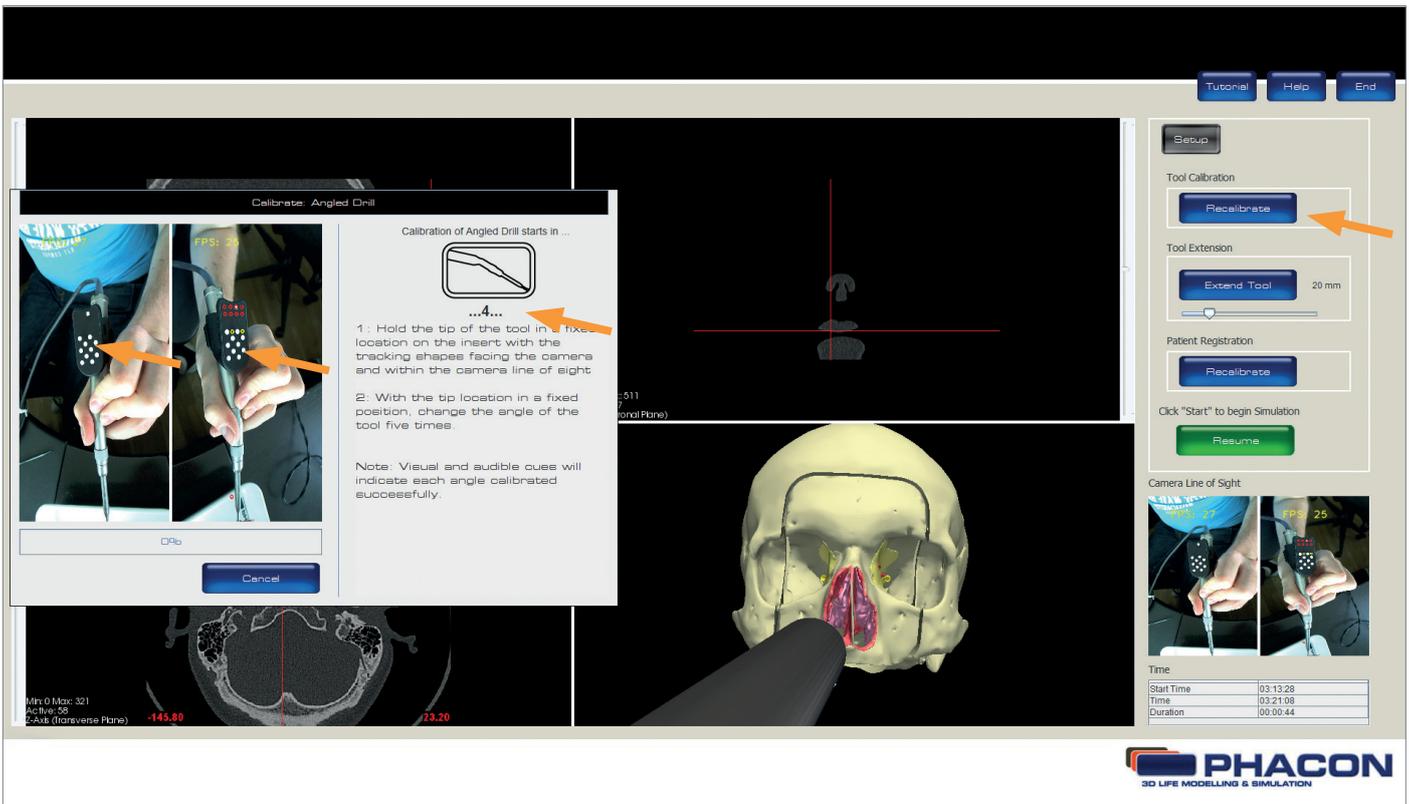


Fig.: 5

ALWAYS make sure the round shapes of the pointer, drill tracker, 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 (Fig. 5). The software automatically detects the current instrument in use.

- SETUP for navigation requires tool calibration and Patient registration.

PERFORM PATIENT CALIBRATION

NOTES:

- Calibration is performed to align the skull model coordinate system with the coordinate system of the pointer, drill, or manual instrument.
- The seven calibration points are visible on the Sinus Patient and within the 3-D windowpane during calibration.
- Sequence numbers and a progress bar are provided in the Patient Calibration dialog window as visual feedback during the calibration procedure.

1. Click on the RECALIBRATE button to begin the calibration process (Fig. 6).
2. Hold the tip of the pointer on the first calibration point of the Patient as indicated in the 3-D windowpane.
3. After visual and audible feedback indicates successful data acquisition, relocate the tip of the pointer to the next calibration point as indicated in the 3-D windowpane.
4. Change the location of the pointer seven times. An INFORMATION MESSAGE pop-up will appear to indicate the successful completion of the calibration procedure.
5. Click on the START/RESUME button to begin or continue the simulation, respectively, if desired.

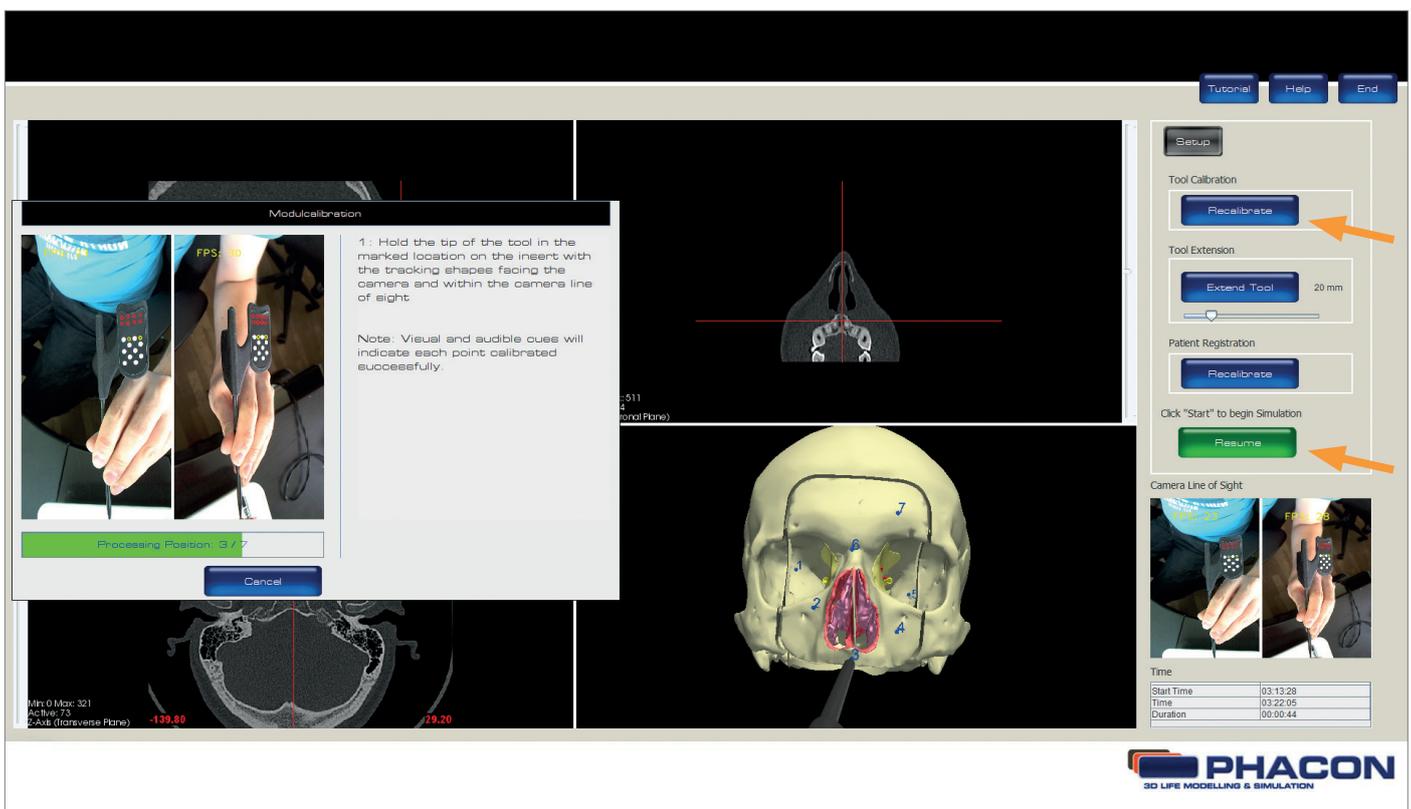


Fig.: 6

PERFORM TOOL CALIBRATION

NOTES:

- Tool Calibration is performed to determine the axis length and tip location of the pointer, drill, or manual instrument.
- Orientation calibration is the last step of Tool Calibration. Orientation calibration is performed to determine the orientation of the pointer, drill, or manual instrument within the 3-D space.
- ALWAYS keep the tip of the pointer, drill, or manual instrument in the same user-defined location during the entire calibration procedure.
- Sequence numbers and a progress bar are provided in the TOOL CALIBRATION dialog window as visual feedback during the calibration procedure.

1. Click on the CALIBRATE or RECALIBRATE button to begin the calibration process (*Fig. 5 page 11*).
2. Make sure the desired tool is selected for calibration.
3. Hold the tip of the tool in a fixed location on the Patient. Make sure the tracking shapes are facing the camera and are within the camera line of sight.

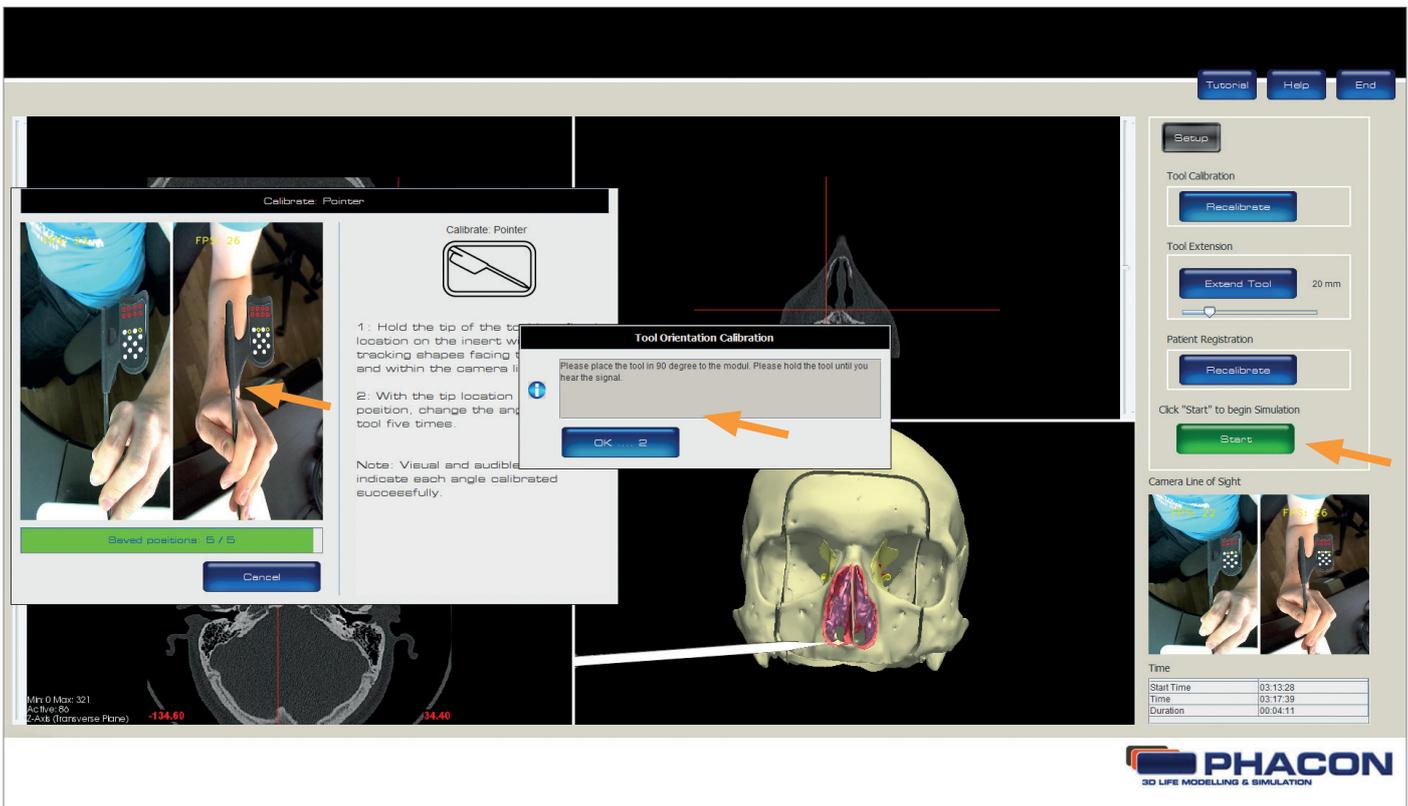


Fig.: 7

4. After visual and audible feedback indicates successful data acquisition, change the angle of the tool while keeping the tip of the tool in a fixed location.
5. Change the angle of the tool seven times with the tip location in a fixed location.
6. Hold the tool perpendicular to the Patient to perform the direction calibration (*Fig. 7*). An INFORMATION MESSAGE pop-up will appear to indicate the successful completion of the calibration procedure. (*As shown in the 3D Scene*)
7. Perform the Patient CALIBRATION if necessary.
8. Click on the START or RESUME button to begin or continue the simulation, respectively, if desired.

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 (Fig. 8).

NOTE: The cross hairs visible within each windowpane represent the location of the pointer, drill, or manual instrument tip when using navigation.

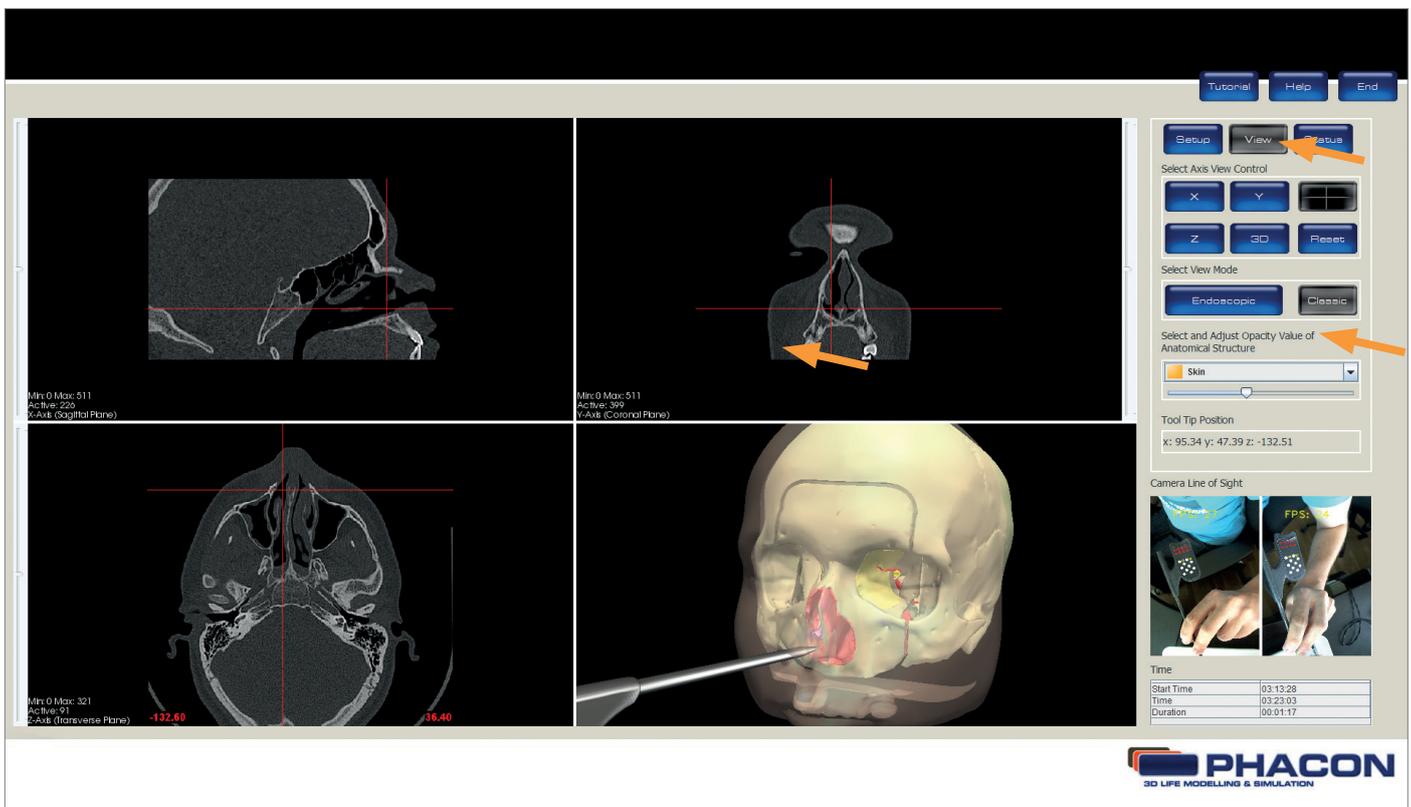


Fig.: 8

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, respectively (Fig. 9).
- 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.

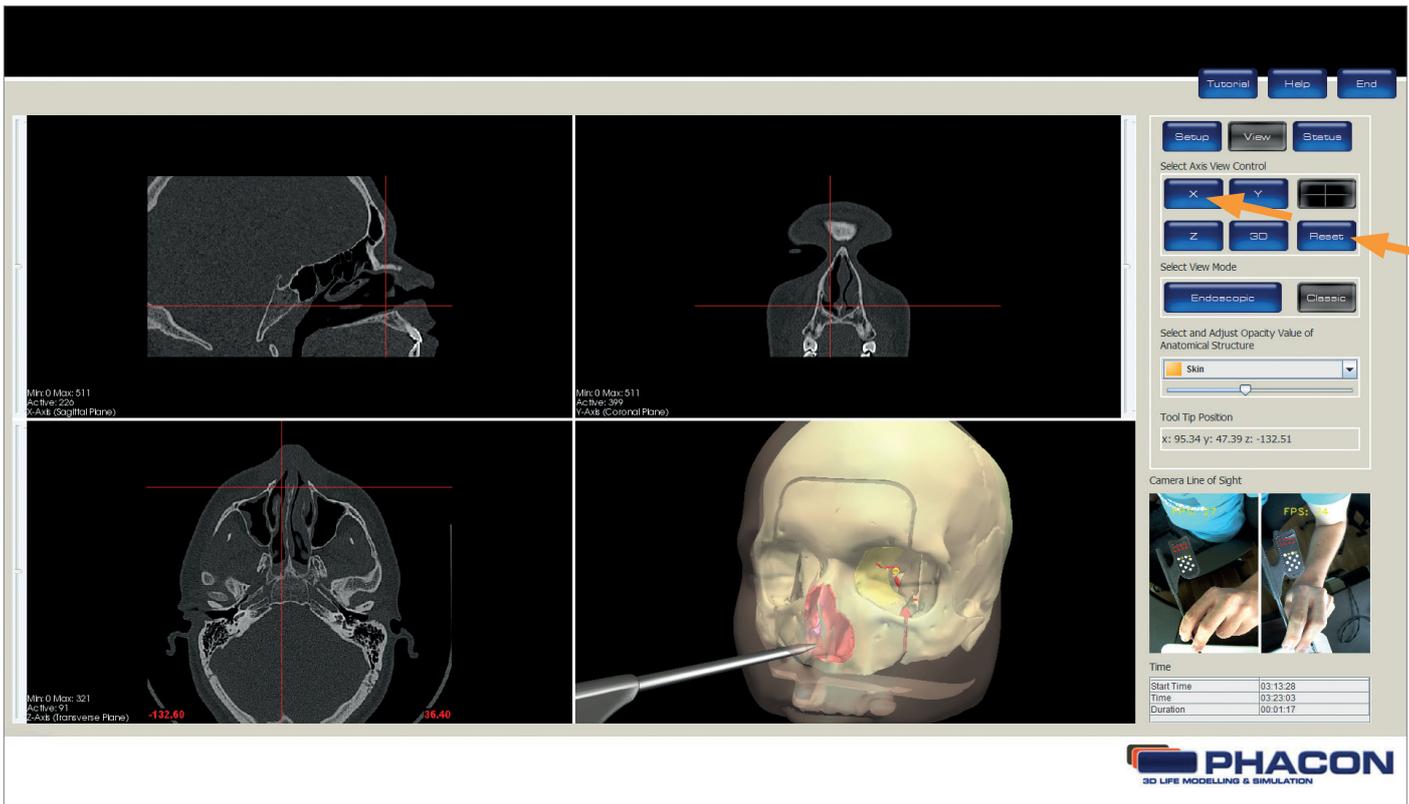


Fig.: 9

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

- To adjust the brightness, click on the desired windowpane, hold down the left mouse button, and move the mouse up and down.
- To adjust the contrast, click on the desired windowpane, hold down the left mouse button and move the mouse left and right.
- To adjust the zoom, click on the desired windowpane, hold down the right mouse button and move the mouse up and down. The mouse wheel 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 navigation, the CT image slice is selected automatically based on the tip location of the pointer, drill, 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.
- To zoom, click on the 3-D windowpane, hold down the right mouse button, and move the mouse up and down. The mouse wheel may also be used.
- To pan, click on the 3-D 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.

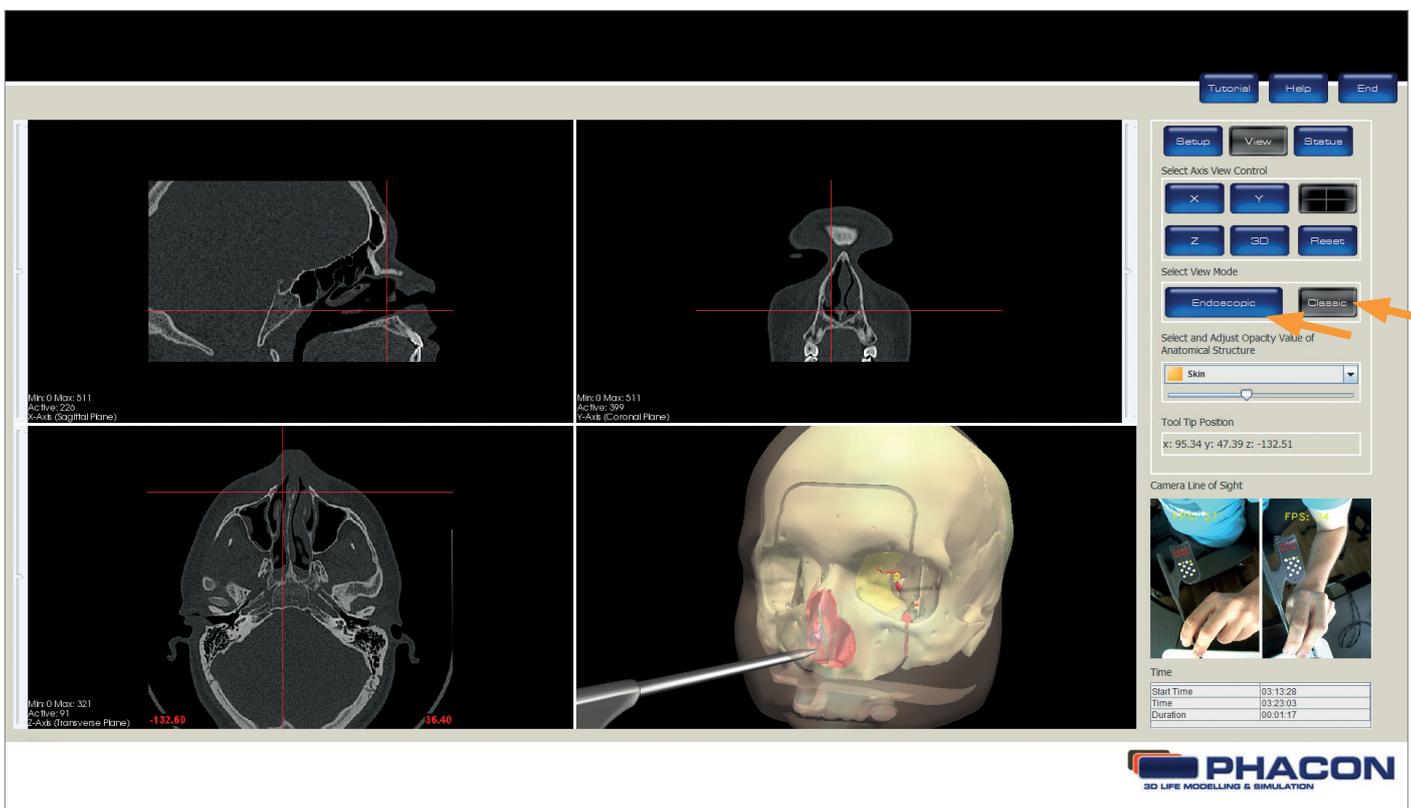


Fig.: 10

CHANGE THE VIEW MODE OF THE 3-D WINDOWPANE DISPLAY

NOTE

- The ENDOSCOPIC view button allows you to use a navigated tool as a virtual endoscope. (Fig. 10).
- The CLASSIC view button is the default 3-D windowpane display option. Click on the CLASSIC button to view the exterior surface of the Patient. Click on the ENDOSCOPIC button to view the interior surfaces of the Patient when using a tool in a navigated fashion.

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 EXTEND TOOL button and move the slider to variable extend the virtual tool extension, shown as a red line in the 3-D windowpane (Fig. 11).

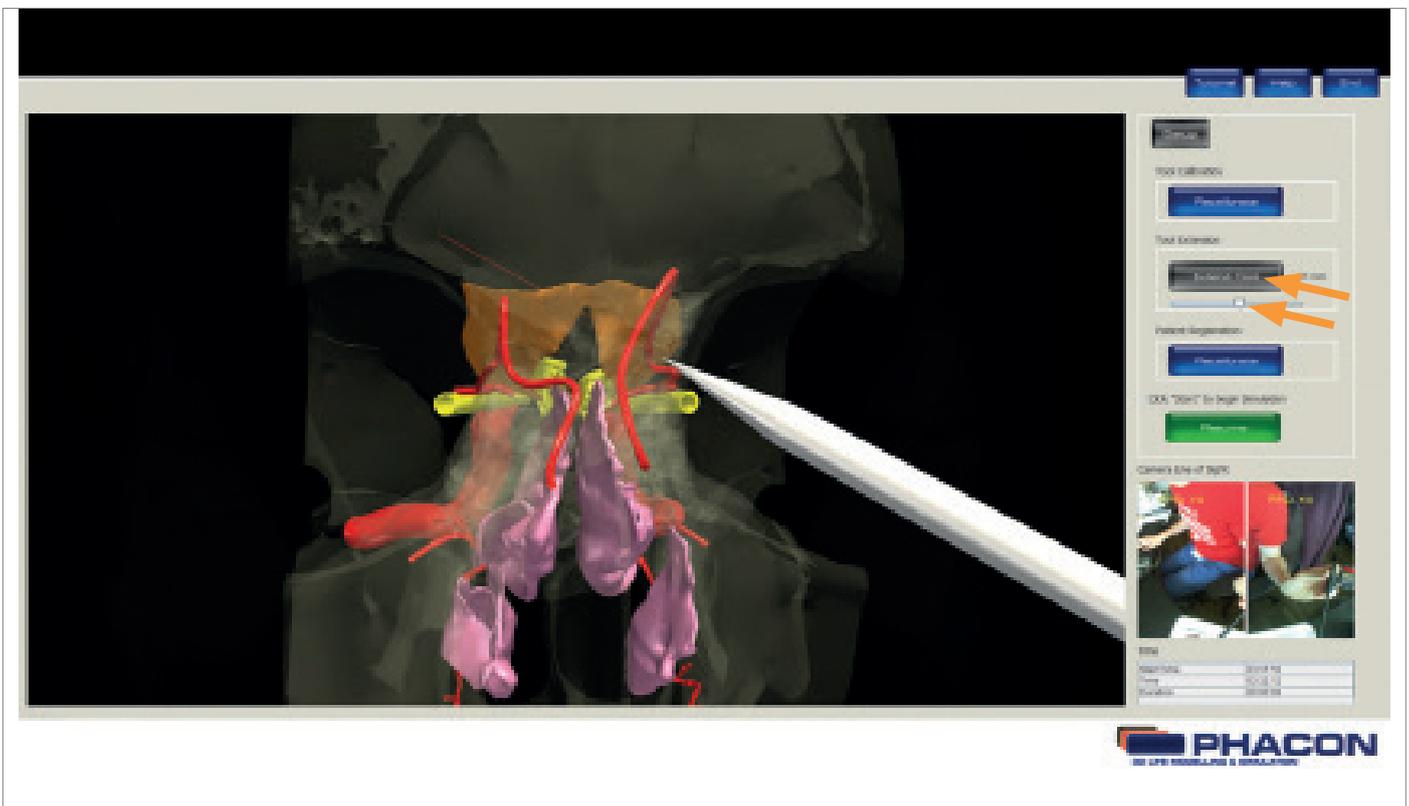


Fig.: 11

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.

1. Click on the drop-down list and select the desired anatomical structure (*Fig.12*).
2. 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).

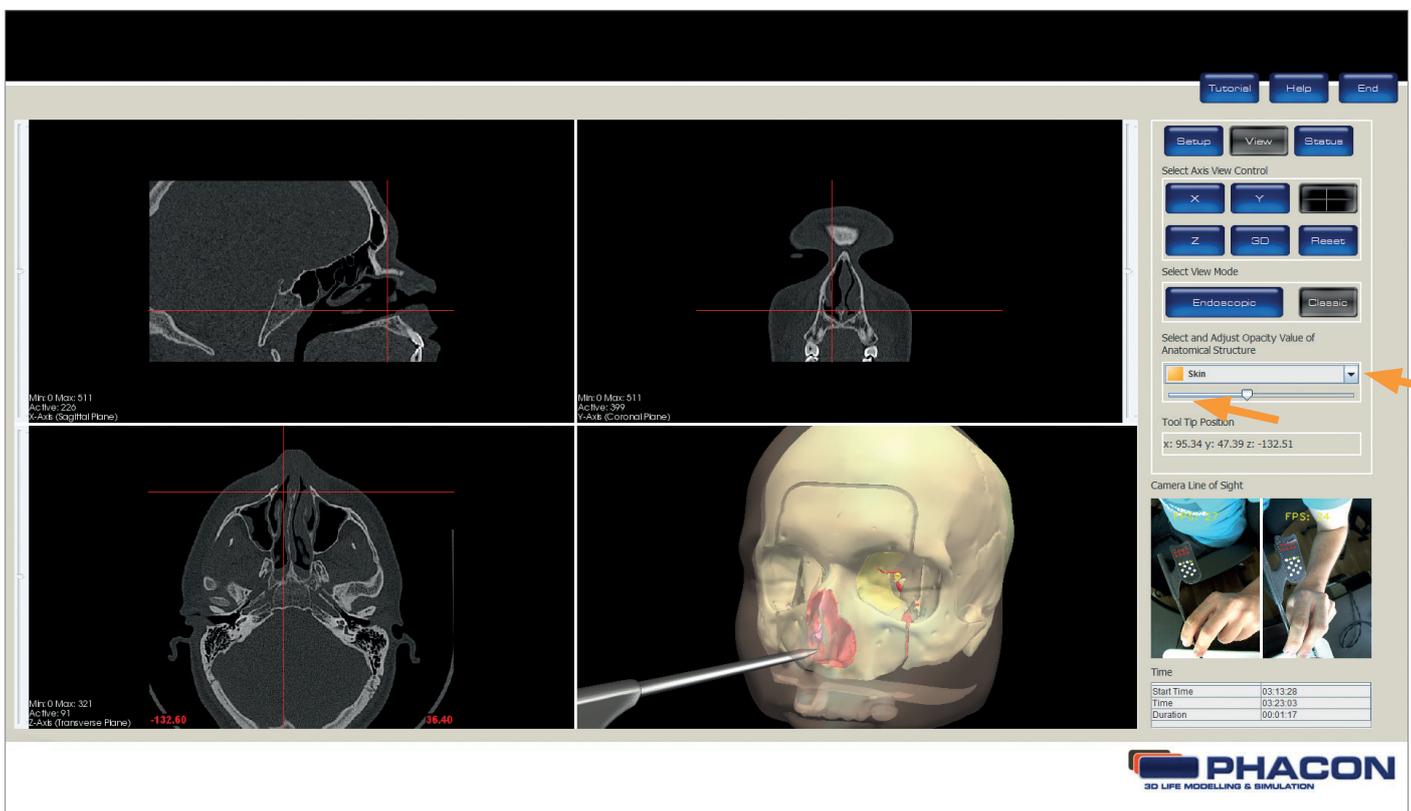


Fig.: 12

VIEW STATUS DURING SIMULATION

From the panel menu bar, click on the STATUS button anytime during the training session to see which risk structure was injured and the time the injury occurred (Fig.13). The start time, current time and duration of the training session is also displayed.

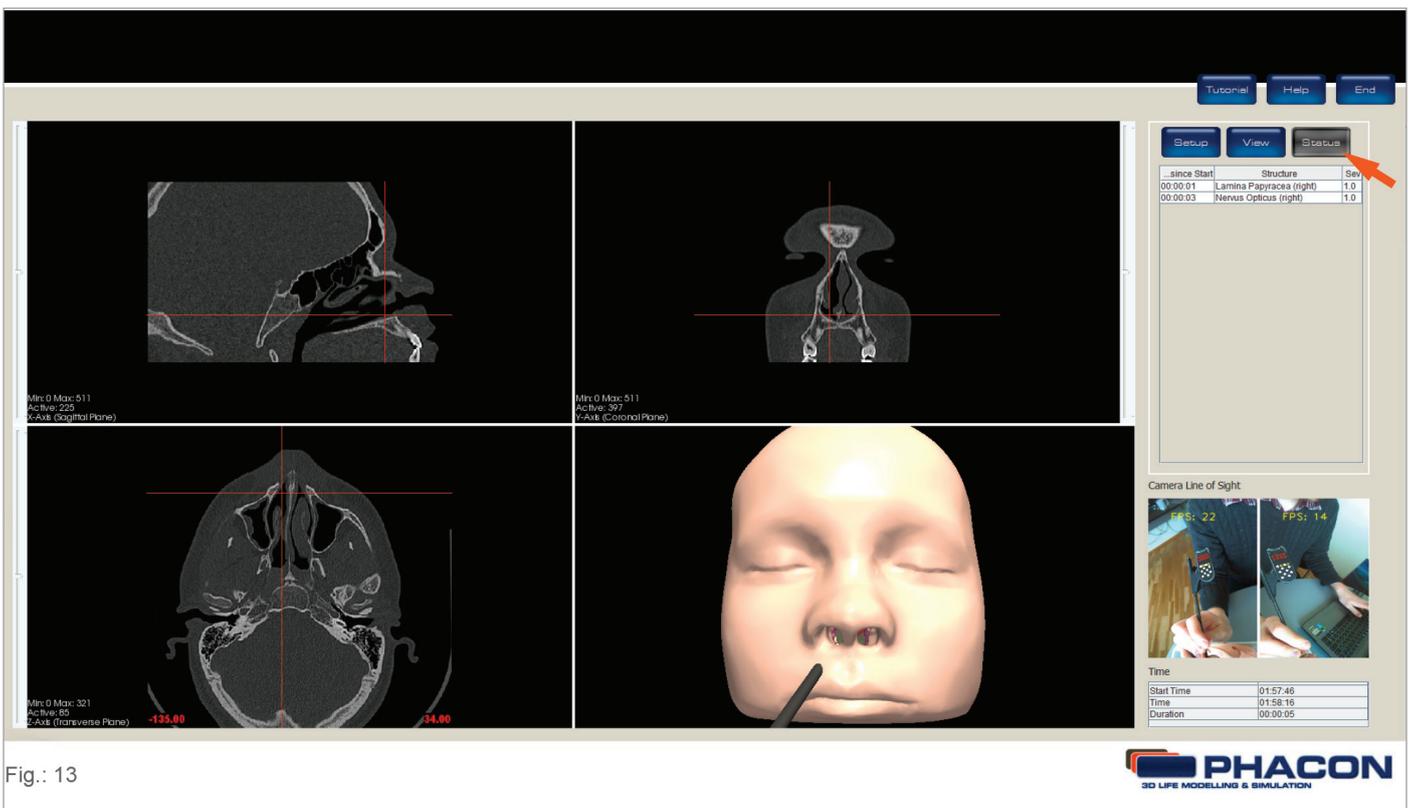


Fig.: 13



Fig.: 13

END THE SIMULATION OR TRAINING SESSION

From the title menu bar, click on the END button to end the training session and return to the MAIN MENU screen.

VIEW THE TRAINING SESSION RESULTS

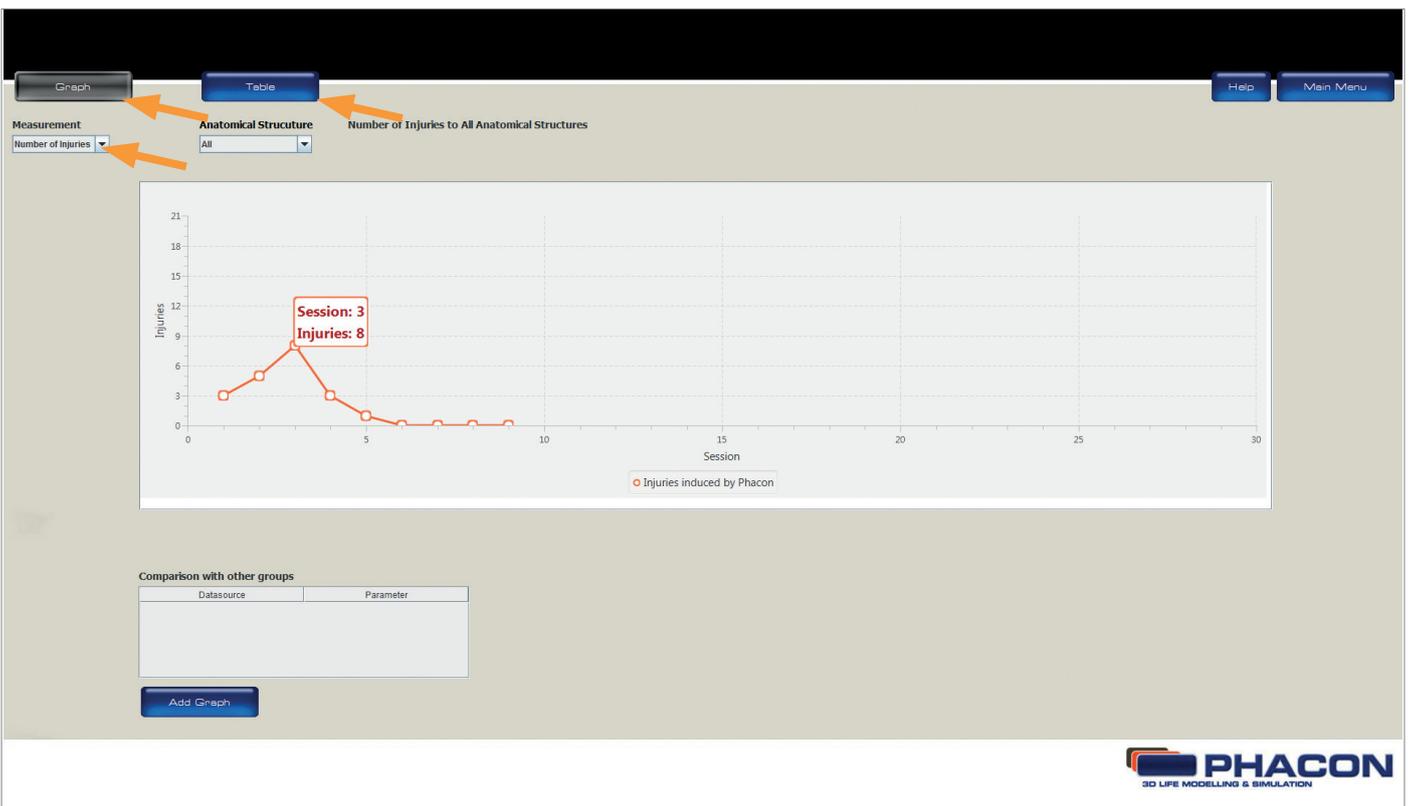
1. From the MAIN MENU screen, click on the RESULTS button (*Fig. 14*).
2. Click on the GRAPH or TABLE button to display the training session data in a graphical or tabular format, respectively (*Fig. 15*).
3. Click on the MEASUREMENT drop-down list to select DURATION (MINUTES) or NUMBER OF INJURIES.

NOTES

The DURATION (MINUTES) option will display how much time was spent in each training session.



Fig.: 14



20 Fig.: 15

VIEW THE TRAINING SESSION RESULTS

- The NUMBER OF INJURIES option will allow access to the ANATOMICAL STRUCTURE drop-down list (Fig.16).

4. Click on the ANATOMICAL STRUCTURE drop-down list.

5. Select the ALL option or a specific risk structure to view the associated number of injuries sustained during a particular training session.

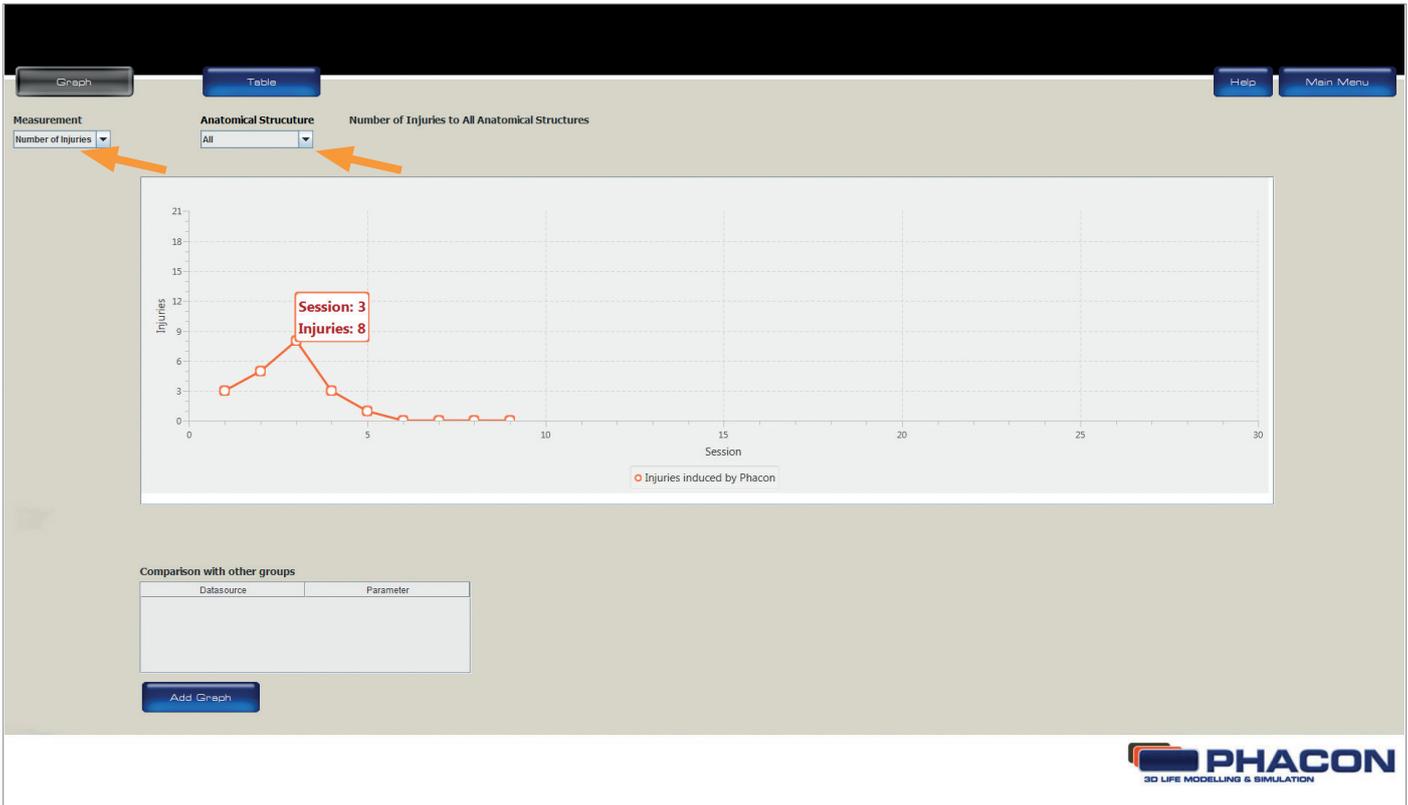


Fig.: 16

COMPARE WITH OTHER GROUP RESULTS

NOTE:

The data collected during each training session is associated with the GROUP NAME selected in the MAIN MENU. The training session results of each user may be compared with other group results. (Fig. 17).

1. Click on the ADD GRAPH button to compare your results with other group results (Fig. 17).
2. From the COMPARISON WITH OTHER GROUPS dialog box, click on the GROUP drop-down list and select a group.
3. Click on the STATISTICAL PARAMETER drop-down list and select a statistical parameter.

NOTE:

The STATISTICAL PARAMETER drop-down list includes maximum, minimum, mean, standard deviation, and median. The selected parameter is applied to the training session data.

4. From the COMPARISON WITH OTHER GROUPS dialog box, click on the COLOR bar and select a color. A unique color is assigned to each selected group and the associated statistical parameter.

REMOVE A GROUP

To remove a group, click on the group name in the table COMPARISON WITH OTHER GROUPS.

The screenshot displays the software interface with the following elements:

- Measurement:** Number of Injuries (dropdown menu).
- Anatomical Structure:** All (dropdown menu).
- Number of Injuries to All Anatomical Structures:** A line graph showing 'Injuries' on the y-axis (0 to 21) and an unlabeled x-axis (0 to 10). Two data series are plotted: a green line with square markers and a red line with square markers.
- Compare with other groups dialog box:** Contains instructions: "To compare your results with other groups, select the group, the statistical parameter and the color for the parameter to be displayed". It has three fields: "Group" (dropdown menu with "Trainees" selected), "Statistical Parameter" (dropdown menu with "Maximum" selected), and "Color" (a red color swatch).
- Swatches dialog box:** Shows a color palette with tabs for Swatches, HSV, HSL, RGB, and CMYK. A "Recent" list is visible on the right.
- Comparison with other groups table:** A table with columns "Data source" and "Parameter". The first row shows "All" under "Data source" and "Maximum" under "Parameter".
- Add Graph button:** A blue button located below the table.
- PHACON 3D LIFE MODELLING & SIMULATION logo:** Located in the bottom right corner.

CLEANING

CLEAN THE SKULL

NOTE:

- Make sure the Patient has been removed from the skull and the skull has been removed from the tray.
- Thoroughly remove all debris from the Patient lever to make sure the lever has complete freedom of movement. Failure to comply may prevent the proper installation of the temporal bone insert into the bone cavity during set up.

1. Remove loose debris from the surface of the skull, including the mounting plate, cables, and suction port using an external vacuum source.
2. Carefully remove all debris from the risk structure contact pins of the skull using a dry brush and an external vacuum source.
3. While articulating the Patient lever, remove all debris from around the lever using a dry brush and an external vacuum source. Make sure the lever has complete freedom of movement.
4. Remove all debris from the spillways within the skull using a dry brush and an external vacuum source. Make sure the spillways are clear to allow water to flow freely during the use of irrigation.
5. Wipe all the surfaces of the skull, including the contact pins, insert lever, and spillways with a soft cloth wet with water.

CLEAN THE SKULL HOLDER WITH TRAY

1. Remove loose debris from the exterior of the tray using an external vacuum source.
2. While articulating the ball-joint mount and each lever, remove all debris from the ball-joint mount using a dry brush and an external vacuum source. Make sure the ball-joint mount and levers have complete freedom of movement.
3. Wipe all the surfaces of the tray, including the ball-joint mount and each lever, with a soft cloth wet with water.

CLEAN THE TRAINER ACCESSORIES

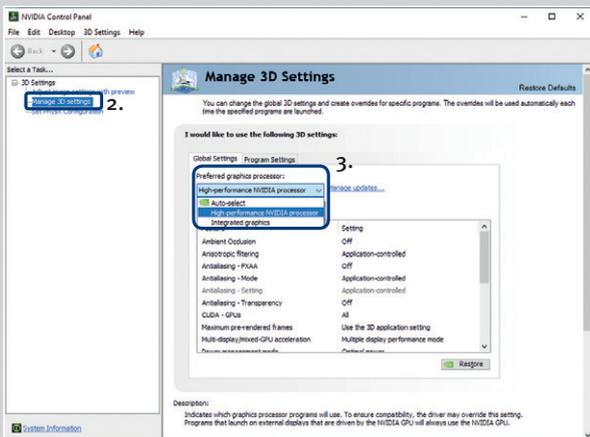
1. Wipe all the trainer accessories, including the pointer, trackers, cables and electrical bur adapter with a soft cloth wet with water.
2. After all the system components and accessories have been cleaned properly, see the Storage and Handling section.

TROUBLESHOOTING

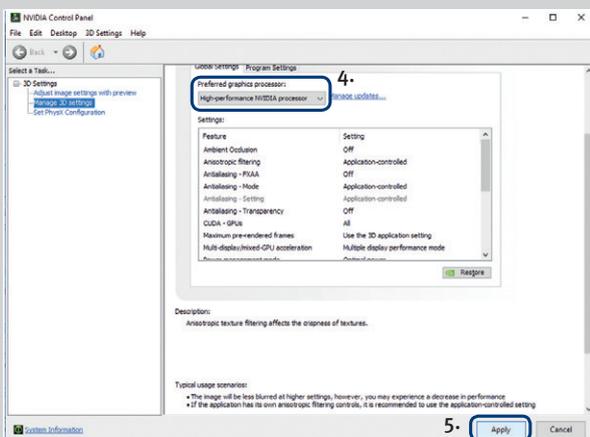
PROBLEM	CAUSE	ACTION
The software application locks up.	The application is experiencing an internal malfunction.	Press the CTRL/ALT/Delete buttons simultaneously to perform a soft reboot. Press the ON/OFF button to perform a hard reboot.
The navigation system is not functioning or is not functioning 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 trainer is not detecting critical risk structures.	The ground cable with magnet is not installed on the instrument tracker or is not making contact with the manual instrument body.	Make sure the ground cable with magnet is installed properly.
	The ground cable with magnet is not installed on the skull and positioned into the allocated cavity on top of the skull.	Make sure the ground cable with magnet is installed properly.
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.

PROBLEM	CAUSE	ACTION
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.

Choose right graphic adapter NVIDIA



- 1: Open the selection window (context menu) with a right click on your desktop and choose NVIDIA Control Panel.
- 2: Select the “Manage 3D settings” in the left column of the NVIDIA Control Panel.
- 3: In the Global Settings click on “High-performance NVIDIA processor”.



- 4: If the “Apply” button does not appear, please select “High-performance NVIDIA processor” again.
- 5: Save settings by click on the “apply” button.

ERROR MESSAGES

MESSAGE	CAUSE	ACTION
Connection to trainer lost.	The USB cable of the skull is not connected to the notebook.	Make sure the USB cable connection between the skull and the notebook is secure. Press the RECONNECT button.
The entered group name already exists in the trainer. Please enter a unique group name.	The entered group name is already used.	Enter a new group name into the trainer (maximum of 150 characters).
The group name field was left empty. Please enter a unique group name.	The required field data was not provided.	Enter 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
Karl-Heine-Str. 15
04229 Leipzig
Germany

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

www.phacon.de

HOW TO PACK THE TRANSPORT CASE

1. First insert the Holder Tray and mask into the recess. Cover the Holder Tray with a layer of foam. Lay the camera on top and position the two camera arms into the recess next to the Tray, the lenses facing down wards. (*Fig. 1*)
2. Cover the camera with the second layer of foam, containing a recess for the tracker box. (*Fig. 2*).
3. Insert the tracker box into the recess. Insert the skull into the recess above the tray. (*Fig. 3*)



PRODUCT WARRANTIES

PHACON END USER WARRANTIES

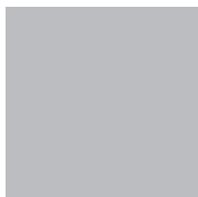
PHACON Surgical Training Hardware, Instruments and Disposables (collectively, the “Products”) are warranted to the original purchaser for a period of one year from the date of purchase. Products are warranted to be free from defects in material and workmanship. The foregoing warranty covers parts, labor, 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 trainer or hardware non-compatibility or a trainer “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.



Manufacturers declaration / Herstellererklärung

We declare that the following named device conforma 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 für das nachfolgend bezeichnete Gerät eingebaut werden soll, den Bestimmungen der EG- Maschinenrichtlinie 89/392/EWG mit Anlage entspricht.

Denomination: Simulation system for sinus surgery, Sinus Trainer

Bezeichnung: Simulations-System für die Nasenchirurgie, Sinus Trainer

Type: Sinus

Typ: Sinus

Identification number Produktnummmr/ Identification number: S-00001

Considered EEC-directives/
Berücksichtigte Richtlinien:

73/23/EEC Low voltage directive /
Niederspannungsrichtlinie



PHACON GmbH
Karl-Heine.Str. 15
04229 Leipzig


.....
Hendrik Möckel
Geschäftsführer


.....
Robert Haase
Geschäftsführer



PHACON GmbH

Karl-Heine-Str. 15
04229 Leipzig, Germany

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

www.phacon.de