Instructions for Use

Neo ADVISE™ software

Advanced Dynamic Visualization of Intraoperative Spinal Equilibrium

R2.0

Neo
BEYOND THE EXPECTED

CE 1936

MD

Table of Content

Introduction

Thank you very much for choosing the Neo ADVISE™ software. This software runs on an Apple iPad and can be used during spinal surgeries to estimate the size and shape of the rods to be used, supports you in Spondylolisthesis and Trauma cases, and generates custom bent rod templates, based on the position of the Neo Pedicle Screw System™ screw extenders.

It is advisable that you read this instruction manual carefully before use.

Special training by Neo Medical is required to be allowed to use the software in surgery.

The Neo Pedicle Screw System

The Neo Pedicle Screw System™ comprises a variety of sizes of rods, screws, connectors as well as instruments. The implants are all delivered sterile and ready to use. They can be locked together into a variety of configurations that are going to be tailor-made for each individual case. The instruments are mainly delivered as single-use sterile, just a few are available as reusable and delivered unsterile.

Overview, showing the Guides, the Rod and the Screw Head Positions
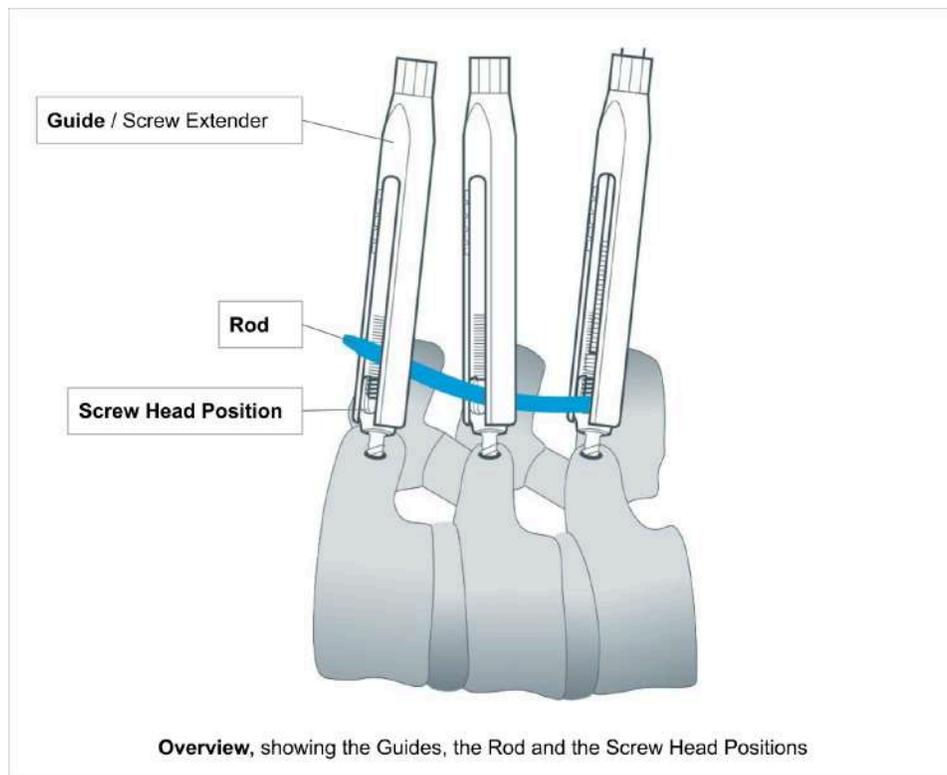
The guide is the screw head extension of the pedicle screw, also called Screw Extender. This extender helps the surgeon to perform rod reduction and manoeuvers during rod placement. We use the term "Guide" for the "Screw Extender" in this document.

The Neo ADVISE software

The Neo ADVISE™ software is designed to estimate the size and type of the rods to be used, and to support surgeons in spine surgeries, based on the position of the guides.

ADVISE stands for

Advanced Dynamic Visualization of Intraoperative Spinal Equilibrium

The software uses Augmented Reality (AR) to provide the user with additional information that is otherwise not available, such as the estimation of the size of the rod or distance between screws.

Note that the **Neo Pedicle Screw System™** can be used, according to the surgical technique available on www.neo-medical.com/ifu, without the software.

Software Features

The Neo ADVISE™ software provides the following features:

- **Scanning the Neo Guides**
  Scanning the guides registers the positions of the pedicle screw heads. The registered guide positions are required for the software to perform all subsequent calculations. The software offers two different methods for scanning of the guides:

  - The 3D-Scanning (limited to ten guides),

  - The Marker Detection (requiring additional hardware, namely the Neo Marker Base, which are sold separately).

- **Calculating and displaying the distances between Guides**

- **Calculating and displaying the sum of all distances between the Guides and the minimal rod length**
  This information helps to decide which rod should be chosen based on the Neo Medical rods portfolio.

- **Showing screw depth adjustments**
  The user can select any of the available rods to test the placement for the given screw positions and adjust the rod position with gestures. The software will measure the gap between the rod and each screw head and provide values in millimeters.

  Showing the potential coronal offset between the different screw heads and the rod. The software will measure the offset and provide values in millimeters.

- **Generate Rod Template**
  Generate a custom bent rod template that passes all screw heads.

- **Rod Template Smoothing**
  To make the rod template easier for bending, the software offers the option to take the 2 mm of tolerable offset of poly-axial screw towards the rod in the coronal plane into account.

- **Rod Template Copying**
  Shows the custom bent rod template on screen at a 1-to-1 scale for the surgeon to be able to bend the actual rod according to the template.

- **Spondylolisthesis Module**
  A tool supporting the surgeon in finding the position of the most caudal guide to achieve the correction pre-defined on pre-operative X-rays and refined during surgery for a selected rod in spondylolisthesis cases.

- **Trauma Module**
  A tool supporting the surgeon in finding the position of the most caudal guide and to custom bent rods to achieve a given correction angle pre-defined on pre-operative X-rays and refined during surgery for a selected rod in trauma cases.

- **Correction Module** (optional)
  A tool supporting the surgeon in intra-operatively achieving pre-operatively planned sagittal and coronal angulation goals in deformity indications.

- **Screen Recorder** (non-clinical function)
  The software allows taking a screenshot and a screen recording using simple in-app controls.

Scanning the Guides

To be able to calculate distances, screw adjustments, and rod templates, the software needs to know the exact position of all relevant guides. This can be achieved using two different methods: 3D-Scanning and Marker Detection.

The Neo ADVISE™ software is designed to work with a mean accuracy of 2 mm point, 3 mm distance, and 2° angular axis displacement. The accuracy and precision tests were performed on a static spine model with known relative positions of the screw heads. The scanning environment (i.e. the lighting conditions) were simulated with an OR lamp and additional diffuse light sources.

3D-Scanning

This method does not use any additional hardware, other than the provided tools of the standard Neo Pedicle Screw System™. The 3D-Scanning method is limited to scanning ten guides. For more complex cases, the Marker Detection method should be used.

Marker Detection

This method requires Neo Markers to be put onto every relevant guide. The Neo Markers can be purchased separately. Please contact Neo Medical for more information. See section [Neo Markers and Neo Marker Base](#) in the Appendix.

Shelf Life

The Shelf Life of Neo ADVISE™ software is 3 years.

Limitations for Use

The safety and effectiveness of the Neo ADVISE™ software have been established only for spinal procedures with a maximum of 10 guides (3D-Scanning) on one side and a total of 30 guides (Marker Detection scanning), which means 15 on each side.

Indications for Use / Intended Purpose

The Neo ADVISE™ software, is a software which uses augmented reality (AR) to identify and visualize the location of the implanted pedicle screw heads, exclusively for the Neo Pedicle Screw System during both open and percutaneous procedures.

From the identified locations, the software measures the distances between the screw heads to give the minimal rod length required by the surgeon for the spinal rod implantation. The software provides a shortlist of applicable rods from the Neo Pedicle Screw System portfolio. It calculates and visualises the distances between the selected rod and the screw heads. If necessary, the software generates a rod template that can be modified by the surgeon, aiding in the contouring of the spinal rod.

The Neo ADVISE™ software does not remove any responsibility for patient safety from the surgeon. The surgeon must bear full responsibility for all consequences resulting from the choices made with regards to the selection of the rod implant and the positioning of the pedicle screws. At the end of the surgery, an intra-operative X-Ray must be taken to finally confirm and document the correct inserting and bending of the rod.

Indications

The below table documents the indications of the Neo Pedicle Screw System where the Neo ADVISE™ software can be implemented to assist the surgeon.

Neo Pedicle Screw System Indications	Neo ADVISE Fixation Module	Neo ADVISE Trauma Module	Neo ADVISE Spondylolisthesis Module	Neo ADVISE Correction Module

Degenerative disc disease	X			X
Spondylolisthesis	X		X	
Trauma	X	X		X
Spinal stenosis	X			
Curvatures	X			X
Tumor	X	X		X
Pseudarthrosis	X			
Failed previous fusion	X			X

Contraindications

The Neo ADVISE™ software must not be used with any other system than Neo Pedicle Screw System™.

For contraindications of the Neo Pedicle Screw System™ refer to the instruction for use published on the Neo Medical website.

Product Label / Software Version

This user manual (instruction for use) is applicable for all software versions R2.x.y (e.g. R2.0.1, R2.1.0) until further notice.

Every screen in the software shows the *Info* Button. By tapping the *Info* button, the software will show the product label containing the version information of the software. The product label also offers a link to the User Manual (this document) and the applicable Privacy Notice.

Important Notes

Compliant Use

The use of this software is reserved for professional use by clinical staff that has been trained. Typically, the software is used by the surgeon responsible for the operation. It is possible, however, to have another person, e.g. a scrub nurse or assistant, interact with the software and provide the information that the software provides to the surgeon.

(i)	**The software does not remove any responsibility for patient safety from the surgeon.** **The surgeon must bear full responsibility for all consequences resulting from the choices made with regard to the selection of the rod implant and the positioning of the pedicle screws.**
(i)	**Any serious incident that has occurred in relation to the software should be reported to the manufacturer and the competent authority of the Member State in which the user is established.**

This software is designed to specifically work with the Neo Pedicle Screw System™. No other products are supported and must therefore not be used in combination with this software.

Any inappropriate use is forbidden.

Sterile Environment

The usage of the software will inevitably lead to bringing the tablet device near or into the sterile environment in the operating room. To protect the iPad and avoid contamination, put the device into a sterile bag provided by Neo Medical. Place the iPad inside the bag following the instructions for use provided with the bag outside the sterile field. **The closure of the bag should not cover the camera**. Once in the protective bag the device can be used.

A list of supported products is listed in section List of Compatible Products in the Appendix. Neo Medical separately sells compatible solutions (visit www.neo-medical.com). The use of non-compatible products might affect the performance of the Neo ADVISE™ software.

Cleaning / Disinfecting the Device

In case the iPad gets contaminated remove the gross dirt immediately with a wipe and then proceed with cleaning and disinfecting it using disinfectant wipes like the Sani-Cloth CHG 2% (chlorhexidine 2% / alcohol 70%).

It is recommended to clean the iPad before each use to ensure proper disinfection. Ensure the iPad is dry and the camera is clean and free from cleaning agent before placing it in the sterile bag.

Notes on electromagnetic compatibility

To ensure electromagnetic compatibility and avoid interferences, do not charge the device in the operating room and turn airplane mode on (disable bluetooth and WiFi connections).

Software Distribution & Installation

Neo Medical takes care of installing and configuring the Neo ADVISE™ software on Neo Medical-owned iPads. Please get in contact with Neo Medical if you want to use Neo ADVISE™ in surgery.

Distribution / Neo Medical MDM

The software comes pre-installed on Neo Medical-owned iPads. These devices are supervised and managed by Neo Medical using a Mobile Device Management (MDM) solution operated by or on behalf of Neo Medical. This allows Neo Medical to provide technical support and reduce maintenance efforts on your side, like upgrading to the latest version of the Neo ADVISE™ software. Furthermore, this allows Neo Medical to limit some of the device's features (e.g. prohibiting the use of other apps on the device) to ensure safe and efficient use of the Neo ADVISE™ software.

While the Neo ADVISE™ software can run completely offline, it is still advisable to connect the iPad to a network after surgery and allow internet access for the device to allow the device to get the latest version of the software automatically. Also, to access the User Manual (this document) on the device, an internet connection is required. Such operation shall be done outside the operating room in an office environment to avoid potential interferences with other devices.

IT Network Characteristics and IT Security Measures

The Neo ADVISE™ software can run completely offline and does not require an internet connection nor communicates with other systems or devices using the network. However, in order to get the latest version of the software or get access to the eIFU, we recommend connecting the device to the network.

IT Network Characteristics

The Neo ADVISE™ software can send crash logs to an external server (sentry.io). This helps the manufacturer to fix potential issues more quickly.

The Neo ADVISE™ software connects to the following endpoints:

Endpoint / IP Range	Port / Protocol	Description
https://neo-medical.com/ifu	443 TCP	Access the Instructions For Use (this document) and the Privacy Notice

https://sentry.io 35.188.42.15/32	any (outbound) TCP	Crash Logger Service (optional)
*.apple.com 17.0.0.0/8	any (outbound) TCP	Apple Services (iOS Updates, Certificate validation, etc)
*.jamfcloud.com	any (outbound) TCP	Mobile Device Management (Jamf Pro)

IT Security Measures

To ensure the safety of the device and surrounding systems in the same network, it is advisable to block connections to other clients or services in the same network.

Change of Hardware / Defects

In case your device stops working or breaks, please get in touch with Neo Medical.

iOS Version Updates

We recommend updating the device to the latest version of iOS. The manufacturer ensures compatibility between major iOS/iPadOS versions by testing the software prior to the release of the OS update. In case an update of Neo ADVISE™ software is required, Neo Medical will get in touch with you.

The installation of the BETA version of iOS is prohibited.

Software Updates

To ensure the safe and efficient use of Neo ADVISE™ software, it is recommended to use the latest version of the software. Software updates are communicated by Neo Medical.

To install the latest available release of Neo ADVISE™ software, connect the device to the internet to allow communication with the update service. If an update is available, the device will update the software automatically.

Starting the Neo ADVISE software

The Neo ADVISE™ software can be started by tapping the Neo ADVISE™ software icon on the device's home screen.

Before Usage

Device Battery and Charger

Using the software in surgery should not affect the duration of the surgery. Nevertheless, it is important to avoid the device shuts down due to a low battery.

(i)	**Make sure that the device's battery is fully charged before starting the surgery.** **Do not charge the device in the operating room.**

To ensure electromagnetic compatibility and avoid interferences, please do not charge the device in the operating room.

Device Overheating Protection

It is possible that in certain situations the device overheats after a long period of using it. Since the performance of the software cannot be guaranteed in an overheated state, the software will stop and show a warning. If you see the overheating warning, please lock the device and let it cool down for a few minutes (3-4 minutes). When unlocking the device, the warning will disappear automatically if the device has cooled down to a normal temperature. You will have to perform the scene analysis again and re-scan all guides.

At no point in time, there is a hazard or possible harm coming from the device overheating. The term overheating refers to the device internals reaching temperatures that are out of the operating range. The operating system will throttle the device's performance and shut down automatically if required.

Access to the User Manual and Privacy Notice

The Neo ADVISE™ software's User Manual (this document) and the Privacy Notice (also found in this document, see section Privacy Policy) are accessible on the home screen of the iPad. To access the User Manual or the Privacy Notice, tap the *Instructions* icon on the home screen of you iPad, select the region where the software is used and tap the link to the User Manual (Instructions for Use) or the Privacy Notice.

You can access the User Manual or Privacy Notice also on any other computer with a browser, by visiting neo-medical.com/ifu.

If you prefer to read the Instructions for Use in printed form, please contact Neo Medical sales. The printed version will be shipped to you within seven business days.

Terms of Use

Before using the Neo ADVISE™ software please carefully read this **User Manual** and the **Terms of Use.** The Terms of Use are also shown when opening the software.

Confirm your agreement by clicking *Accept* in the software.

Training & Preparation

The use of Neo ADVISE™ software is not allowed without training by Neo Medical. It is allowed to use the software without training when assisted by a Neo Medical representative. Please contact Neo Medical if you want to use the Neo ADVISE™ software and did not personally participate in the training for the safe use of the software.

ⓘ	**The Neo ADVISE™ software must not be used without absolving a training session of Neo Medical, unless when assisted by a Neo Medical representative.**

The software should not be used in surgery without understanding how the software works and having tested the scanning of the guides personally before.

ⓘ	**It is strongly recommended to test the software and do some dry runs before using it in surgery.**

Team Instructions

Furthermore, make sure that the whole team is instructed on how the software is used during the surgery, what it does, and how it works. Handling the device in the sterile environment should also be discussed and clear instructions must be given (see section Sterile Environment).

Automatic Device Locking, TouchID & FaceID

Neo Medical configures the device to not automatically lock and disables device passcodes or other authentication methods like FaceID or TouchID. This is to avoid any delays in surgery caused by entering, or worse, not knowing a passcode.

(i)	**Avoid automatic locking of the device during surgery and do not use biometric authentication methods like FaceID or TouchID.**

Note that technologies like FaceID and TouchID will not work efficiently or not at all while wearing gloves, masks, and caps.

Prepare Hardware

Prepare Sterile Bags

Prepare the device to make sure that the device can be used in the sterile environment (see section [Sterile Environment](#)), i.e. put the device into a sterile bag.

Prepare Markers

If the Marker Detection method is chosen for scanning the guides during the operation, make sure that enough markers and marker bases are available and that they are not being used past their expiration date. You might consider preparing the markers, as described in section [8.2 Scanning Instructions (Marker Detection Method)](#) before starting the surgery.

Prepare Mono-axial Screws

If you plan to use the Trauma or Correction Modules features, also make sure you are aware where you have to use mono-axial screws where angles are measured in the sagittal plane. Please refer to the Neo Pedicle Screw System™ for instructions on how to make pedicle screws monoaxial. See section [Trauma Module](#) and [Correction Module](#) for details.

How to Use the Software

Software Overview

The software consists of several screens, each corresponding to a different step needed to get to the state where the supporting information for the surgery is calculated and displayed.

The following diagram shows the different screens and their purpose:

1. Splash Screen	2. Terms of Use	3. Scan Method Selection
4. Guide Version Selection	5. Patient's Head Position	6. Selection Overview & Confirmation
7. Scene Analysis	8. Help Overlay	10. Scanning the Guides
11 Rod Selection & Screw Adjustments	13 Copy Rod Template Screen	14 Trauma Module
15 Spondylolisthesis Module	16 Correction Module	
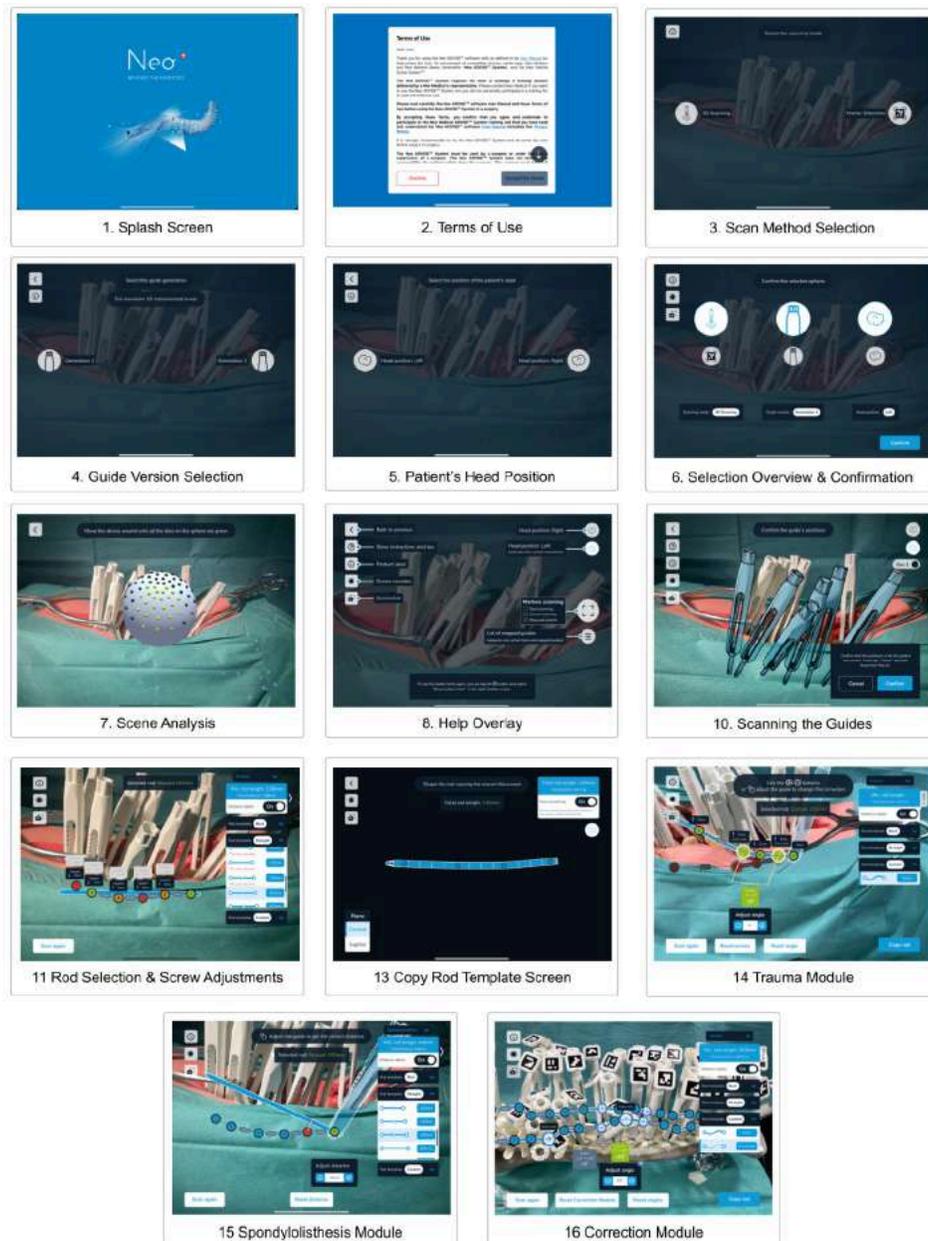
Each of these screens are described in detail in the following chapters.

1 Start the Software

The Neo ADVISE™ software supports the surgeon after the initial placement of the pedicle screws according to the surgical technique of the Neo Pedicle Screw System™.

According to the surgical technique, the next step after placing the pedicle screws is to measure the approximate length of the rod to be implanted using the rod measuring tool and get hints about sagittal screw adjustments. This is where the Neo ADVISE™ software can replace the traditional method and provide more detailed information like sagittal and coronal screw offset & adjustments, the distance between the center of each screw head, the minimal rod length up to generating custom rod templates for controlled fixation.

Note that you can use the Neo Pedicle Screw System™ without the Neo ADVISE™ software and complete the surgery traditionally according to the surgical technique.

1 Splash Screen
Shown during app startup
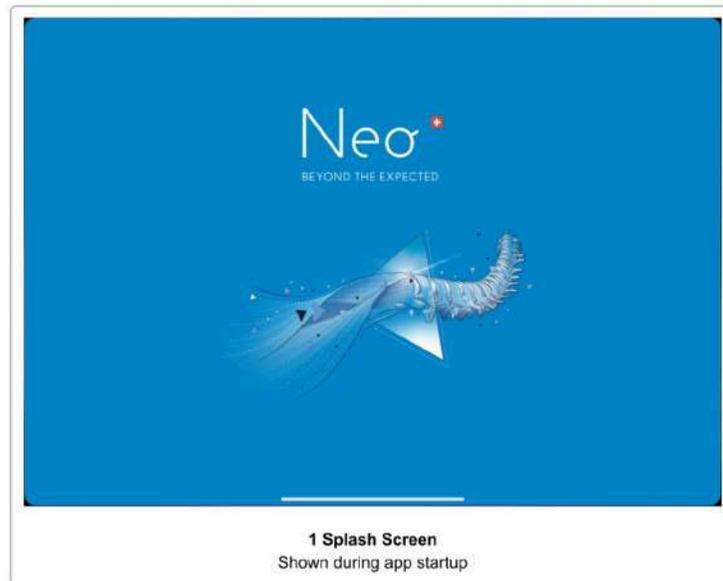
Start and unlock the device (if needed) and start the software by tapping the Neo ADVISE™ software icon on the home screen.

The software will show a splash screen while the software is loading.

2 Terms of Use
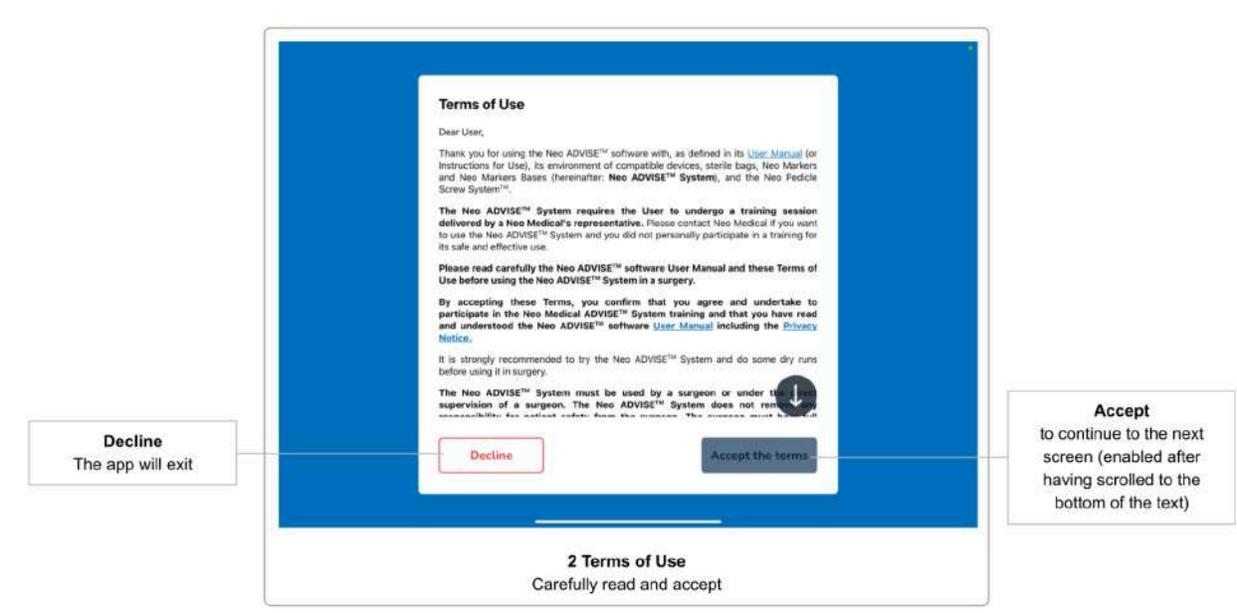
The first screen after the splash screen or the activation screen is the **Terms of Use** dialogue. Please carefully read the terms. Scroll down to the bottom of the text and accept by tapping the *Accept the terms* button.

If you do not agree with the Terms of use and tap the *Decline* button, the software will exit.

3 Scan Method Selection

3 Scan Method Selection
Choose 3D Scanning or Marker Detection
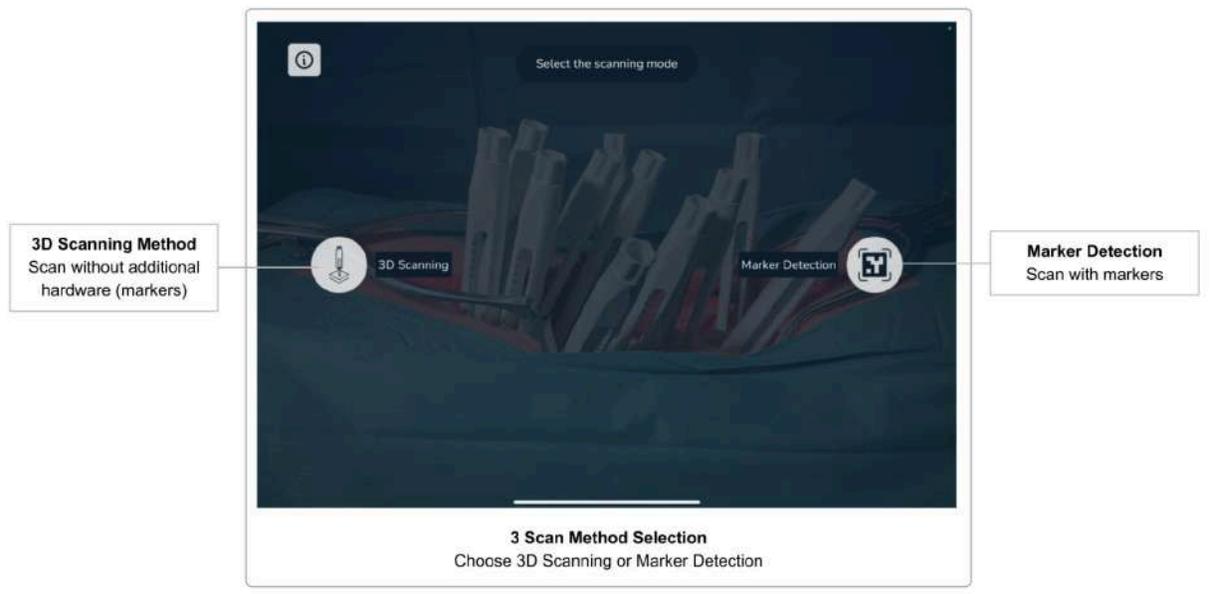
After accepting the terms and conditions, the *Scan Method Selection* screen will appear. Here, you can decide whether to scan the guides using the Neo Markers (Marker Detection) or to scan without using additional hardware (3D Scanning).

Since scanning without the markers is limited to 10 guides, the method using the markers is the preferred method for more complex surgeries.

3.1 3D Scanning Method

This method does not require additional hardware (i.e. markers) and is limited to scanning 10 guides on one side.

For a detailed description and scanning instructions without the markers, see Scanning Instructions (3D-Scanning Method).

3.2 Marker Detection Method

This method requires additional hardware (Neo Markers, sold separately). You can scan up to 30 guides and work on both sides of the spine simultaneously using this method. If you have markers available, you should always prefer this method over scanning without the markers, since this method is easier to handle and takes less time to complete.

ⓘ	**If you have markers available, scanning the guides using the markers (Marker Detection) should always be the preferred method**

For a detailed description and scanning instructions using the markers, see section Scanning Instructions (Marker Detection Method).

If you select the Marker Detection method, you will then be asked whether you want to work on one side of the spine and later work on the other side, or if you want to work on both sides of the spine simultaneously.

After having selected the scan method, you will automatically continue to the next screen.

4 Selecting Guide Version

4 Guide Version Selection
Choose between Gen. 1 and Gen. 2 Guide
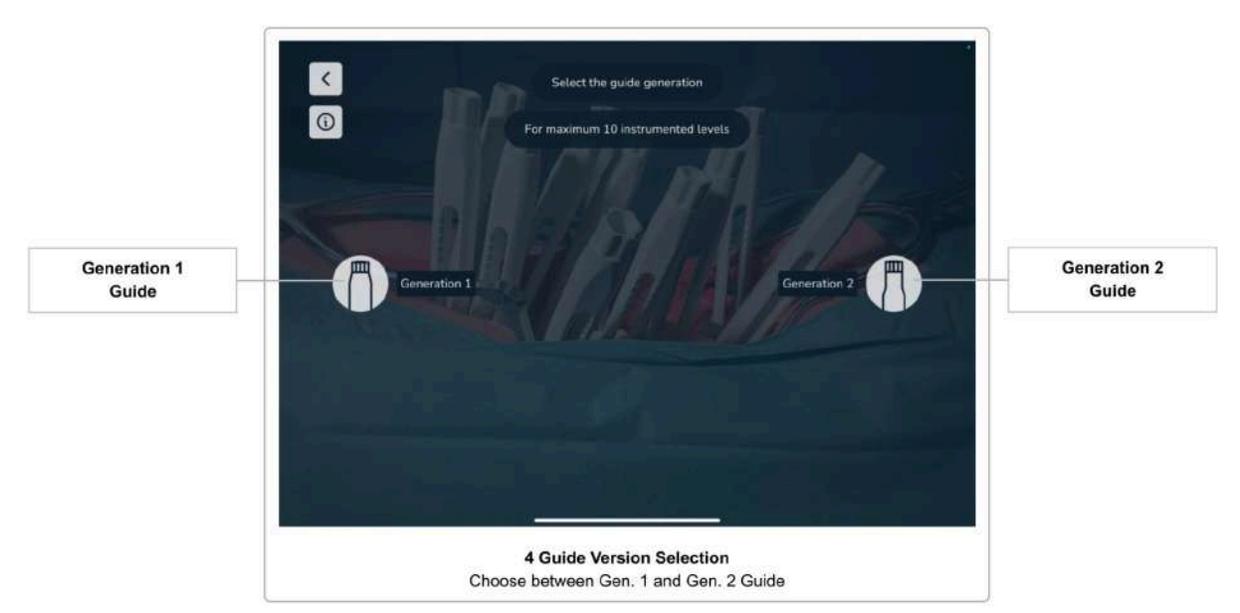
Currently, Neo Medical offers two different versions of the guides (Generation 1 and Generation 2). Although they do not differ in functionality or features, it is important for the software to know which versions are being used.

Please select the version of the guides that you are using. The next screen will appear automatically after selecting the option.

Guide Versions

The following pictures show the two versions of the guides.

Differences between Generations

Generation 1

Generation 2

Guide Generation Comparison
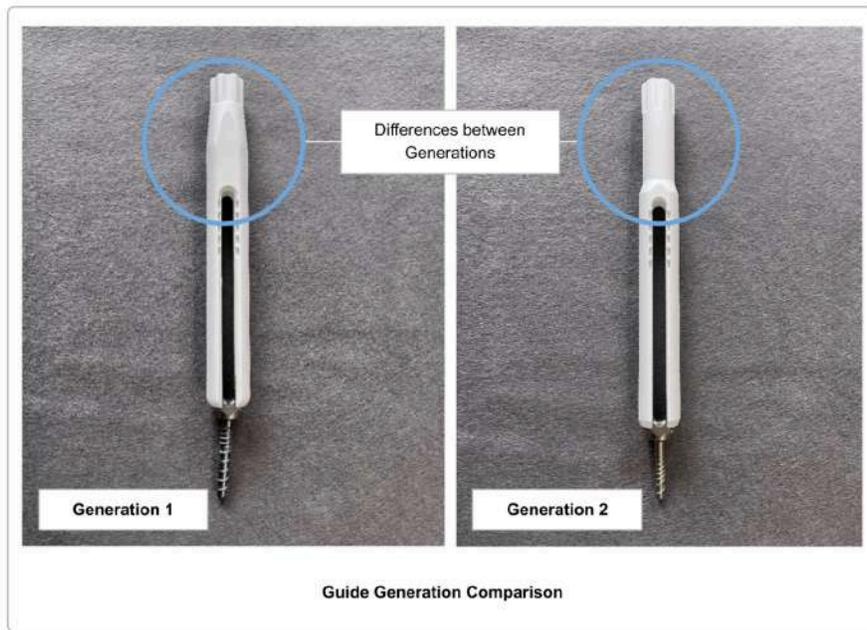
Mixing Guide Versions

It is possible to use both versions of the guides within one surgery. Your choice done in Selecting Guide Version will be the default value used when scanning the guides, however, you can still change the version for each scanned guide individually during the scanning process.

5 Selecting the Patient's Head Orientation
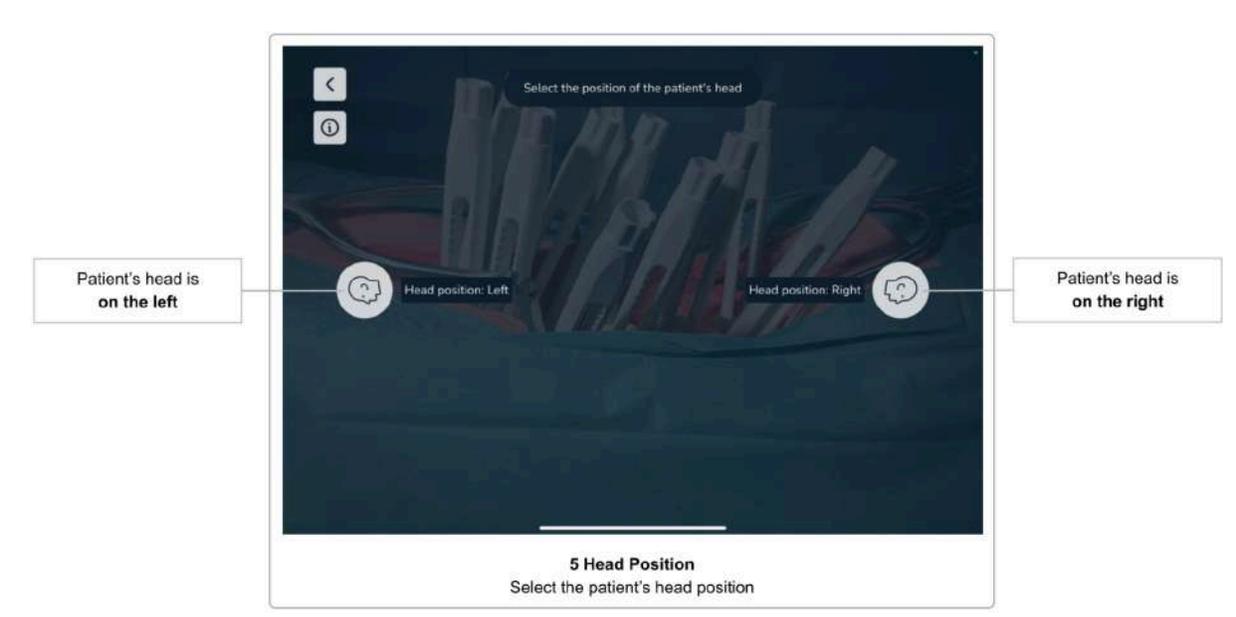
After having selected the guide version, in the next screen, you are asked to select the orientation of the patient's head with respect to the device screen (to the left or to the right). Knowledge of the direction of the craniocaudal axis is important for the software to display the correct rod placement and screw adjustments, and is crucial for the trauma and spondylolisthesis modules.

While the surgeon can change sides at any time during the surgery, the software must only be used on the side which was selected before starting to scan the guides. If the user of the software decides to use the software on the other side of the patient, the orientation of the patient's head must be changed in the software accordingly. Changing the patient's head position in the software can also be done after having scanned the guides (see section Changing the Patient's Head Position), but requires subsequent rescanning of all guides.

(i)	**The software must be used on the side of the patient that was selected in Selecting the Patient's Head Orientation.** **Changing the side requires the rescanning of all guides.**

6 Confirmation Overview

6 Selection Overview
Check and confirm the selected options
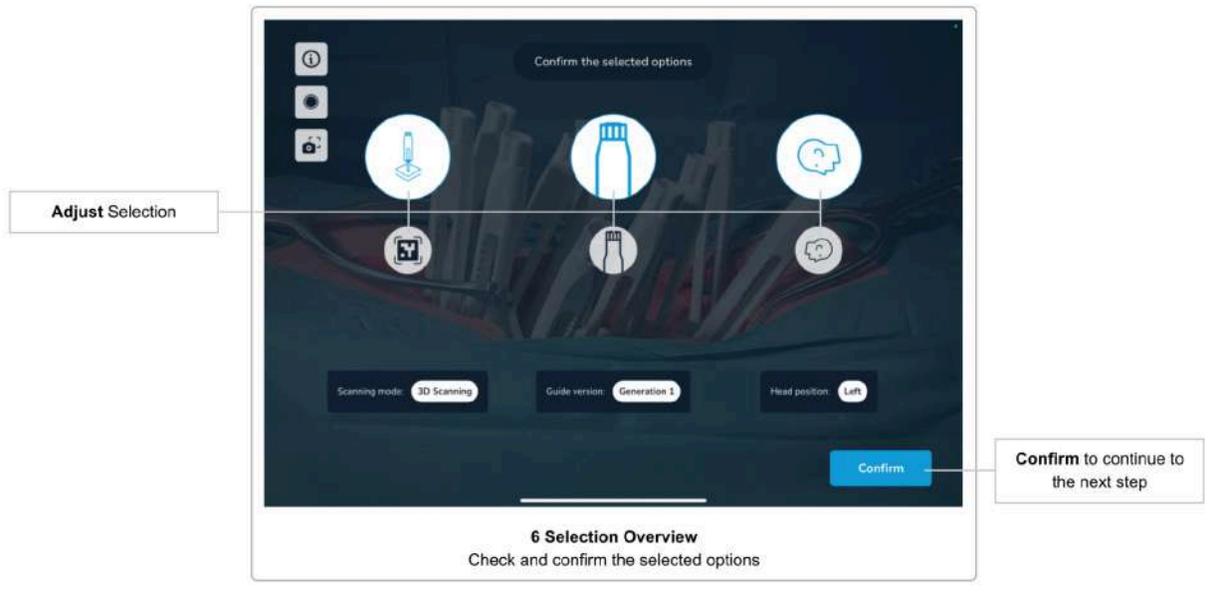
The next screen summarizes the selected options up to this point (scan method, guide version, and patient's head orientation). Please ensure that you have selected the correct options and confirm using the *Confirm* button. If you want to change an option, you cannot go back to the individual screen, but select an option directly on this screen.

Note that the *Confirm* button is disabled if you selected the 3D Scanning method in the previous screens and change the scanning method to Marker Detection. Please first decide whether you want to work on one side of the spine only or on both sides of the spine simultaneously. Only once the Marker Detection side option is selected the *Confirm* button will get enabled again.

7 Scene Analysis

Before you can start scanning the guides, the system must first get an understanding of the environment to be able to map the virtual and the real world.

7 Scene Analysis
Step 1: Point the camera to the patient's body

7 Scene Analysis
Step 2: Make all dots green by orbiting around the sphere
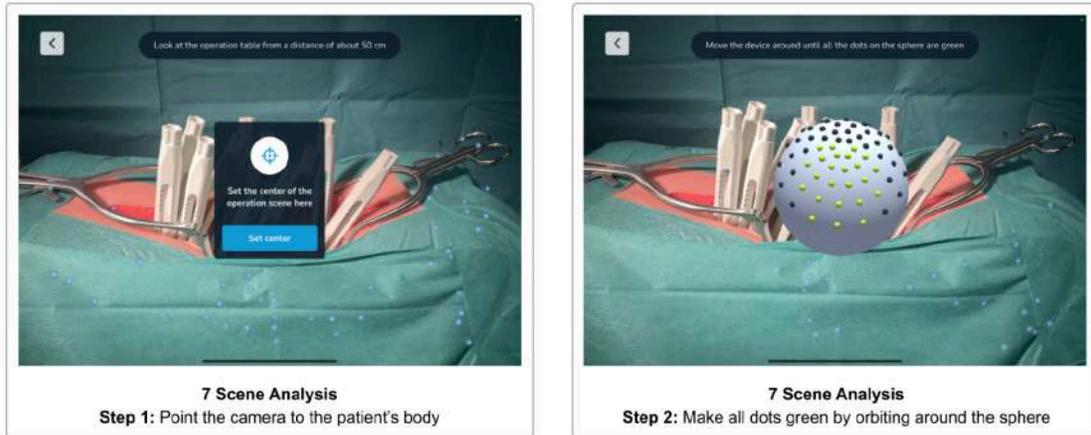
To start the scene analysis, tap the *Start* button. Now, point the device to the patient's body, so that the camera view shows the incision at a distance of about 50 cm. You will see a message if you are too close or too far away. Hit the *Confirm* button to set the center of the operation scene.

For optimal scanning results, we recommend setting the ceiling lights of the room to the maximum brightness and not using OR lights. The very bright and narrow light beam of OR lamps should be avoided since they will cause unwanted reflections and cause shadows that could impact the scanning performance. The surgical table should be lowered to the maximum. See section [Scanning Environment](#) for more details.

You will now see a sphere with gray and green dots on the surface. Orbit the device around the sphere, preserving the distance between the sphere and the device. The goal is to make all dots go green by looking at them from all directions. Move the device slowly and tilt it to always have the sphere in the center of the screen. You will see a warning if you are moving the device too fast.

Once all dots are green, the scene analysis step is complete and the next screen will appear.

Skipping Scene Analysis

Time is critical during surgery. Therefore, the system allows to skip the scene analysis step if the last analysis has been performed within the last five minutes, and no options on the confirmation screen have changed (i.e. scan method, guide version, or the patient's head position).

7 Skip Scene Analysis
Tap *Skip* if conditions met

7 Skip Scene Analysis
Confirm skipping
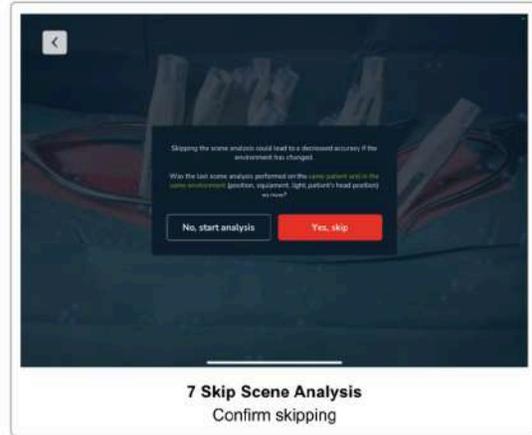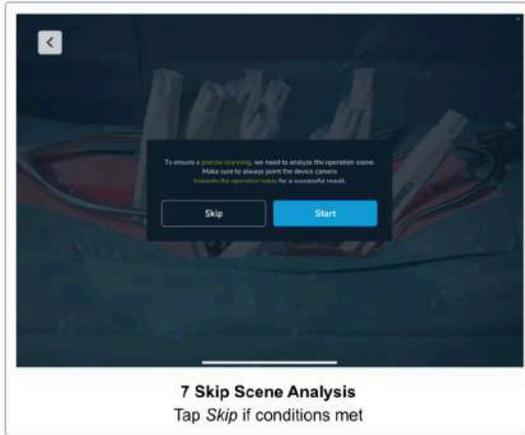
If the above conditions hold, the first dialogue of the scene analysis step shows a *Skip* button. You need to confirm that the previous scene analysis was performed on the same patient, that the patient has not been moved and the lighting conditions are still the same. Do not skip the scene analysis step if any of the just mentioned conditions changed.

8 Help Overlay

8 Help Overlay
Can be accessed using the [?] button, then tapping *Show Button Hints*
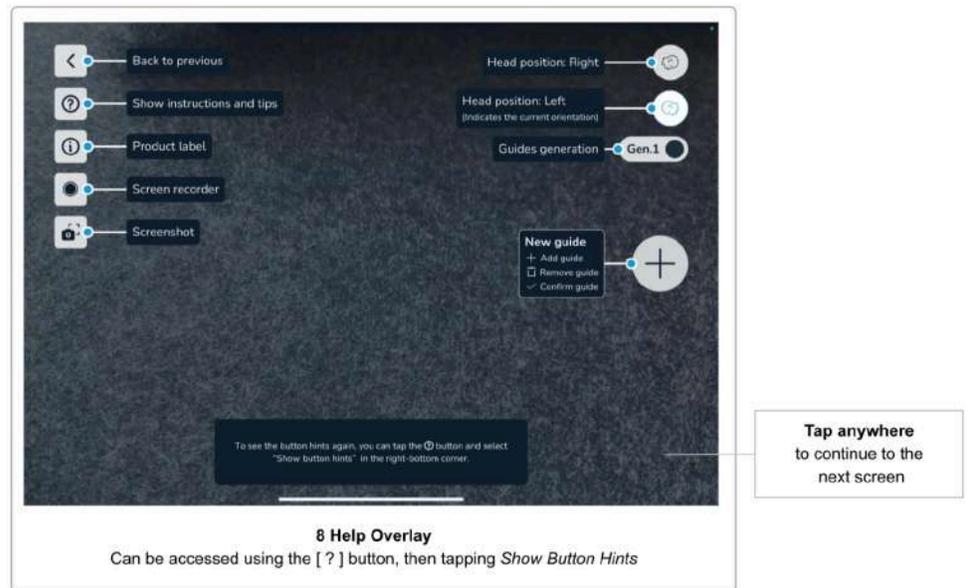
This screen shows a help overlay describing the function of the user interface elements that will be relevant in the coming screens.

The help overlay is displayed only the first time you use the software. You can access the help overlay anytime by tapping the *Help* button, showing the *Scanning Instructions and Tips*, where you find *Show Button Hints* on the bottom-right corner.

Tap anywhere on the screen to continue to the next screen.

9 Screen Recorder and Snapshot Tool

The software features easy controls to take a screenshot and to start a screen recording of your current software session.

(i)	**Please consider that screenshots and video recordings can contain personal information and patient data (e.g. faces of the surgeons and the team, the patient's body, screen content of other systems, etc).** **Always make sure you protect the patient data and other sensitive information according to your allowances. It is your responsibility to ensure that patient data, screenshots and screen recording are not shared without the consent of the patient.**

Screen Recorder

9 Screen Recorder Buttons
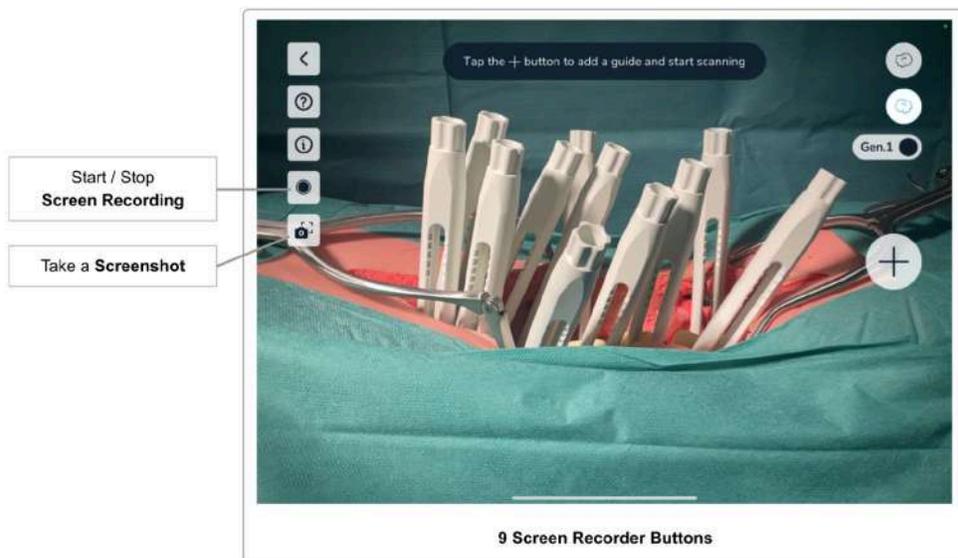
To start a screen recording, tap the *Screen Recorder* button. The first time you use the screen recording feature on this device, you might get asked for permission to allow the software access to the *Photos Library*. This is needed to allow the software to save the recordings on the device. Tap *Allow* to continue.

You will get asked before every screen recording to allow the software to start the screen recording. This is a privacy protection feature of iOS that ensures that you are aware that the software will record the screen content.

The software will record the content you see on screen. This can be helpful after the surgery to discuss the case with other doctors in the course of the patient treatment. Use of data outside the patient treatment and required follow-up is subject to patient consent.

The *Screen Recorder* button indicates an ongoing recording with a red dot. Stop the recording by tapping the button again.

Audio is NOT recorded.

The video recordings are saved in the *Photos App* on the device. You can open the *Photos App* by closing the Neo ADVISE™ software and tapping the *Photos App* app icon to find your recordings.

Screenshot Tool

Use the screenshot button to take a snapshot of the currently displayed screen content. The screenshot is saved in the *Photos App* of the device.

When using this feature for the first time on this device, you might get asked for permission to access the *Photos App*. This is needed for the software to be able to save the screenshots. Tap *Allow* to continue.

10 Scan Guides

10 Scan Screen Overview
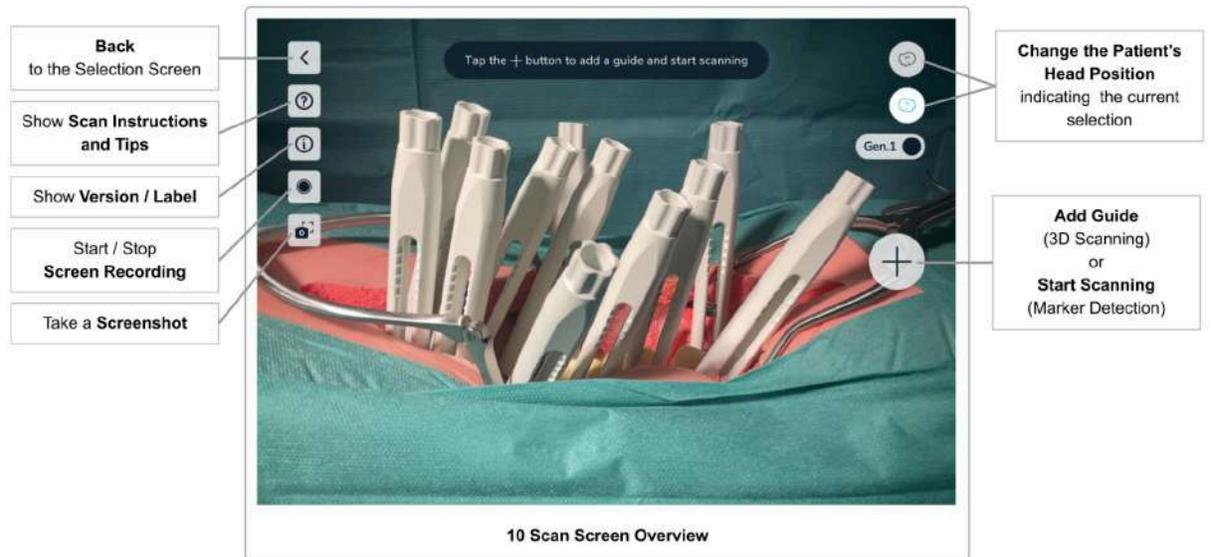
Scanning the Guides is central for calculating the measurements the software will do. By scanning the guides, the software will calculate the exact position of the screw heads and use this information to do the calculations.

It is important to carefully follow the instructions and execute this step slowly and diligently.

Scanning Environment

The performance of the system, especially the scanning accuracy and precision, depends on several factors in the scanning environment. Suboptimal lighting, moving objects in the background, or reflective surfaces can negatively affect the scanning.

During the scanning, it can happen that the virtual guides drift off their original position when moving the device, which will result in inaccurate relative positions of the guides. This is an indication that the scanning environment is not optimal and should be improved.

Avoid Moving Objects

The AR subsystem works by finding so-called feature points in the camera image within each frame that the camera system provides. The position of each feature point is compared between two subsequent frames to determine the movement of the device and therefore calculate the new position of the device in the environment.

If there are moving objects in the background or close to the patient, the feature points that were detected on those objects will move unexpectedly, making it harder for the system to detect the movement of the device. Therefore, moving objects should be avoided. For optimal results, please advise other people in the room to not move during the scanning of the guides.

Optimally, no other people should be standing next to the patient during the scanning to avoid unexpected movements.

Avoid Reflective Surfaces

For the same reason as just explained for moving objects, reflective surfaces should be avoided as well. The system might detect feature points reflected on shiny surfaces, which will move unexpectedly when the camera changes its position.

Therefore, for optimal results, avoid reflective surfaces, like metallic tables, large objects made out of glass, or other shiny, reflective surfaces. Cover them with a cloth if possible.

Optimal Lighting Settings

Good lighting is very critical for the system to work properly. Too bright hotspots, as well as too dark lighting, will impact the system's performance.

For optimal results, please consider the following:

- **Turn up the brightness of the lighting in the room (typically the ceiling lights) to the maximum brightness.** Having multiple, bright, and diffuse light sources is best for optimal results.

- **Avoid bright spotlights**, typically coming from OR lamps. If using OR lamps cannot be avoided, set them to a wide light beam setting and low brightness if possible. Also, adding multiple light sources can be considered.

The problem with bright, narrow light beams is that they will cause the camera system's auto-exposure to extreme settings, leading to dark backgrounds to avoid overcasts in the bright center of the scene. The system then cannot work properly since the system cannot detect the surrounding environment. Furthermore, narrow light beams will cause unwanted shadows or reflections on the guides or markers.

Note that all changes to the environment, especially changing the lighting, can be reverted after the scanning of the guides is completed.

(i)	**For optimal scanning results, use as many diffuse and bright light sources as possible and avoid using OR lamps with narrow light beams.** **Furthermore, avoid reflective surfaces or moving objects in the background.**

Overview of the Scanning Screen

On the scanning screens, the following user interface elements are common for the *3D Scanning* and the *Marker Detection* method.

Button *Scanning Instructions & Scanning Tips*

You can display **Scanning Instructions** and **Scanning Tips** by tapping the *Help* button in the upper left corner. This will give you a quick overview of how to do the scanning and gives you hints on what you can do if you are having difficulty scanning the guides.

During scanning, the help button starts to glow after scanning for 10 seconds to indicate where to find the instructions and tips for scanning.

Button *Version & Product Label*

See [Product Label / software Version](#).

Button: *Screen Recorder*

See section [Screen Recorder](#).

Button: *Screenshot*

See section [Screenshot Tool](#).

Button: *Back*

If you want to revise any decision regarding the scan method, guide version, or the patient's head position, you can go back to the *Confirmation Overview* screen.

Button: *Changing the Patient's Head Orientation*

The two buttons in the upper right corner of the screen are used to indicate and switch the orientation of the patient's head.

The highlighted button indicates the selection made earlier on the screen [Selecting the Patient's Head Orientation](#). By tapping the non-highlighted button, you can change the position at any time.

If you switch the head position of the patient, you have to confirm switching and need to rescan all previously scanned guides.

(i)	**Make sure not to move the patient during or after scanning the guides.** **If the patient has been moved, you need to re-scan the all guides.**

10.1 Scanning Instructions (3D-Scanning Method)

This method does not require additional hardware (i.e. markers) but is limited to scanning 10 guides on one side of the spine.

(i)	**3D Scanning of the guides is limited to 10 guides per side**

The 3D Scanning method is based on computer vision algorithms using the camera image of the built-in camera of the device. Based on the known 3D model of the guides, the software tries to find the positions of the guides in the image. To support this process, the user has to scan each guide separately and move the device in such a way that the virtually overlayed guide matches the guide in the patient's body.

(i)	**When using the 3D Scanning Method, the user has to scan each guide separately**

Please make sure that you only scan guides on one side of the patient's spine at a time (either the left or right side). Including guides of the other side will lead to wrong results.

(i)	**Only scan guides on one side of the patient's spine when scanning using 3D Scanning.** **Scanning both sides at the same time is only supported using the Marker Detection scanning method.**

(i)	**3D Scanning only works if at least half of the guide is visible (i.e. 1 cm of the window / bridge of the guide is still visible).**

Step 1 Adding the first Guide

10.1 Scan Guides (3D Scanning)
Step 1: Add Guide
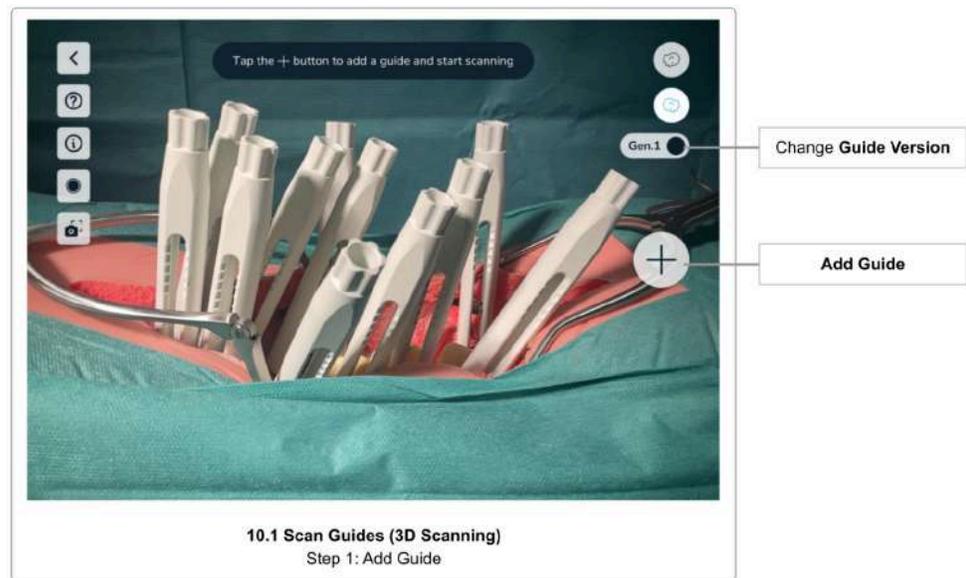
Start scanning the first guide by tapping the *Add Guide* button. Make sure that the correct version of the guide is selected by checking the *Guide Version Selection* toggle.

Change the version of the used guide by tapping the *Guide Version Selection* toggle button.

1. Initial Pose

2. Overlapping the virtual guide with the physical guide

Tap **Chancel** to reset the scanning of the current guide

Move closer to the Guide if the Virtual Guide is yellow

Make sure the **crown and the gap** exactly match when confirming

Tap the **checkmark button** to confirm this guide's position

3. Confirming the position of the virtual guide

Tap **Add Guide** to continue to the next guide

Virtual guide after confirmation (mapped state)
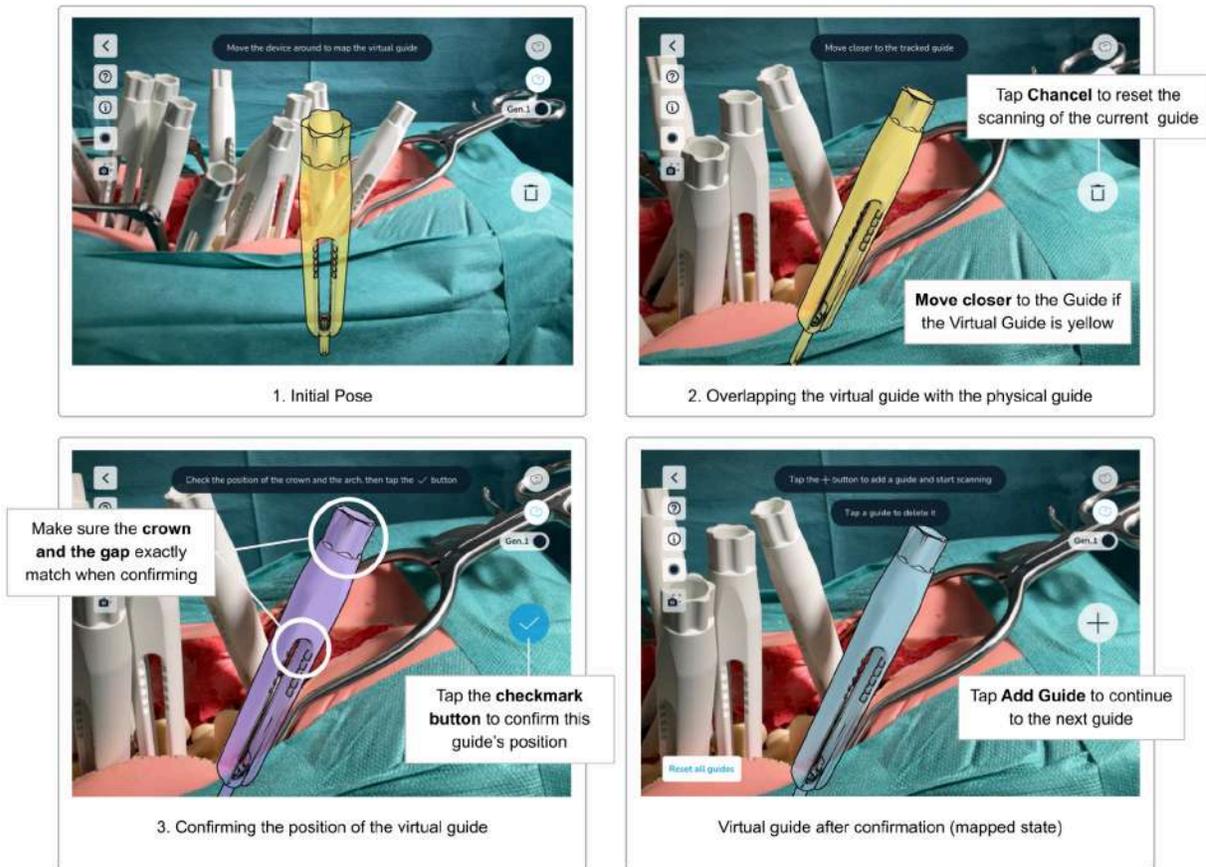
10.1 Scan Guides (3D Scanning)
Step 2: Mapping the Virtual Guide

After tapping the *Add Guide* button, the software will display a virtual model of a guide on the screen.

Move the device in such a way that the virtual guide matches exactly the pose of the guide in the patient's body. For best results, try to focus on the upper part of the guide (the 'crown') and the top end of the window (white highlights in the image above).

As soon as the software finds a guide in the patient's body, the virtual guide snaps to the real-world geometry of the guide. If you are close enough, the virtual guide changes its color to purple to indicate that you are now able to confirm the guide's position. If you are too far away, the virtual guide will keep the yellow color. **Move closer to the guide to get it to the purple state.** Only in the purple state can the guide's position be confirmed.

While in the purple state, carefully observe the small positional updates of the virtual guide with respect to the physical guide that still occurs in this state. **As soon as the virtual and the physical guide overlap completely, tap the *Confirm* button to fix the position for this guide.** The guide will then turn blue (mapped state). Mapped guides will stay at their confirmed

position. However, when moving the device to the next guide, it's possible that the overlay of mapped guides does not overlay with the physical guide anymore (a few millimeters of offset is visible). If this happens repeatedly, this is an indication that the environment is not optimal for scanning. Try changing the lighting and rescan the offset guides, see Scanning Environment for optimal lighting settings.

If you observe an offset between the virtual and the physical guide, you can **rescan single guides by tapping the guide and then use the *Remove Guide* button** (trash icon) to remove the guide. Then, use the *Add Guide* button and rescan the guide.

If you have trouble matching the virtual guide, see section Tips and Troubleshooting 3D Scanning for some tips.

Step 3 Scanning additional Guides

10.1 Scan Guides (3D Scanning)
Step 3: Add more Guides

Continue the scanning process by **tapping the *Add Guide* button again to scan additional guides**. Repeat the same procedure for all the guides you want to scan.

Always make sure to have selected the correct version of the guide before starting to scan the next guide. Change the version using the *Guide Version Toggle* button accordingly.

Note that the order of scanning the guides does not matter, however, it is easiest to scan the guides from left to right meaning from cranial to caudal.

Step 4 Edit mapped Guides and Confirm

10.1 Scan Guides (3D Scanning)
Step 4: Edit and rescan Guides if needed
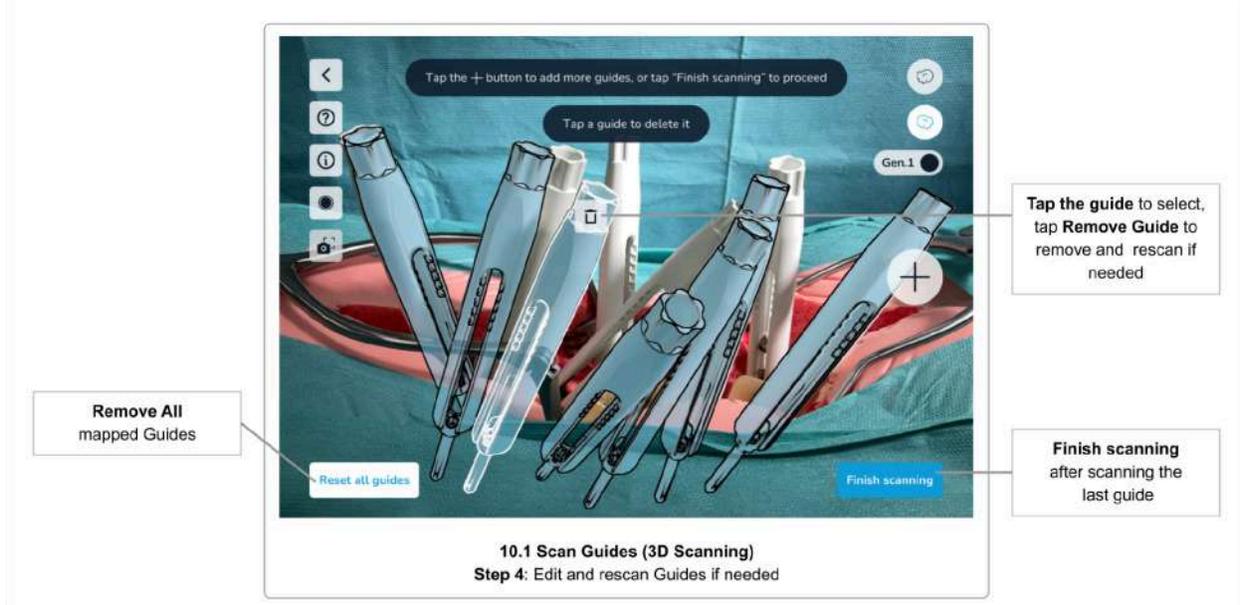
To edit mapped guides (guides that are scanned and have a confirmed position, colored blue), you can simply tap the guide to reveal the *Remove guide* button (trash icon). Use the *Remove Guide* button to delete a guide, either for rescanning or ignoring it completely.

Tapping the *Reset all guides* button will remove all mapped guides. This is useful if for example the patient's body has been moved after or during the scanning, leading to the mapped guides' positions being outdated.

Once you have scanned all guides, **tap the *Finish scanning* button to proceed to the next step**.

Step 5 Confirm Positions

10.1 3D Scanning
Step 5: Confirm Positions

10.1 3D Scanning
Step 6: Confirm the patient's head positions
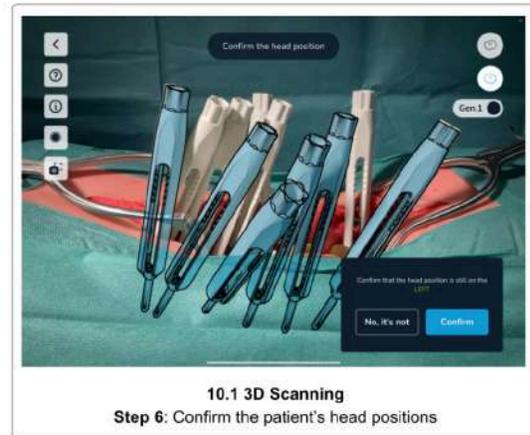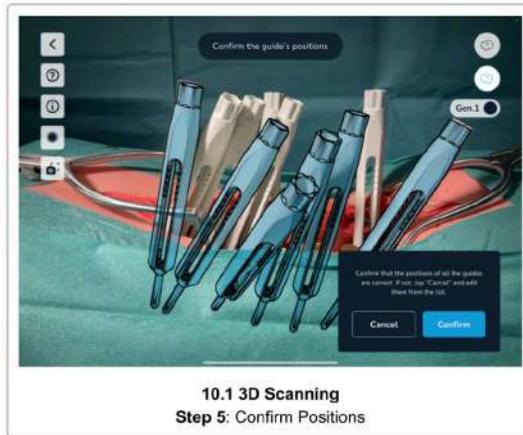
Finally, visually check all positions of all guides again and tap *Confirm* if they are OK. Tap *Cancel* to go back and rescan some or all guides if needed.

ⓘ	**Visually checking and confirming the guides' positions is important.** **Not properly scanned and therefore wrongly positioned guides will lead to wrong results.**

Step 6 Confirm the Patient's Head Position

Before completing the scanning step, please re-confirm the patient's head position. This is required to make sure you have not moved to the other side of the patient while scanning.

Tap *Confirm* if you are still on the same side as before starting the scan, or *No, it's not* to change the registered position of the patient's head to the other side.

After confirming all the guides' positions and the patient's head position, the next screen is the [Rod Selection, Screw Distances & Screw Adjustments](#) screen.

Tips and Troubleshooting 3D Scanning

If you have trouble matching the virtual guide to the guide in the patient's body, the following tips might help:

Tips & Troubleshooting 3D Scanning

- Make sure that the correct scanning method was selected in [Scan Method Selection](#)

- Verify that the correct version of the guide is selected

- Clean the guides. Ensure that the upper part of the guides are clean and outside the patient's body

- Change the lighting conditions to increase the contrast and avoid reflections. Multiple light sources with bright, diffuse light (e.g. ceiling lights) are optimal. Narrow lights beams (e.g. OR lamps) should be avoided

- When matching the virtual guide, try to focus on the crown and the top end of the window (also called arch/bridge)

- Move the device away from the patient's body and then try again by getting closer to it. This supports the auto-focus of the camera system

- Align the physical guides before starting the scan so that all windows of the guides are facing toward the camera.

- When using sterile covers or bags for the device, make sure that the camera lenses are not covered and transparent materials over the lenses sit flat, to not cause distortions or reflections

10.2 Scanning Instructions (Marker Detection)

The Marker Detection scanning method requires **Neo Marker Bases** and **Neo Markers** (sold separately). You can scan up to 30 guides using this method. If you have the markers available, you should always prefer this method over scanning without markers.

i	**If you have markers available, scanning the guides using the markers should always be the preferred method.**

Marker Detection works for scanning the guides on one side of the spine and on both sides of the spine at the same time. See Working with Markers on both sides of the spine for further instructions.

Neo Marker Base & Neo Markers

To use Marker Detection scanning, you have to first assemble the Neo Marker Bases and the Neo Markers before surgery and make sure these are kept in sterile conditions (see Step 1 Preparation).

There are sets of 24 markers and sets of 6 markers. Do not mix identical marker sets. You can mix the 24 set with the 6 to have a maximum of 30 markers, but do not mix two of the same type. The software will show an error if it detects markers from identical sets.

i	**Do not mix identical marker sets.**

i	**Note that the markers and the marker bases are sterile and disposable products. Do not reuse and discard after one use.** **If a marker set contains more markers than needed for the current procedure, the leftover markers cannot be used anymore and must be discarded.**

ⓘ	**When detaching the Marker Base from the Guide, make sure to hold the guide to avoid screw pullout in weak bone structures.**

Step 1 Preparation

Before starting to scan the guides using the markers, prepare the markers and attach them to the guides.

1. **Check Availability**
   Make sure you have enough markers and marker bases available. You need one marker and one marker base per guide.

2. **Stick Markers onto the Marker Bases**
   Unpack the marker and the marker bases and stick the makers on the marker bases, while keeping in mind that both products are sterile and must not get contaminated.
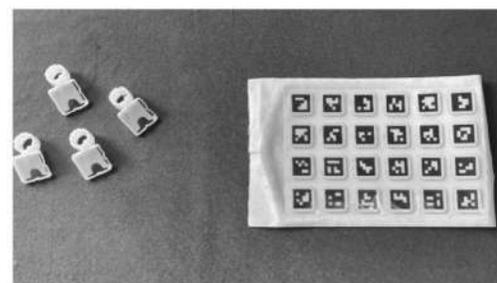
1. Prepare Bases and Markers (both sterile)

2. Prepare Bases and Markers (both sterile)
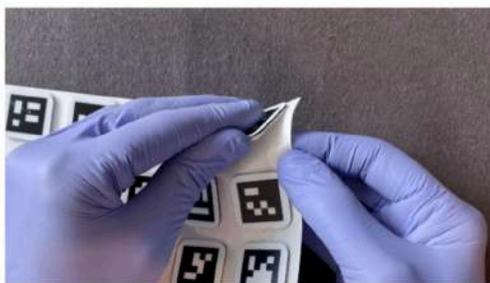
3. Detach a Marker

4. Fit into the Marker Base and check proper fit

10.2 Marker & Marker Base Assembly

3. **Attach the Marker Bases to the Guides**
   Once the pedicle screws have been placed in the pedicles, the marker bases can be

attached to the guides, making sure that the base sits very tight. The top end of the guide and the marker base must be flush.

Ensure proper fit
Push the Marker Base down such that its edge is level with the crown of the guide

10.2 Marker Base Assembly
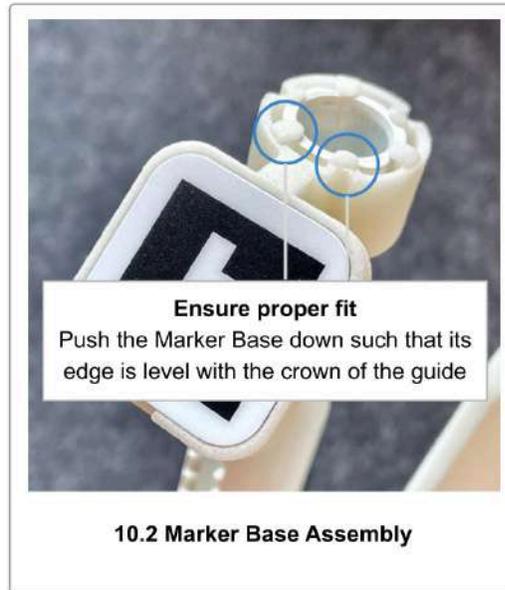
4. **Place the marker bases so that they are not occluding each other**
   You will need to scan every marker from three different angles. When working with many markers, it can be difficult to find an optimal position for each marker. Therefore, take your time to find a position for each marker that leaves as much space between the markers as possible. Place the markers so that they can be viewed from as many angles as possible without occlusion.

10.2 Scan Guides (Marker Detection)
Place the markers to avoid occlusion by other markers

Only put the markers on the side of the spine you currently are working on, if you decide to only work on one side of the spine in one scan.

Step 2 Scan All Markers
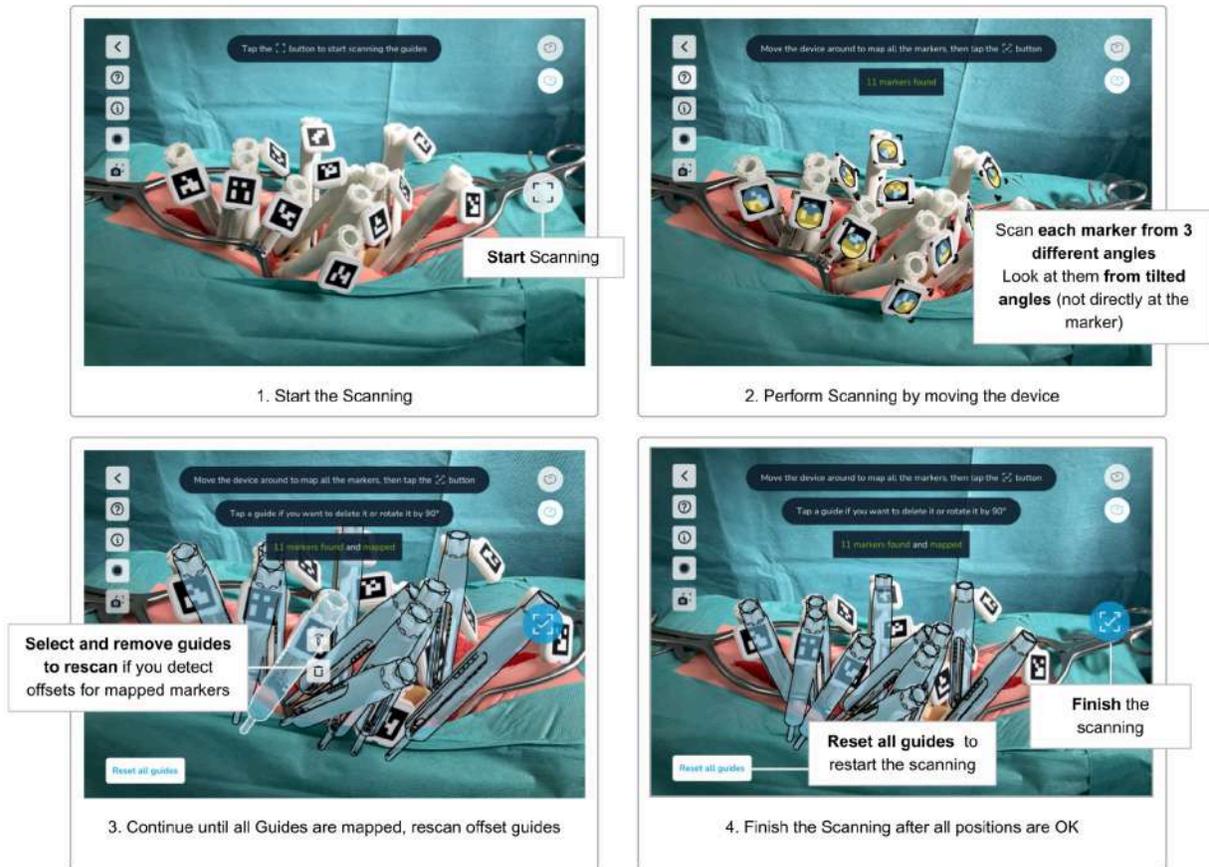
10.2 Scan Guides (Marker Detection)
Scanning the markers

Once you have attached the marker bases onto all guides that you wish to scan and **placed the markers optimally without occlusion**, you may start the scanning process by **tapping the *Start scanning* button**.

Point the camera of the device towards the markers. The recommended scanning distance is about 30 cm. It is not required to focus on a single marker at a time, and you may be able to capture multiple, or even all, markers simultaneously.

The scanning process consists of the following steps:

- Find the markers
- Refine the positions by looking at each marker from three different angles
- Check for misaligned markers (orientation/rotation)
- Confirm the positions
- Partition the guides left/right (only when working on both sides of the spine simultaneously)

As soon as the system detects a marker, the edges of the marker get highlighted with yellow corners. This indicates that **the system detected the marker, but still needs to refine its position**. Additionally, a yellow circle appears on the marker.

Each marker needs to be scanned from **three different angles**. By moving the device **left and right**, but also **top, down, and back and forth** (orbiting), try to get as many angles for each marker as possible. Each detected angle is visualized by a blue segment on the yellow circle on the marker. The blue segment in the circle indicates the detected angles. This means that **the direction of the remaining yellow segments indicate where more angles are still needed** to refine and finally map the guides position.

While scanning a specific marker, try not to point the camera directly at the marker. The position refinement works best with **slightly tilted angles**, while the marker is still fully visible. Too direct angles (facing the camera) are ignored, as well as too flat angles. The optimal angle is between **10° and 45°**.

10.2 Marker Detection
Do not scan the markers directly…

10.2 Marker Detection
…but from an angle of 10° to 45°
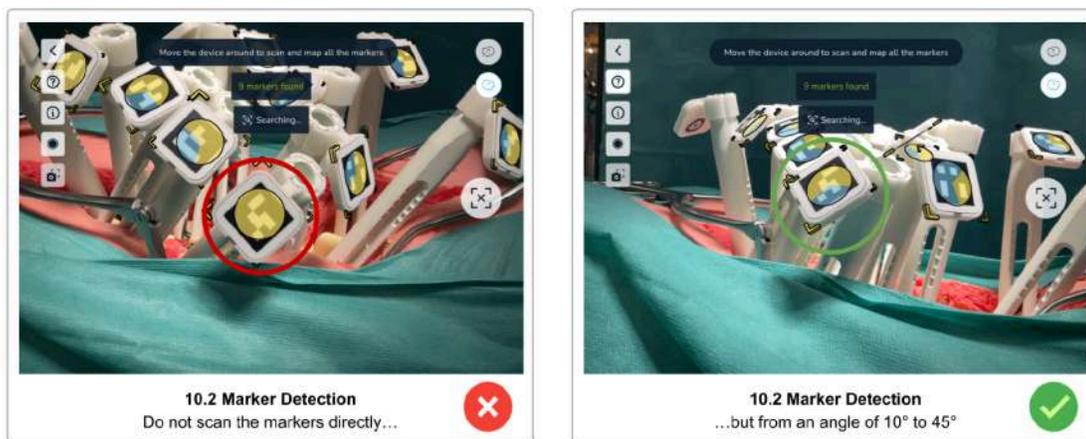
Move the device slowly and avoid abrupt direction changes. If you move the device too fast, a yellow warning message appears.

Once a marker was scanned from three different angles, the yellow corners on the marker disappear, the yellow angle indicator fills all segments to blue and then disappears as well. Finally, the virtual representation of the guide is shown in blue (mapped state).

Continue with the scan until all markers have been successfully mapped.

If you see that a mapped guide is not overlapping with the physical guide or is offset, you can rescan a single guide. **Tap the guide to reveal the *Remove guide* and the *Rotate guide* buttons.** Use the *Remove guide* button to delete the offset guide and rescan the guide until it completely overlaps with the physical guide.

Once all guides have been mapped, the *Scan* button changes to *Finish scan* (checkmark) state and turns blue. **Check all guide's positions again and remove and rescan offset guides**

until each guide's position perfectly overlaps the physical guide. Then, **tap the blue *Finish scan* button to complete the scanning**.

Use the *Reset all guides* button to remove all scanned guides and start over with the scanning. This might be necessary if someone moved the patient during the scanning or if you get interrupted and had to put the device aside.

Step 3 Correct Guide Orientation/Rotation

10.2 Scan Guides (Marker Detection)
Rotate Guides to correct their orientation
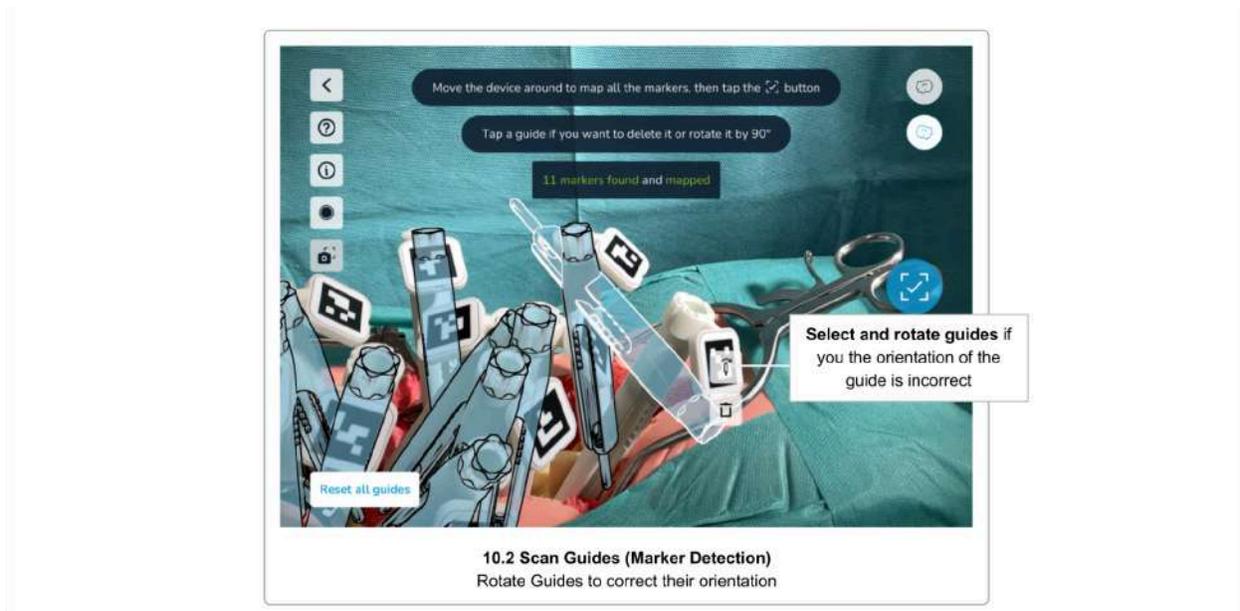
If a physical guide is tilted with an angle more than 45°, the system cannot determine the correct orientation of the guide. In that case, tap the misaligned guide to reveal the *Remove guide* and the *Rotate guide* buttons. **Use the *Rotate guide* button to rotate the virtual guide by 90° until the marker's orientation is correct**.

Step 4 Confirm Positions

10.2 Marker Detection
Step 5: Confirm Positions

10.2 Marker Detection
Step 6: Confirm the patient's head positions
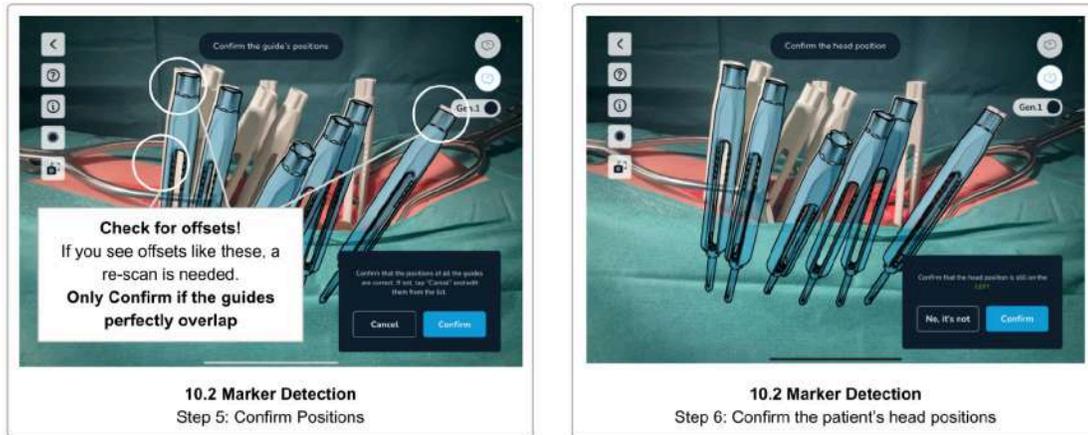
After having scanned all markers and tapped the *Finish scanning* (checkmark) button, again, visually check the virtual guides' positions and orientations. If you see offset guides, tap *Cancel* to go back and rescan offset guides. Only if all guides are perfectly overlapping the physical guides, tap *Confirm* to finish the scanning process.

<table>
<tr><td>(i)</td><td>Visually checking and confirming the guides' positions is important. Not properly scanned and therefore wrongly positioned guides will lead to wrong results and suboptimal instructions for screw adjustments and distances between the guides.</td></tr>
</table>

Step 5 Confirm the Patient's Head Position

Before completing the scanning step, please re-confirm the patient's head position. This is required to make sure you have not moved to the other side of the patient while scanning.

Tap *Confirm* if you are still on the same side as before starting the scan, or *No, it's not* to change the registered position of the patient's head to the other side.

Step 6 Partitioning Left and Right Guides

10.2 Marker Detection
Select all Guides (white) on the right side of the spine
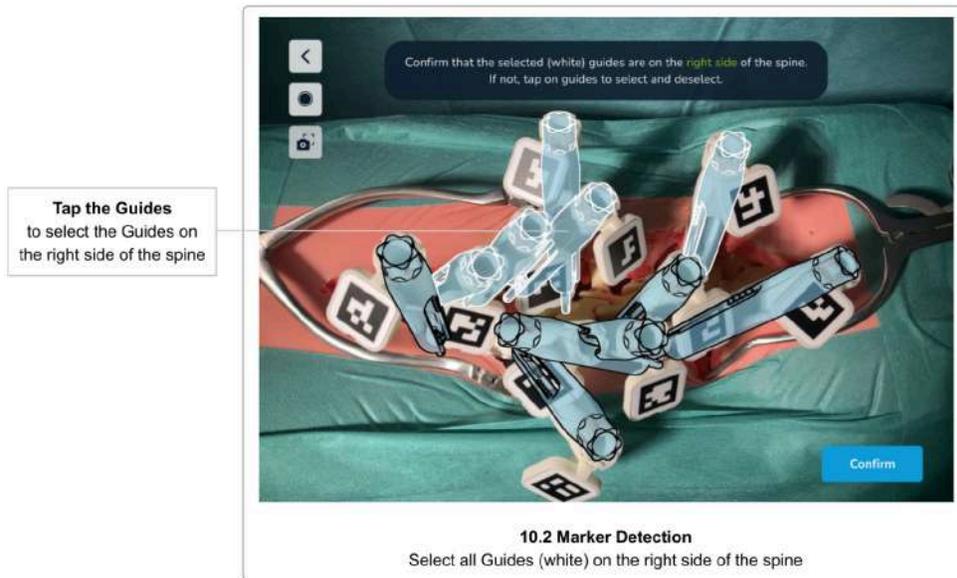
This step is only needed if you selected to work on both sides of the spine at the same time. It is skipped if you have selected to only scan one side of the spine at the time.

This step is to partition the scanned guides left and right. The system tries to figure this out automatically but might need some adjustments.

The system marks the guides on the right side of the spine with a white outline and the guides on the left side of the spine with a black outline. Tap the guides to change their assigned side until all guides are correctly partitioned. At least two guides need to be assigned to either side to be able to continue to the next step.

After confirming all the guide's positions and the patient's head position (and partitioning the screw heads if you work on both sides simultaneously), the next screen is the Rod Selection, Screw Distances & Screw Adjustments screen.

Tips and Troubleshooting Marker Detection Scanning

If you have trouble scanning the markers, the following tips might help:

(i)	**Tips & Troubleshooting Marker Detection Scanning** ● Make sure that the correct scanning method was selected in Scan Method Selection ● Clean the markers. Ensure the markers are clean.

- Change the lighting conditions to increase the contrast and avoid reflections. Multiple light sources with bright, diffuse light (e.g. ceiling lights) are optimal. Narrow light beams (e.g. OR lamps) should be avoided

- Try to avoid pointing the device directly towards a marker. Slightly tilted angles usually work better

- Try to place the markers in a way that they do not overlap and are fully visible from multiple angles

- Move the device slowly

- If the camera image is blurred (out of focus), move the device away and then back again to support the auto-focus of the camera

- When using sterile covers or bags for the device, make sure that the camera lenses are not covered and transparent materials over the lenses sit flat to not cause distortions or reflections

- Check the Troubleshooting section

11 Rod Selection & Positioning, Screw Distances & Adjustments

11 Rod Selection Screen
Select a rod to see it's placement
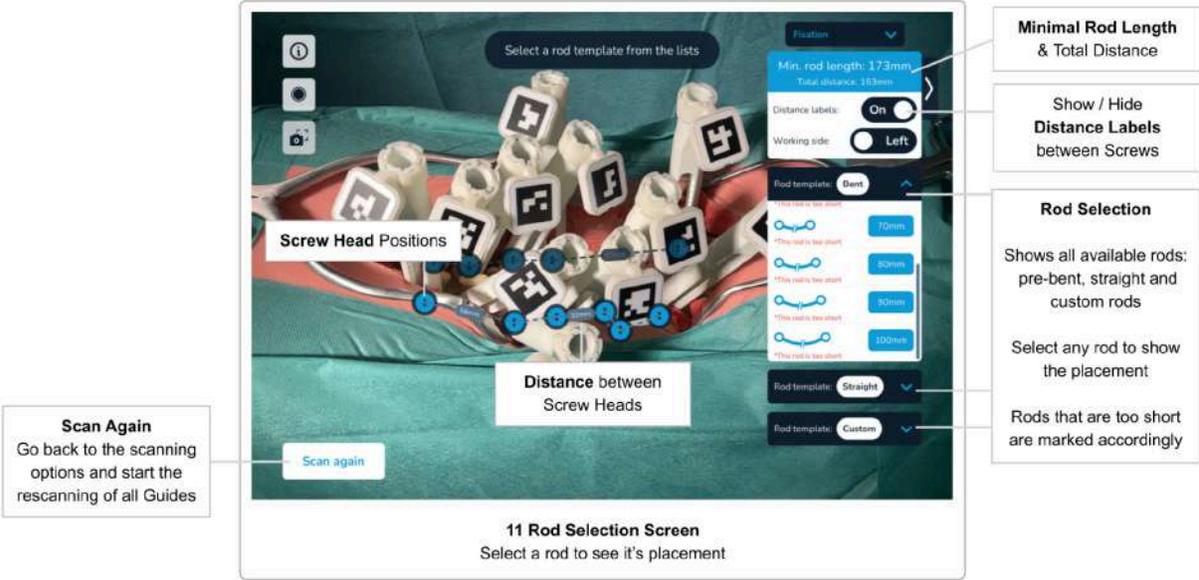
Minimal Rod Length, Total Distance & Distances between Screw Heads

Once all guides have been scanned and their positions have been confirmed, the software will display the **Total Distance** (the sum of all distances between the screw heads), the **distances between the screw heads**, and the **Minimal Rod Length**.

The distances between the screw heads will disappear if you are too far away from the guides, or if there is not enough space to display the values. If you cannot see the values, move the device closer to the patient and the distance values will reappear.

The distances between the screw heads can be disabled using the *Show Distances* switch.

Rod Selection, Rod Positioning & Screw Adjustments

Screw Adjustments (sagittal & coronal) showing the amount and direction of adjustments needed to fit the rod

Screw Colors indicating the level of adjustments needed

green: 0 - 2mm
orange: 2 - 5mm
red: > 5mm

Virtual Rod
Rotate the rod around the most caudal screw head with your finger

11 Rod Placement & Screw Adjustments
Rod Placement & Sagittal and coronal offsets to selected rod
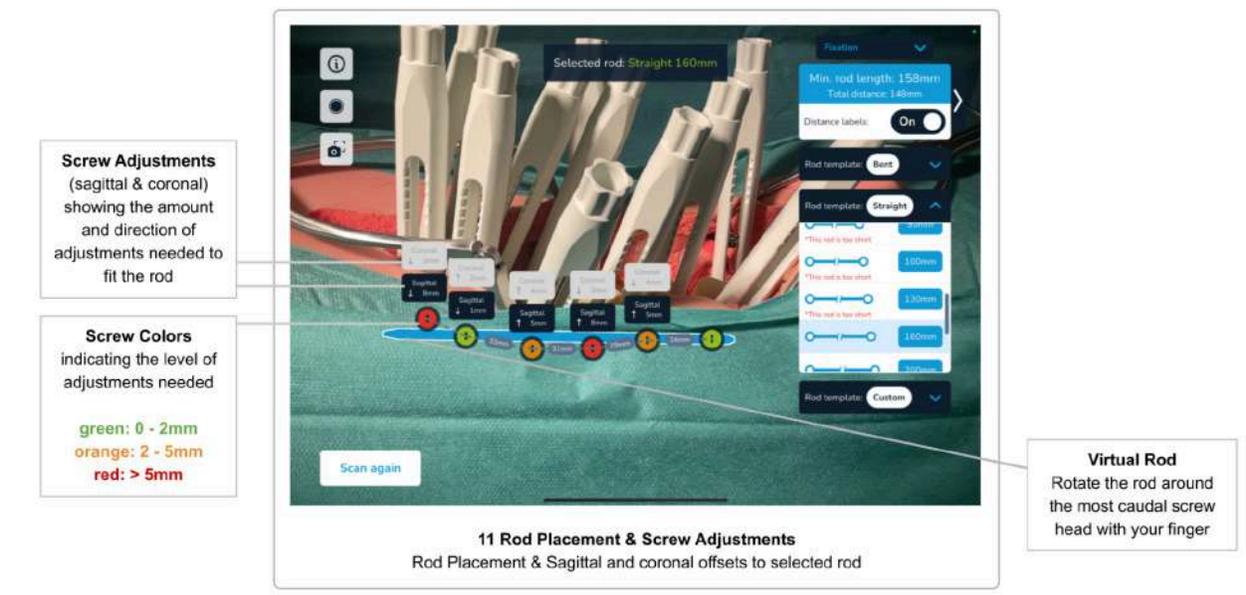
Rod Selection & Rod Positioning

The rod lists on the right side of the screen show the set of available rods. Rods that are deemed too short for the given screw positions are marked accordingly.

Select the rod of your choice to see the rod placement according to the surgical technique:

- The rod is fixed in the most caudal screw head
- For all other screw heads, the rod is placed to have minimal sagittal and coronal offsets

Rod Position Adjustments

After a rod has been selected and positioned as described above, the user can adjust the rod position using up and down gestures. The rod will rotate around the fixed, most caudal screw head, in the sagittal plane (the position in the coronal plane stays fixed). The screw adjustments will update accordingly.

This allows the surgeon to simulate the optimal position of the rod, and to judge whether the screws need adjustments to best fit the rod.

Selecting the same or another rod will reset the adjusted position and re-calculate the position having minimal offsets.

	The Neo ADVISE™ software has no information about the anatomical structures (e.g. vertebrae).
(i)	**The displayed screw adjustments are solely based on the screw head's position - NOT on the actual placement of the screw in the vertebra.**
	The measured screw to rod distances (or offsets) must be carefully considered before applying any adjustment.

The screw to rod offsets are displayed above the screw heads and are given in millimeters. An arrow indicates the direction for the proposed adjustment (up or down).

(i)	**One turn of the screw corresponds to 4mm screw adjustment.**

To adjust a screw by the proposed value, remember that one turn of the screw adjusts the screw by 4mm.

The screw adjustments are color-coded into the virtual screw heads. The colors green, orange, and red indicate different levels of adjustments. The following table shows the definition for the color-coding:

Color	Proposed Screw Adjustment
green	sagittal offset smaller than or equal to 2 mm
orange	sagittal offset between 2 mm and 5 mm
red	sagittal offset bigger than 5 mm

	The calculated screw adjustments and distances are informational and should be considered by the surgeon together with all other information about the patient. **At any given time during the surgery, the responsibility for the final choice and the safety of the patient lies with the surgeon.**

The rod category *Custom* contains rod types for custom bent rods. Selecting a *Correction Rod* does not show screw offsets or adjustments. See Rod Template Generation for details about custom bent rods.

Adjusting Screws - Scan Again

The user can choose different rods and update the rod position using up and down gestures to find a position to fix the rod.

However, as soon as one or more screws have been adjusted, a new scan of all guides is needed to find the new positions and calculate the new distances and adjustments.

	The software does not continue the scanning of the guides and the screw heads after the scanning step has been completed. **Once a screw has been adjusted, a rescan of all guides is needed to find the newly adjusted positions.**

Before adjusting a screw, make sure to adjust the correct one by checking the AR-view of the software.

After adjusting any screw, rescan all guides by tapping the *Scan Again* button to go back to the scanning step.

Scan Again

The *Scan Again* button should be used in the following situations:

● **After making adjustments to the screws**
The software does not continue the scanning of the guides and the screw heads in this stage. Once a screw has been adjusted, you have to rescan to find the new positions

- **When the patient's body has moved**
  Moving the patient's body or the table can lead to the screw heads being displayed at incorrect positions

- **If AR content is misplaced**
  When you put the device on a table and pick it up later, the AR content might be misplaced. If you find the screw heads to be off from where you would expect them, rescan all the guides to update the positions.

- **After finishing the screw adjustments for the current side of the spine**
  Once all screws have been adjusted and you have verified the rod selection and position, the next step is to perform the same process on the other side of the patient. If you selected to work on both sides of the spine simultaneously, use the *Working Side* toggle to switch to the other side, otherwise, use the *Scan Again* button to clear all mapped guides and calculations, move to the other side of the patient. Do not forget to change the patient's head orientation in the software before starting the next scan if you switched the side.

ⓘ	**Do not forget to change the patient's head orientation in the software if you switch the side.**

ⓘ	**Confirm the rod position fluoroscopically as required by Neo Pedicle Screw System™ surgical technique. The rod should always overhang the most distal screw by a few millimeters.**

Working with Markers on Both Sides of the Spine

11 Change Working Side
if you selected to work on both sides earlier (Marker Detection only)

When using the Marker Detection scanning method, you have the option to scan both sides of the spine simultaneously. Select the option either in the dialogue that appears when selecting the Marker Detection scanning method or on the *Confirmation Overview* screen.

If you decide to work with markers on both sides, there is an additional step to be performed after the scanning of the markers, namely the *Partitioning Left and Right Screw Heads.* See Partitioning Left and Right Screw Heads on how to do this.

After the scanning of the guides has been completed, you can switch the current working side on the Rod Selection & Screw Adjustments screen using the *Working Side* toggle. The software will hide and reveal the screw heads for the selected side accordingly.

12 Rod Template Generation

12 Custom Static Rod
Generating a custom bent rod template
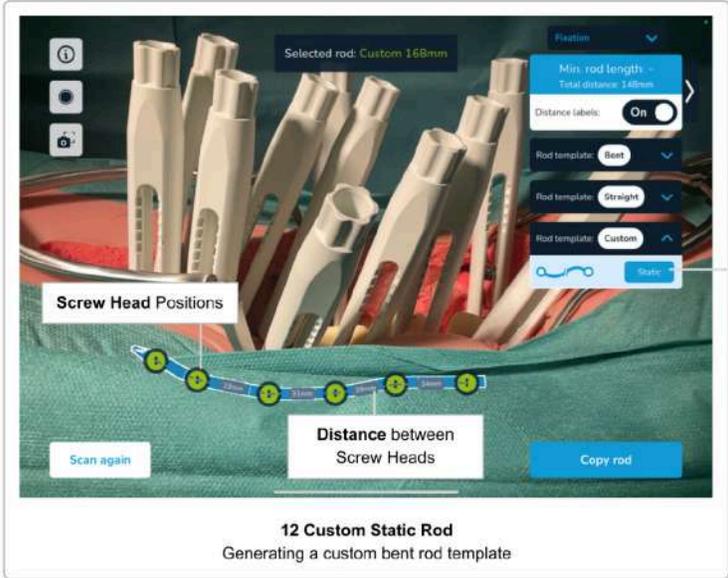
As described in the previous section, you can select any rod from the two categories straight and pre-bent rods. The third category of rods, called *Custom*, allows you to select a custom rod labeled as *static*.

By selecting the *Static Correction Rod Template*, the system will generate a custom bent rod that follows the exact path through each scanned screw head, sagittally and coronally. The generated shape of the custom rod can then be used as a template to bend a rod accordingly in the *Copy Rod Template Screen* (described in the next section).

13 Copy Rod Template Screen

13 Copy Rod Template Screen
Shows the rod in 1-1 scale to be used as a template to bend the final rod
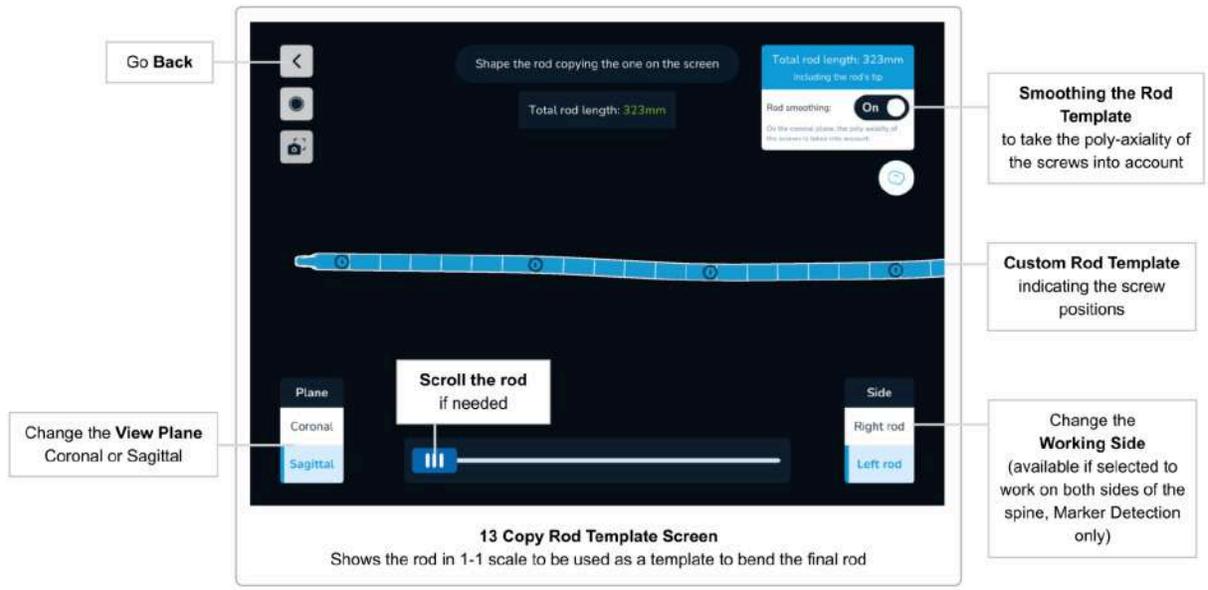
The *Copy Rod Template Screen* shows the shape of a custom-generated rod template on the screen in a 1-1 scale in sagittal and coronal view. This allows the surgeon to bend a custom rod according to the generated shape.

Use the *Coronal/Sagittal* buttons to switch between the two views. If the rod does not fit on the screen, a scroll handle is displayed automatically.

The *Copy Rod Template Screen* can be accessed by tapping the *Copy Rod* button whenever a custom rod template is created (e.g. by selecting the custom *Correction Static Rod*, using the *Trauma Module,* or the *Spondylolisthesis Module*).

Use the *back* button to return to the previous screen.

Smoothing the Rod Template

All screws of the Neo Pedicle Screw System™ have the property of catching the rod by 2 mm in the coronal plane (except mono-axial screws). This means that a coronal offset of up to 2 mm to the rod does not put any unwanted forces on the rod.

To make the rod template easier for bending, the software offers the option to take the 2 mm of tolerable offset towards the rod in the coronal plane into account. By default, the rod smoothing is enabled. To disable the smoothing, tap the *Rod smoothing* toggle. The rod template will then follow the path through each screw head exactly.

14 Trauma Module

The Trauma Module is designed to support the surgeon in Trauma cases. Based on the scanned screw head positions, the software allows the surgeon to adjust the angle between the two vertebrae surrounding the traumatized/fractured vertebrae, and by rotating the most caudal guide to achieve a predefined correction.

Note that the software does not scan the direction of any screws or implants. To be able to measure angles between two vertebrae, the software assumes that mono-axial screws are used where angles are displayed. The software will then use the combination of the screw head's position and the direction of the guide during the scanning to infer the direction of the implants. The software does not measure any anatomical angles (e.g. COBB angles), but only angles between implants.

(i)	**The software does not measure any anatomical angles (e.g. COBB angles), but only angles between implants as each pedicle screw might have been inserted at different angles in the vertebral body.** **Wherever angles are displayed, the use of mono-axial screws is required. Therefore, for the Trauma Module, the two screws surrounding the traumatized vertebrae need to be mono-axial.**

Accessing the Trauma Module

The Trauma Module can be accessed after scanning all relevant guides. Please follow the software flow up to the *Rod Selection & Screw Adjustments* screen, which includes:

- Configure the software on the *Confirmation Overview* screen according to your needs

- Perform the *Scene Analysis* step

- Scan the position of all relevant screw heads

- Confirm the scanned positions and the patient's head position

- Optionally, partition the screw heads left and right, if you select to work on both sides of the spine simultaneously

On the top right corner of the *Rod Selection & Screw Adjustments* screen, use the *Surgery Mode* drop-down to enter the *Trauma Module* by selecting the corresponding option.

The Trauma Module only works on one side of the spine. If you scanned both sides of the spine at the same time, make sure to select the correct side to apply the correction by using the *Working Side* toggle before entering the Trauma Module.

Using the Trauma Module

Selecting two mono-axial screws

14 Trauma Module
Selecting the two mono-axial screw surrounding the traumatized vertebra
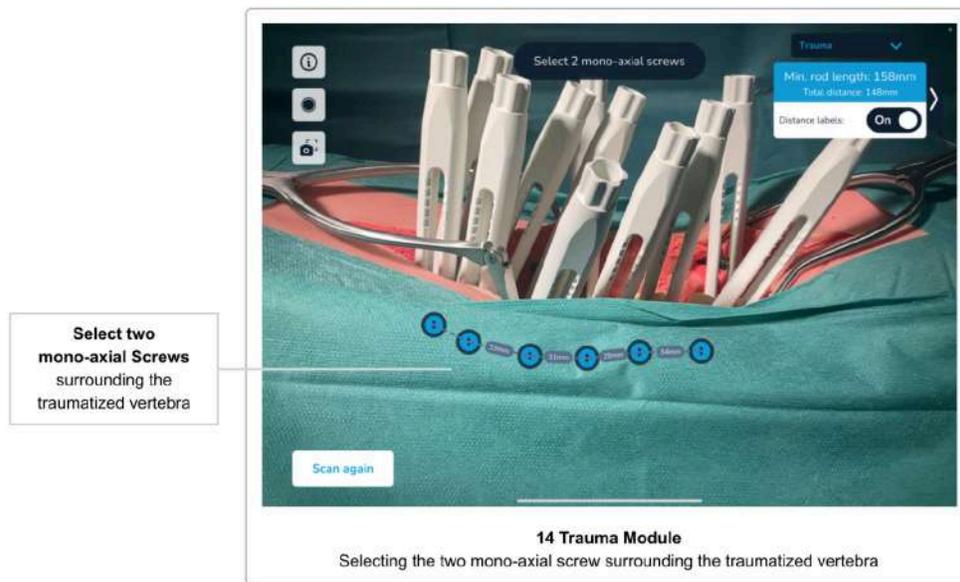
As a first step after accessing the Trauma Module, you have to define the two mono-axial screws surrounding the traumatized/fractured vertebrae. Do this by tapping the virtual guides and then confirming your selection.

Note that it is possible to have implants in the traumatized vertebrae as well. Make sure to only select the screw heads surrounding the traumatized vertebrae, not the damaged vertebrae themselves.

Use the *Reset Screws* button to dismiss and change your current selection.

14 Trauma Case
Select a rod and adjust the angle by rotating the Guide or tapping + or -

After selecting and confirming the two mono-axial screws in the previous step, you can see the angle between the two screws.

Select any rod of any rod category (straight, pre-bent, or correction). After selecting an appropriate rod, the system will place the rod through the two mono-axial screws with a 90° angle between the guide and the screws. This will change the angle between the two mono-axial screws, depending on the selected rod. For straight rods, for example, the angle will change to 0°, since the two screws are now parallel to each other.

The system always shows three values, namely the **initial angle**, the **final correction** angle and the **difference between the initial and the correction angle**.

You can now adjust the final angle by changing the correction angle using one of the two approaches, or the combination of both: *Bending the Rod* and *Rotating the Virtual Guide*.

Bending the Rod

Use the plus and minus buttons to change the angle between the two mono-axial implants. Changing the angle will result in a custom rod shape, based on the selected rod, by bending the rod between the two mono-axial screws.

Rotating the Virtual Guide

Depending on the selection of the two mono-axial screws surrounding the traumatized vertebrae, the software will show a virtual guide overlaid to the most caudal placed guide. The initial position should exactly match the physical guide. Rotate the virtual guide to change the position of the rod according to your needs. Tap the virtual guide and move your finger to rotate it. The software will automatically calculate the new angle, positions, and distances between the

screw heads on the rod. Note that rotating a pre-bent rod will also affect the angle between the two mono-axial screws.

Once you have reached the desired angle by rotating the virtual guide, move the physical guide to match the virtual guide. Once you have reached the position where the virtual and the physical guides overlap, use the set screw to fix the position of the physical guide.

Note that the virtual guide is not shown if you select the most caudal screw as one of the mono-axial screws.

Resetting the Correction

Use the *Reset Correction* button to dismiss any applied correction and go back to the initially scanned positions of the implants.

Copy the Custom Rod Template

Once you start creating a custom rod template (by bending it), the software will automatically show the *Copy Rod* button on the lower-right corner of the screen. Tap it to go to the *Copy Rod Template Screen* (see Copy Rod Template Screen) and use the generated rod shape to bend a custom rod that will result in a custom rod providing the desired correction.

15 Spondylolisthesis Module

The Spondylolisthesis Module is designed to support the surgeon in Spondylolisthesis cases. Based on the scanned screw head positions, the software allows the surgeon to adjust the correction to fix displaced or damaged vertebrae by rotating the most caudal guide.

Accessing the Spondylolisthesis Module

The Spondylolisthesis Module can be accessed after scanning all relevant guides. Please follow the software flow up to the *Rod Selection & Screw Adjustments* screen, which includes:

- Configure the software on the *Confirmation Overview* screen according to your needs

- Perform the *Scene Analysis* step

- Scan the position of all relevant screw heads

- Confirm the scanned positions and the patient's head position

- Optionally, partition the screw heads left and right, if you select to work on both sides of the spine simultaneously

On the top right corner of the *Rod Selection & Screw Adjustments* screen, use the *Surgery Mode* drop-down to enter the *Spondylolisthesis Module*.

The Spondylolisthesis Module only works on one side of the spine. If you scanned both sides of the spine at the same time, make sure to select the correct side to apply the correction using the *Working Side* toggle before entering the Spondylolisthesis Module.

Using the Spondylolisthesis Module

Applying Correction in Spondylolisthesis Cases

15 Spondylolisthesis
Rotate the Virtual Guide or tap + or - to adjust the distance
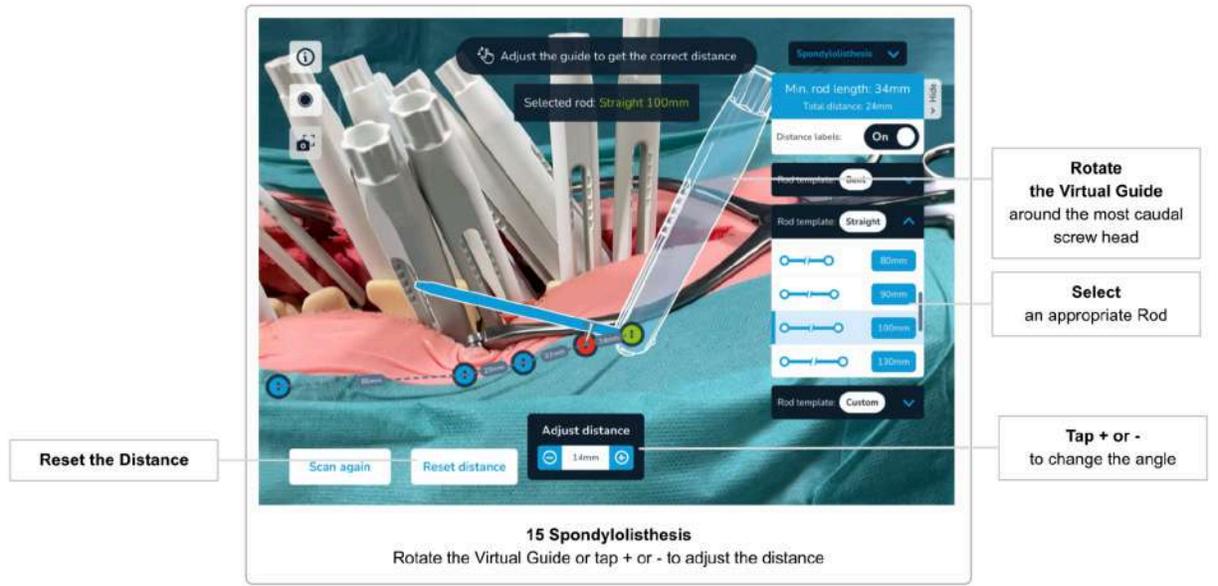
To apply a correction in spondylolisthesis cases, start by selecting a rod from any of the rod categories (straight, pre-bend, correction rods). You can revise your choice at any time simply by selecting another rod.

Correction in spondylolisthesis cases is applied by rotating the most caudal guide. The software will visualize the initial position of the most caudal guide by overlaying a virtual guide on top of the physical guide.

Rotate the virtual guide with your finger to change the distance between the initially scanned screw head next to the virtual guide. The software will automatically update all screw head positions and distances between them. Optionally, you can use the plus and minus buttons to adjust the correction in steps of one degree.

Once you reach the desired angle by rotating the virtual guide, move the physical guide to match the virtual guide until you reach the position where the virtual and the physical guides overlap, use the set screw to fix the position of the physical guide.

Resetting the Correction

Use the *Reset Distance* button to dismiss any applied correction and go back to the initially scanned positions of the implants.

16 Correction Module (optional)

The Correction Module is licensed separately and might not be available depending on your current license. Contact Neo Medical sales if you want to upgrade to the correction module.

The Correction Module is designed to support the surgeon in deformity cases. Based on the scanned screw head positions, the software allows the surgeon to intraoperatively define track and adjust multiple angles between selected vertebraes in order to achieve a predefined correction.

It provides the surgeon with a dynamic tool to intraoperatively assess sagittal and coronal alignment by comparing and monitoring specific angles before, during and and after the custom rod insertion.

Note that the software does not scan the direction of any screws or implants but rather the direction of the scanned guides. To measure angles between two vertebrae, the software assumes that mono-axial screws are used where angles are displayed. The software will then use the combination of the screw head's position and the direction of the guide during the scanning to infer the direction of the implants. The software does not measure any anatomical angles (e.g. COBB angles), but only angles between implants.

(i)	**The software does not measure any anatomical angles (e.g. COBB angles), but only angles between implants as each pedicle screw might have been inserted at different angles in the vertebral body.** **Wherever angles are displayed, the use of mono-axial screws is required. Therefore, for the Correction Module, all screws marked for angle changes need to be mono-axial.**

Accessing the Correction Module

The Correction Module can be accessed after scanning all the relevant guides. Please follow the software flow up to the *Rod Selection & Screw Adjustments* screen, which includes:

- Configure the software on the *Confirmation Overview* screen according to your needs

- Perform the *Scene Analysis* step

- Scan the position of all relevant screw heads

- Confirm the scanned positions and the patient's head position

- Optionally, partition the screw heads left and right, if you select to work on both sides of the spine simultaneously

On the right side of the *Rod Selection & Screw Adjustments* screen, open the list of the *Custom* rod templates and select *Correction*.

The Correction Module offers the possibility to apply corrections on both sides of the spine simultaneously, as well as only on one side.

Using the Correction Module

Verifying the automatic screw pairing

16 Correction Module
Verify, and modify if needed, the pairing of the screw heads installed on the same vertebra

As the first step after accessing the Correction Module, you have to verify the pairing of the screw heads installed on the same vertebra, or the lack of pairing in case of single screws on a vertebra. This confirmation is needed by the software to create an accurate spine model.

The software suggests an automatic pairing based on the relative position and the relative distance between the screw heads. If needed, you can remove an erroneous pairing by tapping a screw, or you can create a new one simply by dragging from one screw toward another one. The software prevents errors in the manual pairing by limiting the possible connections only to the screws on the opposite side and in an 8 centimeters radius.

Once the pairing is correct, tap *Confirm* to proceed to the next step.

Defining correction angles

16 Correction Module
Select screw pairs to define the correction angles
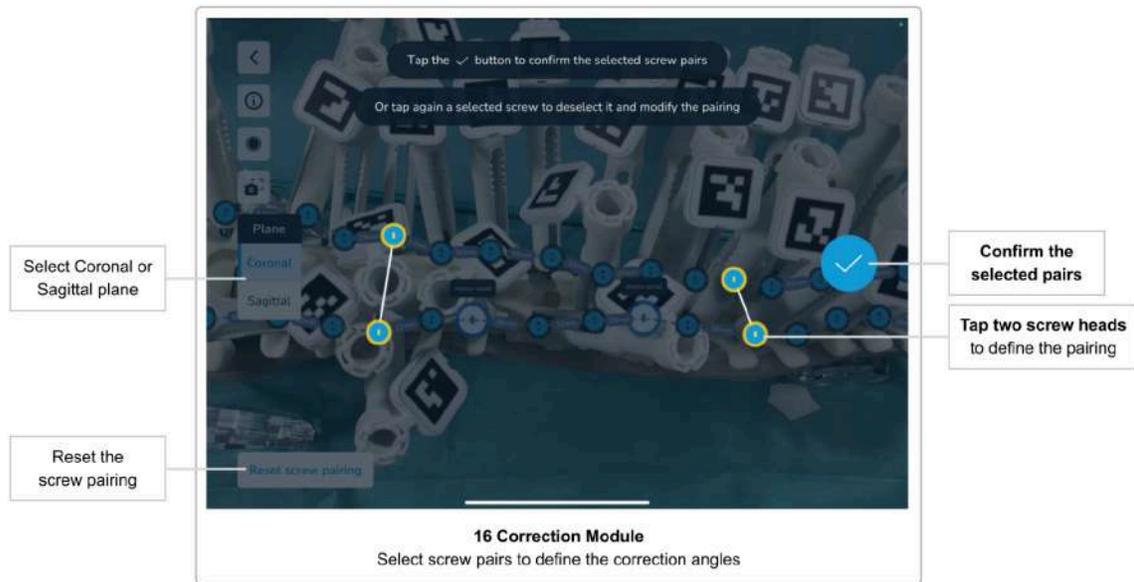
As a second step, you have to define one or multiple correction angles. You can apply correction angles on the coronal plane or on the sagittal plane, or on both simultaneously. To define a correction angle on the sagittal plane you have to select one screw pair, whereas on the coronal plane you have to select two screw pairs.

Select the plane you wish to start with, then tap the desired screw heads to select the screw pair(s) and confirm by tapping the checkmark button. If you want to deselect a screw, you can tap again on the screw head before confirming the pair.

To remove all the screw pairs previously selected and confirmed, tap the *Reset screw pairing* button and confirm the warning dialog.

Once you have confirmed all the desired screw pairs on both planes, tap the *Finish screw pairing* button.

16 Correction Module
Adjust angles
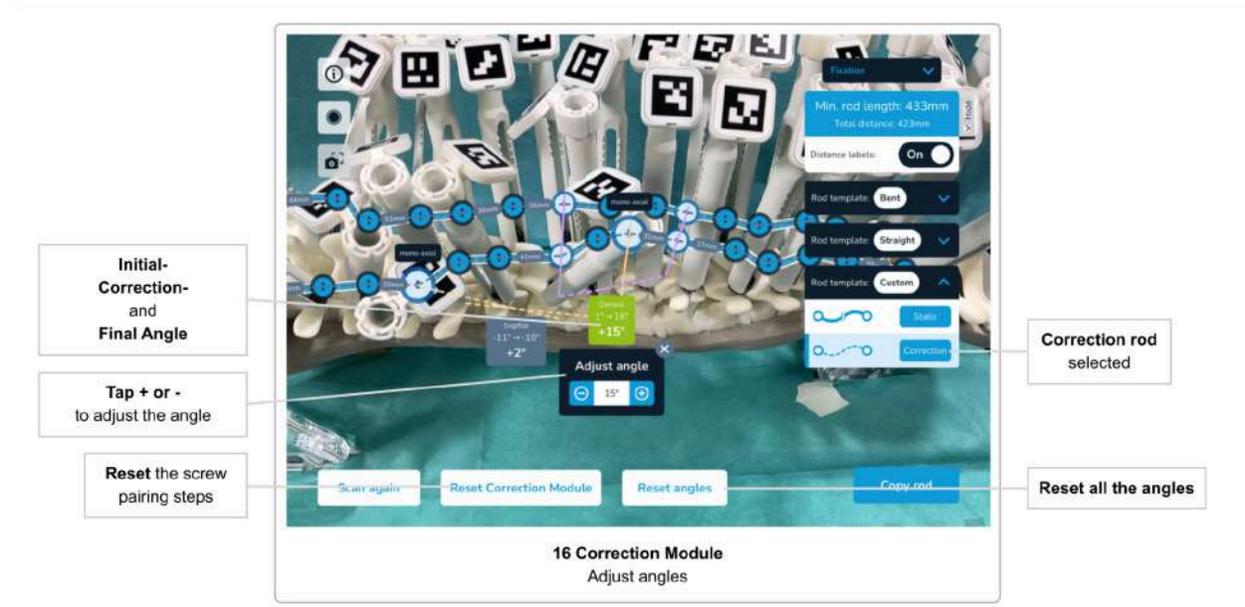
After selecting and confirming the screw pairing in the previous steps, you can see the angles between the predefined pairs.

The default state of the angle label shows the **initial angle** and the plane where the correction gets applied. You can tap the grey angle label to adjust the angle by bending the rod. Once opened, the angle label becomes green and shows three values, namely the **initial angle**, the **final correction** angle and the **difference between the initial and the correction angle**.

Use the plus and minus buttons to change the angle between the two mono-axial screws. Changing the angle will result in a custom rod shape by bending the rod between the two mono-axial screws. You can close the angle widget by tapping the close button, or by tapping another angle label. The closed label becomes grey again and, if you applied any correction to the angle, it still displays the three angle values: the **initial angle**, the **final correction** angle and the **difference between the initial and the correction angle**.

Resetting the Correction

To reset all the corrections applied, you can tap the *Reset angles* button.

If, while applying corrections, you realize that you wish to change the predefined correction angles, you can tap the *Reset Correction Module* button. This will reset both screw pairing steps: the *Automatic screw pairing on the same vertebra* and the *screw pairs to define the angles*, it will also take you back to [the beginning of the Correction Module process](#).

Troubleshooting

Camera Image, Camera Permissions, Overheating

ID	Problem	Possible Causes	Possible Solutions
1	The software does not show the camera image	The camera lenses might be covered or obstructed	Make sure the camera lenses are not covered or obstructed
		Camera permissions have been denied	Go to the settings of the device (Settings/Privacy) and enable camera access to the Neo ADVISE™ software
2	The software shows a device overheating warning and does not work anymore	Due to the heavy computational load on the device, the chips will heat up a lot. At some point, the software has to pause to let it cool down.	Lock the device and put it aside for two to three minutes.

3D Scanning Problems

For scanning instructions and tips, also refer to section Tips and Troubleshooting 3D Scanning.

ID	Problem	Possible Causes	Possible Solutions
3	I cannot scan the guides (3D Scanning) The virtual guide does not snap to the physical guide during scanning	The wrong guide version has been selected	Use the Toggle guide Version switch to change the currently used version. The virtual guide must have the same shape as the physical guide currently being scanned
		The wrong scan method has been selected	Go back to the scanning method selection and select the 3D-Scanning method

ID	Problem	Possible Causes	Possible Solutions
		The guides are too dirty to be recognized by the system	Clean all guides before scanning
		The light conditions are suboptimal	Change the lighting to increase contrast and avoid reflections. Avoid using OR lamps with narrow and bright light beams. Using multiple, diffuse light sources is preferable.
		The guide's orientation is suboptimal and/or covered by another guide	Rotate the physical guides so that the slots are facing the camera. Try to arrange the guides in a way that they don't overlap each other It is possible to move already scanned guides to have better access to the current guide being scanned In complex cases with a lot of guides, consider covering the opposite side of the spine not being scanned with a cover or cloth
4	I cannot scan all needed guides	The 3D-Scanning is limited to ten guides per scan	If you need to scan more than ten guides, please use the Marker Detection method
		Scanning guides of the other side of the spine is not supported	Make sure you only scan the guide of one side of the spine per scan
5	The position of scanned	The scanned position was not	You can re-scan single

ID	Problem	Possible Causes	Possible Solutions
	guides is not correct The virtual guide does not fully overlap with the physical guide The virtual guide is longer or shorter than the physical guide	correct when confirmed	guides by opening the guide table, removing and re-scanning the guide You can re-scan all guides by clearing the guides in the *Guide Table* using the *Clear All* button
		Tracking of previously scanned guides is not working	Make sure that scanning all the guides is not taking too long. The longer it takes to scan all guides, the harder it becomes to keep the position of previously scanned guides. Restart the scanning of all guides by opening the *Guides Table* and tapping the *Clear All* button
		The framerate is low and the software is lagging. The mapped virtual guides show a noticeable offset to the physical guides.	If you experience a low framerate or lags during the use of the software, make sure that no other resource intensive software is running in the background.

Marker Detection Scanning Problems

For scanning instructions and tips, also refer to section [Tips and Troubleshooting Marker Detection Scanning](#).

ID	Problem	Possible Causes	Possible Solutions
6	I cannot scan the guides (Marker Detection)	The wrong scan method has been selected	Go back to the scanning method selection and select the Marker Detection method
		The markers are too dirty to	Clean all markers before

ID	Problem	Possible Causes	Possible Solutions
		be recognized by the system	scanning
		The light conditions are suboptimal	Change the lighting to increase contrast and avoid reflections Avoid using OR lamps with narrow and bright light beams. Using multiple, diffuse light sources is preferable
		The markers are overlapping too much	Try to arrange the markers in a way that no markers are overlapping each other and are pointing more or less in one direction
7	Some guides are not correctly oriented Some guides are rotated by 90° Some guides are pointing upwards	The auto-alignment of the marker direction is not working as expected	The direction, in which the markers are stuck to the marker base, is auto-aligned by the system. This assumes that all guides are pointing down and are not tilted more than a certain angle. If you see some guides wrongly oriented, try to move the guide into a more vertical position and restart the scanning
8	One or more guides are not fully overlapping with the physical guides	The marker base is not attached correctly	Please ensure the proper fitting of the marker base to the guide
		The framerate is low and the software is lagging. The mapped virtual guides show an noticeable offset to the physical guides.	If you experience a low framerate or lags during the use of the software, make sure that no other resource intensive software is running in the background.

ID	Problem	Possible Causes	Possible Solutions
9	I have scanned all guides, but the confirmation button does not appear	The system might have scanned an additional marker somewhere else (e.g. on the table).	Check the instruction label for the number of scanned markers. If you see that there is an additional marker that you did not expect, cancel the current scanning session and start again, making sure the additional maker is not visible.

Rod Position & Screw Adjustments

ID	Problem	Possible Causes	Possible Solutions
10	The virtual rod is pointing in the wrong direction	The patient's head position has been wrongly selected	Note that the rods always have to be inserted in a cranio-caudal way. Go back to scanning the guides and select the correct position of the patient's head
11	Screw to rod offset is anatomically not possible	The software only scans the screw head's positions, not the screw positioning	The surgeon has to decide if an adjustment is feasible or not. You can select the problematic screw as a reference point by selecting it. The calculations then place the rod such that no screw adjustment is needed for the reference point/screw.

Rod Template Generation

ID	Problem	Possible Causes	Possible Solutions
12	The generated rod template looks totally	During the scanning, some screw heads are scanned	When working only on one side of the spine, make

ID	Problem	Possible Causes	Possible Solutions
	wrong.	from the other side of the spine	sure you only scan screw heads from the same side. Including screw heads from the other side of the spine will result in inaccurate rod templates. Please rescan all screw heads by using the *Scan Again* button.
		When working on both sides of the spine at the same time (Marker Detection only), the software asks the user to partition the screw heads left/right. Assigning a screw head to the wrong side will cause incorrect rod templates.	When working on both sides of the spine, make sure to correctly partition the screw heads left/right. Please rescan all screw heads by using the *Scan Again* button.
		Guides with a position of more than 45° need to be rotated to correctly overlay the physical guide. If one or more towers are not rotated correctly after the scanning, the software will assume a wrong position of some screw heads, resulting in incorrect rod templates.	Make sure to check the virtual representation of each guide before confirming the scanned positions of the guides. Ensure that the rotation of each guide is correct. Please rescan all screw heads by using the *Scan Again* button.

Copy Rod Template Screen

ID	Problem	Possible Causes	Possible Solutions
13	The generated rod does not look correct.	See Problem #11	See Problem #11
14	The generated rod does not fit on the screen	Screen size is limited to show the full length of any potential rod.	Use the slider at the bottom to reveal the not visible part of the rod.

Trauma Module

ID	Problem	Possible Causes	Possible Solutions
15	There is no virtual guide displayed	If you select the most caudal screw as mono-axial, no virtual guide is displayed and no rotation is possible.	Make sure you selected the correct screws to be mono-axial. Use the *Reset Screws* button to re-select the mono-axial screws.

Spondylolisthesis Module

ID	Problem	Possible Causes	Possible Solutions
16	The virtual guide is displayed on the wrong screw.	The spondylolisthesis module only works with the most caudal screw.	The most caudal scanned screw is automatically selected as the rotation pivot. Re-scan all screws and make sure to include all relevant screws.

Screen Recorder and Screenshot Tool

ID	Problem	Possible Causes	Possible Solutions
17	The screenshots and videos are not saved in the Photos app.	You need to allow permission to the software to save the images and videos to the Photos app.	Go to *Settings/Neo ADVISE* and enable camera permission.

Correction Module

ID	Problem	Possible Causes	Possible Solutions
17	I can't create a new connection between two screws	Two screws can be connected as being on the same vertebra if the are on opposite sides and maximum 8 centimeters apart	Make sure that you are creating a connection with a screw on the opposite side and not further than 8 centimeters
18	I have selected two screws, but the confirm	Probably you are working on the Coronal plane, which	On the Coronal plane you need two screw pairs.

	button doesn't appear	requires two pairs of screws	Select another screw, the software will automatically select the one on the opposite side.

Product Return

In case of problems with the iPad, please contact Neo Medical and arrange repair or substitution of the device.

For data protection reasons Neo Medical shall not receive an iPad containing any patient data or any personal data. Please ensure that you backup all the data before sending the device to Neo Medical. Upon receiving the devices either for replacement or at the end of the contract, in the event that the device contains any personal data (in particular patient data), Neo Medical will proceed to wipe out all local content on the device.

Manufacturer Contact Information

Manufacturer	Comerge AG
	Bubenbergstrasse 1 8045 Zurich Switzerland +41 44 552 52 62 www.comerge.net
EU Representative EC | REP	MT Promedt Consulting GmbH Ernst-Heckel-Strasse 7 66386 St. Ingbert Germany
EU Importer	Neo Medical GmbH Gottlieb-Daimler-Str. 6 DE-89150 Laichingen Germany
Distributed by	Neo Medical SA Route de Lausanne 157a 1096 Villette Switzerland

Neo Medical Contact Information

For any query about the Neo ADVISE™ software and questions about Neo Pedicle Screw System™ please refer to your local Neo Medical agent or contact us using the contact information on www.neo-medical.com.

Terms of Use

Dear User,

*Thank you for using the Neo ADVISE™ software with, as defined in its User Manual (or Instructions for Use), its environment of compatible devices, sterile bags, Neo Markers and Neo Markers Bases (hereinafter: **Neo ADVISE™ System**), and the Neo Pedicle Screw System™.*

The Neo ADVISE™ System requires the User to undergo a training session delivered by a Neo Medical's representative. *Please contact Neo Medical if you want to use the Neo ADVISE™ System and you did not personally participate in a training for its safe and effective use.*

Please read carefully the Neo ADVISE™ software User Manual and these Terms of Use before using the Neo ADVISE™ System in a surgery.

*By accepting these Terms, you confirm that you agree and undertake to participate in the Neo Medical ADVISE™ System training and that you have read and understood the **Neo ADVISE™ software User Manual including the Privacy Notice**.*

It is strongly recommended to try the Neo ADVISE™ System and do some dry runs before using it in surgery.

The Neo ADVISE™ System must be used by a surgeon. The Neo ADVISE™ System does not remove any responsibility for patient safety from the surgeon. The surgeon must bear full responsibility for all consequences resulting from the choices made with regards to the selection of the rod implant and the positioning of the pedicle screws. At any given time during the surgery, the responsibility for the safety of the patient lies with the surgeon. Any serious incident that has occurred in relation to the Neo ADVISE™ System should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

The Neo ADVISE™ System is for professional use only by spine surgeons that have been trained. The Neo ADVISE™ System is only to be used with the Neo Pedicle Screw System™. It is forbidden to use the Neo ADVISE™ System with other similar pedicle screws and/or rods of other manufacturers. It is also prohibited to use devices, sterile bags, markers or other items which are not compatible with the Neo ADVISE™ software.

After you have used the Neo ADVISE™ System, please make sure you close the software on the tablet before the device is used by any other authorized user (surgeon). The Neo ADVISE™ software can be started again by the new user by tapping on the Neo ADVISE™ software icon on the device's home screen.

Disclaimer

- *Please consider that screenshots and video recordings of the Neo ADVISE^{TM} software session may contain personal information and patient data (e.g. faces of the surgeons and the clinical team or the patient, screen content of other systems, etc). Always make sure you protect the patient data and other personal information and that you have obtained all relevant authorizations. It is the user's responsibility to ensure that patient data and other personal or sensitive information are not disclosed to or otherwise shared with or transferred to Neo Medical.*
- *The usage of the Neo ADVISE^{TM} System will inevitably lead to bringing a specific tablet device near or into the sterile environment in the operating room. Since it is not possible to sterilize such devices, other options must be considered as described in the User Manual.*
- *Make sure that the device battery is charged before starting the surgery.*
- *Visually checking and confirming the guides' positions is important. Not properly scanned and therefore wrongly positioned guides will lead to wrong results and suboptimal instructions for screw adjustments and distances between the guides.*
- *Note that the markers and the marker bases are sterile and disposable products. Do not reuse and discard after one use.*
- *If a marker set contains more markers than needed for the current procedure, the leftover markers cannot be used anymore and must be discarded.*
- *All calculations with the Neo ADVISE^{TM} System are solely based on the screw head's position - NOT on the actual placement of the screw in the vertebra.*
- *Suggested screw adjustments might not be anatomically or physically optimal. The surgeon must decide if a suggested screw adjustment is clinically appropriate.*
- *The calculated screw adjustments and distances are informational and should be considered by the surgeon together with all other information about the patient.*
- *Please confirm the rod position fluoroscopically as required by Neo Pedicle Screw System^{TM} surgical technique. The rod should always overhang the most distal screw by a few millimeters.*
- *Before returning the tablet device to Neo Medical, please make sure the device does not contain any patient data or other personal information and that, as necessary, you have made a local back-up copy of such data and information. Upon receipt of the device (either for replacement or at the end of the relationship), in the event that the device contains any personal data (in particular patient data), Neo Medical will proceed to wipe out all such content.*

Data Protection Declaration

The full Privacy Notice for the Neo ADVISE^{TM} software can be found on Neo Medical website. Please visit https://neo-medical.com/IFU and find the Privacy Notice for the region that applies to you.
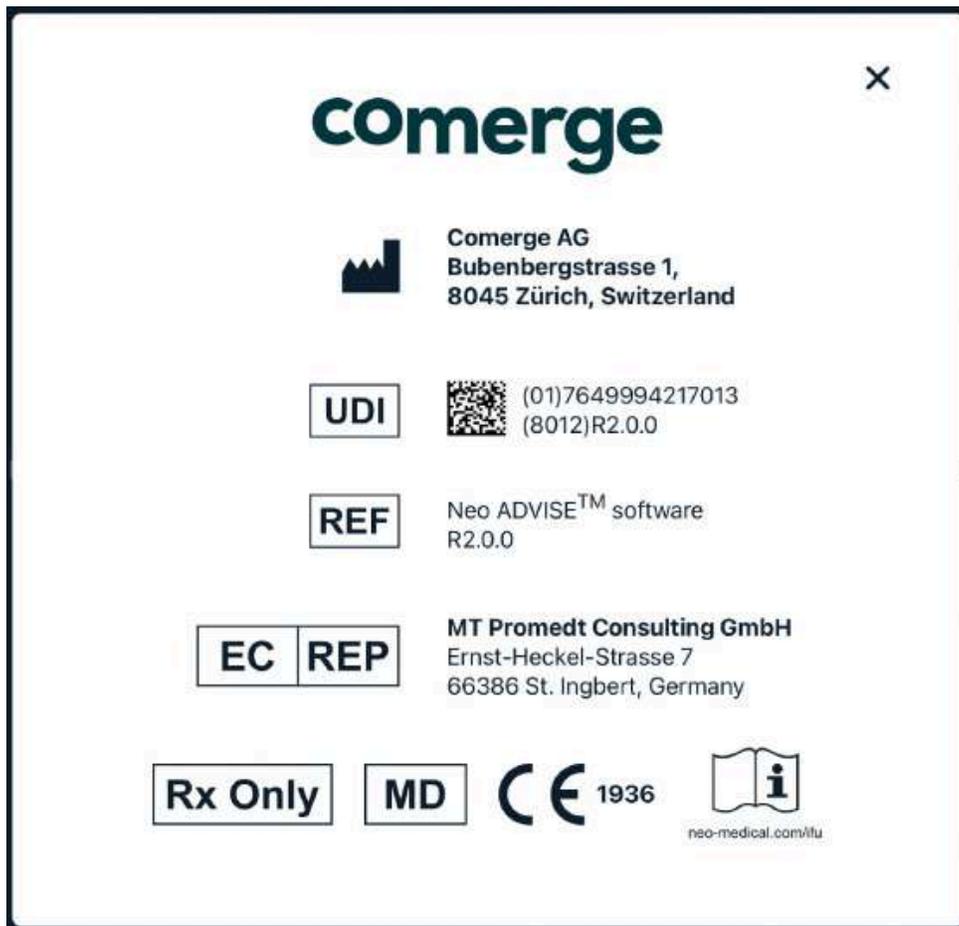
Warranty

Without prejudice to Comerge AG's obligations under applicable laws as legal manufacturer of the Neo ADVISE™ software, Neo Medical as Provider gives its customers a limited warranty for the Neo ADVISE™ software and System, as set out in the General Terms & Conditions ("GTC") relating to the provision by Neo Medical, and to the access and use by the customer's authorized users, of the Neo ADVISE™ software or System.

Copyrights and Trademarks

Apple and the Apple logo are trademarks of Apple Inc., registered in the U.S. and other countries.

Product Label

The product label can be accessed in the software by tapping the (i) button present on all screens.

Signs and Symbols

Symbol	Standard title	Explanation / Symbol title and Reference number
(i)	—	Note of important information
neo-medical.com/ifu	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part1: General requirements	"Consult electronic instructions for use" (5.4.3)
(factory symbol)	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part1: General requirements	"Manufacturer" (5.1.1)
CE 1936	MDR 2017/745	This device/software complies with the Regulation (EU) 2017/745 (MDR)
MD	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part1: General requirements	"Medical Device" (5.7.7)
EC REP	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part1: General requirements	"Authorized representative in the European Community/European Union" (5.1.2)
Rx Only	Use of Symbols in Labeling: FDA-2013-N-0125	Prescription only - Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part1: General requirements	"Unique Device Identifier" (5.7.10)
UDI	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part1: General requirements	"Unique Device Identifier" (5.7.10)
REF	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part1: General requirements	Indicates the manufacturer's catalogue number so that the medical device can be identified.

Abbreviations

ABM	Apple Business Manager
IFU	Instructions for Use (User Manual)
IR	Infrared
LIDAR	Light Detection and Ranging Sensor
MDM	Mobile Device Management
UI	User Interface

Appendix

List of Compatible Products

Sterile Bags and Cases

Products for using tablets in sterile environments, such as the operating room.

The following products have been tested and confirmed to work with the Neo ADVISE™ software:

- **Sterile Tablet Cover**, Protek Medical, USA (not available in the USA)

- **EC2300: eShieldTM Sterile Cover for Tablets,** Whitney Medical, USA

Neo Medical can provide any of these products. Please contact Neo Medical sales.

If you consider using a similar product, ensure that the camera on the device is not affected by the cover or bag by testing the scanning of guides before the surgery.

Neo Markers and Neo Marker Bases

The Neo Marker Bases is a product of Neo Medical. Markers are distributed by Neo Medical. Please contact Neo Medical sales.