

# Instructions for Use

## Neo ADVISE™ System

R2.0 (US)



# Table of Content

<b>Table of Content</b>	<b>2</b>
<b>Introduction</b>	<b>5</b>
The Neo Pedicle Screw System	5
The Neo ADVISE™ System	6
Software Features	6
Scanning the Guides	7
3D-Scanning	7
Marker Detection	7
Shelf Life	7
Limitations for Use	7
Indications for Use	7
Contraindications	8
Product Label / Software Version	8
Access to Instructions for Use	8
<b>Important Notes</b>	<b>9</b>
Compliant Use	9
Sterile Environment	9
Cleaning / Disinfecting the Device	9
Notes on electromagnetic compatibility	10
<b>Software Distribution &amp; Installation</b>	<b>11</b>
Distribution / Neo Medical MDM	11
IT Network Characteristics and IT Security Measures	11
IT Network Characteristics	11
IT Security Measures	12
Change of Hardware / Defects	12
iOS Version Updates	12
Software Updates	12
Starting the Neo ADVISE™ System software	12
<b>Before Usage</b>	<b>13</b>
Device Battery and Charger	13
Device Overheating Protection	13
Terms of Use	13
Training & Preparation	13
Automatic Device Locking, TouchID & FaceID	14
Prepare Hardware	14
Prepare Sterile Bags	14
Prepare Markers	14

<b>How to Use the System</b>	<b>15</b>
System Overview	15
1 Start the Software	16
2 Terms of Use	17
3 Scan Method Selection	18
3.1 3D Scanning Method	18
3.2 Marker Detection Method	18
4 Selecting Guide Version	20
Guide Versions	20
Mixing Guide Versions	21
Granite Screw Guide	21
5 Selecting the Patient's Head Orientation	22
6 Confirmation Overview	23
7 Scene Analysis	24
Skipping Scene Analysis	24
8 Help Overlay	26
9 Screen Recorder and Snapshot Tool	27
Screen Recorder	27
Screenshot Tool	28
10 Scan Guides	29
Scanning Environment / Light Settings	29
Optimal Lighting Settings	29
Overview of the Scanning Screen	30
Button Scanning Instructions & Scanning Tips	30
Button Version & Product Label	30
Button: Screen Recorder	30
Button: Screenshot	30
Button: Back	30
Button: Changing the Patient's Head Orientation	31
10.1 Scanning Instructions (3D-Scanning Method)	32
Step 1 Adding the first Guide	33
Step 2 Mapping and Confirming the Virtual Guide	34
Step 3 Scanning additional Guides	35
Step 4 Edit Mapped Guides and Confirm	36
Step 5 Confirm Positions	37
Step 6 Confirm the Patient's Head Position	37
Tips and Troubleshooting 3D Scanning	37
10.2 Scanning Instructions (Marker Detection)	39
Neo Marker Base & Neo Markers	39
Step 1 Preparation	40
Step 2 Scan All Markers	43

Step 3 Correct Guide Orientation/Rotation	45
Step 4 Confirm Positions	46
Step 5 Confirm the Patient's Head Position	46
Step 6 Partitioning Left and Right Guides	47
Tips and Troubleshooting Marker Detection Scanning	47
11 Rod Selection & Positioning, Screw Distances & Adjustments	49
Minimal Rod Length, Total Distance & Distances between Screw Heads	49
Rod Selection, Rod Positioning & Screw Adjustments	50
Rod Selection & Rod Positioning	50
Rod Position Adjustments	50
Adjusting Screws - Scan Again	52
Scan Again	52
Working with Markers on Both Sides of the Spine	54
12 Rod Template Generation	55
<b>13 Copy Rod Template Screen</b>	<b>56</b>
Smoothing the Rod Template	56
<b>Troubleshooting</b>	<b>57</b>
Camera Image, Camera Permissions, Overheating	57
3D Scanning Problems	57
Marker Detection Scanning Problems	60
Rod Position & Screw Adjustments	61
Rod Template Generation	62
Copy Rod Template Screen	63
Product Return	63
<b>Manufacturer Contact Information</b>	<b>64</b>
<b>Neo Medical Contact Information</b>	<b>64</b>
<b>Terms of Use</b>	<b>65</b>
Disclaimer	66
<b>Data Protection Declaration</b>	<b>67</b>
<b>Warranty</b>	<b>68</b>
<b>Copyrights and Trademarks</b>	<b>69</b>
<b>Product Label</b>	<b>69</b>
<b>Signs and Symbols</b>	<b>70</b>
<b>Abbreviations</b>	<b>71</b>
<b>Appendix</b>	<b>72</b>
List of Compatible Products	72
Sterile Bags and Cases	72
Neo Markers and Neo Marker Bases	72
Si-Bone iFuse Bedrock Granite® Implant System	72

# Introduction

Thank you very much for choosing the Neo ADVISE™ system. This software of the system runs on an Apple iPad and can be used during spinal surgeries to simulate the positioning of off-the-shelf rods and to estimate the size and shape of custom bent rods, based on the position of the Neo Pedicle Screw System™ screw guides.

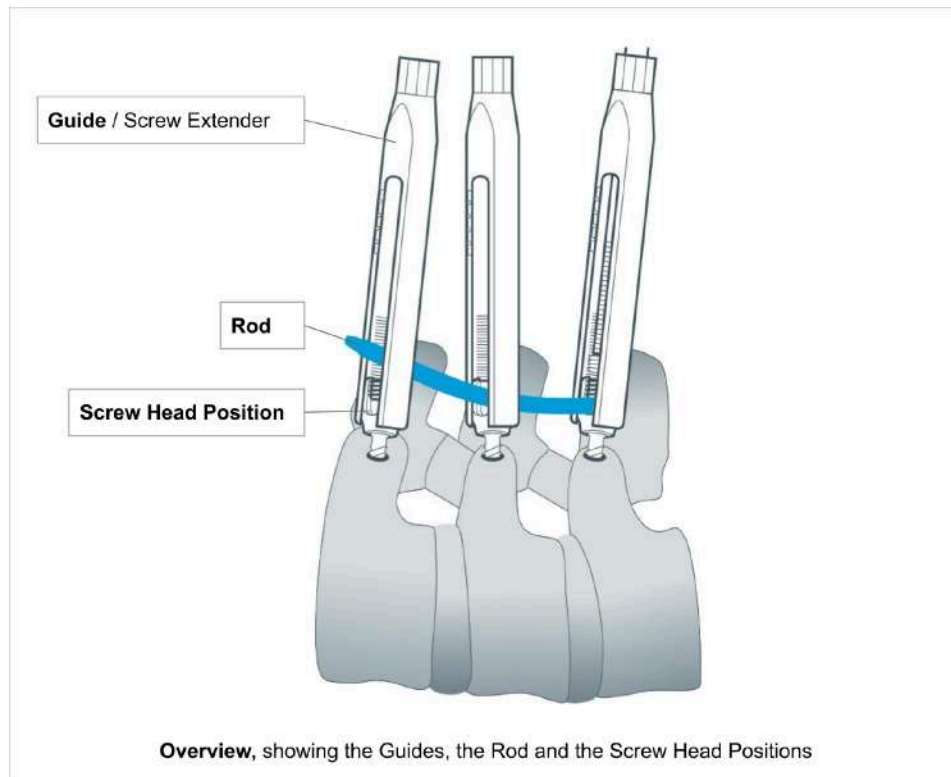
It is advisable that you read these instructions carefully before use.

A paper form of this Instructions for Use can be ordered at no additional cost using the Customer Service contact details on Neo Medical website ([www.neo-medical.com](http://www.neo-medical.com)).

Special training by Neo Medical is required to be allowed to use the system 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.



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 manoeuvres during rod placement. We use the term “Guide” for the “Screw Extender” in this document.

## The Neo ADVISE™ System

The Neo ADVISE™ System 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.

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](http://www.neo-medical.com/ifu), without the System.

## Software Features

The Neo ADVISE™ System 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 (limited to twenty guides, requiring additional hardware, namely the Neo Marker Base, which are sold separately).

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

- **Calculating and displaying the sum of all distances between the screw 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.
- **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.

### 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. The Marker Detection is limited to 20 guides.

## Shelf Life

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

## Limitations for Use

The Neo ADVISE™ System can be used for spinal procedures with a maximum of 10 guides (3D-Scanning) on one side and a total of 20 guides (Marker Detection scanning), which means 10 on each side.

## Indications for Use

The Neo ADVISE™ System is indicated to calculate the relative positions and distances between implanted Neo Pedicle Screw System™ screws, as estimated by visually identifying screw guides, to estimate rod length, visualize rod positioning, and create a rod template that

can be used to visually guide the manually creation a contoured rod by the surgeon, with a mechanical rod bender. The Neo ADVISE™ System can be used in posterior open or percutaneous spine surgery in the thoracic, lumbar, and/or sacral spine when using the Neo Pedicle Screw System™.

## Contraindications

The Neo ADVISE™ System 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.

## Access to Instructions for Use

The Instructions for Use (this document) can be accessed directly on the iPad. Tap the ADVISE IFU icon to view the document. No internet connection is required.



A printed version of this document can be requested from Customer Service of Neo Medical at no additional costs.



# Important Notes

## Compliant Use

The use of this system is reserved for professional use by a surgeon who has been trained.

	<p><b>The system does not remove any responsibility for patient safety from the surgeon.</b></p> <p><b>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.</b></p>
	<p><b>Any serious incident that has occurred in relation to the system should be reported to the manufacturer and the competent authority of the Member State in which the user is established.</b></p>

This system 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 system.

Any inappropriate use is forbidden.

## Sterile Environment

The usage of the system 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](http://www.neo-medical.com)). The use of non-compatible products might affect the performance of the Neo ADVISE™ System.

## 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™ System 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™ System. 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™ System.

While the Neo ADVISE™ System 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. Such operation shall be done outside the operating room in an office environment to avoid potential interferences with other devices.

The User Manual (this document) if available offline on the device.

## IT Network Characteristics and IT Security Measures

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

The Neo ADVISE™ System connects to the following endpoints:

Endpoint / IP Range	Port / Protocol	Description
<a href="https://neo-medical.com/ifu">https://neo-medical.com/ifu</a>	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™ System 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™ System, 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™ System, 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™ System software

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

# Before Usage

## Device Battery and Charger

Using the system 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.

	<p><b>Make sure that the device's battery is fully charged before starting the surgery.</b></p> <p><b>Do not charge the device in the operating room.</b></p>
---	---

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.

## Terms of Use

Before using the Neo ADVISE™ System 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™ System is not allowed without training by Neo Medical.



**The Neo ADVISE™ System must not be used without absolving a training session of Neo Medical.**

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



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

## 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.



**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

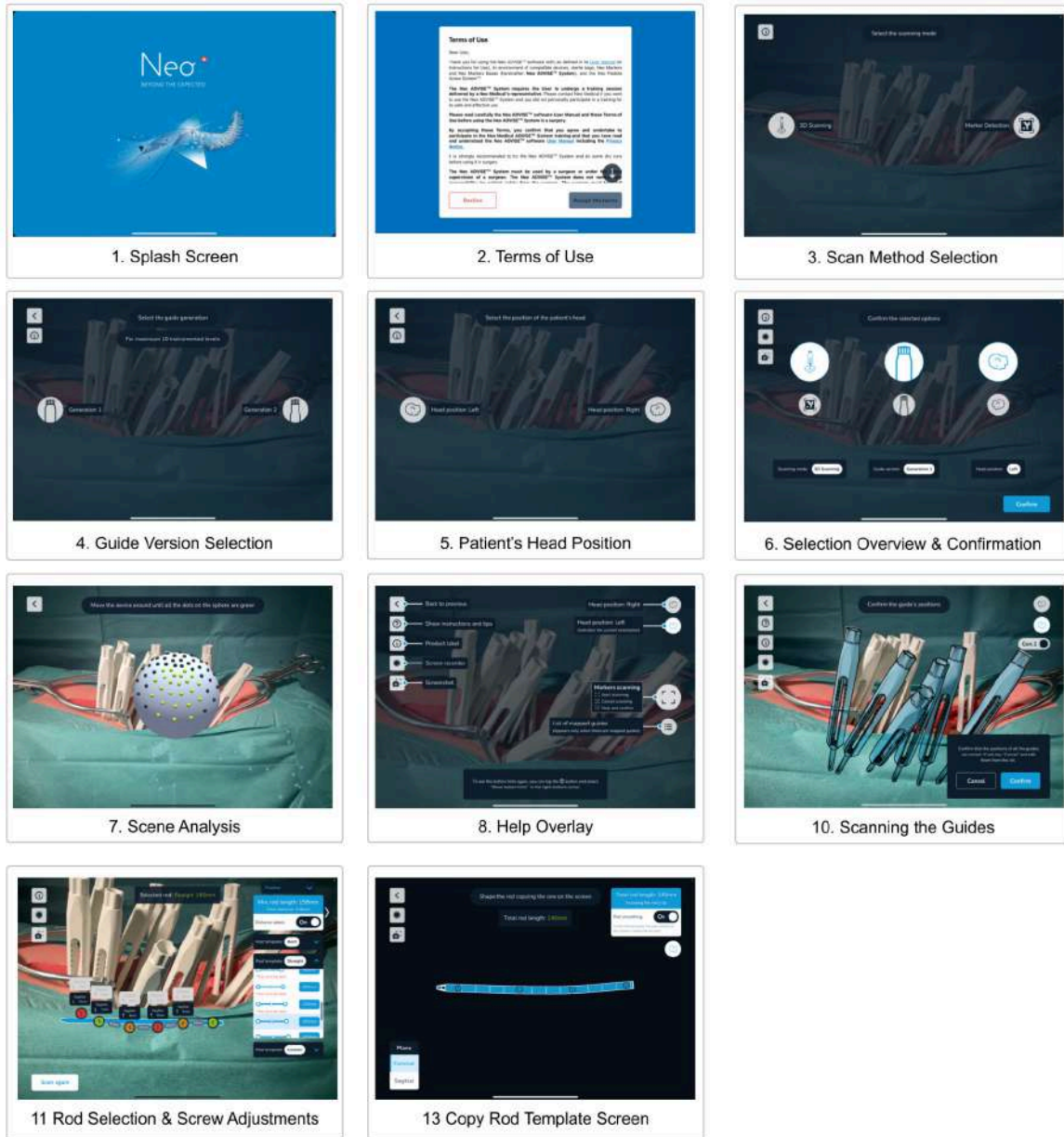
If the Marker Detection method is chosen for scanning the guides during the operation, make sure that enough markers and marker bases are available and that they are not being used past their expiration date. You might consider preparing the markers, as described in section [8.2 Scanning Instructions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

# How to Use the System

## System 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:



Each of these screens are described in detail in the following chapters.

# 1 Start the Software

The Neo ADVISE™ System 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™ System 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™ System and complete the surgery traditionally according to the surgical technique.

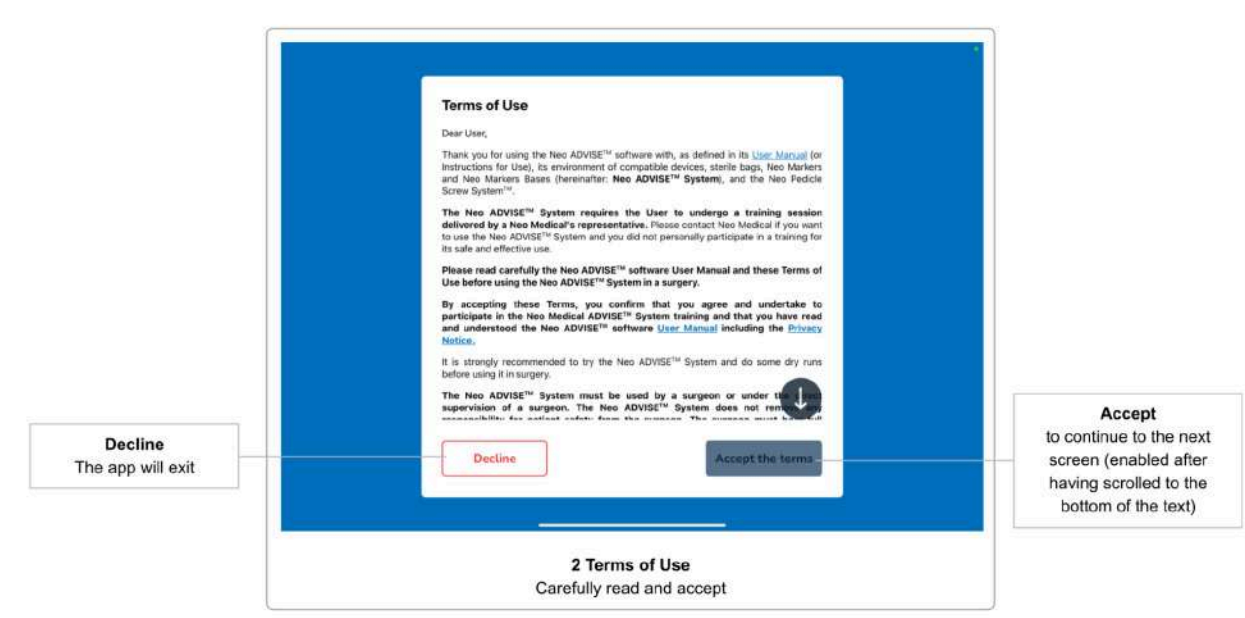


Start and unlock the device (if needed) and start the software by tapping the Neo ADVISE™ System icon on the home screen.

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



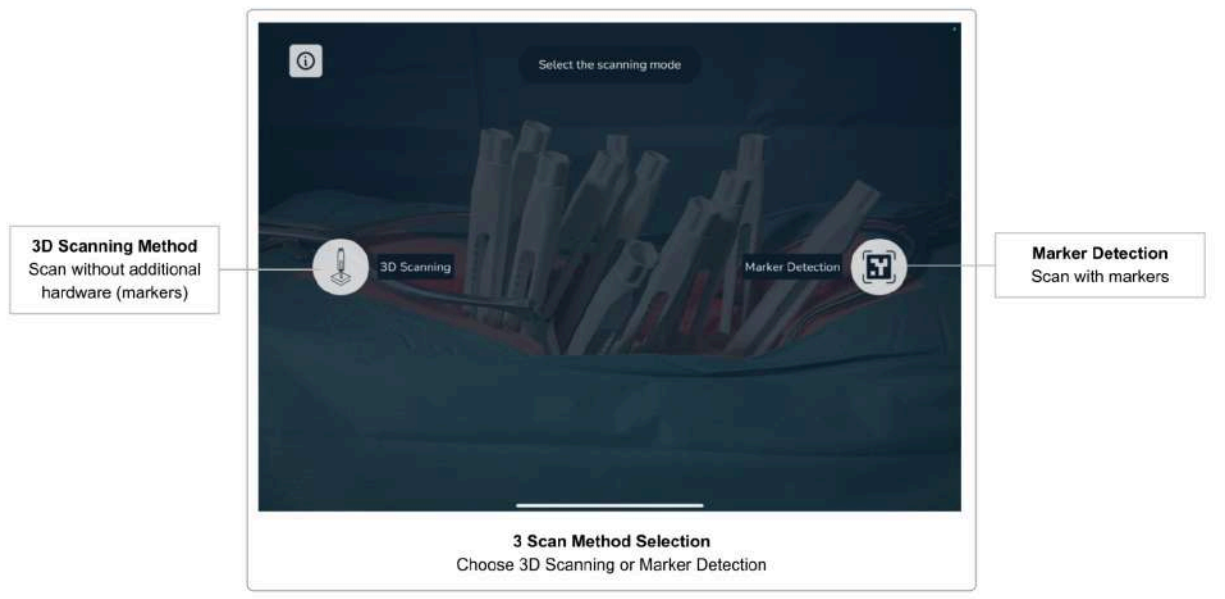
## 2 Terms of Use



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



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 (limited to 20 guides) 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 20 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.



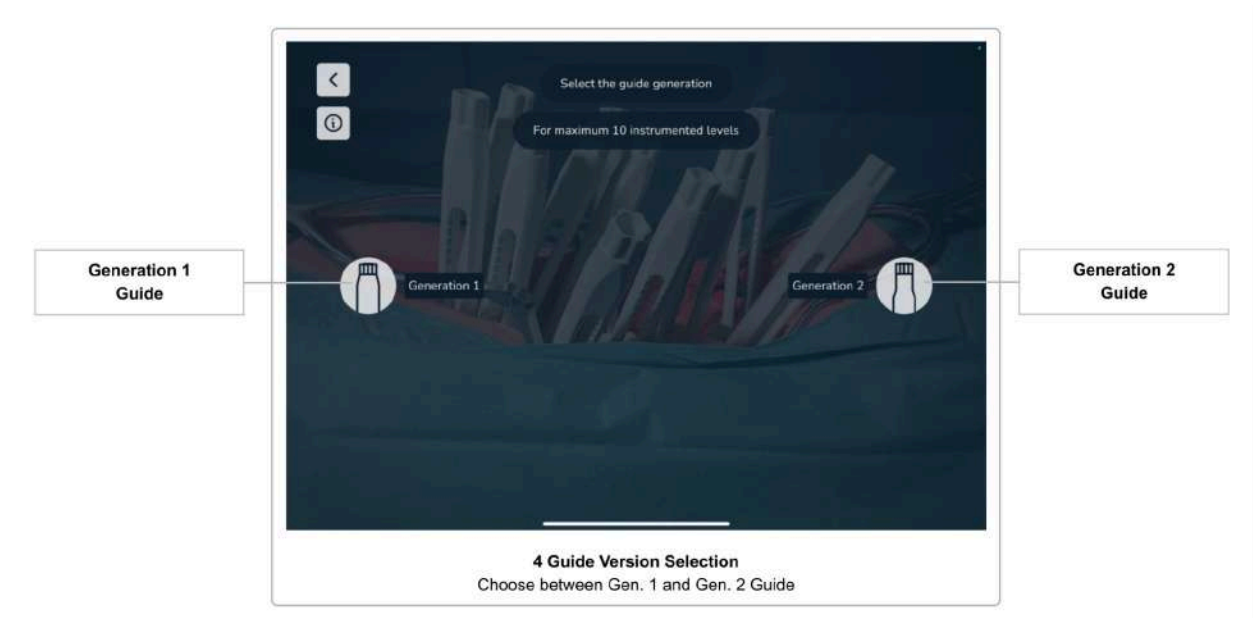
**If you have markers available, scanning the guides using the markers (Marker Detection) should always be the preferred method**

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

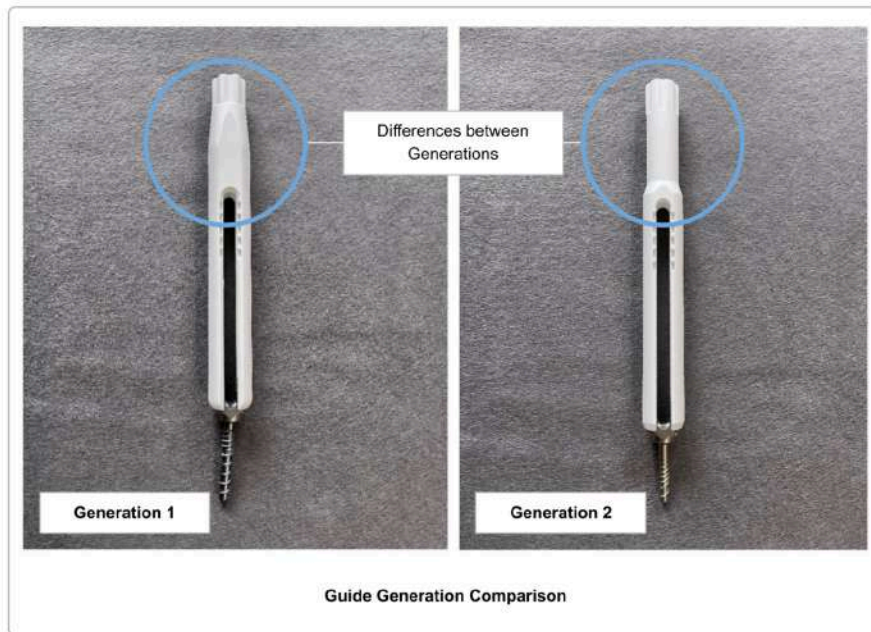


Currently, Neo Medical offers two different versions of the guides (Generation 1 and Generation 2). Although they do not differ in functionality or features, it is important for the software to know which versions are being used.

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.



## Mixing Guide Versions

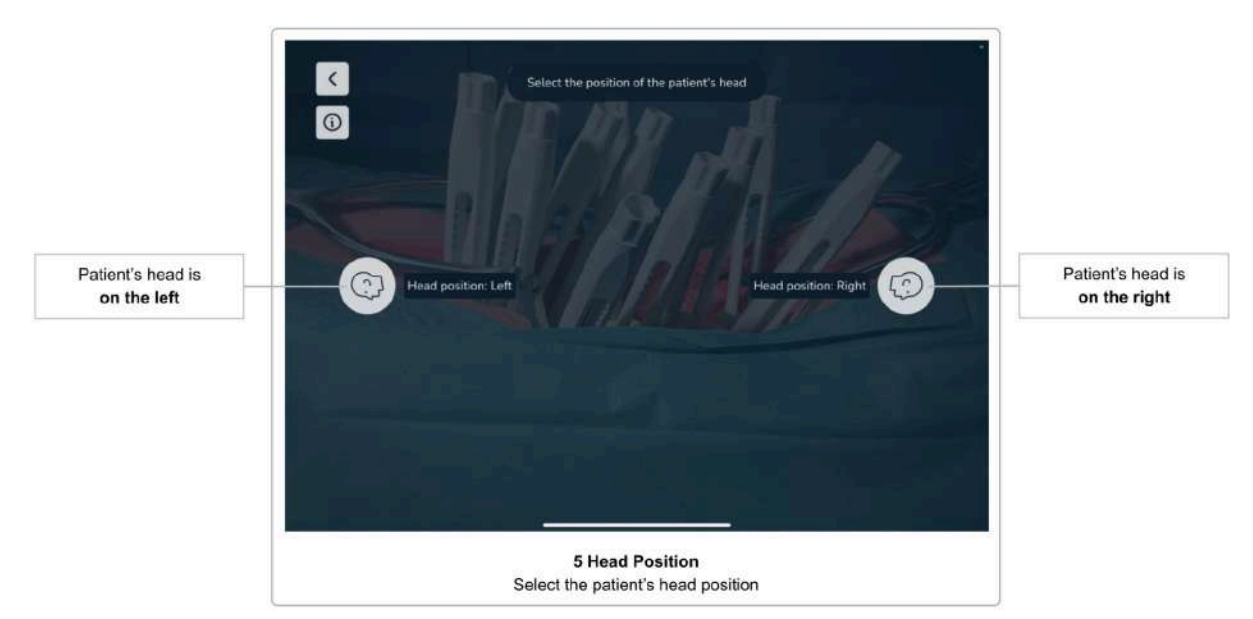
It is possible to use both versions of the guides within one surgery. Your choice done in [Selecting Guide Version](#) will be the default value used when scanning the guides, however, you can still change the version for each scanned guide individually during the scanning process.

## Granite Screw Guide

The Granite Screw Guide is a variation of the Neo Guide 2. Generation that can be attached to the **Si-Bone iFuse Bedrock Granite® implant system**. If you use the Granite Screw Guide with Neo ADIVSE, select the Neo Guide 2. Generation for scanning (for both scanning methods, 3D Scanning and Marker Detection).

For placement of the iFuse Bedrock Granite® implant system, follow the instructions for use and surgical technique provided by the manufacturer SI-BONE, Inc. and the *Addendum to the surgical technique of the Neo Pedicle Screw system* available on request at Neo Medical.

## 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.

## 6 Confirmation Overview

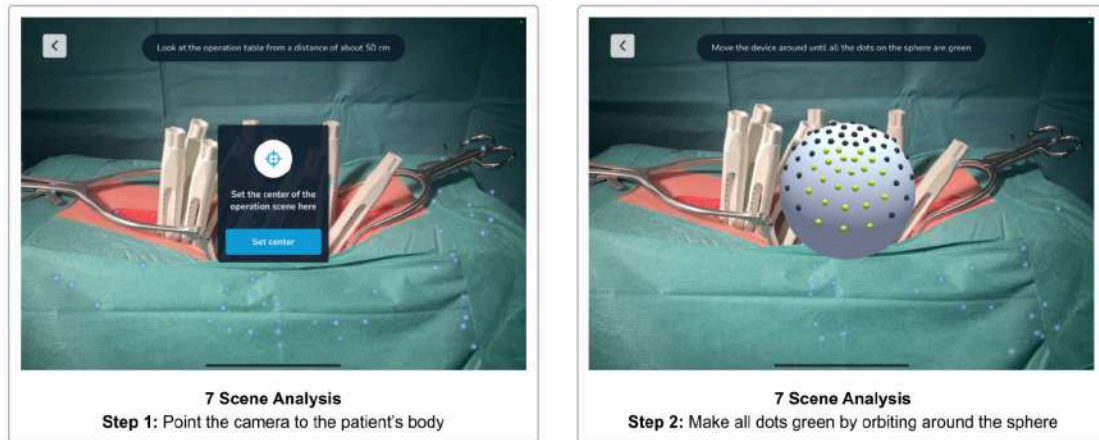


The next screen summarizes the selected options up to this point (scan method, guide version, and patient's head orientation). Please ensure that you have selected the correct options and confirm using the *Confirm* button. If you want to change an option, you cannot go back to the individual screen,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

gBefore 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.



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 / Light Settings](#) for more details.

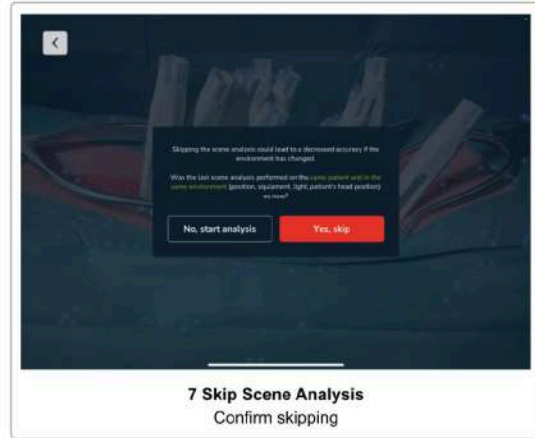
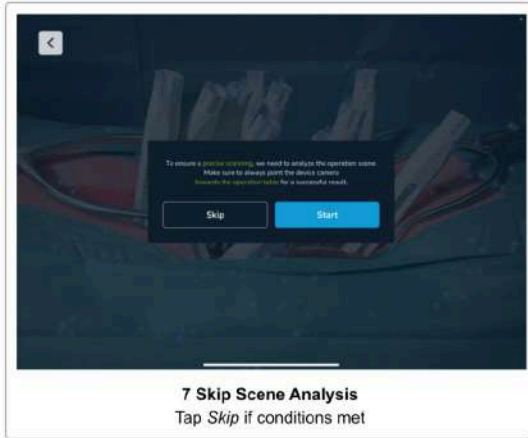
You will now see a sphere with gray and green dots on the surface. Orbit the device around the sphere, preserving the distance between the sphere and the device. The goal is to make all dots go green by looking at them from all directions. Move the device slowly and tilt it to always have the sphere 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

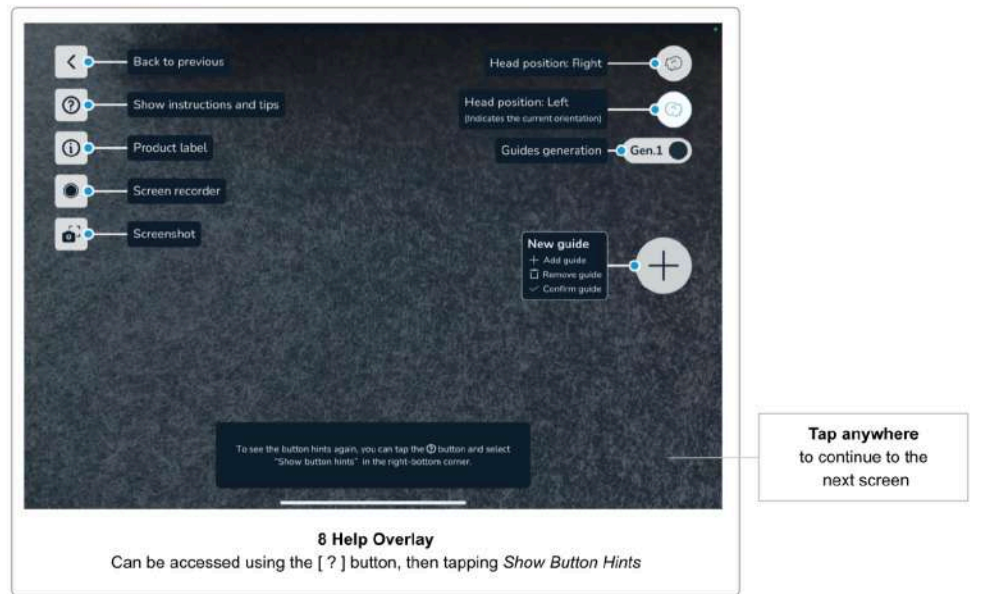
Time is critical during surgery. Therefore, the system allows to skip the scene analysis step if the last analysis has been performed within the last five minutes, and no options on the confirmation screen have changed (i.e. scan method, guide version, or the patient's head position).





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




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.

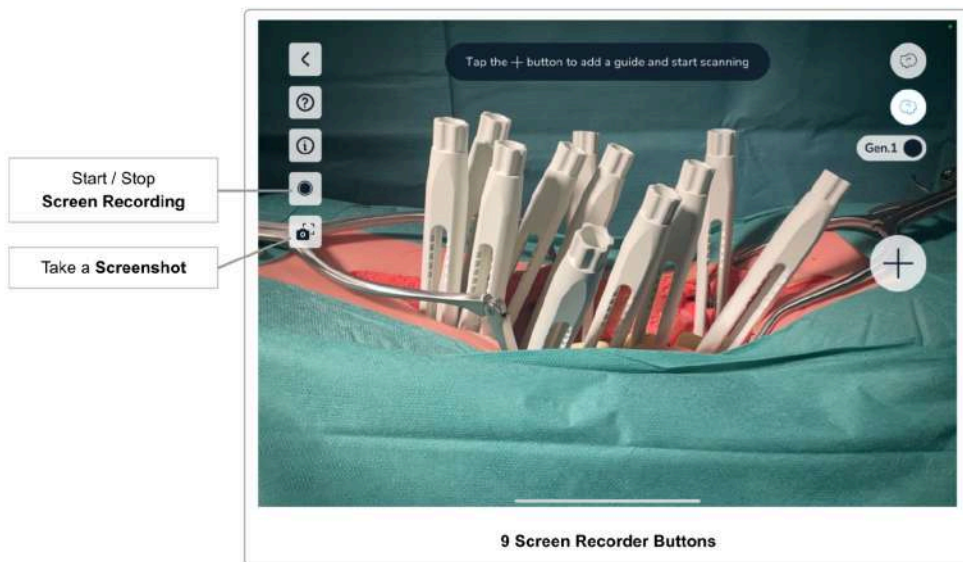
Tap anywhere on the screen to continue to the next screen.

## 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.

	<p><b>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).</b></p> <p><b>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.</b></p>
---	---

### Screen Recorder



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.**

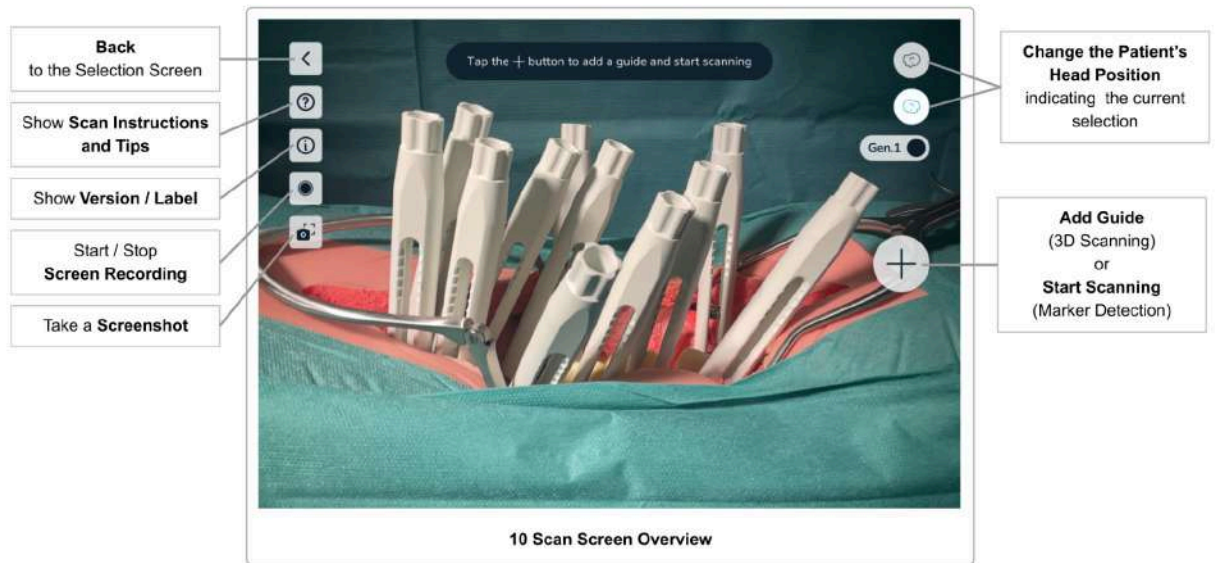
The video recordings are saved in the *Photos App* on the device. You can open the *Photos App* by closing the Neo ADVISE™ System and tapping the *Photos App* app icon to find your recordings.

## 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



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 / Light Settings

The performance of the system, especially the scanning accuracy and precision, depends on several factors in the scanning environment. Suboptimal lighting 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.


#### Optimal Lighting Settings

Good lighting is important for the system to work properly. 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 possible, move the light beam coming from OR lamps temporarily away from the incision during the scanning process.

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

	<b>For optimal scanning results, use as many diffuse and bright light sources as possible and avoid using OR lamps with narrow light beams.</b>
---	---

## 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.


	<p><b>Make sure not to move the patient during or after scanning the guides.</b></p> <p><b>If the patient has been moved, you need to re-scan the all guides.</b></p>
---	---

### 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.

	<b>3D Scanning of the guides is limited to 10 guides per side</b>
---	---

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 overlaid guide matches the guide in the patient's body.

	<b>When using the 3D Scanning Method, the user has to scan each guide separately</b>
---	--

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.

	<b>Only scan guides on one side of the patient's spine when scanning using 3D Scanning.</b> <b>Scanning both sides at the same time is only supported using the Marker Detection scanning method.</b>
---	--

	<b>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).</b>
---	--



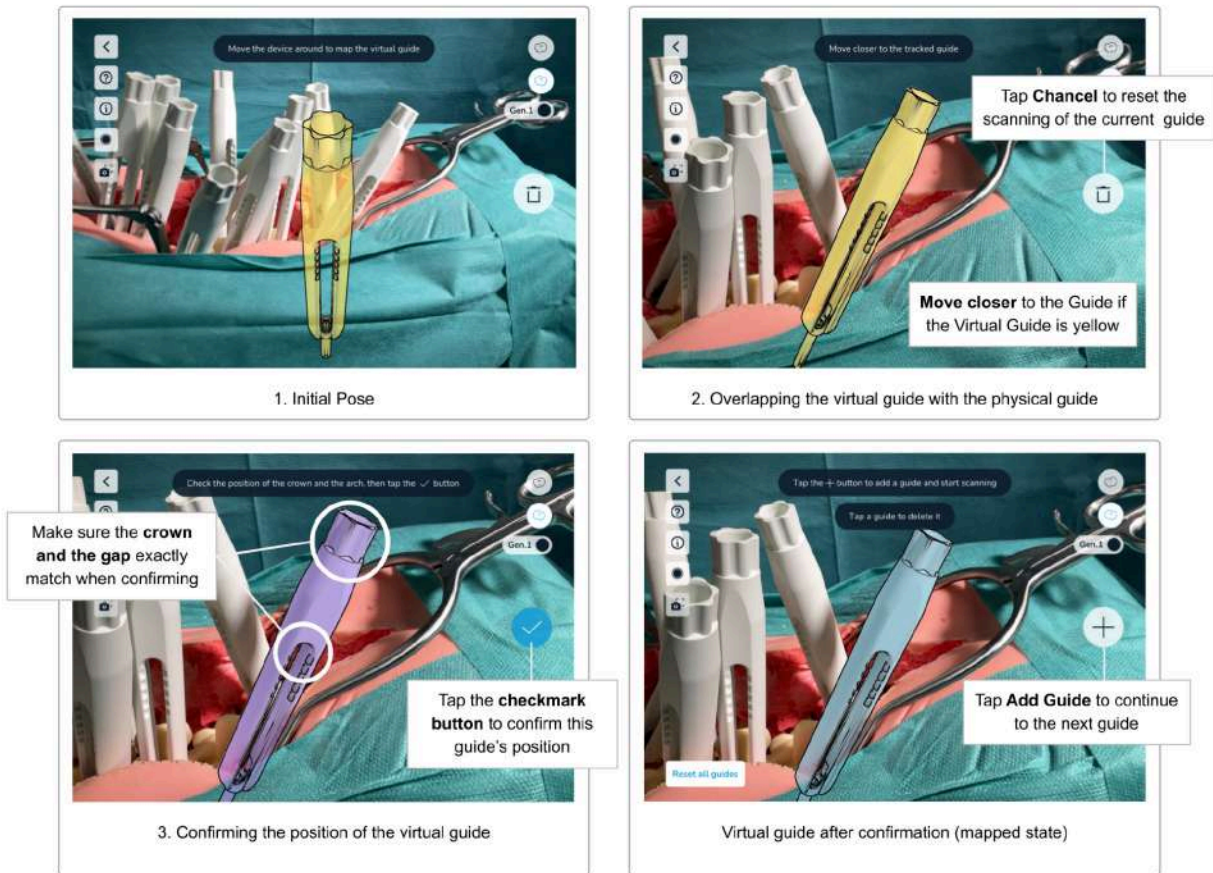
## Step 1 Adding the first Guide



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.

## Step 2 Mapping and Confirming the Virtual Guide



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.

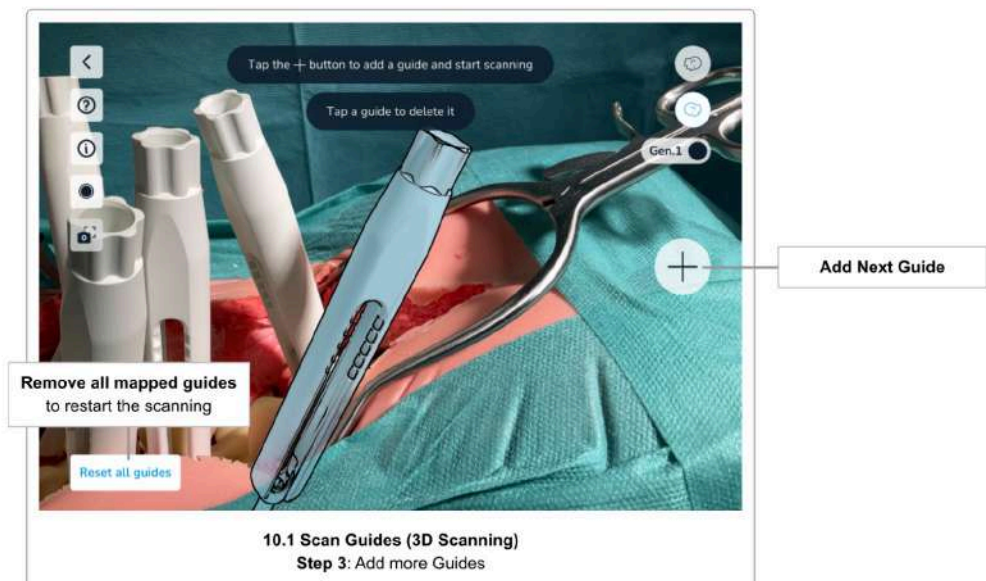
While in the purple state, carefully observe the small positional updates of the virtual guide with respect to the physical guide that still occurs in this state. **As soon as the virtual and the physical guide overlap completely, tap the *Confirm* button to fix the position for this guide.** The guide 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 / Light Settings](#) 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

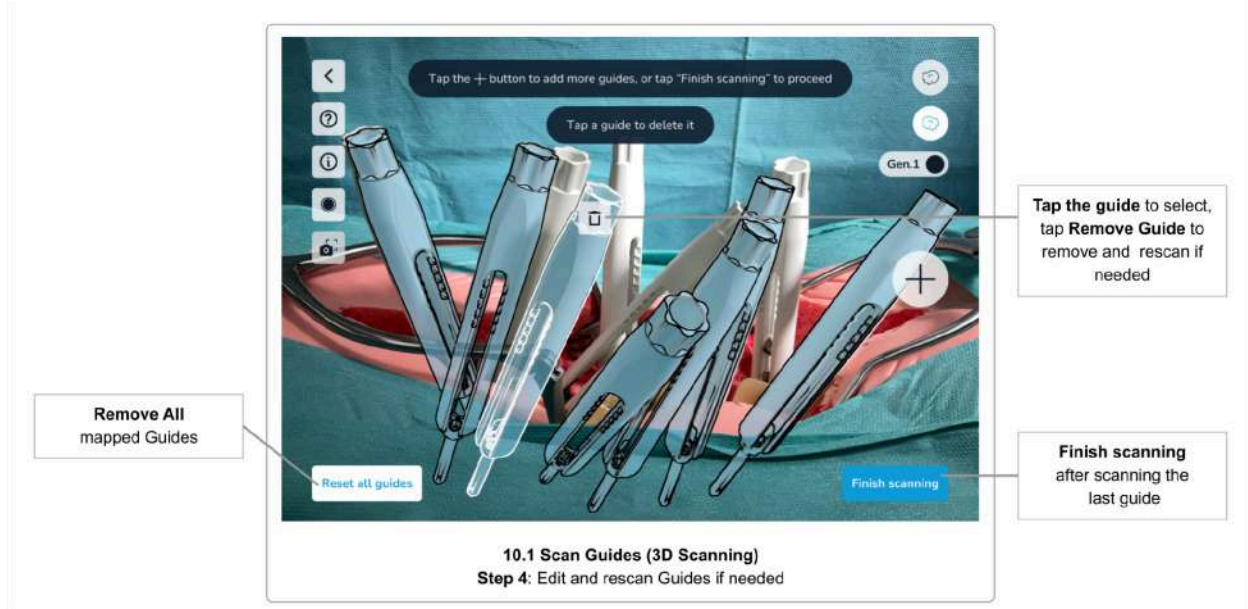


Continue the scanning process by **tapping the *Add Guide* button again to scan additional guides**. Repeat the same procedure for all the guides you want to scan.

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



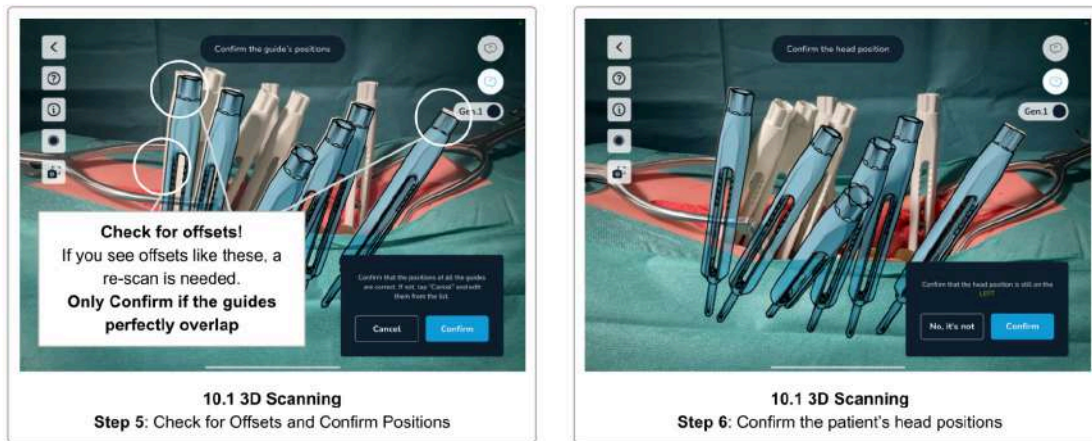
To edit mapped guides (guides that are scanned and have a confirmed position, colored blue), you can simply tap the guide to reveal the *Remove guide* button (trash icon). Use the *Remove Guide* button to delete a guide, either for rescanning or ignoring it completely.

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



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.

	<p><b>Visually checking and confirming the guides' positions is important.</b></p> <p><b>Not properly scanned and therefore wrongly positioned guides will lead to wrong results.</b></p>
--	---

## 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 software
- 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 20 guides using this method. If you have the markers available, you should always prefer this method over scanning without markers.

	<b>If you have markers available, scanning the guides using the markers should always be the preferred method.</b>
---	--


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.

	<b>Do not mix identical marker sets.</b>
---	--

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

	<b>When detaching the Marker Base from the Guide, make sure to hold the guide to avoid screw pullout in weak bone structures.</b>
---	---

## 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.

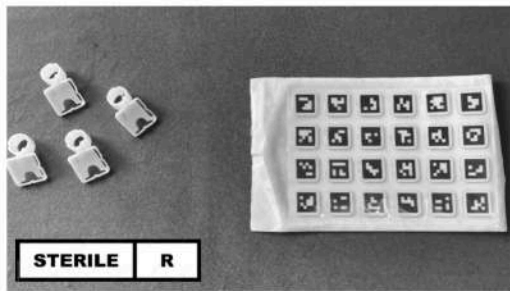


## 2. Stick Markers onto the Marker Bases

Unpack the marker and the marker bases and stick the markers on the marker bases, while keeping in mind that both products are delivered sterile and must not get contaminated. Make sure the marker sits tight in the marker base.



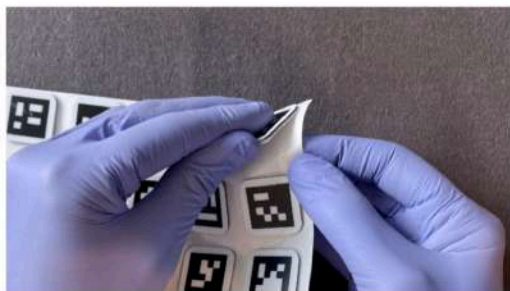
**Opening and assembly of the markers onto the marker bases must be done using sterile technique.**



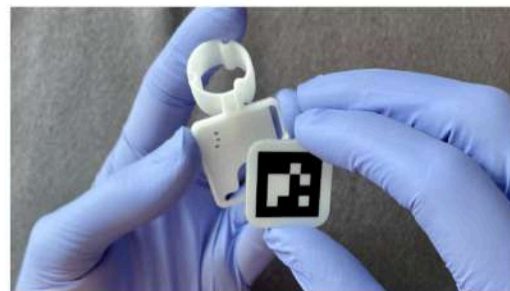
1. Prepare Bases and Markers (both sterile)



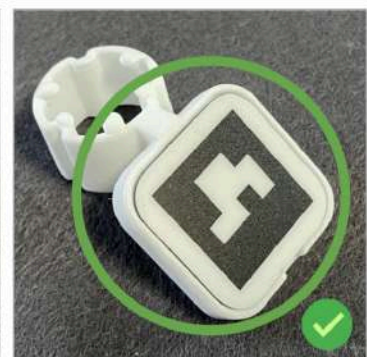
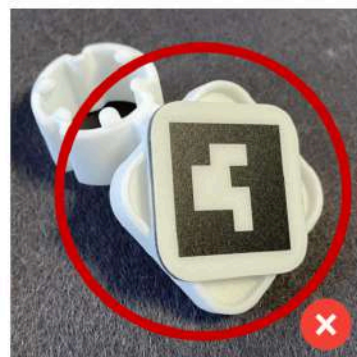
2. Prepare Bases and Markers (both sterile)



3. Detach a Marker



4. Fit into the Marker Base

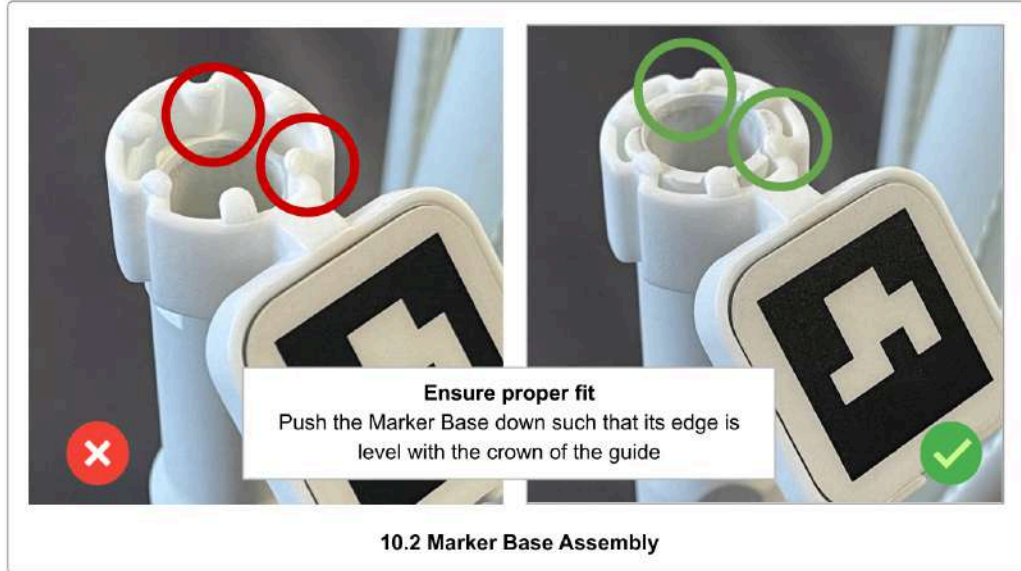


5. Make sure the marker sits tight in the marker base

### 10.2 Marker & Marker Base Assembly

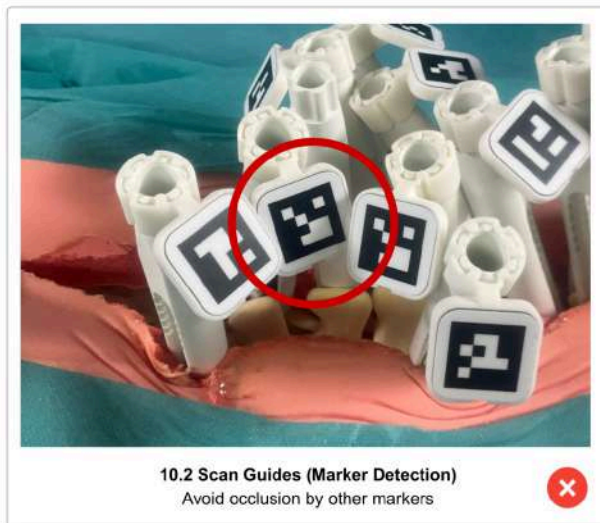
3. **Attach the Marker Bases to the Guides**

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.



4. **Place the marker bases so that they are not occluding each other**

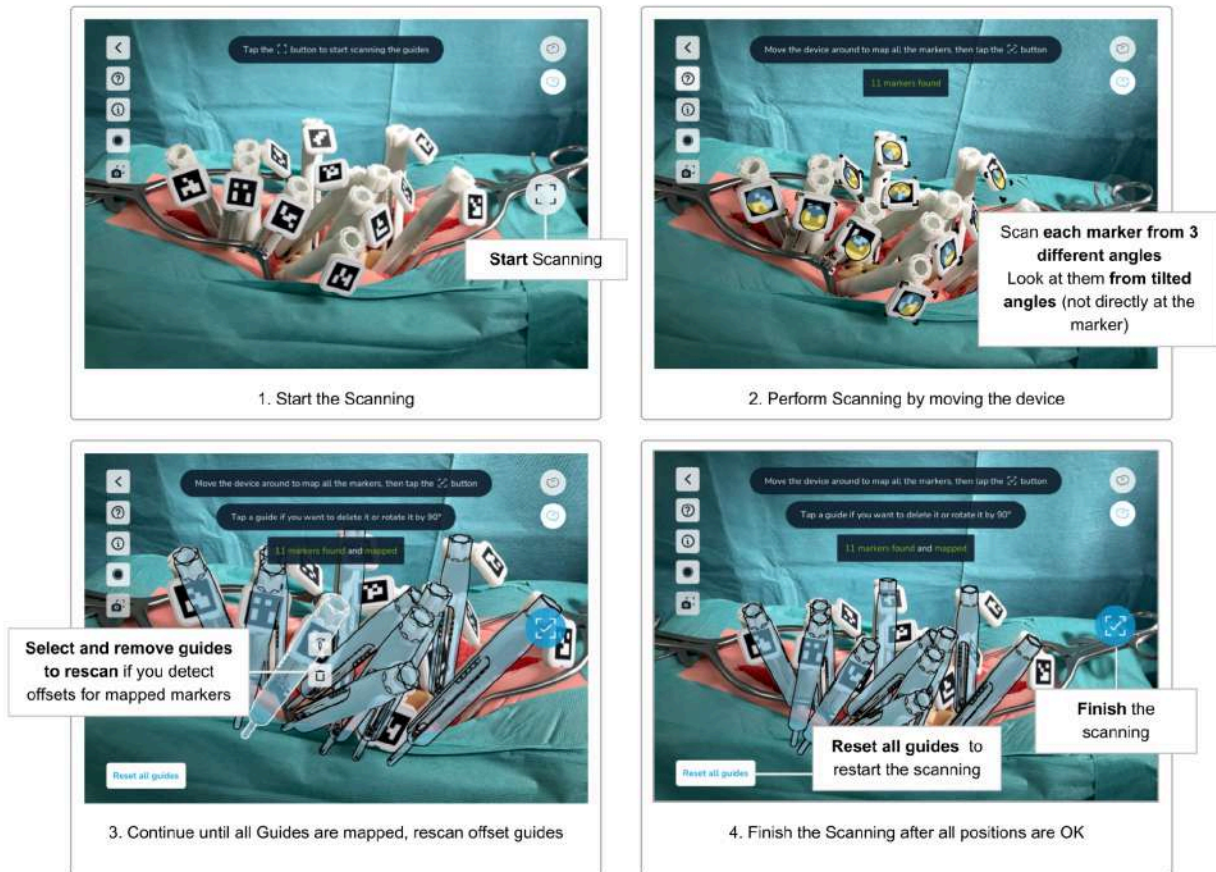
You will need to scan every marker from three different angles. When working with many markers, it can be difficult to find an optimal position for each marker. Therefore, take your time to find a position for each marker that leaves as much space between the markers as possible. Place the markers so that they can be viewed from as many angles as possible without occlusion.





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:

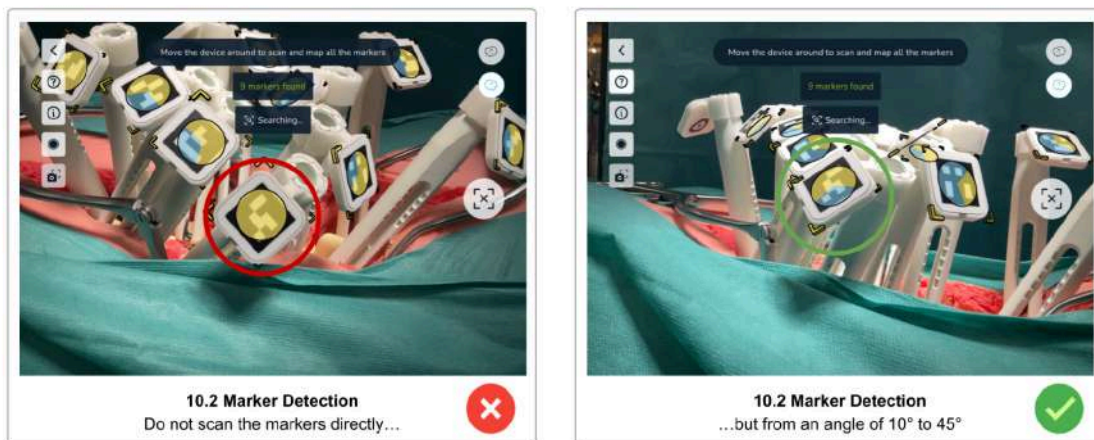
- Find the markers
- Refine the positions by looking at each marker from three different angles
- Check for misaligned markers (orientation/rotation)

- Confirm the positions
- Partition the guides left/right (only when working on both sides of the spine simultaneously)

As soon as the software detects a marker, the edges of the marker get highlighted with yellow corners. This indicates that **the software 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°**.



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).

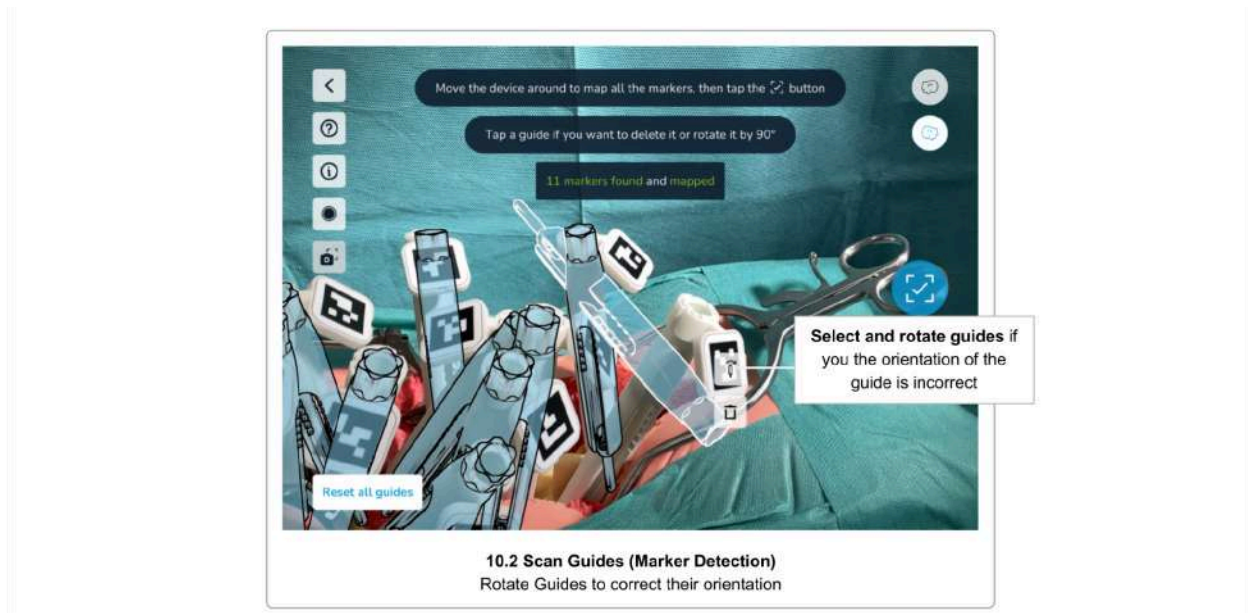
Continue with the scan until all markers have been successfully mapped.

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.**

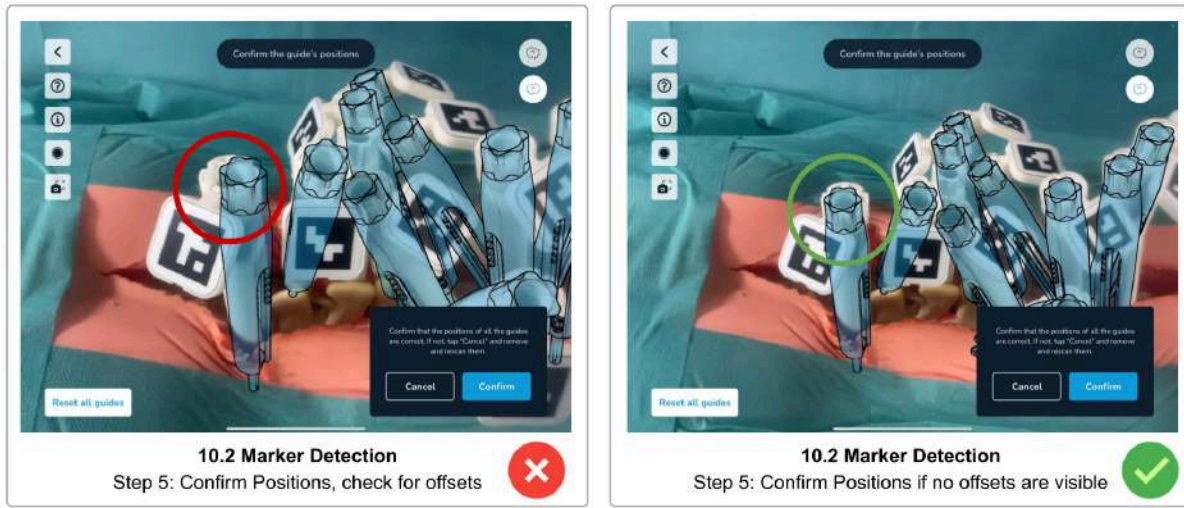
**Use the *Reset all guides* button to remove all scanned guides** and start over with the scanning. This might be necessary if someone moved the patient during the scanning or if you get interrupted and had to put the device aside.

### Step 3 Correct Guide Orientation/Rotation



If a physical guide is tilted with an angle more than 45°, the software 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



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.

	<p><b>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.</b></p>
--	--

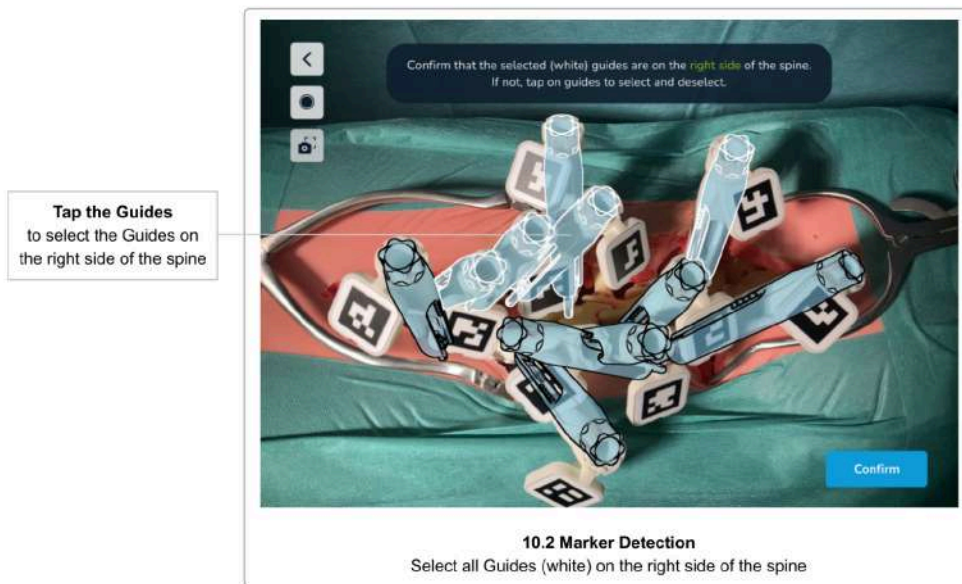
## Step 5 Confirm the Patient's Head Position

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



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 software tries to figure this out automatically but might need some adjustments.

The software 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

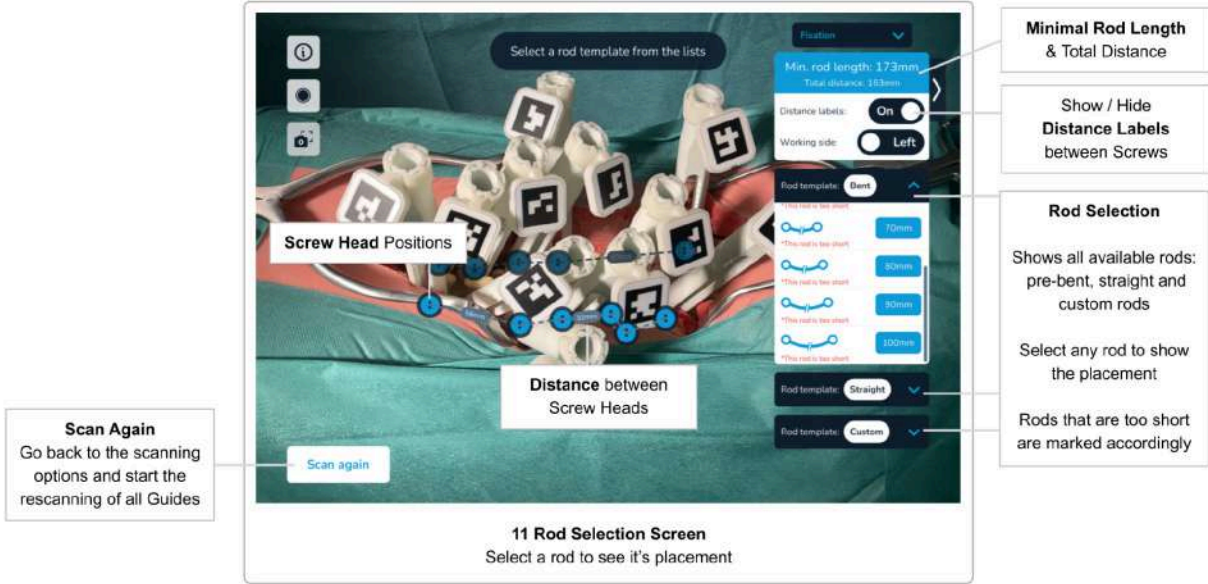
If you have trouble scanning the markers, the following tips might help:

	<p><b>Tips &amp; Troubleshooting Marker Detection Scanning</b></p> <ul style="list-style-type: none"><li>• Make sure that the correct scanning method was selected in <a href="#">Scan Method Selection</a></li><li>• Clean the markers. Ensure the markers are clean.</li></ul>
---	--

- |  |  |
|--|--|
|  | <ul style="list-style-type: none"><li>● 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</li><li>● Try to avoid pointing the device directly towards a marker. Slightly tilted angles usually work better</li><li>● Try to place the markers in a way that they do not overlap and are fully visible from multiple angles</li><li>● Move the device slowly</li><li>● 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</li><li>● 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</li><li>● Check the <a href="#">Troubleshooting</a> section</li></ul> |
|--|--|



# 11 Rod Selection & Positioning, Screw Distances & Adjustments



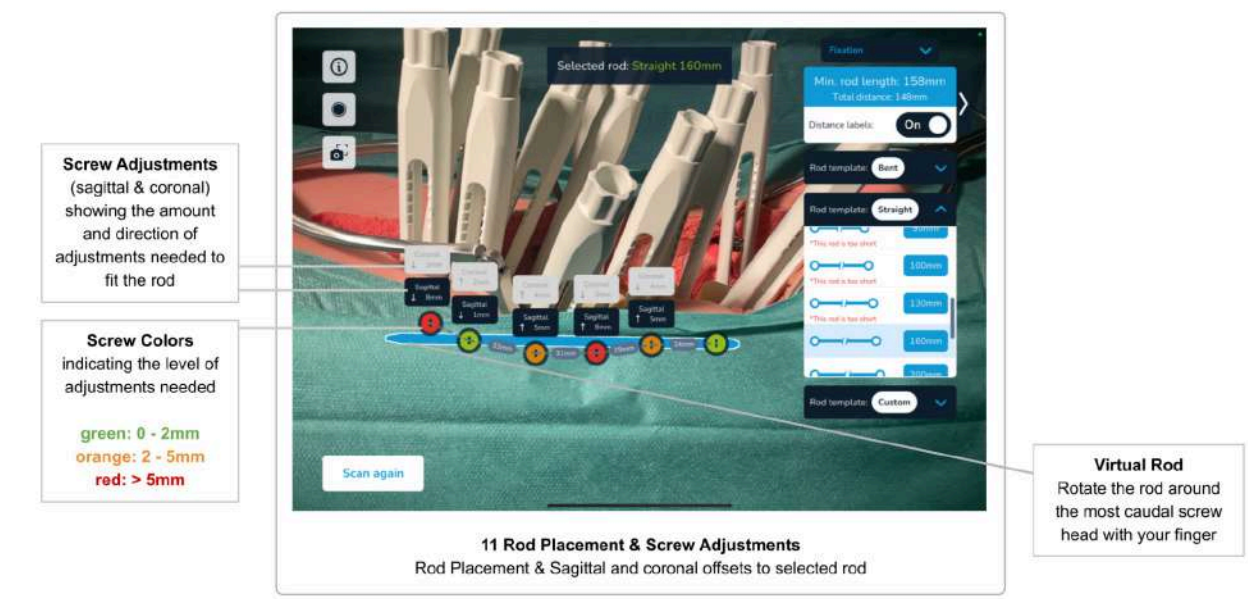
## Minimal Rod Length, Total Distance & Distances between Screw Heads

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



### 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.

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

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).

	<p><b>One turn of the screw corresponds to 4mm screw adjustment.</b></p>
---	--

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:

<b>Color</b>	<b>Proposed Screw Adjustment</b>
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 *Custom 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. If you 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. After the scanning the software asks if the head position is still the one that was initially chosen.



**Do not forget to change the patient's head orientation in the software if you switch the side when starting a new scan.**



**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

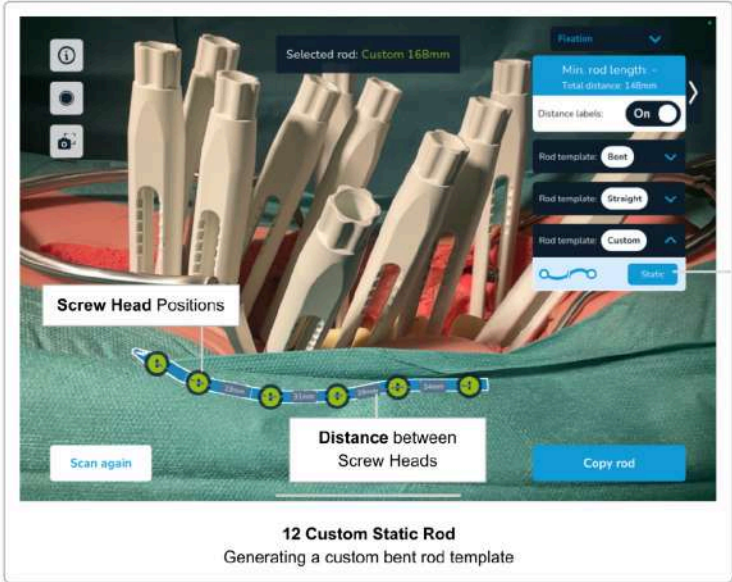


When using the Marker Detection scanning method, you have the option to scan both sides of the spine simultaneously. Select the option either in the dialogue that appears when selecting the Marker Detection scanning method or on the *Confirmation Overview* screen.

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.

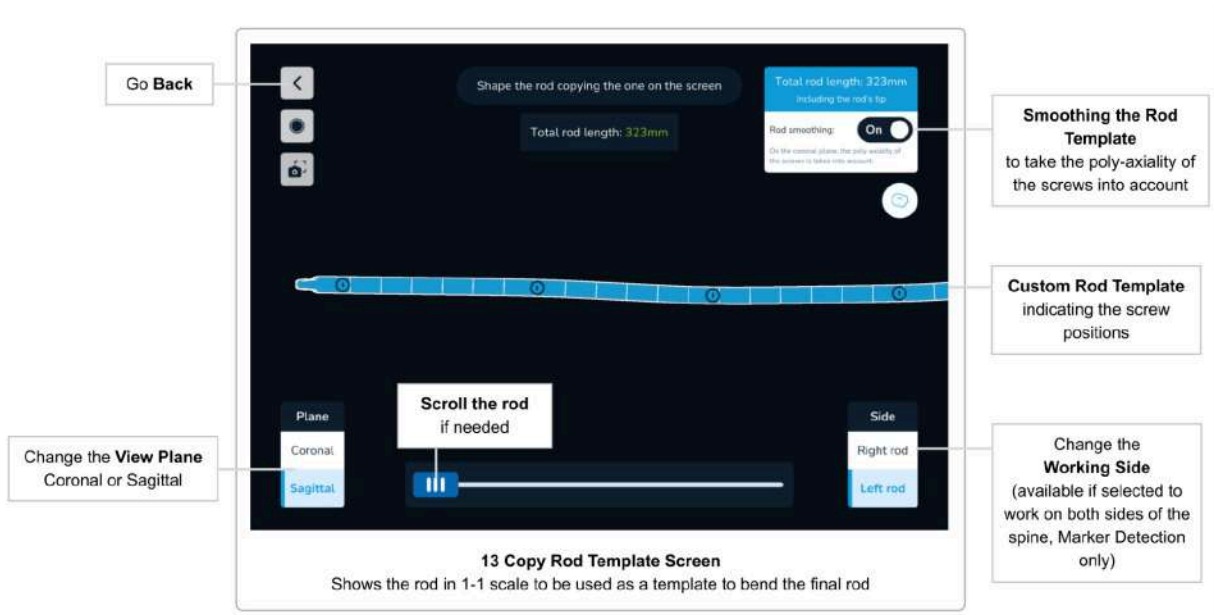
# 12 Rod Template Generation



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*.



## 13 Copy Rod Template Screen



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.

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.



# 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™ System.
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 software.	Clean all guides before scanning.
		The light conditions are suboptimal.	<p>Change the lighting to increase contrast and avoid reflections.</p> <p>Avoid using OR lamps with narrow and bright light beams. Using multiple, diffuse light sources is preferable.</p>
		The guide's orientation is suboptimal and/or covered by another guide.	<p>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.</p> <p>It is possible to move already scanned guides to have better access to the current guide being scanned.</p> <p>In complex cases with a lot of guides, consider covering the opposite side of the spine not being scanned with a cover or cloth.</p>
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
	<p>guides is not correct</p> <p>The virtual guide does not fully overlap with the physical guide</p> <p>The virtual guide is longer or shorter than the physical guide</p>	<p>correct when confirmed.</p>	<p>guides by opening the guide table, removing and re-scanning the guide.</p> <p>You can re-scan all guides by clearing the guides in the <i>Guide Table</i> using the <i>Clear All</i> button.</p>
		<p>Tracking of previously scanned guides is not working.</p>	<p>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.</p> <p>Restart the scanning of all guides by opening the <i>Guides Table</i> and tapping the <i>Clear All</i> button.</p>
		<p>The framerate is low and the software is lagging. The mapped virtual guides show a noticeable offset to the physical guides.</p>	<p>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.</p>

## 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 be recognized by the software.	Clean all markers 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 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 software.  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.

ID	Problem	Possible Causes	Possible Solutions
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 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.
9	I have scanned all guides, but the confirmation button does not appear	The software 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 marker 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

ID	Problem	Possible Causes	Possible Solutions
			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 wrong.	During the scanning, some screw heads are scanned from the other side of the spine	When working only on one side of the spine, make 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 <i>Scan Again</i> 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 <i>Scan Again</i> 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 <i>Scan Again</i> 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.

## 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

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

## Neo Medical Contact Information

For any query about the Neo ADVISE™ System 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](http://www.neo-medical.com).



# Terms of Use

Dear User,

Thank you for using the Neo ADVISE™ System 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™ System 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™ System 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™ System.

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™ System can be started again by the new user by tapping on the Neo ADVISE™ System icon on the device's home screen.

# Disclaimer

- *Please consider that screenshots and video recordings of the Neo ADVISE™ System 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™ 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™ 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™ 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™ System 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™ System, Neo Medical as Provider gives its customers a limited warranty for the Neo ADVISE™ System 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™ System 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
	—	Note of important information
	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)
	ISO 15223-1: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part1: General requirements	“Manufacturer” (5.1.1)
	MDR 2017/745	This device/software complies with the Regulation (EU) 2017/745 (MDR)
	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)
	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)
	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.

<div style="border: 1px solid black; padding: 5px; text-align: center; width: 60px; margin: auto;"><b>UDI</b></div>	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)
<div style="border: 1px solid black; padding: 5px; text-align: center; width: 60px; margin: auto;"><b>REF</b></div>	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™ System:

- **EC2300: eShield™ 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.

#### Si-Bone iFuse Bedrock Granite® Implant System

The Si-Bone iFuse Bedrock Granite® implant system is compatible with Neo ADVISE™ using the Neo Granite Screw Guide. For placement of the iFuse Bedrock Granite® implant system, follow the instructions for use and surgical technique provided by the manufacturer SI-BONE, Inc. and the *Addendum to the surgical technique of the Neo Pedicle Screw system* available on request at Neo Medical.