Exclusively foot & ankle

Paragon 28®

ENOS Hexapod Gradual Deformity Correction System Software 1.0

INSTRUCTIONS FOR USE

2026-03-31

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1. General Information

This User Guide describes the functionality of the ENOS Hexapod Gradual Deformity Correction System software manufactured by Disior™ Oy – A Paragon 28® company and provides instructions how to use it.

Caution: User training is required for safe use of the software.

Caution: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

1.1. Definitions

Definitions used in the software are defined in Table 1.

Table 1 Definitions used in the software.

Term	Definition
Anterior	Refers to the front or front surface of the body.
Apex	Tip or highest point
Distal	Located away from the center of the body or attachment point
Exterior	Outside or away from the center of the body
Internal	Inside or closer to the center of the body
Lateral	Away from the midline of the body
Long	To increase a deformity translation(s)
Medial	Toward the midline of the body
Posterior	Refers to the back of a structure, or towards the back of the body.
Proximal	Toward or nearest the trunk or the attachment point
Rotation	Movement caused by turning a body part around its own axis
Short	To decrease a deformity translation(s)
Translation	Displacement occurring between two fractured ends
Valgus	Outward angulation away from the midline of the body
Varus	Inward angulation toward the midline of the body

1.2. Acronyms

Acronyms used in the software are described in Table 2.

Table 2 Acronyms used in the software.

Acronym	Description
AP	Anteroposterior
CORA	Center of Rotation of Angulation
Deg	Degrees
IFU	Instructions for Use
LAT	Lateral
mm	millimeters
SAR	Structure at Risk

1.3. Description of the software

The ENOS Hexapod System software is intended to be used as a component with Paragon28 multilateral external fixation system with same indications. The ENOS Hexapod System is intended to be used by orthopaedic healthcare professionals for determination of the Strut adjustment schedule or patients indicated for treatment with Monkey Rings™ External Fixation System.

1.4. Intended medical indication

The ENOS Hexapod System software is used with the Paragon 28 Monkey Rings™ External Fixation System for the treatment of traumatic or reconstructive deformities within the indications for use of the Monkey Rings External Fixation System. It is used to generate a prescription of strut adjustments to provide to the patient.

The Monkey Rings™ External Fixation System is indicated in pediatric patients and adults for the treatment and fixation of:

- Open and closed fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis, infected union, non-union, or malunion of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of bony or soft tissue deformity (e.g. orthoplastic surgery)
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
- Management of comminuted intra-articular fractures
- Bone transport

The Monkey Rings™ External Fixation System is indicated in adults for:

- Osteotomy
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Offloading and/or immobilization of ulcers and/or wounds of the foot and ankle
- Lisfranc dislocations
- Ankle distraction (arthrodiastasis)
- Septic fusion

1.5. Intended patient population

The ENOS Hexapod System is intended to be used on both pediatric and adult populations. Refer to “Intended medical indication” section for specific indications for pediatric and adult populations.

1.6.Contraindications / Restricted patient groups

Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon’s education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or for the procedure being utilized. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic, and patients with a history of infection
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the devices
- Osteopathies with reduced bone substance that could affect the function of the devices
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment. The risk of breakage of a fixation device is greater in older patients with mental deficiency, alcoholics or drug addicts or patients who, for other reasons, may ignore the necessary restrictions and precautions to be observed while using the device.
- Known or suspected sensitivity to device materials
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or device failure can occur.

1.7.Intended part of the body and type of tissue applied to

The ENOS Hexapod System is intended to assist in planning deformity corrections for Tibia, Ankle, Foot, and Long Bones.

1.8.Intended user profiles

The intended primary operator users are medical professionals with a license to practice orthopedic surgery of foot and ankle surgery. Sales Representatives are identified as secondary users of the software. Sales representatives are known to assist orthopedic surgeons by entering values on their behalf. Sales representatives are not expected to and are not indicated to use the software without direct supervision from an orthopedic surgeon. They must only use the software under the supervision of a primary user (surgeon).

1.9.Use environment

Hospital office space or medical doctor's office or general office space with computing systems, e.g., laptop or desktop computer using common web browsers.

1.10. Operating principle

The ENOS Hexapod System is a planning software for the Monkey Rings™ External Fixation System. The software allows the Healthcare Professional to define the following inputs:

1. The patient's deformity. The deformity is defined by manual entry of certain anatomical characteristics.
2. The physical characteristics of the Monkey Rings™ External Fixation System's hardware. The physical characteristics are defined by manual entry of the hardware's strut dimensions and ring locations with respect to the defined deformity.
3. The desired final anatomical position. The desired final anatomical position can be defined to automatically correct to a neutral position or can be defined by manual entry of desired anatomical characteristics.
4. The desired rate of correction. The rate of correction is defined by manual entry of the number of corrections per day, and the desired maximum rate of movement in millimeters or degrees per day. It can also be defined using a desired treatment duration.

The software utilizes an algorithm that takes the user-defined inputs and the unique hardware characteristics of the Monkey Rings™ External Fixation System and generates a treatment plan. The treatment plan is provided to the patient, who then manipulates the Monkey Rings™ External Fixation System's user interface per the plan's instructions. The intended end result is that the patient's deformity is corrected to the final anatomical position as defined by the Healthcare Professional.

1.11. System compatibility

ENOS Hexapod System should function with all common web browsers.

Table 3. Compatible operating systems and web browsers, including latest tested version.

Operating system	Web browsers
Microsoft Windows 10 Pro Version 22H2 (OS Build 19045.3693)	Microsoft Edge (142.0.3595.80 (64-bit))
	Google Chrome (142.0.7444.60 (64-bit))
	Mozilla Firefox (145.0, 64-bit)
Microsoft Windows 11 Enterprise Version 24H2 (OS Build 26100.7171)	Microsoft Edge (142.0.3595.80 (64-bit))
	Google Chrome (142.0.7444.60 (64-bit))
	Mozilla Firefox (145.0, 64-bit)
Apple macOS (Version 13.2)	Apple Safari (Version 18.5, 20621.2.5.11.8)

ENOS Hexapod System provides size parameters for Paragon 28® wedges and fixations. Final correction and fixation options are up to surgeon discretion. Fixation options may vary by surgeon preference. Refer to the Paragon 28® Instructions for Use for further information about the system and executing the procedure according to the Surgical Technique Guide.

1.12. Software configuration

ENOS Hexapod System consists of two components:

1) Web user interface used for user to define anatomical characteristics of the deformity and physical characteristics of the Monkey Rings™ External Fixation System's hardware, reviewing and confirming the output treatment prescription.
2) Cloud service providing the treatment prescription based on user-defined inputs and the unique hardware characteristics of the Monkey Rings™ External Fixation System.

The software is used in conjunction with the SMART28℠ Case Management Portal.

ENOS Hexapod System requires connection to Disior™ cloud service (Table 4) and may require actions by Hospital IT (e.g. if connection is prevented by firewalls).

Table 4 Cloud connection

Protocol:	Hypertext Transfer Protocol Secure (HTTPS)
Encryption:	Transport Layer Security (TLS)
API domain	https://apis.smart.paragon28.com/
Port:	443 (TCP)

1.13. Data management

The ENOS Hexapod System has interface to SMART28℠ Case Management Portal with data management feature for downloading existing case reports. See chapter Data processing for further details.

1.14. Cybersecurity

The cybersecurity controls of ENOS Hexapod System are listed in the table below. As a good cybersecurity practice, the user should access the site only by typing the address to browser directly, or from secure links, and to check from the browser that the connection is secure and to the intended web page (see Cloud domain address). In case of detection of cybersecurity vulnerability or incident, or if there is a suspicion that the login information has been compromised (unexpected security

notification e.g. for password reset request), the user should contact support as soon as possible (see Contact Information).

Table 5 Cybersecurity controls

User authentication:	Microsoft Azure Active Directory (AD) B2C
Protocol:	Hypertext Transfer Protocol Secure (HTTPS)
Encryption:	Transport Layer Security (TLS)
Data encryption:	Encrypted data at rest
Event logs:	Microsoft Azure Insight
Firewall:	Local IT Firewall configuration applies
Anti-virus policy:	Computers using ENOS℠ software should have up-to-date virus and malware protection

Caution: Failure to comply with cybersecurity practices of IT network may result to loss of data confidentiality or integrity, and loss of product availability.

1.15. Disclaimer

To the extent permitted by applicable law, the Disior™ Services are provided "as is" without warranty of any kind, either express or implied, including but not limited to the implied warranties of merchantability and fitness for a particular purpose, or accuracy or reliability of results from use of the Disior™ Services, that the Disior™ Services will meet specific requirements, that the Disior™ Services will be uninterrupted, completely secure, free of software errors, defects, and failures.

To the maximum extent permitted by applicable law, Disior™ is not liable to the Customer for any lost profits, or for indirect or consequential damages. For the sake of clarity, it is stated that Disior™ is not liable to the Customer for any damages that result from the use of the Disior™ Services or from the results obtained from the use of the Disior™ Services. These limitations of liability shall not apply in cases of intentional misconduct or gross negligence.

1.16. Contact Information

1.16.1. Software Support & Basic Troubleshooting

Customer support is available through disior.support@paragon28.com. All support requests will be answered within 48 hours.

Product documentation with Instructions for Use and information on release updates can be found at https://www.paragon28.com. A paper copy of Instructions for Use may be requested by contacting disior.support@paragon28.com.

1.16.2. Reporting serious incidents

Any serious incident related to the use of this product should be reported to both the manufacturer at disior.support@paragon28.com and the health authority/competent authority where the product is used.

Please provide the following information:

- Date of the incident
- Description of the incident, including any patient or user impact/injury
- The product version used
- Contact information (facility, address, contact person, title, and telephone number)

2. Safety Information

ENOS Hexapod System interfaces with the SMART28℠ Case Management Portal. ENOS Hexapod System is intended to be operated by orthopedic surgeons who have completed user training of the software and read this Instructions for Use document.

Verification that ENOS Hexapod System meets performance specifications has been achieved through software testing in compliance with IEC 62304:2006+AMD1:2015. Risks remaining in the software are described in Residual Risk.

This Safety Information chapter contains important information for the safe and effective use of the ENOS Hexapod System and is essential for users to read before attempting to use the software. Failure to adhere to the safety information provided in the software or Instructions for Use may result in the occurrence of a hazardous situation.

2.1. Symbols used in the software and documentation

Symbol	Description
	**Manufacturer** Indicates the medical device manufacturer.
	**Manufacturing date** Indicates the manufacturing date.
	**Medical Device** Indicates the product is a medical device.
	**Unique Device Identification** Provides a unique identifier for this product.
	**Consult Instructions for Use** Indicates the need for the user to consult the Instructions for Use or the electronic Instructions for Use. eIFU Indicator may contain the URL of the Instructions for Use (IFU).
	**Caution** Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	**Prescription Use Ony** Indicates that the device is in the possession of a practitioner, such as physicians, licensed by law to use or order the use of such device.

	**Warning** General warning safety sign placed together with a supplementary message or symbol. The message associated with this safety sign indicates if the situation is an Error or Warning and includes a statement describing the associated risk.
	**Mandatory Action to Read Instructions for Use** Mandatory action safety sign indicating required action to read the Instructions for Use.
	**Help** Help menu where users can obtain product information or submit requests.
	**Logout** Option to log out of the application.
	**Rename** Option for renaming data.
	**Delete** Option for deleting data.
	**Reference Ring** Indicates the reference ring that was selected.
	**Moving Ring** Indicates the moving ring that was selected.
	Support Ring Indicates the support ring that was selected.
	**Z-Plate** Indicates the z-plate that was selected.

2.2. Residual Risk

Residual risks are risks remaining in the medical software and should be considered by the user to make informed decisions about software use. Residual risks in the ENOS Hexapod System could generate inaccurate results if not recognized by the user and lead to incorrect clinical decisions causing indirect patient harm.

In all cases, the deformity input values and the output of the software subject to careful orthopaedic assessment. Additionally, users should rely on their clinical expertise to detect and evaluate the impact of geometrical nonconformities.

2.3. Identification of characteristics related to safety

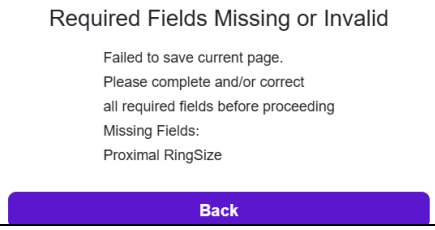
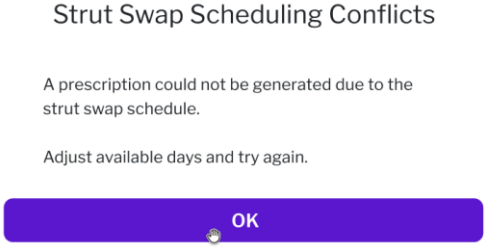
The ENOS Hexapod System is intended to be operated by orthopaedic healthcare professionals. The software itself cannot cause any physical harm to the patients or to the users of the software. The output of the software shall in all cases be subject to careful orthopaedic expert assessment.

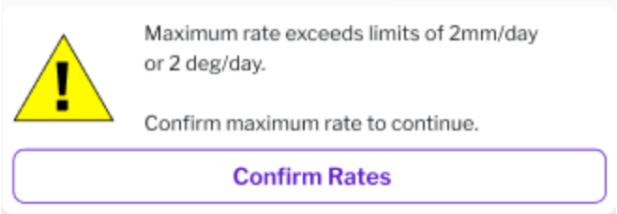
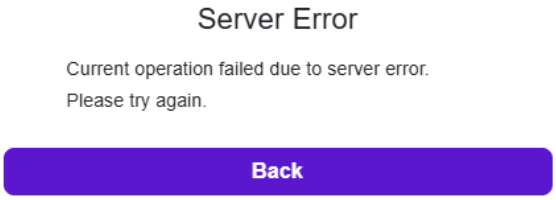
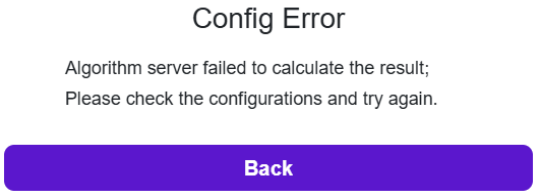
2.4. Identification of characteristics related to cybersecurity

The ENOS Hexapod System is distributed using the Software as a Service (SaaS) delivery model. The service provided by the software is not time-sensitive and thus any unplanned downtime, for example due to a Distributed Denial of Service Attack (DDoS) will not cause harm to the patient or the user. A successful cyberattack could lead to unauthorized data access, deletion of data, or alteration of the software output.

2.5. Warnings

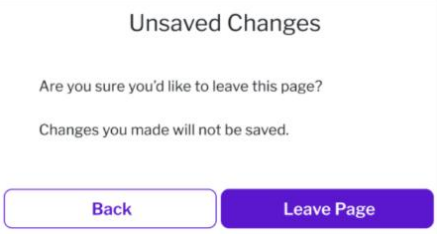
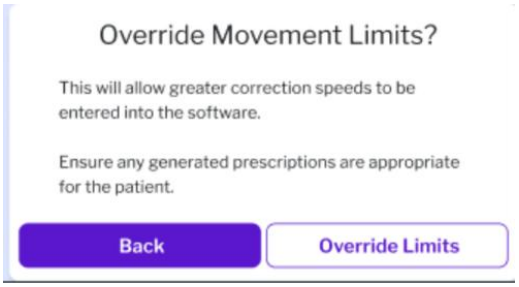
The following warning and error messages with mandatory actions may be issued by the ENOS Hexapod System:

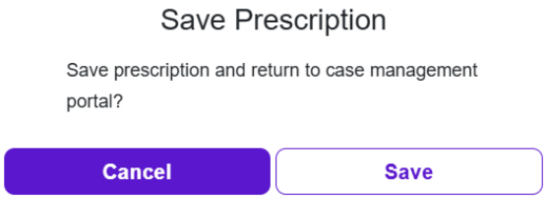
Error/warning	Action/Function	Image Preview
Required Fields Missing or Invalid	Appears if a required field is missing or invalid. Please fill in the missing or invalid fields as indicated in the warning message.	
Value out of Range	If the user enters a value that is out of the acceptable range for that field, a warning will appear. To proceed correct the value to be within the preset limits. Table 6 presents all acceptable ranges used in the software.	
Strup Swap Scheduling Conflicts	If the “Calculate Rates and Duration” button is selected and the prescription cannot be generated due to the Strut Swap Schedule, a warning will appear. Please adjust the available days and try again.	

Maximum Rate Exceeded	This pop-up is triggered when the user selects an advanced calculation rate, duration, and the number of days selected causes the maximum rate to exceed the limit. Confirmation is required to proceed.	
Server Error	This pop-up is triggered when there is an issue communicating with the server. Please try again and if the problem persists contact support.	
Config Erro	This pop-up is triggered when there is an issue calculating the result, e.g., invalid input. Please review the results and try again.	

2.6. Confirmation Messages

The following confirmation messages may be issued by the ENOS Hexapod System:

Message	Condition	Image Preview
Unsaved changes	Appears when user attempts to leave the software without saving. User acknowledgement required.	
Override moment limits	Appears when the user attempts to override the maximum correction (2mm/deg per day). User acknowledgement required.	

Save prescription	Appears when the user attempts to save the prescription and return to the SMART Case Management Portal. User acknowledgement required.	

3. Instructions for Use

3.1. SMART℠ Case Management Portal workflow

Prior to accessing the ENOS Hexapod Gradual Deformity Correction System software, following steps need to be completed in the SMART28℠ Case Management Portal:

1) Login to the SMART28℠ Case Management Portal
2) Click 'Add Patient' and fill in the patient's name. Select 'Save & Start Procedure', choose the ENOS Hexapod Gradual Deformity Correction System procedure, and then click 'Next'.
3) Hospital - Select the Hospital affiliated with this case and set the surgery date.
4) The procedure will appear under 'Active Procedures', it will automatically 'Initialize' and once ready, select 'Open Planning' to access the ENOS Hexapod Gradual Deformity Correction System software.

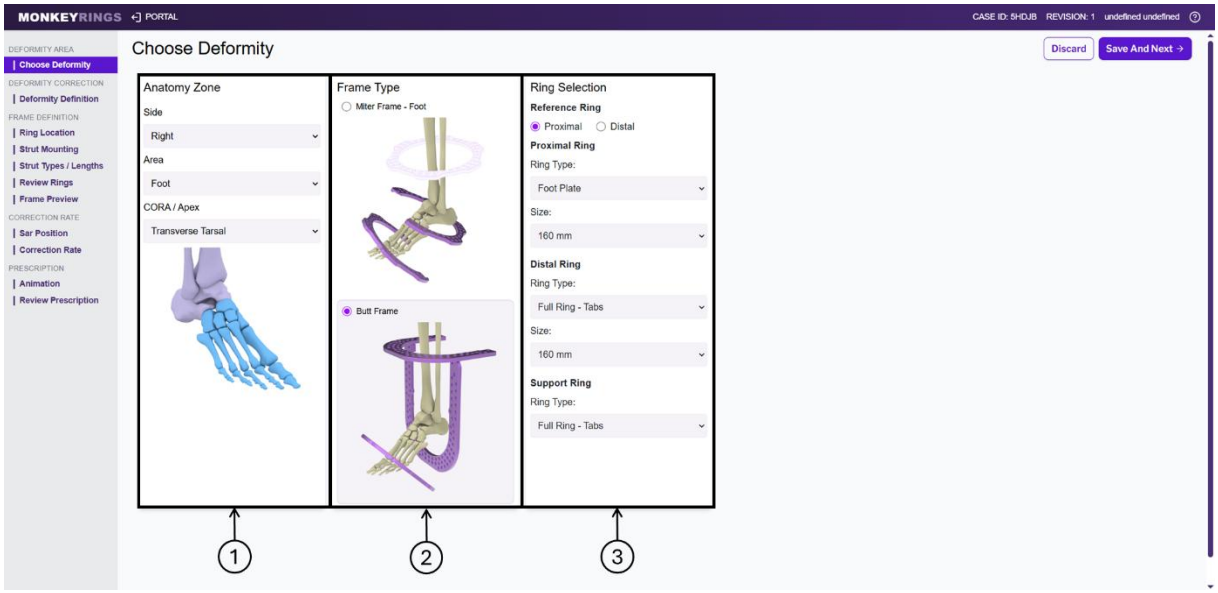
3.2. ENOS Hexapod System software workflow

Please follow the steps below to complete the workflow for ENOS Hexapod System after starting the procedure in the SMART28℠ Case Management Portal:

1) Choose Deformity
    a. Anatomy Zone
    b. Frame Type
    c. Ring Selection
2) Deformity Definition
    a. Pre-Treatment Alignment
    b. Movement Method
    c. Correction Position
3) Ring Location
4) Strut Mounting
    a. Default Strut Placement
    b. Manual Strut Placement
5) Define Strut Types and Lengths
6) Review Ring Location
7) Frame Preview
8) Structure At Risk (SAR) Position
9) Correction Rate
10) Animation
11) Review Prescription

3.3. Choose Deformity

The first step in the case planning process is to choose deformity. A brief description of the steps is explained below.



Anatomy Zone

Start by defining the anatomy zone of the deformity including: the anatomical side, area, and CORA / Apex. Identifying the anatomy zone is required to continue through the software workflow. The intent of this step is to select the general area where the deformity is located. Actual definition of the deformity to match the patient's deformity is performed later, in the Deformity Definition.

Note: see more information about anatomical areas in section Visualizing Area.

Note: The side selection is defined from the patient's perspective – the side selection should match what the patient would consider to be their left or right side. Please see Figure 1 and Figure 2.

Figure 1 Visualizing left side

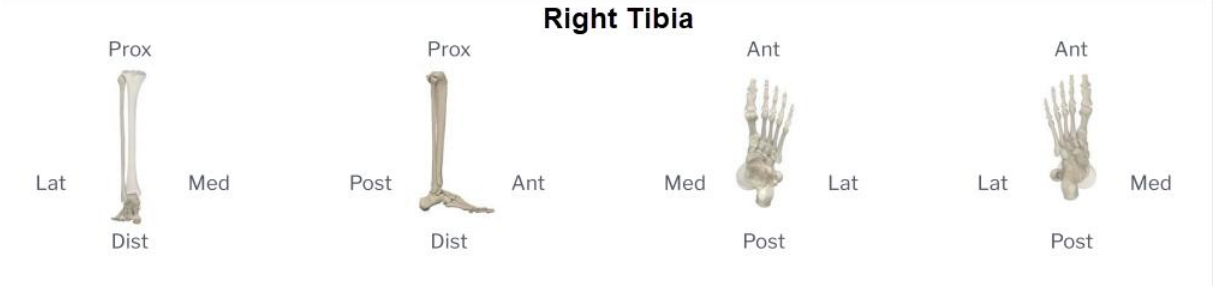


Figure 2 Visualizing right side

Frame Type

In the next step, the frame type can be selected. Identifying the frame type is required to continue through the software workflow. Note that not all frame types are available for all anatomical areas. Refer to section Available Frame Types for more information.

Ring Selection

In ring selection the reference ring can be specified, along with more specific information on the exact rings used. It is necessary to identify the reference ring, and the ring type and ring size of both the proximal and distal rings to continue through the software workflow. Refer to section Available Ring Types for more information.

Note: Some configurations may require a support ring.

Note: The correct selection of the reference ring (Proximal or Distal) is important for the measurement of the mounting parameters, and thus the calculation of the prescription.

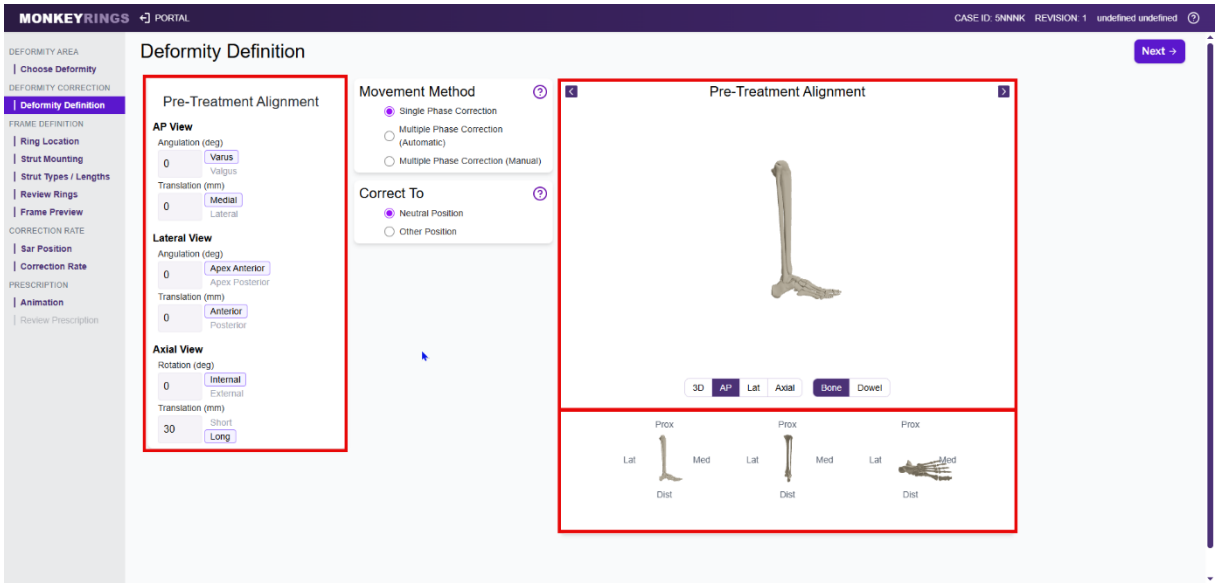
3.4. Deformity Definition

The next step in the case planning process is identifying the deformity. The software requires the pre-treatment alignment to be defined along the AP View (Or “Dorsal View” for foot models), Lateral View, and Axial View. The deformity parameters describe the translation and angulation between the Proximal Reference Point on the proximal fragment and the Distal Reference Point on the distal fragment. At the end of this step, the software is able to reproduce a 3D model of bone deformity based on the user input pre-treatment alignment.

Pre-Treatment Alignment

- The fields for the pre-treatment alignment should be entered based on the patient’s deformity, which is determined outside of the application by the user.
- The user can adjust the direction of each parameter by selecting between the available options. Refer to the table below, for the minimum and maximum values.
- On the right-hand side, the software generates a 3D model based on the user inputs.
    - The model automatically updates as the user adjusts the inputs.
    - Below the 3D model, are three alignment visual images depicting the bone deformity from the AP View (view from the front, labeled as “Dorsal View” for foot models), Lateral View (view from the side), and Axial View (View from the top).

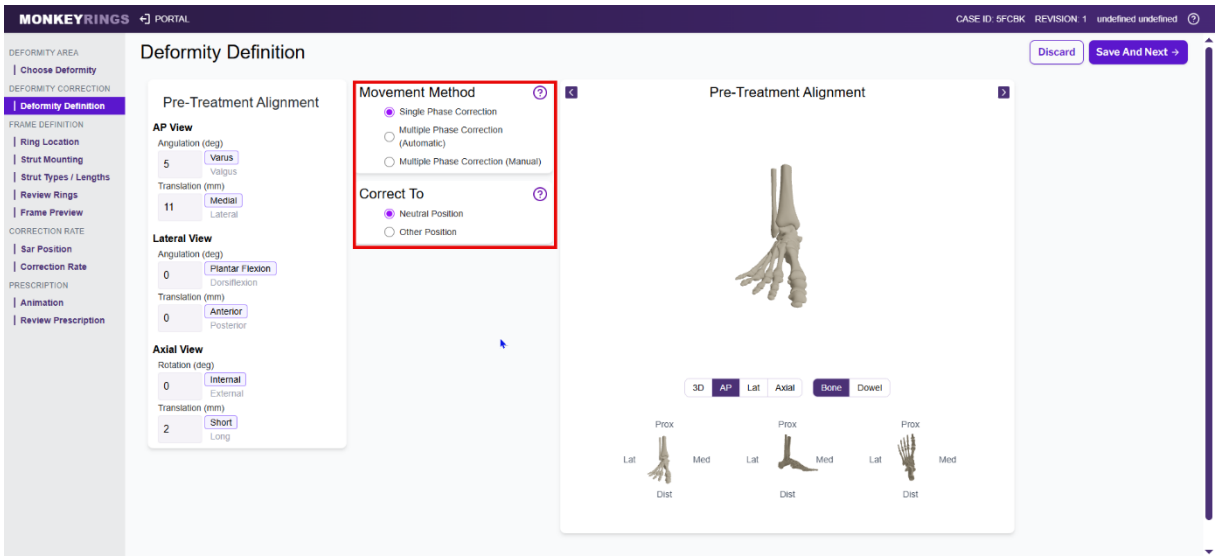
Note: Refer to section Deformity Parameters and Angulation for more information.



Movement Method

Single Phase Correction

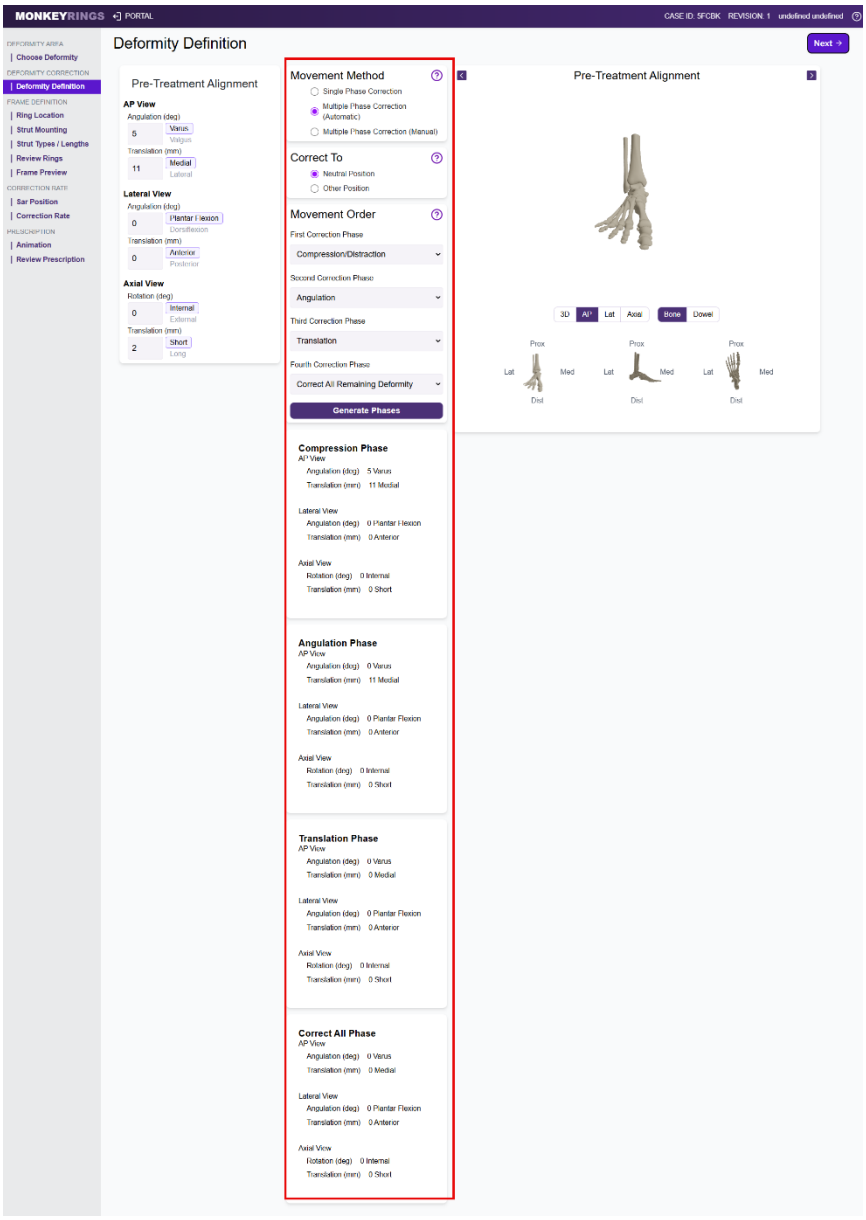
The default deformity correction method can be done by using the Single-Phase Correction method. This selection allows for corrections to be made in one phase. Under this selection, the user is required to identify what the target position should be, referring to the section Correction Position for additional details.



Multiple Phase Correction (Automatic)

Depending on the deformity, there may be a need to correct the deformity in multiple phases. For example, it may be necessary to fix angulation first, followed by rotation, and finally compression. In this instance, the option *Multiple Phase Correction (Automatic)* may be used to identify the phases or parts of the correction method. Note that when using Multiple Phase Correction (Automatic), the final option will always be “Correct All Remaining Deformity”. Under this selection the user is required to

identify the target position. Refer to the section Correction Position for additional information on the target positions.

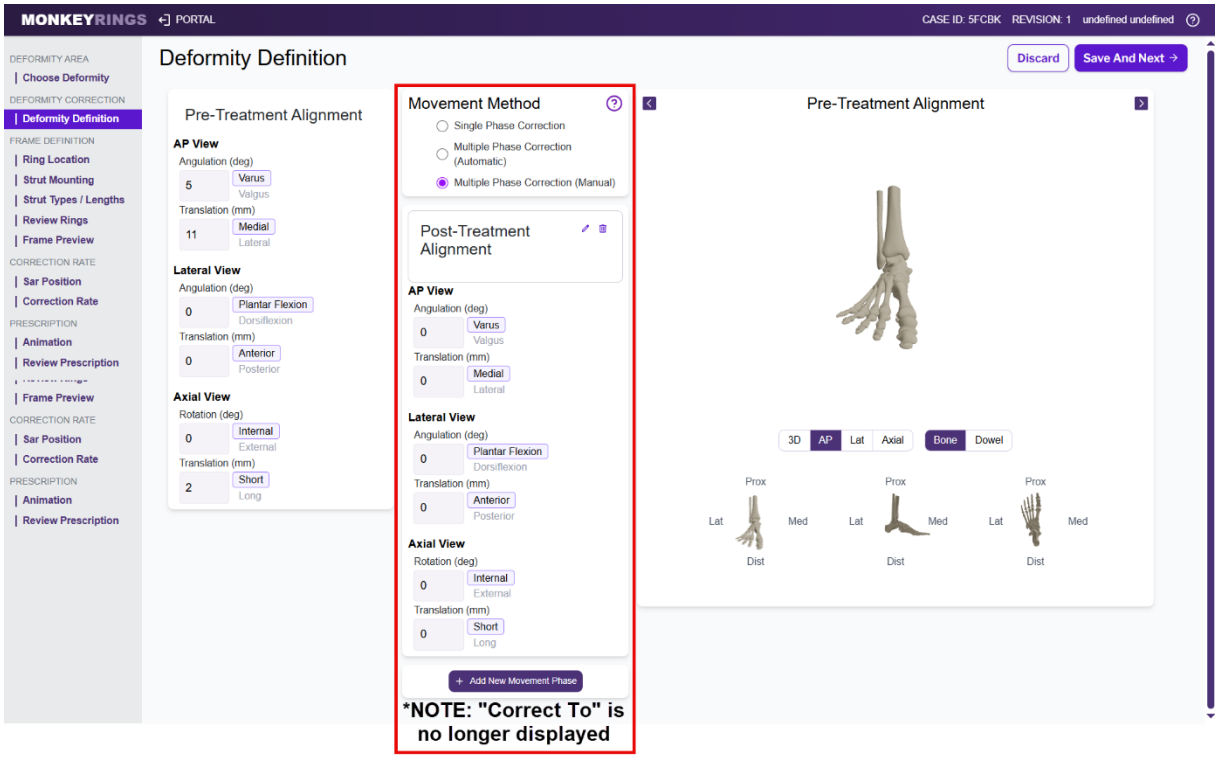


Multiple Phase Correction (Manual)

The last available selection for the movement method is Multiple Phase Correction (Manual). This option gives users the largest amount of customization. Upon selecting this option, the user may now define multiple correction positions that will occur sequentially.

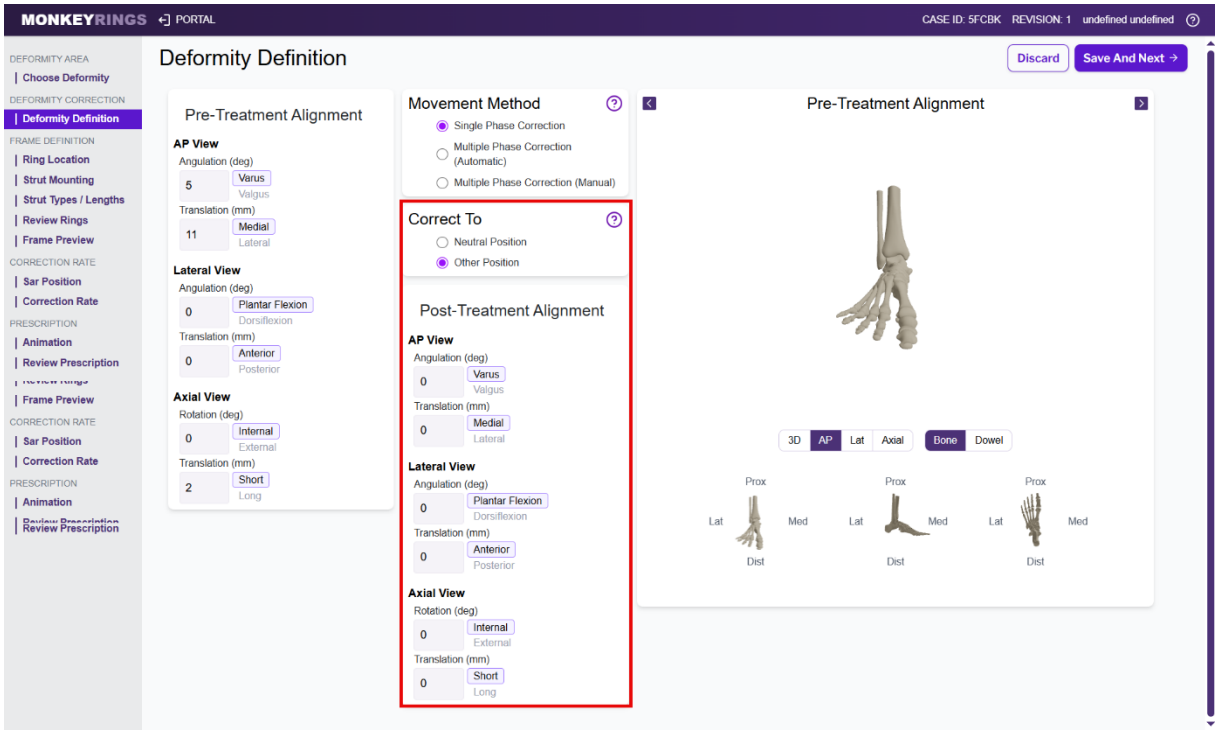
Note: Each manually-define phase describes the residual deformity which will occur at the completion of that phase.

Each new correction position is defined through manual entry of the AP view, Lateral view, and Axial view values, similar to how the correction position is defined during the single or automatic workflows.



Correction Position

- The correction position is defined by the user as the ending position of the bones.
- The user can choose to either automatically correct to the *Neutral Position*, or can specify a desired position other than *Neutral,* such as when a user wishes to over or under correct a deformity.
- The *Neutral* position option will generate a treatment plan that corrects all Pre-treatment alignment values to ‘0’.
- The option *Other Position,* allows the user to manually enter a position other than *Neutral,* which the patient’s deformity will be corrected to.
    - Upon selecting this option the user is required to define the Post-Treatment Alignment values along the AP View, Lateral View and Axial View.



3.5.Ring Location

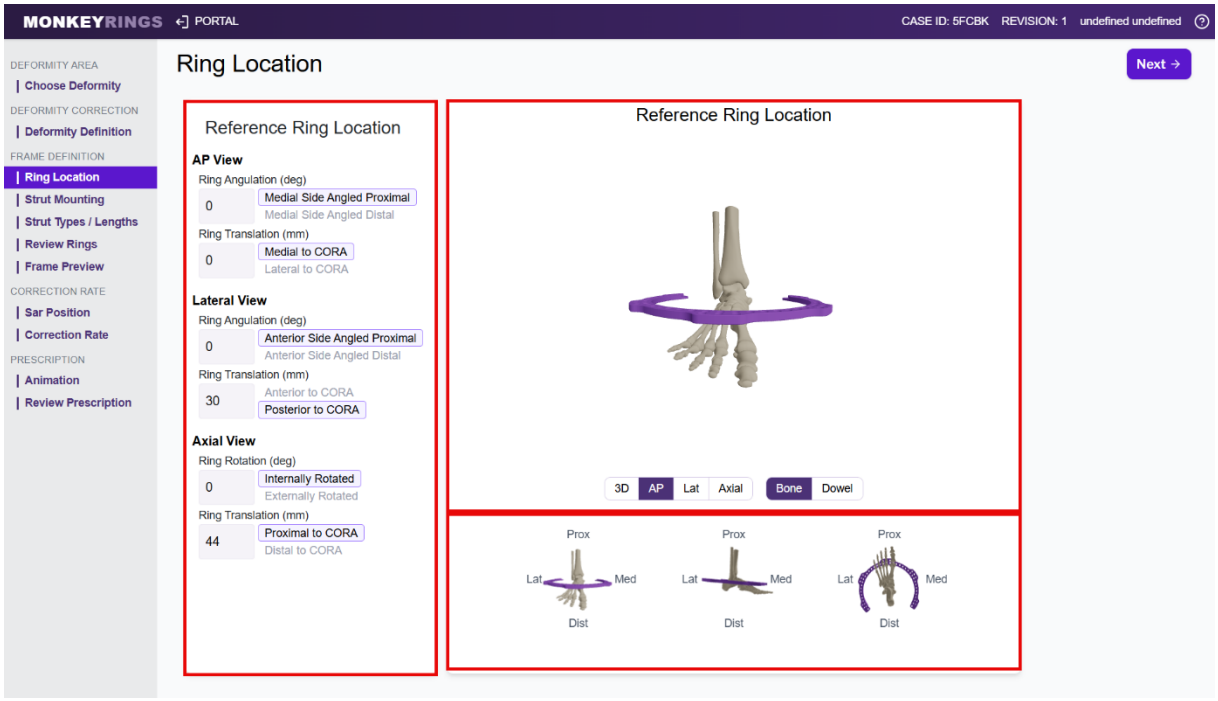
The next step in the case planning process is defining the position of the reference ring. The software requires the following field inputs to be entered, in order to proceed to the next step:

- AP Ring Angulation (deg)
- AP Ring Offset (mm)
- Lateral View Ring Angulation (deg)
- Lateral View Ring Offset (mm)
- Axial View Ring Rotation (deg)
- Axial View Ring Offset (mm)

The ring definition values are defined as the angulation and offsets from the CORA point to the center of the ring.

Upon entering the value and the respective direction, the software displays a preview of the reference ring in relation to the bone deformity. Below the 3D model, are three alignment visual images depicting the reference ring in relation to the bone deformity from the AP View (view from the front, labeled as “Dorsal View” for foot models), Lateral View (view from the side), and Axial View (View from the top). Please refer to section Visualizing Angulations, Translations, and Rotations for more information.

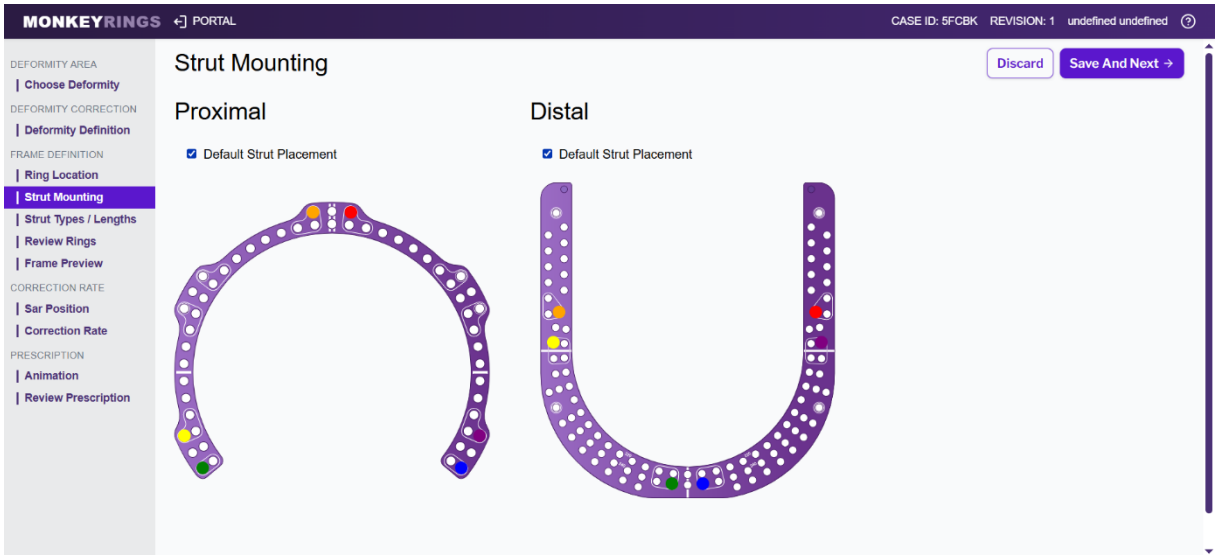
Note: The ‘Moving ring’ will be defined automatically at a later point in the workflow, after the strut placements and characteristics are defined. A 3D model with the reference ring and the moving ring will be visible on the ‘Review Ring Location’ page.



3.6.Strut Mounting

Default Strut Placement

The next step in the case planning process is to define the strut mounting positions. The hexapod contains six struts that are mounted between the proximal and distal rings. There is a *default* mounting position that is frequently used. The software provides the option to toggle the *Default Strut Placement* on or off.



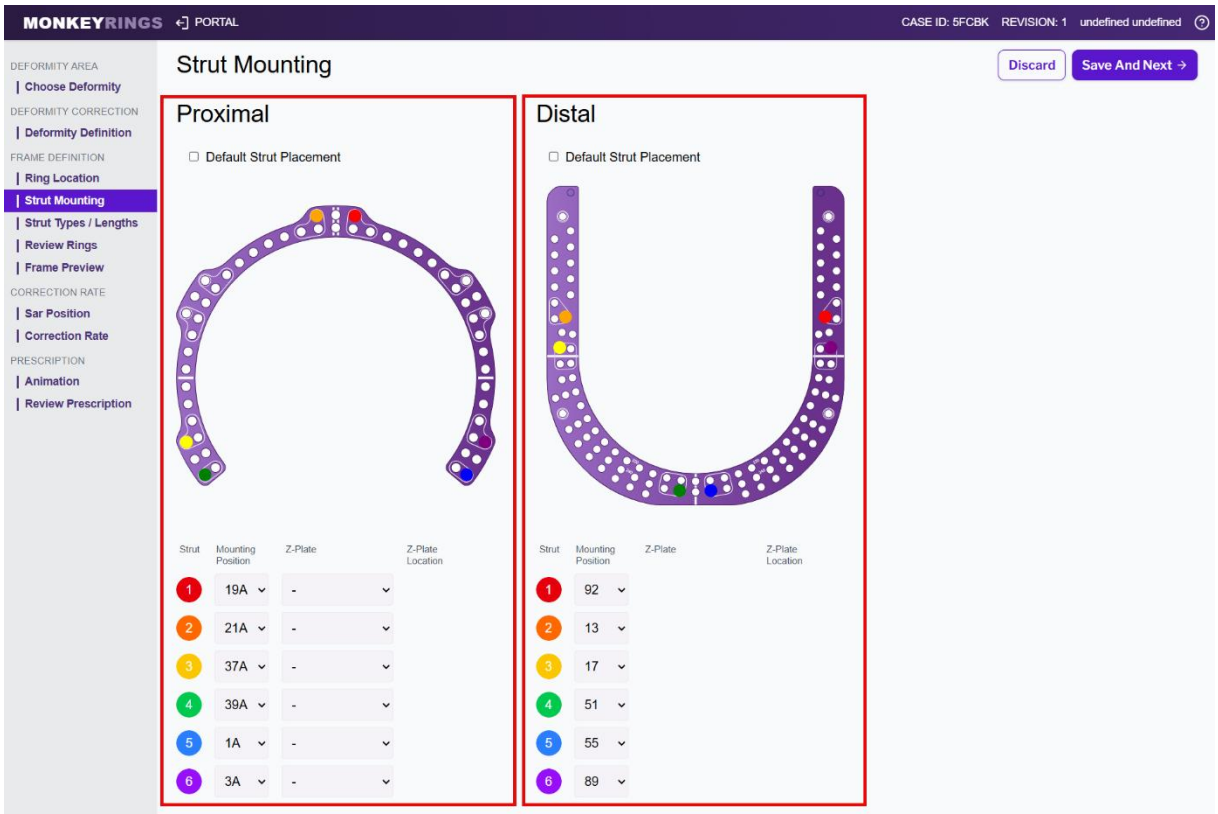
Manual Strut Placement

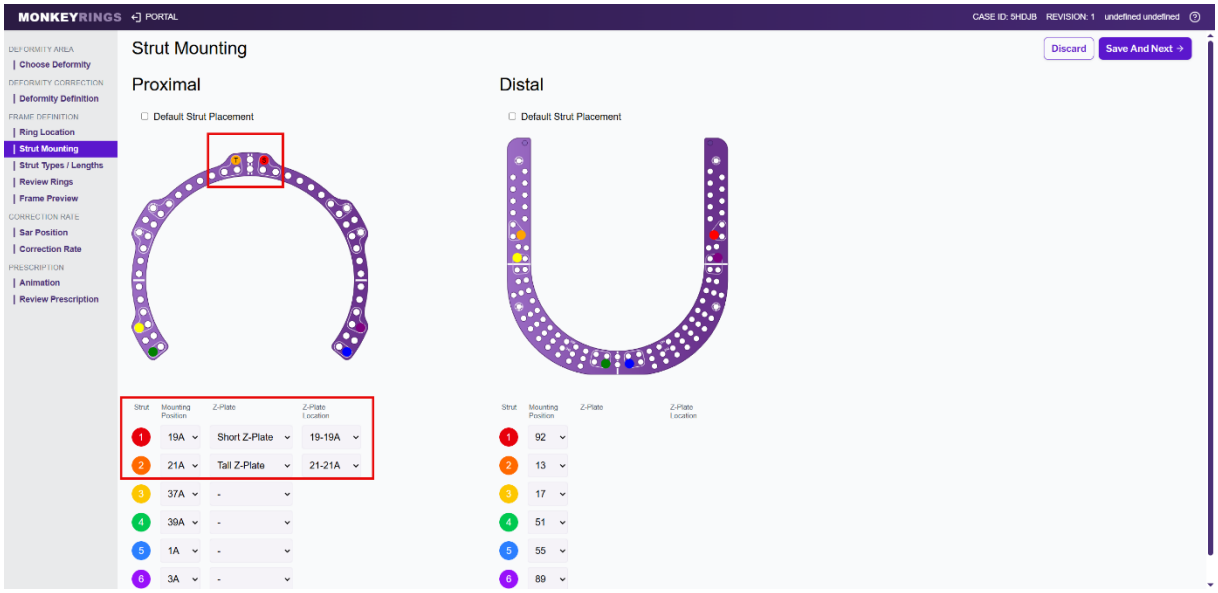
The software provides the ability to manually define the strut placement on both the proximal and distal ring. The struts are color-coded and labeled 1 through 6. Strut 1 is red. Strut 2 is orange. Strut 3 is yellow. Strut 4 is green. Strut 5 is blue. Strut 6 is purple. Additionally, all mounting positions on the rings are clearly marked as such.

Users can input their strut selections via the dropdown menus below the ring (which appear after the ‘default strut placement’ checkbox is removed), or manually by dragging the numbered struts to their desired locations. Struts can be mounted in any of the designated mounting positions on the ring diagram. Designated mounting positions are those which are contained within the thin white lines marked on the ring.

Note: The diagram on the Strut Mounting page is always viewed from the “top” of the proximal ring towards the distal ring

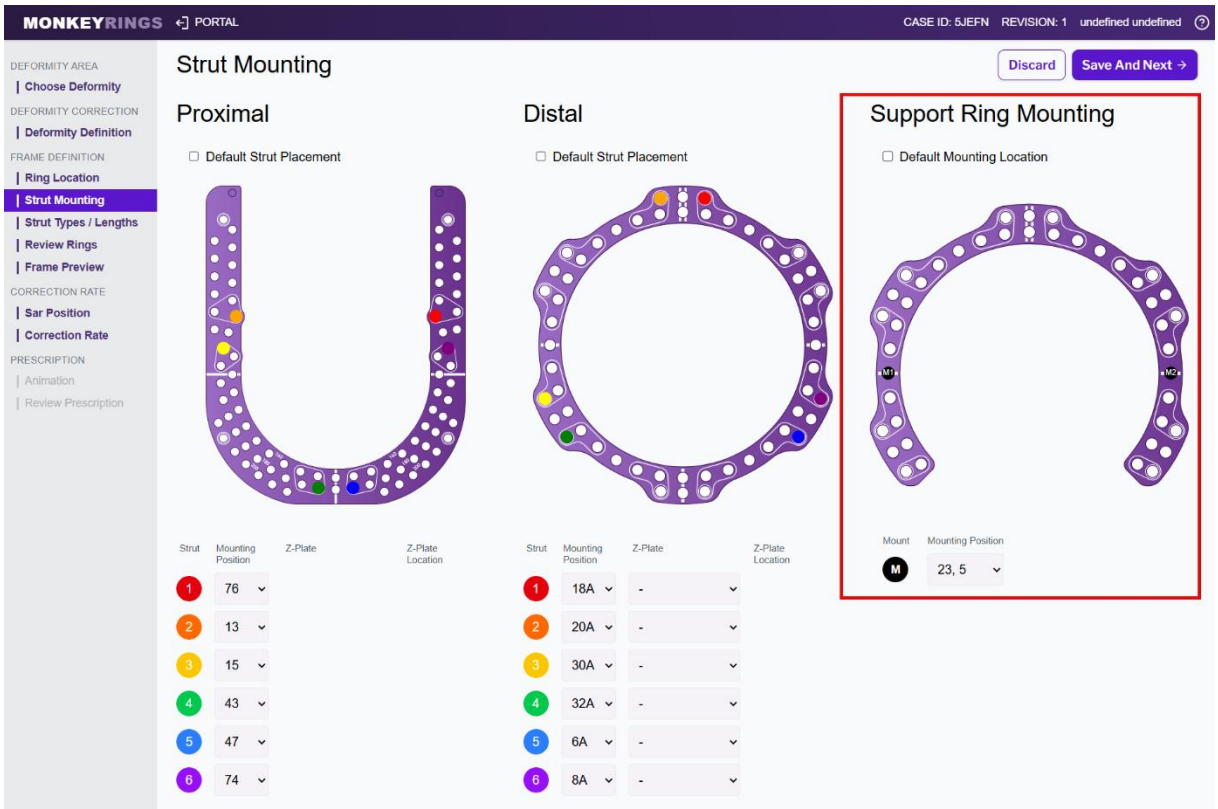
If the strut requires mounting at an alternative height or angle, the user may opt to use a Z-Plate. The process involves selecting the appropriate Z-Plate type and determining the desired mounting location. The Z-Plate is then installed onto the ring, and the strut is subsequently mounted to the Z-Plate instead of directly to the ring. This configuration enables adjustments in mounting height or angle as needed. When a Z-Plate is selected, the strut marker on the ring diagram will have a “T” for Tall Z-Plate or an “S” for Short Z-Plate.





Support Mounting Ring

In some cases, an additional support ring is used. When a support ring is used, the software will also provide the ability to manually define where the struts are mounted on the support ring. In such cases, the user can select the default mounting position on the support ring or manually define the mounting position in the same way that the struts are defined on the proximal and distal rings.



3.7. Define Strut Types and Lengths

The next step in the case planning process is to identify the strut types and lengths. The available strut types are XXS, XS, S, M, and L. The length of the strut is shown after choosing the strut type. Strut length and types are also presented in Table 6 in section Appendix – Supplementary Tables and Figures. Using the drop-down menus the user can select the type of strut to be used. Set the length by typing it in manually or using the arrows on the side. Figure 3 illustrates an Example Monkey Rings External Fixation System strut with length markings.

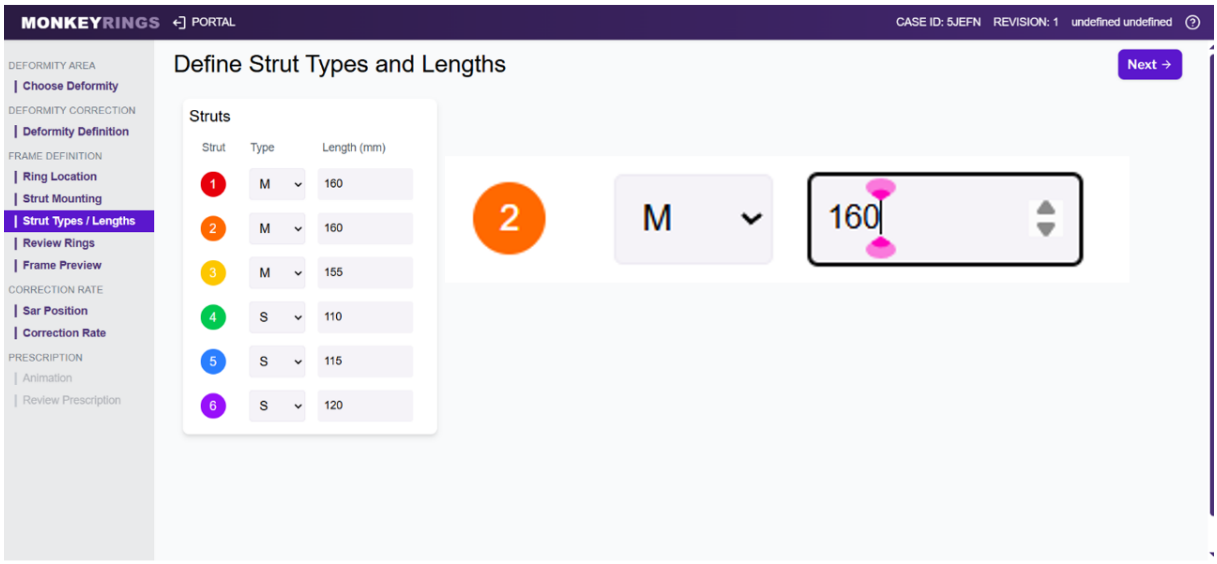


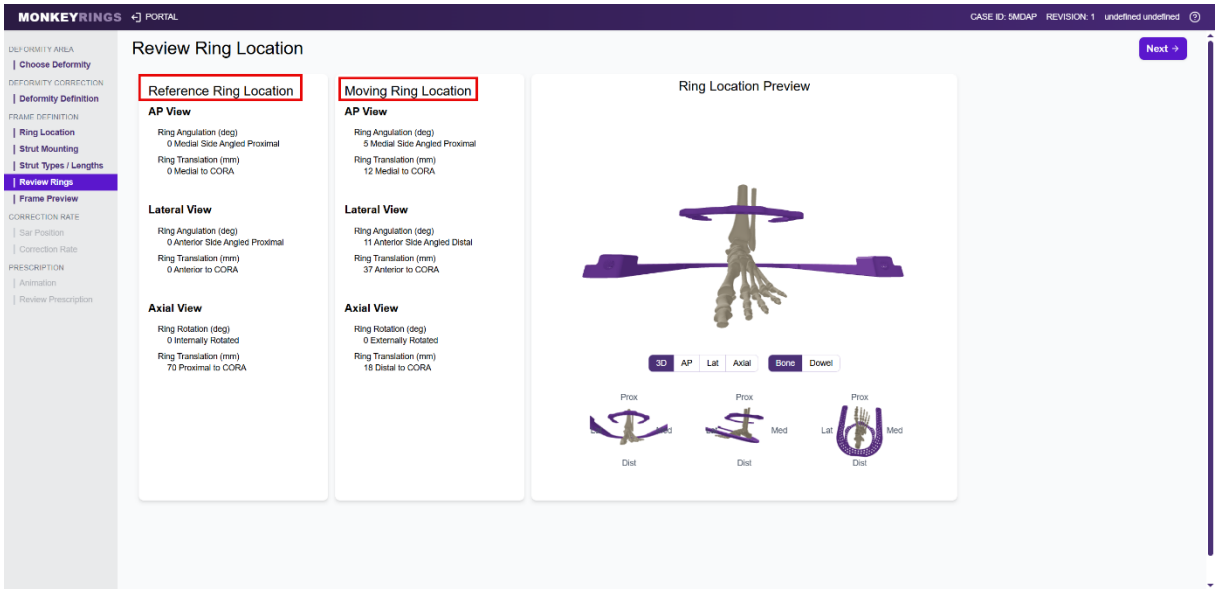
Figure 3 - Example Monkey Rings External Fixation System strut with length markings

3.8. Review Ring Location

The next step in the case planning process is reviewing the ring locations. The software displays the position of the Reference Ring location along the AP View, Lateral View, and Axial View. The software also displays the moving ring positions along the AP View, Lateral View, and Axial View. A model of the bone deformity with the reference ring and moving ring is displayed.

Note*:* the information displayed for the reference ring location should match the information entered on the “Ring Location” page.

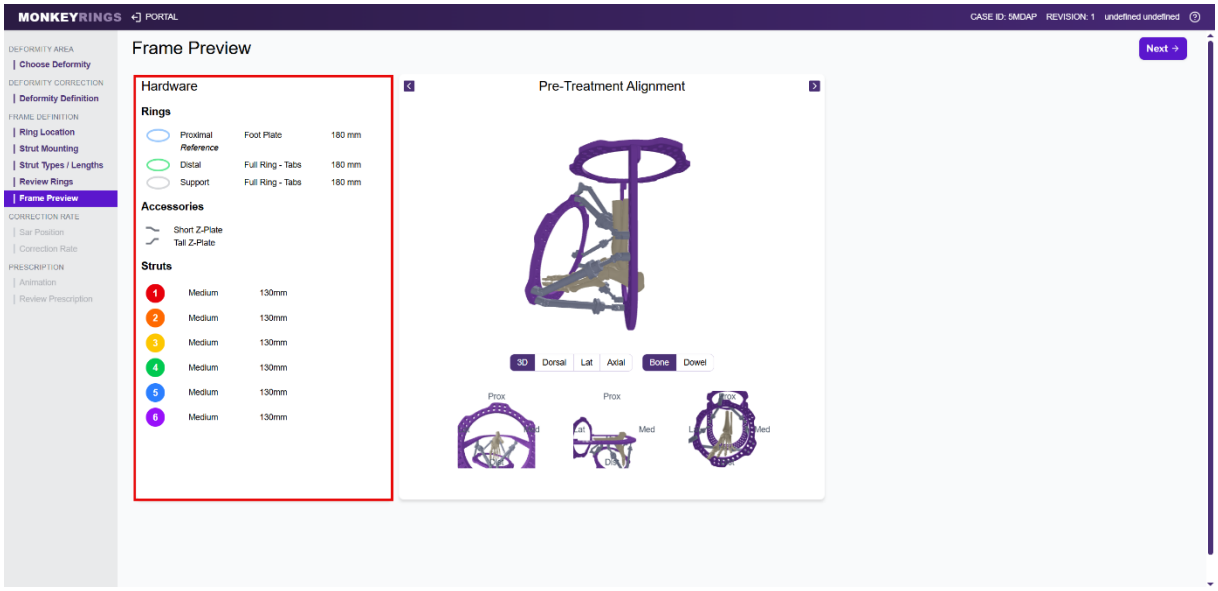
Note*:* the moving ring’s definition is calculated automatically by the software using the information defined for the reference ring on the “Ring Location” page, and the strut information on the “Strut Mounting” and “Define Strut Types and Lengths” page. The location of the moving ring—whether proximal or distal—is determined by the reference ring selected on the first page of the setup.



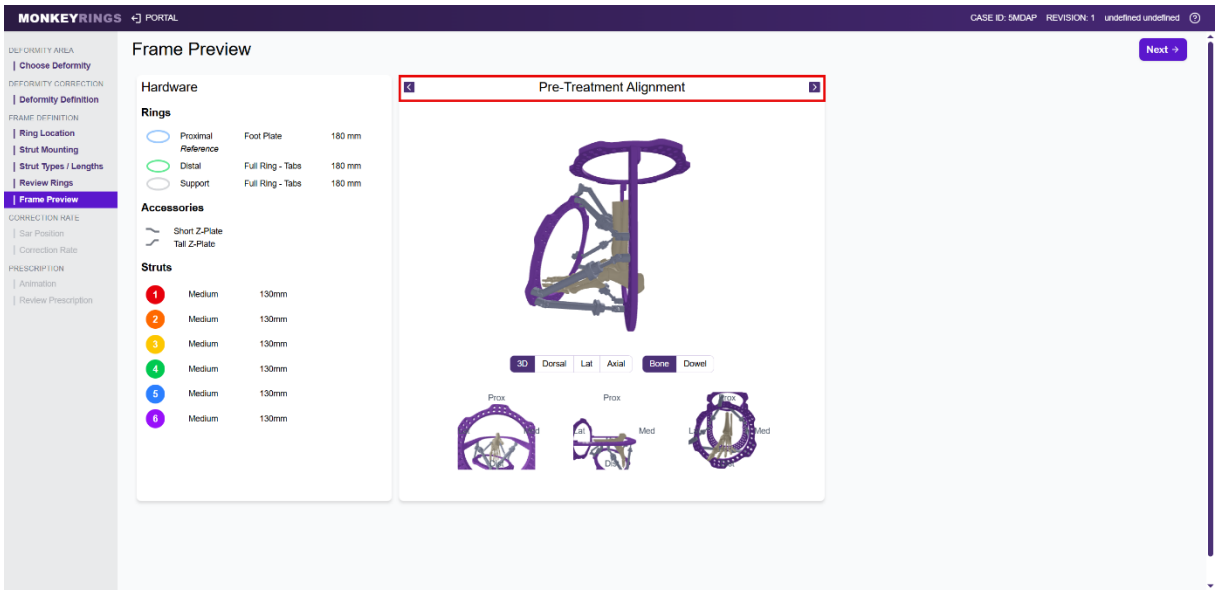
3.9. Frame Preview

The next step in the case planning process is to review the frame preview. The software displays the information for the following hardware:

- Proximal Ring type and size
- Distal Ring type and size
- Support Ring type and size (if defined at the initial steps)
- Accessories (if defined at the initial steps)
- Strut types and lengths



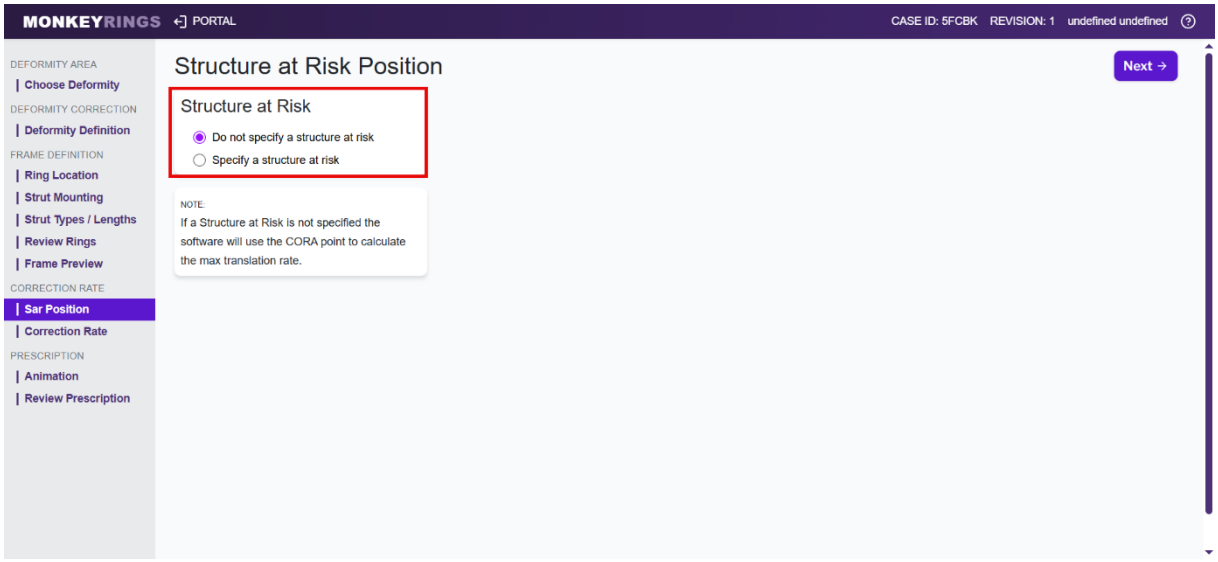
The software also provides the ability to view the hexapod and deformity before and after each movement phase is completed, including the user-defined start and end positions. Using the left-right arrow heads will trigger the model to toggle between the phases (view the image below).

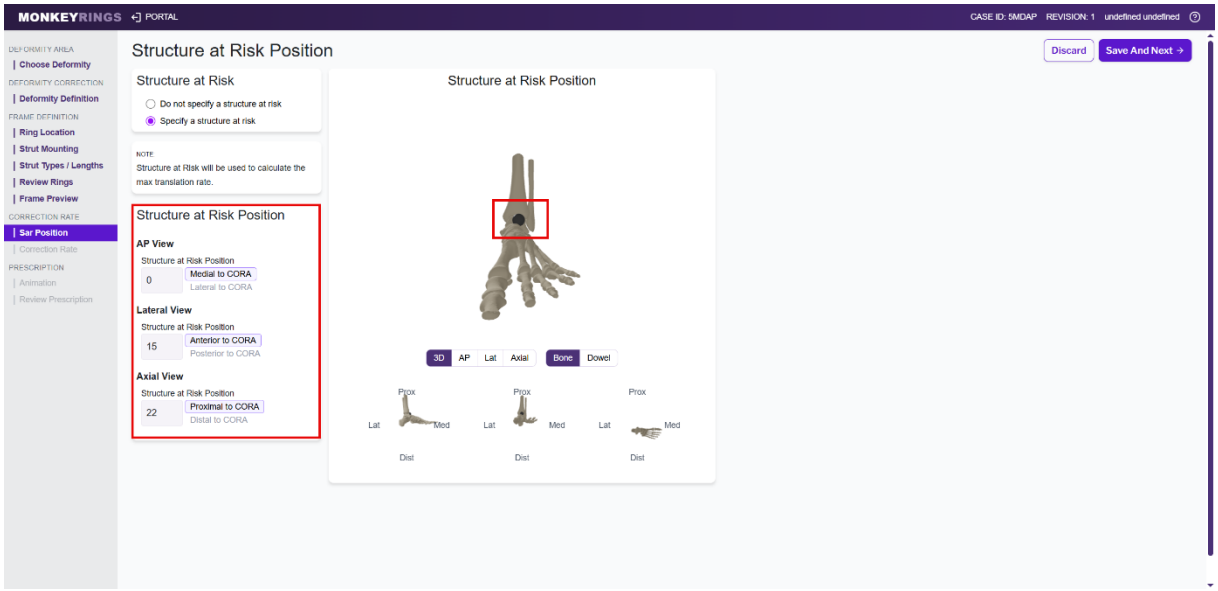


3.10. Structure At Risk (SAR) Position

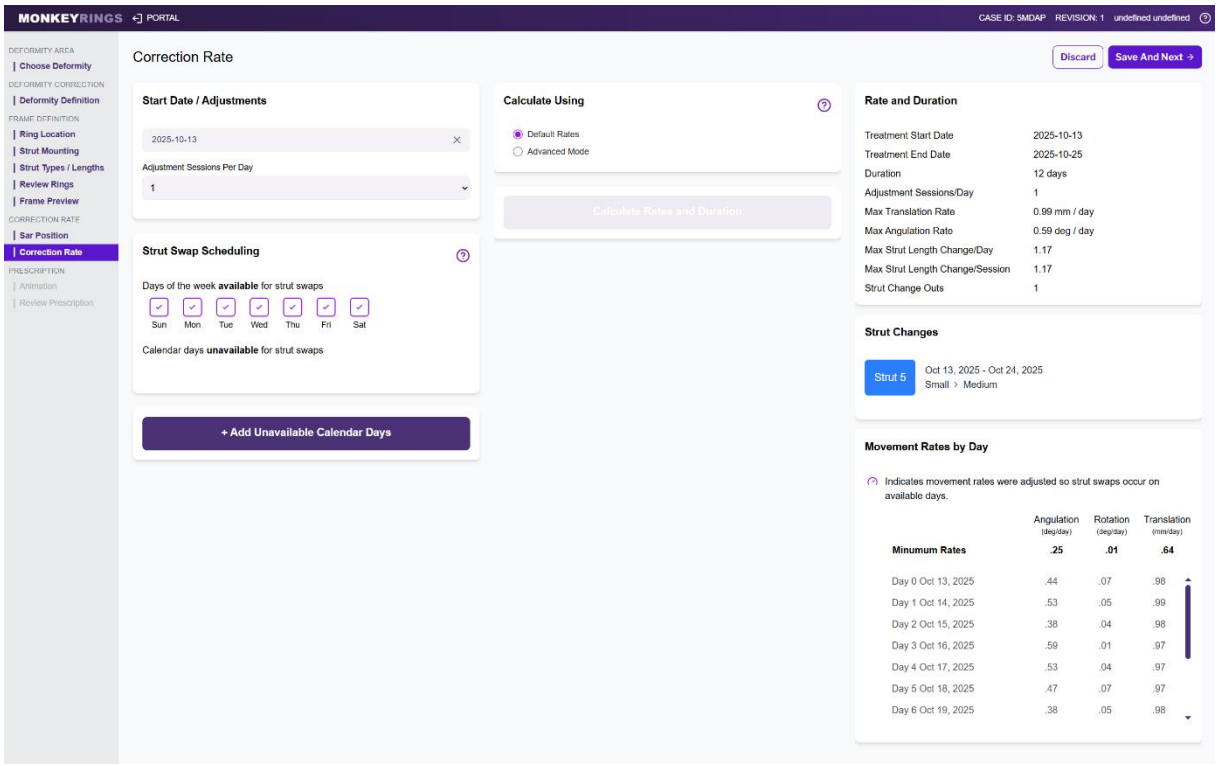
The next step in the case planning process is identifying the structure at risk (SAR), if any need to be considered. Depending on the bone deformity, there may be structures such as arteries or veins that lie near the deformation point. Users will have the ability to specify whether the patient has a structure at risk (SAR), and where this structure exists. The center of the Structure at Risk Position indicator is placed at a distance defined by the user inputs for the Structure at Risk Position values, with an origin point that matches the selected CORA.

Note*:* If a structure at risk is defined by the user, then the structure at risk will be used to calculate the maximum translation rate.





3.11. Correction Rate



Start Date

The next step in the case planning process is defining the start date, number of adjustment sessions per day, and availability for strut swaps. The start date may be manually entered by typing in the date or selected by using the calendar logo. Please note the following fields are required to proceed:

- Start Date
- Number of Adjustment Sessions Per Day
- Days of the week available for strut swaps
- Max Translation Rate (*only if Advanced Mode is selected)*
- Max Angulation Rate (*only if Advanced Mode is selected)*
- Duration (*only if Advanced Mode is selected*)

Number of Daily Adjustments

The number of adjustment sessions per day indicates the amount of times a patient will be required to perform the adjustment. For example, if the user enters 1 adjustment session a day, then the software will generate a prescription where the patient has to turn their strut(s) no more than once a day. The number of adjustments per day ranges between 1 to 4 adjustments a day. For additional information on the daily adjustments refer to the section Patient Actions.

Strut Swap Scheduling

The strut swap schedule may be adjusted by selecting the days of the week that are available for strut swaps or by entering the dates that are unavailable for strut swaps. This is to ensure that strut change out days align with in-clinic days. The available days can be selected by checking off the box above each day of the week. The unavailable dates can be indicated by selecting a single date or a range of dates.

Calculation Method

The correction rate can be calculated by two options: Default Rates or Advanced Mode.

Default Rates

The default rates mode calculates the fastest prescription that prevents the following from occurring:

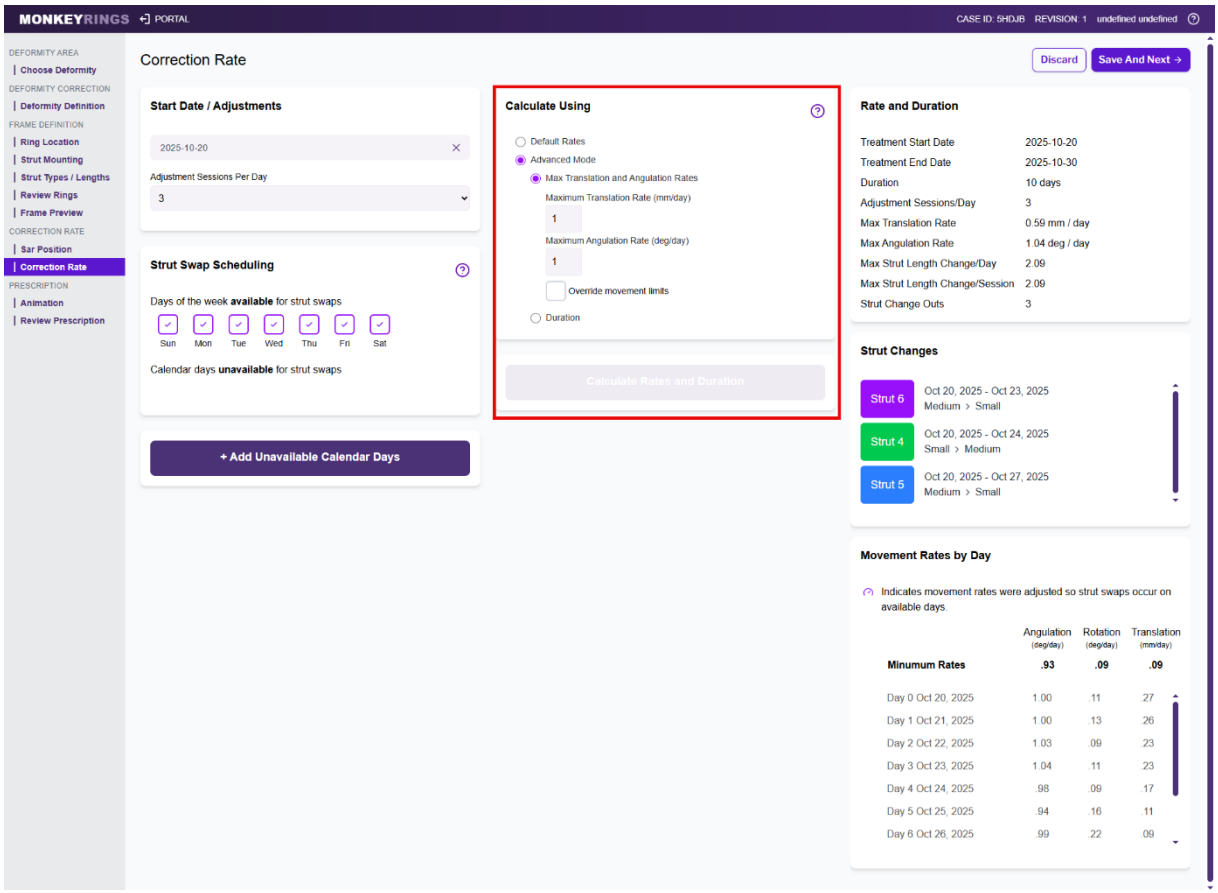
- The generated translation rate for any day to exceed 1 mm / day
- The generated angulation rate for any day to exceed 1 deg / day
- Any individual strut from changing by more than 5 mm in a single adjustment session

Advanced Mode

The advanced mode provides the user multiple options to calculate the correction rate; max translation and angulation rate or duration. Refer to Table 13 for the max translation and angulation rate.

Selecting Max Translation and Angulation Rates as the calculation method, the user can manually enter the Maximum Translation Rate and Maximum Angulation Rate or use the up and down arrow keys to set the max rates for the treatment plan.

Selecting Duration as the calculation method, the user can manually enter or use the up and down arrow keys to set the number of days in the treatment plan.



Rate and Duration

After the calculation method is defined, selecting the Calculate Rates and Duration option will populate the Rate and Duration, Strut Changes, and Movement Rates by Day panels. The software will generate a treatment plan that corrects the patient's deformity from the position defined on the Deformity Definition page to the target position defined on the same page.

If the “Duration” option is defined, the treatment plan will not exceed the selected number of days. If the “Max Translation and Angulation Rates” are defined, the plan will ensure that daily patient turns - when followed correctly - will not cause the projected translation or angulation rate of the bone to exceed the user input values in mm/day or deg/day, respectively.

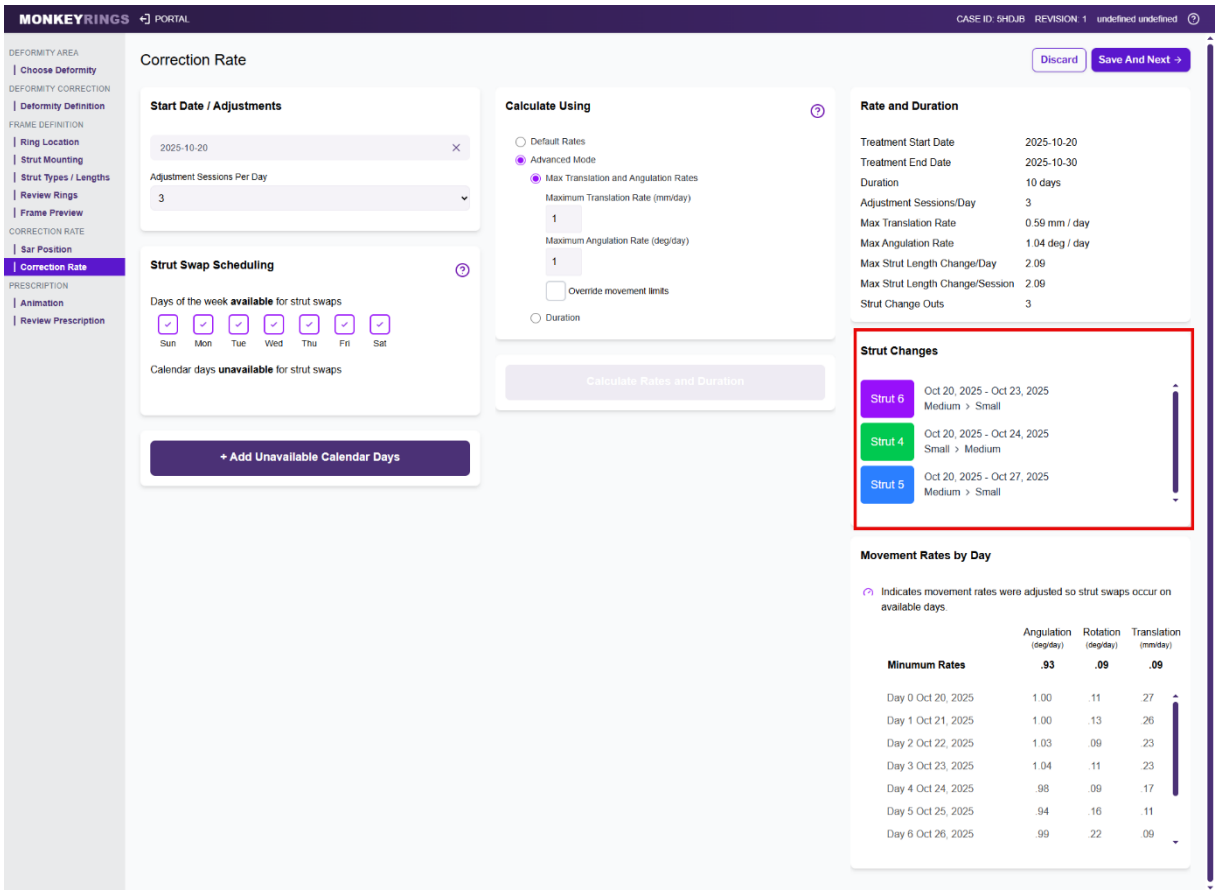
Note: Beyond the inputs selected for Advanced mode, the software also considers the number of adjustment sessions per day, any defined structures at risk, and any “days available/unavailable for strut swaps” when generating the treatment plan.

The following information generated for the treatment plan is displayed once the ‘Calculate Rates and Duration’ button is selected:

- Treatment Start Date
- Treatment End Date
- Duration
- Adjustment Sessions/Day
- Max Translation Rate
- Max Angulation Rate
- Max Strut Length Change/Day
- Max Strut Length Change/Session
- Strut Change Outs
- Strut Changes
- Movement Rates by Day

Strut Changes

Throughout the treatment plan, patients may be required to consult their physician for a strut change. A strut change is necessary when the strut needs to be replaced with a smaller or larger strut.

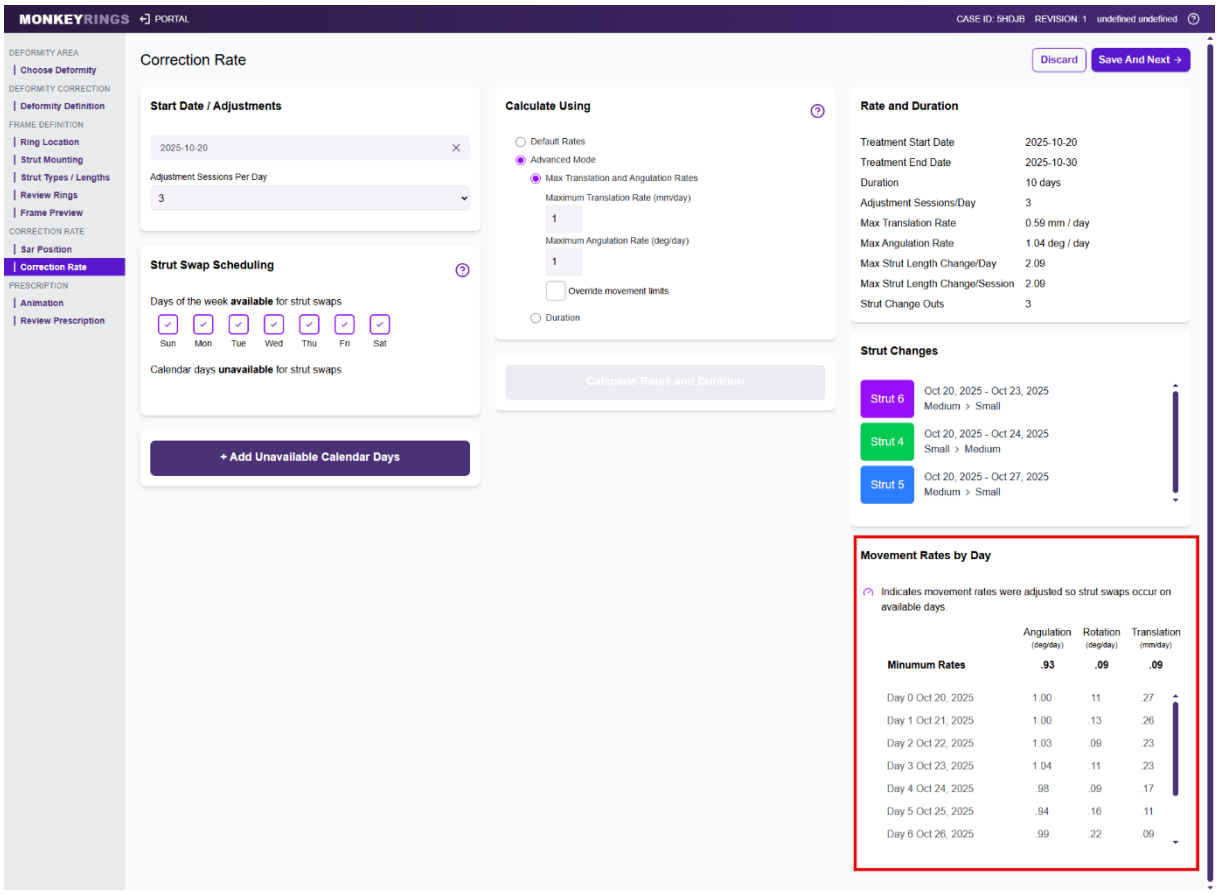


As shown in the figure above, the software will indicate which strut(s) needs to be replaced, the replacement strut type, and the strut change period. The strut change period is the week or set of days in which the strut change is expected to occur.

Movement Rates by Day

There may be different angulation, rotation, and translation rates required on each day of the prescription in order to successfully correct the deformity. As shown in the figure below, the software will indicate the following information:

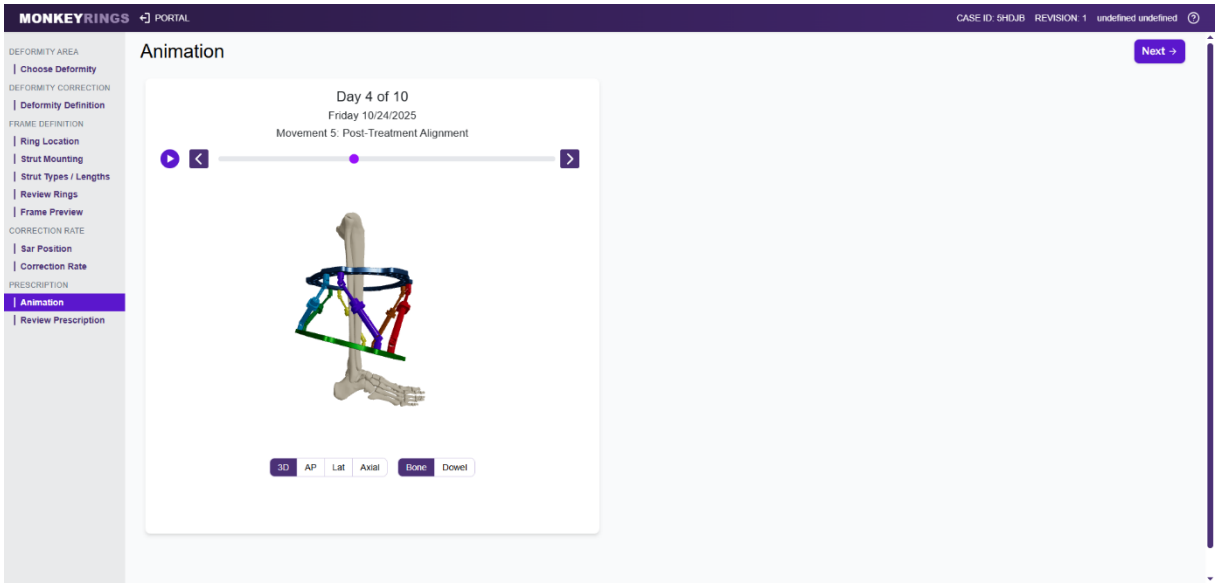
- The software defined minimum angulation rate, rotation rate, and translation rate
- Index for the day in the prescription
- Date for the day in the prescription
- Calculated angulation rate for the corresponding day in the prescription
- Calculated rotation rate for the corresponding day in the prescription
- Calculated translation rate for the corresponding day in the prescription



3.12. Animation

The next step in the case planning process allows users to view an animation of the treatment plan. Using the slider, arrow buttons, or the play button, users can view the hardware transition throughout the correction plan. The animation provides the opportunity to visualize the estimated movement of the fragments for the current plan to confirm its' correctness.

Note: As the animation progresses, the day of the treatment is shown at the top of the model, along with the type of phase (if applicable).



Animation Tools

The animation tools provided by the software include the following:

- ‘AP’ - Setting the view to the AP perspective
- ‘3D’ - Toggling 3D
- ‘Lat’ - Setting the view to the Lateral perspective
- ‘Axial’ - Setting the view to the Axial perspective
- ‘Bone’ - Setting the view to use the 3D bone model
- ‘Dowel’ - Setting the view to use a dowel representation instead of a bone model.

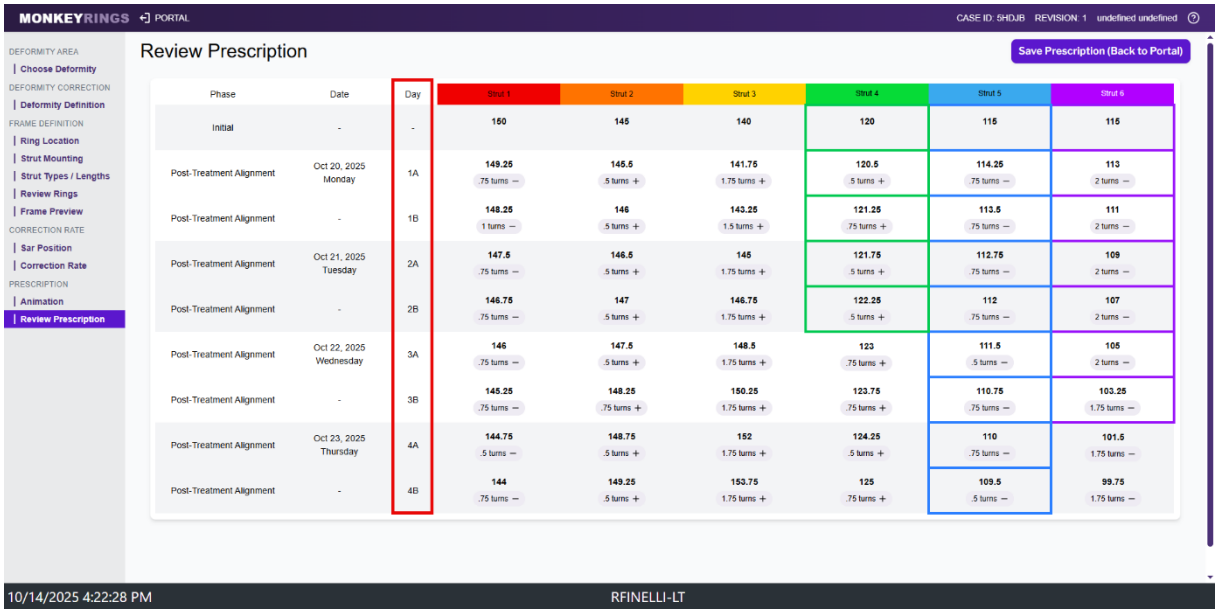
3.13. Review Prescription

The last step in the case planning process is reviewing the prescription. The prescription displays every date in the correction plan detailing the type of phase (lengthening, rotation, etc.), and the necessary patient actions for each strut.

Note: The user should review the prescription for correctness and completeness prior to providing the prescription to the patient.

Phase Day

The number of daily adjustments that the user selected will be used to determine the amount of times a patient is required to maintain their hardware. For example, a user who has selected 2 daily adjustments, would cause a prescription to have two sessions within a day, hence the prescription displays“1A” and “1B” (see image below).

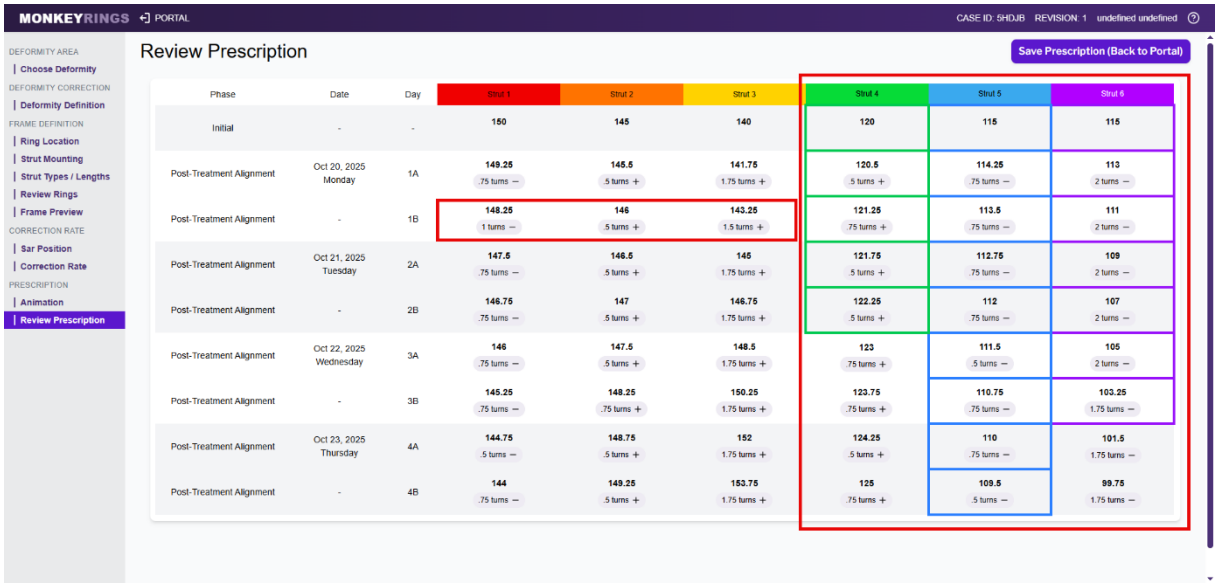


Patient Actions

Additionally, the prescription indicates the action necessary for the Patient to perform for each strut. For example, in the figure below on October 20, 2025, on day 1B:

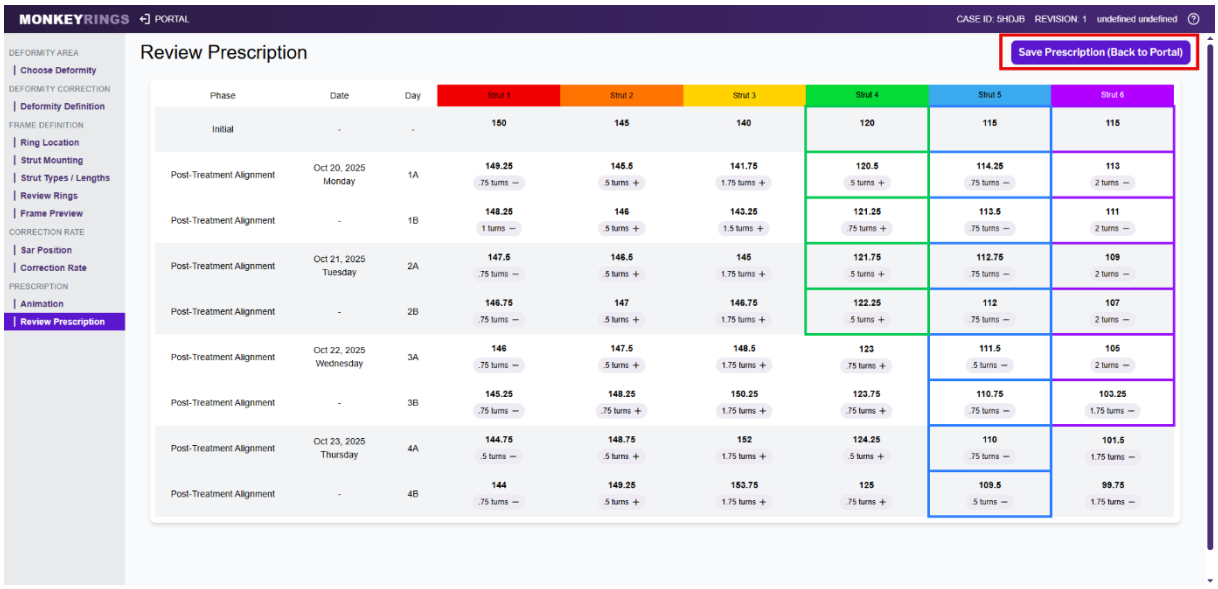
- Strut 1 needs one full turn in the counterclockwise direction to be at 148.25 mm.
- Strut 2 only needs a half of a turn in the clockwise direction to get to 146 mm.
- Strut 3 requires a full turn and a half in the clockwise direction to be set to 143.25 mm.

The strut change out period calculated on the Correction Rate page will be highlighted for each strut using the color of that strut. For example, Strut 5 has a strut change out period from October 20, 2025 – October 23, 2025, so there is a blue highlight around every day in the prescription in the column for Strut 5.



3.14. Review the results

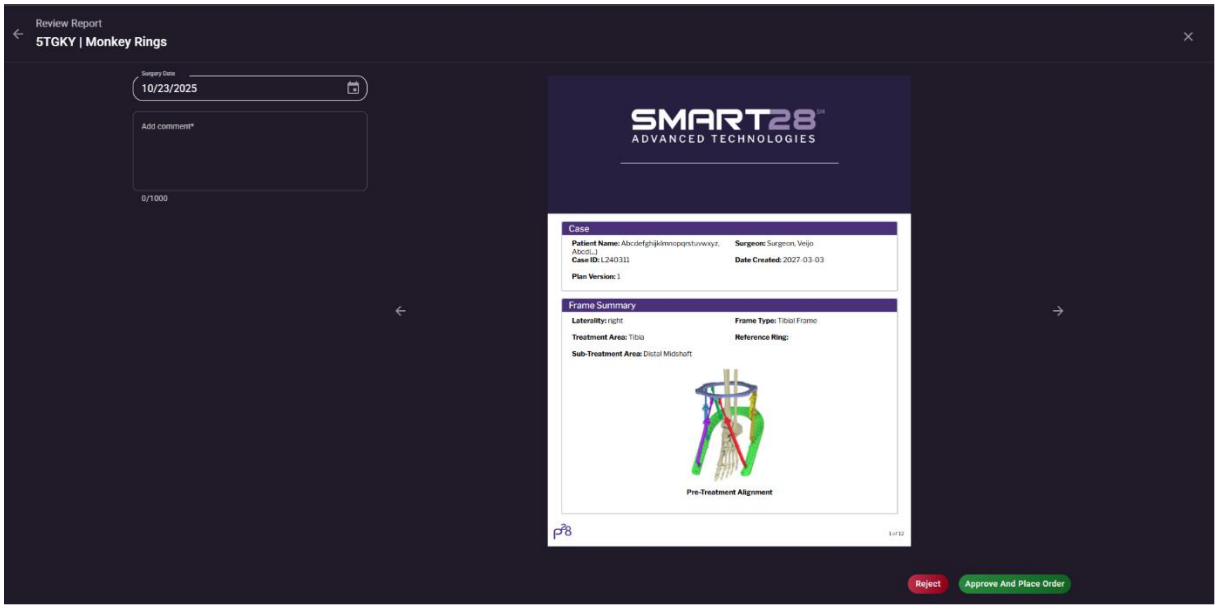
To confirm and save the treatment plan, select ‘Save Prescription (Back to Portal)’ in the top-right corner.



In the SMART28℠ Portal, first select ‘Review and Approve’ to proceed. In the Report Review, use the left and right arrows to browse through the report. To complete the plan, select ‘Approve and Place an Order’. Return to Planning by selecting ‘Reject Plan’. The plan will appear in the Active Plans section and ‘Go to Planning’ is re-activated.

Note: Reports must be approved before they can be exported for external review.

Note: A surgery date is required to approve the plan. A comment is required to reject it.



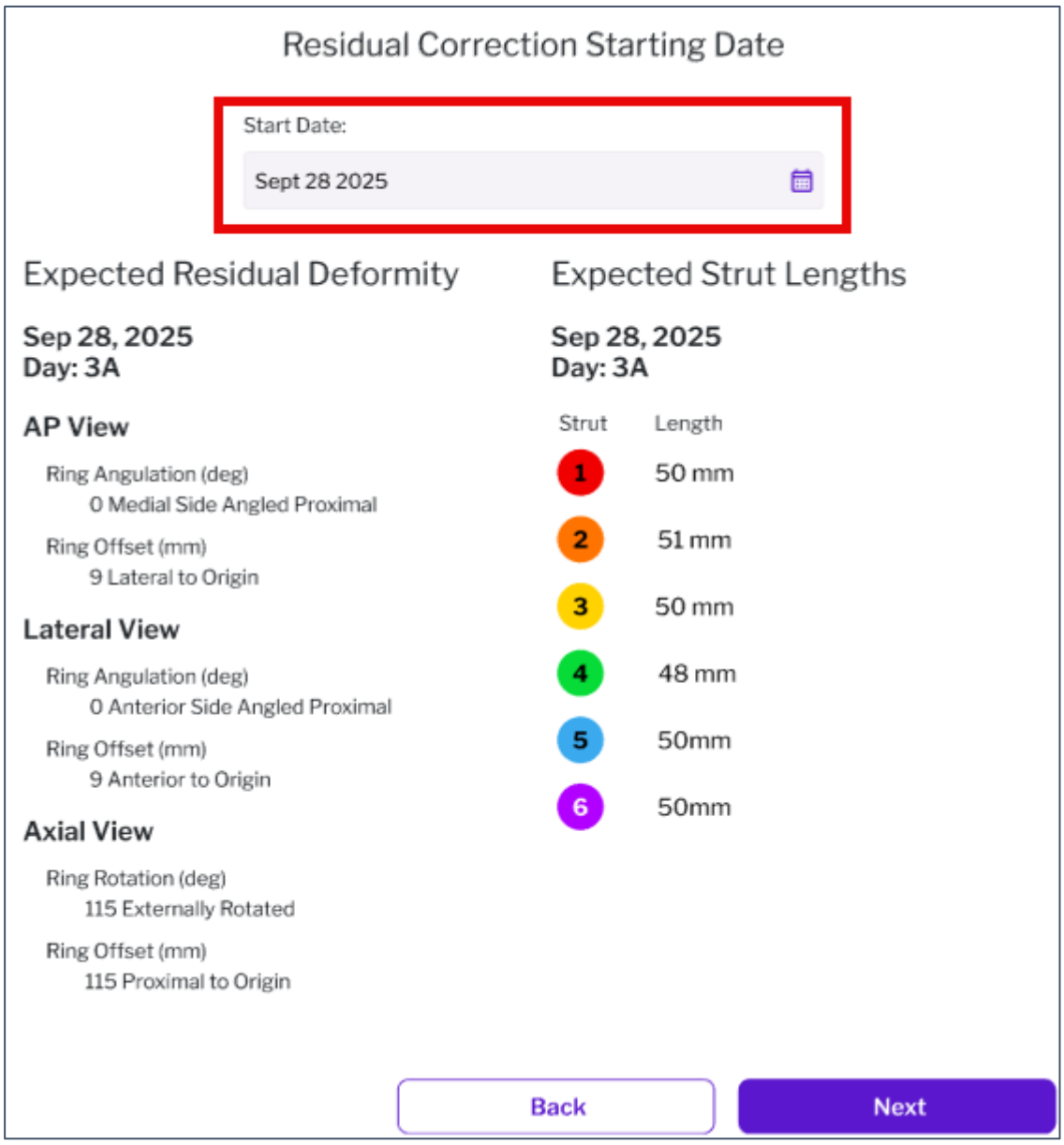
3.15. Performing a Residual Correction (Revise Plan)

If an active or current correction plan is no longer accurate due to a deviation outside of the software, the ENOS Hexapod System provides the ability to perform a residual correction. The residual correction allows users to modify the active correction plan.

The first three steps of the Residual Correction workflow occur in the SMART28 Portal. Select the “Revise Plan” option for the intended patient.

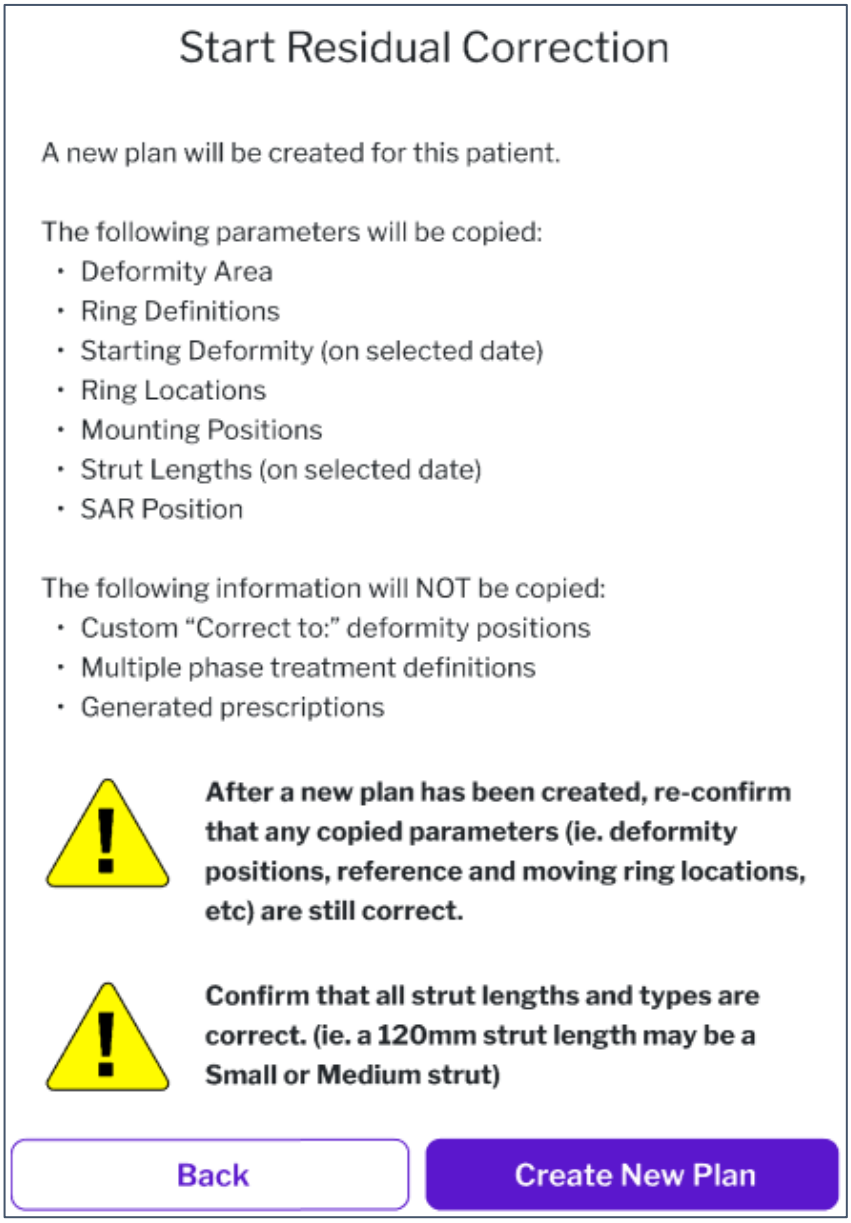
Select a Starting Date

Observe and analyze the patient’s deformity. After analyzing, select the date in the prescription plan that aligns closely with the patient’s hardware. Review the expected residual deformity and expected strut lengths for that date and compare them to the patient’s current deformity and hardware state. Once the date is selected select the option “Next”.



Start Residual Correction

After selecting the start date for residual correction, information is displayed describing what will occur after a residual correction is started along with some warnings. Selecting the “Create New Plan” option will start the residual correction and reopen the ENOS Hexapod System.



All user entries on the Choose Deformity, Ring Location, Strut Mounting, and Structure At Risk (SAR) Position pages from the previous case plan will be directly copied over to the residual correction plan. The Pre-Treatment Alignment fields on the Deformity Definition page will be pre-populated with the expected residual deformity values for the selected starting date of residual correction. The Movement Method and Correction Position fields will be defaulted to Single Phase Correction and Neutral Position, respectively. The strut types and lengths on the Define Strut Types and Lengths page will be pre-populated with the expected strut lengths for the selected starting date of residual correction.

Revising Deformity Definition

The user will be navigated to the Deformity Definition step from the original workflow after starting a residual correction. Note that the 'Pre-Treatment Alignment' values will be updated to match the values that the user selected on the previous page. The user must then review and modify the

movement method and target position as needed. For additional information on how to define the deformity, refer to section Deformity Definition.

Revising the Ring Location

Using the “Save and Next” button will navigate to the next step in the residual correction, which is revising the reference ring. This step allows users to review and modify the reference ring location. Similar to the original correction process, modifying the reference ring parameters will regenerate the 3D model. The 3D model is intended to serve as a tool to help visualize the software-defined location of the reference ring, which should replicate the position the ring is located on the patient. For additional information on defining the Ring Location, refer to section Ring Location.

Revising the Strut Placements

Using the “Save and Next” button will navigate to the next step in the residual correction, which is revising the strut placements. The software allows users to review and modify the strut mounting placements as needed. The strut mounting placements can be reset to default or manually re-defined. If applicable, any support ring mounting positions can also be redefined. For additional information on how to identify the Strut Mounts, refer to section Strut Mounting.

Revising Strut Types and Lengths

Using the “Save and Next” button, users can navigate to the next step in the residual correction. This step allows users to review and redefine the strut types and lengths as needed. For additional information on the strut types and lengths that are available, refer to section Define Strut Types and Lengths.

Revising Ring Locations

Using the “Save and Next” button, users are directed to the review ring location step. The software displays the placement of the reference ring (static ring) and the moving ring. Users should review the reference ring location carefully, to ensure all data previously entered is correct. Similarly, the moving ring location(s) should be carefully reviewed to ensure all data is correct.

Note: If any of the data displayed for either ring is inaccurate, return to the previous step(s) to correct the data. Inaccurate ring definitions will impact the prescription. For additional information on reading the ring locations, refer to the section Review Ring Location.

Revising Frame Preview

Using the “Next” button, navigates users to the frame preview step. On this step, users are expected to review the hardware data that is displayed. The rings, accessories, and struts are intended to reflect the user inputs. If any of the data is incorrect, return to the previous step(s) to correct the data.

Note: If any of the data displayed is inaccurate and not corrected, it will create a prescription that is not reflective of the patient’s hardware. The software also provides the option to view the hardware in the pre-treatment alignment and post-treatment alignment states. For additional information on reviewing the frame preview, refer to the section Frame Preview.

Revising the Structure at Risk

Using the “Next” button, navigates users to the structure at risk position step. Users are able to select if there is a structure at risk, and if so, review and redefine its’ placement if necessary. For additional information on defining a structure at risk, refer to the section Structure At Risk (SAR) Position.

Revising the Correction Rate

Using the “Save and Next” button will navigate users to the correction rate step. Users are able to modify the start date, the number of adjustment sessions per day, the strut swap scheduling availability, the calculation method, and the correction rates / duration. For additional information on how to set the correction rate, refer to the section Correction Rate.

Revising the Animation

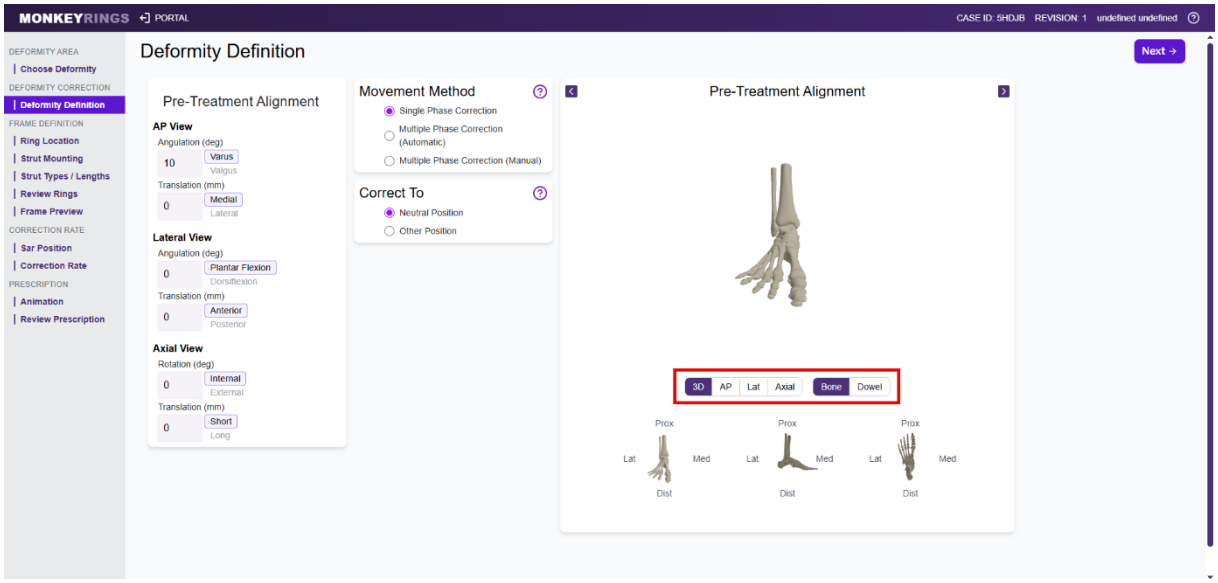
Using the “Save and Next” button will navigate users to the animation step. Users will be able to view the animation of the prescription enacted on the hardware, based on the inputs. For additional information on how to review the animation, refer to section Animation.

Revising Prescription

Using the “Next” button will navigate users to the review prescription step. Users will be able to review the newest prescription plan based on the latest inputs that have been entered. For additional information on how to review the prescription, refer to section Review Prescription.

3.16. 3D Model Capabilities

There is a 3D model located on the Deformity Definition, Ring Location, Review Ring Location, Frame Preview, Structure At Risk (SAR) Position, and Animation pages. The model has four different views – 3D, AP, Lateral, and Axial. In the 3D view, the user can rotate the model (left click), zoom in and out (scroll wheel), and pan (right click). The anatomy portion of the 3D model can also be viewed as bones or as dowels.



4. Appendix – Supplementary Tables and Figures

4.1. Acceptable ranges

Table 6 summarizes the acceptable ranges for all workflow steps.

Note: If the user enters a value that is out of the acceptable range for a field, a warning will appear prohibiting the user from proceeding to the next step.

Table 6 Acceptable ranges.

Deformity Definition	
AP/Dorsal View Angulation	0 deg to 90 deg
AP/Dorsal View Translation	0 mm to 120 mm
Lateral View Angulation	0 deg to 90 deg
Lateral View Translation	0 mm to 120 mm
Axial View Rotation	0 deg to 90 deg
Axial View Translation	0 mm to 120 mm
AP/Dorsal View Ring Angulation	0 deg to 90 deg
Ring Location	
AP/Dorsal View Ring Angulation	0 deg to 90 deg
AP/Dorsal View Ring Offset	0 mm to 90 mm
Lateral View Ring Angulation	0 deg to 90 deg
Lateral View Ring Offset	0 mm to 90 mm
Axial View Ring Rotation	0 deg to 100 deg
Axial View Ring Offset	0 mm to 90 mm
Define Strut Types and Lengths	
XX-Small (XXS)	52 mm to 65 mm
X-Small (XS)	61 mm to 84 mm
Small (S)	79 mm to 121 mm
Medium (M)	111 mm to 184 mm
Large (L)	174 mm to 310 mm
Structure at Risk Position	
AP/Dorsal View Structure at Risk Position	0 mm to 200 mm
Lateral View Structure at Risk Position	0 mm to 200 mm
Axial View Structure at Risk Position	0 mm to 200 mm
Correction Rate	
Maximum Translation Rate (No Override)	0.1 mm to 2 mm
Maximum Angulation Rate (No Override)	0.1 deg to 2 deg
Maximum Translation Rate (Override)	0.1 mm to 5 mm
Maximum Angulation Rate (Override)	0.1 deg to 5 deg
Duration	1 day to 365 days

4.2. Visualizing Area

In the section Anatomy Zone, the anatomical area is chosen. The location where the model transitions from purple to blue indicates where the CORA/Apex will be for that particular selection. The available options for the anatomical areas are presented in Table 7.

Table 7 Available options for anatomical areas with CORA/Apex visualized.

Area	Available Options
Tibia	
Ankle	
Foot	
Dowel	

4.3.Available Frame Types

Table 8 presents the available frame types chosen in section Frame Type. The table identifies the frame types available per the area and sub-area selected. See Figure 4 for visualization of the available frame types.

Table 8 Available frame types per area and sub-area.

Area	Sub-Area	Frame Type
Tibia	Proximal Articular Proximal Metadiaphyseal Proximal Midshaft Distal Midshaft Distal Metadiaphyseal Distal Articular	Tibial Frame
Ankle	Tibiotalar Subtalar	Ankle Frame Miter Frame – Ankle
Foot	Subtalar	Miter Frame – Foot Foot Frame
Foot	Transverse Tarsal Intertarsal Tarsometatarsal	Miter Frame – Foot Butt Frame
Dowel	Long Bone	Tibial Frame

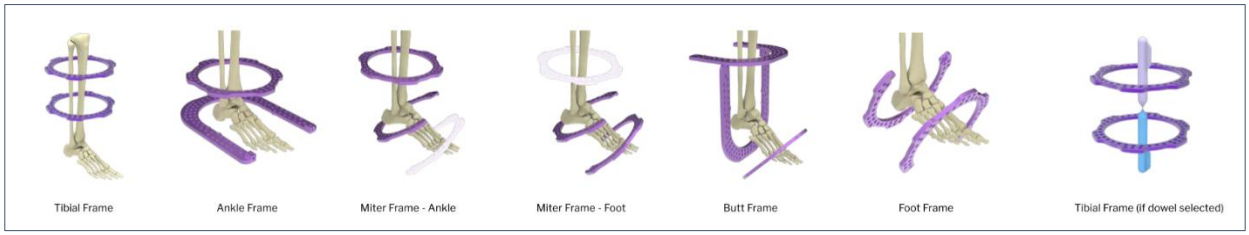


Figure 4 Visualization of frame types

4.4. Available Ring Types

All the available ring types chosen in section Ring Selection are presented in Table 9.

Table 9 Available ring types per frame type.

Frame Type	Proximal Ring Type	Distal Ring Type	Support Ring Type
Tibial Frame	• Full Ring – Tabs • 5/6 Tab Ring • Specialty Tibia Ring • Short Foot Plate	• Full Ring – Tabs • 5/6 Tab Ring • Specialty Tibia Ring • Short Foot Plate	N/A
Ankle Frame	• Full Ring - Tabs • 5/6 Tab Ring • Specialty Tibia Ring • Short Foot Plate	• Foot Plate • Short Foot Plate • 5/6 Tab Ring	N/A
Miter Frame – Ankle	• Full Ring – Tabs • 5/6 Tab Ring • Specialty Tibia Ring	• Full Ring – Tabs • 5/6 Tab Ring • Specialty Tibia Ring	N/A

Miter Frame – Foot Foot Frame	• Full Ring – Tabs • 5/6 Tab Ring • Specialty Tibia Ring	• Full Ring – Tabs • 5/6 Tab Ring • Specialty Tibia Ring • Foot Plate • Short Foot Plate	N/A
Butt Frame	• Foot Plate • Short Foot Plate	• Full Ring – Tabs • 5/6 Tab Ring	• Full Ring – Tabs • 5/6 Tab Ring • Specialty Tibia Ring • Foot Plate • Short Foot Plate

4.5. Deformity Parameters and Angulation

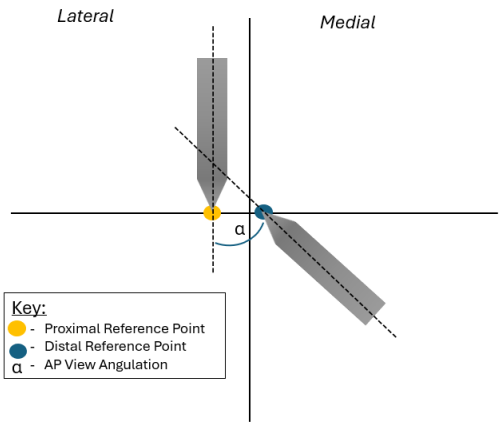
Refer to Table 10 for the minimum and maximum values of deformity parameters for the Pre-Treatment Alignment.

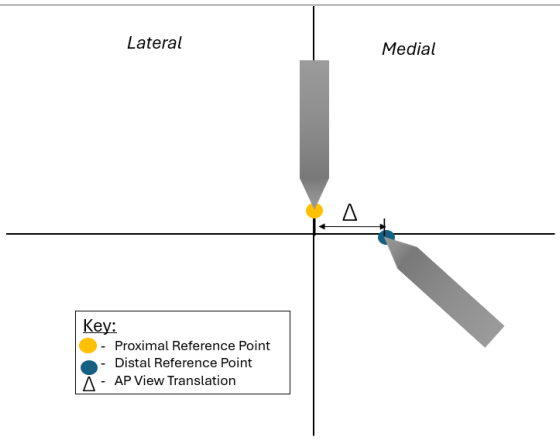
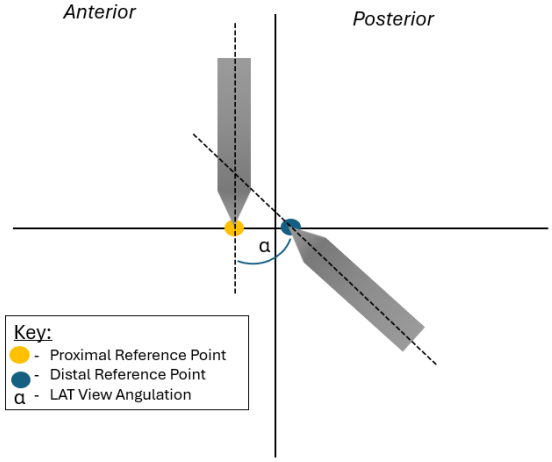
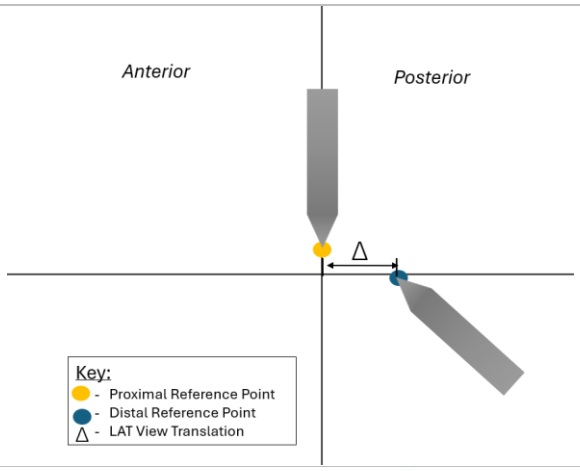
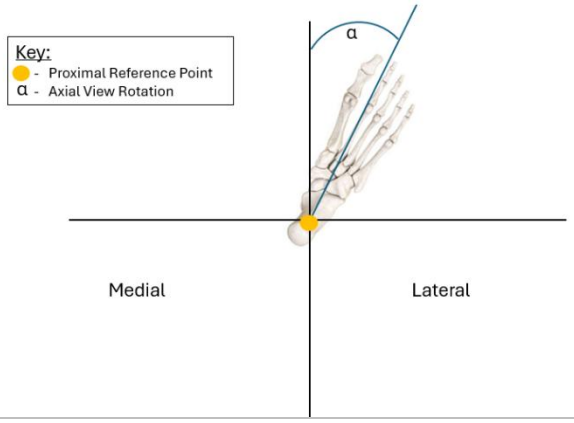
Table 10 Deformity parameter values.

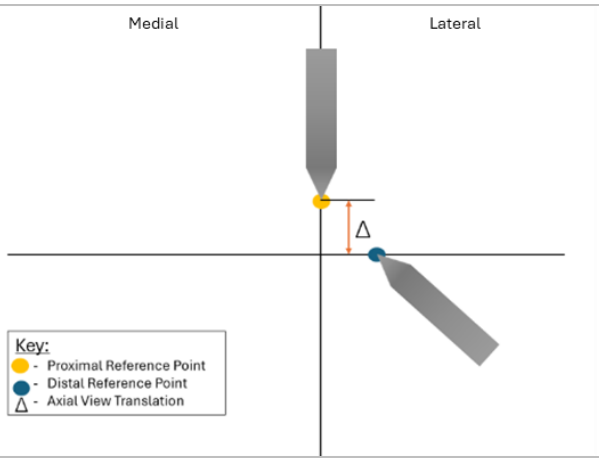
Deformity Parameter	Lower Limit	Upper Limit	Unit
AP View – Angulation	0	90	degrees
AP View – Translation	0	120	mm
Lateral View – Angulation	0	90	degrees
Lateral View – Translation	0	120	mm
Axial View – Rotation	0	90	degrees
Axial View – Translation	0	120	mm

Table 11 illustrates and describes the different translations and angulation of the deformity parameters.

Table 11 Translation and angulation of the deformity parameters.

View	Description	Illustration
AP View Angulation	The coronal angulation value of the distal reference point with respect to the proximal reference point.	

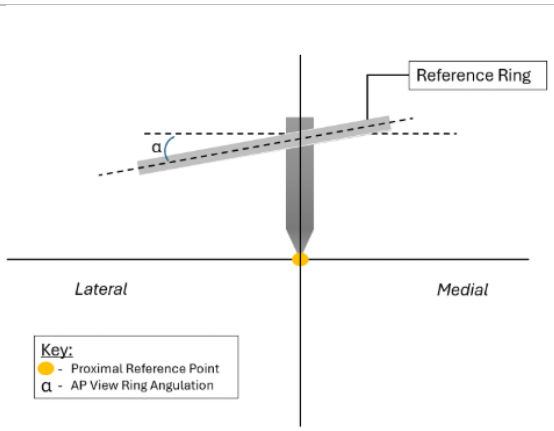
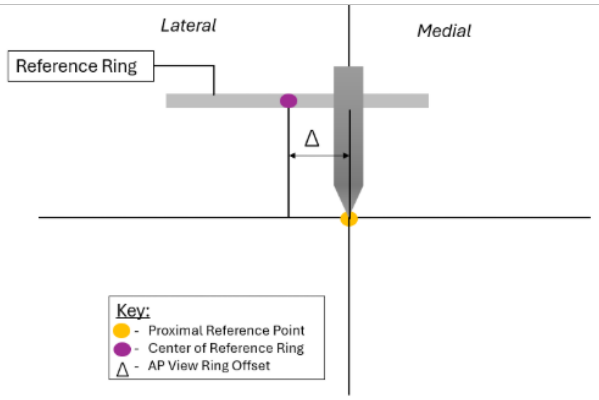
AP View Translation	The anteroposterior translation value of the distal reference point with respect to the proximal reference point.	
Lateral View Angulation	The sagittal angulation value of the distal reference point with respect to the proximal reference point.	
Lateral View Translation	The lateral translation of the distal reference point with respect to the proximal reference point.	
Axial View Rotation	Rotation of the moving fragment from the reference fragment POV. As the moving fragment is rotated from the center line to the Lateral direction, this will be defined in the software as an external rotation. **Note:** When using a distal reference, the proximal fragment would be rotated	

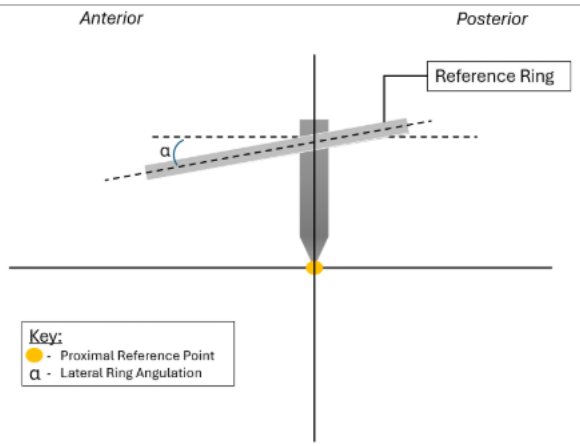
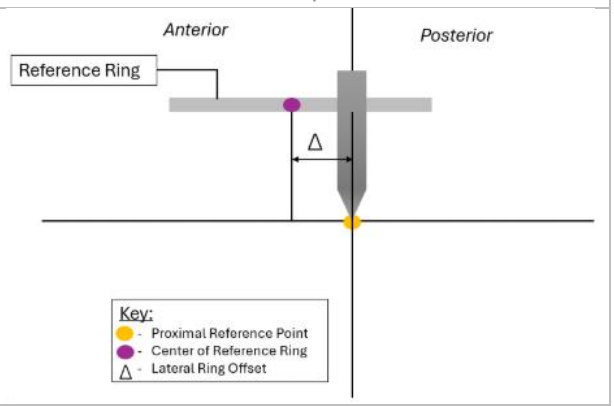
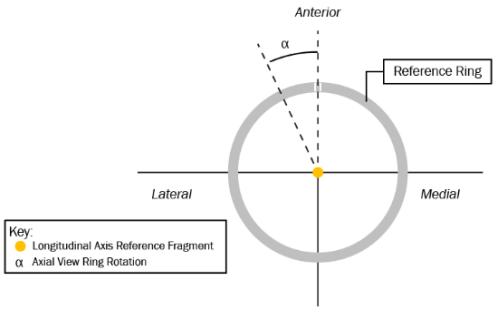
	internally from the distal fragment's POV.	
Axial View Translation	Translation of the deformity along the reference fragment axis. The axial translation would be described in the software as Δ in the Long direction.	

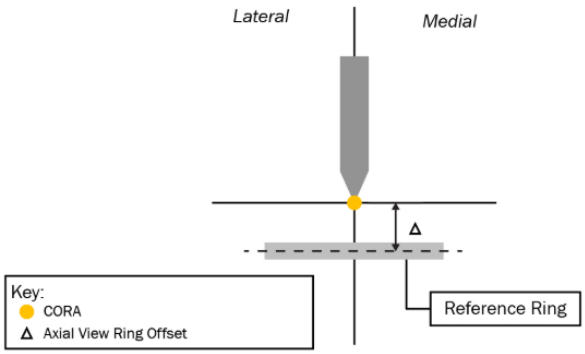
4.6.Visualizing Angulations, Translations, and Rotations

Table 12 visualized the angulations, translations, and rotations used in the section Ring Location.

Table 12 Angulations, translations and rotations visualized.

View	Description	Illustration
AP View Ring Angulation	In the software, the image on the right would be described as Medial side angled Proximal.	
AP View Ring Offset	Here, the ring's center is at an offset of Δ Lateral to CORA.	

Lateral Ring Angulation	In the software, the image below would be described as 'Anterior Side Angled Distal'.	
Lateral Ring Offset	Here, the ring's center is at an offset of Δ Anterior to CORA.	
Axial View Ring Rotation	Describes the angle of rotation of the anterior point of the ring around the axis of the reference fragment. External rotation describes an angle from the sagittal plane to the lateral direction of the reference fragment, and internal rotation describes an angle from the sagittal plane to the medial direction of the reference fragment.	

Axial View Ring Offset	Distance from the center of reference ring to the CORA along the reference fragment axis.	

4.7.Correction rate limits

Table 13 contains the limits for the max translation rate and max angulation rates used for the correction rate.

Table 13 Correction rate limits.

Parameter	Lower Limit	Upper Limit
Max Translation Rate (No override)	0.1 mm/day	2 mm/day
Max Angulation Rate (No override)	0.1 deg/day	2 deg/day
Max Translation Rate (With override)	0.1 mm/day	5 mm/day
Max Angulation Rate (With override)	0.1 deg/day	5 deg/day

5. Data management & software architecture

5.1. SMART28 domain HTTPS addresses

The address to the SMART28 web page is https://smart.paragon28.com/. The domains listed in Table 14 are utilized for the service and network traffic. The system consists of the SMART28 Case Management Portal with associated Cloud elements and the Medical Application.

Table 14 SMART28 domain network addresses.

Portal front-end	https://portal.smart.paragon28.com
Login (Azure B2C)	https://login.smart.paragon28.com
API	https://apis.smart.paragon28.com/
Application-specific domain	https://portal.smart.paragon28.com/

5.2. Microsoft Azure connection specification

The client is connecting to the Microsoft Azure AD B2C service for username verification. The connection is created over the internet utilizing HTTPS (Hyper Text Transfer Protocol Secure) protocol through TCP port 443.

The username and password are client specific. The amount of subsequent connection attempts is restricted against “brute force attacks”, also known as Denial of Service (DoS) attacks.

Data transfer is done using HTTPS protocol secured by TLS certificate (TLS 1.2). Short network disconnections during upload/analysis/download are tolerated by the system, and the process continues after the connection is re-established.

5.3. SMART28 Cloud environment

SMART28 Cloud environment overview:

- SMART28 is a Microsoft Azure based Cloud service, traffic with HTTPS/TLS certificate, domains need to be accessible from the used location
- The SMART28 Cloud is physically located in the USA.
- The client side needs to have whitelisted the domain for SMART28.
- The server is protected by Azure network elements (e.g. Azure API Management) and layered network structure. DoS prevention and firewall at server network.
- The Cloud instance is running on Linux Operating System.
- Cloud instances are updated regularly.

5.4. Data processing Elements

Element 1: SMART28 Case Management Portal (Cloud Service connection)

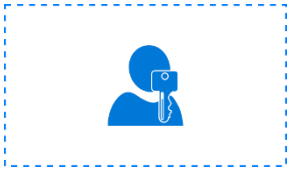
1. SMART28 Case Management Portal contains the Patient Information and access to Medical Applications
2. Login and user authentication is required to access the SMART28 environment
3. Patient data is stored within the SMART28 Case Management Portal

Element 2: SMART28 Medical Application (Cloud Service)

1. SMART28 Medical Application contains case workflow, access through SMART28 Case Management Portal
2. Separate instances are formed for each patient case identified by case ID within the Application
3. Once workflow completed, the report is returned to the SMART28 Case Management Portal
4. Log files for the use are stored

5.5.Data flow description

Step 1: Data handling in client workstation



1. Patient identifiable information is within SMART28 Case Management Portal, case ID displayed on the medical application.
2. The Medical Application case is initiated by user action, case details input within the Application and output report is returned to the SMART28 Case Management Portal.

Step 2: Analysis in SMART28 Medical application

1. Secure information exchange for input data through HTTPS connection
3. Once the user workflow is complete, the resulting report is sent to the SMART28 Case Managmenet Portal

2. Application receives the input information, which is processed interactively.
4. Case accessible before case completion, forced deletion of temporary working files after case archiving.

Step 3: Analysis approval

1. User approves the results report

2. Case is completed. Completed cases remain in the SMART28℠ Case management system and existing case reports can be downloaded by the user.

6. Release notes

Software version number 1.0.22

Notes date March 31st, 2026

Overview

The ENOS Hexapod System software is used with the Paragon 28 Monkey Rings™ External Fixation System for the treatment of traumatic or reconstructive deformities within the indications for use of the Monkey Rings External Fixation System. It is used to generate a prescription of strut adjustments to provide to the patient.

ENOS Hexapod System software (UDI-DI: 06429810209061) with original release software version is (UDI-PI: 1.0.22).

Known Issues:

#	Description	Workaround(s)
1.	The wording of the warning message when required fields are blank or there is an invalid entry is unclear. It doesn't indicate which problem exists.	The user can review fields to identify which fields are not populated and which fields are invalid as there is a separate warning when a field contains a value outside the acceptable range.
2.	When using Dowel view for 3D model, it automatically goes back to Bone view upon any field update	Users can adjust views after they modify to check that their information is still accurate.
3.	When Dowel is selected as the anatomical area, the pages pre-select "Bone" instead of "Dowel" as the 3D model view	Users can manually switch to the Dowel view.
4.	The software header is all white on macOS with Mozilla Firefox	All header functions remain operational, but users can switch to a different supported browser to view the header.
5.	When a case is rejected in the portal and you go back into the software, you are not able to save a new prescription	Users can open a new case for the patient in question and copy-paste all information into the case. No information is lost in this way.
6.	In the Residual Correction Starting Date window, the values are correct for the deformity but the field names are not correct. It is using the field/option names from the Ring Location page instead of the Deformity Definition page.	Once the user in in the ENOS application, the residual correction information is accurate and can be viewed there.
7.	Unsaved Changes popup does not display when leaving correction rate page before calculations are done	Users can either calculate the rates before leaving the page or remember what entries were made before leaving the page.
8.	On first arrival to Ring Location page, it doesn't let you advance if no fields were edited	Users can make any edit on the page and it will allow advancement after that.

9.	Struts / z-plates can be mounted in the same position	Users will be able to observe that two struts are mounted in the same position and can then move one of them to a different position.
10.	Strut Mounting page allows multiple struts to share the same spot under certain circumstances	The Z-plate location mismatch occurs only in specific scenarios and is user-correctable using the existing Strut Mounting controls (drag-and-drop or selecting a valid, available location)
11.	Software doesn't save ring location correctly if user navigates away from page before request is completed	Users should wait for the page to finish loading before navigating to the next page.
12.	For Subtalar Foot Frame, frame preview and animation page, all views are incorrect	Users can manipulate the 3D model to get the desired view.
13.	Prescription Report has more alignment visuals than the software UI	The alignment visuals in the prescription report just offer additional angles for viewing. The models in the report and software are both correct, it just shows different views. Users can reopen the software to observe the original views.
14.	If there are too many strut changes in the prescription (appears to be 6+), they will not be displayed in the report correctly	Strut change information can also be viewed on the prescription instructions page.
15.	Prescription report - Hardware used - should not list unused z-plate	No workaround needed. This is just a UI preference.
16.	Cannot download and open the IFU from within the software	The IFU may be distributed or referenced through external methods.
17.	IFU downloaded from the software is not the final release	The IFU may be distributed or referenced through external methods.
18.	When the rings or struts intersect with the bone, no error messages are displayed	Users can review the 3D models and go back in the workflow to make changes and resolve this conflict.
19.	Moving ring can be calculated even when the bone is not inside of the ring	Users can review the 3D models and go back in the workflow to make changes and resolve this conflict.
20.	When editing an old case, there may be an excessive amount of time needed to load the prescription	Users can either allow the case to load or start a new case and copy over the information.
21.	Save Prescription button appears before prescription gets generated and causes a server error	Avoid clicking the Save Prescription button before the prescription has finished loading.
22.	Strut change windows do not appear if the end of the strut change is not within the prescription	It is not anticipated that a user will need the strut change window information if a patient can perform all necessary actions on a single

		strut. A new prescription should be generated if a strut change is needed in this case.
23.	The calculated maximum rates are occasionally much higher than the inputs	Users can generate a new prescription using different inputs.

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