Exclusively foot & ankle

Paragon 28®

SMART PCFD℠ 1.0

INSTRUCTIONS FOR USE

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1. General Information

This User Guide describes the functionality of the SMART PCFD℠ software manufactured by Disior™ Oy – A Paragon 28® company and provides instructions how to use it.

Caution: A 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. Intended use

The SMART PCFD℠ software is intended to be used by orthopedic healthcare professionals as an application to assist in the characterization of anatomical structures of the foot and ankle using three-dimensional mathematical modeling and radiographic measurements. The combined information from the structural models and the radiographic measurements can be used for diagnostic and treatment planning purposes.

1.2. Indications for use

SMART PCFD℠ software includes AI-powered algorithms and is intended to be used to support orthopedic healthcare professionals in the diagnosis and surgical planning of Progressive Collapsing Foot Deformity (PCFD) in a hospital or clinic environment. The medical image modality intended to be used in the software is weight-bearing CT (WBCT).

SMART PCFD℠ software provides for the user:

- Visualization report of the three-dimensional (3D) mathematical models and measurements of the anatomical structures of foot and ankle and three-dimensional models of orthopedic fixation devices,
- Measurement templates containing radiographic measures of foot and ankle, and
- Surgical planning application for visualization of foot and ankle anatomical three-dimensional structures, radiographic measures, and surgical instrument parameters supporting the following common flatfoot procedures: Medial Displacement Calcaneal Osteotomy (MDCO), Lateral Column Lengthening (LCL), and Cotton Osteotomy (CO).

The visualization report containing the measurements is intended to be used to support orthopedic healthcare professionals in the diagnosis of PCFD. The surgical planning application contains the visualizations of the three-dimensional structural models, orthopedic fixation device models and surgical instrument parameters combined with the measurements is intended to be used to support orthopedic healthcare professionals in surgical planning of PCFD.

1.3. Software contraindications

SMART PCFD℠ software is not intended for other anatomies than the foot and ankle. Using unvalidated medical imaging modality, such as magnetic resonance imaging (MRI), or using medical imaging of non-weight-bearing condition as an input for the software is not allowed. The software output alone cannot be used for diagnostic of the orthopedic healthcare condition and planning of the surgical operation without careful professional assessment. The software output should not be used for planning purposes if the CT scan date is greater than 6 months from the patient's surgery date, or significant changes to the patient's anatomy have occurred since the medical scan was obtained.

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1.4. Target patient group

The intended patient population are adults (over 16 years) to geriatric without any specific limits for demographics with the diagnosis of PCFD. Patients exhibiting the following traits of the PCFD condition may have medical images of sub-optimal quality that must be used with caution in the SMART PCFD℠ software:

1. Unbendable extremities (e.g. due to casts), metal parts within the body (e.g. due to surgical implants), and/or tremors that create image artefacts; and
2. Use of assistive technology (e.g. Wheelchair) or hospital devices (e.g. Hospital bed) during imaging that result in a non-weight bearing situation.

1.4.1. Restricted Patient Groups

Use of SMART PCFD℠ software is restricted in the following patient groups:

1. Children or patients with open epiphyseal growth plates.
2. Patients with contrast agent used for medical imaging.
3. High risk patients with respect to the medical condition.

1.5. Intended Users

The intended user is an Orthopedic surgeon. Supporting surgical professionals (i.e. Physician's Assistant, Registered Nurse) with experience in orthopedic foot and ankle procedures may perform supportive tasks with the software under the supervision and direction of the Orthopedic surgeon.

1.6. System compatibility

SMART PCFD℠ software is a web application without specific hardware requirements for executing the software and should function with all common web browsers. The software has been tested for compatibility with the following operating systems and web browsers versions as presented in Table 1.

Table 1. 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 (Version 131.0.2903.99, 64-bit)
	Google Chrome (Version 131.0.6778.205, 64-bit)
	Mozilla Firefox (Version 132.0.2, 64-bit)
Microsoft Windows 11 Enterprise Version 23H2 (OS Build 22631.3447)	Microsoft Edge (Version 131.0.2903.112, 64-bit)
	Google Chrome (Version 131.0.6778.205, 64-bit)
	Mozilla Firefox (Version 133.0.3, 64-bit)
Apple macOS (Version 13.2)	Apple Safari (Version 18.1.1, 20619.2.8.11.12))

SMART PCFD℠ software 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.

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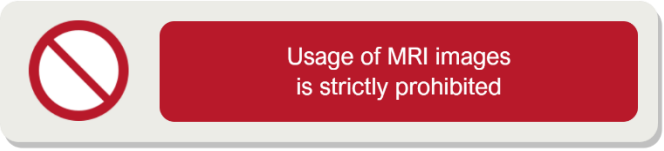
1.7. Imaging data quality requirements

In the SMART PCFD℠ software, the quality of the outputs (including visualizations) is dictated by the quality and resolution of the DICOM images from the WBCT device. Please refer to our DICOM Conformance Statement document for detailed information regarding the required image formats and specifications for upload.



Caution: In case of poor image contrast, low resolution, inadequate Field-of-View, artefacts (e.g. from metallic structures in the image), use of non-weight bearing image, or other image related defects or inaccuracies, the results can be inaccurate.

Caution: Clinical conditions, such as fractured/fragmented bones, fusion structures, deformations, arthritis, osteophytes, osteochondral lesions, displaced sesamoids, and previous surgeries, depending on severity are a potential source of error and results needs to be reviewed with care.

Caution: Conformance to the DICOM standard is required. Incorrect values for Pixel Spacing (0028,0030), Image Position (Patient) (0020,0032), or Image Orientation (Patient) (0020,0037) will cause inaccurate measurement results.

1.8. Software product characteristics

Table 2. Software measurement range and precision.

Range:	±180°, ±500 mm (foot and ankle imaging area)
Precision:	0°, 0 mm (deterministic automatic image analysis)

1.9. Software configuration

SMART PCFD℠ software consists of two components:

1) Web user interface used for confirming input images for analysis, adjusting the plan (optional), reviewing and confirming the output.
2) Cloud service providing the analysis service and the combination of proposed procedures.

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

SMART PCFD℠ software requires connection to Disior™ cloud service (Table 3) and may require actions by Hospital IT (e.g. if connection is prevented by firewalls).

Table 3 Cloud connection

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

1.10. Data management

SMART PCFD℠ software has interface to SMART28℠ Case Management Portal with data management feature for downloading existing case reports. See chapter Data processing for further details.

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1.11. Cybersecurity

The cybersecurity controls of SMART PCFD℠ software are presented in Table 4. 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 4 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 SMART PCFD℠ 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.

1.12. 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.

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1.13. Contact Information

1.13.1. 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.

1.13.2. 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)

1.14. Release Notes

Software version number 1.0.2

Notes date January 26th, 2026

Overview

The SMART PCFD℠ software is intended to be used by orthopedic healthcare professionals as an application to assist in the characterization of anatomical structures of the foot and ankle using three-dimensional mathematical modeling and radiographic measurements.

SMART PCFD (UDI-DI: 06429810209054) original release software version is 1.0.2 (UDI-PI: 1.0.2).

Known issues

- Manual mode out of range (see section Manual mode, page 19): If any measurement value falls outside the acceptable post-op range while manually adjusting the magnitude of the surgical operations, an "Analysis failed" error will appear. After that, the slider values and images might be unsynchronized. Click "OK" to return and make further adjustments to bring the analysis within the acceptable range. See more information in chapter Measurement limits and reference values.

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2. Safety Information

SMART PCFD℠ software interfaces with the SMART28℠ Case Management Portal. SMART PCFD℠ software 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 SMART PCFD℠ software meets performance specifications has been achieved through software testing in compliance with IEC 62304:2006. 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 SMART PCFD℠ software 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 Only 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.
	Prohibition Prohibition safety sign placed together with a supplementary message or symbol. The message associated with this safety sign is a statement describing what is prohibited.

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	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 Mandatory action safety sign placed together with a supplementary message or symbol. The message associated with this safety sign is a command describing the required action.
	Mandatory Action to Read Instructions for Use Mandatory action safety sign indicating required action to read the Instructions for Use.

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 SMART PCFD℠ software could generate inaccurate results if not recognized by the user and lead to incorrect clinical decisions causing indirect patient harm.

In all cases, the Imaging data quality requirements must be observed for input images and the output of the software subject to careful orthopaedic assessment. Additionally, users should rely on their clinical expertise to detect and evaluate impact of geometrical nonconformities.

SMART PCFD℠ software residual risks are summarized below:

Medical Image Registration Inaccuracy

Accurate medical image registration requires the image data inputted into the software to be consistent with the software's structural models. When an inaccuracy is detected, the software issues relevant safety messages (e.g. Warning Messages with Mandatory Action(s)) to the user. The user is expected to adhere to all safety messaging. Additionally, users should rely on their clinical expertise to detect and correct inaccuracies.

Situations that may lead to registration inaccuracy include:

- Input image data that does not meet the Imaging data quality requirements (e.g. images with limited field-of-view, abnormal anatomies).
- Data access or data corruption issues.

Medical Image Registration Failure

A failure in medical image registration may occur if registration inaccuracy is not resolved. When failure occurs, the system issues relevant safety messages (e.g. Safety Messages with Mandatory Action(s)) to the user. The user is expected to adhere to all safety messaging. In this situation it is encouraged to seek an alternative method for patient diagnosis and treatment planning.

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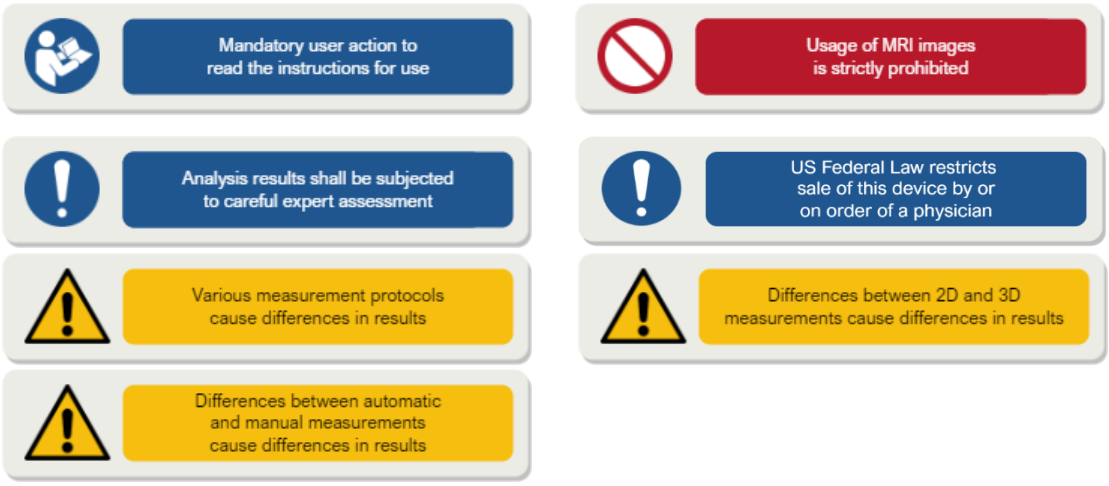
2.3. Safety Messages

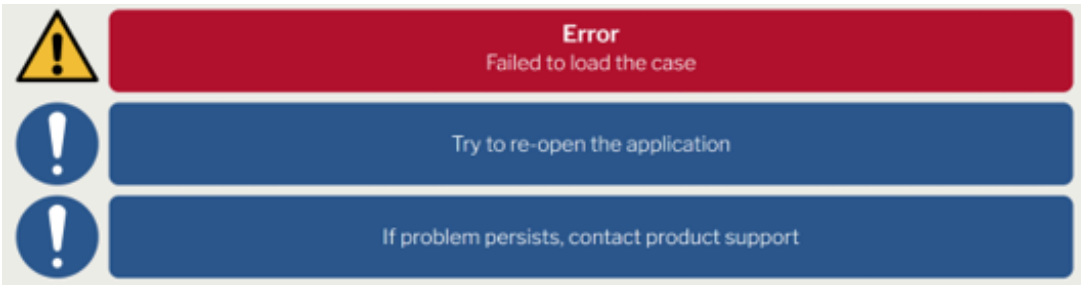
2.3.1. General Safety Information

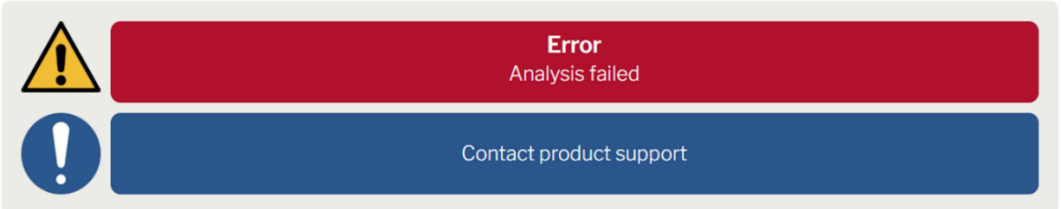
Safety information for the SMART PCFD℠ user is summarized below:



2.3.2. Error Messages

The following error messages with mandatory actions may be issued by the SMART PCFD℠ software:





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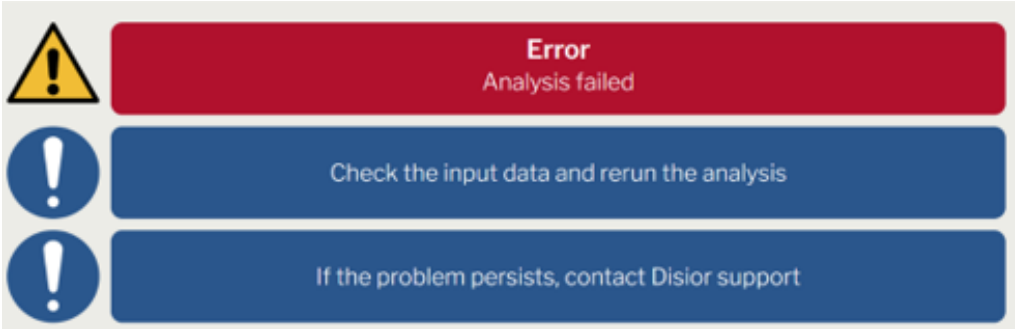
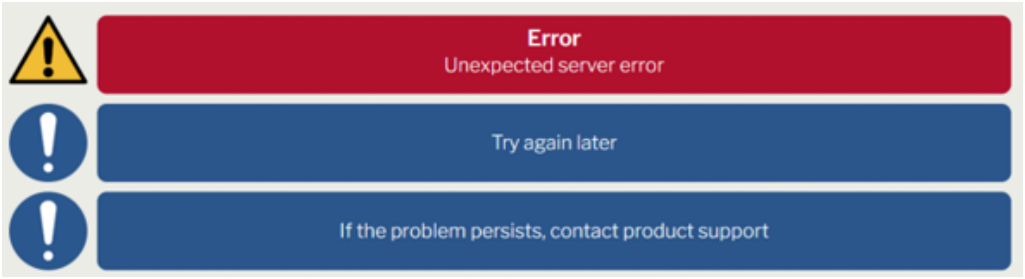
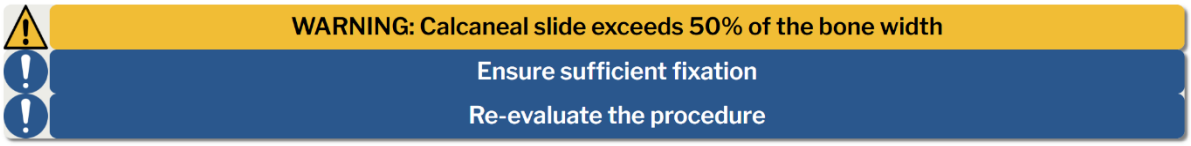
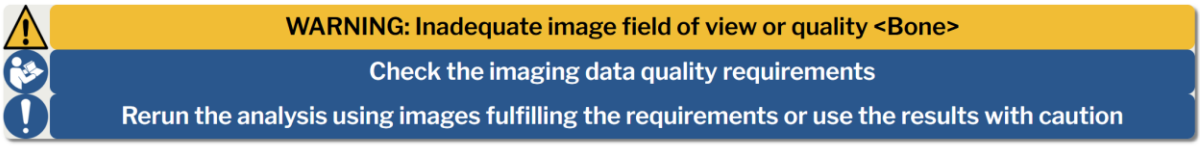


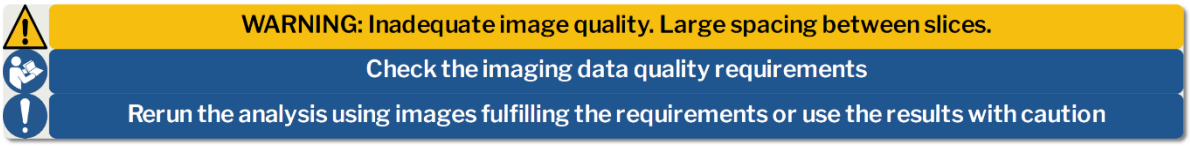


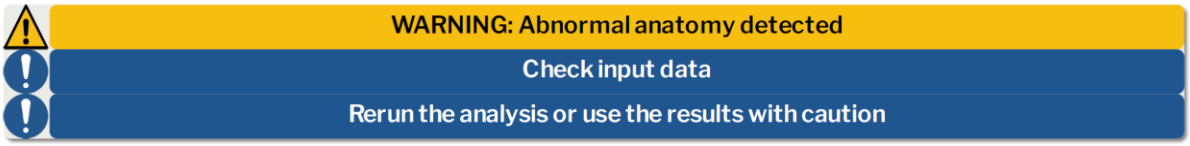
2.3.3. Warning Messages

The following warning messages with mandatory actions (when applicable) may be issued by the SMART PCFD℠ software. These messages appear in the report (when applicable), and some may also be displayed in the user interface.









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2.4. Informative notes

SMART PCFD℠ software issues notes (when applicable) on the Case Report as presented in Table 5.

Table 5 Informative notes

Note	Condition	Position
NOTE: Visualized facet areas are based on general foot model. Individual facet regions may differ.	Always displayed.	Displayed at the bottom of page 3 “Pre-operative state”.
NOTE: Anatomical post-operative visualizations for reference only. Patient-specific mechanics of soft tissue interactions are not simulated. Additional soft tissue procedures may be required to achieve planned correction.	Always displayed.	Displayed at the bottom of page 4 “Estimated post-operative state”.
WARNING: Calcaneal slide amount exceeds 50% of the bone width. Ensure sufficient fixation.	Displayed if the amount of displacement of the calcaneus is greater than half the total width of the bone.	Displayed in the top-right corner of page 5 “PCFD Correction”.
NOTE: For LCL procedures, if the operation sizes exceed or fall below the available graft or wedge sizes, refer to the instructions in the corresponding surgical technique guide.	Always displayed.	Displayed at the bottom of page 5 “PCFD Correction”.
NOTE: Final correction and fixation options are up to surgeon discretion. Fixation options may vary by surgeon preference.	Always displayed.	Displayed at the bottom of page 5 “PCFD Correction” and page 6 “Fixation Hardware Listing”.
NOTE: Cut guides may be used to aid locating a suitable cut position and to avoid possible structures at risk.	Always displayed.	Displayed at the bottom of page 5 “PCFD Correction”.

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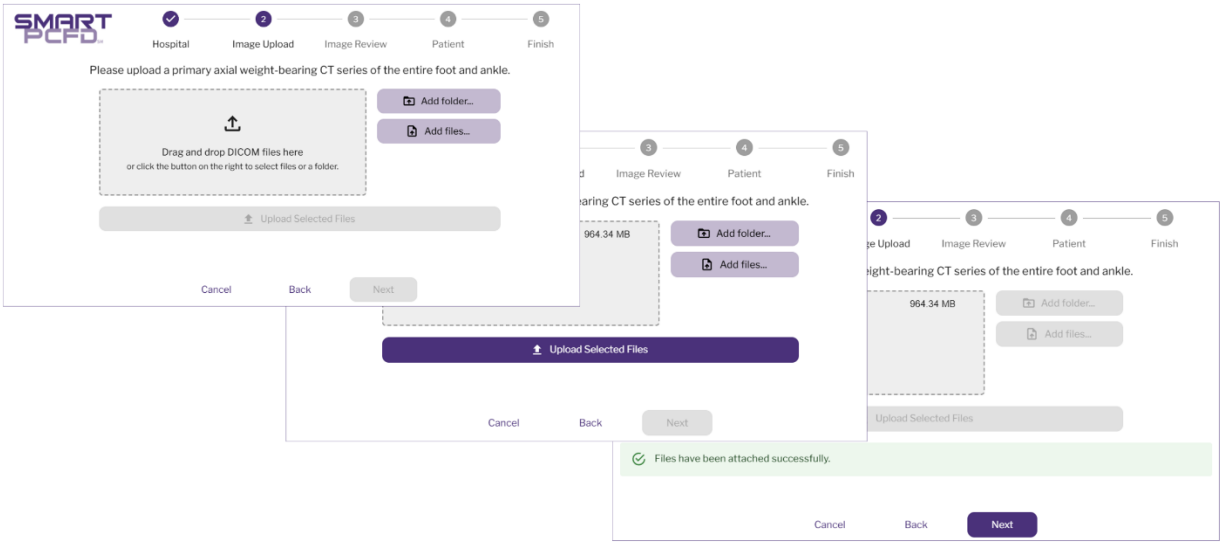
3. Instructions for Use

3.1. SMART℠ Case Management Portal workflow

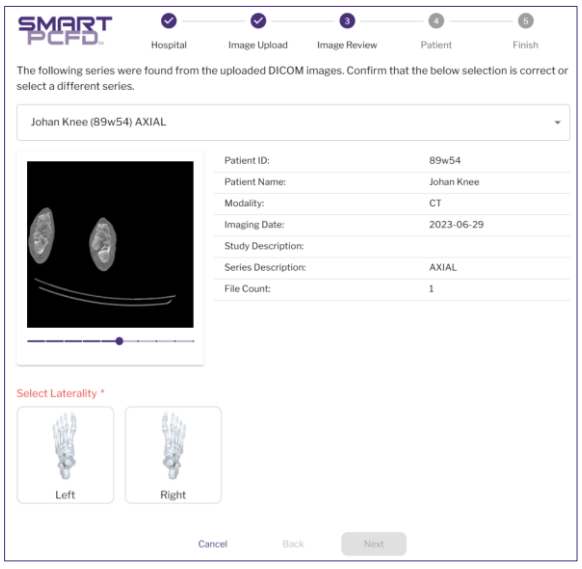
Prior to accessing the SMART PCFD℠ software, following steps need to be completed in the SMART28℠ Case Management Portal:

1) Access the SMART28℠ Case Management Portal
2) Click ‘Create case’ and choose the SMART PCFD℠ product and click ‘Get Started’.
3) Hospital - Select the Hospital affiliated with this case and set the surgery date.
4) Upload DICOM images (primary axial weight-bearing CT series of the entire foot and ankle)
   a. Add a folder or files using the buttons or drag and drop functions.
   b. Click ‘Upload Selected Files’.
   c. Once the files have been attached successfully, select ‘Next’ to proceed.



5) Image Review- The uploaded DICOM series will appear in the preview window. Select the primary axial series. Specify the laterality, then click 'Next' to continue.

Note: If multiple patient’s images are uploaded, select the correct one from the drop-down menu.



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6) Patient - Fill in the patient data and click ‘Next’.
7) Once case has been successfully created, continue by clicking ‘Open the Case Details Page’.

3.2. SMART PCFD℠ workflow

The workflow of SMART PCFD℠ consists of three modes:

- Software suggested (Operation combination suggested by the software).
- Assisted mode (User can manually adjust one operation, and the software optimizes the other two).
- Manual mode (User can manually adjust all three operations).

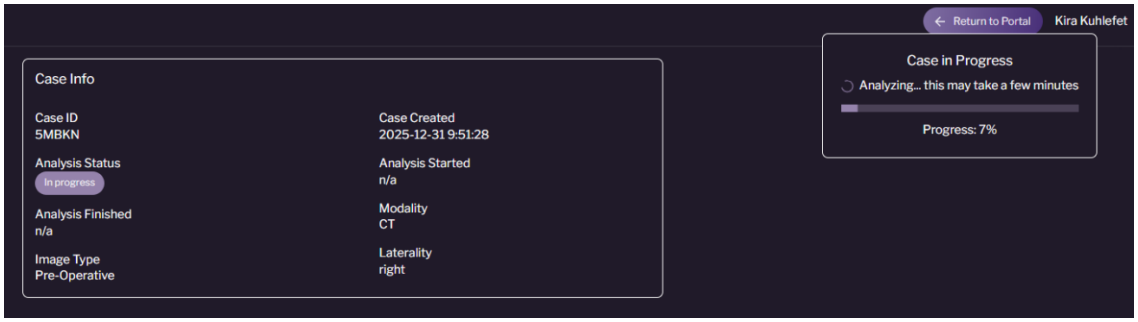
Note: All three modes are available for use; however, only one plan can be confirmed and finalized for each case.

Please follow the steps below to complete the workflow for SMART PCFD℠ after creating a case in the SMART28℠ Case Management Portal:

1) Start Planning
2) Results Preview
3) Review the plan
    a. Software suggested mode
4) Adjust the proposed plan (Optional)
    a. Assisted mode
    b. Manual mode
5) Review the results

Start Planning

The analysis starts automatically after creating the case. To access SMART PCFD℠, click ‘Start planning in SMART PCFD℠’ in the SMART28℠ Case Management Portal. The case information and the progress of the analysis is displayed until the analysis has completed.



Results Preview

Once the analysis is done, Results Preview will pop up. Review the pre-operative foot position, measurement axes, and measurement point to proceed with the analysis. Select ‘Confirm’ to proceed with the analysis or ‘Reject and Exit’ to return to the SMART28℠ Case Management Portal.

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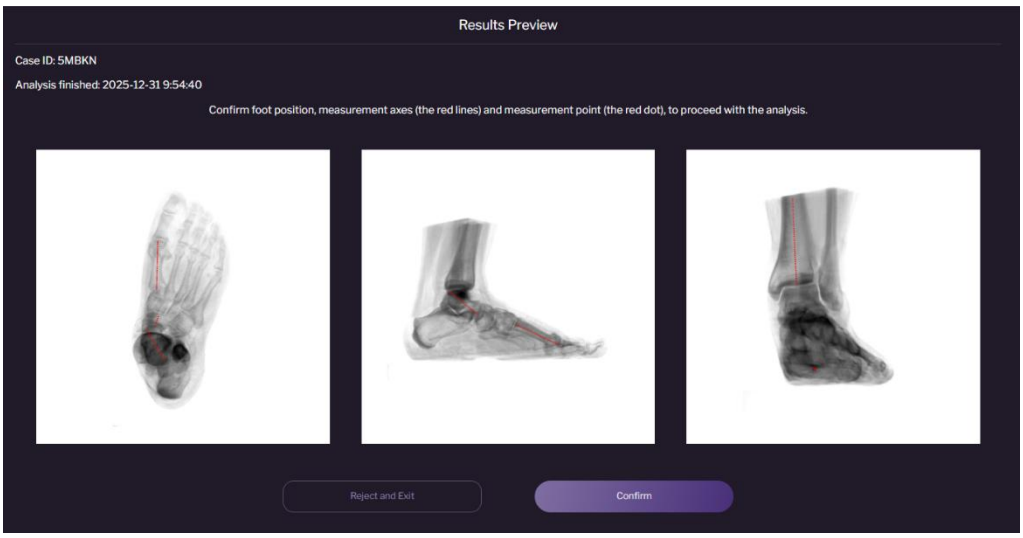

Note: Click the image to view it in full size.

Note: Analysis results are presented as Digitally Reconstructed Radiographs overlain with bone measurement axes and shall be subjected to careful expert assessment. Existing implants and hardware are not visualized, which should be considered by the user if metal exists in the surgical area.

Review the plan

Software suggested mode

The initial software suggested plan is displayed with the proposed combination of surgical operations, including 3D visualizations, pre-op values, and target values.

Note: See more information in chapter Surgical Operations: methodology and definitions.

- The proposed combination of operations with their magnitudes are shown on the left side.
- The 3D visualizations present posterior, axial, and sagittal views, overlaid with pre-operative and target (estimated post-op) bone measurement axes. A red overlay highlights the bones in their pre-operative state for comparison. Click the image to view it in full size.
- The pre-op and target values are shown in graphical format and tabular format.
  - Click the Table icon in the bottom-right corner to view the measurements in tabular format.

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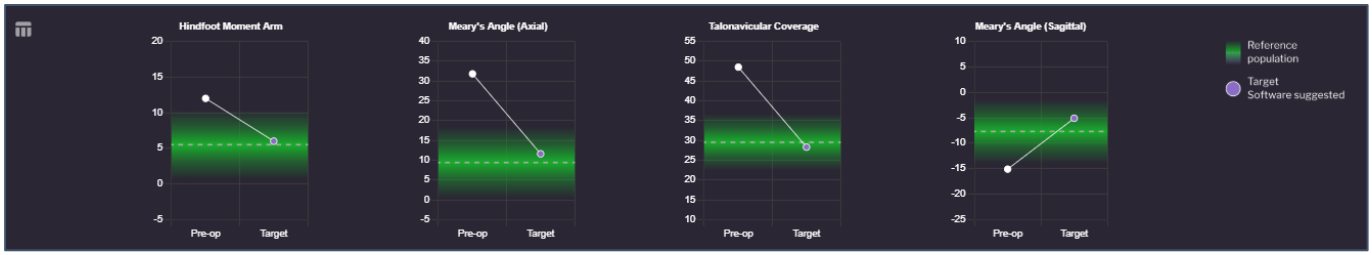
- Tabular format includes pre-op values, target values and the change between the values.

	Hindfoot Moment Arm	Meary's Angle (Axial)	Talonavicular Coverage	Meary's Angle (Sagittal)
Pre-op	12.0 mm	31.8 °	48.5 °	-15.1 °
Change	-6.0 mm	-20.2 °	-20.2 °	10.0 °
Target	6.0 mm	11.6 °	28.3 °	-5.1 °

Click the Graph icon in the bottom-right corner to display the measurements in graphical format.

- Reference population represents the normal population, with pre-defined reference values indicated by the dashed line. The green area illustrates the standard deviation around the average values.
- Target - Software suggested displays the case-specific target values.

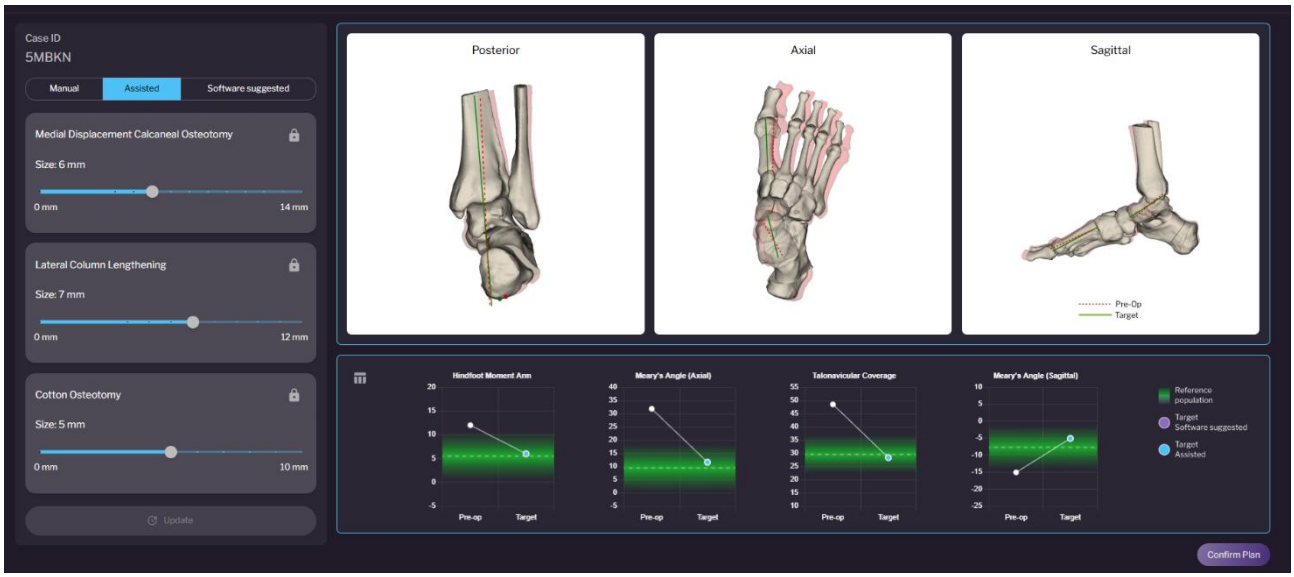
Note: See more information in chapter Measurement limits and reference values.



Adjust the proposed plan (Optional)

Assisted mode

You may adjust the proposed plan if desired. In the top-left corner, navigate to 'Assisted' mode to manually adjust one operation while the software optimizes the other two.



- The proposed combination of operations with their magnitudes are shown on the left side.
- The 3D visualizations present posterior, axial, and sagittal views, overlaid with pre-operative and target (estimated post-op) bone measurement axes. A red overlay highlights the bones in their pre-operative state for comparison. Click the image to view it in full size.

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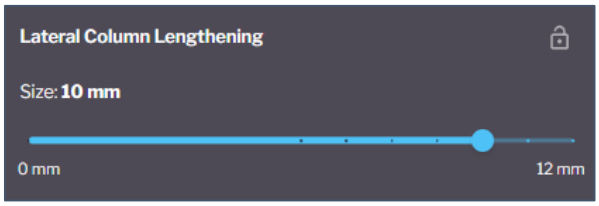
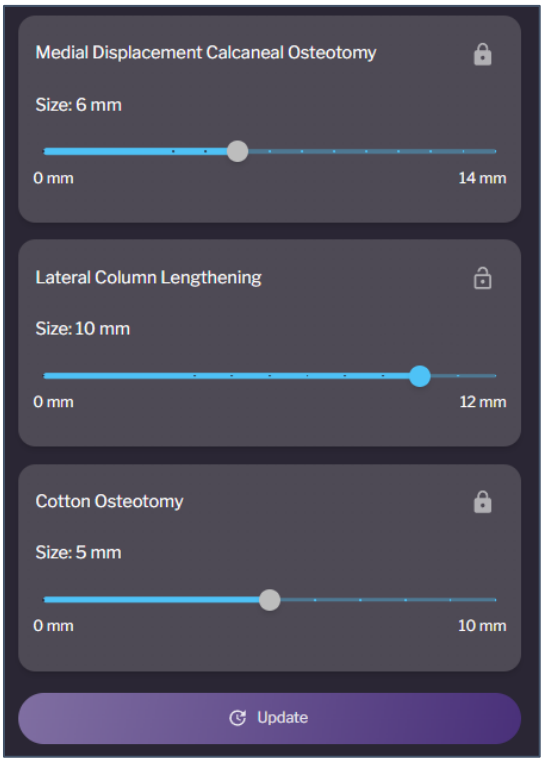
- To start manual adjustment, unlock the desired operation by clicking on the Lock icon
- Manually adjust the size (mm) of the operation using the slider.



- Click ‘Update’ once done. The software adjusts the other two procedures so that the combination brings the estimated post-op foot closest to the pre-defined reference values. A new combination of surgical operations, including pre-op and target values, and 3D visualizations is displayed.



Note: If any measurement value falls outside the acceptable post-op range while manually adjusting the magnitude of the surgical operations, an "Analysis failed" error will appear. Click "OK" to return and make further adjustments to bring the analysis within the acceptable range. See more information in chapter Measurement limits and reference values.

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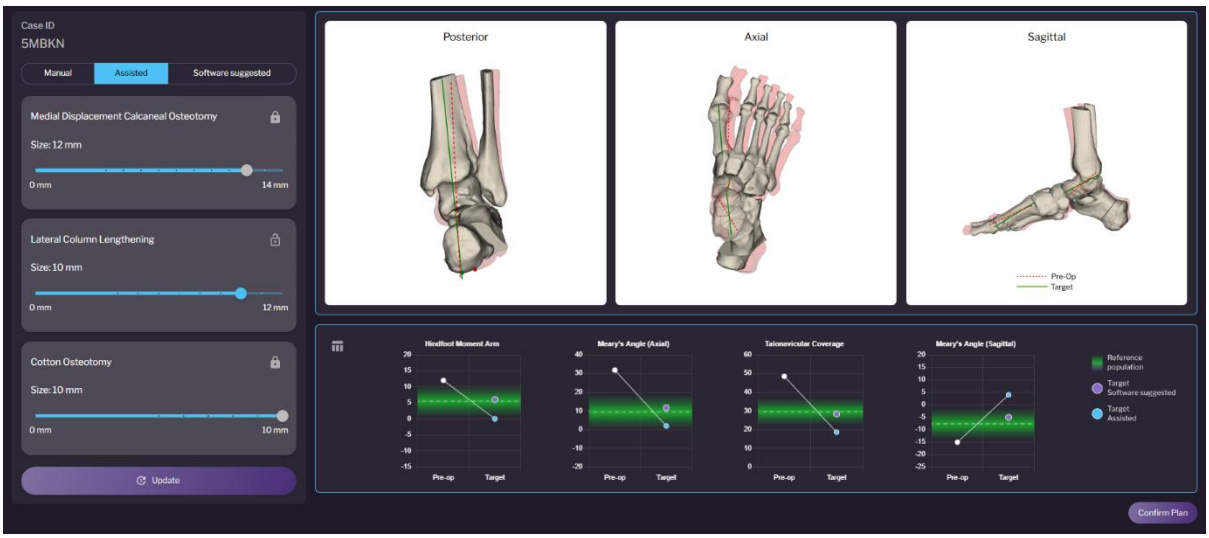
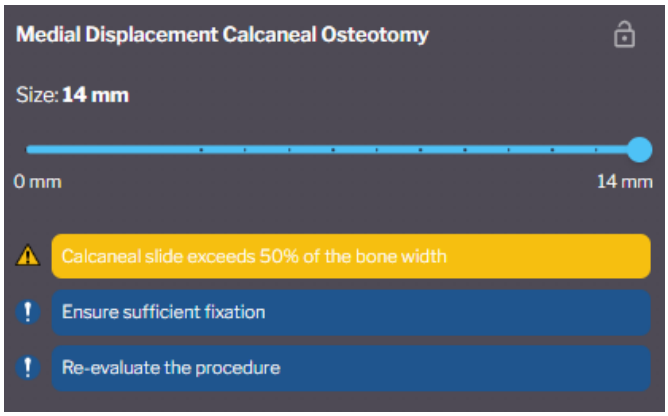


Note: The warning below appears if the magnitude of MDCO causes the calcaneus displacement to exceed half of the bone's total width.



The pre-op and target values are shown in graphical format and tabular format.

Click the Table icon in the bottom-right corner to view the measurements in tabular format.

- Tabular format includes pre-op values, target values and the change between the values.

	Hindfoot Moment Arm	Meary's Angle (Axial)	Talonavicular Coverage	Meary's Angle (Sagittal)
Pre-op	12.0 mm	31.8 °	48.5 °	-15.1 °
Change	-12.0 mm	-29.9 °	-29.9 °	15.0 °
Target	-0.0 mm	1.9 °	18.6 °	-0.1 °

Click the Graph icon in the bottom-right corner to view the measurements in graphical format.

- Reference population represents the normal population, with pre-defined reference values indicated by the dashed line. The green area illustrates the standard deviation around the average values.
- Target - Software suggested displays the case-specific target values suggested by the software.
- Target – Assisted displays the case specific-target values, reflecting the manual adjustment made.

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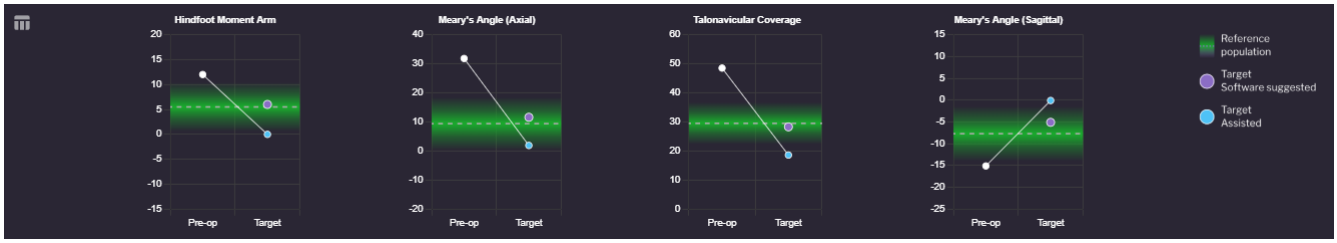
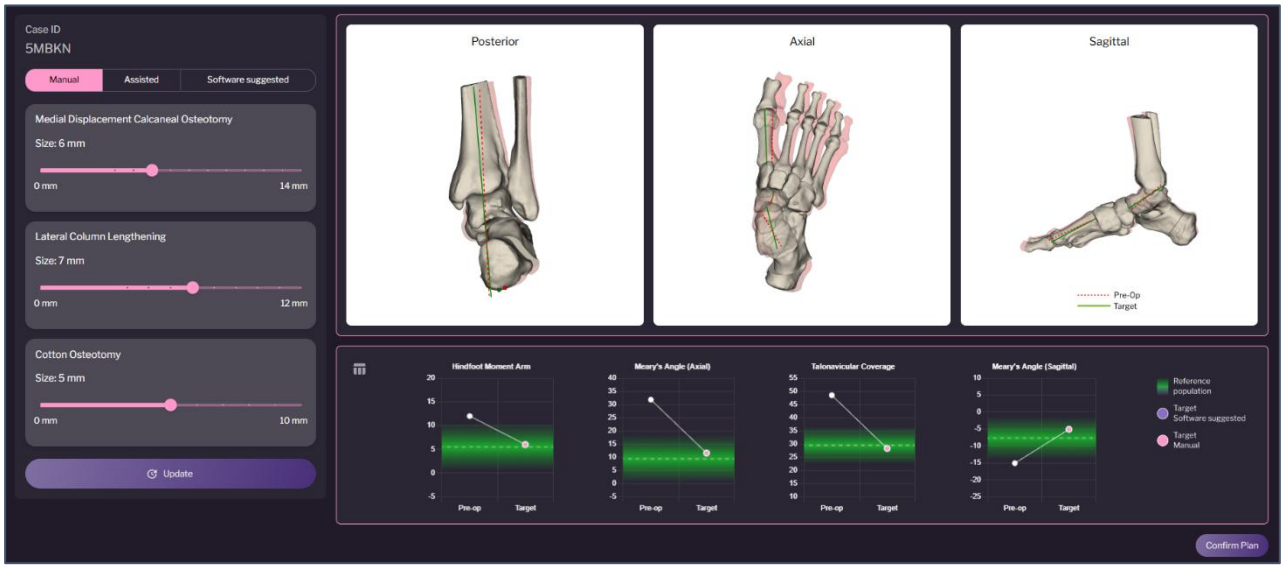
Note: See more information in chapter Measurement limits and reference values.

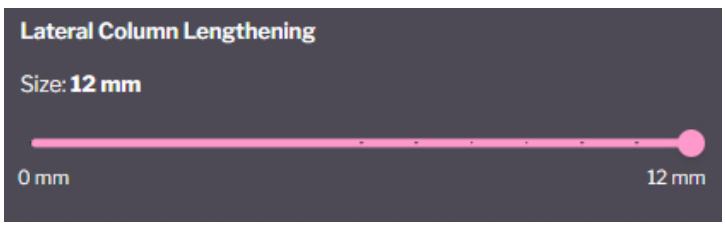


Manual mode

To manually adjust all three operations, navigate to the 'Manual' mode in the top-left corner.



- The proposed combination of operations with their magnitudes are shown on the left side.
- The 3D visualizations present posterior, axial, and sagittal views, overlaid with pre-operative and target (estimated post-op) bone measurement axes. A red overlay highlights the bones in their pre-operative state for comparison. Click the image to view it in full size.
- Manually adjust the size (mm) of the surgical operations of your choosing by using the slider. Repeat for each operation as desired.



- Click 'Update' once done. The software then adjusts the measurements and 3D visualizations according to your selection.

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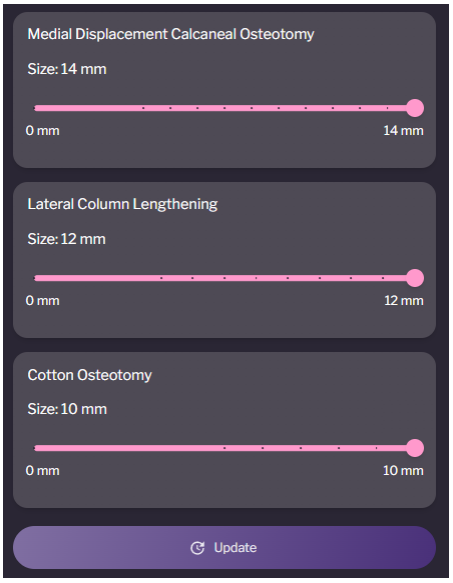
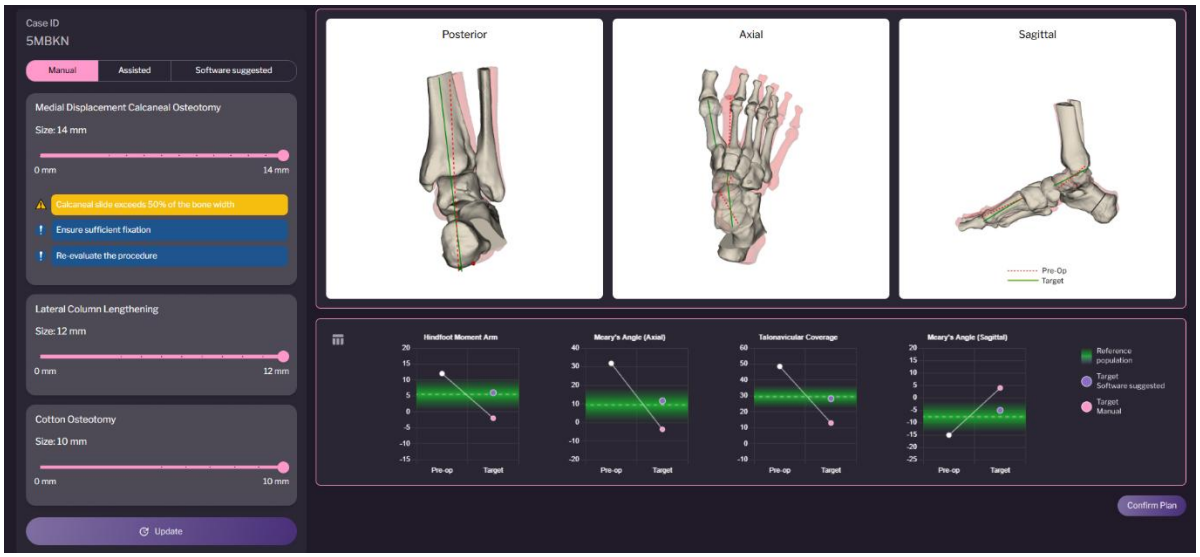


Note: If any measurement value falls outside the acceptable post-op range while manually adjusting the magnitude of the surgical operations, an "Analysis failed" error will appear. Click "OK" to return and make further adjustments to bring the analysis within the acceptable range. See more information in chapter Measurement limits and reference values.

Note: The warning “Calcaneal slide exceeds 50% of the bone width” appears if the magnitude of MDCO causes the calcaneus displacement to exceed half of the bone's total width.



The pre-op and target values are shown in graphical format and tabular format.

Click the Table icon in the bottom-right corner to view the measurements in tabular format.

- Tabular format includes pre-op values, target values and the change between the values.

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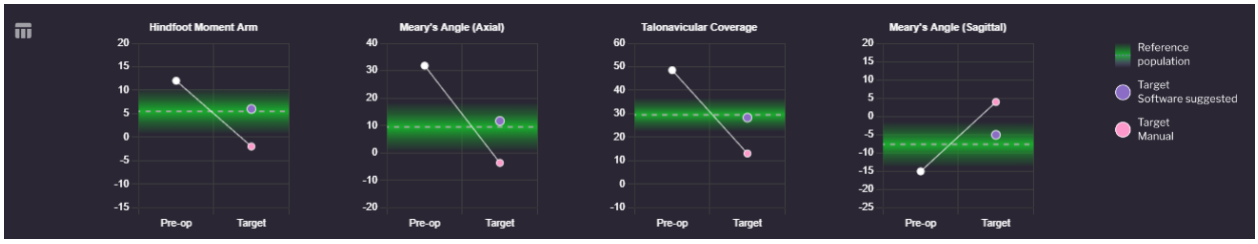
	Hindfoot Moment Arm	Meary's Angle (Axial)	Talonavicular Coverage	Meary's Angle (Sagittal)
Pre-op	12.0 mm	31.8 °	48.5 °	-15.1 °
Change	-14.0 mm	-35.5 °	-35.5 °	19.0 °
Target	-2.0 mm	-3.7 °	13.0 °	3.9 °

Click the Graph icon in the bottom-right corner to view the measurements in graphical format.

- Reference population represents the normal population, with pre-defined reference values indicated by the dashed line. The green area illustrates the standard deviation around the average values.
- Target - Software suggested displays the case-specific target values suggested by the software.
- Target – Manual displays the case-specific target values, reflecting the manual adjustment(s) made.

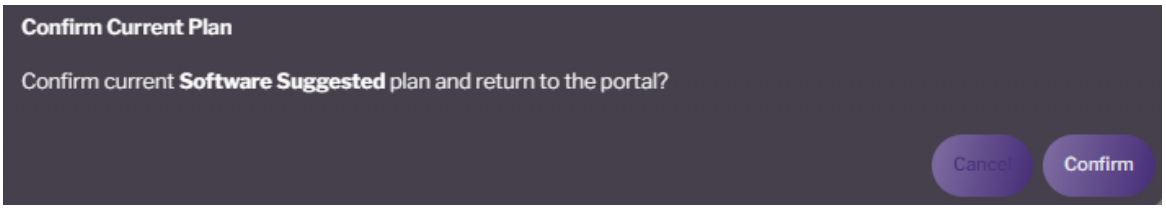


Note: See more information in chapter Measurement limits and reference values.

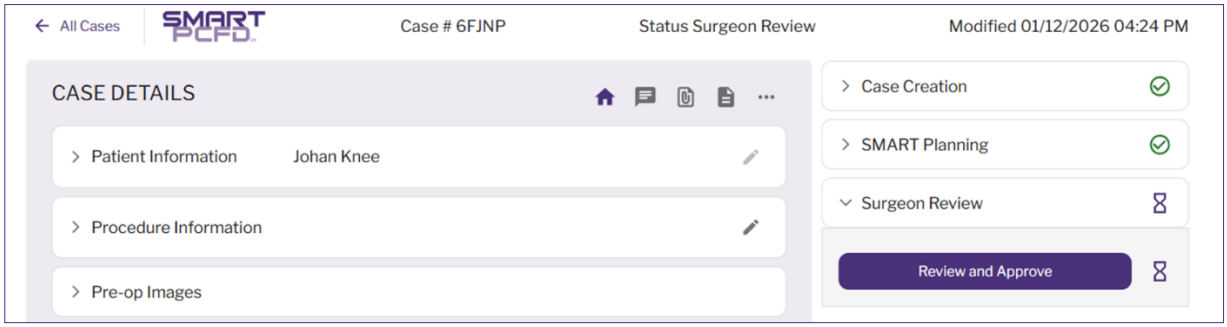
Review the results

To confirm the plan and measurements, select ‘Confirm plan’ in the bottom-right corner. To confirm a plan, ensure that the desired mode is active, as the confirmation applies to the plan currently open.

Note: In Assisted/Manual mode, confirmation applies to the most recent update. If sliders are adjusted without pressing "Update," the confirmation will reflect the previous update’s values.



After confirming the plan and returning to the SMART28℠ Case Management Portal, select ‘Review and Approve’ to proceed.



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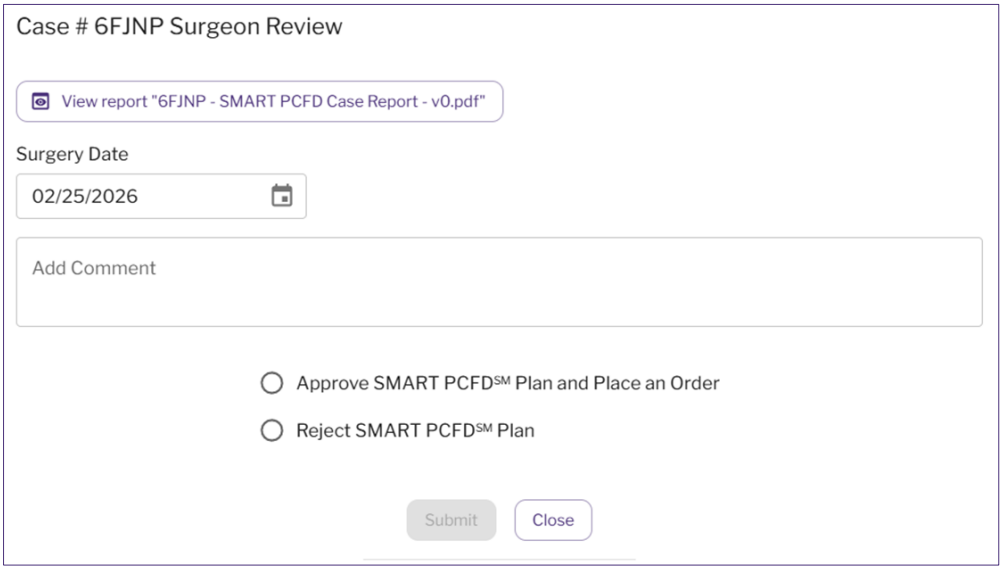
In the Surgeon Review pop-up, view the report by clicking the eye icon ‘View Report’. To complete the plan, select ‘Approve the SMART PCFD℠ Plan and Place an Order’. Rejecting the plan allows you to return to the planning.

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



4. Measurements and axes: methodology and definitions

4.1. Introduction

SMART PCFD℠ automatically calculates distances and angles between bones and specific landmarks necessary to reliably evaluate human anatomy in three-dimensions (3D). This document is a reference for users of SMART PCFD℠. It seeks to:

- Describe the general principles and processes behind the different measurements.
- List and define the measurements currently available.

4.2. General Principles

The automated bone segmentation and shape analysis of SMART PCFD℠ software enables:

- Calculation of inter-bone angles and distances between clinically relevant landmarks in patient specific coordinate system, to propose procedure combinations in PCFD patients.

4.3. Available measurements

This section defines the bone axes and describes the measurements used to calculate measurements relevant to propose procedure combinations to reach the target foot alignment.

1. All angle measurements are calculated based on 2D projections of 3D axes
    - 2D projection planes are deduced from the imaging devices patient coordinate system.
2. Measures are shown with + or – signs to represent the direction of change

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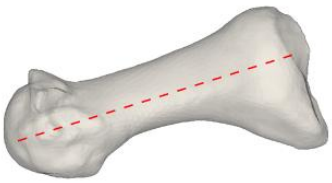
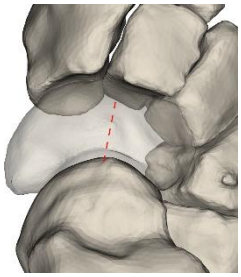
4.3.1. Bone axis definitions



Elongated bones

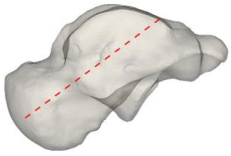
1st Metatarsal and tibia

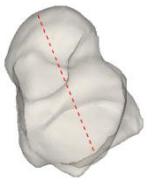
Longitudinal axis: The software determines the shaft region of the bone and its centre curve. Robust line fitting is used to find an axis representative for the curve.



Navicular

Longitudinal axis goes through the talonavicular articular surface weighted centre point and the navicular–medial cuneiform–intermediate cuneiform articular surface weighted centre point.





Talus

The software determines the talus head center point and draws a longitudinal axis that bisects the talus body in lateral view and bisects the talus trochlea in axial view.

4.3.2. Measurements

Image	Definition	Direction of Change
	Meary's Angle ***(Axial)*** The angle between the talus longitudinal axis and the 1st metatarsal longitudinal axis.	Increase in angle → Forefoot abduction Decrease in angle → Forefoot adduction
	Talonavicular Coverage ***(Axial)*** The angle between the talus longitudinal axis and the navicular axis in the axial view	Increase in angle → Forefoot abduction Decrease in angle → Forefoot adduction

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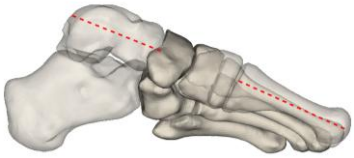
Hindfoot Moment Arm
(Posterior)
The mediolateral distance (mm) between the longitudinal axis of the tibia and most inferior point of the calcaneus.

Larger value in mm → hindfoot shifts towards valgus

Smaller value in mm → hindfoot shifts towards varus

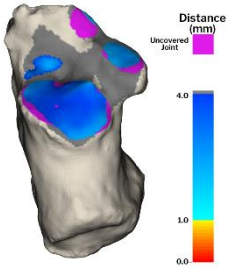


Meary's Angle
(Sagittal)

The angle between the talus longitudinal axis and the 1st metatarsal longitudinal axis.

Increase in angle → foot shifts towards pes cavus (1st MT plantarflexion)

Decrease in angle → foot shifts towards pes planus (1st MT dorsiflexion)



Peritalar distances and coverages

Distance and coverage maps illustrate the peritalar joint areas and highlight the uncovered areas. Quantitative results for covered average distances are shown for the following articular structures:

- Anterior Facet
- Middle Facet
- Posterior Facet
- Sinus Tarsi

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5. Surgical Operations: methodology and definitions

5.1. General

The SMART PCFD℠ software suggests a combination of surgical operations for PCFD correction, and outputs an estimate for post-operative foot alignment using CAD-based planning with virtual osteotomies, followed by bone group translations and rotations. The resulting rotations and translations, as well as the corresponding changes in measurement values, are determined by the selected MDCO size and the geometry of the LCL/Cotton graft or wedge. The geometry of the grafts and wedges are based on the following Paragon 28® wedges and grafts:

- LCL: PRESERVE™ Evans Lateral Column Lengthening Graft
- Cotton Osteotomy: PRESERVE™ Cotton Plantarflexing Osteotomy Graft and TITAN 3-D™ Cotton Plantarflexing Osteotomy Wedge

For further information about the wedges and grafts, please visit Paragon28 flatfoot solutions.

Note: Using implants from other manufacturers may lead to different surgical outcomes compared to Paragon28® implants, due to variations in wedge and graft geometries.

The software first creates a suggestion based on patient's pre-operative foot alignment and the pre-defined reference values, but the user can change the settings, by including or excluding surgical operations or changing their magnitudes. The software contains a foot alignment measurement template with a set of distance and angular measures, and three-dimensional (3D) visualizations. In addition, the software provides a surgical planning scenario including an estimated post-operative foot alignment and operation combination with their magnitudes. The software supports the user to perform the following osteotomies: MDCO, LCL, Cotton Osteotomy. The software compiles the visualizations, the measurements, and the surgical planning scenario into an output report.

Note: The surgical operations presented in the software form the basis for correction. Patient-specific mechanics of soft tissue interactions are not simulated. Therefore, additional soft tissue procedures may be required to achieve the planned or desired correction. These procedures should be based on careful professional assessment and determined at the surgeon's discretion and according to their preferences.

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5.2. Medial Displacement Calcaneal Osteotomy

Surgical planning of an oblique incision on the lateral heel which corrects the hindfoot valgus alignment, resulting in restoration of the medial longitudinal arch. MDCO displaces posterior part of calcaneus medially in the posterior view leading to reduction of Hindfoot Moment Arm by 1 mm per 1 mm of displacement and slight supination of hindfoot in axial view (approximately 0.35 degrees / mm by patient anatomy). Refer to Figure 1 for illustration.

Figure 1 Illustration of MDCO.

5.3. Lateral Column Lengthening

Surgical planning of anterior beak osteotomy of the calcaneus with bone graft lengthening which gives correction of symptomatic flexible flatfoot by adducting and plantarflexing the longitudinal arch and supinating the subtalar joint while preserving the calcaneocuboid joint. Hindfoot rotates in the axial view according to the graft size leading to reduction of axial measurements Meary's Angle and Talonavicular Coverage by approximately 2.5 degrees / mm (Table 6). Refer to Figure 2 for illustration.

Table 6 Graft size effect on axial measurements provided by the software.

Graft size	Medial-lateral angle
4 mm	10.4°
5 mm	13.0°
6 mm	15.5°
7 mm	18.1°
8 mm	20.6°
9 mm	23.1°
10 mm	25.6°
11 mm	28.1°
12 mm	30.5°

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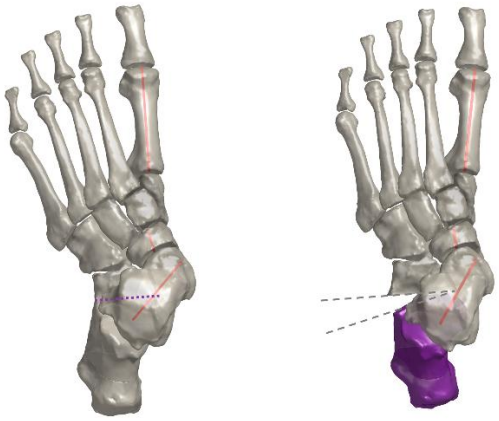

Figure 2 Illustration of LCL.

5.4. Cotton Osteotomy

The planning function supports the user in the surgical planning of the midfoot articular surfaces preserving correction of the distal medial column which gives an additional option to correct the condition of pes planus (the fallen medial longitudinal arch of the foot). The forefoot rotates in sagittal view according to the graft size leading to an increase in the sagittal Meary's Angle by approximately 2 degrees/mm (Table 7). Refer to Figure 3 for illustration.

Table 7 Graft/Wedge size effect on the sagittal arch.

Graft size	Plantarflexion angle
5 mm	10°
6 mm	11°
7 mm	13°
8 mm	15°
9 mm	17°
10 mm	19°

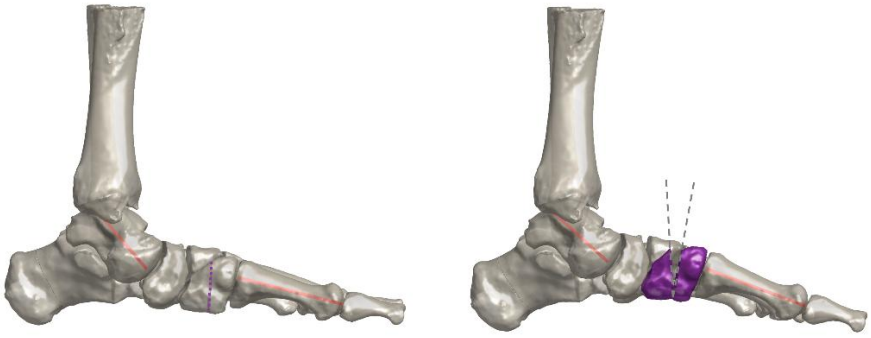

Figure 3 Illustration of Cotton Osteotomy.

5.5. Principles for selecting the surgical operation combination

- Software suggested and Assisted mode attempt to find a combination of operations that brings the estimated post-op foot alignment closest to the pre-defined reference values.

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- All operations are included in Software suggested mode, while Assisted mode allows removal of the procedures. In manual mode, software does not make adjustments to the operation magnitudes.
- Software does not suggest MDCO exceeding half the calcaneus width and LCL exceeding 8mm until both MDCO and Cotton have reached their maximum values (unless selected by the user in the Assisted mode).

5.6. Measurement limits and reference values

There are specific ranges and reference values defined for foot-alignment measurements in the software. The ranges are used as limitations in the software both within pre-operative and post-operative analysis. The reference values are used as pre-defined settings in the software.

The pre-operative foot alignment measurement range has been determined by analyzing a set of PCFD patient's pre-operative imaging datasets and defining their average alignment parameters with ±3SD. This range is used to define the limits for pre-operative foot alignment measurements, meaning that if the pre-operative analysis is outputting any measurement value outside of the defined range, the software is limited to proceed. Similar methodology has been used to define and limit the post-operative foot alignment measurements. The range for each measurement is presented in Table 8.

Table 8 Measurement range used in SMART PCFD℠.

Measurement	Pre-op (Range)	Estimated post-op (Range)
Meary's Angle (Axial)	[-2, 56] °	[-13, 56] °
Talonavicular Coverage (Axial)	[28, 65] °	[10, 65] °
Hindfoot Moment Arm (Posterior)	[3, 42] mm	[-11, 42] mm
Meary's Angle (Sagittal)	[-59, -4] °	[-59, 11] °

The pre-defined reference values for foot alignment have been determined by using the SMART PCFD℠ software and analyzing a set of control feet. The software output for the references is presented as a value with a range of ±1SD in Table 9.

Pre-defined reference values for foot alignment are visualized to the user in the software user interface (UI) and in the output report with the associated standard deviation.

Table 9 Measurements with normal population references, along with their associated standard deviations.

Measurement	Pre-defined reference values (Normal population references)
Meary's Angle (Axial)	9.4° (±9.1)
Talonavicular Coverage (Axial)	29.5° (±7.3)
Hindfoot Moment Arm (Posterior)	5.5 mm (±4.9)
Meary's Angle (Sagittal)	-7.7° (±6.3)

5.7. Graft/wedge size

The SMART PFCD℠ includes wedges and grafts of various sizes to achieve optimal surgical outcomes. The user may adjust the wedge/graft size as presented in Table 10.

Table 10 The value range for wedges/grafts for the different operations.

Operation	Range (mm)

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Medial Displacement Calcaneal Osteotomy	0, 4-14 (with 1 mm interval)
Lateral Column Lengthening	0, 4-12 (with 1 mm interval)
Cotton Osteotomy	0, 5-10 (with 1 mm interval)

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5.8. Performance specification

SMART PCFD℠ performance was validated in compliance with IEC 62304:2006. The performance of SMART PCFD℠ was validated with 50 PCFD patient cases (referred to as 'cases'). The data included cases with co-occurring conditions of osteoarthritis. Three clinicians independently reviewed and graded the 50 case reports from the software. The bones axes are the basis of the pre-operative measurements, and the surgical planning algorithm. The clinicians found that the bone axes were clinically relevant and supported surgical planning in 99.43% of cases. The range of pre-op measurements varied across the validation data (Table 11).

Note: Cases where the pre-op state is outside of this range should be interpreted carefully.

Table 11 Range of pre-op measurements for the validation of SMART PCFD℠.

	Pre-op measurement (min-max)
Meary's Angle (Axial)	(13.8°– 50.4°)
Talonavicular Coverage (Axial)	(33.1°– 62.3°)
Hindfoot Moment Arm (Posterior)	(3.6 – 33.9 mm)
Meary's Angle (Sagittal)	(−51.1° – −10.8°)

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6. Data management & software architecture

Illustration of the SMART PCFD℠ software architecture and listed functionalities is below.

SMART PCFD℠ software is provided as a web user interface and a cloud service with access through SMART28℠ Case Management Portal.

1. DICOM data, user interface
    a. User logs in to the SMART28℠ Case Management Portal with username, password and multifactor authentication. Access is secured with Azure AD B2C token.
    b. DICOM image is uploaded through the web user interface
2. Pre-processing and visualizations, user interface
    a. 2D visualizations of input imaging data are shown on web user interface before computations are started.
    b. Users provide necessary procedure and patient information to start the computations.
3. File upload to cloud, user interface
    a. DICOM data is de-identified. DICOM data and user defined parameters are sent to SMART PCFD℠ software cloud service using HTTPS connection.
    b. HTTPS connection is secured with a TLS certificate.
4. Computations, cloud service
    a. Cloud solver calculates analysis models and measurements.
    b. Results are saved as numeric data.
    c. Original DICOM data is deleted, de-identified data is retained.
    d. Measurement results can be used for diagnostic purposes.
5. Result presentation, user interface
    a. Case specific results are available in the UI. Final analysis report is downloaded via HTTPS connection and accessible via SMART28℠ Case Management Portal.

6.1. Cloud domain address

The HTTPS address to the Disior™ cloud in the US: https://smart.paragon28.com/. The domains listed in Table 12 are utilized for network traffic.

Table 12 Cloud 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

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6.2. 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.

6.3. Disior™ Cloud environment

The analysis server specification:

- The server used for the analysis calculation is physically located in the USA.
- The client side needs to have whitelisted the domain for Disior™ Cloud.
- A separate instance is formed for each analysis calculation.
- The server is protected by Azure network elements and layered network structure.
- The Cloud instance is running on Linux Operating System.

6.4. Data processing

6.4.1. Elements

Element 1: DISIOR™ Cloud connection

1. User authentication to open software
2. Disior™ cloud, Microsoft Azure based, HTTPS/TLS certificate, domain needs to be accessible from the used location
3. DoS prevention and firewall at server network

Element 2: DISIOR™ Cloud

1. The Cloud service is physically located in USA
2. Separate instance is formed for each analysis
3. No patient identifiable information data is stored
4. Log files are stored, and de-identified image data is stored in USA
5. Server is protected by Microsoft Azure API Management
6. Cloud instances are updated regularly

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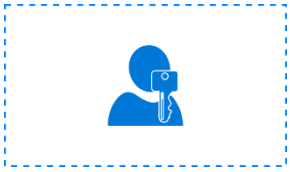
6.4.2. Data flow description

Step 1: DICOM Image handling in client workstation



1. DICOM file(s) is read in DICOM reader
2. No patient identifiable information is displayed on client workstation/software.
3. The analysis is initiated after image upload and the image series is sent to the Cloud for analysis

Step 2: Analysis in DISIOR™ Cloud

1. Client initiates the file transfer through secure HTTPS connection
4. Client monitors cloud analysis in software: the secure HTTPS connection monitors progress until solver is ready
6. Client receives the results files

2. Server receives the image series, which is then de-identified
3. The image series is analysed
5. After the solver is ready and analysis is successful, results file is sent to client through the secure HTTPS connection
7. Forced deletion of original image series files. De-identified image series is retained.

Step 3: Save and exit

1. User saves the analysis

2. Forced deletion of the instance. Analysed cases remain in the SMART28℠ Case management system and existing case reports can be downloaded by the user.

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