Exclusively foot & ankle

Paragon 28®

SMART Bun-Yo-Matic℠ Xray 1.0

INSTRUCTIONS FOR USE

IFU Version 7.0 2025-03-04

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1 General Information

This User Guide describes the functionality of the SMART Bun-Yo-Matic℠ Xray 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 Description of SMART Bun-Yo-Matic℠ Xray

SMART Bun-Yo-Matic℠ Xray software is intended to be used by orthopedic healthcare professionals to assist in the characterization of anatomical structures of foot and ankle using three-dimensional mathematical modeling and radiographic measurements. The combined information from structural models and radiographic measurements can be used for diagnostic and treatment planning purposes. DICOMs from weight-bearing plain film x-ray (WB X-ray) devices are the intended medical image input.

1.2 Indications for use

SMART Bun-Yo-Matic℠ Xray software is to be used by orthopedic healthcare professionals for diagnosis and surgical planning in a hospital or clinic environment. The intended input for the software is medical images from WB X-ray.

The SMART Bun-Yo-Matic℠ Xray software provides:

- Visualization report of measurements in the context of the anatomical structures of foot and ankle and three-dimensional (3D) models of orthopedic fixation devices,
- Measurement templates containing radiographic measures of foot and ankle,
- Surgical planning application for visualization of foot and ankle anatomical three-dimensional structures, radiographic measures, and surgical instrument parameters.

The visualization report containing measurements and models can be used to assist diagnosis of orthopedic healthcare conditions. The surgical planning application contains visualizations of radiographic measurements within the context of 3D structural models of a patient's foot and ankle, models of orthopedic fixation devices and surgical instrument parameters that together can assist physicians in treatment planning and operations to correct orthopedic healthcare conditions of foot and ankle.

1.3 Software contraindications

SMART Bun-Yo-Matic℠ Xray software is not intended for anatomies other than 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 diagnosis and treatment planning of orthopedic healthcare conditions without careful professional assessment. The software output should not be used for planning purposes if the X-ray 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 images were obtained.

1.4 Target patient group

Target patient group is from adults (over 16 years) to geriatric without any specific limits for demographics. The intended target population excludes patients with open epiphyseal growth plates and high-risk population with respect to the medical condition.

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.

1.5 Users

The intended operator users are radiologists or medical doctors (optional specialism in orthopedics).

1.6 System compatibility

SMART Bun-Yo-Matic℠ Xray software is a web application without specific hardware requirements for executing the software. SMART Bun-Yo-Matic℠ Xray 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 124.0.2478.80, 64-bit)
	Google Chrome (Version 124.0.6367.119, 64-bit)
	Mozilla Firefox (Version 125.0.3, 64-bit)
Microsoft Windows 11 Enterprise Version 23H2 (OS Build 22631.3447)	Microsoft Edge (Version 124.0.2478.80, 64-bit)
	Google Chrome (Version 124.0.6367.156, 64-bit)
	Mozilla Firefox (Version 125.0.3, 64-bit)
Apple macOS (Version 13.2)	Apple Safari (Version 16.3, 18614.4.6.1.5)
Apple iPadOS (Version 18.3.1)	Apple Safari (Version 18.3, 20620.2.4)
Android 14 (Version 16.0.198)	Google Chrome (Version 133.0.6943.121)

SMART Bun-Yo-Matic℠ Xray software provides parameters for Paragon 28® Bun-Yo-Matic™ Lapidus Clamp System (Figure 1). Refer to the Paragon 28® Bun-Yo-Matic™ Instructions for Use for further information about the system and executing the procedure according to the Surgical Technique Guide.

Figure 1 Paragon 28® Bun-Yo-Matic™ Lapidus Clamp System.

1.7 Imaging data quality requirements

In the SMART Bun-Yo-Matic℠ Xray software, the quality of the outputs (including visualizations) is determined by the quality and resolution of the DICOM images from the WB X-ray device. This section describes the imaging parameters required for safe and effective use of the software.

1.7.1 Acceptable DICOM images

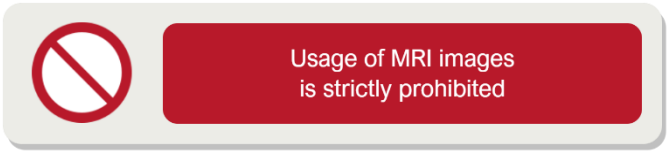
The only acceptable inputs are DICOM images from WB X-ray devices that adhere to the parameters in Table 2.

Table 2 Required image specifications.

Description	Specifications
Patient ID	Original ID is present
Patient Position	• Weight-bearing • Constant pose between scans
Required X-ray Images	• Dorsoplantar series: AP projection with X-ray tube rotated 10° frontally to allow weight-bearing, beam centered on the base of 3rd Metatarsal. • Lateral series: True lateral view, beam centered on the base of the metatarsals.

Field-of-View	• Dorsoplantar (AP) series
	  ○ All bones of the foot (forefoot and hindfoot) completely within view. The Talus and Calcaneus should also be within view even if occluded by distal aspect of tibia and fibula.
	• Lateral series
	  ○ All bones of the foot (forefoot and hindfoot) within view.

Source-Image Receptor Distance (SID)	Approximately 1000mm/40 inches
Exposure	• Tube current: 3-6mAs • Tube voltage: 50-60kVp



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

1.7.2 Required DICOM tags

The DICOM tags listed in Table 3 are required to be present on all images used for analysis in conformance with NEMA PS 3.1 - 3.20 2023e. If a tag is missing, the DICOM image series is not valid, and the software is unable to analyze the image.

Table 3 Required DICOM tags.

Name	DICOM Tag	Required (value) for Image Modality	
		Digital Radiography (DX)	Computed Radiography (CR)
Modality	(0008,0060)	x	x
SOP Class UID	(0008,0016)	x	x
Study Description	(0008,1030)	x	x
Series Description	(0008,103e)	x	x
Imager Pixel Spacing	(0018,1164)	x	x
Study Instance UID	(0020,000d)	x	x
Series Instance UID	(0020,000e)	x	x
Photometric Interpretation	(0028,0004)	(MONOCHROME1 or MONOCHROME2)	
Rows	(0028,0010)	x	x
Columns	(0028,0011)	x	x
Pixel Spacing	(0028,0030)	x*	x*
Bits Allocated	(0028,0100)	(16)	(16)
High Bit	(0028,0102)	x	x

*required if the image has been calibrated

CAUTION: Conformance to the DICOM standard is required. Incorrect values for Pixel Spacing (0028,0030) or Imager Pixel Spacing (0018,1164) will cause inaccurate measurement results.

1.8 Software product characteristics

Table 4. 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 Bun-Yo-Matic℠ Xray software consists of two components:

1) The web user interface used for selecting input images for analysis, reviewing output report and adjusting values for the planning (optional).
2) The cloud service provides the analysis service, measurements and surgical plan.

The software is used in conjunction with the SMART28℠ Case Management Portal. Supported web browsers for web user interface are listed in chapter System compatibility. SMART Bun-Yo-Matic℠ Xray software requires connection to Disior™ cloud service (Table 5) and may require actions by Hospital IT (e.g. if connection is prevented by firewalls).

Table 5 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 Bun-Yo-Matic℠ Xray software has interface to SMART28℠ Case Management Portal with data management feature for downloading existing case reports. See chapter Data processing for further details.

1.11 Cybersecurity

Details of the cybersecurity controls of the SMART Bun-Yo-Matic℠ Xray software are shown in Table 6. As part of good cybersecurity practice, the user should access the site only by typing the address into browser directly, or from secure links, and check from the browser that the connection is secure and to the intended web page (see Cloud domain addresses).). Use of shared computers is not recommended, however, if used, the browser history, cookies and caches should be cleared at the end of the session.

If cybersecurity vulnerabilities or incidents are detected, or there is suspicion that login information has been compromised (e.g. unexpected security notifications that involve password resets) the user should contact support as soon as possible (see Contact Information).

Table 6 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 Bun-Yo-Matic℠ Xray 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 Release Notes

Software version number 1.2.3

Notes date March 4th, 2025

Overview

SMART Bun-Yo-Matic Xray℠ 1.0 (UDI-DI: 06429810209047) original release software version is 1.0.0 (UDI-PI: 1.0.0) (July 9th, 2024). This release note is for software version 1.2.3. Below listed changes from the original release version to the latest.

Modified software features

Version 1.0.3 (August 30th, 2024):

- Planned Bun-Yo-Matic™ rotation correction towards pronation (negative values) are presented as Not Applicable (N/A) value.
- While in SMART Planning, added button to return to the original plan values (according to automated surgical planning methodology).

Version 1.1.5 (November 25th, 2024:

- Streamlined workflow:
    - Analysis initiated after image upload and laterality selection.
    - Case report approval only in Case Management Portal.
    - Metatarsus Adductus selection can be changed through Restart Analysis without rerunning analysis.
    - Support team can help progressing case for the User.
- Minor wording changes with UI and case report.

Version 1.2.3 (March 5th, 2025):

- Analysis of frontal plane Rotation with Xray images adjusted to remove bias compared to CT images (Xray rotation impacted by approximately 4.5 degrees higher values)
- Metatarsus Adductus correction threshold based on 2nd Tarsometatarsal angle was reduced from 24° to 20°
- Improved visualization of metatarsal when Metatarsus Adductus is addressed (4th MT is moved between 3rd and 5th MT)

Software enhancements

Version 1.0.3 (August 30th, 2024):

- DICOM processing improved to support compressed formats.

Version 1.1.5 (November 25th, 2024):

- Analysis improved with low contrast images.
- Enhanced handling of compressed images.

Version 1.2.3 (March 5th, 2025):

- Security updates

1.13 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.

1.14 Contact Information

1.14.1 Software Support

Customer support is available through disior.support@paragon28.com and the software HELP page. 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. Direct link to electronic Instructions for Use is also available through the software HELP page. A paper copy of Instructions for Use may be requested by contacting disior.support@paragon28.com.

1.14.2 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

SMART Bun-Yo-Matic℠ Xray software interfaces with the SMART28℠ Case Management Portal. SMART Bun-Yo-Matic℠ Xray software is intended to be operated by radiologists or medical doctors (optionally with an orthopedic specialty) who have completed user training of the software and read this Instructions for Use document.

Verification that SMART Bun-Yo-Matic℠ Xray X-ray 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 chapter contains important information for the safe and effective use of the SMART Bun-Yo-Matic℠ Xray 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.
	**Medical Device** Indicates the product is a medical device.
	**Consult Instructions for Use (IFU)** Indicates the need for the user to consult the Instructions for Use or the electronic Instructions for Use (eIFU). eIFU Indicator may contain the URL of the 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 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.
	**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 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 the risks that remain in the medical software and should be considered by the user to make informed decisions about software use. Residual risks in the SMART Bun-Yo-Matic℠ Xray 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 orthopedic assessment. Additionally, users should rely on their clinical expertise to detect and evaluate the impact of geometrical nonconformities.

SMART Bun-Yo-Matic℠ Xray 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 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. Error 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.

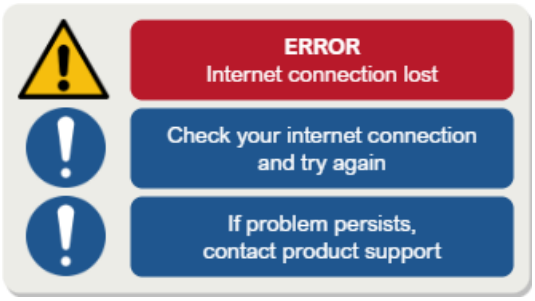
2.3 Safety Messages

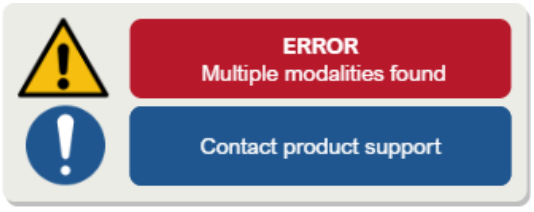
2.3.1 General Safety Information

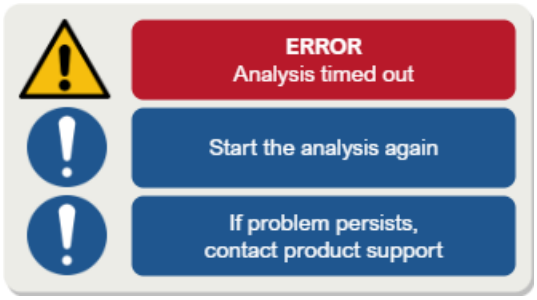
Safety information for the SMART Bun-Yo-Matic℠ Xray user is summarized below:

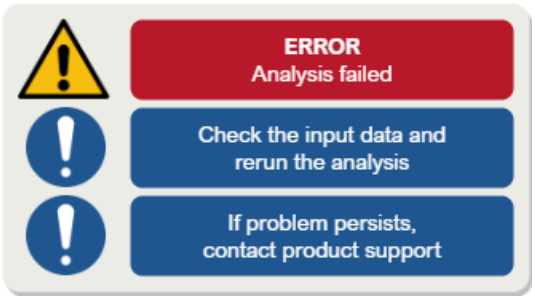
2.3.2 Error Messages

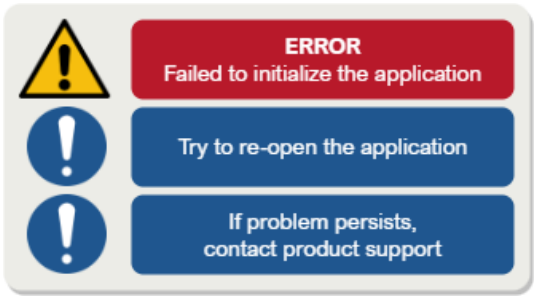
The following Error Messages with Mandatory Actions may be issued by the SMART Bun-Yo-Matic℠ Xray software:

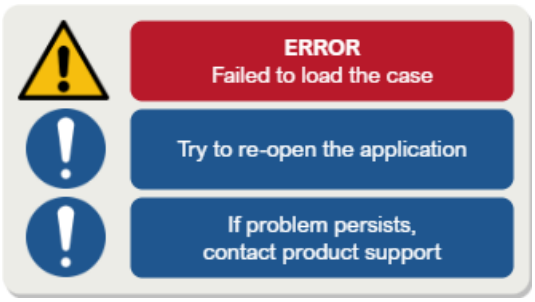


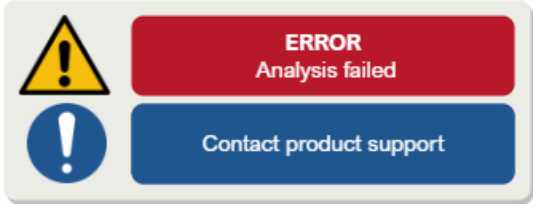






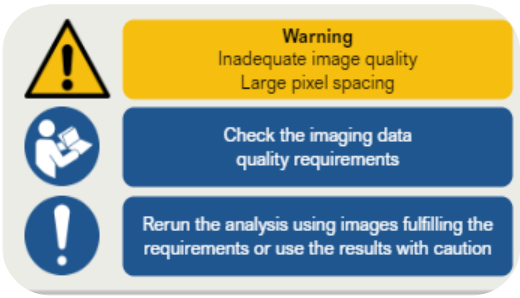


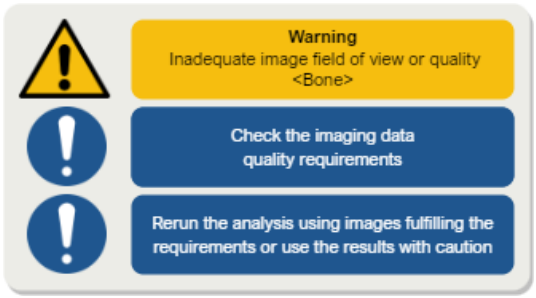


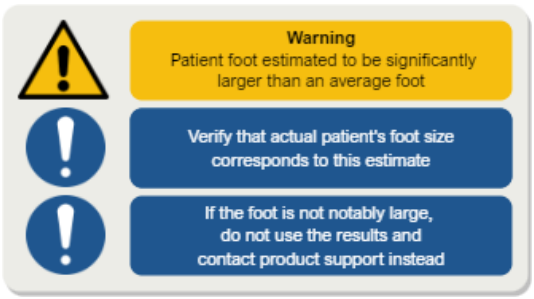


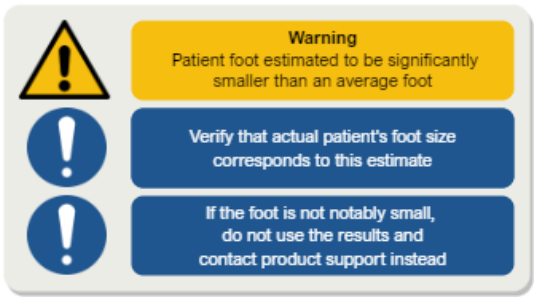
2.3.3 Warning Messages

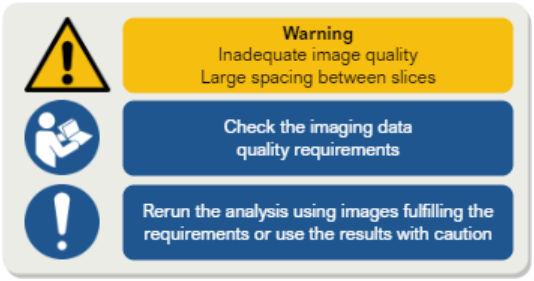
The following Warning Messages with Mandatory Actions (when applicable) may be issued by the SMART Bun-Yo-Matic℠ Xray software:

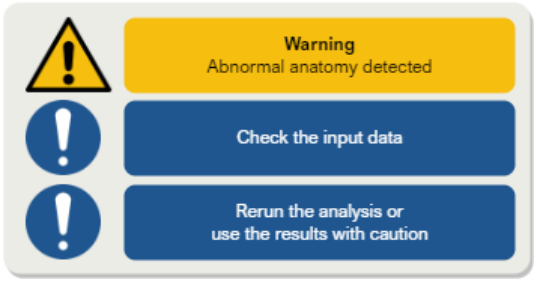


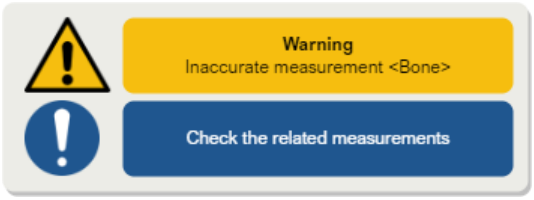


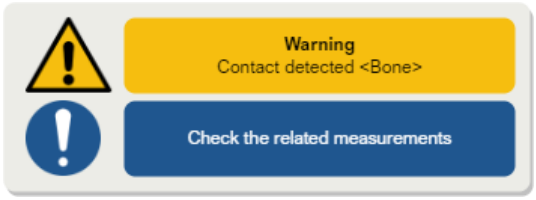


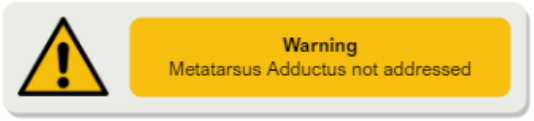


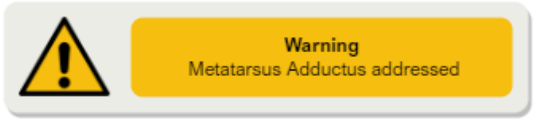


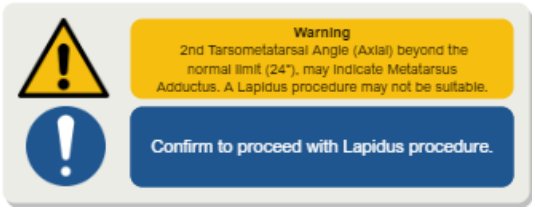


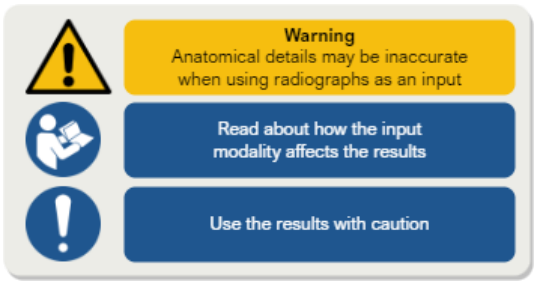












2.4 Informative notes

SMART Bun-Yo-Matic℠ Xray software issues notes (when applicable) on the Case Report as presented in Table 7.

Table 7 Informative notes issued by SMART Bun-Yo-Matic℠ Xray on the Case Report.

Note	Condition	Position
The target IMA was limited by 1st – 2nd Metatarsal head proximity.	Displayed if 1st Metatarsal head is closer than ~2 mm from the 2nd Metatarsal.	Displayed on page 2 "Hallux Valgus correction" below the IMA.
ATTENTION: Metatarsus Adductus correction to be addressed by surgeon. Correction visualized by moving 2nd and 3rd rays to align with normative reference values of Tarsometatarsal Angles; 4th ray moved between 3rd and 5th rays.	Displayed if pre-op value of 2nd Tarsometatarsal Angle is larger than a threshold of 20° and user chose to address Metatarsus Adductus.	Displayed on page 3 "Hallux Valgus correction" below the 2nd Tarsometatarsal Angle.
Potential Metatarsus Adductus not addressed.	Displayed if pre-op value of 2nd Tarsometatarsal Angle is larger than a threshold of 20° and user chose to not address Metatarsus Adductus.	Displayed on page 3 "Hallux Valgus correction" the 2nd Tarsometatarsal Angle.
Structure at risk. Shortening may indicate a decline in plantar soft-tissue function.	Displayed if the difference between the post-op and pre-op values for Relative Length 1st – 2nd Metatarsal is less than -4mm.	Displayed on page 3 "Hallux Valgus correction" below the Relative Length 1st – 2nd Metatarsal.
Cut slots on the Medial Cuneiform Bun-Yo-Matic™ cut guide are spaced 1.45 mm apart. Planned with the distal cut slot.	Always displayed.	Displayed on page 3 "Hallux Valgus correction" below the Relative Length 1st – 2nd Metatarsal.
This angle may indicate PCFD.	Displayed when Meary's Angle (Sagittal) is less than -15°.	Displayed on page 4 "Sagittal plane view" below Meary's Angle.
The 3D visualization does not represent a patient specific anatomy.	Always displayed.	Displayed on page 2 "Hallux Valgus Correction" top-right.

2nd cut slot on Medial Cuneiform Bun-Yo-Matic™ cut guide may be needed.	Always displayed.	Displayed on page 6 “Planned resections” top-right.
Removal of cartilage by scraping with hand tools may be needed.	Always displayed.	Displayed on page 6 “Planned resections” top-right.
Overlap identified between adjacent bones and the metatarsal base. X.X mm of approximate resection on the lateral aspect of the metatarsal base may be required to fully reduce the bones.	Displayed if the base of the 1st Metatarsal overlaps with the 2nd Metatarsal.	Displayed on page 6 “Planned resections” bottom-center
Completing correction with the Bun-Yo-Matic™ settings listed below is a recommendation only. Final correction settings are up to surgeon discretion.	Always displayed.	Displayed on page 7 “Bun-Yo-Matic™ Correction” top-center.
The translation adjustment allowable by the Bun-Yo-Matic™ system ranges from 0mm to 33mm.	Always displayed.	Displayed on page 7 “Bun-Yo-Matic™ Correction” below IMA Adjustment.
The rotation adjustment allowable by the Bun-Yo-Matic™ system ranges from 0° to 35°.	Always displayed.	Displayed on page 7 “Bun-Yo-Matic™ Correction” below 1st Metatarsal Rotation Adjustment.
The Phantom® Nail and screws are provided for visualization purposes only. Proper execution of the Phantom® Nail technique guide is required to determine final implant placement and sizing.	Always displayed.	Displayed on page 8 “Example Fixation Sizing” center.
Final fixation type may vary by surgeon preference.	Always displayed.	Displayed on page 8 “Example Fixation Sizing” center.

3 Instructions for Use

3.1 Case creation

Prior to accessing the SMART Bun-Yo-Matic℠ Xray software, a case needs to be created in the SMART28℠ Case Management Portal:

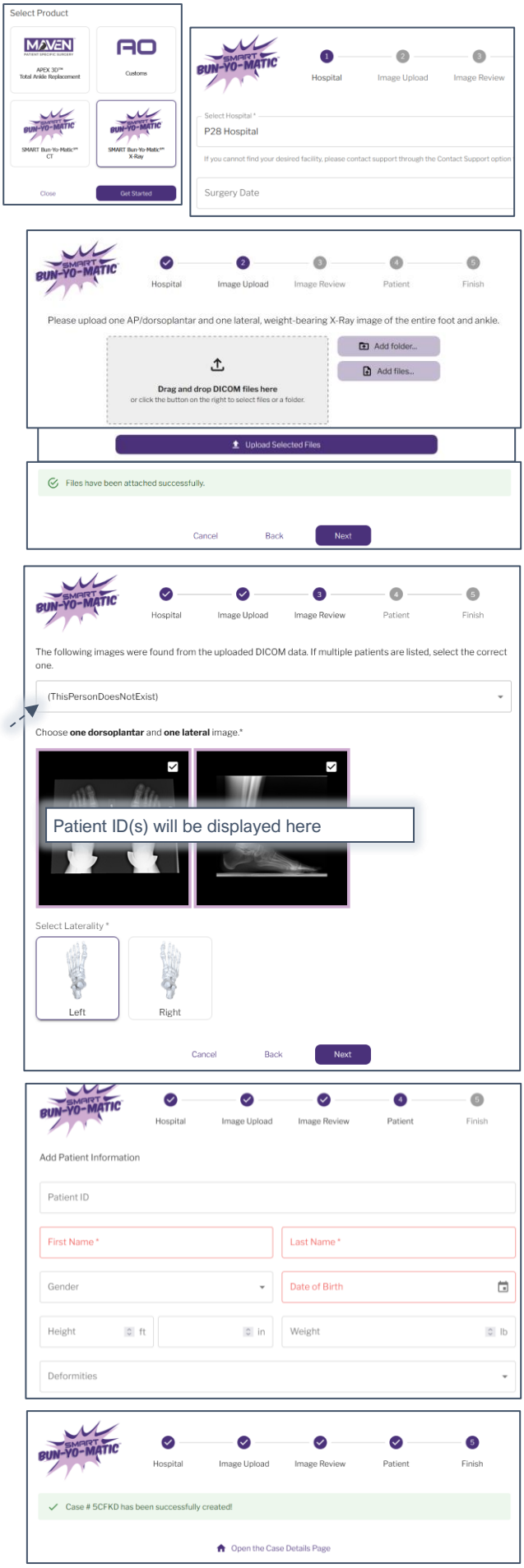
1) Login to the SMART28℠ Case Management Portal.
2) Click ‘Create case’ and choose the SMART Bun-Yo-Matic℠ Xray product and click ‘Get Started’.
3) Hospital - Select the Hospital affiliated with this case and set the surgery date.

Note: High-quality, properly formatted DICOM images are required for successful surgical planning. Ensure that the images selected meet the imaging requirements.

4) Image upload - Upload DICOM images (one AP/dorsoplantar and one lateral weight-bearing image):
    a. Add a folder or files using the buttons or drag and drop functions.
    b. Click ‘Upload Selected Files’. The data is de-identified and securely uploaded to the cloud.
    c. Once files have been attached successfully, select ‘Next’
5) Image Review - The uploaded DICOM images will appear in the preview windows. Select one weight-bearing AP/dorsoplantar and one lateral image for the analysis. Specify the laterality, then click 'Next' to continue.

Note: When images from more than one patient are uploaded, the patient IDs will be listed in the drop-down menu. Select the Patient ID before choosing the images for the case.

6) Patient - Fill in the patient data and click ‘Next’.
7) Finish – The application will generate a unique Case number and notify the user when the case has been created, to continue click ‘Open the Case Details Page’.

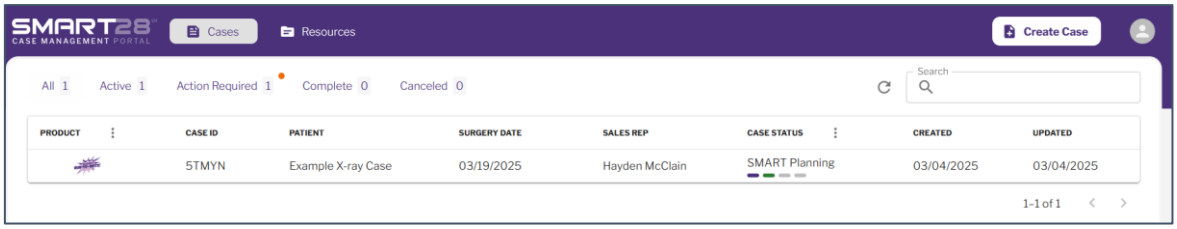


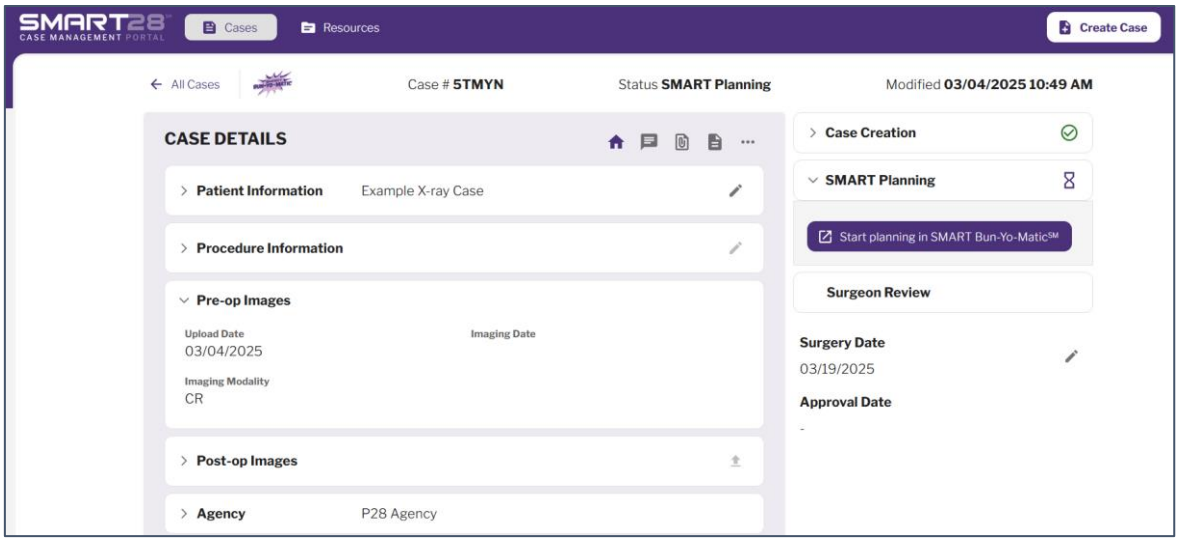
3.2 Automated analysis

The de-identified patient images and information are securely uploaded to the cloud for analysis. The original DICOM data is deleted and only the de-identified data is retained. The cloud service then generates 3D models and measurements.

NOTE: Expected time for case generation and analysis is less than 10 minutes but this is dependent on network speed and bandwidth.

1) Navigate to the 'Case Details Page' at the end of the case creation or click on a previously created case in the SMART28[SM] Case Management Portal.
2) Case Details– to check the status of the analysis click 'Start planning in SMART Bun-Yo-Matic[SM]'. Until the analysis is complete, case information and the progress of the analysis will be displayed.



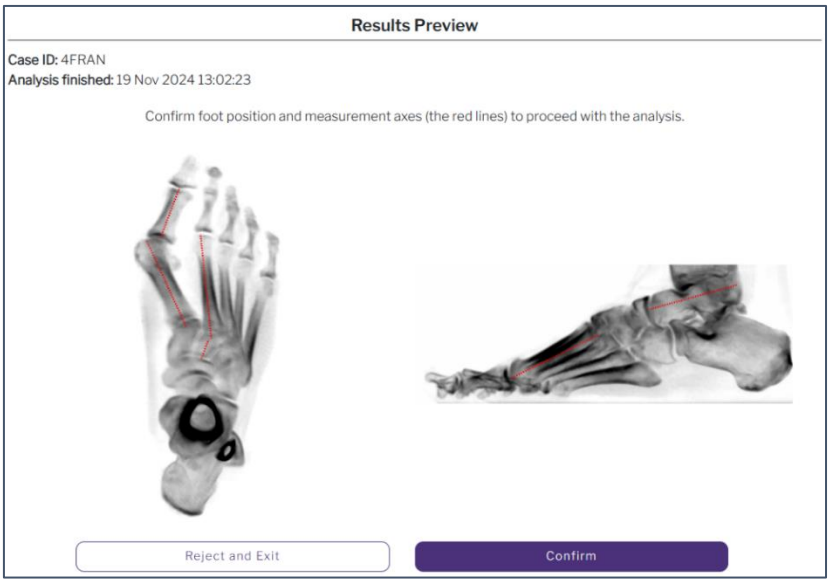


3.3 Surgical planning in SMART Bun-Yo-Matic℠ Xray

3.3.1 Results Preview

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

  Note: Analysis results are presented as native x-rays overlain with bone measurement axes and shall be subjected to careful expert assessment.



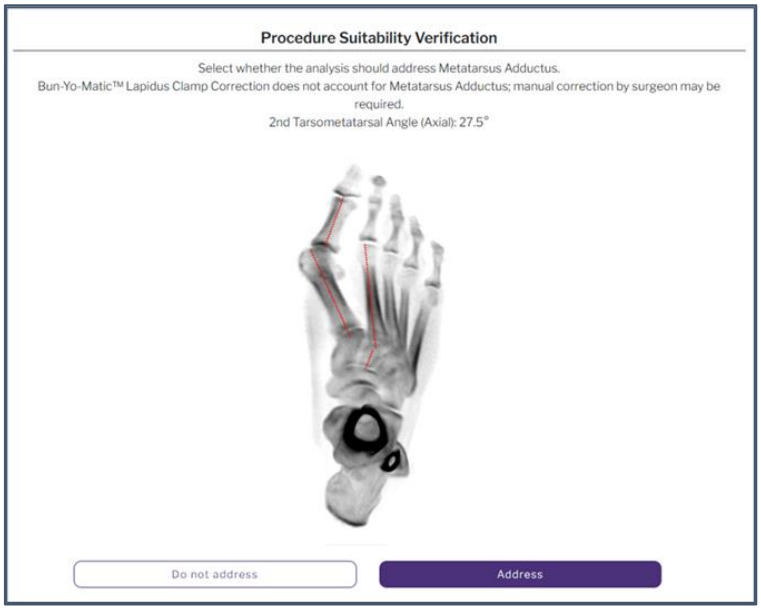
3.3.2 (If indicated) Procedure Suitability Verification

If 2nd Tarsometatarsal angle is larger than the normal limit (20°) it may indicate Metatarsus Adductus and procedure suitability verification is required by the user.

- Select ‘Confirm’ to proceed with Lapidus procedure or ‘Reject and Exit’ to return to the SMART28℠ Case Management Portal.

- Continue analysis either by addressing or not addressing Metatarsus Adductus. See more information about these options in chapter Metatarsus Adductus Correction.

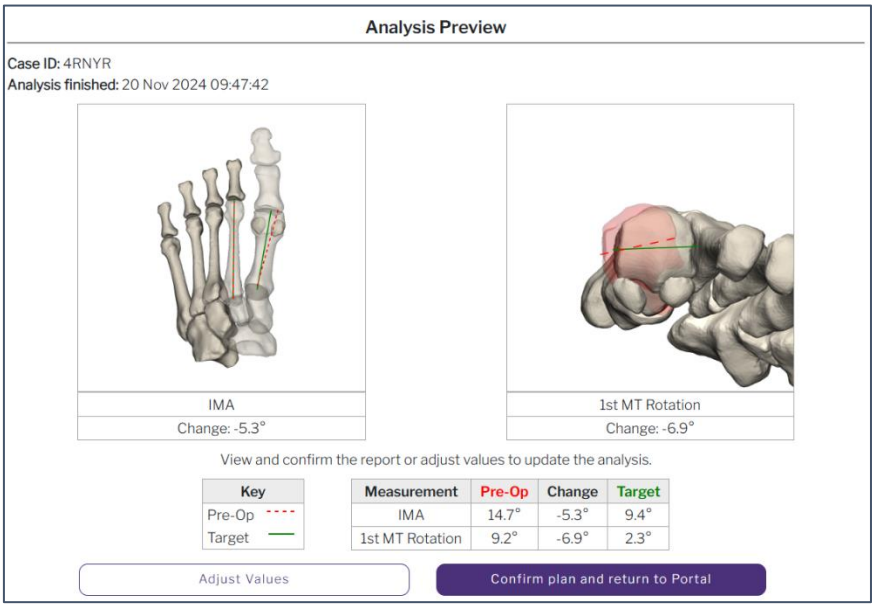
Note: Bun-Yo-Matic™ Lapidus Clamp Correction does not account for Metatarsus Adductus, manual correction by surgeon may be required.



3.3.3 Confirm measurements

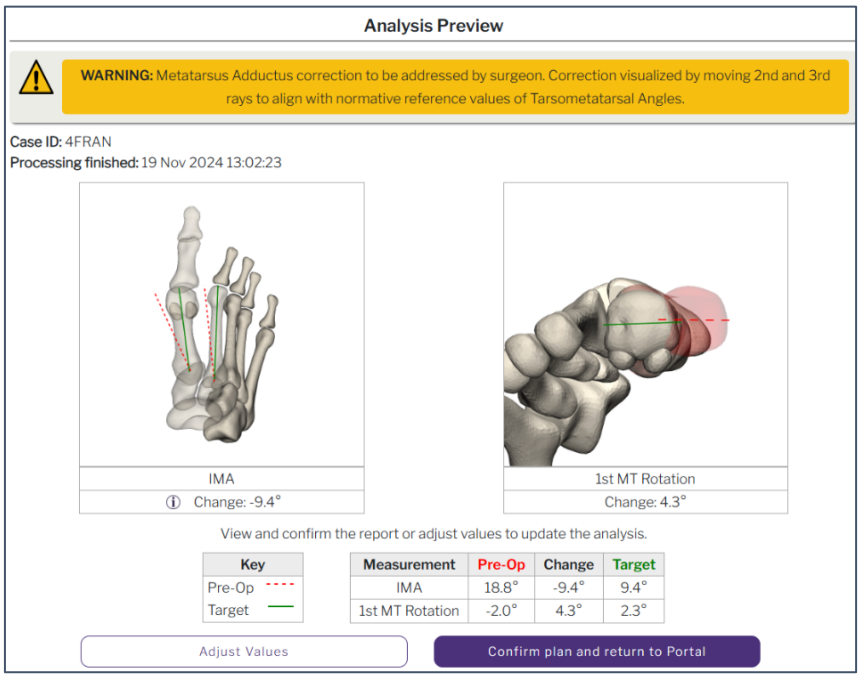
- Analysis Preview – Review preliminary analysis results. Select ‘Adjust values’ to manually adjust target measurements or select ‘Confirm plan and return to Portal’ to confirm current measurements.

Note: See measurement definitions and more information in chapters Available measurements and Automated surgical planning application: methodology and definitions.



- Analysis Preview when Metatarsus Adductus is addressed. When Metatarsus Adductus is addressed, IMA is affected by 1st Metatarsal axis rotation and 2nd Metatarsal axis rotation. Hover the cursor over the icon next to the IMA Change to see the related measurements.

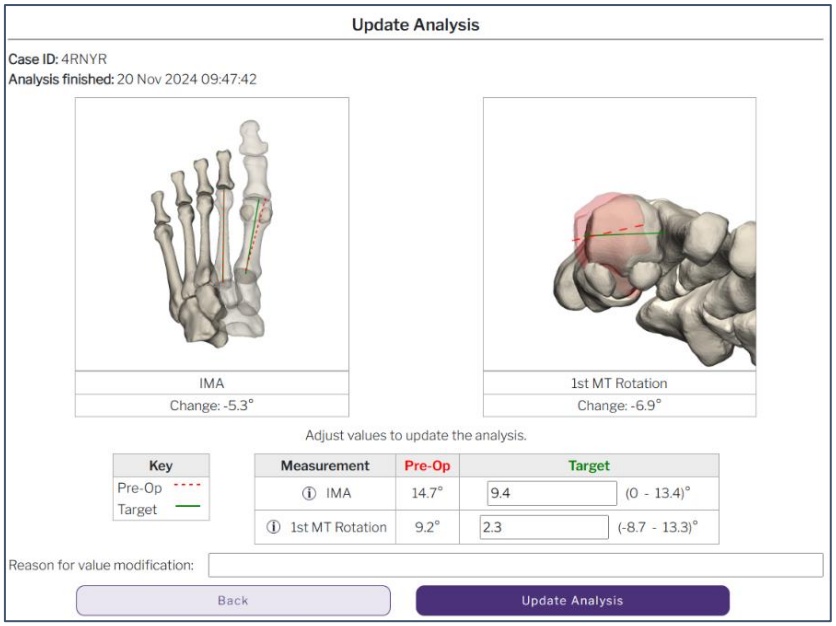
Note: Metatarsus Adductus correction to be addressed by surgeon. The correction is visualized by moving the 2nd and 3rd rays to align with normative reference values of Tarsometatarsal Angles. Additionally, the 4th ray is moved between the 3rd and 5th rays. See section Metatarsus Adductus Correction for more information.



3.3.4 (Optional) Adjust values

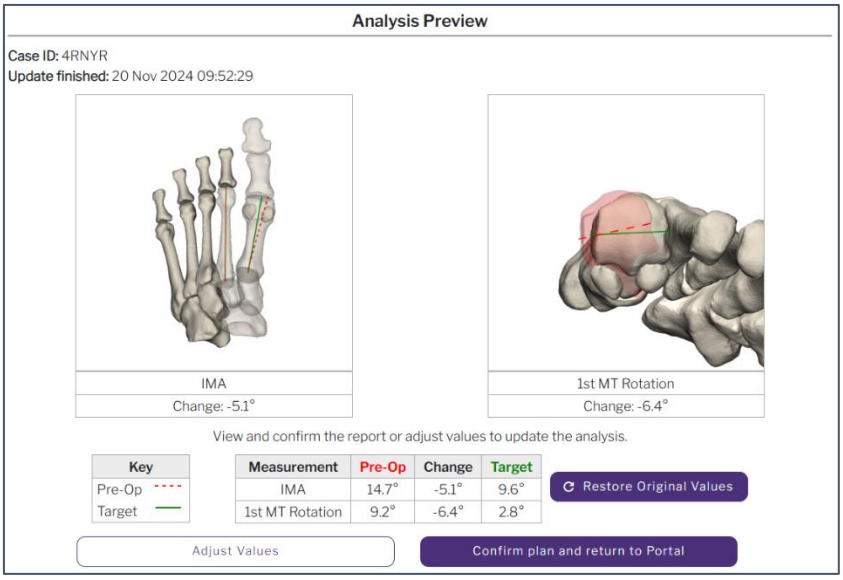
- Update Analysis - If ‘Adjust values’ was selected in previous step, enter desired values in the input box and the reason for value modification in the text box. Select ‘Back’ to return to original values or ‘Update Analysis’ to save changes and proceed to new Analysis Preview.

Note: For sign conventions hover the cursor over the icons next to the measurements. See measurement definitions and more information in sections Available measurements and Automated surgical planning application: methodology and definitions.



3.3.5 (Optional) Restore Original Values

After adjusting values, it is possible to restore the original target values. Select ‘Restore Original Values’ and confirm your choice by selecting ‘Restore’ in the pop-up window.



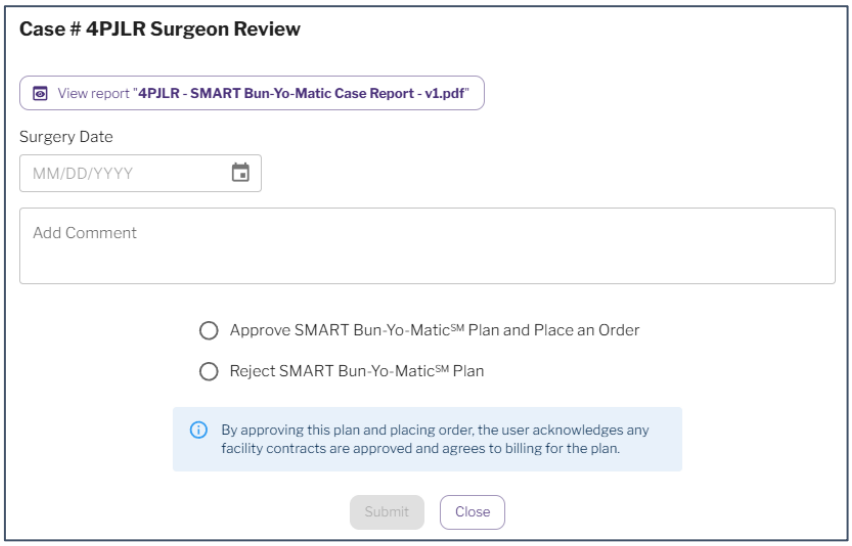
3.3.6 (Optional) Restart planning

There is a possibility to restart the planning process by selecting ‘Restart Planning’ in the top-right corner. This may be utilized for example to change the option of addressing or not addressing Metatarsus Adductus.

3.3.7 Review the results

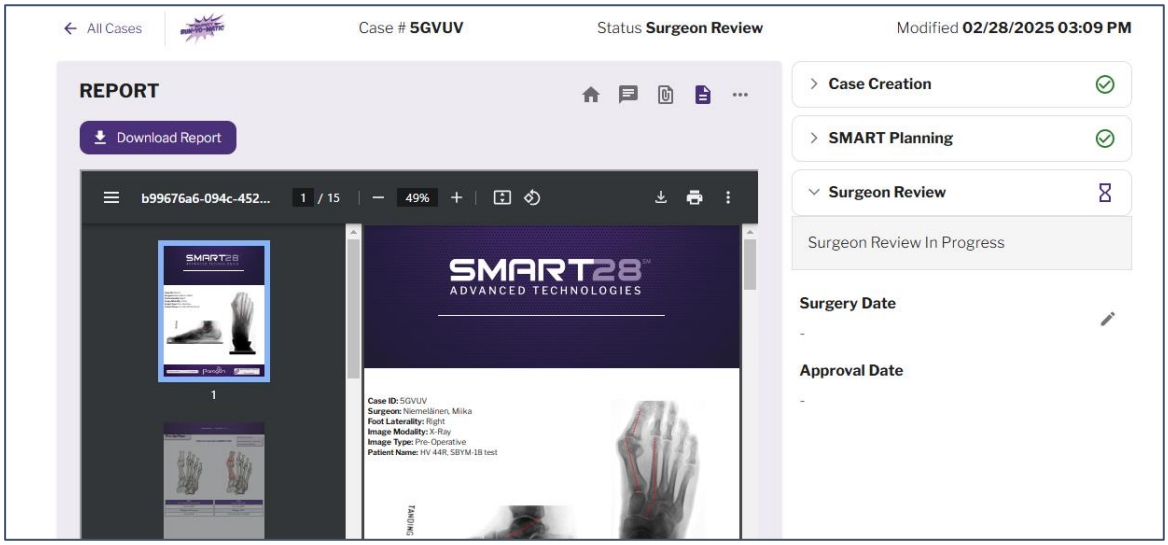
After selecting ‘Confirm plan and return to Portal’ in the Analysis Preview, the results can be reviewed in the Portal.

- In the SMART28℠ Case Management Portal, first select ‘Review and Approve’ to proceed. In the Surgeon Review pop-up, view the report by clicking the eye icon ‘View Report’. To complete the plan, select ‘Approve the SMART Bun-Yo-Matic℠ Plan and Place an Order’.



- Review the report in the current window or select 'Download Report' to export the report for outside review. After review select 'Back to Review' to finalize the plan.

Note: When using the application on a tablet you will need to 'Download Report' to view the complete SMART Bun-Yo-Matic℠ Plan. This will open the Plan in a new window.



4 Troubleshooting guide

This guide is not exhaustive, it may help solve common minor to moderate issues. Product and IT support for all matters can be found by opening a support request using the HELP page or the Contact Support button under your user account icon. Or by direct email to:

- SMART28 Product Support / smart28.support@paragon28.com

Table 8 Troubleshooting guide

When	Common types of errors	Possible reasons for the error	What you can do
SMART28℠ Case Management Portal			
Log in	User cannot sign in.	• Password incorrect • Account information changed • Multifactor authentication (MFA) issue	• Double check the username (email address) and password have been entered correctly. • If a new password is needed, use 'Forgot your Password' option • If the surgeon is no longer able to use the email address that was used to create the account, please contact Product Support. • For issues relating to MFA issues, please contact Product Support.
Case creation	Hospital is not listed in the drop-down menu.	• Hospital has not been linked to the Surgeon or that the Hospital has not been listed yet.	You will need to get an administrator to address this issue, open a support request or email Product Support.
	Case creation failed.	• Network issue • Upload of images failed. • DICOMS did not meet the requirements.	Ensure you have a consistent connection to the internet. Check that you uploaded DICOMS that fit the imaging requirements (IFU §1.7). Please try again later. If the problem persists, please contact Product Support.
	DICOM attribute check failed/ Validation Error	• Missing DICOM tags	Please review the DICOMS you uploaded and make sure that they contain values for the tags that are given in the IFU (§ 1.7). If you need further assistance, contact Product Support.
	Accidental 'wrong' image upload	• Accidental upload of the wrong images when creating a case, e.g.:	If you have uploaded the wrong images (like radiographs in oblique or coronal planes, cropped or extended FOV). You have some options depending on when you notice:

		○ Images from two different patients. • Unsupported radiographic views or planes (coronal, oblique).	1) If you notice before you finish creating the case in SMART Case Management Portal a. Use the “Back” button to return to the image upload step and upload the correct images. 2) If you notice after the case has been created a. Cancel the case and create a new one. **NOTE:** The analysis of the case with the unvalidated or” wrong” images will likely fail, or it will give inaccurate results.
	ERROR: Muliple modalities found	• Images from more than one imaging modality have been detected by reading the DICOM tags. For example, both X-ray and CT DICOMs have been uploaded	Check that the DICOMS you uploaded were from one type of imaging device (X-ray). Create a new case with only X-ray images. If you encounter the message again, after checking that the images are DICOMS from an X-ray machine, please contact Product Support.
Automated analysis	ERROR: Analysis timed out	• Analysis timeout.	If you encounter this error message, they may have been a network or server issue. Please restart the analysis. If you encounter the message again, contact Product Support.
	ERROR: Analysis failed	• Inappropriate input images • Internet connection	Please review the DICOMs you uploaded and make sure that they contain values for the tags that are given in the IFU (§ 1.7). If you need further assistance, please contact Product Support.
SMART Planning in SMART Bun-Yo-Matic℠ X-ray			
Application start up	ERROR: Failed in initialize the application	• Network issue	Please 1) check your internet connection, 2) refresh the website page (option here to restart your internet browser), 3) try logging into the SMART Case Management Portal and accessing the SMART28 application you require again.

			If you encounter the message again, contact Product Support.
Results Preview	ERROR: Failed to load the case	• Back-end issues	If you uploaded images that fulfill the requirements, then you can 1) exit the application, refresh the page, and try to initiate SMART Planning again, 2) contact Product Support.
	ERROR: Failed to load the results	• Internet connection • Backend issues	Try returning to the SMART Case Management Portal and then restarting the SMART Planning in SMART Bun-Yo-Matic. If the problem continues, please contact Product Support
	ERROR: Failed to confirm the results	• Internet connection • Backend issues	If you confirmed the results of the analysis and received this message, please try to confirm the results again. If you receive this error message a second time, please contact Product Support.
Analysis Preview or Update Analysis	ERROR: Analysis failed	• Internet connection • Backend issues	Receiving this error message during user adjustments or metatarsus adductus stages of SMART Planning may indicate a internet connection issue, or a back-end issue. You can: 1) restart planning and try again, 2) exit the application, wait a minute, refresh the page, and try to initiate SMART Planning in SMART Bun-Yo-Matic again, lastly 3) contact Product Support.
Miscellaneous	May occur at any time or stage.		
ERROR: Internet connection lost	• Internet connection	Check your internet connection is active and refresh the website page. Contact your IT department if you have issues with your internet connection.	
ERROR: Unexpected server error	• Server error	There was an issue with the sever, please try again in a few minutes. If the issue is not resolved, please contact Product Support.	
ERROR: Unexpected Error	• Incorrect login information • Inactive session • Failed download of the IFU	Possible actions that you can take will depend on where you encounter this error message. Some examples of where this error may occur are: • During the log-in to the Case Management Portal	

	• During SMART Planning	○ Check you entered your email address and password correctly. If they are correct, please contact Product Support. • You've had the SMART Case Management Portal or SMART Bun-Yo-Matic open for a long time without any activity. The session may have expired. ○ Please log-in again to start an active session. • Attempting to download the Instruction for use (IFU) • During SMART Planning in SMART Bun-Yo-Matic. Check your internet connection and: ○ Return to the SMART Case Management Portal and try starting SMART Planning again. If you have tried any of the above or similar steps and still have issues or have encountered this message outside of the examples given, please contact Product Support.

5 Automated anatomical measurements: methodology and definitions

5.1 Introduction

SMART Bun-Yo-Matic[SM] Xray automatically calculates 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 Bun-Yo-Matic[SM]. It seeks to:

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

5.2 General Principles

The automated bone segmentation and shape analysis of SMART Bun-Yo-Matic[SM] Xray software enables:

- Calculation of inter-bone angles between clinically relevant landmarks in patient specific coordinate system, for example, to quantify dislocations and malformities like hallux valgus.

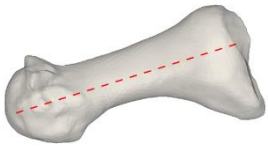
5.3 Available measurements

This section defines the bone axes and describes the measurements used to calculate:

- Forefoot deformity
- Hallux valgus

1. All angle measurements are calculated based on 2D projections of 3D axes
    - 2D projection planes are deduced from the estimated orientation of the Lateral X-ray view and two planes orthogonal to it.
2. Measures are shown with + or – signs to represent the direction of change

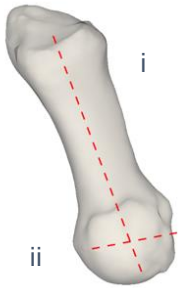
5.3.1 Bone axis definitions



Elongated bones

Metatarsal, Proximal phalange bones

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.

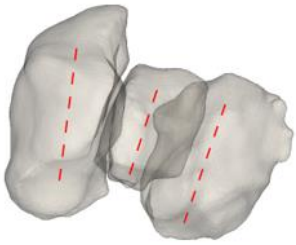


1st Metatarsal Distal Mediolateral Axis

The software determines the distal articular surface of the metatarsal bone and fits a barrel geometry to it. The mediolateral axis direction is the barrel's central axis.

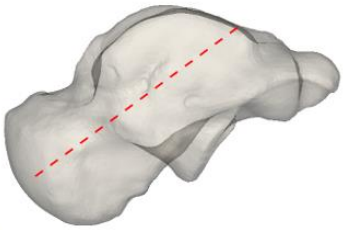
i) longitudinal axis

ii) distal mediolateral axis



Cuneiform bones

Cuneiform anteroposterior axis: The axis drawn between cuneiform posterior and anterior articular surface centre points.



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.

5.3.2 Foot and ankle measurements

Image	Definition	Direction of Change
	**1st – 2nd Intermetatarsal Angle (IMA) *(Axial)*** The angle between the 1st metatarsal (MT) longitudinal axis and the 2nd metatarsal longitudinal axis measured in the axial plane	Increase in angle → 1st MT shifts towards varus Decrease in angle → 1st MT shifts towards valgus

Hallux Valgus Angle (HVA) ***(Axial)***

The angle between the 1st metatarsal longitudinal axis and the 1st proximal phalanx (PP) longitudinal axis, measured in the axial plane

Increase in angle → 1st PP shifts towards valgus

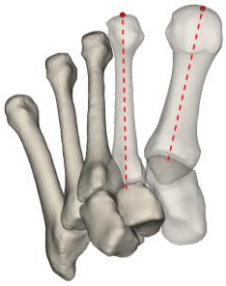
Decrease in angle → 1st PP shifts towards varus

2nd Tarsometatarsal Angle ***(Axial)***

The angle between the longitudinal axes of the 2nd metatarsal and the intermediate cuneiform.

Increase in angle → 2nd MT shifts towards varus

Decrease in angle → 2nd MT shifts towards valgus

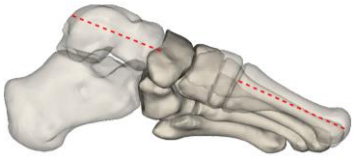


Relative Length 1st – 2nd Metatarsal ***(Axial)***

Distance (mm) between the distal points of the 1st and 2nd metatarsal longitudinal axes, measured along the 2nd metatarsal longitudinal axis.

Increase in value when 1st MT is longer than 2nd MT

Decrease in value when 1st MT is shorter than 2nd MT

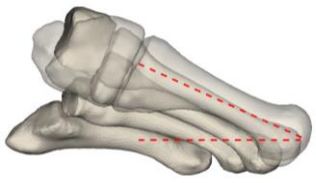


Meary's Angle ***(Sagittal)***

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)

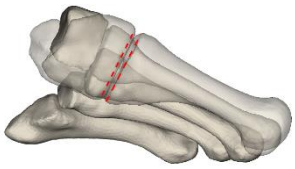


1st Metatarsal Declination Angle ***(Sagittal)***

Angle between the longitudinal axis of the 1st metatarsal and the floor level, measured in the sagittal direction.

Increase in angle → 1st MT shifts towards plantarflexion

Decrease in angle → 1st MT shifts towards dorsiflexion

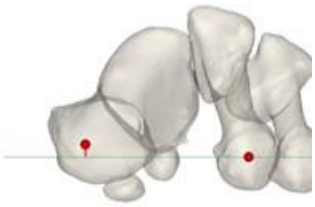


Plantar Gapping Angle
(Sagittal)

Angle between the distal joint surface of the medial cuneiform and the proximal joint surface of the 1st metatarsal, measured in the direction of proximal surface of the 1st metatarsal.

Increase in value if gap opens on the plantar side

Decrease in value if gap opens on the dorsal side

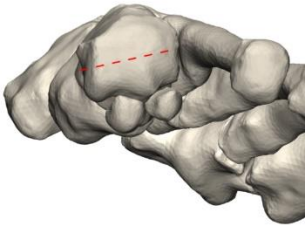


1st Metatarsal Elevation
(Coronal)

The vertical distance (mm) between 1st and 2nd metatarsal longitudinal axis distal points.

Increase in value → 1st MT shifts towards dorsiflexion

Decrease in value → 1st MT shifts towards plantarflexion



1st Metatarsal Rotation
(Coronal)

The angle between the 1st metatarsal distal mediolateral axis and its projection to virtual floor plane, measured in plane perpendicular to 1st metatarsal longitudinal axis

Increase in angle → 1st MT shifts towards pronation

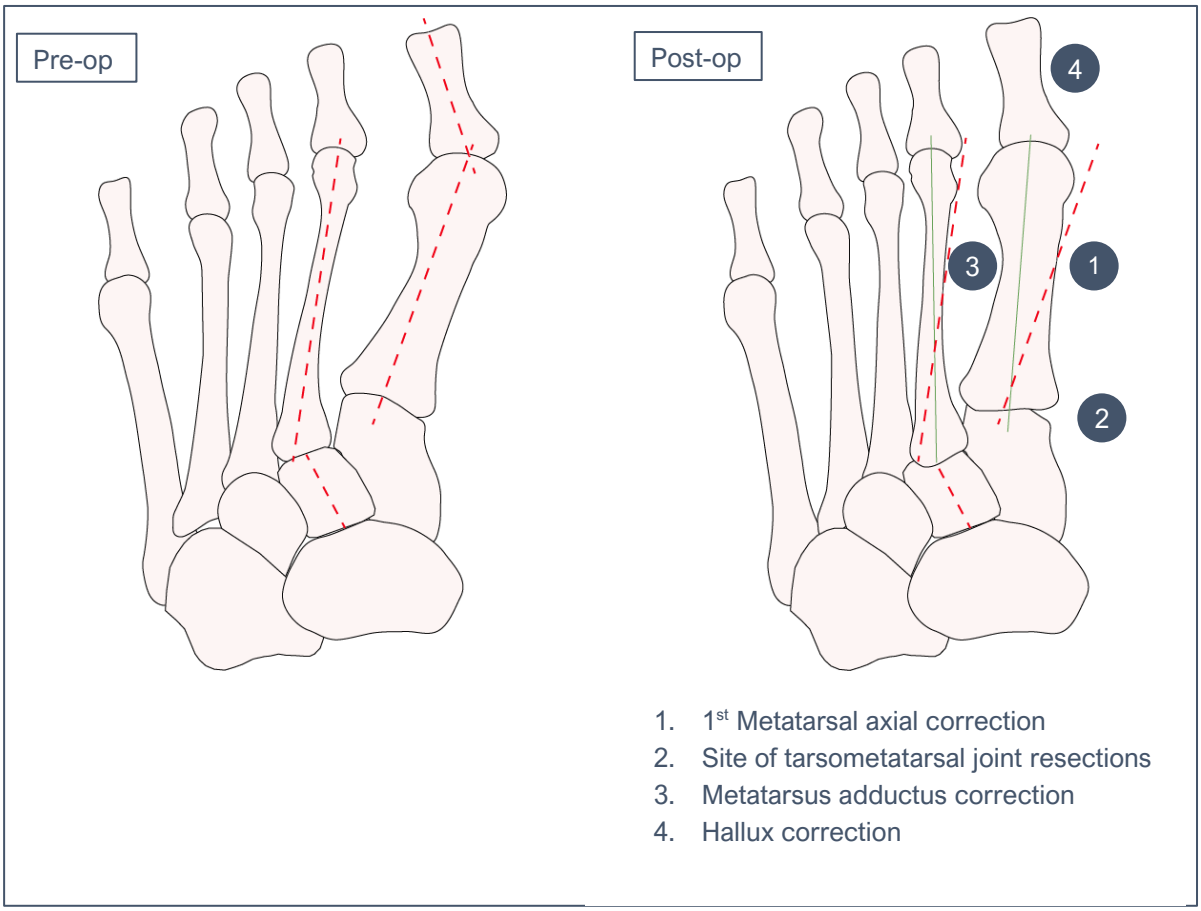
Decrease in angle → 1st MT shifts towards supination

6 Automated surgical planning application: methodology and definitions

6.1 Lapidus procedure

The SMART Bun-Yo-Matic℠ Xray software performs a virtual Lapidus Arthrodesis procedure to correct 1st – 2nd Intermetatarsal Angle (Axial) and 1st Metatarsal Rotation into patient specific target values or into their normative reference values (Table 9). Their measurement values after the procedure are denoted “Target” in the case report. The remaining measurement values after the procedure are denoted “Estimated Post-Op” in the case report. The following sections cover the applied procedures as illustrated in Figure 2.

Figure 2 Visual example of a Lapidus procedure planned the SMART Bun-Yo-Matic℠



6.1.1 Target Value Adjustment

The user may adjust the target values for the following measurements:

- 1st – 2nd Intermetatarsal Angle (Axial): Adjustments within values of 0° to 13.4° are permitted. Note that the software prevents overlap of 1st and 2nd Metatarsal heads (minimum 2 mm gap), thus, the final Intermetatarsal Angle may be larger than target value set by the user.
- 1st Metatarsal Rotation: Adjustments within normative reference value of 2.3° ± 11° are permitted.

Note: The adjustable parameter values after the procedure are denoted “User Adjusted Target” with “Original Target” value shown below. The remaining measurements are not within the user's control and are subject to change based on the manipulation of the 1st metatarsal and the 1st tarsometatarsal joint in the Lapidus procedure.

6.1.2 1st Metatarsal Axial Correction

In the axial correction of the 1st metatarsal, the lateral aspect of the 1st metatarsal is placed on top of the lateral sesamoid. If there is uncertainty in sesamoid detection, the axial 1st – 2nd Intermetatarsal Angle is set to 9.4°, which corresponds to normative reference value of the axial 1st – 2nd Intermetatarsal Angle (see Table 9) with 2° of overcorrection. 1st Metatarsal Rotation is corrected to its normative reference value (see Table 9).

6.1.3 Tarsometatarsal Joint Resections

The SMART Bun-Yo-Matic℠ Xray software virtual tarsometatarsal joint resections simulate the use of off-the-shelf Bun-Yo-Matic™ Lapidus Clamp. The resected 1st metatarsal base is positioned to make the tarsometatarsal joint osteotomy site dorsally flush, minimize the medial step-off, and maintain a minimum gap of 1.6 mm between the 1st and 2nd metatarsal bases. If the medial step-off exceeds 4.5 mm, the software reduces the gap between the metatarsal bases to below 1.6 mm instead of increasing the medial step-off and suggests a lateral resection of the 1st metatarsal. The plantar- or dorsiflexion angle of the 1st metatarsal is kept constant during the procedure.

6.1.4 Metatarsus Adductus Correction

The SMART Bun-Yo-Matic℠ Xray software notifies the user if Metatarsus Adductus is detected (i.e. the axial 2nd Tarsometatarsal Angle is larger than a threshold of 20°). If the user confirms to continue the procedure, the user needs to select whether to continue with or without addressing Metatarsus Adductus.

With the option of addressing Metatarsus Adductus, the 2nd and 3rd rays are axially rotated towards valgus so that the axial 2nd and 3rd Tarsometatarsal Angles match to their normative reference values (see Table 9). Addressing Metatarsus Adductus initially increases the 1st – 2nd Intermetatarsal Angle (IMA) as the 2nd metatarsal is rotated towards valgus. This increase in IMA is compensated with a larger 1st metatarsal axial correction to achieve the original IMA target value.

> **Note**: The corrections of the 2nd and 3rd rays are for simulation and visualization purposes, and no simulated bone resections are provided to effectuate the correction.

With the option of not addressing Metatarsus Adductus, the Lapidus Arthrodesis procedure is performed normally.

6.1.5 Hallux Correction

In addition, SMART Bun-Yo-Matic℠ Xray software performs a Hallux correction procedure to show how the 1st proximal and distal phalanges would appear if their relative placement were corrected according to the normative reference values of Hallux Valgus Angles (axial and sagittal) (see Table 9).

> **Note**: The Hallux correction is provided for visualization purposes only and the software does not provide guidance on the specific surgical procedure to be performed.
>
> **Note:** Additional soft tissue releases may be required to achieve the desired corrections.

6.1.6 Sesamoid Correction

SMART Bun-Yo-Matic℠ Xray software also performs adjustments to sesamoid complex elevation and orientation to follow the 1st metatarsal and 1st proximal phalanx positional and angular changes. These adjustments are done to show how the sesamoid complex would appear when 1st metatarsal and 1st proximal phalanx are corrected to their desired locations.

> **Note**: The sesamoid complex adjustments are provided for visualization purposes only and the software does not provide guidance on the specific surgical procedure to be performed.

6.2 Correction with Bun-Yo-Matic™ Lapidus Clamp

The SMART Bun-Yo-Matic℠ Xray software translates the 1st Metatarsal Axial Correction and 1st Metatarsal Rotation Correction defined in Lapidus procedure into Bun-Yo-Matic™ Lapidus Clamp System parameters. These parameters are provided in the SMART Bun-Yo-Matic℠ Case Report. Refer to the Paragon 28® Bun-Yo-Matic™ Instructions for Use for further information about the system and executing the procedure according to the Surgical Technique Guide.

6.2.1 Bun-Yo-Matic™ Translation

The amount of Bun-Yo-Matic™ translational correction is computed from the planned lateral translation of the 1st Metatarsal head in direction perpendicular to the 2nd metatarsal longitudinal axis, rounded to the nearest millimeter.

6.2.2 Bun-Yo-Matic™ Rotation

The amount of Bun-Yo-Matic™ rotational correction is the planned change in 1st Metatarsal Rotation Angle, rounded to nearest 2.5 degrees. In case the rotation is towards pronation (negative value), Not applicable (N/A) is shown as value as the Bun-Yo-Matic™ system supports only rotation towards supination.

6.3 Reference Values

The normative reference values in Table 9 have been determined by using the analyzer included in the SMART Bun-Yo-Matic℠ software by measuring a set of WBCT images of normal feet. These values align with the corresponding measurement values presented in the literature (Table 10).

Table 9 Summary of the measurements and their normative reference values used for SMART Bun-Yo-Matic℠ Xray correction and shown concomitant procedures.

Measurement	Average (deg.)	Standard deviation (SD)
1st – 2nd Intermetatarsal Angle (Axial)	11.4	2.0
1st – 2nd Intermetatarsal Angle (Sagittal)	3.2	2.1
1st Metatarsal Rotation	2.3	6.2
Hallux Valgus Angle (Axial)	11.3	5.7
Hallux Valgus Angle (Sagittal)	10.6	4.2
2nd Tarsometatarsal Angle (Axial)	19.6	3.1
3rd Tarsometatarsal Angle (Axial)	19.2	2.4

Table 10 Reference values for normal feet presented in the literature.

Measurement	Average (deg.)	Reference
1st – 2nd Intermetatarsal Angle (Axial)	11.3	de Carvalho et al. 2022a
	11.2	de Carvalho et al. 2022b
	11.5	Zaidi et al. 2022
1st – 2nd Intermetatarsal Angle (Sagittal)	3.2	Zaidi et al. 2022
1st Metatarsal Rotation	2.1	Steadman et al. 2021
Hallux Valgus Angle (Axial)	9.6	de Carvalho et al. 2022a
	8.8	de Carvalho et al. 2022b

Measurement	Average (deg.)	Reference
Hallux Valgus Angle (Sagittal)	10.7	de Carvalho et al. 2022b
2nd Tarsometatarsal Angle (Axial)	19.2	Zaidi et al. 2022
3rd Tarsometatarsal Angle (Axial)	19.0	Zaidi et al. 2022

The normative reference values for the other measurements presented in the SMART Bun-Yo-Matic℠ Xray case report are listed in Table 11. These have been determined by using the analyser included in the SMART Bun-Yo-Matic℠ software.

Table 11. Normative reference values for measurements shown in the SMART Bun-Yo-Matic℠ Xray case report.

Measurement	Average	Standard deviation (SD)
Relative Length 1st - 2nd Metatarsal	3.3 mm	2.7 mm
Meary's Angle	-7.5°	7.7°
1st Metatarsal Declination Angle	21.8°	2.9°
Plantar Gapping Angle	-1.0°	1.7°
1st Metatarsal Elevation	3.2 mm	1.7 mm

6.4 Literature references

de Carvalho, K. A. M., Walt, J. S., Ehret, A., Tazegul, T. E., Dibbern, K., Mansur, N. S. B., Lalevée, M., & de Cesar Netto, C. (2022a). Comparison between Weightbearing-CT semiautomatic and manual measurements in Hallux Valgus. Foot and Ankle Surgery, 28(4), 518–525. https://doi.org/10.1016/j.fas.2022.02.014

de Carvalho, K. A. M. de, Mallavarapu, V., Ehret, A., Dibbern, K., Lee, H. Y., Barbachan Mansur, N. S., Laleveé, M., & de Cesar Netto, C. (2022b). The use of advanced semiautomated bone segmentation in Hallux Rigidus. Foot & Ankle Orthopedics, 7(4), 1–7. https://doi.org/10.1177/24730114221137597

Dawoodi, A. I. S., & Perera, A. (2012). Reliability of metatarsus adductus angle and correlation with hallux valgus. Foot and Ankle Surgery, 18(3), 180–186. https://doi.org/10.1016/j.fas.2011.10.001

Steadman, J., Bakshi, N., Arena, C., Leake, R., Barg, A., & Saltzman, C. L. (2021). Normative Distribution of First Metatarsal Axial Rotation. Foot and Ankle International, 42(8), 1040–1048. https://doi.org/10.1177/10711007211001015

Zaidi, R., Sangoi, D., Cullen, N., Patel, S., Welck, M., & Malhotra, K. (2022). Semi-automated 3-dimensional analysis of the normal foot and ankle using weight bearing CT – A report of normal values and bony relationships. Foot and Ankle Surgery, In press. https://doi.org/10.1016/j.fas.2022.12.001

6.5 Performance specification

SMART Bun-Yo-Matic's performance was validated with 51 hallux valgus patient cases (referred to as 'cases'). The data included cases with co-occurring conditions like flatfoot, osteoarthritis, osteophytes, and osteochondral lesions. Potential sources of measurement or segmentation error were found in cases where some co-occurring conditions (e.g. osteoarthritis) cause deformation of the 1st metatarsal head, and severe medial displacement of sesamoids.

Two clinicians independently reviewed and graded the 51 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 97.7% of cases. The range of pre-op 1st-2nd intermetatarsal angle and 1st metatarsal rotation varied across the validation data (Table 12). Cases where the pre-op state is outside of this range should be interpreted carefully.

Table 12. Range of clinical conditions that SMART Bun-Yo-Matic℠ is validated with.

	Pre-op measurement (min-max)
1st-2nd intermetatarsal angle	9.1°-23.2°
1st metatarsal rotation angle	-6.1-35.5

6.5.1 Measurements from X-ray 2D-to-3D reconstruction correspondence with 3D CBCT

There are inherent differences for radiographic measurements based on X-ray and CT images. SMART Bun-Yo-Matic℠ Xray software uses two planar X-ray images (dorsoplantar and lateral) as an input and performs 2D-to-3D reconstruction to represent hard-tissue anatomies present in the X-ray image as 3D models. The 2D-to-3D reconstruction performance was validated by comparing measurements from a set of 3D CBCT image series and digitally reconstructed radiographs of the same images. Average difference between the methods are -0.2 ± 3.7 degrees for 1st – 2nd Intermetatarsal Angle and 0.1 ± 11.4 for 1st Metatarsal Rotation with detailed Bland-Altman plots presented in Figure 3 and Figure 4.

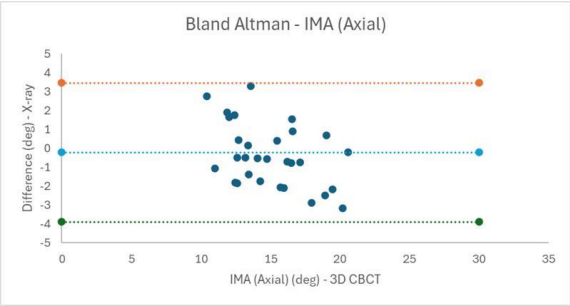


Figure 3 Bland-Altman plot, 1st - 2nd Intermetatarsal Angle (Axial).

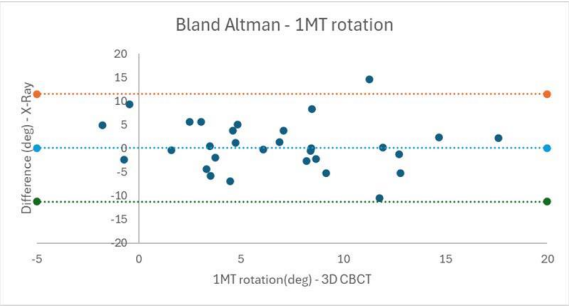


Figure 4 Bland-Altman plot, 1st Metatarsal Rotation.

7 Data management & software architecture

Illustration of the SMART Bun-Yo-Matic℠ Xray software architecture and listed functionalities is below.

SMART Bun-Yo-Matic℠ Xray 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 Bun-Yo-Matic℠ Xray 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.

7.1 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.

7.2 Cloud domain addresses

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

Table 13 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://bym.smart.paragon28.com

7.3 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.

7.4 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.

7.5 Data processing

7.5.1 Elements

Element 1: DISIOR™ Cloud connection

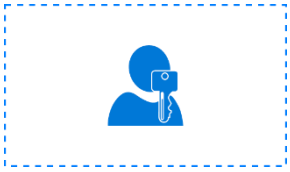
1. User authentication to open software
2. Disior™ cloud, Microsoft Azure based, HTTPS/TLS certificate, domain needs to be accessible from the used location.
3. DoS prevention at server network

Element 2: DISIOR™ Cloud

1. The Cloud service is physically located in USA (for USA customers)
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

7.5.2 Data flow description

Step 1: DICOM Image handling in client workstation



1. DICOM file(s) is read in DICOM reader
2. Following information is displayed on client workstation/software:
   - Patient ID, Patient name
   - Study date, description,
   - Series date, description
3. When user initiates analysis (start analysis), the user is prompted for patient evaluation information
4. After user input, the patient evaluation information 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 Case management system and existing case reports can be downloaded by the user.

8 Manufacturer of SMART Bun-Yo-Matic℠ Xray

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