Exclusively foot & ankle

SMART Bun-Yo-Matic℠ CT 1.0

INSTRUCTIONS FOR USE

IFU version 8.0 2024-08-30

Contents

General Information

This User Guide describes the functionality of the SMART Bun-Yo-Matic℠ CT 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.

℞ Only

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

Description of the software

SMART Bun-Yo-Matic℠ CT 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 the structural models and the radiographic measurements can be used for diagnostic and treatment planning purposes. DICOMS from Weight-Bearing Computed Tomography (WBCT) devices are the intended medical image input.

SMART Bun-Yo-Matic℠ CT Software indications for use

SMART Bun-Yo-Matic℠ CT 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 WBCT.

SMART Bun-Yo-Matic℠ CT software provides for the user:

- Visualization report of the three-dimensional mathematical models 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,
- Surgical planning application for visualization of foot and ankle anatomical three-dimensional structures, radiographic measures and surgical instrument parameters

The visualization report containing the measurements can be used for the diagnosis of orthopedic healthcare conditions. The surgical planning application containing the visualizations of the three-dimensional structural models, orthopedic fixation device models and surgical instrument parameters combined with the measurements can be used for the planning of treatments and operations to correct orthopedic healthcare conditions of foot and ankle.

Software contraindications

SMART Bun-Yo-Matic℠ CT 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 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.

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.

Users

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

System compatibility

SMART Bun-Yo-Matic℠ CT software is a web application without specific hardware requirements for executing the software. SMART Bun-Yo-Matic℠ CT 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)

SMART Bun-Yo-Matic℠ CT 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.

Imaging data quality requirements

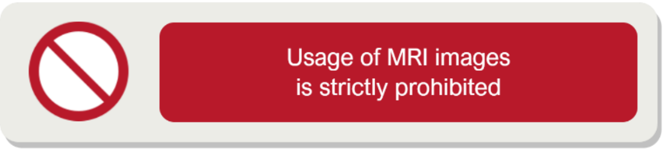
In the SMART Bun-Yo-Matic℠ CT software, the quality of the outputs (including visualizations) are dictated by the quality and resolution of the DICOM images from the WBCT device. This section describes the imaging parameters required for safe and effective use of the software.

Acceptable DICOM images

The only acceptable inputs are DICOM images from WBCT devices that adhere to the parameters in Table 2. Two types of DICOM images (DICOM parameter SOP Class UID) are accepted: 1) original CT DICOMs where data is organized into series with single frames that are accompanied by attributes and terms, and 2) Enhanced Multi-Frame CT objects where multiple frames can be stored in a single object alongside a greater range of descriptors (attributes and terms).

Table 2 Required values of DICOM parameters.

Parameters	Values
Patient ID	Original ID is present
Imaging Modality	Weight-bearing CT
Image Type	Original, Primary, Axial
SOP Class UID	CT ("1.2.840.10008.5.1.4.1.1.2"), or Enhanced CT ("1.2.840.10008.5.1.4.1.1.2.1")
Field-of-View	• Height dimension up to 390mm (Max) • All metatarsals, phalanges, and bones of the midfoot and hindfoot completely in view • Include only the Distal 1/3 of the tibia (200 – 240mm (Max) of the distal most portion of the image stack)
Voxel Size	Slice Thickness: 0.3mm (Min) – 0.6mm (Max)
	Pixel Spacing: 0.3mm x 0.3mm (Min) – 0.6mm x0.6mm (Max)
Tube Voltage	90 – 130kVP
Tube Current	5mA – 10mA
Pulse length	20 ms



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.

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 is not valid, and the software is unable to analyze the image.

Table 3 Required DICOM tags.

Parameter	DICOM Tag	Accepted SOP Class UIDs	
		CT	Enhanced CT
Modality	(0008,0060)	x	x
Image Type	(0008,0008)	x	x
SOP Class UID	(0008,0016)	x	x
Study Description	(0008,1030)	x	x
Series Description	(0008,103e)	x	x
Slice Thickness	(0018,0050)	x	x
Pixel Spacing	(0028,0030)	x	x
Photometric Interpretation	(0028,0004)	x	x
Number of Frames	(0028,0008)		x
Rows	(0028,0010)	x	x
Columns	(0028,0011)	x	x
Bits Allocated	(0028,0100)	x	x
High Bit	(0028,0102)	x	x
Rescale Intercept	(0028,1052)	x	

Rescale Slope	(0028,1053)	x	
Instance Number	(0020,0013)	x	
Image Position (Patient)	(0020,0032)	x	x
Image Orientation (Patient)	(0020,0037)	x	x
Study Instance UID	(0020,000d)	x	x
Series Instance UID	(0020,000e)	x	x

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.

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)

Software configuration

SMART Bun-Yo-Matic℠ CT software consists of two components:

1) Web user interface used for selecting input images for analysis, reviewing output report and adjusting values for the planning (optional).
2) Cloud service providing analysis service, measurements and the 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℠ CT 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)

Data management

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

Cybersecurity

Details of the cybersecurity controls of the SMART Bun-Yo-Matic℠ CT 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 to check from the browser that the connection is secure and to the intended web page (see Cloud domain address). 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
Data Transfer 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℠ CT 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.

Release Notes

Software version number 1.0.3

Notes date August 30th, 2024

Overview

SMART Bun-Yo-Matic CT℠ original release software version is 1.0.0. This release note is for software patch version 1.0.3.

Modified software features in this release

- 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).

Known issues

- Adjusting target values within Analysis Preview may occasionally produce an error, which may be resolved by Reloading Results.

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.

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Contact Information

Software Support & Basic Troubleshooting

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.

Reporting serious incidents

Any serious incident (including cybersecurity incidents) 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)

Safety Information

SMART Bun-Yo-Matic℠ CT software interfaces with the SMART28℠ Case Management Portal. SMART Bun-Yo-Matic℠ CT 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℠ CT 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 Bun-Yo-Matic℠ CT 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 a hazardous situation.

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** Indicates the need for the user to consult the Instructions for Use or the electronic Instructions for Use. eIFU Indicator may contain the URL of the Instructions for Use (IFU).
	**Caution** Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	**Prescription Use Ony** Indicates that the device is in the possession of a practitioner, such as physicians, licensed by law to use or order the use of such device.
	**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 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.

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 Bun-Yo-Matic℠ CT 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 impact of geometrical nonconformities.

SMART Bun-Yo-Matic℠ CT 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.

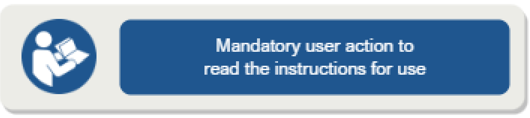
Medical Image Registration Failure

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.

Safety Messages

General Safety Information

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



Analysis results shall be subjected to careful expert assessment

US Federal Law restricts sale of this device by or on order of a physician

Various measurement protocols cause differences in results

Differences between 2D and 3D measurements cause differences in results

Differences between automatic and manual measurements cause differences in results

Reconstruction of 3D models from radiographs may cause inaccuracies in anatomical details

Error Messages

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

ERROR
Failed to confirm the results

Try reconfirming the results

If problem persists, contact product support

ERROR
Failed to load the case

Try to re-open the application

If problem persists, contact product support

ERROR
Internet connection lost

Check your internet connection and try again

If problem persists, contact product support

ERROR
Failed to load the results

Try reloading the results

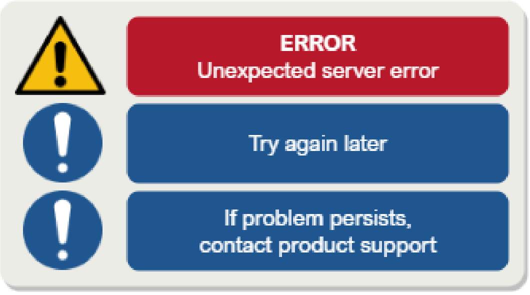
If problem persists, contact product support

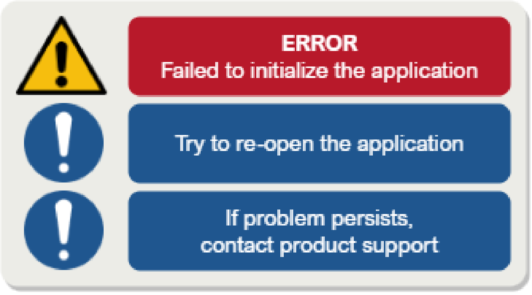
ERROR
<Invalid file reason>

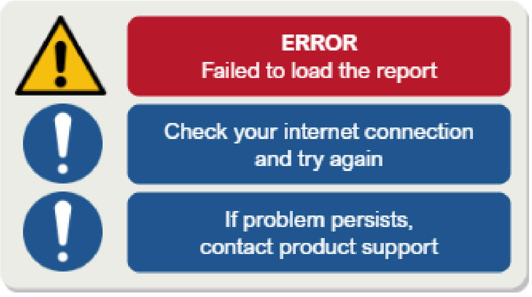
Select a valid file

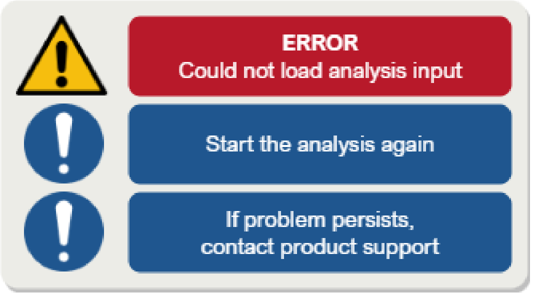
ERROR
Multiple modalities found

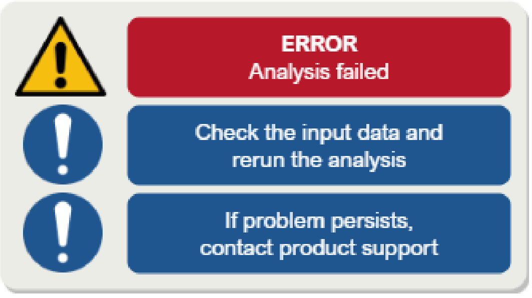
Contact product support

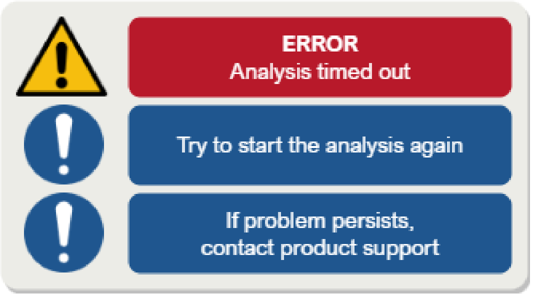


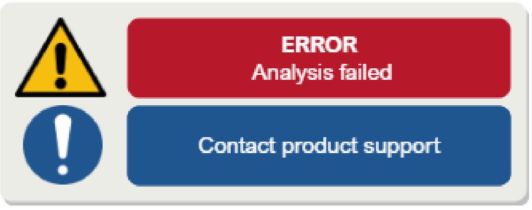






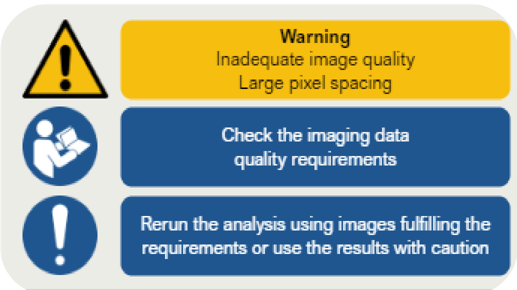


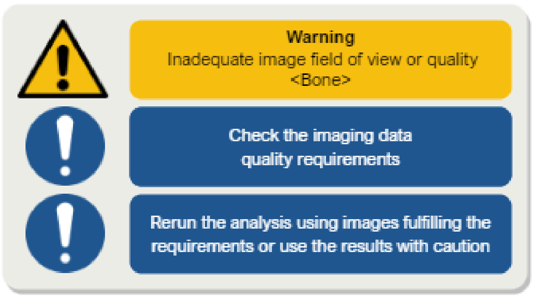




Warning Messages

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





Warning
Patient foot estimated to be significantly larger than an average foot

Verify that actual patient's foot size corresponds to this estimate

If the foot is not notably large, do not use the results and contact product support instead

Warning
Patient foot estimated to be significantly smaller than an average foot

Verify that actual patient's foot size corresponds to this estimate

If the foot is not notably small, do not use the results and contact product support instead

Warning
Metatarsus Adductus addressed

Warning
Inaccurate measurement <Bone>

Check the related measurements

Warning
2nd Tarsometatarsal Angle (Axial) larger than reference (-24°), may indicate Metatarsus Adductus. A Lapidus procedure may not be suitable.

Confirm to proceed with Lapidus procedure.

Warning
Anatomical details may be inaccurate when using radiographs as an input

Read about how the input modality affects the results

Use the results with caution

Warning
Inadequate image quality
Large spacing between slices

Check the imaging data quality requirements

Rerun the analysis using images fulfilling the requirements or use the results with caution

Warning
Abnormal anatomy detected

Check the input data

Rerun the analysis or use the results with caution

Warning
Metatarsus Adductus not addressed

Warning
Contact detected <Bone>

Check the related measurements

Warning
Using Phantom Intramedullary Nail <nail-name> for requested length <nail-length> mm

Check suggested hardware compatibility

Informative notes

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

Table 7 Notes issued by SMART Bun-Yo-Matic℠ 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.
Large IPA may indicate a need for an AKIN.	Always displayed.	Displayed on page 2 “Hallux Valgus correction” below the IPA.
Metatarsus adductus addressed.	Displayed if pre-op value of 2nd Tarsometatarsal Angle is larger than a threshold of 24° and user chose to address Metatarsus Adductus.	Displayed on page 2 and 3 “Hallux Valgus correction” below the 1st – 2nd Intermetatarsal Angle and the 2nd Tarsometatarsal Angle.
Metatarsus adductus not addressed.	Displayed if pre-op value of 2nd Tarsometatarsal Angle is larger than a threshold of 24° and user chose to not address Metatarsus Adductus.	Displayed on page 2 and 3 “Hallux Valgus correction” below the 1st – 2nd Intermetatarsal Angle and 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 1.45mm 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.

Measurements may vary based on actual cartilage thickness.	Always displayed.	Displayed on page 8 “Planned resections” top-right.
2nd cut slot on Medial Cuneiform Bun-Yo-Matic™ cut guide may be needed.	Always displayed.	Displayed on page 8 “Planned resections” top-right.
Removal of cartilage by scraping with hand tools may be need.	Always displayed.	Displayed on page 8 “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 8 “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 9 “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 9 “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 9 “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 10 “Example Fixation Sizing” center.
Final fixation type may vary by surgeon preference.	Always displayed.	Displayed on page 10 “Example Fixation Sizing” center.

Instructions for Use

Workflow

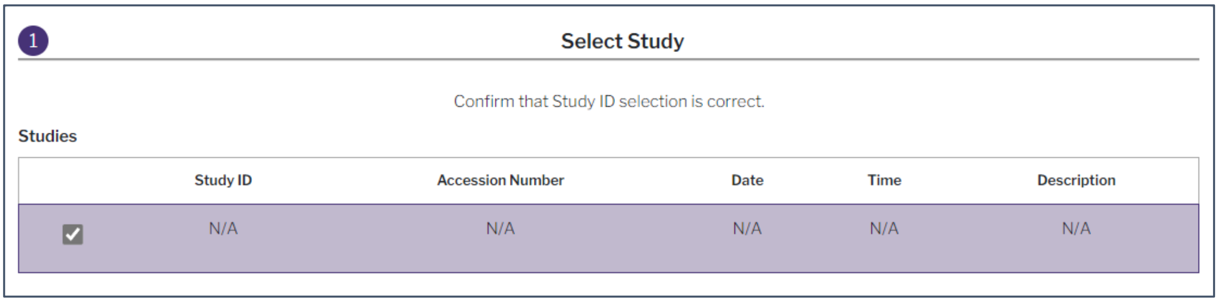
The workflow of SMART Bun-Yo-Matic℠ CT software consists of the following steps:

1) Access SMART Bun-Yo-Matic℠ CT through the SMART28℠ Case Management Portal
2) Confirm study and patient
3) Select laterality
4) Start analysis
    a. (If indicated) Procedure suitability verification
5) Confirm measurements
    a. (Optional) Adjust values
6) View report and save analysis
7) Review results in the SMART28℠ Case Management Portal

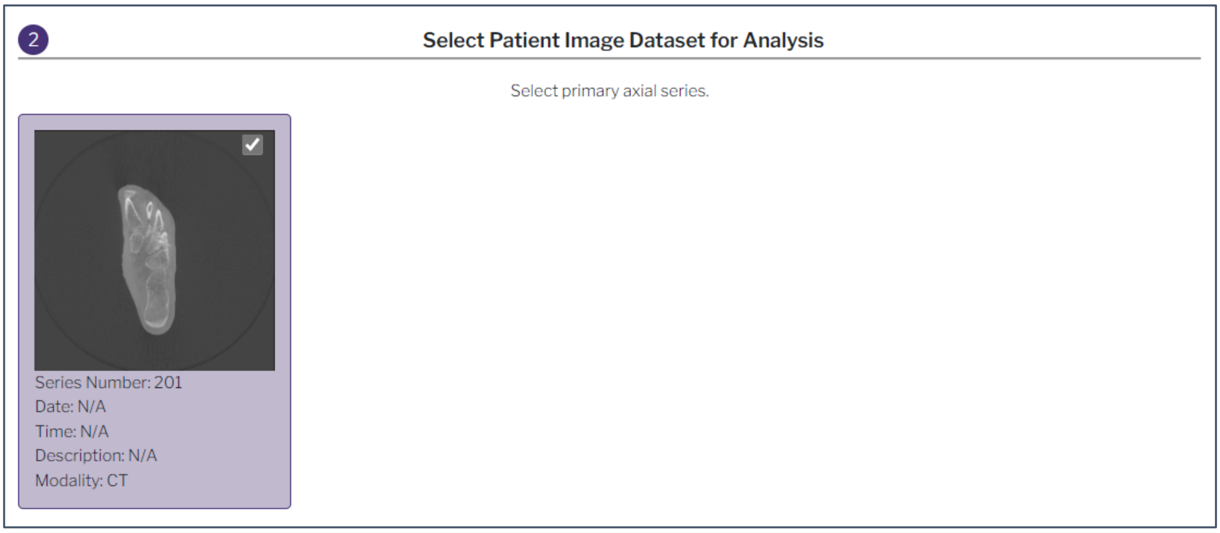
Note: SMART Bun-Yo-Matic℠ CT workflow steps 1 and 7 occur in the Portal - SMART28℠ Case Management Portal.

Confirm study and patient

- Start by confirming the study from the images previously uploaded in the SMART28℠ Case Management Portal. For folders containing multiple DICOM image series, all series will be listed in the software with metadata and image preview displayed.

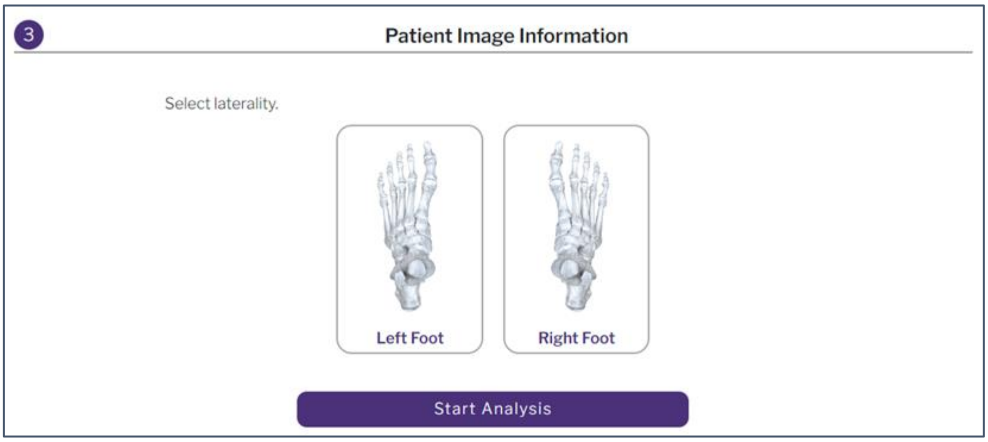


- Select the primary axial DICOM image series to analyze from the list generated.



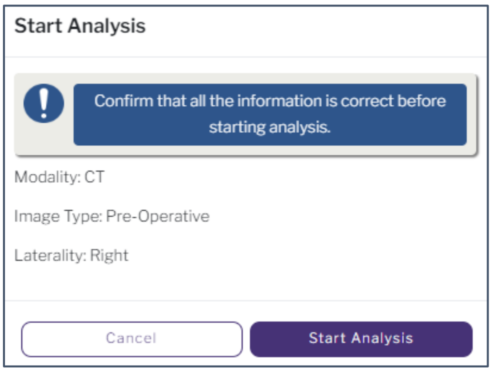
Select laterality

- Select the laterality (Left Foot or Right Foot) of the images for analysis, then select Start Analysis.



Start analysis

- Select Start Analysis to confirm that all information is correct and begin analysis.



- Results Preview – Review pre-operative foot position and measurement axes. Analysis results shall be subjected to careful expert assessment. Select Confirm to proceed with the analysis or Reject and Exit to return to the SMART28℠ Case Management Portal.

(If indicated) Procedure suitability verification

If 2nd Tarsometatarsal angle is larger than the normal limit (24°) it may indicate Metatarsus Adductus and procedure suitability verification is required.

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

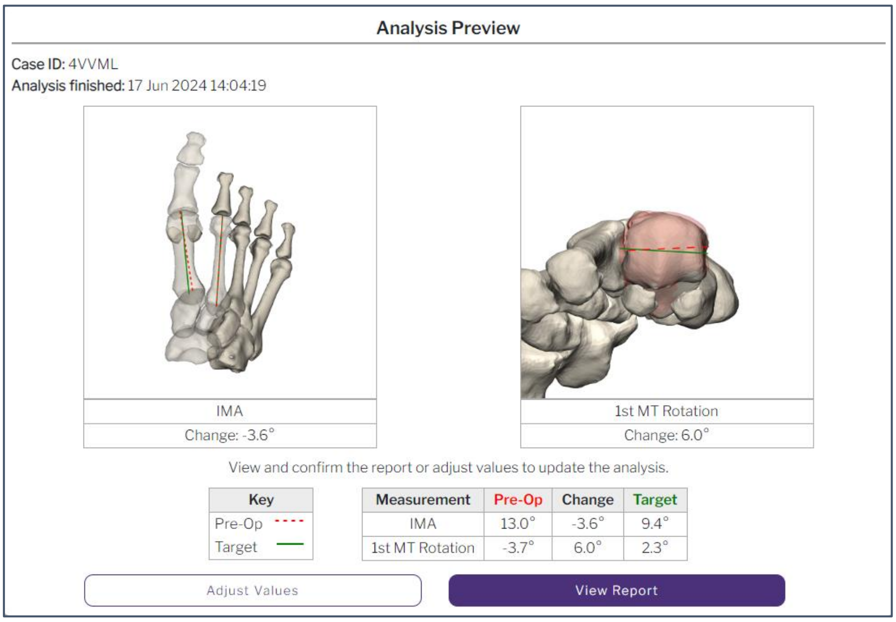
- Continue analysis either by addressing or not addressing Metatarsus Adductus.

Note: See more information about these options in chapter Metatarsus Adductus Correction.

Confirm measurements

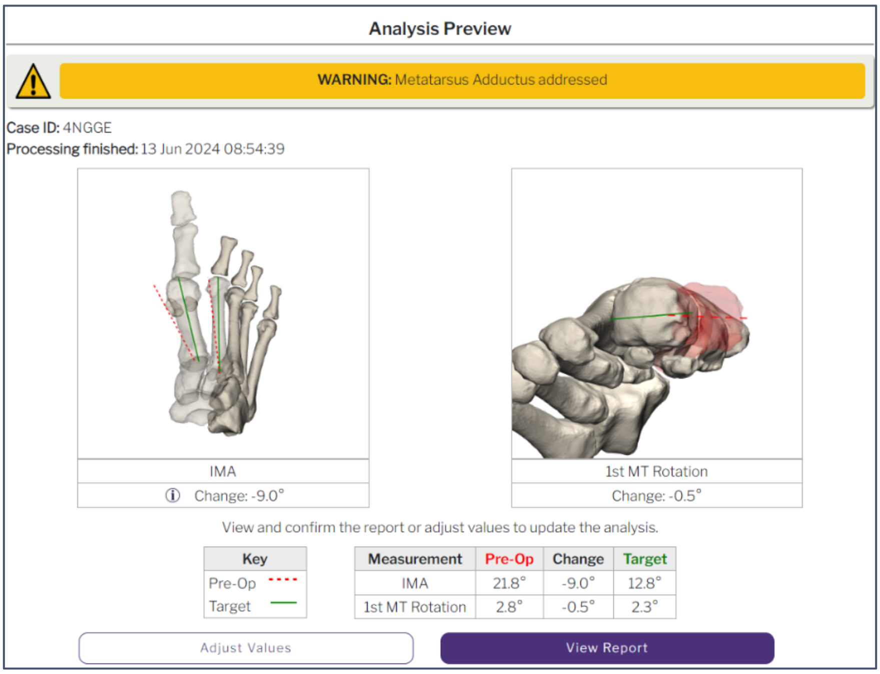
- Analysis Preview – Review preliminary analysis results. Select Adjust values to manually adjust target measurements or View Report to confirm current measurements.

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 – Review preliminary analysis results. Select Adjust values to manually adjust target measurements or View Report to confirm current measurements.

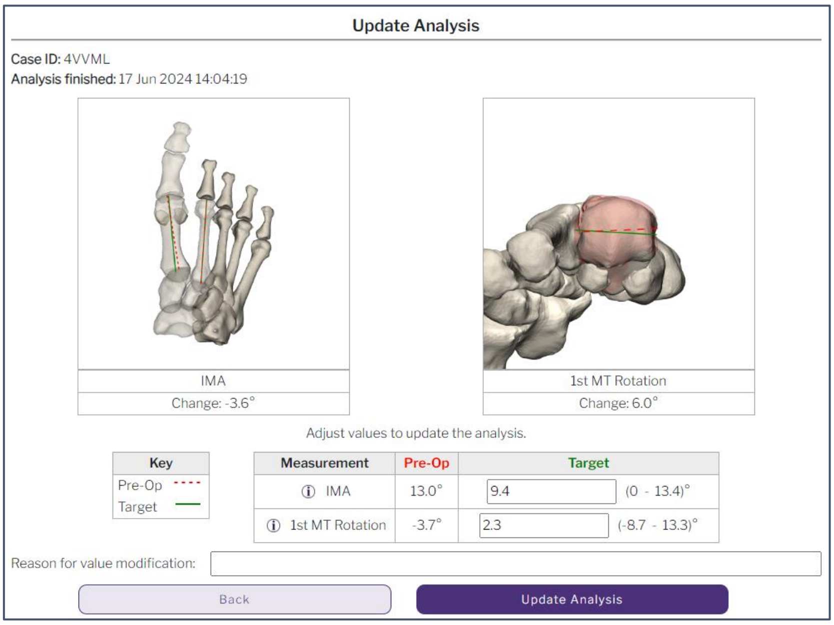
Note: When Metatarsus Adductus is addressed, IMA is affected by 1st Metatarsal axis rotation and 2nd Metatarsal axis rotation. Hover the cursor over the icon next to the IMA Change to see the related measurements. See Metatarsus Adductus Correction for more information.



(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.



View report and save analysis

- Review analysis results in the current window. Select Back to adjust values or Confirm and Return to Portal to save the analysis and complete a final review in the SMART28℠ Case Management Portal.

Note: The analysis from SMART Bun-Yo-Matic℠ CT is saved in the SMART28℠ Case Management Portal where it can be exported for outside review.

Automated anatomical measurements: methodology and definitions

Introduction

SMART Bun-Yo-Matic℠ CT 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 Bun-Yo-Matic℠ CT. It seeks to:

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

General Principles

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

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

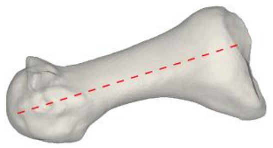
Available measurements

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 imaging devices patient coordinate system.
2. Measures are shown with + or – signs to represent the direction of change

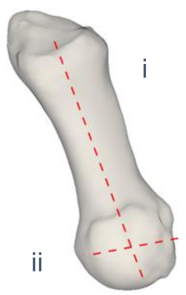
Bone axis definitions



Elongated bones

Metatarsal, Proximal phalange bones (I-V) 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.

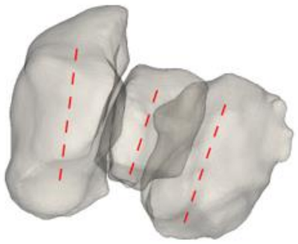


1st Metatarsal Distal Mediolateral Axis

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.

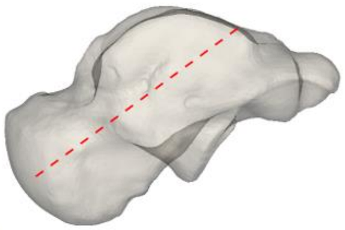
i) longitudinal axis

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.

Foot and ankle measurements

Image	Definition	Direction of Change
	**1^{st} – 2^{nd} Intermetatarsal Angle (IMA) *(Axial)*** The angle between the 1^{st} metatarsal (MT) longitudinal axis and the 2^{nd} metatarsal longitudinal axis measured in the axial plane	Increase in angle → 1^{st} MT shifts towards varus Decrease in angle → 1^{st} MT shifts towards valgus
	**Hallux Valgus Angle (HVA) *(Axial)*** The angle between the 1^{st} metatarsal longitudinal axis and the 1^{st} proximal phalanx (PP) longitudinal axis, measured in the axial plane	Increase in angle → 1^{st} PP shifts towards valgus Decrease in angle → 1^{st} PP shifts towards varus
	**Interphalangeal Angle (IPA) *(Axial)*** The angle between the 1^{st} proximal phalanx longitudinal axis and the 1^{st} distal phalanx (DP) longitudinal axis measured in the axial plane	Increase in angle → 1^{st} DP shifts towards valgus Decrease in angle → 1^{st} DP shifts towards varus

Distal Metatarsal Articular Angle (DMAA) *(Axial)*

Angle between a barrel fitted to the 1st metatarsal distal articular surface and its projection to a plane perpendicular to the 1st metatarsal.

Increase in angle → 1st MT distal articular surface shifts towards valgus

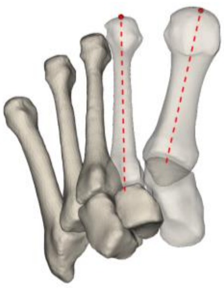
Decrease in angle → 1st MT distal articular surface shifts towards varus

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

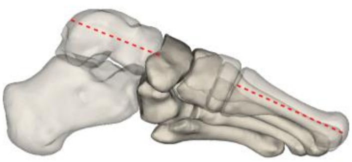


Relative Length 1st – 2nd Metatarsal *(Axial)*

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

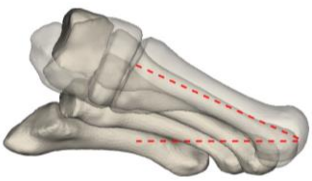


Meary's Angle *(Sagittal)*

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)

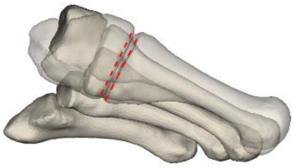


1st Metatarsal Declination Angle *(Sagittal)*

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

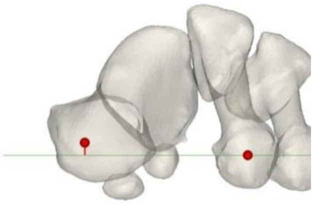


Plantar Gapping Angle
(Sagittal)

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

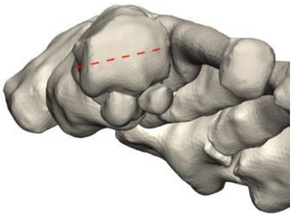


1st Metatarsal Elevation
(Coronal)

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

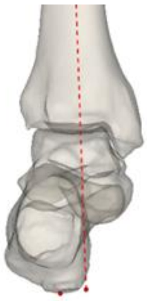


1st Metatarsal Rotation

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



Hindfoot Moment Arm
(Posterior)

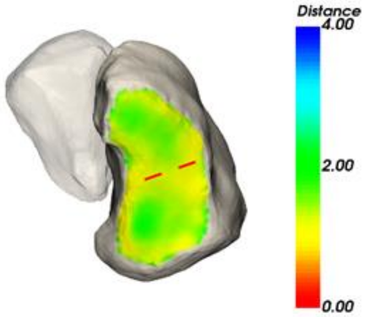
The mediolateral distance (mm) between the longitudinal axis of the tibia and most inferior point of the calcaneus. Only pre-op value is measured.

Larger value in mm → hindfoot shifts towards varus

Smaller value in mm → hindfoot shifts towards valgus

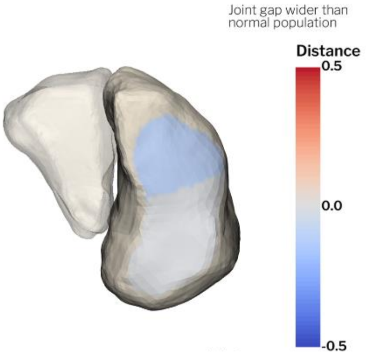
1st / 2nd / Calcaneus Ratio Image *(Axial)*

A visualization of how the 1st metatarsal, 2nd metatarsal and calcaneus are situated in relation to each other. The triangle includes the most inferior point of the calcaneus, the centroid of the 1st metatarsal distal head and the centroid of the 2nd metatarsal distal head.



1st TMT Distance Mapping with Average Gap

Distance map illustrating the joint area between medial cuneiform and 1st metatarsal. Average joint gaps are calculated based on the distance map.



Average Gap Difference From Normal Population

Patient specific results are also compared to normal population values to illustrate possible deviations in joint area to normal.

Automated surgical planning application: methodology and definitions

Lapidus procedure

The SMART Bun-Yo-Matic℠ CT 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 8). 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.

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.

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 8) with 2° of overcorrection. 1st Metatarsal Rotation is corrected to its normative reference value (see Table 8).

Tarsometatarsal Joint Resections

The SMART Bun-Yo-Matic℠ CT software virtual tarsometatarsal joint resections simulate the use of off-the-shelf Bun-Yo-Matic™ cut guides. 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.

Metatarsus Adductus Correction

The SMART Bun-Yo-Matic℠ CT software notifies the user if Metatarsus Adductus is detected (i.e. the axial 2nd Tarsometatarsal Angle is larger than a threshold of 24° (Dawoodi and Perera, 2012)). If the user confirms to continue the procedure despite the possible Metatarsus Adductus, 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 8). 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.

Hallux Correction

In addition, SMART Bun-Yo-Matic℠ CT 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 8).

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.

Sesamoid Correction

SMART Bun-Yo-Matic℠ CT 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.

Bun-Yo-Matic™ Correction

The SMART Bun-Yo-Matic℠ CT 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.

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.

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.

Reference Values

The normative reference values in Table 8 have been determined by using the analyser included in the SMART Bun-Yo-Matic℠ CT software by measuring a set of WBCT images of normal feet. These values align with the corresponding measurement values presented in the literature (

Table *9*).

Table 8 Summary of the measurements and their normative reference values used for SMART Bun-Yo-Matic℠ CT 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 9 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
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℠ CT case report are listed in Table 10. These have been determined by using the analyser included in the SMART Bun-Yo-Matic℠ CT software.

Table 10. Normative reference values for measurements shown in the SMART Bun-Yo-Matic℠ CT case report.

Measurement	Average	Standard deviation (SD)
Interphalangeal Angle	11.4°	4.4°
Distal Metatarsal Articular Angle	3.8°	4.1°
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
Hindfoot Moment Arm (Posterior)	4.1 mm	4.9 mm
1st Tarsometatarsal Joint Average Gap	1.5 mm	0.2 mm
1st Tarsometatarsal Joint Average Gap Superior	1.6 mm	0.2 mm
1st Tarsometatarsal Joint Average Gap Inferior	1.5 mm	0.2 mm

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 Orthopaedics, 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

Performance specification

SMART Bun-Yo-Matic℠ CT'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 11). Cases where the pre-op state is outside of this range should be interpreted carefully.

Table 11. Range of clinical conditions that SMART Bun-Yo-Matic ℠ (CT) is validated with.

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

Data management & software architecture

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

SMART Bun-Yo-Matic℠ CT software is provided as a web user interface and a cloud service.

1. DICOM data, user interface
    a. DICOM image is loaded to SMART Bun-Yo-Matic℠ CT software through the web user interface in the SMART28℠ Case Management Portal.
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. User starts computations.
3. File upload to cloud, user interface
    a. DICOM data and user defined parameters are sent to cloud service using HTTPS connection.
    b. HTTPS connection is secured with a TLS certificate.
4. Computations, cloud service
    a. DICOM data is de-identified.
    b. Cloud solver calculates analysis models and measurements.
    c. Results are saved as numeric data.
    d. Original DICOM data is deleted, de-identified data is retained.
    e. Measurement results can be used for diagnostic purposes.
5. Result presentation, user interface
    a. Analysis report is downloaded via HTTPS connection.

Cloud domain address

The HTTPS address to the Disior™ cloud in the US: https://api.smart28.tech/.

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.

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.

Data processing

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 image data is stored in USA
5. Server is protected by Microsoft Azure API management
6. Cloud instances are updated regularly

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 name, study ID, AC number, comments
   - Study date time, description,
   - Series number, date, time, modality, 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.

Manufacturer of SMART Bun-Yo-Matic℠ CT

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