ORTHOMERICA®

SmartSoc® for Cranial

User's Manual

UM 10-003 Rev. K

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I. Introduction

I.1. Scope of the User's Manual

This user's manual is intended for the *SmartSoc®* system users, which provides general directions to setup and operate the scanning device (i.e., Android or iOS smartphones) with the *CurveCapture™ O&P* mobile app and how to utilize the *eBrace® Global* web-portal. These directions outline how to capture three-dimensional geometry/shapes (SmartScan®) for Cranial products manufactured by Orthomerica Products, Inc.

I.2. Conventions Used in the Manual

The following Conventions are used in this User's Manual:

"`Mono-space`" type is used to show words that appear on the display.

"Italic" and **"Bold"** are used for emphasis.

"SMALL CAP" are used for keys on the computer keyboard and for menu items on the computer display.

Icons on the device screen, computer screen, and eBrace Global ordering site are referenced by name only. Their position may change according to functions being performed.

I.3. Problem Reporting Instructions

Clinical and fabrication questions should be directed to Orthomerica Products, Inc. between the business hours of 9:00 a.m.–5:00 p.m. EST, Monday–Friday.

Telephone: (877) 737-8444
Fax: (877) 737-8445
E-Mail: custserv@orthomerica.com

Hardware and software support for the *SmartSoc* System is provided by Orthomerica Products, Inc.

I.4. Reference Documents

For details of the *SmartSoc* system's Support Program services and software licensing, refer to the ***SmartSoc Purchase Agreement***.

Refer to the ***SmartSoc for Cranial User's Manual*** for instructions related to the operation of *CurveCapture™ O&P* application and *eBrace® Global* web-portal.

Refer to the ***Measurement and Comparison Utility (MCU™) for Cranial User's Guide*** for instructions related to the operation of *Measurement and Comparison Utility (**MCU™**)* application.

Refer to the ***Health & Safety Guide*** regarding the safety of the product.

II. System Overview

II.1. System Objectives and Components

SmartSoc is a 3D geometry digitized system used to capture, process digital 2D data and thus, generate a three -dimensional (3D) shape/geometry (SmartScan®). The generated 3D shapes are used in the applications of orthotic and cranial devices manufacturing.

The *SmartSoc* system consists of a smartphone with proprietary software installed, the *SmartSoc* sleeves, *Registration* tags, landmarks stickers and a customer-supplied computer.

II.2. Theory of Operation

CurveCapture O&P is a proprietary data acquisition application, based on NetVirta's patented computer vision technology, to convert 2D video images into a 3D model. The operation apparatus utilizes a consumer grade smartphone with pre-installed data acquisition software and a stretchable fabric covering (*SmartSoc* sleeves). There are locally non-repetitive color patterns printed on the *SmartSoc* sleeve.

After applying the *SmartSoc* Sleeve to the appropriate body part, the user uses the smartphone to capture video images of the body part, using the *CurveCapture O&P* application. The scanning data is uploaded to a webserver via the internet connection.

The scanning data will be processed by proprietary computer vision software on the server; thus, the 3D geometry/3D CAD data is constructed.

II.3. Features and Specifications

The *CurveCapture™ O&P* is a proprietary data acquisition application, based on NetVirta's patented computer vision technology of converting digital 2D data into 3D shape/geometry (SmartScan®).

The 3D geometry digitizing operation apparatus includes

- The certified consumer grade smartphone with pre-installed *CurveCapture™ O&P* software,
- The stretchable fabric with imprinted non-repetitive color patterns *SmartSoc* sleeves comprises specific configuration dedicating for intended anatomy/geometry.
- The capturing aided *Registration* tag, and
- The anatomy identification landmarks stickers.

Which function altogether in the process of detecting and capturing the color patterns surface of the (forming anatomy/geometry) sleeve. The capturing data are uploaded to a 3D-processing web server via the internet connection, where the data will be processed and constructed into usable 3D geometry (i.e., 3D-CAD data).

II.4. Equipment Supplied by Orthomerica

Orthomerica will supply the entire *SmartSoc* System. This includes a certified smartphone model (Android or iOS) with the CurveCapture O&P software pre-installed. The accessories for the smartphone also include a USB cable, battery, and wall charger.

SmartSoc sleeves, Registration tags, and landmark stickers are provided, and additional supplies are ordered through Orthomerica Products, Inc.

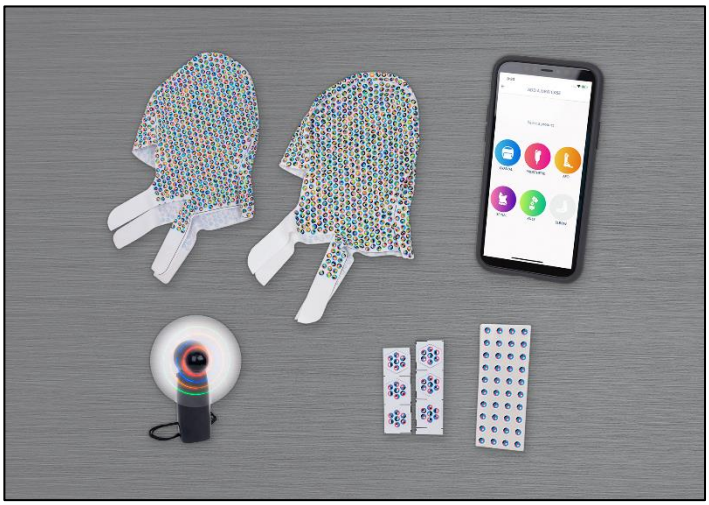

Fig. II.a

II.5. Equipment Supplied by Clinician

SmartSoc user is responsible to provide

- PC or laptop consisting of hardware of at least 1 Gb RAM and graphics capability, connects to the internet accessed wi-fi or local area network (LAN) and enables the capability of the latest up-to-date version of Google Chrome web browser, for *eBrace Global* web-portal operation.

- The internet accessed wi-fi or cellular service with (data) uploading bandwidth of 3.0 Mb (minimum), for device's *CurveCapture™ O&P* mobile apps operation.

II.6. Prohibited Uses

The *SmartSoc* System is **NOT** intended to:

- Be operated by anyone other than medical professionals who are aware of its design purpose, the technology used and the safety aspects of its use.

- Be used as a personal device. Do not use this device for applications other than its design purposes.

Fig. II.b

- Be used with other applications that may be available for the device. Do not download any additional applications to the system.

III. SmartSoc System First Time Setup

- The device (smartphone) should be fully charged prior to the setup process.
- Based on the current version of device firmware, the screen's appearance may vary slightly.

For **Android** devices, proceed to **III.1.** *(Android)* Devices

For **iOS devices**, proceed to **III.2.** *(iOS)* Devices

III.1. *(Android)* Devices

III.1.a Device Security- Lock Screen Setup

Swipe down from the top of the screen to reveal and select the `Settings` icon Error! Reference source not found.

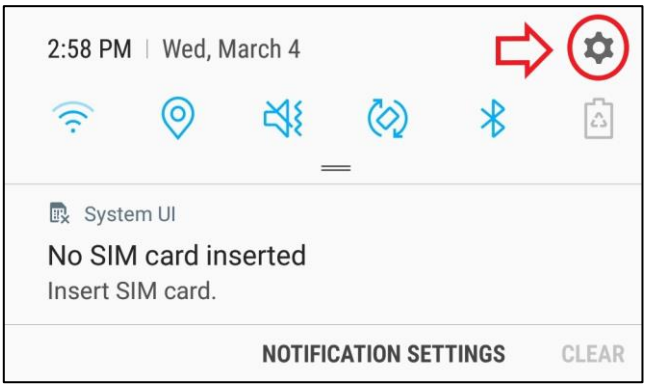

Fig. III.a

- Click on the `Settings` icon.
- Scroll down and select the "Lock screen and security" - **Fig. III.b**
- Select the "Screen lock type" and specify the preferred lock screen method of either *Pattern, PIN, Password or Fingerprints* - **Fig. III.c**

At prompt, follow the device instructions to establish and save the LOGIN configuration for the specific screen lock type, accordingly.

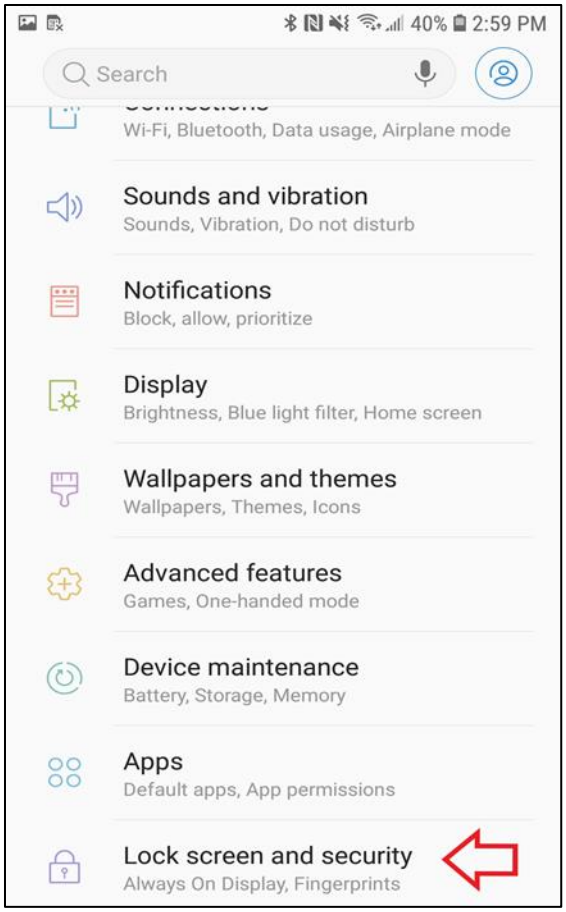

Fig. III.b

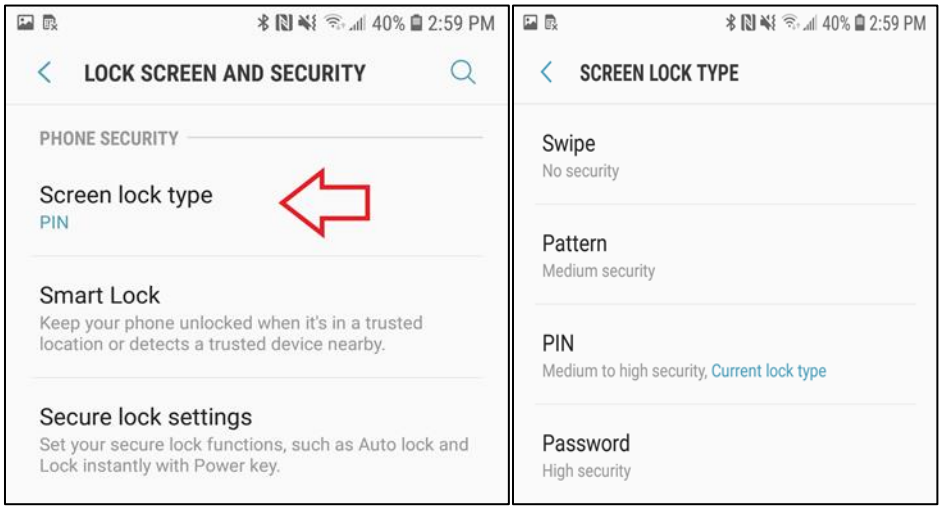

Fig. III.c

III.1.b *(Android)* Device Wi-Fi Setup

At the device's home screen, swipe down from the top of the screen to reveal the *Settings* icon - **Fig. III.a**

- Click on the *Settings* icon.
- Select the "Connections" icon - **Fig. III.d**, and
- Select the "Wi-Fi" - **Fig. III.e**

The list of available wireless networks should be displayed.

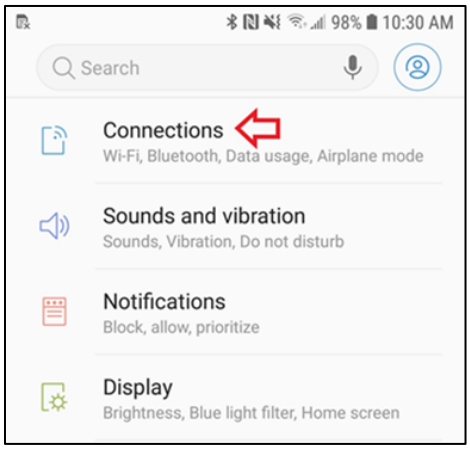

Fig. III.d

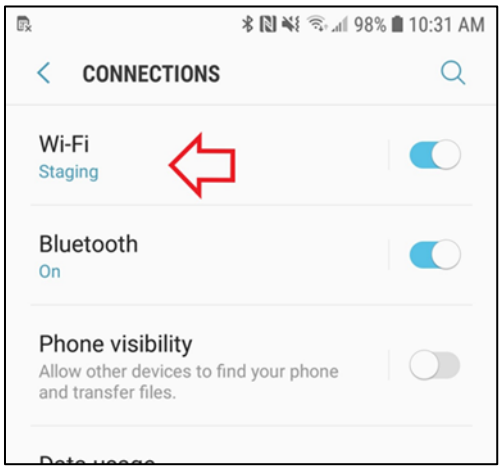

Fig. III.e

Either, Select the wireless network from the list

- At the prompt, type in the networks login *password* and click "Connect" to start the Wi-Fi connection

Or, Tap the "Add network" to add the preferred wireless network

- At the prompt, type in the network's *ID/name* & login *password* and click "Connect" to start the Wi-Fi connection

When device is successfully connected to the specified wireless network, the "Connected" notification will be displaced right under the network ID/Name - **Fig. III.f**

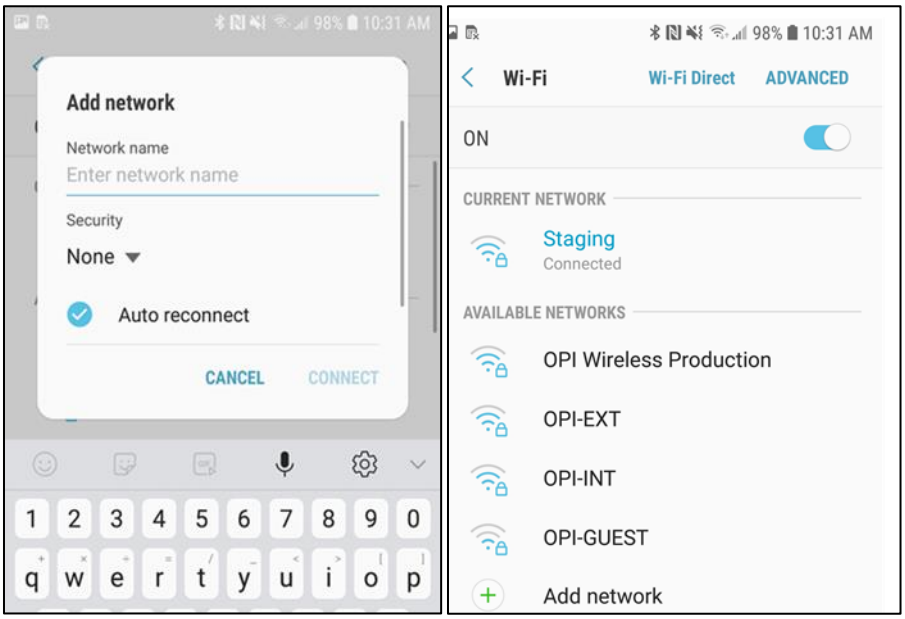

Fig. III.f

Proceed to,

0

(Android & iOS) Device – eBrace Global and CurveCapture O&P Setup

III.2. *(iOS)* Devices

III.2.a Device Security- *Lock Screen Setup*

At the device's home screen, swipe down from the top of the screen to reach the `Current Activities` screen.

- Tap on the `Search` window, and type in "*settings*" - **Fig. III.g**
  The Settings icon will be displayed.
- Click on the `Settings` icon.
- Scroll down and select the "Face ID & Passcode" - **Fig. III.h**
- At prompt, follow the device instructions to

  Either establish or save the new login *passcode* - **Fig. III.i**

  Or confirm the existing login *passcode.*

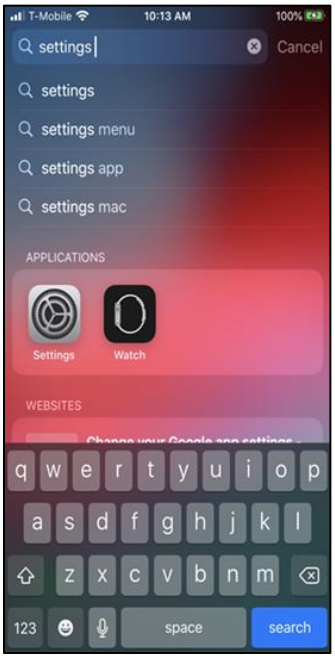

Fig. III.g

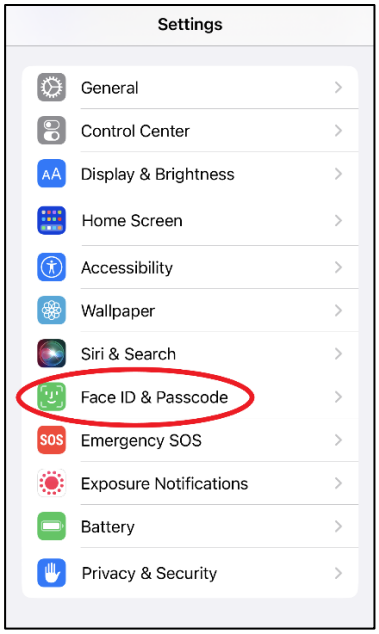

Fig. III.h

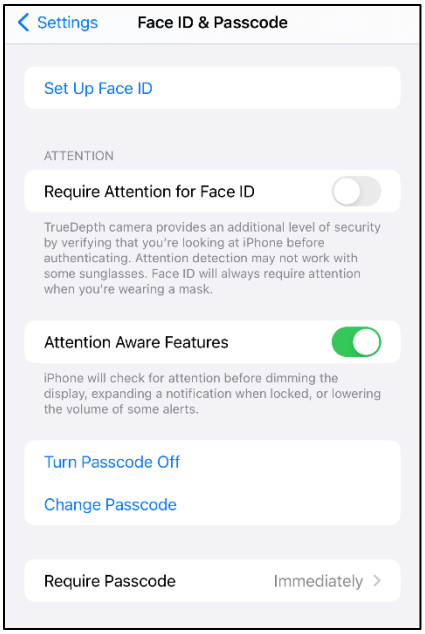

Fig. III.i

III.2.b *(iOS)* Device Wi-Fi Setup

At the device's *home* screen, swipe down from the top of the screen to reach the `Current Activities` screen

- Tap on the `Search` window, and type in the "*settings*" - **Fig. III.g**

  The Settings icon will be displayed.

- Click on the "Wi-Fi" icon

  The list of available wireless networks should be displayed.

Either select the wireless network from the list

- At the prompt, type in the networks login *password* and click "Join" to start the Wi-Fi connection

Or tap the "Other..." to add the preferred wireless network

- At the prompt, type in the networks *ID/name* & login *password* and click "Join" to start the Wi-Fi connection - **Fig. III.j**

When a device is successfully connected to the specified wireless network, the " ✓ " notification will be displaced right in front of the network ID/Name - **Fig. III.k**

Fig. III.j

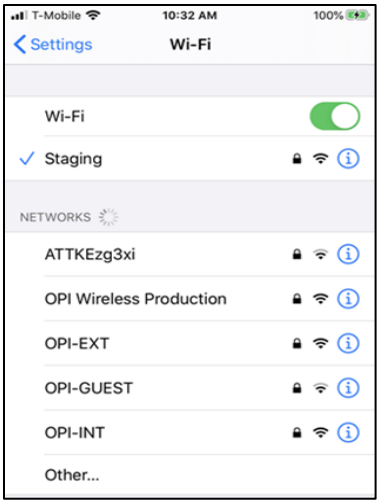

Fig. III.k

Proceed to,

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(Android & iOS) Device – eBrace Global and CurveCapture O&P Setup

Repeat the device Wi-Fi setup process of locating and selecting a Wi-Fi network when using the device for the first time in any new environment.

Cellular Operation

When Wi-Fi network is not available, a device (i.e., *CurveCapture O&P* application) can still be effectively operated by utilizing its existing active cellular service (with internet connection). When a Wi-Fi network (with internet connection) is available, a device (i.e., *CurveCapture O&P* application) will actively be functioned by utilizing the available Wi-Fi service.

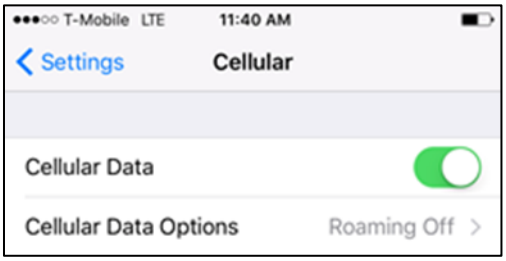


Fig. III.l

Offline Mode

If the device is neither connected to a Wi-Fi network nor a cellular service (with internet connection) is available, *CurveCapture™ O&P* will automatically operate under the *offline* mode.

When operating under the *offline* mode, the capability of searching for existing patients from device and/or uploading scanning data from device to *eBrace® Global* web-portal will not be available.

When operating under the *offline* mode, the scanning data will be preserved within the device's encrypted *storage* place holder, temporarily. The scanning data will automatically be uploaded and/or completely transferred to *eBrace Global* web-portal when the device is connected to a Wi-Fi network and/or a cellular service (with internet connection).

III.3. *(Android & iOS)* Device – eBrace Global and CurveCapture O&P Setup

SmartSoc Registered Account

At the time a CO (user) account is established, a temporary LOGIN password for eBrace® Global web-portal & registered device will be forwarded to the user via their registered email address.

Setup Password for eBrace Global

- Open the eBrace Global web-portal https://ebrace-global.orthomerica.com/login
- At the `LOGIN` screen, type in
    - The *(registered) email address*
    - The *temporary password*
- Click "Sign In"
- For optimal security, the user will be prompted to change the password immediately after logging in for the first time.

  NOTES:

    - New password must contain at least:
        - Twelve characters
        - One uppercase character
        - One lowercase character
        - One special character, and
        - One number
    - The *new password* set here will be used for logging into both: *eBrace Global web-portal* **and** *CurveCapture O&P App*.
- Once the new password has been typed in, click on "Change Password"

IV. SmartSoc System Two-Factor Authentication (2FA)

IV.1. 2FA Setup

Setup Two-Factor authentication (2FA)

On the initial log in to eBrace Global, a pop-up window will appear titled "Setup Two-factor authentication". The CO (user) will have the option to enable 2FA for an added layer of security.

Setup 2FA Opt-IN

- At the *eBrace Global* web portal: https://ebrace-global.orthomerica.com/
    - Log in to eBrace Global with Email and Password, as usual.

- After successfully logging in, the "`Setup two-factor authentication`" window will appear.

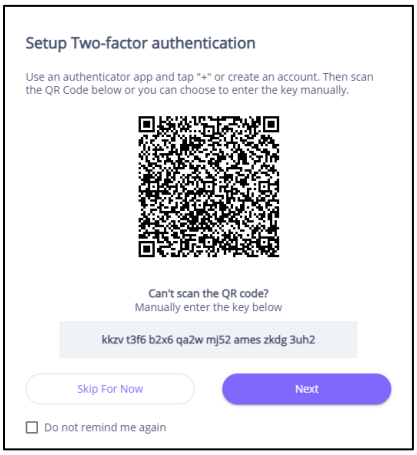


Fig. IV.a

NOTE: Leave the eBrace Global screen as is.

- On the SmartSoc device,
    - Select 'App Store' from the device home screen.
    - Select 'Search'.
    - Enter '*authenticator*' on the search field.

- Select 'Get' to *download and install* your preferred authenticator app on to the device.
  Click on the icon to start the app.

- Click on the 'Get Started'
- Select 'Scan a QR code'.
  - Scan the QR code that was displayed on eBrace Global.
  - On the device, the 'Authentication code' will be provided.

Note: The 'Authentication code' will be reset every 30 seconds.

- On **eBrace Global**,
  - Select 'Next' on the "Setup two-factor authentication" pop-up window.
  - Enter the '**Authentication code**' that appears on the authenticator app.
  - Click 'Verify' to complete the 2FA set-up (i.e., successfully log-in into eBrace Global).
- Continue to operate eBrace Global as normal.

Setup 2FA Opt-OUT

- At the eBrace Global web portal: https://ebrace-global.orthomerica.com/
  - Log in to *eBrace Global* with Email and Password, as usual.

- After successfully logging in, the "Setup two-factor authentication" window will appear - **Fig. IV.a.**

- Select 'Skip for now' if you wish to not receive a 2FA prompt at each login - **Fig. IV.b**

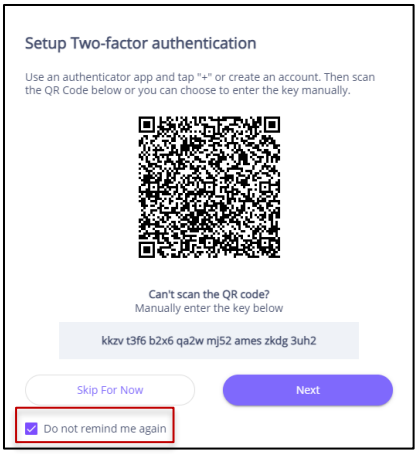


Fig. IV.b

The first sign in process is now complete and the user is ready to start using the eBrace Global web-portal.

Setup 2FA Opt-IN After Opting OUT

- At the eBrace Global web portal: https://ebrace-global.orthomerica.com/
    - Log in to *eBrace Global* with Email and Password, as usual.

- After successfully logging in, click on Your Name on the top right corner.

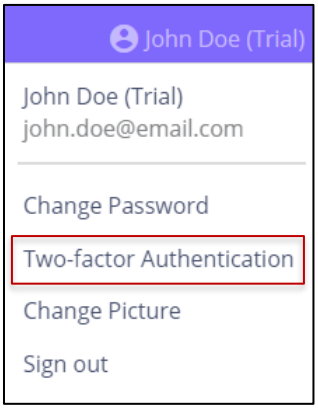


Fig. IV.c

- Select Two-Factor Authentication and **Fig. IV.a** will pop-up.
- Follow the steps in **Setup Two-Factor authentication (2FA)** to opt into the 2FA feature.

IV.2. 2FA Utilization

After successfully initiating the 2FA Opt-In process.

eBrace Global - 2FA Application

- At the eBrace Global web portal: https://ebrace-global.orthomerica.com/
  Log in to *eBrace Global* with Email and Password, as usual.
- After successful login, the `'Two-factor authentication (2FA)'` prompt will appear.

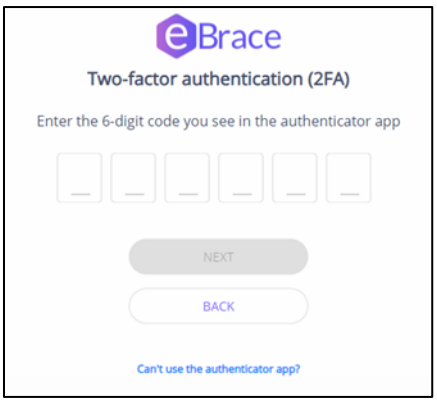


Fig. IV.d

NOTE: Leave the *eBrace Global* screen as is

- On the **device**,
  Click on the `Authenticator` icon to start the app.
- At the **eBrace Global web portal**,
  Enter the 'Authentication code' displayed on the `Authenticator` app.

  NOTE: The '`Authentication code`' will be reset every 30 seconds.

Successfully log-in into eBrace Global,

Continue to operate eBrace Global as normal.

CurveCapture O&P - 2FA Application

- On the **device**,
  Select the CurveCapture O&P icon.
- At the CurveCapture O&P log in screen,
  Log in to CurveCapture O&P with Email and Password, as usual.
- After successful login, the `'Two-factor authentication (2FA)'` prompt will appear.

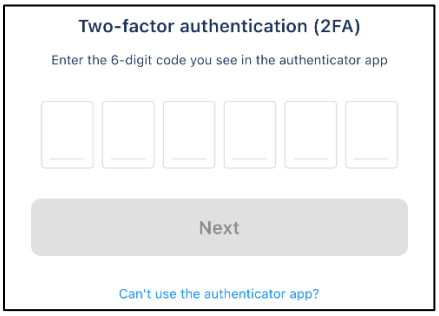


Fig. IV.e

NOTE: Leave the *CurveCapture O&P* screen as is.

- Swipe up from the bottom center edge of the device touch screen *to return to the home screen*.
- Click on the `Authenticator` icon to start the app.
- Make a mental note of the '`Authentication code`'

NOTE: The '`Authentication code`' will be reset every 30 seconds.

- Swipe up from the bottom center edge of the device touch screen *to return to the home screen*.
- Click on the CurveCapture O&P icon to re-open the app.
- Enter the 'Authentication code' from the `Authenticator` app.

Successfully log-in into CurveCapture O&P,
Continue to operate CurveCapture O&P as normal.

IV.3. 2FA Modification

Transfer 2FA (device replacement)

- Follow steps from section eBrace Global - 2FA Application to log-in into *CurveCapture O&P*.
- After logging in successfully,
  Click on your name in the top right corner of the *eBrace Global* web page.
- Select 'Two-factor Authentication'
  The '`Two-factor authentication (2FA)`' window will appear.

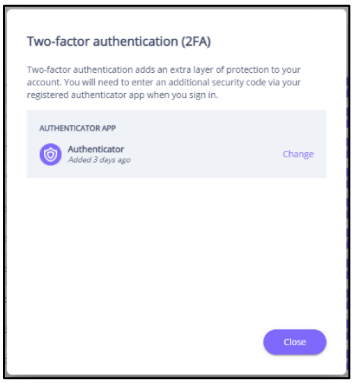


Fig. IV.f

- On the **Authenticator App box**,
  Click 'Change'
- The '`Change authenticator app`' window will appear.

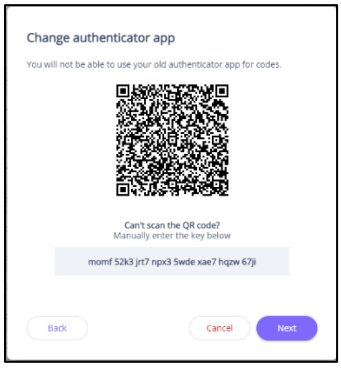


Fig. IV.g

NOTE: Leave the *eBrace Global* screen as is.

- **On the new replacement device**,
  Follow steps in section Setup 2FA Opt-IN to download and install the *Authenticator app* on the new replacement device.

Canceling/Resetting 2FA

- At the ***eBrace Global*** web portal: https://ebrace-global.orthomerica.com/
  Log in to *eBrace Global* with Email and Password, as usual.
- Next, the '`Two-factor authentication (2FA)`' prompt will appear.

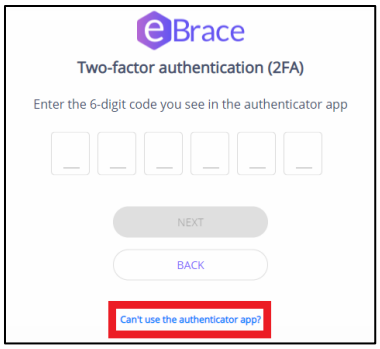


Fig. IV.h

Click on 'Can't use the authenticator app?' to stop using the 2FA utility.

- On the '`Account Recovery`' screen, click 'Confirm' to request cancelling the 2FA utilization.

The 2FA cancellation will be confirmed by Orthomerica SmartSoc Administrator. A notification email will be sent out to the user's login email notifying the user of when 2FA has been reset.

V. Cranial Scanning Operation *(CurveCapture O&P)*

Patient Records

A ***case*** is an individual *scanning session* of a patient that is identified by the ***Case/Scan ID***. A case/scan consists of a patient scanning data, the patient PHI & associated diagnosis and ordering information *(as needed).*

Each generated *case/scan* must be associated to a patient; more than one case/scan can be associated to a specific patient. Thus, the scanning data from generated *cases*, *of a specific patient*, can be utilized for ***(MCU)*** comparison study.

The ***case/scan*** can be classified as either

- **Fabrication** – A scan/case is intended to be utilized for acquiring fabrication products *(i.e., orthosis, prosthetics)*, which the captured scanning data, patient information, patient clinical conditions & product *(i.e., fabrication device)* specifications are required for order submitting.

- **Follow-Up Scan** – The additional scans/cases are generated, during a patient's treatment process and intended to be utilized for monitoring and/or making assessment of *(i.e., measurements, comparison)* a patient's treatment progress, which.
  - The patient's information & clinical conditions are already existent.
  - The product *(i.e., treatment orthosis/prosthesis)* specifications are not required.

The "*Diagnosis & Ordering*" and "*Shipping & Billing*" screens will be greyed out.

As needed, a *follow-up* scan/case can be reset for acquiring fabrication products *(i.e., orthosis, prosthesis)*, which the update product *'s* specifications is required, in addition to the existing patient's information & clinical conditions, for order submitting.

- **End-of-Treatment Scan** – *{Cranial application, ONLY}* The last scan/case is generated, at the end of a patient's treatment process, and intended to be utilized for making assessment of *(i.e., measurements, comparison)* a patient's treatment progress, which
  - The patient's information & clinical conditions are already existent.
  - The product *(i.e., treatment orthosis)* specifications are not required

  The "*Diagnosis & Ordering*" and "*Shipping & Billing*" screens will be greyed out.

A ***patient profile*** is a designated *storage* place holder where the specific patient's ***cases*** are recorded and maintained at. A ***patient profile*** is identified by the ***Patient ID***.

For a specific patient, there is *one and only one* ***patient profile*** generated and utilized. Under the *eBrace Global* operation, ONLY ***cases*** within a ***patient profile*** can be used for the ***(MCU)*** comparison study.

V.1. New Scan/Case Setup

V.1.a New Scan/Case Setup for *NEW* Patient

ATTENTION:
To prevent the additional, duplicate patient records, of the specific patient, from generating unnecessarily, the ***Existing Patient*** searching process - reference the above **V.1.a**– this must be performed to determine whether a **patient already exists** (i.e., a ***patient profile*** has been generated & recorded) within ***eBrace® Global*** system.

For a *new* patient (i.e., a ***patient profile*** has never been generated & recorded), a new ***case*** can be initiated with **either of the following methods**:

CurveCapture™ O&P application

New Scan/Case Setup for NEW Patient

- Start the CurveCapture O&P application

- At the LOGIN screen, type in
  - The *(registered) email address*
  - The login *password* and tap "Login" to operate the *CurveCapture O&P application*
- If applicable, enter 2FA code (refer to Pg. 18-23 for 2FA setup)
- At the SELECT PATIENT screen, click the "New Patient" icon on the top left
- At the ADD NEW PATIENT screen,
  - Type in the new patient information – *First Name, Last Name*
  - Enter patient *DoB* & *Gender*
  - Click "Create" to generate the new patient profile for this new patient
- Select "Cranial" at the SELECT SCAN screen to begin scanning

Proceed to **V.2.** Patient Pre-Scan Preparation

eBrace Global web-portal

New Scan/Case Setup for NEW Patient

- Start the web browser, and type in
  https://ebrace-global.orthomerica.com/login
- At the *eBrace Global* login screen, type in
  - The *(registered) email address*
  - The login *password* and click "SIGN IN" to enter the *eBrace Global* web-portal.

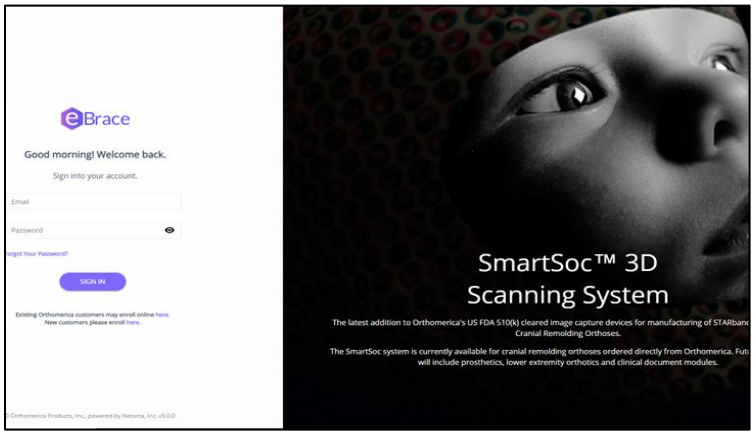


Fig. V.a

- If applicable, enter 2FA code (refer to Pg. 18-23 for 2FA setup)
- Click the "CASE" and select the "Cranial" from the products dropdown list
- At the `Case > Cranial` screen, click the "NEW CASE" to initiate the new Cranial case - **Fig. V.b**.

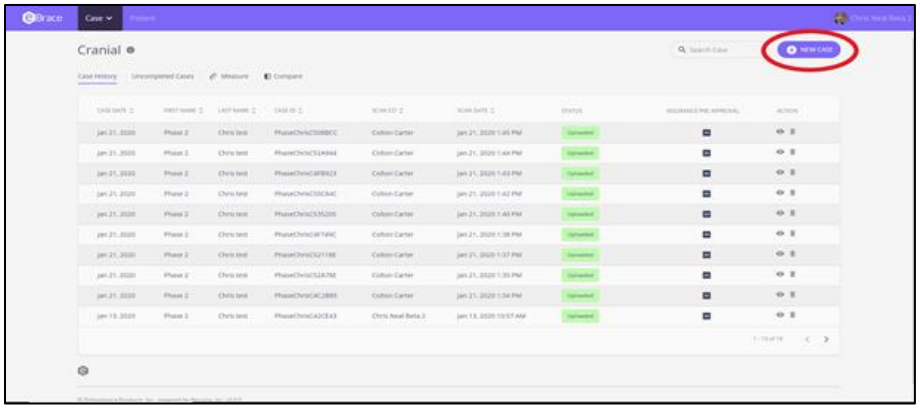


Fig. V.b

- At the `Create New Cranial Case` window, select the "New Patient"
  - Type in the new patient information – *First Name, Last Name*
  - Enter patient *DoB* & *Gender*
  - Click "Create" to generate the new case for this new patient

Proceed to **V.2.** Patient Pre-Scan Preparation

V.1.b New Scan/Case Setup for EXISTING Patient

For an existing patient (i.e., a *patient profile* has been generated & recorded), a *new* ***case*** can be initiated with either of the following methods:

CurveCapture™ O&P Application

New Scan/Case Setup for EXISTING Patient

- Start the *CurveCapture O&P* application.
- At the `LOGIN` screen, type in
  - The *(registered) email address.*

- The login *password* and tap "Login" to operate the *CurveCapture O&P* application.

- If applicable, enter 2FA code (refer to Pg. 18-23 for 2FA setup).
- At the HOME screen, type in the *Patient ID* (*i.e., first name, last name)* in the "Search" field to search for the *existing* patient.

The list of matching Patient IDs will be displayed.

- Tap on a *Patient ID* from the list to select the searching patient.

The Patient Profile page will be displayed.

➢ Tap on the INFORMATION tab on the top right to review the patient information and confirm that it is correct.

If the searched for patient is found and confirmed,

- Click "new scan" to generate the new case for this existing patient and select "Cranial".

Proceed to **V.2.** Patient Pre-Scan Preparation

If the searched for patient is not found,

Proceed to **V.1.a.** New Scan/Case Setup for *NEW* Patient*, as needed.*

eBrace Global web-portal

New Scan/Case Setup for EXISTING Patient

- Start the web browser, and type in
  https://ebrace-global.orthomerica.com/login
- At the *eBrace* login screen, type in
  - The *(registered) email address.*
  - The login *password* and click "Sign In" to enter the *eBrace Global* web-portal.
- If applicable, enter 2FA code (refer to Pg. 18-23 for 2FA setup).
- Click the "CASE" and select the "Cranial" from the products dropdown list.
- At the Case > Cranial screen, click the "NEW CASE" to initiate the new Cranial case.

- At the `Create New Cranial Case` window, select the "Existing Patient" and type in the *patient ID (i.e., first name, last name, …)* in the "Search patient" field.

  The list of matching Patient IDs will be displayed.

- Tap on a *patient ID* from the list to select the searching patient.
  - ➢ Review the patient information and confirm that it is correct.

  If the searching patient is identified and confirmed,

  - Click "Create" to generate the new case for this existing patient

    Proceed to **V.1.** New Scan/Case Setup

  If the searching patient is not found,

  - Click "X" to go back to the ***Patient***, and
    Proceed to **V.1.a.** New Scan/Case Setup for *NEW* Patient, *as needed.*

V.1.c How to Edit an Existing Patient

eBrace Global web-portal

Edit an Existing Patient

- Start the web browser, and type in
  https://ebrace-global.orthomerica.com/login
- At the *eBrace Global* login screen (Fig. V.a), type in
  - The *(registered) email address*
  - The login *password* and click "SIGN IN" to enter the *eBrace Global* web-portal.
- If applicable, enter 2FA code (refer to Pg. 18-23 for 2FA setup)
- Click the "Patient" tab located at the top left-hand corner of the screen to view all patients for this user.

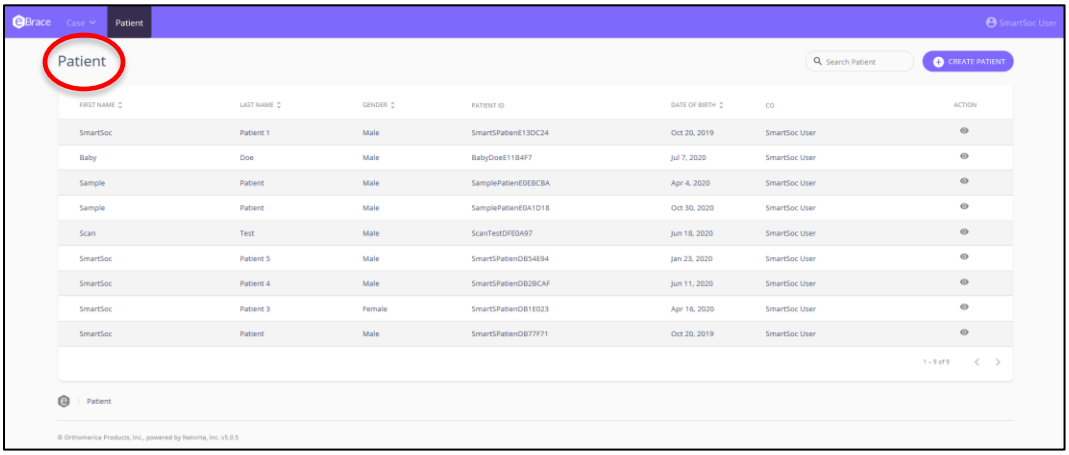


Fig. V.c

- Click the "Action" icon,  , associated with the patient profile to view/edit the following fields
  - *First Name*
  - *Last Name*
  - *Date of Birth (DoB)*
  - *Gender*

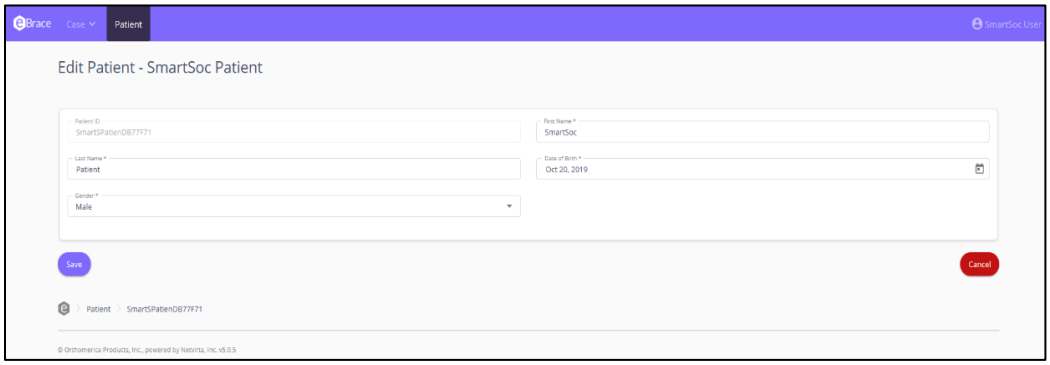


Fig. V.d

- There is additional patient edit options that are reserved for branch admins and organization admins that can benefit your clinical workflow (for example assigning and/or merging patients). Please see eBrace® Global Administration User's Manual UM 10-007 for more information.

  https://www.orthomerica.com/smartsoc-training/

V.2. Patient Pre-Scan Preparation

V.2.a Cranial Sleeve Fitting

Cranial Sleeve – Sizes Available

- There are total of seven (7) sizes of *SmartSoc* cranial sleeves that accommodate the full range of pediatric cranial anatomy - *Ref. the* ***SmartSoc Cranial Sleeve – Sizes Chart***

Size	Model #	Fits Cranial Circumference
Extra Small (XS)	823.04	37.5–39.5 cm
Small (SM)	823.01	39.5–42 cm
Small Medium (SM/MD)	823.05	41–43 cm
Medium (MD)	823.02	42–44.5 cm
Medium Large (MD/LG)	823.06	43–46 cm
Large (LG)	823.03	44.5–48.5 cm
Extra Large (XL)	823.07	48.5–53 cm
Adult Small (Adult SM)	823.08	53–58 cm
Adult Medium (Adult MD)	823.09	58–64 cm

Cranial Sleeve – Correct Size How-To

- Take a circumference measurement *{Metric unit:* ***cm****}* just above the patient's *brow line*
- Match the patient's *Circumference* (@ *just above brow line*) measurement to the *SmartSoc Cranial Sleeve – Size Chart's Circumference Range*, to determine the correct size & the associated ***Model #*** of cranial sleeve that *best fit* the patient.
    - If the patient's *Circumference measurement* matches at the middle of the *Chart's Circumference* range, the smaller size sleeve should be selected/used.

Incorrect size selection of the sleeve will fit poorly and will generate a subpar (scanning) surface, and hinders the device's capturing capability and

operation, resulting in the unreliable capture of scanning data and/or model generation.

An ***oversized*** sleeve will be loosely fitted, which *a)* introduces distortion to the surface (i.e., wrinkle, groove, crease, waving, folding, …) and *b)* potentially moves or shifts, during the scanning process.

An ***undersized*** sleeve will be overly stretched, which *a)* degrades the configuration and/or color of the sleeve's patterns and *b)* applies excessive (radial) compression onto patient's cranial; thus, may distort the shape and size of the *(patient's cranial)* geometry.

Cranial Sleeve – Fitting How-To

- Evaluate the patient before fitting the sleeve for any skin, bone, or other abnormalities and record the information in the *eBrace Global* diagnosis/ordering {*eForm*} chart.

  The digital photos of anomalies present may be forwarded directly to ebrace@orthomerica.com, in addition to the cranial order submission.

- The sleeve should be smoothly applied— **Fig. V.e**— and properly positioned onto the patient's cranial anatomy. The sleeve must be securely stationed, in association to the cranial anatomy throughout the scanning process.

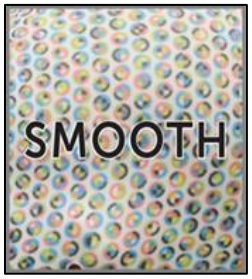


Fig. V.e

- Fit cranial sleeve onto patient's head, such that
  - The cheek areas are smoothly covered as much as possible
  - The neck areas snug and smoothly covered, also.

Fig. V.f

- The superior extension should be securely & snugly knotted across the **front of the chin - Fig. V.f**
- The inferior extension should be comfortably & snugly knotted at **under the chin - Fig. V.f**

When the sleeve is *improperly* fit on the patient's head, it generates distorted (*i.e., wrinkle, groove, crease, waving, folding*) surface, and unreliable scanning data will be captured; thus, it will significantly affect the quality/accuracy of the 3D data.

When the sleeve is *not securely* fit on the patient's head that shifts or moves during the scanning process, inconsistent scanning data will be captured; thus, the inaccurate 3D data will be produced.

V.2.b Registration Tag

In addition to the *SmartSoc* sleeve, the *Registration* tag is one of the **required** components that **must be** used in all *SmartSoc* system scanning processes.

Each *Registration* tag's capturing data is preserved & applied for the specific scanning session, only. The *Registration* tag's capturing data is the essential & required element which will be utilized, during the *SmartSoc* system's 3D processing operation, to process scanning data & facilitate the 3D geometry generation.

Registration Tag – Placement How-To

- Remove the adhesive backing from a *registration tag*.

- Place and secure *Registration tag* onto the *(sleeve covered) patient's* superior aspect of the head— **Fig. V.g**

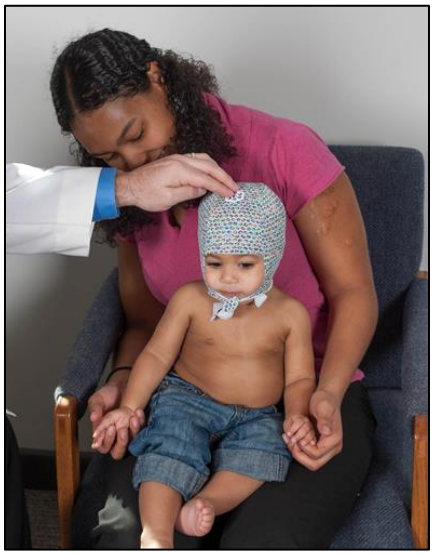


Fig. V.g

A ***Registration tag*** can be reused provided that the *configuration & color* of the color patterns are maintained.

A reused ***Registration tag*** must be kept clean. Avoiding the use of any chemical cleaning solution is a must.

V.2.c Landmarks

In addition to the *SmartSoc* sleeve & the *Registration tag*, landmark markers are also used in *SmartSoc* System's scanning process.

Landmarks are used to visually identify cranial's prominent anatomy, which useful data is recorded, during the scanning process, and provided/utilized for subsequent applications (i.e., alignment, measurements, fabrication).

Landmarks – IDs

- There are landmarks to be applied at a cranial scanning process:

1. Nose Bridge (Sellion)
2. Nose Tip (Pronasale)
3. Cheek *Left* & Cheek *Right*

4. **Tragion** *Left* & Tragion *Right*
5. **Exocanthion** *Left* & Exocanthion *Right*
6. Ear Distal *Left* & Ear Distal *Right*
7. **Subnasion**

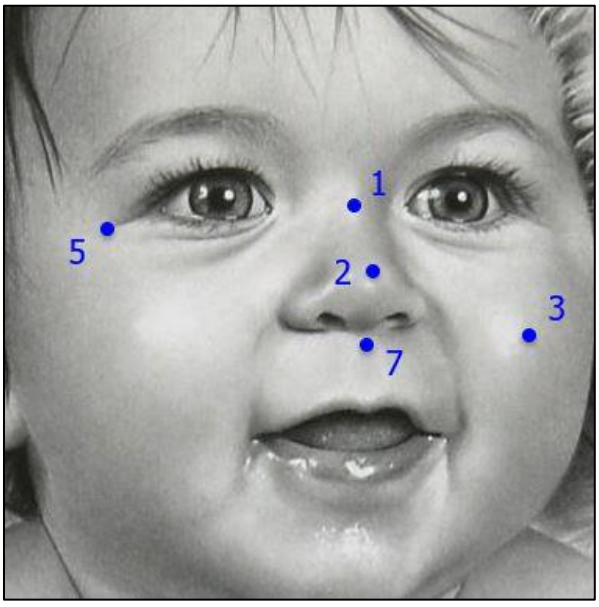


Fig. V.h

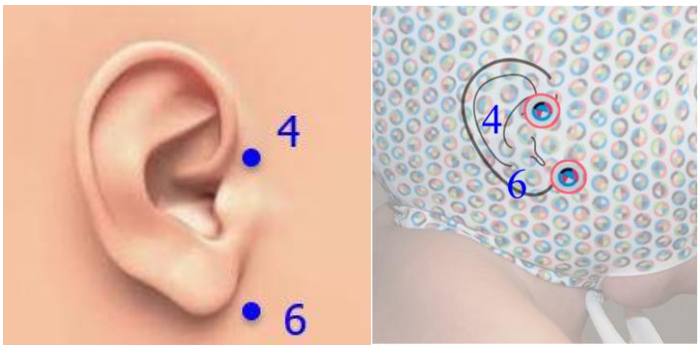


Fig. V.i

Additional *user-defined* landmarks can be used as per user preference.

Required Landmarks

- For GENERAL applications *(i.e., submit for manufacturing)*
  - Nose Bridge (Sellion)
  - Nose Tip (Pronasale)
  - Cheek *Left* & Cheek *Right*
  - Ear Distal *Left* & Ear Distal *Right*

- For MEASUREMENT application utilizing ***MCU Alignment***
  - Nose Bridge (Sellion)
  - Nose Tip (Pronasale)
  - Cheek *Left* & Cheek *Right*

  ❖ ***Ref. the Measurement and Comparison Utility (MCU™) for Cranial User's Guide***.

- For MEASUREMENT application utilizing ***CCU Alignment***
  - Nose Bridge (Sellion)
  - **Tragion** *Left* & ***Tragion*** *Right*

  ❖ ***Ref. the Measurement and Comparison Utility (MCU™) for Cranial User's Guide***.

- For *Craniofacial* MEASUREMENT application, utilizing either ***MCU*** or ***CCU Alignment***

  In addition to the required landmarks for measurement application utilizing MCU or CCU alignment
  - **Tragion** *Left* & ***Tragion*** *Right*
  - **Exocanthion** *Left* & Exocanthion *Right*
  - **Subnasion**

  ❖ ***Ref. the Measurement and Comparison Utility (MCU™) for Cranial User's Guide***.

Landmarks – Placement How-To

- Place and secure each landmark sticker onto the *(sleeve covered) patient's* head, as per following specific placement— **Fig. V.h** & **Fig. V.i**

- The landmark stickers should be placed after the cranial sleeve has been securely applied onto patient— **Fig. V.j**

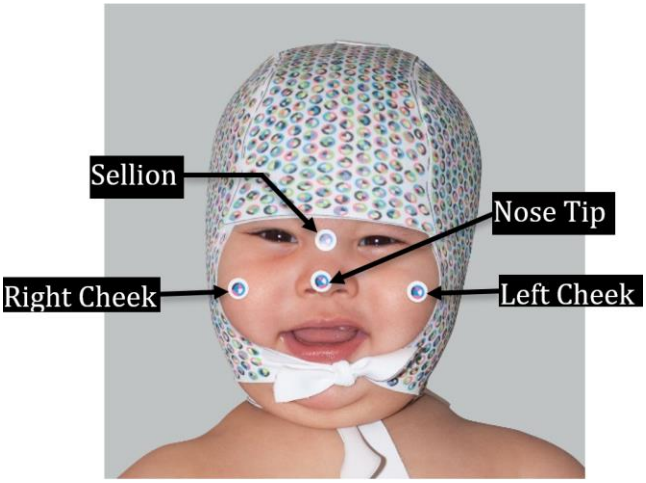


Fig. V.j

The *Nose Bridge* (Sellion) and *Nose Tip* (Pronasale) landmarks should be placed collinear to the midline of the nose - Fig. V.k

Fig. V.k

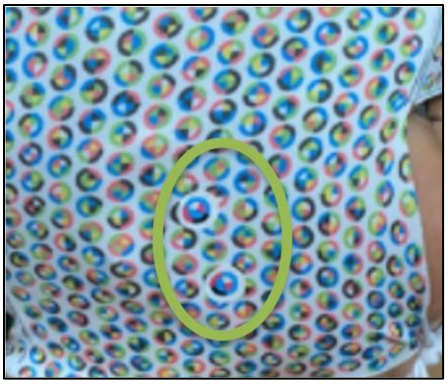


Fig. V.l

The *cheek* landmarks should be placed at the most anterior aspect of the cheekbone - Fig. V.k

Palpate the (i.e, sleeve covered) anatomical landmark - Fig. V.i - to identify the location of Tragion, where landmark sticker can be securely affixed at - Fig. V.l

V.2.d Patient – Scan Position

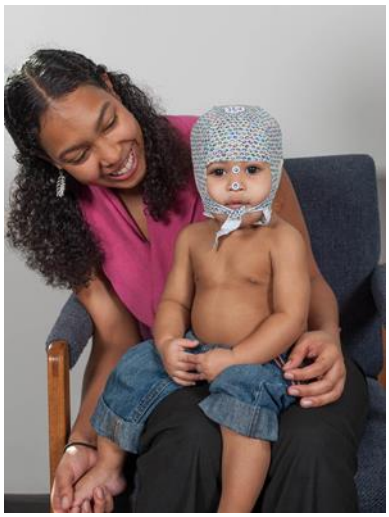
Initially, the patient can be held in a stationary prone or supine position during the Registration tag capturing process – Ref. the section **V.2.b**.

Once the *Registration* tag is captured, the patient should be held in the upright position for the duration of the scanning process.

ATTENTION:

The Registration tag and the covered sleeve must not be shifted or moved throughout the entire scanning process.

- The patient should be positioned on the caregiver's lap or supported in a highchair and **must be** supervised at all times.



- The patient's caregiver should be informed that a short video capturing process of the patient's entire head will be conducted and can benefit from their assistance with positioning the patient.
- With the assistance from the caregiver, the patient will need to be repositioned *(i.e, facing toward to and/or away from the camera, ...)* during the scanning process.
- The patient's arms should be secured by the caregiver, during the scan.
- The patient should be prevented from grabbing and pulling the covered sleeve, which the covered sleeve may shift or move.
- The patient's head should not rest nor contact against the caregiver's body, which the covered sleeve may shift or move.

- The caregiver should avoid holding the patient with arms wrapping under the patient's armpits. The patient's shoulders will potentially be pushed upward that can block the patient's neck and bottom region of cranium.
- The patient should be kept from turning the head abruptly, as possible, that will hinder the camera's focusing/capturing capability.
- The caregiver or an assistant present in the room can help attracting the patient attention, utilizing a provided lighted-fan toy, to maintain the patient in the desired position.
- The patient can be repositioned or moved during the scanning process, provided that the *Registration* tag and the covered sleeve are maintained from altering or shifting from the initial position on the head.

V.3. Cranial Scanning Process

For New SmartSoc Users

All new *SmartSoc* users must:

1. Complete the *SmartSoc Cranial Module* training and be certified to operate the *SmartSoc* scanning system, by Orthomerica
2. Complete and pass the Orthomerica's *STARband Cranial Course*

Prior to utilizing the *SmartSoc* scanning system on actual patients and/or for acquiring actual cranial products, it is also required that new users complete the following requirements

- At least four (4) successful (practice) scanning sessions on the provided *static limb model*.
- At least two (2) successful (practice) scanning sessions on an *actual* person/model.

V.3.a Scan/Case Initiation

✣ Refer to the previous section

- **V.1.a** for New Scan/Case Setup for *NEW* Patient, or

V.3.b V.1.b for New Scan/Case Setup for *NEW* Patient

ATTENTION:
To prevent the additional, duplicate patient records, of the specific patient, from generating unnecessarily, the ***Existing Patient*** searching process - reference the above **V.1.a**– this must be performed to determine whether a **patient already exists** (i.e., a ***patient profile*** has been generated & recorded) within ***eBrace® Global*** system.

For a *new* patient (i.e., a ***patient profile*** has never been generated & recorded), a new ***case*** can be initiated with **either of the following methods**:

CurveCapture™ O&P application

New Scan/Case Setup for NEW Patient

- Start the CurveCapture O&P application
- At the `LOGIN` screen, type in
  - The *(registered) email address*
  - The login *password* and tap "Login" to operate the *CurveCapture O&P application*
- If applicable, enter 2FA code (refer to Pg. 18-23 for 2FA setup)
- At the `SELECT PATIENT` screen, click the  "New Patient" icon on the top left
- At the `ADD NEW PATIENT` screen,
  - Type in the new patient information – *First Name, Last Name*
  - Enter patient *DoB* & *Gender*
  - Click "Create" to generate the new patient profile for this new patient
- Select "Cranial" at the `SELECT SCAN` screen to begin scanning

Proceed to **V.2.** Patient Pre-Scan Preparation

eBrace Global web-portal

New Scan/Case Setup for NEW Patient

- Start the web browser, and type in
  https://ebrace-global.orthomerica.com/login
- At the *eBrace Global* login screen, type in
  - The *(registered) email address*

- The login *password* and click "SIGN IN" to enter the *eBrace Global* web-portal.

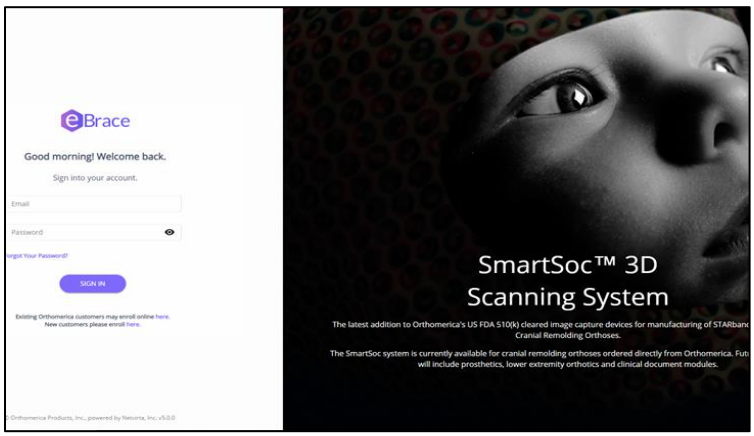


Fig. V.a

- If applicable, enter 2FA code (refer to Pg. 18-23 for 2FA setup)
- Click the "CASE" and select the "Cranial" from the products dropdown list
- At the `Case > Cranial` screen, click the "NEW CASE" to initiate the new Cranial case - **Fig. V.b**.

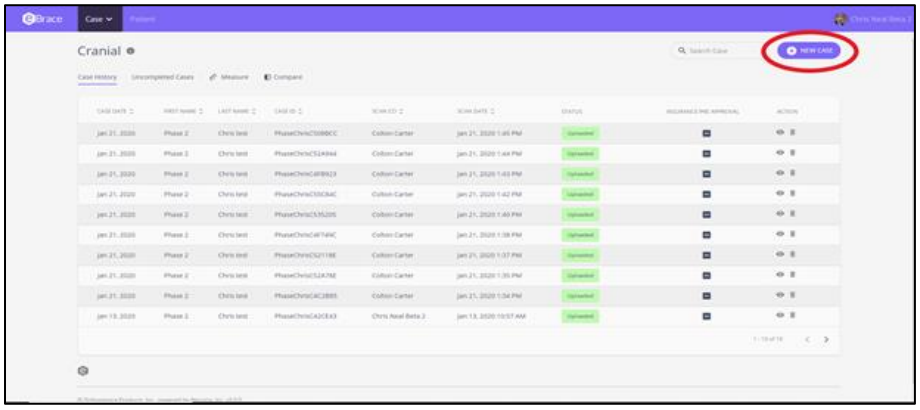


Fig. V.b

- At the `Create New Cranial Case` window, select the "New Patient"
  - Type in the new patient information – *First Name, Last Name*
  - Enter patient *DoB* & *Gender*

- Click "Create" to generate the new case for this new patient

  Proceed to **V.2.** Patient Pre-Scan Preparation

- New Scan/Case Setup for EXISTING Patient.

For practice/training scanning sessions, set up the new case with "TEST" as the patient's ID *(i.e., first name, last name)*

✣ Refer to the previous section **V.2** for Patient Pre-Scan Preparation

- Start the *CurveCapture™ O&P* application
- At the *log-in* screen, type in
  - The (*registered*) *email address*
  - The login *password* and tap "Login" to operate the *CurveCapture O&P* application
- If applicable, enter 2FA code (refer to Pg. 18-23 for 2FA setup)
- At the `Patient` screen, tap on a patient profile from the patient list to open the patient profile.
- Tap on an incomplete case from the scan/case list to select the case & initiate the scanning process - **Fig. V.m**

Completed cases are greyed out and cannot be selected.

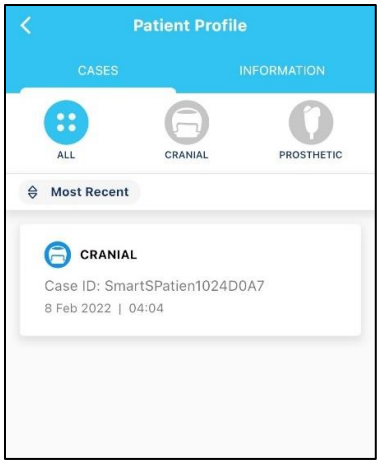


Fig. V.m

- At the `Cranial scan screen`, click "Start" - **Fig. V.n**- to begin the scanning process

  NOTE: The scanning process can be paused at any time, by pressing the icon - **Fig. V.o**

Fig. V.n

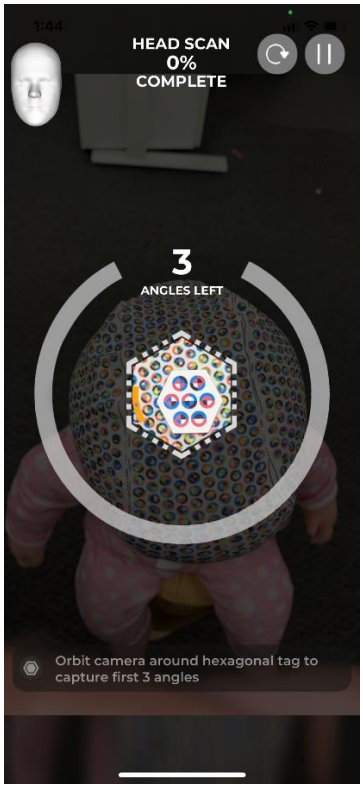


Fig. V.o

V.3.c Registration Tag Capturing Process

✣ Refer to the previous section **V.2.d** for Patient – Scan Position

- Position the *(screen)* hexagon window over the *(cranial) Registration* tag and slowly move the scanning device closer to or further from the *(sleeve covered)* head, such that the tag is maintained within and surrounded by the hexagon window.

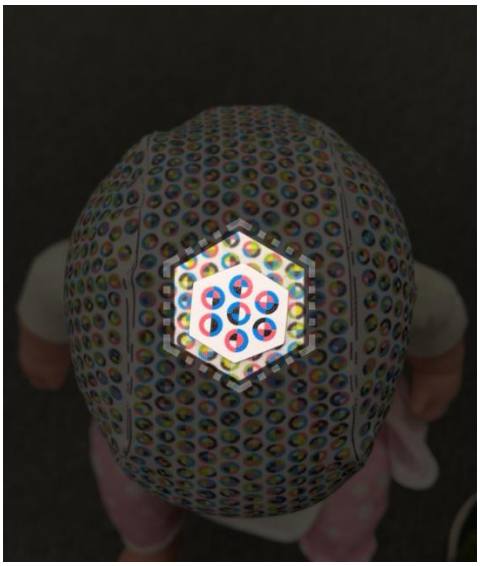


Fig. V.p

The Registration Tag is successfully registered when the device notifies with an audible tone or vibration.

- While maintaining the tag within and surrounding by the hexagon window,
    - Slowly till the device toward a random angle— Fig. V.q —until a *section* of the outer boundary profile turns green
    - Keep slowly tilting the device toward a next random angle, until a second *section* of the outer boundary profile turns green
    - Repeat the same process toward a different random angle, until a third *section* of the outer boundary profile turns green

      The *Registration* tag capturing process is completely done when three sections of the outer boundary profile turn green— Fig. V.r

Fig. V.q

The patient can be held in a stationary prone or supine position during the *Registration* tag capturing process – *Ref. the section* V.2.b. & V.2.d.

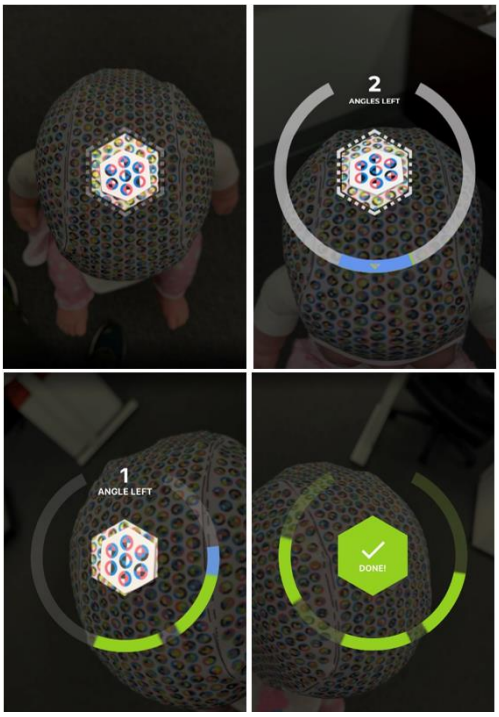


Fig. V.r

To effectively facilitate the capturing process of *Registration* tag, u**ser should remain stationing as-is in one place, throughout the** *Registration* tag capturing process,

- Do not need to walk around the patient or rotate the device; maintain the device's initial orientation— Fig. V.q
- Avoid chasing the head with abrupt movement; maintain the tag within and surround by the *(device)* hexagon window— Fig. V.p

V.3.d Patient - Cranial Scanning Process

Once the *Registration* tag is captured, the patient should be held in the upright position for the rest of the cranial scanning process.

✣ Refer to the previous section **V.2.d** for Patient – Scan Position

ATTENTION:

The covered sleeve must not be shifted or altered throughout the entire scanning process.

The visual aids are interactively presented during the scanning process:

- ***A guidance halo*** - The **guidance** profile/window is resided at the *center* of the screen, which the scanning head should be positioned within, throughout the scanning process.
    - The *guidance* profile turns GREEN - Fig. V.s- Camera is focused on the scanning head (i.e., camera is within the proper distance & stable handling).
    - The *guidance* profile turns YELLOW - Fig. V.t– Camera is pointed at the scanning head but CANNOT focus (i.e., camera is either too close or too far from the proper distance and/or unstable, drastic handling).
    - The *guidance* profile turns GREY – Camera is NOT pointed at and/or NOT focused on the scanning head.

Fig. V.s

Fig. V.t

- ***A work-in-progress (WiP) limb model*** **–** The **WiP** model - Fig. V.u**-** is located at the *top-left* corner of the screen, which is completely *white* blank at the beginning of the scanning process. The model will interactively rotated & partially *"green"* highlighted when the corresponding area of the head is focused at and (data) captured.

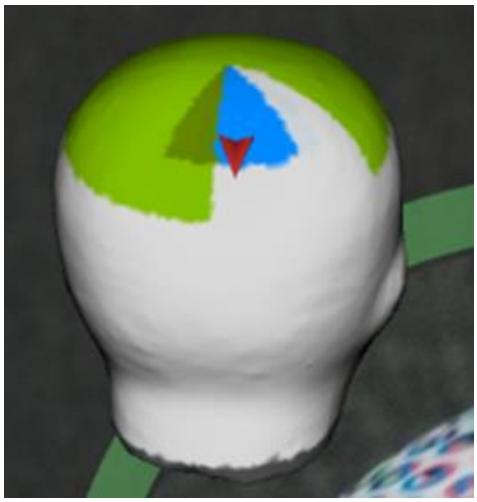


Fig. V.u

  - A section of the model turns *yellow with a red arrow* notifying that the camera should be moved in the indicated direction to return to & cover the necessary area of the head; thus, can complete capturing data at this area.
  - A section of model turns *blue with a red arrow* located adjacent to the captured ***(green)*** area notifies that camera should be moved in the indicated direction to return to the specified area of the head; thus, can complete capturing data at this area.
  - As needed, the WiP model can be manually orbited to desired orientation – in order to identify the unscanned/incomplete area (i.e., scanning progress is NOT at 100%) - by finger touching & shifting it, while the camera is not focused *(i.e., the guidance halo is greyed)* on the scanning head.

Tip: *To disable the audible beep, go to the settings menu by clicking the menu icon in the upper left corner of the Orders page and uncheck "*Sound on image capture*".*

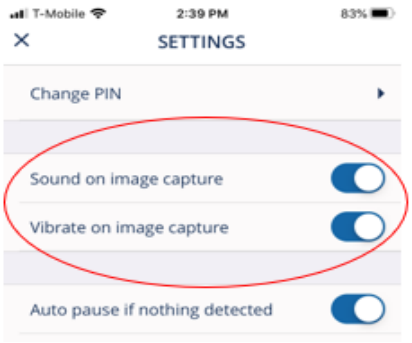


Fig. V.v

The cranial scanning process will be started, once the *Registration* tag capturing process is completed. The scanning process should be carried-out in the following order:

- ***Dome Region*** *(Most Proximal)*
- ***Facial Region*** *(Anterior)*
- ***Sides Region*** ***(****Medial, Lateral & Posterior)*

i. Dome Region – Scanning Process

The scanning device should be held steady and moved in a slow, controlled manner around the head. It is a must to avoid moving the device abruptly.

The camera should be positioned at the level above the head, facing downward at optimal angle of 45 degrees.

The scanning device's camera location varies, depending on the device's *make* and *model*. Thus, position the device onto the specific area of the scanning head, according to the camera location (i.e., NOT at the device's midline/center).

- Position the *camera* above the head, facing downward at 45 degree and slowly move the scanning device *closer to* or *further from* the head, until the *guidance profile* turns *green*.

  While maintaining the same distance from the head *(i.e., guidance profile stays green)*, slowly move the device to the next adjacent area by simply stepping around *(i.e., 360 degrees)* the patient.

  Each (head) sub-section of scanning area is successfully captured, when
  - The corresponding area on the WiP model turns "green", and/or
  - The device notifies with an audible tone or vibration.

It would require six to eight captured sub-sections around the head (*i.e., 360 degrees)* to complete the *dome* region's scanning process.

ii. Facial Region – Scanning Process

The scanning device should be held vertically and parallel to the patient's facial throughout the *facial* region scanning process. It is a must to avoid moving the device abruptly.

The camera should be positioned at the patient's eyes level.

The scanning device's camera location varies, depending on the device's *make* and *model*. Thus, position the device onto the specific area of the scanning head, according to the camera location (i.e., NOT at the device's midline/center).

- Position the *camera* directly in front and at the patient's eyes level. Slowly move the scanning device *closer to* or *further from* the face, until the *guidance profile* turns *green*.

  While maintaining the same distance from the face *(i.e., guidance profile stays green)*, slowly shift the device to the left of the patient's face *(i.e., 15 to 20 degrees)* to capture the second sub-section for the *facial* region.

  Each (head) sub-section of scanning area is successfully captured, when
  - The corresponding area on the WiP model turns "green", and/or
  - The device notifies with an audible tone or vibration.

  Again, slowly shift the device to the right of the patient's face to capture the third sub-section for the *facial* region.

It would require three captured sub-sections from three different angles *(i.e., 15 to 20 degrees apart)* to complete the *facial region's* scanning process.

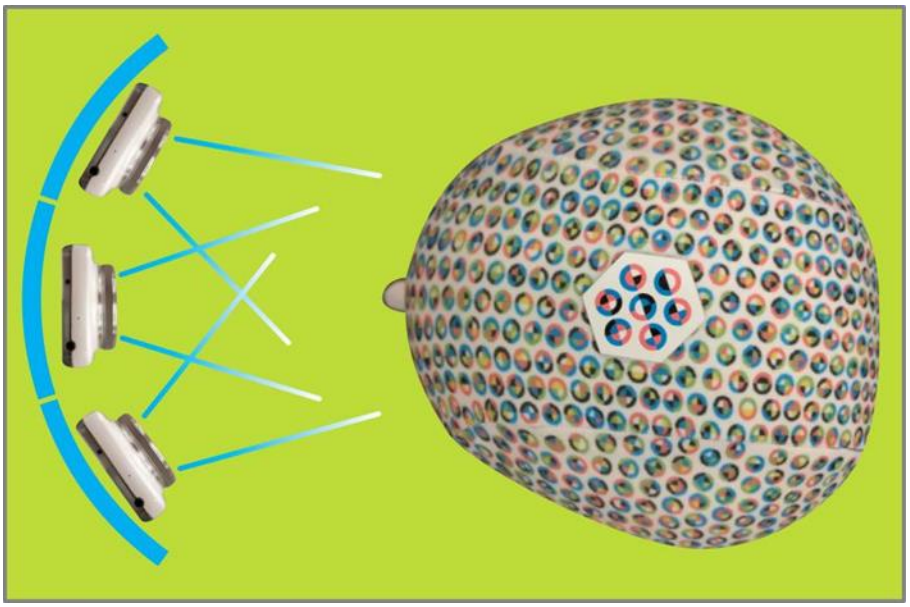


Fig. V.w

To successfully capture & document the *facial* landmarks in the *facial region's* scanning process,

- Avoid extreme bright light condition (e.g., direct bright light, bright sun light coming from windows in the dark ambient room), which may project glare on the landmark stickers.
- The facial landmarks (i.e., Sellion, Nose Tip, Cheek left & Cheek right) should be properly captured in three different angles.

iii. Sides Region – Scanning Process

The scanning device should be held vertically and parallel to the side surface head throughout the *side's* region scanning process. It is a must to avoid moving the device abruptly.

The camera should be positioned at below the patient's eyes level, facing upward at optimal angle of 15 degrees (approx.).

The scanning device's camera location varies, depending on the device's *make* and *model*. Thus, position the device onto the specific area of the scanning head, according to the camera location (i.e., NOT at the device's midline/center).

Fig. V.x

- Position the *camera* at either side of the face and below the patient's eyes level. Slowly move the scanning device *closer to* or *further from* the head, until the *guidance profile* turns *green*.

  While maintaining the same distance from the head *(i.e., guidance profile stays green)*, slowly shift the device to the next adjacent (*sleeve covered)* area by simply stepping around the patient to capture the sub-sections for the *side's* region.

  Each (head) sub-section of scanning area is successfully captured, when

  - The corresponding area on the WiP model turns "green" , and/or
  - The device notifies with an audible tone or vibration.

  Repeat shifting the device to the next adjacent *(sleeve covered)* area to capture the sub-sections for the *side* region.

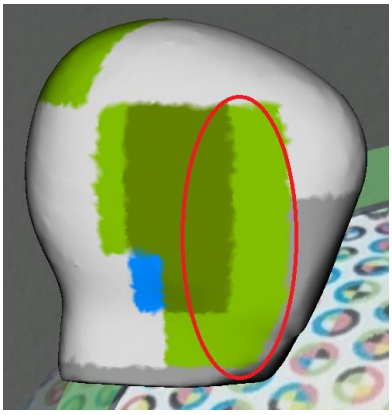


Fig. V.y

It would require at least twelve captured sub-sections around *(i.e., 270 degrees)* the head's sides and posterior surface to complete the *sides* region's scanning process.

NOTES:
The scanning process can be paused at any time, by pressing the "⏸" *{Pause}* icon.

Simply select "Start Scanning" to resume the scanning process, provided that the *Registration* tag and the covered sleeve are maintained from altering or shifting from the initial position on the head.

The real-time progress of the cranial scanning process is reported at the top of the screen.

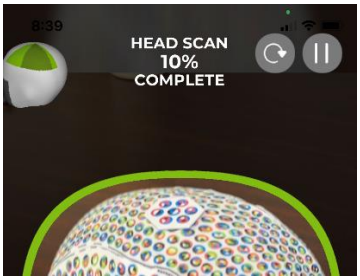


Fig. V.z

- The cranial scanning process is completed, when
- The entire **WiP** model turns "***green***",
    - The scanning progress indicates at 100% completion, and
    - The "`Cranial Scan is 100% Complete`" note is displayed

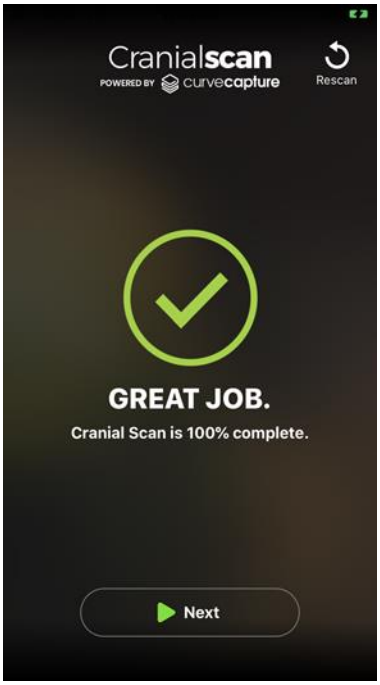


Fig. V.aa

- Click the "Next" to conclude the cranial scanning process

Proceed to **V.3.e.** Facial 2D Overlay - Capturing Process

V.3.e Facial 2D Overlay - Capturing Process

The *facial 2D overlay* capturing process is a supplement utility that is intended for Orthomerica's in-house applications and is not applied for general application, currently.

- Click the "Skip" to bypass this *facial 2D overlay* capturing process.

Fig. V.bb

Proceed to **V.4** New Scan/Case – Data Uploading

V.4. New Scan/Case – Data Uploading

For effectively uploading scanning data to eBrace Global web-portal, a Wi-Fi network and/or cellular service (with internet access) with the uploading bandwidth of 3.0 Mb (min.) is required - *Ref. section* ***II.5- Equipment Supplied by Clinician.***

The scanning data will be automatically uploaded to *eBrace Global* web-portal when the device is connected to the active Wi-Fi network and/or a cellular service (with internet access).

When operating under the *offline* mode, the scanning data will be preserved within the device's encrypted storage place holder, temporarily. The scanning data will automatically be uploaded and/or completely transferred to *eBrace Global* web-portal when the device is connected to a Wi-Fi network and/or a cellular service (with internet access).

- At the prompt, press "OK" to return to the patient `home` screen.

- For a *work-in-progress* uploading scan/case, the progress of "*uploading"* is presented with an interactive *blue-white* circle - Fig. V.cc
- For a *completed* uploading scan/case, the notification of *"Scan Uploaded"* is displayed - Fig. V.dd.

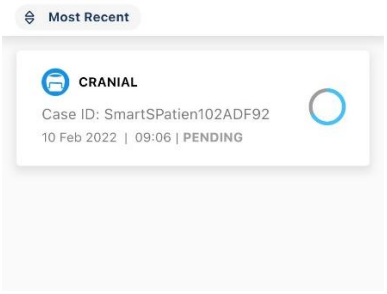


Fig. V.cc

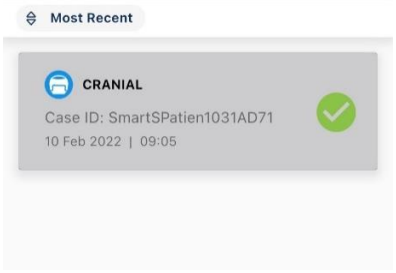


Fig. V.dd

Proceed to **0.**

Cranial Ordering Process–

To submit orders for acquiring Orthomerica's cranial products.

- ***Ref. the "Cranial MCU™ User's Guide" -*** For operation instructions of the measurement and/or comparison study of prosthetic scan.

VI. Cranial Ordering Process

The cranial ordering process should be conducted and completed under the *eBrace® Global* web-portal operation.

VI.1. Scan/Case Initiation

- Start the web browser, and type in
  https://ebrace-global.orthomerica.com/login
- At the *eBrace Global* login screen, type in
  - The *(registered) email address*
  - The login *password*
    and click "SIGN IN" to enter the *eBrace Global* web-portal.

Fig. VI.a

- Enter 2FA code if applicable (refer to Pg. 18-19 for 2FA setup)
- Click the "CASE" and select the "Cranial" from the products drop-down list.

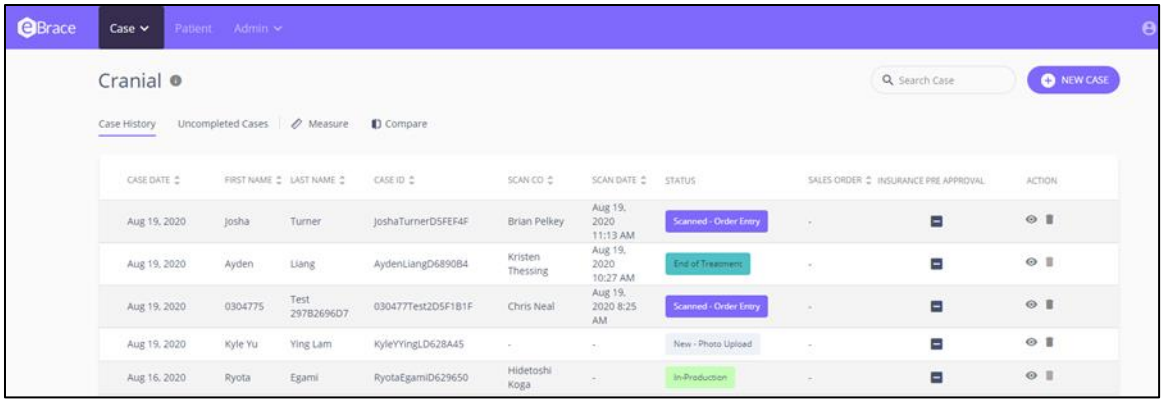


Fig. VI.b

- At the `Case > Cranial` screen, click the "Uncompleted Cases" to enter the list of unprocessed cranial cases

The list of unprocessed cases is displayed, with the most recent case is located at the top of the list

If a cranial scanning process has not been completely carried-out and/or uploaded to ***eBrace Global*** webserver, the *incomplete scanning process* case/scan will be presented, as shown in Fig. VI.c.

The cranial scanning process must be carried out & completed, before proceeding the *Cranial Ordering Process*

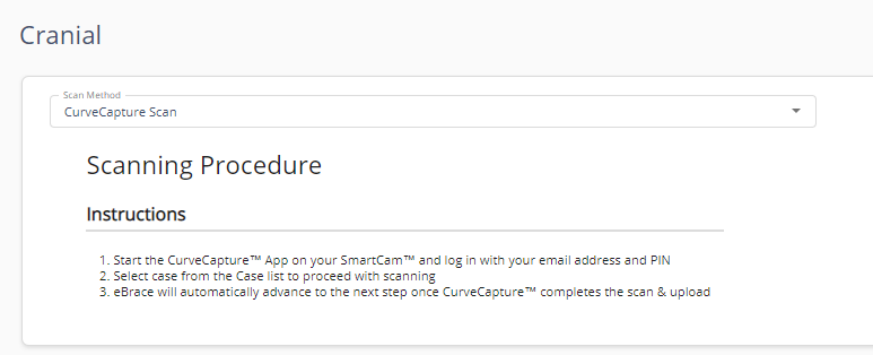


Fig. VI.c

➢ **Either,**

- Select the patient's *scan/case* from the list, by clicking on the case's icon

The "Photos" screen of the patient's case is opened

➢ **Or**

- Search the patient's *scan/case* from the list, by typing the patient's ID *(i.e., first name, last name)* in the *"*`Search Case`*"* box.

The list of the patient's unprocessed cases is displayed, with the most recent case is located at the top of the list

- Select the patient's *scan/case* from the list, by clicking on the case's  icon

The "Photos" screen of the patient's case is opened

The "Photos" screen presents the digital images that each sequentially represents the actual event of the entire scanning process, and corresponding capturing section of the cranial where (i) the scanning data was collected, as well as (ii) scanning conditions occurred – Fig. VI.d**.**

The number of images, of a scanning process, will vary depending on the size of the scanning cranial and condition of the scanning process.

The images can be individually selected for reviewing and/or locally saving for further utilization.

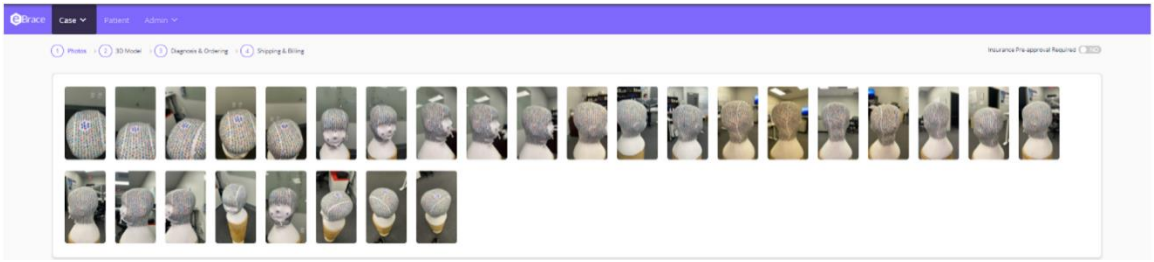


Fig. VI.d

- Click the "Next" icon to proceed to the ***"3D Model"*** screen

Proceed to **VI.2.** 3D Model Reviewing.

VI.2. 3D Model Reviewing

The *"**3D Model**" screen* interactively displays the high-resolution rendering of the 3D shape/geometry of the captured scanning data. The displayed 3D geometry can be instantly reviewed to validate whether the scanning process is successfully completed.

When the scanning process is unsuccessfully completed; the 3D geometry cannot be properly generated due to *subpar* scanning data, the "RESCAN" notification will be prompted, which the *rescanning* process must be immediately performed; thus, the former scanning data shall also be replaced entirely.

The 3D geometry is presented at the optimal *as-is* alignment; thus, the corresponding measurements are displayed for *reference*, only. The 3D geometry can be properly measured and/or compared by utilizing the Measurement and Comparison Utility ***(MCU)***. ***Ref. the*** *"Cranial* ***MCU™ User's Guide"***.

- The 3D model can be interactively
  - Rotated by (mouse) left clicking on the 3D model and shifting,
  - Directed to the preset view by selecting the corresponding icon - *Front, Rear, Right, Left or Top, or*
  - Zoomed by placing (mouse) pointer on the 3D model and scrolling the (mouse) middle wheel, which facilitate the visual inspection of the 3D model for
    - Overall shape/configuration reconstruction
    - Surface continuity & quality
  - Previewed the cross-section measurements by hovering (mouse) over the AXIAL tab at the bottom of the screen and scrolling the (mouse) middle wheel, up and down.
  -

The 3D model's visual inspection would expect

- The essential areas of *mastoids*, *neck*, *sub-occipital*, *forehead* and/or cranial anatomy that included/covered under the helmet should be successfully captured & presented in the 3D model.
- All placed landmark stickers should be successfully captured & presented in the 3D model.

The *non-conformance* 3D model would exhibit

- Abnormal surface (i.e., flat, sink, void, …) that mis-represented cranial anatomy.

- Subpar surface (i.e., wavy, groove, bump, …) that resulted from bunched up *(oversized, etc.)*, improperly fitted or insecurely ties sleeve.
- Missing cranium's distal section, especially along the neckline.
- Missing or mis-displacement landmark stickers.

ATTENTION:

The 3D model's visual inspection & *reference* measurements verification of the newly cranial scan should be conducted & confirmed before concluding the cranial scanning process (i.e., release the patient, ready to submit scan for fabrication).

NOTES:
To enter/move between the Photo, 3D Model, Diagnosis & Ordering or Shipping ***&*** Billing screen, click the "Next" or "Previous" icon, accordingly.

- Click the "Next" icon to proceed to the *"**Diagnosis** & **Ordering**"* screen

  Proceed to **VI.3** Diagnosis & Ordering.

VI.3. Diagnosis & Ordering

The *"Diagnosis & Ordering "screen* provided the interactive fillable *eForm* that the patient information, patient clinical conditions & product *(i.e., fabrication device)* specifications can be thoroughly specified and/or updated.

- The *case type* for an ***uncompleted*** scan/case must be specified, by
  - Clicking the *"*Mark As*"* box, and
  - Selecting the *case type* from the drop-down list, which

For Fabrication Scan/Case

- **Patient PHI**
  - Review the patient's ***ID, Date of Birth***
  - Enter patient's *required* information – ***Corrected Age***
- **Measurements of Baby's Head over *SmartSoc***
  - Specify *measurement* ***Unit***

- Enter the patient's *general measurements* – ***Head Circumference, Width (ML)*** *&* ***Length (AP)***

➢ **Primary Condition**

- Specify the ***flattening*** for specified areas
- Specify the ear ***alignment***
- Specify the ***Primary Condition*** and associated ***information***
- Specify the ***Torticollis*** or ***Positional Neck*** *preference*

➢ **Products**

- Specify the cranial orthosis

➢ **Modification**

- Thoroughly specify the cranial orthosis' relevant ***specifications*** and ***requirements***
-

All required patient's information and order's specifications must be completed, prior to proceeding to the order submission process.

- Click the "Next" icon to proceed to the *"**Shipping & Billing**"* screen.

  Proceed to **VI.4** Order Submission.

For Follow-Up Scan/Case

➢ **Patient PHI**

- Review the patient's existing information
  - ***ID, Date of Birth,*** and
  - The associated information - ***Age*** *&* ***Primary Condition*** to confirm the correct *(patient)* identity.
- Click the "Done" icon, and
  At prompted, click "Yes" to complete specifying the scan/case.

The "Diagnosis & Ordering" and "Shipping & Billing" screens will be greyed out.

As needed, a *follow-up* scan/case can be reset to *fabrication* for the intention of acquiring fabrication products *(i.e., orthosis, prosthetics):*

Proceed to **VI.1** Scan/Case Initiation @ *The* ***Case>Cranial*** *screen,*

- Search the patient's *scan/case* from the list, by typing the patient's ID *(i.e., first name, last name)* in the ***"Search Case"*** box.

The list of the patient's unprocessed cases is displayed

- Select the patient's *scan/case* from the list, by clicking on the case's "  " icon

The "Photos" screen of the patient's case is opened

- Click the "Next" icon to proceed to the "***3D Model***" screen
- Click the "Next" icon to proceed to the "***Diagnosis & Ordering***" screen,
  - Click the "Mark As" box, and
  - Select the "Fabrication" from the drop-down list, and click "Yes"

  Then, ***proceed to the For Fabrication Scan/Case process.***

For End of Treatment Scan/Case

- **Patient PHI**
  - Review the patient's existing information
    - ***ID, Date of Birth,*** and
    - The associated information - ***Age*** & ***Primary Condition*** to confirm the correct *(patient)* identity.
  - Click the "Done" icon, and
    At prompted, click "Yes" to complete specifying the scan/case.

The "Diagnosis & Ordering" and "Shipping & Billing" screens will be greyed out.

eBrace Global's fillable *eForm* can be completed partially that each section may be finalized & saved one at a time, at the user's convenience.

ATTENTION:

The cranial orthosis must be fit within two weeks from the scan date and a delay in order form submission could certainly affect the fabrication lead-time & fitting schedule.

- To enter/move between the ***Photo***, ***3D Model***, ***Diagnosis*** & ***Ordering*** or ***Shipping*** & ***Billing*** screen, click the "Next" or "Previous" icon, accordingly.
- Click "Save" to save the contents of the fillable form. *SAVE* can be selected for each complete page and/or at the end of the form.
- Select REVIEW to review the entire order.
  - Any changes to the order's information can be modified & finalized within the REVIEW session.

VI.4. Order Submission

The required information of the *"Shipping & Billing"* screen must be provided & finalized, prior to submit order for acquiring fabrication products *(i.e., orthotics, prosthetics)*.

- **PO No.**
  - Provide the user's *Purchase Order No.*, as needed.
- **Date Needed** *(Required)*
  - Specify the desired *Delivery Date*.
- **Shipping Address** (*Required)*
  - Select the *Shipping Address* from the drop-down list.
    - As needed, select the "Add New" option from the drop-down list and enter the new additional *Shipping Address.*
- **Shipping Method** (*Required)*
  - Select the *Shipping Method* from the drop-down list.
- **Email, Phone Number & Fax**
  - Select the *Email*, *Phone Number and/or Fax*, respectively, from the drop-down list.
    - As needed, select the "Add New" option from the drop-down list and enter the new additional *Email, Phone Number* and/or *Fax, respectively.*
- Once, all the order information is established, click "Next" to initiate the order submission.

The "Submit" button will blink continuously.

- As needed, select REVIEW to review the entire order.
- Any changes to the order's information can be modified & finalized within the REVIEW session.
- Once the order is submitted, the order's information is finalized and cannot be edited in *eBrace Global* web-portal; contact Orthomerica 's customer service agent for further assistance.

- Once all the order information is reviewed & confirmed, click the "Submit" button to send a cranial order to Orthomerica.

Once the order is successfully submitted, the order's status will be updated & reported accordingly, in the *Case History* screen.

- As needed, the case's scan images, 3D model and order information can be reviewed, at any time, by clicking the corresponding case's "*eye*" icon that is located under the *action* column.

VII. Maintenance Procedures

VII.1. SmartSoc Sleeve Laundering

The *SmartSoc* scanning sleeve is designed and intended for single patient use. As needed, hand wash a sleeve with mild soap and warm water, rinse well and allow to air dry. A maximum of five (5) washings per sleeve; excessive washing may degrade the configuration and colors of the sleeve's-colored patterns, which will negatively affect the integrity of the scanning data.

VII.2. Scanning Device Routine Maintenance

The device's camera lens should be regularly wiped clean, utilizing an eyeglass cleaning cloth.

To optimally preserve the life span of the device's battery,

- Do not allow a device's battery to be fully discharged.
- Avoid over charging a device's battery. Overcharging the device's battery or storing a device while connected to the charging power source may result in the battery exploding, igniting and/or being damaged.

Avoid exposing the device to liquids or hazardous substances.

Improper handling (i.e., dropping, crushing, causing impact) of the device will hinder the device's functions/operations.

Appendix A

@A.1 Customer Support

For any technical support which relates to the software or hardware of the *SmartSoc* System, please contact:

Orthomerica Products, Inc. between the hours of 9:00am–5:00pm EST, Monday–Friday.

Fax: (877) 737-8445

Telephone: (877) 737-8444

Email: custserv@orthomerica.com

Appendix B - Troubleshooting

@ B.1 Troubleshooting

Problem	Cause	Recommendation

Areas of anatomy are missing from the 3D model.	• The color patterns of the specific area **must be** properly captured in at least three (3) different angles/ orientations.
	• The color patterns of the specific area may not be captured properly due to
	  ○ Low ambient light
	  ○ Intense ambient light that cause harsh shadow (e.g. bright window in the background)
		• Verify that the sleeve is properly donned.
		• Avoid obstruction between the sleeve and the device.
		• Take photos from the proper angles and distance as outlined in the scanning process.
		• Operate the scanning process in a well-lit area.

Blurred, out of focus images.	The device's camera is not focusing well due to dirty camera lens.	Regularly clean the camera lens with a lens or glasses cleaning cloth.
The 3D model is not in the correct orientation in the 3D preview display.	The 3D model orientation in the preview display is based on the as-is (unprocessed) alignment of raw data; thus, all associated measurements should be used as reference information.	Using the *Measure & Comparison Utility* (MCU) for properly align the shape.

The 3D model is bumpy or has ridges raising up from the sleeve that do not represent anatomy.	The sleeve is not properly sized (i.e. oversized) or donned.	Don the sleeve and adjust as outlined, smoothing out any bumps or wrinkles.
The dots on the sleeve are very distorted and stretched causing discoloration.	The sleeve (size) is too small and too tight on the patient.	Take the circumference measurement at the knee level and select the corresponding sleeve size accordingly.
The sleeve is baggy, loose, or wrinkled in areas.	The sleeve (size) is too large for the patient or not properly donned and secured.	Take the circumference measurement at the knee level and select the corresponding sleeve size accordingly. Ensure that the sleeve is smoothed out and not bunched or wrinkled.
The patient is poorly lit in the scan.	The patient is backlit or there is not enough artificial ambient light in the room.	Increase ambient light. Remove backlighting by eliminating light source or repositioning so the light is behind the device.
The device will not accept newly *reset* password.	The device is not connected to the internet and cannot communicate with *eBrace Global* to verify the *new* password.	Connect the device to an active network and/or cellular service (with internet access)

The case's scan is not available/present on *eBrace Global*.	The case's scan has not been completely uploaded from the device to *eBrace Global* due to no connection to the internet.	Connect the device to an active network and/or cellular service (with internet access), run the *CurveCapture O&P* for completing the scan upload.
A case's scan cannot be uploaded to the *eBrace Global* web server.	Either, the device is **not** connected to an active network and/or cellular service (with internet access). Or, the device is connected to an ***inactive*** network and/or cellular service (***without*** internet access).	Connect the device to an active network and/or cellular service (with internet access), run the *CurveCapture O&P* for uploading the scan.
Cannot log in on the (device) *CurveCapture O&P*.	Incorrect login *password* and/or *username* has been entered.	Verify the correct login *username* and *password* have been entered. Verify that the device is assigned to the user. If a password reset is required, select "*Forgot Password*" on the *CurveCapture O&P* login screen.

The authenticator app is no longer available and cannot access eBrace Global / CurveCapture O&P without it.	Two-factor authentication requires the use of the authentication app in order to access eBrace Global / CurveCapture O&P.	When prompted for the 2FA code on eBrace Global or CurveCapture O&P, select "Can't use the authentication app?" to request to have the account recovered. A SmartSoc admin will reach out to ensure the request came from the authorized user.
The 3D model in *eBrace Global* cannot be rendered properly.	The browser *(i.e., Google Chrome, …)* cache is full.	Delete the browser cache. And/or, increase the cache storage size.
The device has bulging and runs hot especially when charging or after prolonged use.	The device's battery may be damaged from overcharging or exposure to extreme heat (i.e. left in a hot car).	Contact Orthomerica for replacing/upgrading device.
Registration Tag *angles* are not being registered or taking much longer to register than normal. "Angle indicator" is not behaving in a predictable manner.	The ***initial*** Registration Tag capture process (before the three (3) angle captures) was initiated at an angle. Incorrectly referencing the "center", causing some of the angles to be out of range.	Restart the scan by pressing the "  " icon. Once scan is restarted, ensure that the initial registration capture is directly on top/center of the Registration Tag.

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