SureSmile protocol

Validating a CBCT Scanner with a Phantom Scan
OraMetrix has its headquarters in Richardson, Texas, with offices in Berlin, Germany and Chatswood, Australia. For general information about OraMetrix, visit the OraMetrix website at www.orametrix.com.

Contact us for support

To contact us, please call one of the phone numbers listed below, or email us at customercare@suresmile.com

<table>
<thead>
<tr>
<th>Region</th>
<th>Phone Number</th>
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<tbody>
<tr>
<td>United States &amp; Canada</td>
<td>1 888 672 6387</td>
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<td></td>
<td>or</td>
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<tr>
<td></td>
<td>1 972 728 5902</td>
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<tr>
<td>Europe, Australia, New Zealand, Japan &amp; South Korea</td>
<td>+800 6655 1234</td>
</tr>
<tr>
<td>All other countries</td>
<td>+1 972 728 5902</td>
</tr>
</tbody>
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Note: We are currently rolling out this number on a country-by-country basis. If not yet available in your country, you can still call us by using our All other countries toll number below.

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SureSmile URL: https://login.SureSmile.com/
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Use of CBCT Scanners with SureSmile

The following CBCT scanners are certified for use with SureSmile:

<table>
<thead>
<tr>
<th>System Model</th>
<th>Configured with</th>
</tr>
</thead>
<tbody>
<tr>
<td>i-CAT® Classic</td>
<td>• 14-bit Detector Panel</td>
</tr>
<tr>
<td></td>
<td>• Carbon Fiber Headrest</td>
</tr>
<tr>
<td></td>
<td>• Xoran version 3.1.62 or later</td>
</tr>
<tr>
<td>i-CAT® Next Generation</td>
<td>Software version 1.9.0.19 or later</td>
</tr>
<tr>
<td>i-CAT® FLX</td>
<td>• SmartScan 2.0 or later</td>
</tr>
<tr>
<td></td>
<td>• Treatment Studio 5.2 or later</td>
</tr>
<tr>
<td>CS 9300® or 9500®</td>
<td>• CS Orthodontic Imaging Software version 11.7.0 or later</td>
</tr>
<tr>
<td>CS 8100 3D®</td>
<td>• CS 3D Imaging version 3.4.3 or later</td>
</tr>
<tr>
<td>ProMax® 3D Classic</td>
<td></td>
</tr>
<tr>
<td>ProMax® 3D Mid</td>
<td>Romesis 4.3.0 or later</td>
</tr>
<tr>
<td>ProMax® 3D Max</td>
<td>ProMax 3.7.0 or later</td>
</tr>
</tbody>
</table>

If you have a certified scanner and are unsure whether it meets these requirements, please call the manufacturer. See the manufacturer’s specifications for space measurements and connection requirements.

Prerequisites

The CBCT equipment at your practice must be validated by OraMetrix to work with SureSmile before the Digital Lab can accept CBCT Scans from your practice. To start this process, visit SureSmileU.com

You can also go to Help Center in the SureSmile software or contact SureSmile Customer Care at 1.888.672.6387 and request a copy of the form.

Tools and Materials Needed

- CT Validation Phantom (ASSY-000435) preassembled
- Plastic or clear glass bowl-shaped container, about 1-quart capacity
- About 16 oz. of tap water
Cybersecurity Guidelines

1. Keep your computer’s operating system up to date with patches and fixes.
2. Install and maintain an anti-virus program.
3. Install and maintain a firewall between your LAN and the internet.
4. Avoid installing browser add-ins or plug-ins.
5. Avoid downloading or installing software from unknown sites.
6. Create a hard to guess password by using at least 8 characters of mixed case letters, numbers, and symbols.
7. Avoid using common words or phrases.
8. Do not reuse the same password for any accounts.
9. Consider using a password program to manage passwords, such as KeePass or LastPass.
10. Do not display your password where others can see it.
11. Change your password periodically, every 60 to 90 days.
12. Logout or lock your workstation when leaving your desk.
13. Avoid clicking on links in email. Instead, go directly to the site and login using your user-id and password.

Introduction

Use these instructions to acquire the data needed for OraMetrix validation of your CBCT Scanner for use with SureSmile.

Instructions are included for the following CBCT scanners:

- Imaging Sciences: Classic i-CAT®, Next Generation i-CAT® and i-CAT® FLX
- Carestream Dental CS 9300, 9500 and CS 8100 3D
- Planmeca ProMax® 3D

SureSmile uses a phantom scan to determine whether a CBCT scanner is properly calibrated and capable of providing data for use with SureSmile. This document describes:

a. how to set up and perform the phantom scan
b. which data needs to be sent to SureSmile for evaluation
Phantom Scan Process Overview

The SureSmile CT validation phantom (ASSY-000435) is a half-inch-thick acrylic block about 3 inches square that is embedded with precisely positioned steel and ceramic spheres in an arch pattern similar to a dental arch. (Fig. 1)

![Fig. 1: SureSmile CT Validation Phantom device](image1)

![Fig. 2: Overhead view of SureSmile CT Validation Phantom placed flat in plastic bowl](image2)

Although detailed instructions for the iCAT, Carestream Dental, and Planmeca scanners follow, here are the basic steps common for the phantom scan process:

1. Place the SureSmile CT Validation Phantom device in a quart-sized plastic container and cover it with tap water so that it is completely submerged. The water serves as a surrogate for a patient’s bone and tissue.
2. Position and secure the container on a stand, camera tripod or other stable platform.
3. Align and perform a scan of the phantom device, just as if it were a patient.
4. Reconstruct the scan using the protocols or parameters appropriate for your scanner.
5. Export the multi-file formatted data as a DICOM file to a CD, DVD or network drive.
6. Send the scan data to SureSmile for analysis and verification.

Since OraMetrix already knows the precise location and size of the steel and ceramic spheres, OraMetrix can evaluate the accuracy and completeness of your scanner’s data.

SureSmile URL: [https://login.SureSmile.com/](https://login.SureSmile.com/)
Validating your Imaging Sciences Scanner

Follow these steps in order to validate Imaging Science scanner:

1. Place the SureSmile CT Validation Phantom device in a quart-sized plastic container and cover it with tap water so that it is completely submerged.
   The water serves as a surrogate for a patient’s bone and tissue. If the container has a plastic lid, you may put the lid on to keep the water from spilling as shown in the photos below.

2. Position and secure the container on the CT model stand. (Figs. 3 – 4) A makeshift stand, such as a camera tripod, may be used if needed.
   ✓ Make sure the stand is stable and does not vibrate or move during the scan.
   ✓ Try to keep the container level.
   ✓ The water should completely cover the phantom during the scan.

3. Center the plastic container using the scanner’s alignment lasers. Center the horizontal and vertical lasers to the center of the plastic container.
   NOTE: You may need to raise the model stand and move the gantry forward to bring the container into the field of view.
4. Start a new scan and select the protocol or parameters for the scan, based on the machine type:
   - **Classic iCAT®** – Use the OraMetrix 6cm, 40sec 0.2Voxel Protocol.
   - **Next Generation iCAT®**:
     If using Vision Q version 1.6, double-click the “SureSmile Filters” Icon on the desktop to activate the SureSmile Reconstruction Filters.
     If using Vision Q version 1.9, the SureSmile filters are built-in and no icon is shown on the desktop. If configured, use the SureSmile Quick Pick. Otherwise, select:
     - **Field of View**: “Dia 16cm H 8cm” or “8cm Landscape”
     - **Protocol**: 26.9 sec. and 0.2mm Voxel
   - **i-CAT® FLX** – Use the protocol named **SureSmile Dentition** with the default settings of 16 x 8cm, 0.2Voxel, 26.9 sec

5. Take a preview scan to determine if the Phantom is centered.
   Adjust accordingly.

6. Take the scan according to the manufacturer instructions.
7. Drain the water from the container. Dry the phantom and store for future use.
8. Export the data in **DICOM, Multi-File** format to the network drive that was created for this purpose.
   Name the folder with the site's name and the date of the scan.
9. **Note to FLX users:** The FLX exports the data automatically to a folder at icat > Imageroot > patient name or ID.
   To determine which folder contains the multi-file data, right-click each folder and check Properties to find the folder that contains about 400 files.

SureSmile URL: https://login.SureSmile.com/
Validating your Carestream Dental Scanner

Follow these steps in order to validate Carestream Dental CS 9300© or 9500© scanner:

1. Place the SureSmile CT Validation Phantom device in a quart-sized plastic container and cover it with tap water so that it is completely submerged.
   The water serves as a surrogate for a patient’s bone and tissue.

2. Position and secure the container on the CT model stand. A makeshift stand, such as a camera tripod, may be used if needed.
   ✓ Make sure the stand is stable and does not vibrate or move during the scan.
   ✓ Try to keep the container level.
   ✓ The water should completely cover the phantom during the scan.

3. Start a patient record and select the following settings:

For CS 9300

- On the bottom middle on the Program pane, select the Maxillary/Mandibular Exam Type.
- On the Program pane, select the (10cm x 10cm) Image Type.

- On the Patient Pane, select the medium patient size.

- On the Parameter Pane, select: kV: 85, mA: 4 and um (Voxel): 180.
For 9500

- On the Program Pane, select the Medium Field of View (9cm x 15cm).

- On the Patient Pane, select the medium patient size.

**WARNING:** Do not choose a large field of view. A large field of view cannot capture the minimum voxel size required by SureSmile.

- On the Parameter Pane, select kV: 85, mA: 4 and um (Voxel): 200.

4. Take the scan according to the manufacturer instructions.
   **TIP:** Remember to press and hold the exposure button until the end of the acquisition.

5. Drain the water from the container. Dry the phantom and store for future use.

**NOTE:** Export the data in DICOM, Multi-File format to the network drive that was created for this purpose.

6. After electronic transfer setup has been completed, open the imaging software and return to the patient chart that was created for the test scan.

7. Right-click the 3D Volume in the appointment gallery, and choose Export Object.

8. When asked where to export the data, browse to the network drive that was created for exporting scans to SureSmile and click Make New Folder.

9. Name the folder with the site’s name and the date of the scan.
Follow these steps in order to validate Carestream Dental CS 8100 3D scanner:

1. Insert the 3D bite block support (A) in the chin rest base.
2. Place the scanning platform (B) onto the 3D bite block support (A).
3. Place the black foam (C) on the scanning platform (B).
4. Place the suresmile CT Validation Phantom device on the scanning platform.
5. Start a patient record and select the following settings:
   a. On the Program pane, select the **Lower jaw exam** (8 cm x 5 cm mandible)
   b. On the Patient pane, select the **Medium Adult** patient size
c. On the Parameter pane, select
   1. kV = 80
   2. mA = 2.00

   ![Parameter Display](image)

   d. The Selected Parameter Display should read as follows:

   ![Selected Parameter Display](image)

6. Take the scan according to the manufacturer instructions.
   **TIP:** Remember to press and hold the exposure button until the end of the acquisition.

7. Remove the phantom and store for future use.
   **NOTE:** Export the data in DICOM, Multi-File format to the network drive that was created for this purpose.

8. After electronic transfer setup has been completed, open the imaging software and return to the patient chart that was created for the test scan.

9. Right-click the 3D Volume in the appointment gallery, and choose Export Object.

10. When asked where to export the data, browse to the network drive that was created for exporting scans to suresmile and click Make New Folder.

11. Name the folder with the site’s name and the date of the scan.

**SureSmile URL:** [https://login.SureSmile.com/](https://login.SureSmile.com/)
Validating your Planmeca Scanner

Minimum software version of Romexis is 4.3.0

Follow these steps in order to validate Planmeca ProMax® 3D scanner:

1. Place the SureSmile CT Validation Phantom device in a quart-sized plastic container and cover it with tap water so that it is completely submerged.
   The water serves as a surrogate for a patient’s bone and tissue.
2. Position and secure the container on the CT model stand. A makeshift stand, such as a camera tripod, may be used if needed.
   - Make sure the stand is stable and does not vibrate or move during the scan.
   - Try to keep the container level.
   - The water should completely cover the phantom during the scan.
3. Start a patient record and select the following settings:

Select Software Settings

1. Open Planmeca Romexis, select or create patient and start a 3D capture.

2. Select Special Programs, then choose Braces
   - In addition, this option will NOT allow for a sufficient amount of coverage if you plan to extract data from the 3D image for a cephalometric analysis.
3. Select patient size. ProMax® gives suitable exposure values automatically.
   Click forward.

4. Take Scout image

5. Planmeca ProMax® 3D Classic: Lift the adapter to the highest position.

4. Take the scan according to the manufacturer instructions.
   TIP: Remember to press and hold the exposure button until the end of the acquisition.

5. Drain the water from the container. Dry the phantom and store for future use.

6. After electronic transfer setup has been completed, open the imaging software and return to the patient chart that was created for the test scan.

7. Right-click the 3D Volume in the appointment gallery, and choose Export Object.

   NOTE: Export the data in DICOM, Multi-File format to the network drive that was created for this purpose.
   Remember to export the phantom scan with 15-bit resolution

8. When asked where to export the data, browse to the network drive that was created for exporting scans to SureSmile and click Make New Folder.

9. Name the folder with the site’s name and the date of the scan.

SureSmile URL: https://login.SureSmile.com/
Transferring the Data to OraMetrix

OPTION 1 – for imaging centers or future SureSmile practices
Contact Customer Care to arrange data transfer via a service such as an FTP site, etc.

OPTION 2 – for practices that have already installed SureSmile
In order for this option to work with the given steps below, the SureSmile browser and surescan must be on the same computer.

1. **Start with SureSmile** – log onto SureSmile in the web.

2. Create a demo patient in SureSmile with the following information:
   - First Name: **phantom**
   - Last Name: **scan**
   - Birthdate: **any date that is not within the current year**

3. Click the New drop-down menu in the timeline and select **Therapeutic Model**
   The order page opens.

4. Scroll down to the Select your 3D Scan Data files section.

5. Click the **CBCT Scan** tab

6. Click **Open surescan**. Do not select Create Task button. surescan will open in separate window.

7. **Go to surescan** - If you not logged into surescan, log on when the surescan logon page opens. surescan takes you directly to the External Order page for the patient (phantom scan)

8. Click the **Select CBCT scan data folder**... button to upload your CBCT scan now.

9. Click **Finish Scan** to submit the scan data.
10. Select OK and return to SureSmile in the browser.

11. Do NOT submit the order. Close the patient record and leave the order unsubmitted. The data will transfer automatically.

12. Note the SureSmile patient ID.

13. Send an email to customercare@SureSmile.com with the patient ID to alert them to look for the data transfer.

14. The data will be analyzed, and you will be notified of the results within 5 business days.
   - If the results are acceptable: a time will be scheduled for the necessary office members in your practice to receive training at your practice on how to take and submit CBCT scans.
   - If the results are not acceptable: SureSmile will work with you and your CBCT vendor to resolve the issues.

OPTION 3 – for locations that do not have a network connection

If a network connection is unavailable to support the data transfer, you do not need to create an order. Instead, save the data to a CD or DVD and mail it to:

OraMetrix, Inc.
Attention: SureSmile Service Technician – CBCT Phantom
2350 Campbell Creek Blvd. #400
Richardson, TX  75082

SureSmile URL: https://login.SureSmile.com/
If you have any questions, please contact Customer Care (see contact information on page 3).
To learn more about SureSmile, click the icon in SureSmile web software and select the option for “sure u” or go directly to: [http://SureSmileu.com/](http://SureSmileu.com/)