

CT/CBCT Scan Protocol

For TRUMATCH® CMF Products and Services

This protocol describes the guidelines for a CT or CBCT Scan for ordering the following:

- Milled Patient Specific Plates for Mandible (PSPM)
- PEEK Milled Patient Specific Implants (PSI)
- Patient Specific Plate Contouring (PSPC)
- Titanium 3D Printed Patient Specific Implants, Plates and Guides*
- Polyamide Surgical Guides*
- Acrylic Orthognathic Splints*
- Anatomic Models*

Important

- Use of this scanning protocol as a guideline will result in a more anatomic accurate model, surgical guide, and/or implant.
- CBCT Scans are not accepted for PEEK Milled PSI
- For Titanium 3D Printed Patient Specific Implants and Guides, CBCT scans are only accepted for validated scanners. A list of validated scanners can be found on <http://www.materialise.com/en/medical/cmf-scan-protocols>. Scans coming from non-validated scanners will be rejected.

Warning: Patient specific devices will be designed to fit the patient anatomy at the time of the CT or CBCT scan. Changes in the patient anatomy occurring after the CT or CBCT scan, as well as the use of the device after such changes, may result in a suboptimal fit of the device or implant.

Use the following scan parameters or the closest approximation possible. Scan must be less than four (4) months old.

Preparation of the patient

- Remove any non-fixed metal prosthesis or jewelry that might interfere with the region to be scanned.
- Non-metal dentures may be worn during the scan.
- Make the patient comfortable and instruct him not to move during the procedure. Normal breathing is acceptable but any other movement, such as tilting and/or turning the head, can cause motion artifacts that compromise the reconstructed images, requiring the patient to be rescanned.
- Stabilize the relationship of the jaws during the scan. The patient is preferably scanned with a very thin bite wafer that does not influence the facial soft tissues.

Reconstruction of the images (CT or CBCT)

- Use a proper image reconstruction algorithm to get sharp reformatted images for locating internal structures such as the alveolar nerves. Use the sharpest reconstruction algorithm available.

- Reconstruct the images with a 512 × 512 matrix. (768 × 768 for Titanium 3D Printed Patient Specific Implants and Guides)
- Only the axial images are required, no additional reformatting of the images has to be done.
- Save the images in uncompressed standard DICOM format onto a CD or DVD.

CT Scanning Instructions

- Images scanned under a gantry tilt and oblique or reformatted images negatively influence the accuracy; use only primary axial images.
- All slices must have the same field of view, reconstruction center, and table height.
- Scan with the same slice spacing, less than or equal to the slice thickness.

Patient Positioning

Place the patient supine on the scanner table and move the patient into the gantry, head first.

- Minimize the artifacts caused by metallic dental restorations or orthodontic brackets by aligning the patient's occlusal plane as much as possible with the axial slices.
- Do not deform the soft tissue.
- Depending on the product or service requested, the field of view should include:
 - Nose and chin
 - Left and right TMJ
 - Other regions of interest if required (ex. cranium)
 - For reconstruction cases the complete tumor/defect

CT Scan Parameters

Gantry tilt/oblique angle	0°
Matrix	512 × 512
Slice thickness	Maximum 1.0 mm
Feed per rotation	Maximum 1.0 mm
Reconstructed slice increment	Maximum 1.0 mm
Reconstruction algorithm	Bone or high resolution

However, in cases where this is not possible, slice increments up to 1.25 mm for PEEK Milled PSI and up to 2.5 mm for PSPC for plates and anatomic models will be accepted. PSPC plates and anatomic models have been validated for accuracy with axial slice increments up to 2.5 mm.**

CBCT Scanning Instructions

Patient Positioning

- Position the patient seated, with a natural head position, with the jaws in centric relation (CR)
- Do not deform the soft tissue (no chin cups, no straps)
- The field of view should include:
 - Nose and chin
 - Left and right TMJ
- Region of interest should be at least at 10mm from the border of the field to avoid possible border distortion effect

CBCT Scan Parameters

Use the following scan parameters or closest approximation

Parameter	Ti 3D Printed Implants, Plates, Guides
Matrix	768 × 768
Field of view	Largest available
Scan time	Longest available
Voxel size	0.3 mm
Reconstructed slice increment	Max 0.3 mm
Export	DICOM

Parameter	All the others***
Matrix	512 × 512
Field of view	Largest available
Scan time	Longest available
Voxel size	0.3–0.5 mm
Reconstructed slice increment	0.5 mm (max. 0.5 mm)
Export	DICOM

**DePuy Synthes, Data on File. Patient Specific Plate Contouring Validation, 0000231473.

***CBCT Scans are not accepted for PEEK Milled PSI.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician. Some devices listed herein may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada. Not all products may currently be available in all markets.



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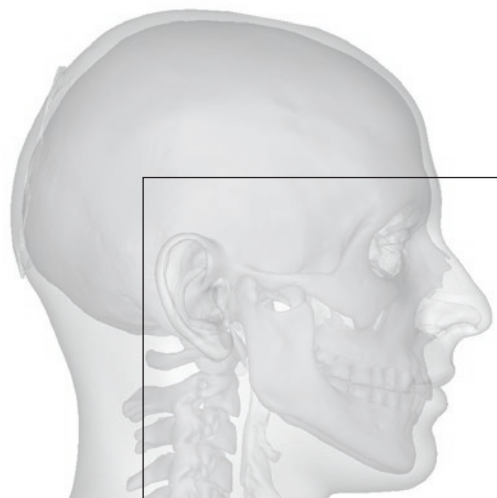
To Order (USA): 800-523-0322
To Order (Canada): 800-946-8999

Note: For recognized manufacturer, refer to the product label

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Required field of view for orthognathic cases

Intraoral scans and other data

Intraoral scan

If using an intraoral scanner, contact the manufacturer to add 'TRUMATCH® CMF' to the dropdown menu for export.

Additional data

(3D) patient photos and cephalometric data may be uploaded in PROPLAN CMF® Online with the CT/CBCT data.

Scan upload

CT/CBCT scans shall be uploaded directly through the PROPLAN CMF Online. Alternatively, send them to:
DePuy Synthes CMF
Attn: Patient Specific Implant Department
1301 Goshen Parkway
West Chester, PA 19380

*Manufactured by:

