

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:

- Titanium 3D Milled Plates for Mandible
- PEEK Milled Implants
- Titanium 3D Printed Guides, Plates and Implants*
- Polyamide Guides*
- Orthognathic Splints*
- Anatomical Models*.

Important

- Use of this scanning protocol as a guideline will result in a more accurate anatomical model, guide, and/or implant.
- CBCT Scans are not accepted for PEEK Milled Implants, Titanium 3D Printed orbital and cranial Implants.

Warning:

Patient specific devices will be designed to fit the patient's anatomy based on the CT, CBCT, intra-oral scan or dental impressions. Changes in the patient's anatomy occurring after the CT, CBCT, intra-oral scan, as well as the use of the device after such changes may result in a suboptimal fit of the device. The scan must be less than 4 months old at time of design and surgery should not be performed later than 6 months from the scan or dental impression date.

Due to potentially lower accuracy of dental surfaces provided by CT/CBCT scans, it is preferred to provide a high-resolution scan of the patient's dentition (e.g. intra-oral scans, optical scan or CBCT scan of plaster casts) or plaster casts.

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. During scanning, the position of the lower jaw needs to be controlled. The patient should be scanned in occlusion with the condylar heads in centric relation. This occlusion needs to be in a relaxed position without clenching the teeth or posturing the lower jaw. A pre-scan occlusion training or a thin non-radiopaque bite wafer that allows contact points between the teeth can be used to achieve this position. This bite wafer should not influence the surrounding soft tissues such as the lips.

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 (usually described as bone or high resolution).
- Reconstruct the images with 512 x 512 or 768 x 768 matrix.
- Only the axial images are required, no additional reformatting of the images is necessary.
- Save the images in uncompressed standard DICOM format.
- Choose appropriate image modality during export of images. Non-corresponding modality can be a reason for rejection of images.

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. Non-overlapping axial slices may decrease the quality of reformatted images.
- Scan each slice in the same direction.

Patient Positioning

- Place the patient supine on the scanner table and move the patient into the gantry, head first. Adjust the table height to position the patient's head in the field of view of the scanner.
- Stabilize the patient's head using a headrest without deforming the facial soft tissues (do not use chin-cups or straps). The patient's head must not move.
- 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.
- 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

General

Gantry tilt/oblique angle	0°
Reconstructed slice increment	≤ slice thickness
Reconstruction algorithm	Bone or high resolution

Head

	Slice thickness		Pixel size
	Recommended	Maximum	Maximum
Cases without orthognathic splints	1.0 mm	1.25 mm	1.0 mm
Cases with orthognathic splints	1.0 mm	1.25 mm	0.5 mm

Bone grafts

	Slice thickness		Pixel size
	Recommended	Maximum	Maximum
Fibula graft	1.0 mm	5.0 mm	1.0 mm
Scapula, hip, rib graft	1.0 mm	2.5 mm	1.0 mm

Note: For a free-flap (fibula, rib, hip, scapula) reconstruction, please provide images of the graft donor site.

However, in cases where this is not possible, slice thickness up to 2.5 mm for PSPC and anatomical models will be accepted.

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 10 mm from the border of the field to avoid possible border distortion effect.

CBCT Scan Parameters¹⁻⁴

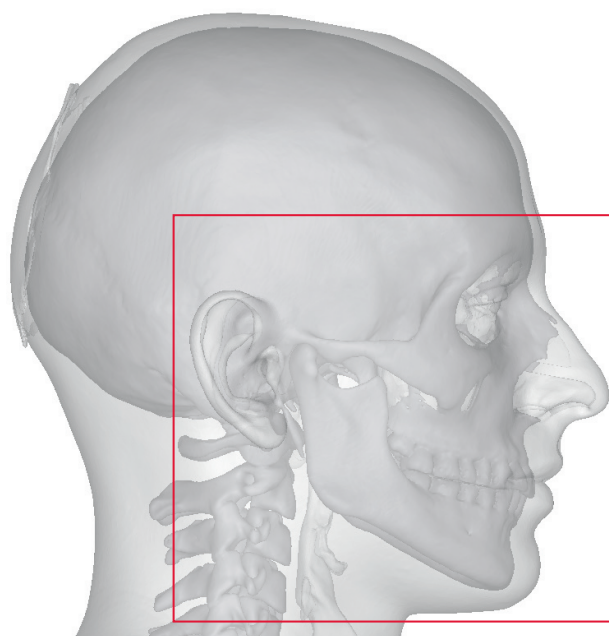
General

Field of view	Largest available
Scan time	Longest available

Device Specific

Cases including	Voxel size	
	Recommended	Maximum
Titanium 3D Printed Guides, Plates and Implants	0.3 mm	0.4 mm
Anatomical models, polyamide guides and orthognathic splints	0.3 mm	0.5 mm
Titanium 3D Milled Plate for Mandible		

Note: CBCTs are not accepted for Titanium 3D Printed Orbital Implants, Titanium 3D Printed Cranial Implants and PEEK Milled Implants.



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.

1. Materialise, HW-CMFSPINT-16100A-verA, November 2021
2. Materialise, HW-CMF-46100A-verA, November 2021
3. Materialise, HW-SynpliciTi-106100A-verA, November 2021
4. Materialise, HW-PorousTi-86100A-verA, November 2021

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.

Not all products are currently available in all markets.

All surgical techniques are available as PDF files at www.depuysynthes.com/ifu.



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Note: For recognized manufacturer, refer to the product label.

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