

CUSTOMIMPLANTS<sup>®</sup>

# CBCT

PROTOCOL FOR COMPUTED TOMOGRAPHY

CUSTOMIMPLANTS®

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## CONTACT



Telephone  
(+34) 900 377 266

**Working time**  
Monday to Friday  
08:00 to 20:00



Email  
comunicacion@customimplants.es



www.customimplants.es



Calle 16, nave 13. Polígono Industrial San Cibrao das Viñas. 32901 - Ourense



The CT scan quality is critical to the design and production of guides and implants. Please, ensure that all protocol steps are followed for an optimum scan quality.

## PRELIMINARY

This protocol describes the guidelines for a CBCT for the following:

- ▷ Milled patient specific plates for mandible (PSPM).
- ▷ PEEK Milled Patient Specific Implants (PSI).
- ▷ Patient Specific Plate Contouring (PSPC).
- ▷ Titanium 3D Patient Specific Implants, Plates and Guides.
- ▷ Polyamide surgical guides.
- ▷ Acrylic Orthognatic Splints.
- ▷ Anatomical models.

CT scan quality is critical to the production of accurate patient specific surgical instruments. Use the following parameters or the closest available. Patient specific devices are designed to fit the patient anatomy at the time of the CT. It is recommended CT not to be less than four (4) months old prior to surgery. Changes in the patient anatomy occurring after the CT may result in a suboptimal design and fit of the device or implant.

Please contact CUSTOMIMPLANTS@ support team if further clarification is required.

### Patient preparation

- ▷ Ensure removal of any non-fixed metal prosthesis or jewelry that might interfere with the region to be scanned.
- ▷ Inform the patient on the procedure.
- ▷ Non-mental dentures may be worn.
- ▷ Make the patient comfortable and instruct him/her 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 repeat the scanning.
- ▷ Stabilize the relationship of the jaws during the scan.
- ▷ Preferably, the patient is scanned with a very thin bite wafer that does not influence the facial soft tissues.

## Scanning recomendations

### 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).

### FIELD OF VIEW (FOV)

Do not deform soft tissue  
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.

### RECONSTRUCTION

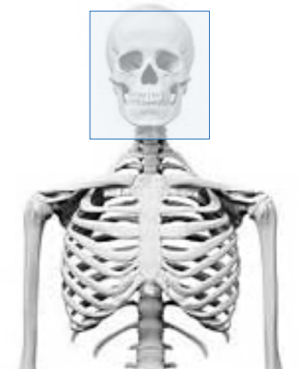
Use a proper image reconstruction algorithm to get the sharp reformatted images for locating internal structures such as alveolar nerves.

Use the sharpest reconstruction algorithm available.

## Scanning parameters

Parameter	Ti 3D Printed Implants, Plates and Guides
Matrix	768x768
Field of view	Largest available
Scan time	Longest available
Voxel size	0.3mm
Reconstructed slice increment	Max. 0.3 mm
Export	DICOM

Parameter	All the others
Matrix	512x512
Field of view	Largest available
Scan time	Longest available
Voxel size	0.3-0.5 mm
Reconstructed slice increment	0.5mm (máx. 0.5mm)
Export	DICOM



## DATA MANAGEMENT

Your site should keep and archive (PACS) copy of the CT exams, in uncompressed DICOM format and the original scanning parameters.



- ▷ Provide 1 localizer + 1 complete data set of images.
- ▷ Only true axial scanning is required.
- ▷ For processing purposes, only uncompressed DICOM is accepted. No .jpg images or other formats are acceptable. Do not submit any other types of reconstructed or reformatted images.
- ▷ Lossy compression is NOT allowed. (ISO\_10918\_1, ISO\_14495\_1, ISO\_15444\_1 or ISO\_13818\_1).
- ▷ 3D images or similar that may seem beneficial for diagnosis are accepted, if available. Submit them separately.

- ▷ Do not erase patient name and ID.
- ▷ Ensure necessary rights are obtained for transfer of data to CUSTOMIMPLANTS®.
- ▷ Data will be anonymized by CUSTOMIMPLANTS® on receipt of the data, after cross-check with prescription of the surgeon to ensure images of the right patient are provided.



We recommend building a "CUSTOMIMPLANTS® CBCT protocol" in your CT with the appropriate ranges and parameters.

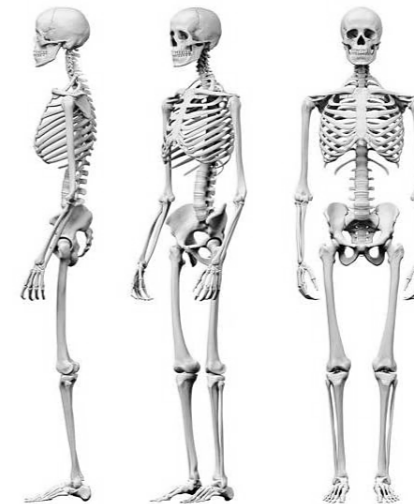
### Disclaimer

The information is intended exclusively for healthcare professionals. A healthcare professional should always rely on his or her clinical and professional opinion when deciding which product is most suitable to treat a patient.

Custom Implants SL do not provide medical advice and recommend that healthcare professionals be trained in the use of any particular product before using it in a procedure or in surgery.

Before using any product from Custom Implants SL., the healthcare professional must always read the instructions which are inside the package, the label of the product and/or the instructions for use, included those for cleaning and sterilization, when applicable. The information provided is for the purpose of showing specific products as well as the wide range of Custom Implants products.

It may occur that not every product be available in all markets due to their availability is subject to the medical or regulatory practice.



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