

CUSTOMIMPLANTS[®]

TC MAXILOFACIAL

PROTOCOL FOR COMPUTED TOMOGRAPHY

CUSTOMIMPLANTS®

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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 CT protocol is aimed at the design of 3D Ti patient specific implants, plates, personalized guides, surgical guides and anatomic models. The CT scan quality –with clear bony edges and details- is critical to the production of accurate patient specific surgical instruments.

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 to 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 recommendations

PATIENT POSITIONING

Supine on the 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. All slices must have the same table height.

FIELD OF VIEW (FOV)

Do not deform the soft tissues. Depending on the product requested, the field of view will include:

- ▶ Nose and chin
- ▶ Left and right TMJ

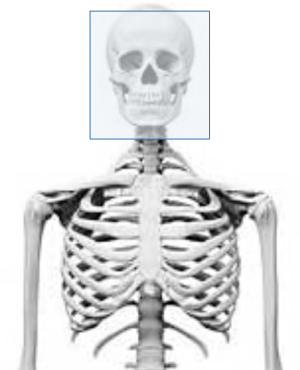
Other regions of interest if required (ex. Cranium). For reconstruction cases the complete tumor/defect. All slices must have same field of view. Scan with the same slice spacing, less than or equal to the slice thickness.

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. Reconstruct the images with a 512x512 matrix (768x768 for Titanium 3D Printed Patient Specific implants and guides). Only axial images are required, no additional reformatting. Images scanned under the gantry tilt and oblique or reformatted images negatively influence the accuracy. All slices must have same reconstruction center.

Scan parameters

Gantrytilt/obliqueangle	0°
Matrix	512x512
Slicethickness	Maximum 1.0mm
Feed per rotation	Maximum 1.0mm
Reconstructedsliceincrement	Maximum 1.0mm
Reconstructionalgorithm	Boneorhighresolution



In cases where this is not possible, slice increments up to 1.25mm are accepted for PEEK plates and up to 2.5mm for PSCP plates and anatomic models.

PSPC plates and anatomic models have been validated for accuracy with axial slice increments up to 2.5mm.

DATA MANAEMENT

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



- ▷ 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 o 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® MAXILOFACIAL protocol" in your CT with the appropriate ranges and parameters.

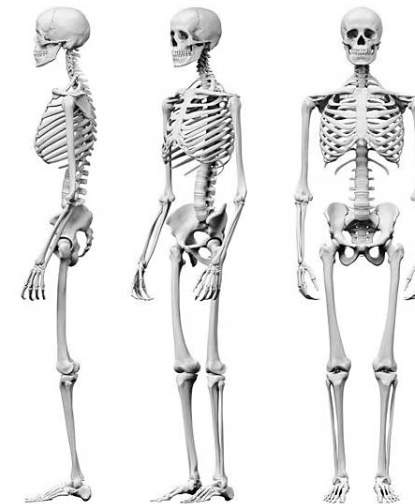
Disclaimer

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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