

This protocol describes the guidelines for a CT or CBCT scan for ordering the following products and services:

- **ACCUSHAPE® Patient-Specific Implants** (CT scans only)
- **ACCUMODEL® Anatomical Models**
- **ACCUPLATE® 3DTI Patient-Specific Plate**
- **ACCUPLAN® Patient-Specific Products and Services**
- **ACCUPLATE® Patient-Specific Plate**

Thank you for taking a moment to read this protocol. The quality of the CT or CBCT scan is the most important aspect of creating patient-specific anatomical models and devices. Your observation of the recommendations made in this protocol will have a significant impact on the accuracy of the final model. We understand concerns about keeping the radiation dose to your patients as low as reasonably achievable, therefore, please apply these guidelines as appropriate to your patients. For questions, please contact us at (214) 453-8864.

Scan considerations

- **Please use a 3D scanning routine that provides high resolution images** as would be suitable for image guided surgery, stereotactic planning or other 3D applications. It may be useful to consult with your CT vendor's Application Specialist for advice on optimal parameters for your machine that provide the best scan with acceptable radiation dose levels.
- **Acquire scans at a high spatial resolution.** Series should be acquired with thin, contiguous image slices (equivalent thickness and spacing of 1.25 mm or less) and as small a field of view (FOV) as possible while still including the patient's anatomy of interest. For CBCT scans, series should be acquired using the largest FOV available. (See tables below)
- **Please provide images in the original scanning plane.** If software post-processing is performed to reorient or reformat the scan volume, then a series of thin slice images in the original acquisition plane **MUST** be included.
- **Do not use gantry tilt during image acquisition.** If series is acquired with a gantry tilt and corrected to 0° with post-processing software, the images will not be accepted. Images must be captured at 0° gantry tilt.
- **Archive the entire study in uncompressed DICOM format** on CD-R or DVD for shipping.

Patient preparation

- **Please take steps to minimize artifact from the presence of metal** (such as non-fixed metal prosthesis or jewelry). Image artifact caused by metallic implants can obscure anatomy of interest. It is useful to position the patient so that the occlusal plane is parallel to the image plane (see Figure 1). This can help to limit artifact from metallic dental restorations to the region around the teeth. Non-metal dentures may be worn during scan.
- **Patient must remain completely still through the entire scan** to ensure that scans are free from motion artifact. Normal breathing is acceptable, but patient motion (such as tilting and/or turning head) can severely distort imaging and compromise the accuracy of a model. If patient motion occurs, the scan must be restarted. Do not deform soft tissue (no chin cups or straps).
- For peri-oral cases, stabilize the relationship of the jaws during the scan with a very thin bite wafer.

Other considerations

- The CT scan date must be within 4 months of surgery date to ensure accurate representation of patient anatomy. Therefore, the device should be used within 4 months of the scan date.
- Changes in the patient anatomy occurring after the CT as well as the use of the device after such changes, may result in a suboptimal fit of the device or implant.
- Adjust parameters according to patient body habitus.
- To reduce radiation dosages to as low as reasonably achievable (ALARA) and limit the need for additional scans, MedCAD recommends the following:
 - Check if any existing scans meet the requirements for MedCAD device design.
 - Limit radiation dosage and the area to be scanned to only the amount clinically necessary.
 - Follow the parameters given in the MedCAD Scan Protocol.
 - Save raw data for at least 14 days after scan in case of error in uploaded data.
 - Exposure to ionizing radiation is of particular concern in pediatric patients. For pediatric use, MedCAD also recommends using reduced dose and child-sized protocols where appropriate.

Please use the following scan parameters or closest approximation:

Recommended protocol for CT scanners	
Matrix	512 x 512
Scan spacing	1.25 mm or less (equal to slice thickness)
Pixel size	0.60 mm or less (equal to scan spacing)
Gantry tilt	0°
Archive media	CD or DVD, then Upload via MedCAD.net
File type	DICOM (uncompressed)
Series	Original/primary/axial (no recon, reformat or post process data)

Recommended protocol for CBCT scanners	
Matrix	512 x 512
Scan time	Longest available
Voxel size	0.3 - 0.5 mm
Field of view	Largest available
File type	DICOM / CT (one file per slice)
Reconstruction	Axial
Compression	Uncompressed

Patient Positioning

Occlusal plane should be parallel to the gantry.

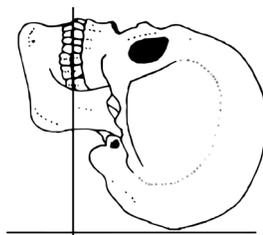


Figure 1

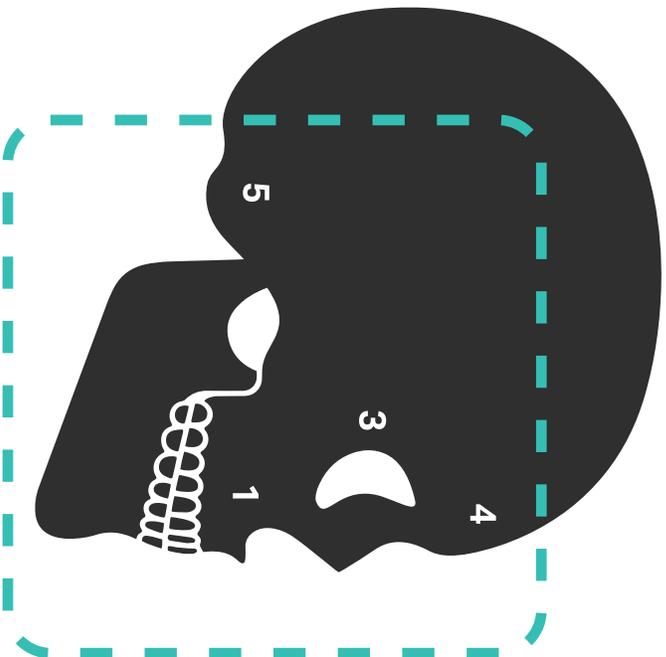


Fig. A

Patient Data Required:

1. Maxilla (full)
2. Mandible (full)
3. Orbits
4. Glabella
5. Condyles / Fossa (posterior to mastoid process)

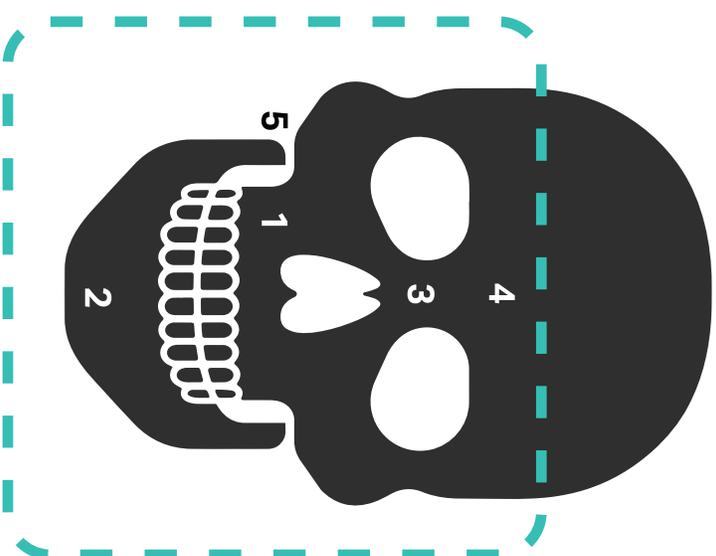


Fig. B

Note:

- This reference shows the minimum anatomical landmarks required in a CT or CBCT scan. Always include all of relevant patient defect.



Fig. A

Patient Data Required:

- 1. Skull (Full)**
- 2. Zygoma**
- 3. Orbits**
- 4. Occipital Bone**

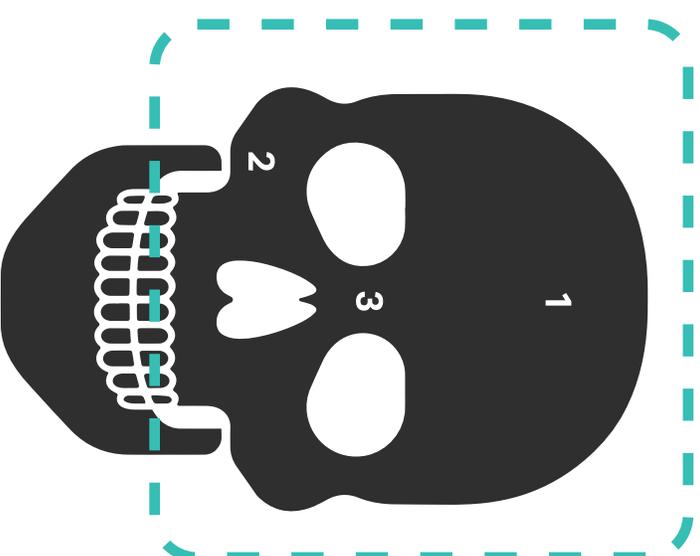


Fig. B

Note:

- This reference shows the minimum anatomical landmarks required in a CT or CBCT scan. Always include all of relevant patient defect.