Medtronic

# StealthStation™ S8 ENT
# StealthStation FlexENT™

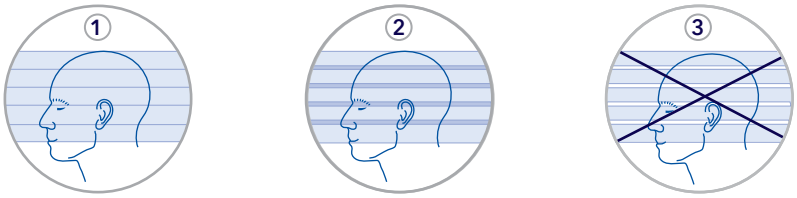
## Imaging Protocol

## ENT B Protocol

| Procedures | Software in which the scans can be used |
|---|---|
| Anterior skull based and sinus procedures | StealthStation™ S8 ENT |

### Slices

- Scan contiguous slices.
  (Slice spacing must equal slice thickness. Make sure that there is no gap or overlap between slices.)
  1. Recommended: contiguous slices with no gap and no overlap
  2. Acceptable: overlap of slices
  3. Not recommended: gap between slices

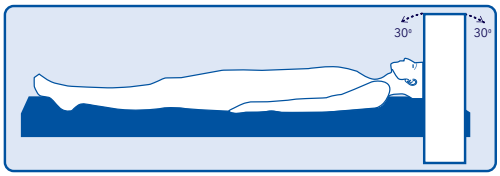



- Use a constant slice thickness.
- Use a slice thickness and slice spacing of 1 mm or less, which usually produces the highest quality dataset for surgical planning and navigation.
  - As slice thickness and slice spacing increases, surgical planning and navigation performance can be impacted.
  - 2 mm is the largest slice thickness and slice spacing acceptable for use with the ENT application.
- Axial slices are preferred for CT scans. MR scans can be acquired in axial, sagittal, or coronal orientation.

### Size

Use a square or rectangular image matrix of up to 1024 x 1024 pixels.

## CT scans



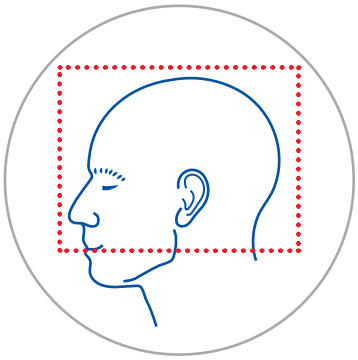

- Use a standard soft tissue algorithm.
- Axial/helical scans are acceptable using a pitch ratio of 1:1. If you use helical scans, make sure that you do not see image artifacts in the reconstructed image slices.
- Use a circular (or square) field of view (FOV). Use the smallest FOV to encompass the region of interest, which is usually up to 25 cm (250 mm). A FOV that exceeds 50 cm (500 mm) in any direction may affect the functional performance, speed, or navigational accuracy of the system.
- Include the top of the head, the skull base, and the nose. If the scan will be merged with other scans using StealthMerge™ software, make sure that there is an air gap around the head.
- If you use gantry tilt, do not exceed ±30 degrees. Only tilt the gantry on one axis in the superior-inferior direction (as shown). An image taken with gantry tilt that exceeds ±30 degrees cannot be used in the software.

## Scan region

Scan from the superior aspect of the horizontal portion of the mandible through the top or vertex of the cranium. Include an air gap above the superior aspect of the head. Include the skull base, the ears, maxillary teeth, and the tip of the nose.

Ensure that the tip of the patient's nose is included in the scan and that it is the most anterior point on the scan. Also, start the scan above any dental work to avoid creating artifacts.

The image to the right shows the typical scan region for ENT anterior skull base≈and sinus procedures.



## Patient position

Place the patient's head on a headrest, a small firm donut, or a folded towel on the scanner table. If the patient cannot remain still, use a headrest.

- Separate the patient's head from the headrest with towels or foam.
- Use padding to prevent patient motion, but make sure that the padding does not distort or shift the skin.
- Make sure that the patient's ears do not touch the sides of the headrest, and that they are not pushed away from their normal position.

## MR scans

- Do not use oblique slices. Scan along the axis of the magnet bore.
- Use single-echo scans. Do not use multi-echo scans.
- Any MR imaging sequence can be used to show anatomy/pathology. However, if the scans will be merged, MR-T1, MR-T2, and combinations thereof, have been evaluated and found effective for use with StealthMerge™ software. Other modalities such as SPGR, MPRAGE, and MRA have not been evaluated.
- MR 3D volume acquisition is acceptable as long as the scan can be reconstructed in a way that conforms to all requirements of the imaging protocol.

## Scans to merge

If you intend to merge two or more exams using StealthMerge™ software, ensure that multiple identifiable landmarks and the skull base are included in all of the scans to enable matching.

CT, MR-T1, MR-T2, and combinations thereof, have been evaluated and found effective for use with StealthMerge™ software. Other modalities such as SPGR, MPRAGE, MEG, CTA, and MRA have not been evaluated.

## Scan examination

The surgeon or imaging technologist should examine the completed scans to verify the following quality criteria:

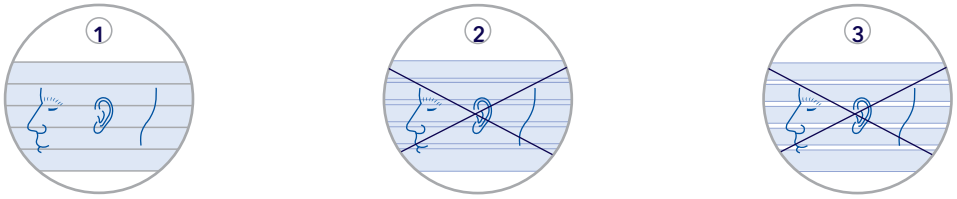
- The patient image orientation is correct.
- The total pathology/region of interest is visible.
- The planned surgical target and entry points are visible.
- The tip of the patient's nose is included in the scan and should be the most anterior point on the scan. Having the tip of the patient's nose as the most anterior point on the scan is preferred for registration.
- The slice thickness is constant throughout the scan.
- No motion artifact is present. Rapidly scroll through the images to make sure they all line up.
- Be aware of phase encoding (ghost) artifacts. If necessary, work with radiology to reduce artifacts.
- Gantry tilt does not exceed ±30 degrees and the gantry is tilted on one axis only in the superior-inferior direction. An image taken with gantry tilt that exceeds ±30 degrees cannot be used in the software.
- All other aspects of the imaging protocol were followed.

# ENT C Protocol

| Procedures | Software in which the scans can be used |
|---|---|
| Sinus procedures (with compact conebeam CT scanners) | StealthStation™ S8 ENT |

## Slices

- Scanning contiguous slices is recommended. (For the best image quality, slice spacing must equal slice thickness with no gap or overlap between slices.)




1. Recommended: contiguous slices with no gap and no overlap
2. Not recommended: overlap of slices
3. Not recommended: gap between slices

- Use a constant slice thickness.
- Use a slice thickness and slice spacing of 1 mm or less, which usually produces the highest quality dataset for surgical planning and navigation.
  - Any fractional slice thickness up to 2 mm is acceptable. However, as slice thickness and slice spacing increases, surgical planning and navigation performance can be impacted.
  - 2 mm is the largest slice thickness and slice spacing acceptable for use with the ENT application.

## Size

Use a square or rectangular image matrix of up to 1024 x 1024 pixels.

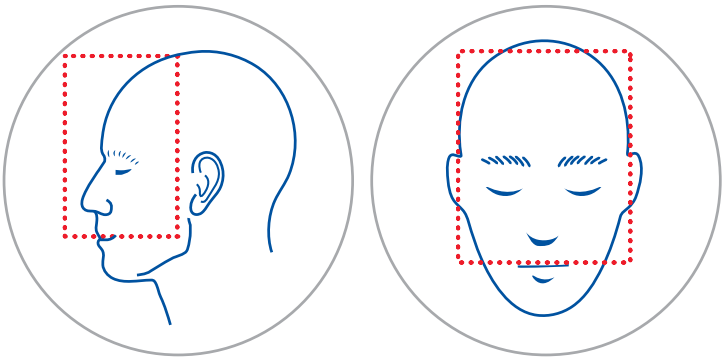
## CT scans

Use a standard soft tissue algorithm.

**Warning:** Do not use StealthMerge™ software with compact conebeam CT image sets. Compact conebeam CT image sets have not been evaluated for use with StealthMerge™ software.

## Scan region

- Scan from the superior aspect of the horizontal portion of the mandible through the top or vertex of the cranium. Start the scan above any dental work to avoid creating artifacts.
- Include the entire anterior skull base, the clivus, maxillary teeth, and the tip of the nose.
- Ensure that the tip of the patient's nose is included in the scan and that it is the most anterior point on the scan.
- The images below show the typical scan region for sinus procedures.



## Patient position

- Place the patient's head on a headrest, temple support, or chin rest, if necessary.
- Separate the patient's head from the headrest with towels or foam.
- Use padding to prevent patient motion, but make sure that the padding does not distort or shift the skin.
- Make sure that the patient's ears do not touch the sides of the headrest, and that they are not pushed away from their normal position.

## Scan examination

The surgeon or imaging technologist should examine the completed scans to verify the following quality criteria:

- The patient image orientation is correct.
- The total pathology/region of interest is visible.
- The planned surgical target and entry points are visible.
- The patient's skin is not interfered with by head straps or patient stabilizers.
- The tip of the patient's nose is included in the scan and should be the most anterior point on the scan. Having the tip of the patient's nose as the most anterior point on the scan is preferred for registration.
- The slice thickness is constant throughout the scan.
- No motion artifact is present. Rapidly scroll through the images to make sure they all line up.
- Be aware of phase encoding (ghost) artifacts. If necessary, work with radiology to reduce artifacts.
- All other aspects of the imaging protocol were followed.

Rx only. Refer to product instruction manual/package insert for instructions, warnings, precautions and contraindications.

For further information, please call Medtronic ENT at 800.874.5797 or consult Medtronic's website at **medtronicent.com**.

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