

Scan storage

- Prepare the digital image data in uncompressed DICOM format according to the surgeon's instructions. (Do not use jpg or bmp formats.)
- Store scans on a CD-R, CD-RW, or DVD. Do not use MagnetoOptical Disks.
- CT and MRI scans must be loaded in one folder (not in multiple folders with smaller scan sections).
- Disk should be given to the surgeon as soon as possible to allow for planning.

Non-clinical testing demonstrated that the WayPoint™ Anchor is MR-conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the WayPoint™ Anchor produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

 **WayPoint™ Anchor MRI Information**
The WayPoint™ Anchor was determined to be MR-conditional according to the terminology specified in the *Highest temperature change +1.5°C*

Therefore, the MRI-related heating experiments for the WayPoint™ Anchor at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.5°C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the WayPoint™ Anchor. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

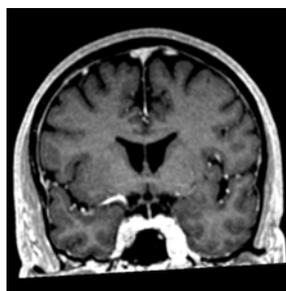
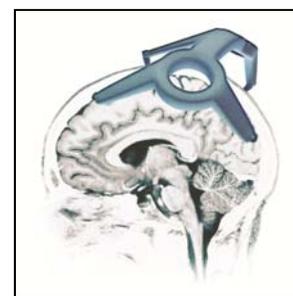
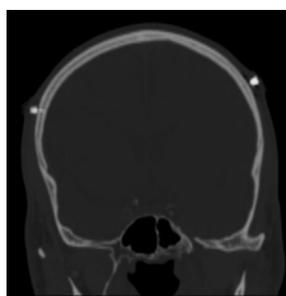
Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	205 mm ²	144 mm ²	463 mm ²	621 mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

American Society for Testing and Materials (ASTM) International, Designation: F2503-08. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania.

CT and MRI Scanning Protocols For WayPoint™ Planner

L011-40-04 (Rev. A4, 2016-02-18)

Contains directions for the following product:
66-WP-PL



WayPoint™



FHC, Inc.
1201 Main Street
Bowdoin, ME 04287
Fax: (207) 666-8292
www.fh-co.com



FHC Europe
(TERMOBIT PROD srl)
42A Barbu Vacarescu Str,
3rd Fl
Bucharest 020281 Sector 2
Romania



24 hour technical service:
1-800-326-2905 (US & Can)
(207) 666-8190

FHC Latin America
Calle 6 Sur Cra 43 A-200
Edificio LUGO Oficina 1406
Medellín-Colombia

CT and MRI Scanning Protocols For WayPoint™ Planner

Symbols	
	WARNING / Caution, consult documents
	Manufacturer
	Catalog number
	Serial number
	Authorized representative in the European community
	In reference to "Rx only" symbol; this applies to USA audiences only
	Caution- Federal law (USA) restricts this device to sale by or on the order of a physician
	Read usage instructions
	Temperature limitation: Storage conditions are between 0°C - 40°C (32°F - 104°F)

This document provides best practices and is not intended to replace the referring surgeon's specific instructions.

- The target area may be 100 slices or more from the area of the anchors at the top of the head, and the anchors may be 25 or more slices from each other. Motionless scans are required for targeting accuracy, therefore, the patient must be still during the entire imaging process.
- The scanner technician should always check the quality of the scan images for displaced slices indicating movement.

Recommended scan protocols

CT	whole head slices ≤1.25 mm thick no gantry angle	Slices ≤1.25 mm Contiguous slices equal spacing
Axial T1 MRI	whole head slices ≤1mm thick no gantry angle	Slices ≤1mm* Contiguous slices equal spacing (*up to 2mm can be used)
Axial T2 MRI	Flared, if desired encompassing target area slices 1-2mm thick no gantry angle	
T2	Confirm target location with surgeon prior to T2 scan. (Targeting the STN, GPI, or VIM may require scans from the lower part of the ear to the middle of the forehead.)	

Patient preparation

- Align the patient's head axially in the scanner, to ensure a gantry angle of zero.
- Secure the patient's head to the headrest with tape. Towels may be used to pad the head and to help prevent movement. Be careful not to disturb the anchors/headframe bars.
- Secure the patient's arms and use pillows or restraints on other parts of the body to make the patient comfortable and relaxed, and to limit movement.
- Inform the patient of the importance of holding still, as the accuracy of the procedure depends on a good scan. The surgeon may recommend light sedation if needed.

Scanning requirements

- Single pass, slice by slice; or
- Single spiral image acquisition

Note: multiple pass images can have gaps or other problems with slice thickness that can affect accuracy or targeting.

microTargeting™ Platform CT scan should start 2.5 cm above the anchors and end 2.5 cm past the target. (The extra space on top and bottom ensures there is no distortion and allows the search algorithm to work.)

Frame CT scan needs to start just below the top ring of the frame and end just above the bottom ring of the frame. This will prevent artifact from impeding the registration of the CT and MRI.

Field of view should include the entire head, but should not be too large. Standard stereotactic frame head protocols are often too large, causing unnecessary time in the scanner, large scan files, and less resolution.

Note: If CT will be the only scan used for planning, set kVp and mA for best tissue discrimination.

Scan review (with patient present)

- Prepare a 3-D reconstruction of the scans and inspect quality. Streaking, blurring, and rotated slices will require a re-scan of the patient.
- Ensure the titanium anchors/frame bars are plainly visible and stand out from the bone by setting up the CT for best anchor/frame visibility.

Note for new sites: It is good practice to allow the surgeon to review the first few scans for suitability prior to the patient leaving the hospital or the scan area.

