

HYPERFINE

Swoop™ Portable MR Imaging

Site Readiness Checklist

- Designate a location where the Scanner is to enter the building.
- Designate a transport path from the building entry to the Scanner storage location.
- Designate drivers for the Scanner who are screened to be safe in an MRI environment (See Contraindications and Patient and Operator Screening).
- Designate operators for the Scanner who are screened to be safe in an MRI environment (See Contraindications and Patient and Operator Screening).
- Designate assistants to support placing patients into the Scanner and who are screened to be safe in an MRI environment (see Positioning the Patient).
- Complete safety training for Scanner drivers – approved by Hyperfine.
- Complete safety training for Scanner operators – approved by Hyperfine.
- Designate a storage location for the Scanner that has the following properties:
 - 158 cm (62 inches) diameter of floor space or an equivalent boundary to contain the 5 Gauss line within a Controlled Access Area.
 - Controlled access to protect entrance by the general public (e.g., locked door and/or barricades).
 - Available standard power outlet to keep the PowerAssist battery charged.
 - Signs indicating the presence of a magnetic field within the storage area.
- Designate transportation paths from the Scanner storage location to patient location where you will perform imaging exams using the Scanner.
- Define a plan for controlled access (e.g., using signs, using the Gauss Guard, barricades, lockable doors at the location) for scanning the patient.
- Define a plan for protecting the 5 Gauss line from the unscreened general public during transportation, using for example:
 - The Scanner's built-in Gauss Guard.
 - Flag people accompanying the Scanner driver.
 - Temporary pathway closures to separate the unscreened general public from the Scanner.



- Define a procedure for screening patients for MRI safety who you will image with the Scanner (See Contraindications and Patient and Operator Screening).
- Define policies and procedures to allow (or disallow) family members to stay in the area during scanning. This may require MRI safety screening if family members are allowed to cross the 5 Gauss boundary.
- Define an approach for network connectivity (Hyperfine's Manufacturer Disclosure Statement for Medical Device Security MDS2 is available upon request) approved by your site's IT and Network Security groups, including approved options for:
 - Connecting the iPad to the Scanner using:
 - The Scanner's private WiFi hotspot and/or
 - A hardwired Ethernet connection between the iPad and the Scanner.
 - Connecting the Scanner to the outside Internet using:
 - A WiFi (2 GHz or 5 GHz) connection and/or
 - A hardwired Ethernet connection (top port is configured for DHCP, bottom port is static).
 - For effective operation, Hyperfine recommends a bandwidth of 2 Mbps.
 - For security measures, Hyperfine recommends using "WPA2 personal".
 - If hospital integration is desired, the site must assign the Hyperfine device an AE title. To set up hospital PACS connectivity, Hyperfine Support will need the Calling AE Title, in addition to the PACS AE Title, the PACS AE Address, and PACS AE Title Port of the hospital's PACS server. Hyperfine's DICOM Conformance Statement is available upon request. Note: Only one local PACS system can be supported at a time. However, the data can be sent to both the Hyperfine Cloud and a local PACS system.
 - If using Hyperfine Cloud, obtain accounts for scanning and access to the Hyperfine Cloud – approved by Hyperfine.
- Define a policy and plan for cleaning and disinfecting the Scanner.
- Consider the following aid and comfort accessories:
 - Flat Top Wedge Bolster (19in. W X 25in. L X 8in. H)
<https://www.rehabmart.com/product/armedica-bolster-wedges-and-rolls1-34607.html>
 - NoMoCo Pillow Support System
<http://nomocopillow.com/products/>
 - Slider Board