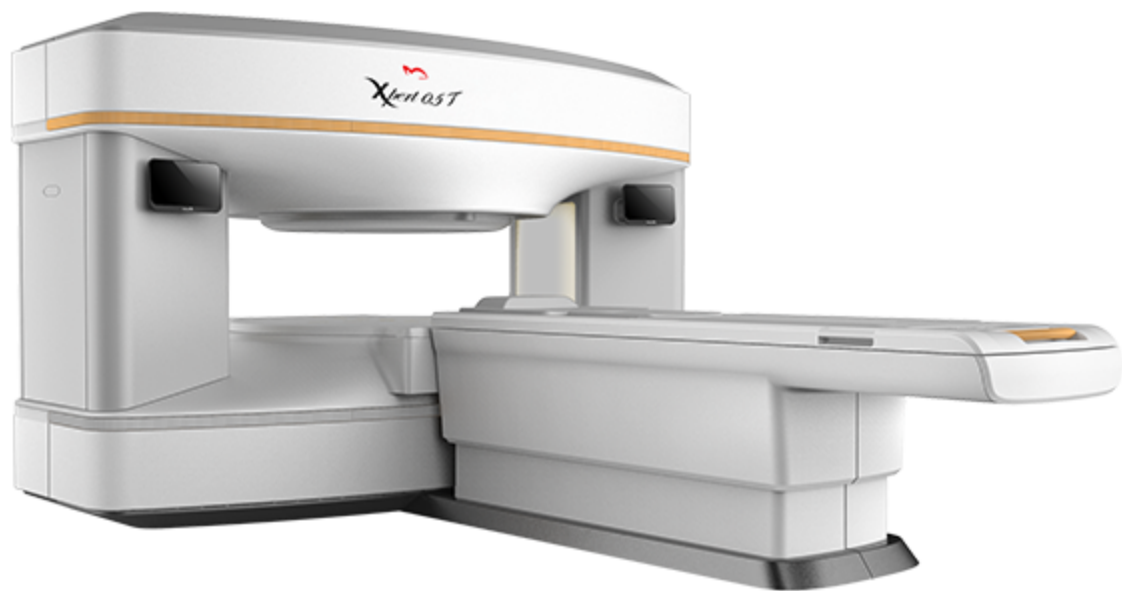


Technical Description Open 0.5T Permanent MRI System



General description of the product

The i_Open 0.5T system is a medical diagnostic magnetic resonance system. The main magnet of the system adopts the "Two Column" shape design. The structure has large open degree (the opening angle is larger than 288 degree), which provides the patient much comfort and acceptance. The main magnet use high purity of magnet materials, which enable the magnet size smaller (3.0m×1.3m×2.0m) and light weight (21T) with the static magnetic field strength up to 0.5T, which is the highest in the field of permanent magnet.

Why do we suggest 0.5T system?

1. High SNR ensures much better image quality than 0.35T and 0.4T: SNR of 0.5T system is 50% higher than 0.4T system and 80% higher than 0.35T system.
2. Faster scanning speed: scanning speed of 0.5T system is 20% higher than 0.4T and 30% higher than 0.35T system.
3. Six way electric patient table, automatic positioning.
4. The first and only one 0.5T permanent MRI system with both CE and FDA approval.

Hardware Description

Magnet The i_Open 0.5T features an Open "Two Column" shape magnet with active shielding. The stability of the magnetic field is ensured via patent design of magnet and a specialized magnet constant temperature system. Magnet constant temperature system is consisted of magnet temperature isolation coat and automatic temperature regulator, which makes magnet working at the stable temperature higher than the magnet room, greatly improved the system stability by cancelling influence from room temperature fluctuation. The magnet's fringe field is small; the 5-G field is contained within 2.5 m or less in all directions allowing the system to be sited in a small space. The complete system can be installed in a space of 30 m². The excellent magnetic field homogeneity is to ensure superior image quality with a 40 cm field of view.

The open magnet design is based on the research and clinical feedback in the area of full body imaging. The result is a high resolution, wide field of view magnet optimized to image of different part of body scan.

- o Field Strength: 0.5T \pm 5%
- o Type: Permanent
- o Field Orientation: Vertical
- o Weight: 21000 Kg
- o Homogeneity 40cm DSV Vrms 2ppm
- o Gradient Strength: 30 mT/m
- o Slew Rate: 100 mT/m/ms
- o Gap: 40 \pm 1 cm
- o Horizontal Open Angle: 288°
- o Environmental: Internal Thermostatic Control System
- o Shimming: Passive + Active

Patient table

The patient table is used for positioning the patient with corresponding RF receiving coils to the iso-center of the magnet for the scanning of MR.

The patient table unit includes two parts: patient table and positioning system. The patient table includes tabletop, tabletop carrier, cushion, etc.

The patient table is electric driven and controlled by dual touch screen.

The positioning system includes laser positioning and LED display screen. Two LED screens display the coordinates of the table simultaneously. The positioning system is fully automatic by just touching one button.

- o Max. Patient Weight: 240kg

Gradient System

The i_Open 0.5T gradient system is state-of-the-art, capable of running at 30 mT/m with a slew rate of 100 mT/m/ms.

- o Maximum Voltage: 150V
- o Maximum Current: 150A

More gradient power will support more gradient strength, enable system to provide less slice thickness and smaller minimum FOV, and allows fast (single-shot) TSE sequences with high turbo-factor and heavy T2-weighting.

Digital RF system

The flat quadrature transmitter coil is integrated in the pole pieces providing a strong uniform field. The 6 kW RF power amplifier allows short pulses to be used, ensuring the execution of fast imaging sequences available now and those of the future.

RF receiving system adapts quantum optical fiber transmitting technology. The A/D conversion and quantum laser modulation are placed inside the magnet room, that helps to significantly reduce signal loss and avoid interference during transmission. As a result, the image quality is effectively improved. SENSE, GRAPPA and other algorithms are applied for fast imaging.

Receive platform

The system is equipped with a fully digital four-channel hardware platform. The technology allows the use of phase array coil. These coils provide image acquisition with higher signal to noise ratio and image quality.

RF Receiving Coils

The i_Open 0.5T RF coils provide excellent signal to noise ratio, due to presence of pre-amplifiers in all elements of the coils and other receiver coils, ensuring proper enhancement of the signal. The i_Open 0.5T comes with a comprehensive set of RF receive coils supporting a wide range of clinical applications from head to toe. Dedicated preset procedures are available for all coils.

- o Coil Design: Phase Array coil
- o RF Receiving Coils: Four channel phase array head coil
Four channel phase array head-neck coil
Four channel phase array knee coil
Four channel phase array body coil (Large and Medium)
Shoulder
Small Joint (wrist)
Flexible (Optional)
Infant Head Coil (Optional)
Breast Coil (Optional)
- o Max. RF Power: 8 kW
- o Preamplifiers: All digital Fixed inside magnet
- o Positioning: Padding set included providing comfortable patient positioning and restricting movement.

Four Channel Phase Array Head Coil

The Phase array Head Coil is optimized for imaging head and upper C-spine. The coil can be opened for fast and easy positioning.

Features:

- o Phase array Coil with high signal to noise ratio
- o Large coverage for easy positioning.
- o Split design for easy positioning

Four Channel Phase Array Head-Neck Coil

The Head-Neck coil has larger coverage than neck coil, meet the needs of doctor to observe bigger field of view. The upper part of the coil can be removed for fast and easy positioning.

Features:

- o Phase array Coil with high signal to noise ratio
- o High uniformity from cerebellum to the upper thoracic spine region.
- o Split design for easy positioning

Four Channel Phase Array Body Coil (Large and Medium)

- o Phase array Coil with high signal to noise ratio
- o High uniformity from cerebellum to the upper thoracic spine region.
- o Split design for easy positioning

The Phase array Body/Spine Coil Large/Medium has four phased array elements suitable for imaging chest, abdomen, pelvis, thoracic and lumbar spine in large sized patients. The upper part of the coil can be removed for fast and easy positioning. In addition the coil also slides under the patient for easy positioning.

Features:

- o Phase array Coil with high signal to noise ratio
- o Split design and sliding support for easy positioning

Four Channel Phase Array Knee Coil

The Phase Array Knee Coil is used for knee. The coil can be opened for fast and easy positioning.

Phase Array Shoulder Coil

The Phase Array Shoulder Coil has a specialized design to fit around the shoulder. Coil loop slides along the arm for easy positioning.

Small Joint Coil (Wrist)

Dedicated design for wrist application.

Phase Array Flexible Body Coil (Optional)

The flexible coil is dedicated for obese patients, and provides wider applicability of i_Open 0.5T system.

Infant Head Coil (Optional)

Special design for infants.

Breast Coil (Optional)

The Breast Coil is design especially for breast.

Computer Control System

Host Computer

Host computer with Intel CORE 2 DUO 3.2G or higher CPU and at least 4 GB RAM for overall system control and processing, allowing simultaneous operation of Patient registration/pre-registration, MR scanning and imaging, Image reconstruction, Image review, print and etc. greatly enhanced patient throughput. 500 GB hard disc is used for system software and data storage. CD/DVD RW for data archive, backup and transfer.

- o CPU
- o Memory (RAM)
- o Hard Disk
- o Image Archiving
- o Operating System: Windows 7
- o Graphical Interface: Windows based
- o Networking: DICOM 3.0 Storage, Media Exchange, Send, Print and Worklist

NOTE: Customer will be required to provide cabling, appropriate interface devices, and network connection from the operator console to the viewing location. Customer is also responsible for all telephone, network and/or internet service provider charges. Contact for specific requirements and recommendations.

Operator's console

The i_Open 0.5T is designed for operation by a single operator. Patient administration and scan control, image data viewing and transfer, image processing and printing, system control can be performed with user-friendly, intuitive controls. Simple mouse clicks enable routine actions, allowing high patient throughput and operator comfort. The Operator's Console comprises:

- o Microsoft Windows 7 operating system for efficiency and ease of operation.
- o A desktop with space for equipment and paperwork
- o 24" TFT-LCD monitor for professional image quality

Patient Environment

The i_Open 0.5T is the most patient friendly of open scanners; even the most anxious and claustrophobic patients will feel at ease. The C-arm magnet has a spacious 41 cm opening to allow maximum access to the patient. The magnet poles are small, providing the patient with a full view to the outside of the system in virtually all examinations.

- o Patient communication system for bi-directional patient communication.
- o A set of soft mattresses ensure patient comfort.
- o Low noise system makes patient feel ease during the whole scanning procedure.
- o A hand-held nurse call button allows the patient to attract the operator's attention without talking (Optional)
- o Patient music system will effectively relieve anxiety and emotional distress (Optional).

Gating Package

Respiratory Gating

Respiratory gating can be utilized to reduce artifacts caused during respiratory motion by acquisition of data on the basis of the phase in the respiratory cycle. The device relies on the relative humidity differences between inspired and expired air.

The respiratory gating package contains:

- o an air ball fixed on the abdomen for pressure sensor
- o a convertor from pressure to digital signal
- o Software display the respiration wave shape
- o Trigger position can be selected by the customer

Pulse Gating

The use of Pulse Triggering and Gating is to monitoring the pulsating

Features:

- o a pressure sensor fixed on the wrist
- o a convertor from pressure to digital signal
- o Software display the pulse wave shape

Software Description

The software package is intended for use with Magnetic Resonance Diagnostic Imaging Systems – i_Open 0.5T. The main software, which called To-Station, will help operators and physicians to step patient registering, system adjusting, 2D & 3D image acquisition, processing, analyzing and storage, it also integrates image enhancement, DICOM printing, etc.

Software Package

- o Scanning control software
- o Image reconstruction software
- o Image processing software
- o Image analyzing software
- o Image format conversion software (JPEG,BMP, etc.)
- o Image view software
- o System inspecting software
- o Real-time printing software (Standard DICOM 3.0)
- o Remote Service Software

Advanced Features

Patient Pre-registration

Support patient pre-registering when scanning, without limitation to amount of pre-registered patients, improves work efficiency.

9 Slices of Scout Images

9 slices of scout images in three dimensions by one pilot scan in 25 seconds, provides you 3 choices in each dimension, greatly enhance precision of the scan positioning, and enable a high patient flow.

Scout Line

Scout image can be displayed at the lower right corner and the side bar. It makes very simple to know exact slice position, which is significant improved the convenience of clinical diagnosis.

Image Comparison

Provide multi-slices comparison on one screen.

Intelligent Icon Management

Enhance operator's efficiency by customizing interface icons, re-arranging the position of each icon, grouping your icons.

Non-film Capability

A smart image reviewer software called "to viewer" has been integrated into the archive VCD/DVD automatically, which enable to review the archive images in any other PC.

Abundant Sequence Database

Provides Sequences upgrade free of charge.

Sequence database can be customized and categorized by operator. System provides operator with reference information and will inspect the validity of parameters automatically.

Parameters can be reset to default

Standard DICOM 3.0 Interface

DICOM Modality Worklist (RIS interface)

Supports database browsing from a DICOM workstation and sends a copy of requested images in DICOM format

The i_Open 0.5T DICOM conformance statement provides full details on the implementation of the DICOM standard.

Remote Service Software

Customer is required to perform a phantom scanning program before first patient scanning every day, system status and parameters will be sent via internet to Service Center at WDM headquarter. Malfunction will be detected automatically meanwhile a message will be sent to service manager, and service center will be able to observe the curves of system running, that will be valuable for engineer to do slight adjustment of each system.

Imaging Sequences and Parameters

Pulse Sequences:

- o Scout image with Spin Echo (3 x 3 scout images, each view has 3 scout images for orientation)
- o Spin Echo (SE)
- o T1 weighted image with Spin Echo
- o Proton density weighted image with Spin Echo
- o T2 weighted image with Fast Spin Echo
- o Proton density weighted image with Fast Spin Echo
- o Dual Contrast image with Fast Spin Echo
- o 3D Fast Spin Echo
- o Gradient Echo (GE)
- o T1 weighted image with Gradient Echo
- o T2 weighted image with Gradient Echo
- o Fast dephase Gradient Echo
- o Fast rephase Gradient Echo
- o Fast dephase Gradient Echo with breath hold
- o 3D Fast dephase Gradient Echo
- o Inversion Recovery (IR)
- o Fat suppress with Inversion Recovery
- o Water suppress with Inversion Recovery
- o Fat suppress with Fast Inversion Recovery (STIR)
- o Water suppress with Fast Inversion Recovery (FLAIR)
- o Heavy T1 weighted image with Inversion Recovery
- o 2D/3D Time of Flight for Angiography (TOF)
- o Magnetic Resonance Cholangiopancreatography (MRCP)
- o Magnetic Resonance Urography (MRU)
- o Magnetic Resonance Myelography (MRM)
- o Magnetization Transfer Contrast (MTC)
- o line-Scan Diffusion Weighted Imaging (LSDWI)

- Image Reconstruction:** 2D Fourier Transform
3D Fourier Transform
Half Scan
- Slice Thickness:** 2-D: From 1.0 mm to 10 mm, 0.1 mm increments
3-D: From 0.4 mm to 10 mm, 0.1 mm increments
- Interslice Spacing:** Contiguous slices available, system default is 10% slice gap
- Slice Orientation:** Transverse
Sagittal
Coronal
Oblique and double oblique
Off center
- Acquisition Matrix:** 2-D: from 128 x 128 to 256 x 256
3-D: from 128 x 128 x 24 to 256 x 256 x 128
- Field of View:** 40 mm to 400 mm, 1 mm increments
- Number of Slices:** 2-D: 1 – 256
3-D: 1 - 500 (maximum 50 slices x 10 slabs)

Imaging Processing and Manipulation

Multi-tasking:

- o All operations can be performed in parallel.
- o Support patient pre-registering when scanning, without limitation to amount of pre-registered patients, improves work efficiency.

Indicator of background task

Exam Queue:

- o Management and planning of scan queue for a complete examination
- o Customization of protocols with archiving

Positioning:

- o Visualize current image with geometrical references on the scout image
- o Graphic positioning by using the mouse

Image Tools (On single image or complete series):

- o Window width/level

- o Zoom
- o Pan
- o Rotate
- o Mirror
- o Measurements
- o Distances
- o ROI (manual, rectangular, oval), size, media, standard deviation
- o Annotation on images
- o Comparison of multi-slices on one screen

Database Functions:

- o Search (alphabetic, chronological, patient ID, Body part, Sex, Age, etc.)
- o Sort
- o Archiving and export functions for CD/DVD-ROM

Archiving in CD/DVD: To enable the images archived in CD/DVD can be reviewed in any windows PC, 'ToViewer' – a smart image browser will be automatically burned into each disk

System Siting Requirements

RF shielding solutions and site planning support is provided

Magnet room requires 24hr isolate Air Conditioning to stabilize the room temperature at 23 °C with deviation of $\pm 1^{\circ}\text{C}$ per hour. Humidity: 40 – 60%.

Electronics room requires air-conditioning, room temperature: 15 - 30 centidegree with deviation less than 3 centidegree per hour. Humidity: 40 ~ 80%.

Air Conditioning Machines are to be provided by customer,

Specifications of Air

Conditioning Machines depend on size of magnet room. Normally it is suggested for the magnet room to have refrigerating capacity no less than 3KW and able to work 24 hrs x 7 days

- o Magnet & table weight: 21000 kg.
- o Electronics Cabinet Weight: 500 kg.
- o Recommended Magnet Room

Dimensions: 6m x 5m x 3m

- o Recommended Room Space for electronics: 6 sqm
- o RF Shielding: Required
- o Power Requirement: 220 VAC single phase, $\pm 10\%$, 10 Amp Service
- o Power Consumption: 15 KVA (Not including consumption of Air Conditioning Machine)
- o Internet: A customer supplied and maintained dedicated high speed internet connection (ADSL or cable modem) is required for Remote Assistance.

Modular RF Cage

The RF cage is a modular enclosure assembled on-site. This "room within a room" features a galvanized steel frame and filter panels with observation window and access door. The RF cage materials weigh is approximately 4000 Kg completed and provides 80 dB of RF attenuation. It is appropriate for sites with ample space (standard cage 6m X 5 m X 3m) and low RF profiles (maximum RF 80 dB PV/m). The floor holding the pavilion should be finished to a flatness of 5mm over 5 m.

The RF cage includes also internal light.

The RF cage may be customized to accommodate your specific space needs.

Includes installation and delivery.

Buyer accepts responsibility for all site modifications, permits and approvals.