

Product Safety and Performance Information

1 Product Description

1.1 Product name and model

Product name: Magnetic Resonance (MR) System

Product model: i_Open 0.3T, i_Open 0.36T, i_Open 0.4T, i_Open 0.5T

1.2 Basic UDI-DI

693896432100N9

1.3 Intended Purpose

i_Open 0.3T/0.36T/0.4T/0.5T Magnetic Resonance (MR) Systems is an MR imaging device, and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by the system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

1.4 Indications for use

i_Open 0.3T/0.36T/0.4T/0.5T Magnetic Resonance (MR) Systems is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique section images of head, body, or extremities. It is designed for imaging portions of the head, neck, shoulder, knee, liver, kidney, pelvic, hand, wrist, elbow, ankle, thoracic and lumbar spine regions.

1.5 Contraindications:

The magnetic and electromagnetic field produced by the MR equipment may produce strong attraction and/or torque to active or passive implants containing conductive materials. They might cause significant artefacts in the MR image, and might cause adverse health effects such as internal heating that result in tissue damage, loss of physiologic function and serious injury. When the implant device is labelled as MR safe or MR conditional, the operator is then informed via the instructions for use of the implant about the safety and possible conditions to be taken into account during scanning, which further information is described in the accompanying documents of the implant manufacturer. Therefore, the following patients are forbidden to take any MR examination:

- Who have metal implants or electrically, magnetically or mechanically activated implants.
- Who rely on electrically, magnetically or mechanically activated external life support systems.
- Who have intracranial aneurysm clips unless the physician is certain that the clip is not magnetically active.

Examination by MR equipment, in terms of patient pre-screening, the following cases should be paid particular attention to:

- Patients with implanted surgical clips (haemostatic clips) or other ferromagnetic materials (which the magnetic field may dislodge);
- Patients with permanent (tattoo) eye-liner or with facial make-up (because severe eyelid irritation has been reported);
- Patients with compromised thermoregulatory systems (e.g. neonates, low-birth-weight infants, certain cancer patient);
- Patients with metal implants;
- Patients with implanted prosthetic heart valves;
- Patients who are pregnant, scanning of pregnant patients with the whole body RF transmit coil should be limited to the normal operating mode with respect to the SAR level. Because the fetus is especially sensitive to potential thermal events during the first trimester. You should avoid scanning patients in the first trimester with unknown pregnancy status. Qualified medical practitioners should determine (after considering alternatives) if the clinical value of the

examination outweighs the risks.

- Patients who need emergency medical treatment more likely for his personal disease history.

1.6 Intended user

The intended users of the MR Systems are radiologists and radiology technologists, users must pass Wandong Medical's clinical use training for the product.

1.7 Intended Patient Population

The Magnetic Resonance (MR) Systems is suitable for all patients except contraindications.

All the patients should be monitored generally from watching window. Suggest users install voice device, so that workers in the operating room can communicate with patients in the scanning room with voice device any time. When the following patients are checked, they should be supervised by clinical physician or nurse in scanning room, and be physiologically monitored by means of devices for measurement or evaluation of various physiological state when necessary:

- Patients who have most possible of heartbeat stopping;
- Patients with acoustical or ocular obstacle, because of which, effective communication can't be kept;
- Patients with no sense or chaotic mentality or egregious composedness, whom can't keep reliable connection with;
- Patients with heart decompensation, fever, claustrophobic individuals, and perspiration maladjustment;
- Patients who can't communication with personnel in operating room for any other reasons.
- Infants who can't be expected to use voice communication channel provided by MR equipment.

2 Product Safety Information

Warnings and Cautions

In order to insure the safe operation and run of MR System, the operators and patients must abide by the follow safety operation warnings.

1) Entrance of scanning room



Danger: Patients with cardiac pacemaker and metal implant are prohibited from entering the scanning room or in 5Gs. If the above patients enter in scanning room or 5Gs, the system may stop working and lead to damage. Please obey above safety warnings posted on the entrance of the scanning room. The figure is shown as follows:



Fig1.7-1 Warning Labels

2) The signs in magnet shell

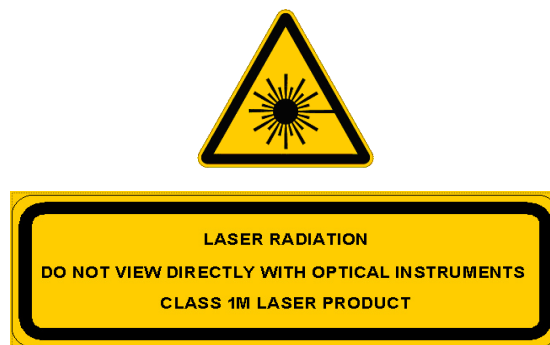




Fig1 Warning: laser beam



Fig2 Non-ionizing radiation

3) Operation table socket

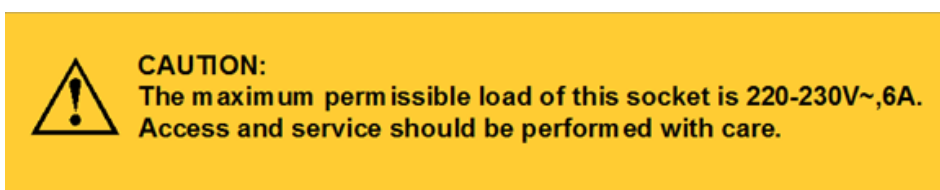


Fig3 warning: operation table socket and electronic cabinet socket

The rated parameters of this socket is 220-230V~, 10A, and the maximum permissible load of this socket is 220-230V~, 6A.



Warning: The socket mustn't be placed on the floor, and an additional multiple socket-outlet or extension cord shall not be connected to the MRI system.

Warning: Connecting any equipment that has not been supplied as a part of the ME SYSTEM to the multiple socket-outlet may cause problems such as system instability and device damage. In addition, excessive power of connected devices may also cause safety hazards such as fire.

4) Electronic Cabinet:





Fig4 Marks for the electronic cabinet

The rated parameters of this socket is 220-230V~, 10A, and the maximum permissible load of this socket is 220-230V~, 6A.

5) Refer to instruction manual



“Refer to instruction manual” mark is respectively pasted on the housing, the front panel of the RF power amplifier and the top of the gradient power amplifier.

6) Signs on the packing boxes

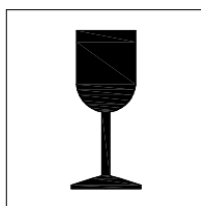


Fig5(a)



Fig5(b)

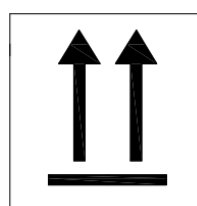


Fig5(c)

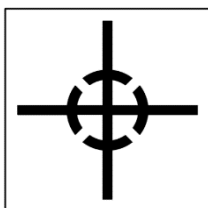


Fig5(d)

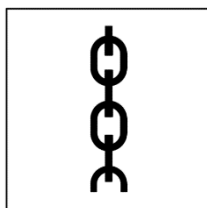


Fig5(e)

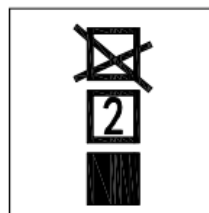


Fig5(f)

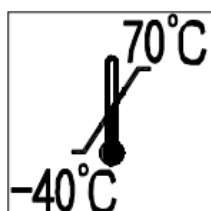


Fig5(g)

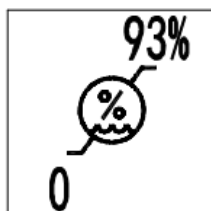


Fig5(h)

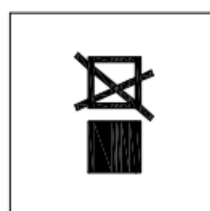


Fig5(i)

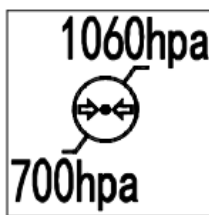


Fig5(j)

The description of the graphic signs above is as following:

Fig5(a): Fragile, handle with care

Fig5(b): Keep dry

Fig5(c): This way up

Fig5(d): Center of gravity

Fig5(e): Sling Here

Fig5(f): Staking limit by number, applicable to packages other than magnets

Fig5(g): Temperature limits

Fig5(h): Humidity limitation

Fig5(i): Staking limit by number, applicable to the magnet package

Fig5(j): Atmospheric pressure limitation

3 Product Performance Metrics

Intensity of magnetic field	$i_Open\ 0.3T: 0.3T \pm 5\%$ $i_Open\ 0.36T: 0.36T \pm 5\%$ $i_Open\ 0.4T: 0.4T \pm 5\%$ $i_Open\ 0.5T: 0.5T \pm 5\%$				
Stray magnetic field	$i_Open\ 0.3T/i_Open\ 0.36T: X \leq 2.5m, Y \leq 2.5m, Z \leq 2.5m$ $i_Open\ 0.4T: X \leq 2.8m, Y \leq 2.8m, Z \leq 2.8m$ $i_Open\ 0.5T: X \leq 2.4m, Y \leq 2.4m, Z \leq 2.4m$				
SNR	Name	SNR			
		$i_Open\ 0.3T$	$i_Open\ 0.36T$	$i_Open\ 0.4T$	$i_Open\ 0.5T$
	Head coil	≥ 70	≥ 75	≥ 75	≥ 80
	Neck coil	≥ 60	≥ 65	≥ 65	≥ 70
	Body-L coil	≥ 55	≥ 60	≥ 60	≥ 65
	Body-M coil	≥ 70	≥ 75	≥ 75	≥ 80
	Knee coil	≥ 80	≥ 90	≥ 90	≥ 100
	Shoulder coil	≥ 70	≥ 80	≥ 80	≥ 90
Ankle coil	≥ 80	≥ 90	≥ 90	≥ 100	

	Wrist coil	≥ 90	≥ 100	≥ 100	≥ 130
Imaging Uniformity	≥ 95				
Slice thickness of 2D scanning	Typical thickness 5mm, the error should be less than 15%				
Ghosting artifact	i_Open 0.3T: I _G /S less than 10% i_Open 0.36T/ 0.4T/ 0.5T: I _G /S less than 5%				
Spatial resolution	$m \geq 0.56$, the spatial frequency is 0.5 mm^{-1} , and the distinguishable voxel size is $1\text{mm} \times 1\text{mm}$				
Geometric distortion of 2D	Less than 5%				

STATEMENT TO USERS

For detailed usage information, please refer to the paper version of the instruction manual.