Product Safety and Performance Information

1 Product Description

1.1 Product name and model

Product name: Magnetic Resonance (MR) System

Product model: i_Vision 1.5T, i_Vision 1.5T Plus, i_Vision 1.5T Pro, i_Vision70 1.5T, i_Vision70 1.5T Plus, i_Vision70 1.5T Pro

1.2 Basic UDI-DI

693896432200NE

1.3 Intended Purpose

The Systems is a whole body magnetic resonance scanner. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, spine, breast, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by the MR Systems reflects the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images when interpreted by a trained physician yield information that may assist in diagnosis.

1.4 Indications for use

The Systems is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, spine, breast, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast

agents may be used.

The images produced by the MR Systems reflects the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images when interpreted by a trained physician yield information that may assist in diagnosis.

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.

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

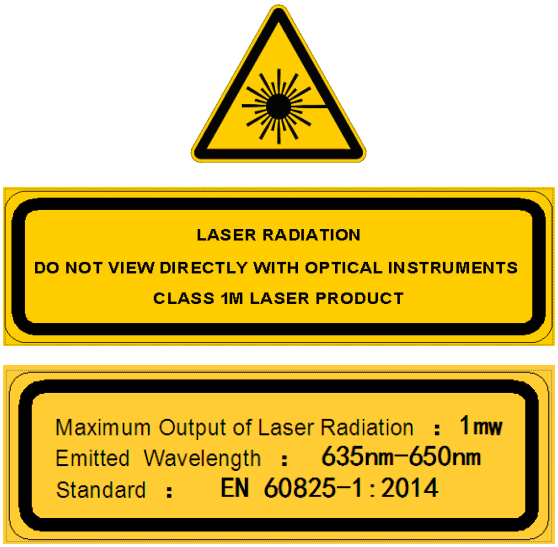


Fig1 Warning: laser beam

Fig2 Non-ionizing radiation

3) Magnet Monitor

Fig3 Warning: Emergency Magnet Off

Fig4 Warning：Emergency Rundown

4) Operation table socket and electronic cabinet socket

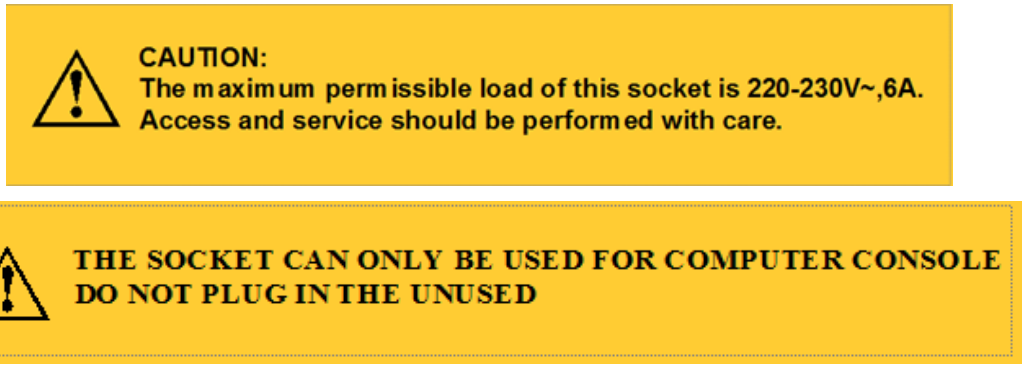


Fig5 warning: operation table socket and electronic cabinet socket

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 extenxion 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.

5) Electronic Cabinet:

6) Filter board

Fig6 warning: filter board

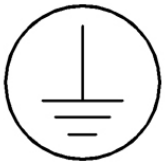
7) Refer to instruction manual

"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.

8) Warning: High voltage

High-voltage warning signs are distributed on the side panel of the gradient power amplifier, the power distribution cabinet in the electronic cabinet, and the rear side of the gradient coil.

9) Protective earth



The Protective earth signs are attached respectively beside the patient bed support frame, on the top of the gradient power amplifier, on the front panel of the RF power amplifier, beside the grounding busbar of the electronic cabinet, on the front side of the bare magnet, on the rear side of the gradient coil, and on the magnet monitoring unit.

10) 5 Gauss line on the floor in the shielding room

No access for person with pacemakers.

11) Signs on the packing boxes

Fig7(a)

Fig7 (b)

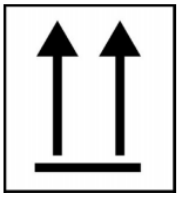


Fig7(c)

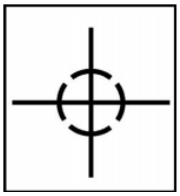


Fig7 (d)

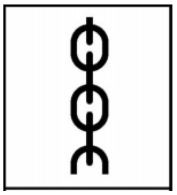


Fig7 (e)

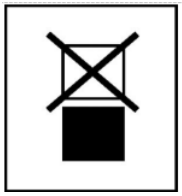


Fig17 (f)

Fig7 (g)

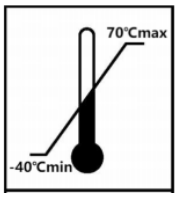


Fig7 (h)

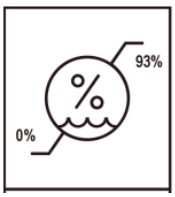


Fig7 (i)

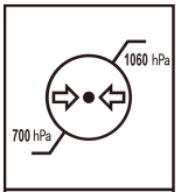


Fig7 (j)

The description of the graphic signs above is as following:

Fig7 (a): Fragile, handle with care

Fig7 (b): Keep dry

Fig7 (c): This way up

Fig7 (d): Center of gravity

Fig7(e): Sling Here

Fig7(f): Staking limit by number, applicable to the magnet package

Fig7(g): Staking limit by number, applicable to packages other than magnets

Fig7(h): Temperature limit

Fig7(i): Humidity limitation

Fig7(j): Atmospheric pressure limitation

3 Product Performance Metrics

Intensity of magnetic field	1.5T±1%
Stray magnetic field	With magnet geometry center as the center, in the direction of the central axis of the superconducting magnet, axial 4 m, radial 2.5m away, the magnetic field strength of any point should be less than 0.5mT.
SNR	Head coil ⩾150 16-Channel Head coil ⩾180 32-Channel Head coil ⩾200 16-Channel Head and Neck combined coil (head) ⩾150 16-Channel Head and Neck combined coil (neck) ⩾100 24-Channel Head and Neck combined coil (head) ⩾150 24-Channel Head and Neck combined coil (neck) ⩾100 32-Channel Head and Neck combined coil (head) ⩾150 32-Channel Head and Neck combined coil (neck) ⩾100 Cervical thoracic combined coil ⩾100

	body coil ⩾120 16-Channel body coil ⩾120 8-Channel body coil (joint use) ⩾120 12-Channel body coil (joint use) ⩾120 16-Channel body coil (joint use) ⩾120 Spine coil ⩾100 18-Channel Spine coil ⩾100 24-Channel Spine coil ⩾100 32-Channel Spine coil ⩾100 Knee Coil ⩾200 16-Channel Knee Coil ⩾250 Shoulder coil ⩾160 12-Channel Shoulder coil ⩾160 Flexible coil ⩾100 4-Channel Large Size Flexible coil⩾100 4-Channel Small Size Flexible coil⩾100 Small Size Flexible coil ⩾100 Ankle coil ⩾150 16-Channel Ankle coil ⩾150 Wrist coil⩾150 16-Channel Wrist coil ⩾250 Breast coil ⩾150 16-Channel Breast coil ⩾150 Body Flexible Matrix Coil (joint use) ⩾120 12-Channel Body Flexible Matrix Coil (joint use)⩾120 16-Channel Body Flexible Matrix Coil (joint use)⩾120 MSK-L Flexible Matrix coil ⩾100 MSK-S Flexible Matrix coil ⩾100
Imaging Uniformity	All Spine coil: ⩾65 Others coil: ⩾90
Slice thickness of 2D scanning	Typical thickness 5mm, the error should be less than 15%
Ghosting artifact	IG/S less than 5%

Spatial resolution	m≥0.56, the spatial frequency is 1 mm^{-1}, and the distinguishable voxel size is 0.5mm×0.5mm
Geometric distortion of 2D	｜Proportional geometric distortion｜<5% Variance geometric distortion<5% ｜Maximum geometric distortion｜<4.4mm

STATEMENT TO USERS

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