

1、 General information

The Quantum CT Q560a is a computed tomography system with a helical scan function manufactured by KuanTeng (Beijing) Medical Technology Co., Ltd. with ingenuity based on a high-end intellect platform.

1.1 Intended Use

The Quantum CT Q560a is an imaging equipment for diagnosis that generates images in accordance with the tissue densities. The equipment processes the X-ray signals traveling through the patient's body from several directions with a computer and then reconstructs the tomographic images for diagnosis.

1.2 Intended Using Occasions

The Quantum CT Q560a is intended to be used in medical institutions such as hospitals, clinics, emergency rooms, physical examination centers, etc.

The equipment should be used in a room with air conditioning. The specific conditions are as follows:

- a) Ambient temperature: Scan room: 18 C - 26°C; Control room: 15°C - 30°C
- b) Relative humidity: Scan room: 30% - 60% (non-condensing); Control room: 30% - 75% (non-condensing)
- c) Atmospheric pressure: 700 hPa - 1060 hPa

d) Electromagnetic environment: should meet the electromagnetic environment requirements regulated in Table 1, Table 2, Table 3, and Table 4 in this manual. Otherwise, the product may function abnormally.

1.3 Intended Populations

1.3.1 Intended User

The target patient population of this product is all populations. However, pregnant women and infants should try to avoid using this system for testing, and pregnant women who have legitimate reasons for testing should pay attention to protecting the embryo and fetus as much as possible under the guidance of a doctor. Children and newborns who have a legitimate reason to be examined should be given effective X-ray protection under the guidance of a doctor.

Users and operators must be Radiology/Medical Imaging.

 **Caution:**

Operators need to meet local regulatory requirements.

NOTE:

Operators of this equipment shall not be under the age of 18 unless the following conditions are met:

- **The operator is an intern in the medical imaging technology major who holds the "Radiation Worker Certificate" and operates under the supervision of the licensed physician;**

- **The content of the operation training shall be approved by the hospital radiation safety committee and recorded in the training file**

1.3.2 Indications for Use

For routine clinical CT examinations, and it supports the angiography scan (except for coronary arteries).

1.3.3 Intended patient population

- All populations.

Caution

The following are the preparations required for scanning infants and young children:

- Assess the need for sedation based on the baby's age and level of cooperation
- Use low dose scanning protocol with parameters adjusted according to body weight
- Use a dedicated baby carrier to ensure stable position
- Continuous monitoring of vital signs (heart rate, respiration, blood oxygen saturation) during the examination

1.3.4 Clinical Benefits

The X-ray Equipment for Computed Tomography scan a certain thickness of a part of the human body with X-ray beam for routine clinical CT examinations, and it supports the angiography scan (except for coronary arteries).

1.4 Contraindications

No absolute contraindications of CT examinations have been found yet. However, avoid scanning the pregnant or infant patients as much as possible. For the pregnant to undergo a CT scan for a valid reason, the physician's instructions should be followed for the most possible protection of embryos and fetuses. For the infants to undergo a CT scan for a valid reason, the physician's instructions should be followed for effective X-ray protection.

If the contrast agent injection is required for the enhanced scan, select the contrast medium for use carefully according to the different brands and types of the contrast agent.

The following are the contraindications of the iodine contrast agent and the situations requiring careful use.

➤ **Contraindications**

- Patients with severe adverse effects of iodine contrast agents in past exams
- Patients with uncured hyperthyroidism
- Patients with other situations not applicable for enhanced exams
- Patients with situations requiring the use of iodine contrast agents with caution
- Patients with mild adverse effects of iodine contrast agents in past exams
- Patients with allergic diseases requiring medical treatment, especially those who have severe allergic reactions to one or more allergens

- Patients with unstable asthmas
- Patients with renal insufficiency
- Patients with severe CVDs (cardiac insufficiency, etc.)

Patients taking the metformin should stop the medicine 48 hours before taking the iodine contrast agent (after taking the iodine contrast agent for emergency patients). Only take the metformin again after taking the iodine contrast agent for 48 hours and confirming that the renal function has not changed compared with before the contrast agent injection. (Perform under the physician's instructions.)

1.5 Side Effects

NOTE:

Operators must read this chapter. CT scans are generally safe, but there are known potential risks and side effects. Operators are responsible for adequately assessing and informing patients before the examination.

The device is generally safe and there are some potential side effects to consider.

The radiation exposure from ionizing radiation, which may slightly increase risk; however, the radiation dose from a single scan is relatively low.

If contrast material is used, some patients may experience mild allergic reactions or temporary side effects including nausea, vomiting, headaches, dizziness, with most reactions resolving on their own.

1.6 Compliance

➤ **Applicable regulations and standards:**

The Quantum CT Q560a scanner complies with the requirements of the following regulations and standards:

- Applicable national standard (GB) and Pharmaceutical Industry Standard (YY) of the People's Republic of China
- Applicable IEC standards

The details are as follows:

The Quantum CT Q560a scanner complies with the requirements of the applicable parts of IEC 60601-1.

The Quantum CT Q560a scanner complies with the requirements of the applicable parts of IEC 60601-1-3.

The Quantum CT Q560a scanner complies with the requirements of the applicable parts of IEC 60601-2-44.

The laser alignment lights of the Quantum CT Q560a scanner comply with the requirements of the applicable parts of IEC 60825-1.

The Quantum CT Q560a scanner complies with the requirements of the applicable parts of IEC 60601-1-1.

All parts of the Quantum CT Q560a scanner are applicable to the patient environment.

The Quantum CT Q560a scanner only can be used with the equipment approved by QuantumTec.

The Quantum CT Q560a scanner complies with the requirements of IEC 60601-1-2.

The Quantum CT Q560a scanner complies with the requirements of IEC 60601-2-28.

The following parts of this chapter describe the detailed EMC information.

The Quantum CT Q560a X-ray Equipment for Computed Tomography has special indications for Electromagnetic Compatibility (EMC), and the EMC information for installation and use instructions are included in this manual. Portable and mobile RF communication equipment may affect the use of the Quantum CT Q560a X-ray Equipment for Computed Tomography.

➤ **Installation requirements and environment control:**

To reduce the interference risks, follow the requirements below:

- **Cable shielding and earthing**

All interconnection cables to the peripherals should be shielded and earthed properly. If the cable shielded and earthed improperly is used, the RF interference of the equipment may occur.

- **The product complies with the radiation regulated in CISPR11 Group 1 Class A.**

The Quantum CT Q560a X-ray Equipment for Computed Tomography is mainly used for non-domestic purposes, and it cannot be connected to a public power supply network directly. The Quantum CT Q560a X-ray Equipment for Computed Tomography is mainly used in the private power supply system (for example, in the hospital) and in a room with X-ray shielding. If it is for domestic use (for example, used in the physician's office), an X-ray-shielded room with a separated AC power distribution board and circuits is recommended to avoid interferences.

- **Power distribution for subsystems and accessories**

All assemblies and subsystem accessories electrically connected to the Quantum CT Q560a X-ray Equipment for Computed Tomography and all AC power supplies for the system should share the same power distribution board and power supply circuit.

- **Stacking the assemblies and the equipment**

 **Warning: DO NOT use the Quantum CT Q560a X-ray Equipment for Computed Tomography adjacent to or stack it with other equipment, and if adjacent or stacked use is necessary, observe the equipment to verify normal operations in the configuration in which it will be used.**

- **Low-frequency magnetic field**

Keep the gantry (digital detector) of the Quantum CT Q560a X-ray Equipment for Computed Tomography one meter away from the generator room and from the analog monitor (CRT). The distance can lower the interference risk of the low-frequency magnetic field as much as possible.

- **Limits of static magnetic field**

The limits of static magnetic field for the surroundings are specified to avoid interferences to the Quantum CT Q560a X-ray Equipment for Computed Tomography. The limits of the static magnetic field for the scan room and the control area should be less than 1 Gauss, and the static magnetic field in the technical room should be less than 3 Gauss.

- **ESD environment and advice**

To reduce the ESD interference, install the charge dissipation floor to avoid static charge accumulation. The relative humidity should be at least 30%. Connect the dissipation material to the system earthing reference points, if applicable.

1.7 Electromagnetic Compatibility (EMC)

The Quantum CT Q560a X-ray Equipment for Computed Tomography complies with the relevant international and national laws and the EMC requirements applicable for such equipment. These laws and regulations specify the electromagnetic radiation level allowed by the equipment and the capacity of the equipment to resist external electromagnetic interferences.

According to the risk and clinical application analysis, the basic performance of the Quantum CT Q560a X-ray Equipment for Computed Tomography includes normal work of the system, free of image artifacts, unchanged set operation parameters, normal output of X-ray, normal mechanical motions of the gantry and patient table, free of unexpected motions, normal indications of laser alignment lights, and normal output and display of images. For the EMC, when the CT system is used in the electromagnetic environment regulated in Table 1, Table 2, Table 3, and Table 4, it functions normally. The patient scan can be finished and CT images for diagnosis can be acquired. The image quality meets the above basic requirements. If it is used in an electromagnetic environment that failed to meet the regulations, the CT system may function abnormally, and the image quality may be degraded, resulting in misdiagnosis and excessive radiation to the patient.

Note:

1. Customers and users of the Quantum CT Q560a X-ray Equipment for Computed Tomography should use it in the electromagnetic environment regulated in Table 1, Table 2, Table 3, and Table 4. Otherwise, the equipment may function abnormally.

2. Portable and mobile RF communication equipment may affect the normal use of the Quantum CT Q560a X-ray Equipment for Computed Tomography. Use the equipment in the recommended electromagnetic environment.

3. NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

 Warning:

1. WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of Quantum CT Q560a could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

2. Stay away from the radio-frequency shielding rooms of active high-frequency surgical equipment and systems used for magnetic resonance imaging in hospitals, where the intensity of electromagnetic interference is high.

3. WARNING: The Operator should not use the system and should inform the customer service, if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES.

4. WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Quantum CT Q560a, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

5. WARNING: The HDMI connection cable of the monitor must be separated from other shielded cables (such as Scanbox cables) to reduce the possibility of electrostatic discharge near the metal or shielded layer, which may cause flash or black screen for a short time.

2、 Important Safety Precautions

All products designed by KuanTeng comply with the corresponding international and national safety standards. However, all medical electrical devices require proper operations and maintenance, thus ensuring the personal and property safety of users, operators, and patients. Therefore, it is vital that you read, remember, and strictly observe all **Danger** notices and all safety precautions on the Quantum CT Q560a scanner.

 **Warning:** If failed to follow the safety scan protocols and operation instructions, the X-ray unit may cause use injury to the patient and operator.

 **Warning:** Before using the Quantum CT Q560a scanner, ensure that the requirements of “Image Performance Quality Assurance” have been satisfactorily completed and that the “Preventative Maintenance Program” is up to date. If any part of the system is known (or suspected) to be operating improperly, DO NOT use it until a repair has been made.

 **Warning:** Improper operation of the equipment or wrong adjustment of components could cause personal injury to the operator or the patient. This could lead to fatal or other serious personal injuries.

 **Warning:** Before scanning the patient with the equipment, any activity related to equipment maintenance is prohibited.

 **Warning:** The product is not intended for use in any liquid. No liquid is required for the normal use of the system.

 **Warning:** DO NOT use the CT system until you have read, understood, and been familiar with all safety information in the “Safety” section and the safety and emergency procedures. Operation of this equipment without understanding the safety use of the CT system could lead to fatal or other serious personal injuries.

⚠ Warning: DO NOT use the CT system until you have received professional training in its safe and effective operation. If you are unsure of your ability to operate this equipment safely and effectively, DO NOT use it. Operation of this equipment without professional training could lead to fatal or other serious personal injuries. It could also lead to clinical misdiagnosis.

⚠ Warning: Never attempt to remove, modify, use, or forcibly move any safety device on the equipment. Operating the safety devices casually may cause fatal or other serious personal injuries.

⚠ Warning: DO NOT use the Quantum CT Q560a scanner for any purpose other than its intended use. Operating the Quantum CT Q560a scanner for any unintended purposes or with incompatible equipment may cause fatal or other serious injuries. It could also lead to clinical misdiagnosis.

⚠ Warning: Make sure that the motion of the patient table is in the direction that will ensure that the patient can be easily released and will not get pressed against the gantry cover.

⚠ Warning: DO NOT remove housings or cables from this equipment. High electrical voltages are present within this equipment. Removing housings or cables may cause serious or fatal personal injuries.

⚠ Warning: To avoid electric shock, the equipment should be connected to the supply mains with protective grounding to avoid electric shock.

⚠ Warning: Strictly follow the shutdown process to shut down the system. Ensure the power supply stability and avoid abnormal power-down events (except in an emergency). DO NOT power off the system forcibly. Otherwise, the system may be damaged.

⚠ Warning: DO NOT remove housings from this equipment. Otherwise, serious or fatal personal injuries may be caused. Only qualified or authorized maintenance personnel can disassemble housings with tools.

⚠ Warning: Flammable or potentially explosive disinfecting sprays should not be used, since the resultant vapor could ignite, causing fatal or other serious personal injuries and/or damage to equipment.

⚠ Warning: Only use extinguishers on electrical or chemical fires that are specifically labeled for those purposes. Using water or other liquids on an electrical fire could cause fatal or other serious personal injuries.

⚠ Warning: Improper use of the X-ray equipment may cause personal injuries. Carefully read and understand the instructions in this manual before the operation. If failed to observe the X-ray operation safety or the advice in this manual is ignored, users or patients may be exposed to harmful X-rays.

⚠ Warning: Each one related to the operations of the scanner should take appropriate measures to gain adequate protection to avoid being harmed.

⚠ Warning: When scanning a patient, no unauthorized personnel is allowed to stay in the scan room. Warn the visitor and patient that violation of relevant instructions may cause injuries.

⚠ Warning: DO NOT perform the daily calibration and testing of the CT scanner or warm up the X-ray tube when the patient or operator is in the scan room.

⚠ Warning: The radiation caused during the CT scan may cause interference with some implanted and externally worn electronic medical devices, such as pacemakers, defibrillators, neurostimulators, and drug infusion pumps. Such

interference could cause malfunctions in the electronic medical devices. Warn the visitor and patient that violation of relevant instructions may cause injuries.

⚠ Warning: The laser beam could cause injury to the eyes. Instruct the patient to close their eyes when turning on laser alignment lights and open their eyes again after the lights are turned off. Using optical instruments, such as eyeglasses with large diopters or mirrors, with the lights will increase eye hazards.

⚠ Warning: DO NOT throw the X-ray tube assembly into industrial or household waste.

⚠ Warning: DO NOT deliver the damaged X-ray tube assembly through national postal services.

⚠ Warning: Before using the equipment, the operator should accept enough training for safe, effective, and skilled operations.

⚠ Warning: Before the contrast examination, the operator should carefully ask the patients about their allergies. Choose other examination methods for those with allergies. If any severe adverse reaction happens during the examination, stop scanning immediately.

⚠ Warning: Failure to report an incident may result in continued risk and affect the safety of others. The manufacturer will analyze the incident and update the product risk information.

For specific warning information, please refer to the attached IFU.

3、 System Performance

1. Image noise

- a) Adult head: not exceed 0.35% (The central dose does not exceed 40 mGy);
- b) Adult body: not exceed 0.35% (The central dose does not exceed 20 mGy);
- C) Children's head: not exceed 0.35% (The central dose does not exceed 13 mGy);
- d) Children's body: not exceed 0.35% (The central dose does not exceed 15 mGy).

2. CT number uniformity

- a) Head: The CT number uniformity of water is ± 4 HU (adult or children's heads);
- b) Body: The CT number uniformity of water is ± 4 HU (adult or children's bodies).

3. CT number accuracy

- a) Head: Air: -1000 ± 10 HU; Water: 0 ± 4 HU (adult or children's heads);
- b) Body: Air: -1000 ± 10 HU; Water: 0 ± 4 HU (adult or children's bodies).

4. CT number linearity

Table 1 CT Numbers and Deviations of Four Materials

Material	Acrylic	Air	Teflon	LDPE
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Standard CT number	120	-1000	950	-100
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Conformity judgment: Taking the intermediate slice of the CT image, and the maximum deviation for the CT numbers of four materials should be less than 50 HU.

5. Spatial resolution

a) Spatial resolution on the X-Y plane:

Spatial resolutions under the typical head condition (central dose ≤ 40 mGy) and the typical body condition (central dose ≤ 20 mGy):

≥ 6.5 lp/cm (10% MTF); ≥ 4.0 lp/cm (50% MTF)

b) Maximum resolution mode:

≥ 13.0 lp/cm (10% MTF); ≥ 8.5 lp/cm (50% MTF)

c) Spatial resolution in the Z-axis:

≥ 11.0 lp/cm (10% MTF); ≥ 7.1 lp/cm (50% MTF)

6. Low contrast resolution

Typical conditions (The head central dose does not exceed 40 mGy, and the body central dose does not exceed 20 mGy): At a contrast level of 0.3%, objects with a diameter of at least 3 mm can be resolved.

The highest low contrast resolution under the rational dose

Adult body:

5 mm @ $\leq 0.3\%$ (The central dose does not exceed 15 mGy.)

7. Running noise

The operating noise is not more than 70 dB (A) at a one-meter distance from the gantry surface.

8. Artifacts

There should be no artifacts in CT images.

9. Section thickness

a) Section thickness parameters (helical scan mode): 0.625 mm, 1.25 mm, 2.5 mm, 5 mm, 10 mm;

b) Section thickness parameters (axial and cine scan modes): 0.625 mm, 1.25 mm, 2.5 mm, 5 mm, 10 mm

c) The error should not exceed the following requirements:

The thickness of the nominal slice larger than 2 mm: ± 1 mm;

The thickness of the nominal slice larger than or equal to 1 mm but smaller than or equal to 2 mm: $\pm 50\%$;

The thickness of the nominal slice smaller than 1 mm: ± 0.5 mm.

10. Image reconstruction speed

The reconstruction speed for routine helical scan images should not be less than 64 frames per second.

11. Image scan slices

Maximum scan slices obtained by single axial scan, when the X-ray source assembly rotates 360°:

- a) Configuration 1: 32-row 32-slice;
- b) Configuration 2: 32-row 64-slice.

12. Helical scan

- a) Pitch factor supported by helical scan: 0.5, 0.75, 1.0, 1.25, 1.5, 1.75;
- b) The maximum continuous helical scan time is 100s;
- c) The longest continuous helical scan distance should not be less than 1500 mm.

13. Gantry performance

- a) The gantry bore diameter is 80 cm, error: ± 1 cm;
- b) Accuracy of the laser alignment lights: with the alignment lights for transverse, sagittal, and coronal planes; When the nominal tomographic section thickness is narrowest, the consistency between the laser beam center and the tomographic section center should be within 2 mm.
- c) Scout image scan function: The X-ray tube assembly performs a scout image scan for the Posterior images, Lateral images, and PosteriorLateral images from the locations of 0°, 90°, 180° and 270° respectively;

d) Rotating speed: The deviation of each of the following levels should not exceed $\pm 5\%$;

The levels of the gantry rotating speed (r/s) are 2.0, 1.5, 1, 0.9, 0.8, and 0.75.

14. Patient table performance

a) Vertical movement range: The adjustment range in the vertical direction is larger than half of the diameter of the gantry collimator coverage.

b) Horizontal movement range: no less than 1750 mm

c) Stepping error: not exceed ± 0.25 mm.

d) Patient table positioning: The vertical position deviation does not exceed ± 1 mm, and the return difference does not exceed ± 1 mm.

e) Max. table bearing capacity: 205 kg.

f) Abnormal status Stop range: not exceed 10mm.

15. Voltage accuracy of X-ray tube

a) X-ray tube voltage: five selectable levels, including 70 kV, 80 kV, 100 kV, 120 kV, and 140 kV.

b) The error does not exceed $\pm 10\%$.

16. Current accuracy of X-ray tube

a) The current adjustment range of the X-ray tube should comply with:

kV	mA	
	SF (small focal spot)	LF (large focal spot)
140	10 - 200	200 - 300
120	10 - 240	240 - 350
100	10 - 290	290 - 350
80	10 - 310	310 - 350
70	10 - 290	290 - 350

b) The error of each level does not exceed $\pm 20\%$, 5 mA interval adjustment.

17. Exposure time

a) The accuracy deviation of exposure time should not exceed $\pm 10\%$.

b) Axial scan: The scan time for each slice is 0.75s, 0.8s, 0.9s, 1.0s, 1.5s, and 2.0s respectively;

c) Cine scan: The longest single continuous exposure time is 100s.

d) Helical scan: The longest single continuous exposure time is 100s.

18. Current time product

The current time product is the product of the mA value of the X-ray tube and the exposure time, unit: mAs. Its regulation ranges from 4.29 mAs to 1400 mAs, and the regulation range has several levels with an error not exceeding $\pm 20\%$ for each.