

Product Safety and Performance Information

1 Product Description

1.1 Product name and model

Product name: Computed tomographs

Product model: TurboTom 5 PRO

1.2 Basic UDI-DI

693896432600P2

1.3 Intended Purpose

This system is used for routine clinical CT examination, and coronary artery examination.

1.4 Indications for use

This Computed Tomographs is intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.

The images delivered by the system can be used by trained staff as an aid in diagnosis, treatment preparation and radiation therapy planning.

This CT system can be used for low dose lung cancer screening in high risk populations.

1.5 Contraindications:

Contra-indications: not found yet. When performing enhancement for patients, the contraindications of contrast agents need to be considered, such as those allergic to iodine-based contrast agents; those with severe liver or kidney dysfunction; and those with significant arrhythmia, valvular insufficiency, or an implanted cardiac pacemakers.

1.6 Intended user

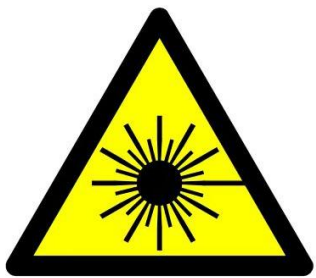
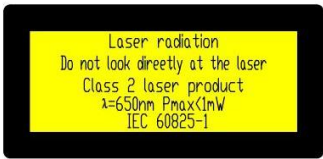


The intended users of this system are radiologists and radiology technologists of the medical institutions, users must pass Wandong Medical's clinical use training for the product.




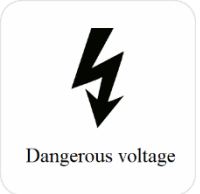

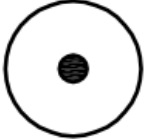
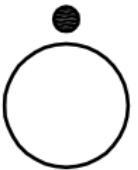


1.8 Intended Patient Population




The system is suitable for adults and children. The intended patient population of this system: patients with weight less than 210kg.

2 Product Safety Information


2.1 Product label Safety Information


Mark	Position	Specification
 	Gantry	Beware of laser marking
	Gantry	Identification of ionizing radiation
	Gantry and couch	Beware of hurt hand signs


	<p>Gantry and couch</p>	<p>Beware of mechanical injury signs</p>
	<p>Computer cabinet</p>	<p>Environmental label</p>
	<p>System nameplate</p>	<p>Indicates that the electrical safety type of the X-ray machine is type B</p>
 <p>Dangerous voltage</p>	<p>Gantry</p>	<p>Dangerous voltage identification</p>
	<p>Couch</p>	<p>No trampling</p>
	<p>Computer cabinet</p>	<p>Keys on CT devices</p>
	<p>Computer cabinet</p>	<p>CT device power off key</p>
	<p>Scram switch</p>	<p>Scram switch</p>
	<p>Computer cabinets, power cabinets, and couch</p>	<p>Follow the instructions</p>


	Gantry	Note radiation hazard mark
	OneDock display	Non-ionizing electromagnetic radiation identification
	Gantry	Protective earthing mark protective earthing mark

2.2 Electrical safety


	<p>Warning</p> <p>To avoid electric shock hazard, the equipment must be connected to the supply network with protective grounding.</p>
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	<p>Warning</p> <p>To ensure the safety of the equipment, electrical safety tests must be conducted in accordance with local safety regulations or as required.</p>
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	<p>Be careful</p> <p>The power supply of the console computer should be connected from the power cabinet, not from other sockets.</p>
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	<p>Danger</p> <p>Hazardous voltages are generated within the system, prohibiting contact with these voltages and internal components. To avoid the danger of electric shock, always disconnect the power supply before repairing the equipment.</p>
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	<p>Do not open the shell of the equipment and touch any parts in the system to avoid the risk of electric shock.</p>
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	<p>Warning</p> <p>Do not allow any liquid to penetrate into the equipment. The liquid seeping into the electrical circuit may enlarge the leakage flow or cause damage to the equipment.</p>
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	<p>Warning</p> <p>The equipment shall not be "forced" with any electrical or mechanical failure, and shall not be used under the removal of the protective circuits and protective facilities of the equipment.</p>
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	<p>Warning</p> <p>Other additional removable porous sockets or extension wires should not be connected to the device. The access of electrical equipment to the equipment may exceed the rated power supply, causing power failure or other serious equipment failure.</p>
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	<p>Warning</p> <p>When the equipment needs to be connected electrically or mechanically to any other manufacturer, please contact the manufacturer to confirm its rationality. The manufacturer shall not be liable for any personal injury or equipment damage caused by the connection of the equipment to other equipment without the manufacturer's consent of the manufacturer.</p>
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2.3 Mechanical safety

**Warning**

Remove any irrelevant objects within the movement range of the device before the inspection starts. Carefully before operation to ensure that there is no interference or collision between \

the patient and other devices. Please confirm that the patient lies safely or sideways during the examination. Red [Emergency Stop] button: In case of an emergency, press the gantry and the patient couch to stop moving, and the X-ray emission will also stop.

2.4 Radiation Protection

	<p>Warning</p> <p>Ensure that all necessary precautions are taken before each X-ray exposure.</p>
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The actual design of any equipment cannot provide complete protection; similarly, for any equipment, even if the operator takes adequate precautions in advance, it cannot avoid the possibility that someone will leak himself or others under the X-ray due to human negligence, ignorance or unintentionally. Therefore, all operators and maintenance personnel authorized to use, install, inspect and maintain the equipment shall be aware of the hazards of excessive exposure to X-ray radiation exposure, receive adequate training and have the required relevant knowledge. The equipment descripticouch in this manual states that the manufacturer, agent and their sales representative are not liable for any injury or damage arising from exposure to X-ray radiation.

Since X-rays are harmful to health, many measures need to be taken to prevent direct X-rays. Some X-ray effects are cumulative effects and can lie dormant for months or even years. For operators, the safest principle is to "avoid direct X-rays at all times".

Any object in the X-ray path produces secondary (scattered) rays, and the intensity of the secondary ray depends on the energy and intensity of the initial ray, and the atomic number of the object on which the ray shines. The intensity of the secondary rays may be stronger than those reaching the film. Measures should be taken to prevent secondary rays.

The X-ray radiation protection measures must be taken:

time protection

The longer the exposure, the greater the cumulative absorcouch dose of the individual. Therefore, the time of exposure should be shortened as far as possible, and all personnel should reduce the time of stay in the X-ray place as much as possible. Workers engaged in X-ray, exposure conditions to optimize exposure to avoid repeated exposure.


distance protection

The amount of X-ray exposure is inversely proportional to the square of the distance. The distance between the person and the X-ray source (focus) is doubled and the exposure is reduced

to a quarter of the original. Therefore, during exposure, all personnel (except the subject) should be kept as far away from the X-ray source as possible; the distance from the focus to the skin should be increased as far as possible while meeting the image quality requirements.

shielding protection

In the X-ray diagnosis or treatment, the time protection and distance protection should be restricted to some extent, and the more effective measure is to adopt shielding protection. Lead shielding is an effective method. To reduce radiation, you can use: lead screen, lead rubber gloves, lead rubber apron, lead glasses, lead protective chair, lead protective car. X-ray protective walls can also be used to reduce radiation.

	<p>Note</p> <p>Do not expose your handles, wrists, arms, or other body parts to direct X-rays while operating or repairing X-ray equipment.</p>
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In the practical work, the following points should also be paid attention to:

When exposing, adjust the irradiation field strictly according to the required irradiation site, and use a reasonable small irradiation field as far as possible. Take appropriate protective measures at the non-irradiated site of the subject.

When the irradiation area is close to the reproductive organs, minimize the radiation damage to the patient, and let the patient wear a lead rubber apron (genital cover or lead rubber cover).

During exposure, people near the patient must wear protective clothing (e. g. lead rubber apron).

Tell the patient in detail to keep breathing as much as possible during the scan and follow the instructions.

3 Product Performance Metrics

➤ Image noise:

Typical adult head: $\leq 0.35\%$

Typical adult body: $\leq 0.35\%$

Typical child head: $\leq 0.35\%$

Typical child body: $\leq 0.35\%$

➤ Uniformity of CT value:

Under typical operating conditions, the uniformity of the CT value of water should not exceed $\pm 4\text{HU}$.

➤ Accuracy of CT value:

Typical operating conditions: air: $-1000\text{HU} \pm 10\text{HU}$, water: $0\text{HU} \pm 4\text{HU}$.

➤ Linearity of CT value

Air: $-1000\text{HU} \pm 50\text{HU}$

Polymethyl methacrylate: $120\text{HU} \pm 50\text{HU}$

Low density polyethylene: $-100\text{HU} \pm 50\text{HU}$

Teflon: $990\text{HU} \pm 50\text{HU}$

➤ Spatial resolution (high contrast resolution)

Optimal resolution reconstruction mode CT image spatial resolution:

X-Y plane, $21.0 \text{ lp/cm} @ 0\% \text{ MTF}$, $17.5 \text{ lp/cm} @ 10\% \text{ MTF}$, $11.0 \text{ lp/cm} @ 50\% \text{ MTF}$

Z-axis direction, $13.0 \text{ lp/cm} @ 0\% \text{ MTF}$, $11.0 \text{ lp/cm} @ 10\% \text{ MTF}$, $5.5 \text{ lp/cm} @ 50\% \text{ MTF}$

The spatial resolution of typical scanning conditions is:

X-Y plane, $8.5 \text{ lp/cm} @ 0\% \text{ MTF}$, $6.5 \text{ lp/cm} @ 10\% \text{ MTF}$, $4.0 \text{ lp/cm} @ 50\% \text{ MTF}$

➤ Low contrast resolution

Highest low contrast resolution mode:

Under 0.3% contrast conditions, a 2mm circular aperture should be able to be distinguished (with a central dose not exceeding 40mGy).

General low contrast resolution mode:

Adult head and body: Under 0.3% contrast conditions, it should be able to distinguish at least 3mm circular holes (with a central dose not exceeding 35mGy).

Children's head and body should be able to distinguish at least 4mm circular holes (with a central dose not exceeding 25mGy) under a 0.3% contrast ratio.

➤ Artifact

There should be no artifacts in the CT image.

➤ Slice thickness

a) Axial

1) The nominal thickness of body layer slices is: 0.5mm, 0.625mm, 1.0mm, 1.25mm, 2.0mm, 2.5mm, 3.0mm, 4.0mm, 5.0mm and 10.0mm.

2) The deviation between the measured and nominal values of body layer slice thickness is: 0.5mm±0.5mm, 0.625mm±0.5mm, 1.0mm±0.5mm, 1.25mm±0.625mm, 2.0mm±1.0mm, 2.5mm±1.0mm, 3.0mm±1.0mm, 4.0mm±1.0mm, 5.0mm±1.0mm and 10.0mm±1.0mm.

b) Helical

1) The nominal thickness of body layer slices is: 0.5mm, 0.625mm, 1.0mm, 2.0mm, 3.0mm, 4.0mm, 5.0mm, 10.0mm

2) The deviation between the measured and nominal values of body layer slice thickness is: 0.5mm±0.5mm, 0.625mm±0.5mm, 1.0mm±0.5mm, 2.0mm±1.0mm, 3.0mm±1.0mm, 4.0mm±1.0mm, 5.0mm±1.0mm, 10.0mm±1.0mm.

➤ Output Normal electric power: 80kW

➤ Tube voltage range: 70kV, 80kV, 100kV, 120kV, 140kV

➤ Tube current range: 5~667mA

➤ Loading time: 0.349s~120s

➤ Scan length: ≥ 1620 mm

STATEMENT TO USERS

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