# Product Safety and Performance Information

## 1 Product Description

### 1.1 Product name and model

Product name: Computed tomographs

Product model: TurboTom 3、TurboTom 2400 PRO、TurboTom 3 S PLUS、TurboTom 1 S PLUS、TurboTom 1 S PRO、TurboTom 5 S PLUS、TurboTom 5 PLUS

### 1.2 Basic UDI-DI

| Basic UDI-DI | UDI-DI | Product Model |
|---|---|---|
| 693896431900PA | 06938964319040 | TurboTom 3 |
| 693896431900PA | 06938964319248 | TurboTom 2400 PRO |
| 693896431900PA | 06938964319088 | TurboTom 3 S PLUS |
| 693896431900PA | 0693896431908 | TurboTom 1 S PLUS |
| 693896431900PA | 06938964319279 | TurboTom 1 S PRO |
| 693896431900PA | 06938964319187 | TurboTom 5 S PLUS |
| 693896431900PA | 06938964319156 | TurboTom 5 PLUS |

### 1.3 Intended Purpose

This system is used for routine clinical CT examination, not for 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 a trained physician as an aid in diagnosis. 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.

Due to the inherent hazards of X-ray radiation caused by medical X-ray diagnosis, pregnant women and infants should be cautious in using this device. It is strictly prohibited for the same patient to use this device multiple times for a long time. Not used for coronary artery examination.

## 1.6 Intended user

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

## 1.8 Intended Patient Population

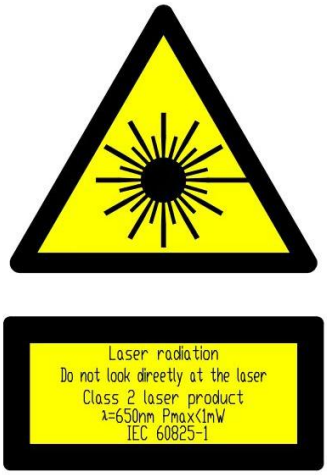
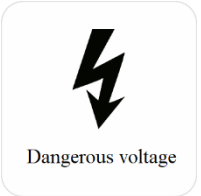
The system is suitable for adults and children. The intended patient population of this system: patients with weight less than 210kg.

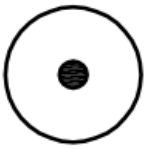
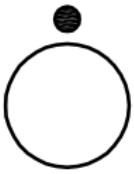
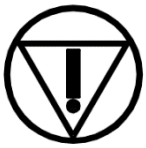
This product is to provide axial scan and spiral scan images during diagnostic procedure. Examples of a clinical application may include: diagnose disease, trauma or abnormality and monitor the effectiveness of therapy (e.g. cancer treatment).

# 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 |
|  | Gantry and couch | Beware of mechanical injury signs |
|  | Computer cabinet | Environmental label |
|  | System nameplate | Indicates that the electrical safety type of the X-ray machine is type B |
|  | Gantry | Dangerous voltage identification |

| | | |
|---|---|---|
|  | Couch | No trampling |
|  | Computer cabinet | Keys on CT devices |
|  | Computer cabinet | CT device power off key |
|  | Scram switch | Scram switch |
|  | Computer cabinets, power cabinets, and couch | Follow the instructions |
|  | Gantry | Note radiation hazard mark |
|  | OneDock display | Non-ionizing electromagnetic radiation identification |
|  | Gantry | Protective earthing mark protective earthing mark |

## 2.2 Electrical safety

| | |
|---|---|
|  | **Warning** |

| | |
|---|---|
| | To avoid electric shock hazard, the equipment must be connected to the supply network with protective grounding. |

| | |
|---|---|
|  | **Warning**<br>To ensure the safety of the equipment, electrical safety tests must be conducted in accordance with local safety regulations or as required. |

| | |
|---|---|
|  | **Be careful**<br>The power supply of the console computer should be connected from the power cabinet, not from other sockets. |

| | |
|---|---|
|  | **Danger**<br>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. Do not open the shell of the equipment and touch any parts in the system to avoid the risk of electric shock. |

| | |
|---|---|
|  | **Warning**<br>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. |

| | |
|---|---|
|  | **Warning**<br>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. |

| | |
|---|---|
|  | **Warning**<br>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. |

| | |
|---|---|
|  | **Warning**<br>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. |

## 2.3 Mechanical safety

| | |
|---|---|
|  | **Warning**<br>Remove any irrelevant objects within the movement range of the device before the inspection starts. C0arefully carefully before operation to ensure that there is no interference or collision between \<br>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

**Warning**

Ensure that all necessary precautions are taken before each X-ray exposure.

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 descricouch 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.

| | |
|---|---|
|  | **Note**<br><br>Do not expose your handles, wrists, arms, or other body parts to direct X-rays while operating or repairing X-ray equipment. |

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

| performance | parameters |
|---|---|
| Image noise | ≤0.35% |
| Uniformity of CT number | Not more than ±4HU |
| Accuracy of CT number | Air：-1000HU±10HU, Water：0HU±4HU |

| | |
|---|---|
| Linearity of CT number | Air：-1000HU±50HU<br>Polymethyl methacrylate：120HU±50HU<br>low density polyethylene：-100HU±50HU<br>Teflon：990HU±50HU |
| Spatial resolution | **TurboTom 3/3 S PLUS:**<br>X-Y plane， 18.0±10%lp/cm@0%MTF， 14.5±10%lp/cm @10%MTF，8.5±10%lp/cm @50%MTF<br>Z-axis direction， 13.0±10%lp/cm@0%MTF， 10.0±10%lp/cm@10%MTF，5.5±10%lp/cm@50%MTF<br>**TurboTom 2400 PRO:**<br>High spatial resolution mode:<br>18.0 lp/ cm@0 %MTF， 14.5lp/cm @10%MTF， 8.5lp/cm @50%MTF<br>General spatial resolution mode:<br>8.5 lp/ cm@0 %MTF， 6.5lp/cm @10%MTF， 4.0lp/cm @50%MTF<br>**TurboTom 1 S PLUS/1 S PRO:**<br>X-Y plane，15.0 ± 10%lp/cm@0%MTF，14.5 ± 10%lp/cm @10%MTF，8.5 ± 10%lp/cm @50%MTF<br>**TurboTom 5 S PLUS/5 PLUS:**<br>X-Y plane， 21.0±10%lp/cm@0%MTF， 17.5±10%lp/cm @10%MTF，11.0±10%lp/cm @50%MTF<br>Z-axis direction， 13.0±10%lp/cm@0%MTF， 11.0±10%lp/cm@10%MTF，5.5±10%lp/cm@50%MTF |
| Low contrast resolution | Highest low contrast resolution mode: |

| | |
|---|---|
| | At a 0.3% contrast ratio, it should be able to distinguish a circular aperture of 2mm (with a central dose not greater than 40mGy).<br>General low contrast resolution mode:<br>Adult head and body: Under 0.3% contrast, it should be able to distinguish at least 3mm round holes (central dose not greater than 35mGy).<br>Children's head and body: Under 0.3% contrast, they should be able to distinguish at least 4mm round holes (central dose not greater than 25mGy). |
| Operating noise | Not more than 70dB(A) |
| Artifact | There should be no artifacts in the CT image |
| Body slice thickness | **TurboTom 3/3 S PLUS:**<br>Axial<br>The nominal body slice thickness is: 0.625mm, 1.0mm, 1.25mm, 2.0mm, 2.5mm, 3.0mm, 4.0mm, 5.0mm and 10.0mm<br>The deviation between the measured value and the nominal value of the body slice thickness is： 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.<br>Helical<br>The deviation between the measured value and the nominal value of the body slice thickness is: 0.625mm, 1.0mm, 2.0mm, 3.0mm, 4.0mm, 5.0mm, 10.0mm.<br>The deviation between the measured value and the nominal value of the body slice thickness is： 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. |

| | |
|---|---|
| | **TurboTom 2400 PRO:**<br>Axial<br>The nominal body slice thickness is: 0.5mm，1.0mm，2.0mm、4.0mm, 8.0mm and 16.0mm.<br>The deviation between the measured value and the nominal value of the body slice thickness is: 0.5mm±0.5mm, 1.0mm±0.5mm, 2.0mm±1.0mm, 4.0mm±1.0mm, 8.0mm±1.0mm and 16.0mm±1.0mm.<br>Helical<br>The deviation between the measured value and the nominal value of the body slice thickness is: 0.5mm,1.0mm,2.0mm, 4.0mm, 8.0mm and 16.0mm.<br>The deviation between the measured value and the nominal value of the body slice thickness is： 0.5mm±0.5mm, 1.0mm±0.5mm, 2.0mm±1.0mm, 4.0mm±1.0mm, 8.0mm±1.0mm and 16.0mm±1.0mm.<br>**TurboTom 1 S PLUS/1 S PRO:**<br>Axial<br>The nominal body slice thickness is: 0.6mm, 1.2mm, 2.4mm, 4.8mm, 9.6mm and 19.2mm.<br>The deviation between the measured value and the nominal value of the body slice thickness is: 0.6mm±0.5mm, 1.2mm±0.5mm,2.4mm±1.0mm,4.8mm±1.0mm,9.6mm±1.0mm and 19.2mm±1.0mm.<br>Helical<br>The deviation between the measured value and the nominal value of the body slice thickness is: 0.6mm, 1.2mm, 2.4mm, 4.8mm, 9.6mm and 19.2mm.<br>The deviation between the measured value and the nominal value of the body slice thickness is: 0.6mm±0.5mm, |

| | |
|---|---|
| | 1.2mm±0.5mm,2.4mm±1.0mm,4.8mm±1.0mm,9.6mm±1.0mm and 19.2mm±1.0mm.<br>**TurboTom 5 S PLUS/5 PLUS:**<br>Axial<br>The nominal body slice thickness is: 0.5mm, 0.625mm, 1.0mm, 1.25mm, 2.0mm, 2.5mm, 3.0mm, 4.0mm, 5.0mm and 10.0mm.<br>The deviation between the measured value and the nominal value of the body 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.<br>Helical<br>The deviation between the measured value and the nominal value of the body slice thickness is: 0.5mm, 0.625mm, 1.0mm, 2.0mm, 3.0mm, 4.0mm, 5.0mm, 10.0mm.<br>The deviation between the measured value and the nominal value of the body 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. |
| Image reconstruction speed | **TurboTom 3/2400 PRO/3 S PLUS:**<br>Not less than 40 images/s<br>**TurboTom 1 S PLUS/1 S PRO:**<br>Not less than 20 images/s<br>**TurboTom 5 S PLUS/5 PLUS:**<br>Not less than 60 images/s |
| Pitch coefficient | **TurboTom 3/2400 PRO/3 S PLUS/1 S PLUS/1 S PRO:**<br>The minimum value is not greater than 0.15, and the maximum value is not less than 1.5 |

| | |
|---|---|
| | **TurboTom 5 S PLUS/5 PLUS:**<br>The minimum value is not greater than 0.15, and the maximum value is not less than 2 |
| Rotary speed | **TurboTom 3/3 S PLUS/5 S PLUS/5 PLUS:**<br>0.49s/r, 0.75s/r, 1.0s/r, 1.5s/r. The deviation of each gear shall not exceed ± 5%.<br>**TurboTom 2400 PRO/1 S PRO:**<br>0.5s/r, 0.75s/r, 1.0s/r, 1.5s/r. The deviation of each gear shall not exceed ± 5%.<br>**TurboTom 1 S PLUS:**<br>0.75s/r, 1.0s/r, 1.5s/r. The deviation of each gear shall not exceed ± 5%. |
| Maximum patient stent weight | 210kg |
| X-ray tube voltage | **TurboTom 3/2400 PRO/3 S PLUS/1 S PRO/5 S PLUS/5 PLUS:**<br>The X-ray tube voltage is divided into five levels: 70kV, 80kV, 100kV, 120kV, and 140kV. The average error of the X-ray tube voltage is not greater than ± 10%<br>**TurboTom 1 S PLUS:**<br>The X-ray tube voltage is divided into five levels: 70kV, 80kV, 100kV, 120kV, and 135kV. The average error of the X-ray tube voltage is not greater than ± 10%. |
| X-ray tube current | **TurboTom 3/2400 PRO/3 S PLUS/1 S PRO/5 S PLUS/5 PLUS:**<br>The X-ray tube current is 10 mA to 350 mA, and can be set at 1 mA intervals. The average error of each set value is not greater |

| | |
|---|---|
| | than ± 20%.<br>**TurboTom 1 S PLUS:**<br>The X-ray tube current is 10 mA to 300 mA, and can be set at 1 mA intervals. The average error of each set value is not greater than ± 20%. |
| Measurement function | The measurement error of 2-dimensional image length and angle is ± 5%<br>The measurement error of 3D image length and angle is ± 5% |

# STATEMENT TO USERS

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