Multi-slice CT Scanner System
NeuViz Prime
User Manual (Vol. 1)

CE 0123

NEUSOFT MEDICAL SYSTEMS CO., LTD.

Neusoft Medical Systems

About This Manual

1. About the Manual

This manual is a user manual for NeuViz Prime CT.

This manual describes the function, safety and use of NeuViz Prime CT. Users must read all chapters carefully before use.

Neusoft Medical Systems Co., Ltd. is responsible for NeuViz Prime CT system, but not responsible for unauthorized usage.

Revision Version: G

Software Version: 1

2.How to Use this Manual

The user must read the manual carefully, especially the chapter about safety, to prevent potential loss or harm. All reminders and warnings (bold font) must be read carefully.

In daily operation, it is recommended that the operator refer to this manual.

3.Copyright

4.Revision History

Rev.	Issue Date	Reasons for Change
1.0	2017.04	First Issued
1.1	2017.07	Company address changed
1.2	2017.08	Revised Chapter 12/13
2.0	2017.10	Revised Chapter 3/6/8/11/12/13
2.1	2018.01	1. Update according to IEC 60601-1.3.1. 2. Add Constancy Test. 3. Add the identification of IEC standards and regulations.
2.2	2018.09	1.Software Update 2.Change the pictures of Patient
B	2019.11	Software Update
C	2019.12	Software Update
D	2020.10	Add the copyright statement of the Gantry Display related software
E	2020.12	Software Update
F	2021.07	Add the chapter of SSDE
G	2021.09	Revised Chapter 12/14

5.Executive Standard

This manual is compliance with the "Medical Equipment Specification and label management provisions ".

6.Patent

The patent right of NeuViz Prime products is owned by Neusoft Medical Systems Co. Ltd.

Contents

Chapter 1 About the Manual

1.1 About this Manual

This manual is intended for safe and effective operation of the device described for users and operators. Before attempting to operate the device, this manual must be read thoroughly, with particular attention paid to all WARNINGs, CAUTIONs, and NOTEs incorporated in it. Additionally, special attention must be paid to all the information given and procedures described in the Safety Instruction section.

In this instruction manual, three safety prompts are included, which are WARNING, CAUTION and NOTE. Before this manual is read, the reader must first be fully acquainted with the safety prompts below. The definitions are as follows:

WARNING:

- **This symbol identifies instructions which must be observed in any case to avoid injury to the patient and/or staff.**

CAUTION:

- **This symbol identifies instructions which must be observed in any case to avoid minor injury to the patient and/or to the staff and/or to avoid damaging the device described in this operation manual.**

NOTE:

- **This symbol is used to identify important advice, e.g. To improve an operating sequence or to point out that certain restrictions should be observed.**

The manual was originally drafted, approved and supplied in the Chinese version.

1.2 Intended Use

The NeuViz Prime Multi-Slice CT Scanner System can be used as a whole body computed tomography X-ray system featuring a continuously rotating X-ray tube and detector array. The acquired X-ray transmission data is reconstructed by computer into

cross-sectional images of the body from either the same axial plane taken at different angles or spiral planes taken at different angles.

WARNING:

- **Safety and effectiveness in pregnant women have not been established.**
- **Federal (U.S.) law restricts this device to be sold or ordered by a physician.**

1.3 Contraindication

None Known.

1.4 Compatibility

Equipment described in this manual should not be used in combination with other equipment or components unless such other equipment or components are recognized as compatible.

Changes and/or additions to the equipment should only be carried out by Neusoft Medical Systems or by third parties expressly authorized by Neusoft Medical Systems. Such changes and/or additions must comply with all applicable laws and regulations within the jurisdiction(s) concerned, and with best engineering practice.

Changes and/or additions to the equipment that are carried out by persons without the appropriate training and/or using unapproved spare parts may lead to Neusoft Medical Systems warranty being voided. As with all complex technical equipment, maintenance by persons not appropriately qualified and/or using unapproved spare parts carries serious risks of damage to the equipment and personal injury.

1.5 Serious Incident Reporting

Notice:

- **If you suspect that any serious incident has occurred and the incident is in relation to this device, please report to Neusoft (Tel: 400 690 8528, Email: nms-service@neusoftmedical.com) and report to the competent authority of your local Member State.**

Herein, serious incident, means any incident that directly or indirectly led, might have led or might lead to any of the following:

(a) the death of a patient, user or other person

(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health

(c) a serious public health threat.

1.6 Compliance

CE 0123

This product is in conformity with Essential Requirement of the council directive MDD 93/42/EEC.

X-ray source assembly is in conformity with IEC60601-2-28 /EN 60601-2-28.

NeuViz Prime with radiation protection is in accordance with IEC60601-1-3/EN 60601-1-3, IEC60601-2-44/EN 60601-2-44.

This product is in conformity with EU RoHS directive, 2011/65/EC Restriction of Hazardous Substances.

Table 1-1 IEC60601 Classification

According to the type of protection against electric shock	CLASS I EQUIPMENT
According to the degree of protection against electric shock	Type BF Applied Part (Couch Board)
According to the degree of protection against ingress of water	Ordinary device
According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE	EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTUREWITH AIR or WITH OXYGEN OR NITROUS OXIDE
According to the mode of operation	CONTINUOUS OPERATION WITH INTERMITTENT LOADING
Interference with other device EN/IEC 60601-1-2	YY0505 Group1, Class A Device

EC REP

EMERGO EUROPE
Prinsessegracht 20, 2514 AP The Hague,
The Netherlands

1.7 Training and After-sales Service

Operators of the NeuViz Prime CT system must have received adequate training on its safe and effective use before attempting to operate the equipment described in this Manual. Users must ensure that operators receive adequate training in accordance with local laws or regulations.

If you require after-sales service or further information about training in the use of this equipment, please contact after-sales service unit: Neusoft Medical Systems Co., Ltd.

Residence of Registrant: No.177-1 Chuangxin Road, Hunnan District, Shenyang, Liaoning, China

Address: No. 177-1 Chuangxin Road, Hunnan District, Shenyang, Liaoning, China

Post Code: 110167

Email: nms-service@neusoftmedical.com

Tel: 400 690 8528

Chapter 2 Safety Instruction

This Chapter provides information about safety precautions and procedures. For users, it is important to understand the warnings and notes of this chapter. This manual should be kept near the scanner desktop for easy access.

2.1 General Safety Matters

WARNING:

- **Whenever the device is found broken or not functioning properly, it should be stopped at once. Do not use the device until qualified maintenance personnel solve the problem.**

NOTE:

- **Do not load any software or data other than the operating software or image data into the local hard disk of the operating console as it could cause problems in the system.**
- **The type designation displayed in the operating interface of this manual might be different from the type that is purchased. Such difference will not influence the application of the operating procedures and methods. Information for a specified type can be found in this manual.**
- **Configuration of the device purchased might be different from what is described in this manual. Please use the purchase contract as a final reference.**
- **Operations must be performed according to the User Manual, and Technical data, Installation, Maintenance and other information can refer to the Product Information Manual.**
- **Only designated persons (service personnel) are to install this system. They are to refer to the proper pre-installation and installation manuals when installing the system.**
- **Only designated persons are to perform service on this system. They are to refer to the proper service manuals when servicing this system.**

- **Working procedures must be followed at all times. Before scanning a patient, make sure to check that all patient information details are accurate. Incorrect patient information details could lead to incorrect examination results.**
- **It is recommended that users restart the console and recon computer once a week, and restart the gantry once a month (including wall power).**
- **Observe the patient at all times. The patient must never be unattended. Pay attention to safety matters, including patient and device operating state.**
- **In daily operation, do not splatter liquid on the system.**
- **The equipment shall not be serviced or maintained while in use with a patient.**

2.2 EMC

2.2.1 EMC Definition and Attentions

Definition: EMC (electromagnetic compatibility) refers to the device performance by which the device inhibits electromagnetic interference from other devices; meanwhile the device itself does not cause the similar electromagnetic interference with other devices.

By its nature, the system will cause electromagnetic interference with other devices via air or cables. The design of the unit complies fully with EMC standard.

NOTE:

- **Using devices such as cellular phones, transmitter-receivers, or remote control toys that transmit radio waves near the device may interfere with the proper functioning of the product. Switch the above devices off if they are near the CT scanner.**
- **Keep this device as far as possible from other electronic devices when installing.**
- **Make sure to use cables provided or designed by our company and connect the cables according to installation regulations.**
- **Please use specified peripherals that can connect with this product. Avoid using other non-specified devices, or EMC properties might be reduced.**
- **Never attempt to modify this product. Alteration to the product could lead to reduction of EMC properties. Alterations include: alteration of cables, alteration of system installation/ lay out, alteration of system**

configuration/components, alteration of fixed system/accessory methods, etc.

- **Ensure that all the bolts are fastened after maintenance. Loose bolts could lead to reduction of EMC properties.**

2.2.2 Resolved Measures Related to EMC

- Keep other devices far from this product to reduce electromagnetic disturbance.
- Electromagnetic disturbance will be reduced through adjusting the position /angle between the system and other devices.
- Electromagnetic disturbance will be reduced through altering the connecting position of other devices' power/signal cables.
- Electromagnetic disturbance will be reduced through altering the power channel of other devices.

2.3 Patient Safety

2.3.1 Patient Scanning Safety

When performing a scan on a patient, please adhere to the following safety instructions and rules:

- Close all doors of the scanner room before a scan process is initiated. Unless given permission by the doctor in charge, no one is allowed to enter the scanner room during the scan process.
- Advise the patient not to move during the positioning or scanning procedures.
- Ensure that the patient's fingers and clothing do not get caught in the device during patient positioning.
- Advise patients not to move their head or move their body during scans.
- Remind patients to not touch any external apparatus, such as infusions and resuscitation devices.
- During any movements of the Gantry (automatic and manual) and the Couch, keep the patient under continuous observation to avoid crushing the patient against the Gantry or Couch parts, as well as to avoid disconnecting any infusion or resuscitation apparatus.
- Ensure that all patient supports (head holders, Couch extension, Arm Supports, Leg Pad, and Infant Cradle) are whole and not damaged. Check that the head holders and Leg Pad are securely on the Couch.

- Unauthorized accessories can cause artifacts, injuries to the patient and operating personnel or damage to the device. Therefore, only use accessories approved by Neusoft Medical Systems and replace defective accessories by new original accessories immediately.
- Ensure that the patient is positioned securely with straps on the Couch top to reduce the risk of the patient falling and hands dangling.
- If damages or defects should occur in the system (Couch, Gantry) in add-ons or accessories, safety of operation is no longer guaranteed. Check for such damages and have these parts repaired or replaced immediately.
- After typing the Increment value and pressing **Enter**, check that the desired value was correctly entered.
- Before pressing the **Scan Start** button, check that all scan parameters, as displayed on the screen, were correctly entered.

2.3.2 Emergency Procedures

2.3.2.1 Emergency Stop

In the event of possible damages, to stop the scanning, Couch movement and X-ray radiation immediately, press the red Emergency Stop button on the top of the Gantry panel or on the CT-Box.

NOTE:

- **Emergency stop can damage the device and shorten the endurance of the device.**
- **When the emergency stop control is actuated or the power supply is unintentionally interrupted, the gantry tilt shall stop within an angle of 0.5°, Z-direction motion shall stop within 25mm and patient support movement (up/down/sideways) shall stop within 10 mm.**

2.3.2.2 Emergency Patient Release

When the Gantry tilts, in the event of a power failure or other conditions such as a slope motor breakdown, use the following procedures to release the patient:

1. When the Couch is locked, press down the emergency release button on the bottom of the Couch to free it;
2. Hold the rear cover of the Couch by hand, and pull backward;
3. Help the patient to dismount;

4. The Couch can be reset safely.

2.3.2.3 Emergency Login

Emergency Login function is used to login CT system when a patient needs an emergent scan, but the user name and password are not available. Emergency login can be repeatedly used within 24 hours after the first login. After more than 24 hours, the system will ban the use of emergency login. After using emergency login, it should be unlocked in user management center to get ready for the next use.

2.3.3 Weekly Test of Safety Devices

Perform the following tests weekly. If any of the tests fail, contact the maintenance service and do not operate the scanner until the problem is corrected.

1. Power-up the CT.
2. When the CT is ready for scanning, press the Emergency Stop button. The sound of the scanner braking to a stop should be heard.
3. Next, try moving the Couch and tilt the Gantry using the buttons on the Gantry control panel, and ensure that no motion takes place.
4. Repeat steps 2 and 3 for each of the Emergency Stop buttons.
5. Press an Emergency Stop button on the Gantry control panel. Pull the stretcher and check that it moves easily.
6. Verify that the Mylar window covering the slice plane is whole and undamaged.

NOTE:

- **Users should ensure that Tube Warm UP and scans are not performed one hour before checking the Emergency Stop button to avoid damages to bulb.**

2.4 X-ray Safety

X-ray Safety

CAUTION:

- **Failure to control, regulate or operate the device in compliance with**

instructions and procedures described in this manual may cause danger and radiation leak.

WARNING:

- **The useful X-rays may result in danger when it is not used properly. This device is designed and manufactured in accordance with electric and mechanical safety regulations and standards. Excessive X-rays can result in serious body injuries. Avoid operation of the device by "unqualified" and "unauthorized" personnel so as to protect the patient, or any other person from unexpected X-ray radiated.**
- **System will set up exposure time to the backup timer in R-host before scanning. The setting time is 110% of the minimum value between needed exposure time and scan time per cycle. R-host will real time monitor this backup timer during exposure period. If real exposure time is beyond setting time, exposure will be ended. At the same time, errors will be reported.**
- **Only personnel who are qualified for relevant national laws and standards for radiological protection can operate the device described in this manual.**
- **The CT scanner room should be inspected and approved for its X-ray protection by related management department before it is put into use to protect patients and personnel from being radiated.**
- **When the system discharges, pay attention to system safety directions and follow the operation directions for the device to ensure the safety of all persons from the harmful radiation or other dangers.**
- **The NeuViz Prime Software controls the NeuViz Prime CT System that controls the Couch and Gantry movement, and also the X-ray on and off. Software failure may cause X-ray to be ON at the wrong position or at the wrong time, which may result in minor injury to a patient from extra radiation.**

2.4.1 Radiation Safety Prompts

The system provides two types of safety prompts:

- Sound Prompt: There is sound in the CT-Box mounted at the operating station when the device discharges.
- Light Prompt: There is a discharge pilot lamp installed on the digital display of the scanning Gantry. An interface has been reserved to install the discharge pilot lamp at a proper place outside the CT scanner room.

2.4.2 Radiation Protection Measures

Take the following protection measures to protect both yourself and the patient.

Anyone who has to be near the patient during scanning must wear protective clothing (lead apron), wear a PEN dosimeter and/or film badge, and stay in the zone shielded by the system (to the side of the gantry or behind a mobile protective wall).

The physician is responsible for protecting the patient from unnecessary radiation.

- Always use a gonadal shield, if possible.
- Use the pediatric mode for children.

WARNING:

- **If it is necessary to enter the room when the system is discharging, the operator and accompanying person must wear protective clothing (lead apron).**

NOTE:

- **When a patient is being scanned, exposure of the patient shall be reduced using the ALARA principle. (As Low as Reasonably Achievable).**

Dose Deterministic Effects

There is the possibility that in normal use, the patient could be exposed to radiation dose levels of 1Gy $CTDI_{100}$ (peripheral) or above, at which deterministic effects may become apparent. Management of the high radiation dose is critical to maintain radiation safety. The available scan settings concerning radiation dose, radiation quality, and image (quality include: mA, kV, scan time and SFOV).

The table below provides the scan duration in seconds required to meet 1Gy $CTDI_{100}$ (peripheral) at 200 mA exposure at the same scan location. This table assumes 200 mA and provides 1s scan time as a practical example for an average patient. The product of the scan time shown and 200mA yields the mAs required to result in 1Gy $CTDI_{100}$ (peripheral). Note that for each kV / Collimating Thickness /SFOV combination in the table, any mA and scan time combination that meets or exceeds the equivalent mAs of this table can also result in deterministic effects of radiation. For obese patients, the mA may be larger than the practical example shown in the table, and the resulting mAs should be used to determine the exposure to the patient.

Table 2-1 Dose Deterministic Effects

Unit : s/Gy $CTDI_{100}$(200mA，large wedge)

Voltage （kV）	Collimating Thickness(*0.625mm)	CTDI phantom	
		16cm	32cm
60	**2**	210	612
	4	183	528
	8	259	746
	12	298	870
	16	323	940
	20	340	988
	24	354	1025
	32	375	1081
	40	385	1126
	64	408	1190
70	**2**	108	273
	4	94	235
	8	133	333
	12	153	388
	16	166	419
	20	175	441
	24	182	457
	32	193	482
	40	198	502
	64	209	531
80	**2**	64	149
	4	55	129
	8	78	182
	12	90	212
	16	98	229
	20	103	241
	24	107	250
	32	114	264
	40	117	275
	64	124	290
100	**2**	31	65
	4	27	56
	8	38	79
	12	44	92
	16	47	99
	20	50	104

Unit : s/Gy $CTDI_{100}$(200mA，large wedge)

Voltage （kV）	Collimating Thickness(*0.625mm)	CTDI phantom	
		16cm	32cm
	24	52	108
	32	55	114
	40	56	119
	64	60	126
120	**2**	18	37
	4	16	32
	8	23	45
	12	26	52
	16	28	57
	20	30	59
	24	31	62
	32	33	65
	40	34	68
	64	36	72
140	**2**	13	24
	4	11	21
	8	16	29
	12	18	34
	16	19	37
	20	20	38
	24	21	40
	32	23	42
	40	23	44
	64	25	46

2.4.3 Implantable Device Safety

WARNING:

- **CT scans may cause interference with implanted or externally worn electronic medical devices such as pacemakers, defibrillators, neurostimulators and drug infusion pumps. The interference could cause operational changes or malfunction of the electronic medical device.**

2.4.3.1 Recommendations prior to scanning

- If practical, try to move external devices out of the scan range.

- Ask patients with neurostimulators to shut off the device temporarily while the scan is performed.
- Minimize the X-ray exposure to the electronic medical device.
- Use the lowest possible X-ray tube current consistent with obtaining the required image quality.
- Do not scan directly over the electronic device for more than a few seconds.

NOTE:

- **For procedures such as CT Perfusion or CT Interventional scans that require scanning over the electronic medical device for more than a few seconds, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.**

2.4.3.2 Recommendations after scanning

- Have the patient turn the device back on if it had been turned off prior to scanning.
- Have the patient check the device for proper functioning, even if the device was turned off.
- To advise the patient to contact his or her healthcare provider as soon as possible if the patient suspects their device is not functioning properly after a CT scan.

NOTE:

- **Recommendations from FDA Preliminary Public Health Notification: Possible Malfunction of Electronic Medical Devices Caused by Computed Tomography (CT) Scan date July 14, 2008.**

WARNING:

- **This system is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the system or shielding the location.**

2.5 Mechanical Safety Matters

2.5.1 Mechanical Safety Precautions

WARNING:

- **Only authorized maintenance personnel can open or dismantle the cover of the scanning Gantry. Never allow patients or working staff to enter the scanner room when the scanning Gantry cover is dismantled for repair or periodic maintenance.**
- **Ensure that no stumbling blocks are in the moving range between Gantry and Couch. Nothing unnecessary to scanning should be put on the surface of the Couch.**
- **Ensure that no one has touched the moving parts of the scanning system, especially the positions that cannot be viewed from the operating station.**
- **Ensure that different patient anatomy, including hands, arms and legs, are not hanging off the edge of the Couch or touching the cover of the Gantry.**
- **Patients must not wear items that fall easily such as glasses, barrettes or watches before scans.**
- **Avoid placing patient's arms and legs too close to the top of the moving couch or edges of the couch. This will prevent anatomy from being clamped and crushed.**
- **Ensure that the affiliated facilities and intravenous tubing does not touch the Couch and Gantry for patient who is receiving intravenous injection or enhanced scanning.**
- **Take proper measures to ensure that the stretcher does not move when the patient is transferred from the stretcher to the CT Couch so that the patient is not harmed during this process.**
- **Adjust the tilt angle of the scanning Gantry to 0°, lock the Couch and set the height at a suitable position for proper patient placement.**
- **For head scans, the patient should keep his/her arms crossed on the body instead of on the edge of the Couch.**

- **For scanning abdomen and parts below, the patient should have his/her arms crossed on the chest or should hold his/ her arms by the head. Elbows must not touch the Gantry cover when the patient is holding his/her arms over the head.**
- **If the Gantry tilts or the Couch top is moved, ensure that the patient does not touch the CT Gantry.**
- **Pay special attention to large patients to protect their skin or limbs from being cramped by the Couch and Gantry.**
- **The maximum load capability of the Couch is 205kg (300kg for USA, optional). Scanning accuracy can be guaranteed within 205kg. If the weight exceeds this limit, the result might be:**
  - **Accuracy reduction of system positioning**
  - **Increased speed of descending of Couch**
  - **Reduction of scanning speed**
  - **Damage and/or harm to patient**
- **Check the connection of the end of the Couch top periodically. If it is damaged or loosened, please repair and replace it.**
- **System can adjust the scanning Gantry and Couch automatically during scans, hence please check there is enough space between the patient and scanning Gantry before scans. Couch can be moved manually to check whether there is enough space or not before scans.**

2.5.2 Implosion Hazard

WARNING:

- **Do not subject the system to serious mechanical shock, as the cathode ray tube (CRT) can fracture if struck or jarred. This may result in flying pieces of glass and phosphor coating that can cause serious injury.**

2.6 Electrical Safety and Grounding

CAUTION:

- **Non-professional persons are not allowed to remove covers from this device or to perform maintenance. High electrical voltages are present within this device. Removing covers could lead to serious personal injuries.**

WARNING:

- **Avoid touching the conductors.**
- **Switch off the device before cleaning. Never let washing liquid splash into the inside of gantry. If this happens, do not switch on the CT until it is completely dried.**
- **Don't install condensation tubes on the top of the Gantry to prevent condensed water from dropping onto the Gantry. If water penetrates into the Gantry, it will cause a short circuit or possibly a system breakdown.**
- **To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth grounding.**
- **The system must be grounded to an earth ground by a separate conductor. The neutral side of the line is not to be considered the earth ground. On device provided with a line cord, the device must be connected to a properly grounded, three-pin receptacle. Do not use a three-to-two pin adapter.**
- **Do not connect the multi-slot socket inside the Console cabinet with any other devices except for the monitor, the operating computer and the power switch for the hub and CT-Box.**
- **Pregnant women, children or infants should be taken care during operation or service.**

2.7 Information Safety

2.7.1 Information Protection

It is important to secure the data and the hardware and software products that create and manage the data. Neusoft is dedicated to helping maintain the confidentiality, integrity, and availability of electronic protected health information.

Maintaining and securing the Information Safety of Neusoft products should be an important part of the facility's security-in-depth strategy. A comprehensive, multi-layered strategy to protect the information and systems from external and

internal threats must be implemented. The security strategy should follow industry-standard practices, addressing physical security, personnel security, procedural security, risk management, security policies, and contingency planning.

The practical implementation of technical elements varies by site and may employ a member of technologies, including firewalls, virus scanning software and authentication technologies. A CT scanner is a kind of computer based system; it needs protection such as firewalls and/or other security devices in place between the medical system and any externally accessible systems, and the system information security is based on these external devices and network protection equipment

Any external device (such as a printer) connected to CT should be authorized by Neusoft.

This section provides advices on security items to protect system from threats and it is intended to help be aware of various situations leading to the reduction of safety. For specific information about security within their institutions, consult with the following offices at their location:

Information Systems Security Officer

Chief Information Officer

HIPAA Officer (In the USA)

Safety Officer

2.7.2 Regulatory Controls

Protect patient's health information

The patient's health related information is the most important asset in the system. It is a legal requirement in some countries to maintain the confidentiality of this information. Therefore, strict security measures must be taken to guard this protected information.

To find guidelines in the USA, refer to http://www.hhs.gov/ocr/hipaa/. Prevent unauthorized device modification.

Prevent unauthorized equipment modification

Neusoft sells high-tech medical devices and system that are highly complex. Any modification of the system must be in accordance with quality assurance procedures stipulated by related rules and regulations to test and verify.

Users and owners of this device must be authorized by Neusoft to modify the system, and all modifications must be performed by the service engineers of Neusoft or based on the published specifications by Neusoft.

2.7.3 Threats and Protective Measures

Besides the before-mentioned patient information and the integrity of devices in the section of law and standards, operators and owners should also pay attention to the security problems and protective measures as follows:

1. Network Security

   NeuViz Prime is incorporated in the Internet. To prevent computer system from virus and other attacks, the Internet must be equipped with such protective measures such as firewall, virus scanning procedures. Network security must high attention paid to it, if external Internet needs to be connected.

2. Virus Pool

   The system carries virus definition documents and latest virus scanning engine, Neusoft will periodically provide the latest virus definition document and/or upgraded version of software to wipe out known loopholes, virus and other threats.

   Anti-virus software will not delete pictures and patient information. Once there are affected executable documents, it is recommended to contact service engineers to reinstall the system.

   No one can install new ungraded virus definition documents or other software other than service engineers in Neusoft and agents authorized by Neusoft.

3. Access Control

   This device needs access control to avoid unauthorized personnel to touch the device accidently, occasionally or intentionally.

   Proper strategies and regulations should be worked out to control staff to enter into the region of NeuViz Prime system and only authorized personnel is allowed to enter into specific regions.

4. Placement of Monitor

   The system monitor should be placed to face the wall in order to avoid unauthorized personnel to see the patient information in monitor from the door, corridor and other area.

   To better protect patient information, system display can be set automatic black screen after it is left unattended, or added restored password to avoid unauthorized personnel to have access to protected information.

5. Login Information Management

   Login information should be secured effectively.

   The lowest standards for logging in the system include:

   - Use strong password. It is the easiest and most effective approach to improve security which should at least include one capital or lowercase, two figures and the length should not be less than 8 characters.
   - User names or passwords cannot go public or be shared.

- Password should be altered on a regular basis.

6. Patient Information should be backed up regularly

   Patient information might be lost, it is recommended to regularly back up patient information through the backups on the desk of Console Cabinet and recovery tools.

7. Removable Storage Media

   When using removable storage media (such as DVD and mobile hardware), the below security problems must be adhered to:

   - Using removable storage media might bring a virus into the medical device.
   - If removable storage media which includes patient information is removed, unauthorized personnel are likely to access patient information.
   - If such storage media needs to be abandoned, it must be destroyed or scrapped to ensure that no one can access the inside information.

NOTE:

- **When storage media is connected to the system, it must be ensured that media does not contain virus that might infect the computer such as Worm and Trojan horse program.**
- **Storage media including images and/or other medical information must be stored in the safe places to which unauthorized personnel cannot access.**

8. Prepare Emergency Plans

   Users should prepare corresponding emergency plans and perform based on their emergency plan guidelines.

2.8 Laser Safety

WARNING:

- **Instruct the patient not to stare into the beam before scanning because the laser beam for patient positioning could harm the eyes.**

2.9 Explosion Safety

WARNING:

- **This device must not be used in the presence of explosive gases or vapors,**

such as certain anesthetic gases. Use of an electrical device in an environment for which it was not designed can lead to fire or explosion.

- **Flammable or potentially explosive disinfecting sprays must not be used, as the resultant vapor could ignite, causing fatal or other serious personal injury and/or damage to the device.**

2.10 Fire Safety

Use of an electrical device in an environment for which it was not designed can lead to fire or explosion.

Conductive fluids that seep into the active circuit components of the Console may cause short circuits that can result in electrical fires. Therefore, do not place any liquid or food on any part of the consoles or other modules of the system. Fire regulations for the type of medical area being used should be fully applied, observed and enforced.

Fire extinguishers should be provided for both electrical and non-electrical fires.

Persons who operate this CT system must be fully aware of and trained in the use of fire extinguishers and other fire-fighting devices, and in local fire procedures.

WARNING:

- **Only use the electrical or chemical fire extinguishers specific for this purpose. Water or other liquid will cause fatal damage or serious bodily harm in electrical fires.**
- **If it is safe to use the electrical or chemical fire extinguishers, please isolate the device from the power supply and other supply sources so as to decrease the risk of electrical shock.**

2.11 Oil Leak

The X-ray tube is oil-cooled. This is a closed-circuit system that is sealed.

WARNING:

- **If oil leak is detected, shut down the CT immediately and contact the nearest Neusoft Medical Systems field service office.**

2.12 Environmental Requirement

Improper treatment of some materials in the CT scanner may cause environmental pollution. These materials include the lead block in Gantry, oil in the conservator and the X-ray tube. Whenever the CT scanner or any element in the CT scanner is disposed of, contact Neusoft Medical Systems service personnel for proper disposal in accordance with national waste disposal regulations.

Packing materials for the device are reclaimable. They must be collected and disposed in accordance with local regulations where the machine or accessories are opened.

⚠

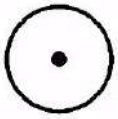
WARNING:

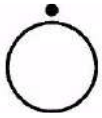
- **This X-ray tube assembly contains materials that are toxic.**
- **Do not discard the X-ray tube assembly together with industrial or domestic waste.**
- **Discard the X-ray tube assembly, the attached parts, the cable connectors, and the cables in a way that refers to the local environmental laws and regulations.**

2.13 Life Span

10 years.

2.14 Symbol

Sign	Instruction
	Alternating current
	Three-phase alternating current with N phase
	Protective earth (ground)
	“On” (Power)

Sign	Instruction
	"Off" (Power)
	CE Mark: Manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.
	Authorized representative in the European Community
	Type B Applied Part
	Ionizing radiation
	Warning, electricity
	Emergency Stop
	It indicates that the waste of electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact Neusoft Medical Systems distributor or the municipal waste collection facility for information on proper disposal.

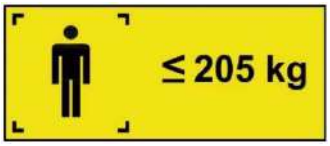
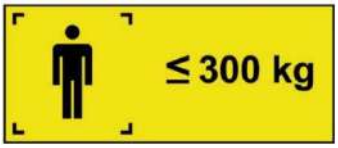
Sign	Instruction
	X-ray Emission
	Refer to the User Manual
	Date of manufacture
	Manufacturer
	Reference No.
	Serial Number
	Attention! Refer to the attachment
	Large Focus (LF) Large Focus
	Small Focus (SF) Intermediate Focus
	Extra Small Focus (XSF) Small Focus

2.15 Labels

2.15.1 Warning Labels

Table 2-2 Warning Labels

Warning Labels	Description	Location
	This label warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed. To be used by authorized personnel only.	This warning label is pasted near the system power switch on the gantry.
	Laser Position Warning Label The labels warn to protect eyes from laser radiation.	This label is pasted on the Gantry.
	Laser Positioning Light Label This label warning: Do not view directly with optical instruments	This label is pasted on the Gantry.
	Warns of a hazard from a laser beam.	This label is pasted on the Gantry.

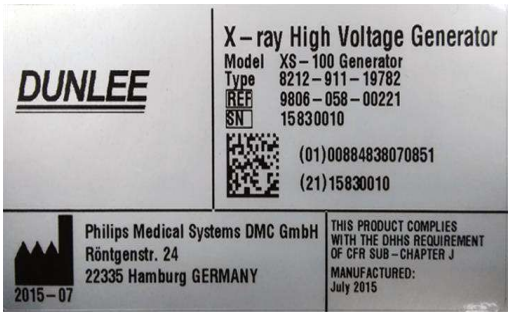
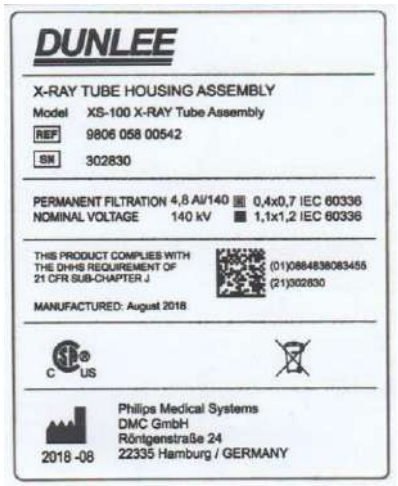
Warning Labels	Description	Location
	Laser Warning Labels	This label is pasted on the laser power line.
	This label means that the maximum load capability of the Couch is 205kg.	This label is pasted on the Couch.
	This label means that the maximum load capability of the Couch is 300kg (optional).	This label is pasted on the Couch.
	The label warns to watch your hand.	This label is pasted on the Couch.
	The label warns to watch your foot.	This label is pasted on the Couch.
	The label warns to watch your hand. Do not grasp the sides of the cradle.	This label is pasted on the Couch.

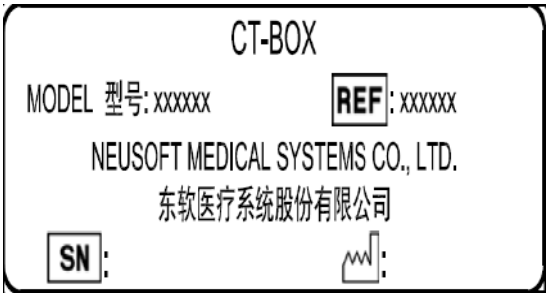
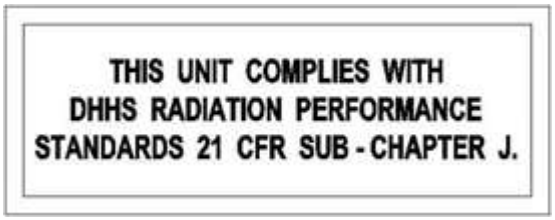
Warning Labels	Description	Location
	No Sitting and Lying Label.	This label is pasted on the mobile monitor

2.15.2 The example of System Name Plates and Parts labels

Table 2-3 The example of System Name Plates and Parts labels

Labels	Descriptions	Position
	System Name Plate	On the gantry
	Gantry model label	On the gantry
	Collimator Label	On the Collimator

Labels	Descriptions	Position
	X-ray High Voltage Generator Label	On the HV Generator
	X-RAY TUBE Housing Assembly Label	On the Tube
	Couch Label	On the Couch
	DMS Label	On the DMS

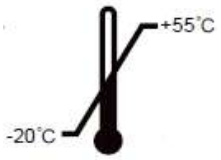
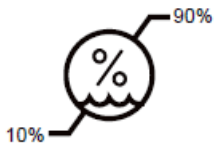
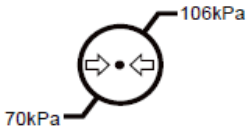
Labels	Descriptions	Position
	Console Label	On the console
	CT-Box Label	On the CT-Box
	Mobile Monitor Label	On the Mobile Monitor
	Certification Label (The system shall conform to applicable requirements of 21CFR Subchapter J) (US only)	On the Gantry, Couch,Collimator,Console

NOTE:

- **Above mentioned are label examples, which may be different with the real objects.**

2.15.3 Symbols Used on the Package Box

Table 2-4 Symbols Used on the Package Box

Labels	Descriptions	Position
	Up	On the Package Box
	Fragile, handle with care	On the Package Box
	Keep dry	On the Package Box
	No stacking	On the Package Box
	No stacking more than 2 layers	On the Package Box
	Temperature limitation	On the Package Box
	Humidity limitation	On the Package Box
	Atmospheric pressure limitation	On the Package Box

Labels	Descriptions	Position
	Center of Gravity	On the Package Box
	Lift Here	On the Package Box

2.16 System Error Messages

When an error occurs, error message will be displayed in message center on the right of workflow bar. In order to resume the system to normal, please take the following steps:

Check the error message in message center

Refer to the following error messages, check reasons and take corresponding actions.

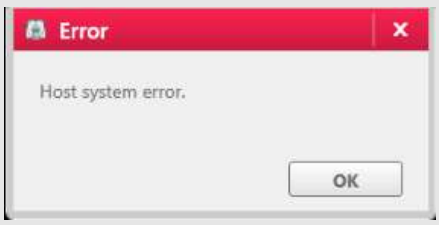
Try to carry out the possible actions in order.

If an error dialog box pops up, please click ok and perform the steps above.

NOTE:

- **If scanning has been interrupted by system failure, the scanned image information will be saved. Keep the patient still and press Continue Current Series button to complete the scan. The system will automatically provide default scanning parameters. Users can also setup scanning parameters manually.**

Table 2-5 System Error Messages List

Messages	Possible Cause	Possible Action
	1. Missing calibration files. 2. Software is not installed correctly.	1. Perform Air calibration. 2. Call service to reinstall software.

Messages	Possible Cause	Possible Action
 Message: Tube or HV Arc.	HV error. Tube error.	1. Press Continue Current Series button. 2. Restart Gantry.
HV prepare time out !	HV error	Restart Scan
Failed to get Ucos mailbox info GPC system error. Restart gantry	GPC firmware breakdown	Restart console software and gantry
Couch code out of range (<0) Console parater error, restart console software	Console software error	Restart console
Couch code out of range (>17700)	Console software error	Restart console
The couch speed can't be zero in Axial scan.	Console software error	Restart console
HVBootTime out of range(>=1s)	Console software error	Restart console
Breath navigation parameter out of range(less than standby time of HV and couch	Console software error	Restart console
The door is open, cannot expose	1.Door of Scanner room is open 2.Door switch error	1. Check the door of scanner room 2. Check the switch of the door
Did not find HV On code, Scan stopped	Scan parameter error	Restart console
Couch target code is out of range(0-17700)	Console software error	Restart console
Q fifo is full.	Console software	Restart console
Slice Parameter for DMS error, it should be an even between 2 to 32	Console software error	Restart console
Filter parameter out of range	Console software	Restart console

Messages	Possible Cause	Possible Action
Injector control error, restart injector and check	CT-BOX Control Board malfunction.	Reconnect CT-Box and injector
Gantry tilt target code is out of range(>700 code)	Console software error.	Restart console
Getting Abort task signal failed	GPC firmware malfunction.	Restart console and gantry
Abort task of "delete Prepare task" failed	GPC firmware malfunction.	Restart console and gantry
Abort task of "delete Scan task" failed	GPC firmware malfunction.	Restart console and gantry
FreeLibrary operation is failed	Library file is damaged or lost.	Restart recon system
ExCellDLL initialization timed out	Computer was slowed down due to the computer resources were largely occupied.	Restart recon computer
ippsSet_16s operation is failed	Third party libraries error	Restart recon computer
ippsSet_32f operation is failed	Third party libraries error	Restart recon computer
Runtime exception	Internal error of Recon system	Restart recon system
List is overflow	Internal error of Recon system	Restart recon system
Start scan time out, restart scan	Scan control parameters error	Restart software
Scan parameters error, restart scan	Console software error	Console software error
Slice control parameters error, restart console	Console software error	Console software error
Gantry error and restart gantry	GPC firmware error	Restart software and gantry

For other messages without self-explanation, please contact your local Neusoft Medical Systems representative. Alternatively, contact: Neusoft Medical Systems Co., Ltd.

Address: No. 177-1 Chuangxin Road, Hunnan District, Shenyang, Liaoning, China

Post Code: 110167

Chapter 3 System Description

This system uses an attenuated X-ray signal to reconstruct body images for the purpose of clinical diagnosis after X-ray penetrates the scanned body.

General scanning process:

After patient positioning, it is available to set appropriate scan planning on the scan interface and start the scan.

Once a scan starts, the Gantry rotates around the patient while the X-ray tube discharges. The detectors collect and transform the X-rays into electronic signals after the X-rays penetrate the body.

Then, DAS (Data Acquisition System) acquires electronic signals and converts them into digital signals, which is called raw data and is received by the console computer. The console computer then performs image reconstruction based on the raw data and displays the reconstructed images on the screen. The images can also be printed as films through laser imaging and transferred in DICOM format or transit to advanced image work station for diagnosis. The images can be saved into many kinds of storage media such as CD/DVD ROM and hard disk.

3.1 System Requirement

3.1.1 Environment

The environment, such as temperature and humidity, which affect the scanner performance especially, image quality, must be checked before system startup or the first scan. The environmental requirements are detailed below:

Table 3-1 Environments List (Temperature Variation ≤5°C/h)

Item	Scanner room	Control Room	Equipment Room
Ambient Temperature	18℃～24℃	18℃～28℃	15℃～30℃
Relative Humidity	30%～60% no condensing	20%～80% no condensing	20%～80% no condensing
Atmosphere Pressure	70kPa ～ 106kPa		

NOTE:

- **Keep the scanner room clean and tidy other than ambient Temperature and Relative Humidity tests because dust and corrosive air may shorten the service life of the whole system.**

3.1.2 Power Supply

The requirements of power supply for the system to function properly are as below:

Table 3-2 Power Supply Requirement

Parameter	NeuViz Prime
Type of power supply	Three-phase source SBW-Y-100kVA
Rated Voltage	380/400VAC ± 10%
Rated power	125kVA
Frequency	50/60Hz±1Hz
Power Voltage load rata	⩽ 5% of rating
Ground Resistance	4Ω for independent grounding system 1Ω for integrated grounding system
Capacity	⩾100kVA
Three-phase unbalance factor	⩽ 5%

3.2 System Composition

The system includes three main components, including the Gantry, the Couch and the Console.

Table 3-3 System Composition

Item	Qty	Specification
Gantry	1	Installed in scanner room.
HV Generator	1	Installed in the gantry.
X-ray source Module	1	Installed in the gantry.
Detector	1	Installed in the gantry.
Couch	1	Installed in scanner room.
Console	1	Installed in operating room.
CT-Box	1	Installed in operating room.

Item	Qty	Specification
Isolation Transformer (Optional)	1	Installed in power distribution
Computerized Imaging Processing System	1	Installed in operating room.
UPS (Optional)	1	Installed in power distribution
Tube		Installed in the gantry.
Micro-control compensative ac stabilizer		Installed in power distribution

3.2.1 Gantry

The Gantry is the kernel component of the scanning task. Its main function is to perform the X-ray exposure and data acquisition. Besides X-ray tube, HV generator, and data acquisition system, the Gantry includes the following components whose detailed information is to be given in the following section:

- Control Panel
- Power Switch
- Digital Display and Emergency Stop
- Patient Positioning Light

3.2.1.1 Gantry Display

Gantry Display is on the upper part of the gantry. It displays CT state and scan information. On the left corner is time. Patient information is on the top, including patient name, gender, patient ID and patient age after registration. The displayed information includes: Stand-by、Positioning、ECG and heart rate、Scanner Ready、Scanning and Scan Over, etc.

Fig 3-1 Gantry Display

In the startup screen of Gantry Display, the copyright statement of "OTS (Off-The-Self) software" is displayed.

3.2.1.2 Control Panel

On the right and left sides of the front and back Gantry, there is a respective control panel. Pressing buttons on the control panels enables the operator to perform the Couch in, Couch out, ascending and lowering operations of the Couch and tilting operation of the Gantry to position patients for scanning.

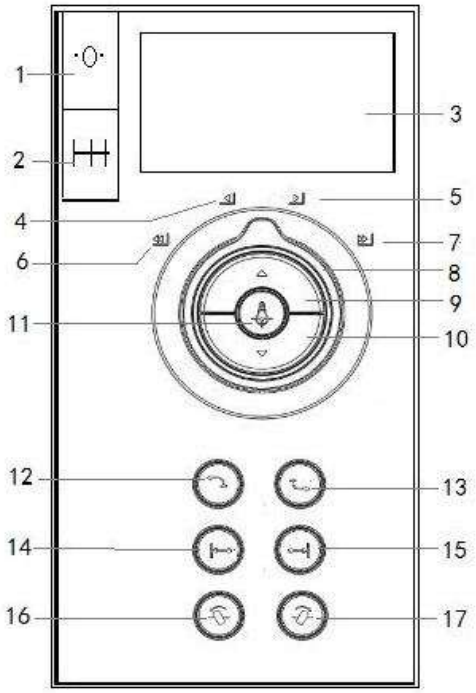


Fig 3-2 Control Panel

1. Reset Button: To set the current Couch position to zero.
2. Safe Range: To show the safe range of the movement of the Couch and the Gantry.
3. Display Screen: To display tilt angle, Couch height, Couch horizontal position, X-ray prompt.
4. Slow Couch-in Light: Turn couch control knob to Slow Couch-in Light, the Couch will carry out Couch-in operation slowly.
5. Slow Couch-out Light: Turn Couch Control Knob to Slow Couch-out Light, the Couch will carry out Couch-out operation slowly.
6. Fast Couch-in Light: Turn Couch Control Knob to Fast Couch-in Light, the Couch will carry out Couch-in operation fast.

7. Fast Couch-out Light: Turn Couch Control Knob to Fast Couch-out Light, the Couch will carry out Couch-out operation fast.
8. Couch Control Knob: Turn Couch Control Knob to certain Couch light to control Couch moving.
9. Couch-up: to elevate the Couch to a predefined height, while the Couch is moving towards the opening to keep a stable relative distance between the Couch and the Gantry. If the distance between gantry and zero is below 2 mm, couch will not move horizontally. When the couch-up light is on, it shows that couch will move up.
10. Couch-down: to make the Couch descend to a predefined height, while the Couch is moving backwards from the opening to keep a stable relative distance between the Couch and the Gantry. If the gantry reaches the end, couch will not move horizontally. When the couch-up light is on, it shows that couch will move down.
11. Laser Light on/off: to turn on or off the internal and external laser lights which are used for positioning the patient.
12. Auto Couch-in: to elevate the couch to 282mm and then move the Couch into the horizontal maximum position and 345mm height automatically, in the process of elevating, if the couch moves up over 280 mm, it will reach the maximum location. If the couch moves up over 280 mm, it will not move vertically and it can only reach the maximum horizontal location.
13. Patient Release: Setup the tilt angle to zero, meanwhile put the couch back near to the absolute zero 2 mm (couch speed 100 mm/s), then descend the couch.

    To move the Couch (out and down) and Gantry (to zero tilt) to positions for easiest patient release at the end of the scanning procedure. The Couch moves to its maximum distance from the Gantry and lowers to its minimal height. When the button is released before completing the process, all motion will stop.
14. Couch Index in: to make the Couch move a certain distance towards the Gantry opening. The distance is that between the internal and external laser light.

    When the height if couch reaches or over 280mm and Couch Index in is on, this button can be used. Press this button, the couch will move in and the distance equals the distance between internal patient position light and external patient position light (approximately 300 mm). When a Couch Index in is achieved, the light is still on, press the button again to move another distance further. If the couch cannot move further or the height of the couch is below 280 mm, the light will be off.

    — Couch Index in is on: the button can be used.

    — Couch Index in is blinking: the couch is moving or the forward reach is less than the distance between internal patient position light and external patient position

light.

— Couch Index in is off：the button cannot be used.

15. Couch Index out: to make the Couch move a certain distance backwards to the Gantry opening. The distance is that between the internal and external laser light.

    When the height of the couch reaches or over 280mm and Couch Index out is on, this button can be used. Press this button, the couch will move away from the gantry and the distance equals the distance between internal patient position light and external patient position light (approximately 300 mm). When a Couch Index out is achieved, the light is still on, press the button again to move backward another distance further. If the couch cannot move backward further or the height of the couch is below 280 mm, the light will be off.

    — Couch Index out is on: this button can be used

    — Couch Index out is blinking：the couch is moving or the backward reach is less than the distance between internal patient position light and external patient position light

    — Couch Index out is off：this button cannot be used.

16. Tilt +: to tilt the Gantry away from the Couch.

17. Tilt -: to tilt the Gantry towards the Couch.

WARNING:

- **Observe the condition of the patient when operating the CT–Box and control panels.**

NOTE:

- **Enable LED Light: Every button of the control panels is activated only when its Enable LED Light is ON. Otherwise, it does not work.**
- **There should be intervals of 3 seconds between twice Couch Index in and twice Couch Index out.**
- **The safe range is just for reference, the operation should be performed based on the condition of the patient or object needs to scan.**
- **The short press of Couch in and Couch out buttons can be used for precise positioning in daily positioning or CCT.**

3.2.1.3 Power Switch

The switch is located on one side of the Gantry.

Fig 3-3 Power Switch

This is the power switch to the CT scanner. Push ⊙ to switch power on and push ○ to switch power off. When the voltage of the power supply is lower than required or the Emergency Stop button is pressed, the scanner is shut down. When the power supply meets the requirement or the Emergency Stop button is reset, it is necessary to switch power off first manually. After that, restart the gantry and then the scanner.

3.2.1.4 Emergency Stop

Fig 3-4 Emergency Stop

In an emergency, please press Emergency Stop to cut the power supply off immediately (slip ring, DMS, tube cooling system and CARC are excluded) to protect the safety of the patient and the system. After pressing the button, the tilt angle of the Gantry will stop in its current status in a range of 0.5° , and the Couch will stop moving within a distance of 10 mm. Before rebooting the system, turn the Emergency Stop knob clockwise to the original position and turn on the power switch manually.

3.2.1.5 Patient Positioning Light (Reference 21 CFR 1020.33(g)(2)(3)(4))

The Laser Light on/off button toggles on and off the marking laser. For precise positioning of the patient in the slice plane, press the Laser Light on/off button.

The slice plane is marked by a long, thin light-beam. The center of the Gantry opening is marked by shorter and thicker perpendicular beams on the top and sides of the body.

The system contains two internal Patient Positioning Lights, which are respectively located on the top left and the right side of the Gantry center in the Z direction.

In addition, the system has four external Patient Positioning Lights. One is on the right side of the front Gantry cover. One is on the left side of the front Gantry cover. The other two are located on the top of the front Gantry cover, which launch a cross laser beam.

When Patient Positioning Light is on, the laser light field indicates the central slice of the first circle to be scanned in # module scanning, while the positioning light indicates the first reconstruction image in * module scanning.

For external laser localizer, the distance from internal localizer is approximately 280mm depending on calibration.

- The precision of the internal Patient Positioning Light is ± 2mm.
- The precision of the external Patient Positioning Light is ± 2mm.

WARNING:

- **The equipment circuit is in the internal part of the Patient Positioning Light module, and damage to the surface anode may lead to failure of the Patient Positioning Light.**

NOTE:

- **Do not stare into the laser beam.**
- **The use of optical instruments, such as eyeglasses with large diopter or mirrors, with this product will increase eye hazard. Ensure that, for head examinations, the patient wears protective glasses when the laser beams are on.**
- **It is not necessary to use a fan in the Patient Positioning Light module; however, good circulation of air near the equipment must be ensured.**
- **Damage caused by unauthorized disassembly, decomposition, modification, vandalism, and misuse to Patient Positioning Light is not included in the warranty.**

3.2.1.6 Breathing Navigation Panel

Fig 3-5 Breathing Navigation Panel

Breathing Navigation Panel is on the back of the gantry. It is used to guide the patients to breathe in, or to hold breath. Breathing Navigation Panel includes an amplifier and indicator lights. During scanning, the amplifier will transmit breathing instruction to the scanner room and the corresponding icon will lighten.

The state of the indicator lights and navigation voice are corresponding:

- Green light on, yellow light off means breathe in;
- Green light off, yellow light off means breathe out;
- Green light off, yellow light on means hold your breath.

3.2.2 Couch

The Couch carries patients to the scan position in the Gantry for scanning.

It consists of the following components:

- Couch top - can independently move in or out of the Gantry from the Couch, and can move up or down;
- Couch-release Button-consisting of two buttons, one on each side of the Couch. To release patients urgently or quickly, the couch release button on the side of couch can be pressed to push the couch manually. Press the button again, the couch can be locked and cannot be moved any longer.
- Couch-release Foot Switch
  - Step on: Releases the Couch. The Couch can be manually moved to the proper position.

- Release: Locks the Couch. The Couch cannot be moved. Rapid or Emergency release of the Couch can be achieved by pressing the Couch-release Button on either side of the Couch. This unlocks the Couch from its driving mechanism and allows it to be manually moved. Press the switches again, and the Couch is locked and cannot be moved manually.

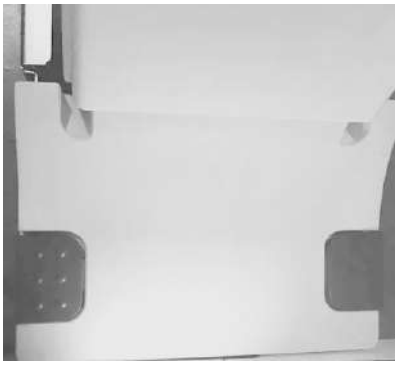


Fig 3-6 Couch-release Foot Switch

⚠

WARNING:

- **The Couch supports a maximum patient weight of 205 kg (300kg for USA, optional).**

NOTE:

- **The cushion is made from foamed plastics covered by thick ethenoid resin protection layer. Head fixation attachments include head cushions, neck cushion, coronal scan head supports and knee cushion etc. all made from polyurethane. Head supports and couch is made from carbon fiber. The cushion and pad materials comply with ISO 10993 for biocompatibility. These materials will not cause allergic reactions when touched by patients.**
- **Cleaning methods and materials that have a known no allergic history are employed.**
- **The Couch will move back when the scanner is initiated.**

3.2.3 Console

The Console contains the following main components:

Monitor

CT-Box

Console cabinet

WARNING:

- **Other than operating software / image data, installation or updating software onto a local hard disc is not allowed.**
- **Do not connect the multi-slot socket inside the Console cabinet with any other devices except for the monitor, console computer and the power switch for hub and CT-Box.**

3.2.3.1 Console cabinet

Console cabinet includes a console computer and recon computer. It is the central control unit and data processor of CT. Operators can setup scan conditions, control the scanning execution, browse patient images, export or transit images and data etc. through console.

3.2.3.2 CT-Box

The CT-Box consists of several buttons to control the Gantry, the Couch, the X-ray exposure and intercom system. The CT-Box has a display panel, which displays the status of the Gantry and the Couch, and a scan control panel.

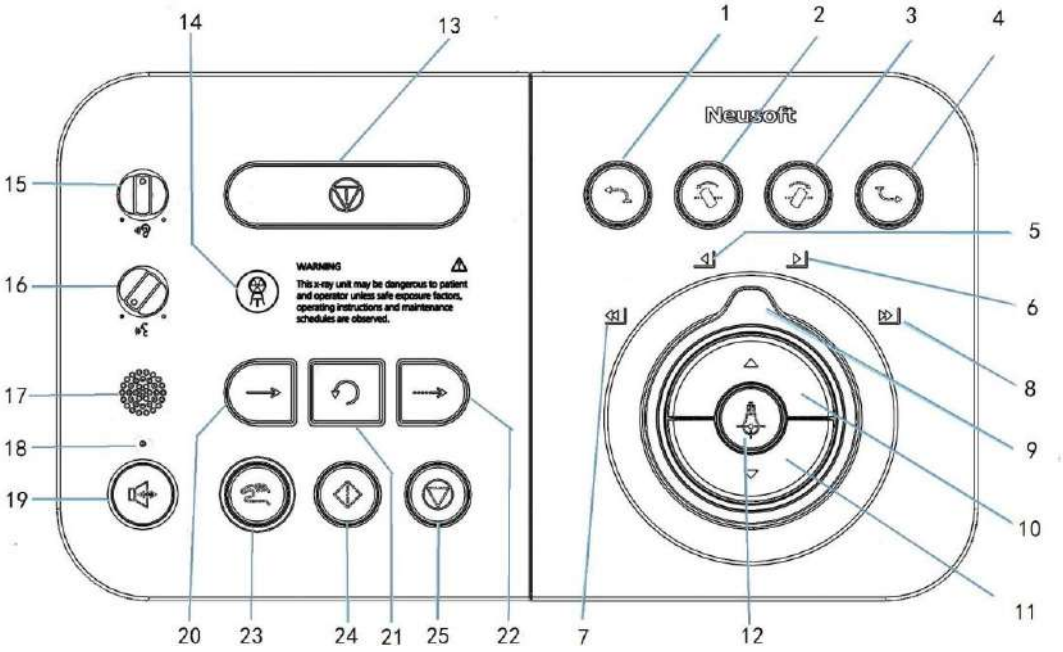


Fig 3-7 CT-Box-1

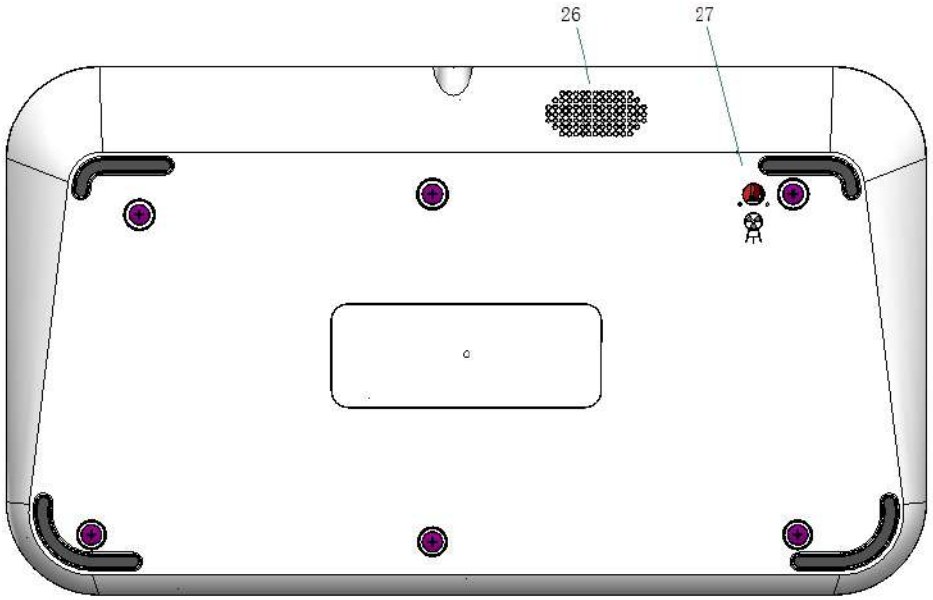


Fig 3-8 CT-Box-2

Table 3-4 CT-Box Button List

No.	Name	Description
1	Auto Couch-in	To elevate the couch to 282mm and then move the Couch into the horizontal maximum position and 345mm height automatically, in the process of elevating, if the couch moves up over 280 mm, it will reach the maximum location. If the couch moves up over 280 mm, it will not move vertically and it can only reach the maximum horizontal location.
2	Tilt+	Press to tilt the Gantry away from the Couch.
3	Tilt-	Press to tilt the Gantry towards the Couch.
4	Patient Release	Setup the tilt angle to zero, meanwhile put the couch back near to the absolute zero 2 mm (couch speed 100 mm/s), then descend the couch. To move the Couch (out and down) and Gantry (to zero tilt) to positions for easiest patient release at the end of the scanning procedure. The Couch moves to its maximum distance from the Gantry and lowers to its minimal height. When the button is released before completing the process, all motion stops.
5	Slow Couch-in Light	Turn couch control knob to Slow Couch-in Light, the Couch will carry out Couch-in operation slowly.
6	Slow Couch-out Light	Turn couch control knob to Slow Couch-out Light, the Couch will carry out Couch-out operation slowly.
7	Fast Couch-in Light	Turn Couch Control Knob to Fast Couch-in Light, the Couch will carry out Couch-in operation fast.
8	Fast Couch-out Light	Turn Couch Control Knob to Fast Couch-out Light, the Couch will carry out Couch-out operation fast.
9	Couch Control Knob	Turn Couch Control Knob to certain Couch light to control Couch moving.

No.	Name	Description
10	Couch-up	Press to elevate the Couch. To elevate the Couch to a predefined height, while the Couch is moving towards the opening to keep a stable relative distance between the Couch and the Gantry. If the distance between gantry and zero is below 2 mm, couch will not move horizontally. When the couch-up light is on, it shows that couch will move up.
11	Couch-down	Press to lower the Couch. To make the Couch descend to a predefined height, while the Couch is moving backwards from the opening to keep a stable relative distance between the Couch and the Gantry. If the gantry reaches the end, couch will not move horizontally. When the couch-up light is on, it shows that couch will move down.
12	Laser Light on/off	To turn on or off the internal and external laser lights which are used for positioning the patient in the slice plane.
13	Emergency Stop	It stops Gantry motions and X-ray generation in the event of an emergency.
14	Radiation Warning	It turns to green during X-ray exposure Lamp and turns to yellow when the tube is ready for exposure. Otherwise, it is OFF.
15	Speak Volume Controls	To set voice volume for talking to the patient in scanner room.
16	Listen Volume Controls	To set volume so that the voice from the scanner room can be heard.
17	Microphone	To broadcast your voice into the scanner
18	Microphone Light	To indicate that the Microphone is ON or OFF.

No.	Name	Description
19	Intercom Switch	Press to talk to the patient in scanner room. Otherwise, the voice from scanner room can be heard. Achieve the half-duplex intercom functions between console and gantry. Usually, the voice from the gantry will be transited to console. Press the button, the voice in the console will be transit to the gantry.
20	Scan next series	Press to scan next series. It's available when it turns green. Otherwise, it is OFF.
21	Repeat Last Series	When the light is on, it shows it can rescan the last scanned non plain radiographs sequences. Press to Repeat (Without scan) the previously scanned series. It's available when it turns green. Otherwise, it is OFF.
22	Continue Current	When the light is on, it shows it can continue scanning on the prescribed location of the scanned series. Press to Continue scanning in the current series. It turns to green when it's available. Otherwise, it is OFF.
23	Scan Start	Press to confirm scan and start X-ray exposure. It turns to green when the tube is ready for exposure. Otherwise, it is OFF.
24	Enable	After setting the Couch position and/or tilt degrees on the Console, keep pressing the button to move the Gantry and/or Couch to the desired position. Cease to press the button before it reaches the destination, the couch and gantry cease to work.
25	Scan Stop	Press to stop scan and X-ray exposure. It turns to white during X-ray exposure. Otherwise, it is OFF.(Reference 21 CFR 1020.33(f)(2)(ii))
26	Loudspeaker	On the back of CT-BOX, to broadcast voice from the scanner room.

No.	Name	Description
27	Radiation Volume Controls	On the back of CT-BOX, to adjust radiation warning volume. Rotate to the left to turn the voice down while rotate to the right to turn the voice up.

3.2.4 X-ray Source Module

The X-ray generator consists of tube and high voltage generator. Tube is actuated by high voltage to produce X-ray. The X-ray source module consisting of X-ray tube, X-ray tube component and collimation to provide necessary X-ray for scans. The X-ray generator is composed of X-ray source module and high voltage generator.

3.2.5 Beam Limiter

Beam limiter is a component of X-ray source module. Based on the scanning part, it sets limits to the range of illumination of X-ray in order to reduce scattered rays and avoid unnecessary X-ray radiation for patients.

3.2.6 Detector

The detector system is mounted on the gantry. The detector faces the X-ray tube to receive X-ray signals and transits electronic signals to the computer system through exaggeration and transformation of A/D.

3.2.7 UPS (Uninterruptable Power Source)

UPS (uninterruptable power source) installed in the operating room to provide uninterruptable power supply to the console system.

Type: BU2002RWL

Rated Output Voltage: 220V

Output Power Capacity: 2000VA/1400W

For detailed operation and maintenance, relevant UPS user manual should be referred to.

3.2.8 Isolation Transformer

Three-phase isolation transformer provides stable rated voltage. For detailed operation system, relevant user manual should be referred to.

Table 3-5 Isolation Transformer Parameters

Parameter	NeuViz Prime
Type	SBW-Y-150kVA
Rated Capacity	150kVA
Power	37KVA rated , 150KVA peak
Frequency	50/60Hz ± 1Hz
Input	190/200/208/220/230/240/380/400/415/440/460/480V
Output	380V
Working condition	Temperature :5-45°C ; 41-113°F
Unsymmetry of Voltage	When compare the three –phase no-load output voltage with the input in terms of unsymmetry, the increment should be less 1%.

3.2.9 Computer Image Processing System

Computer image processing system consisting of main console cabinet and image builder is the central controller and data processor of CT machine. Operator can setup scan conditions, control scan execution, browse patient images, export or transit images and data etc. through the console.

3.2.10 Removable Monitor (optional)

Removable monitor consists of small cart of monitor and monitor. When scanning constant, low-dose living tissue, it is the monitor device to show real-time scan images and condition in the operating room. This is primarily used with the biopsy application. There is roller wheel under the monitor cart to move randomly in the scanner room for convenience.

3.2.11 Working Station (optional)

AVW work station is an independent console which allows doctors to browse and handle clinical images without affecting the process of scanning.

AVW work station is connected with a CT system through a high-speed data exchange link. Details can be found in vol. 2 of the manual。

3.3 Patient Supports (Positioning Aids)

This section gives an overview of the standard and optional patient supports (positioning aids). Use the patient supports to position the patient safely and comfortably to prevent motion artifacts.

⚠

WARNING:

- **Do not use any positioning aids not mentioned in this section.**
- **Unauthorized Neusoft patient supports may cause danger to the patient through collisions with the Gantry. Image quality may also decrease.**
- **If a head holder or support is not engaged securely, it can become loose, causing injury to the patient.**
- **Positioning aids must be used exclusively for their intended purpose: head holder only for positioning the head, Couch extension only for positioning feet first scans.**

NOTE:

- **Patient supports are prone to wear and tear. They must be replaced with original parts if they are dirty or damaged.**
- **Configuration of the device purchased might be different from what is described in this manual. Please use the purchase contract as final configuration.**

Patient Supports :

Coronal Chin Pad (optional) - For patient comfort.

Neck Vertebra Cushion (optional) - For patient comfort.

Head Side Cushions (Large, Medium and small) (optional) and **Head Rest Cushion** (optional) - For patient comfort.

Knee Cushion (optional) - For patient comfort.

Flat Head Rest Cushion (optional) - For patient comfort.

Table Pad (standard) - For patient comfort.

Table Extension Pad (optional) - For patient comfort.

Head Holder (optional) - The head holder is used for most routine child or adult CT head exams. The angle of the holder positions the head naturally for a routine brain scan and minimizes the required Gantry angle to achieve optimal results.

Coronal Head Holder (optional) - This head holder is used for coronal head scans of patients lying on their backs. The slope of the holder positions the patient with the neck extended and the head dropped back.

Flat Head Holder (optional) - The head holder is used for most routine child or adult CT head exams. The angle of the holder positions the head naturally for a routine brain scan and minimizes the required Gantry angle to achieve optimal results.

Head Arm Holder (optional) - To rest arms comfortably above the head.

Arm Support (optional) - To support patient's arm during transfusion.

Infant Cradle （optional）- For baby's support and immobilization.

Table Top Handle（optional）- To aid in table movement.

Table Top Extension Board（optional）- It is used for feet-first positioning of the patient. Examination up to the region of the thoracic spine is possible.

WARNING:

- **Only the patient's feet should be placed in this extension, as it does not support body weight.**

Patient Belt （Optional）-Patient restraints.

WARNING:

- **During all movements of the Gantry (automatic and manual) and the Couch, keep the patient under continuous observation to avoid hitting the patient against the Gantry or between the Couch parts, as well as to avoid disconnecting any infusion or resuscitation apparatus.**
- **During studies, the Couch or Gantry moves automatically. Ensure that there is enough clearance between the patient and the Gantry. Before initiating the scan, perform manual movements to check the clearance.**
- **Make sure that the patient is strapped securely to avoid dangling of the hands. Ensure that the patient is placed securely on the Couch and is not in danger of falling.**
- **Blood and contrast media are harmful for health. Safety and prevention measures should be in place when eliminate blood or remained contrast media.**
- **The fungicide should be approved by authoritative department to clean the cover, including couch, head supports devices and other accessories.**

CAUTION:

- **The couch can be damaged or broken. Once the couch has been damaged, accessories must be replaced. Otherwise, it may lead to safety issues affecting the patient and image quality.**

3.4 Module Accessories

- **7-10 inch tower module**: the module can be used to revise the CT device to make images even, no artifacts and obtain accurate CT value.
- **Ladder Module**: this module can be used to revise the CT device to ensure there is consistency among various receiving units in detectors to avoid annular artifacts.

- **QA Module（optional）**：it consists of head module and body module to evaluate the imaging performances including impulse response, slice thickness, linear CT value, evenness of CT value, noise.

These accessories are made of polyurethane and will not cause allergic reactions, including direct skin contact.

3.5 Key Technical Data

Table 3-6 Key Technical Data

The corresponding NOMINAL X-RAY TUBE VOLTAGE together with the highest X-RAY TUBE CURRENT obtainable from the HIGH- VOLTAGE GENERATOR when operated at that X-RAY TUBE VOLTAGE.	140kV,714mA
The corresponding highest X-RAY TUBE CURRENT together with the highest X-RAY TUBE VOLTAGE obtainable from the HIGH- VOLTAGE GENERATOR when operated at that X-RAY TUBE CURRENT.	833mA, 120kV
The corresponding combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which results in the highest electric output power.	120kV, 833mA
The NOMINAL ELECTRIC POWER given as the highest constant electric output power in kilowatts which the HIGH-VOLTAGE GENERATOR can deliver, for a LOADING TIME of 4s at an X-RAY TUBE VOLTAGE of 120kV.	100kW

Chapter 4 Daily Operations

Daily operations are introduced in this chapter. Read this chapter carefully to ensure proper operations of the system.

NOTE:

- **For most systems, it is recommended to keep the system on continuously. This applies to systems that have 24-hour air-conditioning.**
- **For the system without 24-hour air-conditioning, the gantry power must be turned off by pressing the Power Switch on the gantry side when the cooling is not available.**
- **When ready to resume scanning, follow the start-up procedures in System Start-up.**
- **If shut-down is necessary for maintenance purposes, perform the procedures in System Shutdown.**

4.1 System Start-up

Once meeting the environmental conditions, the system can start up immediately.

To start up the system:

1. Turn on the supply.
2. Turn on the Power Switch on the side of Gantry.
3. Turn on the power of the Console computer.
4. Log into the software.
   - Click the Start button on the desktop, and then select NeuViz Prime Host in the displayed menu.

WARNING:

- **Do not press the bottom buttons in horizontal server cabinet without the guidance of Neusoft specialist.**

NOTE:

- **If the software doesn't respond to the operation, press Alt and Pause on the keyboard at the same time to log out of the software.**

4.2 System Shut down

To shut down the scanner:

1. Log out of the software.
2. Turn off the Console computer.
3. Turn off the Power Switch on the side of the Gantry.

If the temperature of tube is too high, gantry monitor will show the shutdown countdown. The system will shut down when the time is up.

WARNING:

- **Comply strictly with the start-up and shutdown system procedures.**
- **When logging out of the software, if a dialog prompt appears to confirm whether to shutdown the anode, click 'Yes'.**
- **Do not shut down the console computer until logging out of the software.**
- **It is strongly recommended that the wall power is not cut off.**
- **The wall power will keep the DMS inner temperature constant. If the wall power is cut off, at least 1 hour is required to restore the constant inner temperature of DMS before restarting NeuViz Prime.**

4.3 Tube Warm Up

Tube Warm Up is a process that brings the tube to normal operating temperature after a pause in system operation. This process is required daily before any scans can be performed on patients. When the tube heat is too low, a message will appear to remind the operator to perform Tube Warm Up.

To warm up the tube:

1. Ensure that there is nobody in the scanner room.
2. Ensure the scanner room door is tightly closed.
3. Select **Service** on the workflow bar.

Service interface appears.

4. Click **Tube Warm Up**.

Tube Warm Up interface appears.

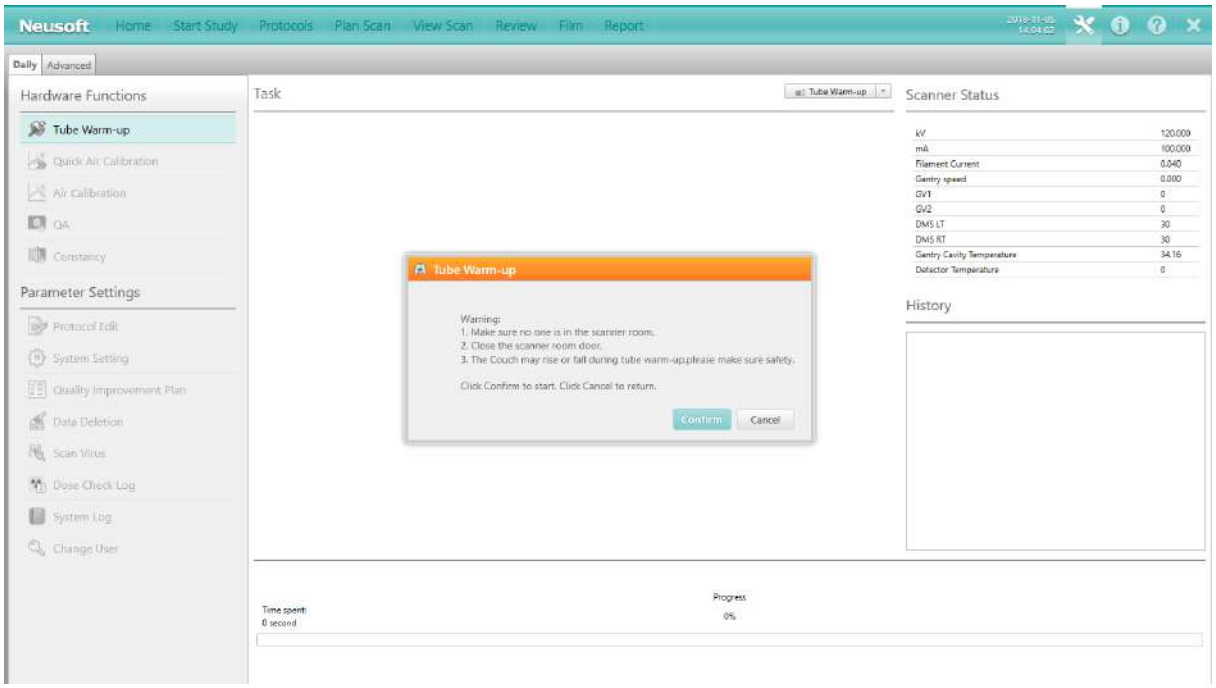


Fig 4-1 Tube Warm Up Interface

5. Perform the operations following the prompts. After the process completes, a message "Tube warm-up completed" appears.

WARNING:

- **Do not perform Tube Warm Up when there is a person in the scanner room.**
- **When using，if there is warning that tube heat is too low, please warm up in advance.**

NOTE:

- **If warm up needs to be terminated, please click the stop button on CT-Box or the cancel button on the interface of warm up to terminate the warm up.**

4.4 Quick Air Calibration

Quick air calibration is a part of daily system maintenance. A complete air calibration is recommended to be performed once a week to ensure image quality. Air calibration must be performed under a stable operating temperature, after scanning a few patients. The complete process takes about 20 minutes.

To perform the quick air calibration:

1. Ensure there is nobody in the scanner room.
2. Ensure the scanner room door is tightly closed.
3. Select **Service** on the workflow bar.
4. Click **Quick Air Calibration**.

Quick air Calibration interface appears.

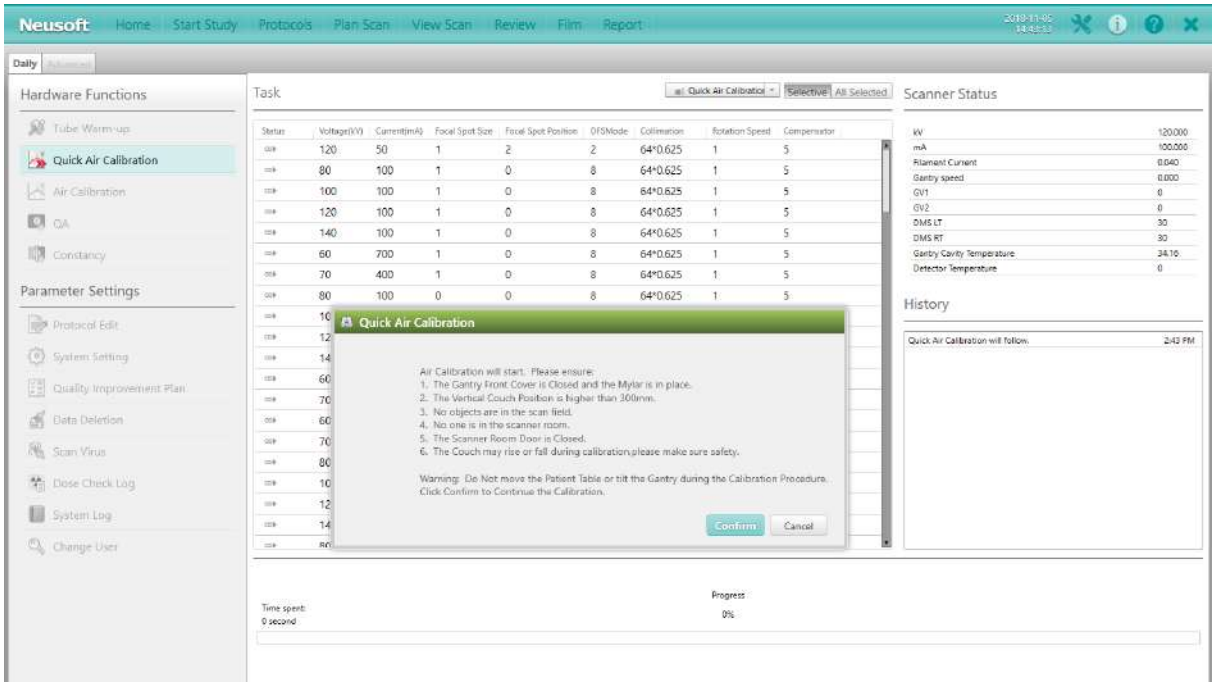


Fig 4-2 Quick Air Calibration

5. Select a calibration mode to perform:

- **All Selected:** to perform all calibration modes.
- **Selective:** to perform selected calibration mode.

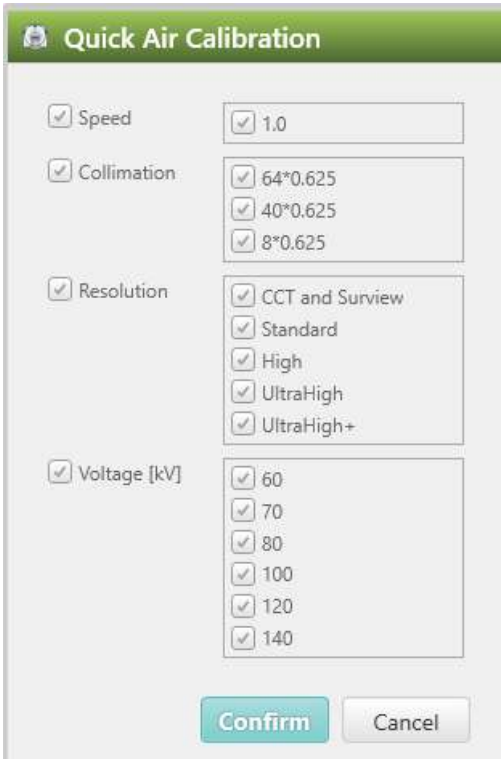


Fig 4-3 Selective Parameters

6. Click **Confirm**.

NOTE:

- **Quick air calibration requires a certain tube heat. If the tube heat is too low, the system will perform tube warm automatically before starting Quick Air Calibrations.**

7. Click **Stop** to stop the calibration if necessary. When clicking Fast Air Calibration again, you may select "to continue the last calibration".

8. Click **Exit** and go back to **Service** interface.

4.5 Air Calibration

Air calibration is a part of daily system maintenance. A complete air calibration is recommended once a week to ensure image quality. Air calibration must be performed under a stable operating temperature, after scanning a few patients. The complete process takes about 2 hours.

To perform the air calibration:

1. Ensure there is nobody in the scanner room.

2. Ensure the scanner room door is tightly closed.

3. Select **Service** on the workflow bar.

4. Click **Air Calibration**.

Air Calibration interface appears.

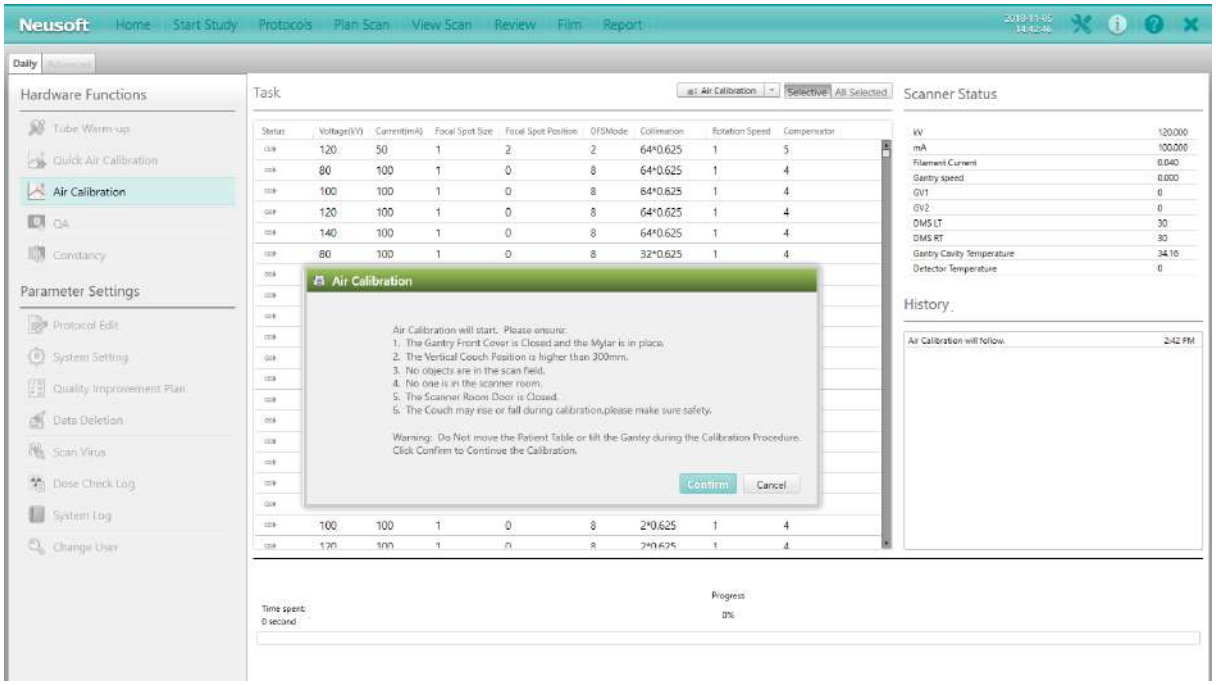


Fig 4-4 Air Calibration

5. Perform the operations following the prompts in the **Air Calibration** dialog box.

6. Select a calibration mode to perform:

- **All Selected:** to perform all calibration modes.

- **Selective:** to perform selected calibration mode.

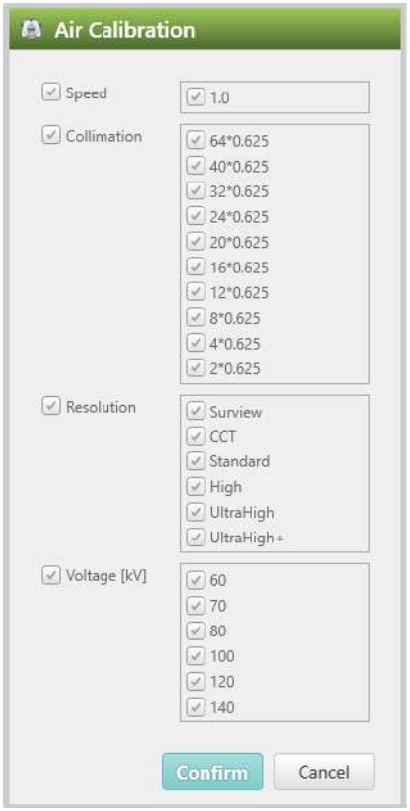


Fig 4-5 Selective Parameters

7. Click **Confirm**.

NOTE:

- **Air calibration requires a certain tube heat. If the tube heat is too low, the system will perform tube warm automatically before starting Air Calibrations**

8. Click **Stop** to stop the calibration if necessary. When clicking Air Calibration again, you may select "to continue the last calibration".

9. Click **Exit** and go back to **Service** interface.

WARNING:

- **Do not perform air calibration when there is a person in the scanner room.**

NOTE:

- **Air calibration requires a certain tube heat. If the tube heat is too low, the system will perform tube warm automatically before starting Air Calibrations.**

- **Please perform air calibration in the following condition:**
- **Use the tube for the first time**
- **Tube hasn't be used for 7 days or more than 7 days**
- **Fail to perform tube warm up**

4.6 Patient Positioning

Press relevant buttons on the Gantry control panels to move the Couch, switch on/off the Patient Positioning Light and tilt the Gantry.

The maximum patient weight that the Couch can support is 205kg (300kg for USA, optional).

Pay more attention when positioning heavy patients on the Couch.

Make sure it is safe for the patient when moving the Couch or tilting the gantry before scanning.

The stability of the Couch is not at risk when scanning a heavy patient, but precisions (such as the moving and localizing precisions) cannot be guaranteed 100%.

The Couch extension can be used to support the patient's legs when the patient lies on the couch on his/her back with legs towards the gantry.

Use the head holder/flat head rest for head scans and the coronal head holder for supine coronal head scans.

WARNING:

- **Only use the disinfectants approved by the relevant governing authority to clean the surfaces of the system including the couch, head holders and other accessories.**

4.6.1 To tilt the Gantry

To tilt the Gantry, use the movement controls:

- On one of the Gantry control panels
- On the CT-Box

When tilting, the Gantry will keep moving with a 1.5 second stop at zero position. The tilting will cease until the button is released.

NOTE:

- **Lower or raise the Couch if the Couch height limits the range of Gantry tilting.**

4.6.2 Couch Movements

Couch up/down

To vertically position the region to be scanned from the lowered position (where the patient can sit and then lie down on the Couch in the Gantry opening), use the Couch up or Couch down button to properly adjust the Couch position.

Couch in/out

To bring the patient's region of interest into the Gantry opening, use the Couch in or Couch out button.

Press Couch in to move the Couch toward the Gantry; Press Couch out to move the Couch away from the Gantry. The couch can be moved out/in in 1mm increments or greater.

Press and release relevant buttons for fine adjustment.

To move the Couch and Gantry manually

To move the Couch and tilt the Gantry, use the movement controls:

On one of the Gantry control panels

On the CT-Box

Release the buttons to stop.

WARNING:

- **Do NOT put feet on the side of Couch or between the Couch and the Gantry when the Couch and Gantry are moving.**
- **Do NOT put fingers into the gap between the Couch and its extension, or the gap between the Couch and the Couch top.**
- **Avoid putting any other devices under the Couch (such as wheelchairs, IV pumps or stretchers). The Couch may collide with them when moving.**

To move the Couch automatically

In automatic mode, when it is necessary to press the Enable button, the system will prompt as below:

A message displays on the screen to prompt using the Enable button.

The Enable LED lights.

When planning a Surview scan or in the scan interval, the Enable button can assist with automatic positioning the patient horizontally or in a tilting angle.

Press and hold the Enable button.

The Enable LED will remain lit in the process of Couch movement until it stops. The horizontal indicator will glimmer during Couch movement. The Couch position and the Gantry angle are fixed as planned when the Enable LED turns off.

Adjust the Couch position manually if necessary.

Release Enable to stop movement immediately.

If Enable is released before reaching the desired position, press and hold Enable again.

WARNING:

- **When bringing an unrestrained child into the Gantry opening, be prepared to prevent him/her from reaching out to grab the Gantry control panels (especially the buttons on the Gantry control panels).**

NOTE:

- **Raise the Couch if the height is too low to move the Couch in.**
- **When performing the emergency stop, the Couch will stop moving within 10mm.**
- **Make sure the height of the Couch is high enough (above 280 mm) to avoid colliding with the Gantry when moving the Couch in manually with the footswitch.**

4.6.3 Patient Release

The Patient Release button on the Gantry control panel can help to release the patient. This will zero tilt the Gantry, and move the Couch out of the Gantry to the max position. When these two steps are completed, the Couch will descend.

NOTE:

- **All movement will stop when the Patient Release button is released.**

Or use Tilt to adjust the Gantry to the vertical position, move the Couch out of the gantry to the max position, and then lower the Couch.

4.6.4 Emergency Patient Release

Press the emergency patient release button to float the couch top. Then move the couch top to release the patient from the Gantry quickly.

If the patient's head is on the side of the Gantry opening, and the limbs are on the other side, release the patient from the leg side.

If the head is too close to the top of the Gantry opening, follow the steps below:

Take away the head support or pillow to lower the head position.

Move the Couch extension.

Turn the head to one side.

WARNING:

- **The Couch will be locked for 2 seconds after pressing the Emergency Stop button; then manually move the Couch horizontally, but not vertically.**

To release the patient during a power failure, please do one of the following:

To move the patient out:

1. Pull the patient out of the Gantry opening if possible.
2. Help the patient dismount.

To move the patient in:

1. Push the patient to the other side of the Gantry if possible.
2. Help the patient dismount.

NOTE

- **In the event of a power failure or an Emergency Stop, it is impossible to move the Couch down. Therefore, it would be advisable to keep a stool or a stepladder on hand.**

Chapter 5 Home

5.1 Home Interface

Home interface is the default display after starting up the system. It consists of a Workflow bar, a Control panel, Data source tools, a Patient information list, an Image information list and an Image display area.

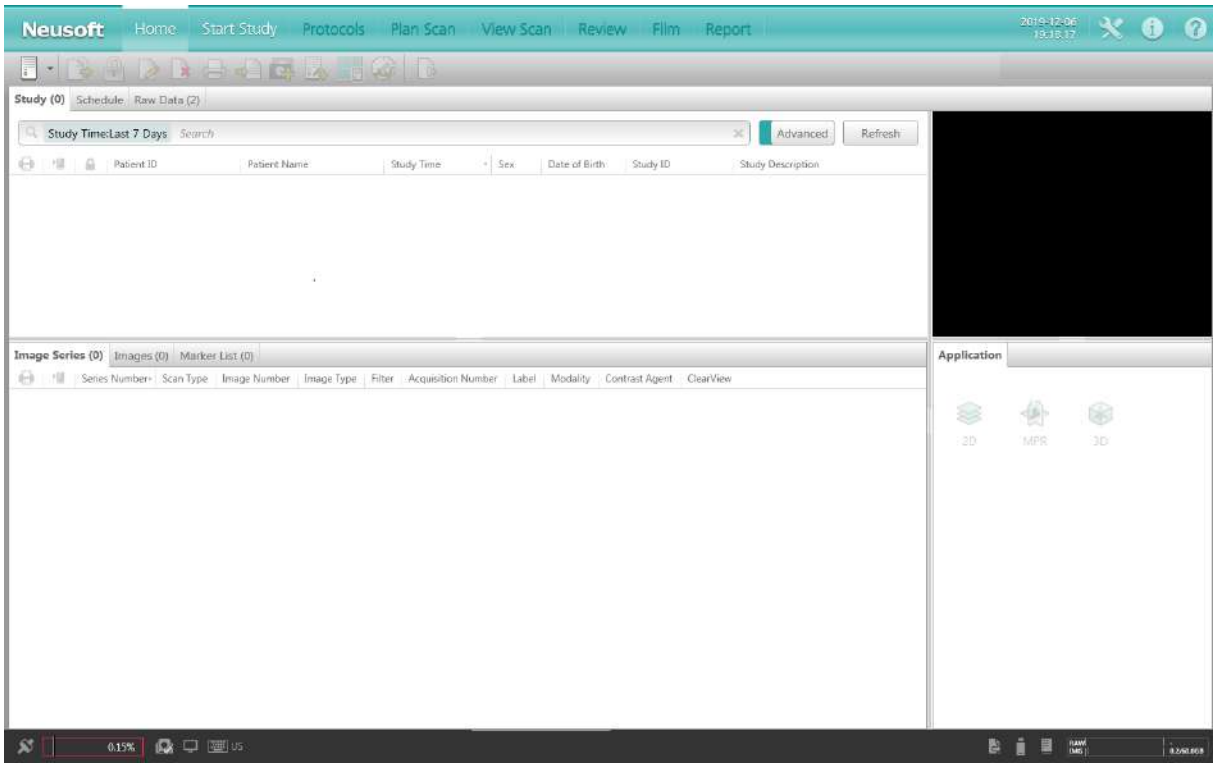


Fig 5-1 Home Interface

Table 5-1 Home

No.	Name
1	Workflow Bar
2	Study
3	Schedule
4	Raw Data
5	Image Information List
6	Image Display Area
7	Application
8	Status Bar

5.2 Workflow Bar

The workflow bar is at the top of the Home interface. Selected options will be highlighted. If the option is not selectable, it will display as grey.

The workflow bar includes:

Fig 5-2 Workflow Bar

1. **Home:** To toggle Home interface.
2. **Start Study:** Displays patient registration page.
3. **Protocols:** To select the scan protocol.
4. **Plan Scan:** To plan the scan.
5. **View Scan:** To review the images after scanning.
6. **Review:** To view images and have access to all post processing applications.
7. **Film:** To view and rearrange the images prior to printing.
8. **Report:** To visit the reports.
9. **Service:** To perform Service Tasks and select System Settings.
10. **Message Center:** System message center.
11. **Help:** To provide System Product Information.

5.3 Study

Click **Study** to enter Patient Study Interface.

5.3.1 Study Tool Bar

Fig 5-3 Study Tool Bar

1. **Data source device:** To view patient data source devices of the system.
2. **Copy to**: To copy the selected patient to other devices.
3. **Lock**: To lock the selected patient. After locking, modification of the patient's information is not permitted.
4. **Modify**: To edit the patient information.

All information can be modified, including Patient ID, First Name, Last Name, Sex, Age, Date of Birth, Patient's Height, Patient's Weight, and Description and so on. Ensure the validity and authenticity of the patient information.

Click **Confirm** to complete the modification. After confirming the modification, another copy of the modified information is stored. The original patient information is not changed.

5. **Delete**: To delete the selected patient and the patient information. This function is optional.
6. **Film**: To send the selected images to the print interface.
7. **Report**: To send the selected images to the report interface.
8. **Combine**: To combine images. This will decrease the number of images for printing/saving. In addition, the image quality will be decreased.

   If the operation is successful, the newly generated image sequence information will be displayed in the image series list.
9. **Offline Reconstruction:** Use this procedure to reconstruct raw data. See detailed introduction in Chapter 6 about **Recon.**
10. **Perform Air Calibration**: Perform air calibration for weekly maintenance or if the quality of the image is not good.
11. **Start New Study**: To start a new scan process.

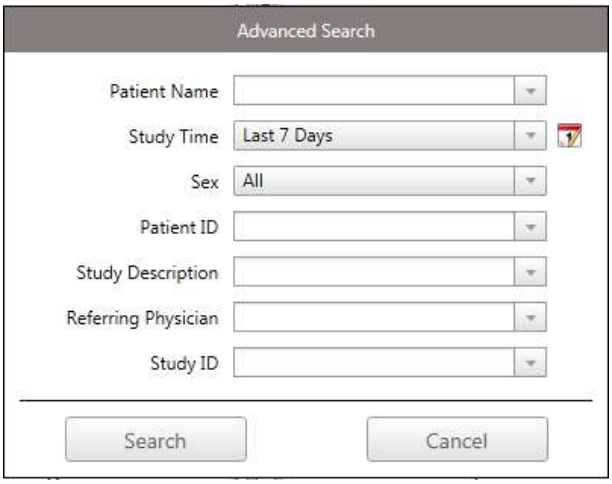


Fig 5-4 Advanced Search

Advanced Search: Click Advanced Search window and patient's information can be searched by Name, Study Time, Patient ID, etc.

5.3.2 Patient Information List

The Patient Information List displays all the patient information of the specified date source, including: Patient Name, Patient ID, Study Time, Sex, Description, etc. Type in the specific icon or letter to filter the results of the patient list you want. Various search methods are provided to search the needed data. It can search information with a single condition or multiple conditions.

Select the data source from the data source device on the upper left side of the Home interface. Click a patient record in the list area and the corresponding row will turn blue indicating that the patient information is selected. The corresponding scan or image series information is displayed in the image information list and image display area.

The printing, sending and locking marks in the patient information list are separately listed, and sorting is supported.

The printing mark or sending mark will be displayed on the Patient Information List, if a patient sequence has been printed or sent to report.

Right click selected information list, in the popped-out menu, the information can be copied, deleted, locked, altered, printed, and sent to report. In addition, start new checks, send images to post-processing and air calibration etc.

5.4 Schedule

Click **Schedule** above the patient information list to enter the **Schedule** interface.

Fig 5-5 Schedule Tool Bar

1. **Data Source**: Select the data source such as local.
2. **Schedule**: Manually pre-register patients. If HIS/RIS is connected to the scanner, an additional worklist tab will display in the Schedule tab.
3. **Delete**: Delete selected scheduled patient from the list.
4. **Reschedule**: Modify the scheduled patient information.
5. **Start New Study**: Start the new study process with the scheduled information.
6. **Search**: Search in the scheduled list.
7. **Bar Code Scan**: Select the text box, and then scan the bar code with bar code reader, the scanned patient information will be displayed in the list.

NOTE:

- **Select Reserved Patient: The patient information needs to meet the reserved agreement coding. After clicking Patient Reservation, the system will automatically load scan protocol and directly enter the plan scan interface.**

5.5 Raw Data

Click **Raw Data** to enter the raw data information interface.

Fig 5-6 Data Tool Bar

1. **Lock**: To lock the selected patient. After locking, modification of the patient's information is not permitted.

2. **Modify**: To edit the patient information.

All information can be modified, including Patient ID, First Name, Last Name, Sex, Age, Date of Birth, Patient's Height, Patient's Weight, and Description and so on. Ensure the validity and authenticity of the patient information.

Click **Confirm** to complete the modification. After confirming the modification, another copy of the modified information is stored. The original patient information is not changed.

NOTE:

- **Do not attempt to change the information which is retrieved from HIS/RIS. The function is only available for manually inputted information.**

3. **Delete**: To delete the selected patient and the patient information. This function is optional.

4. **Export Raw Data**: To export raw data to local disk, USB disk or DVD.

5. **Offline Reconstruction:** Use this procedure to reconstruct raw data. See detailed introduction in Chapter 10 about **Recon.**

6. **Perform Air Calibration**: Perform air calibration if the quality of the image is not good.

7. **Start New Study**: To start a new scan process.

5.6 Image Information List

On the check interface, the image information list the following information:

Image Series: Displays all series information, including Series, Images, Acquisition Number, Label, Modality, etc.

Images: Displays the image information, including Image Number, Slice Location, Description, Image Type, etc.

Marker: Marker is a tool that you can use during your work flow to "save the state" of the current application. You can re-open marker in Home to return to previous saved states.

On the raw data interface, the image information list review the following information:

Scan series: Displays the scan series information, including Series Number, Scan Type, kV, mAs, etc. In the meanwhile, original image marker page turns to raw data marker page.

Raw data: Displays raw data information.

Data: display ID. Right click the selected images or series, in the pop down menu, the patient information can be copied, deleted, locked, altered, transferred to reports, start new checks, transferred to image post-processing, air calibration and export raw data etc. Click the mouse or roller can browse the images forward and backward.

5.7 Image Display Area

The Image Display Area is used to display loaded images. From the image list, select a desired series/image, then the selected image(s) will be shown in this area. Scroll the wheel up and down to review the images forward or backwards. After loading a series, the image display area automatically displays the first image of the series (the image with smallest image).

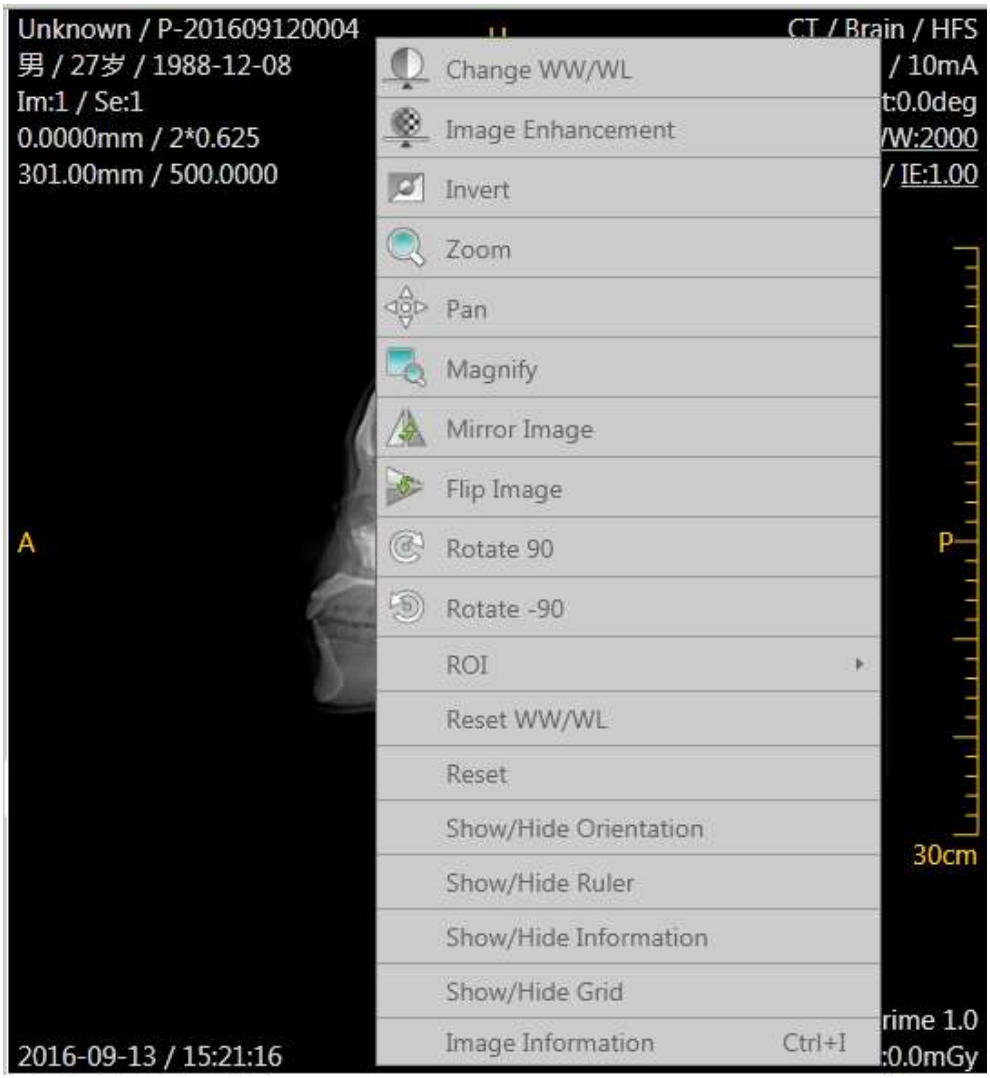


Fig 5-7 Context Menu

Right-click on the image display area and the Context Menu appear. You may change the image Window Level and Window Width display, enhance the image, zoom, pan, and mirror, flip the image, draw ROI on the image and show/hide image display information(ruler, gray bar, grid),etc.

5.8 Application

Application area displays image post-processing function. See details in user manual volume Two.

5.9 Status Bar

In the status bar, from left to right, displays Tube State, Gantry Connection State, Remote Service Request, Input Method, Queue Manager, Film, Disk List, Recon Manager, and Disk space condition.

Fig 5-8 Status Bar

1. **Tube State:** When the tube heat is too low, it will pop up a prompt to warm up the tube.
2. **Gantry Connection State:** To display current gantry connection state, including normal state, warning state, error state and off-line state.
3. **Remote Service Request:** To feedback question description, contact number and email to the service platform.
4. **Input Method:** To display current input method, users can change input method by clicking it.
5. **Queue Manager:** To click **Queue Manager** to enter the queue management interface, then the transferring, printing and receiving the queue can be viewed and operated.

Fig 5-9 Queue Manager Tool Bar

1) **Up**: Move the selected task up in the queue.
2) **Down**: Move the selected task down in the queue.
3) **Move to top**: Move the selected task to the top of the queue.
4) **Move to bottom**: Move the selected task to the bottom of the queue.
5) **Remove**: Remove the selected task from the queue.
6) **Pause**: Pause or resume the selected task.
7) **Pause all**: Pause all tasks in the queue.
8) **Resume**: Retry the selected task.
9) **Resume all**: Retry all the tasks in the queue

Transfer:

Transfer Filter : Sort and display the queue by the status: All, Start, Pause, Waiting, Finish and Failed.

Transfer Queue List : List the queue information in the process of transferring. The task list can reveal the task condition, current schedule, patient ID, patient name, server, local AE, client application title, distant IP, distant port and the start time of tasks.

Receive:

Receive Queue List : List the queue information in the process of receiving. The task list can reveal the patient ID, patient name, check number and image numbers.

6. **Disk List:** Click it and it will display current mobile device. Users should use this function to popup USB device to avoid data loss.
7. **Recon Manager**: Click the **Recon Manager** displays all the reconstructing tasks.

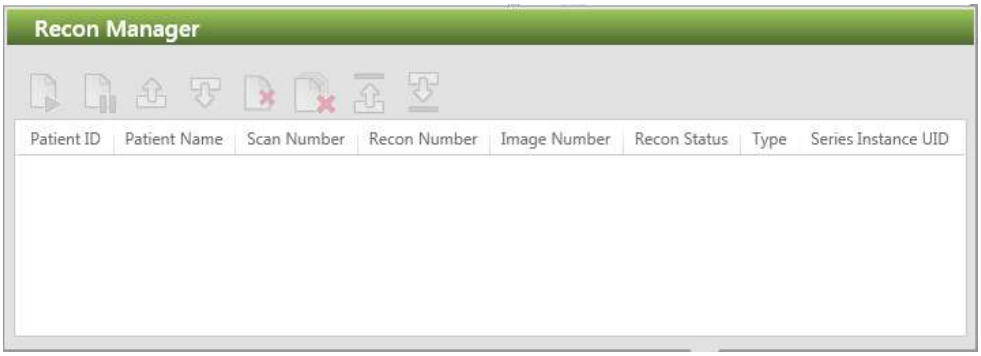


Fig 5-10 Recon Manager

In the list, the task information includes: Patient ID, Patient Name, Scan Number, Recon Number, Image Number, Recon Status, Type and Series Instance UID.

Resume: Retry the selected task.

Pause: Pause or resume the selected task.

Up: Move the selected task up in the queue.

Down: Move the selected task down in the queue.

Remove: Remove the selected task from the queue.

Remove all: Remove all the tasks in the queue.

Move up to the top: Promote the priority of selected reconstruction task to the top.

Move down to the bottom: Decline the priority of selected reconstruction task to the bottom.

NOTE:

- **If the operator wants to remove a task while reconstructing, select series, select pause, then delete.**

8. **Disk Space Condition:** Displays raw data capacity and image capacity in recon computer.

Chapter 6 Scan

A typical scanning includes the following procedures:

- Enter patient information
- Select an exam protocols
- Plan a scan
- Perform a scan
- Review a scan

The scanning process is set up and initialized from the scan control panel on the monitor. Couch movement is controlled by the CT-Box outside of the scanner room or the Gantry control panels inside of the scanner room. This section provides detailed steps to complete a typical exam procedure, as well as descriptions of the available options.

NOTE:

- **In addition to the scanning options, the options to film and conduct post-processing analysis are also available.**

⚠

WARNING:

- **Before beginning a CT scan, a surview is used to determine if implanted or externally worn electronic medical devices are present. If so, their location relative to the programmed scan range.**
- **For CT procedures in which the medical device is in or immediately adjacent to the programmed scan range, the following items should be completed:**
  - **Determine the device type.**
  - **If possible, try to move external devices out of the scan range.**
  - **With medical permission, ask patients with neurostimulators to shut off the device temporarily while the scan is performed.**
  - **Minimize X-ray exposure to the implanted or externally worn electronic medical device by:**

- **Using the lowest possible X-ray tube current consistent with obtaining the required image quality**
- **Ensure that the X-ray beam does not dwell over the device for more than a few seconds**

NOTE:

- **For CT procedures that require scanning over the medical device continuously for more than a few seconds, as with CT perfusion or interventional exams, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.**
- **After CT scanning directly over the implanted or externally worn electronic medical device:**
- **Have the patient turn the device back on if it had been turned off prior to scanning.**
- **Have the patient check the device for proper functioning, even if the device was turned off.**
- **Advise patients to contact their healthcare provider as soon as possible if they suspect their device is not functioning properly after a CT scan.**

6.1 Patient Information Entry

6.1.1 Patient Information Entry

Click **Start Study** button, the patient information interface displays.

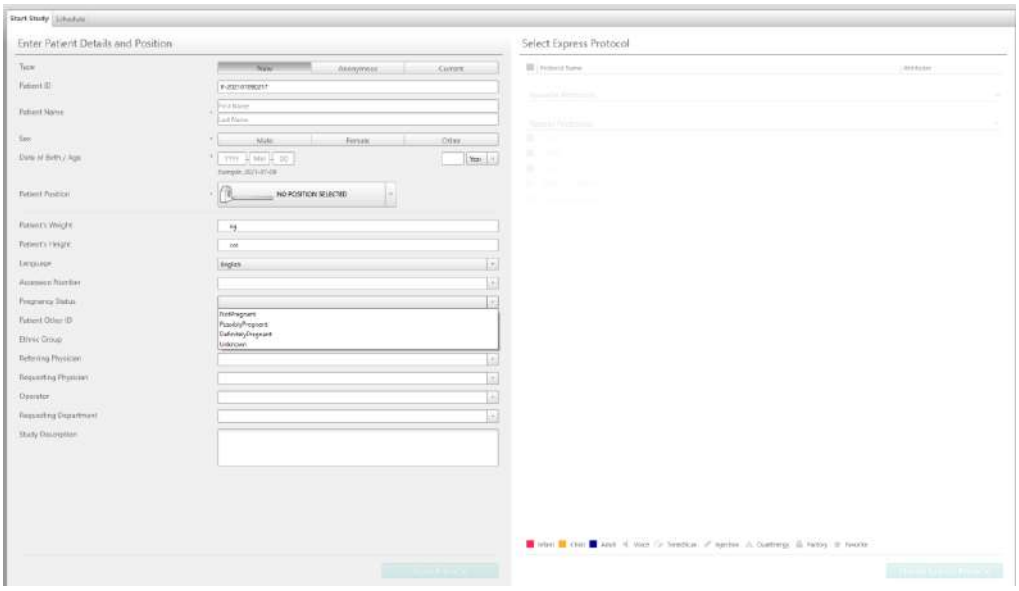


Fig 6-1 Start Study

The following methods all can be used to enter patient information:

For new patients, click **New**.

For current patients, click **Current**. System will fill the current patient information with the last patient information by default.

For anonymous patients, click **Anonymous**. System will automatically fill in the patient information according to the system setting. Date of Birth, Gender and Position are excluded.

For patients in the current patient list, click **Schedule** in the workflow bar. Detailed Operation should refer to **5.4 schedule.**

To edit the scheduled patient information

Select **Schedule** on the workflow bar.

Select the patient whose information needs to be edited in the **Scheduled** list.

Click the **Reschedule** button in the **Operation** area.

Edit the patient information in the displayed interface.

NOTE:

- **Patient ID, Patient Name, Date of Birth, Gender, Age and Position are mandatory fields by default, which all have a red asterisk. After filling in Patient's Weight and Patient's Height, the BMI value will be automatically displayed following Patient's Weight. Other patient information can be selected to fill in. If mandatory fields are not filled in, exam protocol is grey and the next exam protocol cannot be entered.**
- **Before proceeding to protocol selection, verify that the patient information loaded into the patient data fields (from any source) is correct. Failure to do so could result in scanning a patient with the wrong information.**
- **Using anonymous patient registration: If the user does not input the necessary information, the system will prompt the user to input the data during the next step of the patient entry process.**
- **The mandatory fields such as Date of birth and Age can be set in system setting.**

6.2 Select an Exam Protocol

6.2.1 Select an Exam Protocol

An exam protocol is required to be selected during the scan procedure. In order to

acquire optimal images, the factory exam protocols are recommended. See all the details about factory protocols in attachment.

Click **Exam Protocols** in the lower right corner of the window, or click the **Protocols** workflow button. The system displays the **Exam Protocols.**

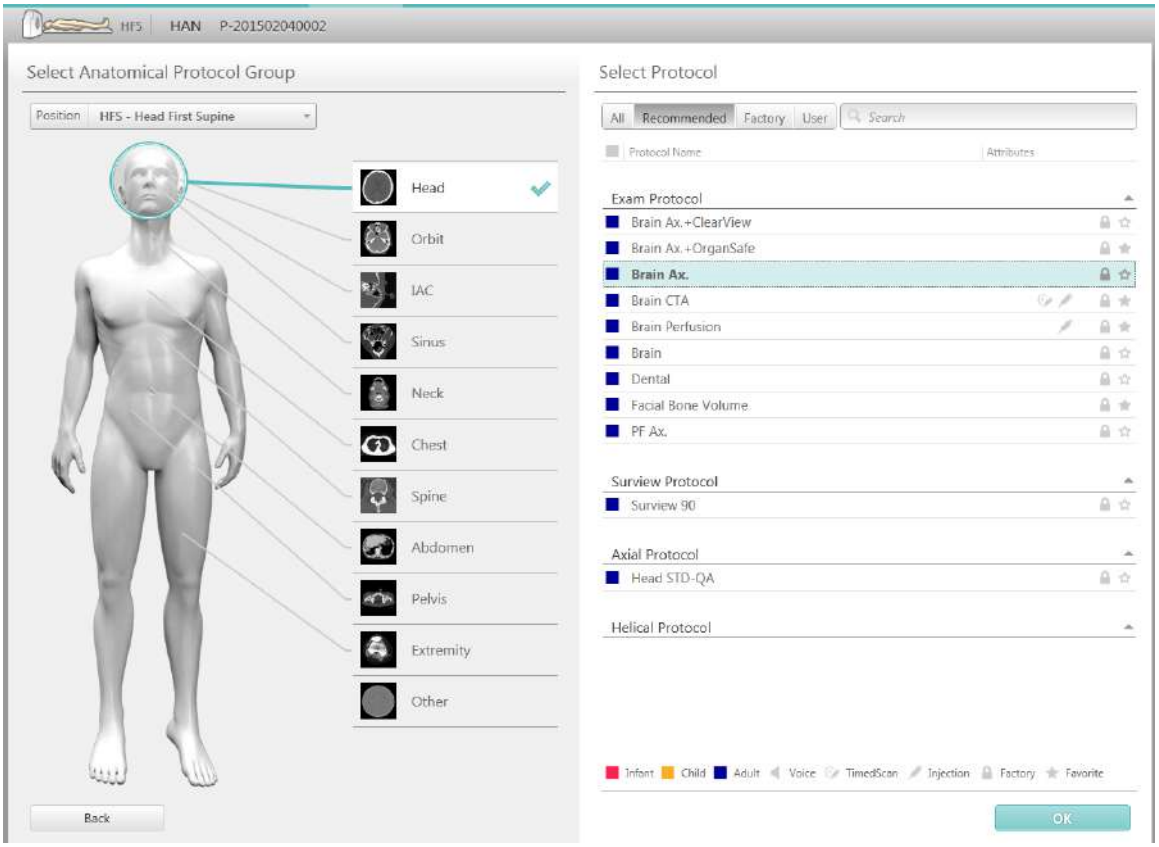


Fig 6-2 Exam Protocols

Protocol groups can be divided into head, orbit, IAC, Sinus, neck, chest, spine, abdomen, pelvis, extremity and other. Each protocol group contains several factory protocols. It is recommended to use factory protocol for consistent image quality. Select a desired protocol group, and then select the exam protocol.

Where:

- Pink: protocols for infants
- Yellow: protocols for children
- Blue: protocols for adults
- : To denote factory protocols that cannot be altered.

- : To denote timed scan or Bolus tracking is selected.

- : To denote scanning with Injector.

- : To denote scanning with auto voice instruction.

- : To denote the protocol has been added in Favorite Protocol.

- : To denote the protocol is a cardiac protocol.

- ： To denote the protocol is dual energy protocol.

The left label page of the protocol group can offer extra categories which includes protocol, surview, axial scan and helical scan.

The menu above the protocol can be filtered through recommending, all, factory and users. Filtered protocol will be on the interface. Users can enter key words of protocol to search protocols on the top and right interface. This function support blur search.

Users can select protocols through the following methods:

- Double click selected protocol
- Click the selected protocol, press confirm button.

Users can sequence by pulling the mouse and sequenced state will be saved automatically.

NOTE:

- **Most of those protocols without above icons could also be used with enhanced/timed scanning and Bolus tracking.**
- **In Protocol Group Interface, patient's Position can be changed.**
- **Recommended protocol is based on the patient's age and BMI. The system automatically selects the appropriate scanning protocol.**

Click a protocol to enter the scan window.

6.2.2 Express Protocol Selection

After filling in the information, express protocol selection can be performed on the right side of interface.

Express protocol selection function provides a way for users to quickly select an exam protocol. The user can directly select a required exam protocol in the patient registration interface.

Express protocol selection is divided into two parts:

- **Favorite Protocols:** It includes frequently used protocols. Users should add favorite protocol into Favorite Protocol manually by clicking on the star mark on the right of the protocol.

- **Recent Protocols:** It includes protocols user used recently. System will add recent used protocols to this area automatically.

Users can sequence by pulling the mouse and sequenced state will be saved automatically.

6.3 Plan a Scan

1. After selecting one protocol, the plan scan window appears. It can be divided into interfaces of surview, axial scan and helical scan. The **Plan Scan** button in the workflow bar will be highlighted.

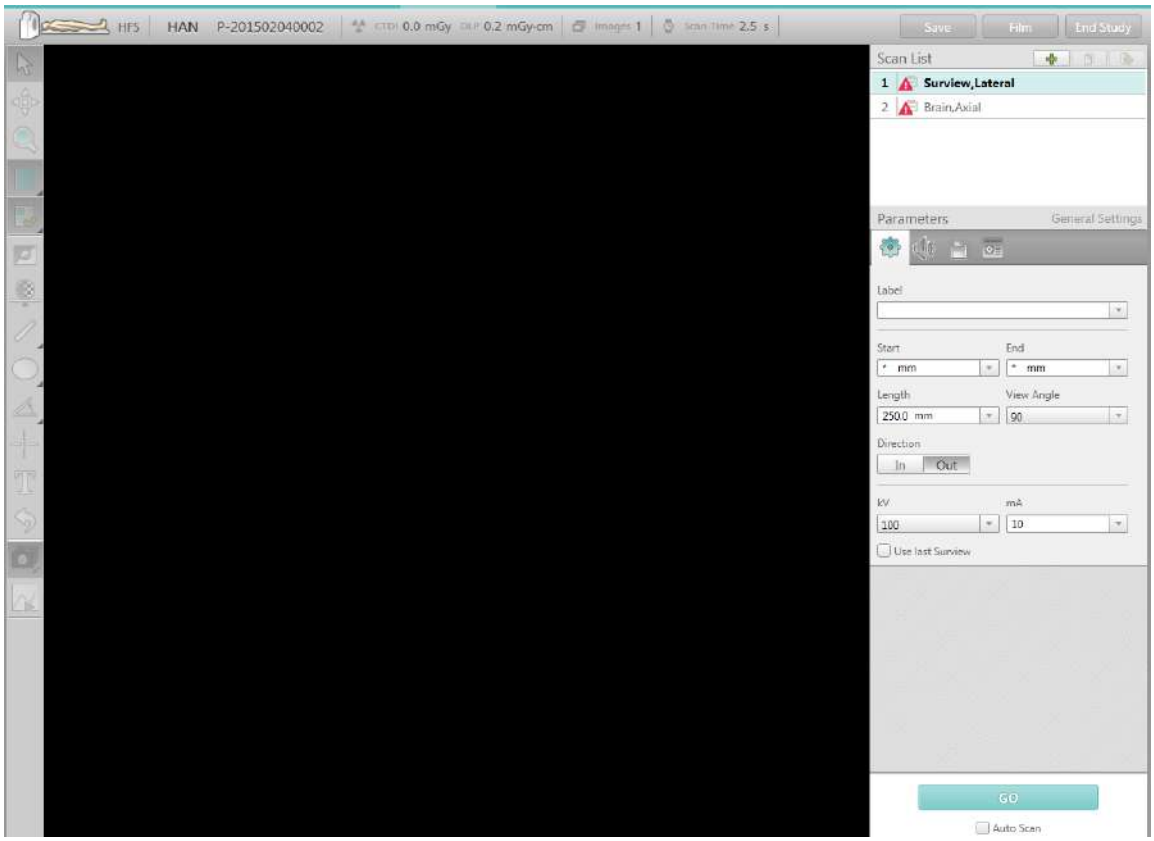


Fig 6-3 Plan Scan

2. Edit the scan parameters in the window if necessary. Confirm all parameters.

3. Click **GO** to start the scan. If the system is ready, the scan prompt will be popped up.
4. There is an arrow button below **GO**. Click it and select **Auto Scan**, the scanner will automatically sequence between two non-timed series without clicking **Next Series**. The user only confirms the status of couch and gantry and then begins by pressing the Scan button.

Fig 6-4 Auto Scan

6.3.1 Patient Information

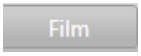
The left top corner displays the patient ID, the patient name and the position.

6.3.2 Toolbar

6.3.2.1 Surview Plan Scan Toolbar

Save: Click the save button on right top corner to save the current plan scan window. It can be saved in the formats of DICOM (derived), DICOM (original) and DICOM (secondary), BMP, JPG, PNG and TIF; It can be saved to local and other data sources; it can adjust the image size and add the image descriptions.

Fig 6-5 Save Option



Film: Click the save button on right top corner to send the images in the plan scan window to Filming.

End Study: Click 【**End Study**】on the top right corner, after ending study, a prompt will pop up to conform the operation, click【Yes】to end the end study. If click 【automatically transfer dose report】, the system will automatically send the dose report.

Fig 6-6 End Study

 **Inverse**: To reverse the grey levels of the image and display negative film.

 **Select**: Fast leafing and also for deselecting the graphics, zoom, and pan button, thus enabling the selection of images.

 **Pan**: To move the selected images within the window.

 **Zoom**: To magnify or reduce the images.

6.3.2.2 Axial/Helical plan scan toolbar

 : Image display layout. From the left, they are 1*1 layout, 2*2 layout, 3*3layout and 4*4 layout.

 : Image display mode. From the left, they are select image, select series and select all.

Select Image: To select an image or more images in the image display.

Select Series: To select a series, which includes the selected image in the Image Display.

Select All: Select the entire series in the image display.

 **Image Enhancement**: To enhance or smooth the images.

Auto Scroll: To automatically scroll to review the images or not.

Time Lapse Mode On/Off: TIBT protocol applies to continuous scanning while injecting contrast in the same slice for the same position. Users can use Time Lapse function when scan interval is 0 in axial scan. Select Time Lapse function, users should draw a region of interest (ROI) in a particular zone of the image, and it will display a CT value changing over time. Users could draw ROI in different images from the first scan lap, and the drawn ROI will be saved when switching images. This function helps doctors to analyze the absorption of contrast agent changing over time.

Fig 6-7 Time Lapse

6.3.3 Series list

6.3.3.1 Composition of series list

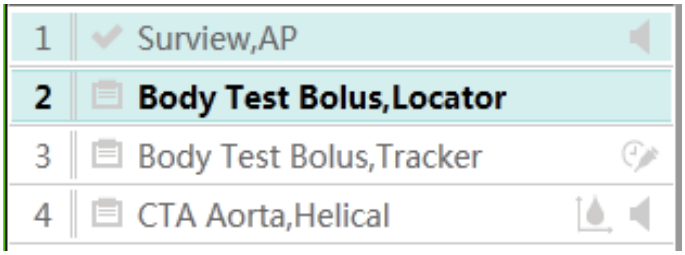


Fig 6-8 Series list

The list includes:

- The scan order of each series, such as 1, 2, 3, etc.
- The scan status, which updates with the scan progress.

- : Scan is planned.

- : Scan is completed.

- : Recon is in progress.

-  : Online recon is paused.

- : Series is added in task queue, waiting for scanning.

  The name of series include:

  — protocol

  — series description（if exists）

  — Surview / axial / helical scan

  — Surview include 180° surview（tube location 180°）、90° surview（tube location 90° ）and double surview（tube location Dual）.

NOTE:

- **When selecting Dual Surviews the system will scan with the tube in 180° position, according to the scan direction selected (couch in/out). The next Surview will be acquired at 90° position, starting from the end location of the first Surview, with the same length. Both Surviews can be used for**

planning.

- **When using Dual Surviews, the system has a Skip function. This allows the user to press Skip during the active 180 degree Surview to shorten the length of the scout. The following 90 degree Surview will match the area covered in the 180 degree Surview.**
- **Yellow caution or Red error icons will be listed in the series, indicating changes or errors. Yellow icons prompt the user of a change. Red icons indicate errors that must be addressed to continue.**

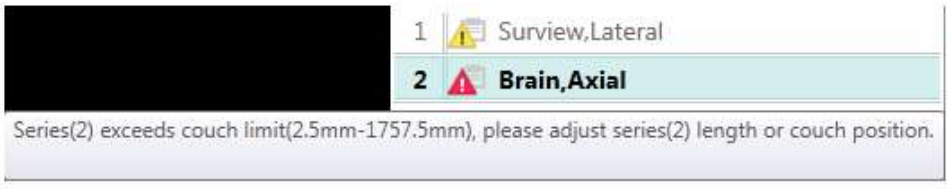


Fig 6-9 Warnings or Errors Prompt

6.3.3.2 Edit series

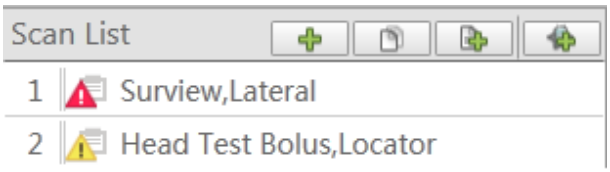


Fig 6-10 Edit series Tools

Insert Protocol: To add a scan series.

- Select one series in the scan list. This series will be highlighted.
- Click this icon, it displays the protocol group.
- Select one protocol, the new scan series is inserted under the last highlighted scan.

NOTE:

- **If the new series has a Surview, the Surview will be automatically cancelled in the series list.**

Copy Series: To duplicate a scan.

- Select a series excluding surview in the scan list, this series is highlighted.
- Click Copy Series.

  The duplicate Series will follow the prior scan series.

 **Add Recon**: To add reconstruction into the current series

Select one series in the scan list. This series will be highlighted.

Click the Add Recon button. The additional reconstruction will follow the last highlighted series.

NOTE:

- **The recon can be moved, pasted or deleted.**

 **MPR Recon:**

- Select one series except the surview in the scan list. This series will be highlighted.
- Click this button, then the MPR series will follow all recon series.
- The parameters of the new MPR series can be set.
- MPR parameter panel contains MPR type (AIP (default), MIP, MinIP), and the corresponding MPR type will be displayed in the four corners information of the image.

【User Previous Surview】

The previous surview can be used for the same patient, considering the patient has not moved. User Previous Surview can replace the need for another Surview, given the same anatomy will be covered.

6.3.3.3 Context Menu

In the series list, right click a series to show the context menu.

Repeat: Repeats the last series.

Copy: To copy the series.

Delete: To delete the series.

Paste: To paste the copied series to the series list. The pasted series is listed below the selected series. If the duplicated series is followed by recon(s), the recon(s) will be pasted too.

Perform air calibration: To perform air calibrations of the scan protocol, right click on the protocol and begin air calibrations for the specific protocol parameters. This air calibration is to quickly calibrate the system for improved image quality.

NOTE:

- **Please strictly follow the prompts during air calibration.**

6.3.4 Plan on Surview

When the Surview scan is complete, the Surview image displays with a plan scan series box. This scan series box represents planning on the surview, determining scanning area.

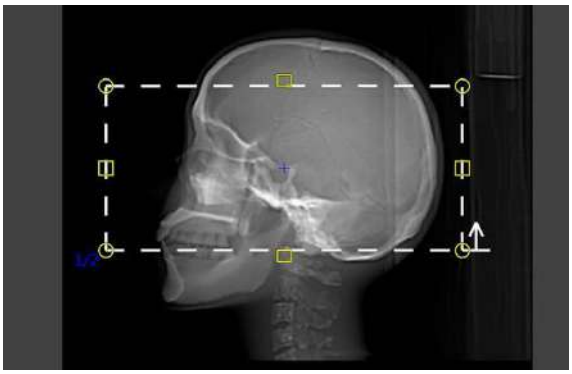


Fig 6-11 Surview

The scan control panel displays the parameters for the next scan.

When two scans have the same type, even if the two scans are not sequential but in the same study, some of the parameters on the second one, such as Start, End and length will follow the first planning box.

Each scan and reconstruction of series have their own surview scanning areas. The length, tilting angel and view can be altered by pulling the border of the scan series box

- Move scanning area

Put the mouse cursor on the central position of the scan series box, the shape of cursor turns to . Then, click and pull the scan series box to the desired scan area.

- Change scan length

Put the mouse cursor on the top or bottom of the scan series box, the shape of cursor turns to .Then, click and pull the upper edge or lower edge of the scan series box, which can alter scan length.

- Change view

Put the mouse cursor on the left edge /right edge of the scan series box, the shape of cursor turns to .Then, click and pull the left edge / right edge of the scan series box, which can alter reconstruction field of view.

- Tilting scan

Only lateral Surviews can be used to plan tilting scan. Put the mouse cursor on the

corner of the scan series box, after the shape of cursor turns to rotatable state, click and pull the cursor to rotate.

- General rules for multiple scan series studies

To ensure accurate planning and execution, it is advisable to not move the Couch up or down after the Surview scan.

Restart the procedure to change the patient's position.

- Defining the position of a scan series

In order to define the position of a scan series, the operator should first be familiarized with the tools provided in the scan window toolbar.

- Context Menu

In the Surview, right-click on the outside of Surview image to show the context menu:

– Change WW/WL (Window Width/ Window Level)

– Image Enhancement

– Invert

– Zoom

– Pan

– Magnify

– Flip Image

– Image Reverse

– Positive Rotate 90°

– Negative Rotate 90°

– ROI Tools

– Reset WW/WL

– Reset

– Show/Hide Orientation

– Show/Hide Ruler

– Show/Hide Grid

– Show/Hide Gray Bar

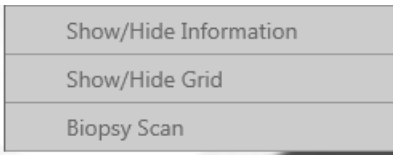
– Show/Hide Information

- Show/Hide Grid

In the Surview, right-click on the inside of Surview image to show the context menu:

- Show Image Line
- Show Image Region
- Show All Series
- Rotate Series
- Delete Series

In the right-click menu of scanned sequence, the "Biopsy Scan" option can be selected, which supports creating new scan sequence through current scan image. The central position of the newly created scan sequence is the location of the current image.



- Fig 6-12 Biopsy Scan

6.4 Protocol Parameters

Before scanning, setup corresponding protocol parameters. Protocol parameters settings include general settings, voice settings, enhanced settings, save settings, advanced settings and O-Dose settings.

6.4.1 General Settings

6.4.1.1 Common Main Parameters

Series Description

This parameter is used to insert a label that will appear on all the images of the series.

In Series Description, a label can be entered with a string of 64 characters. The content of this field can be blank, in this way, there is no series description on the image. In addition, the label preset list can be used to select from.

Start [mm]

The Start value denotes the Couch beginning position for the first image in the scan series. If plan operation is not performed on the surview, the scan will start from the current patient couch position. The * denotes the Start position. When the system is ready to scan, the scan will be set according to the protocol. The start position can be altered according to the accuracy of 0.5mm.

End [mm]

The End value denotes the Couch position for the last image.

Length [mm]

The Length value denotes the sum of the distance between Couch central position for the first image and Couch central position for the last image and thickness of the image. The Length parameter gives the region covered by the Scan.

Voltage [kV]

The Voltage parameter is used to set the voltage according to the absorption characteristics of the scanned body part.

DLP [mGy*cm]

DLP is a calculation of the CTDIvol times the total radiated length, and represents the total dose given to the patient in this scan.

DLP Deviation (Reference IEC 60601-2-44)

The accuracy of the displayed and recorded values of *DLP* is ± 20%.

$CTDI_{vol}$ [mGy]

The $CTDI_{vol}$ is a weighted average measurement in a reference phantom. It depends on $CTDI_w$ and pitch.

$CTDI_w$ parameter gives the average dose over the volume scanned for the set of the scan parameters defined within the protocol.

CTDI Deviation (Reference IEC 60601-2-44)

The accuracy of the displayed and recorded values of $CTDI_{vol}$ is ± 20%.

Time [s]

The Time [s] parameter gives the total time of the scan.

Time value of the scan can be decided by available scan length, complete calibration, rotating time and complementary scan.

SFOV

SFOV denotes the scan field of view. The scan field of view can be altered according to patient size.

6.4.1.2 Axial Scan Parameters

- **Tilt [deg]**

The Tilt value (in degrees) denotes the Gantry Tilt angle for the planned scan on the

lateral (90 degree) Surview scan. The value in this box is copied from Plan on Surview, where it is interactively set by the Rotate function. The Gantry will tilt to the desired tilt angle before the scan starts (while the Enable button is pressed and held). When an asterisk appears, the scan will be executed with the current Gantry Tilt Angle. The range for Axial scans is from -30 to +30 depending on the Couch height.

NOTE:

- **When the Surview scan angle is 180, the Rotate button is grayed out.**
- **Increment [mm]**

The Increment parameter is used to set the distance between two consecutive scans in millimeters. The default value of the Increment is equal to the selected collimation, for example 32 × 0.625mm collimation , namely 20mm。

WARNING:

- **Increment of zero is allowed, but the scanned area will receive an increased amount of radiation. This mode will be used for biopsies, Bolus test and CCT. It is suggested that the dose used in these cases should be as low as allowed by the specific application.**

After the thickness is altered, the increment will be automatically set to be total thickness of one scan, unless the value is zero. If the increment is zero, between adjacent scans, the couch does not move.

- **Thickness [mm]**

Use the Thickness parameter to set the tomographic thickness, which determines the spatial resolution in the axial direction (perpendicular to the plane of the slice). These are the available Slice Thicknesses:

Table 6-1 Slice Thickness (Axial)

Collimation	Thickness (mm)
128 * 0.625	0.625
64 * 0.625	0.625/1.25/2.5/5/10
32 * 0.625	0.625/1.25/2.5/5/10
16 * 0.625	0.625/1.25/2.5/5/10
8* 0.625	0.625/1.25 /2.5/5
2* 0.625	0.625 /1.25

- **Circles**

In the mode of automatic scan, after specified times of the scan are completed, the system will stop working.

- **mAs**

The mAs parameter sets the exposure value during the scan. It is effective mAs. It is determined by the Tube Current and by the Scan Time. The Scan Time is determined by the Rotation time and by the Scan Angle.

A larger mAs factor decreases the image noise and enhances the contrast resolution but increases the radiation dose the patient receives and increases the X-ray tube loading.

When the scan time is changed, the software changes the current in such a way to keep the mAs constant (up to the tube and generator power limitations).

NOTE:

- **Changing mAs settings can affect image quality.**

- **Cycle Time [s]**

The time duration between the start of adjacent scans.

6.4.1.3 Helical Scan Parameters

- **Increment [mm]**

The Increment parameter is used to set the distance between two consecutive reconstructed slices. The value can be entered by typing or selecting an option from the text box. If the Continuous option is selected, the Increment will be set as equal to the Slice Thickness. If the Overlap option is selected, the reconstruction Increment will be set equal to half the Slice Thickness.

WARNING:

- **Increment can be zero, but received radiation level in the scan area will increase. This mode can be used for biopsies, Bolus test and CCT. It is suggested that the dose used in these cases should be as low as allowed by the specific application.**

- **Thickness [mm]**

The Thickness is the spatial resolution in the Z direction (the FWHM of the sensitivity profile, measured along the axis perpendicular to the image plane of the slice). The

thickness can be selected from the thickness selection. For the high resolution scan, the maximum thickness is 5 mm.

- **Collimation [mm]**

The minimum available thickness is always larger than the basic collimation. The tables show Resolution, Collimation and Thickness.

Table 6-2 Slice Thickness (Helical)

Collimatio	Thickness (mm)
128* 0.625	0.625/0.8/1/1.25/1.5/2/2.5/3/4/5/6/7/8/9/10
64* 0.625	0.625/0.8/1/1.25/1.5/2/2.5/3/4/5/6/7/8/9/10
32* 0.625	0.625/0.8/1/1.25/1.5/2/2.5/3/4/5/6/7/8/9/10
16* 0.625	0.625/0.8/1/1.25/1.5/2/2.5/3/4/5/6/7/8/9/10
8* 0.625	0.625/0.8/1/1.25/1.5/2/2.5/3/4/5/6/7/8/9/10
16* 0.3125	0.625/0.4/0.8/1/1.25/1.5/2/2.5/3/4/5/6/7/8/9/10

- **mAs/Slice [mAs]**

The mAs/Slice parameter sets the exposure during the scan. Its range of values is determined by the Tube Current (linearly), by the Rotation Time (linearly) and by the Pitch (inversely proportional).

To change the mAs/Slice, select a value from the mAs settings or type a value within the range displayed. If a value is typed for mAs/Slice that is not within the allowed range, then the nearest value (maximum or minimum, respectively) from the list in the mAs settings.

- If the desired value is higher than the maximum displayed, then decrease the pitch or increase the rotation time.
- If the desired value is lower than the minimum displayed, then increase the pitch or decrease the rotation time.

- **Evolving mode**

When working with Evolving mode, the images are displayed in separate windows, and are dynamically refreshed. To get best quality the user can:

- If Evolving is selected in the options, the zoom, pan, or shift in the x or y direction of the Scan Viewer images can be changed before the final reconstruction begins.
- If Evolving is not selected in the options, only the reconstructed images appear.
- Adjust the window Center and Width for optimal viewing of the image, to

monitor the proper execution of the scanning process.

- Zoom in/out to enlarge or reduce the series of images.
- Pan an image to center the series of images or the region of interest.
- Adjust the window setting.

Click **OK** to begin the Reconstruction.

6.4.2 Injection

6.4.2.1 Contrast Mode

Click 【contrast】, scanning with injector can be selected in corresponding option box.

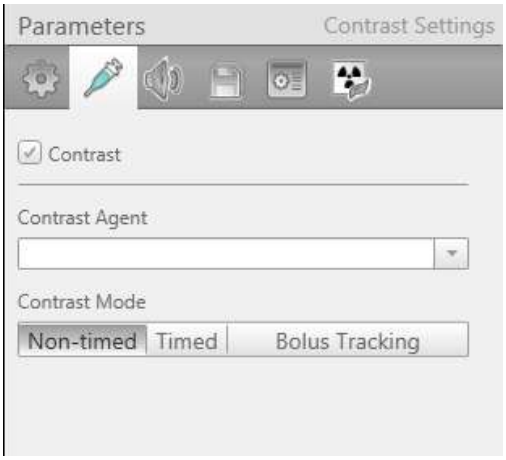


Fig 6-13 Contrast

In scans that use contrast, there are three scan triggering modes:

1. **Non-timed:** In this mode the contrast is injected and when ready press Scan Start button on the CT-Box to start the scan.
2. **Timed:** In this mode after starting the injection, when ready press the Scan Start button on the CT-Box; the scan starts after a Post Injection delay.
3. **Bolus Tracking:** In this mode the clinical scan begins automatically after the Tracker scan reaches the threshold. A post threshold delay is also set.

SAS can be used in timed scan and bolus tracking. See details about SAS in 7.4.Spiral Auto Start (SAS).

⚠

WARNING:

- **The use of contrast does not influence radiation dose for patients.**

- **There is no appointed contrast for NeuViz Prime CT system; it is the responsibility of clinician to decide what type of contrast and when to use it.**
- **The contrast chosen must comply with local regulation.**

NOTE:

- **When Spiral Auto Start is selected, the scan will be triggered automatically after the injector has started and the set delay time is reached.**
- **Axial sequence only supports one sequence, while helical sequence supports 10 sequences.**

6.4.3 AutoVoice

The AutoVoice tab allows you to select AutoVoice options.

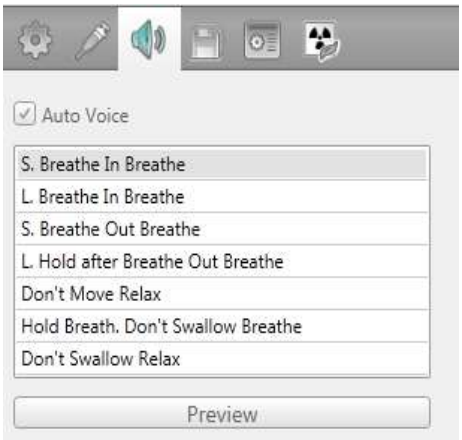


Fig 6-14 AutoVoice

Auto Voice Enable turns the Auto Voice function on and off. When turned on, you can select a pre-recorded message set from the menu for pre-scan (for example, "hold your breath") and post-scan (for example, "you can relax now") directions.

Preview allows the patient to play the selected message.

Click **【Preview】** to hear and review the voice message.

When recording new auto voice, click **【Auto voice setting】** in System Settings in the Service Mode. Click green **【Add】** in the language select area adding voice. Follow the prompts to record and save the new voice command.

6.4.4 Auto Settings

The following information includes the options available from the **Auto Settings** parameters tab. Not all parameters are available in all scan modes.

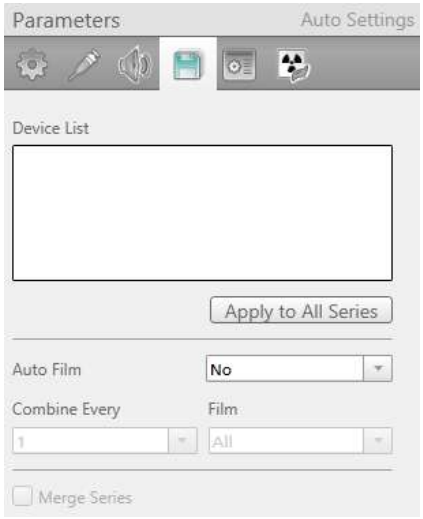


Fig 6-15 Auto Settings

Auto Storage: You can view your current Auto Storage settings from this field.

Storage Devices: Select this to open the Storage Devices dialog box. Make all your selections for storage as desired and click the **OK** button when finished.

Apply to all Series allows you to apply your storage settings to all the series within the current study.

Auto Film: You can select your auto film parameters with this function. Select one of the following:

No

Series end

Study end

If you choose the Series or Study option, you can make further parameter selections as desired. Click the OK button when finished.

Combine Every: Combine the previous sequence with current image to be one sequence.

6.4.5 Advanced

- **FOV (Field of View)**

The FOV parameter denotes the diameter of the reconstructed image. The FOV value can be selected from a list or typed directly in its text box in the range of 50 to 500 mm.

- **Matrix**

The Image Matrix parameter sets the number of pixels that the reconstructed image

will contain. The matrix sizes are 512^2, 768^2 or 1024^2. Understanding the relationship between FOV, resolution mode and reconstruction will help make a matrix choice that produces the best image quality.

- **Center X,Y:**

Center X and Center Y set the Horizontal(X) and Vertical(Y) displacements, in millimeters of the reconstructed image relative to the center of the Gantry opening. They are used to center the ROI in the image frame.

- **Enhancement**

The Enhancement parameter is used to sharpen or smooth images. The range is 1 to 4, with 1 being smoothest and 4 being sharpest.

- **Window Level, Window Width**

Window Width is the range of CT values included in the grey-scale video display of the reconstructed image.

Window Level is the CT value setting in Hounsfield units of midpoint of window width.

- **Filter**

The Filter parameter is used to set the mathematical algorithm which determines the sharpness or smoothness of the image.

The noise in the image increases as the sharpness of the image increases, and vice versa. In general, the low contrast resolution decreases as the spatial resolution (and image noise) increases.

Table 6-3 Filter

Filter	Description	Head	Body
F10	Smoothing filter for soft tissue	○	○
F15	Smoother filter for soft tissue	○	○
F20	Standard filter for soft tissue	○	○
F30	Sharper than F20	○	○
F50	Edge enhancing filter for bone images	○	○
F60	Edge enhancing filter, sharper than F50	○	○
F70	Edge enhancing filter, sharper than F60	○	○
F85	IHD protocol	○	○

Filter	Description	Head	Body
H10	Higher soft tissue contrast than F10	○	×
H15	Higher soft tissue contrast than F15	○	×
H20	Higher soft tissue contrast than F20	○	×
H30	Higher soft tissue contrast than F30	○	×
Lung10	Enhancing lung imaging filter	×	○
Lung20	Enhancing lung imaging filter, sharper than Lung10	×	○
Lung30	Sharpest enhancing lung imaging filter	×	○
IAC10	Designed for inner acoustic canal imaging only	○	×
IAC20	Sharper than IAC10	○	×
Cardiac20	Designed for Cardiac imaging only	×	○
Cardiac50	Sharper than Cardiac20	×	○

"○" stands for "Applicable".

"×" stands for "inapplicable".

- **Pitch**

The Pitch parameter represents the value of the Couch speed.

Pitch =d/T

Where d is the Couch travel in horizontal direction. T is the collimation (Nominal tomographic section thickness).

A larger Pitch enables a longer total coverage for a given scan time but can sometimes produce a lower quality image, in terms of image noise.

The Pitch values in the combo box are recommended from an image quality perspective.

The maximum available pitch is limited by FOV.

- **OrganSafe**

In Axial Scan, OrganSafe function can selectively reduce the radiation dose of sensitive organs such as eyes, thyroid, thymus, breast, small intestine and gonads, etc. This function can reduce radiation doses of the chest or eyes and other sensitive organ without affecting the image quality.

NOTE:

- **OrganSafe function is only available in Axial Scans.**

6.4.6 O-Dose

According to the predicted information of the patient's attenuation for the coming views during scanning, Automatic Exposure Control (AEC) will adjust the scanner exposure by modulating the mA automatically, so that the desired image/noise level will be met. AEC is accomplished in the following two steps:

1. Before scanning, an average mAs, which meet the pre-set image quality/noise level, will be calculated by O-Dose in the scanning scope based on the surview scan of the patient. In this step, a subfunction provided by O-Dose named AutokV, can help to select the lowest-dose kV from the available kVs if AutokV is chosen.
2. During scanning, when prediction on the attenuation information of the patient of the coming views is done, mA needed to meet the pre-set criterion is calculated immediately.

O-Dose function is based on the attenuation of the patient's body, displayed on the surview, and it recommends a mAs value for corresponding image signal-to-noise ratio. The system provides a drop-down option for noise. The operator can input any desired image noise within the scope of 0.3 to 1.7.

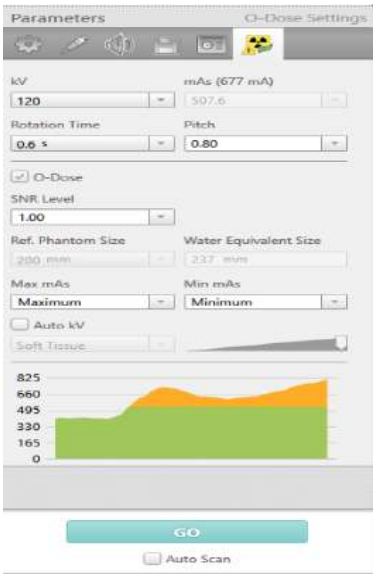


Fig 6-16 O-Dose

NOTE:

- **Signal-to-noise ratio adjustment is only available when O-Dose function is checked on.**

- **When the user changes the O-Dose sensitive parameters and causes other parameters change, the system will give a prompt on the parameter panel. At the same time, alarm ICONS will be shown on the corresponding page.**
- **Users can setup DoseSave Scan Time Threshold in Scan Miscellaneous of System Setting. Message Center will display a message to prompt the user if the user modified sensitive parameters and caused scan time changed greater than set value.**
- **In the [Protocol Edit] page, the [Ref. Phantom Size] can be adjusted by users.**
- **O-dose function still can be activated when tilt scanning.**
- **For the O-dose Warning Box, users can check [This login is not prompted].**

6.4.6.1 Auto kV

Auto kV can obtain the attenuation of the patient's body through plain film in order to reduce radiation. Auto kV function provides a recommend kV value based on O-Dose.

After users enter the CT system, click scanning plan on the main page and select advanced on the right side, Auto kV can be found out.

Operators can choose corresponding options based on different CNR: CTA, Contrast Scan, Bone, and Soft Tissue. On the right side of the options above, there is a sliding bar for fine adjustment. From left to right, CNR increases.

CNR formula: CNR= CT Value Difference / Image Noise

Where: CT Value Difference means the difference of CT value for target area and CT value for background value.

In principle, CNR remains indifferent. If adjust sliding bar slightly, the CT value difference increases and image noise is increased, required scan dose normally reduces. Therefore, in clinical practices, it is suggested for users to select proper gear and the magnitude of slight adjustment according to clinical tasks, height and weight of patient and their clinical experiences.

6.4.6.2 Dose Profile Curve for O-Dose

Dose profile curve shows changes in principle axis direction of patient's body. Operators can adjust top and bottom limitation by dragging mouse.

6.4.7 Prism Imaging (Optional)

If system provides Prism dual image function, it suggest that the system can gain CT images of patients with single-source and single time under different voltages through

this function. Prism dual image function can provide relevant information about chemical human composition based on the data of attenuation difference of various substances and obtain visual and analyzable information about physiology and pathology structure through dual scans.

Through post-processing function of work station Prism, image types can be as follow:

- Base material density image:
  - Water Image
  - Iodine Image
  - Calcium Image
- Effective atomic number sequence image
- Single image(40keV~140keV)

When selecting prism protocol, general parameter settings are as below:

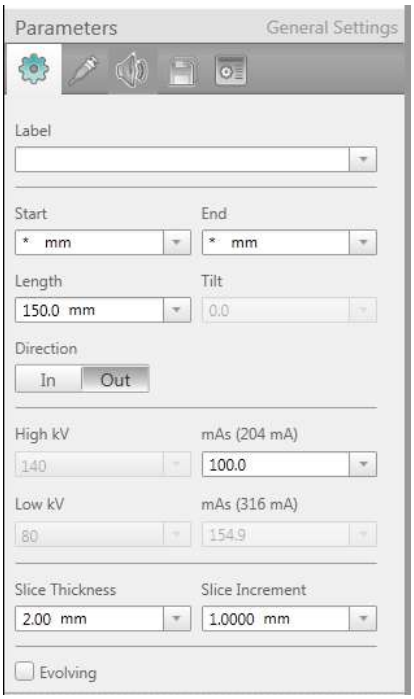


Fig 6-17 Prism Imaging

High kV is 140kV, Low kV is 80kV.

mAs for High kV can be adjusted manually, and mAs for Low kV will be given by the system automatically.

6.5 Start Scan

Click **GO** to start scanning. If the system is ready, prompts appear. Follow the prompts to perform the scan.

If couch moves more than 100mm or the gantry will tilt, information dialog box reveals 【Please press Enable】. At that time, follow the prompt and press Enable, then, another information dialog box 【Please press Enable】appears.

If couch moves less 100mm, information dialog box reveals 【Please press Scan】. At that time, follow the prompt and press Start Scanning.

WARNING:

- **The maximum CTDI dose value of system is 250 mGy, DLP is 2000mGy*cm by default。Otherwise, dose notice will pop up and larger numerical value will be red, at that time, if continue scanning, fill in the reason (optional) or go back to reedit scan parameters.**

Note:

- **Under the circumstances without having to restart the console software, after restarting the gantry, scan can be performed only after waiting for the couch to return to zero. There are two methods to stop scanning in the scanner room.**
- **Press the Couch-release Button to release the Couch.**
- **Step on the Couch-release Foot Switch to release the Couch.**

Once any of the above two methods is used, the Couch would be in float state.

WARNING:

- **The above methods are not applicable to CCT, Biopsy or Axial scan with zero increment.**

6.6 View Scan

6.6.1 Graphic tools

Length: Select Length in the ROI menu or click  on the generic tools panel. Then

the cursor turns to  . Draw lines on the image for measurement.

Rectangle: Select **Rectangle** in the ROI menu or click  on the generic tools panel. Then the cursor turns to  . Select any rectangular area on the image for measurement.

Polygon: Select **Polygon** in the ROI menu or click  on the generic tools panel. Then the cursor turns to  . Select any polygonal area on the image for measurement.

Text: Select **Text** in the ROI menu or click  on the generic tools panel. Then the cursor turns to  . Draw a text edit box, in which input the desired text.

Angle: Select **Angle** in the ROI menu or click  on the generic tools panel. Then the cursor turns to  . Draw an angle on the image for measurement.

Arrow: Select **Arrow** in the ROI menu or click  on the generic tools panel. Then the cursor turns to  . Draw an arrow on the image and a text edit box, in which the needed text can be input.

Pixel Value: Select **Pixel Value** in the ROI menu or click  on the generic tools panel.

Then the cursor turns to  . Click anywhere on the image to get the corresponding pixel report.

Ellipse: Select **Ellipse** in the ROI menu or click  on the generic tools panel. Then the cursor turns to  . Select any ellipse area on the image for measurement.

Remove: Click  to remove all labels.

6.6.2 Examination Flow

The Examination Flow dialog box allows you to make changes during a study.

After surview scanned, the parameter display as below:

Fig 6-18 Surview Examination Flow

Edit Surview: To edit the surview parameter and scan with the modified parameters again.

Repeat Last series: Repeat the previous surview scan.

Next Series: Go to the next series as planned in the Plan Scan interface. After Axial/Helical series Scanned, the parameter display as below:

Fig 6-19 Series Examination Flow

Continue Current Series: Continue scanning in the current series. If desired anatomy has not been covered in the scan, the user can press this button to continue the scan. The system automatically provides default values for the Start Position, Slice, Image Count and Length. These default values can be edited.

Under the below circumstances, this selection can be used:

- Cease to scan in the process of checking
- After the completion of plain film, before the timing scan starts.
- After the completion of all scan plans

WARNING:

- **When use SAS to plan several sequences, all sequences will be scanned in SAS mode. The Examination Flow dialog appears until all sequences are scanned.**

Available options are as follows:

Repeat Last series: Repeat the non-surview sequence which has been completed

Next Series: Go to the next series as planned in the Plan Scan Interface. If this function is not available, it is grey.

Continue Current Series: Continue means to continue scanning in the end location of the current series. The start place, Continue place, Continue length, Continue Start Image Layer, Continue Image numbers connect to the previous end series by default, users can also adjust the above four parameters manually based on clinical demand. In addition, the above four parameters are Continue parameters only.

Note:

- **The Examination Flow dialog box will automatically display between the scan intervals for you to continue the next series or end the examination.**

In expand series options, use scan layers or couch locations to change locations and length.

Scan layer:

1. Entering a numerical value in 【start at slice】can change the start place by default of affiliated images. If continue affiliated images are needed, do not change the start place by default.
2. Entering a numerical value in 【add】. The minimum numerical value by default is one unit of collimation of the last scan series. It can also add affiliated images.
3. Click 【Continue Current Series】。

Scan Place:

1. Entering a numerical value in 【start place】can change the start place by default of affiliated images. If continue affiliated images are needed, do not change the start place by default.

2. Entering a numerical value in 【add】. The numerical value by default is the length of the last scan series. It can also add affiliated length.

3. Click 【Continue Current Series】。

NOTE:

- **For the timed scan or Bolus Tracking mode, the parameter will only be available after all the timed series are scanned.**
- **For continued image code axial scan, add affiliated image sequence, continue current series will automatically add affiliated image sequence with same parameters.**

Chapter 7 Bolus Tracking

Bolus tracking is a technique used in computed tomography imaging to capture peak enhancement of a selected vessel. A bolus of radio-opaque contrast media is injected into a patient via a peripheral intravenous cannula. Depending on the vessel being imaged, the volume of contrast is tracked using a region of interest at a certain level and then followed by the CT scan once it reaches this level. Images are acquired at a rate as fast as the contrast moving through the blood vessels. Bolus tracking in clinical practices is used to help position clinical scan time accurately.

7.1 Hardware Requirement

Injectors which need to be handled manually can be better if equipped with scan stimulator. After the injection, the system will time automatically. The system will scan automatically if it reaches the preset time.

Table 7-1Injector Specification

Item	Qty	Specification
Injector Interface	1	The following kinds of injectors can be used: 1.DDI-200C(Single tube) 2.DDI-400C (Double tube) 3.MEDRAD Stellant SX (Single tube) 4.MEDRAD Stellant D-CE (Double tube) 5. Ulrich XD 2000 CT/MRI Injector system Mississippi 6. Ulrich XD 2001 CT Injector system Missouri 7. Ulrich XD 2002 CT Injector system Ohio tandem 8. Ulrich XD 2003 CT/MRI Injector system Tennessee 9. Ulrich XD 2004 CT/MRI Injector system Ohio M 10.Nemoto Smart Shot Alpha A60 (Single tube) 11.Apostar APO100 (Single tube) 12.Apostar APO200 (Double tube) 13.Mallinckrodt Optivantage (Double tube)

NOTE:

- **The injectors should be connected by Neusoft authorized service engineers.**
- **About injector connection and use, please refer to Injector Use Manual.**
- **Please make sure the injector is in connection state. If the injector failed to connect to CT, please restart the injector or contact service representative.**

7.2 Parameters Settings

Default value of Locator and tracker is 120 kV, and the user can change the value manually. Default layer thickness is corresponding with the protocol collimation.

Default mAs value is 30 mAs, and the user can change the value manually.

Set up scan start time PTD （Post Threshold Delay: Delay time after reaching threshold value）.

The collimation setting of protocol and the tracker, tracker place and whether to use auto voice functions can affect the value of PTD. If the two collimations are the same. PTD reduces accordingly; otherwise, PTD increases relatively.

The number of tracker scans is between 2 and 200, default value is 40. If necessary, user can set up PID（Post Injection Delay: Delay time between injection and scan）.

Default Threshold CT value is 150 CT.

NOTE:

- **System default max CTDI dose is 250 mGy, default max DLP is 2000mGy*cm. If dose is higher than the two values, a dose warning will pop up and the value will turn red. To continue the scan, please input the reason or go back to edit scan parameters.**
- **Threshold value must be higher than the CT value; if lower, a dialog box will pop up, and the scan will be canceled.**
- **If the difference value between threshold value and CT value of ROI is no more than 20 CT value, a prompt will pop up【threshold value and test value in ROI area are too close!】.**
- **There are tracker images for each scan, and images will appear after the radiation is completed within one second.**
- **In order to use the functions that injector and scan can be triggered simultaneously, Spiral Auto Starts (SAS) must be initiated. This option**

can only be applied for the injectors confirmed by NeuSoft. Detailed description can be found out in Vol. 1 7.1 Hardware Requirements.

- **Before using SAS, the right cable connection between the injector and the system must be confirmed and make sure that the injector supports SAS functions.**

7.3 Bolus Tracking Operation

The basic Bolus tracking operation consists of a minimum of four scans: Surview, Locator, Tracker, and Clinical series. These scans are optionally followed by additional clinical scans.

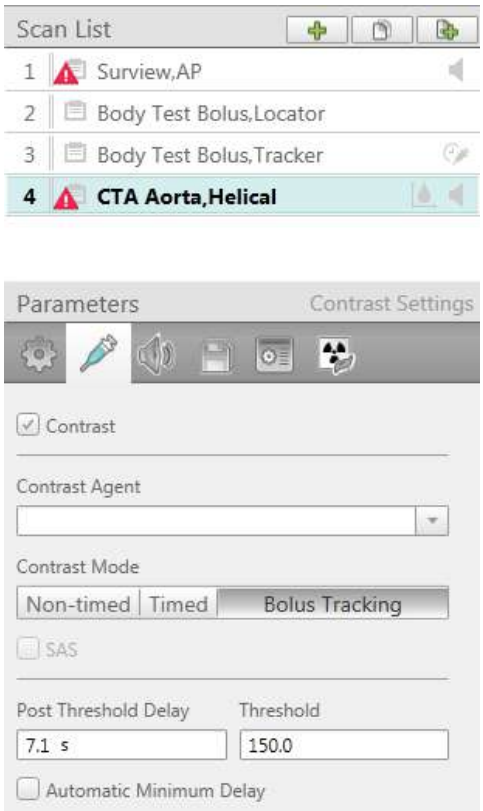


Fig 7-1 Bolus Tracking

NOTE:

- **Users can add Contrast Agent name in Scan Miscellaneous Setting of System Setting.**
- **The Locator and the Tracker scans are executed at the same position and therefore they appear as a single line on the Surview.**

The Locator scan is a single fused scan series, which can be re-planned for better patient positioning. It is performed before contrast injection. It is used to set the

anatomical location to be tracked, the ROI locations and the contrast enhancement threshold for the Tracker scan.

The Tracker scan is a fused axial scan series with fixed intervals between scans, determined by the Cycle Time. The Tracker and Clinical scan(s) are performed after the contrast injection. The Tracker scan monitors the concentration of contrast agent at the specified ROI, and compares it to the set threshold. As soon as the threshold is exceeded, the Tracker scan is terminated, the Couch top moves to the Clinical scan start location and the Clinical scan is performed automatically.

NOTE:

- **The Tracker scan may be terminated manually before the threshold is reached. Manual termination of the Tracker scan is followed by the same sequence of events (Couch movement and Clinical scan) that occurs after automatic threshold termination.**

Click **START CLINICAL SCAN** in the dialog box to terminate the tracker scan and to begin scanning the next series. Press Scan Stop on the CT-Box to completely terminate the whole scan.

The Clinical scan is a scan targeted to run when the level of the contrast agent is at its peak enhancement. The first Clinical scan may be expanded by the addition of consecutive Clinical scans. Optional Clinical scans are preplanned together with the first Clinical scan.

The following pages provide instructions for conducting a Bolus tracking scan.

7.3.1.1 Scan procedure of Bolus Tracking

Click **Start Study** in the workflow.

Enter the patient information in the **Start Study** interface. Make sure the correct patient position is selected.

Click the **Protocols** workflow button.

Click the desired protocol group. The list of protocols displays.

Select the desired protocol with Bolus Tracking mode. The system displays the protocol parameters for the Surview.

NOTE:

- **The Locator and Tracker scans may already be included in the protocol selected. However, they can also be added during the scan set-up.**

If needed, edit the protocol parameters under the injection tab and select Bolus Tracking.

Click **GO** to start the Surview scan. The system displays the Surview image.

Plan on the Surview. If necessary, adjust the scan length. Now that the Surview is completed, continue to the Bolus tracking scan.

If the Locator and Tracker scans are included in the protocol, move the locator to desired level, and select GO to scan Locator.

If the Locator and Tracker scans are not included in the protocol, continue to Bolus tracking scan, step 6.

NOTE:

- **In order to use the injector scan trigger feature, ensure that the Spiral Auto Start (SAS) option is enabled, and the injector supports the SAS function. This feature is for use only with Neusoft approved injectors.**
- **For Bolus Tracking scans, the SAS option is located in the Tracker Scan Series.**

7.3.1.2 Planning the Locator and Tracker scans

If the protocol does not include the bolus tracking option, please add it before using this procedure.

Click Locator in the scan series list. The system displays a locator line on the image.

Move the locator line into the desired position.

Click Tracker in the scan series list. The system displays the tracker line in the same location where the locator line (the lines are connected; moving one causes the other to move) is placed. Set the PID (Post injection delay, the delay from the injection to start the scan) if desired.

NOTE:

- **Make sure placement defines the ROI.**

Click the Clinical scan in the series list. The Main scan parameters display. A time ruler is displayed at the bottom of the screen showing the scan length and the start point relative to the injection start.

To add an additional Clinical scan, click Insert Protocol and select an appropriate scan protocol.

NOTE:

- **The Axial scan cannot be timed, so an Axial scan cannot be added as a clinical scan.**

To change the parameters, follow the same instructions as for the first Clinical scan editing.

NOTE:

- **The PTD (Post Threshold Delay) of the additional Clinical scan is, by default, the shortest available for a given situation. Like the PTD of the first Clinical scan, it is measured relative to the time that the Threshold is reached, at the end of the Tracker scan.**

WARNING:

- **Do not attempt to manually change the Gantry Tilt or the patient Couch up/down position during or between the Locator, Tracker, and Clinical Scans.**

Verify all scan parameters. For the Bolus tracking scan, the Multi phase option can be set.

Click **GO** to begin the Locator scan. When this scan is complete, the system automatically displays the Tracker window. The Locator can be re-scanned using the tools in the toolbar.

Using the tools in the toolbar, define the desired ROI. Then define the threshold for the Tracker scan by dragging the Threshold Line or editing the Threshold value parameter. The ROI can be drawn and re-drawn. Only the last drawn ROI is used to trigger the scan.

NOTE:

- **Use the toolbar tools to mark the ROI and use the graphic tools to adjust the ROI.**
- **The average CT value appears next to each ROI. The value automatically adjusts if the ROI is changed.**

Verify that there is no error message above the time ruler on the bottom of the window. Messages may be due to one of these errors:

Long PTD

ROI is out of the image boundary

Scan parameter selection does not fit the PTD

NOTE:

- **The Scan is planned to start with a programmable delay after the threshold completion. This delay is called PTD (Post Threshold Delay).**

In the graph, the line is the average of the ROI. If desired, the threshold can be reset by typing in the threshold in the dialog box.

Click an option in the message box to continue.

- GO to continue to the Tracker scan. Go to step 13 below.
- Re-plan to exit the results and re-plan the Locator and Tracker scans. Go to step 2 above.

Follow the on-screen instructions to complete the Bolus scan. When using a manual voice, give breathing instructions to the patient when the Tracker crosses the threshold. The system displays the resulting images.

7.4 Spiral Auto Start (SAS)

SAS is an optional injection method for Timed and Bolus Tracking scans.

When the Post Injection Delay (on the injector console) is used, SAS allows the scanner to control most of the total delay. For Timed and Bolus Tracking scans, a time ruler appears at the bottom of the window displaying the injection delay time, injection time, and scan times. If the delay and injection times are not acceptable, a warning message appears. The scan will not start until the delay is within the acceptable parameters.

The Trigger to start the scan can be started manually or automatically. For Helical scans and Axial scans, the scan can be started with Auto Start or SAS.

In SAS or Automatic Mode, after the Go button is pressed, the following message will appear. Press the injector button and the scan will automatically start when the entered Post Injection Delay time is reached.

Fig 7-2 Information when SAS is checked

NOTE:

- **If the injector is stopped during the countdown, and SAS is being used, the scanner will continue to countdown and scan at the planned scan**

delay. To stop the scan, either press the pause button on the CT Box, or manually move the table. The paused scan and the following series are now non-timed. The operator may re-plan the series to Contrast Timed or Bolus Tracking, with the option of selecting SAS again.

- **The injector will need to be reset to original status for the SAS function to work properly when scan has been paused. If the operator does not reset the injector, and SAS is selected, the Please Press Injection Button will appear on the screen, but will not countdown after the injector is started, but will not scan because there communication between injector and scanner is lost.**

In manual mode, the Scan Button and the Injection Button must be pressed at the same time. SAS must be unchecked for manual mode.

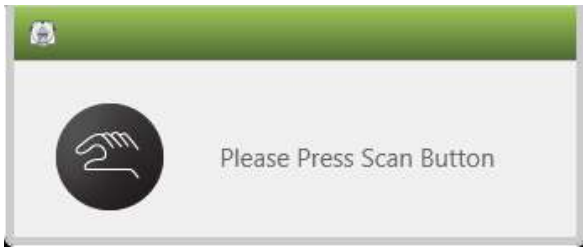


Fig 7-3 Information when SAS is unchecked

Use this procedure to activate SAS with Trigger:

1. Select the Injection tab in the scan protocol box.

2. Select Contrast Tab. The injection options appear:

Bolus name：if operators enter the bolus name, then the entered name appears on the hunted images after injecting the Bolus, otherwise, it is Contrast.

Trigger: non timed, timed (with or without SAS), and bolus tracking(with or without SAS).

Post injection delay: The delay from injection to start of the scan.

3. Select the Timed or Bolus Tracking injection option. The SAS option appears and the time bar appears along the bottom of the window.

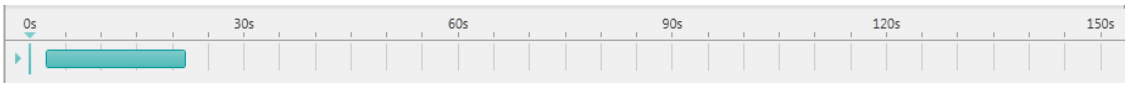


Fig 7-4 Timing Bar

4. Select SAS.

5. Complete the rest of the injection options and verify whether the delay scan is within the acceptable range.

6. After rechecking all parameters, press start scanning button and the system pops up a prompt of injecting Bolus.
7. Press inject Bolus and complete the injection of Bolus, after reaching the setup delay time, the system will start scanning automatically.

NOTE:

- **For Bolus Tracking, the SAS option is found in the Tracker scan.**
- **For timed scan of axial scan and helical scan, the timing bar will display below the scanning image.**

Select SAS.

Complete the rest of the injection options. Verify the scan delay is within the acceptable range.

After reviewing the entire parameters click **GO** to begin the scan.

The countdown of the delay before scanning begins immediately following the triggering signal from the contrast injector.

NOTE:

- **Before using SAS，make sure that the injector has been connected with the gantry accurately and effectively.**
- **When SAS is selected, after clicking "Go", make sure the injection is not started before system prompt "Please Press Injection Button" pops up.**
- **Images captured after the contrast is injected will display the letter "Contrast" on images.**
- **The contrast injection parameters are optional.**

Chapter 8 CCT(optional)

CCT scanning function is an essential performance of this device.

Continuous CT (CCT) is a scanning mode that allows the physician to perform extended, low-dose scans while performing a biopsy. The scan can be controlled by pressing the foot-pedal switch in the scanner room or on the CT Control Box. The resulting images display on a remote monitor in the scanner room, providing near-real-time visual feedback during the biopsy.

8.1 Preparations

CCT function needs two operators to obtain the best performance:

- Radiation technician of the console.
- the doctor performing operations in the scanner room.

The following preliminary preparations must be done before beginning the procedure.

1. Position the monitor in the scanner room at a convenient location, taking into account the expected direction of approach to the patient.
2. Check that the foot pedal is free from any obstacles.
3. Make sure that the Gantry indicator lights are functioning properly by performing a CT scope scan without a patient.
4. Prepare sterile materials, if necessary. For example, a clear sterile sheet with an adhesive strip may be attached over the Gantry panel for operating the Couch motions from the scanner room.
5. Check the intercom for clear communication.
6. Prepare the appropriate radiation shielding equipment and materials.
7. Prepare the intervention kit, including the extended handle and accessories.

NOTE:

- **If users select CCT, confirm that CCT monitor is on before scanning, so real time images will be displayed.**

WARNING:

- **If the monitor is located on a cart, make sure that the cables connected to the device are not in the way of the patient or the personnel in the scanner room.**
- **This procedure should be done with two staff members. The individual at the console should proceed only as instructed by the individual conducting the biopsy procedure to avoid injury to both the patient and the staff.**
- **The laser remains ON until the end of the clinical series. If the patient's eyes are in the path of the laser, turn off the laser to avoid injury.**
- **In the process of CCT, interventional doctors can puncture by moving couch to adjust the patient place. Doctors must avoid operations that can lead to patient infections. The doctor must not touch unsterilized surfaces.**
- **Use disposed sterile gloves.**
- **Assistants operate console.**
- **Operate according to the operation manual strictly.**

8.2 CCT operation

8.2.1 CCT scan parameters

In order to activate the CCT mode select a CCT protocol.

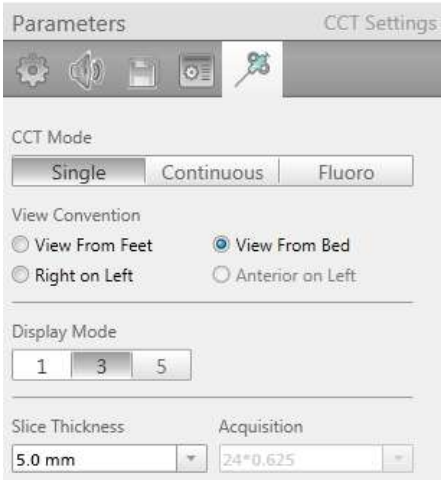


Fig 8-1 Display mode

- **Real mode**

There are three CCT modes.

Single mode: Single mode activates a 240 degree scan each time the pedal is pressed.

The system default scan mode is single mode, default rotation number is 50. The scan mode determines the obtained image quantities for each scan.

Click **GO** to perform scan, the system display a message:【note: position light might be on before the entire clinical scan series end. Operators can turn on /off position light at any time manually】.

NOTE:

- **Repeated scan on the same place. Continue scan to select "yes", otherwise "no".**

After closing the first system message, a message will pop up to suggest pressing the foot pedal to perform single scan. At the same time, the system displays accumulated task time and CTDI value.

Under the state of turning off the X-ray, the horizontal place of the couch can be adjusted between two scan periods manually. After scanning, the system pops up the message dialog box again to press the foot pedal to perform next scan. In the meanwhile, accumulated task time and CTDI value will update accordingly.

Single scan includes three image display modes: 1 × 1、 1 × 3 and 1 × 5.

1 × 3 mode, the top one is the middle layer image, the bottom ones are those images that are close to the head and feet respectively.

1 × 5 mode, the top line displays the second image (located in the middle of head and middle layer) and the forth image (located in the middle of middle layer and feet), the bottom line displays three images which includes those images that are close to the head, middle layer and feet respectively.

Continuous mode: Continuous mode activates sequential scans as long as the pedal is being pressed. One 240 degree scan is executed for each cycle time.

Default rotation numbers are 50.

Click **GO** to perform scan, the system displays a message:【note: position light might be on before the entire clinical scan series end. Operators can turn on /off position light at any time manually】.

After closing the first system message, another message will pop up: 【Repeated scan on the same place. Continue scan to select "yes", otherwise "no". 】. Click【yes】to turn off the system message, the system will pop up another message:【press the foot pedal to continue scan】.

Release the foot pedal, the system displays accumulated task time and CTDI value. A hint is displayed: Press the foot pedal to continue continuous scans.

NOTE::

- **In the current scan, X-ray is always in the stat of alternant on/ off.**
- **In the stat of turning off X-ray, the horizontal place of couch can be adjusted between two scan periods manually.**
- **When CTDI value reaches 500mGy, the scan will stop automatically, in the meanwhile, the system pops up dialog box to hint the accumulated task time and CTDI value.**

The image display only has 1 × 1 mode.

Fluoro mode: Fluoro mode activates sequential scans as long as the pedal is being pressed. One 360 degree scan is executed for each cycle time.

- **Rotation Time**

Only 0.5 or 0.6 rotation times are available.

8.2.2 Fluoro

Total default value of the scan time is 100.0s.

Click **GO** to perform scan, the system display a message:【note: position light might be on before the entire clinical scan series end. Operators can turn on /off position light at any time manually】.

After closing the first system message, another message will pop up: 【Repeated scan on the same place. Continue scan to select "yes", otherwise "no". 】.

Click 【yes】to turn off the system message, the system will pop up another message: 【press the foot pedal to continue scan】.

Release the foot pedal, the system displays accumulated task time and CTDI value. A hint is displayed: Press the foot pedal to continue continuous scans.

NOTE:

- **In the process of performing CCT Fluoro, operator can change the horizontal place of the couch manually.**
- **After 30s of continues radiations in Fluoro scan mode, the system will pop up hint 【press the foot pedal to continue continuous scan】.**

- **View convention**

A list of possible conventions includes:

  - Left on right
  - View from feet
  - View from bed
  - Anterior on left

- **Image display mode**

Set the display mode of the images: 1, 3 or 5.

NOTE:

- **In continuous mode, the only option for display mode is 1.**
- **Thickness**

The thickness parameter plays an important role in CCT. The selected thickness determines both the tomographic thickness of the CCT images and the layout screen of the CCT Viewer.

The tomographic thickness is selected according to the standard needle diameters used in biopsy procedures.

NOTE:

- **To view all images not saved in the Viewer, the study must be reconstructed in Offline Recon after completion of the exam.**

8.2.3 CCT operation procedure

This function requires two people for optimum performance:

- A technologist to operate the scanner and assist the doctor.
- An interventional doctor who conducts the biopsy procedure in the scanner room

To shorten the biopsy procedure, the doctor should activate the foot pedal during the biopsy procedure.

The biopsy procedure starts by positioning the patient on the Couch according to the planned area of the biopsy. In general, a Surview and a sequence of scans are performed to help locate the lesion (the target) and plan the insertion path (trajectory) of the needle. A typical slice is then selected, and using the graphics toolbox (distance and angle measurements), the biopsy planning is easily performed.

The insertion point is marked on the patient skin and the biopsy is initiated. The biopsy needle is inserted and its location can be viewed at almost real-time on the monitor. The interventional doctor activates the pedal and a burst of scans (continuous mode) and a single image (single mode) scan is executed with low dose axial scanning. As the pedal is released the scans and the radiation stop at once.

NOTE:

- **Check the remote monitor cable connection before the CCT procedure.**

During scans, the images display on the remote monitor in format 1, 3 or 5 as selected previously in the protocol.

The doctor follows the needle tip as he/she proceeds with the insertion toward the target.

CAUTION:

- **The displayed images can be shown either as Right on Left, View from Bed, View from Feet, or Anterior on Left. This view may conflict with the normal default image orientations as set in the default setting of the scanner.**

When displaying three images per frame, the images will be displayed simultaneously. Every scan and each image will represent a different slice location. The needle can be seen in more than one slice location and, by identifying the needle tip, the next Couch transition can be planned.

When displaying five images per frame, the images will be displayed simultaneously. Every scan and each image will represent a different slice location. The needle can be seen in more than one slice location and, by identifying the needle tip, the next Couch transition can be planned.

Couch movement is supported during the CCT procedure to reposition the patient for the next scan session. The following movements are permitted while X-rays are off: Couch in/ out and up/down.

If the pedal is released at the end of the burst session, the last needle position remains "frozen" on the screen. These images are also registered in the normal study-viewer and can be used for archiving and filming. The images can be windowed, panned and zoomed, and those settings will be kept for the next scan burst.

Stop, pause, and Couch movement.

The CCT operation can be paused during the scan or stopped at the end of the procedure by the Technologist.

Between scans, the Technologist can move the Couch. If the Couch position is changed, the scan can continue without cancelling the entire scan.

In the normal axial scan, the system will not scan while the Couch is moving.

NOTE:

- **The system can remain in pedal ready mode for 18 minutes.**

8.2.4 Lesion localization process

The different screen layouts provide an easy process for lesion localization.

In Single Mode, if choosing 3 or 5 images frame mode, viewing options depend on the Couch position value used:

- Type in the Couch position to display with the image closest to the Gantry as the first image.
- Leave the default value to display the center image correlated to the laser light.

In the single format, the displayed image is a fused image. The laser marker is located exactly at the Couch Location of the fused image.

CAUTION:

- **If the needle tip is not visible in any of the displayed images, it implies that the needle tip is not present in the beam path indicated by the slice thickness in the corresponding Couch location. The Couch location must be changed so the needle tip is clearly visible in an appropriate slice.**

8.3 Hardware Requirements

- Foot pedal: turn on/off X-ray.
  - — Single mode: Press the foot pedal once, complete an X-ray radiation.
  - — Continuous mode: Press the foot pedal continuously, emit X-ray continuously. Release the foot pedal, the radiation stops.
- Monitor cart: in the scanner room, bear the weight of monitor.
  - — 4 universal medical casters, convenient to move; there are two with brakes for safe parking.
  - — With tray, convenient to place documents, apparatus and other things.
  - — With handles, convenient to move and operate.

— The angel of the monitor is adjustable to avoid light reflections.

WARNING:

- **If the monitor is placed on the cart, please ensure that connection cable will not block the patient or operators of scanner room.**
- **CCT scan is usually completed by two operators. Operators of the console need to operate according to instructions of doctors performing biopsy in the scanner room to avoid injury of patients or doctors in the scanner room.**
- **Patient position laser will be always on before clinical scan ending. If illuminated position of patient position laser is located in patients eyes, please turn off patient position laser to avoid injuries.**

NOTE:

- **Reset the pedal mode by pausing scan process, switch from single mode or continuous mode.**
- **Patient position can be adjusted by Couch in/out in the process of scan, or to obtain the best patient scan area by adjusting patient position laser. Moving the couch can generate motion artifact.**
- **To position accurately, rotate couch in/out rotary knob to couch in /out indicator and release immediately, the couch will move about 1mm.**

WARNING:

- **If releasing the foot pedal, in the middle of the radiation, the reason might be as follows:**
  - **The foot pedal is stuck.**
  - **Cable damages cause short circuit.**
- **Please use emergency switch to stop radiation.**
- **If the needle tip is not visible in any of the displayed images, it shows that the needle tip is not present in the beam path, indicated by the slice thickness in the corresponding Couch location.**

8.4 CCT components

These are the components required to use the Continuous CT application:

- A pedal: used by the physician to activate the CCT scan from within the scanner room.
- CCT System with monitor (on a cart).

WARNING:

- **The doctor must avoid infecting the patient; do not touch the panel or other surface that is not sterile.**
- **Use disposable sterile gloves.**
- **Ask the assistant to operate the panel.**
- **Perform operations on the console only according to the biopsy's instructions.**

8.5 Safety instruction

8.5.1 CCT Accessories Safety

Foot pedal

CCT has a special pedal to activate scans from the Gantry room. Make sure the foot pedal is free of any obstacles to ensure easy and safe access during operation.

CAUTION:

- **Take care not to collide with or step on the pedal housing.**

Monitor Cart

The monitor cart inside the scanner room should not be used to hold anything but the original monitor. The 19-inch monitor-base should always be on top of the stand and secured properly. When not in use, the cart and its cables should be moved to a corner of the room so they do not interfere with routine activities in the scanner room. Care must be taken not to collide with the monitor stand or trip on the monitor cables.

8.5.2 Radiation information

The CCT mode is intentionally designed for scanning with a member of the medical staff in the scanner room.

Scanning is initiated by pressing a foot pedal, which energizes the X-ray generator. In general, the gantry room is equipped with warning lights and a buzzer to give an alarm when the system beams X-rays. The shielding of the scanner room does not provide any protection to the medical staff present in the gantry room. The staff should be aware of the hazard imposed by direct and scattered radiation.

During CCT mode, the Technologist and other personnel should be aware that control of the activation of X-rays originates in the scanner room and from the main console.

The dose to the patient (per cycle) displays to the Technologist upon selecting the protocol. If the Couch increment is 0, the number of the repeated scans multiplies the dose to the patient.

WARNING:

- **If there is any indication that X-rays are not turned off after releasing the Foot Pedal, press one of the Emergency Stop buttons on the Gantry control panels or CT-Box to stop the generation of X-rays, scanner rotation, and Couch motion.**

To recover after pressing Emergency Stop, refer to the Emergency Stop section in Chapter 2.

- **Scattered radiation information**

In the single and continuous CCT mode, scans with a rotation angle of 240 degrees are used, which are centered beneath the patient. The scan conditions of scattered radiation measurements are:

- 140 KV, 250 mA
- 64*0.625 collimation
- 5 mm slice thickness
- 0.5s scan time
- 4 cycles

WARNING:

- **Intervention doctors are advised to use the following occupational area**
- **When performing the CCT operations in effective operation area revealed in the below grey area:**

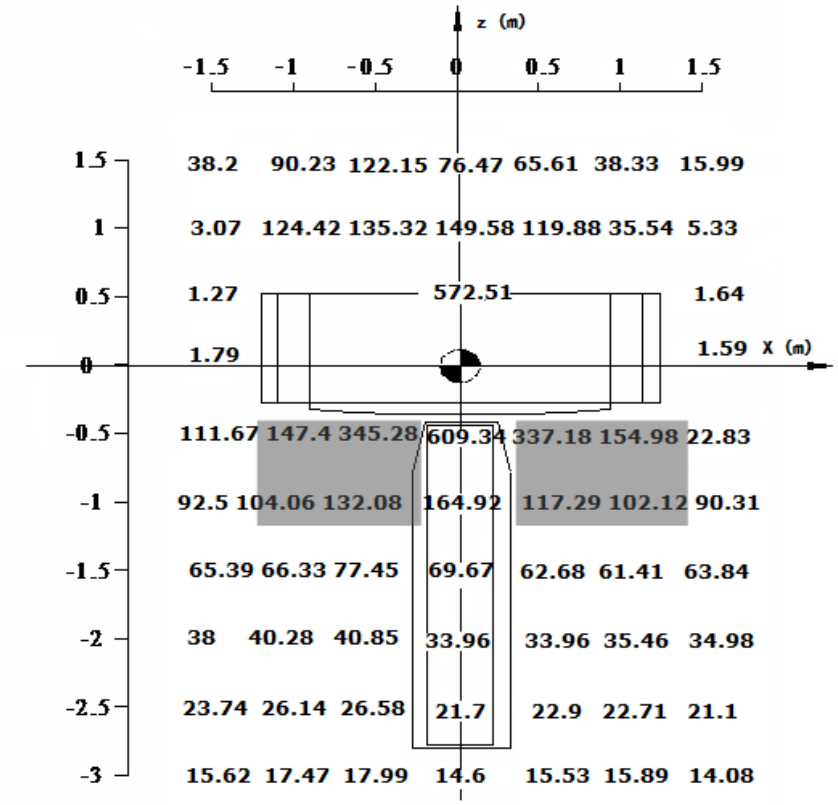


Fig 8-2 Occupational area

Chapter 9 Cardiac Scanning

This Chapter describes how to perform cardiac scanning as well as the additional procedures that may be necessary to complete the desired cardiac scan.

There are two scan modes based on the ECG gating technique for the cardiac scanning: Prospective mode and Retrospective mode. The Prospective mode utilizes axial acquisition for preset R-R phase; the X-rays are only generated during the cardiac phase of interest, as well as the image reconstruction is only available for the defined range. The Retrospective mode allows acquisition of a volume of data while the patient's E CG is recorded, so that the images could be reconstructed at any desired phase. For NeuViz Prime system, the cardiac calcium scoring scan is based on Prospective mode, while the coronary CTA scanning is based on Retrospective mode.

9.1 Preparing the patient

9.1.1 Check the ECG Monitor

In order to achieve the "freeze" cardiac images by the means of ECG gating. System provides inner ECG and outer ECG modes.

Inner ECG cables are provided by Neusoft.

For outer ECG monitor, the following models are suggested:

Table 9-1 ECG Monitor Selective Models

Item	Qty	Specification
ECG Monitor	1	Support the following(Selective Models): 1. Mindray Patient Monitor Mindray iPM8 2. IVY ---IVY3000

NOTE:

- **Neusoft recommends that the customer uses the ECG monitor provided with the scanner.**
- **The users must not use those ECG monitors and cables which are not provided or recommended by Neusoft.**
- **For specific operating instruction, please refer to relevant user manual.**

To prepare for cardiac scan:

1. Connect the ECG Monitor Cable or inner ECG line to the Gantry.

Fig 9-1 ECG Monitor interface

Fig 9-2 Inner ECG interface

2. Turn on the monitor and hook up the monitor to an ECG wave simulator, verify the monitor working status.
3. Enter the **Start Study** interface to scan a cardiac protocol, verify the ECG viewer display.
4. Please refer troubleshooting content to handle the abnormal situation.

Note:

- **When using the inner ECG, do not put inner Monitor Cable beyond the sides of the Couch, in case the line splits when the couch moves.**
- **Do not hang the cable on the couch. The ECG wire movement during scanning may cause the signal quality to decline.**

9.1.2 Preparing the patient

In order to achieve the best results possible, it is important that you prepare the patient correctly.

Detailed explanation of the exam procedure and possible reactions during the scan should be explained to the patient, to insure better compliance.

Keep the patient calm and heart rate stable; if necessary, the administration of medicine to slow the heart rate to achieve an ideal range may be necessary.

Train the patient about proper breath hold to ensure the chest and abdomen are motionless during the exposure. Oxygen may be used to stabilize the patients breathing. Monitor the heart rate change between breathe in and out.

Position the patient as FFS on the couch.

Prepare the electrode for the patient.

(1) Clean the contact sites thoroughly with soap and water to remove oils or scaly outer layers of skin.

(2) The area may need to be shaved to insure proper contact with the leads. Ensure this area is dry before placing the electrodes.

Apply clean electrode this way:

(1) Place the electrode 5-10 minutes before the scanning.

(2) Place the electrode over the right pectoral region, on the left pectoral region and on the left mid-abdomen.

(3) Connect the three ECG leads to the right chest, left chest and mid-abdomeial electrode-marked on the back of the cable as RA (AAMI-white; IEC-red), LA (AAMI-black; IE C-yellow), LL (AAMI-red; IEC-green).

(4) Ensure the ECG wave is available on the scanner and it is consistent with the monitor read out. The heart rate should be below 75 BPM.

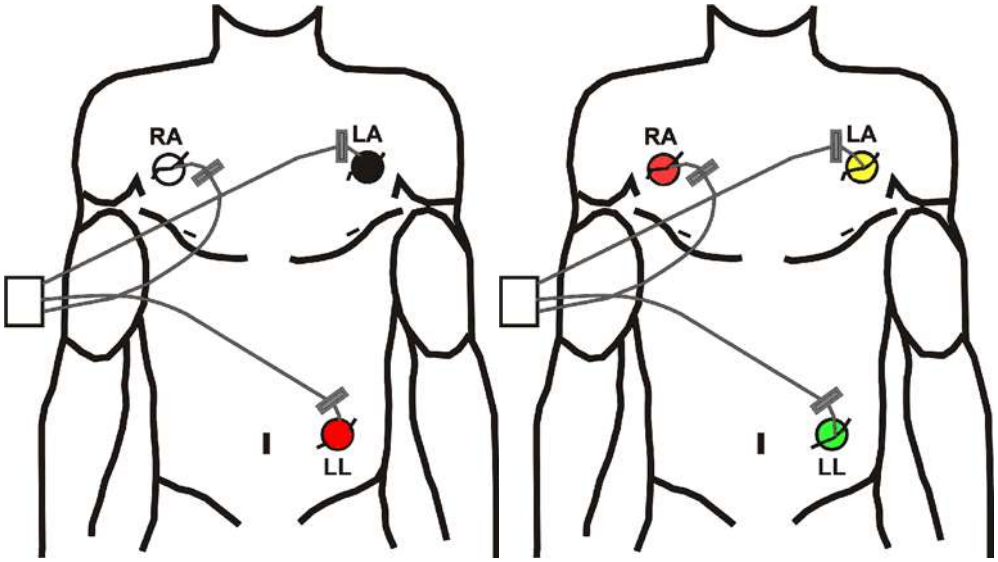


Fig 9-3 Electrode placement (Left: AAMI; Right: IEC)

WARNING:

- **The electrodes are for single use only. Dispose the pads after use. Do not attempt to disinfect the electrodes for re-use. Re-used pads will not function properly.**

NOTE:

- **Before scanning, make sure patient's breath and heart rate smooth and steady.**
- **Do not place leads on the patient's wrists or ankles. Leads must be placed on the patient's chest.**
- **Lead wires must be twisted together to avoid loops. Leave only about 12 cm (5 inches) free for a connection to patient electrodes. Large wire loops will interfere with ECG signal reception.**
- **Avoid skin contact by the lead wires. Use an electrode or a cloth under the wires for insulation.**
- **Do not use dry or expired electrodes. They can block the signal conduction and lead to trigger off and on.**

CAUTION:

- **Connect or disconnect leads from the electrodes by grasping the moulded ends of the leads. Do not pull on the wire part. Failure to comply may result in damage to the leads.**

WARNING:

- **The patient with following symptoms is not suitable for CT coronary scanning: significant arrhythmia, Valvular regurgitation, Placed pacemaker and Contrast agent allergy.**

9.2 Scan parameter

9.2.1 ECG viewer

1. Connect ECG Monitor and patient properly, register patient information and select desired cardiac protocol to enter the plan scan interface, the ECG viewer is displayed at the bottom of the interface.

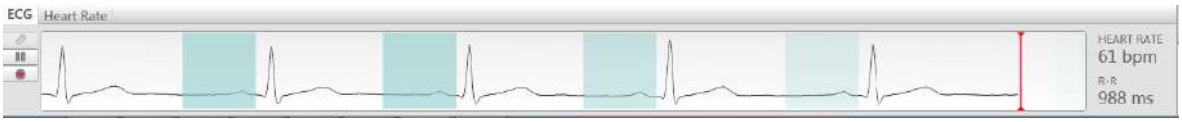


Fig 9-4 ECG Viewer

Measure: Measure the time between two points on the ECG.

Pause: Stops the real-time ECG and enables you to scroll within the recorded ECG using the scroll bar on the right side of the screen.

Record: start recording the real-time ECG at any time during the study.

2. Right-click on the ECG viewer allows selecting the display scale: 5 and 10 seconds. The right column displays the Heart Rate and R-R interval length.

Fig 9-5 ECG Right-click menu

3. Click the HR tab to view the Heart Rate variations before and during the scan.

Fig 9-6 HR tab

4. If heart rate fluctuation is too large, the following prompt message will display.

Fig 9-7 Heart rate fluctuation prompt message ECG high dose, low dose and reconstruction region

High dose region: common scan (O-Dose function is not enabled) and high dose with O-dose functions on, the regions are identified by green line overlaying black line.

Low dose region: low dose with O-dose function on is identified by green line.

Reconstruction region: reconstruction regions of offline, real-time axial scan and helical scan are identified by light green rectangle.

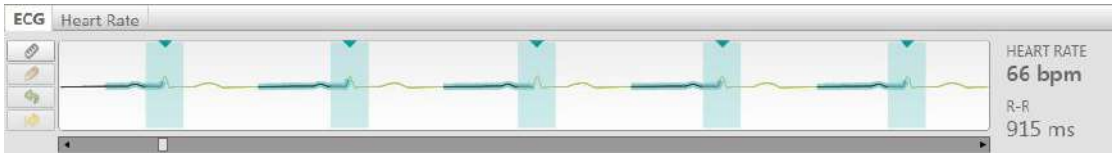


Fig 9-8 ECG high dose, low dose and reconstruction region

9.2.2 Calcium Scoring

Select the corresponding Calcium Scoring protocol, the Cardiac Tab will display the parameters as below:

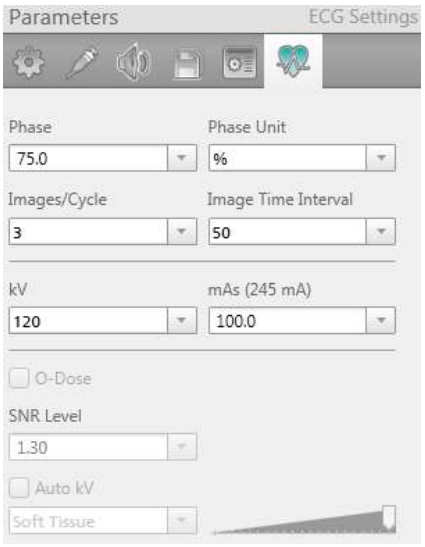


Fig 9-9 Calcium Scoring Parameters

Phase: To set the cardiac phase of interest.

Phase Unit: Selectable from Percentage to Millisecond.

Images/Cycle: The reconstructed images number for each cycle. Image cycles can be set to be 1, 3, 5.

Image Interval Time: If the Image/cycle is 3, the image interval time could be 50 ms or 100ms; if the Image/cycle is 5, the image interval time is 100ms 50ms. The SNR Level default should be 1.

9.2.3 Coronary CTA

Select the corresponding Coronary CTA protocol, the Cardiac Tab will display the parameters as below:

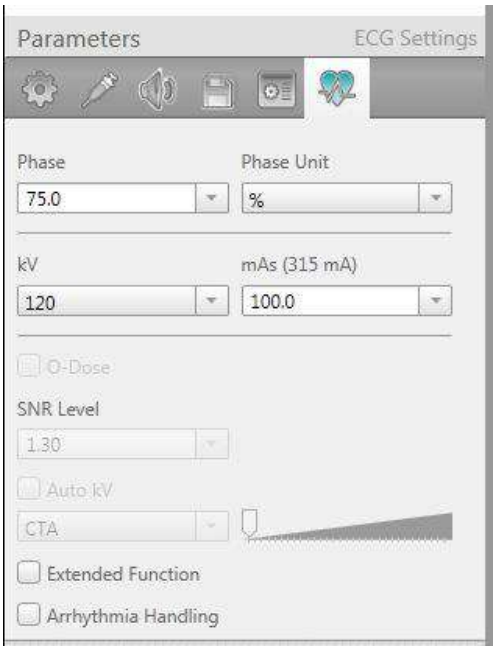


Fig 9-10 Coronary CTA parameters

Phase: To set the cardiac phase of interest. /To set the R-R interval of pre-scan.

Phase Unit: Selectable from Percentage to Millisecond.

Edit Phase: Define the coronaries and functional phases using Edit Phase option. This function allows reconstructing up to 10 phases as needed by your clinician. There are three preset options in the drop-down list: Equally spaced 4 （0,25%，50% 和 75%）, Equally spaced 8（0，12.5%，25%，37.5%，50%，62.5%，75% and 87.5%）and Optimal S/D phase (automatically offer Optimal S/D phase).

O-Dose: The Cardiac O-Dose is a tool used during helical Coronary CTA scanning to reduce the amount of radiation to the patients, while maintaining the best image quality possible. When Cardiac O-Dose is enabled, the scanner uses the planned mAs during the preset phase for reconstruction, while in other areas of the cycle, the mAs is reduced to a level (20%, 30%, 40%or 50%) of the planned mAs.

9.2.4 Arrhythmia Handling

On the page of cardiac options, select arrhythmia Handling, and the system will deal with abnormal R wave which is not considered as trigger R wave during in the process of scanning.

Abnormal R wave occurs when there is a Premature Ventricular Contraction (PVC) or when the RR intervals are less than 15% of the mean RR interval. Mean RR interval is defined as the average value of 4 continuous RR intervals.

When Arrhythmia Handling is selected in the cardiac setting page, the system will handle the abnormal R wave and will not accept it as a triggered R wave.

During exposure, if an abnormal R wave occurs, the system will stop X-ray and couch movement.

If the next normal R wave triggered is normal and the scan is completed smoothly, the couch will move to the next planned position and continue scanning.

NOTE:

- **In one scanning series, if the number of abnormal R waves is more than 4, the system will turn off Arrhythmia Handling and continue scanning.**
- **In one scanning position, if the system re-scans more than twice because of abnormal R waves, the system will not handle abnormal R wave for the following scan.**
- **After scanning, if the maximum $CTDI_{vol}$ or DLP exceeds the alarm limit, the series will be recorded in Dose SR and the Dose Check Log.**

9.2.5 Cardiac Preview (Evolving)

After scanning and before final reconstruction, the system supports previewing the axial images of different phases on the same slices, then the user could select the optimal phases and perform the final reconstructions.

The steps are as below:

From the **Main** Tab, click **Evolving** on.

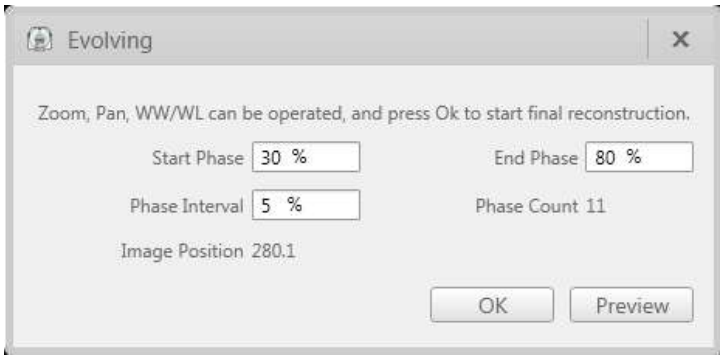


Fig 9-11 Evolving Options

Finish scanning, display the demo images.

View the images, and click the desire images. Input the **Start Phase**, **End Phase** and **Phase Interval**, and then click **Preview**.

View the preview images and choose the optimal images and click **OK** to start final reconstructions.

The user could click add recon to repeat the step 3 and 4 to get the desired images as well.

9.2.6 ECG Editing and Offline Reconstruction

During offline-reconstruction, you can edit the cardiac phase and R wave tags.

NOTE:

- **In each set of raw data there are two ECG vectors: the original vector and the latest corrected vector.**
- **When reconstructing images from raw data, the system includes the ECG viewer with the cardiac images.**
- **The corrected ECG strip is saved only if a reconstruction was performed using it.**

From the series directory, select the series.

Click **Offline Recon** on the right of the interface. The offline ECG viewer and reconstruction protocols appear.

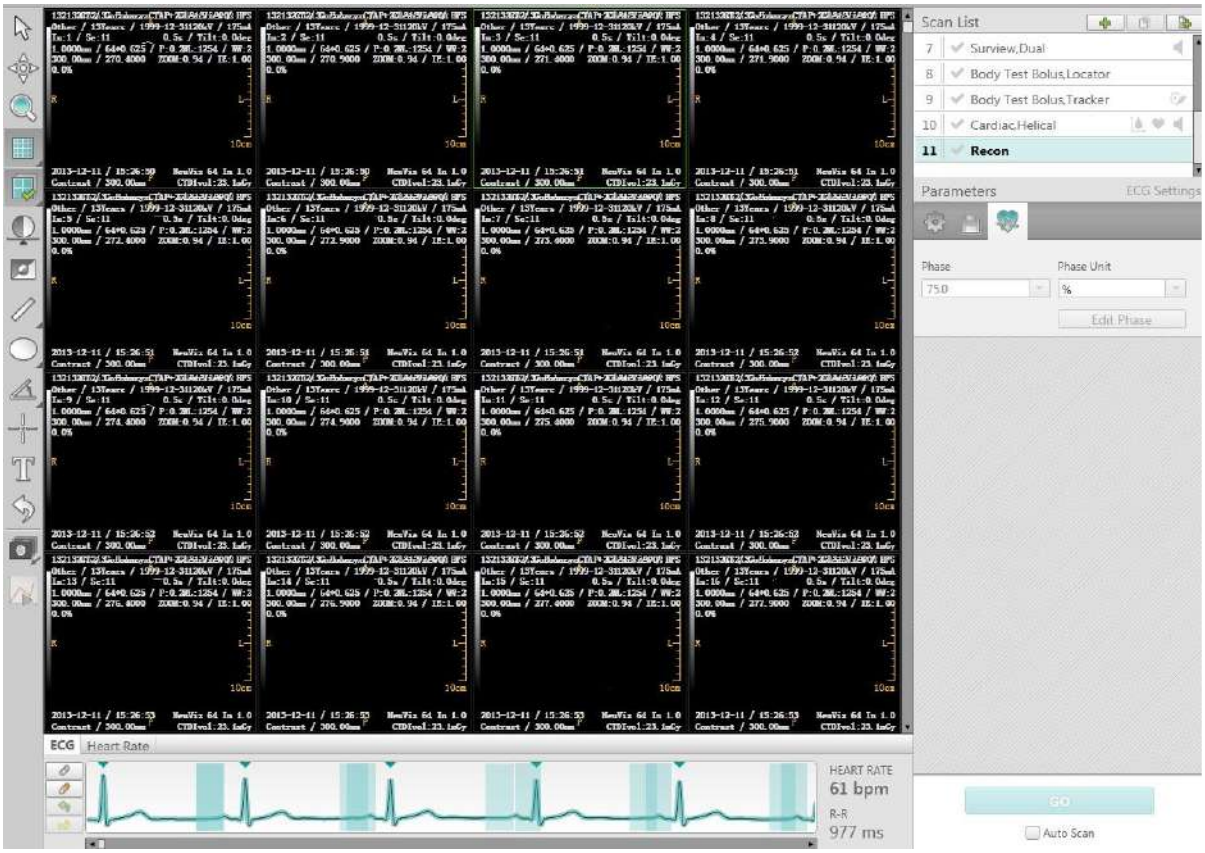


Fig 9-12 ECG Viewer and Reconstruction Protocols

4. Click Edit button on the ECG tool bar. The main function of ECG editing is to allow the R wave tags to be moved to an optimal position (green inverted triangle) and it can also add and delete appropriate R waves. Moving R wave tags allows you to change how images are reconstructed.

R wave tags editing is available:

Before the initial reconstruction process

Before an offline reconstruction

Other ECG editing options are:

Measure

Undo

Reset

Fig 9-13 R Wave Tag Edit

To move the R wave tag-Click on the red dot on the R wave and drag the dot left and right. This allows you to fine tune the R wave tag location, which sometimes can improve the image quality.

You can add or remove an R wave tag by right-click menu on the ECG viewer.

Whenever the ECG is viewed, you can grab and move the phase bar along the R-to-R cycle.

Since only a single heart phase is acquired in calcium scoring scan, there is only the limited amount of data that can be reconstructed.

For the Coronary CTA series, you could reconstruct any phases you want. To define the desired phase, click **Edit Phase** on the **cardiac** tab. This function allows reconstructing up to 10 phases as needed by your clinician. There are three preset options in the drop-down list: Equally spaced 4 （0,25%， 50% 和 75%）, Equally spaced 8 （0,12.5%，25%，37.5%，50%，62.5%，75% and 87.5%）and Optimal S/D phase.

Note:

- **Due to that Calcium Scoring only uses data of one phase, data for reconstruction is quite limited while data in coronary CTA can be reconstructed in any phase.**

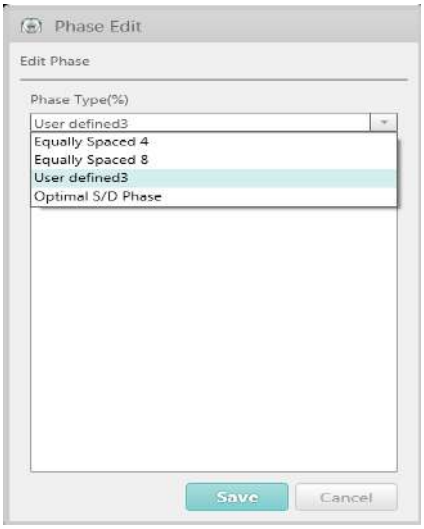


Fig 9-14 Edit Phase

Chapter 10 Recon

If there is no image reconstruction during scans or the location, size and outcome of image are not satisfactory, different reconstruction parameters can be selected to perform image reconstruction.

Image reconstruction allows reconstructions of raw scan data using the following method: off-line raw data is accessed in the CT directory and reconstructed.

NOTE:

- **Raw data file offline reconstruction can be performed for one patient at a time.**
- **The offline reconstruction function can only be operated on raw data files that are stored in the local directory.**

10.1 Reconstruction Parameters

According to the need of diagnosis, select or enter the corresponding values for reconstruction parameters.

10.1.1 General Parameters

- **Start**

The Start value denotes the Couch top position for the first image in the scan series.

- **End**

The End value denotes the Couch top position for the last image in the scan series.

- **Length**

The Length parameter gives the region covered by the Scan. The Length value denotes the sum of the distance between Couch central position for the first image and Couch central position for the last image and thickness of the image.

- **FOV (Field of View)**

The FOV parameter denotes the diameter of the reconstructed image. The default value denotes the last entered value. The FOV value can be selected from a list or typed directly in its text box in the range of 50 to 500 mm.

- **Thickness**

The tomographic Thickness is the spatial resolution in the Z direction (the FWHM of the sensitivity profile, measured along the axis perpendicular to the image plane of the slice). This is a parameter that can be selected from the drop-down list.

- **Increment**

The increment parameter is used to set the distance between two consecutive reconstructed slices. The value can be entered by typing or selecting an option from the

Combo Box. If the Contiguous option is selected, the Increment is set as equal to the Slice Thickness. If the Overlap option is selected, the Increment is set equal to half the Slice Thickness. The operator may also type a desired increment field.

- **Enhancement**

The Enhancement parameter is used to sharpen or smooth images. The range is 1 to 4, with 1 being the smoothest and 4 being the sharpest.

- **Filter**

The Filter parameter is used to set the mathematical algorithm which determines the sharpness or smoothness of the image. See details in table 6-3.

The noise in the image increases as the sharpness of the image increases, and vice versa. In general, the low contrast resolution decreases as the spatial resolution (and image noise) increases.

- **Center X,Y:**

Center X and Center Y set the Horizontal(X) and Vertical(Y) displacements, in millimeters of the reconstructed image relative to the center of the Gantry opening. They are used to center the ROI in the image frame by changing central coordinates and view.

- **Window Level, Window Width**

To change window level and window width of image reconstruction.

Window Width is the range of CT values included in the grey-scale video display of the reconstructed image.

Window Level is the CT value setting in Hounsfield units of midpoint of window width.

- **Matrix**

The Image Matrix parameter sets the number of pixels that the reconstructed image will contain. The matrix sizes are 512^2, 768^2 or 1024^2. Understanding the relationship between FOV, resolution mode and reconstruction will help make a matrix choice that produces the best image quality.

NOTE:

- **Surviews are reconstructed in the 512^2 matrix.**

10.1.2 AF (Adaptive Filter)

The AF enables reduction of the noise pattern (streaks) in nonhomogeneous bodies.

A computer algorithm to improve strip artifacts.

10.1.3 MAR (MAR+)

The MAR (MAR+) is an algorithm to reduce the metal artifact caused by the metal or high CT value part in the images. MAR+ has a better effect on reducing metal artifact.

NOTE:

- **MAR (MAR+) is not suitable when filter is F50 , F60 , F70 , F85 , IAC10 , IAC20 , Lung10 , Lung20 , Lung30.**

10.1.4 ClearView

ClearView reconstruction technology can reduce standard deviation of pixel noise and improve low contrast resolution. ClearView reconstruction algorithm may allow for reduced mAs in the acquisition of images, which results in a lower dose.

After starting the CT system on the computer, user can choose plan scan option on Home Interface, and then choose advanced option  on the right side, where user can find ClearView option.

Fig 10-1 ClearView Interface

The user interface is as above; there are 10 ClearView Levels from 0% to 90%. Users can choose any ClearView level for different dose level. Clearview function involves advanced option, the filter parameters supporting advanced option involve: F10, F15, F20, F30, H10, H15, H20, H30, IAC10, IAC20, Lung10, Lung20, Lung30. Advanced Clearview function is not available in FDA regions.

NOTE :

- **When ClearView 0% is selected, no ClearView is applied.**
- **Although users can select any ClearView level from 10% to 90% for different dose level, we propose to select appropriate ClearView level according to different dose level.**
- **In clinical practice, the use of ClearView reconstruction may reduce CT patient dose depending on the clinical task, patient size, and clinical practice.**

The following form shows recommended ClearView options.

- × area is the recommended option, which users can select as the optimal option;
- √ area is the acceptable option, which users can choose to meet different image noise level;
- Blank area is not recommended, although users can choose but with low quality.

Table 10-1 Low dose - Clearview Level chosen

Low dose level / Clearview level	10%	20%	30%	40%	50%	60%	70%	80%	90%
10%	×	√							
20%	√	×	√						
30%	√	√	×	√					
40%	√	√	√	×	√				
50%	√	√	√	√	×	√			
60%		√	√	√	√	×	√		
70%			√	√	√	√	×	√	
80%				√	√	√	√	×	√
90%					√	√	√	√	×

10.2 Offline Reconstruction

Offline Reconstruction

Use this procedure to reconstruct raw data.

- From the list of patients, select a patient.
- Select the required series from the series list.
- Under Recon tag in the Home, click Offline Recon  .
- You can also select series, right-click and select offline recon or select series and select the offline recon icon in toolbar?
- The system loads the raw data to Offline Reconstruction interface and displays the Offline Reconstruction parameters.

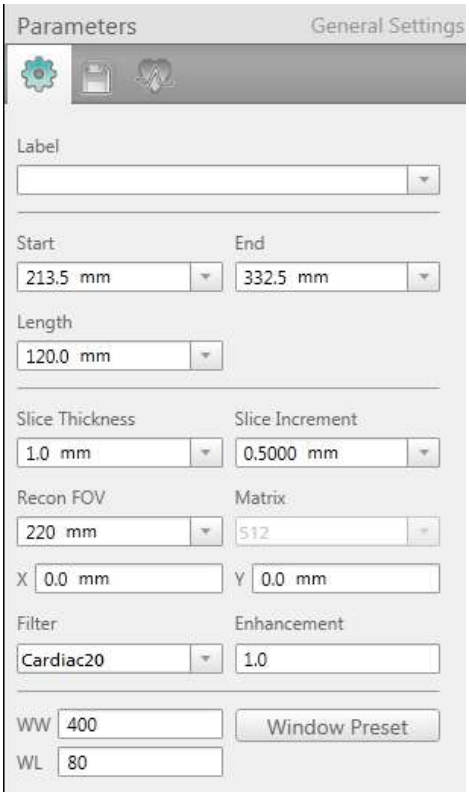


Fig 10-2 Offline Reconstruction

The displayed parameters correspond with the type of scan that was performed. The column includes the scan and the reconstruction parameters of the main reconstruction.

- Change the reconstruction parameters, if desired.
- When completing the reconstruction settings, select an option:

Click **Go** to accept the settings and begin reconstruction.

Click **Exit** to quit from the Offline reconstruction interface.

Evolving mode

When working with Evolving mode, the images are displayed in separate windows, and are dynamically refreshed.

If Evolving is selected in the offline recon options, the zoom, pan, or shift in the x or y direction of the Scan Viewer images can be changed before the offline reconstruction begins.

If Evolving is not selected in the offline recon options, only the reconstructed images appear.

Adjust the window Center and Width for optimal viewing of the image, to monitor the proper execution of the scanning process.

Zoom in/out to enlarge or reduce the reconstructed field of view (FOV).

Pan an image to center the series of images or the region of interest.

Adjust the window setting.

Click **OK** to begin the Reconstruction.

NOTE:

- **Evolving mode is only available for Helical scans.**

Insert Protocol in Offline Recon

The option of inserting a reconstruction into the current study is available. Using this feature will result in a real-time reconstruction.

To insert a reconstruction into the current study, click Insert Protocol. The system displays the Home interface. Select the new series to be reconstructed, load the recon protocol parameters which are the same as those of the planned scan interface or the previous Recon.

If desired, edit the parameters.

- If Evolving is selected in original scans parameters, preview images appear in the image area. Zoom, window, and pan options are available before reconstruction.

- If the Evolving option is not selected in the scan protocol the reconstruction will proceed automatically and the images will not be previewed.

10.3 Fundamental Operations

Select series that need reconstruction in the patient list, click the 【Reconstruction】 on the right side of reconstruction tools.

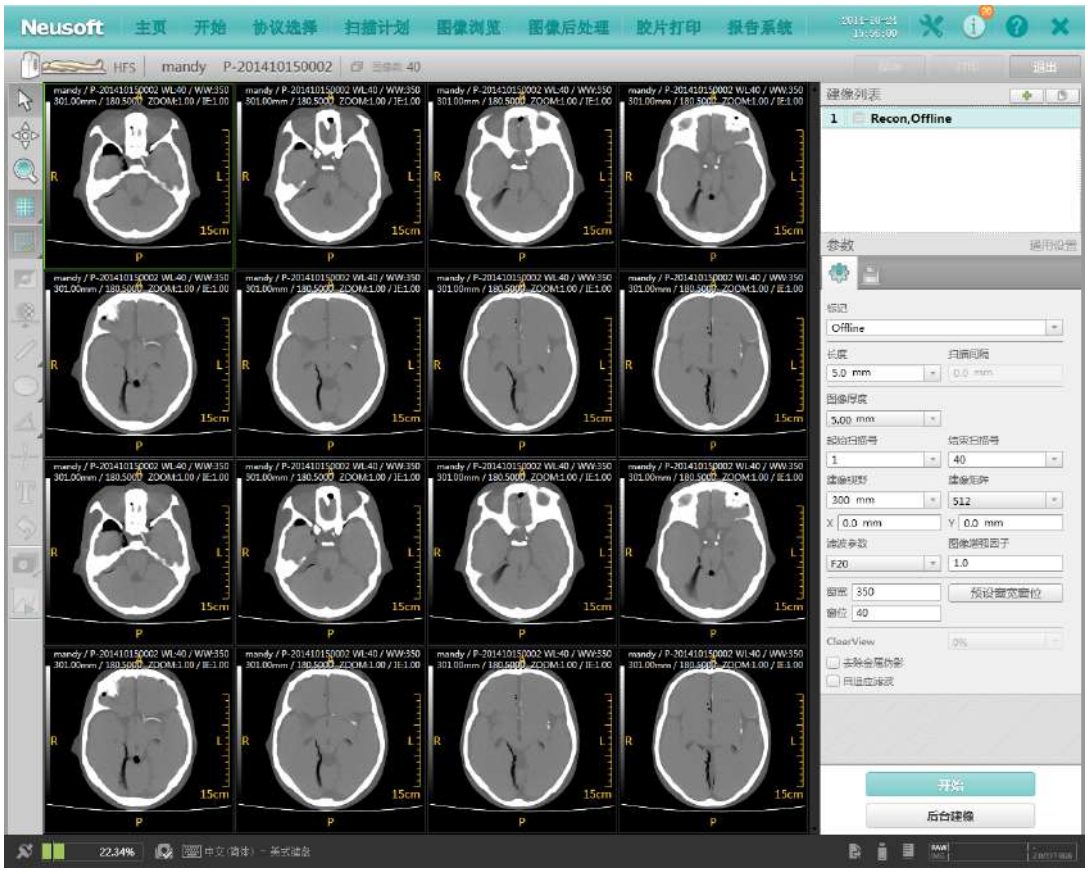


Fig 10-3 Offline Reconstruction Interface

In the mode of offline reconstruction, select Evolving mode(detailed introduction of this mode can refer to 9.2.5(Evolving)), then click【begin reconstruction】, image display area can display example images, the images are updating continuously. Based on demands:

Zoom in/out to enlarge or reduce the reconstructed field of view (FOV).

Pan an image to center the series of images or the region of interest.

Adjust the window setting.

Click **OK** to begin the Reconstruction.

NOTE:

- **Evolving mode is only available for Helical scans.**

When setup all corresponding settings, click 【begin reconstruction】. Click 【quit】, to quit the reconstruction operation interface. Click【background reconstruction】, this reconstruction task will for reconstruction queuing in reconstruction manager.

Chapter 11 System Settings

11.1 Protocol Edit

11.1.1 Generate Protocol

This function is used for creating, editing or deleting Scan Protocols.

1. Click **Service** in the workflow bar.

2. Select **Protocol Edit**. The Generate Protocol dialog box displays and the exam protocol groups display.

3. Select the Exam Protocol Group.

4. Select an existing protocol and the system will open the **Protocol Edit** page.

This selection automatically fills in Exam Protocol Group and Exam Protocol Name in the two fields of the dialog box. At the same time, the Protocol Parameters window opens.

5. Edit the parameters as necessary. After all parameters in that window are correct, click **OK**.

6. In the Edit Protocol Form, select the age group (this selection is mandatory).

7. If desired, these options can also be set:

- Age group
- Weight
- Requesting Physician
- Requested Procedure

8. When all the required information has been filled in, select one of the buttons at the bottom of the Edit Protocol Form dialog box:

Save to permanently replace the parameters in a protocol with the changes that have just been made. Use this option to change an existing user protocol.

Save As to keep the original protocol, but generate a new Protocol with the changes that have just been made. After selecting this, select a protocol group and enter a new protocol name (see creating a new protocol). And you must rename the protocol. Note: When creating a protocol from a factory default, the user must use the Save As option to save the generated protocol.

Delete to delete the selected protocol from the set of protocols.

The system prompts to confirm the selection.

Undo to re-edit the protocol parameters.

Exit to exit the Edit Protocol Form dialog box.

NOTE:

- **The factory protocols are the basic set of default protocols shipped with the system. They can be used as is, and can be viewed and copied, but not deleted. Protocols can be generated by editing copies of the factory procedures, or by copying procedures from backups, or by editing existing protocols.**
- **Users can check【Physical Examination Protocol】in Edit Protocol Properties. For those physical examination protocols, they will not recon immediately after scanning. These protocols will wait in the Recon Manager until all series before finished.**

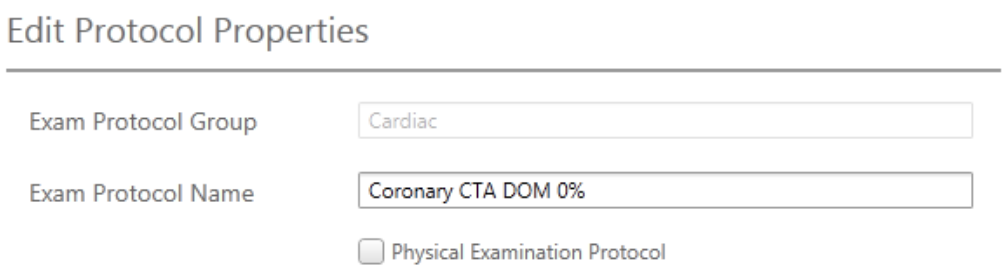


Fig 11-1 Physical Examination protocol

11.1.2 Export Protocols

This function is used for exporting the factory protocols and user protocols.

Click **Service** in the workflow bar.

Select **Protocol Edit**. The exam protocol groups display.

Select **Export Protocols**. The Export Protocol Form dialog box displays.

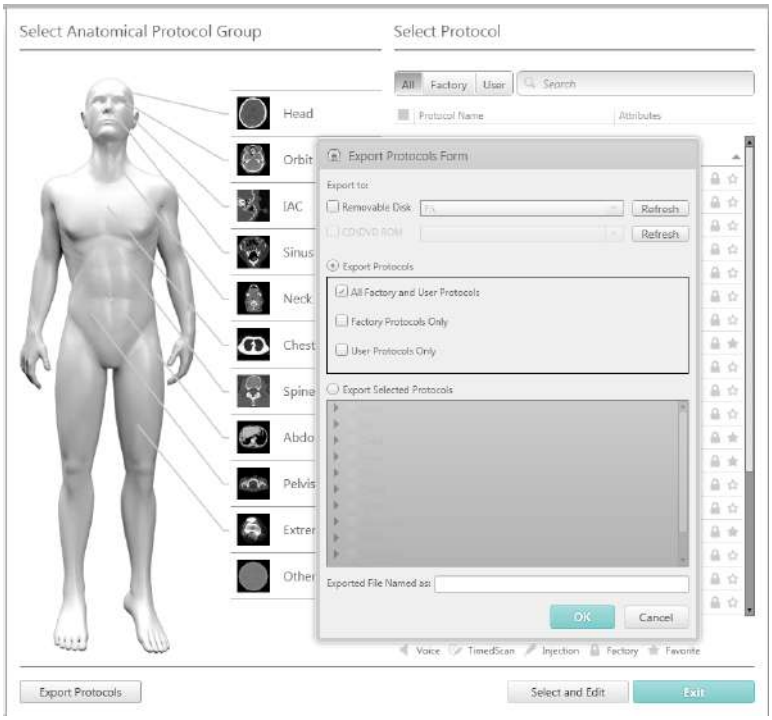


Fig 11-2 Export Protocols

Manipulate the export destination and protocols and name the Exported File. After all parameters in that window are correct, click **OK**.

View the exported protocols after the process completed.

11.2 System Settings

11.2.1 Disk Cleanup Setting

Click **Disk Cleanup Setting** in system setting page to enter the following interface:

Fig 11-3 Disk Cleanup

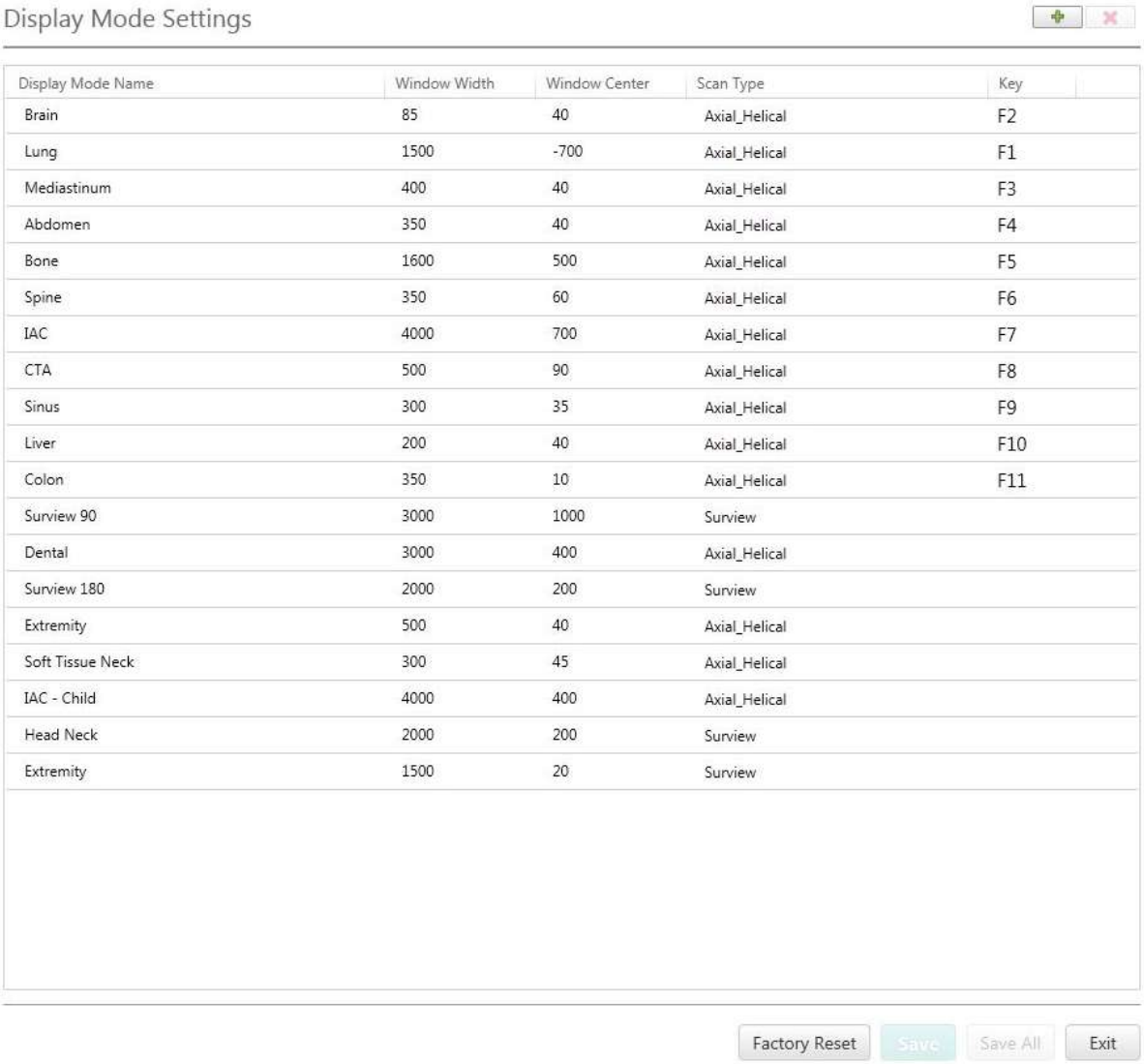
Disk Cleanup can automatically delete unlocked patients' raw data, and then clean up the disk. **No. of Patients Saved** or **Days of Service Raw Data Saved** can be set through **Auto Delete Raw or Auto Delete Image** in **System Setting.** . The raw data or image data deletion will start once the limitation is met. Then, the disk begins to clean up.

NOTE:

- **It takes about one and a half hours to clean up the disk.**
- **Only in Admin mode can users set disk cleanup in System Setting.**
- **The post-deletion results can be checked in the database.**
- **After the cleanup, if there are too many locked patients, the system will remind users of unlocking.**

11.2.2 Display Preset

Click **Display Preset** in system setting page to enter the following interface:



Display Mode Name	Window Width	Window Center	Scan Type	Key
Brain	85	40	Axial_Helical	F2
Lung	1500	-700	Axial_Helical	F1
Mediastinum	400	40	Axial_Helical	F3
Abdomen	350	40	Axial_Helical	F4
Bone	1600	500	Axial_Helical	F5
Spine	350	60	Axial_Helical	F6
IAC	4000	700	Axial_Helical	F7
CTA	500	90	Axial_Helical	F8
Sinus	300	35	Axial_Helical	F9
Liver	200	40	Axial_Helical	F10
Colon	350	10	Axial_Helical	F11
Surview 90	3000	1000	Surview	
Dental	3000	400	Axial_Helical	
Surview 180	2000	200	Surview	
Extremity	500	40	Axial_Helical	
Soft Tissue Neck	300	45	Axial_Helical	
IAC - Child	4000	400	Axial_Helical	
Head Neck	2000	200	Surview	
Extremity	1500	20	Surview	

Fig 11-4 Display Preset

Display Mode Settings function provides Display Mode Name, Window Width, Window Center, Scan Type and shortcut Key settings. User can change these factory settings and can also restore original factory settings by click **Factory Reset**. User can add or delete user-defined display mode.

11.2.3 Patient Information Setting

Click **Patient Information Setting** in system setting page to enter the following interface:

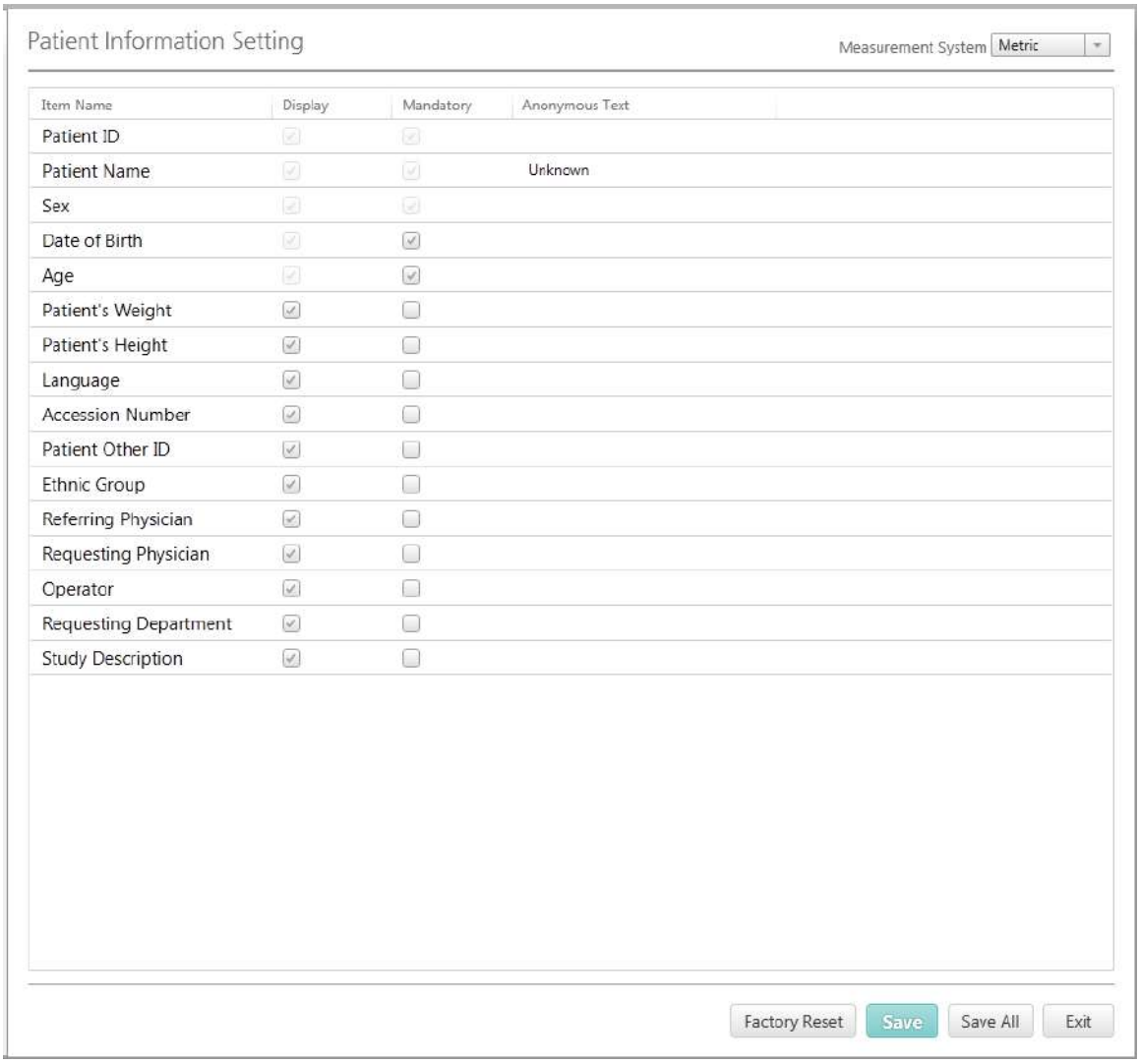


Fig 11-5 Patient Information Setting

User can define which patient information is displayed and which is mandatory by checking it. Patient ID, Patient Name and Sex are mandatory fields. There are two available measurement systems: Metric and U.S.

11.2.4 ID Generator Setting

Click **ID Generator Setting** in system setting page to enter the following interface.

In ID Generator Setting page, user can define generating rules for Patient ID and Study ID. Patient ID and Study ID can be made of number, character and date. The generated ID will display in Preview column.

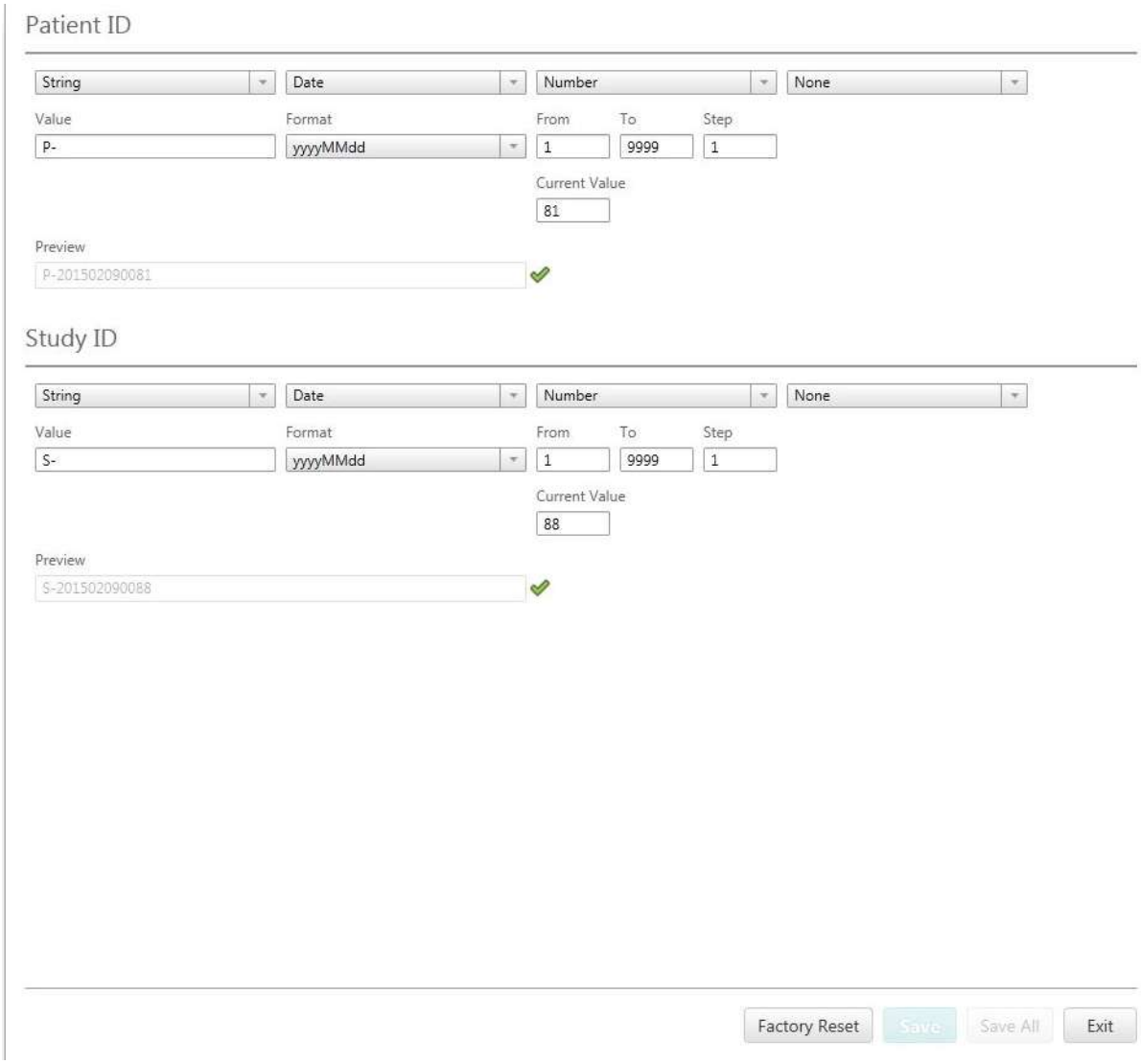


Fig 11-6 ID Generator Setting

11.2.5 Voice Setting

Click **Voice Setting** in system setting page to enter the following interface:

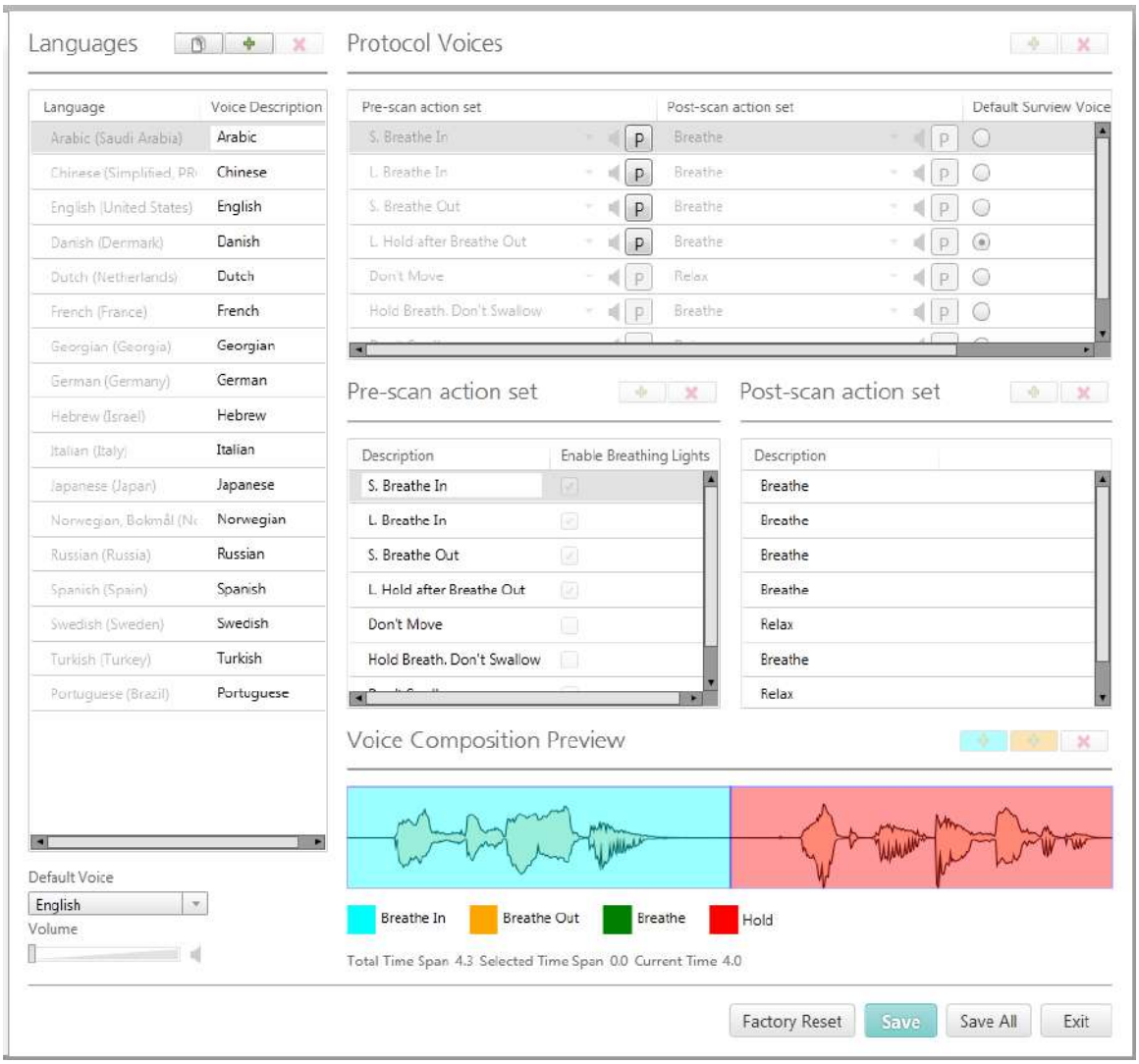


Fig 11-7 Auto Voice Setting

In Auto Voice Setting, user can record a new voice, set up a default voice and edit an existing protocol voice.

Record New Voice: Click Add New Voice button in languages column, and an Add Wizard for Voice Dialog Box will pop up. After recording a new voice, click the front end of the new voice to edit it.

Set up Default Voice: Click drop-down list of Default Voice to choose a voice as default voice.

Edit Protocol Voice: Click Add New Protocol Voice button in Edit Protocol Voice column and a wizard will pop up. Follow the wizard to finish protocol voice edit.

User can edit voice action before or after scan by setting up pre-scan action and post-scan action, and can preview in Voice Composition Preview column.

Click【Save】button, and restart console software, and then the new voice will take effect.

11.2.6 Image Information Setting

Click **Image Information Setting** in system setting page to enter the following interface:

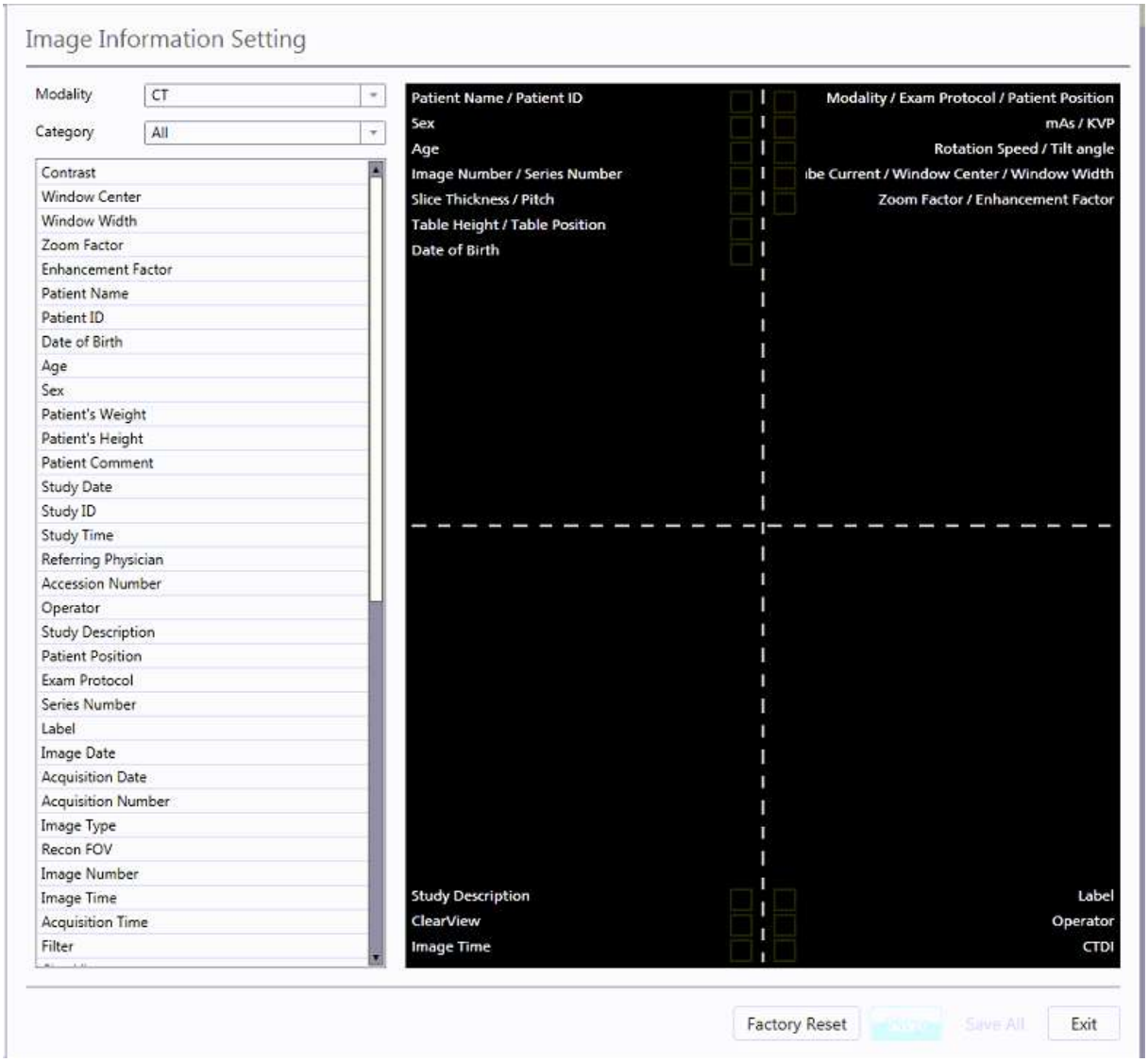


Fig 11-8 Image Information Setting

User can set up information in the four image corners, such as patient information, study information, image information, scanning information and device information, etc.

User can add and delete information by dragging and dropping it or adjust the display area of information by dragging and dropping rectangular box. .

11.2.7 Scan Miscellaneous Setting

Click **Scan Miscellaneous Setting** in system setting page to enter the Scan Miscellaneous Setting interface.

User can set up tube heat, image view convention for recon, scanning dose, contrast and some options.

11.2.7.1 Recon

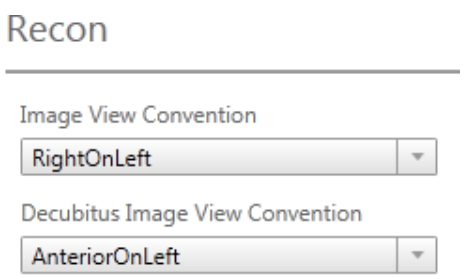


Fig 11-9 Image view convention

Image View Convention: User can change Image View Convention. The system provides three kinds of Image View Conventions, select settings in the top-down list.

Right on Left

View from Bed

View from Feet

Decubitus Image View Convention: User can change Decubitus Image View Convention. The system provides three kinds of Decubitus Image View Conventions, select settings in the top-down list.

Anterior on Left

View from Bed

View from Feet

11.2.7.2 Dose Setting

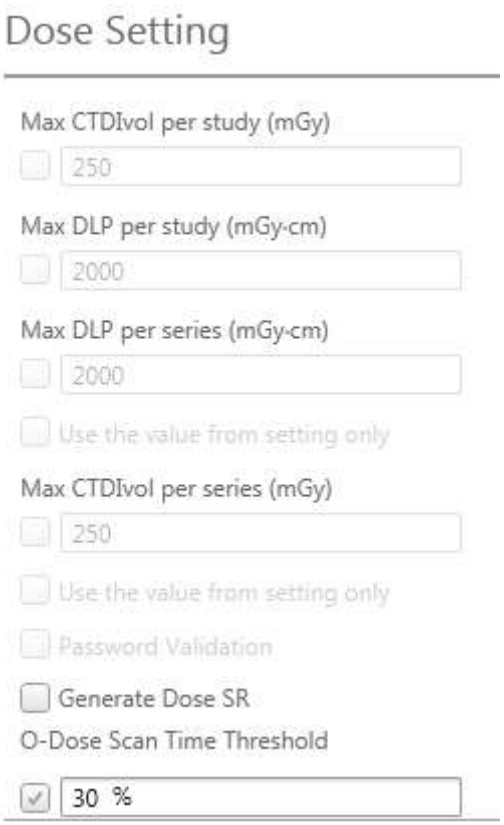


Fig 11-10 Dose Setting

Max $CTDI_{vol}$ per study (mGy) : When scanning, the system will calculate the total $CTDI_{vol}$ automatically. Administrator or higher authority can set up the max $CTDI_{vol}$ value per study. When the total $CTDI_{vol}$ is over the max limited value, a Dose Alert prompt will pop up.

Max DLP per study (mGy·cm) : When scanning, system will calculate the total DLP automatically. Administrator or higher authority can set up the max DLP value for a study. When DLP is over the max limited value, a prompt will pop up.

Max DLP per series (mGy·cm): Administrator or higher authority can set up the max DLP value for a series. When DLP is over the max limited value, a prompt will pop up. If it is checked as mandatory, system will ignore the max DLP value in the protocol but use the max limited value.

Max $CTDI_{vol}$ per series (mGy): Administrator or higher authority can set up the max $CTDI_{vol}$ value for a series. When $CTDI_{vol}$ is over the max limited value, a Dose Notification will pop up. If it is checked as mandatory, system will ignore the max $CTDI_{vol}$ value in the protocol but use the max limited value.

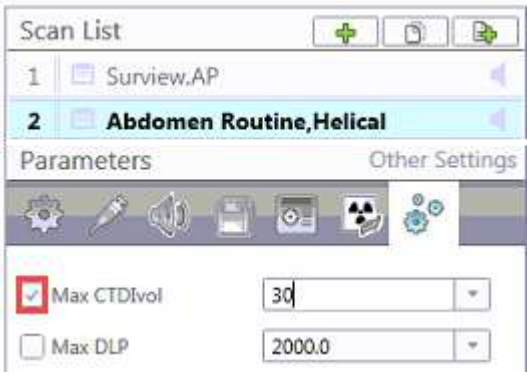


Fig 11-11 Max $CTDI_{vol}$ setting in Protocol Edit

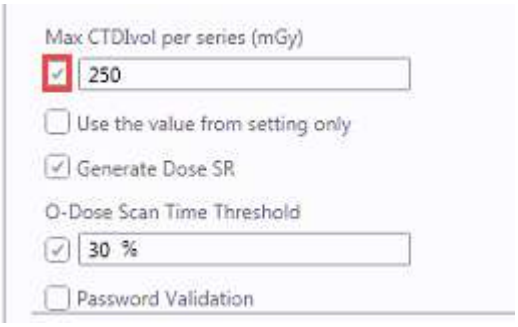


Fig 11-12 Max $CTDI_{vol}$ setting in Dose Setting

NOTE:

- **The Max $CTDI_{vol}$ per series (mGy) must be checked in Protocol Edit in conjunction with Max $CTDI_{vol}$ per series checked in Dose Settings, located in Scan Miscellaneous Setting Dose Setting.**

Password Validation : If password validation is checked and dose is over the max limited value, a prompt will pop up and user must input the login password to continue the scan. Administrator or higher authority can set up the password.

Generate Dose SR : If this option is checked, system will generate a structured dose report. Series number of dose report is 10001, and series number of structured dose report is 10000.

Dose Scan Time Threshold : When O-Dose is used, system will automatically change dose and pitch according to patient locating information. Scanning time will change accordingly. User can set up the percentage change in total time. If the percentage change is over the set value, a prompt will pop up.

11.2.7.3 Options

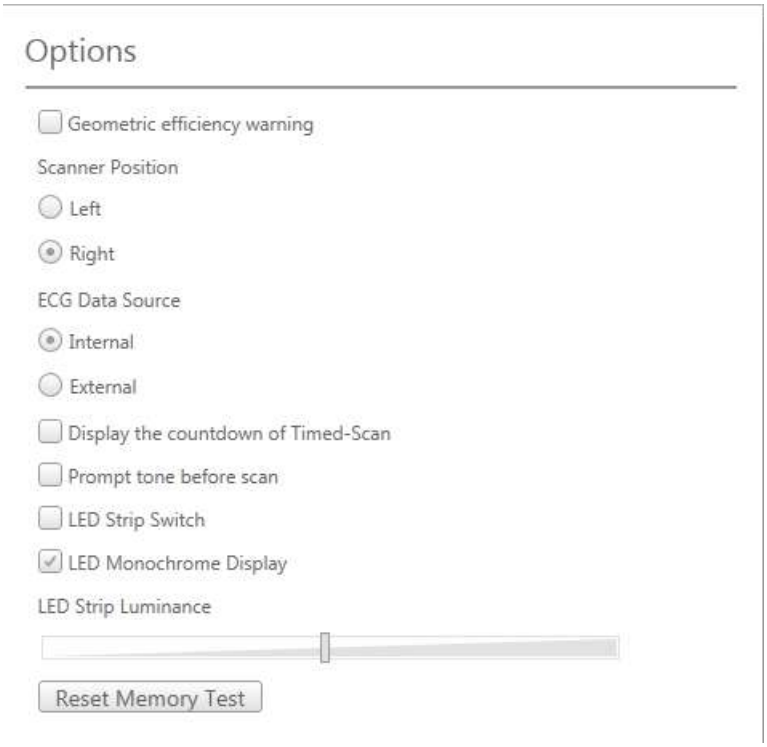


Fig 11-13 Options

Geometric efficiency (Reference IEC 60601-2-44): The geometric efficiency, which is a function of focal spot size and beam collimation, is also automatically computed and displayed on Dose Display. The geometric efficiency is a measure of how much of the z-axis X-ray beam is used by the system.

Table 11-1 Geometric Efficiency

Geometric Efficiency		
Slice combination(mm)	Focus Type	
	1.2	0.7
128*0.625(ZDFS)	87.00%	89.38%
64*0.625	92.49%	95.25%
64*0.625(ZDFS)	77.30%	81.04%
40*0.625	88.53%	92.64%
32*0.625	85.99%	90.89%
32*0.625(ZDFS)	63.65%	68.70%
24*0.625	82.21%	88.27%
20*0.625	79.26%	86.10%
16*0.625	75.39%	83.26%
16*0.625(ZDFS)	47.70%	53.33%

Geometric Efficiency		
16*0.625(ZDFS+iHD+3D)	49.08%	54.89%
16*0.625(ZDFS+iHD+2D)	47.97%	53.67%
12*0.625	69.71%	78.91%
8*0.625	60.59%	71.44%
8*0.625(ZDFS)	32.86%	38.07%
8*0.625(iHD+3D)	62.68%	74.03%
8*0.625(iHD+2D)	60.82%	71.44%
4*0.625	43.28%	55.65%
2*0.625	50.34%	50.49%

Geometric efficiency warning : Under different collimation and different utilization rate of the scanning dose, select this function will prompt the user when scanning collimating is changed and display the efficiency of scanning dose.

Scanner Position: To set up scanner position according to the gantry is set in the left or right of the user. This option is generally set by the service engineers.

ECG Data Source: To set up using inner ECG or outer ECG monitor.

Display the countdown of Time-Scan: When selected, the counter down will be displayed on gantry display screen.

Prompt tone before Scan: When selected, the system will beep when the countdown time is 10, 9 and 8s respectively.

LED Strip Switch: When selected, control the LED strips switch for the gantry, the couch and will be on.

LED Monochrome Display: LED strips for the gantry, the couch and breathing navigation board only display light blue light, and will not change with the color.

LED strip Luminance: To adjust the brightness of the LED strip.

One Click Position: Check this option, couch can reach to the preset position automatically after pressing the enable button in the CT-Box. This function is only applicable when not tilting. After pressing the enable button, a prompt message will pop up: "note: the couch is moving". When the couch moves automatically, press the scan stop button on CT-Box, the couch stops moving, and the scanning process stops at the same time.

Reset Memory Test: If scan is forbidden and a memory change message pops up, user can click reset the memory test to check whether the scan can be continued. This function should be under the guidance of the service engineer.

11.2.7.4 Contrast Setting

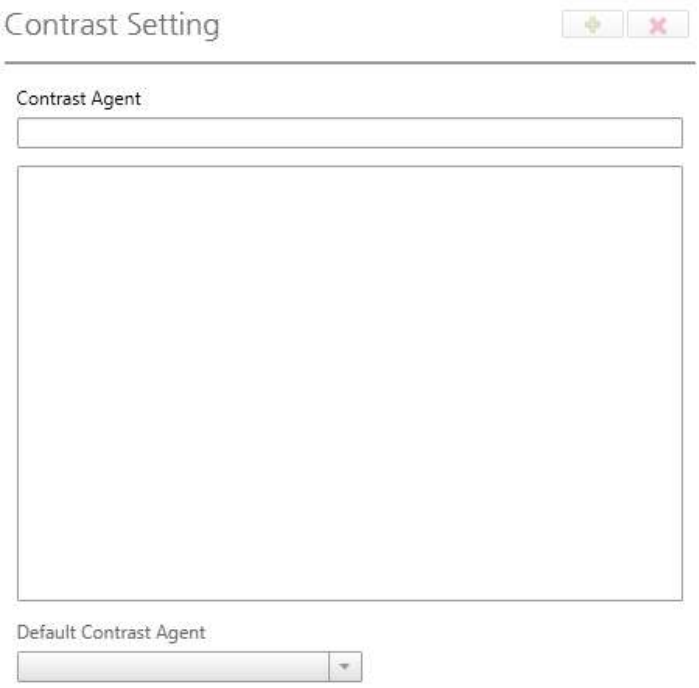


Fig 11-14 Contrast Setting

- **Contrast Agent** : User can add and delete contrast agent in the textbox. During a contrast agent scan, user can choose in the drop-down list as default agent.

  To add a contrast agent: Type contrast agent in textbox below Contrast Agent. Click on  .

  To delete a contrast agent: Select the contrast to be deleted and then click on  . User can choose contrast agent in the drop-down list when executing any contrast scan.

- **Default Contrast Agent:** User can choose a contrast agent in the drop-down list as default agent. To enter and add contrast agents, enter type of contrast, then click + sign. Operator may also select the Default Contrast Agent from the dropdown at the bottom of the Contrast Setting Interface.

11.2.8 Remote Service

Click **Remote Service** in system setting page to enter the following interface.

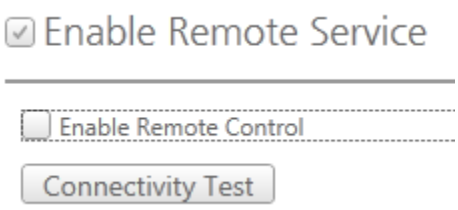


Fig 11-15 Enable Remote Service

On the device equipped with remote service, user can set up interface through remote service to open or close remote control function. Users can test whether the remote connection is ok or not by clicking connectivity test function.

When Enable Remote Service is unselected, the service engineer cannot connect to the user's computer through remote service.

When Enable Remote Service is selected, the following remote connection status can be displayed in the status bar:

Local Mode : Remote service mode is started, but not connected to the remote computer.

Remote View-Only Mode : Connected to the remote computer, but in view-only mode.

Remote Control Share Mode : Remote and local are connected, and both can operate.

NOTE:

- **When the state is in Local Mode, clicking the icon will pop up a remote service request to Neusoft Medical Systems Co., Ltd.**
- **If the connected state is Remote View-Only Mode or Remote Control Share Mode, for safety concerns, the user can stop the connection at any time.**
- **When Enable Remote Service is selected, please ensure than there is no one in scanner room. To ensure safety, relevant responsible parties in hospital must monitor on set, when service engineer perform remote operations on the device.**

11.2.9 Protocol Mapping Setting

Click **Protocol Mapping Setting** in system setting page to enter the following interface.

Fig 11-16 Protocol Mapping Setting

Users can edit mapping plans in protocol mapping setting. In the list of protocol plans, setup the protocol code, appointment protocol description, body part and protocol name.

There are mapping plans and appointment protocol code in appointing patient information on the registration page, but there is no match plans in protocol mapping setting and mapping plans and appointment protocol code can be added automatically in protocol mapping setting.

In protocol edit, if deleted protocol can be referenced by protocol mapping plans, the system pop up prompt: ”This protocol is contained in mapping plans, whether continue to delete?”, after selecting continue, delete protocol mapping relations simultaneously.

In protocol edit, if user changes the name of user-defined protocol and save it, it will be updated in mapping plans.

11.2.10 Certificate Setting

In the interface of【Daily-System Setting】-【Certificate Setting】, local and client certificate can be set, and 【Signing of original images with digital signatures】can be checked in the secure options.

Local certificate settings: used to generate, import and export local certificates.

Client certificate settings: used to import and manage the client certificates for accessing local Dicom services.

Signing of original images with digital signatures: when this option is checked, the system will digitally sign the original image reconstructed from the raw data.

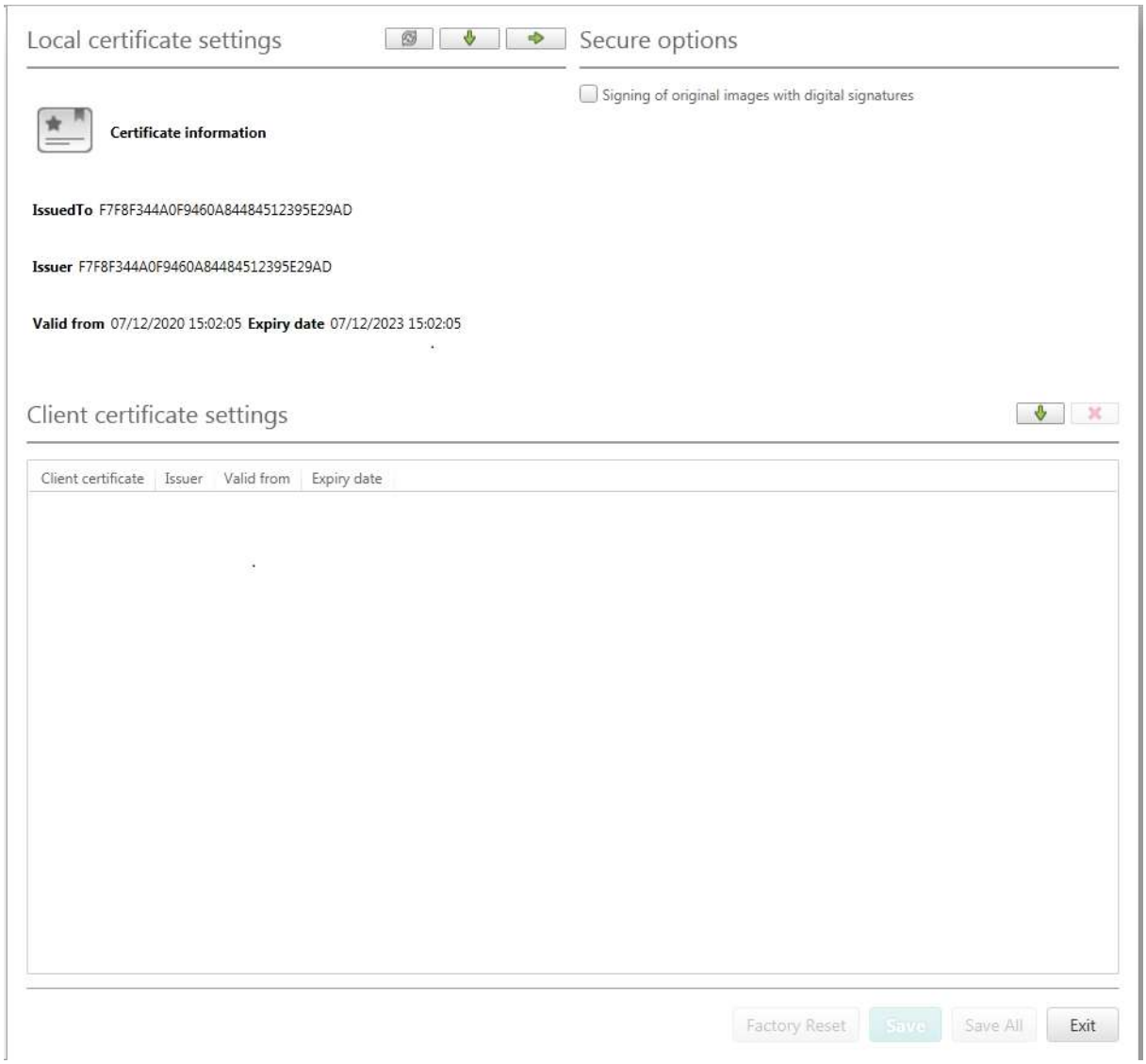


Fig 11-17 Certificate Setting

11.3 Data Deletion

In daily settings, click data deletion and the system will delete data and cleanup disk as disk cleanup setting set.

11.4 Scan Virus

Click **Scan Virus** in system setting page to enter the following interface:

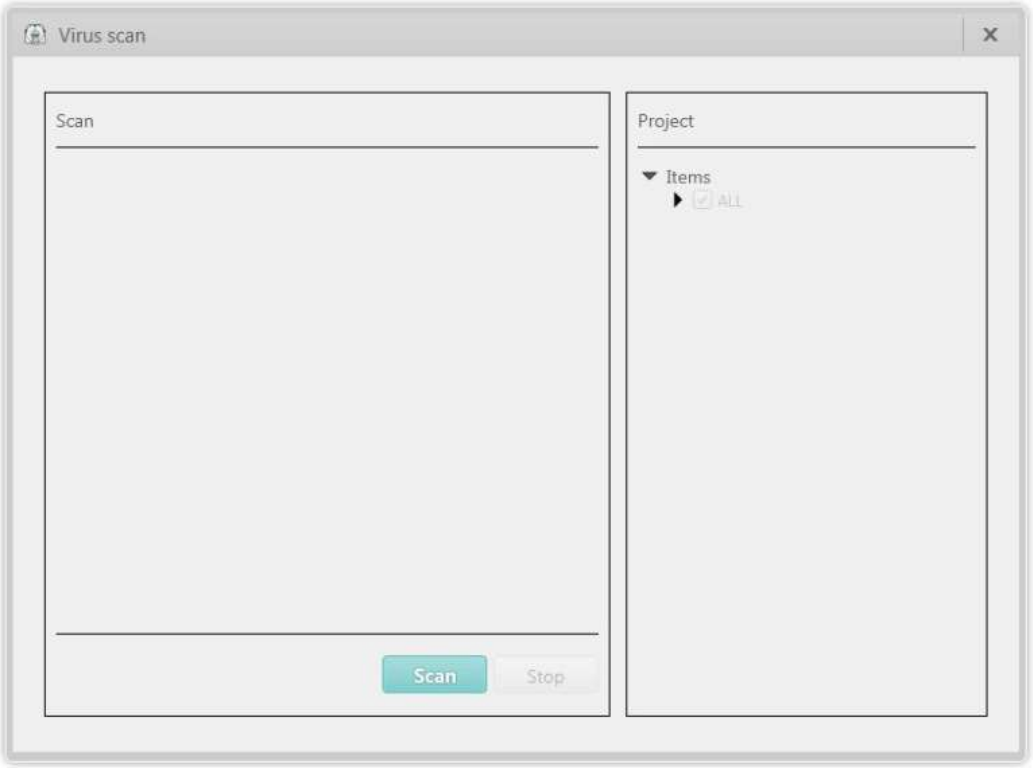


Fig 11-18 Scan Virus

Virus scan function uses a third software AntiVirus to scan disks. Users can chose scan items to start scanning and stop scanning.

11.5 Dose Test Journal

Click Dose Test Journal in daily setting, display the interface of dose test journal. The journal display dose test information including patient ID, time, type, protocol name, mark, kV, mA, CTDIvol, DLP, operator, scanning time, CTDI real dose（mGy）, CTDI limited dose（mGy）, DLP real dose（mGy*cm）, DLP limited dose（mGy*cm）and login username.

Select series that needs to export, click export to export corresponding dose test journal information.

11.6 Change User

Click **Change User** in daily setting page. Click OK to change a user. The following interface will pop up.

Fig 11-19 Change User

User can change a login user through this function, and it is not necessary to restart the software.

NOTE:

- **When changing a user, if there is a study in progress, the system will end the study.**

11.7 Exit

Click **Exit** in daily setting page. The following interface will pop up. Click Yes to end study.

Fig 11-20 Exit

Chapter 12 Quality Assurance

12.1 Overview

Imaging performance of the scanner is checked by scanning head and body system phantoms.

When testing image quality, the system should be properly calibrated. Read this section carefully and follow all instructions regarding scheduling and performance of quality assurance checks.

NOTE:

- **These instructions represent the manufacturer's required QA performance checks. If additional testing is required by your national or local authorities, please contact your Neusoft Service Representative.**

12.2 QA Test (Reference 21 CFR 1020.33(d))

12.2.1 System Test Phantom

QA phantom consists of two portions which cover the aspects of head and body scans. This section covers the specifications of both the head and body portions of the phantom. Familiarize yourself with this information before you scan either portion. The illustration below shows the entire phantom.

The head phantom is a PVC shell filled with water. It is 200 mm in diameter and consists of two layers:

Physical layer

Water layer

The body phantom is a nylon cylinder 300 mm in diameter.

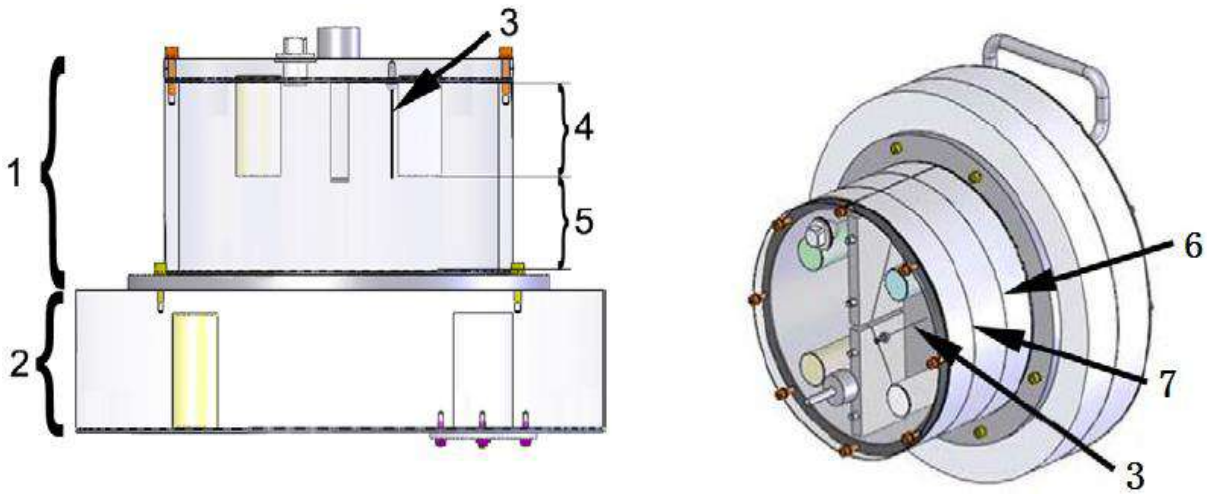


Fig 12-1 QA Phantom Composition

Table 12-1 Phantom Composition-1

No	Name
1	Head Phantom
2	Body Phantom
3	Copper Wire
4	Physics Layer
5	Water Layer
6	Water Layer Center Line
7	Physics Layer Center Line

Table 12-2 Phantom Composition-2

Phantom Layer	Function	Composition
Physics Layer of Head Phantom	Contrast Scale	Four linear measurement phantoms： Teflon、Acrylic、PS、PE
	Slice thickness measurement	Tilt Aluminum
	Spatial Resolution measurement	Fine copper wire
Water Layer of Head Phantom	CT value, CT Value uniformity, noise, low contrast resolution	Purified water
Body Phantom	CT value, CT Value uniformity, noise	Nylon

12.2.2 QA Testing Schedule (Reference 21 CFR 1020.33(d)(2))

The benchmark range of QA tests should meet the requirements in the following table.

Table 12-3 QA test items and requirements

Check Item	Scan Position	Phantom	Check Range	QA Test Frequency
Noise	Head	Water Layer	0.72%±0.1%	Daily
	Body	Body Layer	1.75%±0.26%	Daily
Mean CT values	Head	Water Layer	0±4HU	Daily
	Body	Body Layer	104±8HU	Daily
CT value Uniformity	Head	Water Layer	±4HU	Daily
	Body	Body Layer	±8HU	Daily
Low Contrast Resolution	Head	Water Layer	6.65±2.15	Daily
Tomographic Section thickness	Head	Physics Layer	(2mm,+∞),±1.0mm [1mm,2mm],±50% (-∞,1mm),±0.5mm	Monthly
Spatial Resolution(MTF)	Head	Physics Layer	9.0±0.9 lp/cm @10% 5.3±0.5 lp/cm @50%	Monthly
	Head*	Physics Layer	>6.0 lp/cm @0% >4.5 lp/cm @10% >2.5 lp/cm @50%	Monthly
	Body	Physics Layer	8.5±0.8 lp/cm @10% 5.0±0.5 lp/cm @50%	Monthly
	Body*	Physics Layer	>6.0 lp/cm @0% >4.5 lp/cm @10% >2.5 lp/cm @50%	Monthly
Contrast Scale	Head	Acrylic	125±15HU	Monthly

NOTE:

- **There are no clear requirements in laws or regulations for basic value of the LCR, so requirements can be set by the users themselves.**
- **For dose standard of scan protocols, the head dose should be no more**

than 40 mGy, and the body dose should be no more than 20 mGy.

- **The requirements in the table do not apply to FWHM protocols.**
- **The user must be well trained before performing QA test.**
- **For those marked with "*", manual measurement shall be used. See Chapter 12.2.7 for measurement method.**

12.2.3 Positioning the System Test Phantom (Reference 21 CFR 1020.33(d)(2))

Before performing phantom image quality test or constancy test, adjust the system phantom to the correct position according to the following procedure:

1. Position the system phantom at the head of the Couch top using the Phantom holder.
2. Manually control the Couch height so that the outside laser marker is set to the center of the phantom.
3. Manually move the Couch top so that the Inner laser marker is set to the water layer. The system will try to scan the head phantom after testing, if the place of the head phantom is wrong, the prompt will pop up.

12.2.4 Start QA Tests (Reference 21 CFR 1020.33(d)(2))

Noise, Mean CT values, CT value uniformity and low contrast resolution can be auto-tested by following procedure. While noise, mean CT values and CT value uniformity can also be manual-tested, please see details in chapter 12.2.5.

Spatial Resolution (MTF) and Tomographic Section thickness can also be auto-tested, the details are shown in chapter 12.3.5.

Contrast Scale can be manual-tested as chapter 12.2.6 shows.

Run the tests according to the following procedure:

1. To start the tests select **QA** in service. The QA test interface appears:

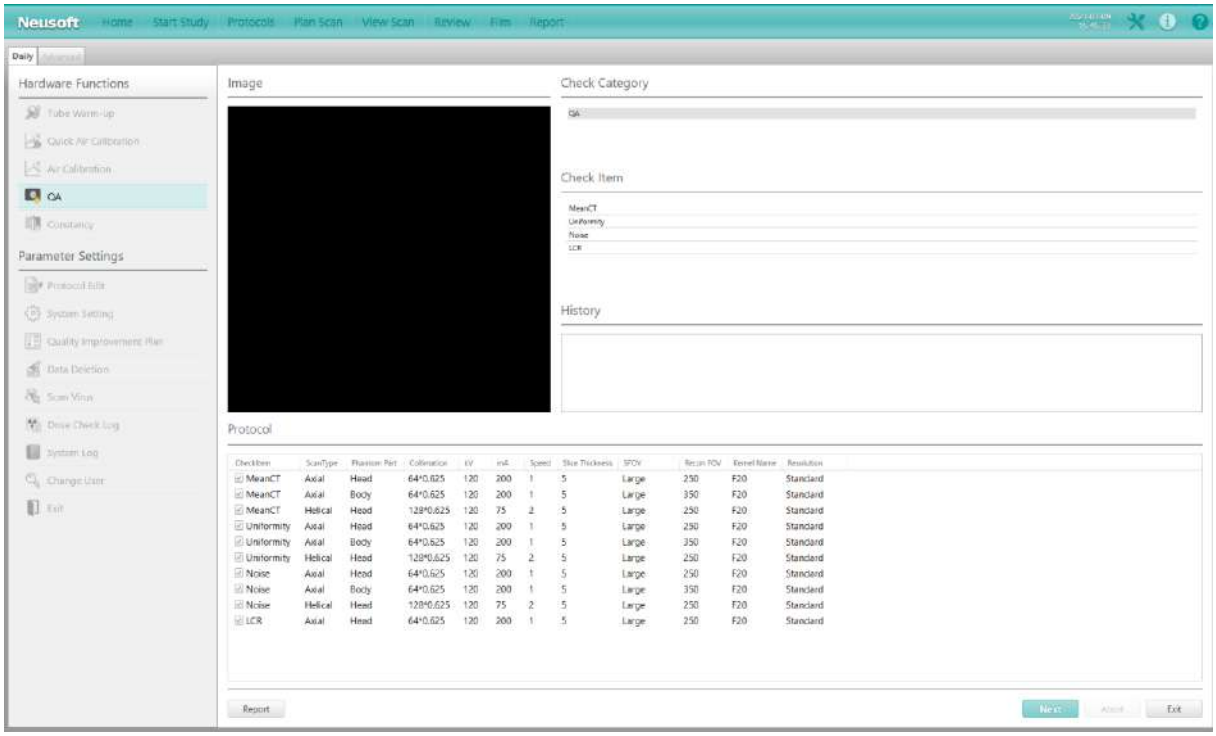


Fig 12-2 QA test

2. Click Next in constancy test page, and an Instructions Dialog appears, enter the following information:

   - Device SN
   - User Name
   - User Address
   - Phantom SN
   - Nylon CT Value
   - FSE name
   - reasons

After entering the above information, click confirm.

Note:

- **Recommended Nylon CT value is 104HU.**

3. An Instructions Dialog appears. Follow the on-screen instructions to position the System Test Phantom, and once it is in position, click **OK** to continue.

4. In the following window, click start to select the desired items, and click **Next** to continue the test, click OK in the new message.

5. The application scans the System Phantom and calculates the position of the System Phantom. If the position is not accepted, the application will provide instructions for adjusting the position of the Phantom.

6. When the System Phantom position is accepted, the system will automatically start the Test. The test automatically runs a sequence of scans. The scans and parameters are listed in the Verify item area.
7. When the image quality of each item is found to comply with the required tolerances, its state is recorded in green as Passed. When the image quality of an item fails to comply with any required tolerance, its state is recorded in red as Failed.
8. When the tests are completed, the QA report is generated automatically and saved. To view the report, click History of Report button. The system also provides function to burn test report to a CD.

WARNING:

Before performing QA test, please ensure that:

- **No person is in the scanner room, and the door of the scanner room is closed.**
- **The system phantom is fixed to the Phantom holder firmly and correctly, and the Couch height is proper to avoid collision between the phantom and the Gantry when the Couch top is moving horizontally.**

NOTE:

- **If any of the sub-items fail during the QA test, repeat the same sub-item or perform it again manually.**
- **When performing QA test, if any item value is beyond the range, user needs to perform air calibration, and then re-perform QA test. If the value is still out of range, please contact the service representative.**

12.2.5 Other Dosimetry Information

12.2.5.1 Noise

1. Overview

Noise is measured using ROI of:

7000 ± 2000 m area for head phantom

14000 ± 1000 m area for body phantom

According to YY/T 0310：≤0.35%

For 40mGy, suggested scan condition is Head STD-QA protocol: Head STD-QA, 120 kV, 280mA, 1s, 64*0.625mm, FOV250, F10, 10mm, Standard Resolution.

Image noise should not be more than 0.35% (Center dose should be less than 40mGy)

According to Reference 21 CFR 1020.33(c)(3)(i):

For head water layer of QA phantom, 0.72%, suggested scan condition is Head STD-QA protocol: 120 kV, 200 mA, 1s, 64*0.625mm, FOV250, F20, 5mm, large wedge.

For body QA phantom, 1.75%, suggested scan condition is Body STD-QA protocol: 120 kV, 200 mA, 1s, 64*0.625mm, FOV350, F20, 5mm, large wedge.

The SD is divided by 1000 and multiplied by 100 to transform it to a percentage.

$$\text{Noise (\%)} = \frac{SD}{1000} \times 100$$

The maximum deviation from the stated noise is 15%. (Reference 21 CFR 1020.33(c)(3)(v)).

2. Measurement of Noise

Respectively put QA water phantom and body phantom in the scanning field of view, and make sure phantom axis coincides with gantry rotation axis. Respectively select Head STD-QA Protocol and Body STD-QA Protocol to scan, and choose a measured area in the center of the image that is not less than 100 pixels and its diameter is not more than 40% of the image diameter. Measuring the standard deviation of CT value of the area, and use the Noise formula to calculate noise value. By this method, get images as follow:

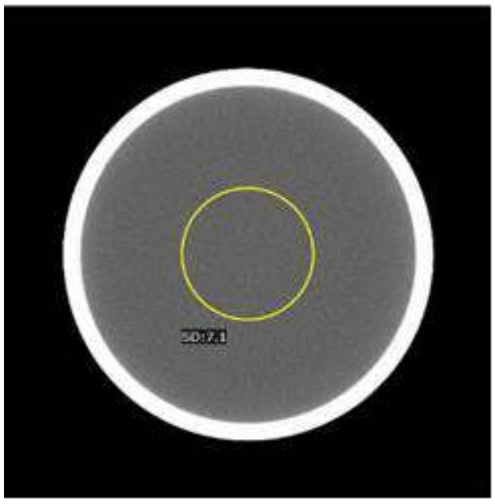


Fig 12-3 Noise Measurement of Water Phantom Using Head STD-QA Protocol

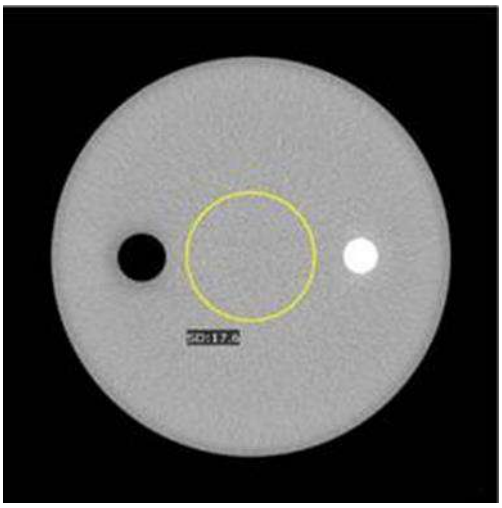


Fig 12-4 Noise Measurement of Body Phantom Using Body STD-QA Protocol

12.2.5.2 Measurement of CT Value

Respectively put QA water phantom and body phantom in the scanning field of view, and make sure phantom axis coincides with gantry rotation axis. Respectively select Head STD-QA Protocol and Body STD-QA Protocol to scan, and choose a measured area in the center of the image that its diameter is about 10% of the image diameter. Measuring the CT value of the area, and get images as follow.

Fig 12-5 CT Value Measurement of Water Phantom Using Head STD-QA Protocol

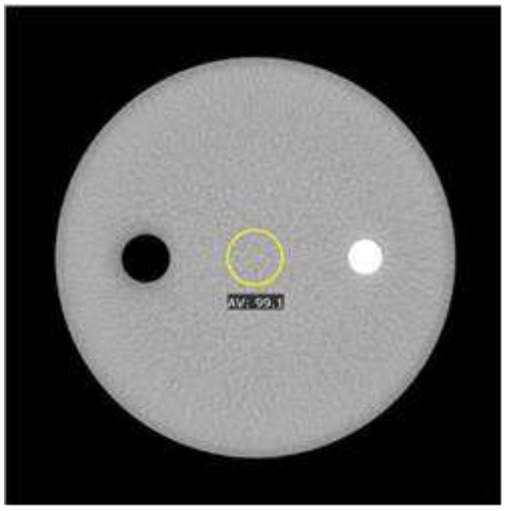


Fig 12-6 CT Value Measurement of Body Phantom Using Body STD-QA Protocol

12.2.5.3 Measurement of CT Value Uniformity

Respectively put QA water phantom and body phantom in the scanning field of view, and make sure phantom axis coincides with gantry rotation axis. Respectively select Head STD-QA Protocol and Body STD-QA Protocol to scan, and choose four measured areas near the phantom edge and one in the center of the image. Center ROI cannot coincide with edge ROI. All ROI diameters are about 10% of the image diameter. One is in the center of the image. Measuring the average CT value of all ROIs, and the CT value uniformity is the maximum difference between center ROI CT value and 4 edge ROI CT values.

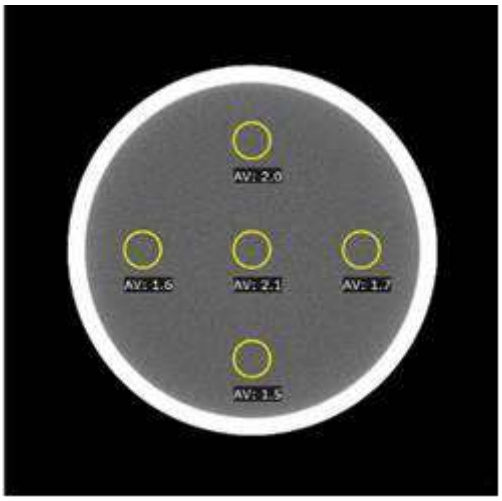


Fig 12-7 CT Value Uniformity Measurement of Water Phantom Using Head STD-QA Protocol

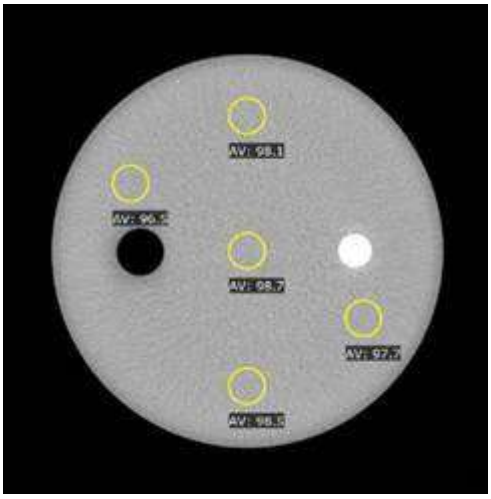


Fig 12-8 CT Value Uniformity Measurement of Body Phantom Using Body STD-QA Protocol

12.2.6 Contrast Scale

Auto- Constancy test includes water CT measurement (MeanCT) and CT measurement of Acrylic, which could be used to calculate contrast scale range. See contrast scale range value of Acrylic in table 12-3 Test items and requirements.

12.2.7 MTF manual test method and test record table

1) The QA phantom is fixed on the table top of the couch through a fixed bracket, and the QA phantom is located in the center of the scanning field through an external light marker;

2) The internal light marker is used to locate the center of physical layer of the QA phantom;

3) In the clinical interface, load the protocol and set the following typical conditions of operations:

MTF	Protocol name	Scanning parameters:	Reconstruction parameters
For Head	Head STD-QA	120 kV, 200 mA, 1s, 64 * 0.625mm, large wedge	FOV 250, F20, standard resolution, 5mm
For Body	Body STD-QA		FOV 350, F20, standard resolution, 5mm

4) Enter the service mode of the console software, select【advanced】, select【image quality evaluation】, and select any four images of physical layer to be measured in the patient list and image sequence. Select MTF mode, select copper wire image, and click the【evaluate】button to display MTF curve and results, record the values.

The expected results should not be less than 6lp/cm@0%, 4.5lp/cm@10%, 2.5lp/cm@50%.

12.3 Constancy Tests (IEC 61223-2-6)

12.3.1 Overview

Constancy test runs during planned maintenance or after component replacement. Constancy measures the performance and stability of the system.

It is mandatory

- to record and reproduce all significant settings of the CT SCANNER and ACCESSORIES each time a test is undertaken, so as to check that the same equipment, components and ACCESSORIES are being used;

- to consider the influence of environmental changes, particularly variations in supply voltage, on the results;

- to check the performance of the test instrumentation regularly, particularly when any significant variation in the CT SCANNER is suspected.

When a significant deviation between CONSTANCY TEST results and BASELINE VALUES is observed, the test equipment and positioning of the instrumentation shall be re-checked, including the TEST DEVICE, and the measurements shall be repeated. If a significant deviation still is observed, please contact the service representative.

The benchmark range of constancy tests should meet the requirements in the following table.

Additionally, acceptance test criteria shall be applied if the same testing methodology was used. If the measured values do not fulfill the criterion, appropriate action shall be taken according to IEC 61223-2-6 or other action to be decided upon by the user.

Table 12-4 Constancy Test items and requirements

Check Item	Type	Check Range	Constancy Frequency
Positioning of the PATIENT SUPPORT	L_{for} and L_{back}	±1 mm	Quarterly
	C_{for} and C_{back}	±1 mm	Quarterly
Patient Positioning Accuracy	Internal patient positioning light	± 2mm	Quarterly
	External patient positioning light	± 2mm	Quarterly

Check Item	Type	Check Range	Constancy Frequency
	Coronal and sagittal patient positioning light	± 2mm	Quarterly
Dose ($CTDI_w$)	Head	[22.30mGy, 33.46mGy]	Semi-annually
	Body	[11.18mGy, 16.78mGy]	Semi-annually
Dose ($CTDI_{free\ air}$)	Head	± 20%	Semi-annually
	Body	± 20%	Semi-annually
Dose ($CTDI_{vol}$)	Head	± 20%	Semi-annually
	Body	± 20%	Semi-annually
Noise	Head	0.72%±0.1%	Monthly
	Body	1.75%±0.26%	Monthly
Mean CT values	Head	0±4HU	Monthly
	Body	104±8HU	Monthly
CT value Uniformity	Head	±4HU	Monthly
	Body	±4HU	Monthly
Tomographic section thickness	Head	（2mm，+∞），±1.0mm [1mm, 2mm]，±50% （-∞，1mm），±0.5mm	Monthly
Spatial Resolution (MTF)	Head	9.0±0.9 lp/cm @10% 5.3±0.5 lp/cm @50%	Monthly
	Body	8.5±0.8 lp/cm @10% 5.0±0.5 lp/cm @50%	Monthly

- **The user must be well trained before performing constancy test.**

12.3.2 Positioning of the PATIENT SUPPORT

12.3.2.1 Overview

Positional accuracy of the PATIENT SUPPORT includes both longitudinal positioning and backlash evaluation.

The accuracy of longitudinal PATIENT SUPPORT positioning is evaluated by moving the PATIENT SUPPORT a defined distance in one direction and confirming the distance travelled.

The accuracy of moving the PATIENT SUPPORT in one direction and moving it back to the starting position is referred to as backlash.

12.3.2.2 Procedure to test positioning of patient support

The test shall be performed with a person-equivalent load not to exceed 135 kg on the PATIENT SUPPORT.

Fix a mark in a convenient way on the moving part of the PATIENT SUPPORT and another one adjacent to it on the ruler.

Drive the PATIENT SUPPORT out a fixed indicated distance and measure the distance L_{for} moved (distance between the two marks).

Return the PATIENT SUPPORT back to the initial indicated position and measure the distance C_{for} between the two marks.

Then repeat the movement to the opposite direction and measure the distances between the markers equivalent to above measurements as L_{back} and C_{back}.

The above procedure shall be repeated under CT CONDITIONS OF OPERATION, driving the PATIENT SUPPORT in scanning mode, in about 10 mm increments, up to a total distance of 30 cm in both the forward and backward directions. The longitudinal positioning and backlash evaluation shall be repeated.

12.3.3 Patient Positioning Accuracy

12.3.3.1 Overview

The correlation of the axial patient positioning light and scan plane is tested by positioning and scanning a thin absorber as positioning light correlation phantom which is a wire with a diameter of about 1 mm.

12.3.3.2 Procedure to test the internal patient positioning light

1. Move away the couch cushion.
2. Position the correlation phantom on the couch.
3. Alignment the metal wire to the iso-center with coronal and sagittal position Line. Alignment the metal wire with Internal Position Line (Parallel with the Scanning Plane).
4. Scan with the following condition:

Scan Mode	KV	mA	Scan Speed	Slice Thickness	Img Thickness	DFOV	Recon Kernel	Resolution
Axial	120	200	1s	16x0.625	0.625	100	F60	High

Current horizontal couch position is h1. Set scan start position as h1-4.7 on parameter setting page.

Among the 16 images, the brightest image of the wire is between Image 6th and Image 11th (included).

12.3.3.3 Procedure to test the external patient positioning light

1. Move away the couch cushion.
2. Position the correlation phantom on the couch.
3. Alignment the metal wire to the iso-center with Coronal and Sagittal position Line.
4. Move out the couch in horizontal. Alignment the metal wire with External Position Line (Parallel with the Scanning Plane).
5. Press Couch Index In button on control panel. The wire shall be centered in the external light parallel to the scan plane.
6. Scan with the following condition:

Scan Mode	KV	mA	Scan Speed	Slice Thickness	Img Thickness	DFOV	Recon Kernel	Resolution
Axial	120	200	1s	16x0.625	0.625	100	F60	High

Current horizontal couch position is h1. Set scan start position as h1-4.7 on parameter setting page.

Among the 16 images, the brightest image of the wire is between Image 6th and Image 11th (included).

12.3.3.4 Procedure to test the coronal and sagittal patient positioning light

1. Remove the scanning cushion.
2. Position the phantom on the Couch.
3. Alignment the metal wire to the isocenter with Coronal and Sagittal position

Line (Vertical with the Scanning Plane).

4. Scan with the following condition:

Scan Mode	KV	mA	Scan Speed	Slice Thickness	Img Thickness	DFOV	Recon Kernel	Resolution	FOV	Recon Center X	Recon Center Y
Axial	120	200	1s	16x0.625	0.625	100	F60	High	200	0	0

Current horizontal couch position is h1. Set scan start position as h1-4.7 on parameter setting page.

Among the 16 images, select the brightest dot image as test target. Use scale plate to measure the perpendicular distances between the brightest dot and image left edge, right edge, up edge and down edge. The criteria is the four distances should within 100± 2mm.

12.3.4 Measurement of Dose (Large Wedge)

12.3.4.1 Dose Measurement Tools

Dose measurement tools include: unfors with ionization chamber, head dose phantom and body dose phantom.

12.3.4.2 Head $CTDI_W$ Measurement

1. Put head dose phantom on coronal head holder on the couch
2. Adjust head dose phantom to central field of view.
3. Connect 100mm ionization chamber to unfors.
4. Select CT-dose function in unfors.
5. Insert 100mm ionization chamber to B5 position of head dose phantom in Fig 14-1.
6. Fulfill the other holes of head dose phantom with test phantom material.
7. Perform axial scan in central field of view.
8. Scan with the following protocols: Head\Axial\Head Std QA.
9. Record measured value for B5.

$$CTDI_{100}(center) = CTDI_{100}(B5) = Value\ in\ unfors\ /4$$

10. Respectively measure values for B1, B2, B3, and B4 position according the method above.

11. Record value in unfors for every test point and calculate $CTDI_{100}$ (B1), $CTDI_{100}$ (B2), $CTDI_{100}$ (B3), and $CTDI_{100}$ (B4).
12. Calculate $CTDI_{100}$(Peripheral)

$$CTDI_{100}(Peripheral)=\{ CTDI_{100}(B1)+CTDI_{100}(B2)+CTDI_{100}(B3)+CTDI_{100}(B4)\}/4$$

13. Calculate $CTDI_W$

$$CTDI_w = \frac{1}{3}CTDI_{100}(\text{Center}) + \frac{2}{3}CTDI_{100}(\text{Peripheral})$$

When recording the results, the following form is recommended:

Table 12-5 Head $CTDI_W$ Measurement

In scan condition: Head STD-QA/Resolution STD/64*0.625 mm/1.0 s/FOV250/F10/10mm/ 120 kV/ 200 mA /large wedge						
Test point	B5	B1	B2	B3	B4	22.30mGy≤CTDIw≤33.46mGy
Test value （mGy）						

12.3.4.3 Body $CTDI_W$ Measurement

1. Put Body dose phantom on the couch
2. Insert 100mm ionization chamber to B5 position of dose phantom in Fig 14-1.
3. Fulfill the other holes of body dose phantom with test phantom material.
4. Perform axial scan in central field of view.
5. Scan with the following protocols: Head\Axial\Body Std QA.
6. Record measured value for B5.

$$CTDI_{100}(\text{Center}) = CTDI_{100}(B5) = \text{Value in unfors} /4$$

7. Respectively measure values for B1, B2, B3, and B4 position according the method above.
8. Record value in unfors for every test point and calculate $CTDI_{100}$ (B1), $CTDI_{100}$ (B2), $CTDI_{100}$ (B3), and $CTDI_{100}$ (B4).
9. Calculate $CTDI_{100}$(Peripheral)

$$CTDI_{100}(\text{Peripheral})=\{ CTDI_{100}(B1)+CTDI_{100}(B2)+CTDI_{100}(B3)+CTDI_{100}(B4)\}/4$$

10. Calculate $CTDI_W$

$$CTDI_w = \frac{1}{3}CTDI_{100}(\text{Center}) + \frac{2}{3}CTDI_{100}(\text{Peripheral})$$

When recording the results, the following form is recommended:

Table 12-6 Body $CTDI_W$ Measurement

In scan condition：Body STD-QA/Resolution STD/64*0.625 mm/1.0 s/FOV250/F10/10mm/ 120 kV/ 200 mA /large wedge						
Test point	B5	B1	B2	B3	B4	11.18mGy≤CTDIw≤16.78mGy
Test value （mGy）						

12.3.4.4 $CTDI_{free\ air}$ for head and body (IEC 61223-3-5 and IEC 60601-2-44)

1. Place 100mm ionization chamber in the front end of couch. Probe can stretch out the couch.
2. Make the 100mm ionization chamber in the center field of view.
3. Perform axial scan in central field of view.
4. Scan with the typical conditions in table 12-7.
5. Record measured value for $CTDI_{free\ air}$.

Table 12-7 Typical body and head conditions of operation

Voltage (kV)	120kV
Thickness (mm)	64*0.625mm
Scan time (s)	1.0s
mA	200mA
Filter	Large wedge

Table 12-8 Expected $CTDI_{free\ air}$ for scan conditions (mGy)

Variation of kV	**Variation of the nominal beam collimation**										
	Body										**Head**
	2*0.625	4*0.625	8*0.625	12*0.625	16*0.625	20*0.625	24*0.625	32*0.625	40*0.625	64*0.625	64*0.625
60kv	——	——	——	——	——	——	——	——	——	4.30	——
70kv	——	——	——	——	——	——	——	——	——	7.57	——
80kV	——	——	——	——	——	——	——	——	——	11.78	——

100kV	——	——	——	——	——	——	——	——	——	22.65	——
120kV	71.29	81.56	57.46	49.60	45.48	43.09	41.57	39.61	38.09	36.23	35.95
140kV	——	——	——	——	——	——	——	——	——	52.40	——

The maximum deviation of $CTDI_{free\ air}$ value is ± 20%.

12.3.4.5 $CTDI_{vol}$

$CTDI_{vol}$ is calculated by $CTDI_w$ measured in typical body or head scan condition:

$$CTDI_{vol} = 1 \times CTDI_w$$

The maximum deviation of $CTDI_{vol}$ is ± 20%.

12.3.5 Start Auto-Constancy Tests

To test noise, mean CT value, uniformity, tomographic section thickness and MTF by running auto-constancy tests according to the following procedure:

1. To start the tests select **Constancy** in service. The constancy test interface appears.
2. Click **Next**, a config information dialog appears; enter the required information.
   - Machine SN
   - Customer Name
   - Customer address
   - Phantom SN
   - Aculon CT Number
   - FSE Name
   - Reason

Click **Ok** after entering the information.

NOTE:

- **The recommended Aculon CT Number is 104.**

3. An Instructions Dialog appears. Follow the on-screen instructions to position the System Test Phantom, and once it is in position, click **OK** to continue.

4. In the following window, click start to select the desired items, and click **Next** to continue the test, click OK in the new message.
5. The application scans the System Phantom and calculates the position of the System Phantom. If the position is not accepted, the application will provide instructions for adjusting the position of the Phantom.
6. When the System Phantom position is accepted, the system will automatically start the Test. The test automatically runs a sequence of scans. The scans and parameters are listed in the Verify item area.
7. When the image quality of each item is found to comply with the required tolerances, its state is recorded in green as Passed. When the image quality of an item fails to comply with any required tolerance, its state is recorded in red as Failed.
8. When the tests are completed, the constancy report is generated automatically and saved. To view the report, click History of Report button. The system also provides function to burn test report to a CD.

NOTE:

- **If any of the sub-items fail during the Auto- Constancy test, repeat the same sub-item or perform it again manually.**
- **When performing Auto - Constancy test, if any item value is beyond the range, user needs to perform air calibration, and then re-perform Auto - Constancy test. If the value is still out of range, please contact the service representative.**

WARNING:

- **Before performing Auto- Constancy test, please ensure that:**

- **No person is in the scanner room, and the door of the scanner room is closed.**
- **The system phantom is fixed to the Phantom holder firmly and correctly, and the Couch height is proper to avoid collision between the phantom and the Gantry when the Couch top is moving horizontally.**

12.4 Representative Quality Assurance Images

Table 12-9 Representative Images — Typical Head Scans

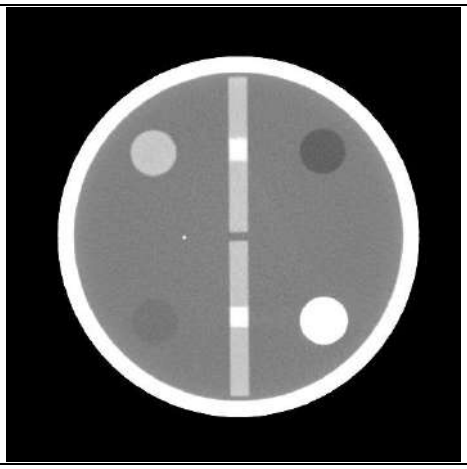
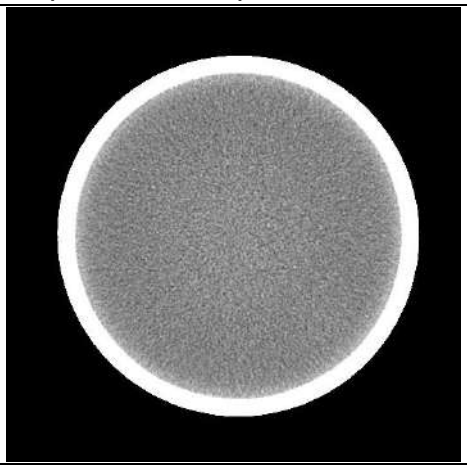
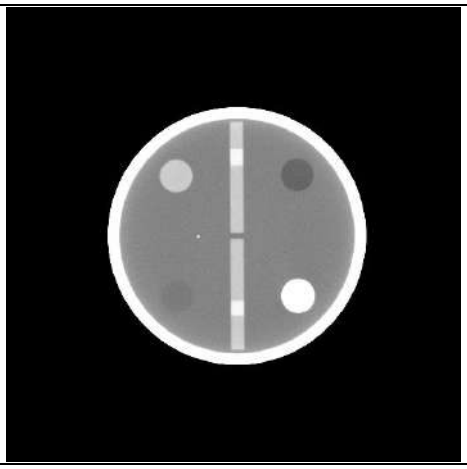
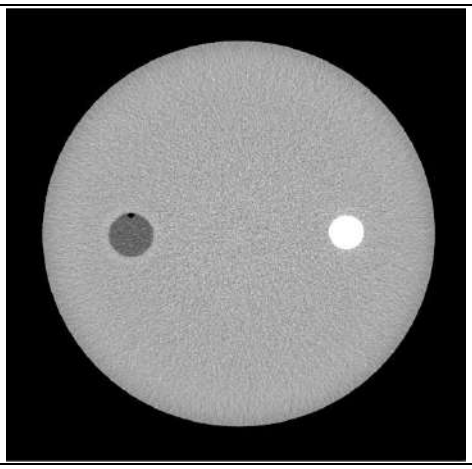
Physics Layer of QA Phantom Contrast Scale/High Contrast Spatial Resolution/Slice Thickness	Head Water Layer of QA Phantom Low Contrast Detectability / CT Number Accuracy & Uniformity, and Noise
	

Table 12-10 Representative Images — Typical Body Scans

Physics Layer of QA Phantom Contrast Scale/High Contrast Spatial Resolution/Slice Thickness	Body Layer of QA Phantom CT Number Accuracy & Uniformity, and Noise
	

12.5 Description of the Quality Assurance Data Storage Method

Quality assurance data can be stored in the normal patient scan format and recalled at a later date. After loading the quality assurance image in the interface of 2D Viewer and these quality assurance data can be measured on images, these image marked with the data can be saved in the CD/DVD or Local disk or Removable disk through clicking the button "Save" on the right side of the 2D Viewer interface. For the detail, please refer to the 2D Viewer chapter in the manual.

Chapter 13 SSDE

13.1 The Definition and Use of SSDE

The size specific dose estimates (SSDE) is an estimate of the average absorbed dose to the scan volume that takes into account the attenuation of the anatomy being scanned (using the water equivalent diameter D_W) and the radiation output of the CT scanner (using $CTDI_{VOL}$).

SSDE is intended to provide a dose estimate for patients of all sizes. SSDE, which is given in units of mGy, is especially important for small paediatric patients since the corresponding applied level of radiation ($CTDI_{VOL}$, also given in units of mGy) does not adequately indicate the absorbed radiation dose.

Potential uses of SSDE include the following:

1) evaluating patient absorbed dose for quality assurance programs;

2) establishing diagnostic reference levels across patient sizes;

3) displaying to the operator an estimate of patient absorbed dose prior to initiation of the CT scan;

4) providing an estimate of absorbed dose for the DICOM RDSR;

5) developing dose notification value and dose alert values that better take into account patient size;

6) providing an estimate of patient absorbed dose for dose registries.

For the terms and definitions, please refer to IEC 62985-2019.

13.2 Implementation of SSDE on CT

After surview is scanned and the following scanning sequence is selected, if the sequence positioning box is within the range of the surview, the SSDE and D_W values will be displayed in the interface, and the displayed SSDE and D_W values are in proximity to the $CTDI_{vol}$ values.

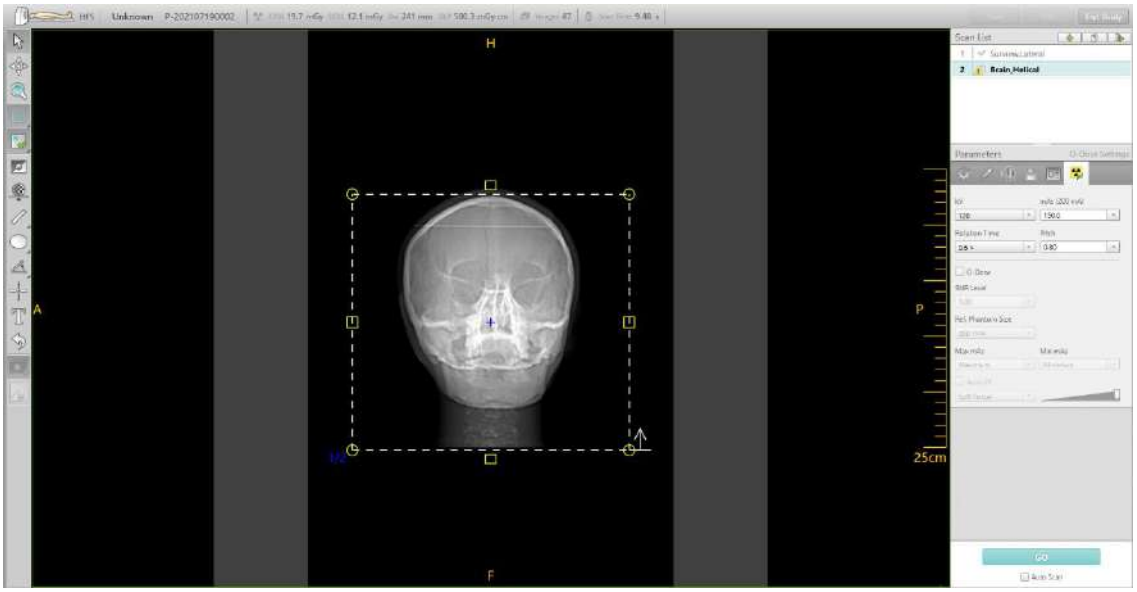


Fig 13-1 SSDE and D_W value displayed

$CTDI_{vol}$, SSDE, D_W and DLP values are displayed from left to right on the interface, and the positions are close to each other.

The SSDE value is displayed as the planned value before scanning, and updated to the actual value after scanning.

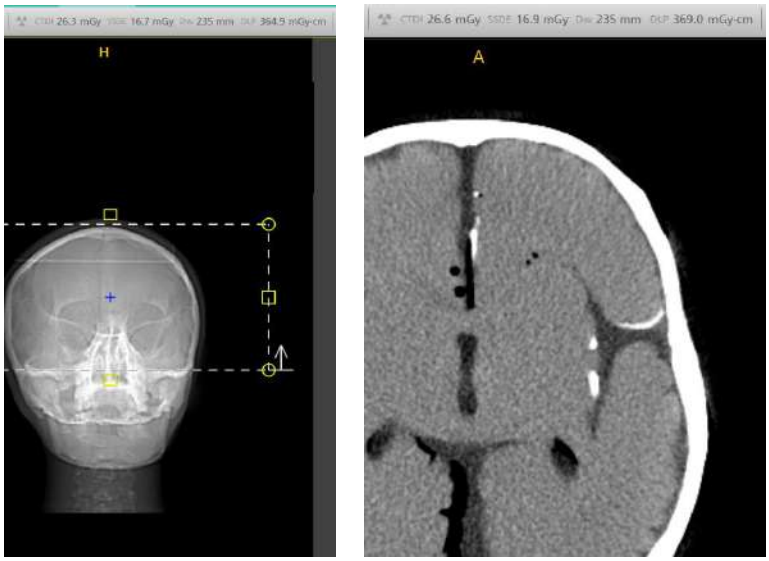


Fig 13-2 SSDE value before scan(Left) and SSDE value after scan(Right)

The left figure shows the SSDE value before scanning, and the right figure shows the updated SSDE value after scanning.

Note :

- **If there is no surview or surview is not scanned, when the following sequence is selected, only $CTDI_{vol}$ and DLP are displayed in the interface.**

For those sequences showing SSDE and D_W values after the scan, the SSDE, D_w, SSDE (z) and D_W (z) values will be recorded in the Radiation Dose Structured Report.

13.3 The calculation and accuracy of SSDE

13.3.1 The calculation and accuracy of SSDE of Small water phantom

13.3.1.1 Phantom

Small water phantom: the phantom's external diameter is 200mm and internal diameter is 190mm. It is a cylindrical phantom made of PMMA and the inside is filled with water.

13.3.1.2 The generation of $D_{w,REF}$ and $D_{w,IMP}$

Adjust the position of QA phantom, and make sure the head water layer of QA phantom is located in the center of the scanning field of view. Make sure there is no additional material in the scan field. Use the following conditions for scanning, adjust the scanning range of each time, and scan 10 times to get the scanning image, which is used for the calculation of $D_{W,\,REF}$ and $D_{W,\,IMP}$

Scan Protocols	Scan parameters	Recon parameters
Head STD-QA	120KV,200mA,1s,8*0.625	FOV250,Standard Resolution , F20 , Image Thickness 5mm

Refer to the calculation method of D_W provided by IEC62985:2019, D_w shall be calculated at each longitudinal position z. The set of D_w values shall be compared to the corresponding out diameter of water phantom. The two values at each positon shall agree to within 7%.

The difference between the D_W value updated after scanning and $D_{W,REF}$ at each z Positions shall be less than 12%.(The D_w value displayed on the interface is $D_{W,IMP}$ value)

13.3.2 The calculation and accuracy of SSDE of Large water phantom

13.3.2.1 Phantom

Large water phantom: the phantom's external diameter is 316mm and internal diameter is 300mm. It is a cylindrical phantom made of PMMA and the inside is filled with water.

13.3.2.2 The generation of $D_{w,REF}$ and $D_{w,IMP}$

Adjust the position of QA phantom, and make sure the body water layer of QA phantom is located in the center of the scanning field of view. Make sure there is no additional material in the scan field. Use the following conditions for scanning, adjust the scanning

range of each time, and scan 10 times to get the scanning image, which is used for the calculation of $D_{W,REF}$ and $D_{W,IMP}$.

Scan Protocols	Scan parameters	Recon parameters
Body STD-QA	120KV,200mA,1s,8*0.625	FOV350,Standard Resolution , F20 , Image Thickness 5mm

Refer to the calculation method of D_W provided by IEC62985:2019, D_w shall be calculated at each longitudinal position z. The set of D_w values shall be compared to the corresponding out diameter of water phantom. The two values at each positon shall agree to within 7%.

The difference between the D_W values updated after scanning and $D_{W,REF}$ at each z Positions shall be less than 12%. (The D_w value displayed on the interface is $D_{W,IMP}$ value)

13.3.3 The calculation and accuracy of SSDE of anthropomorphic phantom

13.3.3.1 Phantom

According to IEC 62985-2019, the verification compares a set of $D_{W,IMP}$ (z) values calculated for an anthropomorphic phantom to the corresponding set of $D_{W,REF}$ (z) values calculated for the same phantoms.

A commercial anthropomorphic phantom used for the verification is whole body phantom PBU-60, which is indicated as below:

Fig 13-3 Anthropomorphic phantom

The anthropomorphic phantom can be regards as a representative of an average adult human from the top of the head to the bottom of the pelvis. The phantom includes simulated soft tissue, lung, and bone and many other embedded organs. For detailed information, please refer to the corresponding specification accompanied with the commercial phantom.

13.3.3.2 The generation of $D_{w,REF}$ and $D_{w,IMP}$

Adjust the position of PBU-60 phantom, and make sure the PBU-60 phantom is located in the center of the scanning field of view. Make sure there is no additional material in the scan field. Use the following conditions for scanning, adjust the scanning range of each time, and scan 10 times to get the scanning image, which is used for the calculation of $D_{W,\,REF}$ and $D_{W,\,IMP}$.

Scan Protocols	Scan parameters	Recon parameters
Head STD-QA	120KV,200mA,1s,8*0.625	FOV250,Standard Resolution , F20 , Image Thickness 5mm
Body STD-QA	120KV,200mA,1s,8*0.625	FOV500,Standard Resolution , F20 , Image Thickness 5mm

The Head STD-QA protocol is used for head scanning, and the Body STD-QA protocol is used for lung, heart, abdomen and pelvis scanning. Each part is scanned separately, and the updated D_W value is recorded every time. The median value of the set of differences between D_w and $D_{w,REF}$ at the same Z position should be less than 10%. (The D_w value displayed on the interface is $D_{W,IMP}$ value)

13.4 Limitations of the SSDE methodology for use

The SSDE is an estimate of the average absorbed dose to the scan volume that takes into account the attenuation of the anatomy being scanned and the radiation output of the CT scanner. (using $CTDI_{VOL}$)

SSDE is intended to provide a dose estimate for patients of all sizes. SSDE, which is given in units of mGy, is especially important for small paediatric patients since the corresponding applied level of radiation ($CTDI_{VOL}$, also given in units of mGy) does not adequately indicate the absorbed radiation dose.

SSDE is calculated using a SSDE conversion factor and $CTDI_{VOL}$.

The data used to determine the SSDE conversion factor covered patient diameters ranging from approximately 8 cm to 40 cm. Because the data exhibited smooth behavior, SSDE is calculated and displayed for patient diameters outside of this range by extrapolation of the SSDE conversion factors.

The concept of SSDE was developed by a task group of the American Association of Physicists in Medicine (AAPM). Initially, SSDE was defined only for scans of the thorax, abdomen, and pelvis [1]. More recently, conversion factors to calculate SSDE for the head were published [4].

It is important to recognize that SSDE is an estimate of the absorbed dose to the scan volume that takes into account patient size. The accuracy of this estimate, compared to the actual absorbed dose to the scan volume, is approximately ±20 % [1]. However, to put this error into context, for infants, the $CTDI_{VOL}$ underestimates the absorbed dose to the scan volume by up to a factor of 3[1]. Conversely, the $CTDI_{VOL}$ value for large patients overestimates absorbed dose to the scan volume; for extra-large adult patients, $CTDI_{VOL}$ can overestimate absorbed dose by as much as 40% [1].

When there are foreign objects in the scan field of view (e.g., metal implants, radiation therapy planning hardware, life support devices, bismuth shields), relatively larger

uncertainty in the reported SSDE exists.

It is important to recognize the SSDE estimates the absorbed dose to a specific scan volume, and is not a global indication of patient dose. Caution should be exercised when interpreting SSDE for scans that cover a very short scan range. For example, summing the values of the SSDE for the bolus tracking scans with the SSDE for the larger diagnostic scan volume will overestimate the dose to the entire scan volume.

SSDE does not include the relatively low dose(s) delivered by the scanned projection radiograph(s).

Additional uncertainty may be introduced into the manufacture's value of $D_{W,IMP}(z)$ for these following special clinical scenarios

- scanned anatomy includes the neck;
- actual scan length exceeds the range of the scanned projection radiograph;
- single or bilateral extremities are scanned;
- patient is not positioned at the center of rotation along the source/detector direction, which will affect the $D_{W,IMP}(z)$ values calculated from the scanned projection radiograph;
- patient anatomy is outside of the scan field of view;
- foreign objects are within the scanned projection radiograph or scan volume (e.g., metal implants, shrapnel, radiation therapy planning hardware, life support devices, bismuth shields).

Reference documents:

[1] AAPMReport No.204, Size Specific Dose Estimates (SSDE) in Pediatric and Adult Body CT Examinations. American Association of Physicists in Medicine, 2011 [viewed 2019-05-13]. Available at: http://www.aapm.org/pubs/reports/RPT_204.pdf

[2] Wang, Jia, et al., Attenuation-based estimation of patient size for the purpose of size specific dose estimation in CT. Part I. Development and validation of methods using the CT image, Medical Physics 39.11 (2012): 6764-6771

[3] Christianson, Olav, Li, Xiang, Frush, Donald, and Samei, Ehsan, Automated Size Specific CT Dose Monitoring Program: Assessing Variability in CT Dose. Medical physics 39.11 (2012): 7131-7139

[4] AAPMReport No. 293, Size-Specific Dose Estimates (SSDE) in Pediatric and Adult Head CT Examinations, 2019

[5] AAPM Report No. 220, Use of Water Equivalent Diameter for Calculating Patient Size and Size Specific Dose Estimates (SSDE) in CT. American Association of Physicists in Medicine, 2014[viewed 2019-05-13]. Available at: http://www.aapm.org/pubs/reports/RPT_220.pdf

Chapter 14 Dose and Maintenance

14.1 Dose and Performance

14.1.1 Tube Filter

14.1.1.1 Filter Information

Table 14-1 Filter Information

Collimator	Material	Filter thickness	Quality Equivalent Filtration
	Ti	0.6mm±0.03mm	2.70mm Al@140kv
	2A12	0.89 mm±0.03mm	1.16mm Al@140kv
Tube QEF Values			>=4.8mm Al @140kV

14.1.1.2 Half Value Layer

Table 14-2 Half value layer relative to different voltage

Tube Voltage(kV) 21 CFR 1020.30(m) and IEC60601-1-3	**Minimum Half Value Layer (mGy)**	**Large (mmAl)**	**Medium (mmAl)**	**Small (mmAl)**
60 kV	1.5	4.77	4.81	4.83
70 kV	1.8	5.69	5.65	5.66
80 kV	2.9	6.47	6.41	6.43
100 kV	3.6	7.70	7.63	7.65
120 kV	4.3	8.81	8.54	8.57
140 kV	5.0	9.41	9.30	9.34

14.1.2 CTDI/Dose Analysis Information

CTDI Definition

Computed Tomography Dose Index (CTDI) is the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomography section thickness and the number of tomograms produced in a single scan, as follows:

$$CTDI_{100} = \frac{1}{NT}\int_{-50mm}^{+50mm} D(z)dz$$

$$CTDI_w = \frac{1}{3}CTDI_{100}(\text{Center}) + \frac{2}{3}CTDI_{100}(\text{circum})$$

Where:

D (z) = Dose to Air ($CTDI_{100}$) at position z

T = Nominal tomographic section thickness

N = Number of tomograms produced in a single scan

The CTDI definition assumes that for a multiple tomogram system the scan increment between adjacent slices is nT.

14.1.3 CTDI Dosimetry Phantom

The CTDI dosimetry phantoms are placed in the center of the Gantry opening on the standard head support with one of the dosimeters at the maximum dose position.

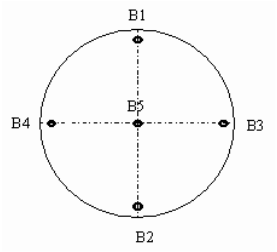


Fig 14-1 Position Schematic Diagram of Measuring the CTDI Dose

The diameter of head phantom is 16 cm.

The diameter of body phantom is 32 cm

The material of phantom is Perspex.

B5: Center

The distance between the outside surface of phantom and the center of B1 to B4 is 1 cm.

B2 is the max CTDI dose position.

The CTDI dosimetry phantoms are right circular cylinders of polymethyl methacrylate (lucite). The density of these phantoms is 1.19 g/cm^3. The head phantom measures 16 cm in diameter and the body phantom has a diameter of 32 cm. The length of each phantom is 15 cm.

The phantom provides means for the placement of dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation, 1.0 cm from the outer surface and within the phantom. The dosimeter is 10 cm long pencil ionization chamber.

14.1.4 Conversion factors for $CTDI_{vol}$ and DLP SFOV

The $CTDI_{vol}$ and DLP dose indexes displayed and reported by the system are measured using the 16cm diameter PMMA phantom for head scans and the 32 cm diameter PMMA

phantom for body scans.

For a patient, it may be more appropriate to use the 16cm phantom as a reference than the 32cm phantom. The table below provides these conversion factors for CTDIvol and DLP for scans.

For example, multiply the displayed DLP (32cm reference phantom) by the conversion factor in the table to obtain the DLP based on a 16cm reference phantom.

Table 14-3 Conversion factors for $CTDI_{vol}$ and DLP from 32cm to 16cm

Collimating Thickness(*0.625mm)	kV					
	60	70	80	100	120	140
2	2.92	2.54	2.35	2.10	1.99	1.89
4	2.89	2.51	2.33	2.08	1.97	1.87
8	2.89	2.50	2.32	2.08	1.97	1.86
12	2.92	2.54	2.35	2.11	2.00	1.89
16	2.91	2.53	2.34	2.10	1.99	1.88
20	2.91	2.52	2.34	2.09	1.99	1.88
24	2.90	2.52	2.33	2.09	1.98	1.87
32	2.88	2.50	2.32	2.08	1.97	1.86
40	2.93	2.54	2.36	2.11	2.00	1.89
64	2.92	2.53	2.35	2.10	1.99	1.89

14.1.5 CTDI $_{free\ air}$ for head and body (IEC/EN 60601-2-44)

NOTE:

- **The maximum deviation of the following CTDI $_{free\ air}$ is ± 20%.**

Table 14-4 Typical body and head conditions of operation

Voltage (kV)	120kV
Collimation (mm)	64*0.625mm
Scan time (s)	1.0s
mA	200mA
Filter	Large Wedge

Table 14-5 Expected CTDI $_{free\ air}$ for scan conditions (mGy)

Variation of kV	Shape filter	Variation of the nominal beam collimation										
		Body									Head	
		2*0.625	4*0.625	8*0.625	12*0.625	16*0.625	20*0.625	24*0.625	32*0.625	40*0.625	64*0.625	64*0.625
60kV	MediumWedge	——	——	——	——	——	——	——	——	——	4.23	——
	LargeWedge	——	——	——	——	——	——	——	——	——	4.30	——
	SmallWedge	——	——	——	——	——	——	——	——	——	4.11	——

Variation of kV	Shape filter	Variation of the nominal beam collimation										
		Body										Head
		2*0.625	4*0.625	8*0.625	12*0.625	16*0.625	20*0.625	24*0.625	32*0.625	40*0.625	64*0.625	64*0.625
70kV	MediumWedge	——	——	——	——	——	——	——	——	——	7.38	——
	LargeWedge	——	——	——	——	——	——	——	——	——	7.57	——
	SmallWedge	——	——	——	——	——	——	——	——	——	7.27	——
80kV	MediumWedge	——	——	——	——	——	——	——	——	——	11.51	——
	LargeWedge	——	——	——	——	——	——	——	——	——	11.78	——
	SmallWedge	——	——	——	——	——	——	——	——	——	11.35	——
100kV	MediumWedge	——	——	——	——	——	——	——	——	——	22.29	——
	LargeWedge	——	——	——	——	——	——	——	——	——	22.65	——
	SmallWedge	——	——	——	——	——	——	——	——	——	22.03	——
120kV	MediumWedge	70.06	80.72	56.50	49.00	44.59	42.40	40.99	38.94	37.75	35.65	35.53
	LargeWedge	71.29	81.56	57.46	49.60	45.48	43.09	41.57	39.61	38.09	36.23	35.95
	SmallWedge	69.35	79.76	56.00	48.25	44.29	42.19	40.38	38.45	37.32	35.45	35.15
140kV	MediumWedge	——	——	——	——	——	——	——	——	——	51.58	——
	LargeWedge	——	——	——	——	——	——	——	——	——	52.40	——
	SmallWedge	——	——	——	——	——	——	——	——	——	51.45	——

14.1.6 Dose Value (CTDI) of Phantom on Different Positions under Typical Parameter

NOTE:

- **The maximum deviation of the following CTDI is ± 20%.**

Table 14-6 Dose Value (CTDI) of Phantom on Different Positions under Typical Parameter Condition for Large Wedge (mGy) (Reference 21 CFR 1020.33(C)(2)(i) and(C)(2)(ii))

Typical Parameters	**120kV, 200mA, 1.0s, 64*0.625mm, large wedge (Reference 21 CFR 1020.33(C)(2)(i))**					
	B1	B2	B3	B4	B5	$CTDI_w$
Head $CTDI_{100}$(mGy)	28.03	29.53	28.40	28.13	26.60	27.88
Body $CTDI_{100}$(mGy)	16.08	17.26	16.06	16.84	8.83	13.98

In position B5 (Reference 21 CFR 1020.33(C)(2)(ii))			
Phantom	**Voltage**	**CTDI (mGy)**	**Normalization factor**
Head	60KV	2.34	0.09
	70KV	4.56	0.17
	80KV	7.72	0.29
	100KV	15.98	0.60
	120KV	26.60	1.00
	140KV	38.83	1.46
Body	60KV	0.53	0.06
	70KV	1.19	0.13
	80KV	2.17	0.25
	100KV	5.03	0.57
	120KV	8.83	1.00
	140KV	13.61	1.54
Phantom	**Collimation**	**CTDI (mGy)**	**Normalization factor**
Head	64*0.625	26.60	1.00
	40*0.625	28.18	1.06
	32*0.625	28.94	1.09
	24*0.625	30.66	1.15
	20*0.625	31.92	1.20
	16*0.625	33.57	1.26
	12*0.625	36.45	1.37
	8*0.625	41.96	1.58
	4*0.625	59.40	2.23
	2*0.625	51.76	1.95
Body	64*0.625	8.83	1.00
	40*0.625	9.33	1.06
	32*0.625	9.72	1.10

	24*0.625	10.25	1.16
	20*0.625	10.63	1.20
	16*0.625	11.17	1.27
	12*0.625	12.08	1.37
	8*0.625	14.10	1.60
	4*0.625	19.92	2.26
	2*0.625	17.12	1.94
Phantom	**Current**	**CTDI(mGy)**	**Normalization factor**
Head	833mA	110.75	4.16
	600mA	79.79	3.00
	422mA	56.06	2.11
	200mA	26.60	1.00
	10mA	1.38	0.05
Body	833mA	36.82	4.17
	600mA	26.51	3.00
	422mA	18.64	2.11
	200mA	8.83	1.00
	10mA	0.46	0.05
Phantom	**Scan.time**	**CTDI(mGy)**	**Normalization factor**
Head	2s	52.48	1.97
	1.5s	39.76	1.49
	1s	26.60	1.00
	0.32s	9.03	0.34
Body	2s	17.58	1.99
	1.5s	13.21	1.50
	1s	8.83	1.00
	0.32s	2.99	0.34
Phantom	**Filter**	**CTDI(mGy)**	**Normalization factor**
Head	Large	26.60	1.00
	Medium	24.38	0.92

	Small	23.19	0.87
Body	Large	8.83	1.00
	Medium	7.47	0.85
	Small	6.90	0.78

Table 14-7 Maximum $CTDI_{100}$ (Normalization) under the X-ray tube voltage for Large Wedge (Reference 21 CFR 1020.33(C)(2)(iii))

Phantom	Voltage	CTDI(mGy)	Normalization factor
Head	60KV	2.86	0.10
	70KV	5.39	0.18
	80KV	8.91	0.30
	100KV	18.01	0.61
	120KV	29.53	1.00
	140KV	43.35	1.47
Body	60KV	1.45	0.08
	70KV	2.84	0.16
	80KV	4.82	0.28
	100KV	10.25	0.59
	120KV	17.26	1.00
	140KV	25.46	1.48

Table 14-8 Dose Value (CTDI) of Phantom on Different Positions under Typical Parameter Condition for Large Wedge (mGy) (IEC 60601-2-44)

Typical Parameters	**120kV, 200mA, 1.0s, 64*0.625mm, large wedge, Mean Value of B1, B2, B3 and B4**		
Phantom	**Voltage**	**CTDI (mGy)**	**Normalization factor**
Head	60KV	2.76	0.10
	70KV	5.19	0.18
	80KV	8.59	0.30
	100KV	17.40	0.61
	120KV	28.52	1.00
	140KV	41.92	1.47
Body	60KV	1.39	0.08
	70KV	2.73	0.16

	80KV	4.61	0.28
	100KV	9.83	0.59
	120KV	16.56	1.00
	140KV	24.58	1.48
Phantom	**Collimation**	**CTDI (mGy)**	**Normalization factor**
Head	64*0.625	28.52	1.00
	40*0.625	29.84	1.05
	32*0.625	30.73	1.08
	24*0.625	32.11	1.13
	20*0.625	33.10	1.16
	16*0.625	34.92	1.22
	12*0.625	37.68	1.32
	8*0.625	43.02	1.51
	4*0.625	59.88	2.10
	2*0.625	46.74	1.64
Body	64*0.625	16.56	1.00
	40*0.625	17.26	1.04
	32*0.625	17.79	1.07
	24*0.625	18.61	1.12
	20*0.625	19.22	1.16
	16*0.625	20.15	1.22
	12*0.625	21.69	1.31
	8*0.625	24.84	1.50
	4*0.625	34.52	2.08
	2*0.625	26.88	1.62
Phantom	**Current**	**CTDI(mGy)**	**Normalization factor**
Head	833mA	118.97	4.17
	600mA	85.62	3.00
	422mA	60.19	2.11

	200mA	28.52	1.00
	10mA	1.44	0.05
Body	833mA	68.87	4.16
	600mA	49.65	3.00
	422mA	34.93	2.11
	200mA	16.56	1.00
	10mA	0.83	0.05

Phantom	Scan.time	CTDI(mGy)	Normalization factor
Head	2s	56.79	1.99
	1.5s	42.70	1.50
	1s	28.52	1.00
	0.32s	9.71	0.34
Body	2s	32.94	1.99
	1.5s	24.74	1.49
	1s	16.56	1.00
	0.32s	5.54	0.33

Phantom	Filter	CTDI(mGy)	Normalization factor
Head	Large	28.52	1.00
	Medium	23.07	0.81
	Small	20.18	0.71
Body	Large	16.56	1.00
	Medium	11.10	0.67
	Small	9.71	0.59

NOTE:

- **Only one parameter was modified each time and the configuration of other parameters is typical value.**

14.1.7 Definitions and Instructions

About definitions and instructions of noise, please see details in chapter 12.2.5.

Modulation Transfer Function

The impulse response and the tomographic thickness (slice thickness) are not dependent upon the phantom dimensions. They are therefore measured on the physics

layer of the system phantom.

The phantom physics layer diameter is 200 mm diameter with PVC shell. The impulse response is measured on a 0.18 mm copper wire using the Impulse Response program.

The MTF profile is calculated from the impulse response on a separate computer.

Head Scan conditions: Head STD-QA protocol, 120KV, 64*0.625, 200mA, 1s, 5mm, F20, FOV250mm, large wedge.

Body Scan conditions: Body STD-QA protocol, 120KV, 64*0.625, 200mA, 1s, 5mm, F20, FOV350mm, large wedge.

The value of MTF should be no less than 6lp/cm@0%, 4.5lp/cm @10% and 2.5lp/cm@50%.

Measurement of Tomographic Thickness

In the phantom shown in chapter 12, two aluminum strips at 23 deg. give projections of the sensitivity profile in the image plane.

The profiles of the projections are equivalent to the sensitivity profiles, and the FWHM of the profile is the nominal tomographic thickness.

The profile is measured by the Slice width program.

The measured thickness values should not deviate from the specified nominal values by more than the values listed below: (Reference 21 CFR 1020.33(c)(3)(v))

For thickness above 2 mm: ± 1.0 mm

For thickness of 2 mm to 1 mm: ± 50%

For thickness less than 1 mm: ± 0.5 mm

14.1.8 Modulation Transfer Function (MTF)

The condition is the same as that of noise tests.

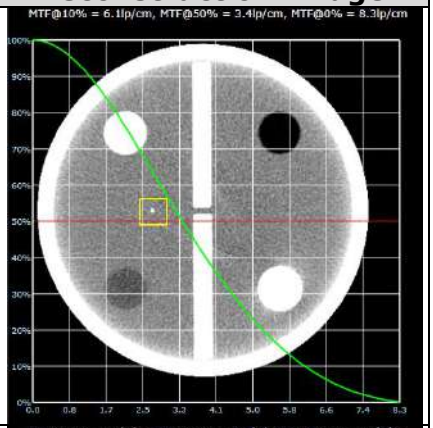
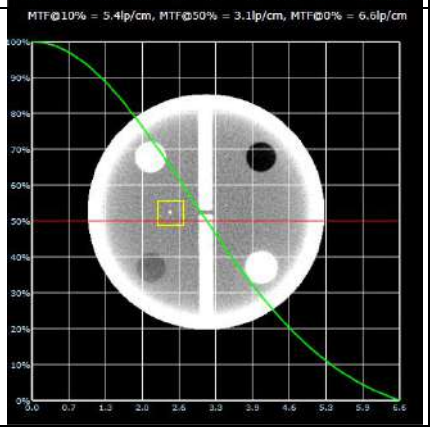
The MTF profile is calculated from the impulse response.

If the MTF is 100% or 1.0, it means there is no signal loss.

If the MTF is 0.0, it means there is no signal.

When MTF is between 0.05 and 0.02, objects with high contrast and small aperture cannot be distinguished.

Fig 14-2 MTF Illustrative Diagram (Typical body and head conditions of operation)

Condition	Reconstruction Image
Typical head conditions Reconstruction Head STD-QA, 120kv, 200mAs, F20,64*0.625, FOV250, 5mm，large wedge, Standard resolution	
Typical Body conditions Reconstruction Body STD-QA, 120kv, 200mAs, F20,64*0.625, FOV350, 5mm，large wedge, Standard resolution	

14.1.9 Linearity of X-ray Output (IEC 60601-2-44)

Large Wedge

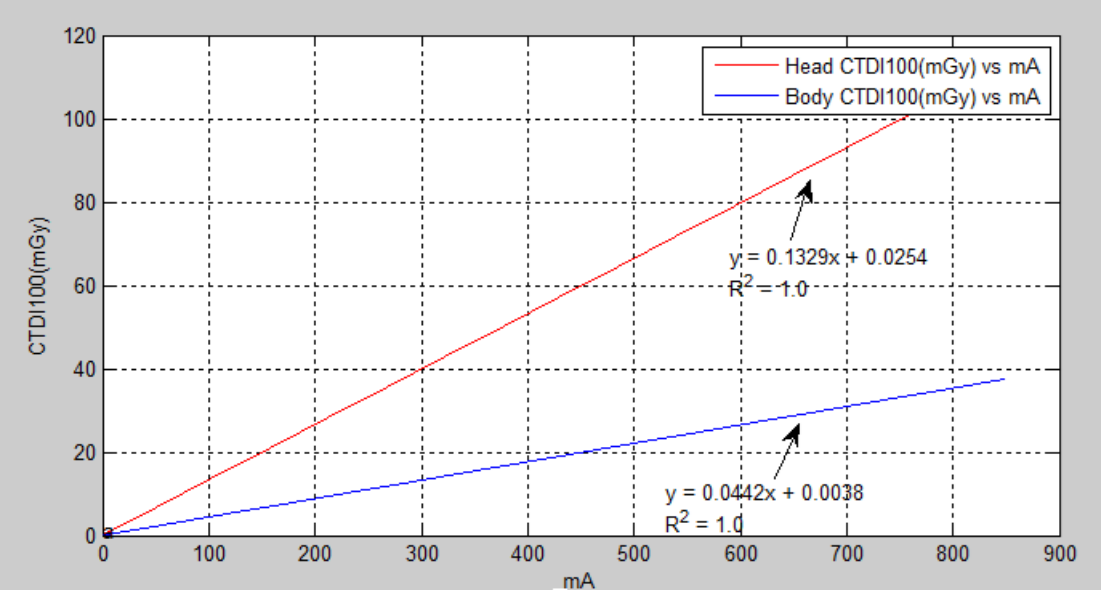


Fig 14-3 Linearity of X-ray Output Dose for Large Wedge

mA	Head CTDI100(mGy)	Body CTDI100(mGy)
10	1.38	0.46
200	26.60	8.83
422	56.06	18.64
600	79.79	26.51
833	110.75	36.82

Medium Wedge

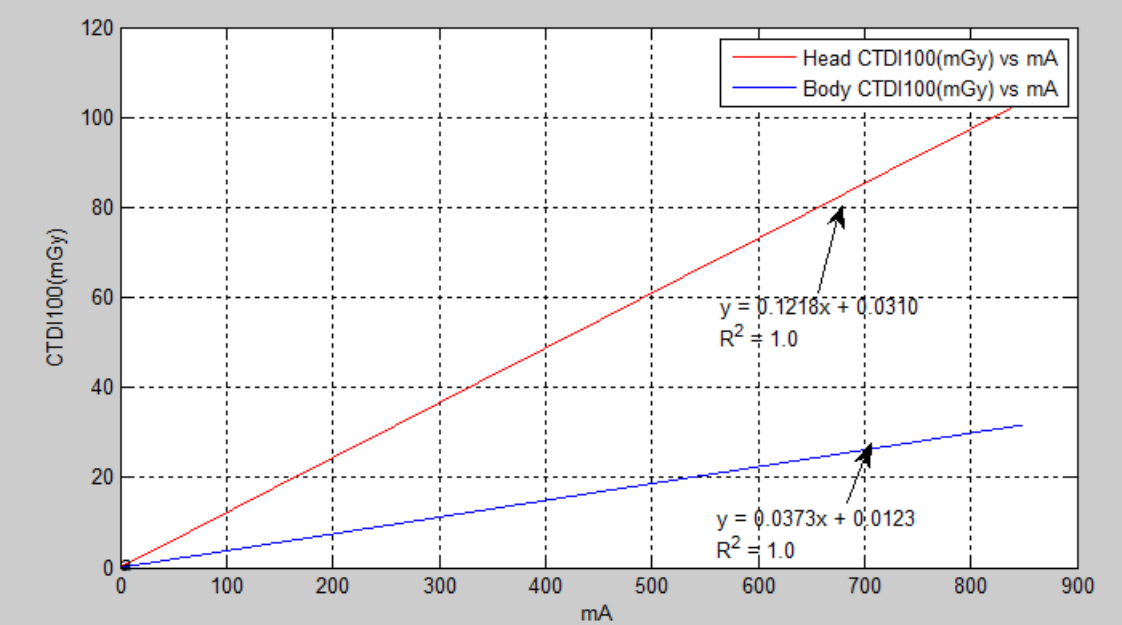


Fig 14-4 Linearity of X-ray Output Dose for Medium Wedge

mA	Head CTDI100(mGy)	Body CTDI100(mGy)
10	1.26	0.39
200	24.38	7.47
422	51.41	15.75
600	73.09	22.40
833	101.48	31.09

Small Wedge

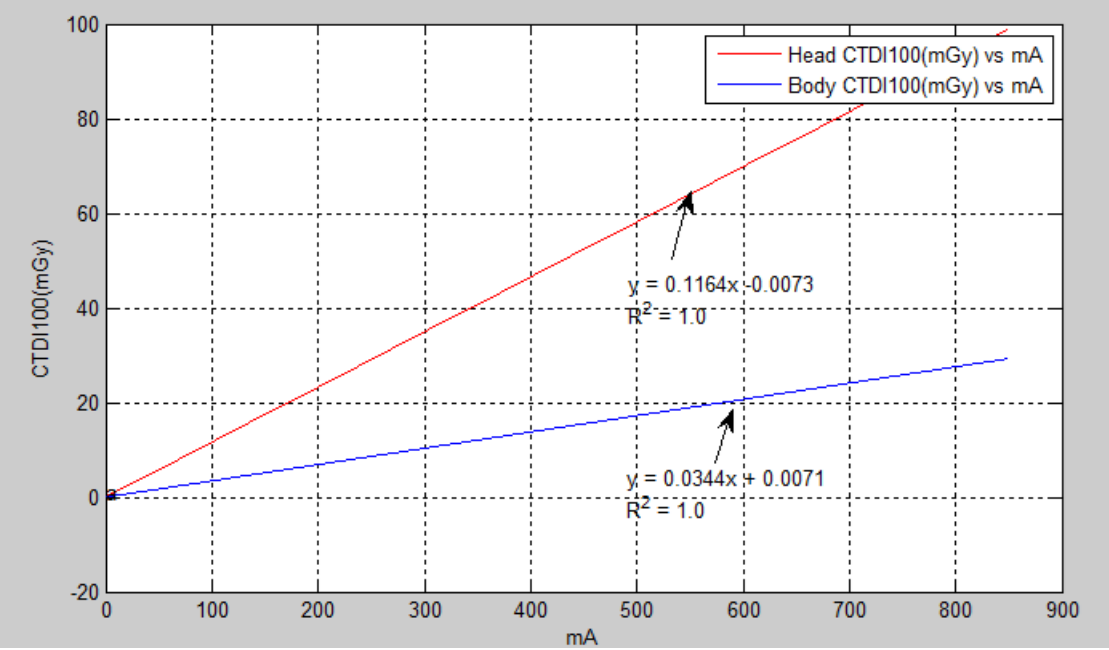


Fig 14-5 Linearity of X-ray Output Dose for Small Wedge

mA	Head CTDI100(mGy)	Body CTDI100(mGy)
10	1.21	0.35
200	23.19	6.9
422	49.11	14.54
600	69.82	20.67
833	96.94	28.70

NOTE:

- **The accuracy of X-ray tube voltage is ± 8%.**
- **The accuracy of X-ray tube current is ± 20%.**

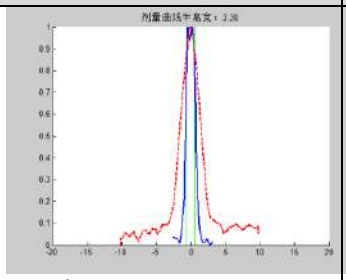
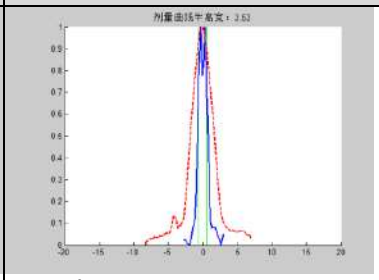
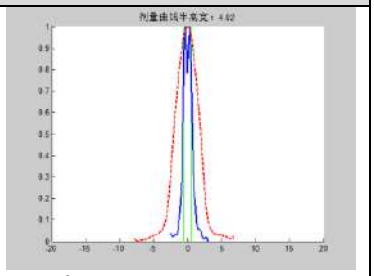
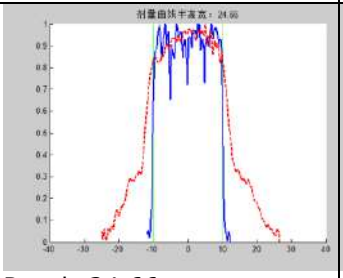
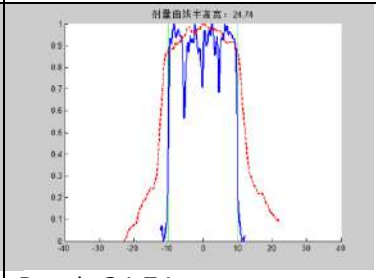
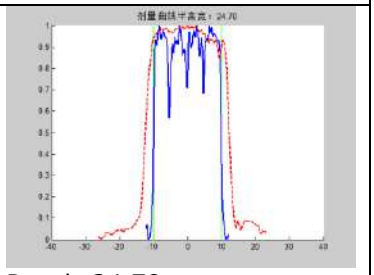
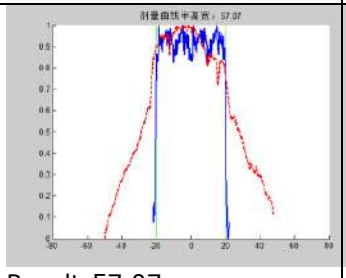
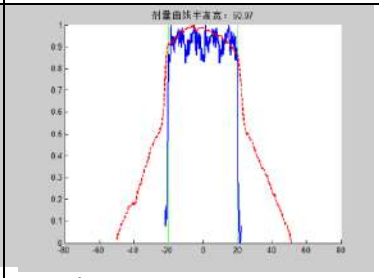
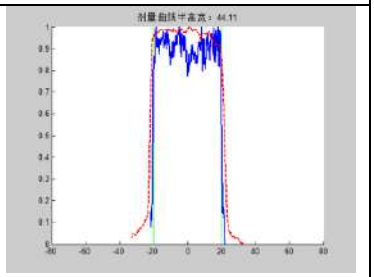
14.1.10 Dose and Sensitivity Profile (Reference IEC 60601-2-44 and 1020.33(c)(2)(iv))

The standard values and maximum deviation of sensitive profile is the same with those of tomographic section thickness.

The standard values of dose profile are as follows:

Collimation	Head Reference value	Body Reference value	Air Reference value	Error range
2*0.625	3.5mm	3.5mm	3.5mm	Max(±30% or ±1.5mm)
32*0.625	25mm	25mm	25mm	Max(±30% or ±1.5mm)
64*0.625	50mm	60mm	40mm	Max(±30% or ±1.5mm)

Table 14-9 Dose and Sensitive Profile

Collimation	Body	Head	Free Air
2x0.625	 Result:3.30	 Result:3.53	 Result:4.02
32x0.625	 Result:24.66	 Result:24.74	 Result:24.70
64x0.625	 Result:57.07	 Result:50.97	 Result:44.11

14.2 IEC Stray Radiation Dose Map

Only qualified and professional institution is to evaluate the shielding of scanner room. The following factors should be taken into consideration: device position, scan workload

and materials of walls, floor, ceiling, doors and windows.

The following figure illustrates the radiation level in the process of scanning a nylon cylinder with 320mm diameter and 140mm length (Body Part) phantom in the scanner room.

Dose unit: μGy /1000 mAs

Body Standard QA axial protocol:

Standard resolution mode, 140kVp, 250mAs, 1.0 sec rotation time, 64*0.625 collimation, 40 mm thickness, 4 cycles.

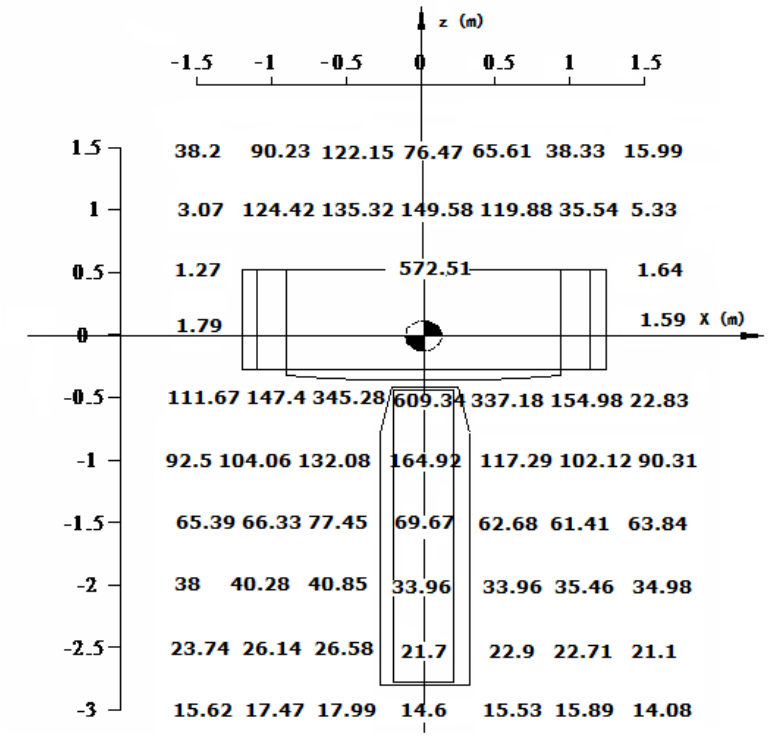


Fig 14-6 IEC stay radiation dose map (x-z)

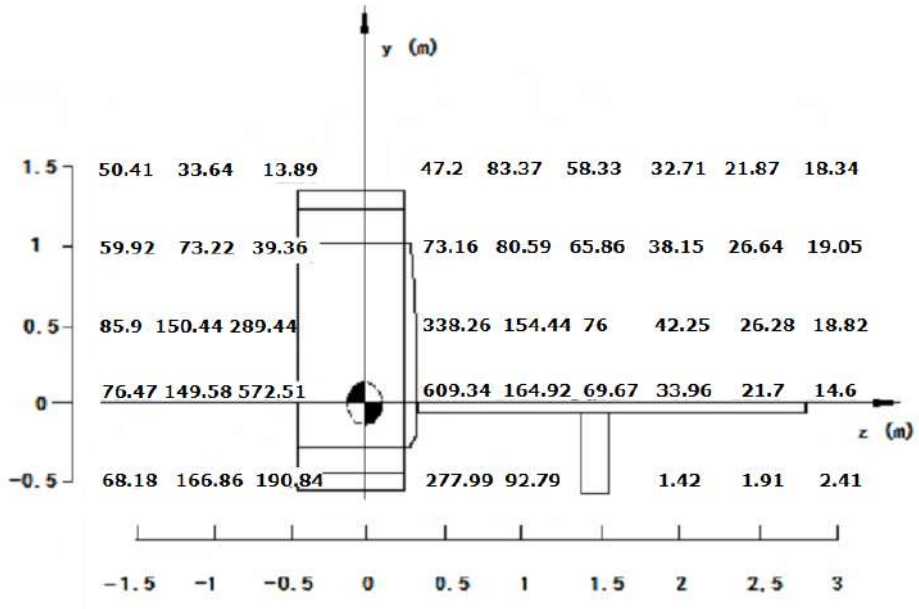


Fig 14-7 IEC stay radiation dose map (y-z)

14.3 Radiology Safety

X-ray and gamma rays are dangerous to both operator and others in the vicinity unless established safe exposure procedures are strictly observed.

The useful and scattered beams can produce serious or fatal bodily injuries to patients and persons in the surrounding area if used by an unskilled operator. Adequate precautions must always be taken to avoid exposure to the useful beam, as well as to leakage radiation from within the source housing or to scattered radiation resulting from passage of radiation through matter.

Those authorized to operate, participate in or supervise the operation of the equipment must be thoroughly familiar and comply completely with the current established safe exposure factors and procedures described in publications, such as the "Diagnostic X-ray systems and their major components", section of subchapter J of Title 21 of the Code of Federal Regulations (CFR), and the National Council on Radiation Protection (NCRP) No 102, "Medical X-ray and gamma ray protection for energies up to 10 MEV equipment design and use", as revised or replaced in the future.

In addition, operators are strongly urged to acquaint themselves with the current recommendations of the International Commission on Radiological Protection, and in the United States, with those of the US National Council for Radiological Protection.

> ICRP, Pergamon Press, Oxford, New York, Beijing, Frankfurt, Sao Paul, Sydney, Tokyo, Toronto
>
> NCRP, Suite 800, 7910 Woodmont Avenue, Bethesda, Maryland 20814, USA

Those responsible for the planning of X-ray and gamma ray equipment installations must be thoroughly familiar and comply completely with NCRP No. 49, "Structural shielding design and evaluation for Medical of X-rays and gamma rays of energies up to 10 MEV", as revised and replaced in the future.

Failure to observe these warnings may cause serious or fatal bodily injuries to the operator or those in this area.

14.4 Preventive Maintenance

Routine preventive maintenance for the whole CT system is scheduled every six months and should be performed by qualified Neusoft Medical Systems personnel.

Every six months, use the diagnostic program to check these items:

Anode voltage

Cathode voltage

Emission current

Exposure time

14.5 Cleaning the System

Use a commercial biocide, approved by your governing authority to clean the surface of the system including the Couch, head holders and accessories. Alternatively, you can also use a solution of bleach and water mixed according to EPA guidelines:

- Standard cleaning requires 500-615 ppm available chlorine
- Cleaning large amounts of body fluid requires 5,000-6,150 ppm available chlorine

When cleaning the buttons and the inside of the Gantry opening, take care to avoid leaking liquid inside. Blood and contrast medium are health risks. Take safety precautions when removing blood or residual contrast medium.

WARNING:

- **Do not use detergents or organic solvents to clean the system. Strong detergents alcohol and organic cleaners may damage the finish and also cause structural weakening.**
- **Blood and contrast medium are health risks. Take safety precautions when removing blood or residual contrast medium.**

Chapter 15 Recycling Passport

Product Name:	NeuViz Prime Multi-slice CT Scanner System	
Product Model:	NeuViz Prime	
Total Weight (in Kg):	2385	
Producer/ Manufacturer:	**Name**	Neusoft Medical Systems Co., Ltd.
	Address	No.177-1, Chuangxin Road, Hunnan District, Shenyang, Liaoning, China

Recycle Inf.		
Hazardous:  To be removed	**Substances**	**Location**
	Examples: Lead (Pb)	Figure 2
Batteries:  To be removed	**Type**	**Location**
	Lithium coin battery	N/A
Special attention: 	**Item**	**Location**
	Air-spring	Figure 1 Figure 6
Fluids/Gases: 	**Item**	**Location**
	High pressure oil tank	Figure 2

Material content (global)	**Weight in kg**	**Material content (continue)**	**Weight in kg**
Lead (Pb)	25.15	Printed circuits boards	6.27
Iron (Fe)	1340	Tungsten (W)	0.37
Aluminum (Al)	620	Molybdenum(Mo)	0.48
Copper (Cu)	55	All other material types	337.73

NOTE : **The weight should be for reference only.**

Locations as mentioned in the Passport (Pictures information).

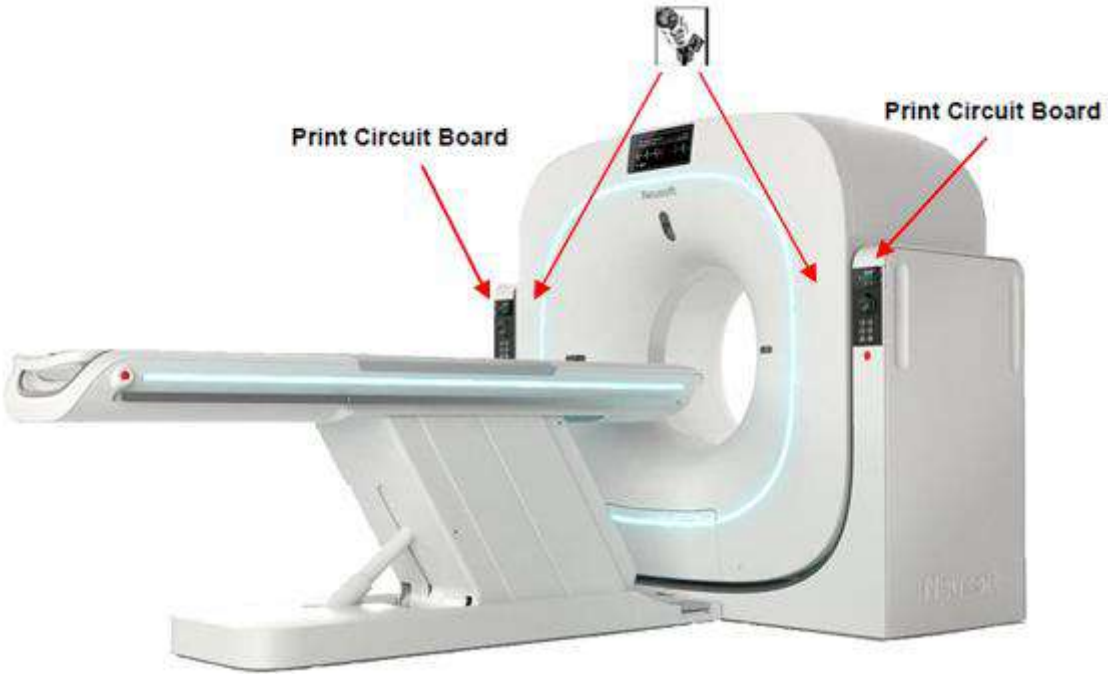


Fig 15-1 CT System Front View

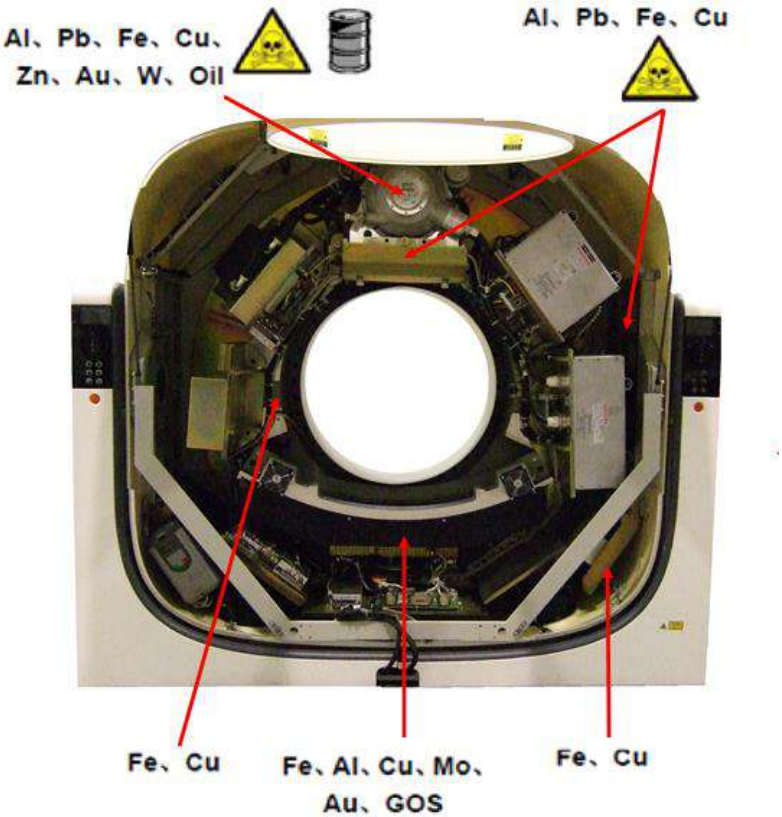


Fig 15-2 Gantry Front View (Without Cover)

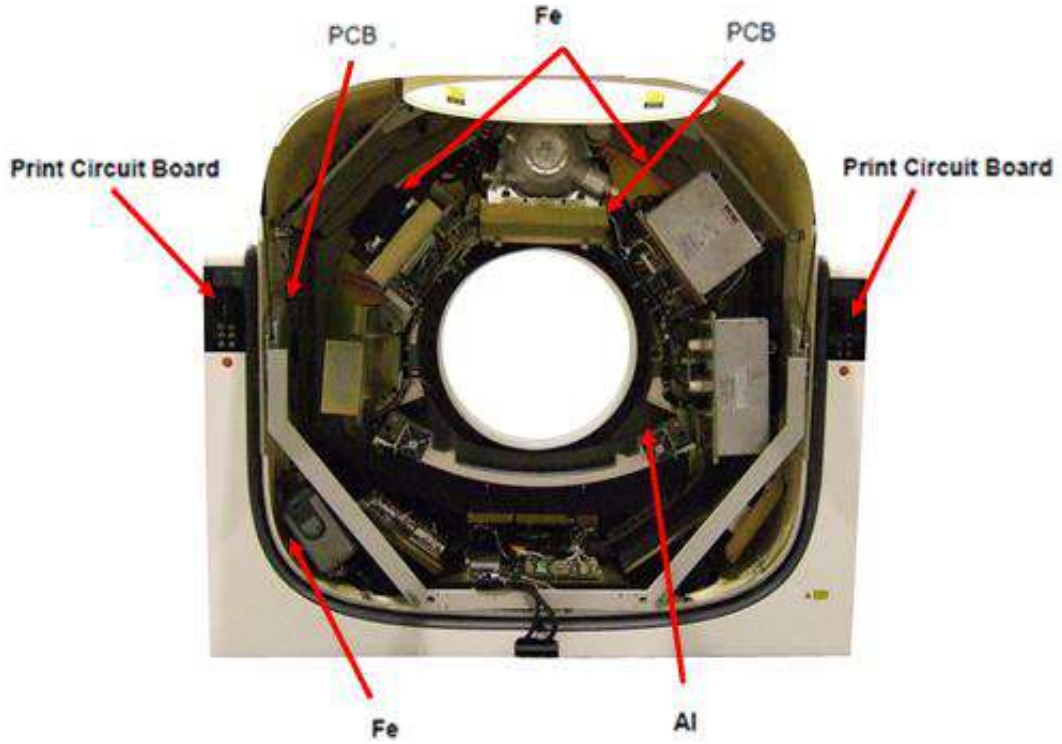


Fig 15-3 Gantry Front View (Without Cover)

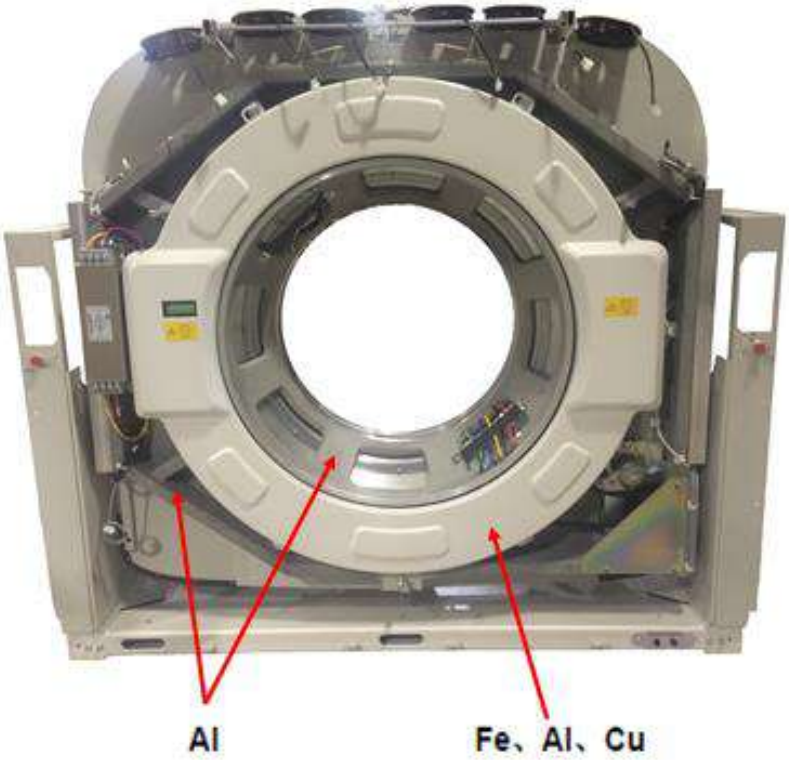


Fig 15-4 Gantry Rear View (Without Cover)

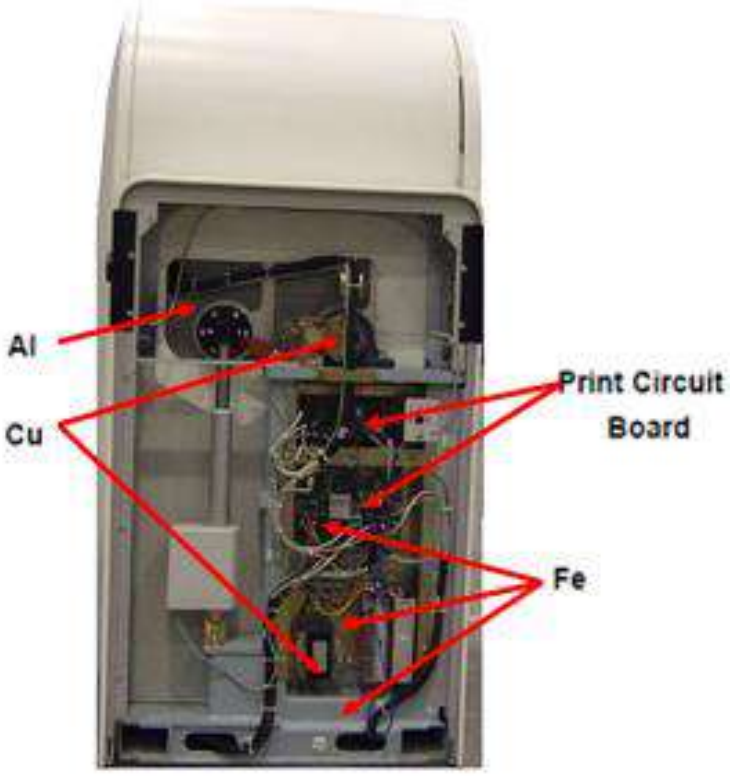


Fig 15-5 Gantry Left Side (Without Cover)

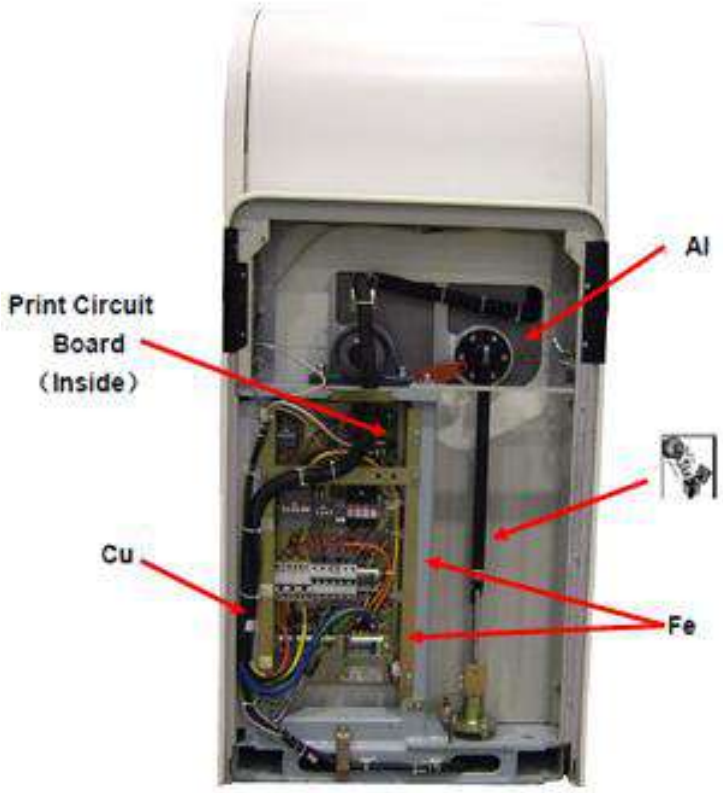


Fig 15-6 Gantry Right Side (Without Cover)

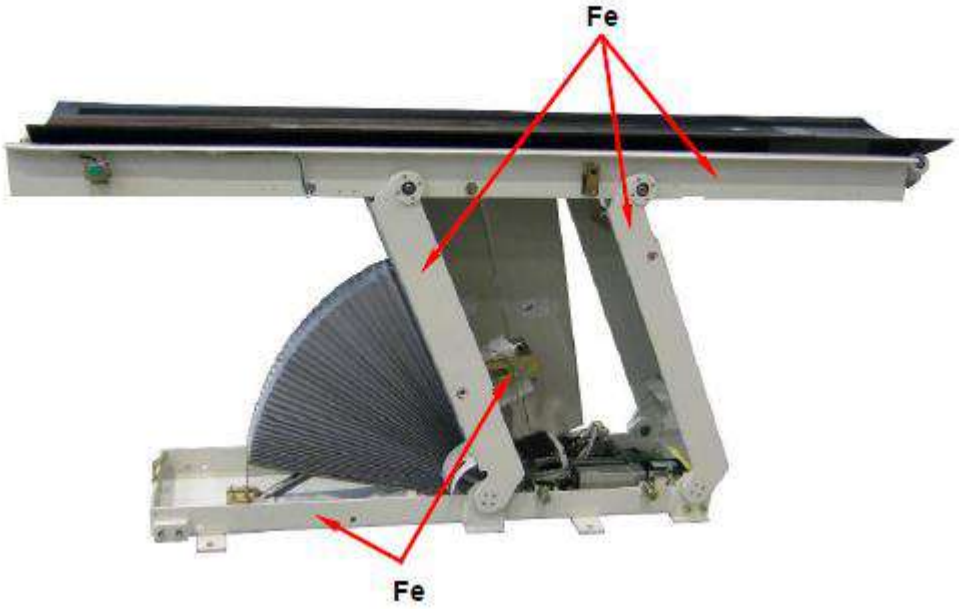


Fig 15-7 Couch System (Without Cover)

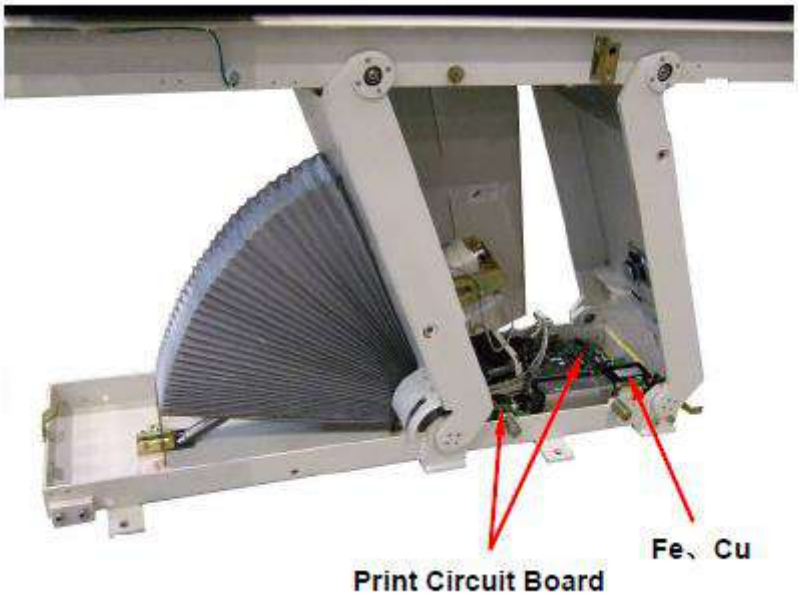


Fig 15-8 Couch (Inside View)

Fig 15-9 Computer Case Front View

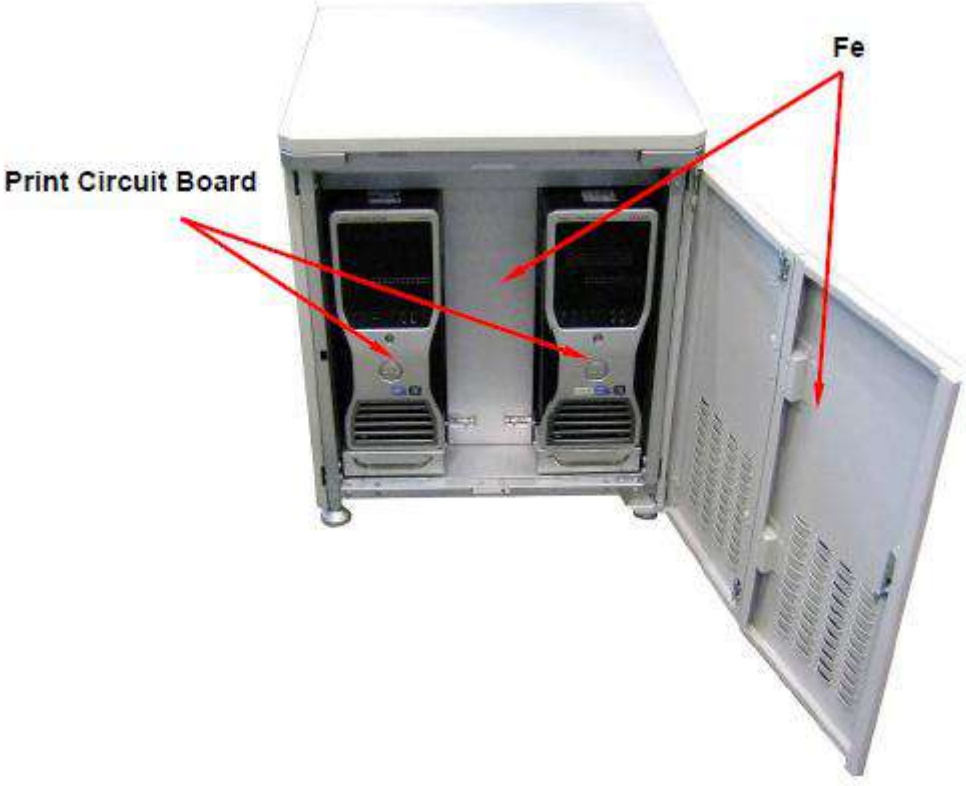


Fig 15-10 Computer Case Front View (Door Open)

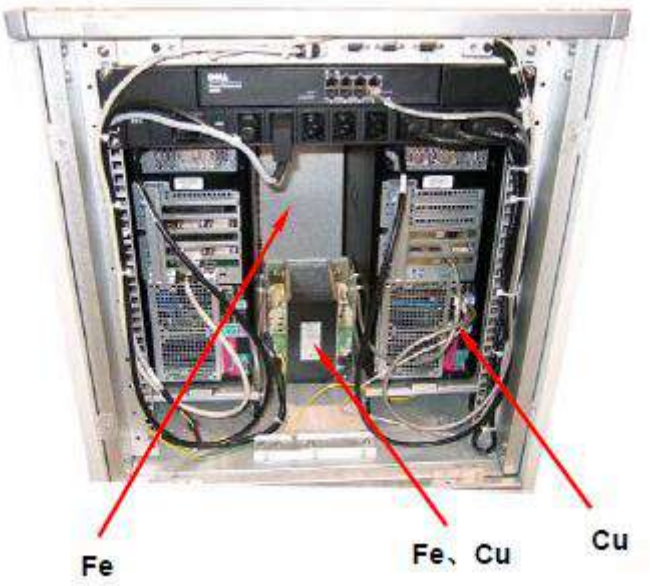


Fig 15-11 Computer Case Rear View

Chapter 16 Factory Protocols

Protocols	IAC Ax.	IAC	IAC iHD Ax.
Brief Description	Axial scan for adult inner ear studies, e.g. inflammatory changes, tumorous processes of pyramids, cerebellopontine angle tumors, post-traumatic change, etc.	Helical scan for adult inner ear studies, e.g. inflammatory changes, tumorous processes of pyramids, cerebellopontine angle tumors, post-traumatic change, etc.	Axial scan for adult inner ear studies using the iHD mode, e.g. inflammatory changes, tumorous processes of pyramids, cerebellopontine angle tumors, post-traumatic change, etc.
kV	120	120	120
mAs	200	200	400
Rotation time(s)	0.8	0.8	1.5
Collimation	8*0.625	32*0.625	8*0.625
Increment(mm)	5	NA	5
Pitch	NA	0.8	NA
Filter	IAC20	IAC20	IAC20
Resolution	High	High	UltraHigh
CTDI (mGy)	42.5	31.3	82.7
DLP(mGy*cm)	339.7	339.1	661.6
O-Dose	OFF	ON	OFF
SNR Level	NA	1	NA
ClearView	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	MPR\3D	NA

Protocols	IAC iHD	IAC 0-6yrs	IAC 7yrs +	IAC Ax. 0-6yrs+OrganSafe
Brief Description	Helical scan for adult inner ear studies using the iHD mode, e.g. inflammatory changes, tumorous processes of pyramids, cerebellopontine angle tumors, post-traumatic change, etc.	Helical scan for 0-6 years old children inner ear studies, e.g. malformation of the inner ear, inflammatory changes, pathologies of the mastoid process, tumor processes of the pyramids, post-traumatic changes, etc.	Helical scan for more than 7 years old children inner ear studies, e.g. inflammatory changes, tumorous processes of pyramids, cerebellopontine angle tumors, post-traumatic change, etc.	Axial scan for 0-6 years old children inner ear studies using organsafe mode, e.g. malformation of the inner ear, inflammatory changes, pathologies of the mastoid process, tumor processes of the pyramids, post-traumatic changes, etc.
kV	120	120	120	120
mAs	600	100	150	100
Rotation time(s)	1.5	0.6	0.8	0.8
Collimation	16*0.3125	32*0.625	32*0.625	8*0.625
Increment(mm)	NA	NA	NA	5
Pitch	0.8	0.6	0.6	NA
Filter	IAC20	IAC20	IAC20	IAC20
Resolution	UltraHigh	High	High	Standard
CTDI (mGy)	119.9	15.6	23.6	11.9
DLP(mGy*cm)	1109.9	133.9	201.7	83.3
O-Dose	ON	OFF	OFF	OFF
SNR Level	1	NA	NA	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	MPR\3D	NA	NA	NA

Protocols	Brain	Brain Ax.	Brain CTA	Brain Perfusion
Brief Description	Helical scan for adult routine neuro studies.	Axial scan for adult routine head studies, e.g. stroke, brain tumors, trauma, cerebral atrophy, hydrocephalus, and inflammation, etc.	Helical scan for cerebral CT Angios, e.g. cerebral vascular abnormalities, tumors and follow-up studies, etc.	Dynamic multiscan at the same table position for neuro studies.
kV	120	120	120	80
mAs	400	400	200	150
Rotation time(s)	0.8	1	0.5	0.5
Collimation	64*0.625	32*0.625	128*0.625	64*0.625
Increment(mm)	NA	20	NA	NA
Pitch	0.8	NA	1.2	NA
Filter	F20	F20	F20	F10
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	54.1	56.8	24.8	245.8
DLP(mGy*cm)	875.8	682	620.1	983.3
O-Dose	ON	OFF	ON	OFF
SNR Level	1	NA	1	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	3D\VA\CTDSA	Brain Perfusion

Protocols	Dental	Facial Bone Volume	PF Ax.	Inf Brain Ax. 0-18m
Brief Description	Helical scan for dental application package to evaluate and reformate the upper and lower jaws.	Helical scan for facial bone studies, e.g. trauma, tumors etc.	Axial scan for posterior cranial fossa studies e.g. stroke, tumor etc.	Axial scan for 0-18 month of children head studies e.g. tumor, hydrocephalus, hemorrhage, abnormalities, etc.
kV	120	120	120	100
mAs	100	150	400	150
Rotation time(s)	0.8	1	1.5	0.5
Collimation	128*0.625	128*0.625	16*0.625	32*0.625
Increment(mm)	NA	NA	10	20
Pitch	0.7	0.9	NA	NA
Filter	F60	F60	F10	F20
Resolution	High	High	Standard	Standard
CTDI (mGy)	12.5	18.6	64.7	13.6
DLP(mGy*cm)	319.6	594.3	323.7	163.5
O-Dose	ON	ON	OFF	OFF
SNR Level	1	1	NA	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	3D\MPR\Dental	MPR\3D	NA	NA

Protocols	Brain Ax. 18m-6yrs	Brain Ax. 7yrs +	Brain CTA 0-6yrs	Brain CTA 7yrs +
Brief Description	Axial scan for 18 month-6 years old of children head studies e.g. tumor, hydrocephalus, hemorrhage, abnormalities, etc.	Axial scan for more than 7 years old of children head studies e.g. tumor, hydrocephalus, hemorrhage, abnormalities, etc.	Helical scan for 0-6 years old children head CT angiography, e.g. cerebral vascular abnormalities, tumors etc.	Helical scan for more than 7 years old children head CT angiography, e.g. cerebral vascular abnormalities, tumors etc.
kV	100	120	80	120
mAs	200	230	300	230
Rotation time(s)	0.5	0.6	0.6	0.6
Collimation	32*0.625	32*0.625	64*0.625	64*0.625
Increment(mm)	20	20	NA	NA
Pitch	NA	NA	0.7	1
Filter	F20	F20	F20	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	18.2	33.7	12.2	31.1
DLP(mGy*cm)	218	404.3	231.1	603.9
O-Dose	OFF	OFF	OFF	OFF
SNR Level	NA	NA	NA	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	3D\VA\CTDSA	3D\VA\CTDSA

Protocols	Brain Ax.+ClearView	Inf Brain Ax. 0-18m+ClearView	Brain Ax. 18m-6yrs+ClearView	Brain Ax. 7yrs+ClearView
Brief Description	Axial scan for adult routine head stduies using ClearView mode, e.g. stroke, brain tumors, trauma, cerebral atrophy, hydrocephalus, and inflammation, etc.	Axial scan for 0-18 month of children head studies using ClearView mode e.g. tumor, hydrocephalus, hemorrhage, abnormalities, etc.	Axial scan for 18 month-6 years old of children head studies using ClearView mode e.g. tumor, hydrocephalus, hemorrhage, abnormalities, etc.	Axial scan for more than 7 years old of children head studies using ClearView mode e.g. tumor, hydrocephalus, hemorrhage, abnormalities, etc.
kV	120	100	100	120
mAs	280	90	120	140
Rotation time(s)	1	0.6	0.6	0.6
Collimation	32*0.625	32*0.625	32*0.625	32*0.625
Increment(mm)	20	20	20	20
Pitch	NA	NA	NA	NA
Filter	F20	F20	F20	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	39.8	8.7	10.7	20.5
DLP(mGy*cm)	477.4	106	128.8	245.9
O-Dose	OFF	OFF	OFF	OFF
SNR Level	NA	NA	NA	NA
ClearView	ON/30%	ON/40%	ON/40%	ON/40%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	NA	NA

Protocols	Brain Ax.+OrganSafe	Inf Brain Ax. 0-18m+OrganSafe	Brain Ax. 18m-6yrs+OrganSafe	Brain Ax. 7yrs+OrganSafe
Brief Description	Axial scan for adult routine head studies using OrganSafe mode, e.g. stroke, brain tumors, trauma, cerebral atrophy, hydrocephalus, and inflammation, etc.	Axial scan for 0-18 month of children head studies using OrganSafe mode e.g. tumor, hydrocephalus, hemorrhage, abnormalities, etc.	Axial scan for 18 month-6 years old of children head studies using OrganSafe mode e.g. tumor, hydrocephalus, hemorrhage, abnormalities, etc.	Axial scan for more than 7 years old of children head studies using OrganSafew mode e.g. tumor, hydrocephalus, hemorrhage, abnormalities, etc.
kV	120	100	100	120
mAs	350	150	171	230
Rotation time(s)	1	0.5	0.5	1
Collimation	32*0.625	32*0.625	32*0.625	32*0.625
Increment(mm)	20	20	20	20
Pitch	NA	NA	NA	NA
Filter	F20	F20	F20	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	51	14.3	16.3	33.6
DLP(mGy*cm)	611.9	171.6	196	402.7
O-Dose	OFF	OFF	OFF	OFF
SNR Level	NA	NA	NA	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	NA	NA

Protocols	Sinus Ax.	Sinus	Sinus Facial 0-6yrs	Sinus Facial 7yrs +
Brief Description	Axial scan for adult sinuses studies, e.g. sinusitis, mucocele, pneumatization, polyposis, tumor, etc.	Helical scan for adult sinuses studies, e.g. sinusitis, mucocele, pneumatization, polyposis, tumor, etc.	Helical scan for 0-6 years old of children sinuses studies, e.g. sinusitis, pneumatization, polyposis, malformations, tumors etc.	Helical scan for more than 7 years old of children sinuses studies, e.g. sinusitis, pneumatization, polyposis, malformations, tumors etc.
kV	120	120	100	100
mAs	150	150	100	150
Rotation time(s)	0.6	0.6	0.5	0.6
Collimation	32*0.625	128*0.625	64*0.625	64*0.625
Increment(mm)	20	NA	NA	NA
Pitch	NA	0.7	0.7	0.7
Filter	F20	F20	F60	F60
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	22	18.6	8.3	12.4
DLP(mGy*cm)	351.8	428.2	157.4	236.1
O-Dose	OFF	ON	OFF	OFF
SNR Level	NA	1	NA	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	NA	NA

Protocols	Sinus Ax.+OrganSafe	Carotid CTA	Neck Soft Tissue	Neck 0-6yrs
Brief Description	Axial scan for adult sinuses studies using OrganSafe, e.g. sinusitis, mucocele, pneumatization, polyposis, tumor etc.	Helical scan for CT angiography of carotid stenosis or occlusions, coarse plaques abnormalities of carotids and vertebral arteries, etc.	Helical scan for soft tissue studies in the cervical region, e.g. tumors, lymphoma, abscesses etc.	Helical scan for 0-6 years of children soft tissue studies in the cervical region, e.g. tumors, lymphoma, abscesses etc.
kV	120	120	120	100
mAs	150	150	200	100
Rotation time(s)	0.6	0.5	1	0.5
Collimation	32*0.625	128*0.625	128*0.625	64*0.625
Increment(mm)	20	NA	NA	NA
Pitch	NA	0.8	0.9	0.8
Filter	F20	F20	F20	F30
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	22.9	9.3	12.4	3.8
DLP(mGy*cm)	366.9	307.6	324.5	72.9
O-Dose	OFF	ON	ON	OFF
SNR Level	NA	1.3	1.3	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	3D\VA\CTDSA	NA	NA

Protocols	Neck 7yrs +	Neck Soft Tissue+ClearView	Carotid CTA Large	Neck Soft Tissue Large
Brief Description	Helical scan for more than 7 years of children soft tissue studies in the cervical region, e.g. tumors, lymphoma, abscesses etc.	Helical scan for soft tissue studies using ClearView in the cervical region, e.g. tumors, lymphoma, abscesses etc.	Helical scan for adult's BMI more than 30 CT angiography of carotid stenosis or occlusions, coarse plaques abnormalities of carotids and vertebral arteries, etc.	Helical scan for adult's BMI more than 30 soft tissue studies in the cervical region, e.g. tumors, lymphoma, abscesses etc.
kV	120	120	120	120
mAs	150	100	180	250
Rotation time(s)	0.6	1	0.5	1
Collimation	64*0.625	128*0.625	128*0.625	128*0.625
Increment(mm)	NA	NA	NA	NA
Pitch	0.8	0.9	0.8	0.9
Filter	F30	F20	F20	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	10	6.2	11.1	15.5
DLP(mGy*cm)	190.7	162.6	369.1	405.6
O-Dose	OFF	ON	OFF	OFF
SNR Level	NA	1.3	NA	NA
ClearView	OFF	ON/50%	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	3D\VA\CTDSA	NA

Protocols	Carotid CTA LD	Neck Soft Tissue LD	Orbit Ax.	Orbit Ax.+OrganSafe
Brief Description	Helical scan using low dose mode for adult CT angiography of carotid stenosis or occlusions, coarse plaques abnormalities of carotids and vertebral arteries, etc.	Helical scan using low dose mode for soft tissue studies in the cervical region, e.g. tumors, lymphoma, abscesses etc.	Helical scan for adult orbital studies, e.g. fracture.	Helical scan for adult orbital studies using OrganSafe, e.g. fracture.
kV	120	120	120	120
mAs	120	150	200	200
Rotation time(s)	0.5	1	1	1
Collimation	128*0.625	128*0.625	32*0.625	32*0.625
Increment(mm)	NA	NA	20	20
Pitch	0.8	0.9	NA	NA
Filter	F20	F20	F60	F60
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	7.4	9.3	28.4	29.1
DLP(mGy*cm)	246.1	243.4	341	349.5
O-Dose	ON	ON	OFF	OFF
SNR Level	1.3	1.3	NA	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	3D\VA\CTDSA	NA	NA	NA

Protocols	Cervical Volume	Thoracic Volume	Lumbar Volume	Spine Ax.
Brief Description	Helical scan for adult Cervical spines, e.g. prolapse, degenerative changes, trauma, tumor etc.	Helical scan for adult Thoracic spines, e.g. prolapse, degenerative changes, trauma, tumor etc.	Helical scan for adult Lumbar spines, e.g. prolapse, degenerative changes, trauma, tumor etc.	Axial scan for adult spine studies, e.g. prolapse, degenerative changes, trauma, tumors etc.
kV	120	120	120	120
mAs	200	250	250	300
Rotation time(s)	1	0.6	0.8	1
Collimation	128*0.625	128*0.625	128*0.625	16*0.625
Increment(mm)	NA	NA	NA	10
Pitch	0.9	0.9	0.9	NA
Filter	F60	F60	F60	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	12.4	15.5	15.4	24.4
DLP(mGy*cm)	346.5	592.4	511.5	24.4
O-Dose	ON	ON	ON	OFF
SNR Level	1.3	1.3	1.3	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	MPR\3D	MPR\3D	MPR\3D	NA

Protocols	Spine Volume+ClearView	Cervical Volume Large	Thoracic Volume Large	Lumbar Volume Large
Brief Description	Helical scan for adult spines using ClearView mode, e.g. prolapse, degenerative changes, trauma, tumor etc.	Helical scan for adult's BMI more than 30 Cervical spines, e.g. prolapse, degenerative changes, trauma, tumor etc.	Helical scan for adult's BMI more than 30 Thoracic spines, e.g. prolapse, degenerative changes, trauma, tumor etc.	Helical scan for adult's BMI more than 30 Lumbar spines, e.g. prolapse, degenerative changes, trauma, tumor etc.
kV	120	120	120	140
mAs	150	250	325	250
Rotation time(s)	0.8	1	0.8	0.8
Collimation	128*0.625	128*0.625	128*0.625	128*0.625
Increment(mm)	NA	NA	NA	NA
Pitch	0.9	0.9	0.9	0.9
Filter	F60	F60	F60	F60
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	9.3	15.5	20.1	23.3
DLP(mGy*cm)	308	433.2	766.9	772.6
O-Dose	ON	OFF	OFF	OFF
SNR Level	1.3	NA	NA	NA
ClearView	ON/50%	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	MPR\3D	MPR\3D	MPR\3D	MPR\3D

Protocols	Spine Ax. Large	Cervical Volume LD	Thoracic Volume LD	Lumbar Volume LD
Brief Description	Axial scan for adult's BMI more than 30 spine studies, e.g. prolapse, degenerative changes, trauma, tumors etc.	Helical scan using low dose mode for adult Cervical spines, e.g. prolapse, degenerative changes, trauma, tumor etc.	Helical scan using low dose mode for adult Thoracic spines, e.g. prolapse, degenerative changes, trauma, tumor etc.	Helical scan using low dose mode for adult Lumbar spines, e.g. prolapse,degenerative changes,trauma,tumor etc.
kV	140	120	120	120
mAs	300	150	175	175
Rotation time(s)	1	1	0.6	0.8
Collimation	16*0.625	128*0.625	128*0.625	128*0.625
Increment(mm)	10	NA	NA	NA
Pitch	NA	0.9	0.9	0.9
Filter	F20	F60	F60	F60
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	36.8	9.3	10.8	10.8
DLP(mGy*cm)	36.8	259.9	415.5	415.5
O-Dose	OFF	ON	ON	ON
SNR Level	NA	1.3	1.3	1.3
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	MPR\3D	MPR\3D	MPR\3D

Protocols	Spine Ax. LD	Aorta CTA	C/A/P	C/A/P LD
Brief Description	Axial scan using low dose mode for adult spine studies, e.g. prolapse, degenerative changes, trauma, tumors etc.	Helical scan for adult thoracic angiography.	Helical scan for adult thoracic, abdomen, and pelvis routine studies.	Helical scan using low dose mode for adult thoracic, abdomen, and pelvis routine studies.
kV	120	120	120	120
mAs	200	150	200	50
Rotation time(s)	1	0.37	0.5	0.5
Collimation	16*0.625	128*0.625	128*0.625	128*0.625
Increment(mm)	10	NA	NA	NA
Pitch	NA	1	1.4	1.4
Filter	F20	F20	F20	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	16.2	9.3	12.4	3.1
DLP(mGy*cm)	16.2	363.8	934.9	233.7
O-Dose	OFF	ON	ON	ON
SNR Level	NA	1.3	1.3	1.3
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	3D\VA	NA	NA

Protocols	C/A/P Large	Chest	Chest LD	HRCT
Brief Description	Helical scan for adult's BMI more than 30 thoracic, abdomen, and pelvis routine studies.	Adult routine helical studies for the region of thorax, e.g. visualization of tumors, metastases, lymphoma, lymph nodes, vascular anomalies etc.	Adult low dose helical studies for the region of thorax, e.g. visualization of tumors, metastases, lymphoma, lymph nodes, vascular anomalies etc.	Helical scan for adult high resolution lung studies, e.g. interstitial changes in the lungs.
kV	140	120	120	120
mAs	150	150	30	150
Rotation time(s)	0.5	0.5	0.6	0.6
Collimation	128*0.625	128*0.625	128*0.625	64*0.625
Increment(mm)	NA	NA	NA	NA
Pitch	1.4	1.2	1.2	0.9
Filter	F20	F20	F20	Lung30
Resolution	Standard	Standard	Standard	High
CTDI (mGy)	14	9.3	1.9	10
DLP(mGy*cm)	1059.1	367.1	73.1	361.3
O-Dose	OFF	ON	ON	ON
SNR Level	NA	1.3	1.3	1.3
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	NA	NA

Protocols	HRCT Ax.	PE	Inf Thorax <10kg	Thorax 10-30kg
Brief Description	Axial scan for adult high resolution lung studies, e.g. interstitial changes in the lungs.	Helical scan for adult pulmonary emboli studies.	Helical routine thorax scan for infant weight lower than 10kg.	Helical routine thorax scan for children weight from 10kg to 30kg.
kV	120	120	100	100
mAs	140	150	50	100
Rotation time(s)	0.5	0.37	0.37	0.37
Collimation	2*0.625	128*0.625	64*0.625	64*0.625
Increment(mm)	10	NA	NA	NA
Pitch	NA	0.7	0.8	0.8
Filter	Lung30	F20	Lung20	Lung20
Resolution	High	Standard	High	High
CTDI (mGy)	2.3	9.3	1.9	3.8
DLP(mGy*cm)	70.8	307.4	49.4	99.2
O-Dose	ON	ON	OFF	OFF
SNR Level	1.3	1.3	NA	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	NA	NA

Protocols	Thorax 30-50kg	Thorax 50-70kg	TIBT	Biopsy
Brief Description	Helical routine thorax scan for children weight from 30kg to 50kg.	Helical routine thorax scan for children weight from 50kg to 70kg.	Low dose axial scan without table movement used to calculate the start delay of a helical scan to ensure optimal enhancement after the contrast medium injection.	Low dose axial scan without table movement used to biopsy.
kV	120	120	120	120
mAs	100	150	30	50
Rotation time(s)	0.6	0.6	0.6	0.6
Collimation	64*0.625	64*0.625	16*0.625	8*0.625
Increment(mm)	NA	NA	0	0
Pitch	0.9	0.9	NA	NA
Filter	Lung20	Lung20	F20	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	6.7	10	2.9	6.2
DLP(mGy*cm)	229.4	344	2.9	3.1
O-Dose	OFF	OFF	OFF	OFF
SNR Level	NA	NA	NA	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	NA	NA

Protocols	CCT Single	CCT Continuous	CCT Fluoro	Chest+ClearView
Brief Description	Single multislice biopsy mode.	Continuous multislice biopsy mode.	Fluoroscopic biopsy mode.	Adult routine helical studies using ClearView mode for the region of thorax, e.g. visualization of tumors, metastases, lymphoma, lymph nodes, vascular anomalies etc.
kV	120	120	120	120
mAs	50	50	50	75
Rotation time(s)	0.37	0.37	0.37	0.6
Collimation	24*0.625	8*0.625	4*0.625	128*0.625
Increment(mm)	0	0	0	NA
Pitch	NA	NA	NA	1.2
Filter	F20	F20	F20	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	4.9	6.9	NA	4.6
DLP(mGy*cm)	7.4	3.4	NA	183
O-Dose	OFF	OFF	OFF	ON
SNR Level	NA	NA	NA	1.3
ClearView	OFF	OFF	OFF	ON/50%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	NA	NA

Protocols	HRCT Ax.+OrganSafe	Aorta CTA Large	Aorta CTA LD	Chest Large
Brief Description	Axial scan using OrganSafe mode for adult high resolution lung studies, e.g. interstitial changes in the lungs.	Helical scan for adult's BMI more than 30 thoracic angiography.	Helical scan using low dose mode for adult thoracic angiography.	Adult'BMI more than 30 routine helical studies for the region of thorax, e.g. visualization of tumors, metastases, lymphoma, lymph nodes, vascular anomalies etc.
kV	120	120	120	120
mAs	150	200	120	180
Rotation time(s)	0.5	0.37	0.37	0.6
Collimation	2*0.625	128*0.625	128*0.625	128*0.625
Increment(mm)	10	NA	NA	NA
Pitch	NA	1	1	1.2
Filter	Lung30	F20	F20	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	2.6	12.4	7.4	11.1
DLP(mGy*cm)	79.7	484.7	291	438.3
O-Dose	ON	OFF	OFF	OFF
SNR Level	1.3	NA	NA	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	3D\VA	3D\VA	NA

Protocols	Abdomen	Abdomen LD	Abdomen Large	Colon
Brief Description	Helical scan for adult routine studies in the region of abdomen.	Helical scan using low dose mode for adult routine studies in the region of abdomen.	Helical scan for adult's BMI more than 30 routine studies in the region of abdomen.	Helical scan for adult of the application CT Colonography.
kV	120	120	140	120
mAs	200	50	250	100
Rotation time(s)	0.6	0.6	0.6	0.6
Collimation	128*0.625	128*0.625	128*0.625	128*0.625
Increment(mm)	NA	NA	NA	NA
Pitch	1.2	1.2	1.2	1.2
Filter	F20	F20	F20	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	12.4	3.1	23.3	6.2
DLP(mGy*cm)	486.3	121.6	918.1	275.9
O-Dose	ON	ON	OFF	ON
SNR Level	1.3	1.3	NA	1.3
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	NA	Colon

Protocols	Liver	Pancreas	Runoff CTA	Renal CTA
Brief Description	Helical scan for adult of the liver.	Helical scan for adult of the pancreas.	Helical scan for adult CTA studies from aorta to extremities artery.	Helical scan for adult renal CTA studies.
kV	120	120	120	120
mAs	200	200	200	200
Rotation time(s)	0.6	0.6	0.37	0.6
Collimation	128*0.625	64*0.625	128*0.625	128*0.625
Increment(mm)	NA	NA	NA	NA
Pitch	1	0.8	1	0.8
Filter	F20	F20	F20	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	12.4	13.4	12.4	12.4
DLP(mGy*cm)	291.1	254.7	1102	285
O-Dose	ON	ON	ON	ON
SNR Level	1.3	1.3	1.3	1.3
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	NA	NA

Protocols	Inf Abd/Pel <10Kg	Abd/Pel 10-30Kg	Abd/Pel 30-50Kg	Abd/Pel 50-70Kg
Brief Description	Helical routine abdomen scan for infant weight lower than 10kg.	Helical routine abdomen scan for children weight from 10kg to 30kg.	Helical routine abdomen scan for children weight from 30kg to 50kg.	Helical routine abdomen scan for children weight from 50kg to 70kg.
kV	100	100	120	120
mAs	50	100	100	150
Rotation time(s)	0.37	0.37	0.6	0.6
Collimation	64*0.625	64*0.625	64*0.625	64*0.625
Increment(mm)	NA	NA	NA	NA
Pitch	0.8	0.8	0.9	0.9
Filter	F20	F20	F20	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	1.9	3.8	6.7	10
DLP(mGy*cm)	46	92.5	229.2	343.8
O-Dose	OFF	OFF	OFF	OFF
SNR Level	NA	NA	NA	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	NA	NA

Protocols	Abdomen + ClearView	Pelvis Routine	Pelvis Bone	Pelvis Routine+ClearView
Brief Description	Helical scan using ClearView mode for adult routine studies in the region of abdomen.	Helical scan for adult pelvis studies, e.g. prostate, urinary bladder, rectum, gynecological indications etc.	Helical scan for adult bone studies and soft tissue studies of the Hip.	Helical scan using ClearView mode for adult pelvis studies, e.g. prostate, urinary bladder, rectum, gynecological indications etc.
kV	120	120	120	120
mAs	100	200	200	100
Rotation time(s)	0.6	0.6	0.8	0.6
Collimation	128*0.625	128*0.625	128*0.625	128*0.625
Increment(mm)	NA	NA	NA	NA
Pitch	1.2	0.8	1	0.8
Filter	F20	F20	F60	F20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	6.2	12.4	12.4	6.2
DLP(mGy*cm)	243.5	473	475.9	235.9
O-Dose	ON	ON	ON	ON
SNR Level	1.3	1.3	1.3	1.3
ClearView	ON/50%	OFF	OFF	ON/50%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	NA	NA

Protocols	Extremity Volume	Knee	Shoulder/Hip Volume	Shoulder/Hip Volume+ClearView
Brief Description	Helical scan for adult high resolution bone studies, e.g. trauma, orthopedic indication etc.	Helical scan for adult knee studies.	Helical scan for adult shoulder or hip studies.	Helical scan using ClearView mode for adult shoulder or hip studies.
kV	120	120	140	140
mAs	150	150	250	130
Rotation time(s)	0.8	0.8	1	1
Collimation	32*0.625	32*0.625	128*0.625	128*0.625
Increment(mm)	NA	NA	NA	NA
Pitch	0.9	0.9	0.8	0.8
Filter	F60	F60	F60	F60
Resolution	High	High	Standard	Standard
CTDI (mGy)	11.6	11.6	23.3	12.1
DLP(mGy*cm)	209.1	209.8	533.7	278.3
O-Dose	ON	ON	ON	ON
SNR Level	1.3	1.3	1.3	1.3
ClearView	OFF	OFF	OFF	ON/50%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	MPR\3D	NA	NA	MPR\3D

Protocols	Extremity iHD	Knee iHD	Calcium Scoring	Coronary CTA
Brief Description	Helical scan using iHD mode for adult high resolution bone studies, e.g. trauma, orthopedic indication etc.	Helical scan using iHD mode for adult knee studies.	ECG-gated axial scan for adult coronary calcium scoring.	ECG-gated helical scan for adult coronary CTA.
kV	120	120	120	120
mAs	400	400	100	650
Rotation time(s)	1	1	0.37	0.37
Collimation	16*0.625	16*0.625	32*0.625	128*0.625
Increment(mm)	NA	NA	20	NA
Pitch	0.9	0.9	NA	0.2
Filter	F60	F60	Cardiac50	Cardiac20
Resolution	High	High	Standard	Standard
CTDI (mGy)	39.3	39.3	8	40.2
DLP(mGy*cm)	641.9	641.9	96.1	486.3
O-Dose	ON	ON	OFF	OFF
SNR Level	1.3	1.3	NA	NA
ClearView	OFF	OFF	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	NA	NA	CCS	Coronary\CFA

Protocols	Calcium Scoring Cine	Coronary CTA + ClearView	Coronary CTA DOM 0%	Coronary CTA DOM
Brief Description	ECG-gated axial scan using cine mode for adult coronary calcium scoring.	ECG-gated helical scan using ClearView mode for adult coronary CTA.	ECG-gated helical scan using DOM mode with 0% dose of non-recon phase for adult coronary CTA.	ECG-gated helical scan using DOM mode for adult coronary CTA.
kV	120	120	120	120
mAs	100	350	650	650
Rotation time(s)	0.37	0.37	0.37	0.37
Collimation	32*0.625	128*0.625	128*0.625	128*0.625
Increment(mm)	20	NA	NA	NA
Pitch	NA	0.2	0.2	0.2
Filter	Cardiac50	Cardiac20	Cardiac20	Cardiac20
Resolution	Standard	Standard	Standard	Standard
CTDI (mGy)	7.6	21.6	40.2	40.2
DLP(mGy*cm)	91.5	261.2	486.9	486.3
O-Dose	OFF	OFF	OFF	OFF
SNR Level	NA	NA	NA	NA
ClearView	OFF	ON/50%	OFF	OFF
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy	Max CTDIvol 250mGy Max DLP 2000mGy
Application	CCS	Coronary\CFA	Coronary	Coronary\CFA

Protocols	Brief Description	kV	mAs	Rotation time(s)	Collimation	Increment(mm)	Pitch	Filter	Resolution	CTDI (mGy)	DLP(mGy*cm)	O-Dose	SNR Level	ClearView	Dose Alert	Application
Coronary CTA Ax.	ECG-gated axial scan for adult coronary CTA.	120	100	0.37	128*0.625	40	NA	Cardiac20	Standard	9.5	117.8	OFF	NA	OFF	Max CTDIvol 250mGy Max DLP 2000mGy	Coronary

NOTE:

- **A protocol must be selected to initiate the scanning sequence. Protocols are used as a basis for routine or established procedures. Protocols save time by using preset established parameters.**

Once chosen for use, any protocol may have any parameters modified as needed for individual case purposes. The system is equipped with a set of Neusoft Reference Protocols that can be used for common types of examinations.

You can use these protocols or modify them to fit particular clinical needs. Refer to known sources for techniques and dose information for viable parameters, as proper techniques must be used to ensure patient safety and image quality.

- **Pediatric protocols are mainly divided by age and weight.**

  a. Head protocols are mainly divided by age:
  0 to 18 months
  18 months to 6 years
  Older than 7 years
  The younger the age, the lower the dose designed.
  b. Body protocols are mainly divided by weight:
  less than 10kg
  10 to 30kg
  30 to 50kg
  50 to 70kg
  The lesser the weight, the lower the dose designed.
  c. Pediatric Protocols use lower voltage and lower mAs.
  d. Pediatric Protocols take less scan time to avoid the effect of motion artifact.

- **For more information about pediatric X-ray Imaging, user may reference to the Image Gently website and the resources in FDA's Pediatric X-ray Imaging webpage**

(http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm).

Fig 16-1 Electronic Information Product Contamination Control Symbol

Table 16-1 Name and Content of Hazardous Substances in Product

Name and Content of Hazardous Substances in Product						
Component Name	Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Tube	×	○	○	○	○	○
Encoder	×	○	○	○	○	○
Ray Box and Top Slice System	×	○	○	○	○	○

The chart is in accordance with SJ/T 11364 stipulations。

○ : It denotes the content of this hazardous substance in all homogenous materials of the component is below the limit requirement of SJ/T 11364 stipulations.

× : It denotes the content of this hazardous substance in at least one homogenous material of the component exceeds the limit requirement of SJ/T 11364 stipulations.

Chapter 17 Abbreviations

Abbreviations	Acronym
CFR	Code of Federal Regulations
cm	Centimeter
CT	Computed Tomography
CTDI	Computed Tomography Dose Index
DAS	Data Acquisition System
FOV	Field of view
DFOV	Display Field of view
SFOV	Scan Field of view
DICOM	Digital Imaging and Communication in Medicine
DLP	Dose Length Product
ECG	Electro cardiogram
EMC	Electro-magnetic Compatibility
FDA	Food and Drug Administration
FWHM	Full Width Half Maximum
HU	Hounsfield Units
HV	High Voltage
IEC	International Electro-technical Commission
ISO	International Organization for Standardization
kg	Kilogram
kV	Kilo-volts
LCR	Low Contrast Resolution
mA	Milliamps
mGy	Milligray
mm	Millimeter
MPR	Multiplanar Reconstruction
s	second
MTF	Modulation Transfer Function
NCRP	National Council on Radiation Protection and Measurements
EU	European Union
ICRP	International Commission on Radiological Protection

Abbreviations	Acronym
AAPM	American Association of Physicists in Medicine
PMMA	Poly-methyl methacrylate
QA	Quality Assurance
ROI	Region of Interest
WL	Window Level
WW	Window Width
Ax.	Axial
STD	Standard resolution
UHR	Ultrahigh resolution

NeuViz Prime
User Manual (Vol. 1)

Neusoft Medical Systems Co., Ltd.
No. 177-1 Chuangxin Road, Hunnan District, Shenyang, Liaoning, China 110167

Email: nms-service@neusoftmedical.com

www.neusoftmedical.com/en

10498632