Multi-slice CT Scanner System
NeuViz 128
User Manual (Vol. 1)

CE 0123

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NEUSOFT MEDICAL SYSTEMS CO., LTD.

Neusoft Medical Systems

About This Manual

1. About the Manual

This manual is a user manual for NeuViz 128 CT.

This manual describes the function, safety and use of NeuViz 128 CT.

This device is also delivered with an electronic *NeuViz 128 User Manual*. The *NeuViz 128 User Manual* is available on the Internet at:
https://partner.neusoftmedical.com/ifu/10631752

Neusoft Medical Systems Co., Ltd. is responsible for NeuViz 128 CT system, but not responsible for the unauthorized part.

Revision Version: B

Software Version: 2.0

2. How to Use this Manual

The user must read the manual carefully, especially the chapter about safety instruction, 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 shall refer to this manual.

3. Copyright

4. Revision History

Rev.	Issue Date	Reasons for Change
A	2023.01	First Release
B	2023.04	Update Information

Contents

Chapter 1 About the Manual

1.1 About this Manual

This manual is intended for safe and effective operation of the device described. 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 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 128 Multi-Slice CT Scanner System can be used as a whole body comput ed tomography X-ray system featuring a continuously rotating X-ray tube and detect or array. The acquired X-RAY transmission data is reconstructed by computer into cr

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

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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.**

1.2.1 Patient Population

Neonate, Child and Adult.

1.2.2 Intended User

Operator & Doctors: Operator and Doctors use the CT scanner to scan the patient and perform post image processing for diagnoses of the patient.

NOTE:

- **The NeuViz 128 system must only be operated by persons with the certified specialist knowledge according to country-specific regulations. As the user, they must have the necessary qualifications and they must also have been instructed in the use of the NeuViz 128 system.**

1.2.3 Operating Conditions

The couch and gantry of the CT machine must be placed in a scanner room with X-ray shielding, and the console must be placed in an operating room.

For details regarding system requirements, like room temperature and humidity, refer to the information in Chapter 3.1.

1.2.4 Contraindication

None Known.

1.3 Clinical Benefits

Benefits of CT include more effective medical management by:

- Determining when surgeries are necessary
- Reducing the need for exploratory surgeries
- Improving cancer diagnosis and treatment

- Reducing the length of hospitalizations
- Guiding treatment of common conditions such as injury, cardiac disease and stroke
- Improving patient placement into appropriate areas of care, such as intensive care units
- In an emergency room, patients can be scanned quickly so doctors can rapidly assess their condition. Emergency surgery might be necessary to stop internal bleeding. CT images show the surgeons exactly where to operate. Without this information, the success of surgery is greatly compromised. The risk of radiation exposure from CT is very small compared to the benefits of a well-planned surgery
- CT scanning provides medical information that is different from other imaging ex aminations, such as ultrasound, MRI, SPECT, PET or nuclear medicine.

NeuViz 128 can provide detailed information to diagnose, plan treatment for, and evaluate many conditions in adults and children. Additionally, the detailed images provided by CT scans may eliminate the need for exploratory surgery.

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 to do so. Such changes and/or additions must comply with all applicable laws and regulations that have the force of law 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 of personal injury.

1.5 Serious Incident Reporting

NOTE:

- **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 the Regulation (EU) 2017/745.

X-ray source assembly of NeuViz 128 IEC60601-2-28/ EN 60601-2-28

NeuViz 128 with radiation protection in accordance with IEC60601-1-3/EN 60601-1-3.

This product is in conformity with EU RoHS directive, 2011/65/EU Restriction of Hazardous Substances and (EU) 2015/863 amending Annex II.

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 B Applied Part（Couch Board） Type BF Applied Part (ECG)(Option, CT-SMC 305 only)
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 FLAMMABLEANAESTHETIC 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	Group1, Class A Device

EMERGO EUROPE
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

1.7 Training and After-sales Service

Operators of the NeuViz 128 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 to be broken or not functioning properly, it should be stopped at once. Do not use the device until qualified maintenance personnel has solved the problem.**

CAUTION:

- **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.**
- **Understand the product specifications, system accuracy, and stability limitations. These limitations must be considered before making any decision based on quantitative values. In case of doubt, please consult your sales representative.**
- **Only use original accessories and equipments. Such as phantom, foot switch, ECG cable, positioning Aids, table top extension board, etc. And use published devices only for their original purpose.**
- **Configuration of the device purchased might be different from what is described in this manual. Please use the purchase contract as final.**
- **The images and calculations provided by this system are intended as tools**

for the competent user. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis. Users are encouraged to study the literature and reach their own professional conclusions regarding the clinical utility of the system.

- **Operations must be performed according to the Operation Manual, and the maintenance must be performed according to the Service 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, be 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 the state of patient's state and running state of the device.**
- **In daily operation, do not splatter liquid on the system.**
- **The equipment shall not be serviced or maintained while in use with a patient.**
- **Do not splatter liquid on the system.**

2.2 EMC

2.2.1 EMC Definition and Attentions

The definition of EMC (electromagnetic compatibility): the equipment and systems shall not emit electromagnetic disturbances that could affect radio services, other equipment or the essential performance of other equipment and systems. The equipment and systems shall have adequate immunity to be able to provide its basic safety and essential performance in the presence of electromagnetic disturbances.

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:

- **For EMC specific information, please refer to the Product Information Manual.**
- **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 to 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 property 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/ lying 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 scanning room before a scan process is initiated. Unless given

permission by the doctor in charge, allow no one to enter the scanning 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 raise 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 the patient is positioned securely with straps on the Couch top to reduce the risk of the patient falling and hands dangling.
- 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 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 locked to the Couch.
- 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

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, the gantry tilt shall stop within an angle of 0.5°, Z-direction motion shall stop within 25mm and patient support movement (up/down) 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 condition 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 need an emergent scan, but the CT operator who knows the code is absent. 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 tilting 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 although 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 qualified personnel can operate the device described in this manual.**
- **The CT scanning 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 radiation.**
- **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.**

- **When tube heating is lower than 10%, Tube Warm Up is required before scanning the patient. Failure to do Tube Warm Up may damage or shorten the life of the tube.**
- **The NeuViz 128 Software controls the NeuViz 128 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.**
- **Prolonged exposure to x-ray in one spot may cause reddening or radiation burns. Users must be aware of the techniques used and exposure time to ensure safe operation.**

2.4.1 Radiation Safety Prompts

The system provides two types of safety prompts:

- Sound Prompt: There is sound in the sound 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 scanning 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 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 CTDI100 (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 CTDI100 (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 CTDI100 (peripheral). Note that for each kV/Collimation 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

Voltage（kV）	Collimation Thickness(*0.625mm)	CTDI phantom	
		16cm	32cm
80	**2**	60	153
	4	53	130
	8	76	185
	12	88	214
	16	97	235
	20	103	249
	24	106	258
	32	112	272
	40	116	280
	64	122	293
100	**2**	30	67
	4	26	57
	8	37	81
	12	43	94
	16	48	103
	20	50	109
	24	52	113
	32	55	119
	40	57	123
	64	60	129
120	**2**	18	38

Voltage（kV）	Collimation Thickness(*0.625mm)	CTDI phantom	
		16cm	32cm
	4	16	33
	8	23	46
	12	27	54
	16	29	59
	20	31	62
	24	32	65
	32	34	68
	40	35	70
	64	37	74
140	**2**	12	25
	4	11	22
	8	16	31
	12	18	36
	16	20	39
	20	21	41
	24	22	43
	32	23	45
	40	24	46
	64	25	49

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 scanning 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 on 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.**
- **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 takes 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 211kg (standard couch and long couch) or 300kg (300kg couch). Scanning accuracy can be guaranteed within 211kg or 300kg of the Couch. If the weight exceeds this limit, the result might be:**

- **Accuracy reduction of system positioning.**
- **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.**
- **When using patient positioning accessories and straps, make sure there are no areas which might cause a pinch point or interfere with patient tubing or IV.**
- **Check to make sure the power injector has enough IV tubing to allow free movement of the cradle. Make sure the unit itself does not interfere with couch travel. Ensure excess tubing length is secured to the couch top. Do not loop additional IV tubing in the patient's fingers.**
- **The patient positioning straps provided with the system do not support the full weight of the patient. Patient positioning straps should be used to aid in patient positioning and are not meant to fully restrain the patient.**
- **The head holder may crack, possibly injuring the patient's head or neck, If the patient tries to brace himself or herself on the head holder during positioning. The head holder and cradle extender are only designed to support 15 kg. Ask the patient to move up into the head holder or manually help the patient into position.**
- **Use of any cradle extension accessories such as the table extension, head holder, coronal head holder, and phantom holder are not accounted for in the couch gantry interference matrix. Therefore, additional care needs to be taken to closely monitor any couch up/down, in/out movement to avoid contact of the extended accessory with the gantry.**
- **Blocked gantry air inlets can cause system overheating that reduces image quality. Diagnostic errors may occur when reading images. Remove any objects blocking the gantry air inlets located on each side of the gantry.**
- **The phantom holder shall be used with the phantom provided by Neusoft. Do not place other heavy items.**
- **In the event of unintentional interruption of the supply mains or power supply, the gantry tilt shall stop within an angle of 0.5°, Z-direction motion shall stop within 60mm(under maximum horizontal motion speed 310mm/s of table top of couch)and patient support movement (up/down) shall stop within 10 mm.**

CAUTION:

- **Temporal sampling may be degraded due to changes in timing for the couch to move from location to location if proper positioning methods are not followed. Make sure that the patient is securely positioned on the couch and their arms are not allowed to drag on the couch or allow clothing, sheets or blankets to get caught causing a couch move problem.**

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. High electrical voltages are present within this device. Removing covers could lead to serious personal injuries.**
- **Ensure that no objects, for example, necklaces, paperclips, or liquids can get into the interior of the device (electrical shock, short circuit).**
- **To ensure patient safety, the conductive parts of the ECG electrodes (including associated connectors) and other patient-applied parts, should not contact other conductive parts, including earth ground, at any time.**
- **Use of defibrillator can cause patient injury (burn) and destroying the ECG unit. Follow the instructions in the operator manual of the defibrillator before using it.**

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 Gantry, it will cause a short-circuit or even a system breakdown.**
- **To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.**
- **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.**
- **Do not connect electric devices to the CT System that are not approved by Neusoft. Do not connect additional extension cords or outlet strips. It may create increased electrical leakage current and there is possibility of electric shock.**
- **The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users' authority to operate the equipment.**
- **Note that some external powered equipment may only be connected by a single cable to Neusoft equipment (for example, a network hub). A separation device is required for equipment that is powered by a different power source.**
- **When using a combination of different electronic devices on one patient, the total leakage current may exceed safety limits.**
- **Do not use more electronic devices on the patient than absolutely necessary.**
- **The total leakage current must be considered when using external**

electronic equipment and CT scanner.

- **The correct function of external devices may also be affected, such as ECG devices.**
- **Do not remove the shell or cable of the device. There is high voltage inside the equipment. Removing the shell or cable of the device may cause serious or fatal injury.**
- **Do not cut cables.**
- **Watch out for cables on the ground.**
- **Please make sure that no movement of the machine hits the cable.**
- **Visually inspect the cable before each use and contact Neusoft medical service personnel if any damage is found.**
- **Do not touch patients when cables (such as high-pressure syringes) in accessories are live.**
- **To avoid electric shock, do not touch the patient when connecting the system accessory cable.**

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 these 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.

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. 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

1. 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.

2. Prevent unauthorized equipment modification

Neusoft sells highly complex medical devices. Any modification must be in accordance with related rules and regulations and be authorized 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 128 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.

It is forbidden for ordinary users to change operating system settings or run executable programs.

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 128 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.**
- **Avoid recording on removable media which already contains clinical data.**
- **Do not remove the CD-R, CD or DVD from the recorder until the recording process has been completed and the status LED has gone out. Use the Transfer menu to eject media.**
- **Never switch off the device while writing to the device.**

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, cut off the power supplies in advance 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.

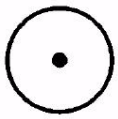
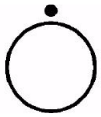
Packing materials for the device are reclaimable. They must be collected and disposed in accordance with local regulations where the machine or accessories are opened.

2.13 Expected Service Life

10 years.

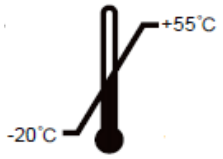
2.14 Symbols

Table 2-2 Symbols

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

Sign	Instruction
	Type BF Applied Part
	Unique Device Identification
	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.
	X-ray Emission
	Refer to the User Manual
	Model Number
	https://partner.neusoftmedical.com/ifu
	Date of manufacture

Sign	Instruction
	Manufacturer
	Reference No.
	Serial Number
	Attention! Refer to the attachment
	Large Focus (LF) Large Focus
	Small Focus (SF) Intermediate Focus
	Up
	Fragile, handle with care
	Keep dry
	No stacking

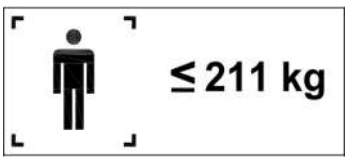
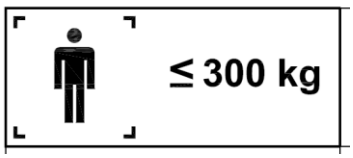
Sign	Instruction
	Temperature limitation
	Humidity limitation

2.15 Labels

2.15.1 Warning Labels

Table 2-3 Warning Labels

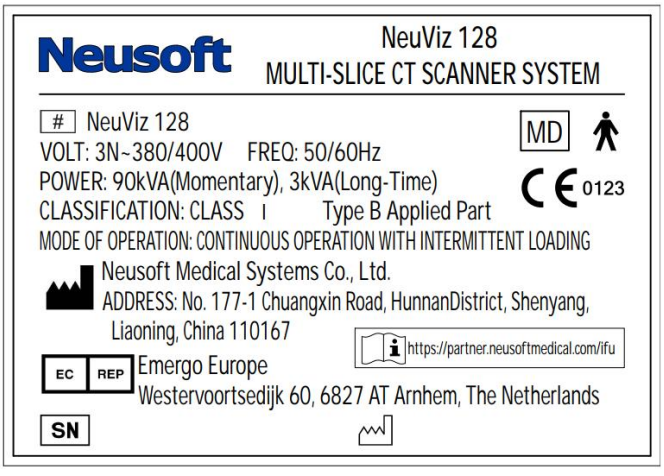
Warning Labels	Instruction	Location
	This label warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed. To be used by authorized personnel only.	This warning label is pasted near the system power switch on the gantry.
	The labels warn to protect eyes from laser radiation.	This label is pasted on the Gantry.

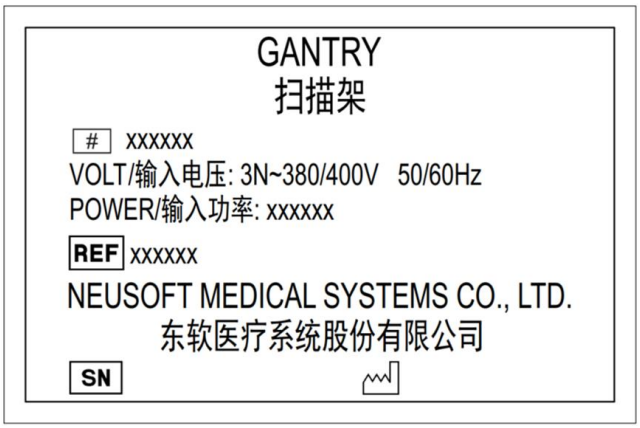
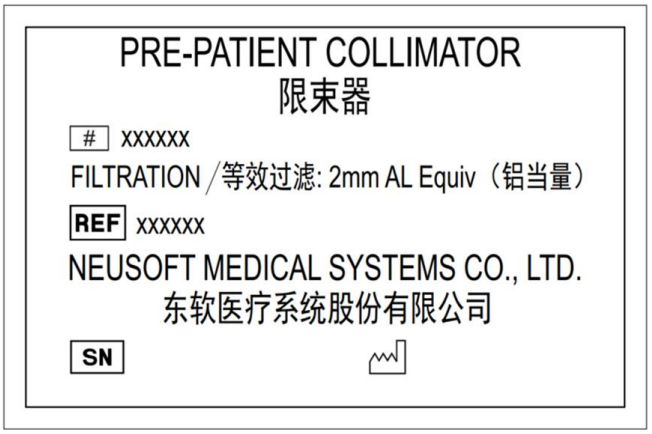
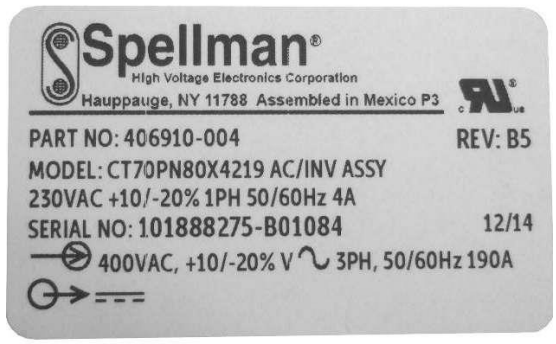
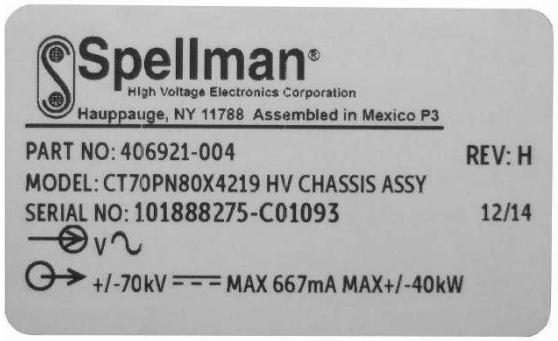
Warning Labels	Instruction	Location
	Warns of a hazard from a laser beam. The labels warn to protect eyes from laser radiation.	This label is pasted on the Gantry.
	Ionizing radiation	This label is posted on CT-Box.
	Warning, electricity	This label is posted on the Gantry and HV assembly.
	This label means that the maximum load capability of the Couch is 211kg (CT –SMC 304 standard couch and CT-SMC 305 long couch).	This label is pasted on the Couch.
	This label means that the maximum load capability of the Couch is 300kg (300kg couch).	This label is pasted on the Couch.
	The label warns to watch your hand.	This label is pasted on the Couch.

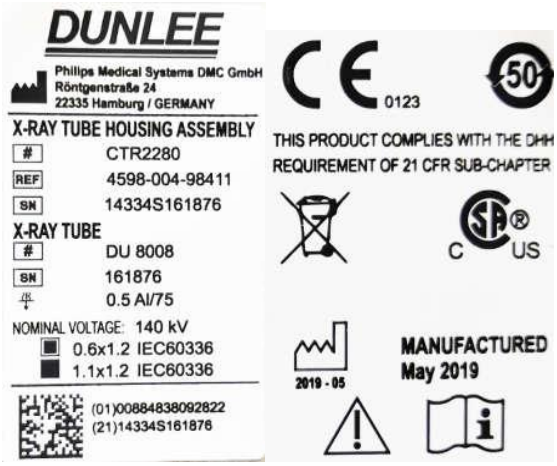
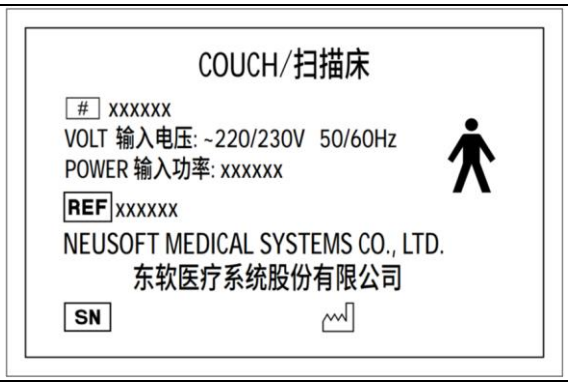
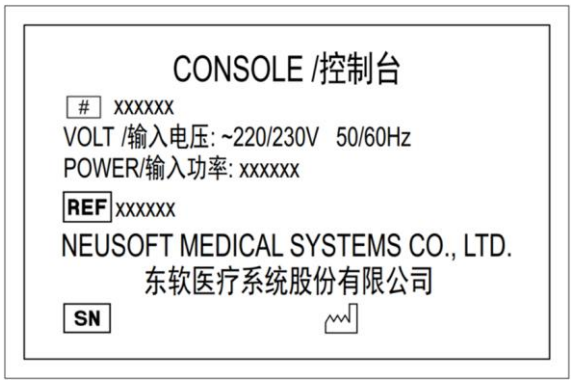
Warning Labels	Instruction	Location
	The label warns to watch your foot.	This label is pasted on the Couch.
	The label warns to watch your hand. Do not grasp the side of the cradle.	This label is pasted on the Couch.
	No Sitting and Lying Label.	This label is pasted on the mobile monitor.

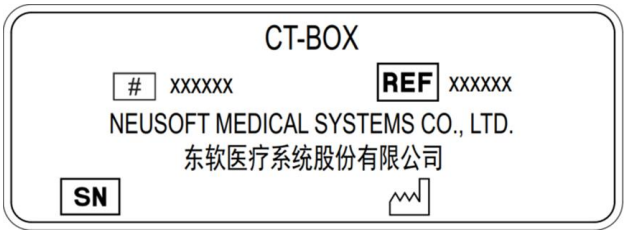
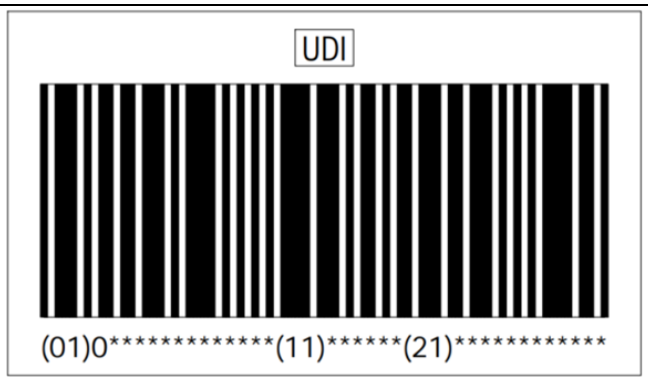
2.15.2 The Example of System Name Plates and Parts Labels

Table 2-4 The example of System Name Plates and Parts labels

Warning Labels	Instruction	Location
	System Name Plate	On the gantry

Warning Labels	Instruction	Location
	Gantry model label	On the gantry
	Collimator Label	On the Collimator
 	X-ray High Voltage Generator Label	On the HV Generator

Warning Labels	Instruction	Location
	X-RAY TUBE Housing Assembly Label	On the Tube
	Couch Label	On the Couch
	DMS Label	On the DMS
	Console Label	On the console

Warning Labels	Instruction	Location
	CT-Box Label	On the CT-Box
	Mobile Monitor Labe	On the Mobile Monitor
	Intelligent Positioning Device	On the Intelligent Positioning Device
	UDI Label	On the Ganty

NOTE:

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

2.16 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:

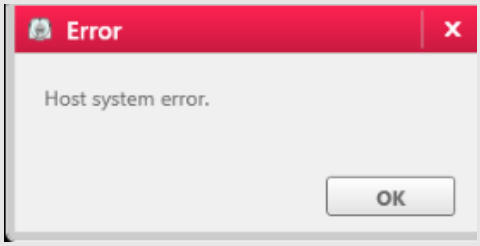
1. Check the message in message center
2. Refer to the following messages and actions table.
3. Try to carry out the possible actions in order.

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 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.
 Message: Tube or HV Arc.	1. HV error. 2. 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 and gantry
Couch code out of range (<0) Console parameter error, restart console software.	Console software error	Restart console

Messages	Possible Cause	Possible Action
The door is open, cannot expose.	1.Door of Scan room is open 2.Door switch error	1. Check the door of scan room 2. Check the switch of the door
Start scan time out, restart scan.	Scan parameter error	Restart the software
Scan parameters error, restart scan.	Console software error	Restart console
Slice control parameters error, restart console.	Console software error	Restart console
Injector control error.	CT-BOX Control Board malfunction.	Reconnect CT-Box and injector
Gantry error and restart gantry.	GPC error	Restart the software and gantry.

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:

1. After patient positioning, it is available to set appropriate scan planning on the scan interface and start the scan.
2. 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.
3. 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. 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	Scanning Room	Operating Room	Equipment
Ambient Temperature	18°C to 24°C	18°C to 28°C	15°C to30°C
Relative Humidity	30% to 60%, no condensing	20% to 80%, no condensing	20% to 80%, no condensing
Atmosphere Pressure	70kPa to 106kPa		

NOTE:

- **Keep the scanning room clean and tidy because dust and corrosive air may shorten the service life of the whole system.**

3.2 System Composition

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

Table 3-2 System Composition

Item	Qty	Specification
Gantry	1	Installed in scanning room.
Couch (Pick One of Three)	1	Installed in scanner room.
Console	1	Installed in operating room.
HV Generator	1	Installed in the gantry.
X-Ray Source Module	1	Installed in the gantry.
Collimator	1	Installed in the gantry
Detector	1	Installed in the gantry.
X-Ray Tube Assembly	1	Installed in the gantry.
CT-Box	1	Installed in operating room.
Isolation Transformer (Option)	1	Installed in power distribution
Computerized Imaging Processing System	1	Installed in operating room.
Display Monitor	1	Installed in operating room.
NeuViz 128 Software	1	Installed in operating room.
Mobile Monitor(Option)	1	Installed in scanner room.
UPS (Option)	1	Installed in power distribution
Intelligent Positioning Device(Option)	1	Installed in scanner room.

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

- Laser Localizer

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, and on the right corner is tube heat capacity. Patient information is on the top, including patient name, gender, patient ID and patient age. The displayed information includes: Stand-by, Positioning, ECG and heart rate, ECG signal amplitude, Scanner Ready, Scanning and Scan Over, etc.

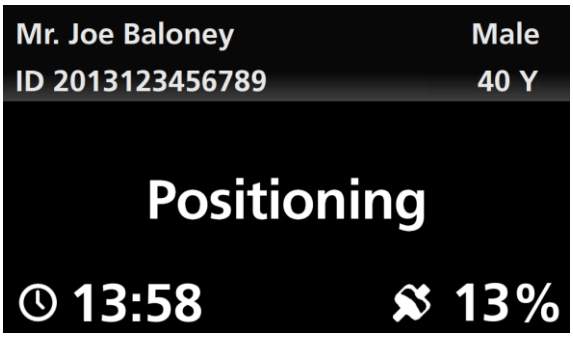


Fig 3-1 Gantry Display

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.

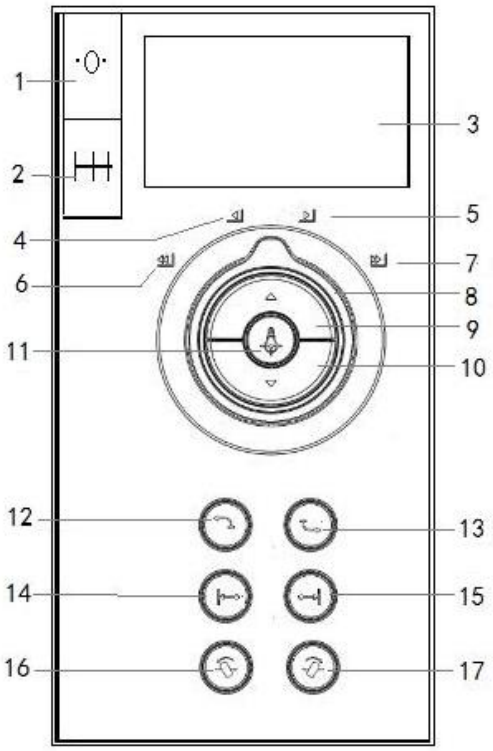


Fig 3-2 Control Panel

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 Couch position is lower than 2mm, the Couch will not move

horizontally.

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 Couch position reaches the end, the Couch will not move horizontally.
11. 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.
12. Auto Couch-in: to elevate the couch to 282mm and then move the Couch in to the horizontal maximum position and 345mm height automatically.
13. Patient Release: 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.
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.
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.**
- **The short press of Couch in and Couch out buttons can be used for precise positioning in 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 scanner.

3.2.1.4 Emergency Stop

Fig 3-4 Emergency Stop

In an emergency, please press Emergency Stop to cut the power supply for both the Gantry and the Couch (the slip ring, DMS and the fan of the tube radiator will not stop working) 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, 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 Laser Localizer(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 laser localizers, 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 laser localizers. 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.

On the interface of Plan Scan, # module is added in the dropdown menu of【Start】and【End】 when selecting axial scan. #module represents that the patient positioning

light indicates the central position of scan, while * module represents the position of the first image.
In CCT protocol, there is only # module in the dropdown menu.

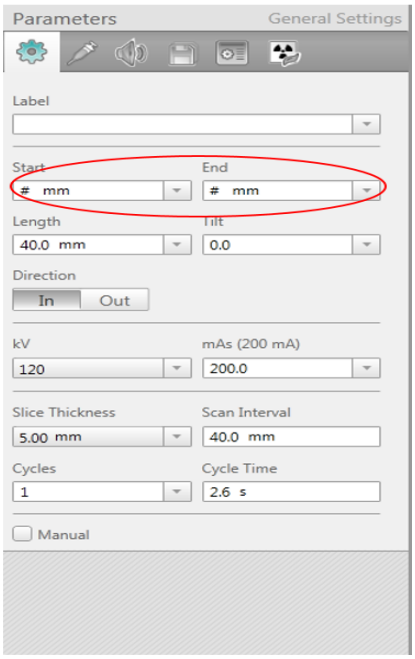


Fig 3-5 # module

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

- The precision of the internal laser localizer is ± 1mm.
- The precision of the external laser localizer is ± 1mm.

WARNING:

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

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 Laser Localizer module; however, good circulation of air near the equipment must be ensured.**
- **Damage caused by unauthorized disassembly, decomposition, modification, vandalism, and misuse to Laser Localizer is not included in the warranty.**

3.2.1.6 Breathing Navigation Panel

Fig 3-6 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 scanning 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;

- 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.

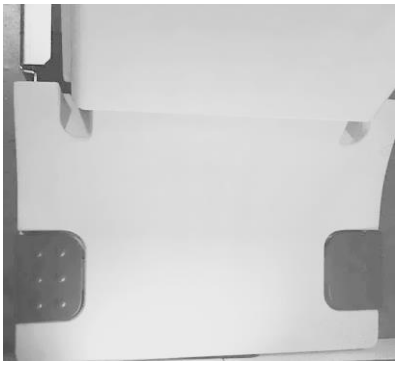


Fig 3-7 Couch-release Foot Switch

⚠

WARNING:

- **The Couch supports a maximum patient weight of 211 kg (standard couch and long couch) or 300kg (300kg couch).**
- **Do not step on the bottom cover of the couch.**

NOTE:

- **The table pads are composed of polyurethane(PU) and polyethylene(PE) materials. Head rest cushion, Neck vertebra cushion, Coronal chin cushion and Knee cushion etc. are composed of polyethylene(PE) and polypropylene(PP) materials. Table pads and accessories are made of materials that 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.

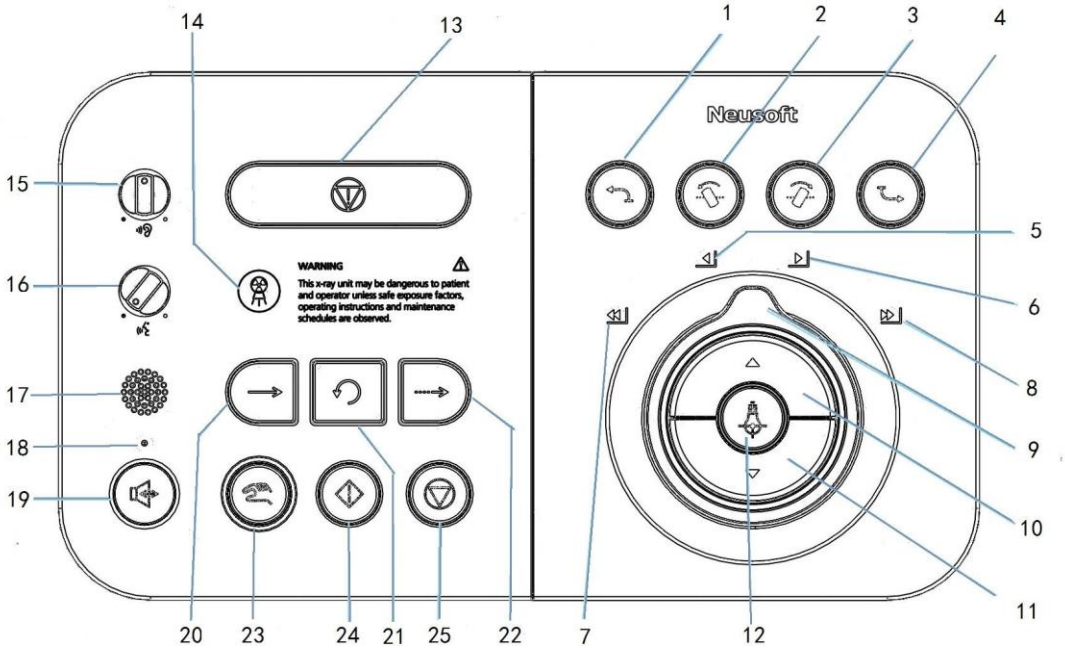


Fig 3-8 CTBox-1

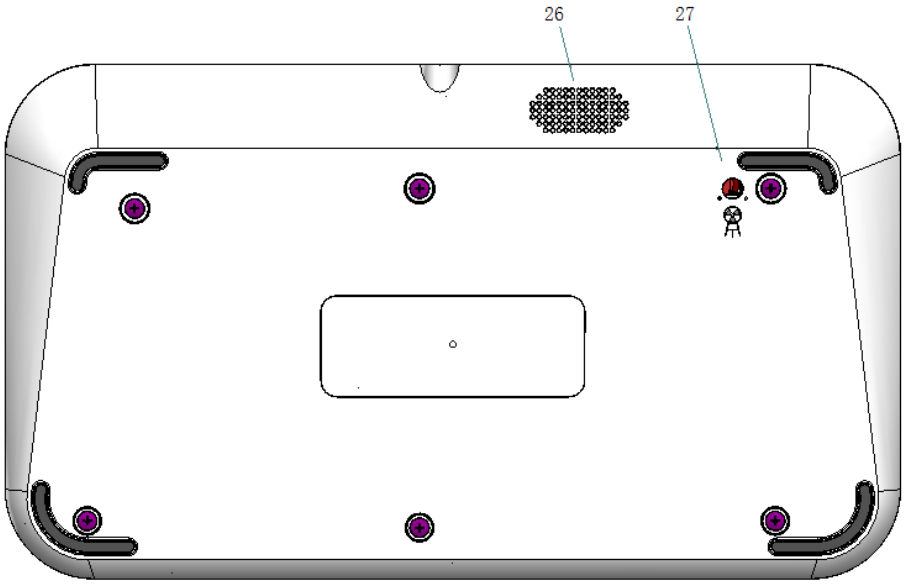


Fig 3-9 CTBox-2

Table 3-3 CT-Box Button List

No.	Name	Description
1	Auto Couch-in	To elevate the couch to 282mm and then move the Couch in to the horizontal maximum position and 345 mm height automatically.

No.	Name	Description
2	Tilt+	Press to tilt the Gantry away from the Couch.
3	Tilt -	Press to tilt the Gantry towards the Couch.
4	Patient Release	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.
10	Couch-up	Press to elevate the Couch.
11	Couch-down	Press to lower the Couch.
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 scanning room.
16	Listen Volume Controls	To set volume so that the voice from the scanning room can be heard.

No.	Name	Description
17	Microphone	To broadcast your voice into the scanning room.
18	Microphone Light	To indicate that the Microphone is ON or OFF.
19	Intercom Switch	Press to talk to the patient in scanning room. Otherwise, the voice from scanning room can be heard.
20	Scan next series	Press to scan next series. It's available when it turns green. Otherwise, it is OFF.
21	Repeat Last Series	Press to Repeat (Without scan) the previously scanned series. It's available when it turns green. Otherwise, it is OFF.
22	Continue Current	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.
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 scanning room.
27	Radiation Volume Controls	On the back of CT-BOX, to adjust radiation warning volume.

3.2.4 X-ray Source Module

The X-ray generator consists of X-ray tube assembly and high voltage generator. X-ray tube is actuated by high voltage to produce X-ray. The X-ray tube assembly consists of X-ray tube, X-ray tube housing assembly and insulating oil to provide necessary X-ray for scans.

3.2.5 Collimator

Collimator is a component of X-ray source module. Based on the scanning part, it sets limits to the range of X-ray irradiation in order to reduce scattered radiation and avoid unnecessary X-ray radiation for patient.

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.

- Rated Output Voltage: 220V
- Output Power Capacity: 2000VA/1400W

The CT system may be installed with a neusoft approved "partial" UPS. A partial UPS is an accessory that can provide temporary power to the control console during hospital power failures. It is not intended to support the whole system. Follow the UPS manufacturer's manual for recommended operating and servicing requirements (includes preventative maintenance, specification summaries, and troubleshooting guidance).

3.2.8 Isolation Transformer

Table 3-4 Isolation Transformer Parameters

Parameter	
Power	37KVA rated , 115KVA 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

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 Intelligent Positioning Device(Option)

With real-time detection of the human body of Intelligent Positioning, the system ca n determine the scanning position automatically according to the body position comb ined with current scanning protocol.

3.2.11 Mobile Monitor(Option)

Mobile 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.

3.3 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:

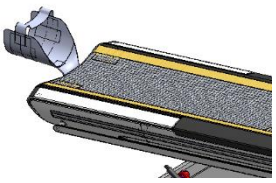
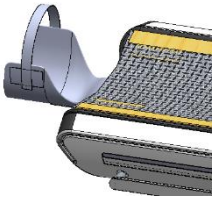
- **Do not use any positioning aids not mentioned in this section.**
- **Unauthorized Neusoft patient supports may cause danger to the patient through collisions with the Gantry. Image quality may also decrease.**
- **If a head holder or support is not engaged securely, it can become loose, causing injury to the patient.**
- **Do not hit accessory against gantry. Patient injury or equipment damage could result.**
- **Accessory may fall and cause injury if not fully inserted into the jack of the couch. Make sure that accessory is fully inserted into the jack of the couch.**
- **Excessive weight can break accessory and cause injury. Do not load more than 15 kg.**
- **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.**
- **When using supporting accessories or the gantry is tilting, be sure to pay**

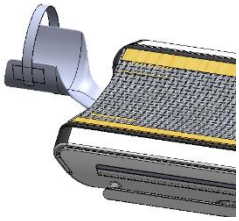
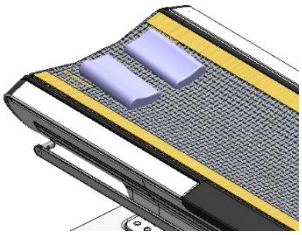
attention to the patients at any time to avoid collision with the gantry.

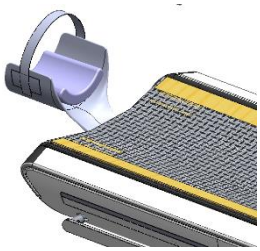
NOTE:

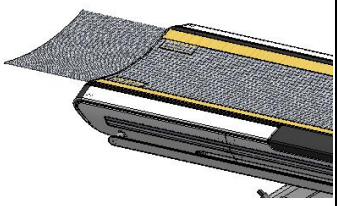
- **Patient supports are prone to wear and tear. They must be replaced with original parts if they are dirty or damaged.**
- **Configuration of the device purchased might be different from what is described in this manual. Please use the purchase contract as final configuration.**

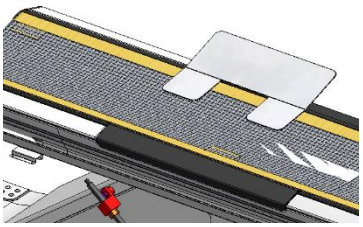
Patient Supports：

Accessories	Instructions for use	Placement
Head Holder 	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.	Insert the head holder into the jack at the front of the couch. 
Coronal Head Holder 	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.	Insert the coronal head holder into the jack at the front of the couch. 

Accessories	Instructions for use	Placement
Flat Head Holder 	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.	Insert the flat head holder into the jack at the front of the couch. 
Head Rest Cushion 	For patient comfort.	Place in the Head Holder
Head Side Cushions (Large, Medium and small) 	For patient comfort.	Place on the couch. 
Coronal Chin Pad 	For patient comfort.	Place in the Coronal Head Holder.

Accessories	Instructions for use	Placement
Neck Vertebra Cushion 	For patient comfort	Place on the couch.
Flat Head Rest Cushion 	For patient comfort.	Place in the Flat Head Holder 
Knee Cushion 	For patient comfort.	Place on the couch.
Table Pad 	For patient comfort.	Place on the couch.

Accessories	Instructions for use	Placement
Table Top Extension Board 	It is used for feet-first positioning of the patient. Examination up to the region of the thoracic spine is possible.	Insert the table top extension board into the jack at the front of the couch. 
Table Extension Pad 	For patient comfort.	Place on the Table Top Extension Board.
Infant Cradle 	For baby's support and immobilization.	According to specific needs, place on the couch.
Head Arm Holder 	To rest arms comfortably above the head.	Place on the couch.

Accessories	Instructions for use	Placement
Arm Support 	To support patient's arm during transfusion.	Place on the couch. 
Table Top Handle 	To aid in table movement.	Place on velcro on the couch.
Patient straps 	Patient restraints.	Place on the couch.
Chin Strap 	Patient restraints.	Place on the Head Holder.

Accessories	Instructions for use	Placement
Table Pad Cover 	It is convenient to wipe and to keep the couch and table pad clean without frequent replacement. It can replace the disposable sheet.	Place on the couch and table pad.

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 Phantom Accessories

- **7-10 inch tower phantom**: the module can be used to revise the CT device to make images even, no artifacts and obtain accurate CT value.
- **Ladder phantom**: the 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 phantom（Option）**: it consists of head module and body module to evaluate the imaging performances including impulse response, slice thickness, linear CT value, CT value uniformity, noise.

3.5 Key Technical Data

Table 3-5 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,571mA
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.	667mA,120kV
The corresponding combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which results in the highest electric output power.	120kV,667mA
The NOMINAL ELECTRIC POWER given as the highest constant electric output power in kilowatts which the HIGH-VOLTAGE GENE RATOR can deliver, for a LOADING TIME of 4s at an X-RAY TUBE VOLTAGE of 120kV.	120kV,667mA,4s,80kW

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 around the clock. 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 Startup

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

To start up the system:

1. Turn on the isolation transformer. (Option)
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 128 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.

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 of the anode, click 'Yes'.**
- **Do not shut down the console computer until logging out of the software.**
- **Wait until the tube heat capacity is lower than 25% before turning off the Power Switch on the Gantry.**
- **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 128.**
- **Save data before shutting down or restarting the system.**

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 capacity is lower than 10%, 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 scanning room.
2. Ensure the scanning 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.

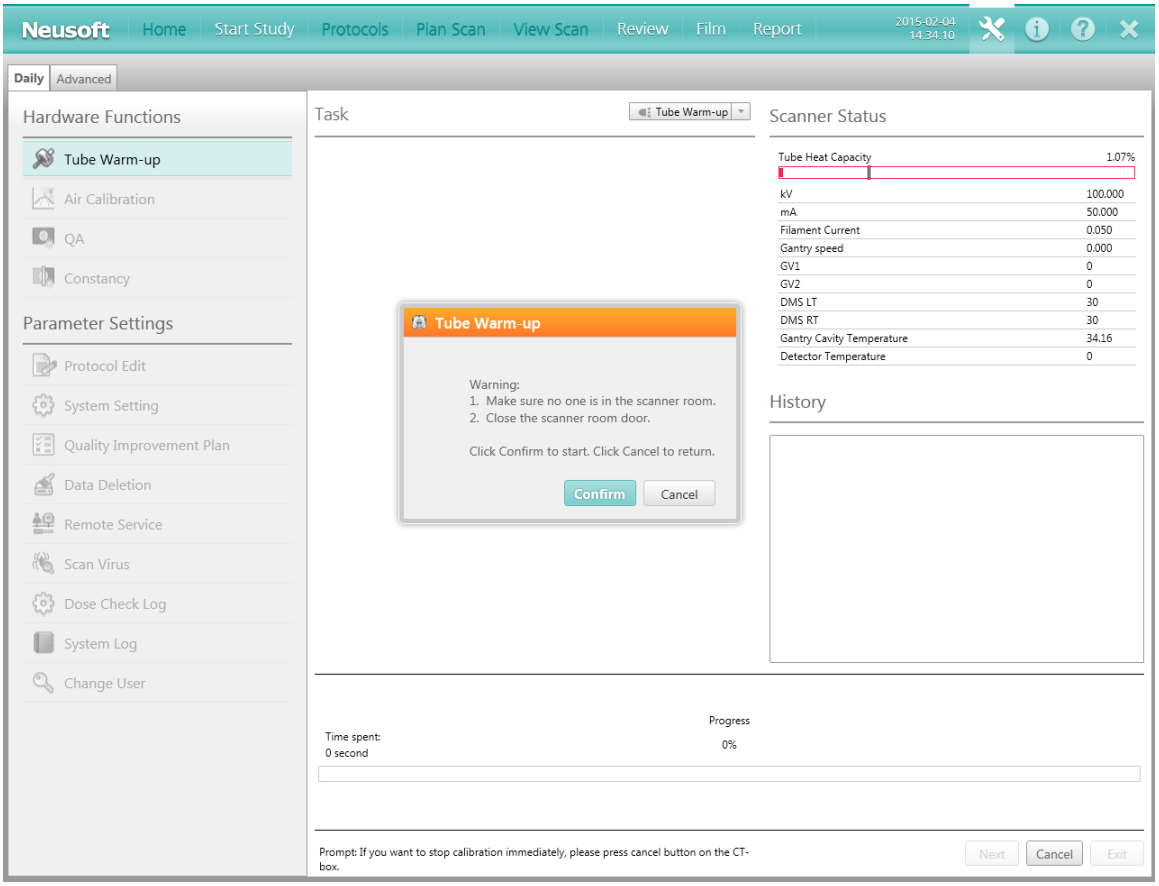


Fig 4-1 Tube Warm Up Interface

5. Perform the operations following the prompts. After the process completes, the tube heat would be equal to the value set in **System Setting**, and a message "Tube warm-up completed" appears.

To set the target tube heat of tube warm-up:

1. Select **Service** on the workflow bar.
2. Click **System Setting**.

   The **System Setting** list appears.

3. Select **Scan Miscellaneous Setting** in the list.
4. Select the checkbox Set Tube Heat.

5. Edit the value in the textbox right beside Set Tube Heat.
6. The new tube heat will take effect after restarting the system.

WARNING:

- **Do not perform Tube Warm Up when there is a person in the scanning room.**
- **If the tube heat capacity is lower than 10%, perform Tube Warm Up before the next scan.**

4.4 Air Calibration

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. Since 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 air calibration:

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

Air Calibration interface appears.

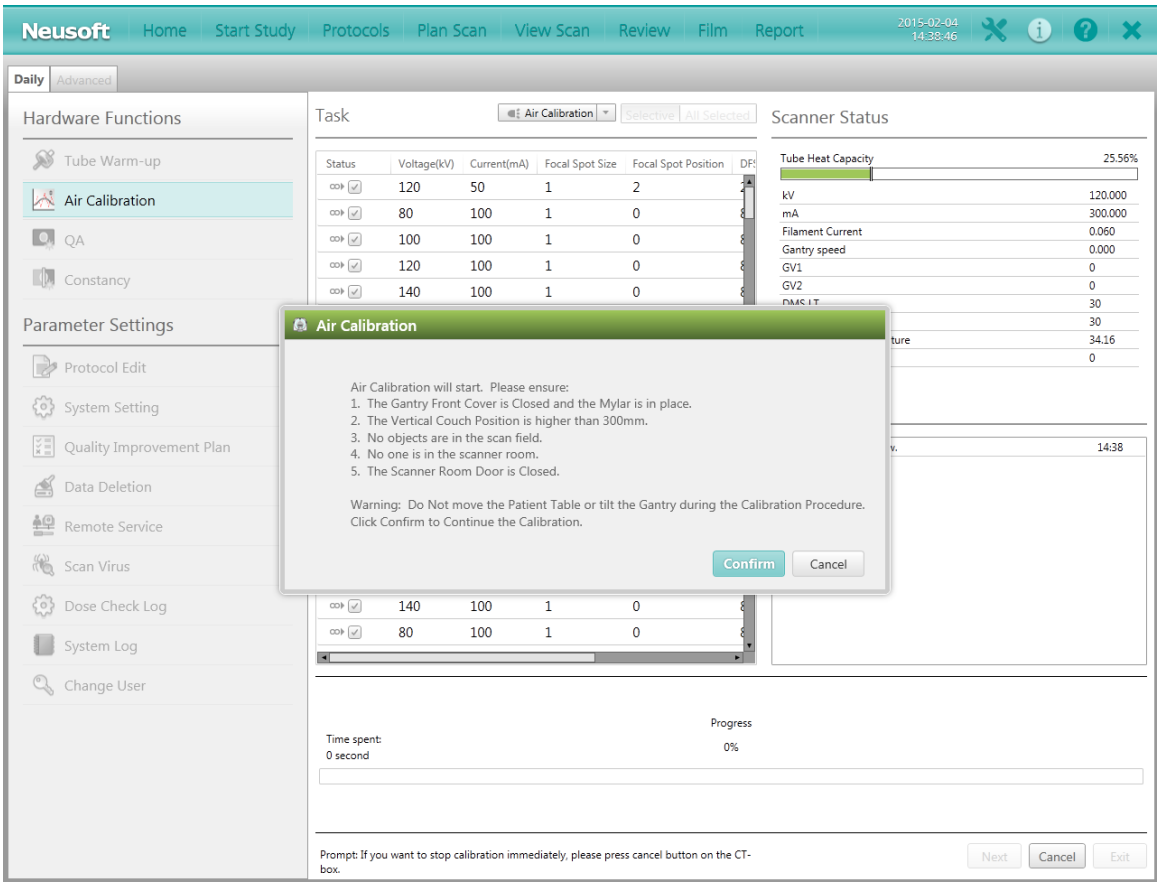


Fig 4-2 Air Calibration

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.

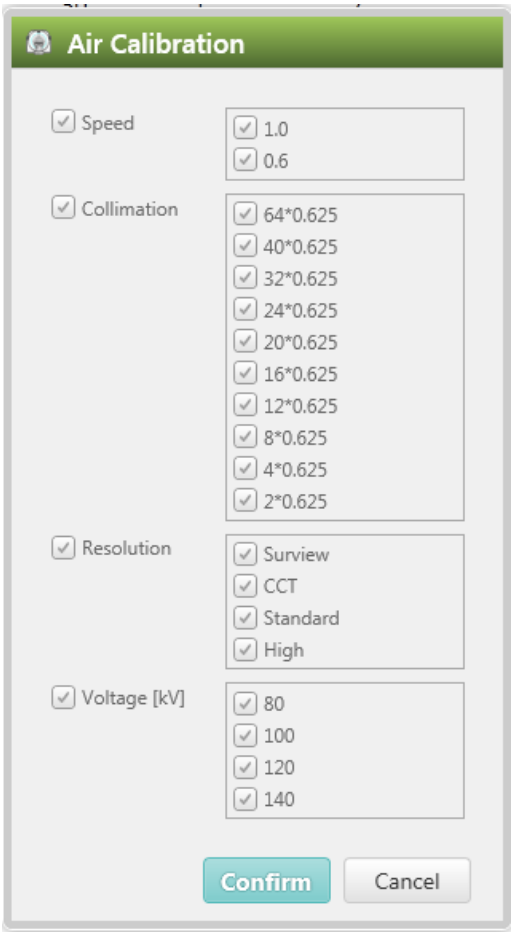


Fig 4-3 Selective Parameters

7. Click **Confirm**.

8. Click **Stop** to stop the calibration if necessary. You may select to continue the last calibration when click **Air Calibration** begins again.

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

WARNING:

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

NOTE:

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

4.5 Patient Positioning

Press relevant buttons on the Gantry control panels to move the Couch, switch on/off the laser localizer and tilt the Gantry.

The maximum patient weight that the Couch can support is 211kg (standard couch and long couch) or 300kg (300kg couch).

- 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.**

CAUTION:

- **If the patient is repositioned without changing position Settings, bilateral markers will be incorrect. This case can cause diagnosis and treatment basis error. Correct patient's position while relocating patient.**

4.5.1 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.**

4.5.2 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, each time 1 mm closer; Press Couch out to move the Couch away from the Gantry, each time 1 mm away from the gantry.
- 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.**

CAUTION:

- **Always keep an eye on client while the bed is moving. Stop scanning in time when the checking bed is found to move in the wrong direction.**

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 help to realize auto-control of positioning the patient horizontally and the tilting angle.

1. 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.

2. Adjust the Couch position manually if necessary.
3. Release Enable to stop movement immediately.
4. 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.**

4.5.3 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.

4.5.4 Emergency Patient Release

Press the emergency patient release button to float the couch top. Then drag the couch top to release the patient fast from the Gantry.

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:

1. Take away the head support or pillow to lower the head position.
2. Move the Couch extension.
3. 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. Be sure to prevent the Couch from any movement.**

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.

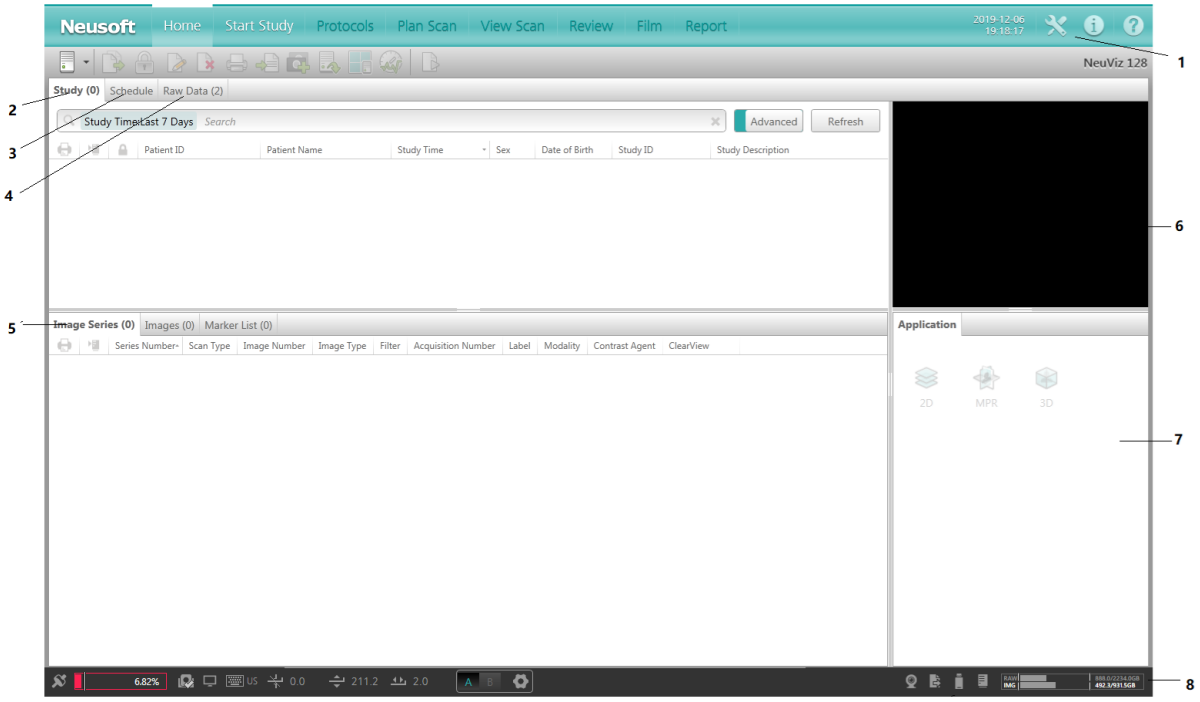


Fig 5-1 Home Interface

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. 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 Product Information, the Operation Manual and Help.

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, Gender, 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.**
- **Use of paper printouts for diagnosis! Wrong diagnosis caused by wrong image information. Only use images on film for diagnostic purpose.**

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.

NOTE:

- **Wrong diagnosis caused by wrong image information.**

7. **Report**: To send the selected images to the report interface.
8. **Combine**: To generate combined series and decrease the image quantity.

If the operation is successful, the newly generated image sequence information will be displayed in the image series list.

9. **Export Raw Data**: To export raw data to local disk, USB disk or DVD.
10. **Offline Reconstruction:** Use this procedure to reconstruct raw data. See detailed introduction in Chapter 6 about **Recon.**
11. **Perform Air Calibration**: Perform air calibration if the quality of the image is not good.
12. **Start New Study**: To start a new scan process.

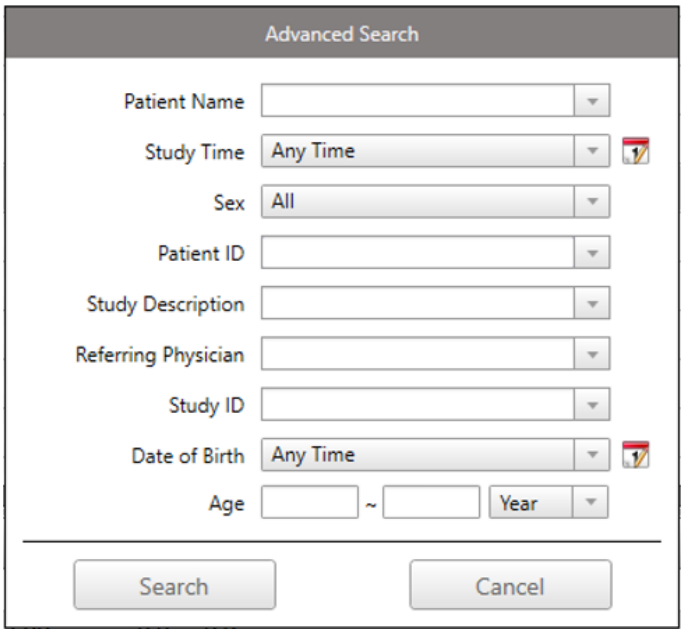


Fig 5-4 Advanced Search

Advanced Search: Click Advanced Search window and patient's information can be searched by Name, Study Time, Patient ID, Age, Date of Birth 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, Gender, Description, etc. Type in the specific icon or letter to filter the result 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 will be displayed on the Patient Information List, if a patient sequence has been printed.

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.

The patient list in the Home supports showing and hiding the setting column. Right-click in the header position of the patient list, and the "Column Settings"

menu item will pop up, as shown in the following figure:

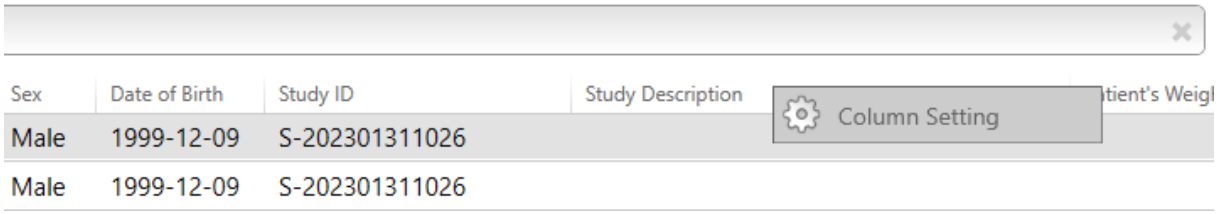


Fig 5-5 Column Setting

Click "Column Settings" to pop up the column settings window in the center of the screen, as shown in the following figure. Hidden columns on the left indicates which columns are hidden, and Show columns on the right indicates which columns are displayed, and all columns are displayed by default. After button 1 is clicked, move the items in the hidden column to the display column; After button 2 is clicked, the items in the displayed column are moved to the hidden column; After button 3 is clicked, the changes take effect immediately; After button 4 is clicked, the changes are invalid and the content is not saved.

NOTE:

- **In the column settings window, patient names and examination times are not allowed to move from "Visible Columns" to "Hidden Columns".**

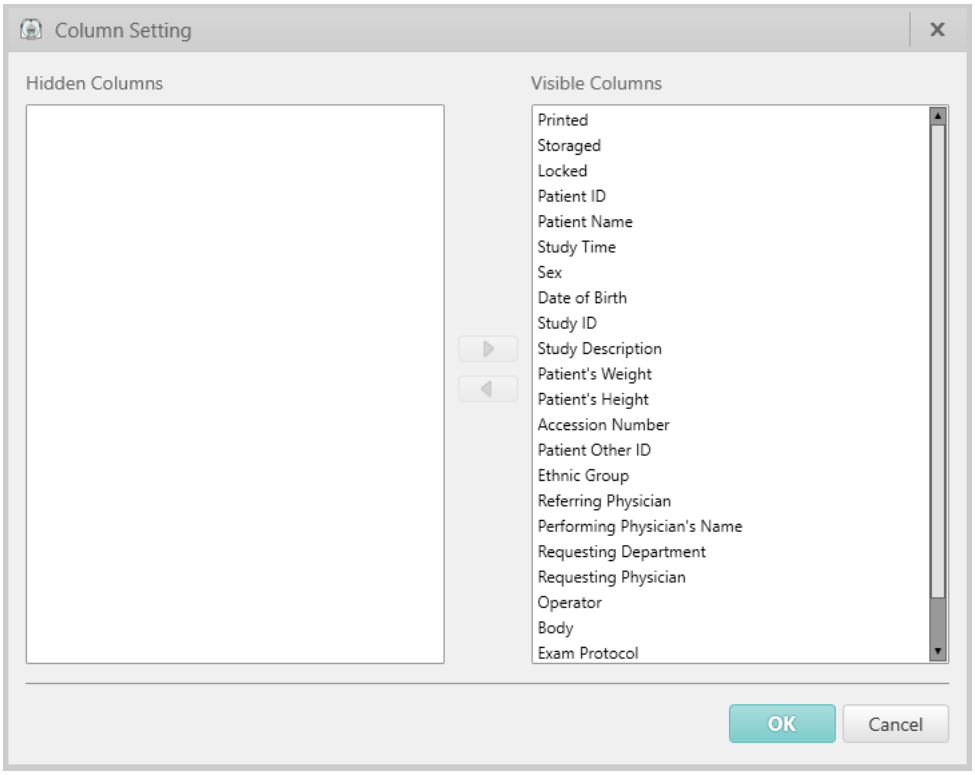


Fig 5-6 Column Setting

The sending mark will be displayed on the Patient Information List, if a patient

sequence has been sent to Report.

5.4 Schedule

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

Fig 5-7 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.

5.5 Raw Data

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

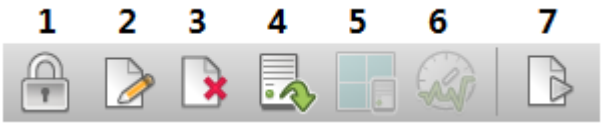


Fig 5-8 Data Tool Bar

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 lists 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 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.

Raw data: Displays the raw data information.

NOTE:

- **Do not attempt to change the information which is retrieved from HIS/RIS. The function is only available for manually inputted information.**
- **【Copy to】,【Delete】and【Export Raw Data】can be applied to one image sequence or several image sequences, but surview sequence or unfinished sequence cannot be deleted.**
- **The Image list adds【Copy to】function, which has already been applied to Image Series list. After Selecting the image, right-click to choose 【Copy**

to】,then the 【Copy to】window will pop up. It supports selecting Local Devices and Remote Devices simultaneously.

- **After finishing the【Copy to】process, the number of images can be viewed in Send Queue Manager.**

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.

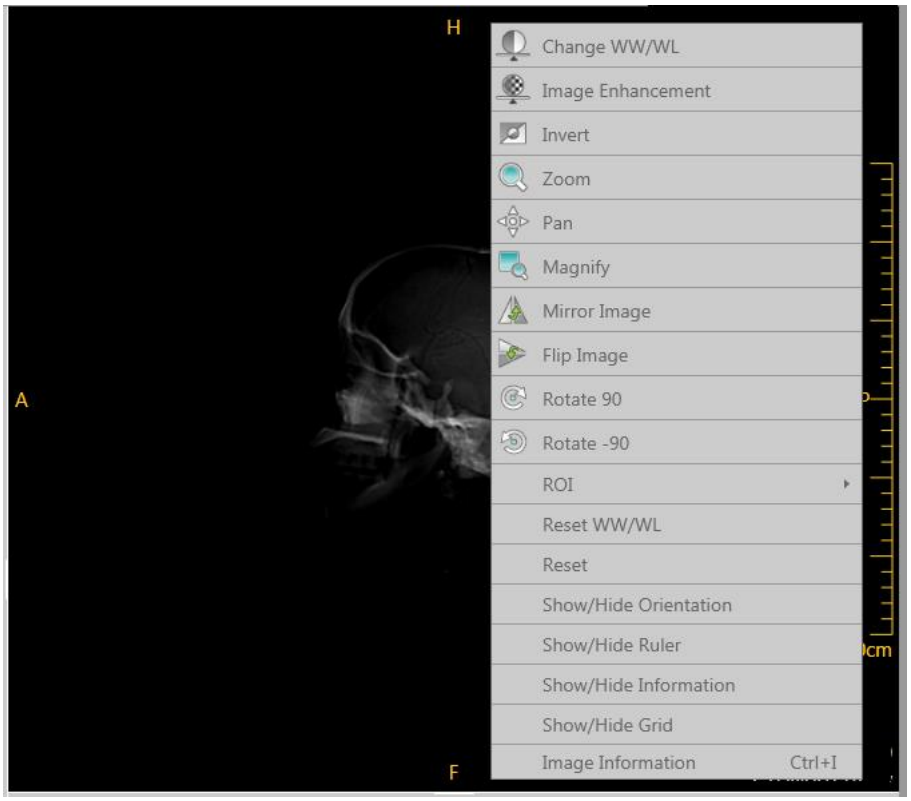


Fig 5-9 Context Menu

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 DicomViewer

The DicomViewer software allows users to view Dicom images. Users can use this software to view and process images, without having to install the software.

5.8.1 DicomViewer Interface

Fig 5-10 DicomViewer Interface

5.8.2 Navigation Bar

Click the different menus on the navigation bar to perform the corresponding operations on Dicom images.

Fig 5-11 Navigation Bar

5.8.2.1 File

Click **File** to bring up the menu options shown below:

Fig 5-12 File

Open

Click **Open** to bring up a menu with different open method options. These options allow users to load a specified DicomDir file or Dicom files into the application.

Save As

Click **Save As** to save the shown images to the specified path as a .jpg or .bmp file. Users can also save frame image as an .avi file.

Exit

Click **Exit** to exit the DicomViewer application. The homepage will automatically close.

5.8.2.2 View

Click **View** to bring up the menu options shown below:

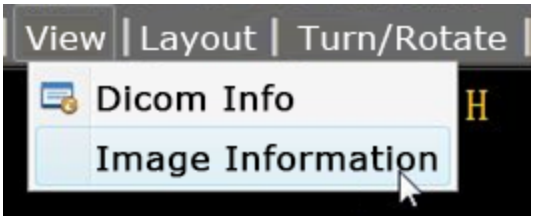


Fig 5-13 View

Dicom Info

Click **Dicom Info** to show the Dicom information window of the image.

Image Information

Click Image Information to show/hide the image information on images.

5.8.2.3 Layout

Click **Layout** to bring up the menu options shown below:

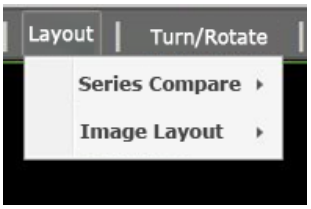


Fig 5-14 Layout

Series Compare

After loading image series, images are displayed as tiles. Each image series is sorted one by one.

Users can switch between the layouts: 1x1, 1x2, 1x3, 2x1, and 2x2 to compare the series.

Image layout

Users can switch between the image layouts: 1x1, 2x2, 3x3, and 4x4.

5.8.2.4 Turn/Rotate

Click **Turn/Rotate** to bring up the menu options shown below:

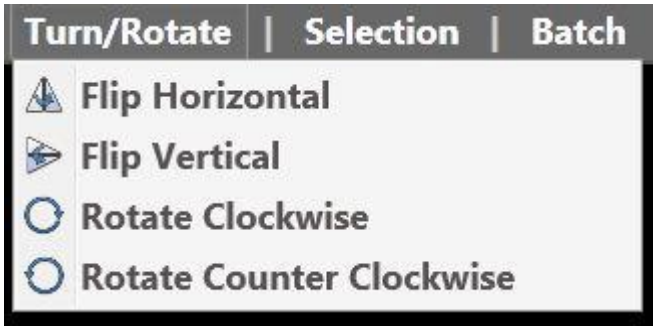


Fig 5-15 Turn/Rotate

Flip Horizontal: Horizontally flips the images.

Flip Vertical: Vertically flips the images.

Rotate Clockwise: Rotates the images clockwise.

Rotate Counter Clockwise: Rotates the images counter clockwise.

5.8.2.5 Selection

Click **Selection** to bring up the menu options shown below:

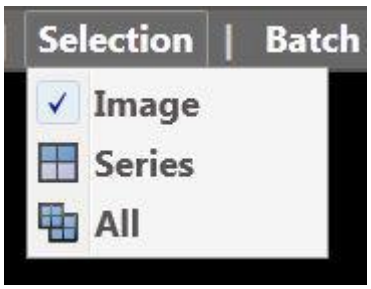


Fig 5-16 Selection

Image: Selects a single image, allowing users to view, zoom, pan the image, and change the window width and level of the image.

Series: Selects an image series, allowing users to view, zoom, pan the images, and change the window width and level of the images.

All: Selects all images, allowing users to view, zoom, pan the image, and change the window width and level of the images.

5.8.2.6 Batch

Click **Batch** to bring up the menu options shown below:

Fig 5-17 Batch

Select

Click **Select** to perform batch setting operations:

Start Point: Defines the start image in the batch.

End Point: Defines the end image in the batch.

All: Defines all images in the batch.

Clear: Clears all defined batch images.

Play

Click **Play** to configure batch play settings: Users can view images in forward or backward playback mode. In addition, users can pause playback and adjust the playback speed.

5.8.2.7 Help

Click **Help** to bring up the menu below:

Fig 5-18 Help

5.8.2.8 Common Tools

Refer to See details in user manual volume Two **Chapter 1.7.3 Common Tools** for more information regarding the tool functions.

5.9 Application

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

5.10 Status Bar

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

Fig 5-19 Status Bar

1. **Tube State**：When the tube heat is too low, it will pop up a prompt to warm up the tube.
2. **Heat Capacity:** Displays current tube heat capacity. It will prompt user to warm up tube in case heat capacity is too low.
3. **Gantry Connection State:** To display current gantry connection state, including normal state, warning state, error state and off-line state.
4. **Remote Service Request:** To feedback question description, contact number and email to the service platform.
5. **Input Method:** To display current input method, users can change input method by clicking it.
6. **Gantry Couch Height, Couch Code:** To show the gantry couch height, couch code.
7. **Couch Height A/B Setting:** To switch the couch height A/B setting, and set A or B to the default.

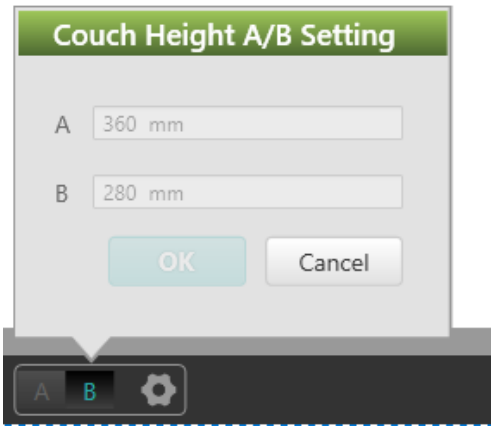


Fig 5-20 Couch Height A/B Setting

8. **Intelligent Positioning Monitor:** Clicking on the icon, the interface of the intelligent positioning camera will pop up. When the displayed interface is Scan Plan and Setting, click this icon will not pop up the same interface as above.

9. **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.

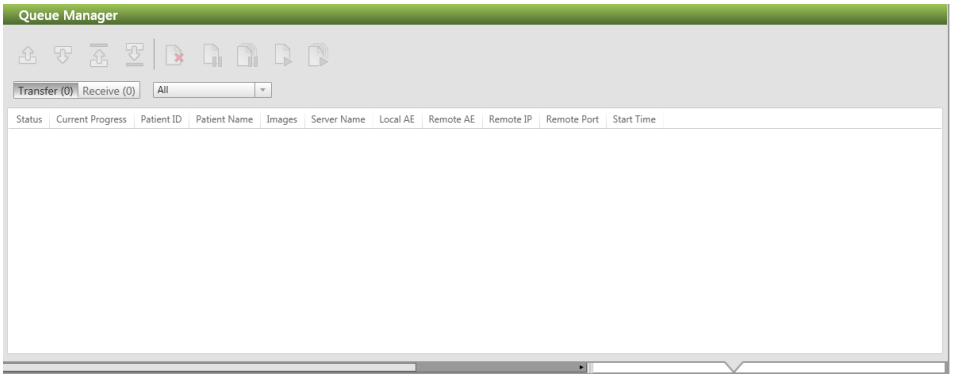


Fig 5-21 Queue Manager

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: Unfinished, Failed and Finished.

Unfinished: Include start, pause, waiting and failed status.

Failed: Include failed status.

Finished: Include finish status.

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.

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

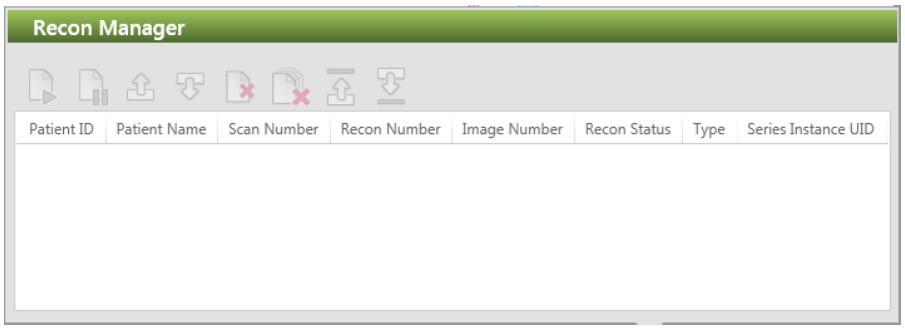


Fig 5-22 Recon Manager

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

12. **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 screen. Couch movement is controlled by the CT-Box outside of the scanning room or the Gantry control panels inside of the scanning room. This section provides detailed steps to complete a typical exam procedure, as well as descriptions of the available options.

WARNING:

- **Before beginning a CT scan, a surview is used to determine if implanted or externally worn electronic medical devices are present and 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.**
  - **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**

CAUTION:

- **Incorrect measurement values due to the projection technique used. Only perform distance measurements in the surview in the longitudinal direction (head-foot direction). Do not perform angle measurements.**
- **CT image reconstruction is in an orientation viewing from the patient's feet. The reconstructed orientation is the orientation the image is installed in the image data base and is the orientation images are networked with to a remote viewing station.**
- **Results can be evaluated and displayed imprecisely due to factors such as display size, rounding error, sub-pixel accuracy, and scaling. Please only perform measurements on images displayed at a 1:1 (1 display pixel = 1 capture pixel) ratio. Be aware of accuracy limitations when using calculated measurements.**

NOTE:

- **In addition to the scanning options, the options to film and conduct post-processing analysis are also available.**
- **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.**
- **If the remote assistance workplace shall be used for diagnostic purposes, ensure that all necessary regulatory and legal requirements for the monitor are fulfilled.**

6.1 Patient Information Entry

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

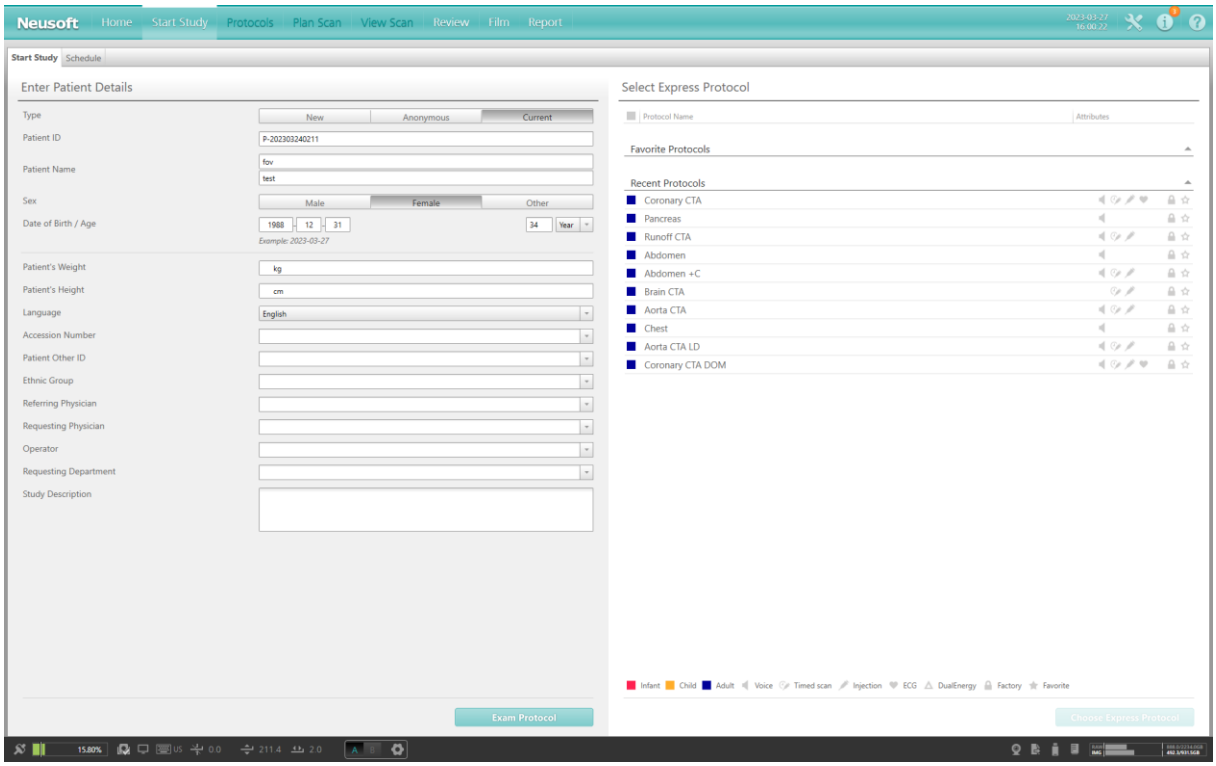


Fig 6-1 Start Study

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.

To edit the scheduled patient information

1. Select **Schedule** on the workflow bar.
2. Select the patient whose information needs to be edited in the **Scheduled** list.
3. Click the **Reschedule** button in the **Operation** area.
4. Edit the patient information in the displayed interface.

The following items such as Patient ID, Patient Name, Date of Birth, Gender, Age and Position are mandatory fields by default, which all have a red asterisk. The mandatory fields such as Date of birth and Age can be set in system setting.

After filling in【Patient's Weight】and【Patient's Height】, the BMI value will be automatically displayed following【Patient's Weight】.

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.**
- **After filling in the height and weight, the BMI value will be automatically displayed after Patient's Weight.**

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.**

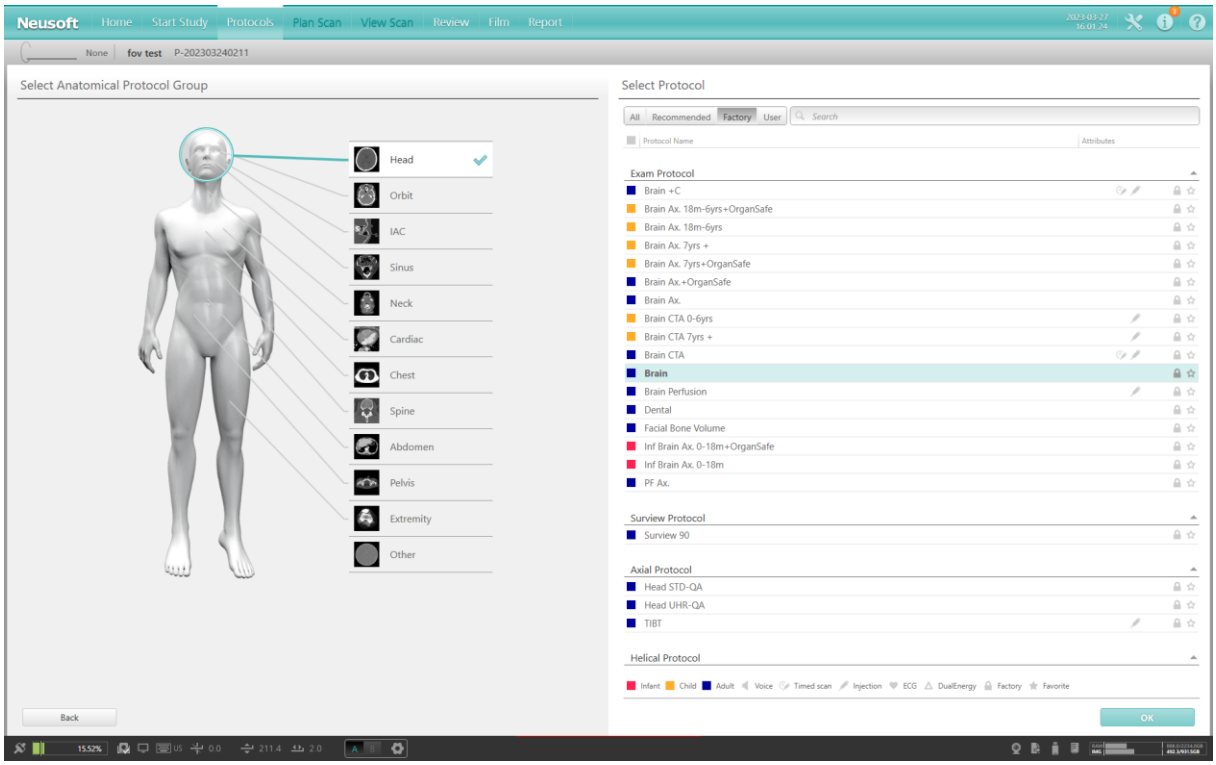


Fig 6-2 Exam Protocols

Protocol groups can be divided into head, orbit, IAC, Sinus, neck, cardiac, 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.

On the interface, the pink square represents protocols for infants, the yellow squarer represents protocols for children and the blue square represents protocols for adults.

- : To denote they are factory protocols.
- : 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 is dual energy Protocol.
- : To denote the protocol has been added in Favorite Protocol.

- ♥：To denote the protocol is a cardiac 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.**
- **In the protocol selection or protocol edit interface, select a protocol, you can use the left mouse button to drag it to any position in the current group.**
- **The sequence of protocols on both protocol selection and protocol edit interface will change at the same time.**

Click a protocol to enter the scan window.

6.2.2 Express Protocol Selection

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 protocols that users often use. 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 zone automatically.

6.2.3 Children Protocols Specification

This product strictly complies with the relevant standards of children's CT in ACR CT certification, scientifically analyzes the risks in children's CT examination, and provides corresponding measures for the risks. Therefore, this product can provide the scanning function applicable to children's examination.

The child protocol group provided for children's examination in this product includes children's head, children's chest and children's abdomen scanning protocol (see Chapter 18 for the list of factory protocol parameters). Among them, children's head protocol is divided into 0-18m, 18m-6yrs, 7yrs + according to their age; children's abdomen protocol is divided into <10kg, 10-30kg, 30-50kg, 50-70kg according to their weight.

6.2.3.1 Children's protocol design principle

1. Basic principle

In the period of early childhood, all organs have not developed well and are in the period of growth. The rate and proportion of cell division and regeneration are much higher than that of adults. Cells have a higher sensitivity to ionizing radiation, especially the eye crystal, thyroid, gonad, blood system and other organs. After being irradiated by radiation, the probability of getting cancer is greatly increased. After receiving the same dose of radiation, children's risk of cancer is much higher than that of adults, especially for children under 10 years old, and the younger the age, the higher the risk. Therefore, in children's CT scan, it has become an important concern that optimizing the scanning parameters to minimize the use of dose, while ensuring the image quality to meet the clinical demands. ALARA (as low as reasonably achievable) principle naturally becomes the basic principle in children CT scan.

2. Children's protocol design

The diagnostic dose reference value (DRL) and pass value standards in 2017 ACR CT certification are shown in table 6-1.

Table 6-1 reference value and pass value of ARC CT certification on dose

Test items	DRLs ($CTDI_{vol}$ mGy)	Pass valu ($CTDI_{vol}$ mGy)
Adult Head	75	80
Adult Abdomen	25	30
Child Head (1year old)	35	30
Child Abdomen (weight 40-50lb) 16cm phantom	15	20

Child Abdomen (weight 40-50lb) 32cm phantom	7.5	10

40~50lb is equivalent to 18.14kg~22.68kg.

1) Child Head Protocol

Referring to statistical relationship between child head circumference and age of WHO (as shown in Figure 6-3), child head CT protocol is firstly classified by age, and divided into three age groups: 0-18m, 18m-6yrs, 7yrs +.

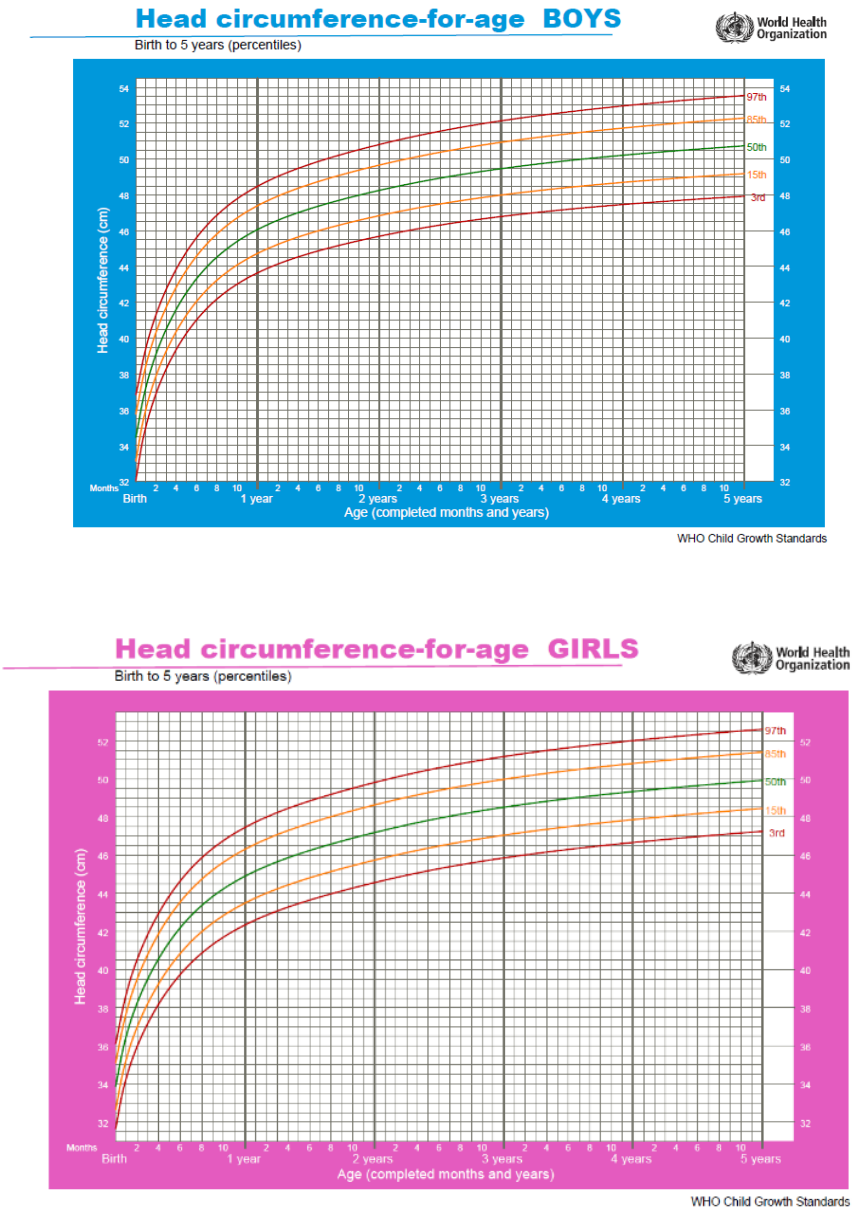


Fig 6-3 the relationship between head circumference and age of boys and girls

In child head Axial protocol, considering the relationship between child head

circumference and age, the use of dose increases with children's age in the child head axial scan protocol. Since the brain development of children in the age of 0-18m is the fastest, the protocol uses a lower dose than the other two age groups. In the case of using contrast for children's head CT scan, 0-18m and 18m-6yrs age groups are combined to form a 0-6yrs range. The dose used was 12.2mgy, which was 53% of the dose used in the axial head scan (without contrast) for children of 18m-6yrs age. In the 7yrs+ age group, the dose of 19mgy used in the contrast-enhanced scan of children's head is in line with the ART CT accreditation standard for no more than 40mGy of the head of the child. Children's head CT scanning protocol strictly complies with the children's protocol regulations in ACR CT certification.

The relationship between kV and children's age in the child head protocol (use contrast (CAT) and without contrast) is shown in Figure 6-4. It can be seen from the figure that the scanning voltage of 0-18m and 18m-6yrs is 100kV and that of 7yrs + is 120kV without using contrast (solid line). After using contrast (dotted line), the scanning voltage of 0-6yrs is reduced to 80kV and that of 7yrs + is reduced to 100kV.

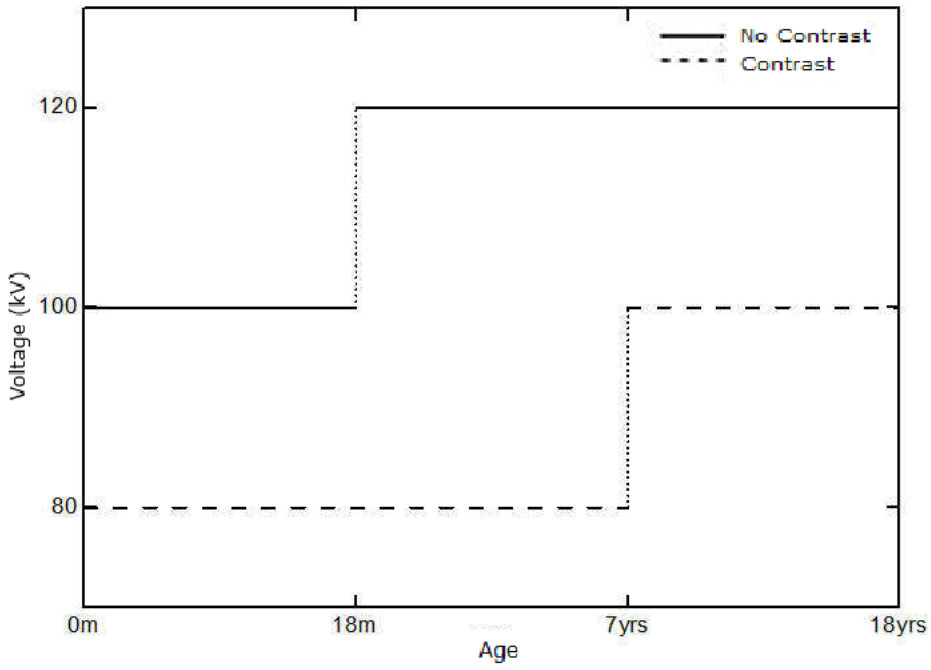


Fig 6-4 kV used in child head protocol

In order to reduce unnecessary motion artifacts when children are in a small age, this product selects a very fast scanning speed. When children are in the age of 7yrs +, the protocol uses a scanning speed of 1 seconds. In the age of 0-6yrs, the protocol uses a scanning speed of 0.8 seconds. In the case of using contrast, the whole head scanning protocol of children uses a scanning speed of 0.6 seconds. This is mainly based on the difficulty of children's clinical cooperation. In order to reduce the motion artifacts, we try to use a faster scanning speed to carry out children's head CT scanning.

For the slice thickness used in the children's head protocol, the collimator is 32 * 0.625mm in children's head axial protocol (without contrast). When using contrast agent, in contrast to the 128 * 0.625mm collimator used in adult head scan, 64 * 0.625mm collimator is selected for children, which is to reduce the invalid pre scanning dose of children in helical scanning.

2) Child Abdomen protocol

It is a common strategy to modulate radiation dose according to children's body shape, and it is also the requirement of ACR CT certification. Since the correlation between the width of children's body and children's weight is stronger than that of children's age, this product classifies the abdomen protocol according to children's weight. The child abdomen protocols are: inf Abd/Pel < 10kg, Abd/Pel 10-30kg, Abd/Pel 30-50kg, Abd/Pel 50-70kg. The protocol with the lowest dose is inf Abd/Pel < 10kg, which is 3.8mgy. The protocol with the highest dose is Abd/ Pel 50-70kg, which is 10.0mgy.The dose is increased with the weight of children.

In the children's body scanning protocol, 100kV is used for children whose weight is less than 10kg and between 10-30kg, and 120kV is used for children whose weight is more than 30kg. Small scan voltage is used for small weight children because low scan voltage will reduce radiation dose to protect children.
For children whose weight is in the range of < 10kg and 10-30kg, the scanning speed of chest and abdomen is 0.5s. For children whose weight is in the range of 30-50kg, the scanning speed of chest and abdomen is 0.6s. For children whose weight is in the range of 50-70kg, the scanning speed of chest and abdomen is 0.6s. Children's body protocol uses faster scanning speed for smaller weight children. Considering that children with small weight are generally young and have poor coordination ability, fast scanning speed is conducive to reducing children's motion artifacts.

For the slice thickness used in children's body scanning, the child body protocol uses a 64 * 0.625mm collimator, which is half the size compared with the 128 * 0.625mm collimator used in adult body scanning. This is also to reduce the invalid pre scanning dose before helical scanning, so as to protect children.

6.2.3.2 Children Protocol for Risk Response in Children’s CT Examination

Focusing on dose safety, the child protocol design follows ALARA principle to optimize the dose used in children's scanning, so as to minimize the risk for children. The methods used to reduce the dose risk are as follows:

(1) According to the relationship between children's head development and age (see Chapter 6.2.3.1 for details), this product provides different scanning protocols according to children's age, such as Brain Ax. 18m-6yrs and other protocols separately provided for children;

(2) For children's abdomen scanning, this product provides different scanning protocols according to children's weight (see Chapter 16 for details);

(3) For some key parts of children that need to be protected, this product provides corresponding Organsafe type protocol (see Chapter 16 for details);

(4) In the child protocol design, this product use low kV, low mA and contrast scientifically and reasonably (see Chapter 6.2.3.1 for details);

(5) Due to the poor cooperation ability of children in scanning inspection, high speed should be used as much as possible in children's protocol to shorten the scanning time, so as to reduce motion artifacts caused by children's improper cooperation (see Chapter 6.2.3.1 for details);

(6) Remind clinicians and radiologists to consider the necessity of CT examination for children carefully;

(7) Provide systematic training to radiologists to make them master the operation of children's examination in this product.

6.3 Plan a Scan

1. After selecting one protocol, the plan scan window appears and the **Plan Scan** button in the workflow bar will be highlighted.

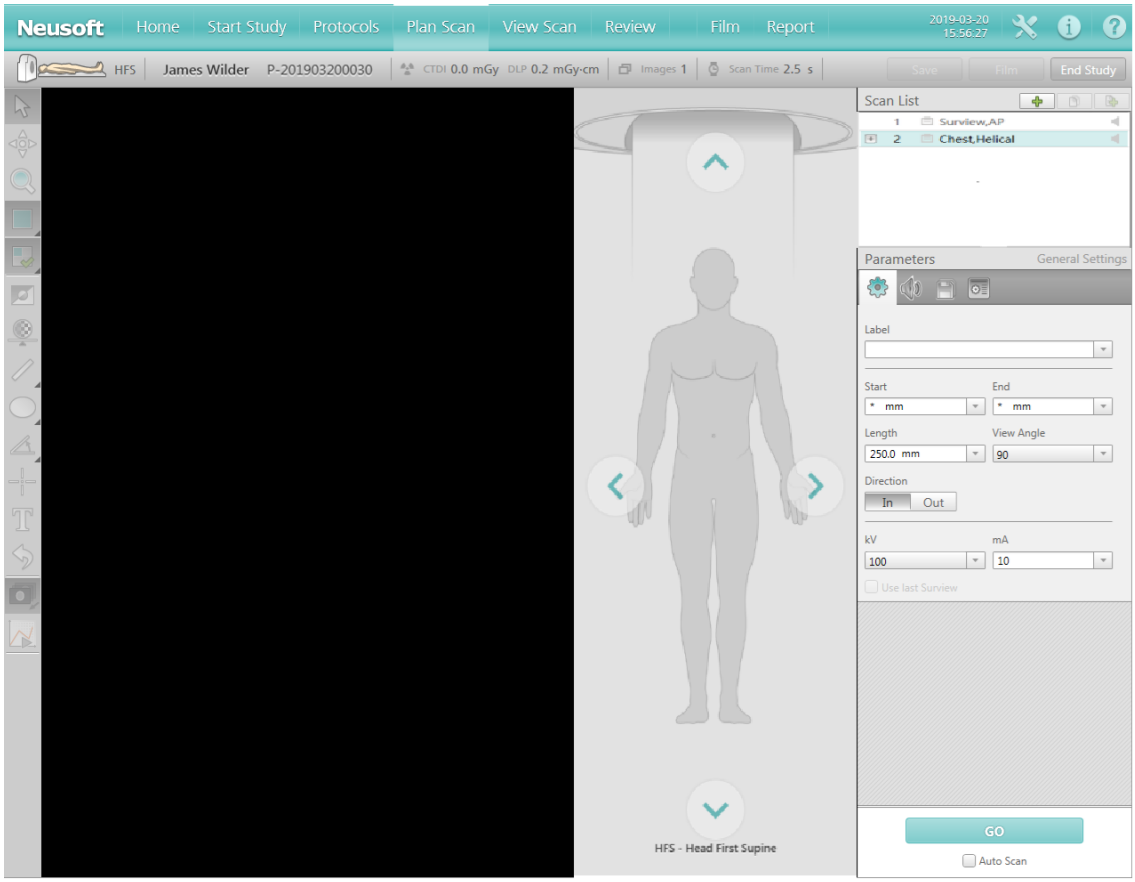


Fig 6-5 Plan Scan

2. According to needs, you can click the four arrows up, down, left and right to select the 8 patient positions, and you can also edit the protocol parameters.

3. There is an arrow button on the right of the **Go**. Click it and select **Auto Scan**, the scanner will prepare automatically between two non-timed series without clicking **Next Series**. The user only confirms the status of couch and gantry and confirm pressing Scan button.

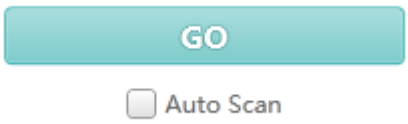


Fig 6-6 Auto Scan

6.3.1 Intelligent Positioning(Option)

The system collects and displays the natural image information of the human body. The system can use the human body image information to automatically calculates the scanning position according to the scanning protocol and using artificial intelligence technology. At the same time, User can also manually draw the scan frame on the human body Image, And Then, the system calculates the scanning position by the scan frame.

According to the scanning protocol, the system can automatically adjust the couch height from intelligence setting. The system support patient position, posture and collision Detection.

6.3.1.1 Intelligent Positioning Mode and Applicable conditions

The intelligent positioning function includes auto mode, manual mode and off mode.

The applicable conditions for auto mode:

Both of the following conditions are met:

- The protocol groups can be Head, Orbit, IAC, Sinus, Neck, Chest, Abdomen, Spine, Pelvis, Extremity and Cardiac.
- The positioning status is Head First Supine or Feet First Supine position.

The system can use auto mode and is on default. In the auto mode, the system detects the position of the human body in real-time through the intelligent positioning device, which is used to calculate the scanning position.

The applicable conditions for manual mode:

Manual mode is supported in all cases except the positioning status of patient is Decubitus Left or Decubitus Right.

The applicable conditions for off mode:

In any case, you can select the off mode. After selecting the off mode, operators can complete the patient positioning through the positioning light.

6.3.1.2 Intelligent Positioning

- **Positioning detection**

When entering the plan scan interface, the system will recognize the patient's position.

If the patient position selected by the operator is different from the patient position identified by the system, the system will prompt "The system detection positioning is xxx, which is inconsistent with the currently selected positioning, please confirm."

After adjusting and confirming the patient's position, continue with the scan.

- **Posture detection**

When entering the plan scan interface, the system will recognize the patient's posture.

After clicking Go, if the patient's posture selected by the operator is different from the patient's posture set in the protocol, the system will prompt "The target posture is xxx, please guide the patient to make posture adjustment".

After adjusting and confirming the patient's posture, then continue the scan.

For the scanning posture settings of patients in the protocol, please refer to the 11.1 protocol edit section.

- **Collision detection**

When entering the plan scan interface, the system will automatically recognize the patient's position.

If the patient's body may collide with the gantry, the system will indicate that "the current patient's posture may collide with the gantry, please adjust accordingly", and the area of the possible collision will be displayed in red.

NOTE:

- **The effectiveness of position detection, posture detection and collision detection is affected by factors such as blankets covering the patient's body, obstruction of the intelligent positioning view by people or devices around or above the patient, strong light, and the presence of highly reflective surfaces. The operator cannot fully rely on these detection functions, and should always observe the patient's status or positioning, and make adjustments if necessary.**
- **Ensure that there is no indication of the incorrect patient in an incorrect positioning or posture before moving the couch. If the patient's positioning or posture is incorrect, please adjust accordingly as needed.**

CAUTION:

- **Please ensure there is no prompt that the patinet's gesture collide with the gantry before the couch moves. If there is a potential collision risk, adjust the patient's gesture as needed to eliminate such situation. The operator cannot completely reply on the collision detection function, and should always observe the patient status to avoid collision.**
- **During the movement of the couch, it is important to continuously observe whether the patient may collide with the gantry due to the movement, or whether it will cause damage to the equipment connected to the patient (e.g. intravenous syringe, ECG gating), etc.**
- **Auto mode**

The system will automatically indentify the scanning starting position according to head recognition and current protocol position, and the corresponding scanning position will be highlighted with a "green" background, as shown in Figure 6-7. (Patients wearing masks can also be identified)

After the system automatically identifies the scanning range, click **Go** to complete the surview scan.

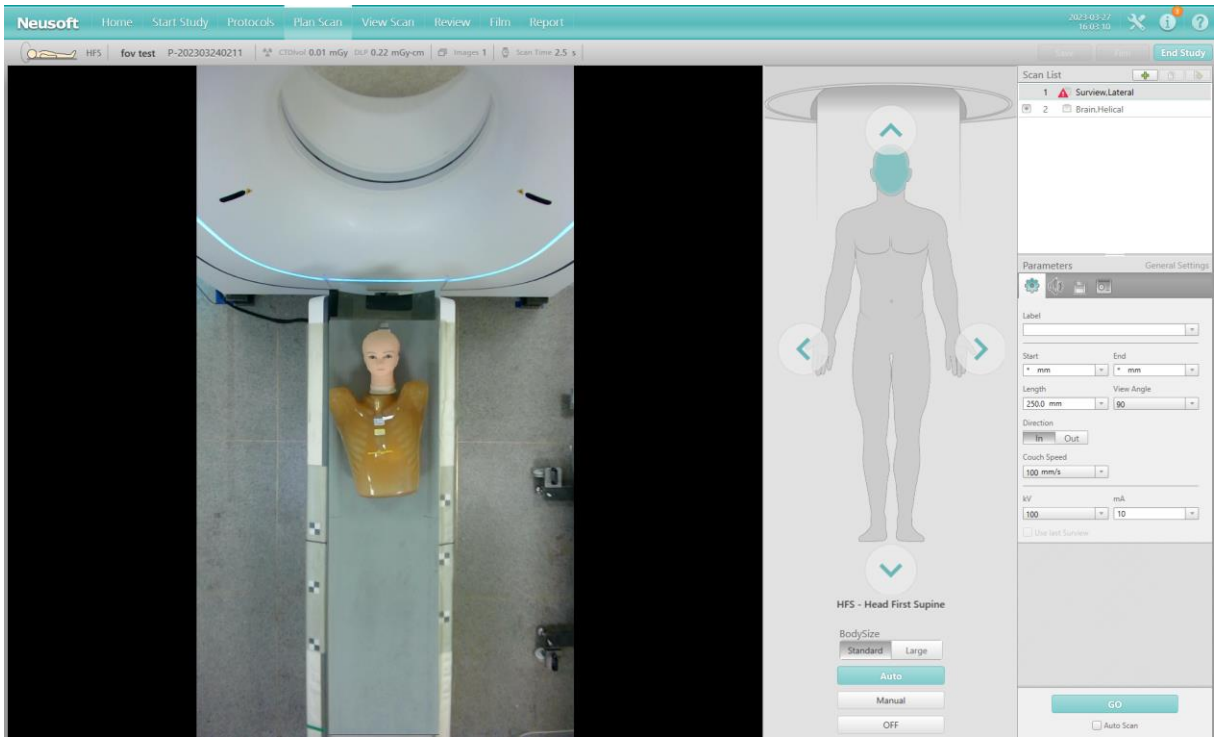


Fig 6-7 Intelligent positioning interface

NOTE:

- **The accuracy of the scanning range determined by the intelligent positioning Auto mode is affected by factors such as the blanket on the patient, the obstruction of people or devices around or above the patient, bright light, and the presence of strongly relective surfaces. Ensure the validity of the scan range and adjust the scan range in manual mode if necessary.**

- **Manual mode**

If the system cannot detect the scanning position, is will prompt the user to switch to manual mode, as shown in figure 6-8.

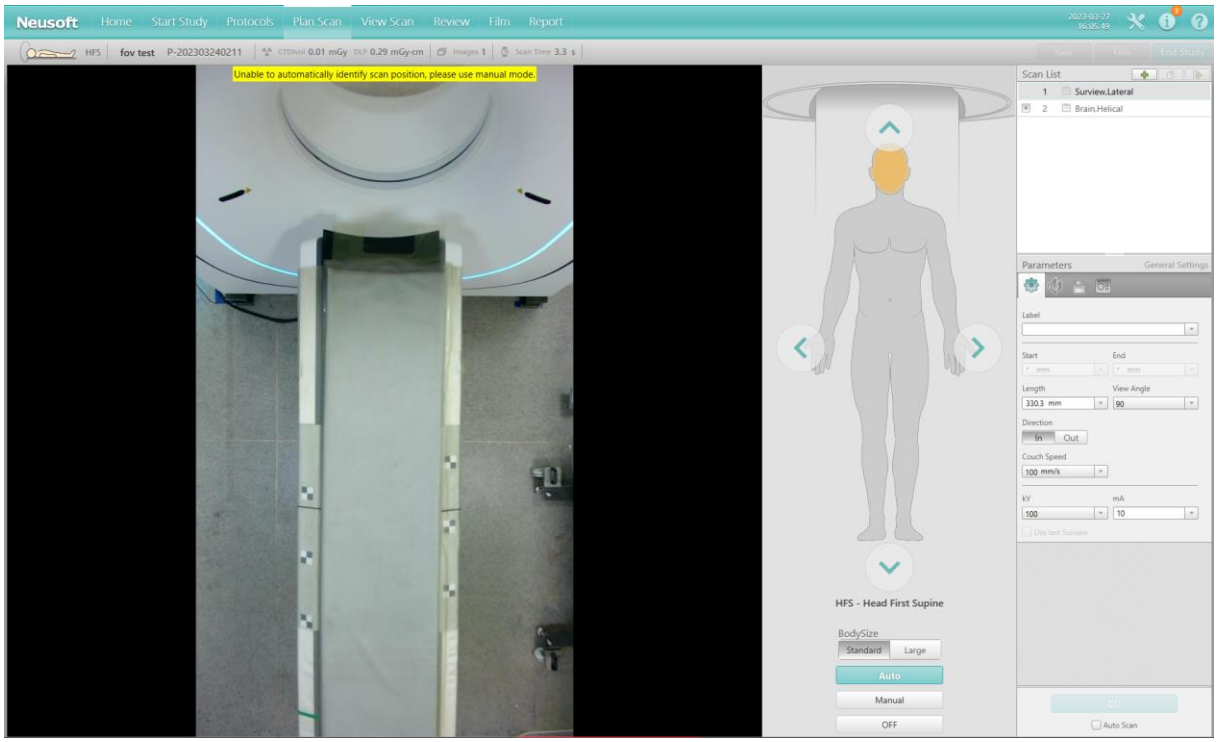


Fig 6-8 Human body cannot be detected

NOTE:

- **In the auto mode, if you click the patient's real-time video image, the system will directly switch to manual mode.**

To use manual mode, you can manually set the scanning area on the patient's real-time video image.

1. Click the left mouse button on the patient's real-time video image to draw a rectangular scanning area, as shown in figure 6-9.
2. Clicking and dragging the start position of the scan series box can move the whole scan series box. Clicking and dragging the end position of the scan series box can change the scanning length and update the scanning length of the surview simultaneously.
3. In manual mode, after the scanning range is drawn, click **Go** to complete the Surview scan.

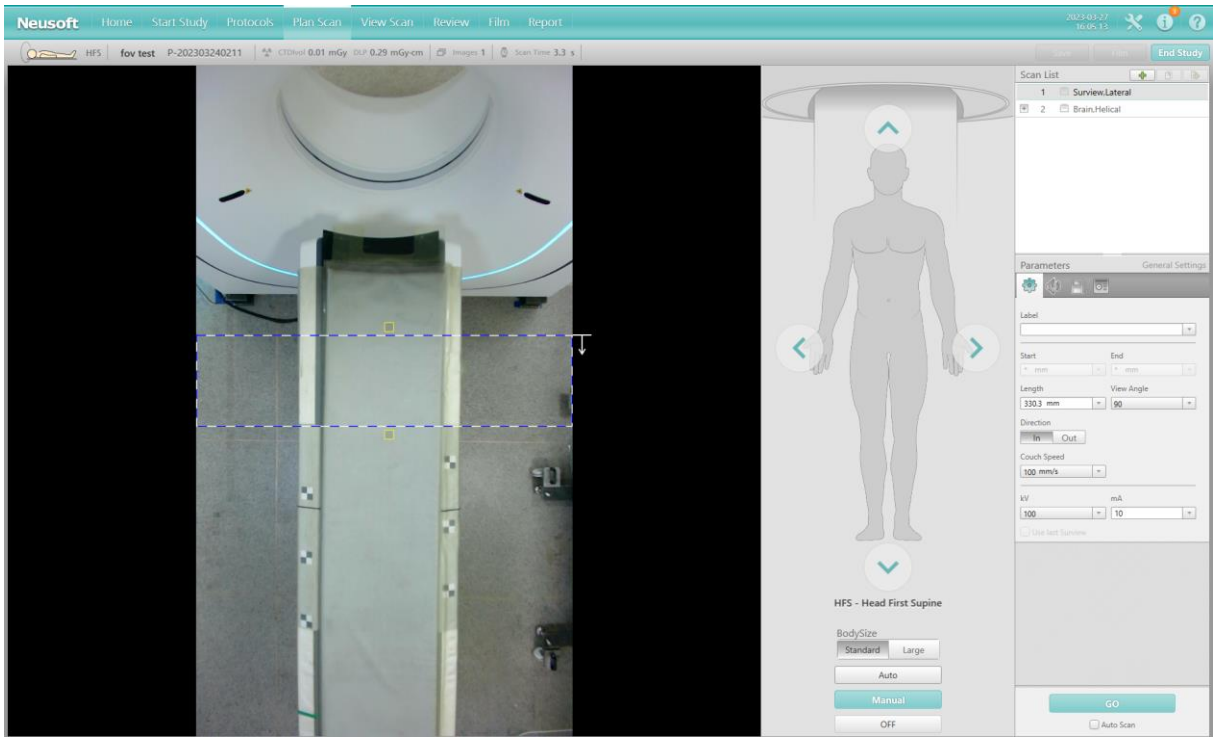


Fig 6-9 Manual mode

- **Off mode**

If you select the off mode, you cannot draw the scanning area on the patient's real-time video image, but you can still observe the real-time video image and use the CT-Box to move the scanning couch to complete patient positioning. At this time, the target scanning part will be no longer highlighted.

NOTE:

- **The intelligent positioning function is hidden when the gantry is disconnected. The intelligent positioning function is displayed when the gantry is connected again and there are surview sequences as planned.**
- **Body size parameters include standard and large. The system defaults to standard.**
- **When the intelligent positioning is in auto mode or manual mode, the start and end position parameters in the parameter panel are "*" and cannot be edited; they can be edited when the intelligent positioning is off.**
- **Please pay attention to the patient's condition during couch movement. In case of emergency, please press the Emergency Stop button on CT-Box to stop the movement of the couch to avoid injury to the patient.**
- **If the intelligent positioning device deviates from the correct position, please call the maintenance department of Neusoft Medical System Co.,**

Ltd for recalibration. Do not use intelligent positioning devices before recalibration.

- **Laser Localizer should always be used to verify patient positioning. Only the intelligent positioning is used to assist patient's positioning.**

6.3.2 Patient Information

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

6.3.3 Toolbar

6.3.3.1 Surview Plan Scan Toolbar

Save: To save the current plan scan window. It can be saved in the formats of DICOM (derived), DICOM (original) and DICOM (secondary).

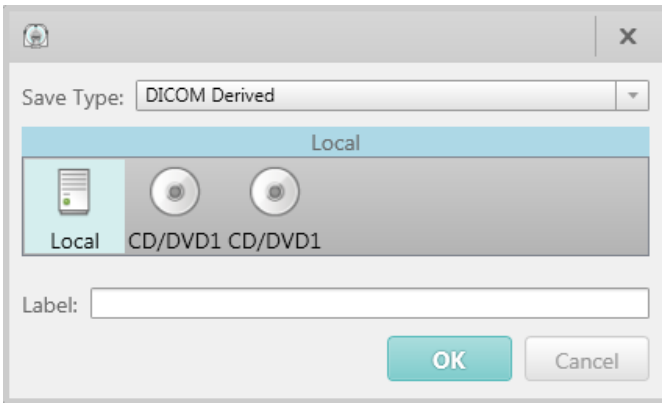
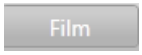
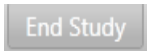


Fig 6-10 Save Option



Film: To send the images in the plan scan window to Filming.



End Study: When all the sequences in the scan list are scanned, and the "Prompt end study " option in the system setting is closed, click **【End Study】** on the top right corner to end study and return to Start; if there are unscanned sequences in the scan list, click **【End Study】** and a prompt will pop up to conform the operation, click 【Yes】 to end study.

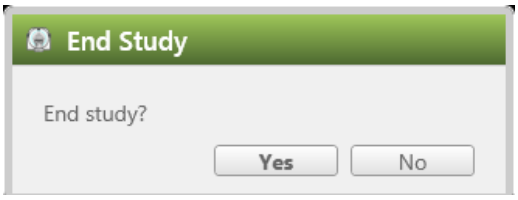


Fig 6-11 End Study

 **Inverse**: To reverse the grey levels of the image.

 **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.

6.3.3.2 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.

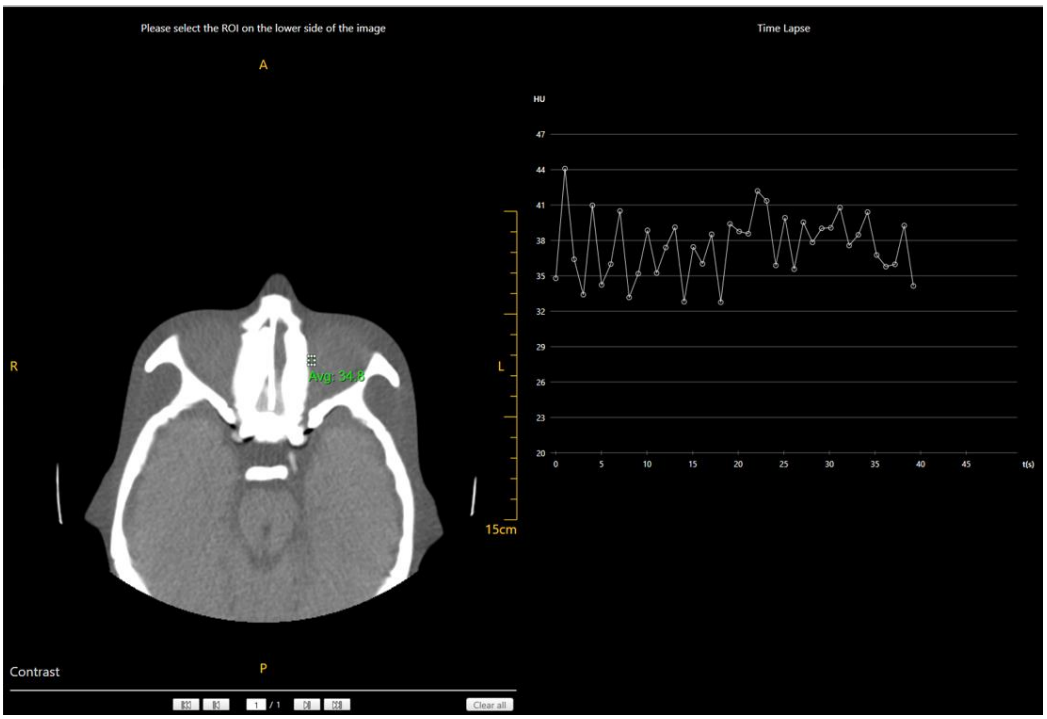


Fig 6-12 Time Lapse

6.3.4 Series list

6.3.4.1 Composition of series list

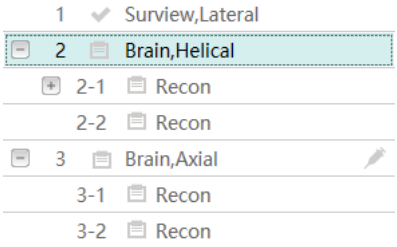


Fig 6-13 Series list

The series list displays mode is multi-level structure. The first level indicates the series to be scanned (main image); the second level is affiliated image series or MPR series based on main image, such as 2-1; the third level MPR series based on affiliated image, such as 3-1-1. Click "+" expand the next level, and click "-" to collapse the next level.

The list includes:

- Series number
- 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 includes:

- Protocol
- Series description (if exists)
- Surview / axial / helical scan
- Surview include 180° surview (tube location 180)、90° surview（tube location 90）and dual surview (tube location Dual).

NOTE:

- **When selecting the Dual Surview, 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 Surview, the system has a Skip function. This allows the user to press Skip during the active 180 Surview to shorten the length of the scout. The following 90 degree Surview will match the area covered in the 180 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.**

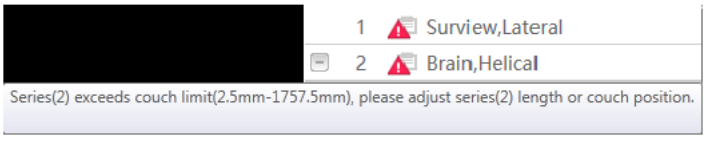


Fig 6-14 Warnings or Errors Prompt

6.3.4.2 Edit series

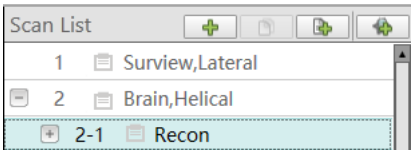


Fig 6-15 Edit series Tools

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.

- If the main series is selected, this icon is highlighted.
- Click this icon, copy the current series and add it to the current main series.
- Surview, Recon and MPR Recon do not support copy series.

Add Recon: To add reconstruction into the current series

- If the main series or Recon is selected, this icon is highlighted.
- Click this icon, add a new Recon after the current Recon of the main series.
- MPR series do not support adding recon.

NOTE:

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

Real-time MPR(Option):

Real-time MPR reconstruction is a recon mode, in the clinical scanning, automatically generate sagittal or coronal MPR images based on the CT axial images. Reduce secondary loading reconstruction time.

- Select one series except the surview in the scan list. This icon will be highlighted.

- If the selected series is main series, a new MPR recon will be added after the Recon. If the selected series is Recon, a new MPR recon will be added to the sublevel of the Recon. If the selected series is MRP recon, a new MPR recon will be added to the current MPR recon.
- 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 thesame anatomy will be covered.

6.3.4.3 Context Menu

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

Repeat: To repeat scan the selected series.

Copy: To copy the series.

Delete: To delete the series.

Paste: To paste the duplicated 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: Perform air calibration after finishing the scan if the quality of the image is not good. Click it to perform air calibration to protocol parameters of scanned series. To obtain the image with normal quality, perform offline reconstruction to the image after air calibration.

NOTE:

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

6.3.5 Plan on Surview

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

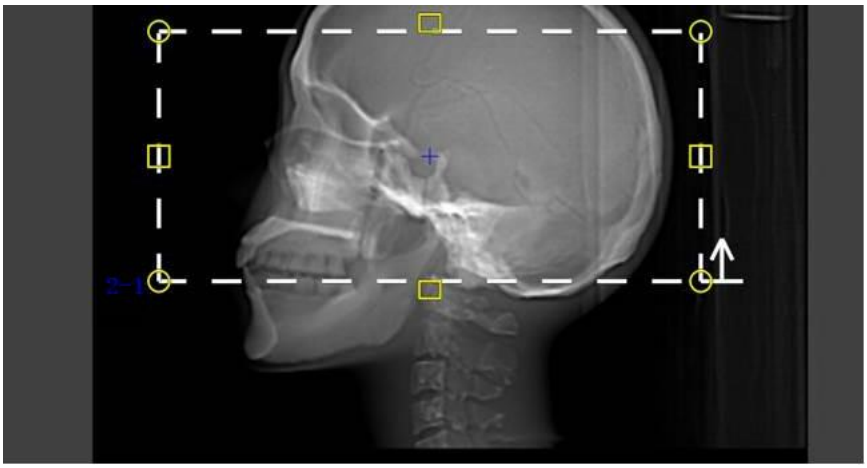


Fig 6-16 Surview

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 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.

- 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 180°
- 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
- 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.

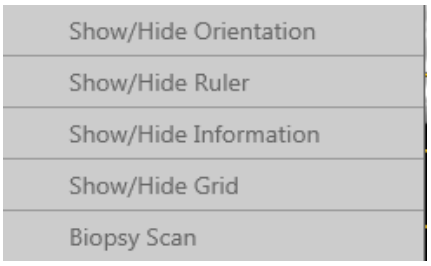


Fig 6-17 Biopsy Scan

6.3.6 Auto FOV

Auto FOV: For the brain and lung protocols, after the surview scanning is completed, the system supports automatic adjusting the positioning frame to the appropriate position.

NOTE:

- **In order to ensure the accuracy of automatic location, please surview scan according to the application scope of scanning protocol.**
- **The Auto FOV function uses deep learning technology to automatically select a suitable FOV range in the surview.**

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 $CTDI_{vol}$ 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 61223-3-5)

The accuracy of the displayed and recorded values of $CTDI_{vol}$ is the larger of ± 20% or 1mGy.

- **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.

6.4.1.2 Axial Scan Parameters

- **Tilt [deg]**

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

WARNING:

- **Increment of zero is allowed, but then the scanned area will receive an increased amount of radiation. This mode will be used for biopsies and the 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 6-2 Slice Thickness (Axial)

Collimation	Thickness (mm)
128 * 0.625	0.625(for 0.3125 only)
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

16*0.625 collimation supports two types of SFOV: large and small, as shown in figure 6-18; other collimation only support one kind of SFOV: large.

Fig 6-18 SFOV

- **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 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.

- **Breathing Cycles**

In the manual axial scan module, there is 【Breathing cycles】setting in scan parameters. When【Breathing cycles】sets 1, it will scan 1 circle during a breathing navigation process. When the【Breathing cycles】sets n(n>1), it will scan n circles during a breathing navigation process. For example, when the 【Breathing cycles】sets 2, it will scan 2 circles during a breathing navigation process.

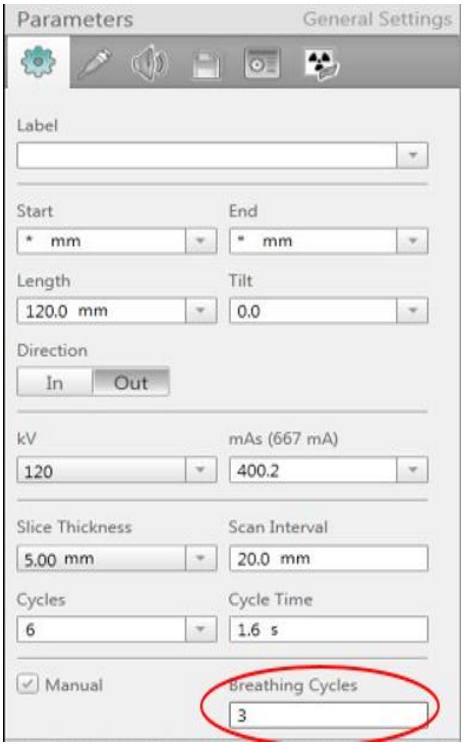


Fig 6-19 Breathing Cycles

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 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 combo box. 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 6-3 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
64* 0.625	0.625/0.8/1/1.25/1.5/2/2.5/3/4/5/6/7/8/9
32* 0.625	0.625/0.8/1/1.25/1.5/2/2.5/3/4/5/6/7/8/9
16* 0.625	0.625/0.8/1/1.25/1.5/2/2.5/3/4/5/6/7/8/9
8* 0.625	0.625/0.8/1/1.25/1.5/2/2.5/3/4/5/6/7/8/9
16* 0.3125	0.625/0.4/0.8/1/1.25/1.5/2/2.5/3/4/5/6/7

- **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 combo box or type a value within the range displayed there. 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 combo box is set.

- If the desired value is higher than the maximum displayed, then decrease the pitch of 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 the 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 Contrast Setting

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

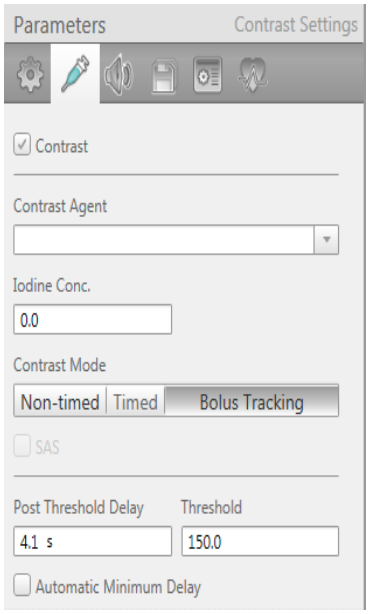


Fig 6-20 Contrast

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

• **Non-timed:** In this mode the contrast is injected and when ready press Scan Start button on the CT-Box to start the scan.

• **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.

• **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).

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 supports 1 sequence and helical sequence supports 5 sequence.**

6.4.3 AutoVoice

The AutoVoice tab allows you to select AutoVoice options.

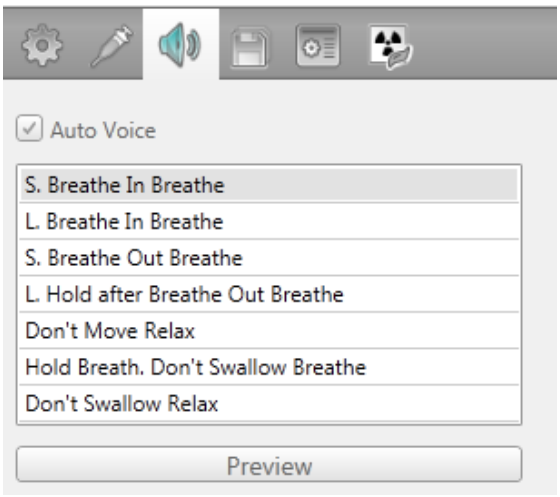


Fig 6-21 AutoVoice

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 hear the selected message set.

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.

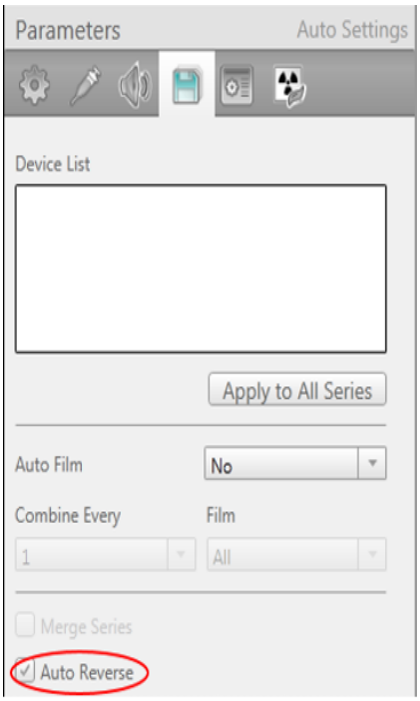


Fig 6-22 Auto Settings

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.

Auto Reverse：A new reverse sequence will exist on Home Page after scanning. The sequence number starts from 10003, and the image display and sequence are both opposite to the original one.

NOTE:

- **The【Auto Reverse】function will not be activated in the surview scan and zero interval axial scan.**

6.4.5 Advanced

- **FOV (Filed 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.

- **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.

- **Pitch**

The Pitch parameter represents the value of the Couch speed.

Pitch $=\Delta d/T$

Where Δd 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.

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 mAs 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 according to X-ray scanning to get attenuation of patient's body, and it recommends mAs for corresponding image signal-to-noise ratio. The system provides drop-down option for noise. The operator can input any desired image noise within the scope of 0.3 to 1.7.

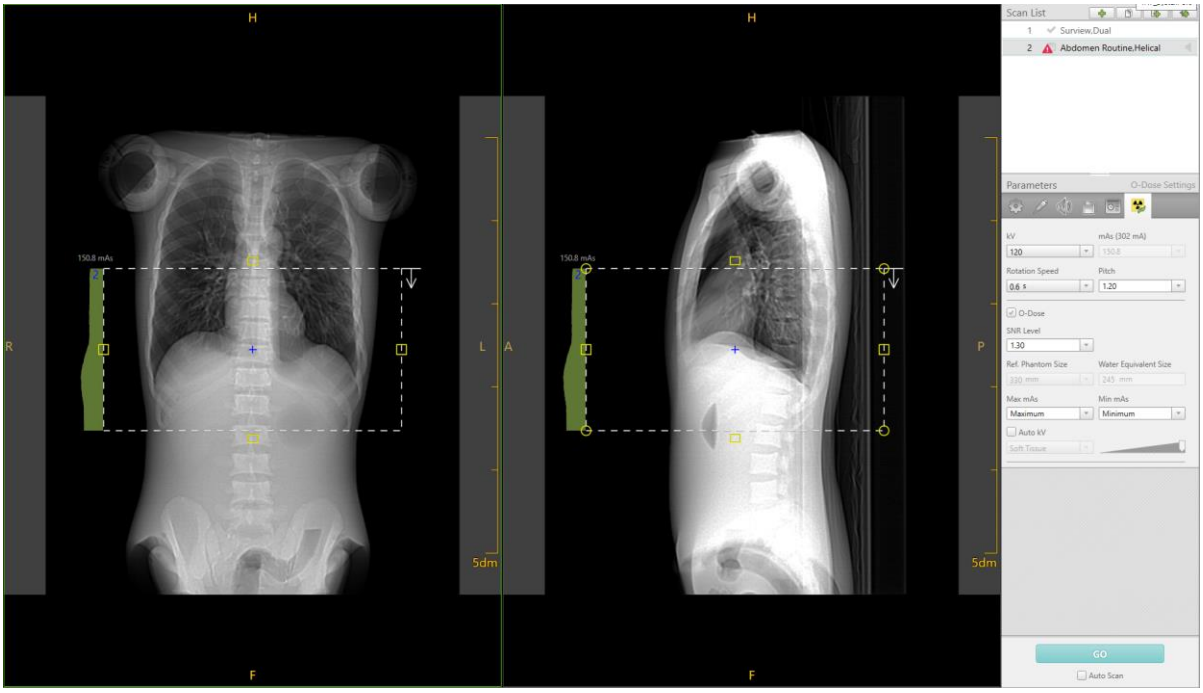


Fig 6-23 O-Dose

NOTE:

- **SNR Level is only available when O-Dose function is checked on. SNR is the ratio of signal to noise. The higher of this value, the higher the recommended dose.**
- **Max mAs and Min mAs are only available when O-Dose function is checked on. They are used to limit the maximum and minimum mAs for scanning.**
- **mAs cannot be edited manually when O-Dose function is checked on.**
- **Allow changing between O-Dose and manual mA control only when editing the clinical protocol of interest, changing during a patient examination not permitted.**
- **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. Ref. 【Ref. Phantom Size】 cannot be modified on the interface of Plan Scan when O-Dose function is checked.**
- **O-Dose function still can be activated when tilt scanning.**
- **For the O-Dose Warning Box, users can check 【This login is not prompted】.**

- **The following protocols do not support the O-Dose function: Brain 4D Perfusion, Abdomen 4D Perfusion, Abdomen.Prism, Coronary CTA DOM 0%.**

6.4.6.1 Automatic Exposure Control

Patients come in all shapes and sizes. For the purpose of achieving a desirable image quality with a scan technique that reflects the patient's size and shape, there are several approaches to employing automatic and manual mA setting modes of CT operation. These approaches are designed to adjust the X-ray output of the system according to the X-ray attenuation presented by a patient's anatomy. For example, the patient's weight or Body Mass Index (BMI) may be used as a guide to set a fixed mAs for the acquisition. Alternatively, some measure of patient thickness or girth, such as anterior-posterior (AP) thickness, lateral width, or patient circumference can be used as a basis to choose an appropriate fixed mAs value, i.e., a value that yields an image adequate for diagnosis with a patient dose as low as reasonably achievable. However, these methods have at least two inherent limitations. First, as they produce a fixed mAs value, they do not adjust for differences in body-region thickness and associated variation in X-ray attenuation along the patient length and/or around the patient circumference. Second, the use of weight, thickness or circumference is an incomplete surrogate for X-ray attenuation, which is one of the most relevant physical parameters affecting image quality and which depends on the elemental composition and density of human tissue as well as on its shape and thickness.

Automatic Exposure Control (AEC), on the other hand, is designed to adjust the scanner radiation output to meet a desired, pre-set level of image quality/noise criterion by empirically assessing the patient's attenuation and automatically modulating the mA accordingly. AEC can provide a desired level of image quality/noise at a lower patient dose than would be possible with a fixed scanner radiation output. In general, CT systems may accomplish AEC in two ways:

1) Modulating the mA dynamically during scanning in the X-Y and/or Z dimensions to adapt to variations in the patient's attenuation.

2) Adjusting the mAs to a fixed value based on measurement and calculation of the patient's overall attenuation: the mAs is constant during scanning, but its value has been quantitatively determined so as to yield an average pre-set level of image noise.

Most AEC systems operate as described in list item 1) above. Discussion of AEC, hereafter, applies to these types of systems unless otherwise indicated.

1. How AEC works

On the basis of a patient's attenuation, AEC sets mA values as the X-ray tube rotates around the patient. The technology uses knowledge about the scanner's imaging chain and the measured attenuation of the patient to appropriately adjust mA values in order

to achieve the desired, constant image noise/quality criterion.
Larger patients typically require scanning at a higher mAs than the mAs used for smaller patients. Similarly, thicker projections (e.g., laterally through the shoulders versus AP through the shoulders) typically require more mAs to achieve the same resultant image noise/quality criterion. Finally, anatomy with greater attenuation (e.g., abdomen or pelvis compared to the lungs) requires more mAs to achieve the same image noise/quality criterion.

2. Adaptation to anatomy

As patient attenuation changes throughout the course of the scan, either rotationally around the patient or along the length of the patient, AEC is designed to adjust dynamically the mA for each body part and projection. If the attenuation does not change, AEC sets the mA at a constant value that is appropriate for the overall patient thickness and that achieves the desired image noise/quality criterion.

3. When to use AEC

AEC technology has the greatest impact when the portion of the patient being scanned has non-uniform size, shape, or density. In these cases, AEC adjusts scanner radiation output to the changing anatomy and modulates the mA in the Z-direction (along the patient) and/or in the XY-direction (around the patient). Even though AEC is used, before scanning the operator must still select scan parameters, including AEC parameters, which provide a desired image noise/quality criterion. Scan parameters including AEC parameters must be chosen to carefully balance patient radiation dose and image performance.
Even when the patient's anatomy has consistent size, shape, and density throughout the planned scan range, AEC technology chooses the appropriate exposure settings to achieve the image noise/quality criterion requested by the user.
When bismuth or other shields are considered for use in the planned scanned range, consult the system user manual for specific information. Additional information about the proper use of bismuth shields can be found in the "AAPM Position Statement on the Use of Bismuth Shielding for the Purpose of Dose Reduction in CT scanning," available at aapm.org.

4. When not to use AEC

AEC might not be available for all scanning modes or on all scanners. When AEC is available, if users do not understand the relationship between AEC parameters, image noise, and dose, AEC should not be used. Also, if the patient cannot be centered in the scanner, AEC is not recommended because the attenuation calculations used for AEC are designed with the assumption that the patient is centered in the gantry. Finally, if there is any question, radiologic technologists should always consult their medical physicist and radiologist to ensure that proper exposure techniques are used.

5. AEC does not guarantee reduction of radiation doses in all patients

Use of AEC does not always result in dose reduction, especially when compared to a fixed mA/mAs protocol. For example, when providing the desired image noise/quality criterion setting for a large patient, AEC might appropriately increase the scanner radiation output as compared to that for an average-sized patient. For most examinations of average-sized or small patients, and for the same image noise/quality criterion settings, AEC use will result in the same or lower $CTDI_{vol}$ as that of a fixed mA/mAs protocol. (However, a larger patient would appropriately require more fixed mA than for a smaller patient.)

NOTE:

- **Radiologic technologists must be fully aware that proper patient centering is critical for accurate AEC function. Improper patient centering can result in an exposure that is either too high or too low to achieve the desired image noise/quality criterion. Note that proper patient centering can be more challenging for smaller pediatric patients, and so special care should be taken.**

6. Effect of AEC control setting

For a given patient, changing the image noise/quality criterion setting in AEC will affect the patient dose: asking for lower image noise/higher image quality criterion will result in more dose to the patient as the Noise Index value is decreased (made smaller). In contrast, asking for higher image noise/lower image quality criterion by increasing (make larger) the Noise Index value will result in less dose to the patient.

7. AEC considerations of patient size, shape, composition, and age

For a given AEC image noise/quality criterion setting, larger patients and more attenuating body regions may result in a higher scanner radiation output. Smaller patients and less attenuating body regions may result in a lower scanner radiation output.
While AEC can be an effective dose-reduction tool for pediatric patients, special care should be taken with this patient group.

8. Dynamic AEC scanning

When a scanning protocol contains multiple X-ray tube rotations at the same table location, the effect on patient dose of incorrect selection of protocol settings will be multiplied by the number of rotations. For such protocols, operators must take extra care when setting manual mAs or AEC parameters to achieve the desired level of image noise/quality criterion. For example, in perfusion scanning, the image noise can often be much higher (yielding a lower dose) than for routine diagnostic scanning of the same region because the primary application of perfusion scan data is for quantitative analysis and characterization of perfusion parameters rather than for diagnostic visualization. The manufacturer’s reference protocol provides an indication as to

whether use of AEC is or is not recommended with these scan modes.

9. How to tell if the dose has changed

For every patient, and any time AEC settings are changed, in order to confirm a correct level of scanner radiation output for that patient’ s size and exam protocol, users should examine the projected $CTDI_{vol}$ and DLP displayed prior to performing the scan, as a step in operator confirmation of system settings. When a large patient is scanned at a particular setting of image noise/quality criterion, the $CTDI_{vol}$ and DLP will be higher than for a smaller patient at the same AEC settings. Projected $CTDI_{vol}$ and DLP values are displayed on the scanner’s dose display on the user interface prior to confirmation of settings for scanning. After scanning, the values are updated to reflect the average of the actual mAs values used in the scan and are displayed on the user interface as well as recorded in the DICOM secondary screen capture and DICOM radiation dose structured report.

10. Summary

AEC is a versatile and powerful tool designed to tailor the scanner’s radiation output to each patient based on the patient’s size, age, shape and attenuation and the users’ requested level of image noise/quality criterion. AEC technology uses estimated patient attenuation values to adjust the mA dynamically in order to achieve the requested level of image noise/quality criterion. However, AEC settings must be chosen with the same care used to choose all other parameters that affect radiation dose to the patient. Before the scan parameters are confirmed, careful attention must be paid to $CTDI_{vol}$ and DLP displayed on the user interface; scanner radiation output associated with the prescribed protocol must be checked and confirmed prior to scanning. Used properly, AEC is a key technology to help ensure that the appropriate radiation dose is used for every patient.

11. AEC performance evaluation

According to Annex G of IEC 61223-3-5 2019, for the dose modulation in the X-Y-Z axis, a PMMA phantom with a diameter of 32 cm is used, and the following methods are used for testing and evaluation.

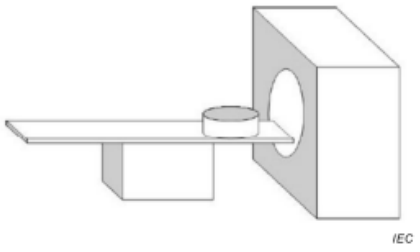


Fig 6-24 Testing diagram

1) Place the body dose phantom on the scanning couch with the axial upwards, and insert the PMMA rods into the 5 holes of the phantom.

2) Place the phantom in the center of the scanning FOV with the positioning light.

3) Load Abdomen protocol.

   A) First scan the surview, 120kV, scan the air, test the CT value of air, if the CT value is -1000HU±50HU, then perform the step B), otherwise perform the surview air correction so that the CT value of the surview air meets the requirements.

   B) Scan surview, 120kV, the scanning range can cover the entire body dose phantom.

   C) Scan Abdomen protocol, 120kV, collimation width less than or equal to 30mm, 1s rotation speed, 1.0 pith, image thickness less than 1.0mm, check O-Dose function, adjust the SNR ratio, so that the mA curve is not truncated, execute scanning.

4) Take the corresponding images showing the diameter of the phantom with a width of 20%, 50%, 80% and 100% from the scanned image. The diameter of the body dose phantom is 320mm. Considering the phantom and measurement errors, the diameter is 64mm±15%, 160mm±15%, 256mm±15%, 320mm±15%.

5) Record the image mA. Take the image mA corresponding to the 100% phantom diameter layer as the benchmark, denoted as mA_base.
   80% of the image mA is A=0.75*mA_base, the value range is A ± max (A*10%,30mA);
   50% of the image mA is B=0.45*mA_base, the value range is B ± max (B*10%,30mA);
   20% of the image mA is C=0.25*mA_base, the value range is C ± max (C*10%,30mA);

6.4.6.2 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.

6.4.6.3 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.

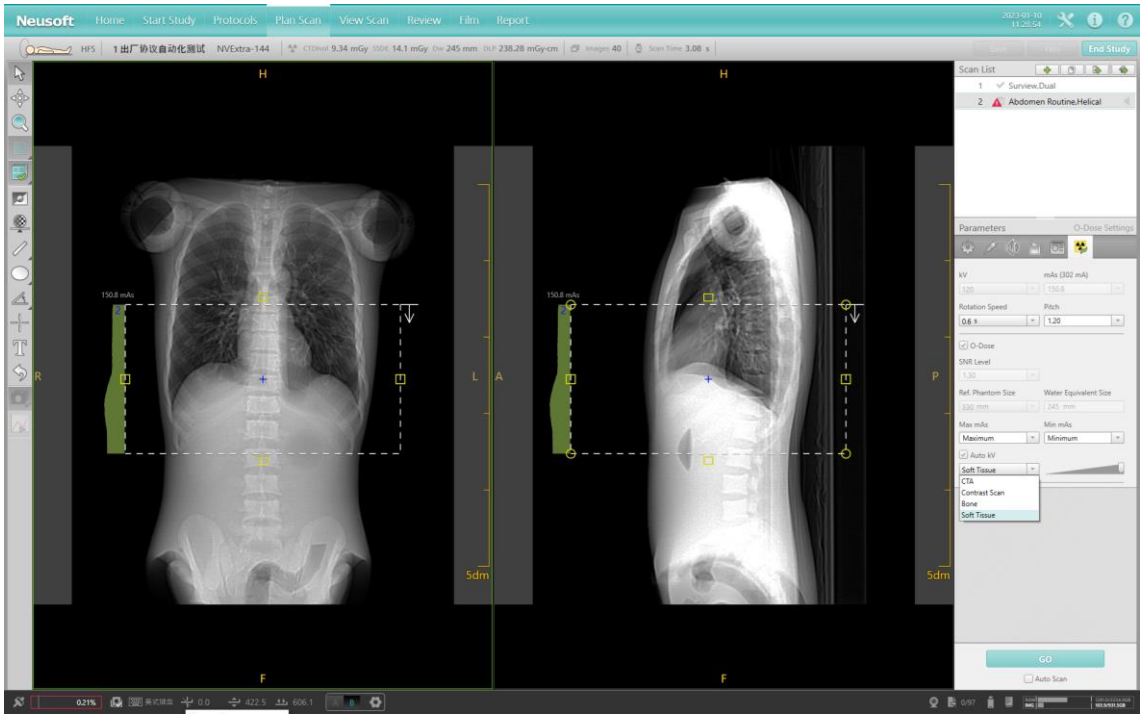


Fig 6-25 Dose Profile Curve for O-Dose

6.4.7 Prism Imaging(Option)

If system provides Prism dual image function, it suggests that the system can gain CT images of patients with single-source and single time under different voltages through this function. Dual Energy Imaging 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 functions of the Prism, image types can be as follow:

- Material Specific image:
  - Water Image

- Iodine Specific Image
- Calcium Specific Image

- Effective Atomic Number Image
- Virtual Monochrome Image(40keV~140keV)

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

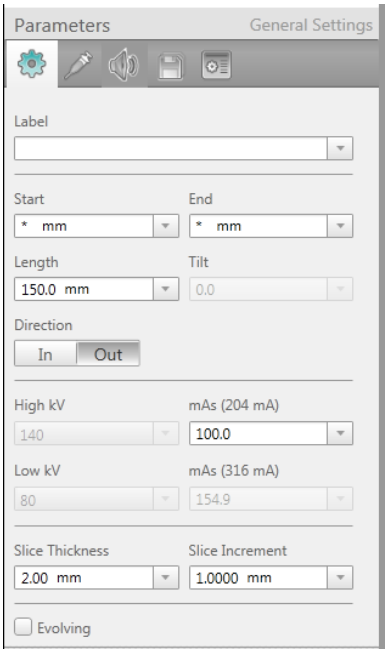


Fig 6-26 Prism Imaging

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.

6.4.8 4D Scan(Option)

NOTE:

- **This function can only be available with long couch (CT-SMC 305).**

The system provides Brain 4D Perfusion and Body 4D Perfusion protocols in the protocol selecting interface. Compared with other protocols, Brain 4D Perfusion and Body 4D Perfusion protocols have 4D parameter page. The Scantype of 4D protocols cannot be modified.

6.4.8.1 Purpose of CT Perfusion

Computed tomography(CT) perfusion studies are used to assess delivery and perfusion of blood to an organ and/or its tissues. Such studies may be valuable for evaluating blood supply to neoplastic and non-neoplastic tissue (including normal and ischemic

tissue). In particular, CT perfusion imaging allows the evaluation of cerebral ischemia or of the extent of angiogenesis associated with a tumor. CT perfusion should be performed only for a valid medical reason and with the minimum radiation dose necessary to achieve an adequate exam. The use of perfusion scans in children should be particularly reviewed for clinical impact and justified. Particular attention should be patid to displayed CTDIvol when modifying protocols.

CT perfusion imaging relies on the linear relationship between CT attenuation, expressed in Hounsfield Unit (HU) and represented in a particular pixel of an image, versus the amount of iodinated contrast material perfusing the corresponding region of tissue attenuating the X-rays. Dynamic CT scanning enables the calculation of perfusion parameter maps, e.g., anatomic images where the pixel value represents mean transit time, blood flow, blood volume, and permeability maps depending upon the post-processing model used.

Scan technique parameters (e.g., kV, mAs) for CT perfusion studies should be set at values lower than those used for routine diagnostic scanning of the same anatomical area. Perfusion imaging involves visualization of temporal changes in iodine enhancement, rather than resolution of small or subtle anatomical detail. The post-scan software processing of the data is relatively insensitive to the increased noise levels; hence, perfusion scans do not require the use of the same radiation levels. In general, lower kV improves visualization of iodine contrast and consequently allows use of lower radiation doses. Lower kV settings are therefore recommended to be used as long as sufficient image quality for perfusion post-processing can be obtained. Body perfusion imaging of obese patients, for example, may be an application that requires use of higher kV values. Users should carefully review the manufacturer’s reference perfusion protocols, which reflect the recommended kV, mA, and scan time for a typical perfusion acquisition. Additional guidance may be obtained from professional societies, regulatory agencies, educational textbooks, or peer-reviewed literature. The American Association of Physicists in medicine provides a set of reasonable scan protocols for CT brain perfusion imaging that is freely available to users via its public webpage. See the recommended readings.

Because CT perfusion requires specialized post-processing software, a CT perfusion acquisition should not be performed unless this software is readily available to the institution. All users should be trained in both CT perfusion acquisitions and post-processing and should follow professional society perfusion practice guidelines. Before any changes are made to the manufacturer’s reference protocols, both a radiologist and medical physicist familiar with CT perfusion should be consulted. Changes in protocol and the reason for the changes should be communicated to the radiologic technologist. Any changes to the protocols should be evaluated with respect to the image quality (less than diagnostic level), temporal sampling and radiation dose of the manufacturer’s original reference perfusion protocols. It is essential that all users understand that CT perfusion images will be much noisier than images of the

same body region acquired for most other diagnostic purposes, and that this level of image quality is sufficient for the calculation of perfusion parameters.

6.4.8.2 Components of a CT Perfusion Study

Assessment of tissue perfusion for stroke includes a diagnostic quality non-contrast brain exam, an optional CT angiogram of the circle of Willis that may include the carotid arteries, and a CT perfusion exam. It may also include a post-contrast CT scan of the brain for assessment of residual lesion enhancement. In the assessment of tumors, a non-contrast scan for localization of the area of interest is often done prior to the CT perfusion exam.

In all cases, the CT perfusion exam should have technique factors that are lower than those used for the other components of the study (e.g., the non-contrast, post-contrast, and angiogram scans). Specific acquisition times for the perfusion exam depend on the post-processing algorithm used, but in all cases the exam must be performed over a relatively long period of time (typically 40 to 50 seconds and potentially up to 3 minutes; consult model-specific user manual and radiologist) in order to measure the time dependent physiologic process of blood flow through the brain. Since the scan location is fixed, the same anatomy is irradiated repeatedly during this scan time. Scan times are also affected by the concentration, volume, and rate of delivery of the contrast agent.

The lenses of the eyes are more radiosensitive than the skin. Scanning through the orbits should be avoided, if possible, by the use of patient positioning. Consult the medical physicist to ascertain appropriate deterministic thresholds across the body.

1. Body perfusion considerations

Perfusion scanning of the torso, typically referred to as body perfusion CT, is not currently performed as frequently as head perfusion scans. It is essential to refer to manufacturers' reference protocols (if provided) and to involve a radiologist and medical physicist familiar with the principles and techniques for body CT perfusion imaging, as well as communicate with the radiologic technologist. Because of the higher attenuation of the torso, body perfusion scans may require a higher kV than head perfusion scanning. Again, the image quality obtained should be noisier than most conventional body CT scans, as the post-processing algorithm is able to extract the needed time attenuation information from the noisy data set. Respiratory motion is an important consideration in body perfusion CT, and methods to limit diaphragmatic motion during the scan, or realign anatomic regions after the scan using registration algorithms should be used to minimize errors introduced from the movement of the tissue of interest during the course of the perfusion scan. In the rare event that a body perfusion scan would be performed in a pediatric patient, sedation in small children may be required.

2. Perfusion acquisition types

Some perfusion scans are performed in a continuous exposure mode, in which the table does not move, and the X-rays are turned on over the entire scan period. This provides the highest degree of temporal sampling; however, such temporal sampling may not be required for a particular application. This acquisition mode delivers the highest dose to the patient since the X-ray beam is always on.

Other techniques and recommended protocols may include a mode where the table does not move, but the X-rays are turned on intermittently during the scan (intermittent scanning). This method can be used to reduce the dose if the temporal sampling rate remains adequate for the post processing software to be used.

Other types of data acquisitions are axial or helical ”shuttle modes,” which are specially designed for perfusion scanning and can extend the coverage of tissue imaged, thus dispersing the dose over a wider area and decreasing peak skin dose. In both cases, the temporal sampling rate is reduced for any specific anatomic location compared with continuous and intermittent exposure modes where the table remains stationary. The user must ensure that the sampling frequency remains adequate for the post-processing software.

In axial shuttle mode, scanning is performed at two adjacent axial locations by moving the table between x-ray exposures, thereby increasing the amount of anatomy that is imaged. As with intermittent scanning, the x-rays are not turned on continuously, and thus peak skin dose and overall delivered x-ray radiation dose are reduced (compared with continuous mode), while overall exam time remains the same.

In helical shuttle mode, the scanner emits x -rays continuously while the table continuously moves back and forth across the prescribed scan range. As a result, the amount of anatomy that is imaged is increased. In helical shuttle mode, the total irradiation exposure is similar to that of a continuous acquisition exposure because the x-rays remain on during the entire acquisition.

The temporal sampling rate varies based on the acquisition mode selected and can affect the total dose for the scan. Table 6-4 lists the scan types that can be used for acquisition of perfusion data.

Table 6-4 Scan Modes for Acquisition of Perfusion Data

Scan Type	Coverage	Temporal Sampling Rate (Time Between Passes)	Acquisition/Dose Considerations
Axial	5,10,20,40mm	Adjustable	Limited coverage/Lower dose due to intermittent scanning
Helical shuttle	Adjustable	Adjustable	Largest coverage/Dose

			similar to cine-mode, however dose is spread across larger anatomic region

Communication of Table 6-4 should be conveyed by the facility to the radiologist, qualified medical physicist and radiologic technologist.

The exam duration for tumor perfusion, whether in the head or body, needs to extend over a longer time interval than a general perfusion scan, starting prior to the arrival of the contrast bolus and include a period of approximately 3 to 3.5 minutes to adequately support the collection of data for the computation of permeability maps. Initially, the temporal sampling rate must be the same as that used for stroke protocols in order to adequately measure the first passage of contrast material through the region. Subsequently, sparser sampling can occur, with temporal intervals ranging from 5 to 20 seconds. This reduces dose by decreasing the number of exposures.

6.4.8.3 Scan parameter effects on dose

kV effects on dose:

The effect on dose from changing kV is non-linear. Holding all other parameters constant, changing from 80 kV to 120 kV will result in approximately a two- to four-fold increase in dose. Consult the applicable section of the user manual for more details on the effect of kV changes on CTDI.

mA effects on dose:

Changing the mA or mAs has a linear effect on dose. Holding all other parameters constant, doubling the mA or mAs will double the dose.

NOTE:

- **The effects of kV and mA or mAs on dose are multiplicative. For example, a three-fold increase in dose that occurs from increasing kV combined with a two-fold increase in dose from doubling the mA will result in a six-fold increase in overall dose.**

6.4.8.4 Considerations for peak skin dose

The highest radiation dose accruing acutely at a single site on a patients' skin, referred to as the "peak skin dose," is an important parameter in assessing risk of erythema (skin reddening) and epilation (hair loss). The necessity for repeated scanning of the same location over extended times results in skin doses that can be higher than those associated with routine CT applications. Factors that influence these doses include kV, mA, scan time, perfusion acquisition type, and table movement, if any, during the perfusion acquisitions. As with patient dose, lower kV settings are recommended and

should be used as appropriate to achieve appropriate image quality for perfusion evaluation with respect to image noise based on body size, region scanned, and scanner type. In all cases, you should refer to the manufacturers' reference perfusion protocols as they reflect the appropriate kV, mA, and scan times for typical perfusion acquisitions. Additional guidance may be found at professional society and/or regulatory websites (see Recommended Reading).

6.4.8.5 Required imaging attributes for perfusion imaging

The purpose of a CT perfusion series is to assess tissue perfusion and delivery of blood to the organ and/or tissues of the organ; the acquisition parameters are different from those needed for routine low contrast CT imaging applications. The acceptable noise level in CT perfusion is typically higher than that for acquisitions routinely used in diagnostic imaging. Automatic exposure control should not be used unless the manufacturer's reference perfusion protocol employs it. Protocols should be adjusted accordingly for patient age, injection rate, injection volume, and exam type (stroke versus tumor evaluation and head versus body).

CT perfusion scans need to acquire data over a sufficiently long duration to accommodate the transit time associated with the physiological process of the contrast bolus moving through the vascular system. The acquisition duration for a stroke study must cover the time from prior to the arrival of the contrast material bolus through the approach of the venous signal to baseline. This duration is directly dependent on the volume of contrast material injected, the rate of injection, and the patient's cardiac output. If contrast material volumes or injection rates change from exam to exam, the scan duration will need to be adjusted accordingly. Consult the perfusion post-processing software manual for more detailed imaging and CT perfusion information.

6.4.8.6 Contrast injection considerations

As the iodine concentration of contrast material decreases, contrast material volume or flow rate may need to be adjusted to deliver the required enhancement. You should pay close attention to the shape of the bolus, follow the bolus with saline, and use an injector capable of delivering the required injection rates.

The contrast injection rate should be determined by referring to the applicable section of this user manual, contrast agent labeling, and in consultation with a physician. Special consideration should be given for children due to their smaller size.

6.4.8.7 Other considerations and references

Due to the necessity to obtain data over an extended time period in order to calculate relevant perfusion parameters, repeated scanning of the same location is required. As a result, CT perfusion acquisitions produce peak skin doses higher than those

associated with routine diagnostic CT imaging. Deterministic effects (e.g., tissue reactions such as skin reddening and hair loss) are a dose-threshold phenomena that can appear with peak skin doses > 2 Gy. As with all CT scanning, the CTDIvol value displayed on the operator console should always be confirmed prior to the scan. For CT perfusion without table motion, the value of CTDIvol tends to overestimate the actual peak skin dose by approximately a factor of two (see reference to Bauhs below). User manuals may contain an informative section that describes means for conversion of the displayed CTDIvol or dose profile to an estimated phantom peripheral dose, which may serve as an estimate for peak skin dose. A typical CT perfusion study should not result in a console-displayed CTDIvol of more than 1,000 mGy. Care should be taken and consideration given prior to rescanning a patient within a short time with a perfusion acquisition for the same anatomy due to concerns about reaching a cumulative peak skin dose value greater than the deterministic threshold for skin injury.

Sites should have a Quality Assurance (QA) program for oversight and review of any protocol changes. As with other scan types, the CTDIvol for a CT perfusion acquisition is recorded in both the DICOM screen capture and the DICOM CT dose structured report and should be used for QA follow up for all scanning.

Additional information on CT perfusion may be obtained in the user manuals for the CT perfusion post-processing software, from the ACR practice guide for CT perfusion, and from the AAPM website that contains reference perfusion protocols as well as other perfusion related information (please visit FDA website for documents related to radiation dose quality assurance).

All the reference protocols provided within the software of this system, including those for CT perfusion, are included in this user manual. This chapter provides a concise description of each scanning series within the protocol, technique factors, and dose information for each.

While the preceding information is specific to perfusion imaging, it is also relevant for other applications where repeated scans of one section of anatomy are required (e.g., interventional, kinematic imaging, etc.).

6.4.8.8 Recommended reading

1. J. A. Bauhs, T. J. Vrieze, A. N. Primak, M. R. Bruesewitz, and C. H. McCollough, 2008, "CT dosimetry: comparison of measurement techniques and devices," Radiographics Vol. 28, pp. 245-253.

2. ACR-ASNR-SPR Practice Guideline for the Performance of Computed Tomography (CT) Perfusion in Neuroradiologic Imaging at American College of Radiology website

3. AAPM CT Scan Protocols website.

4. FDA website on "Radiation Dose Quality Assurance: Questions and Answers".

6.5 Start Scan

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

There are two methods to stop scanning in the scanning 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.**

CAUTION:

- **While scanning, keep the intercom system on. Observe the patient closely when talking to or listening to the patient.**

NOTE:

- **Without restarting the console software, after restarting the gantry, it is necessary to wait for the completion of the couch zeroing operation before scanning.**

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 text they need.

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.

WARNING:

- **Depending on WW/WL settings, objects may display differently. Check WW/WL before depositing measurement points.**
- **Do not use 3D or slab views only to perform any measurements (distance, angle, region of interest, report cursor, area, volume, etc.). Always check measurement points' position and refer to 2D baseline views (acquisition images or reformatted images of minimal thickness) to confirm measurements.**

NOTE:

- **The software calculates and displays measurements with a resolution of one decimal (such as 0.1 mm, 0.1 degree, etc.). You should be aware that**

the real measurement accuracy is generally less for a number of different reasons (image resolution, acquisition conditions, etc.). Distance, angle and area measurements are valid only if all trace segments are longer than the inter-slice distance.

- **Measure error using the straight line distance graphic is ± the largest voxel dimension.**

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:

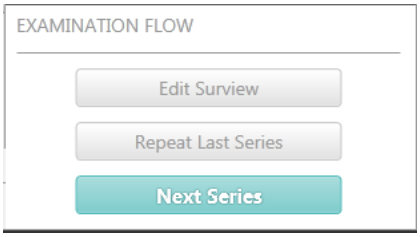


Fig 6-27 Surview Examination Flow

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 displays as below:

Under the below circumstances, this selection can be used:

- Cease to scan in the process of checking
- After completing the surview scan, and 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 (Without scan) the previous series scan.

Next Series: Go to the next series as planned in the Plan Scan interface.

Continue Current Series: Continue scanning in the current series. If scanning has been interrupted, user can press this button to continue the scan. The system automatically provides default values for the Start Position, Slice, Image Count and Length. Users can also setup scanning parameters manually.

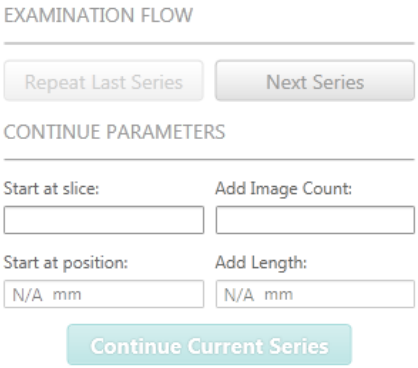


Fig 6-28 Series Examination Flow

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 the【View Scan】interface, as long as the scan sequence has a corresponding surview image, then positioning frame is automatically displayed. The positioning frame will move following the modified scan parameters, but it cannot be dragged manually.

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:

- **The Examination Flow dialog box will automatically display between the scan intervals for you to continue the next series or end the examination.**
- **For the timed scan or Bolus Tracking mode, the parameter will only be available after all the timed series are scanned.**
- **If a scan sequence has its recon sequence, when selecting【Continue Current Series】,the generated sequence will involve recon sequence.**
- **For continued image code axial scan, add affiliated image sequence, continue current series will automatically add affiliated image sequence with same parameter.**

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.

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 monitor the contrast flow and automatically scan when the preset Hounsfield unit is reached.

CAUTION:

- **Please confirm whether linkage mode is used before starting injection. Avoid accidental activation of linkage mode, resulting in excess radiation. If the linkage mode is not set correctly, the contrast agent will not be available.**

Table 7-1 Injector 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.Stellant D-CE 4.Ulrich XD 2001 5.Nemoto Smart Shot Alpha A60 (Single tube) 6.Apostar APO100 (Single tube) 7.Apostar APO200 (Double tube) 8.Mallinckrodt Optivantage (Double tube)

NOTE:

- **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

1. 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.
2. Default mAs value is 30 mAs, and the user can change the value manually.
3. Set up scan start time PTD (Post Threshold Delay: Delay time after reaching threshold value).
4. The number of tracker scans is between 2 – 200, default value is 40. If necessary, user can set up PID（Post Injection Delay : Delay time between injection and scan）.
5. Default CT value is 150 CT.

NOTE:

- **System default max CTDI dosage is 250 mGy, default max DLP is 2000mGy*cm. If dosage is higher than the two values, a dosage 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.**
- **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.

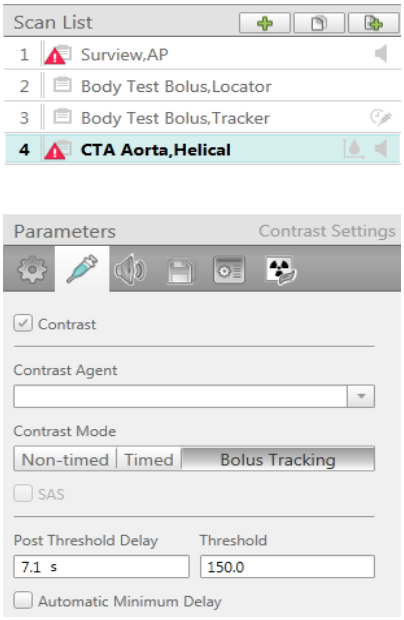


Fig 7-1 Bolus Tracking

NOTE:

- **Users can add Contrast Agent name in Scan Miscellaneous Setting of System Setting.**
- **Tracker sequence, which supports drawing up to three ROIs. If selected in the System Settings - Protocol Edit - Tracker parameters panel. If 'Automatic trigger' (selected by default), the ROI is set to automatically trigger ROI by default when drawing the first ROI.**
- **When the removed ROI is auto trigger, the first of the remaining ROIs is automatically set to auto trigger.**
- **When the 'auto trigger' option of the Tracker sequence is enabled and no auto trigger is set for all ROIs, click 'Go' and a message 'No auto trigger is set, continue to scan?' will pop up, click 'Continue' to scan, click 'No' to edit parameter again.**
- **The Locator and the Tracker scans are executed at the same position and therefore they appear as a single line on the Surview.**
- **When selecting Tracker and Locator sequences, the storage page is newly added to the Parameters tab. Users can set auto printing and auto sending function on this page.**

Fig 7-2 Film and Send Tab

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.

When the Tracker Scan ends, the TimeLapse sequence is automatically saved. This sequence contains 2 images, one is a ROI image of the Locator sequence, and the other is the time density curve.

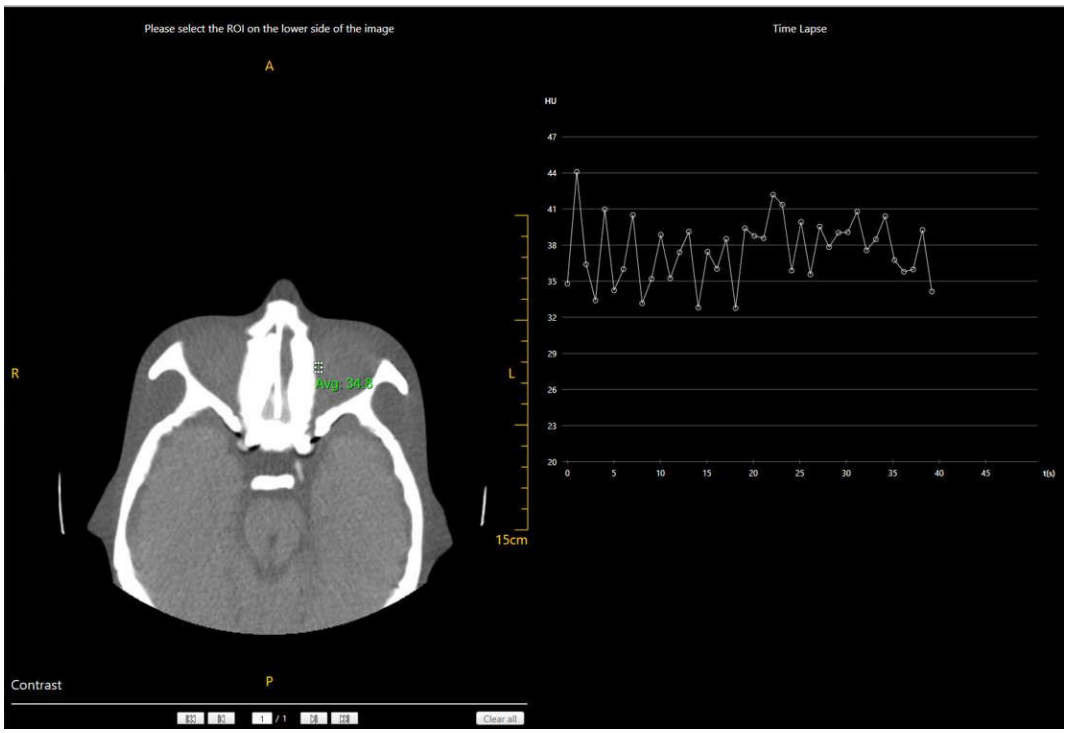


Fig 7-3 TimeLapse

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 Scan procedure of Bolus Tracking

1. Click **Start Study** in the workflow.
2. Enter the patient information in the **Start Study** interface. Make sure the right patient position is selected.
3. Click the **Protocols** workflow button.

4. Click the desired protocol group. The list of protocols displays.
5. 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.**

6. If needed, edit the protocol parameters.
7. Click **GO** to start the Surview scan. The system displays the Surview image.
8. Plan on the Surview. If necessary, adjust the scan length. Now that the Surview is complete, continue to the Bolus tracking scan.

- If the Locator and Tracker scans are included in the protocol, continue to Bolus tracking scan, step 7.
- If the Locator and Tracker scans are not included in the protocol, continue to Bolus tracking scan, step 1.

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.**

7.3.2 Planning the Locator and Tracker scans

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

1. Click Locator in the scan series list. The system displays a locator line on the image.
2. Move the locator line into the desired position.
3. 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.**

4. Click the Clinical scan in the series list. The Main scan parameters display. A time ruler appears at the bottom of the screen showing the scan length and the start

point relative to the injection start.

5. To add a 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.**

6. 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.**

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

8. 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.

9. 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.**

10. 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).**

11. 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.
12. 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.
13. 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 may 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 scan continues will automatically start when the entered Post Injection Delay time is reached.

Fig 7-4 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 again.**
- In manual mode, the Scan Button and the Injection Button must be pressed at the same time. SAS must be unchecked for manual mode.

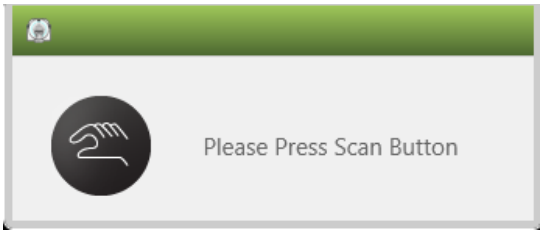


Fig 7-5 Information when SAS is unchecked

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:

- 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. The front end of the timing bar displays the tracker sequence "post injection delay" time, that is, the progress bar of the PID. For a contrast agent tracking scan, the PTD (Post threshold delay time) value is displayed above the progress bar of the subsequent scan sequence, and the scan time of the sequence is displayed below the progress bar. For a timed scan, the PID value is displayed above the timing bar of the PID progress bar, and the scan time of the sequence is displayed below the timing bar.

Fig 7-6 Timing Bar

NOTE:

- **For Bolus Tracking, the SAS option is found in the Tracker scan.**
- **For timed scan of axial scan and helical scan, below the scanning image is the timing bar will show X-ray radiation time from beginning to the end.**

4. Select SAS.
5. Complete the rest of the injection options. Verify the scan delay is within the acceptable range.
6. After reviewing the entire parameters click **GO** to begin the scan.
7. The countdown of the delay before scanning begins immediately following the triggering signal from the contrast injector.

NOTE:

- **When SAS is selected, after clicking "Go", make sure do not start injection before system prompt "Please Press Scan 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(Option)

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 scanning room. The resulting images display on a remote monitor in the scanning 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.

- Position the monitor in the scanning room at a convenient location, taking into account the expected direction of approach to the patient.
- Check that the foot pedal is free from interfering objects.
- Make sure that the Gantry indicator lights are functioning properly by performing a CT scope scan without a patient.
- 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 scanning room.
- Check the intercom for clear duplex communication.
- Prepare the appropriate radiation shielding equipment and materials.
- 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 scanning 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.**
- **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.

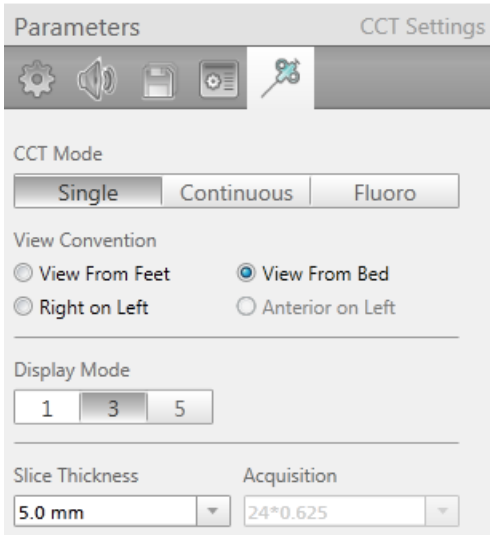


Fig 8-1 Display mode

- **Real mode**

There are three CCT modes.

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

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.

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.

- **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 display mode of the images is only 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.**

8.2.2 CCT operation procedure

This function requires two people for optimum performance:

- A technologist to operate the scanner and assist the doctor.
- An intervention doctor who conducts the biopsy procedure in the scanning 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 intervention 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.**

8.2.3 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.**
- **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.**
- **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 Safety instruction

8.4.1 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 foreign objects 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.

8.4.2 Radiation information

The CCT mode is intentionally designed for scanning with a member of the medical staff in the gantry 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 scanning 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 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:**

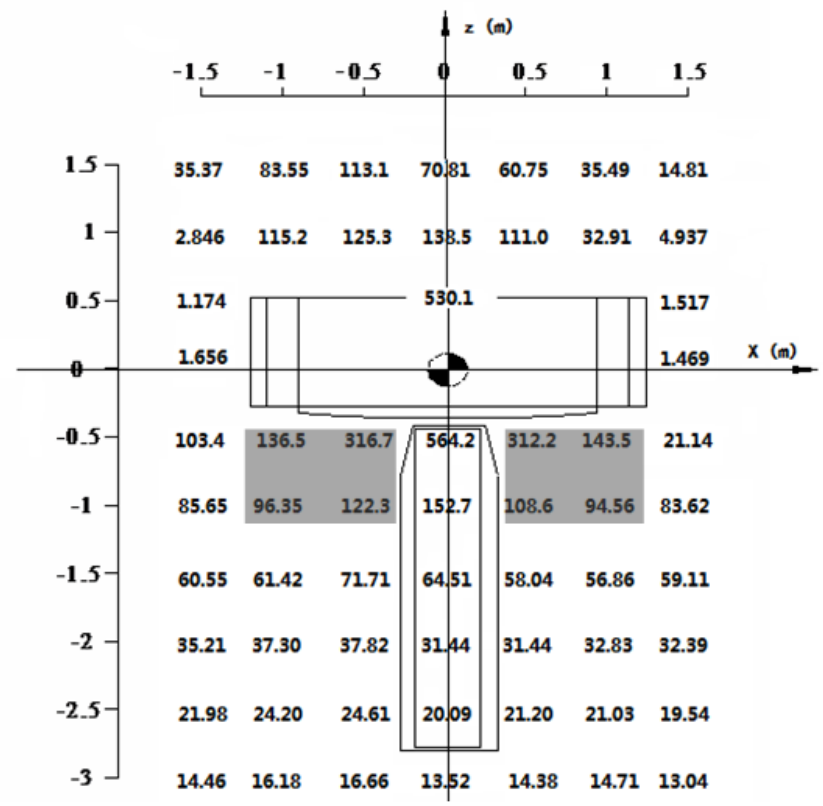


Fig 8-2 Occupational area

Chapter 9 Cardiac Scanning (Option)

This Chapter describes how to perform cardiac scanning as well as the additional procedures that may 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 128 system, the cardiac calcium scoring scan is based on Prospective mode, while the coronary CTA scanning is based on Retrospective mode.

WARNING:

- **The cardiac scanning is for use solely in acquiring CT images using cardiac gating/triggering, not for physiological monitoring. The patient's current condition may not be reflected, resulting in improper emergency treatment.**

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, it is mandatory that you set up and connect the ECG monitor with the NeuViz 128 CT system.

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 ePM10 2. IVY ---IVY7800

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 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:

- **The amplitude of the ECG signal input needs to be greater than or equal to 0.5V or more, that is , the equivalent ECG signal amplitude is more than 0.5mV, and the heart rate is higher than 40bpm. Images**

generated by ECG signal amplitudes that are too low or heart rate too low may not be useful for clinical diagnosis.

- **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 suspend the cable from the couch, movement of the ECG lead during scanning can result reduced signal quality.**
- **This Inner ECG can only be available with long couch (CT-SMC 305).**

9.1.2 Preparing the patient

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

1. Detailed explanation of the exam procedure and possible reactions during the scan should be explained to the patient, to insure better compliance.
2. 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.
3. 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.
4. Position the patient as FFS on the couch.
5. 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.
6. Apply clean electrode this way:

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

   (2) Place the electrode as figure 3. Move the lead wires away from the scanning area being viewed. The patient lead color identification comparison table is as follows:

Lead type	US (AAMI) color	EU(IEC) color
RA - Right Arm	White	Red
RL - Right Leg	Green	Black

LL - Left Leg	Red	Green
LA – Left Arm	Black	Yellow

(3) 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.

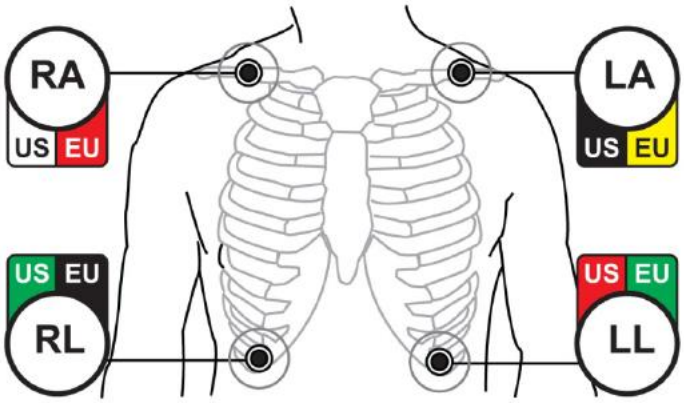


Fig 9-3 Electrode placement (Left: AAMI; Right: IEC)

(4) Place the two upper electrodes directly on the middle portion of the patient's collarbone.

(5) The lead wire should be as close as possible to the scanning center (for example, placed on the patient) and away from the gantry cover, which can effectively reduce noise interference.

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.**
- **Patients with obvious arrhythmia, valvular insufficiency, pacemaker placement, contrast agent allergy and other special circumstances are not suitable for coronary CT scan.**

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.

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.**

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.

: ECG signal amplitude. When the amplitude of the ECG is too low, the following information will be displayed.

Fig 9-5 ECG Signal amplitude

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.

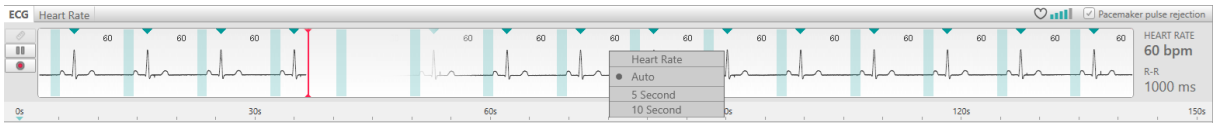


Fig 9-6 ECG Right-click menu

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

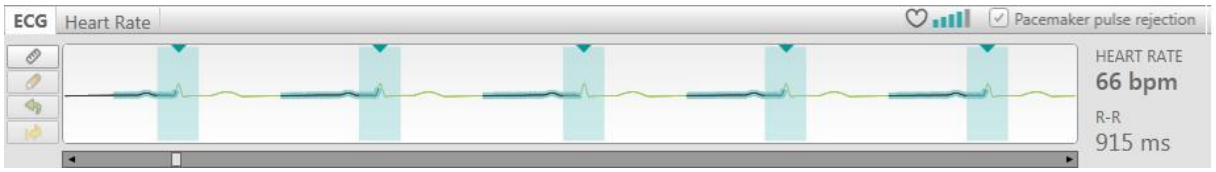


Fig 9-7 HR tab

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

Fig 9-8 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 axial scan and helical scan are identified by light green rectangle.

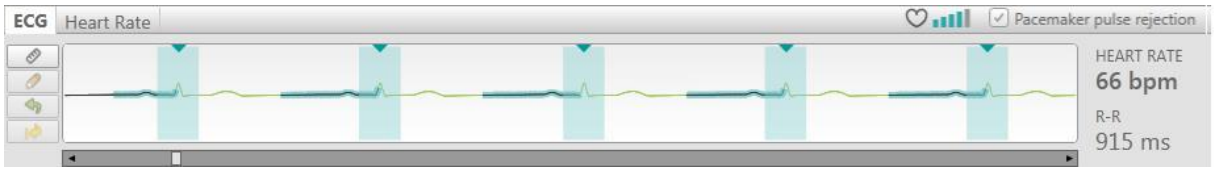


Fig 9-9 ECG high dose, low dose and reconstruction region

9.2.2 Calcium Scoring

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

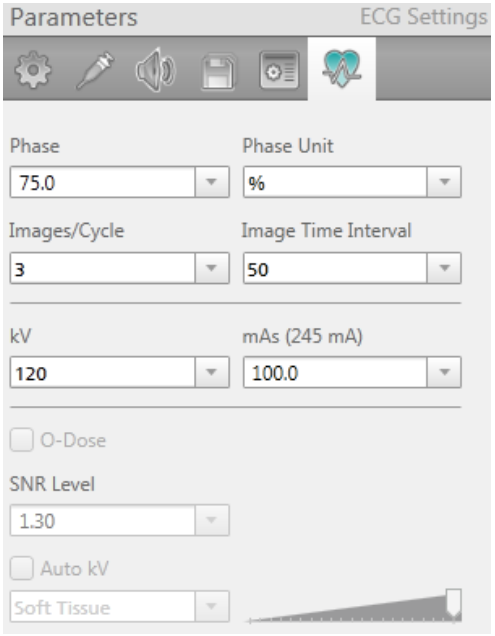


Fig 9-10 Calcium Scoring Parameters

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 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.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:

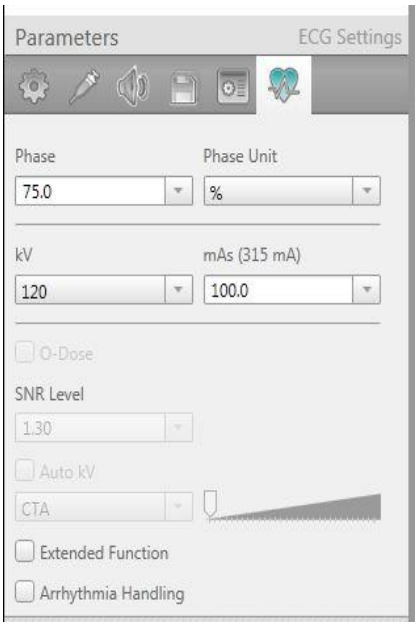


Fig 9-11 Coronary CTA parameters

Phase: To set the cardiac phase of interest.

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, equally spaced 8 and 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(Option)

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, 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.**
- **When selecting the data to export in the Dose Check Log interface, it supports the full selection of the shortcut key Ctrl+A, the Shift+ mouse selects a segment of continuous data, and the Ctrl+ mouse selects multiple discontinuous data. Support exporting to U disk or CD-ROM. The exported data is stored in a file named DoseCheckLog.xml and can be viewed by using IE.**

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:

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

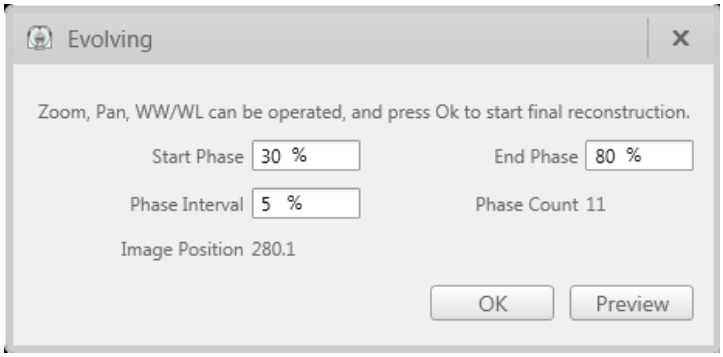


Fig 9-12 Evolving Options

2. Finish scanning, display the demo images.
3. View the images, and click the desire images. Input the **Start Phase**, **End Phase** and **Phase Interval**, and then click **Preview**.
4. View the preview images and choose the optimal images and click **OK** to start final reconstructions.

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

When executing Evolving scan, the Evolving window will pop up as the picture below shows. Operators can right-click in any position of the image. In the right-clicked menu, users can select【Change WW/WL】,【Zoom】and【Pan】to adjust the image as needed. Finish adjusting, then click【OK】. The adjustment results will show in recon sequence.

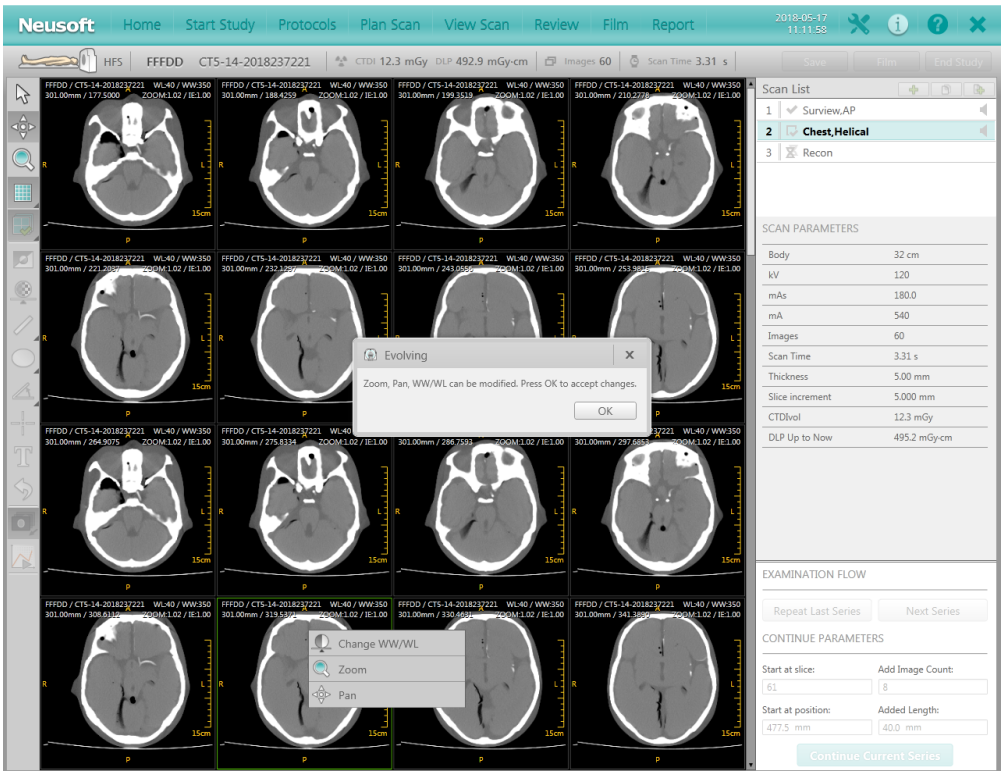


Fig 9-13 Evolving Right-clicked window

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.**

1. From the series directory, select the series.
2. Click **Offline Recon** on the right of the interface. The offline ECG viewer and reconstruction protocols appear.

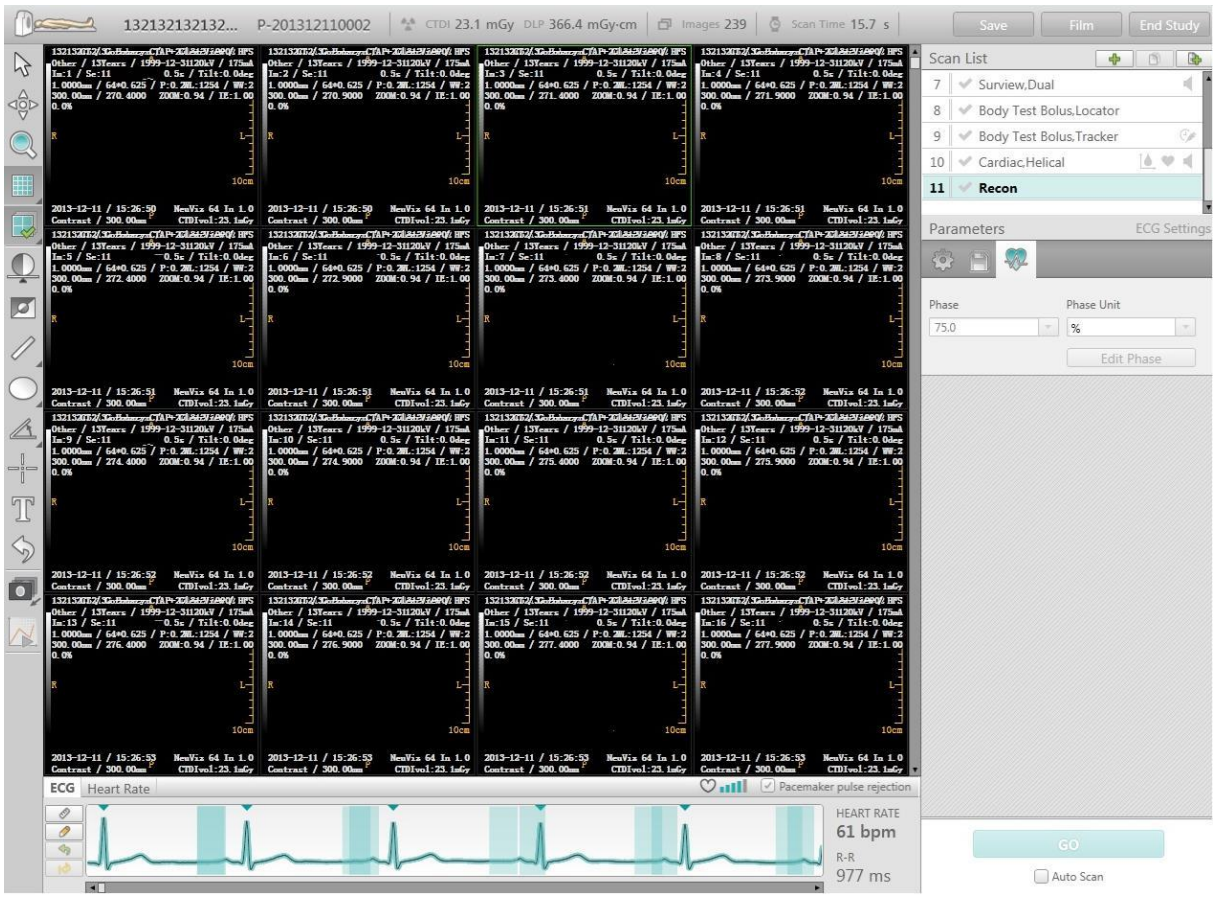


Fig 9-14 ECG Viewer and Reconstruction Protocols

The main function of ECG editing is to allow the R wave tags to be moved to an optimal position (green inverted triangle). 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

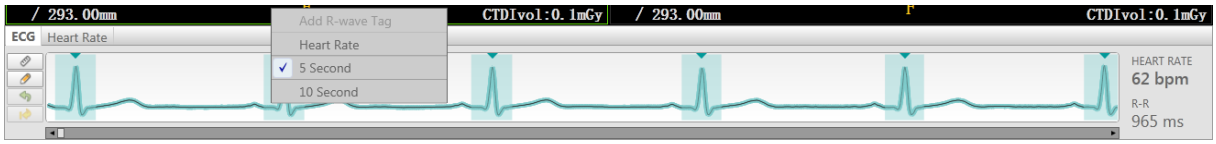


Fig 9-15 R Wave Tag Edit

3. 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.

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.**

4. 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% and 75%）, Equally spaced 8（0,12.5%，25%，37.5%，50%，62.5%，75% and 87.5%）and Optimal S/D phase.

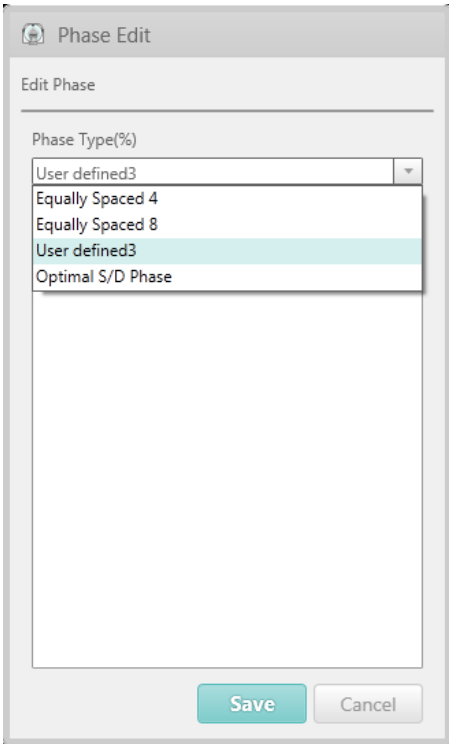


Fig 9-16 Edit Phase

Chapter 10 Recon

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.

- **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.

- **Extended FOV**

When 【Extended FOV】is selected, the maximum field of view is increased to 700mm. Only helical scan protocols of the chest, abdomen and pelvis (except iHD, dual energy and 4D scan protocols) support the【Extended FOV】 function.

- **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.

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.

- **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.

- **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.

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, F80, F90, F95, IAC10, IAC20, Lung10, Lung20, Lung30.**

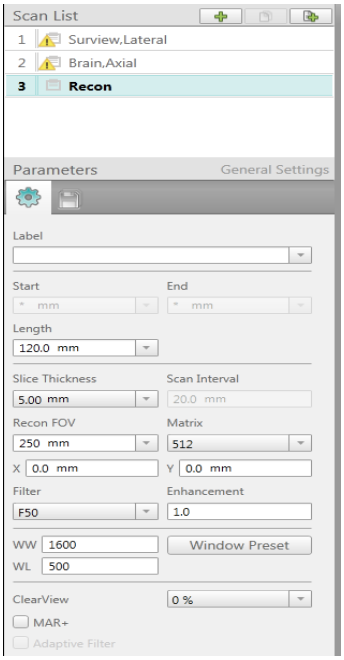


Fig 10-1 MAR+ Page

10.1.4 ClearView(Option)

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.

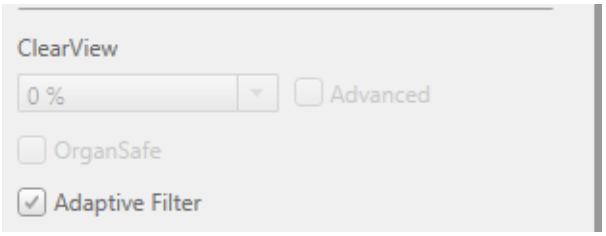


Fig 10-2 ClearView Interface

The user interface is as above; there are 10 ClearView Levels from 10% to 90%. Users

can choose any ClearView level for different dose level. Clearview function involves advanced option. 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%					√	√	√	√	×

10.1.5 ClearInfinity (Option)

10.1.5.1 ClearInfinity Theory

ClearInfinity provides images with lower noise levels, higher clarity and contrast through deep learning technology using specially designed and trained deep neural networks.

Deep learning is a type of machine learning. It simulates the activity of the cerebral

cortex through a deep neural network and a large number of learnable parameters, and trains the neural network through a large amount of data to obtain a model that far exceeds the performance of traditional methods. The ClearInfinity algorithm is a deep learning network dedicated to CT image reconstruction, which consists of dozens of layers and is trained using thousands of real patient data.

The training target is high-quality data, acquired at high dose levels, with low image noise levels and high sharpness and contrast. The input data is low-quality data that uses a physics-based model to simulate from high-dose data to generate near-realistic low-dose data with high noise levels and poor sharpness and contrast. Through supervised learning, the deep learning network learns the relationship between high and low quality images, extracts and removes noise in the images, and improves the image quality. After the learning process, the performance of the algorithm is verified using a large amount of test set data to ensure that the algorithm can adapt to various clinical needs and provide users with high quality images in various scenarios.

ClearInfinity controls the noise retention level through options, allowing users to use a total of 10 options from 0% to 90% for processing. Users can freely adjust the processing amplitude according to personal preference and experience to meet specific clinical needs, but we recommended that users evaluate the image quality level of each option before use, and start the test with the options recommended in table 10-2 below.

The following form shows recommended ClearInfinity 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 10-2 Low dose - ClearInfinity level chosen

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

70%			√	√	√	√	×	√	
80%				√	√	√	√	×	√
90%					√	√	√	√	×

NOTE：

- **When ClearInfnity 0% is selected, no ClearInfnity is applied.**
- **ClearInfinity does not support calcium scoring, CCT, bolus tracking, biopsy and surview scan.**
- **ClearInfinity does not support Evolving.**
- **Images below 0.2mGy have not been tested and image quality cannot be guaranteed, if there are issues, please compare with non-ClearInfinity image reconstruction.**
- **ClearInfinity has not been tested on non-human tissue data such as small animals and cannot guarantee image quality, if there are issues, please compare with non-ClearInifity image reconstruction.**
- **Quantitative analysis of ClearInfinity perfusion applications has not been validated, if there are issues, compare to non-ClearInfinity image reconstructions.**
- **ClearInfinity may cause changes in the shape of the metal in the image, if there are issues, compare to non-ClearInfinity image reconstructions.**
- **When using the ClearInfinity high level, you may see a reduction in contrast for small structures. If a problem area is found, it should be rebuilt using ClearInfinity low level.**
- **ClearInfinity cannot be used simultaneously with ClearView.**
- **Although users can select any ClearInfinity level from 10% to 90% for different dose level, we propose to select appropriate ClearInfinity level according to different dose level.**
- **In clinical practice, the use of ClearInfinity reconstruction may reduce CT patient dose depending on the clinical task, patient size, and clinical practice.**

10.1.5.2 ClearInfinity Reconstruction Overview

ClearInfinity is a CT image reconstruction technology based on deep learning, which uses deep learning convolutional neural networks to achieve image noise reduction and image quality optimization.

The ClearInfinity algorithm uses the deep learning network model to process the intermediate image after preliminary reconstruction by FPB to obtain a high-quality intermediate image, and then obtains a high-quality reconstructed image through algorithm such as weighting and recombination.

Before using ClearInfinity, on-site physicists and radiologists should use different levels of ClearInfinity to jointly evaluate image quality. It is recommended to use ClearInfinity at the recommended level in table 10-2 on the basis of your existing clinical program.

ClearInfinity is not compatible with the following scan types:

- plot;
- locator;
- tracker
- CCT
- Calcium Scoring Cine;
- Biopsy

ClearInfinity is compatible with the following Slice Thickness:

- Helical, 4D not less than 0.4mm;
- Axial greater than 0.3125mm;
- 3D Axial not less than 0.625mm;

ClearInfinity has no requirements on the image increment.

10.1.5.3 ClearInfinity Reconstruction

Prospective reconstruction

1. Prescribe a plan scan on Home;
2. Enter the scan plan interface, click Advanced ;
3. Select the ClearInfinity option and select the corresponding image reconstruction level according to the percentage of scan dose reduction as the following figure;
4. Edit scan parameters as needed;
5. Click **Go** to start scan.

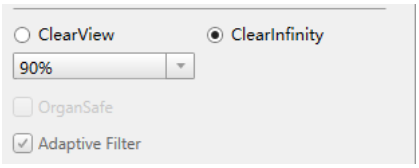


Fig 10-3 Selected ClearInfinity

Retrospective reconstruction

1. Select the sequence that needs to be reconstructed offline on the Home;

2. Click  to enter offline reconstruction;

3. Select the ClearInfinity and the corresponding image reconstruction level according to the percentage of scan dose reduction;

4. Edit reconstruction parameters as needed;

5. Click Start to perform offline reconstruction;

10.2 Offline Reconstruction

1. 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.

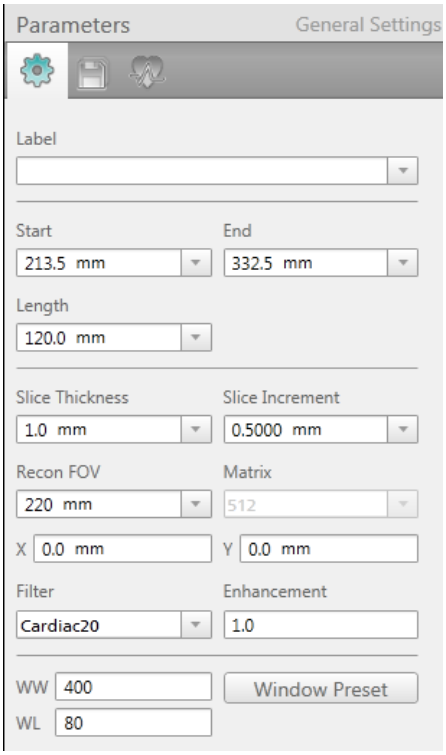


Fig 10-4 Offline Reconstruction

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.

2. 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.**

3. 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 desire 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.

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.

- 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
- Patient Position
- Target Scan Part

NOTE:

- **The target scanning part can be set to the part that the current protocol actually needs to scan, or it can be set to some continuous scanning parts, such as "Cephalothoracic Scanning". The target scan part is the basis of Intelligent Positioning to identify parts.**

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.
- **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.**

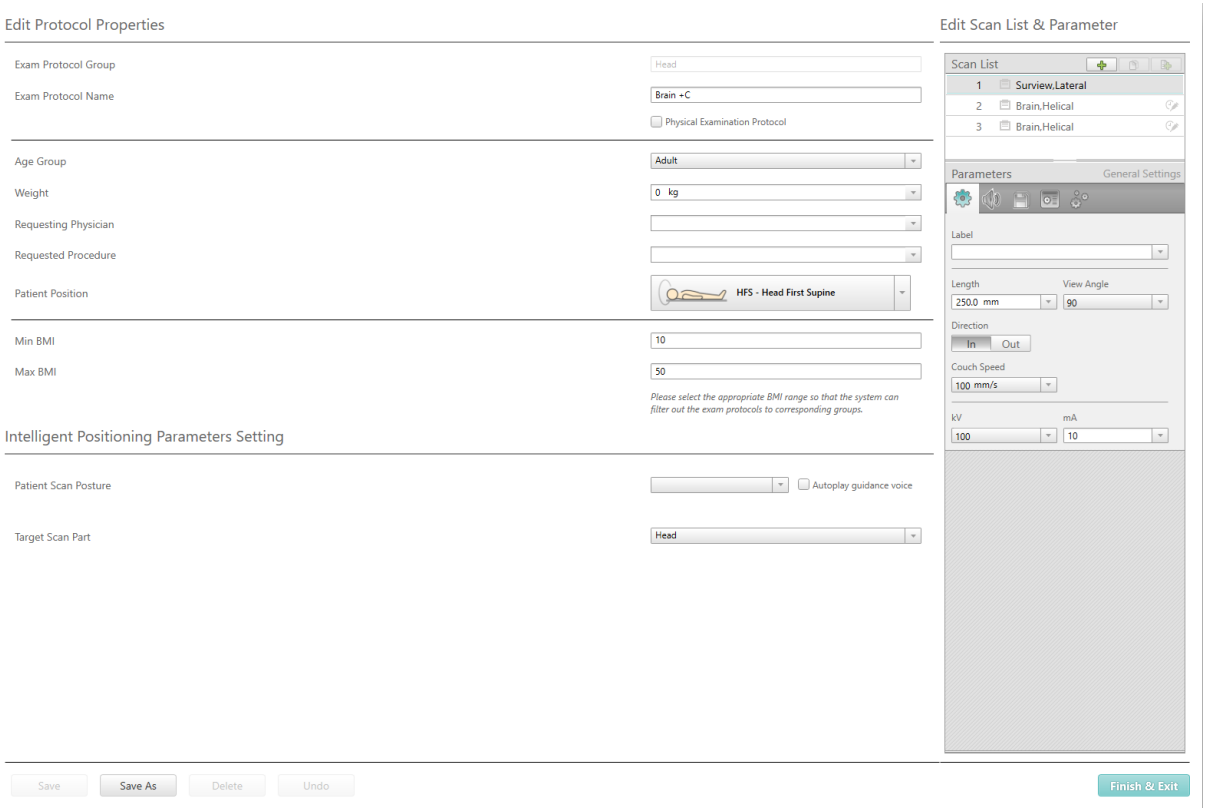


Fig 11-1 Physical Examination protocol

11.1.2 Export Protocols

This function is used for exporting the factory protocols and user protocols.

1. Click **Service** in the workflow bar.
2. Select **Protocol Edit**. The exam protocol groups display.
3. Select **Export Protocols**. The Export Protocol Form dialog box displays.

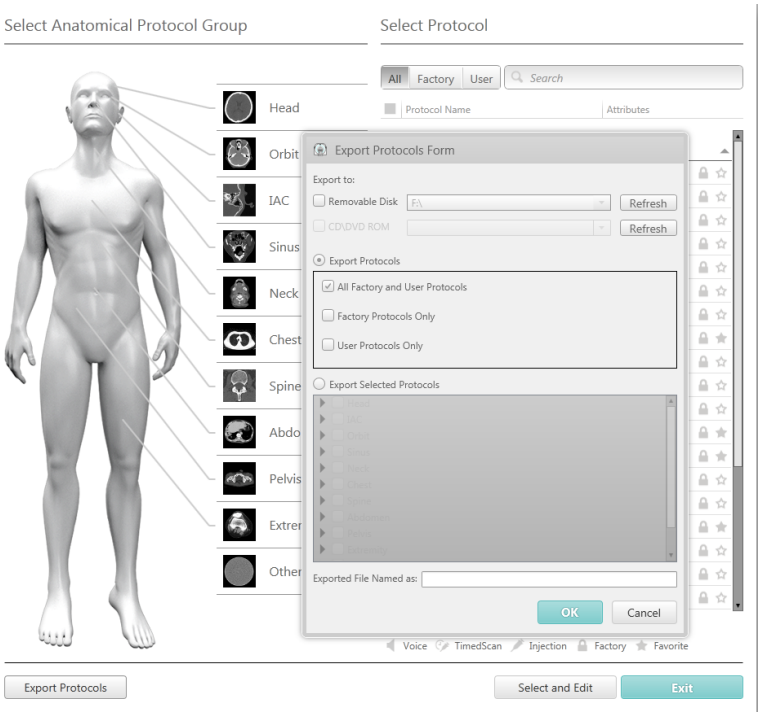


Fig 11-2 Export Protocols

4. Manipulate the export destination and protocols and name the Exported File. After all parameters in that window are correct, click **OK**.

5. View the exported protocols after the process completed.

Protocol Transfer Function:

Applicable Devices

- Protocols can be imported and exported between devices of the same product model or the same series of our company, such as 64In and 64i, 64En and 64e.

Protocol transfer tools

- USB storage facilities and hard/light disks all can be used to import or export protocols.

NOTE:

- **Protocols cannot be imported or exported when the software is running.**

Add protocol export progress bar

- Progress bar displays in the process of exporting protocol, and the exporting file name displays below the progress bar.

11.2 System Settings

11.2.1 Disk Cleanup Setting

Click **Disk Cleanup Setting** in system setting page to enter the following interface:

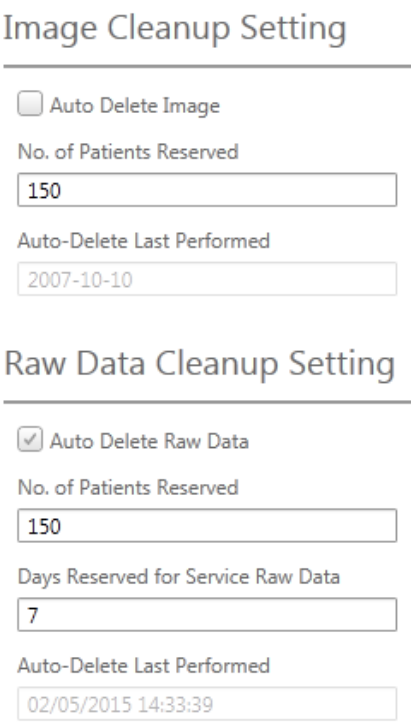


Fig 11-3 Disk Cleanup

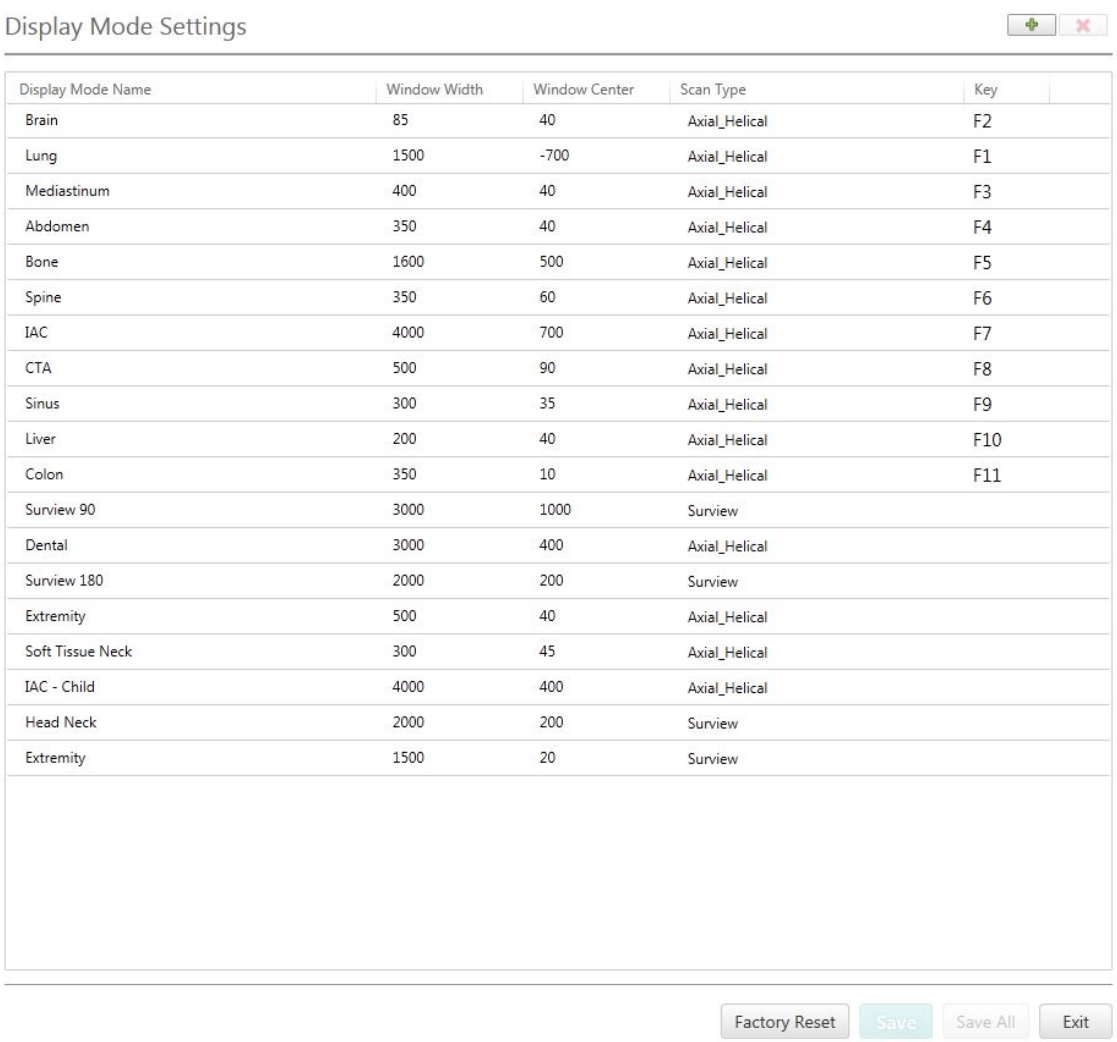
Disk Cleanup can automatically delete unlocked patients' raw data, and then clean up the disk. **No. of Patients Saved** can be set through **Auto Delete Raw or Auto Delete Image** in **System Setting**. The raw data or image data deletion will start once the limitation is met.

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.**

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 Registration Setting

Click **Patient Registration Setting** in system setting page to enter the following interface:

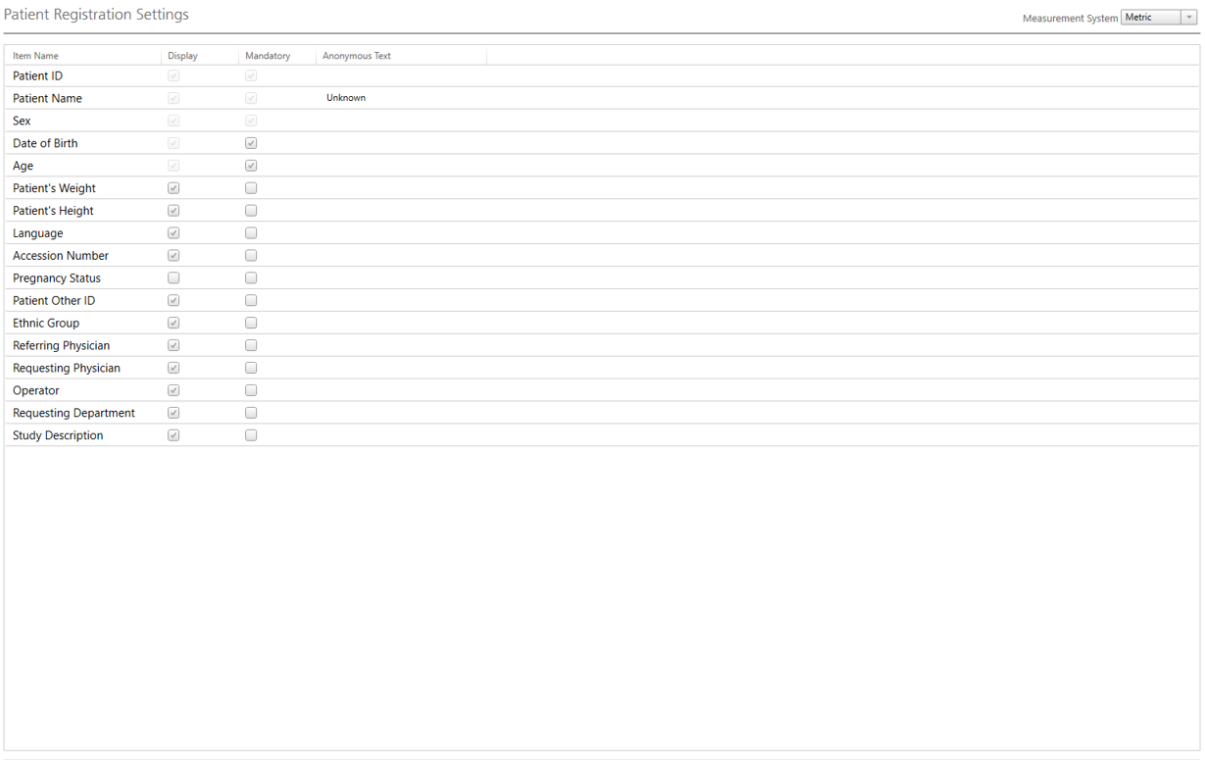


Fig 11-5 Patient Registration Setting

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.

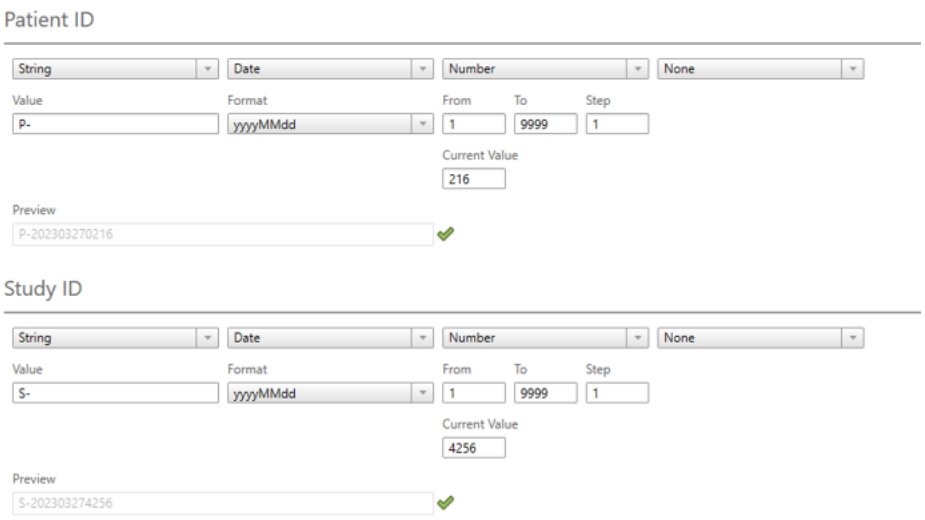


Fig 11-6 ID Generator Setting

11.2.5 Voice Setting

Click **Voice Setting** in system setting page to enter the following interface:

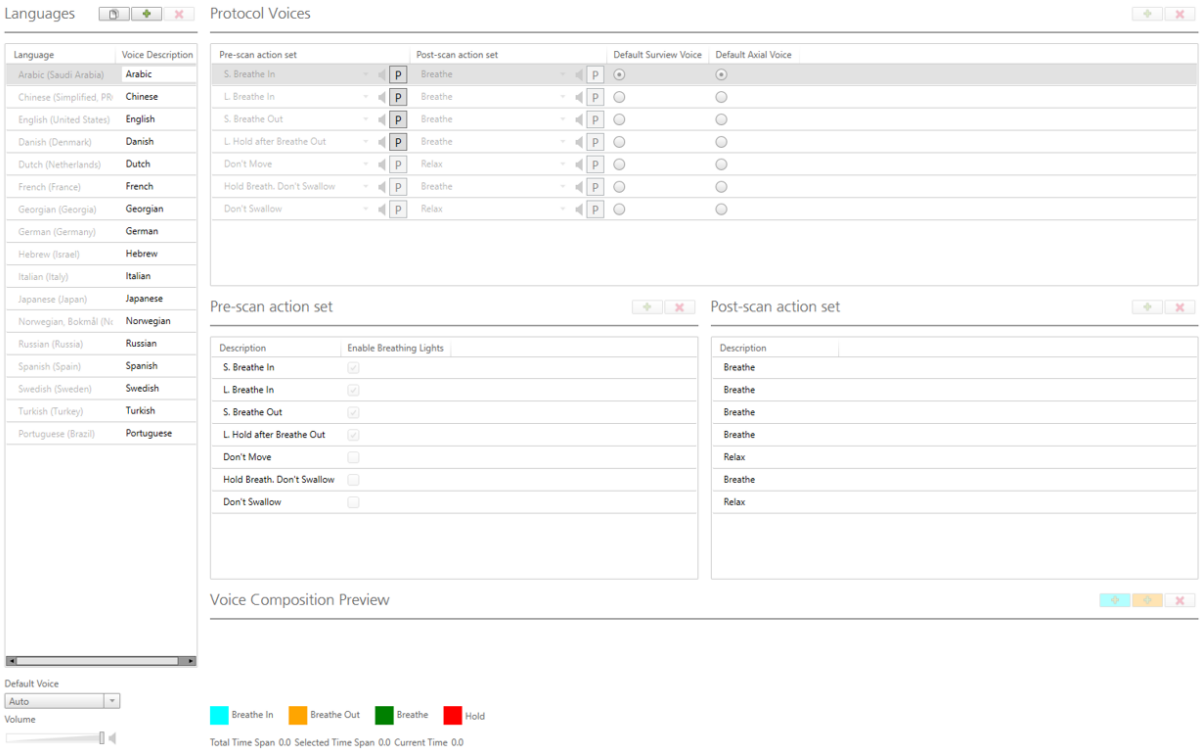


Fig 11-7 Auto Voice Setting

In Auto Voice Setting, user can record new voice, set up default voice and edit protocol voice, etc.

- **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:

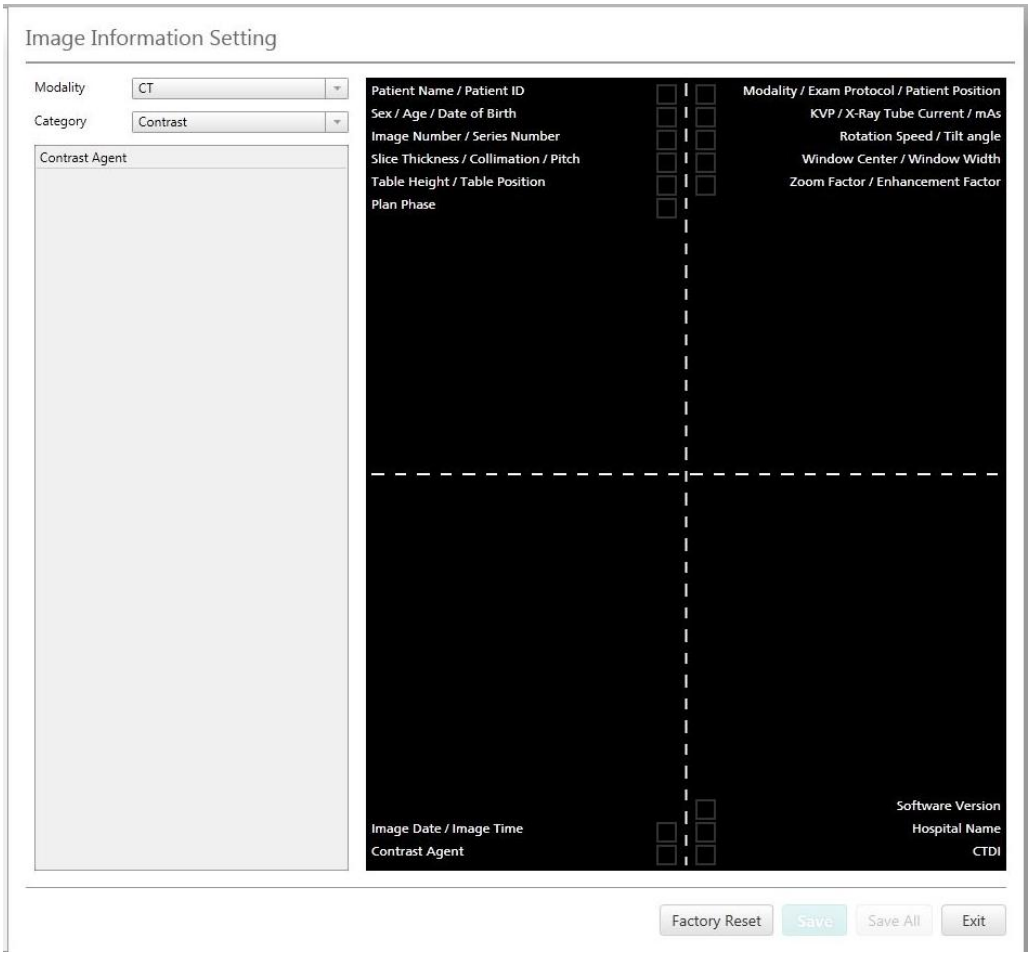


Fig 11-8 Image Information Setting

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.

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 Tube Heat Setting

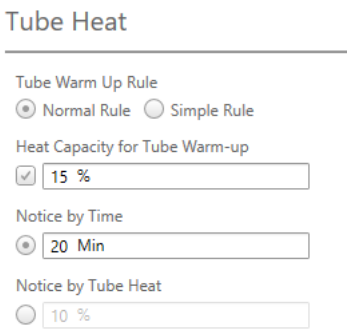


Fig 11-9 Tube Heat Setting

Heat Capacity for Tube Warm-up：User can set up heat capacity for tube warm-up. When tube heat achieved the preset value, tube warm up will auto stop. Default heat capacity is 15%.

Notice by Time：User can set up a notice time before tube heat decreasing to a certain percentage. Time setting range is from 10 Mins to 60 Mins.

Notice by Tube Heat：User can set up a notice threshold value. When tube heat achieves the value, a prompt will pop up to warn user to warm up tube. Tube heat setting range is from 10% to 15%.

NOTE: Notice by time and notice by tube heat are limited as alternative.

11.2.7.2 Recon

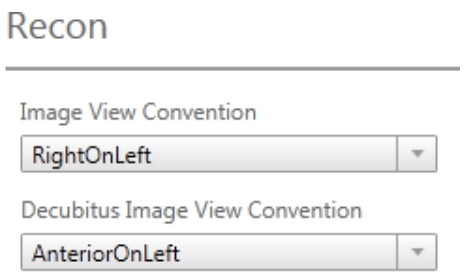


Fig 11-10 Image view convention

- **Image View Convention:**
  - Right on Left
  - View from Bed
  - View from Feet
- **Decubitus Image View Convention:**
  - Anterior on Left
  - View from Bed
  - View from Feet

11.2.7.3 Dose Check

Dose Check alerts you when the estimated dose index is above the limit set by the operating group, practice, or institution. Dose Check complies with the NEMA XR-25 standard.

Dose Check creates awareness of the dose index of the prescribed scan, and launches a notification if the dose index is above the limit. The notification is set at a level above routine or normally expected doses, but not so high as to pose a significant risk to the patient. Depending on patient size or imaging requirements, it may be appropriate to scan at a value above the Notification Value (NV).

Notification Values are not necessarily the same as the published Diagnostic Reference Levels (DRLs). However, these may be consulted as a guide to determine the appropriate NV for your site and patient population. Because routine scanning does involve a range of applicable techniques due to patient sizes and imaging needs, another consideration on where to set the notification level will be the frequency in which your practice would want it posted.

Before using Dose Check, the site physicist, and/or radiation safety officer in collaboration with the radiologist, should understand the current dose levels of site scanning protocols and the maximum dose limit at the site's clinical practice. Using this

information, an appropriate starting point for the Notification Value for each protocol and system Alert Value should be set.

Guidance from such bodies as the American College of Radiology (ACR), US Food and Drug Administration (FDA), European Union (EU), International Commission on Radiological Protection (ICRP) and American Association of Physicists in Medicine (AAPM) may be useful in determining Notification and Alert values. The AAPM Working Group on Standardization of CT Nomenclature and Protocols has published a list of reference Notification values based on anatomical location. These can be found at www.aapm.org.

Before starting the scan, the dose rate ($CTDI_{vol}$ in mGy per second) is displayed on the monitor. During the CT Scan, the accumulated dose ($CTDI_{vol}$) reflecting the patient exposure is displayed on the monitor. The display scale ranges from zero to 3000mGy. If the table is shifted during the exam, the accumulated dose will be distributed to different slices and will be lower than indicated by the display. When a new scan is loaded, the dose display again starts from zero.

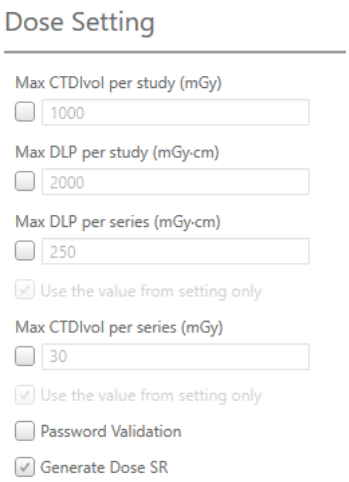


Fig 11-11 Dose Setting

Alert Value (AV):

- **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 Dose Alert prompt will pop up.

Notification Value (NV):

- **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 Dose Notification prompt will pop up. If 【Use the value from setting only】 is checked , system will ignore the max $CTDI_{vol}$ 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【Use the value from setting only】 is checked , system will ignore the max $CTDI_{vol}$ value in the protocol but use the max limited value.

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.

When CTDI and DLP value per series exceed the notification value, the CTDI and DLP value will turn red, and the Dose Notification prompt will pop up. In most cases, you will click【Return】to go back to adjust parameters. If there is a true diagnostic need to perform a scan exceeding NV value, enter the diagnostic reason, then click【Continue】.

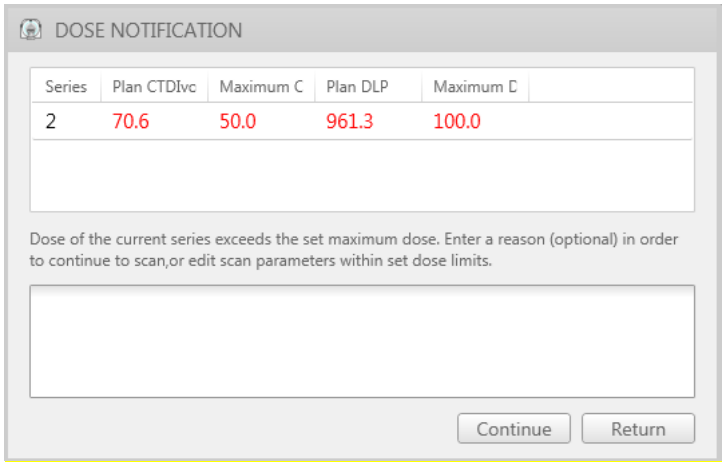


Fig 11-12 Dose Notification

When the CTDI and DLP of a study exceed the Alert Value, the CTDI and DLP value will turn red, and the Dose Alert prompt will pop up. Performing a scan exceeding an AV value demands a high degree of consideration for appropriateness. In most cases, you will click【Return】to go back to adjust parameters. If there is a true diagnostic need to perform a scan exceeding AV value, enter the operator name and diagnostic reason, then click【Continue】. If the password validation in dose setting is checked, users also need to enter the password.

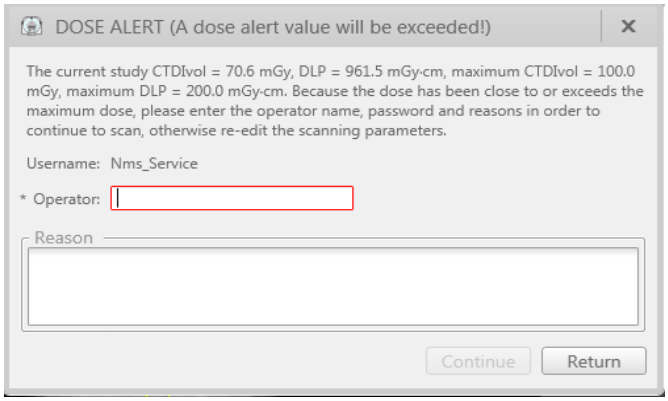


Fig 11-13 Dose Alert

In the protocol edit page, users can set the Max $CTDI_{vol}$ and Max DLP for each protocol respectively. However, if【Use the value from setting only】in dose setting page is checked , system will ignore the max $CTDI_{vol}$ value in the protocol but use the max $CTDI_{vol}$ value per series and DLP value per series in dose setting page.

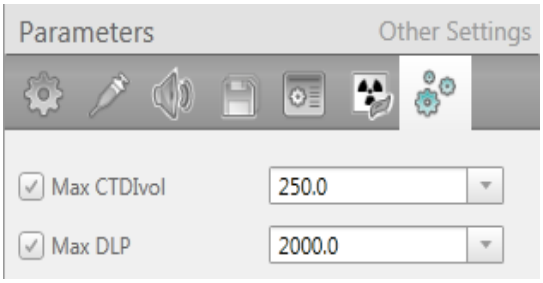


Fig 11-14 Max $CTDI_{vol}$ setting in Protocol Edit

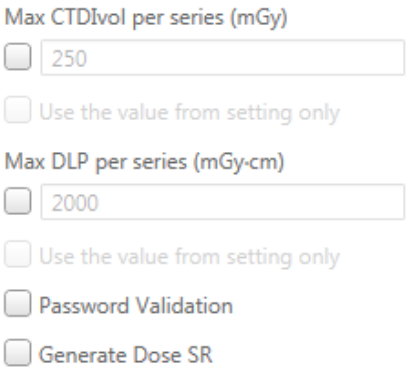


Fig 11-15 Max $CTDI_{vol}$ setting in Dose Setting

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.**

When a scan's CTDI and DLP value exceed NV or AV value, the details of the scan will be recorded in the Dose Check log.

The protocol exported will display the dose check value and whether the dose check function is opened.

Check Dose Alert CTDIvol	On
Dose Alert Max CTDIvol	100
Check Dose Alert DLP	On
Dose Alert Max DLP	200
Physical Examination Protocol	No

Fig 11-16 Protocol Dose Check

11.2.7.4 Options

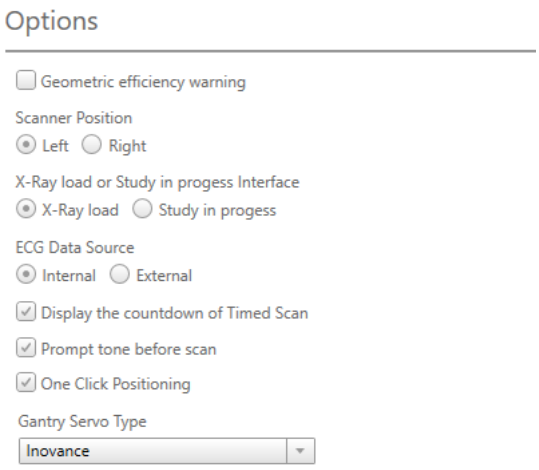


Fig 11-17 Options

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
	Small and Large
128*0.625(ZDFS)	86.46
64*0.625	91.97
64*0.625(ZDFS)	76.57
40*0.625	87.77
32*0.625	85.10
32*0.625(ZDFS)	62.71
24*0.625	81.12
20*0.625	78.20
16*0.625	74.03
16*0.625(ZDFS)	46.70
16*0.625(ZDFS+iHD+3D)	47.16
16*0.625(ZDFS+iHD+2D)	46.14
12*0.625	68.17
8*0.625	58.85
8*0.625(ZDFS)	31.97
8*0.625(iHD+3D)	60.82
8*0.625(iHD+2D)	59.06
4*0.625	41.73
2*0.625	46.61

- **Geometric efficiency warning**：Under different collimation and different utilization rate of the scanning dose, select this function will prompt the user when scanning collimation is changed and display the utilization 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.
- **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.

11.2.7.5 Contrast Setting

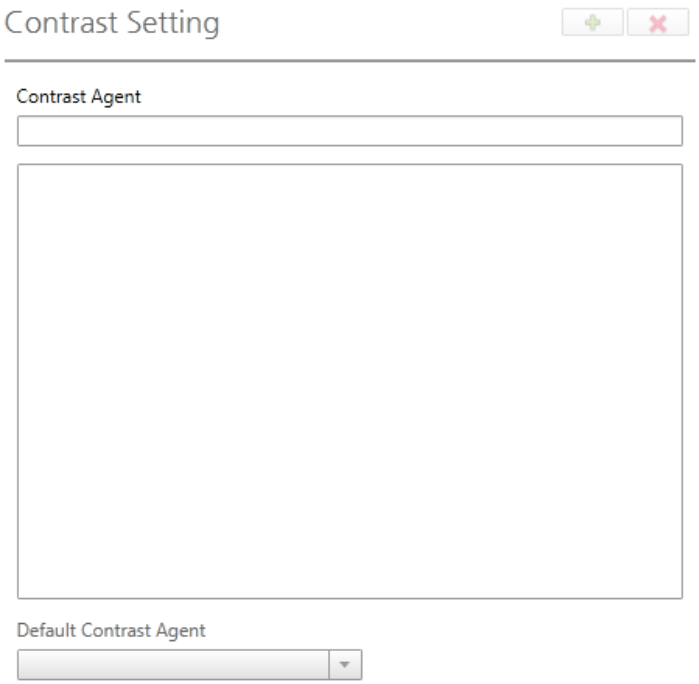


Fig 11-18 Contrast Setting

- **Contrast Agent**: User can add and delete contrast agent in the textbox.
  - 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.

11.2.8 Remote Service

Click **Remote Service** in system setting page to enter the following interface.

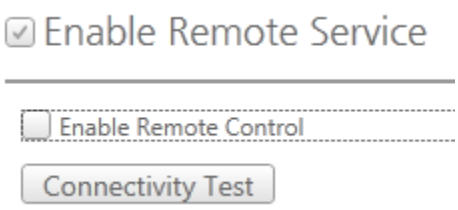


Fig 11-19 Remote Service

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 Local Made, click 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 Intelligent Positioning

After the camera is installed, the Intelligent Positioning is checked, the intelligent positioning is enabled:

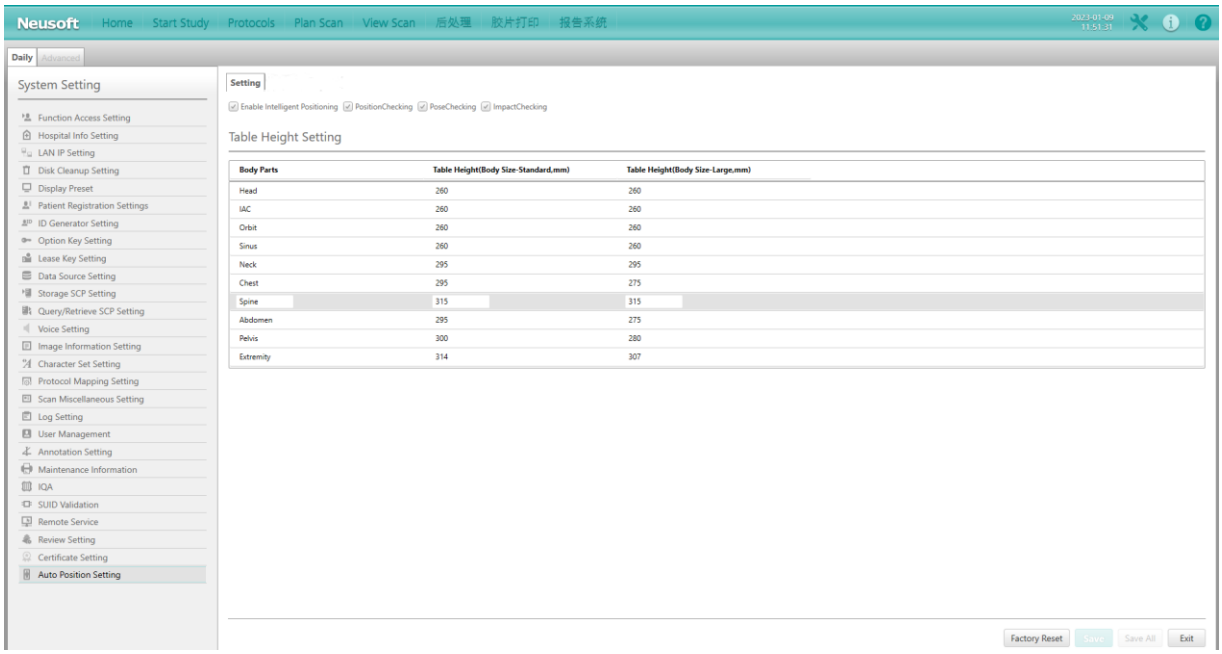


Fig 11-20 Intelligent Positioning

In this interface, you can choose to enable or disable the intelligent positioning, position checking, pose checking and impact checking. Restart the software to take effect. At the same time, it is also possible to set the height of the couch for standard body and fat body. Headers for standard and large can be edited, such as “Adult”and “Paediatric”. After modifying and restarting the software, the new header can be reflected on the Bodysize Button on the page of Plan Scan.

11.3 Data Deletion

In daily settings, click data deletion and the system will delete data and cleanup disk as disk cleanup settings.

NOTE:

- **Before deleting the original data, ensure that any necessary reconstruction is available for final diagnosis.**

11.4 Scan Virus

Click **Scan Virus** in system setting page to enter the following interface:

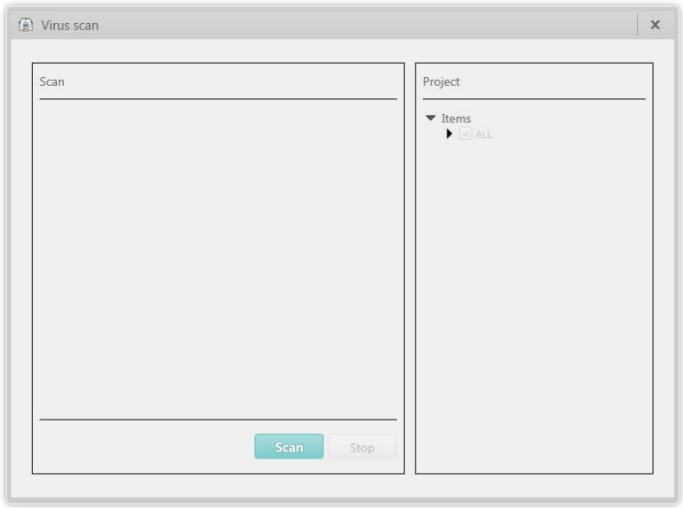


Fig 11-21 Scan Virus

Virus scan function uses a third software AntiVirus to scan disks.

11.5 Change User

Click **Change User** in daily setting page. Click OK to change a user. The following interface will pop up.

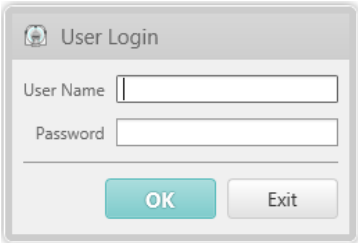


Fig 11-22 Change User

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.**
- **Save data before switching users.**

11.6 Exit

Click **Exit** in daily setting page. The following interface will pop up. Click Yes to end study.

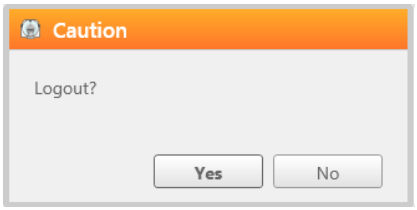


Fig 11-23 Exit

11.7 Access Controls

11.7.1 Overview

Today, most countries have enacted data privacy laws to protect against the unauthorized access and use of health information.

Examples of global privacy laws are:

- Health Insurance Portability and Accountability Act (HIPAA)
- Directive 95/46/EC on Data Protection (Data Protection Directive)
- Personal Information Protection and Electronic Documents Act (PIPEDA)
- NEMA XR 26-2020 Access Controls for Computed Tomography: Identification, Interlocks and Logs

Neusoft has a long-standing reputation for providing customizable, clinical solutions that protect the privacy and security of your organization's unique clinical workflow, as well as your patient's confidentiality.

Make sure to understand the intended use of the product when determining privacy risk relative to patient care and safety. Neusoft is very concerned with providing the best care to patients, and in some cases, we have determined that patient care is more important than the risk to privacy. In these cases, Neusoft takes every precaution to minimize privacy risk.

Security and privacy are maintained across a healthcare system. Any product that is placed into an uncontrolled environment will not be secure and cannot protect privacy. Neusoft designs systems to be implemented in a "secure environment". A secure environment is based on multiple layers of security, a concept known as "defense in depth".

For example, a best practice is to place firewalls between departments, as well as at a DMZ (Demilitarized Zone) between all extranets, and the external internet access point. In this example, a radiology firewall may allow DICOM and HL7 protocol traffic through, but no other protocols. These DICOM and HL7 protocols would be blocked at the DMZ and again at the internet firewall.

11.7.2 Users Management

11.7.2.1 Privilege Levels and Factory Users

In the system setting page, users can manage CT functions listed under users in the User Management settings. User names cannot be repeated. Neusoft systems have 10 privilege levels and 10 factory users representing each level. High level user can see and operate users lower or equal his level after logging in. The changes and the operator will be recorded in the log file. 10 privilege level factory users and corresponding passwords are as followed:

1) Nms_Expert ----------Expert_only
2) advancedengineer---------advancedengineer
3) ctmanu----------manu
4) Dealer----------Dealer
5) Nms_Service--------Service_only
6) O-Level---------O-Level
7) trialuser----------trialuser
8) Admin----------Doctor
9) User----------ct
10) Emergency---------no passwords

NOTE:

- **Emergency user cannot be created or modified, factory user is fixed.**

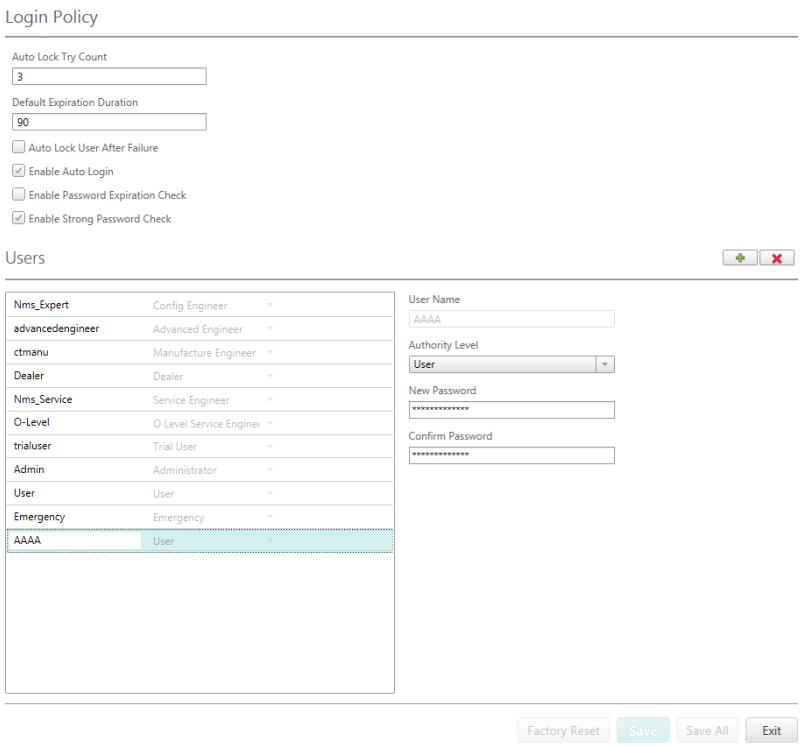


Fig 11-24 User management

11.7.2.2 Login Policy

Users can set login policy in user management part.

1. Users can set auto lock try count themselves, the factory setting is 3. After check the 【Auto Lock User After Failure】, the user whose failure login time exceed the count will be locked.
2. Default expiration duration can be set by users, the factory duration is 90 days. After check 【Enable Password Expiration Check】, the system will prompt user to change login password after password aging.
3. After checking 【Enable Strong Password Check】,the lowest standards for logging password are at least one capital or lowercase, two figures and the length should not be less than 8 characters.

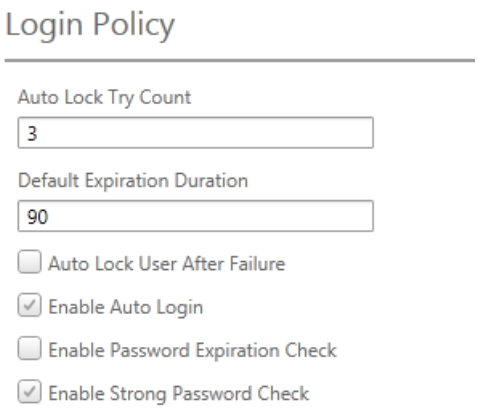


Fig 11-25 Login Policy

11.7.2.3 Create and Delete Users

Operators can add new user which privilege level lower or equal to the login operator by clicking, and delete user by clicking.

NOTE:

- **Factory user cannot be deleted.**

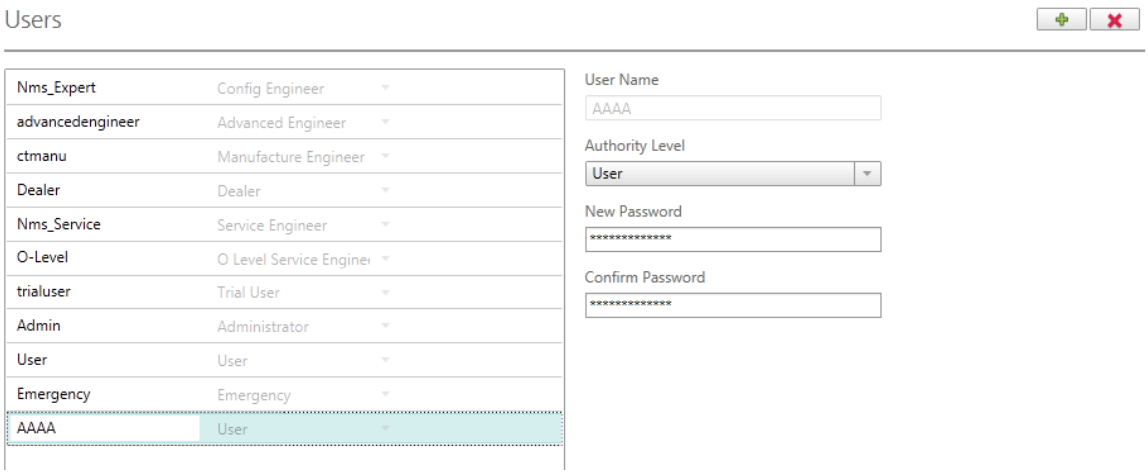


Fig 11-26 Users

11.7.2.4 Modify User Password

Click the user which password need be modified, input new password and confirm it, then click save to finish password changing.

11.7.2.5 Function Access Setting

Users can set function's modify level and access level in Function Access Setting page.

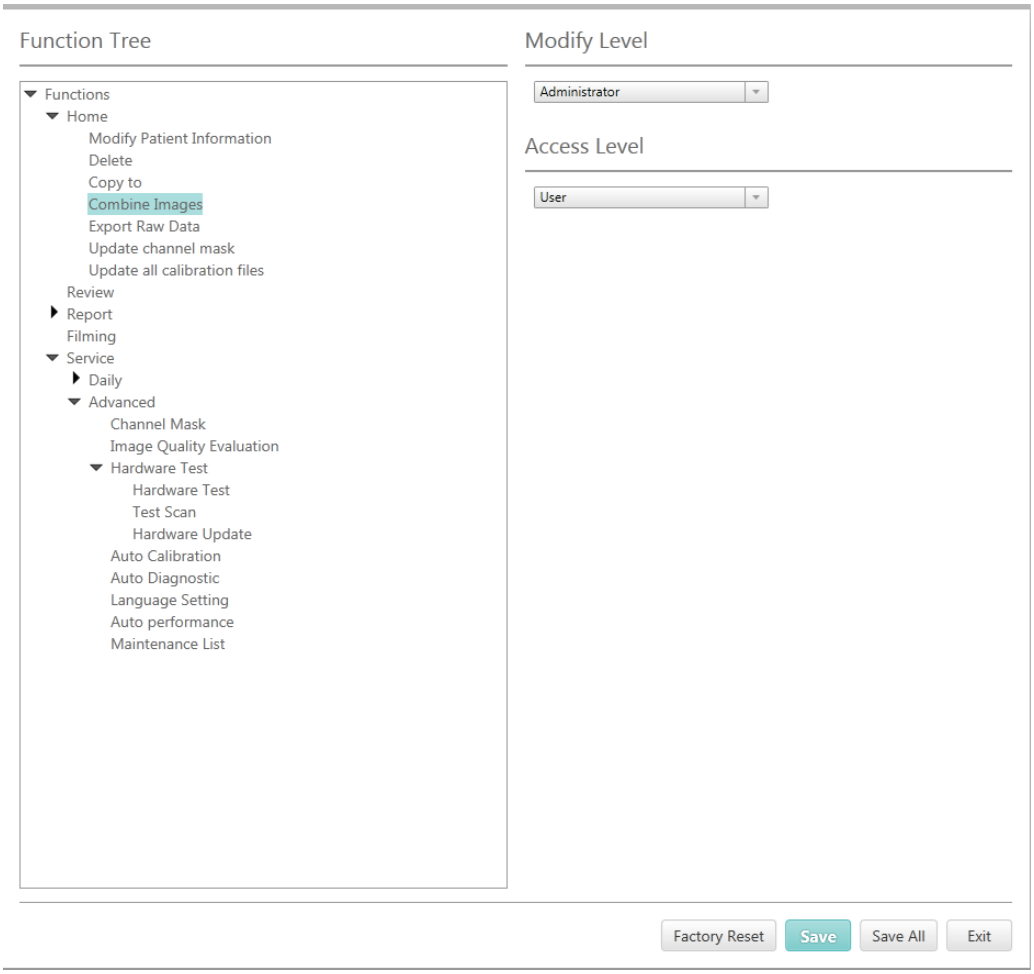


Fig 11-27 Function Access Setting

11.7.2.6 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.

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 three portions: head physical layer, head water layer and body water layer, as shown in the figure below.

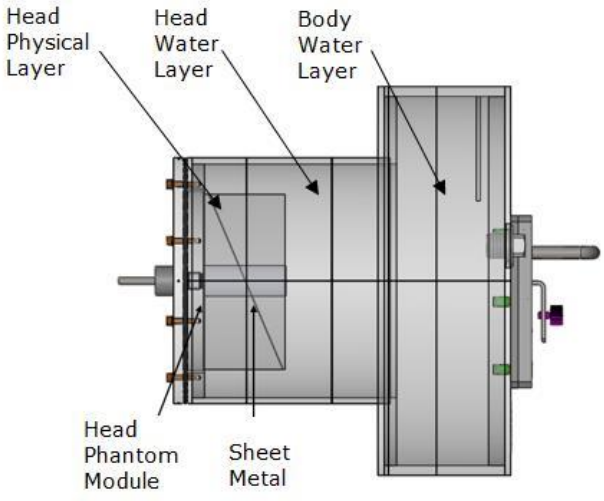


Fig 12-1 QA Phantom Composition

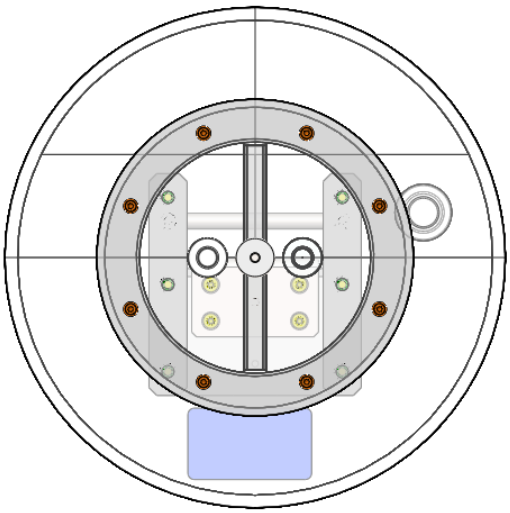


Fig 12-2 QA Phantom Vertical View

Table 12-1 Phantom Composition

Phantom Layer	Function	Composition	Instruction
Head Physical Layer	Linear measurement	One linear measurement	
	Slice thickness measurement	Tilt Aluminum	
	Air separation measurement	Fine copper wire	
	Positioning accuracy measurement	Positioning balls	
Head Water Layer	CT value, CT Value uniformity, noise, low contrast resolution	Purified water	Measured by statistical methods in water layer
Body Water Layer	CT value, CT Value uniformity, noise	Purified water	

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 12-2 QA test items and requirements

Check Item	Scan Position	Phantom	Check Range	QA Test Frequency
Noise	Head	Water Layer	4.8~6.4	Daily
	Body	Body Layer	12.3~16.7	Daily
Mean CT values	Head	Water Layer	±4HU	Daily
	Body	Body Layer	±6HU	Daily
CT value Uniformity	Head	Water Layer	±4HU	Daily
	Body	Body Layer	±8HU	Daily
Low Contrast Resolution	Head	Water Layer	2.9~8.6	Daily
Tomographic Section thickness	Head	Water Layer	(2mm,+∞),±1.0mm [1mm,2mm],±50% (-∞,1mm),±0.5mm	Monthly
Spatial Resolution(MTF)	Head	Physics Layer	5.4~7.4 lp/cm @10% 3.1~4.6 lp/cm @50%	Monthly
	Body	Physics Layer	4.7~6.4 lp/cm @10% 2.6~4.1 lp/cm @50%	Monthly
Contrast Scale	Head	Acrylic	100~135HU	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.**
- **The user must be well trained before performing QA test.**
- **The Mean CT values, CT value Uniformty and noise were given based on typical adult head and body conditions(120kV).**

12.2.3 Positioning the System Test Phantom (Reference 21 CFR 1020.33(d)(2))

Before performing phantom image quality test or consistent 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. Adjust the position of the phantom so that the system phantom is located in the

center of the scanning FOV.

3. Manually control the Couch height so that the outside laser marker is set to the center of the phantom.

4. 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 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. Refer to 12.2.3 for phantom placement.

2. To start the test, select **QA** in Daily of Service. The QA test interface appears:

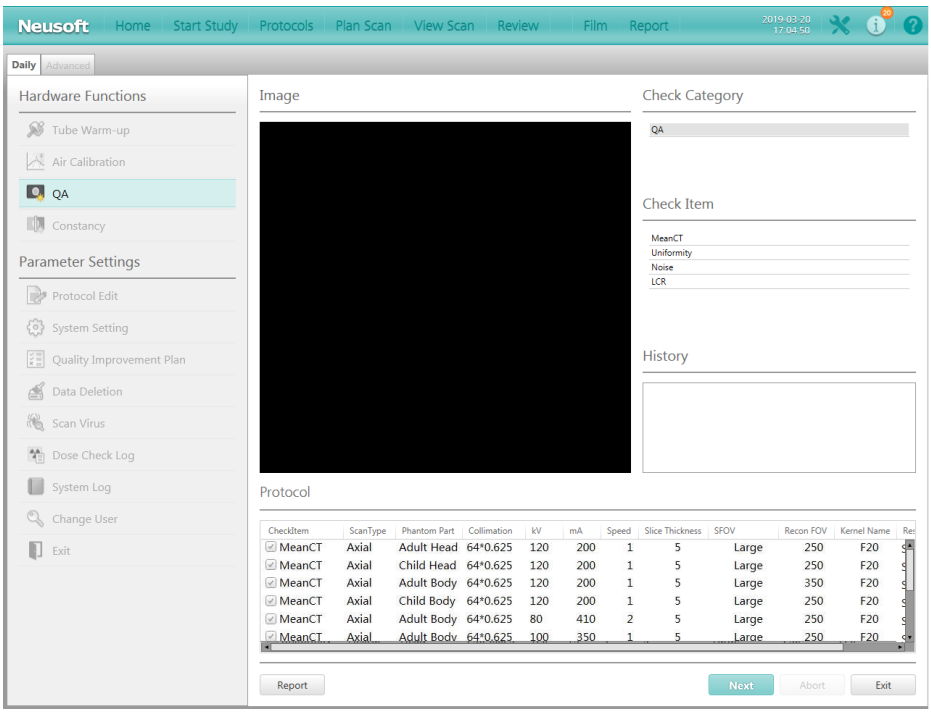


Fig 12-3 QA test

3. Click **Next** to continue.

4. Confirm the content of the prompt and then click **OK**.

5. The content of the test will be displayed in the history. If the position of the phantom is not accurate, the system will prompt how to adjust the phantom and end the test. Adjust the phantom position according to hints in the history, and then repeat steps 3 and 4.

6. 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. Orange is testing.

7. When the tests are completed, the QA report is generated automatically and saved. To view the report, click Report button. The test report can be printed or recorded.

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(according to Reference 21 CFR 1020.33(c)(3)(V)), 0.56%, suggested scan condition is Head STD-QA protocol: 120 kV,200 mA, 1s, 64*0.625mm，FOV250, F20,5mm.

For body QA phantom, 1.45%, suggested scan condition is Body STD-QA protocol: 120 kV, 200 mA, 1s, 64*0.625mm, FOV350, F20, 5mm.

Divide SD by 1000 and multiply by 100 to convert it to a percentage.

$$\text{Noise (\%)} = \frac{SD}{1000} \times 100$$

The measured Noise values should not deviate from the specified nominal values by more than the values listed below:
For Head Scan conditions: 0.56%±0.08%
For Body Scan conditions: 1.45%±0.22% (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:

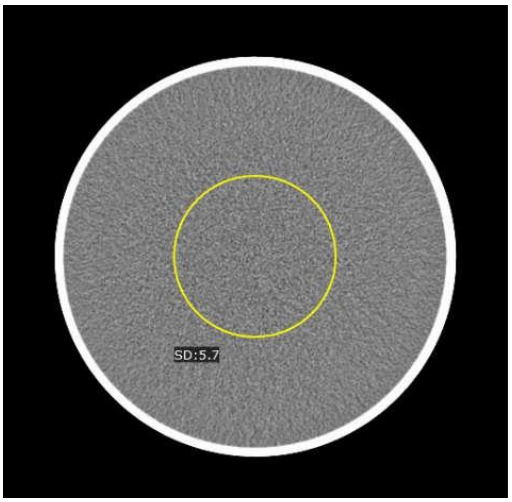


Fig 12-4 Noise Measurement of Water Phantom Using Head STD-QA Protocol

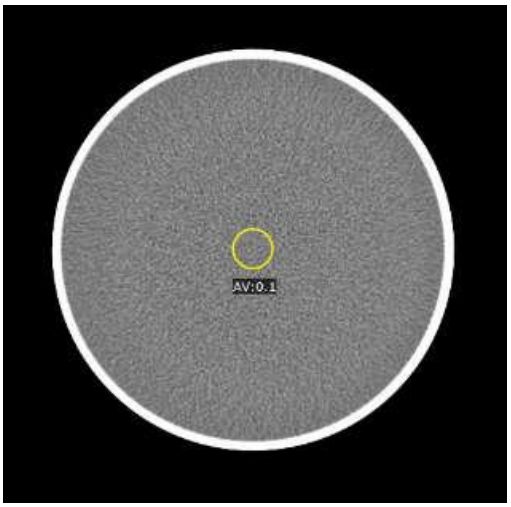


Fig 12-5 Noise Measurement of Body Phantom Using Body STD-QA Protocol

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.

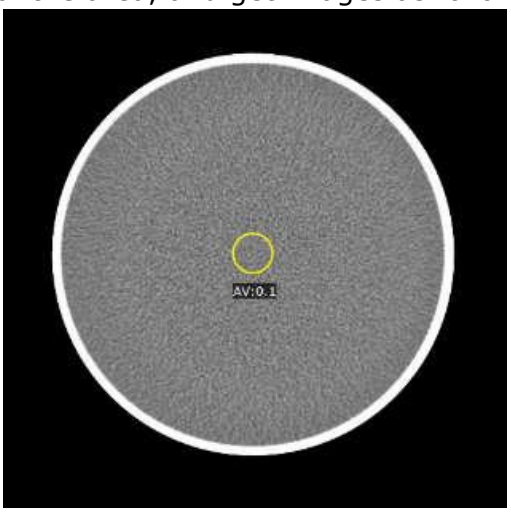


Fig 12-6 CT Value Measurement of Water Phantom Using Head STD-QA Protocol

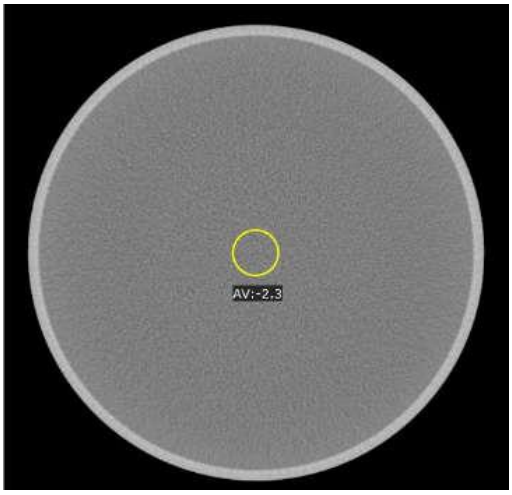


Fig 12-7 CT Value Measurement of Body Phantom Using Body STD-QA Protocol

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.

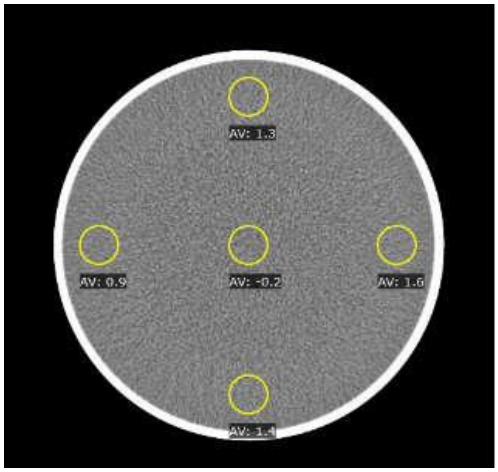


Fig 12-8 CT Value Uniformity Measurement of Water Phantom Using Head STD-QA Protocol

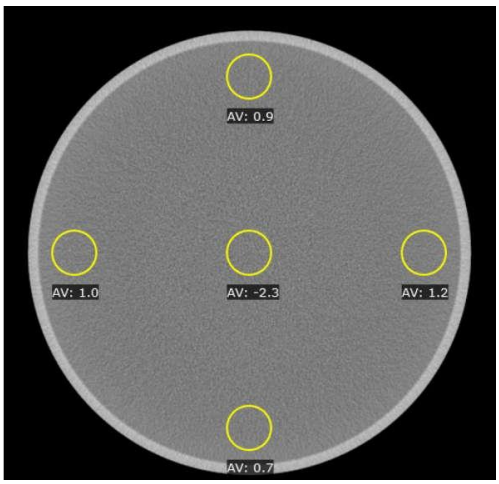


Fig 12-9 CT Value Uniformity Measurement of Body Phantom Using Body STD-QA Protocol

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.

12.3 Constancy Tests

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 should be taken according to the measures recommended in Annex F of the IEC 61223-3-5:2019 standard or the hospital's own quality assurance procedures or other measure determined by the user.

Table 12-3 Constancy Test items and requirements

Check Item	Type	Check Range	Constancy Frequency
Positioning of the PATIENT SUPPORT	L_{for} and L_{back}	± 1mm	Annually
	C_{for} and C_{back}	± 1mm	Annually
Patient Positioning Accuracy	Internal patient positioning light	± 2mm	Annually
	External patient positioning light	± 2mm	Annually
	Coronal and sagittal patient positioning light	± 2mm	Annually
Dose ($CTDI_w$)	Head(Adult Head and Paediatric Head)	[21.65mGy, 32.47mGy]	Annually
	Body(Adult Body and Paediatric Body)	[10.78mGy, 16.18mGy]	Annually
Dose ($CTDI_{free\ air}$)	Head(Adult Head and Paediatric Head)	±max(± 20%,1mGy)	Annually
	Body(Adult Body and Paediatric Body)	±max(± 20%,1mGy)	Annually
Dose ($CTDI_{vol}$)	Head(Adult Head and Paediatric Head)	±max(± 20%,1mGy)	Annually
	Body(Adult Body and Paediatric Body)	±max(± 20%,1mGy)	Annually
Noise	Typical Adult Head	The greater of ± 10% or ±0.5HU	Monthly
	Typical Adult Body		Annually
	Typical Paediatric Head		Annually
	Typical Paediatric Body		Annually

Check Item	Type	Check Range	Constancy Frequency
Mean CT values	Typical Adult Head	± 5HU	Monthly
	Typical Adult Body	± 7HU	Annually
	Typical Paediatric Head	± 5HU	Annually
	Typical Paediatric Body	± 5HU	Annually
	Adult 80kV Body	± 7HU	Annually
	Adult 100kV Body	± 7HU	Annually
	Adult 120kV Body	± 7HU	Annually
	Adult 140kV Body	± 7HU	Annually
	Paediatric 80kV Body	± 7HU	Annually
	Paediatric 100kV Body	± 7HU	Annually
CT value Uniformity	Typical Adult Head	± 4HU	Monthly
	Typical Adult Body	± 8HU	Annually
	Typical Paediatric Head	± 8HU	Annually
	Typical Paediatric Body	± 8HU	Annually
Reconstructed Section Thickness	Head	（2mm，+∞），±1.0mm [1mm, 2mm]，±50% （-∞，1mm），±0.5mm	Annually
Spatial Resolution (MTF)	Head	The greater of ± 15% or ±0.75 lp/cm	Monthly
	Body	The greater of ± 15% or ±0.75 lp/cm	Monthly

NOTE:

- **The user must be well trained before performing constancy test.**
- **The check range of constancy test cannot exceed the acceptance range of acceptance test.**
- **The CT value uniformity, ±4HU and ±8HU belong to the absolute range.**

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

Move away the couch cushion.

Position the correlation phantom on the couch.

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).

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 iso-center 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

12.3.4.1 Dose Measurement Tools

Dose measurement tools include: RADIATION DETECTOR conforms with IEC 61674 for CT use (such as unfors or Raysafe X2 with ionization chamber), head dose phantom and body dose phantom.

12.3.4.2 Head(Adult Head and Paediatric 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 Fig14-1.
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 $CTDI_W$.

$$CTDI_w = \frac{1}{3}CTDI_{100}(\text{Center}) + \frac{2}{3}CTDI_{100}(\text{Peripheral})$$

14. Measurements of CTDIw for the typical Adult Head and Peadiatric Head is consistent.

When recording the results, the following form is recommended:

Table 12-4 Head (Adult Head and Paediatric 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 mAs						
Test point	B5	B1	B2	B3	B4	21.65mGy≤CTDIw≤32.47mGy
Test value （mGy）						

12.3.4.3 Body (Adult Body and Paediatric Body)$CTDI_W$ Measurement

1. Put Body dose phantom on the couch.
2. Insert 100mm ionization chamber to B5 position of head 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).

$$CTDI_{100}(Peripheral)=\{ CTDI_{100}(B1)+CTDI_{100}(B2)+CTDI_{100}(B3)+CTDI_{100}(B4)\}/4$$

10. Calculate $CTDI_{w}$.

$$CTDI_w = \frac{1}{3}CTDI_{100}(\text{Center}) + \frac{2}{3}CTDI_{100}(\text{Peripheral})$$

11. Measurements of CTDIw for the typical Adult Body and Peadiatric Body is consistent.

When recording the results, the following form is recommended:

Table 12-5 Body(Adult Body and Paediatric Body) $CTDI_{w}$ Measurement

In scan condition：Body STD-QA/Resolution STD/64*0.625 mm/1.0 s/FOV350/F10/10mm/ 120 kV/ 200 mAs						
Test point	B5	B1	B2	B3	B4	10.78mGy≤CTDIw≤16.18mGy
Test value （mGy）						

12.3.4.4 $CTDI_{free\ air}$ for Head(Adult Head and Paediatric Head) and Body (Adult Body and Paediatric Body)(IEC 61223-3-5 and IEC 60601-2-44)

1. Place 100mm ionization chamber in the front end of couch. Probe will 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 12-6.
5. Record measured value for $CTDI_{free\ air}$.

Table 12-6 Typical body (Adult Body and Paediatric Body) and Head(Adult Head and Paediatric Head) conditions of operation

Voltage (kV)	120kV
Thickness (mm)	64*0.625mm
Scan time (s)	1.0s
mA	200mA

Table 12-7 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**
80kV	——	——	——	——	——	——	——	——	——	12.07	——
100kV	——	——	——	——	——	——	——	——	——	22.18	——

120kV	53.29	74.57	53.85	46.74	43.33	41.19	39.76	37.91	36.36	34.84	35.01
140kV	——	——	——	——	——	——	——	——	——	49.30	——

The maximum deviation of $CTDI_{free\ air}$ value is the larger of ± 20% or ±1mGy.

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 the larger of ± 20% or ±1mGy.

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. Refer to 12.2.3 for phantom placement.
2. To start the test, select **Constancy** in Daily of Service. The constancy test interface appears.
3. Click **Next** to continue.
4. Select whether to fill in the information on the configuration information as required and then click **OK**.
5. Confirm the content of the prompt and then click **OK**.
6. The content of the test will be displayed in the history. If the position of the phantom is not accurate, the system will prompt how to adjust the phantom and end the test. Adjust the phantom position according to hints in the history, and then repeat steps 3, 4 and 5.
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. Orange is testing.
8. When the tests are completed, the constancy report is generated automatically and saved. To view the report, click History of Report button. The test report can be printed or recorded.

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 12-8 Representative Images — Typical Head Scans

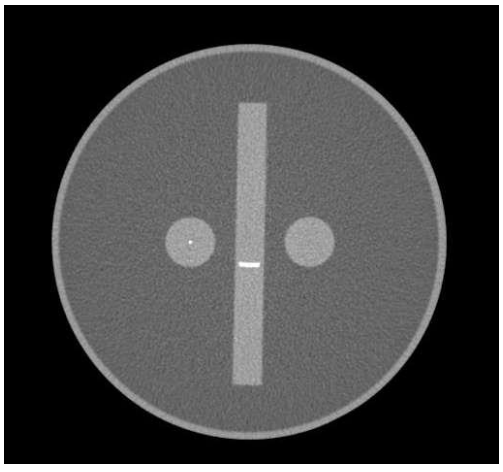
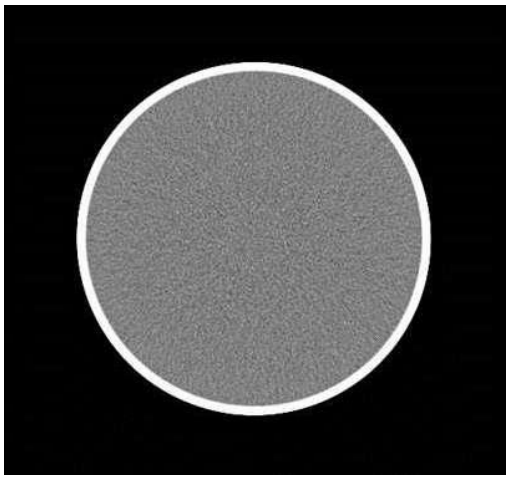
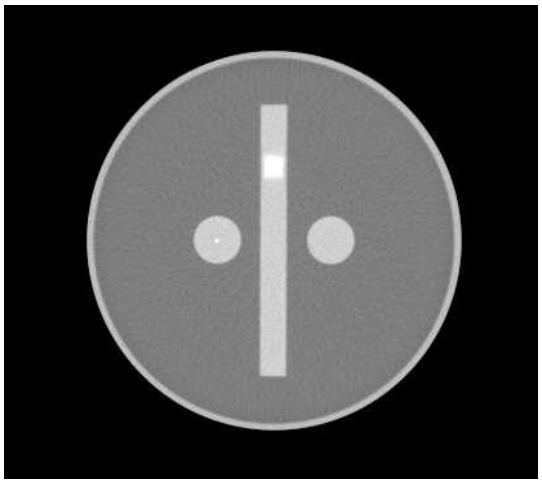
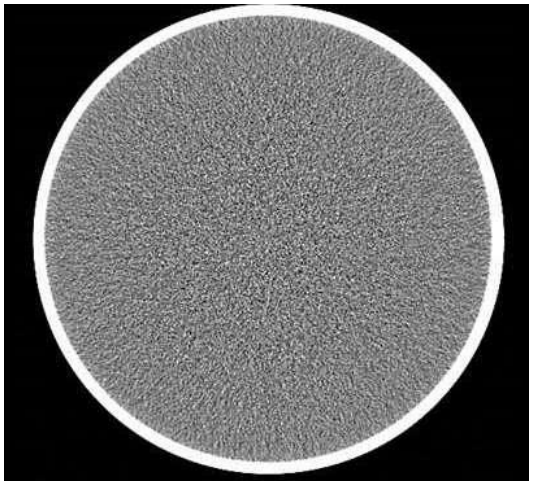
Physics Layer of QA Phantom Contrast Scale/High Contrast Spatial Resolution/Slice Thickness	Head Water Layer of QA Phantom Low Contrast Detectability / CT Number Accuracy & Uniformity, and Noise
	

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.

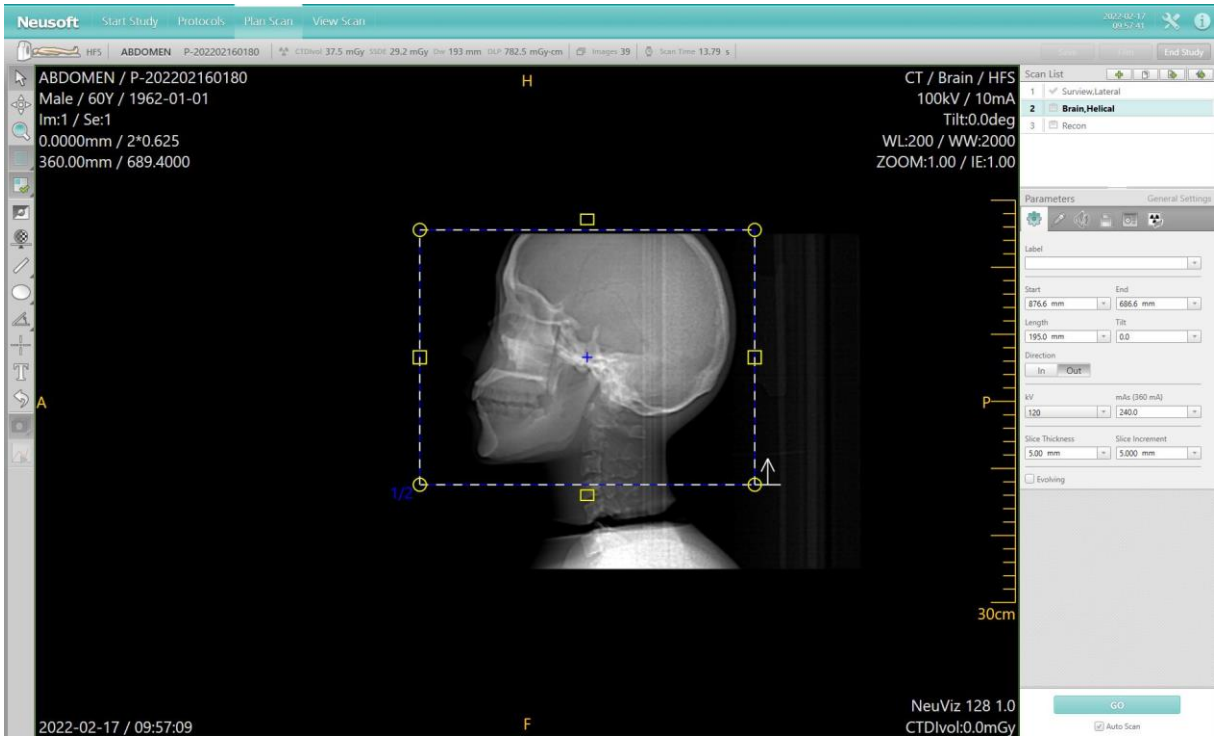
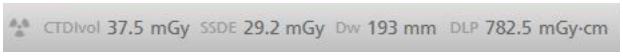
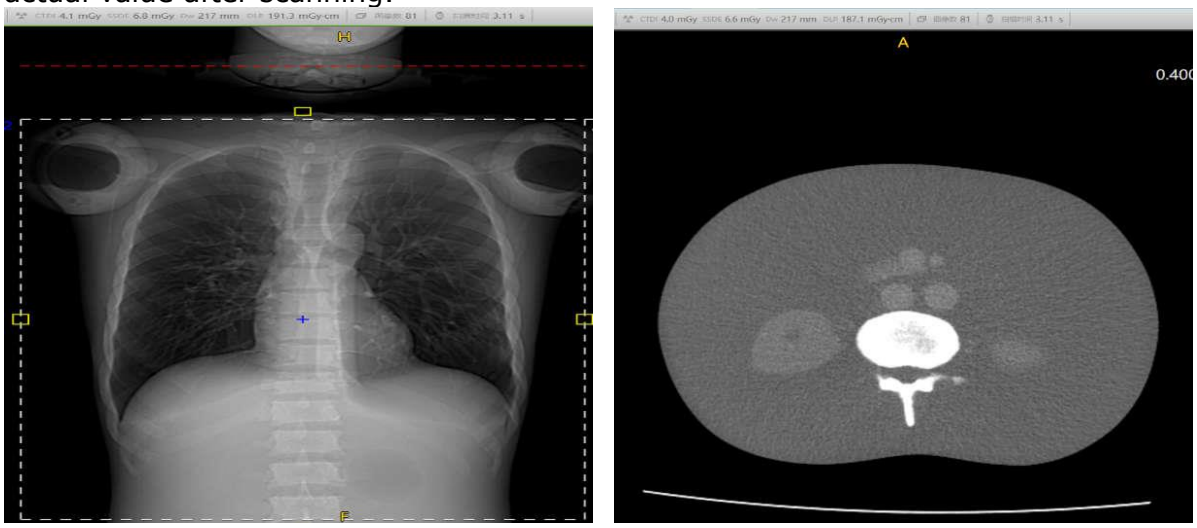


Fig 13-1 SSDE value

$CTDI_{vol}$, 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.



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 Dosage and Maintenance

14.1 Dosage and Performance(Reference IEC 60601 -2 -44)

14.1.1 Filtration information

14.1.1.1 Filter Information

Table 14-1 Filter Information

Collimator	Material	Filter thickness	Quality Equivalent Filtration
	Ti	1.2mm±0.03mm	7.05mm Al@75kv
	Teflon	2 mm±0.03mm	0.67mm Al@75kv
Tube QEF Values			>=0.5mm Al @75kV

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 (mmAl)**	**Measurement(mmAl)**
80 kV	2.9	6.00
100 kV	3.6	7.19
120 kV	4.3	8.13
140 kV	5.0	8.89

14.1.2 Description of 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.

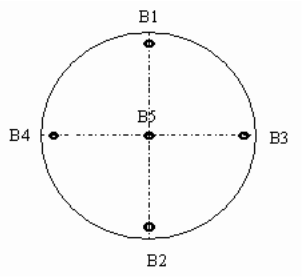


Fig 14-1 Position Schematic Diagram of Measuring the CTDI Dosage

- 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.
- The location of the position where the CTDI gets to maximum is B5.

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.

14.1.3 CTDI/Dosage 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$_{100}$

$$CTDI_{100} = \int_{-50\ mm}^{50\ mm} \frac{D(z)}{N \times T}$$

CTDI $_{free\ air}$

$$CTDI_{free\ air} = \int_{-L/2\ mm}^{+L/2\ mm} \frac{D(z)}{N \times T}\, dz$$

CTDI$_w$

$$CTDI_w = \frac{1}{3} CTDI_{100}(\text{Center}) + \frac{2}{3} CTDI_{100}(\text{circum})$$

CTDI$_{vol}$

For axial scan:

$$CTDI_{vol} = \frac{N \times T}{\Delta d} CTDI_w$$

For helical scan:

$$CTDI_{vol} = \frac{CTDI_w}{CT\ pitch\ factor}$$

For scanning without pre-programmed movement of the table (cine):

$$CTDI_{vol} = N \times CTDI_w$$

For scoutview scan:

$$CTDI_{vol} = \frac{CTDI_w}{mAs} \times \text{Scout mA} \times \frac{N \times T\ [mm]}{Table\ Speed\ [\frac{mm}{s}]}$$

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

N*T = Collimation width

Δd = Couch progress in the z-axis direction between consecutive scans

EPPD ——Estimated Phantom Peripheral Dose

The purpose for determining an EPPD is that it may provide a better estimate of a patient's peak skin dose than $CTDI_{vol}$.

In general, the peripheral CTDI100 for a scan can be derived from the displayed $CTDI_{vol}$ by multiplying the $CTDI_{vol}$ with a given factor that depends on the tube voltage and shaped filter used.

$CTDI_{100}$ (peripheral) is the average of the four values of $CTDI_{100}$ measured around the dosimetry PHANTOM periphery.

Typical Parameter	120KV, 200mA, 1.0s, 64*0.625mm					
Location	B1	B2	B3	B4	B5	$CTDI_w$
Head measurement(mGy.cm)	106.90	118.43	105.57	113.58	102.45	108.23
Head $CTDI_{100}$(mGy)	26.73	29.61	26.39	28.40	25.61	27.06
Body measurement(mGy.cm)	64.25	67.51	61.22	63.61	33.50	53.93
Body $CTDI_{100}$(mGy)	16.06	16.88	15.31	15.90	8.38	13.48

a) For axial scanning with table movement

Shaped filter		large	
Phantom Size		head	body
Tube voltage	80kV	1.03	1.19
	100kV	1.03	1.19
	120kV	1.03	1.19
	140kV	1.03	1.19

b) For helical scanning

Shaped filter		large	
Phantom Size		head	body
Tube voltage	80kV	1.03	1.19
	100kV	1.03	1.19
	120kV	1.03	1.19
	140kV	1.03	1.19

c) For scanning without movement of the PATIENT SUPPORT

Shaped filter		large	
Phantom Size		head	body
Tube voltage	80kV	1.09	1.25
	100kV	1.09	1.25
	120kV	1.09	1.25
	140kV	1.09	1.25

d) For axial and helical scanning involving table travel in two directions

Shaped filter		large	
Phantom Size		head	body
Tube voltage	80kV	1.09	1.25
	100kV	1.09	1.25
	120kV	1.09	1.25
	140kV	1.09	1.25

14.1.4 Conversion factors for $CTDI_{vol}$ and DLP

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 pediatric 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 $CTDI_{vol}$ 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

Collimation Thickness (*0.625mm)	**kV**			
	80	**100**	**120**	**140**
2	2.55	2.27	2.12	2.04
4	2.46	2.20	2.05	1.97
8	2.44	2.18	2.03	1.95
12	2.43	2.16	2.02	1.94
16	2.43	2.17	2.02	1.94
20	2.43	2.17	2.02	1.94
24	2.43	2.17	2.03	1.94
32	2.43	2.17	2.03	1.95
40	2.41	2.15	2.01	1.93
64	2.41	2.15	2.01	1.93

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

Thickness (mm)	64*0.625mm
Scan time (s)	1.0s
mA	200mA

Table 14-5 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
80kV	——	——	——	——	——	——	——	——	——	12.07	——
100kV	——	——	——	——	——	——	——	——	——	22.18	——
120kV	53.29	74.57	53.85	46.74	43.33	41.19	39.76	37.91	36.36	34.84	35.01
140kV	——	——	——	——	——	——	——	——	——	49.30	——

The maximum deviation of CTDI $_{free\ air}$ value is ± 20%.

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 (mGy) (Reference 21 CFR 1020.33(C)(2)(i) and(C)(2)(ii))

Typical Parameters	**120kV, 200mA, 1.0s, 64*0.625mm (Reference 21 CFR 1020.33(C)(2)(i))**				
	B1	B2	B3	B4	B5
Head $CTDI_{100}$(mGy)	26.73	29.61	26.39	28.40	25.61
Body $CTDI_{100}$(mGy)	16.06	16.88	15.31	15.90	8.38

In position B5

Phantom	**Current**	**CTDI(mGy)**	**$CTDI_{100}$(mGy)**
Head	667mA	85.39	3.33
	500mA	64.03	2.50
	350mA	44.82	1.75
	200mA	25.61	1.00

	30mA	4.10	0.16
Body	667mA	27.93	3.33
	500mA	20.94	2.50
	350mA	14.66	1.75
	200mA	8.38	1.00
	30mA	1.34	0.16

Mean Value of B1, B2, B3 and B4

Phantom	Current	CTDI(mGy)	$CTDI_{100}$(mGy)
Head	667mA	90.40	3.25
	500mA	69.45	2.50
	350mA	48.62	1.75
	200mA	27.78	1.00
	30mA	4.45	0.16
Body	667mA	52.46	3.27
	500mA	40.09	2.50
	350mA	28.07	1.75
	200mA	16.04	1.00
	30mA	2.59	0.16

In position B5

Phantom	Scan.time	CTDI(mGy)	$CTDI_{100}$(mGy)
Head	2s	50.20	1.96
	1.5s	38.42	1.50
	1s	25.61	1.00
	0.5s	12.81	0.50
Body	2s	16.50	1.97
	1.5s	12.56	1.50
	1s	8.38	1.00
	0.5s	4.19	0.50

Mean Value of B1, B2, B3 and B4

Phantom	Scan.time	CTDI(mGy)	$CTDI_{100}$(mGy)

Head	2s	52.70	1.90
	1.5s	41.67	1.50
	1s	27.78	1.00
	0.5s	13.49	0.49
Body	2s	30.88	1.93
	1.5s	24.06	1.50
	1s	16.04	1.00
	0.5s	7.9	0.49

In position B5

Phantom	Voltage	CTDI (mGy)	$CTDI_{100}$(mGy)
Head	80KV	7.69	0.30
	100KV	15.62	0.61
	120KV	25.61	1.00
	140KV	37.14	1.45
Body	80KV	2.10	0.25
	100KV	4.77	0.57
	120KV	8.38	1.00
	140KV	12.65	1.51

Mean Value of B1, B2, B3 and B4

Phantom	Voltage	CTDI (mGy)	$CTDI_{100}$(mGy)
Head	80KV	8.86	0.32
	100KV	17.06	0.61
	120KV	27.78	1.00
	140KV	39.02	1.40
Body	80KV	4.84	0.30
	100KV	9.53	0.59
	120KV	16.04	1.00
	140KV	22.28	1.39

In position B5

Phantom	Collimation	CTDI (mGy)	$CTDI_{100}$(mGy)

Head	64*0.625	25.61	1.00
	40*0.625	26.95	1.05
	32*0.625	27.87	1.09
	24*0.625	29.35	1.15
	20*0.625	30.53	1.19
	16*0.625	32.37	1.26
	12*0.625	35.35	1.38
	8*0.625	41.32	1.61
	4*0.625	59.20	2.31
	2*0.625	52.08	2.03
Body	64*0.625	8.38	1.00
	40*0.625	8.80	1.05
	32*0.625	9.09	1.08
	24*0.625	9.55	1.14
	20*0.625	9.92	1.18
	16*0.625	10.50	1.25
	12*0.625	11.44	1.37
	8*0.625	13.32	1.59
	4*0.625	18.92	2.26
	2*0.625	16.08	1.61

Mean Value of B1, B2, B3 and B4

Phantom	Collimation	CTDI (mGy)	$CTDI_{100}$(mGy)
Head	64*0.625	27.78	1.00
	40*0.625	28.95	1.04
	32*0.625	30.35	1.09
	24*0.625	32.00	1.15
	20*0.625	33.16	1.19
	16*0.625	35.04	1.26
	12*0.625	38.25	1.38
	8*0.625	44.10	1.59

	4*0.625	61.80	2.22
	2*0.625	50.08	1.80
Body	64*0.625	16.04	1.00
	40*0.625	16.90	1.05
	32*0.625	17.73	1.11
	24*0.625	18.60	1.16
	20*0.625	19.32	1.20
	16*0.625	20.46	1.28
	12*0.625	22.27	1.39
	8*0.625	25.62	1.60
	4*0.625	35.96	2.24
	2*0.625	28.64	1.79

Table 14-7 Maximum $CTDI_{100}$ (Normalization) under the X-ray tube voltage (B2 Position) (Reference 21 CFR 1020.33(C)(2)(iii))

Phantom	Voltage	CTDI(mGy)	$CTDI_{100}$(mGy)
Head	80KV	9.48	0.32
	100KV	18.36	0.62
	120KV	29.61	1.00
	140KV	42.64	1.44
Body	80KV	5.06	0.30
	100KV	10.13	0.60
	120KV	16.88	1.00
	140KV	24.64	1.46

NOTE:

- **Only one parameter was modified each time and the configuration of other parameters is typical value.**

14.1.7 Dosage and Sensitivity Profile (Reference IEC 60601-2-44 21CFR 1020.33(c)(2)(iv))

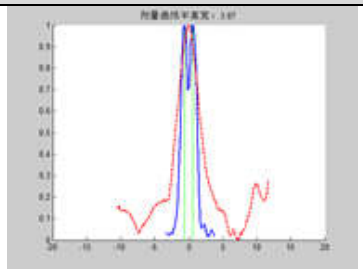
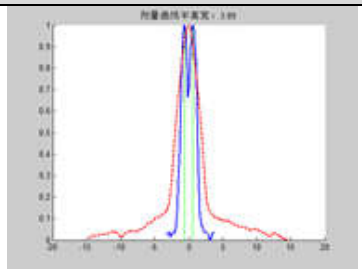
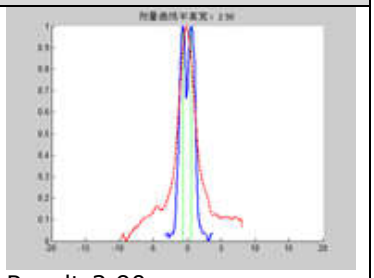
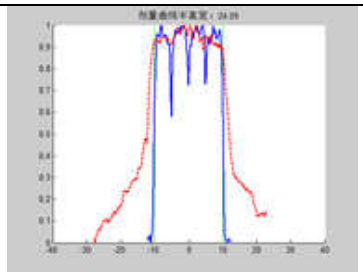
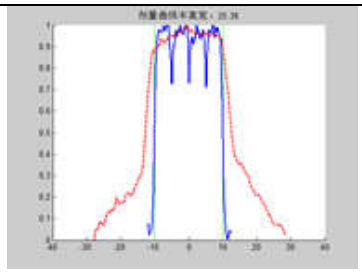
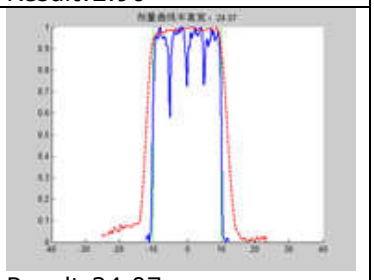
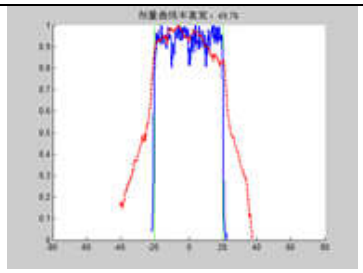
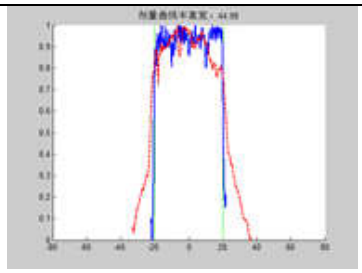
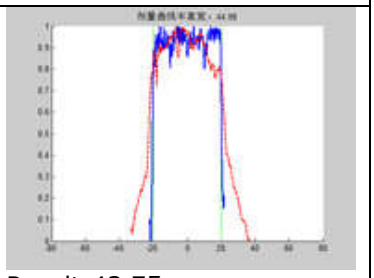
The standard values and maximum deviation of sensitive profile is the same with those of tomographic section thickness.

The standard values of does profile are as follows:

Collimation	Head Reference	Body Reference	Air Reference	Error range

	value	value	value	
2*0.625	3.5mm	3.5mm	2.5mm	Max(±30% or ±1.5mm)
32*0.625	25mm	25mm	25mm	Max(±30% or ±1.5mm)
64*0.625	40mm	50mm	40mm	Max(±30% or ±1.5mm)

Table 14-8 Dose and Sensitive Curve

Collimation	Body	Head	Free Air
2x0.625	 Result:3.87	 Result:3.89	 Result:2.90
32x0.625	 Result:24.09	 Result:25.38	 Result:24.07
64x0.625	 Result:49.76	 Result:44.98	 Result:43.75

14.1.8 Modulation Transfer Function (MTF)

The condition is the same as that of noise tests.

The MTF curve is calculated from the impulse response.

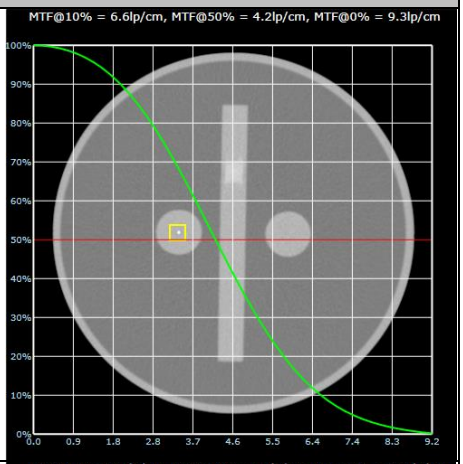
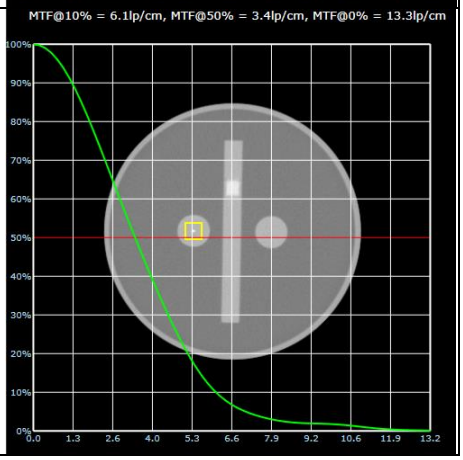
If the MTF is 100% or 1.0, it means there is no signal loss.

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.

Table 14-7 MTF Illustrative Diagram (High Reconstruction and Standard Reconstruction) (Reference 21 CFR 1020.33(C)(3)(ii))

Reconstruction	MTF(Body)

Condition	
Standard Head Reconstruction Condition Head STD-QA , 120kv, 200mA,1s, F20, 64*0.625, FOV250, 5mm , large wedge, standard resolution	
Standard Body Reconstruction Condition Body STD-QA, 120kv, 200mA,1s, F20,64*0.625, FOV350, 5mm, large wedge, standard resolution	

14.1.9 Definitions and Instructions

About definitions and instructions of noise, please see details in chapter 12.2.5.

The QA phantom(accrodingto 1020.33(c)(3)(v))described in chapter 12.2.1 is used to evaluate Modulation Transfer Function (MTF) and tomographic Thickness.

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 curve is calculated from the impulse response on a separate computer.

According to Reference 21 CFR 1020.33(C)(3)(V).

Head Scan conditions: Head STD-QA protocol, 120KV, 64*0.625, 200mA, 1s, 5mm, F20, FOV250mm.

Body Scan conditions: Body STD-QA protocol, 120KV, 64*0.625, 200mA, 1s, 5mm, F20, FOV350mm.

The value of MTF should be no less than 6lp/cm@0%, 4.5lp/cm @10% and 2.5lp/cm@50%.

See the diagrams in table 14-7.

Measurement of Tomographic Thickness

In the phantom shown in this chapter, 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

14.1.10 Linearity of X-ray Output(IEC 60601-2-44)

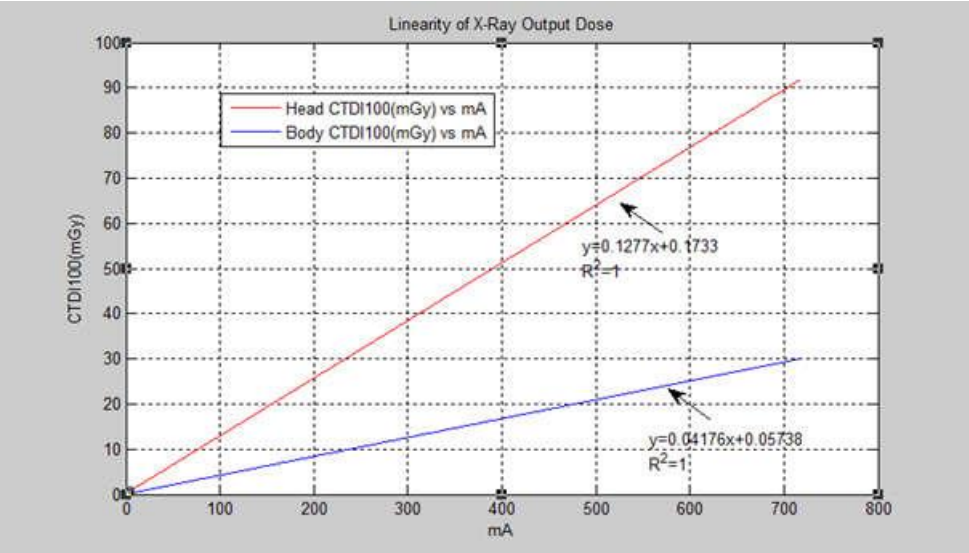


Fig 14-2 Linearity of X-ray Output Dose

mA	Head $CTDI_{100}$(mGy)	Body $CTDI_{100}$(mGy)
667	85.39	27.93
500	64.03	20.94
350	44.82	14.66
200	25.61	8.38
30	4.10	1.34

NOTE:

- **The accuracy of X-ray tube voltage is ±8%.**
- **The accuracy of X-ray tubel current is ±20%.**

14.1.11 IEC Stray Radiation Dose Map

Only qualified and professional institution is to evaluate the shielding of scanning 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 scanning room.

Dosage 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.

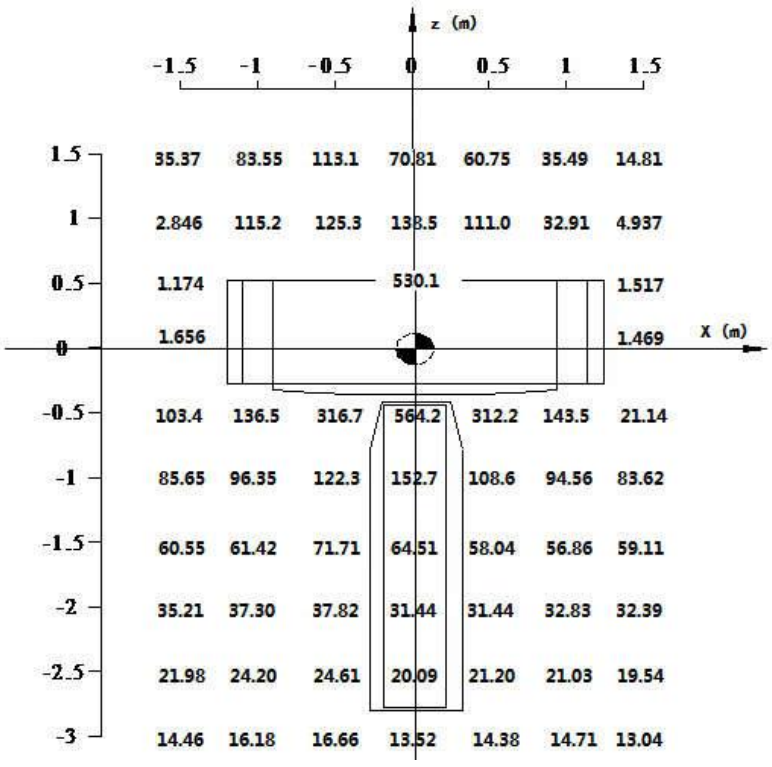


Fig 14-3 IEC stay radiation dose map (x-z)

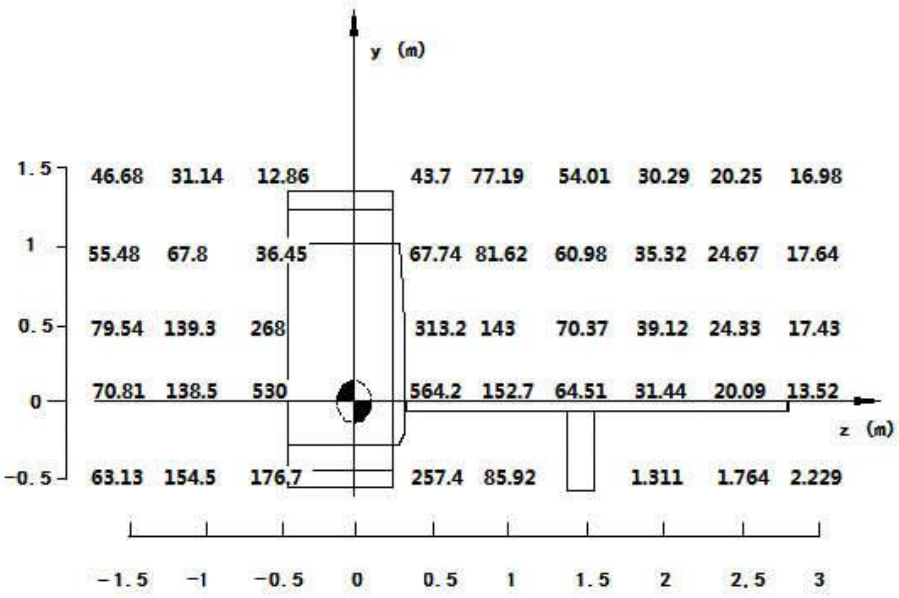


Fig 14-4 IEC stay radiation dose map (y-z)

14.2 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, 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.

14.3 Preventive Maintenance

Routine preventive maintenance for the whole CT system is scheduled every six months, for the hospitals which average daily patient volume>=80, the maintenance is suggested every 4 months, and the maintenance should be performed by qualified Neusoft Medical Systems personnel.

NOTE:

- **For specific maintenance information, please refer to Product Information Manual.**

14.4 Cleaning and Disinfecting

Cleaning Methods:

NeuViz 128 is a large medical equipment and is suitable for manually cleaning. The specific methods are as follows:

Warm soap or detergent can be used. Before cleaning, power off the system. Wipe the equipment with a towel moistened in the soapy water or detergent and use a cotton swab or toothpick to remove the solid substances that are difficult to be wiped around the key. If there is a large amount of splashing, the visible pollutants should be removed with hygroscopic materials first, and then wiped clean.

Disinfecting Methods:

After turning off the power supply and cleaning the equipment, users should wipe the equipment surface with disinfectant. For disinfectant concentration, it should be suitable for the equipment and mixed according to the label instructions. Follow the label instructions for the wipe time, disinfectant concentration, and the contact time of the system with the disinfectant. Make sure the disinfectant concentration and contact time are suitable; air dry or wipe with a disinfected cloth according to the instructions on the disinfectant label.

Select the disinfectant suitable for disinfecting the surface of the equipment, and suitable for wiping, as follows:

Active ingredients	Disinfecting method
Chlorine disinfectant: 500-615ppm chlorine	Wipe
Alcohol disinfectant: 75% medical alcohol	Wipe

WARNING:

- **The painting pad accessories (such as head arm holder) shall not be disinfected with alcohol disinfectant, which should be disinfected with disinfectant containing chlorine. The alcohol disinfectant should not be used for the painting left and right covers of the couch, because the strong disinfectant alcohol will corrode the polished surface of the cover.**
- **When cleaning and disinfecting the system, always wear protective**

glasses and gloves to prevent damage to eyes and skin.

Chapter 15 Recycling Passport

Product Name:	NeuViz 128 Multi-slice CT Scanner System	
Product Model:	NeuViz 128	
Total Weight (in Kg):	2576.63	
Producer/ Manufacturer:	**Name**	Neusoft Medical Systems Co., Ltd.
	Address	No. 177-1 Chuangxin Road, Hunnan District, Shenyang, 110167 Liaoning, China

Recycle Inf.		
Hazardous:  To be removed	**Substances**	**Location**
	Examples: Lead (Pb)	Figure 15-2
Batteries:  To be removed	**Type**	**Location**
	Lithium coin battery	N/A
Special attention: 	**Item**	**Location**
	Air-spring	Figure 15-1 Figure 15-6
Fluids/Gases: 	**Item**	**Location**
	High pressure oil tank	Figure 2

Material content	**Weight in Kg**	**Material content (continue)**	**Weight in Kg**
Lead (Pb)	19.63	Printed circuits boards	6.27
Iron (Fe)	1398.12	Tungsten (W)	1.72
Aluminum (Al)	728.14	Molybdenum(Mo)	1.22
Copper (Cu)	67.34	All other material types	354.19

NOTE: **The weight should be for reference only.**

Locations as mentioned in the Passport (Pictures information).

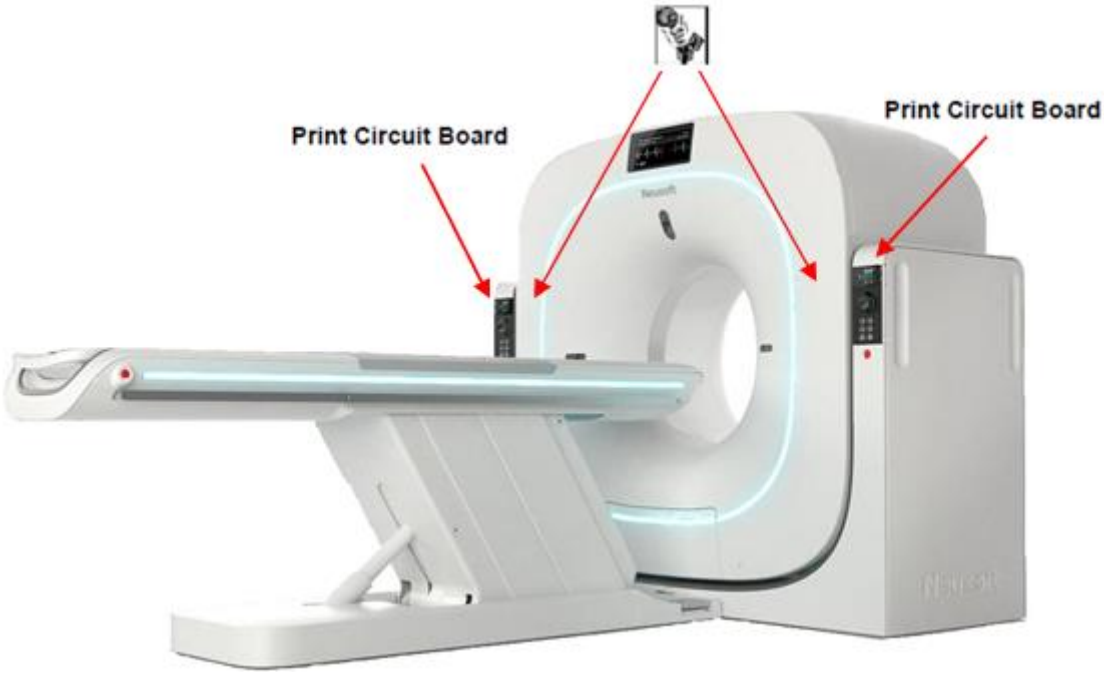


Fig 15-1 CT System Front View

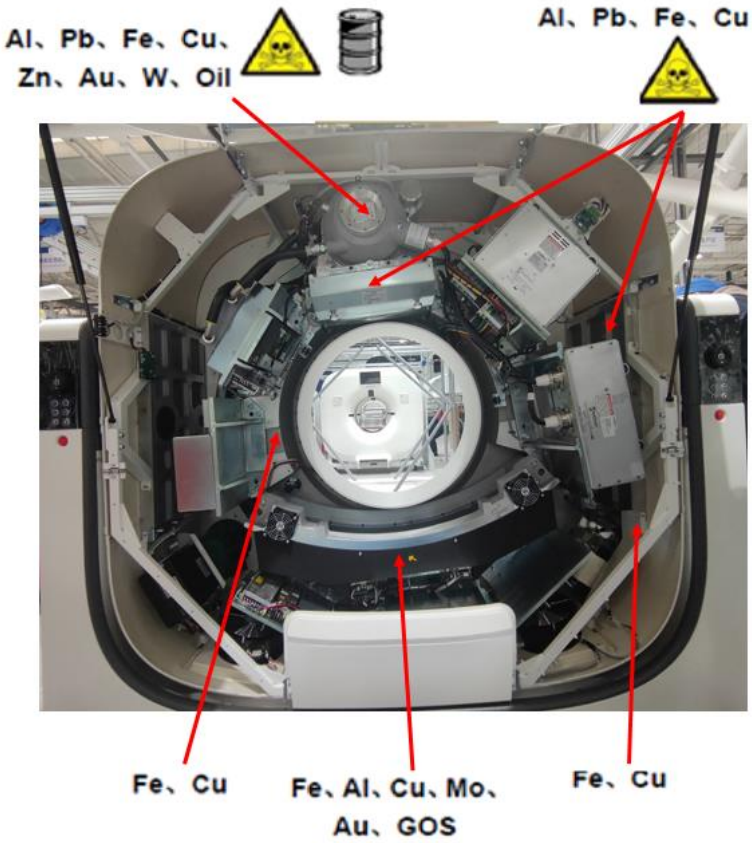


Fig 15-2 Gantry Front View (Without Cover)

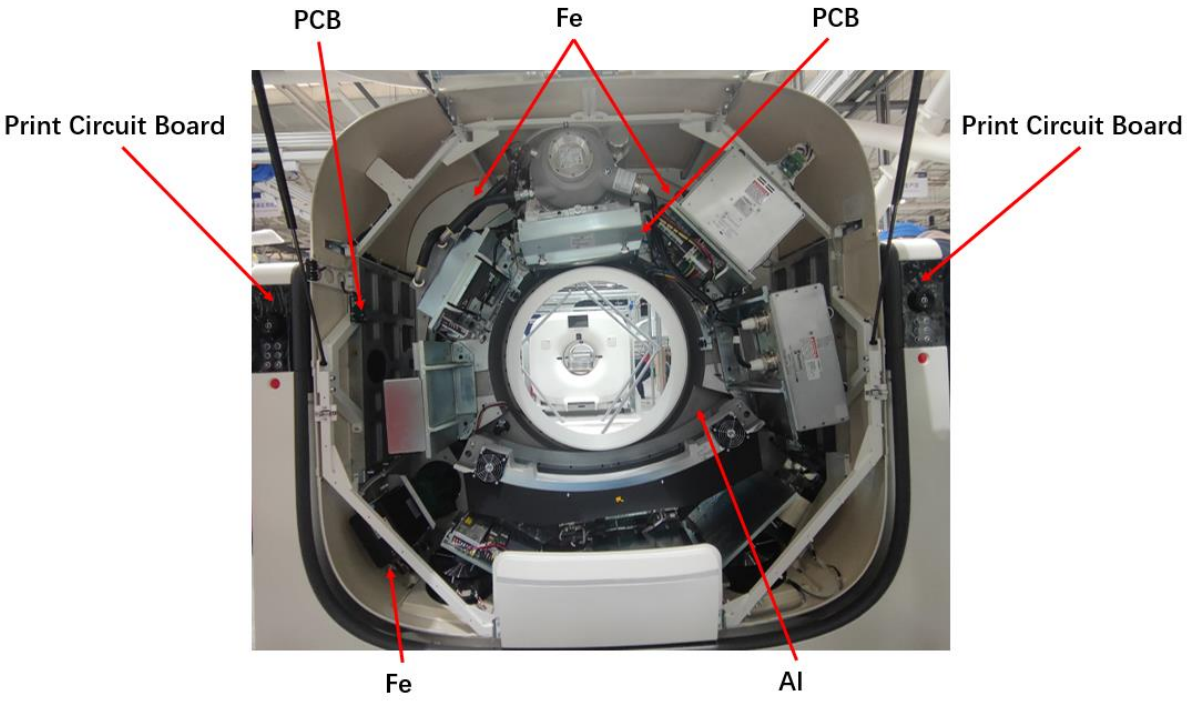


Fig 15-3 Gantry Front View (Without Cover)

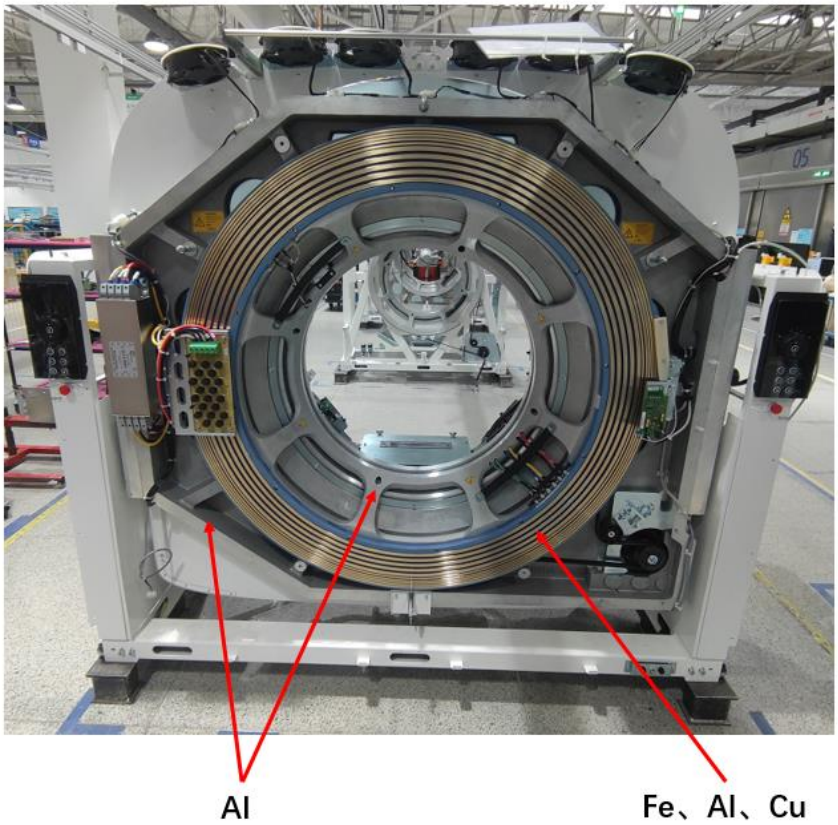


Fig 15-4 Gantry Rear View (Without Cover)

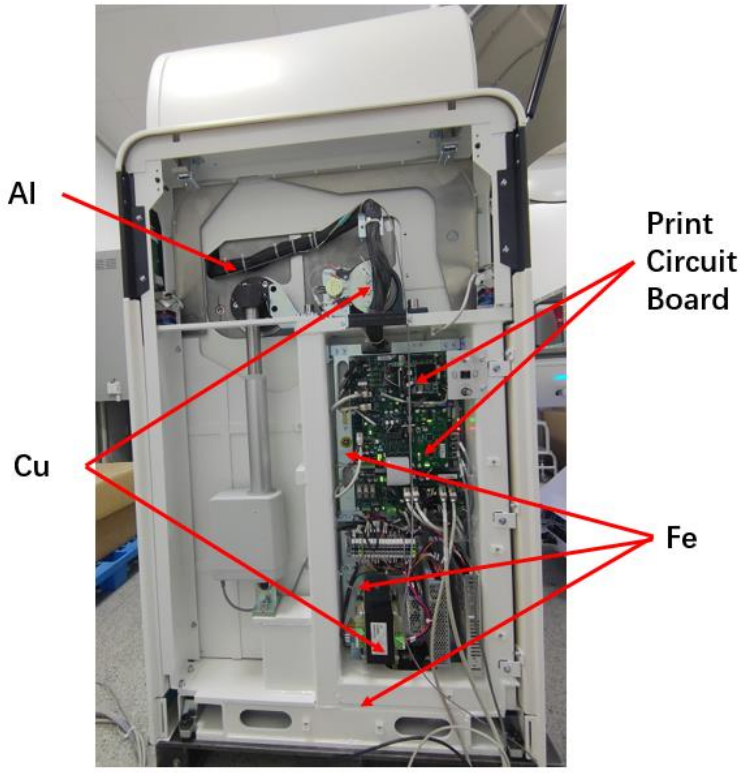


Fig 15-5 Gantry Left Side (Without Cover)

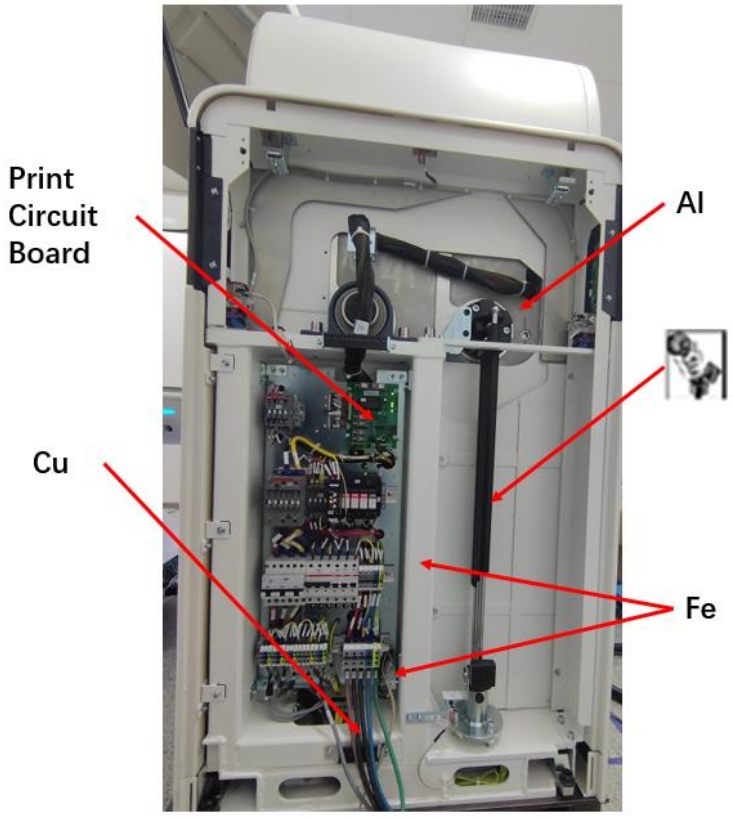


Fig 15-6 Gantry Right Side (Without Cover)

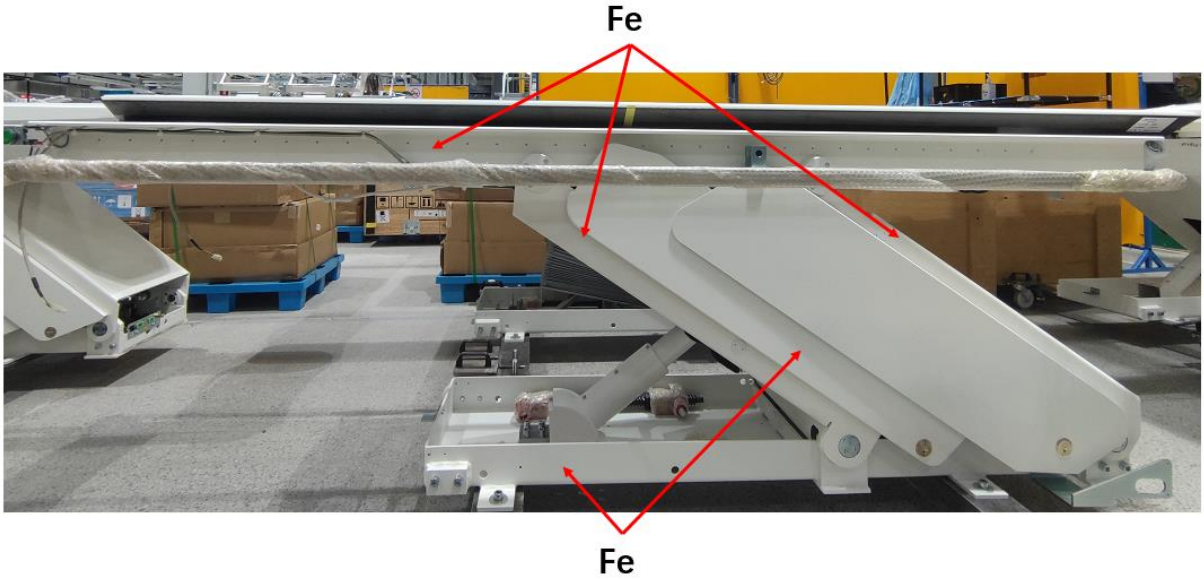


Fig 15-7 Couch System (Without Cover)

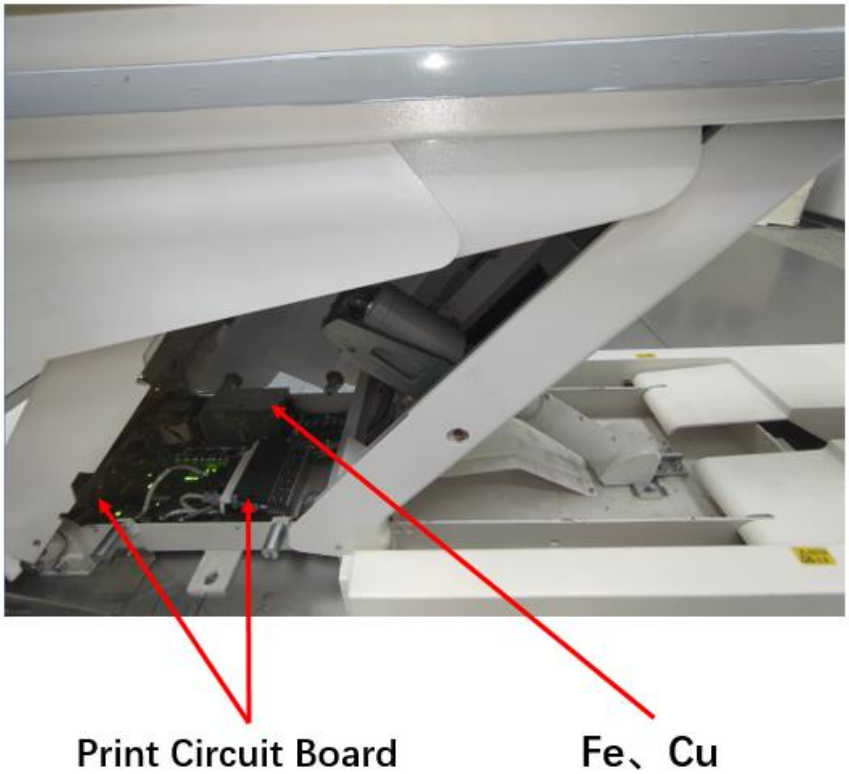


Fig 15-8 Couch (Inside View)

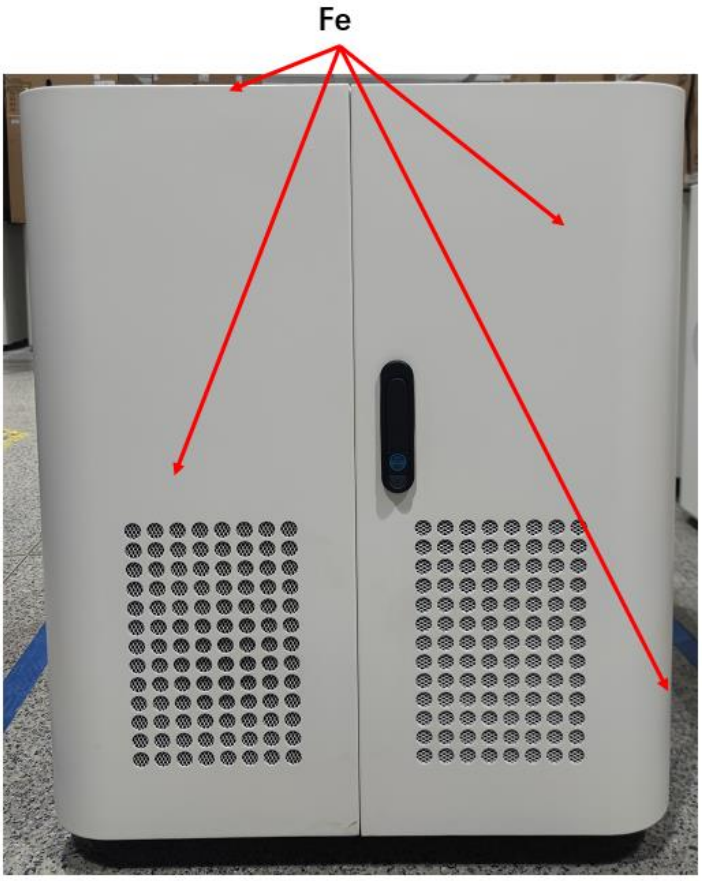


Fig 15-9 Computer Case Front View

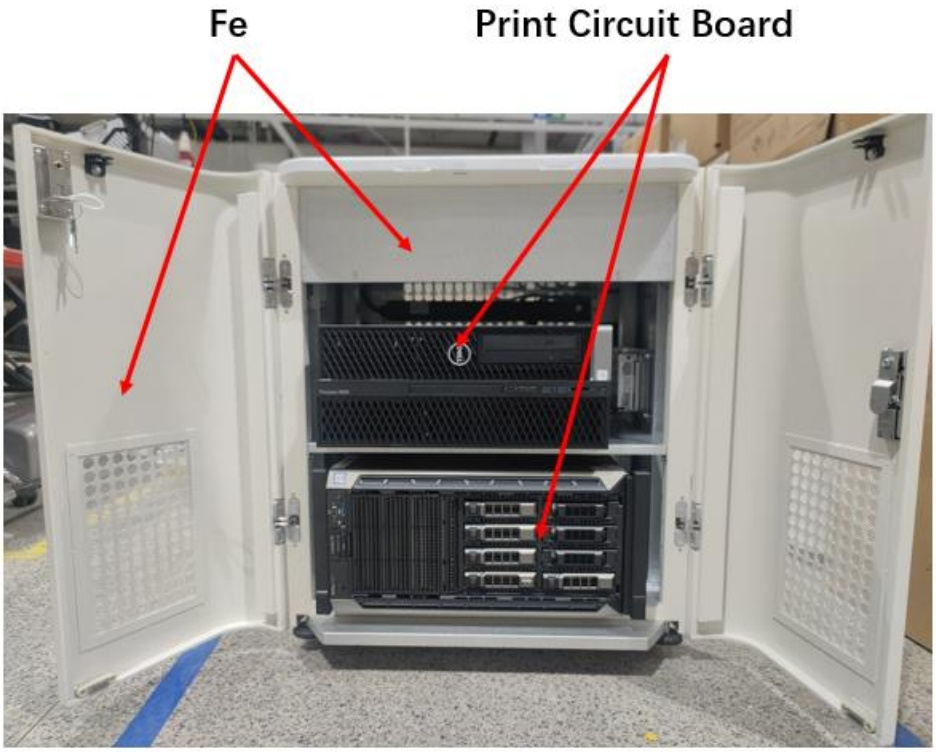


Fig 15-10 Computer Case Front View (Door Open)

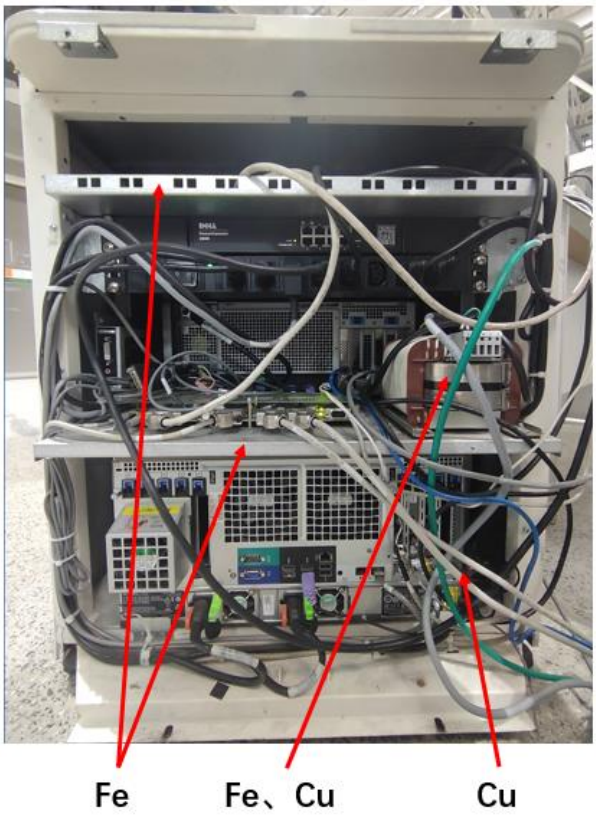


Fig 15-11 Computer Case Rear View

Chapter 16 Factory Protocols

Protocols	Brain+C	Brain Ax. 18m-6yrs+OrganSafe	Brain Ax. 18m-6yrs
Brief Description	Axial scan for head using ClearView Mode	Axial scan for 18 month-6 years old of children head studies using OrganSafe mode	Axial scan for 18 month-6 years old of children head studies
kV	120	100	120
mAs	240	200.1	160
Rotation Speed (s)	0.6	0.6	0.8
Acquisition	64*0.625	32*0.625	32*0.625
Scan Interval(mm)	NA	20	20
Pitch	0.8	NA	NA
Slice Thickness	5mm	5mm	5mm
Slice Increment	5mm	NA	NA
Kernel	F20	F15	F20/F60
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	Brain Ax. 7yrs+	Brain Ax. 7yrs+OrganSafe	Brain Ax. +OrganSafe
Brief Description	Axial scan for more than 7 years old of children head studies	Axial scan for 7years+ of children head studies using OrganSafe mode	Axial scan for adult routine head studies using OrganSafe mode
kV	120	120	120
mAs	240	229.8	350.3
Rotation Speed (s)	1	1	1
Acquisition	32*0.625	32*0.625	32*0.625
Scan Interval(mm)	20	20	20
Pitch	NA	NA	NA
Slice Thickness	5mm	5mm	5mm
Slice Increment	NA	20mm	NA
Kernel	F20/F60	F15	F15
Resolution	Standard	Standard	Standard

O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Brain Ax.**	**Brain CTA 0-6yrs**	**Brain CTA 7yrs+**
Brief Description	Axial scan for adult routine head studies	Helical scan for cerebral CT Angios	Helical scan for more than 7 years old children head CT angiography
kV	120	80	100
mAs	350	300	229.8
Rotation Speed (s)	1	0.6	0.6
Acquisition	32*0.625	64*0.625	64*0.625
Scan Interval(mm)	20	NA	NA
Pitch	NA	0.7	1
Slice Thickness	5mm	2mm	2mm
Slice Increment	NA	1mm	1mm
Kernel	H20/F60	F15	F15
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Brain CTA**	**Brain Perfusion**	**Brain**
Brief Description	Helical scan for cerebral CT Angios	Dynamic multiscan at the same table position for neuro studies.	Helical scan for adult routine neuro studies
kV	120	80	120
mAs	200	150	240
Rotation Speed (s)	0.5	0.5	0.6
Acquisition	128*0.625	64*0.625	32*0.625
Scan Interval(mm)	NA	0	NA
Pitch	1.2	NA	0.9
Slice Thickness	2mm	5mm	5mm
Slice Increment	1mm	NA	5mm
Kernel	F15	F10	H20/F60

Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	0%	30%
ClearInfinty	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Dental**	**Facial Bone Volume**	**Head STD-QA**
Brief Description	Helical scan for dental application package to evaluate and reformate the upper and lower jaws.	Axial scan for facial bone volume studies.	Head standard resolution QA protocol
kV	120	120	120
mAs	240	200	200
Rotation Speed (s)	0.8	0.6	1
Acquisition	32*0.625	64*0.625	64*0.625
Scan Interval(mm)	NA	NA	40
Pitch	0.9	0.9	NA
Slice Thickness	1mm	3mm	5mm
Slice Increment	0.5mm	3mm	NA
Kernel	F60	F20/F60	F20
Resolution	High	High	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	0%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Head UHR-QA**	**Inf Brain Ax. 0-18m +OrganSafe**	**Inf Brain Ax. 0-18m**
Brief Description	Head ultrahigh resolution QA protocol	Axial scan for 0-18 months of children head studies using OrganSafe mode	Axial scan for 0-18 months of children head studies
kV	120	100	100
mAs	200	149.9	160
Rotation Speed (s)	1	0.5	0.8
Acquisition	8*0.3125	32*0.625	32*0.625
Scan Interval(mm)	5	20	20
Pitch	NA	NA	NA
Slice Thickness	0.3125mm	5mm	5mm

Slice Increment	NA	NA	NA
Kernel	U10	F15	F20/F60
Resolution	UltraHigh3D	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	0%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**PF Ax.**	**Brain 4D Perfusion**	**TIBT**
Brief Description	Axial scan for posterior cranial fossa studies	It is a 4D scan of whole organs of the head for the cradle mode.	It is an axial scan for adult heads.
kV	120	80	120
mAs	400.5	149.4	29.9
Rotation Speed (s)	1.5	0.5	0.6
Acquisition	16*0.625	128*0.625	16*0.625
Scan Interval(mm)	10	NA	0
Pitch	NA	0.9	NA
Slice Thickness	2.5mm	5mm	10mm
Slice Increment	NA	5	NA
Kernel	F10	H20	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	0%	0%
ClearInfinity	0%	30%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**IAC 0-6yrs**	**IAC 7yrs+**	**IAC Ax. 0-6yrs +OrganSafe**
Brief Description	Helical scan for 0-6 years old children inner ear studies	Helical scan for more than 7 years old children inner ear studies	Axial scan for 0-6 years old children inner ear studies using organsafe mode
kV	120	120	120
mAs	100	150.7	100
Rotation Speed (s)	0.6	0.8	0.8
Acquisition	32*0.625	32*0.625	8*0.625
Scan Interval(mm)	NA	NA	5

Pitch	0.6	0.6	NA
Slice Thickness	0.625mm	0.625mm	0.625mm
Slice Increment	0.3125mm	0.3125mm	NA
Kernel	IAC20	IAC20	IAC20
Resolution	High	High	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**IAC Ax.**	**IAC iHD Ax.**	**IAC iHD**
Brief Description	Axial scan for adult inner ear studies	Axial scan using iHD mode for adult inner ear studies.	Helical scan using iHD mode for adult inner ear studies.
kV	120	120	120
mAs	200	375	468.8
Rotation Speed (s)	0.8	1	1
Acquisition	8*0.625	8*0.625	16*0.3125
Scan Interval(mm)	5	5	NA
Pitch	NA	NA	0.8
Slice Thickness	0.625mm	0.625mm	0.625mm
Slice Increment	NA	NA	0.3125mm
Kernel	IAC20	U30	U30
Resolution	High	UltraHigh2D	UltraHigh3D
O-Dose	OFF	OFF	OFF
ClearView	0%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**IAC**	**Orbit Ax.+OrganSafe**	**Orbit Ax.**
Brief Description	Helical scan for adult inner ear studies	Axial scan for adult orbital studies using OrganSafe	Axial scan for adult orbital studies
kV	120	120	120
mAs	249.8	200.1	200
Rotation Speed (s)	0.6	1	1
Acquisition	32*0.625	32*0.625	32*0.625

Scan Interval(mm)	NA	20	20
Pitch	0.8	NA	NA
Slice Thickness	1mm	5mm	5mm
Slice Increment	1mm	NA	NA
Kernel	IAC20	F60	F60
Resolution	High	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Orbit**	**Sinus Ax.+OrganSafe**	**Sinus Ax.**
Brief Description	Helical scan for adult orbital studies	Axial scan for adult sinuses studies using OrganSafe	Axial scan for adult sinuses studies
kV	120	120	120
mAs	250	149.9	300
Rotation Speed (s)	0.6	0.6	1
Acquisition	32*0.625	32*0.625	64*0.625
Scan Interval(mm)	NA	20	40
Pitch	0.9	NA	NA
Slice Thickness	3mm	5mm	5mm
Slice Increment	3mm	NA	NA
Kernel	F20/F60	F20	F20/F60
Resolution	High	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Sinus Facial 0-6yrs**	**Sinus Facial 7yrs+**	**Sinus**
Brief Description	Helical scan for 0-6 years old of children sinuses studies	Helical scan for adult sinuses studies, e.g. sinusitis	Helical scan for adult sinuses studies
kV	100	120	120
mAs	100	150	180

Rotation Speed (s)	0.5	0.6	0.6
Acquisition	64*0.625	32*0.625	64*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.7	0.9	0.9
Slice Thickness	3mm	5mm	5mm
Slice Increment	3mm	5mm	5mm
Kernel	F20/F60	F20/F60	F20/F60
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Carotid CTA Large**	**Carotid CTA LD**	**Carotid CTA**
Brief Description	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 using low dose mode for adult CT angiography of carotid stenosis or occlusions, coarse plaques abnormalities of carotids and vertebral arteries etc.	Helical scan for CT angiography of carotid stenosis or occlusions, coarse plaques abnormalities of carotids and vertebral arteries, etc.
kV	120	120	120
mAs	180	120	200
Rotation Speed (s)	0.5	0.5	0.5
Acquisition	128*0.625	128*0.625	128*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.8	0.8	0.8
Slice Thickness	2mm	2mm	1mm
Slice Increment	1mm	1mm	0.5mm
Kernel	F20	F20	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	Neck 0-6yrs	Neck 7yrs+	Neck Soft Tissue+C
Brief Description	Helical scan for 0-6 years of children soft tissue studies in the cervical region	Helical scan for more than 7 years of children soft tissue studies in the cervical region	Helical scan for soft tissue studies using ClearView in the cervical region
kV	100	120	120
mAs	100	150	240
Rotation Speed (s)	0.5	0.6	0.6
Acquisition	64*0.625	64*0.625	64*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.8	0.8	0.9
Slice Thickness	2mm	2mm	3mm
Slice Increment	2mm	2mm	3mm
Kernel	F30	F30	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	Neck Soft Tissue Large	Neck Soft Tissue LD	Neck Soft Tissue
Brief Description	Helical scan for adult's BMI more than 30 soft tissue studies in the cervical region	Helical scan using low dose mode for soft tissue studies in the cervical region	Helical scan for soft tissue studies in the cervical region
kV	120	120	120
mAs	250	150	240
Rotation Speed (s)	1	1	0.6
Acquisition	128*0.625	128*0.625	64*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.9	0.9	0.9
Slice Thickness	5mm	5mm	3mm
Slice Increment	5mm	5mm	3mm
Kernel	F20	F20/F60	F20/F60
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy	Max CTDIvol 250mGy	Max CTDIvol 250mGy

	Max DLP 2000mGy·cm	Max DLP 2000mGy·cm	Max DLP 2000mGy·cm

Protocols	**Aorta CTA Large**	**Aorta CTA LD**	**Aorta CTA**
Brief Description	Helical scan for adult's BMI more than 30 thoracic angiography.	Helical scan using low dose mode for adult thoracic angiography.	Helical scan for adult thoracic angiography
kV	120	120	120
mAs	240	120	200
Rotation Speed (s)	0.5	0.5	0.5
Acquisition	128*0.625	128*0.625	128*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	1	1	1
Slice Thickness	1mm	1mm	1mm
Slice Increment	0.5mm	0.5mm	0.5mm
Kernel	F20	F20	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Biopsy**	**CCT Continuous**	**CCT Fluoro**
Brief Description	Low dose axial scan without table movement used to biopsy.	Continuous multislice biopsy mode	Fluoroscopic biopsy mode.
kV	120	120	120
mAs	50.1	50	49.9
Rotation Speed (s)	0.6	0.374	0.374
Acquisition	8*0.625	8*0.625	4*0.625
Scan Interval(mm)	0mm	NA	NA
Pitch	NA	NA	NA
Slice Thickness	5mm	5mm	2.5mm
Slice Increment	NA	NA	NA
Kernel	F20	F20	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	NA	NA
ClearView	0%	NA	NA

ClearInfinity	0%	NA	NA
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**CCT Single**	**Chest+C**	**Chest Large**
Brief Description	Single multislice biopsy mode.	Adult routine helical studies using ClearView mode for the region of thorax.	Adult's BMI more than 30 routine helical studies for the region of thorax
kV	120	120	120
mAs	50	150	180
Rotation Speed (s)	0.374	0.6	0.6
Acquisition	24*0.625	128*0.625	128*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	NA	0.9	1.2
Slice Thickness	5mm	5mm	5mm
Slice Increment	NA	5mm	5mm
Kernel	F20	F20	F20/Lung20
Resolution	Standard	Standard	Standard
O-Dose	NA	OFF	OFF
ClearView	NA	30%	30%
ClearInfinity	NA	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Chest LD**	**Chest**	**C/A/P Large**
Brief Description	Adult low dose helical studies for the region of thorax	Adult routine helical studies for the region of thorax	Helical scan for adult's BMI more than 30 thoracic, abdomen, and pelvis routine studies.
kV	120	120	140
mAs	30	180	150
Rotation Speed (s)	0.6	0.6	0.5
Acquisition	128*0.625	128*0.625	128*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	1.2	0.9	1.4
Slice Thickness	5mm	5mm	5mm
Slice Increment	5mm	5mm	5mm
Kernel	F20/Lung20	F20/Lung20	F20

Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	0%	30%	30%
ClearInfinity	50%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**C/A/P LD**	**C/A/P**	**HRCT Ax.+OrganSafe**
Brief Description	Helical scan using low dose mode for adult thoracic, abdomen, and pelvis routine studies.	Helical scan for adult thoracic, abdomen, and pelvis routine studies.	Axial scan using OrganSafe mode for adult high resolution lung studies
kV	120	120	120
mAs	50	200	149.9
Rotation Speed (s)	0.5	0.5	0.5
Acquisition	128*0.625	128*0.625	2*0.625
Scan Interval(mm)	NA	NA	10
Pitch	1.4	1.4	NA
Slice Thickness	5mm	5mm	1.25mm
Slice Increment	5mm	5mm	NA
Kernel	F20	F20	Lung30
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**HRCT Ax.**	**HRCT**	**Inf Thorax<10kg**
Brief Description	Axial scan for adult high resolution lung studies	Helical scan for adult high resolution lung studie	Helical routine thorax scan for infant weight lower than 10kg.
kV	120	120	100
mAs	140	180	75
Rotation Speed (s)	0.5	0.6	0.5
Acquisition	2*0.625	32*0.625	64*0.625
Scan Interval(mm)	10	NA	NA
Pitch	NA	0.9	0.8
Slice Thickness	1.25mm	2mm	3mm

Slice Increment	NA	2mm	3mm
Kernel	Lung30	Lung20/F20	Lung20/F20
Resolution	High	High	High
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**PE**	**Thorax 10-30kg**	**Thorax 30-50kg**
Brief Description	Helical scan for adult pulmonary emboli studies.	Helical routine thorax scan for children weight from 10kg to 30kg.	Helical routine thorax scan for children weight from 30kg to 50kg
kV	120	100	120
mAs	150	150	100
Rotation Speed (s)	0.5	0.5	0.6
Acquisition	128*0.625	64*0.625	64*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	1	0.8	1.2
Slice Thickness	1mm	5mm	5mm
Slice Increment	0.5mm	5mm	5mm
Kernel	F20	Lung20/F20	Lung20/F20
Resolution	Standard	High	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Thorax 50-70kg**	**TIBT**	**Cervical Spine Ax.**
Brief Description	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	Axial scan for adult spine studies
kV	120	120	120
mAs	150	29.9	300

Rotation Speed (s)	0.6	0.6	1
Acquisition	64*0.625	16*0.625	8*0.625
Scan Interval(mm)	NA	0	5
Pitch	0.9	NA	NA
Slice Thickness	5mm	10mm	1.25mm
Slice Increment	5mm	NA	NA
Kernel	Lung20	F20	F20/F60
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	0%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Cervical Volume Large**	**Cervical Volume LD**	**Cervical Volume**
Brief Description	Helical scan for adult's BMI more than 30 Cervical spines	Helical scan using low dose mode for adult Cervical spines	Helical scan for adult Cervical spines.
kV	120	120	120
mAs	250	150	200
Rotation Speed (s)	1	1	0.6
Acquisition	128*0.625	128*0.625	64*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.9	0.9	0.9
Slice Thickness	3mm	3mm	3mm
Slice Increment	3mm	3mm	3mm
Kernel	F60/F20	F20/F60	F60/F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Lumbar Spine Ax.**	**Lumbar Volume Large**	**Lumbar Volume LD**
Brief Description	Axial scan for adult spines.	Helical scan for adult's BMI more than 30 Lumbar spines.	Helical scan using low dose mode for adult Lumbar spines

kV	120	140	120
mAs	350	249.8	175.1
Rotation Speed (s)	1	0.8	0.8
Acquisition	16*0.625	128*0.625	128*0.625
Scan Interval(mm)	10	NA	NA
Pitch	NA	0.9	0.9
Slice Thickness	2.5mm	3mm	3mm
Slice Increment	NA	3mm	3mm
Kernel	F20/F60	F60/F20	F60/F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Lumbar Volume**	**Thoracic Volume Large**	**Thoracic Volume LD**
Brief Description	Helical scan for adult Lumbar spines	Helical scan for adult's BMI more than 30 Thoracic spines	Helical scan using low dose mode for adult Thoracic spines
kV	120	120	120
mAs	250	325.3	175.3
Rotation Speed (s)	0.6	0.8	0.6
Acquisition	128*0.625	128*0.625	128*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.9	0.9	0.9
Slice Thickness	3mm	3mm	3mm
Slice Increment	3mm	3mm	3mm
Kernel	F60/F20	F60/F20	F60/F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Thoracic Volume**	**Abdomen +C**	**Abdomen Large**

Brief Description	Helical scan for adult Thoracic spines	Helical scan using ClearView 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.
kV	120	120	140
mAs	250	200	250
Rotation Speed (s)	0.6	0.6	0.6
Acquisition	128*0.625	128*0.625	128*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.9	1.2	1.2
Slice Thickness	3mm	5mm	5mm
Slice Increment	3mm	5mm	5mm
Kernel	F60/F20	F20	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	0%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Abdomen LD**	**Abdomen.Prism**	**Abdomen**
Brief Description	Helical scan using low dose mode for adult routine studies in the region of abdomen.	Helical scan for adult abdomen prism studies.	Helical scan for adult routine studies in the region of abdomen.
kV	120	140	120
mAs	50	150	200
Rotation Speed (s)	0.6	0.5	0.6
Acquisition	128*0.625	128*0.625	128*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	1.2	0.4	1.2
Slice Thickness	5mm	5mm	5mm
Slice Increment	5mm	5mm	5mm
Kernel	F20	F20	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	0%	30%	30%
ClearInfinity	50%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP

			2000mGy·cm

Protocols	**Abdomen 4D Perfusion**	**Abd/Pel 10-30kg**	**Abd/Pel 30-50kg**
Brief Description	It is an abdomen 4D Perfusion scan for cradle mode.	Helical routine abdomen scan for children weight from 10kg to 30kg.	Helical routine abdomen scan for children weight from 30kg to 50kg.
kV	80	120	120
mAs	247.9	100	120
Rotation Speed (s)	0.5	0.5	0.6
Acquisition	128*0.625	64*0.625	64*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.9	0.8	0.9
Slice Thickness	5	5mm	5mm
Slice Increment	5	5mm	5mm
Kernel	F20	F20	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	0%	30%	30%
ClearInfinity	30%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Abd/Pel 50-70kg**	**Adrenal gland**	**Aorta CTA Large**
Brief Description	Helical routine abdomen scan for children weight from 50kg to 70kg.	Helical scan for adult adrenal gland.	Helical scan for adult's BMI more than 30 thoracic angiography.
kV	120	120	120
mAs	150	250	240
Rotation Speed (s)	0.6	0.6	0.5
Acquisition	64*0.625	32*0.625	128*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.9	0.9	1
Slice Thickness	5mm	2mm	1mm
Slice Increment	5mm	2mm	0.5mm
Kernel	F20	F20	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	0%	30%	30%

ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Aorta CTA LD**	**Aorta CTA**	**Aortaventralis CTA**
Brief Description	Helical scan using low dose mode for adult thoracic angiography.	Helical scan for adult thoracic angiography.	Helical scan for adult abdomen.
kV	120	120	120
mAs	120	200	180
Rotation Speed (s)	0.5	0.5	0.5
Acquisition	128*0.625	128*0.625	128*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	1	1	1
Slice Thickness	1mm	1mm	1mm
Slice Increment	0.5mm	0.5mm	0.5mm
Kernel	F20	F20	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Biopsy**	**Body STD-QA**	**Body UHR-QA**
Brief Description	Low dose axial scan without table movement used to biopsy.	Body standard resolution QA protocol.	Body ultrahigh resolution QA protocol.
kV	120	120	120
mAs	50.1	200	200
Rotation Speed (s)	0.6	1	1
Acquisition	8*0.625	64*0.625	8*0.3125
Scan Interval(mm)	0	40	5
Pitch	NA	NA	NA
Slice Thickness	5mm	5mm	0.3125mm
Slice Increment	NA	NA	NA
Kernel	F20	F20	U10
Resolution	Standard	Standard	UltraHigh3D
O-Dose	OFF	OFF	OFF

ClearView	0%	0%	0%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**CCT Continuous**	**CCT Fluoro**	**CCT Single**
Brief Description	Continuous multislice biopsy mode.	Fluoroscopic biopsy mode.	Single multislice biopsy mode.
kV	120	120	120
mAs	50	49.9	50
Rotation Speed (s)	0.374	0.374	0.374
Acquisition	8*0.625	4*0.625	24*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	NA	NA	NA
Slice Thickness	5mm	2.5mm	5mm
Slice Increment	NA	NA	NA
Kernel	F20	F20	F20
Resolution	Standard	Standard	Standard
O-Dose	NA	NA	NA
ClearView	NA	NA	NA
ClearInfinity	NA	NA	NA
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Colon**	**Inf Abd/Pel<10kg**	**Liver+C**
Brief Description	Helical scan for adult of the application CT Colonography.	Helical routine abdomen scan for infant weight lower than 10kg.	Helical scan using ClearView mode for adult routine studies in the region of liver.
kV	120	100	120
mAs	100	100	250
Rotation Speed (s)	0.6	0.5	0.6
Acquisition	128*0.625	64*0.625	128*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	1.2	0.8	0.9
Slice Thickness	2mm	3mm	5mm
Slice Increment	1mm	3mm	5mm
Kernel	F20	F20	F20
Resolution	Standard	Standard	Standard

O-Dose	OFF	OFF	OFF
ClearView	0%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Liver**	**Pancreas**	**Renal CTA**
Brief Description	Helical scan for adult's liver.	Helical scan for adult's pancreas.	Helical scan for adult renal CTA studies.
kV	120	120	120
mAs	250	250	180
Rotation Speed (s)	0.6	0.6	0.5
Acquisition	128*0.625	32*0.625	64*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.9	0.9	1
Slice Thickness	5mm	3mm	1mm
Slice Increment	5mm	3mm	0.5mm
Kernel	F20	F20	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Runoff CTA**	**TIBT**	**Hip joint 7 yrs+**
Brief Description	Helical scan for adult CTA studies from aorta to extremities artery.	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.	Helical scan for hip joint of more than 7 years children.
kV	120	120	120
mAs	180	29.9	150
Rotation Speed (s)	0.5	0.6	0.6
Acquisition	128*0.625	16*0.625	32*0.625
Scan Interval(mm)	NA	0	NA
Pitch	1	NA	0.9

Slice Thickness	1mm	10mm	3mm
Slice Increment	0.5mm	NA	3mm
Kernel	F20	F20	F60/F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	0%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Hip joint**	**Pelvis Routine+C**	**Pelvis Routine**
Brief Description	Helical scan for hip joint of adult.	Helical scan using ClearView mode for adult pelvis studies.	Helical scan for adult pelvis studies.
kV	120	120	120
mAs	250	250	250
Rotation Speed (s)	0.6	0.6	0.6
Acquisition	32*0.625	128*0.625	128*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.9	0.9	0.9
Slice Thickness	3mm	5mm	5mm
Slice Increment	3mm	5mm	5mm
Kernel	F60/F20	F20	F20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Sacroiliac joint**	**ElbowJoint**	**Extremity 7yrs+**
Brief Description	Helical scan for adult sacroiliac joint.	Helical scan for adult elbow joint studies.	Helical scan for extremity of more than 7 years children.
kV	120	140	120
mAs	250	250	120
Rotation Speed (s)	0.6	0.8	0.8
Acquisition	64*0.625	128*0.625	32*0.625
Scan Interval(mm)	NA	NA	NA
Pitch	0.9	0.8	0.9

Slice Thickness	5mm	3mm	3mm
Slice Increment	5mm	3mm	3mm
Kernel	F20/F60	F20/F60	F20/F60
Resolution	Standard	Standard	High
O-Dose	OFF	OFF	OFF
ClearView	30%	30%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Extremity iHD Ax.**	**Extremity iHD**	**Extremity Volume**
Brief Description	Axial scan using iHD mode for adult high resolution bone studies.	Helical scan using iHD mode for adult high resolution bone studies.	Helical scan for adult high resolution bone studies.
kV	120	120	120
mAs	300	400	150.2
Rotation Speed (s)	1	1	0.8
Acquisition	8*0.625	16*0.625	32*0.625
Scan Interval(mm)	5mm	NA	NA
Pitch	0.9	0.9	0.9
Slice Thickness	1.25mm	0.625mm	2mm
Slice Increment	NA	0.3125mm	1mm
Kernel	U10	U10	F60
Resolution	UltraHigh2D	UltraHigh2D	High
O-Dose	OFF	OFF	OFF
ClearView	0%	0%	0%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Extremity.Prism**	**Knee iHD**	**Knee**
Brief Description	Helical scan for adult bone prism studies.	Helical scan using iHD mode for adult high resolution knee studies.	Helical scan for adult knee studies.
kV	140	120	120
mAs	100.5	400	200
Rotation Speed (s)	0.6	1	0.8
Acquisition	128*0.625	16*0.625	32*0.625

Scan Interval(mm)	NA	NA	NA
Pitch	0.4	0.9	0.8
Slice Thickness	5mm	0.625mm	3mm
Slice Increment	5mm	0.3125mm	3mm
Kernel	F20	U10	F60/F20
Resolution	Standard	UltraHigh2D	High
O-Dose	OFF	OFF	OFF
ClearView	30%	0%	30%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm
Protocols	**Shoulder/Hip Volume**	**Calcium Scoring Cine**	**Calcium Scoring**
Brief Description	Helical scan for adult shoulder or hip studies.	ECG-gated axial scan using cine mode for adult coronary calcium scoring.	ECG-gated axial scan for adult coronary calcium scoring.
kV	140	120	120
mAs	250	100.2	100
Rotation Speed (s)	0.6	0.374	0.374
Acquisition	128*0.625	32*0.625	32*0.625
Scan Interval(mm)	NA	20	20
Pitch	0.9	NA	NA
Slice Thickness	3mm	2.5mm	2.5mm
Slice Increment	3mm	NA	NA
Kernel	F60/F20	Cardiac 50	Cardiac 50
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	OFF
ClearView	30%	0%	0%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Coronary CTA+ ClearView**	**Coronary CTA Ax.**	**Coronary CTA DOM 0%**
Brief Description	ECG-gated helical scan using ClearView mode for adult coronary CTA.	Axial scan for adult coronary CTA studies.	ECG-gated helical scan using DOM mode with 0% dose of non-recon phase for adult coronary CTA.
kV	120	120	120
mAs	349.1	99.9	650.8
Rotation Speed (s)	0.374	0.374	0.374

Acquisition	128*0.625	128*0.625	128*0.625
Scan Interval(mm)	NA	31.7	NA
Pitch	0.2	NA	0.2
Slice Thickness	1mm	1mm	1mm
Slice Increment	0.5mm	NA	0.5mm
Kernel	Cardiac 20	Cardiac 20	Cardiac 20
Resolution	Standard	Standard	Standard
O-Dose	OFF	OFF	NA
ClearView	50%	0%	0%
ClearInfinity	0%	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

Protocols	**Coronary CTA DOM**	**Coronary CTA**
Brief Description	ECG-gated helical scan using DOM mode for adult coronary CTA.	ECG-gated helical scan for adult coronary CTA.
kV	120	120
mAs	650	650
Rotation Speed(s)	0.374	0.374
Acquisition	128*0.625	128*0.625
Scan Interval(mm)	NA	NA
Pitch	0.2	0.2
Slice Thickness	1mm	1mm
Slice Increment	0.5mm	0.5mm
Kernel	Cardiac 20	Cardiac 20
Resolution	Standard	Standard
O-Dose	OFF	OFF
ClearView	0%	0%
ClearInfinity	0%	0%
Dose Alert	Max CTDIvol 250mGy Max DLP 2000mGy·cm	Max CTDIvol 250mGy Max DLP 2000mGy·cm

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).

Chapter 17 Abbreviations

Abbreviations	Acronym
ACR	American College of Radiology
Ax.	Axial
CFR	Code of Federal Regulations
cm	Centimeter
CT	Computed Tomography
CTDI	Computed Tomography Dose Index
DFOV	Display 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
IV	Intra-venous
kg	kilogram
kV	kilo-Volts
LCR	Low Contrast Resolution
lb	Pound
mA	Milliamps
mGy	Milligray
mm	Millimeter
MPR	Multiplanar Reconstruction
MTF	Modulation Transfer Function
PMMA	Poly-methyl methacrylate
QA	Quality Assurance
ROI	Region of Interest
WL	Window Level

Abbreviations	Acronym
WW	Window Width
s	second
STD	Standard resolution
SSDE	Size Specific Dose Estimates
UHR	Ultrahigh resolution

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Multi-slice CT Scanner System
NeuViz 128
User Manual (Vol. 2)

CE 0123

NEUSOFT MEDICAL SYSTEMS CO., LTD.

Neusoft Medical Systems

Contents

Chapter 1. 2D Viewer

1.1 Overview

2D application provides several layouts to display one or more series. There are several choices for mode selection. It is possible to flip images, sort images and do batch operations. 2D supports zooming the image, drawing ROI's and other basic operations. These options are found in the generic tool area.

1.2 2D Viewer Interface

In the home page, select the desired images from the patient list and choose the **2D** application.

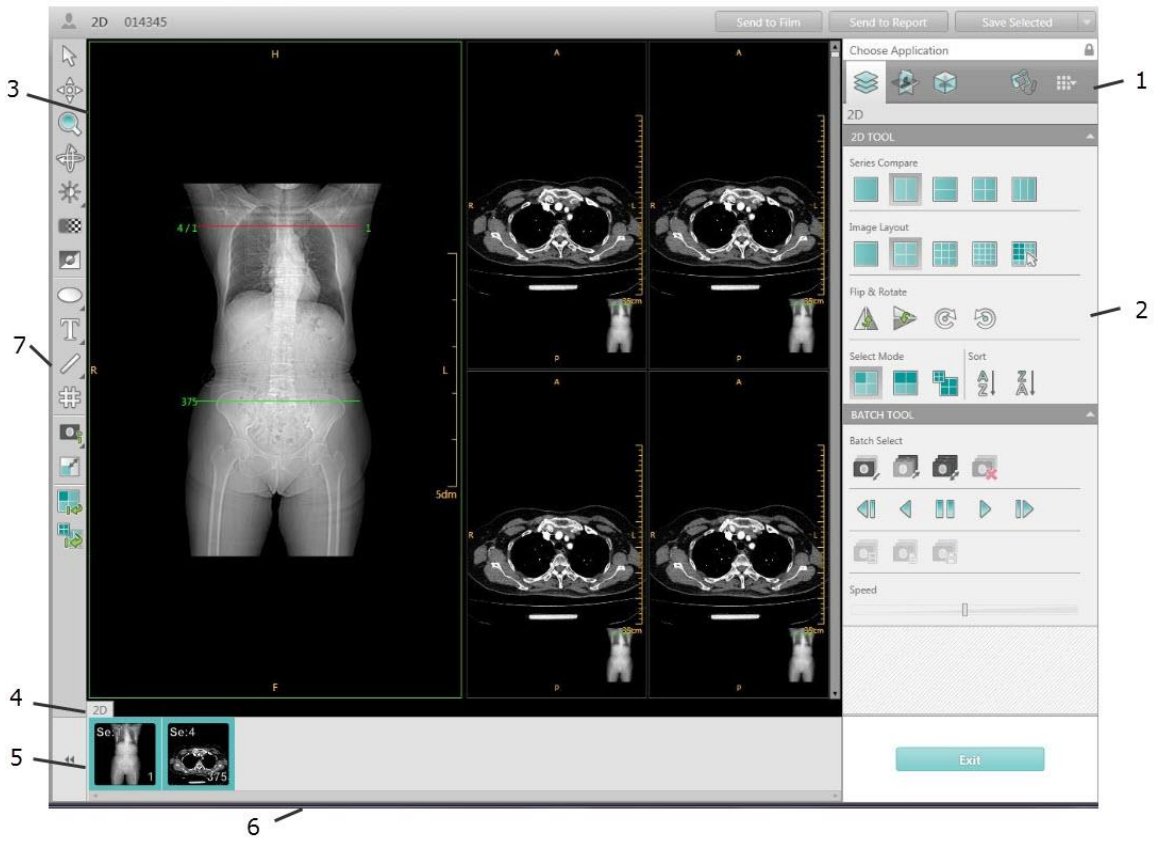


Figure 1-1 2D Interface

Table 1-1 2D Interface

No.	2D Display Interface Component
1	Menu Bar
2	Application Control Panel
3	Image Viewport
4	Patient Series List
5	Patient Image Thumbnails
6	System Information Bar
7	Common Tool Panel

1.3 Menu Bar

A maximum of 4 applications can be displayed on the system menu bar. More than 4 applications can be displayed by expanding the button.

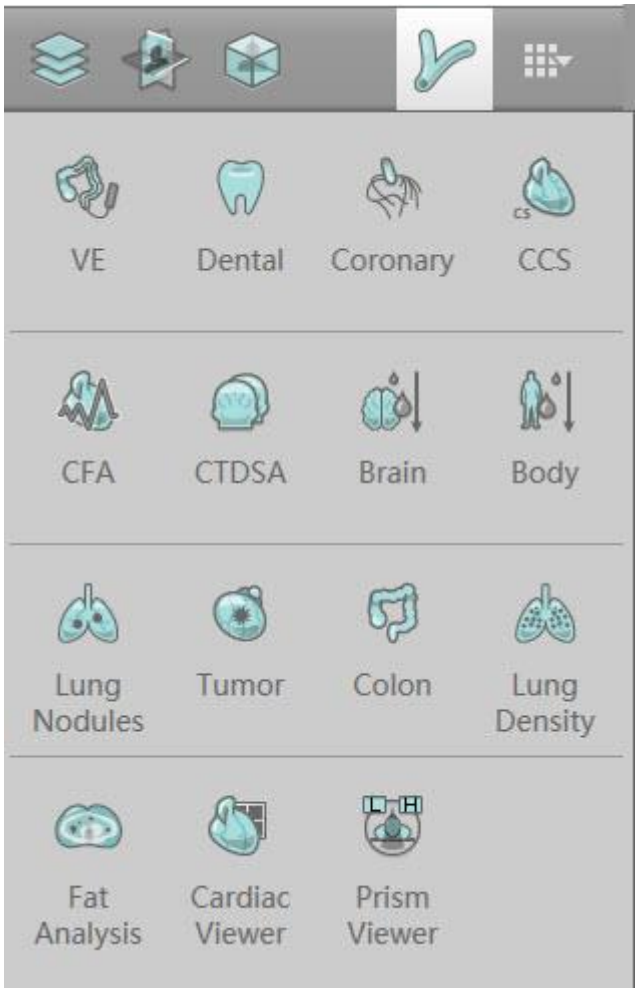


Figure 1-2 Application Options

1.4 Patient Image Thumbnails

1.4.1 Load Images

The number at the lower right corner of each Thumbnail shows how many images are contained in that series. To load the series, double click the Thumbnail. Then the image series will be loaded.

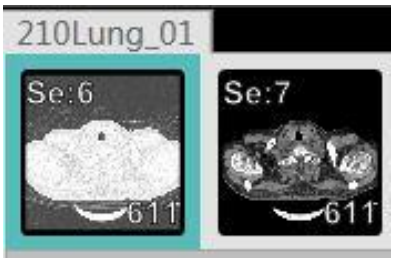


Figure 1-3 Load Images

1.4.2 Series Information

When you right click on the Thumbnail, the Series information is shown.

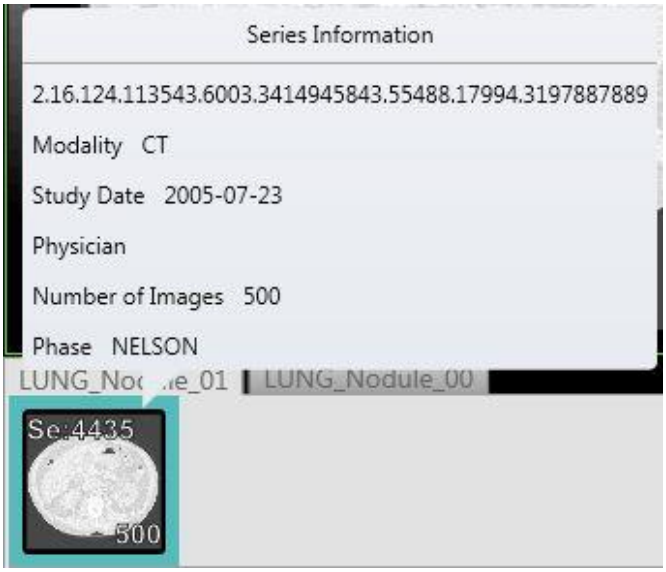


Figure 1-4 Series Information

1.5 Patient Information

Right click the patient icon, and the Patient Information appears.

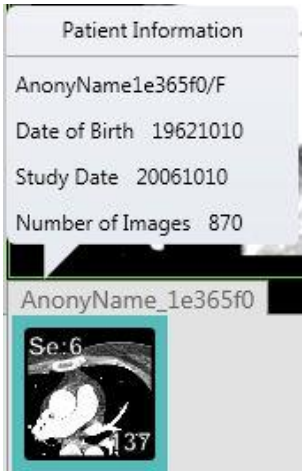


Figure 1-5 Patient Information

1.6 Image Display Region

The image display region can show the images in different layouts. The image layout format can be changed from 1x1 to 10x10.

1.6.1 Window Display

The four corners of the display window show the Patient Information and the Image Information according to the settings determined by the User.

1.6.2 Window Enlargement

Click the Enlarge icon on the left corner of the generic tool panel.Then the image display region will be shown in the enlarged format.

Click the Enlarge icon again, and then the image display region returns to the original display format.

1.6.3 Window Menu

Right click any image in the image display region, then the Right Key menu appears. The Right Key menu is composed of the following choices:

- **Select**

It is used to leaf through the images.

Select this function. The cursor turns to , click on an image and then drag up or down to quickly view the images.

- **Pan**

Select this function. The cursor turns to , click on an image and then drag to move the image to the desired position.

- **Zoom**

Select this function. The cursor turns to  , click on an image and then drag up or down to zoom in or out.

- **Rotate**

Select this function. The cursor turns to  , click on an image and then drag up or down to rotate the image as desired.

- **Modify Window Width and Level**

Select this function. The cursor turns to  , click on an image and then drag up or down to change the desired WL (Window Level) level [Up to increase WL, down to decrease WL]. Drag left or right to change WW (Window Width) [Right to increase the WW level, Left to decrease the WW level].

- **Send to Film**

Select this function and the image will be sent to the Film Interface automatically.

- **Send to Report**

Select this function and the image will be sent to the Report Interface automatically.

- ROI (Region of Interest) [Select from the following ROI types]

- **Rectangle**: Select Rectangle in the ROI menu or click  on the generic tool panel area. Then the cursor turns to  . Select the desired area on the image for measurement.

- **Ellipse**: Select Ellipse in the ROI menu or click  on the common tool panel. Then the cursor turns to  . Select the desired area on the image for measurement.

- **Polygon**: Select Polygon in the ROI menu or click  on the common tool panel. Then the cursor turns to  . Select the desired area on the image for measurement.

- **Text**: Select Text in the ROI menu or click  on the common tool panel. Then the cursor turns to  . Draw a text edit box in the desired position.

- **Arrow**: Select Arrow in the ROI menu or click  on the common tool panel. Then the cursor turns to  . Draw an arrow on the image to point to what you want to draw attention to, such as anatomy or a text box.

- **Line**: Select Line in the ROI menu or click  on the common tool panel. Then the cursor turns to  . Draw the desired line on the image for measurement.

- **Polyline**: Select Polyline in the ROI menu or click  on the common tool panel. Then the cursor turns to  . Draw the desired line on the image for measurement.

- **Angle**: Select Angle in the ROI menu or click  on the common tool panel. Then the cursor turns to  . Draw the desired angle on the image for measurement.

- **Pixel Value**: Select Pixel Value in the ROI menu or click  on the common tool panel. Then the cursor turns to  . Click anywhere on the image to get the corresponding CT values for that pixel.

- **Profile**: Select Profile in the ROI menu or click  on the common tool panel. Then the cursor turns to  . Measure the CT values on a line which goes through the image.

- **Histogram**: Select Histogram in the ROI menu or click  on the common tool panel. Then the cursor turns to  . Select the desired area on the image for measurement.

- **Display**

- Text Orientation: Displays text orientation.

- 3D Orientation: Displays 3D orientation.

- Ruler: Displays Measurement Scale on the image.

- Gray Bar: Displays Gray Scale on the image.

- **Window**

- Normal: Display normal layout.

- Full Screen: Switch the image display to the full screen mode.

- **Reset Image**: The selected image returns to the original status.

- **Display Location Line**: Display Location Line on the Surview image.

- **Display Surview image:** Display demo Surview with Location Line on the image.

- **Copy Annotations to Series:** Copy the annotations in current image to series.

1.7 Control Panel

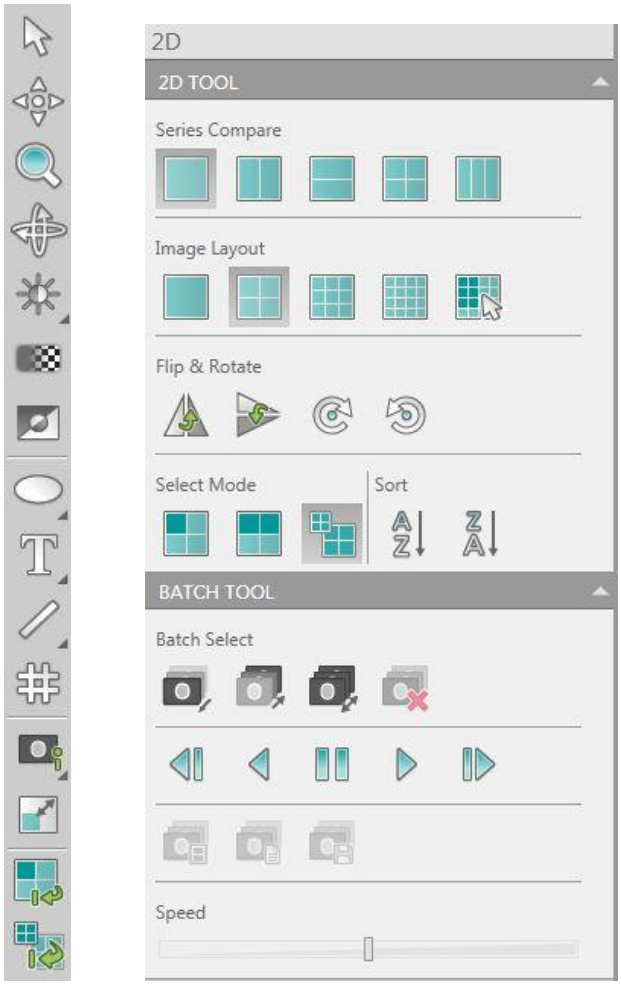


Figure 1-6 Control Panel

Control panel includes three parts: 2D Tool, Batch Tool and the Common tools.

2D Tool is specific to the 2D viewer.

Batch Tool is used to look at a select group of images.

Common tools are applicable for all viewers.

1.7.1 2D Tool

The 2D Tool includes the following:

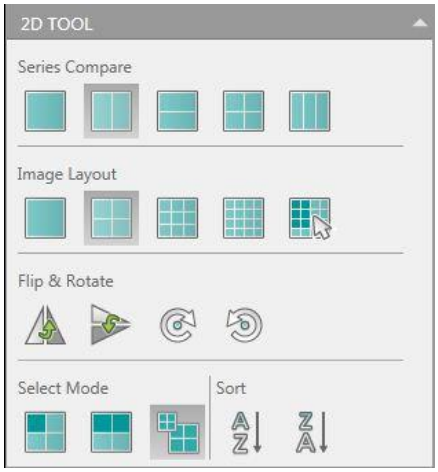


Figure 1-7 2D Tool

Series Compare:

There are 5 different series layouts. They are 1x1, 1x2, 2x1, 2x2 and 1x3.

Click the layout icon to select the desired layout.

Image Layout:

There are 5 different image layout formats. They are 1(Row)x1(Column), 2x2, 3x3, 4x4, customize.

Click the customize icon to set the number of the rows and columns visually. The number of the rows ranges from 1 to 10. The number of the columns ranges from 1 to 10.

Flip/ Rotate:

 : Flip Horizontal

 : Flip Vertical

 : Rotate Clockwise

 : Rotate Counter-clockwise

Selection Mode:

Image: Select one image according to the need. The selected image is framed in green.

Series: Select one series according to the need. The selected entire series is framed in green.

All: Select all the series in the Series List. All the series are framed green.

Sort:

Ascending: Sort the series in ascending order.

Descending: Sort the series in descending order.

1.7.2 Batch Tool

Figure below shows the Batch Tool, including Range, Batch and Cine.

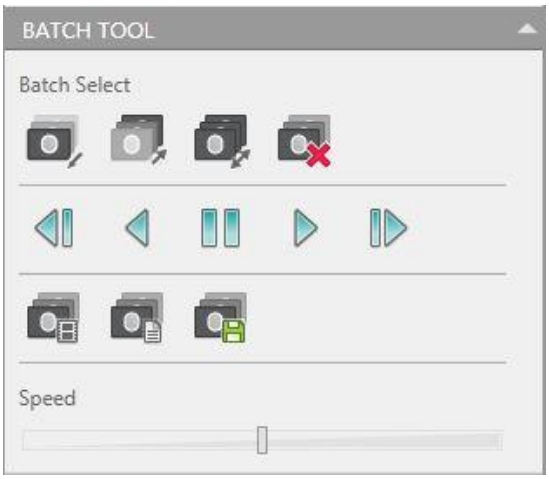


Figure 1-8 Batch Tool

Batch Select

Start: Select the first image in the series to begin the batch.

End: Select the last image of the batch series. This will mark the end of the batch.

All: Select all the images of the series for the batch.

Clear: Clear the images of the batch.

Cine

It's used to continuously display the group of selected images.

Step Backward: Play the batch of images step by step backward.

Backward: Play the batch of images backward.

Pause: Stop playing the batch of images.

Forward: Play the batch of images forward.

Step Forward: Play the batch of images step by step forward.

Speed: Adjust Cine Speed [Left to decrease the speed at which the images are

scrolled through, and right to increase the speed].

Batch

Send Batch to Film: Send the selected group of images to the Film.

Send Batch to Report: Send the selected group of images to the Report.

Save Batch: Select SAVE BATCH to label and send the images to the directory.

1.7.3 Common Tools

The common tools are applicable for all the viewers.

Figure 1-9 Common tools

Modify Window Width and Level: Right click this button and select a protocol from the list. The images will be displayed according to the selected protocol. The other option is Left click on the and drag the mouse right to left or up and down over the image to change the W/W or W/L.

Enhance and Smooth: Click this button and the cursor turns to , click on the

image and then drag up or down to the desired enhancement value.

Inverse: Select an image and then click this button. The images will be displayed by inverse color.

Grid: Click this button. A grid is over laid on the image.

Refer to **Chapter 1.6.3** Window Menu for more information regarding the other ROIs.

Enlarge: Click this button and then the image display layout format becomes 1x1 even if the original layout was not 1x1. Click it again, the format returns to the original setting.

Reset All: All images return to the original status.

1.7.3.1 Image Output

Save Selected Click the arrow in the right corner or right click in the Save Selected region. The Right Key menu appears. The Right Key menu is composed of the following options:

Save Selected, Save Displayed, Save Batch, and Save Marker.

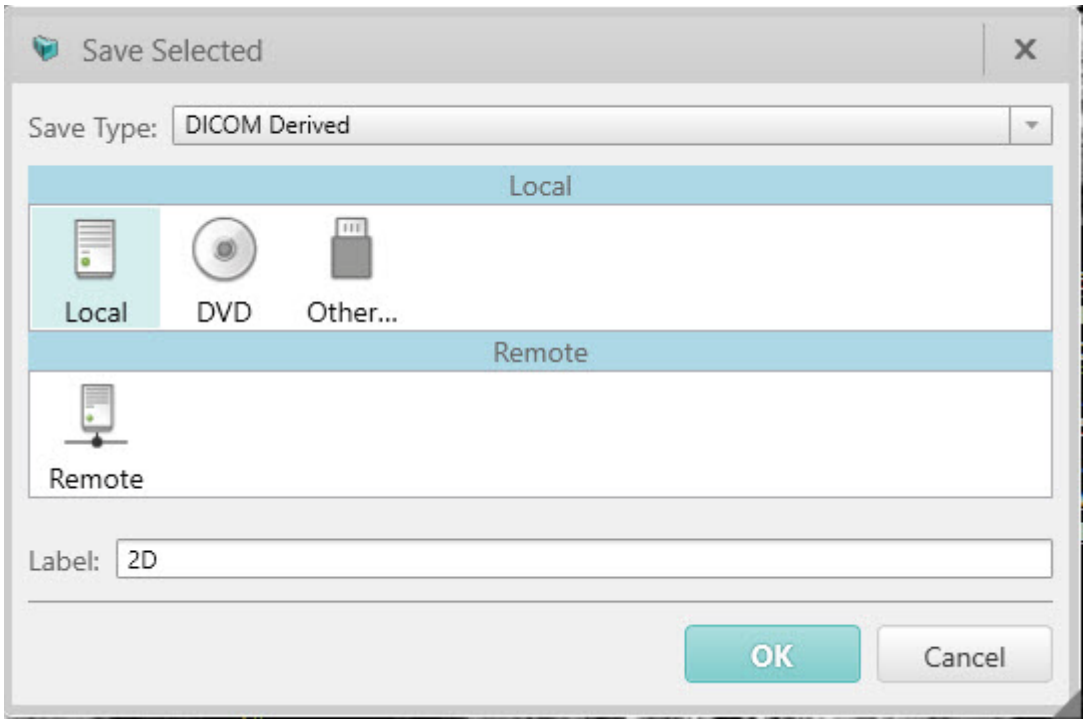


Figure 1-10 Save Interface

The image can be saved to Local, CD/DVD, USB, or Remote Server.

It can be saved in the following formats:

• DICOM (derived), DICOM (screenshot), DICOM (PS), BMP, JPG, PNG, TIF and AVI.

•The DICOM (derived), DICOM (screenshot), DICOM (PS) images can be saved to Remote Server.

•The DICOM (derived), DICOM (screenshot) images can be saved to Local.

• For DICOM (derived), DICOM (screenshot) images, descriptions can be input in the Description area.

• 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.

NOTE:

- **The derived image has the same size as the original image, and records the markers and measurement information as a graphic overlay. Some operations, such as WW/WL adjustment, zoom, marker and measurement are still possible on the derived image.**

- **The secondary capture image is just a screenshot saved in DICOM format. It is not possible to adjust WW/WL, zoom, or add any marker or measurement information to this type of image.**

1.7.3.2 Image Display

 : Click the arrow in the right corner or right click, then the Right Key menu appears. The Right Key menu is composed of the following options:

Image Information: Hide/Show the Patient Information on the image.

Detailed Information: Show all the image parameters.

- Send to Film: Send the image information to the film.

- Save: Save the image information.

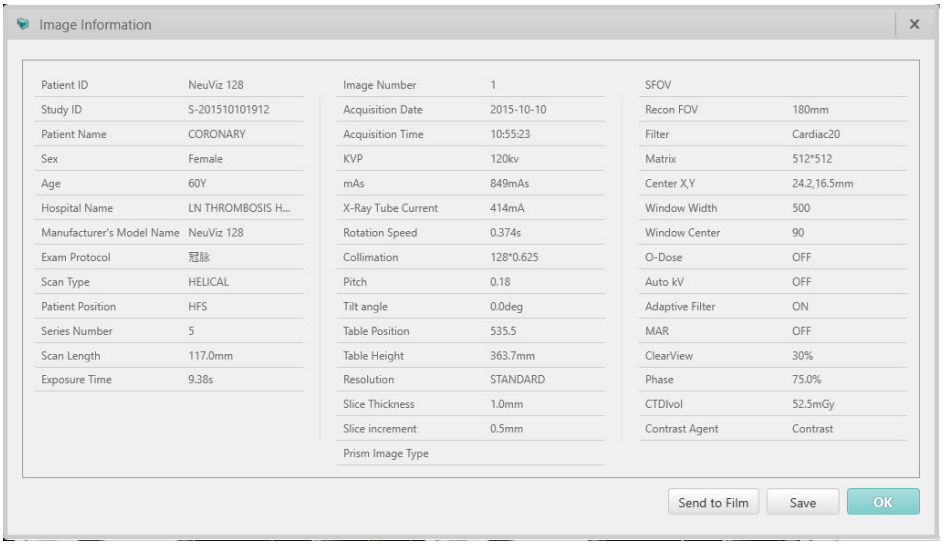


Figure 1-11 Image Information

1.7.3.3 Exit

Exit: Exit the post processing interface and go back to Home.

1.7.3.4 AVW Setting

NOTE:

- **This function is only available for AVW, console software does not support it.**

In the workstation, click the blank region on the right corner of the menu, then you can view Disk Space, Local IP address, Screen Setting, RFR setting and Coronary Motion Clear setting.

Figure 1-12 AVW Setting

Screen Setting: Secondary screen can be set as Review, Film or Report, the default secondary screen is Film.

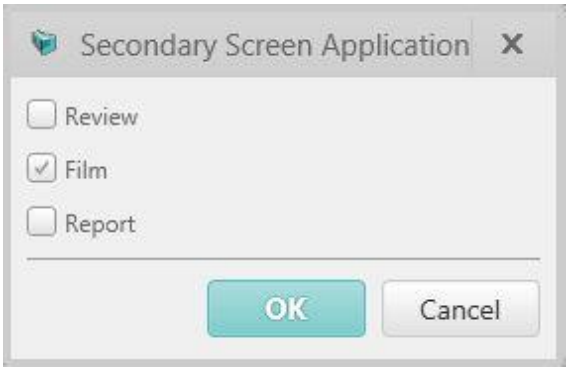


Figure 1-13 Secondary Screen Application

RFR: Ready for Reading

In the workstation, RFR is an application that you can use RFR result as a marker. RFR is a form of automatic post processing.

In the RFR setting screen, You can open or close RFR function, add or modify protocol name and corresponding RFR type. AVW execute RFR function on received images according to protocol, to reduce image processing time and improve efficiency.

A Case Study in coronary, according to protocol, AVW execute RFR function (Coronary automatically extracting) in background on received CAA images, RFR results are saved in Home as marker. You can open RFR result in Home to load data after the Coronary vessels are automatically extract.

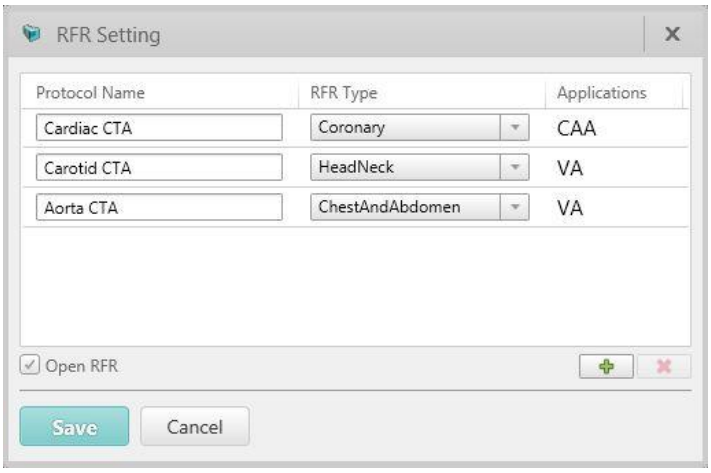


Figure 1-14 RFR Setting

Coronary Motion Clear: Coronary motion artifacts could be corrected by Coronary Motion Clear and then generate a new reconstructed series. (Coronary Motion Clear function is also available in the VR window of CAA application).

Select the Coronary Motion Clear, configure the relative information of remote connection, including AE Title, Remote IP, Remote Port etc. In the VR window of CAA application, select the Coronary Motion Clear in the Right-Click Menu, then select one or more vessels and click OK button. System will automatically display the reconstructed series in the series list.

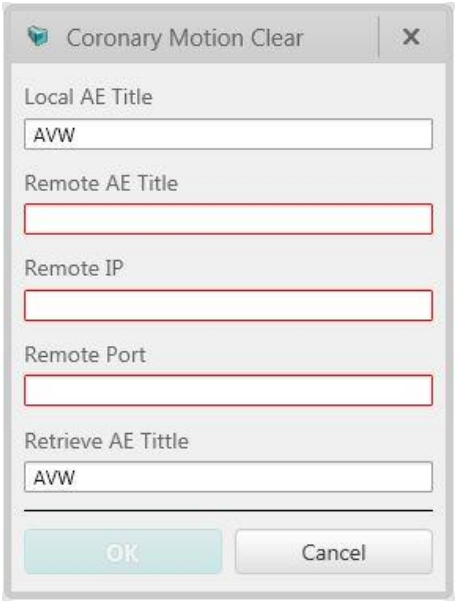


Figure 1-15 Coronary Motion Clear

1.8 Keyboard shortcut

The system offers the following keyboard shortcuts listed below:

Table 1-2 Keyboard shortcut

Key	Function	Viewer
F1	Brain	Common
F2	Lung	Common
F3	Mediastinum	Common
F4	Abdomen	Common
F5	Bone	Common
F6	Spine	Common
F7	IAC	Common
F8	CTA	Common
F9	Sinus	Common
F10	Liver	Common
F11	Colon	Common
F12	Auto Windowing	Common
Arrow Up or Page Up	Scroll up	Common
Arrow Down or Page Down	Scroll down	Common
Home	Scroll to beginning	Common
End	Scroll to end	Common
CTRL + P	Send image to Film	Common
CTRL + R	Send images to Report	Common
CTRL + A	Select All the images	2D,Film
CTRL + S	Save image	Common
Delete	Delete image	Common, Report and Film
ESC	Reset the mouse to select mode	2D,Film
Ctrl + Enter	Enlarge the view	Common
Alt + Enter	Full screen view	Common
Ctrl + Mouse left-click	Select image	Common
Shift+ Mouse left-click	Select image	Common

Hold the right button and move the mouse	Pan	Common
Hold the "left + right" button and move the mouse	Zoom	Common
W	Play Forward	VE
S	Play Backward	VE
A	Move left	VE
D	Move right	VE
X	Move up	VE
Z	Move down	VE
E	Rotate anti-clockwise	VE
Q	Rotate clockwise	VE
Space	Play and pause	VE
A	Axial Orientation	3D
S	Sagittal Orientation	3D
C	Coronal Orientation	3D
R	Flip 3D image	3D
Ctrl+ mouse left-click	Rotate image when defining CPR curve	MPR, Define CPR
Delete	Delete seed point	MPR, Define CPR
Ctrl+ mouse left-click	Extend CPR curve	MPR, Define CPR
Ctrl + C	Copy	Film
Ctrl + X	Cut	Film
Ctrl + V	Paste	Film
Ctrl + B	Swap	Film

Chapter 2. MPR Viewer

2.1 Overview

MPR package is designed for multi-planar reconstruction CT images. The main features include image visualization, different image display modes, CPR, Oblique and Batch. The images can be played, draw ROI, sent to report and printed. MPR can help radiologist evaluate lesions and provide important reference information for clinical treatment.

2.2 MPR Viewer Interface

In the home page, select the desired images from the patient list and choose the **MPR** application.

Figure 2-1 MPR Interface

2.3 Image Display Region

The MPR image display region with the layout of 2x2 is the default display. Four types of images are displayed simultaneously. They are Axial image (upper left),

Coronal image (upper right), Oblique/curved surface reconstruction image (lower left), and Sagittal image (lower right)

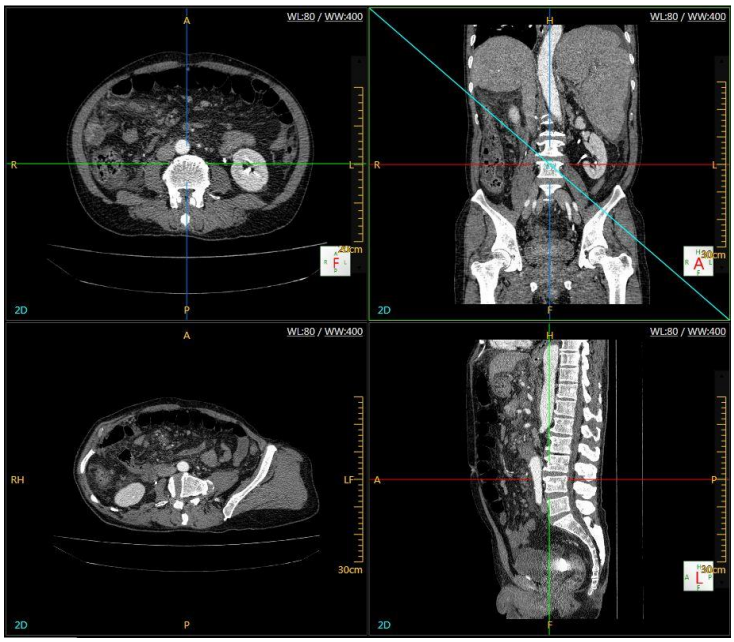


Figure 2-2 Image Display Region

2.3.1 Axial Image

The axial image is located in the upper left corner of the image display region. The axial image is displayed with two cross lines by default. To show/hide the cross lines, select the Crosshair in the MPR Tools on the right of the display. One line represents the Sagittal plane and the other represents the Coronal plane. The crosshair can be rotated to any angle.

2.3.2 Coronal Image

The coronal image is located in the upper right corner of the image display region. The coronal image is displayed with two cross lines by default. To show/hide the cross lines, select the Crosshair in the MPR Tools on the right of the display. One line represents the Sagittal plane and the other represents the Axial plane. The crosshair can be rotated to any angle.

2.3.3 Sagittal Image

The sagittal image is located in the lower right corner of the image display region. The sagittal image is displayed by default with two cross lines. To show/hide the cross lines, select the Crosshair in the MPR Tools on the right of the display. One line represents the Axial plane and the other represents the Coronal plane. The crosshair can be rotated to any angle.

NOTE:

- **Rotate the cross lines. Then the corresponding image will change following the position of the line.**

2.3.4 CPR image

This is located in the lower left corner of the image display region. Select Define Curve button on the MPR Tool panel, draw a path on the Axial image, Sagittal image or Coronal image. Then the CPR image is shown in the lower left corner of the image display region.

2.3.4.1 Image Display Mode

Four render modes are provided in the left corner of the image display region:

2D: Displays the original image.

MinIP: Displays the Minimum Intensity Projection images with the slice thickness.

AIP: Displays the Average Intensity Projection images with the slice thickness.

MIP: Displays the Maximum Intensity Projection images with the slice thickness.

NOTE:

- **Slice thickness field is disabled in 2D mode but enabled in other modes.**

Change the slice thickness:

Slice thickness value can be changed by editing the slice thickness edit box or dragging the slice bar. The slide bar is located in the middle lower portion of the image.

After selecting the application option, the image display changes according to the change in slice thickness. During the process of clicking on the up and down arrow on the right side of the edit box to increase or decrease slice thickness. It is not necessary to press Enter to confirm.

NOTE:

- **After selecting the application option, clicking the arrow at the right side of the edit box may cause a short delay.**

2.4 Control Panel

The control panel includes MPR Tool, Batch Tool and Compare Tool. MPR Tool is specific for the MPR viewer.

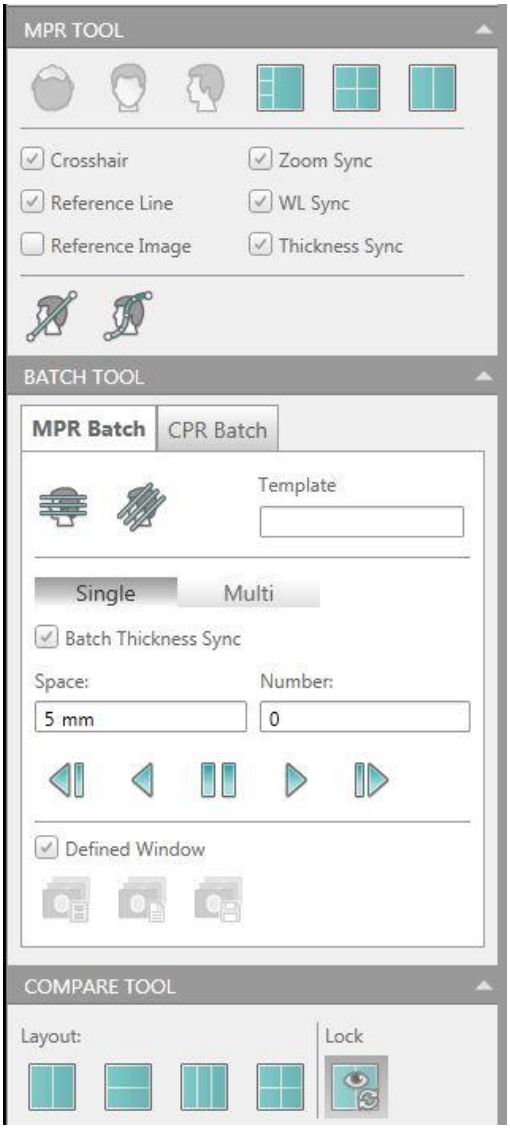


Figure 2-3 Control Panel

2.4.1 MPR Tool

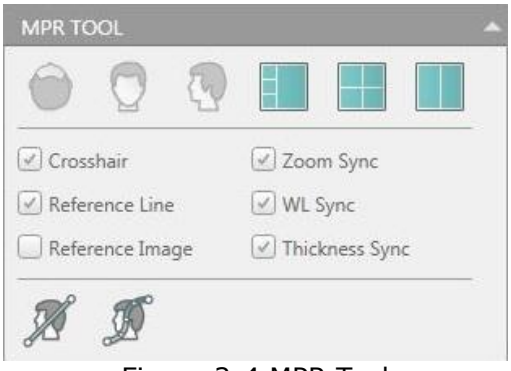


Figure 2-4 MPR Tool

2.4.1.1 View Selection

Click the button on the front of the Options to select or cancel the function.

Crosshair: Show/Hide the crosshair on the images.

Zoom Sync: Check this option and then you can zoom the MPR image window synchronously.

Reference Line: Show/Hide the curve, oblique or batch line on MPR image.

WL Sync: Modify the WL of any window of the four, the other three are modified synchronously.

Reference Image: Show/Hide the mini image on the oblique/ curve/ batch reconstruction image.

Thickness Sync: Change the display mode to MIP, AIP or MinIP, then select one of the three windows, modify its thickness, the other two are modified synchronously.

2.4.1.2 Define Oblique

Define Oblique: This is used to generate Oblique surface images for the evaluation of spatial relationship between the focal point and the surrounding tissue.

2.4.1.3 Define Curve

Define Curve: This is used to generate curved surface images for the observation of space relationships between the focus and the surrounding tissues.

NOTE:

- **Only one curve can be defined at a time.**

2.4.1.4 Move Crosshair

The Crosshair can be panned or rotated. Rotating the crosshair displays different angles to observe the lesion and surrounding tissues.

Pan: Move mouse to the cross point; drag the left key to pan the crosshair.

Rotate: Move mouse to the end of crosshair; drag the left key to rotate the crosshair.

2.4.1.5 Layout

Select from these three options to show different page layouts: 3x1, 2x2 and 1x1.

2.4.2 Batch Tool

The Batch Tool consist of three functions: define batch, modify batch and play batch.

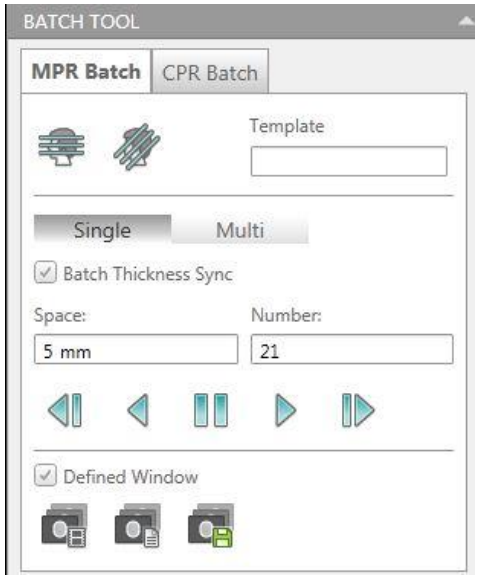


Figure 2-5 Batch Tool

2.4.2.1 Define Batch

Define MPR Batch: Click **Define Batch** button and then create a new batch component from the MPR image.

Click the **Multi** button, then the user can draw several batches.

Choose **Batch Thickness Sync** then modify the space of batch. The thickness of the batch images are modified synchronously.

Delete Batch: Press the **Delete** key on the keyboard to delete batch.

Template: Save a batch template. When a batch is defined the parameters can be saved as a Template. Templates can be saved to quickly achieve the desired parameters for subsequent studies.

Templates store information including: space, number, location, render mode, thickness and WW/WL of a batch.

Space: Set the step size when playing the batch of images.

Number: Set the number of images in the batch.

NOTE:

- **The space and number are linked. The other one will be automatically built when the first one is defined.**

Vertical Batch: Customize the vertical batch range of images.

Horizontal Batch: Customize the horizontal batch range of images.

Blue lines will show on the axial and sagittal images after defining the batch range.

Define CPR Batch: A CPR curve must be defined before applying the CPR batch. Click **Define CPR Batch** button to create a CPR batch component, which is made up of a batch of curves.

2.4.2.2 Batch

Send Batch to Film: Send the batch to Film.

Send Batch to Report: Send the batch to Report.

2.4.2.3 Cine

This is used to continuously display the batch.

Step Backward: Play the batch of images step by step backward.

Backward: Play the batch of images backward.

Pause: Stop playing the batch of images.

Forward: Play the batch of images forward.

Step Forward: Play the batch of images step by step forward.

2.4.3 Compare Function

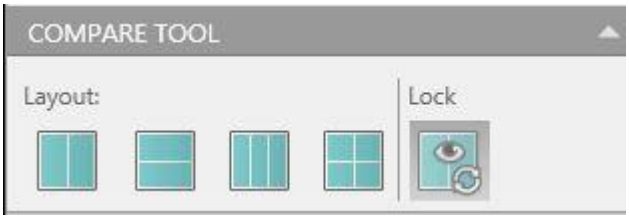


Figure 2-6 Compare Tool

The Compare function allows you to perform a side-by-side review of selected images.

There are different compare layouts: 1x2, 2x1, 1x3, 2x2.

Select Lock, the compare images will be linked side-by-side when zooming and scrolling.

NOTE:

- **Images of oblique, CPR and batch do not support compare function.**

2.4.4 Right-Click Menu

Fusion: Two CT images can be fused, and some measurement tools are provided.

Other functions of right-click menu refer to Chapter 1.6.3 for more information.

Chapter 3. 3D Viewer

3.1 Overview

3D reconstruction application executes three-dimensional reconstruction for CT image. This includes image visualization, image cutting, removing bone, protocol edit, tissue management, segmentation, and the image playback function.

3.2 3D Viewer Interface

In the home page, select the desired images from the patient list and choose the **3D** application.

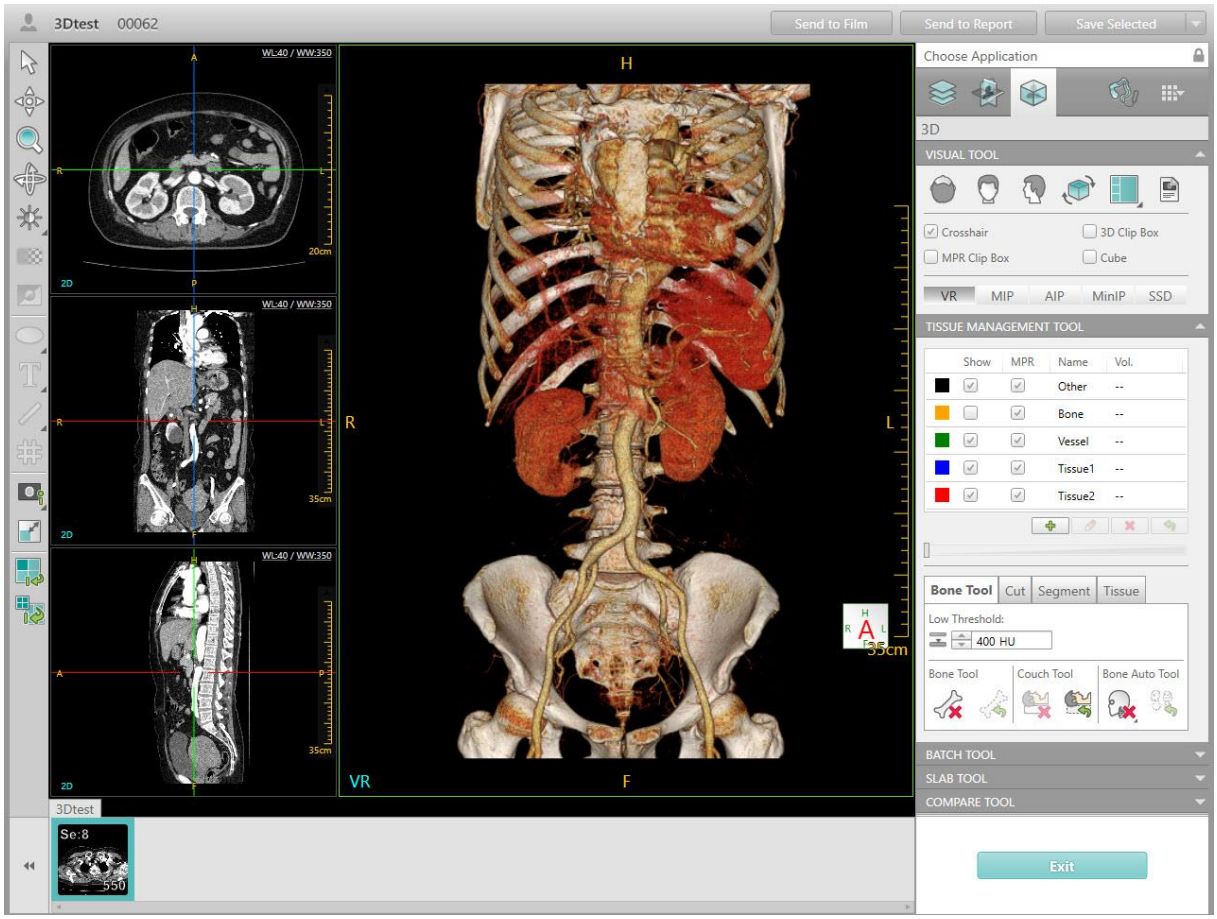


Figure 3-1 3D Interface

3.3 Image Display Region

The image display region of the 3D viewer interface includes two parts: MPR Display Region and Volume Image Display Region.

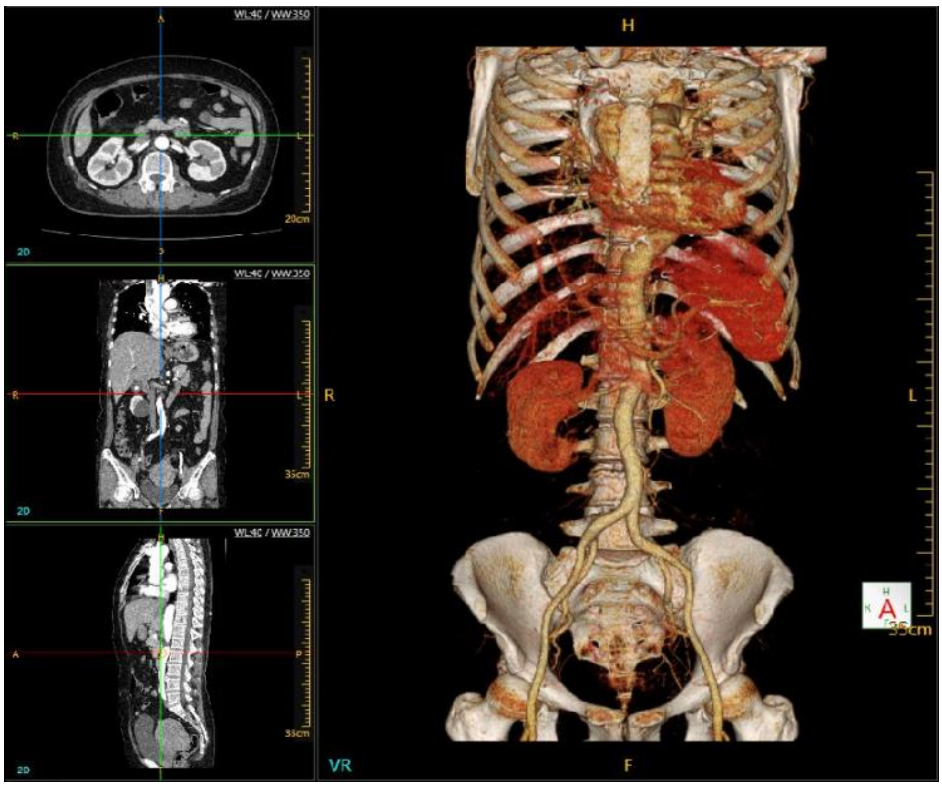


Figure 3-2 Image Display Region

3.3.1 MPR Display Region

As shown, the MPR display region includes the axial display (top left), the coronal display (middle left) and the sagittal display (lower left). On each image, there are two perpendicular lines representing the different positioning planes. The green frame is around the active image.

3.3.2 Volume Image Display Region

The region displays the image resulting from the 3D reconstruction.

3.4 Control Panel

The control panel includes Visual Tool, Tissue Management Tool, Batch Tool, Compare Tool and Slab Tool.

3.4.1 Visual Tool

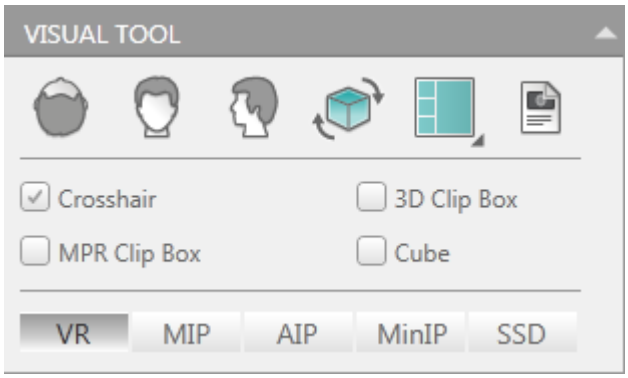


Figure 3-3 Visual Tool

3.4.1.1 View Selection

Crosshair: Show/Hide the crosshair on the MPR images.

3D Clip Box: Show/Hide the clip box on the volume image.

MPR Clip Box: Show/Hide the MPR box on the MPR images.

Cube: Show/Hide the cubic box on volume and MPR images.

Axial: Display the volume image in the axial projection.

Coronal: Display the volume image in the coronal projection.

Sagittal: Display the volume image in the sagittal projection.

Flip VR image: Flip the volume image.

Select these two options to show different page layouts: **3+1** and **2x2.**

3.4.1.2 Show Protocol

Protocol: Show/Hide the 3D protocol list.

Add: Add a protocol to the protocol list.

Click the icon for the Edit Protocol dialog box. Select the CT value and the Opacity to create the desired protocol.

When the cursor stays on the control point of the opacity line, the corresponding CT value and the Opacity will be shown automatically. Then the shape of the cursor becomes a crosshair. Drag to achieve an ideal CT value and Opacity of the control point.

Right click any sliders and then edit the color of the sliders in the Edit Color dialog box.

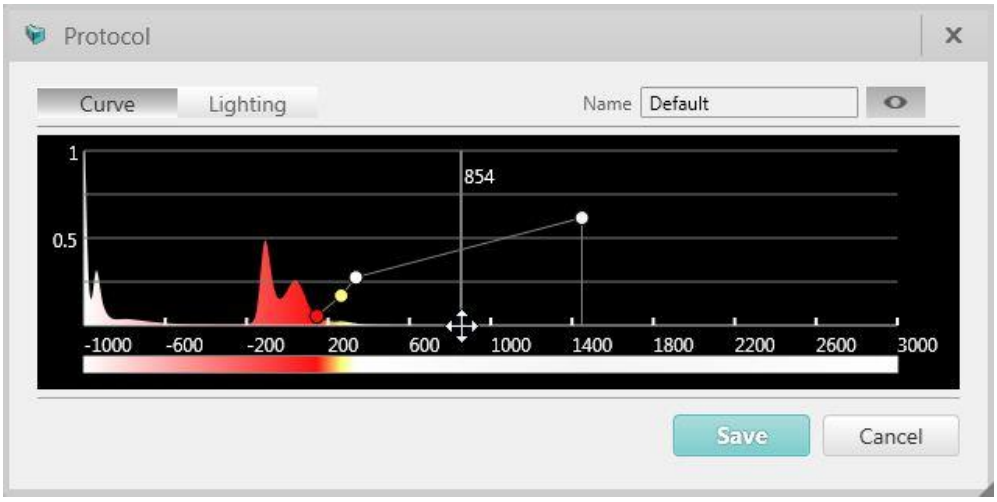


Figure 3-4 Edit Protocol dialog box

Edit: Edit the customized protocol.

Delete: Delete the customized protocol.

NOTE:

- **The default protocols in the list cannot be changed or deleted.**

3.4.1.3 3D Display Mode

3D display modes include SSD, MinIP, AIP, MIP and VR.

SSD (Shaded Surface Display)

Shaded Surface Display performs the reconstruction operation on the surface contour of the organ tissue. This uses the threshold value segmentation method.

The reconstructed 3D images only displays the surface profile of the organs and cannot display the inner structure. Map the CT value of the cross sections of the tissues to be displayed to produce the 3D effect.

The advantage of the surface display is to provide a more direct space relationship between the diseased tissue and surrounding structure for the physician to have a better understanding of the overall position and form of the diseased tissue.

Click **SSD** to enter the shaded surface display operation. The results will be displayed in the volume image display region.

Click  to select the desired color.

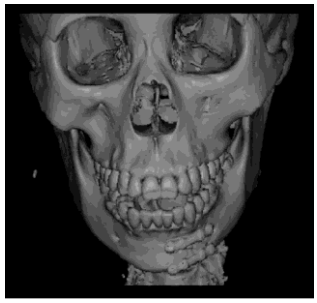


Figure 3-5 SSD

MinIP (Minimum Intensity Projection)

The MinIP records the Minimum Density value of every ray and projections to generate 2D images. The front and rear structures overlap with each other and the 3D images are generated. It is mainly used to display the trachea and air filled organs.

Click **MinIP** to enter the MinIP operation. The results will be displayed in the volume image display region. Change the WW/WL to achieve proper visualization of the anatomical structures.

Figure 3-6 MinIP

AIP (Average Intensity Projection)

The AIP records the Average Density value of every ray and projections to generate 2D images with a similar effect as in X-ray images.

Click **AIP** to enter the AIP operation. The results will be displayed in the volume image display region.

Figure 3-7 AIP

MIP (Maximum Intensity Projection)

The MIP records the Maximum Density value of every ray and projection to generate 2D images. The front and rear structures overlap with each other and the 3D images are generated.

Click **MIP** to enter the maximum intensity projection operation. The results will be displayed in the volume image display region.

Figure 3-8 MIP

VR (Volume Rendering)

Click **VR** to conveniently switch between VR and SSD/MinIP/AIP/MIP.

3.4.2 Tissue Management Tool

The Tissue Management Tool includes the Tissue List and the Tissue Operation Tool.

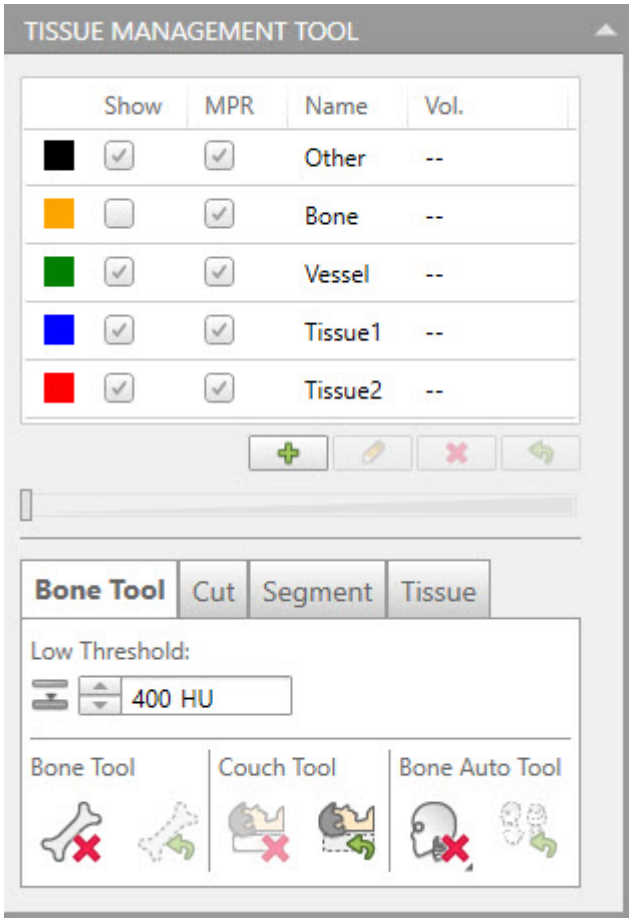


Figure 3-9 Tissue Management Tool

3.4.2.1 Tissue List

Tissue List displays the tissue type and the Tissue Volume. Check the option box

below **Show** and **MPR** to define whether to display the tissue in the MPR images.

Add: Add a tissue name and color.

Delete: Delete a tissue from the Tissue List.

Rename: Rename a tissue in the list.

Clear: Clear the tissue volume display.

3.4.2.2 Tissue Operation

Opacity: Define the tissue Transparency display.

Right click the Tissue list, the following menu is displayed.

Tissue Color: Set the dyed tissue color.

Tissue Protocol: Set the dyed tissue display protocol.

3.4.2.3 Bone Removal

Manually remove:

Manual bone removal is done using the Visual Tool.

1. Set the **Low Threshold**.
2. Click **Bone Removal**.
3. Click the bone that needs to be removed from the volume image on the volume image or on the MPR image.
4. The bone can be removed automatically.

Couch Removal:

Couch Removal: Remove the couch.

Undo Couch Removal: Cancel the Couch removal.

Automatic Bone Removal:

The user can remove the bone automatically with this function.

1. Right click the mouse on the Auto Bone Remove button.
2. Select the option from the button list according to the series type.
3. The bone can be removed automatically.

To cancel the removal, click **Undo Bone Removal**.

3.4.2.4 Cut Tools

Include Cut: To cut the selected 3D reconstructed images.

Exclude Cut: To cut the unselected areas on the 3D reconstructed images.

Click **Include Cut** or **Exclude Cut** and select a point in the volume image display region to start cutting.

Move the mouse to draw the region to be cut. Click again to finish drawing. Then a message pops up inquiring whether or not to submit the cutting operation.

Click **OK** to start cutting. Click **Cancel** to cancel cutting and return to the status before the cutting operation began.

Undo Cut: To reset the system to the original state before the cutting operation began. Click **Undo Cut** to restore 3D image display images to the original state before cutting.

NOTE:

- **This operation is only applicable in the volume image display region. To confine the cutting region within the volume display region, the cursor is restricted to the volume display region. Once the cutting region has been selected the mouse restriction is cancelled.**

3.4.2.5 Segment Tools

High Threshold and **Low Threshold:** Set the maximum and minimum thresholds of the desired area selected for segmenting.

Dye: To manually select the tissue or area on the image:

1. Click **Dye**.

2. Click the area where the tissue is located and needs be changed. The area is dyed to the selected color.

Edit **Dye** parameters:

Dose: Adjust the Dose manually for better bone removal. Select the options from **Low**, **Medium** or **High** to adjust the dose.

Brush: Click the icon to brush the area.

Brush Parameters:

Brush Radius: Adjust the size of the brush by selecting the **Small**, **Medium** or **Large** option.

Eraser: Click the icon to erase the area that is dyed.

Eraser Parameters:

Eraser Radius: Adjust the size of the eraser by selecting the **Small**, **Medium** or **Large** option.

Contour segmentation: Draw the contour on different MPR layer and segment the contour region.

Fill: Click the icon to make the dyed area fully filled.

Expand: Click the icon to expand the dyed area.

Erode: Click the icon to decrease the edge of the dyed area.

3.4.2.6 Tissue

You can select the cardiac, colon, lung in the target list, click the segment button, the system will automatically extract the target tissue, which is displayed in the VR window.

3.4.3 Batch Tool

The batch tool includes **Quick Define** and **Common Define**. After defining the batch, the batch image can be sent to film, sent to report, saved or played.

3.4.3.1 Quick Define

Input the rotation degree and the image number, click the direction icon, and generate the batch rotational images.

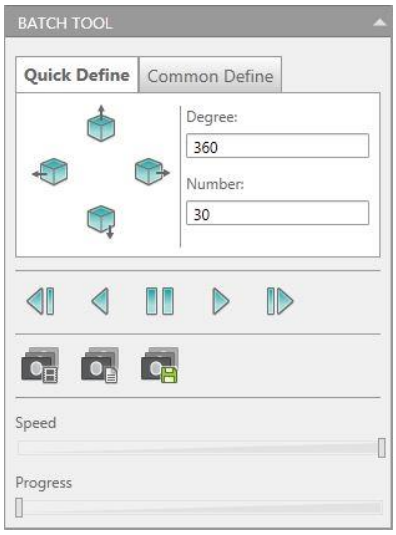


Figure 3-10 Quick Define Batch

3.4.3.2 Common Define

Input the image number, define the start location and end location, it can be set with multiple end locations, click the play icon to generate the batch images. In the location list, right click on a location to delete it, click **Clear** button to clear the location list.

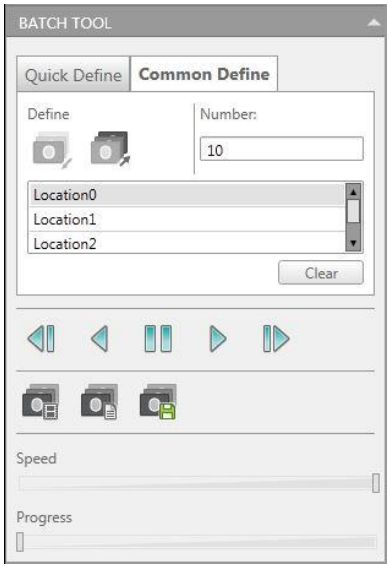


Figure 3-11 Common Define Batch

3.4.4 Slab Tool

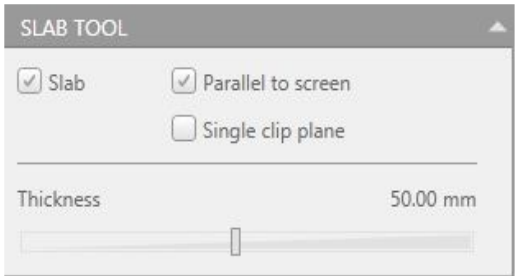


Figure 3-12 Slab Tool

Slab: Select Slab and display clipped image on VR image.

Parallel to screen: Adjust Slab model for parallel screen mode.

Single clip plane: Switch two planes to a single plane.

Users can adjust the slider to modify Slab thickness.

3.4.5 Compare Tool

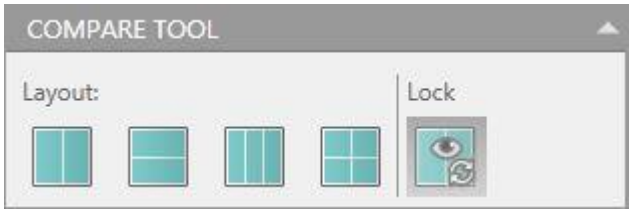


Figure 3-13 Compare Tool

The Compare function allows you to perform a side-by-side review for selected images.

Click any layout button in the compare tool to access the compare mode.

Double-click the image sequence to be compared, the image is automatically loaded into the layout.

Select **Lock**, the compare images will be side-by-side when zooming, rotating and modified Window Width and Level and so on.

There are four kinds compare layouts: 1x2, 2x1, 1x3, 2x2.

When you select a layout that is not in the compare tool, the system automatically exits compare mode.

3.4.6 Right-Click Menu

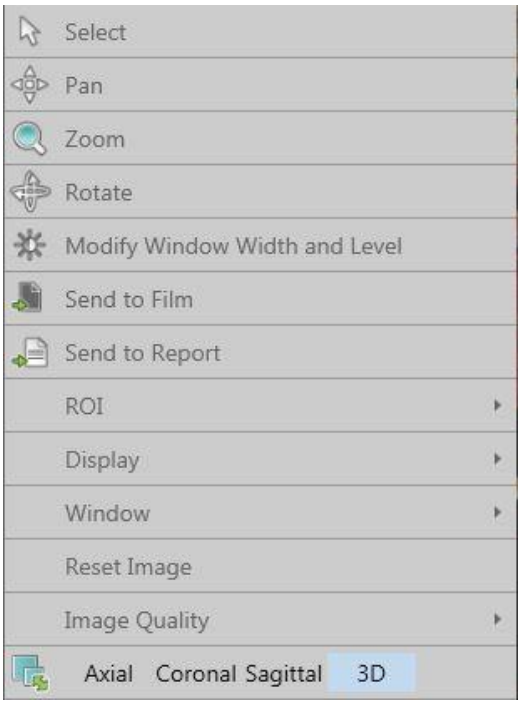


Figure 3-14 Right-click Menu

Refer to **Chapter 1.6.3** Window Menu for more Right-click menu information.

Chapter 4. VE Viewer

4.1 Overview

VE application can be used for navigating, viewing colon lumen, organization manually or semi-automatic, following the path to navigate, record and playback.

4.2 VE Viewer Interface

In the home page, select the desired images from the patient list and choose the **VE** application.

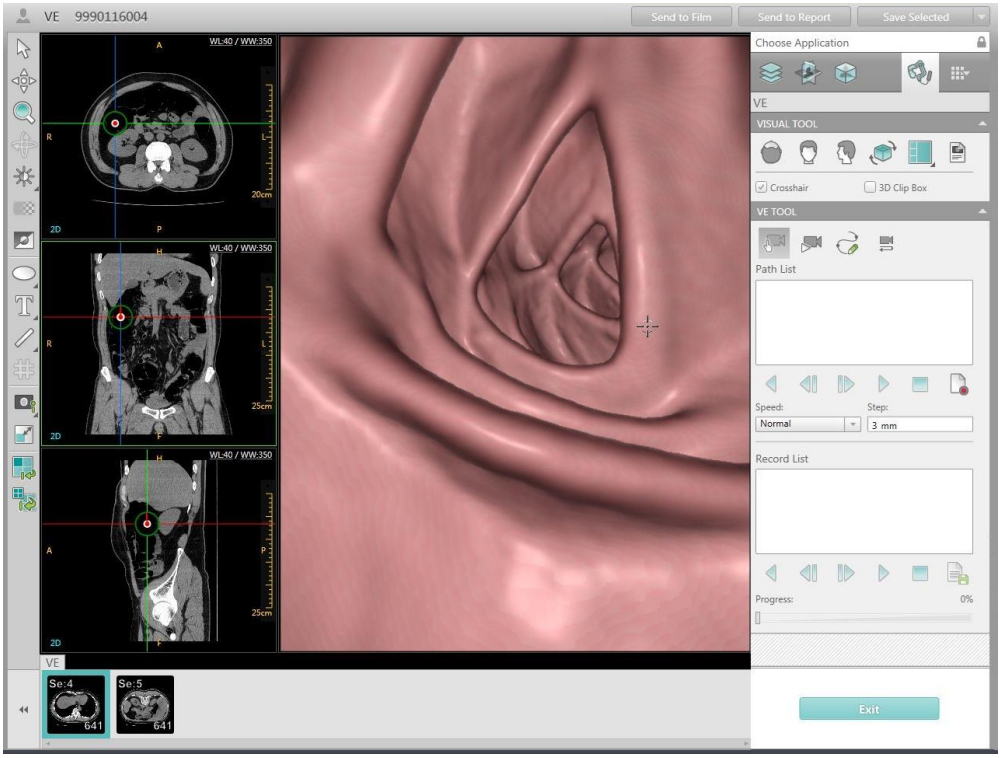


Figure 4-1 VE Interface

NOTE:

- **VE can process the images of the cavity organs such as the trachea, enhanced vessel and vertebral canal etc.**

4.3 Image Display Region

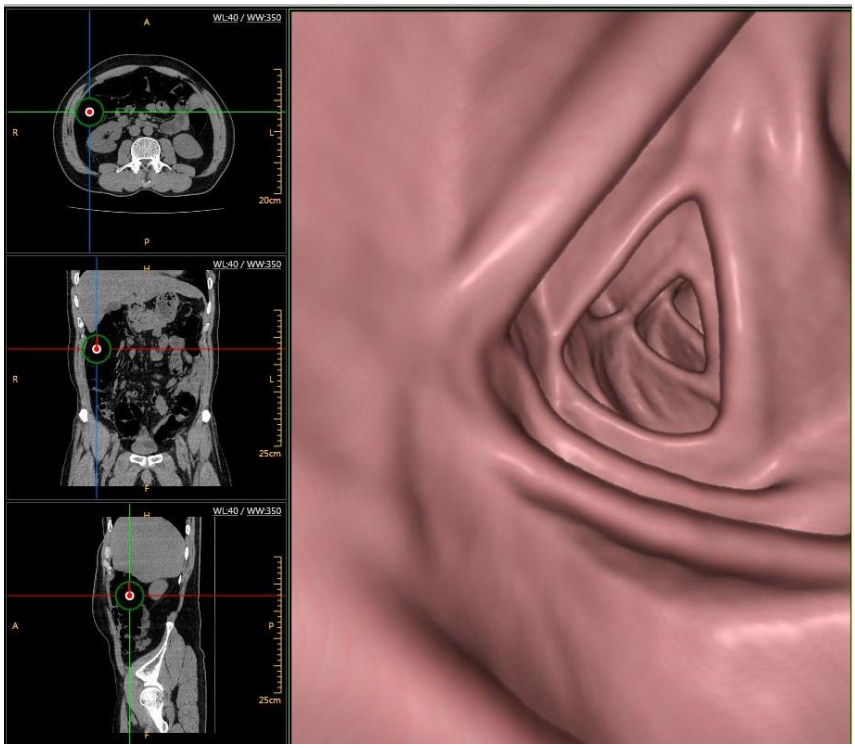


Figure 4-2 Image Display Region

4.3.1 Axial Image

The Axial Image is displayed in the upper left corner of the image display region. It is displayed with two perpendicular lines. The longitudinal line represents the sagittal plane and the transverse line represents the coronal plane.

4.3.2 Coronal Image

The Coronal Image is displayed in the middle left of the image display region. It is displayed with two perpendicular lines. The longitudinal line represents the sagittal plane and the transverse line represents the axial plane.

4.3.3 Sagittal Image

The Sagittal Image is displayed in the lower left corner of the image display region. The sagittal image is displayed with two perpendicular lines. The longitudinal line represents the coronal plane and the transverse line represents the axial plane.

4.3.4 VE Image

The VE Image is displayed on the right part of the image display region.

4.4 Control Panel

The control panel includes Visual Tool and VE Tool.

4.4.1 Visual Tool

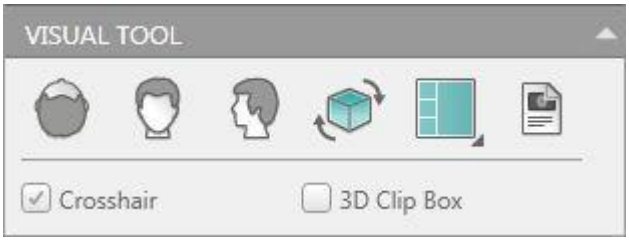


Figure 4-3 Visual Tool

Protocol: Hide/Show the protocol list, in which protocols can be added, edited or deleted.

Crosshair: Show/Hide the crosshair on the MPR images.

3D Clip Box: Show/Hide the clip box on the volume image.

Refer to Chapter **3.4.1** for more information regarding the tools on this panel.

4.4.2 VE Tool

VE tool includes navigation and replay mode.

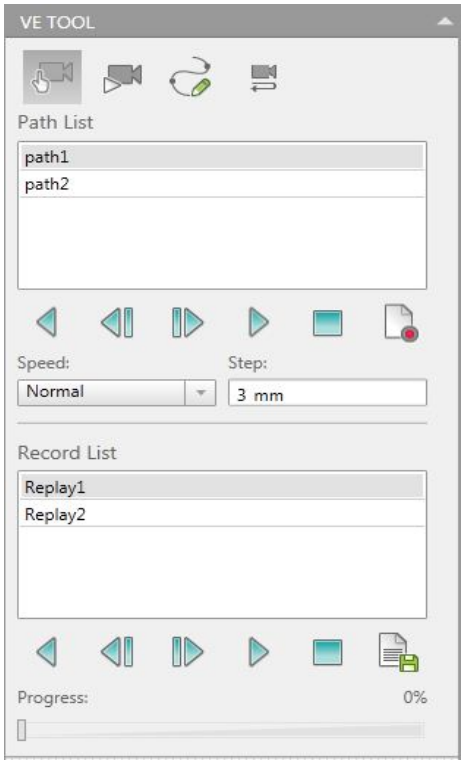


Figure 4-4 VE Tool

4.4.2.1 Navigation

There are three types of navigation modes, Manual, Semi-Automatic and Define Path.

Manual Flythrough: Used to customize the navigation position, direction, and path.

NOTE:

- **The Manual Navigation Mode is the default mode when entering the VE viewer interface. When the Manual Navigation Mode is selected, you can define Camera Position, Direction and Path.**

Semi-Automatic Flythrough: Press down and hold left mouse button to navigate, release the button to stop navigation.

Navigation with a defined path:

Define Path: Customize a path for navigation. Click the icon, and move the cursor on the axial image, the coronal image or the sagittal image, and then draw several navigation points by left mouse single click. Double click to finish the path.

After defining the navigation path, click the **Forward/Backward** icon to navigate along the defined path. During the process of navigating along the path, click the '**Stop**' button to stop navigating.

NOTE:

- **When the navigation starts, the navigation position changes to the starting point of the path and the navigation direction changes to the direction of the path.**
- **Define a path, then the play function is able to be used.**
- **In manual navigation, manipulating the mouse wheel can change the navigation direction horizontally, and clicking can pause the navigation.**

Reverse, Step Backward, Step Forward, Backward, Forward and Stop buttons are used to control the navigation.

Reverse: Reverse the camera direction.

Step Backward: Manually navigate backwards step by step.

Step Forward: Manually navigate forward step by step.

Backward: Manually navigate backward.

Forward: Manually navigate forward.

Path Management: Displays the defined path list which is also selectable.

Record: Save a record of the navigation.

Speed: Define the speed of the navigation.

Step: Define the length of the step.

4.4.2.2 Replay Mode

Record: Record navigation.

Click the **Record** button. Then click **manually Flythrough/Semi Fly through/Define Path** to record a customized navigation. Or, click **Reverse** or **Forward** to record an automatic navigation. Click the **Record** button to stop the recording. Then the play and save record functions are active.

Replay path:

Click **Forward** or **Backward** button, the recorded path is replayed forward or backward.

Click **Step Forward** or **Step Backward** button, the recorded path is replayed step forward or step backward.

Click **Stop** button to stop replay.

Click **Save Result** button, record can be saved to Disc or USB.

Replay progress is displayed by progress bar.

Chapter 5. Dental

5.1 Overview

The Dental application is used to create true-size (life size) images of the Mandible and the Maxilla on film for assisting oral surgeons in planning the implantation of prostheses. The procedure consists of the following steps:

- Defining panoramic views.
- Defining sectional planes.
- Filming the reference, panoramic and sectional images in true size.

NOTE:

- **For true size images, Dental uses the special film layout with a film size of "14 x 17".**
- **On every film, check the scales on the right side of the images to ensure the accurate size of the image.**
- **If filming the images in not true size, maybe the results are not true size.**

5.1.1 Dental Scanning Hints

The following hints will be helpful in producing the best patient images for the Dental application:

- Instruct the patient to remove any dentures or partial plates.
- Use a tongue blade or folded gauze pad to separate the teeth. If the patient does not have teeth, the jaw should also be separated using a folded gauze pad.
- Ensure that the position of the region of interest is (maxillary or mandible) perpendicular to the table to optimize clinical results.

5.2 Dental Interface

In the home page, select the desired images from the patient list and choose the **Dental** application.

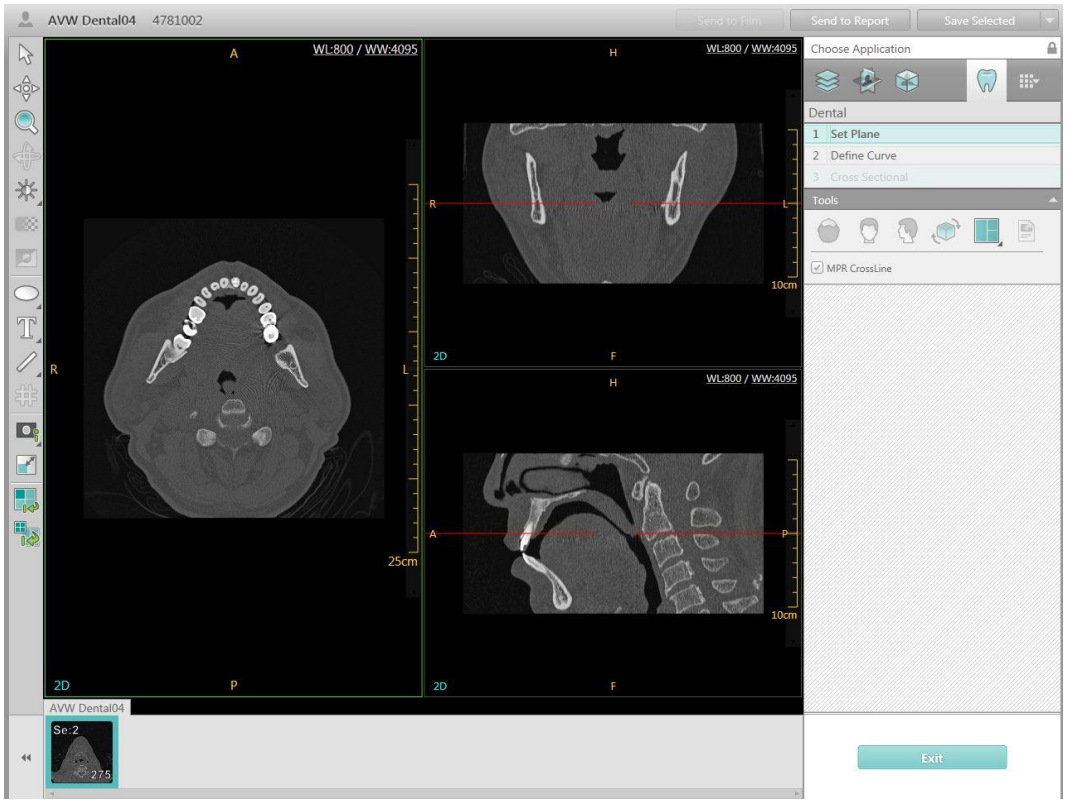


Figure 5-1 Dental Interface

The **Dental** workflow includes: **Set Plane, Define Curve** and **Cross Sectional**.

5.3 Set Plane

The first step is to define the optimal axial image for analysis.

Figure 5-2 Set Plane Tool

MPR Cross Line: Show/Hide cross line on MPR images.

There are two page layouts for review:

- **1+2**: Shows three orientations of the images: Axial, Coronal and Sagittal.
- **2x2**: Shows three orientations of the images: Axial, Coronal, Sagittal and Volume image.

5.4 Define Curve

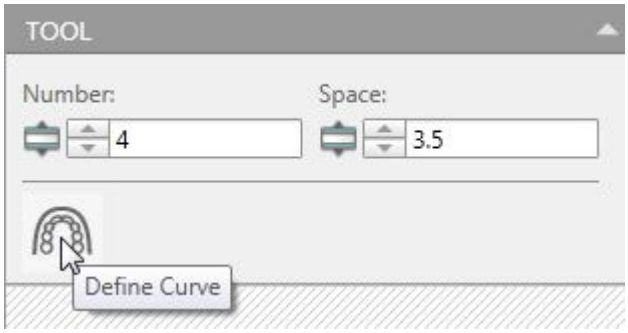


Figure 5-3 Define Curve Tool

Define Curve:

- Click the icon.

- Move the cursor into the axial image viewport, select a starting point and click it. Keep moving along the proposed curve, with the mouse button depressed while moving along the path. A green line will form to show the progress.

- When finished, double-click the end point of the curve.

The planning curves will display after double-clicking, and the panoramic images will display in the right viewport. The number of panoramic images depends on the number of curves.

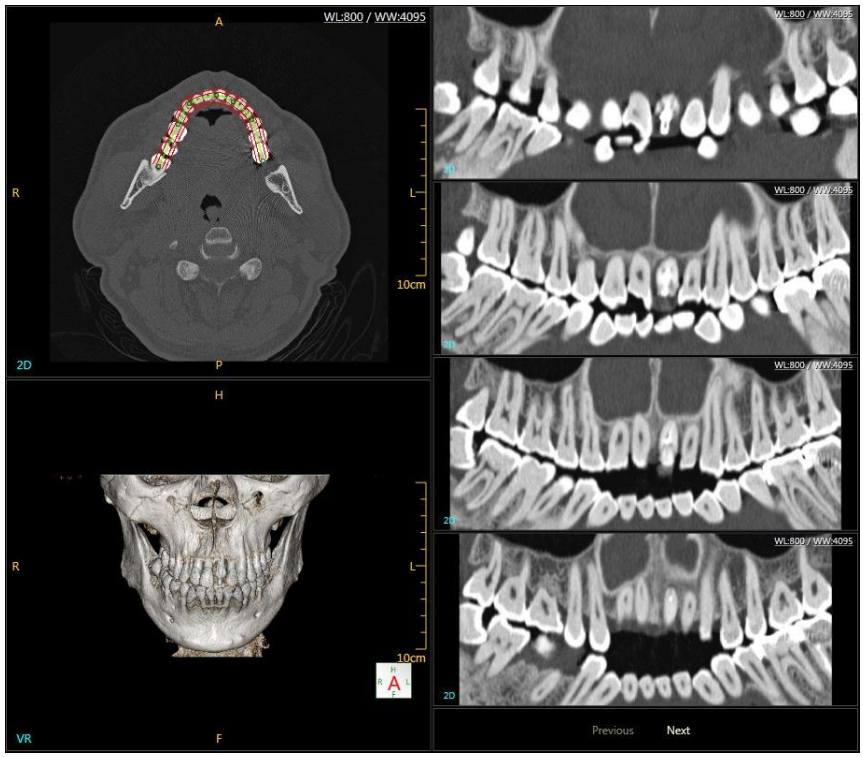


Figure 5-4 Panoramic Images

Check that the panoramic images are in the desired plane. **Next** or **Previous** button

in the bottom of viewport allows all the images to be seen.

Set the number and space of the curves:

- Use the **Number** textbox to set the number of the curves.
- Use the **Space** textbox to set the space between the panoramic curves.

Edit Curve:

- Click the curve.
- Right click the mouse, and select **Edit Curve** in the right-click menu, the mouse becomes edit icon.
- Drag the point to the desired location.
- The curve is connected at this point. Move the curve to the desired location. The panoramic curve display will update in real-time.

Pan Curve:

- Click the curve.
- Right click the mouse, and select **Pan Curve** in the right-click menu, the mouse becomes the pan icon.
- Drag the curve to the desired location.
- The whole curve will move to the desired location and will display the real-time panoramic images.

Delete Curve:

- Click the **Define Curve** icon again, the old curves will disappear.

To draw new curves, repeat the same steps as **Define Curve**.

5.5 Cross Sectional

When the panoramic image is satisfactory, click the **Cross Sectional** icon to begin the next stage of the workflow. The sectional image will display in the bottom-right window of the image display region.

The Sectional Operations define and display a series of sectional paraxial oblique image planes, perpendicular to the curvature of the Mandible or the Maxilla.

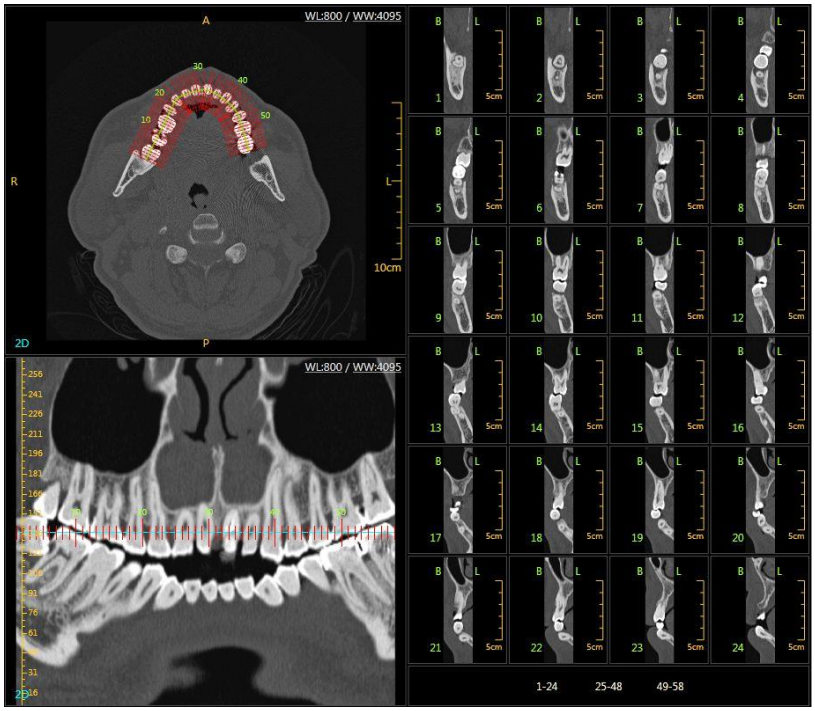


Figure 5-5 Cross Sectional Images

Shown above are sample sectional images, **Page Number** in the bottom of viewport allows all the images to be seen.

The B and L letters designate the Buccal and Lingual side of the teeth.

These tools allow creation and manipulation of several sets of sectional images.

NOTE:

- **Sectional Operations cannot be accessed unless the Define Curve has been defined and the sectional images are shown.**

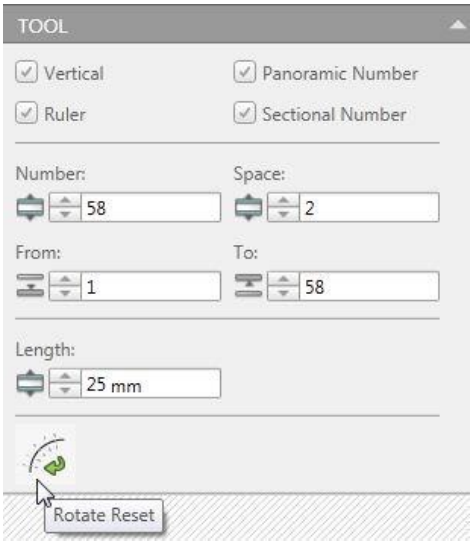


Figure 5-6 Cross Sectional Tool

Set the number and spacing of the sectional lines:

- Use the **Number** textbox to set the number of the sectional lines.
- Use the **Space** textbox to set the space between the sectional lines.

Set the displayed range of the sectional lines:

- Use the **From** and **To** textbox to set the displayed range of the sectional lines.

Set the length of the sectional lines:

- Use the **Length** textbox to set the length of the sectional lines.

Select Line Set:

- Move the mouse pointer to the required set.
- Click the set and then the selected set appears red, while all the other sets appear green.

Add Line Set:

- Decrease the number of sectional lines or shorten the spacing between those lines if necessary. This is in order to insure that there is enough space on the defined curves.
- Click on part of the defined curve where there are no sectional lines. Then a new set of sectional lines are displayed in red, while the original is displayed in green.

NOTE:

- **Ensure that there is enough space on the curve. Otherwise the set will not be created.**

Move Line Set:

- Move the mouse pointer to the required set.
- Click and hold while dragging the set to the desired location along the curves.

Delete Line Set:

- Move the mouse pointer to the desired set.
- Press **Delete** on keyboard to delete it.

Rotate Line Set:

- Move the mouse pointer to the required set.
- Click the set while dragging left or right until the desired angle is achieved.

Rotate Reset:

- Move the mouse pointer to the required set.
- Click the **Rotate Reset** icon, the set of sectional images returns to perpendicular to the curves.

Vertical: Show/Hide the Sectional Lines on the axial and panoramic images.

Panoramic Number: Show/Hide marks representing the original slice numbers on the panoramic images.

Ruler: Show/Hide the horizontal scale at the top of each section image.

Sectional Number: Show/Hide the original image slice numbers on the sectional images.

Chapter 6. Vessel Analysis

6.1 Overview

Vessel Analysis (VA) offers a set of tools for general vascular analysis. Bone removal, vessel extraction, and measurements can be easily performed. Various review modes may be used, such as MIP or VR.

⚠CAUTION:

- **Always use the original CT images to correlate with existing pathology and/or anatomical study.**
- **Vessel Analysis should not be used as the SOLE incontrovertible basis for clinical diagnosis.**
- **Verify that Bone Removal does not remove vessel segments.**
- **Verify the accuracy of vessel extraction results and correct them manually when required.**
- **Verify the accuracy of the centerline curves on the screen and correct them manually when required.**
- **When extracting different types of vessels, the vessels type can be switched. For example, when extracting the carotid and vertebral arteries, "Carotid" should be selected for extraction.**

6.2 VA Interface

In the home page, select the desired images from the patient list and choose the **VA** application.

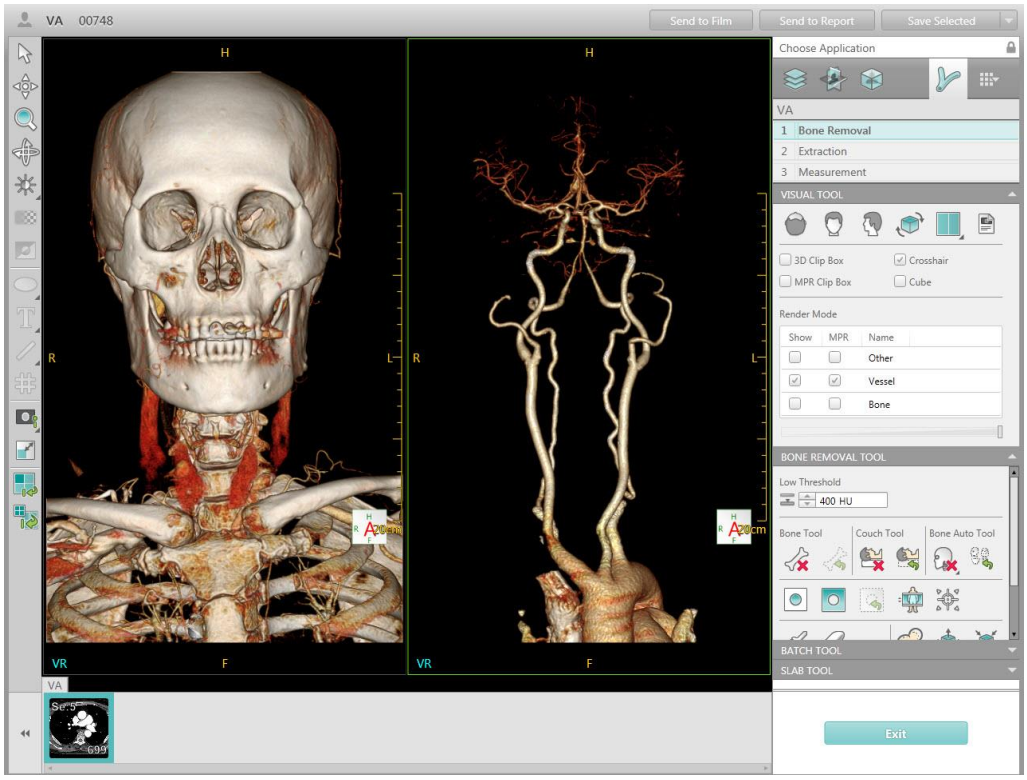


Figure 6-1 VA Interface

VA includes workflow of: Bone Removal, Extraction, Measurement.

6.3 Bone Removal Tool

The Bone Removal stage of VA contains a variety of tools used to reveal the vessel(s) of interest.

6.3.1 Visual Tool

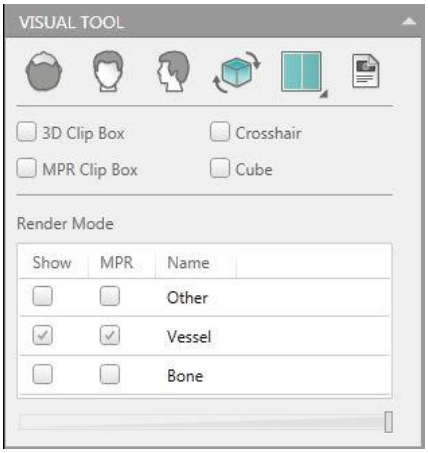


Figure 6-2 Visual Tool

There are two page layouts for review:

1x1: Shows the two 3D images as the setting in the **Render Mode**.

2x2: Shows the three sectional MPR images and Volume image.

The image display region includes two parts: the MPR image display region and the volume image display region. The MPR image on the left include the axial, coronal and sagittal images.

Render Mode: Define the Volume image and MPR images display mode. The options are Bone only, Hide bone, Highlight Bone, Transparent Bone, Vessel only, Transparent Background and All.

Refer to Chapter **3.4** for more information regarding the other tools on this panel.

6.3.2 Bone Removal Tool

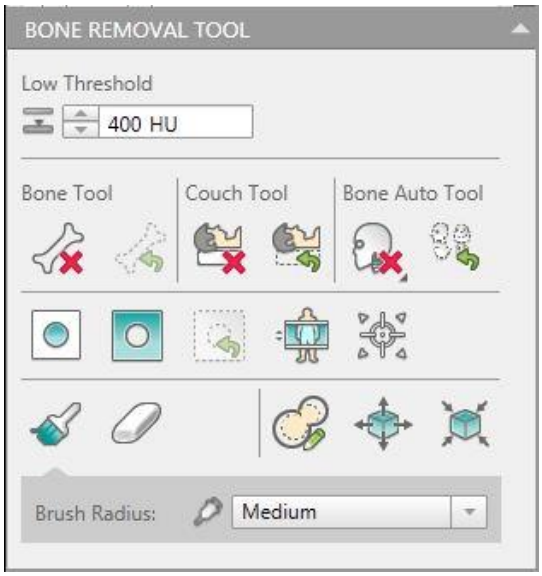


Figure 6-3 Bone Removal Tool

Use Bone Removal Tool to remove the bone manually:

1. Set the **Low Threshold**.

2. Click **Bone Removal**.

3. Click the bone that needs to be removed.

4. The bone can be removed automatically. To cancel the removal, click Undo Bone Removal.

5. To remove the couch, click Couch Removal. To cancel the Couch removal, click Undo Couch Removal.

Auto removed Bone:

There are 5 selections the user can select:

Head Neck, Chest Abdomen (Vessel), Chest Abdomen, Lower Limb, Bone Fragment. To cancel the removal, click **Undo Bone Removal.**

The vessels will be extracted after Head Neck and Chest Abdomen (Vessel) bones are removed.

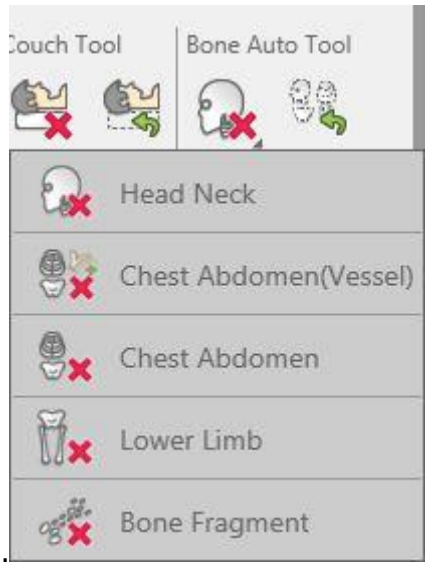


Figure 6-4 Automatic bone removal Tool

VOI Cut : The tissue can be cut in the VOI (volume of interest) region.

Manual Segmentation : User can hold the mouse button in the view to segment the tissue.

Contour segmentation: Draw the contour on a different MPR layer, and segment the contour region. Refer to **Chapter 3.4** for more information regarding other tools on this panel.

6.3.3 Slab Tool

Refer to **Chapter 3.4.4 Slab Tool** for more information regarding slab functions.

6.4 Extraction

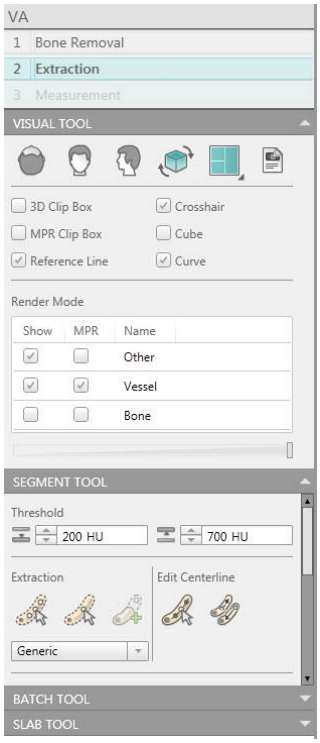


Figure 6-5 Vessel Extraction

The Extraction stage is used for extracting the vessel path, either automatically or manually.

6.4.1 Visual Tool

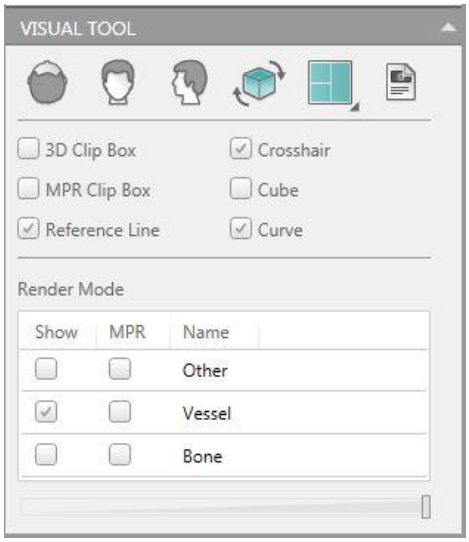


Figure 6-6 Visual Tool

There are four page layouts for review:

 **:** Displays the CPR image (On the top left), MPR image (On the bottom left) and Volume image (On the right of the viewport).

 **:** Displays the three sectional MPR images (On the top of the viewport), CPR MIP (On the bottom left) and Volume image (On the bottom right).

 **:** Displays the three sectional MPR images and Volume image.

 **:** Displays the CPR images of character and reference line and "elongated" vessel image. The "elongated" image is the straightened MPR view of the vessel.

Crosshair: Show/Hide the crosshair on the MPR images.

MPR Clip Box: Show/Hide the MPR box on the MPR images.

3D Clip Box: Show/Hide the clip box on the volume image.

Cube: Show/Hide the cubic box on volume and MPR images.

Curve: Show/Hide the curve on the volume image.

Reference Line: Show/Hide the Reference Line on the MPR images.

Render Mode: Define the volume and MPR images display mode.

Refer to **Chapter 3.4** for more information regarding other tools on this panel.

6.4.2 Segment Tool

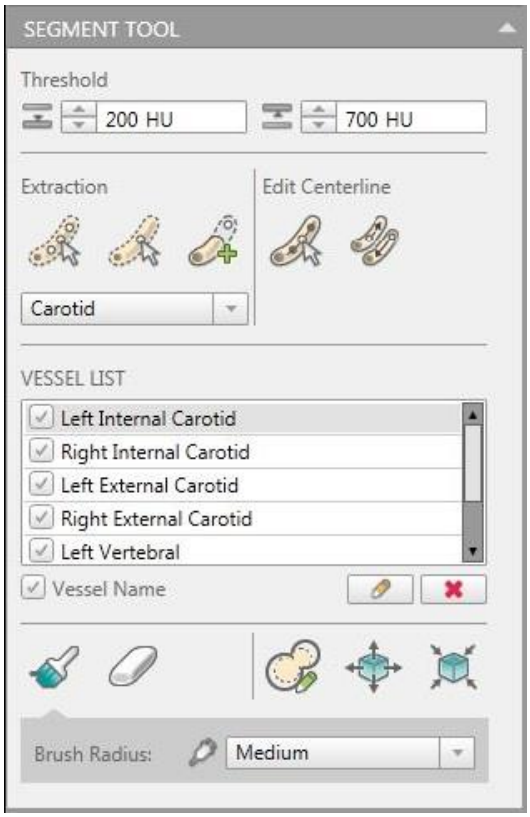


Figure 6-7 Segment Tool

Extraction:

One-point: Select a seed point on the 3D image or the MPR image.

Multi-point: Define at least two seed points on the 3D image or the MPR image.

Edit Centerline: Edit the centerline after the path is generated.

Modify Centerline: Modify points on the centerline.

Switch CPR direction: Exchange two end points of the vessel.

Vessel list: Lists the vessels extracted. The vessels can be deleted and renamed.

6.4.3 Batch Tool

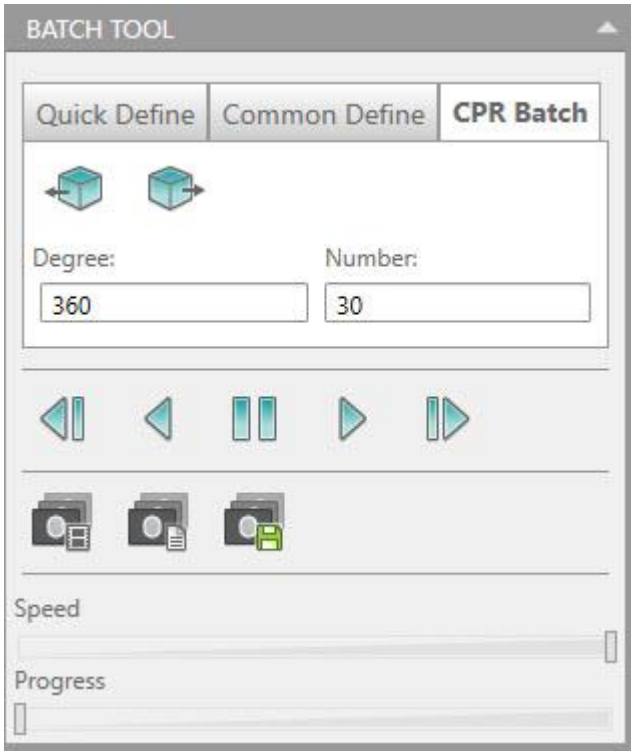


Figure 6-8 Batch Tool

CPR Batch: Input the rotation degree and the image number, click the direction button, and then generate the batch images for CPR image.

Refer to **Chapter 3.4.3 Batch Tool** for more information regarding **Quick Define** and **Common Define** function.

6.5 Measurement Tool

The Measurement function is enabled after the VA calculation is completed. Click **Measurements** to enter the interface.

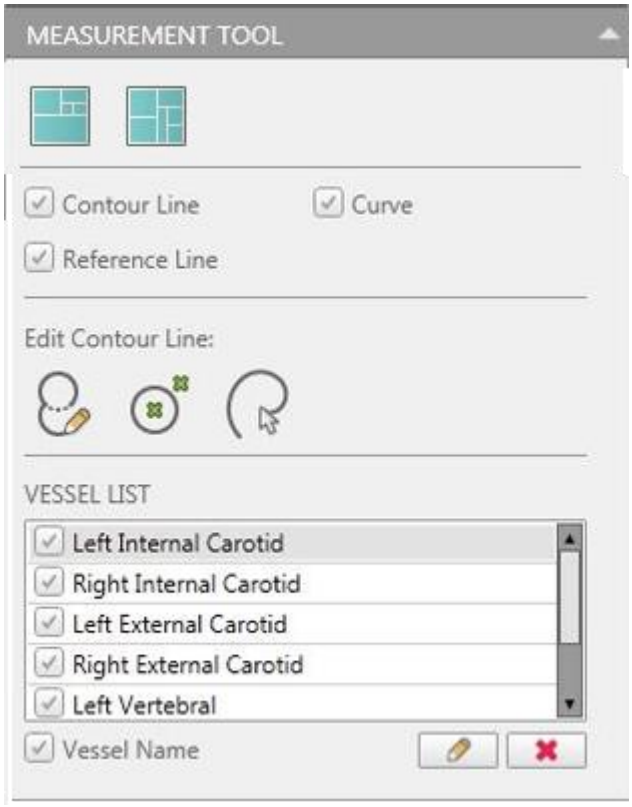


Figure 6-9 Measurement Tool

Contour Line: Show/hide contour line of the ROI.

Edit Contour Line: The user can use this function to:

1. Edit contour.

2. Define contour by two points.

3. Draw contour line manually.

Measurement workflow consists of the measurement result table, MPR&CPR image and Diamater /Area curve.

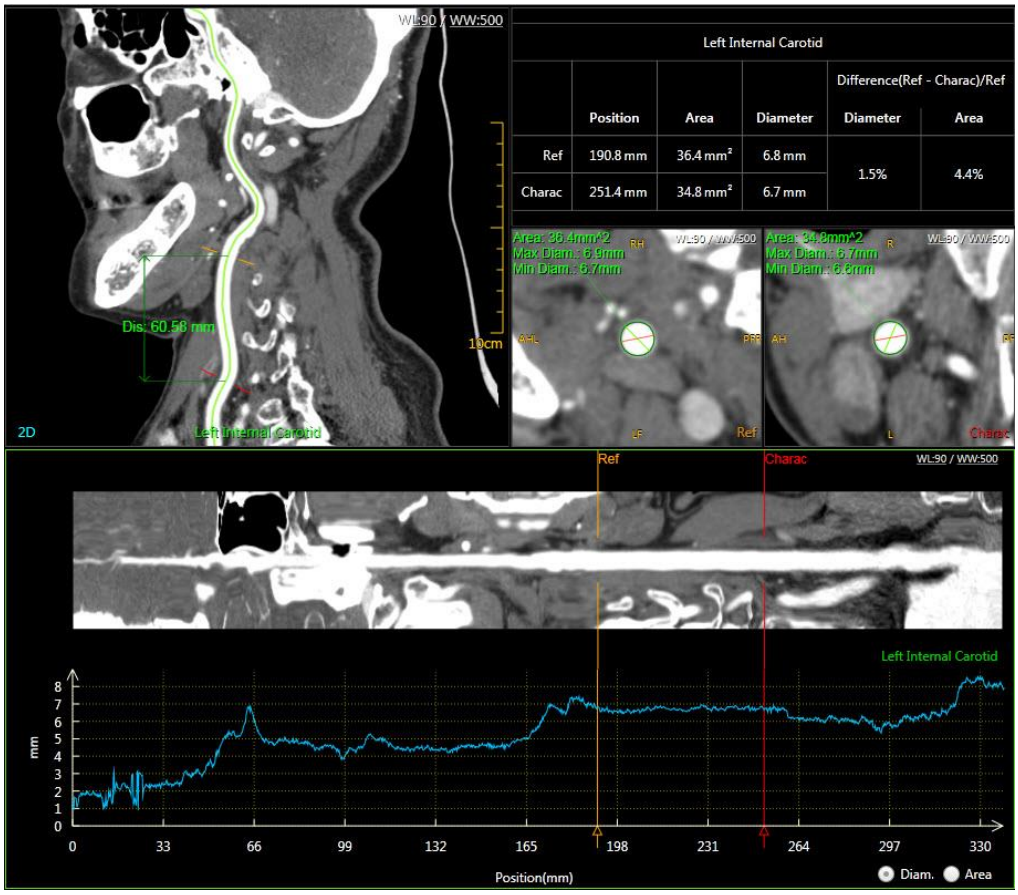


Figure 6-10 Measurement Interface

Chapter 7. Calcium Scoring

7.1 Overview

Cardiac Calcium Scoring (CCS) is mainly used to calculate the calcification scores of coronary arteries. CCS provides a range of support tools for analysis the coronary artery calcifications.

7.2 CCS Interface

In the home page, select the desired images from the patient list and choose the **CCS** application.

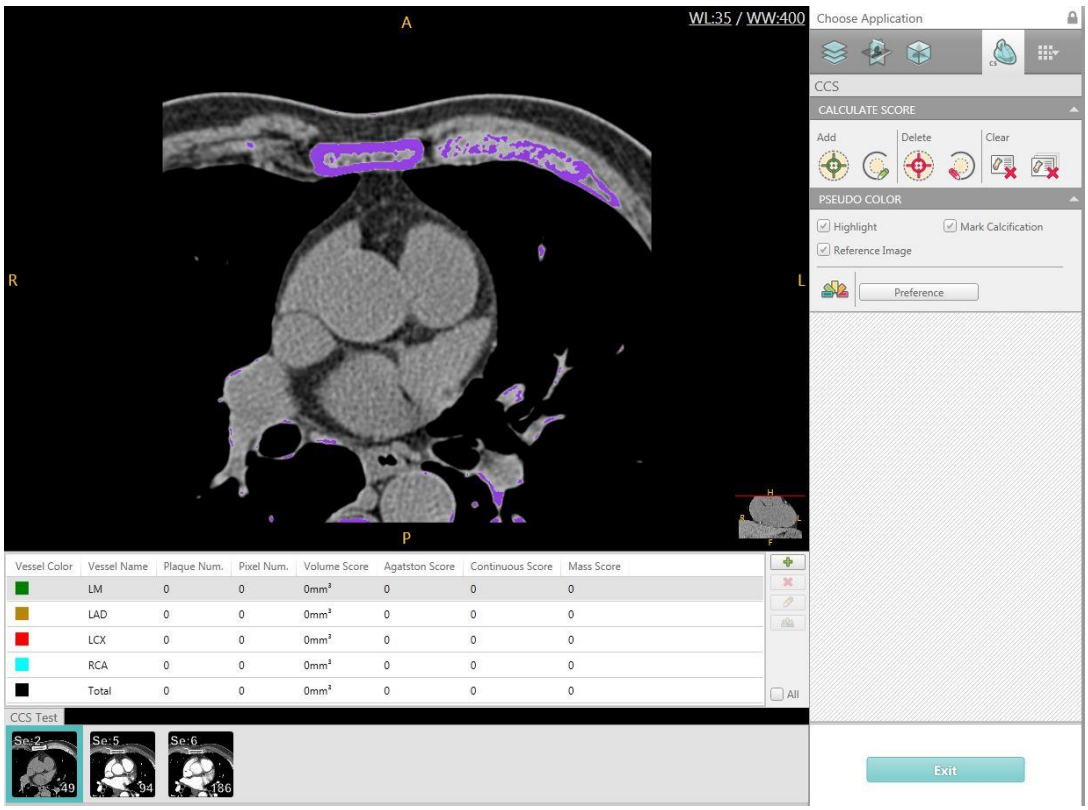


Figure 7-1 CCS Interface

The Calcium Scoring Tools include **Calculate Score** and **Pseudo Color**.

7.3 Image Display Region

In the image display region, the operator can quickly locate suspicious calcification in

the four main coronary arteries and other vessels by reviewing the selected axial images.

The results are displayed in the measurement list in the image display region. This includes **Vessel Color**, **Vessel Name**, **Plaque Number**, **Pixel Number**, **Volume Score**, **Agatston Score**, **Continuous Score** and **Mass Score**.

Click the corresponding icon on the right of the measurement list to add vessel, delete vessel, or modify vessel name and color.

You can calculate and evaluate the coronary calcification score at different stages, It also can be selected to view all the relevant parameters of the cumulative score.

7.4 Calculate Score

Select the desired vessel in the measurement list and mark the plaque in the image display region by scrolling and reviewing the images. After marking is completed, the measurement results will be updated automatically. Show Highlight allows coronary calcifications to be highlighted for better vitalization.

Figure 7-2 Calculate Score

Seed Point: Mark the plaque by creating a seed point.

Draw ROI: Draw a ROI including the plaque to mark the plaque automatically.

Delete by Seed: Delete the selected plaque by seed point.

Delete by ROI: Delete the plaque of region by drawing a ROI.

Delete by Vessel: Delete all the plaque in the selected vessel.

Delete All Calcification: Delete all the plaque in all vessels.

7.5 Pseudo Color

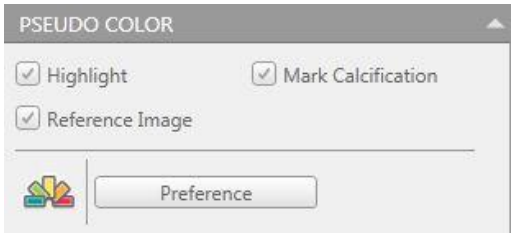


Figure 7-3 Pseudo Color

Highlight: Show/Hide the color of the background.

Mark Calcification: Show/Hide the marked plaque.

Reference Image: Show/Hide reference image window.

Highlight Color Button: Customize the color of the background.

Preference: Set the **Threshold**, **Methods**, **Mass Score** and **Display Result.**

Chapter 8. Coronary Analysis

8.1 Overview

The Coronary Analysis provides viewing and measuring tools that allow you to perform dimensional and quantitative measurements of the coronary arteries to help identify and examine the patient study for stenosis and coronary disease.

8.2 Coronary Analysis Interface

⚠CAUTION:

- **Always use the original CT images to correlate with existing pathology and/or anatomical study.**
- **Coronary Analysis should not be used as the SOLE incontrovertible basis for clinical diagnosis.**
- **Verify the accuracy of vessel extraction results and correct them manually when required.**

In the home page, select the desired images from the patient list and choose the **Coronary** application.

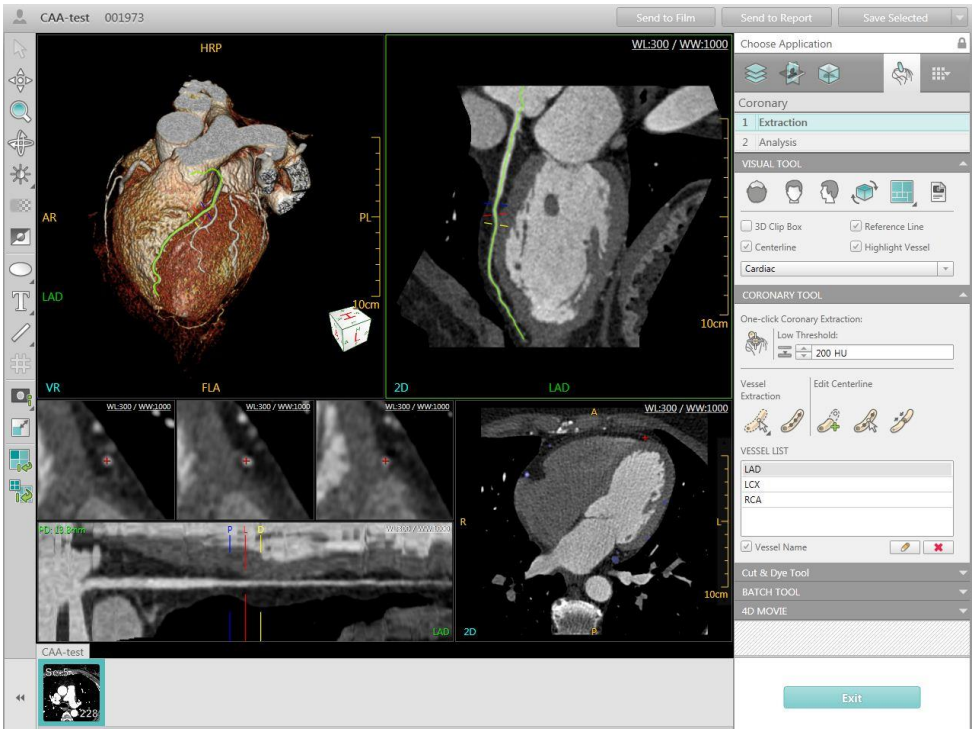


Figure 8-1 CAA Interface

The Coronary Analysis Tool includes Visual Tool, Coronary Tool, Cut & Dye Tool, Batch Tool and 4D Movie.

8.3 Visual Tool

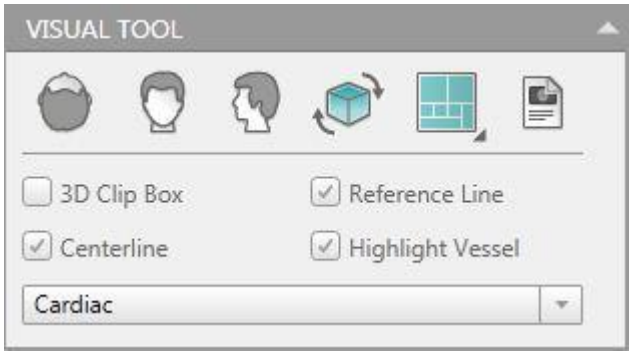


Figure 8-2 Visual Tool

3D Clip Box: Show/Hide the clip box on the 3D image.

Centerline: Show/Hide the centerline of the vessel on the image.

Reference line: Show/Hide the reference line on the image.

Highlight Vessel: Display the vessel on the reference image with Highlight or without highlight.

There are four page layouts for review:

 Display the VR image on the top left of the viewport. Display the Cross Sectional images of the arteries (3 sections in the row).

Display the MPR image of the artery on the bottom right of the viewport. Display the CPR image (along the selected artery centerline) on the top right of the viewport. Display the Straightened CPR image on the bottom left of the viewport.

 Display the CPR image (along the selected artery centerline) and the Reference image on the top of the viewport. Display the Cross Sectional images of arteries (3 sections in the column) and the MPR image of artery on the top left of the viewport. Display the VR image on the bottom right of the viewport. Display the Straightened CPR image on the bottom left of the viewport.

 Display the three Cross Sectional images of the heart on the top of the viewport; Display the VR image on the bottom right; Display the CPR image on the bottom left.

 Display the three Cross Sectional images of the heart on the top and bottom left of the viewport; Display VR image on the bottom right of the view port.

VR display mode: There are five modes: Cardiac, Coronary, Blood Pool, Hide Tree and All.

Axial: Display the volume image in the axial direction.

Coronal: Display the volume image in the coronal direction.

Sagittal: Display the volume image in the sagittal direction.

Flip VR image: Flip the volume image.

Protocol: Show/hide the protocol list.

8.4 Coronary Tool

At the top of the control panel is the analysis toolbox, which provides access to a set of guided workflow steps.

The order of steps in the analysis toolbox is:

- **Extraction**
- **Analysis**

Click on the toolbox to select from the list of workflow steps, or move forward or back one step.

8.4.1 Extraction

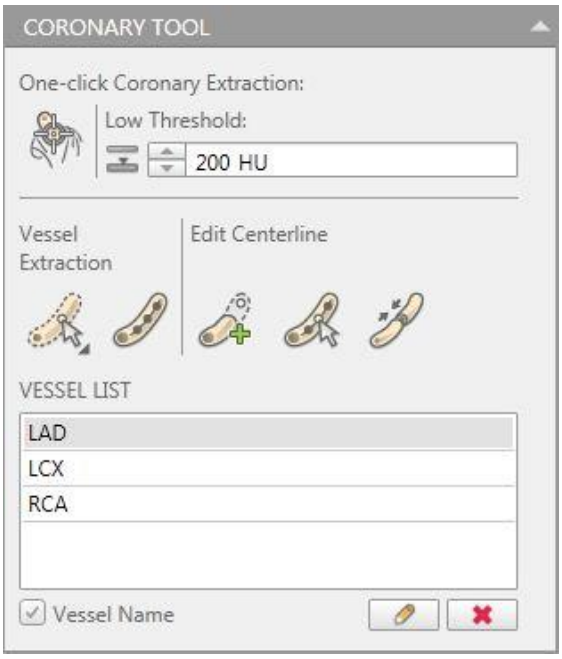


Figure 8-3 Vessel Extraction

The Extraction stage is used for extracting the vessel path, either automatically or manually, and editing the centerline.

Coronary recognition: After images are loaded, CAA application will automatically extract the coronary tree and identify LAD, LCX, RCA branches, and add them to vessel list.

One-click Coronary Extraction: Select the root of aorta as seed point to manually extract the coronary.

Vessel Extraction:

1. Automatic Extraction

a) **One seed point**: Click **One-point** icon to add one seed point on the 3D Image or on the MPR image. The system will generate the vessel path and sectional artery images.

b) **Multiple seed points**: Click **Multi-point** icon to add multiple seed points on the 3D Image or on the MPR image.

2. Manual Extraction

Click **Manual Extraction**, and place seed points by clicking in the vessel on any of the reference images to draw the centerline. Double click the image to finish the centerline.

The centerline will be traced on the main VR image and on the two panoramic CPR views.

Edit Centerline:

1. Extend Centerline

Select the centerline, and click **Extend centerline**. Click the continue position on MPR or VR image. The centerline will be extended.

2. Modify centerline

After extracting the vessel, click **Modify centerline** to add or delete control points of the center line. Click "Apply" to finish edit.

3. Connect Centerline

Select a centerline, and click **Connect Centerline**, and select a Centerline to connect.

You can rename or delete vessels in the vessel list, and can show or hide vessel name.

In the image display region, you can rotate the coronary display in a 360 degree rotation and observe the vessels.

- In the image display region, drag the lesion reference line, it is moved to the coronary artery stenosis.

- In the image display region, drag the proximal reference line, it is moved above the coronary artery stenosis.

- In the image display region, drag the distal reference line, it is moved below the coronary artery stenosis.

8.4.2 Analysis

Click **Analysis** to enter the interface.

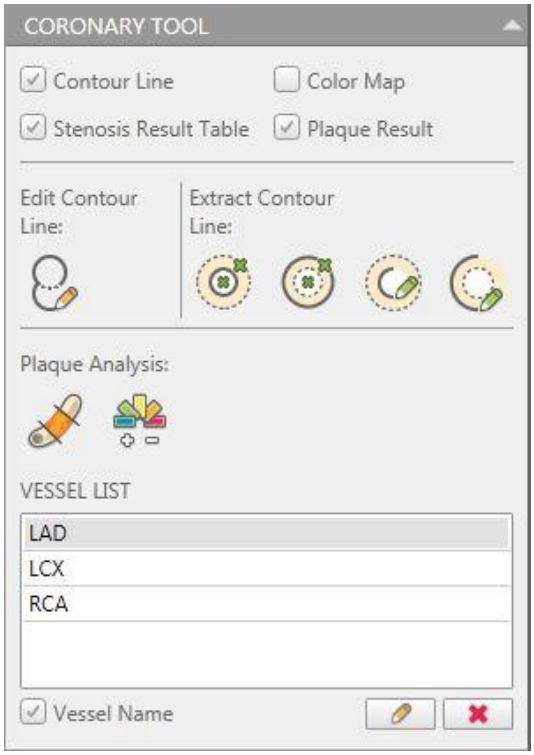


Figure 8-4 Analysis Tool

Contour Line: Show/Hide contour line of the ROI.

Stenosis Result Table: Show/Hide Stenosis Result table.

Color Map: Define the plaque threshold and color.

Plaque Result: Show/Hide plaque result table.

Edit Contour Line: Click **Edit Contour Line** button, and draw contour line on cross sectional images to edit. Click **Edit Contour Line** button again to end edit.

Extract Contour Line: This tool calculates the average density difference between a point marked in the center of the vessel and another point marked outside the vessel. A contour is then drawn to show the density difference.

Plaque Analysis: This tool is used to measure the soft plaques volume. Click the **Define Plaque** button and draw the reference lines on CPR image. The system will automatically calculate the volume of different soft plaques according to the defined lines.

8.5 Cut & Dye Tool

Refer to **Chapter 3.4.2** Tissue Management Tool for more information regarding the cut and dye functions.

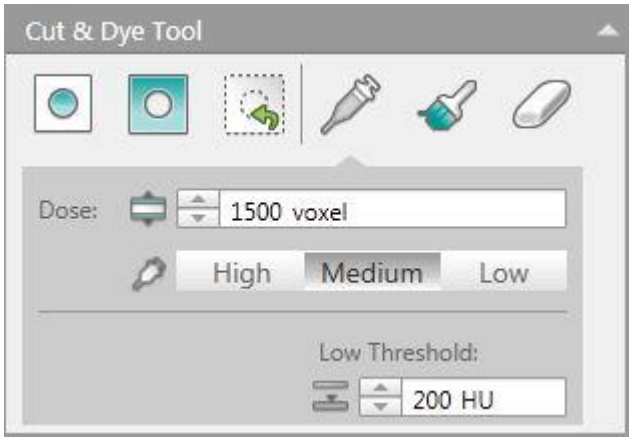


Figure 8-5 Cut & Dye Tool

8.6 Batch Tool

Refer to **Chapter 6.4.3** Batch Tool for more information regarding batch functions.

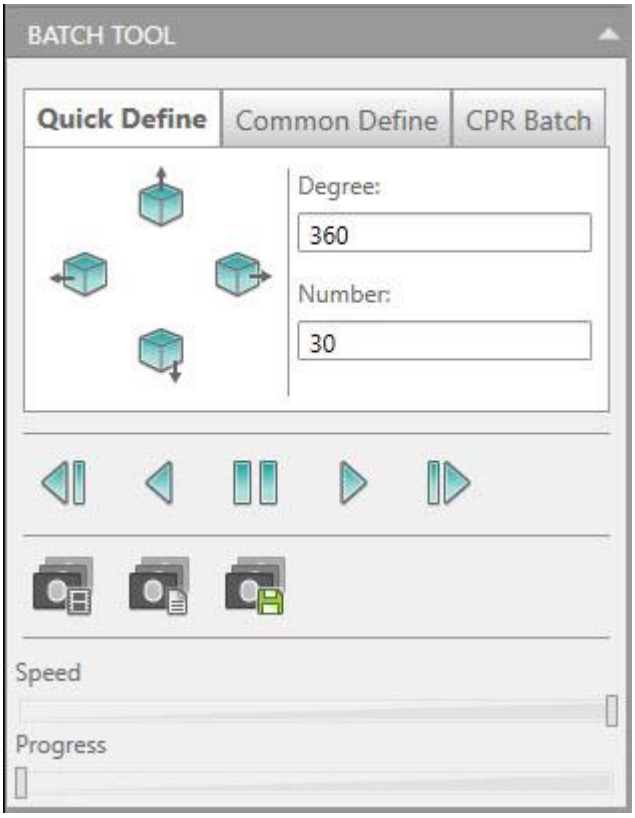


Figure 8-6 Batch Tool

8.7 4D Movie

4D Movie is used to play sequential phases.

Click **Forward** or **Step Forward** button to play, and click **Pause** to stop.

Select **Phase** series, adjust **Speed** or save 4D movie.

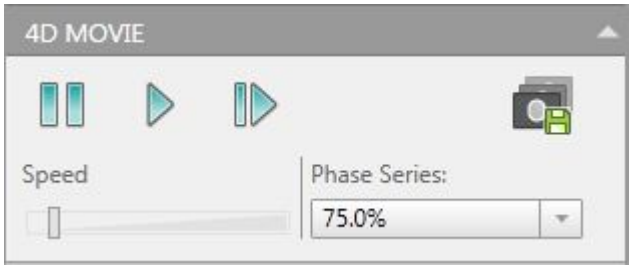


Figure 8-7 4D Movie Tool

8.8 Right-Click Menu

Right click on the images to show the Right-Click menu. Refer to **Chapter 1.6.3** Window Menu for more Right-click menu information.

Chapter 9. Cardiac Function Analysis

9.1 Overview

The Cardiac Function Analysis (CFA) provides viewing and measuring tools that allow you to analyze a variety of heart functions.

9.2 Cardiac Function Analysis Interface

In the home page, select the desired images from the patient list and choose the **CFA** application.

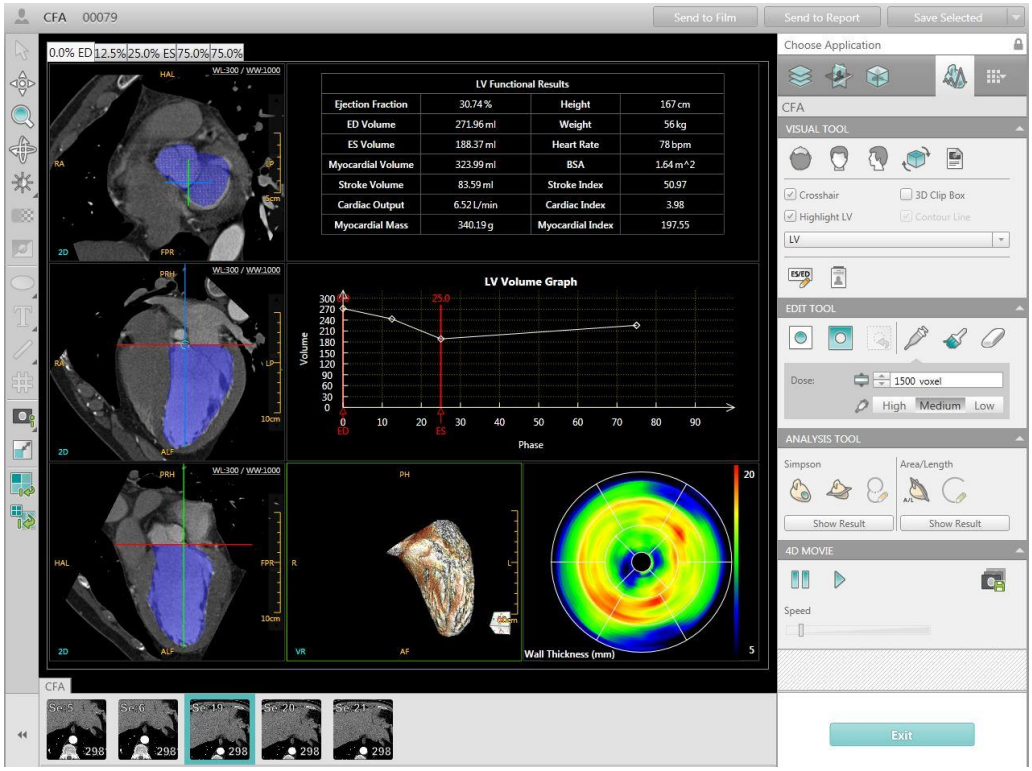


Figure 9-1 CFA Interface

On the top of the interface, click the phase tab to switch and view the images of the desired cardiac phase.

The Cardiac Function Analysis Tool includes: **Visual Tool**, **Edit Tool**, **Analysis Tool** and **4D Movie.**

9.3 Image Display Region

There are three cardiac MPR images displayed on the left of the viewport: Short axis (SA) Image, Horizontal long axis (HLA) image and Vertical long axis (VLA) image.

On the right of the viewport, the LV Function Results Table, LV Volume Graph, VR image and Bull's-eye maps are displayed.

Right-click on the Bull's-eye maps to switch the display between: Wall Thickness Map, Wall Thickening Map, or Regional Wall Thickness Map.

The LV Functional Results Table is used to display the parameters as following:

- Ejection Fraction (%): EF=SV/EDV
- ED Volume (ml)
- ES Volume (ml)
- Myocardial Volume (ml)
- Stroke Volume (ml): SV=EDV-ESV
- Cardiac Output (L/min): CO=SV*Heart Rate/1000
- Myocardial Mass (g): MM=MV*1.05
- Height (cm)
- Weight (kg)
- Heart Rate (bpm)
- BSA (m^2): BSA=0.007246 * Height^0.725 (cm) * Weight^0.425 (kg)
- Stroke Index ((ml/beat)/m^2): SI=SV/BSA
- Cardiac Index ((L/min)/m^2): CI=CO/BSA
- Myocardial Index (ml/m^2): MI=MV/BSA

9.4 Visual Tool

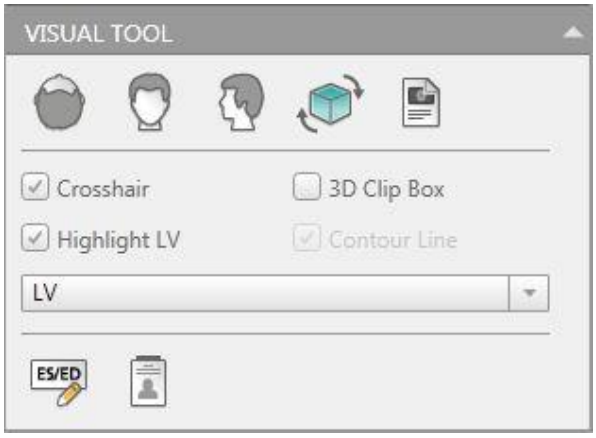


Figure 9-2 Visual Tool

Crosshair: Show/Hide the crosshair on short or long axis images.

3D Clip Box: Show/Hide the clip box on the volume image.

Highlight LV: Show/Hide the color of LV on short or long axis images.

Contour Line: Show/Hide contour line of the short axis images. Selected **Show Short Axis View**, then the check box is usable.

VR display mode: It includes Cardiac, LV and All. To display the Cardiac VR image, the Left Ventricle VR image or the all VR image display modes.

Set ES/ED: From the loaded cardiac phase the software recommends the ED and ES phases. You can accept the recommendations or change them.

Set Patient Info: To set the patient's information such as Heart Rate, Weight and Height. After entering this information, click **OK** button then the LV result table will be updated automatically.

Refer to Chapter **3.4.1** for more information regarding the tools on this panel.

9.5 Edit Tool

Figure 9-3 Edit Tool

9.5.1 Cut

Include Cut: To cut the selected 3D reconstructed images.

Exclude Cut: To cut the unselected areas on the 3D reconstructed images.

Undo Cut: To reset the system to the original state before the last cutting operation began.

9.5.2 Dye

Refer to Chapter **3.4.2.5** for more information regarding the function of the Dye Tool.

9.6 Analysis Tool

Figure 9-4 Analysis Tool

9.6.1 Simpson

Simpson: This method uses dimensions derived from heart contours to calculate the Functional results. Simpson's Rule is a fundamental mathematical principle, it is based on the idea that the volume of an object can be determined by "cutting" the object into thin "slices", measuring the volume of each slice and summing the volumes of all slices.

⚠WARNING:

- **Obtaining accurate Functional results depends on the correct segmentation of the heart. Verify the correctness of the heart segmentation and correct it manually when required.**

When loading the multiple cardiac phase images for analysis, the sys- tem will segment the LV at first. You can click Segment LV again to get a better result.

When using Simpson's method, you can adjust the LV contours in the Short Axis View.

NOTE:

- **Examine all phases for the correct LV segmentation and perform the Correct Axis procedure and Segment LV, if necessary.**

Select **Show Short Axis View**, and the view changes to 3x3 layout with LV

contours.

Select **Edit LV Contour** to enable all contours for editing. With the mouse, drag the control point to the desired locations.

Select **Show Result** to return to the original viewport, showing the LV Function Results Table, LV Volume Graph, VR image and Bull's-eye maps.

The Bull's-Eye Map, which is a color-scaled map showing the functional parameters for each segment of the left ventricle. This is based on the American Heart Association's standardized 16 myocardial segment recommendations for the heart, angle selection and names of the cardiac planes. The system offers three kinds of Bull's-eye maps listed below:

- Wall Thickness: This map represents the left ventricular wall thickness of the loaded cardiac phase with the ventricular volume.

- Regional Wall Thickness: This map represents the region of the left ventricular wall thickness of the loaded cardiac phase with the ventricular volume.

- Wall Thickening: This map represents the percent of change in wall thickness between the two phases in the cardiac cycle, ES and ED.

9.6.2 Area/Length

Select **Show Area/Length View**, the view changes to a 2x2 layout with LV contours. This viewport shows the ED and ES phase in Horizontal Long axis orientation on the top. The ED and ES phase in Vertical Long axis orientation are displayed on the bottom.

Select **Draw Contour** to draw the contour to the correct locations. Right click to delete the previous control point. Double click to end the operation.

Select **Show Result** to return to the original viewport. This will show the chamber functional results table.

Chamber Functional Results			
	Horizontal Long Axis	Vertical Long Axis	Biplane
ED Volume	194.64 ml	214.79 ml	195.59 ml
ES Volume	235.73 ml	173.55 ml	194.21 ml
Stroke Volume	-41.09 ml	41.24 ml	1.38 ml
Cardiac Output	-5.75 L/min	5.77 L/min	0.19 L/min
Stroke Index	-22.33	22.41	0.75
Cardiac Index	-3.12	3.14	0.1
BSA	1.84 m^2		

Figure 9-5 Chamber Result Table

Horizontal Long Axis represents the Horizontal image, Vertical Long Axis represents the Vertical image and Biplane represents the Horizontal and Vertical image.

Volume of Horizontal or Vertical Long Axis can be calculated as follows:

Volume = 8/(3*PI)*area*area/radius,

Where area is the contour area of the long axis image, the radius is the contour diameter of the long axis image.

Volume of Biplane can be calculated as follows:

Volume = 8/(3*PI)*area H*area V/radius.

Where area H is the contour area of the Horizontal Long Axis, area V is the contour area of the Vertical Long Axis, and the radius is the maximum value of the two contour diameters.

9.7 4D Movie

Figure 9-6 4D Movie Tool

Play the multiple cardiac phase together for viewing the heart's dynamic behavior. The 4D movie can be saved.

Chapter 10. Cardiac Viewer

10.1 Overview

Cardiac Viewer application is used to view Cardiac images, execute three-dimensional reconstruction and cardiac extraction. Cardiac Viewer can be used to diagnose various cardiovascular diseases.

10.2 Cardiac Viewer Interface

In the home page, select the desired images from the patient list and choose the **Cardiac Viewer** application.

Figure 10-1 Cardiac Viewer Interface

10.3 Image Display Region

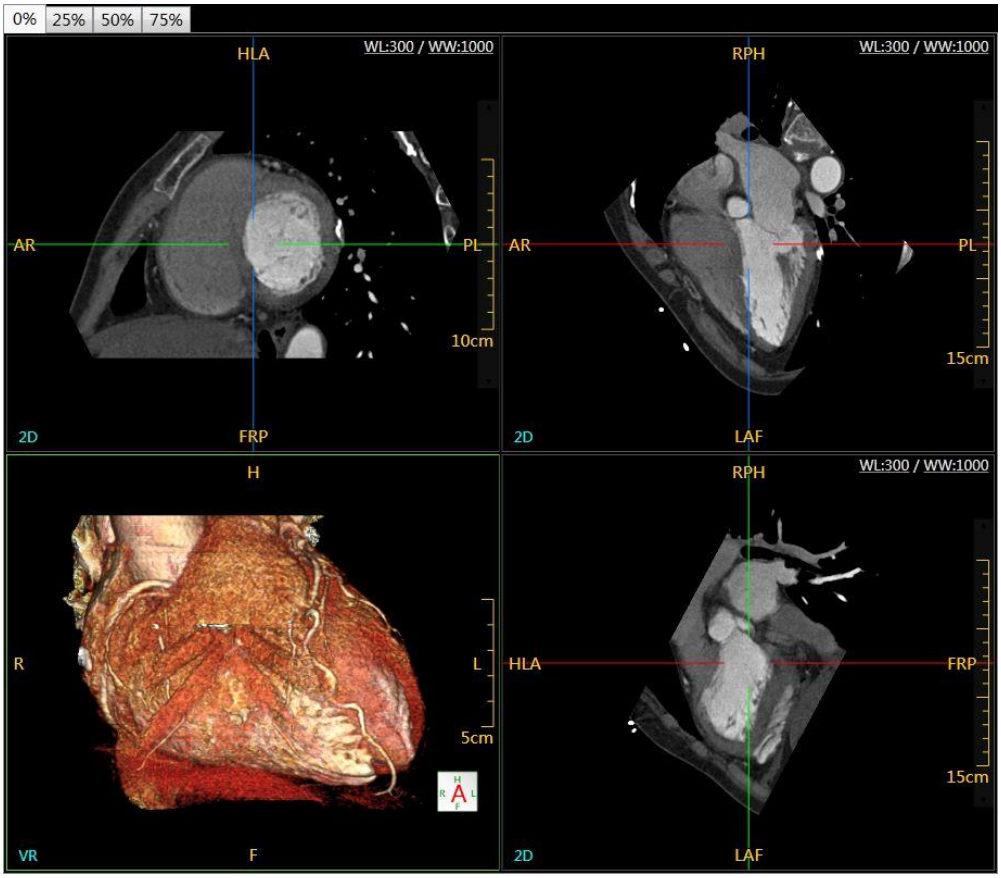


Figure 10-2 Image Display Region

The image display region of the 3D viewer interface includes two parts:

MPR Image Display Region

Volume Image Display Region

Refer to Chapter 9.3 Image Display Region for more information regarding the image display mode.

10.4 Control Panel

The control panel includes Visual Tool, Tissue Management Tool, Batch Tool, Compare Tool and 4D Movie.

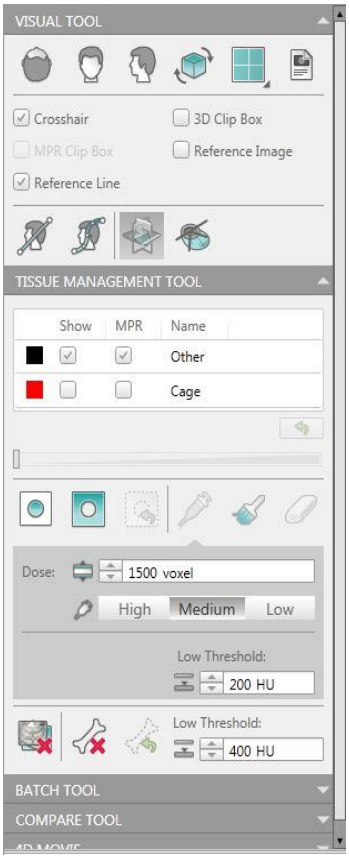


Figure 10-3 Control Panel

10.4.1 Visual Tool

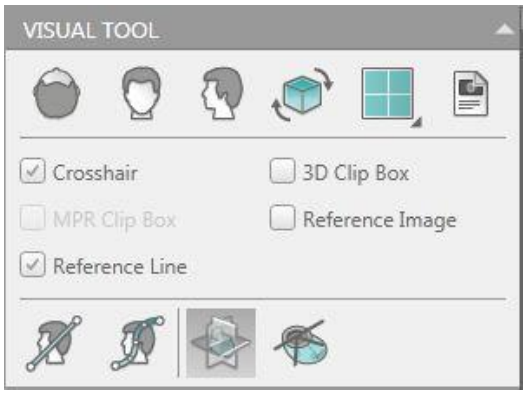


Figure 10-4 Visual Tool

Click the button on the front of the Options to select or cancel the function.

Crosshair: Show/Hide the crosshair on the images.

Reference Line: Show/Hide the curve, oblique or batch line on MPR image.

Reference Image: Show/Hide the mini image on the oblique/ curve/ batch reconstruction image.

Define Oblique: This is used to generate Oblique surface images for the evaluation

of spatial relationships with specific rotations.

Define Curve: This is used to generate curved surface images for the evaluation of spatial relationship between the focal point and the surrounding tissue.

Show Heart Axis View: Display three cardiac axial MPR images, short axis, horizontal long axis(HLA) and vertical long axis(VLA), to evaluate the heart and ventricular wall.

Show Heart Chamber View: Display heart chamber axial view.

Refer to **Chapter 3.4.1** Visual Tool for more information regarding the tools on this panel.

10.4.2 Tissue Management Tool

The Tissue Management Tool includes the Tissue List and the Tissue Operation Tool.

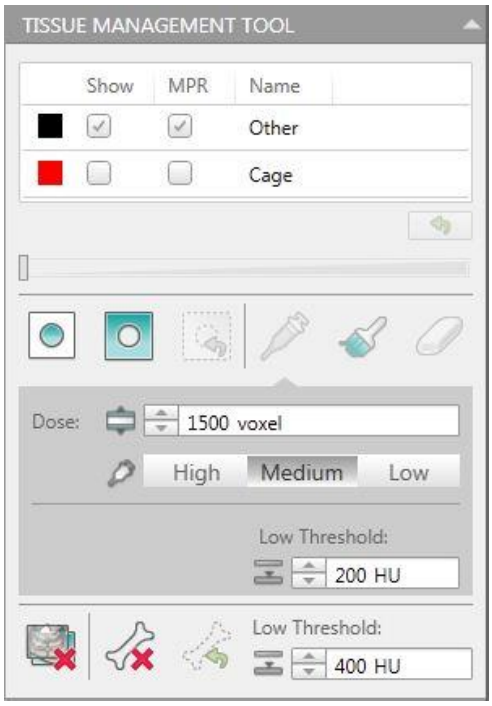


Figure 10-5 Tissue Management Tool

Remove Cage Automatically: Removes the rib cage automatically.

Refer to **Chapter 3.4.2** Tissue Management Tool for more information regarding the tools on this panel.

10.4.3 Batch Tool

Batch tool includes two parts: MPR batch and VR batch.

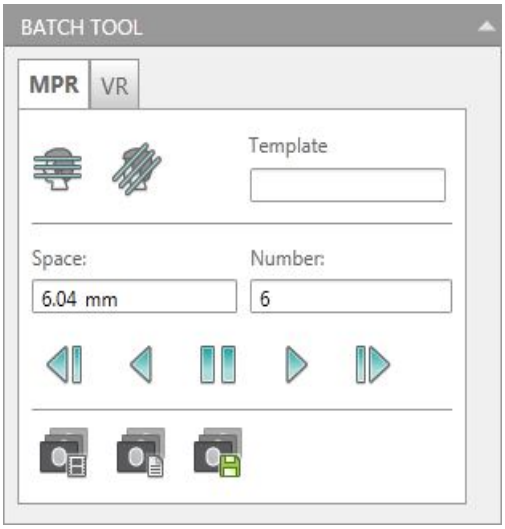


Figure 10-6 MPR Batch Tool

MPR batch includes three parts: define batch, modify batch and play batch.

Refer to **Chapter 2.4.2** Batch Tool for more information regarding the tools on this panel.

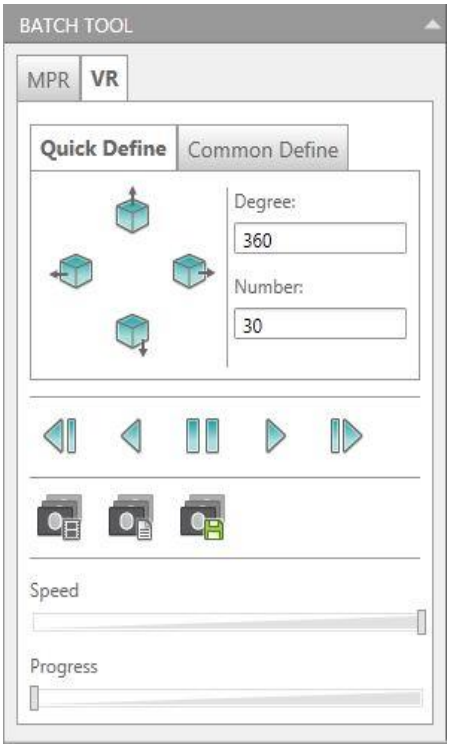


Figure 10-7 VR Batch Tool

VR batch includes three parts: Range, Batch and Cine.

Refer to **Chapter 3.4.3** Batch Tool for more information regarding the tools on this panel.

10.4.4 Compare Tool

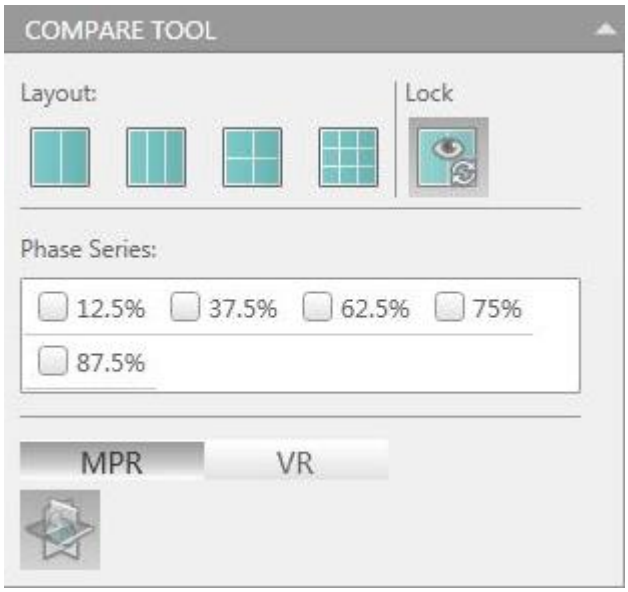


Figure 10-8 Compare Tool

Click any layout button to access compare mode in the compare tool.

Double-click the image series to be compared or check in phase series in the compare layout, the image is automatically loaded into the layout.

Select **Lock**, the compare images will link the images when zooming, rotating and modified Window Width and Level and so on.

There are different compare layouts: 1x2, 1x3, 2x2, 3x3. Up to nine series can be compared side-by-side.

Choose different images to compare. (axis, coronal or sagittal)

When you select a layout that is not in the compare tool, the system automatically exits compare mode.

NOTE:

- **Oblique, curve and batch images are not supported in the Compare Tool**.

10.4.5 4D Movie

Figure 10-9 4D Movie

4D Movie is used to play sequential phases.

Click **Forward** or **Step Forward** button to play, and click **Pause** to stop.

Select **Phase series** or adjust **Speed**.

Click **Save 4D Movie** button to save 4D movie.

10.5 Right-Click Menu

Right click on the images to show the Right-Click menu. Refer to **Chapter 1.6.3** Window Menu for more Right-click menu information.

Chapter 11. Perfusion

Perfusion analysis includes two Viewers: **Brain Perfusion** and **Body Perfusion.**

11.1 Brain Perfusion

Brain Perfusion is a blood flow imaging application that analyzes the uptake of injection contrast bolus, in order to determine functional blood flow. The information displays a specific Region of Interest [ROI]. The ROI is dynamically scanned in the same position and at the same time interval, to determine the rate of vascular flow change.

11.1.1 Brain Perfusion Interface

In the home page, select the desired images from the patient list and choose the **Brain** application.

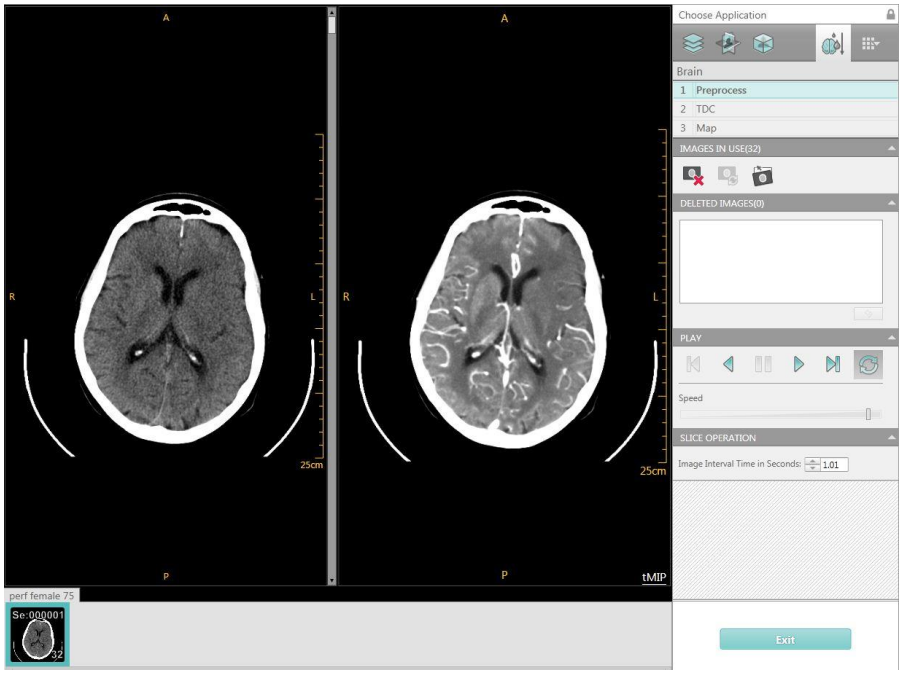


Figure 11-1 Brain Interface

NOTE:

- **For brain perfusion, the loaded series must be scanned dynamically at the same slice.**

The perfusion workflow is specific for the perfusion operation, including Preprocess, Reference Vessel, Calculate, Gray or Pseudo Color and so on.

Every perfusion follows the steps below:

- Load the perfusion series.
- Preprocess the images.
- Select Reference Vessel.
- Calculate.
- Evaluate the function images.
- Draw ROI.

⚠CAUTION:

- **The CT Perfusion application should not be used as the only basis for clinical diagnosis.**
- **Ensure that the scan duration is sufficient to cover the contrast period as well as the entire first pass of the contrast particles injected.**
- **A scan interval must be no longer than 2 seconds. 1 second is suggested.**
- **The contrast injection must be sufficiently rapid as to pro- vide reasonable enhancement.**
- **During the entire scanning process, keep the patient's head still. Otherwise, there will be unreliable functional images.**

11.1.2 Preprocess

The Image area includes the Reference image area and the original image area.

11.1.2.1 Reference Image Area

The Reference image area is in the right corner of the perfusion inter- face. It is used to display the reference (original) image before perfusion calculation and the tMIP image (time Maximum Intensity Projection) after the perfusion calculation.

11.1.2.2 Play

The Play Tool is used to display the images based on time for the loaded perfusion images. It provides an easy way to find motion artifacts.

Figure 11-2 Play Tool

- Click **Play** to start displaying the reference images.
- Click First or Last to show the first or last image.
- Drag the slide on the scrollbar to adjust the display speed of the loaded images.
- Click Loop to display the loaded images in a cycle. Click again to cancel.
- Click Pause to pause the image display.

11.1.2.3 Using Images

Delete Image: To delete the images which are not suitable for analysis.

Recalculate Image: After the middle images with motion artifacts are deleted, new normal images will be created automatically in their place based on the nearby image.

Manual Register: To open the **Manual Register** dialog box for setting the register image, pan, rotate, flag and other operations.

11.1.3 TDC(Time Density Curve)

After pre-processing the images, click the **TDC** icon on the workflow bar to enter the Select Reference Vessel interface.

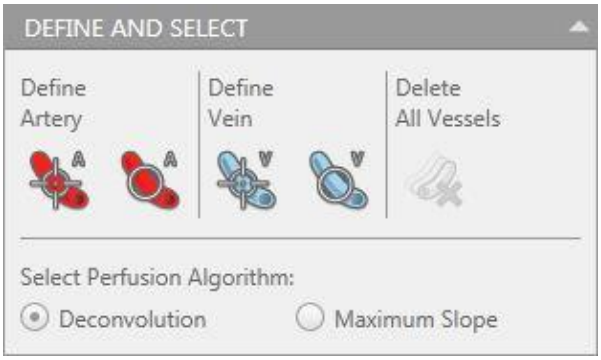


Figure 11-3 TDC Tool

Define Artery:

To define the vessel ROI, click the **Define Vessel by Point** or **Define Vessel by ROI** icon. Then drag the mouse into the Reference Image Area to find an artery vessel Point/ROI. Release the mouse. The ROI will be shown on both the Reference

image and the tMIP image in the Image area. The associated curve will also be shown in the TDC Graphics Area. Up to 10 arteries can be defined.

Define Vein:

To define the vessel ROI, click the **Define Vessel by Point** or **Define Vessel by ROI** icon. Then drag the mouse into the Functional Image Area to find a vein vessel Point/ROI. Release the mouse. The ROI will be shown on both the Reference image and the tMIP image in the Image Area. The associated curve will also be shown in the TDC Graphics Area. You can only define 1 vein.

Algorithm: Used to define the calculate algorithm: Deconvolution or Maximum Slope.

11.1.4 Map

After finding an ideal vessel ROI, click the **Map** icon for further calculation. The tMIP image will be shown in the Reference Image Area. The Function Image Area by default displays all four kinds of post-processing images simultaneously.

11.1.4.1 Function Image Area

The Function image area is in the upper right corner of the Perfusion Interface. Before the perfusion calculation, it is used to display tMIP image (time Maximum Intensity Projection); after the perfusion calculation, it is used to display image showing the perfusion processing.

4 kinds of post-processing images can be created:

- Cerebral Blood Flow
- Cerebral Blood Volume
- Mean Transit Time
- Time to Peak

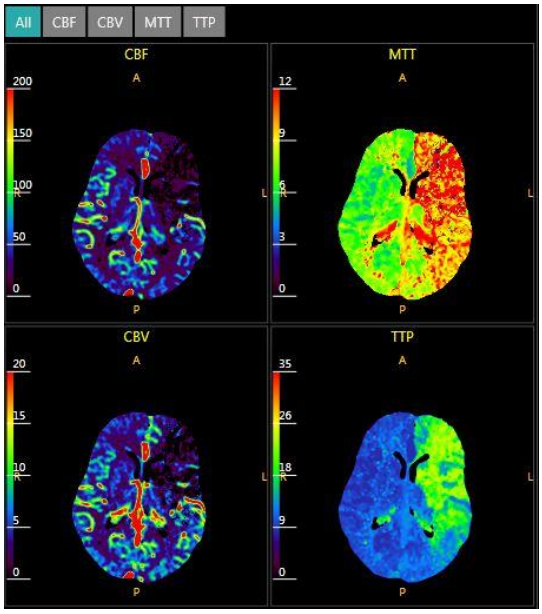


Figure 11-4 Post-processing Images

By manually switching between the options above, one of the 4 images can be displayed. Or select **All** to display all 4 of the images simultaneously in this area.

11.1.4.2 TDC Graphics Area

The TDC Graphics area is in the lower left corner of the perfusion inter- face. It is used to display the TDC (Time Density Curve) graphics of the Tissue ROIs.

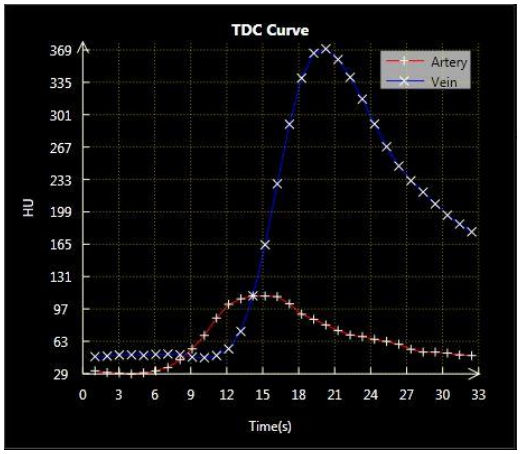


Figure 11-5 TDC Graphics

11.1.4.3 Table Report Area

The Table Report area is in the lower right corner of the perfusion interface. It is used to display the AV (Average Value) of all the Tissue ROI perfusion parameters.

ROI STATISTICS				
ROI	CBV	CBF	MTT	TTP
1	4.12 ml/100g	42.92 ml/100g/min	3.53 s	12.54 s
2	3.59 ml/100g	19.49 ml/100g/min	8.98 s	19.81 s
3	2.02 ml/100g	14.68 ml/100g/min	8.62 s	21.88 s
4	2.77 ml/100g	35.85 ml/100g/min	2.41 s	11.16 s

Figure 11-6 Table Report

- CBF: Cerebral Blood Flow.

- CBV: Cerebral Blood Volume. The volume of blood in a defined portion of the brain at any given time. CBV=CBF*MTT.

- MTT: Mean Transit Time. Can be oversimplified to be considered the time it takes blood to flow from a major cerebral artery feeding a given region of the brain to the major cerebral vein draining that region.

- TTP: Time to Peak. The time that elapses between the start of an IV contrast injection and the maximum attenuation of the contrast enhanced blood as it passes through a defined region of the brain

11.1.4.4 Display Mode

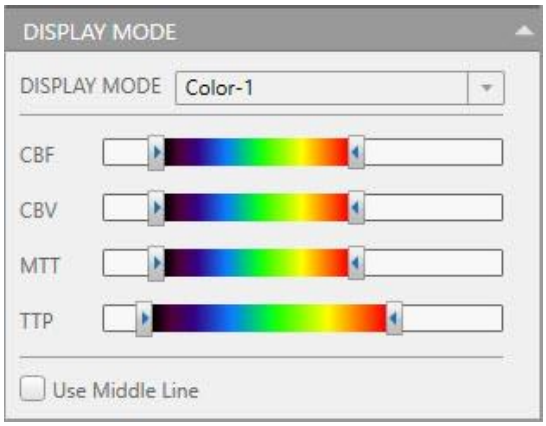


Figure 11-7 Display Mode

The functional image display could be set as a pseudo Color Map or Gray Map by clicking the icon below display mode.

Drag the slide on the scrollbar to adjust the window of the display value.

Use Middle Line: Show/Hide middle line on the images. It also can be used for mirror ROI.

11.1.4.5 Define and Measure

Figure 11-8 ROI Tool

Define Tissue ROI:

After the calculation, click the **Define Tissue ROI by Ellipse** or **Define Tissue ROI by Polygon** icon. Then define the tissue ROI on the image in the Image Area. At most 10 ROIs can be defined at one time.

If **Use Middle Line** is selected, click one of the two icons to find the tissue ROI. In this condition, at most 5 tissue ROIs can be defined. At the same time their counterparts will be shown on the other side of the line.

NOTE:

- **After calculation, the data of these ROIs will display in the report table.**

Delete All ROIs: Cancel all defined tissue ROIs.

Measure Map Pixel Value: Measure the pixel value on the image.

11.2 Body Perfusion

Body Perfusion is a blood flow imaging application that analyzes the uptake of contrast bolus, in order to determine functional blood flow. This includes information concerning a specific Region of Interest [ROI]. The ROI is dynamically scanned in the same position and at the same time interval to determine the rate of vascular flow change.

11.2.1 Body Perfusion Interface

In the home page, select the desired images from the patient list and choose the **Body** application.

After loading the images, the system requires you to select the protocol:

- Liver Protocol.
- Tumor Protocol (Not in Liver).

11.2.2 Liver Protocol

11.2.2.1 Pre-processing

Refer to **Chapter 11.1.2** for more information about this operation.

11.2.2.2 TDC

After pre-processing the images, click the TDC icon to enter the Select Reference Vessel interface.

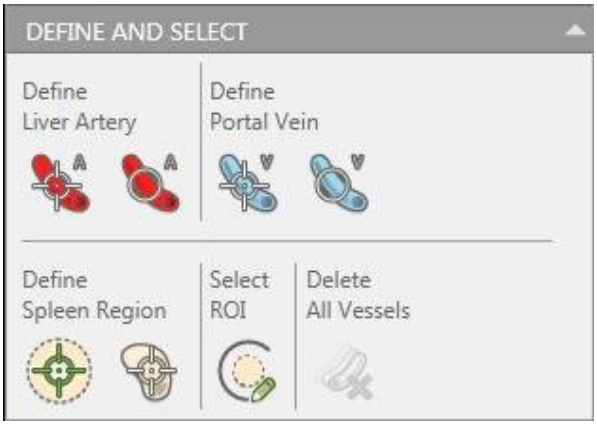


Figure 11-9 TDC Tool

Define Liver Artery: Click the Define Vessel by Point or Define Vessel by ROI icon to define liver artery.

Define Portal Vein: Click the Define Vessel by Point or Define Vessel by ROI icon to define portal vein.

Define Spleen Region: Click the Define Vessel by Point or Spleen Region to define Spleen Region.

Select ROI: Set the ROI to be calculated. If not, the system will calculate all the images.

11.2.2.3 Map

After selecting the ideal vessel ROIs, click the **Map** icon for further calculation.

Before the calculation, click the **Define Tissue ROI by Ellipse** or **Define Tissue ROI by Polygon** icon. Then define the tissue ROI on the image in the Image Area. The data from those ROIs will be shown in the table report area.

The report table is used to display the average value of all the liver perfusion parameters.

In the Function image area, you can display the general perfusion Maps viewport in 7 different forms. Click on a tab at the top of the viewport to select:

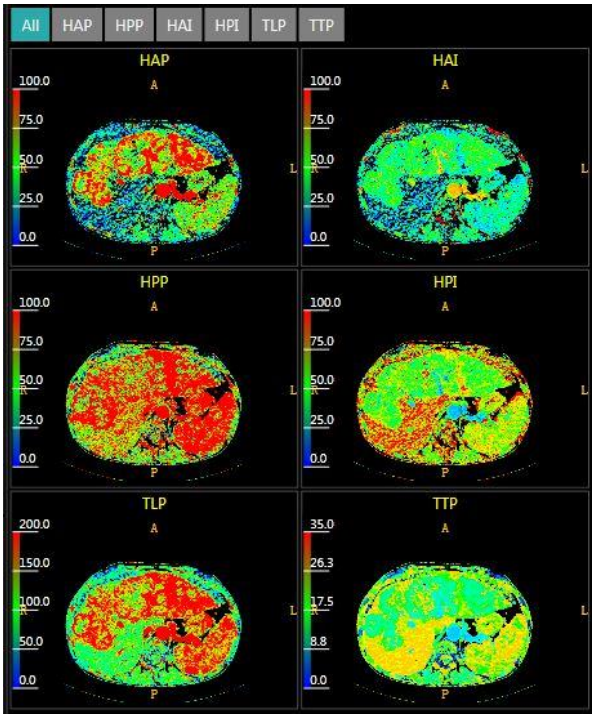


Figure 11-10 Map

- All: (default) click to display all 6 perfusion maps in the area.
- HAP: display the Hepatic Artery Perfusion map.
- HPP: display the Hepatic Portal Perfusion map.
- HAI: display the Hepatic Artery Perfusion Index map.
- HPI: display the Hepatic Portal Perfusion Index map.
- TLP: display the Total Liver Perfusion map.
- TTP: display the Time to Peak map.

11.2.3 Tumor Protocol

11.2.3.1 Preprocess

Refer to **Chapter 11.1.2** for more information about this operation.

11.2.3.2 TDC

After pre-processing the images, click **TDC** icon to enter the Select Reference Vessel interface.

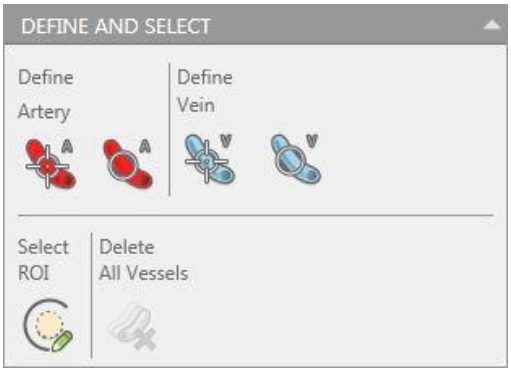


Figure 11-11 TDC Tool

Define Liver Artery: Click the Define Vessel by Point or Define Vessel by ROI icon to define liver artery.

Define Portal Vein: Click the Define Vessel by Point or Define Vessel by ROI icon to define portal vein.

Select ROI: To set the ROI to be calculated. If not, the system will calculate all the images.

11.2.3.3 Map

After selecting the ideal vessel ROIs, click the **Map** icon for further calculation.

Before the calculation, click the **Define Tissue ROI by Ellipse** or **Define Tissue ROI by Polygon** icon. Then define the tissue ROI on the image in the Image Area. The data for those ROIs will be shown in the table report area. The report table is used to display the average value of all the liver perfusion parameters.

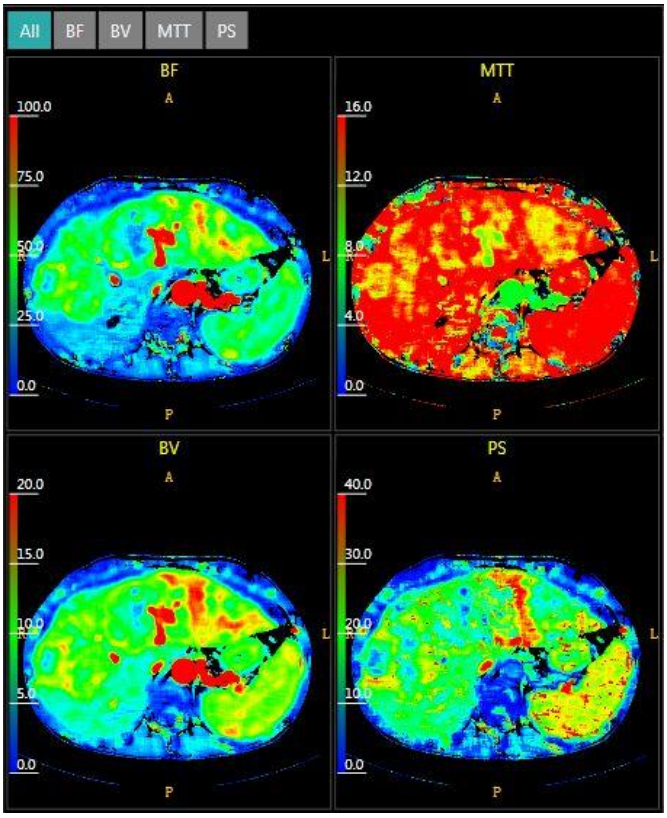


Figure 11-12 Map

In the Function image area, you can display the general perfusion Maps viewport in 5 different forms. Click on a tab at the top of the viewport to select:

- All: (default) click to display all 4 perfusion maps in the area.
- BV: display the Blood Volume map.
- BF: display the Blood Flow map.
- MTT: display the Mean Transit Time map.
- PS: display the Permeability Surface map.

11.2.4 Calculation

11.2.4.1 Liver Protocol

The peak time of the Spleen enhancement, which is also mentioned as time to peak, is set as the assumed demarcation point of the hepatic artery phase and portal vein phase.

HAP is calculated by the liver TDC before this time point; the HPP is calculated after this time point.

HAP=the maximum gradient of liver TDC before the time point/Peak time of hepatic artery enhancement

HPP=the maximum gradient of liver TDC after the time point/Peak time of portal vein enhancement

HAI=HAP/(HAP+PVP)

HPI=PVP/(HAP+PVP)

11.2.4.2 Tumor Protocol

BF= The maximum gradient of TDC/Maximum Input artery enhancement

BV= The maximum enhancement/Maximum Input artery enhancement

$$\frac{c(t)}{b(t)} = PS \cdot \frac{\int_0^t b(t)dt}{b(t)} + \mathrm{BV}$$

Where: C(t) represents the TDC of the tumor and b(t) represents the TDC of the artery.PS and BV are calculated through least squares.

Chapter 12. CTDSA

12.1 Overview

CT Digital Subtraction Angiography (CTDSA) offers a fast bone removal tool which subtracts the bone mask from every contrast phase of the dataset. This technique is well adapted to those neuro cases in which patient motion does not introduce bone deformation.

Only these images can be analyzed by the CTDSA:

- From the same patient
- From the same study
- With same thickness and increment
- With same center X and center Y
- With same FOV
- With same couch height
- With same Tube Voltage
- With same Filter

NOTE:

- **The total image number must be less than 3200.**
- **The duplicate position images shall be more than 30.**

12.2 CTDSA Interface

In the home page, select the desired images from the patient list and choose the **CTDSA** application.

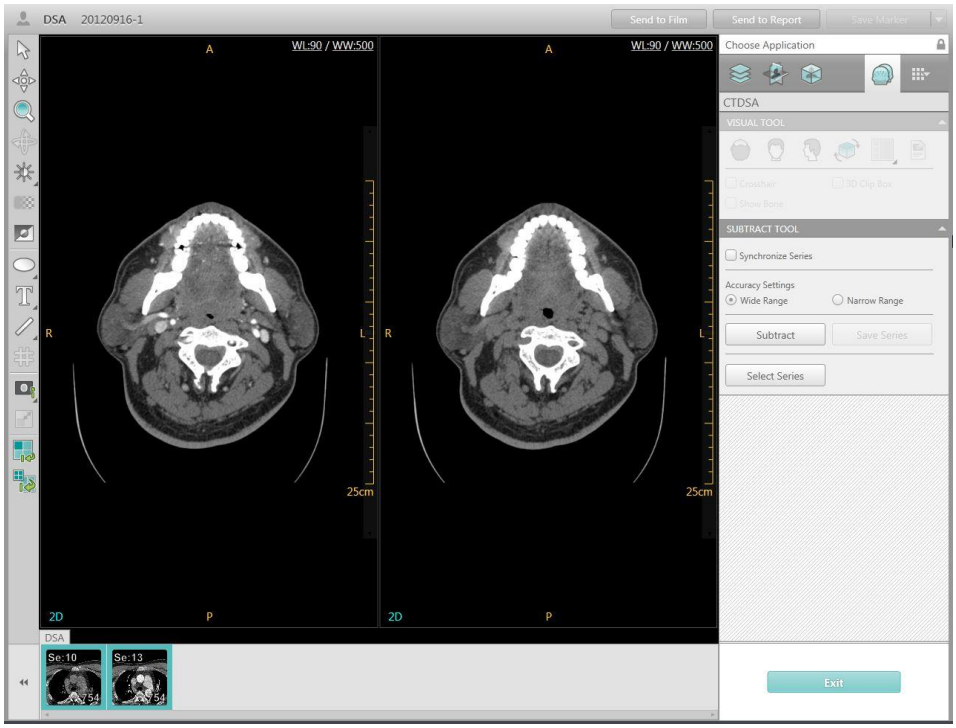


Figure 12-1 DSA Interface

The **CTDSA** Tool includes **Visual Tool** and **Subtract Tool.**

12.3 Image Display Region

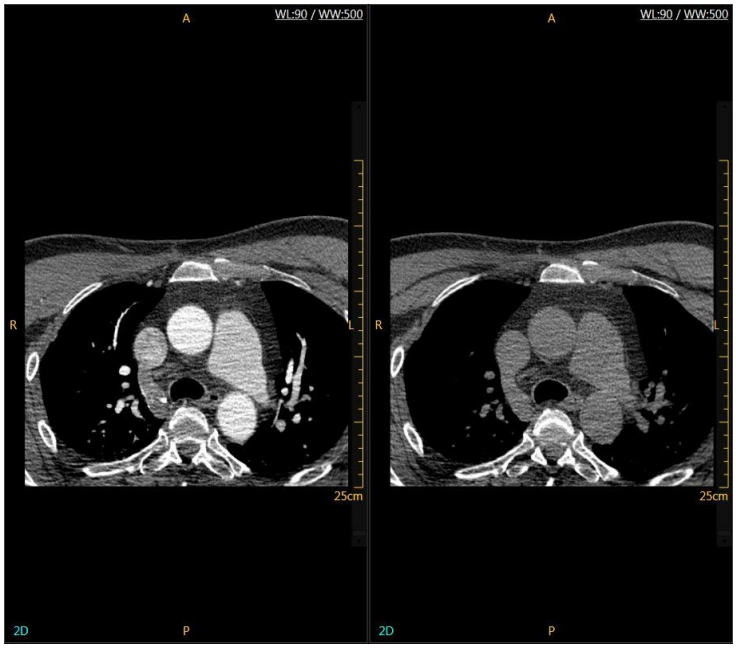


Figure 12-2 Image Display Region

12.4 Tool panel

After subtraction buttons on the Tool panel can be used to highlight.

12.4.1 Visual Tool

Figure 12-3 Visual Tool

Crosshair: Show/Hide the crosshair on the image.

3D Clip Box: Show/Hide the clip box on the 3D image.

Show Bone: Show/Hide the bone on the image.

Axial: Display the volume image in the axial direction.

Coronal: Display the volume image in the coronal direction.

Sagittal: Display the volume image in the sagittal direction.

Flip VR image: Flip the volume image.

Protocol: Show/Hide the protocol list.

There are three page layouts for review:

1x2: Displays the contrast series and non-contrast series images.

3+1: Displays the three sectional MPR images and subtraction result image.

2x2: Displays the contrast series and non-contrast series images on the left; displays the subtraction result series and subtracted bone series image on the right.

12.4.2 Subtract Tool

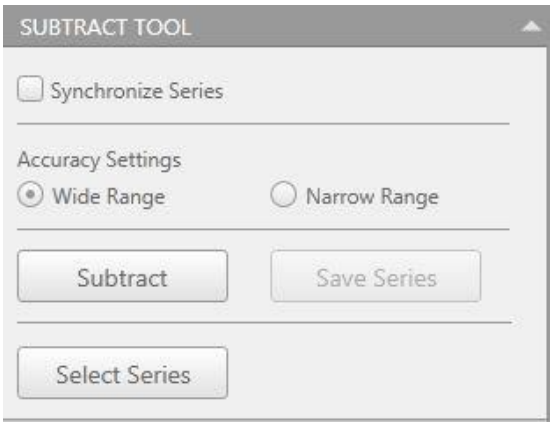


Figure 12-4 Subtract Tool

Synchronize Series: Synchronize series automatically.

Choose the subtraction accuracy setting: **Narrow Range** or **Wide Range**, then click **Subtract** to process the series. The system will automatically display the subtraction images in the result viewport and generate the subtracted bone series in the series list.

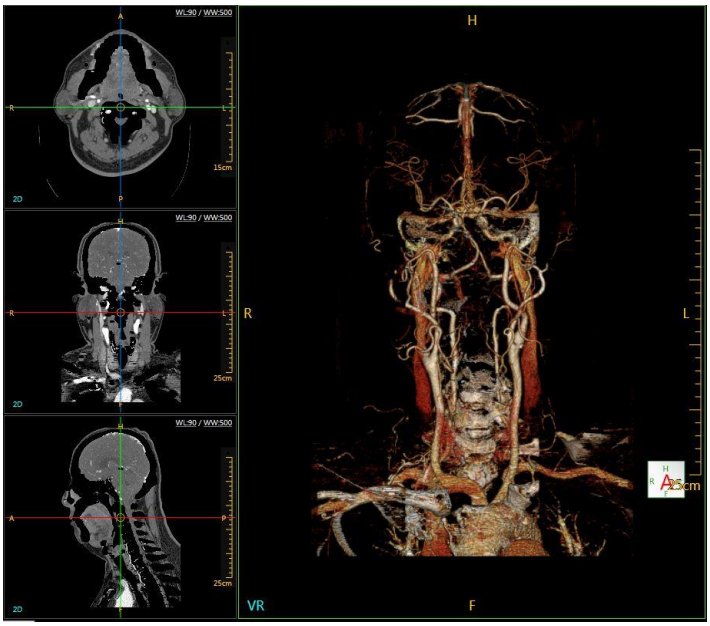


Figure 12-5 Subtraction Result

Save Series: Save subtraction results.

Select Series: Select a series for subtraction.

12.5 Manual Edit

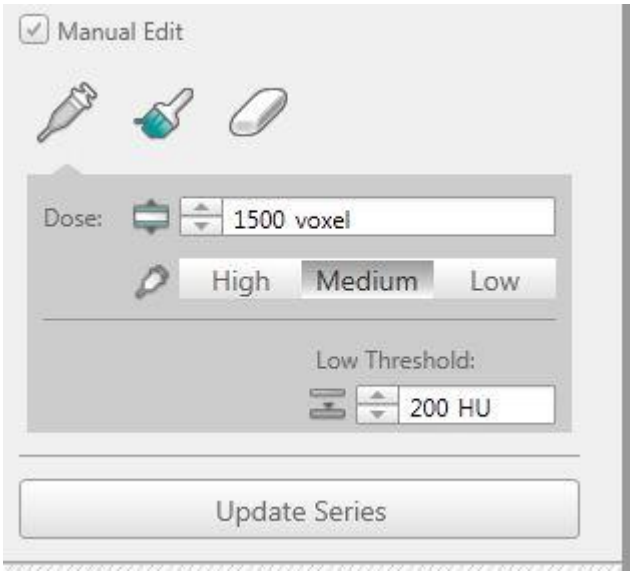


Figure 12-6 Manual Edit

Choose CTA series, you can edit results and then click **Update Series** button.

Chapter 13. Tumor Assessment

13.1 Overview

Tumor application can define and view lesions through original series and followup series, two studies can be compared. This can determine growth of a tumor.

13.2 Tumor Interface

In the home page, select the desired images from the patient list and choose the **Tumor** application.

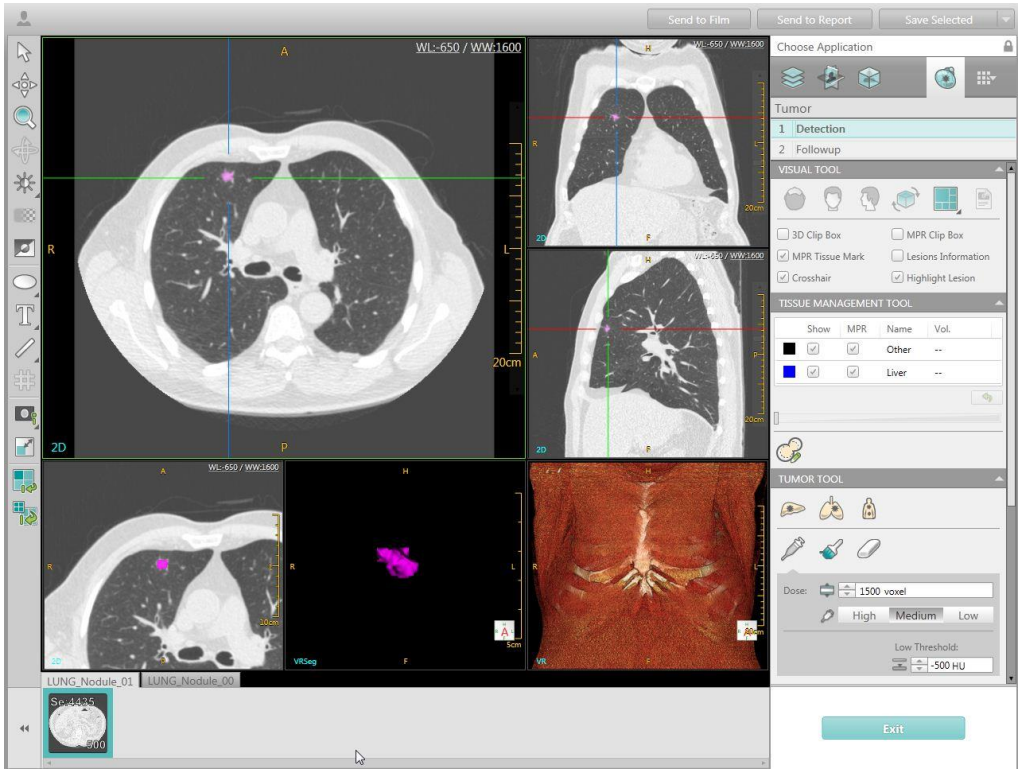


Figure 13-1 Tumor Interface

13.3 Assessment Toolbox

At the top of the control panel is the assessment toolbox, which provides access to a set of guided workflow steps.

The order of steps in the analysis toolbox is

- **Detection**
- **Follow-up**

Click on the toolbox to select from the list of workflow steps, or to move forward or back one step.

Only a series of images meeting the following parameters can be analyzed by Tumor Analysis:

- From the same patient
- With the same thickness and FOV
- Image Thickness less than 5mm

NOTE:

- **4 series can be loaded at one time into the Tumor Analysis tool.**

13.4 Detection

The Detection Tool includes: **Visual Tool, Tumor Tool** and **MPR Play**.

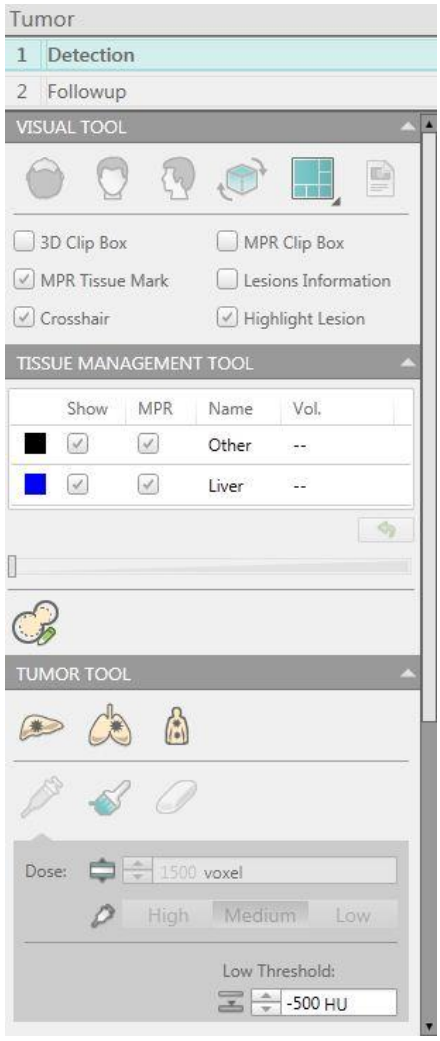


Figure 13-2 Detection Control Panel

13.4.1 Visual Tool

Figure 13-3 Visual Tool

There are two page layouts for review:

2x2: Displays three sectional MPR images and a VR image.

1+2+3: Displays an Axial image on the top left; Displays lesion MPR and VR image on the bottom left; Displays Coronal, Sagittal and VR image on the right.

MPR Tissue Mark: Show/Hide the tissue mark on MPR image.

Lesions Information: Select this box to display the lesion information list, including Organ, RECIST Diam., Max.Vertical Diam., WHO Area, Volume, Avg and Max.Z Diam.

Highlight Lesion: Show/Hide the color of the lesion.

Refer to **Chapter 3.4.1** Visual Tool for more information regarding the tools on this panel.

13.4.2 Tissue Management Tool

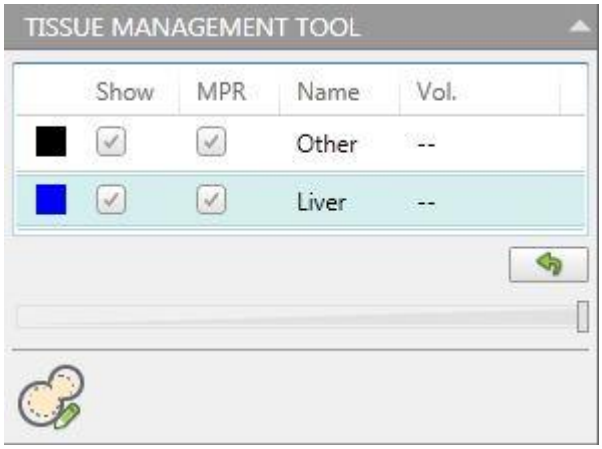


Figure 13-4 Tissue Management Tool

Tissue List displays the tissue name and the tissue volume. Check the option box below Show or MPR to define whether to display the tissue in the VR or MPR images.

Clear: Clear the tissue volume.

Opacity: Define the tissue Transparency display.

Contour segmentation: Draw the contour on different MPR layer and segment the contour region.

13.4.3 Tumor Tool

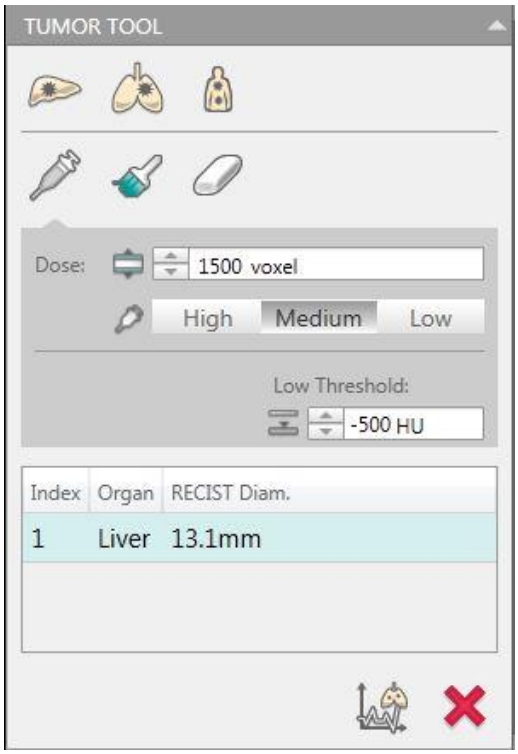


Figure 13-5 Tumor Tool

Select the **Liver**, **Lung** or **Body** icon to extract a lesion, the system will automatically segment and highlight the lesion.

Enter the value of **High Threshold** and **Low Threshold** to get a more accurate result if necessary. Or click the arrow next to the text box to increase/decrease the number.

The lesion list will be updated after you mark the lesion.

Dye: Click the icon to dye the lesion area.

Brush: Click the icon to brush the lesion area.

Eraser: Click the icon to erase the lesion area that is dyed.

Simultaneously the lesion information is calculated and added into the lesion information list.

Del. Lesion: Delete the lesion in the list.

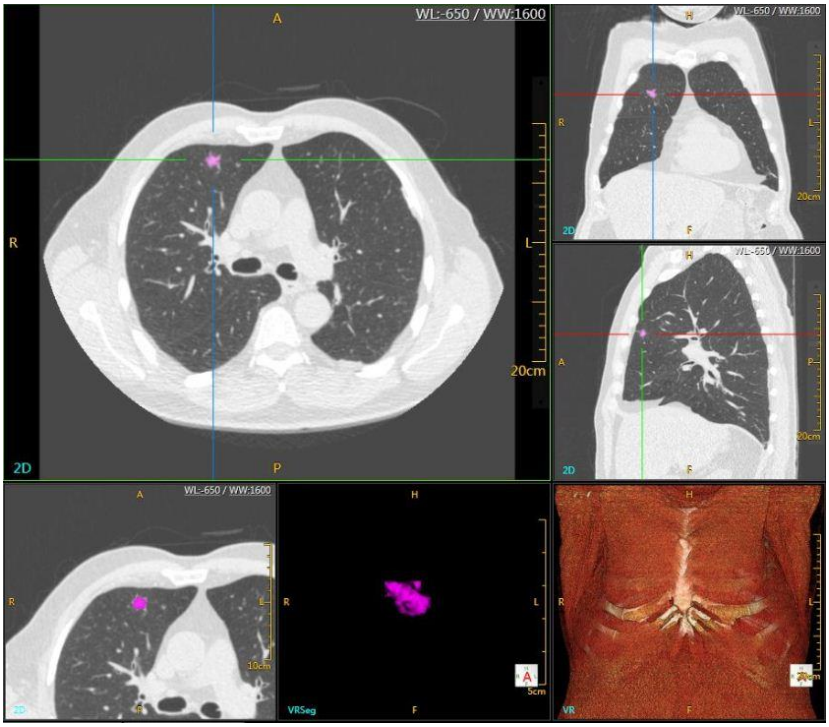


Figure 13-6 Define a Lesion

13.4.4 MPR Play

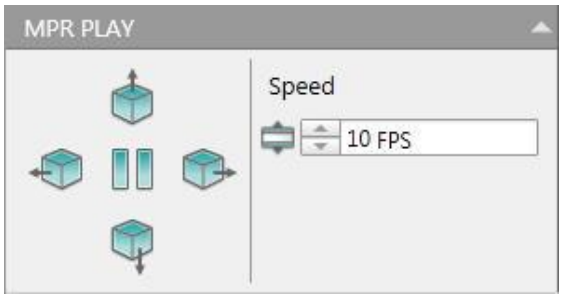


Figure 13-7 MPR Play Tool

Rotate Left, **Rotate Up**, **Rotate Right**, **and Rotate Down**: Select the direction icon to play the MPR images. Select the arrow next to the **Speed** text box to increase/decrease the play speed.

13.5 Followup

Click **Followup** to enter the interface. It is necessary to select two series for analysis.

After selecting the followup series, the system will automatically calculate the followup study and compare it with original study.

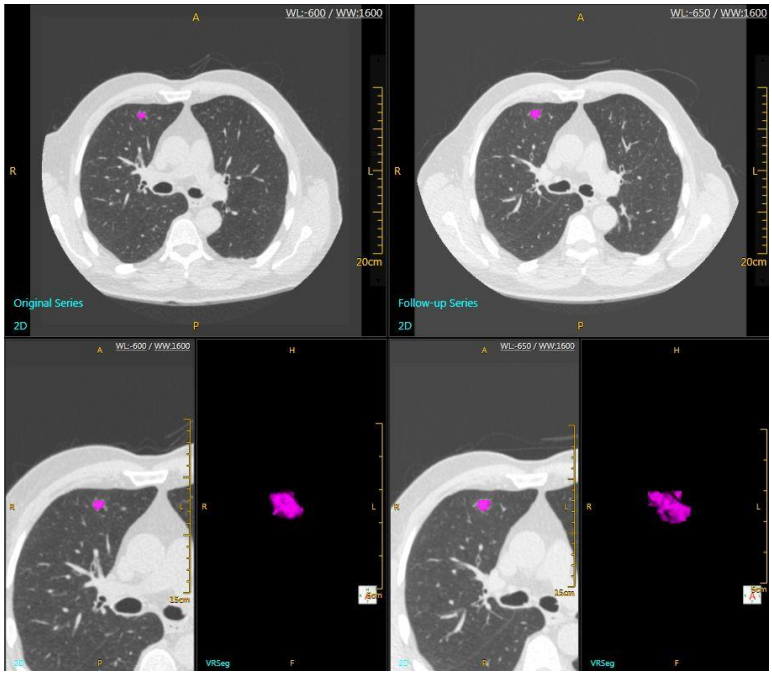


Figure 13-8 Followup Interface

13.5.1 Visual Tool

Figure 13-9 Visual Tool

There are three page layouts for review:

2x2: Displays the Axial images and Lesion VR image of the Original Series and followup Series.

2+4: Displays the Original series on the left. The layout is Axial image on the top and Lesion MPR and VR image on the bottom. Displays the follow up series on the right. The layout is Axial image on the top and Lesion MPR and VR image on the bottom.

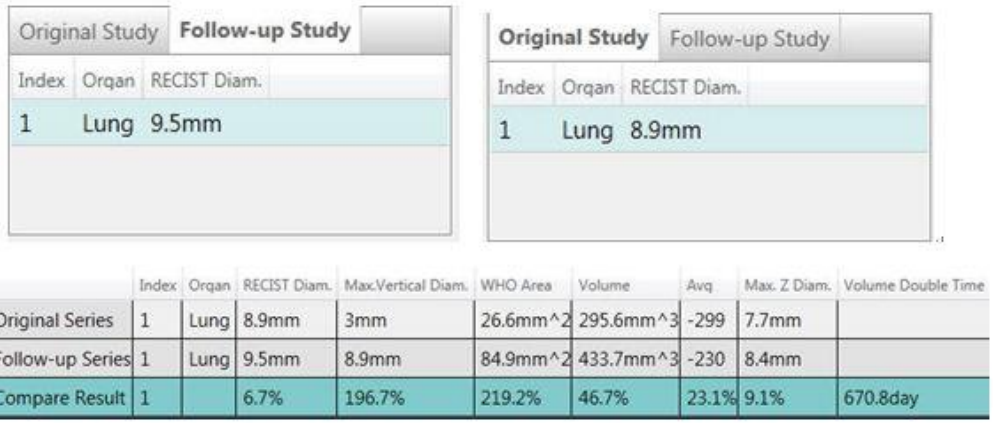
2+4+2: Displays the Original series on the left, the layout is Axial image on the top and Lesion MPR and VR image on the middle, and the lesions information on the bottom; Displays the followup series on the right, the layout is Axial image on the top and Lesion MPR and VR image on the middle, and the lesions information on the bottom.

Synchronize Series: View the Original series and followup series synchronously.

13.5.2 Tumor Tool

Display the lesion information list of the original series and the followup series.

Compare Lesion: To show the Compare Result under the list.



	Index	Organ	RECIST Diam.	Max.Vertical Diam.	WHO Area	Volume	Avg	Max. Z Diam.	Volume Double Time
Original Series	1	Lung	8.9mm	3mm	26.6mm^2	295.6mm^3	-299	7.7mm	
Follow-up Series	1	Lung	9.5mm	8.9mm	84.9mm^2	433.7mm^3	-230	8.4mm	
Compare Result	1		6.7%	196.7%	219.2%	46.7%	23.1%	9.1%	670.8day

Figure 13-10 Tumor Tool

Del.Comparison: Delete the compare result.

13.5.3 MPR Play

Refer to **Chapter 13.4.3** MPR Play for more information regarding the tools on this panel.

13.6 Right-Click Menu

Right click on the images to show the Right-Click menu. Refer to **Chapter 1.6.3** Window Menu for more Right-click menu information.

Chapter 14. Colon

14.1 Overview

Colon Application provides various diagnostic information for the colon. Such as the size and position of colonic polyps.

14.2 Colon Interface

In the home page, select the desired images (consist of two series at most) from the patient list and choose the **Colon** application.

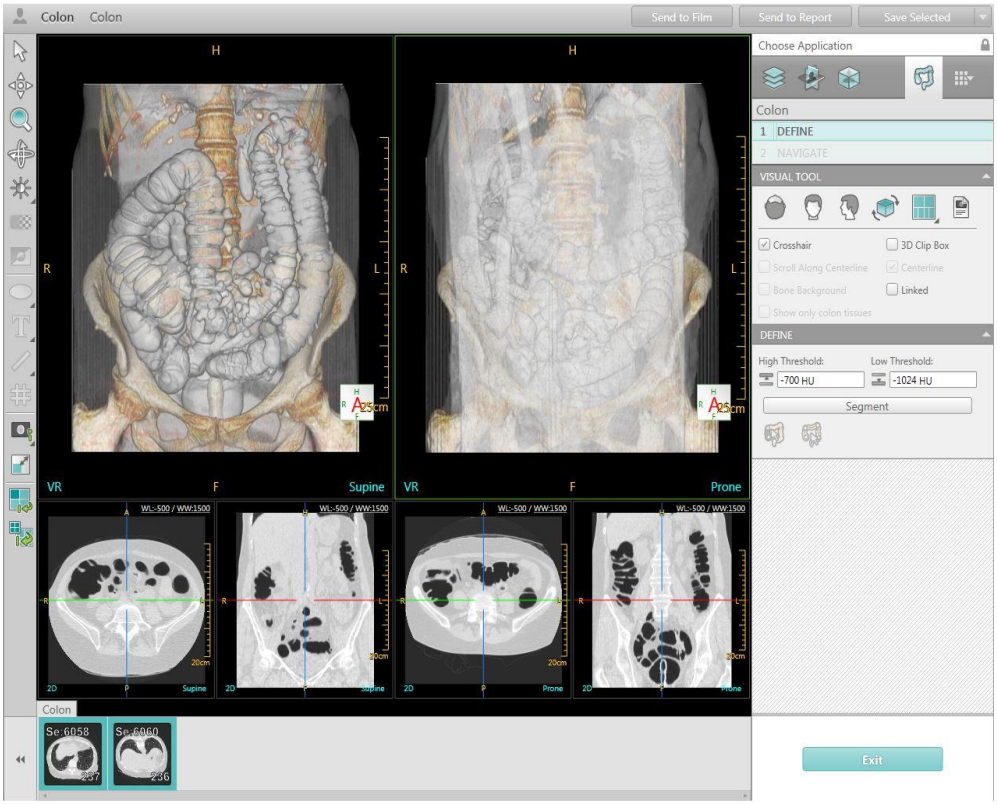


Figure 14-1 Colon Interface

The Colon application includes two workflow steps.

- **Define**
- **Navigate**

14.3 Define

In the **Define** Stage, you can:

- Segment the colon.
- Edit the colon segment curves.
- Edit the centerline.

14.3.1 Visual Tool

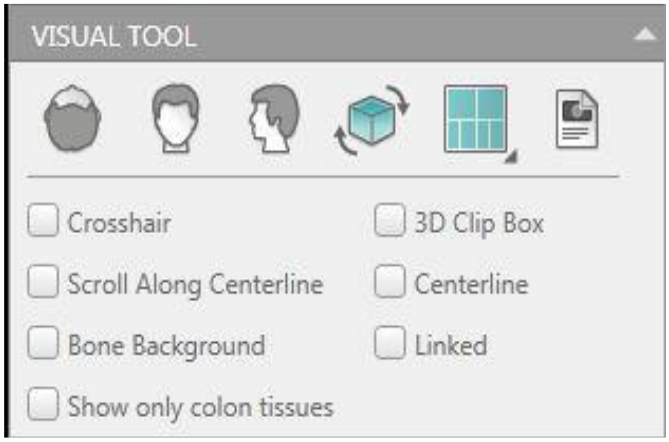


Figure 14-2 Visual Tool

Crosshair: Show/hide the crosshair on MPR image.

3D Clip Box: Show/hide the clip box on 3D image.

Scroll Along Centerline: MPR image scrolls by normal or along centerline.

Centerline: Show/hide the centerline after colon is segmented, it's only available in define workflow.

Bone Background: Show/hide the bone background on the image.

Linked: The two series will navigate synchronously.

Show only colon tissues: Show/hide the rejected tissues.

14.3.2 Colon Tool

Figure 14-3 Colon Tool

After loading the desired study, click **Segment** to segment the air-filled colon. Click on the colon segments, the invalid components will be set as grey. You can hide/show the invalid colon components.

- Select **Edit Segment Curves/Edit Centerline** button and right click on the centerline.
- Select **Delete Curve** to delete the centerline.
- Select **Delete Above** to delete the centerline before the point.
- Select **Delete Below** to delete the centerline after the point.
- Select **Switch End Points** to switch the end points of the centerline.

When you finish the define process, click **Finish** to enter next stage.

Delete Curve is available only in the **Edit Segment Curves** stage.

Figure 14-4 Edit Centerline

14.4 Navigate

Click **Navigate** to enter the interface after you have confirmed the colon

segmentation. The Navigate stage provides a variety of visualization functions.

- A scroll bar in the middle of the viewport allows you to quickly visualize the entire colon along the center line.
- The navigation tools allow you to fly through the colon in the cine mode, continuously or step by step.

14.4.1 Navigate Tool

Series Selection: allows you to view two scans of the same patient, **Prone** and **Supine**.

Colon Page Layout: Right-click or click the arrow on the bottom right corner of the icon to select different page layouts for viewing the colon images, it contains single series and compare series layout.

Single series layout: Standard, Unfold, Unfold + VE;

Compare series layout: Compare VE + VR, Compare Double Unfold, Compare Double VE.

Unfold view style: Length, Angle.

- Standard: 3+2 Layout displays the overview VR image and VE image on the top of the viewport, the cross sectional MPR images on the bottom of the viewport.

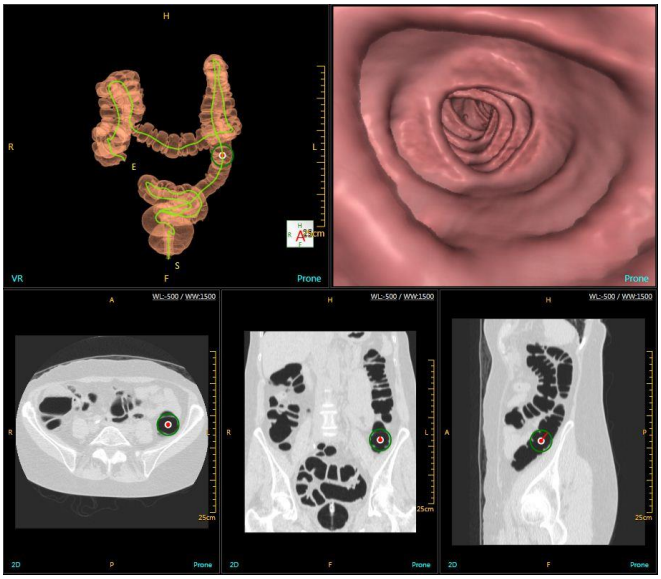


Figure 14-5 Standard

- **Unfold**: **3+1** Layout displays the overview VR image, cross sectional image and the VE image on the top of the viewport, the unfold view is on the bottom of the viewport.

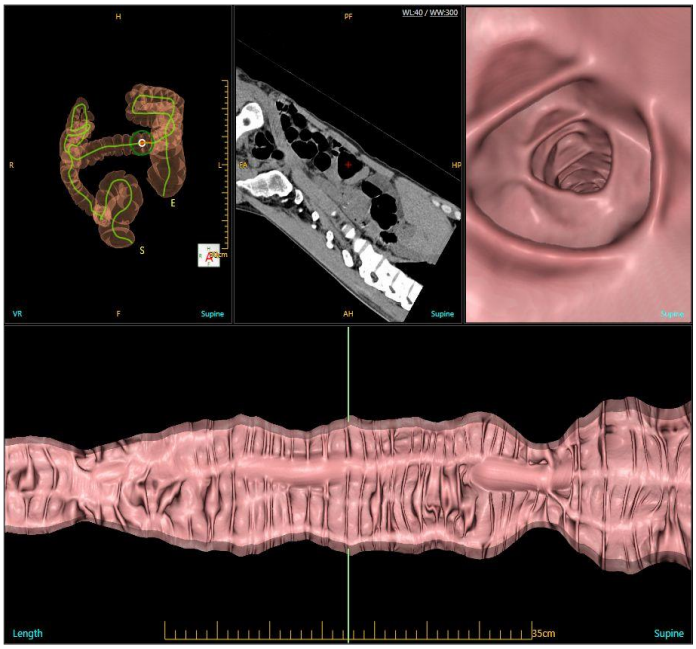


Figure 14-6 Unfold

- **Unfold + VE**: **2x2** layout displays the cross sectional image and fisheye(VE) image on the top of the viewport, the overview VR image and the unfold view on the bottom of the viewport.

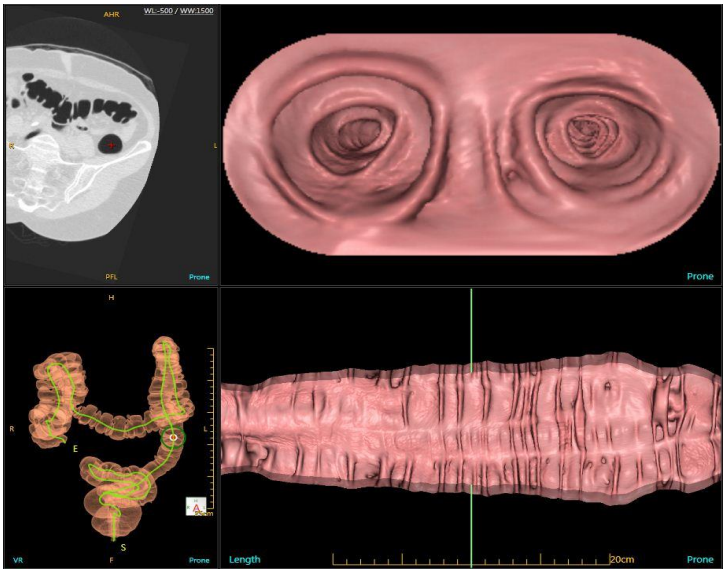


Figure 14-7 Unfold + VE

- **Compare VE + VR**: **2x2** layout displays the supine series on the left of the viewport with VE image and overview VR image; the prone series on the right of the viewport with VE image and overview VR image.

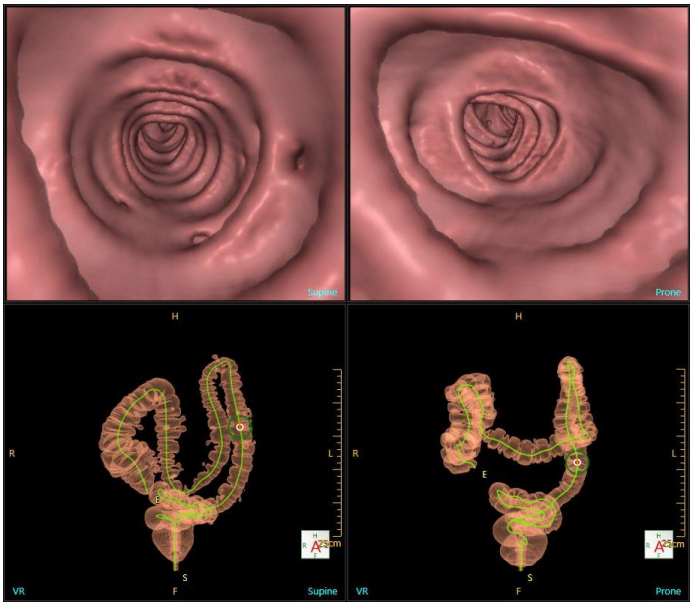


Figure 14-8 Compare VE+VR

- **Compare Double Unfold**: **2+4** layout displays the supine series on the top of the viewport with unfold view, overview VR image and cross sectional image; the prone series on the bottom of the viewport with unfold view, overview VR image and cross sectional image.

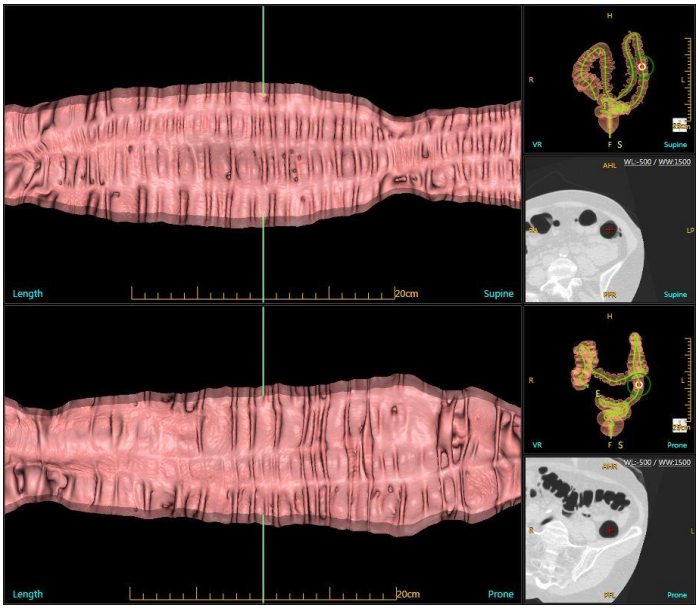


Figure 14-9 Compare Double Unfold

- **Compare Double VE**: **2+4** layout displays the supine series on the top of the viewport with fisheye(VE) view, overview VR image and cross sectional image; the prone series on the bottom of the viewport with fisheye(VE) view, overview VR image and cross sectional image.

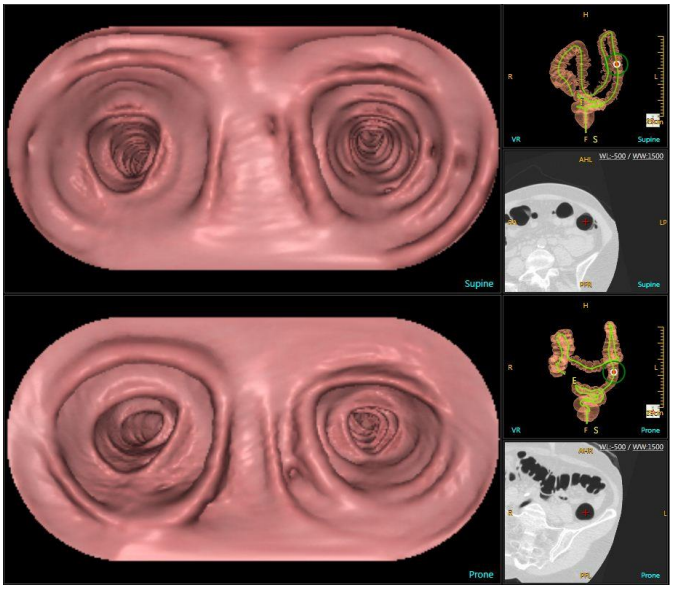


Figure 14-10 Compare Double VE

NAVIGATE Tool: Click play button, images scroll along centerline. Click **Forward/Back** or **Step Forward/Step Backward** button to play, and click **Stop** to stop, click **Reverse** to play in opposite direction. Select **Slow/Normal/Fast** to adjust **Speed**.

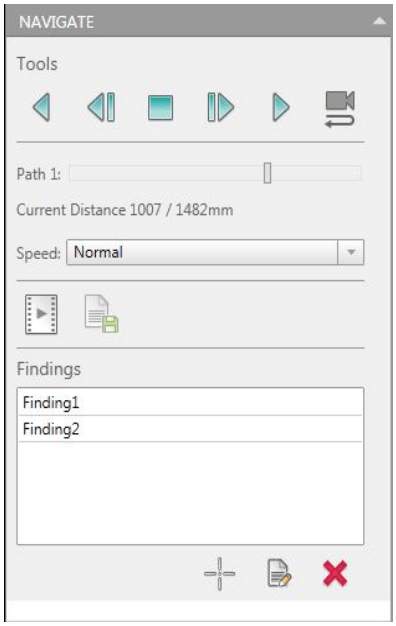


Figure 14-11 Navigate Tool

Select **Linked**, two series scroll along the centerline synchronously.

Click **Record** button to start recording, click once again to stop recording.

Click **Save Result** button to save record.

NOTE:

- **Click on VE window to start navigating manually.**

14.4.2 Polyp Tools

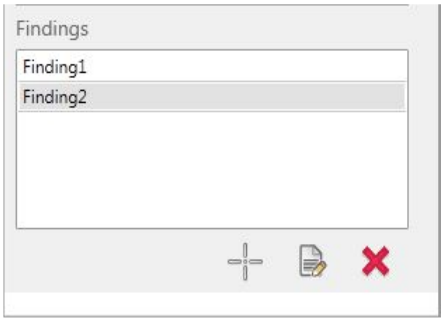


Figure 14-12 Polyp Tools

Finding: Marks the polyp in the image (not VR image). It is displayed on the image and added into the polyp list. Users can edit and delete the selected findings.

Click the **EDIT** to view and modify the polyp detail information.

Polyp detail information includes: Name, Type, Segment, Distance to Rectum, Volume and Description.

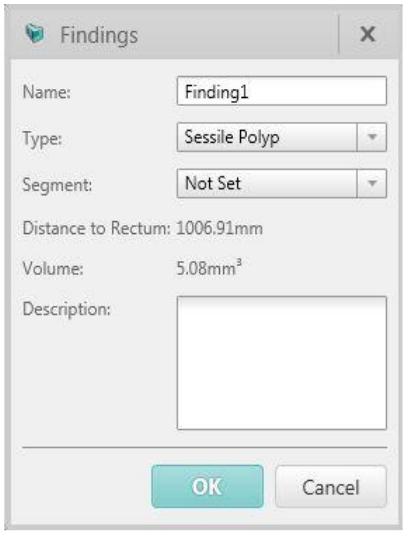


Figure 14-13 Polyp description

Chapter 15. Lung Nodule Assessment

15.1 Overview

Lung Nodule application can define and view lesions using the original series and follow-up series. Two studies can be compared to determine growth of nodules.

15.2 Lung Nodule Interface

The Lung Nodule Assessment assists the radiologist with the detection and quantification of pulmonary nodules and lesions. If a follow-up study of the patient has been acquired, the two studies can be compared. The growth of nodules can be tracked over time.

In the home page, select the desired images from the patient list and choose the **Lung Nodules** application.

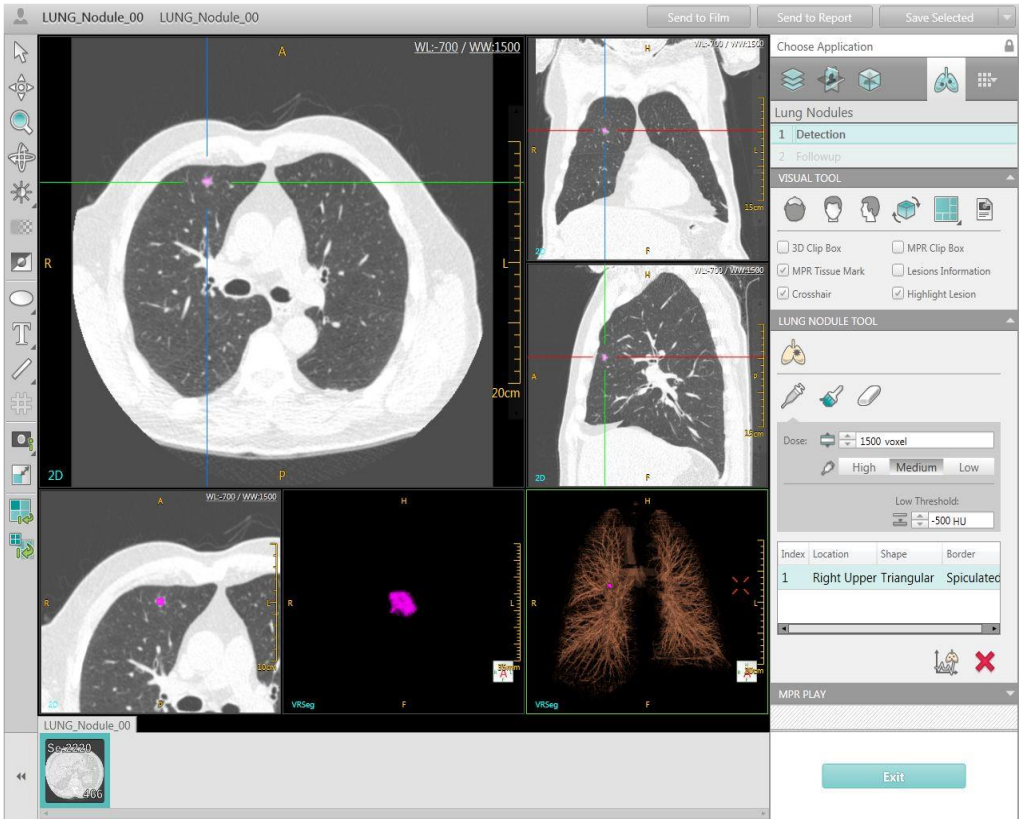


Figure 15-1 Lung Nodules Interface

The Lung Nodules application includes two workflow steps.

- **Detection**
- **Follow-up**

15.3 Detection

15.3.1 Visual Tool

Figure 15-2 Visual Tool

There are two page layouts for review:

2x2: Displays three sectional MPR images and the VR image.

1+2+3: Displays the Axial image on the top of left; the lesion MPR and VR image on the bottom left; and the Coronal, Sagittal and VR image on the right.

MPR Tissue Mark: Show/Hide the tissue mark on MPR image.

Lesions Information: Select this box to display the lesion information list, including Volume, Avg, Max. Z Diam., Location, Shape, Border and Comments. You can click the drop-down arrow to select the desired explanation for Location, Shape and Border.

Highlight Lesion: Show/Hide highlight lesion color.

Refer to **Chapter 3.4.1** Visual Tool for more information regarding the tools on this panel.

15.3.2 Lung Nodule Tool

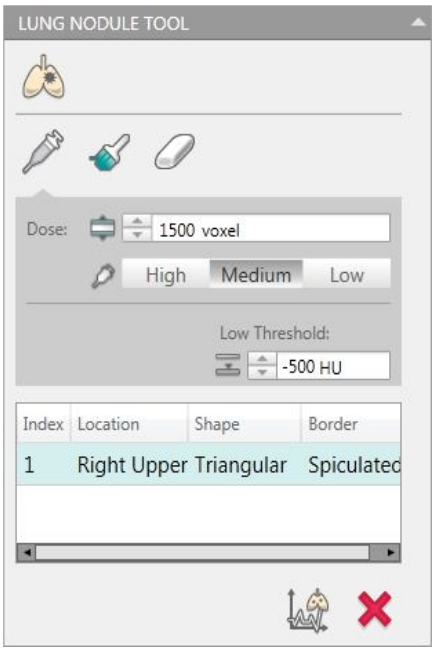


Figure 15-3 Lung Nodule Tool

Click **Select Lesion** icon to extract a lesion. The system will automatically segment and highlight the lesion.

Enter the value of **High Threshold** and **Low Threshold** to get a more accurate result if necessary. Or click the arrow next to the text box to increase/decrease the number.

The lesion list will be updated after you mark the lesion.

Dye/Brush: Click the icon to dye the lesion area.

Eraser: Click the icon to erase the lesion area that is dyed.

The lesion information is calculated and added into the lesion information list simultaneously.

Del. Lesion: Delete the lesion in the list.

15.3.3 MPR Play

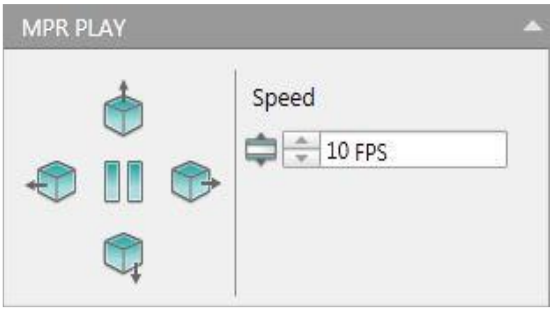


Figure 15-4 MPR Play Tool

Left, **Up**, **Right and Down**: Select the desired direction icon to play the MPR images. Click the arrow next to the **Speed** text box to increase/decrease the play speed.

15.4 Followup

Click **Followup** to enter the interface. Select a second series for analysis.

After selecting the followup series, the system will automatically calculate the followup study and compare it with original study.

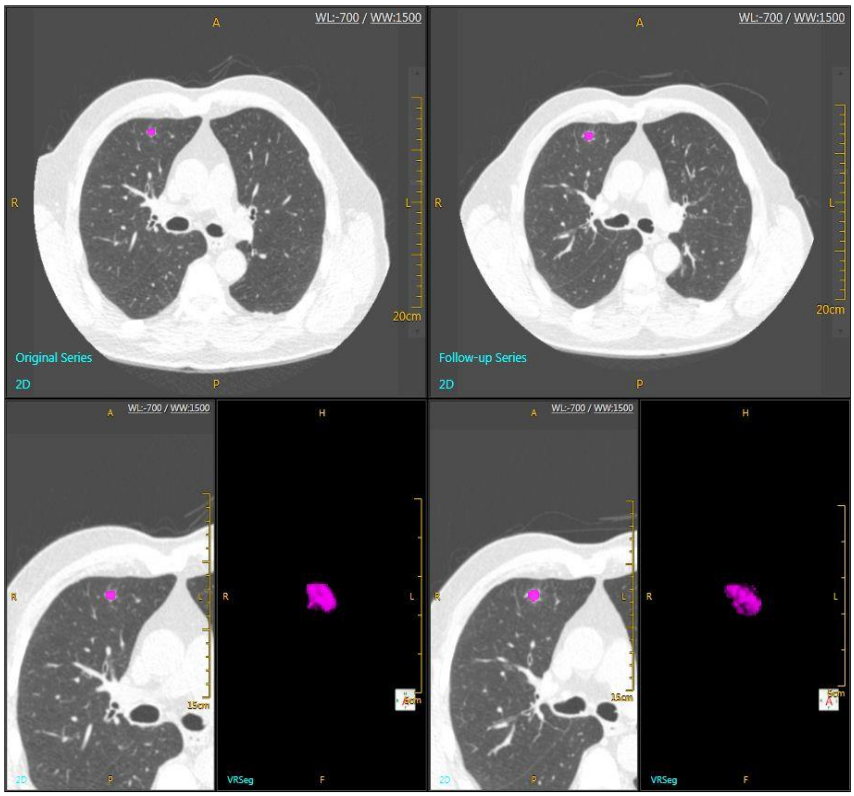


Figure 15-5 Followup

15.4.1 Visual Tool

Figure 15-6 Visual Tool

There are three page layouts for review:

2x2: Displays the Axial images and Lesion VR image of the Original Series and

Followup Series.

2+4: Displays the Original series on the left, with the Axial image on the top and the Lesion MPR and VR image on the bottom. Displays the Followup series on the right, with the Axial image on the top and the Lesion MPR and VR image on the bottom.

2+4+2: Displays the Original series on the left, the layout is Axial image on the top and Lesion MPR and VR image on the middle, and the lesions information on the bottom; Displays the follow up series on the right, the layout is Axial image on the top and Lesion MPR and VR image on the middle, and the lesions information on the bottom.

Synchronize Series: View the Original series and Followup series at the same time.

Compare Lesion: Select this box to display the lesion information list, including Volume, Avg, Max.Z Diam., Volume Double Time, Location, Shape, Border and Comments.

Refer to **Chapter 15.3.1** Visual Tool for more information regarding the tools on this panel.

15.4.2 Followup Tool

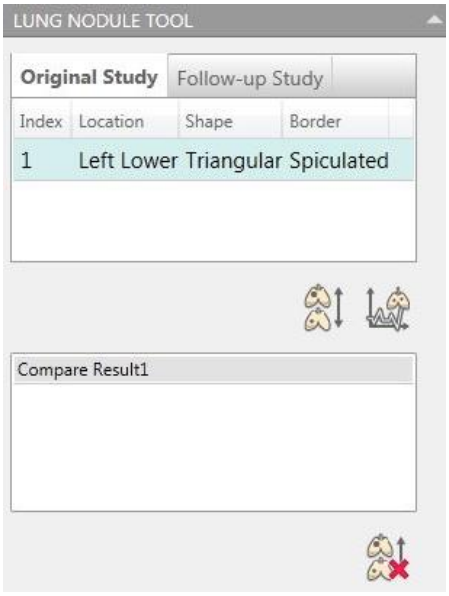
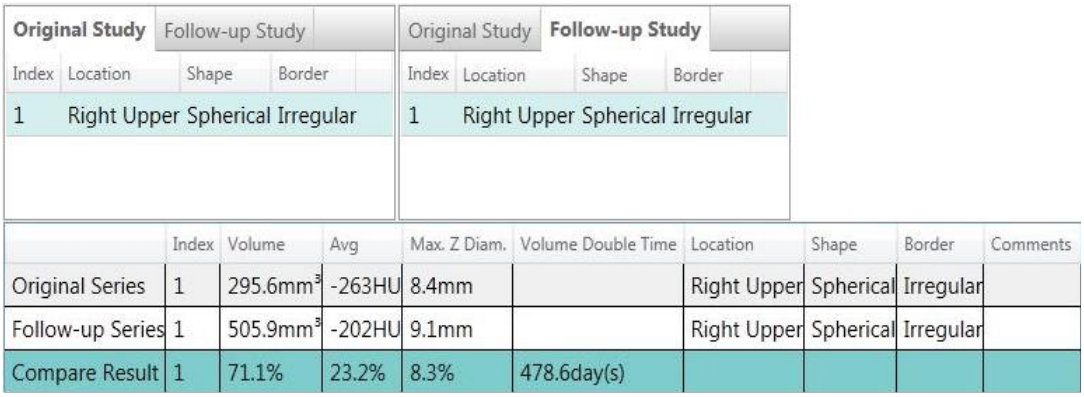


Figure 15-7 Followup Tool

The Lung Nodule Tools interface displays the lesion information list of the original series and the follow up series.

Compare Lesion: To display the Compare Result under the list.

Del. Comparison: Delete the Compare Result.



	Index	Volume	Avg	Max. Z Diam.	Volume Double Time	Location	Shape	Border	Comments
Original Series	1	295.6mm³	-263HU	8.4mm		Right Upper	Spherical	Irregular	
Follow-up Series	1	505.9mm³	-202HU	9.1mm		Right Upper	Spherical	Irregular	
Compare Result	1	71.1%	23.2%	8.3%	478.6day(s)				

Figure 15-8 Compare Lesion

15.4.3 MPR Play

Refer to Chapter 15.3.3 MPR play for more information.

15.5 Right-Click Menu

Right click on the images to show the Right-Click menu. Refer to **Chapter 1.6.3** Window Menu for more Right-click menu information.

Chapter 16. Lung Density

16.1 Overview

The Lung Density application is an automated application that provides the physician with quantitative (Volumetric) lung emphysema measurement and a visual representation of the diffusion of the emphysema.

16.2 Lung Density Interface

In the home page, select the desired images from the patient list and choose the **Lung Density** application.

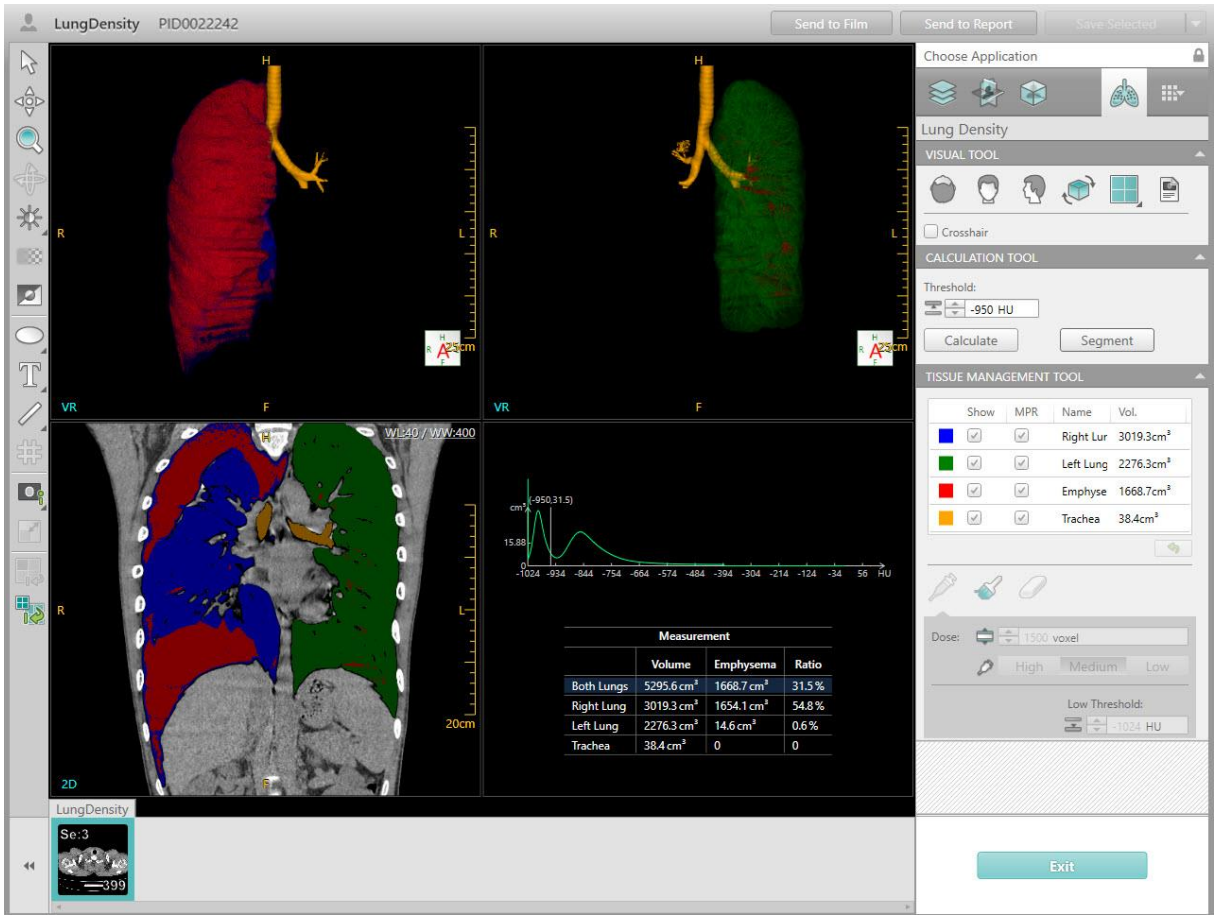


Figure 16-1 Lung Density Interface

NOTE:

- **Only compare the lung scan with the same respiratory state.**

16.3 Visual Tool

Figure 16-2 Visual Tool

Axial: Display the volume image in the Axial direction.

Coronal: Display the volume image in the Coronal direction.

Sagittal: Display the volume image in the Sagittal direction.

Flip VR Image: Flip the volume image.

There are two page layouts for review:

2x2: Display the left Lung and right Lung VR image on the top of the viewport. Display the Coronal Lung MPR image, the measurement result histogram and the table on the bottom of the viewport.

2+3: Display the Coronal Lung MPR image and measurement result histogram and table on the top of the viewport. Display the Coronal Lung MPR image, left Lung and right Lung VR image on the bottom of the viewport.

Crosshair: Show/Hide the cross line on MPR image.

16.4 Calculation Tool

Threshold: Set max threshold to calculate emphysema.

Figure 16-3 calculation Tool

Click the **Segment** button and the auto segmentation is performed on the left and right lungs and the trachea.

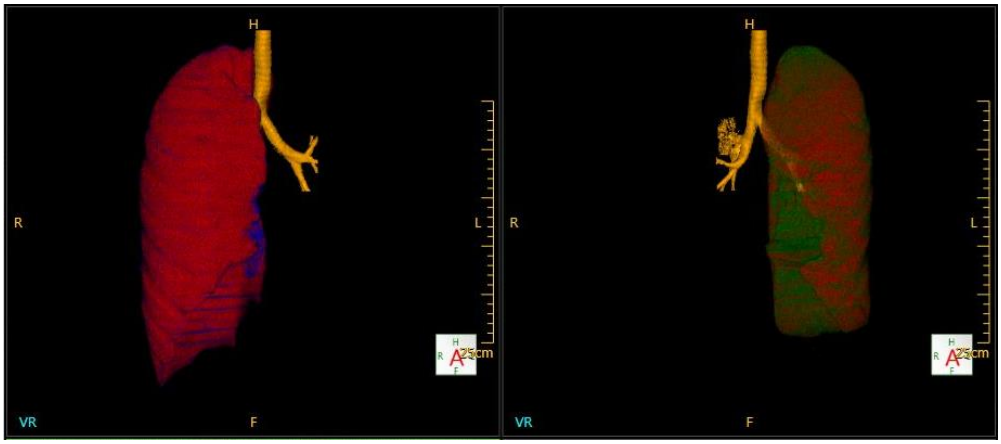
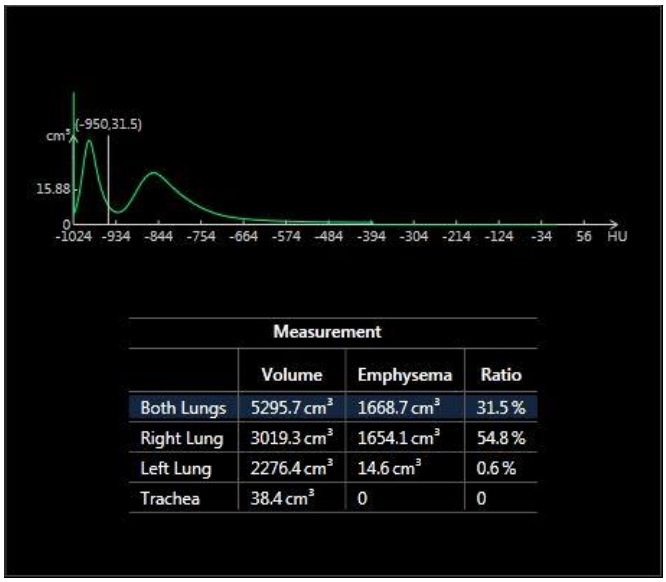


Figure 16-4 Segment Display

Simultaneously, the measurement result table displaying the volume and emphysema calculation result are displayed. Also a histogram displaying the CT number distribution of the lung volume are shown in the corresponding image area.

Select **Calculate** to calculate the results again after you make any changes.



Measurement

	Volume	Emphysema	Ratio
Both Lungs	5295.7 cm³	1668.7 cm³	31.5 %
Right Lung	3019.3 cm³	1654.1 cm³	54.8 %
Left Lung	2276.4 cm³	14.6 cm³	0.6 %
Trachea	38.4 cm³	0	0

Figure 16-5 Measurement Result

16.5 Tissue Management Tool

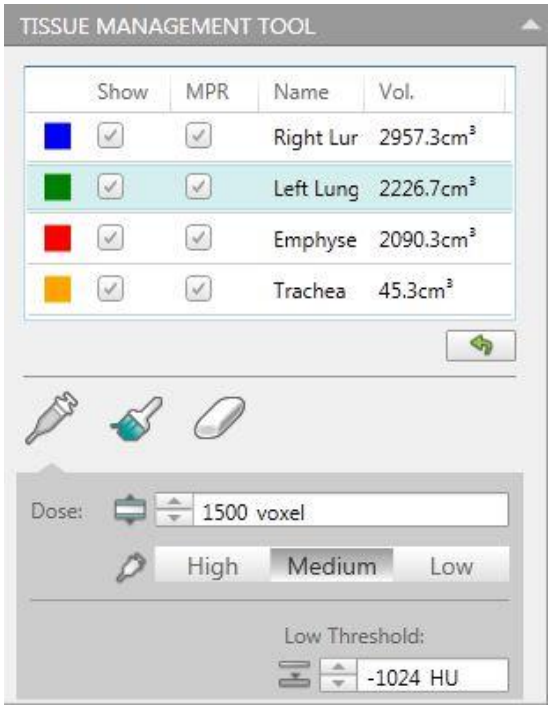


Figure 16-6 Tissue Management Tool

Tissue List displays the tissue name and the tissue volume. Check the option box below Show or MPR to define whether to display the tissue in the VR or MPR images.

Clear: Clear the tissue volume display.

Refer to **Chapter 3.4.2.5** Segment Tools for information about these functions.

Chapter 17. Fat Analysis

17.1 Overview

The Fat Analysis application is used to analyze abdominal fat, segment the subcutaneous fat and visceral fat. Calculate the area of subcutaneous fat, visceral fat, outer circumference and other information.

17.2 Fat Analysis Interface

In the home page, select the desired images from the patient list and choose the **Fat** application.

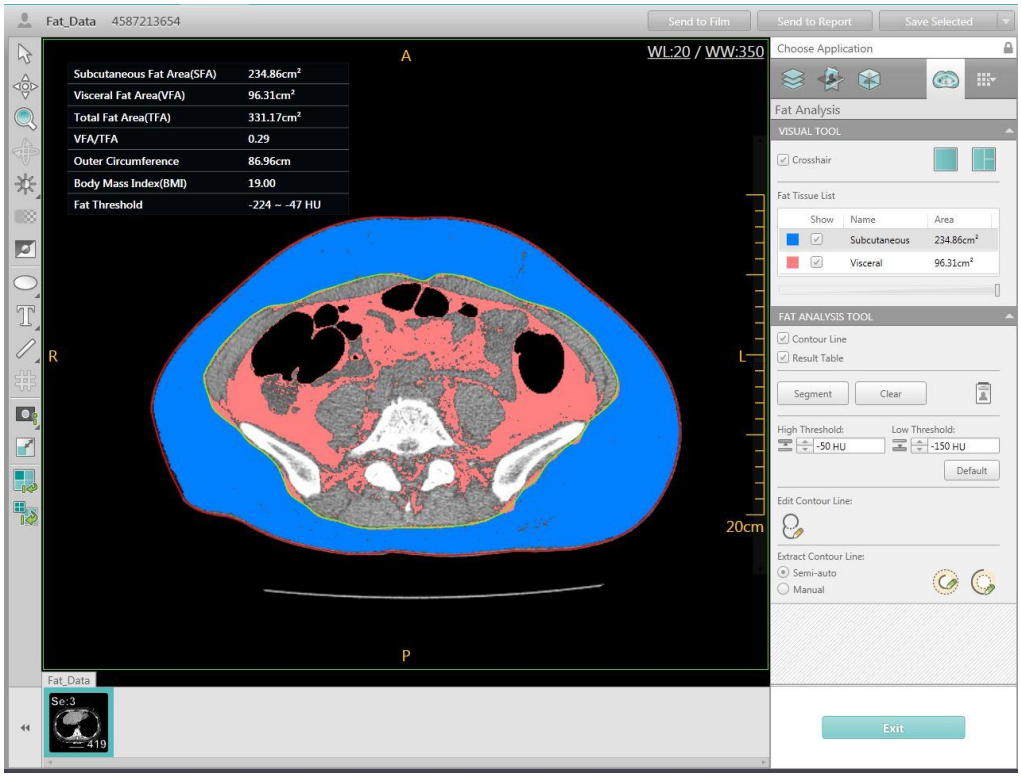


Figure 17-1 Fat Analysis Interface

NOTE:

- **The images sent to Fat Analysis should be Non contrast CT images.**

17.3 Visual Tool

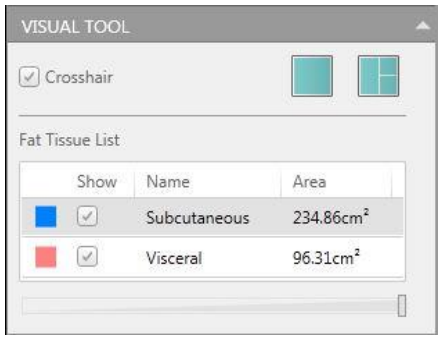


Figure 17-2 Visual Tool

Crosshair: Show/Hide the crosshair on the MPR images.

Layout:

1x1: Show axial image in image display region.

1+2: Show axial image, coronal image and sagittal image in image display region.

Fat Tissue List: Show the area of subcutaneous fat and visceral fat.

Opacity: Define the tissue transparency display.

17.4 Fat Analysis Tool

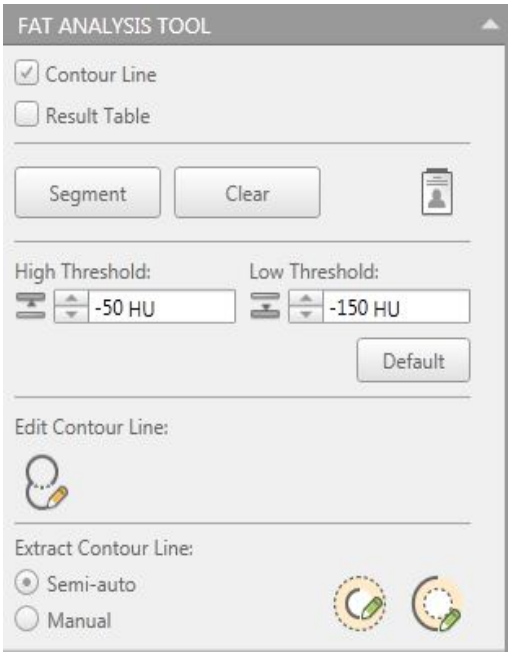


Figure 17-3 Fat Analysis Tool

17.4.1 Fat Segment

Click the **Segment** button, subcutaneous fat, visceral fat and the contour are segmented. On the image segmentation the fat is marked with a different color. The inner contour line and outer contour line is shown.

17.4.2 Edit Contour Line

Click the **Edit Contour Line** button, the control points are shown on the inner contour line and outer contour line, drag the control points to the desired locations. The fat will be calculated automatically.

17.4.3 Extract Contour Line

Semi-auto: select **Semi-auto**, click Draw inner / outer contour line, user can extract the inner / outer contour in semi-automatic way.

Manual: select **Manual**, click Draw inner / outer contour line, user can extract the inner / outer contour in manual way.

17.4.4 Display Region

Contour Line: Show/Hide the Contour Line on the axial image.

Result Table: Show/Hide the Result Table on the axial image.

Result Table including of the contents below:

SFA: Subcutaneous Fat Area.

VFA: Visceral Fat Area.

TFA: Total Fat Area.

VFA/TFA: Visceral Fat Area divided by Total Fat Area.

Outer Circumference

BMI: Body Mass Index, Patient's Weight (kg) divided by the square of Patient's Height (m).

Fat Threshold: Display the range from the Low Threshold to the High Threshold.

NOTE:

- **Click Set Patient Information button, input patient's height and weight, the BMI result is shown.**

Chapter 18. Prism Viewer

18.1 Overview

Prism Viewer application used to view the multi energy images. Display a variety of parameters of the images and provide visual tools, to help users to locate the lesion accurately.

18.2 Prism Viewer Interface

In the home page, select the desired images from the patient list and choose the **Prism Viewer** application.

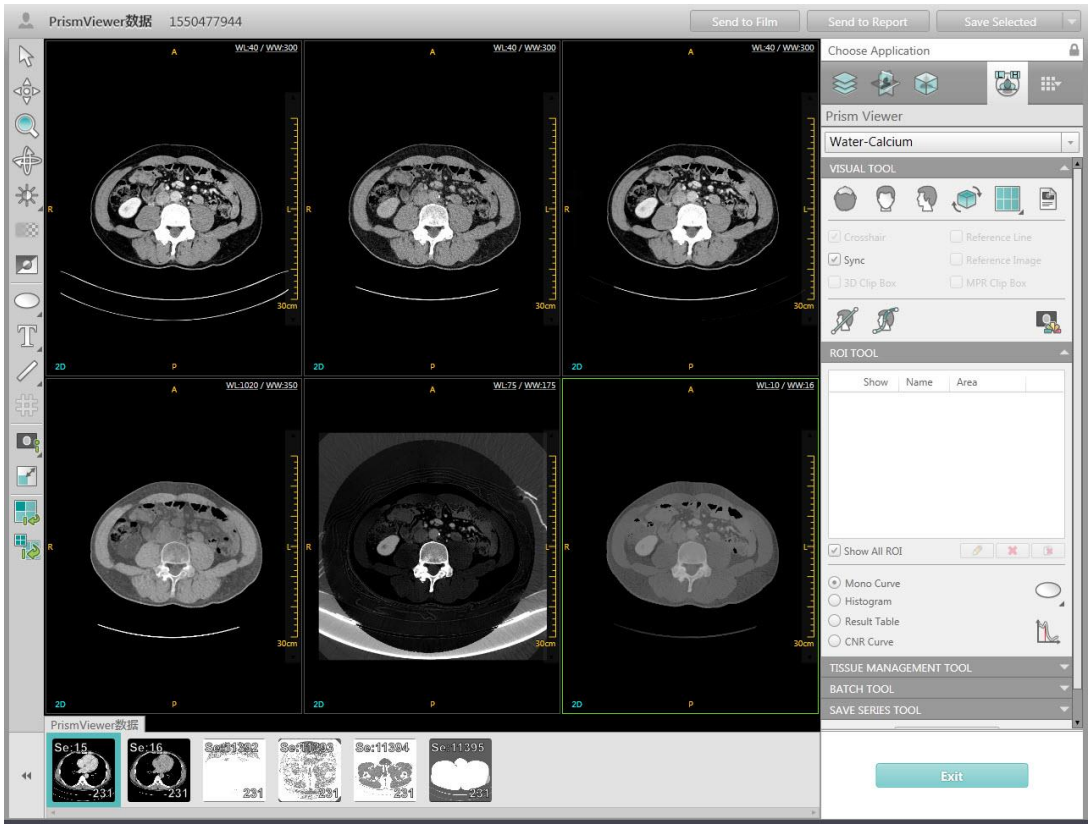


Figure 18-1 Prism Viewer Interface

18.3 Visual Tool

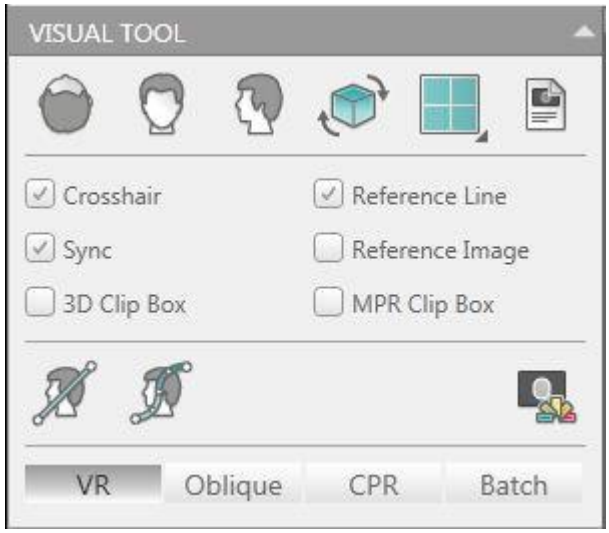


Figure 18-2 Visual Tool

18.3.1 View Selection

Axial: Display the volume image in the axial direction.

Coronal: Display the volume image in the coronal direction.

Sagittal: Display the volume image in the sagittal direction.

Flip VR image: Flip the volume image.

18.3.2 Image Layout

Select different icons to display the layouts: 2x3, 2x2, 2x2(Mono Curve), 3+2, 3+1.

18.3.3 Checkbox

Crosshair: Show/Hide the crosshair on the images.

Reference Line: Show/Hide the curve, oblique or batch line on MPR image.

Sync: Check this option and then you can zoom the MPR image windows, modify the WW/WL, change the display mode synchronously.

Reference Image: Show/Hide the mini image on the oblique/ curve/ batch reconstruction image.

3D Clip Box: Show/Hide the clip box on the volume image.

MPR Clip Box: Show/Hide the MPR box on the MPR images.

18.3.4 Display Mode

Click the different buttons, image display region shows the VR image, Oblique image, CPR image or the batch image.

Refer to Chapter **2.4.1.2 Define Oblique** and Chapter **2.4.1.3 Define Curve** for more information about Visual Tool.

Select an image, click the **PSEUDO COLOR** button then displays the pseudo color image.

18.4 ROI Tool

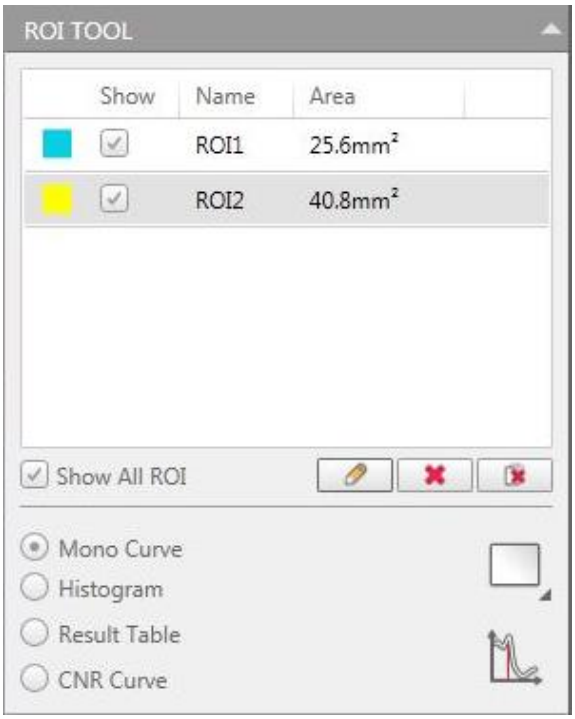


Figure 18-3 ROI Tool

18.4.1 Define ROI

Click the define ROI button, draw ROI on the MPR image. The results are displayed in the result table. This includes the color, name and the area of the ROI. It can also display the Mono curve, histogram and result table. Users can edit the color, rename and delete the ROI.

18.4.2 Calculate CNR

Click the **Calculate CNR** button, draw two ROIs, one is the lesion region, the other is the background region. According to the ROIs, the system will automatically calculate the optimal Kev level to display the lesion. The monochromatic image will be changed to the optimal Kev level.

18.5 Tissue Management Tool

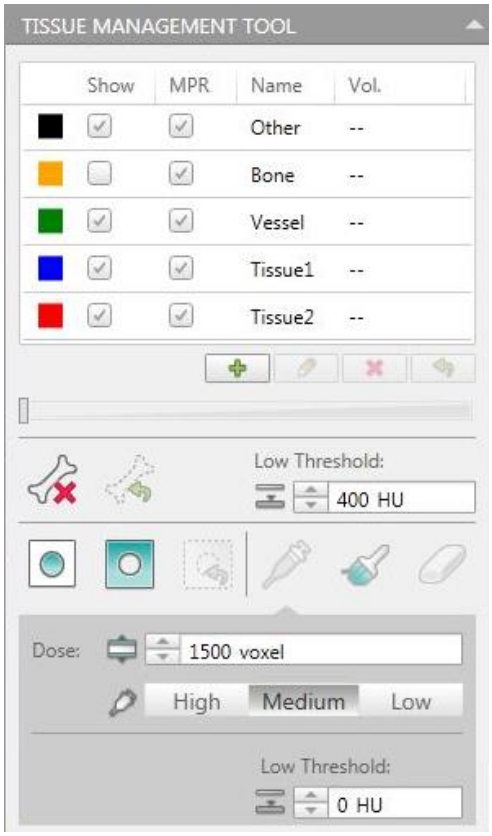


Figure 18-4 Tissue Management Tool

Refer to Chapter **3.4.2 Tissue Management Tool** for more information about Tissue Management Tool.

18.6 Batch Tool

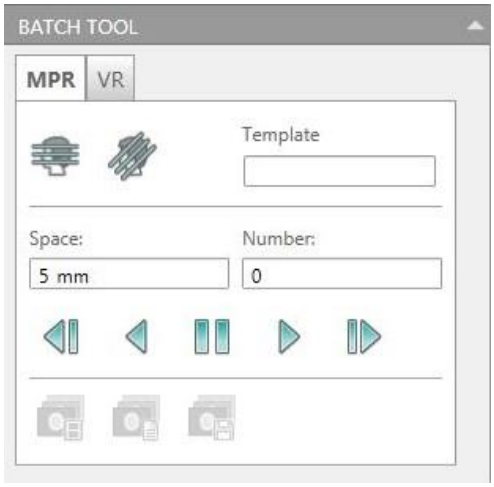


Figure 18-5 MPR Batch Tool

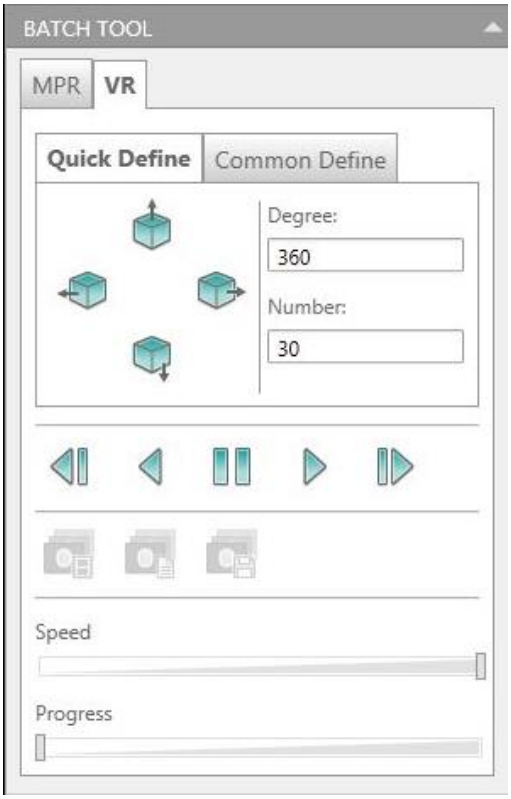


Figure 18-6 VR Batch Tool

Refer to Chapter **2.4.2.1 Define Batch** for more information about MPR Tool.

Refer to Chapter **3.4.3 Batch Tool** for more information about VR Tool.

18.7 Save Series Tool

Input the Kev value (40-140) in the input box, click the **Save Series** button, and the monochromatic image series will be saved in the home page.

Figure 18-7 save series Tool

Chapter 19. Film

19.1 Overview

The Film application is mainly used to receive images, view, manage, set layout, print preview and print.

19.2 Film Interface

In the home page, select the desired images from the patient list and choose the **Film** application. Or in **Review**, select the desired images and choose **Send to Film** button.

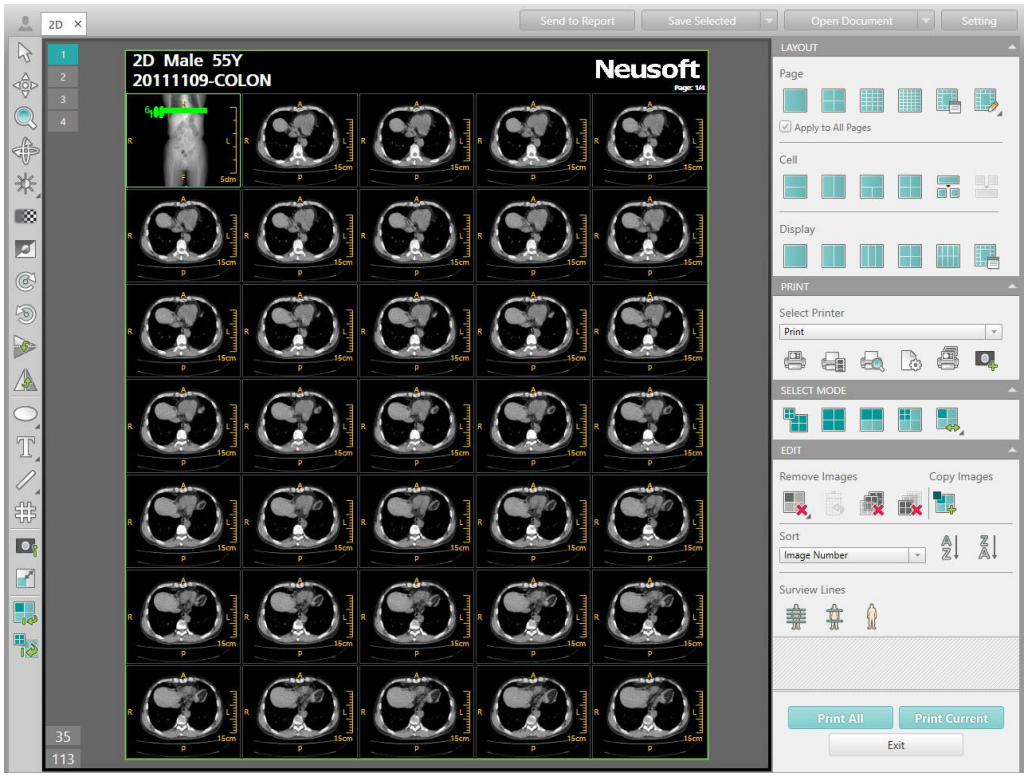


Figure 19-1 Film Interface

The **Film** interface includes: **Information Bar**, **Image Display Region**, and **Control Panel** which includes **Common Tools**. It is used for viewing, rearranging, windowing and zooming images before printing them.

19.3 Information Bar

The information bar includes the patient information, film page number, the quantity of images on the current film, and the total quantity of images. Select any one of the page number icons to review the desired page contents.

19.4 Control Panel

The control panel includes Layout, Print, Select Mode and Edit.

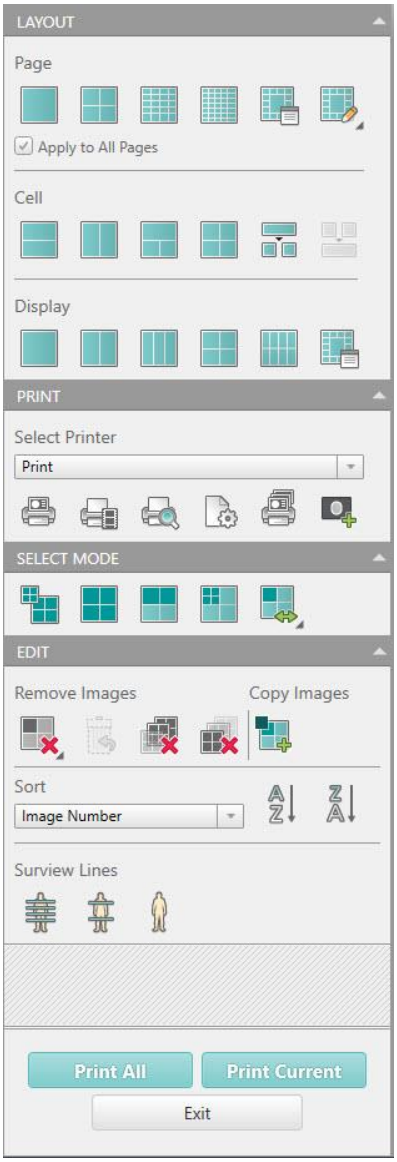


Figure 19-2 Control Panel

19.4.1 Layout

19.4.1.1 Page

STANDARD\1x1: To film in 1on1 format.

STANDARD\2x2: To film in 4 on 1 format.

STANDARD\4x5: To film in 20 on 1 format.

STANDARD\5x7: To film in 35 on 1 format.

Other: Select from the standard layouts or a custom layout. Once you have selected the desired layout, the current film layout will automatically change. Select **Set as Default Layout** to set the selected layout as the default film layout, or select **Delete** to delete the layout from the list.

Custom Split Page: Customize the number of rows and columns for the page layout. Click **Ok** to apply the page layout.

Save Page Layout: Save the layout you created into the custom layout list.

Setting: Set the common layout for the page.

Apply to All Pages: If this box is checked the change will affect all the pages in the Film viewer, or the changes are only applied to the current page.

19.4.1.2 Cell

Split Cell: Provides four standard formats to separate the images, to combine images into one film box or separate images from one film box.

Custom Split Cells: Separates the images from one sub window. Select the window and click **Custom Split Cells** on the control panel to customize the separate cell column and row numbers. Then the images in the window will be separated.

You can also select multiple cells to split simultaneously.

Combine Cell: Select desired images, and click **Combine Cell** on the control panel, the selected images will be combined into one sub window.

19.4.1.3 Display

Split Cell: Switch to view between single page layout and multiple pages layout.

1x1: Display one page of film in the image display region.

1x2: Display two pages of film in the image display region.

1x3: Display three pages of film in the image display region.

2x2: Display four pages of film in the image display region.

2x4: Display eight pages of film in the image display region.

Customize: Display customized pages (from 1x1 to 10x10) of film in the image display region.

19.4.2 Print

Printer List: Switch a printer. The printer chosen will be the default printer for later use.

Custom Print: Set the selected printer, printer scope and number of copies before printing.

Print Preview: Preview the film to be printed.

Paper Print: Print images on paper.

Page Setting: Set the film page size.

Print Queue: View and manage print queue and history.

Add Test Images: Choose the test image from the list and add it into the Film Viewer.

Print All: Print all of the films.

Print Selected: Print current film.

19.4.3 Select Mode

All: Select all images.

Page: Select all images on the same page.

Series: Select all images in the same series.

Cell: Select all images on the same page with the same cell format.

Reverse Selected: Cancel the current selection, and select all the other unselected images.

Cancel Selected: Click the arrow on the bottom right corner of the **Reverse Selected** icon or right-click this icon, select **Cancel Selected** to cancel the current selection.

19.4.4 Edit

19.4.4.1 Delete

Delete the Selected: Delete the selected images.

Delete Front: Delete all the images in front of the selected one.

Delete Behind: Delete all the images behind the selected one.

Delete Interval: Delete the interval images.

Restore Last Deleted: Restore the previous deleted images. The system can restore up to three steps back.

Delete Other Pages: Delete all the images on all the other pages.

Delete Current Page: Delete all the images on the current page.

19.4.4.2 Copy Selected

Copy Selected: Select images and click **Copy Selected**, the copied image will be displayed following the last image in the image display region.

19.4.4.3 Sort

Ascending: Sort the selected images in ascending order by Image Number, Series ID, Slice Location, Time, Name, Study ID and Series Number.

Descending: Sort the selected images in descending order by Image Number, Series ID, Slice Location, Time, Name, Study ID and Series Number.

19.4.4.4 Surview Lines

Show All Surview Lines: Show all the surview lines on the surview image.

Show First And Last Surview Lines: Show the first and last surview lines on the surview image.

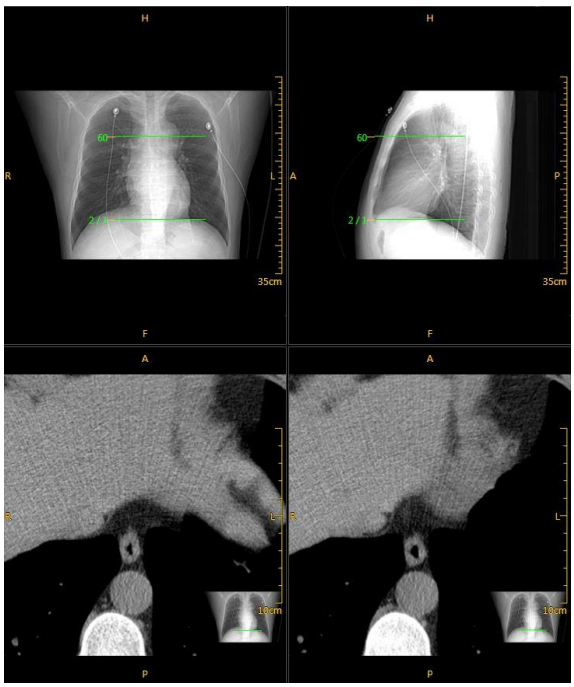


Figure 19-3 Show First and Last Surview Lines

Hide Surview Lines: Hide all the surview lines on the surview image.

NOTE:

- **When the Surview is not loaded, this function is disabled.**

19.4.5 Common Tools

Open Document: Open the document list to select one document to continue working.

Save Document: Save all the images in their current state and page layout as a document.

Setting: Change filming setting, include printer setting, page setting and other setting.

Refer to Chapter **1.7.3 Common Tools** for more information about the other common tools.

19.5 Right-Click Menu

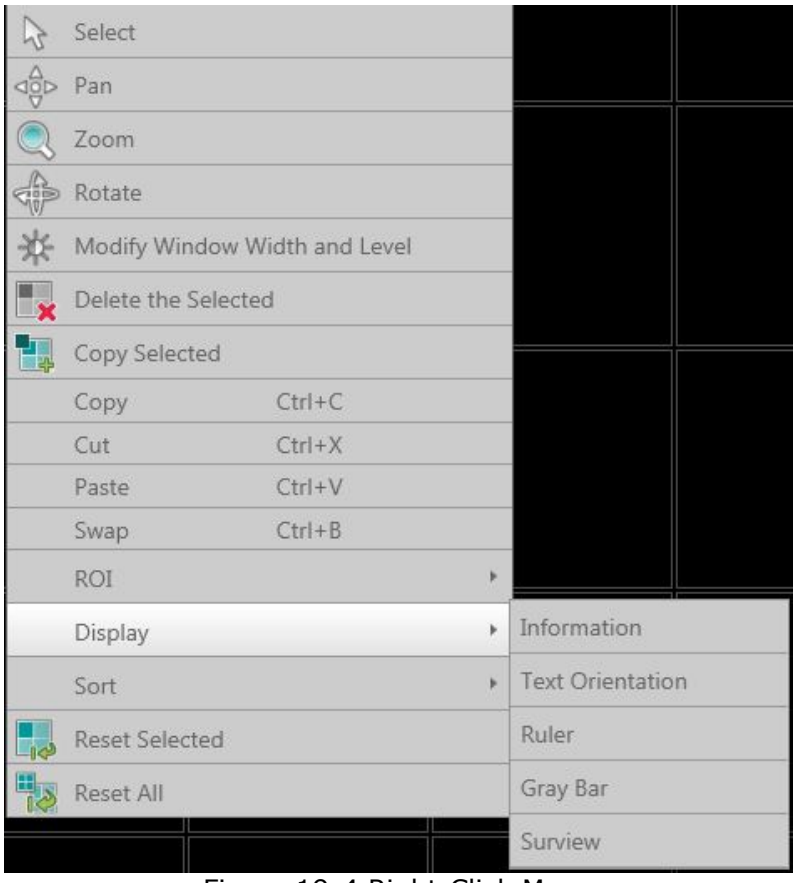


Figure 19-4 Right-Click Menu

Delete the Selected: Refer to **Chapter 19.4.4.1** Delete.

Copy Selected: Refer to **Chapter 19.4.4.2** Copy Selected.

Copy: Copy the selected images.

Cut: Cut the selected images.

Paste: Paste the copied or cut images to the specified position.

Swap: Swap the position of the cut images and the specified images.

Display: Show/Hide **Information**, **Text Orientation**, **Ruler**, **Gray Bar** and **Surview**.

Sort: Refer to **Chapter 19.4.4.3** Sort.

Reset Selected: Reset the current selection of images to its original state.

Reset All: Reset all the images to the original state.

For the other options on the Right-Click menu, refer to Chapter **1.6.3 Window Menu**.

Chapter 20. Report

20.1 Overview

The Report application assist doctors in documenting patient's disease. Post processing Applications sends Dicom images and data information to the report. The doctor can choose a report template or custom templates. The report can be sent to a printer.

20.2 Report Interface

The **Report** workflow includes: **Information Bar**, **Control Panel** and **Report Area**. It also provides a **Report Template Editor** to create or modify report templates.

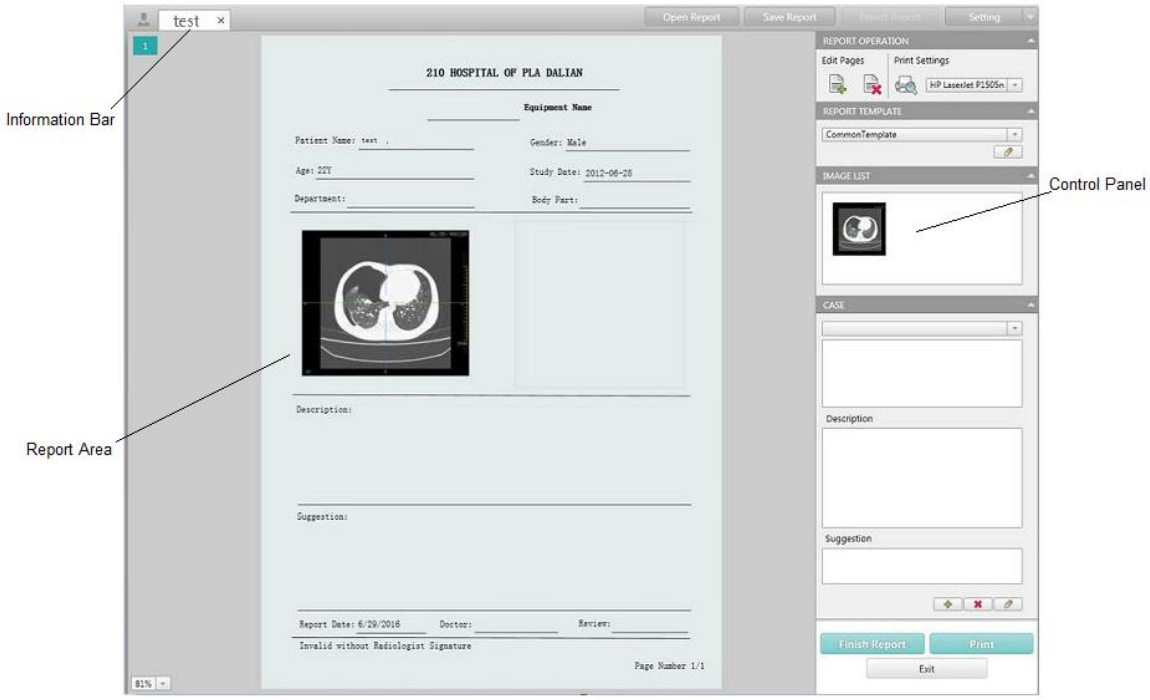


Figure 20-1 Report Interface

To load an image to the **Report** Interface, do one of the following:

• Select the image of interest in **Review**, and click the **Send to Report** icon on the common tool panel.

• Click the **Images** tab on the Image Information List area in the **Home** interface. Select the image, and then click **Send to Report** in the right key menu or on the control panel.

Several reports for different patients can be loaded into the **Report** Interface. Multiple report tabs will be automatically generated for each patient. The patient name is displayed on the tabs in the left top corner.

20.3 Information Bar

The information bar displays the patient information, page information and zoom percentage.

Open Report: Open an existing report from the **Report** list.

Save Report: Save the current report to the **Report** list.

Export Report: Export the report to the local or USB remote device. Only structured reporting supports saving to the local and remote destination. The saved structured reporting can be reloaded to the **Report** application.

Setting: **Export** or **Import** the case template and report template.

The user also can set the report to automatically close after printing.

20.4 Control Panel

Add Report Page: Add a new report page.

Delete Report Page: Delete the current report page.

Print Preview: Preview the report to be printed.

Printer List: Select a printer from the printer list.

Report Template: Select a report template from the **Report Template** List.

Report Template Edit: Edit a new report template.

Image List: Display the images loaded into the report interface. Double click the image to load it into the image display region of the report.

NOTE:

- **To display images, select an image and drag it into the image area of the report.**
- **Press the Delete key on the keyboard or right click to select Delete to remove the selected images from image list.**

Case: Select a case template in the Case list.

Add: Add the case information into current report page.

Cover: Replace the case information in the current report page.

Case Management: Add a new, modify or delete case template in the **Case Manage** Interface.

Finish Report: After modifying the report, click this icon to finish the report process and save the report.

Print: Print the current report.

20.5 Case Template

This section introduces steps to create, modify, or delete a case tem- plate. This includes steps to load and remove the template from the **Case Template** list on the control panel.

To create a case template:

1. Click the **Set** button. The **Case Manage** dialog box opens.

2. Click the **Case Edit** tab.

3. Select **Case** folder in the **Case Library** box, and right click it.

4. Click **Add** in the right key menu. Name and save the case details.

5. Right click the folder and click **Add** from the right key menu to create a case template.

6. Enter the descriptions in the **Description** and **Suggestion** boxes, Click **Save**.

7. The new case template will display in the **All Case** box of the **Selected Case Template** tab. Click the **->** to add this case template to the **Selected Case Template** box, then use it in the **Case Template** list on the control panel. In the same way, click the **<-** to remove this case template from the **Selected Case Template** box, then it will not be seen in the **Case Template** list on the control panel.

To modify a case template:

1. Select a case template in the **Case Edit** list on the control panel.

2. Click the template in the **Case Edit** box.

3. Modify the description.

4. Click **Save** on the control panel to apply the modifications to the case template.

To delete a case template:

1. Click the **Set** button. The **Case Manage** dialog box opens.

2. Click the **Case Edit** tab.

3. Select a template in the **Case Library** box, and right click it.

4. Click **Delete** in the right key menu.

20.6 The General Workflow of Report

1. Send the desired images to the **Report** Interface.

2. Select **Report** on the workflow bar, then enter the **Report** interface. The loaded images are automatically displayed in the **Image list** box.

3. Select a report template in the **Report Template** list on the control panel. Some information is loaded automatically according to the template setting. Enter any other information if necessary.

4. Highlight the image display region, and double click on an image in the **Image list** box. Then the image will be displayed in the image display region.

5. Manually type in **Description** area and **Suggestion** area, or select a case template in the **Case Template** list on the control panel.

6. Save and finish report.

7. Select a printer to print the report.

NOTE:

- **Finish Report will make the report read-only. Save Report will save an editable report.**
- **Ensure the correct paper size is in use before printing.**
- **The printed report will be a validated by default, and will not be editable.**

20.7 Report Template Editor

Report templates can be modified and saved according to the hospital's needs. Click the **Report Template Edit** button, then the **Report Template Edit** dialog box opens. Report template editor includes **Menu Bar**, **Designing Tools** and **Canvas**.

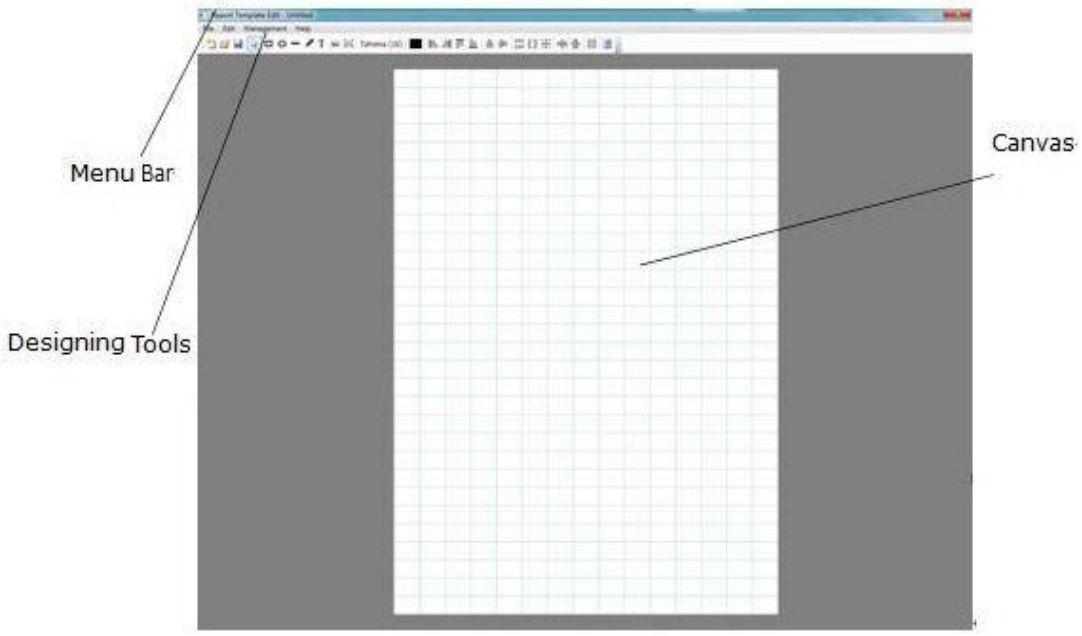


Figure 20-2 Report Template Editor

20.7.1 Menu Bar

The menu bar includes **File**, **Edit**, **Management** and **Help**.

20.7.1.1 File

Click **File** to open the list:

New: Setup a new template.

Open: Select a template and open it.

Save: Save the template.

Save As: Save the template as a new one.

Recent Files: Open the recent template list.

Exit: Exit the **Report Template Editor** interface.

20.7.1.2 Edit

Click **Edit** to open the list:

Select All: Select all the objects on the canvas.

Unselect All: Cancel the selection of all the objects on the canvas.

Delete: Delete the selection of the objects on the canvas.

Delete All: Delete all the objects on the canvas.

Move to Front: Move the selected object to the front layer.

Move to Back: Move the selected object to the back layer.

20.7.1.3 Management

Click **Management** to open the list:

Page: Open the **Page Set** dialog box to configure template size, width and height.

Content: Open the **Content Management** dialog box to configure the content of the report field and DICOM Tag.

Template: Open the **Template Management** dialog box to preview and configure the template.

20.7.1.4 Help

Click **Help** to open the list:

Restore factory setting: Restore back to the factory setting.

About: Show information of the **Report Template Designer**.

20.7.2 Designing Tools

Standard Toolbar: Refer to Chapter **20.7.1.1 File** and Chapter **20.7.1.4 Help**.

Draw Toolbar:

- **Pointer**: Select an object.
- **Rectangle**: Draw a rectangle.
- **Ellipse**: Draw an ellipse.
- **Line**: Draw a line.
- **Polyline**: Draw a polyline.
- **Text**: Draw an area for text input.
- **Image**: Draw an area for image input.
- **Table Area**: Draw an area for table input.
- **Font**: Set the font of the objects.
- **Color**: Set the color of the objects.

Layout Toolbar: Design layout for all of the textbox and images are displayed in the report template.

- **Left Align**: Align the selected objects to the left side.
- **Right Align**: Align the selected objects to right side.
- **Top Align**: Align the selected objects to the top.
- **Bottom Align**: Align the selected objects to the bottom.

NOTE:

- **All of the above alignment actions mean that the top/bottom/right/left edge of the selected area is aligned.**

Horizontal Center: Place the selected object in the horizontal center of the canvas.

Vertical Center: Place the selected object in the vertical center of the canvas.

Same Width: Make the selected objects the same width as the last selected object.

Same Height: Make the selected objects the same height as the last selected object.

Same Size: Make the selected objects the same size as the last selected object.

Horizontal Spacing Equal: Make the selected objects the same horizontal spacing as the last two selected object.

Vertical Spacing Equal: Make the selected objects the same vertical spacing as the last two selected object.

Grid: Show/Hide the grid of the canvas.

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