安科 ANKE

User Manual

ASA-300 CT Enhancement Injector

CE 0123

（2018）V2.0

Shenzhen Anke High-tech Co., Ltd

Dear customer,

It's our honor that you choose the ASA-300 CT Enhancement Injector with independent intellectual rights manufactured by Shenzhen Anke High-tech Co., Ltd ("Anke"). Please read this user manual carefully before installation and use. And install and use the machine according to the user manual. Any incorrect operation will lead to harm and damage to the patient, operating person and the machine. If you have any doubt, Please contact us. We are always ready to service.

Shenzhen Anke High-tech Co., Ltd.

Manufacture address: Block B, LingYa Industrial Zone, Tangtou No.1 Road, Shiyan Sub-district, Bao'an District, Shenzhen, 518108, P.R.China

http://www.anke.com

Postcode: 518108

Tel: 0755-26688889

Fax: 0755-26695307

Free Service Hotline: 800-830-6169

Email: 800@anke.com

European representative

Name: Shanghai International Holding Corp. GmbH(Europe)
Address: Eiffestraße 80, 20537 Hamburg, GERMANY
Phone: +49-40-2513175 **Fax:** +49-40-255726
E-mail: shholding@hotmail.com
Contact person: Jin Liang

Content

1 Brief Introduction about the ASA-300

1.1 Summary

The ASA-300 developed and manufactured by Anke is consist of dual-syringe injection head, touch screen, power box and stander. It is a high pressure injector controlled by computer with high transmission efficiency and injection accuracy. It can be used with a variety of CT equipment for CT enhanced scans to facilitate the definition of lesions and the nature of lesions, which is of great significance for improving the quality of medical care, teaching and research.

The operating interface is touch screen which is easy to operate, understand, reliable and safe. The computer system can control the whole injection according to the procedure set by the doctor. It can also preset and memorize 100 injection procedures which can be invoked or amended at any time.

The dual-syringes syringe, A syringe is contrast while B is saline, not only can meet all CT enhancement technology but can achieve **saline beam technology** which means can inject certain dose of saline after finishing injecting contrast or saline in many times. Saline beam can control the contrast to reach the right place in right time and its injection pressure make the contrast more dense to get stronger signal, reduce artifacts and save contrast. During the scan of the heart, it makes the contrast reach the heart quickly to control the injecting dose of contrast. Another advantage of saline flush is that it can assess if the vein can bear the high-speed injection which is significant for old people.

The injector can inject in phases. It controls the CT scan when the contrast agent reaches the lesion tissue and the concentration is strongest.

According to the classification of electrical safety, this injector is class I Type B（“  ”）, mobile general equipment .

1.2 Intended Use& Contraindications

Intended Use

ASA-300 CT Enhancement Injector is mainly used for contrast agent injection of CT enhancement scanning. It’s intended to be used by professional physicians in clinical facility. This product cannot be used for intra-arterial injections, chemotherapy or other non-use purposes.

Contraindications

Patients with the following conditions prohibit the use of this device:

- Aged over 70;
- Confusion, slurred speech, coma, not stated iodine allergic reaction;
- History of bronchial asthma;
- High blood pressure, and high pressure is more than 170-180mmHg;
- Previous allergic;
- hyperthyroidism;
- coagulation problems;

- acute myocardial infarction;
- Serious heart and kidney dysfunction.

1.3 Transportation and Storage Requirements

(1) Transportation and storage temperature: -10℃～+40℃

(2) Relative humidity: ≤80%

(3) Atmospheric pressure: 86 kPa～106 kPa

1.4 Characteristics about the ASA-300

- The suitability of syringe: The injector can use two 200ml disposable sterile syringe simultaneously.
- Injection capacity: The injection capacity of each syringe can be set in the range of 1 ml to 200 ml. The set step is 1 ml. The deviation between the injection capacity and the set value is ((5%+1.0 ml).
- Injection rate: It can be adjusted in the range of 0.1ml/s to 10ml/s with an adjustment step size of 0.1 ml/s. The deviation between the injection rate and the set value is ±（5%+0.1ml/s）
- Pressure limit: The pressure limit is adjusted from 100psi (0.7MPa) to 300psi (2.1MPa) with an adjustment step size of 50psi (0.35MPa). The pressure limit error is ±0.1Mpa or ± 10% (two takes a large value).
- Maximum injection pressure: The maximum injection pressure of the injector can not be less than 300psi (2.1MPa).
- Scan delay: The scan delay time is set in the range of 0s to 600s with an adjustment step size of 1s. The deviation is ±1s or±1%(two takes a large value).
- Injection delay: The injection delay time is set in the range of 1s to 600s with an adjustment step size of 1s. The deviation ±1s or±1%(two takes a large value).
- Rotation angle of the injector head: The angle between the upward direction of the injector head is ensure that the air in the cylinder is exhausted; the angle between the downward direction and the horizontal plane is greater than or equal to 10°.

1.5 Function about the ASA-300

a) Each injection of the injector can be performed in multiple stages;
b) It is able to store at least 100 sets of injection programs which can be called or modified at any time
c) Be able to display the injected time and injected dose;
d) When the injection pressure exceeds the pressure limit, a clear signal can be given to the user to indicate and stop the injection;
e) Injector should have input and output interface;
f) Injections can be stopped at any time during injection.

2 Safety Issues Relating to the ASA-300

2.1 Profile

This chapter describes the safety tips appeared in this user manual and the equipment labels, and responsibility of the manufacturer.

2.2 Warning, Caution and Attention

All warnings divided into three different forms in different marks:

Warning, Caution, Attention

Below is the definition of warning, caution and attention:

mark	Definition
warning	Suggestion to avoid possible action or state leading to death and injure
caution	Suggestion to avoid possible action or state leading to equipment damage, data errors and invalid operation
attention	Provide useful information about function and program

Warning:

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Warning:

Only qualified maintenance personnel can open the device housing. There is no operator-maintainable parts inside the device. If you suspect a problem with the injector, please contact our qualified engineers.

Warning:

Personnel operating and maintaining this device shall be trained and familiar with all operational and maintenance issues. In order to ensure safety, carefully read all warnings, cautions, and attentions before using this device.

Warning:

Shield other devices not being used in the room to avoid mutual electromagnetic interference that can cause faults and incorrect operation, except CT.

Warning:

Instruction not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.

Attention:

The machine shall be recycled by the manufacturer or European representative when it is scrapped or exceed the

limit of lifetime.

Warning:

No modification of this equipment is allowed.

Warning:

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

Warning:

Use of the cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

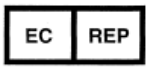
Attention:

The MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT。

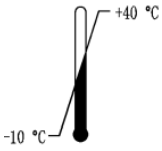
2.3 Symbols and Labels

2.3.1 Symbol-safety

	power on
	power off
	Equipotiential
	Attention: refer to accompanying documents
	Type B equipment
	Alternating current
	Date of Manufacture
	Manufacturer

	Authorized Representative
	CE certification seal. Number code beneath the symbol identifies the notified body code
	Please refer to the user guide for safety instructions
	European WEEE Directive

2.3.2 Symbol-transportation

	Keep this way up
	Keep dry
	Fragile
	Rolling prohibition
	Prohibit stacking
	Humidity storage condition: do not make the product exposed over the humidity environment displayed
	Temperature limit: do not make the product exposed over the temperature environment displayed

2.3.3 Labels

Figure 2.1 System label

2.4 Term

KVO function: inject 0.25ml saline in every 30s when scan delay, injection delay and pause to keep vein open. This function makes sure the blood won't coagulate to block the syringe needle.

Scan delay: Scan delay refers to the interval from the beginning of injection to CT scanning.

Injection delay: The injection delay is the interval between pressing the start button of the injection and starting the injection.

2.5 Electromagnetic Compatibility

The use of the CT Enhancement Injector may cause interference with nearby electronic devices, or it may not operate properly due to the operation of nearby electronic devices. When using the CT Enhancement Injector, keep an appropriate distance from other electrical equipment. If there is any such interference, contact the manufacturer.

The electromagnetic compatibility of the CT Enhancement Injector is meet the requirements of IEC 60601-1-2:2014.

2.6 Environmental Protection

The CT Enhancement Injector is an electronic and electrical product with a service life of 10 years. The production date can be viewed from the system label. The treatment at the end of its service life will be hazardous to human health and environmental health if it is disposed of as household waste. Be sure to submit it to a recycling center designated to deal with such electrical product waste. For more information on such electrical product waste disposal, recovery, and recycling stations, contact your local municipal government, household waste disposal station, the place where the product was purchased, or the manufacturer.

2.7 Responsibility of the Manufacturer

The injector is sold on the basis of below understanding: the manufacturer, manufacture agents and representatives won't take the responsibility of personnel injure and equipment damage caused by inappropriate use (authorized or unauthorized personnel).

3 Installation about the ASA-300

3.1 Site Requirements

Environment requirements:

Working temperature: 5℃～30℃

Relative humidity: ≦80%

Atmospheric pressure: 70kPa~106 kPa

Supply requirements:

Supply voltage: 100-240 VAC

Supply frequency: 50-60Hz

Maximum output: 200 VA

3.2 Unpack

Before unpacking, check the outer packaging for damage first. If there is any damage, you need to contact the sales Department and take a photo. Only with the permission of the sales Department can you unpack the box. If the instrument is damaged, you can file a claim with the transportation department.

After unpacking, verify whether the contents in the box are consistent with the packing list. If there is a shortage, contact the instrument sales department immediately.

3.3 Installation

3.3.1 Structure Introduction of ASA-300 CT Enhancement Injector

The overall structure of the ASA-300 CT Enhancement Injector is shown in Figure 3.1:

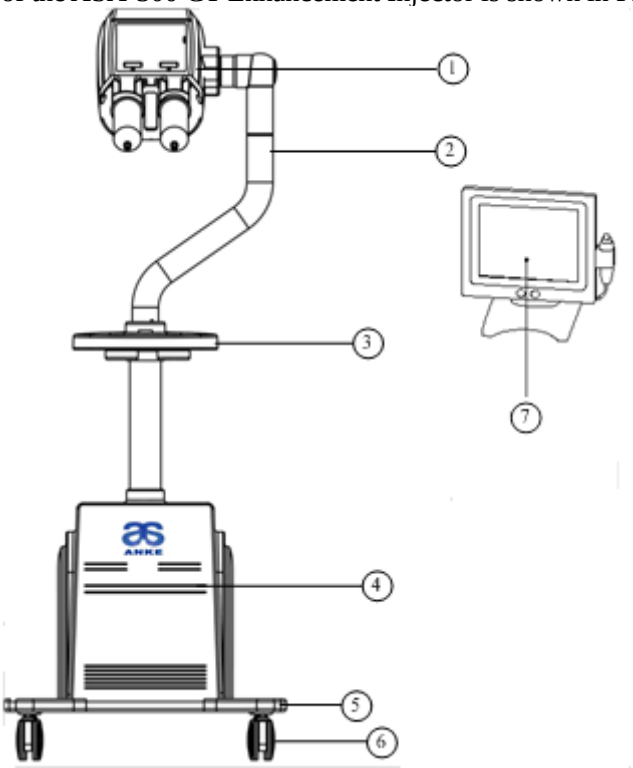


Figure 3.1 ASA-300 Overall Structure Diagram

① injection head ② stander ③ drug tray (Load-bearing 5kg)

④ Power box ⑤ chassis ⑥ idler pulley ⑦ touch screen

3.3.2 Stander mounting

There are components as shown in figure 3.2 when unpacking the box. Make the drug tray pass through the bracket pole. Then fixate the bracket pillar to the screw interface of the bracket pole and tighten the fixing screws. Then screw down the double nuts and the plane bearing on the head screw in Figure 3.2 and keep the gasket on the head screw. The head screw is inserted into the left hole of the bracket interface. The plastic gasket is on the left side of the bracket interface. The plane bearing, flat pad, elastic pad and nut are installed on the right side in sequence. Finally, the nut is tightened with a 19 mm sleeve wrench. The stander is installed. We get the effect drawing as figure 3.3.

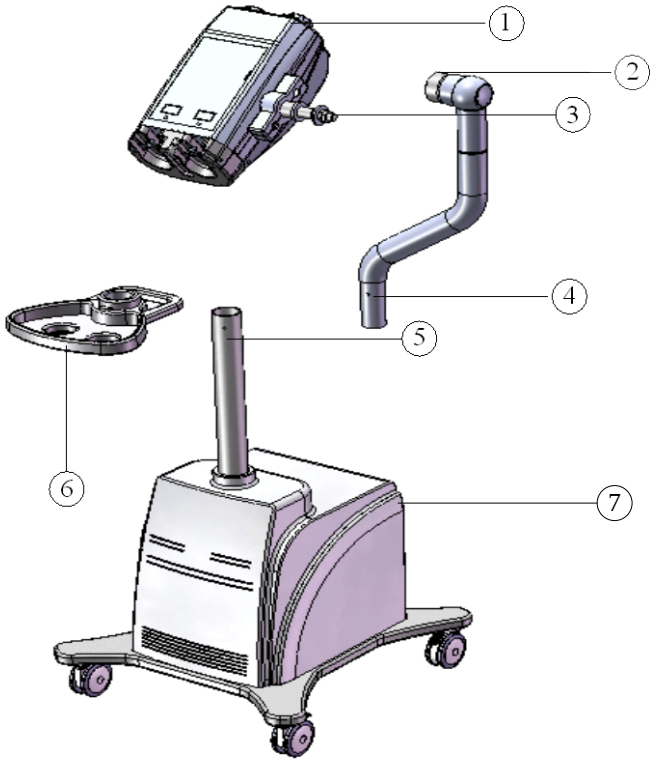


Figure 3.2 all components of the injector

① injection head ② bracket interface ③ head screw ④ bracket pillar ⑤ bracket pole ⑥ tray（rated load: 2kg） ⑦ power box

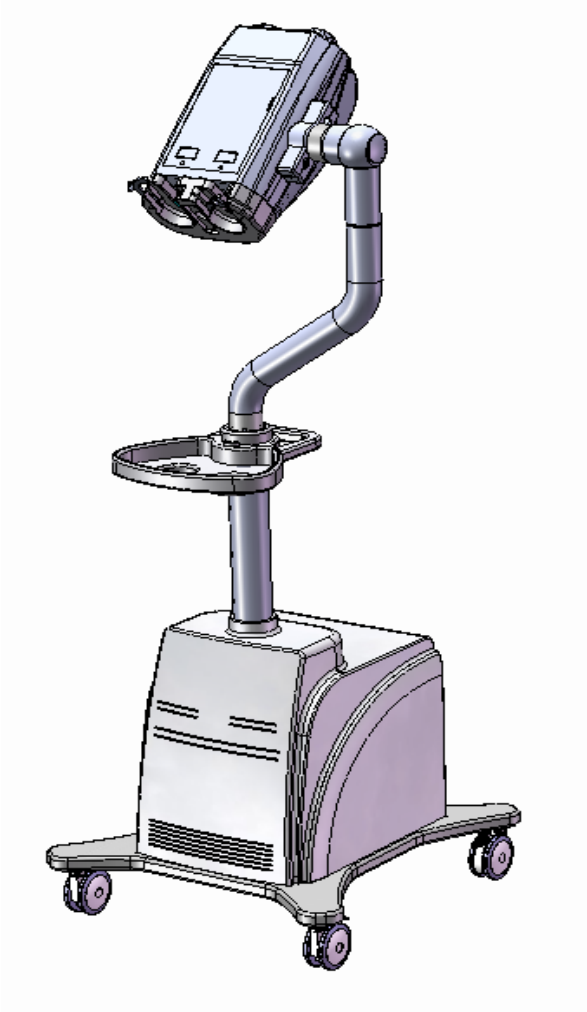


Figure 3.3 Effective drawing of installed injector

We can rotate the injection head up and down according to the method shown in Figure 3.4 to check whether the head is flexible and meets the requirements. The angle between the upward direction of the injector head is ensure that the air in the cylinder is exhausted; the angle between the downward direction and the horizontal plane is greater than or equal to 10°.

Figure 3.4 rotation of the head

3.3.3 Cable Connection of ASA-300 CT Enhancement Injector

After the stander is installed, users simply connect the cable as shown in the diagram.

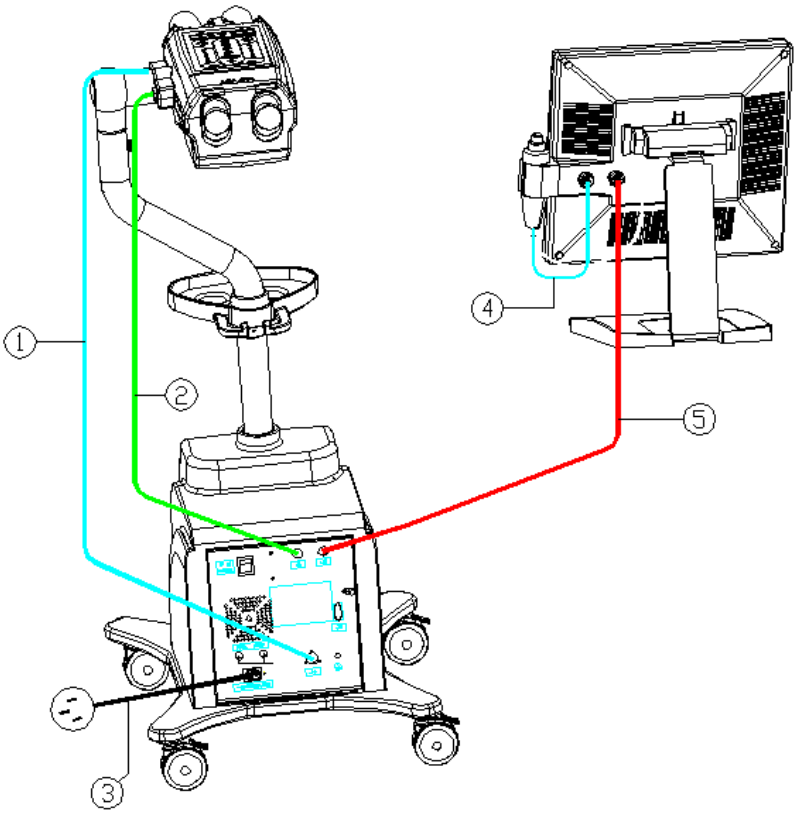


Figure 3.5 Cable connection of the injector

① power cable of the head ② control cable of the head ③ power cable

④ hand brake cable ⑤ Communication cable between power box and the head

The interface and silk screen behind the power box are as shown in the figure below:

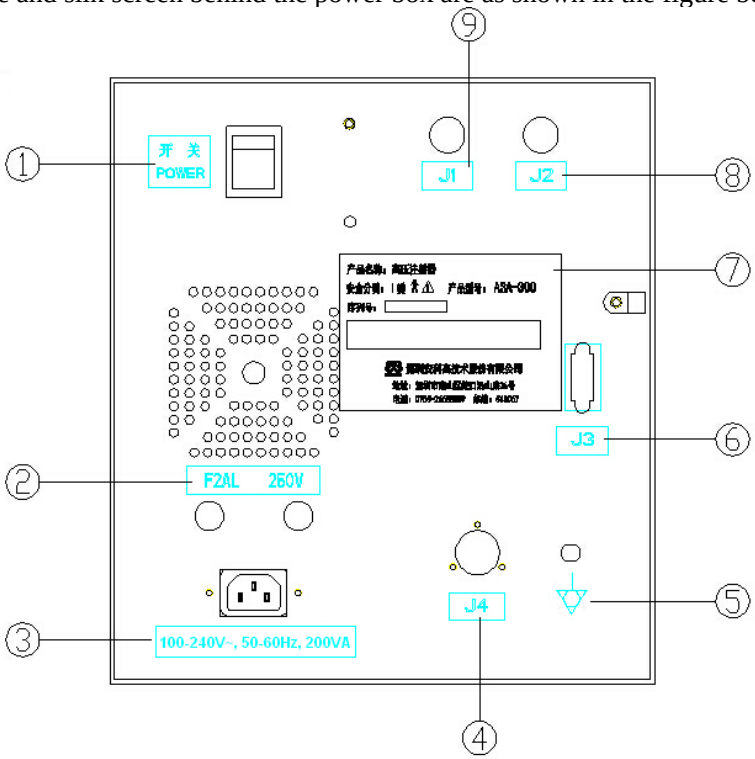


Figure 3.6 Diagram of the Silk Screen behind the power Box

① Power/Switch of the power box ② F2AL 250V~2A is a fuse

③ 100-240V~, 50-60HZ, 200VA is a power interface of the power box

④ J4 is an interface of head power cable

⑤  is an equipotential grounding

⑥ J3 is an interface of CT linked cable

⑦ label of system

⑧ J2 is an interface of the touch screen cable

⑨ J1 is an interface of head control cable

3.3.4 Working Conditions

Below is the location when ASA-300 is working:

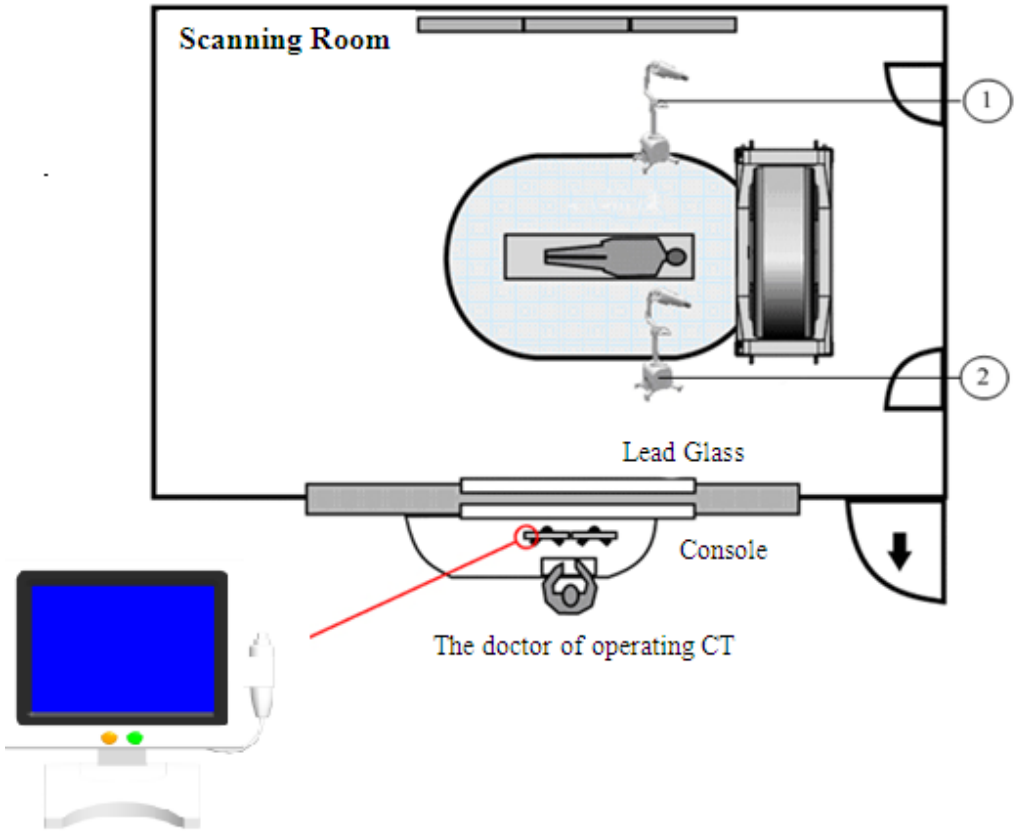


Figure 3.7 Location of ASA-300

The injector will work in the scanning room as figure 3.7. Its location can either ① or ② for convenience of the habit and operation. The touch screen of the injector and operating interface of CT will be put outside shield room for doctor operating.

4 Operation of the ASA-300

Warning:

During the power-on use of the CT Enhancement Injector, please don't touch the signal input / output port and the patient at the same time. Otherwise, the patient may be injured by electric shock.

Warning:

During the power-on use of the CT Enhancement Injector, please don't press or pull out the reel behind the injector, or it may cause damage to the device, which will interrupt the process of injection or make generator locked-rotor and heat.

Warning:

The signal input / output port of the CT Enhancement Injector can only be connected to devices that comply with IEC 60601-1.. Users shall not connect by themselves. If necessary, contact our professional technicians. Otherwise, it may cause harm to the patient.

Warning:

This product shall be operated by qualified medical technicians.

4.1 ON and OFF

After the ASA-300 has been installed by steps, make sure that the power switch on the rear side of the power box is in the “O” position. Insert the ASA-300 power plug into the network power (100-240V~) outlet.

Before startup, be sure to confirm: The system’s protective ground wire of the equipment must be reliably connected!

4.1.1 ON

The power switch on the rear side of the power box is the power switch of the whole machine. Press this switch to the “|” position. The injection head is energized, and the touch screen enters the warning interface after self checking, as shown in Figure 4.1,4.2.

Figure 4.1 The interface of power on self-test

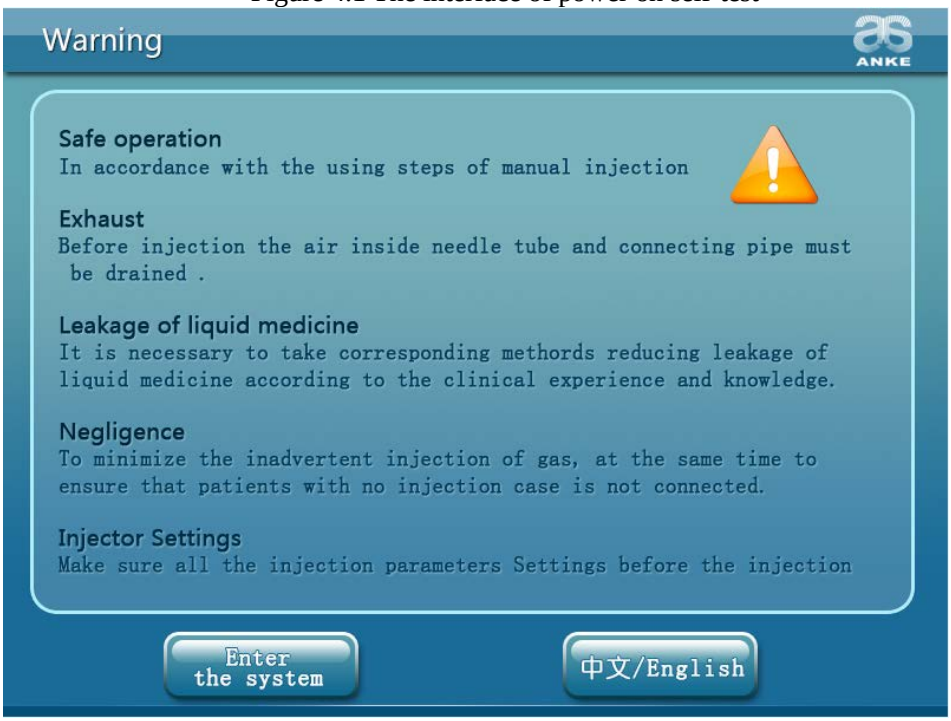


Figure 4.2 Warning interface

4.1.2 Off

Press the switch on the rear side of the electric control box to the “O” position.

4.2The State of Injection Head of ASA-300

The structure of injection head with dual syringe is shown in figure 4.3.

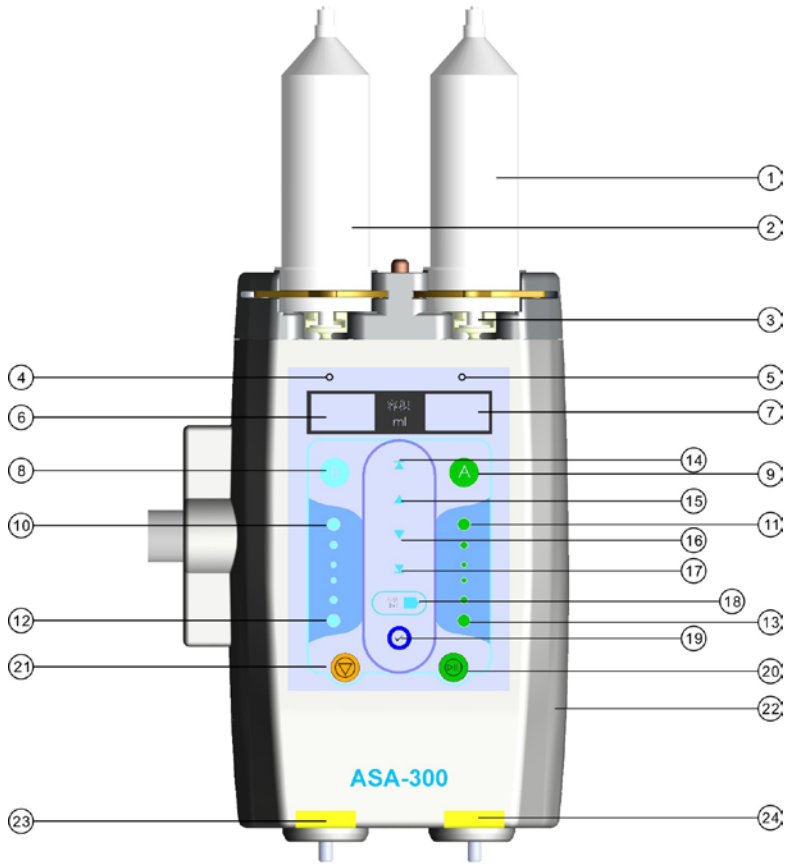


Figure 4.3 The structure of injection head with dual syringe

① syringe A ② syringe B ③ syringe chuck ④ indicator light of syringe B

⑤ indicator light of syringe A ⑥ display window of remaining dose of syringe B

⑦ display window of remaining dose of syringe A ⑧ injection selection button of syringe B

⑨ injection selection button of syringe B

⑩ syringe B forward speedup/backward slowdown button

⑪ syringe A forward speedup/backward slowdown button

⑫ syringe B backward speedup/ forward slowdown button

⑬ syringe A backward speedup/ forward slowdown button

⑭ forward to the limit key ⑮ forward button ⑯ backward button

⑰ backward to the limit button ⑱ an attempt to inject 3ml button

⑲ exhausting confirm button ⑳ inject/pause button

㉑ stop button ㉒ The face shell of injection head

㉓ Status indication of syringe B ㉔ Status indication of syringe A

Note: Recommended to use approved syringes with 200mL capacity.

Detailed meaning of head button operation

1) **Forward "▲" button and Backward "▼" button:** When you press forward or backward button, the piston handspike advance or retreat in a normal speed. the handspike stops

automatically when it reaches the limit position. If you release the button ,then the handspike stop at the location immediately .

2) **Forward to the limit “ ” button and backward to the limit “ ” button:** When you press the forward to the limit button or the backward to the limit button, the handspike will move at a rate of 3ml/s and stop automatically when it reaches the limit even if you release the button. It will stop moving immediately if you press the “stop” button.

3) **Exhausting confirm “ ” button:** The key is to remind operators of determining whether the air in the needle is exhausted which is ensuring the safety of injection. Only after pressing the “Exhaust Confirm” key can the computer accept the “Inject” command. .

4) **An attempt to inject 3ml “ ” button:** Pressing this button after you press the exhausting conform key, The injector will inject 3ml dosage at a rate of 1 ml/s. The function of the key is to ensure whether the injector or the procedure is normal and safe, whether the patient’s puncture is proper, and whether there are any allergic reactions.

5) Syringe A speedup “ ” button: If you press syringe A speedup button after pressing the forward to the limit button or the backward to the limit button when you select syringe A to inject, it will quicken the rate of the injection or the suck of drug.

6) Syringe B speedup “ ” button: If you press syringe B speedup button after pressing the forward to the limit button or the backward to the limit button when you select syringe B to inject, it will quicken the rate of the injection or the suck of drug.

7) Inject/pause “ ” button**:** When you press An attempt to inject 3ml button to determine the injection is normal, then you could set the injecting parameter in the touch screen. The Enhancement Injector will begin to inject with settled injection process in the condition of blinking of the indicator light when you press the Inject/pause “ ” key. If you want to pause during the injection, you just need to press it again.

8) Stop “ ” key: The piston of the injector will stop moving immediately when you press the stop key even it is inhaling, exhausting or injecting.

4.3 Syringe Installation

Before installing the syringe, first set the head down to the proper angle as shown in Figure 4.4 Then retreat to the backward to the limit key to make the injector’s push rod retract to the rear limit. Put the syringe in the slot as figure 4.4. The piston head is completely stuck in the groove of the push rod as figure 4.5. Then lay down the slip to clip the syringe, so that the syringe is installed as figure 4.6. Install the syringe B in the same way. The effect drawing is shown in figure 4.7.

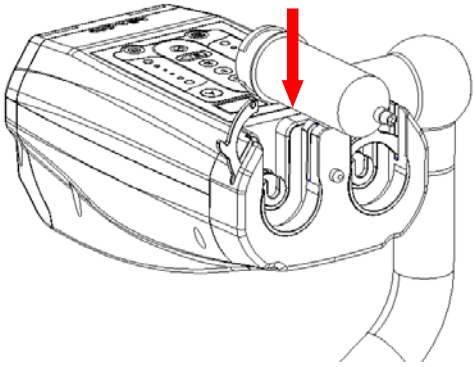


Figure 4.4 Placement of syringe

Figure 4.5 Syringe A in the slot

Figure 4.6 Syringe A finishing installation

Figure 4.7 Dual-syringes finishing installation

4.4 Detailed Operating Steps about the ASA-300

4.4.1 Operating Steps in Scanning Room

The main operations in the scanning room are to suck liquid into the syringe and perform I.V. on patients.

First, move the mounted ASA-300 CT Enhancement Injector and relevant configuration components to the designated location in the scanning room. Then, the corresponding medical staff follows the steps below for operation:

Step 1 Press the A or B button on the head to select A syringe injection or B syringe injection.

Step 2 Choose syringe A as an example, press the Back to rear Limit key （press syringe A

speedup button or slowdown button to adjust speed）, the handspike will move and stop automatically when it reaches the limit. Adjust the direction of the head to tilt it down. Load and clamp a 200ml disposable syringe.

Step 3 Press the forward to the Limit key  to stop automatically for the preparation of further suction.

Step 4 Insert the syringe drug absorption pipe into liquid. Press the Back to rear Limit key to start suction. After the suction action is stopped, replace the absorption pipe to the connecting pipe and adjust the direction of the injector head so that the syringe is upturned as far as possible. Press the Advance key to completely discharge the air floating on the surface in the syringe. Adjust the injector head to the injection state.

Step 5 After confirming that there is no air in the syringe and the connecting tube, press the “Exhaust Confirm” key on the head, and the nurse can begin to perform venous puncture on the patient’s limb and have it fixed. By injecting the "3ml" key for trial injection on the injection head, confirm whether the patient is properly punctured or not. and whether there are any allergic reactions or not. The operation in the scanning room is completed so far.

The orientation of the head corresponding to specific exhausting, injecting and stopping operations is shown in Figure 4.8:

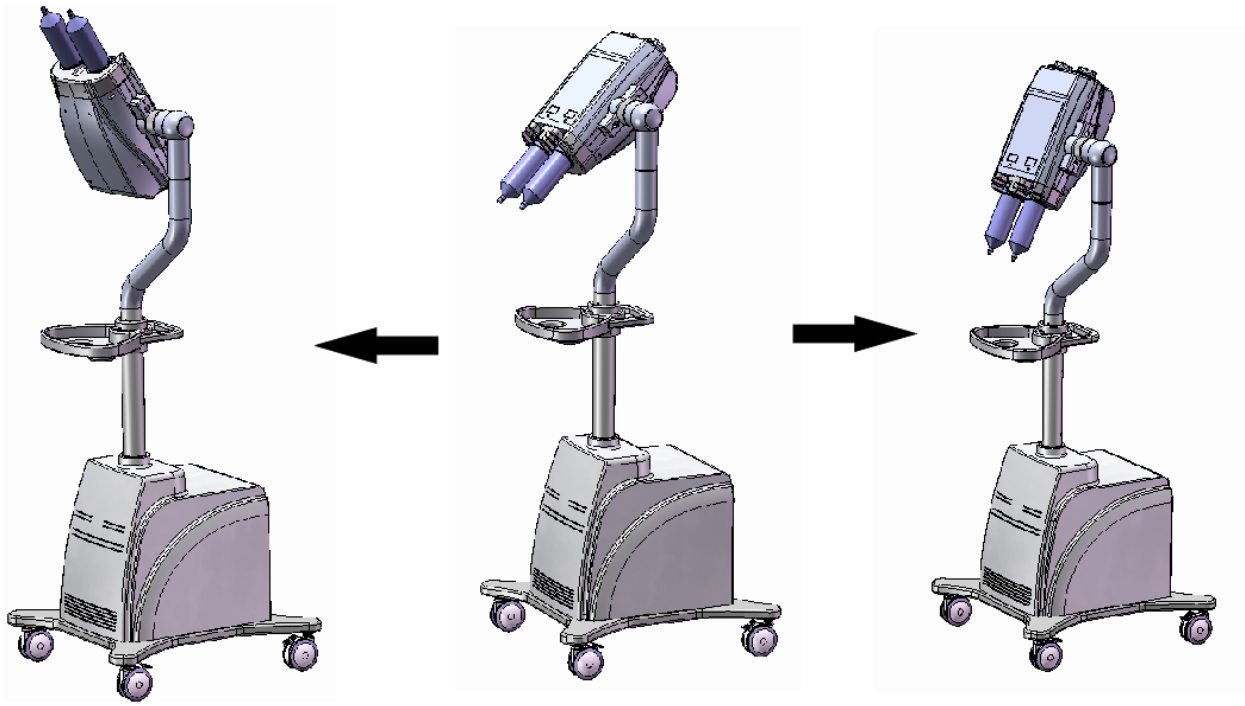


Figure 4.8 the direction of the head when it is exhausting, injecting and stopped

Warning:

Before the injection process begins, please step on the foot brake of the foot wheel to avoid the sliding of the injector during the injection, causing harm to the patient.

4.4.2 Operation Steps of the Touch Screen

While the medical staffs are performing above steps, the doctors set injection procedure on console outside the scanning room according to the following operation steps.

A. Enter the operation interface

After carefully reading the warning content and understanding, click the “Enter the System” button to directly enter the call interface shown in Figure 4.9.

Figure 4.9 Call interface

B. Set the injection parameters

Click the injection scheme below the ‘File name’ in call interface and the selected scheme is highlighted in red to distinguish, at the same time, the parameters set preview box on the right displays the corresponding injection parameters of the selected scheme. Drag the scroll bar on the right side to view all the injection scheme names. If the selected scheme meets your need, you can click on the ‘call’ button, the corresponding injection procedure is invoked automatically into the injection interface. If there is no suitable injection scheme in the scheme list, directly modifying the parameters of the selected injection scheme, the parameters are set as follows.

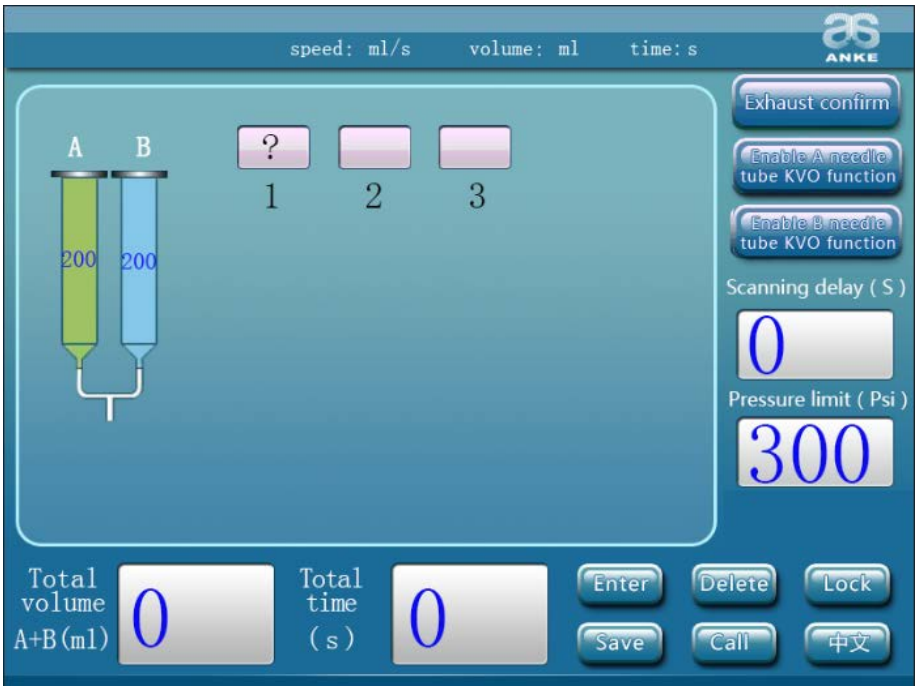


Figure 4.10 Injection interface

After multiple touch 1 in Figure 4.10, it will appear five states as follows: A, B, A/B, "Press ‘start’, go to next stage" and interrupt, which mean syringe A injection, Syringe B injection, syringe A and B injection together(syringe A and B inject together with same rate, but the injecting dose can be set separately), injection pause(when press “start”  , go to next stage), Continue injecting after interruption of time set.

Attention: The interrupt state in the injection stage refers to the injection delay and is set up when the CT linkage is turned on. The injection delay time should not exceed 600S. If the data is out of range, the Enter key will not be valid.

Here, we illustrate with syringe A injection, multiple click 1 until appears the situation shown in Figure 4.11.

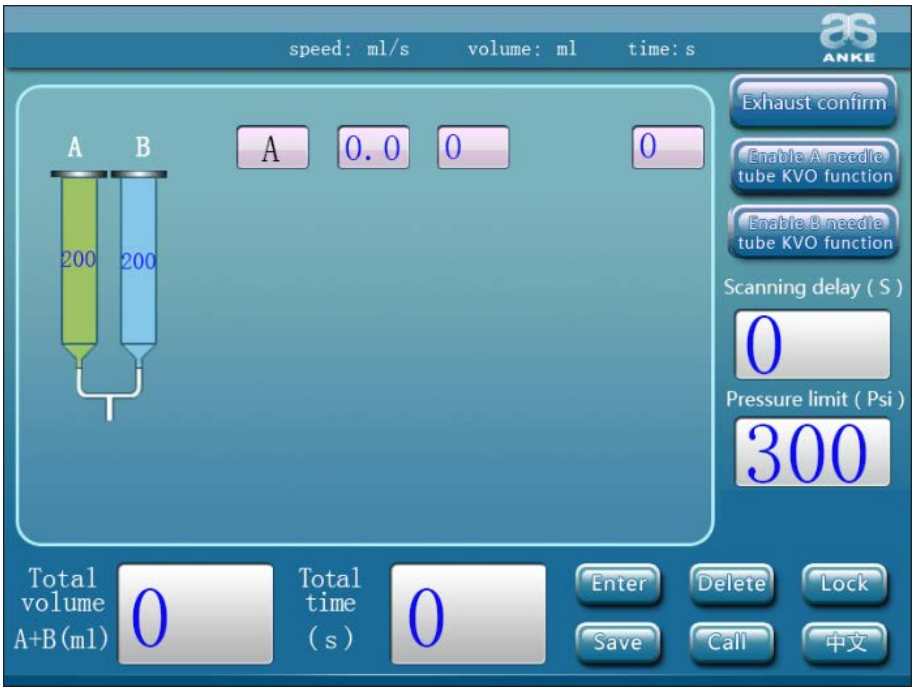


Figure 4.11 Select syringe A injection

Click 2 in Figure 4.10, it will pop-up the number keyboard. Input the injection rate in the keyboard as shown in figure 4.12.

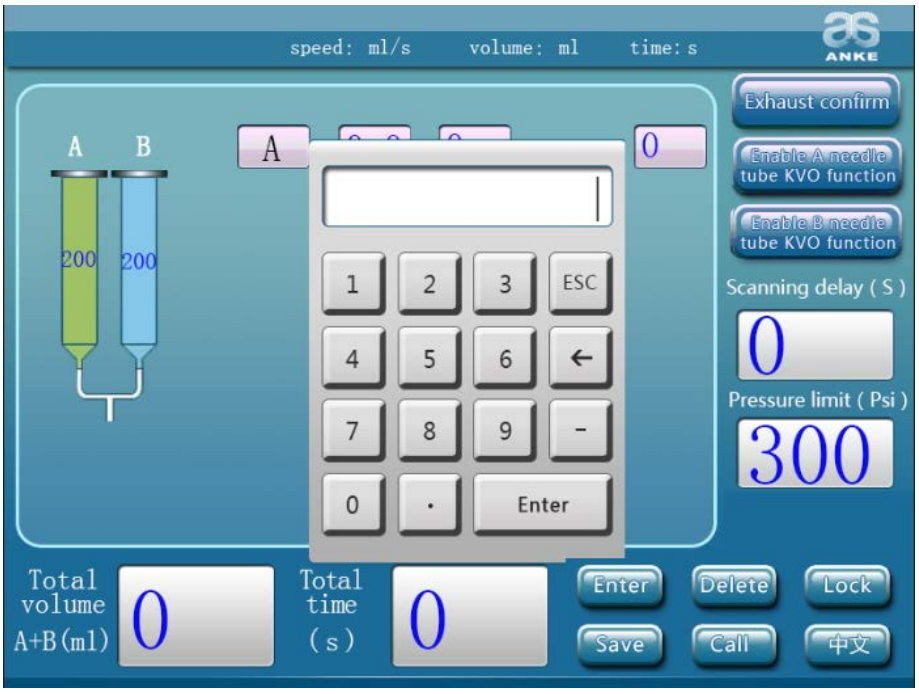


Figure 4.12Interface of inputting injection rate

If you mistakenly input wrong data during the input process, press "  " to delete the last digit and press "Esc" to exit the data input. After the input is completed, click the Enter key to complete the injection rate setting, as shown in Figure 4.13.

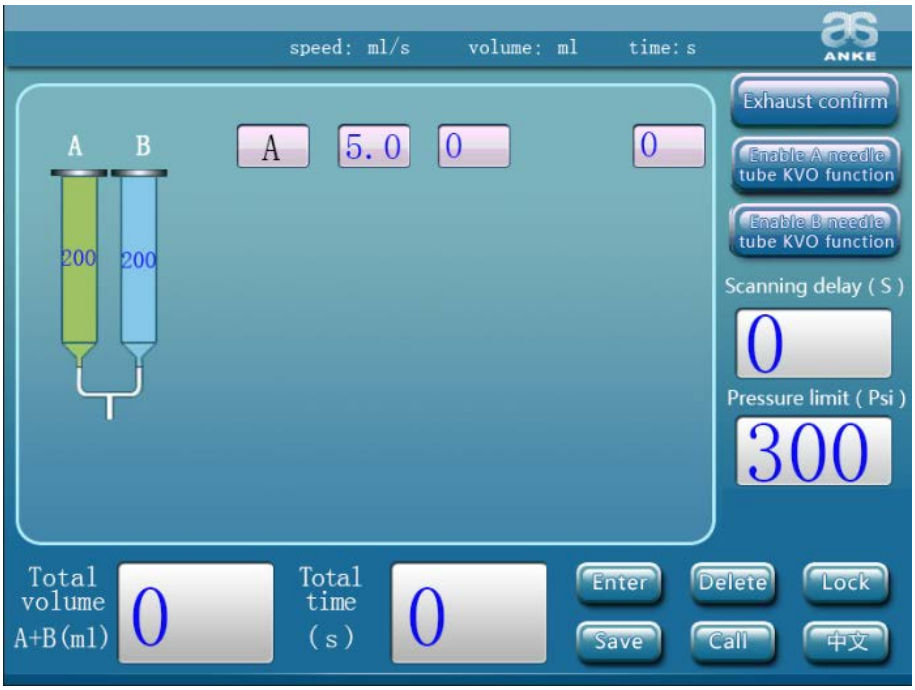


Figure 4.13 Finishing input of injection rate

Attention: The scope of injection rate is 0.1ml/S-10ml/S, if it is out of range, the Enter key is invalid, ie the injection rate data cannot be entered. The data is entered and modified in the same manner as the injection dose, scan delay, injection delay.

After the injection rate setting is completed, click 3 in figure 4.10 to set the injection dose.

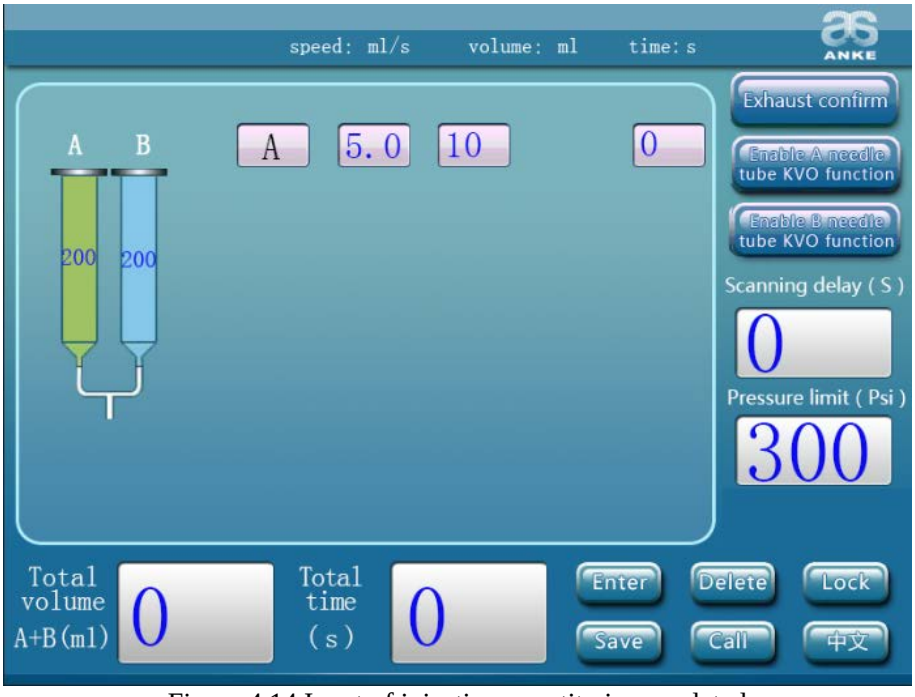


Figure 4.14 Input of injection quantity is completed

If the injection dose you have set exceeds remain dose in the syringe, the system will pop up warning interface as shown in figure 4.15.

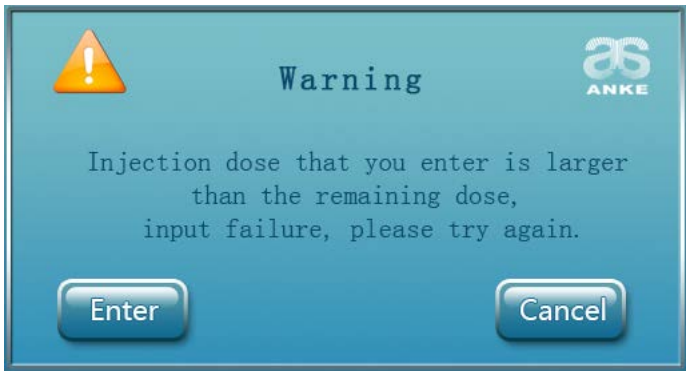


Figure 4.15 The warning interface of the injection dose exceeds the remain dose

At this point, click the Enter button of the warning interface and re-set the dosage within the allowable range.

After finish above steps, click “Enter” button to finish injection parameter setting of one injection phase, as shown in figure 4.16. If you need to set other injection phases, for example, set syringe B injection as second phase, the injection parameter settings are similar to the first phase. After settings, the interface is as shown in figure 4.17. The system automatically calculates the total injection volume and total time for all phases and displays it below the touch screen.

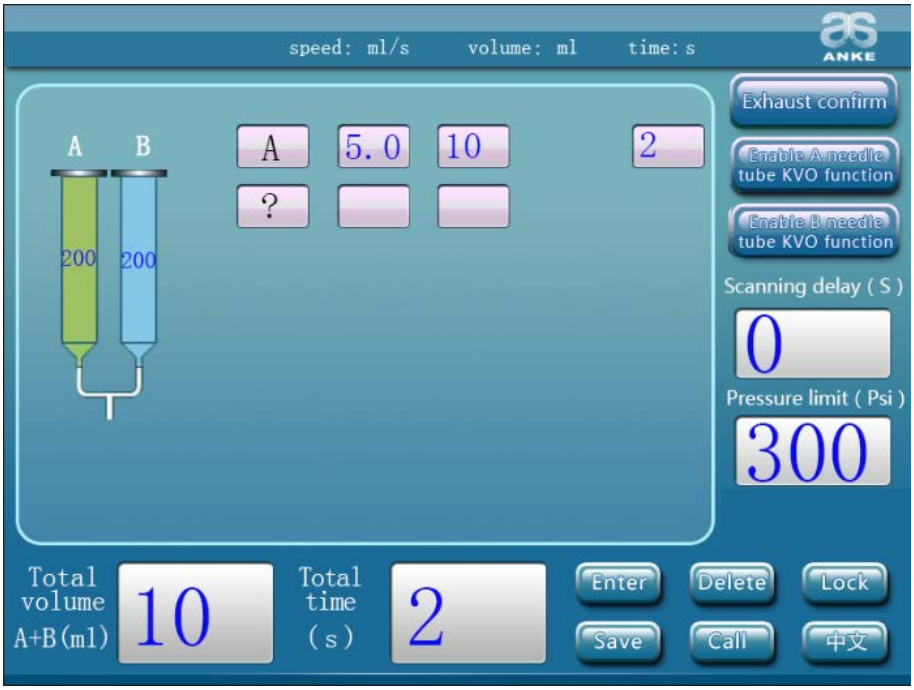


Figure 4.16 The interface of finishing setting injection parameter of first phase

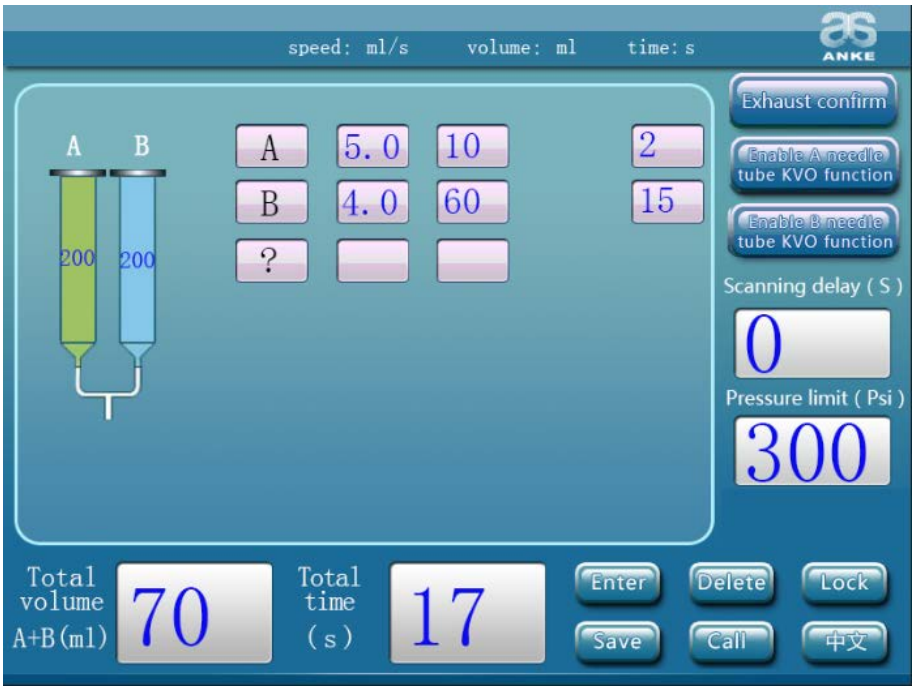


Figure 4.17 The interface after finishing setting injection parameter of second phase

If the injection parameters of the stage are set incorrectly or you want to delete the set stage, please click "Delete" button, and you will return to the last stage of the injection parameter settings completed interface

After all the injection stages are set, the pressure limit, the scan delay can be set according to requirement.

Click the input box under **pressure Limit(Psi)**, then appears 250, 300, 100, 150, 200 etc. pressure value in unit of Psi. You can set the upper limit of injection pressure during the injection according to the specific situation. If the injection pressure exceeds the upper limit during the injection, the touch screen will appear box as shown in figure 4.18 and issue the sound of didi…

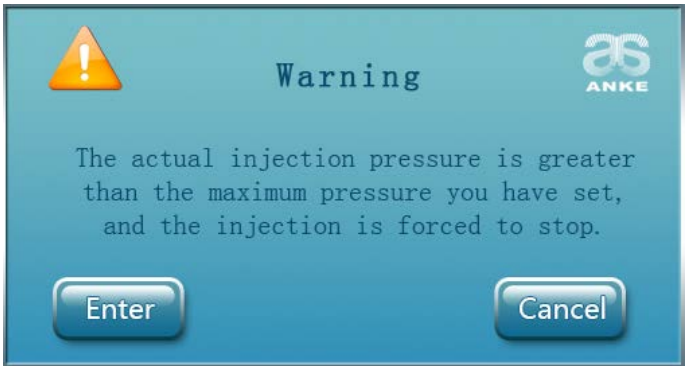


Figure 4.18 The interface when injection pressure exceeds the set upper limit of pressure

Click the input box under the **Scanning delay(S)**, set the scanning delay using the numeric keypad.

Attention: The scanning delay is set up when the CT linkage is turned on. Scanning delay time setting can not exceed 600S, otherwise the Enter button will be invalid.

If you set the scanning delay, injection delay or pause during injection, you need to keep patients' vein open to avoid blood coagulation which leads to life danger and needle block. Please click "Enable A needle tube KVO function" or "Enable B needle tube KVO function", to ensure the smooth flow of patient's vein at 0.25ml per 30s. Here you can only use either A syringe KVO or B syringe KVO instead of both. For example, in the break, we click"Enable A needle tube KVO function", then "Enable A needle tube KVO function" now becomes "Disable A needle tube KVO function" and flashes constantly until you click "Disable A needle tube KVO function", thus KVO function stops.

After the injection parameters are set, if you want to save, click the save button to jump to the save page.

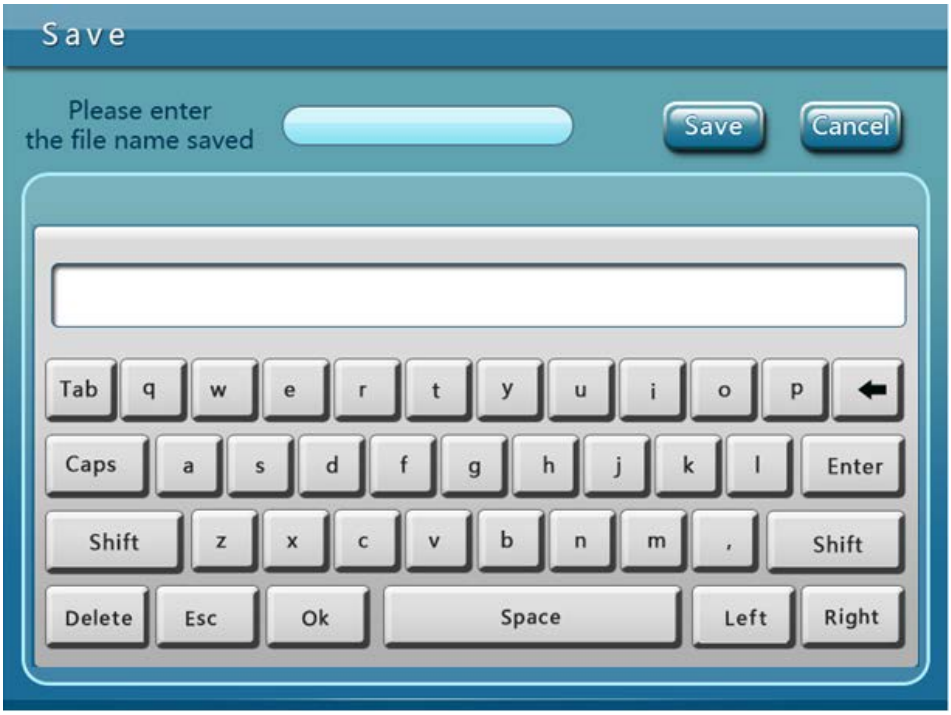


Figure 4.19 The interface injection parameters save

click Text box, it will pop up interface as shown in Figure 4.19, In the pop-up keyboard, enter the file name you want to save, click 'Enter' button after inputting the saving name, and click 'Ok' button to complete the input. press Save to confirm the injection scheme and press Cancel to return to the injection page.

Attention: If you click the save button without inputting file names, then the system will save the file as "unnamed" automatically.

Attention: Modify the injection parameters and preserve them on the basis of the original injection plan, and will not cover the original injection plan

C. Start injection

Thus all parameters have been set. Click the Lock button to complete the lock of all parameters to prevent misuse as well as ensure injection safety. Then the Lock button will change into Unlock and all buttons are invalid until the injection process completed or the

stop key pressed.

Attention: After the parameter is set, click the lock button, otherwise the injection button is invalid.

Ensure that the injection syringes and connecting pipe are without air, then click the exhaust confirm button in the head panel or the touch screen. Start the injection with the handheld switch or touch screen,

The touch screen will display the injection start interface as shown in figure 4.20. The injection Indicator Flashing represents the current stage in process.

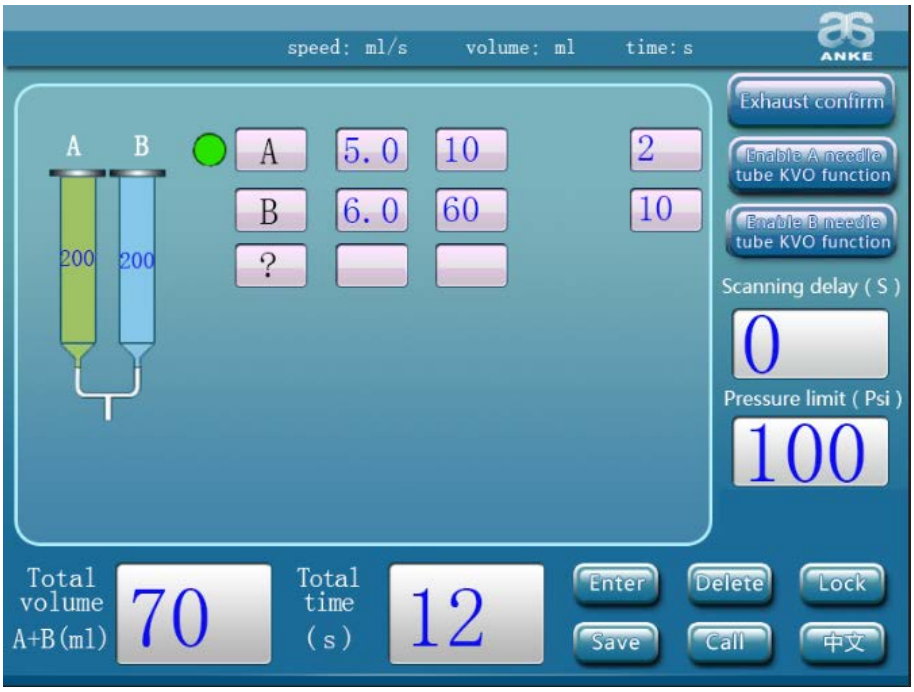


Figure 4.20 The starting interface of first phase injection

Press the handheld switch or click the Start key on the touch screen to pause. Press the handheld switch or click the Start key again to resume the injection.

Click the  Stop key to stop. The system will resume unlocking after stopping.

D. Injection completed

After the injection is complete, the system will automatically unlock. Re-injection under the same parameters can be performed through the exhaust confirmation and lock steps. If you need to switch the scheme, you can click the call button to switch the scheme call interface.

5 Clinical Operation Guides

It is necessary to set the injection program appropriately when using the ASA-300 dual-syringes injector. The settings of the program depend on the issue which resolution is to be increased, patient's weight and the scanning time of the device. The operator should set the program on the operations console according to doctor's requirement. This device can save 100 injection programs while the last modified one is automatically saved. Please mind that computer will automatically save the injection program modified recently.

This chapter provides certain reference information in clinic use. Still, with their experiences, customers could use better injection methods according to different situations. After all, it is very important to pay attention to the special issues described in this chapter. The CT injections with this device should be taken out by doctors in CT room, follow the aseptic operation rules, with the similar contents provided in Chapter 4.

5.1 Injection Application Programming about ASA-300（for reference）

The design of the injection programs includes the following items: the total dose, total time, the dose of each phase, injection rate and time, the pause (the injection delay), the scan delay, the upper limit setting of pressure and the KVO function etc. The setting of above parameters is closely related to factors such as the patient's weight, age, scan location, patient status (mainly referring to the estimation of the patient's cycle time) and CT scanning speed, scanning mode (routine or spiral), purpose (conventional enhancement or CTA), scan layer number, etc. The design of the injection programs is a complex technique which is worth clinical experts' attention.

Anke design many injection schemes for customers' better use of the injector from some specific using conditions in the hospital. It is warmly welcomed that users write academic papers according to own experience to Anke which will be published in *Anke Insight*. The selected papers will be sent to Chinese core journals for publishing.

The total dose of contrast agent is generally calculated per kilogram of body weight.Take 60% contrast for example, the total amount should be 1~2 ml/kg. The detailed method should be performed according to contrast user manual.

5.2 How to Choose the Syringe Needle

There is a certain rate requirement for CT enhanced injection, and corresponding pressure will also be generated. Therefore, the finer the needle, the greater the force of the liquid ejected from the needle. In order to reduce the impact on the walls of veins, try to use thicker needles for venous puncture (if there is no difficulty in venous puncture). If the patient's veins are thin (e.g. infants), and thus only fine needles can be used, the rate must be slowed down.

5.3 Preparation of the Patient

The allergy test should be carried out with the help of nurses. Special needles made for ASA-300 should be adopted in vein puncture. Fix the needle and the connecting pipe on the human surface with tape to avoid flying out of the needing while injection. The conventional injection head should also be fixed on the patient's arm with tap, when allergy test is done and no aspect phenomenon, the preparation is done successfully.

5.4 Syringe Installation

When the power is on, press the backward to the limit button "  " on the injection head to move the injection bar to position last end position, then the injection is ready to installed. According to clinic use, one or two 200ml syringe can be chosen. Put the syringe in the slot, and the piston head is completely stuck in the groove of the push rod. Then lay down the slip to clip the syringe.

Caution:

Before injection: the volume of the syringes assembled should be consistent with the volume shown on the screen.

Warning:

Be sure to use the injection syringes with our recommendation.

Warning:

The syringes are one-off and shouldn't be used for the second time.

Press the "  " button, the injector bar move to the front end position, the "Syringe Volume" is set to "0" automatically and is ready to take medicines.

5.5 Suck Contrast and Exhaust

Put the injector head down about 30° from the horizontal plane. The upper end of the drug absorption pipe's attached to the syringe nozzle, and the other end of the drug absorption pipe is inserted into the contrast agent bottle. Press the  key to retreat to the rear limit. Pump the contrast agent into the syringe. When the contrast agent in the bottle is drained or the syringe is full of liquid, press the "Stop" key to stop the suction. According to this method, the syringe can suck up to 200ml of contrast agent.

Caution:

A drug absorption pipe must be used during suction. Do not use a connecting tube for suction to avoid accidents.

Remove the drug absorption pipe and connect it to a special connecting tube. One end of the connecting tube is connected to the syringe nozzle. Press the Advance key to exhaust air in the syringe and the connecting tube. Then set the head to a depression angle of about 30°.

5.6 Injection

When it's about to inject the agent, the doctor should pull the puncture needle from the normal syringe, then connect the pipe to the pipe on the head.

Caution:

When the connecting tube is connected with the syringe nozzle and the connecting tube at the tail of the puncture needle is connected with this connecting tube, the joint interface must be aligned. The tightening force is to ensure that the connection is tight. Too must force will crack the nozzle of the connecting tube.

After the connection is completed, ensure that the injection syringes and connecting pipe are without air, then perform the trial injection: press the "Exhaust Confirm" button, when the flash is on, press the pre-injection "3ml" button to make sure that the puncture is all right and there is no leakage on the pipe connections.

When the injection program is ready, it's about to inject by pressing the "Injection" button.

Caution:

During the injection process, the syringe end of the injector head shall be kept tilted downwards to prevent liquid from entering the interior of the injector head in the event of an accident.

Warning:

Exhaust before injection to make sure there is no air in the head and pipe.

The doctor should following the rules when injecting:
The injection operation is usually done in the operating room with a touch screen, but there must be a medical staff to stay in the patient's side first to observe for abnormal conditions. 10s after the start of the injection, the medical staff could leave the room in case of no abnormalities.

After the injection is complete, the actual dose and time of the injection is displayed on the touch screen and kept until the next injection begins.

Warning:

Once accident on injection, like bad phenomena、head slippers, etc., press the "inject/pause" or "Stop" button to stop injection.

5.7 Post-Injection Treatment

After the scan is complete, if patients had no adverse reactions, the needle can be removed and the patient can leave the scan room. When the next patient is ready for injection, replacing the connection pipes and exhaust. If there's no other enhancing injections in the day, the operator should remove the connection pipe first, and then press the backward to the limit button to retreat the push rod to the rear limit position, and at last remove the syringe.

Caution:

When the injection is completed and the syringe is to be removed, the connecting tube must be removed from the syringe before the backward to limit key can be pressed to avoid accidents.

Caution:

When using a high-energy output device such as a defibrillation device, the unit's power must be turned off first.

6 Maintenance of the ASA-300

6.1 Cleaning and Disinfection

The device is a kind of high precision medical equipment composed of computers and motor drivers. The mounting surface should be keep clean, especially the head support assembly which is directly touched with the patients and is easily polluted by medical liquid or blood.
The maintainer should clean the device once a week to make sure there is no medical liquid left. The overall cleanup should be taken half a year. Pay close attention to the medical fluid in the conjunction of the injector head assembly.

If necessary, clean the dusts from the operation box, the head control panel and enclosure. Never clean with organic solvent or corrosive cleaning agent. Ensure no power is on in the system and prevent water or cleaning agent from entering the system during the cleaning process since system may be damaged.

Wipe the jogger, bayonet, and other places that may leave a residue of the contrast agent after each usage.

6.2 Quality Control Requirements

The design service life of this instrument is ten years.

The maintainer should test the performance of the device half a year. The velocity should be set to 6ml/s, totally 80ml, with one head of filled with 150ml water, connect the pipe and scalp acupuncture labeled No. 8, when inspecting, make sure to keep the syringe piston stable and horizontally; after 60ml is successfully injected, fasten the hose at the end of the scalp acupuncture, the injector stops injecting and emits sound and light signals to alarm.

The injection head is composed of step motor and ball screw with high precision package. There is also a high speed CPU embedded inside the touch screen. Non authorized specialist is prohibited from disassembling the device to prevent damage.

7 Common Faults and Troubleshooting

When the ASA-300 fails, it is necessary to determine the possible cause of the failure based on the symptoms and use the appropriate solution. See Table 1 for common faults and troubleshooting.

Table 1 Common Faults and Troubleshooting

Fault	Cause	Troubleshooting
A. The power switch indicator on the rear of the power box is off	The power plug is not plugged in or the power outlet is not powered	Make sure that the power outlet has normal power supply, and that the plug is inserted properly.
B. The power box switch indicator light is on, but the injection head indicator is not bright	Power fuse is broken	Replace the fuse. Fuse specifications: F2AL 250V
C. A/B syringe can not be switched	Bad contact or open circuit of the head control cable	Check head control cable connection
D. The volume display of the touch screen and the head is inconsistent	Bad contact or open circuit of the touch screen cable	Check touch screen cable connection
E. Normal exhaust can be confirmed (indicator light). After injection, the indicator light extinguishes the syringe without action	1, Bad contact or open circuit of the head power cable 2, Motor driver failure (red light or green light)	1, Check head power connection 2, Replacement of motor encoder
F, The touch screen is not bright and the head is not displayed	12V switching power failure	Replacement of 12V switching power
G, The touch screen is not bright and the head is normal	Bad contact or open circuit of the touch screen cable	Check touch screen cable connection

Appendix I Guidance and Manufacturer's Declaration – IEC 60601-1-2

Warning: **Use of ACCESSORIES, transducers and cables other than those specified may result in increased EMISSION and/or decreased IMMUNITY of the ASA-300.**

Guidance and manufacturer's declaration –electromagnetic emissions		
The ASA-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the ASA-300 should assure that it is used in such an environment.		
Emission Test	**Compliance**	*Electromagnetic Environment Guidance*
RF emissions CISPR 11	Group 1	The ASA-300 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ASA-300 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuation/ Flicker emissions IEC 61000-3-3	Complies	

Table 1 – Electromagnetic Emissions

Guidance and manufacturer's declaration –electromagnetic immunity			
The ASA-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the ASA-300 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. <5% U_T (>95% dip in U_T) for 5 seconds.	<5% U_T (>95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles. 70% U_T (30% dip in U_T) for 25 cycles. <5% U_T (>95% dip in U_T) for 5 seconds.	Mains power quality should be that of typical commercial and/or hospital environment. If the user of the ASA-300 requires continued operation during power mains interruptions, it is recommended that the ASA-300 be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60Hz) Magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 2 – Electromagnetic Immunity (ESD, EFT, Surge, Dips and Magnetic Field)

Guidance and manufacturer's declaration –electromagnetic immunity

The ASA-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the ASA-300 should assure that it is used in such an environment.

Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ASA-300, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1{,}17 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2,5 GHz	3V/m	$d=1{,}17 \times \sqrt{P}$ 80 MHz to 800MHz $d=2{,}33 \times \sqrt{P}$ 800MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ASA-300 is used exceeds the applicable RF compliance level above, the ASA-300 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ASA-300.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 3 – Electromagnetic Immunity (RF Radiated and conducted)

Recommended separation distances between portable and mobile RF communications equipment and the ASA-300

The ASA-300 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ASA-300 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ASA-300 as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter w	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1{,}17 \times \sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}17 \times \sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}33 \times \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

NOTE1 At 80MHz and 800MHz, the separation distance for higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 4 - Recommended separation distances between portable and mobile RF communications equipment and the ASA-300

Appendix Ⅱ Description on CT Linkage Cable Connection

The J3 interface of the power box is the CT linkage cable interface. The output (triggered CT scan) is the contact signal, and the input (triggered syringe injection) is the contact signal. The interface is defined as follows: