

Contrast Media Injectors



 ***imaStar*** ***CDP***
CT Dual Injection System

Operating Manual



READ BEFORE USING

CE₀₁₂₃

Shenzhen Antmed Co. Ltd.

Table of Contents

Chapter 1	Introduction	4
	Safety Notice	4
	Certificates	4
	Intended Use, Indications	4
	Contraindications	4
	Service life	4
	Safety Declaration	4
	EMC Declaration	4
	Disclaimer	4
	Notified Body	5
	Symbols and Descriptions	5
	ImaStar Series CT-Dual Injector Models	7
	Pressure Limit Safety	7
	Injection Volume and Rate	7
	Warnings, Cautions and Notes	7
Chapter 2	Summary about the System	9
	Control Room Unit	9
	Scan Room Unit (Injector)	10
	Display of Scan Room Unit (Injector Head Screen)	11
	System Prompts	12
Chapter 3	Injection Preparation	13
	Power On	13
	Control Room Unit Safety Screen	13
	Setup Screen of the Control Room Unit	14
	Home Screen	15
	Loading Syringes and Connecting Tubes	15
	Filling Syringe	17
	Heating Sleeves	17
	Injection Programming	18
	Connect to Other Imaging Equipments	20
Chapter 4	Arm and Inject	20

Arm.....	21
Disarm/Cancelling Arm	23
Injecting	24
During Injection.....	25
Programs with Test Injections.....	26
Injection Completion.....	26
Stopping an Injection Program	27
Injection History Records.....	27
Chapter 5 Pause and Delay Options	28
Test Injection.....	28
Simultaneous Injection (A% B%).....	29
Hold and Pause	31
Delay Setup	33
Chapter 6 Storing and Recalling Injection Programs	35
Storing Injection Programs	35
Recalling an Injection Program	36
Chapter 7 Clinical Application - CT, Angio, Cardiac, Injection	37
Chapter 8 Cleaning, Maintenance, Inspection and repair.....	38
Cleaning and Maintenance	38
Inspection.....	39
Operational Inspection	40
Malfunction repair	42
Chapter 9 Product Specifications	43
Weight.....	43
Power	44
Syringe Specifications	44
Injection Specifications Available	44
Piston Rod Control	44
EMI/RFI.....	44
Power supply requirements.....	44
Leakage Current	45
Ground Connection.....	45
Environmental Requirements	45

Performance Considerations	45
Classification	45
Chapter 10 System Installation.....	46
Unpacking	46
Installation	46
Installation of Wireless Communications	47
Installation of the Control Room Unit.....	47
Chapter 11 GUIDANCE AND MANUFACTURER’S DECLARATION	48
Chapter 12 Circuit diagram.....	53

Chapter 1 Introduction

This Operating Manual is intended to serve as the operational guidance as well as the technical instruction for ImaStar CT Dual Injection System for all models. Please read this document carefully and follow the guidelines and instructions before operating the device.

Safety Notice

The operator of the device should be a medical clinician (radiologist) or radiological technologist who has received training and has experience in the field of CT scanning (computed tomography) operation.

Certificates

This device is designed to operate at 100-240 V~, 50/60Hz and to comply with the Standards IEC 60601-1 and IEC 60601-1-2. Shenzhen Antmed Co. Ltd is ISO 13485 certified.

Intended Use, Indications

This device is a contrast media delivery system indicated for the administration of intravenous contrast media into humans in conjunction with CT scanning (computed tomography).

Contraindications

This device is not intended for any drug injection other than iodinated contrast media, chemotherapy or any other uses unless it is indicated in this Operating Manual. ImaStar CT Dual Injection System is NOT designed for portable use.

Service life

This device has a service life of 10 years.

Safety Declaration

This device is designed to comply with IEC 60601-1 .

EMC Declaration

This Device is designed to comply with IEC 60601-1-2. For more information regarding compliance to IEC 60601-1-2 ,please see chapter 10.

Disclaimer

Shenzhen Antmed Co. Ltd shall not assume liability for any modification of the device or any application that relates to other equipment which is not in conformity with the specifications and requirements specified in this Operating Manual. Any action or use of this product outside of the specified use in this document could jeopardize the performance, safety, and/or reliability of this system.

To prevent a medical accident and/or an economic loss, any accessory equipment connected to the ImaStar CT Dual Injection System must be IEC 60601-1 certified. Furthermore, all configurations and signal input and output of other medical devices to be connected with this device should be in

compliance with the requirements of the Standard IEC 60601-1-2. To obtain detailed information or assistance, contact the Service Center of Shenzhen Antmed Co. Ltd.

Notified Body



Indicates that this device conforms to requirements of the European Medical Device Directive 93/42/EEC

Symbols and Descriptions

The following symbols are used on ImaStar CT Dual Injection System and throughout this Manual. These symbols have special meanings to help in operating the device in a safe and proper manner. The symbols and their descriptions are as follows.

	Refer to instruction manual
	Hazardous voltages
	Alternating Current (AC)
	Type B device
	Piston Forward
	Piston Backward
	Piston Hold
	Piston Movement Acceleration
	Hold/Start button
	Stop button
	Forward/Backward direction of the manual rotation
	AIR EXPEL CHECKED button on the touch screen of the injector head. When illuminating GREEN, it indicates that the air in the fluid path has been expelled. YELLOW indicates that air has NOT been expelled.
	Equipotential Connection



Earth Ground point

CLASS 1

In conformity to the Class 1 standards of medical equipment per the Standards IEC 60601-1

IPX1

IPX1 Code that specifies the degree of protection against vertically falling water drops (IEC 60529).



Devices that contain Bluetooth Communications



Indicates separate collection for Electrical and Electronic Equipment per Directive 2002/96/EC



Indicates that the communication is ok



Date of Manufacture/Sterilization



Serial number



Authorized Representative in the European Community



Manufacturer



This Way Up

Bluetooth communication realizes the wireless communication between the injection head and the control box. The distance between the control box and the injection head is in 100m.

The parameters of wireless transmitting and receiving communication are as follows:

Frequency: 2400-2483.5 MHz (TX/RX)

Power: 4~6dBm

Modulation mode: PSK GFSK

Frequency characteristics: AFH

ImaStar Series CT-Dual Injector Models

ImaStar Series CT- Dual Injector Models	
ImaStar CDP:	CT, Dual-head, Pedestal
ImaStar CDC:	CT, Dual-head, Ceiling mount

Pressure Limit Safety

ImaStar CT Dual Injection System Pressure Limit Safety feature can limit injection pressure in order to avoid unsafe injection into the patient and possible consumable damages. The device detects the internal syringe pressure and when it reaches preset limit, the device will automatically limit the pressure by lowering the injecting rate. If the injection pressure exceeds the preset pressure limit, the injection will be stopped with an audible warning and a message on the lower right of the screen.

Injection Volume and Rate

Measures have been taken to prevent excess or insufficient injection volume and rate. The injection volume and rate are displayed on the screen of the Control Room Unit. Before arming the injector, the operator will be reminded by a prompt to check and set the parameters. If the injection volume programmed exceeds that of the contrast media in the syringe, there will be a prompt displayed on the screen of the Control Room Unit to remind the operator. The operator can elect to fill additional contrast media or saline into their respective syringes as required, or they can elect to continue. Should the operator elect to continue the procedure, the injection protocol will deliver fluid from their respective syringes per the chosen protocol until the syringe contents are depleted.

Warnings, Cautions and Notes

Please pay attention to all warnings, cautions and notes provided throughout this Operating Manual:



WARNING: Warning indicates a potentially dangerous situation that could cause death or serious injury to the patient and/or operator. Do not operate the device without reading and understanding the warning message.

Caution: Caution suggests that the situation could cause damage to the device. Do not operate the device without reading and understanding the caution message.

Notes: Notes are information or tips to help avoid errors or incorrect operation.



WARNING: System failure may lead to injury or death to patients. If system failure occurs, disconnect the power supply immediately and disconnect the device from the patient promptly.



WARNING: Injury to patients or operators may occur from injection leakage or breakage. To avoid the leakage or breakage caused by blockage, please only use disposable products and accessories recommended by Shenzhen Antmed Co. Ltd.



WARNING: Explosion hazard: Injury to patients or operators may occur when flammables are present. Avoid flammable anesthetics when operating the device.



WARNING: Fire Hazard: Injury to patients or operators may occur due to the misuse of a fuse. To prevent an electrical fire, make sure that the correct type of fuse is used for replacement. Please contact Shenzhen Antmed Co. Ltd or an authorized dealer before replacing the fuse. Replacement must be done by a qualified person.



WARNING: Injury to patients or operators may occur due to the use of worn-out power cords or improper installation. Therefore, check power cords and cables for cuts, frays, or any other visible damage regularly. Do not use the system if any of the cords or cables shows signs of damage. Please replace the damaged or worn-out cables or power cords immediately upon discovery. For assistance, please contact the Service Center of Shenzhen Antmed Co. Ltd.



WARNING: Potentially hazardous materials are contained in certain electrical parts of this device. Please dispose of them in accordance with the local laws and regulations or consult Shenzhen Antmed Co. Ltd.



WARNING: Using improper spare parts may lead to unsafe operation. Only buy and use the parts recommended by Shenzhen Antmed Co. Ltd.



WARNING: ImaStar CT Dual Injection System is designed as a dual-head injecting system. Each time before injecting, make sure that the contrast syringe, the saline syringe and all connecting products are mounted correctly. Improper loading may cause operational failure. Syringe A is for the filling of contrast media. Syringe B is for saline.



WARNING: Moisture and condensation may cause electrical damage. Do not use the device immediately after it has been moved between extreme temperatures or environments. Make sure to only operate the device when it has been adjusted to room temperature.



WARNING: Improper voltage can cause damage to this device. Please check the power supply accordingly before connecting the device to the power source.



WARNING: Check and confirm that the output of the power supply matches the input of the voltage and frequency of the device properly.



WARNING: Check and confirm that the plug of the Control Room Unit is properly matched to the socket of the power source.



WARNING: If the device is close to a strong magnetic field, it may be disabled or malfunctioning. Do not use radio transmitters, mobile phones, or devices that generate electrostatic discharge near this device.

Chapter 2 Summary about the System

ImaStar CT Dual Injection System is a programmable dual-head injection system. During a contrast enhanced CT scan, the device is used to deliver to the patient accurate doses of CT contrast media and saline flushing solution.

The system consists of two parts, the Control Room Unit (Figure 1) and the Scan Room Unit (injector) (Figure 2). The two units are connected by wireless communication. The Scan Room Unit is to place near the CT scanner.

Control Room Unit

(Figure 1)



Figure 1

1. Touch Screen of the Display

2. Hand-Switch

3. Power On/Off

Scan Room Unit (Injector)

(Figure 2)



Figure 2

1. Injector Head
2. Injector Head Screen
3. The Injector Base of the Scan Room Unit
4. Heating Sleeves
5. Power Switch

Display of Scan Room Unit (Injector Head Screen)

(Figure 3)

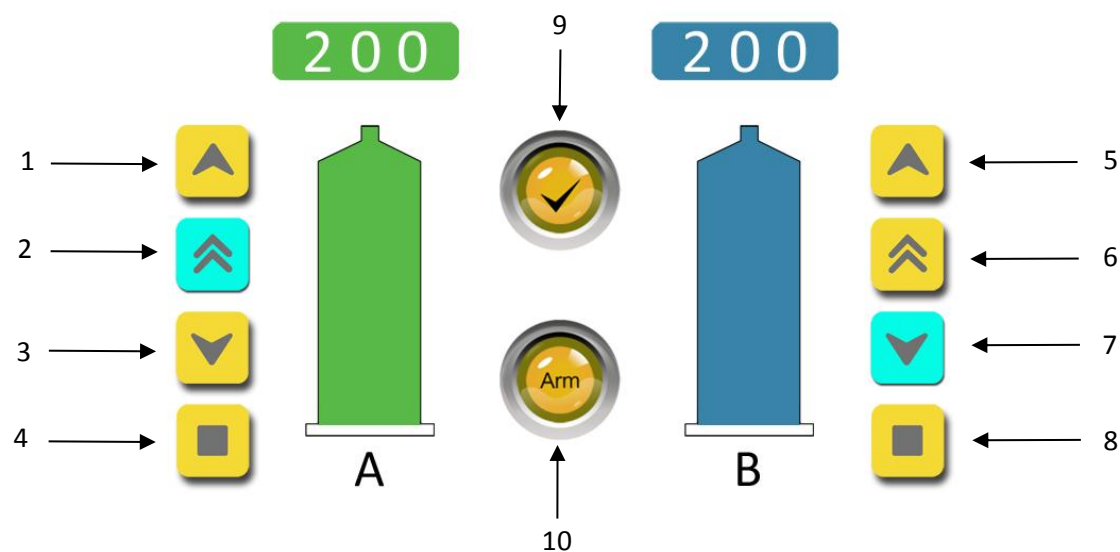


Figure 3

1. Contrast Syringe A Piston Forward Key
2. Contrast Syringe A Piston Movement Acceleration Key
3. Contrast Syringe A Piston Backward Key
4. Contrast Syringe A Piston Hold Key
5. Flush Syringe B Piston Forward Key
6. Flush Syringe B Piston Movement Acceleration Key
7. Flush Syringe B Piston Backward Key
8. Flush Syringe B Piston Hold Key
9. Air Expel Checked Key
10. Arm key

There are two types of messages that will display on the screen. Depending on the operation or situation, two general types are:

1*

OK

The diagram illustrates a contrast injection system. On the left, two syringes are shown: Syringe A (Contrast) and Syringe B (Flush). Syringe A contains 151 ml of contrast, and Syringe B contains 202 ml of flush. The syringes are connected to a common line that leads to a pressure graph. The graph plots pressure in psi (0 to 300) against phase (0 to 1). The pressure curve shows a sharp increase, reaching a peak of 325 psi, which is labeled as 'Pressure Peak 325 psi' in a red box. A red box also contains the text 'Overpressure, stop injection'.

Contrast ml

Flush ml

A
CM
151

B
NaCl
202

psi

300

250

200

150

100

60

0

1

phase

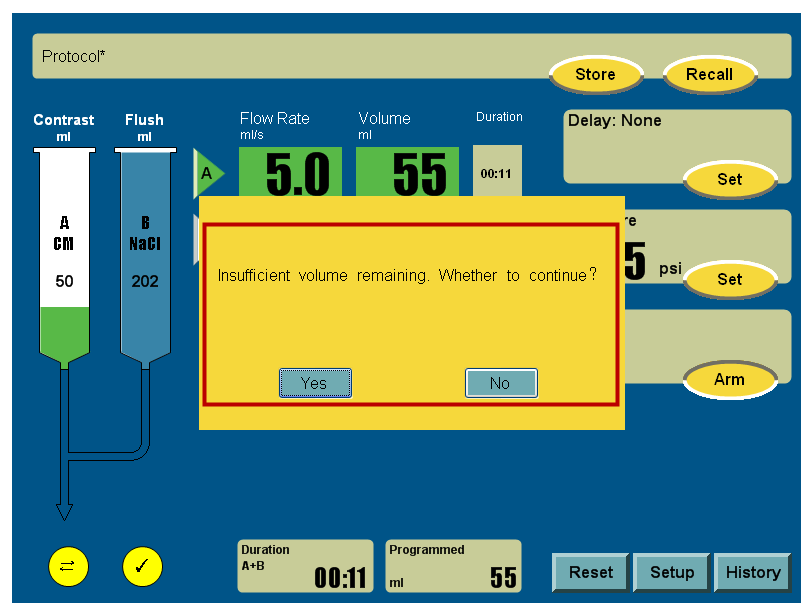
Overpressure, stop injection

Pressure Peak 325 psi

Duration A+B 00:02

Delivered ml 4

Reminder messages (Figure 5): Reminds the operator to check and confirm the operation.



ImaStar CT Dual Injection System

Chapter 3 Injection Preparation

Power On

Control Room Unit

Press and hold the Power Switch on the right side of the monitor for approximately 2 seconds. Then the Safety Screen will appear on the display.

Scan Room Unit

1. Make sure all cables are connected properly and tightly.
2. Turn on the power switch of the power box.
3. Turn on the power switch on the injector base, and make sure the power indicator light is on.

Notes: Programming can be done on the Control Room Unit even when the Scan Room Unit is powered off.

Control Room Unit Safety Screen

The Safety Screen on the Control Room Unit (Figure 6) after powered on provides information on how to operate the injector safely and to avoid potential hazards associated with an injection procedure. Read the content carefully and press Continue.



Figure 6

Setup Screen of the Control Room Unit

Press the Setup in the lower right corner on the Home screen to go to the Setup screen. Setup screen includes the selection of Language (if more than one language is available), Piston Rod Forward mode, Limit Detection switch, Angle Detection switch and the current software version. (Figure 7) If you press Default, the Piston Rod Forward option will be reset to its default value, which is Auto, Limit Detection will be reset to “On” and Angle Detection will be reset to “On”.

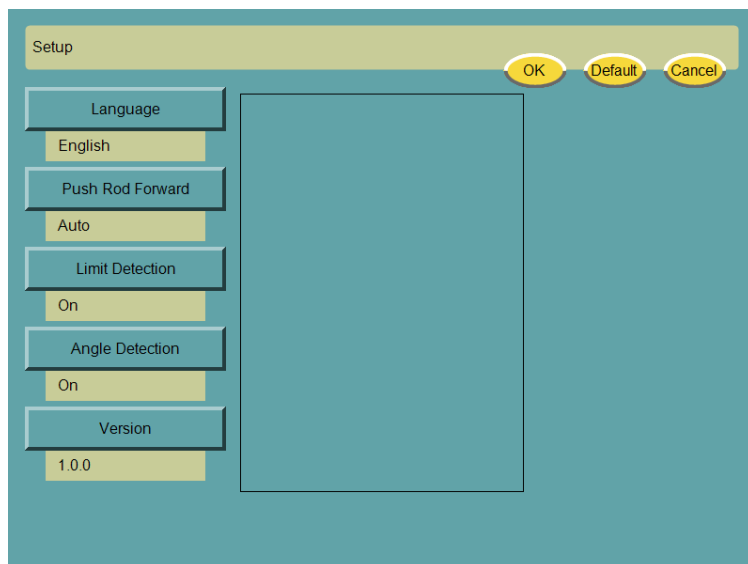
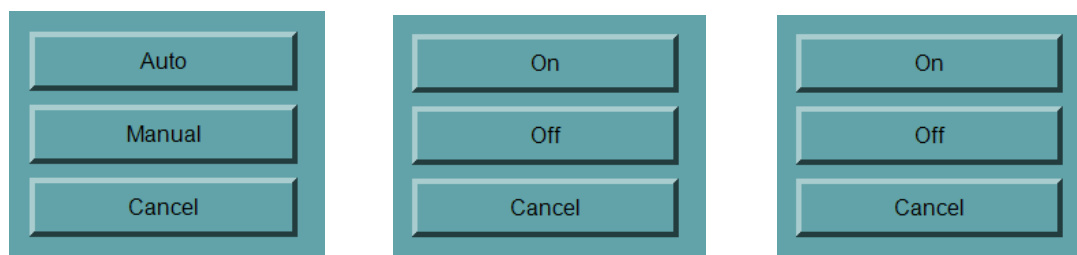


Figure 7

- The Piston Rod Forward option controls the Syringe detect function.
- The Limit Detection option controls the position limit protect function.
- The Angle Detection option controls the angle detect function.

Their values are shown in Figure 8 below:



Piston Rod Forward values

Limit Detection values

Angle Detection values

Figure 8

Caution: Please consult Shenzhen Antmed Co. Ltd. or an authorized dealer before changing the value of the Limit Detection option or the Angle Detection option.

Home Screen

The home screen (Figure 9) is used for program, arm and injection operations. During the procedure, the injection phases are visible on the screen so that operators can see clearly the operation that is carried out.

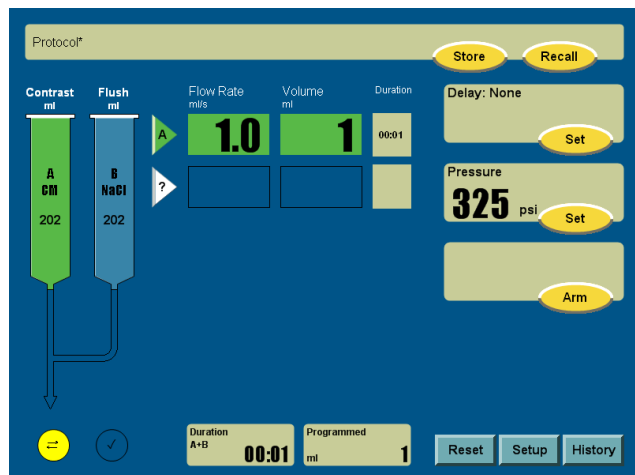


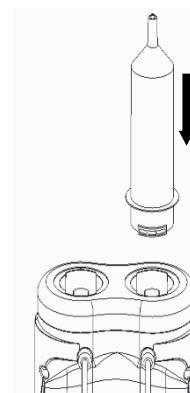
Figure 9

Loading Syringes and Connecting Tubes

On Piston Rod Forward Auto Setting:

With the injector head facing upwards:

1. Press the Backward key to retract the piston rod
2. The flange of the syringe must be aligned with the groove of the syringe head
3. Insert the syringe
4. Turn the syringe 1/4 way clockwise. Make sure that the syringe is fully locked
5. The piston rod will move forward automatically when the syringe is properly mounted.

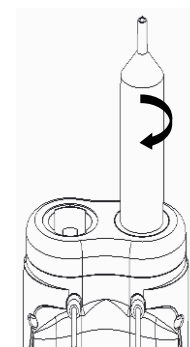


Note: The automatic forward moving can be canceled by selecting Manually instead of Auto in the Piston Rod Forward setup frame on the home screen.

On Piston Rod Forward Manual Setting:

The piston rod will not move forward automatically when the syringe is properly mounted. To expel air, operator must manually press once the Forward keys on either side of the Syringes A and B, air will be expelled at the rate of 1 ml/sec. To increase the rate up to 9.9 ml/sec, press the Accelerating key while air is being expelled.

Press once the Backward keys on either side of the Syringes A and B on the injector head screen and then the process of filling contrast media / saline will proceed.



Note: The process of expelling air and filling contrast media can also be done manually by turning the manual advance/retract knob. Turn the knob towards the direction indicated on the symbol of the knob to turn forward or backward to expel air or fill the syringe.



WARNING: Air embolism may cause injury or even death to patient. Make sure that air is completely expelled out of the syringes, tubes and needles.



WARNING: The use of damaged disposable products may cause injury or death to patient and operator. DO NOT use damaged disposable products. Examine all disposable products before operating the device.



WARNING: When there is a blockage in the connecting tube, the disposable syringe may cause leakage or breakage. Please only use disposable products and accessories recommended by Shenzhen Antmed Co. Ltd.

Caution: When the tube is connected to the syringe, it is necessary to expel air first manually and then make the fluid flow slowly in the tube. If you fail to see the fluid flow clearly, it is an indication that there may be air or air bubbles in the tube.

Caution: Keep the syringe upward while filling contrast media so that air is accumulated at the tapered area of the syringe and easily expelled. Prior to the injection, turn the injector head downward such that in the unlikely event that there is residual air bubbles in the syringe, it will remain in the syringe barrel.

Caution: To reduce the risk of air embolism, make sure that one operator is appointed to fill the contrast media during the entire process. In case of an interruption, the operator must make sure that there is no air in the fluid tube.

Caution: DO NOT try to expel air in the syringe by tapping the syringes.

Caution: Non-sterilized disposable products may cause patient infection. Ensure that all disposable products to be used are sterile. DO NOT save and use unpackaged syringes, tubes and/or needles.

Caution: Using disposable products in the treatment of multi-patients may cause biological contamination. Therefore, do not use disposable products labeled “single use only” multiple times.

Caution: Improper syringe loading will cause injury to patient. Make sure that the syringe is properly and completely loaded onto the injector head. The Piston rod should be latched onto the syringe piston securely. Improper latching will cause syringe damage, leakage or injection failure.

Caution: It is strongly recommended that you use the filling tube, transfer set or fill spike produced by Shenzhen Antmed Co. Ltd. The filling tube can reduce the absorption of air bubbles.

Caution: Standard and careful operation is fundamental in the effort of minimizing the probability of air embolism.

Filling Syringe

1. Syringe A is for the filling of contrast media. Syringe B is for the filling of saline.
2. Keep the syringe head upward while filling
3. Press the Forward keys for both syringes until both syringes indicate they are at 0 ml position
4. Connect the sterile fill tube or spike to the Syringes and then press the Backward key to fill the contrast media into Syringe A and fill saline into Syringe B. Syringe A is for the filling of contrast media. Syringe B is for the filling of saline
5. Press the Forward key to expel air or press the Backward key to continue filling the syringe
6. Attach the connecting tube to the syringe
7. Follow your organization's purge procedure. For Y-tubing, to avoid contrast wastage, fill the tube only to the Y connection with contrast and the rest of the tube with saline is recommend. Make sure that there is NO air in the entire length of the tube.
8. Check and confirm the injector base is locked and air is completely expelled. Then, press the Air-Expel Checked key on the injector head screen.
9. Prior to injection, turn the injector head downward and then press the Arm key

Note: If you press the Backward key of either Syringe A or Syringe B, the Air-Expel Checked key will be deactivated. In this case, the operator must re-check that air has been expelled before proceeding with the injection.



WARNING: Make sure that there is NO air in the syringe, tube and needle before starting the injection.



WARNING: Improper syringe loading may cause injury to patient. Make sure that the positioning mark on the syringe is in alignment with that on the injector head. Make sure that the piston rod and the syringe piston are tightly locked. Improper loading will cause leakage, damage and/or injection failure.

Caution: The detachment of the syringe piston from the syringe will affect the sterile status of the syringe, which may lead to patient infection. DO NOT detach the piston from the syringe.

Caution: The contrast media inside the syringe should be used promptly to avoid bacterial contamination. DO NOT use the syringe left with contrast media/saline for the next patient procedure.

Heating Sleeves

Attached to the injector head of ImaStar CT Dual Injection System is a pair of heating sleeves. After both syringes have been properly mounted and filled with appropriate contrast media/saline solution, apply the heating sleeves to both syringes to help maintain the temperature of the contrast media in the syringe and the saline solution at body temperature.

Injection Programming

Home screen will display the last program entered. If no prior program was saved, the Home Screen will display as follows and shown in Figure 10:

- Parameters is set to for Contrast injection (Green)
- Flow rate: 1.0 ml/sec
- Volume: 1 ml
- Duration: 1 second
- Delay: None

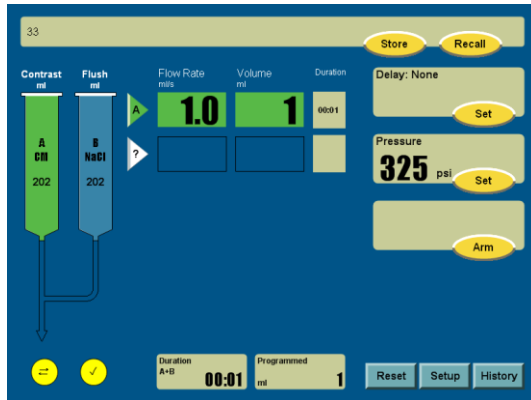


Figure 10

Press the green triangle A to see the options for first phase (Figure 11). Options are:

1. Test Injection
2. Contrast A (Flow Rate and Volume fields are Green)
3. Flush B (Flow Rate and Volume fields are Blue)
4. A% B% (for simultaneous injection)

Please refer to the respective sections in the manual for more instruction on how to set Test Injections and simultaneous injections.

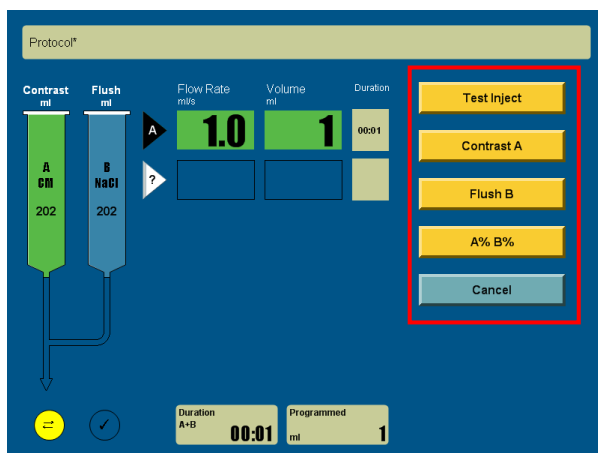


Figure 11

Entering Flow Rate and Injection Volume:

Press on the field for each parameter to input the desired numbers accordingly. A message above the keypad on the right of the screen provides the parameters range for your selected field.

Press the Enter key to confirm the selected value, press << to delete the value just selected, and press the Cancel key if you want to start over for the selected field (Figure 12).

When the Flow Rate, Injection Volume and Delay time are entered, the corresponding numbers are displayed on the screen.

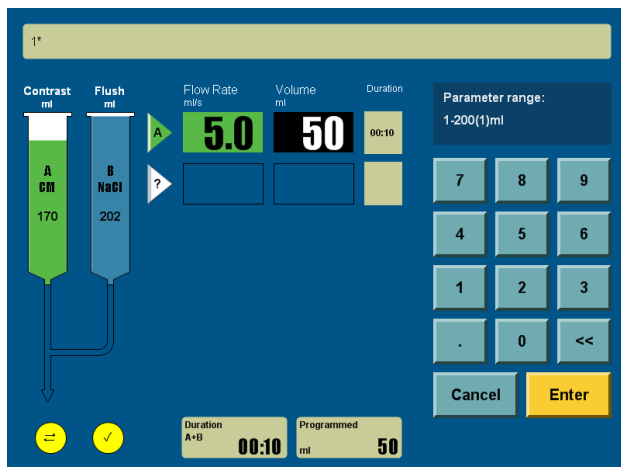


Figure 12

Multi-Phase Programming:

To set up the next Phase, select the white triangle with question in the middle on the next row. A list of function choices available to perform for the next phase is listed on the right side of the screen. Choose the desired function for the next phase and input value as required (Figure 13).

For more information on each of the phase functions, refer to the respective description under Phase and Delay Options section in this menu.

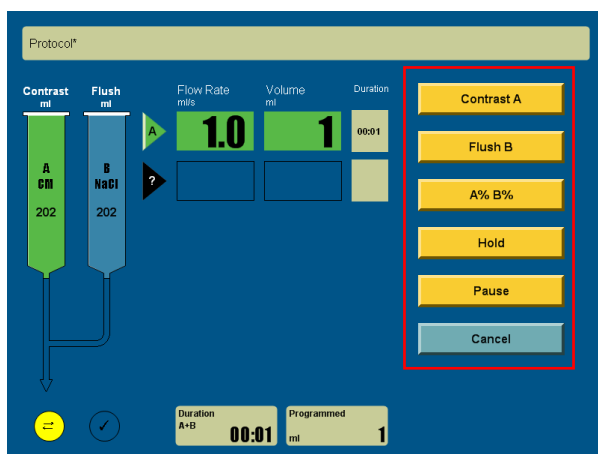


Figure 13

Connect to Other Imaging Equipments

ImaStar CT Dual Injection System supports to connect to other imaging equipments. The Imaging System Interface (ISI) is an option that allows the injector to interface with a CT scanner (Figure 14). The injector interacts with the scanner through a direct cable connection under CAN protocol. Depending upon what mode of operation the scanner is in, it can allow the scanner to automatically request the initiation of an injection, or permit the injector to automatically request the initiation of a scanning procedure.

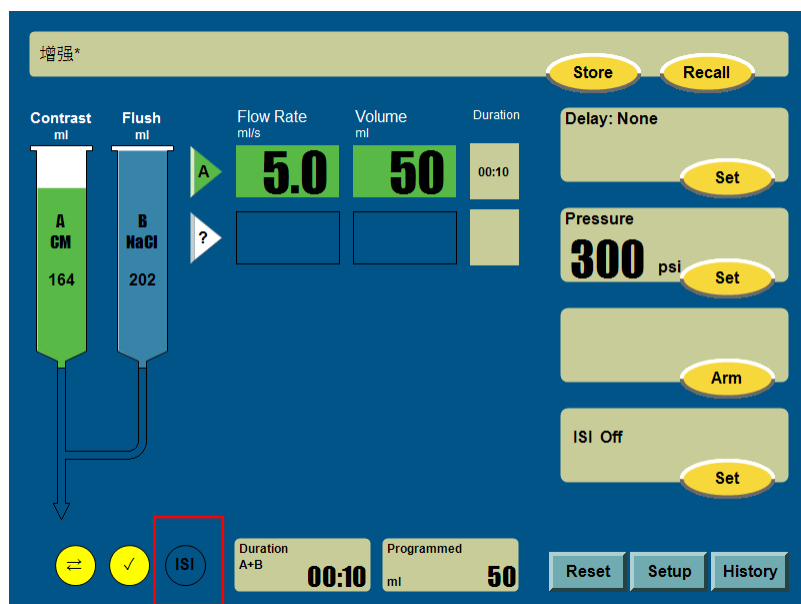


Figure 14

Note: The scanner can not override any injector operation that is considered safety critical; for example, check for air, hold during an injection or stopping an injection.

Note: The scanner manufacturer and/or user must make the final determination of the mode of operation for the coupled injector and scanner. The scanner manufacturer is responsible for providing operation instructions for thier system.

Chapter 4 Arm and Inject

Before arming, please ensure:

- The injector base is securely locked
- Air has been purged
- The injection programs are correctly set
- Check the connection to the connecting tubes
- Confirm the Air Expelled Checked button is illuminating GREEN
- Injector head is turned downward



WARNING: Air embolism may cause serious injury or death to patient. Make sure that all air has been expelled before connecting the device to the patient.



WARNING: Excessive Flow Rates may cause damage to the patient. Make sure that the Flow Rate has been correctly set before Arming the syringe.



WARNING: Syringe piston retraction may cause patient injury. After injection is complete, remove connection from patient promptly to avoid accidental retraction of the piston.



WARNING: Extravasation can cause serious injury to the patient. Please follow good clinical practices and operational instructions to reduce the probability of spillage.



WARNING: Injury may occur to the patient if the high-pressure injector is moved after it is connected. Make sure that the injector base is locked to stop the injector from moving.

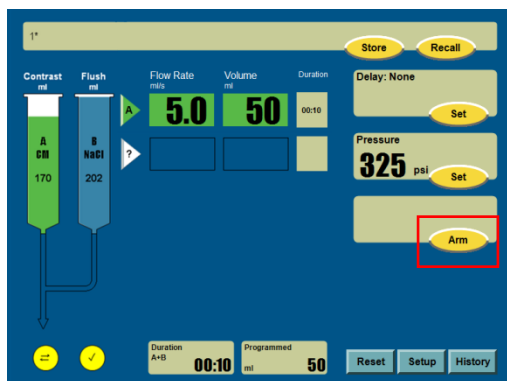


WARNING: Patient injury may result from a system malfunction. If a system malfunction occurs, immediately turn off the injector and detach the injector from the patient.

Note: Medical disposable items should not be reused. Please dispose of them properly after use. Detach the syringe when the program is completed. Remove the syringes and tubes from the injector head and dispose of them properly.

Arm

Press the Arm key before starting an injection (Figure 15). No part of the program can be edited after the injector has been armed.



Before armed

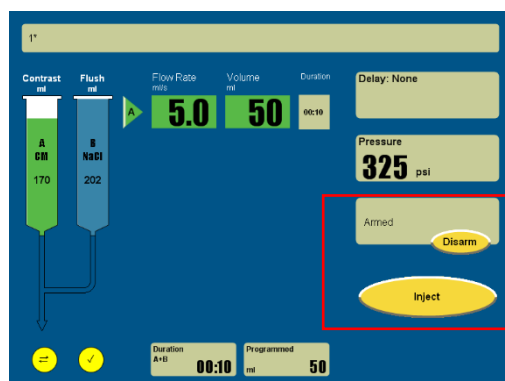


Figure 15

After armed

Note: The device will display a message prompt before the operator can arm for injection (Figure 16). Operator must confirm air has been expelled in order to inject.

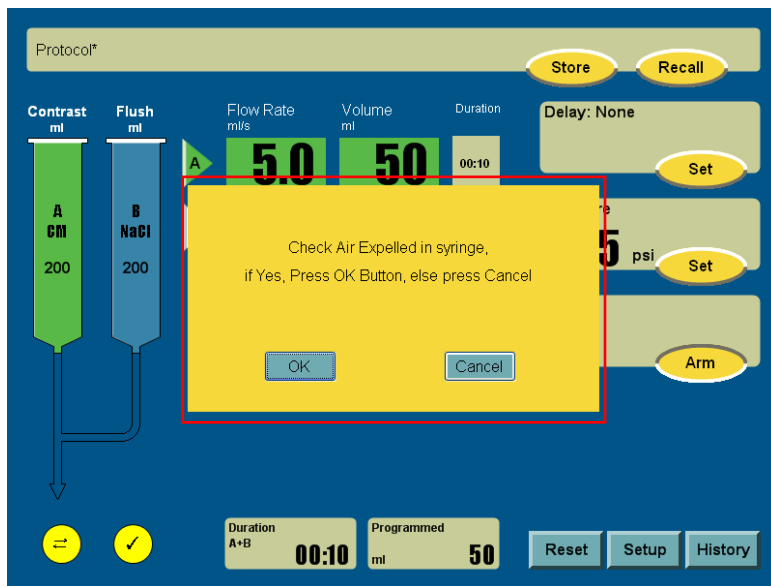


Figure 16

Angle Detection Safety for Injection

The device will detect the angle before injection. The arm for injection is not allowed if the injector head is not facing down (Figure 17). The operator can arm for injection when the injector head detected is facing down (Figure 18).



Figure 17



Figure 18

Insufficient Volume for Injection

If there is insufficient volume of contrast media based on the programmed parameters set, the system will prompt a message on the display screen (Figure 19).

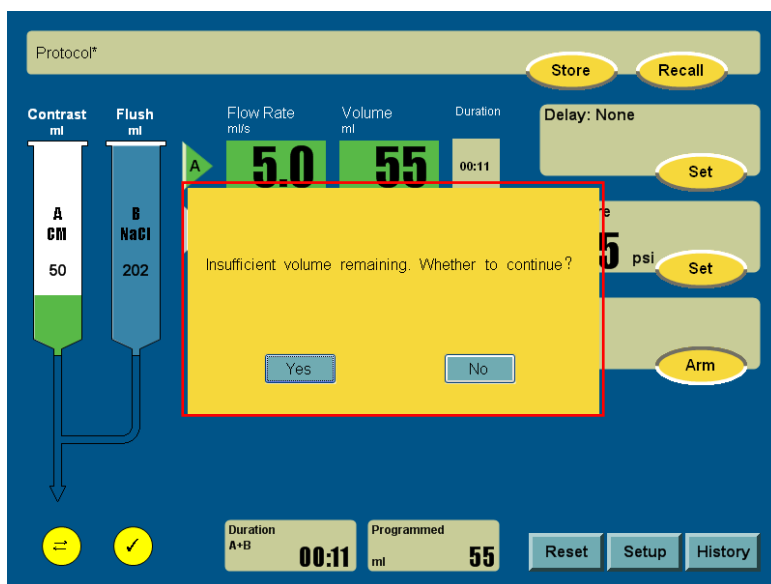


Figure 19

Disarm/Cancelling Arm

Press the Disarm key on the screen or the Stop button on the injector head screen unit and the system will exit from the Armed status (Figure 20).

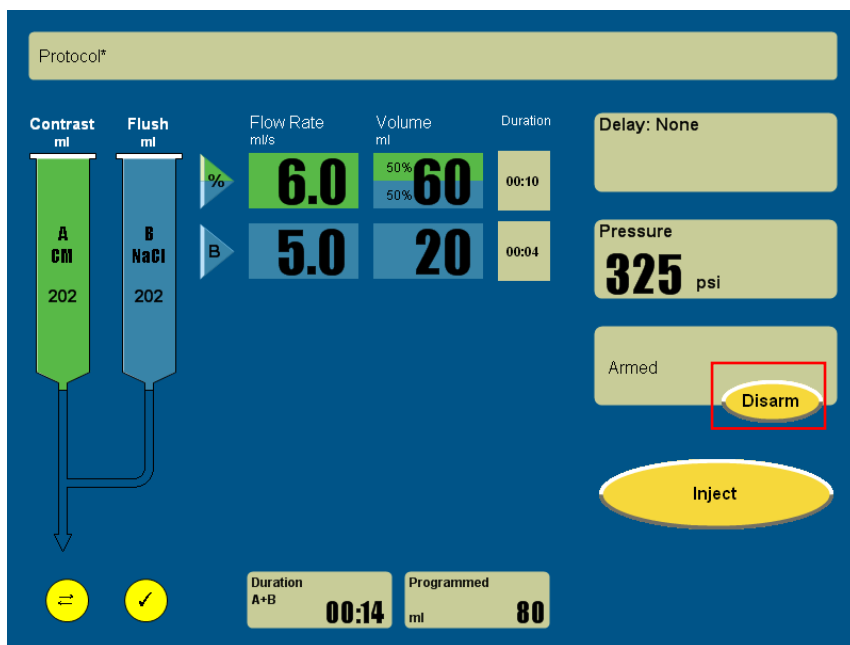


Figure 20

Injecting

When the injector is Armed, press Inject on the display screen or press the button on the Hand-Switch to start injection. Press Hold on the display screen or press the button on the Hand-Switch again to suspend the injection and put the injector in the Hold state.

During injection, press Hold on the display screen to Hold the injection (Figure 21). Injection will be suspended and the system will enter into a Hold state.

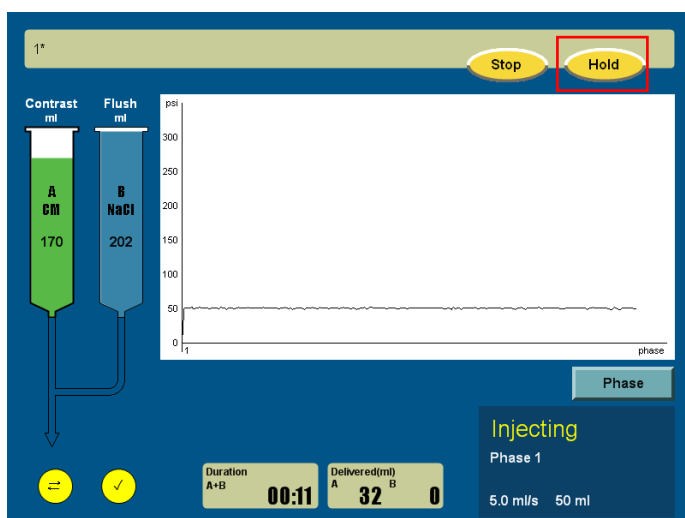


Figure 21

To continue with the injection, press the Start key (Figure 22).

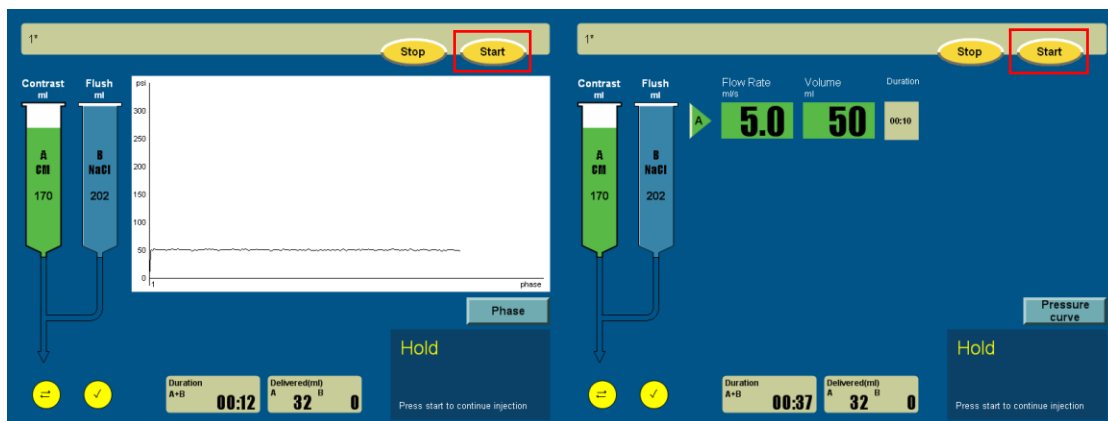


Figure 22

Alternatively, if press the yellow Hold/Start button located on the injector head screen unit, injection will hold and the system will enter into a Hold state. To continue with the injection, press the yellow Hold/Start key. The operator will not be able to change or edit the injection protocol when the system is on Hold.

If you have set an injector Delay Time in the program, to start the program, press Inject and the Delay Time counting will begin. When the counting reaches the Delay Time set value, the injection will start automatically.

During the injector Delay Time counting, if the Hold key is pressed, the Delay Time counting will stop. Counting will start again when you press the Start key. If the Stop key is pressed during the injector Delay Time counting, the Injection program will stop completely.

During Injection

Control Room Unit screen will display:

- Injection Pressure Graph
- The duration of the injection
- Current injection phase
- The contrast and saline volume that has been injected
- The contrast and saline volume that is left

While in the Injection Pressure Graph screen (Figure 23), if the Phase key is pressed, screen will change to display the Injection program (Figure 24). Press the Pressure Curve button on the Injection program screen to go back to the Injection Pressure Graph screen.

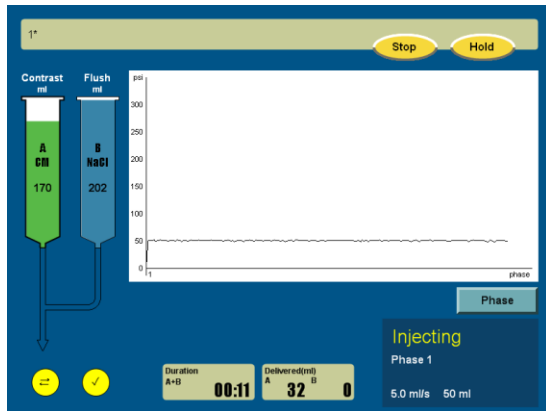


Figure 23

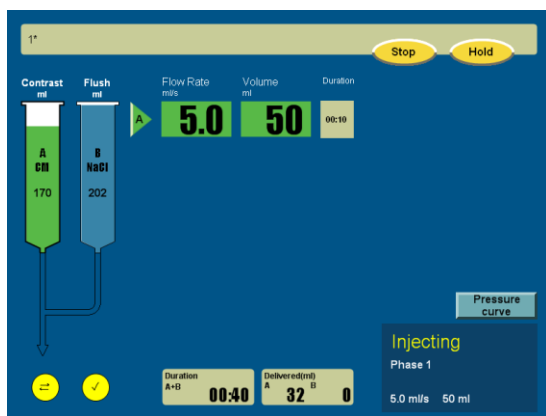


Figure 24

Scan Room Unit:

- After Arm key is pressed, the manual advance/retract knob for Syringe A will flash green and Syringe B will flash blue
- When the injection is underway, the corresponding manual advance/retract knob will stay illuminated while the syringe that is not currently injecting fluid to the patient, its illuminated manual advance/retract knob will remain off.

Programs with Test Injections

During the injection program, if a test inject has been set, the program will start with the test injection, when the test injection has been completed, the injector will go into HOLD phase.

To continue with the injection program, press Start.

Injection Completion

When the injection is completed, the home screen of the Control Room Unit will display as in Figure 25 and 26 below:

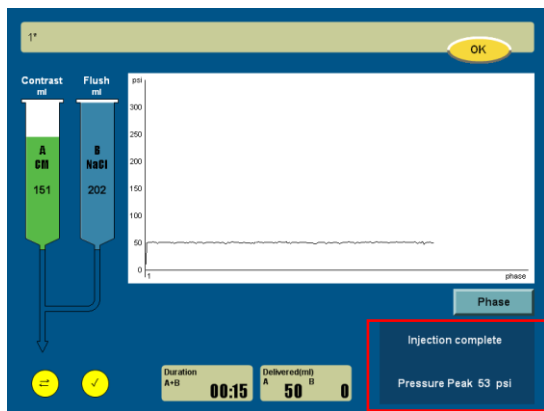


Figure 25

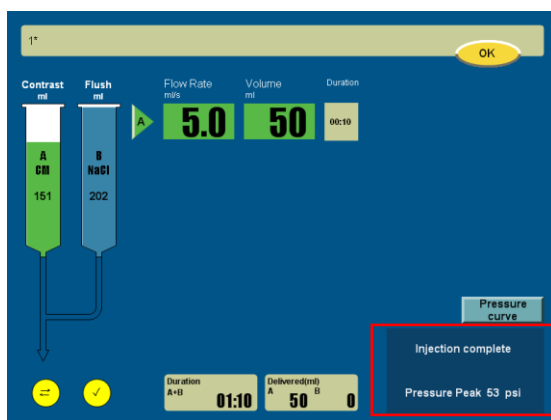


Figure 26

Stopping an Injection Program

There are three ways to stop an injection while it is underway:

1. Press the Stop key on the home screen of the Control Room Unit
2. Press the button on the Hand Switch
3. Press the red Stop button on the Scan Room injector head screen Unit

Injection History Records

Press the History key on the bottom right of the home screen and all saved Injection records are listed in a chronological order (Figures 27 and 28) .

Press the Arrow key to view the next page of records. Press the OK key to exit the current screen.



Figure 27

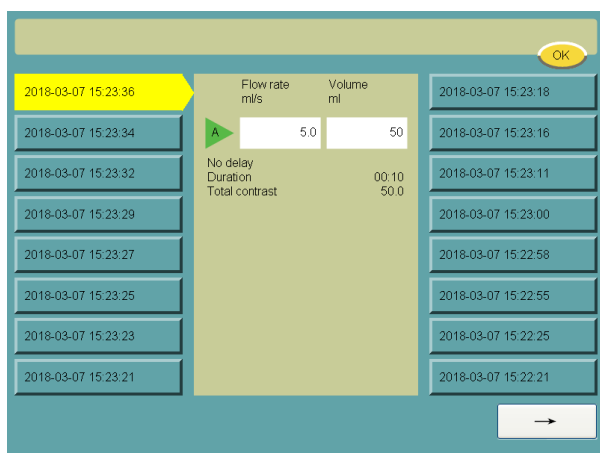


Figure 28



WARNING: After the injection is finished, ensure that you turn the injector head upwards before detaching the syringes.

Chapter 5 Pause and Delay Options

Test Injection

Use a Test Injection to test source, injection rate and injection volume. Test injection option can only be selected before entering a full injection program. When setting up a test injection, program the test injection as if a normal injection program phase.

Press triangle to select test inject (Figure 29), default is Flush B (blue). To change to Contrast A, press the phase triangle again to select contrast (Test Inject A) or Saline (Test Inject B).

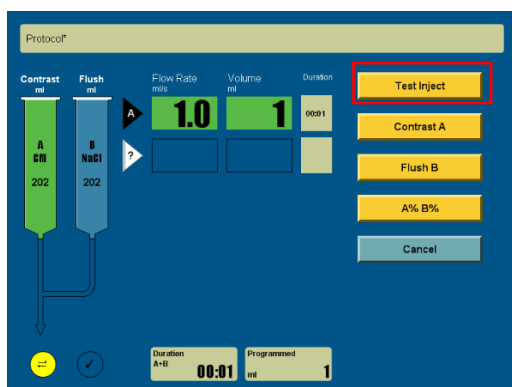


Figure 29

After entering test injection program (Figure 30), follow instructions in the Injection Programming section in this manual to enter desired program. When complete, see instructions in Chapter 4 to Arm and Inject.

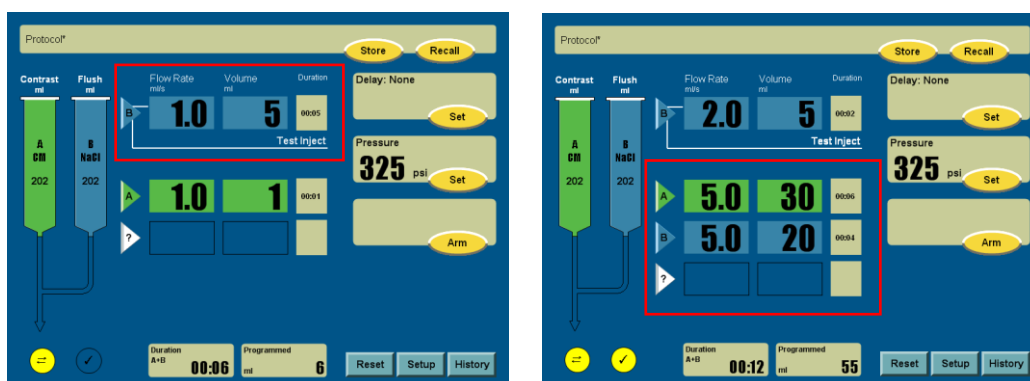


Figure 30

Simultaneous Injection (A% B%)

To program a simultaneous injection for a procedure, Press a triangle for the phase desired. In the list of options on the right of the screen, press A% B% (Figure 31). Then press on the desired simultaneous injection ratio (Figure 32). After the ratio has been selected, a set of default Flow Rate and Volume parameters will appear for that phase. To change the Flow Rate and Volume, press on the field for each parameter to input the desired numbers accordingly (Figure 33). A message above the keypad on the right of the screen provides the parameters range for your selected field. Press the Enter key to confirm the selected value, press << to delete the value just selected, and press the Cancel key if you want to start over for the selected field (Figure 34). Press the white triangle with question mark to add another phase to the injection program (Figure 35).

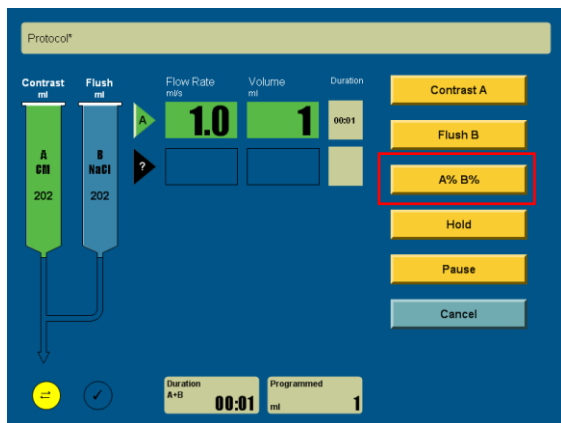


Figure 31

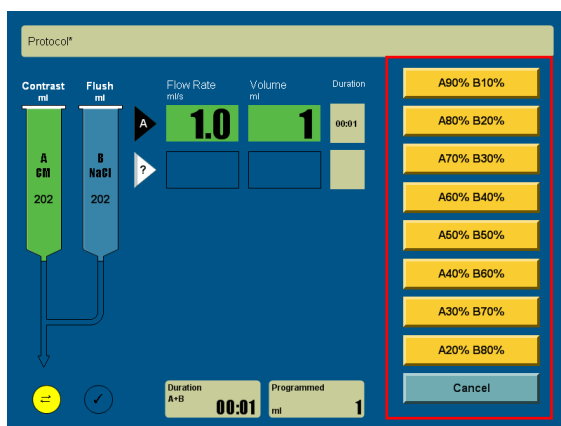


Figure 32

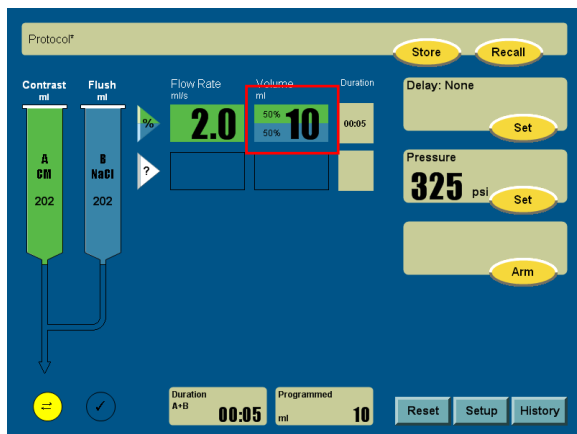


Figure 33

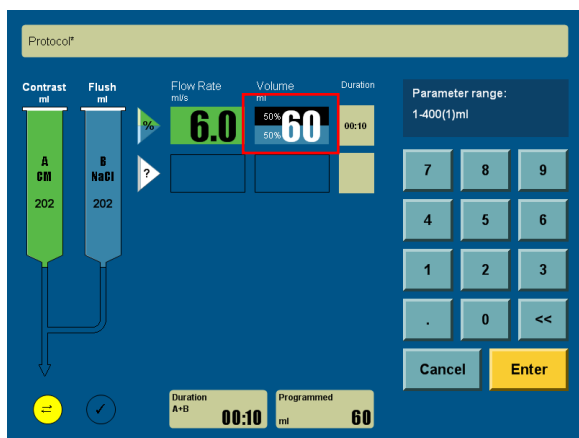


Figure 34

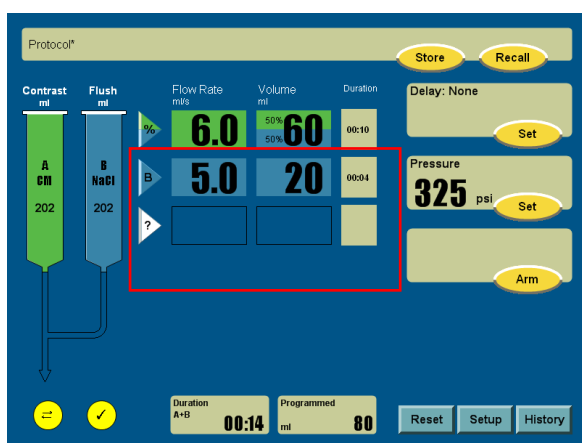


Figure 35

Hold and Pause

Hold and Pause can be edited under the circumstance of multi-phase program, see Figure 36.

Pause means the injection will temporary stop for as long as you have set the duration to be. After the set duration has passed, the injection will continue to the next programmed phase automatically. The maximum Duration of Pause is 15 minutes. The system will not allow an operation to set a pause time that is over 15 minutes, once the set Pause time has been reached, the injector will continue with the remaining injection phases.

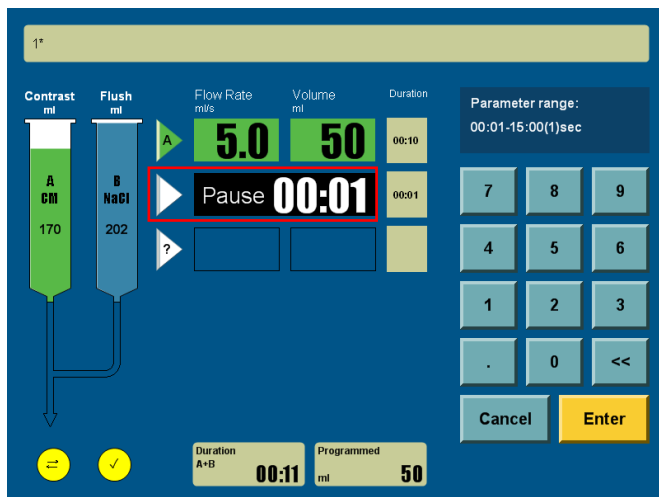


Figure 36

Hold means the injection process will be stopped until the operator takes further action.

The operator can set a Hold phase into injection program as in Figure 37 below.

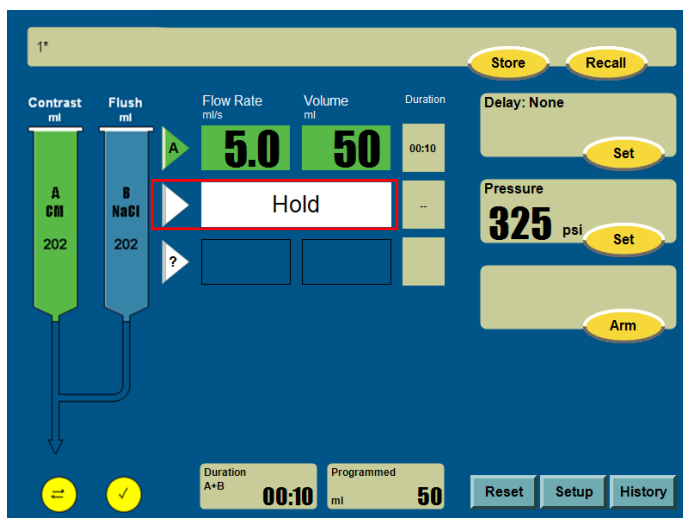


Figure 37

The operator can also hold the inject phase during the injection by pressing the Hold key displayed on the screen as in Figure 38. Please refer to **Chapter 4 Arm and Inject: Injecting** for more information.

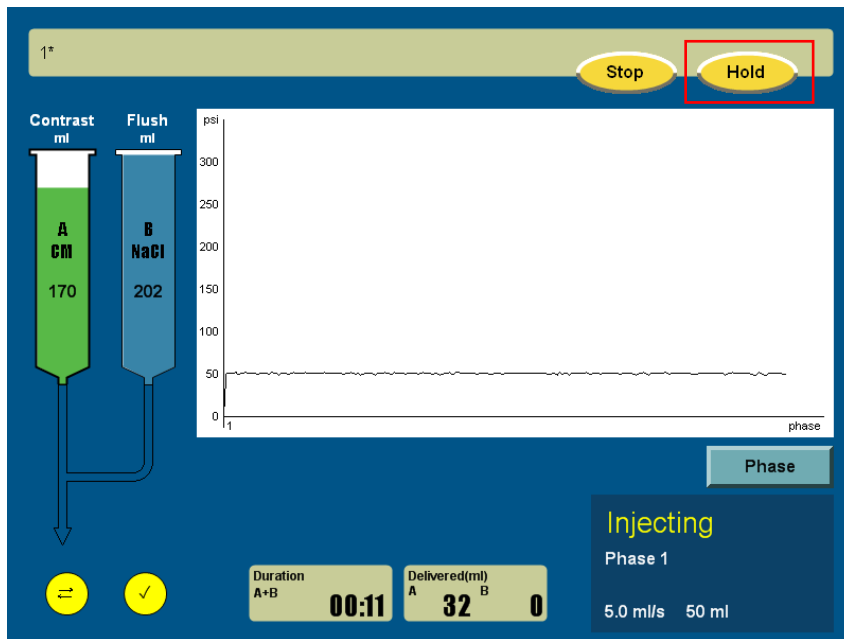


Figure 38

Delay Setup

The operator can set the Delay time with three options: Scan Delay, Injector Delay and No Delay, see Figure 39.

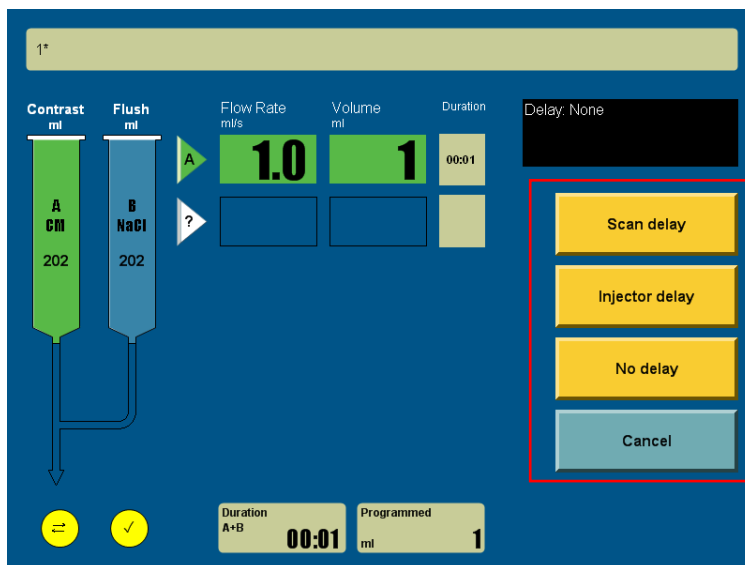


Figure 39

Scan Delay: The scan delay time will start counting after the injection begins, see Figure 40. The time of the Scan Delay will be displayed in the time frame in which the time length gradually increases to the set value in one second increment. When the set value is reached, a prompt tone will be heard.

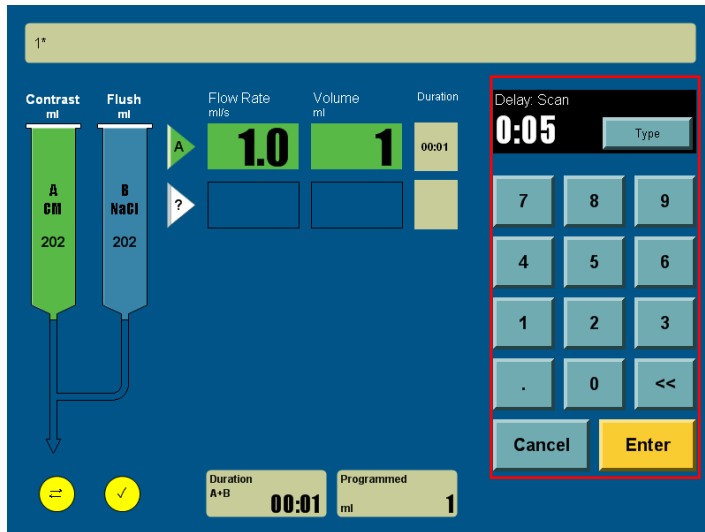


Figure 40

Injector Delay: After the Inject key is pressed, the Injector Delay time starts counting by one second increment, see Figure 41. When the injector delay time has been reached, the injection starts automatically.

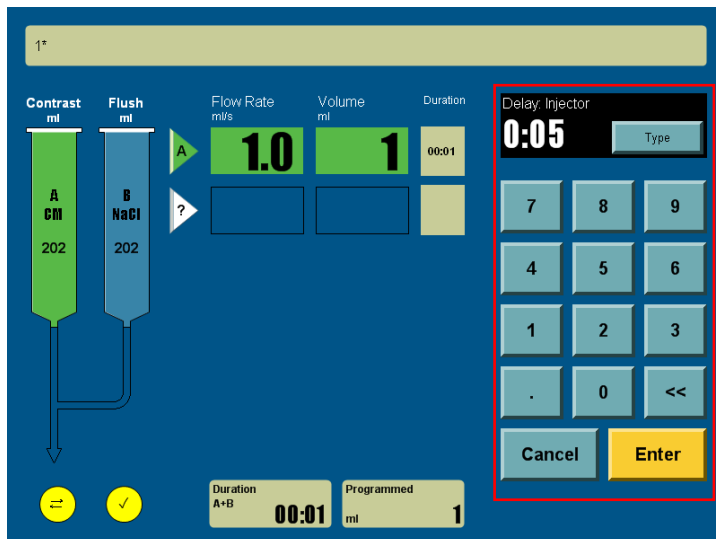


Figure 41

No Delay: If the No Delay is selected, the injection starts the moment the Inject key is pressed. The injection duration will be incrementally counted from the start of the injection.

After setting the Delay type, you can now input a time value to set the Delay Time on the numerical keyboard. If a wrong value has been input, you press the << key to clear the last number entered or press the cancel key to reset a new Delay Time.

System will show a prompt message if Delay time input value is outside of the parameter range allowed (Figure 42).

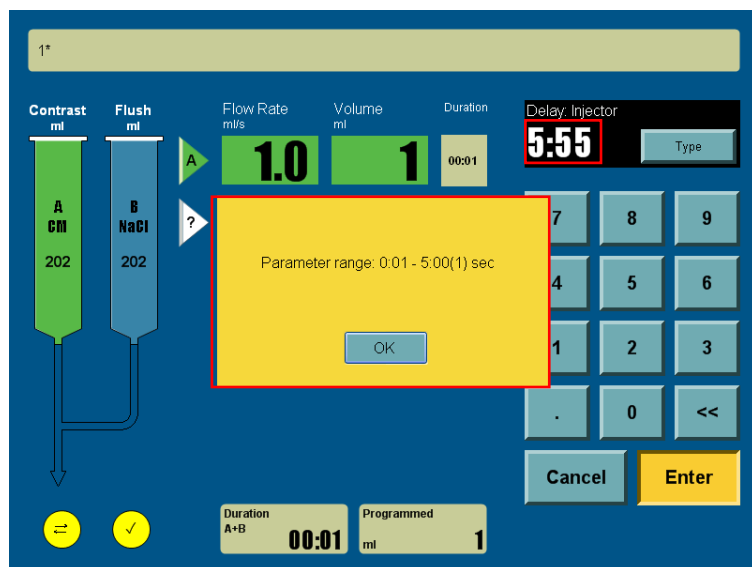


Figure 42

Chapter 6 Storing and Recalling Injection Programs

Storing Injection Programs

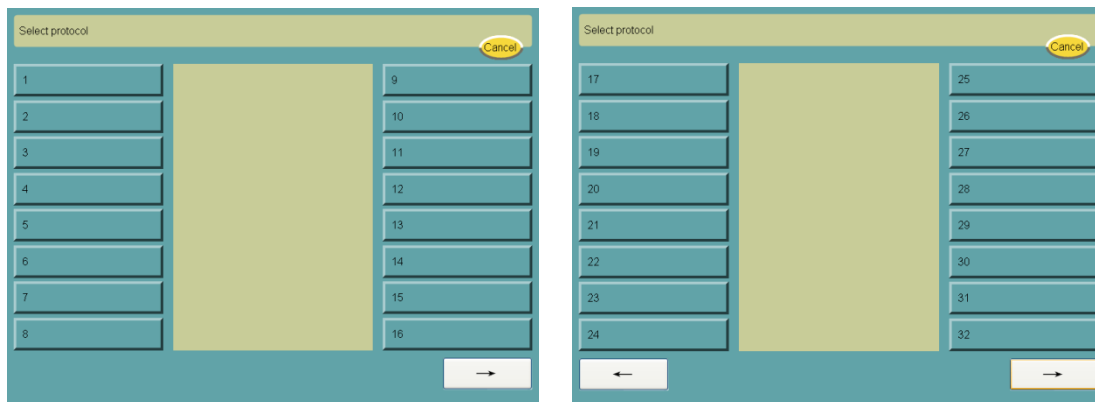
To save and store the program for future use, press the Store key on the top right corner of the screen. The program storing screen will display a digital key board (Figure 43). You can create a new name for the program by using not more than 20 letters. Press << to clear the last letter entered. Press the Enter key to save the program with the new name. If you do not want to save the program, just press the Cancel key on the upper right corner to exit this screen.



Figure 43

Recalling an Injection Program

By pressing the Recall key on the upper right corner of the screen, you can recall the programs you have saved before. All the programs that you have saved before will be listed and displayed, sample screen below in Figures 44. Press the program that you want to select and double check the parameters. If they are what you need, press the OK key to confirm your selection (Figure 45). Press the Delete key to delete the specific program permanently (Figure 46). Press the Cancel key to exit the current screen.



List of Stored Program *Figure 44*

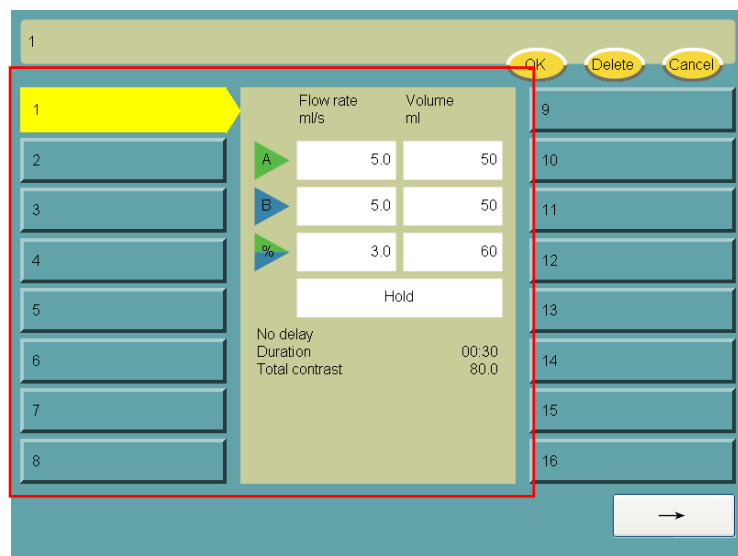


Figure 45

Select one stored protocol

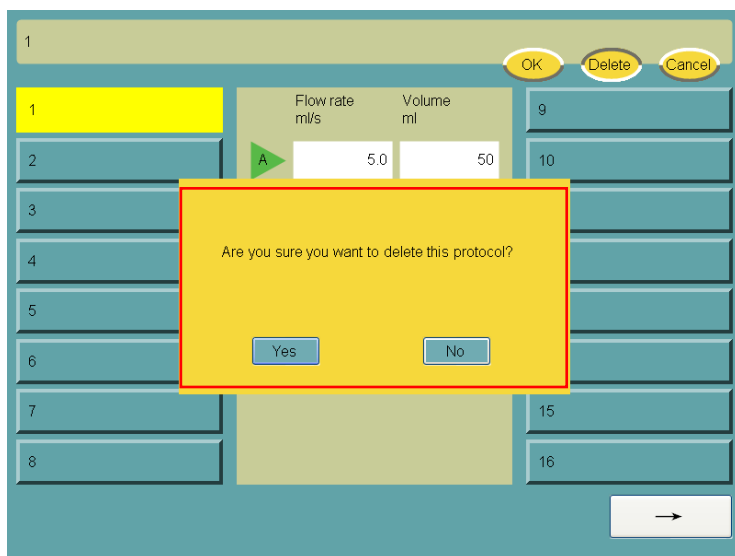


Figure 46

Delete one selected protocol

Chapter 7 Clinical Application - CT, Angio, Cardiac, Injection

ImaStar CT Dual Injection System is a double syringe contrast delivery system needed for advanced clinical CT imaging procedures such as CT, Angio, Cardiac as well as routine Injection. It is available for different modes/protocols and can be configured on the injector for each of the applications – CT/Angio/Cardiac/Injection.

CT: ImaStar CDP injector is a contrast media delivery system indicated for the administration of intravenous contrast media into humans in conjunction with CT scanning (computed tomography). Dual Head Flexibility allows independent injection of contrast and saline, optimize contrast usage and reduce contrast wastage. Simultaneous Flow Feature allows the control of contrast density in both sides of the ventricle, significantly reduces CT artifact and be able to observe the right coronary arteries, right atrium and right ventricle in the same image.

Angio: By using ImaStar CDP injector with multiple phase protocols allows you to optimize the contrast injection for vascular applications. What's more, it allows flushing the arterial supply with saline for organ tissue enhancement and increase the duration of the contrast peak for larger vessel studies. It provides the capability of performing emergency CT non-invasive intracranial vascular imaging for assessment of large vessel occlusions in acute ischemic stroke patients according to the "ship and drip" method, for further decision about initiation of intravenous thrombolytic therapy or referral for endovascular intervention.

Cardiac: ImaStar CDP injector provides 6 injection phases as well the possibility for direct adjustment of contrast concentration with saline. This allows you to perform the popular tri-phasic protocol which consists of 3 phases as pure contrast, diluted contrast and saline which insures the optimal contrast

volume is in the left chambers and the coronary arteries. Simultaneous injection protocol designed for advanced cardiac CTA and Spectral CT imaging exams.

Injection: ImaStar CDP injector with multiple phase protocols is suitable for all other routine CT examinations and contrast injection. The touch screen on the injector allows you to check and adjust the injection protocol according to the patient's clinical conditions.

Chapter 8 Cleaning, Maintenance, Inspection and repair

Routine cleaning, inspection and maintenance of ImaStar CT Dual Injection System is recommended. Below are a set of guidelines for these procedures on a regular basis in order to reduce the chances of problems arising for the device and ensure optimal performance for the overall injection system.

Cleaning and Maintenance

System malfunction may lead to performance failure. For ImaStar CT Dual Injection System to perform efficiently and cost effectively, regular and proper preventive maintenance is needed. Recommendation of regularity and manner of preventive maintenance is provided below, however, depends on how the injection system is used, the types of program performed and how frequently the system is utilized, more scheduled cleaning may be needed.

Recommend preventive maintenance schedule:

Frequency	Task
Every Day	Before and after use each day, clean as recommended by the cleaning guideline below
Once a month	The User should thoroughly clean the entire system and perform an operation check

Note: The local regulations and/or medical facility policies may require that the electrical leakage be checked more frequently. If so, these regulations must be observed.

Note: Failures resulting from lack of proper maintenance are NOT covered under Warranty.

Cleaning the Scan Room Unit:

Caution: If any contrast has leaked into the inside of the injector, proper cleaning should be performed by a qualified technician on site or at the service location.

Note: Residue from contrast media may make ImaStar CT Dual Injection System work improperly. Therefore, clean up or remove the stains on any part of the system by following the instructions and guidelines carefully.

For general day-to-day cleaning, clean all parts with a soft cloth, warm water and a neutral or antimicrobial cleaning agent. Please careful when handling all parts of the device.

Clean all touch screens with a soft cloth or a paper towel that is dampened with a neutral or antimicrobial cleaning agent. Spraying cleaning agent directly onto the surface of the screen may cause damage.

To clean the injector head, piston and syringe interface, please place the injector head vertically upward, DO NOT insert any sharp instruments into this area when cleaning.

- Press the up-arrow keys to advance the pistons fully to the top
- Gently clean the pistons and dry them thoroughly
- Press the down-arrow keys to retract the piston fully back to the home position
- Clean the inner area of the injector and syringe interface
- Clean the injector head enclosure and the Hand-Switch

Cleaning Control Room Unit:

Gently clean all surface areas with a soft cloth or a paper towel that is dampened with a neutral or antimicrobial cleaning agent.



WARNING: Serious injury or death may result from exposure to hazardous voltage which exists inside the system. Disconnect the system from the power supply before cleaning the Control Unit.

Caution: Do not immerse any part of the device in water or let any fluid enter any part enclosure. Do not use excessive water or cleaning agent. Do not use strong industrial cleansing agents or solvents such as acetone and alcohol. Warm water and neutral or antimicrobial cleaning agents is recommended.

Caution: Do not open and device component enclosure. Do not take apart the device. Check regularly to ensure that the cable and the device enclosure are not loosened, warped, dented, deformed and/or broken. If maintenance and repair are necessary, contact the Service Center of Shenzhen Antmed Co. Ltd.

Note: When cleaning the system, please follow your organization standard protocol to avoid fluid contamination.

Inspection

Follow the procedures below for daily inspection of the ImaStar CT Dual Injection System and components. If you have detected any problems, either repair the components by a qualified technician or call Shenzhen Antmed Co. Ltd for maintenance services. Do not use the system until the problem is corrected.

Scan Room Unit:

- Carefully inspect the enclosure for any damage or cracks that could allow fluid to leak inside or weaken the structural integrity of the unit.
- Inspect all the cables connected to the unit. Look for cuts, cracks or other obvious damages. Make sure that all the connections are correct and fit properly.

- If there is any residue from contrast media or saline in or around the interface of the syringe connection, clean according to the cleaning guidelines.
- Inspect the base stand and support arms for any cracks and/or other defects which could weaken the structure.
- Make sure that all the mounting bolts and nuts are securely tightened.
- Make sure that the locking and stopping mechanism of the casters function properly and roll smoothly.
- Inspect all the rotation shafts. Verify that the injector head moves freely and the rotation angle does not exceed 320°.
- Verify that the power supply is connected correctly to the injection system

Note: Please observe all relevant technical practices, local and national laws and regulations concerning the safety installation and maintenance of the electrical cables.

Control Room Unit:

- Inspect all the cables connected to the Control Room Unit. Look for cuts, cracks and/or other obvious damages. Make sure that all the connections are correct and fit properly.
- Verify that the power adapter is connected correctly.

Wireless Communications Unit:

- Inspect the extension cable for the wireless communication unit. Look for cuts, cracks or other obvious damage. Make sure that all the connections are correct and fit properly.
- Verify that the transmitter and the receiver of the wireless communication unit are functional.



WARNING: The voltage inside the injector can cause serious damage or even death.



WARNING: Serious injury or death may result from exposure to the high voltage inside the system. Disconnect the system from the power source before cleaning or maintaining the device. Make sure that the system is completely dry before connecting it to the power source.

Caution: Improper cleaning may cause equipment damage. Do not soak or immerse in water or cleaning agent. Avoid water leakage into the system components.

Caution: If any contrast media has leaked into a subassembly or onto a component of the system, contact a trained engineers or Shenzhen Antmed Co. Ltd. When cleaning on site, pay special attention to avoid any damages to the circuit board and component parts.

Caution: Make sure that all the labels about the system safety and WARNING are not damaged.

Operational Inspection

The inspection of the basic operations of ImaStar CT Dual Injection System should be included as an integral part of the routine maintenance by qualified operator with trained skills for the operation inspection. The following procedures represent a recommended sequence of the activities for a typical inspection of the systematic functions. Follow the procedures carefully for the inspection. If any problems are detected, please contact a qualified technician or Shenzhen Antmed Co. Ltd.

Note: Any problem or hazards detected should be repaired and or resolved before using the injection system for operation again.

Safety and Warning Labels: Make sure that all the safety and warning labels concerning the system are legible.

Follow the procedures below to ensure the system is functioning properly:

1. Turn on the power to the system and wait for the home screen to appear on the screen.
2. Press Forward/Backward for both Syringe A side and Syringe B side. The piston rods should move forward/backward smoothly. This is to confirm that the piston rods of Syringe A and Syringe B function well.
3. Prior to preparing the program, test the syringe performance.
4. On the setup screen, make sure the Piston Rod Forward is on "Auto".
5. Install the syringes and the piston rods should start expelling air automatically. Detach the syringes and the piston rod should start retracting automatically
6. Input the following value and then Save the program:

	Flow rate (ml/s)	Volume
Phase 1 Syringe A	10	20
Phase 2 Syringe B	2.5	10
Phase 3	Pause for 15 seconds	
Phase 4 Syringe A	5	10
Phase 5 Syringe B	0.1	1

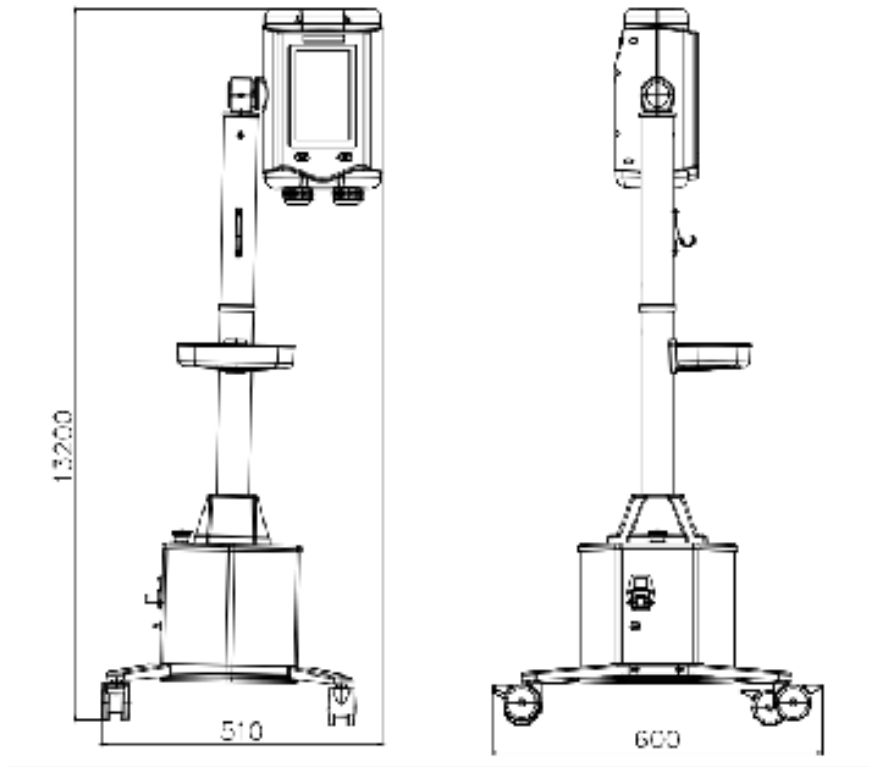
7. Press the Air-Expel Checked button
8. Turn injector head downwards
9. Press Arm and verify if air has been expelled
10. Press Inject
11. When injection is complete, press OK key to return to the Home screen
12. Enter the injection history screen after the injection is finished. Select the most recent saved record to review the Injection program just finished.
13. The actual total injection volume and the total set volume should be consistent with the value 41 ml
14. Press OK key to return to the Home screen
15. Add a 15-second injector Delay to the program
16. Press Arm and verify if air has been expelled
17. Press Inject
18. System will wait for the delay time to be over, the injection will start automatically
19. When the injection ends, turn off the injector

Malfunction repair

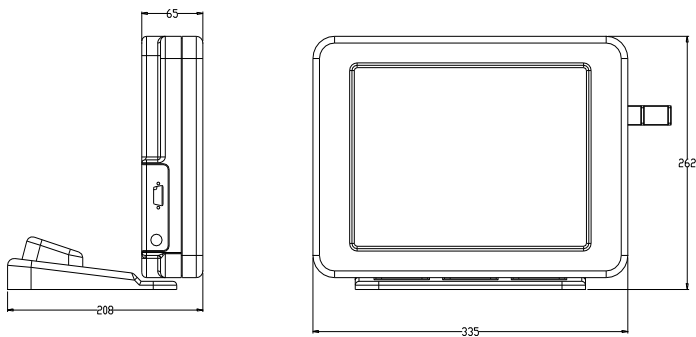
Phenomenon	Approach
After the device is powered on, the power box indicator is off.	Check if the power supply is normal; Check the fuse box on the rear panel of the power box.
Press the head forward or back button of the device, and the piston does not move.	Re-boot after power off; The motor driver has an error.
Pressure protection When the buzzer sounds and the status prompt area prompts: Excessive pressure, stop injection	Indicates that the actual injection pressure is already greater than the set pressure limit, in which case: Check that the pressure limit is set too low. If it is too low, adjust the high pressure limit or decrease the injection rate (if the diagnostic requirements are met). If the above test is normal, please check the infusion channel for distortion and obstruction. If so, you need to divert or replace the infusion channel. If the above test is normal, check if the needle placed in the subject is misaligned. After the above detection, the problem of pressure overrun can be basically eliminated.

Chapter 9 Product Specifications

Scan Room Unit (Injector)



Control Room Unit



Weight

Scan Room Unit weight: approx. 23.5KGS

Control Room Unit weight: approx. 5KGS

Power

AC cable: 1.8 meters

Injector power cable: 10 meters

Syringe Specifications

Syringe A

Syringe Volume: 200ml

Syringe B

Syringe Volume: 200ml

Injection Specifications Available

Volume: Syringe A:

1 ml-200 ml

Volume: Syringe B:

1 ml-200ml

Flow rate (configurable)

0.1 -10 ml/s, in increments of 0.1 ml/s

Pressure Limit

325 PSI

Delay Time

1-300 s, in increments of 1/s

Pause Phase

1-900 s, in increments of 1/s

Injection Phase

6 injection phases

Storage Capacity

Storing up to 2000 injection program records. Each record can contain 6 injection phases. The storage records will be kept even when the system is power-off.

Piston Rod Control

Forward/Retract:

Piston motion controls

The lowest speed:

1 ml/sec

The highest speed:

9.9 ml/sec

The retract Speed :

8 ml/s

EMI/RFI

ImaStar CT Dual Injection System complies with IEC 60601-1 and IEC 60601-1-2 Standards.

Power supply requirements

- 100 — 240 V~
- 50/60 Hz
- 200 VA

Leakage Current

- Injector Leakage Current: $\leq 100 \mu A$
- Patient Leakage Current: $\leq 10 \mu A$

Ground Connection

The resistance from the earth pin of the AC plug to any exposed metal part on the injector should be less than 0.1 ohms.

Environmental Requirements

Non-Operating (transportation and storage)

- Temperature: $-20^{\circ}C$ to $70^{\circ}C$
- Humidity : 5% to 100% R.H., non-condensing
- Air Pressure : 48 kPa to 110 kPa

Performance Considerations

The performance of the device will be affected if the device is running beyond the following conditions:

- Temperature: $+5^{\circ}C$ to $+40^{\circ}C$
- Humidity : 20% to 93% R.H.
- Air Pressure : 69 kPa to 110 kPa

Classification

According to Standards IEC 60601-1 for protection against electrical shock, ImaStar CT Dual Injection System injector is designed as Class I equipment with a Type B applied parts.

Type B refers to patient applied part: Class I equipment identifies the devices to protect the ground connection wire, which will prevent the contact metal parts from being shocked even in a defective insulation condition.

The injector belongs to the common equipment of the IPX1 grade for Protection against Vertically Falling Water Drops.

ImaStar CT Dual Injection System is classified as a medical equipment that cannot be used in an environment with flammable anesthetic gas mixed with air or with oxygen or nitrous oxide.

The Classification of the operation mode for ImaStar CT Dual Injection System is in the category of continuous operation.

Chapter 10 System Installation



WARNING: The voltage inside the injector may cause patient injury or even death. Make sure to use extension cables, adapters, converters and multiple sockets of the right power ratings.

Moisture and condensation may cause electrical damage to the injector. Do not use the device immediately after it has been moved between extreme temperatures or environments. Make sure to only operate the device when it has been adjusted to room temperature.

Injector damage can occur as a result of incorrect voltage. Before connecting the injector to a power source, please verify:

- The voltage and frequency marked on the serial tag on the back of the injector matches the voltage and frequency of the power source.
- The power cable plug of the injector matches the socket of the power outlet appropriately.
- The wireless communication unit of the injector is correctly installed.

Note: Proper system installation is important. For assistance, contact the Service Center at Shenzhen Antmed Co. Ltd. or an authorized dealer.

Note: Cable and wiring must meet the local and national laws and regulations and the relevant requirements of your medical facility.

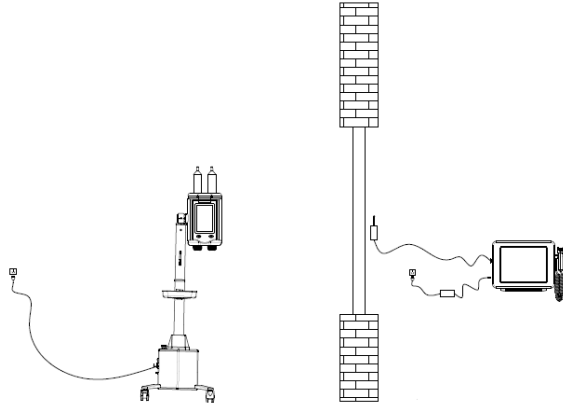
Unpacking

Before installation, please confirm that the following parts are present in the packaging. The standard package contains:

- Scan Room unit
- Control Room Unit and Adapters (100-240V~)
- Wireless communication box
- Power box
- Extension Line
- Hand-Switch and its installation accessories
- One syringe kit (200ml and 200ml syringes)
- Operating Manual
- Certificates and quality inspection reports

Installation

Before installation, identify all the connecting points or interfaces of the following components. Read through this Operating Manual concerning the features, specifications and requirements of each component. In addition, observe local laws and regulations.



Installation of Wireless Communications

Connect the wireless communication unit with the touch screen display unit interface.

Note: Your medical facility, local and national safety regulations should be observed.

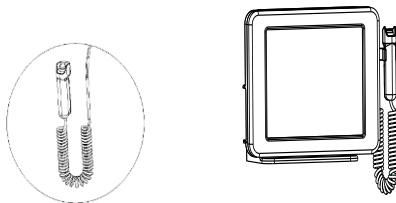
Installation of the Control Room Unit

1. Place the control room components close to the AC power outlet.
2. Insert the power cable into the Control Room Unit socket.
3. Ensure the unit power cable plug conforms to the electric outlet and voltage of your facility.
4. Insert the AC power cable plug into the AC socket.
5. Turn on the power of the Control Room Unit.
6. Run the Operational Inspection test to review the injector is performing according to the Operational Inspection protocol in this Operating Manual.

Hand-Switch Installation

For convenience, the Hand-Switch can be installed in the following positions.

1. For the Control Room Unit, place the Hand-Switch on the display holder.



Chapter 11 GUIDANCE AND MANUFACTURER'S DECLARATION

This section is intended to reflect conformance to IEC-60601-1-2 .The following statements are notices. Notices advise of circumstances that could result in damage to the device. Read and understand these cautions before operating the injector system .

NOTICE

Electro-Mechanical Hazard - Equipment Damage may result.

- For proper operation, use only accessories and options provided by Antmed that are designed specifically for the injector system. Other non-Antmed approved accessories or options may cause equipment damage or may result in increased emissions or decreased immunity of the injector system. Injector system accessories listed in it's operation manual comply with the requirements of electromagnetic emissions and immunity standards IEC 60601-1-2.
- Injector may disarm or fail to operate when exposed to high magnetic fields. Portable and mobile RF communications equipment can affect the injector.
- Do not use injector adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the injector should be observed to verify normal operation in the configuration in which it will be used.

Table 1: Recommended separation distances between portable and mobile RF communications equipment and the injector.

The injector is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the injector can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the injector as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23

0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

INJECTOR REQUIRES SPECIAL PRECAUTIONS REGARDING EMC. Install and put into service according to the EMC information provided below:

Table 2 Guidance and manufacturer's declaration - electromagnetic emissions

The injector is intended for use in the electromagnetic environment specified below. The customer or the user of the injector should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The injector 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	Notice: This injector is intended for use by healthcare professionals only. This injector may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the injector or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	

Table 3: Guidance and manufacture's declaration – electromagnetic immunity

The injector is intended for use in the electromagnetic environment specified below. The customer or the user of The injector should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV Contact ±15kV 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% UT(>95% dip in UT) for 0.5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 sec	<5% UT(>95% dip in UT) for 0.5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the injector requires continued operation during power mains interruptions, it is recommended that the injector be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Table 4 Guidance and manufacturer's declaration - electromagnetic immunity

The injector is intended for use in the electromagnetic environment specified below. The customer or the user of the injector should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the injector, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance. $d = 1.17\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	V/m	$d = 1.17\sqrt{p}$ 80 MHz to 800 MHz $d = 2.33\sqrt{p}$ 800 MHz 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 meters (m). 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 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 injector is used exceeds the applicable RF compliance level above, the injector should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the injector.

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

Chapter 12 Circuit diagram

